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I. Principle

Ultrasound physiotherapy refers to a non-invasive treatment method that uses a safe dose of ultrasonic energy to act on the human body to stimulate the body and improve its function, so as to treat diseases or relieve symptoms. Ultrasonic physiotherapy device is based on the effect of ultrasonic energy in the human body to generate warmth, physicochemical and vibration, and its characteristics of strong directionality, energy concentration and strong penetrating power.

The ultrasonic energy is applied to the diseased part of the human body to assist in the treatment of soft tissue injury and pain.

II. Intended Use

Adjuvant therapy for soft tissue injury pain.

III. Contraindications

Do not use this device in connection with other electronic devices, as follows:

1. Patients with implanted electronic devices such as cardiac pacemakers ;
2. It cannot be used together with life-sustaining equipment such as oxygen generators and artificial hearts;
3. This device is a single-use device and cannot be used together with surgical equipment such as electrocardiograph and high-frequency electric knife.

The following patients should not use this device, only with the consent of the doctor:

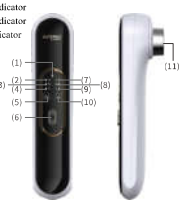
1. Patients with malignant tumor;
2. Patients with hemophilia and bleeding disorders;
3. Suffering from heart disease (especially those with implanted cardiac pacemakers or other implantable devices);
4. Those suffering from acute infectious diseases or purulent wounds;
5. Those suffering from deep X-ray therapy or isotope radiotherapy;
6. Pregnant women;
7. Patients who do not follow the doctor's instructions.

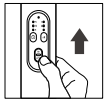
IV. Product Structure and Description

1. Product structure and composition: It is mainly composed of a host, an ultrasonic probe and a power adapter.
2. Model Number: RT400

V. Instruction for Use

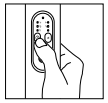
(1)Power-on indicator
(2) 15 minutes automatic shutdown indicator
(3) 10 minutes automatic shutdown indicator
(4) 5 minutes automatic shutdown indicator
(5) Timing button
(6) Power switch button
(7) High gear indicator light
(8) Mid-gear indicator light
(9) Low gear indicator
(10) Gear button
(11) Ultrasonic probe

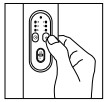




Power on:
Move the power switch up to the "ON" position, the six indicator lights flash alternately in a circular circle, and enter the standby state.

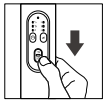
Treatment time:
The treatment time setting is divided into three gears: 5 minutes, 10 minutes, 15 minutes;
Treatment time adjustment: adjust the time button, the treatment time is cycled between 5 minutes, 10 minutes, and 15 minutes.





Parameter settings:
The treatment intensity setting is divided into three gears: L, M, H;
Intensity adjustment: adjust the intensity button, and the treatment intensity will cycle among the three gears of L, M, and H in turn.

Start treatment:
1. Take out the ultrasound gel and evenly apply it to the patient's treatment site;
2. After setting the time and intensity of the treatment device, place the ultrasonic probe in the treatment area to start treatment;
3. In order to avoid discomfort caused by excessive concentration of energy, the ultrasonic probe must be kept in a reciprocating circular motion around the treatment site during the treatment process, and cannot be fixed or stayed in a certain part.



End of treatment:
1. The time indicator stops flashing and the treatment is over;
2. Turn the power switch to the "OFF" position and unplug the adapter;
3. Clean the gel on the the patient's skin and on the equipment;
4. Put the clean equipment in a protective box and place it in a dark and dry place.

Program	Waveform	Pulse duration	Pulse repetition period	Duty Factor	Output (W)	Effective sound intensity (W/cm^2)
L	Pulse	3ms	10ms	3:10	2.88	0.72
M	Pulse	4ms	10ms	4:0	3.84	0.96
H	Pulse	5ms	10ms	5:10	4.8	1.2

⚠ Note: These parts should be used with caution:

- Eyes, reproductive organs, etc.: Most of the body's heat is carried away by the blood. There are few blood vessels in these parts, and it is easy to emit heat and accumulate, resulting in excessive temperature and tissue damage.
- The bony protrusions on the body surface stay: Ultrasound will act on the periosteum, causing excitation of the periosteal nerves and causing pain.

RT400 ultrasound physiotherapy device is a handheld medical device, it can be used only by connecting to a power adapter.

Connect power supply

Insert one end of the power adapter into the socket of the host , and the other end into the single-phase AC 100-240VAC, 50/60Hz power socket.

⚠ Before connecting the power cord, please note that the device's power switch is in the off position.

Ultrasound gel

Check and clean the skin in the treatment area. Apply an appropriate amount of ultrasound gel evenly to the treatment area.

VI. Precautions

1. Please read this manual carefully before use, it is recommended to use it under the guidance of a doctor;
2. Due to the different adaptability and tolerance of people to ultrasound, it is normal for the skin to feel warm and slightly acupuncture during treatment. If the skin feels hot and cannot be tolerated, lower the treatment gear or suspend treatment;
3. There must be enough ultrasonic gel applied to the skin surface of the action site to facilitate the introduction of ultrasonic waves into the human body, and the treatment head must be completely in contact with the skin to ensure the normal conduction of ultrasonic waves. Too little ultrasonic gel or poor touch between the probe and the skin will make it difficult for ultrasonic waves to be transmitted into the human body, and the probe will be easily damaged by heat; it should not be replaced by other items;
4. The ultrasonic probe must move reciprocatingly around the "action part" and cannot be fixed or stayed in a certain part;
5. When the therapeutic device is not used for a long time, the power plug should be unplugged, and attention should be paid to moisture-proof and dust-proof;

6. This device is expected to be used only by professional medical staff. This therapy device may cause radio interference or disrupt the operation of nearby equipment, and it may be necessary to take mitigation measures, such as reorienting, relocating or shielding the corresponding site;
7. This device should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed and verified that it can operate normally in the configuration it is used in;
8. Instructions for avoiding mutual interference with other equipment: Keep away from equipment that can generate electromagnetic field interference around, such as high-power transformers, X-ray machines, CT, nuclear magnetic fields, microwaves and high-frequency electrical radiation sources;
9. This device cannot be interconnected with multiple electrical equipments to avoid safety hazards caused by the accumulation of leakage current;
10. In order to avoid mutual interference with other equipment, it is recommended to stay away from equipment that can generate electromagnetic field interference around, preferably in a separate room;
11. After each use, the treatment head part should be cleaned and disinfected. Pay attention to clean the ultrasonic gel around the treatment head to avoid infection or corrosion of the equipment;
12. Environmental protection: When the device is scrapped, it should not be discarded freely. It should be implemented or notified to the manufacturer according to the national management regulations on medical supplies to avoid pollution to the environment;
13. Although the ultrasonic probe has a waterproof design, please do not put the whole into the water to scrub when cleaning, so as to prevent the liquid from seeping into the treatment interior or the cable interface.

VII. Maintenance and Repair

Maintainance

1. Daily inspection

Before each use, managers must inspect the device and components to confirm that the device is safe:

① Whether the power socket is reliably connected to the ground, if not, please replace the power socket;
② Whether the power adapter cable is deformed or broken,If so, please replace it with a new power adapter, otherwise it may cause a fire due to leakage;
③ Check whether there are cracks or gaps around the treatment head, so as not to cause conductive liquid to penetrate and damage the instrument.

2. Cleaning and Disinfection

When cleaning the instrument, wipe the dust with a soft dry cloth, wipe the dirt with a soft damp cloth, and then use 75% alcohol to wipe the surface of the

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After-sales service : Shenzhen Elite Medical Technology Co., Ltd.

instrument to disinfect. Before cleaning the device, be sure to turn off the power switch and disconnect the power adapter.
① Maintenance should be carried out by professional maintenance personnel to clean the inside of the device;
② When the device is not in use, the power cord should be disconnected and placed in the storage environment specified by the equipment;
③ Routine performance test and calibration interval: six months.

Repair

The company's products will provide a one-year warranty for the host from the date of purchasing of the device (this warranty is limited to the host of the device, excluding power adapters and other accessories that need to be replaced regularly.

■ Failures caused by the following reasons will no longer be covered by the warranty, such as:

A. The product has been subjected to misuse, accident, transportation or other substantial damage, neglect, flooding, flooding or other liquid intrusion;
B. The product defect or problem is due to the use of non-company products or accessories;
C. Unauthorized disassembly, modification of the product or failure caused by it;
D. Failures caused by lack of reasonable maintenance and failure to meet environmental requirements;
E. Failure caused by accidental beating or falling during use and moving;
F. Failure caused by not operating in accordance with the correct instructions in the instruction manual;
G. Failure caused by maintenance without the permission of our unit.
When requesting warranty service, please contact our service center directly by phone, email, letter or fax. If the problem is not covered by the company's limited warranty, the customer will be charged the cost of repair or product replacement and related costs.

VIII. Troubleshooting

1. This device is an electronic medical device product. Due to the limitation of the user's maintenance ability and testing equipment, for the failure that cannot be repaired, it needs to be sent to the company and the nearest maintenance point. The following lists several fault phenomena and possible causes, which are only for reference during maintenance.
2. The device does not work, the display is off when it is turned on.
3. Check whether the power cord of the device is connected well and whether the power switch is turned on.
4. The device operates normally, but the patient does not feel it.
5. Check that the power cord is well connected and not damaged.

List of abnormal treatment of the ultrasound probe

	Malfunctions	Solutions
1	The probe is dirty	Use 75% medical alcohol to wipe it off
2	The probe is loose	Contact the manufacturer for processing
3	The fixed position of the probe is cracked	Contact the manufacturer for processing

IX. Storage and Transportation

Storage: should be placed in the original packaging box, placed in a well-ventilated room, the packaging box should be elevated, the ambient temperature is -20～+55 ℃, the relative humidity is 10%～93%, and the atmospheric pressure is 700 ～ 1060hpa, not allowed There are harmful gases, flammable, explosive substances and corrosive gases.
Transportation: The therapeutic device under the packaging condition is suitable for road, railway, air and water transportation. During loading, unloading and transportation, it should be prevented from severe vibration and impact, and should not be affected by moisture, and should not be mixed with flammable and corrosive substances. The specific requirements are as stipulated in the order contract.
Handling: Please handle the device carefully, avoid rough operation, and prevent damage caused by falling.
Storage period: When the storage period of the therapy device exceeds one year, it should be taken out of the packing box, and can be shipped out of the factory after being re-checked after being electrified.

X. Service Life

1. The service life of this device is 5 years (note: man-made damage is excluded);
2. Scrap device and accessories that have exceeded their service life should be disposed of in accordance with relevant local laws and regulations;
3. Please refer to the nameplate for the production date of this device;
4. The release version number of the software used by this device is V1;
5. The replaceable parts of this equipment are: power adapter. All parts must be replaced by Shenzhen Elite Medical Technology Co., Ltd.; using parts from other companies may cause the output of the device to be unstable.

XI. Technical Specifications

Working environment:
1. Ambient temperature: 5℃～+40℃;
2. Relative humidity: 10%～80%;
3. Atmospheric pressure: 700hpa～1060hpa;
4. Power supply: 100-240VAC, 50/60Hz;

Rated output power accuracy:
1. Rated output power: 4.8W, allowable deviation: ±20%;
2. The deviation between the indicated value of the power and the actual measured value shall not exceed ±20%.

Effective radiation area:
The effective radiation area is 4.0cm2, the allowable deviation: ±20%;

Effective sound intensity:
The absolute maximum effective sound intensity under the nominal value of rated output power should not be bigger than 3W/cm²;

Acoustic working frequency:
Acoustic working frequency: 1MHz, allowable deviation: ±10%;

Beam non-uniformity ratio RBN:
The absolute maximum beam non-uniformity ratio RBN of the treatment head should not exceed 8.0.
The main safety features of the therapy device
1. According to the type of protection against electric shock: Class II;
2. Classification by application part: BF type application part;
3. Classified according to the degree of protection against the liquid: IPX7 (metal part of the ultrasonic treatment head);
4. Classified according to the degree of safety when used in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide: non-AP/APG type;
5. Classification by operation mode: continuous operation;
6. The rated voltage and frequency of the therapeutic device: 100-240VAC, 50/60Hz;
7. The input power of the therapeutic device: 30VA;
8. The therapeutic device does not have the applied part to protect the effect of defibrillation discharge;
9. The therapeutic device does not have a signal output or input part;
10. The therapeutic device is a non-permanent installation device;
11. Electromagnetic compatibility is grouped into Group 1 Class A according to Gb4824.

XII. Disposal

Disposal of this device is subject to Regulation 2012/19/EU (Waste Electrical and Electronic Equipment Directive). In case of doubt, please contact the local authority responsible for waste disposal. Waste electronic materials are not classified as household waste. You are obliged to dispose of it, either through a professional electrical dealer or a local recyclable waste collection point.

Description
Pb=lead;
Cd=cadmium;
Hg = mercury;
Hazardous substances contained in the electronic materials of this product: lead, mercury, The content of hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers, etc. does not exceed
0.1%; the cadmium content does not exceed 0.01%; the product meets the Relevant standards of SJ/T 11363-2006.

ELITE MED

Instruction Manual

Ultrasonic Physiotherapy Device

RT400

Shenzhen Elite Medical Techology Co.,Ltd