Shockwave Centers of America

Mark V Radial ESWT Manual

Dear New SWCA Owner!

Thank you for your purchase of this Mark V Radial Shockwave Therapy device.

This manual will help guide your setup of the device and some best practices for keeping it running properly.

◆◆Before using the instrument, please read this manual carefully and keep it handy for future reference and inquiry.

◆◆Please install, use and operate correctly according to the requirements in the manual.

◆Do not disassemble or modify any parts of the machine.

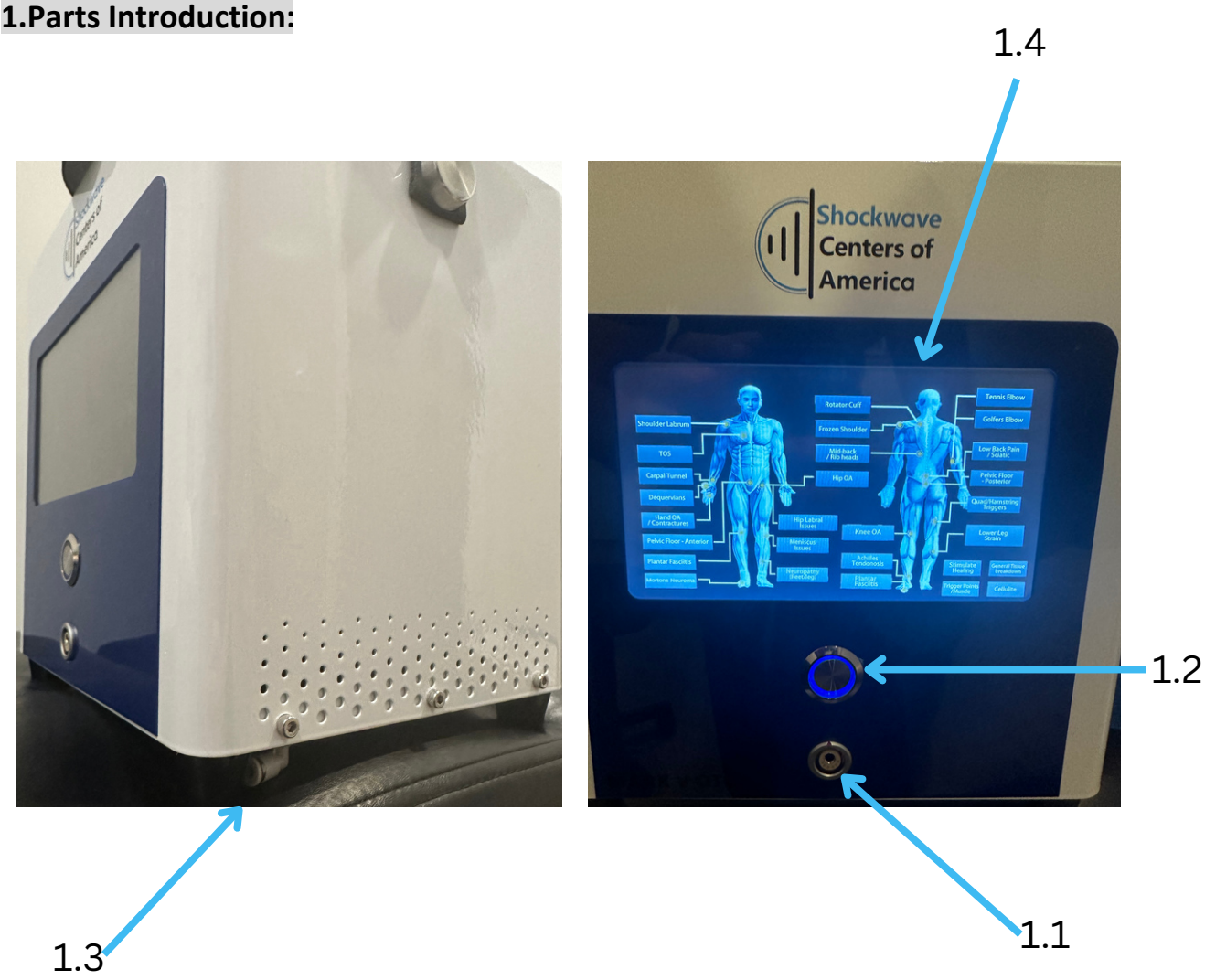
◆◆Except the authorized personnel of the company, it is strictly forbidden for others to open the machine cover and disassemble the main unit.

◆◆It is strictly forbidden for non-professionals to carry out maintenance or updates without authorization.

Please reach out to us at info@shockwavecenters.com for any issues or questions about the maintenance of the machine

Shockwave Centers of America

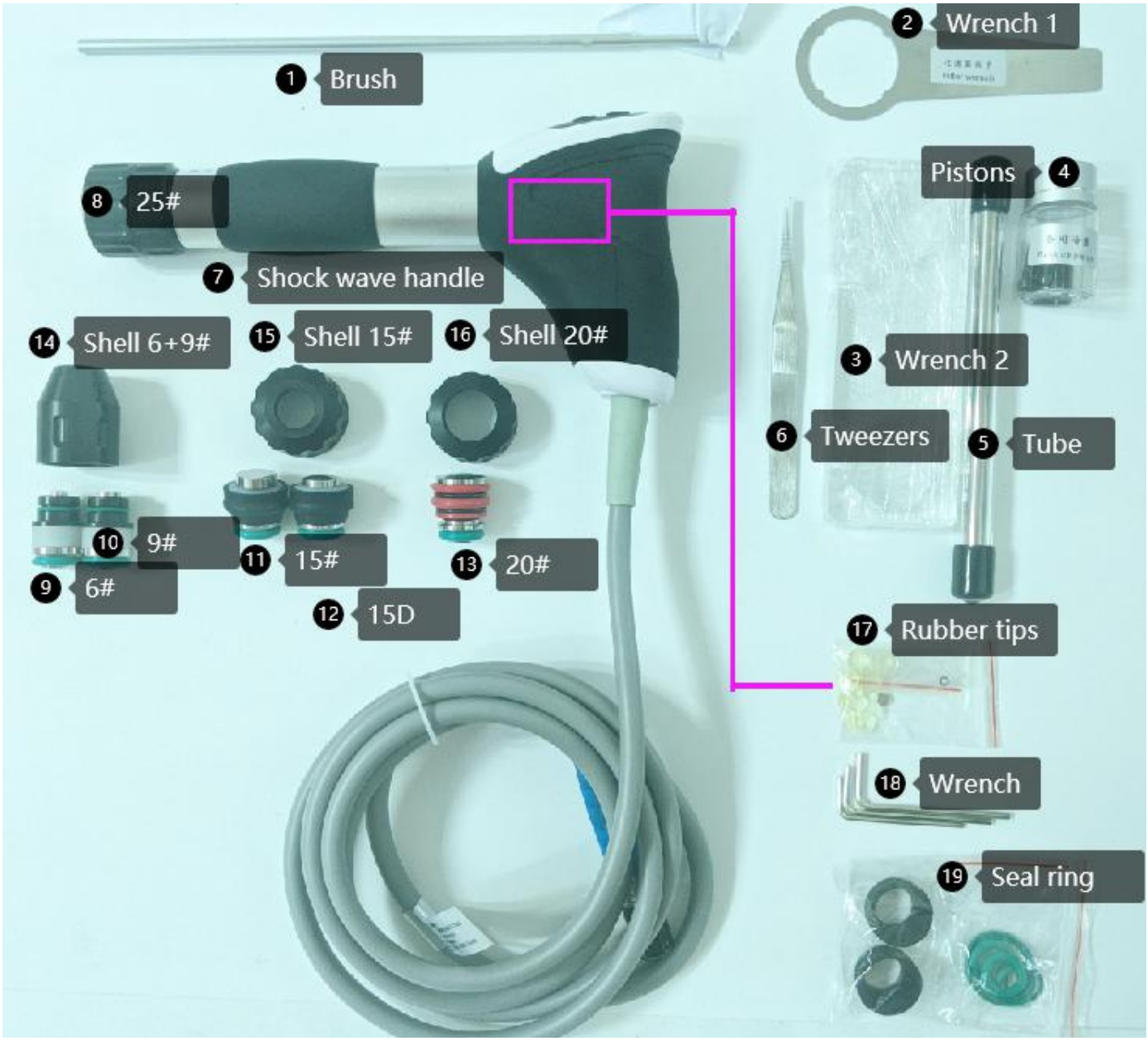
1.Parts Introduction:



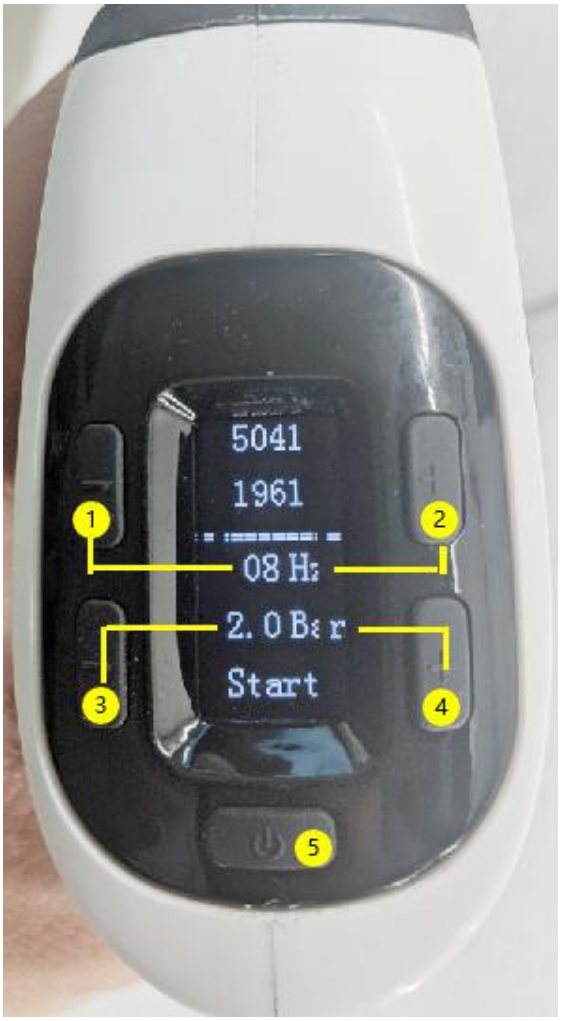
1.1. Socket for the Shockwave handle
1.2. Power Button
1.3. Exhaust tube
1.4. LCD Touchscreen

2.Accessories:

2.1 Handle: Shockwavehandle



1.Cleaning Brush for piston tube
2.Wrench for the Filter
3.Wrenches for Tips and plastic rings
around tips
4.Replacement Bullets
5.Spare / Replacement Piston tube 6.Tweezers for Bullet changes 7.Shockwave Handle
8.#6 Tip (largest) 25mm
9.#1 Tip (smallest) 6mm
10.#2 Tip - 9mm
11.#3 Tip - 15mm Concave
12.#4 Tip - 15mm Convex
13.#5 Tip - 20mm
14.Adapter for Tips #1 &2
15.Adapter for Tip #3&4
16.Adapter for Tip #5
17.Rubber discs
18.Allen Wrenches
19.Seals for handle and rubber ring replacements for #3/4



1. Frequency Decrease

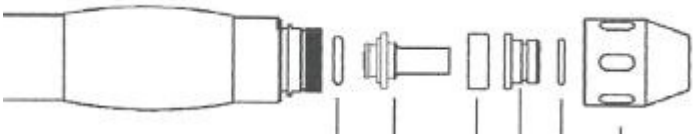
2.Frequency Increase

3.Bar Decrease

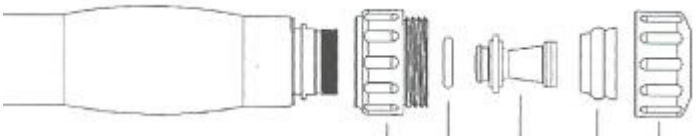
4.Bar Increase

5.Start/Stop

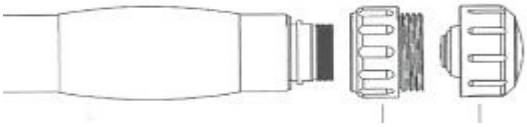
Installing Tips



Install for Tips #1 & #2



Install for Tips #3-#5



Install for Tip #6

Understanding the Tips and adaptors

- Heads #3-5 will completely disassemble for cleaning, #6 will remain encased in the plastic outer ring for stability.
- In your shockwave handle case there is replacement rubber seals for heads #3-5 as well
- The inserts for #1&2 are very specific and will take a little force to install correctly the first few times.
- The adaptor for 1&2 does NOT utilize the base to attach to the shockwave handle
- Keep all metal areas clean and dry. We suggest leaving them open to the air over the weekends/days the machine won't be in use.

4.Shock wave therapy Working theory:

The shock wave therapy device converts the pulsed sound waves generated by the program control of compressed air into high-precision ballistic shock waves, and uses the unique frequency of the device to act on the human body through the positioning and movement of the treatment probe. Shock waves acting on the human body can produce the following effects:

The pressure wave causes direct effects (as one would expect) and also 'indirect' effects associated with the subsequent low pressure part of the cycle (often referred too as the tensile phase), and during this phase, cavitation will occur (as with therapeutic ultrasound). The collapse of these cavitations (bubbles) is in part at least, responsible for the efficacy of the therapy (in focussed mode). The waves are focused in order to achieve the effects in a volume limited zone of tissue, though the focus does not actually come to a 'point' in therapy devices - more like a zone or small volume typically several mm across (2 - 8mm), and thus the destructive effects are eliminated. There is no evidence of tissue destructive effects at therapy level doses or with radial pressure wave.

As the shock wave travels through a medium and comes to an interface, part of the wave will be reflected and part transmitted. There are equations around for calculating this proportional relationship, but effectively, the dissipation of the energy at the interface is almost certainly responsible for the generation of the physical, physiological and thus the therapeutic effects.

The full details of physiological and therapeutic mechanisms are yet to be identified, though a range of effects have been confirmed and several others postulated.

It is now most commonly considered to be a form of mechanotherapy which Huang et al (2013) define as " . . . all therapeutic interventions that reduce and reverse injury to damaged tissues or promote the homeostasis of healthy tissues by mechanical means at the molecular, cellular or tissue level”

Some of the effects relate to an increase in local blood flow which has been clearly evidenced, even in relatively avascular tissues. This increased flow includes an angiogenic response rather than simply increasing the flow in existing vessels. [Calcagni et al 2011; Goertz et al 2014; Ha et al 2013; Huang et al 2016; McKay et al 2021; Mittermayr et al 2012; Notarnicola et al 2012; Scroppo et al 2021; Song et al 2020; Sung et al 2022].

It is suggested that the beneficial effects are partly also due to a stimulation of an inflammatory response – therefore enhancing tissue repair responses, which is especially relevant when dealing with recalcitrant tissues, such as some chronic tendinopathies and delayed and non unions in bone. [Chamberlain and Colbourne 2016; Chen et al 2019; de Girolamo et al 2014; Feichtinger et al 2019; Feng et al 2021; Frairia et al 2012; Liao et al 2022; Mariotto et al 2009; Mittermayr et al 2012; Modena et al 2022; Ozkan et al 2019; Peng et al 2020; Song et al 2021; Waugh et al 2015]. As with other modalities (such as ultrasound and laser/photobiomodulation) this will effectively stimulate or 'enhance' the tissue repair response. At least part of this enhanced inflammation & repair process is achieved by enhanced expression and release of cytokines and chemical mediators such as :

VEGF (Vascular Endothelial Growth Factor) (Chen et al 2018; Heimes et al 2020; Modena et al 2022; Schnurrer et al 2018; Sung et al 2022)
MMP (Matrix Metalloproteinase) (Che et al 2021; Heimes et al 2020)
Interleukins (Chen et al 2020; Kim et al 2019; Notarnicola et al 2012)
Nitric Oxide (NO) (Hayashi et al 2012; Wang et al 2011)
FGF (Fibroblast Growth Factor) (de Lima Morias et al 2019; Rodriguez-Merchan et al 2021)
TGFb (Transforming Growth Factor Beta) (Fan et al 2018; Li et al 2021; Wang et al 2009)
PGE2 (Benson et al 2007; Chen et al 2016; Xing et al 2021)

There is a steadily growing body of evidence which identifies the shockwave stimulates various cells associated with tissue repair [Chao et al 2009; Chi et al 2021; Kuo et al 2009; Manganotti et al 2012; Mittermayr et al 2012; Rinella et al 2016, 2018; Saggini et al 2015; Yang et al 2022; Zhao et al 2021].

In addition to the effects identified above, there is also evidence for a transient analgesic effect (via afferent nerves) and the capacity of focused shockwave to breakdown (or instigate the breakdown) of calcific deposits.

5.Contraindications

1. Patients with bleeding disorders and coagulation disorders
2 Patients with thrombosis
3 Young Children with growing pains
4 Patients with severe cognitive impairment and mental illness
5. Tendon, fascia rupture and severe injury (acute)
6 Do not treat over any electrical implants (treating away from the device is fine)
7 Nonunion caused by acute infection; nonunion patients with bone defect > 2cm
8 Patients with joint fluid leakage.

6.The following are relative contraindications, specific to the doctor's advice:

1 Pregnant Women
2 patients with severe arrhythmia
3 Patients with pacemaker installed
4 Patients with malignant tumors that have metastasized to multiple places
5 Patients with severe hypertension and poor blood pressure control
6 Patients with sensory dysfunction (Test treat on area of normal sensation before treating region of impaired sensation)

Reach out to our clinical team if you have questions about relative contraindication patients.

7.Precautions before use

Before treatment, have the patient remain relaxed in a chair or in bed:
1) Confirm that the therapeutic device is in normal working state; check the device thoroughly before each use: check whether the cable is loose, whether the cable insulation is cracked, whether the control handle shell is cracked, whether the display function is normal or whether the operating element has any flaws
2) Explain the whole treatment process to the patient, and inform the patient to give feedback in time if there is any discomfort
3) Make sure all setting parameters meet the requirements before treatment starts.

8.Precautions in use

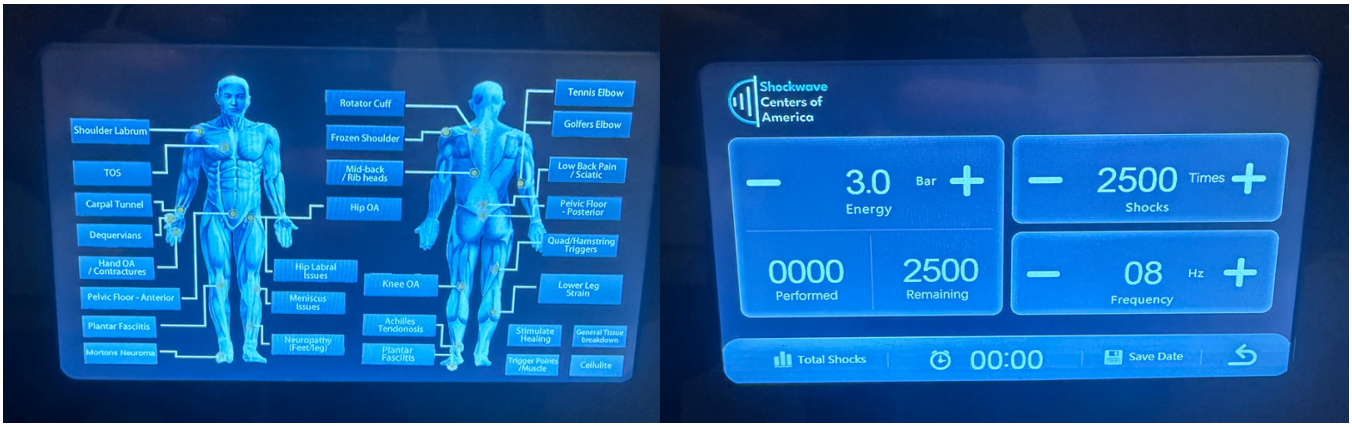
1 Ensure that the output power is at an intensity level that the patient feels comfortable
2 Some paralyzed patients may not be able to judge the degree of stimulation by themselves, pay attention to prevent excessive stimulation
3 Do not exceed the conventional treatment time and impact intensity
4 In order to avoid accidents, it is forbidden to insert metal in the output port
5 Do not disconnect the control handle during the treatment
6 If the device shows any defects or if there are any doubts about its correct and safe function, discontinue treatment immediately.

9.Precautions after use

1 After using the device, turn off the power:
2 Please clean up the equipment and treatment probe after use;
3 The time interval between turning off/on the power switch must be at least 3 seconds apart.

10.operator interface

10.1: Turn ON the Machine and touch the screen to progress to the protocol page
10.2: Touch the protocol you wish to use



10.3: Click the Play button ,then click the on/off on the handle to work the machine.

11. Treatment Methods

Treatment steps: prepare before treatment → determine the treatment → manually set treatment set parameters or use built-in prescription → apply Gel → start treatment → rehabilitation guidance after treatment.

Preparation before treatment

1. Before the treatment, introduce the basic principle, efficacy, safety and reliability of extracorporeal shock wave therapy to the patient in detail, and explain the precautions to eliminate fear. Utilize the Informed consent signature page in your affiliate portal. Instruct and assist the patient to take the correct body position. Before the treatment, the importance of positioning should be explained to the patient, do not move the body position at will during the treatment, and do all the preparations before the treatment.

2. Before determining the treatment site, it is necessary to understand the patient's tolerance to pain in detail, let the patient feel the intensity of the shock wave with his hand first, so as to reduce the patient's fear, in order to prevent the shock wave from moving in the shock after positioning and affecting the treatment Effect.

3. For patients with poor pain tolerance, start treatment on a lower BAR and faster HZ setting than originally recommended to enable them to receive treatment smoothly.

Determine the treatment location

There are currently three positioning methods:

1. Body surface anatomical landmarks combined with pain point positioning: The body surface anatomical landmarks are used as the positioning basis, and the tender point is used as the impact point. At the same time, according to the anatomy of blood vessels and nerves, important blood vessels and nerves are avoided. For example, subacromial bursitis is marked by the acromion, and the tender point is found in the body surface positioning area of the subacromial bursa,and the tender point is used as the shockwave treatment point.

2. X-ray localization: used for localization of bone tissue and calcified tissue. The bone itself has a high density and has a good natural contrast with the surrounding soft tissue, so X-ray examination is one of the most important examination methods in clinical orthopaedics, and it can be supplemented by radiographs if necessary.

3. Ultrasound positioning: Ultrasound can clearly show the soft tissue lesions around the bones, such as muscles, tendons, joint capsules, ligaments, bursae, blood vessels, etc. Ultrasound is non-invasive, non-radiative damage, easy to operate, fast, and inexpensive, and is a very important inspection method. Clinical practice has proved that shock wave treatment of subacromial bursitis, biceps brachii, long head tendinitis, plantar fasciitis, and prepatellar bursitis can improve the curative effect under Ultrasound positioning.

12.Start treatment

Treatment is initiated by pressing the button of the control handle. During the treatment process, the patient should be frequently asked about the feeling of the treatment site to ensure that the center of the treatment impact is at the location, otherwise the treatment should be stopped and repositioned.

13.Recommended treatments:

(1) Shunt strike: along the direction of the origin (stop) of the muscle to the distal divergence.
Advantages: It is not easy to damage normal tissues and does not increase pain;
Disadvantages: frequency and time are long.
(2) Counterattack: The direction is opposite to that of the forward stroke.
Advantages: Sometimes you can take advantage of the situation and get twice the result with half the effort; Cons: Sometimes mild pain.
(3) Oblique hit: The control handle forms a 45° angle with the skin, which is suitable for soft tissue injuries around the ankle joint.
(4) Parallel back-and-forth movement method: It is a method to relieve pain during treatment, and can also be applied to lesions with large-scale damage.
(5) Circling movement method: It is a method to relieve pain during treatment, and it can also be applied to lesions with large-scale damage.

14.Rehabilitation guidance after treatment

After treatment, first check the patient's skin on the treatment area for redness, swelling, and subcutaneous bleeding. Inform the patient that the above symptoms - generally subside within 1 week without special treatment, so as to relieve the patient's nervousness. Nursing staff should do a good job in the observation and nursing of symptoms to reduce the occurrence of complications.

After treatment, patients may experience a transient increase in blood pressure, which generally does not require treatment, and the blood pressure can return to normal after 1 to 2 days of treatment. The principle is that high-energy shock waves can cause physical and biochemical changes in body tissues, causing an increase in angiotensin, resulting in increased blood pressure. Therefore, it is recommended to rest in bed after treatment, pay attention to monitoring blood pressure, ask the patient whether there are symptoms of hypertension such as headache and dizziness, and report any abnormality to the doctor in time.

15. Maintenance

Keep the device clean and do not immerse it in any liquid. Before each use, inspect the device and its accessories (especially cables) for mechanical or other damage. If there is any damage, do not use this device.

15.1 Cleaning of the outside of the equipment

Use a soft cloth lightly dampened with water or a 2% detergent solution to scrub the outside of the device and its parts. Do not use alcohol-based cleaners, ammonia, gasoline to clean. Never use abrasive cleaning materials to wipe the surface of the device. Take care to prevent water or other liquids from entering the inside of the device.

15.2 Cleaning and maintenance of the treatment probe

After each patient use, clean and sterilize the therapy probe with a neutral detergent (e.g.,ethyl alcohol). You can unscrew the end cap of the treatment probe, wash it with warm water or clean it with ethyl alcohol.

15.3 Cleaning, maintenance and upkeep of pipes

When the number of impacts reaches 300,000 times, take out the bullet body, fix one end of the cleaning rod with a fine gauze, insert it into the lumen (inner piston), and wipe it back and forth.

16.Attachment list

1. Laptop-----1pcs
2. Laptop holder---1pcs
3. Handle 1: Shockwave handle with 6 tips
4. Vib+ handle with 2 tips
5. Wrench for the filter---1pcs
6. Wrench for the tip adaptor----2pcs
7. Wrench for opening the machine and the handle-----2pcs
8. Tweezers ------1pcs
9. Piston (back up)----1pcs
10. Bullet (back up)----4pcs
11. Rubber tips+magnet+Handle plug seal ring(red color)
12. Black ring------2pcs; and green ring----5pcs

17.Appendix A: Manufacturer's Declaration on Electromagnetic Compatibility

1. This chapter is a special reminder of electromagnetic compatibility. The equipment should be installed and used according to the electromagnetic compatibility information mentioned in this chapter.
2. Portable and mobile radio frequency communication equipment may affect the normal use of this equipment. When using this equipment, it is recommended to keep away from portable and mobile radio frequency communication equipment or turn it off.
3. In addition to the accessories provided by the company, the use of accessories from other manufacturers may lead to an increase in the emission of this device or a decrease in the immunity.
4. In order to ensure that the device can be used normally and that its emission is not increased and the noise immunity is not reduced, the connecting cables and accessories provided by the company must be used. Among them, the length of each cable is as follows:
Power cord: 1.8 m
Control handle cable: 2.5 m
5. The use of unspecified accessories and cables with this device may result in an increase in the emission of the device or system or a decrease in immunity. .
6. This equipment should not be used close to or stacked with other equipment. If it must be used close to or stacked, it should be observed to verify whether it can operate normally in the configuration it is used in.
7. Basic performance of the product: The equipment operates according to the specified working mode, and there are no unexpected changes.