18 2121.29 dated 02-05-2023

Almag Active Package Labeling

Prepared by

V. Pinchukova _____ (Pinchukova V.)

Date: 02.05.2023

Approved by

V. Varlamov _____ (Varlamov V.)

Date: 2.05.23.

АППАРАТ
МАГНИТОТЕРАПЕВТИЧЕСКИЙ
БЕГУЩИМ ИМПУЛЬСНЫМ ПОЛЕМ

PULSED ELECTROMAGNETIC
FIELD THERAPY DEVICE

ELAMED

MD

ALMAG Active x12

~230 В, 50 Гц, 110 В·А

ШТАМП ОТК

ДАТА ИЗГОТОВЛЕНИЯ _____

НОМЕР ПАРТИИ _____

ALMAG Active x12

~230 V, 50 Hz, 110 V·A

QC stamp

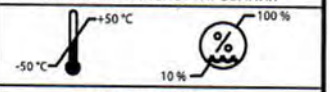
RU

Date of production: xx.xx.xxxx

LOT _____

STORAGE CONDITIONS
УСЛОВИЯ ХРАНЕНИЯ

TRANSPORT CONDITIONS
УСЛОВИЯ ТРАНСПОРТИРОВАНИЯ



OPERATING CONDITIONS
УСЛОВИЯ ЭКСПЛУАТАЦИИ

YELATMA INSTRUMENT MAKING ENTERPRISE, JSC
25 Yanina st., Yelatma, Kasimov District, Ryazan region, 391351, Russia
tel. +7 (4912) 293-418
e-mail: global@elamed.com
www.elamed.com

Изготовитель:
АО " Елатомский приборный завод"
Россия, 391351, Рязанская область, Касимовский район, р.п. Елатьма, ул. Янина, 25

Код товара/ REF :13491

Сделано в России
Made in Russia

Не для продажи на территории РФ
Not for sale in Russia

Importer: Morulaa HealthTech Pvt Ltd.,
Plot No.38, First Floor, Rajeswari Street, Santhosh Nagar,
Kandanchavadi, Chennai – 600096. Phone: +91 7373122211
Importer License Number: XXXXX

№ 211.9.29 dated 02.05.2023

Almag-01 Package Labeling

Prepared by

V. Pinchukova _____ (Pinchukova V.)

Date: 02.05.2023

Approved by

V. Varlamov _____ (Varlamov V.)

Date: 2.05.23

ELAMED

АППАРАТ МАГНИТОТЕРАПЕВТИЧЕСКИЙ БЕГУЩИМ ИМПУЛЬСНЫМ МАГНИТНЫМ ПОЛЕМ МАЛОГАБАРИТНЫЙ "АЛМАГ-01"

PULSED ELECTROMAGNETIC FIELD THERAPY DEVICE

MD

EAC

"АЛМАГ-01" x12

ГИКС.941519.001-03

~230 В, 50 Гц, 51 В·А

"ALMAG-01" x12

GIKS.941519.001-03

~230 V, 50 Hz, 51 V·A

ШТАМП ОТК

QC stamp

ДАТА ИЗГОТОВЛЕНИЯ _____

СЕРИЙНЫЙ № _____

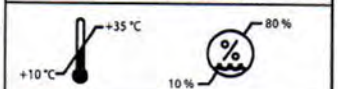
RU Date of production: xx.xx.xxxx

LOT _____

STORAGE CONDITIONS
УСЛОВИЯ ХРАНЕНИЯ

TRANSPORT CONDITIONS
УСЛОВИЯ ТРАНСПОРТИРОВАНИЯ

OPERATING CONDITIONS
УСЛОВИЯ ЭКСПЛУАТАЦИИ



YELATMA INSTRUMENT MAKING ENTERPRISE, JSC
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tel. +7 (4912) 293-418
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Изготовитель:
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Россия, 391351, Рязанская область, Касимовский район, р.п. Елатьма, ул. Янина, 25

Код товара/ REF : 540

Сделано в России
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Importer: Morulaa HealthTech Pvt Ltd.,
Plot No.38, First Floor, Rajeswari Street, Santhosh Nagar,
Kandanchavadi, Chennai – 600096. Phone: +91 7373122211
Importer License Number: XXXXX

N 2116.29 dated 02.05.2023

Almag-02 Package Labeling Opt.1

Prepared by

V. Pinchukova _____ (Pinchukova V.)

Date: 02.05.2023

Approved by

V. Varlamov _____ (Varlamov V.)

Date: 2.05.23

ELAMED

АППАРАТ
МАГНИТОТЕРАПЕВТИЧЕСКИЙ

"АЛМАГ-02" x1

ВАРИАНТ ПОСТАВКИ ИЗД. №1

~230 В, 50 Гц, 60 В·А

ШТАМП ОТК

ДАТА ИЗГОТОВЛЕНИЯ _____

СЕРИЙНЫЙ № _____

PULSED ELECTROMAGNETIC
FIELD THERAPY DEVICE

MD

"ALMAG-02" x1

DELIVERY OPTION №1

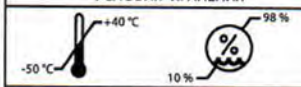
~230 V, 50 Hz, 60 V·A

QC stamp

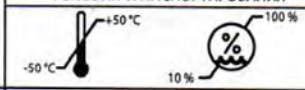
RU Date of production: xx.xx.xxxx

LOT _____

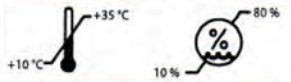
STORAGE CONDITIONS
УСЛОВИЯ ХРАНЕНИЯ



TRANSPORT CONDITIONS
УСЛОВИЯ ТРАНСПОРТИРОВАНИЯ



OPERATING CONDITIONS
УСЛОВИЯ ЭКСПЛУАТАЦИИ



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Код товара/ REF :13531

Сделано в России
Made in Russia

Не для продажи на территории РФ
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Importer: Morulaa HealthTech Pvt Ltd.,
Plot No.38, First Floor, Rajeswari Street, Santhosh Nagar,
Kandanchavadi, Chennai – 600096. Phone: +91 7373122211
Importer License Number: XXXXX

ELAMED Company

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Making Enterprise, JSC
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e-mail: global@elamed.com
elamed.com

OM 29.1080.02
OM Revision Date – March 16, 2023

ALMAG ACTIVE

PULSED ELECTROMAGNETIC FIELD THERAPY DEVICE

USER MANUAL
BEDIENUNGSANWEISUNG
MANUEL D'UTILISATION
ISTRUZIONI D'USO
MANUAL DE INSTRUCCIONES
INSTRUKCJA OBSŁUGI
NAUDOJIMO INSTRUKCIJA

Magnettherapiegerät

Appareil de magnétothérapie

Dispositivo per terapia magnetica

Aparato magnetoterapéutico

Urządzenie magnetoterapeutyczne

Magnetoterapijos prietaisą

DEAR CUSTOMER,

Congratulations! You have just purchased **ALMAG Active** Pulsed Electromagnetic Field Therapy Device (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 User 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 User Manual and follow treatment procedures.*

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


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


User Manual. Please read the User Manual carefully

Duty cycle: work: 20 min, a pause: 10 min

IP41 Control Unit of the product provides the ingress protection against items over 1 mm in diameter as well as vertically dripping water

Medical Device


Manufacturer

Date of manufacture

Serial number

Manufacturer’s Trade Mark;
Device/product Name;
Power consumption;
Rated voltage and frequency;
«Made in Russia» text.

TABLE OF CONTENTS

⚠ 1. WARNINGS AND SAFETY INSTRUCTIONS

Please, read this User 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 User Manual.

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

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 60601-1-2:2015 (IEC 60601-1-2014) 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 60601-1-2:2015 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.

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

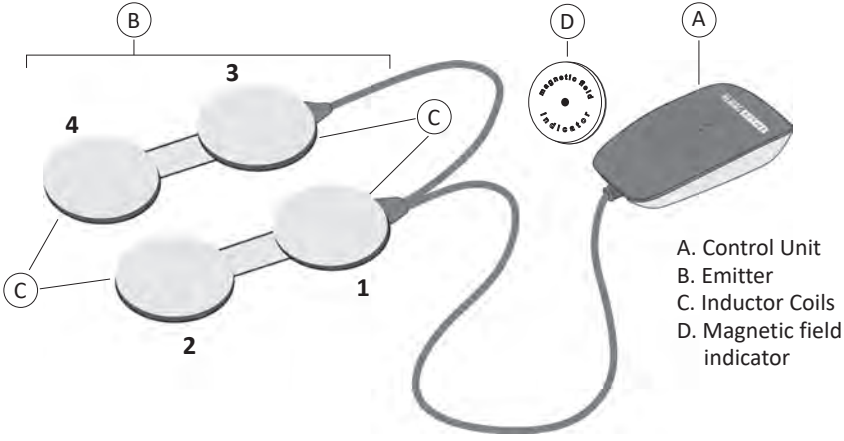
⚠ **Special requirements to ensure electromagnetic compatibility are given in Annex A.**

2. PURPOSE AND OPERATING PRINCIPLE

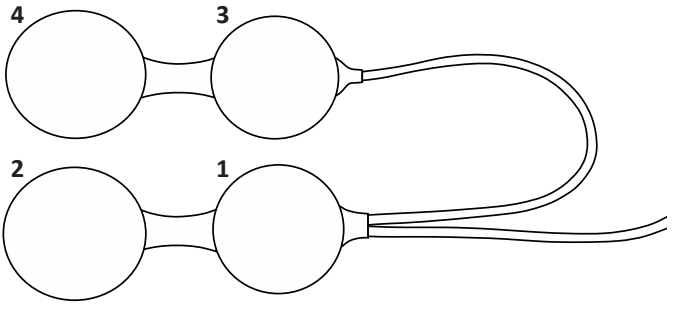
The device is intended to provide physiotherapeutic treatment as well as recovery and rehabilitation measures using a low-frequency pulsed magnetic field, either in medical facilities or at home, upon the recommendation of a doctor.

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.

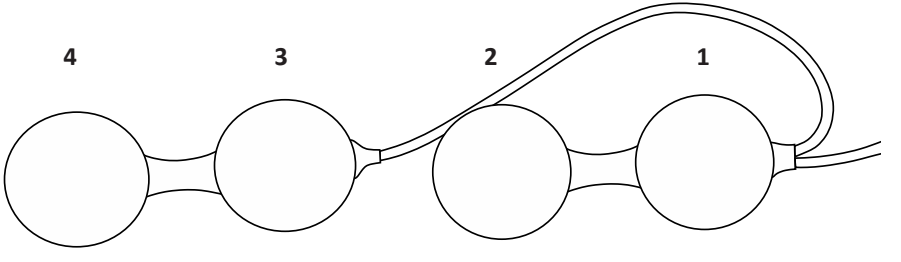


Device overview



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)

3. SCOPE OF DELIVERY

• ALMAG Active Pulsed Electromagnetic Field Therapy Device	1
• Spline fastener	1
• Strap	2
• Magnetic field indicator	1
• User Manual	1
• Retail package	1

4. INDICATIONS FOR USE

Musculoskeletal system diseases:
- osteochondrosis
- humeroscapular periarthrosis
- osteoarthritis
- epicondylitis

Injuries and their after-effects:
- internal joint injuries
- posttraumtic edema
- skeletal injuries (bone fractures, dislocations, damage to the ligamentous apparatus – sprains, tears; damage to skeletal muscles, soft tissue injuries)
- vertebral column and spinal cord traumas

Diseases of peripheral nervous system:
- neuritis
- facial nerve neurtis

- radial nerve neuritis
- ulnar nerve neuritis
- median nerve neuritis
- sciatic nerve (ischias) neuritis
- peroneal nerve neuritis
- plexitis
- neuralgia
- trigeminal neuralgia
- occipital neuralgia
- intercostal neuralgia

Pancreatic diabetes complications:
- diabetic angiopathy
- diabetic polyneuropathy

Diseases of venous system:
- deep vein thrombosis of the lower leg
- chronic thrombophlebitis
- varicose veins

5. CONTRAINDICATIONS

• acute infectious diseases and purulent-inflammatory processes of any location;

• pregnancy;

• diseases and conditions accompanied by impaired hemostasis of the hypocoagulation type (decreased blood coagulation), risk of bleeding and hemorrhagic syndrome, including systemic blood diseases (hemophilia, thrombotic thrombocytopenic purpura, etc.), as well as bleeding of any genesis and location;

• malignancies*;

• conditions preventing from procedure performing: alcohol and drug intoxication, psychomotor agitation of any genesis;

• uncompensated arterial hypertension of Class 3, arterial hypertension crisis of any class;

• arterial hypotension (SBP < 90 mm Hg, DBP < 65 mm Hg);

• aneurysms of aorta and large vessels;

• hemodynamically significant cardiac arrhythmias and/or intracardiac conduction disturbances (atrial fibrillation and flutter, paroxysmal supraventricular and ventricular tachycardia, ventricular extrasystole of degree four or five according to Lown-Wolf-Ryan scale, atrioventricular block degree two or three, sinus bradyarrhythmia);

• any conditions and diseases of the thyroid gland, accompanied by hyperproduction of thyroid hormones;

• active tuberculosis process of any location;

• acute and subacute stage of myocardial infarction;

• 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.

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* *Treatment using the ALMAG Active device may be carried out for patients with the diagnosis of a malignant neoplasm* ***only as directed and under the supervision of the attending physician,*** *after a comprehensive antitumor therapy (surgical treatment, chemotherapy course, radiation therapy) and in the absence of metastasis and progression of the tumor process.*

6. SIDE EFFECTS

In order to avoid adverse events including increase in arterial blood pressure and comorbid diseases, do not exceed the exposure time as specified in the Directions for Use Chapter of this User Manual, defined in sections «General rules of procedure sequence» and «Features of methods of device use in different age groups of patients» of this operation manual. **Before treatment start, be sure to consult your doctor to exclude your existing diseases and conditions contraindicating the use of the device.**

⚠ ***Attention!*** *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 and apply Mode 2 during the next 3 days of treatment. From that time onwards, resume Mode 1 treatment.*

⚠ ***Attention!*** *In case the exposure results in the blood pressure increase or decrease by more than 25 mm Hg consult with your 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.*

7. 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.

⚠ ***Attention!*** ***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.

A 3% hydrogen peroxide solution or a 5% chloramine solution can be used as a disinfectant solution.

8. OPERATION PROCEDURES

8.1. General rules of procedure sequence

⚠ ***Attention!*** ***Before treatment start, carefully read the list of indications and contraindications and be sure to consult your doctor to determine the correct diagnosis and to exclude your existing diseases and conditions contraindicating the use of the device.***

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

• Please, read the instruction carefully before proceeding to get maximum effect. Proceed according to the above procedures.

The effectiveness of magnetotherapy procedures depends on:

- exact conformity with the recommendations relating to the procedure for device use;
- individual magnetic sensitivity of the patient;
- the stage and features of the course of the disease, for which the treatment is being carried out.

• Should you have question(s) and/or concerns during treatment and rehabilitation using the device, please, consult with your attending doctor. You can also seek for advice on the manufacturer's official website (en.elamed.com).

• The duration of the procedure and the treatment modes is determined individually taking into account the patient's age. The recommended combinations of the procedure duration and treatment mode are indicated in section «Features of the methodology of device use in various age categories of patients». The use of the device in pediatric practice for children from 1 month of age and older should be carried out strictly in accordance with the age dosages specified in this manual.

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

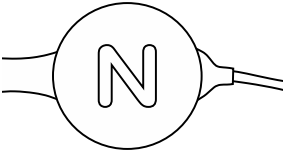
⚠ ***Attention!*** ***The mode set function is only active when there is no exposure.***

• The procedures are carried out once a day, at the same time (at regular time intervals). Provided that it is well tolerated, in order to increase the effectiveness of treatment, it is recommended to increase the multiplicity of the procedure repeats be up to 2 times a day. At the same time, the break between the procedures should be at least 8 hours, and the total duration of the procedures should not exceed 40 minutes per day. When treating two joints, the interval between procedures for alternate joints should be at least 10 minutes.

• The procedure administration methods (the frequency and duration of the procedures, **the impacted area**, the location of the inductor coils, the duration of the treatment course) can be adjusted by the attending physician, **taking into account the individual characteristics of the patient and the particular course of the disease for which the treatment is being carried out**.

• When using the device for its intended purpose, pay attention to the correct placement of the emitter on the body: all the methods stipulate for acting by the north magnetic pole of the inductor coils (marked with the «N» sign on the coil housings). During the procedure, the device is applied directly to the affected organ and surrounding tissue, to its projection area or reflecting zones with the north side («N») facing the body.

ATTENTION!
When performing procedures, locate the emitter with the working surface of inductors with the «N» letter facing the treated area



• 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.

• The optimal position of the patient during the procedure – supine. After the procedure, in order to achieve the maximum effect, it is necessary to remain in a horizontal position for 30 minutes.

• 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 1,5 to 2 months between treatment courses. Shorter pauses between treatment courses are only allowed upon **your attending doctor's** advice.

⚠ ***Attention!*** *It is not recommended at the same time (on the same day) to treat two different diseases.*

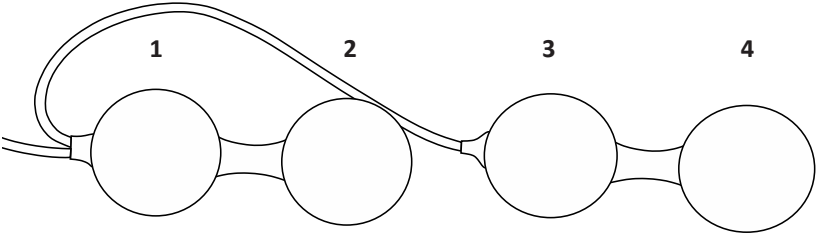
⚠ ***Attention!*** *In case the exposure results in the blood pressure increase or decrease by 10 to 25 mm Hg during the first 6 days of treatment (Mode 3), reduce the treatment duration by 1/3 during the next session and apply Mode 2 during the next 3 days of treatment. From that time onwards, resume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

⚠ ***Attention!*** *In case the exposure results in the blood pressure increase or decrease by more than 25 mm Hg consult with your 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.*

Before starting the procedure, define the configurations of inductor coils in the form of a «flexible spline» or «matrix» (depending on the requirements of the methodology for treating a specific disease).

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:

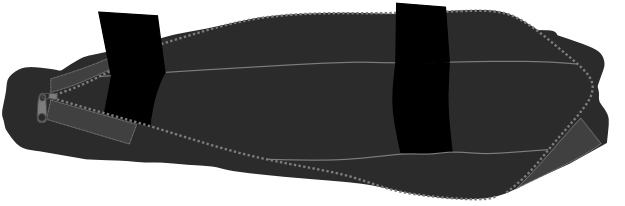
The coil directly connected to the control unit is referred to as the 1st coil. Where the matrix emitter configuration is used, the inductor coils queuing and the direction of the traveling pulsed magnetic field are similar.



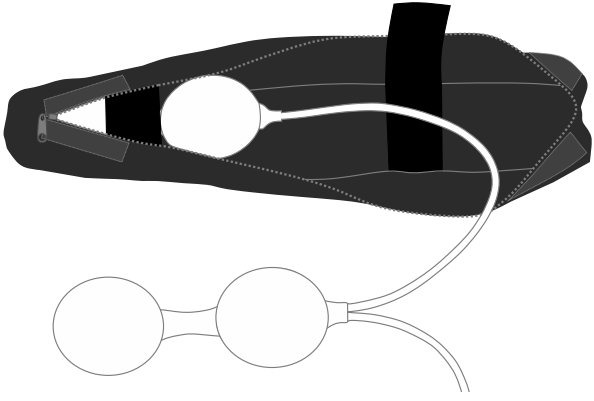
When using the four inductor coils configured in the form of «spline», the spline fastener (hereafter the fastener) is required. The fastener fixes the coils together preventing them from traveling relative to each other.

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

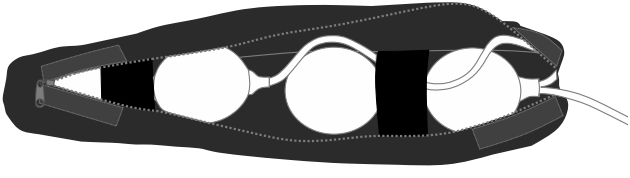
• Unzip the fastener and open the velcros located inside the fastener.



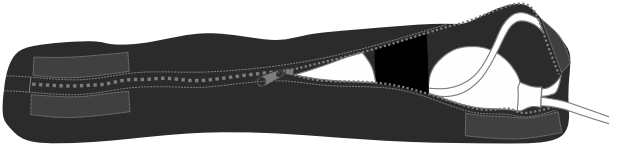
• Take the 3rd and 4th inductor coils of the device and fix them with velcros in the fastener at the 3rd and 4th coils connection point.



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



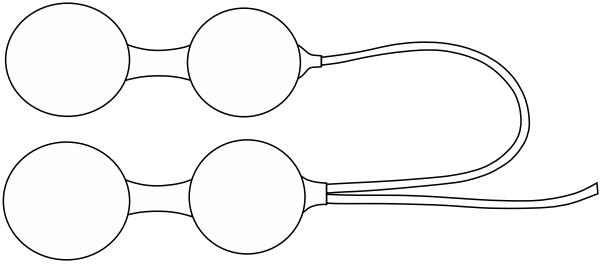
• Zip up the fastener.



• 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.

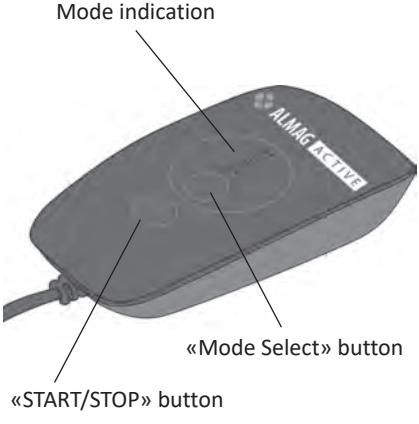


Connect the power cord of the device to the 230 V power network outlet.

⚠ ***Attention!*** *Locate the device at the site comfortable for use. Avoid tension of power cord and emitter cable. Only use working (fault-free) power socket. Make sure that the mains power is supplied to the electronic control unit.*

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.



8.2. Treatment Modes

Set the desired exposure mode using the «Mode Select» button switch. 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 desired treatment mode is set with «Mode Select» button as indicated in Table 1.

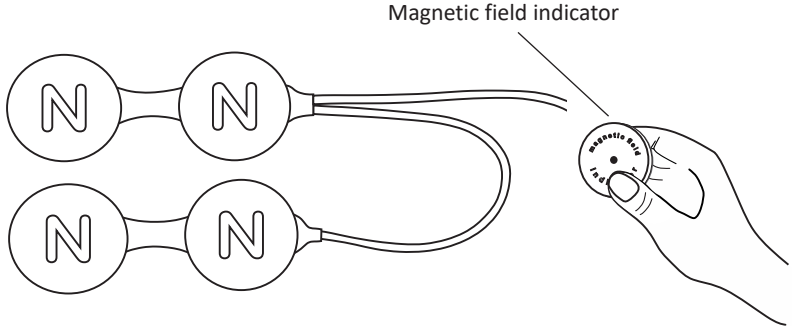
Table 1

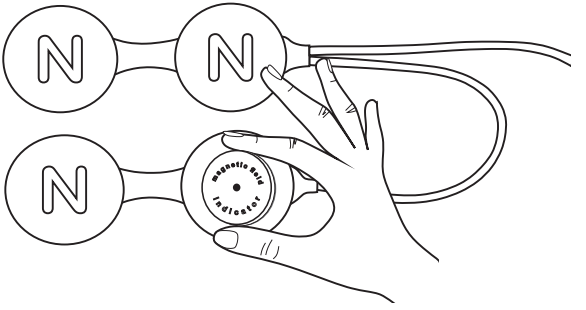
Operating mode	Field type	Inductor coil excitation frequency	Peak (amplitude) value of the magnetic field density on the inductor coil working surface		Mode description
			mT	G	
1	traveling	6.25 (1/8 of the mains frequency 50 Hz)	20±6	200±60	Basic mode of operation
2	traveling	6.25 (1/8 of the mains frequency 50 Hz)	8±2	80±20	Pediatric mode with reduced magnetic field density
3	stationary	100 (doubled mains frequency 50 Hz)	6±2	60±20	Therapeutic mode with pronounced analgesic and anti-inflammatory effects

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

⚠ ***Attention!*** *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.*





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.

Disconnect the device from the mains after use.

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.

8.3. Age-specific dosage prescriptions

Applying treatment to patients over 15 years old

During the treatment, the procedure duration and the treatment mode are chosen in accordance with Table 2.

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	

Applying treatment to patients under 15 years old

If used in pediatric practice, when conducting magnetotherapy procedures for children under the age of 15 years, the procedure duration and the treatment mode is chosen in accordance with Tables 3 thru 6.

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

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

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

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

8.4. Inductors application to deliver disease-specific procedures

Musculoskeletal system diseases:

• OSTEOCHONDROSIS

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 (see Figure 1).

With common osteochondrosis damaging three or more vertebrae the treatment is applied using a line of four inductors directly on the affected spine areas, as shown in Figure 2.

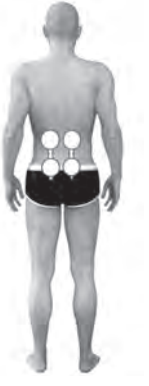


Fig. 1. Application of inductors when treating lumbosacral osteochondrosis

Fig. 2. Application of inductors when treating extensive osteochondrosis

In case of osteochondrosis complicated by radicular syndrome, the treatment is first applied onto the affected area of the spine, after which the device must be turned off, wait for 10 minutes, a line of emitters is installed along the affected nerve covering the nerve root and treat the second area, as shown in Figure 3.

• HUMEROSCAPULAR PERIARTHROSISIS

To correctly complete the procedure, it is necessary to arrange the line of four inductors as follows: the first inductor to which the power cord is connected is located on the front surface of the shoulder joint, the second overlaps back and is installed on the side of the joint, the third inductor is located at the rear, and the fourth inductor is extended towards the cervical spine, as shown in Figure 4.

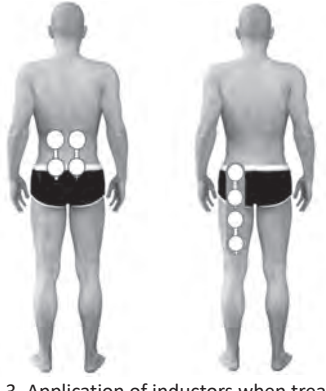


Fig. 3. Application of inductors when treating osteochondrosis complicated by nerve root syndromes

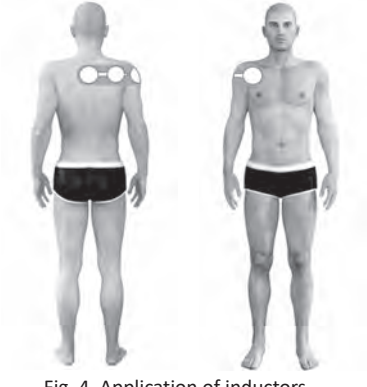


Fig. 4. Application of inductors when treating humeroscapular periarthrosis

• OSTEOARTHRITIS

In case of osteoarthritis of one joint, a line of four inductors is spirally wrapped around the joint covering the surrounding tissue as shown in Figure 5.

If it is necessary to treat two knee joints, one pair of inductors is applied to one affected joint, the second pair to the second, as shown in Figure 6. The interval between procedures is 10 minutes.

The arrangement of inductors for the simultaneous treatment of shoulder and elbow joints is shown in Figure 7.

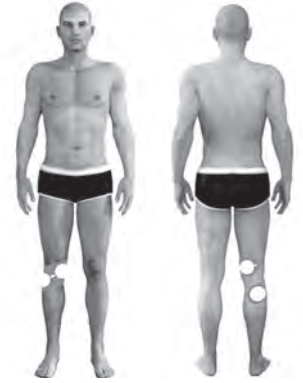


Fig. 5. Application of inductors in case of unilateral lesion of the knee joint

Fig. 6. Application of inductors in case of bilateral lesion of knee joints

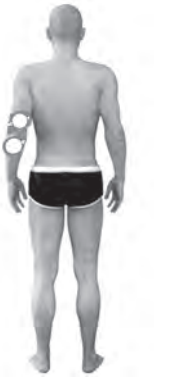


Fig. 7. Application of inductors in the simultaneous treatment of shoulder and elbow joints

If the hip joint is damaged, a line of four emitters is placed on the projection of the hip joint from the inguinal region through the large trochanter of the tibia (the most protruding part) to the sacral region, as shown in Figure 8.

In case of bilateral lesion of hip joints, the procedures are carried out alternately on one and another joints. The interval between procedures is 10 minutes.

If one shoulder joint is damaged, a line of four inductors is wrapped around the joint covering the surrounding tissue, as shown in Figure 9.

In case of bilateral lesion of shoulder joints, the procedures are carried out alternately on one and another joint. The interval between procedures is 10 minutes.

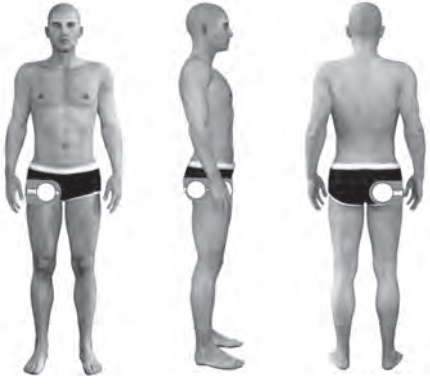


Fig. 8. Application of inductors in case of injured hip joints

Fig. 9. Application of inductors in case of unilateral lesion of the shoulder joint

• EPICONDYLITIS

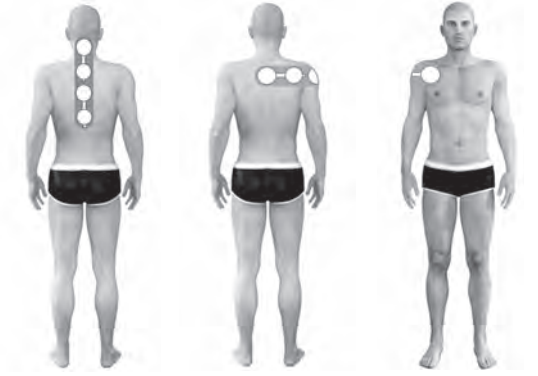
The inductor coils are located around the injured joint.

In case of shoulder epicondylitis, the inductor coils are applied around the joint, as shown in Figure 10.

With epicondylitis of the shoulder joint, in order to increase the treatment effectiveness, the device should act on two areas alternately. First, a line of four inductors is placed on the cervical and thoracic spine, as shown in Figure 11a. The exposure time is 5 minutes. After that, a line of four inductors is applied on the shoulder joint and muscles attached thereto, as shown in Figure 11b.

The exposure time is 15 minutes.

Fig. 10. Application of inductors when treating elbow epicondylitis



a) b)

Fig. 11. Application of inductors when treating shoulder epicondylitis

Injuries and their after-effects:

• BONE FRACTURES

IMPORTANT! In case of bone fracture, the treatment with the device is started on the 3th, 4th or 5th day from the injury occurence.

The inductor coils are installed on a plaster cast or directly on a limb during traction, along or around the bone, as shown in Figures 12 and 13.

The procedures are carried out twice a day. It is possible to use the device to perform short courses of treatment for post-traumatic pain syndrome in the area of a fused fracture during a change of weather, hypothermia.

This course consists of 7 or 8 procedures, the duration of one procedure is 20 minutes.

Repeat the treatment course after one month. The procedures are carried out once a week for 20 minutes. The therapy course lasts for 20 days.

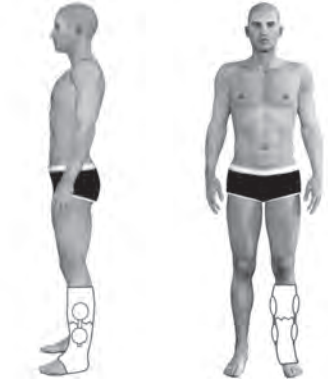


Fig. 12. Application of inductors on the fracture area of the calf

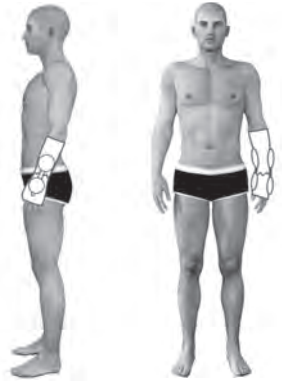


Fig. 13. Application of inductors on the fracture area in the lower third of the shoulder

• INTERNAL JOINT INJURIES

IMPORTANT! In case of hemarthrosis (presence of blood in the joint cavity), the procedures are carried out only after removal of blood from the joint cavity, as directed by the doctor.

A line of four inductors are spirally wrapped around the injured joint covering the surrounding tissue, as shown in Figures 14 to 18.

If two adjacent joints are injured (e.g. shoulder and elbow), the line of inductors is placed along the arm covering of these joints.

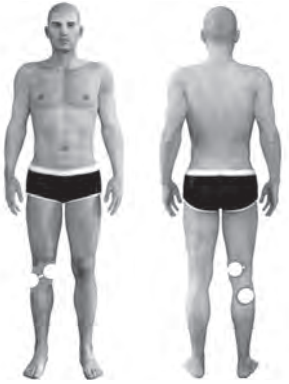


Fig. 14. Application of inductors in case of an injury of the knee joint

Fig. 15. Application of inductors in case of bilateral lesion of knee joints

Fig. 16. Application of inductors in case of injured shoulder and elbow joints

• POSTTRAUMTIC EDEMA

IMPORTANT! The treatment by the device is started no earlier than 12 hours from the moment of the occurence of the injury.

The procedures are carried out twice a day during 10 to 15 minutes. The inductor coils are situated along the lesion focus. If the injury is small, it is possible to limit to 6 to 12 procedures.

• DISLOCATIONS, DAMAGE TO THE LIGAMENTOUS APPARATUS – SPRAINS, TEARS; DAMAGE TO SKELETAL MUSCLES, SOFT TISSUE INJURIES

IMPORTANT! The treatment by the device is started on the 2nd or 3rd day from the moment of injury occurence.

A line of four inductors is wrapped around the injured area. The procedures are carried out twice a day.

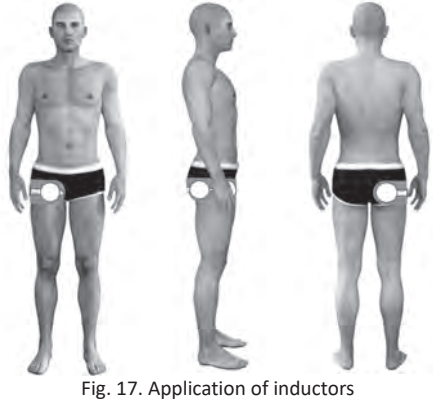


Fig. 17. Application of inductors in case of injured hip joints

Fig. 18. Application of inductors in case of shoulder joint injury

• VERTEBRAL COLUMN AND SPINAL CORD TRAUMAS

The patient's in prone or supine position. A line of four inductors are positioned along the spine. If for any reasons it is prohibited to turn the patient over; he/she can be slightly lifted and the inductors are put under the affected area of the spine so that the first inductor is located closer to the head, and in the injury area it is necessary to apply one of the other three inductors.

Diseases of peripheral nervous system:

NEURITIS

• FACIAL NERVE NEURTIS

One pair of inductors is placed with its working surface on the exit point of the facial nerve without strong pressing. The exit point of the facial nerve is situated under the auricle at the base of the lower jaw, as shown in Figure 19.

Fig. 19. Application of inductors in case of neuritis of the facial nerve

• RADIAL NERVE NEURITIS

A line of four inductors is applied (sequentially) onto the internal nude surface of the lower third of the shoulder, forearm and hand according to the following scheme:

1) the patient is in lying position;

2) the affected arm is laid with its palm up;

3) the first inductor lies on the region of the ulnar fossa, then it is necessary to spirally wrap the forearm with inductors so that the fourth inductor lies down on the palm, as shown in Figure 20. It is recommended to fix device either with an elastic bandage or a scarf.

Fig. 20. Application of inductors
in case of neuritis of the radial nerve

• ULNAR NERVE NEURITIS

A line of four inductors is applied onto the hand of the affected extremity from the palm side, on the area of wrist and on the forearm, as shown in Figure 21. The device's inductors are located from fingers to forearm.

• MEDIAN NERVE NEURITIS

A line of four inductors is applied onto the hand of the affected extremity from the palm side, on the area of wrist and on the forearm, as shown in Figure 21. The device's inductors are located from forearm to fingers.

• SCIATIC NERVE (ISCHIAS) NEURITIS

Procedure performing is according to the treatment procedure of lumbosacral osteochondrosis with radicular syndrome, as shown on figure 3.

Fig. 21. Application of inductors in case of neuritis of the ulnar and median nerves

• PERONEAL NERVE NEURITIS

For convenience, the procedure is recommended to be carried out on the patient while he/she is lying on his/her stomach. The first inductor of the line of four inductors is installed on the upper part of the popliteal fossa, the other three ones are placed on the calf outer surface from the affected side, as shown in Figure 22.

It is possible to perform the procedure on a seated patient. The first inductor of the line of four inductors is laid on the chair's end and is pressed by the affected leg. The rest three inductors are located on the outside of the calf and fixed with elastic fabric (scarf, towel, bandage).

Fig. 22. Application of inductors in case of neuritis of the fibula nerve

• PLEXITIS

Treatment procedure in case of brachial plexitis

The procedure is carried out on the patient lying on his/her back, but it is also possible on seated one.

The first and the second inductors of the line of four inductors are applied onto the area of the clavicle and shoulder joint (projection of the brachial plexus), the third and the fourth ones are located along the inside of the affected arm, as shown in Figure 23.

Treatment procedure in case of lumbosacral plexitis

The treatment using the device of the lumbosacral plexitis is carried out according to the scheme similar to the treatment of lumbosacral osteochondrosis with radicular syndrome as shown in Figure 3.

Fig. 23. Application of inductors
in case of brachial plexitis

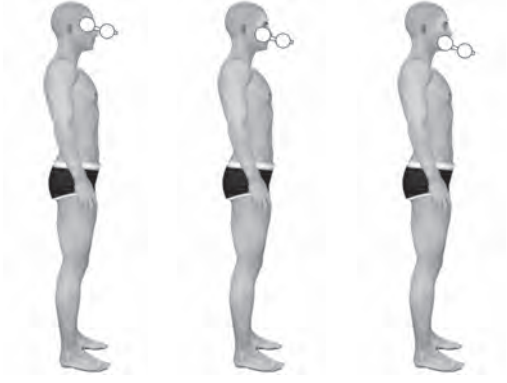
NEURALGIA

• TRIGEMINAL NEURALGIA

One pair of inductors is superimposed on the projection of the exit point of the trigeminal nerve,

depending on which branch of the nerve is affected:

- point 1 is on the upper orbital margin and is palpated 1.5 cm off the sides of the middle of the nose bridge (Fig. 24a);
- point 2 is in the center of the canine fossa (Fig. 24b);
- point 3 is 3 cm on the sides of the middle of the chin, in the projection of the chin opening of the alveolar canal of the lower jaw (Fig. 24c).



a) b) c)

Fig. 24. Application of inductors
in case of neuralgia of the trigeminal nerve

• OCCIPITAL NEURALGIA

One pair of inductors is superimposed on the projection of the exit point of the occipital nerve and the posterior surface of the neck, as shown in Figure 25.

• INTERCOSTAL NEURALGIA

A line of four inductors is placed on the corresponding segment of the spine on both sides and along the affected nerve endings, as shown in Figure 26.

Fig. 25. Application of inductors in case of neuralgia of the occipital nerve

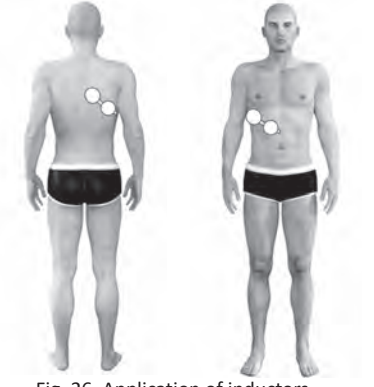


Fig. 26. Application of inductors in case of thoracodynia

Pancreatic diabetes complications:

• DIABETIC ANGIOPATHY AND POLYNEUROPATHY

In the treatment of diabetic polyneuro- and angiopathy, firstly, a line of four inductor coils is located on the front surface of the calf and lower, down to the back of the foot (Fig. 27a). After the end of the exposure, shutdown the device, take a break of 10 minutes, shift the line of four inductor coils to the front inner surface of the thigh, turn on the power and carry out the procedure (Fig. 27b). If both legs are affected, the procedure is applied to one leg, and the next day on the other. In case of trophic ulcer in calf or foot, the ulcer is cleaned before the procedure, a clean dressing is applied, and during the procedure, one of the emitters is installed on the projection of the ulcer (Fig. 27c).

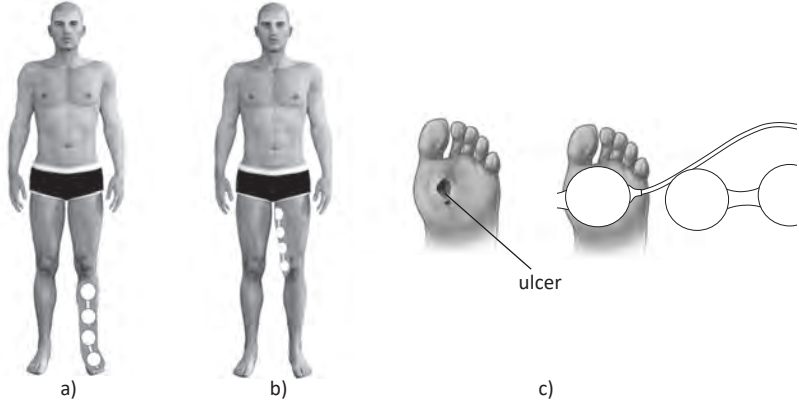


Fig. 27. Application of inductors
in the treatment of diabetic angiopathy and diabetic polyneuropathy

Diseases of venous system:

- DEEP VEIN THROMBOSIS OF THE LOWER LEG
- CHRONIC THROMBOPHLEBITIS
- VARICOSE VEINS

In case of such diseases, a line of four inductor coils is located along the calf back surface up to the lower third of the thigh.

In order to increase the effectiveness of the treatment of varicose veins and its complications, the combined use of magnetotherapy and external drugs prescribed by the attending physician in accordance with the treatment standards, the use of the device and anticoagulants are possible.

If both extremities are affected, the procedures are applied to both extremities once a day. If one leg is affected, then the procedure is repeated at home twice a day with an interval of at least 6 hours.

Fig. 28. Application of inductors in the treatment of diseases of the veins and lymph vessels

In case of trophic ulcer in the lower leg, the ulcer is cleaned before the procedure, a clean dressing is applied, and during the procedure, one of the emitters is placed on the projection of the ulcer.

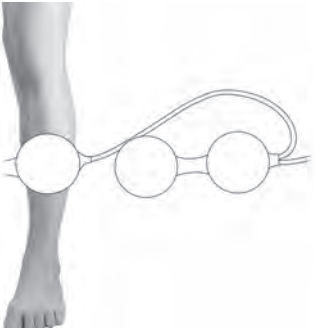


Fig. 29. Application of inductor inductors
when treating trophic ulcers in calves

9. 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 7

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

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 User 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

Warning! During repair device must be powered from isolation transformer.

10. 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 LED blinking, see Table 7)
- Inductor coils disinfection after their use (if necessary)

11. SPECIFICATIONS

Power supply	AC mains
frequency	50 Hz
voltage	~230^{+23}_{-32} V
Nominal power	110 VA
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 ±0.15 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 from 10% to 80% at 25 °C.

During transportation, the device is resistant to climatic factors at ambient temperatures of -50 °C to +50 °C and relative air humidity from 10% to 100%, and in storage packaged, it is resistant to ambient temperatures of -50 °C to +40 °C and relative air humidity from 10% to 98%.

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.

Class of device – IIa.

The device's components' dimensions and weight are given in Table 8.

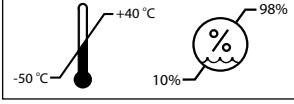
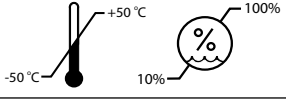
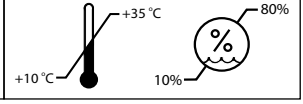
Table 8

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	

12. LIST OF STANDARDS USED

EN ISO 10993-1
EN 60601-1
EN 60601-1-2
EN 60601-1-11
EN 62304

13. STORAGE AND TRANSPORTATION

STORAGE CONDITIONS	TRANSPORT CONDITIONS	OPERATING CONDITIONS
		

14. ANNEX A

Table 1

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	Class B	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	

Table 2

Manufacturer's manual and declaration – interference resistance			
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.			
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV – contact discharge ±2, ±4, ±8, ±15 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	- U_T=0%, 0,5 cycle (0, 45, 90, 135, 180, 225, 270 and 315 degrees) - U_T=0%, 1 cycle; U_T=70%; 25/30 cycles (0 degrees) - U_T=0%; 250/300 cycle	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	30 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_T – is the voltage level of the mains until test exposure is applied.			

Table 3

Manufacturer's manual and declaration – interference resistance			
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.			
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 transmitter.
Conducted disturbances induced by RF fields according to IEC 61000-4-6	3 V (150 kHz - 80 MHz) 6 V (ISM & Amateur)	Complies	The field density in the propagation of radio waves from stationary radio transmitters, according to the results of observations of the electromagnetic situation, should be lower than the level of correspondence in each frequency band.
Radio-frequency electromagnetic field according to IEC 61000-4-3	10 V/m (80 MHz - 2.7 GHz)	Complies	The effect of interference may occur near the equipment marked with the symbol 

15. 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.

16. MANUFACTURER'S WARRANTY

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

Warranty operating life is 24 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 Active Pulsed Electromagnetic Field Therapy Device

Accepted on «____» _____ 20____

Shop foreman _____
surname and signature

Manufacturer's address:
391351, 25 Yanina st., Yelatma, Kasimov District, Ryazan region, Russia
JSC «Yelatma Instrument Making Enterprise»
Tel: +7 (4912) 293-418

WARRANTY CARD

for repair (replacement) during the warranty period
ALMAG Active Pulsed Electromagnetic Field Therapy Device

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

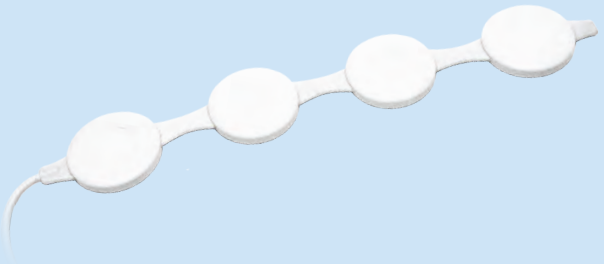
Head of the repair facility _____
(signature)

Head of the operator 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.

Yelatma Instrument
Making Enterprise, JSC
391351, 25 Yanina st.,
Yelatma, Kasimov District,
Ryazan region, Russia
tel. +7 (4912) 293-418
e-mail: global@elamed.com
elamed.com

almag·01



PULSED ELECTROMAGNETIC FIELD (PEMF) THERAPY DEVICE

ELAMED

USER MANUAL BEDIENUNGSANWEISUNG MANUEL D'UTILISATION
ISTRUZIONI D'USO MANUAL DE INSTRUCCIONES

KLEINGERÄT FÜR MAGNETFELDTHERAPIE MIT WANDERIMPULSMAGNETFELD

APPAREIL DE MAGNÉTOTHÉRAPIE PAR CHAMP MAGNÉTIQUE PULSÉ

IL DISPOSITIVO DI MAGNETOTERAPIA A CAMPO PULSATO CORRENTE, COMPATTO

EL EQUIPO DE ESCALA REDUCIDA PARA LA TERAPIA MAGNÉTICA MEDIANTE EL CAMPO MÓVIL DE IMPULSOS

OM 29.301.06
OM Revision Date – March 18, 2023

CONTENTS

DEAR CUSTOMER!

You have purchased ALMAG-01 Pulsed Electromagnetic Field (PEMF) Therapy Device (trademark ALMAG®), (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.

This User 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 User Manual carefully, and follow its instructions during further use to ensure proper treatment procedure and effectiveness.*

⚠ ***ATTENTION!*** *Before treatment start, carefully read the list of indications and contraindications and be sure to consult your doctor to determine the correct diagnosis and to exclude your existing diseases and conditions contraindicating the use of the device.*

If you have any questions when using the device at home, you should consult your doctor or physiotherapist for advice. You can also seek advice by phone +7 (4912) 293-418 or on the official website of the manufacturer en.elamed.com.

Be sure to keep the User 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 and precautions related to safety and operating efficiency


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


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


User Manual. Please read the User Manual carefully

Duty cycle: work: 22 min, a pause: 10 min

IP41
Control Unit of the product provides the ingress protection against items over 1 mm in diameter as well as vertically dripping water

Medical Device


Manufacturer

Date of manufacture

Serial number


Compliant with CU TR 020/2011
Technical Regulations of the Customs Union

Manufacturer's Trade Mark;
Device/product Name;
Power consumption;
Rated voltage and frequency;
«Made in Russia» text.

SAFETY MEASURES

Please study this User 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: ~230V (-32V; +23V), frequency 50Hz. Do not lift or carry the device by power cable!

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 ELECTROMAGNETIC 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;
- If the patient has a combination of various diseases, after the end of the course of treatment of one disease, a break of 10-15 days is taken and another disease is treated. In case of course treatment of the same disease, the interval between treatment courses is 1.5-2 months. Shorter pauses between treatment courses are only allowed upon the doctor's advice.

Attention! *It is not recommended to treat two various diseases at the same time (on the same day, during the same course of treatment).*

Attention! *When procedures are performed twice a day, the interval between procedures should be at least 8 hours, and the total duration of procedures should not exceed 40 minutes per day.*

- The optimal position of the patient during the procedure is the prone position. After completion of the procedure, it is necessary to remain in the horizontal position for 30 minutes to obtain the maximum effect.
- Do not use PEMF therapy after taking alcohol.

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 60601-1-2:2015 (IEC 60601-1-2014) 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.**

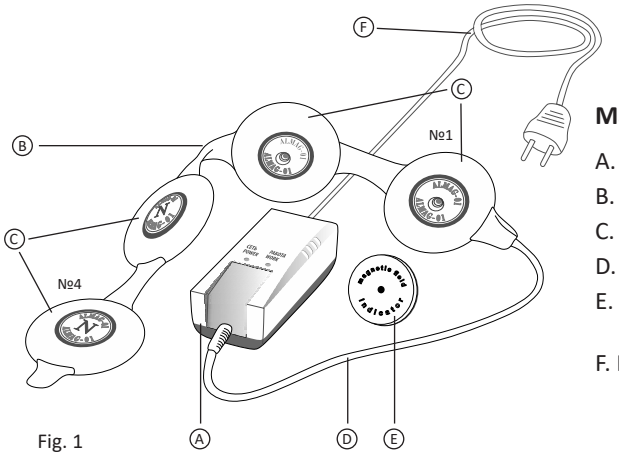
PURPOSE AND PRINCIPLE OF OPERATION

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 cord: (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
F. Power cord

Fig. 1

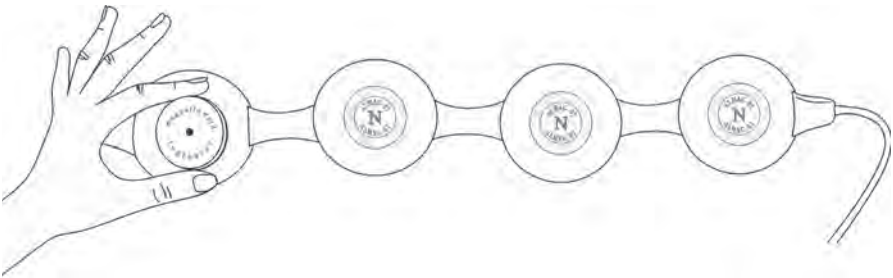
There are two indicator lights (LEDs) of different colours on the control unit box. The green light indicates that the device is connected to the power line. The yellow LED indicator lights up together with the green one and signals that the magnetic field is in action. The yellow LED is connected to a timer and turns off 22 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.**

SCOPE OF DELIVERY

ALMAG-01 Pulsed Electromagnetic Field Therapy Device	1
User 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
- 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

- acute infectious diseases and purulent-inflammatory processes in the acute phase
- pregnancy
- diseases and conditions associated with reduced blood clotting (including systemic blood diseases), continuing bleeding of any localization
- malignancies
- alcohol intoxication
- cardiovascular diseases accompanied by hemodynamic instability: crisis course of grade 3 arterial hypertension; pronounced arterial hypotension; significant cardiac rhythm and/or intracardiac conduction disorders; decompensated chronic heart failure, acute myocardial infarction; aortic and large vessel aneurysm
- thyrotoxicosis
- presence of an implanted pacemaker within a radius of 90 cm or less from the exposure zone

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

SIDE EFFECT

In order to avoid adverse events associated with impaired adaptation mechanisms of patients (increased blood pressure, exacerbation of concomitant diseases), do not allow an increase in the exposure time specified in the sections «General rules of procedure sequence» and «Methods of treatment of various diseases» of this User Manual. **Before starting treatment, be sure to consult your doctor to exclude diseases and conditions that are contraindications to the use of the device.**

ATTENTION! *Since it is possible to increase or decrease blood pressure in some cases against the background of procedures, regardless of which disease is treated, blood pressure should be monitored before the procedure and 20-30 minutes after it, especially during the first 6 days of treatment. Keep a «treatment log» by entering the measurement data required to trace the time course of blood pressure.*

In case of increase or decrease of blood pressure after performed procedure by not more than 10-25 mmHg, during the following procedure, it is necessary to reduce exposure time by 1/3.

In case of increase or decrease of blood pressure after performed procedure by more than 25 mmHg, before the next procedure, it is necessary to consult your doctor to resolve the issue of treatment adjustment.

If during the procedures there is an exacerbation of the symptoms of the disease (pain intensifies, dizziness occurs, etc.), a break in treatment should be taken for one day, after which the treatment should resume reducing the procedure time by 1/3. When the exacerbation reaction disappears, the procedure time is increased daily for 2 minutes. If the exacerbation response persists, it is necessary to consult your doctor to resolve the issue of treatment adjustment.

THE ORDER OF USE

Preparation for 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 and with 5% 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.

General rules of procedures

Before treatment start, carefully read the list of indications and contraindications and be sure to consult your doctor to determine the correct diagnosis and to exclude your existing diseases and conditions contraindicating the use of the device.

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

To get the maximum therapeutic effect, before carrying out the procedures, be sure to study the procedure with the device and strictly follow the recommended treatment methods. The effectiveness of magnetotherapeutic procedures depends on:

- strict compliance with recommendations on the procedure of the device application;
- individual magnetic sensitivity of the patient;
- stages and features of the course of the disease, for which treatment is carried out.

For treatment, the patient should take a comfortable position in which he/she will remain until the end of the treatment session. The optimal position of the patient during the procedure is the prone position. After completion of the procedure, it is necessary to remain in the horizontal position for 30 minutes to obtain the maximum effect.

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.

ATTENTION! *When procedures are performed twice a day, the interval between procedures should be at least 8 hours, and the total duration of procedures should not exceed 40 minutes per day.*

ATTENTION! *If the device affects two areas sequentially (for example, sequentially on the left and right knee joints) and the duration of exposure is more than 10 minutes for each area, after exposure to the first area, the device must be disconnected from the grid, installed on the second area and re-connected to the grid.*

Procedure administration order

1. Remove the device from the consumer container.
2. Before the first use of the device, disinfect it in accordance with the procedure described in the section «Preparation of the device for use».
3. Connect the power cord of the device to the power outlet. The device is now ready for use.

ATTENTION! *Avoid tension of power cord and emitter cable. Only use working (fault-free) power socket. Make sure that mains power is supplied to the electronic control unit.*

4. Take a comfortable, preferably horizontal position.
5. Place the line of emitters in the area of exposure in accordance with the method recommended in the section «Methods of treatment of various diseases» of this manual.
6. Perform the procedure. Recommended time for treatment of various diseases is indicated in the section «Methods of treatment of various diseases» of this manual.
7. Disconnect the mains cord from the power supply.
8. Perform disinfection of the device in accordance with the procedure described in section «Preparation for use».
9. Put the device in the consumer container.

METHODS OF TREATMENT OF VARIOUS DISEASES

MUSCULOSKELETAL SYSTEM DISEASES

Osteochondrosis

In case of procedures in the exacerbation period, exposure is applied only to the spine, and maximum duration of one procedure is 15 minutes. Before the procedure, the device is placed on a couch (bed), after which the patient lies on the device with the affected area of the spine and the treatment is carried out (Fig. 2).

The recommended course of treatment with one-day breaks includes 18 procedures (20 days).

In the first three days, the procedures are carried out with a minimum duration of 3 minutes, 3 times a day with an interval of at least 6 hours. The next three days, the procedure time is increased to 5 minutes for 3 times a day. After the first six days of treatment, a one-day break is taken. The next 6 days, the procedure are carried out for 10 minutes for 2 times a day, and on the 13th day of treatment, a break is taken again. For the last six days, the procedures are carried out 2 times a day during 15 minutes.

Fig. 2

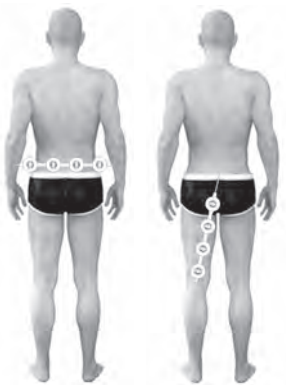


Fig. 3

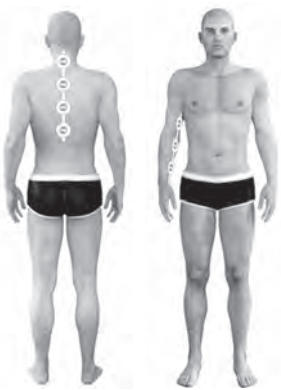


Fig. 4

In case of subacute osteochondrosis, complicated by radicular syndrome, the exposure is first applied to the affected spine (5 minutes), and then immediately to the affected nerve (5 minutes).

In the first 6 days, the procedures are carried out for 5 minutes for 2 times a day, and on the 13th day of treatment, a one-day break is taken. In the following 6 days, the procedures are carried out for 7 or 8 minutes for 2 times a day for each area, then a one-day break is taken again. And during the final six days of treatment, the exposure per each area is applied for 15 minutes 1 time a day.

In case of osteochondrosis of the lumbar spine with nerve root syndrome, the procedure is carried out in 2 stages: the device is first applied to the lumbar region transversely, and then along the sciatic nerve, along the back of thigh, as shown in Fig. 3.

In case of osteochondrosis of the cervical and thoracic regions with radicular syndrome, the device first is applied

to the corresponding spinal part, and then to the arm along the involved nerve, as shown in Fig. 4.

The course of treatment is repeated 30 to 40 days after the end of the first one, and the supportive course is carried out 3 or 4 months after the second one. When repeating the treatment courses, the procedures are carried out once a day for 15-20 minutes. The course of treatment includes 18 procedures (20 days, with breaks for 1 day after 6 and 12 procedures).

Deforming osteoarthritis

If osteoarthritis affects large joints (shoulder, elbow, knee, and ankle joints), the inductors are applied around, wrapping the joint (an example of device application in case of knee joint lesion is shown in Fig. 5).

If finger joints of a hand are affected, then the hands are placed on two medium inductors and covered with the two marginal ones.

In case of damage to adjacent joints, for example, shoulder and elbow or elbow and hand joints, the inductors are placed along the extremity, so that the marginal inductors cover the affected joints. The arrangement of inductors for the simultaneous treatment of shoulder and elbow joints is shown in Fig. 6.

> ***During the treatment of osteoarthritis, the magnetic therapy procedures by the ALMAG device can be combined with the use of ointments or gels with non-steroidal anti-inflammatory agents.***

Fig. 5

Fig. 6

Fig. 7

Then, for six days, the procedures are carried out 2 times a day during 5 minutes per joint. On the seventh day, a break should be taken, and the next six days the procedure are carried out 2 times a day for 8 minutes per joint. On the 13th day of treatment, a one-day break is again made, after which during the next six days, the procedures are carried out once a day. If one or two joints are treated, the duration of exposure per one joint is 15-20 minutes. If three or four joints are treated simultaneously, the duration of exposure per one joint should be no more than 10 minutes.

Attention! *When treating several joints at the same time, the total exposure time should not exceed 40 minutes per day.*

The treatment course is repeated in 1 or 2 months. When repeating the treatment courses, the procedures are carried out once a day for 15-20 minutes. The therapy course lasts for 20 days, no breaks.

If the hip joint is affected, the inductors are placed so that the last inductor is located on the buttock, the two middle inductors are located on both sides of the greater trochanter (protruding bone), and the first is applied above the inguinal fold in front of the joint (Fig. 7). Then, for six days, the procedures are carried out 2 times

a day during 8 minutes. On the seventh day, a break should be taken, and the next six days the procedure are carried out 2 times a day for 10 minutes. On the 13th day of treatment, a one-day break is again made, after which during the next six days, the procedures are carried out once a day for 20 minutes. The treatment course is also repeated in 1 or 2 months.

When repeating the treatment courses, the procedures are carried out once a day for 15-20 minutes. The therapy course lasts for 20 days, no breaks. Preventive therapy courses are carried out 3 to 4 times a year.

Humeroscapular periarthrosis

Device application chart: the first inductor is located on the front surface of the shoulder joint, the second overlaps back and is applied on the joint side, the third inductor is located at the rare, and the fourth inductor is stretched towards the cervical spine (Fig. 8). In the first six days, the procedures are carried out 2 times a day for 7 minutes, then a break is introduced on the seventh day. Then, for six days, the procedures are carried out 2 times a day during 12 minutes. Then, on the 13th day, a break is again made and during the last 6 days the procedures are carried out 2 times a day for 15 minutes.

When repeating the treatment courses, the procedures are carried out once a day for 15-20 minutes. The therapy course lasts for 20 days, no breaks.

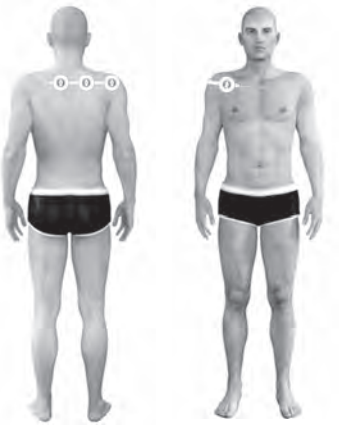


Fig. 8

Arthritis

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

The procedures are carried out twice a day. The inductor coils are located around the injured joint.

In case of shoulder epicondylitis, the coils-inductors of the device are applied around the joint (Fig. 9). The procedures are carried out once or twice a day for 10 minutes. The course of treatment is 20 days with a one-day break after the 10th day of therapy.

Fig. 9

In case of epicondylitis of the shoulder joint, it is necessary to expose the two areas alternately: first, the inductor coils are placed on the cervical and thoracic spine, the exposure time is 5 minutes; then the inducting coils are applied to the shoulder joint so as to cover the muscles attached thereto, the exposure time is 15 minutes. The therapy course lasts for 18 days. The inductor arrangement chart is shown in Figure 8.

For epicondylitis with damage to the Achilles tendon, the treatment regimen is as follows: the first two inductors are placed on the planta, so that the second inductor is located in the heel area; the other two inductors are located along the posterior surface of shin (tendon projection) and the lower part of the gastrocnemius muscle.

The duration of treatment in the first 3 days is 15 minutes, the following days it is increased up to 20 minutes – once a day. The therapy course lasts for 18 days. After 2 months, the second course of treatment is carried out.

When repeating the treatment courses, the procedures are carried out once a day for 15-20 minutes during 20 days, no breaks.

Gout

The treatment method is similar to the therapy in case of arthritis.

Bursitis

In case of bursitis of shoulder, elbow, knee, ankle, hand joints, the inductors are applied around the joint, wrapping the joint (exemplary treatment of the knee joint is shown in Figure 5). If the hip joint is affected, the inductors are placed so that the

last inductor is located on the buttock, the two middle inductors are located on the side surface of thigh, and the first is applied above the inguinal fold (Fig. 7).

The procedures are carried out twice a day with an interval of at least 6 hours. The first course of treatment should be started with a minimum duration of 10 minutes, gradually increasing up to 20 minutes. The maximum duration of the procedure per day may be up to 30 minutes (when carrying out procedures twice a day). The recommended therapy course lasts from 15 to 20 days. After the 6th, the 12th day of treatment, a break of 1 day is taken. In case of bursitis of 2 or more joints, the total time of one procedure should not exceed 20 minutes. No more than two joints can be treated during one course. After the end of the course, it is necessary to take a break for 10 days and the treatment of other joints or other diseases may be started.

In case of damage to adjacent joints, for example, shoulder and elbow or elbow and hand joints, the inductors are placed along the extremity, so that the marginal inductors cover the affected joints. The arrangement of inductors for the simultaneous treatment of shoulder and elbow joints is shown in Fig. 6.

The course of treatment is repeated 30 to 40 days after the end of the first one, and the supportive course 3 or 4 months after the second one is completed. When repeating the treatment courses, the procedures are carried out once a day for 15-20 minutes. The therapy course lasts for 20 days, no breaks.

Myositis

Procedure sequence: the coils-inductors of the device are placed along the affected muscle or muscle group of the back, neck, upper or lower extremities. If trunk muscles are affected, the inductors are placed on the couch (bed), the patient lies on top, so that the inductors are applied along the affected muscles. An example of applying the device in case of myositis of the back muscles is shown in Fig. 10.

The first six days, the exposure is applied 2 or 3 times a day for 3-5 minutes, depending on the severity of the pain syndrome. On the seventh day, a break is taken, after which, in the next six days, the procedure time is increased up to 5-7 minutes, 2 times a day. On the 13th day, a one-day break is

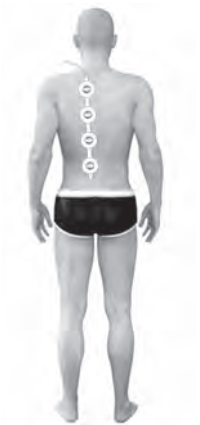


Fig. 10

again taken. If necessary, the treatment is prolonged for another six days, and the procedures are carried out for 10 minutes 1 or 2 times a day.

Tenosynovitis

The treatment is started after acute symptoms remitting. The treatment method is similar to the therapy in case of epicondylitis.

INJURIES AND THEIR AFTER-EFFECTS

Bone fractures

It is recommended to start treating with ALMAG on the 3rd-5th day after its occurrence.

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

The emitters are put on a plaster bandage or directly on a limb along or around the bone (see Fig. 11).

Fig. 11

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.

In case of long-lasting pain syndrome with already fused fracture, a short course of treatment is possible in the area of fracture consolidation (fusion of bone fragments). 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, posttraumatic joint contracture

Attention! 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.

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).

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, wounds

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

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

The treatment is carried out upon a doctor's recommendation on the 2nd or on the 3rd day after immobilization.

The exposure can be applied through a dressing, including a plaster cast.

If the doctor recommends the local application of cold in the injured area, the magnetotherapy procedure is performed immediately after the cooling procedure. Coils-inductors are wrapped around the injured area. On the first day, the procedures are carried out 2 times a day during 10 minutes. In the following days, the procedures are carried out 2 times a day for 15 minutes. The therapy course lasts for 18 days.

Postoperative wounds

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). 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

The treatment with the ALMAG-01 device of purulent wounds, phlegmons and burns is started only after surgical treatment, against the background of using anti-

bacterial therapy or local antiseptics, in the absence of acute infectious inflammation, upon the recommendation of the attending physician.

The coils-inductors are applied over a wet or dry gauze dressing (after wound cleaning) along the affected area. The procedure time is 10 to 15 minutes. The treatment is carried out once a day. The therapy course lasts from 10 to 18 days. The course may be repeated in 30 to 40 days.

DISEASES OF PERIPHERAL NERVOUS SYSTEM

Neuritis

The device is superimposed along the nerve so that the first inductor is located closer to the spine, and the last one is distanced away therefrom. The first course of treatment is carried out in accordance with the methodology specified in Table 1. The treatment course is repeated in 1 month. When carrying out repeated courses of treatment, the technique indicated in Table 2 is used.

Table 1

The first course procedures duration

Treatment day						
1	2	3	4	5	6	7
Total duration for one area (min.)						
5	5	7	10	12	12	Interruption
Treatment day						
8	9	10	11	12	13	14
Total duration for one area (min.)						
12	15	15	15-20	15-20	15-20	Interruption
Treatment day						
15	16	17	18	19	20	
Total duration for one area (min.)						
15-20	15-20	15-20	15-20	15-20	15-20	

Table 2

The repeated course procedures duration

Treatment day						
1	2	3	4	5	6	7
Total duration for one area (min.)						
15-20	15-20	15-20	15-20	15-20	15-20	Interruption
Treatment day						
8	9	10	11	12	13	14
Total duration for one area (min.)						
15-20	15-20	15-20	15-20	15-20	15-20	Interruption
Treatment day						
15	16	17	18	19	20	
Total duration for one area (min.)						
15-20	15-20	15-20	15-20	15-20	15-20	

Facial nerve neuritis

The exposure is applied with one inductor coil, which working surface is superimposed over the exit point of the facial nerve (under the auricle at the base of the lower jaw) (see Fig. 12).

Radial nerve neuritis

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's in lying position;

2) the affected arm is laid with its palm up;

3) the first inductor lies on the region of the ulnar fossa, then it is necessary to spirally wrap the forearm with inductors so that the fourth inductor lies down the palm (see Fig. 13).

Ulnar nerve neuritis

The device is applied in such a way that the first inductor is located closer to the spine. (see Fig. 14).

Median nerve neuritis

Coils-inductors are applied onto the hand of the affected extremity from the palm side, on the area of wrist and on the forearm (see Fig. 14). The device's inductors are located from forearm to fingers.

Sciatic nerve (ischias) neuritis

The procedure is carried out according to the method of treating lumbar osteochondrosis with radicular syndrome.

Peroneal nerve neuritis

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. 15).

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.

Plexitis

With plexitis of the brachial plexus, the first and the second inductors are applied to the area of the clavicle and shoulder joint (projection of the brachial plexus), the third and fourth ones are applied along the inner side of arm on the side of the affected nerve plexus.

Fig. 12

Fig. 13

Fig. 14

Fig. 15

Fig. 16

The treatment of lumbosacral plexitis using the ALMAG device is carried out according to the same regimen as the treatment of lumbosacral osteochondrosis with radicular syndrome.

NEURALGIA

In case of trigeminal neuralgia, occipital nerve and intercostal neuralgia, the device is applied so that the first inductor is located closer to the spine, and the last is at a distance away from the spine. The first course of treatment is carried out in accordance with the methodology indicated in Table 1. The treatment course is repeated in 1 month. When carrying out repeated courses of treatment, the technique indicated in Table 2 is used.

Trigeminal neuralgia

The inductor is superimposed on the projection of the exit point of the trigeminal nerve (see Fig. 17).

Fig. 17

Fig. 18

Fig. 19

Occipital neuralgia

Two emitters are placed on the skin projection of the output point of the occipital nerve and the back surface of the neck (see Fig. 18).

Intercostal neuralgia

A line of emitters is applied to the corresponding intercostal space along the affected nerve terminations (see Fig. 19).

TRAUMAS OF CENTRAL NERVOUS SYSTEM

Vertebral column and spinal cord traumas

The magnetic therapy by the ALMAG-01 device, in case of spinal and spinal cord injuries, is carried out only under the supervision of the attending physician, after providing emergency medical care.

The patient is in prone or supine position. The coils-inductors are placed along the spinal column, in the area of injury so that the first inductor is located closer to the head, and one of the inductors must be applied at the point of the injury itself (see Fig. 20). The first course of treatment is carried out in accordance with the

methodology indicated in Table 1. The treatment course is repeated in 1 month. When carrying out repeated courses of treatment, the technique indicated in Table 2 is used.

Disorders of the spinal blood circulation

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.

Fig. 20

PANCREATIC DIABETES COMPLICATIONS

Diabetic angiopathy

In case of damage to the vessels of legs, at the procedure start, the exposure is applied to the anterior-inner surface of thigh for 20 minutes, and then the tibia is wrapped covering the back of foot and also exposed to the device's action for 20 minutes (see Fig. 21). In this case, the first inductor is located closer to the knee, and the last closer to the foot.

The right and the left extremities are exposed alternately, every other day.

The therapy course is from 15 to 20 days, with 1-day breaks after the 6th and the 12th days of treatment. After 2 months, a second course of treatment is recommended. Supportive magnetic therapy courses are recommended 3 to 4 times a year.

Attention! Control of the glucose level in the blood is required during treatment!

Fig. 21

Diabetic polyneuropathy

The coils-inductors are applied in their respective turn on the back surface of calf and then on the back of thigh (see Fig. 22, 23):

- Field # 1 – the popliteal fossa and the sural muscle;
- Field # 2 – the back of thigh.

The procedures are carried out once a day. The duration of exposure for each zone is 20 minutes. The total exposure time is 40 minutes. Since neuropathy occurs most often on both lower extremities, the procedures are carried out alternately, once a day. The therapy course is from 15 to 20 days, with 1-day breaks after the 6th and the 12th days of treatment. After 2 months, a second course of treatment is recommended. Supportive magnetic therapy courses are recommended 3 to 4 times a year.

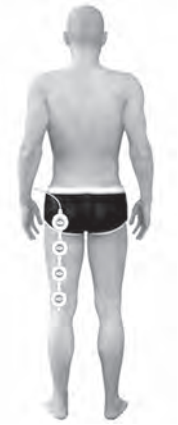


Fig. 22

DISEASES OF THE VENOUS SYSTEM

Deep vein thrombosis of the lower leg

In case of damage to both extremities, the exposure to each extremity is applied once a day, and in case of damage to a single extremity, the exposure is applied twice a day.

The line of emitters is applied along veins (see Fig. 24). 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 12-15 days, with a 1-day break after the 6th day of treatment. A repeated treatment course is carried out in 2 months.

It is possible to carry out combined magnetic therapy procedures by ALMAG-01 using local drugs.

Fig. 23

Chronic thrombophlebitis at a stage of trophic disorders

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 15-20 days, with 1-day breaks after the 6th and the 12th days of treatment.

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.

Fig. 24

Varicose veins

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. 24). 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 15-20 days, with 1-day breaks after the 6th and the 12th days of treatment. A repeated treatment course is carried out in 2 months.

It is possible to carry out combined magnetic therapy procedures by ALMAG-01 using local drugs.

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	~230V (-32V; +23V), frequency 50Hz
Power consumption	51 V·A
Weight, not more than	0.8 kg
Overall dimensions:	
- Power supply unit	135±10 x 58±5 x 44±5 mm
- Emitter (single piece)	90±5 x 15±5 mm
Note: max deviation: ±3%.	
The number of emitters	4
Amplitude value of magnetic induction on an emitter's surface (both flat sides)	20±6 mT
Pulse duration	1,5-2,5 ms
Magnetic field frequency for each emitter	6,25Hz

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 22 min followed by a 10 min break.

The magnetic field effect shuts down automatically after 22 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 – 8 years.

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

Maximum temperature after one operation cycle:

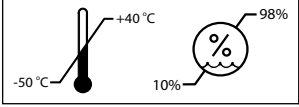
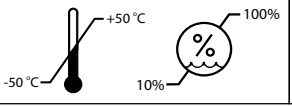
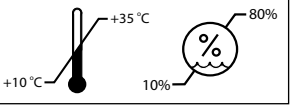
- Control unit, max: +45 °C;
- Emitter, max: +41 °C.

Class of device – IIa.

LIST OF STANDARDS

EN ISO 10993-1
EN 60601-1
EN 60601-1-2
EN 60601-1-11
EN 62304

STORAGE AND TRANSPORTATION

STORAGE CONDITIONS	TRANSPORT CONDITIONS	OPERATING CONDITIONS
		

ANNEX A

Table 1

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	Class B	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	

Table 2

Manufacturer's manual and declaration – interference resistance			
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.			
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV – contact discharge ±2, ±4, ±8, ±15 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	- U_H=0%, 0,5 cycle (0,45,90,135,180,225,270 and 315°) - U_H=0%, 1 cycle - U_H=70%; 25/30 cycles (0°) - U_H=0%, 250/300 cycle	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	30 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.			

Table 3

Manufacturer's manual and declaration – interference resistance			
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.			
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 transmitter.
Conducted disturbances induced by RF fields according to IEC 61000-4-6	3 V (150 kHz - 80 MHz) 6 V (ISM & Amateur)	Complies	The field density in the propagation of radio waves from stationary radio transmitters, according to the results of observations of the electromagnetic situation, should be lower than the level of correspondence in each frequency band.
Radio-frequency electromagnetic field according to IEC 61000-4-3	10 V/m (80 MHz - 2.7 GHz)	Complies	The effect of interference may occur near the equipment marked with the symbol 

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 con-sequences for the environment and human health.

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.

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.

Warranty sheet for repair or replacement works within warranty period
ALMAG-01 (PEMF) Therapy Device
(Trademark ALMAG®)

Accepted on «____» _____ 20____

Shop foreman _____
surname and signature

Manufacturer's address:
391351, 25, Yanina st., Yelatma, Kasimov District, Ryazan region, Russia
JSC «Yelatma Instrument Making Enterprise»
Tel: +7 (4912) 293-418

WARRANTY SHEET
for repair (replacement) within warranty period
of ALMAG-01 Pulsed Electromagnetic Field (PEMF) Therapy Device
(Trademark ALMAG®)

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

Signature of the Head of Repair Center _____
(signature)

Signature of the Owner _____
(signature)

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

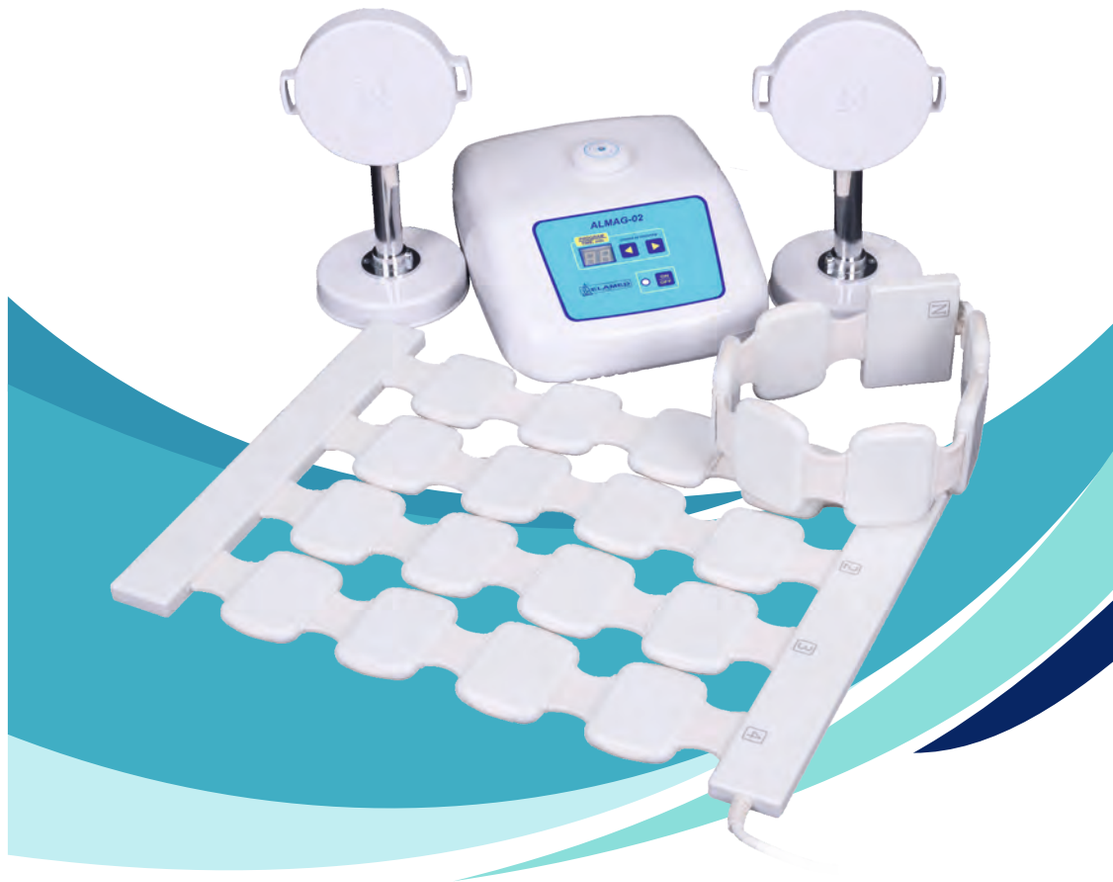
ELAMED Company

Yelatma Instrument
Making Enterprise, JSC
391351, 25 Yanina st.,
Yelatma, Kasimov District,
Ryazan region, Russia
tel. +7 (4912) 293-418
e-mail: global@elamed.com
elamed.com

OM 29.520.03
OM Revision Date – March 21, 2023

ALMAG®-02

- PULSED ELECTROMAGNETIC FIELD THERAPY DEVICE
- GERÄT FÜR MAGNETFELDTHERAPIE
- L'APPAREIL DE MAGNÉTOTHÉRAPIE
- IL DISPOSITIVO DI MAGNETOTERAPIA
- EL EQUIPO DE MAGNETOTERAPIA



USER MANUAL
BEDIENUNGSANLEITUNG
MANUEL D'UTILISATION
MANUALE D'USO
MANUAL DE INSTRUCCIONES

CONTENTS

DEAR CUSTOMER!

You have purchased «ALMAG-02» Pulsed Electromagnetic Field Therapy Device intended for therapy of a wide range of diseases with low-frequency, low-intensity pulsed electromagnetic field (hereinafter referred to as the device).

Please study this User Manual carefully. It serves as the Manufacturer's guarantee of the basic parameters and technical features of the device and identifies therapeutic indications for its use and contraindications, its safety, principles and operation rules. This will allow You to use unique capabilities of the device optimally and reach maximum effectiveness by the hospital use for treatment and prevention of a wide range of diseases, as well as for home use by patients upon doctor`s advice.

⚠ ***ATTENTION!*** *No special training or skills are required to carry out the procedures by the patient at home. In order to perform treatment, please follow the guidelines of this Manual.*

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

⚠ ***ATTENTION!*** *The device should be used to treat the diseases listed in the «Indications» section ONLY after a precise diagnosis has been established.*

If you have any questions when using the device at home, you should consult your doctor or physiotherapist for advice. You can also seek advice by phone +7 (4912) 293-418 or on the official website of the manufacturer en.elamed.com.

Please keep the User 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 User Manual carefully


Emitters are protected with reinforced insulation

Duty cycle: work: 30 min, a pause: 5 min

Medical Device


Manufacturer

Date of manufacture

Serial number

Manufacturer's Trade Mark;
Device/product Name;
Power consumption;
Rated voltage and frequency;
«Made in Russia» text.

SAFETY MEASURES

Please study this User Manual carefully before use.

Carry out the procedures in places suitable for plugging the device into the power supply socket without straining the mains cord. Use only properly functioning sockets with an operating voltage of ~230V (+23V; -32V), frequency 50Hz.

It is **PROHIBITED** to lift or carry the device by the power cord.

To avoid possible damage to the device, keep it away from unsupervised reach of children.

Make sure to examine the device for presence of mechanical damages of the cables, plug, mains cord, as well as the emitters' and power and control unit's housings. Using the device if any of these damages have been detected is **PROHIBITED**.

Store and use the control unit and emitters only in dry places.

Avoid penetration of moisture inside the power and control unit and the emitters while treating their surfaces with disinfectants. Protect the device from dampness, shock and impact, as well as from contact with open flame.

Keep the device away from direct sunlight and high temperatures.

After storage or transportation of the device at low temperatures, keep it at room temperature for at least 4 hours prior to usage start.

Do not twist or bend the cables; store the device in the consumer container after use.

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).

Instructions on environmental protection: Dispose of the device upon termination of its service life as electronic waste at specialized recycling points.

Exclusion of liability: the Manufacturer shall not be held liable for damages resulting from non-observance of the above instructions.

Attention! *The DEVICE requires special measures to ensure ELECTROMAGNETIC COMPATIBILITY and shall be installed and commissioned according to the information related to EMC as given in this Operation Manual.*

Attention! *Use of mobile radio frequency communication means may effect the MEDICAL ELECTRIC PRODUCTS.*

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 60601-1-2:2015 (IEC 60601-1-2014) 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 B.

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

PURPOSE AND PRINCIPLE OF OPERATION

The device is intended for therapy of a wide range of diseases with low-frequency, low-intensity pulsed electromagnetic field. The device is designed for treating patients with acute and chronic diseases of internal organs, cardiovascular, bronchopulmonary, nervous system and locomotor system diseases, traumas, postoperative complications, dysimmunity.

The device generates continuous and pulsed electromagnetic fields (traveling or static) that differ in configuration, intensity, direction, and speed. The device provides storage of 79 preset exposure programs in its non-volatile memory.

The device has a simple, intuitive user interface (with only two buttons to select the program number and a button to launch the action).

The device operates in the following ambient conditions:

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

The device consists of a power and control unit (Fig. 1) and emitters of three types (Fig. 2, 3, 4).

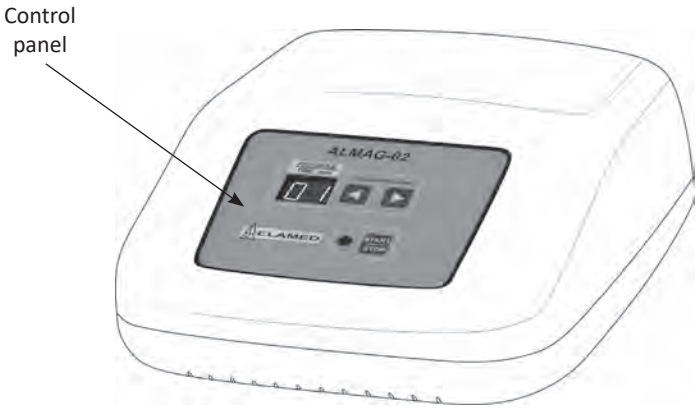


Fig. 1

The main emitter has a flexible emitting surface consisting of 4 flexible emit-ting lines, with 4 individual emitters in each line (Fig. 2). The flexible emitting line is basically a strip comprising a pulse generation unit (PGU) and 6 emitters (Fig. 3). The local emitter consists of a pulse generation unit and two emitters (Fig. 4).

The configuration of the emitters in the shape of a flexible emitting surface and flexible emitting line allows to wrap them around the limbs or spread them out flat for therapy of the body.

The areas that can be exposed to electromagnetic therapy are: lower or upper limbs, lower back, backbone, cervical region, the dorsum (back), and the chest. The local emitter provides only local, focused exposure. The pulsed electromagnetic field formed by the local emitter ensures a deeper penetration than the field formed by other emitters.

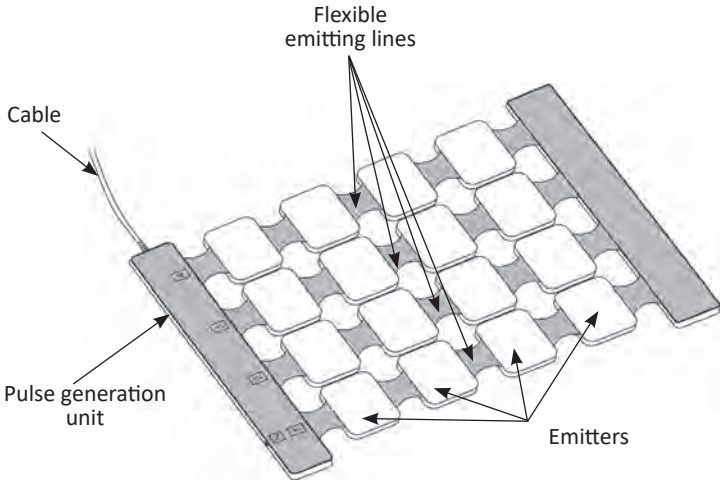


Fig. 2

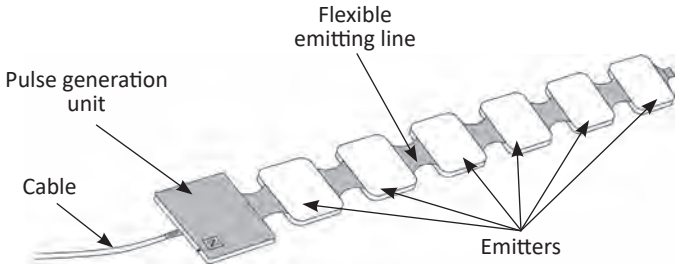


Fig. 3

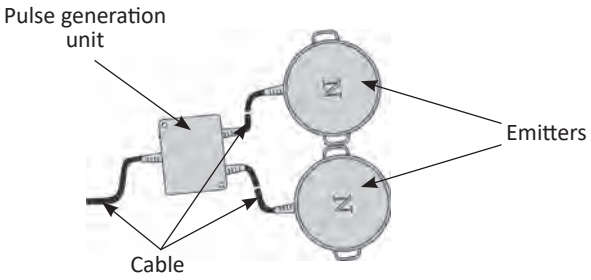


Fig. 4

Functions of the control and display elements

The front panel of the control unit has the following controls and displays (Fig. 5):

1 – «◀» «▶» buttons – program number setup (number downwards/ upwards);

2 – «START/STOP» button – switching the PEMF action on/off;

3 – LED indicator displaying (depending on the operating mode) either the program number, or the exposure time under the selected program, or the error code;

4 – PEMF action indicator.

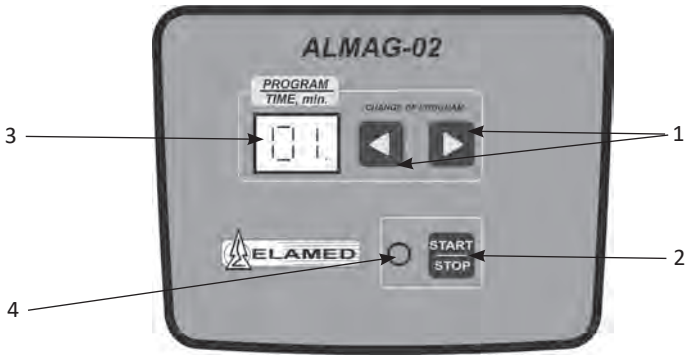


Fig. 5

The pulse generation units (PGUs) of the emitters have indicators (Fig. 6, pos. 1) signaling presence of the magnetic field.

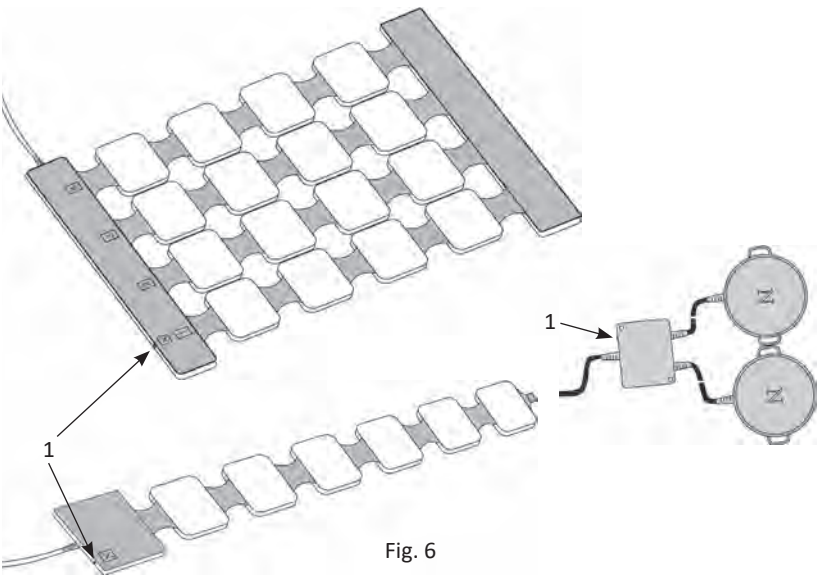


Fig. 6

SCOPE OF DELIVERY

Product complete set is given in the table below.

Table 1

Name	Delivery option 1	Delivery option 2
Power and control unit	1	1
Main emitter	1	1
Flexible emitting line	1	1
Magnetic field indicator	1	1
Local emitter	-	1
Fixing belt	1	1
Handle	-	2
Rack	-	2
Hex key bent (imbus),3 mm	-	1
Hook	1	1
Fastening of the coil group	2	2
User Manual	1	1

INDICATIONS FOR USE

Diseases of nervous system:

Migraine
Disorders of separate nerve roots and plexuses of upper and lower limbs
Diabetic polyneuropathy
Postherpetic neuropathy
Raynaud`s syndrome («dead finger» syndrome)

Diseases of circulatory system:

After-effects of cerebrovascular diseases
Atherosclerotic vascular disease, endarteritis deformans or obliterating endarteritis
Atherosclerotic (discirculatory) encephalopathy
Varicose veins
Deep vein thrombophlebitis of the lower leg
Chronic thrombophlebitis accompanied by trophic disorders

Musculoskeletal system and the connecting tissue diseases:

Gout
Coxarthrosis (arthrosis of the hip joint)
Gonarthrosis (arthrosis of the knee)
Arthrosis of the first carpometacarpal joint
Internal and external humeral epicondylitis (tennis elbow and golf elbow)
Humeroscapular periarthrosis
Acute trophoneurotic bone atrophy (Sudeck`s atrophy)
Tenosynovitis crepitans of the forearm
Tietze's syndrome (aseptic inflammation of coastal cartilages in the area of rib attachment to sternum, more often of ribs II-IV, with a painful thickening)
Osteochondropathy (Kohler disease, Kienbock's disease, Perthes disease, Schlatter disease, Koenig's disease)
Spondylitis deformans (Strumpell-Marie disease)
Osteoarthritis of the temporomandibular joint
Calcaneal periostosis (plantar fasciitis), heel spur
Joint contracture (Dupuytren`s contracture)
Rheumatoid arthritis
Osteoarthritis
Vertebral osteochondrosis (degenerative disk disorder)
Posterior cervical sympathetic syndrome
Vertebrobasilar syndrome
Vertebrogenic myelopathy syndrome
Osteoporosis with pathologic fracture
Osteoporosis without pathologic fracture

Traumas:

Wounds (after surgical debridement)
Posttraumatic hematoma (2-3 days after trauma)

Elbow and forearm traumas:
Dislocation, sprain or strain of the capsular ligamentous apparatus of the elbow joint
Dislocation of head of radial bone
Traumatic rupture of the radial collateral ligament

Nerve trauma at the forearm level:
Ulnar nerve trauma at the forearm level

Wrist and hand traumas:
Finger contusion without nail plate injury
Finger contusion with nail plate injury

Body traumas:
Superficial traumas of upper limbs
Superficial traumas of lower limbs

Coccygeal (tailbone), hip joint area and thigh traumas:
Hip joint contusion
Thigh contusion
Traumatic coccyalgia

Contusion of another clarified or non-clarified part of lower leg:
Multiple superficial traumas of the lower leg
Knee joint dislocation

Ankle joint and foot area traumas:
Ankle joint contusion
Toe contusion without nail plate injury
Toe contusion with nail plate injury
Multiple superficial traumas of ankle joint and foot
Ankle joint dislocation
Ligament rupture at the level of ankle joints and foot
Sprain and strain of ankle joint ligaments

Nerve trauma at the level of ankle joint and foot:
Lateral plantar nerve trauma
Medial plantar nerve trauma

Deep fibular nerve trauma at the level of ankle joint and foot:
Trauma of multiple nerves at the level of ankle joint and foot
Trauma of toe muscle long extensor and its tendon at the level of ankle joint and foot
Trauma of multiple muscles and tendons at the level of ankle joint and foot

Respiratory diseases:
Viral pneumonia in the phase of convalescence

CONTRAINDICATIONS

- acute infectious diseases and purulent-inflammatory processes in the acute phase, febrile state;
- pregnancy;
- diseases and conditions associated with reduced blood clotting (including systemic blood diseases), continuing bleeding of any localization;
- malignancies;
- cardiovascular diseases accompanied by hemodynamic instability: crisis course of grade 3 arterial hypertension; pronounced arterial hypotension; significant cardiac rhythm and/or intracardiac conduction disorders (atrial fibrillation and flutter, paroxysmal tachycardia, ventricular extrasystole of class 4 or 5, atrio-ventricular blockade of degrees 2-3, sinus bradiarrhythmia); decompensated chronic heart failure, acute myocardial infarction; acute period of ischemic and hemorrhagic stroke; aortic and large vessel aneurysm;
- acute tuberculous process;
- thyrotoxicosis;
- implanted pacemaker.

⚠ ***ATTENTION!***

• *Exposure to Device's pulsed electromagnetic field on the background of chemo- and radiotherapy courses is not contraindicated!*

• *Presence of stents or condition after coronary artery bypass surgery is not a contraindication against device application.*

• *Presence of titanium elements is not a contraindication!*

SIDE EFFECT

In order to avoid adverse events associated with impaired adaptation mechanisms of patients (increased blood pressure, exacerbation of the symptoms of concomitant diseases), do not allow an increase in the recommended exposure time and follow the rules and procedures recommended by this User Manual.

Before starting treatment, be sure to consult your doctor to exclude diseases and conditions that are contraindications to the use of the device.

ATTENTION! *Since it is possible to increase or decrease blood pressure in some cases against the background of procedures, regardless of which disease is treated, blood pressure should be monitored before the procedure and 20-30 minutes after it, especially during the first 6 days of treatment. Keep a «treatment log» by entering the measurement data required to trace the time course of blood pressure.*

In case of increase or decrease of blood pressure after performed procedure by not more than 10-25 mmHg, during the following procedure, it is necessary to reduce exposure time by 1/3.

In case of increase or decrease of blood pressure after performed procedure by more than 25 mmHg, before the next procedure, it is necessary to consult your doctor to resolve the issue of treatment adjustment.

THE ORDER OF USE

Preparation for use

After storage in cold premises, the device should be kept at room temperature for four hours before use.

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

Disinfection of the device's outer surfaces is to be carried out by wiping them twice at a 10-15 minute interval with a heavy muslin or gauze cloth moistened with a disinfectant solution (for instance, 3% solution of hydrogen peroxide, or 5% solution of chloramine), making sure to squeeze the cloth out in order to avoid leakage of the solution inside the device.

Connect the emitters required for treatment procedure to the device (the best option is to connect all available emitters to the device, the ones not used will simply be deactivated). The main emitter is to be connected to connector «1», and the flexible line and local emitter are to be connected to connectors «2» and «3» in random order (Fig. 7, 8).

⚠ ***ATTENTION!*** *The numbers on the couplers must correspond to those on the connectors. The markings on the couplers must be facing upwards. After plugging the emitters in, fixate them by bolting them down.*

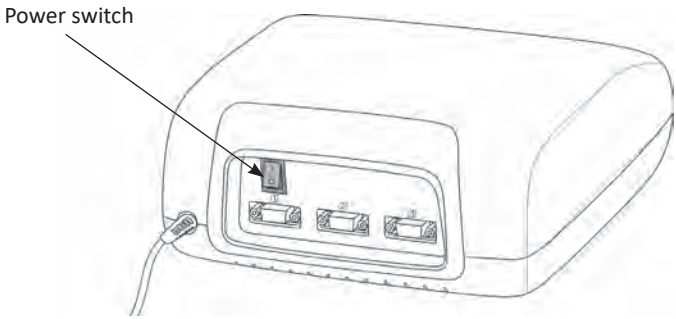


Fig. 7

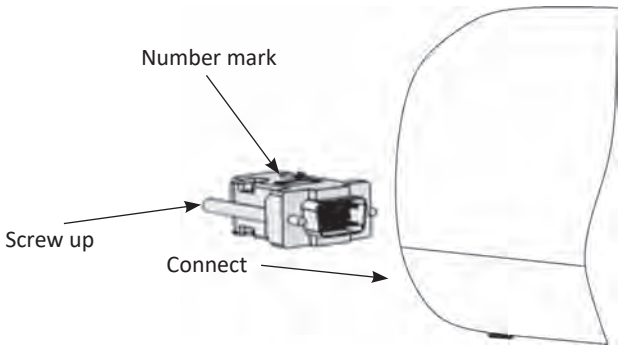


Fig. 8

Press the «POWER» switch to activate the device, while the active state indicators will light on the emitters' pulse generation unit, and the control unit display box will be showing the number of the last program used. A dot will light in the right bottom corner of the display (Fig. 9).

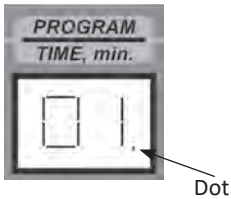


Fig. 9

You must wait for about 1,5-2 seconds.
It is necessary to determine the emitter's status.

Set the number of the required program according to the present Manual's instructions provided in the sections below using the «◀» and «▶» buttons.

Note: execution of programs beginning from 51 to 79 is only possible when the local emitter is used (delivery set option No.2).

Place the required emitters on the patient's body subject to the right magnetic field polarity and direction in accordance with the selected procedure.

After pressing the «START/STOP» button, the PEMF action indicator will light up, while the LED display will be showing the time remaining until the end of the procedure, and the dot in the lower right corner will disappear (Fig. 10). The specific emitters required for the selected procedure are thus activated, and the device starts generating the preset magneto-action.

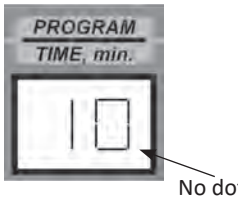


Fig. 10

The PEMF action indicators will light on the activated emitters.

The magnetic field indicator is intended only for checked the presence of a pulsed magnetic field, but not for evaluate its amplitude. The presence of a pulsed magnetic field can be checked using a magnetic field indicator, if it is placed directly on the surface of the emitter coil.

After the countdown of the pre-programmed exposure time is over, a sound indication of the procedure end will be generated, and both the PEMF action indicator on the control panel and the magnetic field indicators on the emitters' pulse generation unit will fade away, while the LED display will return to the last used program number (with the dot in the right bottom corner).

After termination of the exposure procedure, take the emitter off the patient's body.

If a next magneto-therapy session is not planned, switch the power and control unit off by pressing the «POWER» switch.

For a convenient arrangement of the flexible lines of the main emitter and the individual flexible line to form a «solenoid», use the emitters' accessories set.

The arrangement of these accessories is shown in Fig. 11, 12.

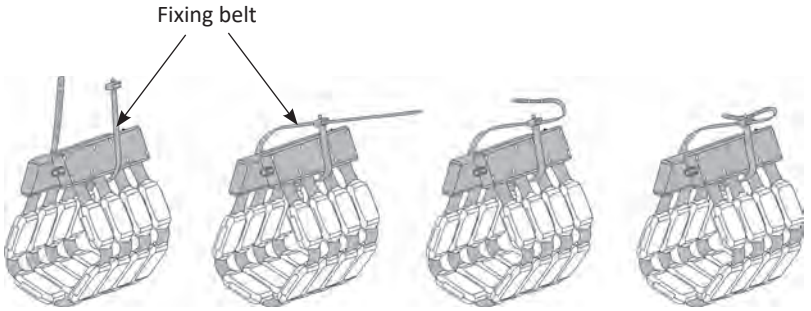


Fig. 11

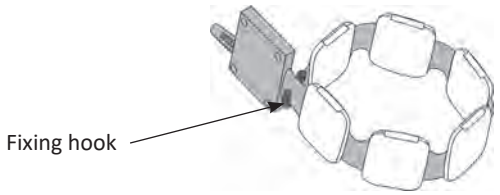


Fig. 12

For a convenient fixing of the flexible emitting line on a limb, use the fastening of the coil group provided on the line (as shown in Fig. 13).

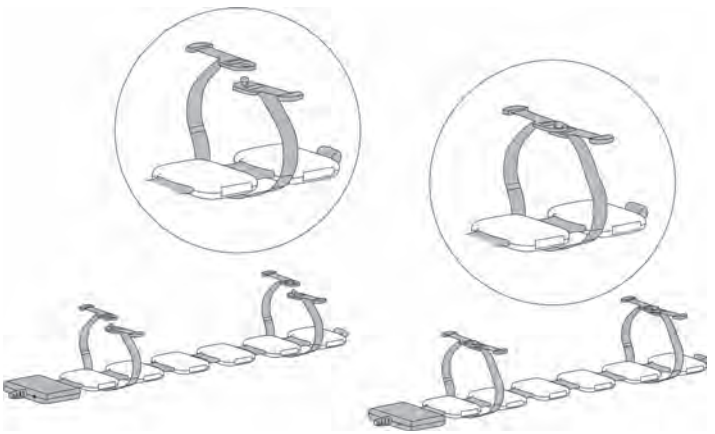


Fig. 13

⚠ ***ATTENTION!*** *To avoid injury, please use the emitters with CAUTION. Hold and carry the main emitter with both hands as shown in Fig. 14.*

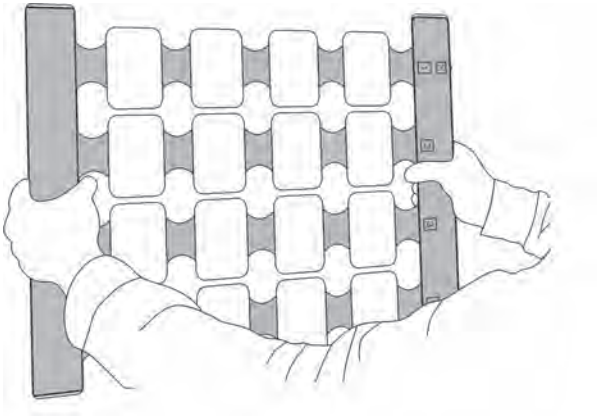


Fig. 14

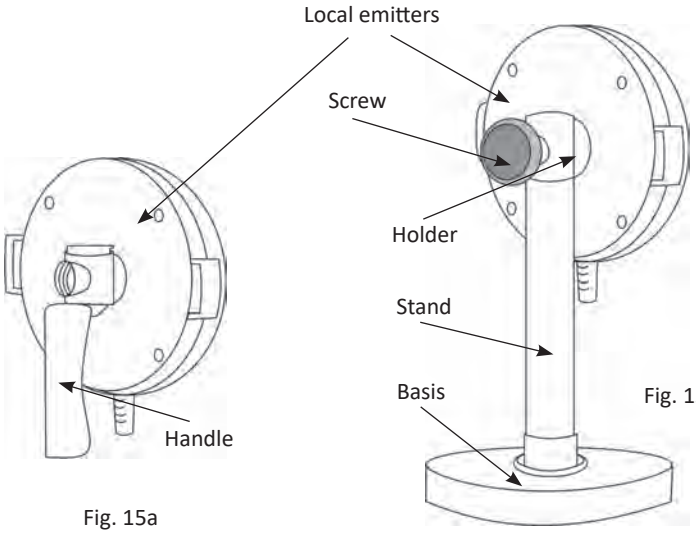


Fig. 15a

Fig. 15b

For procedure convenience, the local emitters can be fixed onto a handle (Fig. 15a) or on a rack (Fig. 15b). The rack consists of a holder with a screw, stand and basis.

To fix the emitter on the rack, use the holder thread segment (screw the emitter into the holder and place it on the rack stand). The vertical position of the emitter on the rack (the height) can be adjusted by means of the holder screw: to adjust the height, loosen the holder screw, position the emitter at the necessary height level, and fix the holder in that position with the screw.

General rules of procedures

Before treatment start, carefully read the list of indications and contraindications and be sure to consult your doctor to determine the correct diagnosis and to exclude your existing diseases and conditions contraindicating the use of the device.

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

To get the maximum therapeutic effect, before carrying out the procedures, be sure to study the procedure with the device and strictly follow the recommended treatment methods. The effectiveness of magnetotherapeutic procedures depends on:

- strict compliance with recommendations on the procedure of the device application;
- individual magnetic sensitivity of the patient;
- stages and features of the course of the disease, for which treatment is carried out.

If the patient has a combination of various diseases, after the end of the course of treatment of one disease, a break of 10-15 days is taken and another disease is treated. In case of course treatment of the same disease, the interval between treatment courses is 1.5-2 months. Shorter pauses between treatment courses are only allowed upon the doctor's advice.

⚠ ***ATTENTION!*** *It is not recommended to treat two various diseases at the same time (on the same day, during the same course of treatment).*

⚠ ***ATTENTION!*** *When procedures are performed twice a day, the interval between procedures should be at least 8 hours, and the total duration of procedures should not exceed 40 minutes per day.*

• During the procedures, the device inductors can be applied directly to the skin, as well as, due to the high penetrating ability of the device magnetic field, the exposure can be carried out through clothes, dry or wet gauze bandage (including impregnated with drugs), longet or plaster bandage up to 1 cm thick.

• The optimal position of the patient during the procedure is the prone position. After completion of the procedure, it is necessary to remain in the horizontal position for 30 minutes to obtain the maximum effect.

Device operation order

1. Choose the required treatment procedure.
2. Study the recommendations for the treatment procedure.
3. Connect the emitters to the power and control unit, then switch the device on and check its operability.
4. Set the program number on the control panel of the power and control unit.
5. Arrange the emitter(s) in accordance with the procedure technique.
6. Press the «START/STOP» button on the power and control unit.

TYPES OF MAGNETIC FIELDS

The device generates two types of pulsed electromagnetic fields: «travelling» and «static».

«Traveling» magnetic field

The main emitter:

The main emitter generates «traveling» magnetic field of three kinds:

1) «traveling horizontal» (Fig. 16, Fig. 17): simultaneous excitation of all emit-ters in one line, followed by one-way excitation of all emitters of the neighboring line according to the cyclic law; the cycle comprises four 'step-by-step' excitations of the emitting lines (according to the number of the lines in the whole emitter).

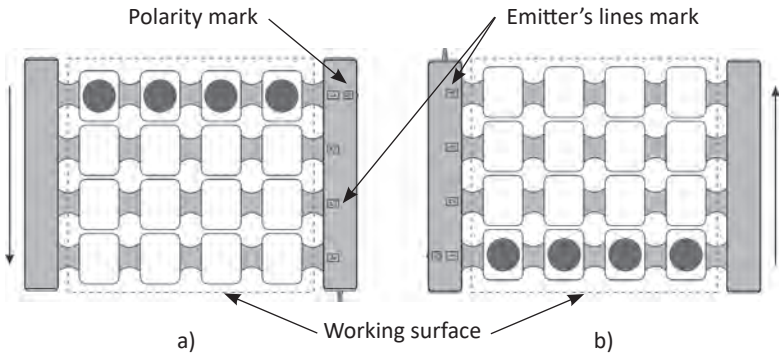


Fig. 16. Traveling horizontal. The emitters are placed with the North surface facing the patient's body (polarity mark – N):
a) the magnetic field direction top - down,
b) the magnetic field direction bottom - up.

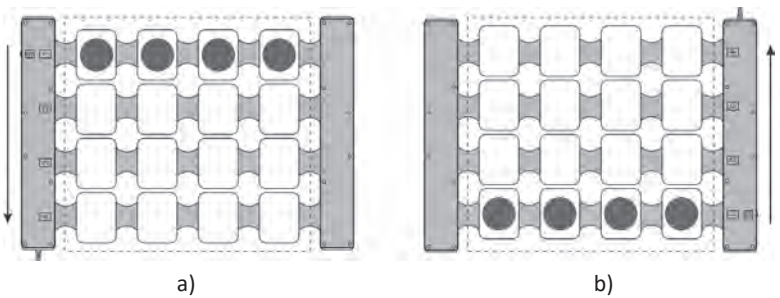
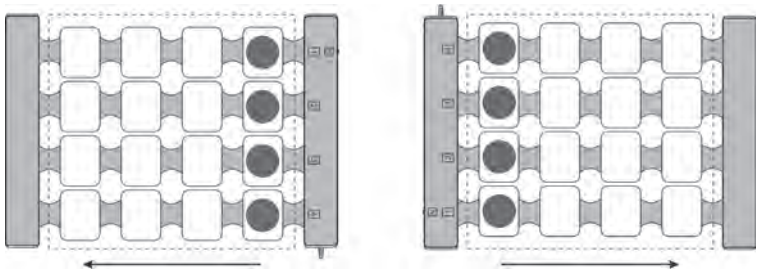


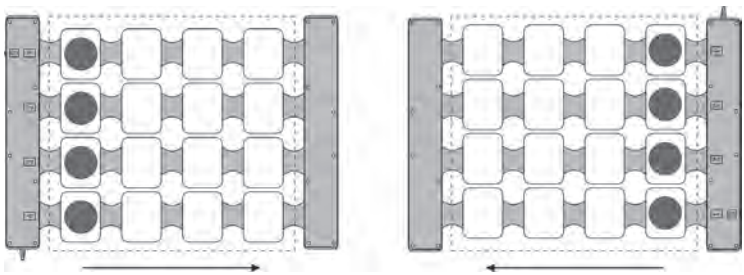
Fig. 17. Traveling horizontal. The emitters are placed with the South surface facing the patient's body (polarity mark – S):
a) the magnetic field direction top - down,
b) the magnetic field direction bottom - up.

2) «traveling vertical» (Fig. 18, Fig. 19) – simultaneous excitation of the emitters of the same position in all four lines (exposure cluster), followed by one-way excitation of the same neighboring emitters according to the cyclic law; the cycle comprises four 'step-by-step' excitations of the neighboring emitters (according to the number of single emitters in one line).



a) b)

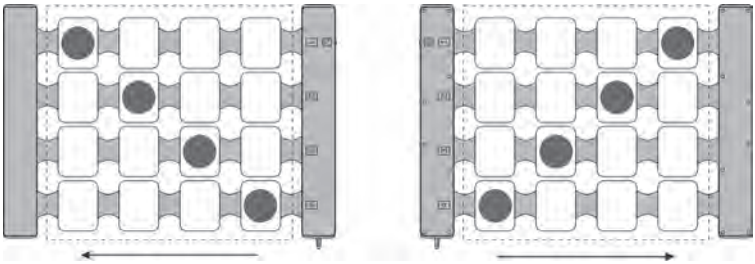
Fig. 18. Traveling vertical. The emitters are placed with the North surface facing the patient's body (polarity mark – N):
a) the magnetic field direction from right to left,
b) the magnetic field direction from left to right.



a) b)

Fig. 19. Traveling vertical. The emitters are placed with the South surface facing the patient's body (polarity mark – S):
a) the magnetic field direction from right to left,
b) the magnetic field direction from left to right.

3) «traveling diagonal» (Fig. 20) – sequential excitation of individual emitters located diagonally against one another, followed by one-way excitation of the neighboring emitters according to the cyclic law; the cycle comprises a seven-'step' excitation of the emitters (according to the number of possible combinations of the emitters' excitation.

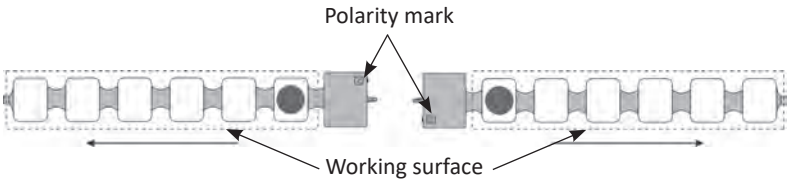


a) b)

Fig. 20. Traveling diagonal. The emitters are placed:
a) with the North surface facing the patient's body (polarity mark – N),
b) with the South surface facing the patient's body (polarity mark – S).

The flexible emitting line:

In case of the separate flexible emitting line, the emitters' excitation under the influence of the «traveling» field type occurs cyclically in one direction (Fig. 21); the cycle for the single line comprises a six-'step' excitation of the adjacent emitters (according to the number of individual emitters in the flexible line);



a) b)

Fig. 21. Flexible emitting line. The emitters are placed with the North surface facing the patient's body (polarity mark – N):
a) the magnetic field direction from right to left,
b) the magnetic field direction from left to right.

Note: The pulsed electromagnetic field in the device's emitting lines travels only in one direction. Changing of the direction of the field area requires changing the emitters' arrangement, e.g. as shown in Fig. 16-19.

«Static» magnetic field

Simultaneous excitation of all the emitters in the whole cluster or line. (Fig. 22).

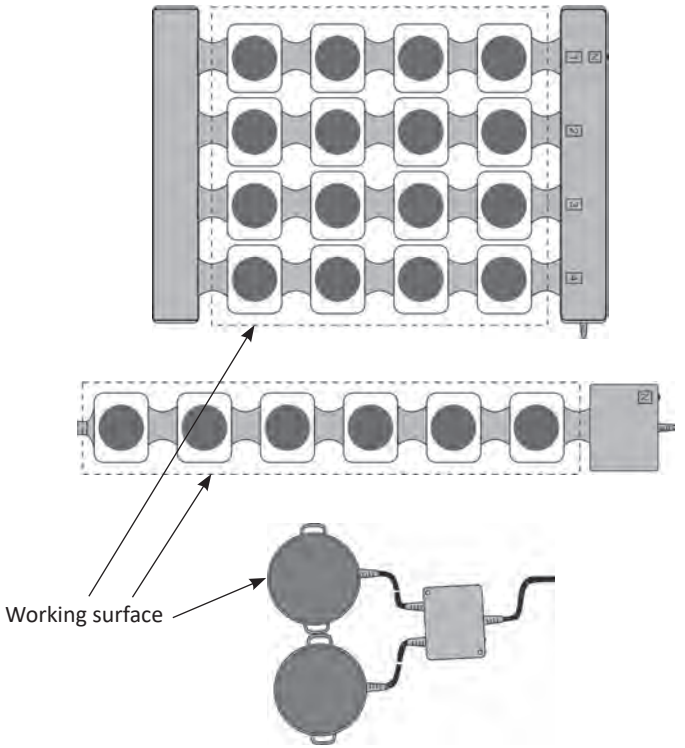


Fig. 22

PARAMETERS AND FEATURES OF THE PRESET EXPOSURE PROGRAMS

Program No.	Emitters used			Type of field and scan	Field density amplitude, mT	Pulse repetition frequency, pulses / sec	Total exposure time, min
	Main	Flexible emitting line	Target (local)				
1	2	3	4	5	6	7	8
1	+	+		travelling horizontal travelling	8 8	3 3	10
2	+	+		travelling horizontal travelling	10 10	10 10	20
3	+	+		travelling	10	12	10
4	+	+		travelling horizontal travelling	20 10	100 100	20
5	+	+		travelling horizontal travelling	10 20	100 100	10
6	+	+		travelling horizontal travelling	10 25	12 12	10
7	+	+		static static	6 6	10 10	20
8	+	+		travelling horizontal static	20 6	10 10	10
9	+			travelling horizontal	20	100	15
10	+			static	6	16	15
11	+			static	6	16	10
12	+			travelling horizontal	25	75	10
13	+	+		travelling horizontal travelling	20 10	100 100	10
14	+			travelling horizontal	20	100	10
15	+			static	6	16	15
16	+	+		travelling horizontal travelling	10 10	100 10	20
17	+	+		travelling vertical static	20 6	10 16	10
18	+			travelling horizontal	20	100	10
19	+			travelling horizontal	20	50	15
20	+			travelling vertical	20	100	20
21	+	+		travelling vertical static	20 6	100 16	30

1	2	3	4	5	6	7	8
22	+			static	6	3	30
23	+			static	6	16	30
24	+			static	6	16	20
25	+			travelling horizontal	25	75	15
26	+	+		travelling vertical travelling	2 2	5 5	8
27	+			travelling vertical	15	100	15
28	+			travelling vertical	10	25	20
29	+			travelling vertical	10	100	15
30	+			travelling vertical	20	10	20
31		+		travelling vertical	20	100	15
32	+			travelling horizontal	20	100	7
33	+			travelling horizontal	25	75	20
34	+			travelling vertical	15	100	15
35	+			static	6	16	20
36	+	+		travelling vertical static	10 6	100 16	10
37	+			travelling vertical	10	100	10
38	+			travelling vertical	25	10	15
39	+			travelling horizontal	10	3	20
40	+			travelling horizontal	15	10	20
41	+			travelling horizontal	2	100	10
42	+			travelling diagonal	20	100	10
43	+			travelling horizontal	10	100	20
44		+		travelling	10	12	10
45	+			travelling horizontal	25	10	20
46		+		travelling	15	12	10
47	+	+		travelling horizontal travelling	20 20	100 100	15
48	+			travelling horizontal	10	8	20
49	+			travelling horizontal	25	75	15
50	+			travelling horizontal	20	100	20
51			+	static	20	50	7
52			+	static	20	50	10
53			+	static	20	10	10
54			+	static	20	5	10

1	2	3	4	5	6	7	8
55	+		 +	static static	6 6	16 16	10
56			+	static	30	50	15
57	+		 +	travelling horizontal static	20 30	10 12	10
58	+		 +	travelling horizontal static	20 30	100 16	15
59	+		 +	travelling vertical static	20 35	100 50	15
60	+		 +	travelling vertical static	10 10	100 100	15
61	+		 +	travelling vertical static	10 10	10 10	15
62			+	static	10	45	15
63			+	static	30	100	15
64			+	static	35	50	12
65			+	static	35	50	20
66	+		 +	travelling horizontal static	10 20	100 50	10
67	+		 +	travelling horizontal static	20 20	100 50	10
68			+	static	20	50	20
69			+	static	10	100	10
70			+	static	15	10	20
71			+	static	8	100	15
72			+	static	15	10	20
73	+		 +	travelling horizontal static	20 30	100 10	15
74			+	static	35	50	15
75			+	static	20	50	15
76			+	static	30	10	20
77	+		 +	travelling horizontal static	15 25	100 50	20
78	+		 +	travelling horizontal static	25 20	100 50	20
79			+	static	6	16	30

Note: A continuous (uninterrupted) exposure mode is used for all programs.

NERVOUS SYSTEM DISEASES

Migraine

Treatment course length – 10-12 procedures, one procedure per day.

Program No. 3 is set.

The emitters used: flexible emitting line.

Emitters' arrangement: the flexible emitting line is placed on collar zone with the «N» surface facing the patient's body (the PGU is on the left). See Fig. 23.

- The magnetic field direction – travelling from left to right;
- Density – 10 mT;
- Frequency: 12 Hz;
- Procedure duration: 10 min.

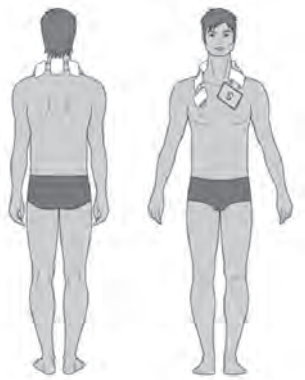


Fig. 23

Disorders of separate nerve roots and plexuses of upper and lower limbs

Radial, median and ulnar nerve diseases

Treatment course length – 10-15 procedures, one procedure per day.

The emitters used: main emitter and flexible emitting line.

Emitters' arrangement: the main emitter is placed over the cervicothoracic area of the vertebral column, the flexible emitting line – along the arm, on the affected nerve projection. Both emitters are placed with the «N» surface facing the patient's body. See Fig. 24.

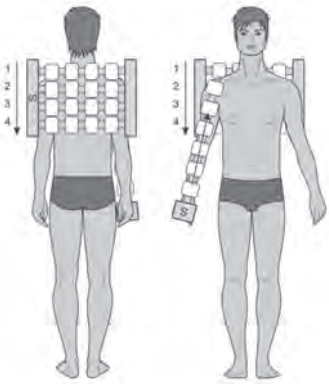


Fig. 24

For the first 5 procedures, Program No.5 is set:

- The magnetic field direction in the main emitter: traveling top-down, in the flexible emitting line: traveling bottom-up;
- Density: main emitter – 1 mT, flexible emitting line – 2 mT;
- Frequency: 100 Hz;
- Procedure duration: 10 min.

For the following 5-10 procedures, Program No.6 is set:

- The magnetic field direction is the same as that for the first 5 days of treatment;
- Density: main emitter – 10 mT, flexible emitting line – 25 mT;
- Frequency: 12 Hz;
- Procedure duration: 10 min.

In case of developing paresis of the corresponding nerve

Treatment course – 15 procedures, one procedure per day.

The emitters used: main emitter and flexible emitting line.

Emitters' arrangement: the main emitter is placed over the cervicothoracic area of the vertebral column, the flexible emitting line – on the affected nerve projection, with the emitters' «N» polarity surface facing the body. See Fig. 24.

Setting of Program No.7:

• The magnetic field direction in the main emitter: static, in the flexible emitting line: static;

• Density: main emitter – 6 mT, flexible emitting line – 6 mT;

• Frequency: 10 Hz;

• Procedure duration: 20 min.

Femoral, sciatic, tibial and fibular nerve diseases

Treatment course length – 10-15 procedures, one procedure per day.

The emitters used: main emitter and flexible emitting line.

Emitter's arrangement: the main emitter is placed over of the lumbosacral area of the vertebral column, the flexible emitting line – on the affected nerve projection. Both emitters are placed with their «N» polarity surface facing the body. See Fig. 25.

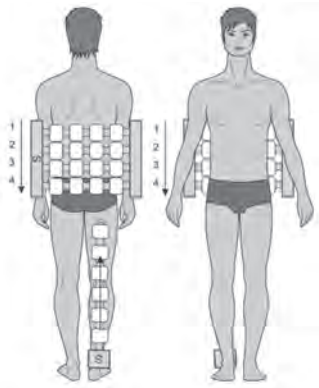


Fig. 25

For the first five procedures, Program No.5 is set:

• The magnetic field direction in the main emitter: traveling top-down, in the flexible emitting line: traveling bottom-up;

• Density: main emitter – 10 mT, flexible emitting line – 20 mT;

• Frequency: 100 Hz;

• Procedure duration: 10 min.

For the following 5-10 procedures, Program No.6 is set:

• The magnetic field direction is the same as that for the first 5 days of treatment;

• Density: main emitter – 10mT, flexible emitting line – 25 mT;

• Frequency: 12 Hz;

• Procedure duration: 10 min.

Diabetic polyneuropathy

Treatment course length – 15-20 procedures, one procedure per day.

Repeated treatment courses can be carried out in 3 months' time, three courses per year.

The emitters used: main emitter and flexible emitting line.

At first, the flexible emitting line is placed over and across the lumbosacral area, and the lower leg including the adjacent knee joint of the affected limb are wrapped with the main emitter, the emitters' «N» polarity surface facing the body. See Fig. 26a.

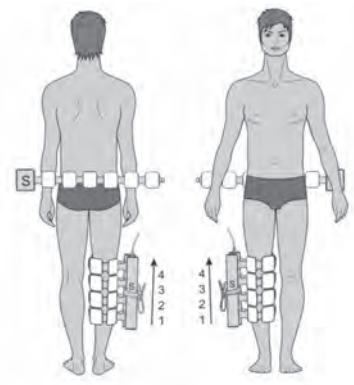


Fig. 26a

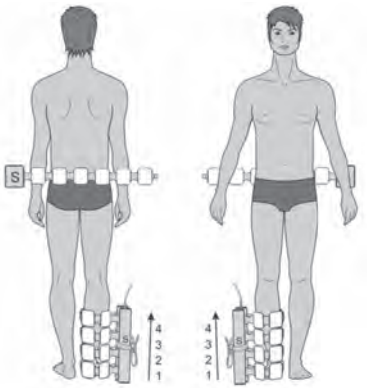


Fig. 26b

Setting of Program No.8:

• The magnetic field direction in the main emitter: traveling bottom-up, in the flexible emitting line – static;

• Density: main emitter – 20 mT, flexible emitting line – 6 mT;

• Frequency: 10 Hz;

• Procedure duration: 10 min.

After the exposure time expires, the device remains plugged in, the flexible emitting line is left across the lumbosacral area, and the main emitter is moved down to wrap the foot of the affected leg or placed over the affected foot, with the emitters' «N» polarity side turned towards the body. See Fig. 26b.

Then Program No.8 is to be set again:

• The magnetic field direction in the main emitter: traveling bottom-up, in the flexible emitting line – static;

• Density: main emitter – 20mT, flexible emitting line – 6 mT;

• Frequency: 10 Hz;

• Procedure time: 10 min.

Attention! Treatment with blood sugar lowering medications and diets MUST BE CONTINUED on the background of magneto-therapy!

Postherpetic neuropathy

Treatment course length – 15-20 procedures. One procedure per day. A repeated treatment course is to be carried out in a month.

The emitter used: main emitter.

Emitter's arrangement: the main emitter is in contact with the affected backbone area, with the «N» polarity surface facing the body.

The main emitter is placed on a treatment couch with the «N» side up. The patient lies with his/her back onto the emitter, making sure to cover the affected backbone area (for the arms – the cervical and thoracic parts, for the body trunk – the thoracic part, for the pelvis and legs – the lumbar part). See Fig. 27a.

At first, Program No.9 is set:

• The magnetic field direction in the main emitter: traveling bottom-up;

• Density: 20 mT;

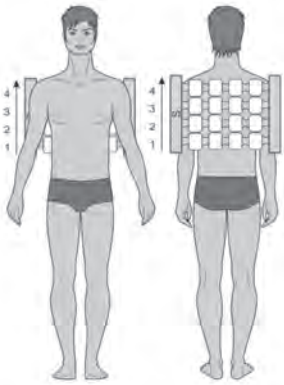


Fig. 27a

Fig. 27b

• Frequency: 100 Hz;
• Procedure time: 15 min.

After exposure termination, the device remains plugged in, and the main emitter is moved onto the affected intercostal nerves area. See Fig. 27b.

Setting of Program No.10:

• The magnetic field direction in the main emitter: static;
• Density: 6 mT;
• Frequency: 16 Hz;
• Procedure time: 15 min.

Raynaud`s syndrome («dead finger» syndrome)

Treatment course – 15 procedures. One procedure per day. A repeated treatment course is to be carried out in two months.

The emitter used: main emitter.

Emitters' arrangement: the main emitter is placed on the cervical collar area with its «N» polarity surface facing the body. See Fig.27b.

At first, Program No.11 is set:

• The magnetic field direction in the main emitter: fixed;
• Density: 6 mT;
• Frequency: 16 Hz;
• Procedure duration: 10 min.

After the procedure termination, the device remains plugged in, and the main emitter is removed and wrapped around the affected limb covering the upper part of the hand, the «N» polarity surface facing the body. See Fig. 28.

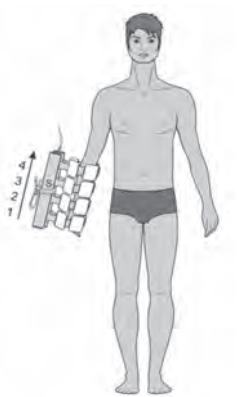


Fig. 28

Setting of Program No.12:

• The magnetic field direction in the main emitter: traveling bottom-up;
• Density: 25 mT;
• Frequency: 75 Hz;
• Procedure duration: 10 min.

DISEASES OF CIRCULATORY SYSTEM

After-effects of cerebrovascular diseases

The treatment course: 10-12 procedures.

One procedure per day.

The emitters used: main emitter, flexible emitting line.

Emitters' arrangement: the main emitter is placed over the cervicothoracic area of the spinal column, the head is wrapped with the flexible emitting line, with the emitters' «N» polarity surface facing the body.

Setting of Program No.16:

• The magnetic field direction in the main emitter: traveling top-down, in the flexible emitting line: traveling clockwise with the emitters' «N» polarity surface facing the body.

• Density: 10 mT;

• Frequency: main emitter – 100 Hz, flexible emitting line – 10 Hz;

• Procedure time: 20 min.

Atherosclerotic vascular disease, endarteritis deformans or obliterating endarteritis

The treatment course: 15 procedures. One procedure per day. A repeated course is carried out in 2-3 months.

The emitters used: main emitter, flexible emitting line.

Emitters' arrangement: the thigh bone is wrapped with the main emitter, the flexible emitting line is placed over the waist sympathetic ganglions projection area, with the emitters' «N» polarity surface facing the body. See Fig. 29a.

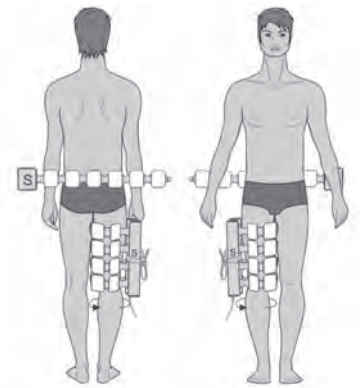


Fig. 29a

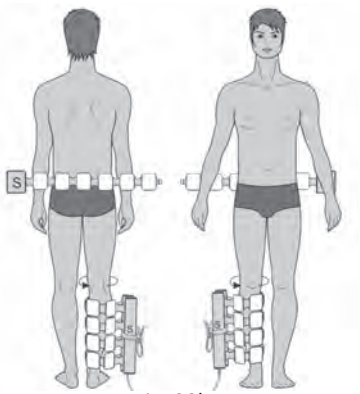


Fig. 29b

Setting of Program No.17:

• The magnetic field direction in the main emitter: traveling from right to left, in the flexible emitting line: static;

• Density: main emitter – 20 mT, flexible emitting line – 6 mT;

• Frequency: main emitter – 10 Hz, flexible emitting line – 16 Hz;

• Procedure duration: 10 min.

After the procedure time expiration, the device remains plugged in, and the main emitter is moved as follows: the lower leg is wrapped with the

main emitter, while the flexible emitting line stays on the waist sympathetic ganglions projection area, with the emitters' «N» polarity surface facing the body. See Fig. 29b.

Setting of Program No.17:

• The magnetic field direction in the main emitter: traveling from right to left, in the flexible emitting line: static;
• Density: main emitter – 20 mT, flexible emitting line – 6 mT;
• Frequency: main emitter – 10 Hz, flexible emitting line – 16 Hz;
• Procedure time: 10 min.

Atherosclerotic (discirculatory) encephalopathy

Treatment course length: 10-12 procedures. One procedure per day.

The procedures can be carried out every other day.

The emitters used: main emitter, flexible emitting line.

Emitters' arrangement: the main emitter is placed over the cervicothoracic area of the spinal column, the head is wrapped with the flexible emitting line, with the emitters' «N» polarity surface facing the body. See Fig. 30.

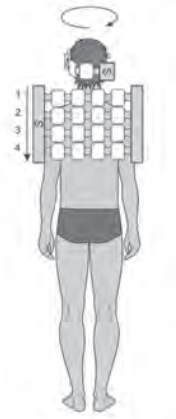


Fig. 30

Setting of Program No.16:

• The magnetic field direction in the main emitter: traveling top-down, in the flexible emitting line: traveling clockwise;
• Density: 10 mT;
• Frequency: main emitter –100 Hz, flexible emitting line – 10 Hz;
• Procedure time: 20 min.

Varicose veins

The treatment course: 15 procedures. One procedure per day.

A repeated course can be carried out in 2-3 months.

The emitters used: main emitter.

Emitters' arrangement: at first, the main emitter is wrapped around the lower leg of the affected limb, with the emitters' «N» polarity surface facing the body. See Fig. 31.

Setting of Program No.18:

• The magnetic field direction in the main emitter: traveling bottom-up;
• Density: 20 mT;
• Frequency: 100 Hz;
• Procedure time: 10 min.

After the procedure time expiration, the device remains plugged in, and the main emitter is moved to wrap the thigh of the affected limb, with the emitters' «N» polarity surface facing the body. See Fig. 31.

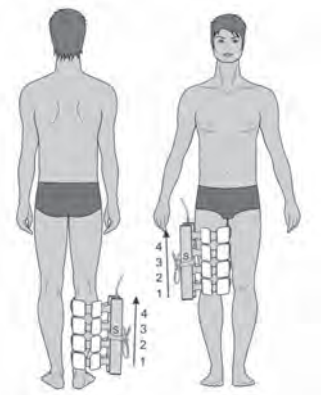


Fig. 31

Setting of Program No.18:

- The magnetic field direction in the main emitter: traveling bottom-up;
- Density: 20 mT;
- Frequency: 100 Hz;
- Procedure time: 10 min.

Deep vein thrombophlebitis of the lower leg

The treatment can be intensified with heparin-based ointments applied before the treatment procedure.

The treatment course: 15 procedures. One procedure per day. A repeated course can be carried out in 2-3 months.

The emitters used: main emitter.

Emitters' arrangement: the main emitter is wrapped around the lower leg of the affected limb, with the emitters' «N» polarity surface facing the body. See Fig. 32.

Setting of Program No.35:

- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure duration: 20 min.

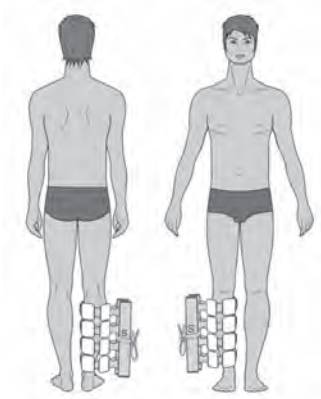


Fig. 32

Fig. 33a

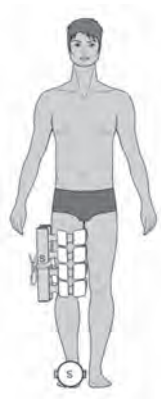


Fig. 33b

Chronic thrombophlebitis accompanied by trophic disorders

During the exposure procedure, the ulcerous defect is to be covered with a sterile bandage or a bandage to which a healing acceleration medication is applied.

The treatment course contains 10 procedures. One procedure per day.

A repeated course is carried out after a 30-day period. The following routine treatment courses can be carried out after 2-3 months.

The emitters used: main emitter, local emitter.

Emitters' arrangement: the main emitter is placed on a couch or bed, and the patient lies down so as to put the lower leg of his/her diseased limb over the emitter, while the local emitter is placed on the bandaged ulcerous area, with the emitters' «N» polarity surfaces facing the body. See Fig. 33a.

Setting of Program No.55:
- The magnetic field direction in the main and local emitter: static;
- Density: 6 mT;
- Frequency: 16Hz;
- Procedure time: 10 min.

After the procedure time expiration, the device remains plugged in, the main emitter remains on the couch or bed, and the patient lies on it with the thigh of his/her diseased limb over the emitter, while the local emitter is placed on the ulcerous area, with the emitters' «N» surfaces facing the body. See Fig. 33b.

Setting of Program No.55:
- The magnetic field direction in the main and local emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 10 min.

Chronic lymphedema (lymphatic edema)

The treatment course: 15 procedures. One procedure per day.

A repeated course is carried out after a 30-day period. The following routine treatment courses can be carried out after 2-3 months.

The emitter used: main emitter.

The lower leg of the diseased limb is wrapped with the main emitter, its «N» polarity side turned towards the body. See Fig. 34a.

Setting of Program No.19:
- The magnetic field direction in the main emitter: traveling bottom-up;
- Density: 20 mT;
- Frequency: 50Hz;
- Procedure time: 15 min.

After the procedure time expiration, the device remains plugged in, and the thigh of the diseased limb is wrapped with the main emitter. See Fig. 34b.

Setting of Program No.19:
- The magnetic field direction in the main emitter: traveling bottom-up;
- Density: 20 mT;
- Frequency: 50Hz;
- Procedure time: 15 min.

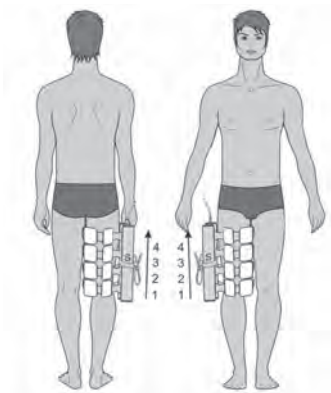


Fig. 34a

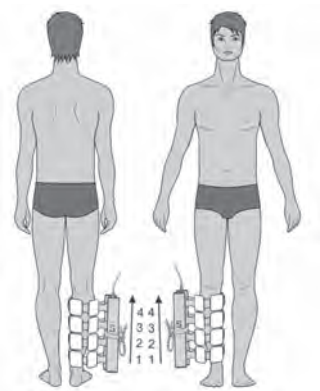


Fig. 34b

MUSCULOSKELETAL SYSTEM AND THE CONNECTING TISSUE DISEASES

Gouty arthritis

The treatment course length is 15 procedures. One procedure per day.

Due to the chronic disease nature, preventive routine courses of pulsed magnetic therapy are recommended to be taken 2-3 times a year.

The emitter used: local emitter.

The first 3 procedures:

The local emitter is placed over the affected joint, with its «N» polarity side turned towards the body.

Setting of Program No.69:

- The magnetic field direction in the local emitter: static;
- Density: 10mT;
- Frequency: 100 Hz;
- Procedure duration: 10 min.

Procedure 4 and up to the treatment course end:

The local emitter is placed over the affected joint, with its «N» polarity side turned towards the body.

Setting of Program No.70:

- The magnetic field direction in local emitter: static;
- Density: 15mT;
- Frequency: 10 Hz;
- Procedure duration: 20 min.

Coxarthrosis

The treatment course: 15 procedures. One procedure per day.

Due to the chronic disease nature, preventive routine courses of pulsed magnetic therapy are recommended to be taken 2-3 times a year.

The emitter used: main emitter.

The first 5 procedures:

The main emitter is wrapped around the affected joint, with its «N» polarity surface facing the body. See Fig. 35.

Setting of Program No.27:

- The magnetic field direction in the main emitter: traveling from left to right;
- Density: 15 mT;
- Frequency: 100 Hz;
- Procedure duration: 15 min.

Procedure 6 and up to the treatment course end:

The main emitter is wrapped around the affected joint, with its «N» polarity surface facing the body.

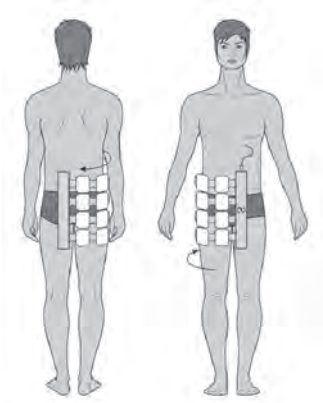


Fig. 35

Setting of Program No.28:

- The magnetic field direction in the main emitter: traveling from left to right;
- Density: 10 mT;
- Frequency: 25 Hz;
- Procedure duration: 20 min.

Gonarthrosis

The treatment course: 15 procedures. One procedure per day.

Due to the chronic disease nature, preventive routine courses of pulsed mag-netic therapy are recommended to be taken 2-3 times a year.

The emitter used: main emitter.

The first 5 procedures:

The main emitter is wrapped around the affected joint, with its «N» polarity surface facing the body. See Fig. 36.

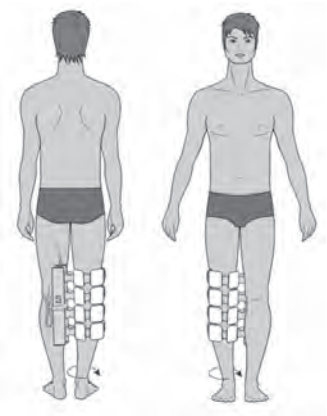


Fig. 36

Setting of Program No.29:

• The magnetic field direction in the main emitter: traveling from left to right;
• Density: 10 mT;
• Frequency: 100 Hz;
• Procedure duration: 15 min.

Procedure 6 and up to the treatment course end:

The main emitter is wrapped around the affected joint, with its «N» polarity surface facing the body. See Fig. 36.

Setting of Program No.30:

• The magnetic field direction in the main emitter: traveling from left to right;
• Density: 20 mT;
• Frequency: 10 Hz;
• Procedure duration: 20 min.

Arthrosis of the first carpometacarpal joint

The treatment course: 15 procedures. One procedure per day.

Due to the chronic disease nature, preventive routine courses of pulsed magnetic therapy are recommended to be taken 2-3 times a year.

The emitter used: local emitter.

The first 3 procedures:

The local emitter is placed against the affected joint, with its «N» polarity surface facing the body.

Setting of Program No.71:

• The magnetic field direction in the local emitter: static;
• Density: 8 mT;
• Frequency: 100 Hz;
• Procedure time: 15 min.

Procedure 4 and up to the treatment course end:

The local emitter is placed against the affected joint, with its «N» polarity surface facing the body.

Setting of Program No.72:

• The magnetic field direction in the local emitter: static;
• Density: 15 mT;
• Frequency: 10 Hz;
• Procedure time: 20 min.

Internal and external humeral epicondylitis (tennis elbow and golf elbow)

The treatment course length – 15-20 procedures. One procedure per day.

The emitter used: flexible emitting line.

Emitter's arrangement: the flexible emitting line is wrapped around the affected elbow, with its «N» polarity surface facing the body. See Fig. 37.

Setting of Program No.31:

• The magnetic field direction in the flexible emitting line: traveling clockwise:

• Density: 20 mT;

• Frequency: 100 Hz;

• Procedure time: 15 min.

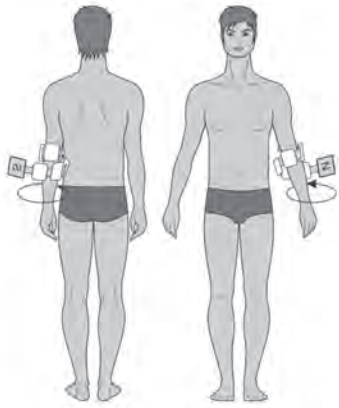


Fig. 37

Humeroscapular periarthrosis

The treatment course: 10 procedures. One procedure per day.

The emitters used: main emitter, local emitter.

Emitters' arrangement: the main emitter is placed over the cervicothoracic area of the spinal column with a shift towards the affected joint, while the local emitter is placed against the affected joint, with the emitters' «N» polarity surfaces facing the body. surface facing the body. See Fig. 38.

Setting of Program No.73:

• The magnetic field direction in the main emitter: traveling top-down, in the local emitter: static;

• Density: main emitter – 20 mT, local emitter – 30 mT;

• Frequency: main emitter – 100 Hz, local emitter – 10 Hz;

• Procedure time: 15 min.

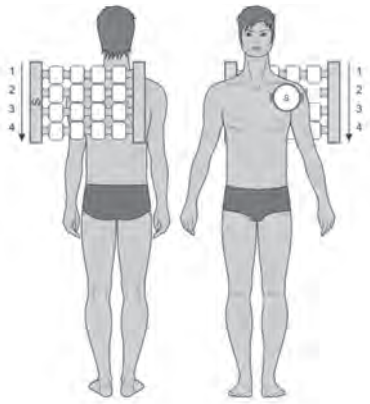


Fig. 38

Acute trophoneurotic bone atrophy (Sudeck`s atrophy)

The treatment course: 10 procedures. One procedure per day.

The emitters used: main emitter.

During the procedure, the main emitter is placed on 2 areas in turn.

At first, the main emitter is placed on the couch or bed, while the patient lies down over it so that his/her cervicothoracic part of the spinal column is against the emitter. The emitter's «N» polarity surface is turned towards the patient`s body. See Fig. 39a.

Fig. 39a

Setting of Program No.32:

• The magnetic field direction: traveling top-down;

• Density: 20 mT;

• Frequency: 100 Hz;

• Procedure time: 7 min.

After that, while the device remains plugged in, the main emitter is wrapped around the forearm and arm, with the «N» polarity surface facing the body. See Fig. 39b.

Setting of Program No.32:

• The magnetic field direction: the main emitter traveling bottom-up;

• Density: 20 mT;

• Frequency: 100 Hz;

• Procedure time: 7 min.

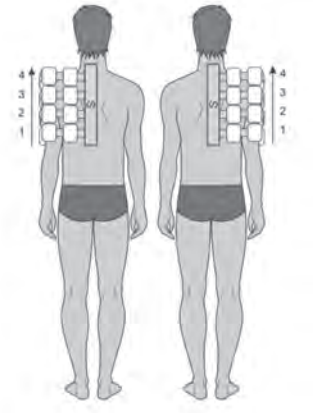


Fig. 39b

Note: This is a severe complication of radial bone fracture in a typical spot (lower third of the forearm). Even when timely and properly immobilized, the patient's arm continues to ache for a long period after cast removal, which is accompanied by a non-resolving swelling of the fingers, wrist and lower forearm; there is a «glass»-like sensation to the fingers, they are cold to touch, and a contracture develops in the wrist, fetlock and interphalangeal joints, manifested on X-ray images as patchy osteoporosis of hand bones. The underlying medical condition, which will most likely lead to the patient's disablement in case of lack of treatment, is a severe microcirculatory dysfunction in the affected arm, with complete cessation of blood flow in some of the capillaries with their subsequent passive dilatation, as well as with an acid-base imbalance shifting towards acidosis, which results in an active proliferation of fibroblasts and synthesis of tropocollagen. This process ends up in a rapid replacement of highly differentiated tissue of the hand's gliding mechanism with scar tissue and the subsequent hand immobility. A contraindication specific for this disease **is absolute exclusion of any kind of thermal exposure (the well-known advice of «heating the hand with steam» is totally prohibited in such cases). Even moving the affected fingers forcedly with the good hand is not allowed**. The therapeutic action of PEMF in these cases affects the blood rheological properties, produces an analgesic, anti-inflammatory, tropho-stimulating and anti-edematous effect, and normalizes microcirculation and the venous blood flow. It is the absence of any thermal effect that makes magneto-therapy essential for application in such cases. Moreover, exposure can be started as early in the treatment process as immediately after plaster fixation. If this was done, such patients experienced edema resolution and restoration of the hand's functions 2-3 weeks earlier than the patients who did not go through a magneto-therapy course.

Tenosynovitis crepitans of the forearm

The treatment course: 15 procedures. One procedure per day.

The emitter used: main emitter.

The affected limb is wrapped with the emitter, with its «N» polarity surface facing the body. See Fig. 40.

Setting of Program No.33:

• The magnetic field direction: the main emitter traveling bottom-up;

• Density: 25 mT;

• Frequency: 75 Hz;

• Procedure time: 20 min.

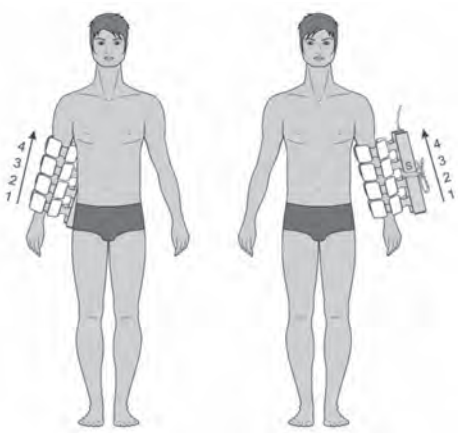


Fig. 40

Tietze's syndrome (aseptic inflammation of coastal cartilages in the area of rib attachment to sternum, more often of ribs II-IV, with a painful thickening)

The treatment course: 15 procedures. One procedure per day.

The emitter used: local emitter.

The local emitter is placed against the affected area with its «N» polarity surface facing the body.

Setting of Program No.74:

• The magnetic field direction: static;

• Density: 35 mT;

• Frequency: 50 Hz;

• Procedure time: 15 min.

Osteochondropathy (Kohler disease, Kienbock's disease, Perthes disease, Schlatter disease, Koenig's disease)

The treatment course: 10 procedures. One procedure per day.

The emitter used: main emitter.

The main emitter is placed over the affected area (which is either covered by or wrapped with it, depending on its location), with the «N» polarity surface facing the body.

Setting of Program No.34:

• The magnetic field direction: the main emitter traveling from left to right;

• Density: 15 mT;

• Frequency: 100 Hz;

• Procedure time: 15 min.

Spondylitis deformans (Strumpell-Marie disease)

In this case, magneto-therapy is effective at early (I-II) stages of the disease. Magneto-therapy is not carried out in cases of a high process activity (blood sedimentation test, acute phase reactants).

The treatment course: 20 procedures. One procedure per day.

The emitter used: main emitter.

The main emitter is placed on a couch or bed with its «N» polarity surface upward, and the patient lies down on it so that his/her cervicothoracic area of the spinal column is above the emitter.

Setting of Program No.11:

- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 10 min.

After the exposure time expiration, the device is left plugged in, and the main emitter is moved down along the couch or bed to the level of the patient's lumbosacral area of the spinal column.

Program No.11 is set again.

Osteoarthritis of the temporomandibular joint

The treatment course: 15-20 procedures. One procedure per day.

The emitter used: local emitter.

The emitter is placed against the affected area with its «N» polarity surface to the body.

Setting of Program No.75:

- The magnetic field direction of the local emitter: fixed;
- Density: 20 mT;
- Frequency: 50 Hz;
- Procedure time: 15 min.

Calcaneal periostosis (plantar fasciitis), heel spur

The treatment course: 15-20 procedures. One procedure per day.

The emitter used: one or two local emitters.

The emitters' arrangement: put the heel on one local emitter or place the two local emitters around the affected heel bone with the emitters' «N» polarity side to-wards the body.

Setting of Program No.76:

- The magnetic field direction: static;
- Density: 30 mT;
- Frequency: 10 Hz;
- Procedure time: 20 min.

Joint contracture (Dupuytren`s contracture)

The treatment course: 15-20 procedures. One procedure per day.

The emitter used: local emitter.

The emitters are placed against both sides of the affected hand bone with their «N» polarity surfaces to the body.

Setting of Program No.65:

- Magnetic field direction: static;
- Density: 35 mT;
- Frequency: 50 Hz;
- Procedure time: 20 min.

Rheumatoid arthritis (exudative stage)

The treatment course: 15-20 procedures.

During the procedure, one or two joints at a time can be exposed (e.g. both knee joints).

The emitters used: main emitter and flexible emitting line.

Emitters' arrangement: the main emitter is placed over the adrenal glands projection area, and the affected joint is wrapped with the flexible emitting line, with the emitters' «N» polarity surfaces turned towards the bod. See Fig. 41.

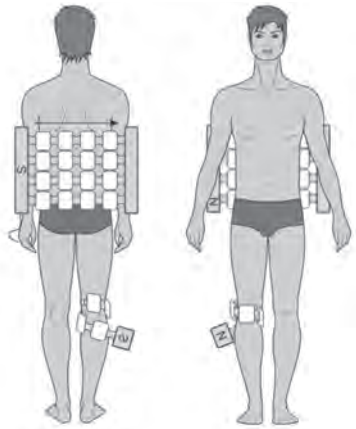


Fig. 41

Setting of Program No.36:

• The magnetic field direction in the main emitter: traveling clockwise, in the flexible emitting line: fixed;

• Density: main emitter – 10 mT, flexible emitting line – 6 mT;

• Frequency: main emitter – 100 Hz, flexible emitting line – 16 Hz;

• Procedure time: 10 min.

In case if there are more than 2 affected joints, the main emitter stays on the adrenal glands projection area, and the other affected joint is wrapped with flexible emitting line, with the emitters' «N» polarity surface facing the body.

Setting of Program No.36:

• The magnetic field direction in the main emitter: traveling clockwise, in the flexible emitting line: fixed;

• Density: main emitter – 10 mT; flexible emitting line – 6 mT;

• Frequency: main emitter – 100 Hz, flexible emitting line – 16 Hz;

• Procedure time: 10 min.

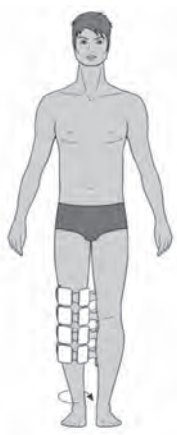


Fig. 42

Osteoarthritis

The treatment course length – 15 procedures.

The emitter used: main emitter.

For severe cases and synovitis

The affected joint is wrapped with the main emitter, with its «N» polarity surface facing the body. See Fig. 42.

Setting of Program No.37:

• The magnetic field direction in the main emitter: traveling clockwise;

• Density: 10 mT;

• Frequency: 100 Hz;

• Procedure time: 10 min.

Without synovitis

The treatment course length – 15 procedures.

The emitter used: main emitter.

The affected joint is wrapped with the main emitter, with its «N» polarity surface facing the body. See Fig. 42.

Setting of Program No.38:
- The magnetic field direction in the main emitter: traveling clockwise;
- Density: 25 mT;
- Frequency: 10 Hz;
- Procedure time: 15 min.

Vertebral osteochondrosis

The treatment course: 12-15 procedures.

The emitter used: main emitter.

The main emitter is placed over the affected vertebral area, with its «N» polarity surface facing the body. See Fig. 43.

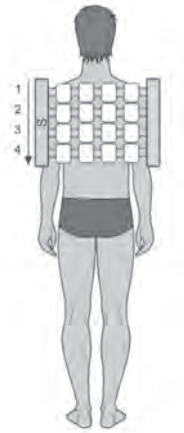


Fig. 43

The first 3 procedures:

Setting of Program No.39:
- The magnetic field direction in the main emitter: traveling top-down;
- Density: 10 mT;
- Frequency: 3 Hz;
- Procedure time: 20 min.

Procedure 4 up to the treatment course end:

Setting of Program No.40:
- The magnetic field direction in the main emitter: traveling top-down;
- Density: 15 mT;
- Frequency: 10 Hz;
- Procedure time: 20 min.

Posterior cervical sympathetic syndrome

Clinical symptoms of the disease: a burning, constrictive pain in the back of the head, neck, front chest wall, shoulder, or interscapular area. The syndrome is likely to develop on the background of cervical osteochondrosis.

The treatment course: 15 procedures. One procedure per day.

The emitter used: main emitter.

The main emitter is placed over the cervicothoracic area of the spinal column, with its «N» polarity surface facing the body. See Fig. 44a.

Fig. 44a

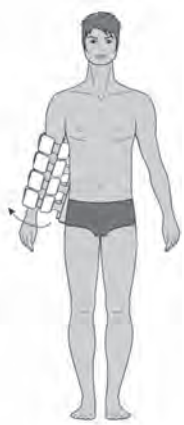


Fig. 44b

Setting of Program No.41:
- The magnetic field direction in the main emitter: traveling top-down;
- Density: 2 mT;
- Frequency: 100 Hz;
- Procedure time: 10 min.

After the procedure end (without unplugging the device), the main emitter is wrapped around the diseased limb, with its «N» polarity surface facing the body. See Fig. 44b.

Setting of Program No.42:

- The magnetic field direction in the main emitter: traveling clockwise;
- Density: 20 mT;
- Frequency: 100 Hz;
- Procedure time: 10 min.

Vertebrobasilar syndrome
(reflex compressive syndrome of the vertebral artery)

It is a widespread combination of cerebral and autonomic irritable symptoms occurring during stimulation of the sympathetic plexus of the vertebral artery, deformation of its wall or change in its lumen (herniated disc, spondylitis deformans, tension of neck muscles during muscular tonic syndromes, etc.). Typically manifested by stabbing, shooting, throbbing, burning pains in the cervico-occipital area spreading to the parietal (top of the head), postaural (behind the ears), temporal and fronto-occipital regions, often occurring when turning the head or as a result of its uncomfortable position during sleep. The following symptoms may also be present: ear buzzing, ringing, stuffiness, or a combination of pain with the signs of vertebrobasilar insufficiency (dizziness, staggering while walking, a sudden sensation of motion sickness while in transport).

The treatment course: 15 procedures. One procedure per day. A repeated course to be taken in 1.5-2 months.

The emitters used: main emitter, flexible emitting line.

The first 5 procedures:

At first, the main emitter is placed over the cervicothoracic area of the spinal column, with its «N» polarity surface facing the body. See Fig. 45a.

Setting of Program No.43:

- The magnetic field direction in the main emitter: traveling top-down;
- Density: 10 mT;
- Frequency: 100 Hz;
- Procedure time: 20 min.

After the procedure is over (without unplugging the device), the head is wrapped with the flexible emitting line, with its «N» polarity surface turned to the body. See Fig. 45b.

Fig. 45a

Fig. 45b

Setting of Program No.44:

- The magnetic field direction in the flexible emitting line: traveling clockwise;
- Density: 10 mT;
- Frequency: 12 Hz;
- Procedure time: 10 min.

Procedure 6 up to the treatment course end:

At first, the main emitter is placed over the cervicothoracic region of the spinal column, with its «N» polarity side turned towards the body.

Setting of Program No.45:

• The magnetic field direction in the main emitter: traveling top-down;
• Density: 25 mT;
• Frequency: 10 Hz;
• Procedure time: 20 min.

After the procedure end (without unplugging the device), the head is wrapped with the flexible emitting line, with its «N» polarity surface facing the body. See Fig. 45b.

Setting of Program No.46:

• The magnetic field direction in the flexible emitting line: traveling clockwise;
• Density: 15 mT;
• Frequency: 12 Hz;
• Procedure time: 10 min.

Vertebrogenic myelopathy syndrome

The syndrome implies weakness and numbness in the lower limb(s) on the background of lumbar degenerative disc disease, atrophy (usually unilateral) of lower leg muscles, prancing gait («foot dropping»), trophic disorders, active incontinence of urine, occasional intermittent claudication (jitter legs).

The treatment course: 15 procedures. One procedure per day. A repeated course is taken in 1.5-2 months' period.

The emitters used: main emitter, flexible emitting line.

Emitters' arrangement: the main emitter is placed over the lumbosacral area of the spinal column, and the flexible emitting line is spread along the thigh bone and lower leg, with the emitters' «N» polarity surfaces facing the body. See Fig. 46.

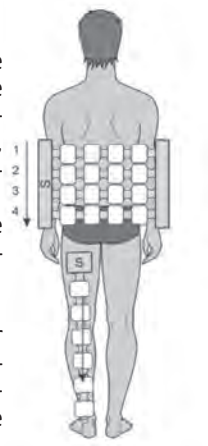


Fig. 46

Setting of Program No.47:

• The magnetic field direction in the main emitter: traveling bottom-up, in the flexible emitting line – traveling;
• Density: 20 mT;
• Frequency: 100 Hz;
• Procedure time: 15 min.

In case of paresis:

The course length – 15 procedures. One procedure per day. A repeated course is taken in 1.5-2 months.

The emitters used: main emitter.

At first, the emitter is placed on a couch or bed with its «N» polarity surface upward, and the patient lies down with the lumbosacral area of his/her spinal column over the emitter (the pulse generation unit can be placed at any side of the body). See Fig. 47a.

Setting of Program No.10:

• The magnetic field direction in the main emitter: static;
• Density: 6 mT;
• Frequency: 16 Hz;
• Procedure time: 15 min.


Fig. 47a

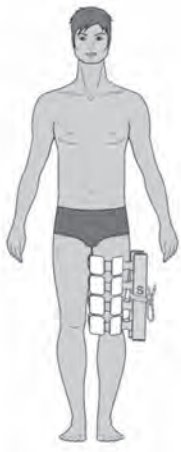


Fig. 47b


Fig. 47c

After the procedure is over (without unplugging the device), the main emitter is wrapped around the thigh bone of the affected limb, with its «N» polarity surface facing the body. See Fig. 47b.

Setting of Program No.10:

- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 15 min.

After the exposure termination (without unplugging the device), the main emitter is wrapped around the lower leg part of the affected limb, with its «N» polarity surface facing the body. See Fig. 47c.

Setting of Program No.10:

- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 15 min.

Osteoporosis with and without pathologic fracture

The treatment course: 15 procedures. One procedure per day. A repeated course is taken in 1.5-2 months' period.

The emitter used: main emitter.

The main emitter is wrapped around the affected limb with the «N» polarity side turned towards the body. See Fig. 48.

Setting of Program No.48:

- The magnetic field direction in the main emitter: traveling top-down;
- Density: 10 mT;
- Frequency: 8 Hz;
- Procedure time: 20 min.

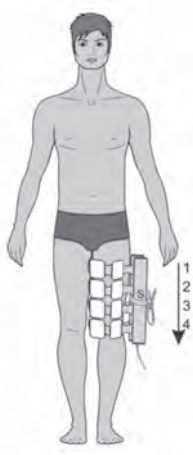


Fig. 48

TRAUMAS

Wounds (after surgical debridement)

The treatment course: 15-20 procedures. One procedure per day.

The emitter used: local emitter.

The emitter is placed onto the wound (over the bandage) with its «N» polarity surface facing the body.

Setting of Program No.68:

- The magnetic field direction: static;
- Density: 20 mT;
- Frequency: 50 Hz;
- Procedure time: 20 min.

Bursitis (including the post-operative condition, starting from the third day after surgery)

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

An injured joint is wrapped with the main emitter, with its «N» polarity surface turned towards the body. Fig. 49.

Setting of Program No.18:

- The magnetic field direction in the main emitter: traveling bottom-up;
- Density: 20 mT;
- Frequency: 100 Hz;
- Procedure duration: 10 min.

Fig. 49

General treatment procedure for traumas (contusion, joint dislocation)

The treatment course: 10 procedures. One procedure per day.

The emitter used: main emitter.

An injured joint is wrapped with the main emitter, with its «N» polarity surface turned towards the body. See Fig. 49.

Setting of Program No.50:

- The magnetic field direction in main emitter: traveling bottom-up;
- Density: 20 mT;
- Frequency: 100 Hz;
- Procedure time: 20 min.

ELBOW AND FOREARM TRAUMAS

Dislocation, sprain or strain of the capsular ligamentous apparatus of the elbow joint

Dislocation of head of radius

Traumatic rupture of the radial collateral ligament

Magneto-therapy is to be started on the 3rd-5th day after trauma occurrence.

Treatment course length – 10 procedures. One procedure per day.

The emitter used: main emitter.

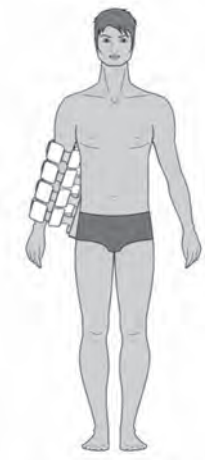


Fig. 50

Fig. 51

The injured joint is wrapped with main emitter, with its «N» polarity surface facing the body. See Fig. 50.

Setting of Program No.23:

- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz.
- Exposure time: 30 min.

COCCYGEAL (TAILBONE), HIP JOINT AREA AND THIGH TRAUMAS

Traumatic coccyalgia

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: local emitter.

The emitter is placed over the pelvic area with the «N» polarity towards the body. See Fig. 51.

Setting of Program No.65:

- The magnetic field direction: static;
- Density: 35 mT;
- Frequency: 50 Hz;
- Procedure time: 20 min.

Hip joint contusion

Treatment course length – 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The main emitter is placed over the affected hip joint, with the «N» polarity surface towards the body.

Setting of Program No.23:

- The magnetic field direction: fixed;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

Thigh contusion

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured thigh is wrapped with the main emitter, with its «N» polarity surface facing the body. See Fig. 52.

Setting of Program No.23:

• The magnetic field direction in the main emitter: fixed;
• Density: 6 mT;
• Frequency: 16 Hz;
• Procedure time: 30 min.

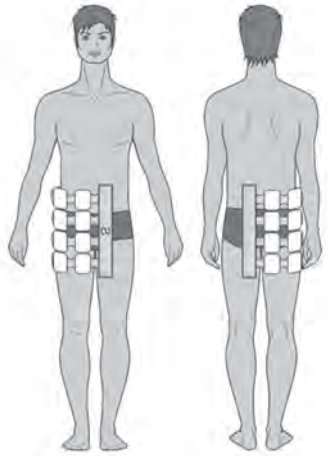


Fig. 52

KNEE AND LOWER LEG TRAUMAS

Contusion of another clarified or non-clarified part of lower leg

Multiple superficial traumas of the lower leg

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured lower leg is wrapped with the main emitter, with its «N» polarity surface towards the body. See Fig. 53.

Setting of Program No.23:

• The magnetic field direction in the main emitter: static;
• Density: 6 mT;
• Frequency: 16 Hz;
• Procedure time: 30 min.

Dislocation of knee

The magneto-therapy can be started on the 3rd-5th day after trauma.

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The Injured knee is wrapped with the main emitter, with its «N» polarity surface towards the body. See Fig. 54.

Setting of Program No.23:

• The magnetic field direction: static;
• Density: 6 mT;
• Frequency: 16 Hz;
• Procedure time: 30 min.

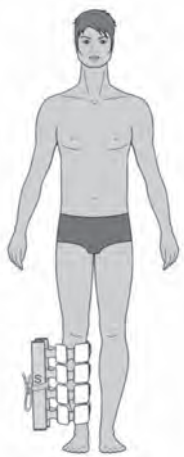


Fig. 53

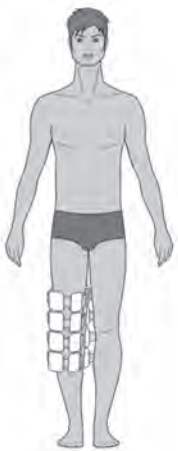


Fig. 54

ANKLE JOINT AND FOOT AREA TRAUMAS

Sprain and strain of ankle joint ligaments (72 hours after trauma)

The treatment course: 10 procedures. One procedure per day.

The emitter used: main emitter.

The injured joint is wrapped with the main emitter, with its «N» polarity side to-wards the body. The pulse generation unit is placed on the right from the limb.

Setting of Program No.50:

- The magnetic field direction in the main emitter: traveling bottom-up;
- Density: 20 mT;
- Frequency: 100 Hz;
- Procedure time: 20 min.

Ankle joint contusion

Treatment course length – 10-15 procedures.

The emitter used: main emitter.

The injured ankle joint is wrapped with the main emitter, with its «N» polarity surface facing the body. See Fig. 55.

Setting of Program No.23:

- The magnetic field direction: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

Toe contusion without nail bed injury

Toe contusion with nail bed injury

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured foot is wrapped with the main emitter, with its «N» polarity surface facing the body.

Setting of Program No.23:

- The magnetic field direction in main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

MULTIPLE SUPERFICIAL TRAUMAS OF ANKLE JOINT AND FOOT

Ankle joint dislocation

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured ankle and foot joints are wrapped with the main emitter, with its «N» polarity surface facing the body.

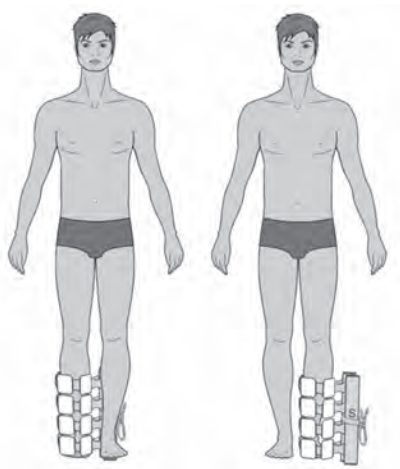


Fig. 55

Setting of Program No.23:
- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

Ligament rupture at the level of ankle joints and foot

Magneto-therapy is to be started after immobilization by means of a plaster bandage.

Treatment course length – 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured lower leg, ankle joint and foot are wrapped with the main emitter, with its «N» polarity surface facing the body.

Setting of Program No.23:
- The magnetic field direction: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

Sprain and strain of ankle joint ligaments

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The Injured foot is wrapped with the main emitter, with its «N» polarity surface facing the body.

Setting of Program No.23:
- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

NERVE TRAUMAS AT THE LEVEL OF ANKLE JOINT AND FOOT

External lateral plantar nerve trauma
Internal medial plantar nerve trauma

Treatment course length – 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured ankle joint and foot are wrapped with the main emitter, its «N» polarity surface facing the body.

Setting of Program No.23:
- The magnetic field direction: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

Deep fibular nerve trauma at the level of ankle joint and foot
Trauma of multiple nerves at the level of ankle joint and foot
Trauma of toe muscle long extensor and its tendon at the level of ankle joint and foot

Treatment course length – 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured lower leg, ankle joint and foot are wrapped with the main emitter, its «N» polarity surface facing the body.

Setting of Program No.23:

- The magnetic field direction: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

Trauma of multiple muscles and tendons at the level of ankle joint and foot

Other muscles and tendons' trauma at the level of ankle joint and foot

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured lower leg, ankle joint and foot are wrapped with the main emitter, with its «N» polarity side turned towards the body.

Setting of Program No.23:

- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

Nerve traumas at the level of forearm

Ulnar nerve trauma at the level of forearm

Magneto-therapy is to be started from the 2nd-3rd day after trauma.

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured elbow joint and forearm are wrapped with the main emitter, its «N» polarity surface facing the body.

Setting of Program No.23:

- The magnetic field direction in the main emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

WRIST AND HAND TRAUMAS

Finger contusion without nail bed injury

Finger contusion with nail bed injury

The treatment course: 10-15 procedures.

The emitter used: local emitter.

The emitter is placed directly over the trauma area or over the edematous area of the injured limb (the injured hand is placed between the two local emitters), with the «N» polarity surfaces turned towards the body. See Fig. 56.

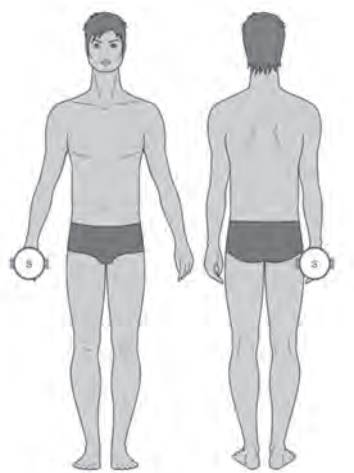


Fig. 56

Setting of Program No.79:
- The magnetic field direction in the local emitters: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

TRAUMAS INVOLVING SEVERAL BODY REGIONS

Multiple surface traumas of upper limbs
Multiple surface traumas of lower limbs

Treatment course length – 10-15 procedures. One procedure per day.

The emitter used: main emitter.

The injured limb is wrapped with the main emitter, its «N» polarity surface facing the body.

Setting of Program No.23:
- The magnetic field direction: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

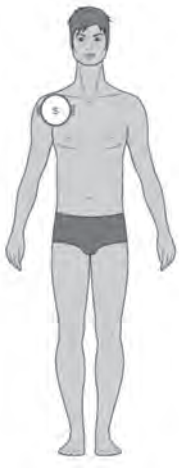


Fig. 57

Posttraumatic hematoma (2-3 days after trauma)

The treatment course: 10-15 procedures. One procedure per day.

The emitter used: local emitter.

The local emitter is placed over the hematoma area with its «N» polarity surface turned to the body. See Fig. 57.

Setting of Program No.79:
- The magnetic field direction in the local emitter: static;
- Density: 6 mT;
- Frequency: 16 Hz;
- Procedure time: 30 min.

RESPIRATORY DISEASES

Viral pneumonia in the phase of convalescence as a supporting treatment under supervision of doctors

The treatment course: 15 procedures. One procedure per day.

The emitter used: main emitter.

The main emitter is placed on the projection of the lung root, its «N» polarity surface facing the body. See Fig. 58.

Setting of Program №20:
- The magnetic field direction in the main emitter: travelling from right to left;
- Density: 20 mT;
- Frequency: 100 Hz;
- Procedure time: 20 min.


Fig. 58

MAINTENANCE SERVICE

Maintenance of the device includes repairs, routine inspection, cleaning from dust and dirt, disinfection, and periodic control of its operability.

The device is provided with the function of self-diagnostics: in case of a malfunction, the exposure stops, and an error code is indicated on the display, accompanied by a sound signal. The list of malfunctions and troubleshooting methods are given in Table 2.

Table 2

Visual and audible Indication of a malfunction	Possible cause	Troubleshooting method
1. An alarm sound signal is generated and an «E1» code is displayed	- There is a bad contact in the main emitter's connector. - Beak in the connecting cable.	- Switch the device off. Check the connector fixation. Switch the device on. - Contact the service office.
2. An alarm sound signal is generated and an «E2» code is displayed	- There is a bad contact in the connectors of the flexible emitting line or local emitter. - Beak in the connecting cable.	- Switch the device off. Check the connector fixation. Switch the device on. - Contact the service office.
3. An alarm sound signal is generated and an «E3» code is displayed	- Malfunction of the main emitter.	- Contact the service office.
4. An alarm sound signal is generated and an «E4» code is displayed	- Malfunction of the flexible emitting line or local emitter.	- Contact the service office.
5. An alarm sound signal is generated and an «E5» code is displayed	- The emitter required for the preset procedure is missing.	- Switch the device off. Correct the connection of the required emitter. Switch the device on.

The periodic control of the device operability is to be carried out at least once a year. For this purpose, do the following:

- connect the emitters to the device and arrange them in a way to provide easy access to all the individual emitters;
- plug the device into the mains and press the «POWER» switch to activate it;
- select an exposure program which involves action of the main emitter and the flexible emitting line (preference is to be given to a program with the maximal parameters of field density and pulse repetition frequency, e.g. Program No 47);
- activate the magneto-action;
- check the presence of magnetic field in each of the activated emitters with the help of the magnetic field indicator;

- stop the action;
- select an exposure program which involves action of the local emitter (with the maximal parameters of field density and pulse repetition frequency, e.g. Program No 64);
- activate the magneto-action;
- check the presence of magnetic field in each of the activated emitters with the help of the magnetic field indicator;
- stop the action;
- press the «POWER» switch to deactivate the device and unplug it from the mains.

Routine inspection is to be performed at least once every three months. During the inspection, it is necessary to check the integrity of the cables, plug, mains cord, the emitters, and the control unit housing.

SPECIFICATIONS

The device is functional with power supply from alternating current mains of ~230V (+23V; -32V), frequency 50Hz.

Device power consumption: 60 VA.

Magnetic pulses repetition frequency:

For the main emitter and flexible emitting line:

for «traveling» field type:

- from 1 pulse / sec to 75 pulses / sec with field density of 25 mT;
- from 1 pulse / sec to 100 pulses / sec with field density of 2-20 mT;

for «static» field type:

- from 1 pulse / sec to 16 pulses / sec with field density of 2-6 mT;

For the local emitter:

- from 1 pulse / sec to 50 pulses / sec with field density of 35-45 mT;
- from 1 pulse / sec to 100 pulses / sec with field density of 2-30 mT.

Absolute deviation of the field density peak value on the emitters' surface for values from 2 up to 20 mT for set one (A) is within ±[0.2A+0.6] mT, for values from 25 up to 45 mT it is within ± 6.3 mT.

Magnetic pulses repetition frequency – with a range of 1-100 pulses / sec.

Relative deviation of magnetic field pulses repetition frequency is within ±5%.

Total magnetic exposure time intervals range from 1 to 30 min. The relative deviation of the treatment course exposure time is within ±5%.

The device generates two types of pulsed electromagnetic fields: «travelling» and «static».

The main emitter generates «traveling» magnetic field of three kinds: «traveling horizontal», «traveling vertical» and «traveling diagonal».

The device provides storage of 79 exposure programs in its non-volatile memory, including preset parameters and types of the magnetic field, as well as the total exposure time (See Annex A).

Temperature of the emitters' surfaces, max: 41 °C.

Device operating mode setting time, max: 30 s.

The surfaces of the device emitters contain markings of the magnetic field polarity: 'N' – north, 'S' – south.

In case of the device malfunction, generation of alarm signaling and automatic termination of the exposure mode is provided.

The device displays the following indications:

Visual indications:

- program number;
- magnetic exposure time;
- malfunction code;
- power supply network;
- procedure execution;
- presence of magnetic field in the emitters.

Audible indications:

- deactivation of the emitters;
- case of the device malfunction.

Mean service life – 5 (five) years.

The exterior surfaces of the device components are resistant to disinfection with any chemical solution approved in medical practice for application on plastic and metal products.

The overall dimensions and weight of the device components are given in Table 3.

Table 3

Component name	Overall dimensions, mm				Weight, kg, max.
	diameter	length	width	height	
Power and control unit		240±5	299±5	114±5	3,0
Main emitter		540±7	400±7	18±2	3,0
Flexible emitting line		700±8	100±5	18±2	1,0
Local emitter, including:					1,8
- coil (single emitter)		165±5	140±5	28±2	
- pulse generation unit		100±5	90±5	50±2	
- connective cables between the coils and pulse generation unit		1100±100			

LIST OF STANDARDS

EN ISO 10993-1

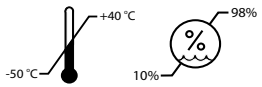
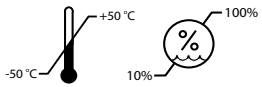
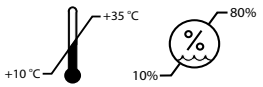
EN 60601-1

EN 60601-1-2

EN 60601-1-11

EN 62304

STORAGE AND TRANSPORTATION

STORAGE CONDITIONS	TRANSPORT CONDITIONS	OPERATING CONDITIONS
		

Annex B

MANUFACTURER'S MANUAL AND DECLARATION – ELECTROMAGNETIC EMISSIONS AND IMMUNITY

Table 1

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	Class B	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	

Table 2

Manufacturer's manual and declaration – interference resistance			
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.			
Interference resistance test	The test level according to IEC 60601	Compliance level	Electromagnetic environment – instructions
Electrostatic discharge (ESD) according to IEC 61000-4-2	±8 kV – contact discharge ±2, ±4, ±8, ±15 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	- U_H=0%, 0,5 cycle (0,45,90,135,180,225,270 and 315°) - U_H=0%, 1 cycle - U_H=70%; 25/30 cycles (0°) - U_H=0%, 250/300 cycle	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	30 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.			

Table 3

Manufacturer's manual and declaration – interference resistance			
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.			
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 transmitter.
Conducted disturbances induced by RF fields according to IEC 61000-4-6	3 V (150 kHz - 80 MHz) 6 V (ISM & Amateur)	Complies	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 
Radio-frequency electromagnetic field according to IEC 61000-4-3	10 V/m (80 MHz - 2.7 GHz)	Complies	

MANUFACTURER'S WARRANTY

The Manufacturer hereby guarantees that the quality of the device conforms to the requirements of the User Manual («Specifications» section), provided that the conditions of proper storage, transportation, and usage are met by the Customer.

Warranty period is 24 months from the date of sale.

Within the warranty period, the Manufacturer shall repair or replace the defective device or its parts at their own expense.

Warranty terms

The warranty does not cover the following cases:

- if the device bears traces of outside interference or repair attempts by non-authorized servicing companies;
- if unauthorized changes into the design or construction of the device have been detected;
- if the device has any mechanical damages;
- if the device has been damaged as a result of penetration of foreign objects, substances or liquids;
- if the device has been damaged as a result of connecting it to a power line that does not comply with the national standards.

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

Warranty card for repair or replacement works during the warranty period
ALMAG-02 Pulsed Electromagnetic Field Therapy Device

Accepted on «____» _____ 20____
Shop foreman _____
surname and signature

Manufacturer's address:
391351, 25 Yanina st., Yelatma, Kasimov District, Ryazan region, Russia
JSC «Yelatma Instrument Making Enterprise»
Tel: +7 (4912) 293-418

WARRANTY CARD

for repair (replacement) during the warranty period
ALMAG-02 Pulsed Electromagnetic Field Therapy Device

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 operator 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.