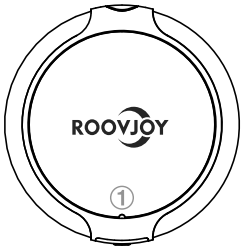
M101A-UK1-B

Instruction Manual For
Combo Electrotherapy Device



This manual is valid for the M101A-UK1-B(M101A-UK1-B indicates the host)M101A-UK1.R-C4D-WH1.M100A-WH1,R-C4D-RW1,R-W100A,R-W100BR-W100C,R-W100D.R-W100E,R-W100,R-W101A R-W101B. R-W101C.R-W101D, R-W101E.R-W101 stimulator

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

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Shenzhen Roundwhale Technology Co., Ltd.

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Declaration of conformity:

Shenzhen Roundwhale Technology Co., Ltd. declares that the device complies with following normative documents:IEC60601-1, IEC60601-1-2, IEC60601-1-11, IEC60601-2-10, IEC62304, ISO10993-5, ISO10993-10, ISO10993-1,ISO10993-23, ISO14971

CONTENS

01 FOREWORD

1.1 Introduction

The M101A-UK1 is a dual-output electrical stimulation therapy device controlled by a remote controller. Before using the device, it is essential to thoroughly read all the instructions provided in the user manual and to keep it safely for future use. This comprehensive guide will ensure that you understand the proper operation and application of the M101A-UK1, maximizing its therapeutic benefits while minimizing any potential risks associated with its use. By following the usermanual, you can ensure that the device is used effectively and in accordance with the manufacturer's recommendations, which is crucial for the safety and efficacy of the treatment. Proper storage of the manual will also allow for easy reference in the future, should any questions or concerns arise during subsequent uses of the M101A-UK1.

1.2 Medical background

1.2.1 ABOUT PAIN

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

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

1.2.2 WHAT IS TENS ?

TENS (Transcutaneous Electrical Nerve Stimulation) is effective in relief of pain. It is daily used and clinically proven by physiotherapists,

caregivers and top athletes around the world. High-frequency TENS currents activates the pain-inhibiting mechanisms of the nervous system. Electrical impulses from electrodes, placed on the skin over or near the pain area, stimulate the nerves to block the pain signals to the brain, causing the pain go unperceived. Low-frequency TENS currents facilitate the release of endorphins, the body's natural painkillers.

1.2.3 WHAT IS EMS ?

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

1.2.4 WHAT IS MASSAGE ?

The massage function is non-medical function. The Massage stimulation program provides relaxing muscle vibration to loosen tight muscles.

02 SAFETY INFORMATION

2.1 Intended use

Intended purpose

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

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

Target population

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

Intended user

Medical staff or lay persons.

Intended condition

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

Indications

1)It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, joint, hip, hand, abdomen, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.

2)Relaxation of muscle spasms.

3)Prevention or retardation of disuse atrophy.

4)Increasing local blood circulation.

5)Muscle re-education.

6)Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.

7)Maintaining or increasing range of motion.

2.2 Important Safety Precautions and Warnings

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

SAFETY SYMBOLS USED IN THIS MANUAL

⚠ 2.2.1 Contraindication

1 

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

2 

The device should not be used when cancerous lesions or other lesions are present in the treatment area.

3 

Stimulation should not be applied over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g.phlebitis, thrombophlebitis, varicose veins, arteriosclerosis obliterans etc.).

4 

Electrode placements must be avoided that apply current to the carotid sinus region (anterior neck) or transcerebrally (through the head).

❺ 

Apprehensive patients-usage of Electrical stimulation requires patient cooperation, hence the procedure shouldn't be attempted in patients with a communication handicap or a mental disability.

❻ 

Patients with cerebrovascular problems-patients with a history of aneurysm, stroke and transient ischaemia shouldn't be treated using electrical stimulation, as it stimulates peripheral blood flow which can be fatal in such cases.

❼ 

Epileptic patients-Electrical stimulation "pulses" have the potential to trigger a seizure.

❽ 

Acute pain cases/pain of unknown etiology-usage of TENS in undiagnosed cases may hinder in the diagnosis.

❾ 

Do not use in pregnancy, especially in the first trimester.

⚠ 2.2.2 WARNING

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

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

⚠ 2.2.3 Precautions

1) TENS is not effective for pain of central origin including headache
2) TENS is not a substitute for pain medications and other pain management therapies.
3) TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
4) Effectiveness is highly dependent upon patient selection by a practitioner qualified in the management of pain patients
5) Since the effects of stimulation of the brain are unknown, stimulation should not be applied across your head, and electrodes should not be placed on opposite sides of your head.
6) The safety of electrical stimulation during pregnancy has not been established.
7) You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (silica gel).

8) If you have suspected or diagnosed heart disease or epilepsy, you should follow precautions recommended by your physician.
9) Caution if you have a tendency to bleed internally, e.g. following an injury of fracture.
10) Consult with your physician prior to use the device after a recent surgical procedure, because stimulation may disrupt the healing process.
11) Caution if stimulation is intended to be applied over the menstruation or pregnant uterus.
12) For single patient use only.
13) This stimulator should not be used by patients who is noncompliant and emotionally disturbed including whom with dementia or low IQ.
14) The instruction of use is listed and should be obeyed; any improper use may be dangerous.
15) Rare cases of skin irritation may occur at the site of the electrode placement following long-term application.
16) Do not use this device in the presence of other equipment which sends electrical pulses to your body.
17) Do not use sharp objects such as a pencil or ballpoint tip to operate the buttons on the control panel.
18) Check the electrode connections before each use.
19) Electrical stimulators should be used only with the electrodes recommended for use by the manufacturer.
20) When output of device more than 10mA or 10 V, the intensity of Channel will filcker.
21) Users should consult a healthcare professional before using the device.
22) The user shall report any serious incident related to the device to the manufacturer and the competent authorities of the Member States establishing the user and / or the patient.

2.2.4 Adverse Reactions

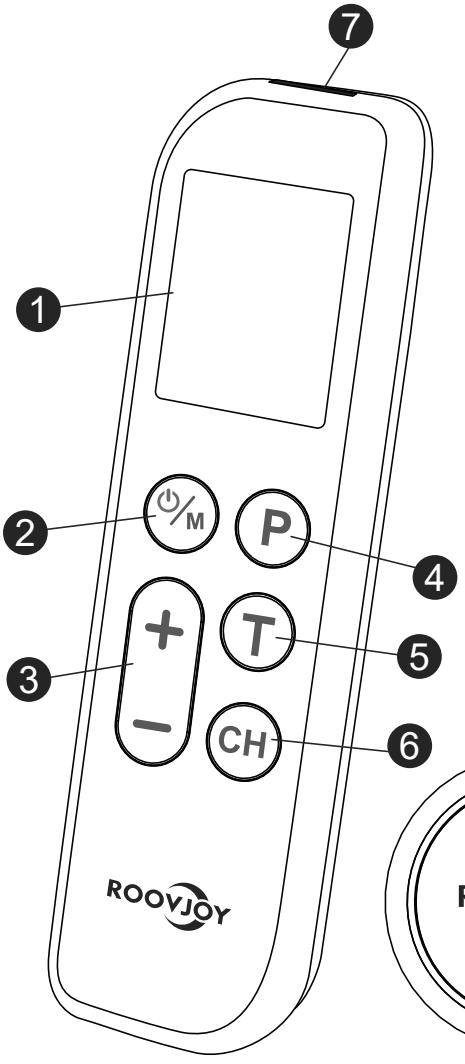
1) Possible skin irritation or electrode burn under the electrodes may occur.
2) Possible allergic skin reaction to tape or gel may occur.
3) On very rare occasions, first-time users of EMS report feeling light-headed or faint. We recommend that you use the product while seated until you become accustomed to the sensation.

4) If symptoms of tachycardia and extrasystolia (rapid heartbeat or extra stimulation) appear during treatment, stop the treatment and seek medical attention immediately.

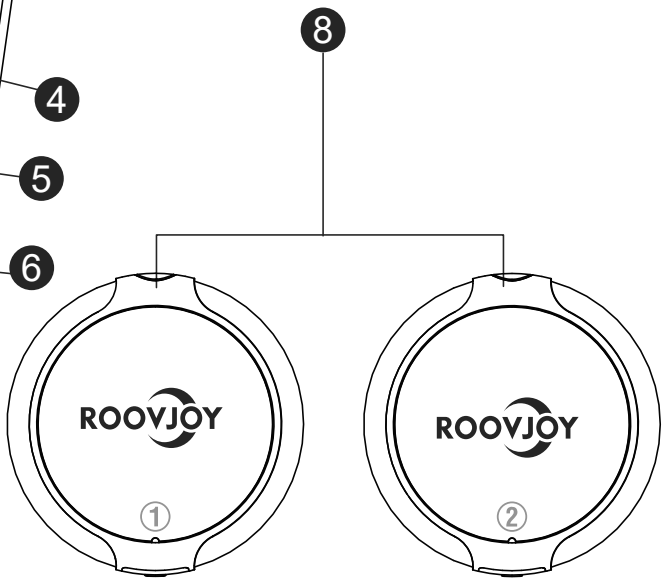
5) If the stimulation makes you uncomfortable, reduce the stimulation Intensity to a comfortable level and contact your physician if problems continue.

03 GETTING TO KNOW YOUR DEVICE

Product Details



1.LCD Screen
2. Power Switch Button/Mode Switch
3.Strength Increase/decrease Button
4.Program For Receiver Button
5.Treatment Time For Receiver Button
6.Chanel switch button
7.USB Socket
8.Wireless Receiver pods



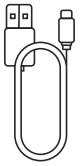
3.1 Package includes

2pcs
Wireless Receiver pods

1pc
Wireless Remote

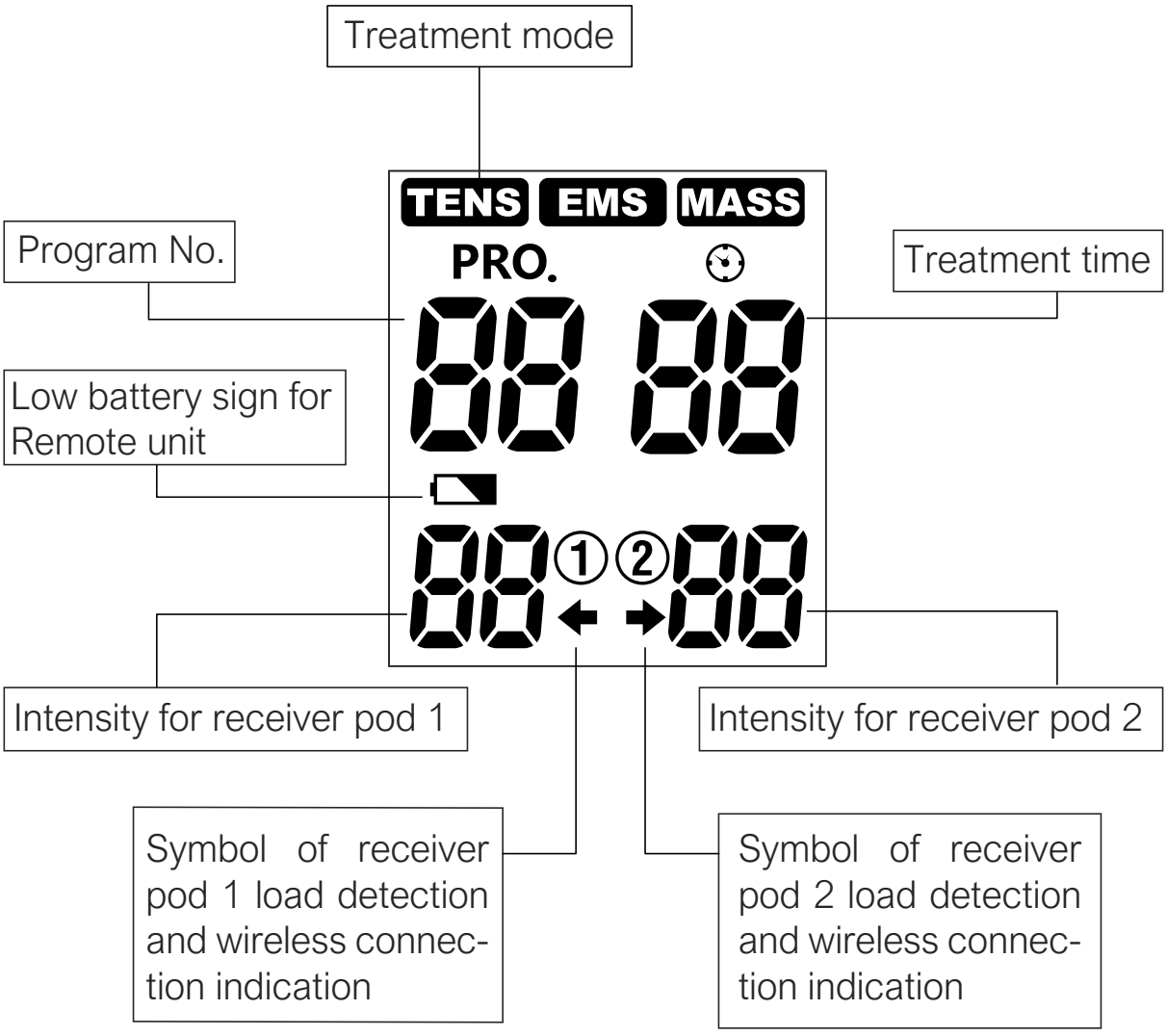
2pcs
Electrode pad

1pc
User manual



1pc
USB cable

3.2 LCD display for remote



3.3 Device illustration

Button Instructions

At power saving mode, press the [ON/OFF/M] button to turn on the Remote
At standby mode, press and hold the [ON/OFF/M] button to turn off the Remote
At standby mode, press the [ON/OFF/M] button select to treatment mode.

At standby mode and treating mode, press the [CH] button to swtich the treatment Receiver pod

At standby or treating mode, press the [+] button to increase the intensity of Receiver pod 1 or Receiver pod 2.

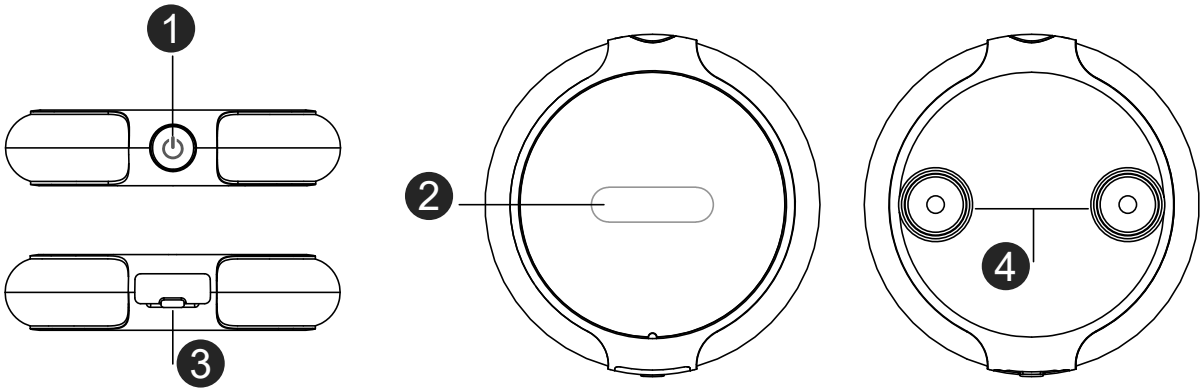
At treating mode, press [–] button to decrease the intensity of Receiver pod 1 or Receiver pod 2.

At standby mode, press the [P] button select to treatment program for Receiver pod 1 or Receiver pod 2.

At standby mode, press the [T] button to adjust the treatment time for Receiver pod 1 or Receiver pod 2.

Charger indicator:
When the device is charging, the indicator light will be red.
When charging is completed, the indicator light will be green.

Receiver pod 1 / 2



1. Power Switch button:

At power saving mode, press the button to turn on the Receiver pod.
At standby mode, press and hold the button to turn off Receiver pod.
At treating state, press the button briefly to stop the output.

2. LED indicator

Work state indicator :

Green (steady on): in standby mode;
Green (flashing): In treating mode;
Red (lights up based on the state, steady on in standby mode, flashing in treating mode): Low battery;

Charger indicator:

During charging, the red LED lights up
When fully charged, the green LED lights up

3. USB socket

4. Output socket

04 SPECIFICATION

4.1Technical information

Device name	Combo Electrotherapy Device
Model/type	M101A-UK1
Power sources	3.7 V Li-ion battery
Power supply	Input: 100-240V AC, 50/60Hz,0.2A; Output: 5V DC, 300mA
Output channel	Dual channel
Waveform	Bi-phase square-wave pulse
Output voltage	Max. 60V (at 1000ohm load)
Output intensity	0 to 20 levels, adjustable
Treatment mode	TENS, EMS and MASSAGE mode
Number of programs	18 program
Pulse rate	2Hz ~ 100Hz
Pulse width	30uS ~ 260uS
Treatment time	10 minutes ~ 90 minutes
Operating condition	5°C to 40°C with a relative humidity of 15%-93%, atmospheric pressure from 700 hPa to 1060 hPa
Storage condition	-10°C to 55°C with a relative humidity of 10%-95%, atmospheric pressure from 700 hPa to 1060 hPa
Dimension	Remote unit: 135 * 42 * 10mm (L x W x H) Receiver pod 1/2: 58.5 * 57.5 * 13mm (L x W x H)
Weight	Remote unit: About 41g Receiver pod 1/2: About 24g
Automatic shutoff	Remote unit: 2.5 minute
Device service life	5 years
Electrode pads shelf life	3 years
Classification	BF type applied part, internal power equipment, IP22
Size of electrodes pad	120 x 60mm
Communication method	2.4 G
Output precision	±20% error is allowed for all the output parameters

For TENS Programs

When using any of the TENS programs for pain relief always start with the lowest intensity and gradually increase the level of intensity until you feel a “tingling” sensation. All programs are different and therefore feel differently. You may try all programs in the beginning and choose one that feels pleasant. Never increase the intensity to a level so that it hurts, always stay under the point of discomfort. Start with short sessions of 5 or 10 minutes until your body gets used to the stimulation.

Mode	Program NO.	You should feel
TENS	1	High-frequency stimulation that causes a tingling sensation.
	2	Continuous comfortable tingling. The underlying pain should decrease gradually after treatment.
	3	Comfortable pulsing sensation. The underlying pain should decrease almost immediately.
	4	Variable comfortable tingling and pulsing sensation (sensation should appear to come in waves). Pain should ease and there should be relief after treatment.
	5	Variable comfortable pulsing and pumping action (action will appear to come in waves).
	6	Continuous comfortable tingling. The underlying pain should decrease gradually after treatment.
	7	Continuous comfortable tingling. The underlying pain should decrease gradually after treatment.
	8	Variable comfortable mild tingling sensation (sensation will appear to come in waves).
	9	High-frequency stimulation that causes a tingling sensation.

For EMS Programs

When using the device for muscle stimulation (EMS) any of the 5 programs may be used. The intent is to cause a muscle to contract, and then release. All 5 programs will achieve contraction and vary mainly by the rate and duration of the contractions. As with any exercise regiment, start out slowly with low intensity levels for a warm-up (5~10min). You may increase intensity level and treatment time as you progress with your muscle performance. Use the device regularly over a longer period of time as to maintain the benefit you may have gained during “exercise”.

Mode	Program NO.	You should feel
EMS	10	This program produces muscle twitches at very low frequency and it feels like a tapping massage, for muscle recovery from fatigue and becoming more relaxed with reduced stiffness.
	11	This program is similar to P10, except that the muscle twitch rate slows down during the session. It feels like a tapping massage, but softer than P10.
	12	Simulate the process of muscle training. During the exercise, there are 'work' and 'rest' phases
	13	Simulate the process of muscle training. During the exercise, there are 'work' and 'rest' phases
	14	Simulate the process of muscle training. During the exercise, there are 'work' and 'rest' phases

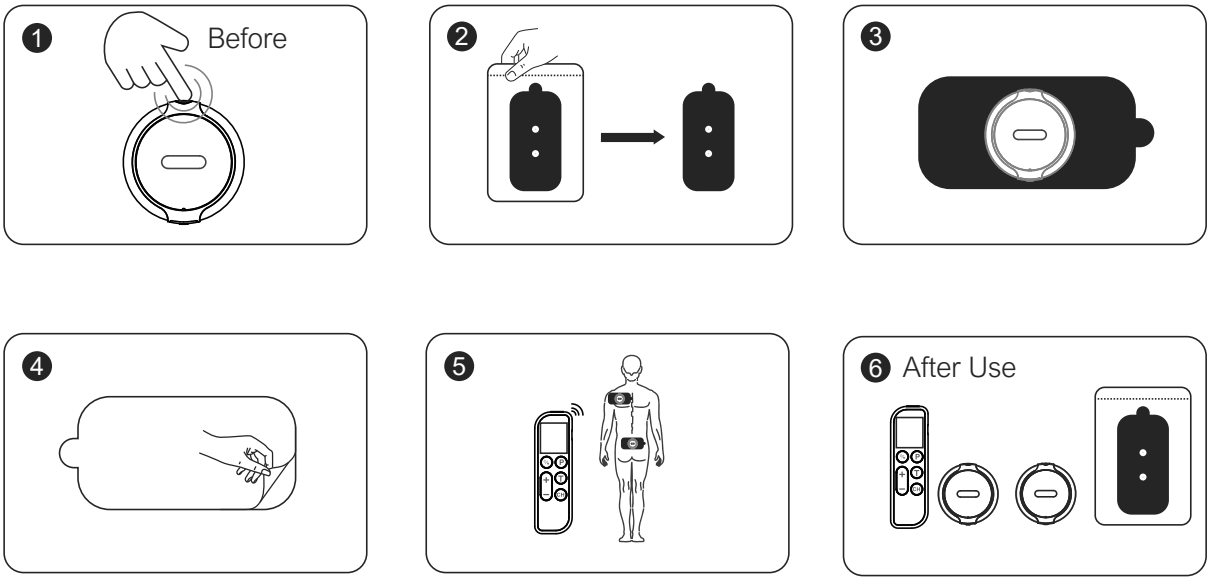
For MASSAGE Programs

The massage function is non-medical function. The Massage stimulation program provides relaxing muscle vibration to loosen tight muscles.

Mode	Program NO.	You should feel
MASSAGE	15	Comfortable slapping feeling.
	16	It feels like a patting massage
	17	It feels like a kneading massage
	18	It feels like a rubbing massage

05 OPERATING INSTRUCTION

5.1 Attach electrode pads to Receiver pod



Before proceeding to this step, ensure that the Receiver pod is completely switched OFF. Tear the electrode pad transparent plastic bag to take out the electrode pads. Fasten the electrode pad buckle with the magnetic buckle of the Therapy Device, remove the electrode pad protective film, paste the adhesive surface on the treatment site, e.g.back, and keep the electrode pad in tight contact with the skin; after use, paste back the protective film for later use.

5.2 Electrode

5.2.1 Electrode options

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

5.2.2 Place electrodes on skin

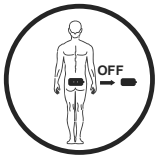
Place the electrode on the body part in need of treatment, according to the instruction of this user manual. Please make the skin clean before use and ensure the skin and electrode connect well.

⚠ Caution

❶ Always remove the electrodes from the skin with a moderate pull in order to avoid injury in the event of highly sensitive skin.

❷ Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.

❸ Do not turn on the device when the self-adhesive electrodes are not positioned on the body.



❹ To remove or move the electrodes, switch off the device or the appropriate channel first in order to avoid unwanted irritation.

❺ Never remove the self-adhesive electrodes from the skin while the device is still on.

5.3.3 Electrode placement

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

Position of electrode placement under TENS , EMS and MASSAGE programs

Mode setting:

TENS

The TENS mode offers 9 different type, each with a unique frequency and pulse width. You can choose the type and intensity that suits you best or provides the most comfort for your treatment, but the intensity should not be adjusted beyond the threshold that make muscle contraction, so the muscle contractions are not visible in TENS mode.

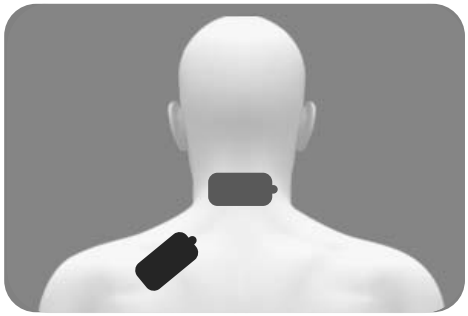
EMS

The EMS mode offers 5 different type, each type has a different characteristic discharge rule, you can choose the type and intensity that suits you best or provides the most comfort for your treatment. You can see a significant contraction of the muscles. The force is applied in the same direction or opposite direction when the discharge contracts,then rest for 15 seconds.

MASSAGE

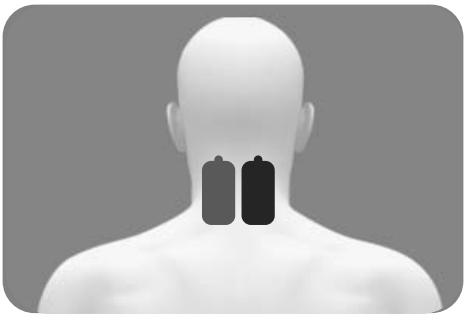
The MASS mode offers 4 different type, each type has a different characteristic discharge rule, you can choose the type and intensity that suits you best or provides the most comfort for your treatment. The feeling is like someone giving you a nice body massage.

Neck placemen



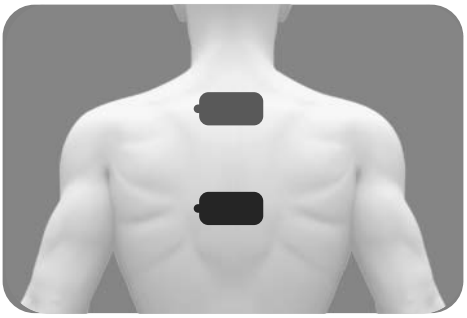
1.Chronic cervical spine pain

Channel 1 is attach to the Both sides of spinous process of Cervical pain segment.
Channel 2 is attach to the Middle of the superior trapezius muscle.



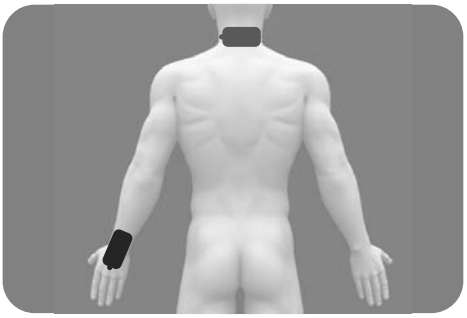
2.Paravertebral muscle strain

Channel 1 is attach to the longitudinally between the upper and lower vertebrae of the cervical pain segment.
Channel 2 is attach to the longitudinally between the upper and lower vertebrae of the cervical pain segment.



3.Pain in the upper back and medial margin of the scapula

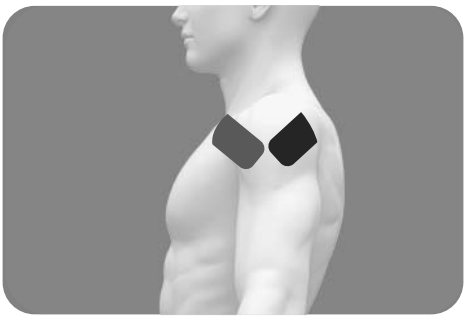
Channel 1 is attached to the cervicothoracic junction.
Channel 2 is placed between the medial margin of the scapula and the painful segment of the thoracic vertebra.



4.Cervical radiculopathy with distal radiating pain

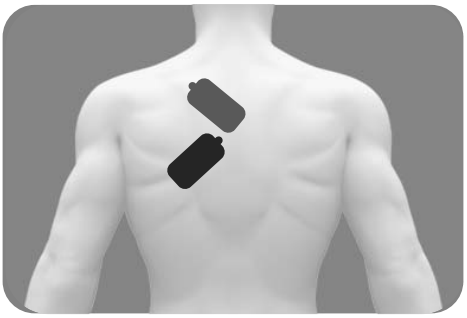
Channel 1 is attach to the both sides of spinous process of Cervical pain segment.
Channel 2 is attach to the area of the arm or palm that is numb and radiating pain.

Shoulder placement



1.Pain from periarthritis of shoulder

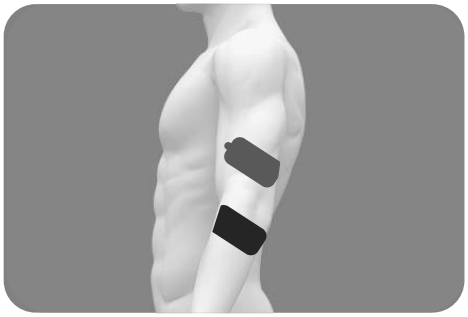
Channel 1 attaches to the anterior deltoid tract, around the head of the humerus.
Channel 2 is attached to the posterior shoulder joint, the posterior deltoid tract.



2.Pain around the shoulder blades

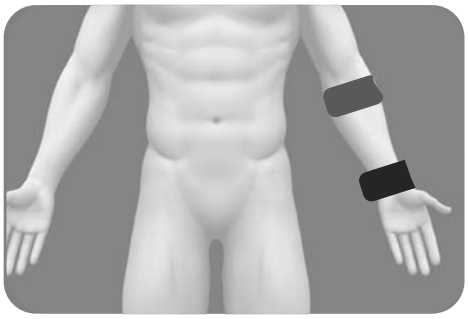
Channel 1 is attached to the upper corner of the scapula, parallel to the scapula.
Channel 2 is longitudinally attached to the inner edge of the scapula.

Arm placement



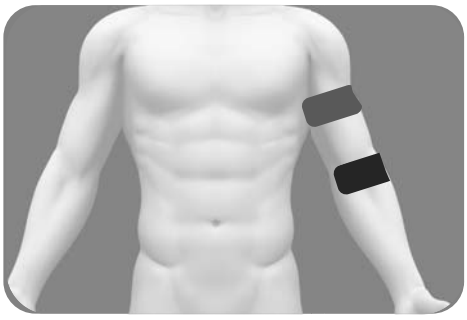
1.Tennis elbow pain

Channel 1and Channel 2:Tow electrodes cross the pain area-lateral epicondyle of humerus.



2.Sore or radiating muscles in the arm

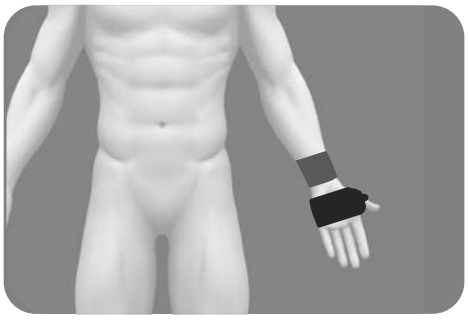
Channel 1 is attached to the distal upper arm.
Channel 2 is attached to the wrist.



3.Muscle strain or DOMS(Delayed onset of muscle)in the upper extremities

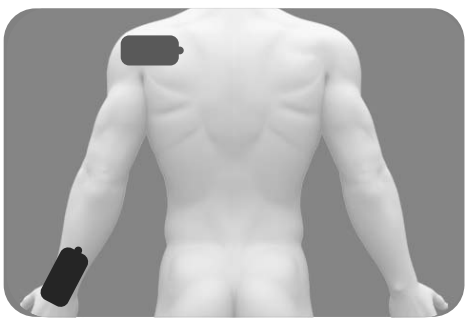
Channel 1and Channel 2 : Locate the pain area and cross channel 1 and channel 2 here，Like the pain points in the biceps and triceps

Hand placement



1.Hand pain or carpal tunnel syndrome

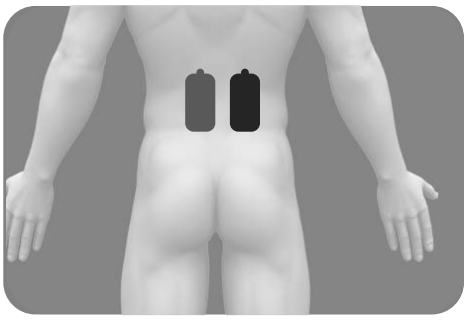
Channel 1 is attached to the distal upper arm.
Channel 2 is attached to the wrist.



2.Shoulder and neck pain accompanied by numbness in the fingers

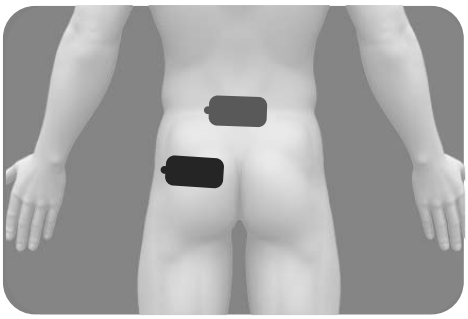
Channel 1 is attached to the upper posterior axilla.
Channel 2 is attached to the numb palm or back of the hand.

Back placement



1.Lumbar disc herniation or lumbar muscle strain pain—No radiating pain in the lower extremities

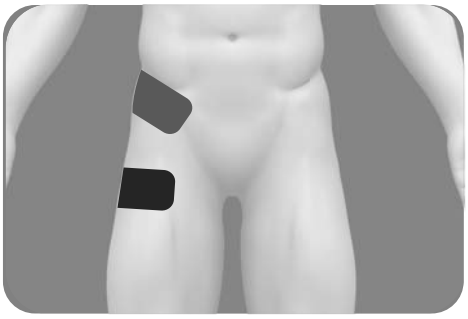
Channel 1and Channel 2 :Locate the pain area and cross channel 1 and channel 2 here.



2.Lumbar disc herniation with sciatica

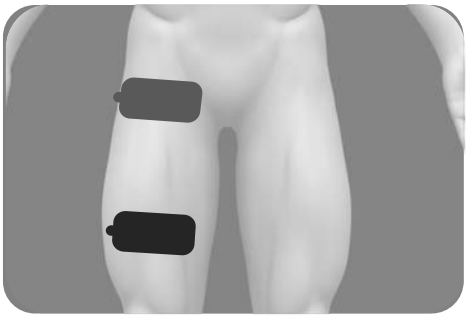
Channel 1 is attached to the pain area of low back.
Channel 2 is attached to the gluteus maximus (sciatic nerve outlet, beside the sacrum).

Leg placement



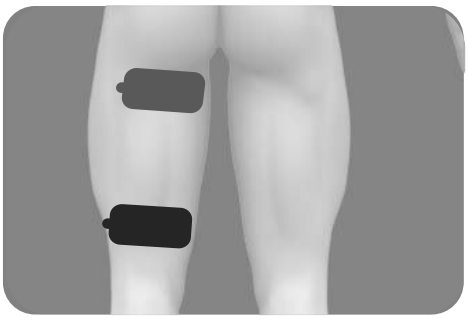
1.Hip strain pain

Channel 1 is attached to the groin.
Channel 2 is attached to the greater trochanter on the outside of the leg.



2.DOMS (Delayed onset of muscle) after leg training

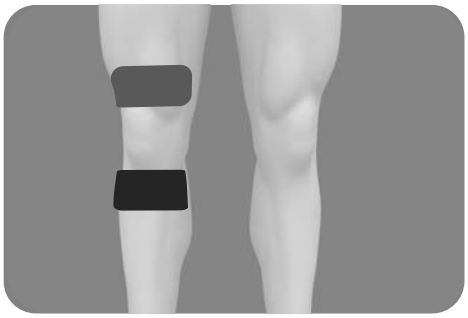
Channel 1and Channel 2: Locate the pain area and cross channel 1 and channel 2 here.



3.Soreness or strain in the hamstring

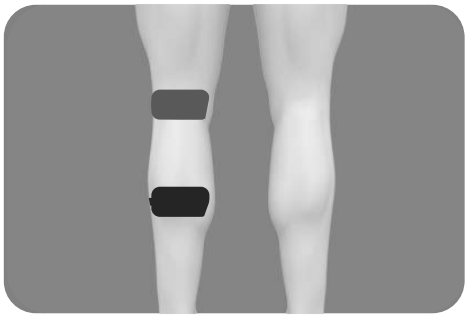
Channel 1 is attached to the ischial tubercle on the upper leg.
Channel 2 is attached to the upper popliteal space.

Knee joint placement



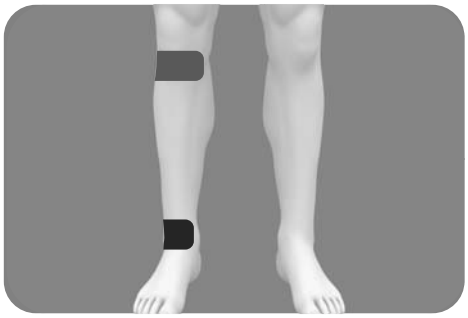
1.Knee osteoarthritis pain/Pain after cruciate ligament reconstruction of knee joint/Pain after overworking the knee joint

Channel 1: Cross the diagonal of the patella.
Channel 2: Cross the diagonal of the patella.



2.Soreness or strain in calf

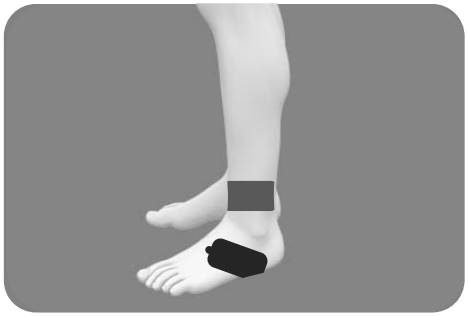
Channel 1 and Channel 2 : Locate the pain area and cross channel 1 and channel 2 here.



3.Foot drop due to nerve injury/atrophy of anterior tibial muscle/muscle soreness after exercise in front of calf

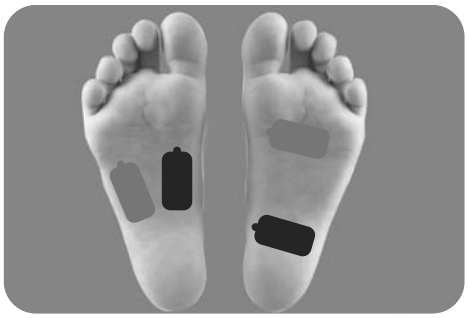
Channel 1 is attach to the lateral common peroneal nerve outlet of the knee joint.
Channel 2 is attached above the lateral ankle join.

Ankle and foot placement



1.Pain after spraining the ankle

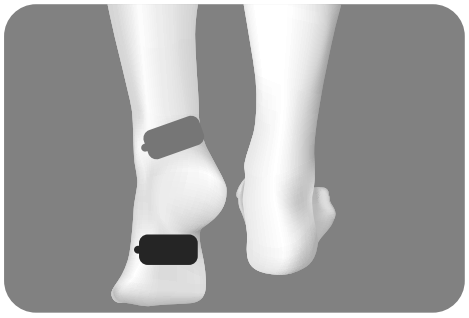
Channel 1 and Channel 2 are placed across the outside of the ankle joint



2.Plantar fasciitis

Channel 1 is attach to the medial arch of foot.
Channel 2 is attach to the lateral arch of foot.

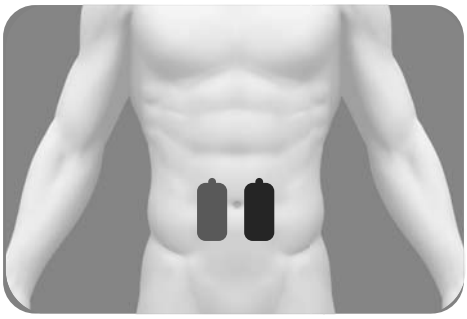
Channel 1 is attached to the bottom of the front foot.
Channel 2 is attached to the bottom of the back foot.



3.Calcaneodynia

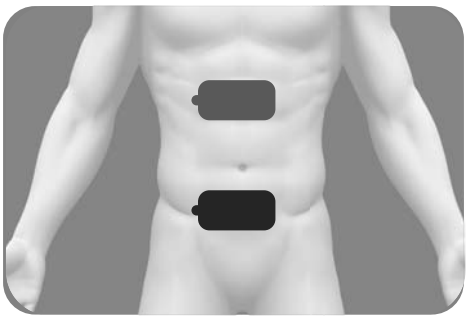
Channel 1 is attached to the Achilles tendon.
Channel 2 is attached to the bottom of the back foot.

Abdomen placement



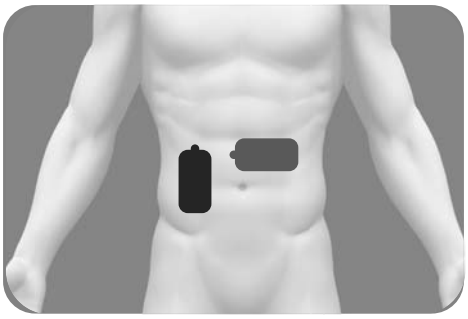
1.Dysmenorrhea/abdominal pain

Channel 1 and Channel 2 : Locate the pain area and cross channel 1 and channel 2 here.



2.Abdominal muscle training/relax/pain relief

Channel 1 is attached to the upper abdominal muscles.
Channel 2 is attached to the lower abdominal muscles.



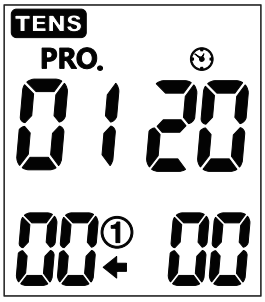
3.Stomach

Channel 1 is attached to the stomach.
Channel 2 is longitudinally attached to the contralateral abdominal muscle.

06 INSTRUCTIONS FOR USE

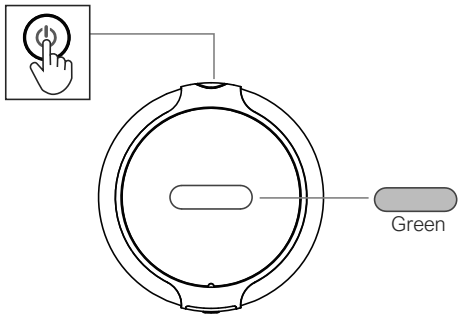
6.1 Control operations for the Receiver pod 1

❶ Turn on



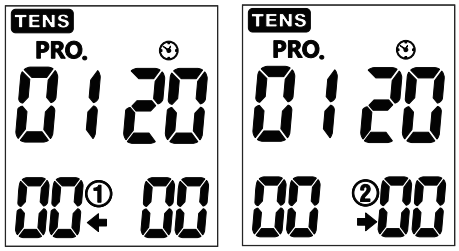
Press the [ON/OFF/M] button on the Remote to turn it on. After the screen displays completely, enter standby mode. The screen display is as follows:

❷ Turn on



Press the [ON/OFF] button on Receiver pod 1 to turn it on, and the green LED indicator light stays on.

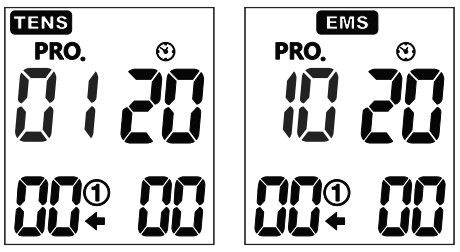
❸ Select the Receiver pod



Press the [CH] button on the Remote to select the treatment Receiver pod. The screen display is as follows:

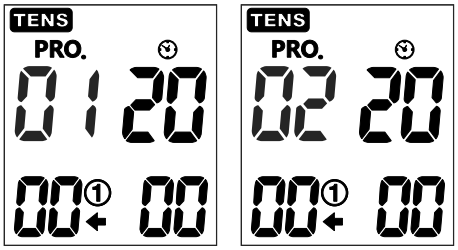
⚠ Note: If any Receiver pod is not turned on (cannot connect), the channel indicator will flash (00①/②00)

❹ Select treatment mode



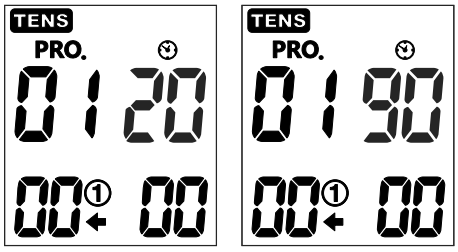
The user, based on their needs, presses the [ON/OFF/M] button on the Remote to select the treatment mode.

❺ Select treatment program



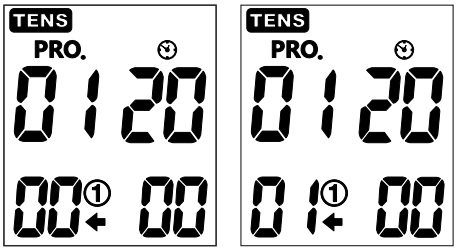
The user, based on their needs, presses the [P] button on the Remote to select the treatment program.

❻ Adjust treatment time



The user, based on their needs, in standby mode, presses the [T] button to adjust the treatment time.

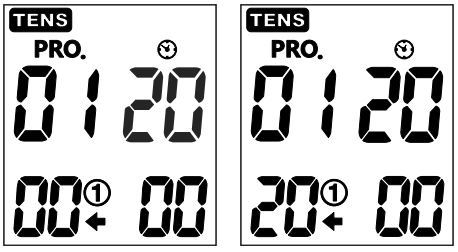
❼ Start treatment



Receiver pod 1 to the electrode pads and place them on the appropriate body part. Press the [+] button on the Remote to start treatment. The Remote display is as follows:

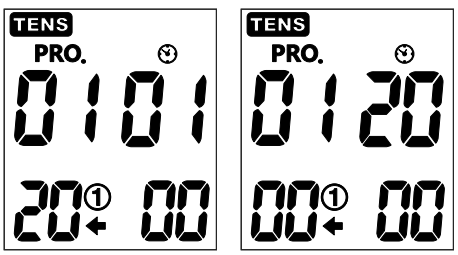
At this point, the green LED light on Receiver pod 1 flashes.

❽ Adjust treatment intensity



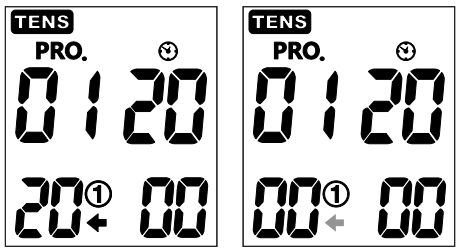
After the user starts treatment, the intensity of Receiver pod 1 can be adjusted by pressing the [+] and [-] buttons on the Remote .

❾ Stop treatment output



Adjust the intensity of Receiver pod 1 to 0, or when the treatment time ends, the Receiver pod 1 will automatically stop the treatment output and return to standby mode. The Remote display will be as follows: At this point, the green LED light on Receiver pod 1 will stop flashing and remain steady on.

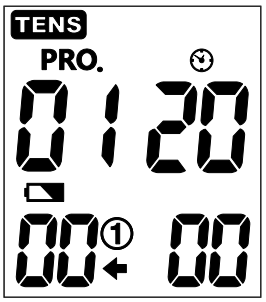
⑩ Load detection function



During use, if the intensity level is set to 5 or higher and the electrode pads are poorly connected or detached, Receiver pod 1 will automatically detect this and set the intensity to 0. The corresponding load indication symbol (←) on the remote control screen will flash, and the intensity display will show 0. The screen display is as follows:

At this point, the green LED light on Receiver pod 1 will stop flashing and remain steady on.

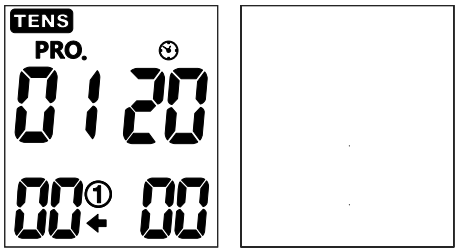
⑪ Low voltage indication function



When the Remote battery voltage is below 3.5V, the low voltage symbol starts flashing to indicate that the Remote battery is low, reminding the user to charge it. The screen display is as follows:

When the battery voltage of Receiver pod 1 is below 3.5V, the green LED light turns into a red LED light.

⑫ Turn off the device



Long press the [ON/OFF/M] button on the Remote to turn off the device.

Long press the [ON/OFF] button on Receiver pod 1 to turn off Receiver pod 1.

6.2 Control operations for the Receiver pod 2

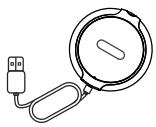
Receiver pod 2 has the same control steps as Receiver pod 1. Please refer to the control steps of Receiver pod 1 for operation.

6.3 Charging the Battery:

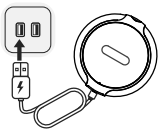
❶ This device cannot be used while charging.

❷ Make sure that the device is no longer connected to the patient .

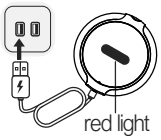
❸ Connect the USB cable to the charging port on the device.



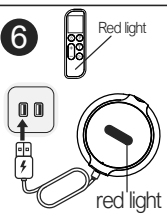
❹ Connect the USB cable to the charger.



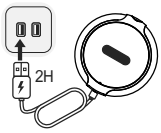
❺ During charging, the red LED lights up for Receiver pod



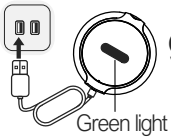
❻ During charging, the Red LED lights up for Remote



❼ It could take up to 2 hours to reach a full charge.



❽ When fully charged, the green LED lights up



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

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

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

6.4 Usage of electrode pads

1 The electrode may only be connected with the Combo Electrotherapy Device. Make sure that the device is turned off when attaching or removing the electrode pads.

2 If you want to reposition the electrode during the application, turn the device off first.

3 The usage of electrode may lead to skin irritations. If you experience such skin irritations, e.g. redness, blistering or itching, discontinue using them. Do not use the Combo Electrotherapy Device permanently on the same body part, as this may also lead to skin irritations.

4 Electrode pads are private and intended for single person use. Please avoid using them by different persons.

5 The electrode must connect entirely to the skin surface to prevent hot spots, which may lead to skin burns.

6 Do not use the electrode pads for more than 15 times, as connection between the electrodes and the skin deteriorates over time.

7 The adhesive force of the electrodes depends on the skin properties, storage condition, and the number of applications. If your electrode pads no longer fully stick to the skin‘s surface, replace them with new ones. Stick the electrode pads back onto the protective foil after use and store them in the storage bag to prevent them from drying out. This retains the adhesive force for a longer period.

8 Do not use detergent to clean the electrode pads before and after use to avoid damaging the adhesion of the electrode pads.

9 The electrode pads must always be touched with clean hands, it is recommended to replace the electrode pads if they become dirty.

Caution:

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

6.5 Where do I attach electrode pads?

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

07 CLEANING AND MAINTENANCE

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

7.1 Cleaning and care for the device

7.1.1 Pull the electrodes out of the stimulator, clean the device with a soft, slightly damp cloth. In case of heavier dirt build-up, you may also apply a mild detergent.

7.1.2 Do not expose the Combo Electrotherapy Device to moisture or dampness. And do not hold the Combo Electrotherapy Device under running water, nor submerge it in water or other liquids.

7.1.3 The Combo Electrotherapy Device is sensitive to heat and may not be exposed to direct sunlight. And do not place it on hot surfaces.

7.1.4 Clean the surface of the electrode pads carefully with a damp cloth. Make sure the device is turn off!

7.1.5 For reasons of hygiene, each user should use his/her own set of electrodes.

7.1.6 Do not use any chemical cleaners or abrasive agents for cleaning.

7.1.7 Ensure that no water penetrates into the machine. Should this happen, use the device again only when it is completely dry.

7.1.8 Do not clean the device during treatment. Be sure that the device is turned off and the battery is unloaded before cleaning.

7.2 Maintenance

7.2.1 The manufacturer didn't authorize any maintenance agencies abroad. If your device has any problems, please contact the distributor. The manufacturer will not be responsible for the results of maintenance or repairs by unauthorized persons.

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

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

Each product in manufacturing has been through the systematic validation. The performance is stable and does not need to undertake calibration and validation.
If your product can't reach the expected performance and the basic function has changed in normal use, please_contact the retailer.

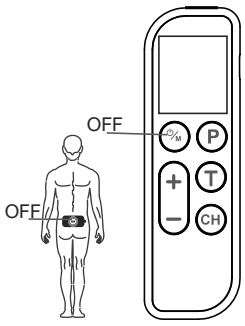
08 TROUBLESHOOTING

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

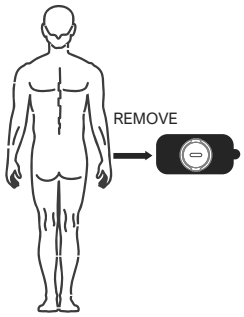
Malfunction	Common reasons	Countermeasure
No display	The battery is exhausted	Charge in time
No sensation of stimulation or weak stimulation	1. The electrode does not connect well to the skin. 2. If the connection between electrode connects well to the stimulator. 3. The battery is used up. 4. The skin is too dry.	1. Check and re-paste it on skin. 2. Check the connection. 3. Charge. 4. Wipe the electrode and the skin with a wet cotton cloth.
Automatic halt in the treatment	1. The electrode loses connection with the skin. 2. If the battery is used up.	1.Check and replace the electrode properly on the skin. 2. Charge
Rash or tickle on the skin occurs in the treatment	1. The treatment time lasts too long. 2. The electrode does not stick well to the skin. 3. The interface of the electrodes is dirty or dry. 4. The skin is sensitive to the electrode.	1. Do the treatment once a day and shorten the treatment time. 2. Check and stick the electrode well. 3. Wipe the electrode with a wet cotton cloth before use. 4. Check your allergic history. Please change the sticking place or shorten the treatment time.If your skin is over-sensitive, you should stop the treatment or go to see a doctor

09 STORAGE

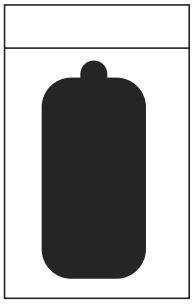
9.1 Storing the Electrode Pads



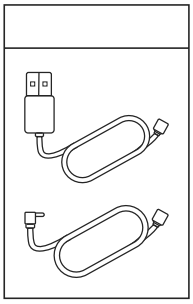
1. Turn the device off .



2. Remove the electrodes from your body.

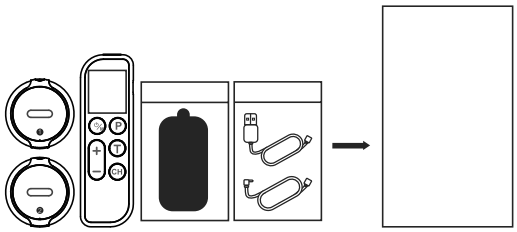


3. Place the electrodes into the plastic film and then store into the sealed package.

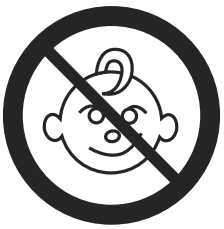


4. Wrap the lead wires and store into the sealed package.

9.2 Storing the Unit

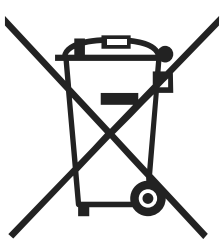


1. Place the unit, electrodes and manual back into the gift box. Store the box in a cool, dry place, -10℃ ~ 55℃; 10% ~ 95% relative humidity.



2. Do not keep in places that can be easily reached by children

10 DISPOSAL



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

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

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

11 ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and manufacture's declaration-electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Class B	The device is suitable for use in all establishments including those directly connected to the public low-voltage power supply network that supplies to buildings power used for domestic purposes
Harmonic emissions IEC61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions IEC61000-3-3	Not applicable	

Guidance and manufacture's declaration — electromagnetic immunity

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

Immunity test	Electrostatic discharge (ESD) IEC61000-4-2
IEC 60601 Test level	±8kV direct & indirect contact; ±15kV air discharge
Compliance level	±8kV direct & indirect contact; ±15kV air discharge
Electromagnetic environment-guidance	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%

Immunity test	Electrical fast transient/burst IEC 61000-4-4
IEC 60601 Test level	±2 kV for power supply lines
Compliance level	not applicable
Electromagnetic environment-guidance	not applicable (for INTERNALLY POWERED ME EQUIPMENT)

Immunity test	Surge IEC 61000-4-5
IEC 60601 Test level	± 1 kV line(s) to line(s)
Compliance level	not applicable
Electromagnetic environment-guidance	not applicable (for INTERNALLY POWERED ME EQUIPMENT)

Immunity test	Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11
IEC 60601 Test level	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec
Compliance level	not applicable
Electromagnetic environment-guidance	not applicable (For INTERNALLY POWERED ME EQUIPMENT

Immunity test	Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8
IEC 60601 Test level	10V/m
Compliance level	10V/m
Electromagnetic environment-guidance	Power frequency magnetic fields should be at levels characteristic of a typical location in typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacture's declaration – electromagnetic immunity

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

Immunity test	Radiated RF IEC 61000-4-3
IEC 60601 test level	10V/m & table 9
Compliance level	10V/m & table 9
Electromagnetic environment-guidance	Portable and mobile RF communications equipment should be used not closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.167\sqrt{P}$ 80 MHz to 800 MHz $d=2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (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 vicinity of equipment marked with the following symbol: 

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

NOTE 2
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

ⓐ Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the

device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

ⓑ Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [Vi] V/m.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Table 9)						
Test frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [c] ±5kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4,25; UMTS	Pulse modulation[b] 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[b] 217Hz	2	0.3	28
5240	5100-5800	WLAN 802. 11 a/n	Pulse modulation[b] 217Hz	0.2	0.3	9
5500						
5785						

NOTE

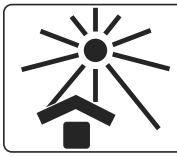
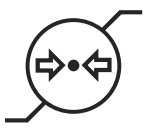
If it is necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

a For some services, only the uplink frequencies are included.

b The carrier shall be modulated using a 50 % duty cycle square wave signal.

c As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because it does not represents actual modulation. It would be worst case.

12 NORMALIZED SYMBOLS

	WEEE Symbol		Applied part of type BF
	Refer to instruction manual	IP22	IP classification
LOT	Batch code	EC REP	Authorized representative in the European Community
	Manufacturer		Date of manufacture
	Fragile, handle with care		Keep away from sunlight
	Keep dry		Temperature limit
	Use-by date	SN	Serial number
	Humidity limitation		Atmospheric pressure limitation

Caution

Recycling symbol

Users of the artificial pacemaker are prohibited from using the device

CE 2460

CE mark

Packaging material cycle mark

UDI

Unique device identifier

MD

Mdeical device

13 WARRANTY

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

The warranty terms are as below:

1. The warranty period for this device is 1 year from date of purchase. In case of a warranty claim, the date of purchase has to be proven by means of the sales receipt or invoice.
2. Repairs under warranty should be in the warranty period either for the device or for the replacement parts.
3. The following cases are excluded under the warranty
   - All damages that arise due to improper operation, e.g. nonobservance of the user instruction.
   - All damages due to repairs or tampering by the customer or unauthorized third parities.
   - Damage which has arisen during transport from the manufacturer to the consumer or the service centre.
   - Accessories which are subject to normal wear and tear.
   - Device damages due to privately dissembling devices.
4. Liability for direct or indirect consequential losses caused by the unit is excluded even if the damage to the unit is accepted as a warranty claim.

Shenzhen Roundwhale Technology Co., Ltd.

Address:
202, 2/F, Building 27,Dafa Industrial Park, longxi community,longgang street, longgang district, Shenzhen, China.

E-mail: info@roovjoy.com

EC REP

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

CE 2460

FCC Caution：

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

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

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

-Reorient or relocate the receiving antenna.

-Increase the separation between the equipment and receiver.

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

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

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