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Dear customer!

You have got "ALMAG-02" magneto-therapy device (hereinafter - device), intended for therapy of a wide range of diseases by low-frequency, low-intensity magnetic field.

The operating manual is the document identifying basic technical parameters, and characteristics, therapeutic indications and contraindications of the device guaranteed by manufacturing enterprise.

Besides the document let us learn about the device design, principle and rules of its operation the observance of which provides the device undisturbed operation.

1. DESTINATION

1.1 General information

The device is designed to be used for low-frequency, low-intensity magnetic field therapy. It is indicated for patients with cardiovascular, bronchopulmonary, nervous, loco-motor systems, internal organs acute and chronical diseases, immunity disturbance, traumatic injuries and their complications.

Device provides generation of continuous and discontinuous pulsed magnetic fields (traveling, fixed) differ in configuration, intensity, direction and speed of magnetic field traveling in space. The device ability to influence the large affected areas (extremities, body), the combination of this action together with the local one increases its magnetotherapy efficiency resulting in oedema and inflammation quick relief, process regeneration and immunity stimulation.

The device is designed to be used in both patient care and treatment-prophylactic institutions physio-therapeutic rooms, as well as at home conditions according to doctor prescription. Special training is not required to use the device.

The device is used in following environmental conditions:

- air temperature: from +10 °C to + 35 °C;
- air relative humidity; up to 80% at the temperature +25 °C.

1.2 Indication for application

Mental and behavioral disorders:

Neurocirculatory dystonia on hypertonic type

Illnesses of nervous system:

Migraine.
Transient transitional cerebral ischemic attacks and congenerous symptoms.
Affection of separate nervous roots and plexuses of upper and lower extremities.
Alcoholic polyneuropathy
Diabetic polyneuropathy
Postherpetic neuralgia
Raynaud`s syndrome (syndrome of hand “dead finger”)

Ear, throat and nose illnesses:

Chronic maxillary sinusitis (antritis), chronic frontal sinusitis (frontitis)
Acute and chronic eustachitis (salpingootitis)
Acute laryngitis
Chronic laryngitis
Sensorineural deafness

Illnesses of circulatory system:

Hypertensive disease
Stable angina of I-II stress functional class
Insult

Aftereffects of cerebrovascular illnesses
Vessels atherosclerotic illness, deforming or an obliterating endarteritis
Aterosclerotic encephalopathy
Varicose disease
Lower leg deep vein thrombophlebitis
Chronic thrombophlebitis accompanied with trophic disorders
Chronic lymphedema (lymphatic edema)

Illnesses of respiratory organs:

Virus pneumonia
Bacterial pneumonia
Chronic bronchitis non-acute condition
Bronchial asthma and chronic obstructive pulmonary illness
Exudative pleurisy (after liquid extraction from pleural cavity, three days later after theracocentesis)

Illnesses of digestive apparatus:

Reflux-esophagitis
Stomach and duodenum ulcer.
Gastritis and duodenitis
Chronic hepatitis
Toxic kidney affection
Syndrom of irritant large intestine without diarrhea
Liver alcoholic illness
Cholecystitis
Biliary dyskinesia
Gallbladder hypomotor dyskinesia (cholecystopathy without gall-stones)
Chronic pancreatitis
Syndrom of operated stomach
Postcholecystectomy syndrom

Illnesses of the skin and subcutaneous fat:

Keloid cicatrix
Lichen ruber planus
Limited neurodermatitis, skin itch, nettle-rash, eczema, neurodermatitis, prurigo, atopic dermatitis
Psoriasis
Hydradenitis

Osteomuscular system and the connecting tissue diseases:

Podagra
Polyarthrosis
Coxarthrosic
Gonarthrosis
Arthrosis of the first carpometacarpal joint
Internal and external (tennis elbow) (golf elbow) humeral epicondylitis
Scapulohumeral periarthrosis
Acute trophoneurotic bone atrophy (Sudeck`s atrophy)
Paratenonitis (crepitant forearm tendovaginitis)
Tietze`s syndrom (aseptic coatal cartilage inflammation in the area of rib joining to sternum, more often II-IV ribs with the painful thickening)
Osteochondropathy (Celer disease, Kienböck`s disease, Perthes`disease, Schlatter disease, Cenig disease)
Ankylosing spondylitis (Bechterew`s disease)

Temporomandibulat joint osteoarthrosis
Calcaneal periosteosis, heel spur
Joint contracture (Dupuytren`s conracture)
Rheumatic ioint inflammation
Spinal column osteochondrosis
Cervical migraine
Vertebro-Вертебро-basilar syndrom
Vertebrogen myelopathy syndrom
Osteoporosis with pathologic fracture
Osteoporosis without pathologic fracture

Urogenital system diseases:

Chronic tubulointerstitial nephritis (tubulointerstitial and tubular injuries caused by medicinal agents and heavy metals)
Renal and ureteral caluluses
Cystitis
Salpingits and oophoritis

Traumas:

Wounds (after surgical treatment of wound)
Injuries (after surgical treatment of wound)
Post-traumatic hematoma (2-3 days after trauma)

Elbow and forearm traumas:

Elbow joint capsular-ligamentous apparatus dislocation, sprain, defatigation.
Transradial styloid dislocation
Radial collateral ligaments traumatic rupture

Nerves trauma on the level of forearm:

Elbow nerve trauma on the level of forearm

Wrist and hand trauma:

Hand`s fingers hurt without nail plate injury
Hand`s fingers hurt with nail plate injury

Body traumas:

Upper extremities surface traumas
Lower extremities surface traumas

Pelvic, thigh, hip joint area traumas:

Hip joint hurt
Thigh bone hurt
Traumatic coccygodynia
Clarified and non-clarified part of lower leg hurt
Lower leg multiply surface traumas
Knee-joint dislocation

Ankle joint and foot area traumas:

Ankle joint hurt
Foot toes hurt without nail plate injury
Foot toes hurt with nail plate injury
Ankle joint and foot multiply surface traumas
Ankle joint dislocation
Joints rupture on the level of ankle joints and foot
Ankle joint strain and overstrain

Nerves trauma on the level of ankle joint and foot:

Lateral plantar nerve trauma
Medial plantar nerve trauma

Deep fibular nerve trauma on the level of ankle joints and foot

Several nerves traumas on the level of ankle joints and food

Big toe musculus extensor and its tendon trauma on the level of ankle joint and foot

Several muscles and tendons trauma on the level of ankle joint and foot

1.3 Contraindications:

– hemorrhage and coagulopathy;
– blood systemic diseases;
– malignant new formations;
– cardiac rate severe disorders (fibrillation, paroxysmal tachyarrythmia);
– cardiac aneurism, aorta and big vessels aneurism;
– myocardial infarction acute period;
– ischemic and hemorrhagic stroke acute period;
– purulent processes, acute tuberculous process, infection diseases acute stages, febrile diseases;
– thyrotoxicosis;
– pregnancy;
– implanted cardiostimulator.

Attention!

- The application of "ALMAG-02" device pulsed magnetic field is not contraindicated on the back ground of both the chemotherapy and ray therapeutics course!
- The presence of stents or the condition of post coronary artery grafting is not considered as contraindication to device application.

1.4 Magnetic field physiologic and therapeutic effect mechanism:

The magnetic field effect on the human body is characterized by:

- individual sensitivity of the body to magnetic field exposure;
- magnetic field remedial effect on human organism and its functional systems;
- the degree of therapeutic efficiency in organism is more evident in case of an alternating and pulsed magnetic field compared to a permanent one;
- trace character of a magnetic field effect. After a magnetic field single exposure the body response lasts for 1-6 days, and after a procedure course – 30-45 days, this fact provides the necessity of interval between repeated procedure courses in chronic diseases treatment.

Magnetic field exposure on background of organ or system hypo-function resulting in its normalization, while the application of the magnetic field in the condition of depressed system is followed with its hypo-function.

The response of various organs and systems to a magnetic field effect is not similar. Selectivity of the body response depends on tissues electric and magnetic properties, the difference in their micro-circulation, metabolism intensity.

According to various organs and systems sensitivity to a magnetic field exposure nervous system takes the first place, then goes endocrine system which is followed by sense organs, cardiovascular system, muscular, digestive, excretory, respiratory and bone systems.

Magnetic field effect on nervous system central parts and reflector zones is characterized by the change of body behavior, its conditioned-reflex activity, physiologic and biologic processes. The most apparent response of central nervous system is ob-

served in hypothalamus followed by cerebral cortex, hippocamp, midbrain reticular formation. This somehow explains a complicated mechanism of body organism response to magnetic field exposure as well as dependence on its initial functional state, nervous system being in the first place. These are due to stimulation of inhibition processes declaring themselves in sedative effect and favorable action of magnetic field on sleep and emotional state.

As regards hypothalamus, magnetic field causes synchronization of secretory cell activity, synthesis increase and neurosecretion release from its nuclei. Simultaneously, functional activity of all hypophysis lobes. However, in case of durable and powerful (more than 70mTl.) exposure there may be inhibition of neurosecretory function and the development of productive-dystrophy processes in the cells of central nervous system.

Under the effect of magnetic field with low-intensity induction there are decrease of cerebral vascular tension , improvement of cerebral blood supply, activation of nitrogenous and carbohydratephosphoric metabolism which results in brain stability to hypoxia. When exposing to cervical sympathetic ganglia, suboccipital and transcerebral area magnetic field causes the improvement of cerebral blood flow (rheoencephalography findings). Apparent improvement of cerebral hemodynamics has neen noted when applying a magnetic field to suboccipital area in patients with circulatory insufficiency in vertebrobazilar system. So alternating magnetic field exposure can also result in improvement of hemodynamics with different pathological state.

Peripheral nervous system responds to the magnetic field effect by:

– decreased sensitivity of peripheral receptors thus providing an analgesic effect with traumas;

– improvement of conductance function facilitating a favorable effect on functional recovery of injured peripheral nerve endings due to accelerated axon growth, myelinization and inhibition of connective tissue growth.

Stimulation of hypothalamo-hypophysial system provokes chain reaction activating peripheral endocrine glands-targets under the influence of releasing factors, the synthesis of which is stimulated in hypothalamo- hypophysial system followed by numerous ramified metabolic reactions. When endocrine system is effected by an alternating magnetic field with the induction up to 30mTl. And frequency of 50Hz, the the exposition time being max.20 minutes there is the development of training reaction and inncreased activity of all branches of endocrine systems.

Stimulation of thyroid gland function is noted being exposed by a magnetic field in contrast to a inhibitory effect of many other stimuli, this considered as a precondition for magnetic complex therapy in case of its hypofunction.

Showing only a slight activation at the beginning of a magnetotherapy course sympatheticoadrenal systen begins to form inhibition of peripheral adrenoreceptors by the 7th-9th day of treatment which is of great significance in producing antistress effect.

Under the action of alternating (trans-cerebral exposure on collar area) and travelling pulsed magnetic field (on collar area) there is reaction from the side of cardiovascular system giving the basis to make the conclusion of these fields reflex nature effect.

Pressure decrease in the system of deep and subcutaneous veins as well as in arteries is noted. Simultaneously, vascular tension increases, elastic properties and bioelectric resistance of vascular walls change. Hemodynamics alteration, hypotensive effect in particular, is due to the development of bradycardia effect and thanks to the reduction of contractile myocardial function. This property finds its application in hypertension therapy and when heart stress is to be reduced.

Magnetic field produces changes in microcirculatory channel of numerous tissues. At the beginning of a magnetotherapy course a short-term (5-15 minutes) retardation of capillary blood flow occurs followed by microcirculation intensification. During and upon the termination of the magneto-therapy course there are acceleration of capillary blood flow; vascular walls contractile capacity improvement, vascular blood filling increase. The lumen of functioning components in the microcirculatory channel becomes larger, conditions promoting the opening of preexisting capillaries, anastomoses and bypasses develop.

Under the effect of magnetic fields there is increase of vascular and epithelial permeability leading to accelerated resolution of edemas and injected medicinal preparations. Thanks to this effect magnetotherapy began to be widely used to remove edemas of different aetiology (traumatic and inflammatory).

The exposure of a permanent, an alternating and a travelling pulsed magnetic field stimulates metabolic processes in the area of bone regenerative tissue (in case of bone fractures), and the earlier development of fibro-and-osteoblasts is noted in the regeneration zone, the process of bone substance formation being more intense even at the earlier stages.

Under the effect of magnetic fields there is the change of blood rheological properties. Hypocoagulatory effect is noted due to:

- activation of anticoagulative system,
- reduction of intravascular parietal thrombogenesis,
- decrease of blood viscosity through the effect produced by magnetic fields of low intensity on enzymatic processes, electric and magnetic properties of blood corpuscles participating in hemocoagulation.

Magnetic field produces a considerable effect on body metabolism. When exposed to a particular system it increases the protein and globulin content in blood serum raising their tissue concentration owing to α- and γ- globulin fractions. This is accompanied by protein structure change. Short-term daily general effects of magnetic fields decrease the content of pyruvic and lactic acids not only in the blood but also in the liver and muscles. This is not accompanied by the increase of glycogen content in the liver.

Magnetic field effect reduces the number of *Na*-ions with simultaneous increase of *K*-ions concentration which indicates the change of cellular membrane permeability.

Fe concentration reduction in brain, heart, blood, liver, muscles, spleen is noted with its increase in bone tissue. Such Fe-redistribution is associated with the hemopoietic organs state change.

This is accompanied by *Cu*-concentration increase in the cardiac muscle, spleen and testicles leading to the activation of adaptation-compensatory processes in the body. *Co*- concentration is decreased in all organs and its redistribution between blood, individual organs and tissues occurs. There is increase of Mg biological activity under the influence of magnetic field. This results in reduction of pathological processes in liver, heart and muscles.

It has been noted that low induction magnetic fields stimulate the processes of tissue respiration changing the ratio of free and phosphorylation oxidation in the respiratory tract. Nuclein acid metabolism and protein synthesis are intensified producing the action on plastic processes.

Metabolism activation of carbohydrates and lipids is considered to be a characteristic feature of magnetic effect on human body. This is proved by increased concentration of nonesterificated fatty acids and phospholipids in the blood and inner organs as well as by blood cholesterol reduction.

Thus,magnetic field short-term exposure make diverse effect on body organs ans systems thus facilitating the development of favorable effects. The most evident and clinically significant are:

- sedative,
- hypotensive,
- antiinnflammatory,
- antiedematic,
- trophicoregenarative.

Under certain condition, e.g. when exposing the large vessels, magnetotherapy produces deaggregation and hypocoagulation effect, improves micro-and-regional circulation, favourably effects immunoreactive and neurovegetative processes.

Megnetic field exposure generally does not provoke endogenic heat, temperature rise or skin irritation. It is well tolerated by weak and elderly patients suffering from concomitant cardiovascular diseases which allows the devices to be applied when other physical procedures are contraindicated.

2. INTENDED USE

2.1 Device preparation for work

After device storage in the cold premise it should be kept for two hours at the room temperature.

Disinfection of the the device outer surfaces (if required) is to be carried out with their twice wiping by the calico napkin, moistened in solution, with 10-15 minute interval between wiping (the napkin should be wrung out in order to prevent disinfection solution to be penetrated inside the device).

2.2 Device operation order

Before device application be sure of its serviceability: check the ability both to set program and formation of magnetic induction according to corresponding indication arranged on power and control block-unit and emitters pulse generation block-unit.

The application of the device

Connect emitters, required for treatment procedure, to the device (the optimal variant - connect all available emitters to the device, not required ones will be simply deactivated). The basic emitter is to be connected to connector «1» and the flexible stripe-line and local emitter are to be connected to connectors «2» and «3» in random order (Fig.1).

ATTENTION

To exclude emitters improper connection, pay attention to marking signs «1», «2» and «3» on the emitters` connectors. They should be turned upwards.

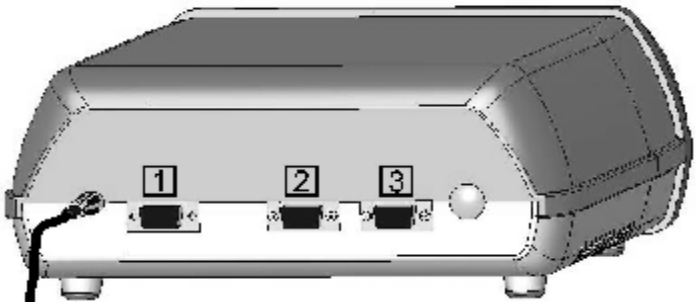

Fig. 1

Then, switch the device power on with a help of switch “POWER”. Activation state indicators start to light on emitters pulse generation block-unit and the number of the last used program is displayed on the power and control block unit indicator. The point will light in the indicator right bottom corner (Fig. 2).

Fig. 2 Point

With a help of buttons «←» и «→» set number of required program **according to Application manual.**

Note: realization of programs beginning from 51 to 79 is possible when we use local emitter (shipment variant №2).

The required emitters are to be placed on the patient body subject to magnetic field marking in accordance with selected procedure.

Press «**ON/OFF**» it is followed with indicator of magneto-therapeutic exposure lighting, and display of time left for the procedure termination in the LED indicator, the point in the right bottom corner stops lighting (Fig. 3). Emitters required for taking procedure are left activated and the device begins the formation of set magneto-therapeutic exposure. Only emitters required for taking procedure are left activated by the device and it begins the formation of magneto-therapeutic exposure setting.

Activation indicator and magnetic field formation indicators will light on activated emitters.

Note:

- In case the emitter required to carry out procedure is not available or there is malfunction in the device operation, the device generates audible indication and displays the malfunction code on the indicator.

- Magnetic field presence on the emitting stripe-lines working surfaces can be checked with a help of magnetic field indicator. For this you should choose the program (in accordance with the application instruction) with the magnetic induction value not less than 25mTl. Putting magnetic field indicator to the working surfaces of emitting stripe-lines coils (assembly exposure units) you can see the blinking of its light emitting diode proving the magnetic field presence.

When the exposure time, set by the program, be counted there will be formation of audible indication on procedure termination, both indicator of magneto-therapeutic exposure on the control panel and magnetic field indicators on emitters pulse formation block-unit will dim, and the program number will display again in the LTD indicator (with a point in the right bottom corner).

Take the emitter off the patient body after the procedure termination.

Fig. 3 No point

If the next procedure of magnet-therapeutic exposure is not followed, switch the power and control block- unit off, pressing switch "POWER" on the front panel.

For emitters flexible stripe-lines convenient arrangement on the human body you can use emitters accessories set. The arrangement of these accessories is shown in the fig.4.

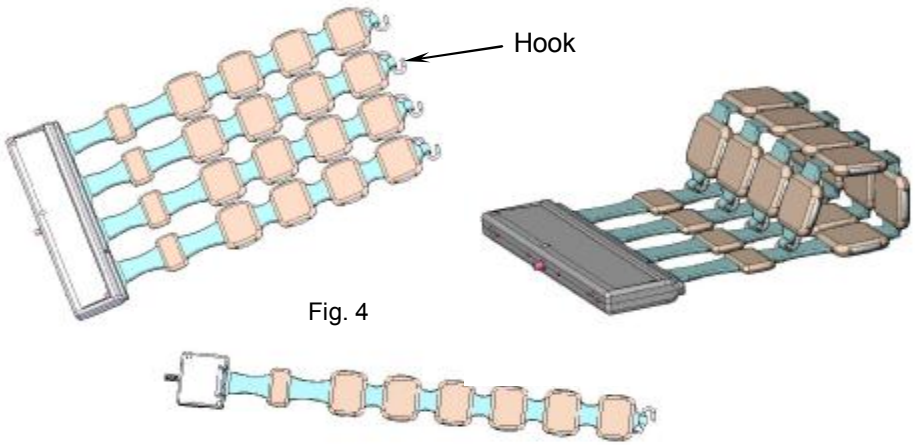

Fig. 4

The scheme of putting emitters back into the case

Place the emitter with surface “N” downwards on case and insert flexible stripe-lines ends into case`s loops

Cover emitter with the case top part (Fig. 5), drawing attention to loop parts `coincidence with hook loops of the corresponding “adhesive tapes”. Press the top part of case to the bottom one in the places of “adhesive tapes” arrangement for effective fixation (Fig. 6).

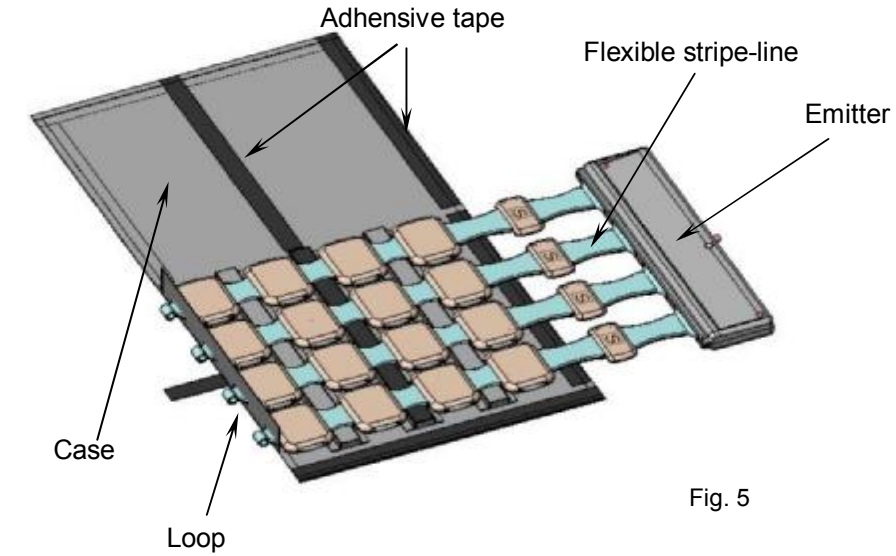

Fig. 5

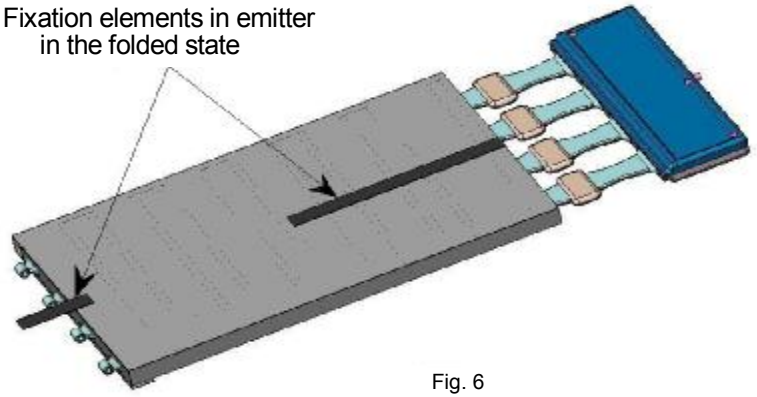

Fig. 6

For procedure convenience, local emitter inductors can be fixed on the handle (fig.7a) or in the support (Fig 7b). The support consists of holder with crew, stand and basis.

To fix inductor to the support use the holder thread segment (crew the holder into inductor and place it on the support stand).The location of the inductor on a support (throughout the height) can be varied with the help of the holder screw for what loosen the holder screw, place the emitter`s inductor to the necessary height and fix the holder in the given position by the screw.

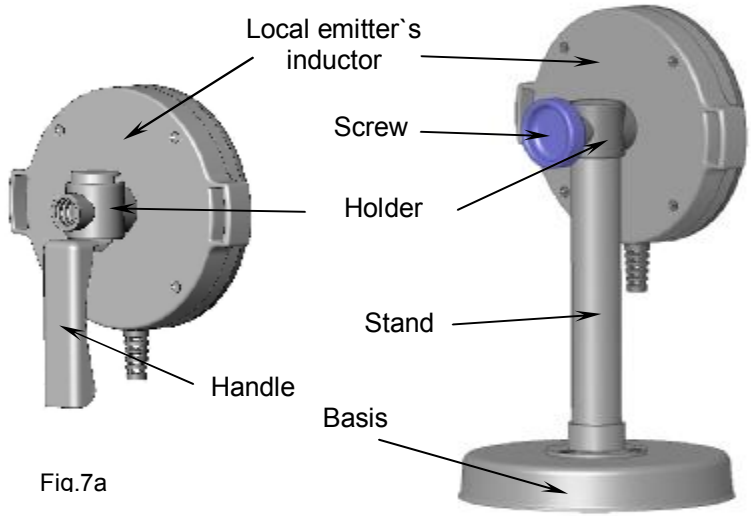

Fig.7a

The device has the functions of self-diagnostics, in case of malfunction, the exposure mode stops, on the indicator the error code is displayed, and you can hear sound signal. The list of malfunctions and a method of their elimination are given in table 1.

Таблица 1

The name of malfunction, its external manifestation and additional signs	Malfunction the probable reason	Method of elimination
1. The alarm sound signal is generated and in the indicator there is an inscription: "E1"	- There is a bad contact in the basic emitter connector. - Beak in the connecting cable.	- Switch the device off. Check the connector fixation. Switch the device on. - Apply to service office.
2. The alarm sound signal is generated and in the indicator there is an inscription: “E2”	- There is a bad contact in connector of both flexible emitting stripeline or local emitter. - Beak in the connecting cable.	- Switch the device off. Check the connector fixation. Switch the device on. - Apply to service office.
3. The alarm sound signal is generated and in the indicator there is an inscription: “E3”	- Malfunction of the basic emitter.	- Apply to service office.
4. The alarm sound signal is generated and in the indicator there is an inscription: “E4”	- Both flexible emitting stripe-line or local emitter malfunctions.	- Apply to service office.
5. The alarm sound signal is generated and in the indicator there is an inscription: “E5”	- The absence of the required emitter for procedure.	- Switch the device off. Correct the attachment of required emitter. Switch the device on

3. SAFETY MEASURES

- Prior to the device application study the operating manual carefully.
- Be sure of the absence of cables, plug, mains cord, emitters bodies, power and control block-units body mechanical damages. It is **FORBIDDEN** to use the Device with the presence of these damages.
- When treating the outer surfaces of the Device with disinfectants avoid moisture penetration inside both the power and control block- units and emitters. Protect the Device from dampness, shock and impact and open fire contact
- The device is to be arranged in the places convenient to exclude the cable tension when you plug it to mains. You should use only operative mains socket. The working mains voltage: ~220 V (±10%), frequency 50 Hz.

IT IS FOBIDDEN:

- lift or carry the device by the power cable;
- to twist emitters connecting cables;
- to switch the device on if the plug and socket do not match each other;
- to unplug the device by the power cord;
- to touch the bared plug pins just after device disconnection;
- to move the emitters in the process of magneto-therapeutic procedure;
- to place the activated device next to (less 0,5m.) data carrier, audio and video sets

Attention! In order to avoid the device failure it is FORBIDDEN to switch it on when the position of emitter cables connectors connected to power and control block-unit are not fixed with a help of crews.

Attention! It is FORBIDDEN to operate a device at the ambient air more than +35 °C.

Attention! For the time of magnetic exposure the ACTIVATED EMITTERS should not be at min.0,9m distance from the OPERATOR.

Attention! Use the disinfected fabric to protect the patient`s contact to the emitters accessible parts.

4. SPECIFICATIONS

4.1 The device is serviceable at mains alternating circuit voltage 220V (-10%; +10%), frequency 50Hz.

4.2 Device power consumption: 50±7,5 VA.

4.3 Pulsed magnetic field parameters and characteristics.

Induction amplitude value on the emitter inductors surface:

a) for «traveling» field type:

- for basic emitter and flexible emitting stripe-line: from 2 to 25 mTl.

b) for«fixed» field type:

- for basic emitters and flexible emitting stripe-line: from 2 to 6 mTl.
- for local emitter: from 2 to 45 mTl.

Absolute deviation of induction amplitude value on the inductions surface for values from 2 up to 20 mTl from set one (A) is in the ranges ±[0,2A +0,6] mTl, for values from 25 up to 45 mTl. is in the ranges ±6,3 mTl;

Magnetic field pulses repetition frequency:

For the basic emitter and flexible emitting stripe-line:

a) for «traveling» field type:

- from 1 pul./s. to 75 pul./s with induction of 25 mTl;
- from 1 pul./s. to 100 pul./s with induction of 2-20 mTl;

b) for«fixed» field type:

- from 1 pul./s. to 16 pul./s. with induction of 2-6 mTl;

For local emitter:

- from 1 pul./s. to 50 pul./s with induction of 35-45 mTl;
- from 1 pul./s. to 100 pul./s with induction of 2-30 mTl.

Relative deviation of magnetic field pulses repetition frequency is in the ranges ±5%;

4.4 Total magnetic exposure time intervals range: from 1 to 30 min. Treatment course time exposition relative deviation is in the ranges ±5%.

4.5 Device provides the nonvolatile storage of 79 exposure programs including the magnetic field set parameters and types, as well as the time of total exposure.

4.6 Temperature of the emitters surfaces, max.: 41 ºC.

4.7 Device operating mode time setting, max.: 30 s.

4.8 There are magnetic field polarity marking: «N» – north, «S» - south on the device emitters.

4.9 The device provides identification of the basic malfunctions, their signaling and exposure mode automatic stop.

4.10 The device provides the indication of parameters and modes as follows:

- program number;
- exposure time ;
- malfunction code;
- availability of magneto-therapeutic exposure;

- emitters activation /dis-activation ;
- generation of the magnetic field in the emitters;

4.11 Mean service life - five years.

4.12 The outer surfaces of the device component parts are stable to disinfection by chamical solution allowed in medical practice for products made of plastic and metal.

4.13 Overall dimensions and weight of the device component parts are given in the table 2:

Таблица 2

The name of the component parts	**Overall dimensions, mm, max.**				**Weight, kg, max.**
	diameter	length	width	height	
Power and control block-unit		250	300	120	3,0
Basic emitter		410	730	35	4,0
Flexible emitting stripe-line		110	950	35	1,0
Local emitter, including:					1,8
- coil		165	140	50	
-pulses generation unit		110	100	50	
- connective cables between coils and pulses generation unit		2000			
Support	190			220	0,6
Case		520	880	30	0,15
Hook	7	45		60	0,03

5. COMPLETE SET

Product complete set and its possible delivery variants are given in the table 3.

Table 3

Name	Delivery	
	Variant of delivery №1	Variant of delivery №2
Power and control block-unit	1	1
Basic emitter	1	1
Flexible emitting stripe-line	1	1
Magnetic field indicator	1	1
Local emitter	-	1
Handle (for carrying)	1	1
Handle	-	2
Support	-	2
Case	2	2
Hook	5	5
Elastic medical bandage	-	1
Operating manual	1	1
Application instruction	1	1

Attention! *Delivery variant 2 does not include local emitter, handle, stand and medical elastic bandage.*

6. ARRAGEMENT and OPERATION

In the variant of delivery №2 the device consists of power and control block-unit (fig. 9) and emitters of three types (fig. 10, 11, 12).

Basic emitter contains flexible emitting surface, consisting of 4 flexible emitting stripe-lines of 4 inductors each (fig. 10). For ease of handling, the basic emitter is placed into the special case (fig. 11). Emitter in the form of separate flexible emitting stripe-line contains 6 inductors (fig. 12). Local emitter contains two inductors (fig. 13).

Emitters` design in the form of flexible emitting surface and flexible emitting stripe-line let them be wrapped around extremities or unwrapped on the body exposure. The areas of magnetic exposure are: lower and upper extremities, waist, vertebral column, cervical spine, back and chest. The local emitter in the shape of “washer” provides only local, concentrated action. Pulsed magnetic field generated by local emitter has the deeper penetration as compared with that one generated by the other emitters.

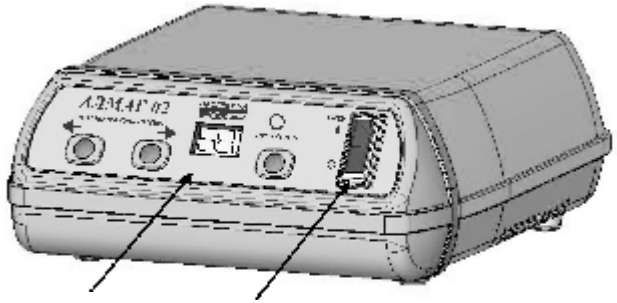

Fig. 9

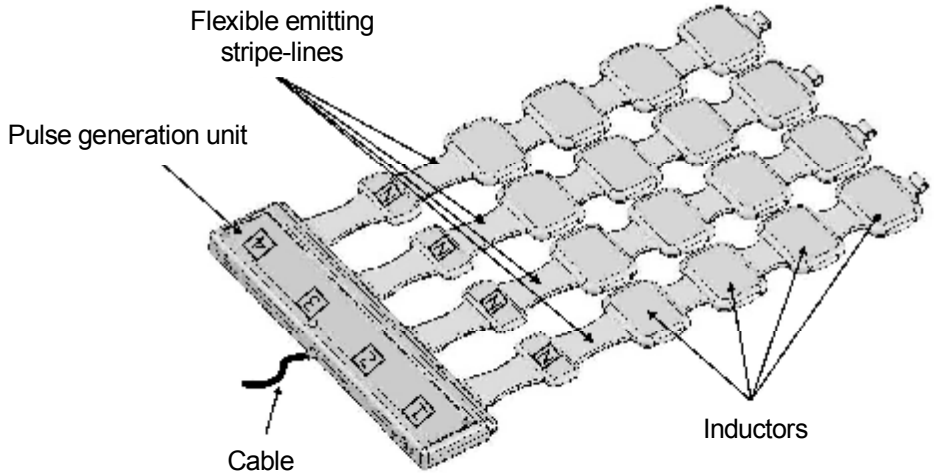

Fig. 10

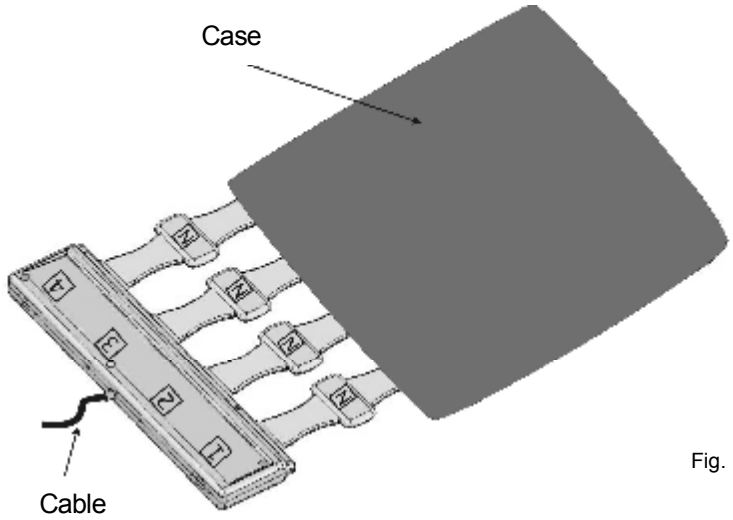

Fig. 11

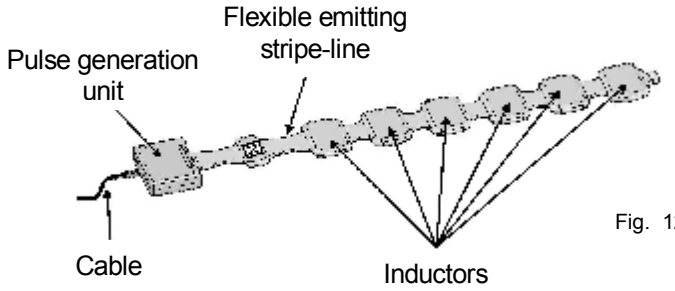

Fig. 12

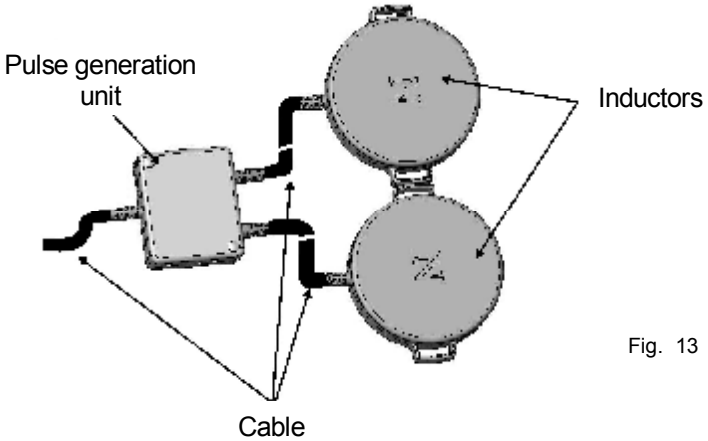

Fig. 13

⚠ For easy displacement use the handle (fig. 14).
Attention! *In order to avoid injury you should be careful in emitters operation. The emitter is to be carried by two hands: one hand on the handle, and the second one on one of the end surfaces of pulse generation unit body.*

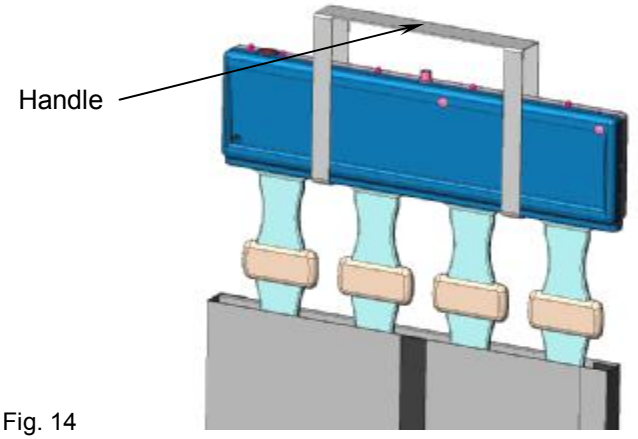

Fig. 14

The device generates two types of pulsed magnetic field - «traveling» and «fixed».
In the basic emitter "traveling" magnetic field has scans of three types:
- «traveling horizontal» (fig. 15) - simultaneous excitation of all inductors in one stripe- line with the following one-way excitation of all inductors of the neighboring stripe-line according to the cyclic law, cycle for this scan type makes up four "step" excitation of inductors` stripe-lines (according to the number of stripe-lines in the emitter);

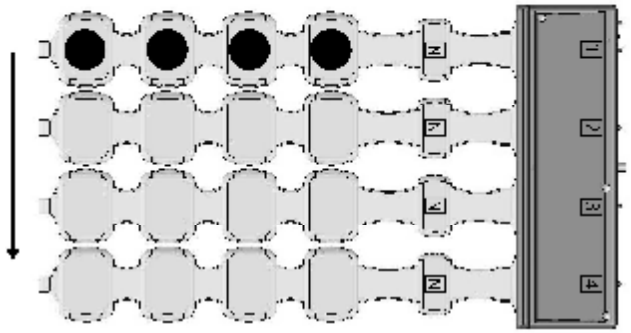

Fig. 15

- «traveling vertical» (fig. 16) - simultaneous excitation of the same name coil-inductors in all stripe-lines (coils assembly exposure unit) with the following one-way excitation of the neighboring coil-inductors according to the cyclic law, cycle for this scan type forms four “step” excitation of neighboring coil- inductors (according to the number of coil-inductors in the stripe-line);

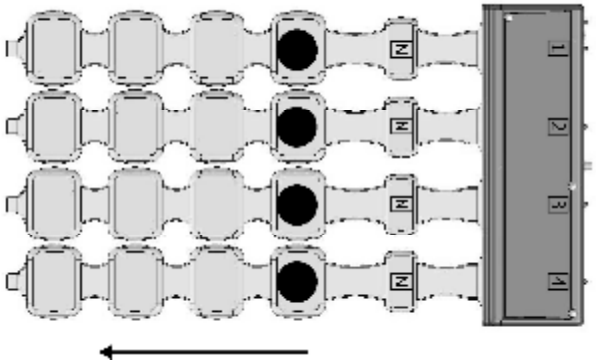

Fig. 16

- «traveling diagonal» (fig. 17) - sequential excitation of the coil-inductors, being placed diagonally, with the following one-way excitation of the neighboring coil-inductors according to the cyclic law; cycle for this scan type forms coil-inductors seven “step” excitation (according to the number of coil-inductors excitation possible combination: 1-2-3-4-3-2-1).

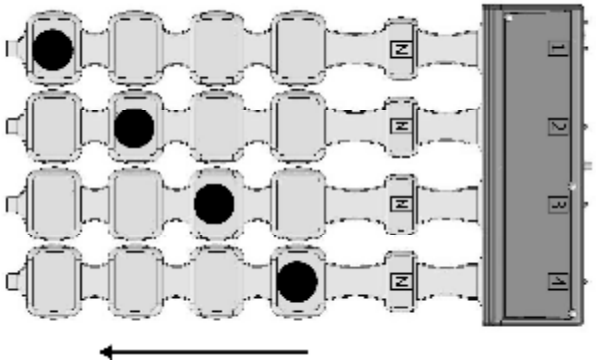

Fig. 17

In “traveling” field flexible emitting stripe-line (fig. 18) - coil-inductors excitation according to cycle low in one direction; cycle for stripe-line forms six “step” excitation of the neighboring coil-inductors (according to the number of coil-inductors in the stripe-line).

Fig. 18

Note: *pulsed magnetic field in the device emitting stripe lines - is traveling only in one direction. To change the direction of field area it is necessary to change arrangement of the emitter , e.g. as it is shown in the fig.19. At the same you should pay attention both to "north-south" marking, flexible stripe-lines numeration and place emitters in accordance with application manual.*

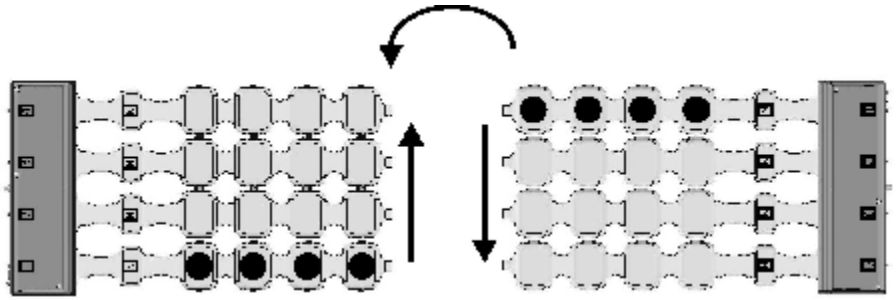

Fig 19

«Fixed field» (fig. 20) - simultaneous excitation of emitters all inductors.

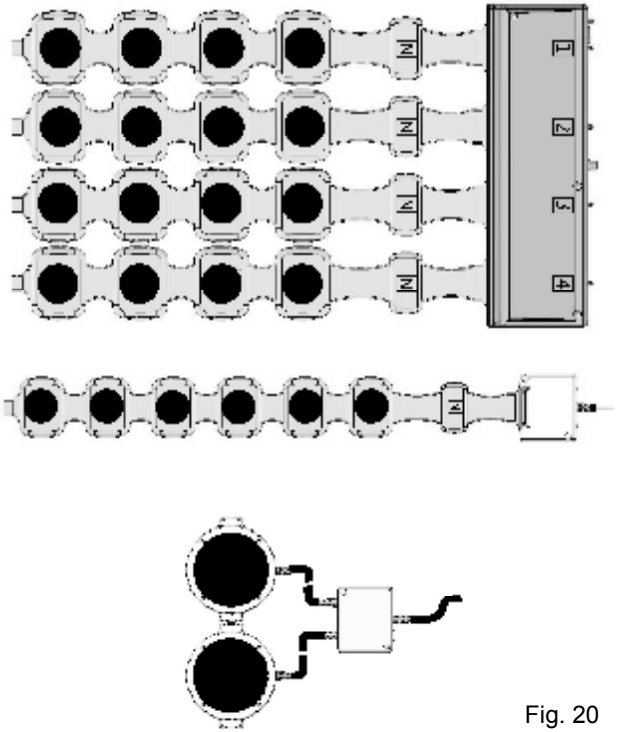

Fig. 20

Function of control and indication units

On the power supply and control block-unit panel there are control and indication organs as follows: (fig. 21):

1 - Mains switch;

2 - «←» button - program number setting (in the direction of the number down-growth);

3 - «→» button - program number setting (in the direction of number up-growth)

4 - «**ON/OFF**»button - magneto-therapeutic exposure activation/dis-activation;

5 - LED indicator with the display, depending on operating mode, either the program number or exposure time according to selected program, or malfunction code on it;

6 - magneto-therapeutic exposure indicator.

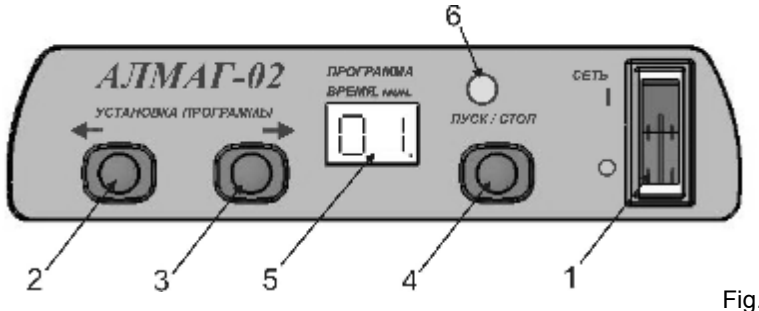

Fig. 21

On the basic emitter pulse generation unit body there are: (fig. 22):

1 - four magnetic field generation indicators in each of the stripe-lines;

2 - activation state indicator.

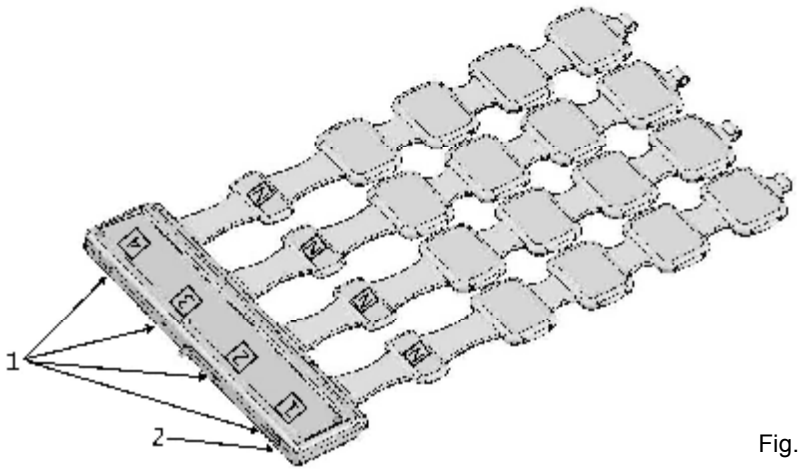

Fig. 22

On flexible stripe-line pulses generation unit and local emitter there are (fig. 23):
1 - indicator of magnetic field generation in stripe-line / local emitter;
2 - activation state indicator.

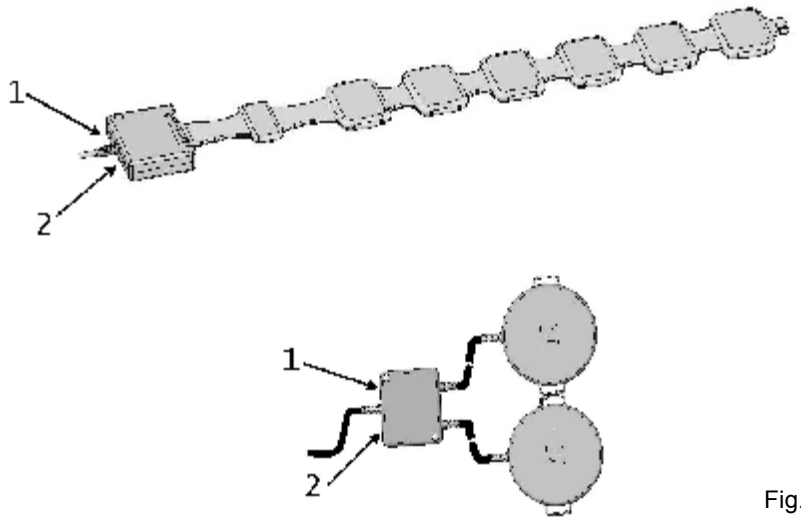

Fig. 23

Marking
The device has the signs as follows:

"Class II product".
Sign identifying the device safety class as Class II device according to ГОСТ Р 50267.0-92 (IEC 601-1-88);

Sign denoting the necessity to apply to operating documents according to ГОСТ Р 50267.0-92; in accordance with IEC 60601-1:2005 it is device safety and operation efficiency related warnings;

"The working part of BF type".
Sign defining the device working part as BF type according to electrical shock protection ГОСТ Р 50267.0-92 (IEC 601-1-88);

Sign indicating necessity to apply to operational documents according to IEC 60601-1:2005.

7. MAINTENANCE SERVICE

Maintenance service of the device includes repair, routine inspection, dust and a dirty clearing, disinfection and the periodic inspection of its serviceability.

The periodic inspection of the device state of operability is carried out not less than once a year. For what it is necessary:

- to connect emitters to the device and arrange them to provide easy access to all emitters` coil-inductors;
- to plug the device and press “POWER” button to switch the device on;
- to select exposure program which involves the basic emitter and the flexible emitting stripe-line (preference is to be given to the program with the maximal induction of a magnetic field and pulses maximal pulse-repetition frequency setting parameters);
- to activate magneto-therapeutic exposure ;
- to check the availability of field in each of the used coil-inductors with the help of magnetic field inductor;
- to stop exposure;
- to select the exposure program which involves the use of local emitter (preference is to be given to the program with the maximal induction of a magnetic field and pulses maximal pulse-repetition frequency setting parameters);
- to activate magneto-therapeutic exposure;
- to check the availability of field in each of the used coil-inductors with the help of magnetic field inductors;
- to stop exposure;
- press “POWER” button to switch the device off and unplug the device.

Routine inspection is made not less than once three months. You should pay special attention to cables, plug, mains cord,emitters and control block-unit body integrity.

Disinfection is to be carried out when it is necessary

8. ROUTINE MAINTENANCE

Device routine maintenance is carried out under the Agreement between medical establishment and the manufacturing plant or its agency after the nature and the degree of the device malfunction technical survey by manufacturer`s representatives

The device malfunctions may be:

- body`s mechanical damages;
- emitters flexible stripe-lines mechanical damages;
- emitters` cables and mains cord mechanical damages;
- impossibility of program exposure setting;
- the absence of exposure process indication;
- emitters` inductors local overheating.

Malfunctions during routine maintenance are eliminated by elements and details replacement or restoration, device adjustment in conformity with the data of the present manual.

After the repair termination the device is delivered to the user with the determination of warranty period which starts from the date of its delivery.

9. STORAGE AND TRANSPORTATION

The device stands the storage in the non-heating premises at the environment temperature from -50 °C to +40 °C, relative humidity : up to 98%.

the device is transported by all covered transportation facilities in accordance with cargo transportation rules for the condition 5 according to ГОСТ 15150-69 at the ambient temperature between - 50 °C - +50 °C and relative humidity max. 98%.

ACCEPTANCE CERTIFICATE

"ALMAG-02" magneto-therapeutic device works serial No. _____ is manufactured and accepted in conformity with ГИКС.941519.104 ТУ and is recognized as ready for operation.

☐ Variant of shipment №1

☐ Variant of shipment №2

Date of output _____

_____
(signature of the person responsible for acceptance)

Seal

"ALMAG-02" magneto-therapeutic device is packed in accordance with the requirements of design documentation.

Package date _____

The package is done by _____

Seal

11. MANUFACTURER'S WARRANTY

The manufacturer guarantees the conformity of the device quality to the requirements of the user manual`s clause “Technical characteristics” provided the user`s maintenance conditions of proper usage, transportation and storage.

During the guarantee period the manufacturing works undertakes to eliminate any malfunctions by means of repair or complete or partial replacement of its component parts at their own expense on against the presentation of guarantee coupon.

Guarantee conditions

The warranty is valid provided the availability of right filled-in guarantee coupon having the serial number, date of sale and a clear stamp of the seller.

The guarantee does not cover the cases when:

- the device has the evidence of unauthorized interference or an attempt of its repair at a non-authorized servicing center;.
- there are the signs of design or construction unauthorized changes;
- the device has any mechanical damages;
- the device`s damage is caused by the penetration of the foreign objects, substances or liquid inside it;
- the device has damages caused by the non-conformity of power supply mains parameters to the requirements of the National Standards;

The manufacturer sends electric circuits, the description and other engineering specifications by inquiry of the authorized service centers.

The faulty device together with the operating manual and an explanatory note are sent to the address:

JSC “Yelatma Instrument-Making Enterprise, 25, Yanina st.,391351, Yelatma town, Ryazan region, Russia.

The additional information on repair you can get by phones:

Ryazan: (4912) 28-43-60, 44-06-61

Yelatma: (49131) 2-09-60

Round-the-clock free-of-charge hot line phone number - 8-800 200 01 13

E-mail: admin@elamed.com

INTERNET: www.elamed.com