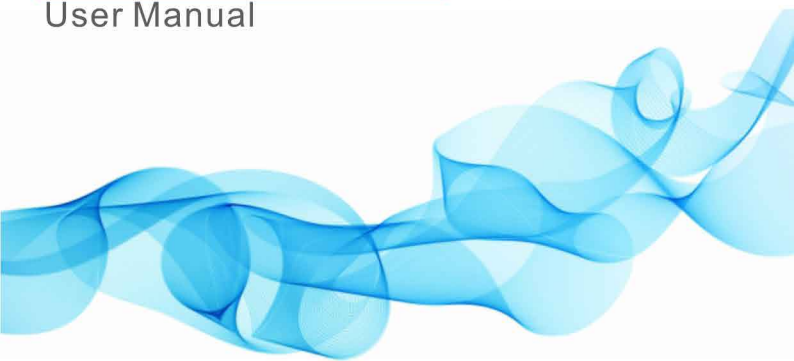
Pelvifine®

(Model:KM530)

Biofeedback Nerve and Muscle Stimulator User Manual



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Contents

1.Foreword

Thanks for your purchasing Biofeedback Nerve and Muscle Stimulator(hereinafter referred to as Biofeedback device). Please refer through the User Manual before using and pay special attention to all safety precautions as well as following them strictly. Meanwhile, the User Manual should be well kept for your reference at any time.

1.1 Abbreviation Cited

- EMG: Electromyography
- ETS: Electromyography triggered stimulation
- STIM: Neuromuscular stimulation

1.2 Introduction

This Biofeedback device is a new type of biofeedback and neuromuscular electrical stimulation therapy device for patients with muscle dysfunction through the evaluation of myoelectric signal acquisition, multimedia biofeedback training, electromyography triggered electrical stimulation, passive electrical stimulation training and treatment. Perform routine muscle training, combined with individualized electrical stimulation therapy, awaken and activate muscles, accelerate the recovery of muscle tone and elastic, and have a good effect on preventing and treating muscle disorders.Features are as shown below:

- Four operation modes (EMG Test, EMG Game, ETS, and STIM) have been set up to assist patients in exercising.
- Independent dual-channel EMG signals acquisition. EMG data of multiple sites are obtained simultaneously to provide basis for treatment.
- Independent dual-channel electrical stimulation output, convenient for the treatment of different sites or complete the treatment in coordination.
- Ergonomic design, effectively prevent the vaginal anal probe off and rotation, to ensure that treatment effect.
- All patient-contacting materials are tested and passed the bio-compatibility according to ISO10993-1 requirements.

1.3 Indications for Use

The device is for home use and the intended operator is patient who has muscle dysfunction.

For EMG:
To determine the activation timing of muscles for:
1. Retaining of muscle activation
2. Coordination of muscle activation

An indication of the force produced by muscle for control and maintenance of muscle contractions:
1. Relaxation muscle training
2. Muscle re-education

For EMG triggered Stim:
1. Stroke rehab by muscle re-education
2. Relaxation of muscle spasms
3. Prevention or retardation of disuse atrophy
4. Increase local blood circulation
5. Muscle re-education
6. Maintaining or increasing range of motion

As nonimplanted electrical continence device:
The device is a non-implanted muscle stimulator designed to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles and restoration of neuromuscular control during the treatment of urinary continence.

2. Safety Precautions

Please read the entire instruction manual before you use the Biofeedback device. It will give you a better understanding of how the product works. If you are unsure whether a medical condition should preclude you from using the device, consult your physiotherapist, osteopath, or medical practitioner. During the heavy days of your period do not use the unit. Biofeedback device is intended to use on healthy muscle only.

2.1 Contraindications

The stimulator must not be used in combination with the following medical devices:
- Internally transplanted electronic medical devices, such as a pacemaker.
- Electronic life support equipment, such as respirators.
- Electronic medical devices attached to the body, such as electrocardiographs.
- Using this stimulator with other electronic medical devices may cause erroneous operation of those devices.

The stimulator must not be used on the following people:
- Pregnant women, because the safety of electrical stimulation during pregnancy has not been established;
- Children or infants, because the device has not been evaluated for pediatric use;
- People incapable of expressing their thoughts or intentions;
- People with extra-urethral incontinence (fistula, ectopic ureter);
- People with overflow incontinence due to outflow obstacle;
- People with serious retention of urine in the upper urinary tract;
- People with complete peripheral denervation of the pelvic floor.

2.2 Warnings

- Consult with your physician before using this device, because the device may cause lethal rhythm disturbances in certain susceptible individuals.
- Do not use this device for treatment during menstruation, vaginal or urinary tract inflammation or infection.
- The electrodes, vaginal and anal probe all are designed for single patient use, in order to avoid mutual infection, do not cross-use.
- Stimulator should not take place while the user is connected to high-frequency surgical equipment, it may cause burn injuries on the skin under the electrodes, as well as problems with the stimulator.
- Do not use the stimulator in the vicinity of shortwave or microwave therapy equipment, since this may affect the output power of the stimulator.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Any electrodes that have current densities exceeding 2mA/cm^2 may require special attention of the operator.
- Stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart.
- Avoid trans-thoracic stimulation.
- Avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.
- Do not maintain the device while in use with the patient.

DO NOT use this stimulator under these activities:
- When in the bath or shower;
- While sleeping;
- While driving, operating machinery, or during any activity in which electrical stimulation can put you at risk for injury.

2.3 Precautions

- Inspect the stimulator prior to use.
- The stimulator is intended for use by one person. Do not share with another person.
- The stimulator should not be applied over the menstruating or pregnant uterus.
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Consult your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- Patients with prolapsed uterus, vagina should be stimulated with greatest caution.
- Patients with urinary tract infections must be treated and clear of infection before starting therapy with this device. Consult your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- If the stimulator is not functioning properly or you feel discomfort, immediately stop using the device.
- If tissue irritation should occur, treatment should be temporarily discontinued. If problems continue, please contact your physician.
- Always turn the power off before removing or changing the location.
- Always adjust the output intensity in the comfort level. If you feel uncomfortable, adjust the output intensity or stop treatment.
- Do not use for any other purpose except for what it is intended for.
- After use, the part of the component contact with human should be cleaned.
- Dispose of the device, batteries, and components according to applicable legal regulations. Unlawful disposal may cause environmental pollution.
- The service life of the device may vary by the frequency of washing, vaginal condition, and storage state.
- Keep the device away from young children.
- Be careful to strangulation due to cables and hoses, particularly due to excessive length. Keep unit out of the reach of young children pets. The electrode cord can cause strangulation.
- Use the device only with the accessories recommended by the manufacturer. Do not maintain or service the device while the device is in use.
- Cannot use in the environment of negative oxygen, rich oxygen, do not use in sunshine.
- Devices connected to the host, USB charger, should be checked in accordance with EN 60101-1 safety requirements.
- Please stop use it when allergies occur .
- Do not modify the device without authorization of the manufacturer.
- Do not use the device if it is damaged. Otherwise it may cause injure, improper results, or serious danger.
- If you have any problems with the device, such as setting up, maintaining, or using, please contact our customer service.

2.4 Adverse Reactions

These kinds of stimulations have been used for many years to stimulate muscle and nerve fibers to treat a number of muscle and nerve related conditions. Over the last 30 years numerous clinical trials and papers have been written. Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

2.5 Conformity Standards

- IEC 60601-1-2 Medical Electrical Equipment --Part 1: General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1: Medical Electrical Equipment --Part 1-2: General Requirements for Basic Safety and Essential Performance --Collateral Standard: Electromagnetic Disturbances –Requirements And Tests.

- IEC 60601-1-11Medical Electrical Equipment --Part 1: General Requirements for Basic Safety and Essential Performance --Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
- IEC 60601-2-10Medical Electrical Equipment --Part 2-10: Particular Requirements for The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators
- IEC 60601-2-40Medical Electrical Equipment --Part 2-40: Particular Requirements for the Basic Safety and Essential Performance of Electromyographs and Evoked Response Equipment.
- ISO 10993-5Biological Evaluation of Medical Devices –Part 5: Test for In Vitro Cytotoxicity.
- ISO 10993-10 Biological Evaluation of Medical Devices –Part 10: Test for Irritation and Skin Sensitization

2.6 Symbol Interpretation

Information essential for proper use shall be indicated by using the corresponding symbols. The following symbols may be seen on the device and its labelling.

Symbol	Meaning
LOT	Batch code
SN	Serial number
	Manufacturer
	Date of manufacture
	Type BF applied part
	Caution
	Follow instructions for use
	"WEEE (Waste Electrical and Electronic Equipment)". The wasteproducts should be handled legally.
IP 21	According to EN 60529, I represents the equipment's anti-dust rating as level 2: protection against 12.5mm in diameter and larger solid alien detectors, sphere 12.5mm in diameter and should not be fully entered. P stands for protection against water inflow level 1: water droplet protection: vertically falling water droplet should not cause damage
	Neuromuscular Stimulators (STIM) and ETS are not suitable for patients with cardiac pacemakers, and please consult your attending physician
	Keep dry
CE 0197	CE mark and noticed body code
EC REP	Authorised representative in the European community

2.7 EMC Statement

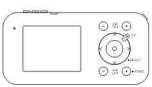
1) This product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile radio frequency (RF) communications equipment.
2) Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3) Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation.
4) Caution: This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Manual and manufacturer's statement details are in the end of the article. (Annex I)

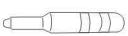
3 Description of the Device

3.1 Package Content

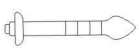
Accessories included in the package:



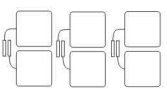
Main unit



Vaginal probe

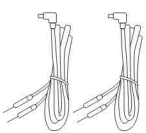


Anal probe (optional)



Electrode patches

REF signal wire



Electrode wires

USB wire

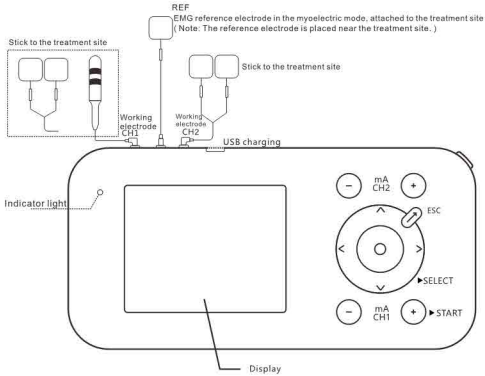
User manual

- 1 Main unit
- 3 Electrode patches
- 1 Vaginal probe
- 1 Anal probe (optional)
- 2 Electrode wires (white)
- 1 REF signal wire (black)
- 1 USB wire
- 1 User Manual

Note: Anal probe is as an optional component and user can choose to purchase according to their needs

3.2 Product Structure

The Biofeedback device mainly consists of main unit, electrode patches and electrode wires, vaginal probe, anal probe and USB wires. The applied parts of device are electrode patches, vaginal probe and anal probe.

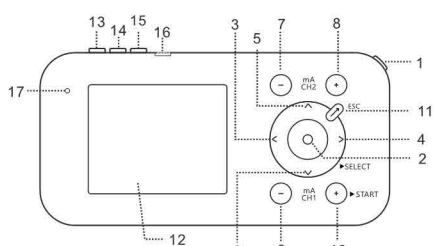


List of the device and its components

Components	Quantity	Components	Quantity
Main device	1 pcs	Electrode patch	3 pairs
Vaginal probe	1 pcs	Anal probe (optional)	1 pcs
Electrode wires (white)	2 pcs	REF Signal wire (black)	1 pcs
USB wire	1 pcs	User manual	1 pcs

Note: the anal probe is as an optional component and user can choose to purchase according to their needs

3.3 Functions of the Biofeedback



- **Main unit**

The main unit is composed of LCD display and keypad control two parts.User can select appropriate mode and other parameters such as intensity, through control buttons on the main unit and know about the operation status through LCD at any time. The details are described as below:

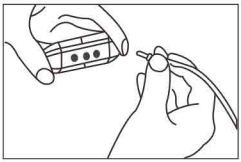
Keypad control

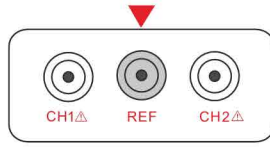
1) ON/OFF button: Long press this button two seconds to power on, and press this button one second again to power off.
2) Confirmation button (OK Key)
3) " < " button: It is used to go left to select the menu, and change the parameters in the parameter setting interface.
4) " > " button: It is used to go right to select the menu, and change the parameters in the parameter setting interface.
5) " ∨ " button: It is used to up to select the menu.
6) " ∧ " button: It is used to down to select the menu.
7) "CH2 mA-" button: It is used to decrease the intensity level of electrical stimulation in Channel 2.
8) "CH2 mA+" button: It is used to increase the intensity level of electrical stimulation in Channel 2.
9) "CH1 mA-" button: It is used to decrease the intensity level of electrical stimulation in Channel 1.
10) "CH1 mA+" button: It is used to increase the intensity level of electrical stimulation in Channel 1.
11) ESC button: It is used to exit the current mode and return to the previous interface.
12) Display screen: It is used to display information.
13) CH1 port: It is used to connect the electrode patch, vaginal probe or anal probe.
14) REF port: It is used to connect the reference electrode.
15) CH2 port: It is used to connect the electrode patch.
16) USB port: It is used to connect the USB wire for charge.
17) LED indicator: It is used to display the status of device operation: #i) It will flash when the running stays on the main interface; #ii) It will normal light on when the running stays on ETS or STIM mode.

LCD display

• Accessories

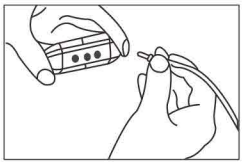
REF signal wire (black)
The REF signal wire is used to make a connection between one piece of reference electrode patch and REF port, as well as must be used in the treatment of EMG Test, EMG Game and ETS mode, in order to ensure the accuracy of EMG value. Meanwhile, the reference electrode should be applied near the treatment site when using.

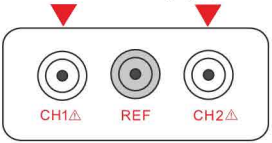




Electrode wires (white)

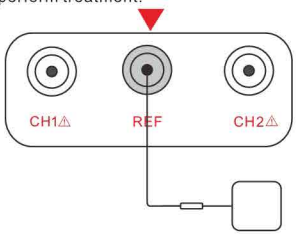
There are two electrode wires: CH1 and CH2 Electrode wires. They are used to make a connection between the specified components and CH1/CH2 port respectively, according to the instruction for use, for electrical stimulation or electromyographic biofeedback.



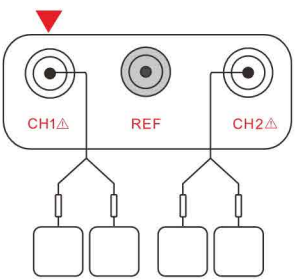


Electrode patch

There are two types of electrode patches: one piece of electrode is used to as the reference electrode and two pair of electrodes is used to as the working electrode. The electrodes are to be attached to bare skin to perform treatment.

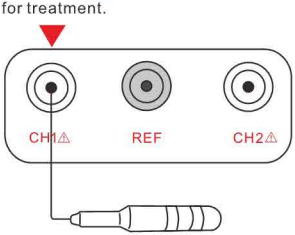


Working electrode



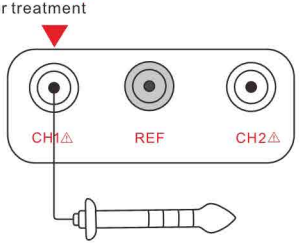
Vaginal probe

Insert the CH1 vaginal probe into the vagina for treatment.



Anal probe

Insert the CH1 anal probe into the anus for treatment



USB wire
This wire is used to make a charging connection between the main unit and power adapter (not included). Please use the adapter charger DC5V, 0.5mA.

• Others
Battery charge
- Please charge first when using the device for the first time, in order to ensure its normal use. Or when the battery shows low-battery 6.8V±0.2V, the battery icon will display a red box to remind the user to charge.
- When the battery voltage is lower than 6.2V±0.2V, the device will automatically power off.
- Make a charging connection between the main unit and power adapter by means of the USB wire. If the power adapter is not matched with the device, please select adapter of 5V,0.5mA,which had obtained UL certificated or has passed 60601-1 test. Do not use the product while charging.

Load detection
I n the process of the electrical stimulation output, when its output intensity is greater than 10mA, the intensity will be directly reduced to 10mA to ensure the safety of the user, At this time, the intensity adjustment can only be adjusted to 10mA at maximum, there is a prompt of electrode falling off sign on the LCD screen.

3.4 Product Technical Specification

Product Name		Biofeedback Nerve and Muscle Stimulator	
Model		KM530	
Software version identification		KM530 Please check the software version in Setting.	
Basic Unit Specifications			
Dimensions	Main unit (L*W*H)	140×25×70mm	
	Electrode patch	50×50mm	
	Vaginal probe	145mm Φ25mm	
	Anal probe	110mm Φ12mm	
Weight (Included batteries)		195g	
Power Supply		7.4V DC/1200mAh rechargeable lithium battery	
Number of channels		2 channels	
Number of modes		6 modes	
Output Intensity Level		0-90mA(the output current increases by about 1mA for each additional level of strength)	
Charging port voltage		DC5V,500mA	
Safety Category		BF type	
Service life		3 years	
Biofeedback performance (Dual-channel acquisition)			
Measurement range		0.2-2000μV	
Maximum resolution ratio		<0.2μV	
Input noise		<1μV	
Transmission bands		20Hz-500Hz,precision ±10% (-3dB) (not including trapped wave)	
Differential-mode input impedance		> 5MΩ	
Common mode rejection ratio		> 100dB	
Accuracy		Error no more than ±10% or 2μV take the maximum of both	
Power frequency wave trap		50Hz, the amplitude after attenuation shall not be greater than 5μV (peak-valley value)	
Electrical Stimulation Output Specifications			
Mode		**ETS**	**STIM**
Waveform and Shape		Symmetrical、Asymmetric	Symmetrical、Asymmetric
Maximum Output Voltage (±10%)		90V@1kΩ	90V@1kΩ
Maximum Output Current (±10%)		90mA@1kΩ	90mA@1kΩ

Pulse Duration	50~450μs	50~450μs
Frequency	2~100Hz	2~100Hz
Net charge	For pulsed asymmetric,15.68μC @ 500Ω	
Maximum Phase Charge	51.4μC @ 500Ω	
Maximum Current Density	Probe: 3.32mA/ cm2@ 500Ω,Electrode patch: 1mA/ cm2@ 500Ω	
Maximum Power Density	Probe: 0.041W/cm2@ 500Ω,Electrode patch: 0.0125W/cm2@ 500Ω	
Treatment Time	(1~99)min, adjustable	(1~99)min, adjustable
Preset Programs	22 species and3 customizations	
Introduction to electrode material (ISO 10993-1, ISO 10993-5, ISO 10993-10)		
Electrode patch	Non-woven cloth, conductive silicon gel	
Vaginal probe	Medical plastic ABS, medical 304 stainless steel	
Anal probe	Medical plastic ABS, medical 304 stainless steel	
Additional Features		
Environment for Operation	Temperature:5℃~40℃ Humidity:≤80%RH Atmospheric pressure: 70~106kPa	
Environment for Transportation & Storage	Temperature: -10℃~+55℃ Humidity: ≤90%RH Atmospheric pressure: 50~106kPa	

3.5 How the Device works

Biofeedback is an effective adjunctive therapy. Biofeedback training can regain the kinetic energy of the affected muscle of the patient; it can effectively coordinate single or multiple muscle activities; it can also reduce sputum and control the dysfunction of its receptors.

Biofeedback electrical stimulation is the use of electromyography biofeedback technology combined with a variety of electrical stimulation modes for muscle training to improve muscle function, help patients reconstruct and restore normal muscle function, widely used in cerebral vascular and central nervous system damage. Motor dysfunction and pelvic floor muscle dysfunction.

4. How to Use the Device

4.1 Before Treatment

Please charge first when using the Biofeedback device for the first time, in order to ensure the normal use of the device. Before applying electrodes, be sure the skin surface is cleaned and dried. Tear off the protective films on electrodes, and then apply electrodes to the specified area.Make sure the electrodes are placed firmly to the skin and make good contact between the skin and electrodes.

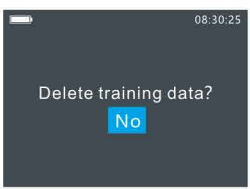
NOTE: During charging, the device cannot be used for treatment. When the charge is full, the battery icon will become full.

Select the SETTING icon in the main interface, click the confirmation button to enter system setting interface. This interface contains the settings of data and time, brightness, sound, delete record and restore factory, can be switched by " ∧ " and " ∨ " button.

Data and Time Setting

Brightness Setting

Sound Setting

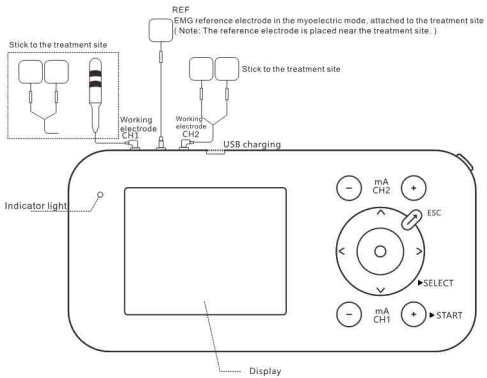


Data Delete Setting

Restore Factory Setting

4.1.2Electrodes connection

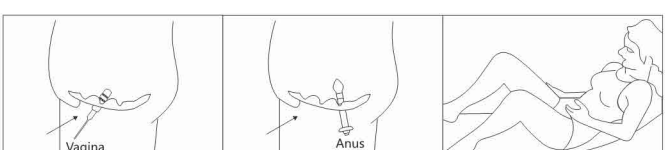
Make a connection between the main unit and electrodes or probe according to the following figure. Specific electrode connection for each mode is explained in section 4.1.3.



4.1.3Position of Electrodes and Probe

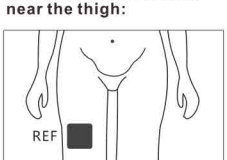
Prior to attach the electrodes, please make sure the targeted treatment area is in good condition without any injury and wound as well as is clean. The device is used in individual independent environment, patient can lie down or adopt other posture that feels comfortable. Attaching the electrodes correctly is vital for effective and safe treatment.The electrodes position are determined by the physician or therapist.The illustration below shows the position of the electrodes and probe.

In EMG test, EMG game mode:
The electrode placement of the CH1 channel is as follows:
Electrode Placing Example

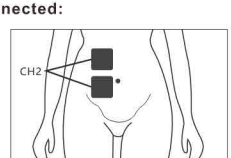


The patient lies on her back, relaxed and with the upper body slightly elevated. The legs are upright and tited slightly to the outside. It is advisable to support the legs on the sides in order to improve relaxation.

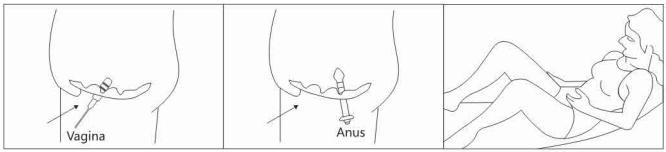
REF electrode is placed near the thigh:



CH2 is placed in the abdomen area or not connected:

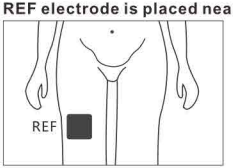


In ETS Therapy mode:
The electrode placement of the CH1 channel is as follows:
Electrodes Position Example



The patient lies on her back, relaxed and with the upper body slightly elevated. The legs are upright and tited slightly to the outside. It is advisable to support the legs on the sides in order to improve relaxation.

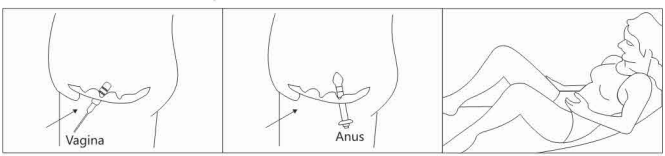
REF electrode is placed near the thigh:



CH2 is not connected:

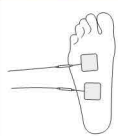
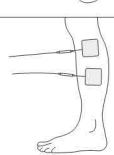
In STIM mode:
When doing basin electrical stimulation training, the CH1 electrodes are connected as follows:

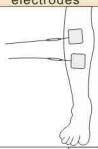
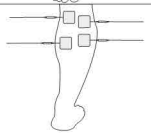
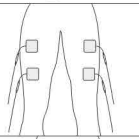
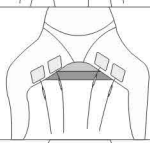
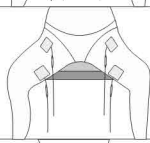
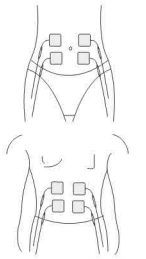
Electrode Position Example

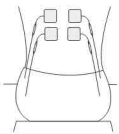
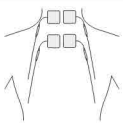
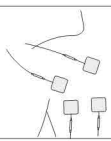
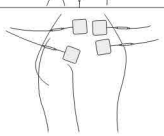
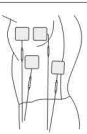
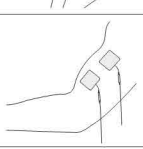


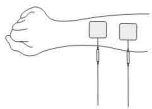
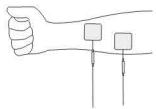
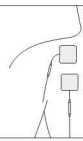
The patient lies on her back, relaxed and with the upper body slightly elevated. The legs are upright and tited slightly to the outside. It is advisable to support the legs on the sides in order to improve relaxation.

Refer to the following for other parts of the body

Group of Muscle	Positioning of the electrodes	Stimulation positions	Cause the contraction (muscle tension) yourself.
Foot sole		Sitting position, place your feet on the floor.	Vigorously tense your foot sole muscle by trying to dig the toes in the floor.
Shank		Sitting position, place your feet on the floor.	Vigorously tense your calf bone muscle by pressing the big toe firmly against the floor and lifting the outer toes from the floor at the same time.

Group of Muscle	Positioning of the electrodes	Stimulation positions	Cause the contraction (muscle tension) yourself.
Anterior shin bone muscle		Sitting position, place your feet like the picture showed that the ankles can no longer be bent.	Vigorously tense your anterior shin bone muscle by firmly pressing the forward sections of your feet upwards against a resistance that counteracts this movement.
Calf muscle		Sitting position in such a manner that your back and feet are supported. The easiest way would be to sit down in a door frame.	Vigorously tense your calf muscle by firmly pressing the forward sections of your feet upwards against a resistance that counteracts this movement.
Posterior thigh muscle		Lie prone; your ankles are fixed in such a manner that it feels comfortably.	Vigorously tense your posterior thigh muscle by trying to bend your knee.
Adductors(legs)		Sitting position, position a hard object between your knees (in such a manner that it feels comfortably).	Vigorously tense your adductors (legs) by trying to firmly press your knees towards each other.
Anterior thigh muscle		Sitting position. You can select between two options for this exercise: either statically - for this block the movement of your knees; or dynamically- for this, carry out this movement against a resistance and use objects with heavy weight.	Vigorously tense your anterior thigh muscle by trying to stretch your legs.
Gluteal muscle		Lie prone or take a standing position.	Vigorously tense your gluteal muscle by contracting them and trying to bring your thigh behind your trunk.
Muscles of the abdomen		Lie on your back which can be slightly raised. You can select between two options for this exercise: either statically - for this, simply start contracting the muscle by carrying out the movement described next to the figure; or dynamically - for this, additionally move your trunk to your thighs; in this case, you must ensure not to put the emphasis on the lumbar spine; your knees should always be firmly tied.	Tense your muscle of the abdomen by trying to vigorously raise your head and shoulder from the floor.

Group of Muscle	Positioning of the electrodes	Stimulation positions	Cause the contraction (muscle tension) yourself
Lower back muscle		Sitting position. Please note: Due to the anatomical feature of lower back muscle, the training in this mode requires a particularly strong musculature. Position the electrodes, as is shown in the picture, at the height of the back muscle.	Vigorously tense your lower back muscle by trying to sit as upright as the possible.
Back muscle		Sitting position	Vigorously tense your back muscle by trying to sit as upright as possible.
Muscle of the cervical vertebra		Sitting position	Vigorously tense your back muscle by trying to sit as upright as possible.
Trapezius muscle		Sitting position	Tense your trapezius muscle by trying to vigorously raise and lower your shoulders
Shoulder joint muscle		Sitting position, keep your elbows inside the armrests in such a manner that the armrests represent a resistance to the movement away from your body	Vigorously tense your shoulder joint muscle by pressing your elbows away from your body.
Large back muscle		Sitting position, keep your elbows outside the arm rests in such a manner that the armrests represent a resistance to the movement towards your body.	Vigorously tense your large back muscle by pressing your elbows towards your body.
Posterior upper arm muscle		Sitting position, your hands and forearms rest on the table.	
Anterior upper arm muscle		Sitting position, your forearms rest on the table, the palms of the hands must point upwards. Fix your elbows in such a manner that they cannot move during the stimulation.	Vigorously tense your anterior upper arm muscle by moving the palms of your hands towards your shoulders.

Group of Muscle	Positioning of the electrodes	Stimulation positions	Cause the contraction (muscle tension) yourself.
Extensor carpis of the hand		Sitting position, your forearms and palms of the hands rest on the table.	Vigorously tense the extensor carpis of your hands by trying to raise your hands.
Flexor carpis of the hand		Sitting position, your forearms rest on the table. Take a resistant and hard object in your hands; your fingers are slightly bent.	Vigorously tense the flexor carpis of your hands by encompassing the object in your hand tightly.
Pectoral muscle		Sitting position, the palms of your hands touch each other. Warning concerning the positioning of the electrodes on the heart region: increased risk of cardiac fibrillation.	Vigorously tense your pectoral muscle by pressing the palms of your hands against each other.

Note:

1. The surface of the electrodes and probe should be kept clean to avoid dirt.
2. Electrodes and probe can only be used by one person. For special use only, the same patient can reuse the electrodes or probe.
3. The average life expectancy of electrodes is 30-50times(30minutes each time).The average life expectancy of probe is 12-18 months.
4. The electrodes can not be restored after being cleaned for many times, please purchase new electrode patch from retailer or manufacturer.
5. Only use electrodes equipped with the product. The size of electrodes is about 50mm (L) ×50 mm (W). Please do not use electrodes of other size. Otherwise, too high a current density can flow and injuries may be caused.
6. The recommended distance between the working electrodes should not be smaller than approx. 1cm and not be longer than approx. 10cm.
7. Each person reacts differently to an electric stimulation. The positioning of the electrodes might thus deviate from the standard positions. If the treatments are not successful, please consult your doctor as to which position are most suitable for you.
8. Make sure the connection between electrodes probe and main unit is good, or else it might affect the function of the product.
9. Rinse the probe with clean water after each use and dry thoroughly before storage.
10. Do not use boiling water to clean the probe.
11. Do not dispose the electrode or probe casually. Please follow the local environmental requirements.
12. Regarding the depth of the probe in the body, please ensure the second metal ring is completely in the body.

4.2 Device Power On

Long press the ON/OFF button for two seconds to turn on the device, and then enter the main menu interface.

You can choose the appropriate treatment mode for treatment while entering the main menu interface. The operation of each mode and each interface is described below.

4.3 Direction for Use (Introductions of Each Menu Interface)

We have four treatment mode: EMG Therapy, EMG Game,ETS, and STIM mode:

4.3.1EMG Therapy Mode/Interface

Explanation of the usage for CH1 channel, CH2 channel and REF channel:

- CH1 channel: It is used to connect electrode patch or probe, which is pasted to the treatment area(only for EMG acquisition, not for generating electrical stimulation);
- CH2 channel: It is used to connect electrode patch, which is pasted near the treatment area (Only for EMG acquisition, not for generating electrical stimulation);
- REF channel: It is used to connect reference electrode patch, which is pasted near the treatment area (not for generating electrical stimulation).

Below is the Electrodes Position Example:

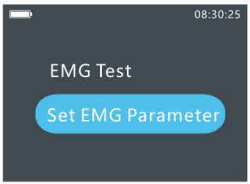
For the specified position of electrodes or probe, please refer to section 4.1.3 Position of Electrodes and Probe.

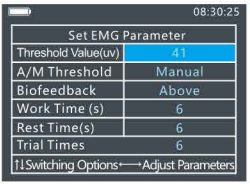
NOTE: The device will only report on the muscle strength test of the muscle at the CH1 channel junction. The EMG value displayed by the CH2 channel is the EMG value of the area to which the CH2 electrode is attached, and is used for user reference. When the CH2 channel is not attached to the body, this channel is not connected to the load at this time, so the EMG value in the LCD screen may be large, and the data is not used as a reference. For example, during the pelvic floor muscle evaluation, the EMG value of the abdomen was collected by placing the electrode of CH2 on the abdominal position and using it as a reference for the muscle evaluation of the CH1 basin. The EMG value of the abdomen collected by CH2 at the assessment of the pelvic floor muscle of CH1 was basically consistent with that at the time of abdominal relaxation.

Step#1.Select the EMG Therapy mode in the main interface and press the confirmation button to enter the next interface.

Step#2. Set EMG Parameter

- Select Set EMG Parameter and then press the confirmation button to set the EMG parameter.This interface displays the parameter setting table of EMG test, in which the white is unchangeable item and the blue is the modifiable item.





- Use the "＜" and "＞" button to set the parameter value, as well as "∧" and "∨" button to switch options.

NOTE:The parameter can only be set under the directions of physicians and professionals.

- Parameter setting interface is described below:

Parameter name	Parameter option or range	Parameter explanation
Threshold Value (uV)	0.2-2000	Threshold setting, the default value is 40. The displayed EMG value exceeds this value, indicating that the trainer's muscle strength has reached the set effect.
A/M Threshold	Manual/Auto	Change mode for threshold value setting: manual Automatic. The default setting is Manual. In the automatic (Auto) mode: If the average value of the EMG of this training is higher than the set threshold, the next EMG threshold increases by 20% of the average value. If the average value of the EMG is lower than the set threshold, the next EMG threshold is reduced to 80% of the average value. In the manual mode, the next EMG threshold does not change with the EMG value of the current training.
Biofeedback	Below/above/off	Prompt tonemode: below / above / off. The default setting is Above. Below: Plays a beep when the muscle strength is below the set threshold. Above: Plays a tone when the muscle strength is above the set threshold. Off: Turns off the beep.
Work Time (s)	2-99	Working time: muscle contraction.The default value is 6.
Rest Time (s)	2-99	Break time: muscle relaxation. The default value is 6.
Trial Times	2-99	Test and training times: one work and one break for one training.The default value is 6.

- After the EMG parameter setting is completed, click the ESC button to exit and the setting is automatically saved at this time.

NOTE:

Once the parameters are modified, the device will perform the EMG test according to the modified parameters. Please operate with caution.

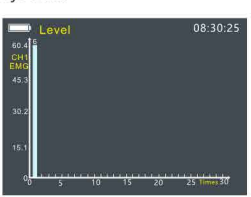
Step#3. Select EMG test and then press the confirmation button to enter the EMG test curve interface.

EMG test curve interface is described below:

- Threshold value:The set EMG threshold is divided into automatic and manual setting mode. The value displayed by EMG exceeds this value, indicating that the trainer's muscle strength has reached the set effect.
- Time:The total time of this EMG test does not include preparation time.
- Status:Prepare, wait for the user to press the confirmation button to enter the EMG test; rest, prompt the user to let the muscle relax; work, prompt the user to let the muscles contract.
- CH1 EMG value: The EMG value of the CH1 channel is displayed in real time.
- CH2 EMG value: The EMG value of the CH2 channel is displayed in real time.
- Peak value line: The upper limit of the interface curve, which cannot be exceeded. The excess part overlaps with the peak value line by default.
- Red horizontal line:Threshold value reference line.

Green curve: Real-time curve of the EMG acquisition value of CH1.CH2 EMG values should be maintained in a relaxed state when the electrodes are placed on the abdomen. Or you can leave it at that point where the value of CH2 is unreferenced. In the EMG interface, according to the prompt on the screen, the confirmation button to start the device .

Step#4. During the EMG , perform the action according to the prompt (#i.work--contract muscle; #ii.rest--relax muscles) on the screen, and then the screen will display real-time muscle strength test values and curves. After the test is completed, the EMG chart is automatically generated and displayed in the form of a coordinate system.



EMG chart is described below:

- Y-axis represents the measured EMG value.
- X-axis represents the and last 30 times.
- Middle region represents a histogram of the EMG and the top of the histogram is the EMG test level.
- The EMG test chart shows the most recent 30 times of EMG test, and the histogram shows the trend of the user's EMG changes.

EMG level is described below:

EMG level	EMG Value (EMG Average Value)	Effect to the muscle
Level 1	0-19	There is almost no contraction of the muscle, only very low electromyography values
Level 2	19-29	Slight muscle contraction. The electromyography values is increased compared to the level1. The continuous contraction time of the muscle is temporary.
Level 3	29-39	Moderate muscle contraction.The electromyography values is increased compared to the level2. The continuous contraction time of the muscle is also increased compared to the level 2.
Level 4	39-49	Firm muscle contraction.The electromyography values is increased compared to the Level3. The continuous contraction time of the muscle is also increased compared to the level3.
Level 5	49-59	Strong muscle contraction. The electromyography values is increased compared to the level4. The continuous contraction time of the muscle is also increased compared to the level4.
Level 6	≥59	Robust muscle contraction. The continuous contraction time of the muscle is greatly increased.

4.3.2 EMG Game Mode Interface

Explanation of electrode connection:

- CH1 channel: It is used to connect electrode patch or probe, which is pasted to the treatment area (only for EMG acquisition, not for generating electrical stimulation);
- CH2 channel: This port is not used for this mode;
- REF channel: It is used to connect reference electrode patch, which is pasted near the treatment area (not for generating electrical stimulation).

For the specified position of electrodes or probe, please refer to section 4.1.3 Position of Electrodes and Probe.

Step#1.Select the EMG Game mode in the main interface and press the confirmation button to enter the next interface.

The EMG Game mode is an active training for the user to contract the muscle of the treatment area. The device will show the status of the user's training in the way of the game, making the training more interesting. Electrical stimulation is not generated throughout the training process.

The EMG Game includes six types of training games as below:

Step#1.Set the parameter

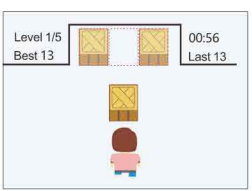
- Use the "<" and " >" button to choose the game which need to set the parameter.
- Use the "<" and " >" button to set the game parameter, as well as "∧" and "∨" button to switch options.

NOTE: The parameter can only be set under the directions of physicians and professionals.
- Parameter setting interface is described below:

Parameter name	Parameter option or range	Parameter explanation
Base Threshold (uv)	1-1000	The default value is 30uV.The base threshold is the initial muscle strength of the game's first level. The recommended setting range is 10-30 uv.
Increment Value (uv)	2-1000	The default value is 20uV.If the base threshold is set to 30uV, and the increment value is set to 20uV,then the threshold of Level 1is 30uV,the threshold of Level 2 is 50uV, and the threshold of Level 3 is 70uV... The recommended setting range is 5-20uv.
Game Time (min)	1-30	The default value is 1 min.The game time is the time set for each level.

- After the EMG game parameter setting is completed, click the ESC button to exit and the setting is automatically saved at this time.
NOTE: Once the parameters are modified, the device will perform the EMG Game according to the modified parameters. Please operate with caution.

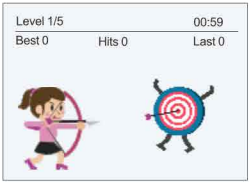
Step#3. Select the training games according to the user's needs, and press the confirmation button to enter the game.
Game1: Sokoban game for training muscle



When the user contracts the muscle forcefully, if the detected EMG value is greater than the set threshold value, then the boy pushes the box forward; otherwise he will stop pushing the box.The user needs to frequently contract the muscle of the treatment are to push the box to the designated position within a specified time.After the countdown is over, if the box is still not pushed to the designated position, then the game is over. Press the confirmation button to restart this level.
If the box is pushed to the designated position within the specified time, the screen will display congratulations, and then enter the next level. There are 5 levels in total.
Game 2: Mouse game for training explosive power and speed.

When the mouse game is selected, the mouse appears randomly at the position of the screen. When the user contracts the muscle forcefully, if the detected EMG value is greater than the set threshold value, then the mouse is killed.
If the number of mice being hit in this level does not reach one-third of the total, then the game is over. Press the confirmation button to restart the level. If the hits are more than one-third of total, the screen will display congratulations, and then enter the next level. There are 5 levels in total.

Game 3:Targeting game for training explosive power and speed.

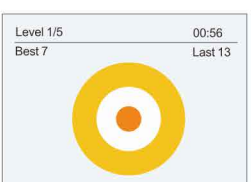


When the user contracts the muscle forcefully, if the detected EMG value is greater than the set threshold value, then the arrow can hit the target.
If the number of target being hit in this level does not reach one-third of the total, then the game is over. Press the confirmation button to restart the level. If the hits are more than one-third of total, the screen will display congratulations, and then enter the next level. There are 5 levels in total.
The above three games are mainly to train the explosive power of the user's muscle. The following three games mainly train the sustained strength of the user's muscle strength.

Game 4:Balloon game for training explosiveness and sustainability.

When the user contracts the muscle forcefully, if the detected EMG value is greater than the set threshold value, then the balloon gets bigger; otherwise the balloon gets smaller.
After the countdown is over, if the balloon still not gets biggest, then the game is over. Press the confirmation button to restart this level.After the countdown is over, if the balloon gets biggest, the screen will display congratulations, and then enter the next level. There are 5 levels in total.

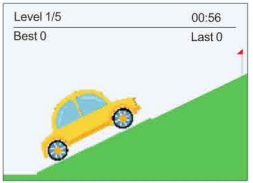
Game 5:Ball game for training explosiveness and sustainability.



When the user contracts the muscle forcefully, if the detected EMG value is greater than the set threshold value, then the little ball can be pushed into the circle; if the detected EMG value is continuously greater than the set threshold value,then the circle can be gradually expanded; if the detected EMG value is lower than the set threshold value, then the circle can be gradually shrank;

If the circle cannot be expanded to the biggest within the specified time, then the game is over. Press the confirmation button to restart this level.If the circle is expended to the biggest within the specified time, then the screen will display congratulations, and then enter the next level. There are 5 levels in total.

Game 6: Car game for training explosiveness and sustainability.



When the user contracts the muscle forcefully, if the detected EMG value is greater than the set threshold value, then the car moves upward;if the detected EMG value is lower than the set threshold value, then the car moves downward;
If the car falls to the lowest position, then the game is over. Press the confirmation button to restart this level. If the car moves to the end line within the specified time, then the screen will display congratulations, and then enter the next level. There are 5 levels in total.

4.3.3 ETS Mode Interface

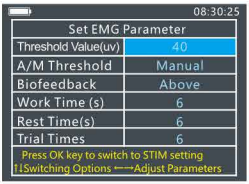
Explanation of electrode connection:

- CH1 channel: It is used to connect electrode patch or probe, which is pasted to the treatment area (not only for EMG acquisition, but also for generating electrical stimulation when the EMG value reaches the set threshold);
- CH2 channel: It is used to connect electrode patch, which is pasted near the treatment area (Only for EMG acquisition, not for generating electrical stimulation);
- REF channel: It is used to connect reference electrode patch, which is pasted near the treatment area (not for generating electrical stimulation).
  For the specified position of electrodes or probe, please refer to section 4.1.3 Position of Electrodes and Probe.

NOTE:
The device will only report on the muscle strength test of the muscles at the CH1 channel junction. The EMG value displayed by the CH2 channel is the EMG value of the area to which the CH2 electrode is attached. CH2 channel can be connected to electrodes pasted to the abdomen to check whether the pelvic floor muscles are trained correctly (many users contract the abdominal muscles instead of pelvic floor muscles). The significance lies in that the value of CH2 during pelvic floor muscle training is taken as a reference, and the correct way is that the abdominal muscles are in a relaxed state during basin muscle training and evaluation, and the value of CH2 at this time is basically consistent with the value of the relaxed state of abdominal muscles.When the CH2 channel is not attached to the body, this channel is not connected to the load at this time, so the EMG value in the LCD screen may fluctuate, and the data is not used as a reference.

Step#1. Select the ETS Therapy Mode in the main interface and press the confirmation button to enter the next interface.

Step#2. Set ETS Parameter
- Select the Set ETS Parameter, click the confirmation button, and then enter the setting interface.
- The interface is divided into two layers. The first layer is the EMG parameter setting.The default parameters are as follows:

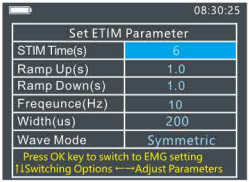


- Use the " < " and " > " button to set the parameter value, as well as " ∧ " and " ∨ " button to switch options.

NOTE:
The parameter can only be set under the directions of physicians and professionals.
- Parameter setting interface is described below:

Parameter name	Parameter name	Parameter explanation
Threshold Value (uV)	0.2-2000	Exceeding this threshold value indicates that the ETS training requirements are met, and ETS will give the muscle an electrical stimulation. Below this threshold value indicates that the ETS training requirements are not met and there will be no electrical stimulation. When the displayed EMG value exceeds this threshold value, there will be a voice broadcast -"Good".
A/M Threshold	Manual/Auto	Change mode for threshold value setting : manual / automatic. In the Automatic (Auto)mode, the threshold value for the next "WorkTime" is 80% of the average muscle strength value for this "WorkTime". If we set the threshold value to 40uV,the threshold value for the first"Work Time" will be 40uV; during the first "Work Time", if the average muscle strength value is30uV,then the next threshold value will be 30*80%=24uV.The greater the average muscle strength value means the stronger the muscle contraction, the greater the next threshold value will be. The smaller the average muscle strength value means the more relaxed the muscle contraction, the smaller the next threshold value will be. In the manual mode, the threshold value does not change during ETS training. If we set the threshold value to 40uV, the threshold value will always be 40uV.
Biofeedback	Below/above/off	Prompt tone mode: below / above / off. Below: Plays a beep when the muscle strength is below the set threshold. Above: Plays a tone when the muscle strength is above the set threshold. Off: Turns off the beep.
Work Time (s)	2-99	Working time: muscle contraction.
Rest Time (s)	2-99	Break time: muscle relaxation.
Trial Time(s)	2-99	Test and training times: one work and one rest for one training.

- After the EMG parameter setting, press confirmation button (OK Key) to switch to STIM setting.The default parameters are as follows:



- Use the " < " and " > "button to set the parameter value, as well as " ∧ " and " ∨ " button to switch options.

NOTE:
The parameter can only be set under the directions of physicians and professionals.
-Parameter setting interface is described below:

Parameter name	Parameter option or range	Parameter explanation
STIM Time(s)	2-99	Electrical stimulation duration
Ramp Down(s)	0.1-9.9	Pulse rise time
Ramp Down(s)	0.1-9.9	Pulse fall time
Frequency (Hz)	2-100	Pulse frequency
Width(uS)	50-450	Pulse Width
Wave Mode	Normal/Relaxed	Waveform type: normal/ relaxed The pulse output in the normal mode is a biphase symmetric waveform, and the output of the generated electrical stimulation is very strong. The pulse output in the relaxed mode is a biphase asymmetric waveform, and the output of the generated electrical stimulation is relatively weak. In the same programand the same current intensity, the output intensity of the symmetric waveform is much higher than that of the asymmetric wave.

- After the STIM parameter setting is completed, click the ESC button to exit and the setting is automatically saved at this time.

NOTE:
Once the parameters are modified, the device will perform the ETS Test according to the modified parameters. Please operate with caution.

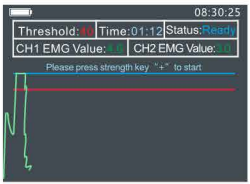
Step#3.Select ETS test in the ETS Therapy Mode interface

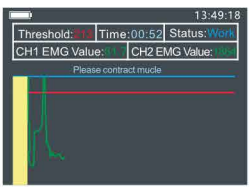
After entering the ETS test,please contract the muscle of the treatment site according to the prompts.The device will automatically detect the EMG value of the CH1 contracted by the user. When the EMG value reaches the set threshold, the electrical stimulation is triggered. This mode is a combination of active and passive treatment modes, which exercise the self-contracting ability of the user.

NOTE:

According to the prompt to contract the muscle of the treatment area, there will be no electrical stimulation at this time.

ETS testing interface is shown as below:

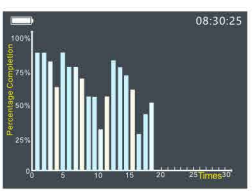




- Threshold:Set threshold value;
- Time:Current training time;
- EMG value:Current tested CH1 EMG value;
- Status:Indicates the current training state. The training state is divided into 4 types: Ready, Rest, Work and Electrical Stimulation Output.When the displayed EMG value reaches the set threshold value, the Electrical stimulation will be triggered, and the interface is shown as below:

When the electrical stimulation output, the LED indicator lights up.

A training chart appears after the training is completed, showing the most recent 30 treatment records.



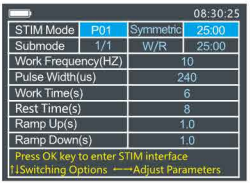
4.3.4 STIM Mode Interface

Explanation of electrode connection:

- CH1 channel: It is used to connect electrode patch or probe, which is pasted to the treatment area (for generating electrical stimulation);
- CH2 channel: It is used to connect electrode patch, which is pasted to the treatment area (for generating electrical stimulation);
- REF channel: Not connected.

For the specified position of electrodes or probe, please refer to section 4.1.3 Position of Electrodes and Probe.

Step#1. Select the STIM mode in the main interface and press the confirmation button to enter the next interface.



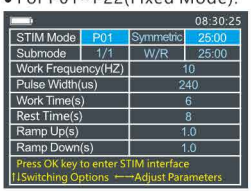
Step#2. Set STIM Parameter

- This interface displays the parameter setting table of STIM Mode, in which the white is unchangeable item and the blue is the modifiable item.
- Use the "< " and "> " button to set the parameter value, as well as "∧ " and "∨ " button to switch options.

NOTE: The parameter can only be set under the directions of physicians and professionals.

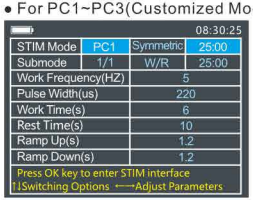
- Parameter setting interface is described below:

• For P01~P22(Fixed Mode):



Parameter option	Parameter explanation
STIM Mode	Mode switching (P01~P22).
Normal/ Relaxed	Waveform type: normal/ relaxed The pulse output in the normal mode is a biphase symmetric waveform. The pulse output in the relaxed mode is a biphase asymmetric waveform.

• For PC1~PC3(Customized Mode):



Parameter option	Parameter explanation
STIM Mode	Mode switching (PC1~PC3).
Normal/Relaxed	Waveform type: normal/ relaxed The pulse output in the normal mode is a biphase symmetric waveform. The pulse output in the relaxed mode is a biphase asymmetric waveform.
Submode	Indicates the submode of the mode.If the screen shows submode is1/5: indicates that this mode have 5 submodes, and the current submode is 1; If the screen shows submode is 2/5:indicates that this mode have 5 submodes, and the current mode is 2.

Parameter option	Parameter explanation
Work/Rest Or Cont (Continuous)	If we choose the W/R (Work/Rest),the electrical stimulation will be output for a period of time and then stop output for a period of time, repeatedly. If we choose the Cont (Continuous), the electrical stimulation will be always output.
10:00	This is the running time unit min of the current stage; 50:00 is the total running time of each stage when and after.
Work frequency (Hz)	It is the pulse output frequency of the current Submode, ranging from 1 to 100
Pulse width (us)	It is the pulse output width of the current Submode, ranging from 50 to 450.
Working time (s)	When the Submode works as W/R (work/rest), this parameter is valid and could be modified.It is the pulse output time of the Sub Mode, ranging from 2 to 99.
Rest time (s)	When the Submode works as W/R (work/rest), this parameter is valid and could be modified.It is the time when the pulse of the Sub Mode stops outputting, ranging from 2 to 99.
Ramp Up (s)	When the Submode works as W/R (work/rest), this parameter is validand could be modified.It indicates that the output intensity of the electrical stimulation of the Sub Mode should be rise to the set intensity during this time period. The value ranges from 0.1 to 9.9.
Ramp Down (s)	When the Submode works as W/R (work/rest), this parameter is valid can could be modified.It indicates that before the pulse stops outputting, the output intensity of the electrical stimulus of the Sub Mode should be reduced to 0 from the set intensity during that time period. The value range is from 0.1 to 9.9.

- After the STIM parameter setting is completed, click the ESC button to exit and the setting is automatically saved at this time.

NOTE: Once the parameters are modified, the device will perform the STIM Therapy according to the modified parameters. Please operate with caution.

- There are the detailed introduction of each modes:

• Fixed mode 1:

Mode	P01	Process 1	25:00
Process Type		W/R	
Process Time(min)		25	
Work Frequency (Hz)		10	
Rest Frequency (Hz)		0	
Width(μS)		240	
Work Time(s)		6	
Rest Time(s)		8	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	

• Fixed mode 2:

Mode	P02	Process 1	25:00
Process Type		W/R	
Process Time(min)		25	
Work Frequency (Hz)		10	
Rest Frequency (Hz)		0	
Width(μS)		250	
Work Time(s)		6	
Rest Time(s)		10	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	

• Fixed mode 3:

Mode	P03	Process 1	25:00
Process Type		CONT	
Process Time(min)		25	
Work Frequency (Hz)		10	
Width(μS)		220	

• Fixed mode 4:

Mode	P04	Process 1	04:00
Process Type		W/R	
Process Time(min)		4	
Work Frequency (Hz)		20	
Rest Frequency (Hz)		0	
Width(μS)		220	
Work Time(s)		6	
Rest Time(s)		8	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	

• Fixed mode 5:

Mode	P05	Process 1	20:00
Process Type		W/R	
Process Time(min)		20	
Work Frequency (Hz)		35	
Rest Frequency (Hz)		0	
Width(μS)		250	
Work Time(s)		6	
Rest Time(s)		10	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	

• Fixed mode 6:

Mode	P06	Process 1	20:00
Process Type		W/R	
Process Time(min)		20	
Work Frequency (Hz)		35	
Rest Frequency (Hz)		0	
Width(μS)		250	
Work Time(s)		6	
Rest Time(s)		15	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	

• Fixed mode 7:

Mode	P07	45:00	
		Process 1	Process 2
Process Type		W/R	CONT
Process Time(min)		35	10
Work Frequency (Hz)		35	
Rest Frequency (Hz)		0	
Width(μS)		300	300
Work Time(s)		6	
Rest Time(s)		9	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	20
Frequency(Hz)			20

• Fixed mode 8:

Mode	P08	Process 1	30:00
Process Type		W/R	
Process Time(min)		30	
Work Frequency (Hz)		35	
Rest Frequency (Hz)		0	
Width(μS)		450	
Work Time(s)		7	
Rest Time(s)		9	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	

• Fixed mode 9:

Mode	P09	25:00		
		Process 1	Process 2	Process 3
Process Type		W/R	W/R	W/R
Process Time(min)		10	10	5
Work Frequency (Hz)		10	35	10
Rest Frequency (Hz)		0	0	0
Width(μS)		240	220	200
Work Time(s)		5	5	5
Rest Time(s)		7	8	8
Ramp UP(s)		1.0	0.8	1.0
Ramp DOWN(s)		1.0	1.0	1.0

• Fixed mode 10:

Mode	P10	35:00				
		Process 1	Process 2	Process 3	Process 4	Process 5
Process Type		W/R	W/R	W/R	W/R	W/R
Process Time(min)		5	10	5	10	5
Work Frequency (Hz)		4	10	10	40	10
Rest Frequency (Hz)		0	0	0	0	0
Width(μS)		240	300	200	270	200
Work Time(s)		6	6	5	5	5
Rest Time(s)		8	6	8	8	8
Ramp UP(s)		1.0	1.0	1.0	1.0	1.0
Ramp DOWN(s)		1.0	1.0	1.0	1.0	1.0

• Fixed mode 11:

Mode	P11	Process 1	20:00
Process Type		W/R	
Process Time(min)		20	
Work Frequency (Hz)		35	
Rest Frequency (Hz)		0	
Width(μS)		220	
Work Time(s)		6	
Rest Time(s)		12	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	

• Fixed mode 12:

Mode	P12	28:00				
		Process 1	Process 2	Process 3	Process 4	Process 5
Process Type		W/R	W/R	W/R	W/R	W/R
Process Time(min)		5	6	6	6	5
Work Frequency (Hz)		4	10	20	35	10
Rest Frequency (Hz)		0	0	0	0	0
Width(μS)		250	220	220	200	220
Work Time(s)		6	6	7	6	6
Rest Time(s)		7	9	7	10	8
Ramp UP(s)		1.0	1.0	1.0	1.0	1.0
Ramp DOWN(s)		1.0	1.0	1.0	1.0	1.0

• Fixed mode 13:

Mode	P13	14:00		
		Process 1	Process 2	Process 3
Process Type		CONT	W/R	W/R
Process Time(min)		4	5	5
Work Frequency (Hz)			10	35
Rest Frequency (Hz)			0	0
Width(μS)		260	300	300
Work Time(s)			6	6
Rest Time(s)			8	8
Ramp UP(s)			0.8	0.7
Ramp DOWN(s)			1.0	1.0
Frequency (Hz)		4		

• Fixed mode 14:

Mode	P14	30:00			
		Process 1	Process 2	Process 3	Process 4
Process Type		W/R	W/R	W/R	W/R
Process Time(min)		5	10	10	5
Work Frequency (Hz)		4	10	20	35
Rest Frequency (Hz)		0	0	0	0
Width(μS)		240	300	300	240
Work Time(s)		6	8	7	7
Rest Time(s)		7	7	7	7
Ramp UP(s)		1.0	1.0	0.8	0.7
Ramp DOWN(s)		1.0	1.0	1.0	1.0

• Fixed mode 15:

Mode	P15	24:00				
		Process 1	Process 2	Process 3	Process 4	Process 5
Process Type		W/R	W/R	W/R	W/R	W/R
Process Time(min)		5	5	5	5	4
Work Frequency (Hz)		4	10	20	35	10
Rest Frequency (Hz)		0	0	0	0	0
Width(μS)		220	240	240	220	200
Work Time(s)		6	6	6	5	5
Rest Time(s)		8	8	8	8	8
Ramp UP(s)		1.0	1.0	0.8	0.7	1.0
Ramp DOWN(s)		1.0	1.0	1.0	1.0	1.0

• Fixed mode 16:

Mode	P16	28:00				
		Process 1	Process 2	Process 3	Process 4	Process 5
Process Type		W/R	W/R	W/R	W/R	W/R
Process Time(min)		4	10	5	5	4
Work Frequency (Hz)		4	10	20	35	20
Rest Frequency (Hz)		0	0	0	0	0
Width(μS)		200	200	200	200	200
Work Time(s)		5	5	5	5	5
Rest Time(s)		10	10	12	12	10
Ramp UP(s)		1.0	1.0	1.0	1.0	1.0
Ramp DOWN(s)		1.0	1.0	1.0	1.0	1.0

• Fixed mode 17:

Mode	P17	25:00			
		Process 1	Process 2	Process 3	Process 4
Process Type		W/R	W/R	W/R	W/R
ProcessTime(min)		5	10	5	5
Work Frequency (Hz)		4	10	35	10
Rest Frequency (Hz)		0	0	0	0
Width(μS)		220	220	200	200
Work Time(s)		6	5	5	5
Rest Time(s)		8	9	10	8
Ramp UP(s)		1.0	1.0	1.0	1.0
Ramp DOWN(s)		1.0	1.0	1.0	1.0

• Fixed mode 18:

Mode	P18	Process 1	25:00
Process Type		W/R	
Process Time(min)		25	
Work Frequency (Hz)		10	
Rest Frequency (Hz)		0	
Width(μS)		220	
Work Time(s)		5	
Rest Time(s)		8	
Ramp UP(s)		1.0	
Ramp DOWN(s)		1.0	

• Fixed mode 19:

Mode	P19	23:00			
		Process 1	Process 2	Process 3	Process 4
Process Type		CONT	W/R	W/R	W/R
Process Time(min)		5	10	4	4
Work Frequency (Hz)			40		10
Rest Frequency (Hz)			4		0
Width(μS)		240	300	240	200
Work Time(s)			8		6
Rest Time(s)			8		8
Ramp UP(s)			0.7		1.0
Ramp DOWN(s)			0.7		1.0
Frequency(Hz)		4		500	

• Fixed mode 20:

Mode	P20	30:00	
		Process 1	Process 2
Process Type		CONT	CONT
Process Time(min)		20	10
Frequency (Hz)		3	10
Width(μS)		200	200

• Fixed mode 21:

Mode	P21	25:00				
		Process 1	Process 2	Process 3	Process 4	Process 5
Process Type		W/R	W/R	W/R	W/R	W/R
Process Time(min)		3	10	5	4	3
Work Frequency (Hz)		3	10	20	30	40
Rest Frequency (Hz)		0	0	0	0	0
Width(μS)		250	250	250	200	200
Work Time(s)		4	4	4	4	4
Rest Time(s)		4	4	4	6	6
Ramp UP(s)		0.8	0.8	0.8	0.7	0.7
Ramp DOWN(s)		0.8	0.8	0.8	0.8	0.8

- Fixed mode 22:

Mode	P22	Process 1
Process Type		W/R
Process Time(min)		20
Work Frequency (Hz)		2
Rest Frequency (Hz)		0
Width(μS)		220
Work Time(s)		6
Rest Time(s)		10
Ramp UP(s)		1.2
Ramp DOWN(s)		1.2

- **Customized 1**(Below is the factory default setting, the user could set the parameter according to Step#2 Set STIM Parameter of Section 4.3.4 STIM mode):

NOTE: The parameter can only be set under the directions of physicians and professionals.

Mode	PC1	25:00				
		Process 1	Process 2	Process 3	Process 4	Process 5
Process Type		W/R	W/R	W/R	W/R	W/R
Process Time(min)		05:00	05:00	05:00	05:00	05:00
Work Frequency (Hz)		5	10	15	20	25
Rest Frequency (Hz)		0	0	0	0	0
Width(μS)		220	220	220	220	220
Work Time(s)		6	6	6	6	6
Rest Time(s)		10	10	10	10	10
Ramp UP(s)		1.2	1.2	1.2	1.2	1.2
Ramp DOWN(s)		1.2	1.2	1.2	1.2	1.2

- **Customized 2** (Below is the factory default setting, the user could set the parameter according to Step#2 Set STIM Parameter of Section 4.3.4 STIM mode):

NOTE: The parameter can only be set under the directions of physicians and professionals.

Mode	PC2	25:00				
		Process 1	Process 2	Process 3	Process 4	Process 5
Process Type		W/R	W/R	W/R	W/R	W/R
Process Time(min)		05:00	05:00	05:00	05:00	05:00
Work Frequency (Hz)		20	30	40	50	60
Rest Frequency (Hz)		0	0	0	0	0
Width(μS)		250	250	250	250	250
Work Time(s)		6	6	6	6	6
Rest Time(s)		10	10	10	10	10
Ramp UP(s)		1.2	1.2	1.2	1.2	1.2
Ramp DOWN(s)		1.2	1.2	1.2	1.2	1.2

- **Customized 3** (Below is the factory default setting, the user could set the parameter according to Step#2 Set STIM Parameter of Section 4.3.4 STIM mode):

NOTE: The parameter can only be set under the directions of physicians and professionals.

Mode	PC3	25:00				
		Process 1	Process 2	Process 3	Process 4	Process 5
Process Type		W/R	W/R	W/R	W/R	W/R
Process Time(min)		05:00	05:00	05:00	05:00	05:00
Work Frequency (Hz)		25	35	45	55	60
Rest Frequency (Hz)		0	0	0	0	0
Width(μS)		250	250	250	250	250
Work Time(s)		6	6	6	6	6
Rest Time(s)		6	6	6	6	6
Ramp UP(s)		1.2	1.2	1.2	1.2	1.2
Ramp DOWN(s)		1.2	1.2	1.2	1.2	1.2

Step#3. Select one mode such as PC1 to start electrical stimulation.

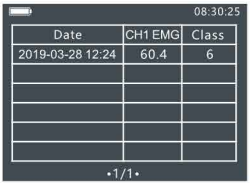
- After setting the STIM parameters, press the Confirmation Button (OK Key) to go to the electrical stimulation therapy interface.
- Press the intensity button (mA+/mA- button) of the corresponding channel to set the intensity. If the intensity of one of the channel is above 0, then the treatment starts.
- Time: Indicates the total remaining time of treatment.
- Sub-time: Indicates the remaining time of the treatment in the submode.
- On the left is the output intensity of the CH1, and on the right is the output intensity of the CH2.
- The intensity can be changed by the corresponding intensity button (mA+ / mA- button) during the treatment. The default output starts at 0mA. If the electrode patch is detached or the contact is poor when the intensity output of electrical stimulation is greater than 10 mA, it will be forcibly reduced to 10 mA, thereby ensuring that the reaction is not too sensitive when the person suddenly contacts the electrode piece.

Note:
Adjust the intensity to a level that the user feels comfortable and not painful.
Custom programs are only set under the direction of physicians and professionals.

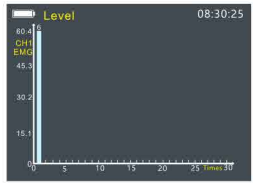
4.4 Treatment record interface

- Select the Therapy Record in the main interface and press the confirmation button to enter the next interface.

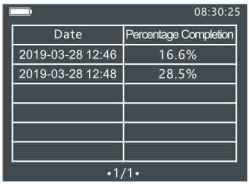
- Below is the EMG Record interface

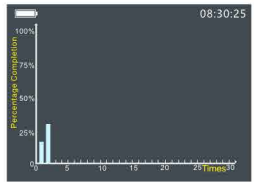


- Below is the EMG Chart interface

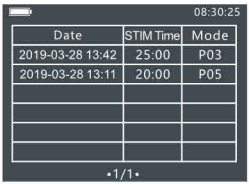


- Below is the ETS Record interface

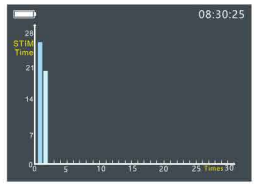




- Below is the STIM Record interface

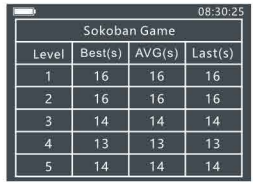


- Below is the STIM Chart interface



- For the EMG Game Record:
Select the EMG Game Record and press the Confirmation button to enter the next level interface as below:

Select one of the Game Record you need to check. Below is the Sokoban Game Record:



There are 5 levels for the Sokoban Game. The records will show the best value, the average value, and the most recent value for each level.

4.5 Device Power Off

When the treatment is completed, press and hold the ON/OFF button for one second to turn off the device. Then remove all accessories connected to the main unit.

NOTE: Do not pull the wires, this could damage your accessories.

4.6 After the Treatment

User can clean and maintain the device according to the following instructions:

Main unit

- Make sure to turn off the device and unplug all accessories from the main unit before cleaning.
- Clean the surface of the device with a damp cloth or 75% alcohol cotton before and after treatment.
- Please keep out of reach of children.
- Do not store in a place exposed to direct sunlight, high temperature or humidity.
- Please keep it in a dry and ventilated place.
- Do not disassemble, repair or modify this product without manufacturer's permission, which may cause accidents or malfunctions.
- In order to avoid environmental pollution, please do not discard this device when it is scrapped. Please dispose of it according to local environmental protection requirements.
- The service life of the main unit is 3 years.

Built-in battery

- The device is powered by DC7.4V/1200mAh rechargeable built-in lithium battery.
- When the battery voltage is too low, the battery icon will turn red. Please charge in time.
- After the battery power alarm, it will take about 2 hours to be fully charged each time, and it can be used continuously for about 6 hours after being fully charged.
- In order to ensure the performance of the battery, when the product is not used regularly, please charge the product once 1-2 months.
- The battery of the product is built-in, when the product is scrapped, please dispose of the battery following the local environmental regulations.
- The battery is irreplaceable.

Wires

- All wires should be handled with care and not pulled by force, which may affect the output of the device.
- Check the wires before treatment to prevent the wires from loosening or damaging.
- Avoid pulling or twisting the wire.
- The average service life of the wire is about 24 months.
- Carefully store the wires after each use.
- USB wire is universal micro-USB cable, please connect D.C. 5V /0.5mA power charger.
- Please dispose of the wires according to local environmental protection requirements.

Vaginal probe or anal probe

- Only for special use.Reused only by the same person. The average service life of the probe is 12 to 18 months.
- The surface of the probe should be kept clean to avoid dirt.
- Rinse with clean water after each use and dry thoroughly before storage.
- Do not use boiling water to clean the probe.
- In order to facilitate the enhancement of conductivity and lubrication, it can be used after flushing with clean water.
- In order to avoid environmental pollution, please do not discard the probe when it is scrapped. Please dispose of it according to local environmental protection requirements.

Electrode patch

- Do not overlap use, and the electrode patch should be in full contact with the skin.
- Only for special use.Reused only by the same person.Please replace when there is no adhesion or damage. The average service life is 30-50 times.
- Try to avoid touching the adhesion side of the electrode patches by hand.
- The area to be attached the electrode patches should be clean and in a good condition.
- Do not wipe the patches with a tissue or cloth.
- In order to avoid environmental pollution, please do not discard the electrode patch when it is scrapped. Please dispose of it according to local environmental protection requirements.

4.8 Accessory Replacement Instruction

- The replaceable parts of this product are wires, electrode patches, and probes. When you need to replace the these parts, please contact our company for purchase.

NOTE: Please use the wires, electrode patches and probes provided by our company. The use of other accessories not equipped by our company may affect the safety and effectiveness of the product. If the accessories are damaged or reach the end of life, please contact our customer service. Contact details can be found in this manual.

4.9 Product Repair

If the product is in need of repair, please send it back to the local dealer. Do not disassemble or repair the product without authorization.KONMED will provide circuit diagram, calibration guidance, component list and other necessary information to service personnel.

5 Storage and Disposal

Storage

- Store it in a clean, dry place. We recommend that you keep your device and its accessories in the original gift box.
- Store the device in a place where it is out of reach of children.
- Do not disassemble the device without authorization.
- If you do not use the device for a long time, charge it once every 1 - 2month.
- Do not disassemble for repair without prior notification or you may void your warranty.

Disposal

DO NOT throw away the device with normal household waste at the end of its life, but hand it in to an official collection point for recycling (Contact your local town or city officials for recycling information). By doing this, you help to preserve the environment.

6 Trouble Shooting

If your device is not operating properly, please check below for common problems and suggested solutions. If the recommended action does not solve the problem, please contact our customer service.

Problem	Possible Cause	Solution
Not working	1、The battery is low 2、Product damaged 3、The button does not work	1、Please charge 2、Return to factory for maintenance 3、Return to factory for maintenance
EMG test is unstable	1、The connection of probe or electrode is poor and the reference electrode is not connected.When the electrode plate or probe is not in stable contact, the Impedance at the contact point will be increased and the external interference will be greater, resulting in the instability of EMG value from the actual value. 2、Unnecessary movement during EMG collection interferes with EMG collection at the collection site.	1、Connect electrodes 2、Avoid unnecessary exercise distractions
No stimulation output	1、The electrode is detached or connection is poor. 2、Internal electrical stimulation output circuit is damaged	1、Connect electrodes 2、Return to factory maintenance
No display on screen	1、Broken screen 2、The internal connection of the host is damaged 3、Internal components are damaged	Return to factory for maintenance
There is no voice	1、System voice shutdown 2、Damaged horn or host	1、System setting to adjust the voice size 2、Return to factory for maintenance

7 Warranty Contents

Disclaimer

Shenzhen Konmed Technology Co., Ltd reserves that the final explanation of Biofeedback device, any third party applies device with the related information of Konmed, the legal action will be taken and we will take legal action. In any case, Konmed is not responsible for any consequences caused by improper use of consumers.

Warranty

1)The stimulator carries a limited warranty of one year from the date of delivery. During the warranty period, defective items will be repaired or replaced at no charge. Any evidence of misuse, abuse, alternations, or externally caused damage may have this warranty invalid.
2)Warranty services outsides the scope of warranty shall be charged according to regulations.
3)When applying for warranty, please provide the product security code and serial number, as well as purchase vouchers to contact our company for warranty. For more information, please contact the manufacturer.

Support

Customer Service Center
Company name: Shenzhen Konmed Technology Co., Ltd.
Address: 601,Building B4 Shenchengtou creative factory life science park, Julongshan A Road, Xiuxin block, Kengzi Street, Pingshan District, Shenzhen,China 518118
Tel.: +86 755 8670 4556 | Fax: +86 755 8670 4556
E-mail: sales@konmed.cn

Manufacturer:
Company name: Shenzhen Konmed Technology Co., Ltd.
Address:601,Building B4 Shenchengtou creative factory life science park, Julongshan A Road, Xiuxin block, Kengzi Street, Pingshan District, Shenzhen,China 518118
Tel.: +86 755 8670 4556 | Fax: +86 755 8670 4556
Website: www.konmed.cn
E-mail: sales@konmed.cn

Authorized Representative
Shanghai International Holding Corp. GmbH (Europe)
ADD: Eiffestrasse 80, 20537 Hamburg,Germany

8 Annex I. Manufacturer's EMC Statement

Table 1

Information regarding Electromagnetic compatibility and interference(EMC

Pelvifine products are designed to produce very low levels of radio frequency(RF) emissions(interference),to be immune from effects of interference produced by other equipment operating in their vicinity and damage due to electrostatic discharge all when operating in a typical domestic and or clinical environment. They are certified to meet the international EMC standard EN60601-1-2. For more information please refer to the tables 201, 202, 204 and 206.

Table 201: Guidance and manufacturer's declaration electromagnetic emissions
The Pelvifine product is intended for use in the electromagnetic environment specified below the customer or the user of the Pelvifine product should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The pelvifine product 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 CISPR 11	Group B	The Pelvifine product is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2 IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 202: Guidance and manufacturers declaration electromagnetic emissions

The Pelvifine product is intended for use in the electromagnetic environment specified below. The customer or the user of the Pelvifine product should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±8 kV contact ±2 kV,±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV,±4 kV, ±8 kV, ±15 kV air	Floors should be wood,concrete or ceramic tile.If floors are covered with synthetic material,the relative humidity should be at least 30%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at characteristic levels of a typical location in a typical commercial or hospital environment.

Table 204: Guidance and manufacturer's declaration electromagnetic immunity

The Pelvifine product is intended for use in the electromagnetic environment specified below. The customer or the user of the Pelvifine product should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Pelvifine product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d=1.2P(150kHz to 80 MHZ), d=1.2P(80 MHz to 800MHZ), d=2.3P(800MHz to 2.5GHZ), where P is the maximum out put power rating of the transmitter in watts(W)according to the transmitter manufacturer and d is the recommended separation distance in meters(m).Field strengths from fixed RF transmitters. as determined by an electromagnetic site survey. (a)should be less than the compliance level in each frequency range; (b)interference may occur in the vicinty of equipment marked with the following symbol:
IEC 61000-4-6	150 khz to 80 MHZ 3V/m	150kHz to 80 MHz	
Radiated RF IEC 61000-4-3	80 MHZ to 2,5 GHz	3V/m 80 MHZ to 2,5 GHz	

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 reflect ion 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 radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electro magnetic environment due to fixed RF transmitters, an electromagnetic site survey should be consi dered. If the measured field strength in the location in which Pelvifine product is used exceeds the app licable RF compliance level above, the Pelvifine product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pelvifine product.
(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 206: Recommended separation distances between portable and mobile RF communications equipment and Pelvifine product

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

Rated maxiumum output power of transmitterw	Separation distance according to frequency of transmitter		
	150KHz to 80MHz $d=1.2\sqrt{p}$	80MHz to 800MHz $d=1.2\sqrt{p}$	800MHz to 2,5MHz $d=2.3\sqrt{p}$
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 distances in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where Pis the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacturer.
NOTE1: At 80 MHz and 800 MHz, 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 reflection from structures, objects and people.

9 Clinical References

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[A3] Clinical analysis of 36 cases of female patients with stress urinary incontinence treated with pelvic floor biofeedback

[A4] Pelvic Floor Muscle Exercise by Biofeedback and Electrical Stimulation to Reinforce the Pelvic Floor Muscle after Normal Delivery,In-Sook Lee, RN, PhD1, Euy-Soon Choi,RN, PhD 2,Journal of Korean Academy of Nursing (2006) Vol. 36, No. 8, 1374-1380.

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