PEMI

Portable Electro Magnetic Induction

OPERATING INSTRUCTIONS

Distribution, Sales & Support
Pure Wave Holdings LLC
1014 Gateway Boulevard, Boynton Beach, Florida 33426
Telephone: 561-965-7777 · E-Mail: info@purewavenow.com

Manufacturer:
gbo Medizintechnik AG
Kleiststraße 6 · D-64668 Rimbach

NOTES IN ACCORDANCE WITH EC-DIRECTIVE AND MEDICAL DEVICE DIRECTIVE (MDD)

The PEMI is a powered magnetic field therapy device of protection class **I**.

The device is in accordance with the EC directive for medical devices (93/42/EWG) and therefore carry the CE sign with the registration number of the notifi ed body for medical devices. The according graphical symbol is placed on the type plate.

According to the MDD, The **PEMI** is a class IIa device.

The manufacturer is only responsible for the safety, operational reliability and functionality of the device if:

- the device is used in accordance with the operating instructions;
- the electrical installation of the location where the device will be used meets the respective current requirements of electrical safety;
- the device is not used in hazardous environments and humid locations;
- mountings, enhancements, re-adjustments, modifications or repair works are carried out only by personnel authorized by the manufacturer;
- the operator regulation of this EC directive is observed within the scope of MDD.

Technical support may be obtained by the manufacturer, dealers or service authorized by the manufacturer. The product's duration of life as scheduled by the manufacturer is 10 years.

The **PEMI** is an electronic device. For their disposal the according regulations for electronic devices have to be observed. Incidentals have to be disposed with residual waste.

On request, the manufacturer will provide you with further technical descriptions for all repairable parts of the device, such as circuit diagrams, spare parts lists, and adjustment instructions as far as these are necessary for the qualifi ed technical staff of the operator.

Comments on electromagnetic compatibility (EMC)

Medical, electrical devices are subject to special precautions concerning the EMC. They must be installed and operated according to the EMC-advice given in the accompanying documents. In particular medical, electrical devices may be infl uenced by portable and mobile RF-communication devices.

The manufacturer guarantees the conformity of the unit with the EMC-requirements only when using accessories which are listed in the EC declaration of conformity. The usage of other accessories my cause an increased emission of electromagnetic disturbances or may lead to a reduced electromagnetic immunity.

The unit must not be arranged physically close to other devices or stacked with other devices. If such an order is necessary nevertheless, the unit must be observed in order to check it for the intentional operation.

You find more EMC-comments in the chapter "Warnings and Safety Precautions" of this manual as well as in the Technical Information on the next two pages.

NOTES IN ACCORDANCE WITH EC-DIRECTIVE AND MEDICAL DEVICE DIRECTIVE (MDD)

In accordance with the EMC-regulations for medical products we are obliged by law to provide the following information.

Guidance and manufacturer's declaration – electromagnetic emissions

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions, CISPR 11	Group 1	The equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class B	The equipment 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.
Harmonic emissions, IEC 61000-3-2 (*)	Class A	
Voltage fluctuation/flicker emissions, IEC 61000-3-3 (*)	Complies	

(*) Note: For devices with a power consumption between 75 W and 1000 W only.

Guidance and manufacturer's declaration – electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601 - test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD), IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative h umidity should be at least 30%.
Electrical fast transient/burst, IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	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, IEC 61000-4-11	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles (60% dip) 70% U_τ for 25 cycles (30% dip) <95% U_τ for 5 s (>5% dip)	<5% U_τ for ½ cycle (>95% dip) 40% U_τ for 5 cycles (60% dip) 70% U_τ for 25 cycles (30% dip) <95% U_τ for 5 s (>5% dip)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: U_τ is the a.c. mains voltage prior to application of the test level.

NOTES IN ACCORDANCE WITH EC-DIRECTIVE AND MEDICAL DEVICE DIRECTIVE (MDD)

Guidance and manufacturer's declaration – electromagnetic immunity

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

Immunity test	IEC 60601- test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF, IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	3 V_{eff}	$d=1.2\sqrt{P}$
Radiated RF, IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d=1.2\sqrt{P}$ for 80 MHz to 800 MHz $d=2.3\sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
			Interference may occur in the vicinity of equipment marked with the following symbol:

Recommended separation distances to portable and mobile RF communication equipment

The equipment is intended to be operated in an electromagnetic environment, where radiated RF interference is controlled. The user can help in avoiding interferences by means of meeting minimum separation distances between portable and mobile RF communication equipment (transmitters) according to the maximum output power of the communication equipment.

Rated power of the transmitter (W)	Separation distance according to the tranmission frequency (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2,5 GHz $d=2.3\sqrt{P}$
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

CONTENTS

Chapter 1	describes the device's basic characteristics and offers a brief introduction into its operation.
Chapter 2	explains the device's setup and initiation. Essential settings are described.
Chapter 3	describes all of the device's functions and their operation.
Chapter 4	states indications about the use of applicators and accessories.
Chapter 5	explains how to carry out the therapies.
Chapter 6	lists possible failures, their indication as well as their possible causes.
Chapter 7	states indications of safety-related checks according to the MDD as well as routine maintenance.
Chapter 8	lists possible contraindications of Therapy, in addition to advices for avoiding hazards.
Chapter 9	states all of the device's relevant technical data.
Chapter 10	depicts the device's scope of supply and further accessories including the corresponding part numbers.
Chapter 11	Index

1.1 INTENDED USE

The Quantron Resonance System is the result of more than 20 years of fundamental research by leading international scientists. A qualitative breakthrough has been achieved with this system in the domain of magnetic fi eld therapy, placing this therapy on a sound scientifi c basis, which will ensure its place in medicine.

The PEMI, in short, serves for therapy and has proven successful in many indications even without further pharmaceutical therapies.

It supports the cell vitalization as well as the cell metabolism through precise ion transport. This process activates the whole metabolism, stabilizes the immune defense and improves the cell regeneration, thus naturally strengthening weakened body functions.

According to intense international investigation and users' journals no harmful side effects could be located to date (since 1993 about 200,000 devices have been field tested).

The method is internationally patented (patent no. EP 0594 655).

Through the applicators the control unit create a low frequency, variable,vibrant magnetic field of the body's frequency pattern with a precisely defined wave shape. The intensity/frequency is adapted according to the vital parameters and specific to the biological frames of the cell structures to be treated as indicated. Since the individual electromagnetic hypersensitivity varies depending on the patient's health and his blood's acidity, the magnetic field intensity may be altered to achieve the ideal effect. The magnetic field intensity must be explicitly chosen via operation.

The **PEMI** works with magnetic field intensities up to 40 micro Tesla and thus lies below the WHO limit. For comparison:

Highest PEMI intensity	**40 µT**
Terrestrial magnetic field	**50 µT**
WHO limit	**100 µT**

On this scale the therapy's intensity may be adapted to the current patient's state of health manually.

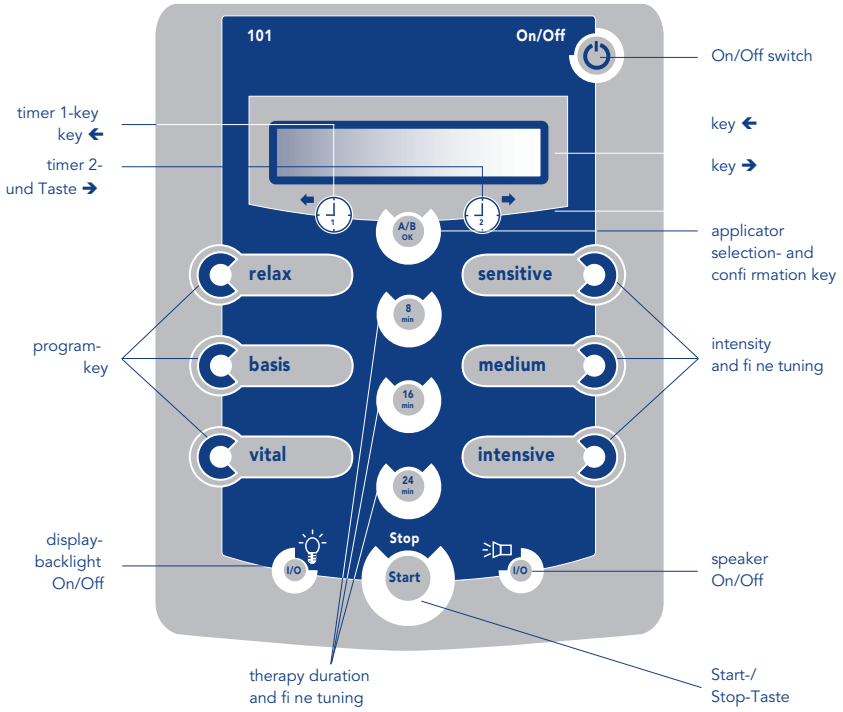
The treatment time can be perfectly adapted to each person's individual needs. After an individually set time (1-60 minutes) the control unit automatically switches the magnetic field off.

The positive physiological effects which are started through the use of the **PEMI** magnetic field usually take place within 8 hours (healthy organism). The regular recommendation is a treatment in the morning, in the midday and in the evening.

The **PEMI** is a "Home Device". With this device it is possible to carry out therapies with the Basis, Vital and Relaxed programs without a chip card.

1.2 VIEW OF PEMI

1.3 DESCRIPTION OF THE KEYS



1.4 DESCRIPTION OF THE DISPLAY

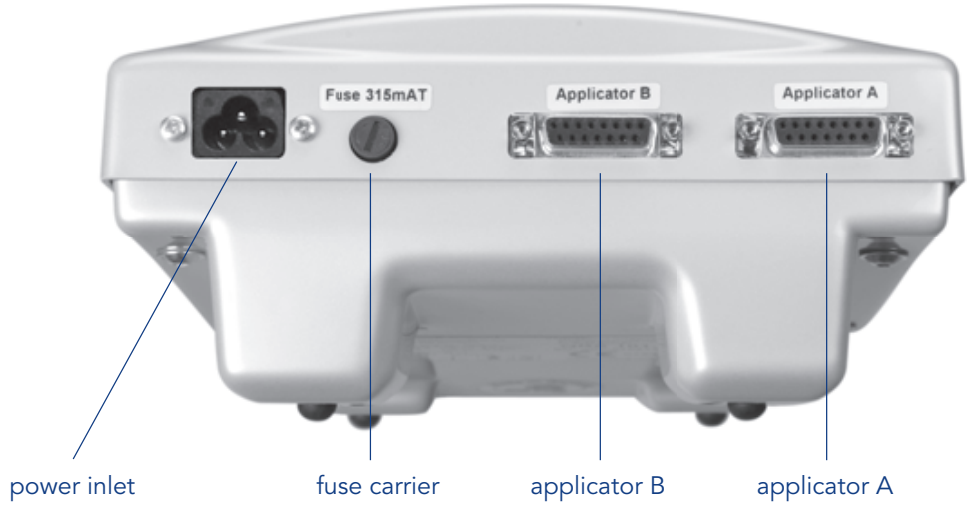
The **PEMI** has a 16-digit display. Their contents depend on the current device function. For detailed information please refer to chapter 3, Functional Characteristics.

Example:

17:34 current time

2.1 TRANSPORT AND ASSEMBLY

The image above shows supply and fuse on the device's upper quoin.



The **PEMI** is mobile, mains-powered appliances that shall not be moved during intended operation. Any location on a level surface is suitable. The devices should not be placed in front of a heater or radiator (leave approx. 1 m clearance). There are no further requirements concerning wall distance or ventilation.

The device meets the requirements DIN/VDE 0750, EN 60601-1, EN 60601-1-2 and belongs to the protection class **I**. It is part of class IIa within the scope of the Medical Device Directive.

ATTENTION

The unit is not designed to be operated in places with the inherent risk of explosions. If it is used in dangerous areas of anaesthesia departments, the possibility of an explosion cannot be excluded.

ATTENTION

In order to prevent the risk of electric shock, the unit must be connected only to a supply network with protective conductor.

If the patient and/or an applicator(-cable) is directly exposed to a radiator of a medical device for high frequency heat therapy, the damage of the device or danger to the patient cannot be excluded. As a rule, a distance of 3 m is suffi cient.

2.2 POWER SUPPLY

The **PEMI** is intended to be connected to mains voltages of 115 V or 230 V and a mains frequency of 50 or 60 Hz. Within this range there is no need for further change or alteration on the devices.

Connect the device's power jack to a grounded socket by means of the attached power cord.

NOTE

The PEMI allows a time-controlled operation (Timer Mode). In this case the device starts automatically at a predefined time, selected either via key programming (see 3.4, Timer Mode) or via chip card (see 3.3, Chip Card Mode). This functionality is available since the control unit permanently surveys its time-controlled routines in the so-called stand-by mode, even if it has been turned off via the on/off switch. It is thus mandatory that the control unit is continuously connected to the power supply through its mains cord.

Please do not remove the mains cord from the device and never connect the device to the power supply via a switched supply (power strip).

2.2.1 MAINS FUSES

Mains fuses serve to protect the device from further damage in case of a serious error. Mains fuses are not subject to aging or wear. Thus, a defect mains fuse always indicates an internal device error.

If the device does not show any function after being switched on (display stays dark), first make sure that the socket and mains cord conduct line voltage. Should this be futile, please check the mains fuse and replace it by a **new fuse with the same values** if it is defect.

The mains fuse is located in the fuse carrier as shown in the image above. The fuse is accessible by gently pressing the fuse carrier toward the device and turning it about 1/8th turn counter-clockwise.

ATTENTION

Please contact an authorized service partner in case of doubt after a defect fuse or after multiple defects.

2.3 CONNECTING THE APPLICATOR

Please connect the applicator(s) (pillow, mat, pen) to the 15-pole jack(s) (submin-D).

ATTENTION

The applicator's 15-pole jacks are provided with 2 thumb screws for attachment. Always hand-screw these into the stud bolts of the device's jacks. Never apply tools to tighten these screws.

2.4 TURNING ON THE DEVICE

- To switch on the device please press the - 

key.
- The illuminated display shows the following text

(V1.1 is the current software version's label and may change during the device's development cycle.)

- The device now performs an automatic function test. The display shows

- In case of grave errors the display shows an error code (see chapter 6, Troubleshooting).
- If everything works properly. The display will show

- If required please adapt application-specific settings (see chapter 3.1).
- The device is now ready for operation, it displays the last operating state and waits for your input.

NOTE

The PEMI comes with a time-out, turning the device off 8 minutes after not having been used (8 minutes after the end of therapy or 8 minutes after the last key-click). After this shutdown the device has to be restarted as described above.

3.1 BASIC FUNCTIONS

3.1.1 SELECTING THE APPLICATOR JACK

The **PEMI** is equipped with 2 jacks for 2 applicators (see image in chapter 2, Start of Operation). The physical identification for those 2 jacks are "A" (more to the side of the case) and "B" (almost in the center). 2 **PEMI** applicators may be attached to these two jacks. If 2 applicators are connected you may toggle the A/B button under the the led window to select applicator of choice.

All of the **PEMI** applicators are coded, they will identify the connected applicator's type. Therefore the display will not show the applicator's physical identification ("A" or "B") but the *descriptive*, identification ("mat", "pillow", "pen", "headphone", "glasses"). You may for example see the following display:

This display will be shown for 1.5 seconds before returning to the display of the operating mode.

You may switch to the respective other applicator by pressing the -key a second time while the above stated display is still visible.

NOTE

You may only switch to another applicator if 2 applicators are actually connected to the device. If only one applicator has been connected, it may be displayed but the cursor symbol (→) will not appear on the display.

3.1.2 TURNING THE DISPLAY LIGHT ON/OFF

The display's backlight may be turned on or off. If it is turned on it stays active during the whole operation. If it is turned off the display will light up for every operation (keys) but shuts down independently after one minute.

The backlight status may be checked by simply pressing the -key. Depending on its status one of the following displays will appear

or

These are always visible for 1.5 seconds before returning to the previous status. If the 

-key is being pressed while the display shown above is visible, the display light's status will be changed, i.e. the switched-on display light will be turned off and vice versa.

3.1.3 TURNING THE SPEAKER ON/OFF

The **PEMI** contains a speaker, called ‚beeper' in the following. This beeper signalizes a key-click, an error or the end of therapy with different sounds, each.

The key-click's acoustical echo, as well as the error signal may not be turned off, contrary to the acoustic signal at the end of therapy, since the latter disturbed some patients.

The end of therapy's signal status may be checked by simply pressing the 

-key. Depending on its status one of the following displays will appear

or

These are always visible for 1.5 seconds before returning to the previous status. If the 

-key is being pressed while the display shown above is visible, the end of therapy signal's status will be changed, i.e. the switched-on signal will be turned off and vice versa.

3.1.4 SETTING THE TIME

The **PEMI** possess a clock (battery backed RTC). To set the time the device's user interface offers you convenient menu guidance. You may reach the corresponding menu by

- turning the device off,
- pressing the 

-key and keeping this key pressed, while the device stays turned off and
- turning the device on via the 

-key.

You are now positioned in the menu to set the time and see the display (exemplary time)

The blinking cursor is positioned on the time's first digit, „1", as shown above. You may now change the time by increasing the digit positioned below the cursor by pressing the ➔-key, or to lessen it via the ←-key. The 

-key confirms the current value and goes to the next position.

After confirming the last time digit you automatically reach the menu to set the date. The corresponding display may look as follows:

Please proceed accordingly to set the date. By confirming the last date digit the menu is closed and the device will be started with its standard functionality.

NOTE

- **You may leave the menus to set time and date at any time by pressing the** 

-key. The currently made (incorrect) settings will then not be effective.
- **Only the German format for time and date are available, exclusively.**

3.1.5 SETTING THE NATIONAL LANGUAGE

You may operate The **PEMI** in different languages. To set the standard language the device's user interface offers you convenient menu guidance. You may reach the corresponding menu by

- turning the device off,
- pressing the 

-key and **keeping this key pressed, while the device stays turned off** and
- turning the device on via the 

-key.

You are now positioned in the menu to set the national language and see the display

You may now move the cursor  or  through the menu to chose among various languages. The abbreviation of the currently selected language is marked between brackets „[" and „]".

The following languages are available:

- DE German
- EN English
- FR French
- IT Italian
- ES Spanish
- SE Swedish

Pressing the 

-key confirms the current selection, leaves this menu and starts the device and its standard functionality.

NOTE

You may leave the menu to set the language at any time by pressing the der 

-key. The currently made (incorrect) setting will then not be effective.

3.1.6 RESTORE BASIC SETTINGS

Through a certain hot key you may restore the factory-made basic device settings.

You may restore these basic settings by

- turning the device off,
- pressing both 

and 

-keys **simultaneously, keeping them pressed, while the device stays turned off** and now
- turning the device on via the 

-key.

The **PEMI** will now reset to the following basic settings:

- display light OFF
- speaker ON
- language DE (German)

Basic settings

- therapy program relax
- therapy intensity medium
- therapy duration 8 min
- timer 1 OFF and 06:00 o'clock, "vital", "medium", 8 min.
- timer 2 OFF and 22:00 o'clock, "relax", "medium", 8 min.

3.2 PEMI-THERAPY

The PEMI therapy describes a mode of operation where a therapy is performed via simple key programming.

The operation is quite simple. For each therapy 3 parameters have to be defined:

- the therapy program (relax, basis or vital),
- the therapy intensity (sensitive, medium or intensive) and
- the therapy duration (8, 16 or 24 minutes).

You may select the stated parameters via control keys on the keyboard, arbitrarily. The therapy will be started after setting these parameters by pressing the 

-key.

Before starting the therapy you may typically see the following display:

Here, the current time is shown on the display's left side, the right side will alternately display the selected parameters for the therapy program, the therapy intensity or the therapy duration (e.g. therapy intensity, as depicted above).

After starting the therapy the display will change to the following typical view:

On the display's left side the current therapy program and selected therapy intensity are shown, alternately, the right side displays the remaining time until the end of therapy. The time (of day) and the pre-defined therapy duration are not displayed during the therapy.

NOTES

- **The PEMI therapy may not be performed if a chip card has been inserted into the card reader. Please remove the chip card, first.**
- **The therapy intensity „intensive" is not available for the therapy program "relax". The intensity "medium" will always be chosen, whenever the intensity "intensive" is being selected.**

3.2.1 FINE-TUNING OF INTENSITY AND THERAPY DURATION

When necessary the intensity and duration of the home-therapy can be fine tuned.

The therapy duration can be adjusted starting from any time key (8 min, 16 min, 24 min). Press the key for 2 sec. until the time in the display flashes and shows e.g. „16 MIN.". By pressing the key ← the time decreases in 1 minute steps and by pressing the key → the time increases in 1 minute steps.

The intensity can be adjusted starting from any of the intensity keys (sensitive, medium, intensive). Press the key for 2 sec. until the intensity in the display changes and shows e.g. „INT=05". By pressing the key ← the intensity decreases and by pressing the key → the intensity increases. The intensity range starts from „SE" (=sensitive) up to 1 -10. The therapy program „relax" allows only values up to 5.

After having reached the desired setting press the confirmation key („OK") and continue with normal operation.

3.3 CHIP CARD MODE (Currently Not Available)

A chip card contains an electronic prescription and will be given to you by your physician or therapist. The chip card may include up to 4 different therapies. All required parameters have been saved on the corresponding chip card.

To perform a therapy through chip card, please insert it into the card reader. At this point it is irrelevant whether or not **QRS®-101** resp. **QRS®-101 P** have already been turned on.

NOTES

- **The chip card depicts the direction in which it has to be inserted into the card reader. All other possible directions (3 out of 4) will cause the following error:**

- **If a chip card is inserted in the control unit all pressing of control keys to perform a home therapy will be ignored.**

After inserting a valid chip card you will alternately see one of the following 3 typical displays:

Here, the display's left side shows the current time, its right side displays the chip card's therapy index (therapy 1, 2, 3 or 4). If several therapies (max. 4) have been prescribed on the chip card, you may page within those with the keys  and  .

Following the therapy number the plain text therapy description will be displayed, for example:

This plain text has been chosen by your physician or therapist and serves solely as mnemonical description to identify the therapy. If this text is longer than 16 characters they will be displayed as a sort of ticker, as running text.

Following the therapy description the respective applicator jack will be displayed, finally. This is either the 

or 

.

Afterwards the display routine will repeat by presenting the time and therapy number..

The therapy is started via the 

-key.

After starting the therapy the display will show the following typical contents:

On the display's left side the current therapy number and therapy description (plain text) will be shown, alternately, on its right side you can see the remaining time until the end of therapy. The time of day, the corresponding applicator jack, as well as the preselected therapy duration are not displayed during the therapy.

NOTES

- **In making a chip card the maximum number of therapies to be performed by the patient will be prescribed. This credit of therapy units will be deduced by one after performing each therapy. As soon as this credit has been exhausted the corresponding therapy may no longer be selected from this chip card. Please contact your physician or therapist as soon as possible.**
- **If a PEMI control unit, containing a chip card with automatically, time-controlled start of therapy ("autostart" option), is taken out of the power supply and reconnected later, the device will switch on, independently, display the text „AUTOMODE" and switch off again. The same display appears if a chip card is inserted into a switched-off control unit.**

3.4 TIMER MODE

The **PEMI** contains 2 independent "timers". These programmable timing circuits serve to automatically start a therapy. Here you are free to choose the starting time as well as all therapy parameters (therapy program, intensity, duration and applicator).

The timers have to be programmed and activated before their first use. Afterwards the timers will start the selected therapy every 24 hours, unless they have been deactivated explicitly.

NOTES

- **To perform a therapy in timer mode the device may be turned off but must be connected to a live power supply (see chapter 2.2, Power Supply).**
- **At the first use of the timers they are set as described in chapter 3.1.6, Restore Basic Settings.**

Both of the **PEMI** timers are equal and will be activated and programmed the identical commands.
The following example shows the commands for timer 1. Timer 2 is to be handled identically.

Activation and deactivation of both timers start on a switched-off device. To program the timer 1 please press the -key keeping it pressed. Now turn the device on via -key. The display will then show

To activate the timer apply the -key, to deactivate the timer apply the -key. The display will change, accordingly. This command must be confirmed via the -key.

If the timer is deactivated, the device will now start with the standard operating mode. If the timer is activated you may now start with its programming.

As its first programming step you will set the time at which the therapy shall be started, automatically. The display will show the following menu (exemplary time):

The blinking cursor is positioned on the time's first digit „2", as shown above. You may now change the time by increasing the digit positioned below the cursor by pressing the -key, or to lessen it via the -key. The -key confirms the current value and goes to the next position.

After confirming the last time digit you automatically reach the menu to set the therapy parameters. Alternately you can now see the settings programmed for this timer regarding therapy program, therapy intensity, therapy duration and applicator. To change one or several of these settings you may press the corresponding control key in any given order.

Should 2 applicators be connected to the control unit you may also change the respective applicator via -key. After the first click on this key the programmed applicator will be displayed for 1.5 seconds. The respective applicator will be changed by pressing the -key a second time while the display is still visible – i.e. no later than 1.5 seconds after the first click.

Programming the timer is concluded by pressing the or -key. In both cases all previously set values will be saved for this timer. By pressing the Start-/Stop-key the device will be set to the standard operating mode. The on/off-key will turn the device off.

NOTE

If a PEMI control unit with activated timer is taken out of the power supply and reconnected later, the device will switch on, independently, display the text „AUTOMODE" and switch off again.

4. APPLICATORS

The patented control unit generates, in the mat or pillow applicator, a pulsating magnetic field of the body's own frequency pattern with an exactly defined waveform. The fi eld strength corresponds to the biological windows of humans. To achieve an optimal effect the field strength was designed to be variable, because the electro sensitivity is subject to variations depending on the health of users and the acidity of the blood. The fi eld strength or intensity of the magnetic field can be chosen in 3 steps, Sensitive, Medium and Intensive.

The control unit automatically switches off after 8 minutes, unless it has been individually programmed from 1 to 60 minutes. Treatment with the **PEMI** magnetic field triggers positive effects on the human organism which continue for up to 8 hours. To vitalize and stabilize good health in healthy people we recommend 2 treatments per day, about 8 hours apart.

The **PEMI** system has several applicators at its disposal. These guarantee the most effective therapy results, even at the large variety of different indications.

One of the applicator specific characteristics is the corresponding magnetic flux density, especially regarding the setting of a definite intensity on the control unit. For your information the following table states the magnetic fl ux density in micro Tesla (µT) – measured directly at the applicator (± 10% tolerance) – for the three most common applicators.

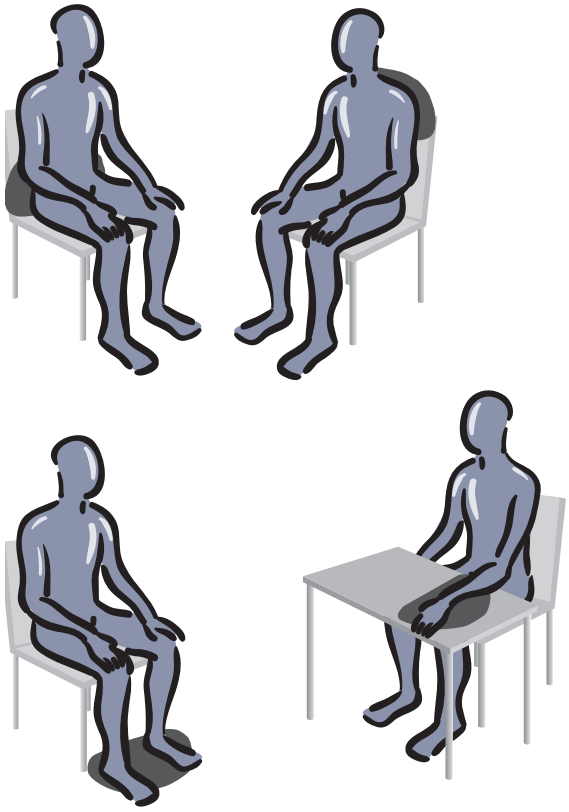
Level	Mat (µT)	Pillow (µT)	Pen (µT)
sensitive	0.3	0.4	0.15
1	3	4	1.5
2	6	8	3
3	9	12	4.5
4	12	16	6
5 medium	15	20	7.5
6	18	24	9
7	21	28	10.5
8	24	32	12
9	27	36	13.5
10 intensive	30	40	15

Duringtherapytheapplianceensuresthatelectrosmogcannotpollutethebodyandthereforedegradesthe therapy. Only **PEMI** has this ability, a process that is patented internationally (EU-Pat. 0 621 795 PCT-WO. 94/11062).

4.1 THE COIL PILLOW

The pillow is applied purposefully for individual parts of the body without influencing other regions with the pulsating magnetic field.

- Coil Pillow K1

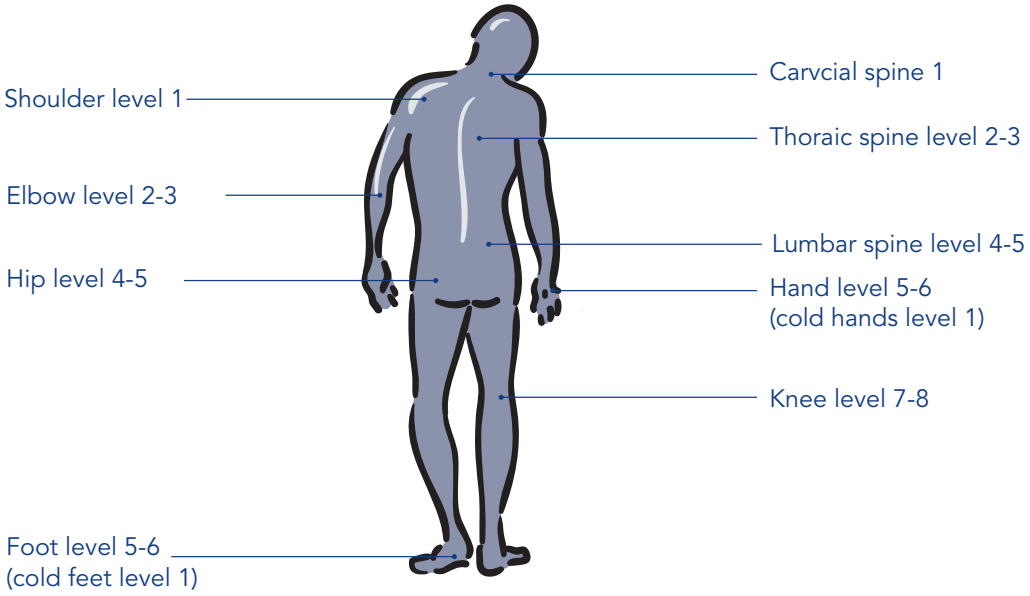


ATTENTION

The magnetic field effectively spreads up to 0.3 meters sideways and up to 1.2 meters vertically, which means that people in the immediate proximity during treatment will receive a gentle stimulation. People not requiring treatment should remain outside the above-mentioned range.

4.1.1 DOSAGE GUIDELINES FOR THE PILLOW APPLICATOR

Following are some setting examples for the pillow applicator.



4.2 THE COIL FULL BODY MAT

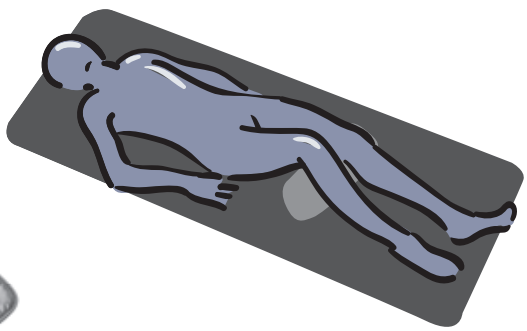
The coil mat M1 creates a magnetic field of different strength depending on the control unit settings.

For the "Sensitive"setting the magnetic field strength lies at about 0.3 µ, for level intensive the magnetic field strength increases up to 30 µT.

The magnetic field is distributed over the whole coil mat, uniformly. Its impact ranges 0.5 meters beyond the mat and approx. 1.2 meters above and below the mat. The body is embedded into the magnetic field and penetrated, uniformly.

4.2.1 APPLICATION OF COIL FULL BODY MAT

The following illustrations show some examples of how to adjust the coil pillow.



- Coil Mat M1

4.3 THE MAGNETIC FIELD BAR (PEN APPLICATOR)

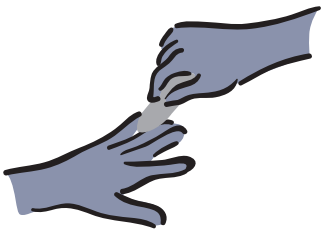
The magnetic field bar creates a magnetic field from a punctiform source. The magnetic field disperses conically, the highest strength being at the top of the rod.

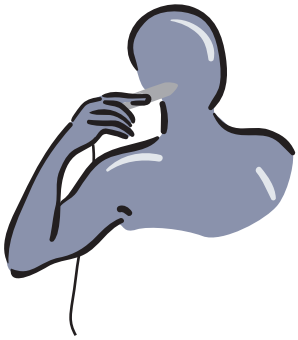
- Magnetic field bar

Local Application

Preferred for small joints (fingers, jaw, elbow), for specific pain (e.g. tennis elbow) or for indications regarding the head (eyes, ears, jaws and paranasal sinuses). The selection of intensity and duration ensues the same as for the coil pillow.

PW





Magnetic Acupuncture

Especially recommended for children and adults who are afraid of pinpricks. Also applicable for acupuncture massage.

Toning – one minute for each acupuncture point, level intensive, basic program

Sedation – three minutes for each acupuncture point, level medium, basic program.

Maximum Therapy Duration – Unlimited

Recommended Time of Day – none; except for the head (only low intensity in the evening)

Magnetic proportions at level intensive:
magnetic field: diameter 15 x 30 cm = 2 µT
magnetic field: diameter 8 x 15 cm = 10 µT
magnetic field: pen point = 15 µT

Provisions for the ideal impact of the PEMI therapy are:

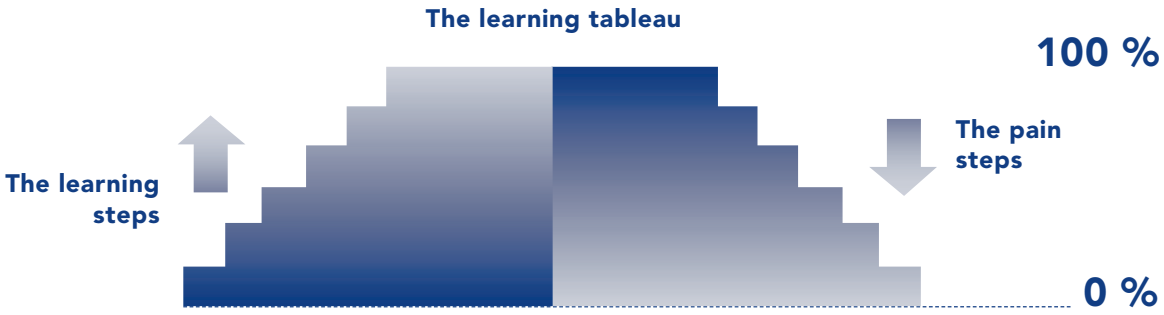
- to drink sufficiently: 1 glass of water before and after each application.
- support through vitamins, minerals, trace elements (mainly magnesia).
- regular, sensible and balanced nutrition.
- refrain from radical diets.
- no abrupt discontinuation of medication.
- regular application of the **PEMI** therapy.
- stable placement of applicator as well as patient's position.
- improved results with additional light-, thermal- or kinesitherapy.
- start **PEMI** therapy at low intensity, increasing slowly.

Information regarding the magnetic field strength settings is given in the preceding chapter.

Treatment times: Possible treatments per day: 3 times (morning, midday and evening). After 6 PM the setting of the Basis program should not be higher than setting medium. Use the Relax program to avoid negative influence on sleep. Therapy duration per day: Up to 2 hours is safe (according to a study by Prof. Dr. Dr. A. Varga, Heidelberg).

The pain memory

The learnt pain memory works in steps, up and down. After every improvement a slight pain can start again, until the pain level is brought down to 0 %.



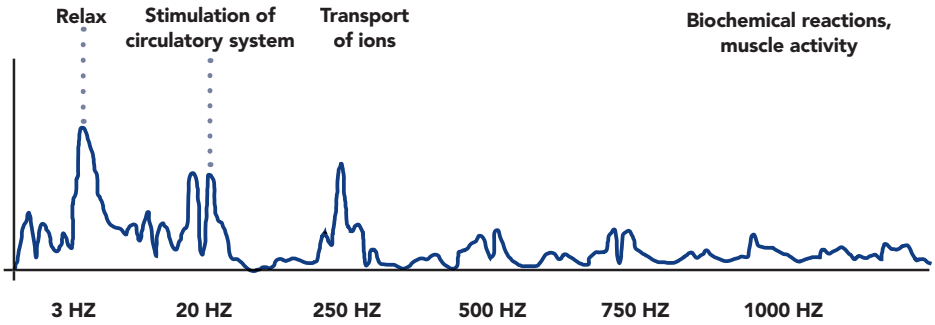
5.1 THREE RELIABLE PROGRAMS: BASIS-, VITAL- AND RELAX- PROGRAMS

Experience with the reliable and internationally patented **PEMI** signal has lead to the **PEMI** and **PEMI** magnetic field therapy device with 3 programs, with intensities selectable from sensitive to intensive. The following programs can be chosen:

The Basis-program

The Basis-program is the traditional and effective **PEMI**-program and is applied using the Treatment Advice recommendations. It covers the frequency spectrum from 0.1 to over 1000 Hz.
This Basis-program is described in the international patent "Device for transporting ions, especially "protons". Extract of the patent text:

> *"As the experiments showed, basically every biological organism can be treated, especially organisms with a blood- or lymph-circulation. The device is recommended for treating humans in the medical and sporting fi elds, above all in cases of bone fractures."*



The Relax-program

Indications: Relaxation, immune system stimulation, reduction of sleep disorders. To achieve these effects, special frequencies for the circulatory system were reinforced in the Relax-program, compared to the Basis-program. It can be used with the settings sensitive and medium. The intensity intensive is not sensible and therefore prohibited.

The Vital-program

Indications: Increase of vitality and attention (also of elderly people), reduction of sensitivity to weather changes. Also in the Vital-program, in comparison to the Basis-program and Relax-program, special frequencies are reinforced whilst others have been eliminated.

6. TROUBLESHOOTING

The **PEMI** may recognize error situations by its own and show the corresponding messages on display. Some of these errors may be corrected by the user himself, without outside help.

The following description classifies errors roughly as those which may be shown on display with a comprehensive message and others which may not be described, if only incomprehensibly.

For all errors the symptoms – and if possible – also the cause and the remedy are described.

ATTENTION

- **In case of any doubt please contact the manufacturer, an authorized service partner or your distributor!**
- **For all actions reaching beyond the measures as described in chapters 2 and 3 the mains cord has to removed from the socket or the device's jack!**

6.1 ERROR MESSAGES ON THE DISPLAY

No applicator has been connected, or the connected applicator does not correspond to the one selected in a chip card therapy.

➥ Please connect an applicator respectively the one prescribed on the chip card.

The applicator does not conduct current. The applicator or its connection cable may be defect, usually caused by rough or inappropriate handling.

➥ Please check if the applicator has been connected and tightened correctly. If available test another applicator on the device's corresponding connection. In case of visible (mechanical) defects please contact your service partner or distributor.

The control unit has detected an error during its self-test.

➥ Turn the control unit off and back on after a few seconds. If this is a permanent or recurring error, please contact your service partner.
Please note the error code »nn« **and forward it to your service partner!**

6.1.1 ERROR CODES DURING TIMER THERAPY

If a timer therapy (activated by the user through a chip card or via timer programming) could not be performed a fault report will appear on the display the next time the device is started. This report must be acknowledged by pressing the Start/Stop-key.

For each possible time-controlled therapy – timer 1 and timer 2, therapy 1 through 4 (chip card) – the display will show the following messages:

In the last stated message the »N« states the number of the timer or therapy, »xyz« represents an error code, meaning the following:

E101 No applicator has been connected, or the applicator does not correspond to the applicator selected in a chip card therapy.

➥ Please connect an applicator respectively the one prescribed on the chip card.

E102 The applicator does not conduct current. The applicator or its connection cable may be defect, usually caused by rough or inappropriate handling.

➥ Please check if the applicator has been connected and tightened correctly. If available test another applicator on the device's corresponding connection. In case of visible (mechanical) defects please contact your service partner or distributor.

E103 The therapy could not be started since the device was already in operation, ulteriorly at the programmed starting time.

➥ Please check the starting times, correct them, if required and repeat the therapy, if necessary.

E104 The therapy could not be started due to an error within the device (communication problem).

➥ Please contact your service partner.

6.2 FURTHER ERROR SITUATIONS

Symptom	Cause / Remedy
The device cannot be turned on, the display stays dark and empty.	Please check if the socket and mains cord conduct line voltage, if necessary check the mains fuse (see chapter 2.2.1). If necessary please contact your service partner.
A permanent alarm signal resounds after connecting the device to the mains power supply.	The control unit's program memory has the wrong content. Please contact your service partner.
The menu to set the time appears every time the device is turned on.	The control unit's clock is powered by a battery (its regular life-span averages at more than 5 years). The battery is empty and must be replaced. Please contact your service partner.

Functionality, reliability, and safety characteristics of the device are only guaranteed in case of proper use in accordance with the operating instructions. Safety control, maintenance work, repair work, and modifications shall be carried out only by the manufacturer or by service agents authorized by him. In case of a failure, parts which influence the safety of the device shall be only replaced by original spare parts of the manufacturer. The electric installation must correspond to the requirements in accordance with VDE/IEC.
The device does not contain any parts which need maintenance work done by the user.

7.1 SAFETY CONTROLS

7.1.1 STATUTORY REQUIREMENTS AND REGULATIONS

The device is subject to the provisions of the "Medical Device Directive". The safety controls have to be carried out on the basis of this directive. Thereby, the "Ordinance on Operators of Medical Devices" has to be especially observed.

NOTES

Safety controls have to be made on a basis of the Ordinance on Operators of Medical Devices, an ordinance connected with Medical Device Directive 93/42/EEC. Please let us point out clearly that.

- **the Medical Device Directive is not valid outside the EC.**
- **the Ordinance on Operators of Medical Devices is not valid for medical devices which serve neither commercial nor economic purposes and in whose danger zone no employees are required to work.**

7.1.2 PERFORMANCE OF SAFETY CHECKS

Irrespective of the legal rules or beyond the scope of the Medical Device Directive, it is recommended to have the device checked by the manufacturer or by a service agency authorized by him at 24-months intervals

The check shall consist of at least the following criteria:

- Electrical safety check in accordance with the test plan of the manufacturer
- Check of the device in respect of external integrity
- Check of all display and operating elements in respect of damages
- Check of all inscriptions in respect of legibility

7.2 CLEANING, DISINFECTION AND CARE

For cleaning and disinfection of the device and its accessories there should not be used any agents containing higher portions of phenol derivatives, alcohol, compounds of chlorine or peracetic acid. It is recommended to use disinfectants on aldehyde basis.

We recommend to clean the device with a soft, damp cloth. For tenacious stains you may also apply mild detergent used for delicate plastic surfaces.

The device is not suited for heat sterilization or for sterilization with gases.

ATTENTION

Before cleaning or disinfection unplug the power supply out of the socket!

The device is suited for wiping disinfection. It has to be observed that no liquids enter the device. In no case shall the plug or socket get wet. For cleaning or disinfection the device may not be drizzled.

Control Unit, Pillow Applicator

Do not immerse in water! Use normal household cleaners for synthetic materials. Only wipe with a damp cloth. Be sure to keep sharp, pointed objects away from mat applicator and pillow applicator.

Do not expose the system to direct sunlight and protect it from frost.

Placing Mat under a Mattress

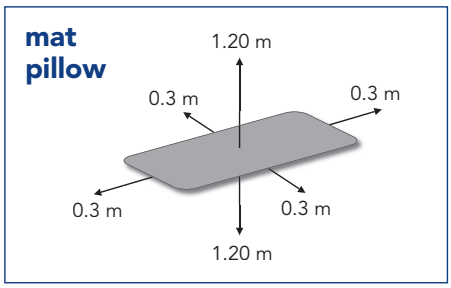
The mat can be placed under a mattress. A woolen blanket should be placed between the mattress and the mat in order to avoid undesirable bacteria or fungi caused by sweat.

ATTENTION!

- With the following contraindications the **PEMI** application should be done under medical guidance:
  - pregnancy
  - epilepsy
  - hyperthyroidism
  - cardiac arrhythmia
  - loss of blood
  - cancer
  - severe hypo- and hypertension
  - burnout syndrome
  - severe mycosis and
  - bacteroidosis
- The **PEMI** application is unobjectionable for metal implantation or pace makers which comply with the standards or EN 60601-2-31. For patients with other implanted electronical devices a risk assessment must be performed, and if required a therapy under surveillance.
- Jewelry and glasses must be taken off during the therapy.
- Cell phones must be turned off or placed at a three-meter distance from the device.
- If the patient and/or applicator or its connecting lead be located in the immediate sphere of a high frequency-, short wave- or microwave therapy device the possible damage of device or patient may not be excluded. Please keep a distance of at least 3 m.
- The device is not intended to be used in areas with the risk of an explosion. If it is used in anesthesia rooms, in an endangered area, a possible explosion cannot be ruled out.
- For all recognizable malfunctions, please contact your distributor or an authorized service partner.

8.1 OPERATING STAFF SECURITY

The pulsating magnetic field is distributed up to 0.3 m beyond the mat/pillow applicator and up to 1.2 meters above and below. Persons who are not being treated should stay beyond the stated range during an ongoing therapy.



8.2 APPLICATION FOR BABY AND CHILD

Children tend to react exuberantly. Therefore the device may not be applied on children below the age of 10 without surveillance.

- For babies you should only apply the field strength „sensitive“ with the pillow applicator.
- For children aged two to 10 the intensity setting medium should be selected as a maximum.

8.3 FURTHER ADDITIONAL REACTIONS IN THE APPLICATION

- In case of **allergic reactions** always cover the applicator with a bio-compatible cloth or paper.
- In case of **rising blood pressure**, which sometimes occurs in the beginning of a **PEMI** therapy, please lower the field strength until the patient has grown accustomed to the **PEMI** therapy. It may also be useful to reduce the therapy duration to 2 minutes and to increase it, gradually.
- In case of **vertigo**, which may also occur in the beginning, please lower the field strength and/or reduce the application to once a day.
- In chronic illnesses **initial aggravations may occur, as they are known from homeopathic medicines**. The therapy should not be ended, though. Biological initial aggravations namely indicate the beginning reaction and/or loosening of blockades within the body.
- A **secondary aggravation** may occur after several weeks of **PEMI** application. Then you should also reduce duration and field strength of the respective application and increase them, slowly.
- Should the patient be on **medication** according to indication, it may be assumed that these can/must be reduced after a certain time.

8.4 EXPLANATION OF THE SIGNS USED

CE Conformity sign with the identifying number of the notified body for medical productse

Attention!
Observe the instructions for use!

Application part ungrounded, protection degree Type BF

This product complies with WEEE Directive 2002/96/EG (waste electrical and electronic equipment). Separate collection for electrical and electronic equipment.

9. TECHNICAL DATA

Mains voltage, frequency and power consumption:	115/230 V, 50/60 Hz, 7 W	
Power consumption in stand-by mode:	maximum 800 mW	
Fuse:	315 mA slow blow	
Output signal:	As a maximum 3 V, 170 mA, 40 µT	
MDD device class:	IIa	
Safety class:	I	
Protection degree:	BF	
Protection against ingress of water:	IPX0	
Dimensions:	92 mm x 190 mm x 215 mm (h x w x d)	
Weight:	1.2 kg	
Display:	DOT-matrix, 16 characters	
Environmental conditions:	Operation of the device:	Temperature range +10 °C up to +40 °C Relative humidity 30 up to 75 %
	Transport and storage:	Temperature range +5 °C up to +50 °C Relative humidity < 90 %, none condensing

Magnovit International AG reserves the right to modify the design and speci-fi cation without prior notice.

NOTES