XFT-2001E

Nerve and Muscle Stimulator (Trade name: Foot Drop System)

User Manual

Caution: Federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

Content

1. For Your Health and Safety

- To avoid any danger or loss caused by inappropriate use, please read this manual carefully;
- In the precautions, the hazards and losses caused by improper use are stated, and the safety precautions are divided into three parts: “contraindications”, “warning” and “attention”;
- Please keep this manual carefully.

List of Symbols

	Contraindications, or will cause danger
	Mandatory Abidance, or will cause accident / physical discomfort
	Type BF Equipment
	Use with Caution
	Non-ionizing radiation
	Date of manufacture
	Manufacturer
	Serial Number
	Declaration of conformity according to the applicable European directives and number of the notified body (0123)
	European Authorized Representative
	Consult instructions for use
	Please dispose of the device/battery/accessory/packing in accordance with the legal obligation in your area

Contraindications

- Do not use with electronic monitoring equipment, NMR-imaging, pace-maker, defibrillator and high-frequency medical device.
- Do not use near short-wave, microwave. (such as 1m)
- Patients with 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 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.

Warning

- 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.
- Be careful if the electrode positioning areas show following situations:
  - Bleeding trend caused by serious trauma;
  - 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 area show partial occlusion, when the patient has vascular atrophy because of hemodialysis, or when the vascular system shows instability.
- Please use with caution when the output current density exceeds 10mA/cm^2 (r.m.s).
- Please use with caution if the used areas have structural deformity.
- This product should be conducted by doctors.
- Patients should keep stable and not move 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.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC warning:

Any Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

-Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

-Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

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.

Table 1

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">This equipment is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">This equipment is suitable for domestic establishments and those directly connected to the public low-voltage power supply network.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 61000-3-3</td><td>Complied</td></tr>
</table>

Table 2

Guidance and manufacture'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) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	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 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be typical commercial or hospital environment. UPS power is recommended if this device needs to be used continuously.
	0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0% U_T; 250/300 cycle	0% U_T; 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: U_T is the A.C. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacture's declaration – electromagnetic immunity			
This equipment should be used 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**
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz 6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz (a)	3Vrms 6Vrms	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: $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7GHz
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz	10 V/m	$d = 6\sqrt{P}/E$ 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). Interference may occur in the vicinity of equipment marked with the following symbol: 
Note1: At 80MHz and 800MHz, the higher frequency range applies. Note2: 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] ± 5 kHz 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 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

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 test distance is permitted by IEC 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 distance between portable and mobile RF communications equipment and the 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. Note1: At 80M and 800MHz, the separation distance for the higher frequency range applies. Note2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.			

2. Overviews

2.1 Indication for 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 or pathways to the spinal cord. 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 reeducation, and maintained or increased joint range of motion.

How does XFT-2001E Foot Drop System work?
When the leg swings to the angle of threshold, the electrical stimulation will be triggered.

2.3 Features and Innovation

- Bluetooth 4.0, more stable and reliable data transmission, easy operation and setting.
- Thin and light Stimulator & Cuff with patented design, easy and simple to wear.
- Integrated stainless steel electrode, fully enclosed waterproof design, no need for additional consumables, easy to clean and store.
- Automatic shutdown function: low voltage or automatic shutdown after 30 minutes of standby.
- Built-in rechargeable battery; one single charge for long-term use.
- Electrical stimulation constant current output & low voltage alarm function.
- It has two modes of walking and training, which can be selected according to the patient's state;
- Equipped with APP management software; able to manage user information and store gait data. It is simple and convenient to set the parameters of the host through the mobile phone.

2.4 Use Cycle

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

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

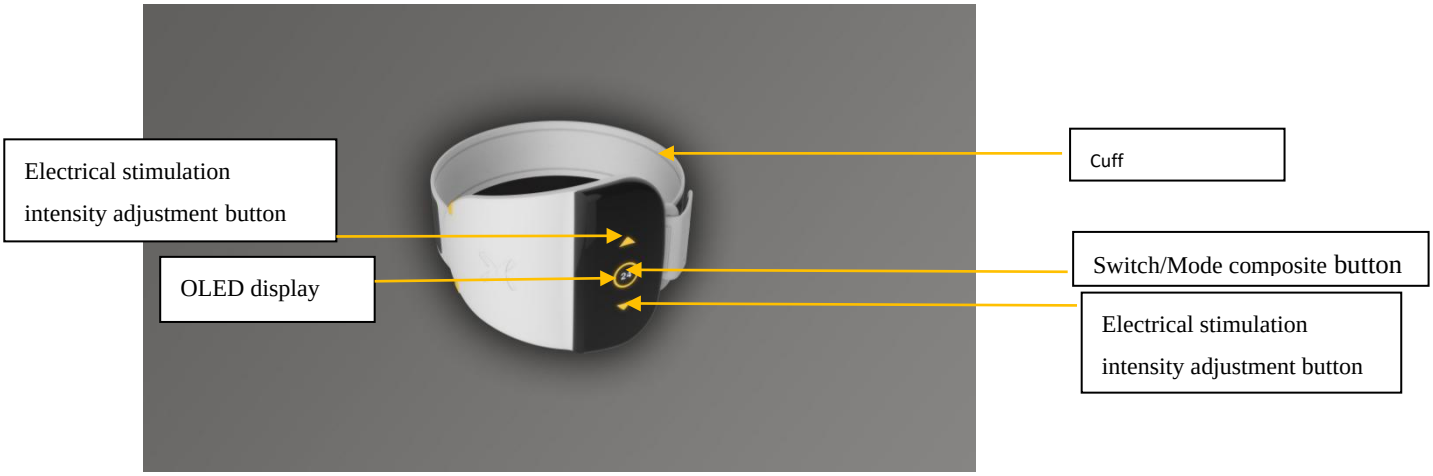
Stimulator

3.1.2 Parts

Power Adapter & charging cable

3.2 Operation Panel

3.2.1 Operation buttons



This unit contains 3 buttons (1 switch / mode composite button, 2 electrical stimulation intensity adjustment buttons), and 1 OLED display.

Switch/Mode composite button: Press and hold this button for 2 seconds to turn the unit on; after power on, the unit display shows "XFT" LOGO for 2 seconds; tap this button to switch the working mode (gait mode and training mode switching). When the unit is turned on, press and hold this button for 2 seconds to turn off the unit. In the working state, tap this button to pause the electrical stimulation output.

Electrical stimulation intensity adjustment button: Tap this button to start electrical stimulation and increase or decrease the electrical stimulation intensity; click the up button to increase the electrical stimulation, and click the down button to decrease the electrical stimulation intensity.

OLED display: display various working states of the unit; such as gait mode, training mode, electrode loose, low battery icon, electrical stimulation output icon, electrical stimulation intensity, etc.

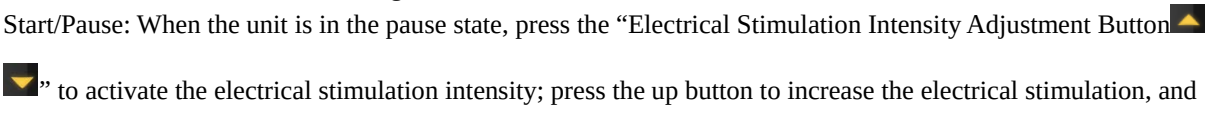
3.2.2 Indicators

- Power-on indication: Press and hold the switch/mode composite button for 2 seconds to turn the unit on; after power-on, the unit display shows "XFT" LOGO for 2 seconds; tap this button to switch the working mode (gait mode and training mode switching).

LOGO Gait mode Training Mode

- Mode switching: After the unit is turned on or the unit is paused, press "  Switch/Mode Switch" to switch the mode.

Gait mode Training Mode

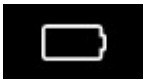
- Start/Pause: When the unit is in the pause state, press the "Electrical Stimulation Intensity Adjustment Button  " to activate the electrical stimulation intensity; press the up button to increase the electrical stimulation, and press the down button to decrease the electrical stimulation. The display will show the corresponding stimulus intensity.

- Electrical stimulation output prompt: When the unit is in the state of electrical stimulation, the display will show the lightning symbol, and the electrical stimulation will stop showing the electrical stimulation intensity. When the gait mode is activated, there will be a “bee” sound prompt for each output of the electrical stimulation (the sound can be muted by the APP software setting).


Lightning Symbol Electrical Stimulation Intensity

- Load detection: When the electrode of the unit is in poor contact with the skin, the display screen will have an exclamation point icon and an electrode loose icon alternately displayed. The unit automatically stops the electrical stimulation output and has 3 “bee” prompts. After the electrode of the unit is in full contact with the skin of the leg, press the electrical stimulation intensity adjustment button to continue the current mode.


- Low voltage / charging prompt: When the unit is low, there will be a battery icon display (battery display zero capacity) at low voltage and flash at 1 second interval. When the battery voltage is as low as the shutdown voltage, the unit automatically shuts down. The dynamic charging icon is displayed while charging, and the full battery icon is displayed when charging is completed.





Low battery, flash every 1 second Start charging Charging... Charging... Full Charge

- Automatic screen saver/shutdown: When there is no change in the content of the display, the brightness of the display will automatically reduce after 30 seconds, and enter the screen saver animation after 60 seconds; the screen saver "XFT" LOGO in animation form will move to the right; when the unit is low voltage to the shutdown voltage, automatic shutdown; the unit will automatically shut down in the standby (no electrical stimulation output) for 2 hours.

Screen Saver Icon

3.3 APP Software Description (optional)

- Hardware requirements:
  iPhone 5s and subsequent release models of the iPhone.

- Software Environment:
  System environment: IOS 8.x/9.x/10.x/11.x;
  Development environment: Xcode 8.0 and above;
  Security software: none;
  Network requirements: none.

4. Operation Instruction

4.1 How to wear G4?

This product can be used separately or with APP software.

4.1.2 Use separately

Please check if the Stimulator is fully charged before use. If necessary, please charge the unit; when charging, the main unit display will indicate the icon.

During use, if you find that the electrical stimulation intensity is weak or the low-power icon appears on the main unit display, please charge it in time; the main unit can be charged for about 3 hours, and it can be used for about 10 hours after being fully charged; if the unit is not used, please shut down the host and storage it.

Note: Please use the charger supplied by our company to charge. When charging, please do not wear the unit.

4.1.2.1 Wear the Stimulator

- Preparations: clean the covered area with a wet towel and keep the skin moist. If the hair is more, you can trim it. Sit on a comfortable stool, relax the affected leg and bend naturally.
- Place the Stimulator to correct position under the knee.

4.1.2.2 Power on and operate

- Press and hold the switch/mode composite button for 2 seconds to turn the unit on; after power-on, the unit display shows “XFT” LOGO for 2 seconds; tap this button to switch the working mode (gait mode and training mode switching).

LOGO Gait mode Training Mode

- When the Stimulator is in the pause state, press the “Electrical Stimulation Intensity Adjustment Button” to activate the electrical stimulation intensity; press the up button to increase the electrical stimulation, and press the down button to decrease the electrical stimulation.

Note: In order to allow the skin area covered by the unit to be breathable and to prevent skin irritation and redness, the unit should be suspended and removed at regular intervals to allow the skin to be fully breathable in the process of using the product.

4.1.2.3 Power off

When the Stimulator is turned on, press and hold the switch/mode composite button for 2 seconds to turn off it.

4.1.3 Use with APP

4.1.3.1 Install APP

1) First install the XFT-2001E foot drop APP on your mobile phone. Download the APP from APP Store, register an account and remember your account and password when log in for the first time. Turn on the XFT-2001E Stimulator, open the Bluetooth on your mobile phone and run the APP to connect the Stimulator.

Mobile phone hardware requirements: iPhone 5s and subsequent release models of the iPhone.

Mobile phone software environment: system environment: IOS 8.x/9.x/10.x/11.x;

development environment: Xcode 8.0 and above;

security software: none;

network requirements: none.

APP interface: “Use” is used for each function and parameter setting; “Help” is for checking company news, product usage guide, video and FAQ; “Me” is user and system related functions.

Log in

Search Stimulator

4.1.3.2 Wear the Stimulator

- Preparations: clean the covered area with a wet towel and keep the skin moist. If the hair is more, you can trim it. Sit on a comfortable stool, relax the affected leg and bend naturally.
- Place the Stimulator to correct position under the knee.

4.1.3.3 Power on and operate

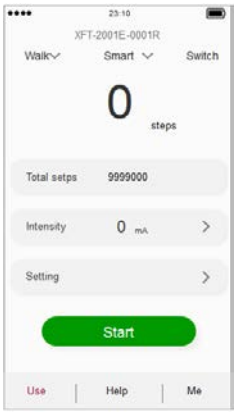
- Turn on

Press and hold the switch/mode composite button for 2 seconds to turn the unit on; after power-on, the unit display shows “XFT” LOGO for 2 seconds; Turn on the phone Bluetooth and run the software to connect to the main unit.

Log in interface

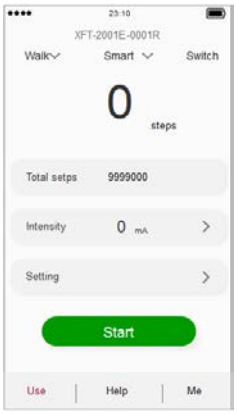
Search Stimulator interface

List of Stimulators

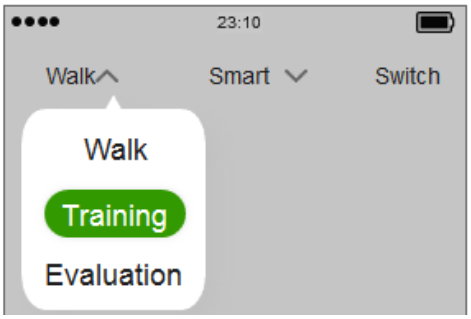


Successful connection interface

- Choose mode

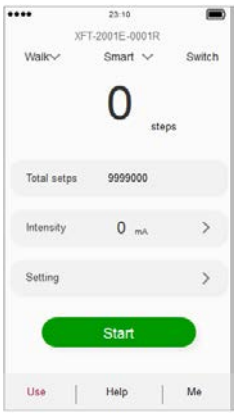


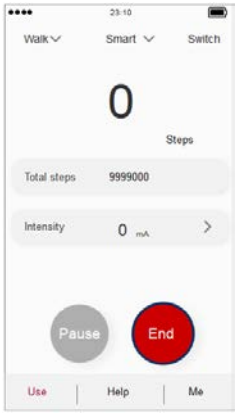
Successful connection interface



Choose one mode

- Gait mode
  - Start: The App sends the gait mode parameter and the walking start command to the host, receives the host reply, and enters the walking working interface.
  - Pause: The App sends a gait mode pause (stop) command to the host, receives a reply from the host, and pauses the walk.
  - Continue: The App sends the gait mode (start), at which time the current intensity given in the parameter setting is the current intensity before the pause. After receiving the host reply, the walking work continues.
  - Stop: After long press for 2s, send the gait mode stop command to the host, receive the host reply, and the gait mode stops.
  - During the walking process, the number of steps of the host is sent, and the App will display synchronously.





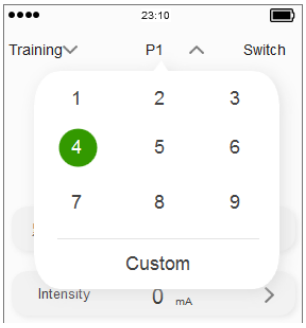
- Under the gait mode, user can choose among smart mode, normal mode, and manual mode. Click the “smart mode” position to pop up the mode selection list and select one.

  a. Smart mode: The host automatically calculates the tilt angle A of the electrical stimulation and the tilt angle B of shutting down electrical stimulation according to the gait data of the first four steps of the patient. The parameters that can be adjusted are the electrical stimulation intensity, frequency and pulse width in the lower level interface of the “Parameter Settings”.

  b. Normal mode: The host 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 Setting”.

  c. Manual mode: After starting this mode, the host performs electrical stimulation according to the electrical stimulation button of the interface; press the button to start electrical stimulation, stop the electrical stimulation by the release, and continue to hold the electrical stimulation for continuous output. The parameters that can be adjusted are the electrical stimulation intensity and the frequency and pulse width in the lower level interface of the “Parameter Settings”.

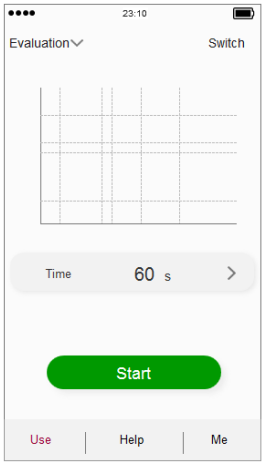
- Training mode
  - The training mode performs electrical stimulation based on a combination of parameters of the selected training mode. The parameters combine 9 fixed combinations and one custom. The electrical stimulation can be adjusted after the fixed mode starts, and other parameters cannot be adjusted. All parameters can be adjusted under custom.
  - Start: The App sends the training mode parameters and mode start command to the host, receives the host reply, and enters the training work interface.
  - Pause: The App sends a training mode pause (stop) command to the host, receives a host reply, and the training is suspended.
  - Continue: The App sends the training mode (start), at which point the current intensity given in the parameter settings is the current strength before the pause. After receiving the host response, the training work continues.
  - Stop: After long press and stop for 2s, send the training mode stop command to the host, receive the host reply, and the training mode stops.

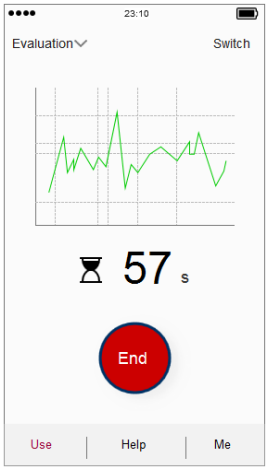


1-9 Built-in 9 training modes with fixed parameters; custom parameters can be adjusted.

- Evaluation mode
  - Evaluation mode: Collect the angle data generated by the host during the patient's walking. The collection duration is 60s by default and the maximum is 90s. The acquisition begins to draw an angle waveform and displays the countdown of the acquisition time. Can stop in the middle. The acquisition is completed to display the evaluation results.
  - Start: The App sends an evaluation mode to start the command to the host, receives the host reply, and enters the evaluation work interface.

- Stop: After long press and stop for 2s, send the evaluation mode stop command to the host, receive the host 4 reply, and the evaluation mode stops.
- 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.





4.2.3 Shut down

When the instrument is turned on, press and hold the switch/mode composite button for 2 seconds to turn off the instrument.

5. Attentions

5.1 Device Power Off

Force shut down: Press the shutdown button.
System shut down:
1) When the treatment duration set by the channel has ended, the functions stop.
2) When the battery voltage is low, the system will automatically shut down.
3) The host will automatically shut down when it is in standby (no electrical stimulation output) for 2 hours.

5.2 Troubleshooting

Malfunction indicator will show the following troubles:

5.2.1 Electrodes loose

The malfunction indicator flashes slowly (the frequency is 1 Hz). When the system detects that the electrode is off, it indicator will display and the device will stop running. This trouble can be resolved by simply connecting the electrode pads.

5.2.2 Low battery voltage

When the battery voltage is low, there will be a battery icon display (the battery display capacity is empty) at low voltage and flash at 1 second intervals. When the battery voltage is as low as the shutdown voltage, the unit automatically shuts down.

Low battery, flash every 1 second

5.3 Integrated electrode use precautions

The integrated electrode piece can be replaced and be used for long-term. Pay attention to clean the contact surface or pay attention to clean the skin surface during use (users with more hair should pay attention to trimming, and conductive adhesive can also be used to increase conductivity).

5.4 Skin Care

Before and after using the device, please examine the skin, it is normal that skin slightly turns red, which shows faster blood flow.

Allergy Prevention Advice:

- Do not position on the skin with makeup or oil.
- Remove arm's hair 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 Device Storage

- Please do not store it in the place of direct sunlight, high temperature, moist, dusty, or corrosive gas.
- Please store it in the place where children cannot reach.
- The user does not need to maintain the hose device, please ask the seller or manufacturer.
- Please use wet cloth with neutral detergent or alcohol to clean the surface of the Stimulator.
- Please do not immerse the electronic components into to water.
- Please do not throw, tread on, or heavy press the device.

6.2 Product Life

The product is designed to be used for 5 year, after which, please deal with product and battery according to the provisions of the electronic products processing.

6.3 Use of Rechargeable Battery

- Do not charge/discharge exceed the specified current.
- Do not short the battery/battery pack. May cause permanent damage to the battery/battery.
- Do not burn or destroy the battery/battery pack.
- Do not expose the device to adverse conditions such as extreme temperatures, deep cycling and overcharging, otherwise battery life may be reduced.
- Store the battery/battery pack in a cool, dry place.
- Stay away from children. If swallowed, contact doctor immediately.
- Avoid sealing the battery compartment and ensure ventilation

※Rechargeable battery maintenance instructions

Periodic charge and discharge: If the unit is not used for a long time (when the battery is stored for more than 6 months), it is recommended to do it once for the host.

7. FAQ & Troubleshooting

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

A. -Adjust the placement position.

-Adjust the electrical stimulation intensity through the host or APP software.

-If the host is running low, please charge it in time.

-Wet the skin and increase the electrical conductivity between the electrode and the skin.

Q2. After turning on the training mode or gait mode on the unit, although the indicator light is on, there is no electrical stimulation reaction.

A. -Check if the host is tied and close to the skin.

-Check if the current intensity set by the host is adjusted to the appropriate intensity.

-Add some water to the surface of the electrode sheet to increase the conductivity of the electrode sheet.

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

A. 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 host.

Q4. The unit display battery icon is turned off after 1 second interval flashing.

A. This indicates that the host is running low and needs to be recharged. It takes about 3 hours for the unit to charge; after the battery is fully charged, the unit can last for about 10 hours. When the battery is low, please charge it in time.

Q5. The host LED light flashes quickly, what should I do if the main unit display "  ", "TBD Icon" flashes alternately?

A. This indicator is a reminder that the electrode is off. Please check if the host is fastened. Or the skin is too dry and needs to moisturize the skin. After re-fixing to the leg, press the main power stimulation adjustment button or press the stimulation adjustment button in APP software to continue.

Q6. What happens when there is sporadic strong electrical stimulation?

A. -The surface of the electrode is not wet enough to sprinkle some water on the surface.

-Check if the skin in the area covered by the electrode is red or has a wound.

-Check if the cuff of the main unit is loose and the position of the electrode is accurate.

Q7. Why is there no electrical stimulation at the time of electrical stimulation?

A. Usually because the cuff position has been moved or the gait mode has changed. Please wear the cuff again or reset the walking parameters.

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

A. No, please make sure the skin is clean before using the stimulator and fully wet the adhesive surface of integrated electrode.

8. Product Configuration

8.1 Product specifications

Communication method: Bluetooth 4.0

Communication frequency: 2.4-2.4835GHz

8.2 Stimulator

Power Supply	3.7V rechargeable lithium battery or DC 5V, power adapter
Classification	Type BF applied part,  internally powered equipment
Shutdown current	≤10μA
Working current	≤120mA

Wave form	Asymmetric biphasic balanced wave
Frequency	16-50Hz (±10%), respectively in 16、20、25、33、40、50Hz
Pulse Width	50-300μs (±10%), respectively in 100、150、200、250、300μs
Output intensity	0-90mA (±10% or ±2mA, whichever is greater, with 500Ω load)
Dimension	419*103*13mm

8.3 Power Adapter

Dimension	71*41*31.5mm
Input	AC100-240V, 50-60Hz, 0.3A
Output	DC 5V, 1.2A

8.4 Working and storage environment

- Working Conditions:
  Temperature 5~40°C,
  Relative humidity ≤80% (Non-condensing)
  Atmospheric pressure 86~106KPa
- Transport and Storage Conditions:
  Temperature -20~55°C,
  Relative humidity ≤93%(Non-condensing)
  Atmospheric pressure 70~106KPa
- Production date: see the label
- Service life: 5 Years (battery is not included)

8.5 Accessories

Stimulator	1pc
Charging Cable	1pc
User manual	1pc
Power Adapter	1pc

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: IP66.
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. 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.

Product Name: Nerve and Muscle Stimulator
Model: XFT-2001E

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