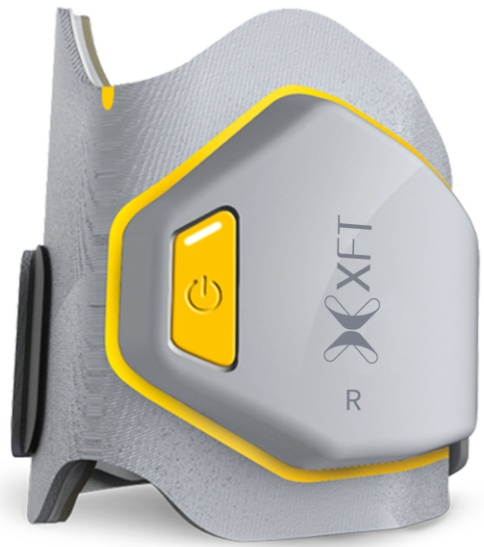
尺寸：140X205MM

XFT

G3
Foot Drop System



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

Manufacturer: Shenzhen XFT Medical Limited
Add: Room 203, Building 1, Biomedicine Innovations Industrial Park,
#14 Jinhui Road, Pingshan District, Shenzhen, China
Tel: 86-755-29888818 Fax: 86-755-28312625
Web: www.xft-china.com Mail: xft@xft.cn

EC REP ShangHai International Holding Corp.GmbH (Europe)
Eiffestrasse 80 D-20537 Hamburg Germany.

CE 0123

Date: July 15, 2019
No.: XFT-2001D-A(G)
Rev. C1

Technology Upgrades
Our Life

User Manual

Thanks for buying our product, please read the user manual carefully before use and keep it properly.

Contents

For Your Health and Safety

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	Declaration of conformity according to the applicable European directives and the number of the notified body (0123)
	European Authorized Representative
	Manufacturer
	Date of Manufacturer

Contraindications

- Do not use on persons with implanted demand-type cardiac pacemakers or defibrillators.
- Do not place the electrodes over malignant tumors.
- Do not place the electrodes over areas in which symptoms of existing thrombosis is present.
- Do not use if person has a history of seizure disorder.
- The XFT-2001D should not be used on a leg where a regional disorder, such as fracture or dislocation, would be adversely affected by motion from the stimulation.
- The XFT-2001D should not be used on a leg where strength testing or strength training is planned.

Warnings about Functional Electrical Stimulation (FES)

WARNINGS are used to identify a hazard that may lead to death or serious injury.

- The use of XFT-2001D may interfere with the proper functioning of electronic monitoring equipment such as EKG machines. However, the operation of the XFT-2001D device will not be affected by the use of electronic monitoring equipment.
- The XFT-2001D should not be worn while receiving an MRI scan.
- The use of electrodes not supplied by XFT, may diminish results or increase risk of burns or discomfort. Do not place electrodes over open wounds, broken skin or metal objects beneath the skin, such as surgical staples.

Warranty Card

Product name: _____ Model no.: _____

Purchase date: _____ Product serial no.: _____

Buyer'sinformation: _____

Distributor's information: _____

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

Distributor Seal: _____

Warranty Statement

1. The XFT-2001D Foot Drop System is provided with one year warranty starting from the date of purchasing.

2. We will not provide free repair for the malfunctions caused by the following behaviors.
   a) Disassemble or modify the product without authorization.
   b) Accidentally blow or drop the product during use or transportation.
   c) Lack of reasonable maintenance.
   d) Operate not according to the instruction.
   e) Repaired by unauthorized repair store.

3.When asking for guarantee service, please take with the guarantee card.
   Note: It is charged according to the stipulation for the repair service out of the warranty.

- The safety of XFT-2001D for use during pregnancy has not been established.
- Do not use simultaneously with high frequency hospital equipment (e.g. diathermy equipment). It may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Improper or prolonged use of electrodes may result in increased risk of skin irritation or burns and decreased effectiveness. Infrequently, an allergic response to the electrode adhesive or gel may occur. Do not place electrodes on skin which is already irritated, as this will increase the risk of discomfort with stimulation or skin burns.
- As a FES device, XFT-2001D should be used by the patient after consulting a physician or a qualified clinician.
- Care should be taken while using XFT-2001D therapy in close proximity (e.g. less than 1 meter) to devices which emit radio frequencies such as cellular phones or two-way radios, as some types of transmitters may cause undesirable stimulation to the user.
- External defibrillation of a person wearing an FES device can damage the device or injure the patient even when the device is turned off. Under some circumstances, there may be risk of burns under the electrode sites during defibrillation. To eliminate any risk, the FES electrodes should be removed before defibrillation paddles are applied.
- Effects of long-term chronic stimulation are unknown in this particular application.

Specific Warnings

- Care should be taken when using the XFT-2001D for people who experience dizziness or have difficulty maintaining balance. The XFT-2001D is not designed to prevent from falling.
- The user should follow doctor's advice to relocate the position of the electrodes within the cuff. Do not use the XFT-2001D without electrodes.
- Never use the XFT-2001D on any area of the body other than the leg.
- Stop using the XFT-2001D if stimulation does not come on at the appropriate time when walking and/or there is a change in the sensation perceived while the stimulation is on.
- XFT-2001D is not intended for use around flammable environments.
- Care should be taken to minimize excessive impact to the XFT-2001D Control Module. This includes standing or kneeling on the unit, or impact from any hard surfaces.
- The FES cuff should not be worn over swollen, infected or inflamed areas or skin eruptions such as phlebitis, thrombophlebitis and varicose veins.

Precautions: Used to identify a hazard that may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

- Inflammation in the region of the FES cuff may be aggravated by motion, muscle activity, or pressure from the FES cuff. Advise patients to stop using the XFT-2001D until any inflammation is gone.
- After removing FES cuff, it is normal for the areas under the electrodes to be red and indented. The redness should disappear in approximately one hour. Persistent redness, lesions or blisters are signs of irritation. Use of the XFT-2001D should be temporarily halted until any inflammation is resolved completely.

Directions for Use

- Patients should not wear the XFT-2001D during x-ray examinations.
- Specific physician clearance should be obtained before using the XFT-2001D on the patients who have an alteration of normal arterial or venous flow in the region of the FES cuff because of local insufficiency, occlusion, arteriovenous fistula for the purpose of hemodialysis or a primary disorder of the vasculature.
- Specific physician clearance should be obtained before using the XFT-2001D when patients have a structural deformity in the area to be stimulated.
- Skin problem where the FES cuff is worn may be aggravated by the XFT-2001D.
- Turn off the XFT-2001D before removing or replacing the electrodes.
- Adult supervision and assistance should be provided for anyone needing help while using the XFT-2001D system.
- Protect all electronic components from contact with water, such as from sinks, bathtubs, shower stalls, rain, snow, etc.
- Should any technical problems occur that is not covered in this guide, contact Shenzhen XFT Medical Limited, Do not attempt to repair the XFT-2001D.
- The FES cuff is only to be worn on the leg of the patient for whom it is fitted. It should not be worn by anyone else or any other part of the body.
- Turn off the XFT-2001D before putting on the FES cuff. Do not turn on the XFT-2001D until the FES cuff is fastened in place.
- Medical electrical equipment needs special precautions for electromagnetic compatibility.
- Use caution in applying electrical stimulation to persons suspected of having heart disease. More clinical data is needed to show that such persons will not experience adverse results.
- Use caution when placing electrodes on areas of the skin with reduced response to normal sensory stimuli, due to the risk of skin burns.
- XFT-2001D devices should be kept out of the reach of children.
- Use caution in applying electrical stimulation to persons suspected of having epilepsy. More clinical data is needed to show that such a person will not experience adverse events.
- Do not use XFT-2001D following recent surgery where muscle contraction may disrupt the healing process.
- Do not use lotion or oil in the area that the electrodes make contact with the skin. Stimulation may not be effective.
- The safety and efficiency of XFT-2001D depends on the proper use and handling of the stimulator. Improper use of the device or electrodes can result in injury to the patient. Regularly check accessories for wear and replace as needed. Electrodes should be firmly secured to the skin.
- Never use the XFT-2001D if it appears to be malfunctioning. If there is a change in the way it usually works (i.e. change in sensation, surging of stimulation, intermittent stimulation) do not use the XFT-2001D and contact your clinician immediately.
- The XFT-2001D should be used with electrodes supplied by Shenzhen XFT Medical Limited.

Packing & Shipping Requirements

Be careful while the goods being packed and shipped
Frangible

Keep upwards while the goods being shipped or packed.
Upwards

Prevent from being wet or rainy
No Rain

 : Date-Month-Year

 : Manufacturer: Shenzhen XFT Medical Limited
Add: Room 203, Building 1, Biomedicine Innovations Industrial Park,
#14 Jinhui Road, Pingshan District, Shenzhen, China

Temperature range: -20℃-55℃
Relative humidity range: ≤93% (Non-condensing)
Atmospheric pressure: 70kPa-106kPa

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.			

- The stimulator should not be used while operating potentially dangerous equipment such as automobiles, power lawn mowers or large machinery. Abrupt changes in stimulation level could create a hazard.
- The XFT-2001D should not be worn or used while sleeping or bathing.
- The use of heat or cold producing devices such as electric blankets, heating pads or ice packs may affect the electrodes or the person's circulation and increase the risk of injury. A medical doctor and clinician should be consulted before using with XFT-2001D.
- Medical electrical equipment needs special precautions for electromagnetic compatibility. This product conforms to standards IEC60601-1-2 of EMC.

ADVERSE REACTIONS

- In the unlikely event that any of the following occurs, advise patient to stop using the XFT-2001D immediately and consult his/her physician:
  - Signs of significant irritation or pressure sores where the FES cuff contacts the skin
  - A significant increase in muscle spasticity
  - A feeling of heart related stress during stimulation
  - Swelling of the knee, leg, ankle or foot
  - Any other unanticipated reaction

  Skin irritations and burns have been reported with the use of powered muscle stimulators.

- Skin irritation and burns beneath the electrodes have been reported with the use of surface functional electrical stimulation devices. Do not leave the electrodes in place for long periods of time without checking or cleaning the skin underneath them. It is normal to observe slightly reddened areas under the electrode placement. However, the redness should disappear within an hour. Signs of irritation are maintained redness, small pimple-like lesions or blisters. DO NOT continue stimution over irritated skin.

  Notify the medical doctor if these conditions persist and discontinue the use of the XFT-2001D until the problem is solved.

Cautions

- ALWAYS use the XFT-2001D under specific instruction of a qualified clinician.
- NEVER use the XFT-2001D in a situation where an unexpected or unusual stimulus may occur, such as driving or operating motorized equipment.
- NEVER use the XFT-2001D unit with frayed or broken leads.
- ALWAYS handle the unit carefully. DO NOT expose the unit to water, excessive heat or vibration.
- DO NOT place electrodes anywhere other than below the knee on the leg for which the XFT-2001D is prescribed.
- AVOID dropping the XFT-2001D. Although robustly designed, damage may occur that could cause the unit to malfunction.
- **DO NOT open the unit . The XFT-2001D has no user or clinician** serviceable parts inside the control module enclosure.
- TURN OFF the unit if sitting for an extended period of time.

Introduction to Your XFT-2001D

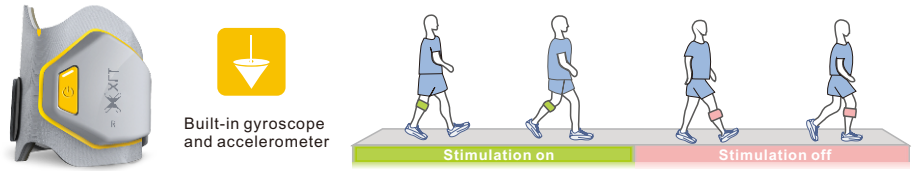
1. Introduction

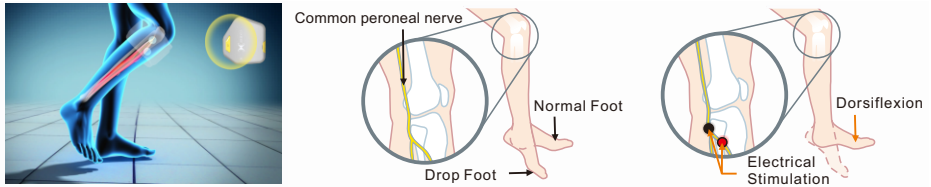
XFT-2001D Foot Drop System is an advanced functional electrical stimulation (FES) device which brings remarkable effect on foot drop patient. Dropped-foot patient due to central nervous system injuries, such as Stroke, Incomplete Spinal Cord Injury, Traumatic Brain Injury, Cerebral Palsy, Multiple Sclerosis may benefit from the device.

XFT-2001D Foot Drop System adopts advanced MEMS sensor technology and intelligent algorithms, precisely controlling the time and duration of electrical stimulation by tracking the swing angle and pace of patient's leg. XFT-2001D delivers electrical pulses to the common peroneal nerve as well as the tibialis anterior and other muscles to make the movement of dorsiflexion and eversion. Those mild electrical pulses stimulate patient's leg muscles, making them lift the foot at an appropriate phase while walking and therefore enabling patient to walk more steadily, naturally and safely.

※ Please use the Foot Drop System patient kit under the recommendation of a doctor or physician.

How does XFT-2001D Foot Drop System work?





When the leg swings to the angle of threshold, the electrical stimulation will be triggered.

2. Intended Use

For rehabilitation and walking aids of foot drop patients due to stroke or other central nervous system injuries.

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	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 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.

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.

3. Functions and Features

- 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.
- OLED screen on remote control.
- Auto off in low voltage or after 30 minutes of standby.
- Gait and training mode for choice.

Components of Your XFT-2001D

1. Components

XFT-2001D Foot Drop System patient kit mainly consists of the following parts:

Stim unit & Cuff

Remote Control

Quick-fit Electrode

Gel Electrode

Power Adapter

Table 3

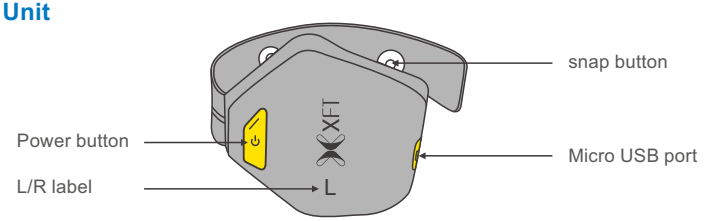
Guidance and manufacture's declaration – electromagnetic immunity			
This equipment should be used in the electromagnetic environment specified below. User should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz AM 80% 1kHz Modulation, step1 % Dwell time 1s	3Vrms	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 $d=6\sqrt{P}/E$ 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: 
	6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz (a)	6Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80MHz to 2.7GHz AM 80% 1kHz Modulation, step1 % Dwell time 1s	10 V/m	

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 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 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 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	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.			

2. Stim Unit & Cuff

Stim Unit



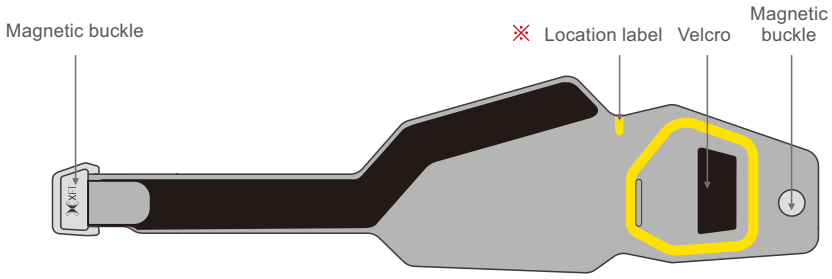
Power button: press and hold for 1 second to turn on the stim unit, and the indicator turns green. Press and hold for 1 second again to turn it off.

L/R label: L is for left leg, R is for right leg.

Micro USB port: for device charging. It needs to charge for about 3 hours when completely drained of power. It is designed to work for 10 hours with a full charge.

Snap button: for connection between stim unit and electrode.

Cuff

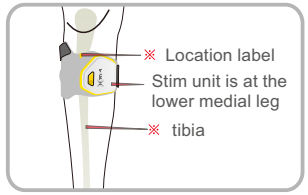


Cuff: to fix the stim unit on the leg

Magnetic buckle: to fix the cuff around the leg with one-handed operation.

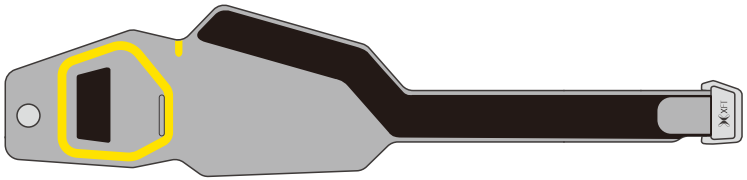
Location label: to place the location mark under the knee and align it with the tibia.

Velcro: to fix the stim unit on the cuff.

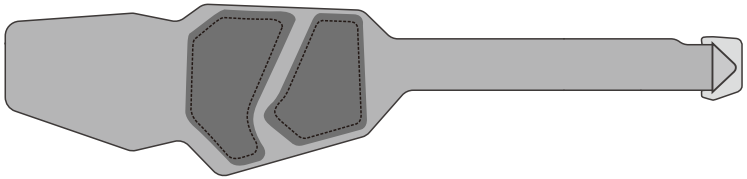


Generally, the location label should be aligned with the tibia.

3. Quick-fit Electrode



Front



Back

Electromagnetic Compatibility (EMC)

Declaration of Conformity to R&TTE Directive 1999/5/EC

The Bluetooth Module in the XFT-2001D is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

The following standards were applied during the assessment of the product against the requirements of the Directive 1999/5/EC:

Radio Spectrum: ETSI EN 300 328 V1.8.1 (2012-06)
EMC: ETSI EN 301 489-1 V1.9.2 (2011-09) ETSI EN 301 489-17 V2.2.1 (2012-09)
Safety: EN 60950-1: 2006 + A11: 2009 + A1: 2010 + A12: 2011 + A2: 2013
Health: EN 62479: 2010

Notified Body number 1313

Table 1

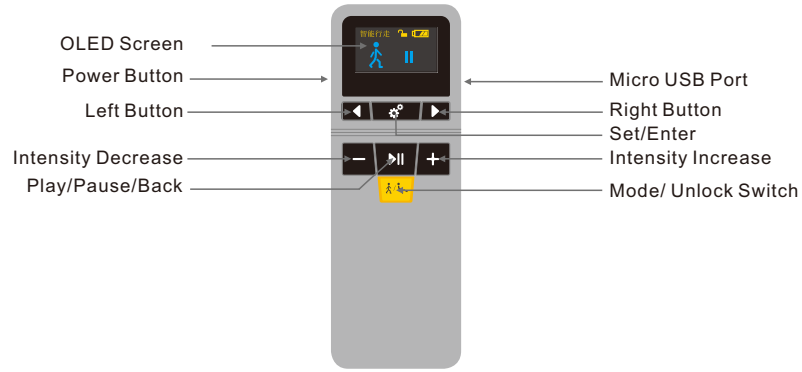
Guidance and manufacture's declaration – electromagnetic emission		
This equipment is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions 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	

Configurations

	Stim Unit	1 pc
	Cuff	1 pc
	Remote Control	1 pc
	Quick-fit Electrode	2 pcs
	Gel Electrode	5 pcs
	Charger	1 pc
	User manual	1 pc

Configuration is subject to change without notice.

4. Remote Control



Buttons

- Power Button: press and hold for 1 second to turn on the remote control, press and hold for 1 second again to turn it off.
- Set/Enter: press the button to enter Settings.(this function is only available on the clinician version)
- Play/Pause/Back: press the button to start or pause electrical stimulation. In Setting mode, press the button to return to previous menu.
- Mode Switch: switch between Gait mode and Training mode.Press the Mode/ Unlock switch and the power button to unlock the parameter settings.
- Left/Right choose: choose different items in Setting mode.(this function is only available on the clinician version)
- Intensity Increase/Decrease: adjustment for intensity and parameters.
- USB Interface: for device charging and software upgrades.

OLED Screen

	Charge Indicator: the remote is charged with a dynamic charging icon on the top right corner of the screen, and the icon will be full when charging is complete.
	Gait mode: the icon will show in Gait mode.
	Training mode: the icon will show in Training mode.

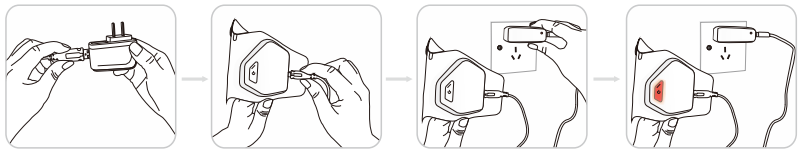
※ The Stim Unit will shut off when the Remote Control has been in pause for 5 minutes. During the normal operation, the screen of the Remote Control will become dark if there is no operation on the Remote Control for 2 minutes.

Daily Use of Your XFT-2001D

1. Charging for Stim Unit and Remote Control

1) Charging for Stim Unit

When the Stim Unit is in low battery, connect it to power adapter. The indicator on Stim Unit will turn red in charging, and it will turn green when charging is complete.



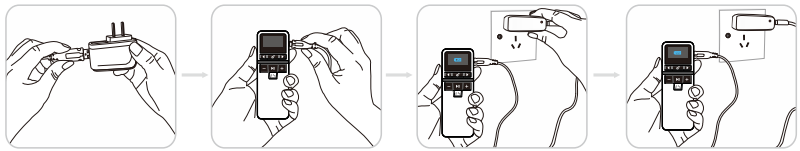
※ Note:

During the use, if the stimulation goes down or low battery icon shows in the screen of remote, please charge the Stim Unit immediately. It needs about 3 hours to charge when completely drained of power. It is designed to work for 10 hours with a full charge. Please turn off the device when not in use.

Note: Do not use the Stim Unit while charging.

2) Charging for Remote Control

When the remote is in low battery, connect it to power adapter. A dynamic charging icon will show in the screen in charging, and the icon will be full when charging is complete.



Note: Do not use the Remote Control while charging.

Power adapter

Input	AC100-240V, 50-60Hz, 0.3A
Output	DC5V, 1.2A
Size	71 x 41 x 31.5mm

Quick-fit Electrode

Material	Conductive fabric
Size	495 x 117mm

Gel Electrode

Material	self-adhesive non-woven electrode
Size	∅ 50mm

Working and storage conditions for Stim Unit and other parts:

Working Condition:
Temperature: 5℃-40℃
Humidity: ≤80%HR(Non-condensing)
Atmospheric pressure: 86kPa - 106kPa

Conditions for transport and storage
Temperature range: -20℃-55℃
Relative humidity range: ≤93% (Non-condensing)
Atmospheric pressure: 70kPa-106kPa

Production Date: see the product number on the Stim Unit

Product Service Life: 5 years (battery is not included)

Specifications

Communication: Bluetooth 4.0
Communication band: 2.4-2.4835 Ghz
Modulation type: GFSK
Effective radiated power: +4dBm

Stim Unit

Power Supply	DC3.7V, rechargeable lithium battery
Classification	Type BF Equipment
Protection Grade	IP22
Shutdown Current	<10uA
Working Current	<110mA
Wave form	asymmetrical balanced biphasic wave
Frequency	16.7-33Hz (±10%)
Pulse Width	100-300μs (±10%)
Output current	90mA at the max (load: 500Ω)
Output voltage	90V at the max (load: 1000Ω)
Size	73 x 70 x 10mm
Weight	43g

Other parts

Cuff

Size	495 x 117 x 2mm
Weight	40g

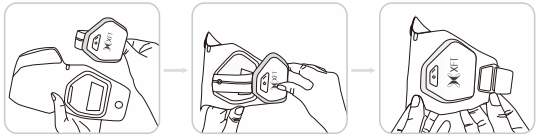
Remote control

Power Supply	DC3.7V, rechargeable lithium battery
Shutdown Current	<10uA
Working Current	<50mA
Size	107 x 38 x 11mm
Weight	39g
Control Distance	0-10m

2. Use with Quick-fit Electrode or Gel Electrode

The product has Quick-fit Electrode and Gel Electrode, patients can choose according to their needs.

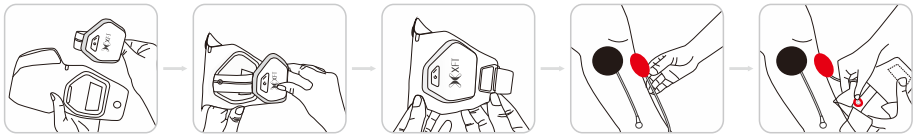
2.1 Use with Quick-fit Electrode



Note: The Quick-fit Electrode has 2 versions: for left leg and right leg.

2.2 Use with Gel Electrode

2.2.1 Install the Stimulator on the Cuff
2.2.2 Attach the Gel Electrodes to the common peroneal nerve and the tibialis anterior under the knee.
2.2.3 Connect the Gel Electrodes to the Stimulator



3. Wear the Product

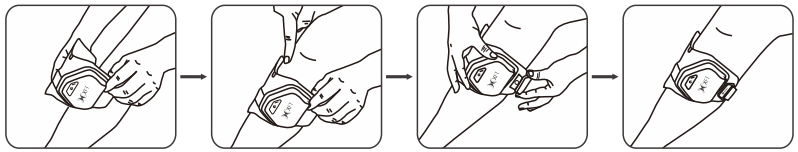
1) Preparation

a) Skin care: to achieve an ideal effect of stimulation, please use wet towel to clean the skin of the leg.

b) Sitting posture: the patient should sit on a chair, bending and relaxing the leg.

2) Operation

Apply the Product below the knee, keep the yellow location label aligned with the tibialis anterior (now the Stim Unit is at the medial leg).

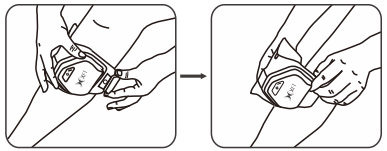


Note:

Duration time
In order for the breath of the skin underneath the cuff, please take off the Product at intervals. Generally, it is not necessary to deal with the hair on the skin, trim it by scissors to avoid skin irritation if needed.

4. Remove the Product

1) Make sure the Stim Unit is powered off.
2) Loosen the magnetic buckle, carefully lift the edge of the Stim Unit, and take off it slowly.



3) Put the entire device into the suitcase and store it properly.

Frequently Asked Questions

1. The stimulation is weak.
   a. Use the Remote to increase the intensity;
   b. If the Stim Unit is in low battery, please recharge it;
   c. Adjust the position of the Quick-fit Electrode;
   d. Use water to wet the skin underneath the Quick-fit Electrode.

2. There is no stimulation when turning to Gait mode or Training mode.
   a. Adjust the position of the Quick-fit Electrode;
   b. Use water to wet the skin underneath the Quick-fit Electrode.

3. The skin area underneath the cuff turns red with pricking or allergy.
   Stop using the device immediately, continue to use it only after the skin is recovered. Please take off the Device periodically for the breath of the skin.

4. The indicator on the Stim Unit turns red and flashes; “ low battery” shows on the screen on the Remote.
   Recharge the stim Unit and Remote.

5. The indicator on Stim Unit turns red and flashes, the “ ” shows on the screen of the Remote.
   Use water to wet the skin underneath the Quick-fit Electrode; replace the Quick-fit Electrode.

6. The Stim Unit has occasional strong stimulation.
   a. Adjust the position of the Quick-fit Electrode and fully attach it to the skin;
   b. Check if the skin area underneath the Quick-fit Electrode become red or has wound;
   c. The Quick-fit Electrode is used for a long time, please replace it.

7. No stimulation in due time.
   Generally it is because the position of Quick-fit Electrode is moved or the Gait mode is changed, please re-wear the Quick-fit Electrode and set the parameter in Gait mode.

Care and Maintenance

1. Stim Unit and Cuff

- Stim Unit
  As the electrical components are not waterproof, please do not immerse the Stim Unit in water.Please use a soft cloth with neutral detergent or alcohol to wipe the surface of the Stim Unit.

- Cuff
  - The cuff is expected to be used for 3 months, please replace it in due time.
  - The cuff is not expected to be immersed into water, please use soft brush with water to clean the surface.
  - Use dry towel to wipe off the water, and air dry it for the next use.

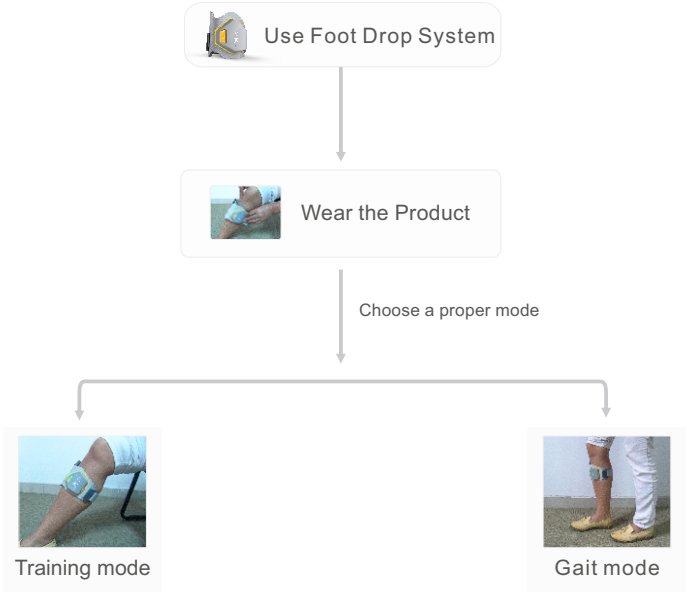
2. Quick-fit Electrode

- The life circle of the electrode differs from person to person, generally it needs to be replaced every 2 months, or 30 to 50 times of use.
- Please dry the skin area for electrode placement after shower or exercise.
- Do not share the electrodes with others.
- Do not bend the electrodes.

3. Storage:

- Storage for the Stimulator and Remote
  Turn off the Stimulator and Remote and put them in the carrying case when not in use.
  The life time for the device is 5 years, please dispose of it according to your local environmental regulations.
- Storage for the quick-fit electrode
  - Keep the surface of the electrode clean
  - Air dry the electrode and store it in dry environment.

Steps for Use



Gait mode

Gait mode is an active rehabilitation training mode, which provides rehabilitation electrical stimulation while walking;

1) Wear the Product

Wear the cuff on the leg and stand up.

2) Choose Gait Mode

Turn on the Stim Unit and Remote, press “ ” to switch to “ Gait mode”.

3) Start Walking

Press “ ” button on the remote, and take steps (start with the unaffected leg)

4) Adjust the Intensity

User can press “ ” or “ ” to adjust the intensity while walking.

There is no stimulation in the first 4 steps, as the device is analyzing the patient's gait. Stimulation will start from the fifth step.

Training mode

Training mode is suitable for patients who lack of active training, patients lay or sit down during the training.

1. Wear the Product

Have a seat and wear the Cuff on the leg.

2. Choose Training Mode

Turn on the Stim Unit and Remote, press “ ” on the Remote to switch to “ Training mode”.

3. Start Training

Press the “ ” button to start training.

4. Adjust the Intensity

User can press “ ” or “ ” to adjust the intensity.

The training cycle is 20 minutes, with the stimulation of 1 second and interval of 2 seconds.