尺寸：140X200mm　材质：封面彩色157G双铜+内页黑白128G双铜

百年华佗，传承创新，继往开来
携手共创人类健康！

SDZ-Ⅱ型

电子针疗仪

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DATE OF REVISION：2015/11

华佗牌 Hwato
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
Electronic Acupuncture Treatment Instrument
SDZ-Ⅱ Nerve and Muscle Stimulator

新 NEW

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

CONTENTS

Respected users:

Welcome to use Hwato product.

Please read carefully before using. Please keep it well for reference.

INTRODUCTION:

SDZ-II Nerve and Muscle Stimulator is combined with micro computer technique, traditional chinese medicine acupuncture and meridian theory, based on the traditional electronic acupuncture treatment instrument.It doesn't contain acupuncture needles, but with Filiform Needle Electrode Metal Clip. Can use acupuncture needles as Electric-Acupuncture therapy, and recommend to use disposable acupuncture needles. Electrode needle should be used in accordance with GB2024 and YY0780-2010 standard 4.5 Electrode Needle Requirements. Its material is 06Cr19Ni10 or austenitic stainless steel, must meet with medical device product registration certification requirements.

INTENDED USE:

SDZ-II Nerve and Muscle Stimulator as a kind of TENS, EMS devices, may be used to apply low frequency pulse electrical current to stimulate the acupoints of human body through electrodes on a patient's skin to treat pain.

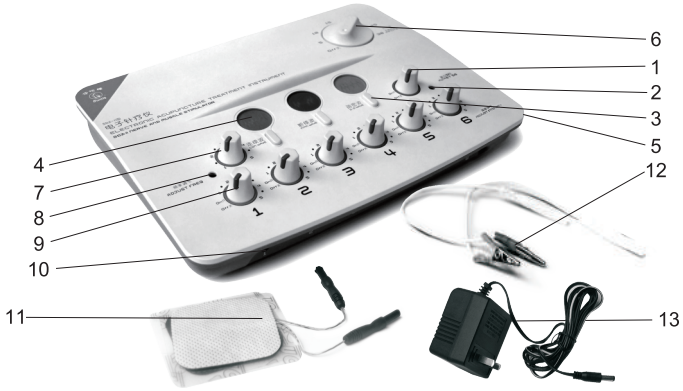
WARNINGS AND PRECAUTIONS: ⚠

- 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, 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.
- 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) 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 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.
- Electro-acupuncture therapy is allowed to be performed by professional acupuncture doctors only. Sterile acupuncture needles for single use 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. 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.

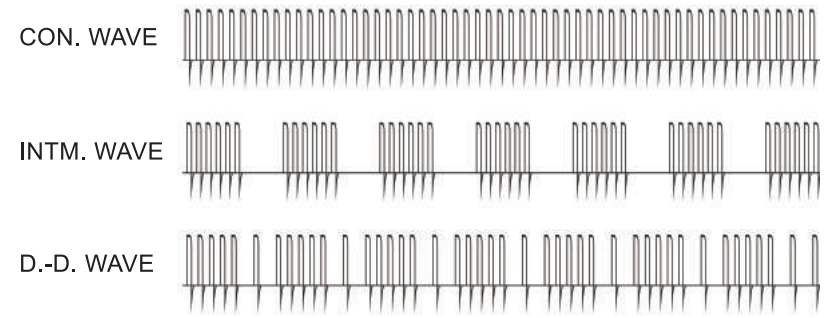
The device should be used by qualified practitioners or under the guidance of qualified practitioners.

INDICATORS AND CONTROLS:

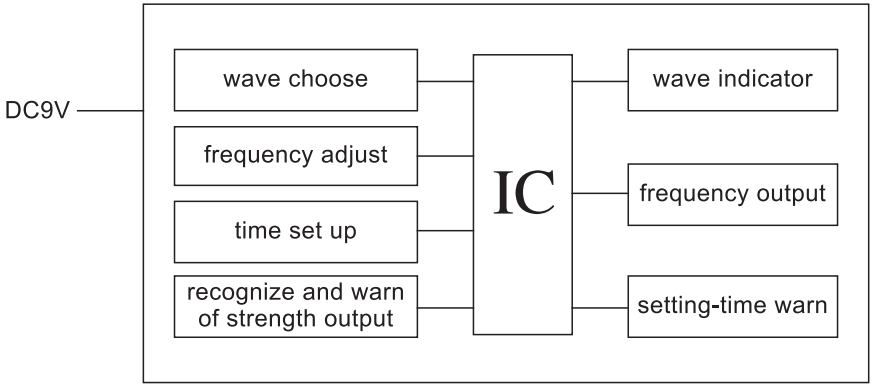


1.ON/OFF
2.Switch light
3.Wave choose key
4.Wave showing window
5.DC socket
6.Timer
7.Frequency adjusting knob
8.Frequency indicator light
9.Output strength adjusting knob
10.Six-output socket
11.Self-adhesive electrode
12.Metal clamp(Filiform needle-electrode)
13.DC9V AC Adapter

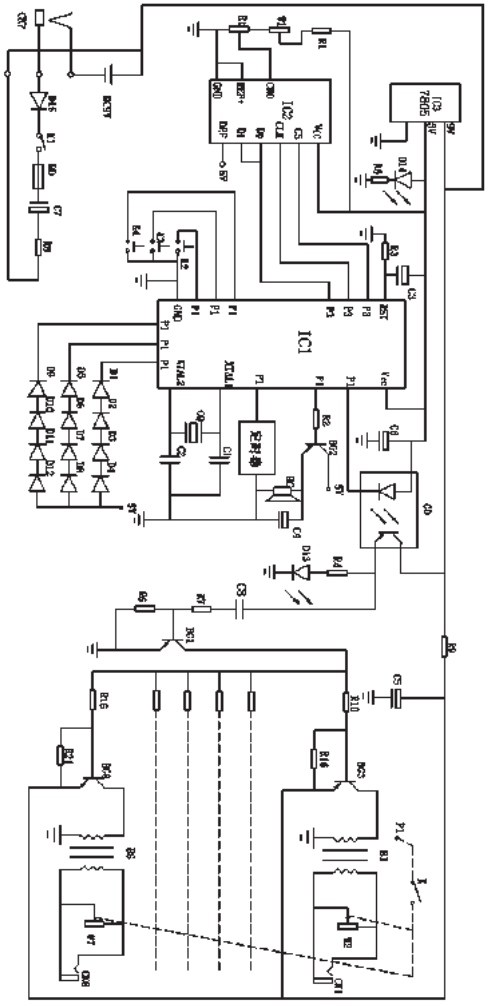
WAVE FORM:



BLOCK DIAGRAM:



CIRCUIT DIAGRAM:



LIST OF PARTS AND SPECIFICATION:

LIST OF PARTS AND SPECIFICATION			
No.	Element Name	Code	Quantity
1	Integrated Circuit Block(IC)	IC	3
2	Crystal Oscillator	CQ	1
3	Light-electricity Connector	GD	1
4	Time Setting		1
5	Transistor	BG	8
6	Output	B	6
7	Rheostat	W	1
8	Rheostat	W	6
9	Rheostat	RT	1
10	Output Plug	CK	6
11	DC Plug	CK	1
12	Switch	K	3
13	Photo Electric Diode	D	14
14	Photo Electric Diode	D	1
15	Capacitor	C	7
16	Resister	R	20
17	With-end Sound Breaker	HC	1
18	Warranty Wire(1A,φ5×20mm)	RD	1
19	Warranty Wire Plug		1

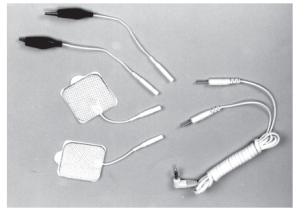
INSTRUCTIONS FOR USE:

1.Preparation:
Put six pieces R14、UM2 batteries in the back battery box of the instrument or put the DC Socket of the instrument right to the power of DC 9V.

1. If the users should choose AC Adapter which got the GS or CE certificate according to IEC60601 standard.The polarity of power output should accord with the sign of the instrument's external power supply receptacle.
2. If using AC Adapter, the output plugs of AC Adapter should be Inserted into the external power supply receptacle before opening the instrument's 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 instruments.

Clean the acupoints with alcohol or heat towel in order to enhance the curative effect.
Put the output wire into the socket of Self-adhesive electrode; take off the anti-stick paper of the Self-adhesive electrode and stick it on the acupoint, then put the other end of the electric wire in the output socket of the instrument.

If selecting the electric needle in treatment, put the electrode output wire in the metal clamp(filiform needle-electrode), then clamp the output mental clamp on the handle of the needle. The electric needle should be used by special acupuncture doctor, strictly according the operating regulations of electric needle therapeutics.



1. The output wires of the instrument can be used together with the Self-adhesive electrodes and acusector metal clamp(mini needle electrodes), it's easy to change for users and reliable in connecting. Do notdraw the wires too hard so that the wires are broken.
2. EA must be used by professional doctors, The instrument is suitable for use acupuncture needles specification: Diameter Φ 0.18 ~ 0.40mm, length13 ~ 75mm. Should be used in accordance with GB 2024 and YY0780-2010 standard 4.5 requirements.
3. Recommend using self-adhesive electrodes size: 50mm×50mm.

Check the strength adjusting switch and turn the switch to OFF.

2.Turn on the instrument:
Turn on the device switch, the indicator light is on.
If the instrument has the sound of “didi” ,check the strength adjusting switch and turn it to OFF, then re-turn on the device.

3.Set up
Press the wave choose key, the user can select one wave form the CON.WAVE, INTM. WAVE and D.-D.WAVE .
Press “CON.WAVE” key, the corresponding wave indicator diagram will indicate the working wave, the instrument will output continuously pulse wave according to the set frequency; Press “INTM. WAVE” key, the corresponding wave indicator diagram will indicate the working wave, the instrument will output uncontinuously pulse wave according to the set frequency; Press “D.-D.WAVE” key, the corresponding wave indicator diagram will indicate the working wave, the instrument will output pulse waves of distant wave and dense wave alternatively in certain frequency set by user. The user need select different waveform for treatment of different illness .
Turn the “timer” in normal direction according to the treatment time, to set up the treatment time of the instrument, the time is adjustable in 1min—30min.

4.Treatment:
After selecting the wave and time, turn the “ADJUST INTENSITY” knob in normal direction to turn on the strength adjusting switch and adjust the output pulse strength, which is adjustable in 0V—50V, then the instrument begin to work .
Turn the “ADJUST FREQ” knob in normal direction according to the treatment frequency, adjust the output pulse frequency so that the User feels comfort.
After setting up the time, the instrument will sound “DiDi” , the wave indicator diagram and frequency adjusting indicator light will be off, to indicate the treatment has end.

1.If it is need to exchange the pulse wave or treatment parts before and during the treatment, person should adjust the lowest output strength, enlarge slowly the output strength after self-adhensive electrode or metal clamp (filiform needleelectrode) been mounted, or the user will feel pain because of uncomfortable .
2.Do not use the electric needles or self-adhensive electrodes on the left and right of up half part of body in the same time, it can be put on the down part of body or the same side of the body, to avoid the electric-current to pass through the heart .

5.Turn off the Instrument:
Turn off the “ADJUST FREQ” knob, “ADJUST INTENSITY” knob in un-normal direction, turn off the Device.
Take off the needles or the self adhensive electrode, take out the electrode wire.
Take off the out-connecting AC adapter.
6. Reset:
If want to turn on the strument again after turning off, please wait for 5 seconds after resetting it.

MAIN TECHINCAL SPECIFICATIONS:

- Power: DC9V $^{+5\%}_{-10\%}$ Internal Electrical Power Source
  or AC Adapter (input AC220V 50Hz/AC110V 60Hz, output DC9V)
- Power input: MAX 10.0VA (including AC Adapter)
- Output pulse wave: Un-symmetry bi-directional pulse wave
- Output pulse channel: six channels
- Power output: MAX 0.3VA (Load 250Ω)
- Output pulse frequency: 1~100Hz adjustable
  Working mode:
  Continuous Wave: Continuously
  Intermittent Wave: interval time between Continuous Wave groups 15 sec, duration time of Continuous Wave 5 sec. Distant-dense Wave: frequency of distant wave is one fifth of the frequency of dense wave, the duration time of distant wave 5 secretary, the duration time of dense wave 10 sec.
- Output current: ⩽10mA (Load 250Ω)
- Output DC amount: 0
- Output pulse width: 0.2ms±30% (EMC TEST)
- Volume: 360mm×255mm×95mm
- quality: 1.4kg

Note: load impedance does not influence the DC component, the output pulse width, the output pulse frequency. it and the output are positive correlation.

– The instrument does not belong to the AP or APG equipment, the degree of splash-proof IPX0
– The instrument complies with IEC60601-1 requirements of Class II BF equipment
– 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, included all DC components should be ⩽ ±30%.
– If the variety of power voltage is within ±10%, measure the variety of output pulse amplitude, pulse width, or repeated pulse frequency, the results should be ⩽ ±10%.

GUIDANCE AND MANUFACTURER'S DECLARATION

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 —— electromagnetic emissions —— for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emission		
The SDZ-II Nerve and Muscle Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the SDZ-II Nerve and Muscle Stimulator should assure the instrument is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The SDZ-II Nerve and Muscle Stimulator 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 CISPR 11	Group B	The SDZ-II Nerve and Muscle Stimulator is suitable for use in all establishments, including 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	Compliant	

■ Guidance and manufacturer's declaration —— electromagnetic immunity —— for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The SDZ-II Nerve and Muscle Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of SDZ-II Nerve and Muscle Stimulator should assure the instrument 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 to power supply lines ±1 kV to input/output lines	±2 kV to power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV lines to lines ±2 kV lines to ground	±1 kV lines to lines ±2 kV lines to ground	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_T, (>95% dip in U_T) for 0.5 cycle 40% U_T, (60% dip in U_T) for 5 cycle 70% U_T, (30% dip in U_T) for 25 cycle <5% U_T, (>95% dip in U_T) for 5 seconds	<5% U_T, (>95% dip in U_T) for 0.5 cycle 40% U_T, (60% dip in U_T) for 5 cycle 70% U_T, (30% dip in U_T) for 25 cycle <5% U_T, (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment.If the user of the SDZ-II Nerve and Muscle Stimulator requires continued operation during power mains interruptions, it is recommended that the SDZ-II Nerve and Muscle Stimulator be powered from an uninterruptible power supply.
Power frequency magnetic field (50Hz/60Hz) IEC 61000-4-8	3A/m	3A/m	If image distortion occurs, it may be necessary to position the SDZ-II Nerve and Muscle Stimulator further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic filed should be measured in the intended installation location to assure that it is sufficiently low.
Note: U_T 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

The SDZ-II Nerve and Muscle Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of SDZ-II Nerve and Muscle Stimulator should assure the instrument is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiation conduction IEC 61000-4-6 RF Radiation IEC 61000-4-3	3 V (Effective value) 150kHz ~ 80MHz 3V/mc 26MHz ~ 1GHz 10V/md 26MHz ~ 1GHz	3 V (Effective value) 3V/mc 10V/md	Portable and mobile RF communications equipment should be used no closer to any part of the SDZ-II Nerve and Muscle Stimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{p}$ $d=1.2\sqrt{p}$ 26MHz ~ 800MHz $d=2.3\sqrt{p}$ 800MHz ~ 2.5GHz 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 surveya, should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 : At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 : These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio(cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the SDZ-II Nerve and Muscle Stimulator is used exceeds the applicable RF compliance level above, the SDZ-II Nerve and Muscle Stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SDZ-II Nerve and Muscle Stimulator.
b Over the frequency range 150 kHz ~ 80 MHz, field strengths should be less than 3 V/m.
c Over the frequency range 26MHz ~ 1GHz, and immunity test level less than 3V/m, continuously perform the expected function required by the manufacturer.
d Over the frequency range 26MHz ~ 1GHz, and immunity test level range 3V/m ~ 0V/m, continuously perform the expected function required by the manufacturer. Or it fails but no safety risk happens.

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 SDZ-II Nerve and Muscle Stimulator

The SDZ-II Nerve and Muscle Stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SDZ-II Nerve and Muscle Stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SDZ-II Nerve and Muscle Stimulator 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		
	150kHz to 80MHz $d=1.2\sqrt{p}$	80MHz to 800MHz $d=1.2\sqrt{p}$	800kHz to 2.5GHz $d=2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 hou-sing is unprotected.


Caution.


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


WEEE symbol.


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


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


Consult accompanying documents.

ACCESSORIES:

- Six pieces of output electrode wires
- Six pairs of Self-adhesive electrode (size: 50mm×50mm)
- Six pairs of Metal clamp for Filiform needle-electrode (size: ⩽28mm)
- One user manua
- One certificate of product quality conformity
- One foam box against shock


The accessory output wires and self-adhesive electrodes attached with the instrument are used with instrument, if the wires or self-adhesive electrodes are destroyed or need to be changed, please use special wires or the self-adhesive electrodes manufactured by us, 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.


Avoiding to pollute theenvironment, the instrument, accessories and the used dry battery should be disposed according to the common electric rubbish rather than throw away at random .

PROBLEM AND SOLUTION:

Symptom	Cause analysis	Advice to remove the breakdown
Switch Light is not normal	Having not installed the batteries properly	Turn off the instrument and install the batteries again
	The batteries has run out of energy	Turn off the instrument and change the new batteries
Wave showing windows is not normal	The lamp is wrong	Contact the factory
	The batteries has run out of energy	Turn off the instrument and change the new batteries
	The battery is not installed properly	Turn off the instrument, take out battery and re-install again
Output no pulse (No stimulation on electrode)	Having not plug the output plug properly or the plug is in poor contact	Re-insert the output wires
	The skin is too dryness or too greasiness	Wipe the point with alcohol or heat towel
	The wire has broken down	Contact the factory
	There is some wrong with the instrument	Contact the factory
The treatment is over,buzzer does not give out “DiDi” sound	Buzzer is damaged	Contact the factory

If your instrument couldn't work properly according to the above information or you can not remove the breakdown, please get touch with the factory or nearest sell agency where you can access the help.

ENVIRONMENTAL CONDITIONS FOR TRANSPORT AND STORAGE

Ambient temperature range: -40℃ ~ 55℃
Relative humidity range: ≤95%
Packed devices should be stored in the condition of below RH95%, and good ventilation, avoided exposure to corrosive atmosphere.
Avoid exposing the Unit to direct sunlight.

OPERATION CONDITIONS :

Ambient temperature range: 5℃ ~ 40℃
Atmosphere pressure range: 86kPa~106kPa
Relative humidity range: ≤80%
Power: DC 9V $^{+5\%}_{-10\%}$ Internal Electrical Power Source
or AC Adapter (input AC220V 50Hz/AC110V 60Hz,output DC9V)
Continuous Operation

GUARANTEE AND SERVICE:

There is a year guarantee with the instrument and eternal maintenance of the product, but it is out the guarantee if it is man-made damage the guarantee does not included output wires, self-adhesive electrodes and metal clamps, but it can be provided on preferential prices, we can provide circuit diagram, parts lists, Legend, notes or other informations that can help qualified technician to repair it.the service contents after sale see service card. Please keep the receipt and service card properly so that you can deserve the services according that.
If there is any problems of the quality or need, please get touch with the shop, agency or manufacturer, we will provide you with the high-quality services at any time. The telephone that full-time engaged in service is 0512-65110061, you are always welcome.