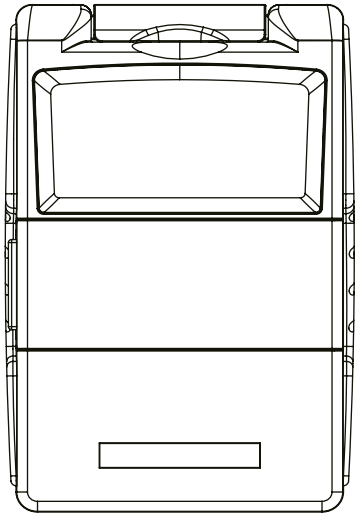
INSTRUCTION MANUAL

Med-Fit 3 TENS



R-C101I

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Be sure to read this instruction manual before operation

This user manual is published by Shenzhen Roundwhale Technology Co., Ltd

1 FOREWORD

1.1 Introduction

The Med-Fit 3 TENS Device is classified as an electrical stimulation system with one primary function: TENS therapy.

Functionality of the Med-Fit 3: The device features 5 modes (Burst, Normal, Modulation, Strength Duration 1, and Strength Duration 2) as well as 7 pre-set programs. It applies low-frequency electric currents for therapeutic purposes. Each program controls the generated electric impulses, adjusting their intensity, frequency, and pulse width.

The mechanism of the electrical stimulation equipment simulates the body's natural impulses. It generates electric impulses that are transmitted transcutaneously to nerves or muscle fibres through electrodes. The dual channel's intensity can be adjusted independently, allowing for individualised application to specific body parts. This device can accommodate four electrodes, enabling simultaneous stimulation of multiple muscle groups with a variety of standard programs. The electrical pulse is first transmitted to the tissue and subsequently affects stimulation transmission in nerves and muscle tissues in the targeted body areas.

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1.2.1 About Pain

Pain is an important warning signal in the human body. It alerts us when something is wrong; without it, abnormal conditions can go unnoticed, potentially causing damage or injury to vital parts of our bodies. While pain serves a necessary role in diagnosing trauma or dysfunction, persistent pain can sometimes be counterproductive and serve little purpose.

Pain is not felt until a message is encoded and travels to the brain, where it is decoded, analysed, and responded to. This process begins when a signal from the injured area travels along small nerves to the spinal cord. From there, the message is relayed to various nerves that ascend through the spinal cord to the brain. Once the pain message reaches the brain, it is interpreted, leading to the experience of pain.

1.2.2 What is TENS?

TENS (Transcutaneous Electrical Nerve Stimulation) is a proven and effective method for pain relief. Used daily by physiotherapists, and caregivers, TENS therapy harnesses electrical impulses to alleviate discomfort. High-frequency TENS stimulates the nervous system's pain-inhibiting mechanisms, blocking pain signals before they reach the brain. Meanwhile, low-frequency TENS promotes the release of endorphins, the body's natural painkillers, providing long-lasting relief. By placing electrodes on the skin near the affected area, TENS therapy offers a non-invasive, drug-free solution to managing pain.

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.

Target population

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

Intended user

Medical staff or lay persons.

Intended condition

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

Indications

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.

2.2 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 the risk of injury, and avoid situations that could result in damage to the device.

SAFETY SYMBOLS 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).

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

2.2.2 ⚠ Warning

1) Consult your physician before use if you have received medical or physical treatment for your pain.
2) Discontinue use and consult your physician if your pain persists for more than five days, worsens beyond mild discomfort, or fails to subside.
3) Avoid applying stimulation to your neck, as it may cause severe muscle spasms, airway obstruction, breathing difficulties, or adverse effects on heart rhythm or blood pressure.
4) Do not apply stimulation across your chest, as electrical currents in this area may disrupt heart rhythm, potentially leading to life-threatening conditions.
5) Avoid applying stimulation over or near cancerous lesions.
6) Do not use the device near electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), as it may interfere with their operation.
7) Never use the device in water, including during baths or showers.
8) Avoid using the device while sleeping.
9) Do not use the device while driving, operating machinery, or engaging in activities where electrical stimulation could increase the risk of injury.
10) Apply stimulation only to healthy, intact, and clean skin.
11) The long-term effects of electrical stimulation are unknown, and this device is not a substitute for medication.
12) Avoid using the device during high-frequency surgical procedures, as it may cause skin burns under the electrodes or damage the stimulator.
13) Do not use the device near shortwave or microwave therapy equipment, as it may affect the stimulator's performance.
14) Never apply stimulation near the heart area, particularly on the front of the thorax (ribs and breastbone) or the pectoral muscles, as it may increase the risk of ventricular fibrillation or cardiac arrest.

15) Avoid using the device on the eyes, head, or face.
16) Do not apply stimulation near the genitals.
17) Avoid using the device on areas of the skin with reduced or absent sensation.

18) Ensure electrodes remain separate during use, as contact between them may cause improper stimulation or skin burns.
19) Keep the device out of reach of children.
20) Consult your doctor if you have any doubts or concerns about using the device.
21 Discontinue use and avoid increasing the intensity if you experience discomfort during treatment.

2.2.3 ⚠ Precautions

1) TENS is not effective for pain originating from the central nervous system, including headaches.
2) TENS is not a replacement for pain medications or other pain management therapies.
3) TENS provides symptomatic relief by suppressing pain sensations that would otherwise serve as a protective mechanism.
4) The effectiveness of TENS depends greatly on patient selection by a qualified pain management practitioner.
5) Since the effects of electrical stimulation on the brain are unknown, do not apply stimulation across your head or place electrodes on opposite sides of your head.
6) The safety of electrical stimulation during pregnancy has not been established.
7) Skin irritation or hypersensitivity may occur due to electrical stimulation or the conductive medium (such as silica gel).
8) If you have a suspected or diagnosed heart condition or epilepsy, follow the precautions recommended by your physician.

9) Use caution if you have an increased risk of internal bleeding, such as after an injury or fracture.
10) Consult your physician before using the device following a recent surgical procedure, as stimulation may interfere with the healing process.
11) Use caution if applying stimulation over the uterus during menstruation or pregnancy.
12) For single-patient use only.
13) This device should not be used by patients who are non-compliant or have emotional disturbances, including dementia or cognitive impairment.
14) Follow the instructions for use carefully; improper use may be dangerous.
15) In rare cases, skin irritation may occur at the electrode placement site after prolonged use.
16 Do not use this device near other equipment that delivers electrical pulses to your body.
17 Avoid using sharp objects, such as pencils or ballpoint pens, to operate the control panel buttons.
18) Always check electrode connections before each use.
19 Use the electrical stimulator only with the electrodes recommended by the manufacturer.
20 When the device output exceeds 10mA or 10V, the channel intensity indicator will flicker.
21) Users should consult a healthcare professional before using the device.
22) Users must report any serious incidents related to the device to the manufacturer and relevant regulatory authorities in their country.

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2.2.4 ⚠ Adverse Reactions

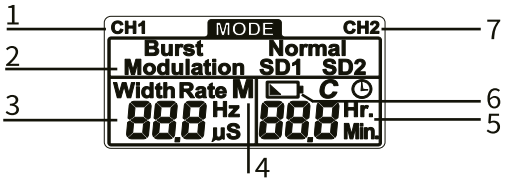
1) Possible skin irritation or electrode burn under the electrodes may occur.
2) Possible allergic skin reaction to tape or gel may occur.
3) If symptoms of tachycardia and extrasystolia (rapid heartbeat or extra stimulation) appear during treatment, stop the treatment and seek medical attention immediately.
4) 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	Med-Fit 3 Device	1pc
2	Electrode Pads (50mm x 50mm)	8pcs
3	Electrode Wires	2pcs
4	9 Volt Battery	1pc
5	User Manual	1pc
6	Patient Guide to TENS	1pc

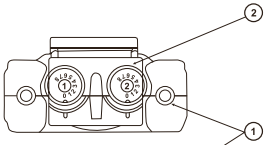
3.1 LCD Display



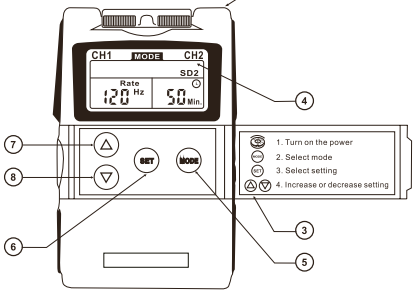
No.	Function Description	No.	Function Description
1	Icon for Channel 1	4	Memory Icon
2	Treatment Mode	5	Treatment Time
3	Pulse Width, Pulse Rate P01 to P02 Programmes	6	Low Battery Icon
		7	Icon for Channel 2

3.3 Device Illustration

Top



Front



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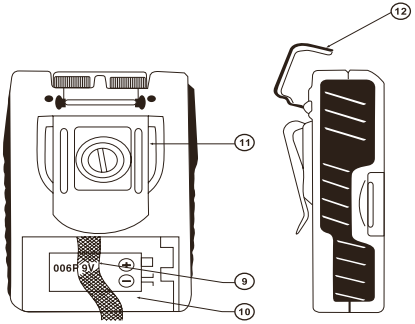

Back Side

No.	Function Description
1	Lead Connector
2	Intensity Control (ON / OFF Switch)
3	Panel Cover
4	Liquid Crystal Display
5	Mode Control
6	Set Control
7	Increment Control
8	Decrement Control
9	Battery Strip
10	Battery Case
11	Belt Clip
12	Case Protector

4 SPECIFICATION

4.1 Technical Information

Device name	Med-Fit 3 TENS
Model / type	R-ClOll
Power sources	One 9 volt battery
Output channel	Dual channel
Waveform	Bi-phase square-wave pulse
Output current	0-S0V (Load:500 ohm)
Output intensity	adjustable
Treatment mode	TENS 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	10.1 cm (L) x 6.1 cm (W) x 2.45 cm (H)
Weight	111 grams with battery
Classification	BF type applied part, internal power equipment
Size of electrodes pad	50mm x 50mm
Output precision	±20% error is allowed for all the output parameters
P.W. (Pulse Width)	Adjustable, from 50 to 300 μs, 10 μs/step
P.R. (Pulse Rate)	Adjustable, from 2 to 150 Hz, 1 Hz/step
Time	Adjustable, from 1 to 60 minutes or continuous.

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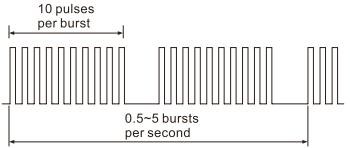
Modes	B (Burst), N (Normal), M (Modulation) SDI (Strength Duration) 5D2 and 7 preset programs from P0I to P07.
Burst Mode	Burst rate: adjustable, 0.5 -5 Hz, Pulse with adjustable, 50-300 µs Frequency fixed= 100 Hz
Normal Mode	The pulse rate and pulse width are adjustable. It generates continuous stimulation based on the setting value.
Modulation Mode	Modulation mode is a combination of pulse rate and pulse width modulation. The pulse rate and width are automatically varied in a cycle pattern. The pulse width is decreased by 50% from its original setting in the 0.5 second, then the pulse rate is decreased by 50% from its original setting in the 0.5 second. Total cycle time is 1 second. In this mode, pulse rate (2-150Hz) and pulse width (50-300µs) are fully adjustable.
SDI Mode	The SDI(Strength-Duration) mode consists of automatic modulation intensity and pulse width in 40% range. The intensity is always increasing while the pulse width is decreasing and vice versa. The intensity is decreased by 40% while the pulse width is increased by 40% in 5 seconds. In the next 5 seconds, the intensity is increased by 40% while the pulse width is decreased by 40%. Total cycle time is 10 seconds. Pulse rate (2-150Hz) and pulse width (50-300µs) are fully adjustable.

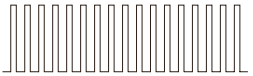
SD2 Mode	The SD2 (Strength-Duration) mode consists of automatic modulation intensity and pulse width in the 70% range. The intensity and pulse width are in 70% range. The intensity is always increasing while the pulse width is decreasing and vice versa. The intensity is decreased by 70% in 5 seconds. In the next 5 seconds, the intensity is increased by 70% while the pulse width is decreased by 70%. Total cycle time is 10 seconds. Pulse rate (2~150Hz) and pulse width (50-300us) are fully adjustable
POI (Burst) Mode	Burst rate: 2Hz Pulse width: 180us Frequency fixed: 100 Hz
P02 (Normal) Mode	Pulse rate: 100Hz - Pulse width: 180us
PO3 (Normal) Mode	Pulse rate: 2Hz - Pulse width: 200us
P04 (Modulation) Mode	Pulse width: 180us Pulse rate: 15Hz
P05 (Modulation) Mode	Pulse rate: 80Hz Pulse width: 180us
P06 (SD2) Mode	Pulse rate: 10Hz - Pulse width: 200us
P07 (SD1) Mode	Pulse rate: 50Hz - Pulse width: 250us
Patient Compliance Meter	This unit can store 60 sets of operation records. Total recorded time is 999 hours
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

The waveforms of the 5 stimulation modes are as follows.

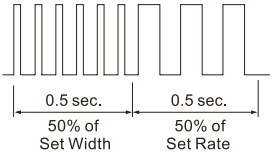
1. Burst



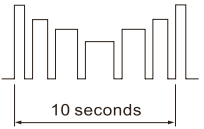
2. Normal



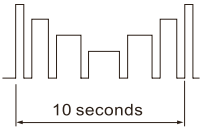
3. Modulation



4. SDI (Strength-Duration)



5. SD2 (Strength-Duration)

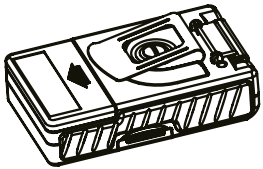


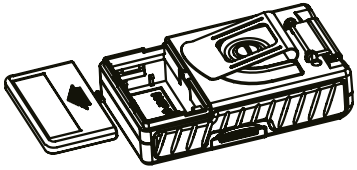
5. OPERATING INSTRUCTIONS

5.1 Battery

5.1.1 Check/ replace batteries

Open the battery cover, insert one 9 volt battery into the battery compartment. Make sure you are installing the batteries properly. Be sure to place the batteries according to the markings of positive terminal (+) and negative terminal (-) in the battery compartment of device.





5.1.1 Check/ replace batteries

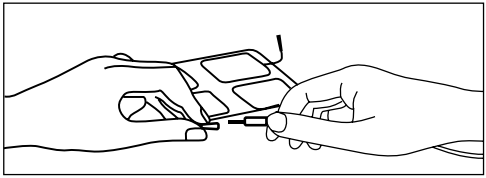
Spent batteries do not belong to the household waste. Dispose of the battery following the current regulations. As a consumer, you have legal obligation to return spent battery to the Recycle Bin.

1. If a battery was swallowed accidentally, please seek medical assistance immediately!
2. In case of battery leakage, please avoid contacting with the battery through skin, eyes and mucus membranes. Once it occurs, please wash the contacted part with plenty of clean water and contact your doctor immediately.
3. Battery cannot be dismantled, thrown into fire or short-circuited.
4. Protect battery from excess heat; Take the battery out of the product if they are spent or you don't use it for a long time. This can prevent device from damage due to the battery leakage.

5. Replace all of the batteries simultaneously!
6. Always replace the device with the same type battery.

5.2 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, 1SO10993-1/-5/-10 and IEC/ EN60601-1-2, as well as CE and FDA 510(K) regulation.

5.3 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.

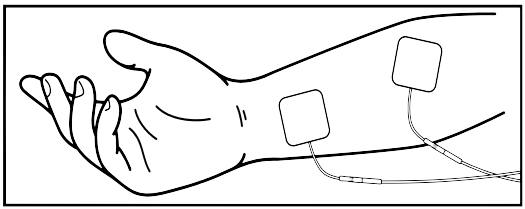
5.4 Electrode

5.4.1 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.

5.4.2 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.

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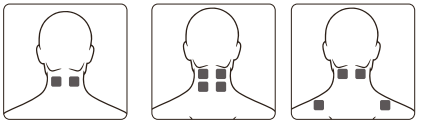
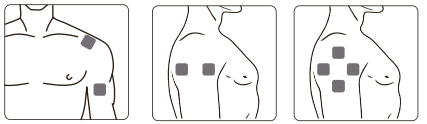
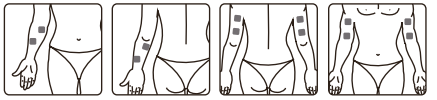
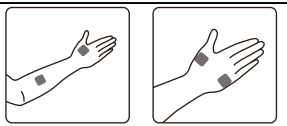
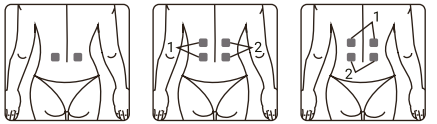
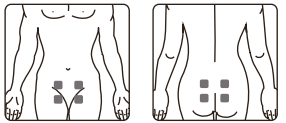
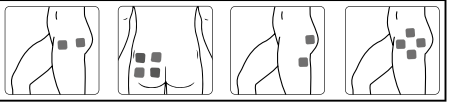
4. To remove or move the electrodes, switch off the device or the appropriate channel first in order to avoid unwanted irritation.
5. It is recommended that, at minimum, l.S”x 1.5” self-adhesive square electrodes are used at the treatment area.
6. Never remove the self-adhesive electrodes from the skin while the device is still on.

5.4.3 Electrode placement

R-ClOll is a kind of OTC stimulator, suitable for home use. 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 using aTENS treatment

Neck	
Shoulder	
Arm	
Hand	
Back	
Abdomen	
Hip	

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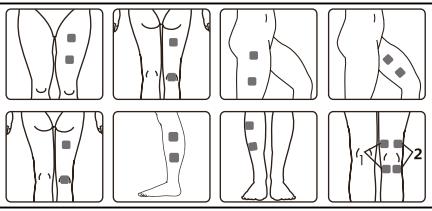
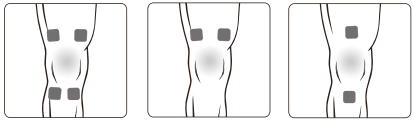
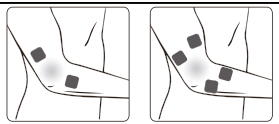
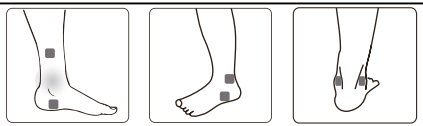
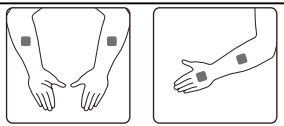
Leg	
Foot	
Joint (Knee)	
Joint (Elbow)	
Joint (Ankle)	
Joint (Wrist)	

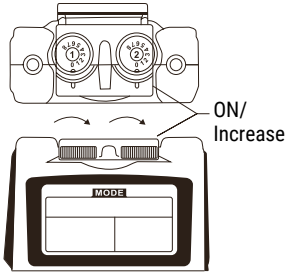
6. INSTRUCTIONS FOR USE

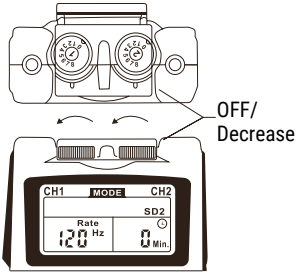
6.1 Power On/Off Switch and Intensity Controls:

If both controls are in the off-position, the device is switched off. By turning the controls clockwise, the appropriate channel is switched on and the indicator of power (CH! or CH2) will reveal on the LCD. The current strength of the impulses transmitted to the electrodes increases further when the control is turned clockwise.

To reduce the amount of current or power off, turn the control counter clockwise to the required setting or off position.

The controls are protected by a cover to prevent inadvertent change of intensity.





6.2 Lead Connector

The connection of the electrodes is performed with the two lead wires. The device must be turned off before connecting cables. Both intensity controls must be in the off position . The electrodes should be placed firmly on the skin.

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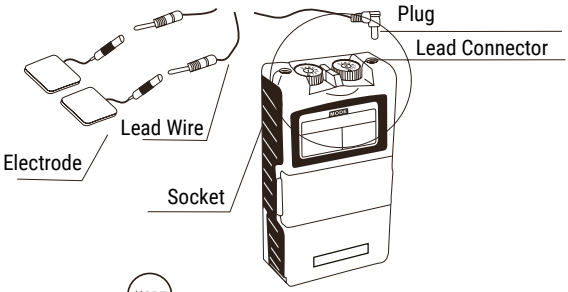
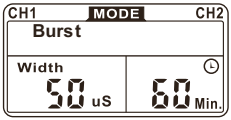
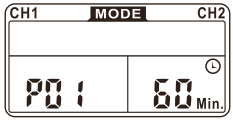


6.3 Mode Control (MODE)

There are 5 Modes and 7 preset modes available - Burst, Normal, Modulation, SD1 SD2 and P01-P07 preset modes. The therapeutic mode can be selected by pressing the “Mode” control.





6.4 Configuration Control (SET)

By pressing the “SET” button, you can enter the value of the configuration to perform. You can begin to set the value by pressing the controls of “increase” and “decrease” when the value flashes.

6.5 Increment Control (△)

By pressing the “SET” button, you can enter the value of the configuration to perform. You can begin to set the value by pressing the controls of “increase” and “decrease” when the value flashes.

6.6 Decrement Control (▽)

This button controls the increase of settings. When you press this button, the parameter increases.

6.7 Timer

The unit: has a timer of 1- 60 minutes and Continuous. It can be adjusted by pressing the”Set” and”Increment” or”Decrement”controls. The treatment time will countdown automatically one minute by one minute. Its output will be shut off when time is up.

6.8 Low Battery Indicator

A low battery indicator will show up on the liquid crystal display when the battery needs to be replaced. The unit may continue to operate for a few more hours depending on the settings intensity level.

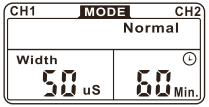
6.9 Steps to Set a New Program

a. Turn on the intensity

After the electrodes are placed firmly on skin and the lead wires are plugged in the socket of device, turn the on/off control clockwise. The liquid crystal display will be light up.

b. Select a Mode

Select a mode by pressing the “MODE” control. The mode you select will show up on the top of liquid crystal display. There are 5 adjustable modes of your option, including -Burst, Normal, Modulation, SDl and SD2.



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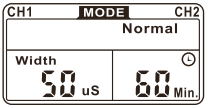
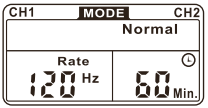
c. Set Pulse Width

Pulse Width is adjustable from 50 μs to 300 μs. Press “SET” control to enter this menu, then press “Increment” or “Decrement” to adjust the setting. If no instructions regarding the pulse width are given in therapy, set the control to the suggested 70-120 μs setting.



d. Set Pulse Rate

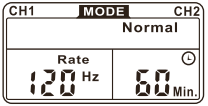
Pulse rate is adjustable 2Hz to 150Hz. Press “SET” control to enter this menu, then press “Increment” or “Decrement” to adjust the setting. Unless otherwise instructed, turn the pulse rate control to the 70-120 Hz setting.

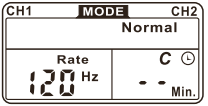


e. Set Timer

Press “SET” to enter this setting. The treatment time is adjustable from 1 to 60 minutes or Continue. Press “Increment” or “Decrement” control to adjust setting. Your settings will be stored in this unit eternally unless they are adjusted again.

You can set the timer to “Continuous” mode by pressing the “increment” control when it shows 60 minutes.





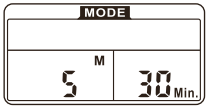
Continuous

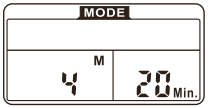
6.10 Patient Compliance Meter

This unit can store 60 sets of operation records. Total treatment time up to 999 hours can be stored.

Check and Delete Individual Records

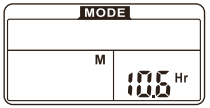
Press “Mode” control and tum on the power simultaneously. The LCD will show the number of records and operation time. Press the “Increment” and “Decrement” button to check each record. To delete a record, press “SET” control for 3 seconds.

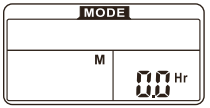




Check and Delete Accumulative Record

At the individual records menu, press “Mode” control to switch to accumulative record menu. Press the “Set” control first, then press the “Mode” control simultaneously for 3 seconds and all of the records will be deleted followed by a beeper sound.

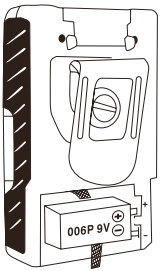




6.11 Check/Replace the Battery:

Over time, in order to ensure the functional safety of TENS, changing the battery is necessary.

1. Make sure that both intensity controls are switched to off position.
2. Slide the battery compartment cover and open.
3. Remove the battery from the com partment.
4. Insert the battery into the compartment.



Note the polarity indicated on the battery and in the compartment.
5. Replace the battery compartment cover and press to close.

Notice of batteries:

1. Batteries may be fatal if swallowed. Therefore, keep the batteries and the product out of the reach of children. If a battery is swallowed, go to a hospital immediately.
2. If there's battery leakage, avoid contact with skin, eyes and mucus membranes. Rinse the affected spots with plenty of clear water immediately and contact a physician right away.
3. Batteries must not be charged, dismantled, thrown into fire or short-circuited.
4. Protect batteries from excess heat. Take the batteries out of the device if they are spent or in case that you will no longer use the them. This prevents damage caused by leaking batteries.

6.12 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. The electrode can only be connected to the Med-Fit 3. Ensure that the device is turned off when attaching or removing the electrode pads. If you need to reposition the electrode during application, please turn off the device first.
3. Be aware that electrodes might cause skin irritations. If you experience any irritation, such as redness, blistering, or itching, discontinue use immediately. Avoid using the Med-Fit 3 on the same body part permanently, as this can also lead to skin irritations.
4. Electrode pads are for single-person use only. The electrode must make complete contact with the skin to prevent hot spots, which can result in skin burns.

5. Do not use the electrode pads more than 15 times, as the connection between the electrodes and your skin deteriorates over time. The adhesive effectiveness of the electrodes may vary based on skin properties, storage conditions, and the number of applications. If the electrode pads no longer stick fully to your skin, please replace them with new ones.
6. After use, store the electrode pads by sticking them back onto their protective foil and placing them in the storage bag to prevent them from drying out. This will help maintain their adhesive properties for a longer period.
7. Avoid using detergents to clean the electrode pads, as this can damage their adhesive quality. Always handle the electrode pads with clean hands, and replace them if they become dirty.
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 be handled 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 switched on.
3. Only use the electrode pads provided by the manufacturer. Usage of other companies' products could result in injuries to the user.

6.13 Where do I attach the 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.

Usage advice for TENS:

If you don't feel any discomfort during the treatment, we advise you to use the device until the session ends. Normally, the pain relief occurs after a 1 hour treatment session.

If you feel discomfort during the treatment, you can either pause the session or decrease the intensity of the output. Normally, we advise 1- 2 treatments per day and one week as a period of treatment;

After a period of treatment, if the pain relief is not achieved or the pain gets even worse, please consult your doctor.

7. CLEANING AND MAINTENANCE

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

7.1 Cleaning and care for the device

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

7.1.2 Do not expose the 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 For reasons of hygiene, each user should use his/her own set of electrodes.

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

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

7.1.7 Do not clean the device during treatment. Be sure that the device is turned off before cleaning.

7.2 Maintenance

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

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

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

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

8. TROUBLESHOOTING

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

Malfunction	Common reasons	Countermeasure
No display after replacing the battery.	1. There's foreign body in the battery compartment. 2. The battery has been used up or installed incorrectly. 3. There is foreign body in the battery interface. 4. The battery is not the correct type.	1. Check and clean the compartment. 2. Replace the new battery or install the battery correctly. 3. Check and clean the battery connections 4. Replace the battery with the correct type.
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. Replace the battery.

Malfunction	Common reasons	Countermeasure
No sensation of stimulation	1. The electrode does not connect well to the skin. 2. Poor connection between the patient lead and the electrode 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. Replace the battery. 4. Wipe the electrode and the skin with a wet cotton cloth.
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 a llergic history. Please change the sticking place or shorten the treatment time. If your skin is oversensitive, you should stop the treatment or go to see a doctor.

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9. STORAGE

9.1 Storing The Electrode Pads and Lead Wires

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

9.2 Storing the Unit

1. Place the unit, electrodes, lead wires and manual back into the carrying case. Store the box in a cool, dry place, -l0°C ~ SS°C; 10% ~ 90% relative humidity.
2. Do not keep in places that can be easily reached by children.
3. When not in use for a long period, remove the battery before storage.

11. 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 life cycle, do not throw this product into the normal household garbage, but bring it to a collection point for the recycling of electronic equipment. Obsolete electrical and electronic equipment may have potentially harmful effects on the environment. Incorrect disposal can cause toxins to build up in the air, water and soil and jeopardize human health.

11. ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES

Guidance and manufacture's declaration - electromagnetic emissions.		
The device is intended for use in the electromagnetic environment specified below. The customer or the user has to assure that it is used in such environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPRII	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 CISPRII Harmonic emissions IEC61000-3-2 Voltage fluctuations Flicker emisions IEC61000--3-3	Class B N/A N/A	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

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

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Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	±8kV direct & indirect contact; ±l5kV air discharge	±8kVdirect & indirect contact; ±l5kVair 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	±2kV for power supply lines	N/A	Not applicable (for INTERNALLY POWERED ME EQUIPMENT)
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	N/A	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	N/A	Not applicable (for INTERNALLY POWERED ME EQUIPMENT)
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	lOV/m	lOV/m	Power frecuency 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	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Radiated RF IEC 61000-4-3	IOV/m & table 9	IOV/m & table 9	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 $d = 1.167\sqrt{P}$ 80MHz to 800MHz $d = 2.333\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transitter manufacturer and dis the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,' 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 1 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, obiects and people.			

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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	TETRA400	Pilse modulation [b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5KHz deviation 1kHz sine	1.8	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation [b] 217Hz	0.2	0.3	9
745						
780						
710	800-960	GSM800/900 TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18Hz	0.2	0.3	28
745						
780						
1720	1700-1990	GSM1800 CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4, 25, UMTS	Pulse modulation [b] 217Hz	0.2	0.3	28
1845						
1970						

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (M)	Immunity Test Level (V/m)
2450	1700-1990	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217Hz	0.2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217Hz	0.2	0.3	28
5500						
5785						

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

a) For some services,only the up link frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse mod-ulation at 18 Hz may be used because it does not represents actual modulation. It would be worst case.

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.

12. NORMALISED SYMBOLS

	WEE Symbol		Applied part of type BF
	Refer to instructions	IP22	IP classification
	Batch code		Authorised representative in the European Community
	Manufacturer		Authorised representative in the United Kingdom
	Fragile, handle with care		Date of manufacture
	Keep dry		Keep away from sunlight
	Use by date		Temperature limit
	Humidity Limitation		Serial number
	Caution		Atmospheric pressure limitation
	Users of the artificial pacemaker are prohibited from the device		Recycle symbol
	Packaging material cycle mark	CE 2460	CE mark
UDI	Unique device identifier	MD	Medical device

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