**XFT-2001EA**

**G4 Foot Drop System**
**User Manual**


Technology Upgrades
Our Life

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**

- Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.
- 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 long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions
- 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.

**Precautions**

- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:

a. When there is a tendency to hemorrhage following acute trauma or fracture;
b. Following recent surgical procedures when muscle contraction may disrupt the
c. healing process;
d. Over the menstruating or pregnant uterus; and
e. Over areas of the skin which lack normal sensation.

- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
- Powered muscle stimulators should be kept out of the reach of children.
- Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- Powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

**Adverse Reactions**

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.

**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 EMC in this manual.

⚠ Caution: This section will list the contents described in the YY0505-2012 form. It is the responsibility of the user to ensure that this equipment and its nearby equipment meet the RF interference parameters indicated in the general safety requirements.

⚠ 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**

| **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, IEC 61000-3-2 | Class A | |
| Voltage fluctuations/flicker emissions, IEC 61000-3-3 | Complied | |

**Table 2**

| **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. | | | |
| Immunity test | IEC60601 test level | Compliance | Guidance |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6kV contact ±8kV air | ±6kV contact ±8kV air | Floors should be wood, concrete or ceramic tile. Humidity should be at least 30% if it is synthetic materials. |
| Electrical fast transient burst (EFT) IEC 61000-4-4 | ±2kV power lines ±1kV I/O electric cable (length>3m) | ±2kV power lines | Main power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1kV differential mode ±2kV common mode | ±1kV differential mode ±2kV common mode | |
| Voltage dips, short interruptions and voltage variations IEC 61000-4-11 | <5% UT (>95% dip in UT) 0.5 cycle 40% UT (60% dip in UT) 5 cycle 70% UT (30% dip in UT) 25 cycle <5% UT (>95% dip in UT) 5s | <5% UT (>95% dip in UT) 0.5 cycle 40% UT (60% dip in UT) 5 cycle 70% UT (30% dip in UT) 25 cycle <5% UT (>95% dip in UT) 5s | Mains power quality should be typical commercial or hospital environment. UPS power is recommended if this device needs to be used continuously. |
| Power frequency (50/60Hz) | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic |

| | | | |
|---|---|---|---|
| IEC 61000-4-8 | | | 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**

| **MANUFACTURER'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 | Guidance |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150k~80MHz | 3 Vrms | 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:<br>$d = 1.2\sqrt{p}$<br>$d = 1.2\sqrt{p}$ 80MHz to 800 MHz<br>$d = 2.3\sqrt{p}$ 800MHz to 2.5GHz<br>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 a) should be less than the compliance level in each frequency range b) interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80M~2.5GHz | 3 V/m | |
| Note1: at 80MHz~800MHz, the higher frequency range applies.<br>Note 2: these guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people. | | | |

a) 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.

b) Field strengths should be less than 3V/m in the frequency range of 150k~80MHz.

**Table 4**

| **Recommended Separation Distance** | | | |
|---|---|---|---|
| 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 -2MHz $d = 1.2\sqrt{P}$ | 80MHz -800MHz $d = 1.2\sqrt{P}$ | 800MHz -2.5GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.38 | 0.38 | 0.73 |
| 1 | 1.2 | 1.2 | 2.3 |
| 10 | 3.8 | 3.8 | 7.3 |
| 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.<br>Note1: at 80M~800MHz, the separation distance for the higher frequency range applies.<br>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-2001EA 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-2001EA 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.

How does XFT-2001EA 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 Stim Unit & 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 Stim Unit through the mobile phone.

### 2.4 Use Cycle

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

| 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-2001EA consists of the Stim Unit, Power Adapter, charging cable, and APP software (optional).

#### 3.1.1 Stim Unit

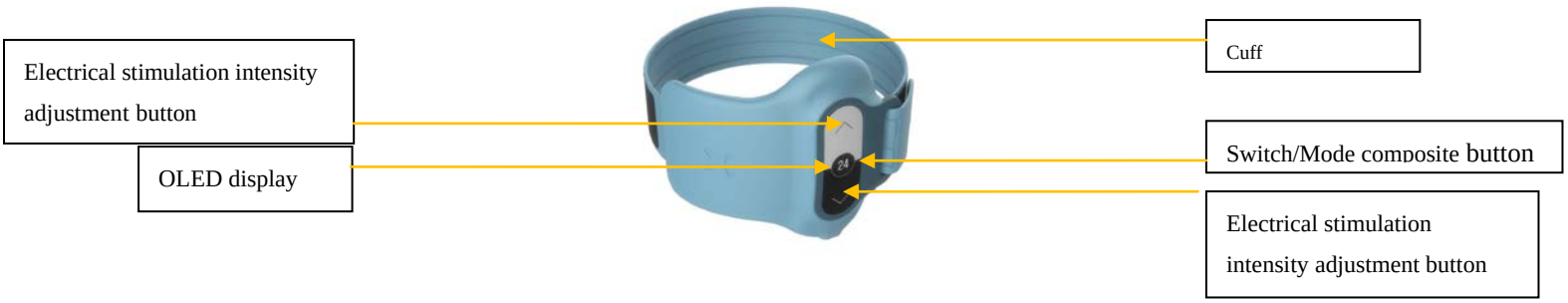
Stim Unit

#### 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.
- Start/Pause: When the unit is in the pause state, press the “Electrical Stimulation Intensity Adjustment Button  or  ” 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.

| | |
|---|---|
|  | Stimulation intensity |
|  | Stimulation 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 |
|  | 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.

| | |
|---|---|
|  | Electrode loose |
|  | Electrode loose |

- 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 |
|  | 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 Stim Unit 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 8 hours, and it can be used for about 10 hours after being fully charged; if the unit is not used, please shut down the Stim Unit 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 Stim Unit

- 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 Stim Unit 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).
- When the Stim 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.

  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 Stim Unit 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-2001EA 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-2001EA Stim Unit, open the Bluetooth on your mobile phone and run the APP to connect the Stim Unit.

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 Stim Unit |

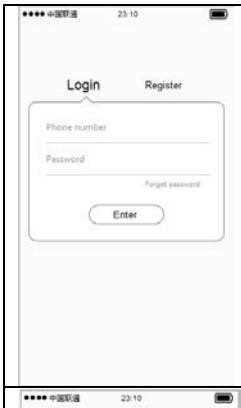
4.1.3.2 Wear the Stim Unit

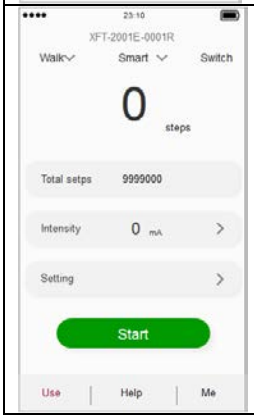
- Preparations: clean the covered area with a wet towel and keep the skin moist. If the hair is more, you can trim it. Sit on a comfortable stool, relax the affected leg and bend naturally.
- Place the Stim Unit to correct position under the knee.

4.1.3.3 Power on and operate

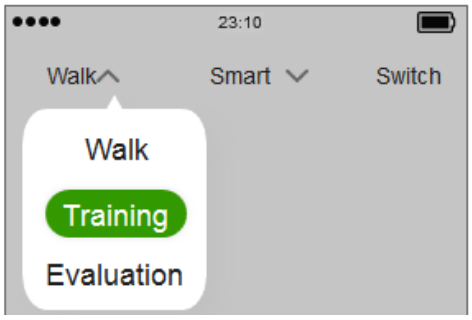
- Turn on

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.

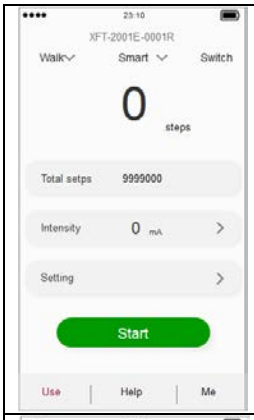
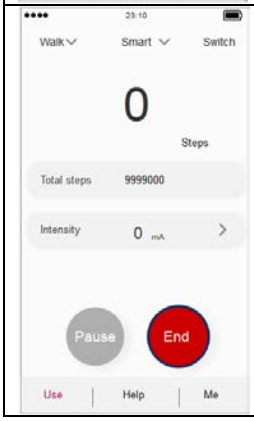
| | |
|---|---|
|  | Log in |
|  | Search Stim Unit |

| | |
|---|---|
|  | List of Stim Units |
|  | Successful connection interface |

- Choose mode

| | |
|---|---|
|  | Choose one mode |

- Gait mode
  - Start: The App sends the gait mode parameter and the walking start command to the Stim Unit, receives the Stim Unit reply, and enters the walking working interface.
  - Pause: The App sends a gait mode pause (stop) command to the Stim Unit, receives a reply from the Stim Unit, 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 Stim Unit reply, the walking work continues.
  - Stop: After long press for 2s, send the gait mode stop command to the Stim Unit, receive the Stim Unit reply, and the gait mode stops.
  - During the walking process, the number of steps of the Stim Unit is sent, and the App will display synchronously.

| | |
|---|---|
|  | Gait mode interface |
|  | Start gait mode |

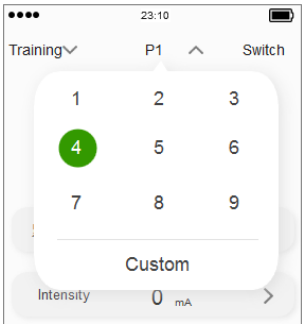
- Under the gait mode, user can choose among smart mode, normal mode, and manual mode. Click the “smart mode” position to pop up the mode selection list and select one.

  a. Smart mode: The Stim Unit 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 Stim Unit 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”.

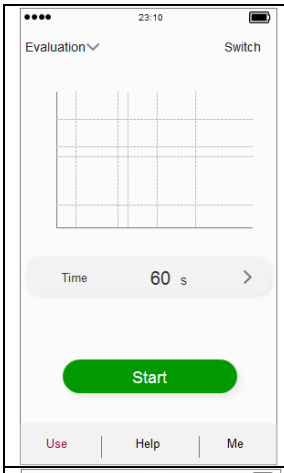
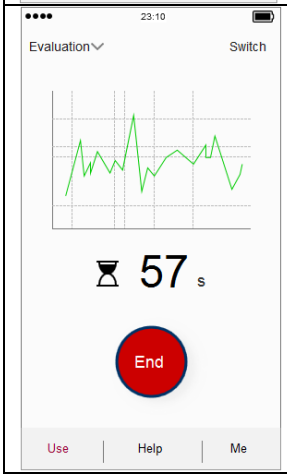
  c. Manual mode: After starting this mode, the Stim Unit performs electrical stimulation according to the electrical stimulation button of the interface; press the button to start electrical stimulation, stop the electrical stimulation by the release, and continue to hold the electrical stimulation for 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 Stim Unit, receives the Stim Unit reply, and enters the training work interface.
  - Pause: The App sends a training mode pause (stop) command to the Stim Unit, receives a Stim Unit 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 Stim Unit response, the training work continues.
  - Stop: After long press and stop for 2s, send the training mode stop command to the Stim Unit, receive the Stim Unit reply, and the training mode stops.

| | |
|---|---|
|  | Choose a training program |

Note: 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 Stim Unit 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 Stim Unit, receives the Stim Unit reply, and enters the evaluation work interface.
  - Stop: After long press and stop for 2s, send the evaluation mode stop command to the Stim Unit, receive the Stim Unit 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.

| | |
|---|---|
|  | Evaluation mode |
|  | Start evaluating |

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 Stim Unit 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.

### 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 device 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 Stim Unit.
- 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 Stim Unit.

**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 Stim Unit or APP software.

-If the Stim Unit 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 Stim Unit is tied and close to the skin.

-Check if the current intensity set by the Stim Unit 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 Stim Unit 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 Stim Unit.

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

A. This indicates that the Stim Unit 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 Stim Unit 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 Stim Unit 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 device 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 Stim Unit**

| | |
|---|---|
| Power | DC3.7V, rechargeable lithium battery |
| Safety class | Internal power supply type BF type equipment |
| Shut down current | ≤50μA |
| Working current | ≤120mA |
| Stimulation wave | Biphasic asymmetric balanced wave |
| Frequency | 16-50Hz (±10%) |
| Pulse | 100-300μs (±10%) |
| Output current & voltage | Output current: load impedance 500Ω, maximum 90mA<br>Output voltage: load impedance 500Ω, maximum 45V |
| Dimension | 413*104*17mm |
| Weight | 139g±10g |

**8.3 Power Adapter**

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

**8.4 Stim Unit and other accessories work and storage environment**

- Working environment:
  Temperature 5−40℃,
  Relative Humidity: ≤80% (non-condensing)
  Atmospheric pressure 86−106KPa
- Storage and transportation environment:
  Temperature -20−55℃,
  Relative Humidity: ≤93% (non-condensing)
  Atmospheric pressure 70−106KPa
- Production date: see the label
- Service life: 5 Years (battery is not included)

**8.5 Product configuration**

| | |
|---|---|
| Stim Unit | 1pc |
| Power Adapter | 1set |
| User manual | 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.

**Warranty Card**

Be sure to call for authorization before returning any equipment!

Remove or copy this form and include it with the unit(s).

Include copy of original invoice and return to the address in the Returning Equipment section.

| | |
|---|---|
| Company | |
| Address | |
| Phone No. | |
| Date Purchased | |
| From Whom | |
| Model Name | |
| Serial Number | |
| Problem | |

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

Shenzhen XFT Medical Limited
Room203, Building 1, Biomedicine Innovations Industrial Park,
#14 Jinhui Road, Pingshan New District, Shenzhen, China

EC REP ShangHai International Holding Crop.GmbH(Europe)

Eiffestrasse 80 D-20537 Hamburg Germany

US Agent:
Yang LingYun
605 Sherwood Forest Place, Cary, North Carolina
Cary , NC 27519
Phone: 919 4751044 Ext
Email: Usagency@126.Com

Date：2018/12/17
Doc. No.: XFT-2001EA-E
Version: C