Extracoporal Shock Wave Therapy SYSTEM

AS-ESWT

USER MANUAL

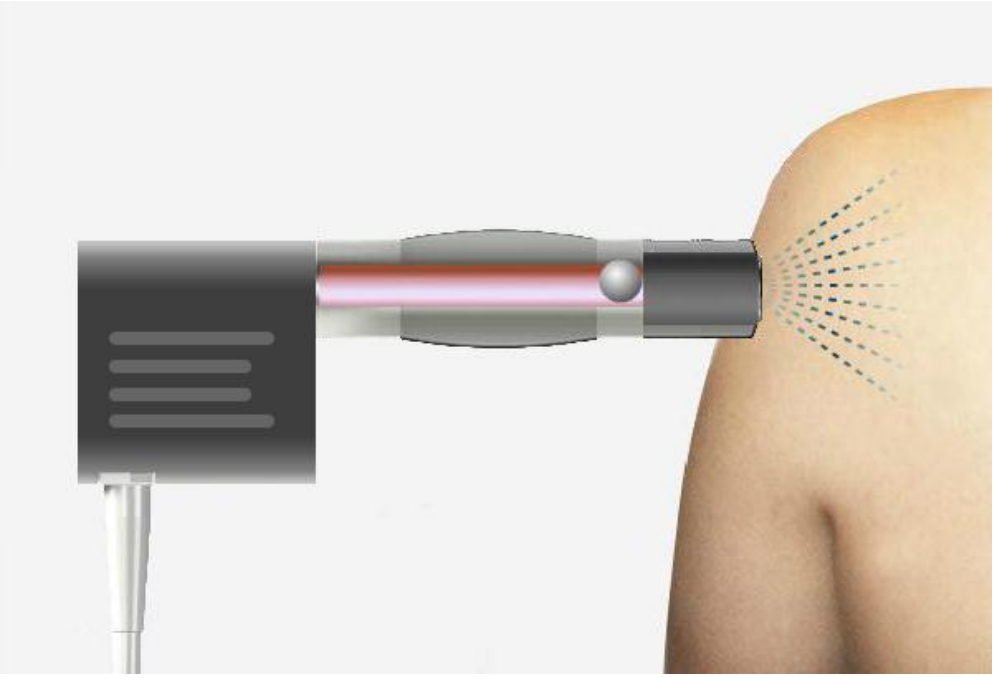
Introduction

PRINCIPLE

Extracorporeal Shock Wave Therapy Equipment also called Acoustic Wave Therapy Equipment, mainly for physical therapy treatment, sports injury, rehabitation treatment and cellulite reduction.

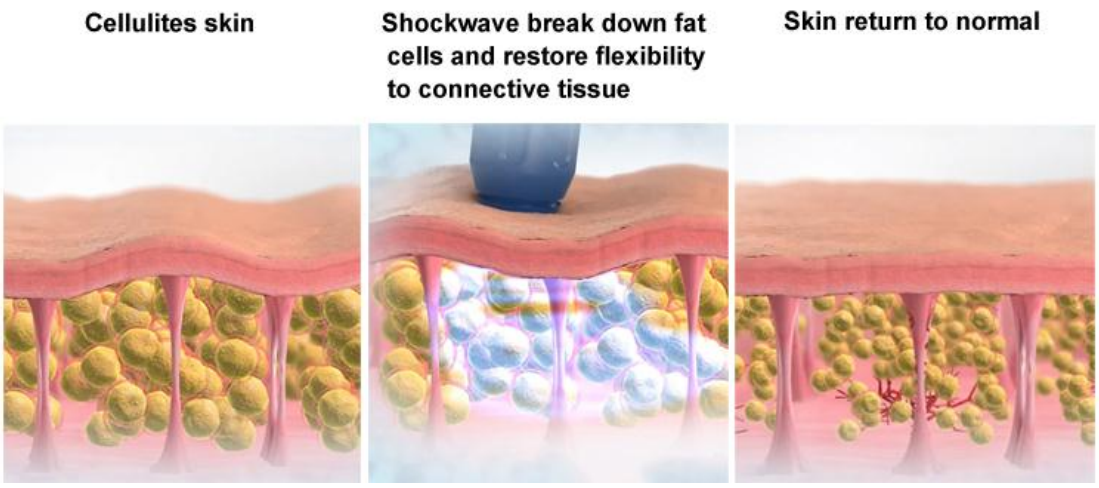
Shockwave therapy principle

The shockwave therapy equipment is based on the technology of unfocused low energy radial waves, which is a kind of acoustic wave which carries high energy to painful spots and fibrous or myoskeletal tissues with subacute, subchronic and chronic conditions. This energy promotes healing, regenerating and reparative processes of the tendons and soft tissue. The unfocused low energy radial waves scientifically proved to have a large impact on collagen structure and the skin connective tissue, improving blood circulation and the metabolism of fat cells. The mechanical massage effect reduces the edema and improves the lymphatic drainage of toxins. It stimulates collagen formation, while the skin becomes more elastic and its firmness is visible after only a few treatments.



How shockwave remove cellulite?

Extracorporeal Shock Waves Therapy (ESWT), emitting like pulses and create vibrations to attack fibrous strands around fatty deposits under the skin. It is a technique of loosening and breaking the fibers and releasing of fat, water, and toxins. Simultaneously stimulate the production of very active and healthy new collagen fibers and gradually restores elasticity and strength of the skin. Through waves accelerates blood circulation and so much more oxygen and nutrients to reach these areas. The end result is a much smoother and tighter skin quickly and permanently.



PARAMETER

Energy generated	Compressed air
Screen	8.4 inch true color touch screen
Pulse frequencies	1 – 20 Hz, steeping at 1Hz
Energy levels	1.0 – 6.0 Bar, stepping at 0.1Bar
Transmitters	A6,R15,D15,D20,D35 (F15 option)
Counter	yes
Handpiece revision	1,000,000 shots
Weight	8Kg
Dimension	38cm*37cm*21cm
Power Specification	AC110-230V / 50Hz-60Hz 16A

System functions and use

Before a treatment with Radial Pressure Wave, a correct examination and diagnosis should be performed.

Please stay current with the latest developments and medical publications on Radial Pressure Wave therapy for details on contraindications and side effects not known at the time of manufacturing.

Radial pressure wave therapy is indicated for the following:

Myofascial Trigger Points (MTrP)

Localizing and Deactivating Trigger Points

Triggers are localized at the low energy level (approximately 2 bar) by passing the transmitter over the muscle region being treated (increased sensitivity to pain) and then deactivated using a higher energy level (approximately 3 bar).

Activation of Muscle and Connective Tissue

Increasing Circulation

Promotes blood flow through the tissue and boosting metabolism.

Pulse Vibration Massage

Soothing relief from muscle strain and stress.

Disorder of Tendon Insertions

Plantar Fasciitis, Heel Pain, or Heel Spur

Plantar Fasciitis is an inflammatory condition of the foot caused by excessive wear to the plantar facia that supports the arch

Tendinosis Calcarea/Supraspinatus-Tendon

Shoulder calcifications and chronic shoulder pain

Radial and Ulnar Humeral Epicondylitis

Tennis elbow, inflammation of tendon attachments on cubital or radial part of elbow joint (humeral)

Achillodynia

Pain due to inflammation of the Achilles tendon or the bursa associated with it.

Retropatellar Pain Syndrome

Pain in the front of, behind, and around the kneecap.

Tibial Edge Syndrome

Pain located along or just behind the medial edge of the tibia

Proximal Iliotibial Band Friction Syndrome/Trochanteric Insertion Tendonitis

Pain or aching on the outer side of the knee or hip

AESTHETICS PURPOSE

Body reshaping
Anti-cellulite treatment
Treatment of skin irregularity after liposuction
Skin elasticity improvement
Connective tissue tightening
Scar and wrinkle smoothing
Reduce stretch marks
Lymphatic system stimulation

Contraindications

- Do not use Radial Pressure Wave treatment on any body part during pregnancy.
- Over the pregnant or potentially pregnant uterus. Therefore, radial pressure wave treatment should not be applied over the uterus unless specific assurance can be attained from the patient that she is not pregnant.
- Haemophilia, or other coagulation disorders.
- Anticoagulant pharmaceuticals, especially Marcumar.
- Acute inflammations. Do not use over swollen, inflamed, infected tissue, skin eruptions or on other acute tissue lesions.
- Polyneuropathy area. A Diabetes patient often obtains disturbed sensory and nervous function in the polyneuropathic area.
- Cortisone therapy: Wait minimum 6 weeks after local cortisone injection before treatment with radial pressure waves.
- Patients with hemorrhages or risk of hemorrhage.

- Patients with malignant tumors and undiagnosed tumors.
- Swellings that still feel warm.
- Implants, areas where implants have been removed, damaged implants, and metal inclusions.
- Over superficial endoprosthesis or metal implants.
- Severe arterial obstructions (stage III and IV).
- Gynecological disorders involving acute inflammation.
- Deep vein thrombosis, phlebitis, varices.
- Arterial disease, circulatory insufficiency.
- Over eyes.
- Over reproductive organs.
- Over cardiac pacemakers and defibrillators, cochlear implants, bone growth stimulators, deep brain stimulators, spinal cord stimulators, and other nerve stimulators.
- Over open lamina (after laminectomy; spina bifida).
- Directly over the carotid sinuses, ceruical stellate ganglion, or Vagus nerve located in the anterior neck triangle.
- Direct application over cancerous tumors or lesions due to its potential to increase blood flow to the area of malignancy.
- Neoplastic tissues or space occupying lesions.
- Occlusive vascular disease, such as arteriosclerosis obliterans and thromboangitis obliterans, in which organic occlusion and ischemia are evident.
- In the presence of systemic or local infection (sepsis, osteomyelitis, tuberculosis) or if the patient has an elevated temperature.
- Shock waves must not be applied to target areas located above air filled tissue (lungs), nor to any regions near large nerves, vessels, the spinal column or head.

ADDITIONAL PRECAUTIONS

When administering radial pressure wave treatment, keep in mind the following:

- Radial pressure wave treatment should be applied with caution over bone where minimal (bony prominence) or no (Stage IV wounds) soft tissue is present.
- Hearing aids should be removed.
- The function of other patient connected equipment may be adversely affected by the operation of the pulsed radial pressure wave equipment. Maintain maximum distance between units in order to reduce any tendency to interaction.
- Any bleeding tendency is increased by heating because of the increase in blood flow and vascularity of the heated tissues. Care, therefore, should be used in treating patients with therapeutic radial pressure wave treatment who have bleeding disorders.
- Frequent monitoring of intensity level and skin response should occur during all treatments.
- Always apply the transmitter on the skin with small circular movements.
- Never use Radial Pressure Wave therapy on the head.
- Do not treat direct in an area with a metal implant.
- Patients with active autoimmune diseases may not respond positively with the

treatment.

Possible Side Effects

Side effects could occur after a treatment with Radial Pressure wave therapy. The majority will appear after 1-2 days.

Do not repeat a treatment until the previous side effects have diminished. Common side effects include:

- Reddening
- Swelling
- Pain
- Hematoma
- Petechiae, red spots
- Skin lesions after previous cortisone therapy

These side effects generally abate after 5 to 10 days.

SETUP

UNPACKING THE UNIT

Inspection

Immediately upon unpacking the unit, perform the following steps:

1. Verify the delivery documents to make sure that the delivery is complete.
2. Check the external components and accessories for possible damage due to transport.

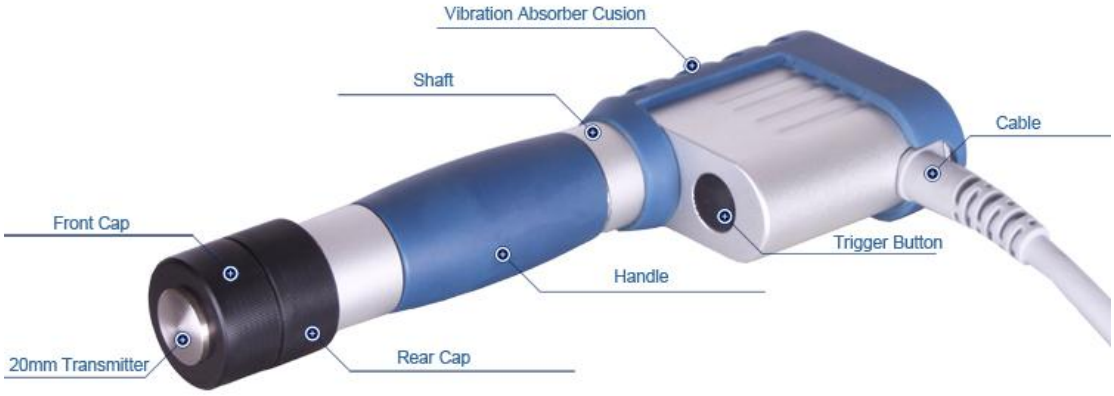
DANGER
In case of damage from transport that could endanger personal safety, the unit must not be connected to the Mains Power Supply before inspection is complete.

3. Verify that the packaging contains the following

A. AS-ESWT unit
B. User Manual
C. Handpiece Applicator
D. Handpiece Accessory Kit that Includes the following:
    - 15 mm ESWT Transmitter
    - 20 mm Transmitter
    - Sealing Set
    - Bullets and barrels set
    - Cleaning Brush
E. Power cord

4. Retain the original packaging. It may prove useful for any equipment transport.

HANDPIECE INTRODUCTION

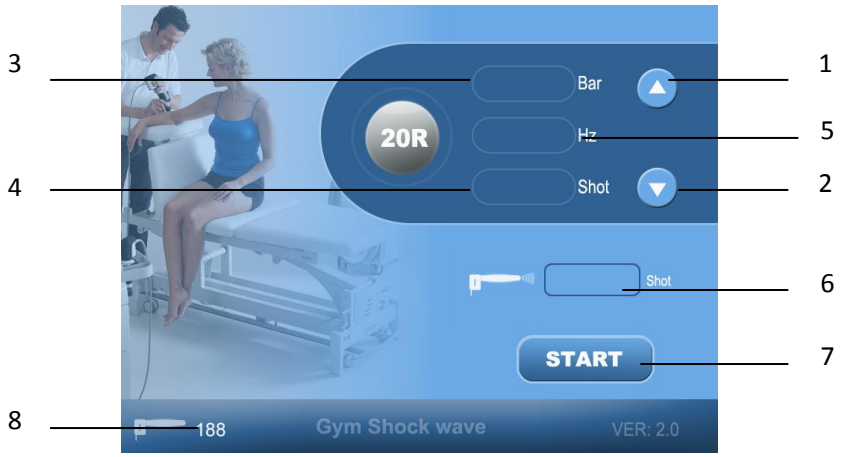


SYSTEM INTRODUCTION

1. Fuse
2. Power supply socket
3. Main switch
4. Probe holder
5. Water outlet connector
6. Handpiece connector

TOUCH SCREEN

Welcome interface
(OEM interface, use your own logo)



Selection of setting display:

1. Increase of value of Bar, Hz, Shot
2. Reduction of value of Bar, Hz, Shot
3. Bar value selector key
4. Shock number selector key
5. Frequency selector key
6. Display shot number used after handpiece electrified
7. Confirm setting and electrify handpiece
8. Total shot display

Procedure:

Select desired configuration(Bar, Hz, Shot) and press “START” to confirm.
Press “START” again to electrify off the handpiece.

OPERATION

INSTALLING THE APPLICATOR

Replacing and Installing the Transmitter

The handpiece is shipped fully assembled, but if the transmitter ever requires replacement, do the following:

1. Unplug the unit.

2. Unscrew the rear cap by turning it counterclockwise and holding the handpiece.

3. Unscrew the front cap by turning it counterclockwise and holding the rear cap.

4. Press the transmitter and spacers through the rear cap

5. Press the front cap onto the rear cap and turn the rear cap clockwise to tighten it.

CAUTION

Do not cross-thread the two caps with tightening.

6. Fit the rear cap onto the handpiece and turn it clockwise and holding the handpiece. Tighten until snug.

7. Align the red dot on the connector with the red dot on the socket and press the connector into the socket.

WARNING

- Do not cross cables.
- To remove the cable from the handpiece, make certain the power is off. Hold the handpiece while removing the cable to prevent the handpiece from dropping to the floor.
- Observe the patient at all times during therapy.

PREPARING THE UNIT FOR THERAPY

The unit has been completely assembled in the factory and is ready for use except for connection of the handpiece and the power cord.

Proceed as follows in order to prepare the unit for operation:

- Make sure that the voltage rating on the serial decal conforms to the system voltage of the building.
- Install the required transmitter (insert) into the handpiece.
- Plug the handpiece cable into the socket on the back of the unit.
- Check the condition of the housing and the insulation of the handpiece, handpiece connection cable, and the power supply cable. Also make sure that the cables have been routed correctly.
- Insert the power cord plug into an earthed socket outlet. There is no need to plug the power cord into an isolated circuit for the proper function of this unit.

PREPARING THE PATIENT FOR THERAPY

Before applying radial pressure wave to the patient, you must first prepare the patient's

skin. By properly preparing the patient's skin for therapy, you will allow more energy to reach the targeted areas and reduce the risk of skin irritation.
To prepare the patient's skin for therapy, do the following:
1. Thoroughly wash the skin on which you intend to administer therapy with mild soap and water or alcohol wipe.
2. Dry the skin thoroughly.
3. Apply the coupling gel generously to the target area on the patient.

BASIC OPERATION

1. Connect the male end of the power supply cord to an appropriate electrical outlet.
2. Connect the female end of the power supply cord into the IEC connector on the rear of the unit.
3. Turn clockwise the key switch or release the emergency button, the following occurs

- the red LED illuminates
- the Home Screen displays.

The operator is able to view parameter options on the display and make selections by pressing the buttons directly on the LCD. The LCD provides continuous information during the treatments concerning intensity and the number of pulses given. The output can be stopped by the user by pressing the START or STOP buttons located on the Operator Interface.

APPLICATION ENERGY

Shock wave application has an analgesic effect, which makes the therapy as pleasant as possible for your patients:
Begin with an initial energy level of approx. 1.5 – 2 bar. Energies up to 3 bar will generally be sufficient.
When the patient reports abatement of pain, you can gradually increase the energy level with the arrows.
Select the application energy according to the patient‘s sensitivity to pain (bio-feedback).

OPTIONAL TRANSMITTERS

A6: Ø 6 mm, acupuncture
D15: Ø 15 mm, Energy Beam
R15: Ø 15 mm, pain therapy

F15(option): Ø 15 mm, Focus lens transmitter, energy focus area
D20: Ø 20 mm, trigger points, muscle activation
D35: Ø 35 mm, muscle and connective tissue activation, muscle smoothing

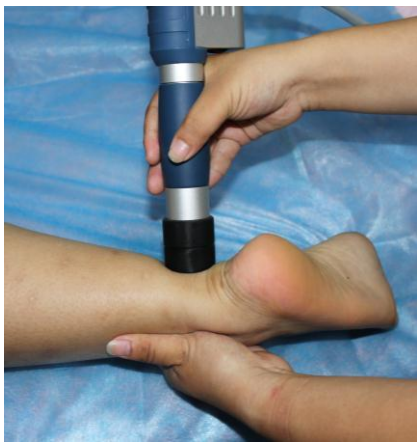
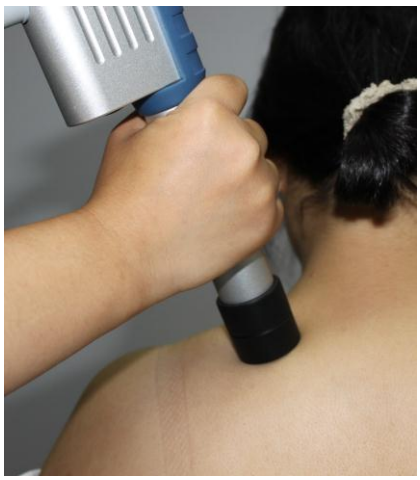
TREATMENT TIPS

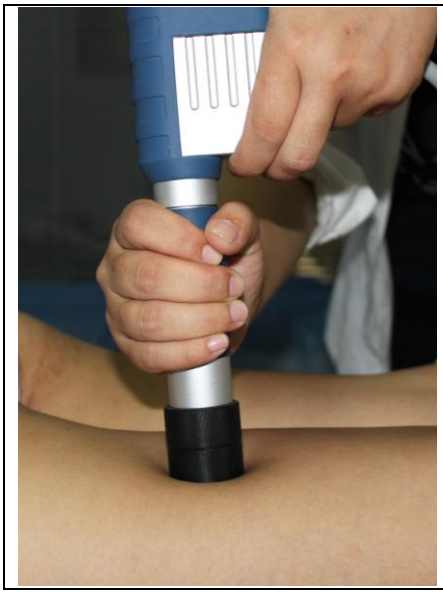
The applicator is placed over the previously diagnosed pain region. To start and stop shock wave application, the trigger button provided on the applicator must be pressed Keep in mind the following:

- Do not apply more than 300 pulses to the same spot.
- Avoid pressing the transmitter into the treatment area with excessive pressure. Excessive pressure is not needed for effective and successful treatment.
- Stop treatment after a maximum of 6000 pulses.

Positioning the Handpiece

Position the handpiece on the part of the body to be treated according to the medical indication.

	**Holding the Handpiece as a Pen** The handpiece is held behind the rear cap. This way of holding the applicator is recommended for tactile treatment.
	**Holding the Handpiece as a Bar** The handpiece is grasped with the entire hand behind the rear cap. This way of holding the applicator is recommended for the treatment of pain regions covering relatively large areas.

	**Using Both Hands to Hold the Handpiece** This way of holding the applicator is recommended for the treatment of pain confined to specific points.

WARNING

Operating the unit at pressures higher than 3 bar without an impact surface can result in damage to the handset.

MAINTENANCE

Routine Maintenance

Keep in mind the following when maintaining the unit:

• As the manufacturer, is responsible for the safety and reliability of the unit only if it is used in accordance with this user manual.

• Safety inspections, maintenance, repairs, and modifications may be performed only by a certified service center or field technician certified by manufacturer.

Cleaning and Disinfection

When cleaning the unit, keep in mind the following:

1. Unplug the power plug from the power outlet before cleaning or disinfecting the unit.
2. Wipe off excess coupling gel from the transmitter.
3. Clean the base unit using a soft, clean cloth dampened with water and a mild antibacterial detergent.

Avoid the use of abrasive materials and cleaning solvents.

4. After each patient use, clean the handpiece (remove the front and rear caps first). Use a soft, clean cloth dampened with alcohol, an alcohol based surface cleaning wipe, or a mild antibacterial detergent. Avoid the use of abrasive materials and cleaning solvents.

5. To clean the handle, remove the protective cushion by pulling it up and off the handle. Use a soft, clean cloth dampened with water or a mild antibacterial detergent to wipe off the handle.
Avoid the use of abrasive materials and cleaning solvents

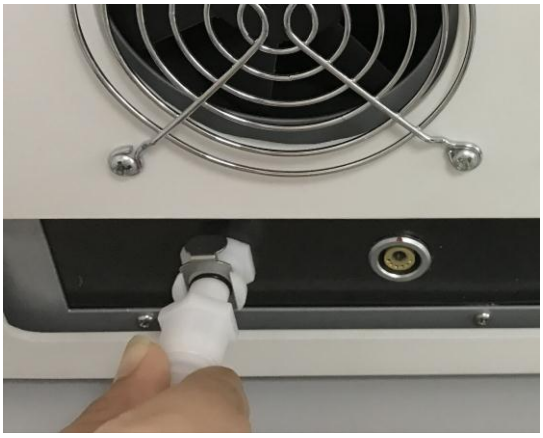
6. Wait until the unit is completely dry before operating it again.
7. It is recommended that the transmitters be cleaned with an ultrasound cleaning bath designed for disinfecting heat sensitive, reusable medical instruments. If an ultrasonic bath is unavailable, clean parts under running water and wipe with an alcohol based surface cleaner wipe, or spray with alcohol-based surface cleaner and wipe with a soft, clean cloth.

8. When cleaning the transmitter, push aside the spacer ring so that the interior cavity can be cleaned.

9. Re-assemble the transmitter and handpiece by reversing the procedures in steps 4 and 3.

Removing Water

The filter is installed inside machine, we equip the CPC connector to drain out water weekly. To do this, do the following:
1. Unplug the unit from the Mains Power.



2. Insert the CPC connector: water will flow out of the connector simultaneously, make sure the water will be gathered with a tool.

3. Take off the CPC connector: press the metal plate on the male connector, the connector will release automatically

Replacing the Projectile and Guide Tube

Projectiles and guide tubes should be changed after 200,000 pulses. To change the transmitter, do the following:

1. Unplug the unit and remove the handpiece cable from the socket on the unit.

2. Unscrew the rear cap by turning it counterclockwise and holding the handpiece.

3. Unscrew the shaft from the handpiece by turning it counterclockwise.

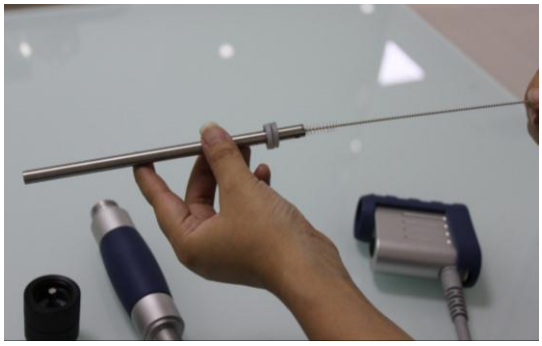
4. Remove the shaft from the handpiece housing.

5. The projectile may be laying inside the handle.
Place your hand over the hole in the handle and turn it over so that the projectile falls out in your hand.
If the projectile is in the shaft, place your hand over the open end of the shaft and turn it over so that the projectile falls out in your hand.
NOTE: Make certain that the entire projectile is retrieved. It may have broke apart during use.

6. While holding the shaft with one hand, pull the guide tube out of the shaft with the other hand.

7. Dispose of the used projectile.

8. Clean the outside of the shaft, transmitter, and screw cap using a soft, clean cloth dampened with water or a mild antibacterial detergent.
Avoid the use of abrasive materials and cleaning solvents.
NOTE: Wait until the cleaned components are dry before continuing with step 9.



9. Clean the inside of the shaft with the cleaning rod and brush.

10. If necessary, replace the sealing sleeve on the guide tube.

11. Insert the new guide tube into the shaft.
NOTE: Make certain to insert the end of the guide tube without the holes into the shaft.

12. Press the guide tube into the shaft until it seats.

13. Insert the new projectile into the guide tube.

14. Insert the shaft into the handle and turn clockwise until snug.

15. Reattach the rear cap by turning it clockwise and holding the handpiece.

18. Plug in the unit and connect the handpiece cable to the output socket on the unit.

DANGER

- Under no circumstances may liquid penetrate the openings on the unit (e.g. the connecting sockets of the handset cables). Therefore, do not use cleaning or disinfectant sprays.
- The unit, handpiece, and cables may not be sterilized using steam or gas.
- Never clean the unit with abrasives, disinfectants, or solvents that could scratch the housing or LCD or otherwise damage the unit.
- In order to prevent electrical shock, unplug the power plug from the power outlet before cleaning or disinfecting the unit.

Safety Inspections

The following safety inspections must be performed on this unit. This must be done by persons who, based on training, knowledge or practical experience, are capable of conducting the inspections correctly and independently.

Visual Inspection (Daily)

When performing daily inspections of the unit, pay particular attention the following areas of potential damage:

- Deformation of unit housing
- Power cable damage
- Handpiece connection damage
- Handpiece cable damage

Functional Test (Daily)

When performing daily inspections of the unit, pay particular attention the following areas of potential damage:

- Correct function of indicators
- Display of operating modes

NOTE: It is the responsibility of the health care facility to verify that the unit complies with the facility, local, and national Earth Leakage limits.

Service

The AS-ESWT unit must be recalibrated if it is not operating within specifications after routine maintenance and safety inspections have been performed.

Should the unit require service, contact the selling dealer or company Service

Department.
All units returned to the factory for service must include the following:
Warranty Repair/Out of Warranty Repair
1. Written statement containing the following information:
• Unit model number
• Unit serial number
• Contact person with phone
• Shipping address (where to ship unit after repair)
• Detailed description of problem or symptoms
2. Copy of original invoice issued at purchase of the unit.
3. Ship the unit to address specified by an certified service technician.
NOTE: The unit was calibrated during the manufacturing process and is ready to be placed into service upon delivery.

The company warrants that the AS-ESWT ("Product") is free of defects in material and workmanship. This warranty shall remain in effect for 1 year (12 months) from the date of original consumer purchase. If this Product fails to function during the first year warranty period due to a defect in material or workmanship, at the Company's Option, Company or the selling dealer will repair or replace this Product without charge.
All repairs to the Product must be performed by a service center certified by the Company. Any modifications or repairs performed by unauthorized centers or groups will void this warranty.
The warranty period for accessories is 180 days.

This Warranty Does Not Cover:
• Replacement parts or labor furnished by anyone other than the Company, the selling dealer or a certified Company service technician.
• Defects or damage caused by labor furnished by someone other than Company, the selling dealer or a certified Company service technician.
• Any malfunction or failure in the Product caused by product misuse, including, but not limited to, the failure to provide reasonable and necessary maintenance or any use that is inconsistent with the Product User's Manual.
COMPANY SHALL NOT BE LABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES.
Some areas do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Application Reference Sheet

Treatment	Setting
Plantar fasciitis/heel spur/heel pain	Energy level: 2 – 3.0 bar Pulses/session: 3000 – 3500 Frequency: 15 – 20 Hz Transmitter: R15, D20 Therapy region: smoothing of calf muscles and foot sole
Calcific tendonitis/shoulder pain	Energy level: 1.8 – 3.0 bar Pulses/session: 2000 – 3000 Frequency: 15 – 20 Hz Transmitter: D20 Therapy region: upper arm and cervical muscles, smoothing of surrounding muscles
Radial/ulnar humeral epicondylitis	Energy level: 1.8 – 3.0 bar Pulses/session: 2000 – 3000 Frequency: 15 – 20 Hz Transmitter: R15, D20 Therapy region: forearm extensors and/or forearm flexors
Achillodynia	Energy level: 1.6 – 3.0 bar Pulses/session: 2000 – 3000 Frequency: 15 – 20 Hz Transmitter: R15, D20 Therapy region: smoothing of surrounding calf muscles and foot sole
Patellar tendonitis (Jumper‘s knee)	Energy level: 1.8 – 2.2 bar Pulses/session: 2000 – 3000 Frequency: 15 – 20 Hz Transmitter: R15, D20 Therapy region: quadriceps muscle, tensor fasciae latae muscle, iliotibial band
Tibial stress syndrome (Shin splint)	Energy level: 1.8 – 2.8 bar Pulses/session: 2000 – 3000 Frequency: 15 – 20 Hz Transmitter: R15, D20 Therapy region: smoothing of surrounding muscles
Trochanteric tendonitis	Energy level: 2.0 – 3.0 bar Pulses/session: 2000 – 3000 Frequency: 15 – 20 Hz Transmitter: D20, D35 Therapy region: Application over large surface area, stretching, localization of additional trigger points in associated muscles by palpation and shock wave

	stimulation, stretching, depending on position, considering bio-feeback and referred pain
Myofascial pain syndrome	Energy level: 1.0 – 4.0 bar Pulses: 300 – 1000/trigger point, 500 – 4000/muscle area Frequency: 10 – 20 Hz Transmitter: R15, D15, D20, D35 Therapy region: muscle smoothing over large surface area
Acupuncture therapy	Number of sessions:6 – 12 Energy level: 1 – 2 bar Pulses: 10 – 50/acupuncture point Frequency: 1 – 5 Hz Transmitter: A6
Cellulites Removal	Energy level: 2.6 – 4.2 bar Pulses/session: 2500 – 3000 Frequency: 12 Hz Transmitter: D20 Treatment: Use enough coupling gel in the area to ensure good transmission. Always move the handpiece in the direction of the lymph flow. Dosage: Use more pulses and higher energy levels for more severe stages of cellulite, but be sure that a session never is painful for the client. 8-12 treatment sessions in total, 1-2 times a week. Always let the body rest 2-3 days between treatments.
Erectile Dysfunction	Energy level: 1.5 – 2 bar Pulses/session: 2500 – 3000 Frequency: 10 Hz Transmitter: D35

Dosage: 3-6 treatments with 5-10 days interval.

Caution: Do not apply more than 200 – 500 pulses at one point of treatment.

Timeline for improvements:
1. First improvements after 3 sessions
2. Further noticeable improvements after 3 months