MAGNETER PRO



USER MANUAL

- Instructions -

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Cap.1 - PRESENTATION

MAGNETER PRO belongs to MODUL LINE, the new type of electromedical instruments for physiotherapy, that can combined together up to 3 different therapies in the same machine. The reduced dimensions, the facility of use and the versatility are the principal characteristics of this innovative line of products.

- What is MAGNETER PRO

The constant search in the sector of the medical devices has brought to the creation of the new system for magnetotherapy, constituted by the generator MAGNETER PRO. The innovative system of the software, electronic cards of small dimensions inserted inside the instrument, allow the generation of magnetic fields to therapeutic purpose for the treatment of common pathologies (lesions, accidents, illnesses) through the use of preset programs ready to use.

The possibility to adjourn the device and the programs, the technological innovation and the facility of employment make it an extremely versatile and innovative product in the electromedical instruments field.

- What is MAGNETER PRO for?

With MAGNETER PRO it is possible to apply magnetic fields with benefits effects on the reconstruction of the bones and, in general, for the regeneration of damaged tissues. Checking the effects and the course of the therapy, it is possible to suit the therapy for the demands of the patient.

– Who can use MAGNETER PRO?

MAGNETER PRO finds in the medical field (physiotherapy particularly) the fittest environment to express completely his/her own potentialities. Nevertheless, for the simplicity of use, it is usable, over that from physicians and therapists of the rehabilitation, also from who desires to use it at home, thanks to the immediateness and versatility of the product.

ATTENTION: for home use follow carefully the indications of the therapist.

ATTENTION: READ CAREFULLY THE INSTRUCTIONS BEFORE USE

Cap.2 - INDICATIONS AND CONTRAINDICATIONS

- Indications

The pathologies most common that are taken care of with the magnetic fields they are those to load of the apparatus osteo-muscle-tendineo and, particularly they are suitable in the treatment of:

- periostitis;
- tenonitis;
- arthrosis;
- muscular contractures;
- cicatrizations:
- organized oedemas.

Besides, the magnetic fields preserve today also one born validity in the treatment of rheumatologic abarticular alterations as the shoulder periarthritis, the epicondylitis of the elbow and other pathologies, thanks to the analgesi, fybrolitic and decontracturant effect.

The interested structures mainly suffer the most greater traumas in the physical activity but, in many cases, they can also be caused by the aging (rheumatisms, muscular ipotrofia, lack of equilibrium for the scarce movement); these cases, are particularly in strong increase for progressive rising of the middle age, not followed by a suitable improvement of the quality of the life.

In the sporting disciplines the most frequent traumas strike the articulations of the knee and the ankle and they can be treated with the magnetic fields through of the daily and repeated applications for a certain number of sessions. The treatments are effected above all to analgesic purpose propedeutico to the sessions of kinesitherapy.

Contraindications

The magnetic fields have the same side effects of the phisic therapies that act with the endogenous production of heat:

- degenerative osteoporosis;
- presence of metallic fragments;
- varicose veins;
- thrombosis and acute thromboflebitis:
- arteriopathologies with hemorrhages;
- menstruations;
- tumors:
- tuberculosis:
- acute inflammatory trials;
- cutaneous lesions:

• alterations of the sensibility.

In the applications of magnetic fields, the use is dissuaded on:

- specialized tissues (fertile metafisis, testicles, ovaries), because they can be damaged;
- avoid the use in cardiac area and, particularly, in presence of electric equipments (pace-maker), because it can cause permanent damages.

NOTES:

- Particular precautions must be adopted when applications are effected on the back bone of patients, with diagnosis of laminectomia, for possible damages to the bone marrow.
- The applications cannot be effected in the immediate proximities of the ocular globes and the uterus (abdomen / lumbar zone) in case of pregnancy for the risk to provoke the phenomenon of the cavitation, dosing hips corrected.
- The presence of articular prosthesis and a halves of metallic synthesis is problematic because they can absorb a superior quantity of magnetic fields and be deteriorated or cause damages to the adjacent structures.
- The use of this physical therapy is dissuaded the treatment of pathologies of the juvenile age and, above all, childish (ex. fertile cartilages of conjugation).

Cap.3 - OPERATIONS



- 1 Display TOUCH SCREEN
- 2-STOP BUTTON
- 3- KNOB + PUSH BUTTON
- 4-OUTPUT 1
- 5-OUTPUT 2

6 – START/PAUSE

7 – PROGRAMS

NOTE: before applying the magnetotherapy check the side effects and consult a physician.

- Solenoids' connection and application

Connect the cable of the solenoids to the front output of the instrument. Insert the connector by rotating till the connections coincides with the output; screw until the connector fix tight. To use the rubber solenoids, apply them over the zone to treat and fix them with the elastic bands.

ATTENTION: when you apply two solenoids one in front of the other (ex. 8/21

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Joints like elbow, knee, ankle), place on the skin the same draw (spiral) so that the magnetic fields of the two solenoids is added.

To use cushion and carpet (not included), just apply over them the interested zone (ex. head, shoulders, back, basin, feet, etc.) or the whole body; the magnetic band (not included) can be used: closed like a ring for the limbs (arms, legs, joints) or open and applied above the treating zones. To perform correctly the applications follow the indications of the Chap. APPLICATIONS and see the attached photos.

NOTE: if the carpet (not included) is connected to one channel, it is not possible to connect other solenoids into the other channel (ERR4).

- Turn on the device

To turn on MAGNETER PRO press 1 on the rear key ON/OFF. The display shows firm and device's name and places on the first program.

- Program selection

Select the program with **DOWN/UP** keys (see list of Chap. PRESET PROGRAMS).

Starting the therapy

Press (start) to begin the therapy.

<u>NOTE:</u> do not press **start** with no solenoid connected to the device (the display show the message "Insert solenoid 1 Insert solenoid 2"; after connecting one or two solenoids, press **start**.

3.1.1 - Manual mode

Press **START** on the initial screen to access the manual mode area. In this area, by **TURNING THE KNOB** you can vary the value of the parameter selected, whereas by **PRESSING THE KNOB** you pass from one parameter to the next. The concerned parameters are: power output of the ultrasound, duration, modulation, frequency.

3.1.2 - Preset program mode

Press **START** on the initial screen (touch screen) to access the work area. Then press **PROGRAMS** (on touch screen) to enter the Menu for choosing specific protocols where first of all the therapy to be used is selected, by turning the encoder and then pressing **ENTER** (touch screen) or else **PRESSING THE KNOB** to confirm the program selected.

3.1.3 - Personal program mode

The custom-made programs are at the bottom of the list of pre-set programs. Press **START** on the initial screen (touch screen) to access the work area. Then press **PROGRAMS** (on touch screen) to enter the Menu for choosing specific protocols. At the bottom of the list first of all the therapy to be used is selected, by turning the encoder and then pressing **ENTER** (touch screen) or else **PRESSING THE KNOB** to confirm the program selected.

NOTE: if the ultrasound head cable is not inserted in the device, the display will show "elettr. Dist". When the cable is put in, press START and the program restarts. To go back to the previous Menu press PAUSE STOP.

- Setting the intensity

The intensity (G=Gauss) is preset but can be manually set with the encoder knob of the used Channel. The minimum increase is of 1 G and the maximum is 200 G. Set an intensity of 50 G for the briefer daily applications (30-60 minutes) and inferior to 50 G for a prolonged therapy (more than 60 minutes); in case of pain or elevated heating in the treated zone it is necessary to decrease the intensity with the knob or interrupt the therapy by pressing **pause stop**.

If only one output cable is connected to the device, the display show the message "N.C." on the unused channel.

NOTES: the instrument recognizes the type of connected solenoids (it doesn't recognize different solenoids from those suitable from the house builder). If the greatest solenoids are connected (carpet or pillow - not inclusive) the preset and the maximum intensity varies in the following way:

- 1) carpet: maximum intensity 600 G.
- 2) cushion: maximum intensity 300 G.
- 3) **velcro band**: maximum intensity 300 G.

End or interruption of the session

To interrupt before the end press the key **pause stop**: once for a break (to continue press **start**); twice to finish the program.

- Turn off the device

To turn off the instrument press 0 (zero) on the rear key ON/OFF.

Cap.4 - PRESET PROGRAMS

MAGNETER PRO has 72 different preset programs The programs are listed in the following chart.

N° Prog.	Program name (on the display)	Output (continuous/modul ated)	Frequency (Hz)	Preset intensity (G)	Timer (min)
P.1	Fractures	Cont	40	50	35
P.2	Rec. Fract.	Cont	75	100	45
P.3	S Fractures	Cont	40	80	40
P.4	L Fractures	Cont	80	100	60
P.5	Consol.delay	Cont	12	90	60
P.6	Pseudoar.I	Cont	12	40	45
P.7	Pseudoar.A	Cont	12	80	55
P.8	Osteopor.I	Cont	10	60	50
P.9	Osteopor.A	Cont	20	100	60
P.10	Artrithis	Cont	10	40	35
P.11	Periarthritis	Cont	10	80	25
P.12	Arthropathy	Cont	40	70	45
P.13	S. Arthrosis	Cont	15	40	35
P.14	L. Arthrosis	Cont	40	80	50
P.15	Intercostal Algia	Cont	70	80	30
P.16	Reumatoid Arthrosis	Cont	50	100	30
P.17	Hips arthrosis	Cont	50	100	30
P.18	Shoulder Arthrosis	Cont	50	100	30
P.19	Dorsal Arthoris	Cont	50	100	30
P.20	Edemas	Cont	40	80	30
P.21	Brachialgia	Cont	80	100	30
P.22	Headache	Cont	50	100	30
P.23	Flebitis	Cont	20	60	25
P.24	Tingle hand/feet	Cont	30	40	20
P.25	Acute Coxoartr.	Cont	10	50	40
P.26	Chronic Coxoartr.	Cont	25	80	50
P.27	Chronic Ankle Spr.	Cont	30	75	35
P.28	Acute Ankle Sprain	Cont	60	100	45
P.29	Knee sprain	Cont	80	90	55
P.30	Dislocation	Cont	50	100	60

P.31	Stiff neck	Cont	30	60	35
P.32	Whiplash injury	Cont	20	40	40
P.33	Loc. Contr.	Cont	30	50	45
P.34	Widespread Cont.	Cont	70	80	60
P.35	Contracture	Cont	20	60	40
P.36	Strains	Cont	80	90	50
P.37	Myositis	Cont	10	70	60
P.38	Tendinitis	Cont	30	100	30
P.39	Tenovagin.	Cont	10	80	35
P.40	Carpal Tunnel	Cont	12	60	25
P.41	Bursitis	Cont	40	90	40
P.42	Chronic Epicond.	Cont	20	60	30
P.43	Acute Epicond.	Cont	40	80	40
P.44	Foot Tendonitis	Cont	70	90	30
P.45	Cervical	Cont	15	40	50
P.46	ChronicvLumbalgo	Cont	20	70	45
P.47	Acute Lumbalgo	Cont	40	90	55
P.48	Sciatalgia	Cont	50	100	60
P.49	Skin lesions	Cont	35	80	40
P.50	Loc. Bed sores	Cont	10	60	45
P.51	Widespr. Bed sores	Cont	25	85	60
P.52	Acne	Cont	10	50	30
P.53	Psor. Ecz.	Cont	15	60	35
P.54	Scars	Cont	30	40	40
P.55	Dermatitis	Cont	15	50	35
P.56	Inf. Urog.	Cont	12	60	55
P.57	Menstrual probl.	Cont	10	50	50
P.58	Haemorrhoids	Cont	20	80	45
P.59	Arteriop.	Cont	50	50	60
P.60	MigraineHeadache	Cont	12	40	30
P.61	Toothache	Cont	15	40	30
P.62	Diabetic Ulc.	Cont	12	90	60
P.63	Metatarsalgia	Cont	70	50	50
P.64	Vascular Pathologies	Cont	50	30	30
P.65	Consol. Delay 4h	Cont	12	30	4h
P.66	Pseudoarthros.4h	Cont	12	30	4h
P.67	Osteoporosis 4h	Cont	15	30	4h
P.68	Consol. Delay 8h	Cont	12	20	8h
P.69	Pseudoarthros.8h	Cont	12	20	8h

P.70	Osteoporosis 8h	Cont	15	20	8h
P.71	Acute pain	Cont	100	50	30
P.72	Chronic pain	Cont	80	50	60

Cap.5 - APPLICATIONS

See in the attached photos some examples of possible applications with the solenoids and with carpet, pillow and band (not included); **read carefully the contraindications before using the therapy**.

- Therapy planning

Apply the magnetic therapy following your doctor's indications. Generally magnetotherapy is used every day and, if necessary, 2 or 3 sessions a day after some hours. At the end of the programmed therapy if the problem is still present talk to the doctor.

Intensity regulation

The intensity can be increased, during the program, to produce more effects or decreased in case of overheating or feeling of pain.

NOTE: if the intensity or its regulation cause elevated heating or pain in the treated zone, it is necessary to reduce immediately the intensity of stimulation or eventually to interrupt the application.

Recommended intensities for most common applications:

Zone of application	Intensity adviced		
Bones	50 G		
Muscles	40-50 G		
Tendons / Ligaments	30-40 G		
Joints / Cervical / Lumbago	30-50 G		
Prolonged applications (+ di 60 minutes)	20-30 G		

Body position during the sessions

The ideal position of the body during the sessions is relaxed and supine or prone according to the application zone. The position must be maintained during all the session to facilitate the effects produced by the magnetic field, particularly the increased local blood flow, consequence of the induced heating in the treated zone.

Cap.6 - POWER SUPPLY

MAGNETER PRO must be supplied by power mains with the provided cable.

For the correct identification of power supply cable furnished in endowment of base, consult the Chap. "Technical characteristics". Neither the feeder, neither the battery must be replaced from personal not experienced and with different devices from those furnished from the house builder.

Cap.7 - SYMBOLS



CLASSE II DEVICE



BF TYPE DEVICE



ATTENTION, CONSULT THE ATTACHED DOCUMENTATION



THIS DEVICE IS CE MARKED ON CEE NORM 93/42 No. 0476.

Cap.8 - MAINTENANCE

- Solenoids, band, cushion and carpet

The cable of connection must periodically be checked for verifying that there is no cracks, possible cause of the dispersion of the magnetic fields,; clean periodically solenoids, cushion and carpet and with a damp cloth.

Device and power supply cable

To clean power supply cable and instrument, use a damp cloth. Don't use in any case liquids, because these devices are not protected from their entry (IP20).

- Feeder substitution

Check the state of the isolations of the power supply cable, before connecting it. If it's damaged, also only partially, immediately replace it.

- Immediate maintenance

- Immediate maintenance must be executed by New Age Italia or authorized personnel if one of the following situations happens:
- external mechanical solicitations (ex. serious falls);
- strong overheating (ex. if left next to sources of intense heat);
- some liquids can be penetrated inside the device;
- the feeder, the wrap or other parts of the instrument are damaged, broken or lacking;
- the functionality of the instrument appears altered.

To the goals of the safety it recommends him not to operate with accessories (es. you manipulate and feeder) different from the furnished ones as endowment of base.

The frequency of maintenance, of functional control and verification of correspondence to the safety norms EN60601-1 for the medical devices, to perform him with secur-tester, it is annual. The useful life of the tool is guaranteed only from the firm if such maintenance is regularly effected.

NOTE WELL: it is recommended to make the controls be performed only by New Age Italia; the device can be sent directly to the laboratories of assistance or delivered to the retailer where it has been purchased.

Assistance center:

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Cap.9 - WARNINGS

- Do particular attention in the employment of the solenoids not to compromise the effectiveness of the treatment.
- Use the instrument only with electric structures conforming to the actual safety Norms.
- The instrument has degree of protection IP20 (see Chap. "Technical features") and do not use it close to liquids, because it's not protected from their entry.
- Do not use close to cellular telephones (maintain at least one meter of distance).
- To operate close (less than 1 meter) to an instrument with short waves therapy or microwaves, because it can produce instability in the emission.
- Don't simultaneously connect the patient with the MAGNETER PRO and with a surgical instrument HF, to avoid dangers for the patient and for the instrument.
- The device works according to its specifications if the environment is maintained to a temperature between the 5° and the 40° C and with damp inferior to the 80%. The same conditions must be maintained during the transport and the store.

- In case of malfunctions and breakdowns, it is opportune to exclusively send the device to the house builder.
- It's recommended not to operate in proximity of inflammable substances.
- Don't use gel and different accessories from those furnished in endowment.
- It's important to inform the patient on the type of feeling to perceive during the therapy, to immediately intervene or interrupt the session switching off the device or removing the solenoids, in case of different or uncorrect perceptions.
- If the power or its regulation cause elevated heating or pain in the treated zone it is necessary to immediately reduce the intensity of stimulation or eventually interrupt the application.
- Keep away from children.

Cap.10 - TECHNICAL FEATURES

Power supply

Power supply: power mains PRI: 230V~50 Hz

- Output features

Max power intensity (P): 200 Gauss for solenoid

300 Gauss for pillow

300 Gauss for band

400 Gauss for the mattress

Frequency (f): 1-100 Hz

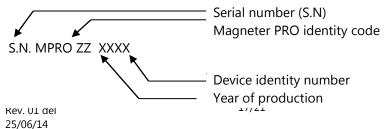
Frequency modulation: continue Modulation wave form: rectangular

- Other features

- ➤ Dimensions: 225x170x120h [mm]
- ➤ Weight: about 1 [Kg]
- ➤ Class: I Tipo: BF
- ➤ Classification to liquids entry: IP20
- Safety in presence of inflammable anaesthetic gas: it's not of AP or APG cathegory
- > Device for working: continuous

Built according to the rules:

- EN 60601-1 (1998) Electromedical devices: Safety General rules
- EN 60601-1-2 (1998) Collateral norm: Electromagnetic compatibility Prescriptions and tests
- EN 60601-1-4 (1997): Collateral rule: electromedical programmable systems
- EN 60601-2-5 (2001) Electromedical devices: particular rules for the safety of the equipments of magnetotherapy
- IEC 601-2-10 (1987) Electromedical devices: particular rules for the safety of neuromuscular stimulators.
- CEI 62-84 (1997) Symbols for electromedical devices
- EN60601-1-1 (2002): Collateral rule: Safety prescriptions for electromedical systems.



Cap.11 - ENDOWMENT OF BASE / ACCESSORIES

Endowment of base

Device Power supply cable N.1 rubber solenoids couple N.2 elastic bands Instructions

- Accessories and consumed materials

Rubber solenoids couple Elastic bands Band solenoid with welcro cm 91,5x20,5 (open) Cushion solenoid cm 45x45 Carpet solenoid cm160x60

Cap.12 - BIBLIOGRAPHY

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DECLARATION OF CONFORMITY

The undersigned New Age Italia s.r.l. Via De Brozzi,3 – 48022 Lugo (RA) Tel: +39 0545 32019 – Fax +39-0545 369028

in the person of its legal representative, Mr. Barnabè Manuel declares that

the following class IIa device:

Brand Name: New Age Italia

Model: Magneter PRO

is a MADE IN ITALY product, made by New Age Italia s.r.l.;

is up-to the requisites prescribed in EEC Directive 93/42CEE modified by Directive 2007/47CE concerning health regulations and absorbed by Legislative Decree no. 37 dated 25/01/2010;

that the procedure for the evaluation of conformity described in Annex II to the above-mentioned Directive has been duly performed;

and that the following harmonized standards have been applied:

EN 60601-1: 2007

EN 60601-1-2: 2003

EN 60601-1-4: 1997

EN 980-2003

EN 1041:1998

The notified authority no. 0476 has, in virtue of the certificate MED26017, issued a permission to apply a CE conformity mark to the above-mentioned regulations prescribed in EEC Directive 93/42CEE and modified by Directive 2007/47CE absorbed by Legislative Decree no. 37 dated 25/01/2010.

Lugo, 03/11/2010

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