

USER MANUAL

kimatur

Radial Shockwave Therapy



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1 Safety Regulations

1.1 Application Requirements

Please read the following instructions carefully:

The application of shockwave requires clinical knowledge and it should only be used by appropriately trained users. Improper handling from users may cause serious harm to the patients. Training can be offered by TUR on request.

1.2 General Information

Attention!

Before starting the device the user manual should be carefully read and the instruction should be well comprehended. The manufacturer is not liable for any direct or indirect material or personal damage due to improper use or maintenance.

Warning!

kimatur is a sophisticated medical device, which is produced under constant quality control. Proper care and maintenance is essential for safe use of medical devices. The manufacturer recommends that, upon receipt and before each use, the user should make a careful examination of the equipment and accessories for proper operation and good condition to prevent injuries to patient or to operator. During therapy and in case the patient feels uncomfortable either due to pain or to any other reason, therapy should be immediately terminated.

Warning!

The function of kimatur may be distorted by electromagnetic interference higher than 3V/m. Special attention should be paid while using devices such as mobile phones or other systems in Kimatur environment, which exceed the standard EN 60601-1-2 specified values. Also, seldom EMV- disturbances can cause a switch- of the whole system. In this rare case please restart the device setting the shock number at the remaining number.



New devices and new equipment must be cleaned before first use.

The contents of this user manual may be subject to technical changes without prior notice.

This document may only be copied and its contents may be used commercially with TUR's written agreement.

1.3 Accessories

Kimatur may only be used with accessories provided by the manufacturer. There is high safety risk when inappropriate accessories are used. Please contact your local dealer or distributor for a price list of the Kimatur accessories if one needs to be replaced.

1.4 Packaging and Disposal of the Device

Keep the original packaging of the kimatur up to its permanent disposal. You can always use the original packaging for the transport or storage of your system.

This device contains no harmful components. Please remember to comply with the applicable disposal regulations of your country when throwing away the whole system, its accessories or its packaging.

2 Application and Function

2.1 Application and Further Information

2.1.1 Technology Description

Radial Shockwave Therapy is a non-invasive procedure to be administrated to outpatients for a variety of neuromuscular pathologies. A shockwave is an intense rapid energy wave. Differing from patient to patient's sensitivity threshold to pain, the targeted region might be subject to local anaesthesia.

How are kimatur pressure waves generated?

A specially designed projectile is accelerated by means of a precisely burst of compressed air. The energy of the projectile is transferred into the tissue through an applicator installed at the handpiece. Through the applicator the energy is administrated to the region to be treated. The pressure is regulated by a pump/valve system to ensure constant delivery of the preset pressure value. There is no connection between the pressure and the energy generated by a SW device. The actual energy transfer is dependent on the material of the applicator and the technological solutions adopted during the design.



2.1.2 *Physiological Effects of RSWT*

The discovery that RSWT applications produced important responses at the infra-cellular level changed the concept on their action from pure physical/mechanical implications to profound action mechanisms in tissues. Specifically, it has been found that RSWT promotes

- Neovascularization. RSWT increase the expression of angiogenic growth factors such as the Vascular Endothelial Growth Factor / VEGF as well as the Proliferating Cell Nuclear Antigen / PCNA.
- Improvement to the micro-circulation. RSWT mechanically stimulates the intrinsic movement of the smallest terminal vessels in the micro-vascular system. This action is an elementary characteristic of micro/angiodynamics that allows the blood flow through the vascular bed to be regulated.
- Increase of the cell's membrane permeability as a result of the delivered shots.
- Bone remodelling and regeneration has been clinically proven. Investigation on the physiological mechanism is in progress and it appears to correlate the clinical benefit to the decrease of the expression of DKK1 gene. Wang et al, 2008.
- Decrease of pain sensation combined with lessen of the muscle strain. Prevailing theories suggest that shockwave therapy actions up reorganization of pathologically stored information related to chronic pain making possible lasting relief of it. SW action expands to reflex based reactive processes to pain, resulting in afferent algogenic signals to be transmitted and stored. Afferent fibres also control muscle tone associating pain and muscular tone from the view of therapeutic results.

2.1.3 *Indications*

The list of indications for shock wave treatment keeps increasing as research all over the world explores new therapeutic possibilities of the technology. Main indications are:

- Achilles tendonitis
- Calcified tendonitis
- Radial and ulnar humeral epicondylitis
- Patellar tendonitis
- Plantar fasciitis
- Chronic tendinopathy
- Anterior tibial syndrome
- Acupuncture shockwave therapy
- Myofascial trigger points
- Delayed unions



- Lateral epicondylitis (tennis elbow)
- Non-unions
- Osteonecrosis of the femoral head
- Peyronie's disease
- Rotator cuff tendonitis (shoulder pain)
- Stress fractures
- Wound healing
- Pseudoarthrosis
- Dupuyten's disease
- Cellulitis

2.1.4 *Contraindications*

- Pregnancy
- Children in growth
- Tumor diseases
- Acute inflammations
- Thrombosis, phlebitis
- Coagulation Disorders
- Use of anticoagulant
- Prolonged Cortisone therapy
- Non Cooperative patients

2.1.5 *Not Suggested (from the view of clinical results) use on/to*

- Patients with conditions that lead to poor tissue quality, such a fibromyalgia and irritable bowel syndrome.
- Organs with air filled cavities such as the lungs.
- Vertebrae, especially the cervical ones
- Open scars
- Big blood vessels such aortae
- Un-precise and non-palpable pain area.

2.1.6 Quick Therapy Guide

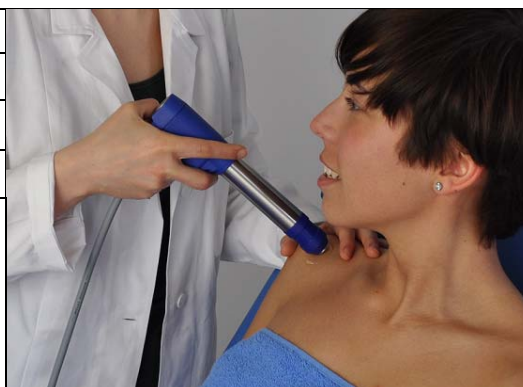
Calcified Shoulder Tendonitis

Calcific tendonitis is a condition that causes the formation of a small, usually about 1-2 centimetre size, calcium deposit within the tendons of the rotator cuff. These deposits are usually found in patients at least 30-40 years old, and have a higher incidence in diabetics.

Frequency	14Hz
Pressure	2/4 Bars
Shots	2000
Sessions/Week	2-3

Note!

Ultrasound localization of the calcification is strongly suggested. Otherwise X-ray is necessary to confirm the exact position of the calcific deposits. After delivering the 2000 shots, it is suggested to treat all the shoulder area with low pressure e.g. 0,5 bar with further 500 shots to increase the blood circulation of the area.

**Patellar Tendinopathy**

Patellar tendinopathy is a common and significant syndrome encountered in sports medicine. Referring to a clinical condition characterized by activity-related, anterior knee pain associated with focal patellar-tendon tenderness, patellar tendinopathy is believed to result from repeated loading of the knee extensor mechanism, and is thus most prevalent in sports involving some form of jumping.

Frequency	10Hz
Pressure	2Bars
Shots	2000
Sessions/Week	1

Note!

Palpation of the pain area prior to therapy is necessary. The number of shots can be increased. Start with lower pressure and increase up to 2Bars depending on patient's acceptance.



Plantar Fasciitis

Plantar fasciitis is inflammation of the thick tissue on the bottom of the foot. This tissue is called the plantar fascia. It connects the heel bone to the toes and creates the arch of the foot. Plantar fasciitis occurs when the thick band of tissue on the bottom of the foot is overstretched or overused. This can be painful and make walking more difficult.

Frequency	10Hz
Pressure	2,5Bars
Shots	2000
Sessions/Week	2/3

Increase the frequency to the last 300 shots, and scan the whole region of the plantar fascia, regardless the pain area.



Achillodynia

The pain in the Achilles tendon or its bursa. Mainly due to inflammation of the heel cord that is the extension from the triceps surae group of muscles characterised by simultaneous swelling along the tendon sheath proximal to the calcaneus.

Frequency	5Hz
Pressure	2,5Bars
Shots	2000
Sessions/Week	2/3

Treat Achilles tendon to its full length. Increased number of shots can be applied. Apply moderate pressure during therapy.



Radial Ulnar Epikondylitis

A painful and sometimes disabling inflammation of the muscle and surrounding tissues of the elbow caused by repeated stress and strain on the forearm near the lateral epicondyle of the humerus.

Frequency	10Hz
Pressure	2,0Bars
Shots	2000
Sessions/Week	3/5

Palpation of the painful area should be performed to define the treatment area.

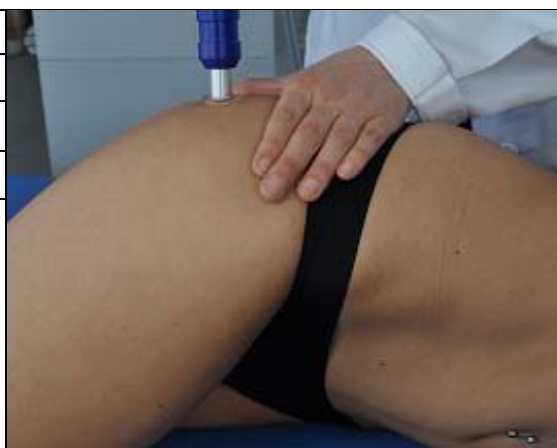


Trochanteric Bursitis

Trochanteric bursitis is characterized by painful inflammation of the bursa that is located just superficial to the greater trochanter of the femur. Patients typically complain of lateral hip pain, although the hip joint itself is not involved, because pain may radiate down the lateral aspect of the thigh.

Frequency	10Hz
Pressure	2,5Bars
Shots	2000
Sessions/Week	3/5

Apply moderate to high pressure, while treating the area. Preferably use applicator MT.



Trigger Points / Myofascial Pain Syndrome

Myofascial pain syndrome is a chronic pain disorder. In myofascial pain syndrome, pressure on sensitive points in muscles (trigger points) causes pain in seemingly unrelated parts of the body. This is called referred pain. Myofascial pain syndrome typically occurs after a muscle has been contracted repetitively. This can be caused by repetitive motions used in jobs or hobbies or by stress-related muscle tension.

Frequency	4 / 15Hz
Pressure	1,5Bars
Shots	2000
Sessions/Week	1
Do not apply pressure on the point. Each point should be treated with 1000 shots at 4Hz, and then the whole area should be treated with 15Hz.	



2.2 Function Information

Kimatur [e] is a microprocessor-controlled unit. The number of shots, the pressure and the frequency are all carefully controlled by a complex electronic structure. The system was developed using the latest technical and clinical knowledge.



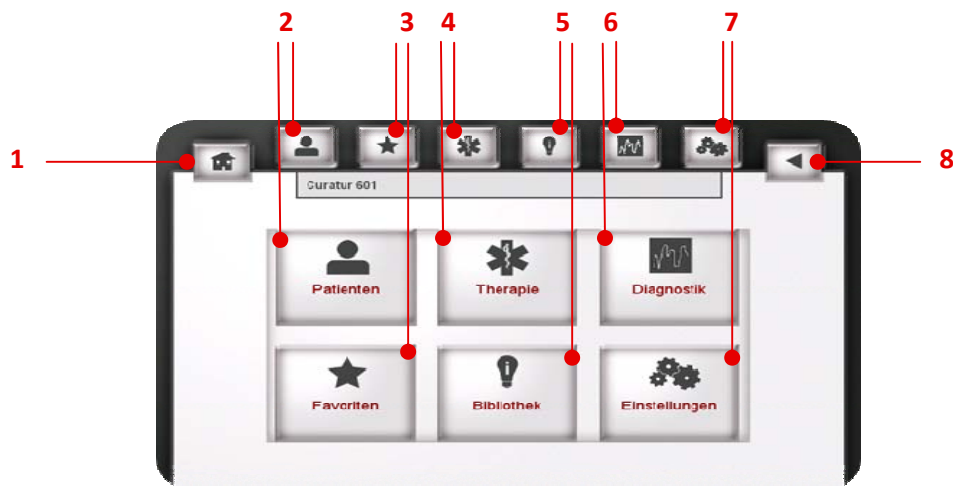
3 System Preparation

3.1 Standard Accessories

- Handpiece with hose connection
- Power Cable
- User Manual
- Contact Gel
- 1 spare set of fuses
- 1 Applicator S – metal
- 1 Applicator M – metal
- 1 Applicator MTrigger – metal
- 1 Applicator XL

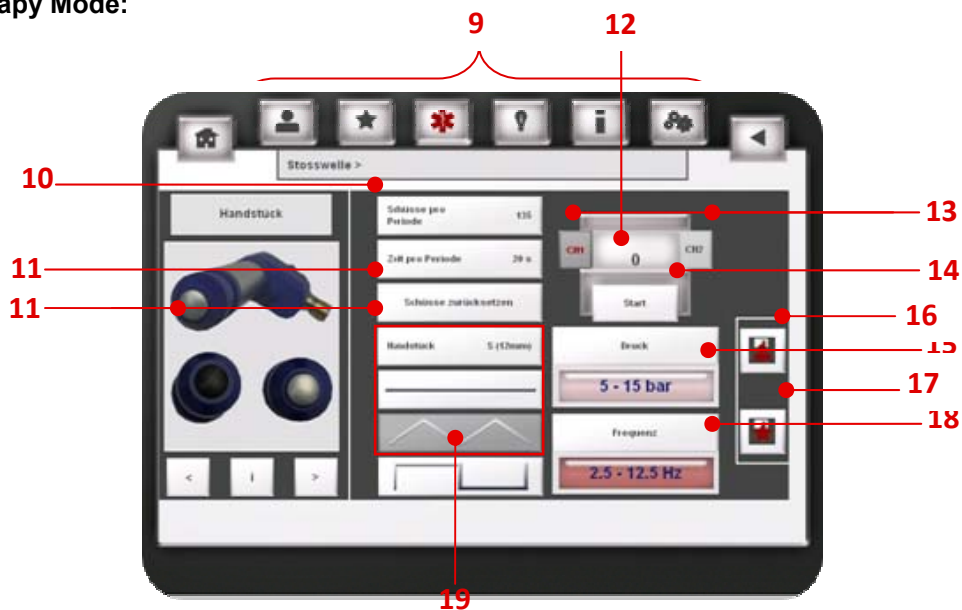
3.2 User Interface

Main Menu



Picture 1 Kimatur Main Menu

- | | |
|---|---|
| 1 | Home |
| 2 | Patient database |
| 3 | Favourites |
| 4 | Therapy |
| 5 | Indication Library |
| 6 | Device Information |
| 7 | Device Settings / Service Menu |
| 8 | Return button (visible in all submenus) |

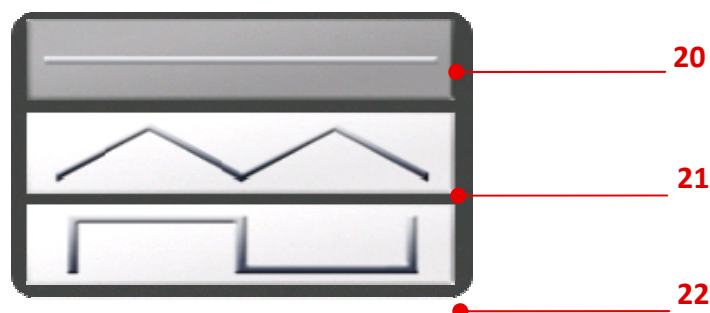
Therapy Mode:

- 10 Number of Set Shots
- 11 Clear Real Shot
- 12 Shots Count in Real Time
- 13 Channel Activated
- 14 Start and Stop Button
- 15 Pressure Setting
- 16 Save to Patient Database
- 17 Save to Favourites
- 18 Frequency Setting
- 19 Mode Selection

Modulation Selection

There are three available pressure/frequency modulations in kimatur:

- Continuous / Pressure and Frequency are steady
- Saw / Maximum and Minimum Values for Pressure and Frequency need to be selected
- Hi – Low / Maximum and Minimum Values for Pressure and Frequency need to be selected



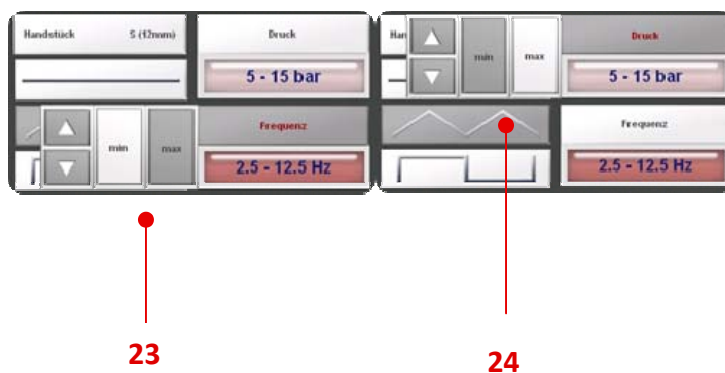
20 Continuous

21 Saw

22 Hi - Low

23 Selection of $P_{\max}$ and $P_{\min}$

24 Selection of $F_{\max}$ and $F_{\min}$



3.3 Settings Menu



25 Firmware & Software Versions

26 Device & Hand-piece Shots

3.4 Operation

Operation via the handpiece

Start:

Keep the button of the handpiece pressed for more than 3sec. The compressor starts. After 5 more sec. the handpiece starts working. The operation stops automatically when the preset number of shots is reached.

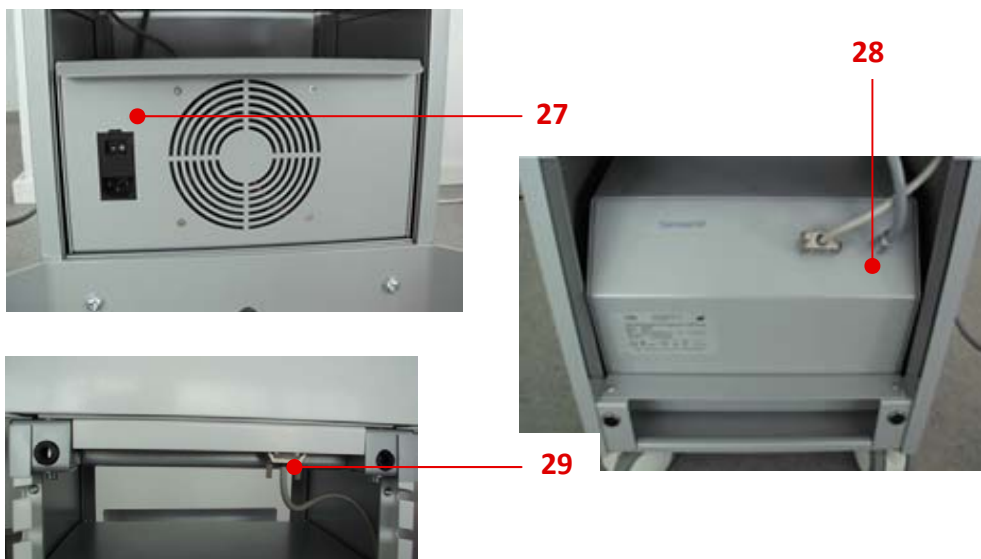
Stop:

Keep the button (19) pressed for 3 Sec. The device stops working.

Operation via touch screen

The start-stop function has no time delay.

The treatment ends for the safety of patients at each 99 999 shot bound. The number of shots may be at any time set to zero by pressing the "Clear Real Shot" (11).



27 Power socket and on/off switch with fuse holders

28 Handpiece socket

29 Data transfer cable connected to Touch Screen

3.5 Identification plate



TUR Therapietechnik GmbH
Grubenstrasse 20
18055 Rostock



Radial extracorporeal wave therapy unit
Unité de thérapie d'onde radiale extracorporelle

kimatur[e]

Item no. / article no.: 48 8600

Serial no. / no de série: xxxxxx

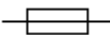
Transport and storage conditions / Les conditions de transport et de stockage

ambient temperature / température ambiante: -10 °C - +40 °C
RH: 10 % - 95 %
atmospheric pressure / pression atmosphérique: 500 hPa - 1060 hPa

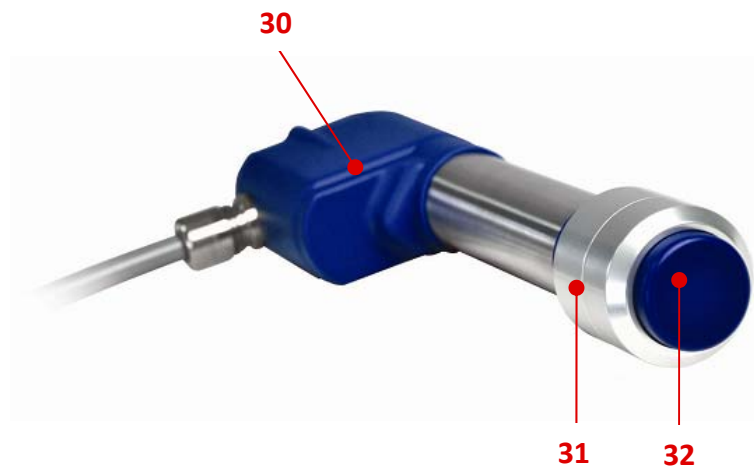


Made in Germany /
Fabriqué en Allemagne

3.6 Symbol Description

	Alternating Current
	Safety Fuses
	This product conforms with the Directives for medical products (93/42/EWG)
	Classification BF
	Accompanying documents
	Disposal in accordance to the disposal directives for electrical and electronic devices
	Production Date (year)

3.7 kimatur handpiece



- 30 Start Button
- 31 Applicator
- 32 Applicator Cap



4 Installation and Assembly and Operation Hazards

4.1 Handpiece Connection

Warning!

For safety reasons the handpiece should never been connected to the device during maintenance.

Connect the power cable to the socket (20) of kimatur and then to the power supply. The socket of the power supply has to fit to the power cable. An earth contact has to be guaranteed on the socket of the power supply has to be guaranteed. Turn on the power switch (20). After switching on the system, the compressor runs a system check. The touch screen lights up after you hear a “beep” sound and the company logo appears after 30 seconds. The device is ready for use and therapy can start.

4.2 Operation Hazards

Warning!

The device should not be used in sensitive body areas or to areas where internal organs can be affected

Warning!

Ensure that the ventilation slots on the device are not covered.

Warning!

It is important to have the system off when you change applicator.



5 Cleaning

5.1 Device

The control panel of kimatur/ [e] can be easily cleaned with a soft cloth dampened with water. If necessary, you can use a liquid, non-corrosive solvent or a scratch-free cleaning agent (eg, window cleaner or plastic cleaners).

Ensure that there is no liquid leakage in te device. Carefully dry!

5.2 Handpiece and Applicators

The handpiece can be cleaned as the device with a soft, dampened cloth. If necessary, you can use a liquid, non-corrosive solvent or a scratch-free cleaning agent (eg, window cleaner or plastic cleaner).

To clean the applicator, remove it from the applicator cup. Unscrew the cup and dismantle the applicator and carefully clean separately. Intended use should only be applied to intact healthy skin. Disinfection has to be performed in accordance to the national regulations for cleaning components that come in contact with healthy skin. In most cases cleaning with mild alcohol containing detergent is required.

Ensure that there is no liquid leakage in te device. Carefully dry!

- Handle the applicator cautiously. Rough Handling can affect its operation.
- Do not bring the applicator in contact with sharp or pointed objects.



6 Maintenance

6.1 General

Before any maintenance action the device should be disconnected from the main

The unit and the handpiece should not be opened for any reason by an unauthorized person. All maintenance and repair work must be performed only by TUR Therapietechnik GmbH or authorized representatives.

To ensure both patient and user safety, it is necessary to follow certain maintenance procedures. They are also necessary to maintain the safety and functional features of the system

6.2 Safety checks

(1) The operator of medical devices, for which the manufacturer has requested regular safety checks, must perform as specified by the manufacturer and the generally recognized rules of technology and in the time periods specified by the manufacturer

The operator has to perform the safety checks in accordance with generally accepted engineering standards and on the basis of the experience must be carried out that possible defects can be detected well ahead

The safety check should not be carried out later than every two years to The safety controls include the measurement functions.

(2) The operator must follow authorities that specify shorter periods than mentioned in paragraph 1.

(3) A record that contains the date of execution and the results of the safety inspection, indicating the measured values, the methods of measurement and other assessment results must be created. The protocol has to keep by the operator at least until the next safety inspection.

(4) A safety inspection may be carried out only by persons

1. who have a record of sufficient training, skills and practical work experience to be responsible for the proper implementation of safety controls
2. who is not subject to external influence or conflict of other interests
3. has access to appropriate measuring and testing equipment

(5) The operator shall appoint only persons who fulfill condition stated in § 4 (1-3).

6.3 Maintenance

The maintenance should be performed by authorised personal only. Maintenance Instructions can be found in the Service Manual Section 4. Please contact your local TUR distributor for the service. The service should be performed according the operation interval schedule underneath:

Item	Maintenance Reason	Interval	Action	Performed from:
O-Rings	Wear	250.000 Shots	Replacement	Service Staff / Local Representative
Applicator	Wear	1.500.000 Shots	Replacement	Service Staff / Local Representative
Tube and Projectile	Wear	750.000 Shots	Replacement	Service Staff / Local Representative
Main Unit	Control Unit	24 Months unless local regulation recommend shorter intervals	Safety check	By authorized staff

TUR provides (on request) to service companies (which are authorized by TUR) the service manual and related drawings.

To be sure that your device works properly always follow the manufacturer's instructions when you change the O-rings or the applicators.

The manufacturer may be considered liable for the safety and reliability of the kimatur only if:

- the unit is connected to a regular outlet with earthing contact (note VDE 0107),
- the device is used in accordance to the instructions
- Extensions, readjustments or modifications are performed only by authorized persons.



7 Trouble Shooting

System does not turn on

- Inspect Power Cable for apparent wear
- Check fuses and replace if necessary
 - To change the fuses you do not need to open the device.
 - Disconnect the main supply cable
 - The fuses can be found next to the main switch (20).
 - To open the fuse holder use a flat screw driver and carefully put it in the slot of the fuse holder. Open it by applying minimum force.
 - Pull the fuse holder out.
 - Replace both fuses with identical ones. Put the fuse holder back and push to lock it.
(1 set of fuses is included in your device)
- Contact the manufacturer

The display does not turn on

- Turn off the device. Check if the power cable is properly connected to the mains and to the device.
- Run a system check. Turn off the system and check the condition of the data transmission cable.
- Contact the manufacturer.

The performance of the handpiece has deteriorated

- Change Applicator
- Change the projectile acceleration tube
- Check the connection hose (27) for distortion, narrowing, or other apparent damages.
- Contact the manufacturer.

The unit does not turn off

Unplug the power cord from the unit and wait 30 seconds. Then connect the unit to the power supply and test it again.

If the device does not work properly after implementing the aforementioned actions, please contact the manufacturer.



8 End of life time, Scrapping

Unlimited as long as both the maintenance requirements and replacement of parts that are mentioned in the Chapter are fulfilled. Check you national regulation for discarding electronic devices.

9 Technical Data

Operating Conditions	
Ambient temperature	+ 10 °C to + 40 °C
Relative humidity	30 % to 75 %
Atmospheric pressure	700 hPa to 1060 hPa
Position	Vertical
Maintenance	On a predefined number of shots
Transport and Storage Conditions	
Ambient temperature	- 10 °C to + 55 °C
Relative humidity	25 % to 85 %
Atmospheric pressure	650 hPa to 1100 hPa
Additional conditions	transport only in the original packaging
Power supply	
Main Unit max Input	420VA
Mains voltage	220...240 V ~
Frequency	50Hz
External exchangeable fuse	2A
Power switch according to IEC 601 - 1	YES
Design	
Complete unit dimensions (w x h x d)	500 x 1027 x 460 mm
Main unit dimensions (w x h x d)	290 x 220 x 365 mm
Dimensions - Screen (w x h x d)	400 x 355 x 40 mm
IP code	according to EN 60 529 IP 20
Display unit	
Display units	Graphic colour touch screen diag. 12.1" / 30.7 cm, resolution 600x800 pixels
Classification	
Applied part	type BF
Class according to MDD 93/42/EEC	Ila
Adjustable Values	
Shock intensity	max. 5 Bar (maximum instantaneous value)
Shock frequency	max. 22 Hz
Therapy period	0 – 9999 shocks