biomag® Lumina 3D-e

en | Instructions for Use

Pulsed Magnetic Therapy Device

Data on completeness of product
Údaje o kompletnosti výrobku

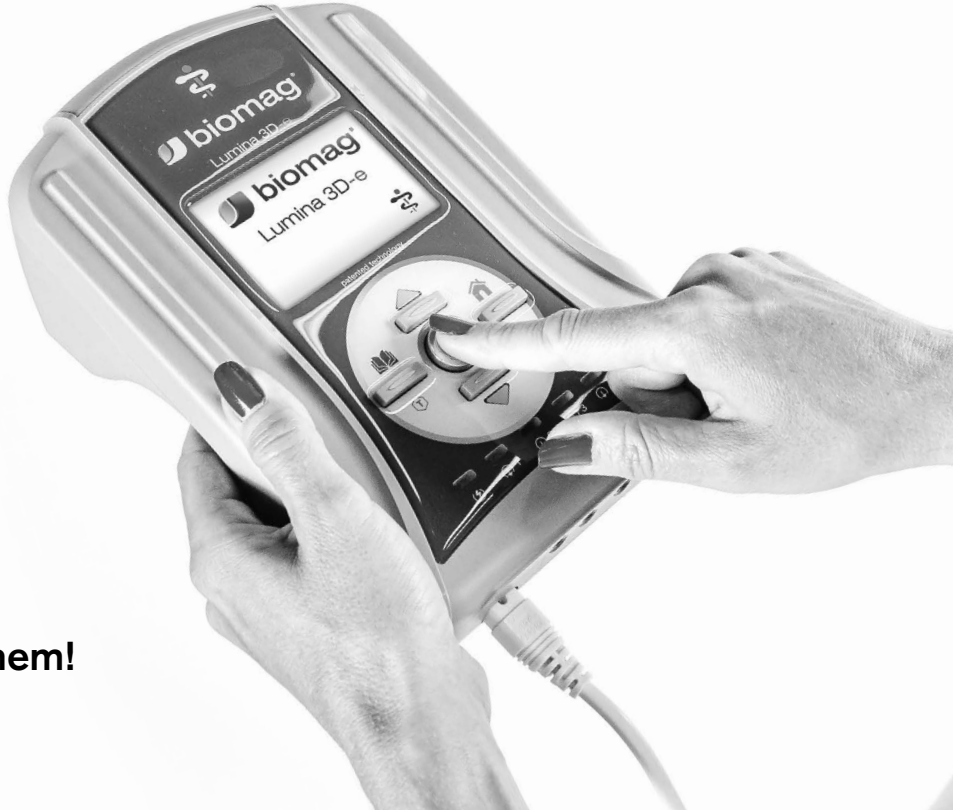
Serial number / Equipment / Mode
Výrobní číslo / Vybavení / Režim

medical device

Pulsed Magnetic Therapy Device BIOMAG®

model

Lumina 3D-e with applicators



Thank you for purchasing a BIOMAG® medical device.

Read these Instructions for Use in detail and follow them!

1 SAFETY INSTRUCTIONS AND WARNINGS

⚠ **WARNING – The manufacturer is not responsible for improper use of the medical device!**
⚠ **WARNING – Observe the Intended Purpose, Indications, Contraindications, and other provisions and instructions in this Instructions for Use.**
⚠ **WARNING – Modifications to this medical device are prohibited.**
⚠ **WARNING – Do not wrap the power cords of the medical device around your neck – there is a risk of strangulation.**
⚠ **WARNING – The medical device may cause radio interference or interrupt the operation of nearby equipment. It may be necessary to take measures to mitigate this effect, such as reorienting or relocating the medical device. The medical device may damage nearby devices such as wristwatches during application, magnetic media, credit cards, etc. A distance of 1 m or more is safe.**
⚠ **WARNING – Failure of the customer to ensure that the service check is performed at the specified intervals will void the warranty of the medical device and cause loss of responsibility for its continued operation by the manufacturer.**

- **Before using the medical device for the first time, read the Instructions for Use thoroughly!**
- **The medical device must not be used for any other purpose and by other persons than described in this manual. The manufacturer is not liable for any damages. The risk is borne by the user.**
- **The medical device may only be operated and handled by persons who meet the Operator Profile and, when using it, follow these instructions.**
- **In case of missing product labelling, contact the dealer or manufacturer.**
- **Do not plug in anything else than the original BIOMAG® applicators into the connectors on the device.**
- **Protect the medical device from falling and damaging, paying particular attention to the device connectors and applicators.**
- **Do not place the applied part (applicator) on broken skin (abrasions, bedsores, cuts, etc.), always use a protective layer, such as a disposable or other hygienic pad, when applying.**
- **The medical device must not be soaked, washed with water or used in wet or humid environments (bathing, sauna, etc.). Do not expose the medical device to moisture.**
- **If the medical device is used by several users, disinfection of the applicators is necessary before each subsequent use.**
- **Do not place the medical device near heat sources.**
- **Do not place the device near a light source for better legibility of the display.**
- **Do not use the medical device if it is damaged.**
- **Any tampering with the medical device is prohibited.**
- **The medical device must be connected to a suitable electrical supply source with no signs of damage to the supply cable. If you are not sure, have an inspection performed by an inspection technician.**
- **Do not use the medical device if the supply cables of the applicators are damaged. Have an inspection performed by a service technician.**
- **Do not pull on the supply cables of the medical device.**
- **Contact the dealer or manufacturer in case of damaged or missing parts of the instruction manual.**
- **In case of doubt regarding the instructions in the instructions for use contact the manufacturer's customer support.**

2 INTRODUCTION, CONTENTS OF THE INSTRUCTIONS FOR USE

Pulsed Magnetic Therapy Device BIOMAG® Lumina 3D-e is an active therapeutic medical device – consisting of a device and attachable applicators. It is used for the application of low-frequency pulsed magnetic therapy.

Use the medical device in accordance with its intended purpose. The manufacturer is not responsible for improper use, which is considered to be any use contrary to the instructions and recommendations in the Instructions for Use.

1 SAFETY INSTRUCTIONS AND WARNINGS p. 2

2 INTRODUCTION, CONTENTS OF THE INSTRUCTIONS FOR USE p. 3

3 INTENDED PURPOSE, INDICATIONS, CONTRAINDICATIONS, SYMBOLS p. 4
3.1 Intended purpose p. 4
3.2 Indications / clinical benefits p. 4
3.3 Contraindications p. 5
3.4 List of abbreviations and symbols used p. 6

4 BASIC INFORMATION p. 8
4.1 Principle of biological action p. 8
4.2 Profile of a patient, operator and trainer p. 10

5 TECHNICAL SPECIFICATIONS: MEDICAL DEVICE, DEVICE AND APPLICATORS p. 11
5.1 Technical description of the medical device p. 11
5.2 Technical description, parameters and device software p. 11
5.2a) Technical description of the device p. 11
5.2b) Technical parameters of the device p. 12
5.2c) Device software p. 13
5.3 Technical description and specifications of applicators p. 14
5.3a) Common parameters and instructions for all applicators p. 14
5.3b) Technical specifications of flat, combined and local applicators p. 15
5.3c) Technical specifications of circular applicators p. 16

6 DEVICE DESCRIPTION AND CONTROL p. 17
6.1 Device description p. 17
6.2 Operation – commissioning the medical device p. 18

7 APPLICATION – WHEN AND HOW OFTEN TO APPLY p. 20
7.1 Recommended number of applications p. 20
7.2 Applicator selection p. 20
7.3 Program selection p. 21
7.4 General information p. 22
7.5 Example of correct connection of the medical device before starting the application p. 23
7.6 Operation of the device and other possible settings p. 24

8 INFORMATION FOR MEDICAL DEVICE USERS p. 26
8.1 Safe operation rules p. 26
8.2 Health protection during work with low-frequency pulsed magnetic field p. 26

9 MAINTENANCE, FUNCTIONALITY, SERVICE, INSPECTION p. 27
9.1 Device maintenance p. 27
9.2 Applicators maintenance p. 27
9.3 Necessary functionality p. 27
9.4 Service p. 27
9.5 Safety technical inspection p. 27

10 OPERATING AND STORAGE ENVIRONMENT, DISTRIBUTOR, EMC p. 28
10.1 Operating environment p. 28
10.2 Storage environment p. 28
10.3 Information for distributors p. 28
10.4 Information on electromagnetic compatibility p. 28

11 FAULTY CONDITIONS p. 32

12 WARRANTY p. 35

13 DISPOSAL p. 35

14 ADVICE AND TIPS p. 35

15 CONTACT INFORMATION p. 36

3 INTENDED PURPOSE, INDICATIONS, CONTRAINDICATIONS, SYMBOLS

3.1 Intended purpose

The medical device is designed for additional symptomatic treatment to support the alleviation of pain, swelling, spasms and detoxification, to improve blood circulation (vasodilation) and to accelerate healing.
It is used for various health conditions involving the musculoskeletal system, for degenerative disorders and after accidents, injuries, surgical procedures, etc.

⚠

Intended for use on intact skin through a protective layer, e.g., disposable or other sanitary pads.
When using the medical device, it is necessary to follow in particular the **Principles of safety operation** together with the **Contraindications** / **Indications** and to operate it in accordance with the specified environmental conditions.
Basic safety information is shown on the device display as well.

Read the Instructions for Use, follow them and the safety information given in the introduction, observe the purpose of use, indications and contraindications.

3.2 Indications / clinical benefits

In accordance with the intended purpose, the basic indications for the use of the medical device are certain specific manifestations (symptoms) of the medical conditions described in the intended purpose, in particular:

Pain – pain-relieving effect
Promotion (stimulation) of tissue regeneration – healing effect
Swelling – anti-swelling effect
Cramps (spasms) – myorelaxing effect
Blood disorders – vasodilating effect
Metabolic disorders – metabolic-detoxifying effect

These indications occur as manifestations of various medical conditions and therefore the medical device can be used for various medical conditions in medical fields such as rehabilitation, orthopaedics, surgery, neurology, rheumatology, balneology, sports medicine, urology, geriatrics and others.

Before beginning the use of the medical device, a qualified assessment of the reason for these manifestations should be made. Establish a diagnosis and at the same time exclude contraindications by a doctor.

3.3 Contraindications

Medical device is not permitted to be used in the following contraindications:

- **Pregnancy**
- **Pacemaker**
- **Bleeding conditions**
- **Menses (bleeding phase)**
- **Neoplasms**
- **Serious septic states**
- **Fever conditions**
- **Active tuberculosis**
- **Mycosis at the site of the application**
- **Paroxysmal nerve diseases**
- **Hyperthyroidism**
- **Adrenal hyperfunction**
- **Myasthenia gravis**
- **Hypothalamus and pituitary gland diseases**
- **Psychosis**
- **Pain of unknown origin**
- **Unspecified diagnosis**
- **Conflict with a professionally determined therapeutic procedure**

Side effects of the medical device:

No serious and persistent side effects have been reported. Rarely (approximately 1% of cases), mild side effects related to the spa effect may occur, namely:

- **Temporary increase in sensitivity to soreness at the application site**
- **Mild headache**
- **Decrease in blood pressure and dizziness**

Preventive measures of the medical device:

- The medical device is intended for use in combination with other medical procedures and devices or alone.
- Particular care should be taken when used in patients with **hypotension** (or a tendency to it) and **hypertension**.
- The individual effects and use of magnetic therapy should be assessed according to the **specific condition** and response of the individual patients.
- Discontinue applications in case of unexpected reactions! It is advisable to resume the application after checking by the attending physician based on the procedure determined by the physician.
- As with other medical devices, this medical device may only be used to positively influence such medical conditions, which have been diagnosed by the patient's physician after having competently ruled out **Contraindications** and observing the **Patient profile**.

Failure to observe the contraindications may result in damage to health!
If a lay person is not satisfied with the result of the therapy, it is necessary to consult a doctor and follow the instructions in the chapter safe operation principles.
In case of doubt, the operator (health care professional or lay person) can check the suitability of the programmed equipment and accessories with the manufacturer.
Low-frequency magnetic field therapy cannot cause an overdose.

3.4 List of abbreviations and symbols used

List of symbols used on the label

	Proceed according to the Instructions for Use		Alternating current (AC)
	Device with protection Class II		Direct current (DC)
	BF type applied part		Caution, important warning
	Input for applicator		Keep safe from heat
	Power supply symbol		Keep away from moisture
	Electric equipment intended for indoor use		Temperature limitation
	Environmentally friendly disposal of the device		Humidity limitation
	Applicator polarity symbol		Atmospheric pressure limitation
 2265	A product label by which the manufacturer indicates that the medical device is controlled by an authorised person and complies with the applicable requirements for being on the market in the European Economic Area		
	Manufacturer		Date of production
	Distributor	SN	Serial number
MD	Medical device	REF	Catalogue name of the product
UDI	Unique Device Identifier (a series of numeric characters created based on a globally recognised standard for medical device identification and coding)		

List of abbreviations

PEMF	Pulsed electromagnetic field (Pulsed ElectroMagnetic Field)
LPMF	Low-Frequency Pulsed Magnetic Field
MIMI	Maximum Intensity of Magnetic Induction
mT	Millitesla = unit of magnetic induction
f	Frequency = pulse rate
Hz	Hertz = frequency unit
min	Minute = time unit
s	Second = time unit
EMC	Electromagnetic compatibility
*	Explanation provided

Explanatory notes

Medical device = device with applicators
Device = electronic control unit
Applicator = attachable applied part of the device

List of used symbols on the medical device and in the Instructions for Use

	Pulsed Magnetic Therapy Device BIOMAG®		BIOMAG® manufacturer's logo
	List of ALL PROGRAMS		Time
	MY PROGRAMS		Comment setting
	Confirmation button		Sound / volume down
	Navigation within the menu		Output settings
	Next menu		EXTRA mode extension
	Run repeat program		Time button
	Program information		Intensity button
	Continue with program selection		PIN 1 / PIN 2
	Copy to MY PROGRAMS		Language selection
	Remove from MY PROGRAMS		Key lock
	View MENU		Number of pre-paid applications
	Return		Accumulator
	View operation information		Application history
	View basic effects		Program type
	Contraindications		Indications
	Instrument settings		Rotary programs (3D)
	Confirmation or refusal of setting selection		Synchronized programs (without 3D)
	Favourite programs		Gradual switch-on of inputs
	Personal memory		3-pin connector / 2-pin connector / 1-pin connector
	Transfer of programs		Avoid touching the display when holding, moving or handling the device

4 BASIC INFORMATION

4.1 Principle of biological action

Magnetic therapy is based on the influence of an artificial magnetic field of certain parameters on the human body. It is a physical therapy that generates a large-area low-frequency pulse magnetic field.
As is stated in the intended purpose, physiological changes in tissue after the application of magnetic therapy occur due to pain mitigation and vasodilation of capillaries and precapillaries, which leads to the following treatment effects:

- **pain-relieving** – analgesic, reduces pain
- **healing** – promoting regeneration, anti-inflammatory and anti-rheumatic effects
- **anti-swelling** – reduces swelling (oedema)
- **myorelaxing** – relaxes muscles
- **vasodilating** – improves micrococirculation in particular
- **metabolic-detoxifying** – accelerates the elimination of toxins and metabolites

The low-frequency pulsed magnetic field (LPMF) acts on the cell membrane permeability, i.e., it improves and accelerates metabolism. It leads to the vasodilation of tiny capillaries and precapillaries at the application site and markedly increases blood perfusion and oxygenation of a body part (microcirculation improvement) to which the LPMF is applied.
It results in increased metabolism and improved supply of exposed tissue with oxygenated blood and nutrients and creates optimal conditions for the healing and regeneration of damaged tissue. Due to joint influence, these processes enable the above given healing effects. Pulsed electromagnetic field (PEMF) therapy goes through the entire body, affects each cell in the entire exposed tissue and can affect deep and surface structures when applied.

Pain-relieving effect
Due to electromagnetic induction, the PEMF determines the formation of current in nerve fibres. This induced current blocks the passage of painful sensations from the painful site through the spinal cord to the brain centres. As a result of this and some other mechanisms, pain is suppressed. These other mechanisms also include the increased formation of endorphins, suppression of inflammation and swelling. Furthermore, the myorelaxing mechanism or myotonus release are applied. Increased production of endorphins and control of calcium ion transfer through the cell membrane also helps achieve vasodilation, and analgesic and calming effects. After applying PEMF, increased lactate dehydrogenase activity in exposed muscles was proven. Lactate dehydrogenase determines the removal of lactic acid, which stimulates neural receptors and causes pain.

Healing effect
The healing and regenerative effect of PEMF on bones and soft tissue is explained by the non-specific irritation of the cytoplasmic (cellular) membrane. In this membrane, the metabolic chain is activated and its key point is the ratio change between cAMP and cGMP, thus the ratio change between cyclic adenosine monophosphate and cyclic guanosine monophosphate. In case of using regenerative effect on bones, the applications lead to the increase of osteoclasts and to the subsequent start of the process of bone tissue regeneration. The PEMF considerably increases healing, activates the creation of new tissue, calcification and leads to increased parathormone sensitivity which, in addition to other things, helps control the level of calcium in the body. Better blood perfusion of tissue and greater oxygen saturation helps to quickly reduce inflammation in all tissue and, at the same time, the effect of possible antibiotic treatment is potentiated.
Healing of damaged peripheral nerves is considerably accelerated, and the regeneration of neurofibrils (fibres in neurons) and the growth of central axons (fibres coming out from cells) is also accelerated.

Anti-swelling effect
Swelling is caused by the disorder of blood circulation at the level of blood capillaries with the subsequent accumulation of fluid between cells. PEMF applications aim to counteract the main causes of swelling, i.e., increased blood pressure in capillaries (the smallest blood vessels in the body), the disorder of fluid outflow from tissue and also the possible increase in the permeability of the capillaries walls. Improved perfusion, i.e., better tissue flow, plays an important role in the anti-flow effect of PEMF. Accelerated metabolism after the application of low-frequency pulsed magnetic therapy enables faster re-absorption of swelling and significant anti-inflammatory and analgesic effects in the affected area.

Myorelaxing effect

The PEMF accelerates the flushing of acidic metabolites that cause painful irritation in muscles and sites of chronic inflammations. The flushing of these metabolites is given by improved perfusion (flow through tissues) and by the increased activity of lactate dehydrogenase, which conditions the degradation of lactic acid. PEMF applications considerably reduce muscle spasms (cramps). The therapy also decreases radicular irritation, which often causes tingling and throbbing or burning pain. By suppressing pain, the PEMF modulates reflexive changes in the body. Modulation of these reflexes in the body causes muscle spasms or contractures and cramps to relax. This relaxation results in additional pain relief. PEMF application leads to the relaxation of skeletal muscles and improved mobility. This improved mobility will enable further extension of therapy, e.g., in the form of light physiotherapy exercises.

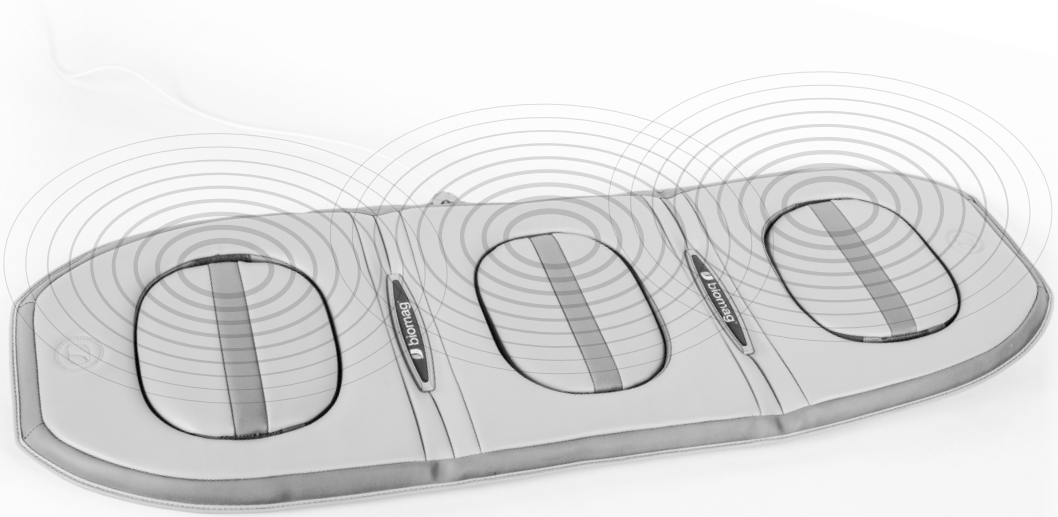
Vasodilating effect

With suitably set parameters, the PEMF acts against blood sludging, i.e., agglutination of the erythrocytes which transport oxygen in blood. This results in the repeated dispersion of individual erythrocytes so the area of oxygen binding becomes larger. The blood which has passed through a suitable magnetic field thereby has a higher ability to bind oxygen and transport it to the tissue. Low-frequency pulsed magnetic therapy activates the parasympathetic nervous system and promotes the reflux of Ca^{2+} ions, which leads to relaxation of the blood vessel muscles (pre-capillary sphincters in particular) and to subsequent vasodilation.

The LPMF application affects the polarisation of red blood cells by positive charge. Polarisation of blood cells acts on the tone of fine vessels, arterioles and capillaries. It results in the enlargement of this blood pool (vasodialtion and microcirculation improvement), thus in the better supply of tissue with oxygenated blood and nutrients. Improved microcirculation also contributes to the faster conduction of toxic substances and metabolites from tissue. PEMF also considerably increases partial pressure of oxygen and acts on blood cell plasticity or elasticity. More elastic blood cells can then pass through the blood pool better. In addition, with long-term applications of this method, neovascularisation also occurs and thus faster formation of new vessels. At the same time, the magnetic field reduces the risk of blood clots (thrombi).

Metabolic-detoxifying effect

PEMF passes evenly through human tissue and can is one of the few methods that can also act at sites of internal inflammation. Where PEMF is applied, it acts on each cell and induces weak electric currents in it. Due to this induction, the surface potentials of cells change. The basis of every detoxifying process is a better supply of nutrients and better removal of metabolic waste products from tissue.



4.2 Profile of a patient, operator and trainer

Patient profile

Who can use the medical device?

- **Patient over 9 years of age.**

⚠

The medical device may only be used to positively influence medical conditions that have been diagnosed by a physician after having competently ruled out all contraindications.

Operator profile

Who can use and operate the medical device?

- **Trained medical staff in health care institutions (doctors, physiotherapists, nurses) or according to the acts and regulations of the given country.**

Training is performed by the manufacturer's trained representative or the distributor's trained representative.

- **A lay operator (adult) or a patient (may be a lay operator) in a home care setting, and only after training in the use of the device and following the instructions and directions in the manual.**

Training is performed by the manufacturer's trained representative or the distributor's trained representative.

The medical device must not be handled by children and other unauthorised and untrained persons.

Familiarity with the characteristics of the medical device, the conditions of use and the operator profile shall be confirmed by the signature of the trained person.

Profile of trained instructor

Who can instruct and train for the medical device?

- **An authorised employee of the manufacturer or a representative authorised by the manufacturer with written confirmation (e.g. distributor).**

The training record may be a part of the purchase contract; the training is recorded separately for additionally trained persons.

⚠ CAUTION

The medical device must not be used for any purpose or by any person other than that described in this chapter or in any manner other than that described in these Instruction for Use.

The manufacturer does not bear any responsibility for possible damage. A user bears the responsibility themselves.

Serious adverse events must be reported to the manufacturer and to the relevant authority of the Member State.

5 TECHNICAL SPECIFICATIONS: MEDICAL DEVICE, DEVICE AND APPLICATORS

5.1 Technical description of the medical device

Medical device designed for non-continuous operation.
It is constructed for the application of pulsed magnetic fields of low frequency (the scope of frequency is 4–81 Hz), the new model is based on the previous series.

The medical device consists of a device and attachable applicators.The device is a control unit from which electric pulses of specified parameters are sent to the applicators, which are equipped with a cable and a connector, with which the applicators are connected to the device outputs. The applicator is the applied part of the medical device.

Standard equipment:

- Device with a network cable
- 2 standard issue applicators
- Instructions for Use, tester, fixation strap
- Bag

The content can be enlarged according to the requirements and needs of a user.

5.2 Technical description, parameters and device software

5.2a) Technical description of the device

The device is an electronic control unit that is housed in a plastic box, with an information display on the top. At the bottom of the device there is an input for the power connector and 4 outputs for applicators.

The back side includes a label with identification data of the system and the manufacturer. The device itself is provided with control software having 6 programs with the 3D function or without 3D. The application is ended when the selected program has finished. The software version can be displayed on the display by concurrently pushing the button. All indications and controls are located on the front of the device in the chapter **Description of the device**.

Technical design is based on the medical devices Pulsed Magnetic Therapy Device BIOMAG®. The medical device features **3D technology** 3D. The 3D technology is described in the marketing materials as being based on controlled sequential switching on of the individual outputs for the applicators on the device, so that the power of the device is directed to only one output at any given time. Thus, during the application the output is transferred to the applicator gradually, so each part of the applicator is switched on separately. This cycle is repeated continuously, so each application is maximally effective and optimally efficient.

The radiation of the magnetic field from such separately switched-on parts takes place undisturbed at the moment of the pulse and is not adversely affected by the radiation of adjacent or opposite parts. It is necessary to stress that this connection does not mean a new property of the magnetic field, but only the provision of the more effective transfer of the magnetic field (energy) to the patient. The speed of the magnetic field direction to individual parts of the applicator is pre-set to the maximum, but it is possible to reduce it.

In order to take advantage of this feature of the medical device, special applicators have been designed in which the sequential engagement of their parts is structurally secured. These applicators are connected to the device by the special 3-pin connector.

Because the full power of the device goes to each output separately, connecting multiple standard applicators provides more efficient performance than medical devices without this technology.
Medical device standard setting secures the gradual, regular alternation of pulses on individual outputs, always between each pulse.

The device has two modes: EASY and CLINIC

BIOMAG® Lumina 3D-e with software applicators EASY is designed for patients in terms of ease of use in home care. However, it can also be used by healthcare providers.

BIOMAG® Lumina 3D-e with software applicators CLINIC is designed with its setting options for the needs of healthcare providers, but also for patients in home care, who want to take advantage of the device's setting options.

Important warning

When handling and carrying the device, do not hold it by the display.

5.2b) Technical parameters of the device

Description	Values	
Software version	Display on the screen www.biomag-medical.com/info/	
Power supply voltage	~100 to 240 V, 50/60 Hz	
Device input power	60 VA	
Voltage of integrated power source	24 V DC	
Device insulation class	II.	
Applied part type	BF type	
Power cord	H05VVH2-F 2 x 0.75 mm / H03VVH2-F 2 x 0.75 mm	
Environment	Normal	
Protection grade	IP 30 *	
MIMI – maxim intensity of magnetic induction	Max. 35 mT	
Output regulation (intensity)	EASY Without regulation	CLINIC 12 levels 1, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90,100%
Number of outputs for applicators	4	
Number of EASY programs	6 programs	
Basic number of programs in MY PROGRAMS for the EASY mode (possibility of copying the program without changing the name / with changing the name)	** 1 most frequently used + 8 possibilities	
Number of CLINIC programs	6 programs	
Basic number of programs in MY PROGRAMS for the CLINIC mode (possibility of copying the program without changing the name / with changing the name)	*** 1 most frequently used + 200 possibilities	
Frequencies of programs	EASY 4–81 Hz	CLINIC 4–81 Hz
Pulse shape	Rectangle (modified according to frequency)	
Pulse leading edge width (dependent on the selected program and applicator induction)	0.4-2.5 ms	
Pulse width	1.1-11.1 ms ****	
Pulse descending edge depending on the applicator induction	0.5-3.5 ms	
Number of time ranges	9	
Application times	5, 10, 15, 20, 25, 30, 45, 60, 90 min	
End of application	Acoustic indication + Display	
Warning messages	Acoustic indication + Display	
EMC – electromagnetic compatibility	CSN EN 60601-1-2 ed. 3:2016	
Ambient temperature around the device	+5°C to +35°C	
Device dimensions	240 x 162 x 75 mm	
Display	3.5' TFT	
Device weight	0.845 kg	
Type of accumulator (if included in the system)	Lithium battery LIP745690P/2S	
Accumulator weight	165 g	
Operation time when powered from accumulator (with 4 outputs occupied)	approx. 160 min	
Accumulator recharging time	7 hours	

5.2c) Device software

Programs and their parameters								
Order	Name	Frequency / sequence time			Wobbling	Intensity	Pulse shape	Application time
Program No. 1	PAIN-RELIEVING EFFECT promoting pain relief	5–12 Hz 2 min 30 s	15 Hz 15 s	25 Hz 15 s	Gradually increasing	EASY: without regulation CLINIC: 1–100%	Rectangle	EASY: 20 min CLINIC: 20 min (5–90 min)
Program No. 2	HEALING EFFECT promoting healing accompanied by regeneration, anti-inflammatory and anti-rheumatic effects	50–81 Hz 2 min 30 s		12 Hz 30 s	gradually increasing / after pulse	EASY: without regulation CLINIC: 1–100%	Rectangle	EASY: 20 min CLINIC: 20 min (5–90 min)
Program No. 3	ANTI-SWELLING EFFECT promoting the reduction of swellings	12–15 Hz 2 min 30 s		50–75 Hz 30 s	Gradually increasing	EASY: without regulation CLINIC: 1–100%	Rectangle	EASY: 20 min CLINIC: 20 min (5–90 min)
Program No. 4	MYORELAXING EFFECT promoting the reduction of spasms and swellings	10–12 Hz 3 min			Gradually increasing	EASY: without regulation CLINIC: 1–100%	Rectangle	EASY: 20 min CLINIC: 20 min (5–90 min)
Program No. 5	VASODILATING EFFECT promoting vasodilation and blood circulation	12 Hz 1 min		50–80 Hz 2 min	after pulse / gradually increasing	EASY: without regulation CLINIC: 1–100%	Rectangle	EASY: 20 min CLINIC: 20 min (5–90 min)
Program No. 6	DETOXIFYING EFFECT promoting metabolism and detoxification	4–12 Hz 2 min		50–81 Hz 1 min	Gradually increasing	EASY: without regulation CLINIC: 1–100%	Rectangle	EASY: 20 min CLINIC: 20 min (5–90 min)

Sequence = the group of frequencies that repeat periodically over the application time.

Explanation notes to Table 5.2b)

* IP 3 – protected from the penetration of solids of 2.5 mm in size and larger
IP 0 – not protected against water

** 1 most frequently used + 8 possibilities
The function automatically saves the most commonly used programs; it is also possible to copy 8 more programs with the individual name of the selected programs.

*** 1 most frequently used + 200 possibilities
The function automatically saves the most commonly used programs; it is also possible to copy 200 more programs with the individual name of the selected programs.

**** Changes between three levels based on the program to induce maximum cell response.

5.3 Technical description and specifications of applicators

We always select the most suitable applicators from the offer for the particular therapeutic intention in terms of size and shape. When assessing the suitable use of individual applicators, we concentrate on the applicator being comfortably placed on the body as close as possible to the affected place. Some applicators can be fixed to the affected part of the body with an elastic strap.

The applicators are an applied part of the medical device consisting of air coils wound with enamelled copper or other wire into a special construction. During the operation, applicators produce quiet tapping sounds in the rhythm of pulses. The applicator surface is made of quality artificial leather. All applicators are provided with plastic clips holding labels with the manufacturer's logo. The applicators have 1-pin connectors  , 2-pin connectors  , 3-pin connectors  , which are used to connect them to the device.

▪ Round applicators
The applicators of the solenoid type have a hollow cylinder shape. They are used where emphasis is placed on even magnetic field action. We use them for deep applications according to their diameter by putting them on the given part of body.

▪ Flat applicators
The applicators have a board or pad shape and are placed on the larger parts of body according to their size. They are used where emphasis is placed on the size and possible bending of individual parts. We use them for application to the entire body or limbs.

▪ Combined applicators
The applicators have a flat shape with openings. They are used where universal properties are important. We use them for the application to the selected part of body as a flat applicator or put them on the particular part of body as a round applicator.

▪ Local applicators
The applicators have a round or oval shape pointing towards the point. They are used where emphasis is placed on intensive magnetic field action. We use them for application to the targeted local part of body.

5.3a) Common parameters and instructions for all applicators

1 | Output cable CYLY 4x0.50 mm, length 1.6 or 2.8 m
2 | Cable ending connector JACK 3.5 mm
(1x, 2x or 3x – according to the applicator type)
3 | The applicator is the type BF applied part
4 | Operation temperature (applicator warming) max. 41°C
5 | Ambient temperature around the device +5°C to +35°C
Ambient temperature for the A6P2, AL21 applicator
+5°C to +28°C
6 | Operating position unlimited
7 | Recommended application method through a disposable or other hygienic pad
8 | Most flat applicators can be fastened by fixation aids

Important warning
It is forbidden to use non-original applicators with the medical device, except for accessories authorised by the manufacturer.
Do not switch magnetic field direction of the A6P2 applicator during ongoing application.

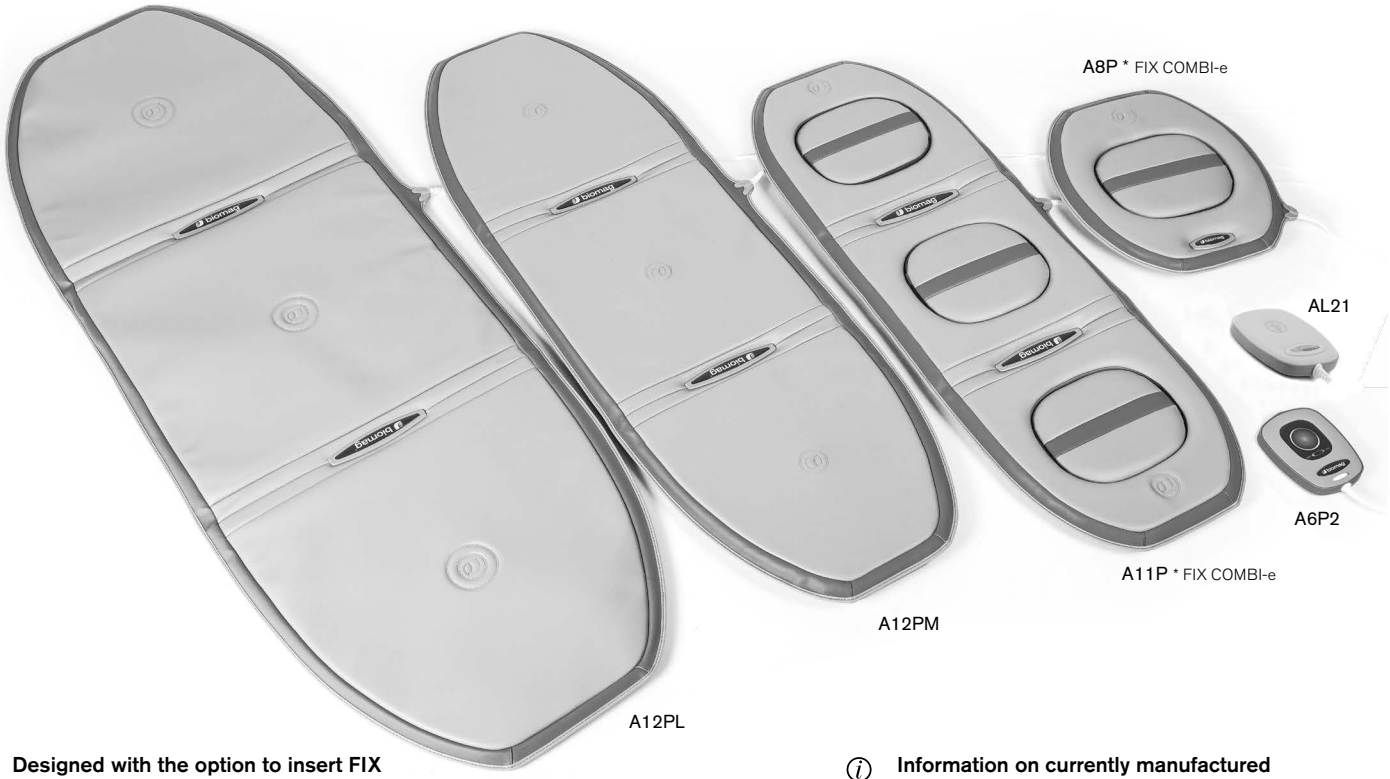
Biomag tester
Using the tester you can detect magnetic pulses coming from the applicator and vibrating in the rhythm of frequencies. The north polarity of the applicator is indicated on the nameplate by a circle with a letter Ⓝ.

Additional accessories
You can find all additional accessories (cases, straps, strips, bags, etc.) at your distributor or manufacturer on request.

5.3b) Technical specifications of flat, combined and local applicators

A12PL	**Three-piece rounded flat applicator with 3D pulses**
	MIMI 2.4 mT; connector 3x JACK 3.5 mm; length 1 780 mm; width 600 mm; height 40 mm; weight 3.68 kg
A12PM	**Three-piece rounded flat applicator with 3D pulses and possibility of connecting to a closed shape or fixation**
	MIMI 3.5 mT; connector 3x JACK 3.5 mm; length 1 400 mm; width 450 mm; height 40 mm; weight 2.60 kg
A11P *	**Three-piece rounded combined applicator with openings with 3D pulses, with possibility of connecting to a closed shape or fixation**
	MIMI 3.0 mT; connector 3X JACK 3.5 mm; length 1 170 mm; width 420 mm; height 40 mm; weight 2,00 kg
A8P *	**One-piece rounded combined applicator with an opening and possibility of fixation**
	MIMI 2.5 mT; connector 1x JACK 3.5 mm; length 440 mm; width 390 mm; height 40 mm; weight 0.72 kg
A6P2	**Switching local applicator with the magnetic field direction** design **SPOT** = point magnetic field design **WIDE** = wide magnetic field
	MIMI 35.0 mT – SPOT / MIMI 20.0 mT – WIDE; connector1x JACK 3.5 mm; length 170 mm; width 130 mm; height 23 mm; weight 0.58 kg
AL21	**Intensive local applicator**
	MIMI 35.0 mT; connector 1x JACK 3.5 mm; length 210 mm; width 160 mm; height 26 mm; weight 1.10 kg

Pictures of applicators



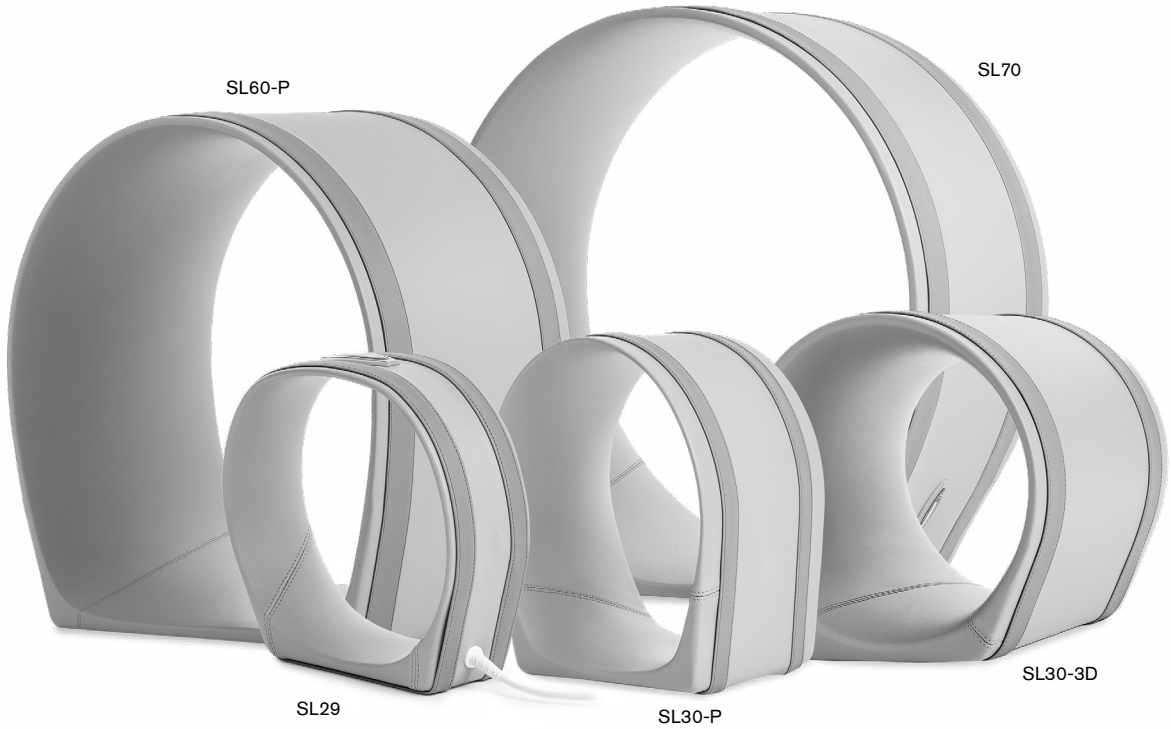
* Designed with the option to insert FIX COMBI-e into slots (accessory for more convenient use of the applicator)

ⓘ Information on currently manufactured applicators is provided by the manufacturer

5.3c) Technical specifications of circular applicators

SL29	**Oval round applicator of the solenoid type with the flat bottom**
	MIMI 4.0 mT; connector 1x JACK 3.5 mm; diameter 290 mm; depth 80 mm; weight 1.30 kg
SL30-P	**Round applicator of the solenoid type with the flat bottom**
	MIMI 5.0 mT; connector 1x JACK 3.5 mm; diameter 300 mm; depth 170; weight 2.55 kg
SL30-3D	**Round applicator of solenoid type with a flat bottom and 3D impulses**
	MIMI 4.0 mT; connector 3x JACK 3.5 mm; diameter 300 mm; depth 340 mm; weight 4.85 kg
SL60-P	**Round applicator of solenoid type with a flat bottom**
	MIMI 1.5 mT; connector 1x JACK 3.5 mm; diameter 600 mm; depth 340 mm; weight 12.65 kg
SL70	**Round applicator of solenoid type for assembly on the sliding bed**
	MIMI 2.0 mT; connector 1x JACK 3.5 mm; diameter 700 mm; depth 300 mm; weight 14.30 kg

Pictures of applicators



ⓘ **Information on currently manufactured applicators is provided by the manufacturer**

6 DEVICE DESCRIPTION AND CONTROL

6.1 Device description

1a Information graphic display

1b Device mode (clinic / easy)
- Picture of the device starting

2 UP button

3 The button for **entry to the list of all installed programs**

T TIME
- Time setting for the EXTRA offer

4 START / STOP confirmation button

5 Button for **entry to the MY PROGRAMS list**

I INTENSITY
- Setting of magnetic field intensity for the EXTRA offer

6 DOWN button

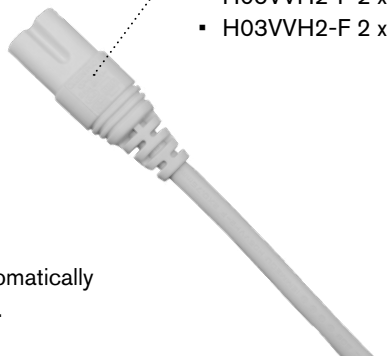
8-11 Blue signalling diodes
- Connection of applicators (permanently emitting light)
- Applicator failure (blinking or not emitting light)

13-16 Outputs for connecting the applicators
- ↓1- ↓4

7 Green signaling diode
- Connection to the power supply (permanently emitting light)
- Battery charging (pulsing)

12 Connector for connecting a power cord

Power cord
- H05VVH2-F 2 x 0.75 mm
- H03VVH2-F 2 x 0.75 mm



Note:
- If the device is provided with the extended EXTRA E offer, it is only possible to control it before starting the program with the T and I buttons.
- Opening for attachment of the fixation strap at the top and bottom.
- At the back – opening for the system restart button.
- The device was out of operation for 6 minutes, the display was automatically switched off to save power. Press any button to turn on the display.

6.2 Operation – commissioning the medical device

1 | Using the power cord, connect the device to the mains
The medical device starts up by an audible signal accompanied by an introductory screen shown on the display (mode information). After the introductory screen, the display shows the last used program.
ⓘ *Before first operational use, you will be called to select the language.*

2 | Connect 1 to 4 applicators
The outputs for applicators are at the bottom of the device. Apply the applicators comfortably on the affected areas of the body.

3 | Program selection
Use the left button to display the list of all programs.
Use the right button to display the most frequently used programs.
Use the upper and lower buttons to scroll to the required program.

4 | Starting the program
Start the selected program by pressing the central button.
The application is running.
After 5 minutes, the display switches over to the energy saving mode.

5 | Switching off the device
First, using the central button, interrupt the ongoing program (in case of running application).
Hold the button down for 6 beeps and use the button to select YES to confirm the device switch off.
When the battery-powered medical device is idle, the device automatically switches off after 6 minutes.

PROGRAM SETTING

Description> Selection of the program and its possible settings and launch.

Procedure> In EASY mode, start the program with the button no setup required. In CLINIC mode, confirm the program with the button to display the **Run preset items** or **Set**. To run the program without the need for setup, confirm with the button **Run preset items**. To change the time or reduce the intensity of the program, select **Set** and confirm with the button.

ⓘ *To change the time range (5-90 min) and intensity (1-100%) use the buttons and confirm the selected value by pressing the button.*

ⓘ *Simultaneous pressing of buttons start the 3D program with time-extended rotation **3D extended** (if included).*

ⓘ *The program can be interrupted at any time by briefly pressing the .*

ⓘ *By pressing the button again continue the application.*

ⓘ *The program will end after the time shown on the display has elapsed.*

MY PROGRAMS

Description> The user can freely name the program according to the patient's name or number. The saved program will be displayed in the **MY PROGRAMS** chapter. To view the created programs, select the button. Buttons scroll through to the desired program.

Procedure> By double-clicking the button display the **Program details** and use the button to select **Copy to MY PROGRAMS**. After confirming the item, the menu for adding a program will appear.

ⓘ *Maximum capacity of created items in the MY PROGRAMS list: mode EASY 8 / mode CLINIC 200.*

Adding a program without renaming>
Use buttons to select **Copy without renaming** and confirm with the button. The program is saved in the **MY PROGRAMS** list under its original name.

ⓘ *To quickly copy a program to the MY PROGRAMS list, triple-click on the button.*

Adding a program and renaming it>
By selecting **Rename and copy** and confirming the button we get to the touch keyboard, using which we can type any text. Save the renamed program with the button to the **MY PROGRAMS** list.

ⓘ *To quickly rename a program in the MY PROGRAMS list, triple-click button .*

Removing a program>
Programs stored in this way can be removed in a similar way. Press the right button , to get to the **MY PROGRAMS** list, scroll through using the buttons , select the desired program and double-click the button to get to the **Program Details**. Use the buttons , to select **Delete program from MY PROGRAMS**. By using buttons , choose YES and confirm by pressing , to remove the program.

ⓘ *To quickly remove a program from the MY PROGRAMS list, triple-click on the button .*

Program search>
To find names comfortably in the **MY PROGRAMS** list, press the button again . A screen with a touch keyboard appears. Enter any characters that are included in the program name and confirm by pressing . A list of programs containing the specified characters will be displayed.

ⓘ *Number of names searched in the MY PROGRAMS list : EASY mode 8 / CLINIC mode 200.*

SET PROGRAM

Description> Functions that allow you to design an appropriate therapy using the six basic therapeutic effects. These effects have a wide range of applications in supporting the control of the manifestations of various health problems. All effects can be alternated or combined as required. When using the device, follow the instructions for use and follow the professionally prescribed medical procedure.

Procedure> In **MY PROGRAMS** list triple-click on the button **SET PROGRAM** (available in CLINIC mode) to create **SET PROGRAM** is composed of a group of 1-4 effects (as required). Follow the instructions shown on the display. Using buttons effects can be chosen in order to compose a group of effects for **SET PROGRAM**. Shortly press the button numerical order in the effect group. To save the effect group, long press the for the length of 3 beeps. A screen with a touch keyboard will appear, where you can type the name of the program and confirm with the button .

SET PROGRAM is saved into **MY PROGRAMS** .

ⓘ *To interrupt the SET PROGRAM setting, press the button and return to the List of ALL PROGRAMS.*

ⓘ *Maximum capacity of created SET items in MY PROGRAMS list : 200.*

AUTOMATIC PROGRAM REPEAT

Description> Allows you to repeat the selected program 4 times in a row. Each repetition starts two hours after the start of the program application. The progress information is shown on the display of the device.

Procedure> Activate by double-clicking button on the selected program, the **Program details** will be displayed. Click to select the **Next menu** item to confirm the **Start automatic repetition** .

ⓘ *Quickly start the automatic program repeat by holding the button on the selected program for 3 beeps.*

ⓘ *Progression of the automatic program repetition: first application 20 min + 1 h 40 min pause, second application 20 min + 1 h 40 min pause, etc.*

SIMULTANEOUS LAUNCH OF THE SECOND PROGRAM

DESCRIPTION> This function allows separate operation of two programs (available in CLINIC mode). Can be used when the output connectors of the instrument are split. Splitting of outputs can be selected in **Instrument settings** : **3/1** (1st, 2nd, 3rd output separated from 4th output) or **2/2** (1st, 2nd output separated from 3rd, 4th output).

Procedure> To activate the second program, first run the first program in the normal way for outputs 1 2 3 or 1 2 (chapter Operation - commissioning the medical device). Activation of separate operation for output 4 or 3 4 is done by triple-clicking the button and by using buttons select the second program (purple text underlining). To start the program, press the button .

ⓘ *For devices with equipment without separate 1st, 2nd, 3rd, 4th outputs (4/0), the user cannot use this function.*

ⓘ *The progress of applications can be monitored on the display. By double-clicking the button switch between the current Application 1 and Application 2.*

ⓘ *To deactivate concurrently running programs, press the to interrupt the first program (Application 1), and then double-click to switch to the second program (Application 2), which is interrupted again by pressing the button . If both programs are paused, use the button to return to the List of ALL PROGRAMS, or the button .to return to the MY PROGRAMS list.*

EXPANDING EXTRA MODE

Description> Additional mode EXTRA (E) to modes EASY and CLINIC. To view the item in the **Instrument settings** menu contact your distributor or the manufacturer.

Procedure> After activating Finest Top, button (T) can be used to set the time, while button (I) is used to set intensity. Within these, buttons are used to change the value.

ⓘ ***Finest Top*** *function locks the device to control the programs stored in* ***MY PROGRAMS*** *. You can start the quick program control with the button . Triple-click (T) to deactivate.*

ⓘ *Use the* ***Frequent*** *function to set the number (1 or 4) of the most frequently used programs in the* ***MY PROGRAMS*** *menu .*

ⓘ ***Synchronised programs*** *function sets up programs without 3D technology. To restore the function of 3D rotation programs deactivate synchronised programs.*

7 APPLICATION – WHEN AND HOW OFTEN TO APPLY

7.1 Recommended number of applications – how often to apply

2x a day; in more severe cases it can be performed 3 times a day on average, or more often, usually for at least 2 weeks, and in case of chronic conditions significantly longer. The pre-set individual program times of 20 minutes are the recommended time for the induction of the relevant effect and can be extended up to 90 minutes. The minimum recommended number of applications is 10; the maximum number of applications and maximum recommended application times are not stipulated and the applications can be repeated according to the doctor's recommendation on a long-term basis.

7.2 Applicator selection and taking a position before application – how to apply

As for the applicators in our offer (chapter **Technical description and specifications of applicators**), we always select the most suitable one for the particular therapeutic purpose and place it as close to the surface of the treated part of the body as possible. If pain reduction is needed, it is better to place the applicator on the treated part of the body with the north polarity; when other symptoms should be eased it is better to place the applicators with the south polarity. Polarity marking is given on the production label and described in the technical specifications.

Preparation before application and the application itself should be carried out according to chapter **Example of correct connection medical device**.

Prior to the actual application, we have to ensure that we know all of the safe operation rules and there are no contraindications (chapter **Safe operation rules** / chapter **Contraindications**).

When selecting the program, it is possible to find out the information on its effects in the description of manifestation and effects of individual programs given in chapter **Principle of biological action**.

7.3 Program selection

Program No. 1 – PAIN-RELIEVING EFFECT

= ANALGESIC
(the dominant effect is pain relieving)
Preferably used in case of all types of pain where pain is one of the main symptoms of disease and we have to reduce it as a matter of priority.
After achieving pain relief, we move to healing and regenerating programs.
This program may also be used in following cases:
- with all diagnosed problems where the dominant manifestation is pain;
- with radicular (root) and pseudoradicular syndromes (sciatica, compression of nerves for various reasons);
- if the pain relief must precede, e.g., rehabilitation exercises, locomotor therapy, etc.;
- to relieve special types of pain.

Program No. 2 – HEALING EFFECT

(the dominant effect is healing promoting regeneration, anti-inflammatory and anti-rheumatic effects)
Preferably used in case of speeding up the healing process and regeneration of damaged tissue using anti-inflammatory and anti-rheumatic effects.
This program may also be used in following cases:
- with rheumatic joint and soft tissue disease;
- with all impairment where acute pain was relieved during the previous phase and it is suitable to continue in follow-up treatment and healing.

Program No. 3 – ANTI-SWELLING EFFECT

(the dominant effect is anti-swelling)
We can use it to promote the remission of swelling for various reasons.
This program may also be used in the following cases:
- disorder of fluid outflow from tissue, improvement in perfusion, flow through tissue, acceleration of metabolism, faster swelling absorption, considerable anti-inflammatory and pain relieving effect;
- in case of all post-traumatic and postoperative conditions to promote perfusion, accelerate swelling absorption and to promote healing.

Program No. 4 – MYORELAXING EFFECT

= ANTISPASMODIC
(the dominant effect is myorelaxing)
We use it for the targeted requirement to promote the reduction of spasms (cramps) in cases where the dominant manifestation is not pain but mobility disorder and other problems.
This program may also be used in the following cases:
- in persons with muscle spasms and stiffness limiting the total mobility of limbs and neurodegenerative disorders with the manifestation of muscle stiffness.

Program No. 5 – VASODILATING EFFECT

(the dominant effect is vasodilating)
We use it for problems with the requirement to improve microcirculation (vasodilation) in ischaemic manifestations for various reasons.
This program may also be used in following cases:
- ischaemic diseases of upper and lower limbs for various reasons;
- with non-healing varicose ulcers and all disorders of blood perfusion issues, e.g., bedsores, etc.;
- reducing the risk of clot formation.

Program No. 6 – DETOXIFYING EFFECT

(the dominant effect is metabolic-detoxification)
We use it for promoting metabolism and detoxification, i.e., in case of the requirement for faster removal of toxic substances and metabolites from tissues, reducing internal inflammations and simultaneous requirement for increasing nutrient intake.
This program may also be used in following cases:
- need for general detox for various causes;
- to induce local detox effects achieved by applying the applicator to the problem area – muscle, joint, etc.

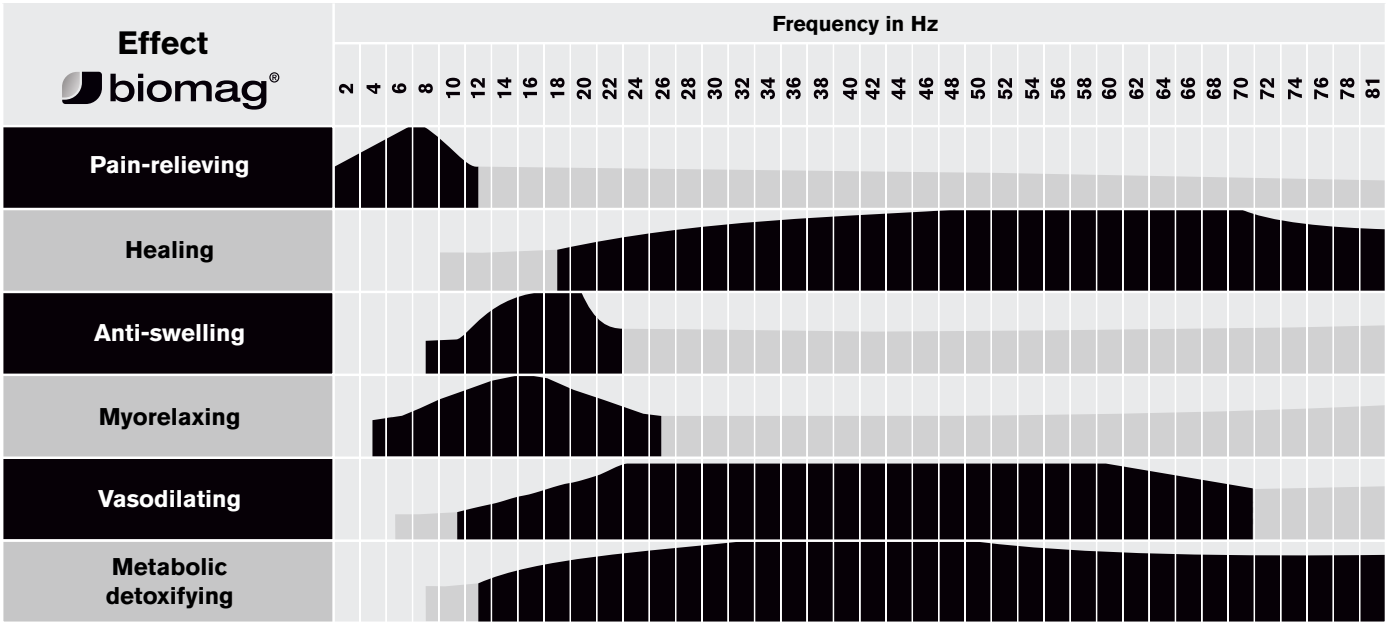
Note:
All the programs induce a different extent of all therapeutic effects with the fact that the parameters of individual programs are set so that they purposefully induce the **dominant action of one or two effects.**

Based on the **Intended Purpose**, the medical device is used for the application of pulsed magnetic fields.

7.4 General information

- The physiological mechanisms of therapy operate at the systemic, organ, tissue, cellular, and molecular levels, and these changes produce beneficial therapeutic effects in the body.
- Magnetic field lines penetrate all parts of the body, bones and tissue equally, the patient does not need to undress, nor are plaster casts a problem.
- Before the application, select the program according to the manifestations (symptoms) of diagnosed health conditions which you want to affect preferably.

Informative chart of the predominant effects of magnetic therapy by frequency



= the most effective range of frequencies for the given therapeutic effect

= the range of frequencies for the given therapeutic effect with less considerable effect

7. 5 Example of correct connection of the medical device before starting the application

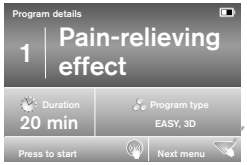
The operator, user or patient are familiarised with the principles of safe operation. The application will provide its effect when meeting all of the conditions given in the **Patient profile** / **Operator profile**.
Before application, contraindications must be professionally excluded.

1. The selected applicators are placed on the application site or sites and the patient is in a comfortable position (lying or sitting).
   The patient is dressed or has a disposable or another hygienic pad inserted between the applicator and the applied body part.

2. The device is connected to the mains (it is not necessary when powered from the accumulator) and is placed on the stable mat within the reach of the patient's application position.

3. Selected applicators are properly connected to the device. The device is switched on and the patient receives the selected application program.

7.6 Operation of the device and other possible settings



Double-click the central button of any program to display **Program details**. Use the button with **Next menu** to control the device.

Next menu

Start automatic repetition
Confirm and start program repeating.

About the program
Confirm and display the information on individual programs.

Continue with program selection
Press the button to see the list of all programs.

Copy to MY PROGRAMS
Confirmation of enables you to copy any program from the list of all programs to MY PROGRAMS with the possibility of name creation.

View MENU
Confirmation of enables you to go through the MENU.

List of all programs
Confirm the to see the list of all programs.

View operator instructions
Confirm and display Information on device operation.

View basic effects
Confirmation of enables you to display Information the on basic effects of magnetic therapy BIOMAG®.

View contraindi-cations
Confirmation of enables you to display the list of contraindications – pay increased attention to it!

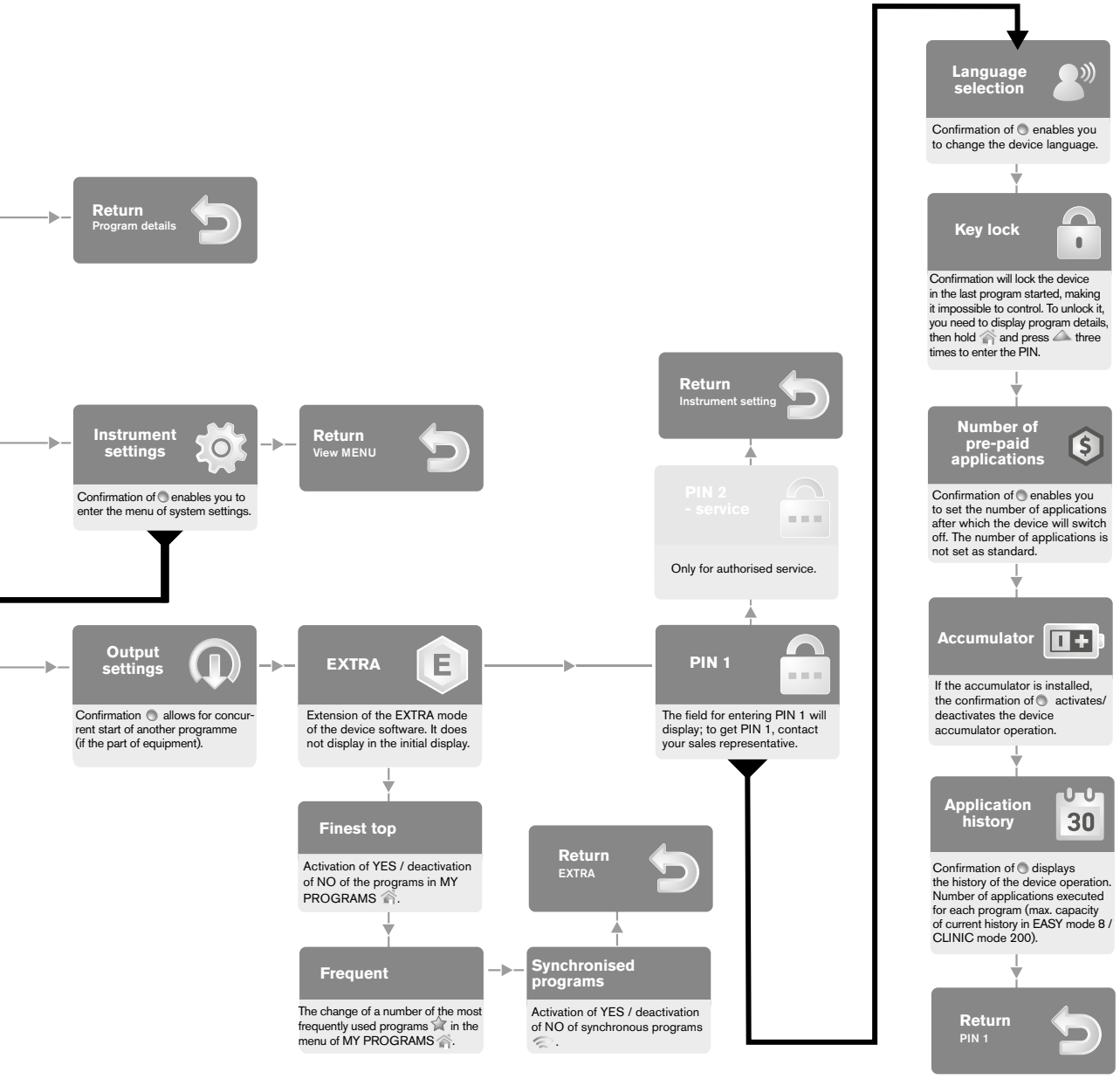
Personal memory
Check medical device functionality will take place by confirming the item.

Transfer of programs
Confirmation of enables adding or removing the programs from the List of all programs TO MY PROGRAMS.

Time setting
Press the button and set time.

Comment setting
Confirmation of enables you to set up to 3 reminders.

Sound setting
Confirmation of enables you to set the volume of the device sound signalling (welcoming tone, buttons tone, failure notice, program end, reminder).


Return
Program details
Instrument settings
Confirmation of enables you to enter the menu of system settings.
Return
View MENU
Output settings
Confirmation allows for concurrent start of another programme (if the part of equipment).
EXTRA
E
Extension of the EXTRA mode of the device software. It does not display in the initial display.
Finest top
Activation of YES / deactivation of NO of the programs in MY PROGRAMS.
Frequent
The change of a number of the most frequently used programs in the menu of MY PROGRAMS.
Return
EXTRA
Synchronised programs
Activation of YES / deactivation of NO of synchronous programs .
PIN 1
The field for entering PIN 1 will display; to get PIN 1, contact your sales representative.
PIN 2
- service
Only for authorised service.
Return
Instrument setting
Language selection
Confirmation of enables you to change the device language.
Key lock
Confirmation will lock the device in the last program started, making it impossible to control. To unlock it, you need to display program details, then hold and press three times to enter the PIN.
Number of pre-paid applications
$
Confirmation of enables you to set the number of applications after which the device will switch off. The number of applications is not set as standard.
Accumulator
If the accumulator is installed, the confirmation of activates/ deactivates the device accumulator operation.
Application history
30
Confirmation of displays the history of the device operation. Number of applications executed for each program (max. capacity of current history in EASY mode 8 / CLINIC mode 200).
Return
PIN 1

8 INFORMATION FOR MEDICAL DEVICE USERS

8.1 Safe operation rules

1 | Read the instructions for use thoroughly before using the medical device for the first time!
2 | The medical device may only be operated and manipulated by persons who meet the **Operator profile** and who follow these instructions for use.
3 | Pulsed magnetic fields can affect functional disorders, not fixed pathological changes.
The therapy is non-addictive, meets all safety standards and uses a completely user-safe method.
4 | The first five applications should be made, if possible, on the following days.
5 | If no treatment response occurs with the initial applications, continue therapy anyway. Positive effects may occur later.
6 | If there is a slight worsening of the condition during the initial days of treatment, these are known processes in the reactive phase. It is recommended continuing applications after consulting a physician.
With further applications, the pain usually disappears and significant improvement occurs.
7 | Metal implants are not contraindicated for therapy.
8 | Do not apply the applied part (applicator) to broken skin (abrasion, bedsore, cut, etc.), always use a protective layer, such as a disposable or other hygienic pad, during application.
9 | In case of use of the medical device by several patients, disinfection of the applicators is necessary before each use by another patient.
10 | Do not plug anything else than the original applicators into the connectors on the device.
11 | Do not remove the applicator from the device connector when the application program is running.
Exit the program first or wait for the application to finish.
12 | Protect the medical device from dropping and damage, paying particular attention to the device connectors and applicators.
13 | The medical device must not be soaked, rinsed in water or used in wet or humid environments (bathing, sauna, etc.).
Do not expose the medical device to moisture.
Do not place the medical device near heat sources.
14 | Do not use the medical device if it is damaged.
15 | Any tampering with the medical device is prohibited.
16 | The medical device must be connected to a suitable electrical supply without any signs of damage to the supply cable.
If you are unsure, have an inspection performed by an inspection technician.
17 | Do not pull on the supply cables of the medical device.
18 | Portable and mobile radio frequency communication devices may affect the medical device. No wireless communication equipment should be operated within a distance of 3.3 m, it could affect the operation of the medical device.
19 | The medical device may cause radio interference or interrupt the operation of nearby equipment that is located next to or in a block with other equipment.
It may be necessary to take measures to mitigate this effect, such as reorienting or relocating the medical device.
20 | Applicators may damage nearby devices such as wristwatches, magnetic carriers, credit cards, etc. during application.
A distance of 1 m from the applicator is already safe.
21 | When using multiple applicators within a single treatment, ensure that the applicators are spaced apart so that they do not interfere with each other.

WARNING – The manufacturer is not responsible for improper use of the medical device!
NOTE – When using the medical device in therapeutic applications, respect the legal standards of the individual countries.
NOTE – Check the website https://www.biomag-medical.com/info/ for current and other important information and user instructions, including warranty extension options.

8.2 Health protection during work with low-frequency pulsed magnetic field

There is no restriction when working with LPMF. It is advisable to follow the Operator's Profile and the Instructions for Use. When using the medical device, observe the Safe Operation Rules together with the Contraindications and operate it in accordance with the specified environmental conditions.

In other cases, consideration of the operator's current medical condition and mode of operation may be recommended. Furthermore, the regulations for working with electrical equipment must be observed when operating and handling the medical device.

9 MAINTENANCE, FUNCTIONALITY, SERVICE, INSPECTION

9.1 Device maintenance

The device may only be used in the environment for which it is designed. To ensure reliable function, it must be protected against mechanical damage and dirt. Maintenance and disinfection of the device is performed with the Sani-Cloth® Active agent or with other agents of identical composition. It includes antiseptic napkins without alcohol designated for the disinfection of surfaces and devices in all the types of health care institutions. The instructions for use are stated on the agent cover. During cleaning, the device must always be disconnected from the power supply! It is not recommended to clean the device using chemicals such as thinners and solvents that might damage the surface of the device. Do not expose the device to higher temperatures.
The device must be used in the manner for which it is intended given its equipment. The device equipped with a lithium battery (optional) may only be used with the mains cable while charging charging the lithium battery. After charging, the device is disconnected from the mains and the operation of the device is ensured by the battery. If the battery is discharged, the mains cable must be reconnected to the mains. Do not leave the battery discharged for a long time. Regularly check the battery status according to the charge indicator in the upper right corner of the device display (battery icon). The battery is replaced by the manufacturer or by an authorised service centre as an after-sales service two years after purchase.

9.2 Applicators maintenance

Maintenance and disinfection of the applicators is performed with the Sani-Cloth® Active agent or with other agents of identical composition. These are antiseptic napkins without alcohol designated for the disinfection of surfaces in all the types of health care institutions. The instructions for use are stated on the agent cover.
In a domestic environment, it is recommended to clean as needed, but at least once a month.
Never use thinners or other chemical solvents for cleaning or maintenance of the applicators.

9.3 Necessary functionality

If a medical device loses its function, there is no intrinsic risk.

9.4 Service

Service during the warranty period and after-sales service should be provided by the manufacturer or an authorised service centre. Especially during the warranty period, contact with the customer is ensured by the authorised dealer. Diagrams, parts lists, descriptions and calibration instructions or other information to assist the service personnel in repairing those parts of the medical device that the manufacturer determines are repairable by service personnel, shall be available from the manufacturer upon request.
The user is strictly forbidden to modify or make any changes to the medical device or the applicators!

9.5 Safety technical inspection

The Class IIa medical device is subject to regular functional and safety inspections in accordance with applicable legislation.
For a medical device used by a healthcare provider, the first safety and technical inspection is prescribed by the manufacturer after 2 years from the date of commissioning. Each subsequent inspection shall be prescribed after 12 months. After 8 years from commissioning, each subsequent inspection shall be prescribed after 6 months. For the medical device intended for individual use in home care, the first service check is prescribed by the manufacturer after 2 years from the date of commissioning of the medical device. Each subsequent inspection shall be prescribed after 24 months. In the event of non-compliance with this recommendation, the manufacturer may not be held liable for any damages (chapter **Safety instructions**).
A medical device equipped with a lithium battery is always subject to a safety inspection or service check every 12 months from the date of commissioning (chapter **Safety instructions**).

The safety and technical inspection or service inspection is carried out by the manufacturer or an organisation authorised by him. On the basis of the checks carried out, the lifetime of the medical device may be extended. The medical device may be used beyond its useful life under the manufacturer's predefined conditions.

10 OPERATING AND STORAGE ENVIRONMENT, DISTRIBUTOR, EMC

10.1 Operating environment

Operation of the medical device is permitted in the environment for which it is intended. It includes health care facilities, institutions, including households and premises which are directly connected to the public low-voltage network supplying buildings used for housing purposes under the following conditions:

- temperature +5°C to +35°C;
  Ambient temperature +5°C to +28°C with A6P2, AL21 applicator;
- relative humidity 15% to 93% without condensation;
- atmospheric pressure 700 to 1,060 hPa.

10.2 Storage environment

The environment in which the medical device is stored and transported must be dry, dust-free, free of mechanical shocks and chemical influence. Premises must meet following conditions:

- temperature -25°C to +70°C;
- relative humidity 15% to 93% without condensation;
- atmospheric pressure 700 to 1,060 hPa.

If the temperature falls below +5 °C or rises above +35 °C during storage or transport, the medical device must be allowed to reach the required operating temperature range before use.

10.3 Information for distributors

Comply with the applicable legislation concerning medical devices in the country where the Pulsed Magnetic Therapy Device BIOMAG® is used. This includes both the periodic functional and safety inspections to which this Class IIa medical device must be subjected, as well as other requirements set by local laws and regulations. Compliance with local laws and regulations helps to ensure the safety and effectiveness of the use of this medical device, while protecting the health and safety of patients.

10.4 Information on electromagnetic compatibility

The medical device must be used in the environment for which it is intended.

The medical device may be used in all institutions, including homes and those premises directly connected to the public low-voltage network that supplies buildings used for residential purposes. Included in the medical device: the device including a 1,5 or 3 m mains cable (type H05VVH2-F 2 x 0,75 or H03VVH2-F 2 x 0,75) and attachable applicators. Medical device may only be used with these accessories. If necessary, the above accessories can be ordered from the manufacturer or dealer.

⚠ **WARNING** – The use of accessories or cables other than those specified or provided by the medical device manufacturer could cause increased electromagnetic emissions or reduce the electromagnetic immunity of the medical device and cause improper operation.

⚠ **WARNING** – Portable RF communication equipment (including terminal equipment such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer.

Portable and mobile RF communication devices may affect the medical device. No wireless communication equipment should be operated within 3.3 m (3.3 ft). Otherwise, the functionality of the medical device may be impaired.

The medical device should not be used in close proximity to other devices or placed on top of other devices. Respect the information given in the instructions for use for these devices. If the medical device is used in close proximity to or positioned on other devices as necessary, the medical device should be monitored to verify normal operation in the configuration in which it will be used.

Electromagnetic emissions

The medical device is designed for use in electromagnetic environments in accordance with applicable standards.
The medical device is tested according to the valid IEC 60601-1-2 d. 3:2014 standard. It is classified in Group 1, Class B according to CISPR 11, according to the IEC 61000-3-2:2014 to Class A standard and complies with the IEC 61000-3-3:2013 standard.

The medical device is designated for use in the electromagnetic environment specified below. The user of the medical device should ensure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
High-frequency emission CISPR 11:2015+A1:2016	Group 1	The medical device uses high frequency energy only for its internal operation. Therefore, its high-frequency emissions are very low and are not likely to cause any interference with electronic equipment in its close vicinity.
High-frequency emission CISPR 11:2015+A1:2016	Class B	The medical device is suitable for use in all institutions, including homes and those premises that are directly connected to the public low-voltage network supplying buildings used for residential purposes.
Harmonic emissions IEC 61000-3-2:2014	Class A	
Voltage fluctuation / flicker emissions IEC 61000-3-3; 2013	Compliant	

Electromagnetic resistance

Phenomenon	**Basic standard for EMC or testing method**	**Testing levels of resistance**	
		Professional health care institutions environments	**Home health care environments**
ELECTROSTATIC DISCHARGE	IEC 61000-4-2:2008	±8 kV for contact discharge ±2 kV, ±4 kV, ±8 kV for air discharge	
RF EM fields propagated by emission	IEC 61000-4-3:2006 +A1:2007+A2:2010	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz
Close fields from RF wireless communication devices	IEC 61000-4-3:2006 +A1:2007+A2:2010	See chapter 8.10. of standard IEC 60601-1-1-2:2014	
Magnetic fields of STIPULATED power frequency	IEC 61000-4-8:2009	30 A/m 50 Hz or 60 Hz	

The medical device is designated for use in the electromagnetic environment specified below. The user of the medical device should ensure that it is used in such an environment.			
Phenomenon	**Basic standard for EMC or testing method**	**Testing levels of resistance**	
		Professional health care institutions environments	**Home health care environments**
Electrical fast transient / groups of pulses	IEC 61000-4-4:2012	±2kV Sequential rate 100 kHz	
Surges, integrated	IEC 61000-4-5: 2014+A1:2017	±0.5 kV, ±1kV	
Surges between the phase and earth	IEC 61000-4-5: 2014+A1:2017	±0.5 kV, ±1 kV, ±2 kV	
Conducted interferences, induced by RF fields	IEC 61000-4-6:2013	3 V 0.15 MHz-80 MHz 6 V in bands of ISM between 0.15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz to 80 MHz 6 V in bands of ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Short-term drops of voltage	IEC 61000-4-11: 2004+A1:2017	0% U_T; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	
		0% U_T; 1 cycle and 70% U_T; 25 / 30 cycles the only phase: at 0°	
Voltage interruption	IEC 61000-4-11: 2004+A1:2017	0% U_T; 250 / 300 cycles	

The electromagnetic environment – real relative humidity should be more than 50% and the conductive floor.
In this environment, air discharge should be no larger than 8 kV.
There could be a deterioration or loss of function of the medical device, which will not result in an unacceptable risk.

Recommended separation distances between portable and mobile radio frequency communication equipments and medical device

The medical device is intended for use in an electromagnetic environment in which radiated high frequency interference is controlled. The user of the medical device can help prevent electromagnetic interference by maintaining minimum distances between portable and mobile radio frequency communication devices (transmitters) and the medical device, as recommended below according to the maximum output power of the communication devices.

Stipulated maximum output power of the transmitter W	Separation distance depending on the transmitter frequency m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters whose determined maximum output power is not listed above, the recommended separation distance d in metres (m) can be estimated using the equation appropriate for the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) specified by the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These Instructions for Use may not apply to all situations.
Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

11 FAULTY CONDITIONS

In cases when the short-circuit (failure) condition at the device output or in the applicator occurs, the LED indicator on the device flashes.
* MD = medical device

PROBLEM	PROBABLE CAUSE	SOLUTION
POWER SUPPLY		
Device goes out, non-functioning MD * due to power fluctuations in the network	Loss and increase in mains voltage, the device goes out and does not start again	Have the wiring checked by an expert
Device goes out, non-functioning MD due to external conditions	Short circuit in the instrument due to a loose component on the circuit board	Send the device to a service centre for repair
Device goes out, non-functioning MD due to external conditions	Short circuit in the device due to the intrusion of unwanted substances	Send the device to a service centre for repair
Device goes out, non-functioning MD due to external conditions	MD exposed to an electrostatic discharge of more than 8 kV	Send the device to a service centre for repair
Device goes out, non-functioning MD due to leaking currents	Breach of the device and applicator packaging (cutting or forced entry)	Send MD to a service centre for repair
Non-functioning MD	Damage to the power cable	Send MD to a service centre for repair
HEAT		
Increased the temperature of the device	Temperature exceeds specified operating conditions	Move the device to another location, if malfunctioning, send it to a service centre for repair
Increased the temperature of applicators	Temperature exceeds specified operating conditions	Move the applicator to another location, if malfunctioning, send it to a service centre for repair
Hardened and cracked leather of the applicator	Decreases in ambient temperature or temperature fluctuations caused damage to the applicator	Send the applicator to a service centre to replace the cover
Non-functioning MD, damaged board circuit board	Lowering the ambient temperature caused damage to the MD by moisture condensation	Send the device to a service centre for repair
Non-functioning MD, the device reports with an audible error signal	MD may be affected by another heat source	Move MD to another location, if malfunctioning, send it to a service centre for repair
CHEMICAL INFLUENCE		
Damaged device cover	Unsuitable cleaning agent	Send the device to a service centre to replace the cover
Device goes out, non-functioning MD due to entry of an unwanted substance	Fluid intrusion into the circuit board	Send the device to a service centre for repair
Damaged applicator leatherette	Unsuitable cleaning agent	Send the applicator to a service centre to replace the cover
Hardened and cracked leatherette of the applicator	Unsuitable cleaning agent or other liquid	Send the applicator to a service centre to replace the cover

PROBLEM	PROBABLE CAUSE	SOLUTION
MECHANICAL ISSUE		
Non-functioning MD	Fall of the device or applicator	Send MD to a service centre for repair
MD is not working properly	The instrument display shows an output error and the LED flashes	Send the device to a service centre for repair
MD is not working properly	The device display shows the applicator disconnected accompanied by an audible signal	Send the applicator to a service centre for repair
MD is not working properly	The device display repeatedly shows an output error and applicator disconnected	Send MD to a service centre for repair
FUNCTIONALITY		
Non-functioning MD	Motherboard error	Send MD to a service centre for repair
Sudden interruption of MD operation, display goes off	Interruption of power supply	Restore power supply, revision of electrical distribution
Non-functioning MD, the device reports with an audible signal to indicate a malfunction	MD may be affected by another piece of equipment	Move MD to another location, if malfunctioning, send it to a service centre for repair
Non-functioning MD, malfunctioning MD	Software error	Send MD to a service centre for repair
Non-functioning MD, malfunctioning MD	SD card error	Send MD to a service centre for repair
Malfunctioning MD	Device control button stuck	Send the device to a service centre for repair
USER ERROR		
Non-functioning MD	Unauthorised components used	Send MD to a service centre for repair
Non-functioning MD	The instrument is used beyond its lifespan, timely safety and technical inspection was not carried out	Send MD to a service centre for repair
Non-functioning MD	The device is used in unsuitable conditions	Send MD to a service centre for repair
Non-functioning MD	Neglected maintenance of the external electrical source	Send MD to a service centre for repair
Malfunctioning MD	Improper handling of the battery	Send MD to a service centre for repair
Malfunctioning MD	Failure to ensure regular technical safety inspections or service checks	Send MD to a service centre for repair
Malfunctioning MD	Improper handling caused failure of internal components on the circuit board	Send MD to a service centre for repair
Non-functioning MD	Damaged and non-functioning display	Send MD to a service centre for repair

PROBLEM	PROBABLE CAUSE	SOLUTION
USER ERROR		
Non-functioning MD	Unprofessional interference	Send MD to a service centre for repair
Non-functioning MD	Motherboard failure	Send MD to a service centre for repair
Interruption of MD operation, device display goes out	Cause of failure due to the environment, does not meet the parameters specified in the instructions for use	Send MD to a service centre for repair
Non-functioning MD	The mains cable connector is not fully plugged into the power connector of the device	Insert the mains cable into the device
Non-functioning MD	The power cord is not properly plugged into the power outlet	Plug the mains cable into an electrical socket
Illegible device display	The device is exposed to strong sunlight	Move the MD away from the light source
Malfunctioning MD	No applicator is connected to the output of the device	Attach the applicator

Temporary loss of function or failure of a medical device due to electromagnetic interference does not cause an unacceptable risk.

- Interruption or termination of the application may occur earlier than the set program time
- spontaneous change of program may occur
- an error may occur - loss of function of the medical device

ⓘ **DEVICE RESTART**
If the system does not respond to controls or if its function is unreliable (especially the display), restart the system.
The opening for restart is placed in the bottom part of the back side of the device; use, e.g., a paper clip.

For other problems not described, please contact your distributor.
They will arrange for professional service from the manufacturer.

12 WARRANTY

The medical device is under warranty for 24 months from the date of sale. The warranty covers the repair and replacement of parts that have become damaged due to the use of defective materials, defective design or faulty manufacturing process.

The warranty does not cover wear and tear caused by normal use of the medical device, for example, parts with a limited service life (battery, etc.).

The warranty is void if the medical device has been tampered with, forcibly damaged, handled improperly in violation of the instructions or damaged due to force majeure.

In the event of warranty repair, the proof of purchase or the seller's warranty certificate with the same date as the date of receipt of the goods must be presented. In addition, the entire medical device must be presented, i.e. the device including the applicators.

The warranty does not cover any surface modifications that do not affect the function of the medical device.

The manufacturer is not liable for improper use of the medical device.

13 DISPOSAL

When disposing of the medical device, the disposal of hazardous waste (e-waste) must be carried out in accordance with the relevant legislation of the country concerned. Disposal shall also be provided by the dealer or the manufacturer.

14 ADVICE AND TIPS ⓘ

- Follow the instructions on the display to set other device properties. Double-click the button (the application is not running) and then click to get to **Next menu**. Use to select an item and confirm by using to show a menu.
- While the application is running, buttons show **Instructions and recommendations**. Instructions can be viewed when the application is not running by double-clicking and using buttons to select **About the program**.
- To change the device's language, press the top, bottom and left buttons simultaneously as soon as the device is switched on. Hold the buttons for 3 s. When the buttons are released, the start screen appears, followed by the language selection.
- Time setting monitors real-time battery. Follow the instructions on the display to configure the settings.
- Reminder setting alerts about the next therapy. The display shows an alarm clock and is accompanied by a beeping sound. Three reminders can be selected.
- Sound setting customizes the sound signalling (volume off, medium volume, maximum volume).
- Functionality check of the medical device is performed by selecting Personal memory. The test runs for 25 min.
- **PIN1** contains a menu for selecting the language, keyboard lock, number of prepaid applications, accumulator and application history.
- If the device contains an **accumulator** and the accumulator is charged (charging takes place whenever the device is connected to the mains), we can carry out applications in the same way as when the device is connected to the mains.
- Due to the lower power of the device when running on accumulator power the application time is automatically extended by 30% for preset programmes. E.g. 20 min mains operation = 26 min battery operation.
- 3-pin and 2-pin connectors are correctly inserted when the side of the **connector with the logo** is facing up.
- Simultaneous clicking of prompts a code entry screen to appear (when purchasing additional device features).
- Simultaneous clicking of prompts a screen with information useful for contacting service centres.

15 CONTACT INFORMATION

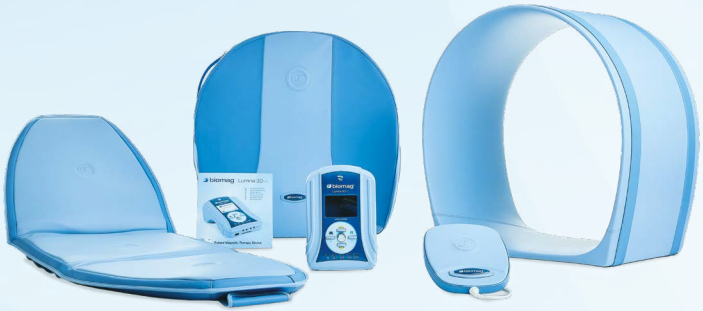
Follow the latest and other important information and instructions for users on https://www.biomag-medical.com/info/. You did not find the certificate or declaration of conformity of your product? Ask the manufacturer for the documents in electronic form.

Contact your distributor (manufacturer's representative) if you need assistance with setup, use and maintenance of the medical device or incidents. If you do not have a contact to your distributor, please contact the manufacturer directly.

Manufacturer
Karel Hrnčíř – BIOMAG
Chomutice 81
507 53 Chomutice
Czech Republic

Place of business and delivery address
Karel Hrnčíř – BIOMAG
Průmyslová 1270
506 01 Jičín
Czech Republic
biomag@biomag.cz
www.biomag.cz

biomag® e-series



BIOMAG® Lumina 3D-e Clinic

BIOMAG® Lumina 3D-e Easy

Information regarding any current offers in a given region is available from the producer, authorised retailers and on https://www.biomag-medical.com/.

Informace o aktuální nabídce v daném regionu jsou k dispozici u výrobce, autorizovaných distributorů a na webových stránkách https://www.biomag.cz/.

biomag® Lumina 3D-e

en Aesthetic design and schematics of devices and applicators are registered with the Industrial Property Office of the Czech Republic and other international institutions.
Modification of the appearance not affecting the functions is reserved.
The colour shown in the illustrations may vary from your particular model.

cs Vzhled a technická provedení přístrojů a aplikátorů jsou registrovány u Úřadu průmyslového vlastnictví České republiky a u dalších mezinárodních institucí.
Změna vzhledu neovlivňující funkci vyhrazena.
Barevné vyobrazení nemusí odpovídat barvě dodávaných výrobků.

Karel Hrnčíř – BIOMAG
Chomutice 81
507 53 CHOMUTICE
CZECHIA – EU

www.biomag.cz

MEDICAL DEVICE CLASS IIa

CE 2265

3D Patented Technology