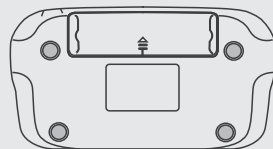


华佗全球信赖的品牌



### SDZ-II 型 电子针疗仪

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DATE OF REVISION: 2015/12



China  
Time-honored  
Brand  
中华老字号

## 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 acupuncture treatment instruments, the Nerve and Muscle Stimulator combines modern micro computer technology with Traditional Chinese Medicine acupuncture and meridian theory. It consists of an external low-intensity, low frequency pulse multimode generator and electrodes.

### Intended Use

Hwato SDZ-II Nerve and Muscle Stimulator is for low frequency pulse treatment on human acupoints.

### 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.



### Warnings and Precautions

- When the instrument is in use, it is not allowed to touch metal objects.



- When the instrument is in use, 2 metal clamps (filiform needle electrodes) or 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 or acupuncture needles which have been used by others.



- 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.




### Warnings and Precautions

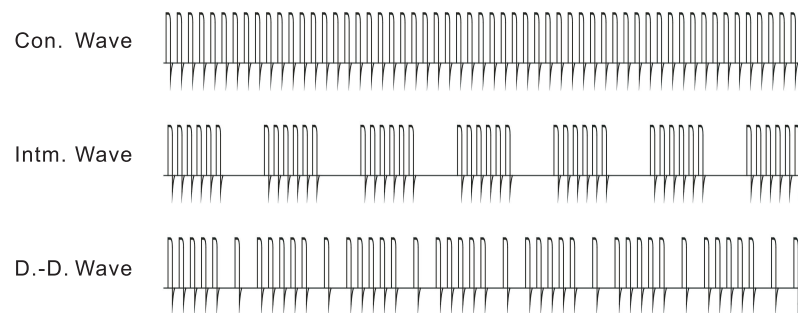
- Electro-acupuncture therapy is allowed to be performed by qualified practitioners of acupuncture only. Sterile disposable acupuncture needles are recommended. Never use the acupuncture needle if it is deformed, oxidized, rusted or dirty. When adjusting the output intensity, please operate from low to high very slowly. If the treated area is close to the Medulla Oblongata or spinal cord, please use small current to avoid accidents. Never change to high intensity in a sudden, otherwise a strong muscle contraction may happen and cause needle bent, broke, or needle sickness.

※ A warning on the following potential hazards:

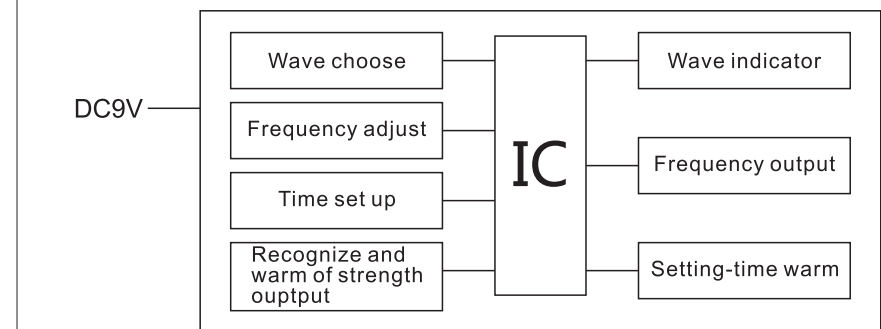
- Simultaneous connection of a patient to a h.f. surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operation in close proximity (e.g. 1 m) to a shortwave or microwave therapy equipment may produce instability in the stimulator output.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- 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.
- 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

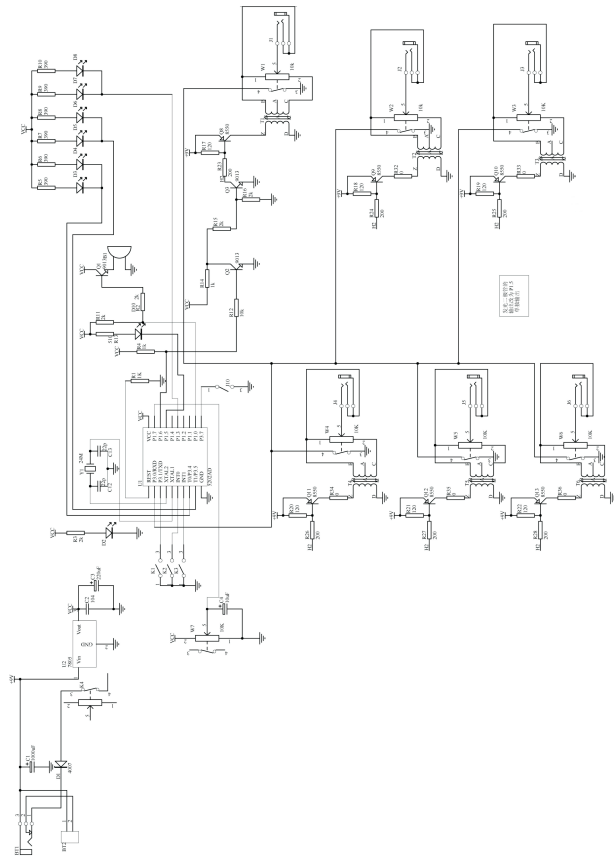


### Parts List

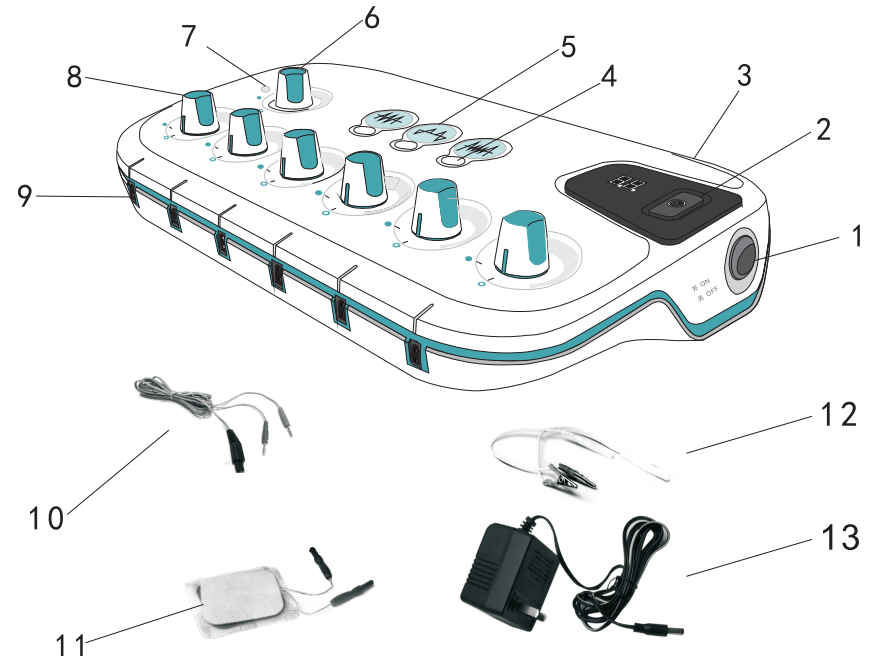
No.	Name	Code	Quantity
1	Integrated Circuit Block (IC)	IC	2
2	Crystal Oscillator	Y	1
3	Timer	----	1
4	Transistor	Q	9
5	Output Transformer	T	6
6	Switch	K	1
7	Frequency Potentiometer	W	1
8	Switch Potentiometer	W	6
9	Output Socket	J	6
10	DC Socket	BT	1
11	Touch Switch	K	3
12	Light Emitting Diode	D	8
13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

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

### Circuit Diagram



### Indicators and Controls

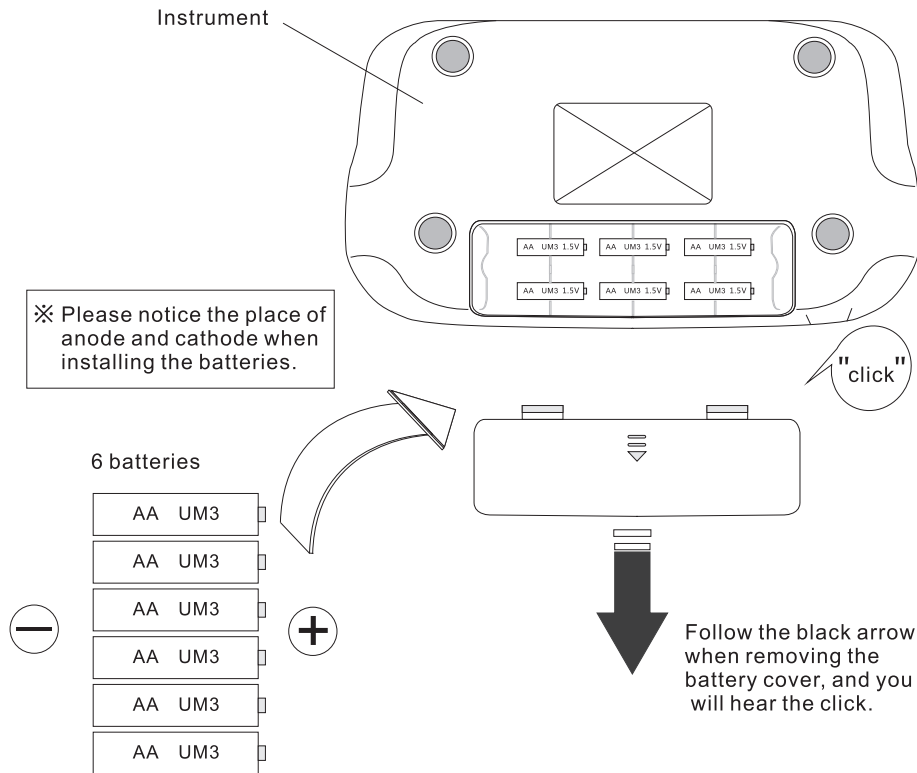


- |                        |   |
|------------------------|---|
| 1. Device Switch       | 8. Intensity Knobs                            |
| 2. Timer               | 9. Output Jacks                               |
| 3. DC Jack             | 10. Lead Wires                                |
| 4. Wave Buttons        | 11. Self-adhesive Electrodes                  |
| 5. Wave Screens        | 12. Metal Clamps (filiform needle electrodes) |
| 6. Frequency Knob      | 13. DC 9V Power Adapter                       |
| 7. Frequency Indicator |   |

## Instructions for Use

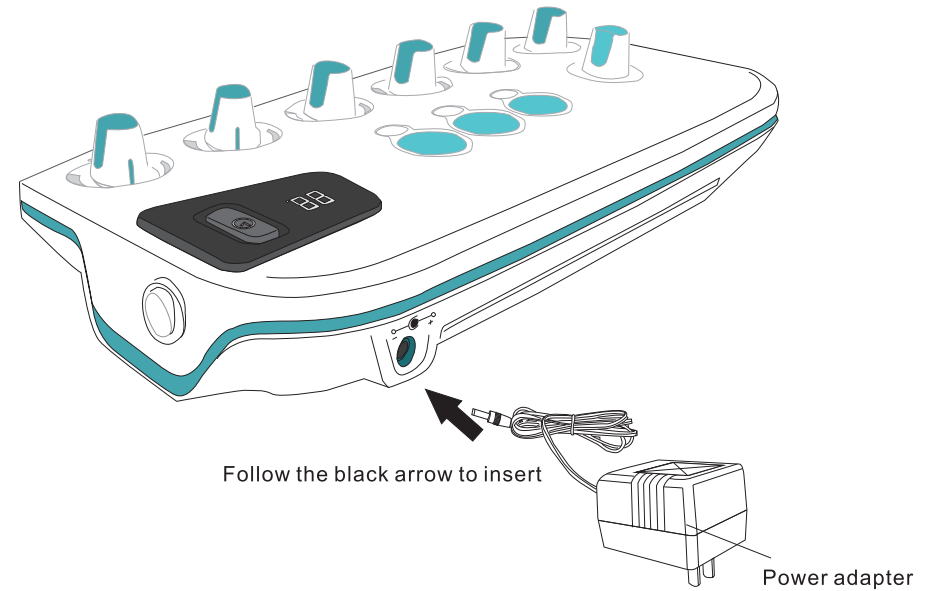
### ①. Preparation

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



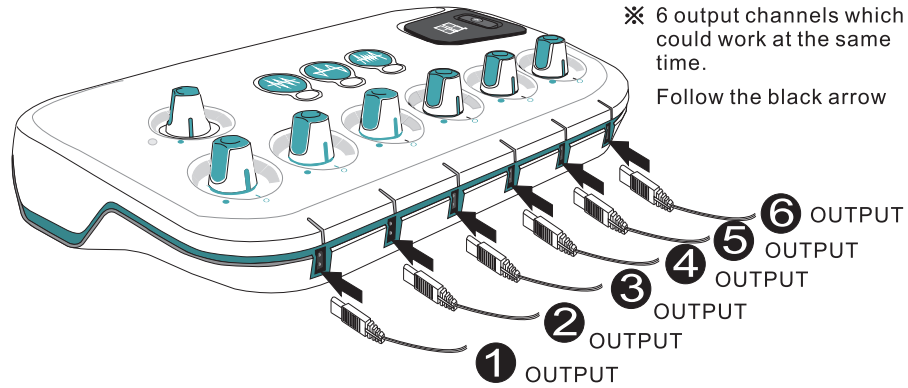
Follow the white arrow when installing the batteries

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

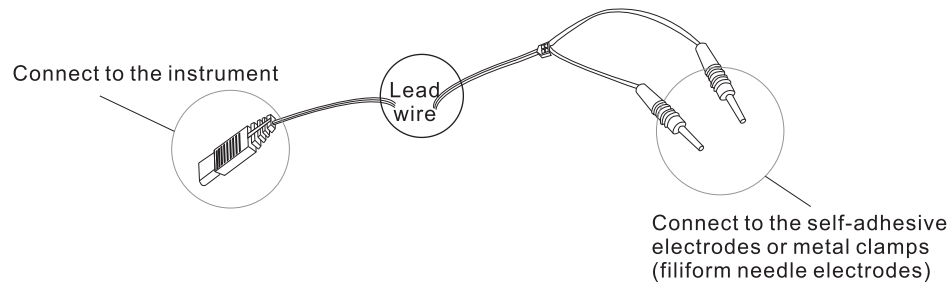


CAUTION

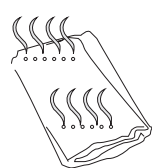
1. Users should choose AC adapters which are GS or CE certificated according to IEC60601. The polarity of power output should accord with the sign of the instrument's external DC supply receptacle.
2. If using AC Adapter, make sure its input voltage and frequency requirement comply with the domestic mains power. The output plug of AC adapter should be inserted into the external DC supply receptacle before opening the instrument's Device supply switch, then connecting the net power supply. Pulling out the plugs of AC adapter from the net power supply after turning off, then separating the output plugs from the instrument.



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



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

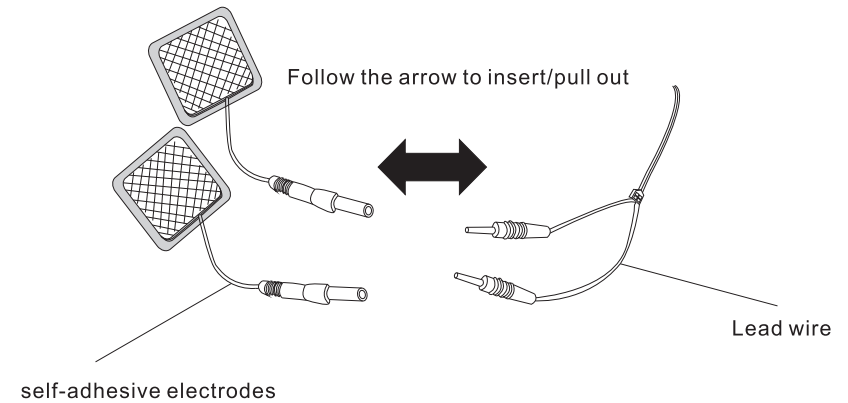


Recommended



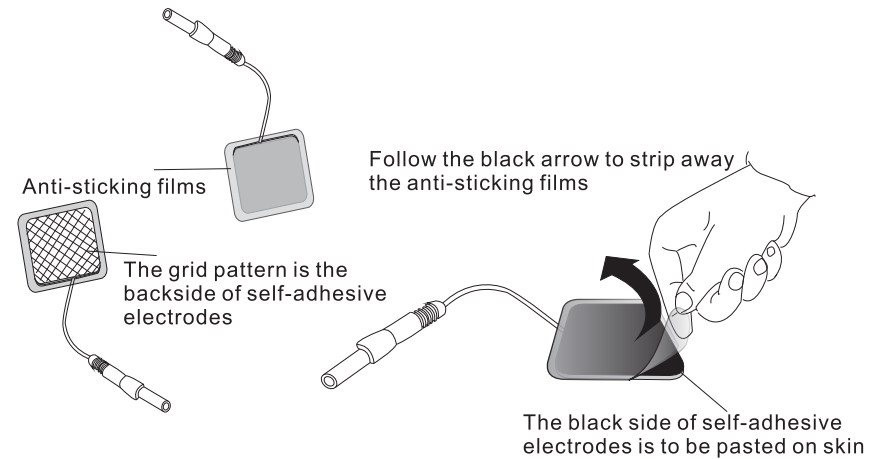
### Treatment with Self-adhesive Electrodes

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



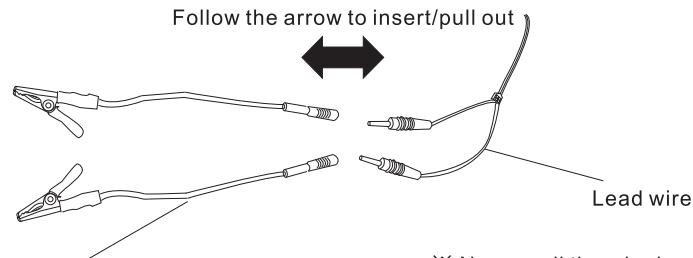
※ Never pull the wire hard otherwise it might break.

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



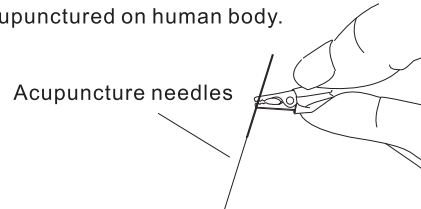
## Electro-acupuncture Treatment

- For electro-acupuncture, please connect the metal clamps to the lead wire.



※ Never pull the wire hard otherwise it might break.

- Then clip the metal clamps to the acupuncture needles which have already been acupunctured on human body.



- Then connect the lead wire to the output jack.

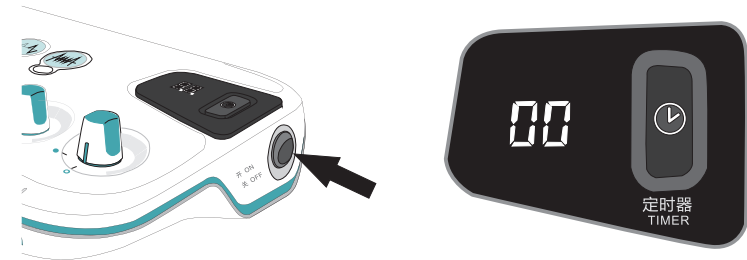
### ⚠ CAUTION

1. The lead wires of this instrument could be used together with the self-adhesive electrodes and the metal clamps (filiform needle electrodes). It is easy to change and reliable in connecting for users. Never pull the wire hard otherwise it might break.
2. Electro-acupuncture therapy are allowed to be performed by professional acupuncture doctors only. It should be strictly performed according to the operating rules of electro-acupuncture therapy.
3. Recommended self-adhesive electrode size: 50mm x 50mm.

※ Check the Intensity knob, and adjust it to “○” state (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 “○” 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



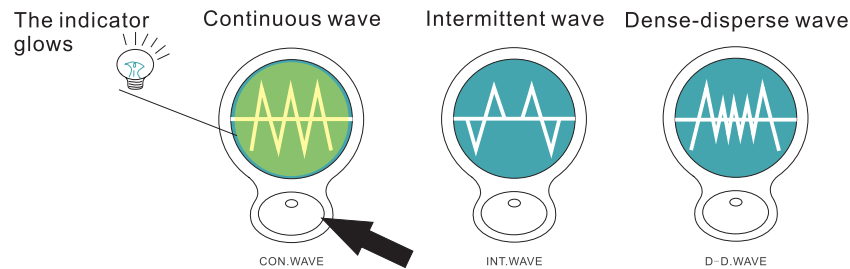
INT.WAVE



D-D.WAVE

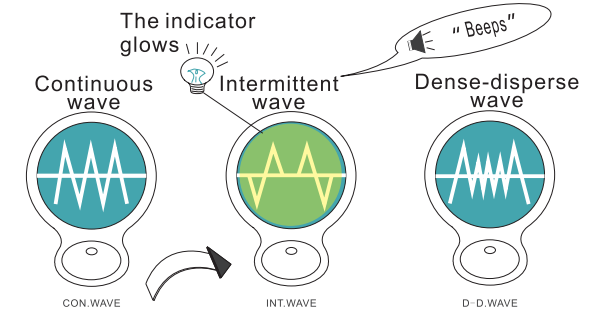


- Press the CON. WAVE button, it glows and the instrument produces continuous wave at the frequency set by the user.
- Press the D.-D WAVE button, it glows and the instrument produces dense-disperse wave at the frequency set by the user.
- Press the INTM. WAVE button, it glows and the instrument produces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

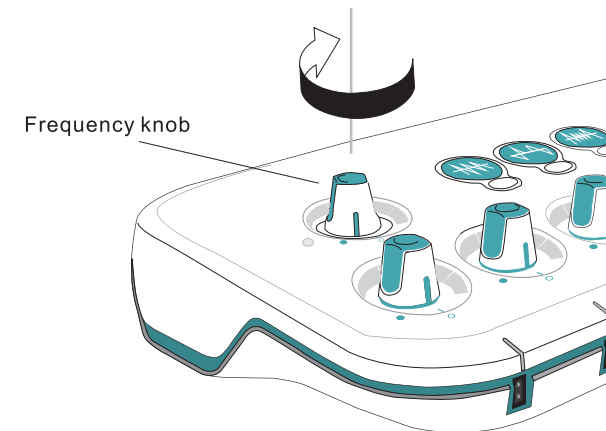


**CAUTION**

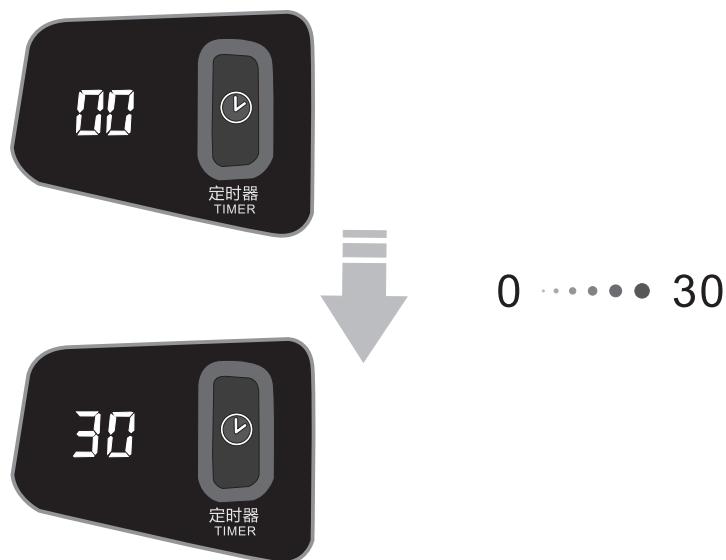
Users could choose different operation mode based on the need of treatment. The instrument will produce 4 warning beeps when user changes the output mode during use.



- After selecting an outputs mode, users could adjust the output pulse frequency by adjusting the Frequency knob.



- 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.

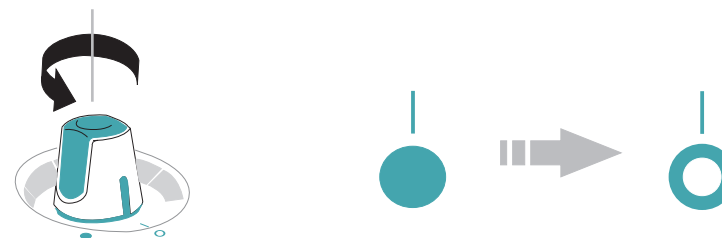
- When the operation time is out, the instrument beeps, and the wave screen and frequency indicator goes off.

### ⚠ 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 or the metal clamps (filiform needle electrodes) are fixed well, users should increase the output very slowly; otherwise the users treated will feel uncomfortable because of intense stimulation.
2. During treatment, never apply the 2 metal clamps or 2 self-adhesive electrodes which are from the 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 acupuncture needles or 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  $\begin{matrix} +5\% \\ -10\% \end{matrix}$   
Power adapter (Input AC 230V 50Hz, Output DC 9V)
- 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 250Ω load impedance)
- 6) Output Pulse Frequency: 1 to 100Hz Adjustable,  $\pm 15\%$  tolerance
- 7) 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  $\pm 15\%$ ).
- 8) Output Current Limit (r.m.s):  $\leq 10\text{mA}$  (at 250Ω load impedance)

- 9) Output Direct Component: 0
- 10) Output Pulse width: 0.2ms $\pm 30\%$  (Basic performance tested by EMC)
- 11) Measurement: 292 mm x 156 mm x 47mm
- 12) Total weight: 1kg

Rated load impedance: 500Ω when using self-adhesive electrodes; 250Ω when using metal clamps (filiform needle electrodes)

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  $\pm 10\%$ , 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  $\pm 10\%$ , measure the variety of output pulse amplitude, pulse with, or repeated pulse frequency, the results should be  $\leq \pm 10\%$ .



**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**

**Guidance and manufacturer's declaration – electromagnetic emissions – for all EQUIPMENT and SYSTEMS**

Guidance and manufacturer's declaration – electromagnetic emission		
The Nerve and Muscle Stimulator (SDZ-II) is intended for use in the electromagnetic environment specified below. The customer or the user of the Nerve and Muscle Stimulator (SDZ-II) should assure that it is used in such and environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The Nerve and Muscle Stimulator(SDZ-II) 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 emission CISPR 11	Class B	The Nerve and Muscle Stimulator(SDZ-II) is suitable for use in all establishments includes domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

**Guidance and manufacture's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS**


Guidance and manufacture's declaration – electromagnetic immunity			
The Nerve and Muscle Stimulator (SDZ-II) is intended for use in the electromagnetic environment specified below. The customer or the user of Nerve and Muscle Stimulator (SDZ-II) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	<5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 0.5 cycle 40% U <sub>T</sub> (60% dip in U <sub>T</sub> ) for 5 cycles 70% U <sub>T</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>T</sub> (>95% dip in U <sub>T</sub> ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Nerve and Muscle Stimulator(SDZ-II) requires continued operation during power mains dip & interruptions, it is recommended that the Nerve and Muscle Stimulator(SDZ-II) be powered from an uninterruptible power supply or a battery.

Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields Should be at levels characteristic of a typical location in a typical commercial or hospital environment.
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NOTE  $U_r$  is the a.c. mains voltage prior to application of the test level.

**Guidance and manufacturer’s declaration – electromagnetic immunity –  
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Guidance and manufacturer’s declaration – electromagnetic immunity			
The Nerve and Muscle Stimulator (SDZ-II) is intended for use in the electromagnetic environment specified below. The customer or the user of Nerve and Muscle Stimulator (SDZ-II) should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Nerve and Muscle Stimulator(SDZ-II), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance $d = \frac{3.5}{V_1} \sqrt{P}$ $d = \frac{3.5}{E_1} \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \frac{7}{E_1} \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

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 Nerve and Muscle Stimulator (SDZ-II) is used exceeds the applicable RF compliance level above, the Nerve and Muscle Stimulator (SDZ-II) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Nerve and Muscle Stimulator(SDZ-II).
- b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING**

**Recommended separation distances between portable and mobile RF communications equipment and the Nerve and Muscle Stimulator (SDZ-II)**

The Nerve and Muscle Stimulator (SDZ-II) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Nerve and Muscle Stimulator (SDZ-II) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nerve and Muscle Stimulator (SDZ-II) as recommended below, according to the maximum output power of the communications equipment.









Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter(m)		
	150 kHz to 80 MHz $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.

**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 manufacturer's serial number. )
-  Date of manufacture (The symbol shall be accompanied by a date to indicate the date of manufacture. )
-  Consult accompanying documents.

## Accessories

- 6 sets lead wires (in six different colors)
- 6 pairs of self-adhesive electrodes (size: 50mm x 50mm)
- 6 pairs of metal clamps (size: ≤28mm)
- 1 instruction manual
- 1 certificate of product quality conformity
- 1 product warranty card

### CAUTION

The accessory output wires, self-adhesive electrodes and metal clamps 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 long time, 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.



In order to avoid polluting the environment, the instrument, accessories and the dry battery used should be disposed according to the common electric rubbish or 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 <sup>+5%</sup>/<sub>-10%</sub>  
Power adapter (Input AC 230V 50Hz, Output DC 9V)  
Continuous operation

### Guarantee and Service

The product is supplied with one year warranty form 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 and metal clamps 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.