DEAR CUSTOMER,

Congratulations! You have just purchased ALMAG+ Magnetotherapy Device incl. accessories (hereinafter – Device). The Device is classified as medical equipment product and is listed in the nomenclature of physiotherapeutic devices authorized for use in medical practice.

Please, read this Operation Manual carefully that is the document certifying the main parameters guaranteed by the manufacturer as well as specifications, indications for use, intended use procedures and safety precautions. This knowledge will allow you to make the best use of the unique product capabilities on the treatment and prevention of a wide range of diseases, either under medical facility environment where the physiotherapy department is present or by patients themselves at home, on their doctor's advice.

⚠ ***Attention!*** *Carrying out the treatment sessions by the patient at home does not require any special training and/or skills. To be more effective in using the device, please, read the Operation Manual and follow treatment procedures.*

⚠ ***Attention!*** *Should you have question(s) and/or concerns on the use of the device, please, consult with your local physiotherapist.*

Please, retain the Operation Manual all of the way through a product's lifecycle. Whenever the device is transferred to third parties, the Operation Manual shall be transferred with the product.

Symbolic notations on the device

Warnings and precautions related to safety and operating efficiency.

Type BF working part.
The working part of the device is protected with reinforced insulation.

Compliant with national regulatory documents.

Class II product. The housing is protected with reinforced insulation, no protective earthing is required.

Operation Manual. Please read the Operation Manual carefully.

IP 41

Control Unit of the product provides the ingress protection against items over 1 mm in diameter as well as vertically dripping water.

Manufacturer's Trade Mark;
Device/product Name;
Factory number;
Power consumption;
Rated voltage and frequency;
Date of manufacture;
Specification symbol;
«Made in Russia» text.

TABLE OF CONTENTS

⚠ WARNINGS AND SAFETY INSTRUCTIONS

Please, read this Operation Manual prior to proceeding with medical or prophylactic procedures using the device.

To protect the device from damage, keep it out of the reach of children if unsupervised.

Visually inspect the device before you start performing treatment. **DO NOT** use the device in case its housing or cable is damaged!

Store and use the device in a dry room.

Keep control unit and emitter away from humidity when treating surfaces with disinfectant solution(s). Keep the device in dry place avoiding its exposure to shocks and vibrations.

Do not expose the device to direct sunlight or high temperatures.

In case the device was transported or stored at low temperatures, first keep it at least 2 hours at room temperature before use.

Do not twist or bend the cables. After using, keep the device in the retail packaging.

⚠ Precautions for therapeutic use:

Use the device in locations where control unit can be comfortably connected to the socket and cable tension can be avoided during operation.

DO NOT:

• use the device with mechanically damaged control unit housing and/or control unit cable and/or inductor coils;

• use the device with disassembled control unit housing and/or inductor coil housing;

• lift and carry the device using cable, do not plug it out of the socket by the mains cable.

Directions for environmental protection: Dispose of the device at the end of its lifecycle as electronic waste at dedicated disposal locations.

Disclaimer of liability: The manufacturer will not be liable for damages resulting from non-compliance with the directions given above.

IP$_{42}$ The emitter provides the ingress protection against items over 1 mm in diameter as well as vertically dripping water with the housing inclined by 15°.

Attention! The device needs special measures to ensure ELECTROMAGNETIC COMPATIBILITY and is subject to commissioning in accordance with the EMC-related information given in this Operation Manual.

Attention! The use of mobile RF communication devices may interfere with MEDICAL ELECTRICAL EQUIPMENT.

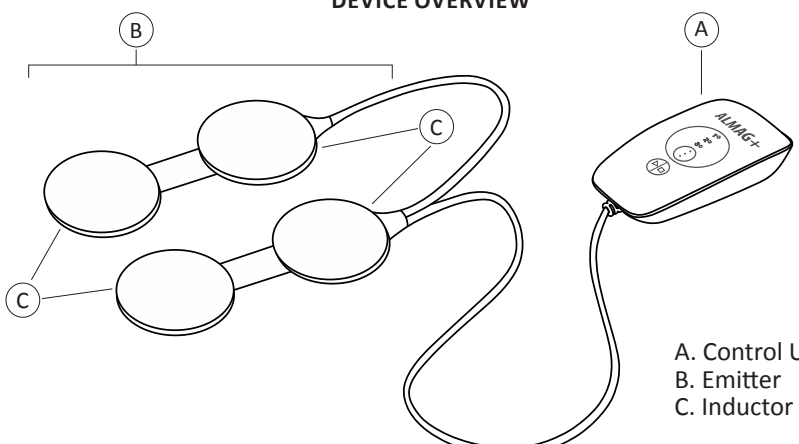
PURPOSE AND OPERATING PRINCIPLE

The device is intended to provide physiotherapeutic treatment as well as recovery and rehabilitation measures using a low-frequency pulsed magnetic field, either in medical facilities or at home, upon the recommendation of a doctor.

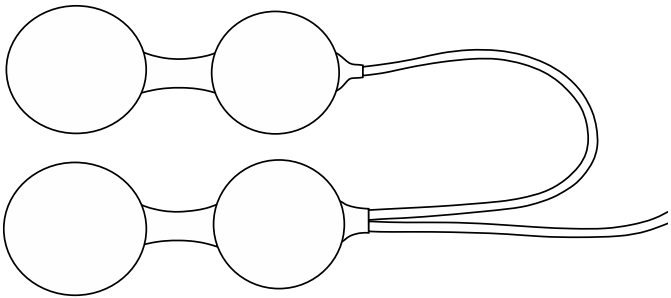
The device consists of the control unit (current pulse generator) and an emitter comprising four interconnected inductor coils used to provide exposure to individual parts of the body.

The device is designed to be used under regular climatic conditions: Ambient temperature +10 °C to +35 °C, atmospheric pressure 86.6 kPa to 106.7 kPa (600 to 800 mm Hg).

DEVICE OVERVIEW

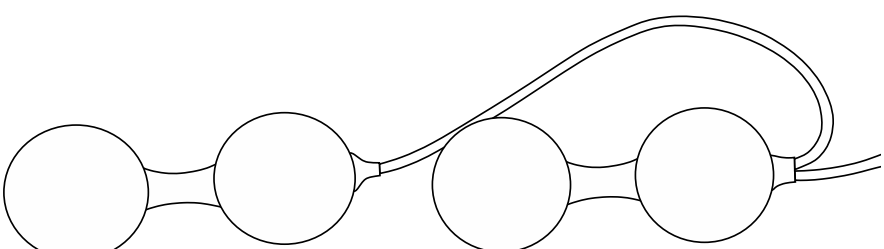


A. Control Unit
B. Emitter
C. Inductor Coils



Matrix layout of the inductor coils

Inductor coils are combined into two groups of two coils per group. The groups may be configured in the form of 2x2 matrix and/or «spline» composed of four inductor coils. «Spline» emitter configuration is achieved using corresponding fastener included in delivery.



«Spline» emitter configuration composed of four inductor coils
(fastener is omitted for clarity)

SCOPE OF DELIVERY

• ALMAG+ Magnetotherapy Device	1
• Accessories:	1
Spline fastener	1
Strap	2
Magnetic field indicator	1
• Operation manual	1
• Retail package	1

STORAGE AND TRANSPORTATION

The device can be stored indoors at temperatures of -50 °C to +40 °C and relative humidity up to 98% at a temperature of +25 °C.

The device is transportable using any mode of transport within temperate and cold macroclimatic areas at ambient temperatures of -50 °C to +50 °C.

During operation, after being used for the intended purpose, the device should be stored in a retail package at an ambient temperature of +1 °C to +40 °C.

In case of return for exchange or repair, the device must be fully packed.

INDICATIONS FOR USE

- Arthritides, arthroses, osteochondropathy, or bone spur;
- Dorsopathy including osteochondrosis vertebralis, herniated nucleus pulposus, or scoliosis;
- Osteoporosis;
- Hypertensive disease of the I and II degree;
- Dystonia (vegetovascular dystonia);
- Complications of diabetes mellitus Type I and II;
- Atherosclerosis;
- Vein and lymph vascular disease including varicosity and its complications as well as lymphostasis;
- Asthma;
- Bronchitis;
- Nerve root and plexus disorders in extremities including post-traumatic as well as poststroke disorders;
- Injuries (fractures).

CONTRAINDICATIONS

- Acute pyoinflammatory conditions;
- Aortic aneurysm;
- Pregnancy;
- Systemic blood diseases;
- Malignancies;
- Thyrotoxicosis;
- Alcoholic intoxication;
- Atrial fibrillation;
- Implanted cardiostimulator present in the exposure area.

Metal inclusions, if present in bone tissue, is not a contraindication to administration of the device in therapeutic doses.

Metal dental crowns, if present in mouth cavity, is not a contraindication to administration of the device in therapeutic doses.

SIDE EFFECTS

Do not exceed the exposure time as specified in the Directions for Use Chapter of this Operation Manual, to avoid adverse events including increase in arterial blood pressure and aggravated morbidities.

PREPARATION FOR USE

In case the device was transported or stored for a long time at temperatures below 10 °C, first keep it at least 2 hours at a temperature in between 10 °C and 35 °C before turning on.

⚠ Ensure that there is no mechanical damage to the cable and the housing of the device. **DO NOT** use the device if any of the above damage occurs!

Disinfection methods

Disinfect the external surfaces of the device before its first use and as required from then on by double wiping with a coarse calico or gauze cloth moistened with disinfectant solution approved for use in medical practice to protect the plastic and metal items from dermatomycosis infection. Keep interval between wipings according to the directions for use of disinfectant solution. Keep control unit and emitter internals away from contacting with disinfectant solution. Next wipe the surfaces with cloth moistened with water and then wrung-out, and dry at ambient temperatures below +50 °C.

When using at home, it is recommended to disinfect externals with 0,5% to 1% aqueous chlorhexidine/CHX/Gibitan solution. The product is odour-free and is classified as low-hazardous substance. Use any appropriate vessel or dishware to prepare the treatment solution by mixing with water.

⚠ ***Attention!*** Please, wear rubber gloves when preparing the solution.

OPERATION PROCEDURES

Please, consult with your attending doctor. Take a close look at the list of indications and contraindications.

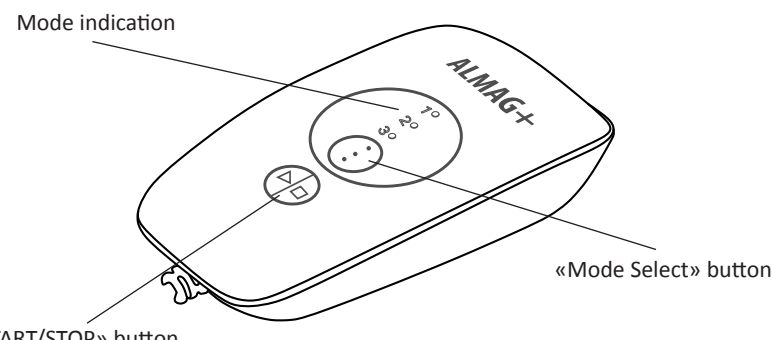
Locate the device at the site comfortable for use. Avoid tension of power cord and emitter cable. Only use working (fault-free) power socket.

There are device controls on the upper casing of the control unit.

Visual Display

When the device is powered on, the Start/Stop button («▶/■») LED starts blinking to indicate that the device is on and in waiting mode.

The device changes the mode into normal operation mode upon brief pressing any button. The «START/STOP» button LED stops flashing, and 1-2-3 mode indicator LEDs light on and off sequentially, and then the LED corresponding to the last previously set mode number (1, 2, or 3) lights up and a sound signal is heard corresponding to the mode. The device is now ready for operation.



Treatment Modes

The desired treatment mode is set with «Mode Select» button as indicated in Table 1.

Table 1

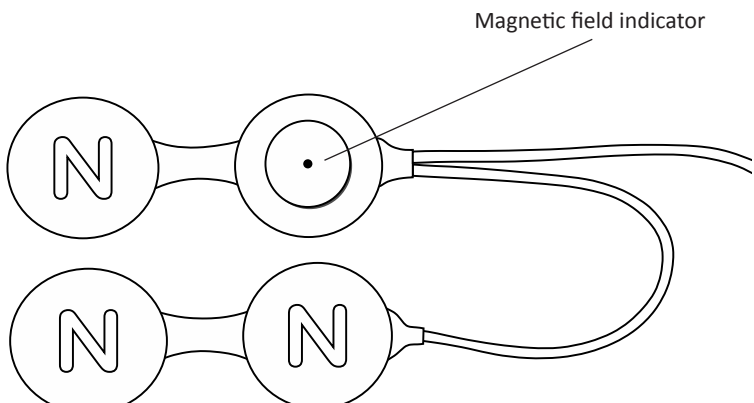
Operating mode	Field type	Inductor coil excitation frequency	Peak (amplitude) value of the magnetic field density on the inductor coil working surface (mT)	Mode description
1	traveling	6.25 (1/8 of the mains frequency)	20±6	Basic mode of operation
2	traveling	6.25 (1/8 of the mains frequency)	8±2	Pediatric mode with reduced magnetic field density
3	stationary	100 (doubled mains frequency)	6±2	Therapeutic mode with pronounced analgesic and anti-inflammatory effects

The desired mode is selected by pressing the «Mode Select» button (Mode 1 – Mode 2 – Mode 3 – Mode 1) in sequence, and a sound signal is heard repeatedly where the number of repetitions corresponds to the mode number. Mode indication is provided by corresponding LED indicator.

The exposure (treatment duration) is set automatically to 20 minutes for all the treatment modes.

The treatment is initiated and terminated by pressing the «START/STOP» button and is accompanied by sound signal and non-flashing glow of the «START/STOP» button LED indicator.

The operability of the device with the treatment mode switched on can be further checked with magnetic field indicator applying it alternatively to the inductor coils on the side where «N» letter is located. The pulsed magnetic field if present is evidenced by the LED lamp glowing in the middle of indicator display.



The device generates the sound signal each 5 minutes when in treatment mode.

To set the recommended treatment duration (less than 20 minutes), terminate the treatment forcedly by pressing the «START/STOP» button again.

Once the exposure is completed (or terminated forcedly), the «START/STOP» button LED indicator blinks off and the sound signal is heard. After the completion of the treatment, the device waits for 5 minutes and then switches to standby mode. The mode number LED indicator blinks off and the «START/STOP» button starts blinking.

The device provides work for 8 hours in the recursive short-time mode: The exposure time is 20 minutes for all the modes followed by 10 minutes idle period.

Notes:

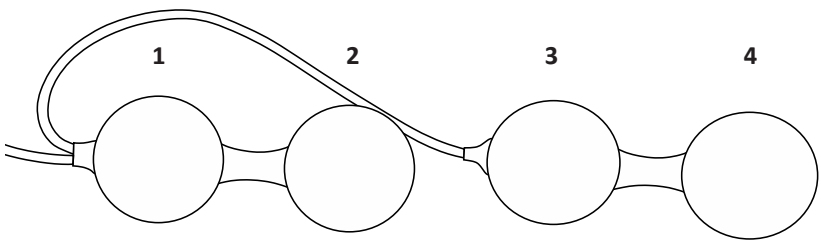
- The mode set function is only active when there is no exposure.
- Disconnect the device from the mains after use.

Detailed Procedures

The treatment is carried out by acting on the lesion itself, the surrounding tissues and reflectory zones by applying the inductor coils of the device directly to skin. Due to high penetrating ability of the magnetic field induced by the device, the treatment can also be carried out through clothing, dry or wet gauze bandage, or a plaster bandage up to 1 cm thick.

When using the device as intended, pay attention to the correct deployment of the emitter according to recommendations of the treatment procedure (i.e. the direction of the traveling pulsed magnetic field and the exposure to the northern magnetic pole). All the procedures include the exposure to the northern magnetic pole from the inductor coils indicated with **«N»** letter on the coil bodies i.e. the coil is to be applied to the body with the end where **«N»** is located.

The traveling pulsed magnetic field is to be directed from the 1st inductor coil to the 4th inductor coil when «spline» emitter configuration is used, namely:

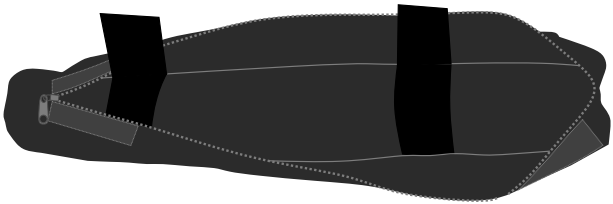


The coil directly connected to the control unit is referred to as the 1st coil. Where the matrix emitter configuration is used, the inductor coils queuing and the direction of the traveling pulsed magnetic field are similar.

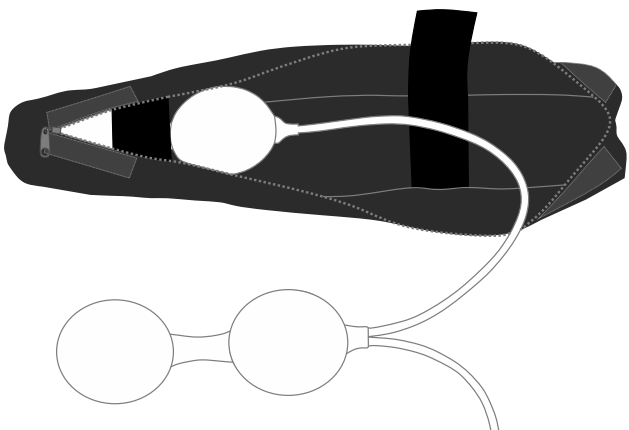
When using the four inductor coils configured in the form of «spline», the spline fastener (hereafter the fastener) is required. The fastener fixes the coils together preventing them from traveling relative to each other.

Place the inductor coils into the fastener stepwise according to the «spline» arrangement as follows:

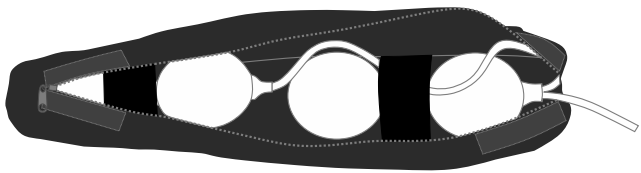
• Unzip the fastener and open the velcros located inside the fastener.



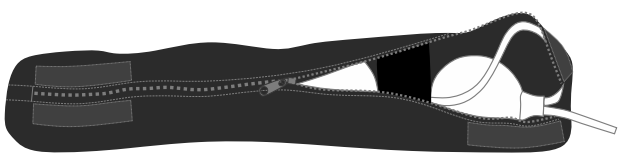
• Take the 3rd and 4th inductor coils of the device and fix them with velcros in the fastener at the 3rd and 4th coils connection point.



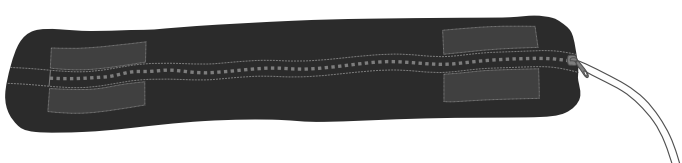
• Place the rest 1st and 2nd inductor coils into the fastener and fix them with velcros.



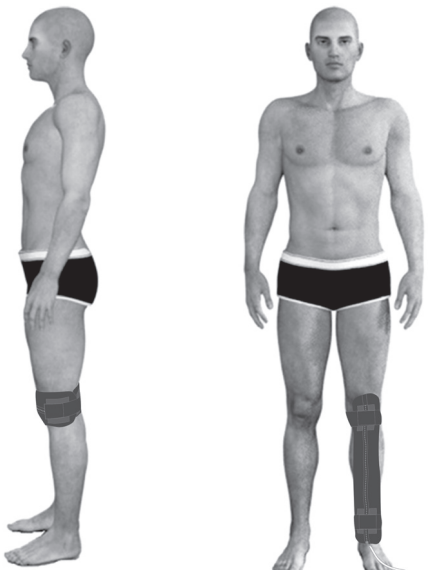
• Zip up the fastener.



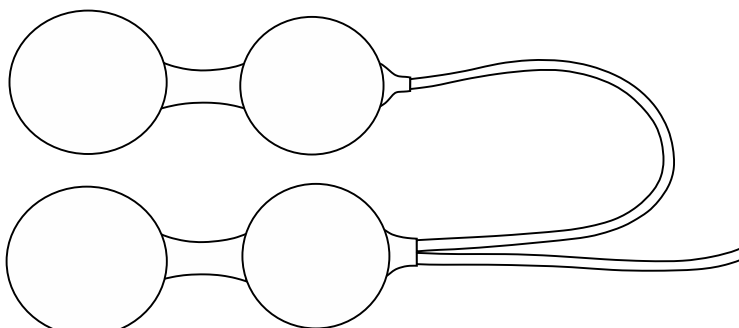
• Four inductor coils are now arranged in the form of «spline».



• Use the accessory straps delivered with the device to fix the «spline» to the extremities. Locate the straps over the zipper and fix them with velcros.



Where 2x2 matrix inductor coil configuration is recommended, the following emitter arrangement option should be used (no spline fastener is required): the emitters are placed pairwise directly to the exposure areas according to the treatment procedures.



DEVICE USER MANUAL

Attention!

1. Prior to initiating the course of treatment, the exact diagnosis should be established and any contraindications should be excluded.

2. Carrying out the treatment sessions by the patient at home does not require any special training and/or skills.

3. Please, read the instruction carefully before proceeding to get maximum effect. Proceed according to the above procedures. Should you have question(s) and/or concerns during treatment and rehabilitation using the device, please, consult with your local physiotherapist.

4. In case the treatment is administered by the doctor, the doctor can modify the procedure based on the personal characteristics of the patient.

5. Overall treatment duration should not exceed 40 minutes per day.

6. Pediatric use of the device shall comply with the age-specific dosage prescriptions (see Tables 3-6).

All the relevant diseases and conditions
can be treated by exposure of the affected organs and reflectory zones
to the north (N) and according to the age-specific dosage prescriptions.

Place the patient in prone position during treatment session.

AGE-SPECIFIC DOSAGE PRESCRIPTIONS

Applying treatment to patients over 15 years old

In case of using the device in a healthcare institution, proceed with Mode 3 first for 3 to 5 days, and then proceed with Mode 1. The treatment session will last for 10 to 20 minutes, and the treatment course will last for 7 to 12 days based on the doctor's prescription.

In case of using the device at home, it is recommended to schedule treatment sessions at regular time intervals, and once or twice a day. The first course of treatment should include 10 minute sessions for 3 days; next, on Days 3, 4 the duration of treatment will be reduced to 7 minutes (for 2 days), and then the duration of treatment will increase up to 15 to 20 minutes.

After the first 6-day course of treatment, make a break for 1 day, then apply another 6-day course of treatment and make a 1-day break again, and finally, provide the last 6-day course of treatment.

Table 2. Course treatment procedure of patients over 15 years old

Treatment day	1	2	3	4	5	6	7
Mode	3	3	3	3	3	3	Interruption/Break
Duration (min.)	10	10	7	7	10	10	
Treatment day	8	9	10	11	12	13	14
Mode	1	1	1	1	1	1	Interruption/Break
Duration (min.)	12	12	12	15	15	15	
Treatment day	15	16	17	18	19	20	
Mode	1	1	1	1	1	1	The course is completed
Duration (min.)	15	15	15	20	20	20	

Repeat the treatment once or twice a day in compliance with dosages.

Keep time interval between sessions at least 8 hours.

Among persons with arterial hypertension, blood pressure should be monitored in the first 6 days of treatment just before session and 20 to 30 minutes after treatment. This is necessary to evaluate the magnetic field sensitivity and assess quality of treatment.

In case the exposure results in the blood pressure **increase or decrease by 10 to 25 mm Hg** during the first 6 days of treatment (Mode 3), reduce the treatment duration by 1/3 during the next session.

In case the exposure results in the blood pressure **increase or decrease by 10 to 25 mm Hg** during the first 6 days of treatment (Mode 1), apply Mode 2 during the next 3 days of treatment. From that time onwards, resume Mode 1 treatment.

In case the exposure results in the blood pressure **increase or decrease by more than 25 mm Hg** consult with your local physiotherapist or attending doctor prior to the next session to adjust the treatment procedure. Keep a log by entering the measurement data required to trace the time course of blood pressure.

If the device is required to treat several diseases or conditions, proceed as follows: Bring the 1st disease treatment course to completion, then make a break for 10 to 15 days and finally proceed to the 2nd disease treatment course. If the device is required to treat the single disease or condition, keep the pause of 6 to 8 weeks between treatment courses. Shorter pauses between treatment courses are only allowed upon the physiotherapist's advice.

Applying treatment to patients under 15 years old

Pediatric use of the device shall comply with the age-specific dosage prescriptions as follows:

4 weeks to 1 year old

Table 3. Course treatment procedure for patients at the age of 4 weeks to 1 year old

Treatment day	1	2	3	4	5
Mode	3	3	3	3	2
Duration (min.)	3-4	3-4	3-4	3-4	3-4
Treatment day	6	7	8	9	10
Mode	2	2	2	2	2
Duration (min.)	3-4	3-4	3-4	3-4	3-4

1 to 3 years old

Table 4. Course treatment procedure for patients 1 to 3 years old

Treatment day	1	2	3	4	5
Mode	3	3	3	3	2
Duration (min.)	5	5	5	5	5
Treatment day	6	7	8	9	10
Mode	2	2	2	2	2
Duration (min.)	5-6	5-6	5-6	5-6	5-6

3 to 7 years old

Table 5. Course treatment procedure for patients 3 to 7 years old

Treatment day	1	2	3	4	5
Mode	3	3	3	3	2
Duration (min.)	7-8	7-8	7-8	7-8	7-8
Treatment day	6	7	8	9	10
Mode	2	2	2	2	2
Duration (min.)	7-8	7-8	7-8	7-8	7-8

7 to 15 years old

Table 6. Course treatment procedure for patients 7 to 15 years old

Treatment day	1	2	3	4	5
Mode	3	3	3	3	2
Duration (min.)	10-12	10-12	10-12	10-12	10-12
Treatment day	6	7	8	9	10
Mode	2	2	2	2	2
Duration (min.)	10-12	10-12	10-12	10-12	10-12

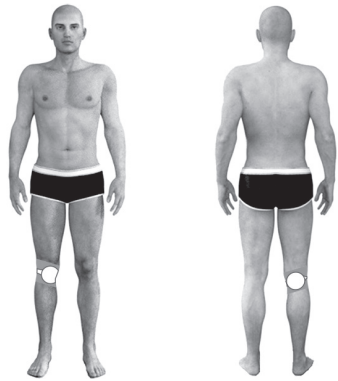


Fig. 1

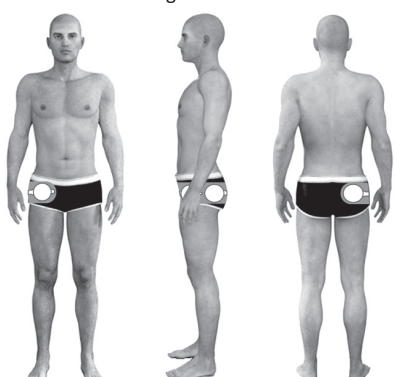


Fig. 2

INDUCTORS APPLICATION TO DELIVER DISEASE-SPECIFIC EXPOSURES

Musculoskeletal system disorders:

• ARTHRITIDES AND/OR ARTHROSES

For patients with the single joint arthritis, apply the «spline» of four inductor coils helically around the joint engaging the surrounding tissues. For patients with two joints affected, apply the first pair of inductor coils to the first joint and the second pair of inductor coils to the second joint.

See Figure 1 for the exemplary knee joint arthritis treatment, and Figure 2 for the exemplary hip joint arthritis treatment.

• OSTEOCHONDROPATHY AND/OR BONE SPUR

For patients with osteochondropathy or bone spur, use transversal application technique; locate the inductor coils pairwise on both sides of the abnormal focus.

See Figure 3 for the exemplary bone spur treatment.

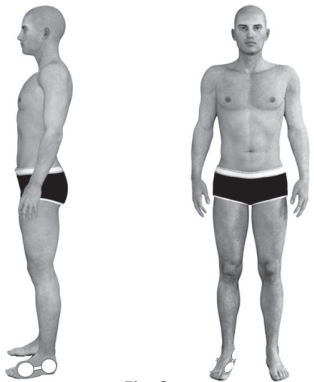


Fig. 3

• OSTEOCHONDROSIS VERTEBRALIS INCLUDING HERNIATED NUCLEUS PULPOSUS, OR SCOLIOSIS

Locate the inductor coils pairwise in parallel along the spine over the long back muscles in such a way that the vertebrae of concern are between the inductor coils.

For patients with large-scale vertebral changes, apply the «spline» of four inductor coils directly to the affected spine areas.

See Figure 4 for the exemplary lumbar osteochondrosis treatment.

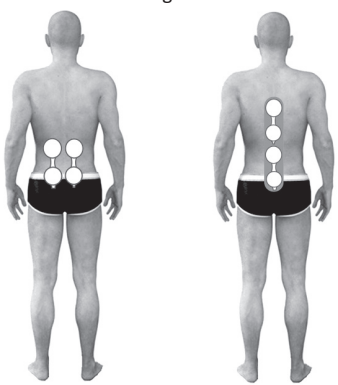


Fig. 4

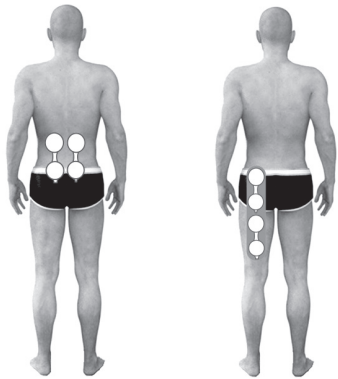


Fig. 5

For patients with osteochondrosis (herniated nucleus pulposus), treat the spine area of concern first, and then apply the inductor coil «spline» down the affected nerve, and expose the second area.

See Figure 5 for the exemplary treatment of a patient with lumbar osteochondrosis and nerve root syndrome.

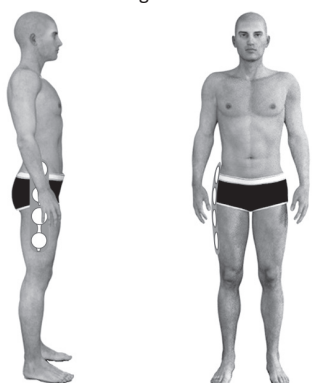


Fig. 6

• OSTEOPOROSIS

Apply the «spline» of four inductor coils along the bone where the pain syndrome is apparent.

The duration of a session shall comply with the age-specific dosage prescriptions.

See Figure 6 for the exemplary osteoporosis treatment.

Cardiovascular diseases:

• HYPERTENSIVE DISEASE of the I and II degrees (essential hypertension)

For patients with hypertensive disease of the I and II degrees, apply the «spline» of four inductor coils to the collar zone.

The exposure time shall comply with the age-specific dosage prescriptions.

See Figure 7 for the exemplary hypertension treatment.

• DYSTONIA

For patients with dystonia apply the «spline» of four inductor coils to the collar zone.

The exposure time shall comply with the age-specific dosage prescriptions.

Complications of diabetes mellitus:

When treating patients with diabetic poly-, neuro- and angiopathy, first apply the «spline» of four inducttor coils along the anterior leg surface, down the dorsum of foot. Once the exposure is completed, move the «spline» of four inductor coils to the anterointernal hip surface and expose to the field. For patients with both the legs affected, expose the 1st leg on day 1 and the 2nd leg on the next day.

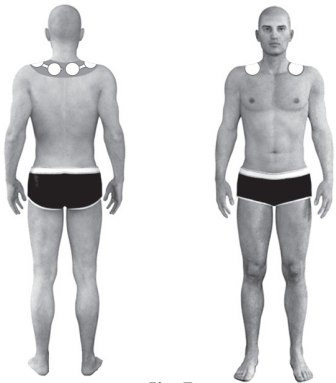


Fig. 7

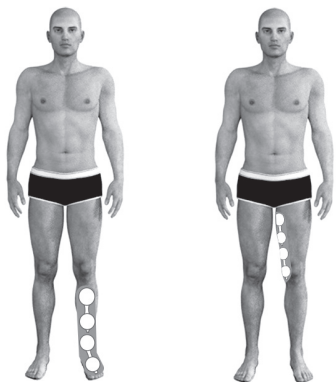


Fig. 8

Fig. 9

See Figure 8 for the exemplary diabetes treatment.

Blood vessel diseases:

• LEG ATHEROSCLEROSIS (OBLITERATING ENDARTERITIS)

For patients with lower extremity arterial atherosclerotic occlusive disease apply the «spline» of four inductor coils along the anterior leg surface, down the vessels (top-down) and nerves, starting from the occlusion zone and below. Place the first inductor coil proximally (closer to the body).

For patients with both the extremities affected, expose both the legs once a day. If one leg is affected, expose twice a day when treating at home.

See Figure 9 for the exemplary leg atherosclerosis treatment.

Fig. 10

Vein diseases (chronic venous insufficiency including ulcerous and inflammation) and lymphatic vessel disorders:

For patients with vein diseases (lower limb varicosity including ulcerous and inflammation, chronic venous insufficiency) and lymphatic vessel disorders (lymphostasis), apply the «spline» of four inductor coils along the posterior leg surface and above. Place the 1st inductor coil distally (closer to the ankle joint), and the 4th inductor coil in the popliteal region.

For patients with both the extremities affected, expose both the legs once a day. If one leg is affected, expose twice a day at least 6 hours apart when treating at home.

See Figure 10 for the exemplary varicose vein disease treatment.

Pulmonary diseases:

• ASTHMA

First locate the inductor coils pairwise on two areas, in parallel with the spline over interscapular region. Following the interscapular region exposure as per age-specific dosage prescriptions, join two inductor coils pairs into the «spline» and apply it along the lower edge of the costal arch to provide effect on the lower lungs and adrenal glands. For adults, the exposure time over this area is 10 minutes; for children, adjust the exposure time according to the age-specific dosage prescriptions. Provide the treatment once a day.

See Figure 11 for the exemplary asthma treatment.

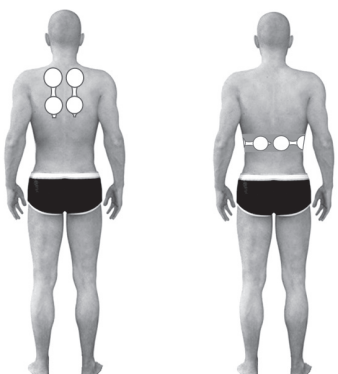


Fig. 11

Fig. 12

• BRONCHITIS

Locate the inductor coils pairwise on two areas, in parallel with the spline over interscapular region.

See Figure 12 for the exemplary bronchitis treatment.

Neurological conditions:

• INDIVIDUAL NERVE ROOT AND PLEXUS DISORDERS IN UPPER AND LOWER EXTREMITIES INCLUDING POST-INJURY AND POST-STROKE

For patients with individual nerve root and plexus disorders in upper and lower extremities (incl. neuritides, infantile cerebral palsy and associated pareses, or hypertonia), apply the inductor coils to the affected plexus and along the affected nerve according to the age-specific dosage prescriptions. Adjust the number of inductor coils based on the length of the affected nerve root.

See Figure 13 for the exemplary ischias treatment.

For patients with post-stroke nerve root disorders, treat once day as follows: first expose the collar zone to the field emitted by the «spline» of four inductor coils, then apply the inductor coils over the projection of the affected nerve roots and plexuses, and provide the treatment according to the age-specific dosage prescriptions.

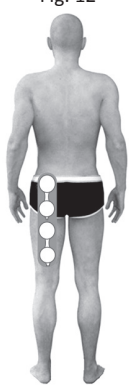


Fig. 13

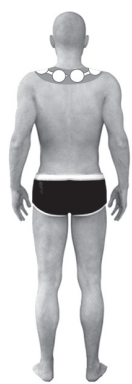


Fig. 14

See Figure 14 for the exemplary post-stroke disorders treatment.

Injuries (fractures):

Place the inductor coils along the projection of the affected area. The treatment through the gauze or plaster bandage is allowed. The number of inductor coils will depend on the surface area of the injured region.

See Figure 15 for the exemplary lower leg bone fracture treatment and Figure 16 for the exemplary forearm's bone fracture treatment.

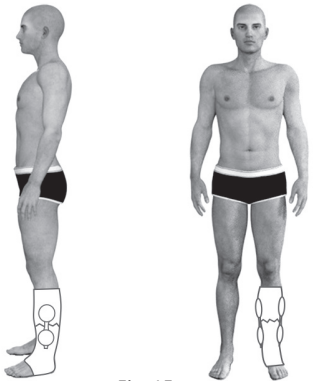


Fig. 15

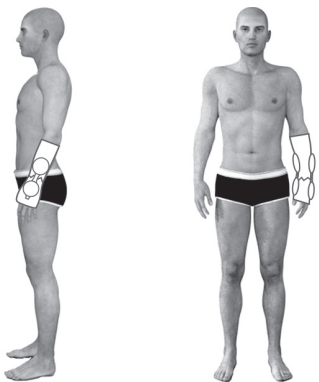


Fig. 16

SPECIFICATIONS

Power supply	AC mains	
frequency	50 Hz	60 Hz
voltage	~230^{+23}_{-32} V	~120^{+6}_{-10} V
Nominal power	110 VA max	55 VA max
Emitter to Control Unit cable length	1.2 m ±0.1 m	
Cable length between two pairs of inductor coils	0.4 m ±0.05 m	
Power cord length	2.0 m ±0.1 m	

Parameters and specifications of pulsed magnetic fields
Field types:
- **«traveling»** field where series exciting of all the inductor coils occurs;
- **«stationary»** field where simultaneous exciting of all the inductor coils occurs.

Operation modes are summarized in the Table 1.

The device provides work for 8 hours in the recursive short-time mode: The exposure time is 20 minutes for all the modes followed by 10 minutes idle period. The exposure time is set automatically on program selection.

During operation, the device is resistant to climatic factors at ambient temperatures of +10 °C to +35 °C and a rated value of relative humidity of 80% at 25 °C.

During transportation, the device is resistant to climatic factors at ambient temperatures of -50 °C to +50 °C, and in storage packaged, it is resistant to ambient temperatures of -50 °C to +40 °C.

The average service life is 5 years.

The easily touched parts of the device are made of biosafety materials. Outer surfaces of the device's components are resistant to chemical disinfection using any disinfectant solution approved for use in medical practice to protect the plastic and metal items.

The maximum temperature on the surface of inductor coils contacting with the human body is not more than +41 °C, for the control unit surface, the maximum temperature is +45 °C.

The exposure (magnetic field treatment duration) is set automatically to 20 minutes ±5% for all the treatment modes.

The sound signal indicating the intermediate exposure time intervals will be generated every 5 minutes ±5% from the treatment start time and on.

The time delay before switching to standby mode after the completion of the treatment is 5 minutes ±5%.

The device provides data storage in the internal non-volatile RAM including the last set treatment mode saving and retrieval.

The letter «N» on the body of each inductor coil corresponds to the north pole of the magnetic field induced by the inductor coils.

The hazard class dependent on the potential application-associated risk is 2a (moderate-rated risk medical product/device).

The device's components' dimensions and weight are given in Table 7.

Table 7

Component name	Dimensions, mm			Weight, kg, not more than
	length	width	height	
Control Unit	142±10	75±10	35±5	0.8
Emitter	890±15	88±5	18±5	

Important electromagnetic compatibility (EMC) information

Since electronic devices like PCs and mobile (cell) phones become increasingly popular, medical equipment in use may be sensitive i.e. it interferes with electromagnetic noise generated by other devices. Electromagnetic interference may impair the operation of the medical device and create a potentially unsafe situation.

Medical devices, in turn, should not impair the operation of other devices.

EN 60601-1-2:2007 standard was implemented to introduce EMC requirements and further prevent the emergence of unsafe situations associated with the use of products. The standard specifies the levels of immunity to electromagnetic interference as well as the maximum levels of electromagnetic emission as applicable to medical equipment. This device produced by ELAMED complies with the requirements of EN 60601-1-2:2007 concerning the immunity to EM interference and emitted radiation.

Nevertheless, some precautions should be observed, namely:

• The use of components and cables other than those supplied with the device may result in increased emissions or malfunctions. The exception may be parts supplied by ELAMED as spare parts.

⚠ **Special requirements to ensure electromagnetic compatibility are given in Appendix A.**

• Make sure that the equipment operates correctly if the operating environment differs from what specified in the tables of Appendix A.

LIST OF STANDARDS USED

IEC 60601-1;2005 «Medical electrical equipment. Part 1. General requirements for basic safety and essential performance».

IEC 60601-1-2:2007 «Medical electrical equipment. Part 1-2. General requirements for basic safety and essential performance. Collateral standard. Electromagnetic compatibility. Requirements and tests».

ISO 10993-1:2009 «Medical devices. Biological evaluation of medical devices. Part 1. Evaluation and testing».

MAINTENANCE

Maintenance of the device does not require special skills, and it will be conducted by representatives of the healthcare institution where the device is operated, or by the user himself/herself at home.

Maintenance scope includes preventive inspection and monitoring of the technical condition of the device including:

- Integrity checks of housings/casings/bodies and cables of the Control Unit and inductor coils as well as accessory fastener integrity check;
- Functional checks of control buttons, light and sound indication elements of the Control Unit;
- Troubleshooting (sound signal and treatment Mode2/Mode 3 LED blinking, see Table 8).
- Inductor coils disinfection after their use (if necessary).

OPERATING REPAIR

General instructions

Operating repair of the device will be carried out by the manufacturer or its representative office based on technical examination by manufacturer's representatives to determine the nature and extent of the malfunction.

Symptoms of the malfunction are:

- mechanical damage to the power supply unit or coil group casings;
- mechanical damage to the cable;
- lack of glow for any of LED indicators;
- light and sound alarms in case the malfunction is detected by the device itself during self-testing.

If a malfunction is detected, contact the manufacturer or its representative.

Table 8

Possible malfunctions self-detected by the device during operation

Data displayed by Control Unit	Malfunction
Sound signal and Mode 2 LED blinking	Emitter cable wire is broken
Sound signal and Mode 3 LED blinking	Inductor coil control output circuit malfunction

Malfunctions found during operating repairs will be eliminated by replacing or recovering elements, parts, or components; then the device will be re-adjusted to bring it in line with the data of this Operating Manual.

After the repair the device will be transferred to the user with the warranty period, the beginning of which is calculated from the moment of the transfer.

Safety measures

There is no need in special precautions during repair.

APPENDIX A

Manufacturer's manual and declaration – electromagnetic emission		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure its use in the specified electromagnetic environment.		
Electromagnetic emissions test	Compliance	Electromagnetic environment – instructions
Radio-interferences according to Special International Committee for Radio-Electronic Interferences 11	Group 1	The device uses radio-frequency energy only to perform internal functions. The emission level of the radio frequency interference is low and might not lead to disturbances in the functioning of the electronic equipment located close to it
Radio-interferences according to Special International Committee for Radio-Electronic Interferences 11	Classes A	The device is suitable for use in all the locations, including residential buildings and buildings directly connected to a distribution network that supplies residential buildings
The harmonic current components of IEC 61000-3-2	Class A	
Voltage fluctuations and flicker according to IEC 61000-3-3	Complies	

Manufacturer's manual and declaration – interference resistance			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure its use in the specified electromagnetic environment.			
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV – contact discharge ±8 kV – air discharge	Complies	The floor in the facility must be covered with wood, concrete or ceramic tiles. If the floor is covered with synthetic material, relative humidity must be minimum 30%
Electrical fast transient/burst according to IEC 61000-4-4	±2 kV – for powersupply lines ±1 kV – for input-output lines	Complies	Power quality in mains in accordance with the typical conditions of a commercial or hospital environment
High energy microsecond pulse interferences according to IEC 61000-4-5	±1 kV when applying «wire-to-wire» interference ±2 kV when applying «wire-to-ground» interference	Complies	Power quality in mains must be provided in accordance with the typical conditions of the commercial or hospital environment
Voltage dips, average interruptions and voltage fluctuations in the input power lines according to IEC 61000-4-11	<5% U_H (voltage dip>95% U_H) during 0.5 of period 40% U_H (voltage dip 60% U_H) during 5 periods 70% U_H (voltage dip 30% U_H) during 25 periods <5% U_H (voltage dip >95% U_H) during 5 s	Complies	Power quality in mains in accordance with the typical conditions of a commercial or hospital environment If the user of the device needs to provide seamless operation in the conditions of possible interruptions of the line voltage, it is recommended to power the device from an uninterruptive power supply or battery
Power frequency magnetic field (50/60 Hz) according to IEC 61000-4-8	3 A/m	Complies	The levels of power frequency magnetic field must be provided in accordance with the typical conditions of the commercial or hospital environment
Note: U_H – is the voltage level of the mains until test exposure is applied.			

Manufacturer's manual and declaration – interference resistance			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure its use in the specified electromagnetic environment.			
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
Conducted disturbances induced by RF fields according to IEC 61000-4-6	3 V (root-mean-square) in-band from 150 kHz to 80 MHz	3 V	The distance between the mobile radiotelephone communication systems used and any element of the device, including the cables, should not be less than the recommended separation distance which is calculated in accordance with the expressions below with reference to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$
Radio-frequency electromagnetic field according to IEC 61000-4-3	3 V/m in-band from 80 MHz to 2.5 GHz	3, V/m	$d = 1,2\sqrt{P}$ (from 80 to 800 MHz); $d = 2,3\sqrt{P}$ (from 800 MHz to 2.5 GHz). Where d is the recommended separation distance, m b); P is the nominal maximum transmitter output power, W, as specified by the manufacturer. The field density in the propagation of radio waves from stationary radio transmitters, according to the results of observations of the electromagnetic situation a), should be lower than the level of correspondence in each frequency band b). The effect of interference may occur near the equipment marked with the symbol 

a) The field density in the propagation of radio waves from stationary radio transmit-ters, such as base stations of radio telephone networks (cellular / wireless), and surface-mobile radios, amateur radio stations, AM and FM broadcast transmitters, television transmitters can not be determined by calculation with sufficient accuracy. This requires practical measurements of field density. If the measured values at the location of the device exceed the applicable levels of compliance, the operation of the device should be monitored to verify their normal functioning. If a deviation from normal functioning is detected during the observation process, then it may be necessary to take additional measures, such as reorienting or moving the device.

b) Field density should be less than 3 V/m out of band from 150 kHz to 80 MHz.

Notes:

1 A greater value of the field density is applied at frequencies of 80 and 800 MHz.

2 The expressions are not applicable in all the cases. The propagation of electromagnetic waves is affected by absorption or reflection from structures, objects and people.

Recommended values for separation distance between portable and mobile radio frequency communication means and the device

The device is intended for use in an electromagnetic environment in which the levels of radiated interference are monitored. The purchaser or the user of the device can avoid the effects of electromagnetic interference providing a minimum separation distance between portable and mobile radio frequency communication devices (transmitters) and the device, as recommended below, taking into account the maximum output power of transmission equipment

Nominal maximum power output of the transmitter, P, W	Separation distance d, m, depending on the frequency of the transmitter		
	$d = 1,2\sqrt{P}$ in-band from 150 kHz to 80 MHz	$d = 1,2\sqrt{P}$ in-band from 80 to 800 MHz	$d = 2,3\sqrt{P}$ in-band from 800 MHz to 2.5 GHz
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

Notes:

1. A greater value of the field density is applied at frequencies of 80 and 800 MHz.
2. The reduced expressions are applicable in all the cases. The propagation of electromagnetic waves is affected by absorption or reflection from structures, objects and people.
3. At determining recommended values of separation distance d for transmitters with nominal maximum power output, which is not mentioned in the table, the nominal maximum output power P in Watts specified in the transmitter manufacturer's documentation is substituted into reduced expressions.

ACCEPTANCE CERTIFICATE

ALMAG+ Magnetotherapy Device incl. accessories, S/N _____ complies with GIKS.941519.114 TU specifications and is classified as fit for operation.

Software version: GIKS.21-0101.

Date of manufacture: _____ Stamp here

_____
(Full name and signature of the person responsible for acceptance)

ALMAG+ Magnetotherapy Device incl. accessories has been packaged in compliance with the requirements of the design documentation.

Packing date _____ Stamp here

Packaged by _____
(Full name and signature)

CARING FOR THE ENVIRONMENT

The body parts of the device, made of high-quality plastics, are recyclable in the form of structural materials for reuse. Electrical and electronic components shall be disposed of separately in dedicated centers in accordance with local legislation. Do not dispose of these components with household waste.

Proper disposal of the waste product will help in preventing the potential negative consequences for the environment and human health.

The devices used in healthcare institutions are to be disposed of upon completion of their lifecycle in accordance with the rules for Class B waste.

MANUFACTURER'S WARRANTY

1. The manufacturer guarantees the conformity of the device's quality to the requirements of the Operation Manual, provided that the consumer observes the conditions and rules for storage, transportation and operation.

Warranty operating life is 12 months from the date of sale.
Warranty period of storage is 60 months from the packing date.

During the warranty period, the manufacturer will repair or replace the device and/or its components free of charge upon presentation of the warranty card.

2. Terms of warranty

The warranty does not cover the following cases:

- If the unit has signs of extraneous interference or attemptedrepair in an unauthorized service center;
- If unauthorized changes to the design or scheme were found;
- If the device has mechanical damages;
- If the device has damages due to ingress of foreign objects, substances, or liquids;
- If the device has damages due to non-compliance of the mains parameters with the requirements of the national standards.

3. The manufacturer will send electrical wiring diagrams and repair documentation upon request submitted by authorized service centers.

Warranty card for repair or replacement works during the warranty period
ALMAG+ Magnetotherapy Device as per GIKS.941519.114 TU specification
incl. accessories

Accepted on «____» _____ 20____

Shop foreman _____
surname and signature

Manufacturer's address:
25, Yanina st., Yelatma, 391351, Ryazan region, Russia
JSC «Yelatma Instrument Making Enterprise»
Tel/fax: +7 (4912) 503-023, +7 (49131) 2-04-57

WARRANTY CARD

for repair (replacement) during the warranty period
ALMAG+ Magnetotherapy Device as per GIKS.941519.114 TU specification
incl. accessories

Manufacturing date _____ No. _____

Purchased _____
(to be filled in by the trading organization)

Put in operation _____
(date, signature)

Accepted for warranty service by the service center

Date _____ City _____

Released after repairs _____
(date, signature)

Stamp here

Head of the repair facility _____
(signature)

Head of the perator company _____
(signature)

The present warranty card should be sent to the Manufacturer and serves as the basis for the invoice to reimburse repair costs within warranty period.