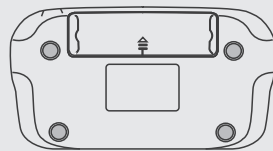


华佗全球信赖的品牌



SDZ- II 型 电子针疗仪

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China
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技术使用说明书

INSTRUCTION MANUAL FOR USE

苏州医疗用品厂有限公司
Suzhou Medical Appliance Factory

SDZ- II 型

电子针疗仪

SDZ-II Nerve and Muscle Stimulator
ELECTRONIC ACUPUNCTURE TREATMENT INSTRUMENT



使用前, 请仔细阅读本说明书。
Please read these instructions completely before using.

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■ Dear customers:
Thanks for choosing our Hwato® products.Please read the instruction manual carefully before using, and keep it properly.

Introduction

Nerve and Muscle Stimulator (SDZ-II) can output low frequency pulse. It is indicated for treatment of pain of human body. It is intended for Hospitals, clinics use.

Nerve and Muscle Stimulator (SDZ-II) is an advanced electro-therapy unit, featuring 6 output channels, as well as a timer and adjustable frequency levels. Based on the traditional electronic treatment instruments, the Nerve and Muscle Stimulator combines modern micro computer technology with Traditional Chinese Medicine theory.

Intended Use

SDZ-II Nerve and Muscle Stimulator is used for applying low frequency pulse to stimulate the human body, may be used to apply an electrical current to electrodes on a patient's skin to treat pain, which is indicated for use by qualified practitioners .

Warnings and Precautions

- Not applicable for patients with implanted medical devices, such as Cardiac Pacemaker.
- Not applicable for pregnant women, or patients with acute diseases, communicable diseases, heart diseases, cancer, etc.
- Can not be used on skins with ulcer, scratch, new scar, wound or irritation.
- Never use the instrument when driving or operating a machine.
- Advice that stimulation should not be applied across or through the head, directly on the eyes, covering the mouth, on the front of the neck, (especially the carotid sinus), or from electrodes placed on the chest and the upper back or crossing over the heart
- When the instrument is in use, it is not allowed to touch metal objects.
- When the instrument is in use 2 self-adhesive electrodes of a same group shouldn't touch each other, otherwise it might cause short-circuit and damage the instrument.
- To avoid cross contamination, never use self-adhesive electrodes which have been used by others.

Warnings and Precautions

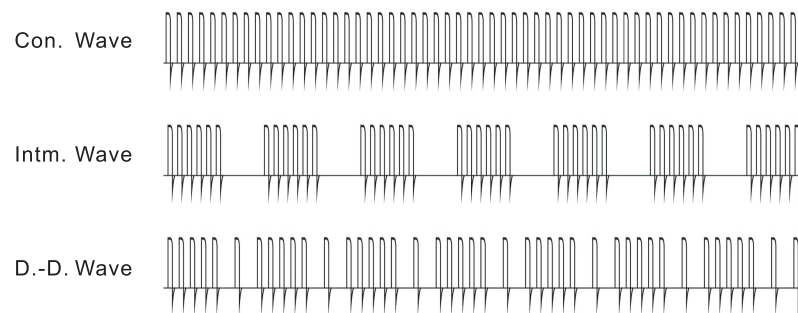
- Never use the instrument when bathing and sweating.
- Never apply the self-adhesive electrodes on eyelids, throat, heart and chest.
- Never use the instrument in the place where there is flammable and explosive gas.
- The instrument should have a certain distance from TVs, radios, and other electrical instruments, in case of electromagnetic interference.
- Users should avoid the circuit loop to get through the heart.
- When the instrument is in use ,All parts of the instrument shall not be serviced or maintained.
- under the guidance of a doctor,All functions the patient can safely use ,and maintenance the patient can perform.
- Plug of AC/DC adapter is intended to be used as isolation device from supply mains, please always make isolation device easy to operate.
- Do not modify the instrument without authorization of the manufacturer".
- If you notice any unexplained changes in the performance of the device, if it is making unusual sounds, if the device or the power supply are dropped or mishandled, or if the enclosure is broken, discontinue use and power off the equipment, then contact your provider or Service Center.
- This equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

※ A warning on the following potential hazards:

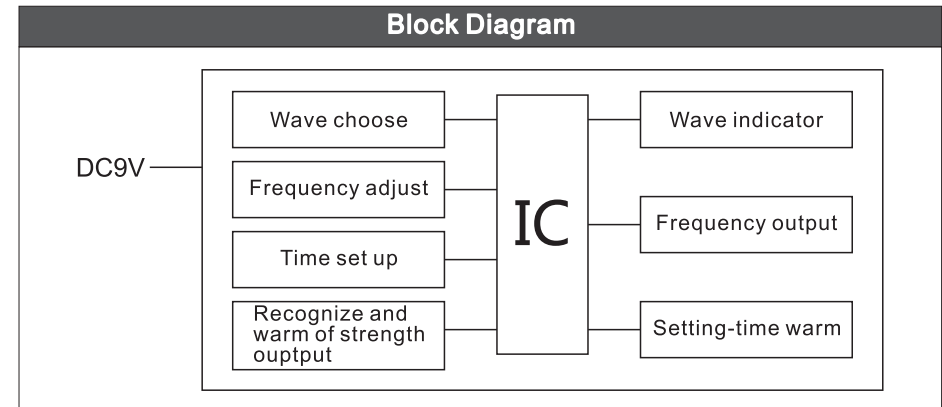
1. Simultaneous connection of a patient to a h.f. surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
2. Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
3. Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
4. Except the power adapter supplied by the manufacturer as spare parts, using any unspecified accessories or power adapter may cause increasing emission or decreasing immunity of the instrument.
5. When the instrument is in use, never put it near other instruments or stack it on other instruments. If you have to put it near other instruments or stack it on other instruments, please inspect and verify if the instrument could run normally.

⚠ The instrument should be used by qualified practitioners or under the guidance of qualified practitioners.

Wave Form



Block Diagram

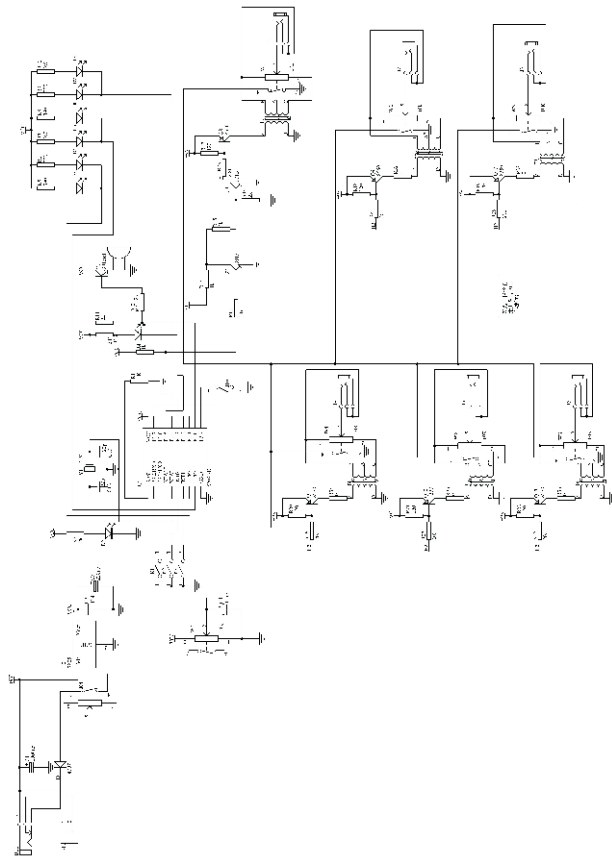


Parts List

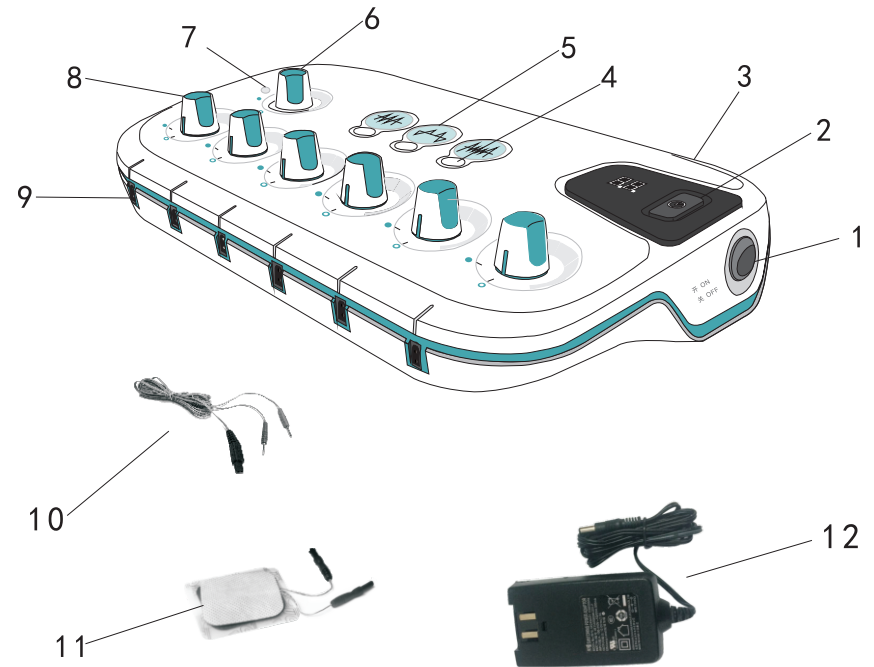
No.	Name	Code	Quantity
1	Integrated Circuit Block (IC)	IC	2
2	Crystal Oscillator	Y	1
3	Timer	----	1
4	Transistor	Q	9
5	Output Transformer	T	6
6	Switch	K	1
7	Frequency Potentiometer	W	1
8	Switch Potentiometer	W	6
9	Output Socket	J	6
10	DC Socket	BT	1
11	Touch Switch	K	3
12	Light Emitting Diode	D	8
13	Rectifier Diode	D	1
14	Fuse (500mA,L,250V, Ø5x20mm)	F	1

15	Capacitor	C	7
16	Resistor	R	27
17	Buzzer (Active 5V)	-----	1

Circuit Diagram



Indicators and Controls



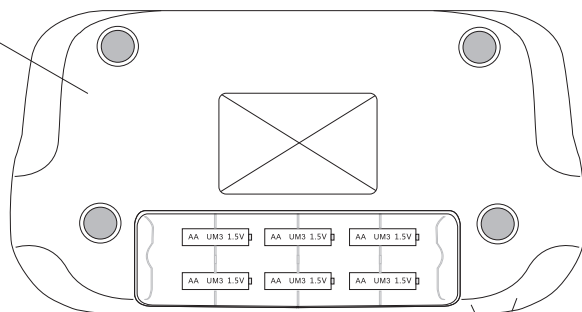
- | | |
|------------------|-----------------------------|
| 1、Device Switch | 7、Frequency Indicator |
| 2、Timer | 8、Intensity Knobs |
| 3、DC Jack | 9、Output Jacks |
| 4、Wave Buttons | 10、Lead Wires |
| 5、Wave Screens | 11、Self-adhesive Electrodes |
| 6、Frequency Knob | 12、DC 9V Power Adapter |

Instructions for Use

①. Preparation

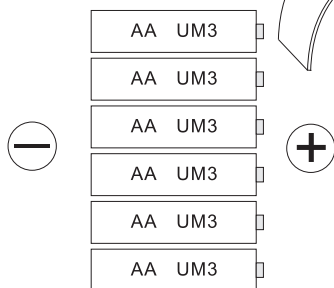
- (1) Remove the battery cover from the backside of the instrument and install six pieces batteries (Type: AA UM3).

Instrument

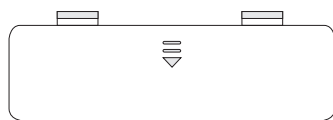


※ Please notice the place of anode and cathode when installing the batteries.

6 batteries

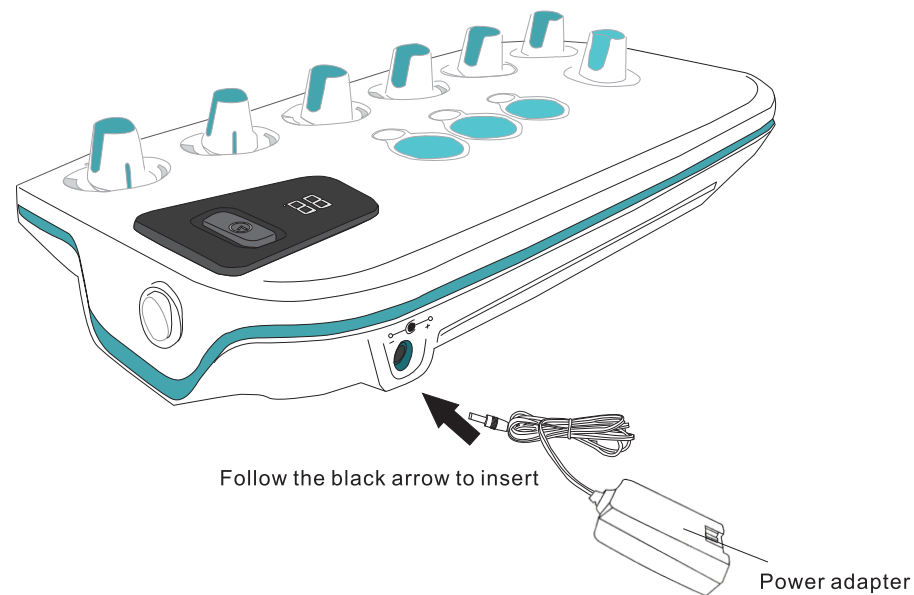


Follow the white arrow when installing the batteries



Follow the black arrow when removing the battery cover, and you will hear the click.

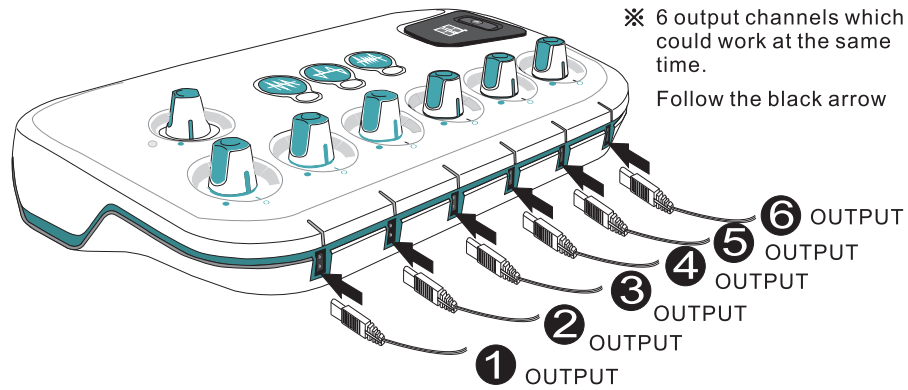
- (2) Or connect the instrument to the power supply through DC 9V power adapter.



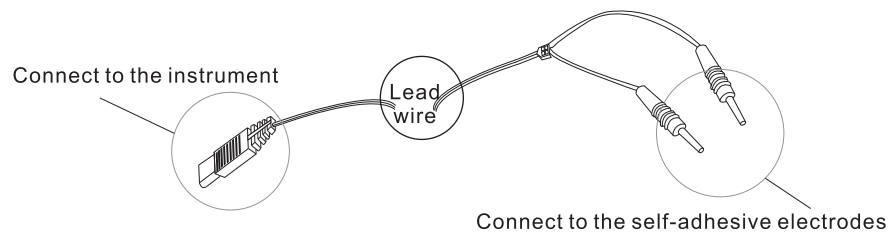
CAUTION

Power adapter is the special accessories for the instrument ,can not be used with other models(Model NO. UE08WCP-090020SPA)

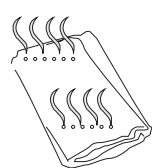
Applied part:
the stimulator electrodes and all parts conductively connected to them



- Plug one end of the lead wire into the output Jack.



- Before use, clean the treated areas with warm towel or medical alcohol.

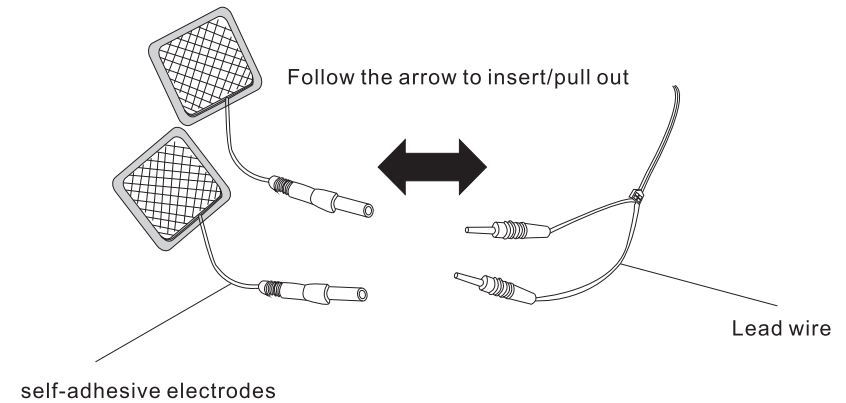


Recommended



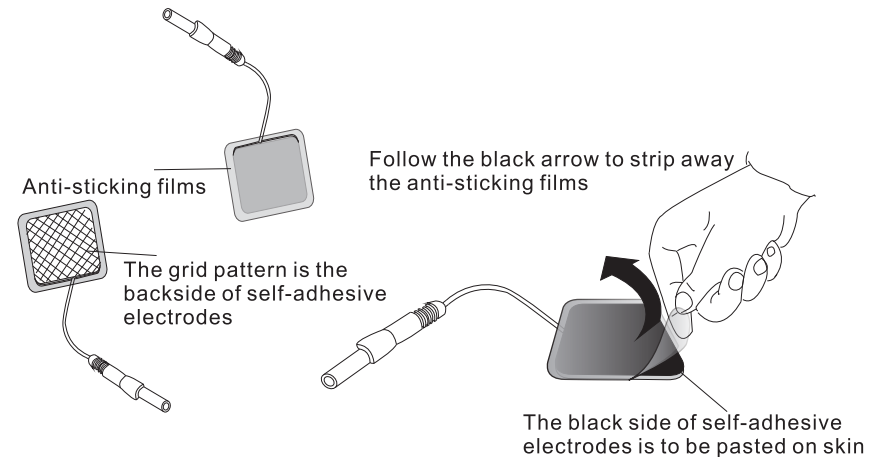
Treatment with Self-adhesive Electrodes

- Connect the other end of lead wire to self-adhesive electrodes.



※ Never pull the wire hard otherwise it might break.

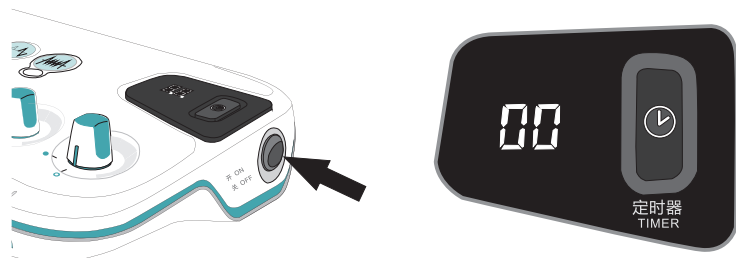
- Strip away the anti-sticking films from the self-adhesive electrodes, then apply the self-adhesive electrodes on the treated areas.



※ Check the Intensity knob, and adjust it to “OFF” state.

②. Turn on the instrument

- Turn on the device switch. The timer is set for 0 minute by default (The LED shows 00).



Press the device switch to turn on the instrument.

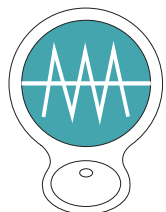
- If the instrument beeps after turned on, please check the Intensity knob, adjust it to “OFF” state and turn the device switch on again.

③. Set the instrument

Choose the Operation Modes

Press the Wave Choosing button to choose 3 outputs modes: Continuous wave, Intermittent wave or Dense-disperse wave:

Continuous wave Intermittent wave Dense-disperse wave



CON.WAVE

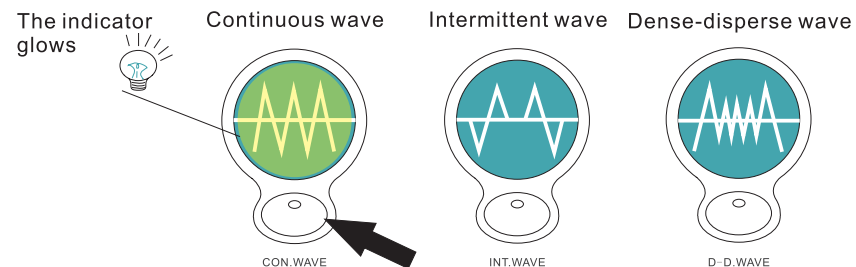


INT.WAVE



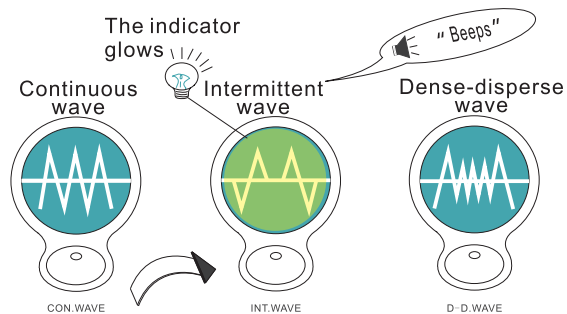
D-D.WAVE

- Press the CON. WAVE button, it glows and the instrument produces continuous wave at the frequency set by the user.
- Press the D.-D WAVE button, it glows and the instrument produces dense-disperse wave at the frequency set by the user.
- Press the INTM. WAVE button, it glows and the instrument produces intermittent wave at the frequency set by the user.

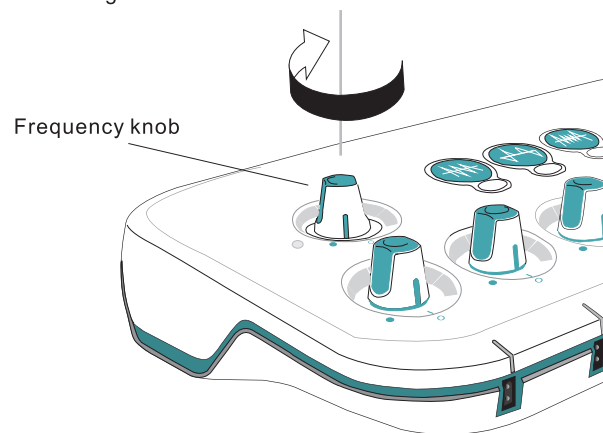


CAUTION

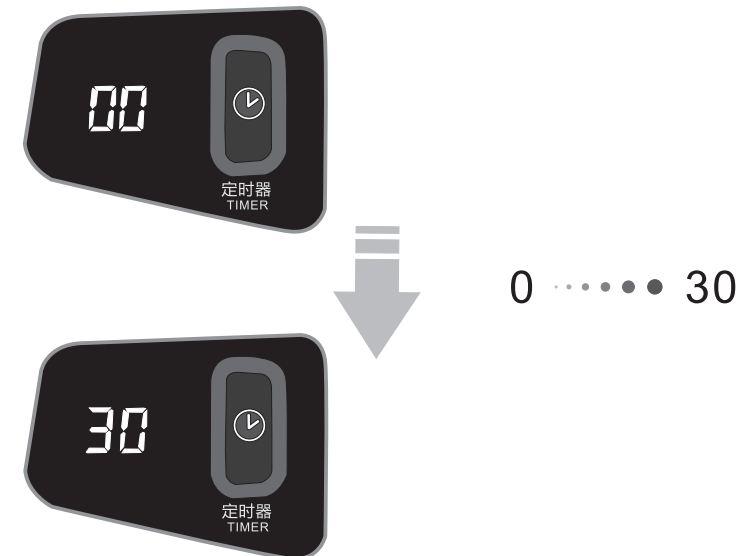
Users could choose different operation mode based on the need of treatment. The instrument will produce 4 warning beeps when user changes the output mode during use.



- After selecting an outputs mode, users could adjust the output pulse frequency by adjusting the Frequency knob. The frequency indicator light is green, and the bigger the knob value, the faster the flashing.



- Press the Timer button (TIMER) to set operation time. It is continuously adjustable from 0 to 30 minutes.



④.Treatment

Output Adjustment

- After selecting the output mode and time, turn on the intensity knob (ADJUST INTENSITY) to adjust the output pulse intensity until it is appropriate to the user.
- According to the need of treatment, adjust the frequency knob (ADJUST FREQ) to adjust output frequency until it is appropriate to the user.

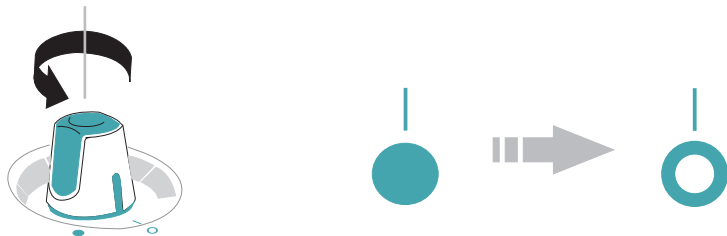
- When the operation time is out, the instrument beeps, and the wave screen and frequency indicator goes off.

CAUTION

1. Before or during treatment, if it is needed to change treatment area, please adjust the output intensity to MIN. at first. After the self-adhesive electrodes are fixed well, users should increase the output very slowly; otherwise the users treated will feel uncomfortable because of intense stimulation.
During treatment, never apply 2 self-adhesive electrodes which are from the
2. same output port, on the left and right side of upper body simultaneously, so as to avoid the electric current to pass through the heart.

⑤. Turn off the instrument

- When the operation time is out, please switch off the frequency knob and intensity knob anti-clockwise. Then turn off the device switch.



- Remove the self-adhesive electrodes, and unplug the lead wire.
- If a power adapter is used, please disconnect it from mains power, then remove the power adapter from the instrument.

Technical Specifications

- 1) Power: Internal power supply DC 9V ^{+5%}/_{-10%}
Power adapter (input AC 100-240V~50-60Hz, output DC 9V)
(Model NO. UE08WCP-090020SPA)
- 2) Input Power: 10.0VA
- 3) Output Pulse Wave: Asymmetric biphasic square wave
- 4) Output Channels: 6 Channels
- 5) Max. Output Power: 0.3VA (at 0.9% saline load impedance)
- 6) Output Pulse Frequency: 1 to 100Hz Adjustable, $\pm 15\%$ tolerance
- 7) Output peak pulse voltage: $\leq 500V$ (open) ;
- 8) The range of output pulse amplitude: $0 \sim 2V \pm 25\%$ (at 0.9% saline load impedance)
- 9) Output direct component: 0
- 10) Output Modes:
 - Continuous wave: Continuous
 - Interrupted wave: 15 seconds of continuous wave and 5 seconds of pause
 - Dense-disperse wave: The ratio of disperse wave frequency to dense wave frequency is 1:5, disperse wave works 5 seconds and dense wave works 10 seconds.
(Time allowance for Interrupted wave and Dense-disperse wave is $\pm 15\%$).
- 11) Output Current Limit (r.m.s): $\leq 10mA$ (at 0.9% saline load impedance)

- 12) Output Direct Component: 0
- 13) Output Pulse width: 0.2ms±30% (Basic performance tested by EMC)
- 14) Measurement: 292 mm x 156 mm x 47mm
- 15) Total weight: 1kg

Power adapter Technical specifications:

Input: 100-240VAC, 50-60Hz, 400mA
Output: 9.0V $\bar{\square}$ 0.2A

load impedance: 0.9% saline

Remark: load impedance has no effect on direct component, output pulse width, and output pulse frequency. It is positively correlated to the max. output amplitude.

CAUTION

This instrument is not an AP or APG equipment. Its waterproof grade is IPX0.

This instrument conforms to the requirements of Class II the Internal Power Supply Type BF Applied Part of IEC 60601-1.

- When measuring if the load resistance's variety is within ±10%, the variety of pulse width of pulse durative period, repeated pulse frequency and pulse amplitude caused, including all DC components should be no more than 30%.
- If the variety of power voltage is within ±10%, measure the variety of output pulse amplitude, pulse with, or repeated pulse frequency, the results should be ≤ ±10%.



CAUTION:

The instrument conforms to the requirements of electromagnetic compatibility of IEC 60601-1-2. This instrument doesn't require any installation. Please use and operate this instrument according to the Guidance and Manufacturer's Declaration in below table.

Guidance and Manufacturer's Declaration

1. List of cables

Name	Lengths(m)	Whether the cable is shielded
Cable(OutPut)	1.8	No
Cable(DC)	1.8	No

2. Technical description

2.1 Compliance information for Emission test

Emission test	Compliance
RF emissions CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

2.2 Compliance information for Immunity test

Immunity test	Compliance level
Electrostatic discharge(ESD) IEC61000-4-2	±8kV contact ±2kV, ±4kV, ±8kV,±15kV air
Electrical fast transient/burst IEC61000-4-4	±2kV 100kHz repetition frequency for power supply lines
Surge IEC61000-4-5	±0.5kV , ±1kV (line-to-line)differential mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	Voltage Dips 0%U _T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0%U _T ; 1.0 cycle And 70%U _T ; 25/30 cycles Single phase at 0° Interruptions 0%U _T ; 250/300 cycle
Power frequency(50Hz) magnetic field IEC61000-4-8	30A/m 50 or 60 Hz
Radiated RF EM fields IEC61000-4-3	10 V/m 80 MHz -2,7 GHz 80 % AM at 1 kHz
Conducted disturbances induced by RF fields IEC61000-4-6	3 V rms 0.15MHz – 80 MHz 6V rms in ISM bands between 0.15MHz to 80MHz 80% AM at 1kHz
NOTE U _T is the a.c mains voltage prior to application of the test level.	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

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)} 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ^{c)} ±5 kHz deviation 1 kHz sine	2	0,3	28
710 745 780	704-787	LTE Band 13,17	Pulse Modulation ^{b)} 217 Hz	0,2	0,3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation ^{b)} 18 Hz	2	0,3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation ^{b)} 217 Hz	2	0,3	28

Test Frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum Power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation ^{b)} 217 Hz	2	0,3	28
5240	5100-	WLAN 802.11	Pulse	0,2	0,3	9
5500	5800	a/n	Modulation ^{b)}			
5785			217 Hz			

NOTE If 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 while it does not represent actual modulation, it would be worst case.

2.3 Precautions

According to IEC60601-1-2:2014, The Nerve and Muscle Stimulator (SDZ-II) complies with all applicable electromagnetic compatibility requirements (EMC). It may have harmful interference with other devices if you do not following the instructions. However, there is not certain it has not interference with other devices if you following the instructions. If it does have interference with other device, you can amend interference by the following methods.

- a) Enlarge the distance between this device and other device.
- b) Connect the two devices with different power socket.
- c) Ask engineer for help.

Symbol Explanation



Indicates the instrument conforms to the degree of protecting against electric shock for the Type BF Applied Part.



Indicates the instrument belongs to the Class II Equipment.

IPX0

Indicating the degree of splash-proof of the instrument housing is unprotected.



Caution.



The instrument is conform with the requirements of Medical Devices Directive MDD.



WEEE symbol.



Serial number (The symbol shall be accompanied by the manufacture's serial number.)



Date of manufacture (The symbol shall be accompanied by a date to indicate the date of manufacture.)



Follow instructions for use.

Accessories

- 1 piece Power adapter (Model NO. UE08WCP-090020SPA)
- 6 sets lead wires (in six different colors)
- 6 pairs of self-adhesive electrodes (size: 50mm x 50mm)
- 1 instruction manual
- 1 certificate of product quality conformity
- 1 product warranty card



CAUTION

The accessory output wires, self-adhesive electrodes attached with the instrument are used with the instrument. If these accessories are damaged and need to be changed, please use the dedicated accessories supplied by our company, to ensure the normal use of instrument.

Care and Maintenance

- Please store the appliance in the place out of reach of children.
- Never let the appliance fall or smash from high, extrude or soaking.
- Store the appliance in dry and ventilated place without corrosive gases. Avoid direct sunlight.
- The appliance has been tested strictly before leaving factory. Please do not disassemble or assemble the appliance yourself. Suggest that the host use period for five years.
- Never clean the appliance with water. Please wipe it with soft and clean cloth, or with 75% isopropyl alcohol solution for better cleaning effect. Clean the appliance every month. The self-adhesive electrodes could be cleaned with water or medical alcohol. It should be cleaned before and after every time of use so as to avoid dust. Please change to use new self-adhesive electrode if its adhesive effect is getting worse.
- Please take out the battery if you will not use the appliance for a week, so as to prevent damage to the appliance caused by battery leakage.
- When unplug the wire, please hold the plug and pull it out. Never pull the wire directly otherwise the wire might be damaged.
- To prevent the wire of power adapter damaging, check periodically per month.
- To prevent the screw of device fall off, check periodically per month.



In order to avoid polluting the environment, the instrument, accessories and the dry battery used should be disposed according to requirements of local authority rather than throw them away at random

Trouble Shooting

Problem	Likely Causes	Solution
The timer screen doesn't work or works improperly after the instrument is switched on.	The digital display is wrong.	Contact the supplier for repairing.
	The batteries are not installed properly	Turn off the instruments, re install the batteries.
	Battery runs low.	Change new batteries.
The wave screen doesn't work.	The indicator lamp is wrong.	Contact the supplier for repairing.
	The batteries are not installed properly.	Turn off the instruments, re install the batteries.
	Battery runs low.	Change new batteries.
Button or switch doesn't work.	The button or switch is wrong.	Contact the supplier for repairing.
No pulse output.	The lead wires, self-adhesive electrodes or metal clamps are not connected, or is in poor contact.	Re connect the lead wires and metal clamps.
	The lead wires, self-adhesive electrodes or the metal clamps are damaged.	Contact the supplier for change.
	The skin is too dry or too greasy.	Clean the treated areas with alcohol or warm towel.
	The instrument is wrong.	Contact the supplier for repairing.
The instrument doesn't beep when treatment time is over.	The buzzer is wrong	Contact the supplier for repairing.
Other		Contact the supplier.

If you're unable to solve the problem with the information above, please contact the supplier.

Environmental Conditions for Transport and Storage

Ambient temperature range: -40°C ~ 55°C

Relative humidity range: ≤95%

Packed devices should be stored in the ventilated place (≤95%RH) without corrosive gases.

Operation Conditions

Ambient temperature range: 5°C ~ 40°C

Atmosphere pressure range: 86kPa ~ 106kPa

Relative humidity range: ≤80%

Power: Internal power supply DC 9V ^{+5%}_{-10%}

Power adapter (input AC 100-240V~50-60Hz, output DC 9V)

Continuous operation

Guarantee and Service

The product is supplied with one year warranty from the date of purchase. Warranty is only valid under normal use. Damage due to operator's misuse is not covered under warranty.

Spare parts, including lead wires, self-adhesive electrodes are not within the scope of the warranty. Please purchase the parts manufactured by us from local Hwato dealer to ensure the normal use of instrument.

If you need more information, please contact your local Hwato dealer.