User's manual of the

shock-wave therapy device

StarDevice®

UA.TR.099

Version 1EN

Scientific company
KOLIBRI LLC
Prov. Kinnyi 8a. Kharkiv,
61001, Ukraine
Tel.: +380913011110
email: info@kolibri.one
URL: https://kolibri.cloud

EC REP **The official representative in the EU:**
"ONKOCET Ltd."
4 Kutuzova str., 90201 Pezinok, Slovakia,
tel.: +421 (2) 44 64 09 77
Email: onkocet@onkocet.eu
URL: www.onkocet.eu

CONTENTS OF THE USER'S MANUAL

SYMBOLS AND CONVENTIONAL SIGNS:

	Warning		Prohibition
	Obligatory action		Character pattern of obligatory actions
	Be sure to read the instruction	IP20	Degree of protection of the device against penetration of solid objects
	Protective ground		Working part of type BF
ON	To turn the power on	100-240VAC	Supply voltage of the device
OFF	To turn the power off	T4AL250V	A fuse
FR+	To increase frequency	F+	To increase force
FR-	To decrease frequency	F-	To decrease force
	Manufacturer	OK	Enter a value
	Date of manufacture	SN	Serial number of the device
	It is disposed as used electronic equipment		

1 GENERAL REVIEW

1.1 PURPOSE OF THE DEVICE

The shock-wave therapy the device STARDEVICE® (hereinafter - the device) is intended for the treatment of the musculoskeletal system, rehabilitation of back and head injuries, including those complicated by partial or complete paralysis. Also, the device can be used for other types of therapy, which require forced stimulation of blood circulation in tissues.

The manipulator of the device generates mechanical shocks of a given frequency and force. A doctor with the manipulator makes a mechanical (percussive) effect on ligaments, muscles or vertebral segments of a patient.

The shock-wave therapy is recommended for patients from 23 years and older, according to the recommendation of the Vertebrology and Rehabilitation Institute (Kiev, Ukraine).

1.2 INDICATORS FOR USE

The device can be used in various areas of therapy: orthopaedics, neurology, rheumatology, cosmetology (getting rid of cellulite) and many others. The usage of the device, in those or other cases, is limited only by the knowledge of the specialist. Main diseases and injuries in which the use of the device STARDEVICE® is recommended:

- Pain in the shoulder girdle with calcification or without calcification;
- Pain in knee joints;
- Pain syndrome with ankle sprain or muscle strain after physical exertion;
- Achillodynia;
- The acetabular bursitis / friction syndrome or the otibial tract («a knee of a runner»)
- Lateral and medial epicondylitis («An elbow of a tennis player», «A golfer's hand»);
- Tendonitis in various areas;
- Treatment of trigger zones in deep muscles;
- Treatment of trigger zones in the superficial muscles and myofascial trigger zones (Myofascial syndrome);
- Chronic back pain (a cervical / a lumbar spine);
- Deforming osteoarthritis (arthrosis) of large joints;
- Osteochondrosis of different parts of a spine;
- Intervertebral hernia;
- Myofascial syndrome;
- Heel spurs (plantar fasciitis), flat feet;
- Sport injuries of the bone-ligament-articular union (during rehabilitation);
- Shoulder-scapular peri arthropathy;

- Rehabilitation after injuries of the spinal cord and the brain, accompanied by paresis and paralysis;
- Rehabilitation during fractures (in the case of slow fusion of bones);
- Rehabilitation after an end oprosthetics operation of a joint (with persistent pain);
- Synovitis of various joints (not infectious);
- Trochanteritis;
- Osgood–Schlatter disease
- Osteochondrosis of the tubercle of the tibia;
- Syndrome of a chronic pelvic pain / prostatitis;
- Peyronie's disease;
- Trigger zones of the muscles of the pelvic floor;
- Vascular erectile dysfunction;

1.3 CONTRAINDICATIONS

Proper examination and diagnosis must be performed, before starting treatment with shock waves. Please keep up to date with the latest developments and medical publications on shock-wave therapy for detailed information on contraindications and side effects not known at the time of the device's manufacture. Contraindications listed in this section are given at the time of writing of the Instruction. No claims regarding the completeness or unlimited duration of this list of contraindications are accepted. Before carrying out the procedures, a medical specialist should be convinced of the expediency of using this procedure, the responsibility for which he bears personally.

The use of the device is contraindicated in the following cases:

• Violation of blood clotting (hemophilia, hemorrhage, risk of bleeding, etc.);

• Deep vein thrombosis, phlebitis, varicose veins;

• The use of anticoagulants, especially marcoumar;

• Severe arterial obstruction (grade III and IV);

• Peripheral vascular disease, circulatory insufficiency;

• The presence of bleeding, open wounds, ulcers and (or) damage of the skin;

• Occlusive vascular diseases, such as obliterating arteriosclerosis and obliterating thrombangiitis (Buerger disease), in which organic occlusion and ischemia are evident;

• In case of acute inflammation: it is prohibited to use the device on tissues that have swelling, inflammation and traces of infection, skin rashes or other acute tissue lesions;

• In case of systemic or local infection is present (sepsis, osteomyelitis, tuberculosis) or if a patient has a fever;

• For patients with malignant tumours, undiagnosed tumours and neoplasms;

• Pregnancy;

• With severe somatic pathology;

• Areas of epiphyseal growth zone closure of children;

• For patients who have been treated with hormones - up to 6 weeks before the first procedure;

• Over pacemakers and defibrillators, cochlear implants;

• In the presence of stimulators of bone growth and neurostimulants (brain, spinal cord and other stimulants of nerves);

• In the area where the implants are installed / were installed, above the surface endoprosthesis and the metal implants;

• Above the open plate (after laminectomy, splitting of the spine);

• In the eye area;

• In the field of reproductive organs;

• Directly above the carotid artery, the stellate ganglion or a vagus nerve, located in the triangle on the front of the neck;

1.4 SIDE EFFECTS

The use of the device can cause the following side effects:

• Swelling, redness, bruises;

• Spot haemorrhages;

• Pain;

• Skin infection after previous cortisone therapy.

These side effects usually depart after 5-10 days.

After a course of shock-wave therapy, the pain syndrome can be increased, the chronic process exacerbated, which depends solely on the strength and intensity of the exposure and the individual susceptibility of patients.

2 WARNINGS AND SAFETY INSTRUCTIONS

2.1 SAFETY SINGS ON THE DEVICE

The manipulator is protected by reinforced insulation and has no galvanic connection to the ground.

IP20 – A degree of protection against penetration of solid objects.

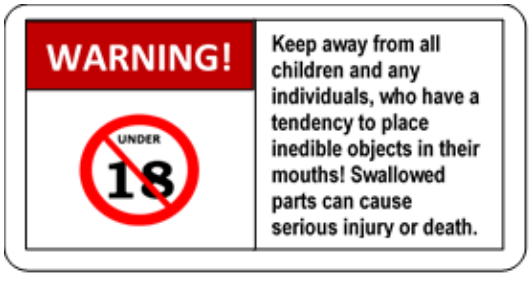
2.2 WARNINGS AND SAFETY INSTRUCTIONS

The user must have the proper technical and medical qualifications and know the user's manual of this device in order to use this device. All maintenance procedures recommended by the manufacturer must be performed by personnel with appropriate approvals.

It is allowed to use the device in medical centres, in rehabilitation and sports medicine centres, SPA centres, massage rooms for adult patients (23 years and older).

The operator must inspect the housing of the electronic unit, the manipulator and the tips, as well as the power cord and the manipulator cable before using the device, to ensure there is no external damage. Operation of the device with a damaged housing of the electronic unit or a manipulator, a damaged manipulator cable or a power cord is prohibited!

This device complies with the requirements of the electrical safety standard EN 60601-1: 2010.
It is necessary to connect the device to the mains supply in accordance with the national electrical safety regulations.



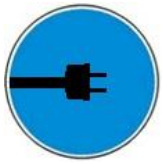
The device must be placed beyond the reach of a patient, especially children, as the device has small working tips, moving parts and removable parts that can cause injury (small elements can be swallowed).

Certified and safe materials are used for the device. Potentially, a patient's allergic reaction to parts that come in contact with the skin surface during the treatment procedure is possible.

ATTENTION! Modification of the product is not allowed!

CAUTION! To avoid the risk of electric shock, the product must only be connected to a mains supply that has a protective ground.

Disconnect the device from the power supply, before performing any cleaning or maintenance work. The means of simultaneous electrical separation of the supply circuits of the device from the circuits of the supply network is the mains switch of the device.



Connect the device only to a working socket with a rated voltage within the range 100 - 240V 50-60Hz. The location of the device should ensure that there is no tension on the power cord and the manipulator cable, unhindered connection and disconnection of the power cord from the mains to quick disconnection of the device from the mains in emergency situations.

Do not allow humidity to enter the electronics housing and the manipulator. Do not expose the device to dampness, vibration, or shock.

It is prohibited to use the device in a potentially explosive atmosphere, i.e. in the presence of a mixture of flammable anaesthetic gas with air, oxygen or nitrogen oxide.
It is prohibited to use the device in rooms where flammable and potentially explosive substances are stored or used.

There is a risk of transmission of germs! Disinfect the tips before and after each use!

It is forbidden to impulse organs containing gas, in particular, lungs.

Therapy with shock waves can make an undesirable effect on a heart. It is necessary to continuously monitor a patient's condition during the procedure. The patient is allowed to act no more than 3000 shocks per a treatment session.

Only procedures recommended in this manual are allowed! The user must correctly position the tip and correctly select a place of exposure according to the user's manual.

2.3 MEASURES TO PREVENT DAMAGE OF EQUIPMENT AND THE DEVICE

Connect the device to the mains through a circuit breaker with the characteristic "C" and a rated current of not more than 6A.

The placement of the device must ensure uninterrupted connection and disconnection of the power cord from the mains. Do not allow the situation where the manipulator cable or power cord is under the feet of a user or patient! Do not squeeze, stretch, attack, etc. mechanical stress on the manipulator cable and power cable!

There are ventilation slots in the walls of the electronic unit that can't be closed by other objects. Do not cover the device during operation.

It is forbidden to disconnect the manipulator from the electronic unit of the device during operation and when the power is on. Hold the manipulator either in hand or in the holder. Do not allow the manipulator to be on the floor!

This device complies with the requirements of the EMC standard (IEC 60601-1: 2005-12 3rd ed.). As a rule, the level of emitted electromagnetic interference is not sufficient to disrupt an operation of the most devices. However, it should exclude an operation of the device in close proximity to sensitive equipment. It is recommended to place the device no closer than 1m to such equipment.

The tips for the device must be stored in a place protected from direct sunlight's.

It is necessary to exclude contact of the tips with various solvents, gasoline, kerosene and other substances that destroy rubber and polyurethane.

It is forbidden to install the device on slippery surfaces to prevent the device from falling.

3 A BRIEF DESCRIPTION OF THE DEVICE STARDEVICE®

The device STARDEVICE® is intended for the treatment of the musculoskeletal system, rehabilitation of back and head injuries, including complicated partial or complete paralysis. Also, the device STARDEVICE® can be used in other types of therapy, that require forced stimulation of blood circulation in tissues.

The device STARDEVICE® consists of the electronic unit and the manipulator, that is the working part of the device. Mechanical pulses of a specified frequency and force are generated by the manipulator. A

doctor with the help of the manipulator makes a mechanical (percussive) effect on ligaments, muscles or vertebral segments of a patient. The frequency of shocks is set in the range from 4 to 12 beats / sec., in increments of 0.1 beats / sec. Force / intensity of shocks can be varied within the limits of 4.54 kg / cm2 - 15.87 kg / cm2 in 2.2 kg / cm2 increments, which corresponds to a scale from 10 to 35 points. There are appropriate tips in the set of the device to influence different areas or organs of a body.

4 BEFORE USING THE DEVICE STARDEVICE®

4.1 THE LIST OF PREPARATORY ACTIONS

Before using the device STARDEVICE®, you should:

• To make sure that the power supply network is used with a protective ground; that the voltage in the network is in the range 100 - 240V, 50 - 60 Hz. The device STARDEVICE® is intended for connection to type F (Schuko) sockets (European socket with CEE 7/4 grounding, DIN 49440 standard). Suitable adapter is required to connect to other types of sockets; in any case, the presence of a protective ground in the power socket is mandatory!
• To ensure the presence and storage of 70 - 96% hydroalcoholic solution to clean the tips;
• To ensure the presence and storage of medical alcohol wipes or cotton discs for cleaning the tips.
• To ensure the presence and storage of wet wipes for a screen that do not contain alcohol to clean the display of the device STARDEVICE®!
• To organize the workplace of the operator so that the device is placed on a solid, smooth, dry and not slippery surface, and to comply with the measures listed in the paragraph 2.3.
• Remove the device from its packaging. Check if there is no damage to the electronics housing, the manipulator, the power cord and the manipulator cable. Switch the main switch to the "Off" position.
• Connect the manipulator cable to the corresponding connector on a back panel of the electronic unit.
• Connect the power cord to the power connector on a back panel of the electronic unit, plug the power cord into a power socket.

4.2 THE OPERATOR'S QUALIFICATION

The device STARDEVICE® is intended for use by the operators having special knowledge in the field of application of this device and the operators who has been trained how to use properly the device, as well as the operators who has practical skills in working with similar medical procedures. The operator must have basic physical and cognitive prerequisites, such as sight, hearing and literacy.

Besides, the operator must take into account the manufacturer's recommendations (**Chapter 1, item 1.2** "Indications for use" and item **1.3 "Contraindications"**) to be aware of the latest developments and medical publications on shock-wave therapy for detailed information on contraindications and side effects, not known at the time of manufacture.

It is forbidden to use the device STARDEVICE® for operators with disabilities (disabled people), whose physical or mental deficiencies do not allow to actually monitor and perform a treatment procedure.
The operator must pass the appropriate training regarding the correct operation of the device before working with the device STARDEVICE®:

• Targeted use of the device with practical exercises;
• The mechanism of action and function of the device;
• Settings of all components;
• Indications for use of the device;
• Contraindications and side effects of the shock-wave therapy;
• An explanation of safety signs in all modes of operation;
• Method of functional verification of the device.

Further recommendations for training may vary depending on the country. Please contact your local representative of SC KOLIBRI LLC for more information on training the operation of this device.

5 AN OPERATING PROCEDURE OF THE DEVICE STARDEVICE®

The user is obliged to be healthy and vigorous (rested) during the use of the device because a patient's health and even his life is highly dependent on the user during the procedures, before the application the user must not take psychotropic substances, analgesics, opiates, sleeping pills, drugs or alcohol for at least 48 hours, half of which is wakefulness.

5.1 THE PATIENT'S LOCATION

Before you start you need to place a patient correctly:
The patient must be located in a C-shaped position, during treating a spine and upper extremities for stretching vertebral joints and general relaxation. This posture is the most effective for the shock-wave therapy of a spine.
The lower extremity therapy is performed lying on a couch, except for special procedures.

5.2 THE OPERATOR'S POSITION WHEN PERFORMING THERAPY ON A SPINE

The operator must be at the back of the patient. If the operator is working with his right hand, then his left foot should be pointed forward towards the support of the patient's head, and the right leg is directed perpendicular to the left (the so-called L-pillar). If the doctor works with his left hand - the location should be mirrored.

5.3 TIPS

It is necessary to use certain tips to treat different areas and segments. The tips are inserted into the manipulator with pushing the rod of the tips into the hole of the manipulator. Before use and after use, wipe the tip with a water-alcohol solution.
The surface of the patient's skin should be dry and clean to avoid slipping of the tips.

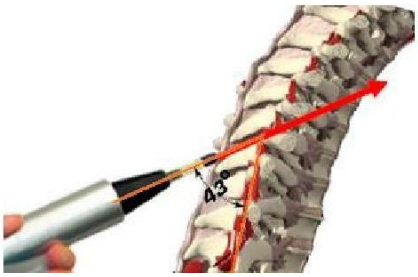
Used tips and their recommended usage:

TIP #1	TIP #2	TIP #3
It is used to correct all the segments of the spine.	A small nozzle is used to correct all the segments of the spine	It is used only for certain protocols.
TIP #4	**TIP #5**	**TIP #6**
A pediatric tip is used to correct all the segments of the spine.	A tip with a bulging head. It is used for therapy of trigger points and acupuncture massage.	They are used for correction and treatment of small joints and muscles
TIP #7	**TIP #8**	**TIP #9**

They are used for medium to large joints and muscle correction and treatment	They are used for correction and treatment of medium and large joints, and muscles.	They are used for correction and treatment of large joints, and muscles.

5.4 HOW TO HOLD THE MANIPULATOR

Hold the manipulator in either hand or in the holder. Do not allow the manipulator to be on the floor!



An angle of application

The manipulator must be applied at an angle of 43 ° to the spine during the correction of the vertebral segments - this angle excludes the load and injury of the facet joint. In all other cases, the angle of application is chosen by the doctor at his own discretion, based on the tasks assigned.

Stabilization of the tip

It is also necessary to stabilize the tip to prevent it from slipping and to prevent the stretching of the tissues during the correction procedure in addition to observing the angle of inclination.

Stabilization is performed by using three fingers of the left hand (if the doctor works with his right hand):

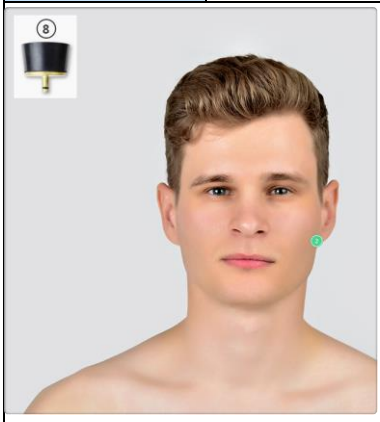
1. The index finger should be placed on the spinous process of the vertebra.
2. To put the middle and thumb on the top of the tip in the place where the rubber caps are attached to the metal part of the tip. Do not press down the metal part of the correction tip. Do not put your fingers in front of the tip or on the upper tips of the rubber caps of the tip.

The angle of the manipulator application is 90 ° when correcting other anatomical areas.

5.5 RECOMMENDED TREATMENT PROTOCOLS

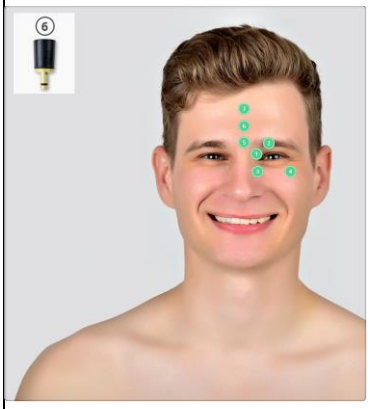
The protocols for the treatment of certain diseases include a brief information of recommended treatment algorithm: the choice of a tip force and frequency of shocks, the position of the patient.

Temporomandibular joint			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
10	12	90° to the surface	25
Tip:	(Tip No.8) a large rubber protocol tip		
Note	** Treatment without preload. How to level the preload: Take the head in the hand, move the moving part of the tip with the thumb and index finger. So you can remove a threekilogram load before percussion.*		



Test a patient with a 75% opened mouth, the side with the changes being the side of the correction. The place of contact is the entire mandibular joint. IMPORTANT: Instruct the patient NOT TO CLOSE his mouth and clench his teeth. The patient quickly opens and covers his mouth so that only 50% of the movement of the joint is involved (25% -75%) in the process of correction. Repeat the previous steps, check the movement of the lower jaw joint. Do not make more than three sessions per visit. Repeat the protocol three times a week for one to three weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Sinus			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
10	12	90° to the surface	10-15
Tip:	(Tip No.6) a small rubber protocol tip		
Note	** Treatment without preload. How to level the preload: Take the head in the hand, move the moving part of the tip with the thumb and index finger. So you can remove a threekilogram load before percussion.*		

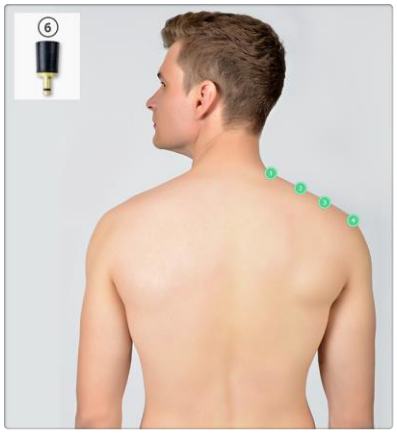


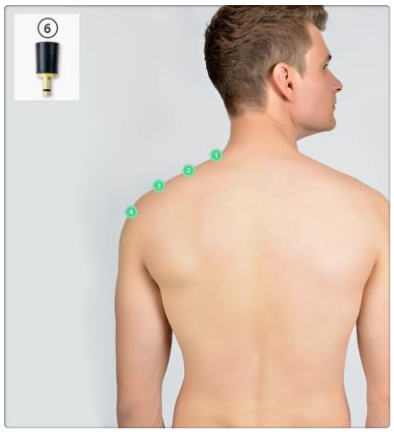
Point 1: frontal process. Point 2: supraorbital fossa. Point 3: nasal bone, anterior edge of the orbital plate. Point 4: the middle of the malar bone. Point 5: glabella. Point 6: 12mm above the glabella. Point 7: 25mm above the glabella. Percuss the points mentioned above and then repeat the procedure again. Perform as necessary for 1-4 weeks.

Cervical ROM

Force	Frequency	Load line	The number of shocks per point:
20-25	12	90° to the surface	50
Tip:	(Tip No.6) a small rubber protocol tip		
Note:	** The number of shocks per point depends on the patient's tolerance.* *Test the range of motion of the cervical region.*		

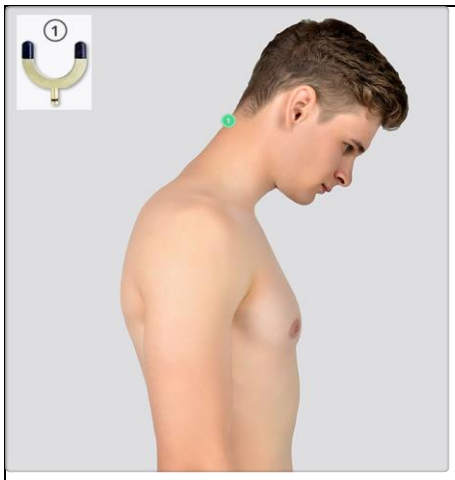
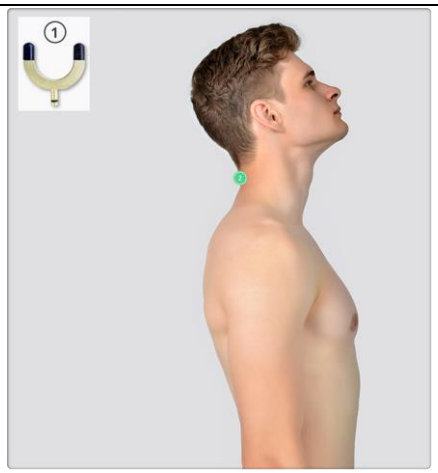
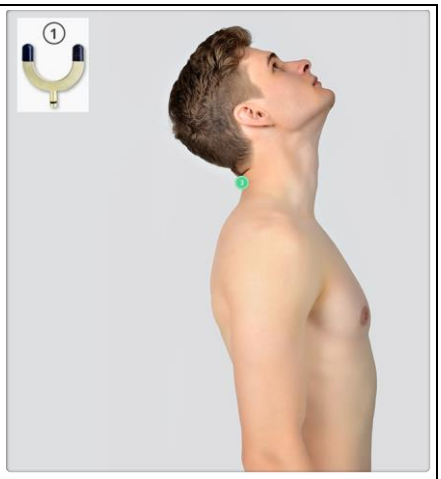
Point 1: middle-upper part of the trapezius muscle. Percussion while the patient turns his head in the opposite direction. Direct the movement with your free hand. Point 2: 13 mm lateral to point 1 on the trapezius muscle, the patient repeats the active rotation of the head with maximum force. Point 3: 26 mm lateral to point 1, the patient repeats the active turn of the head. Point 4: 26 mm lateral to point 3, the patient repeats the active turn of the head with maximum effort. Repeat the procedure on the other side. Test the range of movement of the neck in both directions, pay attention to the improvement. Repeat the protocol three times a week for one to three weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times on a day of treatment.





Cervical Extension			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20-25	12	varied angle	25
Tip:	(Tip No.1) a middle rubber protocol tip		
Note	Test the range of motion of the cervical region.		

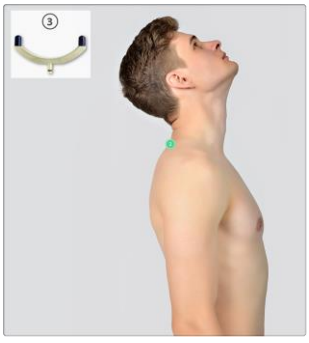
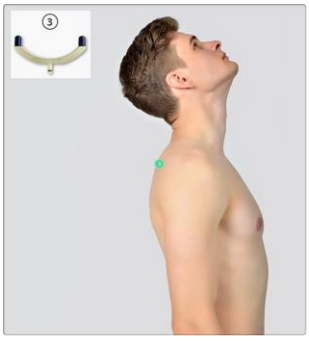
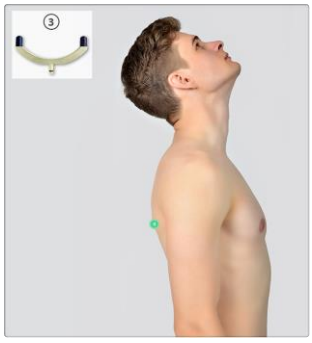
Begin with the head down, attach the tip to the middle of the neck (point 1) and percussion while the patient raises his head and throws it back. Follow the curve of the neck throughout the movement during the procedure. Repeat the procedure at points 2 and 3. Require the greatest effort from the patient for maximum results. Give the patient a short rest and repeat the whole process again at points 1, 2 and 3. Repeat the protocol three times a week for one to two weeks. Instruct the patient to apply ice for 20 minutes at home, then to remove the ice for 40 minutes. Repeat the procedure three times on a day of treatment.

treatment.

Bridge			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
25	12	90° to the spine	100 depend's on the patient's tolerance
Tip:	(Tip No.3) a tip long horn		
Note			

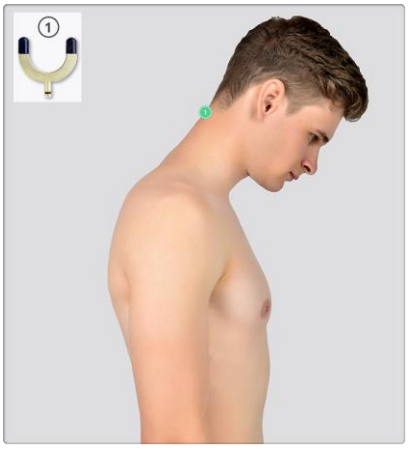
Put your fingers on the patient's forehead so that he reclines his head back as much as possible. Do not apply force to the reclined head. Start with a neutral position. Once the patient's head began to retreat back, you should percuss paravertebral muscles at the level of T1 (point 1), let the patient recline maximum his head back. Return his head to the neutral position. Repeat the procedure at the level of T2 and T3 (points 2 and 3), each time returning the patient to a neutral position. Finally, place the tip on the very back of the thoracic region (point 4). Instruct the patient to stick out his chest, while maximally to throw back his head and to bend back. Percuss point 4 to maximize proprioceptive changes, then return the patient to a neutral position. Repeat the protocol three times a week for one to four weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times on a day of treatment.

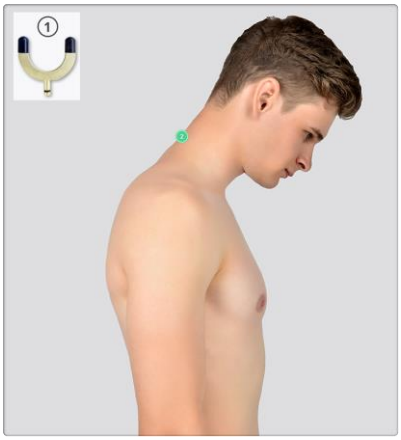





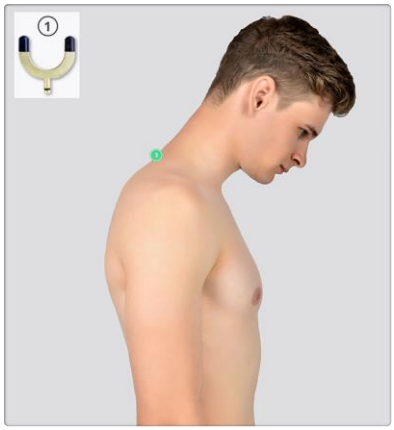
C.T.S.			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
30-35	4	90° to the spine/a limb	10-15
Tip:	(Tips No1, 6) a medium standard and a small rubber protocol tips.		

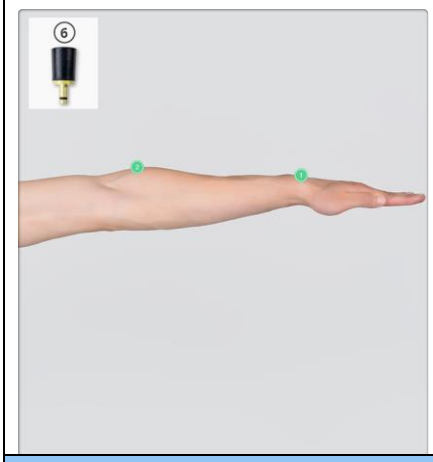
Note	Be careful with the heavy loads in this protocol. You can use smaller force of a shock wave at the beginning, gradually increasing it as the tolerance of the patient increases. The cervical and forearm are involved in the process.

The cervical spine: put the chin on the chest from the neutral position, with the greatest possible arching of the neck. Percuss the cervical spine in the indicated areas (C3, C4, C5), marking the point with the largest shoulder reaction. Percuss this point again, keeping the angle of 90 degrees to the surface.





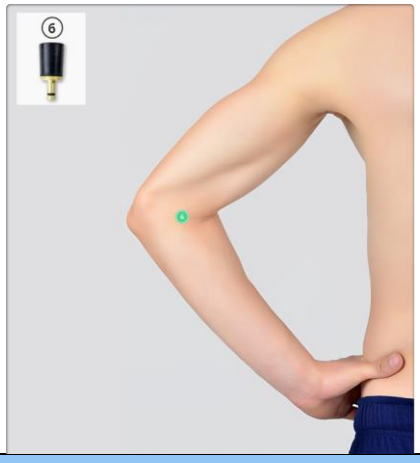




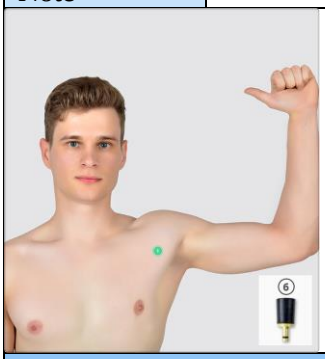
Forearm: Percuss the posterior surface of the semilunar bone (a small rubber tip). Percuss the extensors of the hand and fingers. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times on a day of treatment.

Elbow			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
15-20	12	90° to the surface	15-20
Tip:	(Tip No.6) a small rubber protocol tip		
Note			

The lateral side of the elbow: Point 1 is the head of the radius, Point 2 is 26 mm further from the head of the radius, Point 3 is 52 mm further from the head of the radius, Point 4 is far end of the lateral head of the triceps, Point 5 is distal end of humerus, from behind inner side of elbow: Point 6 is inside the distal end of humerus. Perform the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

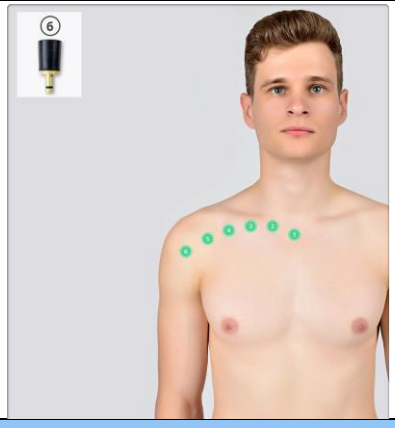
Shoulder Extension			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the surface	15-20 or up to an automatic stop
Tip:	(Tip No.6) A small rubber protocol tip		
Note			

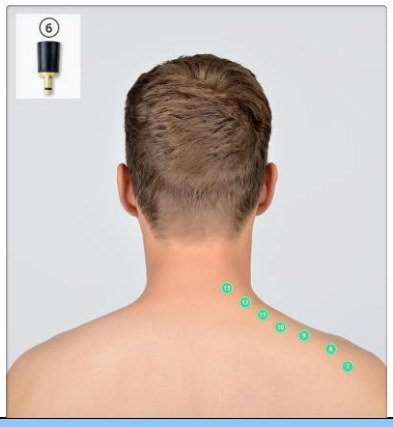


The load line goes into the head of the humerus through the deltoid and subscapular muscles, the short head of the biceps and the beak-brachial muscle. The patient holds his arm elongated and bent at the elbow by 90 degrees, pulls the forearm as far back as possible, percuss point 1. The doctor passively stretches the shoulder to the end when the active limit of the range of motion is reached. Repeat the procedure twice. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Shoulder			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the surface	15-20 or up to an automatic stop
Tip:	(Tip No.6) A small rubber protocol tip		
Note			

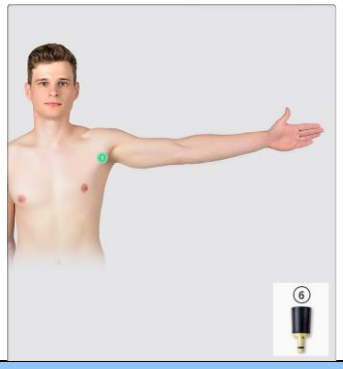
Percuss by points, making sure not to slip off the clavicle contact points.
Before: Point 1 is a sternoclavicular joint of the shoulder, Point 2 is to 26 mm lateral to the sternoclavicular joint, the lower side of the clavicle, Point 3 is to 52 mm lateral to the sternoclavicular joint, the lower side of the clavicle, Point 4 is middle of the clavicle, the lower side of the clavicle, Point 5 is 26 mm from the acromioclavicular joint, Point 6 is front side of the acromioclavicular joint. Back: Point 7 is back of the shoulder joint Point 8 is joint of the clavicle and shoulder blade Points 9-13 are back of the trapezius muscle, move to the middle step in 26 mm until you reach the bases of the neck. Follow the protocol three times a week for 1-3 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

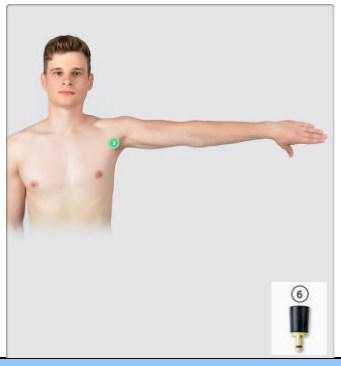




Shoulder Pronation			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the surface	15-20 or up to an automatic stop
Tip:	(Tip No.6) A small rubber protocol tip		
Note			

The load line goes to the head of the humerus through the deltoid and subscapular muscles, the short head of the biceps and the beak-brachial muscle. The patient rotates an arm inside during percussion with an elongated forearm and a humerus bent at 90 degrees. The doctor passively turns the patient's hand to the end when the active limit of the range of movement is reached. At the same time, he holds the patient by the shoulder, not by the elbow. Repeat the procedure twice. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

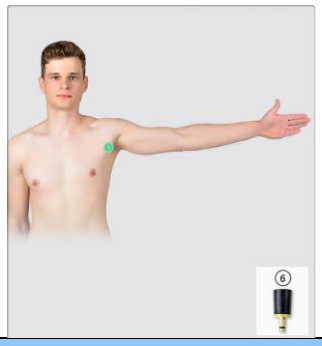


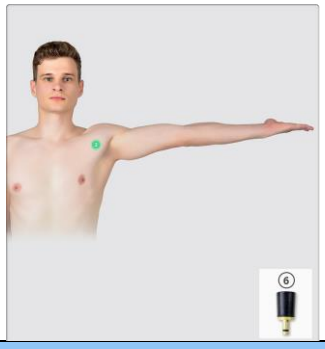


Shoulder Supination			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the surface	15-20 or up to an automatic stop
Tip:	(Tip No.6) A small rubber protocol tip		
Note			

The load line goes to the head of the humerus through the deltoid and subscapular muscles, the short head of the biceps and the beak-brachial muscle. The patient rotates an arm outward during percussion with an elongated forearm and a humerus bent at 90 degrees. The doctor passively turns his hand to the end when the active limit of the range of movement is reached. At the same time, he holds the patient by the houlder, not by the elbow.

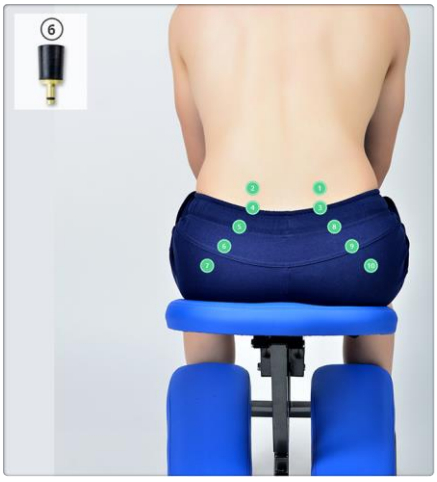
Repeat the procedure twice. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on the day of treatment.





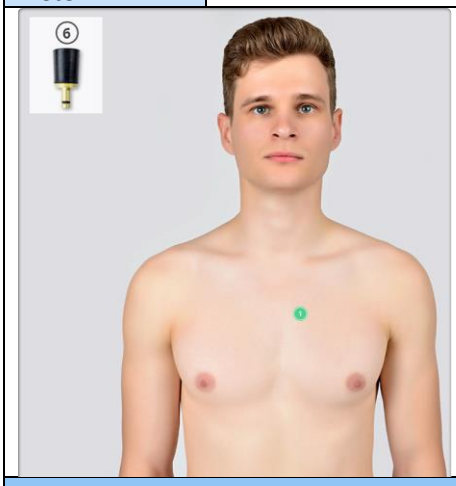
Chronic Low Back			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the surface	25
Tip:	(Tip No.6,2) a small rubber protocol tip and a small standard tip		
Note			

Follow the standard protocol for the lower back. Points 1 and 2 are 13 mm from the corners of the sacrum on both sides. Points 3 and 4 are 26 mm lateral to S2 on both sides. Points 5, 6 and 7 are diagonally oriented, starting from a point 52 mm lateral to S3, every 52 mm, following the gluteus majorus, above the sciatic notch, towards the left thigh. Points 8, 9 and 10 are the mirror image to the right. Chronic low back pain usually (85%) includes the head of the left fibula and the Achilles tendon area. Percuss the head of the fibula with a small rubber protocol tip. Next, percuss the distal end of the Achilles tendon using a small standard tip. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.



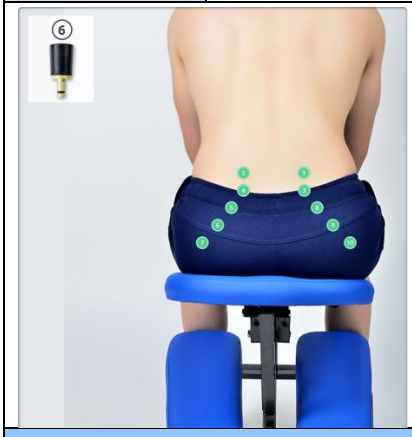
Inferior Rib			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	Bottom-up, from the medial to the lateral at the junction of the sternum	15-20 or up to an automatic stop

		and cartilage.	
Tip:	(Tip No.6) A small rubber protocol tip		
Note			



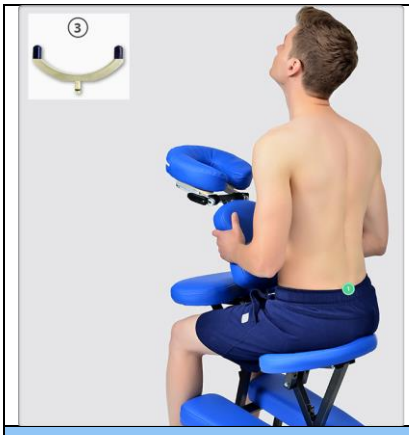
Percuss the distal articulation of the rib using the load line which is described above. Repeat twice. Do not use more than three times a day. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Low Back			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20-25	12	90° to the surface	25
Tip:	(Tip No.6) A small rubber protocol tip		
Note			



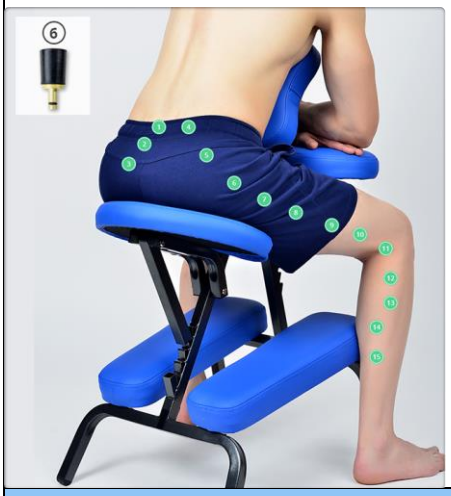
Points 1 and 2 are 13 mm from the corners of the sacrum on both sides. Points 3 and 4 are 26 mm lateral to S2 on both sides. Points 5, 6 and 7 are diagonally oriented, starting from a point 52 mm lateral to S3, every 52 mm, following the gluteus majorus, above the sciatic notch, towards the left thigh. Points 8, 9 and 10 are the mirror image to the right. Repeat the procedure. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Low Back Unlock			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
25	12	90° to the surface	15-20 or up to an automatic stop
Tip:	(Tip No.3) a long horn tip		
Note			



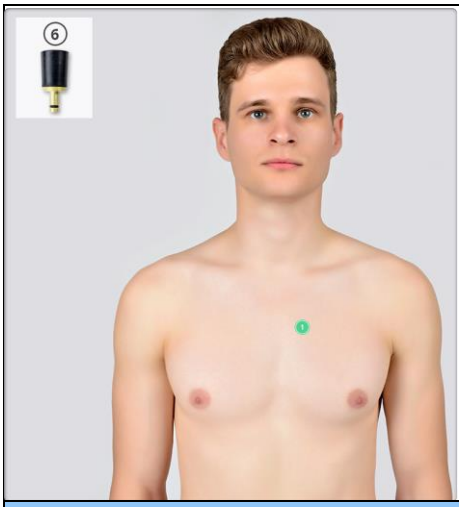
Put your fingers on the patient's forehead so that he could arched his back as much as possible. Do not apply force to the thrown head. Start with a neutral position. As soon as the patient begins to bend back, percuss the paravertebral muscles at the level S1, let the patient arch the back as much as possible. Return the patient to a neutral position. Repeat the procedure twice. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Spine-Rib-Pelvis Sciatica			
Force	**Frequency**	**Load line**	**The number of shock per point:**
20	12	Load line: 90° to the surface	25
Tip:	(Tip No.6) A small rubber protocol tip		
Note			



Percuss the following points: Point 1 is on the corner of the sacrum, opposite to the painful side. Point 2 is 26 mm lateral, at level S3 on the same side as point 1. Point 3 is 52 mm lateral, at level S5 on the same side as points 1 and 2. Points from 4 to 6 are the same as points 1 -3, but on a painful side. Points from 7 to 15 are the sciatic nerve of the painful side. Marks: Point 7 is a muscle gluteus maximus Point 8 is a lower part of the large trochanter Points 9, 10 and 11 is an iliac-tibial tract Point 12 is a lateral epicondyle Point 13 is a lateral head of fibula Point 14 is an upper gastrocnemius (posterior) Point 15 is an abdomen of the gastrocnemius. Repeat the procedure, DO NOT perform more than 3 times a day. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice or 40 minutes. Repeat the procedure three times a day on a day of treatment.

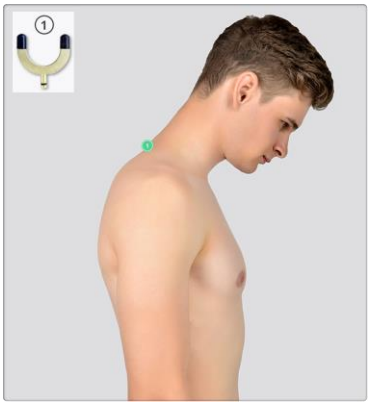
Superior Rib			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	Bottom-up, from the medial to the lateral at the junction of the sternum and cartilage.	15-20 or up to an automatic stop
Tip:	(Tip No.6) A small rubber protocol tip		
Note			

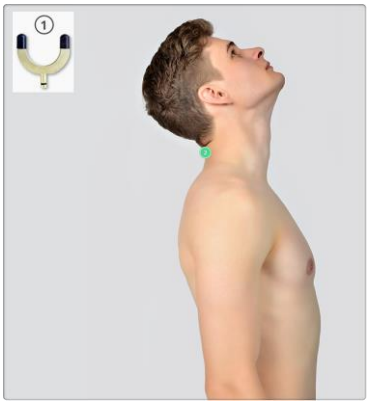


Percuss the distal articulation of the rib using the load line which is described above. Repeat twice. Do not use more than three times a day. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Thoracic Unlock			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20-30	12	changing angle	100 or up to an automatic stop
Tip:	(Tip No.1) a middle standard tip		
Note			

Test the range of motion. Start with the cervical spine in full inflexion. Set the head on T1 and percuss during the extensional process. Continue to percussion, when the patient bends and unbends the neck, until the maximum range of motion is reached. Repeat the procedure. In a severe case, it may be necessary to repeat this protocol at levels T2 and T3. Test the range of motion and mark improvements. Follow the protocol three times a week for 1-2 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

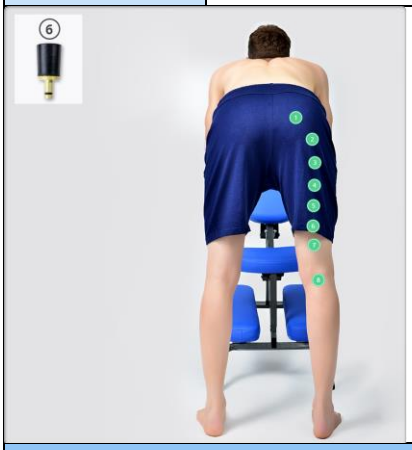




Knees			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the surface	20
Tip:	(Tip No.6) A small rubber protocol tip		

Percuss points as it is shown on the picture. The anterior lower part of the knee: Point 1 is the lower patella. Point 2 is the patellar ligament. Point 3 is the tuberosity of the tibia. The medial site of the knee: Point 4 is the medial meniscus. Point 5 is the medial epicondyle. Anterior upper knee: Point 6 is the middle line of the quadriceps muscle, 8 cm above the patella. Points 7-8 are down from point 6, each is at a distance of 26mm, on the patellar ligament. Lateral part of the knee: Point 9 is the distal part of the ilealtibial tract. Point 10 is the lateral meniscus. Point 11 is the head of the fibula. Point 12 is the proximal epiphysis of the fibula. Follow the protocol three times a week for 1-2 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Hamstring			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the surface	10-15
Tip:	(Tip No.6) A small rubber protocol tip		
Note			



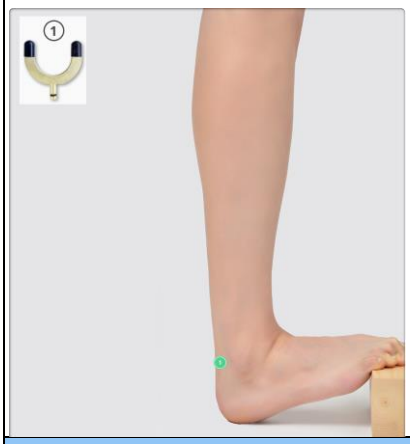
Point 1 is the beginning of the hamstring. Points 2-6 is the body of the hamstring, with a passive stretching. Point 7 is a posterior projection of the knee. Point 8 is the body of the gastrocnemius muscle. Percuss the points along the hamstring while the patient supports himself. Give the patient a rest between sets. Repeat the procedure. Follow the protocol three times a week for 1-3 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

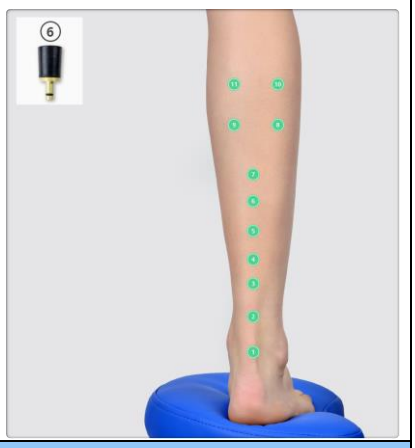
Cuboid Ankle			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the cuboid bone	15-20
Tip:	(Tip No.6) A small rubber protocol tip		

Percuss the cuboid bone in the lateral medial direction, from below-upward. Repeat twice. Follow the protocol three times a week for 1-4 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

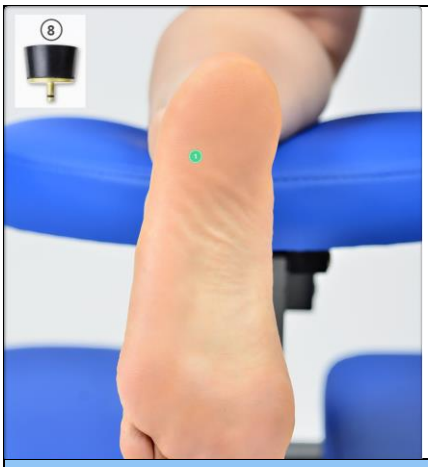
Achilles			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
25	12	90° to the surface	10-15
Tip:	(Tip No.1,6) A small standard and a small rubber protocol tips.		
Note			

Achilles: Place a small standard tip on Achilles and percuss until the foot is in flexion. Posterior tibia: (a small rubber protocol tip). Points 1-7 are the middle of Achilles from the heel of the calcaneus to the connection with the gastrocnemius muscle. Point 8 is the medial aspect of the lower part of the gastrocnemius muscle. Point 9 is the lateral aspect of the lower part of the gastrocnemius muscle. Point 10 is the medial aspect of the middle of the gastrocnemius muscle. Point 11 is the lateralaspect of the middle of the gastrocnemius muscle. Repeat the procedure. Follow the protocol three times a week for 1-3 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.





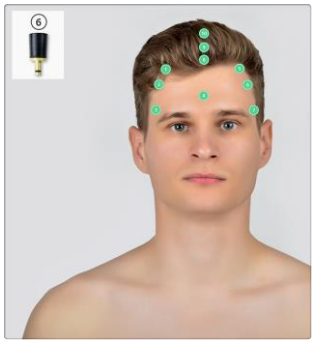
Plantar Fascitis			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
20	12	90° to the surface	20
Tip:	(Tip No.8) A big rubber protocol tip.		

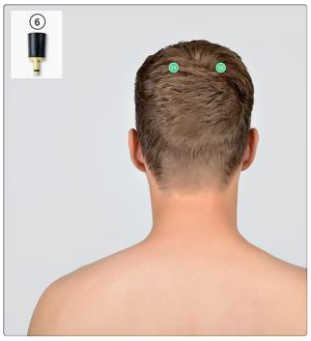


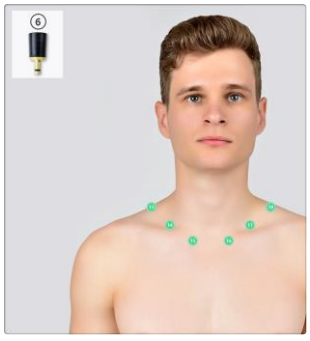
Percuss point 1 at the point where the fascia of the foot adjoins the calcaneus. Repeat two more times. Follow the protocol three times a week for 1-3 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Anxiety-Depression			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
15	12	90° to the surface	15-20 or up to an automatic stop
Tip:	(Tip No.6) A small rubber protocol tip		
Note			

Percuss the following points: a skull in front: Point 1 is an anterior-upper part of the right temporal muscle. Point 2 is an anterior-lower part of the right temporal muscle. Point 3 is the most lateral part of the right eyebrow. Point 4 is an overlapping. Point 5-7 is a mirror reflection of points 1-3 on the left side. Point 8 is the lowest aspect of the sagittal seam. Point 9 is 26 mm above the point 8 along the sagittal suture. Point 10 is 52 mm above the point 8 along the sagittal suture. A skull behind: Point 11 is at 52 mm above the upper lining line, posterior left aspect of the skull. Point 12 is 52 mm above the upper outline, the posterior right aspect of the skull. Upper part of the trunk: Point 13 is the middle upper aspect of the right trapezius muscle. Point 14 is the middle of the right collarbone. Point 15 is the right sternoclavicular joint. Point 17 is the left sternoclavicular joint. Point 18 is the middle upper aspect of the left trapezius muscle. Repeat the procedure. Follow the protocol three times a week for 1-3 weeks. Instruct the patient at home to apply ice for 20 minutes, then to remove the ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.



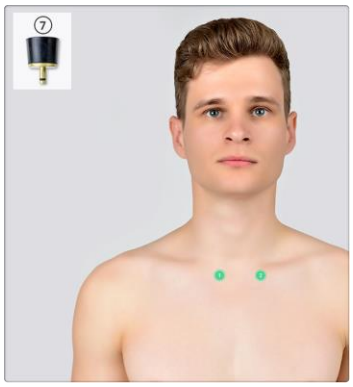


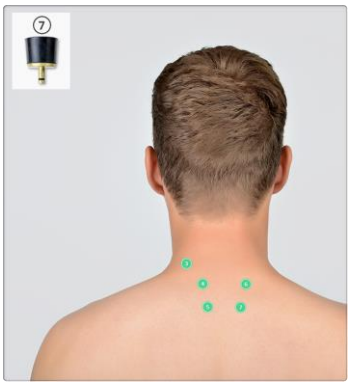


Asthma			
Force	**Frequency**	**Load line**	**The number of shocks per point:**

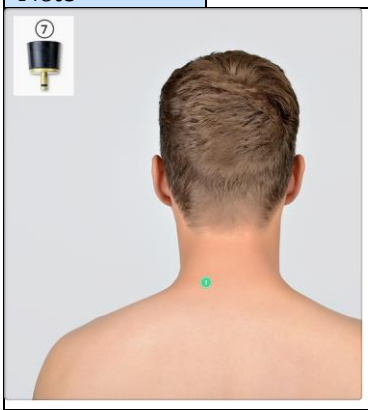
15	12	90° to the surface	15-20
Tip:	(Tip No.7) a middle rubber protocol tip		

Percuss the following points: a body in front: Point 1 is a right sternoclavicular joint Point 2 is a left sternoclavicular joint. The body from behind: Point 3 is a left transverse outgrowth T1 Point 4 is the left transverse outgrowth T2 Point 5 is the left transverse outgrowth T3 Point 6 is a right transverse outgrowth T2 Point 7 is the right transverse outgrowth T3. Follow the protocol three times a week for 1-3 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.





Breathing			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
25	12	90° to the surface	15-20 or up to an automatic stop
Tip:	(Tip No.7) a middle rubber protocol tip		
Note			

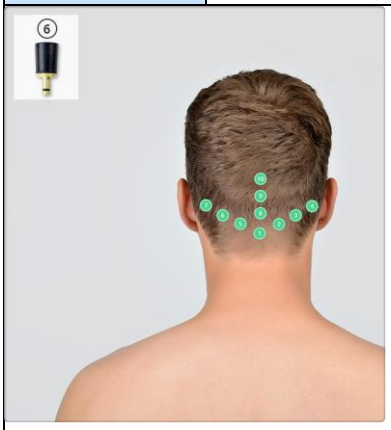


Percuss the left transverse outgrowth T1 with a protocol tip. Repeat the procedure two more times, up to an automatic stop. Follow the protocol three times a week for 1-3 weeks.

Constipation			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
15	12	90° to the surface.	10-15
Tip:	(Tip No.7) a middle rubber protocol tip		

Point 1 is 52 mm medially to the anterior superior iliac spine (ASIS). Point 2 is 26mm above point 1. Point 3 is 52mm above point 1, following the ascending colon. Point 4 is below the 10th rib, on the line of the middle of the clavicle. Point 5 is 26mm below and lateral to the xiphoid process. Point 6 is under the xiphoid process. Points 7-11 is a mirror reflection of points 1-6 on the left side, along the descending colon. Point 12 is 104 mm to the middle of the left lower anterior iliac awn (AIIS). Point 13 is 104 mm to the middle of the right lower anterior iliac awn (AIIS). Percuss the points, then repeat the process again. Follow the protocol three times a week for 1-3 weeks.

Headaches			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
15	12	90° to the surface.	10-15
Tip:	(Tip No.6) A small rubber protocol tip		
Note			



Point 1 is an external occipital protuberance. Points 2, 3 and 4 are the fringe line laterally in the direction of the ear, with a distance of about 18 mm. Points 5, 6 and 7 are the mirror reflection of points 1-3 along the fringe line. Point 8 is 13 mm higher than the external occipital protuberance. Points 9 and 10 are above point 8 in the middle. Repeat the procedure. Do not repeat the protocol more than 3 times a day. Follow the protocol three times a week for 1-3 weeks. Instruct the patient at home to apply ice for 20 minutes, then remove ice for 40 minutes. Repeat the procedure three times a day on a day of treatment.

Trigeminal Systemic Regulation			
Force	**Frequency**	**Load line**	**The number of shocks per point:**
1-10	4	The tool should be pointed towards the Turkish saddle at most of the points.	unlimited number
Tip:	(Tip No.6,8) a small rubber protocol tip, a large rubber tip		

Treatment of the terminal branches of the trigeminal nerve has a local reflex effect on the innervation of the trigeminal nerve, but it is more important that treatment often has a great influence on the vegetative system of the whole system. After completing the protocol, patients often note a feeling of mental and visual clarification, cardinal changes in the sensation of pain, a relaxed state and, sometimes, the manifestation of emotional discharge. Since this protocol has a very strong effect, it is NOT recommended to use it in everyday practice, but it is very good to use in the initial stage of treatment of prolonged chronic diseases, forcing the effect of other protocols and medications provided by the device STARDEVICE®. It can also be used to enhance the response of the central nervous system to treatment. The protocol can be executed both on one side and on both sides of the face, as necessary. The device selects a frequency within 4 Hz and sets the unlimited number of pulses. A small rubber protocol tip is used. The areas of the face covering the branches of the trigeminal nerve that will be stimulated are very sensitive, so the therapist must be very careful when palpating and using the instrument. The

force should not exceed 10. The tool should be directed towards the Turkish saddle at most points. In total, the protocol consists of palpation, scanning and treatment of points on the face, corresponding to the main branches of the nerve and the three zones of its innervation.
1) The chin nerve (the third zone of innervation of the trigeminal nerve, the mandibular nerve).
2) The infraorbital nerve in the pterygo-palatine fossa near the lateral edge of the nose (the second zone of innervation of the trigeminal nerve, the maxillary nerve).
3) The skull nerve on the line of the angle of the lower orbital fissure, under the malar bone (the second zone of innervation of the trigeminal nerve, the maxillary nerve).
4) Supraorbital nerve on the line of the pupil at the level of the eyebrows.
5) The supraclavicular nerve and the middle branch of the supraorbital nerve (both are extensions of the ophthalmic branch of the trigeminal nerve) at the medial end of the eyebrow.
6) Gabella.
7) Supraorbital nerve (additional 1-3 points) on the pupil line, above the eyebrow under the front hair line.
8) Ear-temporal nerve (the third zone of innervation of the trigeminal nerve, the mandibular nerve) on the posterior surface of the zygomatic area near the neck of the articular process of the lower jaw.

Alternatively, you can use a large rubber tip over the entire ear area, removing the preload and leaving a gap around the auditory canal.

5.6 SWITCHING THE DEVICE ON

1. Connect the manipulator of the device to the corresponding socket on the back panel of the device.
2. Press the power button on the back panel of the electronic unit of the device. The green "Power" LED should light up on the front panel of the electronic unit after 3-5 seconds.

3. The opening window will be displayed on the build-in display of the device:

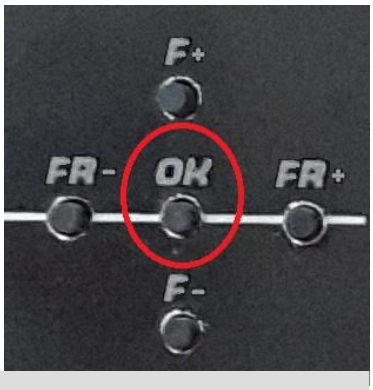
A global pulse counter

Global working hours

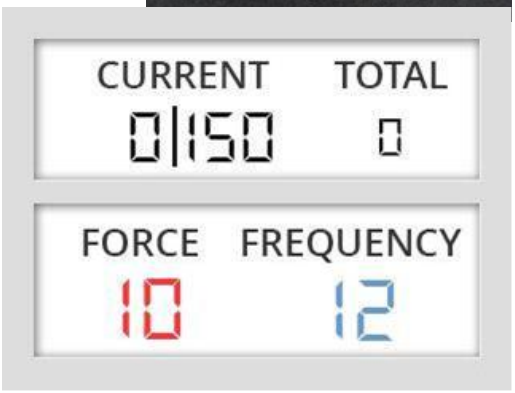
The indicator of the connection of the manipulator

The instructions about the beginning of work

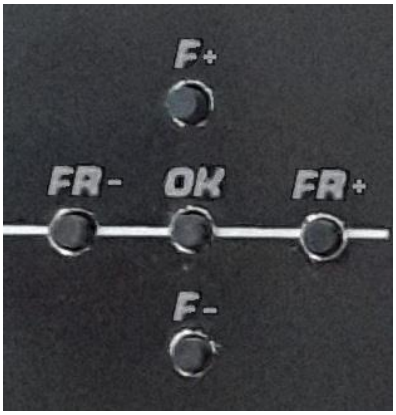
1. Press «OK» to start working



2. Then the window of main menu will appear
   The device is ready to work.



5.7 DESCRIPTION OF CONTROLS



Control is carried out by 5 buttons on the front panel:

F+ to increase the force of a shock;

F- to reduce the force of a shock;

FR+ to increase the frequency of shocks;

FR- to reduce the frequency of shocks;

OK menu / exit menu

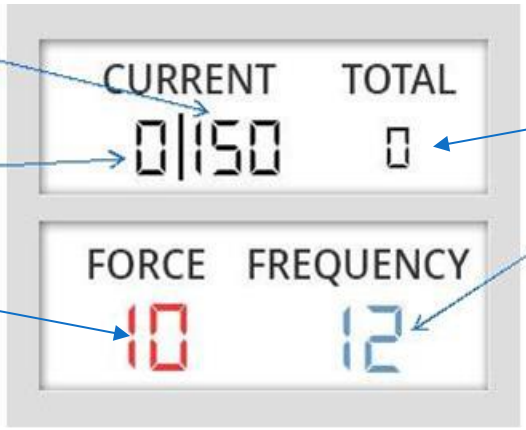
5.8 MAIN MENU

Main menu contains the following information:

The number of shocks per session

The number of performed sh

Shocks force



Total shocks counter

Shocks frequency

Correction occurs with the help of a correcting head (the manipulator) and various tips.

The doctor sets the correction settings, depending on the area of influence and the desired effect at his discretion.

The manipulator automatically stops and a beep sounds after the specified number of shocks have been executed.

Pulse frequency

The pulse frequency of the manipulator is set by the doctor from 4 to 12 shocks per second. The doctor can change the frequency value during work at his own discretion. It is forbidden to change the settings during the correction session (when the manipulator knocks).

Pulse force

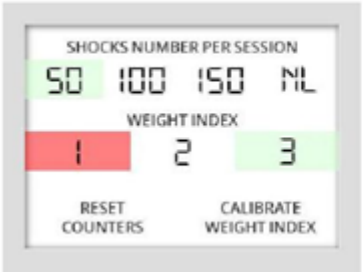
The intensity or force of the correction can be set at the range from 4.54 kg / cm2 (Value 10) to 15.87 kg / cm2 (value 35).

There are the following recommended settings of force of a shock for different areas of the spine:

For the cervical spine: 10-15
For the thoracic spine: 15-25
For the lumbar spine: 25-35

The doctor chooses the settings for other joints / soft tissues at his own discretion.

5.9 SUBMENU



You need to press the central button «OK» to enter submenu.

The submenu allows you to change the number of shocks in the therapy session, to change the load index, to reset the shock counters and to calibrate the manipulator.

You can change the parameters of submenu by using the red carriage. The current settings are marked in green. The carriage is moving up / down by using the F + and F- buttons respectively. Moves to the right / left are performed by using the buttons FR + and FR-, respectively. To apply the parameters, you need to move the carriage to the next line and to press the central button «OK».

Shocks number per session

You can set 50, 100, 150 shocks per session or an unlimited session - NL in the line of shocks number per session.

Weight index

The weight index sets the number of depressions for stronger penetration in cases where the patient has overweight. Scale graduation: 1 - up to 70 kg, 2 - up to 100 kg, 3 - more than 100kg.

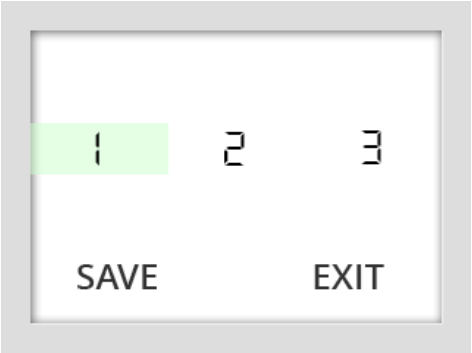
Attention! Only value 1 is allowed to use when exposed to the head and neck area.

Reset counters

Move the carriage to the RESET COUNTERS line and press the centre button «OK" to reset counters. If the reset is successful, DONE is displayed for a second and then automatically switches to the main menu.

The calibration of the manipulator

The calibration of the manipulator sets the force with which the manipulator must be pressed.
To enter the calibration menu of the manipulator, select "CALIBRATE WEIGHT INDEX" in the submenu and click "OK".



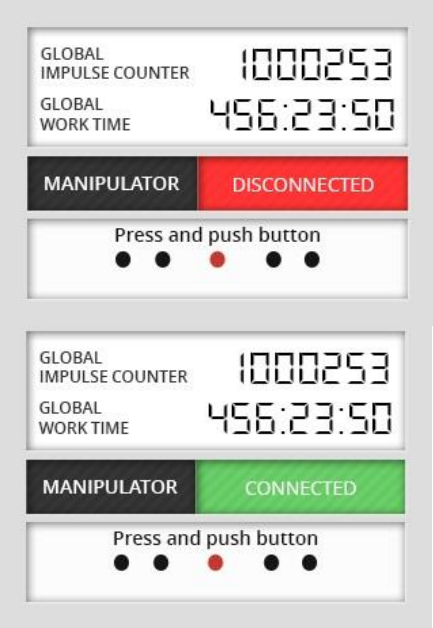
The load index "1" has already been automatically selected in the appeared window of the manipulator calibration. Now you need to press the manipulator with the required force and press the button «OK».

The device will measure the effort and will move the carriage to the index «2». This procedure must be repeated for indices 2 and 3.

You should select "SAVE" and click «OK" to apply this data. If you do not want to apply this calibration, you should select "EXIT" and click "OK".

Submenu screen is displayed after completing the process of calibration.

5.10 MESSAGES



The manipulator stops working if the manipulator cable is not connected to the socket on the back panel of the electronic unit when the device is turned on or during operation then the initial window is displayed with a message about the unconnected manipulator and there is a repeated sound signal (sound power less than 85 dB). To be able to perform an operation it is necessary to connect the manipulator cable to the corresponding socket on the back panel of the electronic unit.

The message about the connected manipulator will be displayed on the opening window after connecting the cable and further operation of the device will become possible (see 5.5). The beep sound turns off.

5.11 COMPLETION OF WORK WITH THE DEVICE

To complete the work with the device you need:

- To switch off the device using the power button on the back panel of the electronic unit
- To remove the tip from the manipulator and wipe it with a water-alcohol solution (see also item 6.2).
- To fold tips and the manipulator for storage for next use.

5.12 STARDEVICE-PC SOFTWARE STARDEVICE VER. 1.3

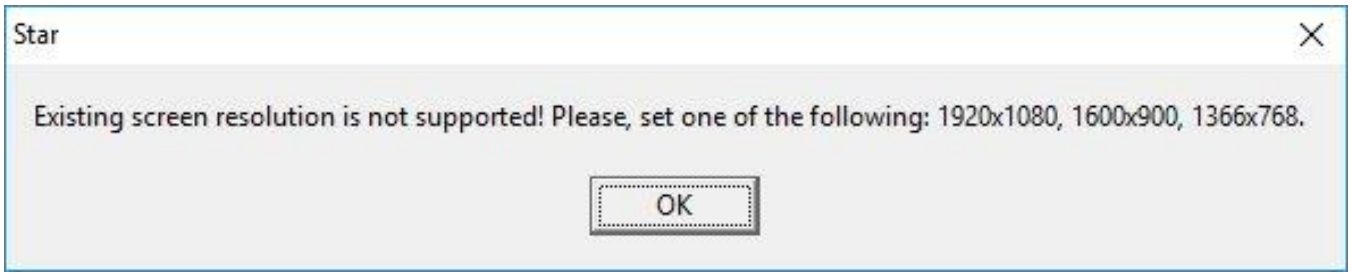
FIRST START OF THE STARTEVICE SOFTWARE V1.3.

To install the software on your computer, run the installation package. An icon will be created on the desktop of your computer to start the program after the installation of the StarDevice V1.3 program is completed.

Connect the device StarDevice® to your computer by using a USB cable. Turn on the device StarDevice®, as it is described in section 5.6.

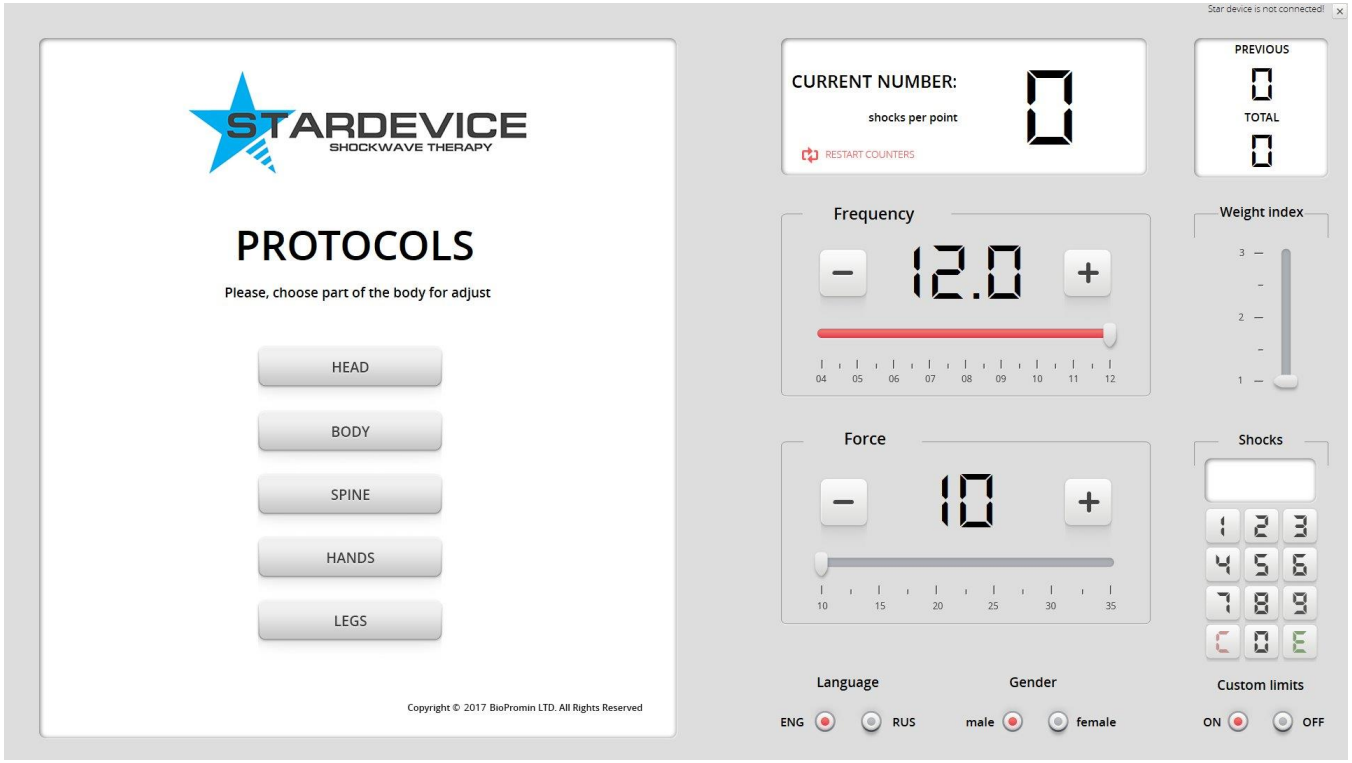
Run the software V1.3 of the device StarDevice®.

If on your computer the resolution of the screen differs from 1920x1080, 1600x900, 1366x768, then a warning window will appear on the screen.

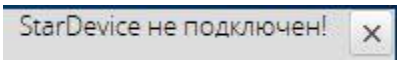


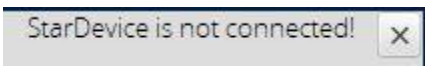
Set one of the suggested screen resolutions in your Windows operating system to display the program in full-screen mode.

The start window will appear after starting the program.



If you did not connect the StarDevice to the computer, a warning entry "Star device is не подключен" or "Star device is not connected!" would appear in the upper right corner of the program's working window.

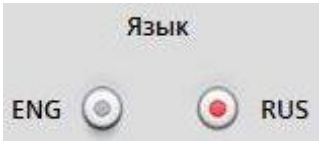


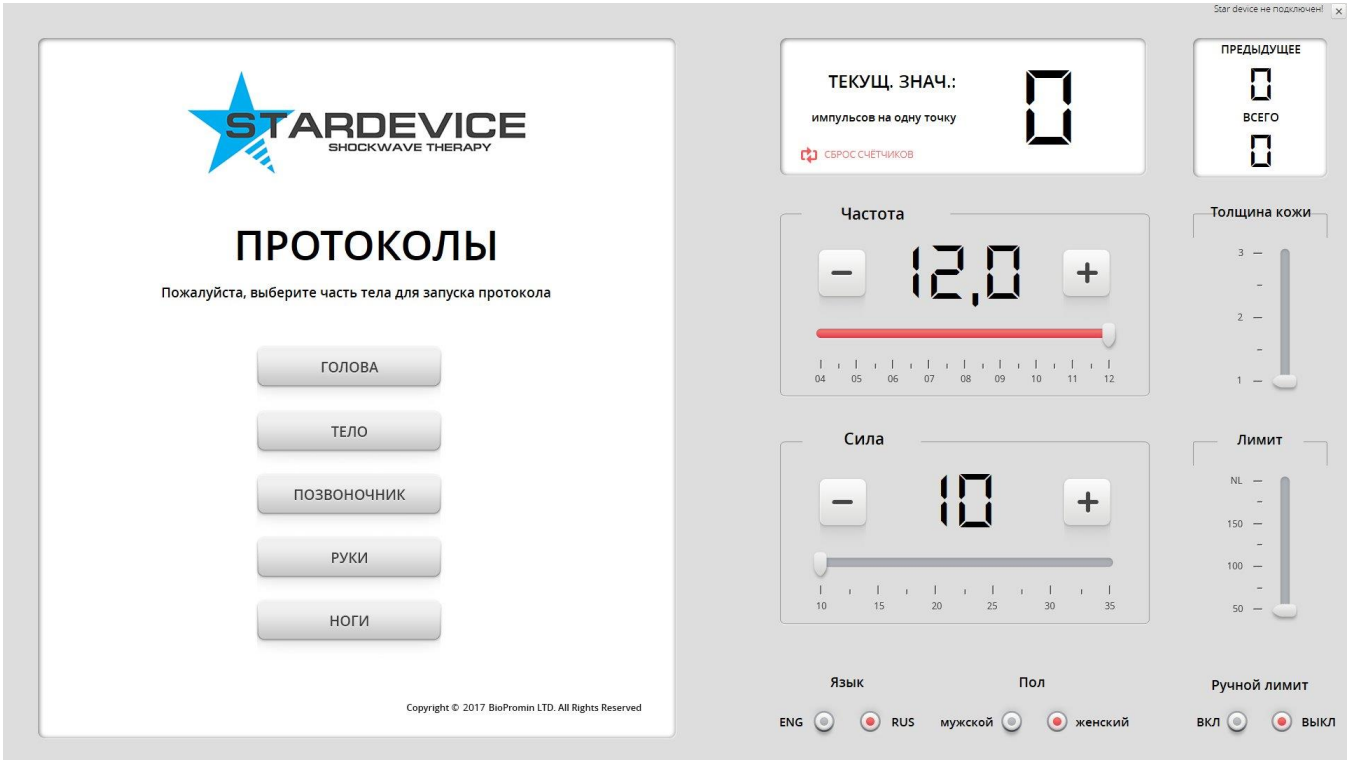


In this case, check whether the device is connected to the computer with a USB cable, if it is connected, replace the cable with a working one.

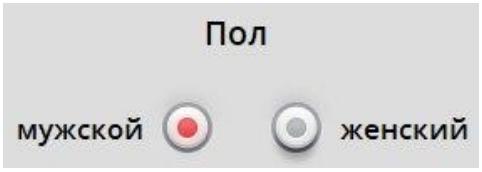
INTERFACE SETTING OF SOFTWARE STARDEVICE V1.33

Use the following bottoms to set a language

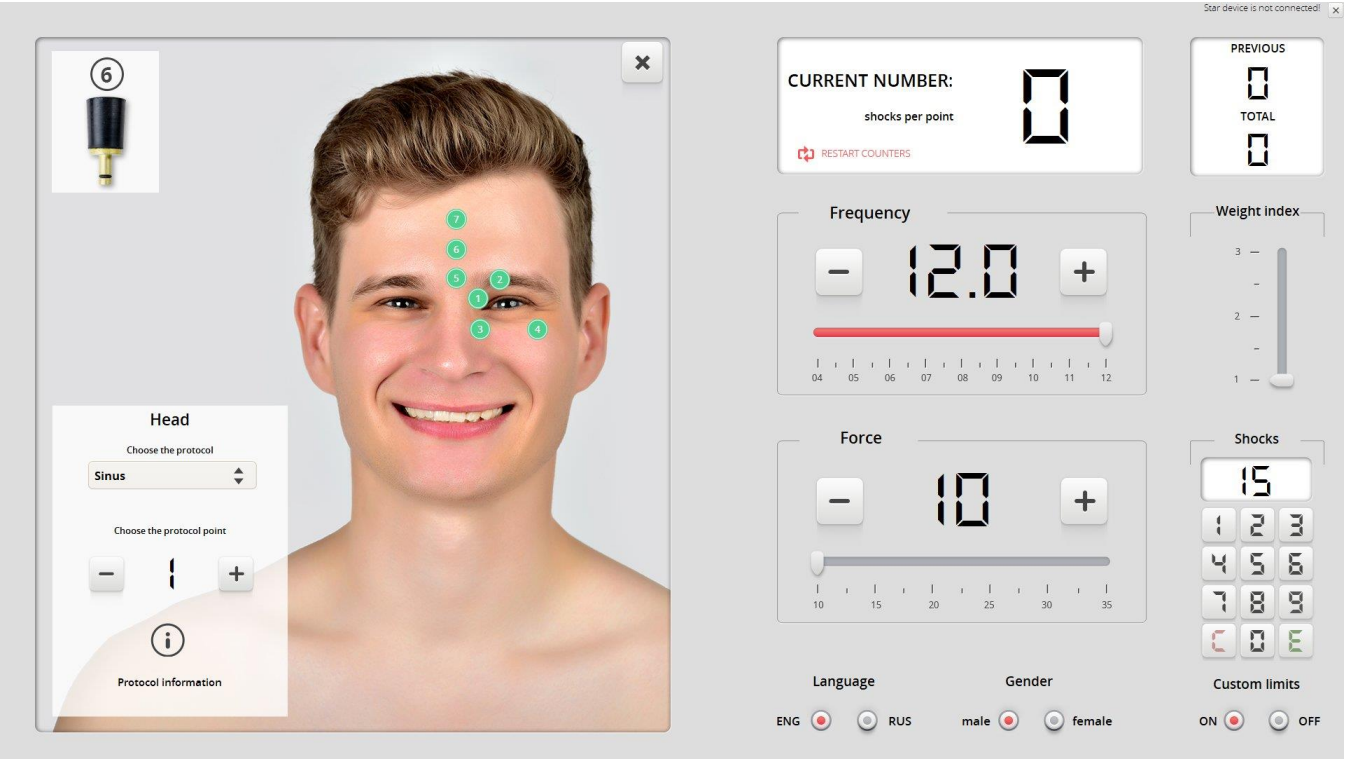




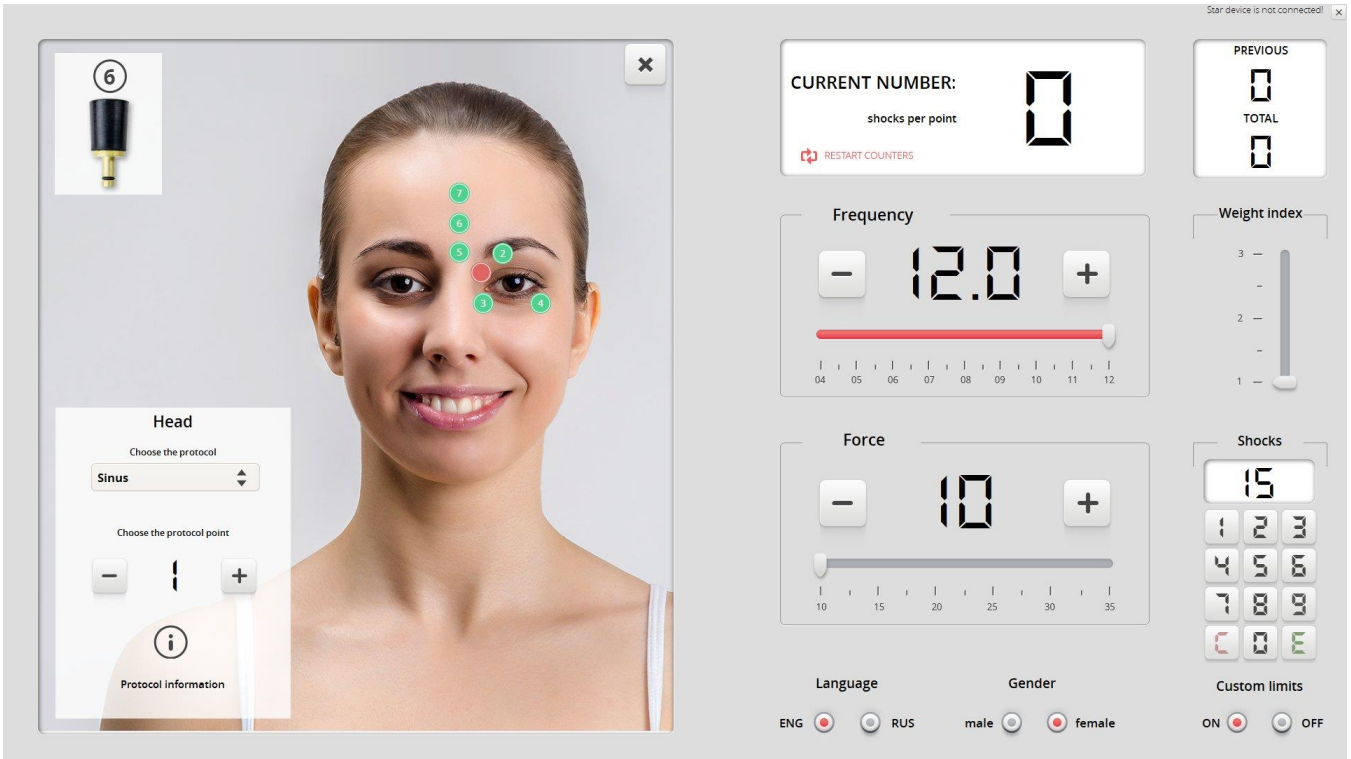
To set a photo model (male or female) use the other buttons.



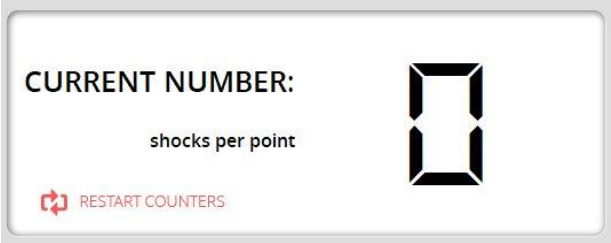
Depending on your choice, the program interface will look like this:



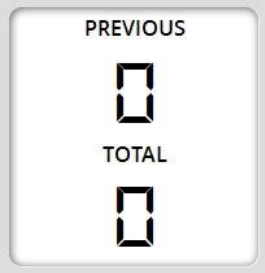
or:



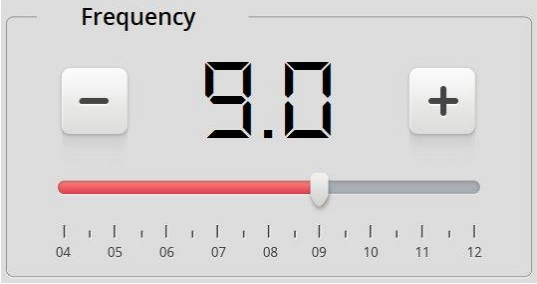
The window for calculating shocks of the manipulator.



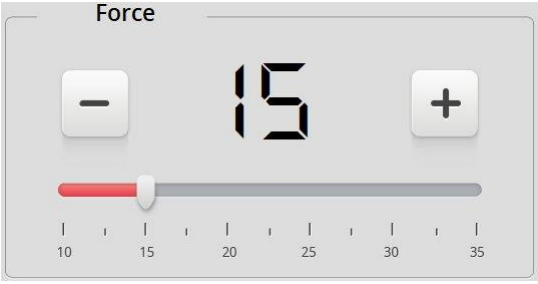
The previous value of the number of shocks of the manipulator and the total number of shocks per session.



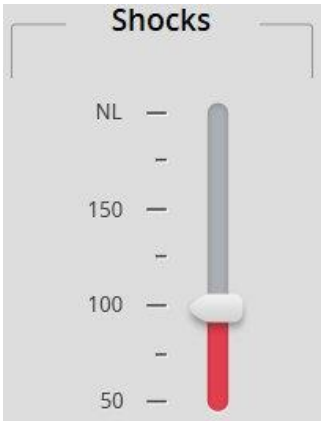
The choice of the shocks frequency is displayed as follows. You can independently choose the frequency of the manipulator's shocks with the help of the plus and minus buttons, or with the help of the slider.

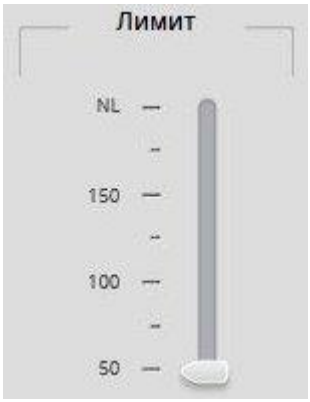


You can also set force of shocks at your own discretion.

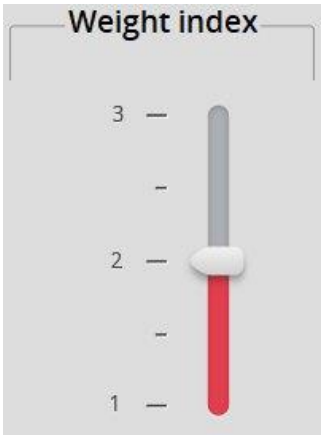


In manual mode, you can set the preprogrammed number of shocks of the manipulator by moving the slider. 50, 100, 150 shocks, or NL - an unlimited number of shocks.

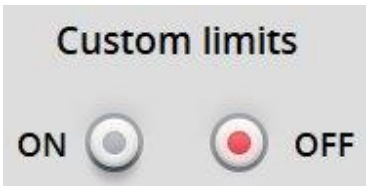


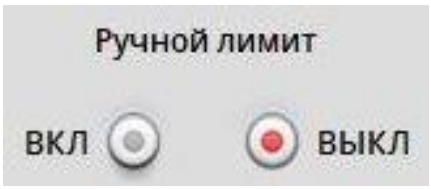


You can set the position of the slider "Skin thickness" to a division of 1, 2 or 3, when performing the procedure in manual mode. Usually 1 is chosen for face (head) therapy, where the skin has the smallest thickness.

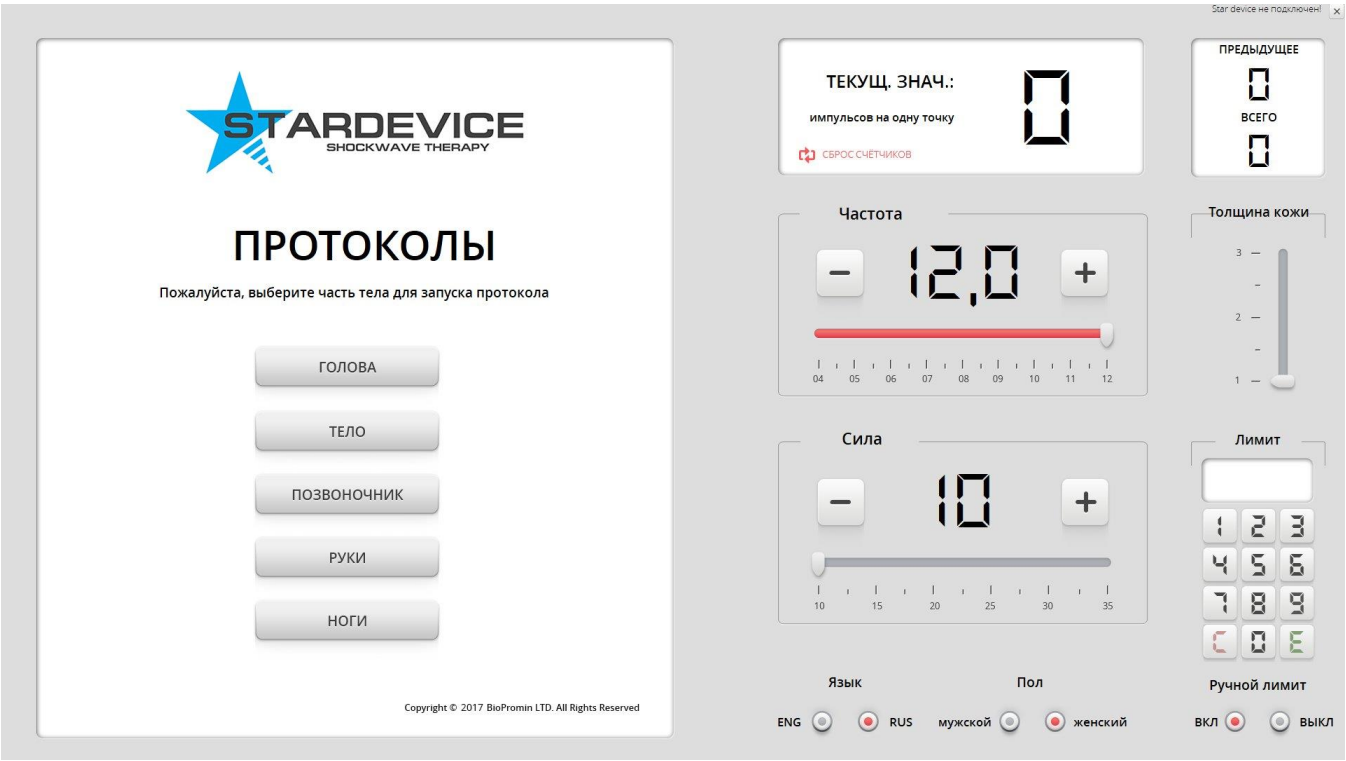


To set or exit the manual mode, use the buttons:





The interface of the main window will change when you set the manual mode:



You can set any number of shocks of the manipulator with numbers from 0 to 9. If you need to erase an incorrectly entered number, use the "C" button-reset the whole number or "E" - delete the last entered number.

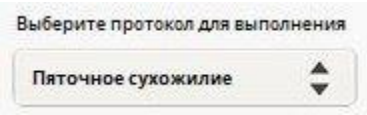
SELECTION OF PRESET THERAPY PROTOCOLS

Use the menu buttons on the left side of the StarDevice 1.3 main screen to select a preset therapy protocol.

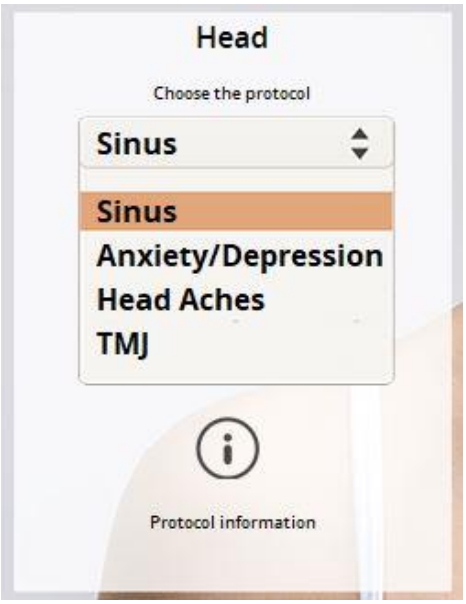
You will get a drop-down menu with a list of protocols by clicking on the button. Use it to select.

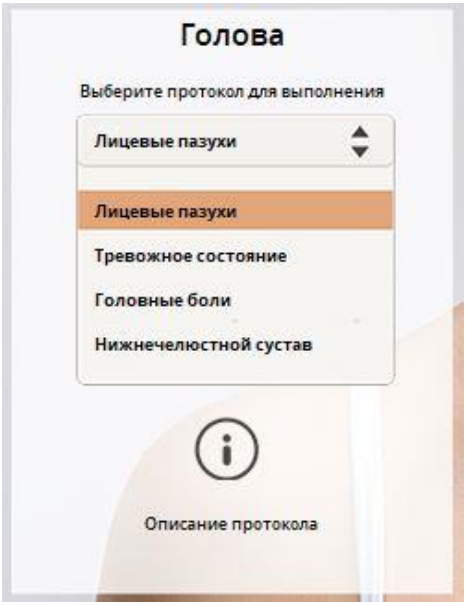
If you select the button "LEGS", the interface will change:

Use the list to select the desired protocol.



Use the bottom to review a protocol’s description.

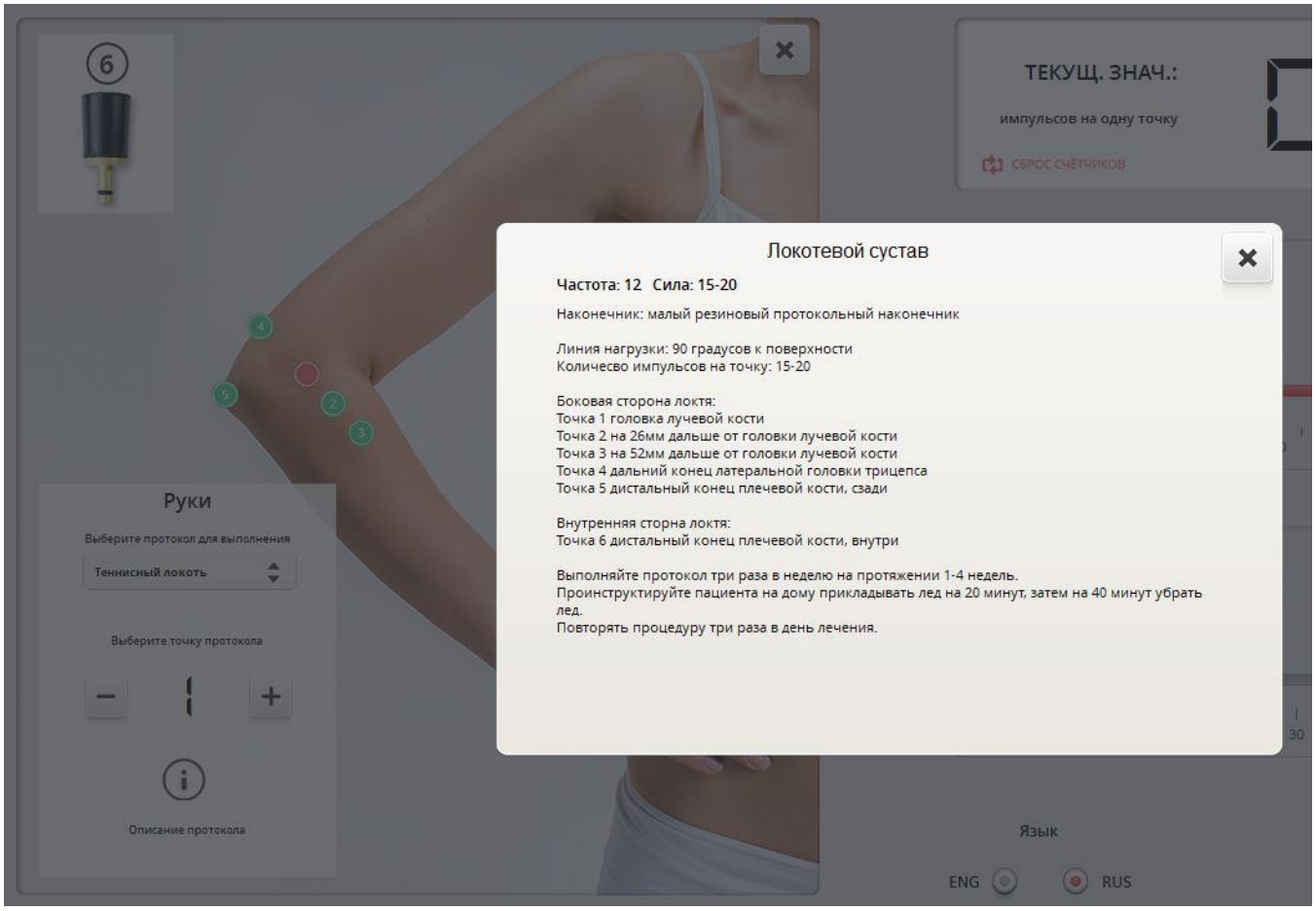

Head
Choose the protocol
Sinus
Sinus
Anxiety/Depression
Head Aches
TMJ
Protocol information

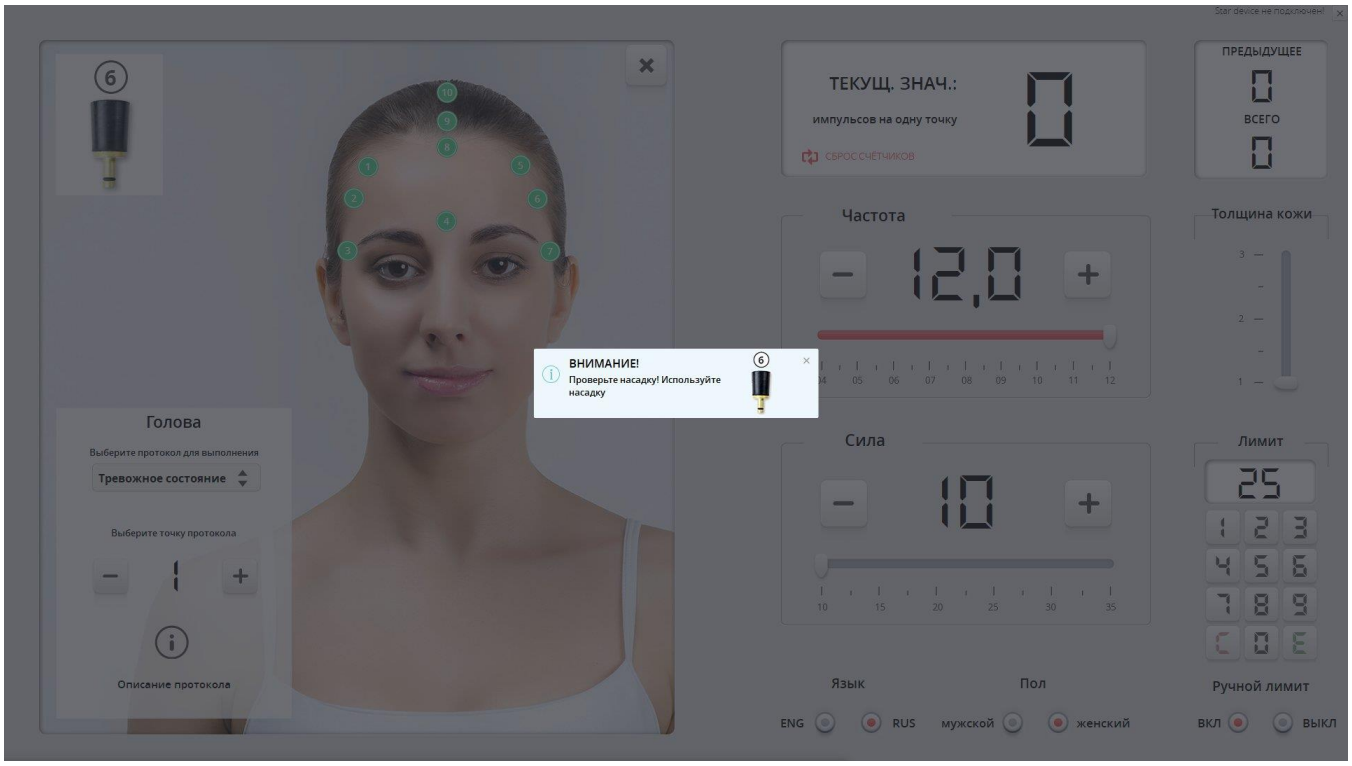

Голова
Выберите протокол для выполнения
Лицевые пазухи
Лицевые пазухи
Тревожное состояние
Головные боли
Нижнечелюстной сустав
Описание протокола

In the description of the protocol, you will get information about the rules of its use, and also read about the sequence of actions when performing it.

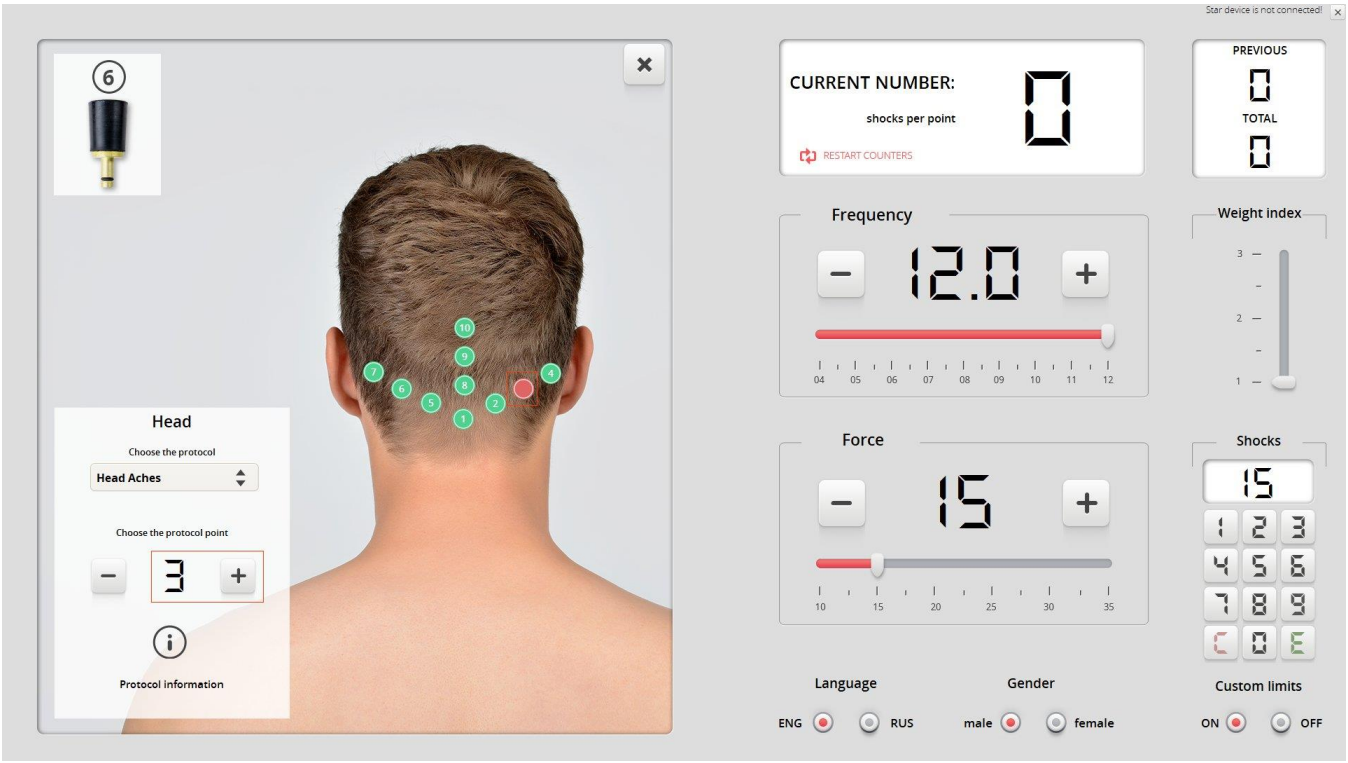
	All recommended treatment protocols are described in detail in this manual in section 5.5.

When choosing the protocol, you need, the program can show a hint about the need to change the tip in the manipulator, by showing its appearance in the upper left corner of the program interface.





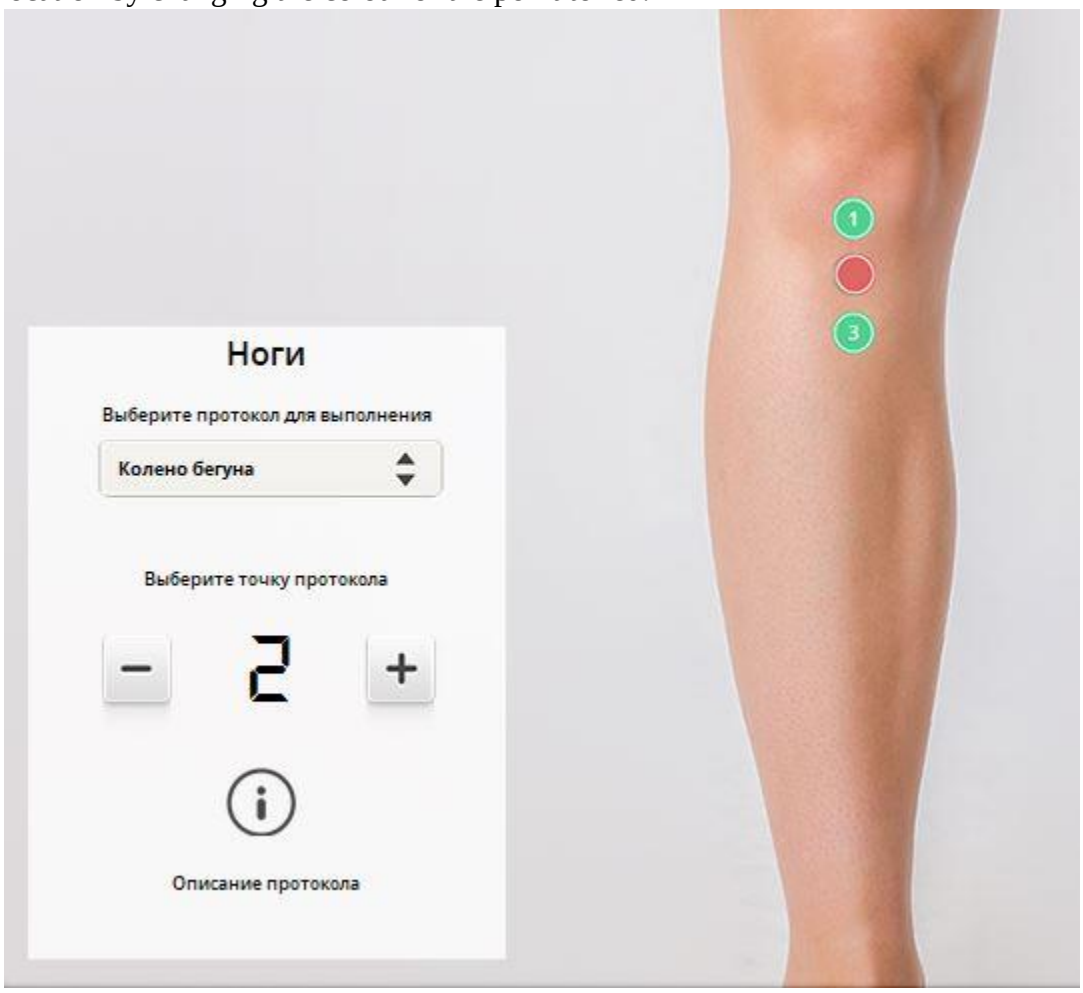
Places for the procedure of the treatment are marked with green dots with consecutive numbering starting with the digit "1" on the image of the model.



Begin the process of therapy (treatment) by applying the manipulator with the appropriate tip, starting with the place marked with a red "1". The dot flashes to attract your attention.

	When carrying out treatment (therapy), hold the angle at which the procedure should be performed correctly. Detailed information on the angle is contained in the description of each protocol (section 5.5 of this manual).

When you finish the manipulation on the first point go to the next. The program automatically tells you about its location by changing the colour of the point to red.



You can independently switch to the point you need by using the buttons "-" or "+". The number in the middle indicates the point number that is proposed for therapy (treatment).

6 SERVICE OF THE DEVICE STARDEVICE®

6.1 CLEANING OF THE DEVICE

Regular cleaning of the device ensures reliable and trouble-free operation of the device STARDEVICE®.

You should disconnect the manipulator from the electronic unit and the electronic unit itself from the mains before beginning any cleaning and / or repair operations.

General external cleaning is performed depending on the frequency of usage and application of the device.

All the details that are in contact with the patient must be treated with medical alcohol wipes or cotton wool soaked in 70-96% aqueous-alcohol solution.

It is very important to avoid contact with the liquid inside the electronic unit and the manipulator.

It is necessary to keep clean the ventilation slots of the electronic unit and the body of the manipulator.

Only special non-woven napkins for LCD monitors are allowed to clean the TFT display. These wipes should not contain alcohol.

6.2 CLEANING OF THE TIPS

Cleaning of the tips is performed with the help of medical alcohol wipes or wadded disks, soaked in 70-96% aqueous-alcoholic solution.

Attention! It is forbidden to clean the tips in any other way that is not described here!
You should clean the tips before each use and after the procedures.
The tips should be stored on a purposefully designed panel.
It is necessary to treat the panel with alcohol solution at least once a month to store the tips.

6.3 REPLACING OF A FUSE

If the device does not work, after connecting to a power source and turn on you should check and replace a fuse / fuses: maybe one of them is blown. The fuse holders are located on the back panel of the electronic unit of the device, they have the marking "T4AL250V". Please follow these steps to replace the fuse:

1. Unplug the power cord from the power socket.
2. Unscrew one of the fuse holders from the panel (marked "T4AL250V").
3. Remove the blown fuse from the holder.
4. Install a new T4AL250V fuse in the holder.
5. Insert the fuse holder back into the panel and tighten it until it clicks into place.
6. Replace the other fuse by following the instructions above.

6.4 MAINTENANCE AND SECURITY CHECK

Preventive maintenance is not necessary. However, regular maintenance can help to identify possible defects at an early stage and thus to increase safety and to extend the life of the device.

It is recommended to perform functional checks and security checks of the device at least once a year. It is necessary to follow national regulatory documents if the national security regulations for medical devices require a more frequent periodicity of tests and inspections. Functional and security checks are carried out at the producing factory or at authorized service centers.

6.5 DISPOSAL AND THE ENVIRONMENTAL PROTECTION

The device STARDEVICE® is disposed of as used electronic equipment after the end of its useful life. Please dispose of the device in accordance with the applicable regulations in your country.

Packaging disposal: Packaging components (cardboard, expanded polystyrene, etc.) are classified as a solid waste and therefore they can be easily recycled by using recycling processes. Before recycling, it is necessary to check local legislative requirements in this regard and it is necessary to comply strictly with local recycling requirements.
PRODUCT DISPOSAL: The device STARDEVICE® consists of various materials. Nevertheless, all of them (metal, plastic, electrical conductors, printed circuit boards, chips, etc.) do not contain hazardous substances and they can be transferred to special processing centres in the same way as electronic equipment. Before recycling, it is necessary to check the local legislative requirements in this respect and strictly observe them.

6.6 REPAIRS

Only personnel who has appropriate approvals from the company SC KOLIBRI LLC can carry out repairs of faulty devices STARDEVICE®. Only original spare parts used by SC KOLIBRI LLC must be used for this purpose. Both employees of SC KOLIBRI LLC and the representatives of intermediaries and sales agents of SC KOLIBRI LLC can be the personnel who has the appropriate approvals.

6.7 SHELF-LIFE

The following shelf-life of the device and the components (with the mandatory fulfilment of the packaging, storage, transportation and use conditions set forth in this manual) is established according to the characteristics of similar equipment on the market, as well as the actual period of existence of the device STARDEVICE® (from 2013).

- 4 years or 10 000 operating hours - for the electronic unit of the device STARDEVICE®;
- 2 million shocks for the manipulator;
- 12 months for the tips.

The probability of failure of the components and the accessories of the device increases after exceeding of the shelf-life.

7 RECOMMENDED CLEANING MATERIALS

It is recommended to apply the following things to clean the tips:

- 70 - 96% water-alcohol solution;
- Medical alcohol wipes or cotton pads;

It is recommended to use wet wipes for monitors that do not contain alcohol to clean the display of the device STARDEVICE®.

8 GENERAL VIEW OF THE DEVICE

8.1 The device STARDEVICE®

8.2 The device STARDEVICE®-PC

8.3 The manipulator of the device STARDEVICE®

9 TECHNICAL DESCRIPTIONS

9.1 CLASSIFICATION OF THE DEVICE STARDEVICE®

The device belongs to the 1-st class with a working part of type BF according to the method of protection from electric shock.
The degree of protection against penetration of water or solid particles IP20.
The operating mode of the electronic unit of the device is long. However, the manipulator of the device is not designed for continuous operation. Maximum operating time of the manipulator is 10 minutes; the minimum time of an inactive state of the manipulator after work is 30 minutes.
The device belongs to the IIa class according to Directive 93/42 / EEC in terms of the degree of risk of medical use.

9.2 TECHNICAL DATA

The electronic unit	
Input voltage of the network	100-240 V alternating current ± 10%
Network frequency	50/60 Hz
The mains fuse	T4H250V
Electricity consumption	max.300 W
The ambient temperature during the operation process	5 – 40 °C

The ambient temperature during a storage and transportation	-25 ° C without relative humidity control + 70 ° C with relative humidity control This class 7K3 as described in IEC/TR 60721-4-7:2001
Ambient air pressure	700-1060 hectopascal
Air humidity	15%-93%, without condensation
Total weight	6,5 kg.
Net weight	5,1 kg
Dimensions of the device STARDEVICE® (D / W / H)	270x390x95 mm.
Dimensions in the working set (D / W / H)	270x500x240 mm
Dimensions of the packaging for transportation and storage	500x370x190 mm.
Protection against water penetration	IP20
Software version	V.1.3
The manipulator	
The frequency of the manipulator's work	4 Hz– 12 Hz
The ambient temperature during the operation process	5 – 40 °C
The ambient temperature during a storage and transportation	-25 ° C without relative humidity control + 70 ° C with relative humidity control This class 7K3 as described in IEC/TR 60721-4-7:2001
Ambient air pressure	700-1060 hectopascal
Air humidity	15%-93%, without condensation
Weight of the manipulator	700 gm.
Protection against water penetration	IP20

The mains switch of the device is the means of simultaneous electrical separation of the power circuits of the device STARDEVICE® from the supply network circuits.

The documentation for repair and service of the device STARDEVICE® (electric schematic diagrams, instructions for repair and calibration, etc.) is provided to the local representative of SC KOLIBRI LLC on request.

Minimum requirements to a computer, both for hardware and software, which are enough to use with MD

<table>
<tr><th colspan="2">Minimum hardware requirements</th><th>Minimum software requirements</th></tr>
<tr><td>HDD/SSD</td><td>min. 128 Gb (256Gb is preferable)</td><td>Operating system</td></tr>
<tr><td>RAM</td><td>min. 3 Gb and more</td><td rowspan="3">Windows 7 and higher, Window 10 is preferable.

It is necessary to have <u>administrator rights</u> for access to OS Windows.
If the user does not have permission to create/add/modify information on system C drive, the program SD will not be able to work stably.</td></tr>
<tr><td>Display</td><td>min. 12” and more
definition HD, FHD, QHD or more</td></tr>
<tr><td>USB ports</td><td>USB 2.0 or 3.0 and higher
PC should be equipped with 2 or more USB ports:
1 - for SD (if necessary, to connect SD via USB);
1 - for printer (optionally, if necessary)</td></tr>
<tr><td>Bluetooth</td><td>3.0 and higher</td><td>Antivirus software</td></tr>
<tr><td colspan="2">Medical grade computer is recommended for use in combination with the MD SD. In any case, the local regulations and requirements regarding computers in medical care institutions must be followed by the user.</td><td>Any antivirus software, if it is installed by a user, must be configurated in such a way, when the software StarDevice isn’t blocked.</td></tr>
</table>

9.3 STORAGE AND TRANSPORTATION

Transportation and storage of the device STARDEVICE® is only permitted in the manufacturer's packaging.

You should avoid shaking and impacting of the package during transportation and storage.

Storage and transportation conditions of the device:

- -25 ° C (without relative humidity control) to + 70 ° C (with relative humidity control),
- relative humidity 15% -93% without condensation
- And also, the absence of aggressive impurities that cause corrosion in the air.

10 WARRANTY COMMITMENTS

The warranty for the device STARDEVICE® is 36 months from the date of sale.

The warranty does not cover quickly wearing parts (the manipulator, tips), power cables and fuses.

The manufacturer or his authorized representative performs free repair of malfunctions or replacement of the device during the warranty period, if there is detection of manufacturing defects or defects in materials. The warranty for such a device does not apply if there are faults caused by the user, due to a violation of the operating rules of the device described in this manual, or the usage of the device for other purposes.

The warranty also does not cover damages caused by the user violating the storage and transportation rules set out in this manual, as well as the force majeure.

Warranty claims for quickly wearing parts are accepted only on condition that the manipulator or a tip is returned in its complete configuration, in its pure form, without external mechanical damages and traces of disassembly / opening.

Transportation costs and the risk of accidental loss during the delivery of the returned product shall be borne by the customer.

ATTENTION! It is not allowed to make any changes in the design of the device. Any unauthorized opening, repair or modification of the system by unauthorized personnel releases the manufacturer from his obligations and responsibility for the safe operation of the device. In this case, the warranty is automatically declared invalid even before the expiration of the warranty period. The warranty is cancelled if the customer has made a modification or made any uncoordinated changes to the software of the device without the written consent of the company SC KOLIBRI LLC.

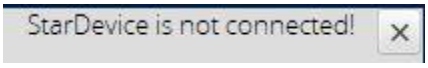
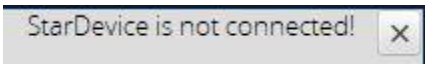
For all questions regarding the operation of the device, please contact our customer service:

Scientific company
KOLIBRI LLC
Prov. Kinnyi 8a. Kharkiv,
61001, Ukraine
Tel.: +380913011110
email: info@kolibri.one
URL: https://kolibri.cloud

EC REP

The official representative in the EU:
"ONKOCET Ltd."
4 Kutuzova str., 90201 Pezinok, Slovakia,
tel.: +421 (2) 44 64 09 77
Email: onkocet@onkocet.eu
URL: www.onkocet.eu

11 POSSIBLE ERRORS AND MALFUNCTIONS. WAYS TO RESOLVE THEM.

	Error / problem	Possible reasons	Indicators / Disposal
E1	**The correction / treatment session does not begin** 	The manipulator is not connected	***Indicator*:** the "Manipulator" line on the device's display is highlighted as red "Disconnected", a repeated warning signal sounds (sound power less than 85 dB). ***Disposal:*** Connect the manipulator to the device. The indicator changes color to green, "Connected" appears, the sound turns off.
E2	**The manipulator does not work**	The manipulator is not connected to the device	Connect the manipulator to the device (the same as E1)
		The mechanical parts of the manipulator are broken down	Contact the service center in your area or the manufacturer
E3	**The device does not turn on.**	No power supply	-Check the presence of an electrical current in the mains. In case of absence, try again later. - Check the connection of the power cord to the device and to an electrical outlet. - Check the network cable for defects if there are any and replace it.
		The refractory fuses are defective or missing	Check the installed refractory fuses; replace the damaged ones or install the missing ones.
		The device STARDEVICE® is not connected to the computer with a USB cable.	Check the connection of the device STARDEVICE® to the computer with a USB cable.
		Faulty USB cable.	Replace the USB cable with a working one

12 CHECKLISTS

No	Date	Comment	Remark	Performer	Sign
1.					

Director _____.

13 PRODUCT ACCEPTANCE PROTOCOL

The device STARDEVICE®, No. SD_____ complies with the technical requirements and is completely serviceable.
The warranty period is 36 months from the date of delivery of the equipment.

Date of manufacture "_____" _____ 20___.

Scientific company
KOLIBRI LLC
Prov. Kinnyi 8a. Kharkiv,
61001, Ukraine
Tel.: +380913011110
email: info@kolibri.one
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EC REP

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4 Kutuzova str., 90201 Pezinok, Slovakia,
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Email: onkocet@onkocet.eu
URL: www.onkocet.eu

14 PACKING LIST

The device **STARDEVICE**®, **№ SD** _____ is packed in the company SC KOLIBRI LLC in accordance with the technical requirements.

Date of packing «_____» _____ 20_____.

A packer:

Signature First name and Last name

Scientific company
KOLIBRI LLC
Prov. Kinnyi 8a. Kharkiv,
61001, Ukraine
Tel.: +380913011110
email: info@kolibri.one
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15 THE WARRANTY CERTIFICATE

For repair (replacement) during the warranty period
Medical Equipment - **STARDEVICE®**

Serial number of the device
SD_____

Date of manufacture

«_____» _____20___

Date of purchase
«_____» _____20___

Signature and seal of the seller

Date of commissioning
«_____» _____20___

Signature

The operating time of the device
_____ hours (the device)
_____ blows (the manipulator)

Signature

The warranty for the device STARDEVICE® is 36 months from the date of sale.

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The manufacturer or his authorized representative performs free repair of malfunctions or replacement of the device during the warranty period, if there is detection of manufacturing defects or defects in materials. The warranty for such a device does not apply if there are faults caused by the user, due to a violation of the operating rules of the device described in this manual, or the usage of the device for other purposes.

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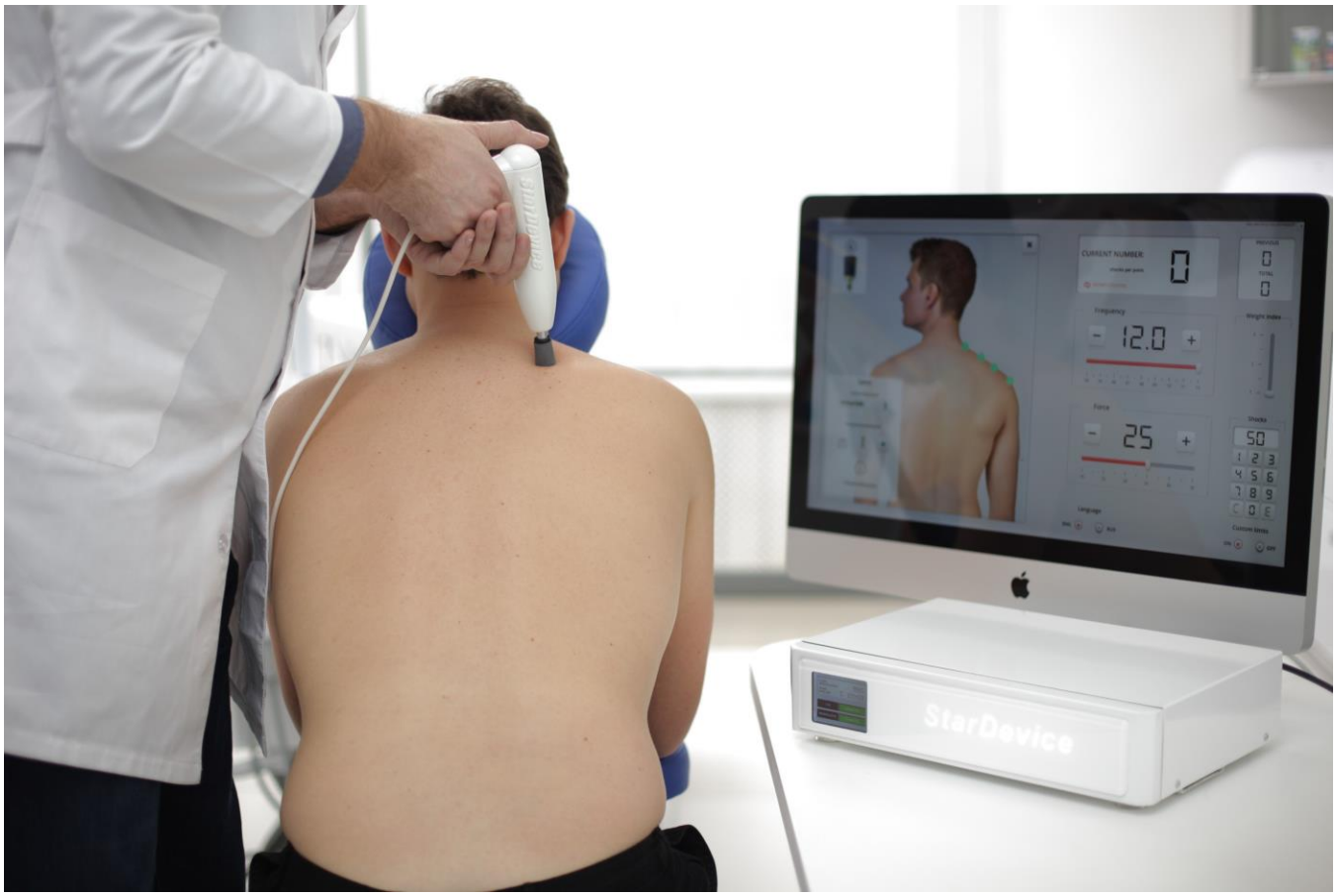
All valid permits and certificates are available on the manufacturer's website kolibri.one/certificate

16 PICTURES OF TREATMENT PROCEDURES



17 MARKING OF THE DEVICE STARDEVICE®

18 DECOMMISSIONING AND DISPOSAL OF SOFTWARE

To remove the program from your computer, use the standard procedure for OS Windows.
The software does not contain or store any personal data.

19 THE COMPLETE SET OF STARDEVICE

Name of a part		Quantity
	The unit of MD StarDevice and tips holder	1
	Power cable (Type C13)	1
	Manipulator	1
	Tips	9
	Software protected key (SPK)	1

	USB-A to USB-B cable	1
	Packaging for transportation and storage of the STARDEVICE® device	1
IFU (offered in electronic form available on web)		1

20 DOCUMENT HISTORY AND VERSION CONTROL

Version	Version Date	Summary of changes	Author	Related documents
1.0	2021-01-12	Created	Pulavskyi A, Kolyesnik O	