

MAGNETO BIOLIFE

Portable, wearable magnetotherapy

MANUAL

Instructions for use

New Age Italia srl

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Cap.1 – PRESENTATION

MAGNETO BIOLIFE is part of the new line of portable electromedical devices for physiotherapy. Compact size, easy use and versatility are the main features of this innovative line of products.

1.1 – What is MAGNETO BIOLIFE

Constant research in the medical devices sector led to the creation of the new magnetotherapy system composed of the MAGNETO BIOLIFE generator, compact in size yet with professional features. The innovative software enables generation of magnetic fields for therapeutic purposes to treat common pathologies (cuts, injuries, illnesses) by using **preset** programs ready for use. Technological innovation and easy use makes the **product extremely innovative** in the electromedical devices sector.

1.2 – Why use MAGNETO BIOLIFE

MAGNETO BIOLIFE enables application of magnetic fields with beneficial effects on the reconstruction of bone tissue and, in general, regeneration of damaged tissue, as well as obtaining analgesic, anti-inflammatory and anti-edemigenous action.

1.3 – Who should use MAGNETO BIOLIFE

MAGNETO BIOLIFE is most suited for home use to avail of its full potential. The compact size also ensures it is easily transported and the rechargeable battery allows its use while travelling and in any location where application is needed; **do not use the device in very hot or humid environments (see WARNINGS chapter).**

ATTENTION: for home use, follow the instructions given by the doctor who prescribed magnetotherapy.

READ THE MANUAL CAREFULLY BEFORE USE

Cap.2 – INSTRUCTIONS AND CONTRAINDICATIONS

2.1 – Instructions

The most common pathologies treated with magnetotherapy are bone and joint related. In particular, magnetic fields are indicated to treat:

- recent fractures, delayed union;
- osteoporosis, bone atrophy;
- pseudoarthrosis, arthrosis, arthritis;
- inflammatory and degenerative arthropathies;
- oedema;
- algodystrophy;
- tendinitis;

You are advised to consult a doctor for diagnosis and control of the therapy.

2.2 – Contraindications

Magnetic fields have certain common contraindications with other physical media which react with endogenous heat production.

- presence of metal fragments;
- cancer (tumours);
- tuberculosis;
- acute inflammatory processes;
- skin lesions;
- changes in sensitivity.
- pace-maker
- pregnancy.

Cap.3 – OPERATION



1 – LCD display

2 – ON/OFF START/STOP:

3 – (+) AND (-) KEYS

4 – Output socket for applicator

5 – Input socket for power supply unit

NOTE: check the contraindications before applying magnetotherapy; follow the instructions carefully of the doctor prescribing magnetotherapy.

3.1 – Connection and application

Connect the cable of the applicator to the device output. Position the applicator on the zone to treat (also over stockings or clothing) fastening it so it fits with the elastic strap (see colour photo in the APPLICATIONS chapter).

3.2 – Power supply for use

MAGNETO BIOLIFE can be battery operated or use 230V, connecting the power supply unit to the device and a normal electricity socket.

3.3 – Switching on the device

To switch on MAGNETO BIOLIFE Keep the **(I) ON/OFF** key pressed. The display shows the name of the device followed by the program.


3.4 – Select the program

Choose the desired program with the +/- keys (see Programs Table);

Programs Table

PROGRAMS	No.	FREQ (Hz)	DURATION	INTENS. G
STIM	1	75	4h	15
KNEE/ELBOW	2	70	1.5h	20
SHOULDER	3	65	2h	20
BUNION	4	75	4h	15
ANKLE	5	70	1.5h	20
WRIST	6	80	1h	15

3.5 – Starting stimulation

When the desired program appears on the display, press the START button. Once the program is activated on the display, the TIMER appears to indicate the remaining time and at the bottom of the display this signal  will appear to indicate treatment has started.

3.6 – Timer Adjustment

You can increase the duration of the program (Timer) to prolong therapy by some hours or for night applications, up to a maximum of eight hours. To adjust the timer when a program is in progress, use the + and - keys

ATTENTION: for the duration of the sessions, follow the instructions of the doctor who prescribed magnetotherapy, in particular for applications from 4 to 8 hours.

3.7 – Stop/terminate therapy

If you want to stop therapy before the end, press the STOP key: once to pause (to continue press START).

3.8 – Switch off device

To switch off the device, keep the **(I) ON/OFF** key pressed for a few seconds.

3.9 – Symbols on the display



- BATTERY STATUS: battery power supply and load level

Cap.4 – APPLICATIONS

4.1 – Therapy sessions

Apply magnetotherapy according to medical prescription. Applications can be carried out every day, with the most suitable program for the patient's pathology, until the problem is healed or significantly reduced; if necessary, 2-3 applications can be carried out daily a few hours apart, without exceeding the 8 hours per day of therapy. **If the problem persists, consult your doctor.**

4.2 – Position to maintain during the sessions

MAGNETO BIOLIFE allows you to have therapy sessions while going about everyday activities.

EXAMPLES OF APPLICATIONS

SHOULDER APPLICATION

KNEE APPLICATION

ANKLE APPLICATION

ELBOW APPLICATION



FOOT APPLICATION




WRIST APPLICATION




Cap.5 – POWER SUPPLY


MAGNETO BIOLIFE can be powered by the electrical mains using the power supply unit provided or an internal rechargeable Ni-Mh 8.4V – 900mAh battery, which, in normal use conditions, has an autonomy of a few hours. Guaranteed autonomy varies based on the type of emission used, the intensity set and the application time.

 To correctly identify the battery and the power supply unit provided as standard, consult the "Technical features" chapter. The power supply nor the battery must be replaced by inexperienced staff and in particular using equipment differing from that supplied by the manufacturer.

5.1 – Charge indications

When MAGNETO BIOLIFE is powered by the internal battery, the symbols bar on the display shows the BATTERY "■" symbol.

Legend: ■ - Battery charged indication  - Battery flat indication

The intermediate charge levels are indicated by a partial blackening of the BATTERY symbol .

When the flat battery status is signalled, proceed with the recharge cycle. To safeguard the battery, MAGNETO BIOLIFE is equipped with an auto-power off system.

5.2 – Charge

To charge the MAGNETO BIOLIFE battery:

- 1- **switch off** the device;
- 2- **connect the power supply unit** to the electricity mains and to MAGNETO BIOLIFE;
- 3- **leave the device charging** (the display shows the outline of the battery symbol flashing as it charges) **until the battery symbol is full** (a complete recharge cycle lasts approx. **7 hours**); every now and then, you are advised to leave it charging for 8-10 hours or all night);
- 4- **Disconnect the power supply unit** from the electricity mains and from MAGNETO BIOLIFE;


5.3 – Battery maintenance

The life of a rechargeable battery is linked to the number of charge/discharge cycles it is subjected to and the way these cycles are executed.

If you do not frequently use MAGNETO BIOLIFE, we suggest you **charge the battery on a monthly basis**. To prolong the life of the battery, you are advised to discharge it as much as possible (see flat battery symbol) and every 3 weeks completely recharge for 8-10 hours (e.g. all night).

5.4 – Replacing the battery

An indicator of battery exhaustion is the duration of the battery after normal recharge. When you note the duration of the battery is considerably less than that of a new battery, you need to replace it. To replace the battery, contact NEW AGE ITALIA SRL.

 Never invert the poles of the battery connections, which would destroy the electronic circuits.

5.5 – Precautions for use

- (1) Do not throw the old battery in ordinary waste, but give it to authorised staff for its disposal.
- (2) Do not open or throw the battery on the fire.
- (3) Do not short circuit the terminals.
- (4) Avoid causing sparks, or flames, over or around the battery.
- (5) If material leaks from the battery and comes in contact with the skin, or with clothing, immediately wash with water. If it comes in contact with your eyes, wash with plenty of water and immediately seek medical advice.

Cap.6 – MAINTENANCE

6.1 – Multi-use applicator

Periodically check the connection cable to check for any cracks, a possible cause of dispersion of magnetic fields; clean the applicator periodically with a damp cloth.

6.2 – Device and power supply unit

Use a damp cloth to clean the power supply unit and the device. **Never use liquids for any reason, because they are not protected against liquid entering (IP20).**


6.3 – Replacing the power supply unit


Check the isolations (casing and cables) on the power supply unit for wear, before connecting it to the mains. If damaged, even if partially, replace the power supply unit immediately.

6.4 – Immediate maintenance:

Immediate maintenance in New Age Italia or authorised staff if:

- the device was subjected to external mechanical stress (e.g. serious fall);
- the device was subjected to strong overheating (e.g. if left near intense heat sources);
- if you doubt liquids can penetrate inside;
- the power supply unit, the casing and other parts of the device are damaged, broken or missing;
- device functionality appears altered.

 For safety purposes, you are advised not to work with accessories (e.g. knobs and power supply unit) other than those provided as standard equipment.

 The frequency for maintenance, functionality testing and correspondence checking with safety standards EN60601-1 for medical devices should be carried out annually using a safety tester. The operation lifespan of the device is guaranteed by the manufacturer only if maintenance is carried out regularly.















NOTE: you are advised to only have the device tested by New Age Italia. The unit can be sent directly to the company support lab or handed to the dealer that sold the device.

Support centre:

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Cap.7 – WARNINGS

-  Pay particular attention when using the solenoids to avoid compromising treatment efficiency.
-  Use the device only with electrical systems complying with applicable safety standards in force.
-  The device has a protection rating of IP20 (see “Technical features” chapter). Do not use near liquids, as the device is not impermeable.
-  Do not use in the immediate vicinity of mobile phones (keep at least a few metres distance).
-  Using close (e.g. 1 metre) to a short wave or microwave therapy device may cause instability of the stimulator output.
-  Do not use in the presence of monitoring equipment for vital signs.
-  Do not simultaneously connect the patient to MAGNETO BIOLIFE and a HF surgical device, as this may be hazardous for the patient and the device itself.
-  The device performs as specified only if surroundings are kept at a temperature between 5 and 40° C and with humidity less than 80%. The same conditions are required for transport and storage.
-  In the event of malfunctions or faults, do not use the device and send it for repair.
-  Do not use near inflammable substances.
-  Do not use gel and accessories other than those supplied as standard.
-  It is imperative to inform the patient in advance of the sensation experienced during therapy, so that the session may be interrupted immediately using the controls on the device or removing the solenoids, if the sensation is not correct.
-  If the output intensity setting or its subsequent adjustment causes excessive heat or pain in the area treated, reduce the intensity of the treatment or stop the application, if necessary.
-  Keep out of reach of children.

Cap.8 – TECHNICAL FEATURES

8.1 – Power supply

Power supply unit: Ktec KSAD1200 140W 1EU

PRI: 230V ~ 50Hz SEC: 12V- 1.4A

Internal power supply: Rechargeable battery Ni-MH 8.4V- 900mAh

8.2 – Output features

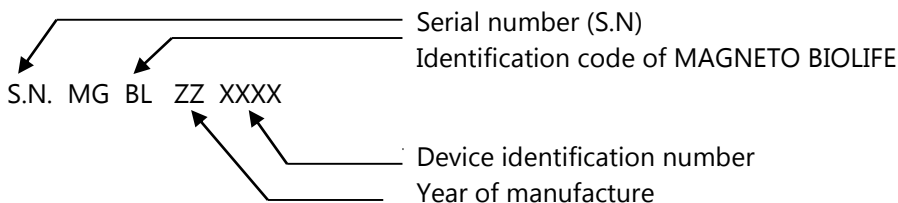
Max intensity of magnetic induction (B): 20 Gauss

8.3 – Other features

- Dimensions: 100x40x30h [mm]
- Weight: 200 [g]
- Class: IIa Type: BF
- Impermeability protection rating: IP20
- Safety rating for use near inflammable anaesthetic gases: AP or APG
- Device operation: continuous

Manufactured in compliance with the following regulations:

- EN 60601-1 (2007) – Electromedical devices: General regulations for safety
- EN 60601-1-2 (2007) – Collateral regulation: Electromagnetic compatibility – Prescriptions and tests
- EN 60601-1-4 (1997) – Collateral regulation: Programmable electromedical systems
- EN 62304 (2006) – Software cycle
- EN 60601-1-6 – Usability



Cap.9 – SYMBOLS



APPLICATOR TYPE BF



ATTENTION, CONSULT THE DOCUMENTATION ATTACHED



THIS DEVICE IS CE MARKED ACCORDING TO
DIRECTIVE EEC 93/42 AMENDED BY 2007/47/EC.



WASTE DISPOSAL ACCORDING TO DIRECTIVE 2002/96/ECC
AND 2003/108EEC

Cap.10 – STANDARD EQUIPMENT AND ACCESSORIES

10.1 – Standard equipment

Device
Applicator
Power supply unit
No.1 elastic strap
User manual

10.2 – Accessories and consumable material

Elastic fixing strap

Cap.11 - ELECTROMAGNETIC COMPATIBILITY

Table 201-Electromagnetic emissions declaration


Guidance and manufacturer's declaration - electromagnetic emissions		
The MAGNETO BIOLIFE device is intended for use in the electromagnetic environment specified below. The user must ensure it is used in this environment.		
Emissions test	Conformity	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 2	The MAGNETO BIOLIFE device must emit electromagnetic energy to perform the functions for which it was created. Electronic equipment nearby could be affected.
RF emissions CISPR 11	Class B	The MAGNETO BIOLIFE device is suitable for use in all establishments, including domestic and directly connected to the low voltage energy supply mains that supplies buildings used for domestic purposes.
harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / emission flicker IEC 61000-3-3	Not applicable	

Table 202-Declaration – Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The MAGNETO BIOLIFE device is intended for use in the electromagnetic environment specified below. The user must ensure it is used in this environment.			
Immunity test	Test level IEC 60601	Conformity level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be in wood or ceramic. If floors are covered with synthetic material, relative humidity should be at least 30%.

Table 204-Declaration – Electromagnetic immunity

Guidance and manufacturer's declaration - electromagnetic immunity			
The MAGNETO BIOLIFE device is intended for use in the electromagnetic environment specified below. The user must ensure it is used in this environment.			
Immunity test	Test level IEC 60601	Conformity level	Electromagnetic environment - guidance
RF	3 Vrms	3Vrms	RF communications portable and mobile

<p>conducted IEC 61000-4- 6 RF radiated IEC 61000-4- 3</p>	<p>150 kHz to 80 MHz 3V/m 80 MHz to 2.5 GHz</p>	<p>3 V/m</p>	<p>equipment should not be used too near any part of the MAGNETO BIOLIFE device, including cables, but take into account the separation distance recommended calculated based on the equation applicable to transmitter frequency.</p> <p>Recommended separation distance:</p> $d = 12\sqrt{P}$ $d = 12\sqrt{P} , 80\text{MHz to } 800\text{MHz}$ $d = 23\sqrt{P} , 800\text{MHz to } 2,5\text{MHz}$ <p>Where “P” is the maximum emission power of the transmitters calculated in watts (W) according to the manufacturer of the transmitter and “d” is the recommended separation distance in metres.</p> <p>Fixed RF transmitters force fields. As determined by research on an electromagnetic site,^a it must be lower than the conformity threshold of each frequency range.^b</p> <p>Interference may manifest near devices marked with the following symbol:</p> 
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NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies,
 NOTE 2 These guidelines do not apply to all situations, electromagnetic propagation is influenced by absorption and reflection of structures, objects, people.

^A Fixed transmitter force fields as radio station bases for radio (mobile/cordless phones)
 Telephones and mobile radios, amateur radios, radio transmissions, AM, FM and TV transmissions cannot be theoretically precisely planned. To assess the electromagnetic environment due to fixed RF transmitters, you need to consider

an electromagnetic site. If the force of the magnetic field in the location where the MAGNETO BIOLIFE device is used exceeds the RF conformity levels mentioned above, the device should work normally. If you note a functional anomaly, additional manoeuvres are necessary, such as re-positioning of MAGNETO BIOLIFE.

^b over the frequency range from 150 kHz to 80 MHz, the forces of the magnetic field should be less than (V) V/m.

Table 206-Recommended separation distances between portable and mobile RF telecommunication equipment and the MAGNETO BIOLIFE device

Recommended separation distances between portable and mobile RF telecommunication equipment and the MAGNETO BIOLIFE device			
The MAGNETO BIOLIFE is intended for use in an electromagnetic environment in which RF radiated disturbance is controlled. The user must avoid electromagnetic interference by maintaining a minimum distance between portable and mobile telecommunications equipment and the MAGNETO BIOLIFE device as recommended above, based on the maximum emission power of the telecommunications equipment.			
Maximum emission power of the transmitters calculated in watts (W)	the recommended separation distance in metres based on the transmitter frequency		
	150 kHz to 80 MHz $d = 12\sqrt{P} \sqrt{P}$	80 MHz to 800 MHz $d = 12\sqrt{P} \sqrt{P}$	800 MHz to 2,5 GHz $d = 23\sqrt{P} \sqrt{P}$
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 at maximum power not listed above, the recommended distance “d” in metres “m” can be estimated using the equation applicable to the transmitter frequency, where “p” is the maximum emission power of the transmitters calculated in watts (W) according to the manufacturer of the transmitter. NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies, NOTE 2 These guidelines do not apply to all situations, electromagnetic propagation is influenced by absorption and reflection of structures, objects, people.			

Cap.12 – BIBLIOGRAPHY

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