Pelvifine®

Pelvy Pro KM530

Neuromuscular stimulator and Biofeedback

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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 type of biofeedback and neuromuscular electrical stimulation therapy device for patients with pelvic floor muscle dysfunction through the evaluation of myoelectric signal acquisition, multimedia biofeedback training, electromyography triggered electrical stimulation, passive electrical stimulation training and treatment.
Features are as shown below:

- Four operation modules (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.
- Ergonomic design, effectively prevent the vaginal probe off and rotation, to ensure that treatment effect.
- The vaginal probe and electrode patches are tested and passed the bio-compatibility according to ISO 10993-1 requirements.

1.3 Indications for Use

The device is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women.

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. Read carefully and follow the instructions.

2.1 Contraindications

The Biofeedback device must not be used in combination with the following medical devices:

- Internally transplanted electronic medical devices, such as cardiac demand 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 Biofeedback device must not be used on the following people:

- Do not use this device under the age of 22.
- 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 Precautions

- Please inspect the stimulator prior to use.
- The stimulator and the corresponding electrode patches is intended for use by one person. Do not share with another person.
- Safety of powered muscle stimulators for use during pregnancy has not been established.
- Caution should be used for patients with suspected or diagnosed heart problems.
- Caution should be used for patients with suspected or diagnosed epilepsy.
- Caution should be used in the presence of the following:
  a.When there is a tendency to hemorrhage following acute trauma or fracture;
  b.Following recent surgical procedures when muscle contraction may disrupt the healing process;
  c.Over the menstruating or pregnant uterus;
  d.Over areas of the skin which lack normal sensation.
- Patients with total/subtotal 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.
- 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.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
- If tissue irritation should occur, treatment should be temporarily discontinued. If problems continue, please see a doctor promptly.
- Please place electrode patches and set stimulation correctly according to the instructions.
- 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.
- Do not use the vaginal probe violently such as hitting hard objects with it. Otherwise, the vaginal probe will be damaged.
- Do not place the vaginal probe in a high temperature environment (>105°C), otherwise the probe will be damaged.
- Biofeedback Nerve and Muscle Stimulator should be used only with the leads, electrode patches and vaginal probe recommended for use by the manufacturer (Model: KM-503, from Shenzhen Konmed Technology Co., Ltd. Manufacturer).
- Do not use in a negative oxygen or oxygen-rich environment. Do not use it under heavy sunlight or dust.
- The device connected to the main unit, USB charger, should be checked to meet the safety requirements of IEC 60601-1.
- Discontinue to use the electrode patches and probe when allergies occur.
- Do not modify the device without authorization of the manufacturer.
- Do not use the device if it is damaged. The continued use of a damaged unit may cause injury, 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.

2.3 Warnings

- The long-term effects of chronic electrical stimulation are unknow, therefore, it is recommended not to use the device for a long time without interruption.
- Do not use this device for treatment during menstruation, vaginal or urinary tract inflammation or infection.
- The electrode patches and vaginal 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 electrode patches, 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 electrode patches near the thorax may increase the risk of cardiac fibrillation.
- Any electrode patches that have current densities exceeding 2mA /cm2 may require special attention of the operator.
- Stimulation should not be applied across or through the head, directly on the eyes, or from electrode patches placed on the chest and the upper back or crossing over the heart. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
- Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
- Stimulation should not be applied transcerebrally.
- Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Avoid trans-thoracic stimulation.
- Avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.
- Users should not perform other operations during use, such as cleaning or maintenance.
- Powered muscle stimulators should be kept out of the reach of children. Be careful to strangulation due to cables and hoses, particularly due to excessive length. Keep unit outof the reach of young children/pets. The electrode cord can wrap around a child and cause suffocation.
- Do not using the USB port for any other purpose but charging the device.
- MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment.

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 involuntary muscle contractions may put the user at undue risk of injury.

2.4 Adverse Reactions

Skin irritation and burns beneath the electrode patches have been reported with the use of powered muscle stimulators. Patients should stop using the device and should Please seek medical attention immediately 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 60601-1-11 Medical 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 60601-2-10 Medical Electrical Equipment - Part 2-10: Particular Requirements for The Basic Safety And Essential Performance Of Nerve And Muscle Stimulators
- IEC 60601-2-40 Medical Electrical Equipment - Part 2-40: Particular Requirements for the Basic Safety and Essential Performance of Electromyographs and Evoked Response Equipment
- ISO 10993-5 Biological 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	Device protected against foreign objects ≥12.5 mm and against vertically falling water dripping
	Keep dry
CE 0197	CE mark and noticed body code
EC REP	Authorised representative in the European community
MD	Indicates the item is a medical device.
	Fragile, handle with care.
	Keep away from sunlight.
	Neuromuscular Stimulators (STIM) and ETS are not suitable for patients with cardiac pacemakers, and please consult your attending physician.
	On transport packaging. To indicate the correct upright position.
	To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

2.7 EMC Statement

This product needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided.

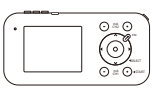
Warning:

1) Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.
2) Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this device and the other equipment should be observed to verify that they are operating normally.
3) The use of accessories and cables other than those specified with the exception of cables sold by the manufacturer as replacement parts for internal components, may result in increased emissions or decreased immunity of this device and result in improper operation.
4) Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
5) Manufacturer's statement details are in the end of the article. (Annex I).

3 Description of the Device

3.1 Package Content

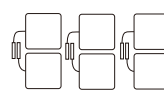
Accessories included in the package:



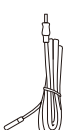
Main unit

Vaginal probe

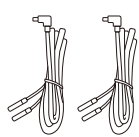
Anal probe (optional)



Electrode patches



REF signal wire



Electrode wires

USB wire

User manual

List of the device and its components

Components	Quantity	Components	Quantity
Main device	1 pc	Electrode patch	3 pairs
Vaginal probe(model: KM-503)	1 pc	REF Signal wire (black)	1 pc
Electrode wires (white)	2 pcs	User manual	1 pc
USB wire	1 pc	Anal probe(model: KM-502)	1 pc (optional)

Note: Please use the probe (model: KM-503/ KM-502), electrode patch, REF signal wire (black), Electrode wires (white) and USB wire accessories provided by Shenzhen Konmed Technology Co., Ltd.

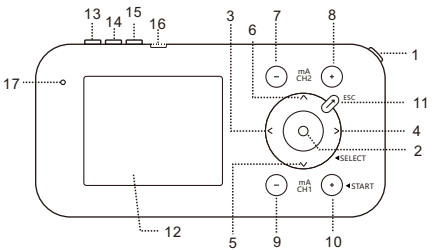
3.2 Product Structure

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

3.3 Functions of the Biofeedback

Main unit

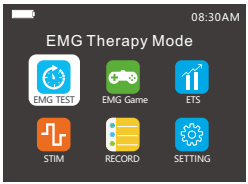
The main unit is composed of display screen and keypad control two parts. User can select appropriate module and other parameters such as intensity, through keypad control (control buttons) on the main unit and know about the operation status through display screen at any time. The details are described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



Keypad control

1) ON/OFF button: Long press this button two seconds to power on, and press this button two seconds again to power off.
2) Confirmation button (OK Key): Confirm selected menu.
3) button left: It is used to go left to select the menu, and change the parameters in the parameter setting interface.
4) button right: It is used to go right to select the menu, and change the parameters in the parameter setting interface.
5) button down: It is used to go down to select the menu.
6) button up: It is used to go up 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 vaginal 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: used to display the stimulation status of device operationin ETS or STIM module.

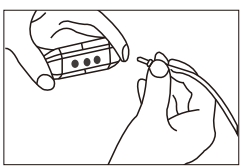
Display screen

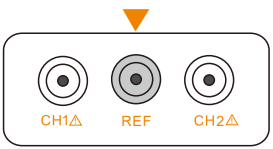


● Accessories

REF signal wire (black)

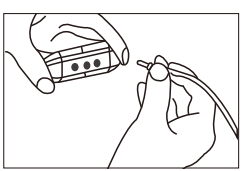
The REF signal wire is used to make a connection between one piece of reference electrode patch and REF port, as well as must be used in the treatment of EMG Test, EMG Game and ETS mode, in order to ensure the accuracy of EMG value. Meanwhile, the reference electrode should be applied near the treatment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

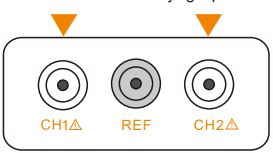




Electrode wires (white)

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.

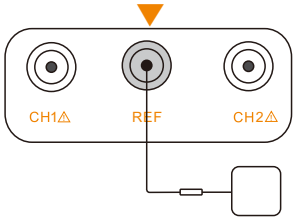




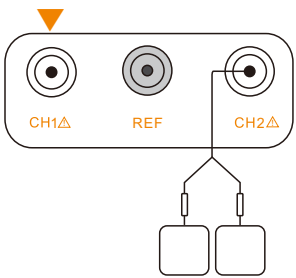
Electrode patch

There are two types of electrode patches: one piece of electrode is used as the reference electrode and two pairs of electrode patches are used to as the working electrode. The electrode patches are to be attached to bare skin to perform treatment. Stop using it when there is an allergy. There is no difference in the appearance between the working electrode patch and reference electrode patch. They have the same material and specifications.

▶ **Reference electrode**

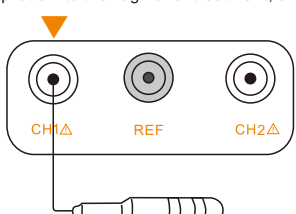


▶ **Working electrode**



▶ **Vaginal probe or Anal probe**

Insert the **CH1** vaginal probe into the vagina for treatment, or Anal probe into the anus.



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, 0.5A.

● **Others**

Battery charge

- Please charge first when using the device for the first time in order to ensure its normal use. When the battery is low power, 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. Power adapter is not equipped with the device, and please select adapter of 5V, 0.5A which has obtained UL certificate or has passed IEC 60601-1 test. Do not use the product while charging.

Load detection

- In 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		V1.3.1.0.0.01		
Basic Unit Specifications				
Dimensions	Main unit (L*W*H)	140.5×25.5×69mm		
	Electrode patch	50×50mm		
	Vaginal probe	145mmΦ25mm		
Weight (Included batteries)		192g		
Power Supply		7.4V DC/1200mAh rechargeable lithium battery		
Number of channels		2 channels		
Therapy Mode		EMG Therapy, EMG Game, ETS, and STIM		
Output Intensity Level		0-90mA(the output current increases by about 1mA for each additional level of strength)		
Charging port voltage		DC 5V, 0.5A		
Safety Category		BF type		
Service life		3 years		
Biofeedback performance (Dual-channel acquisition)				
EMG sampling rate		3kHZ		
EMG detection (bipolar/monopolar)		Bipolar		
EMG range (μV)		0.2-2000μV		
EMG bandwidth		20Hz-500Hz		
EMG signal processing		Root mean square (RMS)		
Electrical Stimulation Output Specifications				
Waveform and Shape		Pulsed symmetric, asymmetric, biphasic, square wave		
Maximum Output Voltage (±10%)		47.2V @500Ω	108V @2kΩ	150V @10kΩ
Maximum Output Current (±10%)		94.4mA @ 500Ω	54mA @ 2kΩ	15 mA @ 10kΩ
Pulse Duration		50-450μs		
Frequency		2~100Hz		
Net charge		For pulsed asymmetric, 0μC @ 500Ω		
Maximum Phase Charge		42.48μC @ 500Ω		
Maximum Current Density		6.01 mA/ cm2 @ 500Ω		
Maximum Power Density		0.2814 mW / cm2@ 500Ω		
Timer range		1-99min		
STIM Programs		22 species		
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		

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 electrode patches or probe, be sure the body surface is cleaned and dried. When use the electrode patches, tear off the protective films on electrode patches. Then apply electrode patches or probe to the specified area. Make sure the electrode patches or probe are placed firmly to the body and make good contact between the body and electrode patches/probe.

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

4.1.1 Check for these situations before use

Please identify your type of incontinence:

1)Urge urinary incontinence: You have a particularly strong feeling for suddenly want to urinate and you will loss control of this, maybe will wet on your pants before you get in a bathroom.

2)Stress urinary incontinence: It is the loss of small amounts of urine associated with coughing, laughing, sneezing, standing up, exercising or other movements that increase intra-abdominal pressure and thus increase pressure on the bladder, then cause the urinary incontinence.

3)Mixed urinary incontinence: Mixed urinary incontinence is when you have both Urge urinary incontinence and Stress urinary incontinence together.

4.1.2 System setting

▶ Select the “SETTING” icon in the main interface through four arrow keys, click the confirmation button to enter system setting interface.

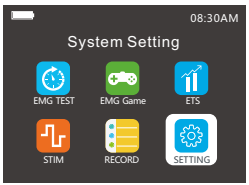


Figure 4-1 the main interface

▶ The system setting interface contains the settings of date and time, brightness, sound, delete record and restore factory, can be switched by “∧” and “∨” button.

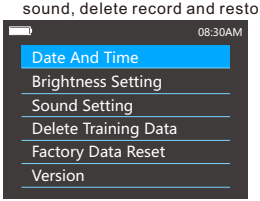
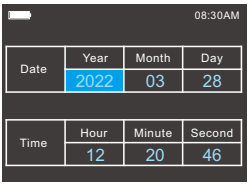
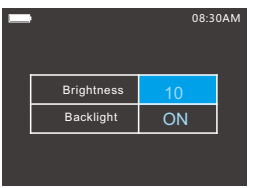
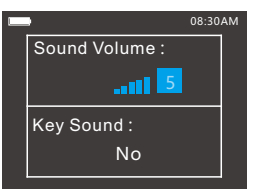
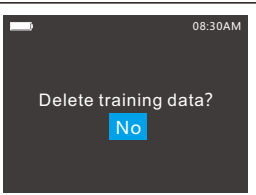
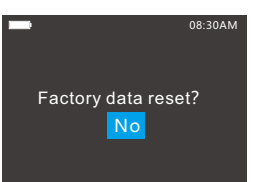
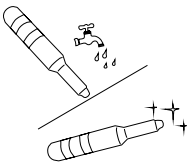


Figure 4-2 the system setting interface

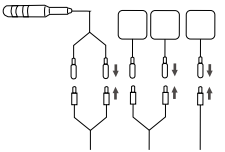
System Setting		
Option	Interface	Operation
Date and Time Setting		• Select “Date And Time” to enter the setting interface. • Choose to modify “Year/Month/Day” through the up and down buttons,adjust the value through left “ < ” and right“ > ” button. • Switch to time option through the down button, select “Hour/Minute/Second” through the up and downbuttons,adjustthe value through left “ < ” and right“ > ” button.
Brightness Setting		• Press confirmation button to enter the “Brightness Setting” interface, which has two options, brightness and backlight. • Switch options through up and down buttons. • Select brightness to modify backlight level which can be adjusted through left “ < ” and right“ > ” button from 1 to 10. Backlight option represents backlight duration which can be set as 5s, 10s, 15s, 20s, 25s ,30s, 35s,40s, 45s, 50s, 55s, 60s and ON. • Modify the value through left “ < ” and right“ > ” button. In case of no operation, backlight will automatically dim when the time set is reached, so as to lower the power consumption.
Sound Setting		• Press confirmation button to enter the “Sound Setting” interface, which has two options, sound volume and key sound. • Sound volume is to set sound level which can be adjusted from 1 to 10 through left “ < ” and right“ > ” button. • Key sound is switched between yes and no through left “ < ” and right“ > ” button to open or close key sound.
Delete Training Data		• Press confirmation button to enter the “Delete Training Data” interface. • Modify by pressing left “ < ” and right“ > ” button, and press confirmation button under "Yes" to delete the user's training records.
Factory data reset		• Press confirmation button to enter the “Factory Data Reset” interface. • Switch between Yes/No through left “ < ” and right“ > ” button. • Select Yes, then parameters set will be reset to factory state, but the user's training records will not be cleared.

4.1.3 Electrode patches connection

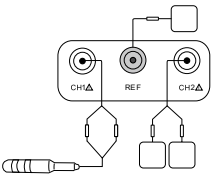
Make a connection between the main unit and electrode patches or probe according to the following figure. Specific electrode connection for each mode is explained in section 4.3.



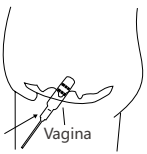
1) Rinse the probe with clean water.



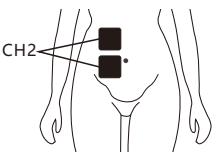
2) Connect the pin of the electrode wire with the probe and the patch electrode.



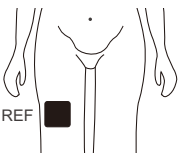
3) Connect the plug of the electrode wire to the host.



4) Put the vaginal probe into the body.



5) Place the CH2 patch electrode on the abdomen.



6) Place the REF patch electrode on the thigh.

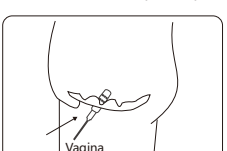
4.1.4 Position of Electrode patches and Probe

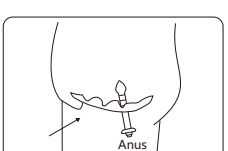
Prior to attach the electrode patches or probe, please make sure the targeted treatment area is in good condition without any injury and wound as well as is clean. The device is used in individual independent environment, patient can lie down or adopt other posture that feels comfortable.

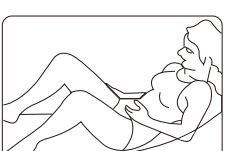
Attaching the electrode patches or probe correctly is vital for effective and safe treatment. The position of electrode or probe should be placed according to specific requirements under the instructions of the manual. The illustration below shows the position of the electrode patches and probe.

In EMG test:

When doing pelvic training, the CH1 electrode patches are connected as follows:
The electrode and probe placement of the CH1 channel is as follows:



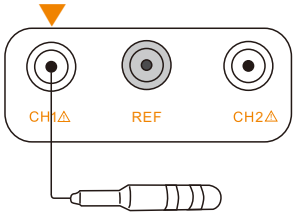




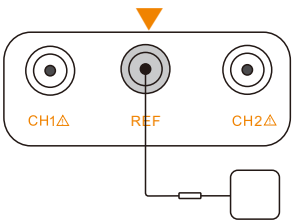
The patient lies on her back, relaxed and with the upper body slightly elevated. The legs are upright and tilted slightly to the outside. It is advisable to support the legs on the sides in order to improve relaxation.

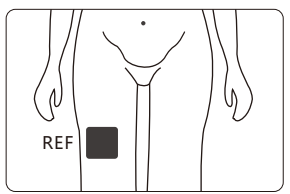
Vaginal probe or Anal probe

Insert the **CH1** vaginal probe into the vagina for treatment, or Anal probe into the anus.

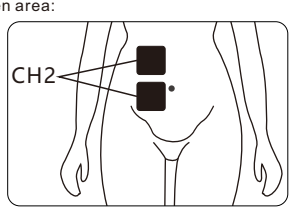


REF electrode is placed near the thigh:



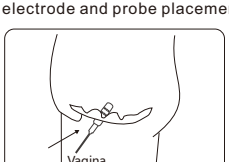


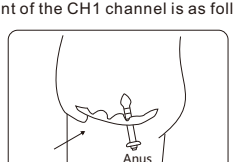
CH2 is placed in the abdomen area:

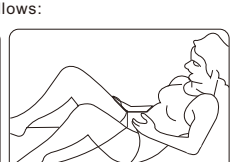


In EMG game module

When doing pelvic training, the CH1 electrode patches are connected as follows: The electrode and probe placement of the CH1 channel is as follows:



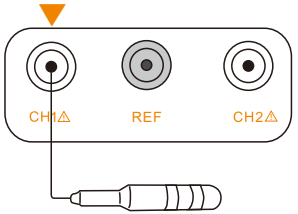




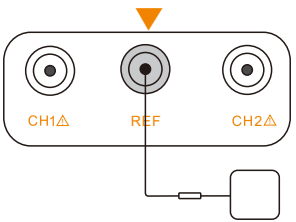
The patient lies on her back, relaxed and with the upper body slightly elevated.
The legs are upright and tilted slightly to the outside. It is advisable to support the legs on the sides in order to improve relaxation.

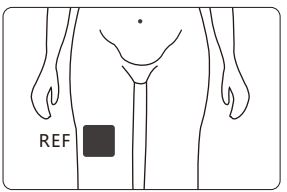
Vaginal probe or Anal probe

Insert the **CH1** vaginal probe into the vagina for treatment, or Anal probe into the anus.



REF electrode is placed near the thigh:

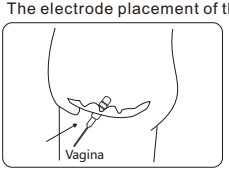


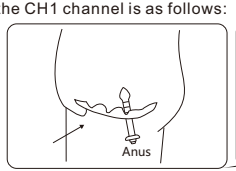


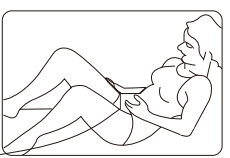
CH2 is not connect.

In ETS Therapy module

When doing pelvic electrical stimulation training, the CH1 electrode patches are connected as follows:
The electrode placement of the CH1 channel is as follows:



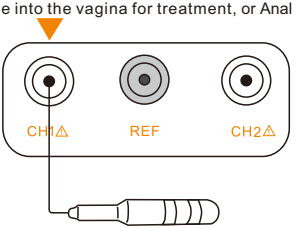




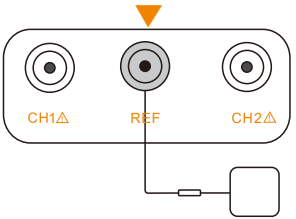
The patient lies on her back, relaxed and with the upper body slightly elevated.
The legs are upright and tilted slightly to the outside.
It is advisable to support the legs on the sides in order to improve relaxation.

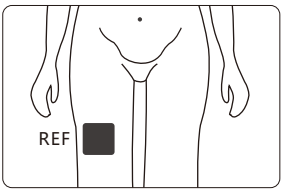
Vaginal probe or Anal probe

Insert the **CH1** vaginal probe into the vagina for treatment, or Anal probe into the anus.

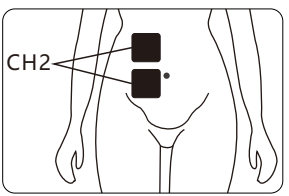


REF electrode is placed near the thigh:



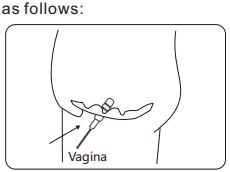


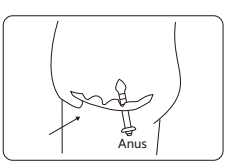
Ch2 is placed in the abdomen area:

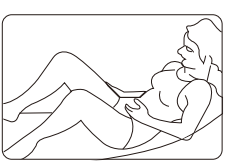


In STIM module

When doing pelvic electrical stimulation training, the CH1 electrode patches are connected as follows:



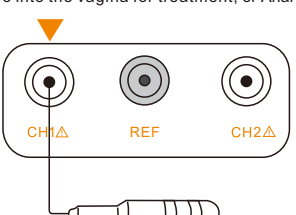




The patient lies on her back, relaxed and with the upper body slightly elevated.
The legs are upright and tilted slightly to the outside.It is advisable to support the legs on the sides in order to improve relaxation.

Vaginal probe or Anal probe

Insert the **CH1** vaginal probe into the vagina for treatment, or Anal probe into the anus.



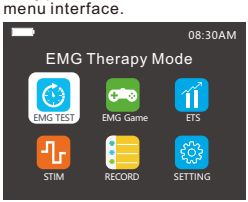
CH2 is not connected.
REF is not connected.

Note:

1. The surface of the electrode patches and probe should be kept clean to avoid dirt.
2. Electrode patches and probe can only be used by one person. For special use only, the same patient can reuse the electrode patches or probe.
3. The average life expectancy of electrode patches is 50 times (30minutes each time). The average life expectancy of probe is 12-18 months. Stop using the electrode and probe when there is allergy.
4. When electrode patches' viscidity can't be restored even after being cleaned for many times, please purchase new electrode patch from retailer or manufacturer.
5. Only use electrode patches equipped with the product or purchased from retailer or manufacturer. The size of electrode is about 50mm (L)×50mm (W). Please do not use electrode patches of other size. Otherwise, too high a current density can flow and injuries may be caused.
6. The recommended distance between the working electrode patches should not be smaller than approx. 1cm.
7. Each person reacts differently to an electric stimulation. The positioning of the electrode patches might thus deviate from the standard positions.
8. Make sure the connection between electrode patches/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 modules for treatment while entering the main menu interface. The operation of each module and each interface is described below.

4.3 Direction for Use (Introductions of Each Menu Interface)

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

Therapy Mode	Model description	Model USES
EMG Therapy	Uses EMG-based to help show and control the pelvic floor muscles in the treatment of urinary incontinence and help users test pelvic floor muscle strength.	A weekly test is recommended to assess changes in pelvic floor muscle strength.
EMG Game	Uses EMG Game to help User control and strengthen they pelvic floor muscles in the treatment of urinary incontinence. According to the user's muscle contractions,muscle strength is measured and converted into training interface movements which has six ways to train for explosiveness, speed, and sustainability.	It is recommended to train once a day.
ETS	This device provides a passive pulse when the contraction level reaches a threshold through electrical feedback from the pelvic floor muscles. Use pulse to stimulate pelvic floor muscle, strengthen the central nervous control of muscle,reshape muscle function.	ETS treatment is especially useful for pelvicMuscle improvement, urinary incontinence.
STIM	It can provide electrical stimulation and use the low-frequency current stimulates pelvic floormuscles, nerves, and blood vessels, promotes blood circulation for the purpose of increases blood and oxygen supply to local tissues and rehabilitation of weak pelvic floor muscles for the treatment of stress urinary incontinence, urge urinary Incontinence and mixed urinary incontinence in women and to maintain urinary continence in women.	The Neuromuscular stimulation (STIM) modes has 22 models chooses to make your pelvic floor muscles be strengthen.

4.3.1 EMG Therapy

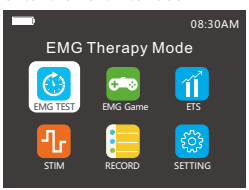
Explanation of the usage for CH1 channel, CH2 channel and REF channel:

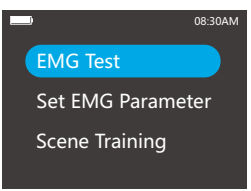
- CH1 channel: It is used to connect probe, which is inserted into the vagina (only for EMG acquisition, not for generating electrical stimulation);
- CH2 channel: It is used to connect electrode patch, which is pasted near the treatment area (Only for EMG acquisition, not for generating electrical stimulation);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

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, 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 screen may be large, and the data is not used as a reference. For example, when the pelvic floor muscle is evaluated, the electrode patch of CH2 is attached to the abdomen position to collect the EMG value of the abdomen, which is used as a reference for evaluation of the pelvic floor muscle of CH1; In the evaluation of the pelvic floor muscle of CH1, the EMG value collected by CH2 was basically the same as the EMG value when the abdomen was relaxed.

Step#1. Select the "EMG Test" 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.

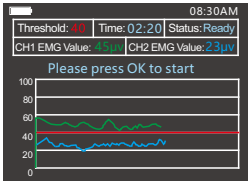
- Parameter setting interface is described below:

Parameter name	Parameter option or range	Parameter explanation
Threshold Value (μV)	5-2000	Threshold setting, the default value is 40. If the displayed EMG value exceeds this value, it indicates that the trainer's muscle strength has reached the set threshold value.At this point, the device will continue to broadcast voice, prompting theuser to reach the target. When the EMG value is below the threshold, no voice will be broadcast.
A/M Threshold	Manual/Auto	Change mode for threshold value setting: Manual/ Automatic. The default setting is Manual. In the Automatic (Auto) mode: 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	above/off	Prompt tone mode: Above / Off. The default setting is Above. Above: Tells you when the muscle strength is above the set threshold. Off: Turns off the voice.
Drawing Cap(μV)	50-2000	Adjust from 50-2000 according to Threshold Value. If the Threshold Value is set at 40 then the Drawing Cap should be set at approximately 100. If the Threshold Value is 100 then the Drawing Cap should be around 200. The curve of the Threshold Cap will show more detailed information when it is close to the value of the Drawing Cap.

● 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:

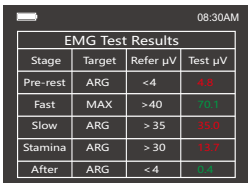
- Threshold value: The set EMG threshold is divided into automatic and manual setting mode. In Automatic mode, the threshold will be adjusted according to the user's muscle strength during the previous work period. In Manual mode, the threshold will not change.
- Time: The total time of this EMG test does not include preparation time.
- Status: Ready (wait for the trainer to press the confirmation button to enter the EMG test); Rest (prompt the trainer to let their muscles relax); Work (prompt the trainer to make their 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.
- Drawing Cap: The upper limit of the interface curve, which cannot be exceeded. If the user exceeds the set Drawing Cap, the total will still remain at 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.
- Blue horizontal line: CH2 reference acquisition for observing the trainer's ability to contract the pelvic floor without contracting the abdomen.

The CH2 electrode pads are placed on the abdomen for observing the EMG of the abdomen during the pelvic floor contraction movement to judge whether the muscle contracted by the user is the pelvic floor muscle. When the electrode pad is not placed on the abdomen, its value has no reference significance.

In the EMG interface, according to the prompt on the screen, press the confirmation button to start the test.

Step#4.Start testing

- During the EMG, perform the action according to the prompt (#i.work--contractmuscles; #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.



Description of biofeedback evaluation data

Phase No.	Phase Name	Parameter name	Refernce Value
1	Pre resting stage	Average value	< 4μv
2	Fast muscle stage	Maximum value	> 40μv
3	Slow muscle stage	Average value	> 35μv
4	Stamina test stage	Average value	> 30μv
5	Post resting stage	Average value	< 4μv

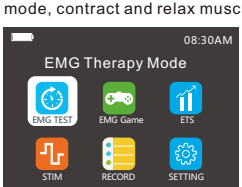
The curves at the pre and post rest stages should be as stable as possible, and the test value should be less than the reference value. The greater the value or the more the curve beat changes, the more serious the pelvic floor muscle over activity.

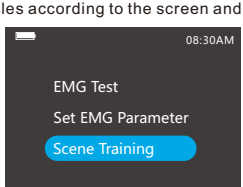
- The fast muscle test value should be as large as possible. The larger the value is, the greater the fast muscle strength of the pelvic floor muscle is, and the stronger the muscle strength is; the smaller the value is, the smaller the muscle strength of fast pelvic floor muscle is, and the weaker the muscle strength is.
- The average value of slow muscle was tested at slow muscle and endurance stage. The greater the test value, the stronger the slow muscle endurance and muscle strength of pelvic floor muscle; The smaller the test value, the weaker the slow muscle endurance and muscle strength of the pelvic floor muscle.

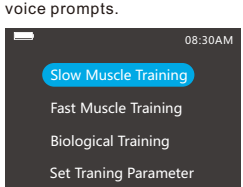
(Reference: Chinese Journal of Obstetrics and Gynecology, Vol. 18, Issue 3, May 2017, Application of Glazer Assessment in Postpartum Pelvic Floor Muscle Function Assessment, written by Zhou Zhichun, Zhu Haiyun, Cao Hongmin)

Step #5: Scene training

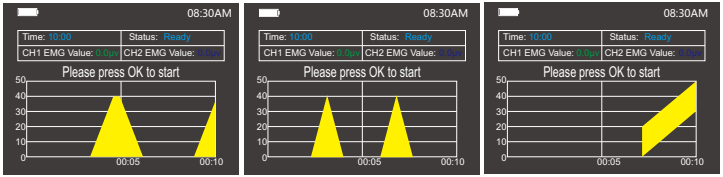
Using steps: Enter the EMG test interface, select Scene Training, then select your desired mode, contract and relax muscles according to the screen and voice prompts.







There are Slow Muscle Training, Fast Muscle Training and Biological Training. The three modes can be used alternately every day or selected according to user' s own muscle conditions. If the explosive force is insufficient, select Fast Muscle Training, and if the endurance is insuifficient, select Slow Muscle Training.



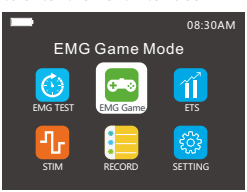
1. **Slow Muscle Training:** enhance the endurance of slow muscle contraction, so that the pelvic floor muscles are not easy to feel tired.
2. **Fast Muscle Training:** enhance the explosive force of fast muscle contraction, and make the contraction strength of pelvic floor muscle stronger.
3. **Boilogical Training:** collect pelvic floor muscle contraction signals, amplify the signals, make the pelvic floor contract, achieve the purpose of exercising pelvic floor muscle contraction, and form conditioned reflex through repeated training.

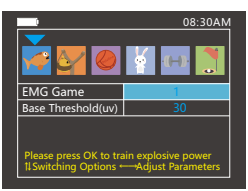
4.3.2 EMG Game

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).

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





- The EMG Game is an active training for the user to contract the muscles 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 shown in Step #3.

Step#2. Set the parameter

- Use the "<" and " >" button to choose the game which need to set the parameter.
- Use the "∧" and "∨" to switch to switch to Base Threshold then "<" and " >" button to set the game parameter

NOTE: Game parameters can be set according to user needs by referring to the table below.

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 1-1000uv.

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

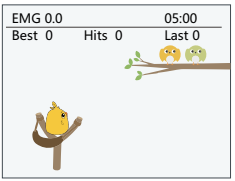
NOTE: Once the parameters are modified, the device will perform the EMG Game according to the modified parameters. Please operate with caution.

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

- Six kinds of EMG feedback game training methods are used for the explosive and continuous strength of muscles

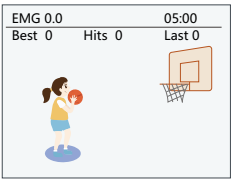
Big Fish

Training explosive power



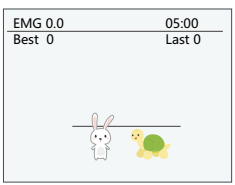
Angry Bird

Training explosive power



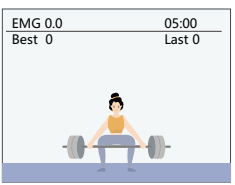
Shoot

Training explosive power



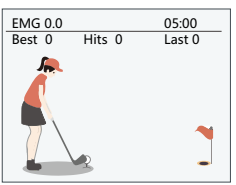
Race

Training sustainability



Weightlifting

Training sustainability



Golf

Training explosive power

- EMG feedback game training rules: Connect the device to the electrode pads, enter the game interface, within the specified time, if the EMG value is greater than the set threshold, the game will go on smoothly, then you will be prompted to congratulate for passing the game.

4.3.3 ETS

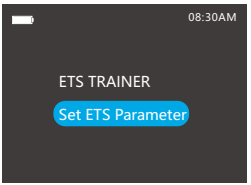
Explanation of electrode connection:

- 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(not only for EMG acquisition, but also for generating electrical stimulation when the EMG value reaches the set threshold);
- 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:

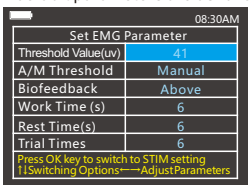
- The device will only report on the muscle strength test of the muscles at the CH1 channel junction. The EMG value displayed by the CH2 channel is the EMG value of the area to which the CH2 electrode is attached. CH2 channel can be connected to electrodes pasted to the abdomen to check whether the pelvic 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 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.

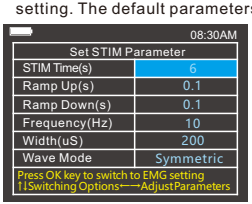
NOTE: The parameters can be set according to user needs by referring to the table below.

- Parameter setting interface is described below:

Parameter name	Parameter option or range	Parameter explanation
Threshold Value (uV)	5-2000	• 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". Threshold setting, the default value is 40.
A/M Threshold	Manual/Auto	• Change mode for threshold value setting: manual / automatic. • In the Automatic (Auto) mode, the threshold value for the next " Work Time" is 80% of the average muscle strength value for this " Work Time". 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. The output intensity value of the electrical stimulation can be modified by referring to the threshold of the EMG. When the threshold of the EMG is large, the intensity of the stimulation output can also be appropriately increased. • 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. • The default setting is Manual.

Parameter name	Parameter option or range	Parameter explanation
Biofeed back	above/off	• Prompt tone mode: above / off. • Above: Plays a tone when the muscle strength is above the set threshold. • Off: Turns off the beep. The default setting is Above.
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 (Number of cycles)	2-99	During ETS training, one working time and one rest time of EMG are counted as a cycle, and the total time is the sum of working time and rest time in multiple cycles. If muscle electrical stimulation is stimulated, it is not counted as the total time.

- Users can perform EMG tests through preset or manually set thresholds. When the pelvic floor muscle contraction value reaches the threshold, a voice prompt will be issued and STIM stimulation will be performed. On the contrary, there will be no voice reminder and STIM stimulation. At the same time, when the user sets the "Auto Threshold", the larger the average muscle strength value, the stronger the muscle contraction, and the larger the next threshold value. The smaller the average muscle strength value, that is, the more relaxed the muscle contraction, the smaller the next threshold. The output intensity value of the electrical stimulation can be modified with reference to the threshold value of the EMG. When the threshold value of the EMG is larger, the intensity of the stimulation output can also be appropriately increased. If the user is set to "manual mode", the threshold will not change each time. until the end of the stimulation time.
- 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 parameters can be set according to user needs by referring to the table below.

- Parameter setting interface is described below:

Parameter name	Parameter option or range	Parameter explanation
Frequency (Hz)	2-100	Pulse frequency, the default value is 10.
Width (uS)	50-450	Pulse Width, the default value is 200.
Wave Mode	Symmetric/ Asymmetric	•Waveform type: Symmetric/Asymmetric. • The pulse output in the Symmetric mode is a biphase symmetric waveform, and the output of the generated electrical stimulation is very strong. • The pulse output in the Asymmetric mode is a biphase asymmetric waveform, and the output of the generated electrical stimulation is relatively weak. • In the same program and the same current intensity, the output intensity of the symmetric waveform is much higher than that of the asymmetric wave. • The default setting is Symmetric.

- The specific parameter settings have been set in the 22 STIM stimulation programs. Please check the pulse frequency and pulse width of the 22 STIM stimulation modes for selection (see 4.3.4 STIM interface table for details). After the STIM parameter setting is completed, click the ESC button to exit and the setting is automatically saved at this time.

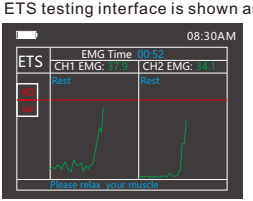
NOTE: Once the parameters are modified, the device will perform the ETS Test according to the modified parameters. Please operate with caution.

Step#1. Select ETS test in the ETS Therapy interface.

After entering the ETS test, please contract the muscles 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 is a combination of active and passive treatment, which exercise the self-contracting ability of the user.

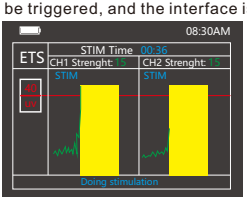
NOTE: According to the prompt to contract the muscles of the treatment area, there will be no electrical stimulation at this time.

ETS testing interface is shown as below:

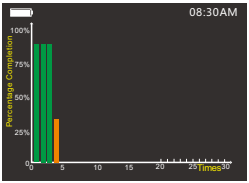


- Threshold: Set threshold value;
- Time: Current training time;
- EMG value: Current tested CH1 and CH2 EMG value;
- Status: Indicates the current training state. The training state is divided into 4 types: Ready, Rest, Work and Electrical Stimulation Output.

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.

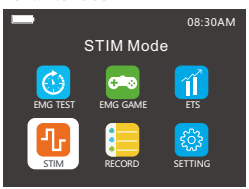


4.3.4 STIM

Explanation of electrode connection:

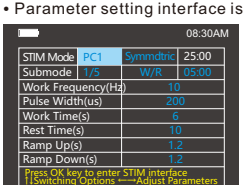
- CH1 channel: Used to connect the probe (for generating electrical stimulation);
- CH2 channel: Not connected.
- REF channel: Not connected.
- Please refer to 4.1.4 for diagram of electrode placement for STIM.

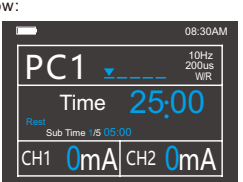
Step#1. Select the STIM in the main interface and press the confirmation button to enter the next interface.



Step#2. Set STIM Parameter

- This interface displays the parameter setting table of STIM, in which the white is an unchangeable item and the blue is the modifiable item. P01-P22 are fixed programs. On fixed programs you can adjust whether the program uses Symmetric or Asymmetric waveform. PC1, PC2, and PC3 can be custom programmed. All settings may be customized in these programs.
- Use the "<" and " >" buttons to switch programs or set the parameter value, as well as "^" and "v" button to switch options.Press the Okay button to enter the program. The strength of each program can be adjusted. The strength setting is referred to as the mA's. Use the +/- keys associated with the channel being used to adjust the strength (mA's).
- Parameter setting interface is described below:





- For P01~P22(Fixed program):

Parameter name	Parameter explanation
STIM Mode	P01~P22
Symmetric/ Asymmetric	• Waveform type: Symmetric/Asymmetric • The pulse output in the Symmetric mode is a strong biphase symmetric waveform. • The pulse output in the Asymmetric mode is a soft biphase asymmetric waveform.

- See the detailed parameters of each mode below:

Model:KM530B							
Programs	Type of urinary Incontinence	Frequency (Hz)	PulseWidth (μS)	Work Time (s)	Rest Time (s)	Sub Time (min)	Total Time (min)
P01	Urge Incontinence	10	240	6	8	–	25
P02	Frequent Urination	10	250	6	10	–	25
P03	Bladder Active Stimulation	10	220	Continue	0	–	25
P04	Sensory Nerve Regeneration	20	220	6	8	–	4
P05	Stress Incontinence	35	250	6	10	--	20
P06	Stress Incontinence	35	250	6	15	--	20
P07.1	Stress Incontinence	35	300	6	9	35	45
P07.2		20	300	Continue	0	10	
P08	Muscle Training	35	450	7	9	--	30
P09.1	Mixed Incontinence	10	240	5	7	10	25
P09.2		35	220	5	8	10	
P09.3		10	200	5	8	5	
P10.1	Sensory Nerve Regeneration	4	240	6	8	5	35
P10.2		10	300	6	8	10	
P10.3		15	280	6	8	5	
P10.4		40	270	5	8	10	
P10.5		10	200	5	8	5	
P11	Tighten Vagina	35	220	6	12	--	20
P12.1	Pelvic Muscle Exercise	4	250	6	7	5	28
P12.2		10	220	6	9	6	
P12.3		20	220	7	7	6	
P12.4		35	200	6	10	6	
P12.5		10	220	6	8	5	
P13.1	Pelvic Muscle Exercise	4	260	Continue	0	4	14
P13.2		10	300	6	8	5	
P13.3		35	300	6	8	5	
P14.1	Exercise pelvic floor muscle Endurance	4	240	6	7	5	30
P14.2		10	300	8	7	10	
P14.3		20	300	7	7	10	
P14.4		35	240	7	7	5	
P15.1	Maintain Pelvic Muscle Exercise	4	220	6	8	5	24
P15.2		10	240	6	8	5	
P15.3		20	240	6	8	5	
P15.4		35	220	5	8	5	
P15.5		10	200	5	8	4	
P16.1	New Mother	4	200	5	10	4	28
P16.2		10	200	5	10	10	
P16.3		20	200	5	12	5	
P16.4		35	200	5	12	5	
P16.5		20	200	5	10	4	
P17.1	Exercise After Hysterectomy	4	220	6	8	5	25
P17.2		10	220	5	9	10	
P17.3		35	200	5	10	5	
P17.4		10	200	5	8	5	

P18	Cystocele, Prolapse	10	220	5	8	--	25
P19.1	Lack of Sensitivity	4	240	Continuous	0	5	23
P19.2		40	300	8	8	10	
P19.3		50	240	Continuous	0	4	
P19.4		10	200	6	8	4	
P20.1	Pelvic Muscle Pain	3	200	Continuous	0	20	30
P20.2		10	200	Continuous	0	10	
P21.1	Lack of Sensitivity	3	250	4	4	3	25
P21.2		10	250	4	4	10	
P21.3		20	250	4	4	5	
P21.4		30	200	4	6	4	
P21.5		40	200	4	6	3	
P22	Pelvic Muscle Exercise	2	220	6	10	--	20
PC1-PC3	Custom Settings as Needed	2-100	50-450	2-99	2-99	--	1-99

Note: Programs PC1, PC2 and PC3 are customizable programs. Set parameters according to trainer's needs.

Customization process:

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

- Select PC1-PC3 in the STIM Mode option to start customizing settings. This interface displays the parameter setting table of STIM Mode, in which the white is an unchangeable item and the blue is the modifiable item.
- Use the "<" and " >" buttons to to set the parameter value, as well as "∧" and "∨" button to switch options.

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

The range of custom parameter settings is as follows:

Parameter option	Parameter explanation
STIM Mode	Mode switching (PC1~PC3).
Symmetric/ Asymmetric	Waveform type: Symmetric/Asymmetric The pulse output in the Symmetric mode is a strong biphase symmetric waveform. The pulse output in the Asymmetric mode is a soft biphase asymmetric waveform.
Sub Mode	Indicates the Sub Mode of the program. A Sub Mode is a layer of settings within a single program allowing the trainer to use several different settings in a cycle during the program. If the screen shows Sub Mode is 1/5: this indicates that this program has 5 Sub Modes, and the current Sub Mode is 1; If the screen shows Sub Mode is 2/5: this indicates that this program is on Sub Mode 2.
Work/Rest Or Cont (Continuous)	If we choose 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 never have a 0 (zero) stimulation rest period.
10:00	This is the running time of the current Sub Mode; ranging from 01:00 to 95:00 minutes.
Work frequency (Hz)	This is the pulse output frequency of the current Sub Mode, ranging from 2 to 100.
Pulse width (us)	This is the pulse output width of the current Sub Mode, ranging from 50 to 450.
Working time (s)	When the Sub Mode is set as W/R (work/rest), this parameter will represent the amount of time that current is delivered, ranging from 2 to 99 seconds.
Rest time (s)	When the Sub Mode is set as W/R (work/rest), this parameter will represent the amount of 0 drop rest time between work times, ranging from 2 to 99 seconds.
Ramp Up (s)	When the Sub Mode is set as W/R (work/rest), this parameter sets how long in seconds that the current will take to increase back up from 0 to the last set mA's. The value range is from 0.1 to 9.9 seconds.
Ramp Down (s)	When the Sub Mode is set as W/R (work/rest), this parameter sets how long in seconds that the current will take to drop to 0 during the rest portion of the program. The value range is from 0.1 to 9.9 seconds.

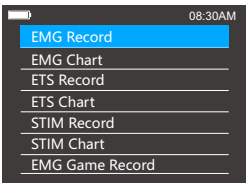
- After the STIM parameter setting is completed, click the ESC button to exit and the setting is automatically saved at this time.

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

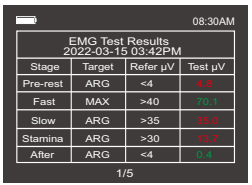
4.4 Treatment Record

• In the main interface, select "RECORD", and then click confirmation button to enter the record interface.

NOTE: Programs that were not completed will not be recorded.

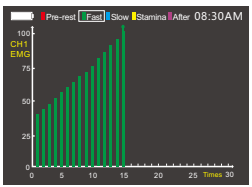


• In the EMG record interface



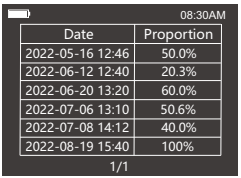
You will see the last EMG training date displayed at the top of the screen. The last 30 EMG test results can be accessed here using the “^” and “v” buttons. The top record is the latest record. If there are more than 30 records, the latest record will replace the last record. The red value indicates that the required standard is not met. Green value meets the standard.

• In the EMG chart interface



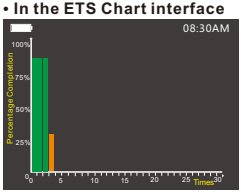
You will see a two-dimensional coordinate graph. The bottom line, or X-axis, represents the number of test times charted; the lateral, or Y-axis, represents the measured EMG value. We will record the test values of the 5 stages of the EMG testing process through 5 pages. 5 colors distinguish 5 testing stages,The colors of the bars are labeled at the top of the screen. Red: Pre-rest, Green: Fast twitch muscle strength, Blue: Slow twitch muscle endurance, Yellow: Stamina, Purple: After exercise muscle tension. The chart can more vividly reflect the user's EMG test results and graph their EMG change trend.Use the "<" and " >" button to select and view the test records of different stages.Note: During normal testing, the test values during the Pre-rest and After stages should be below 50μv. The other test values should be lower than 100μv. Therefore, we will limit the maximum value in the Pre-rest and After stage in the recording icon to 50μv, and the maximum value in other stages to 100μv. If the test value exceeds the maximum limit, the bar chart will only display the maximum value of 50 or 100μv, and an arrow will be displayed at the top for marking. The test value exceeds the maximum limit, and the test results may be inaccurate. Please do not use it as a reference,or retest.

• In the ETS Record interface



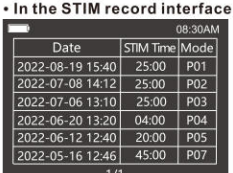
In ETS records, the calculation of percentage: the denominator is the number of times the vaginal muscles are broadcasted during one stage of work and rest, and the numerator is the number of times electrical stimulation is triggered (when the vaginal muscles have poor muscle strength and control, the contraction of the vaginal muscles will not exceed the threshold, and electrical stimulation cannot be triggered). The percentage here is used to represent muscle strength and control ability. The higher the percentage, the stronger the muscle strength and control ability.
The ETS treatment date and the percentage of the number of electrical stimulation triggered in each therapy are recorded. Up to 30 records can be recorded. The top record is the latest record. If there are more than 30 records, the latest record will replace the last record.

• In the ETS Chart interface



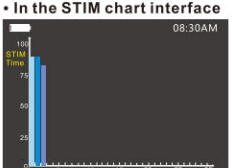
You will see a two-dimensional coordinate used. The bottom X-axis represents the number of test times; the lateral Y-axis represents the percentage of times stimulation was triggered in each therapy session. Bar charts with more than 50% of triggered electrical stimulation times will be green, and those with less than 50% will be orange.

• In the STIM record interface



The STIM therapy date, time and mode are recorded. Up to 30 records can be recorded. The top record is the latest record. If there are more than 30 records, the latest record will replace the last record.

• In the STIM chart interface



You will see a two-dimensional coordinate used. The bottom X-axis represents the number of test times; the lateral Y-axis represents time of electrical stimulation. The color of the bar chart is only used for interval differentiation and has no other meaning.

4.5 Device Power Off

• When the treatment is completed, press and hold the ON/OFF button for 2 seconds 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 main unit 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 D.C. 7.4V/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 indication, it takes about 2 hours to fully charge each time. After fully charged, it can be used continuously for about 6 hours.
• 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 built-in rechargeable battery is not allowed to be disassembled and replaced without permission. If you need to replace the battery, please contact us.

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 /0.5A power charger.
• Please dispose of the wires according to local environmental protection requirements.

Vaginal probe and Anal probe

• Only for use by one person. Do not share your probe or use another person's probe
The average service life of the probe is 12 to 18 months.
Please use the probes provided.
• 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.

• Rinse with water before use to enhance lubrication and conductivity.
• 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.

NOTE: As you should whenever receiving vaginal penetration, it is important to urinate after using your vaginal probe to remove any normal bacteria from the urethra. This will help to prevent UTI's.

Electrode pad

• Do not overlap use, and the electrode pad should be in full contact with the skin.
• Do not use on more than one person.Please replace when there is no adhesion or damage. The average service life is 50 times(30minutes each time).Service life is diminished in the presence of lotion,oil,dirt and hair.Please visit our website when it is time to replace your electrode pads.
  ▸ Model: KM-805A
  ▸ Size: 50*50mm
• Try to avoid touching the adhesion side of the electrode pads by hand.
• Ensure the skin you are attaching them to is clean and dry and free from injury.
• Do not wipe the pads with a tissue or cloth.
• In order to avoid environmental pollution, please dispose of accessories according to local environmental protection requirements.

4.7 Accessory Replacement Instruction

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

NOTE: Please use the wires, electrode pads 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.

4.8 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

5.1 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 1-2 month.
• Do not disassemble for repair without prior notification or you may void your warranty.

5.2 Disposal

DO NOT throw away the device with normal household waste at the end of its life. Lithium batteries require special disposal. Please 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	Possible Fix
Not booting	1. The battery is low 2. The product is damaged 3. Power button failure	1. Please charge 2. Repair or replace as needed
EMG test is unstable	1. The connection of probe or electrode is poor and the reference electrode is not connected. If the contact of the electrode pad or the probe is unstable, the impedance at the contact will become larger, and the external interference will be larger, resulting in an unstable EMG value and deviating from the actual value. 2. Unnecessary movement during the EMG acquisition process, interfere with EMG acquisition at the collection part.	1. Connect electrode pads 2. Avoid unnecessary motion disturbances
No stimulation output	1. The electrode is detached or connection is poor. 2. Internal electrical stimulation outputcircuit is damaged	1. Reinsert or replace electrode 2. Repair or replace as needed
No display on the screen	1. Screen damaged 2. The internal connection of the main unit is damaged Internal device damaged	Repair or replace as needed
No sound	1. The system sound is off 2. The speaker or the main unit is damaged	1. System settings to adjust the volume 2. Repair or replace as needed

7. Warranty Contents

7.1 Disclaimer

Shenzhen Konmed Technology Co., Ltd has provided all information regarding the operation of this biofeedback device. This information has been translated by our US representatives. No intentional changes to use or function have been made. Konmed is not responsible for any consequences caused by improper use by consumers.

7.2 Warranty

1) The stimulator carries a limited warranty of one year from the date of purchase. 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 invalidate this warranty.
2) Warranty services outsides the scope of warranty shall be charged according to regulations.
3) When applying for warranty, please provide your order number along with the mailing address associated with your purchase to our US customer care team using the contact information below.

7.3 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, Guangdong, CHINA.
Post code: 518118
Tel.: +86 755 8670 4556
Fax: +86 755 8670 4556
Website: www.konmed.cn
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, Guangdong, CHINA.
Post code: 518118
Tel.: +86 755 8670 4556
Fax: +86 755 8670 4556
Website: www.konmed.cn
E-mail: sales@konmed.cn

8.Annex I. Manufacturer's EMC Statement

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not application
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not application

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air	±8kV contact ±2kV, ±4kV, ±8kV, ±15kV air
Electrical fast transient/burst IEC 61000-4-4	Not application	Not application
Surge IEC 61000-4-5	Not application	Not application
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not application	Not application
Power frequency magnetic field IEC 61000-4-8	30A/m 50Hz/60Hz	30A/m 50Hz/60Hz
Conducted RF IEC 61000-4-6	3V and 6V in ISM and amateur radio bands between 0,15MHz and 80MHz 80% AM at 1kHz	3V and 6V in ISM and amateur radio bands between 0,15MHz and 80MHz 80% AM at 1kHz
Radio-Frequency Electromagnetic Field Amplitude Modulated IEC 61000-4-3	10V/m 80MHz – 2,7GHz 80% AM at 1kHz	10V/m 80MHz – 2,7GHz 80% AM at 1kHz
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic Immunity						
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)						
Test Frequency (MHz)	**Band** (MHz)	**Service**	**Modulation**	**Modulati on** (W)	**Distance** (m)	**IMMUNITY TEST LEVEL**(V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5kHz deviation 1kHz sine	2	0.3	28
710	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11b/g/n, RFID 2450,LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5875						

info@meditaliaservice.com
www.meditaliaservice.com
+39 3314605453
Via delle Barozze, 6 A
Rocca di Papa (RM)
Italia