# Jbiomag<sup>®</sup> Lumina 3D-e VET

en Instructions for Use





Pulsed Magnetic Therapy Veterinary Device



Serial number / Equipment / Mode Serial number / Equipment / Mode



# veterinary technical device

# Pulsed Magnetic Therapy Device BIOMAG®



# Lumina 3D-e VET with applicators

Thank you for purchasing a BIOMAG® veterinary technical device. These products have been manufactured with the utmost care and emphasis on quality conforming to normative requirements.

Please study the Instructions for Use thoroughly prior to operation and adhere to them accordingly!

### 1 SAFETY INSTRUCTIONS AND WARNINGS

MARNING - The manı	ufacturer shall not be held liable fo	r improper use of the veterinary	device!
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- MARNING Adhere to the intended purpose, indications, contraindications and other information in these Instructions for Use.
- / WARNING Modification of this veterinary device is strictly prohibited.
- MARNING The device must be kept out of reach of animals to prevent damage to the power cable by chewing, etc.
- MARNING The veterinary device may cause radio interference or disrupt the operation of nearby devices.

Measures such as reorienting or relocating the veterinary device may be required to mitigate such effects.

The veterinary device may affect nearby devices, such as wristwatches, magnetic media, credit cards, etc., during operation. A distance of at least 1 m is considered safe.

MARNING – Failure to have the device inspected at the prescribed intervals by the customer results in forfeiture of warranty and loss of the manufacturer's responsibility for continued operation.

- Before first use, carefully read the veterinary device Instructions for Use.
- The veterinary device must not be used for any purpose other than that described in these instructions.
  The manufacturer shall not bear any responsibility for possible damage. The risk is borne by the user.
- The veterinary device is exclusively intended for use on animals.
- The veterinary device is solely intended for intermittent operation.
- Only persons meeting the requirements specified in the Operator profile, and complying with this manual, may handle or operate the veterinary device.
- In the event of a missing product label, contact the distributor or manufacturer.
- Only applicators approved by the manufacturer may be connected to the device's connectors.
- Protect the device from impact and damage, paying particular attention to the connectors and applicators.
- The application pad is intended for use on intact skin, but in the case of bite wounds, lacerations, pressure ulcers, etc., use a disposable or other hygienic barrier.
- The device must not be immersed in water, washed or used in wet and humid environments (e.g. near water bowls). Avoid exposing the veterinary device to moisture.
- When used with multiple animals, applicators must be disinfected before each subsequent application.
- Do not place the device near sources of heat.
- To ensure optimal display readability, do not place the device near a light source.
- Do not use the veterinary device if it is damaged.
- Any veterinary device tampering is prohibited.
- The veterinary device must be connected to a suitable electrical supply with undamaged power cables.
   If in doubt, the check should be performed by a safety inspector.
- Do not use the veterinary device if the applicator cables are damaged.
  - Have a qualified service technician inspect the device.
- Prevent animals from damaging the veterinary device power cables (e.g. by biting).
- In the event of missing or damaged parts of the Instructions for Use, contact the distributor or manufacturer.
- If there is any uncertainty regarding the instructions, please contact the manufacturer's customer support line.

# 2 INTRODUCTION, CONTENTS OF THE INSTRUCTIONS FOR USE

The BIOMAG® Lumina 3D-e VET Pulsed Magnetic Therapy Device is an active veterinary technical device (hereinafter referred to as the **veterinary device**) comprising the main unit and connectible applicators. It is intended for the application of low-frequency pulsed magnetic therapy.

The veterinary device must strictly be used in accordance with its intended purpose. The manufacturer is not responsible for improper use, which includes its use against the directions and recommendations given in the Instructions for Use.

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# 3 INTENDED USE, INDICATIONS, CONTRAINDICATIONS, SYMBOLS

### 3.1 Intended purpose

The veterinary device is intended for adjunctive symptomatic therapy to aid in the alleviation of pain, swelling, spasms and detoxification, to improve blood circulation (vasodilation) and to accelerate healing.

It is used in a variety of musculoskeletal conditions, including degenerative disorders, post-traumatic injuries, post-operative recovery and similar clinical scenarios.





The device is intended for external use to maintain animal well-being, alleviate pain, support metabolism, and enhance the immune system and regenerative capacity of the body. It is suitable as part of a physiotherapy programe or as a complementary element of treatment. The veterinary device is exclusively intended for use on intact animal skin. In the presence of bite wounds, cuts, pressure ulcers or similar lesions, we recommend using a disposable or other hygienic barrier.

When using the veterinary device, it is essential to adhere to the **Principles of safe Operation** alongside the listed **Contraindications** / **Indications** and use it in compliance with the specified environmental requirements.

Basic safety information is also shown on the device display.

The use of the veterinary device is described in the final section of the Instructions for Use.



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 🖁

The range of veterinary indications is as broad as in human medicine, encompassing post-operative states, spinal disorders, joint conditions, arthrosis, dermatological conditions, fractures and post-exertion recovery. The veterinary device is suitable for companion animals, livestock and working animals (e.g. horses, dogs, cats, rabbits, etc.). It is also utilised in sports to enhance performance and to aid in the recovery of working animals (e.g. draught horses, assistance dogs, police dogs), as well as to promote relaxation and calm in healthy animals. The technology allows for deep tissue and lymphatic massage and provides additional therapeutic effects related to enhanced metabolism and circulation via increased oxygen supply.

- Pain relief pain-relieving effect
- Tissue regeneration support (stimulation) healing effect
- Oedema anti-swelling effect
- Spasm myorelaxing effect
- Circulatory disorders vasodilating effect
- Metabolic disturbances detoxifying effect

Given the minimal contraindications in animals (e.g. acute bleeding) and the substantial health benefits supported by years of practical use, the veterinary device is appropriate for widespread application in both clinical and field-based veterinary care.

### 3.3 Contraindications A

#### The veterinary device must not be used under the following contraindications:

- Pregnancy or relative pregnancy, subject to consultation with a veterinary surgeon
- Pacemaker implanted cardiac pacemaker
- Bleeding conditions
- Neoplasms possible exception subject to veterinary consultation
- Serious septic states
- Febrile conditions

- Mycosis at the site of application
  - possible exception based on consultation to veterinary consultation
- Paroxysmal nerve diseases
- Hyperthyroidism
- Pain of unknown origin
- Unspecified diagnosis
- Conflict with the professionally determined treatment procedure

#### Side effects of the veterinary device:

There are no documented serious or persistent adverse effects. In rare cases (approx. 1% of applications), mild side effects related to the spa effect may occur, such as:

- Temporary hypersensitivity or pain at the application site
- Mild headache
- Reduced blood pressure and dizziness

#### Preventive measures associated with the veterinary device:

- The veterinary device may either be used independently or in conjunction with other veterinary procedures or devices.
- Animals suffering from low blood pressure (or prone to it) or high blood pressure must particularly be observed during application.
- Individual effects of magnetic therapy must be assessed based on the particular condition and reactions of individual animals.
- In animals exhibiting increased sensitivity, it is advisable to begin therapy with reduced intensity or duration to preserve
  the benefits of magnetotherapy.
- In case of unexpected reactions, cease the application immediately! Continued application may resume on the recommendation
  of a veterinary surgeon procedural plan.
- As like with other devices, the veterinary device may only be used to positively influence health conditions
  that have been diagnosed in the animal by a qualified veterinary surgeon, and for which Contraindications
  have been duly ruled out in compliance with the Patient profile.

#### Relative contraindications for operating the veterinary device:

- Pregnancy
- Pacemaker (electric pacemaker)
- Bleeding conditions
- Menstrual bleeding
- Neoplasms
- Serious septic states
- Febrile conditions
- Active tuberculosis
- Mycosis at the application site

- Paroxysmal nerve diseases
- Hyperthyroidism
- Adrenal hyperfunction
- Myasthenia gravis
- Hypothalamus and pituitary gland diseases
- Psychosis
- Pain of unknown origin
- Unspecified diagnosis
- Conflict with the professionally determined treatment procedure

#### Failure to observe contraindications may result in harm to both the animal and the operator.

If a layperson is dissatisfied with the results of therapy, a veterinary consultation is required, and the instructions in the **Principles of safe operation** section must be followed.

In case of uncertainty, the operator (whether a veterinarian or layperson) may consult the manufacturer to confirm the suitability of the software and accessories.

Overdose through low-frequency magnetic field therapy is not possible.

# 3.4 List of abbreviations and symbols used

List of	symbols used on the labe			List of a	abbreviations	
<b>③</b>	Proceed according to the Instructions for Use	~	Alternating current (AC)	PEMF	Pulsed electromagnetic field (Pulsed ElectroMagnetic Field)	
	Device with protection Class II		Direct current (DC)	LPMF	Low-frequency pulsed magnetic field	
*	BF type applied part	$\triangle$	Caution, important warning	МІМІ	Maximum intensity of magnetic induction	
$\bigcirc$	Input for applicator	紫	Protect from heat	mT	Millitesla = unit of magnetic induction	
(*)	Power supply symbol	Ť	Keep away from moisture	f	Frequency = pulse rate	
	Electric equipment intended for indoor use	$\mathcal{X}$	Temperature limitation	Hz	Hertz = frequency unit	
X	Environmentally friendly disposal of the device	<b>(2</b> )	Humidity limitation	min	Minute = time unit	
4	Fragile, handle with care	$\Theta$	Atmospheric pressure limitation	s	Second = time unit	
<b></b>	Manufacturer	<u>~</u>	Date of manufacture	ЕМС	Electromagnetic compatibility	
	Distributor	SN	Serial number	<b>Ø</b>	Applicator polarity symbol	
\$	Veterinary technical device (for animal use only)	REF	Catalogue name of the product	*	Note on explanatory information	
C€	A product label by which the manufacturer indicates that the veterinary product is controlled by an authorised person and complies with the applicable requirements for placing on the market in the European Economic Area					

#### **Explanations**

Veterinary device = device with applicators

Device = electronic control unit

Applicator = attachable part



List of symbols	s used on the veterinary device and in the manual		
\$	Pulsed Magnetic Therapy Device BIOMAG®	9	Manufacturer's logo: BIOMAG®
	List of ALL PROGRAMS	C	Time
	MY PROGRAMS		Reminder setting
	Confirmation button		Sound/volume down
	Navigation within the menu		Output settings
	Next menu	E	EXTRA mode extension
9	Run repeat program	(T) (I)	Functional button for time/intensity
i	Program information		PIN 1 / PIN 2
	Continue with program selection	<b>3</b> "	Language selection
	Copy to MY PROGRAMS	00	Keyboard lock
俞	Remove from MY PROGRAMS	\$	Number of pre-paid applications
	Display the MENU	charged discharged	Accumulator
5	Back	CAUTION Phase balloy 26,63 Wh	Battery-powered device
	Display operation information	30	Application history
	Display basic effects	00	Program type
	Contraindications	. &	Indications
<b>ं</b>	System settings	@ O	Synchronous program (non-3D) Rotational program (3D)
<b>(x)</b>	Confirmation or refusal of setting selection	(3D)	Sequential switching Simultaneous switching
$\Rightarrow$	Favourite programs		3-connector / 1-connector
8	Personal memory	$\sim$	Applicator shaping into various positions
\$6	Transfer of programs		Do not lift or carry by the display

### **4 BASIC INFORMATION**

## 4.1 Principle of biological action



Magnetic therapy uses the effects of an artificial magnetic field with precisely defined parameters on the organism. It is a physical therapy generating a large-area low-frequency pulse magnetic field.

As 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 effect analgesic, reduces pain
- Healing promoting regeneration, anti-inflammatory and anti-rheumatic effects
- Anti-swelling reduces swelling (oedema)
- Myorelaxing relaxes muscles
- Vasodilating improves microcirculation in particular
- Detoxifying accelerates the elimination of toxins and metabolites

The low-frequency pulsed magnetic field (LPMF) acts on the cell membrane permeability, i.e., 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 the 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 mutual 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

PEMF therapy, via magnetic induction, induces 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 muscle relaxant or muscle tone (pressure) relief mechanisms 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. Increased lactate dehydrogenase activity in exposed muscles was proven after PEMF application. 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, which means the ratio change between cyclic adenosine monophosphate and cyclic guanosine monophosphate. When using the regenerative effect on bones, the application leads to the increase of osteoclasts and the subsequent start of the bone tissue regeneration process. 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. Healing of damaged peripheral nerves is considerably accelerated, and the regeneration of neurofibrils (fibres in neurons) and the growth of central axons (fibres emanating from cells) is also accelerated.

#### Anti-swelling effect

Swelling is caused by the disorder of blood circulation at the blood capillary level 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 potential increased permeability of capillary walls. Improved perfusion, i.e., better tissue flow, plays an important role in the anti-swelling 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

PEMF accelerates the flushing of acidic metabolites that cause painful irritation in muscles and sites of chronic inflammation. The flushing of these metabolites is given by improved perfusion (flow through tissues) and by the increased activity of lactate dehydrogenase, which is required for 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.

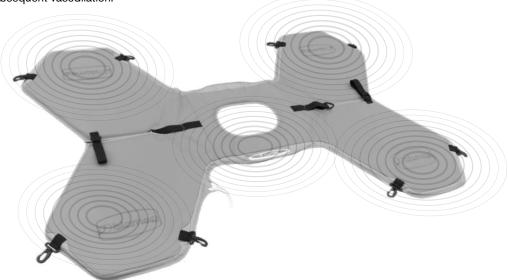
#### Vasodilating effect

With appropriately set parameters, PEMF counteracts the aggregation of red blood cells (rouleaux formation), which carry oxygen in blood. The final outcome is re-dispersion of red blood cells and an increased the surface area available for oxygen binding. Blood that 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<sup>2+</sup> ions, which leads to relaxation of the blood vessel muscles (pre-capillary sphincters in particular) and to subsequent vasodilation.

LPMF application affects the polarisation of red blood cells with a 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 (vasodilation and microcirculation improvement), thus also in the better supply of tissue with oxygenated blood and nutrients. Improved microcirculation additionally facilitates more efficient removal of toxins and metabolic waste from tissue. PEMF significantly increases the partial pressure of oxygen and enhances red blood cell elasticity. More elastic blood cells can then better pass through the blood circulation. In addition, with long-term applications of this method, neovascularisation resulting in faster formation of new blood vessels occurs. At the same time, the magnetic field reduces the risk of blood clots (thrombi).

#### **Detoxifying effect**

PEMF passes evenly through animal tissue and can also act, as one of the few methods, 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 of electric currents, the surface potentials of cells change. Every detoxifying process is based on a better supply of nutrients and better removal of metabolic waste products from tissue.



# 4.2 Patient, operator and trainer profile

#### Patient profile

Who is the veterinary device intended for?

• The device is solely intended for animals.

Applicable to companion, farm and working mammals (e.g. horse, dog, cat, rabbit).



The veterinary device may only be used if contraindications have been professionally ruled out.

#### Operator profile

Who may operate the veterinary device?

- A trained veterinary surgeon or assistant (technician).
   Training is performed by a trained representative of the manufacturer or distributor.
- An adult person trained in operating the veterinary device, who is familiar with the instructions for use and complies with them, including the contraindications for both animal and operator.



Training is performed by a trained representative of the manufacturer or distributor.

Children and other unauthorised or untrained persons must not handle the veterinary device.

Familiarisation with the characteristics of the veterinary device, its conditions of use and its operator profile is confirmed by the consent of the trainee, in paper or electronic form, or in any other appropriate form allowing for traceability.

#### Profile of trained instructor

Who is authorised to instruct and train the user of the veterinary device?

• An authorised employee or representative of the manufacturer (e.g. distributor).

A record of the training may form part of the purchase agreement, and for persons trained subsequently, a separate record must be made.

#### **↑** CAUTION

The veterinary device must not be used for any other purpose, by other persons or in any other manner than specified in this section and in these instructions.

The manufacturer shall not bear any responsibility for possible damage. The risk is borne by the user.

Any serious adverse event must be reported to the manufacturer and to the competent authority of the relevant member state.

# 5 TECHNICAL SPECIFICATIONS: VETERINARY DEVICE, DEVICE AND APPLICATORS

# 5.1 Technical description of the veterinary device

The veterinary device is solely intended for intermittent operation. It is designed for applications of pulsed magnetic fields in the low-frequency range (4-81 Hz) and is a new model developed from a previous series.

The veterinary device comprises the control unit and connectible applicators. The device is a control unit from which electric pulses of specified parameters are sent to the applicators by way of cables that are connected to the device outputs. The applicator is the attachment part of the veterinary device. Detailed usage instructions are provided in the final section of the Instructions for Use.

The veterinary device's lifespan is dependent upon regular execution of safety and technical inspections.

# 5.2 Technical description, parameters and device software

#### 5.2a) Technical description of the device

The electronic control unit is housed in a plastic casing with an information display on the upper surface. At the bottom it has an input for the power connector and 4 applicator outputs.

On the back of the device there is a label with identification information about the device and the manufacturer. The device itself is provided with control software that has 6 programs with or without the 3D function. The application terminates after the selected program ends. The software version can be shown on the display by simultaneously pushing the button. All indicator and control elements are located on the front panel, as detailed in the **Device description** section. The use of the device is described in the final section of the Instructions for Use.

The control unit must be connected to an appropriate electrical supply. It may be equipped with an internal battery, which serves to complete a therapy session in the event of a power failure or when the mains electricity is temporarily unavailable (power LED off). Upon restoration of power, the battery is deactivated, the device switches back to mains operation (power LED on) and the battery recharges automatically (power LED pulsing).

The technical design is derived from the BIOMAG® Pulsed Magnetic Therapy Device medical device. The veterinary device is equipped with **3D technology** (3P).

In marketing materials, 3D technology refers to the controlled sequential activation of individual applicator outputs on the device, ensuring that at any given moment the device's output is directed exclusively to a single channel.

The power is thereby gradually transferred to the applicator during the application and each part of the applicator is switched on separately. This cycle is repeated continuously, so each application is maximally effective and optimally efficient.

The emission of the magnetic field from each separately activated segment occurs during the pulse without interference and always at full intensity. The operation of adjacent or opposite segments is not affected. It should be noted 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.

To take advantage of this feature of the veterinary device, special applicators that are designed to allow sequential activation of their respective segments were developed. These applicators connect to the device using a specialised 3-connector system ...

As each output device operates independently at full power, even the connection of multiple standard applicators provides more effective output than in veterinary devices lacking this technology. The standard configuration of the veterinary device ensures the sequential and regular alternation of pulses across the outputs.

#### Lumina 3D-e VET Device with EASY mode, without battery **biomag** Lumina 3D-e 6x 3D programs, 4 outputs, basic intensity and time settings. program repetition, mains flex cable, fixation strap, tester, manual Lumina 3D-e VET EB Device with CLINIC mode, without battery **biomag** 6x 3D programs, 4 outputs, adjustable intensity and time, program repetition, independent launch of 2 programs, Lumina 3D-e VET CB mains flex cable, fixation strap, tester, manual Device with EASY mode, with battery **biomag** easy vet 6x 3D programs, 4 outputs, basic intensity and time settings, program repetition, Lumina 3D-e VET EA mains flex cable, fixation strap, tester, manual Device with CLINIC mode, with battery **biomag** 6x 3D programs, 4 outputs, adjustable intensity and time, program repetition, independent launch of 2 programs, Lumina 3D-e VET CA mains flex cable, fixation strap, tester, manual

# 5.2b) Technical parameters of the device

Description		Values	
Software version		ay on the screen	
	www.biomag-medical.com/info/		
Power supply voltage	~100-240 V / 50/60 Hz		
Device input power		60 VA	
Voltage of integrated power source		24 V	
Battery input voltage		7.4 V	
Device insulation class		II.	
Power cord	H05VV	/H2-F 2x 0.75 mm	
Applied part type		Type BF	
Environment		Normal	
Protection grade		IP 30*	
MIMI - Maximum intensity of magnetic induction	1	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 (modif	fied according to frequency)	
Pulse rise time (depending on program selection and applicator induction)		0.4-2.5 ms	
Pulse width	1.1	1-11.1 ms****	
Pulse descending edge depending on the applicator induction		0.5-3.5 ms	
Application time	EASY 1 time range 20 min	CLINIC 9 time ranges 5, 10, 15, 20, 25, 30, 45, 60, 90 min	
End of application	Audio ir	ndication + display	
Warning messages	Audio ir	ndication + display	
EMC – electromagnetic compatibility	CSN EN 60601	-1-2 ed. 3:2016+A1:2021	
Ambient temperature around the device	+5°C - +35°C		
Device dimensions	240 x 162 x 75 mm		
Display	3.5' TFT		
Device weight	0.845 kg		
Type of battery (if included in the system)	Lithium battery LIP7456	690P/2S (3550 mAh / 26.63 Wh)	
Battery weight		165 g	
Operation time when battery-powered (with 4 outputs occupied)	ар	prox. 160 min	
Full battery charging time		7 hours	

#### 5.2c) Device software

Programs and their parameters							
Program No.	Name	Frequen	cy / sequer	ice time	Frequency modulation	Intensity	Application time
Program	PAIN-RELIEVING EFFECT	5-12 Hz	15 Hz	25 Hz		EASY: without	EASY: 20 min
No. 1	Pain-relief support	2 min 30 s		15 s	Gradually increasing	regulation CLINIC: 1-100%	CLINIC: 20 min (5-90 min)
	HEALING EFFECT					EASY: without	
Program No. 2	Supports healing and regeneration, anti-inflammatory and anti-rheumatic effects	50-8 2 min		12 Hz 30 s	Gradually increasing / post-pulse	regulation CLINIC: 1-100%	EASY: 20 min CLINIC: 20 min (5-90 min)
Program	ANTI-SWELLING EFFECT	12-1	ō Hz	50-75 Hz		EASY: without	EASY: 20 min
No. 3	Promoting the reduction of swellings	2 min 30 s		30 s	Gradually increasing	regulation CLINIC: 1-100%	CLINIC: 20 min (5-90 min)
Program	MYORELAXING EFFECT	10-12 Hz 3 min				EASY: without	EASY: 20 min
No. 4	Muscle spasm and oedema relief				Gradually increasing	regulation CLINIC: 1-100%	CLINIC: 20 min (5-90 min)
Program	VASODILATING EFFECT	12	Hz	50-80 Hz	Post-pulse /	EASY: without	EASY: 20 min
No. 5	Support of vasodilation and circulation	1 m	1 min		Gradually increasing	regulation CLINIC: 1-100%	CLINIC: 20 min (5-90 min)
Program	DETOXIFYING EFFECT	4-12	Hz	50-81 Hz		EASY: without	EASY: 20 min CLINIC: 20 min (5-90 min)
No. 6	Support of metabolism and detoxification	2 m	4-12 Hz 2 min	1 min	Gradually increasing	regulation CLINIC: 1-100%	

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

#### The device has two modes: EASY and CLINIC

The BIOMAG® Lumina 3D-e VET with applicators using EASY software \$\bigset\$ is designed for ease of use and intended for animals in home care. However, it may also be used by veterinary professionals.

The BIOMAG® Lumina 3D-e VET with applicators using CLINIC software  $\[ \]$  is tailored for veterinary professionals due to its customisable settings, but can also be used in home care where the operator may use the customisation.

#### **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 options
   This function automatically saves the most frequently used program.
   It also allows for the storage of up to 8 additional programs with user-defined names.
- 1 most frequently used + 200 options
   This function automatically saves the most frequently used program.
   It also allows for the storage of up to 200 additional programs with user-defined names.
- \*\*\*\* 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 area. Some applicators can be fixed to the affected area of the body with an elastic strap.

Applicators are the attachment part of the veterinary device, comprising air-core coils wound from enamelled copper or other wire in a specialised configuration. Each applicator has the north pole (indicated on the product label) on one side and south pole on the opposite side During operation, a faint clicking sound may be heard, synchronised with the pulsing rhythm. The applicator surface is made of high-quality artificial leather. All applicators are provided with plastic clips with labels bearing the manufacturer's logo. Applicators connect to the device via 1-connectors or 3-connectors depending on the model.

#### Flat applicators

Large-sized applicators.

Suitable for broad-area magnetic field exposure with a design allowing for bending of individual segments. Depending on the selected size and the ability to shape the applicator, they are suitable for use on larger body areas, or even the entire body of the animal.

#### Local applicators

Smaller-sized applicators.

Suitable for targeted and intensive application of the magnetic field. Used for the treatment of specific points or smaller body areas.

#### **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 product label by a circle containing the letter **(1)**.

# 5.3a) Common parameters and instructions for all applicators

- 1 | Output cable CYLY 4x0.50 mm
- 2 | Cable ending: connector JACK 3.5 mm (1x or 3x depending on the applicator type)
- 3 | Attachment part type BF
- 4 | Operating temperature (applicator warming): max. 41°C
- 5 | Operating temperature (around the applicator) +5°C +35°C with the exception for AV6P2: +5°C +28°C
- 6 During therapy, the animal should remain in a resting position under supervision of the operator
- 7 | Recommended method of application is through a disposable or other hygienic barrier
- 8 | Most flat applicators allow for fixation using securing aids

Applicator descriptions are provided on the following pages. Instructions for the use of individual applicators are provided in the final section of the Instructions for Use.

#### Important warning

Only connect or disconnect the applicator when no program is running on the device.

The use of applicators other than the original applicators, or other accessories approved by the manufacturer, is prohibited for the veterinary product.

When operating the device on battery power, the intensity of the magnetic field in the applicators is reduced.

For the A6P2 applicator, do not switch the direction of the magnetic field during application and adhere to the pre-set usage time (20 minutes of application and 40 minutes to reach the operating temperature).

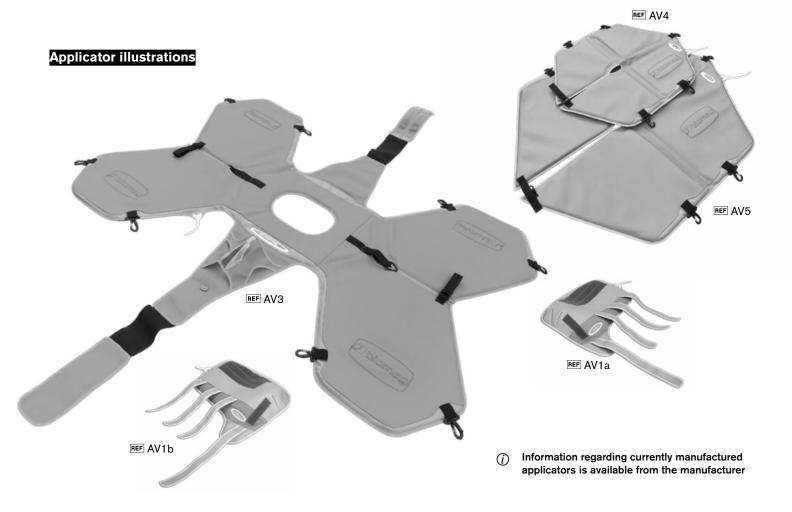
#### Additional accessories

You can find all additional accessories (cases, straps, strips, bags, etc.) at your distributor or manufacturer on request. Specifications available at: https://www.biomag-medical.com/info/.

### 5.3b) Technical data of veterinary applicators

MIMI 5.0 mT; connector 3x JACK 3.5 mm; length 1,600 mm; width 1,160 mm; height 20 mm; weight 4.30 kg

AV1a	Local applicator for right-sided limbs with fixation option	AV4	Four-section flat applicator with universal shaping capability
	MIMI 7.0 mT; connector 1x JACK 3.5 mm; length 440 mm; width 420 mm; height 30 mm; weight 0.90 kg		MIMI 3.0 mT; connector 1x JACK 3.5 mm; length 740 mm; width 650 mm; height 20 mm; weight 1.30 kg
AV1b ĕ ↑	Local applicator for left-sided limbs with fixation option	AV5	Four-section flat applicator with universal shaping capability
	MIMI 7.0 mT; connector 1x JACK 3.5 mm; length 440 mm; width 420 mm; height 30 mm; weight 0.90 kg		MIMI 3.5 mT; connector 3x jack 3.5 mm; length 1,110 mm; width 960 mm; height 20 mm; weight 2.70 kg
AV3	Multisection flat applicator for practical use		mail 555 mm, noight 25 mm, woight 2.70 kg



### Continued in section 5.3b

AV2	Two-section flat applicator with fixation option	AV3b ĕ ≬	Two-section flat applicator with fixation option
	MIMI 3.0 mT; connector 1x JACK 3.5 mm; length 530 mm; width 820 mm; height 20 mm; weight 1.10 kg		MIMI 2.0 mT; connector 1x JACK 3.5 mm; length 960 mm; width 1,550 mm; height 20 mm; weight 2.50 kg
AV3a ङ∥	Two-section flat applicator with fixation option	AV6P2	Local applicator with magnetic field switching and directional capability
	MIMI 2.0 mT; connector 1x JACK 3.5 mm; length 800 mm; width 1,550 mm; height 20 mm; weight 2.10 kg	·	version <b>SPOT</b> = focused magnetic field version <b>WIDE</b> = wide magnetic field
			MIMI 35.0 mT – SPOT / MIMI 20.0 mT – WIDE; connector 1x JACK 3.5 mm; length 170 mm; width 130 mm; height 25 mm; weight 0.60 kg

### Applicator illustrations



# **6 DEVICE DESCRIPTION AND OPERATION**

# 6.1 Device description

Diomagi

Lumina 3D-8

Lumina 3D-8

Reasyldinic vel 11

- 7 Green indicator LED
  - Mains connection (lit continuously)
  - Battery charging (pulses)

#### Note:

Do not handle or transport the device by holding the display

Connector for mains

cable connection (\*)

- If the device is equipped with the extended EXTRA menu **E**, it can only be operated before the program is started using the and **T** buttons. **()**.
- Opening for attachment of the fixation strap at the top and bottom.
- At the back opening for the system restart button.

- 1a Graphical information display
- 1b Device mode (clinic/easy)
  - Display shown upon device start-up
- 2 UP button
- 3 Button for accessing the list of all installed programs
  - TIME
  - Time setting for the EXTRA offer
- 4 START/STOP confirmation button
- 5 Button for accessing the list of MY PROGRAMS
  - (I) INTENSITY
  - Adjustment of magnetic field intensity for EXTRA settings
- 6 DOWN button ▼
- 8-11 Blue indicator LEDs
  - Applicator connection (lit continuously)
  - Applicator failure (blinking or not emitting light)
- 13-16 Outputs for connecting applicators
  - (<u>)</u> 1-(<u>)</u> 4
  - Power cord
    - H05VVH2-F 2x 0.75 mm
    - Disconnecting from the mains is performed by unplugging the mains cable

# 6.2 Operation – activating the veterinary device

#### 1 | Using the power cord, connect the device to the mains

The veterinary device gives an acoustic signal accompanied by the start-up screen on the display (information on the mode). After the start-up screen, the most recently used program will be displayed.

(i) Before first use, you will be prompted to select the language.

#### 2 | Connect 1 to 4 applicators

The applicator outputs 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 UP and DOWN buttons to scroll \_\_\_\_ \to to the desired program.

#### 4 | Starting the program

Start the selected program by pressing the central \_\_\_\_ button. The application is running.

#### 5 | Switching off the device

To cancel an ongoing program (in case the application has not finished), press the centre confirmation button. Hold the button down for 6 beeps and use the button to select YES to confirm the device switch off. If left idle while running on battery power, the device will automatically shut off after 6 minutes.

#### PROGRAM SETTINGS

**Description>** Selection of program and its available settings and launch options.

Procedure > In EASY mode, the program is started using the confirmation button without further adjustment. In CLINIC mode, upon program confirmation with the central button, a menu appears with the Run pre-set items or Set options. To start the program without any modifications, confirm Run pre-set items with the central button. To change the time or reduce the intensity of the program, select the Set option and confirm by pressing the button.

(i) Adjustments to the time range (5-90 minutes) and intensity (1-100%) are made using the buttons, and the selected value is confirmed by pressing the button. (i) By pressing the buttons simultaneously, the 3D program with time-expanded 3D extended rotation can be launched (if available in the configuration).

- You can interrupt the program at any time by pressing the button.
- (i) Press the (iii) button again to continue the application.
- (i) The program will stop after timeout is shown on the display.

#### MY PROGRAMS

Description > The user may freely name the program, e.g., by patient name or number. The saved program appears in the MY PROGRAMS section. To view the created programs, press the → button. Use the → buttons to scroll through the available programs. Procedure > Double-clicking the → button opens Program details, where the → button is used to select the option Copy to MY PROGRAMS → Upon confirmation, a menu will appear to add the program.

(i) Maximum number of saved items in the MY PROGRAMS list: EASY mode 8 / CLINIC mode 200.

#### Add program without renaming>

If Copy without renaming is selected using the buttons, confirm by pressing the button. The program will be saved in the MY PROGRAMS list under its original name.

(i) To quickly copy a program into MY PROGRAMS, use a triple-click of the 💹 button.

#### Add program with renaming >

If Rename and copy is selected, the confirmation button opens a touchscreen keyboard, allowing any text to be entered Save the renamed program into MY PROGRAMS by pressing the confirmation button.

i) To quickly rename a program in MY PROGRAMS, use a triple-click of the button.

#### Delete program >

Saved programs can be removed in a similar way. Press the right-hand button to access the MY PROGRAMS list. Use the buttons to select the desired program, then double-click the confirmation button to open Program details. Using buttons, select Remove from MY PROGRAMS. Select the YES option using the buttons and delete the program by confirming with the buttons.

(i) To quickly remove a program in MY PROGRAMS, use a triple-click of the houtton.

#### Searching for a program >

To conveniently search by names/titles in MY PROGRAMS, press the subtron again. The keyboard screen is displayed. Enter any characters contained in the program name/title and confirm with the button.

A list of the programs containing the entered characters will appear.

*Maximum* searchable program names in MY PROGRAMS <a>♠</a>:
 EASY mode − 8 / CLINIC mode − 200.

#### **SET PROGRAM**

**Description** > A function enabling the creation of a suitable therapy using six fundamental therapeutic effects (available in CLINIC mode). These effects are widely used to help alleviate manifestations of various health conditions. All effects may be alternated or combined as required. Use the device in accordance with the Instructions for Use and follow the professionally indicated veterinary treatment protocol.

Procedure > In the MY PROGRAMS list, a SET PROGRAM can be created by triple-clicking the button.

SET PROGRAM comprises a group of 1-4 effects (as required). Follow the instructions on the display. Use the \_\_\_\_\_\_\_\_ buttons to select the effects to include in the effect group for the SET PROGRAM. Briefly press the \_\_\_\_\_\_\_ button to define the order within the group. To save the group of effects, press and hold the \_\_\_\_\_\_ button for 3 beeps. A touchscreen keyboard will appear, enter the program name and confirm with the \_\_\_\_\_\_\_ button. SET PROGRAM will be saved in MY PROGRAMS \_\_\_\_\_\_\_.

- (i) To exit the SET PROGRAM set up, press the 💹 button to return to the ALL PROGRAMS list.
- (i) Maximum number of created SET entries in MY PROGRAMS 200.

#### **AUTOMATIC PROGRAM REPEAT**

**Description** > Enables the selected program to be repeated up to 4 times in succession. Each repeat is started 2 hours after the beginning of the program application. The information on the course is shown on the device display.

Procedure > Activate by double-clicking the button on the selected program to open Program details. Using the button, select Additional options, where the Start automatic repeat function is confirmed.

- (i) To start the automatic repeat quickly, press and hold the button on the selected program for 3 beeps
- (i) Automatic repeat sequence: First application 20 min + 1 h 40 min pause + second application 20 min + 1 h 40 min pause + etc.

# SIMULTANEOUS EXECUTION OF SECOND PROGRAM

**Description** > This function allows for separate execution of two programs (available in CLINIC mode). It can be used with split device output connectors. Output splitting a can be configured in **device settings** as follows : 3/1 (outputs 1, 2, 3 separated from output 4) or 2/2 (outputs 1, 2 separated from outputs 3, 4).

Procedure > To activate the second program, first launch the primary program in the usual manner on output 1 2 3 or 1 2 (see the Device operation – activating the veterinary device section). To activate the separate running for output 4, or 3 4, click on the button three times and use the button to select the second program (purple background colour). To start the program, press the button.

- (i) With devices without separate outputs 1., 2., 3., 4. (4/0) the user cannot use this function.
- (i) You can watch the course of applications on the display. Double-click the (ii) button to toggle between Application 1 and Application 2.
- (i) To deactivate simultaneously running programs, stop Application 1 by pressing the (ii) button, then double-click the (iii) button to switch to Application 2, and stop it by pressing the (iii) button again. If both programs are paused, press the (iii) button to return to ALL PROGRAMS, or press the other (iii) button to return to MY PROGRAMS.

#### **EXTRA MENU EXPANSION**

**Description** > Additional EXTRA configuration for EASY and CLINIC modes. To display the items in menu *Device setting* , contact your distributor or manufacturer.

**Procedure** > After activating Finest Top, use the functional buttons to set the time and intensity . Use the buttons to change values.

- ① The **Finest Top** function locks the device for operating programs stored in MY PROGRAMS. ②. Use the ② button to start the quick control of the program. To deactivate, use a triple-click of the 🔳 button.
- (i) With the **Frequent** function, set the number (1 or 4) of most frequently used programs under the MY PROGRAMS menu.
- (i) The **Synchronous programs** function sets programs without 3D technology. To renew the function of 3D rotational programs , deactivate synchronous programs.

## 7 APPLICATION – WHEN AND HOW OFTEN TO APPLY

# 7.1 Recommended number of applications - how often to apply

2x a day, and 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 program durations of 20 minutes are the recommended period to induce the desired effect and may be extended up to 90 minutes. The minimum recommended number of applications is 10, while the maximum number of applications and maximum recommended application times are not stipulated and the applications can be repeated according to the veterinarian recommendation on a long-term basis.

# 7.2 Applicator selection and taking a position before applicationhow to apply

From the available applicators (see the **Technical description and specifications of applicators** section), always select the most appropriate one for the specific therapeutic intention and place it as close as possible to the surface of the treated body part.

Preparation prior to application and the application itself should follow the procedure (see Example of proper veterinary device connection prior to application section).

Before commencing treatment, ensure you are familiar with all principles of safe operation, and that there are no contraindications in the animal (see the **Principles of safe operation / Contraindications** section).

When selecting a program, more detailed information about its effects can be found in the descriptions of the effects of individual programs (provided in the **Principle of biological action** section).



### 7.3 Program selection

#### Program No. 1 – PAIN-RELIEVING EFFECT



(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 the following cases:

- with all diagnosed problems where the dominant manifestation is pain;
- radicular and pseudoradicular syndromes (nerve compression from various causes), non-healing wounds, pododermatitis, dermatitis, microtrauma;
- if the pain relief must precede, e.g., rehabilitation exercises, locomotor therapy, etc.;
- for alleviation of specific types of pain.

#### Program No. 2 – HEALING EFFECT



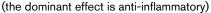
(the dominant effect is healing promoting regeneration, anti-inflammatory and anti-rheumatic effects)

This program is preferentially used where there is a need to accelerate the healing and regeneration of damaged tissue by employing anti-inflammatory and antirheumatic effects.

This program may also be used in the 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



We can use it to promote the remission of swelling for various reasons.

This program may also be used in the following cases:

- disorders of fluid drainage from tissue, improved perfusion, enhanced tissue flow, accelerated metabolic exchange, faster absorption of oedema, significant anti-inflammatory and analgesic action;
- gingivitis, allergic rhinitis, where the anti-swelling and anti-inflammatory effect alleviates symptoms and support healing;
- 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 myorelaxant)

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 animals with conditions in which muscle spasms and stiffness limit limb mobility, and in neurodegenerative diseases manifesting with muscular rigidity (e.g. cauda equina syndrome in dogs), muscle regeneration after sport or work activity, muscle relaxation prior to physiotherapy.

#### Program No. 5 - VASODILATING EFFECT



(the dominant effect is vasodilatory)

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 the following cases:

- ischaemic diseases of upper and lower limbs for various reasons;
- non-healing chronic wounds, circulatory disorders;
- reduction of thrombotic risk (e.g. thrombi affecting pelvic limbs).

#### Program No. 6 – DETOXOFYING EFFECT (O



(the dominant effect is metabolic-detoxification)

Used to support metabolic exchange and detoxification, i.e., when rapid clearance of toxins and metabolites from tissues is desired, along with inflammation reduction and concurrent nutrient delivery enhancement.

This program may also be used in the following cases:

- need to support tissue regeneration following infection (hepatitis, hepatopathy), toxic tissue damage, as well as dermatitis and allergy;
- support for total detoxication exposure of the liver area stimulates liver function and accelerates and enhances detoxification processes in the whole body:
- localised effects achieved by placing the applicator over the problem area, e.g., muscle, joint, etc.

#### Note:

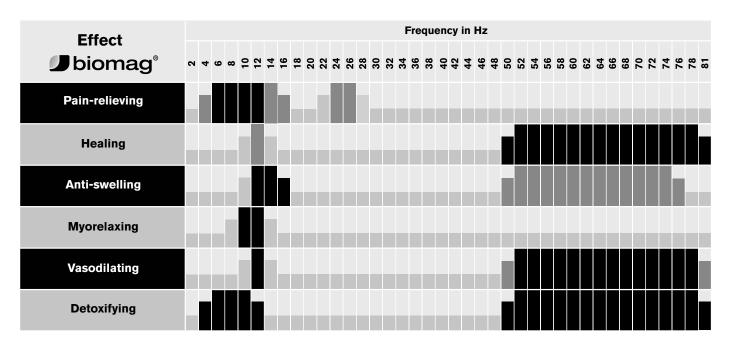
All the programs induce a different extent of all therapeutic effects while the parameters of individual programs are set so that they purposefully induce the dominant action of one or two effects.

In accordance with its **Intended Use**, the veterinary device is applied to generate pulsed magnetic fields.

### 7.4 General information

- The physiological mechanisms of therapy act on systemic, organ, tissue, cellular and molecular levels, and through these changes, beneficial therapeutic effects are produced within the body.
- Magnetic field lines penetrate all parts of the body, including bones and tissues, uniformly. The animal may lay on a pad during therapy, and the presence of plaster casts does not interfere with therapy. The moist method may be used (an open wound covered with a dressing that is no longer bleeding).
- Before initiating therapy, an appropriate program is selected based on the symptoms of the diagnosed condition to be specifically targeted.

Informative chart of predominant magnetotherapy effects by frequency



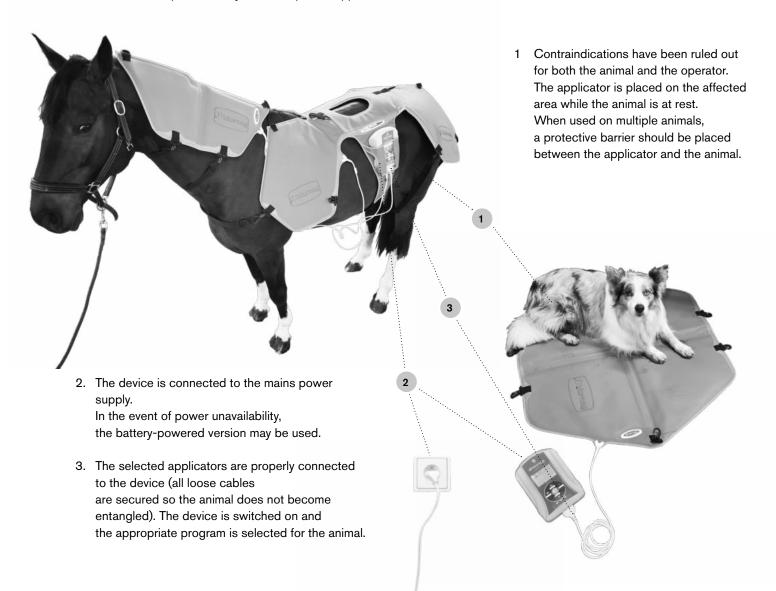
= the most effective range of frequencies for the given therapeutic effect

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

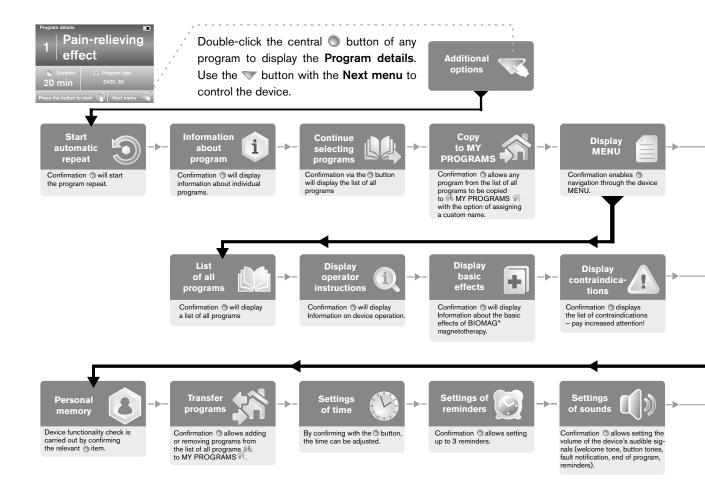
# 7.5 Example of proper veterinary device connection prior to application

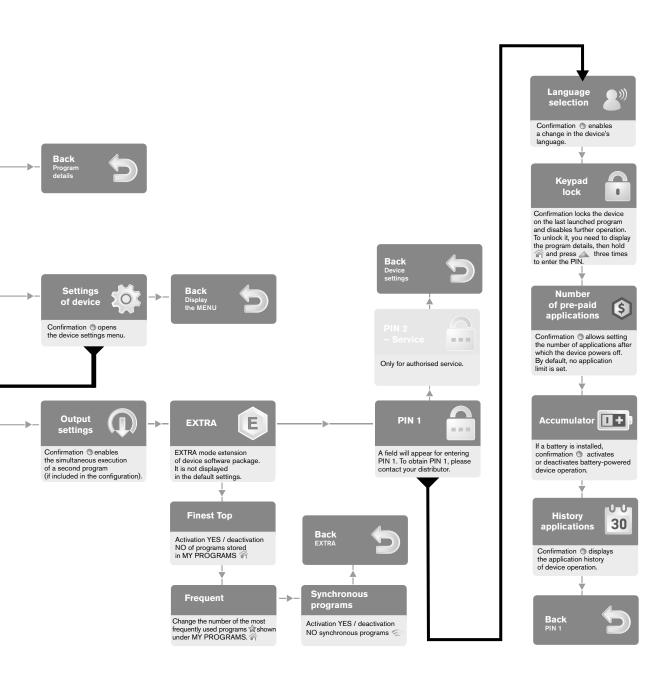
The operator/user is familiar with the principles of safe operation and adheres to them and to the Instructions for Use. The application will only be provided to the animal if the conditions outlined in the **Patient profile** / **Operator profile** are fulfilled.

Contraindications are professionally assessed prior to application. The animal must not be left unattended during application!



# 7.6 Device operation and additional possible settings





# **8 USER INFORMATION FOR THE VETERINARY DEVICE**

# 8.1 Principles of safe operation

- 1 | Before first use of the veterinary device, thoroughly familiarise yourself with the Instructions for Use.
- 2 | Operation and handling of the veterinary device may only be performed by individuals who meet the requirements specified in the **Operator profile**, and who follow these Instructions for Use.
- 3 | The veterinary device is exclusively intended for animals.
- 4 | The veterinary device is only intended for intermittent operation.
- 5 | Pulsed magnetic fields may influence disorders of function, but not fixed pathological changes. The therapy is non-addictive, complies with all safety standards and uses a method that is entirely safe for users.
- 6 | To achieve optimal results, it is recommended that the first five applications are carried out within the initial days.
- 7 | If no observable effects occur during the initial applications, continue with the therapy.
  - Positive effects may manifest later.
- 8 If a mild worsening of the condition occurs during the first days of therapy, this is a recognised part of the reactive phase. With subsequent applications, pain typically subsides followed by significant improvement.
- 9 | Implanted metallic devices are not a contraindication to therapy.
- 10 | The applied part is intended for use on intact skin, but in the case of bite wounds, lacerations, pressure ulcers, etc., use a disposable or other hygienic barrier.
- 11 When used with multiple animals, applicators must be disinfected before each subsequent application.
- 12 Only applicators approved by the manufacturer may be connected to the device's connectors.
- 13 | Do not remove the applicator from the device connector while an application program is running. Stop the program first or wait for the application closing.
- 14 | Protect the veterinary device from falls and damage, and pay increased attention to the connectors of both the device and the applicators.
- 15 | The veterinary device must not be immersed in water, washed or used in wet or humid environments, e.g., water bowls.
  Do not expose the device or applicators to moisture.
  Do not place the device near sources of heat.
- 16 | The veterinary device must not be used while the animal is moving freely.
- 17 | The application must be performed under supervision. Do not leave the animal unattended.
- 18 Do not use the veterinary device if it is damaged.

- 19 Any interference with the veterinary device is prohibited.
- 20 | The veterinary device must be connected to a suitable electrical supply with no visible damage to the power cable. If in doubt, the check should be performed by a safety inspector.
- 21 | Ensure the cable is kept at a safe distance from the animal to prevent it from being chewed.
- 22 | Portable and mobile high-frequency communication devices may interfere with the veterinary device. Wireless communication systems should not be operated within a 3.3 m distance as they might impact the Biomag functionality.
- 23 | The veterinary device may cause radio interference or may disrupt the function of nearby equipment, especially if placed adjacent to or stacked with other devices. Measures may be required to mitigate such interference, such as reorienting or relocating the veterinary device.
- 24 | Applicators may damage nearby devices during application, such as wristwatches, magnetic storage media, credit cards, etc. A distance of 1 m from the applicator is safe.
- 25 | When using multiple applicators in a single therapy session, ensure sufficient distance between them to prevent mutual interference.

**WARNING** – The manufacturer is not responsible for improper use of the system!

**NOTE** – During therapeutic applications of the veterinary device, the applicable legal regulations of the respective country must be observed.

**NOTE** – Monitor current and additional important information and instructions for users, including the possibility of warranty extension on https://www.biomag-medical.com/info/.

# 8.2 Occupational health and safety when using low-frequency pulsed magnetic fields

It is recommended to follow the Operator profile and adhere to the Instructions for Use. When operating the veterinary device, follow the Principles of safe operation together with the contraindications and operate the device under the prescribed environmental conditions. In other cases, it is recommended to consider the operator's current health and the operation mode. Furthermore, operation and handling of the veterinary device must comply with applicable electrical equipment safety regulations.

# 9 MAINTENANCE, FUNCTIONALITY, SERVICE, INSPECTION

The expected service life of the veterinary device is 10 years. This service life may be extended by regular preventive safety inspections as defined in the Safety-technical inspection section. The expected service life of the battery is 12 months. The storage life of the battery is also 12 months.

#### 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. Device cleaning and disinfection should be performed using a Sani-Cloth® Active or another product with the same composition. It includes antiseptic napkins without alcohol designated for the disinfection of surfaces and devices in all types of veterinary 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 accordance with its intended purpose, taking into account its equipment configuration. Devices equipped with a lithium battery (optional equipment) must be used with the supplied power cable for recharging the battery. The device should remain connected to the mains for continuous charging of the battery. The battery is primarily intended for completing the application in the event of a power failure, or during temporary unavailability of mains electricity. Do not leave the battery discharged for extended periods. Regularly check the battery status via the charge level indicator in the top-right corner of the device's display (battery icon). Battery replacement must be performed by the manufacturer or authorised service provider as part of a post-warranty service, typically two years after purchase.

### 9.2 Applicators maintenance

Applicator cleaning and disinfection should be performed using a Sani-Cloth® Active or another product with the same composition. These are antiseptic napkins without alcohol designated for the disinfection of surfaces in all types of veterinary 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 the veterinary device loses functionality, no unacceptable risk is posed.

#### 9.4 Service

A 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. The diagrams, lists of parts, descriptions and instructions for calibration or other information determined for the assistance to service staff during the repair of these parts of the veterinary device are available on request from the manufacturer. If service inspection determines that the device is not safe to operate, no longer fulfils its intended purpose or is irreparable, its service life is considered expired.

Users of the veterinary device are prohibited from making any unauthorised interventions into the device or its applicators.

# 9.5 Safety technical inspection

The veterinary device is subject to regular functionality and safety inspections. These inspections follow a defined procedure, conducted at prescribed intervals by trained personnel, to verify the safety and efficacy of the veterinary device.

For veterinary devices used by professional care providers, the first safety-technical inspection is required by the manufacturer after 2 years of operation. All subsequent STIs should be performed at 12-month intervals. After 10 years of operation, each subsequent inspection must be carried out every 6 months.

For veterinary devices intended for individual home care use, the first safety-technical inspection by the manufacturer is required after 2 years of veterinary device operation. All subsequent STIs should be performed at 24-month intervals. After 10 years of operation, each subsequent inspection must be carried out every 12 months. Failure to comply with these recommendations may result in the manufacturer disclaiming responsibility for any resulting damage (see the **Safety instructions** section).

For devices equipped with a lithium battery, the preventive safety-technical inspection must be carried out every 12 months from the commissioning date (see the **Safety instructions** section).

This safety-technical inspection is conducted by the manufacturer or an authorised organisation. Based on the results of the inspection, the service life of the device may be extended. If the preventive safety-technical inspection determines that the device is not safe to operate, no longer fulfils its intended purpose or is irreparable, its service life is considered expired.

# 

## 10.1 Operating environment

The veterinary device is intended for use in veterinary institutions, including households and premises that are directly connected to the public power grid supplying buildings used for housing purposes. In facilities designated for the housing or treatment of animals, the veterinary device may only be used if the electrical installation complies with the relevant national regulations, has undergone proper inspection and is fitted with a socket equipped with a surge protector of appropriate rated value. Operating environmental conditions:

- Temperature range: +5°C +35°C
   Ambient temperature +5°C +28°C with AV6P2 applicator;
- Relative humidity 15% 93% without condensation;
- Atmospheric pressure 700 1,060 hPa.

# 10.2 Storage and transport environment

The storage and transport environment of the device must be dry, dust-free, and free of mechanical shocks or chemical exposure. Premises must meet following conditions:

- Temperature -25°C +70°C
- Relative humidity 15% 93% without condensation;
- Atmospheric pressure 700 1,060 hPa.

If the storage or transport temperature drops below +5°C or rises above +35°C, the veterinary device must be allowed to acclimatise to the prescribed operating temperature range before use.

To maximise the battery's service life, the device with an accumulator should be stored within a temperature range of +10°C - +25°C.

The device with an accumulator may be transported using standard modes of transport, including air travel, without the need for a special authorisation from the carrier. Nevertheless, it is advisable to verify current transport regulations with the specific carrier in advance. The LIP745690P/2S battery is categorised as low-risk (up to 100 Wh) and is permitted in both carry-on and checked baggage. The device is clearly labelled with a symbol (Wh) capacity.

#### 10.3 Information for distributors

Applicable national legislation on veterinary devices must be observed in the country where the BIOMAG® Pulsed Magnetic Therapy Device is used. This includes mandatory periodic safety and performance inspections, as well as other regulatory requirements for the veterinary device set by local laws and regulations. Compliance with these provisions ensures the safe and effective use of the veterinary device and protects both animal and operator health and safety.

# 10.4 Information on electromagnetic compatibility

The veterinary device must be used in the environment specified below. The device is suitable for use in all institutions, including domestic environments and facilities connected to the public low-voltage network supplying residential buildings. The veterinary device includes the main unit with a power cable (length 1.5 m or 3 m, type H05VVH2-F 2x 0.75) and compatible applicators. The device must only be used with the supplied accessories. If needed, the above-mentioned accessories may be ordered from the manufacturer or distributor.

⚠ WARNING – Use of accessories or cables other than those specified or supplied by the manufacturer may result in increased electromagnetic emissions or reduced electromagnetic immunity of the veterinary device and may lead to improper operation.

⚠CAUTION – The portable RF communication device (including end equipment such as antenna cables and outside antennas) is not to be used closer than 30 cm (12 inches) from any parts of the device, including the cables specified by the manufacturer.

Portable and mobile high-frequency communication equipment may interfere with the device. No wireless communication system should be operated within a 3.3 m distance. Otherwise, this could lead to reduced performance of the veterinary device.

The veterinary device should not be used in close proximity to or stacked with other equipment. Respect the information given in the Instructions for Use for this equipment. If operation near or in stacked configuration with other equipment is necessary, the device must be observed to ensure it functions properly in the intended configuration.

#### **Electromagnetic emissions**

The veterinary device is intended for use in electromagnetic environments compliant with applicable standards for medical devices. The veterinary device is tested as a medical device in accordance with IEC 60601-1-2:2014/AMD1:2020.

It is classified as Group 1, Class B under CISPR 11, and complies with Class A of IEC 61000-3-2 and with IEC 61000-3-3.

The veterinary device is intended for use in the electromagnetic environment specified below. The user must ensure the veterinary device is operated within this environment.

Emission test	Compliance	Electromagnetic environment – guidance
High-frequency emission CISPR 11:2015+AMD1:2016+AMD2:2019	Group 1	The device uses radio-frequency energy solely for internal function.  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+AMD1:2016+AMD2:2019	Class B	The device system is suitable for use in any institutions, including households
Harmonic emissions: IEC 61000-3-2:2018/A1:2020/AMD2:2024	Class A	and premises that are directly connected to the public power grid supplying buildings
Voltage fluctuation / flicker emissions IEC 61000-3-3:2013 +AMD1:2017+AMD2:2021	Compliant	used for housing purposes.

### **Electromagnetic resistance**

	Basic standard	Testing levels of resistance		
Phenomenon	for EMC or testing method	Professional environment	Home care environments	
ELECTROSTATIC DISCHARGE	IEC 61000-4-2:2008	±8 kV for contact discharge ±2 kV, ±4 kV, ±8 kV, ±15 kV for	air discharge	
RF EM fields propagated by emission	IEC 61000-4-3:2020	3 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz	
Close fields from RF wireless communication devices	IEC 61000-4-3:2020	See Clause 8.10 of IEC 60601-	1-2:2014/AMD1:2020	
Nearby magnetic fields	IEC 61000-4-39:2017	See Clause 8.11 of IEC 60601-	1-2:2014/AMD1:2020	
Magnetic fields of STIPULATED power frequency	IEC 61000-4-8:2009	30 A/m 50 Hz or 60 Hz		

The veterinary device is intended for use in the electromagnetic environment specified below. The user must ensure the veterinary device is operated within this environment.

	Basic standard	Testing levels of resistance		
Phenomenon	for EMC or testing method	Professional environment	Home care environments	
Electrical fast transient / groups of pulses	IEC 61000-4-4:2012	±2 kV Sequential rate 100 kHz		
Surges, integrated	IEC 61000-4-5: 2014+A1:2017	±0.5 kV, ±1 kV		
Surges between the phase and earth	IEC 61000-4-5: 2014+A1:2017	±0.5 kV, ±1 kV, ±2 kV		
Conducted RF interference	IEC 61000-4-6:2023	3 V 0.15 MHz – 80 MHz 6 V in ISM bands 0.15 MHz – 80 MHz 80% AM at 1 kHz	3 V 0.15 MHz - 80 MHz 6 V in ISM bands and amateur radio bands 0.15 MHz - 80 MHz 80% AM at 1 kHz	
		0% U⊤; 0. at 0°, 45°, 90°, 135°, 180	•	
Short-term drops of voltage	IEC 61000-4-11:2020/ COR1:2020/COR2:2022	0% Uτ; 1 cycle and 70% Uτ; 25/30 cycles the only phase: at 0°		
Voltage interruption	IEC 61000-4-11:2020/ COR1:2020/COR2:2022	0% Uτ; 250/300 cycles		

The electromagnetic environment – real relative humidity should be more than 50% and floor should be conductive. In this environment, air discharge should be no larger than 8 kV.

A degradation or loss of function of the veterinary device may occur, though this does not represent an unacceptable risk.

# Recommended separation distances between portable and mobile high-frequency communication equipment and the veterinary device

The veterinary device is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The user can help prevent electromagnetic interference by maintaining minimum separation distances between portable and mobile RF communication equipment (transmitters) and the veterinary device, as recommended below based on the maximum output power of the communication equipment.

Rated maximum output power of the transmitter	Separation distance depending on the transmitter frequency  m				
W	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 not listed above, the recommended separation distance (d) in metres (m) can be estimated using the equation for the frequency of the transmitter, where P is the rated 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 may not apply to all situations.

Electromagnetic propagation is affected by absorption and reflection from buildings, objects and people.

# 11 FAULT 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.

\* VD = veterinary device

CONDITION	PROBABLE CAUSE	REMEDY
ELECTRICAL ENERGY		
Device shuts down, non-functional VD* due to power fluctuations	Loss or surge in mains voltage causes the device shuts down and cannot be restarted	Have the electrical installation inspected by a qualified professional
Device shuts down, non-functional VD due to environmental factors	Short circuit due to a dislodged component on the circuit board	Send the device for servicing
Device shuts down, non-functional VD due to environmental factors	Short circuit due to ingress of foreign substances	Send the device for servicing
Device shuts down, non-functional VD due to environmental factors	VD exposed to air discharge above 8 kV	Send the device for servicing
Device shuts down, non-functional VD due to leakage current	Damage to the casing of the device or applicator (e.g. cutting or forced intrusion)	Send the VD for servicing
Non-functional VD	Damaged power cable	Send the VD for servicing
THERMAL ENERGY		
Increase in device temperature	Operating temperature exceeds permissible range	Relocate the device, and if non-functional, send for servicing
Increase in applicator temperature	Operating temperature exceeds permissible range	Relocate the applicator to a different location, and if non-functional, send it to the service centre for repair
Hardened and cracked applicator leatherette	Lower ambient temperatures or temperature fluctuations damage the applicator	Send the applicator to the service centre for replacement of the cover
Non-functional VD, damaged printed circuit board	Reduced ambient temperature causes damage to the VD through moisture condensation	Send the device for servicing
Non-functional VD, device signals a fault acoustically	VD may be affected by another heat source	Relocate the VD to another place, non-functional, send for servicing
CHEMICAL EFFECTS		
Damaged device casing	Incorrect cleaning agent	Send the device to the service centre for replacement of the casing
Device shuts down, non-functional VD due to ingress of undesirable substances	Ingress of liquid onto the printed circuit board	Send the device for servicing
Damaged applicator leatherette	Incorrect cleaning agent	Send the applicator to the service centre for replacement of the cover
Hardened and cracked applicator leatherette	Incorrect cleaning agent or effects of another liquid	Send the applicator to the service centre for replacement of the cover



CONDITION	PROBABLE CAUSE	REMEDY
MECHANICAL EFFECTS		
Non-functional VD	Device or applicator dropped	Send the VD for servicing
VD does not function correctly	An output error appears on the device display and the LED flashes	Send the device for servicing
VD does not function correctly	Applicator disconnection is shown on the device display with an accompanying acoustic signal	Send the applicator for servicing
VD does not function correctly	Output error repeatedly displayed and applicator disconnected	Send the VD for servicing
FUNCTION EFFECTS		
Non-functional VD	Component base malfunction	Send the VD for servicing
Sudden interruption of VD operation, display shuts down	Power supply interrupted	Restore the power supply, inspect the electrical wiring
Non-functional VD, device signals a fault acoustically	VD may be affected by another device	Relocate the VD to another place, non-functional, send for servicing
Non-functional or incorrectly operating VD	Software error	Send the VD for servicing
Non-functional or incorrectly operating VD	SD card error	Send the VD for servicing
VD does not function correctly	Stuck control button on the device	Send the device for servicing
USER ERROR		
Non-functional VD	Unauthorised components used	Send the VD for servicing
Non-functional VD	Device operated beyond its service life without timely safety-technical inspection	Send the VD for servicing
Non-functional VD	Device operated under unsuitable conditions	Send the VD for servicing
Non-functional VD	Neglect of maintenance of external power source	Send the VD for servicing
VD does not function correctly	Improper handling of the device with battery	Send the VD for servicing
VD does not function correctly	Failure to ensure regular safety-technical or service inspections	Send the VD for servicing
VD does not function correctly	Improper handling resulting in damage to internal components on the printed circuit board	Send the VD for servicing
Non-functional VD	Damaged and non-functional display	Send the VD for servicing

CONDITION	PROBABLE CAUSE	REMEDY
USER ERROR		
Non-functional VD	Unqualified intervention	Send the VD for servicing
Non-functional VD	Component base malfunction	Send the VD for servicing
Interruption of VD operation, device display shuts down	Cause of malfunction due to environmental factors, not compliant with parameters specified in the instructions for use	Send the VD for servicing
Non-functional VD	Power cable connector not fully inserted into the power socket of the device	Insert the power cable into the device
Non-functional VD	Power cable not correctly connected to the electrical outlet	Insert the power cable into the electrical outlet
Illegible device display	Device exposed to intense sunlight	Move VD away from the light source
VD does not function correctly	No applicators are connected to the device output	Connect the applicator
Applicator heating	Incorrect use	Observe the application duration

Temporary loss of function or degradation in the operation of the veterinary device due to electromagnetic interference does not pose an unacceptable risk.

Interruption or end of application might occur earlier than the set program time.

Spontaneous change of the program might occur.

A fault condition may occur - loss of veterinary device function.

#### **(i) DEVICE RESTART**

If the system does not respond to controls or if its function is unreliable (especially the display), restart the system. The restart opening, which can be activated by, e.g., a paper clip, is located in the bottom part of the rear side of the device.

For any other unlisted issues, contact your distributor.

They will arrange a professional manufacturer's service for you.

#### **12 WARRANTY**

The veterinary device is covered by a 24-month warranty from the date of sale. The warranty covers the repair of the system and replacement of components that are damaged due to the use of defective materials, faulty design or workmanship.

The warranty does not cover wear and tear caused by normal use, such as parts with a limited lifespan (battery, etc.). The expected service life of the battery is 12 months.

The warranty is void in case of unauthorised tampering with the veterinary device, damage by force, improper handling contrary to the manual or damage occurring due to force majeure.

For any warranty repair you should provide the purchase document and/or the dealer's warranty card with an identical date to that of the product acceptance. The entire veterinary device must be presented, i.e., the device including applicators.

The warranty does not apply to any surface finishes that do not affect the function of the veterinary device.

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

### 13 DISPOSAL

When disposing of the veterinary device, follow the hazardous waste (electronic waste) disposal regulations applicable in the relevant country. Disposal is also arranged by the manufacturer or distributor.

### TIPS AND ADVICE (1)

- If you want to set other features of the system, follow the instructions on the display. Double-click the button (application not running) and then press the button again to access the **Additional menu** item. To select an item, use the buttons and confirm the selection with the button to display the menu.
- If the application is running, press the \_\_\_\_\_\_ buttons and the Instructions and recommendations appear \_\_\_\_. You can display the instructions when the application is not running by double-clicking the \_\_\_\_\_ button, and use the \_\_\_\_\_ buttons to select Information on the program [i].
- To change the device language, simultaneously press the upper, lower and left buttons immediately after switching on the device.

Hold the buttons for 3 seconds. Upon release, the start-up screen appears, followed by the language selection  $\mathbb{R}^{3}$ .

- Time setting monitors the battery in real-time. Follow the instructions on the screen to set it.
- Reminder setting No notifies you about the next therapy. The screen will display the alarm clock with beeping. You can select 3 reminders.
- Sound setting 1) adjusts acoustic signalling (switch off sound, medium volume, maximum volume).
- Functionality inspection of the veterinary device is performed by confirming the Personal memory **(a)** item. The test runs for 25 minutes.
- Under the PIN1 item, the menu for language selection is available (a), keyboard lock (a), number of prepaid applications (s), battery (a) and application history (30).
- If a **battery** is installed in the device and is charged (charging occurs whenever the device is connected to the power supply), applications may be performed in the event of a power outage or temporary unavailability of electrical power in the same manner as when the device is connected to the mains.
- The 3 connectors are properly inserted when the side of the connector with the logo is facing upwards.
- Press the 🔊 🍙 buttons simultaneously to display the screen for setting the code (when buying other functions of the system).
- Press the \_\_ buttons simultaneously to display the screen for your communication with the service centre.

# **14 CONTACT INFORMATION**

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

Should you require assistance with setting up, operating or maintaining the veterinary device, or in the event of another incident, please contact your distributor (manufacturer's representative). If you do not have contact with 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



## 15 USE OF THE VETERINARY DEVICE

# List of veterinary device components

The veterinary device provides animals all the advantages and benefits available to humans. The applicators not only provide high comfort and convenience for horses, but also for other small animals such as dogs and cats. Biomag magnetotherapy not only greatly benefits humans, but also our animal companions.



#### Lumina 3D-e VET

magnetotherapy device with battery generating pulses to connected applicators (e.g.: Lumina 3D-e VET EA, Lumina 3D-e VET CA)



#### Lumina 3D-e VET

magnetotherapy device without battery generating pulses to connected applicators (e.g.: Lumina 3D-e VET EB, Lumina 3D-e VET CB)



#### AV1a

applicator intended for application to the right-sided joints of the animal's limbs



#### EPV1a / EPV1b

bedding of 2,260 mm for AV4 applicator bedding of 3,280 mm for AV5 applicator



#### AV1b

applicator intended for application to the left-sided joints of the animal's limbs



#### EPV2

Flexible strap with a 2,500 mm pocket for securing the device to the animal's body using Velcro.



#### AV2

applicator designed for the cervical region of the animal



#### EPV3

580 mm length strap fitted with plastic clips for attachment to the applicator's carabiners and fastening to the animal's body.



#### AV3

applicator intended for application to the entire trunk of the animal



#### EPV4

1,270 mm length strap fitted with plastic clips for attachment to the applicator's carabiners and fastening to the animal's body.



#### AV3a

applicator intended for application to the anterior part of the animal's body



#### EPV5

1,740 mm length strap fitted with plastic clips for attachment to the applicator's carabiners and fastening to the animal's body.



#### AV3b

applicator intended for application to the posterior part of the animal's body



#### EPV6

790 mm elastic strap with a hook-and-loop fastener, intended for securing the EPV7 casing.



#### AV4

applicator intended for application to the cervical region of the animal or a recumbent animal



#### EPV7

Casing intended to hold the AV6P2 applicator with optional EPV6 elastic strap fastening.



#### AV5

applicator intended for application on a recumbent animal



#### EPV8

130 mm length strap ending with plastic clips allowing attachment to snap-hooks between individual applicators



#### AV6P2

applicator intended for intensive application to specific localised issues of the animal

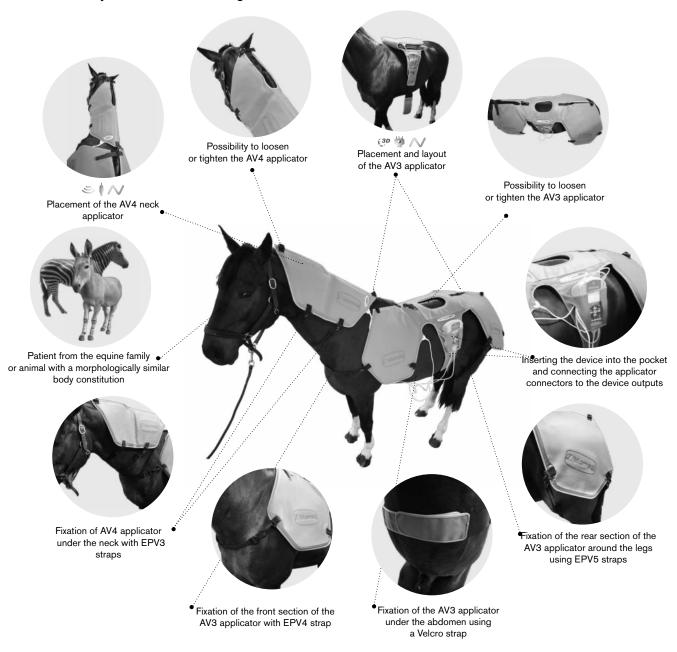


#### EPV9

700 mm length strap with Velcro fastening suitable as for use as a headband applicator

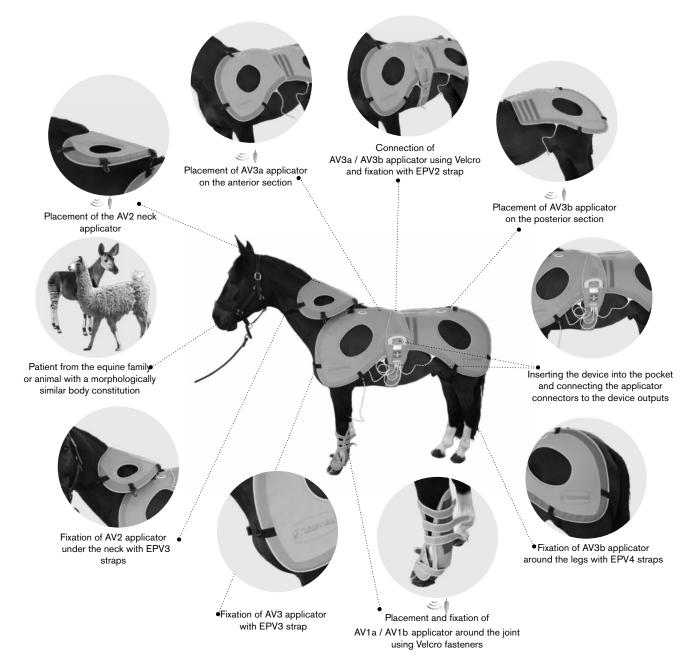
# Practical use of the device with AV3 and AV4 applicators

\* Observe the safety instructions and warnings



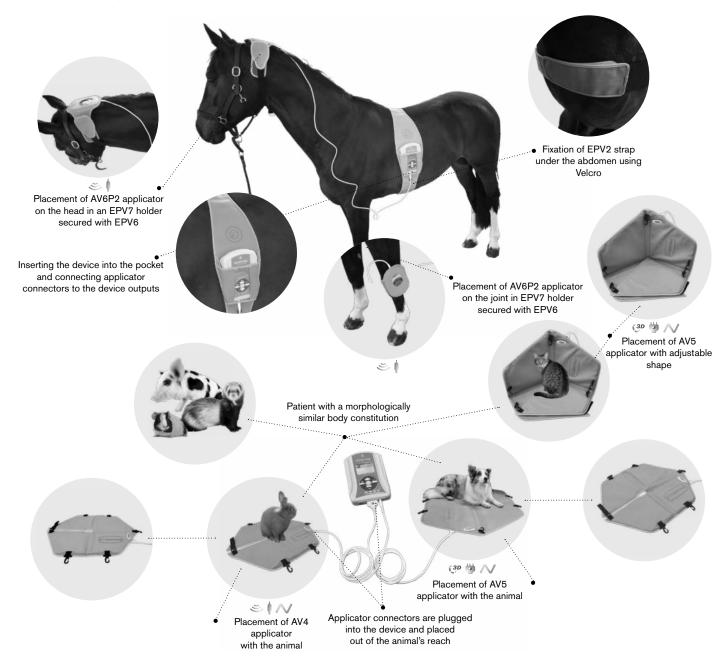
# Practical use of the device with AV1a, AV1b, AV2, AV3a and AV3b applicators

\* Observe the safety instructions and warnings



# Practical use of the device with AV4, AV5 and AV6P2 applicators

\* Observe the safety instructions and warnings



# **Jbiomag**° e-series



BIOMAG® Lumina 3D-e VET Clinic

BIOMAG® Lumina 3D-e VET 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/.

# **Jbiomag**<sup>®</sup> Lumina 3D-e VET

en The 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 appearance not affecting the functions is reserved.

The colour shown in the illustrations may vary from your particular model.

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.



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