INSTRUCTION MANUAL
FOR
Combo Electrotherapy Device

Model: R-C101W



Shenzhen Roundwhale Technology Co., Ltd.

This manual is valid for the R-C101W Stimulator

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

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Declaration of conformity:

Shenzhen Roundwhale Technology Co., Ltd. declares that the device complies with following normative documents:
IEC60601-1, IEC60601-1-2, IEC60601-1-11, IEC60601-2-10, IEC62304, ISO10993-5, ISO10993-10, ISO10993-1, ISO10993-23, ISO 14971

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1. FOREWORD

1.1 Introduction

The device R-C101W is a dual channel output TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electronic Muscle Stimulation), IF (Interferential) , Russian and Microcurrent (MIC) stimulator. Before using, please read all the instructions in this user manual carefully and keep it safe for future use.

1.2 Medical background

1.2.1 ABOUT PAIN

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

Aside 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 IF ?

Interferential Stimulation (IF) is an anti-inflammatory based treatment modality. Interferential stimulation is characterized by two alternating-current sine waves or square

waves of differing frequencies that “work” together to produce an interferential current that is also known as a beat pulse or alternating modulation frequency. One of the two currents is usually held at 5,000Hz (or 10,000Hz),and the other can be held constant or varied over range of 5,001 to 5150Hz (or 10,001 to 10150Hz).
Because of the frequency, the interferential wave meets low impedance when crossing the skin to enter deep into soft tissues. The interferential currents reportedly can stimulate sensory, motor, and pain fibers. These large impulse fibers interfere with the transmission of pain messages at the spinal cord level.This deep tissue penetration stimulates parasympathetic nerve fibers for increased blood flow and edema reduction.It utilizes the low electric-current to stimulate muscle nerves to achieve the symptomatic relief of chronic intractable pain, post-traumatic pain, and post-surgical pain.

1.2.5 WHAT IS RUSS ?

Russian stimulation uses medium frequencies to provide electrical stimulation to muscle groups and is used to reduce muscle spasms as well as for muscle strengthening. Russian stimulation is a specific form of electro-stimulation with a Symmetrical Biphasic Square waveform produced by dividing a 2,500Hz carrier frequency into 20 - 80Hz packets. This method was claimed by its author (Kots) to produce maximal muscle strengthening effects without significant.

1.2.6 WHAT IS MICROCURRENT (MIC)?

Microcurrent stimulation is a type of therapy in which very low current is sent into the cells of the body. Microcurrent is a very faint current that is so small it is measured in millionths of an amp (Microamps). Human cells generate a current that is in the microamp range which is why you can’ t feel it the current is so low it doesn’ t stimulate the sensory nerves. Microcurrent is a physiological electric modality that increases ATP (energy) production in the cells of your body. This dramatically increases the tissue’ s healing rate. The immediate response to the correct microcurrent frequency suggests that other mechanisms are involved as well.The exact effects or changes in the tissue are unmistakable; scars will often suddenly soften; trigger points often become less painful within minutes when the “correct” - frequency is applied. In many situations the changes seen seem to be long lasting and in many cases permanent.

2. SAFETY INFORMATION

2.1 Intended use

Intended purpose

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

prevention of muscular atrophy, muscle strengthening and improve，Increasing local blood circulation and facilitate muscle performance.

Target population

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

Intended user

Medical staff or lay persons.

Intended condition

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

Indications

1)It is used for temporary relief of pain associated with sore and aching muscles in the neck, shoulder, back, joint, hip, hand, abdomen, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.
2)Relaxation of muscle spasms.
3)Prevention or retardation of disuse atrophy.
4)Increasing local blood circulation.
5)Muscle re-education.
6)Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
7)Maintaining or increasing range of motion.

2.2 Important Safety Precautions and Warnings



It is important that you read all the warnings and precautions included in this manual because they are

intended to keep you safe, prevent risk of injury and avoid a situation that could result in damage to the device.

SAFETY SYMBOLS USED IN THIS MANUAL

⚠ 2.2.1 Contraindication

1) Do not use this device if you are 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).
5) 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.





6) Patients with cerebrovascular problems-patients with a history of aneurysm, stroke and transient is chaemia

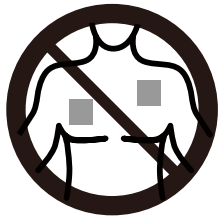
shouldn’ t be treated using electrical stimulation, as it stimulates peripheral blood flow which can be fatal in such cases.

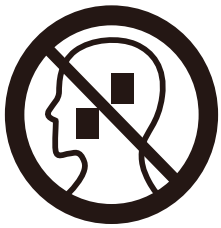
7) Epileptic patients-Electrical stimulation “pulses” have the potential to trigger a seizure.
8) Acute pain cases/pain of unknown etiology-usage of TENS in undiagnosed cases may hinder in the diagnosis.
9) Do not use in pregnancy, especially in the first trimester.

2.2.2 ⚠ WARNING

1) If you have had medical or physical treatment for your pain, consult with your physician before use.
2) If your pain is not subdued, 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 re-

sult 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 using 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 flicker.
21) Users should consult a healthcare professional before using the device

22) The user shall report any serious incident related to the device to the manufacturer and the competent authorities of the Member States establishing the user and / or the patient.

2.2.4 Adverse Reactions

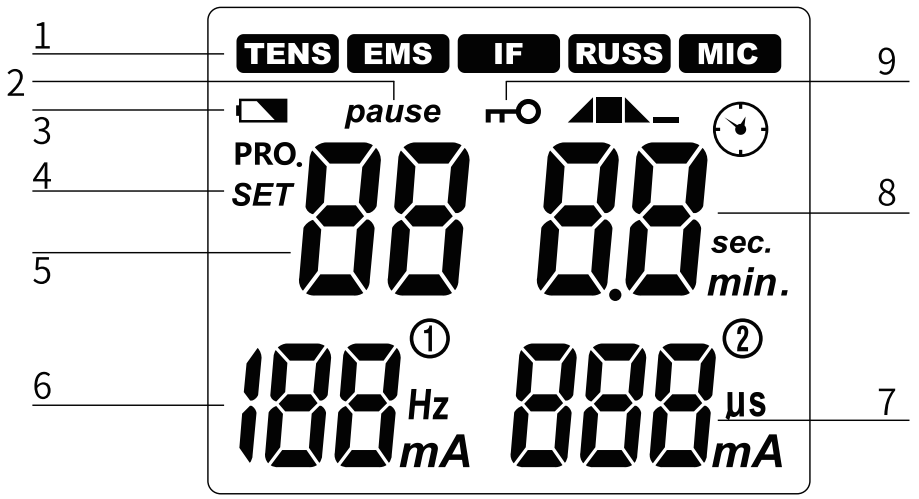
1) Possible skin irritation or electrode burn under the electrodes may occur.
2) Possible allergic skin reaction to tape or gel may occur.
3) On very rare occasions, first-time users of EMS report feeling light-headed or faint. We recommend that you use the product while seated until you become accustomed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

3. GETTING TO KNOW YOUR DEVICE

3.1 Package includes

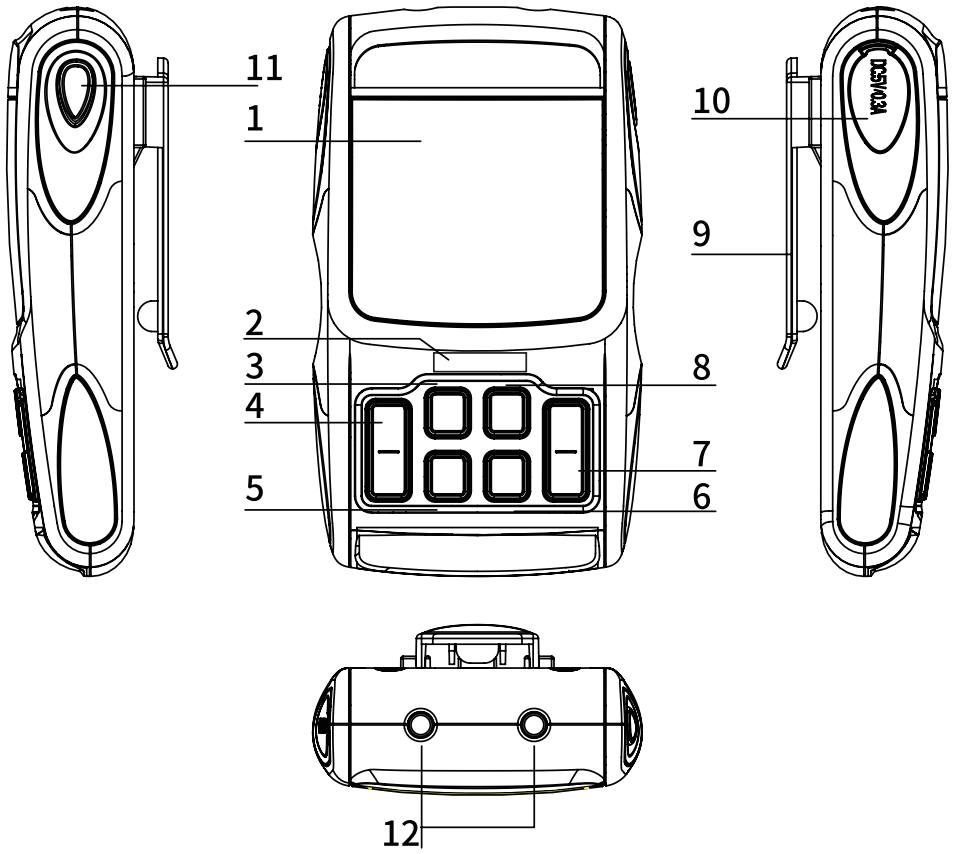
No.	Description	QTY
1	Combo Electrotherapy Device	1PC
2	Electrode pad （50mm×50mm)	4PCS
3	Electrode wires	2PCS
4	USB cable	1PC
5	User manual	1PC

3.2 LCD display



No.	Function description	No.	Function description
1	Treatment mode	6	Pulse rate and Intensity for Channel1
2	Pause symbol	7	Pulse width and Intensity for Channel2
3	Low battery symbol	8	Treatment time
4	SET symbol	9	Key locking symbol
5	Program NO.		

3.3 Device illustration



No.	Description
1	LCD display
2	Charger indicator : When the device is charging, the indicator light will be yellow. When charging is completed, the indicator light will be green.
3	[M] button: At standby mode, press the [M] button to select the treatment mode.
4	[+] /[-] button for Channel 1 : At standby mode, press the [+] / [-] button to increase or decrease the Channel 1 output intensity; At setting mode, press the [+]/[-] button to increase or decrease the programparameter.

5	[T/II] button: At standby mode, press the [T/II] button to increase the treatment time. At treating mode, press the [T/II] button pause or regain treatment. At setting mode,press the [T/II] button to select the parameter to adjust.
6	[S] button: At the standby mode,press the [S] button to enter the setting mode. At setting mode,press the[S]button to return to standby mode.
7	[+] /[-] button for Channel 2 : At standby mode, press the [+] /[-] button to increase or decrease the Channel 2 output intensity; At setting mode, press the [+]/[-] button to increase or decrease the program parameter.
8	[P] button: At standby mode, press the [P] button to select the treatment program.
9	Belt Clip
10	USB socket
11	[ON/OFF] button: At power-off state:press the [ON/OFF] button to enter standby mode. At standby mode,long press the [ON/OFF] button to turn off the device. At treating mode,press the [ON/OFF] button to return to standby mode.
12	Output socket

4. SPECIFICATION

4.1Technical information

Device name	Combo Electrotherapy Device
Model/type	R-C101W

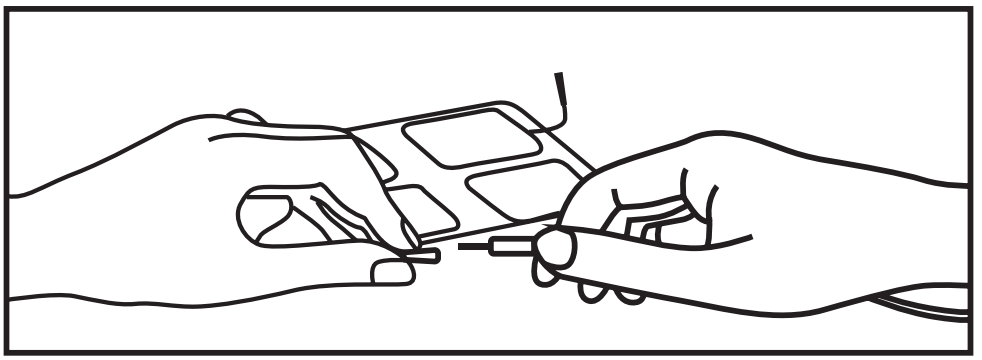
Power sources	3.7 V Li-ion battery
Power supply	Input: 100-240V AC, 50/60Hz,0.2A; Output: 5V DC, 300mA
Output Channel	Dual channel
Waveform	MIC: Mono-phase square pulse wave Other: Bi-phase square-wave pulse
Output current	TENS/EMS/RUSS :0-90mAp; IF: 0-60mApp; MIC:0-0.7mAp (At Load:1000 ohm)
Output intensity	TENS/EMS/RUSS :0-90Vp; IF: 0-60VppV MIC:0-700mVp (At L0ad:1000 ohm)
Treatment mode	TENS, EMS, IF,RUSS and MIC mode
Operating condition	5 ° C to 40 ° C with a relative humidity of 15%-93%, atmospheric pressure from 700 hPa to 1060 hPa
Storage condition	-10 ° C to 55 ° C with a relative humidity of 10%-95%, atmospheric pressure from 700 hPa to 1060 hPa
Dimension	120.5 x 69.5 x 27 mm (L x W x T)
Weight	about 155g
Classification	BF type applied part, internal power equipment, IP22
Size of electrodes pad	50x50mm, square
Output precision	±20% error is allowed for all the output parameters
P.W. (Pulse Width)	TENS/EMS: 50 to 400 μS; RUSS:200μS; IF:50us/100us; MlC:2ms -500ms
P.R. (Pulse Rate)	TENS/EMS: 2 to 150 Hz ; MIC:0.1Hz- 150Hz; RUSS: Carrier F 2.5KHz Burst F 10Hz -70Hz; IF: Carrier F 5KHz/10KHz Beat F 1Hz -199Hz
Treatment time	Adjustable, from 5 to 90 minutes.
Automatic shutoff	1 minute

Low Battery Indication	A low battery indicator will show up on the LCD when the battery is low.
Device service life	5 years
Electrode pads shelf life	3 years

5. OPERATING INSTRUCTION

5.1 Connect electrode pads to electrode wires

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



⚠ Caution

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

5.2 Connect electrode wires to device

Before proceeding to this step, ensure that the device is completely switched OFF. Hold the insulated portion of the

electrode wire connector, and insert the plug into the receptacle on the top of the main device.
Ensure the electrode wires are inserted correctly. The device has two output receptacles controlled by Channel 1 and Channel 2 at the top of the unit. You may choose to use one channel with one pair of electrode wires or both channels with two pairs of electrode wires. Using both channels gives the user the advantage of stimulating two different areas at the same time.

⚠ Caution

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

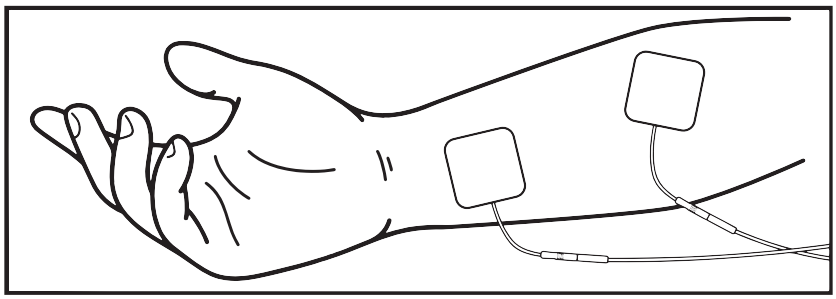
5.3 Electrode

5.3.1 Electrode options

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

5.3.2 Place electrodes on skin

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



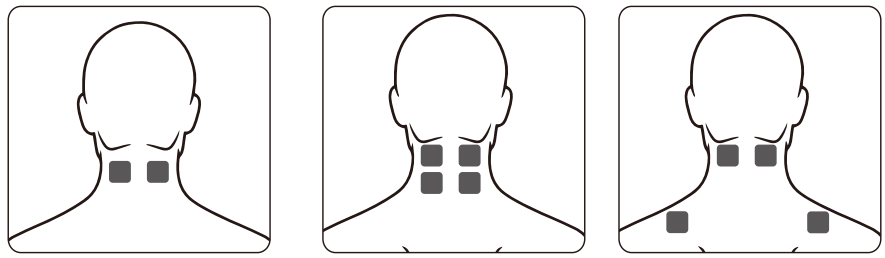
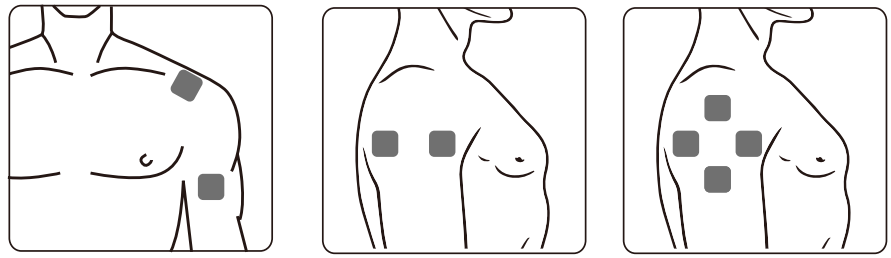
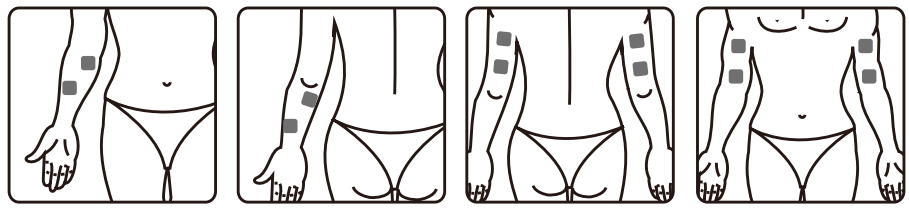
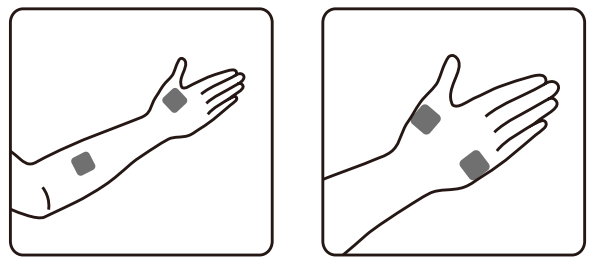
⚠ Caution

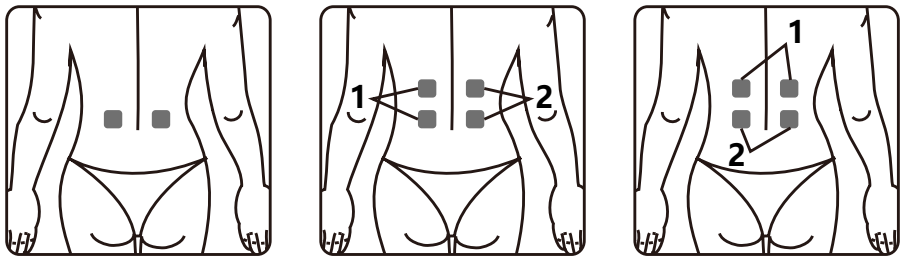
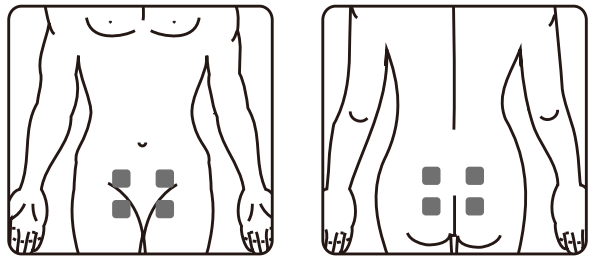
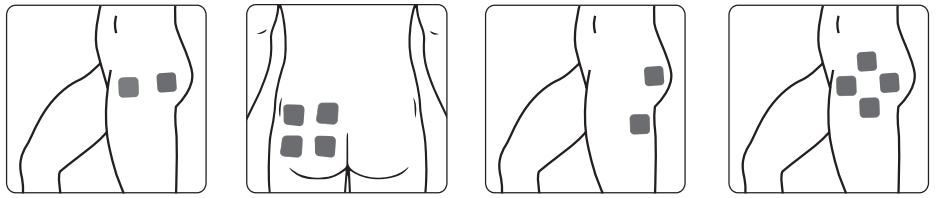
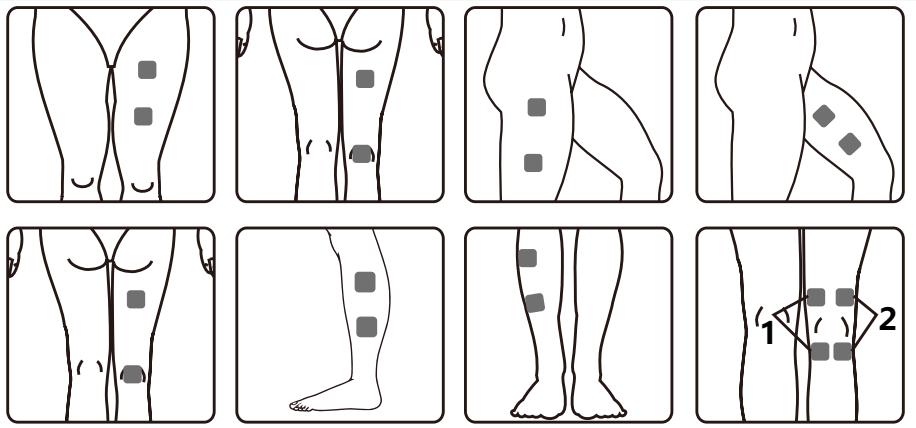
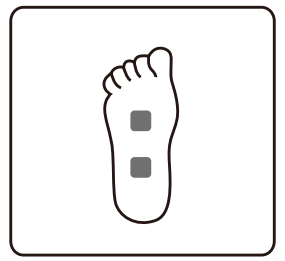
1. Always remove the electrodes from the skin with a moderate pull in order to avoid injury in the event of highly sensitive skin.
2. Before applying the self-adhesive electrodes, it is recommended to wash and degrease the skin, and then dry it.
3. Do not turn on the device when the self-adhesive electrodes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

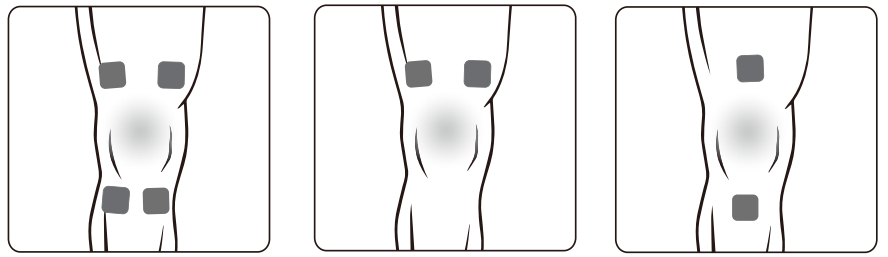
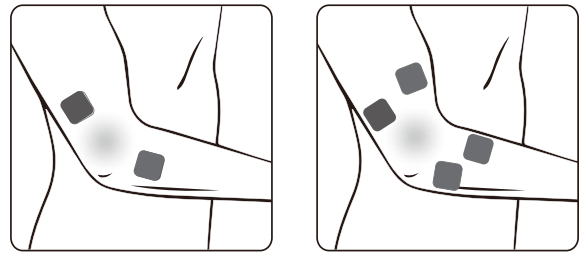
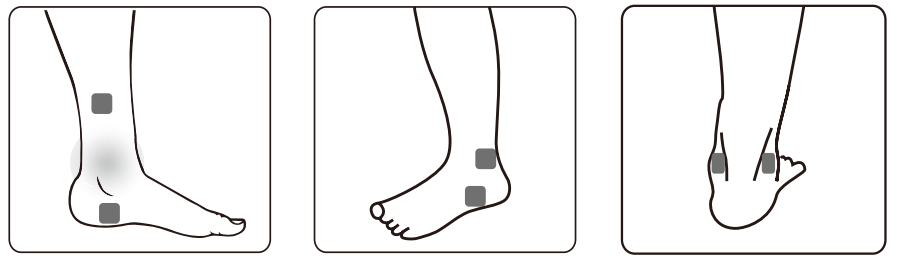
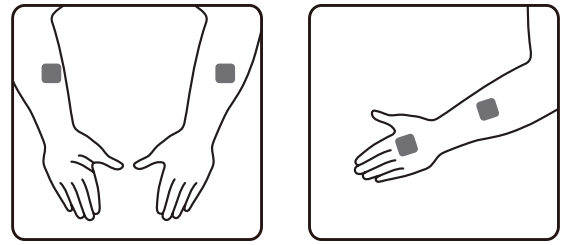
5.3.3 Electrode placement

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.

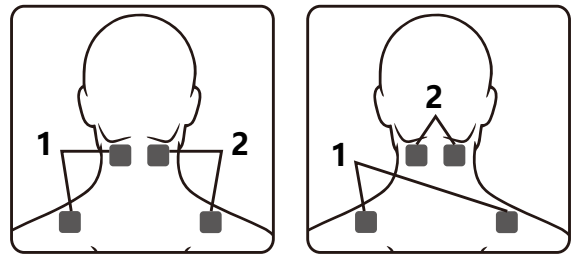
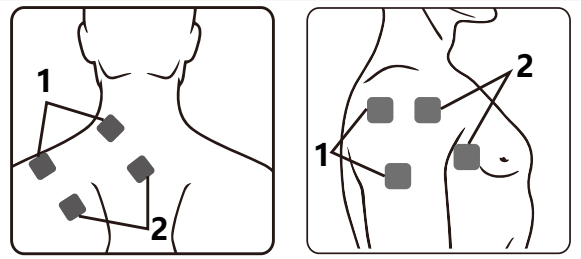
Position of electrode placement under TENS, IF and MIC programs

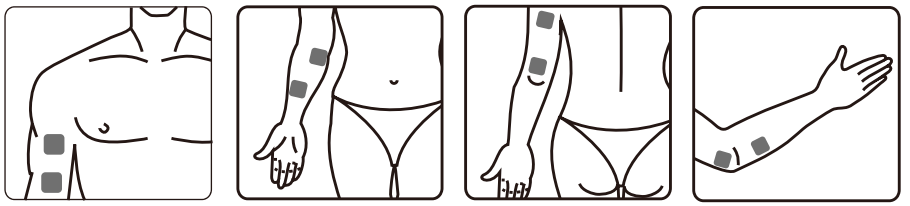
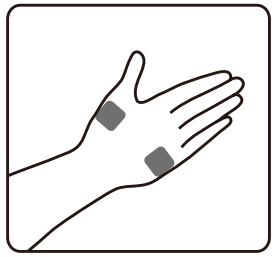
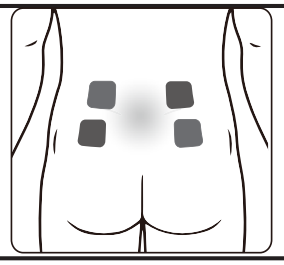
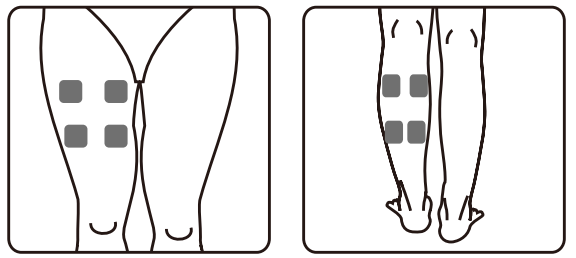
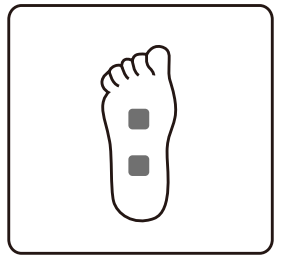
Neck	
Shoulder	
Arm	
Hand	

Back	
Abdomen	
Hip	
Leg	
Foot	

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

Position of electrode placement under EMS and RUSS programs

Neck	
Shoulder	

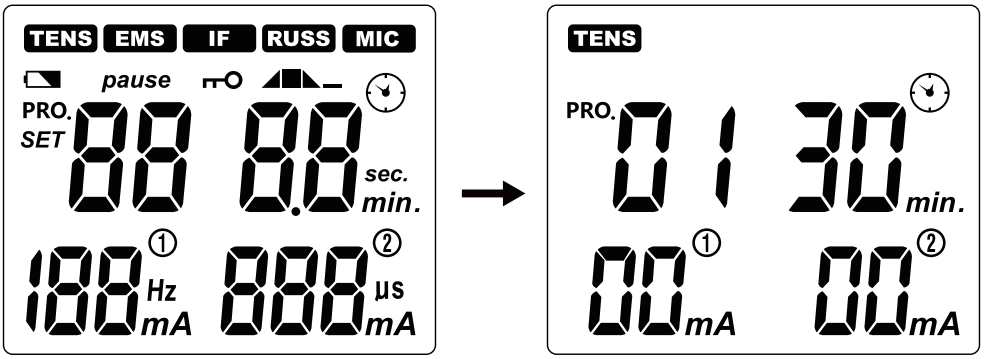
Arm	
Hand	
Back	
Leg	
Foot	

6. INSTRUCTIONS FOR USE

6.1 Turn on

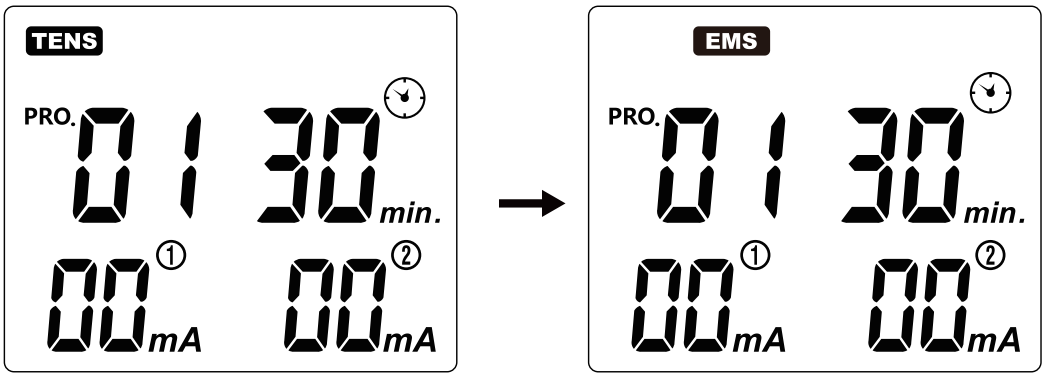
Press the [ON/OFF] button to turn on the device, the LCD will be lit. And then it goes into the standby mode as the

picture shows.



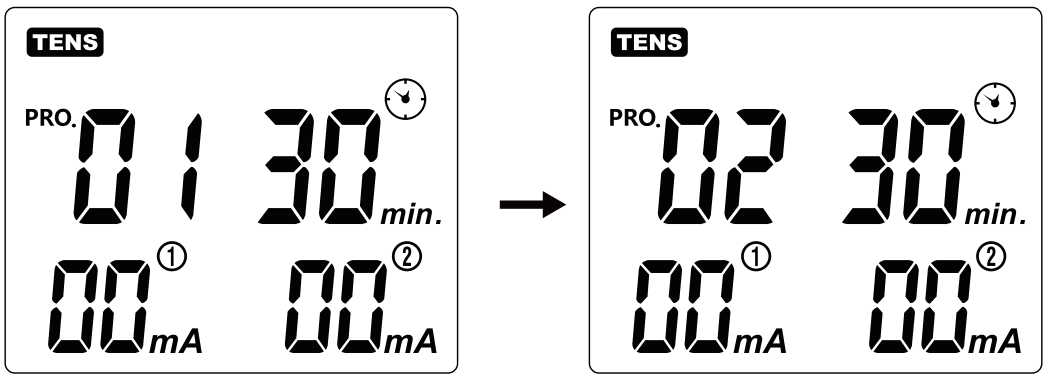
6.2 Select treatment mode

Press the [M] button to select which treatment mode you will use. The LCD displays as follows:



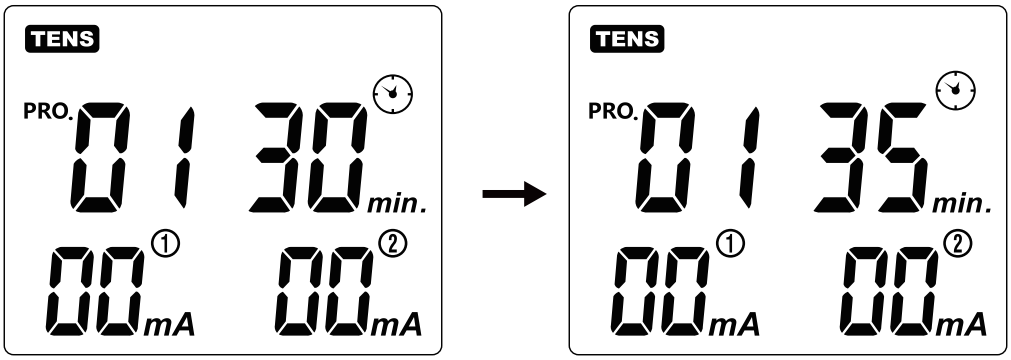
6.3 Select treatment program

Based on your need, press [P] button to select the treatment program. The LCD displays as follows :



6.4 Set treatment time

Based on your need, Press the [T/||] button to adjust treatment time. The LCD displays as follows:



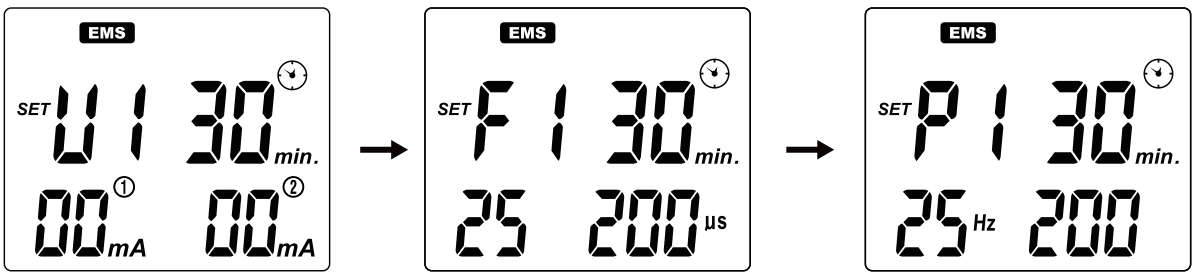
6.5 Set program parameter

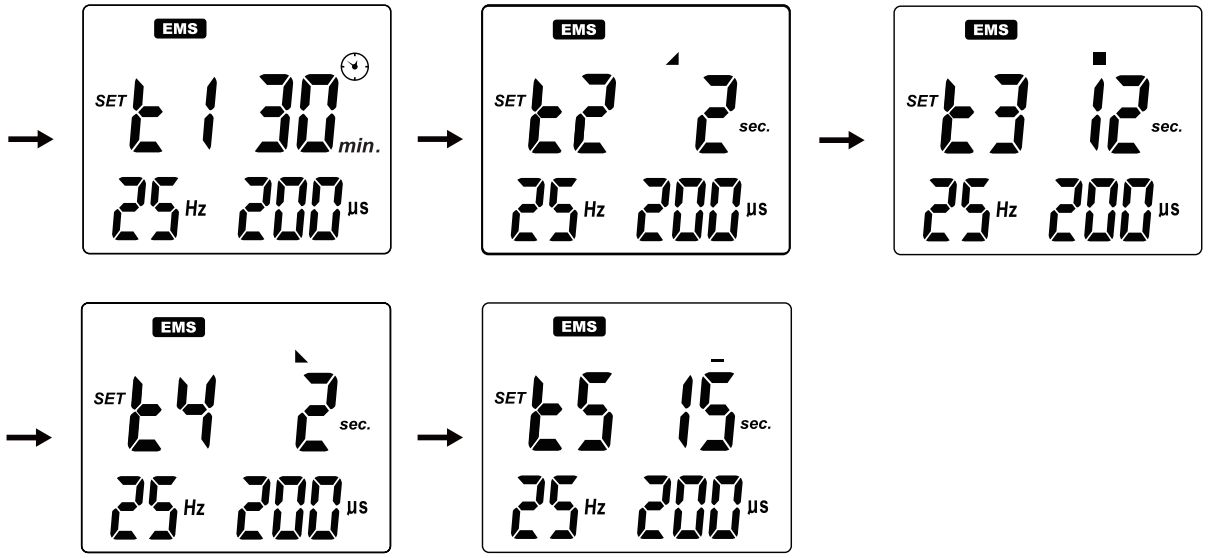
For detailed default parameters of each program, please refer to Chapter 7 TREATMENT PROGRAM DEFAULT PARAMETERS.

1) In standby mode, adjust the treatment program to U1. Press the [S] button to enter the setting program, and the corresponding icon starts flashing.

2) Short press [T/||] button to set the parameter adjust frequency - pulse width - treatment time (EMS/Russian: frequency -pulse width - treatment time - ramp up time - contraction time - ramp down time - relaxation time).

Short press [+]/[-] button to adjust corresponding parameters.





MODE	PRO.	F1(Hz)	F2(Hz)	P1(us)	P2(us)	t1(min)
TENS	U1	1-5	/	50-400	/	5-90
	U2	2-150	2-150	50-400	50-400	5-90
	U3	2-150	2-150	50-400	/	5-90
	U4	2-150	/	50-400	50-400	5-90
	U5	2-150	2-150	50-400	50-400	5-90
	U6	2-150	/	50-400	/	5-90
IF	U1	1-199	1-199	/	/	5-90
	U2	1-199	1-199	/	/	5-90
	U3	1-199	1-199	/	/	5-90
	U4	1-199	1-199	/	/	5-90
	U5	1-199	1-199	/	/	5-90
	U6	1-199	1-199	/	/	5-90
	U7	1-199	1-199	/	/	5-90
	U8	1-199	1-199	/	/	5-90
	U9	1-199	1-199	/	/	5-90

MODE	PRO.	F1 (Hz)	F2 (Hz)	P1 (us)	P2 (us)	t1 (min)	t2 (S)	t3 (S)	t4 (S)	t5 (S)

EMS	U1	2-150	/	50-400	/	5-90	1-9	1-90	1-9	1-90
	U2	2-150	/	50-400	/	5-90	1-9	1-90	1-9	1-90
	U3	2-150	/	50-400	/	5-90	1-9	1-90	1-9	1-90
	U4	2-150	/	50-400	/	5-90	1-9	1-90	1-9	1-90
	U5	2-150	/	50-400	/	5-90	1-9	1-90	1-9	1-90
	U6	2-150	/	50-400	/	5-90	1-9	1-90	1-9	1-90
	U7	2-150	/	50-400	/	5-90	1-9	1-90	1-9	1-90
RUSS	U1	10-70	/	/	/	5-90	1-9	1-90	1-9	1-90
	U2	10-70	/	/	/	5-90	1-9	1-90	1-9	1-90
	U3	10-70	/	/	/	5-90	1-9	1-90	1-9	1-90
	U4	10-70	/	/	/	5-90	1-9	1-90	1-9	1-90
	U5	10-70	/	/	/	5-90	1-9	1-90	1-9	1-90
	U6	10-70	/	/	/	5-90	1-9	1-90	1-9	1-90

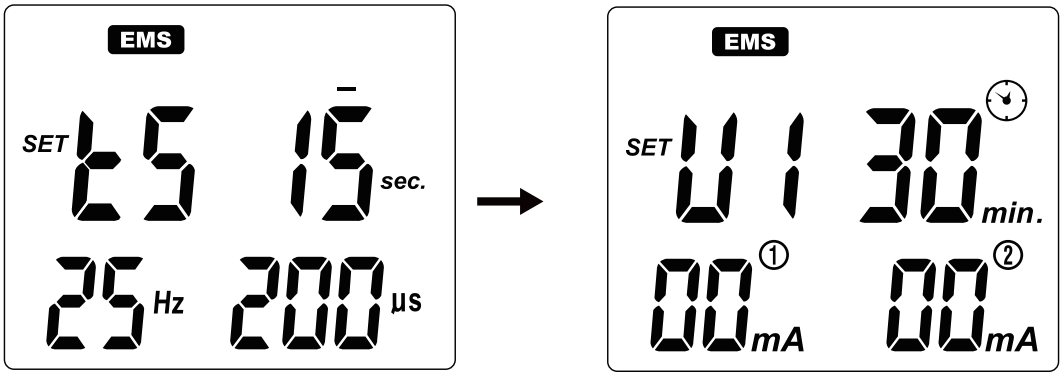
MODE	PRO.	F1(Hz)	F2(Hz)	P1(ms)	P2(us)	t1(min)
MIC	U1	0.1-150	/	2-500	/	5-90
	U2	0.1-150	/	2-500	/	5-90
	U3	0.1-150	/	2-500	/	5-90

Note:

F1: frequency 1; F2:frequency 2; Pl:pulse width 1;
P2:pulse width 2; t1:treatment time; t2:ramp up time;
t3:contraction time; t4:ramp down time; t5: relaxation time;
MIC mode :

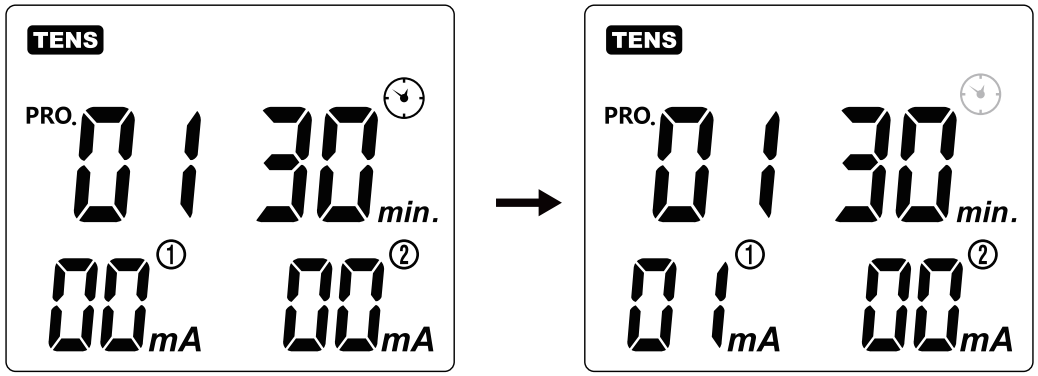
$$P.W. \leqslant \frac{1}{2 \times P.R.} \qquad P.R. \leqslant \frac{1}{2 \times P.W.}$$

3) Press [S] button to return to the standby mode.



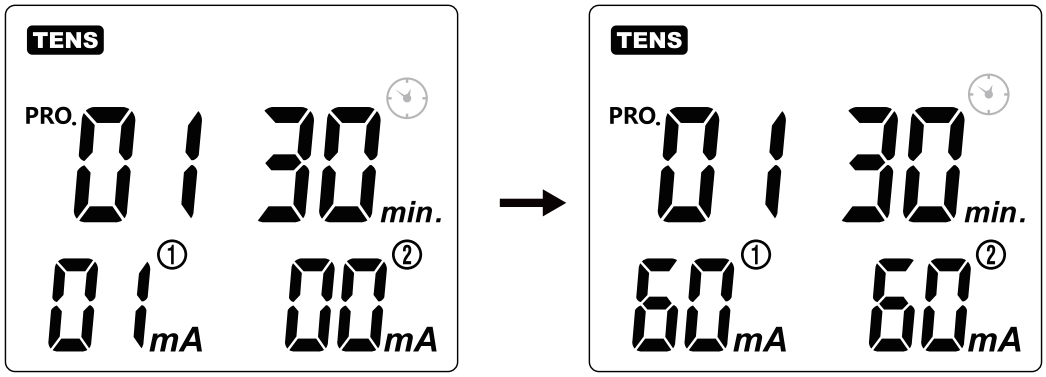
6.6 Start treatment

Press the[+] button to increase the intensity of the selected treatment channel.The LCD displays as follows:

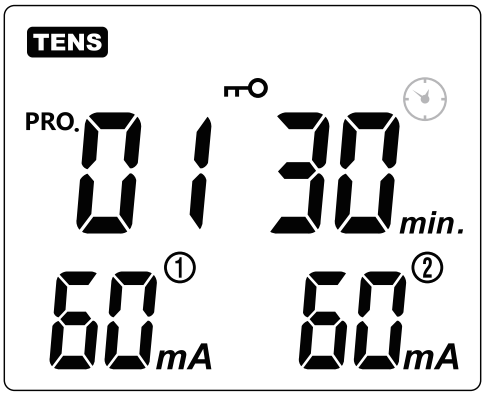


6.7 Adjust the output intensity

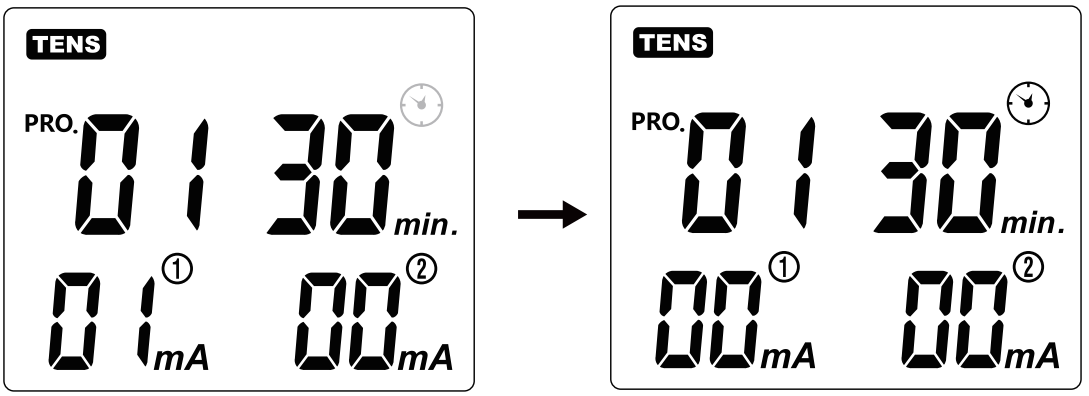
Press the [+] button to increase output intensity. It will be increased to a higher level after each press. Please adjust the intensity to the condition that you feel comfortable. The level of output intensity will be shown on the LCD:



To avoid unintentional output increment by user, the device will auto-lock the keypad after idle for 20 seconds during treatment. Press [-] button to unlock.



If you feel it too strong, you can press [-] button to decrease the intensityto a lowerlevel each time.When the output intensity of both channels decrease tozero,the stimulator will return to the standby mode. The LCD displays as follows:

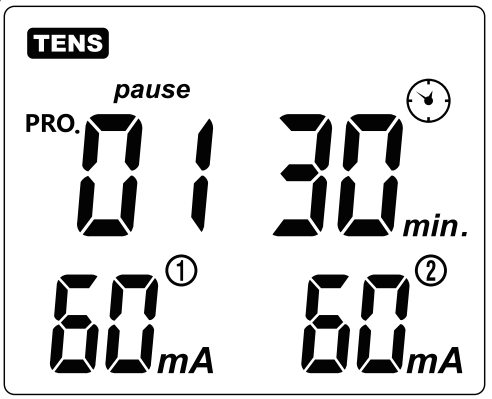


Caution:

If you feel or become uncomfortable, reduce the stimulation intensity to a more comfortable level and consult with your medical practitioner if problems insist.

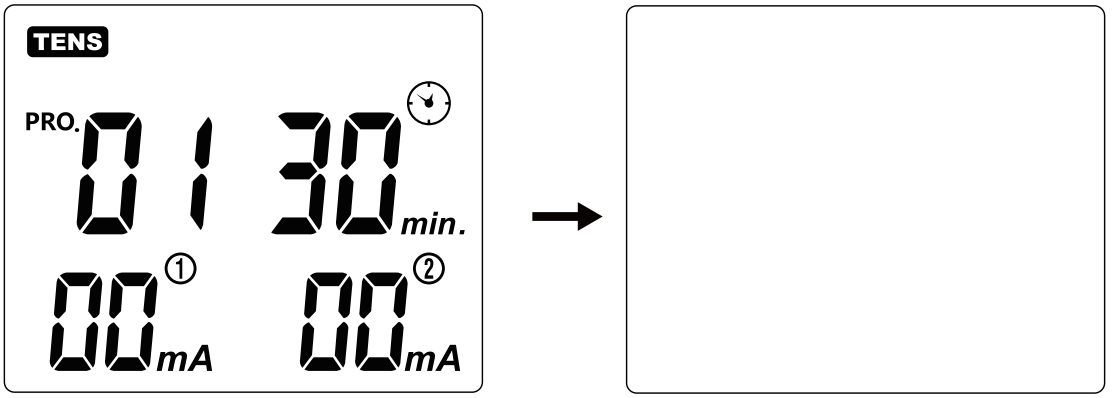
6.8 Pause function

On the treating mode, press the [T/||] button to pause the treatment, and the LCD will display the icon. Press the [T/||] button agin to regain the treatment.



6.9 Stop thetreatment and turn off the device

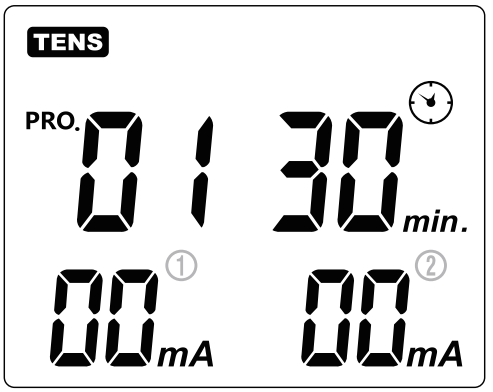
Press the [ON/OFF] button to stop treatment during the treating mode. Press and hold the [ON/OFF] button to turn off the device, and the LCD will be blank.



6.10 Load detection

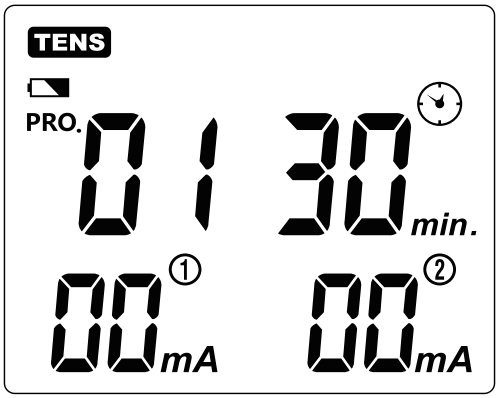
It will automatically detect the load if theintensity is above level 10 (1F:15, MiC doesn’t have this feature). If it hasn’t detected the load or the electrode contacts the skin not well enough, the intensity will automatically return to level

0and the symbol ‘①’ or ‘②’ twinkles. And the stimulator returns to the standby mode.



6.11 Low battery detection

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



Charging the Battery:

Proceed as follows to recharge the battery:

- This device cannot be used while charging.
- Make sure that the device is no longer connected to the patient (the output cables and electrodes must be disconnected).

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

• Connect the USB cable to the charger.

• When the device is charging, the indicator light will be red.

• It could take up to 3 hours to reach a full charge.

• When charging is completed, the indicator light will be green.

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

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

• Whenever the device is not used frequently, charge the battery once a month.

• For longer battery life, discharge the battery as much as possible.

6.12 Sound prompt function

a. In the waiting state, when the sound prompt function is on, press and hold the [S] button, and the device will emit a long ‘DI’ to turn off the sound prompt function.

b. In the waiting state, when the sound prompt function is off, press and hold the [S] button, and the device will make two short “DI” to turn on the sound prompt function.

Note: Reinstall the battery and the sound prompt function is turned on.

6.13 Usage of electrode pads

1. The electrode may only be connected with the COMBO stimulator. Make sure that the device is turned off when attaching or removing the electrode pads.
2. If you want to reposition the electrode during the application, turn the device off first.
3. The use 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 stimulator permanently on the same body part, as this may also lead to skin irritations.
4. Electrode pads are private and intended for single person use. Please avoid use 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. Use of other companies' products could result in injuries to the user.

6.14 Where do I attach electrode pads?

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

7. CLEANING AND MAINTENANCE

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

7.1 Cleaning and care for the device

7.1.1Pull 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 stimulator to moisture or dampness. And do not hold the COMBO stimulator under running water, nor submerge it in water or other liquids.

7.1.3 The COMBO stimulator 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 problem, 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 changes in normal use, please contact the retailer.

8. TROUBLESHOOTING

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

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

Rash or tickle on the skin occurs in treatment	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.

9. STORAGE

9.1 Storing the Electrode Pads and Lead Wires

1. Turn the device off and remove the lead wires from the

unit.
2. Remove the electrodes from your body and disconnect the lead wires from the electrodes.
3. Place the electrodes 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, lead wires and manual back into the gift box. Store the box in a cool, dry place, -10°C ~ 55°C ; 10% ~ 95% relative humidity.
2. Do not keep in places that can be easily reached by children

10. DISPOSAL



Spent batteries do not belong to the household wastes. Dispose 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.
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 lEC61000-3-2	Not applicable	
Voltage fluctuations/ Flicker emissions lEC61000-3-3	Not applicable	

Guidance and manufacture’s declaration — electromagnetic immunity
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guid-ance
Electrostatic discharge (ESD) IEC61000-4-2	±8kV direct & indirect contact; ±15kV air discharge	±8kV direct & indirect contact; ±15kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	not applica-ble	not applicable (for INTERNALLY POWERED ME EQUIPMENT)
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	not applica-ble	not applicable (for INTERNALLY POWERED ME EQUIPMENT)

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	not applicable	not applicable (For INTERNALLY POWERED ME EQUIPMENT
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	10V/m	10V/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a 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 an environment.			
Immunity test	IEC 60601 test level	Compli-ance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	10V/m & table 9	10V/m & table 9	Portable and mobile RF communi-cations equipment should be used not closer to any part of the device, including cables, than the recom-mended separation distance calcu-lated 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 trans-mitter manufacturer and d is the recommended separation distance in metres (m).

Radiated RF IEC 61000-4-3	10V/m & table 9	10V/m & table 9	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.

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

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

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

Test frequency (MHz)	Band [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
	Batch code		Authorized representative in the European Community
	Manufacturer		Date of manufacture
	Fragile, handle with care		Keep away from sunlight
	Keep dry		Temperature limit

	Use-by date		Serial number
	Humidity limitation		Atmospheric pressure limitation
	Caution		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	Medical device		

13. WARRANTY

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

The warranty terms is 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 damage 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.



Quirumed S.L.U. CIF B97267405
C/ Corretger 117, Pq. Emp.Táctica,
46980 Paterna, Valencia (Spain)



Shenzhen Roundwhale Technology Co., Ltd.
Add: 202, 2/F, Building 27, Dafa Industrial Park, longxi community, longgang district, Shenzhen, China.
Tel: +86-755-23212776
Fax: +86-755-23212776
Email: info@roovjoy.com

EU REP

Shanghai International Holding Corp. GmbH(Europe)
Address: Eiffestrasse 80,20537 Hamburg, Germany
E-mail:shholding@hotmail.com

CE 2460

Made in China