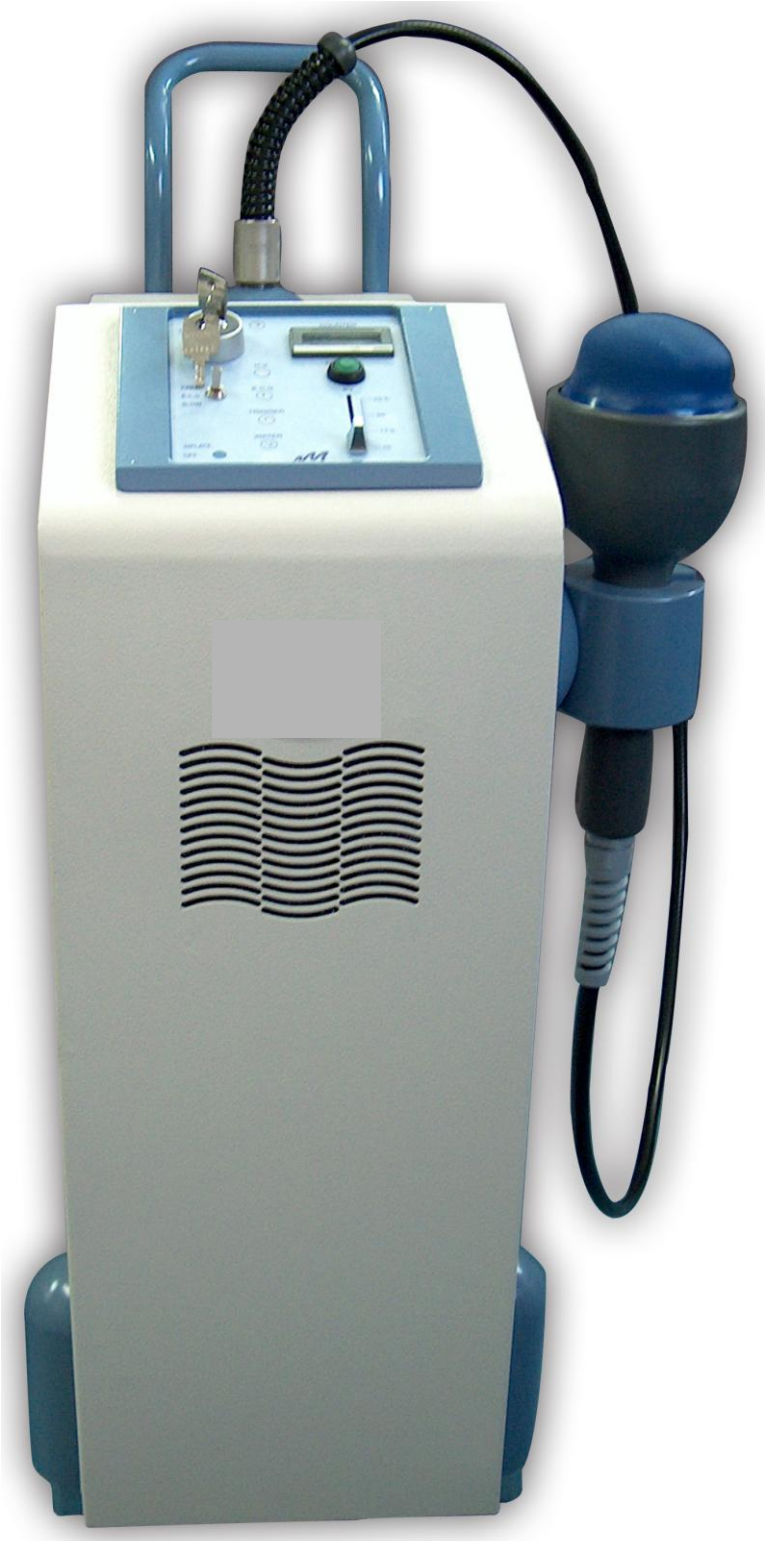
SIALOWAVE

Shockwave Therapy
For The Treatment of Sialolithiasis

OPERATING MANUAL

CE 0482
MED CERT

Fig. 1 – Sialowave™



The instruction in this manual is to be considered as recommendation only. Treatment procedures and practices must be determined and implemented by the physicians supervising the treatment.

This manual may be amended by the company without prior notice at any time.

Approved: Date _____
By _____

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1. INTRODUCTION

The **Sialowave** ™ is designed for the treatment of Parotid gland and submandibular gland sieladenitis, when the stone is too big for endoscopic removal,or located in the glands parenchyma. It serves as an antecedent treatment or a solitary treatment.

CAUTION: ***The device should be used only by qualified and trained personnel under the supervision of a physician***.

2. WARNINGS

2.1 Warnings

1. Operators of the **Sialowave** ™ should be proficient with the anatomy of the treated area, and skilled in the proper use of the device, in delivering the appropriate number of shocks in the correct intensity, to the treated area.
2. Shock wave therapy with the **Sialowave** ™ is prescribed by and performed under the supervision of a physician trained and experienced in the care of Sieladenitis.
3. CAUTION: This Product Contains Natural Rubber Latex membrane which may cause allergic reactions.
4. There is no experience with the effect of shock wave therapy on pregnant women. Therefore it is recommended to refrain from treatment in these cases.
5. The caregiver should refrain from directing the reflector to large vessels.

2.2 Precautions

1. Never remove any of the cabinet covers to the system's electronics. The high-voltage power supply circuits, utilized by extra corporeal shock wave systems use voltages that are capable of causing serious injury or death from electric shock.
2. If the device malfunctions during treatment or the treatment is discontinued, the therapeutic effects may not be as noticeable.

3. SYSTEM DESCRIPTION

3.1 Shock Wave Unit

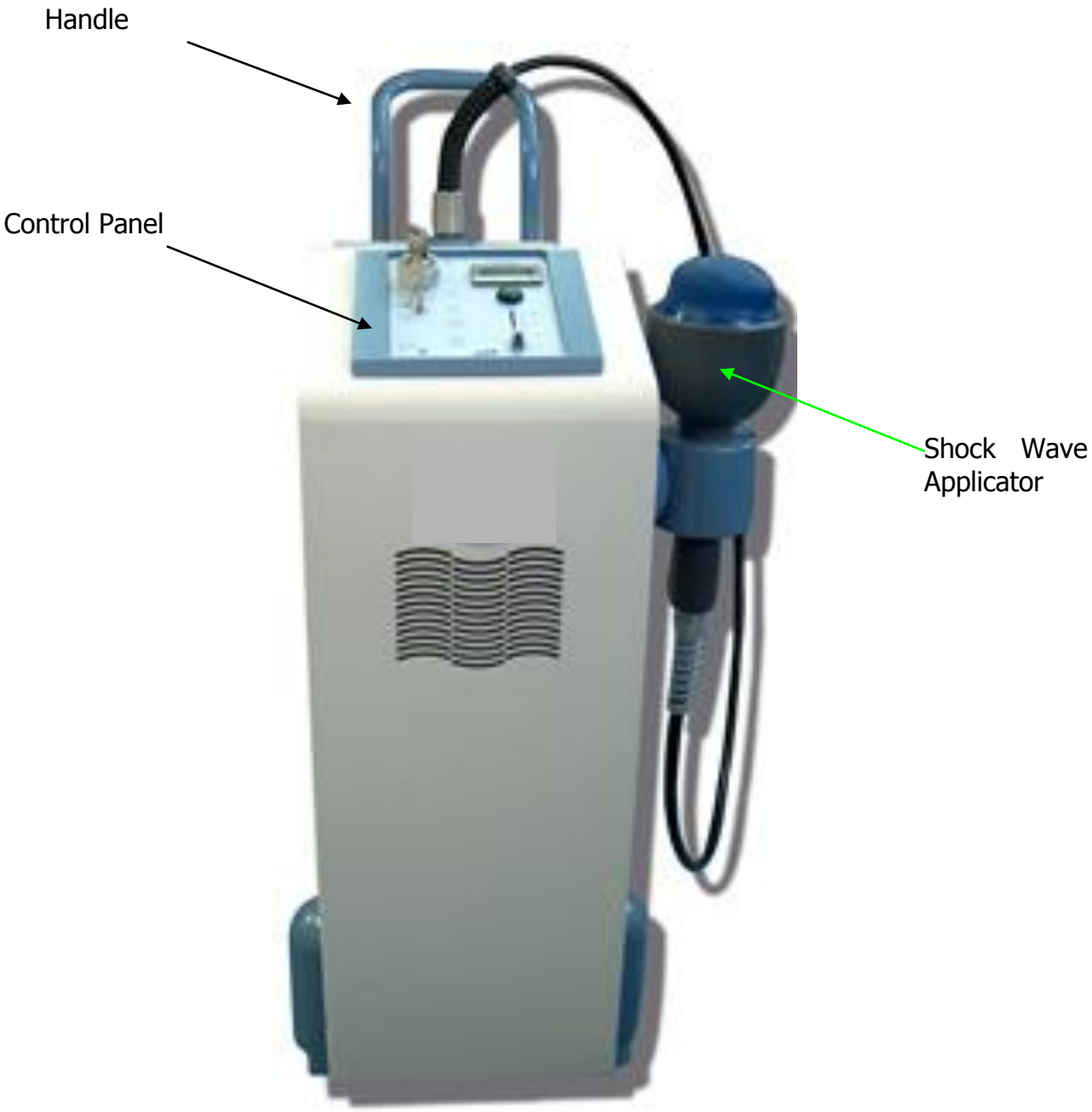
The Shock Wave Unit consists of a reflector and a dry natural rubber membrane called contact membrane filled with water, an underwater electrode and a high voltage power supply. The electrode is positioned in the stainless steel reflector.

The reflector is attached to an arm which can be moved all directions.

The shock wave is generated from the electrode by an electric spark, and transmitted to the treatment site via the membrane in contact with the patient.

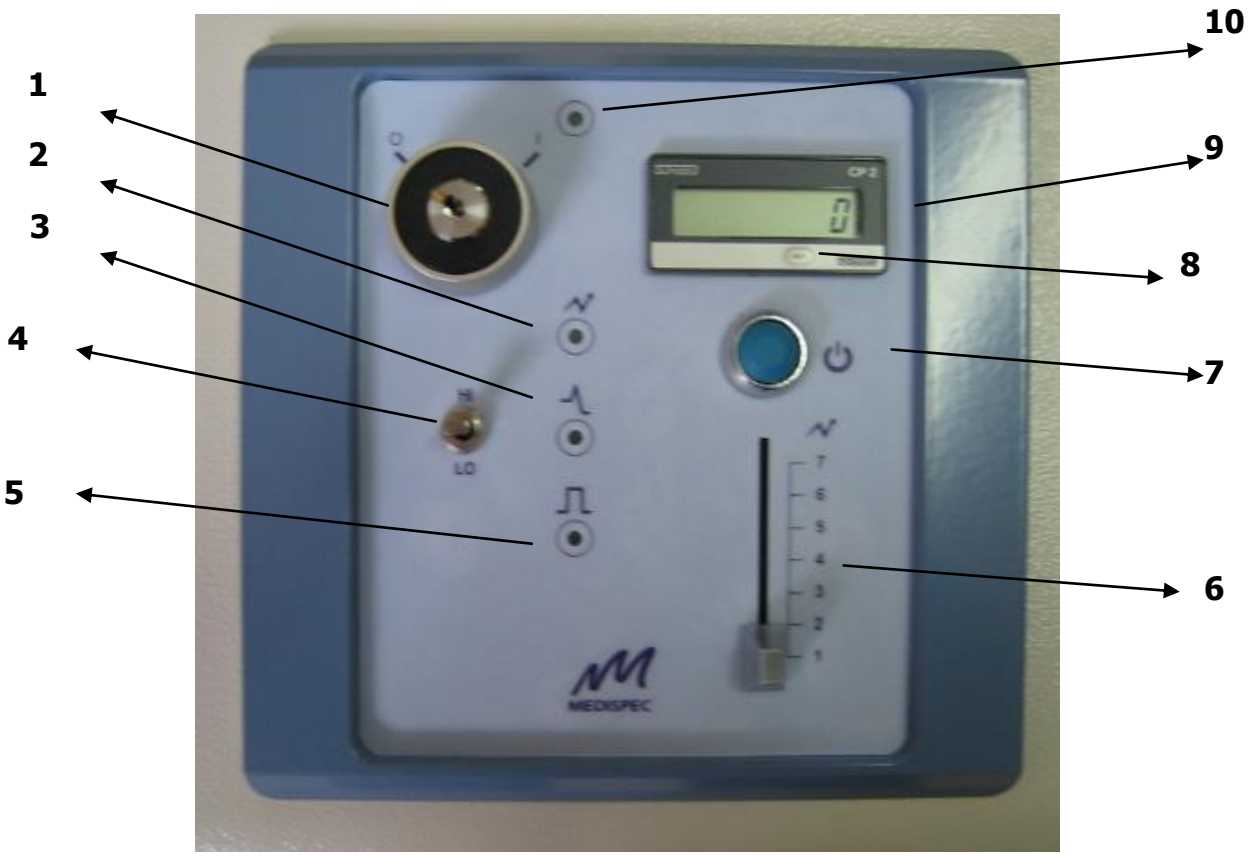
The energy of the shock wave can be adjusted between 10 to 24 Kv.

Fig.2 - System Description



3.2 Control Panel

Fig. 3 – Control Panel



1 – Main Power Key Switch
2 – High Voltage Indicator Light
3 – ECG Indicator Light
4 – Rate Selector
5 – Trigger Indicator Light
6 – High Voltage Selector
7 – Operate Switch
8 – Reset Push Button
9 – Treatment Counter
10 – Main Power Indicator Light

The control panel contains the following switches and indicators.

1. ***Main Power Key Switch*:** The power switch and KEY provide primary power to the system and prevent unauthorized use.

2. ***High Voltage Indicator Light*:** Indicator light is on when the high voltage switch is turned on.

3. ***ECG Indication Light:*** This LED will light momentarily with each pulse from the ECG input or at regular intervals when the ECG simulation switch is depressed and locked ON.

4. ***Rate Selector:***

- *Fast: Provides simulator signal at the rate of 96 PPM. When selected, its indication LED lights ON.*
- *Slow: Provides simulator signal at the rate of 60 PPM. When selected, its indication LED lights ON.*

5. ***Trigger Indicator Light:*** This LED will blink synchronically with the generation of shock waves when the system is triggered.

6. ***High Voltage Selector:*** This selector is used to increase or decrease the system's high voltage power level.

7. ***Operate Switch:*** This switch, when pressed ON, permits delivery of shock waves.

8. ***Reset Push Button:*** This push button resets to zero (0) and is used before starting the treatment.

9. ***Shock Wave Treatment Counter*:** This LED counter displays a count of the number of shock waves given to a patient during a single treatment session.

10. ***Main Power Indicator Light:*** This LED will come ON when the power key lock switch is turned ON and when primary power is available to the system.

3.3 Consumables Description

Shock Wave Applicator (SWA)

The SWA consists of a Reflector, an Electrode and the coupling membrane which filled with liquid. The Reflector Kit is a disposable part and needs to be replaced after 50,000 shocks. The number of SWA shocks can be monitored on the SWA counter.

Fig. 4 – Shock Wave Applicator **(SWA)**

4. SYSTEM SETUP AND OPERATION

4.1 preparation and Power-Up Procedure

1. Verify that the **Sialowave** ™ is placed in a clear area with access to power outlet.

2. Verify that the membrane is intact. Look for leaks or tears. If it is damaged, Replace the whole SWA.

3. Verify that the brakes of the unit are in locked position.

4. Turn the system power switch to the I position.

5. Verify Power LED is ON.

6. Reset the treatment Counter.

7. Depress and Light on the Energy Selection button.

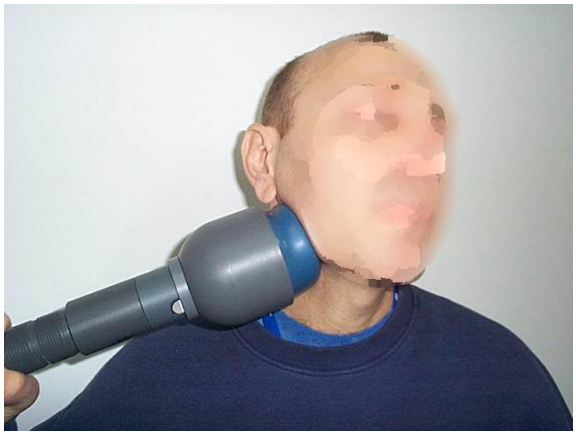
8. Adjust the Energy level to the proper treatment. It is recommended to start at energy level #1 = 10Kv and to increase progressively during the treatment according to the judgment of the operator and tolerance of the patient.

9. Adjust the treatment Frequency as follows:
   Fast: for 120ppm.
   Slow: for 96ppm.

10. Depress Energy Selection button again to disable shocks at the preparation phase.

4.2 Treatment Procedure

Fig. 5 – The Treatment



Treatments:

CAUTION: ***The wheels of the unit must be locked to prevent movement during treatment.***

1. Place the patient on a treatment chair and locate the **Sialowave** ™ by the patient.
2. Identify the plaque and mark its borders with a non washable marker.
3. A local anesthetic may be spread on the area to be treated.
4. The penis should be laid flaccid on a soft supporting surface, the area to be treated being in an accessible position.
5. Position the SWA toward the treatment zone. See Fig.5.
6. Apply the coupling solution on the membrane and the patient skin area
7. Ensure contact of patient skin with the SWA membrane.
8. Verify that treatment counter is set to zero. If the counter is not at zero, use the reset button on the counter face to set it to zero.
9. Push the OPERATION button to start generating the shock waves,

(It is recommended to begin the treatment with the lowest energy levels).

4.4 Shut-Down Procedure

1. To interrupt the treatment, depress the OPERATION button.
2. The OPERATION LED will Light Off.
3. Move the treatment chair and the patient away from the system.
4. Verify that the following LED indicators are OFF: OPERATION and ENERGY Selection.
5. Switch Off, POWER "0" position, the Main power using Switch key and remove the key.
6. Verify that all indicators are OFF with the exception of the Counters.
7. Clean the membrane with a germicidal solution per established infection control protocols.

CAUTION: ***Disinfect the membrane between patients to minimize danger of infection. Cross-contamination hazard exists.***

5. SAFETY AND PROTECTIVE MEASURES

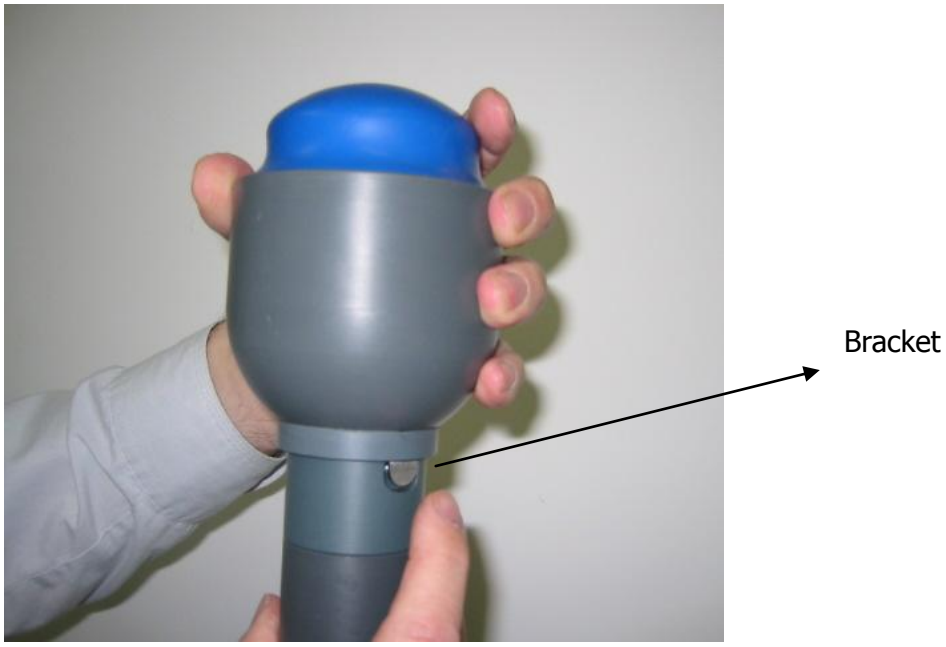
Authorization	**Sialowave** [TM] should only be used by authorized personnel under the supervision of a licensed practitioner of medicine.
Maintenance	Regular maintenance and inspection by authorized technicians is required for continuous safe operation of the Sialowave**.**
High Voltage	The power supply of the **Sialowave** [TM] [p]**provides** high voltage and will be HAZARDOUS if misapplied. The power supply panel should NEVER be opened, except by properly trained personnel.
Fire Hazard	The treatment room must be free of flammable or explosive substances such as volatile solvents, gas anesthetics, etc.
Air	Avoid applying waves to any anatomical region containing or likely to contain air, in particular, to lungs and intestines. The shock wave energy can damage soft tissue.
Coupling solution	Gel or Coupling solution should be applied to the patient's treated area to prevent presence of air between the patient and the membrane.

6. PREPARATION PROCEDURE

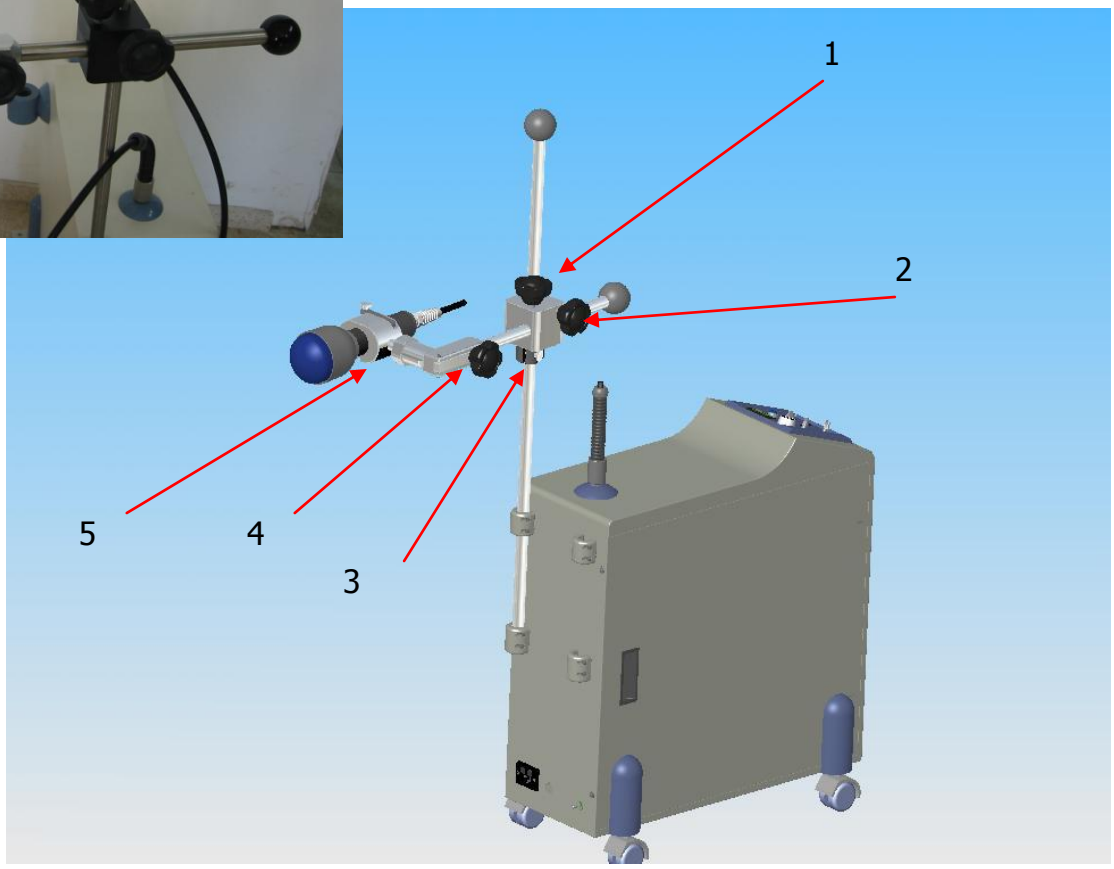
6.1 SWA Replacement Procedure

1) Switch OFF the main power and remove the key.
2) Push on the bracket and pull out the SWA (see Fig. 6).
3) Insert a new SWA .

Fig.6 - SWA Replacement



6.2 SWA Support



1 – Horizontal Motion Lock
2 – Vertical Motion Lock
3 – Up/Down Stopper
4 – Ball Motion Lock
5 – SWA Motion Stopper

APPENDIX 1
TECHNICAL SPECIFICATIONS

SHOCK WAVE CONTROL UNIT

Treatment parameters	
Focal Point Dept	15mm x 15mm x 25mm
Focus Area Dimensions at 50%	Length: 35 mm
Isobar	Width: 10mm
Energy level	10 - 24 kv
Frequency (or Pulse rate)	• 96 • 120

Dimensions:	Height: min. 1000 mm; Width: 420 mm Length: 1000 mm
Weight:	35 kg
Power Supply:	115V/230V; single phase 60/50Hz; 10/5 A

Shock Wave Applicator	
Weight:	2.5Kg
Dimensions:	Diameter: 92mm Length: 115mm
Shock Wave Source:	Electrohydraulic
Penetration Dept:	120mm
Life Span:	25,000 Shocks
Energy Flux Density:	Up to 0.3mj/mm2

Compliance with Standards:	ISO 9001/EN46001 CE 0482