

# INSTRUCTION MANUAL FOR

## Combo Electrotherapy Device

### **Model: F100**



Shenzhen Roundwhale Technology Co., Ltd.  
This manual is valid for the F100 Stimulator

Be sure to read this instruction manual before operation and keep it  
where safe.

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### Declaration of conformity:

Shenzhen Roundwhale Technology Co., Ltd. declares that the device complies with following normative documents:

IEC60601-1, IEC60601-1-2, IEC60601-1-11, IEC60601-2-10, IEC62304, I-  
SO10993-5, ISO10993-10, ISO10993-1, I ISO10993-23, SO14971

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# **1. FOREWORD**

## **1.1 Introduction**

The device F100 is TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electronic Muscle Stimulation) stimulator. Before using, please read all the instructions in this user manual carefully and keep it safe for future use.

## **1.2 Medical background**

### **1.2.1 ABOUT PAIN**

Pain is an important signal in the human body warning system. It reminds us that something is wrong, without which, abnormal conditions may go undetected, causing damage or injury to vital parts of our bodies. Even though pain is a necessary warning signal of trauma or malfunction in the body, nature may have gone too far in its design. A side from its function in diagnosis, long-lasting persistent pain serves useless purpose.

Pain does not occur until encoded message travels to the brain where it is decoded, analyzed, and reacted to, from the injured area along the small nerves leading to the spinal cord. There the message is transmitted to different nerves that travel up the spinal cord to the brain. Then the pain message is interpreted, referred to and pain is felt.

### **1.2.2 WHAT IS TENS ?**

TENS (Transcutaneous Electrical Nerve Stimulation) is effective in relief of pain. It is daily used and clinically proven by physiotherapists, caregivers and top athletes around the world. High-frequency TENS currents activates the pain-inhibiting mechanisms of the nervous system. Electrical impulses from electrodes, placed on the skin over or near the pain area, stimulate the nerves to block the pain signals to the brain, causing the pain go unperceived. Low-frequency TENS currents facilitate the release of endorphins,

the body's natural painkillers.

### **1.2.3 WHAT IS EMS ?**

Electrical Muscle Stimulation is an internationally accepted and proven way of treating muscular injuries. It works by sending electronic pulses to the muscle needing treatment that causes the muscle to exercise passively. It is a product deriving from the square waveform, originally invented by John Faraday in 1831. Through the square wave pattern it is able to work directly on muscle motor neurons. The EMS System has low frequency and this in conjunction with the square wave pattern allows direct work on muscle groupings.

## **2. SAFETY INFORMATION**

### **2.1 Intended use**

#### **Intended purpose**

The device is designed to be used for temporary relief of pain, including the acute and chronic pain relief.

The device is designed to be used for stimulate muscles for prevention of muscular atrophy, muscle strengthening and improve , Increasing local blood circulation and facilitate muscle performance.

#### **Target population**

The device using the object (patient) must be 18 years or older of adults.

#### **Intended user**

Medical staff or lay persons.

#### **Intended condition**

Intended for use in the home, hospital and health care facilities.

#### **Indications**

- 1). It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, joint, hip, hand, abdomen,

upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

- 2). Relaxation of muscle spasms.
- 3). Prevention or retardation of disuse atrophy.
- 4). Increasing local blood circulation.
- 5). Muscle re-education.
- 6). Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- 7). Maintaining or increasing range of motion.




## 2.2 Important Safety Precautions and Warnings



It is important that you read all the warnings and precautions included in this manual because they are intended to keep you safe, prevent risk of injury and avoid a situation that could result in damage to the device.

### SAFETY SYMBOLS USED IN THIS MANUAL

#### 2.2.1 Contraindication

- 1) Do not use this device if you are using a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic devices. Such use could cause electric shock, burns, electrical interference, or death.
- 2) The device should not be used when cancerous lesions or other lesions are present in the treatment area. 
- 3) Stimulation should not be applied over swollen, infected, inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins, etc.).
- 4) Electrode placements must be avoided in the carotid sinus area (anterior neck) or trans cerebrally (through the head).
- 5) Apprehensive patients-usage of Electrical stimulation requires patient co-operation, hence the procedure shouldn't be attempted in patients  



with a communication handicap or a mental disability.

- 6) Patients with cerebrovascular problems-patients with a history of aneurysm, stroke and transient ischaemia shouldn't be treated using electrical stimulation, as it stimulates peripheral blood flow which can be fatal in such cases.
- 7) Epileptic patients-Electrical stimulation "pulses" have the potential to trigger a seizure.
- 8) Acute pain cases/pain of unknown etiology- usage of TENS in undiagnosed cases may hinder in the diagnosis.
- 9) Do not use in pregnancy, especially in the first trimester.

### 2.2.2 WARNING

- 1) If you have had medical or physical treatment for your pain, consult with your physician before use.
- 2) If your pain is not subdued, which becomes more than mild, or lasts for more than five days, stop using the device and consult with your physician.
- 3) Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- 4) Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to your heart, which could be lethal.
- 5) Do not apply stimulation over, or in proximity to, cancerous lesions.
- 6) Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when electrical stimulation device is in use.
- 7) Do not apply stimulation when in bath or shower.
- 8) Do not apply stimulation while sleeping.
- 9) Do not apply stimulation while driving, operating machinery, or during any activity when electrical stimulation can put you at risk

of injury.

- 10) Apply stimulation only to normal, intact, clean, healthy skin.
- 11) The long-term effects of electrical stimulation are unknown. Electrical stimulation device cannot replace drugs.
- 12) Stimulation should not take place while the user is connected to high-frequency surgical equipment, which may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
- 13) Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
- 14) Never use it near the cardiac area. Stimulation electrodes should never be placed anywhere on the front of the thorax (marked by ribs and breastbone), but above all not on the two large pectoral muscles. There it can increase the risk of ventricular fibrillation and lead to cardiac arrest. 
- 15) Never use it on the eye, head and face area. 
- 16) Never use it near the genitals.
- 17) Never use it on the areas of the skin which lack normal sensation
- 18) Keep electrodes separate during treatment. It could result in improper stimulation or skin burns if electrodes are in contact with each other.
- 19) Keep the stimulator out of reach of children.
- 20) Consult your doctor if you are in any doubt whatsoever.
- 21) Discontinue it and do not increase the intensity level if you feel discomfort during use.

### 2.2.3 Precautions

- 1) TENS is not effective for pain of central origin including headache.
- 2) TENS is not a substitute for pain medications and other pain management therapies.



- 3) TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- 4) Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients.
- 5) Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head.
- 6) The safety of electrical stimulation during pregnancy has not been established.
- 7) You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (silica gel).
- 8) If you have suspected or diagnosed heart disease or epilepsy, you should follow precautions recommended by your physician.
- 9) Caution if you have a tendency to bleed internally, e.g. following an injury of fracture.
- 10) Consult with your physician prior to use the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- 11) Caution if stimulation is intended to be applied over the menstruation or pregnant uterus.
- 12) For single patient use only.
- 13) This stimulator should not be used by patients who is non compliant and emotionally disturbed including whom with dementia or low IQ.
- 14) The instruction of use is listed and should be obeyed; any improper use may be dangerous.
- 15) Rare cases of skin irritation may occur at the site of the electrode placement following long-term application.
- 16) Do not use this device in the presence of other equipment which sends electrical pulses to your body.
- 17) Do not use sharp objects such as a pencil or ballpoint tip to oper-

ate the buttons on the control panel.

- 18) Check the electrode connections before each use.
- 19) Electrical stimulator should be used only with the electrodes recommended for use by the manufacturer.
- 20) When output of device more than 10mA or 10 V, the intensity of Channel will flicker.
- 21) Users should consult a healthcare professional before using the device
- 22) The user shall report any serious incident related to the device to the manufacturer and the competent authorities of the Member States establishing the user and / or the patient.

## 2.2.4 Adverse Reactions

- 1) Possible skin irritation or electrode burn under the electrodes may occur.
- 2) Possible allergic skin reaction to tape or gel may occur.
- 3) On very rare occasions, first-time users of EMS report feeling light-headed or faint. We recommend that you use the product while seated until you become accustomed to the sensation.
- 4) If symptoms of tachycardia and extrasystolia (rapid heartbeat or extra stimulation) appear during treatment, stop the treatment and seek medical attention immediately.
- 5) If the stimulation makes you uncomfortable, reduce the stimulation Intensity to a comfortable level and contact your physician if problems continue.

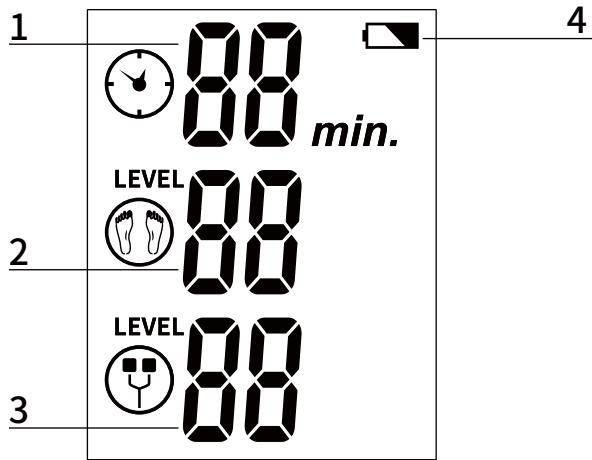
## **3. GETTING TO KNOW YOUR DEVICE**

### **3.1 Package includes**

No.	Description	QTY
1	Foot massage device	1PC
2	Electrode pad (50mm×50mm )	2PCS
3	Electrode wires	1PC

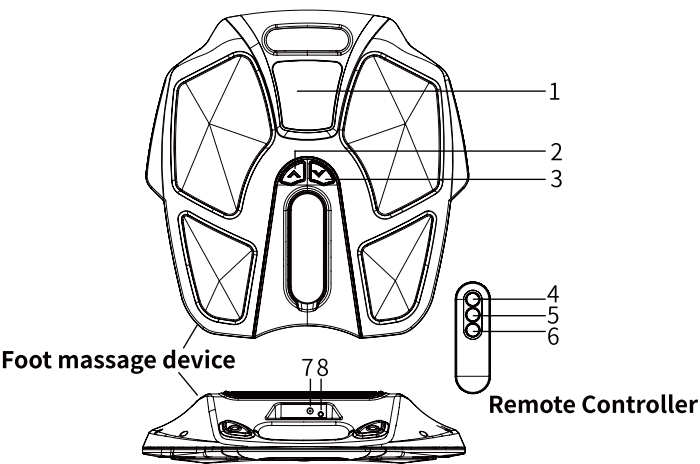
4	USB cable	1PC
5	User manual	1PC
6	AAA battery	2PCS
7	Remote controller	1PC

### 3.2 LCD display



No.	Function description	No.	Function description
1	Treatment time	3	Intensity for Body part
2	Intensity for Foot	4	Low battery indicator

### 3.3 Device illustration



No	Description
1	LCD display
2	[+ /ON] button for Foot massage device: At power saving mode, press the [+ /ON] button to turn on the device; At standby mode, press the [+ /ON] button to increase the Foot output intensity;
3	[- /OFF] button for Foot massage device: At standby mode, press the [- /OFF] button to turn off the device; At treating mode, press the [- /OFF] button to decrease the Foot output intensity;
4	[+] button for Remote controller : At standby mode, press the [+] button to increase the Foot/Body part output intensity;
5	[-] button for Remote controller : At standby mode, press the [-] button to decrease the Foot/Body part output intensity;
6	[M] button for Remote controller: At the standby or treating mode, press the [M] button to select to Treatment time , Foot mode or Body part mode.
7	Charge socket
8	Output socket for body stimulation.

## 4. SPECIFICATION

### 4.1 Technical information

Device name	Combo Electrotherapy Device
Model/type	F100
Power sources	Foot massage device : d.c. 3.7 V Li-ion battery Remote controller : d.c. 3.0V 2*AAA batteries
Power supply	Input: 100-240V AC, 50/60Hz, 0.2A; Output: 5V DC, 300mA
Output channel	Dual channel
Waveform	Bi-phase square-wave pulse
Output current	0-90mA (At Load:1000 ohm)

Output intensity	0-90V (At Load:1000 ohm)
Treatment type:	TENS and EMS mode
Operating condition	5 ° C to 40 ° C with a relative humidity of 15%-93%, atmospheric pressure from 700 hPa to 1060 hPa
Storage condition	-10° C to 55° C with a relative humidity of 10%-95%, atmospheric pressure from 700 hPa to 1060 hPa
Dimension	367 mm (L) x 361 mm (W) x 80.5 mm (H)
Weight	About 1500 grams
Classification	BF type applied part, internal power equipment
Size of electrodes pad	50x50mm, square
Output precision	±20% error is allowed for all the output parameters
P.W. (Pulse Width)	200μs
P.R. (Pulse Rate)	Carrier F 2.5KHz Burst F 10Hz -50Hz
Time	Adjustable, from 10 to 90 minutes.
Shelf life of device	5 years
Shelf life of electrode pads	3 years
Automatic shut off	5 minutes.

## **5. FOOT AND LEG STIMULATION**

### **5.1 Place the device on the floor.**

Place the device on the floor a comfortable distance from your chair. Sit down on your chair.



**Caution:**

- **Never stand on the Circulation pedal.**

## 5.2 Place both bare feet on to the footpads.

Remove all socks and stockings and place bare feet onto the footpads. The arch of your foot should be positioned on the raised instep on the footpads. It does not matter if your feet are smaller or bigger than the footpads.




The Foot massage device can tilt back and forth. This gently and involuntarily features create ankle joint movement for increasing circulation and reducing swelling. The Foot massage device will tilt back and forth as per your feet rocking motion. This type of exercise therapy is recommended widely by health professionals to improve circulation and when used in conjunction stimulation, the results are significant.

### **Caution:**




- Two feet are required to create the stimulation. Sit with your knee both at a 90 degree angle.

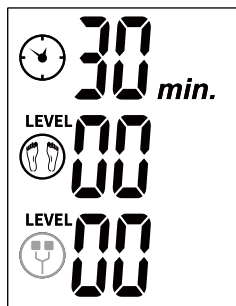
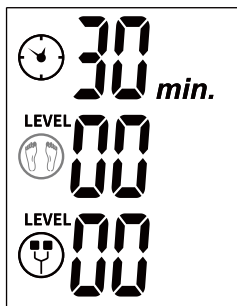
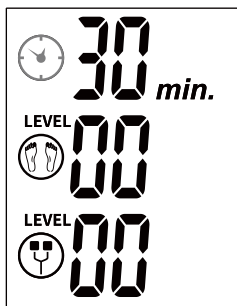
## 5.3 Turn on the device

To turn on the device. Press the power button [+ / ON] on the device.

In the default setting, the display lights will read '  ' 30 minutes, '  ' 00 output intensity, '  ' 00 output intensity.

## 5.4 Select set parameter

Using the remote controller to select treatment mode, press [M] button select set treatment time mode '  ', foot stimulation mode '  ' and body stimulation mode '  '.

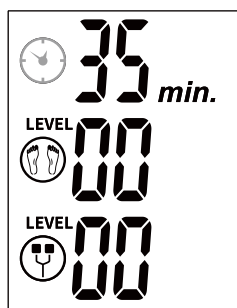
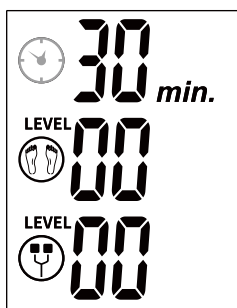


## 5.5 Setting the treatment time

Using the remote controller to set the treatment time, press [M] button select set treatment time mode, and the symbol '🕒' twinkles.

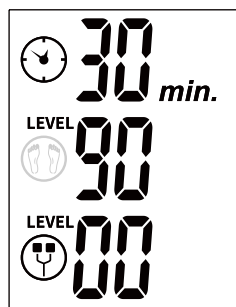
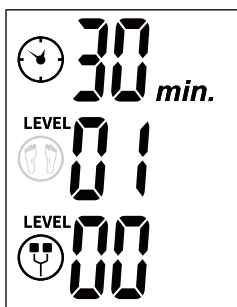
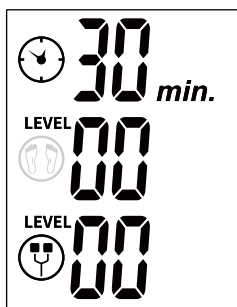
Press [+] button or [-] button adjust treatment time.

The LCD displays as follows:



## 5.6 Start treatment and adjust intensity

In foot stimulation mode '👣'. Using either the remote controller or button on the device to set the intensity level. The treatment will begin and the display will start counting down the remaining minutes of treatment.



### **Caution**

- We recommend using a heel balm on your feet to improve conductivity and stimulation.
- Each person may require a different intensity level to obtain the optimal muscle stimulation. The device can safely be used on intensity level 1 to maximum level 90.
- There are 15 therapeutic modes working as a cycle. 15 therapeutic modes will work alternately, every 1 minute it will change a mode.

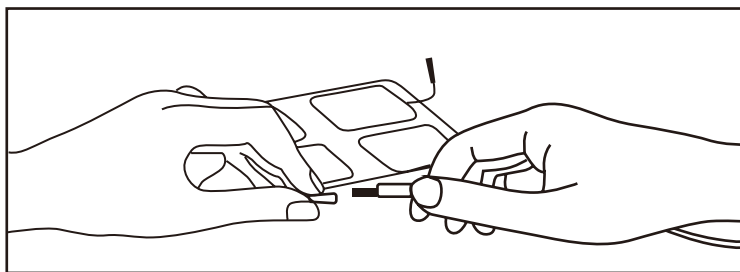
## **5.7 Turn off the device**

To turn off the device. Press the [-] button on the device or press and hold the power button 3s on the remote control.

# **6. BODY STIMULATION**

## **6.1 Connect electrode pads to electrode wires**

Insert the electrode wires connector into electrode connector. Make sure they are properly connected to ensure the good performance. Please refer to the picture.



### **Caution**

Always use the electrode pads which comply with the requirements of the IEC/EN60601-1, ISO10993-1/-5/-10 and IEC/ EN60601-1-2, as well as CE and FDA 510(K) regulation.



## 6.2 Connect electrode wires to Foot massage device.

Before proceeding to this step, ensure that the device is completely switched OFF. Hold the insulated portion of the electrode wire connector, and insert the plug into the receptacle on the bottom of the Foot massage device.

### Caution

Do not insert the plug of the electrode wires into any AC power supply socket.

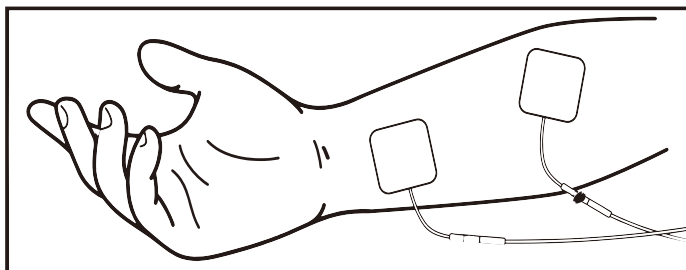
## 6.3 Electrode

### 6.3.1 Electrode options

The electrodes should be routinely replaced when they start to lose their adhesiveness. If you are unsure of your electrode adhesive properties, please order new replacement electrodes. Replacing electrodes should be re-ordered under the advice of your physician or the device manufacturer to ensure proper quality. Follow application procedures outlined on electrode packing when using the new replacement electrodes to maintain optimal stimulation and to prevent skin irritation.

### 6.3.2 Place electrodes on skin

Place the electrode on the body part in need of treatment, according to the instruction of this user manual. Please make the skin clean before use and ensure the skin and electrode connect well.



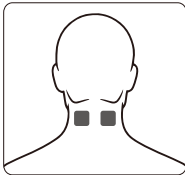
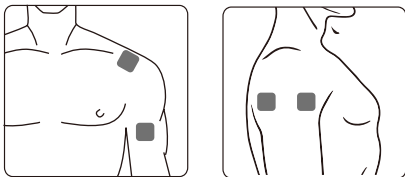
## Caution

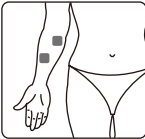
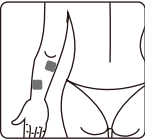
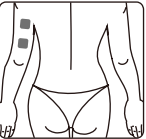
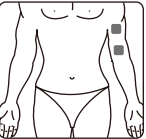
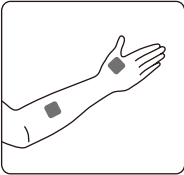
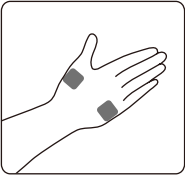
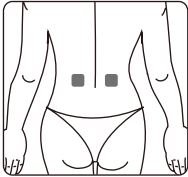
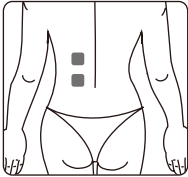
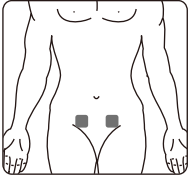
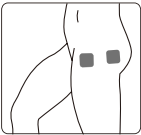
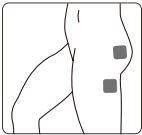
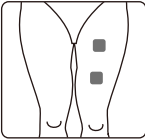
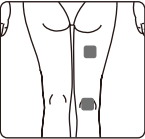
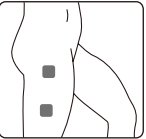
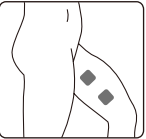
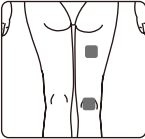
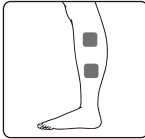
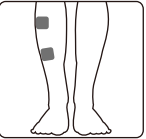
1. Always remove the electrodes from the skin with a moderate pull in order to avoid injury in the event of highly sensitive skin.
2. Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
3. Do not turn on the device when the self-adhesive electrodes are not positioned on the body.
4. To remove or move the electrodes, switch off the device or the appropriate channel first in order to avoid unwanted irritation.
5. It is recommended that, at minimum, 1.97" x 1.97" self-adhesive square electrodes are used at the treatment area.
6. Never remove the self-adhesive electrodes from the skin while the device is still on.

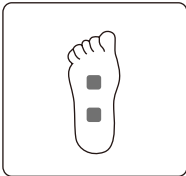
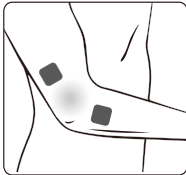
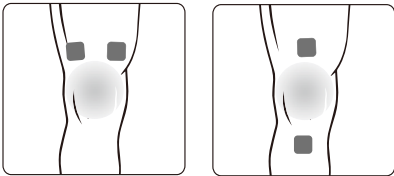
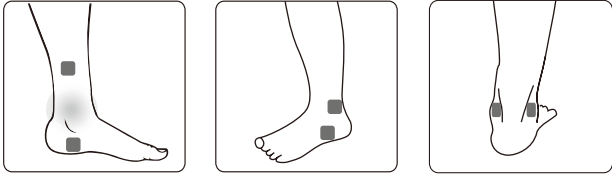
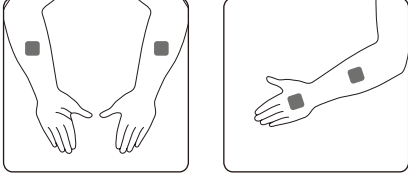
### 6.3.3 Electrode placement

You only have to use according to the user manual, place the electrode on the position where you feel pain. Conduct exercise, treatment and adjustment based on your own feeling.

#### Position of electrode placement

Neck	
Shoulder	

Arm	   
Hand	 
Back	 
Abdomen	
Hip	 
Leg	      

Foot	
Joint (knee)	
Joint (elbow)	
Joint (ankle)	
Joint (wrist)	

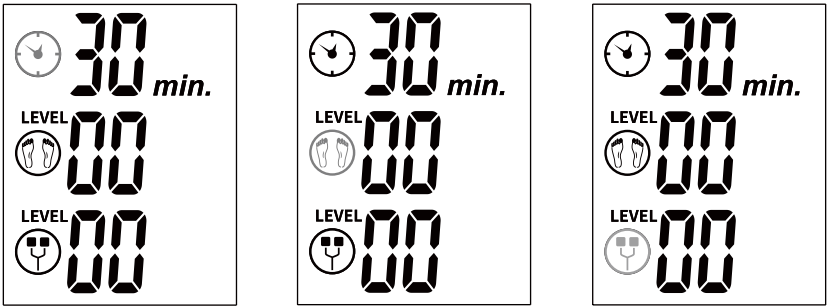
### 6.4 Turn on the device

To turn on the device. Press the power button [+ / ON] on the device.

In the default setting, the display lights will read ' ⌚ ' 30 minutes, ' 👣 ' 00 output intensity, ' 🧘 ' 00 output intensity.

### 6.5 Select set parameter

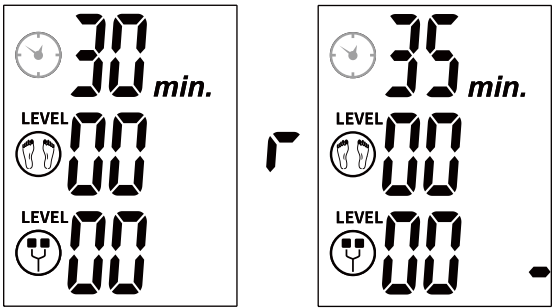
Using the remote controller to select treatment mode, press [M] button select set treatment time mode '🕒', foot stimulation mode '👣' and body stimulation mode '👤'.



### 6.6 Setting the treatment time

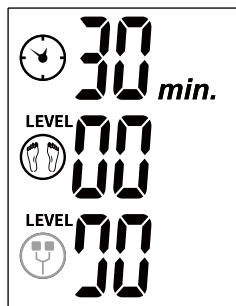
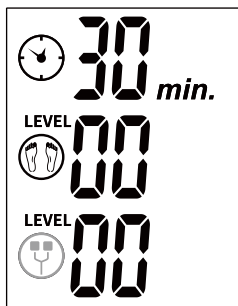
Using the remote controller to set the treatment time, press [M] button select set treatment time mode, and the symbol '🕒' twinkles. Press [+] button or [-] button adjust treatment time.

The LCD displays as follows:



### 6.7 Start treatment and adjust intensity

In body stimulation mode '👤'. Using either the remote controller or button on the device to set the intensity level. The treatment will begin and the display will start counting down the remaining minutes of treatment.



## Caution

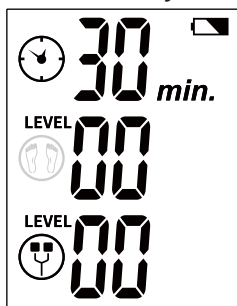
- Each person may require a different intensity level to obtain the optimal muscle stimulation. The device can safely be used on intensity level 1 to maximum level 90.

## 6.8 Turn off the device

To turn off the device. Press the [-] button on the device or press and hold the power button 3s on the remote control.

## 6.9 Low battery detection

When the battery is low, the '  ' icon will twinkle to indicate it, stop the device and charge the battery.



## Charging the Battery:

Proceed as follows to recharge the battery:

- This device cannot be used while charging.

- Make sure that the device is no longer connected to the patient (the output cables and electrodes must be disconnected).
- Connect the USB cable to the charging port on the device.
- Connect the USB cable to the charger.
- When the device is charging, the indicator light will be yellow.
- It could take up to 2 hours to reach a full charge.
- When charging is completed, the indicator light will be green.

The life of a rechargeable battery depends on the number of recharging/rundown cycles it undergoes and how these cycles are performed.

The following suggestions will help prolong the life of the battery:

- Whenever the device is not used frequently, charge the battery once a month.
- For longer battery life, discharge the battery as much as possible.

## 6.10 Usage of electrode pads

1. The electrode may only be connected with the TENS stimulator. Make sure that the device is turned off when attaching or removing the electrode pads.
2. If you want to reposition the electrode during the application, turn the device off first.
3. The usage of electrode may lead to skin irritations. If you experience such skin irritations, e.g. redness, blistering or itching, discontinue using them. Do not use the TENS stimulator permanently on the same body part, as this may also lead to skin irritations.
4. Electrode pads are private and intended for single person use. Please avoid using them by different persons.
5. The electrode must connect entirely to the skin surface to prevent hot spots, which may lead to skin burns.
6. Do not use the electrode pads for more than 15 times, as connec-

- tion between the electrodes and the skin deteriorates over time.
7. The adhesive force of the electrodes depends on the skin properties, storage condition, and the number of applications. If your electrode pads no longer fully stick to the skin's surface, replace them with new ones. Stick the electrode pads back onto the protective foil after use and store them in the storage bag to prevent them from drying out. This retains the adhesive force for a longer period.
  8. Do not use detergent to clean the electrode pads before and after use to avoid damaging the adhesion of the electrode pads.
  9. The electrode pads must always be touched with clean hands, it is recommended to replace the electrode pads if they become dirty.

### Caution:

- 1) Before applying the electrode, it is recommended for users to wash and degrease the skin, and then dry it.
- 2) Never remove the electrode from the skin while the device is still on.
- 3) Only use the electrode pads provided by the manufacturer. Usage of other companies' products could result in injuries to the user.

## 6.11 Where do I attach electrode pads?

- 1 Each person reacts differently to electric nerve stimulation. Therefore, the placement of the electrodes may deviate from the standard. If application is not successful, contact your physician to find out which placement techniques are best for you.
- 2 Do not use any adhesive electrodes with a size smaller than those the original manufacturer attached. Otherwise the current density may be too high and cause injuries.
- 3 The size of the adhesive pads may not be changed, e.g. by clipping off parts of them.
- 4 Make sure that the region radiating the pain is enclosed by the electrodes. In case of painful muscle groups, attach the electrodes



in such a way that the affected muscles are also enclosed by the electrodes.

## **7. CLEANING AND MAINTENANCE**

Fully comply with the following necessary daily maintenance requirements to make sure the device is intact and guarantee its long-term performance and safety.

### **7.1 Cleaning and care for the device**

- 7.1.1 Pull the electrodes out of the stimulator, clean the device with a soft, slightly damp cloth. In case of heavier dirt build-up, you may also apply a mild detergent.
- 7.1.2 Do not expose the stimulator to moisture or dampness. And do not hold the stimulator under running water, nor submerge it in water or other liquids.
- 7.1.3 The stimulator is sensitive to heat and may not be exposed to direct sunlight. And do not place it on hot surfaces.
- 7.1.4 For reasons of hygiene, each user should use his/her own set of electrodes.
- 7.1.5 Do not use any chemical cleaners or abrasive agents for cleaning.
- 7.1.6 Ensure that no water penetrates into the machine. Should this happen, use the device again only when it is completely dry.
- 7.1.7 Do not clean the device during treatment. Be sure that the device is turned off before cleaning.

### **7.2 Maintenance**

- 7.2.1 The manufacturer didn't authorize any maintenance agencies abroad. If your device has any problems, please contact the distributor. The manufacturer will not be responsible for the re-

sults of maintenance or repairs by unauthorized persons.

7.2.2 The user must not attempt any repairs to the device or any of its accessories. Please contact the retailer for repair.

7.2.3 Opening of the equipment by unauthorized agencies is not allowed and will terminate any claim to warranty.

Each product in manufacturing has been inspected through the systematic validation. The performance is stable and does not need to undertake calibration and validation.

If your product can't reach the expected performance and the basic function has changed in normal use, please contact the retailer.

## 8. TROUBLESHOOTING

Should any malfunction occur while using the device, check whether the parameters are set appropriately for therapy, and adjust the control correctly. Please see the following table:

Malfunction	Common reasons	Countermeasure
No display	The battery is exhausted	Charge in time
No sensation of stimulation or weak stimulation	1. The electrode does not connect well to the skin. 2. If the connection between electrode connects well to the stimulator. 3. The battery is used up. 4. The skin is too dry.	1. Check and re-paste it on skin. 2. Check the connection. 3. Charge. 4. Wipe the electrode and the skin with a wet cotton cloth.
Automatic halt in the treatment	1. The electrode loses connection with the skin. 2. If the battery is used up.	1. Check and place the electrode properly on the skin. 2. Charge

Rash or tickle on the skin occurs in treatment	<ol style="list-style-type: none"><li>1.The treatment time lasts too long.</li><li>2.The electrode does not stick well to the skin.</li><li>3. The interface of the electrodes is dirty or dry.</li><li>4. The skin is sensitive to the electrode.</li></ol>	<ol style="list-style-type: none"><li>1. Do the treatment once a day and shorten the treatment time.</li><li>2. Check and stick the electrode well.</li><li>3. Wipe the electrode with a wet cotton cloth before use.</li><li>4. Check your allergic history. Please change the sticking place or shorten the treatment time. If your skin is over-sensitive, you should stop the treatment or go to see a doctor.</li></ol>
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## **9. STORAGE**

### **9.1 Storing the Electrode Pads and Lead Wires**

1. Turn the device off and remove the lead wires from the unit.
2. Remove the electrodes from your body and disconnect the lead wires from the electrodes.
3. Place the electrodes onto the plastic film and then store into the sealed package.
4. Wrap the lead wires and store into the sealed package.

### **9.2 Storing the Unit**

1. Place the unit, electrodes, lead wires and manual back into the carrying case. Store the box in a cool, dry place, -10°C ~ 55°C ; 10% ~ 95% relative humidity.
2. Do not keep in places that can be easily reached by children.
3. When not in use for a long period, remove the battery before storage.

## 10. DISPOSAL



Spent batteries do not belong to the household wastes. Disposal of the battery according to the current regulations. As a consumer, you have the obligation to dispose of batteries correctly. Consult your municipal authority or your dealer XXXXXXXXXX for information about disposal.

At the end of the product life cycle, do not throw this product into the normal household garbage, but bring it to a collection point for the recycling of electronic equipment.

Obsolete electrical and electronic equipment may have potentially harmful effects on the environment. Incorrect disposal can cause toxins to build up in the air, water and soil and jeopardize human health.

## 11. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

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

The device is intended for use in the electromagnetic environment specified below. The customer or the user has to assure that it is used in such environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CIS-PR11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CIS-PR11	Class B	The device is suitable for use in all establishments including those directly connected to the public low-voltage power supply network that supplies to buildings power used for domestic purposes
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Not applicable	

## Guidance and manufacture's declaration — electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.


Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electro-static discharge (ESD) IEC61000-4-2	$\pm 8\text{kV}$ direct & indirect contact; $\pm 15\text{kV}$ air discharge	$\pm 8\text{kV}$ direct & indirect contact; $\pm 15\text{kV}$ air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	$\pm 2\text{ kV}$ for power supply lines	not applicable	not applicable (for INTERNALLY POWERED ME EQUIPMENT)
Surge IEC 61000-4-5	$\pm 1\text{ kV}$ line(s) to line(s)	not applicable	not applicable (for INTERNALLY POWERED ME EQUIPMENT)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	$<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0.5 cycle  $40\% U_T$ ( $60\%$ dip in $U_T$ ) for 5 cycles  $70\% U_T$ ( $30\%$ dip in $U_T$ ) for 25 cycles  $<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 5 sec	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT)

Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	10V/m	10V/m	Power frequency magnetic fields should be at levels characteristic of a typical location in typical commercial or hospital environment.
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NOTE U<sub>T</sub> is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture’s declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of device should assure that it is used in such environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10V/m & table 9	10V/m & table 9	<p>Portable and mobile RF communications equipment should be used not closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p><math>d = 1.167 \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.333 \sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>

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

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection 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 the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [Vi] V/m.

**Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment** (Table 9)

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation <sup>b)</sup>	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation <sup>b)</sup> 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM <sup>c)</sup> ±5kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18Hz	2	0.3	28
870						
930						

1720	1700-1990	GSM1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	Pulse modulation <sup>b)</sup> 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217Hz	0.2	0.3	9
5500						
5785						










NOTE If it is 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 test distance is permitted by IEC 61000-4-3.

- a) For some services, only the up link 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 it does not represents actual modulation. It would be worst case.

## 12. NORMALIZED SYMBOLS

	WEEE Symbol		Applied part of type BF
	Refer to instruction manual	<b>IP22</b>	IP classification
	Batch code		Authorized representative in the European Community
	Manufacturer		Date of manufacture
	Fragile, handle with care		Keep away from sunlight
	Keep dry		Temperature limit
	Use-by date		Serial number



	Humidity limitation		Atmospheric pressure limitation
	Caution		Green Dot
	Users of the artificial pacemaker are prohibited from using the device		CE mark
	Packaging material cycle mark		Unique device identifier
	Medical device		

## **13. WARRANTY**

Please contact your dealer or the device center in case of a claim under the warranty. If you have to return the unit, enclose a copy of your receipt with clear statement of defect description.

### **The warranty terms are as below:**

1. The warranty period for this device is 1 year from the date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs under warranty should be in the warranty period either for the device or for the replacement parts.
3. The following cases are excluded under the warranty
  - All damages that arise due to improper operation, e.g. nonob-

servance of the user instruction.

- All damages due to repairs or tampering by the customer or unauthorized third parties.
  - Damage which have arisen during transport from the manufacturer to the consumer or the service center.
  - Accessories which are subject to normal wear and tear.
  - Device damages due to privately disassembling devices.
4. Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

**FCC Caution:**

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, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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 general RF exposure requirement. The device can be used in portable exposure condition without restriction.



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