ALFESS™

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

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CE 0123

Date:2022-08-15
Doc.No.:XFT-2001EB-GB
Version:C2

Nerve and Muscle Stimulator

XFT-2001EB

User Manual

Caution: Thanks for choosing our product. Please read this manual before use and keep it safe.

Warranty Card

Product Name: _____ Model No.: _____

Purchase Date: _____ Product Serial No.:_____

Buyer's Information: _____

Distributor's Information: _____

Manufacturer: Shenzhen XFT Medical Limited
Add: Room 203, Building 1, Biomedicine Innovations Industrial Park,
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Distributed by Alfimed A/S and Allard Int

Distributor Seal: ----------

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1. Glossary

FES: Functional electrical stimulation
NMES: Neuromuscular electrical stimulation is the elicitation of muscle contraction using electric impulses.

2. For Your Health and Safety

- To avoid any danger or injury 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”;

List of Symbols

	Type BF Equipment
	Warning
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This product must not be disposed off with other household waste
	Refer to user manual
SN	Serial Number
CE 0123	The number of the notified body (0123)
EC REP	Authorized Representative in the European Community
	Fragile
	Keep upward
	Keep dry
	Prohibit the rolling
LOT	Batch code
IP67	This product is: 1. Dust tight. 2. Protected against the effects of temporary immersion in water.
	Temperature limit
	Humidity limitation
	Atmospheric pressure limitation
MD	Medical device
	Single Patient-multiple use
	Consult instructions for use

13. Use Specification

Item	Description
Product Name	Nerve and Muscle Stimulator
Model No.	XFT-2001EB
Intended use/Indications for use	During the swing phase of walking, 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.
Intended patient population	Foot drop patient
Intended part of the body or type of tissue applied to or interacted with	The intact skin surface of the lower leg
Intended user profile	Intended user includes patient, medical persons, other operators, they are required to meet below requirement at least: -Ability to read and understand user manual, and follow the instruction to operate device; -They are healthy or use the device under doctor's direction; -No nationality or race limitation; Can identify parts of body.
Use environment	-Reusable -Hospital use or home use -Use the EMC environment for class 1 group B -Work conditions: Temperature 5~40°C, humidity ⩽80%(Non-condensing) Atmospheric pressure 86~106kPa
Operation principle	Place the Stimulator to correct position under the knee . To optimize individual function the stimulator position might be adjusted slightly.
Contraindications	• Do not use with electronic monitoring equipment, NMR-imaging, pace-maker, defibrillator and high frequency medical device. • Do not use near short-wave, microwave. (no closer than 1 m) • Patients with heart disease, severe hypertension and skin disorder are forbidden to use this product. • Patients with active hemorrhage, acute purulent Inflammation, malignant neoplasms, thrombophlebitis, sepsis and cardiopulmonary failure are forbidden to use this product. • Do not use this product for purpose other than treatment. • Do not apply this product to unconscious patients. • Do not disassemble, repair or rebuild this product. • Do not touch the charging connector/battery and the patient simultaneously when charging/using. • Patients with any of the following conditions are forbidden to use this product :epilepsy,pregnant,acute dislocations or fractures of the ankle, regional cancer in the lower limb,metal implants,automic dysreflexia.

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. (no closer than 1 m)
- Patients with heart disease, severe hypertension and skin disorder are forbidden to use this product.
- Patients with active hemorrhage, acute purulent Inflammation, malignant neoplasms, thrombophlebitis, sepsis and cardiopulmonary failure are forbidden to use this product.
- Do not use this product for purpose other than treatment.
- Do not apply this product to unconscious patients.
- Do not disassemble, repair or rebuild this product.
- Do not touch the charging connector/battery and the patient simultaneously when charging/using.
- Patients with any of the following conditions are forbidden to use this product :
  - Patients with epilepsy.
  - Patients that are pregnant.
  - Patients with acute dislocations or fractures of the ankle.
  - Patients with regional cancer in the lower limb.
  - Patients with metal implants.
  - Patients with automic dysreflexia.

Warning

- Do not use the XFT-2001EB while receiving any MRI scan.
- Do not use the XFT-2001EB while sleeping, bathing or operating a vehicle.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be used near the chest which may increase the risk of cardiac fibrillation.
- 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 transcerebrally.
- 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 has not been determined.
- Electrode pads' positioning and stimulation parameters' setting should be conducted by professionals. If you keep feeling uncomfortable stimulation or experience a skin irritation or rash, please stop using this product.
- Please do not position the electrode pads in the area of malignant neoplasms, neck arteries (throat) or thrombus.
- Please do not position the electrode pads on the affected skin or other affected area, such as fracture and dislocation.
- 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 if the used areas have structural deformity.

- This product should be prescribed by a physician.
- Please stop using this product if the body shows any unforeseen adverse medical condition while using this device.
- The charging cable is long and it is recommended to wrap the overly long part. Keep it out of the reach of children.
- Do not replace the battery without authorization of XFT.

Precautions

- Do not use near (within one meter) of short-wave technology or a microwave.
- 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.
- 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 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 healing process;
  c. Over the belly of a pregnant women.
  d. 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.
- Caution: the temperature of big electrode may reach to 41.5°C under continuous operating at environment temperature 40.0°C; To avoid injury from heat , please don’t keep long contact with it.

Adverse Reactions

Skin irritation or hypersensitivity due to the electrodes has been reported with the use of powered muscle stimulators.

12. 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.

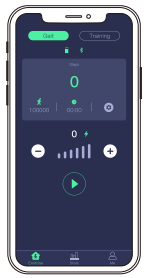
Table 5

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.			

3. Overviews

3.1 Product Introduction

The Foot Drop Rehab System is a wearable functional electrical stimulation rehabilitation device operated with either a smart phone or a remote control.



This device has integrated electrodes to provide a safe and simple use. The software is designed for simple and effective self-programming providing a safe user experience for medical personnel and patients.

Indication for use

XFT-2001EB 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 device 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.

3.2 Treatment Principle

XFT-2001EB detects and analyzes the patient’s gait patterns in real time through the internal tilt and accelerometer sensors, and then simultaneously delivers low frequency comfortable electrical stimulation to the common peroneal nerve which in turn will evoke muscle contraction and enabling patients to actively walk with a more normalized gait.The most common use of FES is as a treatment for foot drop where disruptions in the nerve pathways between the legs and brain which means the front of your foot can't be lifted to the correct angle when walking.

3.3 Use Cycle

Adhere to the principle of gradual progress when using.

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: Remove the device for 15 minutes after each use.

4. Product Illustration & Product Parts

This device consists of the stimulator, power adapter(EU and UK plug),remote control, charging cables, extension strap and APP software (optional).

4.1 Stimulator & Remote Control

Stimulator

Remote Control

4.2 Parts

No.	Parts	Picture	
1	Power Adapter		The Power Adapter and Charging Cable are used to charge the device, EU & UK plug included. (Additional cable for remote control)
2	Charging Cable		
3	Charging Cable for Remote Control		
4	Remote Control		
5	Extension Strap		To be used in patients with larger calf.

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	2	0.3	28
710	704-787	LTE Band 13,17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 85, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation [b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

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

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.

4.3 Operation Panel

4.3.1 Operation Buttons

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

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

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

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

4.3.2 Indicators

Power-on indication

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

		
LOGO	Gait Mode	Training Mode

Mode switching

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

	
Gait mode	Training Mode

Start/Pause

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

	
Stimulation Intensity	Stimulation Intensity

Electrical Stimulation Output Prompt

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

	
Lightning Symbol	Stimulation Intensity

Electrode Loose Indication

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

	
Electrode Loose	Electrode Loose

Low Battery / Charging Prompt

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

			
Low Battery, flash once per second	Charging	Charging	Full Charge

Table 3

Guidance and 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 level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz	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	10Vrms	
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.			

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
This equipment is intended for use in the electromagnetic environment specified below. User should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) 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; 1 cycleand 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycleand 70 % UT; 25/30 cycles Single phase: at 0°	Main power quality should be that of a typical commercial or hospital environment.
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.			

Automatic Screen Saver

The screen will sleep in 30 seconds if there is no operation on the stimulator, and then the screen saver icon will show up in 1 minute and move from left to right.

Screen Saver Icon

4.4 APP Software Descriptions

Software Name：Foot Drop Rehab

Operational Environment:

Hardware Requirements:

iPhone 5s and subsequent release models of the iPhone.
Mobile phone with Android 6.0 and later.

Software Environment:

iOS:
System environment: iOS 9.0 or later;
Android:
Android 6.0 and later.
Security software: none;
Network requirements: Bluetooth communication.

Data Transmission

Data is transmitted between APP and Stimulator via Bluetooth communication.

Storage Medium

APP software data is stored in the mobile terminals.

User Login

User name and password shall only be set by user.

Detection, response and recovery of network security events

Data transmission between APP software and device is carried out through specific Bluetooth service channel, data format and data verification requirements are required at the same time, which can avoid connection and control of other devices or software.
When the connection between APP software and device is interrupted during usage, APP software will give a reminder of disconnection, and you can control the device by pressing the button on the device.
After the Bluetooth connection between the APP software and the device is disconnected, the APP will search and connect the device that has been turned on if the device needs to be re-controlled by the APP.

Software Update

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

5. General Operation Instruction

5.1 How to clean the device?

- Use a sponge or a soft cloth to remove dust and dirt from the electrode surface before use,please keep the electrodes clean.
- After cleaning, wipe the electrode with a sponge or a soft cloth dampened with disinfectant . The disinfectant is a 75% medical alcohol.
- Wipe the electrode 3 times with a sponge or a soft cloth dampened with disinfectant.

5.2 How to use the device?

It can be operated with an APP (smart phone), with a remote or by display only.

Please make sure that the stimulator is fully charged before use. If necessary, please charge the stimulator; when charging, the stimulator display will indicate the battery icons.

Connect the charging cable to the power adapter	Connect the cable to the Stimulator and then to the power socket	Mount the correct socket connector to the power adapter
		

How to charge the stimulator

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

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

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

5.3 Putting on the Device

Before putting on the device, make sure that the skin of the lower leg is intact, and that the device is clean and without any damages.

- Use wet towel to clean the skin of the leg.
- Connect gel is highly recommended to use on to the leg to improve contact. We recommend Alfess connect gel.
- Sit on a chair, bend and relax the leg.
- Place the stimulator to correct position under the knee.

Table 1

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

11. 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 separation 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.

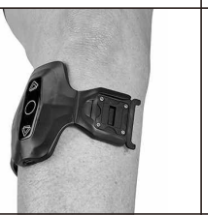
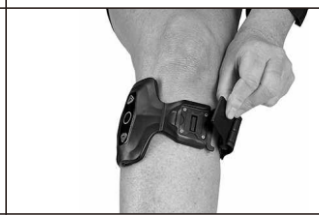
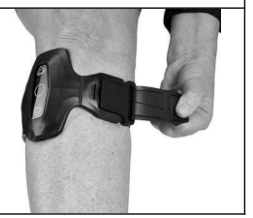
⚠ **Caution:** manufacturer will not responsible for any unauthorized actions that cause interference.

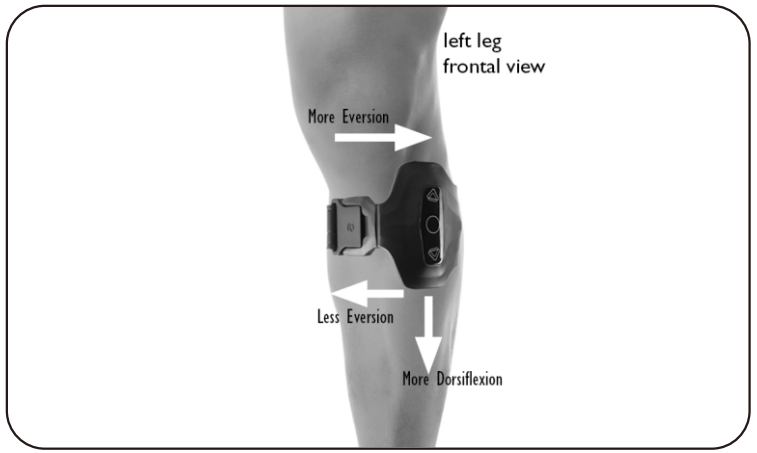
Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

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

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

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

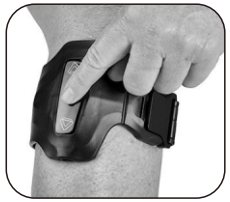
1.The front with display is placed on the lateral side of the leg, below the knee	2. Keep the vertical line aligned with tibia. Mount the magnetic buckle.	3. Tight the cuff with the strap.
		



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

5.3.1 Power on and Operate

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



		
LOGO	Gait Mode	Training Mode

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

	
Stimulation Intensity	Stimulation Intensity

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

5.3.2 Power off

Turn off the stimulator by pressing the Power/Mode Button for 2 seconds.

5.4 Operate with APP

5.4.1 Install APP

Procedure	Operation Description
Step 1	Go to APP Store or Google Play and search “Foot Drop Rehab” to find the APP, and install it on your mobile phone.
Step 2	Run the APP on your mobile phone and create an account for the first time.

Data rate	1Mbps
Occupied band wide	2MHz
Channel separation	2MHz
Maximum transmission distance	10m
Wireless QoS	I/U(intended-to-unintended)Ratio≤-1dB Throughput≥0.3Kbps Latency(one-way delay)≤1s Jitter(latency variation)≤1s PER(Packet error rate)≤3%

The wireless QoS need

The XFT-2001EB Foot Drop System was designed and tested to have a response rate of 10-100ms latency depending on system configuration.

Wireless Interference

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

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

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

10. Product Classification

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

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

Rechargeable lithium battery

Model	Sh652432
Specification	3.7V 520mAh

9.5 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: 3 Years

9.6 Accessories

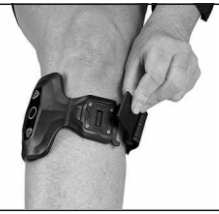
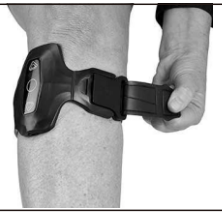
Stimulator	1pc,
Power Adapter	1pc,Optional
Extension Strap	1pc
Charging Cable	1pc,Optional
Charging Cable for remote control	1pc,Optional
Remote Control	1pc,Optional
App Software	1pc,Optional
User Manual	1pc

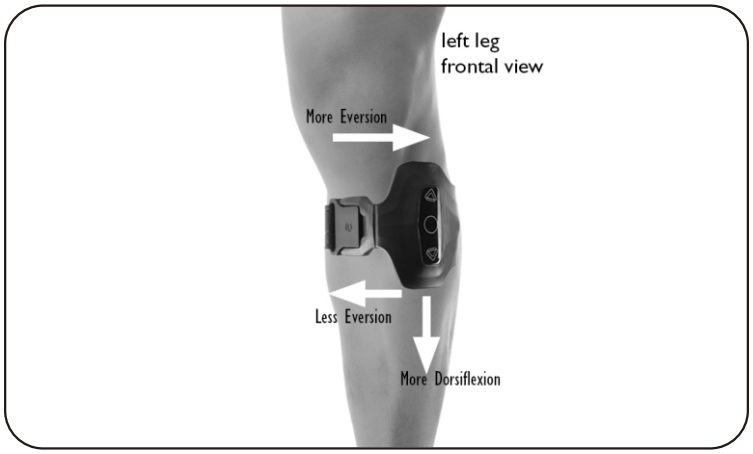
9.7 Wireless Technology Description

Type of wireless technology	Bluetooth V4.0 BLE
Wireless function	Transmission the device data and the patient data from transmission terminal equipment to receiving terminal equipment, as well as ensuring the integrity and security of data during transmission.
Modulation Type	GFSK
Modulation Signal Type	Digital
RF Band wise	2402MHz~2480MHz
Channel Number	40(CH0-CH39)

5.4.2 Wear the Stimulator

- Use wet towel to clean the skin of the leg.
- Connect gel is highly recommended to use on to the leg to improve contact. We recommend Alfess connect gel.
- Sit on a chair, bend and relax the leg.
- Place the stimulator to correct position under the knee.

1.The front with display is placed on the lateral side of the leg, below the knee	2. Keep the vertical line aligned with tibia. Mount the magnetic buckle.	3. Tight the cuff with the strap.
		



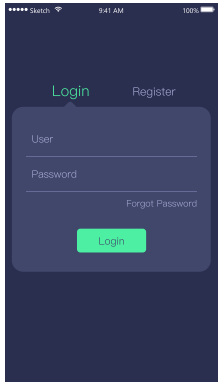
To optimize individual function,the stimulator position might be adjusted slightly, please consult the fitter.

5.4.3 Power on and Operate

- **Power on**

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

5.4.3.1 Login the APP and connect the stimulator to the APP via Bluetooth.

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

9. Product Specifications

9.1 Product Specifications

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

9.2 Stimulator

Power Supply	3.7V rechargeable lithium battery
Classification	Type BF applied part, internally powered equipment
Shutdown current	≤50μA
Working current	≤120mA
Wave form	Asymmetric biphasic balanced wave
Frequency	16-50Hz (±10%)
Pulse Width	100-300μs (±10%)-
Output intensity	0-90mA(±10% or ±2mA, whichever is greater, with 500Ω load)
Dimension	(130mm±5mm)*(126mm±5mm) *(104.29mm±0.3mm)
Weight	⩽200g

9.3 Remote Control

Power Supply	DC3.7V, 520mAh rechargeable lithium battery
Shutdown Current	⩽ 10 μA
Working Current	⩽ 50 mA
Size	107 x 38 x 11 mm
Weight	39 g
Control Distance	0-10 m

9.4 Power Adapter

The power adapter used with the unit can be purchased from our company, or in the market according to the following requirements:
The rated output of the power adapter is DC 5V, 1.2A. The power adapter shall comply with the requirements of IEC 60601-1.

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

8. FAQ & Troubleshooting

Q1. What should I do if the stimulation intensity is weak?
-Adjust the intensity through the stimulator or the APP.
-Adjust the position of the electrode.
-If the stimulator battery is low, please charge it in time.
-Wet the skin with some water or the connect gel so as to increase the electrical conductivity between the electrode and the skin.

Q2. I have turned on the stimulator and choosen the Training or gait mode. The indicator light is on, but there is no reaction for the electrical stimulation, why?
-Check whether the stimulator has been fastened well to the leg and close to the skin.
-Check whether the intensity has been adjusted to the appropriate value.
-Wet the skin with some water or the connect gel so as to increase the conductivity between the electrode and the skin.

Q3. What should I do if the skin in the area covered by the electrode and the cuff is severely red, stinging or allergic ?
-Stop using it immediately. After observing for a period of time, if no abnormality is found, wait until the skin is completely improved before continuing to use the device. Remember to regularly ventilate the skin covered by the stimulator.

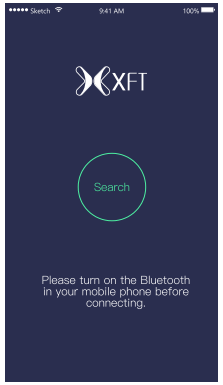
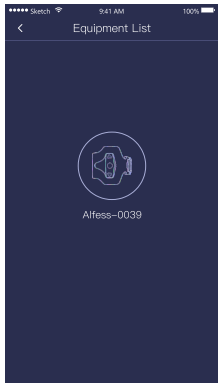
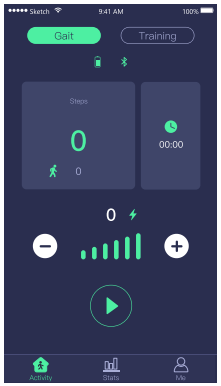
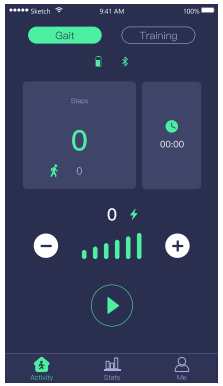
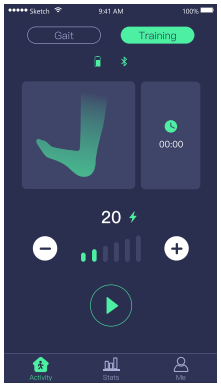
Q4. The stimulator automatically shutdown after the battery icon flashes on the screen.
-This indicates that the stimulator battery is low and needs to be recharged. It takes about 8 hours for the stimulator to charge. After the battery is fully charged, the stimulator can last for about 10 hours. When the battery is low, please charge it in time.

Q5. What should I do if the screen shows " ⚠ " and " Drop " icon alternately?
-This icons are reminders of electrode loose. Please check whether the stimulator has been fastened well. Or please check whether the skin is wet enough. If not, please wet the skin with some water or the connect gel before using.

Q6. What should I do if there is sporadic strong electricalstimulation?
-Wet the skin with some water or the connect gel so as to increase the conductivity between the electrode and the skin.
-Check whether the skin in the area covered by the electrode is red or has a wound.
-Check whether the stimulator has been fastened well to the leg or the electrode has been placed on the corrent position.

Q7. Why can't I feel the stimulation when there should be stimulation output?
-Normally it is because the cuff position has been changed or the gait mode has been changed. Please wear the stimulator again or reset the parameters of gait mode.

Q8. Can I use oil or lotion on my legs?
-No, please make sure the skin is clean before using the stimulator and wet the skin with some water or the connect gel so as to increase the conductivity between the electrode and the skin.

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

- Gait Mode

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

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

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

2. Normal Mode: The stimulator performs electrical stimulation according to the set parameters. The parameters that can be adjusted are the electrical stimulation intensity, and the frequency, pulse width, tilt angle A, tilt angle B, duration, delay time, rise time and fall time in the lower-level interface of the “Parameter Settings”.

3. Manual Mode:The clinician can manually press the "Start " button to deliver stimulation at certain time by observing the patient's gait when the patient is walking.The parameters that can be adjusted are the electrical stimulation intensity,frequency and pulse wideth in the lower level interface of the "Parameter Settings."

- Training Mode

The stimulator performs electrical stimulation based on a combination of parameters of the selected training mode. The parameters combine 9 preset modes and 1 custom mode. The electrical stimulation can be adjusted after the preset mode starts, and other parameters can’t be adjusted. All parameters can be adjusted in the custom mode.

- Start: The app sends the training mode parameters and the mode start command to the stimulator, receives the stimulator’s reply, and enters the training work interface.
- Pause: The APP sends a training mode pause (stop) command to the stimulator, receives the stimulator’s reply, and the training is suspended.
- Continue:The APP sends the training mode (start) and you have to adjust the intensity again. After receiving the stimulator's reply, the training work continues.
- End: After long press and stop for 1.5 seconds, send the training mode stop command to the stimulator, receives the stimulator’s reply and the training mode stops.

7.5 Product Service Life

The service life of the XFT-2001EB is 3 years. At the end of its life expectancy or the device ceases to continue working, please dispose of it in accordance with the local and national regulation.

7.6 Battery Safety

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

7.7 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.

7. Care and Maintenance

Before using this device every time, you should follow below steps to clean:
1) Use a sponge or a soft cloth to remove dust and dirt from the electrode surface before use, please keep the electrode clean.
2) After cleaning, wipe the electrode with a sponge or a soft cloth dampened with disinfectant .The disinfectant is a 75% medical alcohol.
3) Wipe the electrode 3 times with a sponge or a soft cloth dampened with disinfectant.
4) Please apply contact gel on the unit and leg.

7.1 Maintenance for Stimulator

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

7.2 Maintenance for the Metal Electrodes

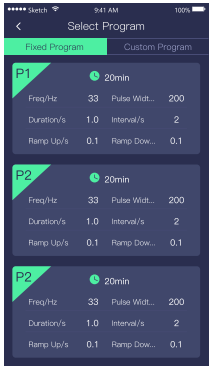
- Metal electrodes can be used in long term. Please keep them clean.
- Use medical alcohol to clean the electrode surface and use clean towel to wipe it.
- Do not wash with detergent or hot water.
- Electrodes should be kept clean, covered and carefully stored when not in use.

7.3 Skin Care

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

7.4 Skin Irritation Prevention Advice

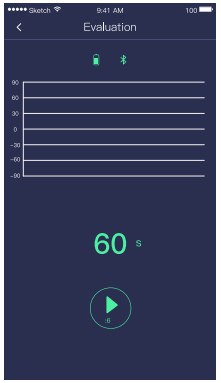
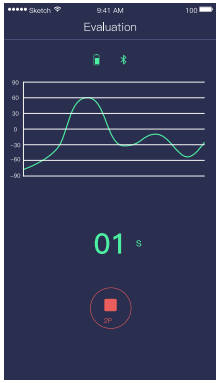
- Use water to remote all makeup, unclean areas or oil from the skin.
- Do not position the electrodes over an irritated area of the skin.
- Removing the leg's hair may enhance the electrical intensity and enhance the motor response. If necessary, an electric razor or a pair of scissors is recommended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

Choose one mode


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

- Evaluation Mode for Pro Version

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

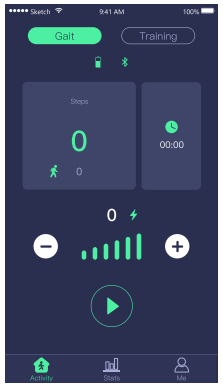
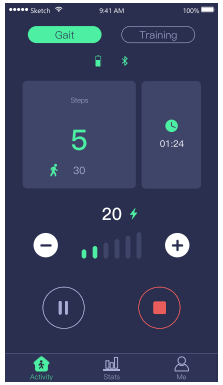
Evaluation Mode	Start Evaluating
	

- Shut Down

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

5.4.3.2 The APP Consists of 3 Sections: Activity , Stats , and Me .
5 .4 .3 .2 . 1 Activity

Gait Mode

Procedure	Operation Description	APP Interface
Step 1	Start the session.	
Step 2	Adjust the stimulation intensity.	

6. Attentions

6.1 Troubleshooting

Malfunction indicator will show the following troubles:

6.1.1 Electrodes loose

The malfunction indicator flashes slowly once pen second. When the system detects that the electrode is off, this will be indicated on the display and the device will stop running. Please adjust the place of the electrodes and press the Power/Mode Button again.

6.1.2 Low battery

When the stimulator is in low battery, there will be a battery icon flashing once per second in the screen.

Low battery, flash once per second

6.2 Allergy Prevention Advice

- Do not place the device on skin with makeup or oil.
- Remove the leg'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.

5.5.2.2 Training Mode

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

1. Wear the Product
   Have a seat and wear the stimulator on the leg.

2. Choose Training Mode
   Turn on the Stim Unit and Remote, press " " on the Remote to switch to " Training mode".

Please set the parameters in Training mode, if necessary

Setting in Training Mode

Press " " on remote, press " " or " " to choose Training mode setting, and press " " again to enter the setting in Training mode.

The parameter setting should be only for professionals.

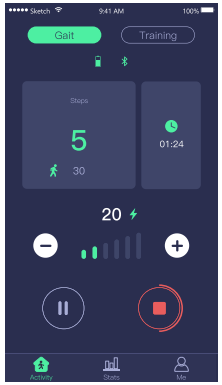
3. Start Training
   Press the " " button to start training.

4. Adjust the Intensity
   User can press " " or " " to adjust the intensity.

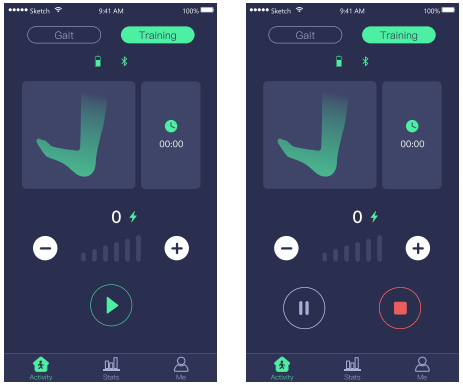
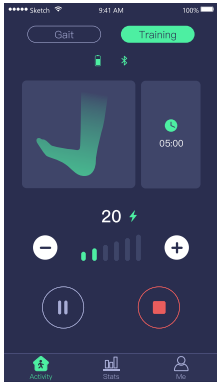
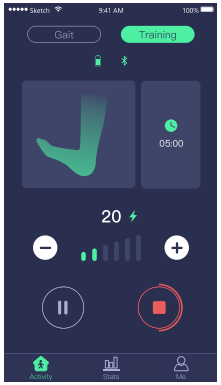
Specification of 1-9 preset prescriptions are as below, the training time of each is 20 minutes, and it will auto shut off when time is up.

Mode	Stimulation	Interval
1	1 sec	2 sec
2	1.5 sec	3 sec
3	2 sec	4 sec
4	2.5 sec	5 sec
5	3 sec	6 sec

Mode	Stimulation	Interval
6	3.5 sec	7 sec
7	4 sec	8 sec
8	4.5 sec	9 sec
9	5 sec	10 sec
custom	—	—

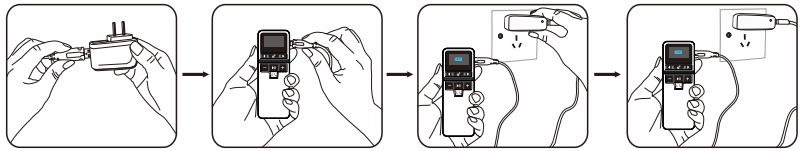
Step 3	Press and hold the button for 1.5 seconds to end the session.	

Training Mode

Procedure	Operation Description	APP Interface
Step 1	Start the session.	
Step 2	Adjust the stimulation intensity.	
Step 3	Press and hold the button ■ for 1.5 seconds to end the session.	

5.5.1 Charging the 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.

5.5.2 System mode

5.5.2.1 Gait Mode

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

1) Wear the Product
Wear the stimulator on the leg and stand up.

2) Choose Gait Mode
Turn on the Stim Unit and Remote, press "▶" to switch to "▶".

Please set the parameters in Gait mode, if necessary

Setting in Gait Mode
Press "⚙" on remote, press "◀" or "▶" to choose Gait mode setting, and press "⚙" again to enter the setting in Gait mode.

3) Start Walking
Press "▶II" 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.

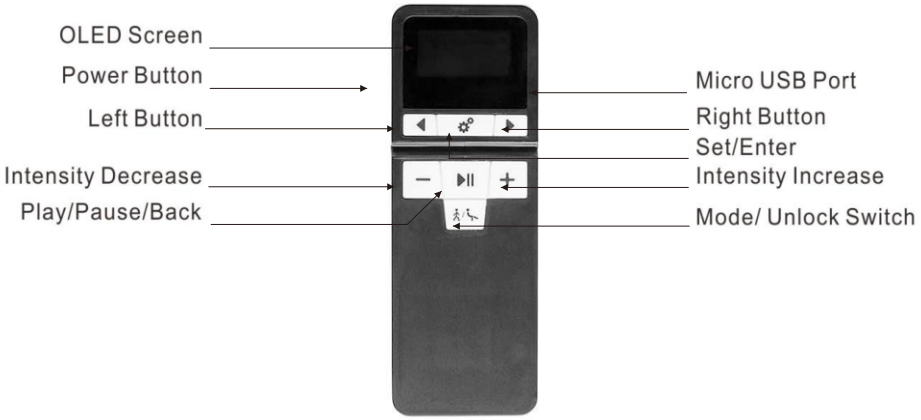
The parameter settings should be only for professionals.

Parameter Setting in Gait Mode

Parameter	Range	Increment	Default
Pulse width	100-300μs	50μs	200μs
Frequency	16-50Hz	–	33Hz

5.5 Operate with Remote Control

Buttons



Power Button: press for 1 second to turn on the remote control, press for 1 second to turn off.
Set/Enter: press the button to enter Settings.
Play/Pause/Back: press the button to start or pause electrical stimulation. In Setting mode, press the button the back to previous menu.
Mode Switch: switch between Gait mode and Training mode.
Left/Right choose: choose different items in setting mode.
Intensity increase/Decrease: adjustment for intensity and parameters
USB Interface: for device charging and software upgrades.

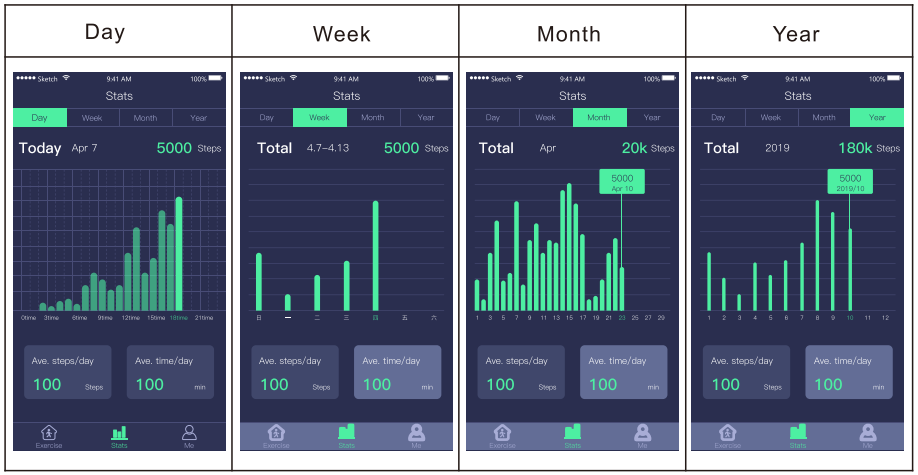
Symbols presented on the screen

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

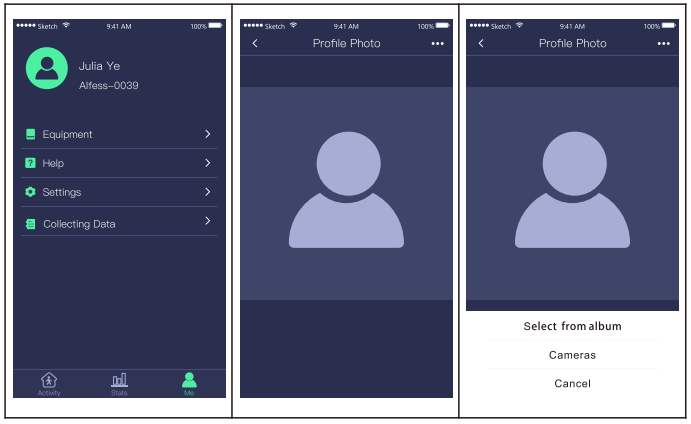
5.4.3.2.2 Stats

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

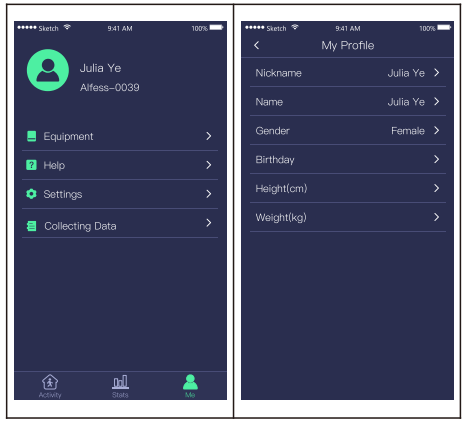


5.4.3.2.3 Me

Change your profile photo

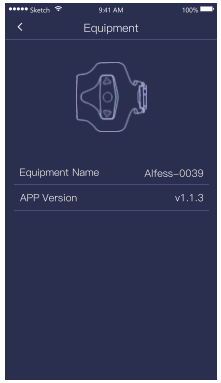


Edit personal information



Equipment Information

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

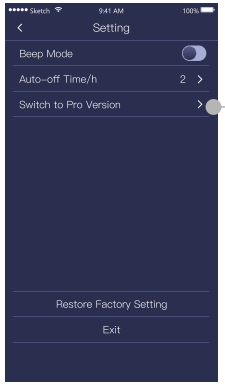


Help

You can go to the help page for Attention, Introduction, Quick Guide, and FAQ.

Setting

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



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