



## User Manual Nerve and Muscle Stimulator

(Trade Name: Hand Rehab System) [XFT-2003E] MNL-0022

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

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## **Glossary**

EMG: Electromyography, it is an electro diagnostic medicine technique for evaluating and recording the electrical activity produced by skeletal muscles.

sEMG: Surface EMG uses electrode like sensors to assesses muscle function by recording muscle activity from the surface above the muscle on the skin

FES: Functional Electrical stimulation.

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

ETS: EMG triggered electrical stimulation.

PAS: Power assistant stimulation.

UE: Upper Extremity

## 1. For Your Health and Safety

- To avoid any danger or injury caused by inappropriate use, please read this manual carefully.
- Safety precautions include danger or injury caused by inappropriate use and are categorized into sections of: Contraindications, Warning and Precautions.
- · Please read this manual carefully.

### **List of Symbols**

O	Contraindications, that may cause danger		
0	Mandatory requirement or may cause an injury or physical discomfort		
<b>*</b>	Type BF Equipment		
	Warning		
(((*)))	Non-Ionizing Radiation		
M	Date of Manufacture		
<u>l</u>	Manufacturer		
Ā	This product must not be disposed of with other household waste		
€>	Refer to user manual		
SN	Serial Number		
C € 0123	The number of the notified body (0123)		
EC REP	European Authorized Representative		
<u>[]</u>	Fragile		
[11]	Keep upward		
[#]	Keep dry		
IP22	Degree of Ingress Protection (for Control Unit)		
[X]	Temperature limit		
[Ø]	Humidity limitation		
[ <u></u>	Atmospheric pressure limitation		
Ωi	Consult instructions for use		
MD	Medical device		
(ii)	Single Patient-multiple use		

### O Contraindications

- Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.
- Do not use with electronic monitoring equipment, NMR-imaging, pace-maker, defibrillator or high-frequency medical device.
- Do not use if you have a history of autonomic dysreflexia.
- Do not use FES following recent surgery where muscle contraction may disrupt the healing process.

### **Marning**

- Do not use the XFT-2003E while receiving any MRI scan.
- Do not use the XFT-2003E while sleeping, bathing or operating a vehicle.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- The safety of usage during pregnancy has not been determined.
- Electrode 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 in the area of malignant neoplasms, neck arteries (throat) or thrombus.
- Please do not position the electrode 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.

### Precautions

- Do not use near (within one meter) of short-wave technology or a microwave.
- Patients with heart disease, severe hypertension and skin disorder are forbidden to use this product.
- Patient with epilepsy is 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.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
  - a. When there is a tendency to hemorrhage following acute trauma or fracture:
  - 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.
- Patients who use the device at home need to be trained by a doctor and follow the treatment plan set by their doctor.

#### **Adverse Reactions**

Skin irritation beneath the electrodes has been reported with the use of powered muscle stimulators.

### 2. Overviews

#### 2.1 Product Introduction

XFT-2003E detects and monitors the EMG muscle activity signal of a patient and delivers an electrical stimulation pulses according to EMG signal strength to stimulate the patient in order to achieve a muscle contraction. With multiple training modes and interactive gaming applications patients can actively participate in the rehabilitation process and receive treatment with greater enjoyment and customization. The device is also equipped with an evaluation function to establish baseline data and threshold levels as well as track rehabilitation progress to help medical professionals customize evidence based, objective and effective rehabilitation treatment programs for each patient.

#### Innovations:

- Collection and processing technology that records the patient's EMG signals.
- EMG triggered stimulation to assist the central nervous system in a more natural recovery process.
- The latest generation of real-time Power Assistant Stimulation based on EMG.
- A combination of biofeedback interactive games and rehabilitation training based on EMG.
- Multiple training modes utilizing a rehab focused smart phone app.

### 2.2 Treatment Principle

The XFT-2003E detects and analyzes the patient's EMG signals in real time through the electrode and then simultaneously delivers low frequency comfortable electrical stimulation according to the EMG signal which in turn will evoke muscle contraction and enable patients to actively participate in activities of daily living.



#### 2.3 Indications for Use

#### **Functional Electrical Stimulation (FES)**

Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury.

#### **Neuromuscular Electrical Stimulation (NMES)**

- 1) Increase or maintain hand range of motion
- Reduce muscle spasms
- 3) Retard muscle atrophy
- 4) Reeducate muscles
- 5) Increase local blood circulation

### 3. Product Illustration

### 3.1 Components

The XFT-2003E consists of the Stimulator, Power Adapter, Charging Cable, Electrode Cables (optional), and Hydrogel Electrodes (optional).

#### 3.1.1 Stimulator

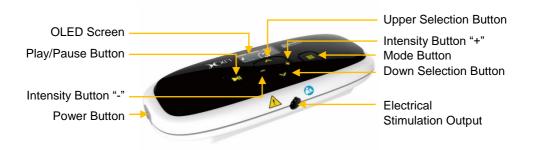


#### 3.1.2 Parts

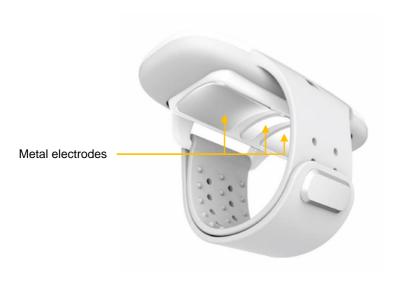
No.	Parts	Picture	Description
1	Power Adapter		The Power Adapter and Charging Cable
2			are used to charge the device.
3	Electrode wire (Optional)		Used for connecting electrode piece and equipment.
4	Conductive adhesive skin electrode (Optional)		After connecting the electrode wire, it is attached to the treatment site.

### 3.2 Operation Panel

### 3.2.1 Operation button instruction







# This device has 7 buttons (1 power button and 6 function buttons), and 1 USB Type-C port.

- Power Button: Press and hold for 1 second to turn on / turn off the stimulator.
- Mode Button: Switch and select among NMES, ETS, PAS, EMG and GAME mode.
- Upper/Down Selection Button: Press up button to check the stimulator version, and switch the system language (Chinese and English are available)
- Play/Pause Button: Start or pause in NMES, ETS, PAS and EMG mode.
- Intensity Buttons: Adjust the stimulation intensity during operation. Press "+" to increase intensity or "-" to decrease intensity.
- · Intensity adjustment:
  - <10mA, the intensity increases by 1mA increment;</p>
  - 10-30mA, the intensity increases by 0.5mA increment;
  - >30mA, the intensity increases by 0.1mA increment;
- User can feel the stimulation each lime increasing the intensity.
- USB Type-C Port: The stimulator is equipped with a USB Type-C port for device charging.
- Velcro Wristband: To be worn on the arm to fix the stimulator.

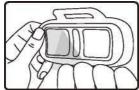
### 3.3.2 Screen Icons

Icon	Function	Explanation
	Battery level	It will flash once per second when the battery is lower than 10%, and the stimulator will stop and auto off in 5 minutes. The stimulator will auto off in 5 seconds when the battery is lower than 2%.
	Charging	The scrolling battery icon indicates that the device is charging, and when the battery icon shows a full battery, the device is fully charged.
NMES	NMES Mode	Under this mode, user can download different prescriptions from APP for different needs.
AAA ETS	ETS Mode	Under this mode, user can set up a threshold by APP; The stimulation will be triggered when the EMG signal reaches the threshold.
AAA PAS	PAS Mode	The stimulation will be triggered when user contacts the muscle.
EMG	EMG Mode	It displays when you choose EMG mode. The columnar and parameter represent the EMG power, train by following the instruction, 3-second relax for 3 times and 6-second measuring cycle, the stimulator will change the ETS threshold to the average value of 3 times measuring data.
SAME	GAME Mode	The stimulator can connect to the APP under this mode.
*	Bluetooth Indicator	When you need to connect to the smart phone app please switch to GAME mode, then you can see the Bluetooth indicator flashes; operate the app and stimulator by Bluetooth and you can see the Bluetooth indicator display. Now, you can control the stimulator by the app.
<b>†</b> <u></u>	Electrodes loose Indicator	The electrodes loose indicator will display and the stimulator will stop when the electrodes and the skin have poor contact. Re-adjust the electrodes and tightness of the cuff and press Play/Pause button again to restart.

### 4. Setup Instruction

#### 4.1 Use with metal electrodes

- 1) Peel off the transparent film from the metal electrodes;
- 2) Add some water to the area of skin;
- Wear the Stimulator on the arm and make sure that the metal electrodes attach to the extensor muscles wrist extensors.
- 4) Press the power button to turn on the device.
- Press the mode button to choose the mode (NMES mode, ETS mode, PAS mode, EMG mode, GAME mode) to start the treatment.
- 6) After, the treatment is complete, press the power button to turn off the device.
- Take off the device from the arm.
- 8) Clean the metal electrode and the device with a soft cloth, and then store it in the portable case.



 Peel off the transparent film



2. Add some water to the area of skin



Wear the Stimulator



4. Press the power button



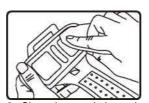
Press the mode Button



6. After treatment, press the power button to turn off.



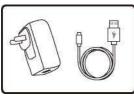
7. Remove the Stimulator



8. Clean the metal electrode

### 4.2 Charging the Stimulator

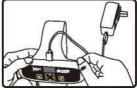
- 1) Take out the Power Adapter and the Charging Cable from the packaging.
- 2) Insert the USB end on the charging cable into the USB port of the charger.
- Connect the magnetic end of the charging cable to the charging port of the Stimulator.
- The battery icon will display on the screen of the Stimulator to indicate charging.
- The battery icon will display on the screen of the device when it is fully charged.



Take out the Power
 Adapter and the Charging
 Cable



Connect the Power
 Adapter and the Charging
 Cable



Connect the Stimulator Cable and the Stimulator



Battery icon on the Stimulator



5. Fully charged

### 5. Operation Instruction

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

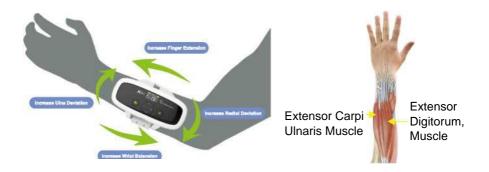
The Stimulator can be used with or without the app.

### 5.1 Uses without the App

#### 5.1.1 Wear the Stimulator

Please wear the device on the right location according to your need.

Electrode Placement (Stimulated Muscles)	Motion	
Extensor Digitorum Muscle	Finger Extension and Wrist Extension	
Extensor Carpi Ulnaris Muscle	Wrist Extension, and Wrist Adduction	



#### 5.1.2 Power on

Before using the device, please use water to clean and wet the skin area where electrodes will be attached. Hold the power button for 1 second and you will see the following interface. It will go to the default NMES mode in 3 seconds. Press the mode button to switch and select among NMES, ETS, PAS, EMG and GAME mode.



#### 5.1.3 Mode Selection

#### 5.1.3.1 NMES

Press the Play/Pause button to start the treatment and press "+" or "-" to adjust the intensity.



#### 5.1.3.2 ETS

Press the Play/Pause button to start the treatment, and press "+" or "-" to adjust the intensity. The stimulation will be triggered when user contracts the muscle and the EMG signal reaches the threshold.



#### 5.1.3.3 PAS

Press the Play/Pause button to start the treatment, and press "+" or "-" to adjust the intensity. The stimulation will be triggered when user contracts the muscle.



#### 5.1.3.4 EMG

Press the Play/Pause button to start EMG signal test. The stimulator will test the EMG signal in 3 cycles of 3 seconds relax and 6 seconds flex, and then comes the average value.



#### 5.1.3.5 GAME

GAME mode is not available if the device is not connected with APP.



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### 5.2 Uses with the app

#### 5.2.1 Download or update app

#### 1) Connect to WIFI

Check in "Settings" to see if your iPad is connected to a Wi-Fi network. If not connected, select the WiFi that can be connected and enter the password to connect.



#### 2) Install / Update

Click "Get" to start the installation. If it is already installed, click "Update", wait for the download to complete, and the installation or update is successful. XFT-2003E can be used along with iPad, which is installed with a software (The APP software Rev. 1) provided by the manufacturer.

The device has two parts, the XFT-2003E and APP software, which is installed on iPad. User interface is located on APP software, including parameters setting and display of images. There is specific communication protocol between XFT-2003E and APP software

#### Software:

- Rev.VI
- The XFT-2003EApp named as SEMG-2003E system App for iOS;
- iOS: iOS 9.0 or above;

#### iPad Recommend:

- iPad 4 and later iPad:
- WIFI support: No;
- · Network: Bluetooth:
- SSD storage: more than 16G;

Network requirements when using the APP: The APP will not be connected to the Internet during the use of the APP, and there is no need to connect to the Internet.

#### **Data and Device Interface:**

The data in the APP is limited to internal storage access in the APP. It neither accesses patient information data from other systems or software nor imports patient information data into other systems or software.

The internally stored data is a patient information form and a medical treatment record form. The APP controls the device and transmits the data from the device to the APP according to a specific encrypted instruction protocol via Bluetooth communication.



### 5.2.2 Wearing the Stimulator

Wear the device at the correct location (See 5.1.1 Wear the Stimulator) according to your need and corresponding motor response. Add ample amounts of water to the area of skin that will be in contact with the electrodes.

#### 5.2.3 Power on

Hold the power button for 1 second and you will see the following interface: The display will go to the default NMES mode in 3 seconds. Press the mode button to switch and select among NMES, ETS, PAS, EMG, GAME mode.



#### 5.2.4 Connect with app

- Press "Mode" button to select the "GAME" mode on the stimulator.
- 2) Run SEMG-2003E app on the iPad.
- 3) Account registration is required for the first use.
- Enter the account number, password and confirmation password as required.
- 5) If you forget your password, you can click to change it.
- 6) Enter and confirm the password as required.
- 7) Log in on the iPad.
- 8) Click "Search" to search the Stimulator.
- 9) Choose the Stimulator and Click "Connect".
- 10) Enter the home interface on the iPad.



1. Select GAME mode

Run the SEMG-2003E APP

2. Run the SEMG-2003E app on the iPad



3. Register an Account



5. Change Password



7. Log in on the iPad



4. Log in the account, Confirm Password



6. Enter Password and Confirm Password



8. Search device







10. APP home page

#### 5.2.5 Create Patient Information

- 1) Click the patient icon to enter patient list page.
- 2) Click "+" icon to add patient record.
- 3) Edit the patient information and Save.



 Click the patient icon to enter patient list page



2. Click "+" icon to add patient



3. Edit the patient information and Save

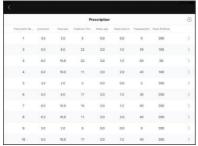
#### 5.2.6 Mode Selection

#### 5.2.6.1 NMES Mode

- 4.
- 1) Click icon to enter the home page of NMES mode.
- 2) Click the prescription number to enter the prescription list page.
- 3) Select the desired prescription and a pop-up window will show.
- 4) Click "OK" to send the selected prescription to the Stimulation.
- 5) Another pop-up window will display to indicate that the prescription is sent successfully; click "OK" to return to the home page of NMES mode.
- 6) Click "Start" icon to start the treatment, press "+" or "-" on the stimulator to adjust the intensity.



1. Click NMES icon



3. Select a prescription

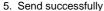


2. Click the prescription



4. Send the selected prescription







6. Press Start icon to start the treatment

#### **Prescription Selection:**

The user can choose different programs based on his/her needs. According to the international standard for electrical stimulation, we have provided 42 preset programs and 8 customizable programs.

#### 5.2.6.2 ETS Mode

- 1) Click icon to enter the home page of ETS/PAS mode.
- 2) Click ETS icon to switch to ETS mode.
- 3) Click Setting icon to pop up the window of parameters.
- 4) Adjust the parameters by sliding the finger on the screen for each parameter.
- After all the parameters are set, click "OK" to return to the home page of ETS mode.
- 6) Click Start icon to start the treatment.
- 7) Press "+" or "-" on the stimulator to adjust the intensity, and the intensity value will display on the iPad.
- User can click icon of "LOW", "MED", or "HIGH" to display different range of EMG.



1. Click ETS/PAS icon



2. Select ETS icon



3. Click the setting icon



5. Click "OK" to send the parameters



7. Intensity value



4. Set the parameters



6. Press Start icon to start the treatment



8. EMG ranges

#### **Parameter Setting:**

Threshold: 2-1000uV;

• Pulse width: 50\*450 us, 10ps increment,

Frequency: 2-100Hz, 1 Hz increment,

Ramp up: 0-5s, 0.1s increment,

Ramp down: 0-5s, 0.1s increment,

Duration: 1-10s, 0.1s increment,

· Delay: 0-5s, 0.1s increment,

#### 3 different ranges of EMG:

"LOW": 0-300uV"MED": 0-600uV"HIGH": 0-1000uV

#### 5.2.6.3 PAS Mode

- 1) Click icon to enter the home page of ETS/PAS mode.
- 2) Click PAS icon to switch to PAS mode.
- 3) Click Start icon to start the treatment.
- 4) Press "+" or "-" on the stimulator to adjust the intensity, and the intensity value will display on the iPad.
- User can click icon of "LOW", "MED", or "HIGH" to display different range of EMG.



1. Click ETS/PAS icon



3. Press Start icon to start the treatment



5. EMG range



2. Select PAS icon



4. Intensity value

#### 3 different ranges of EMG:

"LOW": 0-300uV"MED": 0-600uV"HIGH": O-1000uV

#### 5.2.6.4 EMG Mode

- 1) Click icon to enter the home page of EMG mode.
- 2) Click Start icon to start EMG test and the whole process will last 15 seconds.
- 3) User can click icon of "LOW", "MED", or "HIGH" display different range of EMG.
- 4) When the EMG test is complete, the result will show on the iPad.



1. Click EMG icon



3. EMG ranges



2. Start EMG test



4. Test result

#### **EMG Waveforms:**

X axis: time (s)

Y axis: EMG value (uV)

#### The screen can show 3 different ranges of EMG:

"LOW": 0-300uV"MED": 0-600uV"HIGH": 0-1000uV

#### 5.2.6.5 GAME Mode

Six games are now available for muscle strength training, endurance training and coordination training. Patients control the games by contracting certain muscles while enjoying the fun of a rehabilitation game mode format.

- 1) 1) Click icon to enter the home page of EMG mode.
- 2) Six games are now available for muscle strength training, endurance training and coordination training. Patient control the games by contracting certain muscles, enjoying the fun in rehabilitation.







2. Home page of GAME mode

#### **Global Trip**

- 1) Click the game icon of Global Trip, and it will enter the game page.
- 2) Click the setting icon, a pup-up window will show the threshold of the EMG. Set the appropriate threshold by sliding the finger on the screen. Press Start icon to start the game.
- 3) Contact and relax the muscles to control the game. Once the EMG value exceeds the threshold, the game character will be triggered to move on.
- 4) Click the "<" to return to the home page of GAME mode.





3. Threshold setting



2. Game page



4. Return to home page

#### **Zombie Avenger**

- 1) Click the game icon of Zombie Avenger, and it will enter the game page.
- 2) Click the setting icon, a pup-up window will show the threshold of the EMG. Set the appropriate threshold by sliding the finger on the screen. Press Start icon the start the game.
- Contract and relax the muscles to control the game. Once the EMG value exceeds the threshold, the game character will be triggered to move on.
- 4) Click the "<" to return to the home page of GAME mode.



1. Click the game icon of Zombie Avenger



2. Game page



Threshold setting



4. Return to home page

#### **Funnies**

- 1) Click the game icon of Funnies, and it will enter the game page.
- Click the setting icon, a pup-up window will show the threshold of the EMG.
   Set the appropriate threshold by sliding the finger on the screen. Press Start icon the start the game.
- Contract and relax the muscles to control the game. Once the EMG value exceeds the threshold, the game character will be triggered to move on.
- 4) Click the "<" to return to the home page of GAME mode.



1. Click the game icon of Funnies



3. Game page



2. Setting



4. Return to home page

#### **Dancing Melody**

- 1) Click the game icon of Dancing Melody, and it will enter the game page.
- 2) Click the setting icon, a pop-up window will show the threshold of the EMG. Set the appropriate threshold by sliding the finger on the screen. Press Start icon the start the game.
- Contract and relax the muscles to control the game. Once the EMG value exceeds the threshold, the game character will be triggered to move on.
- 4) Click the "<" to return to the home page of GAME mode.



1. Click the game icon of Dancing Melody



2. Setting



3. Game page



4. Return to home page

#### **Jigsaw Show**

- 1) Click the game icon of Jigsaw Show, and it will enter the game page.
- 2) Click the icon of "Choose Picture" and select a picture from the iPad album.
- 3) Click the setting icon, a pup-up window will show the threshold of the EMG. Set the appropriate threshold by sliding the finger on the screen. Press Start icon the start the game.
- 4) Contract and relax the muscles to control the game. Once the EMG value exceeds the threshold, the game character will be triggered to move on.
- 5) Click the "<" to return to the home page of GAME mode.



1. Click the game icon of Jigsaw Show



Game page



5. Return to home page



2. Setting



4. Start game

#### **Clever Baboon**

- 1) Click the game icon of Clever Baboon, and it will enter the game page.
- 2) Click the setting icon, a pup-up window will show the threshold of the EMG. Set the appropriate threshold by sliding the finger on the screen. Press Start icon the start the game.
- Contract and relax the muscles to control the game. Once the EMG value exceeds the threshold, the game character will be triggered to move on.
- 4) Click the "<" to return to the home page of GAME mode.



1. Click the game icon of Clever Baboon



3. Game page



2. Setting



4. Return to home

### 5.3 Other Functions

#### 5.3.1 Treatment Time Limit

The user can limit the treatment time in the application and the stimulator will stop and once the time is up. The stimulator will be unavailable until another treatment time limit is set.



Note: If user doesn't want the treatment time to be limited, then the limit value can be set as 0.

### 5.3.2 Treatment Intensity Limit

The user can set up an intensity limit by using the application for example if the user sets up the maximum intensity to 25mA, then the maximum electrical output would be 25mA. The limit range is 0-60 mA.



### 5.3.3 Low Battery Indication

It will flash once per second when the battery is lower than 10%, and the stimulator will stop and auto off in 5 minutes. The simulator will auto off in 5 seconds when the battery is lower than 2%.

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### 5.3.4 Loose Electrodes Indication

The electrodes loose indicator will display and the stimulator will stop when the electrodes and the skin have poor contact. Please adjust the electrodes and press Play/Pause button again to restart.

### 5.3.5 Auto Off

The stimulator will auto off in 15 minutes if there is no operation.

### 6. Care and Maintenance

### 6.1 Maintenance for Stimulator

- Always handle the stimulator carefully.
- Do not expose the stimulator to water, excessive heat or vibration.
- · Keep it away from children.
- Use wet cloth with little neutral detergent or alcohol to clean stimulator's 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.

### 6.2 Maintenance for the Metal Electrodes

- Integrated electrode can be used for a long time without exchange. 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 covered with the film when not in use. Keep it clean and restore it carefully.

### 6.3 Skin Care

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

### 6.4 Skin Irritation Prevention Advice

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

### 6.5 Product Service Life

The service life of the XFT-2003E is 5 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.

### 6.6 Battery Safety

Please charge this device only with the original charger and do not use the device while charging. The XFT-2003E Nerve and Muscle Stimulator has a rechargeable battery that can only be replaced by an XFT. Battery cycle times 500 times. The device needs about 3 hours to charge when completely drained of power. The device is designed to work for 9 hours with a full charge.

#### Medical power adapter specification:

Model No.: GTM41078-0605-USB
 Input: AC 100-240V, 50~60Hz, 0.3A

Output: DC 5V, 1.2A

### 7. Product Configuration

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

Note: Product configuration is subject to change without notice.

### 8. Product Specifications

### 8.1 Stimulator Specifications

Stimulator Specifications				
Dimensions	140*58*27mm			
Weight	120g			
Service life	5 Years			
Environmental Ranges	Working Condition Temperature: 5°C- Relative humidity: Atmospheric press Transport Conditio Temperature: -20°	40 °C (41° ≤80% (nor sure: 86kPa n:	n-condens a-106kPa	ing)
	Relative humidity: Atmospheric press	≤93% (nor	n-condens	
1. Technical Parameters				
Measuring range	10uV-1000uV			
Resolution	≤2uV			
System noise	≤1uV			
Transmission bands	Broader than 20Hz	z -500Hz (-	3dB, exce	pt trap frequency)
Differential mode input impedance	>5MΩ	•		
Common mode rejection ratio	>100dB			
Power frequency notch	50Hz/100uV (Peak-to-valley); after attenuation ≤5uV (Peak-to-valley)			
Indication accuracy	±10% /±2uV; whichever is greater			
Feedback threshold accuracy	±10% central frequency			
Type of stimulation output	Constant current			
Electrical stimulation intensity	0-60mA (Peak valu 500 Ω)	ue±10% /+	2mA, whic	chever is greater,
2. Performance Parameters				
Classification	Type RF (Radio Fr	equency)	Equipmen	t
Power Supply	Rechargeable lithiu	um battery	7.4V	
Shutdown current	≤0.1mA			
Working current	≤250mA			
	NMES Mode	ETS	Mode	PAS Mode
Waveform	Symmetrical balan	ced bipha	sic wave	
Frequency	2-100Hz (±10% or whichever is greate increment	,	18Hz (±2	2Hz)
Pulse width	50-450ps (±10%), increment	•	200us (±	<u>,                                      </u>
Output current	0-60mA (±10% or ±2mA, whichever is greater, with 500Ω load)		greater, with 500Ω	
EMG Setting Threshold	NA	2-1000u	V	NA

### 8.2 Parts Specification

Metal electrodes Specification		
Material	Stainless Steel	
Size	37.94*36.75mm 2 pcs	
	35.77*9.94mm 1pc	
Power Adapter Specifications		
1. Input		
Voltage	AC100-240V	
Frequency	50-60Hz	
Current	0.3A	
2. Output		
Voltage	DC 5V	
Current	1.2A	

Note: Do not use the device when it is in charging.

Wireless Technology Description		
Operating Frequency Band	2402-2480MHz	
Type of Modulation	GFSK	
Type of Modulating Signal	Digital	
Data Rate [=Frequency of Modulating Signal]	1Mbps	
Effective Radiated Power	4dBm	
Receiver Bandwidth	2402-2480MHz	
Operating Distance and Ranges	0-10 meters	
Bit Error Rate	0.1%	
Packet Loss	Not available	
Signal-to-noise Ratio	-88dBm	

#### The wireless QoS need

XFT-2003E Nerve and Muscle Stimulator was designed and tested to have a response rate of 10-100ms latency depending on system configuration.

#### **Wireless Interference**

The XFT-2003E Nerve and Muscle Stimulator was designed and tested and as demonstrated NO interference from other RF devices (including other XFT-2003E Nerve and Muscle Stimulator, WiFi networks, cellular devices, microwaves and other Bluetooth devices).

XFT-2003E Nerve and Muscle Stimulator 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 the performance of the XFT-2003E Nerve and Muscle Stimulator is affected by other equipment. The user should turn the XFT-2003E Nerve and Muscle Stimulator off and move away from the interfering equipment.

### 8.3 Treatment Programs

_	Parameter					
Program No.	Duration/ Interval (s)	Time (min)	Ramp up (s)	Ramp down (s)	Frequency (Hz)	Pulse width (uS)
1	3/2	5	0	0	5	250
2	5/8	22	2	1	35	150
3	8/15	20	3	1	60	50
4	6/10	11	2	2	45	100
5	3/2	5	0	0	5	200
6	5/8	17	2	1	30	200
7	8/15	16	3	1	60	200
8	6/10	11	2	2	45	200
9	3/2	5	0	0	5	200
10	5/10	17	2	1	40	200
11	6/15	11	2	1	60	200
12	6/8	13	2	2	40	200
13	3/2	5	0	0	5	300
14	6/6	25	2	1	25	150
15	8/12	25	2	1	35	100
16	6/5	21	2	2	40	50
17	3/2	5	0	0	5	300
18	6/6	25	2	1	25	200
19	8/12	25	2	1	60	50
20	6/5	21	2	2	40	100
21	3/2	5	0	0	5	300
22	6/6	25	2	1	25	300
23	8/12	25	2	1	35	300
24	7/10	17	5	0	40	150
25	5/4	10	2	1	5	300
26	6/15	11	2	1	60	50
27	6/12	17	2	2	40	100
28	6/4	19	2	2	40	100
29	3/2	5	0	0	5	400
30	5/8	22	2	1	30	400
31	8/15	20	3	1	60	400
32	6/10	11	2	2	40	400
33	3/2	5	0	0	5	400
34	5/8	22	2	1	30	400
35	8/15	20	3	1	60	300
36	6/10	11	2	2	40	400
37	3/2	5	0	0	5	400
38	5/8	17	2	1	35	400
39	8/15	16	3	1	60	100
40	6/10	11	2	2	40	400
41	3/2	5	0	0	5	200
42	5/10	17	2	1	40	200
43	N/A	N/A	N/A	N/A	N/A	N/A
50	N/A	N/A	N/A	N/A	N/A	N/A

### 9. Troubleshooting

Error	Description of Error	Solution
<b>↑</b> ⚠	Electrode loose	Wet the skin with water to improve the electrical conductivity.     Check the contact between the skin and the electrodes, and adjust the place of the electrodes.
/	Stimulator cannot power on	1. Confirm that the power button is in good contact. Release the power button, gently wipe the button and finger with water, then press the power button again to turn it on.  2. Confirm if the battery is low. Charge the Stimulator; try again after the stimulator is fully charged.
	Low battery	Charge the Stimulator. When the device prompts that the charging is completed, it can be turned on and used normally.

### 10. Frequently Asked Questions

## 10.1 What should I do if the electrical stimulation intensity is weak?

- a) Adjust the placement position.
- Adjust the electrical stimulation intensity through the stimulator or app software.
- c) Check the battery and charge if low.
- d) Wet the skin to increase the electrical conductivity between the electrode and the skin.

# 10.2 What should I do if the skin in the area covered by the electrode and the stimulator band is severely red, stinging or allergic?

- a) Stop using the device immediately.
- Continue to use the device only after the skin completely recovers to normal.
- If the skin irritation continues cease use of the device and notify your physician.

# 10.3 What happens when there is sporadic, strong electrical stimulation?

- The surface of the electrode is not wet enough. Add some additional water to the skin and electrodes.
- Check if the skin in the area covered by the electrode is red or has a wound.
- Check if the cuff of the stimulator is secure and the position of the electrode is accurate.

### 10.4 Can I use oil or lotion on my upper limb?

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

### 10.5 How to restore the factory default settings?

Warning: Factory reset will restore your device to the state where it was made out in the factory. This implies that your passwords, accounts and other personal data that you may have stored on the device App will be wiped out clean.

- No matter for which reason you need to perform a factory reset on your device, it is
  effective and quick to bring your device back to work again.
- Power off the device, long press the power button and mode button at the same time for about 8 seconds, until the OLED screen is light up, then the factory rest is successful.

### 10.6 How to backup data?

No need to back up your personnel data, the device will back up your data and system setting automatically.

### 10.7 How to keep my device safe from Cyber Threats?

- a) Only buy smartphones from vendors who authorized, ensure your mobile phone operation system is officially released by android or iOS.
- Consider using security software that will protect your mobile device from malware and riskware.
- Please download the app only from official app store (Google Play or App Store depends on your operation system of mobile phone).
- d) Do not save the passwords for your App account, and make sure your WiFi network is secure, which can help keep your login information safe.
- e) You also must make sure to update your software on your device when prompted, to ensure the app is up to date.
- f) Do not login into your account at the public WiFi hotpots; it is far more secure to use a 3G or 4G instead, or to use a VPN.
- g) Do not share your account and password for others.

### 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 attempt 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 user'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. The clinician has the responsibility to warn user or any others to comply with this rule.



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

Guidance and manufacture's declaration -electromagnetic emission

#### Table 1

The XFT-2003E Nerve and Muscle Stimulator is intended for use in the electromagnetic environment specified below. The user should comply with specifications ensuring the device is only used in an appropriate environment.			
Emission 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	
Harmonic emissions IEC 61000-3-2	Class A	establishments and those directly connected to the public low-voltage power	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complied	supply network.	

**OMNIHI5 USER MANUAL** 

Table 2

### Guidance and manufacture's declaration - electromagnetic emission

The XFT-2003E Nerve and Muscle Stimulator is intended for use in the electromagnetic environment specified below. The user should comply with specifications ensuring the device is only used in an appropriate environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance	
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kVair	±8 kV contact ±2kV, ±4kV, ±8kV, ±15kVair	Floors should be wood, concrete or ceramic tile. Humidity should be at least 30% if it is synthetic materials.	
Electrical fast transients/bursts (EFT) IEC 61000-4-4	±2kV 100kHz repetition frequency	±2kV 100kHz repetition frequency	Main power quality should be that of a	
Surge 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	typical commercial or hospital environment.	
Voltage dips	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	
IEC 61000-4-11	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	used continuously.	
RATED power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or60Hz	30A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.	

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

Table 3

### Guidance and manufactured declaration - electromagnetic immunity

The XFT-2003E Nerve and Muscle Stimulator is intended for use in the electromagnetic environment specified below. The user should comply with specifications ensuring the device is only used in an appropriate environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF I EC 61000-4-6	3Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any
	6Vrmsin ISM and amateur radio bands between 150 kHz and 80 MHz (a)	6Vrms	parts than the recommended separation distance that calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance: d = 1.2-/P 150 kHz to 80 MHz
Radiated RF I EC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	d = 1.2VP 80MHzto800 MHz d = 2.3VP 800MHz to2.7GHz d = 6VP/E At RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device). Where "P" is the maximum output power rating of the transmitter in watts according to transmitter manufacturer and "d' is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (b), should be less than the compliance level in each frequency range (c).Interference
			may occur in the vicinity of equipment marked with the following symbol:  (((**)))

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

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

- a) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHZ are6.765 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 1.8MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHZ, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.
- b) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this is used exceeds the applicable RF compliance level above, this should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating.
- c) Field strengths should be less than 3V/m in the frequency range of 150k~80MHz.

**Table 4**Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	IMMUNITY Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 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
710 745 780	704-787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9
810		GSM 800/900, TETRA 800.	Pulse			
870	800-960	iDEN 820,	modulation <sup>b)</sup>	2	0.3	28
930		CDMA 85, LTE Band 5	18 Hz			
1720	1700	GSM 1800; CDMA 1900;	Pulse			
1845	1990	GSM 1900; DECT; LTE	modulation <sup>b)</sup> 217 Hz	2	0.3	28
1970	1990	Band 1,3 ,4, 25;UMTS	217 112			
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation <sup>b)</sup> 217 Hz	2	0.3	28
5240 5500 5785	5100 - 5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	0.2	0.3	9

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

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

#### Table 5

Recommended separation distances between portable and mobile RF (Radio Frequency) communications equipment and the XFT-2003E Nerve and Muscle Stimulator

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nerve and Muscle Stimulator as recommended below, according to the maximum output power of the communications equipment.

This device can be used under the environment that radiated RF disturbances are controlled. User should maintain a minimum distance between portable and mobile RF communications equipment to prevent electromagnetic interference. Following recommended distance is calculated according to the maximum output power of the communication equipment.

Rated maximum	Separation distance according to frequency of transmitter (m)		
output power of transmitter (W)	150kHz -80MHz d=1.2 √P	80MHz -800MHz d=1.2 √P	800MHz-2.7GHz d=2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.79	3.79	7.27
100	12	12	23

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

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

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

### 12. Use Specification

Item	Description
Product Name	Nerve and Muscle Stimulator
Product model	XFT-2003E
Intended use/indications for use	Functional Electrical Stimulation (FES). Improvement of hand function and active range of motion in patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury. Neuromuscular Electrical Stimulation (NMES); Increase or maintain hand range of motion; Reduce muscle spasms; Retard muscle atrophy; Reeducate muscles; Increase local blood circulation.
Intended patient population	Patients with limited hand function.
Intended part of the body or type of tissue applied to or interacted with	The intact skin on the area of the upper limb to be stimulated.
Intended user profile	Intended user includes patient, medical persons and/or other operators, they are required to meet below requirement at least:  • Ability to read and understand user manual, and follow the instruction to operate device;  • Are healthy or use the device under doctor's direction;  • No nationality or race limitation;  • Can identify parts of body.
Use environment	<ul> <li>Reusable</li> <li>Hospital use or home use</li> <li>Use the EMC environment for group 1 class B</li> <li>Work conditions:         Temperature 5~40°C,         Humidity ≤80%(Non-condensing)         Atmospheric pressure 86~106kPa     </li> </ul>
Operation principle	Place the Stimulator to correct position: Extensor Digitorum Muscle. To optimize individual function the stimulator position might be adjusted slightly.
Contraindications	<ul> <li>Do not use with electronic monitoring equipment, NMR-imaging pace-maker, defibrillator and high-frequency medical device.</li> <li>Powered muscle stimulators should not be used on patients with cardiac demand pacemakers</li> <li>Do not use if you have a history of autonomic dysreflexia</li> <li>Do not use FES following recent surgery where muscle contraction may disrupt the healing process.</li> </ul>
Install type	Wearable

### 13. After-Sale Service

13.1 The original XFT-2003E product you have purchased is covered by a 24-month warranty that begins on the date of purchase.

# 13.2 The distributor will not provide free repair for the malfunctions caused by the following behaviors:

- Dismantle or modify the product without authorization.
- Accidentally blow or drop the product during use or transportation.
- Lack of reasonable maintenance.
- Not using the device in according to instruction.
- · Unauthorized repair.

# 13.3 When asking for warranty services please use your warranty card.

 Please contact the distributor or medical facility where you purchased the device if you need warranty service.

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### **Warranty Card**

Product Name:	Model No.:
Purchase Date:	Product Serial No.:
Buyer's Information:	
Distributor's Information:	

Manufacturer: Shenzhen XFT Medical Limited

Add: Room 203, Building 1, Biomedicine Innovations Industrial Park,

#14 Jinhui Road, Pingshan New District, Shenzhen, China

Tel: 86-755-29888818 Web: www.xft-china.com Mail: xft@xft.cn

Distributor Seal:

Product Name: Nerve and Muscle Stimulator (Trade Name: Hand Rehab System) Model No.: XFT-2003E



Shenzhen XFT Medical Limited
Room 203, Building 1, Biomedicine Innovations Industrial Park,
#14 Jinhui Road, Pingshan New District, Shenzhen, China
Tel: 86-755-29888818 Fax:86-755-28312625
Website: http://www.xft-china.com E-maii:xft@xft.cn



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