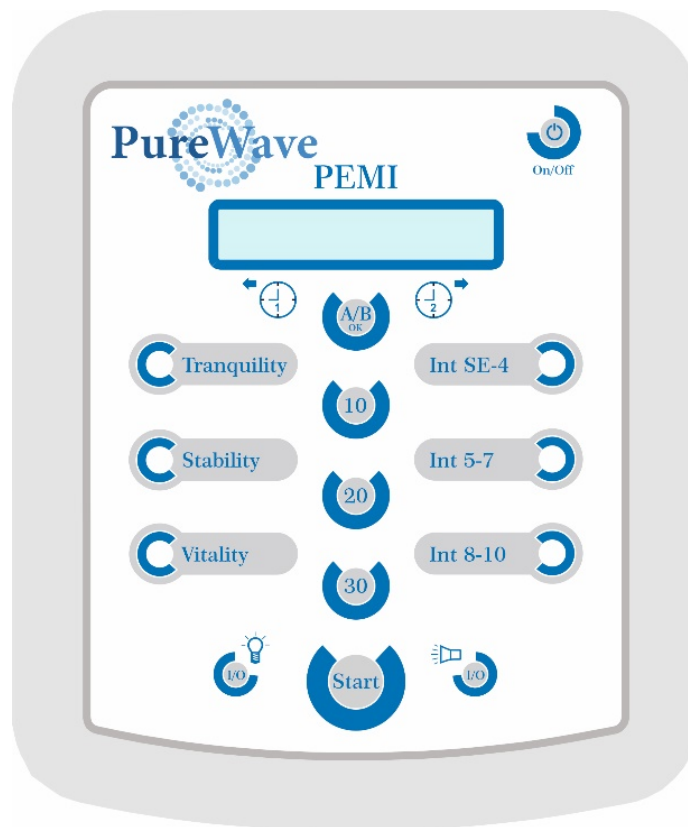


# PureWave

## PEMI User Manual



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## Notes in accordance with ec-directive and medical device directive (MDD)

CA-HC and CA-HC P are mains-powered magnetic field therapy devices of protection class I. The devices are in accordance with the EC directive for medical devices (93/42/EWG) and therefore carry the CE sign with the registration number of the notified body for medical devices. The according graphical symbol is placed on the type plate. According to the MDD, CA-HC and CA-HC P are class IIa devices.

**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. CA-HC and CA-HC P are electronic devices. 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 qualified 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 influenced 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 may 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.

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 Voltage fluctuation/flicker emissions, 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 humidity 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 phase-to-phase conductors ±2 kV phase-to-earth	±1 kV phase-to-phase conductors ±2 kV phase-to-earth	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% Ut for ½ cycle (>95% dip) 40% Ut for 5 cycles (60% dip) 70% Ut for 25 cycles (30% dip) <95% Ut for 5 s (>5% dip)	<5% Ut for ½ cycle (>95% dip) 40% Ut for 5 cycles (60% dip) 70% Ut for 25 cycles (30% dip) <95% Ut 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: Ut 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 <sub>eff</sub> 150 kHz to 80 MHz	3 V <sub>eff</sub>	$d=1.2\sqrt{P}$
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 transmission 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

# 1. Introduction

## 1.1 Intended use

The PureWave PEMI 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 field therapy, placing this therapy on a sound scientific basis, which will ensure its place in medicine.

The PureWave PEMI System serves for pain therapy and has proven successful in many indications even without further pharmaceutical therapies. It supports both cell revitalization and cell metabolism by targeted ion transport. The whole metabolism is activated, the immune system stabilised and cell regeneration improved, thereby strengthening weakened body functions in a natural way.

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. PureWave PEMI work with field strengths up to 40 micro Tesla and therefore well below the WHO limit or so-called geomagnetic earth radiation.

For comparison:

Highest PureWave PEMI intensity	40 $\mu$ T
Terrestrial magnetic field	50 $\mu$ T
WHO limit	100 $\mu$ T

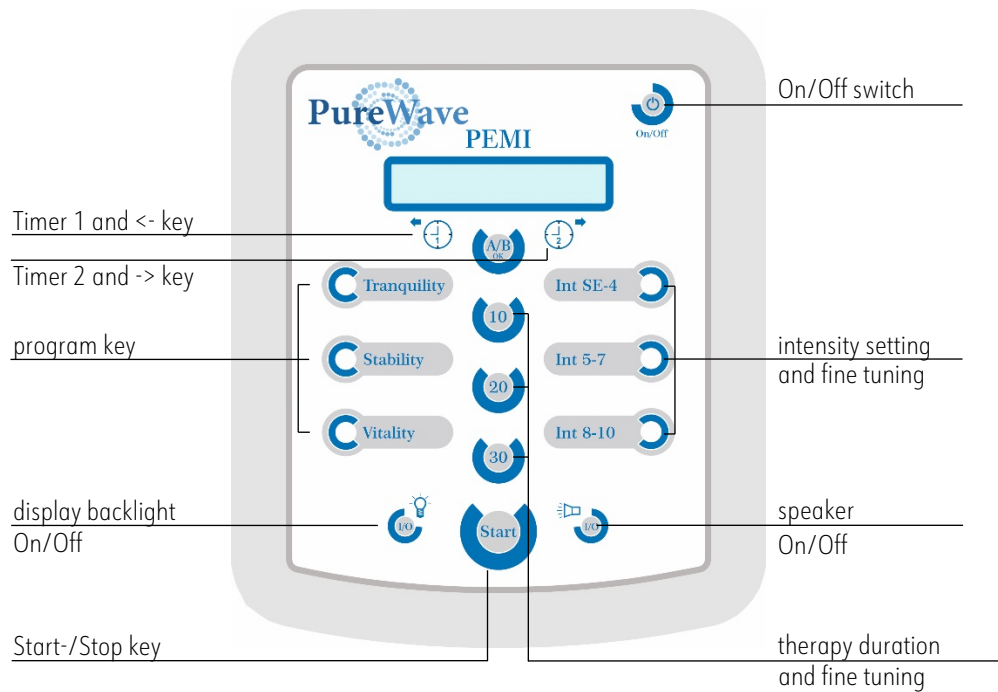
On this scale the therapy's intensity may be adapted to the current patient's state of health manually.

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 PureWave 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 PureWave PEMI System is a „Home Device“. With this device it is possible to carry out therapies with the Stability, Vitality and Tranquility programs without a chip card. Moreover, a chip card created at the doctor's surgery can be used as an electronic prescription.

## 1.2. Description of the keys



## 1.3. Description of the display

The PureWave PEMI system have a 16-digit display. Their contents depend on the current device function. For detailed information please refer to chapter 3, Functional characteristics.

Example:

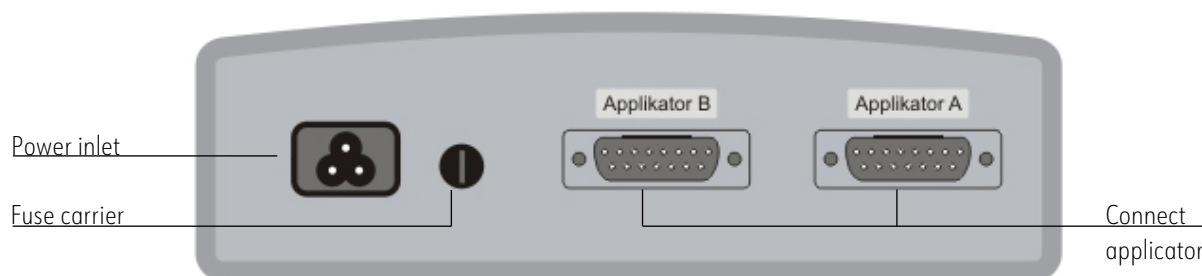


current time, selected therapy program

## 2. Start of operation

### 2.1. Transport and assembly

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



PureWave PEMI are 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 (MDD).

#### 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 anesthesia 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 sufficient.

### 2.2. Power supply

The PureWave PEMI system 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 PureWave PEMI system allow 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, Chipcard mode). This functionality is available since the control unit permanently surveys its time-controlled routines in the so-called standby 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 1/8<sup>th</sup> turn counter-clockwise.

#### ATTENTION

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

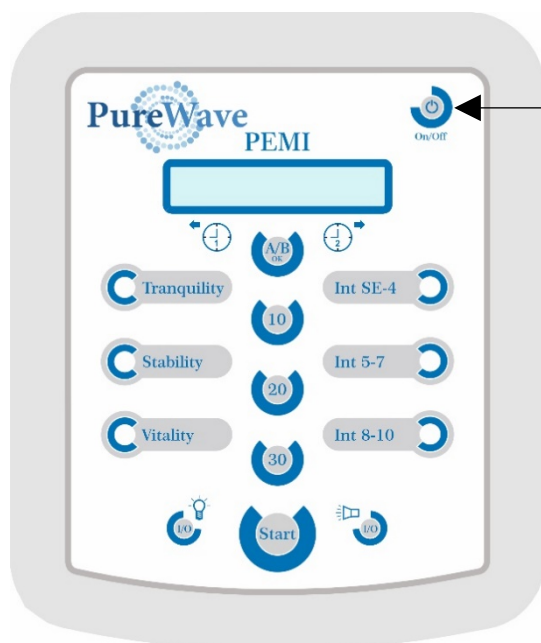
## 2.3. Connecting the applicator

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 On/Off key.

The display shows the following text

PureWave V1.5

V1.5 is the current software version's label and may change during the device's development cycle.

The device now performs an automatic function test.

SYSTEMCHECK

In case of grave errors the display shows an error code (see chapter 6, Troubleshooting).

If everything works properly, the display will show

SYSTEM OK

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

Purewave PEMI come 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.

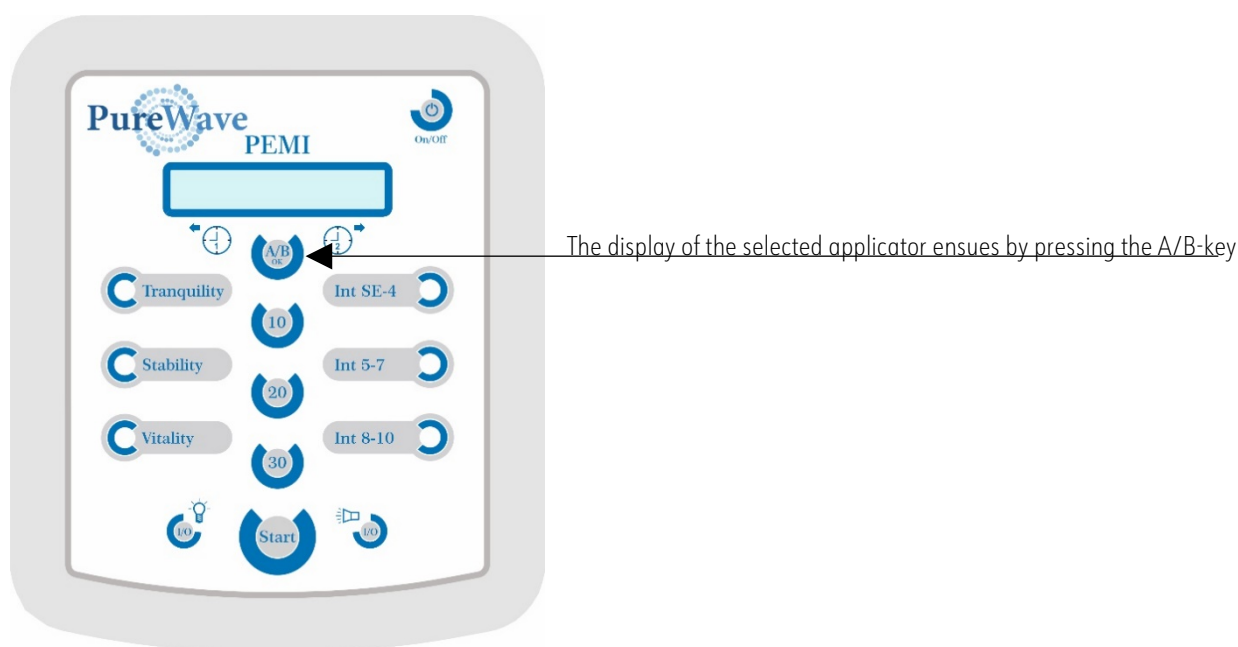


## 3. Functional Characteristics

### 3.1. Basic functions

#### 3.1.1 Selecting the applicator jack

Purewave PEMI is equipped with 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 quoin center). If 2 applicators are connected – which have not already been predefined by an electronic prescription (see 3.3, Chipcard mode), you may chose the applicator to be applied for the next therapy on the device.



All of the Purewave-System's applicators are coded, thus the device may identify the connected applicator's type. Therefore the display will not show the applicator's physical identification („A“ or „B“) but the descriptive, logical identification („mat“ or „pillow“).

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.

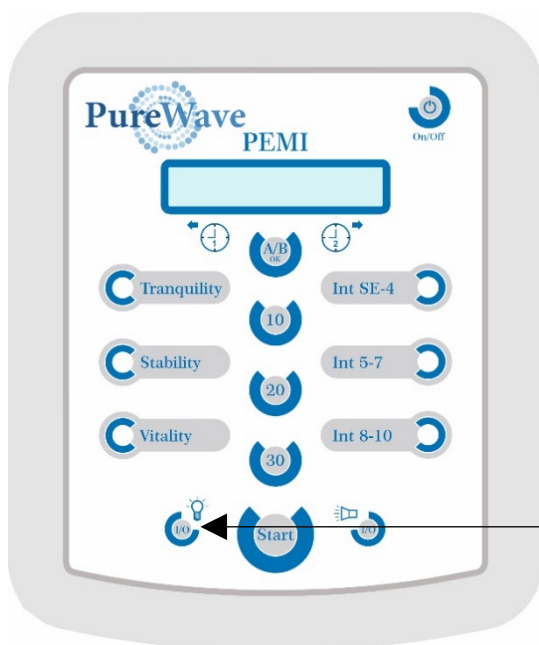
You may switch to the respective other applicator by pressing the A/B-OK-key a second time while the above stated display is still visible.

#### 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 I/O-key

Depending on its status one of the following displays will appear

BACKLIGHT ON

or

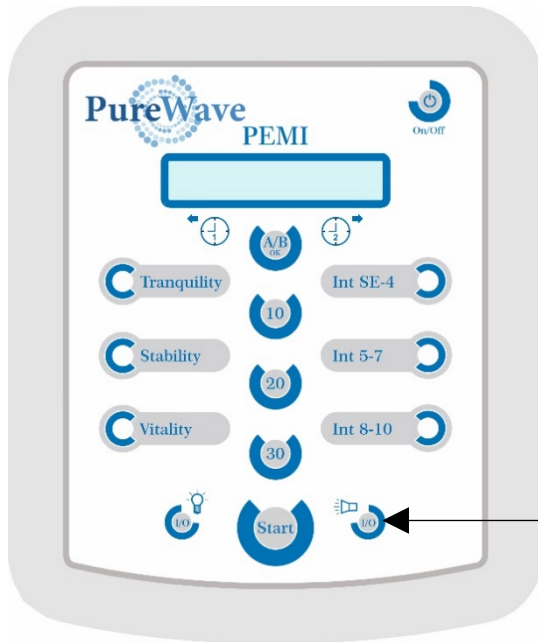
BACKLIGHT OFF

#### NOTE

These are always visible for 1.5 seconds before returning to the previous status. If the I/O-key is being pressed while the display shown above is visible, the display light's status will be changed, i.e. the switchedon display light will be turned off and vice versa.

### 3.1.3 Turning the speaker on/off

The PureWave PEMI contain 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 I/O-key

Depending on its status one of the following displays will appear



or



#### NOTE

These are always visible for 1.5 seconds before returning to the previous status. If the I/O-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.

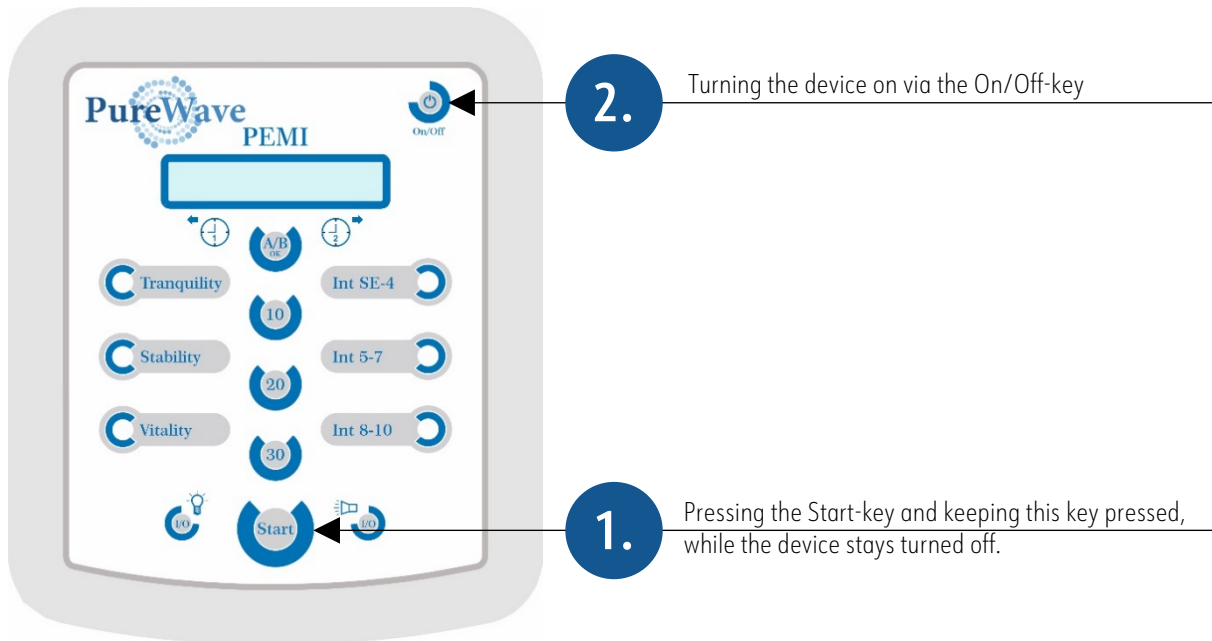
### 3.1.4 Setting the time and date

PureWave PEMI possess a clock (battery backed RTC). To set the time the device's user interface offers you convenient menu guidance.

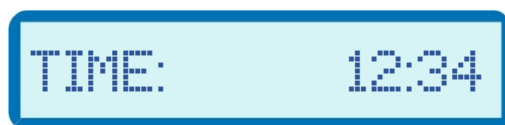
#### NOTE

Turning the device off before.

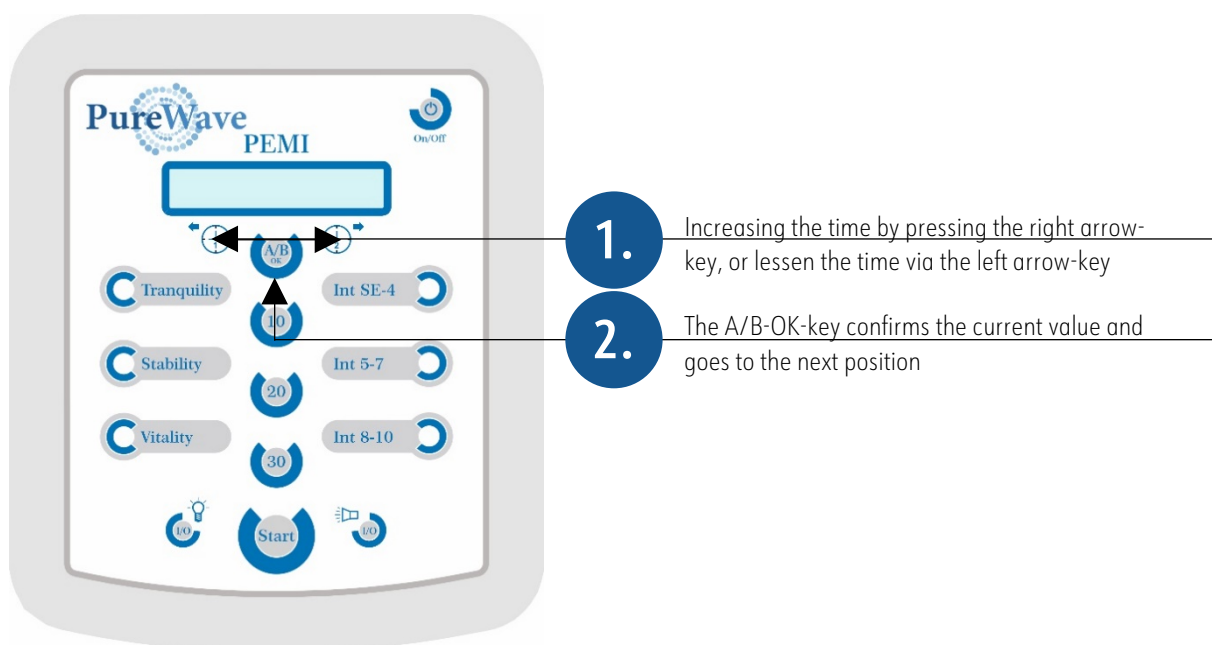
You may reach the corresponding menu by



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 right arrow-key, or to lessen it via the left arrow-key.



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 Start-Stop-key. The currently made (incorrect) settings will then not be effective.

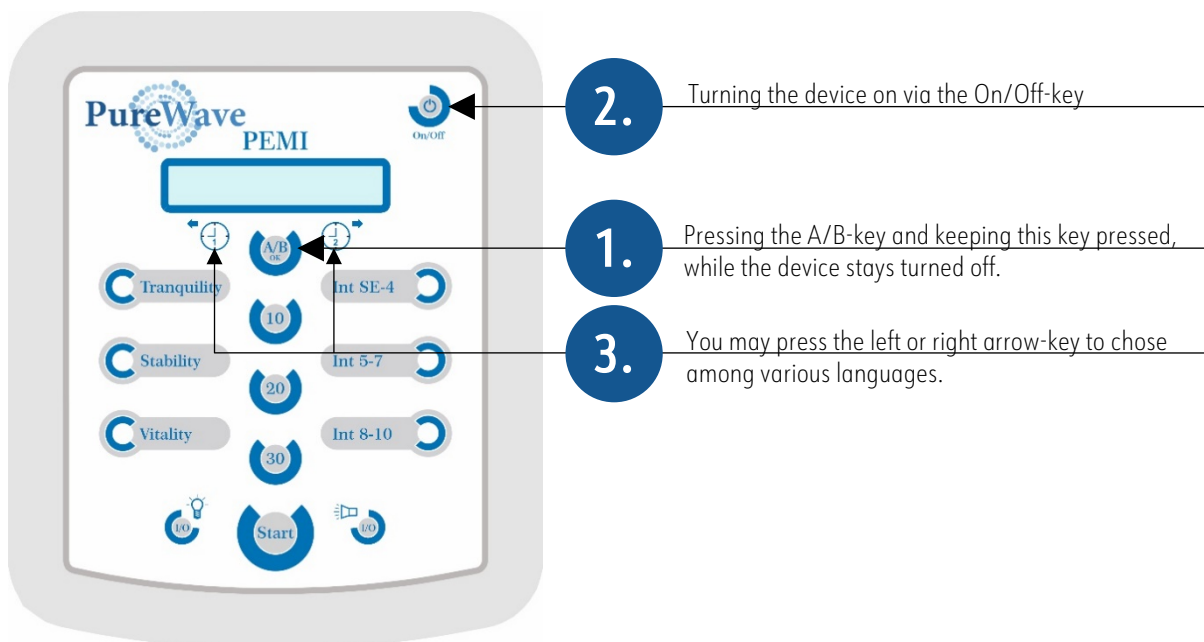
### 3.1.5 Setting the language

You may operate the PureWave PEMI in different languages. To set the standard language the device's user interface offers you convenient menu guidance.

**NOTE**

Turning the device off before.

You may reach the corresponding menu by



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



The abbreviation of the currently selected language is marked between brackets „[“and„]“.

The following languages are available:

[EN] English    [DE] German    [FR] French    [IT] Italian    [ES] Spain    [SE] Swedish

Pressing the AB/OK-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 Start-Stop-key. The currently made (incorrect) setting will then not be effective.

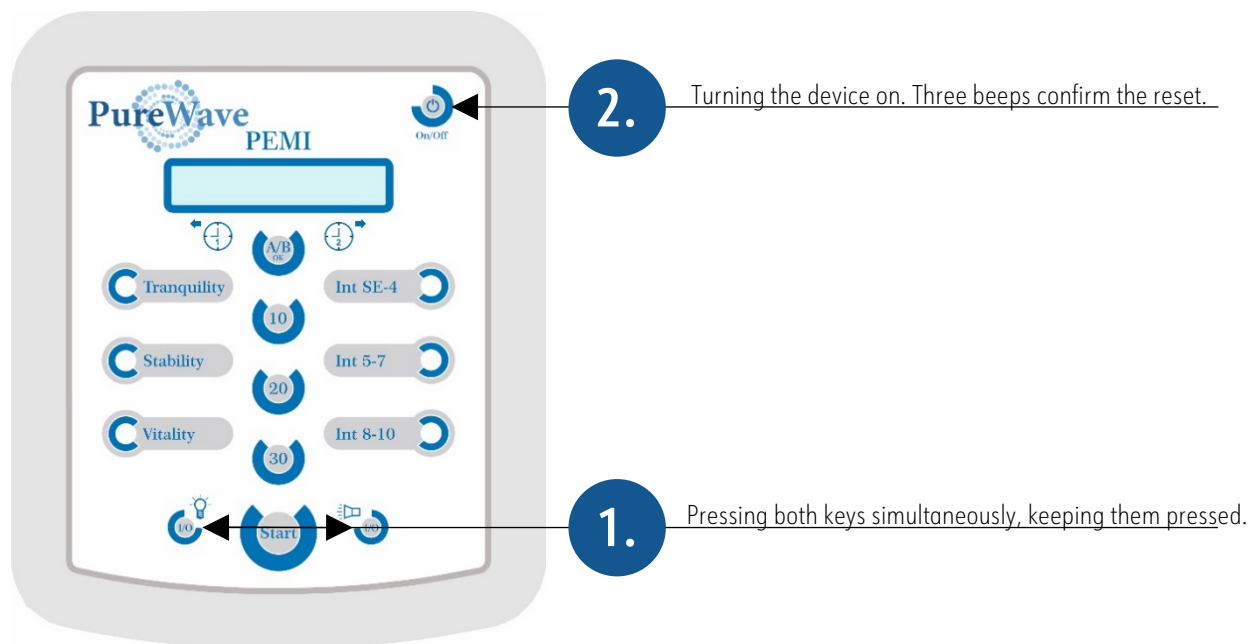
### 3.1.6 Restore basic settings

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

**NOTE**

Turning the device off before.

You may restore these basic settings by



The restored basic settings

- display light off
- speaker on
- language EN (english)
- therapy program tranquility
- therapy intensity medium
- therapy duration 10 min
- timer 1 off and 06:00 o'clock, „Vitality“, „medium“, 8 min.
- timer 2 off and 22:00 o'clock, „Tranquility“, „medium“, 8 min.

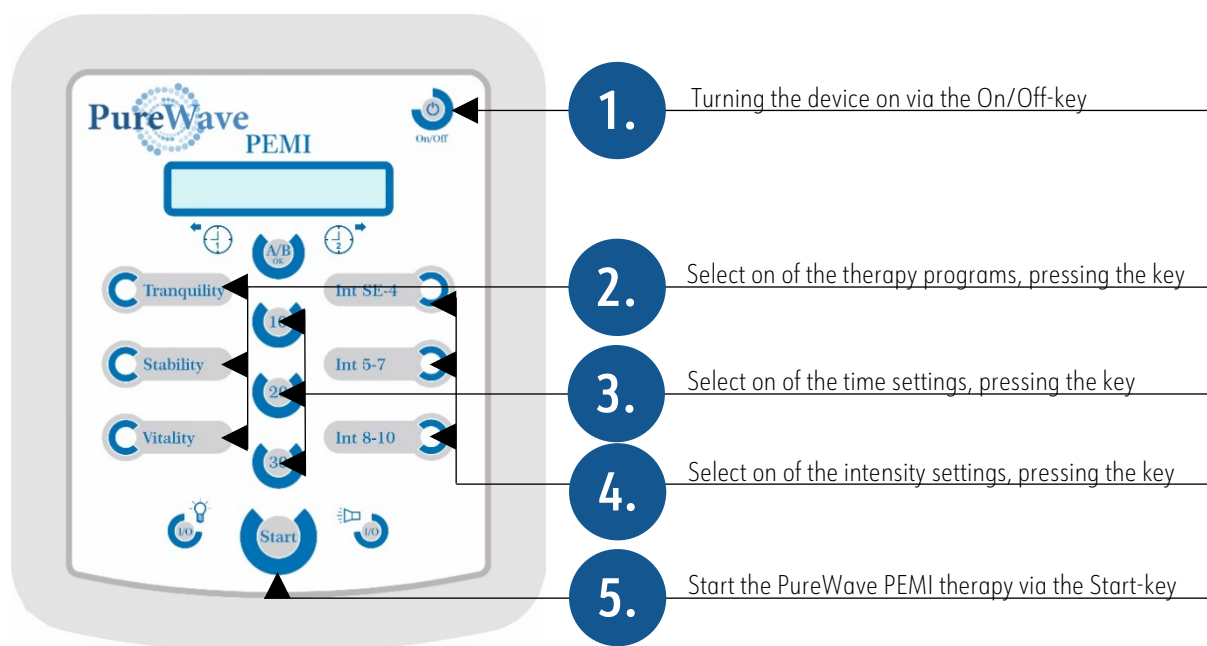
## 3.2. Therapy functions

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

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

- the therapy program (Tranquility, Stability or Vitality),
- the therapy intensity (Int SE-4, Int 5-7 or Int 8-10) and
- the therapy duration (10, 20 or 30 minutes).

You may select the stated parameters via control keys on the keyboard, arbitrarily.



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



On the display left side the current therapy program and selected therapy intensity are shown alternately.



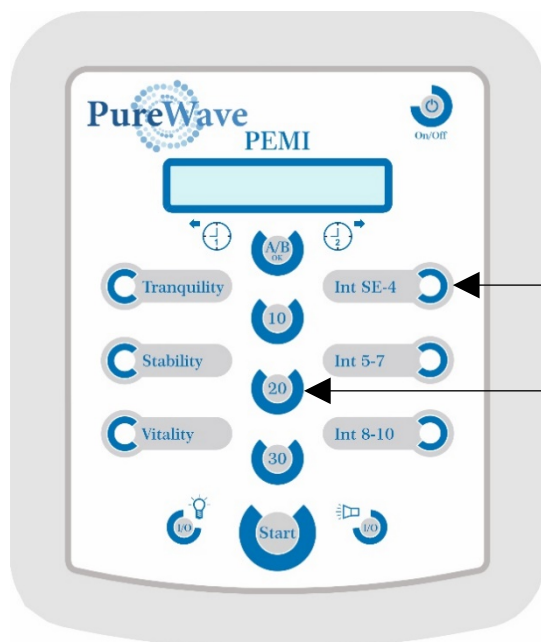
The right side displays the remaining time until the end of therapy.

### NOTE

The home 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 5 will always be chosen, whenever the intensity „5-7“ is being selected.

### 3.2.1 Finetuning of intensity and therapy duration

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



Changing intensity setting:  
press the key for 2 sec. until the time in the display flashes

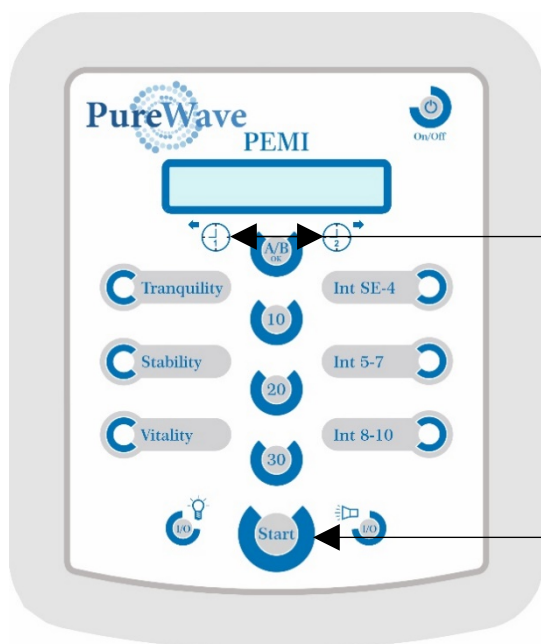
Changing therapy duration:  
press the key for 2 sec. until the intensity in the display flashes



The therapy duration can be adjusted starting from any time key (10 min, 20 min, 30 min). Press one of the time keys for 2 sec. until the time in the display flashes.



The intensity can be adjusted starting from any of the intensity keys (Tranquility, Stability, Vitality). Press the key for 2 sec. until the intensity in the display flashes.



Decreases/increases time and intensity setting:  
By pressing the left arrow key the time decreases in 1 minute steps and by pressing the right arrow key the time increases in 1 minute steps. By pressing the left arrow key the intensity decreases and by pressing the right arrow key the intensity increases. The intensity range starts from „SE“ (=sensitive) up to 1-10.

After having reached the desired setting press the A/B-OK key and continue with normal operation. Also you can start directly the therapy with pressing this Start key.

#### NOTE

The therapy program „tranquility“ allows only values up to 5.  
The last settings are saved until you set something else.



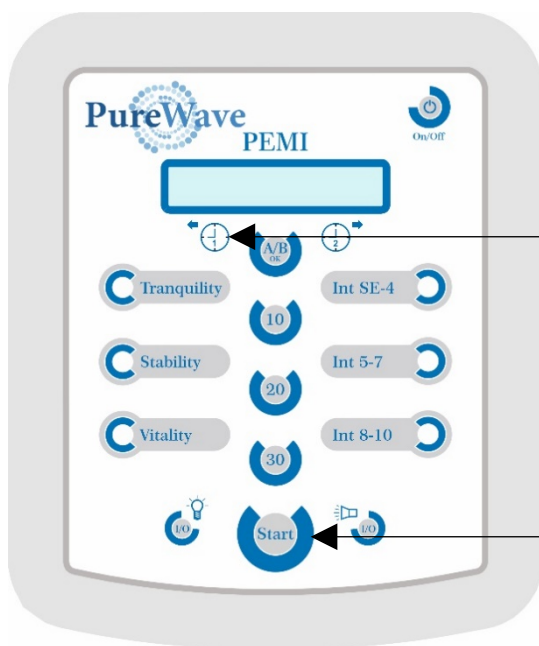
### 3.3. Chipcard mode

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. 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 arrow keys.

The therapy is started via the Start key.

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 mnemonically 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.

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.

#### NOTE

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.

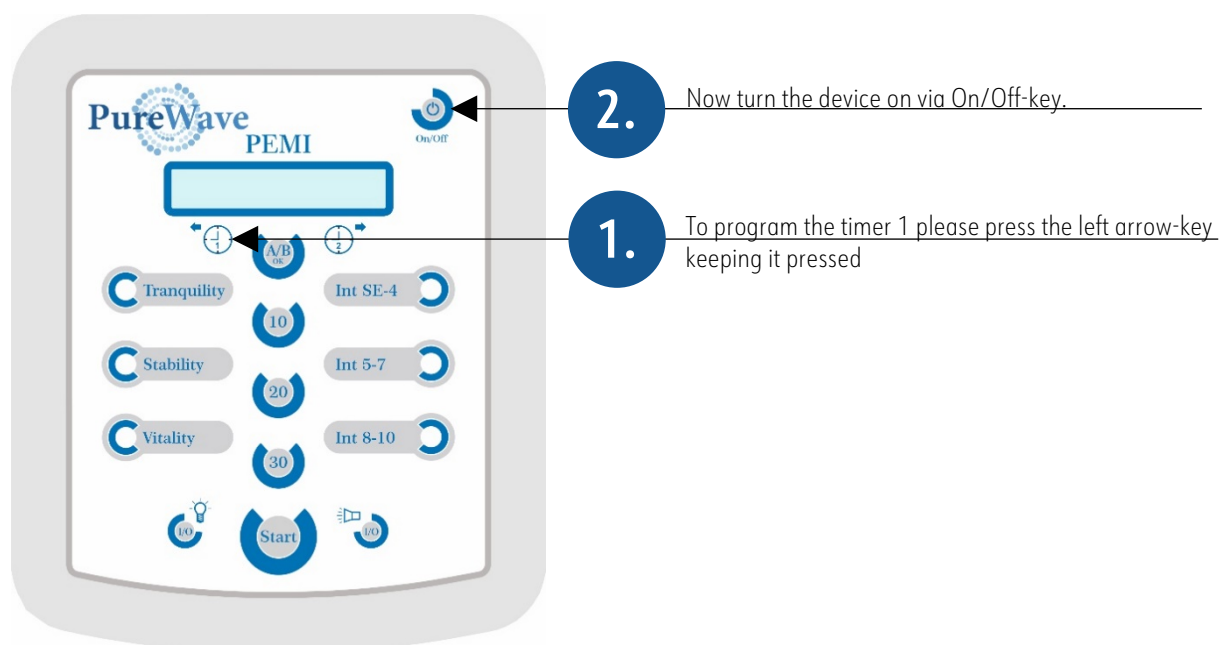
### 3.4. Timer mode

PureWave PEMI contain 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.

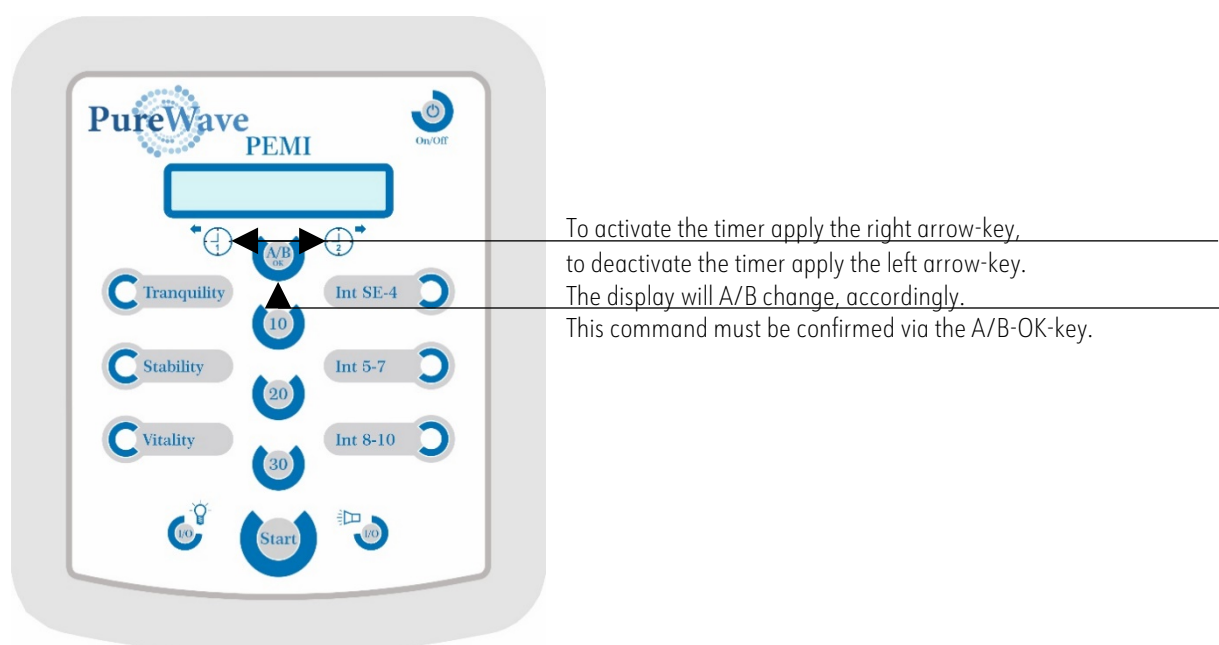
#### NOTE

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 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.



The display show the timer is off.



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):



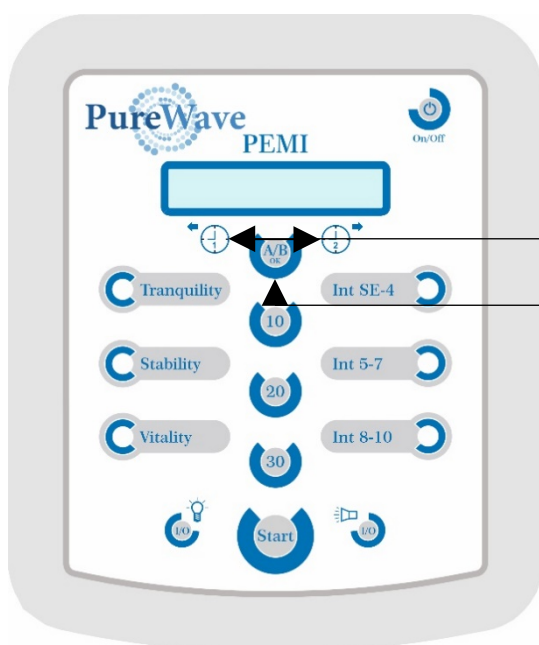
For setting Timer 1 press and hold the left arrow-key and then press the On/Off-key.



For setting Timer 2 press and hold the right arrow-key and then press the On/Off-key.

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 right arrow-key, or to lessen it via the left arrow-key.



Increasing the digit positioned below the cursor by pressing the right arrow-key, or to lessen it via the left arrow-key. Pressing the A/B-OK-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 A/B-OK-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 A/B-OK-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 Start-key or the On/Off-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 PureWave 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 PureWave 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 field 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 field strength or intensity of the magnetic field can be chosen in 3 steps, SE-4, Int 5-7 and Int 8-10.

The control unit automatically switches off after 8 minutes, unless it has been individually programmed from 1 to 60 minutes. Treatment with the PureWave 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 PureWave 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 flux density in micro Tesla ( $\mu\text{T}$ ) – measured directly at the applicator ( $\pm 10\%$  tolerance) – for the three most common applicators.

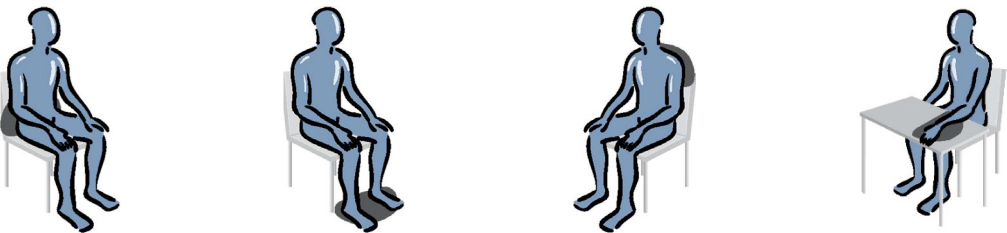
Level	Mat ( $\mu\text{T}$ )	Pillow	Pen
sensitive	0,3	0,4	0,15
1	3	4	1,5
2	6	8	3
3	9	12	4,5
4	12	16	6
5 medium	15	20	7,5
6	18	24	9
7	21	28	10,5
8	24	32	12
9	27	36	13,5
10 intensive	30	40	15

**NOTE**

During therapy the appliance ensures that electrosmog cannot pollute the body and therefore degrades the therapy.

### 4.1. The coil pillow

The pillow is applied purposefully for individual parts of the body.

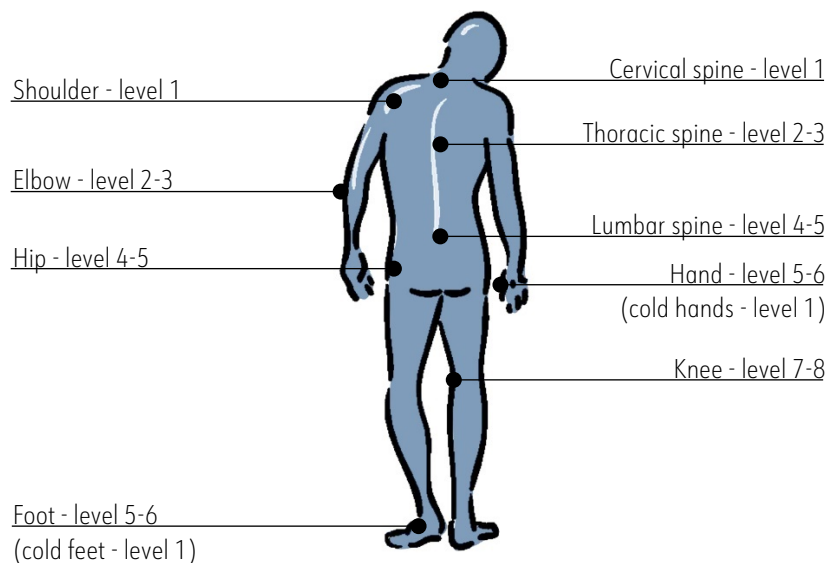


**ATTENTION**

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.

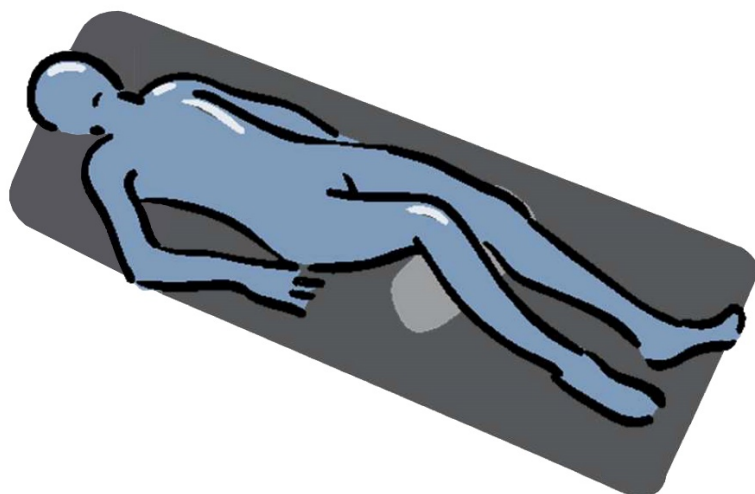
### 4.1.1 Dosage guidelines for the pillow applicator

Following are some setting examples for the pillow applicator.



### 4.2 The coil mat

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



## 5. The PureWave magnetic field therapy

Provisions for the ideal impact of the PureWave 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 PureWave therapy.
- start PureWave 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.

## 5.1 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 %.



## 5.2 Three reliable programs:

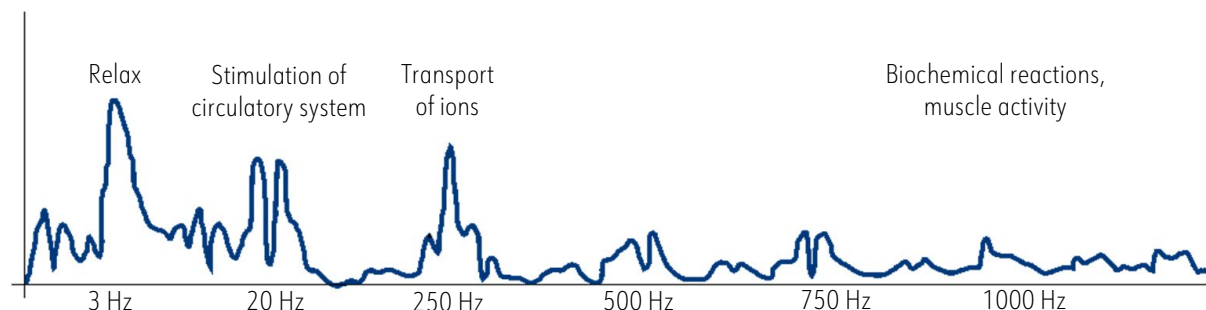
### Stability, Vitality and Tranquility program

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

#### 5.2.1 The Stability-program

The Stability-program is the traditional and effective PureWave-program and is applied using the Treatment Advice recommendations. It covers the frequency spectrum from 0.1 to over 1000 Hz. This program is transporting ions, especially protons.

„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 fields.“



#### 5.2.2 The Tranquility-program

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

#### 5.2.3 The Vitality-program

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

## 6. Troubleshooting

The PureWave system 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 be removed from the socket or the device's jack!

### 6.1 Error messages on the display

CONNECT APPLIC!

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.

CARD NOT VALID

The chip card may not contain a therapy credit, may be inserted the wrong way or may be mechanically damaged.

- ➔ Please check if the chip card has been inserted correctly (see label), otherwise please contact your physician, therapist, service partner or distributor.

APPLIC.DEFECTIVE

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.

ERRORCODE: NN

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 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:

FAULT REPORT:

(PLS SEE MANUAL)

GO ON WITH START

TIMER N: E XYZ

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, ulterior 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.



## 7. Maintenance

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, Applicators

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. When using the coil mat and coil pillow, please make sure that no sharp objects are pressed in. 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.

## 8. Contraindications and safety precautions

### ATTENTION!

In the case of the following contraindications the CA-HC application should only be used under medical monitoring:

- pregnancy
- epilepsy
- massive hypothyroidism
- very severe heart rhythm disturbances
- cancer
- severe hypo- and hypertension

The PureWave application is unobjectionable for metal implantation or pace makers which comply with the standards or EN 60601-2-31. In the case of patients with other implanted electronic EN devices a risk assessment should be carried out, and if necessary therapy under supervision.

- 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. Persons who are not being treated should stay beyond the stated range during an ongoing therapy.

### 8.2 Application for baby and child

As infants and children sometimes respond more sensitively than adults, CA-HC therapy should be started gradually with low intensities. Basically there are no contraindications because therapy is performed well below the so-called geomagnetic earth radiation levels.

- 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 the case of possible allergic reactions cover the applicator with biocompatible fabric or paper.

- If the patient's blood pressure increases, as may sometimes be observed at the beginning of PureWave treatment, please reduce the intensity until the patient has become accustomed to the PureWave treatment.
- In the case of possible feelings of vertigo, which may also occur at the beginning of treatment, please lower the intensity 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.
- Possible second deterioration may occur once more after several weeks of PureWave application. If necessary, the length of application and the intensity should then be reduced and thereafter slowly increased again.
- 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



## 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	1 A	
Output signal	As a maximum 3 V, 170 mA, 40 $\mu$ T	
MDD device class	IIa	
Safety class	I	
Protection degree	BF	
Protection against ingress of water	IPX0	
Dimensions, Weight	40 mm x 190 mm x 215 mm (h x w x d), 0,688 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

PureWave reserves the right to modify the design and specification without prior notice.

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