ENG Operating instructions

Iris Magneton MF

Wellness therapy

Edition 09 / 2012

BIEGLER
MEDIZINELEKTRONIK

These operating instructions constitute an accessory of the device. They must therefore be kept in a suitable place near the device and kept with the device. If the device is given to other users, the operating instructions must be included with the device.

For proper and safe use of the device, it is essential that the operating instructions, including the warnings and safety instructions, are read and observed before using the device.

If a malfunction is suspected, the device must be switched off immediately. Suitable warning signs should be attached to the device to ensure that it cannot be used before necessary service and repair works have been carried out.

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1 WARNINGS AND SAFETY INSTRUCTIONS

- Before using the device, ensure that the device and its applicators are not close to sensitive medical or electronic devices.
- For hygienic reasons, the patient must only be exposed to magnetic field therapy when clothed.
- Before therapy starts, all electronic objects or those that could be influenced by the magnetic field must be removed so as to avoid damage (e.g.: watch, credit card, mobile phone etc.).
- The device and applicators must not be covered during operation and rest period, as this prevents heat from escaping.
- The 343rd MFTGV "Regulations on magnetic field therapy devices for own use" must be observed in Austria. According to these regulations, magnetic field therapy devices may only be given to amateurs for own use on the basis of a medical prescription.
- The device must only be used in areas in which the electrical installations are in accordance with the standards and regulations in force.
- Unplugging the mains plug is the only safe way to disconnect from the mains power supply.
- The device must not be used in rooms with potential explosion hazard.
- Persons and services authorized by BIEGLER must carry out repairs and modifications on the device.
- The device must not be immersed in liquids or sterilized with steam or by thermochemical methods.
- All extraneous influences such as electromagnetic waves or high temperatures are to be kept to a minimum.
- Avoid exerting force on the device or its accessories.
- If the device is dropped, damaged due to force, or functions in a way other than described in the operating instructions, stop using the device immediately and return it to the service center.
- Periodic technical safety inspections must be carried out as described in the "Periodic inspections" section.

CONTRAINDICATIONS

Important:

The Iris Magneton wellness device is to be used exclusively for wellness applications.

Magnetic field therapy cannot replace medical treatment.

Treatment with magnetic field therapy devices can only be started after a proven medical diagnosis and relevant consultation.

Always obtain medical advice before using magnetic field therapy devices if you are taking medication of any kind.

This system may not be used by people with epilepsy, electronic implants (e.g. pacemakers), metal splinters or during pregnancy.

Always consult a doctor if you have a serious illness.

2 DESCRIPTION

2.1 GENERAL DESCRIPTION

As a result of its modular structure and progressive system architecture, Iris Magneton is suitable for the following wellness applications:

Please pay careful attention to the contraindications on page 5!

Each Iris Magneton is delivered with a universal chip card. Please refer to the "Program" list for its updated contents.

Program Number	Name
1	Introduction
2	Relaxation
3	Pacification
4	General Revitalization
5	Skin Revitalization
6	Insomnia
7	Jetlag
8	Muscle Building
9	Muscle Relaxation
10	Sport Balance
11	Sport Relax
12	Circulation
13	Bone Strength
14	Immune System
15	Harmonization

The following operating modes / therapy forms are currently available as options and can be saved on the patient chip card as required.

SIN Sinus, MSI Multi–Sinus, DRE saw tooth or triangle,

IMP impulses or square, AM 1-3 Sinus with amplitude scan

MUL Multi-resonance, mPST magnetic pulsed stimulated therapy and combinations (also refer to the list on page 27)

2.2 MATERIAL AND ACCESSORIES DELIVERED

Accessories are available according to requirements. Order numbers:

Complete Iris Magneton control unit with mat and cushion	PC 1010003
Coil mat for the entire body	FE 1004002
Coil cushion for local use	FE 1004001
Bar applicator for local use	FE 1004005
Body part coil for local use	FE 1004003

3 STARTING THE DEVICE

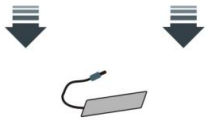
Observe the operating instructions! Users must thoroughly familiarize themselves with the contents of these instructions before putting the system in operation.

3.1 SETTING UP PROCEDURE

Insert the mains cable.

Insert the relevant chip card into the card reader until it clicks into place.

Insert coil mat and/or cushion (any Biegler applicator can be inserted into any socket).

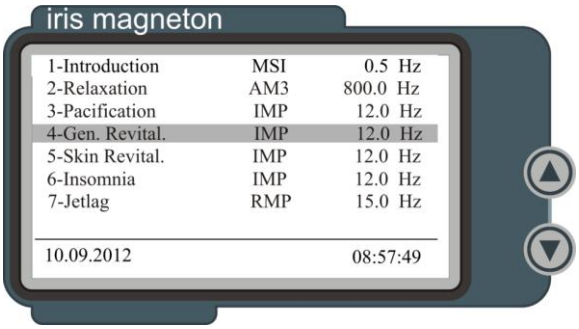


Switch on mains switch on the back of the device.

Once the device self-test is complete, the first applications are displayed on the screen. The first program is highlighted. This bar can be moved using the arrow keys. If the bar is on the last program position on the screen and you press the down arrow, you move to the next program position if other programs are available. If you want to go back to the previous programs, press the up arrow.

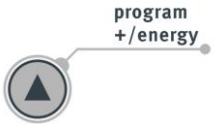
If an application is highlighted, therapy starts by pressing the start button. The end of the program is indicated by a sound alarm. The device ends the application automatically.

FIGURE 1



Selection: 04-General revitalization
DRE 13.8 Hz

Notes:
Program number 04
Application name General revitalization
Signal form or operating mode DRE
Frequency in Hz 13.8 Hz
Date and time

Press the buttons 

and 

to select the relevant program.

You can also use these buttons during the bipolar field type therapy to set the energy between 1 and 200% and between 1 and 100% for the single pole field type therapy.

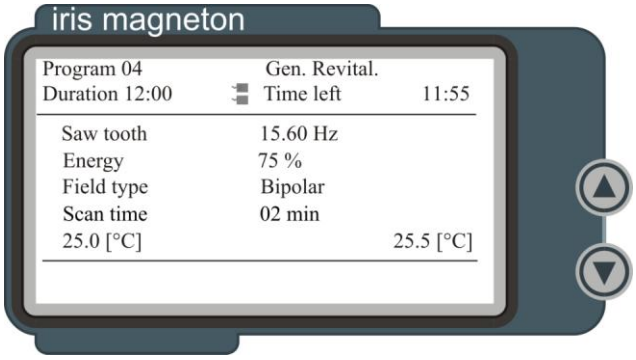
Press the button 

to start therapy.

The following data is displayed on the screen to the patient depending on the program selected.

- Program number - then the application name
- Signal form / operating mode with the current frequency (between 0.1 Hz and 15000 Hz)
- Energy in % (states the relative magnetic flux. 1% is the minimum value and 200% the maximum)
- Field type bipolar or single pole (bipolar = alternating field, single pole = alternating field with constant field)
- Scan time with value (the duration of a complete amplitude change or of pulse packets)
- Scan stating the upper and lower frequency
- Follow-up program with stop or program number with name
- Duration (minutes : seconds) and remaining time (minutes : seconds)

FIGURE 2



Selection: Program 04 Gen. revital.

Notes:

Program number	04
Application name	Revitalization
Duration	Time in minutes and seconds for the selected program
Remaining time	Time in minutes and seconds for the remaining treatment time
Applicator	The number of inserted applicators is shown symbolically between duration and remaining time (e.g. above: 2 applicators)
Saw tooth 16.45 Hz	Signal form stating the current frequency
Energy 150%	Relative value with current magnetic flux in %
Field type bipolar	Alternating field
Scan time 2 min	The application starts at 13.8 Hz, rises in 1 minute to 35.4 Hz and falls after another 1 minute to 13.8 Hz
Scan 13.8 - 35.4 Hz	13.8 is the lower and 35.4 Hz is the higher frequency (alternatively visible with Scan time)
Temperature 25.0 °C	The temperature of both applicators is measured
Follow-up program	The stated harmonization application (harmonization) is added to the active program and runs automatically. If the Stop follow-up program is displayed on the screen, the application ends automatically after the program has ended.

As already described above, the energy can also be set during therapy.

Press the button 

to pause the therapy ahead of time.

3.2 ON-SCREEN INDICATORS

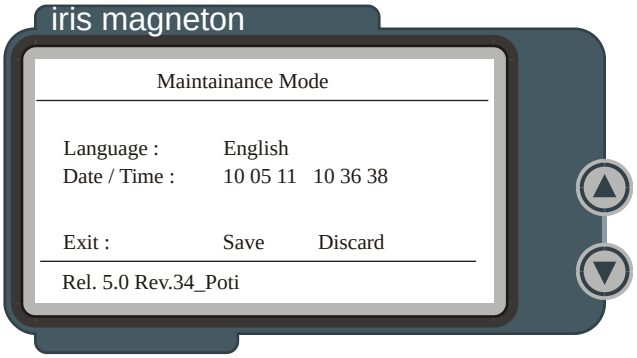
The device has a self-test and diagnosis mode. The following indicators are used for localization.

1. Device self-test

The device self-test is carried out by Iris Magneton immediately after switching on the main switch. ►

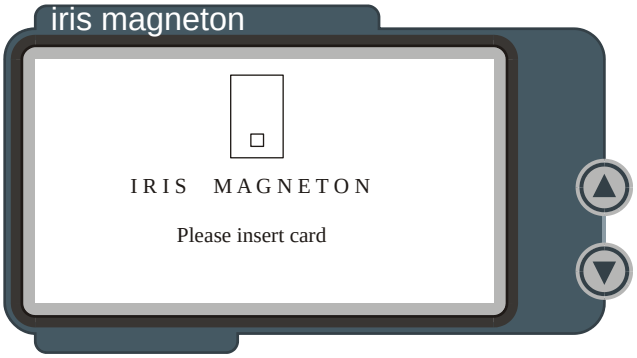
2. Maintenance mode

If you press the Stop and Minus buttons at the same time, the program jumps to Maintenance Mode. (Language choice, date and time setting)
Minus button = Save ►



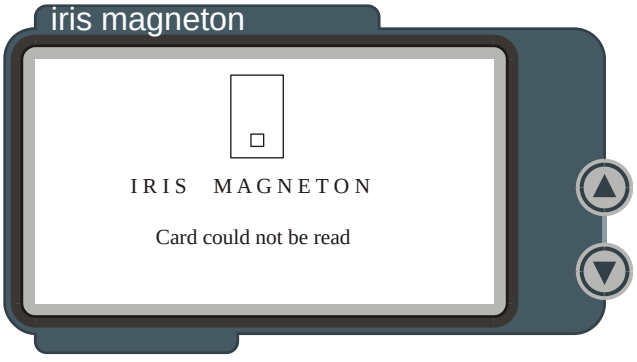
3. Please insert card!

If no chip card has been inserted, the user is requested to insert the relevant chip card into the card reader. ►



4. Chip card

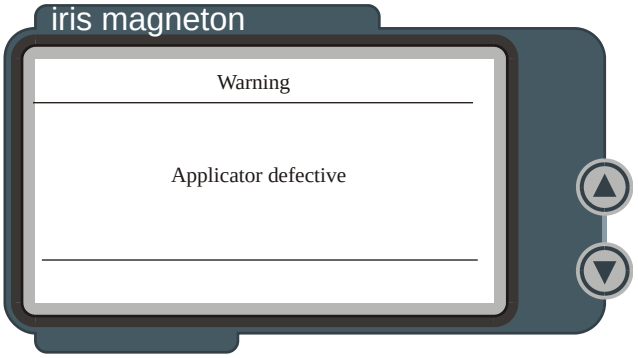
If an error occurs when reading the chip card, this is indicated to the user. ►



5. Applicators

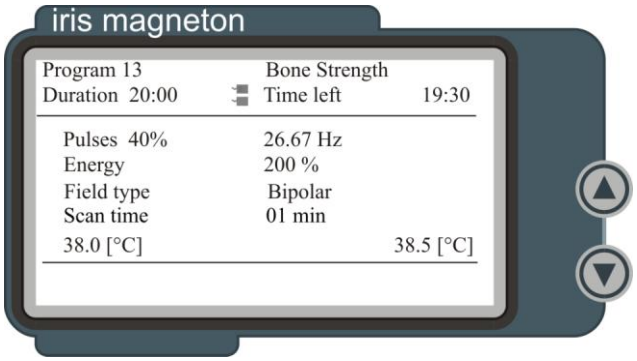
If you press the start button without inserting an applicator, the following text is displayed on the screen. ►

If there is a fault with the applicator, the following message is displayed. ►

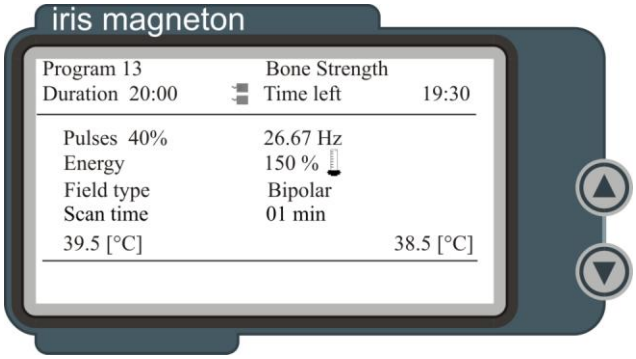


6. Applicators / device

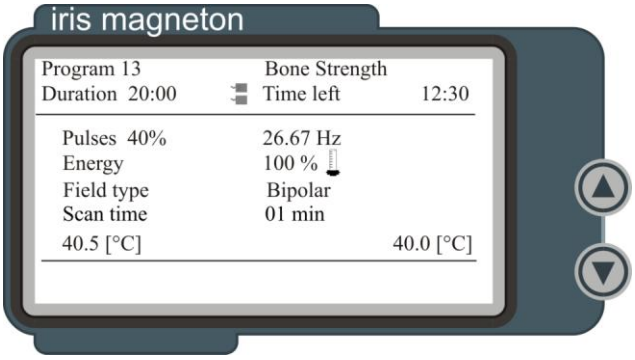
If the applicator's temperature is below 39 °C, the therapy runs at full power. ►



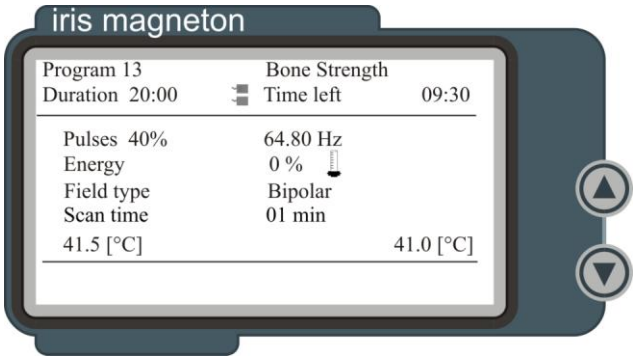
If the applicator's temperature is over 39.0 °C, the output is reduced by 25%. ►



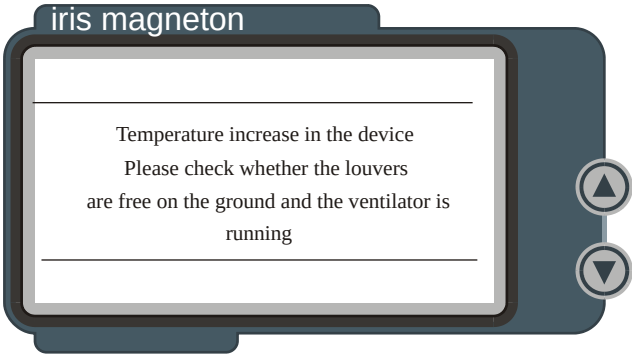
If the applicator's temperature increases further over 40.0 °C, the nominal power is reduced by 50%. ►



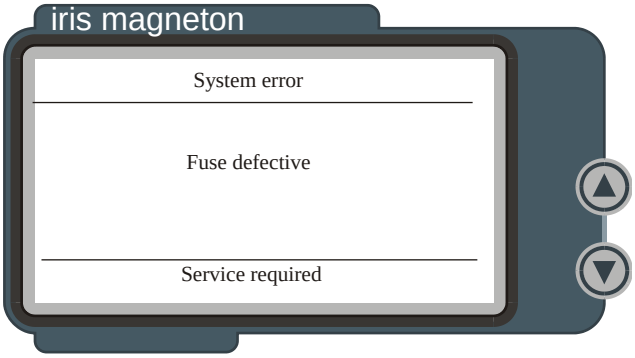
If the applicator's temperature reaches 41.0 °C, the power is switched off completely. When the applicator's temperature falls, the power increases again step by step. ►



If the temperature in the device increases, for instance due to covered louvers or a technical defect (ventilator), the following message is displayed alternating with the therapy screen. Simultaneously, the output power will be reduced to 50%. As soon as cooling takes place, the output increases again automatically. ►



A potential fuse failure on the device is indicated with the following text. ►



3.3 APPLICATORS

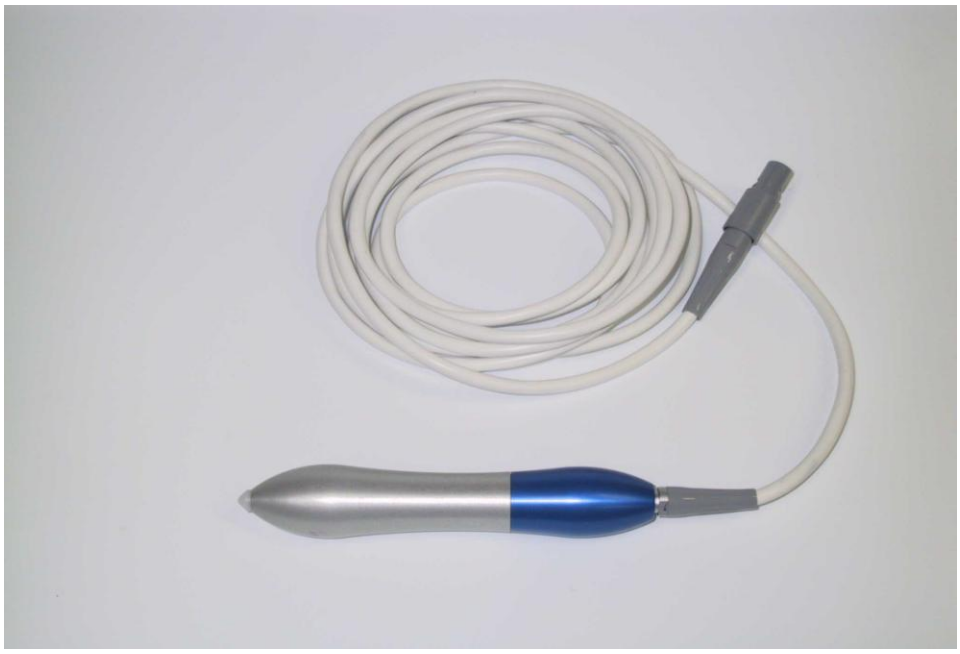
Mat: Whole body applicator

Recumbent position: Head at cable output

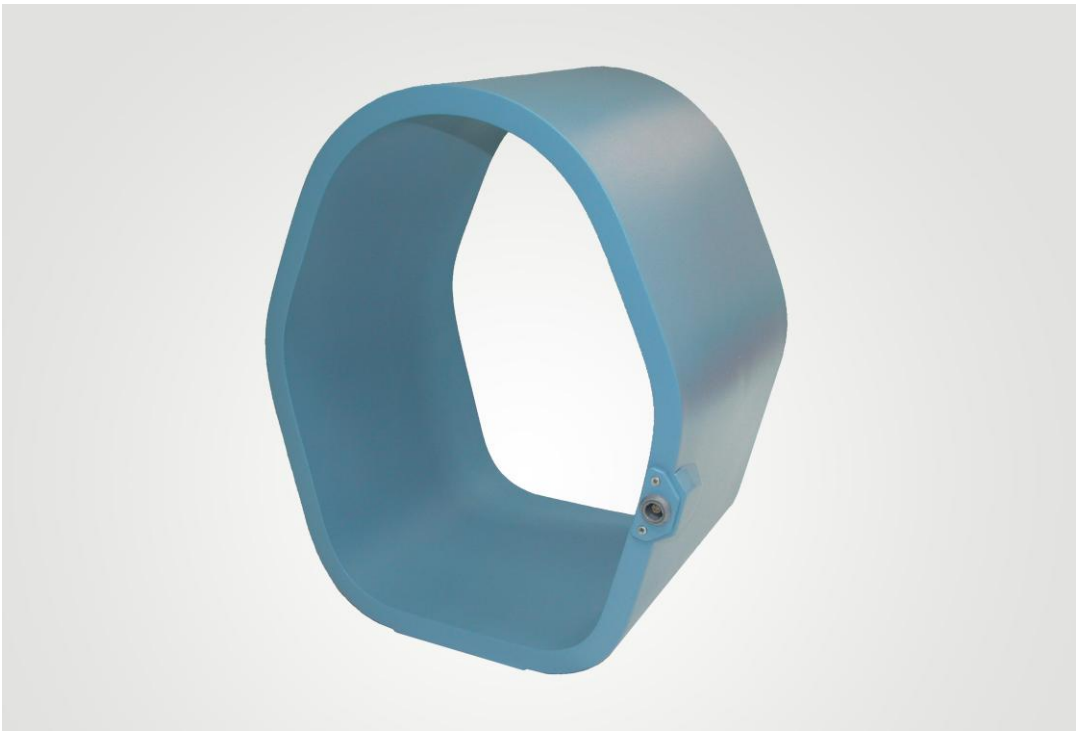
Flux: max. 1.2 mT at 100 Hz

Cushion: Applicator for local applications

- higher flux - max. 4mT at 100 Hz



Bar applicator: Special application
Small joints
Triple effect: electromagnetic max. 120µT / 100 Hz
mechanical – small vibrations
Light – LED Diode Λmax. 595 nm



Partial body coil: Joints - gonarthrosis, coxarthrosis
- Flux max. 1.5 mT at 100 Hz

4 MAINTENANCE

The Iris Magneton has been designed to be maintenance free. For long-term maintenance of quality and functional safety, we would like to ask you to bear the following points in mind:

- Always keep the device clean (see the "Cleaning and disinfection" section).
- Periodic technical safety inspections must be carried out as described in the "Periodic inspections" section.

5 CLEANING AND DISINFECTION

The device and its accessories must only be cleaned using a soft cloth with water-soluble, non-aggressive cleaning agents or special cleaning agents for plastics.

For the purposes of disinfection, only ready-made alcohol-based spray disinfectants must be used.

Important: Before cleaning or disinfection, the device must always be disconnected from the mains power supply.

6 PERIODIC INSPECTIONS

The periodic technical safety inspections (according to applicable local standards – e.g. EN 62353) must be carried out on the Iris Magneton and its accessories at least every 36 months, by persons authorized to carry out such inspections based on their training, knowledge and practical experience.

The fuse inserts must meet the values specified by the manufacturer (nominal current and switch off characteristics).

The safety labels on the device and its accessories must be easily legible.

The mechanical status of all components must permit an additional and safe use.

The control unit and its accessories must not have any dirt that could reduce safety.

Measuring the earth conductor resistance (target: < 0.3 Ω)

Measuring the replacement device leakage current (target: < 1.0 mA)

Results of the periodic inspection along with the date and the testing station are to be entered on the reverse side of the instructions for use.

Important: If a malfunction is discovered during the periodic inspection, suitable warning signs should be attached to the device to ensure that it is not used before the required service and repair work has been carried out.

7 MANUFACTURER'S LIABILITY

The manufacturer and the supplier of the device reject any liability if:

- the device is not used in accordance with the directions for use
- the user is not sufficiently informed about the functioning of the device corresponding with the directions for use and the safety instructions
- repairs are not performed exclusively by the manufacturer or by persons and service centers expressly authorized by the manufacturer
- the device is used at locations where the electrical installations do not correspond with the relevant national standards
- original spare parts are not used or the maintenance interval is not complied with.

Disposal of the device and its accessories is to be carried out in accordance with the applicable local regulations.

8 WARRANTY CONDITIONS

The manufacturer guarantees that all material and manufacturing defects that arise within 24 months from date of purchase will be repaired free of charge. Claims are only accepted under the following terms:

- The manufacturer and/or supplier is informed immediately of the fault for which the warranty claim is being made.
- The instructions of the manufacturer and/or supplier regarding storage or return of the device are complied with.
- Presentation of a legible copy of the invoice for the device concerned, showing the date of purchase.
- An exact description of the defects or malfunctions identified by the customer.

The manufacturer's warranty will be void if it is found that the maintenance,

disinfection and inspection instructions have not been followed according to the operating instructions, the device has been damaged by force or operating error or has been used in any way contrary to the operating instructions and safety instructions. The warranty will also be void if original Biegler materials were not used as replacement parts, or measures for repair were undertaken by persons not authorized by the manufacturer or supplier.

If the manufacturer is required to meet a warranty claim in accordance with these terms, the customer shall bear the costs and risks of transport of the device from and to the place of use.

The manufacturer and/or supplier shall under no circumstances assume liability for slight negligence. The compensation for lost earnings and profits is likewise excluded.

9 RETURN OF DEVICES

Devices must be carefully cleaned and disinfected before being placed in the original packaging for returning.

If the original packaging is no longer available, the product has to be suitably packaged for the method of dispatch.

10 MANUFACTURER'S DECLARATION

Iris Magneton is a wellness therapy device and conforms to:

- 2006/95/EC Low Voltage Directive (LVD)
- Directive 2004/108/EC Electromagnetic Compatibility
- EN ISO 62233:2008 Measurement methods for electromagnetic fields of household appliances and similar apparatus with regard to human exposure to electromagnetic fields

This is documented through the CE mark.

11 ELECTROMAGNETIC COMPATIBILITY

Table 201 – Guidelines and manufacturer's declaration – Electromagnetic emissions - for all DEVICES and SYSTEMS (refer to section 6.8.3.201 a) 3))

<table>
<tr><th colspan="3">Guidelines and manufacturer's declaration – Electromagnetic emissions</th></tr>
<tr><td colspan="3">The IRIS MAGNETON is intended for use in the environment specified below. The customer or the user of the IRIS MAGNETON should ensure that it is used in an environment of this type.</td></tr>
<tr><th>Transient emission measurements</th><th>Compliance</th><th>Electromagnetic environment - guidelines</th></tr>
<tr><td>RF emissions acc. to CISPR 11</td><td>Group 1</td><td>The IRIS MAGNETON only uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.</td></tr>
<tr><td>RF emissions acc. to CISPR 11</td><td>Class B</td><td rowspan="3">The IRIS MAGNETON is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Emission of harmonics acc. to IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions acc. to IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

Table 202 – Guidelines and manufacturer's declaration – Electromagnetic immunity for all EQUIPMENT and SYSTEMS (see Section 6.8.3.201 a) 6))

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The IRIS MAGNETON is intended for use in the electromagnetic environment specified below. The customer or the user of the IRIS MAGNETON should ensure that it is used in an environment of this type.			
Immunity tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Electrostatic discharge acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Fast transient electrical bursts acc. to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surges acc. to IEC 61000-4-5	± 1 kV differential mode voltage ± 2 kV common mode voltage	± 1 kV differential mode voltage ± 2 kV common mode voltage	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines acc. to IEC 61000-4-11	< 5% U_T (>95% dip in U_T) for ½ period 40% U_T (60% dip in U_T) for 5 periods 70% U_T (30% dip in U_T) for 25 periods < 5% U_T (>95% dip in U_T) for 5 seconds	< 5% U_T (>95% dip in U_T) for ½ period 40% U_T (60% dip in U_T) for 5 periods 70% U_T (30% dip in U_T) for 25 periods < 5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the IRIS MAGNETON requires continued operation during power mains interruptions, it is recommended that the IRIS MAGNETON be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field acc. to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

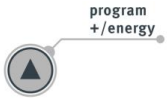
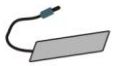
Table 204 – Guidance and manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT or SYSTEMS that are not LIFE-SUPPORTING (see Section 6.8.3.201 b))

Guidelines and manufacturer's declaration – Electromagnetic immunity			
The IRIS MAGNETON is intended for use in the electromagnetic environment specified below. The customer or the user of the IRIS MAGNETON should ensure that it is used in an environment of this type.			
Immunity tests	**IEC 60601-test level**	**Compliance level**	**Electromagnetic environment - guidelines**
Conducted RF disturbance variables acc. to IEC 61000-4-6 Radiated RF disturbance variables acc. to IEC 61000-4-3	3 V 150 k to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the IRIS MAGNETON, including cables, than the recommended safety distance calculated through the equation applicable to the frequency of the transmitter. **Recommended protection distance:** $d = 1.17\sqrt{P}$ $d = 0.35\sqrt{P}$ for 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ for 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *k* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be theoretically predicted with accuracy. An electromagnetic site survey should be considered to assess the electromagnetic environment with respect to the fixed RF transmitters. If the measured field strength in the location in which the IRIS MAGNETON is used exceeds the applicable RF compliance level above, the IRIS MAGNETON should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IRIS MAGNETON. [b] Over the frequency range from 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEMS that are not LIFE-SUPPORTING (see Section 6.8.3.201 b))

Recommended separation distances between portable and mobile RF communications equipment and the IRIS MAGNETON			
The IRIS MAGNETON is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the IRIS MAGNETON can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IRIS MAGNETON as recommended below. This distance depends on the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Safety distance according to the frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.69	1.11	2.21
100	11.67	3.50	7.00
For transmitters rated at a maximum output power not listed above, the recommended safety distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter's manufacturer. NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

12 SYMBOLS

CE	Certifies compliance with the Low Voltage Directive 2006/95/EC
	Adhere to the directions for use
SN	SN: Series number
	Do not dispose of this product as unsorted municipal waste
	To increase the power division or to "scroll up"
	To reduce the power setting or "scroll down"
	Used to start the therapy
	Used to interrupt therapy ahead of time in an emergency
	Insertion direction and position of the chip card
	Applicator sockets (choice of one or two applicators possible)

13 OPERATING AND STORAGE CONDITIONS

Permitted environmental conditions for operation:

Temperature	10 – 30 °C
Relative humidity	30 – 75%
Air pressure	700 – 1060 hPa (mbar)

Permissible environmental conditions for transport and storage:

Temperature	-10 – 104.00 ºC
Relative humidity	30 – 75%
Air pressure	700 – 1060 hPa (mbar)

If the environmental conditions for operation do not match the environmental conditions for transport or storage, wait for 12 hours before using the device.

Values higher or lower than the ranges specified above may cause damage to the device or its accessories.

14 TECHNICAL DATA

Device	Magnetic field wellness therapy
Type designation	Iris Magneton MF
Voltage	230 V / 50-60 Hz
Power consumption	max 80 VA
Protective class	I
Type	BF
Humidity protection	without special safety
Guards	primary 2 x T500mA secondary 3x T1.25A
Device dimensions	w x d x h 305 x 280 x 125 (mm)
Device weight	3 kg
Classification	IIa
Mat dimensions	w x d x h 1780 x 610 x 35 (mm)
Cushion dimensions	w x d x h 435 x 315 x 35 (mm)
Operating mode	Ongoing operation
Signal form basis	Sinus Saw tooth Rectangle
Energy	single pole - max. energy 100% bipolar - max. energy 200%
Frequency	0.1 Hz - 15 000 Hz

15 MANUFACTURER AND SALES

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Space for notes

Prg. No.	Name	Freq.	Dur.	Energy	Signal	Pol.	Start	Stop	Period.	Follow-up program
1	Introduction	7.8 Hz	8min	1%	DRE	bipol	1.0 Hz	223.0 Hz	2min	stop
2	Relaxation	12.0 Hz	16min	60%	MUL	bipol	12.0 Hz	37.0 Hz	1min	Harmonization
3	Pacification	12.0 Hz	16min	25%	SIN	bipol	8.0 Hz	12.0 Hz	16min	stop
4	Gen. Revitaliz.	24.6 Hz	12min	75%	DRE	bipol	13.8 Hz	35.4 Hz	2min	stop
5	Skin Revitaliz.	100.0 Hz	8min	10%	MSI	bipol	100.0 Hz	15,000.0 Hz	560ms	Harmonization
6	Insomnia	6.0 Hz	20min	10%	SIN	single pole	0.3 Hz	6.0 Hz	10min	stop
7	Jetlag	6.0 Hz	20min	10%	SIN	bipol	0.3 Hz	6.0 Hz	10min	stop
8	Muscle building	33.0 Hz	20min	150%	MSI	bipol	7.0 Hz	33.7 Hz	70ms	stop
9	Muscle relax.	8.0 Hz	20min	60%	MUL	bipol	8.0 Hz	37.0 Hz	1min	stop
10	Sport Balance	999.0 Hz	16min	90%	DRE	bipol	0.1 Hz	999.0 Hz	8min	Harmonization
11	Sport Relax	220.0 Hz	20min	150%	MSI	bipol	0.1 Hz	220.0 Hz	70ms	stop
12	Circulation	51.0 Hz	16min	150%	MSI	bipol	0.5 Hz	51.0 Hz	70ms	Harmonization
13	Bone Strength	100.0 Hz	16min	200%	IMP	bipol	12.0 Hz	100.0 Hz	1min	Harmonization
14	Immune System	223.0 Hz	16min	100%	DRE	bipol	1.0 Hz	223.0 Hz	1min	Harmonization
15	Harmonization	3.0 Hz	4min	25%	SIN	bipol	0.0 Hz	0.0 Hz	0min	stop