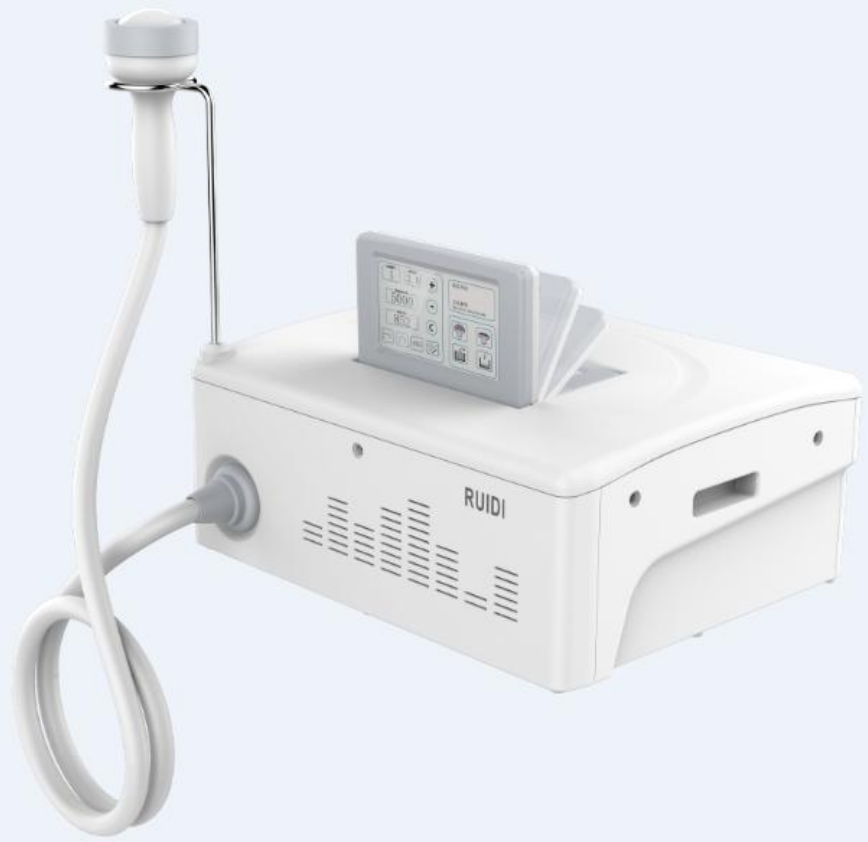
睿迪医疗
RUI DI MEDICAL

Shock wave therapy instrument

RUIDI.SWT001

Instruction Manual



Revision Records

Version	Date	Pages	Change contents
1.0	2018.5.22	All	Initial issued

Please read this manual before operating this equipment and make sure you have understood and mastered the warnings and operation methods of this equipment.

Contact

Manufacturer: Shenzhen Rui Di Medical Devices Co, Ltd.
Address:
Rm.601, Bldg.B1, Jin Wei Yuan Industrial Factory, Ju Long Shan Area, Pingshan Street Big Industri al Zone, Pingshan New District, Shenzhen City, Guangdong Province 518118 P.R. China.
TEL: 0755-28419227 | FAX: 0755-28419227
E-mail: ruidi@szruidi.com
Website: www.szruidi.com

European Authorized Representative: Wellkang Ltd
Website: www.CEmark.com, www.CE-mark.com, www.CE-marking.eu
TEL: +44(20)30869438, 032876300
E-mail: AuthRep@CE-marking.eu

Londonderry Office:
The Enterprise Hub
North West Business Complex
1 Beraghmore Rd.
Derry, BT48 8SE
Northern Ireland
Tel 1: +44(20)3287 6300
Tel 2: +44(33)3303 1126
Fax: +44(20)76811874

Dublin (Registered) Office:
The Black Church, St. Mary's Place
Dublin 7, D07 P4AX
Ireland
Ph 1: +353 (1) 25 42 900
Ph 2: +353 (1) 44 33 560
Fax: +353 (1) 44 33 566

CONTENT

1. Product brief introduction

The Shock wave therapy instrument (Model: RUIDI.SWT001) is a medical device produced by Shenzhen Rui Di Medical Devices Co, Ltd.

It is an assisting treatment device for scapulohumeral periarthritis and external humerus epicondylitis. It is intended to be used only by, or under the supervision of, suitably qualified medical staff. It is the responsibility of the operating physician to determine appropriate conditions and procedures based on the latest knowledge of modern medicine. Before treating a patient with a pacemaker, the risk of shock wave therapy should be evaluated based on criteria and standards published to date. It can only be treated without risk.

2. Product intended use

The Shock wave therapy instrument is for use in the area of assisting therapy of scapulohumeral periarthritis and external humerus epicondylitis.

3. Contraindication

1) Pregnant woman;
2) Surgical patients;
3) Patients with osteoporosis;
4) Growing period children;
5) Patients with coagulation disorders;
6) Patients with a pacemaker;
7) Patients with bone disunion due to acute infection;
8) Bleeding tendency patients;
9) Patients with mental disorder;
10) Cancer patients;
11) Patients with skin infection.

4. Principle

RUIDI.SWT001 produced shock wave by coil discharge. When a pulse voltage is applied to both ends of the coil, a discharge to ground occurs, thereby generating a shock wave, and the shock wave is converged using a metal diaphragm with a spherical surface. Through the conduction of water. This structure that generates shock waves is called an electromagnetic shock wave source.

The device uses the energy generated by the shock wave generator to gather in a specific part of the human body and achieves therapeutic purposes through the physical and physiological effects of the pressure generated by the shock wave on the internal tissues of the human body.

The main effects of shock waves on human tissues are:

a）If the interfaces of different tissues are near the focal point and the stress generated by the difference in impedance when the shock wave passes through can be sufficiently large, the tissues at the two interfaces will be damaged to varying degrees.

b）In the vicinity of the focal point, due to the high-speed propagation of the shock wave and the accumulation of energy, the tissues or bones in the affected part of the body are subjected to a certain degree of stress squeezing, expansion and impact shock. The energy size causes the patient's tissues to undergo "changes" or "changes" to varying degrees. damage". In the orthopaedics department, some physical effects caused by the characteristics of shock waves can be used to achieve therapeutic goals.

At present, these phenomena have been clinically confirmed:

a）Can release the "adhesion" of joint soft tissue;

b）Can "stimulate and activate" the cells, improve oxygen absorption function of erythrocyte, and accelerate microcirculation;

c）Clinical studies show that shock waves have a significant inhibitory effect on some pains. A large amount of data and clinical practice have proved that the correct use of shock waves

will not harm the human body and it is safe. During the orthopedic therapy process, no irreversible adverse side effects were found in clinical trials.

5. Safety Information

RUIDI.SWT001 is for use by medical institutions only, and the product should be used by professional operators under the guidance of a doctor.

5.1 Manufacturer's responsibility

Shenzhen Rui Di Medical Devices Co, Ltd. Is only liable for certain possible consequences if the following conditions are met:

a）The installation, commissioning, repair, maintenance and modification of this product are performed by personnel authorized by Shenzhen Rui Di Medical Devices Co, Ltd.

Note: Personnel authorized: personnel trained by Shenzhen Rui Di Medical Devices Co, Ltd.; or personnel trained by an agency authorized to conduct training.

b）Electrical facilities at the installation site of this product should comply with local national standards.

c）The operation and use of this product comply with the provisions of this manual.

5.2 User's responsibility

a）Before starting this product. Users must read and understand this manual.

b）Any user must follow all instructions of this manual when using this product.

c）Electrical facilities at the installation site of this product should comply with local national standards.

d）The operation and use of this product comply with the provisions of this manual.

5.3 Patient's safety

To avoid putting the patient or other person in danger, the user must make sure that the

product is in normal working condition before use. It is the responsibility of the operator to introduce the patient to the therapy process in advance. In particular, it must be noted that the patient must be told that the shock wave will be accompanied by greater noise. This helps the patient not to be conscious of the movement or to cause the patient to move as a result of the panic.

5.4 Operator's safety

Caution

The product is only for use by medical institutions and the product should be used by professional operators under the guidance of a doctor.
Operator’s training:

Our company provides detailed and comprehensive training for the operators of this product.

In any case, untrained or unqualified personnel cannot operate this product. The use training was provided by personnel authorized by Shenzhen Rui Di Medical Devices Co, Ltd.

When using or cleaning the equipment, both operators and cleaning personnel should be careful.

The operator must fully read and understand this manual before starting the device.

Do not use this device in an explosive or flammable atmosphere. This air environment may be caused by volatile gases from anesthetics, detergents, or disinfectants.

5.5 Cleaning and disinfection

Before the device is cleaned or disinfected, its power connection must be disconnected. The surface of the water bladder is disinfected with a disinfectant and pharmaceutical agent that does not erode with latex to prevent contact cross-infection caused by viruses such as hepatitis B bacteria and skin diseases.

Disinfection method: Keep the surface of the system clean and dry; wipe the surface of the therapy head with a soft gauze after daily use and wipe it with 75% ethanol at least twice.

5.6 EMC

⚠ Caution

1. Shock wave therapy instrument (Model: RUIDI.SWT001) meet the requirement of electromagnetic compatibility in IEC 60601-1-2 except during the shock waves triggered. According to the provisions of IEC 60601-2-36, Shock wave therapy instrument could not meet the requirements of IEC 60601-1-2 for EMC when the shock waves triggered, which is acceptable.
2. The user needs to install and use according to electromagnetism compatibility information which is attached with it.
3. Portable and mobile RF communication device may influence the performance of RUIDI.SWT001, so this equipment should be kept away from strong electromagnetic interference, such as close to the cell phones, microwave ovens, etc.
4. Guidance and manufacture's declaration stated in the table below.

⚠ Warning:

- RUIDI.SWT001 should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the RUIDI.SWT001 should be observed to verify normal operation in the configuration in which it will be used.
- Class A equipment is intended to be used in industrial environment. As RUIDI.SWT001 conducts emission and radiation emission, there may be potential difficulties in ensuring electromagnetic compatibility in other environments.
- The use of accessories and cables other than those specified, with the exception of accessories and cables sold by our company as replacement parts for internal components, may result in increased EMISSIONS of decreased IMMUNITY of the RUIDI.SWT001.

Guidance and manufacturer's declaration – electromagnetic emissions

The model RUIDI.SWT001 is intended for use in the electromagnetic environment specified below. The customer of the user of the model RUIDI.SWT001 should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-- guidance**
RF emissions EN 55011	Group 1	The model RUIDI.SWT001 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 EN 55011	Class A	The model RUIDI.SWT001 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	N/A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The model RUIDI.SWT001 is intended for use in the electromagnetic environment specified below. The customer or the user of the model RUIDI.SWT001 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 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 ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	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 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 seconds	<5 % UT (>95% dip in UT.) for 0.5 cycle 40 % UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95 % dip in UT) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the model RUIDI.SWT001 requires continued operation during power mains interruptions, it is recommended that the model RUIDI.SWT001 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3A/m	3A/m,50Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The model RUIDI.SWT001 is intended for use in the electromagnetic environment specified below. The customer or the user of the model RUIDI.SWT001 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 V	Portable and mobile RF communications equipment should be used no closer to any part of the model RUIDI.SWT001, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d= 1.2\sqrt{P}$ $d=1.2\times P^{1/2}$ 80 MHz to 800 MHz $d=2.3\times P^{1/2}$ 800 MHz to 2.7 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur In the vicinity of equipment marked with the following symbol: 
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 model RUIDI.SWT001 is used exceeds the applicable RF compliance level above, the model RUIDI.SWT001 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the model RUIDI.SWT001.
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 model RUIDI.SWT001

The model RUIDI.SWT001 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the model RUIDI.SWT001 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the model RUIDI.SWT001 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 ～ 80 MHz $d = 1.2\sqrt{P}$	**80 MHz ～ 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz～ 2.5 GHz** $d = 2.3\sqrt{P}$
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 meters (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.

5.7 Air environment

Do not use this product in an air environment that is likely to explode or flammable. This air environment may be caused by volatile gases in anesthetics, detergents or disinfectants.

5.8 Installation of electrical equipment

The electrical safety conditions at the installation site must meet the national standards for use.

This product requires functional grounding and protective grounding installation, with

independent ground wire. The ground resistance is less than or equal to 4 ohms. Shock waves may interfere with other devices when triggered.

This equipment is not allowed to be used in parallel with other instantaneous heavy load equipment (welding machine, elevator, etc.).

When the shock wave is triggered, do not allow the product to be close to electronic devices such as ECG monitor in working state.

This product must be installed by the personnel authorized by Shenzhen Rui Di Medical Devices Co, Ltd.

⚠ Warning:

- Before starting the equipment, the protective grounding and functional grounding must be installed.
- Do not place the device in a position where it is difficult to operate the power plug, which is used to isolate the electrical circuit from the power source.
- After installation or reinstallation, electrical testing of the equipment must be carried out.

Please refer to the "safety inspection" chapter of this manual for detailed instructions

Prior to transportation, all external connections of the equipment, such as power cables, shock wave cables, water pipes, must be removed.

5.9 The use of shock waves

Operators who use shock waves for treatment must be knowledgeable about their medical problems. These include the appropriate conditions for connecting the currently available use and related side effects. Special attention should be paid to screening for contraindications such as shock wave therapy for hemolysis. **The shock wave from the device attenuates when it passes through muscle tissue, and the rest of its energy is absorbed by the lesion and bone.**

The dose of shock wave (i.e. the amount of shock wave intensity and the number of times of

shock wave) is directly related to histologic hematoma. However, it cannot be concluded that the higher frequency of shock wave triggering must have side effects. Although it has not been scientifically proven, medication, high age, high blood pressure or vascular weakness (especially in the kidney) can increase the risk of side effects in shockwave therapy. But because excessive shock waves can lead to hematoma, vessels in sensitive renal parenchyma are at greater risk of damage. In view of this, the shock wave dose must be kept as low as possible at all times. The triggering frequency of shock wave must be reduced while the intensity of shock wave is increased.

⚠ Caution

Before the shock wave is triggered, the patient must have good contact with the water bladder. If there is air between the two, the shock wave will be attenuated, thus failing to achieve a satisfactory therapeutic effect and may produce erythema of the skin.

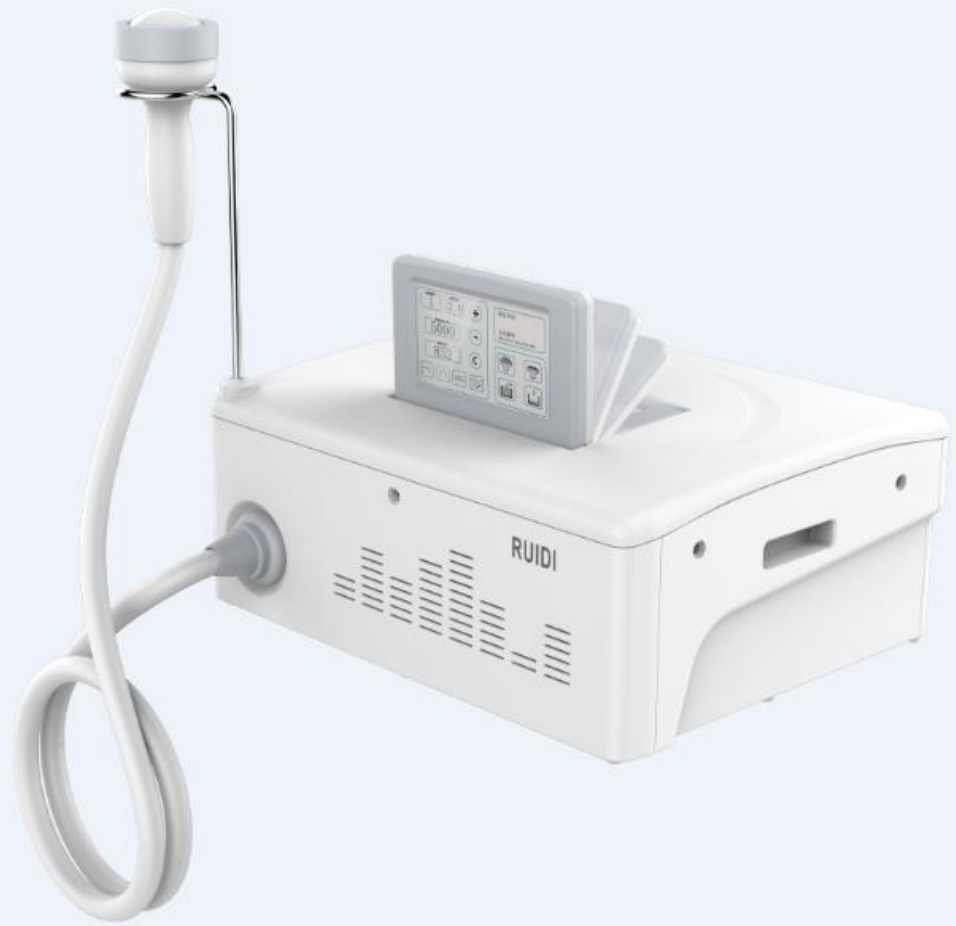
⚠ Caution

The use of shock waves may cause bleeding from skin lesions. The operator must observe the treatment site in a timely manner during the treatment.

⚠ Warning:

Before the shock wave treatment, it is necessary to prompt noise when the shock wave triggers. It is recommended that both the operator and the patient wear earplugs during the treatment. Pressure pulses can cause harmful heart activity. Shock waves can cause tissue damage when passing through gas-filled organs such as the intestines and lungs. Shock waves must be avoided from impacting organs and the heart, such as the intestines and lungs. The operator must pay attention to any exercise that may be life-threatening for the operator and the patient.

6. Product Components



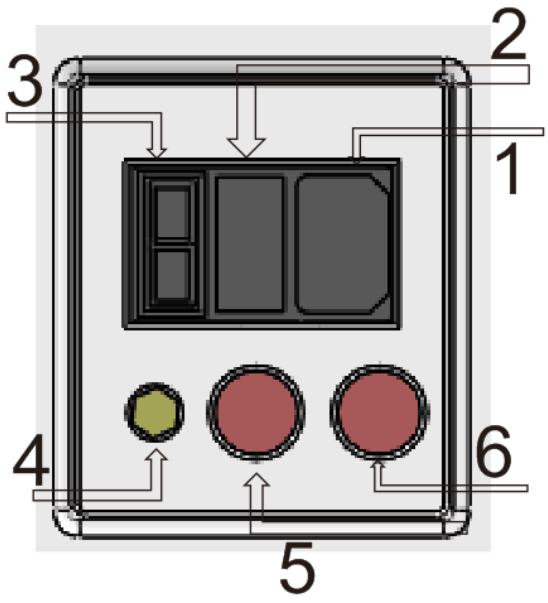
The product mainly consists of a controller and therapeutic head (treatment head).

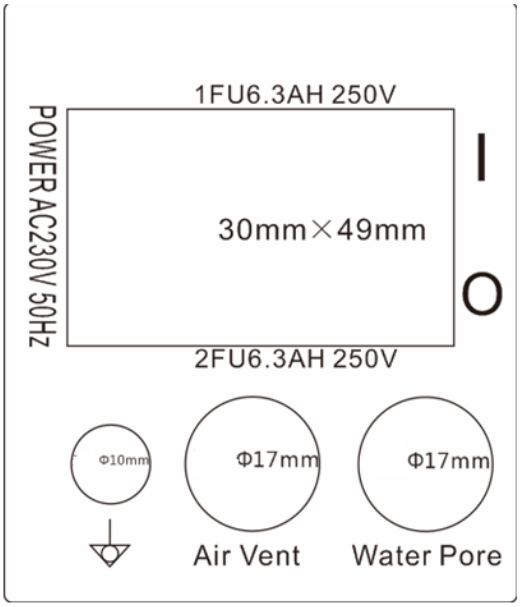
The controller is comprised of the enclosure, power supply, main board and touch screen.

Product parts are identified as follows:

Parts		Description
Controller	Enclosure	Support all electrical components
	Power supply	Provide power
	Main board	Control the function
	Touch screen	
Therapeutic head		Releasing shock waves

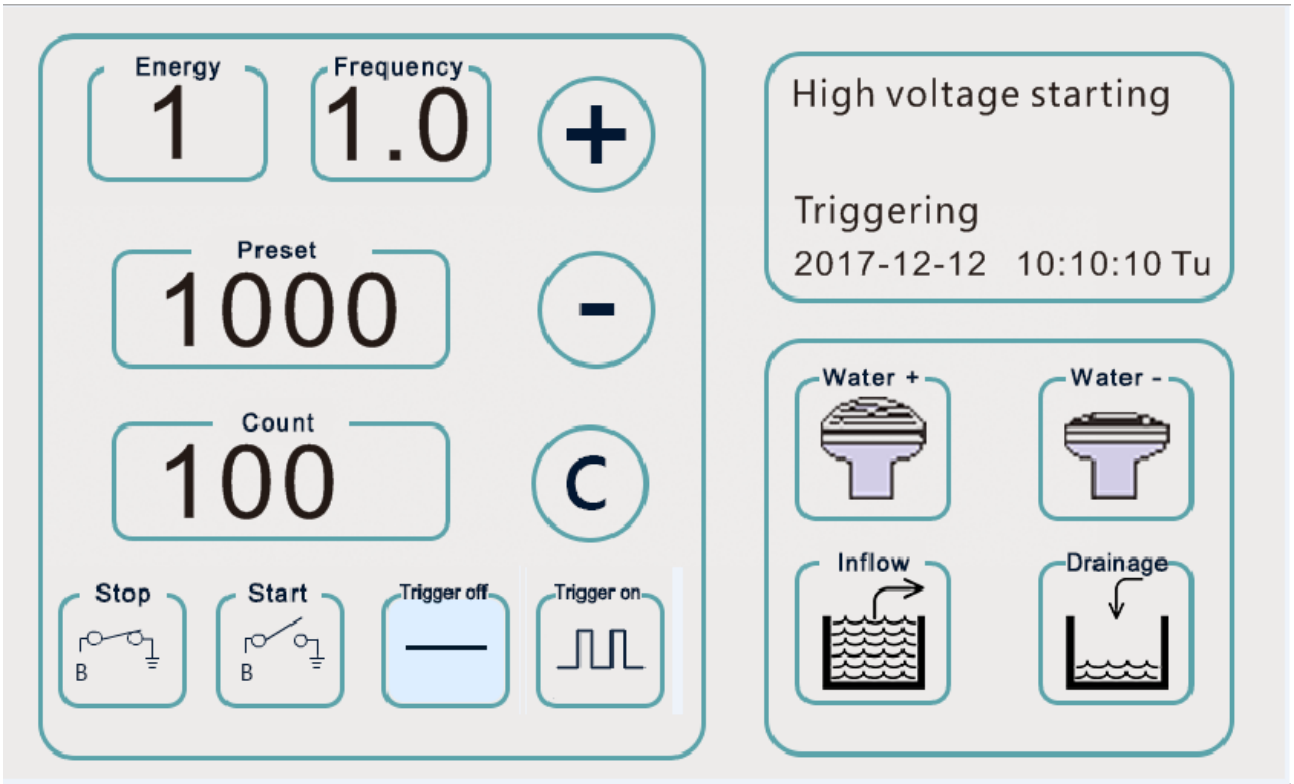
The structure chart of power socket is as below:

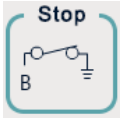
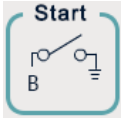


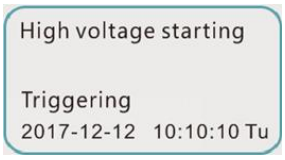
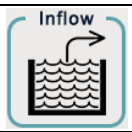
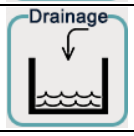


#	Part name	Note
1	Power socket (input AC230V 50Hz,600VA)	POWER AC230V 50Hz
2	Fuse wire (the fuse wire of power input; They are connected in series on the N and L lines)	1FU6.3AH250V ,2FU6.3AH 250V
3	Power switch	I O
4	Equipotential terminal	
5	Air vent	Air intake and outlet
6	Water pore	Interface for adding and reducing water.

7. The shock wave motion control button description



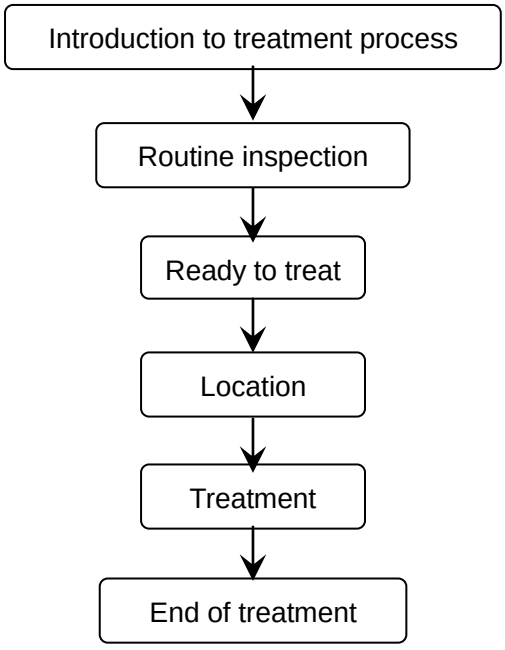
#	Button	Description
1		Shock wave energy levels: there are 11 energy levels, 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10.
2		Shock wave trigger frequency display: a total of 21 frequency points can be displayed. The trigger frequency display range is 1.0HZ, 1.1HZ, 1.2HZ...2.9 HZ, 3.0 HZ.
3		Display preset number of treatments: preset number of shock treatments. Minimum 100, maximum 5000.
4		Display real-time shock wave treatment times. Count range 1-5000.
5		Increase button: when selecting energy, frequency or preset count, press this button to select the item to increase accordingly.
6		Reduce button: when selecting energy, frequency or preset count, press this button to reduce the selected item accordingly.
7		Count reset button: touch this button to reset the count.
8		High voltage stop button (stop treatment button): touch this button in the corresponding status display window will display stop treatment, and the water circulation will stop working.
9		High voltage start button (start treatment button): touch this button in the corresponding status display window to display the ready treatment, while the water circulation starts to work.
10		Trigger stop button: touch this button to stop pulse output, count stop.
11		Trigger button: Touch this button to trigger the pulse output and start the trigger count.

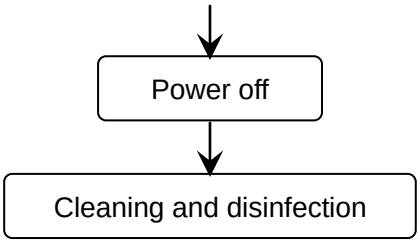
12		Display the current working state of the device.
13		Water bladder add water button: touch this button to add water to the wave source.
14		Water bladder reduce water button: touch this button to drain water from the wave source.
15		Water tank inlet button: touch this button to add water to the tank.
16		Water tank drain button: touch this button to drain water out of the water tank.

8. Operation

The safety information has been stated in chapter 5 and must be complied with.

Operation procedure is as below:





8.1 Routine inspection

Visual inspection	Check the following parts for abnormal signs: 1. Is there any damage to the water bladder? 2. High voltage cable connection head has no shedding, looseness, damage. 3. Is LCD touch screen damaged or not? 4. There is no looseness or leakage in water connector. 5. Protective grounding and functional grounding terminals have no loose signs.
⚠ Caution	Before starting the equipment, routine inspection should be carried out, which is helpful to avoid the danger caused by equipment damage.
⚠ Warning	If the protection grounding and functional grounding are not installed, do not start the equipment. Only personnel authorized by Shenzhen Rui Di Medical Device Co., Ltd. can perform the above visual inspection. Authorized personnel refer to: personnel trained by Shenzhen Rui Di Medical Device Co., Ltd. or qualified personnel trained by institutions authorized to conduct training.

⚠ **Warning:** If any damage to the equipment is found during routine inspection, do not start the equipment.

Equipment routine safety inspection:

Prior to starting the equipment, at least the following routine safety inspection shall be performed: is the protective grounding good? Is the moving part comfortable? Is the water

bladder intact? Is the gas in the water bladder drained?

Water tank add water and reduce water

Inlet the water: Insert the water pipe into the water pore and then insert the other end of the water pipe into the water container. Press the Water tank inlet button until the water in the air vent flows out.

Drain the water: Insert the water pipe into the container and press the Water tank drain button until the water does not flow out.

Water bladder add water and reduce water

Add water: Press and hold the Water bladder add water button to increase the height of the bladder to the appropriate position.

Reduce water: Press and hold the Water bladder reduce water button to decrease the height of the bladder to the desired position.

Water bladder exhaust gas

If there are air bubbles in the bladder before treatment, remove air bubbles by this method. First add the appropriate amount of water to the wave source, if any air bubbles are found in the water bladder. Press the high voltage start button, the water cycle begins to work, and then the wave source is tilted 60° to align the bubbles with the red exhaust gas mark on the wave source so that the air bubbles can be exhaust through the water cycle until the gas is completely exhausted.

The use of coupling agents

The couplant is evenly applied to the surface of the water bladder without bubbles. Attach the patient to the water bladder and be careful not to have air bubbles between them. During the treatment process, the operator must often check whether the patient's connection with

the water bladder is abnormal. If the patient's skin is abnormal, the trigger shock wave should be stopped immediately.

⚠ **Warning:** When the device leaks at any time, the power should be turned off immediately to solve the leakage problem and wipe the water stains to ensure that the device is normal before restarting.

⚠ **Warning:** If the protective grounding is not installed, do not start the equipment. Only authorized personnel can perform the above inspection. If any damage to the equipment is found during routine inspections, do not start the equipment. Do not activate the device if there is air bubbles in the bladder.

8.2 Ready to treat

- Disinfection of water bladder surface
- Power on
- Start the device and set the energy to the appropriate value for treatment.
- Positioning the patient's lesion.
- Trigger treatment to ensure that the device is in normal working condition

8.3 Location

The treatment method depends on different lesions, but the key is to first accurately determine the distance of the lesion from the human epidermis to determine the height of the second focal point to adjust the height of the water bladder, such as scapulohumeral periarthritis, after finding the focal point, it is estimated that the depth of the lesion is 20mm (h) from the epidermis, and the height of the bladder should be adjusted to a height of 50mm (H). (The distance from the top of the electromagnetic cup to the top of the bladder is 50mm) Formula:

$$H+h=70mm$$

The focal length of the device is 70 (the distance from the focus of the electromagnetic cup),

and the focal length is a constant. After adjusting the height of the bladder, apply ultrasonic couplant on the bladder. For the treatment of scapulohumeral periarthritis and external humeral epicondylitis, the shock wave is made to enter the tender point. If there are multiple tender points, it is necessary to enter from multiple tender points, and the number of treatments at each tender point with the appropriate voltage about 100 times. After each tender point is treated, it can help the patient to massage the following joints or tender points to check the treatment effect. In general, each patient can be treated with shock waves for hundreds to one thousand times.

8.4 Treatment

The extracorporeal shock wave treatment requires a basic location of the patient. Before triggering the shock wave, apply a layer of couplant on the skin of the patient's treated area and the area where it contacts the water bladder. Then adjust the wave source of this device to focus on the tender point of the patient.

⚠ **Warning:** Before starting treatment, the operating doctor must inform the patient about the treatment process. In particular, it must be noted that the patient must be told that the shock wave is accompanied by considerable noise. This helps the patient not to be conscious of the movement or to cause the patient to move as a result of the panic.

Shock wave frequency setting

Start **frequency** adjustment settings, touch increase or decrease button, you can increase or decrease the trigger frequency of the shock wave. In general, lower frequencies are used when starting treatment, and the frequency of shock waves can be gradually increased after the patient has adapted.

Shock wave intensity setting

Start the **energy** adjustment setting and touch the increase or decrease button to increase or decrease the shock wave intensity. In general, a relatively low shock wave energy intensity should be set at the start of treatment, and the shock wave intensity can be gradually increased after patient has adapted.

⚠ **Warning:** Throughout the treatment, the operating doctor must always observe the patient's condition. If the patient feels unwell or has an emergency situation, the treatment should be discontinued immediately.

⚠ **Warning:** Shock waves can only be triggered if the patient is well coupled. The interface between the water bladder and the air bubble refracts and reflects the shock wave. This refraction and reflection can damage the water bladder and affect the service life of it.

8.5 End of treatment, power off, cleaning and disinfection

1) Click the trigger off button to stop the shock wave trigger.
2) Set the energy value to “0” to degrade the voltage energy to 0 level.
3) Trigger several times in a row, release the remaining charge.
4) Press the stop button to make the device to exit the start-up state.
5) Press and hold the water reduction button to drain water from the bladder to the tank to reduce water in the bladder.
6) Press the locking mechanism of the wave source support arm to separate the wave source from the patient's treatment site.
7) Press the power off button to turn off the power.
8) Clean the skin of the patient's treatment site.
9) Cleaning equipment, treatment head, water bladder.
10) Fixed wave source support arm.

⚠ **Warning: Shock hazard! Do not skip step 3 of the above step when shutting down! Make sure to discharge the capacitor's power before shutting down.**

Observation of patient after treatment

After treatment, the competent doctor needs to observe the patient.

Common complications and their treatment: The common complications of extracorporeal shock wave therapy are skin erythema. If it occurs, it should be given the appropriate treatment.

Skin erythema: Occurs at the skin of the patient in contact with the water bladder. The skin became reddened, slightly painful, and the skin was not fully coupled with the water bladder. Generally, no special treatment is required. Individuals can be treated with anti-inflammatory drugs.

⚠ **Warning:** When necessary (such as when the equipment is being repaired), opening the device front cover can easily reach the inside of the host. Only use tools to open the back cover. Only the personnel authorized by Shenzhen Rui Di Medical Device Co., Ltd. can open the front cover. The device must be switched off before opening the front cover.

⚠ **Warning:**

Prompt: If the temperature of the treatment head reaches 41℃, the temperature indication area of the display status bar will turn red and there will be text prompts. If the temperature is too high, the shock wave high voltage will automatically stop working, and then reset the parameters to normal operation after the temperature is restored.

⚠ **Warning:**

Any discomfort in the patient during the treatment should be stopped immediately.

9. Technical description

9.1 Product main feature

The main product features of RUIDI.SWT001 are as follows:

- Classification according to the type of protection against electric shock: Class I

- Type B Applied Part
- Rated voltage and frequency of the equipment: ~220V 50Hz Powered by the network power supply
- Continuous operation
- The input power of the device: 600VA
- The ergonomic design makes set-up and operation simple;
- Mains powered, to ensure instant shock output effect; adjustable energy and frequency;
- Designed to be easily portable.
- Shape structure: A3 host sheet metal parts, ABS shell
- Appearance: white and green paint surface

9.2 Technical parameter

Volume and weight

Whole machine	Weight	25KG±10%
	Dimensions	500mm×400mm×215mm (Error 1%)
	Package	600mm×500mm×345mm (Error 1%)

Power supply

Voltage	AC230V±10%
Frequency	50Hz±1Hz
Power	600VA

Environmental requirements

Item	Temperature requirement	Humidity requirement	Atmospheric requirement
Operating environment	5℃～40℃	≤80% RH (No coagulation phenomena)	860hPa～106hPa
Storage/Transport environment	-10℃～40℃	≤70% RH (No coagulation phenomena)	700hPa～1060hPa

Shock wave performance parameter

Treatment depth	70mm
Focusing range	Radial ± 80mm; Axial ± 45mm
Peak systolic pressure	5.3 ~ 30MPa

Shock wave pulse width	≤ 2μs
Shock wave front	≤ 1μs
Wave source lifetime	≥ 1 million times
Energy level	7KV～12.5KV (10 levels)
Storage energy	10～30J
Shock frequency	1.0~3.0Hz
Energy storage capacitor box lifetime	≥ 1 million times
Electromagnetic disk specification	Φ63mm
Water bladder specification	Φ63mm
Wave source weight	3KG
Device service life	8 years

10. Applicable standards

The product conforms to the following standards and laws:

EN 60601-1:2006/A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A1:2012)

EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2 2014)

11. Maintenance and care

11.1 Safety inspection

Routine safety inspection

Safety inspection refers to the periodic maintenance and adjustment of equipment;

Safety inspection ensures safe and reliable use of equipment;

Shenzhen Rui Di Medical Devices Co., Ltd. recommends that the device be checked once a year for safety (grounding impedance, patient leakage current, electrolyte strength, second focus location and size).

Temporary safety inspection

If one of the following conditions occurs, the device must be inspected for safety:

- Installation
- Re-installation
- Maintenance
- Consumables replacement
- If required by the user, Shenzhen Rui Di Medical Devices Co., Ltd. can provide a list of safety inspection items for free.
- After the battery is discharged 1 million times, the equipment can be used again only after safety inspection is conducted by an engineer of Shenzhen Rui Di Medical Device Co., Ltd. or a person authorized by Shenzhen Rui Di Medical Device Co., Ltd.

⚠ **Warning:** Only personnel authorized by Shenzhen Rui Di Medical Device Co., Ltd. can perform safety inspections. The safety inspection by personnel not authorized by Shenzhen Rui Di Medical Device Co., Ltd. may result in personal injury or equipment damage.

11.2 Daily maintenance and care

- Maintain the lubrication of mechanical parts, often refuel rails, bearings, moving joints, and clean equipment surface dust;
- Check at least once a month whether the connection of the equipment's internal ground wire is tight;
- Check whether the connections of the lines are normal and firm before starting the device each time and whether the device operates abnormally.
- Keep it dry and guard against damp.

⚠ **Warning:** Only personnel authorized by Shenzhen Rui Di Medical Device Co., Ltd. can perform the above routine maintenance and care!

12. Cleaning and disinfection

The device should be cleaned and disinfected before each patient is treated. In order to prevent B virus, skin diseases and other viruses causing contact cross infection.

1) Turn off the device main power

2) Clean and disinfect the equipment as follows

Cleaning: Use a sponge or soft cloth to remove dust and dirt from the surface of the device.

Disinfection: After cleaning, wipe the surface of the device with sponge or a soft cloth dampened with a suitable amount of disinfectant (do not place too much disinfectant liquid on a sponge or a soft cloth so as not to drip into the device causing malfunction or danger). Available disinfectants include: medical alcohol, formalin disinfectant, etc.

Before each treatment, the following application parts and appearance of the device should be disinfected:

1) Shock wave source (including water bladder)
2) Any other device appearance that may touch the patient and operator.

⚠ **Warning:**

- Before cleaning and disinfecting, always turn off the power and pull out the device's main power cord.
- Never use gas or spray disinfectants to clean or disinfect equipment.
- Never penetrate liquids inside the device.
- Observe the manufacturer's safety information for disinfectants and cleaners.
- Observe the regulations regarding disinfection and cleaning in national laws.

13. Waste disposal

In the process of using this equipment, it will produce consumables such as couplant, water bladder, capacitor box, electromagnetic disk, etc., and may produce pollutants such as foam packaging materials and capacitor electrolyte, but the quantity is very small. In addition, the equipment will be scrapped after the end of its service life. Although the severity of the risk of these wastes may be classified as having no or almost no possibility of harm. It will have a certain degree of destructiveness to the environment. Therefore, these wastes must be properly treated to reduce the hazard value.

For different materials, such as packaging, electrical waste, plastics, metals, waste water, etc., must be handled in accordance with relevant national laws and regulations.

After the service life of the equipment, the equipment must be disposed of in accordance with local laws and regulations.

To inquire about how to avoid personal injury and environmental pollution, please contact Shenzhen Rui Di Medical Devices Co., Ltd. before the end of service life of the equipment.

14. Consumables replacement

This product has the following types of consumables:

- Capacitor box;
- Electromagnetic disk
- Water bladder

Only the personnel of Shenzhen Rui Di Medical Device Co., Ltd. or qualified personnel trained by Shenzhen Rui Di Medical Device Co., Ltd. can replace the above-mentioned consumables.

14.1 Replacement method of water bladder

1) Drain the water in the bladder;
2) Cut off the power

3) Unscrew the water bladder cover by hand
4) Open the fixed ring of the water bladder
5) Put on a new bladder
6) Tighten the fixed ring of the water bladder
7) Tighten the water bladder cover

⚠ **Warning:** Use the consumables provided by Shenzhen Rui Di Medical Device Co., Ltd. or other suppliers designated by Shenzhen Rui Di Medical Device Co., Ltd.

Losses and accidents caused by the use of consumables not related to our company shall be borne by the user.

14.2 Replacement method of fuse

Fuse specification can also refer to the appendix (electrical circuit diagram)

No.	Specification	Model
1FU	SPT 5mm×20mm	0001.2521 6.3AH 250V
2FU	SPT 5mm×20mm	0001.2521 6.3AH 250V
3FU	SPT 5mm×20mm	0001.1011 5AH 250V
4FU	SPT 5mm×20mm	0001.1011 5AH 250V

When replacing the fuses, the power must be cut off first. According to the above table (or electrical circuit diagram requirements) replace the fuses that meet the relevant regulations

14.3 Add water to the tank

When it is used for the first time, water must be added to the tank. Insert the extension tube at the water inlet, insert the tube into the water tank, and press the add water button until the water discharge from the air outlet continues.

In general, water should be added to the tank every 2 to 3 months during normal use. Users should always check whether the tank needs to add water and observe whether the water quality has changed.

15. Troubleshooting

Fault phenomenon	Cause analysis	Solution
“Dummy guns”	Usually caused by changes in the performance of the capacitor box. 1. The capacitor box has reached its self-life. 2. The capacitor box is aged. 3. The trigger ball is oxidized.	Replace capacitor box.
Continuous, often uncontrolled discharge	Usually caused by changes in the performance of the high-voltage charge and discharge system: 1. Trigger ball discharge gap is too small. 2. The voltage rise is too high. 3. The capacitor box has reached its self-life.	Replace capacitor box.
Triggered but not discharged	Nothing happens when triggered	It may be that the high-voltage system is faulted (this fault needs to contact the manufacturer).
	Blue light is seen from the water bladder when triggered, indicating that the electromagnetic disk has been damaged	Replace electromagnetic disk.

⚠ **Warning:** Only personnel of Shenzhen Rui Di Medical Devices Co., Ltd. or qualified personnel trained by an institution authorized by our company can repair the equipment. Conducting safety inspections by personnel other than Shenzhen Rui Di Medical Devices Co., Ltd. or personnel trained by an unauthorized institution, may result in patients’ injury or equipment damage.

When carrying out high-pressure maintenance, the charge of the capacitor box must be released first, and then the power must be cut off to avoid electric shock. There must be at least 2 people on site at the time of maintenance to perform maintenance work.

16. Shelf life and stability

Except consumables, the service life of this equipment is 8 years. During the period of use, in order to avoid the risk of abnormal aging of the equipment to the patient, the equipment shall be tested periodically for stability under the following items. Our company is committed to providing the testing method:

- Shock wave performance;
- Protective grounding impedance
- Working continuous leakage current and patient leakage current
- Overall dielectric strength
- Noise test

⚠ **Warning:** Equipment that exceeds its shelf life should be scrapped and can no longer be used! After the service life is exceeded, if it is still necessary to continue to use this equipment, a nationally recognized testing organization must be commissioned to test the equipment in accordance with the above stability test items. Our company is committed to providing test methods.

17. Test method for detecting focus position and size

Test of the pulse width, front edge, and focus range of the second focus shock wave

17.1 Shock wave performance requirements

- ✓ Sound pressure peak: The peak systolic pressure of shock wave of pulse focus should be 5.3 ~ 30MPa; expansion pressure peak <5.5MPa.
- ✓ Pressure pulse width: ≤2μs.
- ✓ Pressure pulse rise time: ≤1μs.
- ✓ Focus size: The radial range is ±8 mm, and the axial range from the pressure pulse focal point to the near shock wave source cup-rim is ±40 mm.

17.2 Test equipment

- ✓ Pressure sensor: A pressure sensor with a frequency response of not less than 2 MHz and a measurement level of not less than 100 MPa.
- ✓ Oscilloscope: A digital storage oscilloscope with a sampling frequency of at least 20 MHz or a memory oscilloscope with a frequency response of at least 100 MHz.

17.3 Test procedure

- ✓ Place the sensor at the second focal point for continuous testing 10 times, 40% of the waveform should meet the requirements of 17.1. Accurately test 10 valid waveforms.
- ✓ The use of sensors to test the focus range of the second focus should meet the requirements of 17.1.

Test procedure for Pulse focal length

Distance from the focal point of the shock wave cup-rim: 70mm.

Test method: The square distance of the simulated focal point from the shock wave cup-rim should be measured with a square ruler, and the requirements of the pulse focal length of the shock wave should be met.

⚠ **Warning:** If you find that the focal length, rising front, pulse width, and focus range of the second focus shock wave do not meet the requirements, please contact the manufacturer in time to resolve it.

Test procedure for any physical variable deviation that increase patients' risk

Procedures for detecting the actual energy of the shock wave higher than the displayed value:

- ➢ The high-voltage attenuation rod with a range of 100KV is used to directly test the high-voltage output end of the shock wave;
- ➢ The voltmeter whose rated range exceeds AC500V is used to test the primary input voltage of the high-voltage transformer. The measured value multiplied by the ratio of the high-voltage transformer should be equal to the value measured by the high-pressure

rod. The deviation should be within ± 5% (without deviation).

⚠ **Warning:** If you find a physical variable that increase risks to the patient, please contact the manufacturer in time to resolve it.

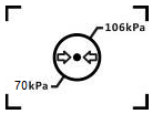
Test procedure for counter display error leads to excessive absorption of energy

During the treatment, the counter reflects the dose of shock wave received by the patient. Each pulse is counted once, but if the counter fails, for example, the count is not counted, the number of actual impacts may exceed the count display value. If the doctor does not pay attention, it is possible for the patient to receive a dose that greatly exceeds the preset value. The possible causes of the error are: the counting circuit is faulty; the counting circuit is disturbed; the reset button of the counter is accidentally pressed, and the counted number is not added.

Test method: Use the stopwatch to calculate whether the trigger value in a certain period of time is consistent with the counter display value.

18. Symbols

Label	Explanation	Label	Explanation
	Serial number		Caution
	Manufacturer		CE mark
	Authorized representative in the European Community	IPX0	Degrees of protection against water: non-protected.
	Date of manufacture		Refer to instruction manual
	This way up		Keep dry
	Type B applied part		"WEEE (Waste Electrical and Electronic Equipment)". The waste products should be handled legally.
	Alternating current		Transport package shall not be rolled.
	Stacking limit by 4		Equipotentiality
	Anti-electromagnetic radiation		Handle with care
	“OFF” (power)		“ON” (power)
	Dangerous voltage		Warning, electricity

	*Temperature limitationThe product package should be stored at a temperature between -10 and 55 degrees (centigrade).*		*Upper limit of humidityThe product package should be stored at humidity between 5% and 80%.*
	*Atmospheric pressure limitation* *The product package should be stored at an atmospheric pressure between 70 kPa and 106 kPa.*		*Earth (ground)*