XFT-2003E

Nerve and Muscle Stimulator (Trade Name: Upper Extremity Rehab System)

User Manual

ONLY

Technology Upgrades
Our Life

Caution: This is a class II FDA cleared medical device. Federal regulations restricts the order or delivery of this medical device to certified clinicians licensed by the law of the State in which he/she practices to use as indicated within their scope of practice. Order and delivery of this medical device for patient home use must be accompanied by a physician prescription. Thanks for choosing our product. Please read this manual before use and keep it carefully.

Content

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.

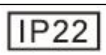
PAS: Power assistant stimulation.

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 are categorized into sections of: danger, warning and attention.
- Please read this manual carefully.

List of Symbols

	Contraindications, that may cause danger
	Mandatory requirement or may cause an injury or physical discomfort
	Type BF Equipment
	Use with Caution
	Non-Ionizing Radiation
	Date of Manufacture
	Manufacturer
	This product must not be disposed of with other household waste
	Refer to user manual
	Serial Number
	The number of the notified body (0123)
	European Authorized Representative
	Fragile
	Keep upward
	Keep dry
	The protection level against dust and water is IP22
	Temperature limit

	Humidity limitation
	Atmospheric pressure limitation

Contraindications

- Do not use the device where a cancerous lesion in present or suspected.
- Do not use the device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Use of the device in conjunction with any of the above may cause electric shock, burns, electrical interference, or death.
- Do not use the device on an arm where a regional disorder, such as a fracture or dislocation, would be adversely affected by motion from the stimulation.

Warning

- 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 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.

FCC warning

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

operate the equipment.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

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

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

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

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

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.
- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
    a. When there is a tendency to hemorrhage following acute trauma or fracture;
    b. Following recent surgical procedures when muscle contraction may disrupt the 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.
- Stimulators should be kept out of the reach of children.
- Stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
- 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.

2. Overviews

2.1 Product Introduction

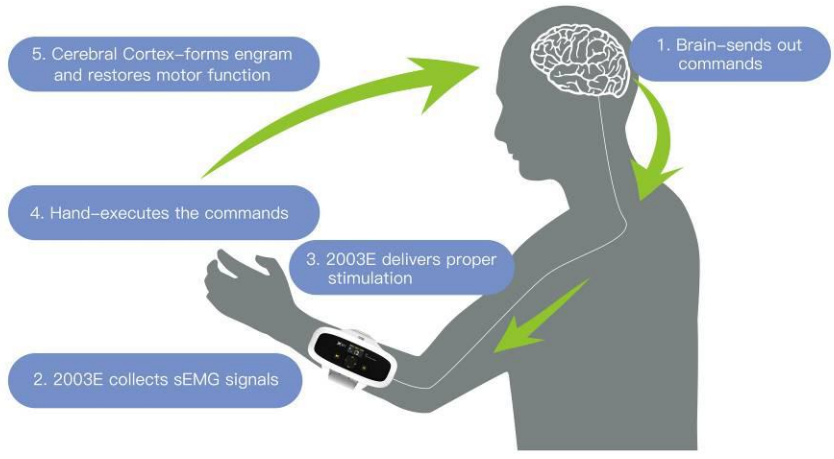
XFT-2003E detects and monitors the EMG muscle activity signal of a patient and delivers an electrical stimulation pulses according to EMG signal strength to stimulate the patient in order to achieve a muscle contraction. With multiple working modes and interactive gaming applications patients can actively 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 APP.

2.2 Treatment Principle

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



2.3 Functions and Feature

- EMG detection
- EMG Triggered Stimulation
- Power Assistant Stimulation
- Functional Electrical Stimulation

- OLED screen
- Multimedia interactive biofeedback rehab training (strength training, endurance training, coordination training)
- Functional electrical stimulation prescription management.
- Electrode isolation technology: EMG input and stimulation output through the same electrodes.
- Bluetooth 4.0
- Low battery indication
- Treatment time limit
- Symmetric biphasic balanced wave
- Rechargeable lithium battery + USB Type-C port
- Auto off after 15 minutes of standby.
- Electrode loose indication

2.4 Indications for Use

The Nerve and Muscle Stimulator is an electrical stimulation device indicated for the following uses:

Functional Electrical Stimulation (FES)

Improvement of hand and upper extremity 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 and/or maintain hand range of motion
- Prevention and/or retardation of disuse atrophy
- Increase of local blood circulation
- Reduction of muscle spasms
- Muscle re-education

2.5 Intended population

The device is intended to be used for patients with hemiplegia due to stroke or upper limb paralysis due to C5 spinal cord injury

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

Front

Back

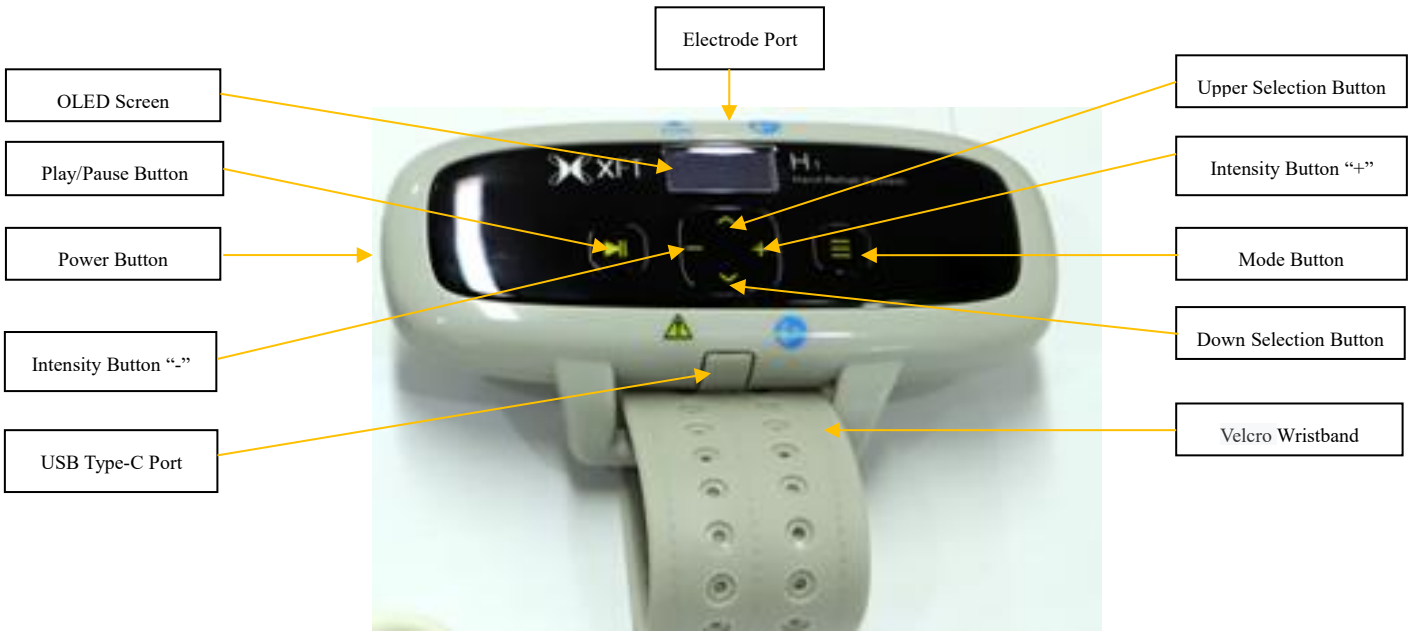
3.1.2 Parts

No.	Parts	Picture	Remark
1	Power Adapter and Charging Cable		The Power Adapter and Charging Cable are used to charge the device.
2	Electrode Cable (Optional)	   Size 1 Size 2 Size 3	The Electrode Cable is used to connect between the device and the hydrogel electrodes. There are 3 size Electrode Cables for choice to meet different patient's need. Size 1: Electrode Cable (L= 1300mm) Size 2: Electrode Cable (L= 468mm) Size 3 Electrode Cable (L= 318 mm)

3	Hydrogel Electrodes (Optional)		The hydrogel electrodes used for the device have been cleared under 510(k) K132588. While in use, they are connected to the device through the electrode cable, providing intramuscular stimulation to where they are placed on. The diameter of the hydrogel electrode is 50 mm, and the length of the lead wire is 12cm.

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 1second 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 GAME 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;

- 10-30mA, the intensity increases by 0.5mA increment;
- >30mA, the intensity increases by 0.1mA increment;

- User can feel the stimulation each time 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.

3.2.2 Screen Icons

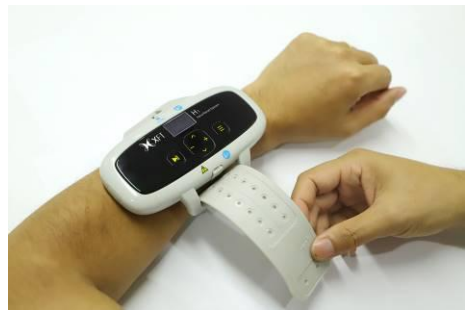
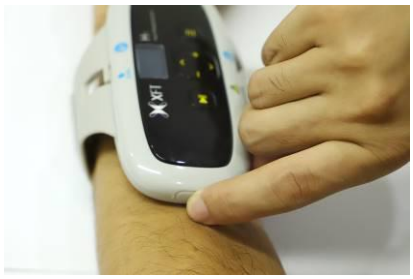
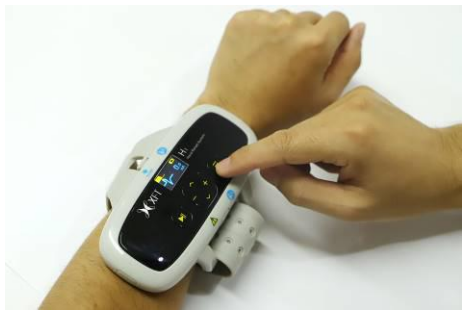
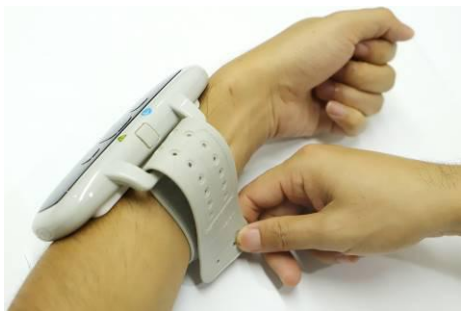
Icon	Function	Explanation
	Battery level	It will flash once per second when the battery is lower than 10%, and the stimulator will stop and auto off in 5 minutes. The stimulator will auto off in 5 seconds when the battery is lower than 2%.
	NMES Mode	Under this mode, the stimulation will run as pre-programmed.
	ETS mode	Under this mode, the stimulation will be triggered when the EMG signal reaches the threshold.
	PAS mode	The stimulation will be triggered when user contracts the muscle.
	EMG mode	It displays when you choose EMG mode. The columnar and parameter represent the EMG power, train by following the instruction,3 cycles of 3-second relax plus 6-second flex..
	GAME mode	The stimulator can connect to the APP under this mode.
	Bluetooth indicator	When you need to connect to the 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.
	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

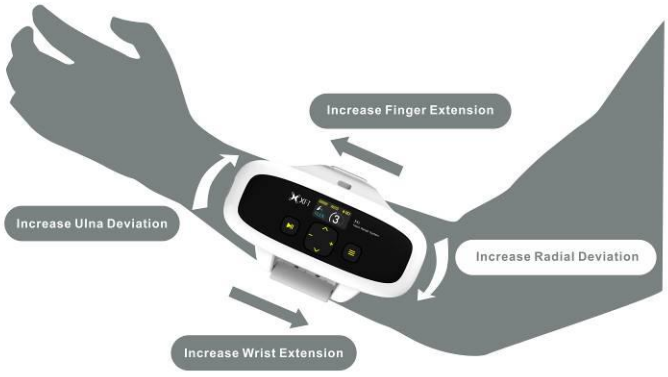
1) Peel off the transparent film from the metal electrodes.
2) Add some water to the area of skin that will be in contact with the electrodes.
3) Wear the Stimulator on the arm and make sure that the metal electrodes attach to the extensor muscles wrist extensors.
4) Press the power button to turn on the device.

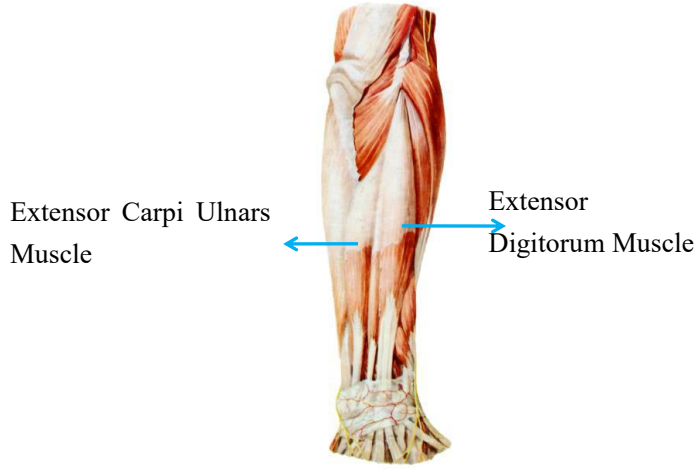
5) Press the mode button to choose the mode (NMES mode, ETS mode, PAS mode, EMG mode, GAME mode) to start the treatment.
6) After, the treatment is complete, press the power button to turn off the device.
7) Remove the Stimulator from the arm
8) Clean the metal electrode and the device with a soft cloth, and then store it in the portable case.

1. Peel off the transparent film 	2. Add some water to the area of skin 	3. Wear the Stimulator 
4. Press the power button 	5. Press the mode button 	6. Press the power button 
7. Remove the Stimulator 	8. Clean the metal electrodes 	

*User can adjust the position of the stimulator as the following picture to achieve different motion.

Electrode Placement (Stimulated Muscles)	**Motion**
Extensor Digitorum Muscle	Finger Extension and Wrist Extension
Extensor Carpi Ulnars Muscle	Wrist Extension,and make the wrist adduction





4.2 Use with electrode cable and hydrogel electrodes

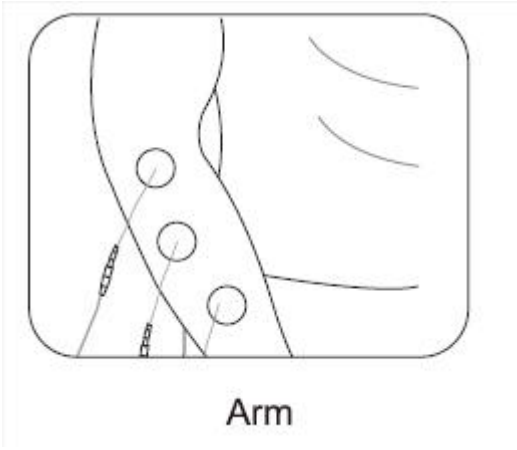
Warning: DO NOT use the hydrogel electrodes for multiple times. The hydrogel electrodes are only intended to be single used.

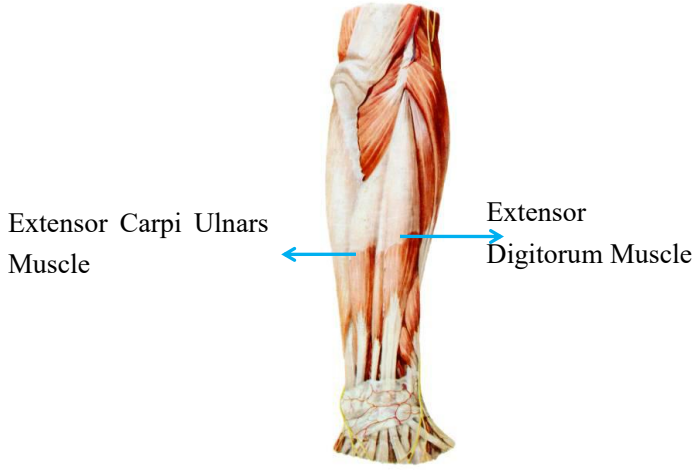
1) Plug the electrode cable into the electrode port of the Stimulator.
2) Connect the electrode cable to the hydrogel electrodes
3) Attached the electrodes to the desired body part i.e. shoulder, tricep, bicep or forearm flexors.
4) Press the power button to turn on the device.
5) Press the mode button 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. Press the Power button to turn the device off.
7) Peel off the hydrogel electrodes from the body part, store the device and the accessories in the portable case

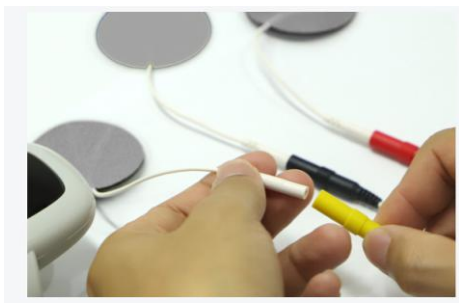
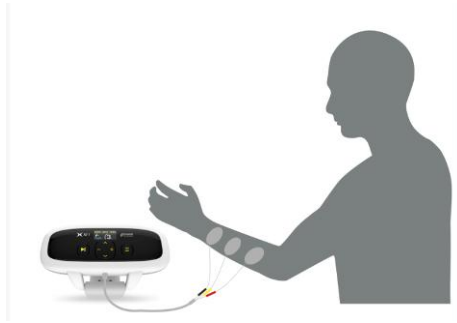
*User can adjust the position of the stimulator as the following picture to achieve different motion.

Mode	Electrode Placement	Stimulated Muscles	Motion
ETS mode, PAS mode, EMG mode, GAME mode	Electrode connected to red, yellow and black wires	Extensor Digitorum Muscle	Finger Extension and Wrist Extension EMG Test and GAME
NMES mode	Electrode connected to red and yellow wires	Extensor Digitorum Muscle	Finger Extension and Wrist Extension
ETS mode, PAS mode, EMG mode, GAME mode	Electrode connected to red, yellow and black wires	Extensor Carpi Ulnars Muscle	Wrist Extension, and make the wrist adduction; EMG Test and GAME
NMES mode	Electrode connected	Extensor Carpi Ulnars	Wrist Extension, and make

	to red and yellow wires	Muscle	the wrist adduction





1. Connect Stimulator and Electrode Cable 	2. Connect Hydrogel Electrodes and Electrode Cable 	3. Place Hydrogel Electrodes 
4. Press the power button 	5. Press the mode button 	6. Press the power button 
7. Remove the Hydrogel Electrodes		

4.3 Charging the XFT-2003E Upper Extremity Rehab System

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.
3) Connect the Type-C end on the charging cable to the charging port on the Stimulator.
4) The battery icon will display on the screen of the Stimulator to indicate charging.
5) The battery icon will display on the screen of the device when it is fully charged

1. Take out the Power Adapter and the Charging Cable	2. Connect the Power Adapter and the Charging Cable	3. Connect the Stimulator Cable and the Stimulator
		
4. 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% ethyl alcohol.
- Wipe the electrode 3 times with a sponge or a soft cloth dampened with disinfectant to disinfect the product surface for at least 30s.
- Before using the device please use water to clean and wet the skin area where electrodes will be attached.

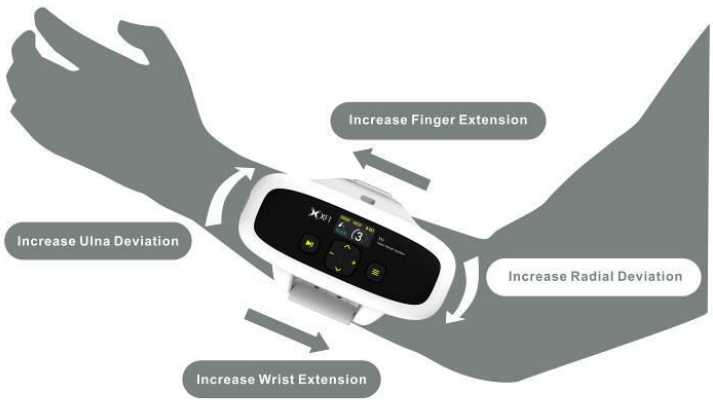
The Stimulator can be used with or without the APP.

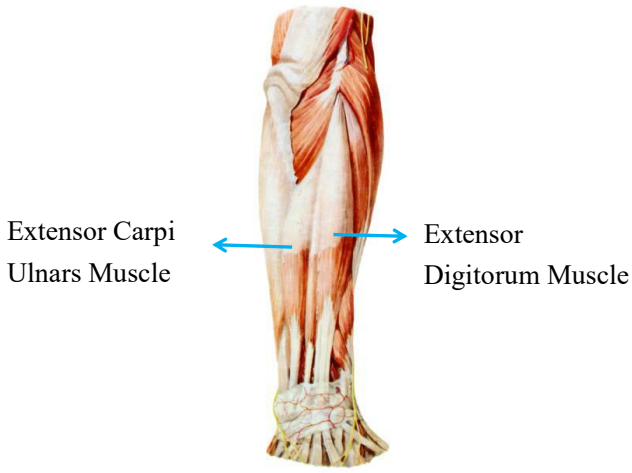
5.1 Use without APP

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 Ulnars Muscle	Wrist Extension,and make the wrist adduction





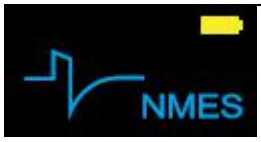
5.1.2 Power on

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 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 the user contracts the muscle and the EMG signal reaches the threshold.

5.1.3.3 PAS

Press 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

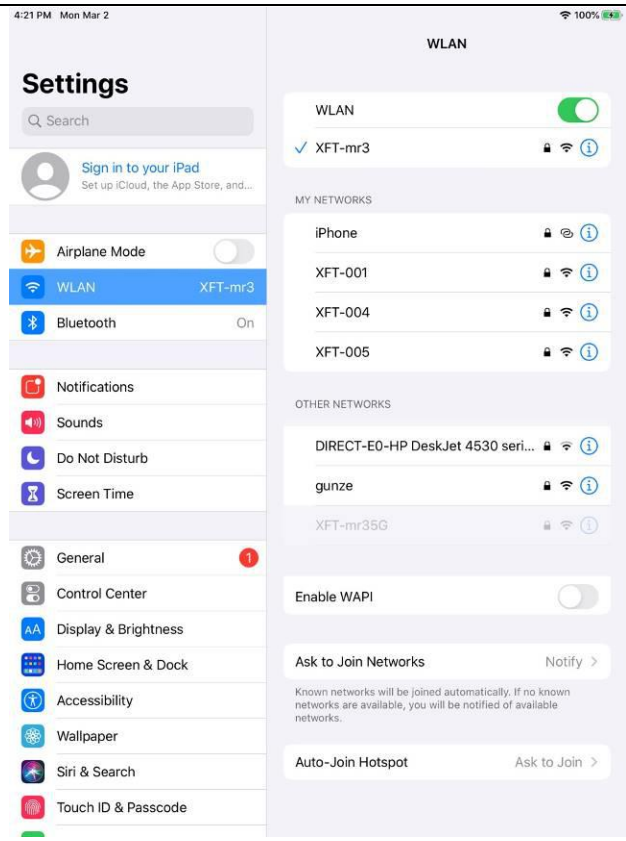
GAME mode is not available if the device is not connected with the application.

5.2 Use with the APP

Download or update APP

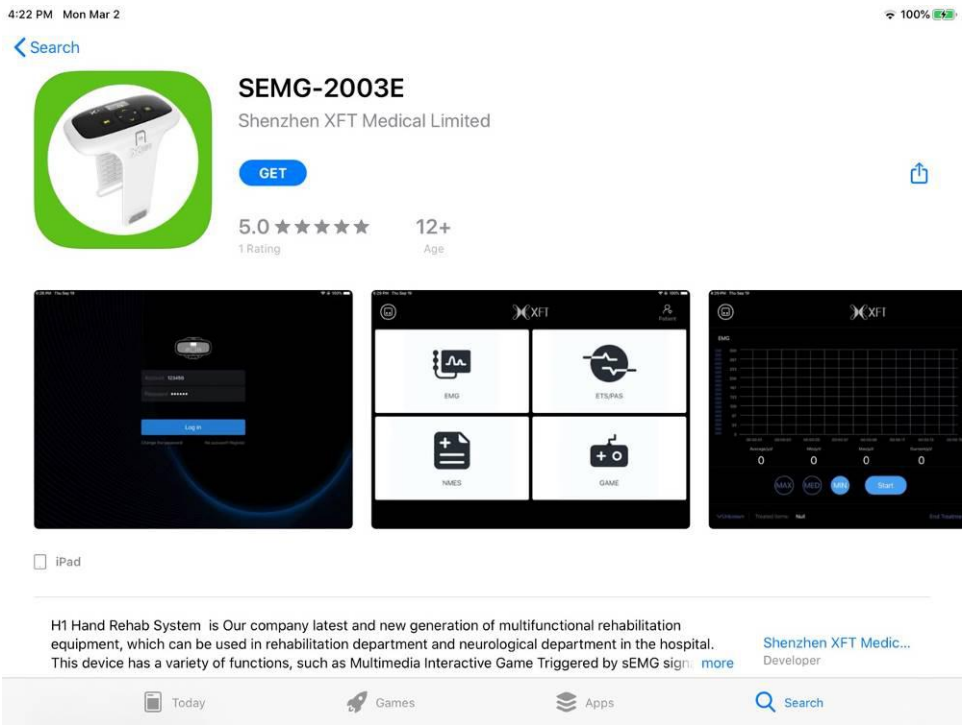
Connect to WiFi

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



Install / Update

Using your iPad, search for “SEMG-2003E” in App Store. Click "Get" in the below figure to start the installation. If it is already installed, click "Update", wait for the download to complete, and the installation or update is successful.



APP operation environment:

The New iPad, and subsequent iPad.

Hardware Requirement:

Software Requirement: iOS 9.0 or later

Requirement of security software: no

Requirement of Internet: BLE

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.

5.2.1 Wearing the Stimulator

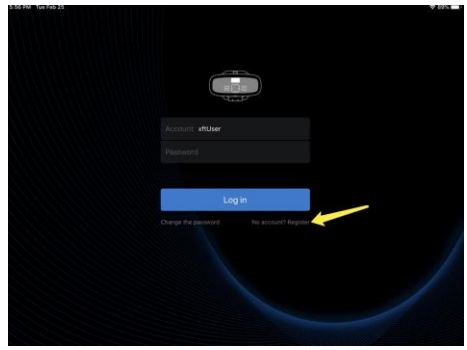
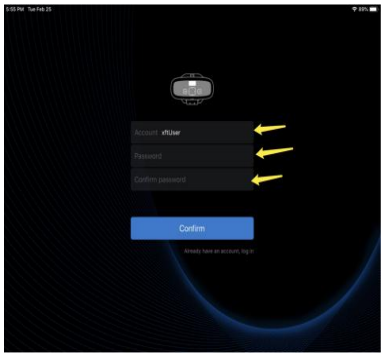
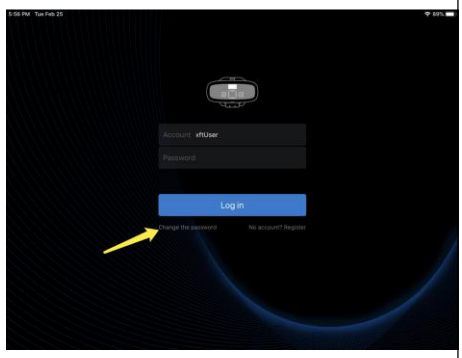
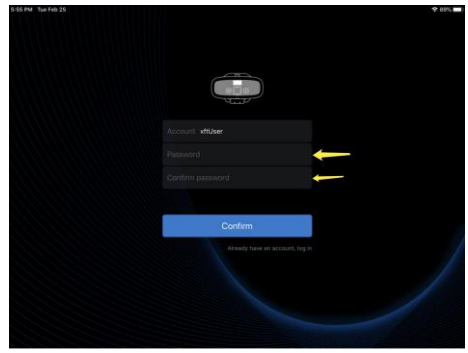
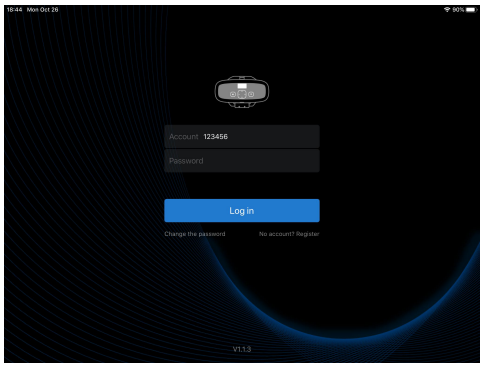
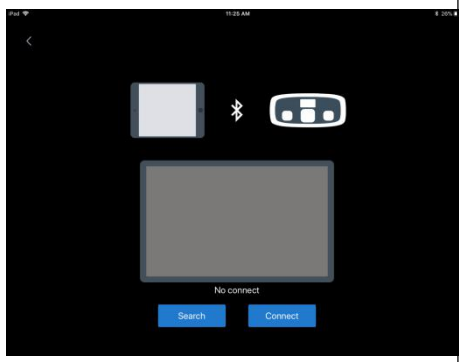
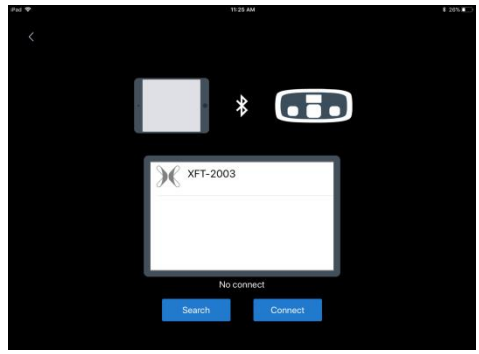
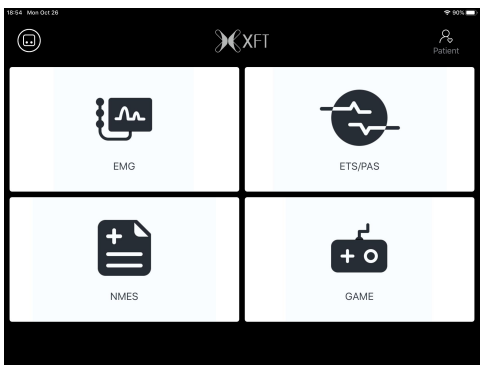
Wear the device at the correct location according to your need and corresponding motor response. Add some water to the area of skin that will be in contact with the electrodes.

5.2.2 Power on

Hold the power button for 1 second and you will see 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.

5.2.3 Connect with APP

- Press “Mode” button to select the “GAME” mode on the stimulator.
- Run SEMG-2003E APP on the iPad.
- Account registration is required for the first use.
- Enter the account number, password and confirmation password as required.
- If you forget your password, you can click to change it.
- Enter and confirm the password as required.
- Log in on the iPad.
- Click “Search” to search the Stimulator.
- Choose the Stimulator and Click “Connect”.
- Enter the home interface on the iPad.

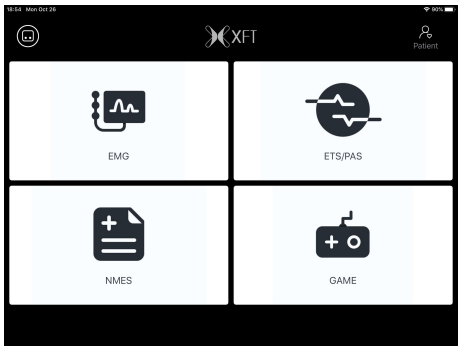
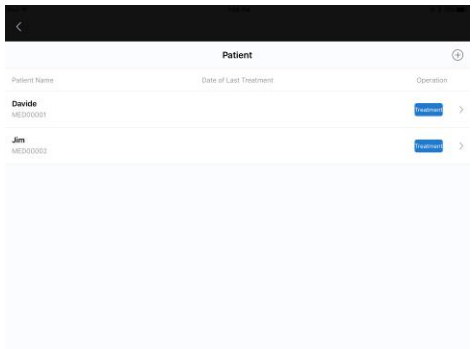
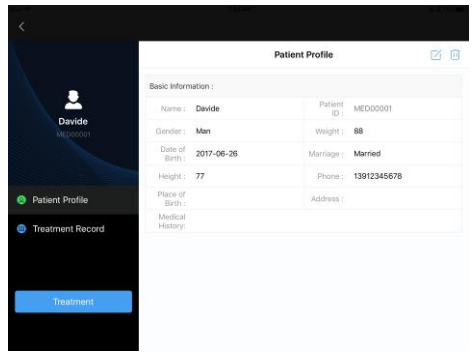
1.Select GAME mode 	2.Run the SEMG-2003E APP on the iPad 	3.Register an Account 
4.Log in the account、Password、Confirm Password 	5.Change Password 	6.Enter Password and Confirm Password 
7.Log in on the iPad 	8.Search device 	9.Connect device 
10.APP home page 		

5.2.4 Create Patient Information

5.2.4.1 Click the patient icon to enter patient list page.

5.2.4.2 Click “+” icon to add patient record.

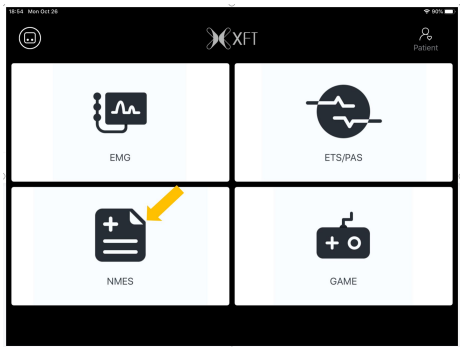
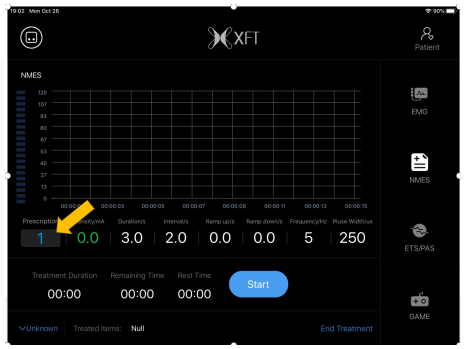
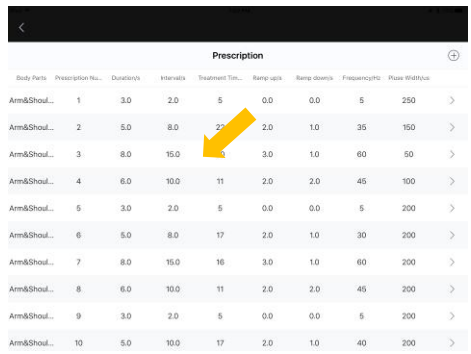
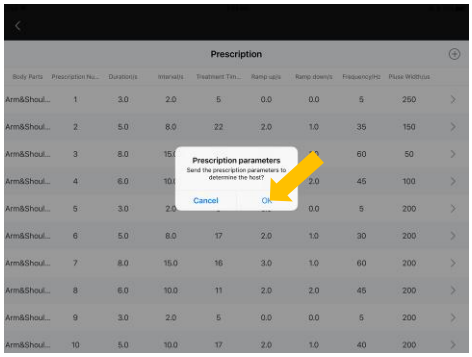
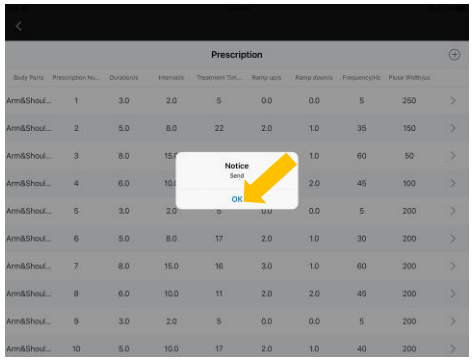
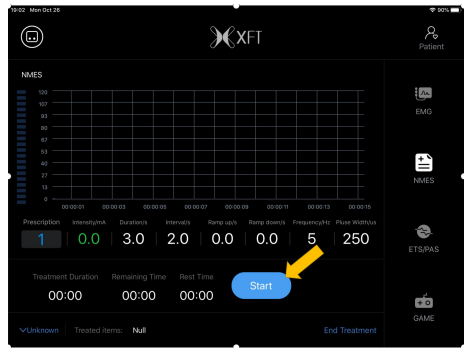
5.2.4.3 Edit the patient information and Save.

1. Click the patient icon to enter patient list page	2. Click “+” icon to add patient record	3. Edit the patient information and Save
		

5.2.5 Mode Selection

5.2.5.1 NMES Mode

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.
7) Press “+” or “-” on the stimulator to adjust the intensity.

1. Click NMES icon	2. Click the Prescription	3. Select a prescription
		
4. Send the selected prescription	**5. Send successfully**	**6. Press Start icon to start the treatment**
		

Prescription Selection:

The user can choose different prescription based on his/her needs. According to the international standard for electrical

stimulation, we have provided 42 preset prescription and 8 customizable prescription.

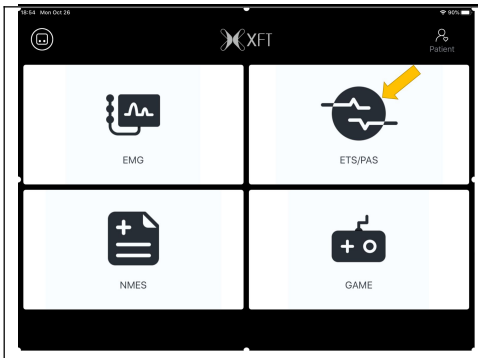
Preset prescriptions No.	Parameters					
	Duration / Interval (s)	Time (min)	Ramp up (s)	Ramp down (s)	Frequency (Hz)	Pulse width (μs)
1	3/2	5	0	0	5	250
2	5/8	22	2	1	35	150
3	8/15	20	3	1	60	50
4	6/10	11	2	2	45	100
5	3/2	5	0	0	5	200
6	5/8	17	2	1	30	200
7	8/15	16	3	1	60	200
8	6/10	11	2	2	45	200
9	3/2	5	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	35	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	200

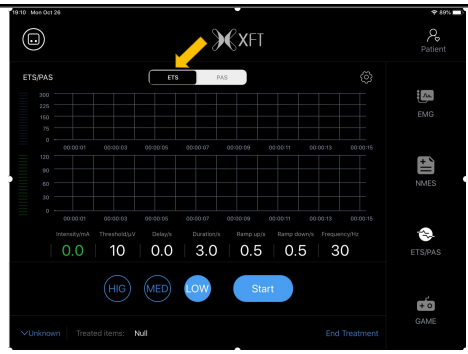
29	3/2	5	0	0	5	400
30	5/8	22	2	1	30	400
31	8/15	20	3	1	60	400
32	6/10	11	2	2	40	400
33	3/2	5	0	0	5	400
34	5/8	22	2	1	30	400
35	8/15	20	3	1	60	300
36	6/10	11	2	2	40	400
37	3/2	5	0	0	5	400
38	5/8	17	2	1	35	400
39	8/15	16	3	1	60	100
40	6/10	11	2	2	40	400
41	3/2	5	0	0	5	200
42	5/10	17	2	1	40	200
8 customizable prescriptions	Duration / interval, Time, Ramp up, Ramp down, Frequency and Pulse width can be set by the user.					

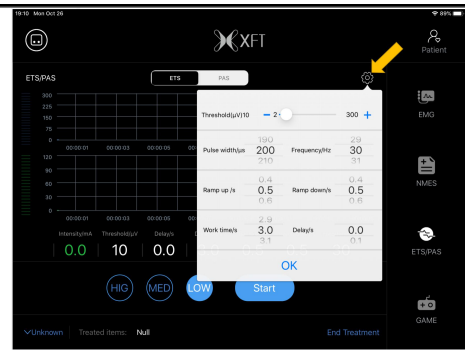
5.2.5.2 ETS Mode

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.
5) 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.
8) User can click icon of “LOW”, “MED”, or “HIG” to display different range of EMG.
    - “LOW”: 0-300μV
    - “MED”: 0-600μV
    - “HIG”: 0-1000μV

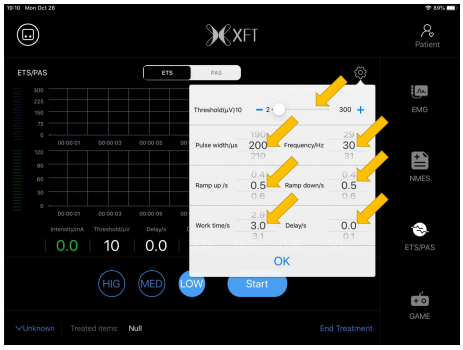
1. Click ETS/PAS icon	2. Select ETS icon	3. Click the setting icon



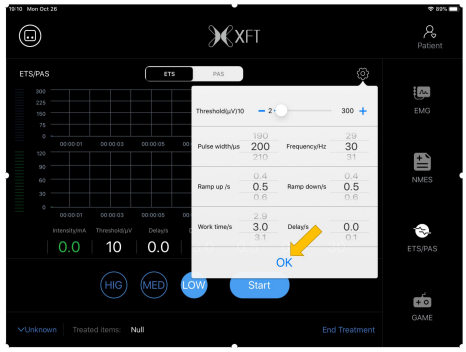




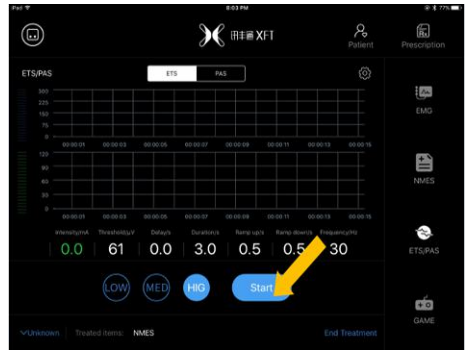
4. Set the parameters



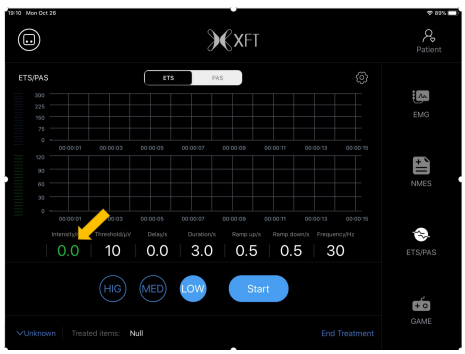
5. Click “OK” to send the parameters



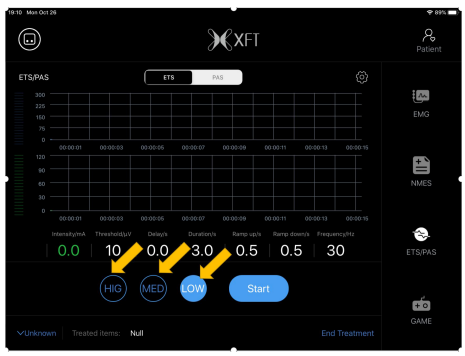
6. Press Start icon to start the treatment



7. Intensity value



8. EMG ranges

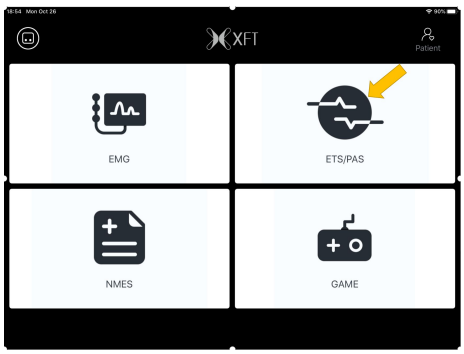


Parameter Setting:

Parameters	Range
Threshold	It can be adjusted start from 2μV to 1000 μV with 1uV increment. The default is 10μV.
Pulse width	It can be adjusted start from 50μs to 450μs with 10μs increment.
Frequency	It can be adjusted start from 2Hz to 100Hz with 1Hz increment.
Ramp up	It can be adjusted start from 0 s to 5s with 0.1s increment.
Ramp down	It can be adjusted start from 0 s to 5s with 0.1s increment.
Duration time	It can be adjusted start from 1 s to 10s with 0.1s increment.
Interval time	It can be adjusted start from 0 s to 5s with 0.1s increment.

5.2.5.3 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.
5) User can click icon of “LOW”, “MED”, or “HIG” to display different range of EMG.
    - “LOW”: 0-300μV
    - “MED”: 0-600μV
    - “HIG”: 0-1000μV

1. Click ETS/PAS icon	2. Select PAS icon	3. Press Start icon to start the treatment
		
4. Intensity value	5. EMG ranges	
		

Parameter Setting:

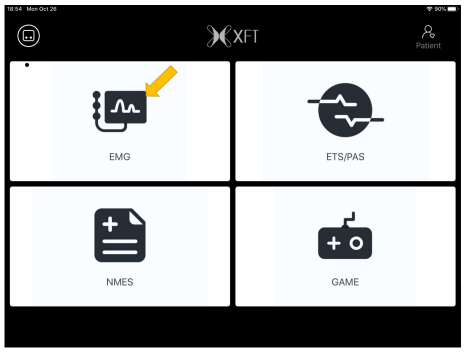
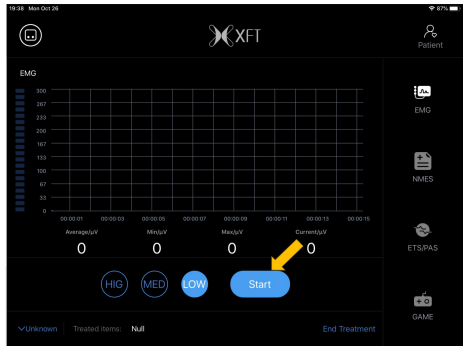
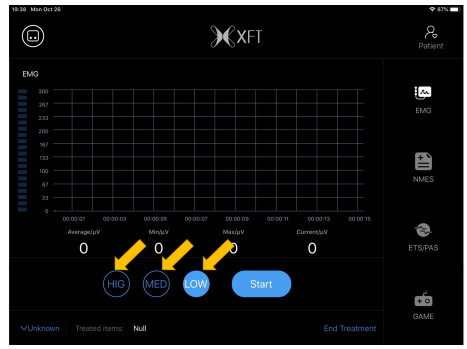
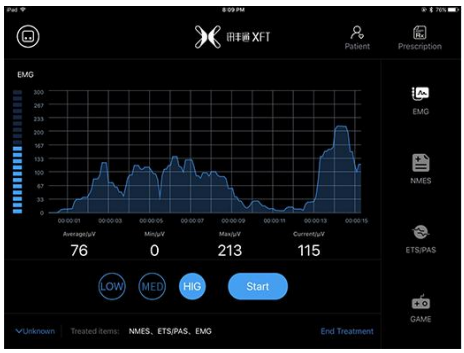
Under PAS mode, the stimulator outputs NMES electrical stimulation at regular pulse width (200μs), frequency (18Hz). The intensity of electrical stimulation is controlled by the patient’s spontaneous EMG intensity.

5.2.5.4 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 “HIG” to display different range of EMG.
    - “LOW”: 0-300μV

- “MED”: 0-600μV
- “HIG”: 0-1000μV

4) When the EMG test is complete, the result will show on the iPad.

1. Click EMG icon	2. Start EMG test	3. EMG ranges
		
4. Test result		
		

EMG Waveforms:

X axis: time

Y axis: EMG value (μV)

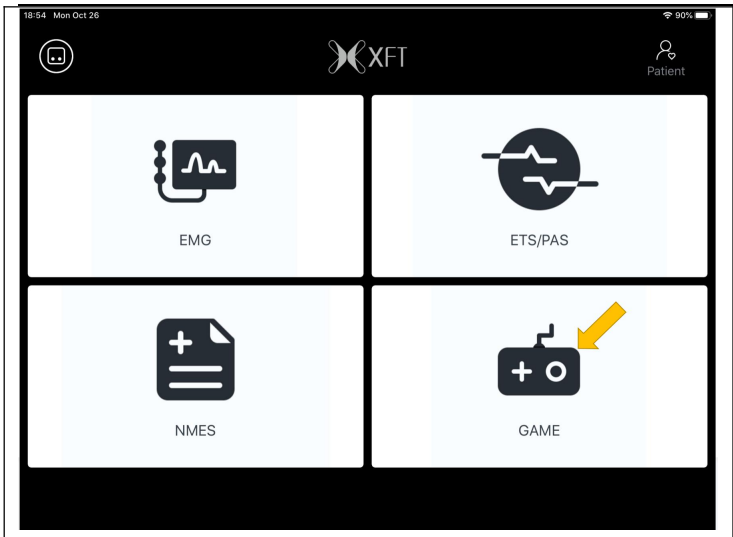
5.2.5.5 GAME Mode

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) Click  icon to enter the home page of GAME mode.

2) Six games are now available for muscle strength training, endurance training and coordination training. Patients control the games by contracting certain muscles, enjoying the fun in rehabilitation.

1. Click GAME icon	2. Home page of GAME mode



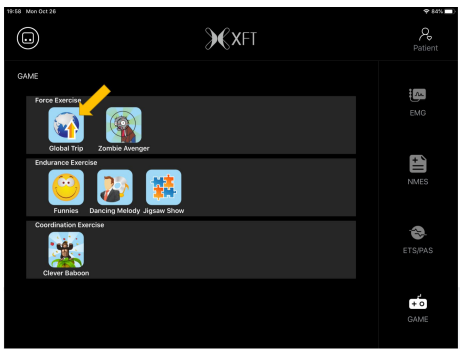
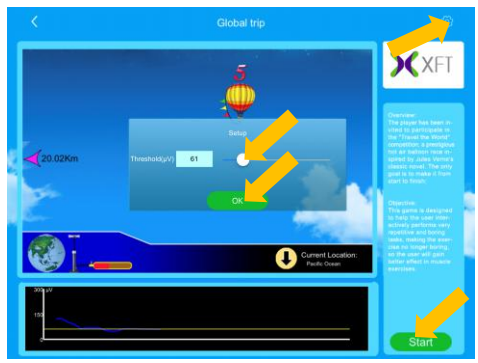
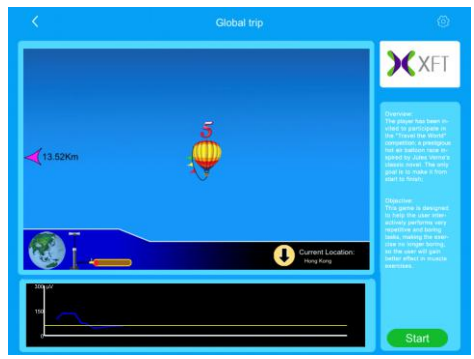
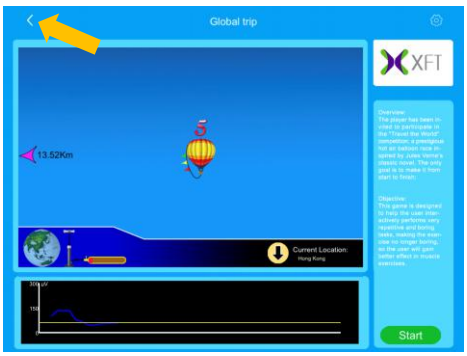
Global Trip

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 the start the game.

3) 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 Global Trip	2. Setting	3. Game page
		
4. Return to home page		
		

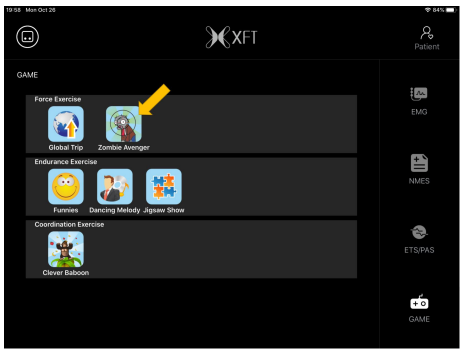
Zombie Avenger

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.

3) 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. Setting 	3. Game page 
4. Return to home page 		

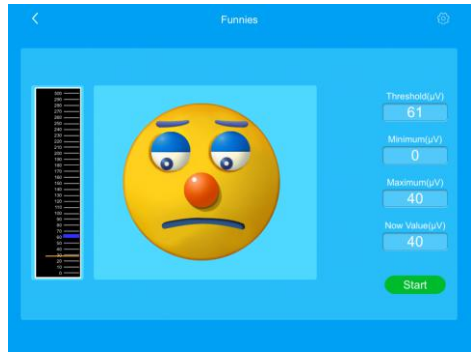
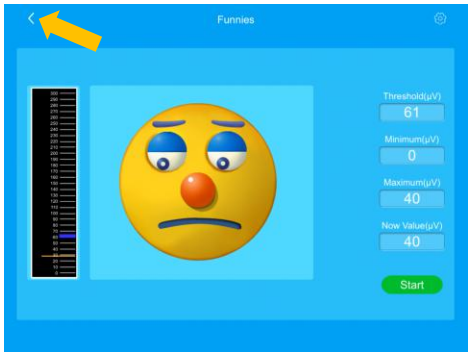
Funnies

1) Click the game icon of Funnies, 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.

3) 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	2. Setting	3. Game page
		
4. Return to home page		
		

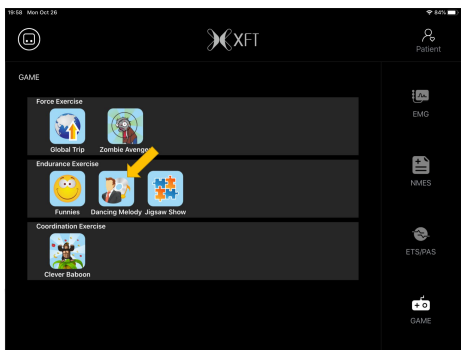
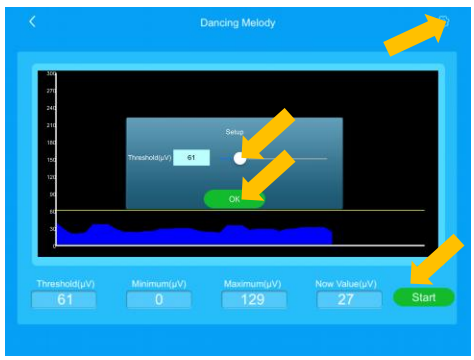
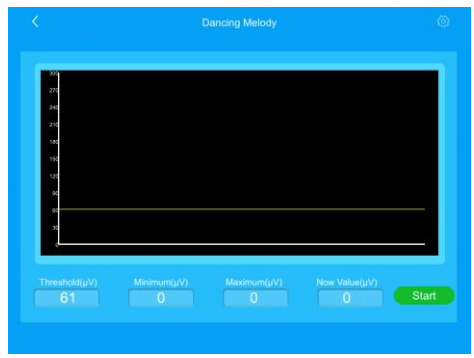
Dancing Melody

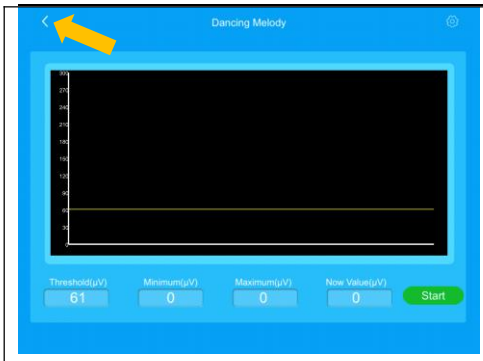
1) Click the game icon of Dancing Melody, and it will enter the game page.

2) Click the setting icon, a 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.

3) 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.

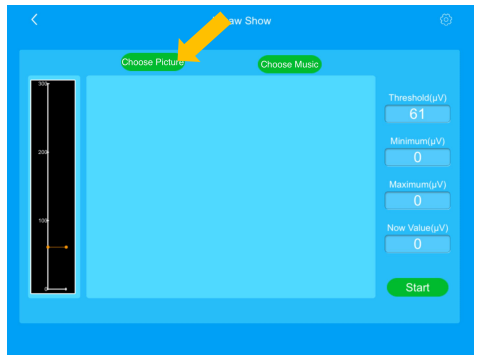
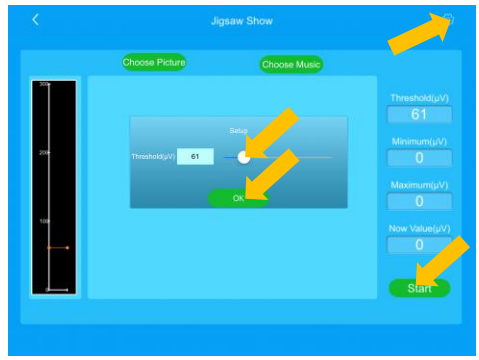
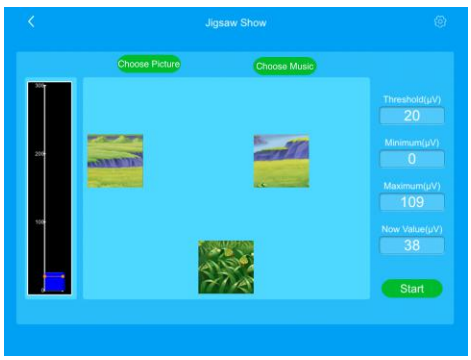
4) Click the "<" to return to the home page of GAME mode.

1. Click the game icon of Dancing Melody	2. Setting	3. Game page
		
4. Return to home page		

Jigsaw Show

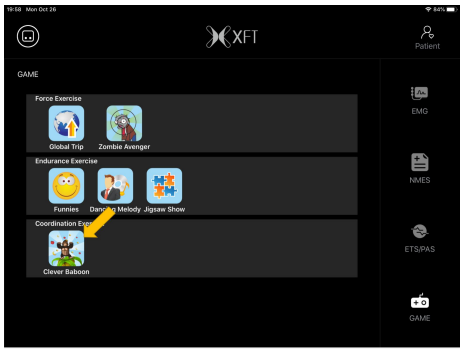
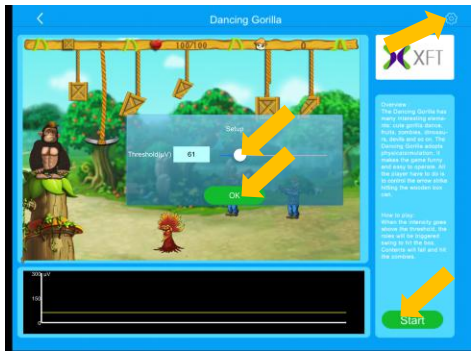
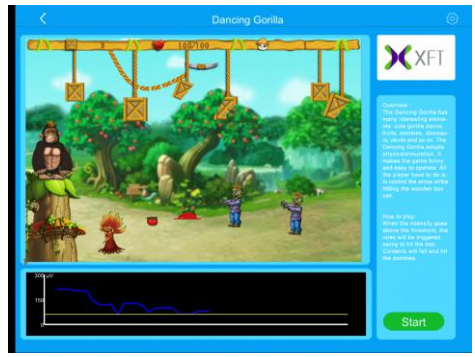
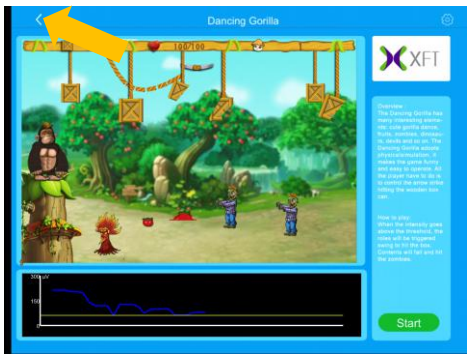
1) Click the game icon of Jigsaw Show, and it will enter the game page.
2) Click the icon of “Choose Picture” and select a picture from the iPad album.
3) Click the setting icon, a pup-up window will show the threshold of the EMG. Set the appropriate threshold by sliding the finger on the screen. Press 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	2. Game page	3. Threshod setting
		
4. Start game	**5. Return to home page**	
		

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.
3) 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.

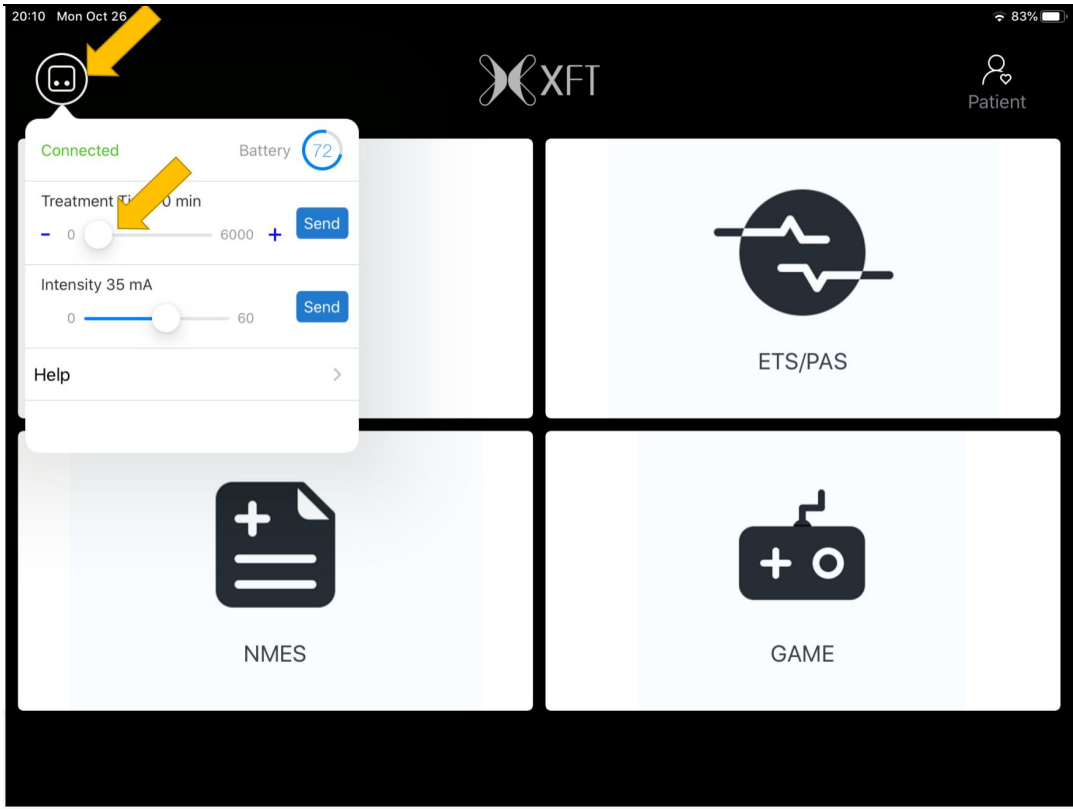
4) Click the “<” to return to the home page of GAME mode.

1. Click the game icon of Clever Baboon	2. Game page	3. Threshod setting
		
4. Return to home page		
		

5.3 Other Functions

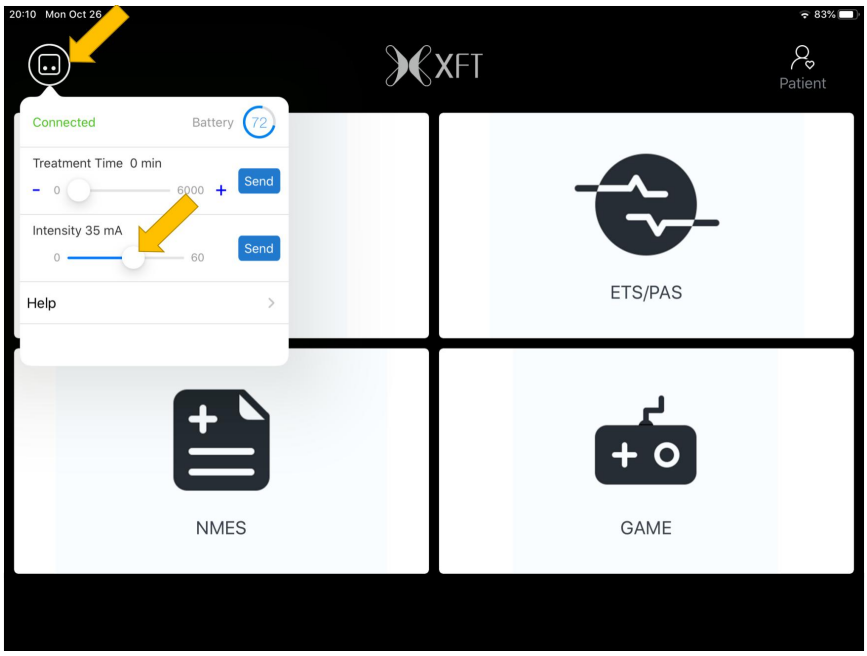
5.3.1 Treatment Time Limit

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.



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.



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

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%.

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 75% ethyl alcohol to clean the electrode surface and use clean towel to wipe it after each use.
- 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 Maintenance for the Hydrogel Electrodes

- Electrode efficiency and durability depends entirely on the application, storage and care of the electrodes by the well-informed XFT-2003E user. The durability of the electrodes is dependent upon keeping the hydrogel clean, hydrated and free from foreign debris. Other factors relating to electrode durability are skin condition, wearing environment, usage and climate. In all cases, the electrodes must be changed every 1 to 2 weeks (or reused around 30 times) to maximize function and minimize the potential for skin irritation.

6.4 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.

6.5 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 are recommended to trim the hair where the skin contact the electrodes. Shave the night before. 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.

6.6 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.

6.7 Battery Safety

Please charge this device only with the original charger and do not use the device while charging. The XFT-2003E Upper Extremity Rehab System 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.

7. Product Configuration

Stimulator	1 pc (include wristband)
Hydrogel Electrode	1 pair
Electrode cable	1pc
Power Adapter	1 pc
charging cable	1 pc
Manual	1 pc

Note: Product configuration is subject to change without notice.

8. Product Specifications

Stimulator Specifications	
Dimensions	140*58*27mm
Weight	120g
Service life	5 Years
Environmental Ranges	Working Condition: Temperature: 5℃-40 ℃ Relative humidity: ≤80% (non-condensing) Atmospheric pressure: 86kPa-106kPa
	Transport Condition and Storage Condition: Temperature: -20℃-55℃ Relative humidity: ≤93% (non-condensing) Atmospheric pressure: 70kPa-106kPa
1. Technical Parameters	
Measuring range	10μV-1000μV
Resolution	≤2μV
System noise	≤1μV
Transmission bands	Broader than 20Hz -500Hz (-3dB, except trap frequency)

Differential mode input impedance	>5MΩ		
Common mode rejection ratio	>100dB		
Power frequency notch	50Hz/100μV (Peak-to-valley); after attenuation, ≤5μV (Peak-to-valley)		
Indication accuracy	±10% / ±2μV ; whichever is greater		
Feedback threshold accuracy	±10% central frequency		
Type of stimulation output	constant current		
Electrical stimulation intensity	0-60mA (Peak value±10% /±2mA, whichever is greater, 500 Ω)		
2. Performance parameters			
Classification	Type BF Equipment 		
Power Supply	Rechargeable lithium battery 7.4V		
Shutdown current	≤0.1mA		
Working current	≤250mA		
	NMES Mode	**ETS Mode**	**PAS Mode**
Waveform	symmetrical balanced biphasic wave		
Frequency	2-100Hz (±10% or ±2Hz, whichever is greater), 1Hz increment,		18Hz (±2Hz)
Pulse width	50-450μs (±10%), 10μs increment,		200μs (±10%)
Output current	0-60mA (±10% or ±2mA, whichever is greater, with 500Ω load)		
Threshold	NA	2-1000μV	NA

Parts Specification

Metal electrodes Specification	
Material	Stainless Steel
Size	37.94*36.75mm 2 pcs 35.77*9.94mm 1pc
Electrodes and Electrode Cable Specifications	
Material	Hydrogel nonwoven fabric
Size	Diameter 50mm
Length of Electrode Cable	1.3m There are 3 size Electrode Cables for choice to meet different patient's need. Size 1: Electrode Cable (L= 1300mm) Size 2: Electrode Cable (L= 468mm) Size 3 Electrode Cable (L= 318 mm)
Power Adapter **Specifications**	
1. Input	
Voltage	AC100-240V
Frequency	50-60Hz

Current	0.3A
2. Output	
Voltage	DC 5V
Current	1.2A

Note 1: The metal electrodes and the hydrogel electrodes cannot be used at the same time. The 2 types of electrodes perform the same function when they are in use separately.

Note 2: Do not use the device when it is in charging.

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.
Operating Frequency Band	2402-2480MHz
Type of Modulation	GFSK
Type of Modulating Signal	Digital
Data Rate [=Frequency of Modulating Signal]	1Mbps
Receiver Bandwidth	2402~2480MHz
Maximum transmission distance	10 meters
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%

Wireless Interference

The XFT-2003E Upper Extremity Rehab System was designed and tested and as demonstrated NO interference from other RF devices (including other XFT-2003E Upper Extremity Rehab System, WiFi networks, cellular devices, microwaves and other Bluetooth devices.)

Caution: If the performance of the XFT-2003E Upper Extremity Rehab System is affected by other equipment the user should turn the XFT-2003E Upper Extremity Rehab System off and move away from the interfering equipment.

9. Troubleshooting

Error	Description of Error	Solution
	Electrode loose	1. if used with metal electrodes, wet with skin with water to improve the electrical conductivity 2. if used with hydrogel electrodes, check the connection between the Electrode Cable and device, or between the Electrode Cable and the hydrogel electrodes; or replace the hydrogel 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?

-Adjust the placement position.

-Adjust the electrical stimulation intensity through the stimulator or app software.

-Check the battery and charge if low.

-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?

-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 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 backup your personnel data, the device will backup your data and system setting automatically.

10.7 How to keeping my device safe from Cyber Threats?

-Only buy smartphones form vendors who authorized, ensure your mobile phone operation system is officially released by 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).

-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.

-You also must make sure to update your software on your device when prompted, to ensure the app is up to date.

-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.

-Do not share your account and password for others.

11.Electromagnetic Compatibility (EMC)

 **CAUTION**

The Nerve and Muscle Stimulator complies with the requirements of IEC 60601-1-2:2014 (EMC Collateral Standard) including the E-field susceptibility requirements at a [level of RF immunity testing from IEC 61000-4-3 of 60601-1-2; e.g. level of 10 volts per meter], at frequencies from 80 MHz to 2.7 GHz. However, even at this level of device immunity, certain transmitting devices (cellular phones, two-way radios, cordless phones, paging transmitters, RFID devices, etc.) emit radio frequencies that could interrupt external functional neuromuscular stimulator operation if operated in a range too close to the External functional neuromuscular stimulator. Practitioners should be aware of possible radio frequency interference if portable devices are operated in close proximity to the External functional neuromuscular stimulator.

Common emitters such as Electronic Article Surveillance Systems (EAS), Radio Frequency Identification Systems (RFID), Tag Deactivators, and Metal Detectors may cause interreference with the device. It is recommended to keep 20 cm away from such common emitters.

This equipment generates, uses, and radiates radio frequency energy. The equipment may cause radio frequency interference to other medical or non-medical devices and to radio communications.

If this equipment is found to cause interference, which can be determined by turning on and off the equipment, the operator or qualified service personnel should take following actions:

- Reorient or relocate the affected device;
- Increase the distance between the equipment and the affected device;
- Power the equipment by another source;
- Consult the service engineer for further suggestions.

 Caution: it is the 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 user has the responsibility to warn user or any others to comply with this standard.

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

Table 1

MANUFACTURER'S DECLARATION-ELECTROMAGNETIC EMISSION		
This equipment is intended for use in the electromagnetic environment specified below. The user should comply to specifications ensuring the device is only used in an appropriate environment.		
Emissions test	Compliance	Electromagnetic Environment - Guidance
RF emissions, CISPR 11	Group 1	This equipment uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic.
RF emissions, CISPR 11	Class B	This equipment is suitable for domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Complied	

Table 2

MANUFACTURER'S DECLARATION-ELECTROMAGNETIC EMISSION			
This equipment is intended for use in the electromagnetic environment specified below. The user should comply to 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, ±15 kV air	±8 kV contact ±2kV, ±4kV, ±8kV, ±15 kV 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.

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	
Voltage dips IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be typical commercial or hospital environment. UPS power is recommended if this device needs to be used continuously.
	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	
RATED power frequency magnetic fields IEC 61000-4-8	30A/m 50Hz or 60Hz	30A/m 50Hz or 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: UT is the A.C. mains voltage prior to application of the test level.			

Table 3

MANUFACTURER'S DECLARATION-ELECTROMAGNETIC IMMUNITY			
This equipment should be used in the electromagnetic environment specified below. The user should comply to specifications ensuring the device is only used in an appropriate environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3Vrms 150 kHz to 80 MHz 6Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz (a)	3Vrms 6Vrms	Portable and mobile RF communications equipment should be used no closer to any parts than the recommended separation distance that calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80MHz to 800 MHz $d = 2.3\sqrt{P}$ 800MHz to 2.7GHz at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device). Where “P” is the maximum output power rating of the transmitter in watts according to transmitter manufacturer and “d” is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (b), should be less than the compliance level in each frequency range (c). Interference may occur in the vicinity of equipment marked with the following symbol: 
Note1: at 80MHz-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) Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which this is used exceeds the applicable RF compliance level above, this should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating. b) Field strengths should be less than 3V/m in the frequency range of 150k～80MHz.			

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

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460. FRS 460	FM [c] ± 5kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 85, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900;	Pulse modulation [b] 217 Hz	2	0.3	28
1845						

1970		GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS				
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.

Table 5

Recommended Separation Distance			
This device can be used under the environment that radiated RF disturbances are controlled. The 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	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance “d” in meters can be estimated using the equation applicable to the frequency of transmitter, where “p” is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer. Note1: at 80M-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.			

12.After-Sale Service

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

12.2 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

12.3 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.

Warranty Card

Be sure to call for authorization before returning any equipment. You must receive a return authorization number and specific instructions on the process.

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

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

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

Product Name: Nerve and Muscle Stimulator

Trade Name: Upper Extremity Rehab System

Model: XFT-2003E

Shenzhen XFT Medical Limited

Room203, 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-mail: xft@xft.cn

US Agent

605 Sherwood Forest Place, Cary, North Carolina

Cary , NC 27519

Phone: 919 4751044 Ext

Date:2020/10/21

No.: XFT-2003E-A

REV: C