

# Nerve and Muscle stimulator

| XFT-2001F |

User Manual

**Caution:**

- Please read the instruction manual carefully and thoroughly before operating this device.
- Also please keep it available for future reference.

# Content






















1. For Your Health and Safety .....	01
2. Overviews .....	04
3. Product Illustration .....	06
4. General Operation Instruction .....	10
5. Attentions .....	52
6. Care and Maintenance .....	53
7. FAQ & Troubleshooting .....	54
8. Product Specifications .....	55
9. Electromagnetic Compatibility (EMC) .....	57
10. After-sales Service .....	64

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# 1. For Your Health and Safety

- To avoid any danger or loss caused by inappropriate use, please read this manual carefully;
- The hazards and losses caused by improper use are stated in the safety precaution section, and divided into "Contraindications" and "Warnings"and "Precautions"
- Please keep this manual carefully.

	Type BF equipment
	The power adapter is a Class II device
	Non-ionizing radiation
	Contraindications
	Use with caution
	Date of manufacturer
	Manufacturer
	Serial Number
IP66	Protection against particulate matter and harmful ingress of liquids is IP66
	Read to user manual
	Fragile, handle with care
	Keep upward
	Keep dry
	Don't rolling while moving
	This product should not be disposed of together with other domestic waste, and the disposal of electronic waste should follow local regulations or government regulations
	Temperature limitation
	Humidity limitation
	Atmospheric pressure limitation
	Refer to user manual
	Declaration of conformity according to the applicable European directives and number of the notified body (0123)
	Authorized representative in the European Community
	Medical device

## **Contraindications**

The following must be strictly forbidden

- 1) Not to be used by patients with implanted cardiac pacemakers or defibrillators, or any electrical and metallic implants.
- 2) Do not place electrodes in the area of the carotid arteries (at the throat).
- 3) Do not place electrodes on malignant tumors.
- 4) Do not place electrodes on areas showing symptoms of thrombus.
- 5) Should not be used by people with a history of epilepsy.
- 6) Do not place on diseased area. For example: fractures, dislocations.
- 7) Do not use close to the chest, electrodes can increase heart fibrillation.
- 8) Do not throw batteries into fire or short-circuit them, as there is a risk of explosion.
- 9) Do not place electrodes on the head, face (eyes, mouth, etc.).

## **Warnings**

Please use it carefully in the following situations, otherwise accidents or adverse consequences may occur.

- 1) The safety of usage during pregnancy or menstruation has not been determined.
- 2) If you feel pains or rash during long time use, please stop using this product until the inflammation is completely resolved before continuing to use it.
- 3) Caution should be used in patients with suspected and diagnosed heart disease.
- 4) The following conditions should be used with caution in the fixed area of the stimulator:
  - When there is a tendency to hemorrhage due to severe trauma.
  - Recently had surgery, muscle contractions can disrupt the entire recovery process.
  - When the skin in the area covered by the strap is not sensitive.
- 5) The selection of the placement position of the electrodes and the parameter setting of the electrical stimulation should be performed according to the user manual.
- 6) The stimulator may pose any significant risk due to mutual interference during a particular diagnosis or treatment.
- 7) This product should be used with caution when the normal arteries and veins at the site of use are partially occluded and the flow is not smooth, or when changes such as vascular atrophy and vascular system disorder are caused by hemodialysis.
- 8) Caution to use when the stimulated area has structural deformities.
- 9) Do not use it with other electronic monitoring equipment, magnetic resonance imaging, high-frequency hospital equipment, defibrillators, etc. at the same time.
- 10) Do not use near short-wave, microwave. (such as 1 m).
- 11) Patient with Active hemorrhage, acute purulent inflammation, malignant tumor, thrombophlebitis, sepsis, and heart and lung failure may cause adverse reactions or injuries.
- 12) Do not use it while charging, it is necessary to remove the main unit to ensure that the output electrodes are separated from the patient's skin.
- 13) Please do not use it on other body parts.
- 14) Please do not throw or trample this product.
- 15) Please do not disassemble, repair or rebuild this product.
- 16) If there are any technical problems not mentioned in this manual, please contact your distributor or XFT company.

 **Precautions**

Please pay attention to the following situations, otherwise it will lead to incorrect use:

- 1) If you feel abnormal in this product or your body, please stop using it.
- 2) If you feel uncomfortable during use, please stop using it immediately; if necessary, please go to the hospital in time.
- 3) If you have any doubts during use, please consult your doctor.
- 4) Do not move the electrode or be touched while using this stimulator.
- 5) Do not perform maintenance or maintenance work on this device during use.
- 6) Do not throw the stimulator into fire.
- 7) Keep out of reach of children
- 8) Do not store and use in places with high humidity such as bathrooms.
- 9) Do not wear or use this product while sleeping, bathing, or driving.
- 10) Do not use this product for purpose other than treatment.

## 2. Overviews

### 2.1 Indication for Use

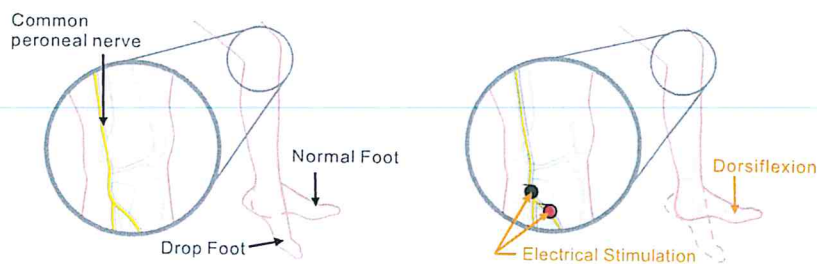
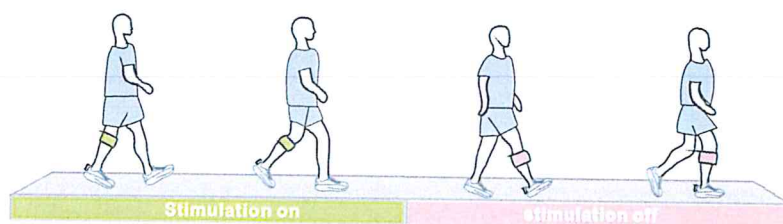
XFT-2001F low-frequency electronic pulse stimulator is a functional electrical stimulation (FES) device, which has a significant effect on improving the gait of patients with foot drop. It is helpful for patients with foot drop caused by central nervous system damage such as stroke, incomplete spinal cord injury, traumatic brain injury, hemiplegia, and multiple sclerosis.

XFT-2001F low-frequency electronic pulse stimulator controls the timing and duration of electrical stimulation by tracking the position, angle and speed of the patient's calf swing back and forth when walking. During walking, the system controls the dorsiflexion and eversion of the ankle and foot by electrically stimulating the common peroneal nerve and the tibialis anterior muscle and other muscles innervated by the common peroneal nerve. Those mild electrical pulses stimulate patient's leg muscle, making them lift the foot at an appropriate phase while walking and therefore enabling patient to walk more steadily, naturally and safely.

XFT-2001F Foot Drop System adopts the latest MEMS sensing technology, and continuously learns and tracks the patient's gait through XFT's patented AI algorithm. Timely electrical stimulation is given when the patient wants to lift the leg, and the repeated motor pattern information is transmitted to the central nervous system to achieve the goal of neural grid function reconstruction.

The influence of FES on the spatiotemporal parameters of stroke patients with foot drop may be through the sensory and motor input of paralyzed limbs. Utilize the plasticity of the central nervous system to promote the reorganization of brain function, thereby promoting the recovery of gait function in stroke patients.

How does the XFT-2001F stimulator work?



The electrical stimulation is started when the forward tilt of the calf reaches a critical point, and the electrical stimulation is turned off when the backward tilt reaches a critical point, and the duration of the electrical stimulation is controlled according to the patient's gait cycle.

## 2.2 Treatment Principle

### 1) Exciting neuromuscular tissue

The frequency, waveform, intensity, and duration of the low-frequency current in the low-frequency electrical pulse stimulator can excite the neuromuscular tissues and induce muscular contraction.

### 2) Improve local blood circulation

- Low-frequency current stimulates the skin, causing axon reflex;
- Low-frequency current stimulates nerves, causing vasodilation;
- Low-frequency current stimulates the skin, and the skin is stimulated to release histamine, which dilates the capillaries and causes a long-term skin hyperemia reaction after treatment;
- Electrical stimulation causes muscle to contract rhythmically, and its metabolites after activity, such as lactic acid, have a strong vasodilation effect and can improve blood supply to muscle tissue.

## 2.3 Scope of application

XFT-2001F Foot Drop System is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord. During the swing phase of walking, the XFT-2001 Felectrically stimulates the appropriate muscles that cause ankle dorsiflexion and may thus improve the individual's gait. Medical benefits of Functional Electrical Stimulation (FES) may include prevention/retardation of disuse atrophy, increased local blood flow, muscle reeducation, and maintained or increased joint range of motion.

## 2.4 Contraindications

- 1) Patients with heart disease, abnormally high blood pressure, skin non-tactile syndrome or abnormal skin are forbidden to use;
- 2) Patient with a history of epilepsy need to consult doctor for use;
- 3) Patient with active bleeding, acute suppurative inflammation, malignant tumor, thrombophlebitis, sepsis, cardiopulmonary failure are forbidden to use.

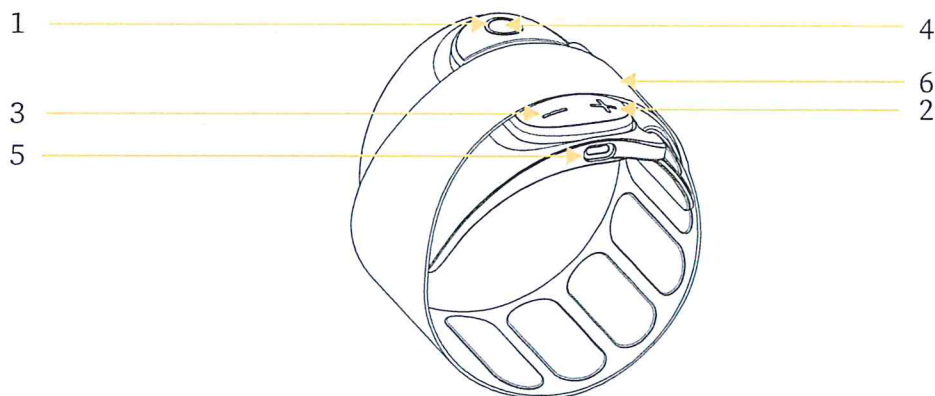
### 3. Product Illustration

#### 3.1 Product Parts

XFT-2001F consists of stimulator. Detachable Cuff. Power Adapter(optional). TYPE-C Charging Cable; Software(APP, optional) and Remote Control(optional).

#### 3.2 Stimulator & Remote Control

##### 3.2.1 Buttons and structure description















The stimulator contains 3 buttons (1 Power/Mode Button, 2 Intensity Buttons), and 1 OLED display.

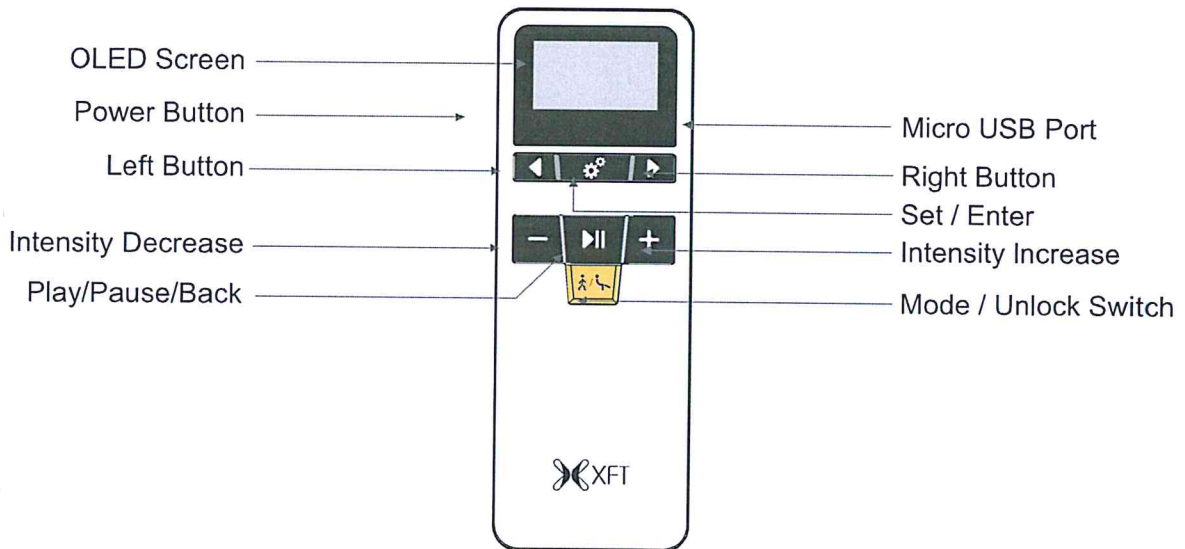
Item	Picture	Describe	Function Description
1		Power/ Mode Button	1. Press and hold this button for 2 seconds to turn the stimulator on under the stimulator turning off; When the stimulator is turned on, press and hold this button for 2 seconds to turn off the stimulator. 2. Tap this button to switch between Gait mode and Training mode When the stimulator is turned on; this button can not be operated when the stimulator connected to the APP.
2		Intensity Increase Buttons	Tap this button to increase electrical stimulation intensity when the stimulator is not connected to the APP to work. This button can not be operated when the stimulator connected to the APP.
3		Intensity Decrease Buttons	Tap this button to decrease electrical stimulation intensity when the stimulator is not connected to the APP to work. This button can not be operated when the stimulator connected to the APP.
4		OLED Display	Display various working states of the stimulator; such as electrical stimulation intensity, Gait mode, Training mode, electrode loose, low battery icon, etc.
5		Type-C Charging Port	Users can charge the stimulator by connected stimulator and power adapter via the charging port.










### 3.2.2 OLED Display Indicators





Display	Describe	Icon Description
	LOGO	The stimulator display shows "XFT" LOGO for 2 seconds after turn it on.
	Gait Mode	It means the current mode is Gait Mode. Tap the Power/ Mode Button to select this mode after the stimulator turn on (not connecting with APP).
	Training Mode	It means the current mode is Training Mode. Tap the Power/ Mode Button to select this mode after the stimulator turn on (not connecting with APP).
	Stimulation Output	It mean the stimulator is working and delivering electrical stimulation.
	Stimulation Intensity	When stimulator is not connected to APP, this number shows the electrical stimulation intensity. It won't appear when stimulator is connected to APP.
	Electrode Loose	When  and, <b>Drop</b> alternately appear on the display with 3 times "Beep" tones, it means the electrode falls off and requires sufficient contact between stimulator's electrode and skin of leg. Press then the  or  to adjust to suitable parameters, continue to work in current mode.
	Low Battery	When battery of stimulator is low, this low battery icon appears and flashes once per second. When battery volume goes to shutdown level, stimulator shutdowns automatically.
	Charging	When stimulator is charging, the charging icon displays scrolling sequentially until fully charged with the icon 

### 3.2.3 Operate with Remote Control



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

Symbols presented on the screen

	<b>Charge Indicator:</b> the remote is charged with a dynamic charging icon on the top right corner of the screen, and the icon will be full when charging is complete.
	<b>Gait Mode:</b> the icon will show in Gait mode.
	<b>Training Mode:</b> the icon will show in Training mode.
	<b>Unlock icon:</b> Show this icon in unlocked state.

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

### **3 .3 Cuff**

#### Replacement

1. It is recommended to replace the cuff every 3 months.
2. Wash and clean the cuff with water or alkaline water below 36°C. Please do not knead or scrub during cleaning, otherwise it may get injured or damaged.
3. Cuff is consumable, please stop using and buy new cuff when it is injured or damaged.

### **3 .4 Instruction of Power Adaptor**

It is available to purchase the power adaptor that matches the stimulator from XFT, meanwhile also available to purchase from the market with specs below:  
Adaptor with rated output DC 5V, 1.2A; Comply with GB9706.1-2020 standards.

### **3 .5 APP software instructions (Optional)**

Software name: G5 FES

Software model: XFT-2001F

Software launched version: V1

Operating environment:

Hardware:

iOS: iPhone 6s and followed up iPhone models.

Android: Android phones adapting Android 6 .0 and above version.

Software:

iOS System: Adapting iOS 9 .0 and versions above

Android System: Adapting Android 6 .0 and versions above

Safety software: N/A

Network requirements: Bluetooth

## 4. General Operation Instruction

The simulator can be used both with and without APP.

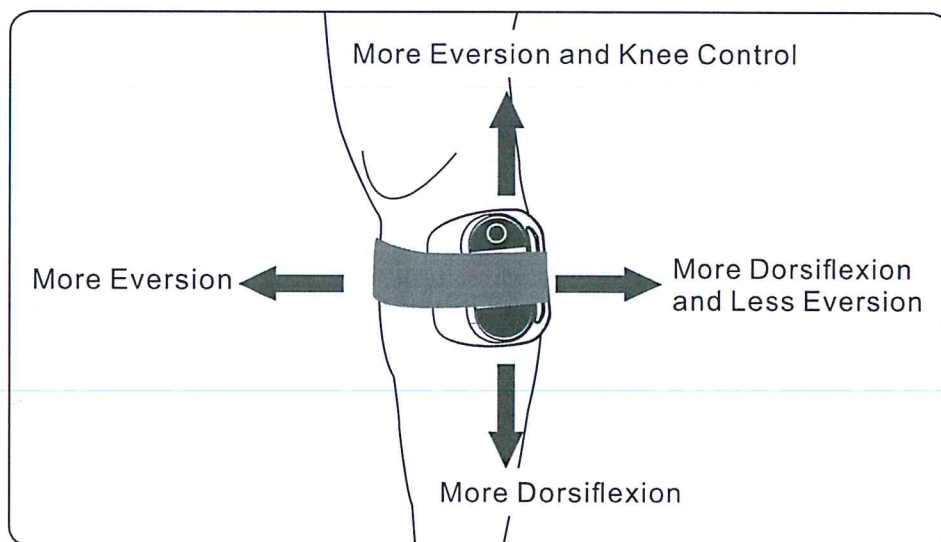
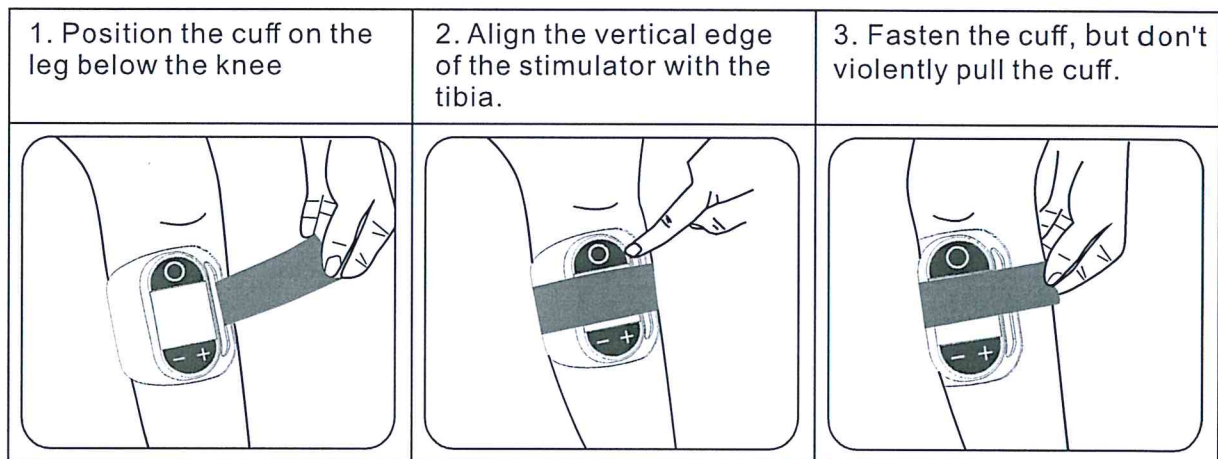
### 4.1 With APP

Please check if the stimulator is fully charged before use. If necessary, please charge the stimulator. The display will indicate the battery icons when charging.


#### 4.1.1 Wear the stimulator

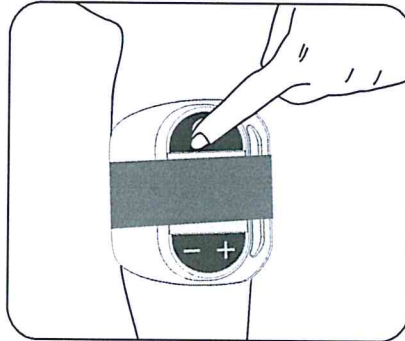
a. Preparation: Use a wet towel to clean the skin of the leg. Trim the hair if there is too much, then sit on a chair, bend and relax the leg.


b. Place the stimulator in the correct position under the knee.



### 4.1.2 Power On and Operate

Press and hold the  for 2 seconds to turn the stimulator on, and the stimulator display shows "XFT" LOGO for 2 seconds. Tap this button to switch between Gait mode and Training mode.



Press  button to increase and  button to decrease the electrical stimulation intensity. The display will show the corresponding intensity value.

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


### 4.1.3 Power Off

When stimulator is turned on, press and hold  button for 2 seconds to turn it off.

## 4.2 Use with App

### 4.2.1 Preparation

1) Install the APP

Steps	Operation description
1	iOS devices: Search "G5 FES" in  (APP Store) and download the App Android devices: Search "G5 FES" in smart phone manufacturer or other App store, and download the App.
2	Run the App, create a user ID for the first time.

2) Wear the stimulator

Note: Wear the stimulator ,see pages 10 of this manual for details.

### 3) Power On and Operate

Note: The Power On and Operate, see pages 10 of this manual for details.

### 4) Connect the stimulator to the APP via Bluetooth

Switch on Bluetooth, run the APP, register and login the APP, then search the stimulator via Bluetooth, connect to the correct stimulator. You will enter the homepage when connection is successfully done. There are 3 sections of homepage: "Activity" "Stats" "Me".

"Activity" includes use of functions and parameter settings.

"Stats" shows the records of gait and training modes.

"Me" goes to company news, edit photo, guidance of use, help, customer service, device info and system settings etc.

Note: The APP has Lite - personal version and Pro - clinical version, when the stimulator is connected to the APP, it runs with Lite version by default.

Lite version is for regular users; Pro version requires corresponding professional knowledge and skills, It is suitable for in-service rehabilitation physicians, paramedic, or those with rehabilitation physiotherapy and rehabilitation treatment qualifications. The Lite version does not include functions and configurations corresponded to the Pro version.

#### 4.2.3.9 Me

Note: The Lite Version Me interface is the same as the Pro Version Game Mode interface, see pages 29-30 of this manual for details.

#### 4.2.4 Power off

When stimulator is powered on, press and hold  for 2 seconds

## 5. Attentions

### 5.1 Shutdown instructions

Forced shutdown: press shutdown button.

System shutdown:

- 1) When the set treatment time has expired, the function stops working
- 2) When voltage is below shutdown voltage, stimulator shutdowns automatically.
- 3) Stimulator in standby (no stimulation output) condition for over 15 minutes will shutdown automatically.

### 5.2 Use of Electrode

The integrated stainless steel electrode can be used without replacement for long time, attention should be paid to cleaning of contact surface or skin surface during use. (Hairy users could trim the hair properly, conductive glue could also be used to increase conductivity.)

Cleaning: Use sponge or soft cloth to wipe off dust and dirt on surface of electrode, to keep the electrode clean and hygiene.

Disinfecting: After cleaning, wipe the electrode with sponge or soft cloth moistened with disinfectant (should take appropriate amount of disinfectant liquid and soak on sponge or soft cloth to avoid liquid spilling into the inside of stimulator and causing malfunction or danger). Disinfectant: 75% medical alcohol.

### 5.3 Skin care

Please check skin condition before and after using the stimulator. Slightly redness is normal and it indicates that blood circulation is faster in this area. If electrode touched area of skin is uncomfortable please reduce the frequency of use or temporarily stop using, and continue to use when the condition is improved.

※ Skin Irritation Prevention:

- Do not use the main unit on skin covered with lotion or oil.
- Do not position the electrodes over an irritated area of the skin.
- If any skin irritation or allergy occurs, please stop using the stimulator immediately and follow doctor's instructions.
- Poor electrode contact may be caused by excessive hair on the skin area that the electrode contacts. If it is necessary to shave, it is recommended to use an electric shaver to shave or trim with small scissors.