ALMAG-01 Pulsed Electromagnetic Field Therapy Device

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# DEAR CUSTOMER!

You have purchased ALMAG-01 Pulsed Electromagnetic Field (PEMF) Therapy Device (trademark ALMAG<sup>®</sup>), (hereinafter referred to as ALMAG) intended for hospital use for treatment and prevention of a wide range of diseases, as well as for home use by patients upon doctor's advice. In order to perform treatment, please follow the guidelines of this Manual.

ALMAG has been included in the List of physiotherapy devices approved for medical application by the Committee on New Medical Technology under the Ministry of Health of the Russian Federation.

This Operating Manual serves as the Manufacturer's guarantee of the basic parameters and technical features of the ALMAG device.

▲ **ATTENTION!** No special training or skills are required to carry out the procedures by the patient at home. Prior to first usage of the device, please study this Operating Manual carefully, and follow its instructions during further use to ensure proper treatment procedure and effectiveness.

▲ **ATTENTION!** Prior to application of the device, a consultation of a physiotherapist or a local physician is advisable.

Be sure to keep the Operating Manual throughout the whole service life of the device. When handing the device over to another user, please make sure to hand in the Manual as well.

# Marking



Warnings on safety and efficacy of operation



The mark defines the device as complying to Class II in terms of electrical safety according to IEC 60601-1



Read the Operating Manual carefully



Emitters are protected with reinforced insulation

**IP**<sub>41</sub> The enclosure of this product is protected against access of solid particles and against vertically falling drops of water

**C**€ 0044 Compliant with MDD/93/42 EEC

# SAFETY MEASURES

Please study this Operating Manual carefully before use.



Examine the device before use carefully. Make sure that all parts of the device are undamaged. CAUTION! Do not use the device if its case, emitters, or cables are damaged.



Make sure the cable is not twisted or taut. AC mains voltage: ~120V (-10V; +6V), frequency 60Hz. Do not lift or carry the device by power cable!

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During chemical disinfection or wiping of the device make sure that the moisture does not get inside the control unit or the emitters. Protect the device from dampness, shock and impact.



Do not place an operational device nearby (less than 0.5 m apart from) magnetic data carriers (floppy disks, credit cards, video records, mobile memory units and other magneto-sensitive devices).



**ATTENTION!** The device requires special measures to ensure ELECTRO-MAGNETIC COMPATIBILITY and shall be installed and commissioned according to the information related to EMC as given in this Operation Manual.

# Safety instructions for treatment sessions:

- the first treatment session should last no longer than 20 minutes;
- if two areas are under treatment, the total treatment time should not exceed 30 minutes;
- the first 3 sessions of cervicothoracic area treatment (the area of the neck and the chest) should last no longer than 10 minutes;
- using the device on the heart and brain areas is prohibited.

# Important information about electromagnetic compatibility (EMC)

Considering that the number of such electronic devices as PC and mobile (cellular) phones increases, medical devices can be sensitive to electromagnetic interference produced by other devices. Electromagnetic interference may disturb operation of a medical device and create potentially unsafe situation.

Medical devices also should not disturb functioning of other devices.

This device manufactured by ELAMED Company meets the requirements of EN 60601-1-2:2007 in terms of resistance to electromagnetic interference and radiation emitted.

Nevertheless, some precautions shall be followed:

• Use of the components and cables different from the supplied together with the set of the device may result in increased emission or failures in the device operation. Exception: components supplied by ELAMED Company as spare parts.

• Check correct operation of the equipment if the conditions differ from the specified in tables given in Annex A.

Special requirements for ensuring the electromagnetic compatibility are given in Annex A.

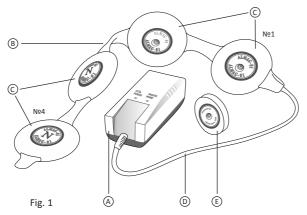
# **DEVICE DESCRIPTION. OPERATING PRINCIPLE**

ALMAG has been designed for therapeutic treatment of the human body by means of pulsed electromagnetic field, to be performed either by medical staff at physiotherapy departments of healthcare facilities, or by individual patients at home.

ALMAG consists of:

- a control unit (pulse generator) connected to four emitters;
- emitters connection cable: (2.1±0.1)m;
- power cable: (1.2±0.1)m.

All connections of the individual units are flexible and non-detachable.



# Main unit

A. Control unit

- B. Emitters line
- C. Induction coils (emitters)
- D. Emitters connection cable
- E. Pulsed electromagnetic field (PEMF) indicator

There are two indicator lights (LEDs) of different colours on the control unit box. The green light indicates that the device is connected to the power line. The yellow LED indicator lights up together with the green one and signals that the magnetic field is in action. The yellow LED is connected to a timer and turns off 18 minutes after start of operation, thus indicating deactivation of the magnetic field. For further use, please unplug the device from the power line and then switch it on again (but at least 10 minutes after shutdown).

Unplug the device after the treatment session is over.

Flashing green indicators in the center of each of the four emitters indicate that the magnetic field is active, and ALMAG is functioning properly. During operation the indicators should flash at regular intervals.

ALMAG's functioning can additionally be checked by applying the PEMF indicator onto the side marked with «N» of each emitter in turn, while the device is powered. Flashing of the green light in the middle of the indicator shall confirm the PEMF presence.

# *NOTE:* For treatment apply ALMAG to the skin on the affected area with the side that has no LED light and is marked with the «N» sign. The «N» stands for the north pole of the emitter.

PEMF travels from emitter 1 to emitter 4. The first emitter is the only one connected to the control unit cable.

Due to the high penetrating ability of ALMAG's magnetic field, the treatment can as well be performed through clothing, dry or damp gauze bandage, or plaster bandage up to 1 cm thick.



*NOTE:* To position the device on the body properly, please follow the instructions herein. Pay attention to the direction of PEMF travel and the working side of the emitters.

## **SET OF SUPPLY**

«ALMAG-01» device	1
Operating Manual	1
Consumer packaging	1
Pulsed electromagnetic field (PEMF) indicator	1

#### INDICATIONS FOR USE

# Musculoskeletal system diseases:

- osteochondrosis
- deforming osteoarthritis
- humeroscapular periarthrosis
- arthritis
- epicondylitis
- gout
- bursitis
- myositis
- tenosynovitis

# Injuries and their after-effects:

- bone fractures
- internal joint injuries
- posttraumatic joint contracture
- wounds
- soft tissue bruises
- hematoma
- posttraumatic edema
- ligament and muscle injuries
- postoperative wounds
- keloid scar
- sluggish purulent wounds, phlegmons, burns

# Diseases of peripheral nervous system:

## - neuritis

- facial nerve neuritis
- radial nerve neuritis
- ulnar nerve neuritis
- median nerve neuritis
- sciatic nerve (ischias) neuritis
- peroneal nerve neuritis
- plexitis

# - neuralgia

- trigeminal neuralgia
- occipital neuralgia
- intercostal neuralgia

# Traumas of central nervous system:

- vertebral column and spinal cord traumas
- disorders of the spinal blood circulation

# Pancreatic diabetes complications:

- diabetic angiopathy
- diabetic polyneuropathy

# Diseases of venous system:

- deep vein thrombosis of the lower leg
- chronic thrombophlebitis
- varicose veins

## CONTRAINDICATIONS

- pyoinflammatory diseases in the acute phase
- pregnancy
- systemic blood diseases
- oncological diseases
- thyrotoxicosis
- alcohol intoxication
- presence of an implanted pacemaker in the treated area

Inclusions of metal elements in bone tissues are not a contraindication for therapeutic usage of the device.

# THE ORDER OF USE

After storage or transportation at temperatures below +10 °C or above +35 °C, keep the device in a room at a temperature from +10 °C to +35 °C for at least 4 hours prior to plugging it in.

Before use, wipe the outer surfaces of the control unit and the emitters with a piece of cloth moistened with 3% solution of hydrogen peroxide mixed with 0.5% solution of a household detergent, or with 1% solution of chloramine. While cleaning, avoid leakage of the disinfectant solution or detergent inside the control unit or the emitters.

Use the PEMF indicator to check the presence of electromagnetic field on the emitters of the actuated device by applying the indicator onto the working side of the emitters (marked with «N» sign) and making sure the green LED turns on.

For treatment, the patient should take a comfortable position in which he/she will remain until the end of the treatment session.

Carry out the treatment sessions (usually 10-20 for the treatment course) at regular intervals, preferably before meal. It is not recommended to have meal for at least 1 hour after the treatment session.

The first few sessions of a treatment course should be carried out daily and should take no longer than 10 minutes. Increase the duration of the treatment sessions gradually within 2-3 days until the maximum duration is achieved. The usual time of a treatment session is 10-20 minutes. A change in the treatment duration is possible upon doctor's advice.

Carry out the procedures twice a day. Treat only one disease during one treatment course. If necessary, repeat the treatment course in 30-40 days, and then in 3-4 months, that is a total of 3-4 courses a year for one disease.

During these intervals between the treatment courses for one disease, treatment of another disease is possible, provided there is a 10-day break before starting a new treatment course.

In case the treatment sessions cause an exacerbation of the disease (increased pain, dizziness, etc.) or other undesirable symptoms, reduce the frequency of the sessions to every other day with the same duration. If this does not eliminate the undesirable symptoms, treatment should be stopped.

PEMF treatment is allowed for patients from 2 years of age and above.

ALMAG has demonstrated a good tolerability among elderly patients and people suffering from cardiovascular diseases, which makes ALMAG applicable in cases when other therapeutic methods are not recommended.

The treatment procedure causes a warm sense in the area where the ALMAG emitters are applied.

In some chronic cases, the patients might experience exacerbation of pain during the first 3 days of treatment. The symptoms usually disappear after a few sessions.

Due to the deferred effect of exposure to PEMF, improvement can come after 15-20 days of treatment.

Do not use PEMF therapy after taking alcohol.

#### PHYSIOLOGICAL EFFECT OF PULSED ELECTROMAGNETIC FIELD ON THE HUMAN BODY

According to various scientific data, the therapeutic effect of magnetic fields involves their ability to control the flow of charged particles and to act on magnetised objects regardless of their motion state. This results in a positive effect on natural biological processes as the intracellular and intercellular metabolism intensifies. Magnetic field therapy thus activates the body's self- restorative function in the healing process by direct stimulation – without surgical intervention, drugs, or side effects. Among various types of magnetic fields, the strongest medical effect is demonstrated by the travelling pulsed electromagnetic field (that of the ALMAG device), as compared to static or alternating magnetic fields. This effect is achieved because ALMAG's PEMF frequency is within the biological frequencies range of the human organism (4-16 Hz).

The unique design of ALMAG's induction coils (i.e. emitters) ensures PEMF penetration of up to 8 cm deep into the patient's tissues, which is successfully applied for treatment of internal organs diseases. The regular rhythmical travelling PEMF emitted by the device produces a healing effect on the cells of diseased organs and stimulates recovery.

The magnetic field also improves the blood flow in the exposed area, thus reducing blood viscosity and, consequently, the risk of blood clot formation (thrombosis). The blood vessels are widened, additional capillaries are opened, and their permeability enhances. All of the above boosts blood circulation in the affected area, supplies the cells with extra oxygen, and stimulates formation of building and protective proteins in the cells, whilst removing the inflammation products out of them. This activation of metabolism prevents disease progression and accelerates regeneration processes and recovery of the diseased cells.

Application of low-frequency PEMF as a treatment procedure has a number of beneficial effects on a patient's body:

- a sedative effect caused by stimulation of nervous inhibition processes, which results in emotional stress relief and sleep normalisation;

- cerebral vascular tone release, improvement of cerebral blood circulation, activation of metabolism processes that increase resistance to cerebral hypoxia;

- lowering of systolic and diastolic pressure down to normal values;

- an analgesic effect created by reduction in the sensitivity of peripheral nervous receptors;

- improved functionality of the endocrine system due to stabilised production and release of the respective hormones into blood;

- faster reduction of swelling and dissolution of medications as a result of increased permeability of blood vessels and epithelial tissue;

- suppression of pathologic processes in the liver, heart and other organs through enhanced metabolism;

- increased resistance to unfavourable conditions.

Generally, a low-frequency pulsed electromagnetic field produces analgesic, anti-inflammatory and anti-edematous effects and stimulates metabolic process. The key organs of the immune system (thymus gland, spleen, lymph nodes, etc.) are especially PEMF-responsive, which is confirmed by an increase in leukocyte count (the number of white blood cells) during the treatment course. In addition to that, exposure to PEMF affects the biologically active spots all over the human body, causing reflex responses in the corresponding muscles and inner organs. Continued treatment by ALMAG results in a smooth build-up of the patient's adaptation level (the ability of a human organism to withstand unfavourable environmental load combined with self-healing ability), which is a valuable support in the treatment of both acute and chronic diseases.

#### TREATMENT PROCEDURES

#### **MUSCULOSKELETAL SYSTEM DISEASES**

#### Osteochondrosis

Osteochondrosis is a degenerative dystrophic disease characterized by deterioration of intervertebral disks and connective tissues of the backbone and the nervous system. Intervertebral disks lose their cushioning ability, which results in compression and deformation of a nerve root, a vessel, or the spinal cord, and causes pain.

The backbone consists of 33-34 vertebrae, which constitute cervical (neck), thoracic (chest), lumbar (lower back), sacral and coccygeal (tailbone) regions of the spine. The spaces between the vertebrae are layered with soppy cartilage tissue of the disks whose function is to absorb the impacts experienced by the spine. Nerve roots are located close to each disk and connect the spinal cord with other human organs. Spinal cord nerves influence the functioning of all human organs and systems. If the disks are in a sound condition, they allow the vertebral segments to move easily and do not pinch the nerves. If the disks are worn out, they can sag, which will eventually cause the adjacent vertebrae to get so close to each other that they will touch and irritate the nerve roots during movement. Without timely intervention, this process can later on develop into spinal disk herniation, also known as slipped disk.

The mostly affected regions of the spine are the lumbar and cervical ones, while the thoracic spine degenerates less frequently.

#### **Typical symptoms**

The patients with lumbar spinal degeneration suffer from lower back pain caused by physical exercise, a stiff movement, a long period of tension, or exposure to cold. The patient may also feel pain in the intestinal tract and genitals, since their nerves are connected to the nerves of the spinal cord. Slipped disk is often accompanied by shooting pains and muscle weakness.

Cervical spine disorders are associated with compression of not only nerve roots and their arteries, but also of the spinal cord and vertebral artery. This comes out in neck pain shooting up the shoulder or the back of the head. Slipped disk in this vertebral region can cause pain in the arm, shoulder blade, or the front area of the chest.

Osteochondrosis of the thoracic spine induces spinal pains, a pain syndrome in various body organs (heart, stomach, lungs, liver, kidneys, urinary bladder, pancreas) and dyskinesia, a disorder of the movement function of these organs.

Very often osteochondrosis has neurological complications as a result of nerve ending compression.

It is recommended to start treatment with a short bed rest for 2-3 days. As the pain syndrome subsides, strengthening of the back muscle core with appropriate physical exercises is required.

PEMF therapy with ALMAG is prescribed since the first days of treatment after the disease was diagnosed.

#### Therapeutic effect

ALMAG's anti-inflammatory and anti-edematous action ensures a distinctive pain-killing effect. This helps improve the conduction of the nerve endings compressed between the vertebrae, which, in its turn, benefits the recovery of the functions of the correlated end organs. PEMF stimulates the blood flow to the diseased area and increases metabolic activity in the surrounding tissues, leading to gradual recovery of the disk tissue and normalization of its functions.

A complex therapy combining PEMF treatment courses, physical exercise, and medication suppresses further disease development and improves the patient's quality of life.

#### **Treatment procedure**

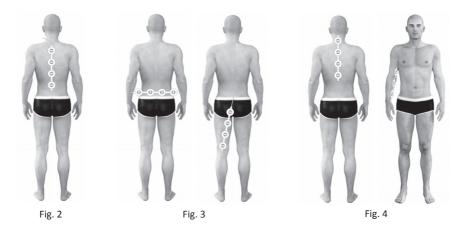
The best time for the procedure is right before bedtime, since it is not recommended to put any stress on the backbone afterwards. If the patient is required to stay in the prone position during an acute stage of the disease, the treatment sessions are carried out twice a day, in the morning and in the evening, with an interval of at least 6 hours.

For treatment, ALMAG is placed on the bed along the axis of the patient's vertebral column. The patient lies his/her back on the emitters (see Fig. 2).

For the first 3 days of treatment the procedures are to be carried out for 3 minutes 3 times a day. For the next 3 days the procedures is increased up to 5 minutes (3 times a day). A 1 day break should follow, after which the treatment continues for 6 days (procedure duration is 10 minutes, 2 times a day). Another 1 day break should be made before the last 6 days of treatment (procedure duration is 15 minutes, 2 times a day). Total length of the course is 20 days.

It is undesirable to stand and it is not allowed to sit within 1 hour after the treatment.

ALMAG is effective for acute osteochondrosis complicated with neuritis, but the procedures are taken once a day in this case. Treatment begins with the diseased



region of the spine (cervical or lumbar), followed by device application to the areas along the affected nerves:

- sciatic, tibial, fibular (see Fig. 3);
- radial, ulnar, median (see Fig. 4).

The first 6 days the treatment is to be carried 2 times a day no longer than 5 min. If required, 2 areas can be treated in this way within one day. Make a pause for 1 day and continue treatment for the next 6 days (procedure duration is 7-8 minutes, twice a day). Another 1 day break should be made before the last 6 days of treatment (procedure duration is 15 minutes, twice a day). Avoid sitting or standing during 30 minutes after the treatment procedure.

The treatment course can be repeated in 30-40 days after end on the 1st course. Supportive treatment course should be made in 3-4 months after completion of the second treatment (procedure duration is 15-20 minutes, total course length is 20 days).

In case for patients with hypertension, blood pressure should be checked before the treatment procedure and in 30 minutes after it. If blood pressure increases or any other undesirable symptoms appear, perform treatment every other day with the same or minimum (10 min) duration. If blood pressure does not lower down or the undesirable symptoms remain, stop the treatment and consult with attending physician.

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# Deforming osteoarthritis

Deforming osteoarthritis is a dystrophic disease of joints characterized by degeneration of articulate cartilages and periarticular tissues.

# **Typical symptoms**

The disease causes pain in the joints, fractures, bent limbs (thigh bones in particular), associated arthritis (inflammation of joints), joint stiffness in the morning.

Women above 40 years of age are more commonly exposed to osteoarthritis. Osteoarthritis patients should avoid physical overloads and joints traumas. It is recommended to use chairs with a straight back instead of soft armchairs and to sleep on a hard bed. For people with excess weight, a change of diet is recommended. Exercise therapy, especially swimming, is of great importance for osteoarthritis patients. PEMF therapy by ALMAG has a significant role in the complex treatment process and prevention of the disease.

# Therapeutic effect

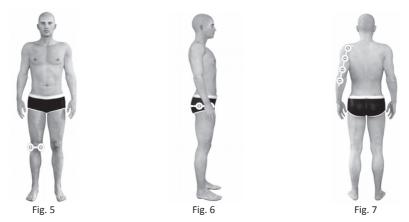
PEMF has a positive anaesthetic action, removes edemas, improves metabolism in periarticular tissues, and produces regenerating effect on articulate cartilages, all of which ultimately helps to prevent further disease progression.

# **Treatment procedure**

The process of joints treatment is very convenient due to the four connected emitters of ALMAG. If a shoulder, elbow, knee, ankle, or hand joints are affected by osteoarthritis, the emitters are wrapped around the joint (see Fig. 5 for an example of treatment of a knee joint).

During the first 6 days the treatment is to be carried 2-3 times a day for 5 min. for each joint. If 4 joints are affected the procedure is to be carried out twice a day for no longer than 5 minutes for each joint. Make a pause for 1 day and continue treatment for 6 days (procedure duration is 8 minutes, twice a day). Another 1 day break should be made, before the last 6 days of treatment (procedures are carried out once a day). If 1 or 2 joints are under treatment, the procedure duration for each joint is no longer than 15 minutes. If 3 or 4 joints are under treatment, the procedure duration for each joint is no longer than 10 minutes. In 1-2 months a repeated course of treatment is to be taken.

If a hip joint is affected, the emitters are placed in such a way that the 4th emitter rests on a buttock (i.e. the back projection of the joint). The two middle emitters are to be placed on the lateral joint projection, and the 1st one on the front projection (see Fig. 6).



The first 6 days the treatment is to be carried 2-3 times a day for 8 min. Make a pause for 1 day and continue treatment for 6 days (procedure duration is 10 minutes, twice a day). Another 1 day break should be made before the last 6 days of treatment (procedures are carried out once a day for 20 minutes). In 1-2 months a repeated course of treatment is to be taken. In this case procedures are carried out once a day for 15-20 minutes, the course length is 20 days without breaks.

For simultaneous treatment of shoulder and elbow joints is shown in Fig. 7.

Preventive treatment should be made every 3 months.

It is not recommended to treat two diseases simultaneously within one course, for example, osteoarthritis and osteochondrosis.

Repeated course of treatment can be carried out 30-40 days after the first one, and the supporting (precautionary) course in 3-4 months after completion of the second one.

#### Humeroscapular periarthrosis

Humeroscapular periarthrosis is characterised by pain and stiffness in a shoulder joint related to various diseases, such as: joint trauma, pancreatic diabetes, diseases of peripheral vessels, heart ischemic disease, bursitis, periarthritis.

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# **Typical symptoms**

Shoulder pain during movement which increases at night time, dextrality of affection (right side for right-handers), tenderness at thumb pressure.

Patient suffering from humeroscapular periarthrosis should limit the load on the diseased joint and do physical exercise regularly, also immediately after completion of a PEMF course.

#### Exercise No.1

Bend forward, the arms hanging down loosely: this enables the articular capsule to relax under its own weight.

#### Exercise No.2

Bend forward, the healthy arm rested upon the chair back, your back relaxed. The diseased arm hanging down loosely, start making pendular swings with it.

It is better to take PEMF by ALMAG after physical exercise and a hot compress to warm the joint.

#### Therapeutic effect

Treatment procedures with travelling PEMF have a number of positive effects: improvement of blood microcirculation and lymph efflux in the affected area, as well as enhancement of capillaries permeability, which ultimately results in normalization of metabolic processes, improvement of the joint's function, or suppression of the disease at the least.

#### Treatment procedure

The emitters are placed around the affected zone, embracing the joint and the surrounding tissues (see Fig. 8). The first 6 days the treatment is to last no longer than 7 minutes 2 times a day. If required, 2 areas can be treated in this way within one day. Make a pause for 1 day and continue treatment for the next 6 days (procedure duration is 12 minutes, twice a day). After another 1 day pause carry out treatment for the last 6 days (procedure duration is 15 minutes, twice a day).



Fig. 8

ATTENTION! It is essential to check blood pressure before the procedure and in 15 minutes after it during the first 3 days of treatment. In case blood pressure increases (by 10-15 mm Hg) do not stop the treatment, but make the treatment procedures and the treatment course 2 times shorter.

If you take the second course of treatment, the procedure should be carried out for 15-20 min once a day. The course length is 20 days without breaks.

#### Arthritis

Arthritis is a joint inflammation arising primarily in the internal synovial membrane of a joint. Inflammatory process can also affect the other structures of the joint (cartilage, joint capsule) and periarticular tissues (ligaments, tendons).

#### **Typical symptoms**

Pain during active and passive movements, symmetric or asymmetric affection of major or smaller joints depending on the disease form, movement stiffness, joint redness, swelling, local or overall temperature rise. It is very important to know that the treatment efficiency greatly depends on the patient's direct participation in the

treatment. The main goal of the treatment is to preserve the joint's functional ability and to prevent further development of the disease. The patient should properly estimate all the unfavourable factors (excessive physical activity or heat loss) and early disease symptoms, such as fatigability and weakness, and take adequate measures, i.e. limit the load on the affected joints, sleep regularly and have a short period of bed rest to let the joints relax and strengthen.

#### Therapeutic effect

ALMAG plays a major role in the prevention of relapses and support of long remission.

Joint treatment with travelling PEMF helps to improve blood circulation, relieve the inflammation processes and the pain, and enhance permeability of the vascular walls, which ensures faster decomposition of edemas. Normalisation of metabolic activity in the diseased joint inhibits further disease progression and individual complex therapy promotes the functional recovery of the joint.



Fig. 9

# Treatment procedure

The emitters are placed around or along the affected joint, embracing the surrounding tissues. The emitters' position for treatment of knee joint arthritis is shown on Fig. 5. Procedures are to be carried out twice a day. The emitters' position for treatment of elbow joint arthritis is shown on Fig. 9.

Treatment procedure is the same as for deforming osteoarthritis.

# Epicondylitis

Epicondylitis is an inflammation of tendon tissues in the place of their attachment to a bone. It is caused by microtraumas, joint inflammation, and intense physical activity. Physical labour workers, agricultural workers, and sportsmen mainly suffer from this disease.

# **Typical symptoms**

Joint pain during movement and tenderness to palpation along the affected tendon. Epicondylitis of an elbow joint tendon can be accompanied with elbow nerve neuritis. When the heel tendon is affected, heel pain during walking is experienced.

Shoulder epicondylitis is a chronic dystrophic affection of the inner and outer shoulder epicondyles as a result of repeated stereotype movement of forearm, sport trauma, or neck osteochondrosis.

It is clinically characterised by pain of different intensity in the affected epicondyle area, which is felt at the corresponding surface of forearm and intensifies during palpation. At the initial stage of the disease, rest of the affected joint for several days is recommended.

# Therapeutic effect

Among other physiotherapy procedures, PEMF by ALMAG has an important place. Under the influence of the travelling PEMF, the pain is relieved, edemas resolve, the local blood flux improves, the metabolism is normalised, and the muscle spasm of the hand extensors and flexors reduces. All of this alleviates the inflammation and promotes quicker restoration of the joint's function.

# Treatment procedure

Procedures are carried out twice a day. Emitters are placed around the affected joint (for example, see Fig. 5 for the treatment procedure of knee joint epicondylitis).

The treatment process for **epicondylitis of an elbow joint** tendon complicated with elbow nerve neuritis is as follows:

1) The patient lies on his/her back;

2) ALMAG is placed parallel to the body;

3) The first emitter is put on the elbow joint, the second on the elbow fold in such a way as to cover the joint from two sides;

4) The other two emitters are put on the internal surface of the shoulder up to the armpit.

The procedures are carried out 1-2 times a day for 10 minutes. The course duration is 20 days with a 1-day break after the 10th day of treatment.

For a more efficient treatment of **shoulder joint epicondylitis**, it is necessary to expose the two below areas alternately:

Procedure No.1: the emitters are placed along the cervical and thoracic spine, embracing the 5-10 cm area on both sides of the spinal column. Procedure duration is 5 minutes.

Procedure No. 2: the emitters are placed on the affected epicondyle of the shoulder joint, including the initial section of the attached muscles. Procedure duration is 15 minutes.

Both procedures are to be carried out in turn within one day provided the activity of the affected arm is reduced after procedure. The min treatment course is 18 procedures.

The treatment process for **Achilles tendon (heel cord)** is as follows:

1) A chain of emitters is put on the floor, the patient steps with his/her foot sole on the first two emitters, so that the heel is positioned in the centre of the second emitter;

2) The other two emitters are placed along the back surface of the lower leg (i.e. the tendon projection) and the bottom part of the calf muscle and are fixed by fastening (see Fig. 10).

In the first 3 days of the treatment course, the procedure time should be 15 minutes once a day, followed by gradual increase up to 20 minutes. The course duration is 18 days. The repeated treatment course, if required, can be performed in 2 months. For repeated courses of treatment procedure duration is 15-20 min., the course length is 20 days without breaks.



Fig. 10

# Gout

The gout is a variety of rheumatic joint disease caused by deposition of uric acid salts (urates). Excess quantity of uric acid can crystallize and deposit in the joints, causing inflammation and intense pain. Attack of the disease starts suddenly and continues with different intensity for several days. The gout can affect any joints of fingers, hands, elbows, knees and feet. Men over 40 years of age and women after menopause usually suffer from this disease.

A good curative effect is achieved through complex treatment: anti-inflammatory medications prescribed by doctor are to be combined with ALMAG procedures. Regular physical activity and a balanced diet will do you good as well.

#### Therapeutic effect

Therapy by ALMAG is aimed at reduction of pain syndrome during the disease attack, termination of the inflammatory process, normalisation of metabolic activity in the joint, which ultimately lead to dissolution of uric acid crystals.

The procedure technique depends on the degree of the pain syndrome.

#### Treatment procedure for the acute form of the disease

Due to the fact that even the slightest touch of the affected joint during this phase causes severe pain, treatment by ALMAG is carried out without direct contact of the emitters with the joint area. An emitter is taken in a hand and placed above the affected joint at a distance of 1-2 cm. Perform the procedure for 3 minutes 2-3 times a day.

#### Treatment procedure for the sub-acute form of the disease

After suppression of the severe pain syndrome, ALMAG is applied directly to the affected joint. The emitters are placed around the respective joint during treatment of knee, foot, elbow, and hand joints. When toe joints are affected, emitters are put on the floor, then the foot is placed on them: the heel is put on the first emitter, the toes on the second, while the third and fourth emitters cover the top of the foot. The emitters can be fastened. Procedure duration is 10 minutes. Procedures are carried out twice a day. The total course length is 18-21 days.

The repeated course should be carried out 30-40 days after completion of the first one, and the supporting (precautionary) course in 3-4 months after completion of the second one. For repeated courses the procedures are carried out once a day for 15-20 minutes. The total length of the repeated course is 20 days without breaks.

#### **Bursitis**

Bursitis is the inflammation of the periarticular bursa of a joint. It arises as a result of joint trauma, excess physical activity, or as an aftereffect of arthritis and some other infectious diseases. There are acute and chronic forms of bursitis.

## **Typical symptoms**

Pain in the area of periarticular bursa, swollenness, restricted moving ability of the joint.

# Therapeutic effect

In case of the acute disease period, treatment procedures with ALMAG are to be taken after the acute process subsides (usually on the 3rd-7th day). In case of the chronic form, treatment is to be performed in the stage of disease remission. Treatment by ALMAG is aimed at relieving the pain syndrome, stopping the inflammatory process, restoring the joint function. Under the action of travelling PEMF, the blood supply to periarticular bursa and adjoined tissues is improved, metabolic processes are normalized, edema resolution is accelerated, and the inflammation subsides. The treatment results in recovery or at least suppression of the further progression of the chronic disease by extending the remission period.

# Treatment procedure

The treatment process is made very easy and handy due to the four emitters of ALMAG. If bursitis strikes the joints of a shoulder, elbow, knee, foot, or hand, the emitters are embraced around a joint (for an example of a knee joint treatment, see Fig. 5). In case of a hip joint problem, emitters are placed in such a way that the last one rests on a buttock (i.e. the back projection of the joint). The two middle emitters are to be placed on the lateral joint projection, and the first one on the front projection (see Fig. 6).

Procedures are recommended to be performed twice a day, with an interval of at least 6 hours. If two or more joints are affected with bursitis, procedures are to be carried out 2 times a day, one procedure per one joint at a time (for example, one joint in the morning, the other in the evening). The total time of one procedure should not exceed 20 minutes. Within one course of treatment it is allowed to treat no more than two joints. After the course completion, it is necessary to have a 10day break before starting treatment of other joints or a different disease.

Another technique of treatment may be used for adjacent joints (for example, a shoulder and an elbow joint). In this case the chain of emitters is placed along the

arm, with the ends embracing both joints. The procedures can be carried out twice a day, one procedure for each group of adjacent joints.

The first course of treatment should be started with minimal time duration (10 minutes), followed by gradual extension up to 20 minutes. Maximum total procedure time is 30 minutes (when the procedures are carried out twice a day). Recommended course length is 18 days, maximum – 20 (for chronic disease form), minimum – 15. After the 6th and 12th treatment days, a one-day break should be taken. Repeated course of treatment can be carried out 30-40 days after the first one, and the supporting (precautionary) course in 3-4 months after completion of the second one. For repeated courses the procedures are carried out once a day for 15-20 minutes. The length of the course is 20 days without breaks.

#### **Myositis**

Myositis is an inflammation of skeletal muscles. It arises as a result of injury of tight muscles (during sports activity), excessive physical activity or heat loss, as well as of acute and chronic purulent processes, chronic infectious diseases, viral diseases, parasitic infections.

#### **Typical symptoms**

Aching pain in the muscles of arms, legs, torso, which increases with motion. Affected muscles are swollen and weakened. Sometimes the disease is accompanied by chill and temperature rise.

Myositis is typically characterized by painful sensation at palpation of muscles and the presence of painful small knots in them.

During complex treatment of the disease, the patient is strongly advised to observe the recommended activity regimen, to do therapeutic exercises, and to avoid exposure to cold.

# Therapeutic effect

The pulsed electromagnetic field of ALMAG has a beneficial effect on the clinical course of the disease: it produces an anti-edematous action, improves nutrition of tissues, facilitates removal of inflammation products,



Fig. 11

and stimulates regeneration processes. The procedures are prescribed as part of combined therapy with external anti-inflammatory medications.

#### **Treatment procedure**

The emitters of ALMAG are placed along the affected muscles of the back, abdomen, arms or legs. If the body muscles are affected, the emitters are placed on a couch, and the patient lies down onto them so that they are spread along the affected zone. If the muscles of upper or lower limbs are affected, the emitters are placed along the affected muscles and the adjacent tissues. For an example of AL-MAG's position in case of myositis of the back muscles, refer to Fig. 11. During the 1st six days of treatment the procedures are carried out 2-3 times a day for 3-5 minutes depending on the pain intensity. The more intense the pain is the shorter the procedure should be. After a 1-day break continue the treatment for the next 6 days increasing the procedure time up to 5-7 minutes. If required, make another 1-day break and continue the treatment for the next 6 days. Perform the procedure for 1-2 times a day, the duration is increased up to 10 min.

#### Tenosynovitis

Tenosynovitis is an inflammation of tendon sheaths (a 'soft cover', fibrous coating of a tendon) as a result of an acute or repeated trauma, which, in its turn, develops from a long hard work involving repeated movements, or from a sports load. Tenosynovitis affects the area of Achilles tendons and that of the hand extensor or flexor tendon.

It is always recommended to begin treatment with limiting the mobility of the joints of the affected limb by fixing it with a rigid bandage (a splint) for 3-4 days. After that, treatment with ALMAG can be started.

# Therapeutic effect

PEMF in this case is aimed at producing an analgesic, anti-inflammatory, and dissolving action.

# Treatment procedure

The emitters are placed along or around the affected zone. The treatment procedure is the same as for epicondylitis.

## **INJURIES AND THEIR AFTER-EFFECTS**

## **Bone fractures**

A fracture is an infringement of the integrity of bone tissue structure. Fractures can be closed, open, with displacement and without it. A fracture is usually accompanied by intensive pain and fracture area deformation, as well as edema of the surrounding tissue.

It is recommended to start treating such traumas with ALMAG on the 3rd-5th day after its occurrence, either in clinic-based (in case of compound fractures), or home-based conditions.

# Therapeutic effect

The pulsed electromagnetic field of ALMAG stimulates resolution of the tissue edema, improvement of blood circulation, acceleration of bone tissue regeneration. Application of the device considerably speeds up the time of fracture treatment, reduces the rehabilitation period, facilitates formation of callus, and strengthens the adjacent tissue. A well-timed application of ALMAG reduces the muscular spasm, prevents muscles atrophy and rigidity of the adjacent joints, and normalises the functions of the vegetative nervous system.

NOTE: presence of metal elements used to hold the bone fragments together is not a contraindication against ALMAG application.

# Treatment procedure

The emitters are put on a plaster bandage or directly on a limb along or around the bone (see Fig. 12).

Procedures should be carried out 2 times a day.

Procedure duration is 10-15 min. The treatment course length is 20 days.

In case of a compound fracture demanding a bone stretching procedure and immobilization, a repeated course of treatment is to be carried out in 30-40 days.

For children aged 2 to 5, the procedure time is reduced to ¼ of the procedure time for adults. If an injured child is over 5 years of age, the procedure is the same as for adults.

ALMAG can be used to perform short-term courses for treatment of the pain syndrome appearing in the area of the healed fracture during periods of weather



Fig. 12

change or after exposure to cold. Such treatment course consists of 7-8 procedures. The procedure duration is 15-20 minutes. In 30 days the treatment course should be repeated. The procedures should be carried out once a day for 15-20 minutes. Repeated course length is 20 days without breaks.

# Internal joint injury

Internal joint injury is a traumatic injury of a joint without infringement of the periarticular capsule's integrity.

Treatment with ALMAG can be started on the 3rd day after trauma provided that there is no blood in the joint cavity. In case of joint bleed the treatment can be performed only after blood is removed from the joint and only upon the doctor's approval.

# Therapeutic effect

Rapid reduction of tissue edema, accelerated dissolution of the accumulated liquid and blood out of the joint cavity, increased metabolic activity in the influenced area due to the improvement of blood flow, resulting in joint tissue regeneration. Treatment with ALMAG reduces the possibility of the formation of a contracture (permanent restriction of the joint mobility).

# Treatment procedure

Treatment procedure is the same as for arthritis.

The emitters are placed around the affected joint (for an example of a knee joint treatment, see Fig. 5). If two adjacent joints are injured (for instance, a shoulder and an elbow), the emitters are placed along the arm covering these joints.

Procedures are to be carried out 2 times a day.

Procedures duration is 10-15 min. The course length is 18 days.

In case if the trauma requires joint immobilization, the supporting treatment course is carried out in 30-40 days.

# Soft tissue bruises, hematoma, posttraumatic edema

ALMAG treatment is to be started 12 hours after the trauma occurrence.

# Therapeutic effect

Under the influence of PEMF, permeability of capillaries (including lymphatic ones) increases, edemas resolve rapidly. Reduction of blood clotting ability in the influenced area leads to resolution of hematoma (bruises). The pain sensitivity of the nerve endings reduces, thus alleviating and stopping the pain.

## Treatment procedure

The procedure duration is 10-15 minutes twice a day. The emitters are placed along or around the lesion focus. In case of a trivial (smaller) trauma, the treatment course can be limited to 6-12 procedures.

# Ligament and muscle injuries

# **Typical symptoms**

The presence of hematoma, edema, restricted joint movement caused by intensive pain.

# Therapeutic effect

For those ligament and muscle injuries that do not require emergency surgery and were caused in the last 20-30 minutes, apply cold to the affected area. For injuries sustained more than 24 hour ago no cooling is required.

ALMAG is applied on the 2nd or 3rd day after primary medical treatment, if the injured ligament or muscle has been stitched or bandaged with plaster. The procedure can be done through any dressing, including a plaster bandage. The depth of ALMAG's PEMF penetration is sufficient to produce the required curative effect. It also has an anaesthetic action, reduces edema, speeds up tissue regeneration, and facilitates the joint functional recovery.

# Treatment procedure

The emitters are placed around the injured joint. Treatment can be started in the first hours after the trauma occurrence. In that case, first apply a cold compress for 5-10 minutes to the joint, and then start the PEMF treatment with ALMAG. The device is wrapped around the joint. During the first day this complex treatment is to be made 3 times. After this 1st complex treatment procedure, lock the joint mobility and avoid physical activity.

The next days the procedures are carried out twice a day, procedure time is 15 minutes.

Beginning from the 5th day, it is recommended to apply a hot compress before the treatment procedure with ALMAG. At this stage, the procedures are carried out once a day. The treatment course takes 18 days.

## Postoperative wounds Therapeutic effect

Therapeutic effect of PEMF on the wounded surface entails reduction of the wound healing period, with formation of a fine flexible scar. The application of the device after a surgery prevents development of different complications and reduces the probability of herniation (in case of abdominal surgeries).

#### **Treatment procedure**

Treatment is to be started on 2nd-3rd day after the day of surgery (if no contamination takes place). ALMAG can be applied onto the wounded area through a gauze or plaster bandage (if redressing of the wound is required, then the procedure is done after it is cleaned and freshly dressed). Under the influence of PEMF, the effect of the applied ointment is increased, which greatly benefits the healing process. The emitters are placed along or around the lesion focus. The procedure duration is 15 minutes, once a day. The course length is 7-18 days.

# Sluggish purulent wounds, phlegmons, burns

A wound may contain pieces of clothing or other foreign particles, or may be contaminated by the object which inflicted it or during the fall of the wounded person. Under the conditions which are favourable for development of pathogenic flora in the wound and for spreading of infectious agents in the surrounding tissue, complications of the wound process may develop, including phlegmon, a purulent complication.

Phlegmon is an acute generalized purulent inflammation of soft tissues accompanied by spreading of the purulent fluid in the cells. Phlegmon appears as a result of bacteria penetration in the soft tissues and can develop practically in any part of the body. Burns may be thermal, electric, chemical, and radiation. ALMAG is applied mainly

to treat the aftereffects of thermal burns.

Treatment of purulent wounds, phlegmons and burns by ALMAG is to be started after the urgent surgical actions have been taken, and the wound has been treated with antibiotics, antiseptics, and other medicines.

# PEMF therapy should be prescribed by the attending physician.

The running PEMF stimulates regeneration of the injured tissues due to improvement of blood circulation and metabolism, decreases the pain syndrome, and speeds up epithelisation processes, which greatly facilitates the healing. A good therapeutic effect is achieved by application of ALMAG combined with medication.

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# Treatment procedure

The emitters are placed over a wet or dry gauze bandage along or around the affected area (after wound cleaning). Procedure duration is 10-15 minutes once a day. The treatment course length, depending on the burn degree, is 10-18 days. It is recommended to repeat PEMF therapy with ALMAG, especially in severe cases, in 30-40 days: this minimises the cosmetic defects after a wound or burn.

# DISEASES OF PERIPHERAL NERVOUS SYSTEM

# Neuritis

Neuritis is an inflammation of a peripheral nerve characterized by various motion and sensitivity disorders.

This disease may be caused by bacterial and viral infections, internal and external intoxication, exposure to cold, lack of vitamins, vascular and other disorders, traumatic nerves compression.

ALMAG is applied for local neuritis with the following symptoms: steady dull pain spreading attack-like along the nerve length, sensitivity and motor disorders, minor reduction of muscle size and weight (atrophy) in the affected area.

Recovery process takes 2-3 weeks in mild cases, but more often lasts longer, especially with patients of middle age and older.

# Treatment procedure

The device is placed in such a way that the first emitter is in the area closest to the spinal column, and the last one in the area farthest from it. The first 6 days the treatment is to last no longer than 3-5 min. 3 times a day. If required, 2 areas can be treated in this way within one day. Make a pause for 1 day and continue treatment for the next 6 days (procedure duration is 7 minutes, twice a day). Max. total procedure time is 30 min. (when the procedures are carried out twice a day). Recommended course length is 18 days, maximum – 20 (with the chronic disease form), minimum – 15. After the 6th and 12th day of treatment, a 1-day break is to be taken. In 1 month a repeated course of treatment is to be taken. In this case procedure duration is 7-10 min., the course length is 20 days.

# **Facial nerve neuritis**

Neuritis of the facial nerve is the most common one among cerebral nerve disorders. The possible causes are: exposure to cold, infection, intoxication or trauma.

# Therapeutic effect

Amplification of the anti-inflammatory effect of complex therapy, activation of blood circulation and lymph outflow in the facial area, improvement of the facial nerve conduction, restoration of the mimic muscles' function, prevention of formation of muscle contracture (permanent mobility restriction).

In the acute disease stage, ALMAG is applied only under prescription of the attending physician.

## Treatment procedure

The emitter is placed on the output spot of the facial nerve, without pressing it too hard. The output spot is under an auricle at the lower jaw base (see Fig. 13). This output area is treated first, followed by treatment of the mimic muscle contracture area. The other 3 emitters not involved in the treatment process are held aside from the patient's face.



Fig. 13

# **Radial nerve neuritis**

Radial nerve is most frequently damaged in the area of middle third of the arm as a result of fracture or getting pressed to this area in deep sleep.

#### Therapeutic effect

ALMAG provides accelerated recovery of the radial nerve conduction, reduced degree of muscles' atrophy, improved blood supply of tissues in the area of radial nerve innervation, restored function of hand extensors.

#### **Treatment procedure**

The emitters are placed on the inner surface of the lower third of the arm, forearm, and hand in the following way:

1) the patient should lie on his/her back;

2) the emitters' chain is placed over the diseased hand with the palm up;

3) the first emitter's edge reaches the heel of the hand, the second emitter is placed in the approximate centre between the palm and the elbow pit; the third emitter is over the elbow pit, the fourth is on the palm and is fixed with an elastic band (see Fig. 14).

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## Ulnar nerve neuritis

Ulnar nerve neuritis is caused by injuries of elbow joint or infection.

The aim of PEMF by ALMAG in this case is the same as for radial nerve neuritis. The device is placed in such a way that the first emitter is on the area closest to the vertebral column and the last one on the area farthest from it.

## Median nerve neuritis

# Therapeutic effect

Speeding up the recovery of median nerve conduction, reduction of muscle atrophy, improvement of the tissue blood supply in the area of median nerve innervation, recovery of the function of hand extension muscles.

# Treatment procedure

The emitters are placed on the inner surface of the arm (along the nerve trunk) with the palm up (see Fig. 15).

# Iciatic nerve (ischias) neuritis

Ischias is an inflammation of the sciatic nerve.

# **Typical symptoms**

Burning, shooting pain in the lumbar spine and in the leg along the sciatic nerve. The diseased person is not able to bend or straighten themselves up. There is a feeling of stupor, tingling along the nerve length, lack of muscle strength in the leg, especially in the foot which flaps during walking and becomes hard to control.

# Therapeutic effect

Sedative, anti-edematous and anti-inflammatory action both on the sciatic nerve and the adjacent tissue; relief of the vascular and muscle spasm; normalisation of blood circulation, tone, and metabolism.



Fig. 14



Fig. 15

#### **Treatment procedure**

Treatment procedure is as for treatment of osteochondrosis complicated with neuritis of sciatic nerve (see Fig. 3).

#### Peroneal nerve neuritis

Peroneal nerve neuritis may occur following a trauma or different infections and intoxications.

# Therapeutic effect

Exposure of the peroneal nerve innervation area to PEMF produces a soothing, anti-edematous, and anti-inflammatory effect; relieves the vascular and muscular spasm; normalises blood circulation, tone, and metabolism in the tissue of the innervated muscles.

#### **Treatment procedure**

Treatment is to be carried out in the sub-acute period when the pain subsides. For convenience, the procedure is recommended to be done while lying on the stomach. The first emitter is placed on the upper part of the popliteal fossa ('kneepit'), the other three are placed along the outer surface of the shin at the damaged side (see Fig. 16).

Patients can sit during the procedure. In this case, one emitter is put on the chair edge and pressed by the damaged leg. The other three emitters are placed on the outer surface of the lower leg and fixed with elastic tape.



Fig. 16

#### Plexitis

Plexitis is an impairment of a nerve plexus. The causes may be: an infection, a trauma, intoxication. Among plexitis forms, the most frequent are brachial (shoulder) and lumbosacral plexitis.

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#### Therapeutic effect

Anti-inflammatory action in the nerve plexus area, recovery of the nerve and muscle system conduction in the lesion focus area and of the function of the muscles affected by paresis.

#### Treatment procedure for brachial (shoulder) plexitis

During treatment the patient can lie on his/her back or sit. The 1st and the 2nd emitters are positioned on the area of the clavicle and the shoulder joint. The 3rd and the 4th should be put along the inner side of the arm affected by paresis (Fig. 17).

#### Treatment procedure for lumbosacral plexitis

The procedure is the same as for osteochondrosis.

#### NEURALGIA

Neuralgia is a burning and shooting pain occurring along the nerve trunk and its branches and located in the area of certain nerves or nerve roots. Neuralgia can come as a result of a trauma or intoxications stemming from liver and kidney diseases, salts of heavy metals, bacterial toxins, alcohol, metabolic disorders at diabetes mellitus, chronic processes in gastrointestinal tract, and others.

Fig. 17

ALMAG is indicated for treatment of trigeminal, occipital, and intercostal neuralgia.

#### Treatment procedure

In case of severe pain syndrome put a soft cloth between the affected area of the body and ALMAG.

The first 6 days the treatment is to last no longer than 3-5 min. performed 3 times a day. If required, 2 areas can be treated in this way within one day. Make a pause for 1 day and continue treatment for the next 6 days (procedure duration is 7 minutes, twice a day). Max. total procedure time is 30 min. (when the procedures are carried out twice a day). Recommended course length is 18-20 days. After the 6th and 12th day of treatment, a 1-day break is to be taken.

In 1 month a repeated course of treatment is to be taken. In this case procedure duration is 7-10 min., the course length is 20 days.



#### Trigeminal neuralgia Typical symptoms

Acute burning and shooting pain in the cheek, upper and lower jaws, and, less commonly, in frontal bone. The pain attack may last from several seconds to several hours.

#### Therapeutic effect

The treatment is aimed at relieving the pain syndrome and eliminating its causes. The action of AL-MAG's travelling PEMF brings about a reduction in the peripheral nerve receptors sensitivity, improvement of blood circulation to the branches of the affected nerve, resulting in the relief of pain sensations and shortened duration and frequency of pain attacks. ALMAG has an anti-inflammatory and vasodilating action. Application of the device as part of complex treatment of trigeminal neuralgia combined with appropriate medication considerably increases the medical effect.

#### Treatment procedure

The first emitter is placed on the affected part of the face covering the cheeks and the base of the lower jaw bone. The rest of the emitters are put along the collarbone area (see Fig. 18). The treatment duration and frequency is described above.

#### **Occipital neuralgia**

#### Treatment procedure

The emitters are placed on the skin projection of the output point of the occipital nerve and the back surface of the neck (see Fig. 19).

The treatment duration and frequency is described above.



Fig. 18



Fig. 19

### Intercostal neuralgia

#### Typical symptoms

Persistent or colicky belting pain spreading from backbone to the chest or central line of abdomen into one or both sides. The pain increases with physical activity, body movement, coughing, sneezing, or deep breathing. The therapeutic effect is directed towards elimination of the disease cause and a rapid relief of the pain syndrome.

### Therapeutic effect

Therapy by ALMAG improves the efficiency of a complex therapy. The major advantages of PEMF therapy are a nearly complete absence of side effects and a good tolerance of the magnetic field by patients with whom other physiotherapy procedures may disagree.

#### Treatment procedure

ALMAG is placed bilaterally on the corresponding segment of the backbone along the affected nerve endings (see Fig. 20). The treatment duration and frequency is described above.

#### TRAUMAS OF CENTRAL NERVOUS SYSTEM

#### Vertebral column and spinal cord traumas

Traumas of the vertebral column and spinal cord are very dangerous, as they may lead to functional disorders of many organs and body systems, and even to a paralysis. Spinal nerve endings (roots) innervating different body organs are located on the spinal cord. For instance, if lumbar spine is affected, one can feel pain in the bowels or genitals. Spine traumas are often accompanied by ruptures of blood and lymphatic vessels, resulting in deteriorated nutrition of the spinal cord and spinal nerves and in impaired nerve conduction that limits or disables their functioning processes.

If there are no contraindications, PEMF therapy with ALMAG is to be started after completing the urgent medical treatment. The magnetic field has an analgesic, anti-inflammatory, anti-edematous action, and accelerates metabolism and tissue regeneration. Moreover, exposure to a magnetic field stimulates a faster



Fig. 20

nerve transmission rate and activates the work of the immune system organs, thus strengthening the host defense.

#### **Treatment procedure**

The patient's position – lying on the back or on the stomach. Emitters are placed along the spine column. If it is not possible for any reasons to turn the patient over to his/her stomach, the person is slightly lifted, and the emitters are put under the affected area of the spine column so that the first emitter is close to the head and one of the others is directly upon the skin projection of the injured area. Start treatment with 10 min procedures performed twice a day during 6 days. Have 1-day break and continue treatment with 15 min procedures performed twice a day for the next 6 days. After this another 1-day break should follow. For the last 6 days increase duration of the procedure up to 20 minutes, perform it once a day. Total course duration is 20 days.

#### Disorders of the spinal blood circulation

The spinal cord is supplied with blood from several artery branches. The anterior and the two posterior spinal arteries going down to the lower end of the spinal cord are 'replenished' from the spinal branches of other arteries entering the spinal canal through intervertebral foramina (openings). These foramina are formed between two adjacent vertebrae. When the intervertebral disks are affected with osteochondrosis, the intervertebral foramen narrows, the adjacent vertebrae come closer to each other and start traumatizing the nerve roots and clamping the blood vessels. The disease progression leads to an onset of ischemic (insufficient blood supply) zones in different regions of the backbone. In the cervical spine, osteophytes (bone spurs) are formed, resulting in a chronic disorder of spinal circulation (myelopathy).

#### Therapeutic effect

As part of a medical treatment complex, PEMF therapy by ALMAG has a high efficiency level. Exposure to pulsed electromagnetic field stimulates additional capillaries to open and improves the blood fluidity in general, which partly compensates for an insufficient blood supply of the spinal cord's ischemic zones. Treatment by the device, alongside with medication, helps reduce or completely stop the disease progression, as well as normalise the functions of the spinal cord and spinal nerves.

#### Treatment procedure

The patient's position is lying on the stomach or on the back. Emitters are placed along the vertebral column covering the cervical part. If it is impossible to lay the patient on the stomach, he/she is slightly lifted and the emitters are put under the backbone.

The treatment begins with a 10 minute-long procedure performed once a day, increasing the procedure time by 2 minutes within 5 days to achieve the duration of 20 minutes.

Recommended course length is 20 days. One-day interval is to be taken after the 6th and 12th day of treatment. The treatment course is to be repeated in 1.5-2 months.

#### PANCREATIC DIABETES COMPLICATIONS

#### **Diabetic angiopathy**

Diabetic angiopathy is a vascular complication of long-term poorly controlled diabetes and of the associated disorders of carbohydrate and lipid metabolism. The mostly affected body parts are the lower limbs. The forms of affection – from low-grade trophic disorders up to trophic ulcer and diabetic foot gangrene leading to leg amputation.

ALMAG is applied as a compulsory element of complex angiopathy therapy in pregangrenous period. ALMAG's pulsed electromagnetic field has an analgesic and antispasmodic action and a favorable effect on carbohydrate, lipid, and protein metabolism. It also improves collateral blood circulation (a collateral is a lateral vessel providing a bypath for blood which cannot go through a clogged vessel).

#### **Treatment procedure**

When shin vessels are affected with diabetic angiopathy, the shin (lower leg) is wrapped with ALMAG covering the back of the foot (see Fig. 21).

# IMPORTANT! The first emitter is placed closest to the knee, the last one to the foot. The procedures are carried out twice a day.

In case of the femoral (hip) segment vessels affection, the procedures are carried out once a day. At first ALMAG is placed on the anterointernal surface of the hip, and then on the lower leg (see Fig. 21). In case if the vessels are affected along the whole length of the lower limb, the emitters are placed on the affected areas in turns. Remember the right position of the emitters: the first one should be placed closer to upper body, and the last one to the foot. The optimal patient's position: lying on the back, or sitting as an option. ALMAG can be fixed onto a leg with the fastening elements.

Attention! Application of ALMAG is a component of complex therapy of diabetic angiopathy. The treatment course is to be carried out only under doctor's advice and supervision.

Control of the glucose and lipids level in the blood, as well as an endocrinologist's consultation, is required during treatment!

#### **Diabetic polyneuropathy**

Diabetic polyneuropathy is a diabetes complication characterized by an affection of the peripheral nervous system.

#### **Typical symptoms**

The below symptoms can occur individually or altogether:

- sensation of chill in the legs;

- loss of perceptibility and numbness;

- burning, unpleasant sensations appearing when touching clothes or bed linen;

- sudden severe numbness of feet;

- muscles atrophy;

- poor healing of scratches and wounds (one or two months instead of one or two weeks), with dark marks left after healing that would not disappear;

- severe pains in the lower legs in the state of rest at night time.

#### Therapeutic effect

ALMAG is applied as part of complex therapy aimed primarily at the underlying disease. Exposure to the magnetic field results in improved conduction of nervous impulses along the nerve fibers that stimulates recovery of the functions of the affected peripheral nerve endings. Due to the pain relieving action, the pain syndrome subsides. Microcirculation in the area covered by the emitters is improved, which leads to normalization of the metabolic processes in the peripheral nerve endings and around them. All of this combined with proper medication inhibits the disease progression and improves the patient's quality of life.



Fig. 21

#### Treatment procedure

The patient's position – lying on the stomach or sitting. The emitters are placed on two areas (see Fig. 22, 23):

- area No. 1 - the posterior surface of the hip;

- area No. 2 – the popliteal fossa and the gastrocnemius (calf) muscle.

The procedures are carried out once a day, preferably in the evening time. The total procedure time – 30 minutes, 15 minutes for each zone. When both legs are affected, the procedures are performed in turn, once a day. The treatment course lasts 20 days. In 2 months after completion of the first course, a repeated course can de started upon doctor's recommendation. Supporting courses of PEMF therapy are recommended to be carried out 3-4 times a year.

Attention! Control of the glucose and lipids level in the blood, as well as an endocrinologist's consultation, is required during treatment!

# DISEASES OF THE VENOUS SYSTEM OF THE UPPER AND LOWER LIMBS

#### Deep vein thrombosis of the lower leg

Deep vein thrombosis of the lower leg is characterized by a feeling of weight in the legs, arching pains, and lower leg edema. The predisposing factors leading to the progress of the disease are traumas, change of blood coagulability, haemostasia (venous congestion) caused by varicose veins or body overweight.

#### **Typical symptoms**

Pains, sensation of weight, edema, accompanied by thrombosis complications (the most frequent among them being thrombophlebitis, i.e. veins inflammation).

#### Therapeutic effect

Treatment with the PEMF generated by ALMAG helps reduce the blood coagulability in the exposed area (which is typically increased with this disease). There is also an im-



Fig. 22



Fig. 23

provement of microcirculation and of the vascular walls permeability. This results in partial dissolution of the thrombus, edema reduction, and alleviation of the pain sensations, and contributes to prevention of thrombophlebitis.

#### **Treatment procedure**

The treatment is recommended to be carried out once a day if both limbs are affected, and twice a day if one is affected.

### IMPORTANT! ALMAG is placed along the veins so that the first emitter is closest to the foot, and the fourth closest to the knee or directly upon the knee fossa (see Fig. 23).

Procedure time is 10-15 minutes. The course length is 18 days. A repeated treatment course is carried out in 2 months. Combined application of ALMAG (upon the attending physician's advice) with ointments containing Heparin and anti-inflammatory medications increases the therapy effect.

#### Chronic thrombophlebitis at a stage of trophic disorders

Chronic thrombophlebitis at a stage of trophic disorders is an inflammatory disease of veins more often arising on the background of varicose veins of the lower leg.

#### **Typical symptoms**

Pain and induration along the affected veins, skin redness over them. A long-term clinical process can lead to formation of trophic ulcer in the lower third of the shin, in the ankle joint area, as a result of venous blood haemostasia and the subsequent dysregulation of tissue nutrition.

#### Therapeutic effect

Treatment of chronic thrombophlebitis at a stage of trophic disorders by ALMAG combined with proper medication ensures a decrease in blood coagulability, dissolution of the thrombus, and restoration of the blood flow in the vessel. The anti-inflammatory action reduces the inflammation process in the affected vessels. Improved microcirculation around the affected vein and the trophic ulcer results in an increased inflow of blood rich with structural elements and oxygen, as well as the outflow of the accumulated products of inflammation and carbon dioxide. The combination of the above eliminates the inflammatory processes and heals the trophic ulcer.

#### **Treatment procedure**

When treating chronic thrombophlebitis complicated with a trophic ulcer, exposure to PEMF of the trophic ulcer area is carried out after cleansing and change of the bandage twice a day. Treatment is to be done through a gauze bandage. The first emitter is placed on the trophic ulcer area (gauze bandage) and the others along the affected veins. Procedure time is 10-15 minutes. The course length is 20 days without breaks.

Since the disease is chronic and requires a long supporting treatment in order to avoid relapses, a repeated course is to be taken after an interval of 40 days. Further on, for remission maintenance it is recommended to carry out another treatment course provided there is a 2-3 month interval between the courses.

#### Varicose veins

Varicose veins is a disease characterized by venous dilation related to weakness or malfunction of the valve apparatus and vascular wall.

The predisposing factors leading to the disease progress are: congenital weakness of the vascular wall, pregnancy, body overweight, long-term standing position, heavy physical labour. Varicose veins are also connected with vessel traumas and thrombo-phlebitis. The disease has three stages: compensation, subcompensation, decompensation.

Treatment by ALMAG can be done at all three stages of varicose veins <u>upon the</u> <u>attending physician's advice</u>.

#### Therapeutic effect

Increased capillary blood flow; improved contractility of the vascular wall; reduced sizes of the varicose veins, especially at the first stage of the disease.

All of these help to prevent further spreading of the pain syndrome and the spasms. Improved microcirculation stimulates the metabolic processes and healing of the ulcers. Reduced blood coagulability under the influence of the alternating magnetic field prevents thrombophlebitis development.

#### **Treatment procedure**

The procedures are carried out once a day if both legs are affected, and twice a day if one is affected. ALMAG is placed along the veins (see Fig. 23).

# IMPORTANT! The first emitter is placed closest to the foot, and the fourth one directly upon the knee fossa.

Procedure time is 10-15 minutes. The course length is 18 days. A repeated treatment course is carried out in 2 months. Combined application of ALMAG (upon the attending physician's advice) with ointments containing Heparin and anti-inflammatory medications increases the therapy effect.

#### MAINTENANCE

Actions necessary for maintenance of the device are enlisted in the table below.

Description	Frequency
Visual inspection of the device case and the power cable to confirm that they are undamaged	Before each use
Cleaning, disinfection	Once a month or when the device is handed over to another user

The device functional test is performed by means of indicators on the electronic unit and on coils-emitter inductors or by the magnetic field indicator.

#### SPECIFICATIONS

AC power supply:	~120V (-10V; +6V), frequency 60Hz
Power consumption	35 V·A
Weight:	max. 0.62 kg
Overall dimensions:	
- Power supply unit	137x60x45 mm
<ul> <li>Emitter (single piece)</li> </ul>	Ø 90 mm, 15 mm thickness
Note: max deviation: ±3%.	
The number of emitters	4
Amplitude value of magnetic induction on an emitter's surface (both flat sides) Pulse duration	(20±6) mT 1,5-2,5 ms
Magnetic field frequency for each emitter	7,5Hz

The device has LED indicators that light up when it is connected to the power line and PEMF is generated.

The device operates in the following mode within 6 hours: operation period of 18 min followed by a 10 min break.

The magnetic field effect shuts down automatically after (18±1) min of operation. The surfaces of the device can be safely disinfected with any solution approved for disinfection of plastic objects in medical institutions.

Mean lifetime – 10 (ten) years.

The device is made of hypoallergenic materials and may be used by hyper-sensitive patients.

Maximum temperature after one operation cycle:

- Control unit, max:	+45 °C;
- Emitter, max:	+41 °C.

Class of the device according to MDD 93/42/EEC – Class IIa.

#### LIST OF STANDARDS

EN ISO 10993-1-2011 EN 60601-1 EN 60601-1-2 EN 60601-1-11 EN 63204:2006

#### STORAGE AND TRANSPORTATION

The device endures storage in a non-heated storage room with air temperature from -50 °C to +40 °C with relative air humidity of up to 98%.

The device can be transported by all covered vehicles according to the rules of carriage at an ambient temperature from -50 °C to +50 °C and relative air humidity of 100%.

#### ANNEX A

**Warning.** The present equipment/system may cause radio reception deterioration and it may disturb the operation of the equipment located nearby. In this case it may be necessary to take measures to reduce disturbances such as orientation or location changes.

Table 1

Mar	Manufacturer's manual and declaration – electromagnetic emission				
These devices are 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
	ed for use in the electrom its use in the specified el		nent specified below. The customer or the user of wironment.
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, (voltage dip>95% U,) during 0.5 of period 40% U, (voltage dip 60% U,) during 5 periods 70% U, (voltage dip 30% U,) during 25 periods <5% U, (voltage dip >95% U,) 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

	Manufacturer's manual	and declaration	on – interference resistance
	led for use in the electror e its use in the specified e		onment specified below. The customer or the user of c environment.
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
			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 trans- mitter. Recommended separation distance:
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	$d = 1, 2\sqrt{P}$
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	$d = 1, 2\sqrt{P} \text{ (from 80 to 800 MHz);}$ $d = 2, 3\sqrt{P} \text{ (from 800 MHz to 2.5 GHz).}$ 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.

Table 4

#### 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	Separation distance d, m, depending on the frequency of the transmitter				
power output of the transmitter, P, W	$d = 1,2\sqrt{P}$ 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-01 Pulsed Electromagnetic Field Therapy Device (trademark ALMAG<sup>®</sup>), factory serial number \_\_\_\_\_\_ is hereby validated as ready-for-service.

Software version:

- GIKS.10-0101	- GIKS.10-0101E
Software date issue:	
- 07.10	- 02.11

Depending on the software security the device is ranked as Class A according to EN 63204:2006.

Date of production \_\_\_\_\_ Stamp

(signature of the person responsible for acceptance)

ALMAG-01 Pulsed Electromagnetic Field Therapy Device (trademark ALMAG<sup>®</sup>) is packed in compliance with the requirements specified in the design documentation.

Date of packing \_\_\_\_\_

Packed by \_\_\_\_\_

Stamp

GIKS.941519.001-

51

#### MANUFACTURER'S WARRANTY

The manufacturer hereby guarantees that the quality of the device conforms to the requirements of the user manual, provided that the conditions of proper transportation, usage, and storage are met.

#### Warranty period is 36 months after date of sale. The garanteed shelf life is 60 months after date of packing.

Within the Warranty period, the manufacturer shall repair or replace the defective device or its parts free of charge upon presentation of the Warranty sheet.

#### Warranty conditions:

#### The Warranty becomes invalid if:

- the device bears traces of outside interference or repair attempts by non-authorized servicing companies;
- unauthorized changes into the design or construction of the device have been detected;
- the device has been damaged;
- the device has been damaged as a result of penetration of external objects, substances or liquids;
- the device has been damaged as a result of connecting it to a power line with improper features.

For any questions on the device quality and maintenance service, please contact the Manufacturer's representative.

			Manufacturer's address:	
			391351, 25, Yanina st., Yelatma, Kasimov District, Ryaza	an region, Russia
			JSC «Yelatma Instrument Making Enterpri	se»
			Tel/fax: +7 (4912) 503-023, +7 (49131) 2-04	4-57
Warranty sheet for repair or replacement works within warranty period ALMAG-01 (PEMF) Therapy Device (Trademark ALMAG")			WARRANTY SHEET for repair (replacement) within warranty pe of ALMAG-01 Pulsed Electromagnetic Field (PEMF) T (Trademark ALMAG <sup>*</sup> )	
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### Environmental responsibility

The external covers of the device are made of high-quality plastics and can be recycled and re-used as building materials. The electric and electronic components are to be disposed of separately in special facilities used for this purpose under the local law. Disposal of these components together with household waste is prohibited.

Proper disposal of a worked-out product helps prevent potential negative consequences for the environment and human health.