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# Device applying electric or electromagnetic signals for promoting biological processes EP 0995463 A1

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#### Résumé

The device has a coil (2) to generate a pulsed electromagnetic field and a pulse generator (1) to control the coil. The pulsed electromagnetic field comprises a number of single pulses of frequencies between 1 Hz and 1 kHz. The amplitude of each single pulse agrees with a given equation. The amplitude, y, of each single pulse is of the function: y = (kxaesin (xb))/c + d, where x is the pulse time, a is a parameter to adjust the amplitude of each pulse, b is the number of the overlaid pulse, c is a factor to adjust the amplitude, d is an offset value, and k is a factor to adjust the amplitude of the overlaid pulse.







#### Description Langue du texte original : Allemand

• [0001]

The invention relates to a device and an electrical or electromagnetic signal for influencing biological processes in a living tissue, in particular a human body. By applying at least a portion of the tissue with a pulsed electromagnetic field

• [0002]

Since the early 70s devices are known which generate electromagnetic fields and are routinely used in clinics specifically in the field of orthopedics for therapeutic purposes. First, this semi-invasive methods have been used with pulsating magnetic fields. The sinusoidal magnetic fields showed a frequency of 2 Hz to 20 Hz and magnetic flux densities between 1 mT and 10 mT in accordance with the principle of induction were fixed by external magnetic fields, which flood the treated body part along its longitudinal axis, due to the temporal change of the magnetic flux at the implanted electrodes with the aid of a so-called. secondary element generates an alternating voltage. The implanted electrodes referred for treatment of bone fractures in the form of an intramedullary nail or screw on Even back then, was the possibility of a non-invasive treatment without implanted secondary element known, although in the treated body part that had to be located in the center of the coil, only very weak electric currents were induced. Also since the beginning of the 70s are devices for whole-body therapy known, the field lines spread evenly in the body.

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All previously known devices for treatment of the human body, however, rarely lead to the desired effect of accelerating the healing process. It is especially problematic that in previous devices for achieving a significantly accelerated healing success, the application must be repeated frequently, leading to an increased burden on patients and result in significantly higher treatment costs.

• [0004]

The object of the invention is to provide a device and an electrical or electromagnetic signal with which a faster and wider in their physiological effect influencing, in particular stimulating, biological processes is made possible.

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This object is inventively achieved in that a device is provided which comprises a pulse generator and a field generating device for generating a pulsed electromagnetic field. The pulse generator is used to drive the field generating device, wherein the pulse generator the field generating device through suitable current-voltage processes so controls that the pulsating electric or electromagnetic field consists of a plurality of, characteristically shaped with respect to their temporal amplitude response of individual pulses having a frequency between 1 and 1000 Hz, Such a single pulse may be, of another of a superposition according to a power function or descending base pulse having a series of pulses of each patch shorter period of time and of different shape and temporal sequence construct.

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The temporal amplitude response of such a single pulse could correspond approximately to the following function:  $y = x^{a} \cdot k \cdot e^{sin(xb)} c + d$ 

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The parameters of this formula each describe:

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y is the amplitude of the generated in the pulse generator voltage waveform, x the course of time, wherein the time X for each single pulse anew with the same initial value begins, a the temporal amplitude response of each basic pulse (envelope), b - in a manner density function - the number and edge steepness of the superimposed pulses, k is the amplitude of the superimposed pulses, c a factor for setting the amplitude and offset value d.

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Likewise, an electric or electromagnetic signal is specified, consisting of a plurality of individual pulses having a frequency between 1 Hz and 1000 Hz. Each of these individual pulses thereby has a profile which corresponds to the following formula:  $y = x^{a} \cdot k \cdot e^{\sin(xb)} c + d$ 

• [0010]

Like the electrical or electromagnetic signal as compared to traditional devices improved device results in a significantly faster stimulation of metabolic processes in irradiated tissue. This could be due to the fundamental pulses superimposed pulses improve the physiological processes of exchange on intracorporeal membrane systems because the patch pulses according to the law of induction (Maxwell's equations) according to their special form, eg induce growing slew rates, higher levels of electromagnetic field peaks, for example, by using the influence they pose electromotive force effects which generally highly selective physicochemical reaction mechanisms by an appropriate broadband reduction of the activation energies and so - stimulate the physiological processes of exchange - especially in membrane regions. This stimulation leads in particular to an increased O  $_2$  -Utilisation.

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A particular advantage of the device and the signal present invention is that it also leads to a local irradiation leads to an activation of the metabolic processes throughout the body including the non-irradiated areas of the individual.

• [0012]

With such irradiation beneficial effects in various medical applications can be achieved. An increased O  $_2$  - Utilisation leads among other things on the one hand to an increased connective tissue and cartilage formation and an additional vascularization.

• [0013]

On the other hand, possibly favored by the above O  $_2$  -Utilisation, be based on the bioelectric effect of the induced voltages and mineralization of connective tissue due to increased ion exchange. The bone metabolism is very closely linked to the assembly and disassembly of cartilage, as evidenced by endochondral ossification or similar running secondary fracture healing. Correspondingly, the joint determining for the consolidation of bone fragments calcium entry and Ausflußkinetik of chondrocytes by pulsing electromagnetic fields can be influenced. This is particularly noticeable in the cartilage, which strongly depends on the O  $_2$  diffusion, there is increased oxygen availability of the chondrocytes induced by the magnetic field, and noticeable results in increased synthesis performance of the cell. By a shape-preserving and regenerating action of these electrically induced bone formation succeeds the organism with a minimum of material and energy to build up the necessary structures. An injury or disease mere reduction in the elasticity of bone leads to disruption of cell structure, the matrix production and mineralization. By pulsating electromagnetic fields, the lack of functional stress and loss of energy and information can be compensated and accelerate bone formation and fracture healing significantly.

• [0014]

The membrane of the membrane systems are either directly or influenced by the potential generated in the collagen or only a change in the microenvironment of the cell. This mechanism is based on an electrochemical transmission that modifies the cell activity by displacement of the ion atmosphere in the extra- and thus also in the intracellular space. The capacitive charging of the cell membrane by the electric component of pulsed electromagnetic fields is doing is a crucial factor. Caused by the structure and charge transfer in the membrane, especially in the area of the pores, the possibility of a change in permeability with a resultant influence of passive ion-transport and diffusion processes. The close coupling of surface

reaction and transmembrane transport seem particularly active transport systems such as the Na-K pump, represent an important starting point for the induced energy. In this case, an increased Na-K-adenosine triphosphatase activity causing an increased sodium intake by the competent ion pump. Only the excitation leads to an optimum, inventive amplitude response of the individual pulses via probably an increase in the surface concentration of the corresponding ions for exciting the active transport complexes.

• [0015]

Particularly good results in the stimulation of metabolic exchange are achieved when the curve corresponds to each individual pulse following function:  $y = x^3 \cdot e^{\sin(x^3)} c$ 

• [0016]

With the parameters used in this formula can be achieved a generally good for most types of tissue stimulation.

• [0017]

An optimization of the effect of the inventive device on the body can be improved by feedback. For this purpose, sensors may be used that measure one or more different body parameters, to optimize the excitation of the body through the elektomagnetischen pulses. The sensors can be, for example, blood pressure, temperature, pulse and respiration volume collect and use to optimize the parameters of the device for generating electromagnetic radiation.

• [0018]

Further advantageous embodiments of the invention are specified in the dependent claims.

• [0019]

Reference to the drawing, the invention is explained in detail. Shown

- Figure 1 is a schematic representation of an embodiment of the inventive device for influencing biological processes.
- Fig. 2 shows the time course of a single pulse;
- Fig. 3 shows the time sequence of several individual pulses within the pulse groups.
- [0020]

As shown in Fig. 1, an apparatus according to the invention consists at least of a pulse generator 1 which generates a field forming apparatus or coil 2, a pulsating electromagnetic field, which comes into the living tissue 3, in particular the body of a patient to be treated to effect. To adjust, especially optimization, the pulse parameters of pulsed electromagnetic field in the generator 1, a sensor can detect certain body 4 parameters. Such parameters include, for example, body temperature, blood pressure, pulse rate, or oxygen content of the blood. The detected parameter is a control unit 6 via a feedback line 5, which evaluates the parameters and the pulse generator 1 controls accordingly. For improved optimization, it is possible to detect several body parameters to optimize the pulsating magnetic field at the same time and evaluated.

• [0021]

In addition, a sensor 4 for detecting the transmitted through the irradiated body frequencies of the field generating device 2 may be provided. The detected frequencies are supplied via the line 5 to the control unit 6. From the differences, in particular in the spectral composition, between the frequencies and the frequencies detected by the sensor 4 generated by the field generating device, the control device 6 calculates the transfer function of the irradiated body. In response to this transfer function, the control unit 6 sets the respective optimum values for the parameters a, b, c, d and k fixed.

• [0022]

In such a field generating devices 2, the field strengths can also be varied within the geometry of the field generating device 2.

#### • [0023]

With the method and apparatus of the invention, a pulsating electromagnetic field is generated such that single pulses are generated whose shape basically corresponds to the curve shown in Fig. 2. In FIG. 2, the amplitude of a single pulse 10 and the period between two consecutive individual pulses is shown over time. The individual pulses 10, which compose the pulsed electromagnetic field start, at a time t <sub>a</sub> low amplitude. At the end of the single pulse 10 at time t <sub>b</sub> decreases towards the (average) amplitude resistant. The increase in amplitude is preferably carried out according to a power function. But there are also other possible functions that describe the (average) increase in the amplitude of a single pulse 10 over time. The optimal form and sequence of sub-pulses is very individual. It depends on the nature of the irradiated tissue, on the desired cure rate and on the particular individual. It has been shown that the optimum pitch it can vary between 1 and 1000 Hz. A "rest period" of certain length can be located between the individual pulses 10, which is necessary due to the relaxation time of the exchange processes presumably. The duty cycle between rest period (. Times t <sub>c</sub> and t <sub>a</sub> in Figure 2) and active pulse time (t <sub>a</sub> and t <sub>b</sub>) from 3: 1 to 1: 3 vary, it is preferably about 1: 1. In most applications, however, the rest is superfluous.

#### • [0024]

Every single pulse 10 are added impetus superimposed (hereinafter referred to as sub-pulses) 11. At the beginning of each individual pulse 10, the amplitude of the superimposed pulses 11 with a zero or a preselected offset value and at about the end of the single pulse begins at time t<sub>b</sub> it reaches the maximum amplitude of a single pulse 10 (or vice versa). Between time t<sub>a</sub> and time t<sub>b is</sub> the amplitude of the superimposed pulses under 11 has increased steadily, from or changes to any size. These combined sub-pulses 11 lead to the stimulation of the physiological processes of exchange and contribute significantly to the acceleration of the healing process mentioned in. The important feature is that the amplitude of these sub-pulses 11 varies in the course of each individual pulse 10.

#### • [0025]

Has a crucial role in the stimulation of exchange processes in the body tissues probably the high proportion of other or falling edge sections generated by the plurality of sub-pulses superimposed 11.

• [0026]

According to the invention takes the steepness of the rise of the superimposed high frequency pulses 11 from the beginning of a single pulse to 10 by the end of a single pulse 10. Here, the slope directly at successive superimposed pulses 11, depending on the factor k or k (x) also decrease temporarily.

• [0027]

According to the invention, each of the individual pulses, for example, a course on which corresponds to the following function:  $y = x^{a} \cdot k \cdot e^{\sin(xb)} c + d$ 

• [0028]

This formula indicates the variation of the amplitude y x against time for each single pulse 10. The time x intercepts for each single pulse 10 at the beginning of this pulse again with the same initial value, preferably 0 to. This formula only gives the history of the "active" pulse time. Each be provided breaks between the individual pulses are not given by this formula. In the time between the individual pulses the signal or the pulsating electromagnetic field takes the value 0 or a preset fixed value. This means that the area that the parameter x passes, depends on the duration of the "active" from pulse duration. This is determined by the frequency of the individual pulses may be between 1 Hz and 1000 Hz, and the duty cycle between "active" and "passive" pulse duration. The time variable x preferably varies between -4.5 and +4.5, wherein for the most applications, the range of 0 to approximately +4 (ie 0 to 3 - 4) is sufficient.

• [0029]

The exponent a indicates with which slope increases the amplitude of the basic pulse during the "active" pulse duration. Using this parameter, each individual pulse is as it were a kind of "envelope" for the actual course set. Preferred values for a are in the range of a = 1 to a = 5, the value 3 is preferably used. The parameter can also assume corresponding negative values.

• [0030]

The exponent b describes the number and slope of the relation defined by the parameter a basic pulse waveform superimposed sub-pulses 11. The larger the parameter b is chosen, the more sub-pulses 11 are superimposed on each basic pulse. The b parameter preferably assumes values between 2 and 5, in general, the value 3 is used.

• [0031]

The parameter c represents a kind of scaling factor. With it, a maximum signal or field strength value can be set each individual pulse. The larger the parameter c is chosen, the smaller the maximum amplitude value reached. The parameter c is chosen so that in each country different allowable electromagnetic field strengths can be met. The WHO suggests values less than 100  $\mu$ T ago in continuous use in the low frequency range. The exact value to be used for each c is therefore dependent on the characteristics of the coil or field generating device 2 used. The parameter as a function of time for special applications, for example, by a program-dependent control, vary. All things being equal pulse frequency signal, for example, initially a minute can be operated with a low, followed by 2 minutes with a higher field strength, and more.

• [0032]

The parameter d can be a kind of "bias" of the individual pulses 10 determine that it can be set a background signal value (offset value) on the "Replace" the individual pulses 10 each. This base value must correspond to any firm selected amplitude value, but can also vary over time (Nulliniensymmetrie or Nullinienasymmetrie). In this electrophoretic operations can be influenced by a suitable choice. Preferably, a value between -1 and +2 is used generally 0. The parameter is especially to be chosen so that the allowable field strength range is not exceeded.

• [0033]

In a preferred embodiment of the invention is selected for the parameters a value of 3, for the parameter B is the value 3, for the parameter k, the value 1 and for the parameter d is the value 0 (the parameter c is a function of the above boundary conditions to choose and so the following is not further specified with). If the individual pulses 10 have such a history, a particularly advantageous stimulation of biological processes can be achieved. The amplitude response of each individual pulse 10 corresponds to the following formula:  $y = x^3 \cdot e^{\frac{sin(x - 3)}{2}}$ 

• [0034]

If are using sensors certain parameters of the living tissue, especially of the human body, senses, the course can be any single pulse 10 is adapted to the actual conditions that an optimal stimulation is achieved. To be a function of the detected tissue parameters (or the sensed tissue parameters), the parameters of the pulse curve, ie a, b, c, d and k, changes accordingly. In this way, an adaptive adjustment of stimulation to the sensitivity of the tissue to be stimulated is possible. The extent to which a variation as a function of tissue parameters is possible, depends on the type of fabric, the desired excitation and in particular on the physical quality of the sensed tissue parameters.

• [0035]

If a Einzelimpulaverlauf chosen according to the above-indicated particularly advantageous embodiment of the invention, as can be changed over such a feedback loop parameters to a lesser extent, to compensate for an adjustment of the pulse shape at a caused for example by encouraging self sensitivity change of the applied tissue.

• [0036]

Fig. 3 shows the individual pulses 10 of FIG. 2 in a larger time scale. The individual pulses 10 are combined to form pulse groups 12, 13, in which a plurality of individual pulses following each other. Between the time t<sub>1</sub>, which marks the beginning of such a pulse group and the time t<sub>2</sub>, which marks the end of a group of pulses, corresponds to the course over time of each pulse to the curve shown in Fig. 2. For simplicity, the amplitude response of each individual pulse in Fig. 3 is indicated with a triangle. The duration of each pulse group is a function of the external conditions is between 0.25 sec and 1.2 sec. Advantageously, the duration of the pulse groups during the period of exposure of the fabric is varied by the pulsating magnetic field as a function of time. It has been found to be particularly advantageous to allow the length of the pulse groups increase with increasing application time. Between such groups of pulses is a pulse interval (t<sub>2</sub> to t<sub>3).</sub> Between 0.05 times and three times the duration of a pulse group 12, 13 may vary Such pulse intervals lead to a better experience has shown that stimulation of the living body tissue.

#### Revendications(11) Langue du texte original : <u>Allemand</u>

1. A device for influencing biological processes in a living tissue, in particular a human body, by subjecting at least a portion of the tissue with a pulsed electromagnetic field characterized by

a field-generating device (2) for generating the pulsating electromagnetic field and

a pulse generator (1) for driving the field-generating device (2), wherein the pulse generator (1) the field generating device (2) controls so,

that the pulsating electromagnetic field consists of a large number of individual pulses (10) having a frequency between 1 Hz and 1000 Hz,

that the amplitude of each individual pulse (10) corresponds to the following function:  $y = x^{a} \cdot k \cdot e^{\sin(xb)} c + d$  where the parameters respectively indicate:

У

the amplitude of the signal curve generated,

Х

the time course, wherein the time X for each individual pulse (10) starts anew with the same initial value, a

a parameter for setting the temporal amplitude response of each individual pulse (10)

b

the number of superimposed pulses,

С

a factor to adjust the amplitude,

d

an offset value and

k

a factor for adjusting an amplitude of the superimposed pulses.

- 2. Apparatus according to claim 1, characterized in that a modulated individual pulse (10) of the pulsating electromagnetic field corresponds to the following function:  $y = x^3 \cdot e^{\sin(x^3)} c$
- 3. Apparatus according to claim 1 or 2, characterized in that the individual pulses (10) occur in pulse groups (12,13), wherein the duration of each pulse group (12,13) between 0.25 seconds and 1.2 seconds.
- 4. Apparatus according to claim 3, characterized in that the duration of the pulse groups (12,13) during the period of exposure of the fabric varies with the pulsating electromagnetic field in a function of time.
- 5. Apparatus according to claim 3 or 4, characterized in that the pulse ratio between the individual pulses (10) and the intervening rest periods within the pulse groups (12,13) 3: 1 to 1: 3.
- 6. Device according to one of claims 1 to 5, characterized in that the apparatus further comprises:

at least one sensor (4) for detecting each of a tissue parameter and

a control unit (6), which the detected from the at least one sensor (4) tissue parameters is supplied to the optimization of the profile of the pulsating magnetic field by evaluating the recorded tissue parameters and driving the pulse generator (1).

7. An electrical or electro-magnetic signal for influencing biological processes in a living tissue, in particular a human body, by subjecting at least a portion of the tissue with a pulsed electromagnetic field characterized in

that the signal consists of a plurality of individual pulses (10) whose frequency is between 1 Hz and 1000 Hz,

that the amplitude of each individual pulse (10) corresponds to the following function:  $y = x^{a} \cdot k \cdot e^{\sin(xb)} c + d$  where the parameters respectively indicate:

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the amplitude of the signal curve,

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the time course, wherein the time X for each individual pulse (10) starts anew with the same initial value, a

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a factor for adjusting an amplitude of the superimposed pulses.

- 8. An electrical or electro-magnetic signal according to claim 1, characterized in that a modulated individual pulse (10) of the electrical or electro-magnetic signal corresponds to the following function:  $y = x^3 \cdot e^{\sin(x)}$
- An electrical or electro-magnetic signal according to claim 1 or 2, characterized in that the individual pulses (10) occur in pulse groups (12,13), wherein the duration of each pulse group (12,13) between 0.25 seconds and 1.2 seconds is located.
- 10. An electrical or electro-magnetic signal according to claim 3, characterized in that the duration of the pulse groups (12,13) varies during the period of exposure of the tissue as a function of time.
- An electrical or electro-magnetic signal according to claim 3 or 4, characterized in that the pulse ratio between the individual pulses (10) and the intervening rest periods within the pulse groups (12,13) 3: 1 to 1: 3.

Brevet cité	Date de dépôt	Date de publication	Déposant	Titre
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DE4221739A1 *	2 juil. 1992	14 janv. 1993	Fischer Ag	LF pulse generator and transmission antenna for proton transport in blood - has coil which induces higher energy in electrolyte fluid than thermal energy and within cell-specific amplitude window
<u>US4428366</u> *	6 mai 1981	31 janv. 1984	Alfred B. Kurtz	Electromagnetic apparatus and method for the reduction of serum glucose levels
<u>US5181902</u> *	21 sept. 1990	26 janv. 1993	American Medical Electronics, Inc.	Double-transducer system for PEMF Therapy
WO1996032158A1 *	15 avr. 1996	17 oct. 1996	Stephen John Walpole	Therapeutic field generator
* Cité par l'examina Citations hors breve	teur ets			
Référence				
1 None				
Référencé par				
Brevet citant	Date de dépôt	e Date de publication	Déposant	Titre
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014045500770	24 août	10		De des fan de sections en de site de starte de site finite de la site de sector

Device for generating a pulsed electromagnetic field with pulse control

Vorrichtung zur Erfassung von Wirkungen gepulster Magnetfelder auf einen

#### Citations de brevets

CN101553277B

DE10110365B4 \*

18 mai 2011

16 mai 2013

2007

3 mars

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Quanten-

Brevet citant	Date de dépôt	Date de publication	Déposant	Titre
	2001		Medicine Ag	Organismus
DE102009017229B4 *	9 avr. 2009	8 nov. 2012	Knut Pfeiffer	Vorrichtung und Verfahren zur Erzeugung eines magnetischen Signals
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WO2010086301A1	26 janv. 2010	5 août 2010	Peter Gleim	Apparatus for modulating perfusion in the microcirculation of the blood
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WO2011023634A1	20 août 2010	3 mars 2011	Peter Gleim	Apparatus for stimulating homeostatic autoregulatory mechanisms in the organism
WO2011023635A1	20 août 2010	3 mars 2011	Peter Gleim	Apparatus for stimulating local and higher homeostatic autoregulatory mechanisms in the organism

\* Cité par l'examinateur

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Like the electrical or electromagnetic signal as compared to traditional devices improved device results in a significantly faster stimulation of metabolic processes in irradiated tissue. This could be due to the fundamental pulses superimposed pulses improve the physiological processes of exchange on intra-corporeal membrane systems because the patch pulses according to the law of induction (Maxwell's equations) according to their special form, eg induce growing slew rates, higher levels of electromagnetic field peaks, for example, by using the influence they pose electromotive force effects which generally highly selective physicochemical reaction mechanisms by an appropriate broadband reduction of the activation energies and so - stimulate the physiological processes of exchange - especially in membrane regions. This stimulation leads in particular to an increased O <sub>2</sub> -Utilisation.

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A particular advantage of the device and the signal present invention is that it also leads to a local irradiation leads to an activation of the metabolic processes throughout the body including the non-irradiated areas of the individual.

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With such irradiation beneficial effects in various medical applications can be achieved. An increased O  $_2$  -Utilisation leads among other things on the one hand to an increased connective tissue and cartilage formation and an additional vascularization.

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On the other hand, possibly favored by the above O <sub>2</sub> -Utilisation, be based on the bioelectric effect of the induced voltages and mineralization of connective tissue due to increased ion exchange. The bone metabolism is very closely linked to the assembly and disassembly of cartilage, as evidenced by endochondral ossification or similar running secondary fracture healing. Correspondingly, the joint determining for the consolidation of bone fragments calcium entry and Ausflußkinetik of chondrocytes by pulsing electromagnetic fields can be influenced. This is particularly noticeable in the cartilage, which strongly depends on the O <sub>2</sub> diffusion, there is increased oxygen availability of the chondrocytes induced by the magnetic field, and noticeable results in increased synthesis performance of the cell. By a shape-preserving and regenerating action of these electrically induced bone formation succeeds the organism with a minimum of material and energy to build up the necessary structures. An injury or disease mere reduction in the elasticity of bone leads to disruption of cell structure, the matrix production and mineralization. By pulsating electromagnetic fields, the lack of functional stress and loss of energy and information can be compensated and accelerate bone formation and fracture healing significantly.

#### • [0014]

The membrane of the membrane systems are either directly or influenced by the potential generated in the collagen or only a change in the microenvironment of the cell. This mechanism is based on an electrochemical transmission that modifies the cell activity by displacement of the ion atmosphere in the extra- and thus also in the intracellular space. The capacitive charging of the cell membrane by the electric component of pulsed electromagnetic fields is doing is a crucial factor. Caused by the structure and charge transfer in the membrane, especially in the area of the pores, the possibility of a change in permeability with a resultant influence of passive ion-transport and diffusion processes. The close coupling of surface reaction and transmembrane transport seem particularly active transport systems such as the Na-K pump, represent an important starting point for the induced energy. In this case, an increased Na-K-adenosine triphosphatase activity causing an increased sodium intake by the competent ion pump. Only the excitation leads to an optimum, inventive amplitude response of the individual pulses via probably an increase in the surface concentration of the corresponding ions for exciting the active transport complexes.

• [0015]

Particularly good results in the stimulation of metabolic exchange are achieved when the curve corresponds to each individual pulse following function:  $y = x^3 \cdot e^{\sin(x \cdot 3)} c$ 

• [0016]

With the parameters used in this formula can be achieved a generally good for most types of tissue stimulation.

• [0017]

An optimization of the effect of the inventive device on the body can be improved by feedback. For this purpose, sensors may be used that measure one or more different body parameters, to optimize the excitation of the body through the elektomagnetischen pulses. The sensors can be, for example, blood pressure, temperature, pulse and respiration volume collect and use to optimize the parameters of the device for generating electromagnetic radiation.

• [0018]

Further advantageous embodiments of the invention are specified in the dependent claims.

• [0019]

Reference to the drawing, the invention is explained in detail. Shown

- Figure 1 is a schematic representation of an embodiment of the inventive device for influencing biological processes.
- Fig. 2 shows the time course of a single pulse;
- o Fig. 3 shows the time sequence of several individual pulses within the pulse groups.
- [0020]

As shown in Fig. 1, an apparatus according to the invention consists at least of a pulse generator 1 which generates a field forming apparatus or coil 2, a pulsating electromagnetic field, which comes into the living tissue 3, in particular the body of a patient to be treated to effect. To adjust, especially optimization, the pulse parameters of pulsed electromagnetic field in the generator 1, a sensor can detect certain body 4 parameters. Such parameters include, for example, body temperature, blood pressure, pulse rate, or oxygen content of the blood. The detected parameter is a control unit 6 via a feedback line 5, which evaluates the parameters and the pulse generator 1 controls accordingly. For improved optimization, it is possible to detect several body parameters to optimize the pulsating magnetic field at the same time and evaluated.

• [0021]

In addition, a sensor 4 for detecting the transmitted through the irradiated body frequencies of the field generating device 2 may be provided. The detected frequencies are supplied via the line 5 to the control unit 6. From the differences, in particular in the spectral composition, between the frequencies and the frequencies detected by the sensor 4 generated by the field generating device, the control device 6 calculates the transfer function of the irradiated body. In response to this transfer function, the control unit 6 sets the respective optimum values for the parameters a, b, c, d and k fixed.

#### • [0022]

In such a field generating devices 2, the field strengths can also be varied within the geometry of the field generating device 2.

• [0023]

With the method and apparatus of the invention, a pulsating electromagnetic field is generated such that single pulses are generated whose shape basically corresponds to the curve shown in Fig. 2. In FIG. 2, the amplitude of a single pulse 10 and the period between two consecutive individual pulses is shown over time. The individual pulses 10, which compose the pulsed electromagnetic field start, at a time t <sub>a</sub> low amplitude. At the end of the single pulse 10 at time t <sub>b</sub> decreases towards the (average) amplitude resistant. The increase in amplitude is preferably carried out according to a power function. But there are also other possible functions that describe the (average) increase in the amplitude of a single pulse 10 over time. The optimal form and sequence of sub-pulses is very individual. It depends on the nature of the irradiated tissue, on the desired cure rate and on the particular individual. It has been shown that the optimum pitch it can vary between 1 and 1000 Hz. A "rest period" of certain length can be located between the individual pulses 10, which is necessary due to the relaxation time of the exchange processes presumably. The duty cycle between rest period (. Times t <sub>c</sub> and t <sub>a</sub> in Figure 2) and active pulse time (t <sub>a</sub> and t <sub>b</sub>) from 3: 1 to 1: 3 vary, it is preferably about 1: 1. In most applications, however, the rest is superfluous.

• [0024]

Every single pulse 10 are added impetus superimposed (hereinafter referred to as sub-pulses) 11. At the beginning of each individual pulse 10, the amplitude of the superimposed pulses 11 with a zero or a preselected offset value and at about the end of the single pulse begins at time t<sub>b</sub> it reaches the maximum amplitude of a single pulse 10 (or vice versa). Between time t<sub>a</sub> and time t<sub>b is</sub> the amplitude of the superimposed pulses under 11 has increased steadily, from or changes to any size. These combined sub-pulses 11 lead to the stimulation of the physiological processes of exchange and contribute significantly to the acceleration of the healing process mentioned in. The important feature is that the amplitude of these sub-pulses 11 varies in the course of each individual pulse 10.

• [0025]

Has a crucial role in the stimulation of exchange processes in the body tissues probably the high proportion of other or falling edge sections generated by the plurality of sub-pulses superimposed 11.

• [0026]

According to the invention takes the steepness of the rise of the superimposed high frequency pulses 11 from the beginning of a single pulse to 10 by the end of a single pulse 10. Here, the slope directly at successive superimposed pulses 11, depending on the factor k or k (x) also decrease temporarily.

#### • [0027]

According to the invention, each of the individual pulses, for example, a course on which corresponds to the following function:  $y = x^{a} \cdot k \cdot e^{\sin(xb)} c + d$ 

#### • [0028]

This formula indicates the variation of the amplitude y x against time for each single pulse 10. The time x intercepts for each single pulse 10 at the beginning of this pulse again with the same initial value, preferably 0 to. This formula only gives the history of the "active" pulse time. Each be provided breaks between the individual pulses are not given by this formula. In the time between the individual pulses the signal or the pulsating electromagnetic field takes the value 0 or a preset fixed value. This means that the area that the parameter x passes, depends on the duration of the "active" from pulse duration. This is determined by the frequency of the individual pulses may be between 1 Hz and 1000 Hz, and the duty cycle between "active" and "passive" pulse duration. The time variable x preferably varies between -4.5 and +4.5, wherein for the most applications, the range of 0 to approximately +4 (ie 0 to 3 - 4) is sufficient.

#### • [0029]

The exponent a indicates with which slope increases the amplitude of the basic pulse during the "active" pulse duration. Using this parameter, each individual pulse is as it were a kind of "envelope" for the actual course set. Preferred values for a are in the range of a = 1 to a = 5, the value 3 is preferably used. The parameter can also assume corresponding negative values.

#### • [0030]

The exponent b describes the number and slope of the relation defined by the parameter a basic pulse waveform superimposed sub-pulses 11. The larger the parameter b is chosen, the more sub-pulses 11 are superimposed on each basic pulse. The b parameter preferably assumes values between 2 and 5, in general, the value 3 is used.

• [0031]

The parameter c represents a kind of scaling factor. With it, a maximum signal or field strength value can be set each individual pulse. The larger the parameter c is chosen, the smaller the maximum amplitude value reached. The parameter c is chosen so that in each country different allowable electromagnetic field strengths can be met. The WHO suggests values less than 100  $\mu$ T ago in continuous use in the low frequency range. The exact value to be used for each c is therefore dependent on the characteristics of the coil or field generating device 2 used. The parameter as a function of time for special applications, for example, by a program-dependent control, vary. All things being equal pulse frequency signal, for example, initially a minute can be operated with a low, followed by 2 minutes with a higher field strength, and more.

#### • [0032]

The parameter d can be a kind of "bias" of the individual pulses 10 determine that it can be set a background signal value (offset value) on the "Replace" the individual pulses 10 each. This base value must correspond to any firm selected amplitude value, but can also vary over time (Nulliniensymmetrie or Nullinienasymmetrie). In this electrophoretic operations can be influenced by a suitable choice. Preferably, a value between -1 and +2 is used generally 0. The parameter is especially to be chosen so that the allowable field strength range is not exceeded.

• [0033]

In a preferred embodiment of the invention is selected for the parameters a value of 3, for the parameter B is the value 3, for the parameter k, the value 1 and for the parameter d is the value 0 (the parameter c is a function of the above boundary conditions to choose and so the following is not further specified with). If the individual pulses 10 have such a history, a particularly advantageous stimulation of biological processes can be achieved. The amplitude response of each individual pulse 10 corresponds to the following formula:  $y = x^3 \cdot e^{\sin(x/3)}$ 

#### • [0034]

If are using sensors certain parameters of the living tissue, especially of the human body, senses, the course can be any single pulse 10 is adapted to the actual conditions that an optimal stimulation is achieved. To be a function of the detected tissue parameters (or the sensed tissue parameters), the parameters of the pulse curve, ie a, b, c, d and k, changes accordingly. In this way, an adaptive adjustment of stimulation to the sensitivity of the tissue to be stimulated is possible. The extent to which a variation as a function of tissue parameters is possible, depends on the type of fabric, the desired excitation and in particular on the physical quality of the sensed tissue parameters.

#### • [0035]

If a Einzelimpulaverlauf chosen according to the above-indicated particularly advantageous embodiment of the invention, as can be changed over such a feedback loop parameters to a lesser extent, to compensate for an adjustment of the pulse shape at a caused for example by encouraging self sensitivity change of the applied tissue.

#### • [0036]

Fig. 3 shows the individual pulses 10 of FIG. 2 in a larger time scale. The individual pulses 10 are combined to form pulse groups 12, 13, in which a plurality of individual pulses following each other. Between the time t <sub>1</sub>, which marks the beginning of such a pulse group and the time t <sub>2</sub>, which marks the end of a group of pulses, corresponds to the course over time of each pulse to the curve shown in Fig. 2. For simplicity, the amplitude response of each individual pulse in Fig. 3 is indicated with a triangle. The duration of each pulse groups is a function of the external conditions is between 0.25 sec and 1.2 sec. Advantageously, the duration of the pulse groups during the period of exposure of the fabric is varied by the pulsating magnetic field as a function of time. It has been found to be particularly advantageous to allow the length of the pulse groups increase with increasing application time. Between such groups of pulses is a pulse interval (t <sub>2</sub> to t <sub>3).</sub> Between 0.05 times and three times the duration of a pulse group 12, 13 may vary Such pulse intervals lead to a better experience has shown that stimulation of the living body tissue.

#### Revendications(11) Langue du texte original : Allemand

1. A device for influencing biological processes in a living tissue, in particular a human body, by subjecting at least a portion of the tissue with a pulsed electromagnetic field characterized by

a field-generating device (2) for generating the pulsating electromagnetic field and

a pulse generator (1) for driving the field-generating device (2), wherein the pulse generator (1) the field generating device (2) controls so,

that the pulsating electromagnetic field consists of a large number of individual pulses (10) having a frequency between 1 Hz and 1000 Hz,

that the amplitude of each individual pulse (10) corresponds to the following function:  $y = x^{a} \cdot k \cdot e^{\sin(xb)} c + d$  where the parameters respectively indicate:

#### у

the amplitude of the signal curve generated,

#### х

the time course, wherein the time X for each individual pulse (10) starts anew with the same initial value,

#### а

a parameter for setting the temporal amplitude response of each individual pulse (10)

b

the number of superimposed pulses,

С

a factor to adjust the amplitude,

d

an offset value and

k

a factor for adjusting an amplitude of the superimposed pulses.

- 2. Apparatus according to claim 1, characterized in that a modulated individual pulse (10) of the pulsating electromagnetic field corresponds to the following function:  $y = x^3 \cdot e^{\sin(x \cdot 3)} c$
- 3. Apparatus according to claim 1 or 2, characterized in that the individual pulses (10) occur in pulse groups (12,13), wherein the duration of each pulse group (12,13) between 0.25 seconds and 1.2 seconds.
- 4. Apparatus according to claim 3, characterized in that the duration of the pulse groups (12,13) during the period of exposure of the fabric varies with the pulsating electromagnetic field in a function of time.
- 5. Apparatus according to claim 3 or 4, characterized in that the pulse ratio between the individual pulses (10) and the intervening rest periods within the pulse groups (12,13) 3: 1 to 1: 3.
- 6. Device according to one of claims 1 to 5, characterized in that the apparatus further comprises:

at least one sensor (4) for detecting each of a tissue parameter and

a control unit (6), which the detected from the at least one sensor (4) tissue parameters is supplied to the optimization of the profile of the pulsating magnetic field by evaluating the recorded tissue parameters and driving the pulse generator (1).

 An electrical or electro-magnetic signal for influencing biological processes in a living tissue, in particular a human body, by subjecting at least a portion of the tissue with a pulsed electromagnetic field characterized in

that the signal consists of a plurality of individual pulses (10) whose frequency is between 1 Hz and 1000 Hz,

that the amplitude of each individual pulse (10) corresponds to the following function:  $y = x^{a} \cdot k \cdot e^{\sin(xb)} c + d$  where the parameters respectively indicate:

у

the amplitude of the signal curve,

х

the time course, wherein the time X for each individual pulse (10) starts anew with the same initial value,

а

a parameter for setting the temporal amplitude response of each individual pulse (10)

b

the number of superimposed pulses,

С

a factor to adjust the amplitude,

d

an offset value and

k

a factor for adjusting an amplitude of the superimposed pulses.

- 8. An electrical or electro-magnetic signal according to claim 1, characterized in that a modulated individual pulse (10) of the electrical or electro-magnetic signal corresponds to the following function:  $y = x^3 \cdot e^{\sin(x^3)} c$
- 9. An electrical or electro-magnetic signal according to claim 1 or 2, characterized in that the individual pulses (10) occur in pulse groups (12,13), wherein the duration of each pulse group (12,13) between 0.25 seconds and 1.2 seconds is located.
- 10. An electrical or electro-magnetic signal according to claim 3, characterized in that the duration of the pulse groups (12,13) varies during the period of exposure of the tissue as a function of time.
- 11. An electrical or electro-magnetic signal according to claim 3 or 4, characterized in that the pulse ratio between the individual pulses (10) and the intervening rest periods within the pulse groups (12,13) 3: 1 to 1: 3.

#### Citations de brevets Date de Date de Brevet cité Titre Déposant publication dépôt Therafield Holdings 6 oct EP0266907A2 \* 11 mai 1988 Electrotherapeutic apparatus 1987 Limited LF pulse generator and transmission antenna for proton transport in blood - has coil which 2 juil. DE4221739A1 \* 14 janv. 1993 Fischer Ag induces higher energy in electrolyte fluid than thermal energy, and within cell-specific 1992 amplitude window 6 mai US4428366 \* 31 janv. 1984 Alfred B. Kurtz Electromagnetic apparatus and method for the reduction of serum glucose levels 1981 21 sept. American Medical 26 janv. 1993 Double-transducer system for PEMF Therapy US5181902 \* 1990 Electronics, Inc. WO1996032158A1 15 avr. Stephen John 17 oct. 1996 Therapeutic field generator 1996 Walpole \* Cité par l'examinateur7 **Citations hors brevets** Référence 1 None Référencé par Date de Date de Brevet citant Déposant Titre dépôt publication 6 nov. EP1594567A2 \* 16 nov. 2005 Zvi Nachum Method and device for restoring kidney function using electromag netic stimulation 2003 24 août CN101553277B 18 mai 2011 皮特·格雷姆 Device for generating a pulsed electromagnetic field with pulse control 2007 3 mars Quanten-DE10110365B4 ' 16 mai 2013 Vorrichtung zur Erfassung von Wirkungen gepulster Magnetfelder auf einen Organismus 2001 Medicine Aa DE102009017229B4 9 avr. Knut Pfeiffer 8 nov. 2012 Vorrichtung und Verfahren zur Erzeugung eines magnetischen Signals 2009 24 août US8216121 10 juil. 2012 Peter Gleim Device for generating a pulsed electromagnetic field with pulse control 2007 28 janv. US8667732 11 mars 2014 Peter Gleim Method for the treatment of plants using electromagnetic fields 2010 1 nov. Hansen WO2002036198A1 \* Magnetic field therapy device 10 mai 2002 2001 Hergen Device for the regeneration and prevention of degeneration of the cartilaginous tissue and 29 janv. WO2007131809A1 \* 22 nov. 2007 Igea Srl subchrondral bone and the proliferation of chondrocytes by means of a pulsed electromagnetic 2007 field 24 août WO2008025731A1 \* 6 mars 2008 Peter Gleim Device for generating a pulsed electromagnetic field with pulse control 2007 26 janv. WO2010086301A1 5 août 2010 Peter Gleim Apparatus for modulating perfusion in the microcirculation of the blood 2010 28 janv. WO2010086367A1 5 août 2010 Peter Gleim Method for the treatment of plants using electromagnetic fields 2010 20 août WO2011023634A1 3 mars 2011 Peter Gleim Apparatus for stimulating homeostatic autoregulatory mechanisms in the organism 2010 20 août Apparatus for stimulating local and higher homeostatic autoregulatory mechanisms in the WO2011023635A1 3 mars 2011 Peter Gleim 2010 organism

\* Cité par l'examinateur

# Device for magnetic field therapy and magnetic field signal to be applied EP 2050481 A1

#### Résumé

The device has a coil (2) for generating a pulsating magnetic field, and a pulse generator (1) controlling the coil. The generator is formed such that the magnetic field is made from a sequence of main pulses, where pulse repeat rate ranges between 0.001 and 1000 hertz. An amplitude response of the main pulses of different forms is formed by a specific function. The main pulses are adjustable and selectable with different combinations of parameter values. A sensor (4) detects a tissue parameter. The parameter is fed to a control device (6) for optimizing a response of the magnetic field.

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## Description Langue du texte original : Allemand

Field of the Invention

• [0001]

The invention relates to a device for magnetic field therapy, as for example, in <u>EP 0995463 B1</u> is described.

State of the art

• [0002]

Since the early 70s devices are known which are also used for therapeutic purposes partly routinely primarily in the field of orthopedics in hospitals, medical centers, and for home use.

• [0003]

A generator serves to control a magnetic field generating device, wherein the generator, the magnetic field generating device controls so that the magnetic field consists of a plurality of, with respect to a time interval and amplitude course characteristic of shaped parent pulses and main pulses, the pulse frequency is usually between 0 and 1000 Hz. Such a main pulse can eg sinusoidal, trapezoidal, sawtooth ( <u>EP 0594655 B1 (King Herbert</u>) <u>EP 0729 318 B1 (Gerhard Fischer</u> . <u>EP-A-0377284</u>) Or in <u>EP 0995463 B1</u> (<u>Kafka Wolf A</u>) Can be realized by an exponential increase in the Middle sinusoidally modulated field intensity variation with magnetic flux densities in areas of nanoTesla to several milliTesla, so that the main pulses, such as in <u>EP 0995463 B1</u>, Composed of a series of consecutive sub-pulses which differ in their amplitude and / or rise and fall slopes lies, ultimately therefore also in their individual lives.

• [0004]

The generation of the magnetic fields is often done by one or more of each other and independently controlled electrical coils. From the variety of devices for electromagnetic therapy, time-varying field intensities oriented documents apply by analogy to the generation, for example, in EP 1364679 A2 . EP-A-0266807 . EP-A-0266907 . DE-A-4221739 . US-A-5,181,902 . WO-A-96/32159 . UA-A-4,428,366 . EP 0995463 B1 ,

• [0005]

The therapeutic application for reasons of operational costs and the risks involved today usually not invasive.

• [0006]

The influence of the biological system is based on an idea by common shares in its energy as yet unknown interaction of the generated by the devices magnetic and electric field components. The induced physiological and biological effects based then on the direct, by magnetic or / and on the principle of induction (Maxwell's equations) the indirect, caused by electric force effects influence (energetic activation) of the physical-chemical reactivity of the inherent and self preservation oriented regulatory mechanisms involved ional, atomic and molecular lump sum referred to as molecular structures in the following blocks.

• [0007]

As described, for example, that the use of specific apparatus <u>EP 0995463 B1</u> in comparison with untreated controls biological objects as a series of differentiated physical-physiological processes such as leads to significant activation of processes:

- in the formation of high-energy compounds, especially of adenosine triphosphate (ATP) and bis-2-3-phospoglycerat (BPG) in human erythrocytes [Spodaryk C (2001) Red blood hemoglobin oxygen affinity and metabolism: effect of electromagnetic fields on healthy adults. In Kafka WA (ed) 2nd World Congress Int Bio-Electro-Magnetic-Energy-regulation. EMPHYSPACE 2: 15-19; Kafka WA, Spodaryk C (2003) Effects of extremely weak BEMER 3000 type pulsed electromagnetic fields on red blood metabolism and hemoglobin oxygen affinity. Fizoterapia 11 (3): 24-31]
- to improve the functional state of the microcirculation in particular with regard to the circulation behavior (especially in diabetes-related circulatory disorders) and the oxygen utilization [Klopp R (2004) Vital microscopy and reflexionsspektrometrische studies on the effect of the device system "BEMER 3000 "on the functional state of the microcirculation. Report from the Institute of Microcirculation in Berl; Klopp R, Niemer W (2007) Effect of pulsed electromagnetic field stimulation with vasomotor a restricted functional state of the microcirculation. Complement. Integr Med 08/2007. 47-53] and
- in the course of safeguards in particular regarding an accelerated flow described in Klopp 2004 infectious triggered, worn by a complex interplay of signaling and adhesion molecules leukocyte immune defense reactions
- in the protection against chemical stressors in particular the reduction of chemically induced (by the teratogen cyclophosphamide) abnormalities in the ontogeny of warm-blooded vertebrate embryos (modeled from chicken eggs) [Jelinek R, Bláha J, Dbalý Jaroslav (2002) The electromagnetic BEMER 3000 signal modifies response to teratogens. In Kafka WA (ed) 3nd Int. World Congress Bio-Electro-Magnetic Energy Regulation, Bad-Windsheim, Germany, EMPHYSPACE 3
- at Reparationsvorgängen especially in terms of improved healing default generated wounds [Kafka WA, Preißinger M (2002) Improved wound healing by coupled BEMER 3000 type pulsed Elektromagnetfeld- and LED light therapy using the example of comparative studies of standardized wounds after ovariectomy in cats (felidae ). In: Edwin Ganster (Eds) Austrian Society of Animal Health (ÖGT) Small Animal Dermatology 2nd day. 3 March 2002 Salzburg Congress]
- with anti-oxidative regulations in particular with regard to enzymatic spectrophotometry and certain accelerated reduction reaction rates [Spodaryk K (2002) The effect of extremely weak electromagnetic field treatments upon signs and symptoms of delayed onset muscle soreness of: A placebo-controlled clinical double blind study. Medicina Sportiva 6: 19-25; Klopp R, W Niemer, Pomrenke P, Schulz J (2005) Magnetic field therapy: complementary therapeutic sense or nonsense? Opinion in the light of new research results with the device system BEMER 3000, Institute of Microcirculation in Berl]
- improvement in performance in elite sport [Spodaryk K and Kafka WA (2004) The influence of extremely weak BEMER3000 typed by pulsed electromagnetic fields on ratings of Perceived exertion at ventilatory threshold. In: Marincek C, Burger H (eds) Rehabilitation Sciences in the New Millennium Challenge for Multidisciplinary Research. 8th Congress of ERDF, Ljubljana. Medimont International Proceedings: 279-283]
- replication and proliferation mechanisms in particular with regard to a significant reduction of tumor growth in athymic but not in comparatively studied normal mice [Rihova B (2004) The effect of electromagnetic fields of the BEMER 3000 on the growth of experimental murine EL 4T cell lymphoma, SAMET Congress, Interlak s; Rihova B, Dbaly J, Kafka WA Exposure to special (BEMER type) pulsed weak electromagnetic fields does not accelerate the growth of mouse EL4 T cell lymphoma, submissed]
- protein formation and activation in particular with regard to differential the up and down regulation genexprimierter amounts of protein. As part of a gene chip analysis it could be shown that the application of the device <u>EP 0995463 B1</u> on bone marrow stem cells (bone and cartilage

cells) compared with untreated the amount of proteins produced affected differently: the amount (expression) of the proteins produced is thus partly increased, partly decreased, partly it is (interestingly, among other things, for the expression of oncogenes) unaffected [Kafka WA, Sagittarius N, Walther M (2005) use of extremely low frequency (BEMER typical) pulsed weak electromagnetic fields in orthopedics (Application of extreme low frequent (BEMER type) pulsed electromagnetic fields in orthopedics). Orthopaedic Practice 41 (1): 22-24; Walther M, Meyer F, Kafka WA, Sagittarius N (2007) Effects of weak, low frequency pulsed electromagnetic fields (BEMER type) on gene expression of human mesenchymal stem cells and chondrocytes: an in vitro study. Electromagnetic Biology and Medicine, Manuscript ID: 257936].

- psychovegetative processes, particularly the reduction of (dental) anxiety caused by a dental treatment immediately vorrausgehende electromagnetic local stimulation of the solar plexus [Michels-Wakili S and Kafka WA (2003) BEMER 3000 Pulsed low-energy electromagnetic fields reduce dental anxiety: a randomized placebo-controlled single -blind study. 10th International Congress on Modern Pain Control 5-8 June 2003 Edinburgh, GB]
- the reduction lumbargisch initiated subsequent reactions in particular the reduction of motion pain, insomnia and anxiety [Bernatzky G, Kullich W, Aglas F, Take Winkler M, Likar R, PiPAM W, H. Schwann H, Kafka WA (2007) Effects of special (BEMER typical) pulsed electromagnetic fields on quality of sleep and chronic low back pain of musculoskeletal (low back pain): A double-blind randomized study Duo Center (Pain, in press].
- the analgesic effect, especially in terms of reducing polyneuropathic pain as a result of oxidative stress after chemotherapy [Gabrys M (2004) Pulsed magnetic field therapy with cytostaticinduced polyneuropathy. German Journal of Oncology 36: 154-156].

• [0008]

Additional summary reports can be found at: Carpenter DO, Aryapetyan S (1994) Biological effects of electric and magnetic elds. Sources and mechanism, vol 1 Beneficial and harmful effects, Vol 2. Academic Press; Bohn W, Kafka WA (2004) Energy and Health: BEMER 3000 Bio-Electro-Magnetic Energy Regulation by Prof. Dr. Wolf A. Kafka. Haug Verlag, Stuttgart (Thieme): 1-130; Kafka WA (2006) The BEMER 3000 Therapy: A new complementary " <u>electro-magnetic drug</u> "Effectively supports widespread prophylactic and therapeutic treatments scattered. In: Kochueva E (ed) Achievements in space medicine into health care practice and industry 3rd European practice matured congress COPY PRINT sponsored by ESA, DLR & Pocko MOC]; Quittan M, Schuhfried O, Wiesinger GF, Fialka-Moser V (2000) Clinical effectiveness of magnetic therapy - a literature review. Acta Medica Austriaca 3: 61-68; Rudiger Matthes (2003) Guidance on deterministic mining compliances of exposure to pulsed and complex non sinusoidal waveforms below 100 kHz with ICNIRP GUIDELINES. The International Commission on Non-Ionizing Radiation Protection ICNIRP Secretariat, Federal Office for Radiation Protection, Institute of Radiation Hygiene, Ingolstadt Road, D-85764 Oberschleissheim, Germany].

• [0009]

These results, in particular concerning the differentiated effect on tumor growth and gene expression, confirm and imply acceptance of introduction mentioned that the electromagnetically induced biological effects on the activation of the cause of different molecular mechanisms are based, and, in particular with respect to the above-differentiated gene expression, for example, not be explained by the improvement in the condition of the microcirculation. According to the different amount of energy therefore required for each activation, thus confirming the (already described in Maxwell's equations) importance of marked (by different amplitudes and slew rates of the superimposed sub-pulses) time intensity distribution. - According to the differentiated in this way "electromagnetic" active properties of the temporal field intensity variations thus a similar significance in the electromagnetic field therapy as the structure-activity relationships of active pharmaceutical ingredients in the pharmaceutical industry.

## • [0010]

Just on the edge is drawn to reports of WHO, therefore comparing the use of such weak energy devices expect no harmful side effects [Electro Magnetic Fields (EMF) ff *http: // www.who.int / peh-emf / s /;. . http: // www.who.int / topics / electromagnetic\_fields / en /*] In this direction also includes a report of a responsible for the certification of medical devices German regulator [LGA 2005 report], specifically for the - according to statistical surveys since 1998 to the present estimated several million times used - device <u>EP 0995463 B1</u> health no negative effects confirmed.

Underlying problems

## • [0011]

Although all known devices for treatment of the human body lead to the desired effect of accelerating healing processes, but can still improve in their effect. Without taking into account of whether a patient actually benefited from such treatment, the statements refer in addition in the form of so-called surrogate parameter studies often only on the treatment of laboratory values such as to parameters of the cycle, lipid transport (LDL, HDL), lung function, bone mineral density or other material sales. This is problematic in that for achieving a significantly accelerated healing success, the application frequently, often with variation of the field intensity ratios must be repeated, which not only leads to an increased burden on patients, but also to significantly higher treatment costs.

## • [0012]

Obviously, the relation between the temporal intensity ratios of the applied electromagnetic fields and the respective induced biological effect in the device EP 0995463 B1 still insufficiently exploited. According to the abovementioned ideas for effects have there particular in their absolute (regardless of sign) intensity with respect to the following steeper and higher rising sub-pulses of the main pulse due to their amplitude and flank slopes on a principle less potential for individual influence of the physiological biological reactions modulating activation energies. Simply put, in EP 0995463 B1 generated temporally immediately successive sub-pulses of the main pulse are always smaller than the following terms of their amplitude and slope. Accordingly, and in addition, because of which, according to the Maxwell's equations thus different building electric field components deliver these over the respective following sub-pulses within the meaning of the targeted possible widespread activation of regulatory mechanisms only a limited accordingly lower energy contribution. With reference to the in EP 0995463 B1 envelope described as connecting the upper and lower extreme values of the sub amplitude factor is that the coordinate axis closer envelope of this increasingly removed within the pulse sequence: In terms of the amplitude would therefore successive sub-pulses compared to those in which the envelope described by the coordinate axis less "removed" have a lower activation potential. - For the purposes of the intended broad activation are therefore in EP 0995463 B1 described forms the main and sub-pulses in terms of duration and amplitude and amplitude sequence still graded inadequate.

Task and problem solving

## • [0013]

The object of the invention is to provide a device for magnetic field therapy and a magnetic signal, in particular based on amplitude, slew rates and sequence of the individual pulses, characterized by a finer gradation and thus a broader spectral composition, and thus, a broad band of electromagnetic activatable

molecular structures appealing, ensuring wider physiological effect width. The invention is thus based on a widely effective as possible energetic support of the normal course of life-determining complex network of molecular regulation processes. Notwithstanding the usually symptom-based treatment regimens accordingly pursues a holistic and thus preventive, just geared towards regeneration, maintenance and well-being therapy concept.

• [0014]

This object is achieved according to the invention by the independent claims, wherein advantageous developments are specified in dependent claims.

• [0015]

So that a device is provided which comprises a pulse generator and a field generating device for generating an electromagnetic field (Fig. 1). The pulse generator is used to drive the field generating device, wherein the pulse generator the field generating device by means of suitable current or voltage sequences drives so that the pulsating magnetic field composed of a number of individually adjustable main pulses and a plurality of therein with respect to slew rates and amplitudes of fine stepped subpulses so that the spectral composition reaching the greatest possible energy density. Such a main pulse can be composed from a set on average constant in amplitude or in the manner of a power function in other funds or descending amplitude sequence of different edge gradients in their sub-pulses. Characterized by the connection of the extrema Linen (envelope) of the individual pulses, the main pulses, as described below and FIG. 2 and Fig. 3 executed precisely, suppose depending on the chosen conditions even a pulse shape. In particular, it can be achieved that the average distance between the coordinate axis and one of the facing envelope within a main pulse, notwithstanding <u>EP 0995463 B1</u> Remains largely constant.

• [0016]

When a voltage drive, make sure that the inductance of the coil causes the applied voltage signal does not lead to identical magnetic field signal because the inductance of the coil reproduces the waveform to higher frequencies with lower amplitudes. This can easily be counteracted that the desired time function of the magnetic field via a Fourier transformation converted into the frequency domain, where the high frequencies are raised accordingly, to obtain the then suitable time signal for the voltage waveform. Another possibility is to use a voltage-controlled current amplifier, the current signals applied to the coil with a profile which corresponds to the desired magnetic signal.

#### • [0017]

The duration of treatment is derived from the sum of the periods for the application of the individual main pulses and the pauses in between / ta - tb /. For each between 2 rest periods lying amplitude curve y = f(t) results in the time domain t1 <t <t2 a main pulse y = ft and t = fx and  $t = t \boxtimes 2 - t \boxtimes 1 * x / x \boxtimes 2 - x \boxtimes 1$  with  $x \boxtimes 1 < x < x \boxtimes .2$ 

y = f(t) und t = f(x) und  $t = (t2 - t1)^{x}/(x2 - x1)$  mit x1 < x < x2.

 $y(x) = k1 + k2*EXP(SIN(x^k3)+SIN((x^k4)^k5)+x^k6);$ 

## • [0018]

The function describes a substantially by a defined by the parameters k1, k2, k3, k4, k5 k6 and exponential modulation course, with this modulation curve is characterized by two SIN functions that are determined by the parameters k3, k4 k5 and. After a SIN function can only take values between +1 and -1, is the sum of both the EXP function determining SIN functions between -2 and +2. The EXP function can therefore only values between EXP (-2) = 0.135 and EXP (+2) = 7.39 suppose if one of the other term + x \* k6 apart, then specifies a further increase. The SIN-functions themselves with the corresponding parameters are chosen such that a fine adjustment to the successive amplitude values is achieved in the sub-pulses thus defined with a high range of variation.

## • [0019]

## Where:

- Oy (x) = amplitude of the magnetic field within a main pulse as a function of x;
- ox = calculated substitute measure for the time t (see below);
- o k1 = value;
- o k2 = multiplication factor for the function EXP (SIN (x  $^{k3}$ ) + SIN ((x  $^{k4}$ )  $^{k5}$ ) + x  $^{k6}$ );
- o k3 = exponent of x;
- o k4 = multiplication factor of x;
- o k5 = exponent of (x \* k4);
- o k6 = multiplication factor of x;
- o EXP = exponential function with base e = 2.71;
- o = SIN sine function.
- [0020]

k1 - k6 are parameters that are freely selectable within certain limits, to give the amplitude profile of different forms (cf. examples. Figure 2 and Figure 3 ).

- x is a reference value which is a mathematical parameter that is used to represent, to reflect the time course of the magnetic signal within a main pulse. During the time interval t1 between the beginning and the end t2 of a main pulse passes through the values x from x1 to x2, x1 so <x <x2. Thus, at any time within a main pulse is associated with an amplitude y. Practical limits for x1 are at -5 <x2 and at +5, with excerpts from this range are feasible, ie for example -3 <x <+4.</li>
- [0021]

The selectable parameters k1 to k6 have the following meaning and effect on the magnetic signal:

- k1 is a presettable basic velocity value in a basic signal value or a premagnetization can specify to which the main impetus 10 "Fit" (Nulliniensymmetrie or Nullinienasymmetrie). This core value has no fixed value selected amplitude correspond but can in the time sequence for each main pulses vary individually (see FIG. Waveforms in Fig. 3 a, b, c, d, e, f).
- k2 is a multiplication factor for the EXP function; The larger k2 is chosen, the larger is the maximum achievable modulation amplitude value of a main pulse which is added to the base amplitude value. k1 and k2 can be - depending on k6 - limit such that the different in each country permitted field levels are not exceeded (see curves. Fig. 3 d, e, f).

- k3 determined as a kind of temporal scaling factor k4 and k5, together with the time course (slope and amplitude) of the modulated signal or magnetization value of the individual pulses. The larger the parameter K3 is selected, the greater the "waviness" of the envelope connecting the extreme values of the sub-pulses (see FIG. Waveforms Fig. 3 d and e ).
- k4 determined together with k3 and k5 also number and slope but in particular, as a kind of density based on the temporal sequence of the individual pulses of sub-pulses (k4 ≠ 0); The larger the parameter is selected k4, the denser the individual sub-pulses in the different "waves" of the envelopes of each main pulse stored (see FIG. Curves Fig. 3 a, b, f).
- k5 is, similar to K3, a kind of temporal scaling and dimensioning factor over which in combination with the parameters K3 and K4 of the temporal modulation curve (slope, amplitude, and density in the sequence within the "waves" as described above) of the signal or magnetization value of the individual pulses can be adjusted within a main pulse. (See FIG. Curves Fig. 3 c, d).
- k6 is a normalization and dimensioning factor for setting one of K1 and K2 dependent and can be fixed to the main sequence of the individual pulses mean amplitude value. It indicates with which the slope amplitude of the main pulse during the "active" pulse duration increases or decreases. k6 thus also describes the mean amplitude increase of the stored in the main pulse sub-pulses. For example, lead values k6> 0 increasing in the middle or at k6 <0 to decreasing in the middle in particular by the envelope connecting the extreme values of the sub-pulses verdeutlichten -. Amplitude values of the sub-pulses (cf. curves Fig. 3 a, b, c). This has made it especially on the abscissa axis facing away from the envelope. According to the invention is in particular the distance of the abscissa axis, however, facing almost constant. In k6 = 0 the amplitude values of the sub-pulses in the medium remain constant and the envelope parallel to the x-axis.</li>
- [0022]

As in the embodiment and in FIG. 2 to FIG. 5 further performed can be thus suitably selected parameter variations, a sequence of main pulses - generate individually or in groups, different sub-pulses - in terms of medium size and gradation fineness.

• [0023]

The key difference between <u>EP 0995463 B1</u> in which to grow the sub-pulses with respect to their amplitudes and slew rates from the start of the main pulse to the end of the main pulse steadily and further away in the middle of the coordinate axis, is omitted in the present apparatus in the temporal sequence of amplitude and slope conditions <u>EP 0995463 B1</u> formally specified limitation of the biological activation options.

• [0024]

Finer, using the example of the pulsation of the envelope curve specially made clear gradation of slope steepness and amplitude parameters (ultimately by the coupled thereto duration of the individual pulses), the spectral composition of each main pulse within the meaning of the targeted task solution, the widest possible choice of in the regulation to address involved molecular control mechanisms accordingly improved.

• [0025]

The present device results in a faster and wider excitation of the regulatory mechanisms involved in molecular interactions and metabolic processes. Based on the findings outlined above could be due to the opposite <u>EP 0995463 B1</u> significantly increased number of specially shaped (eg amplitude and slew rates characterized) Under pulses for each regulatory processes necessary to maintain the individual energetic activations corresponding to a wider range of amounts of energy available to them.

## • [0026]

Based on the fundamental importance of this is crucial to the life flow regulatory mechanisms can thus be with such Feldbeaufschlagung favorable effects in various medical applications achieve. For example, with respect to the processes for improving the functional state of the microcirculation and the resulting increased O<sub>2</sub> -Utilisation this leads to a further increased production of the processes of transcription, translation, the formation and modulation of the activity state of proteins energetically supporting energy carrier ATP, and - further consequence also an accelerated setting proteomics, ie a more efficient provision of these regulations modulating proteins.

• [0027]

In particular, this can also lead to a further improved support for the extremely complex marked on Signalstoff- and various forms of adhesion molecules sequence of immune responses.

• [0028]

In conjunction with an increased synthesis capacity increased O  $_2$  leads -Utilisation inter alia on the one hand to increased connective tissue and cartilage formation and an additional vascularization and thus reinforcing of O  $_2$  diffusion in cartilage heavily dependent formation of chondrocytes. By a shapepreserving and regenerationsfördemde effect of these electrically induced bone formation, it is possible to fix the necessary structures to injury and disease and related disorders in bone formation accelerates the organism with a minimum of materials and energy.

• [0029]

On the other hand, the bioelectric effect of the induced voltages, in conjunction with an activation of the ATP formation supporting proton pump and further favored by the O  $_2$  -Utilisation, over an increased ion exchange can lead to mineralization of connective tissue. Because of the tightly coupled to bone metabolism up and dismantling processes of cartilage apparatus of the invention may also affect the joint determining for the consolidation of bone fragments calcium entry and Ausflußkinetik of chondrocytes.

#### • [0030]

Which are important for intra- and intercellular signaling and metabolic exchange membranes of the membrane systems are affected either directly or through the potential generated in the collagen or about a change in the microenvironment of the cell. This mechanism is based, possibly also as described above in connection with electromagnetic support of the proton transport mechanisms, probably due to an electrochemical transmission that modifies the cell activity by displacement of the ion atmosphere in the extra- and thus also in the intracellular space. The capacitive charging of the cell membrane by the electric component of pulsed electromagnetic fields is doing is a crucial factor. Caused by the structure and charge transfer in the membrane, especially in the area of the pores, the possibility of a change in permeability with a resultant influence of passive lonentransport- and diffusion processes. The close coupling reaction surface and transmembrane transport appear next to the proton pump, other membrane-bound proteins, such as the Na-K pump, represent important receiver structures for the induced energy. In this case, an increased Na-K-adenosine triphosphatase activity causing an increased sodium intake by the competent ion pump. Only the excitation leads to an optimum, according to the invention the amplitude course of the main pulses over probably an increase in the surface concentration of the corresponding ions for exciting the active transport complexes.

• [0031]

In its positive effect on the complex cross-linked complex regulatory processes in the life expiry of the list of supported single mechanisms could advantageously be further extended in this manner. Apart from the above-mentioned general positive impact on the competitive sports, the inventive device can thus generally contribute to optimized support general nature given protective and curative maintenance processes and well-being.

• [0032]

In conjunction with the reduction in the occurrence of chronic disorders general this invention could ultimately Narrow about their influence on the vital processes of substance and energy expenditure and thus the reduction of coupled thereto medications and the development of general illness costs.

• [0033]

A particular advantage of the device and the signal of the present invention that it can also lead to a local treatment resulted in a stimulation of metabolic processes throughout the body of the patient.

• [0034]

Good results can also be achieved, if the parameters of the amplitude function y will not be kept constant during a treatment period, but may be varied according to a preset pattern on the patient. These sets of parameters are defined, then enter to be selected time periods apply in turn.

## Concrete example

• [0035]

A generally good for most types of tissue stimulation can be used with this formula  $y = k \boxtimes 1 + k \boxtimes 2 * EXP$  (SIN  $x \land k \boxtimes 3 + SIN \boxtimes x * k \boxtimes 4 \land k \boxtimes 5$ ) +  $x * k \boxtimes 6$ ;

 $y(x) = k1 + k2*EXP(SIN(x^k3)+SIN((x^k4)^k5)+x^k6);$ 

achieve when for the course of the main pulse function parameters k1 to k6, chosen from the following ranges of values (detailed functional description see above under task and problem solving):  $-6 < k \boxtimes 1 \cdot k \boxtimes 2 \cdot k \boxtimes 6 < 6$  in also possibl in increments of 0  $\cdot$  1

-6 < k1, k2, k6 < 6 in (auch möglich in Schritten von 0,1)

- 6 < k ⊠ 3 . k ⊠ 5 < 6 ganzahlig

-6 < k3, k5 < 6 (ganzahlig)

- 10 < k⊠4 < 10

## -10 < k4 <10

(Comp. See also FIG. 2 to FIG. 4)

• [0036]

This is true with y = EXP (SIN  $x \land \boxtimes 3 + SIN x * 2 \land \boxtimes 3 + x * 0 . 2$ );

## $y(x) = EXP(SIN(x^3)+SIN((x^2)^3)+x^{*}0,2);$

for example, the following parameter values in the range of -5 < x < 5: k  $\boxtimes$  1 = 0; k  $\boxtimes$  2 = 1; k  $\boxtimes$  3 = 3; k  $\boxtimes$  4 = 2; k  $\boxtimes$  5 = 3; k  $\boxtimes$  6 = 0.2;

## k1 = 0; k2 = 1; k3 =3; k4 = 2; k5 =3; k6 = 0,2;

• [0037]

The above function is, for each main pulse 10 the course of the amplitude y (x) and hence y (t) again, since T is a function of x. The end of each main pulse 10 begins at eg x = -5 and ends at x = +5. This formula only gives the history of the "active" pulse time. The rest each be provided between the main pulses / ta - tb / are not described by this formula. In the time between the main pulse, so the rest takes the signal or the pulsating magnetic field to the value 0 or a preset fixed value. The area that the parameter x is running through preset and depends on neither the duty cycle of the pulse repetition yet. In other words, this means that each main pulse, regardless of its duration is associated with a timing that is determined by the above formula.

• [0038]

Referring to the drawings (FIG. 1 to FIG. 5) The invention is explained in more detail. Shown

- Fig. 1 a schematic representation of an embodiment of the inventive device for influencing biological processes;
- FIGS. 2 through Fig.4 each of the basic time course of the main impulses for different parameter values k1 k6 and the period of x = -5 to x = 5;
- Fig. 5 any time segment of a possible in principle, separated by pulse intervals 13 series of in accordance with FIG. 2 to FIG. 6 custom main pulses in a larger time scale for a treatment time 15 marked by different parameter values main impulses are symbolized here to simplify marked by differently with respect to hatching and height rectangles. Depending on the rules themselves can in different main pulses, also in groups 14 to replace, in chronological order.
- [0039]

In detail Fig. 1 an apparatus according to the invention consisting of at least one pulse generator 1, which generates in the coil 2, a pulsating magnetic field, which comes into the living tissue 3, in particular the body of a patient to be treated to effect. To adjust, especially optimization, the pulse parameters of the pulsating magnetic field in the generator 1, a sensor can detect certain body 4 parameters. Such parameters include, for example, body temperature, blood pressure, pulse rate, or oxygen content of the blood. The detected parameter is a control unit 6 via a feedback line 5, which evaluates the parameters and the pulse generator 1 controls accordingly. For improved optimization, it is possible to detect several body parameters to optimize the pulsating magnetic field at the same time and evaluated. In response to these effects, the control unit 6 may automatically set the optimum values for the parameters k1 to k6 and respectively.

• [0040]

In addition, a sensor may be provided for detecting the frequency dependence of the transmitted to the body effect of the field generating device 2. From the differences, especially in the spectral composition between the field energy generated by the field generation and detected by the sensor, the controller determines the transmitted on the treated body part.

• [0041]

In response to this action, the controller sets 6, the optimal values for the parameters k1 to k6 himself firmly.

• [0042]

In such a field generating devices 2, the field strengths can also be varied within the geometry of the field generating device 2.

• [0043]

With the method and apparatus of the invention, a pulsating magnetic field is generated such that a succession of main pulses 10 is produced, the shape, depending on the parameters k1, k2, k3, k4, k5, k6, in principle in the FIG. 2 to FIG. 4 History shapes shown corresponds. The main pulses 10, which make up the pulsed magnetic field begin at a time t1 and reach, depending on the sign of k6 their mean minimum or maximum value. The mean amplitude of the main pulse 10, and the periodically modulated herein amplitudes increase (in k6> 0) or fall (k <0) on average in the end of each of the main pulse. Increase or decrease made in accordance with an exponential function. But there are also other possible functions describing the mean increase (decrease) of the amplitude of the main pulse within the time. The optimal shape of the sequence of sub-pulses is very individual. It depends on the nature of the tissue acted upon by the field, from the desired healing success and of the respective individual.

• [0044]

The main sequence of individual pulses can be separated by breaks 13 see. Fig. 4, It has been shown that the optimal fundamental frequency can vary inclusive intermediate selectable intervals from 0.01 to 1000 Hz. These breaks are probably necessary because of the relaxation time of the exchange processes and lead to a better experience has shown that stimulation of the living body tissue. They are from 0 to 200 ms, for example of the order. The duty cycle between sleep time (time points ta to tb FIG. 2) And pulse repetition period T is preferably between 0% and 300%.

• [0045]

Each main pulse 10 is modulated pulses with sub-11. At the beginning of each main pulse 10 at t1, the amplitude of the superimposed sub-pulses 11 begins with a magnetization value previously selected and rises or falls depending on the sign of K6 to the end of the main pulse at the time t2. Although between the time t1 and the time t2 (time of a main pulse 10) varies the amplitude of the superimposed sub-pulses, but exposed in the time sequence within a main pulse (substantially depending on the parameter values K3, K4, and K5) of varying density successive pulsations, The average distance between the x-coordinate axis and a facing said envelope can, depending on k6, but are kept substantially constant.

• [0046]

In particular, the curve showing the course in Figure 2 and Fig. 3 That the density and thus also slope of the consecutive in the main pulse 10 sub pulses 11 and thus also the "waviness" (pulsations) of the connecting their extrema envelope 12, depending on the respective values of x symmetrically to the ordinate axis at x = 0 with increasing magnitude values of x and increasing values of k3, k4, k5 and constantly increases (see FIG. particular curves Fig. 3 d, e, f).

• [0047]

Over time, a main pulse, between times t1 and t2 vary considerably depending on the parameter value k6 besides, the amplitudes of these above formula according to the invention modulated sub-pulses. The mean amplitudes of these sub-pulses 11, and the average distance of the connecting their extrema envelope 12 of the x-axis assumed for values of k6> 0 in the middle, under otherwise identical values for k1 to k5 k6 values continuously or for <0 constantly from. For k6 = 0 the amplitudes and accordingly also the average distance between the envelopes and the x-axis remains constant. (Representative of k6 are in Fig. 3 only curves for k6> 0 shown, the curves for negative values of k6 caused by reflection in the x = 0 y axis).

• [0048]

These combined sub-pulses 11 lead to the stimulation of the physiological processes of exchange and contribute significantly to the acceleration of the relevant regulatory and healing processes involved. It is particularly important that the amplitude of these sub-pulses 11 varies in the course of each main pulse 10 and substantially opposed to <u>EP 0995463 B1</u> That these sub-pulses are much finer graded with respect to slope amplitude and timing.

• [0049]

The optimal form and sequence of sub-pulses is very individual. It depends on the type of the applied field of tissue from the desired healing and success of each individual.

• [0050]

A crucial role in the stimulation of exchange processes in the body tissues probably high, 11 caused by the large number of sub-pulses superimposed proportion of on or falling edge sections.

• [0051]

If are using sensors certain parameters of the living tissue, especially of the human body, recognized, the course can each main pulse 10 so adapted to the actual conditions that optimal stimulation is achieved. To be a function of the detected tissue parameters

• [0052]

An optimization of the effect of the present device to the organism can be enhanced by a feedback. For this purpose, sensors may be used that measure one or more different body parameters, to optimize the excitation of the body by the electromagnetic pulses. The sensors tissue parameters such as blood pressure, temperature, pulse, pH or tidal volume can be captured and used for the purposes of adaptive adjustment of the stimulation to the sensitivity of the tissue to be stimulated to optimize the parameters of the device for generating electromagnetic fields. In particular, allowed themselves to offset on such a feedback loop potential by encouraging self-induced changes in the sensitivity acted tissue.

• [0053]

A further optimization is obtained from the detection of the frequency dependence of the transmitted to the body effect. From the differences, especially in the spectral composition between the field and the energy captured by the sensor, the controller determines the transmitted on the treated body energy content generated by the field generation 2. Depending on the control unit 6 may determine the optimal values for the parameters k1 to k6 itself.

## Revendications(10) Langue du texte original : <u>Allemand</u>

 A device for influencing biological processes in a living tissue, in particular a human body, for applying at least a portion of the tissue with a pulsed magnetic field, with a field generating device (2) for generating the pulsating magnetic field and a pulse generator (1) for driving the field-generating device (2) characterized in

**that** the pulse generator (1) is designed such that the pulsating magnetic field of a succession of main pulses (10) of which the pulse repetition rate from 0.01 to 1,000 Hz,

**that** the amplitude course of a main pulse, having the following feature:  $y x = k \boxtimes 1 + k \boxtimes 2 * EXP$  (SIN x  $\land \boxtimes k \boxtimes 3 + SIN x * k \boxtimes 4 \land \boxtimes k \boxtimes 5 + x * k \boxtimes 6$ );

## $y(x) = k1 + k2*EXP(SIN(x^k3)+SIN((x^k4)^k5)+x^k6);$

it mean:

y (x) = amplitude of the magnetic field within a main pulse as a function of x; x = calculated substitute measure for time t during a main pulse;

k1 = value;

 $k^2$  = multiplication factor for the function EXP (SIN (x ^ k3) + SIN ((x \* k4) ^ k5) + x \* k6);

k3 = exponent of x;

- k4 = multiplication factor of x;
- k5 = exponent of (x \* k4);
- k6 = multiplication factor of x;
- EXP = exponential function with base e = 2.71;
- SIN = sine function.

k1 - k6 are parameters that are freely selectable within certain limits, to give the amplitude profile of different shapes.

Apparatus according to claim 1, characterized in that the parameter of the function with the properties k1 to k5, and k6 are integers selected in decimal gradation from the following value ranges: - 6 < k ⊠ 1 . k ⊠ 2 . k ⊠ 6 < 6 in also possibl in increments of 0 . 1</li>

-6 < k1, k2, k6 < 6 in (auch möglich in Schritten von 0,1)

- 6 < k  $\boxtimes$  3 . k  $\boxtimes$  5 < 6 ganzahlig

-6 < k3, k5 < 6 (ganzahlig)

- 10 < k 🛛 4 < 10

-10 < k4 <10

(See. Also FIG. 2 to FIG. 4) for example: k ⊠ 1 = 0 ; k ⊠ 2 = 1 ; k ⊠ 3 = 3 ; k ⊠ 4 = 2 ; k ⊠ 5 = 3 ; k ⊠ 6 = 0 . . 2

k1 = 0; k2 = 1; k3 = 3; k4 = 2; k5 = 3; k6 = 0,2.

- Apparatus according to claim 1 or 2, characterized in that the main pulses are adjustable and can be selected with different combinations of parameter values.
- Apparatus according to claim 3, characterized in that a group of different combinations of parameter values (14) can be found in order to bring in a defined time sequence are used, while the duration of a burst (14) between 0.25 seconds and 1.2 seconds.
- Apparatus according to claim 4, characterized in that that the duration of the pulse groups (14) during the period of exposure of the fabric is made variable with the pulsating magnetic field as a function of time.
- Device according to at least one of claims 1 5 characterized in, that the ratio between the main pulses (10) and the intervening rest periods within the pulse groups (14) is between 0% and 300%.
- 7. Device according to at least one of claims 1 to 5, characterized in that the apparatus further comprises:

at least one sensor (4) for detecting each of a tissue parameter and a control unit (6), which the detected from the at least one sensor (4) tissue parameters is supplied to the optimization of the profile of the pulsating magnetic field by evaluating the recorded tissue parameters and driving the pulse generator (1).

8. Device according to at least one of claims 1 to 5, characterized in that the apparatus further comprises:

at least one sensor (4) for detecting the difference between the applied and the field energy absorbed by the body and

a control unit (6), which the detected from the at least one sensor (4) energy value is fed to optimize the course of the pulsating magnetic field by evaluating the recorded parameters and controlling the energy of the pulse generator (1).

9. Magnetic field **signal, characterized** in **that** it comprises the following amplitude curve for each main pulse:  $y x = k \boxtimes 1 + k \boxtimes 2 \times EXP$  (SIN  $x \land \boxtimes k \boxtimes 3 + SIN x \times k \boxtimes 4 \land \boxtimes k \boxtimes 5 + x \times k \boxtimes 6$ )

$$y(x) = k1 + k2*EXP(SIN(x^k3)+SIN((x^k4)^k5)+x^k6))$$

it mean:

- y (x) = amplitude of the magnetic field within a main pulse as a function of x;
- x = calculated substitute measure for time t during a main pulse;

k1 = value;

- $k^2$  = multiplication factor for the function EXP (SIN (x ^ k3) + SIN ((x \* k4) ^ k5) + x \* k6);
- k3 = exponent of x;
- k4 = multiplication factor of x;
- k5 = exponent of (x \* k4);
- k6 = multiplication factor of x;
- EXP = exponential function with base e = 2.71;

SIN = sine function.

k1 - k6 are parameters that are freely selectable within certain limits, to give the amplitude profile of different shapes.

10. Magnetic field signal according to claim 8, **characterized in that** the parameters of the function k1 to k6 obtained from the following ranges of values - 6 < k ⊠ 1 . k ⊠ 2 . k ⊠ 6 < 6 in also possibl in increments of 0 . 1

## -6 < k1, k2, k6 < 6 in (auch möglich in Schritten von 0,1)

- 6 < k  $\boxtimes$  3 . k  $\boxtimes$  5 < 6 ganzahlig

-6 < k3, k5 < 6 (ganzahlig)

- 10 < k 🛛 4 < 10

-10 < k4 < 10

## (See. Also FIG. 2 to FIG. 4)

and, for example, have the following values:  $k \boxtimes 1 = 0$ ;  $k \boxtimes 2 = 1$ ;  $k \boxtimes 3 = 3$ ;  $k \boxtimes 4 = 2$ ;  $k \boxtimes 5 = 3$ ;  $k \boxtimes 6 = 0 \dots 2$ 

k1 = 0; k2 = 1; k3 = 3; k4 = 2; k5 = 3; k6 = 0,2.

#### Citations de brevets

Brevet cité	Date de dépôt	Date de publication	Déposant	Titre
<u>EP0266807A2</u>	24 août 1987	11 mai 1988	Metallgesellschaft Ag	Method of catalytically reducing nitrogen oxide
<u>EP0266907A2</u>	6 oct. 1987	11 mai 1988	Therafield Holdings Limited	Electrotherapeutic apparatus
<u>EP0377284A2</u>	29 nov. 1989	11 juil. 1990	LIFE RESONANCES, INC. (a Montana corporation)	Improved method and apparatus for regulating transmembrane ion movement
<u>EP0594655B1</u>	3 juil. 1992	6 mars 1996	Dr. Fischer Ag	Device for transporting ions, especially protons
<u>EP0729318B1</u>	8 oct. 1994	7 mai 1997	Dr. Fischer Ag	Device for determining the effect of pulsed magnetic fields on an organism
<u>EP0995463B1</u>	21 oct. 1998	16 août 2001	Wolf. A. Prof. Kafka	Device applying electric or electromagnetic signals for promoting biological processes
<u>EP1364679A2</u>	8 mai 2003	26 nov. 2003	de la Cal, Antonio Madronero	Device for generating multiple magnetic fields used in magnetotherapy, and magneto acupuncture
<u>DE4221739A1</u>	2 juil. 1992	14 janv. 1993	Fischer Ag	LF pulse generator and transmission antenna for proton transport in blood - has coil which induces higher energy in electrolyte fluid than thermal energy, and within cell-specific amplitude window
<u>DE10313259A1</u> *	25 mars 2003	21 oct. 2004	Medizintechnik Bergstraße GmbH	Magnetic-field system with field energy in form of bundled pulses, for application to human body, has pulses in each bundle increasing in accordance with Euler function

\* Cité par l'examinateur

Référencé par

Brevet citant	Date de dépôt	Date de publication	Déposant	Titre
DE202011004080U1	7 avr.	12 oct 2011	Julia	Universelle, im Magnetfeldapplikator integrierte Steuereinheit zum Erzeugen
DE20201100498901	2011	12 000. 2011	Günther	von Magnetfeldern für die Magnetfeldtherapie

## An apparatus for generating a pulsed electromagnetic field with pulse control

Langue du texte original : <u>Allemand</u> DE 102006041365 A1

## Résumé Langue du texte original : Allemand

The invention relates to a device for generating a pulsed electromagnetic field with pulse control, in which the outgoing from the pulse generator pulses represent periodic pulses, ascending and descending envelopes have with harmonic or anharmonic oscillation profile within the envelope, the pulse sequence in the range of 1 pulse / 20 minutes is up to 10 pulses / 1 minute using pulse train, pulse function type and electromagnetic flux density values are controlled, the play features of the blood microcirculation by non-invasive methods of measurement of a target tissue, for the function type such pulses with exponential functions are included. It can be achieved stronger and longer-lasting improvements in the microcirculation.

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Inventeurs	Peter Gleim, Rainer Dr. med. Klopp
Déposant	Peter Gleim
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Liens externes: DPMA (Office allemand des brevets et des marques), Espacenet

## Revendications(8) Langue du texte original : Allemand

- 1. An apparatus for generating a pulsed electromagnetic field with pulse control, comprising a pulse generator which is connected with a coil for generating an electromagnetic field, characterized in that emanating from the pulse generator pulses represent periodic pulses, the ascending and descending envelope curves exhibit with harmonic or anharmonic oscillation profile within the envelope, and that the pulse sequence in the range of 1 pulse / 20 minutes to 10 pulses / 1 minute and that the control pulse train, pulse width, pulse function type and electromagnetic flux density measurement data are based, using non-invasive vital microscopic, spectrometric play, laser-Doppler or oxygen partial pressure measuring methods on a target tissue characteristics of the micro-circulation of the blood, which for the function type such pulses are exempted exponential functions.
- 2. An apparatus according to claim 1, characterized in that the pulses corresponding to a function type whose rise and fall of the envelope is curved.
- 3. An apparatus according to claim 2, characterized in that the pulse function type for the envelope corresponds to the type of a rectified Kosinusstromes.
- 4. Apparatus according to claim 1, characterized in that the pulse train in the range from 1 pulse / 5 minutes to 6 pulses / minute, preferably from 1 pulse / minute to 4 pulses / minute.
- 5. Apparatus according to claim 1, characterized in that the pulse control measurement data from the blood microcirculation underlie selected from the group consisting of the venular oxygen utilization, the number of blood cell-perfused nodal points, venular stream flow, local hematocrit in a microvessel, local hematocrit in all microvessels, the arteriolar vasomotion, number of adhering white blood cells on a

defined venule inner wall, local changes of substance concentrations in tissue and a plurality of these features.

- 6. Apparatus according to claim 4, characterized in that the pulse control measurement data for the venule oxygen extraction are based.
- 7. Apparatus according to claim 4, characterized in that the pulse control measurement data for the arteriolar vasomotion underlie.
- 8. Apparatus according to claim 1, characterized in that the pulse strength is in the range of from 5 to 300  $\mu$ T, preferably from 50 to 250  $\mu$ T, especially from 80 to 150  $\mu$ T.

#### Description Langue du texte original : Allemand

• [0001]

The invention relates to a device for generating a pulsed electromagnetic field with pulse control.

• [0002]

From the <u>EP 0594655 B1</u> is a device consisting of a generator and transmitter, known with which an ion transport from intracorporeal electrolytic fluids to take place into and through vascular walls and in which the applied pulsed currents have certain properties, in particular correspond to the amplitude of the fundamental pulse to an exponential function and a series of pulse sequences for 0.3-1 seconds is sent with pauses of 0.7-5 seconds.

• [0003]

The <u>EP 0995463 B1</u> claims a device for influencing biological processes in a living tissue, be delivered to the pulses on the tissue in which the amplitude of each individual pulse corresponds to a mathematical relationship with the e<sup>sin</sup> e-function <sup>(x high b)</sup> wherein x is the time course and b the number of superimposed pulses.

• [0004]

The waveforms generated with the known devices, which have consistently exponential functions are to either improve muscle formation and joint regeneration or stimulate metabolic processes.

• [0005]

The invention has for its object to provide a device with which pulses of a pulsating magnetic field by certain other features may be improved by body functions.

• [0006]

The present invention provides a device for generating a pulsed electromagnetic field with pulse control, comprising a pulse generator which is connected with a coil for generating an electromagnetic field, characterized in that emanating from the pulse generator pulses represent periodic pulses, the ascending and descending envelope curves have with harmonic or anharmonic waveform within the envelope, and that the pulse train in the range of 1 pulse per 20 minutes is up to 10 pulses per minute, and that the control of pulse sequence, pulse width, pulse function type and electromagnetic flux density measurement data are based, by non-invasive vital microscopic, spectrometric, play laser Doppler or oxygen partial pressure measuring methods on a target tissue characteristics of the micro-circulation of the blood, which for the function type such pulses are exempted exponential functions.

## • [0007]

It has been found that pulses with exponential functions and in the described frequency of the pulse sequence of a maximum of 5 seconds and a maximum of 3 seconds rest Although to some extent affect some features of the functional state of the microcirculation both in healthy and sick leave, however, only with short-term and limited influence on the mechanisms of local regulation of microcirculation, so that no long-term prophylactically and therapeutically relevant changes can be caused.

• [0008]

It was further found that, for a total of marked slowdown of the pulse sequence and pulses with no exponentially ascending and descending envelope significantly much larger and longer lasting characteristic changes in the functional state of the microcirculation can be achieved due to a significantly greater direct influence local control mechanisms of the microcirculation.

• [0009]

The micro-circulation, the flow of blood cells and blood plasma in the smallest blood vessels (with diameters of <200 microns), the functionally important part of the human blood circulation, since the mass transfer is realized by the cells of an organ tissue. This affects the supply of oxygen and substrate to the cells and the removal of metabolic end products. The respective functional state of the microcirculation of an organ determines the width rule for adapting the microperfusion to changing metabolic needs and thus organ function. Furthermore, an undisturbed microcirculation prerequisite for an unhindered flow of the first steps of an immunological reaction. Because of the microcirculation has moved to the center clinical pathophysiological research for quite some time. Of special interest is the study of possible effects on the local regulation of microcirculation, especially the autorhythmic contraction movements of the vessel wall smooth muscles in arteriolar and venular microvessels is (so-called. Vasomotion).

• [0010]

Among the most important criteria for the characterization of normal or disturbed microcirculation

- o The respective state of distribution of blood in the microvessel networks;
- $\circ \quad$  The autorhythmic vessel wall motions in arterioles and venules (vasomotion).
- [0011]

Vasomotor function of the determined state of adjustment substantially the width of the microcirculation to changing metabolic needs and thus the local rule width of the microcirculation.

- - The stream flow in the arteriolar and venular flow of effluent from the capillary networks;
- - Rheological characteristics (local hematocrit);
- Flow rates of blood cells;
- - Diameter of microvessels;
- Possibility of accumulation of white blood cells in the microcirculation, adhesion to the endothelium and transmigration of white blood cells into the tissue.
- [0012]

Therefore, measurement data from the microcirculation of the blood for the control of pulses of an electromagnetic field are used according to the invention. These metrics are selected from the group consisting of the venular oxygen utilization, the number of blood cell-perfused nodal points, venular

stream flow, local hematocrit in a microvessel, local hematocrit in all microvessels, the arteriolar and venular vasomotion, number of adhering white blood cells a defined venule inner wall, local changes in concentration of substances in the tissue. It is advantageous to use more of these features is.

• [0013]

The venule oxygen extraction Apo  $_2$  is specified as a percentage change compared to the respective output value at the time t = 0. Determining the absolute difference of oxygen saturation of hemoglobin in the afferent and efferent arterioles venules of the network of a selected tissue targets. As the target tissue sections are of skin or intestine which have the desired blood vessel networks of the organism and are also one of the immo logically active organs, and continue to be readily available for non-invasive measurements selected.

• [0014]

In the current number of blood cell-perfused nodal points in a defined microvascular network, nNP, the number of blood cell-perfused branching sites in this network is used as a measure of the state of blood distribution. As a border flow velocity of red blood cells V  $_{RBC}$  = 80 microns / s defined. The assessments are + or - (compared to the defined initial value n = 60). Borderline cases are measured at +0.5 or -0.5.

• [0015]

The venular stream flow Qven and the arteriolar stream flow Qart is the particle (blood cell flow) in defined venules and arterioles. It is expressed in microns  $^3$  / s.

• [0016]

The local hematocrit in a blood vessel, which is also referred to as Tube hematocrit, Hk <sub>t</sub>, is the hematocrit in a particular microvessel. It is expressed as the percentage change compared with the starting value.

• [0017]

The hematocrit of the microcirculation Hk  $_{\rm MC}$  is measured in all microvessels with diameters <200 microns.

• [0018]

The arteriolar (or venular) vasomotion, A  $_{VM}$  is determined by the distance-time diagram of the autorhythmic contraction movements smooth muscle arteriolar vessel wall is determined (measurement of the distance perpendicular to the microvessel longitudinal axis of endothelial surface to opposing endothelial surface at equidistant time points; 60 measurements per second, determination of the composite vibration; Fourier analysis; determining the amplitude-frequency spectrum). Criterion is the area A under the envelope of the amplitude-frequency spectrum of the arteriolar vasomotion (a composite wave). This column lists the value as a percentage change compared with baseline.

• [0019]

The number of adhering white blood cells on a defined venule inner wall, nWBC / A is measured at the defined inner surface of the venule with A = 18000 microns <sup>2</sup>. Counts all white blood cells adhering to the endothelium longer than 20 seconds.

• [0020]

Local changes in the concentration of various substances in the tissues, eg for mediators, the adhesion molecule ICAM-1 and other measured. They are given in relative units of 0-10, where 0 means no proof and the value 10 is assigned to the highest detected in a sample value.

## • [0021]

Basis for measuring these characteristics of human tissue are described eg in Bollinger et al, Microvasc Res 7 (1974) 61-72;. Fagrell B, Angiology 23 (1972) 284-298; Fagrell et al, Am J Physiol 233 (1977. ) H318-321;. Wiedemann et al, An introduction to microcirculation, Academic Press, NY, 1981; and Lankowicz JR (ed.): Topics in Fluorescence Spectroscopy, Plenum Press, New York, London, Vol 1-5 (1991-1997), incorporated herein by reference..

## • [0022]

For all collected data will make use of a parameter-free test methods for small samples. To apply the Wilcoxon rank sum test arrives at the significance level  $\alpha$  = 5%. The critical values for T are taken from the literature (G Ferguson, Statistical analysis in psychology and education, McGraw-Hill, NY 1959, 318).

• [0023]

Of particular importance is the vasomotion. Prophylactically and therapeutically relevant is to influence the disturbed vasomotion towards a physiological vasomotion rhythm, ie the "imprinting" of a physiological vasomotion rhythm in case of illness. In case of illness, the arteriolar and venular microvessels vasomotions are significantly altered (usually slows significantly, sometimes only 1 to 2 vasomotions in the course of several minutes). According to the invention, the aim is to lead the disturbed vasomotion into the region of physiological vasomotion (about 1 to 4 vasomotions per minute). The same applies to pathological states with significantly accelerated vasomotion.

• [0024]

Therefore, it was found that in addition to the described effects of specific pulsed electromagnetic fields in the tissues, especially a change in the rhythm of the disturbed vasomotion can be achieved, mostly in terms of stimulating the autorhythmic contraction movements of the vessel wall smooth muscles in the smallest blood vessels (vasomotion of arterioles and venules). When significant changes in the pulse sequence (slowing of the pulse sequence comparison with known methods) and pulses not exponentially increasing and / or decreasing or abruptly dropping envelope significantly much larger characteristic changes of microcirculation of blood can be effected.

• [0025]

Preferably therefore be generated by the inventive device pulse sequences that are in the range of from 1 pulse / 10 minutes to 6 pulses / minute, preferably from 1 pulse / 5 minutes to 4 pulses / minute, in particular from 1 pulse / minute to 4 pulses / minute , In 4a and 4b are exemplary such advantageous pulse sequences shown without respect to the intensity.

• [0026]

Under "pulse train" for the purposes of the present invention will be understood the distance of those oscillation maxima (pulse maxima) from each other, which are above the intensity baseline in an intensity-time diagram such as in 4c shown. If a basic oscillation is present, which may be consistent in terms of intensity, stochastically different or sinusoidally varied as in 4d and 4e and 4f shown, means "burst" the distance of those oscillation maxima from each other, which is well above the basic oscillation.

• [0027]

Pulse sequence is thus the frequency of occurrence of the maximum magnitudes of the envelope in the time unit.

• [0028]

For example, a continuous basic wave of an intensity of 80  $\mu$ T are present having a pulse width of about 30 microseconds, and a much stronger one-shot pulse of 150  $\mu$ T with a larger pulse width of 0.3 s, the stronger single-pulse three to five occurs times per minute. This then also corresponds to the pulse sequence for the purposes of the invention.

• [0029]

Such a pulse arrangement may be beneficial, ie on the aforementioned pulse or the above pulse sequence ( 4a and 4b ) Add a higher-frequency pulse with lower electromagnetic flux density B. These additional pulses may in their amplitudes (and frequencies) vary in different ways, as exemplified in the 4c to 4h is shown. They are generally from 50 to 80  $\mu$ T.

• [0030]

Advantageously, the width of a single pulse at 50 to 300 ms and the pulse width of a base at 10 to 60 ms; preferably 80 to 200 ms and 20 to 40 ms.

• [0031]

The so-called. "Intensity" or pulse intensity is physically the electromagnetic flux density B with the unit tesla.

• [0032]

The pulses generated by the device according to the invention are given periodically and ask for drawing representation in their envelopes arcuate as sine or cosine up parabola-like constructs. Within the envelope occur harmonic oscillations with the same or different amplitude, which may also overlap to anharmonic vibrations, By "envelope" is meant the curve, the maxima of the different levels of the amplitudes of a certain sequence of amplitudes affected and thus this sequence in the ascending and descending part "wrapped" (see 2 ). For superimposed anharmonic oscillations this always affects only the maxima of the adjacent next higher amplitude.

• [0033]

Preferably, thus corresponding to a pulse function type whose rise and fall runs of the envelopes as curved as in rectified currents.

• [0034]

The pulses are composite oscillations or waves, which are formed from a plurality of harmonics as the harmonic or anharmonic different amplitude and frequency, with the partial frequencies of  $\sim$  20 to 3000 Hz.

• [0035]

"Envelope" connects the different amplitudes of the harmonics (amplitude = max. Elongation of a partial oscillation). The "envelope" approximately reflects the history of the composite oscillation or wave.

• [0036]

Particularly preferred is a pulse function type for the envelope that corresponds to the type of rectified Kosinusstromes. Such a rectified cosine current is in the development of a Fourier series representation of periodic functions as follows Image non disponible.

• [0037]

In graphical presentation fulfills the 1c,

• [0038]

Under "arcuate course of a curve" means a type of curve that has no turning points and is negatively curved, as exemplified in 1a . 1b and 1c is shown.

• [0039]

Examples of the superimposition of harmonic oscillations and the resulting anharmonic vibration are in 4 listed.

• [0040]

Optimal treatment results are obtained when the signal (pulse) is varied on the basis of simultaneously measured in accordance with features of the microcirculation. Here, amplitudes and frequencies of the individual pulses, pulse trains or pulse intervals or intensities can be changed. Intensities of nano-Tesla range up to milli-Tesla range are possible eg 50 nT to 800 mT, but usually they are in the micro-Tesla range from about 5-300  $\mu$ T.

• [0041]

Very good measurement results in terms of biological effects vasomotion and functional state of the microcirculation were  $\mu$ T to 150, obtained using electromagnetic flux densities in the range of about 50  $\mu$ T to about 250  $\mu$ T, preferably from 80  $\mu$ T. These are always averaged amounts.

• [0042]

For the desired effects in the microcirculation is a variation of the electromagnetic flux densities compared with a variation of the pulse types, and especially of the pulse sequence is of less importance.

• [0043]

The apparatus of the invention can be used in the sense of a healthy power increase or to infections and / or stress-exposed persons in the elderly with reduced physical performance and reduced immune defense and also in case of illness. The treatment of mammals is within the scope of the invention. For prophylactic use in particular the effects on vasomotion (feature A  $_{VM}$ ) and the distribution state of the blood in the microvascular networks (characteristic nNP) of meaning and thus for improving physical performance and improved organ function due to an expansion of the microcirculatory regulation width.

• [0044]

Compared with devices in which follow impulses that exponential functions, and higher pulse sequences (higher incidence of pulses per unit of time) are applied, are obtained with the apparatus of the invention significantly larger and much more prolonged characteristic changes in the functional state of the microcirculation.

• [0045]

For example, if pulses with exponential functions a change in the characteristic A maximum of 10 is reached and a decay of the change occurs after about 20 minutes, signal to the invention shows a maximum of about 22%, a period of time is only slightly sloping to this height and sounds slowly from about 50 to 60 minutes. Overall, this is a significantly improved overall effect is achieved.

• [0046]

Is advantageously a (complementary-therapeutic) use of the device according to the invention in various diseases such as peripheral circulatory disorders, diabetic microangiopathy, diabetic neuropathy, wound healing and bone healing disorders and ulcers (such as in leg ulcers in the setting of chronic venous insufficiency), multimorbid geriatric patients among other things,

• [0047]

The invention will be explained in more detail by examples. In the accompanying drawings:

• [0048]

1a Arch shaped pulse with a steep rise and steep drop;

• [0049]

1b Arch shaped pulse with gentle slope and shallow waste;

• [0050]

1c Pulse type rectified cosine current;

• [0051]

2 Envelope (dashed line) of a modified amplitude wave;

• [0052]

3 Superposition of three harmonic oscillations U  $_{1,}$  U  $_{2}$  and U  $_{3}$  equal amplitude and phase and frequency ratio  $\omega_{1,} \omega_{2}$  and  $\omega_{3}$  = 1: 2: 3;

• [0053]

4a preferred pulse sequence 2 for 1 minute;

• [0054]

4b Pulse sequence 1 per 3 minutes;

• [0055]

4c Intensity-time diagram with pulse train 3 per minute (150 ms and 163  $\mu$ T) with basic pulses shorter intervals and lower intensity (30 ms and 78  $\mu$ T);

• [0056]

4d Section of a pulse sequence of 1 pulse per minute (150 ms and 163  $\mu$ T) with base pulses (30 ms and 78  $\mu$ T) continuously;

• [0057]

4e Section of a pulse sequence of 1 pulse per minute with basic pulses stochastic intensity profile and

• [0058]

4f Section of a pulse sequence of 1 pulse per minute with basic pulses having a sinusoidal intensity pattern.

• [0059]

In the figures, the pulse widths that are only in the range of milliseconds, not shown to scale.

- Example 1
- [0060]

In a number of subjects with peripheral circulatory disorders repräsentive features of the functional state of the microcirculation by means of a vital microscopic examination unit, by reflection spectroscopy, laser micro-flow measurement and white light spectroscopy measured: Number of blood cell-perfused nodal points in a defined microvascular network nNP, arteriolar vasomotion / area under the envelope of the amplitude-frequency spectrum of the arteriolar vasomotion A  $_{\rm VM.}$ 

• [0061]

Thereafter, the use of a pulse Ratos genes are generated with the pulses which are supplied to an electromagnetic coil occurs. The coil is in contact with a skin surface (target tissue). It is provided by means of this device on impulses the target tissue at intervals of 1 day, 3 days, 6 days, 9 days and 12 days. The measurement of the above parameters was performed 10 minutes after completion of the impulse. Number of subjects: 16

Age: 55-65 years Channels: 5 per minute Pulse Type: approximately rectified sinusoidal Pulse intensity: single pulse of 180  $\mu$ T and a pulse width of 150 ms; additionally base pulse with 60  $\mu$ T and a pulse width of 30 ms Treatment duration: 2 x 25 minutes in the interval of 2 h Treatment sequence: every 2nd day

• [0062]

Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha = 5\%$ .

• [0063]

The percent change for A  $_{\rm VM}$  was on the 3rd day about 11% and increased to 12 days to about 22%.

• [0064]

The percent change for nNP was on the 3rd day about 10% and increased to 12 days to about 24%.

- Comparative Example 1
- [0065]

It has been worked in the same manner as in Example 1 with a group of 16 subjects. Channels: 30 per second Pulse type: special exponential function  $e^{\sin(x \text{ high } 3)}$  according to EP 995463 Pulse intensity: 50 µT with 30 ms pulse width

• [0066]

Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha = 5\%$ .

• [0067]

The percent change for A was on the 3rd day about 3% and increased to about 4% on day 12.

• [0068]

The percent change for nNP was on the 3rd day about 4% and increased to 12 days to about 6%.

• [0069]

These changes do not represent therapeutically relevant changes and show that both pulse type nor pulse sequence involve no significant influence on the local regulatory mechanism of the microcirculation.

- Example 2
- [0070]

In a number of subjects with diabetic microangiopathy was worked in the same manner as in Example 1. Number of subjects: 14 Age: 60-70 years • [0071]

Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha = 5\%$ .

• [0072]

The percent change for A  $_{\rm VM}$  was on the 3rd day more than 9% and increased to 12 days to about 25%.

• [0073]

The percent change for nNP was on the 3rd day about 12% and increased to 12 days to about 30%.

- Comparative Example 2
- [0074]

It has been worked in the same manner as in Example 2 with a group of 14 subjects. Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha = 5\%$ .

• [0075]

The percent change for A was on the 3rd day about 5% and increased to 12 days to about 8%.

• [0076]

The percent change for nNP was on the 3rd day is around 5% and increased to 12 days to about 7%.

• [0077]

These changes do not represent therapeutically relevant changes and show that both pulse type nor pulse sequence involve no significant influence on the local regulatory mechanism of the microcirculation.

- Example 3
- [0078]

For a number of healthy elderly subjects was carried out in the same manner as in Example 1. Number of subjects: 16

Age: 55-65 years without pathological findings

• [0079]

Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha$  = 5%.

• [0080]

The percent change for A  $_{\rm VM}$  was on the 3rd day about 7% and increased to 12 days to about 12%.

• [0081]

The percent change for nNP was on the 3rd day about 8% and increased to 12 days to about 16%.

- Comparative Example 3
- [0082]

It has been worked in the same manner as in Example 3 with a group of 16 subjects. Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha = 5\%$ .

• [0083]

The percent change for A was on the 3rd day about 4% and increased to 12 days to about 5%.

• [0084]

The percent change for nNP was on the 3rd day about 5% and increased to 12 days to about 6%.

• [0085]

These changes that bring in applications both this pulse type and pulse sequence compared to the use of the inventive device smaller influences on the functional state of the microcirculation. The values in Example 3 show at the end of the study period, however, a 2- to 3-fold increase.

#### Citations de brevets

Brevet cité	Date de dépôt	Date de publication	Déposant	Titre
<u>DE3340974A1</u> *	11 nov. 1983	23 mai 1985	Werner Dipl Phys Kraus	Electrotherapy apparatus
<u>DE10304085A1</u> *	31 janv. 2003	12 août 2004	Günther, Andreas	Anordnung und Verfahren zur Durchführung einer Magnetfeldtherapie
EP0594655B1 *	3 juil. 1992	6 mars 1996	Dr. Fischer Ag	Device for transporting ions, especially protons
<u>EP0995463B1</u> *	21 oct. 1998	16 août 2001	Wolf. A. Prof. Kafka	Device applying electric or electromagnetic signals for promoting biological processes
WO1999020345A1 *	16 oct. 1998	29 avr. 1999	Axel Muntermann	Device for magnetic field therapy

\* Cité par l'examinateur

Référencé par

Brevet citant	Date de dépôt	Date de publication	Déposant	Titre
US20100160713 *	18 juil. 2008	24 juin 2010	Qisc B.V.	Device and method for electromagnetic stimulation of a process within living organisms

\* Cité par l'examinateur

# An apparatus for generating a pulsed electromagnetic field with pulse

**control** Langue du texte original : <u>Allemand</u> DE 102006041365 B4

## Résumé Langue du texte original : <u>Allemand</u>

An apparatus for generating a pulsed electromagnetic field with pulse control, comprising a pulse generator which is connected with a coil for generating an electromagnetic field, characterized in that the pulse generator is configured in such a way that the emanating from it pulses represent periodic pulses, the arcuate ascending and descending envelope curves with harmonic or anharmonic have waveform within the envelope, and that the pulse sequence is in the range of 1 pulse / 20 minutes to 4 pulses / 1 minute, being present for the pulse train base pulses to 90  $\mu$ T and higher single pulses to 180  $\mu$ T and the pulse width of the base impulses is 10-60 ms, and the width of the individual pulses 50 -300 ms; and

that a control pulse train, pulse width, pulse function type and electromagnetic flux density measurement data are based, reflect characteristics of blood microcirculation using non-invasive vital microscopic, spectrometric, laser-Doppler or oxygen partial pressure measuring methods on a target tissue, with those for the function type pulses are exempted exponential functions.

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Inventeurs	Peter Gleim, Rainer Dr. med. Klopp
Déposant	Peter Gleim
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Liens externes: DPMA (Office allemand des brevets et des marques), Espacenet

#### Description Langue du texte original : Allemand

• [0001]

The invention relates to a device for generating a pulsed electromagnetic field with pulse control.

• [0002]

From the <u>EP 0594655 B1</u> is a device consisting of a generator and transmitter, known with which an ion transport from intracorporeal electrolytic fluids to take place into and through vascular walls and in which the applied pulsed currents have certain properties, in particular correspond to the amplitude of the fundamental pulse to an exponential function and a series of pulse sequences for 0.3-1 seconds is sent with pauses of 0.7-5 seconds.

• [0003]

The <u>EP 0995463 B1</u> claims a device for influencing biological processes in a living tissue, be delivered to the pulses on the tissue in which the amplitude of each individual pulse corresponds to a mathematical

relationship with the e  $^{sin}$  e-function  $^{(x high b)}$  wherein x is the time course and b the number of superimposed pulses.

• [0004]

The waveforms generated with the known devices, which have consistently exponential functions are to either improve muscle formation and joint regeneration or stimulate metabolic processes.

• [0005]

From MedReport no. 49, 28, born, 2004, p 12, it is known that certain measurement data of the microcirculation such as number of blood cell-perfused nodal points, higher pressure gradient between arterioles and venules and arteriolar and venular improved vasomotion can be improved by pulsating magnetic fields.

• [0006]

The invention has for its object to provide an apparatus with which by certain pulses and pulse trains of a pulsating magnetic field characteristics of blood microcirculation can be improved.

• [0007]

The present invention provides a device for generating a pulsed electromagnetic field with pulse control, comprising a pulse generator which is connected with a coil for generating an electromagnetic field, characterized in that emanating from the pulse generator pulses represent periodic pulses, the other arcuate and descending Envelopes have with harmonic or anharmonic waveform within the envelope, and in that the pulse sequence is in the range of 1 pulse per 20 minutes to 4 pulses per minute, wherein the pulse train base pulses up to 180  $\mu$ T, are present up to 90  $\mu$ T and higher individual pulses and the pulse width of the base pulses is 10-60 ms, and the width of the individual pulses is 50-300 ms, and that a control of pulse sequence, pulse width, pulse function type and electromagnetic flux density measurement data are based, using non-invasive vital microscopic, spectrometric, laser-Doppler or oxygen partial pressure measuring methods reflect from a target tissue characteristics of the microcirculation of the blood, which for the function type such pulses are exempted exponential functions.

• [0008]

It has been found that pulses with exponential functions and in the described frequency of the pulse sequence of a maximum of 5 seconds and a maximum of 3 seconds rest Although to some extent affect some features of the functional state of the microcirculation both in healthy and sick leave, however, circulation for a short time and with little immediate effect on the mechanisms of local regulation of micro, so that no long-term prophylactically and therapeutically relevant changes can be caused.

• [0009]

It was further found that, for a total of marked slowdown of the pulse sequence and pulses with no exponentially ascending and descending envelope significantly much larger and longer lasting characteristic changes in the functional state of the microcirculation can be achieved due to a significantly greater direct influence local control mechanisms of the microcirculation.

## • [0010]

The micro-circulation, the flow of blood cells and blood plasma in the smallest blood vessels (with diameters of <200 microns), the functionally important part of the human blood circulation, since the mass transfer is realized by the cells of an organ tissue. This affects the supply of oxygen and substrate to the cells and the removal of metabolic end products. The respective functional state of the microcirculation of an organ determines the width rule for adapting the microperfusion to changing metabolic needs and thus organ function. Furthermore, an undisturbed microcirculation prerequisite for an unhindered flow of the first steps of an immunological reaction. Because of the microcirculation has moved to the center clinical pathophysiological research for quite some time. Of special interest is the study of possible effects on the local regulation of microcirculation, especially the autorhythmic contraction movements of the vessel wall smooth muscles in arteriolar and venular microvessels is (so-called. Vasomotion).

• [0011]

Among the most important criteria for the characterization of normal or disturbed microcirculation

- - The respective state of distribution of blood in the microvessel networks;
- o The autorhythmic vessel wall motions in arterioles and venules (vasomotion).
- [0012]

Vasomotor function of the determined state of adjustment substantially the width of the microcirculation to changing metabolic needs and thus the local rule width of the microcirculation.

- o The stream flow in the arteriolar and venular flow of effluent from the capillary networks;
- - Rheological characteristics (local hematocrit);
- - Flow rates of blood cells;
- o Diameter of microvessels;
- - Possibility of accumulation of white blood cells in the microcirculation, adhesion to the endothelium and transmigration of white blood cells into the tissue.
- [0013]

There are used for the present invention measurement data from the microcirculation of the blood for the control of pulses of electromagnetic field. These metrics are selected from the group consisting of the venular oxygen utilization, the number of blood cell-perfused nodal points, venular stream flow, local hematocrit in a microvessel, local hematocrit in all microvessels, the arteriolar and venular vasomotion, number of adhering white blood cells a defined venule inner wall, local changes in concentration of substances in the tissue. It is advantageous to use more of these features is.

• [0014]

The venule oxygen extraction Apo  $_2$  is specified as a percentage change compared to the respective output value at the time t = 0. Determining the absolute difference of oxygen saturation of hemoglobin in the afferent and efferent arterioles venules of the network of a selected tissue targets. As the target tissue sections are of skin or intestine which have the desired blood vessel networks of the organism and are also one of the immo logically active organs, and continue to be readily available for non-invasive measurements selected.

• [0015]

In the current number of blood cell-perfused nodal points in a defined microvascular network, nNP, the number of blood cell-perfused branching sites in this network is used as a measure of the state of blood distribution. As a border flow velocity of red blood cells v<sub>RBC</sub> = 80 microns / s defined. The assessments are + or - (compared to the defined initial value n = 60). Borderline cases are measured at +0.5 or -0.5.

• [0016]

The venular stream flow Qven and the arteriolar stream flow Qart is the particle (blood cell flow) in defined venules and arterioles. It is expressed in microns  $^{3}$  / s.

• [0017]

The local hematocrit in a blood vessel, which is also referred to as Tube hematocrit, Hk <sub>t</sub>, is the hematocrit in a particular microvessel. It is expressed as the percentage change compared with the starting value.

• [0018]

The hematocrit of the microcirculation Hk  $_{\rm MC}$  is measured in all microvessels with diameters <200 microns.

• [0019]

The arteriolar (or venular) vasomotion, A  $_{VM}$  is determined by the distance-time diagram of the autorhythmic contraction movements smooth muscle arteriolar vessel wall is determined (measurement of the distance perpendicular to the microvessel longitudinal axis of endothelial surface to opposing endothelial surface at equidistant time points; 60 measurements per second, determination of the composite vibration; Fourier analysis; determining the amplitude-frequency spectrum). Criterion is the area A under the envelope of the amplitude-frequency spectrum of the arteriolar vasomotion (a composite wave). This column lists the value as a percentage change compared with baseline.

• [0020]

The number of adhering white blood cells on a defined venule inner wall, nWBC / A is measured at the defined inner surface of the venule with A = 18000 microns <sup>2</sup>. Counts all white blood cells adhering to the endothelium longer than 20 seconds.

• [0021]

Local changes in the concentration of various substances in the tissues z. B. for mediators, the adhesion molecule ICAM-1 and other measured. They are given in relative units of 0-10, where 0 means no proof and the value 10 is assigned to the highest detected in a sample value.

• [0022]

Basis for measuring these characteristics of human tissue are, for example described in Bollinger et al, Microvasc Res 7 (1974) 61-72..; Fagrell B, Angiology 23 (1972) 284-298; . Fagrell et al, Am J Physiol 233 (1977) H318-321; . Wiedemann et al, An introduction to microcirculation, Academic Press, NY, 1981; and Lankowicz JR (ed.): Topics in Fluorescence Spectroscopy, Plenum Press, New York, London, Vol 1-5 (1991-1997), incorporated herein by reference.. • [0023]

For all collected data will make use of a parameter-free test methods for small samples. To apply the Wilcoxon rank sum test arrives at the significance level  $\alpha$  = 5%. The critical values for T are taken from the literature (G Ferguson, Statistical analysis in psychology and education, McGraw-Hill, NY 1959, 318).

## • [0024]

Of particular importance is the vasomotion. Prophylactically and therapeutically relevant is to influence the disturbed vasomotion towards a physiological vasomotion rhythm, ie the "imprinting" of a physiological vasomotion rhythm in case of illness. In case of illness, the arteriolar and venular microvessels vasomotions are significantly altered (usually slows significantly, sometimes only 1 to 2 vasomotions in the course of several minutes). According to the invention, the aim is to lead the disturbed vasomotion into the region of physiological vasomotion (about 1 to 4 vasomotions per minute). The same applies to pathological states with significantly accelerated vasomotion.

## • [0025]

Therefore, it was found that in addition to the described effects of specific pulsed electromagnetic fields in the tissues, especially a change in the rhythm of the disturbed vasomotion can be achieved, mostly in terms of stimulating the autorhythmic contraction movements of the vessel wall smooth muscles in the smallest blood vessels (vasomotion of arterioles and venules). When significant changes in the pulse sequence (slowing of the pulse sequence comparison with known methods) and pulses not exponentially increasing and / or decreasing or abruptly dropping envelope significantly much larger characteristic changes of microcirculation of blood can be effected.

• [0026]

Preferably therefore be generated by the inventive device pulse trains in the range of 1 pulse / 5 minutes to 4 pulses / minute, in particular from 1 pulse / minute to 4 pulses / minute. In 4a and 4b are exemplary such advantageous pulse sequences shown without respect to the intensity.

• [0027]

Under "pulse train" for the purposes of the present invention will be understood the distance of those oscillation maxima (pulse maxima) from each other, which are above the intensity baseline in an intensity-time diagram such. B. 4c shown. If a basic oscillation is present, which may be consistent in terms of intensity, stochastically different or sinusoidally varied as in 4d and 4e and 4f shown, means "burst" the distance of those oscillation maxima from each other, which is well above the basic oscillation.

• [0028]

Pulse sequence is thus the frequency of occurrence of the maximum magnitudes of the envelope in the time unit.

• [0029]

For example, a continuous basic wave of an intensity of 80  $\mu$ T are present having a pulse width of about 30 microseconds, and a much stronger one-shot pulse of 150  $\mu$ T with a larger pulse width of 0.3 s, the

stronger single-pulse three to five occurs times per minute. This then also corresponds to the pulse sequence for the purposes of the invention.

• [0030]

Such a pulse arrangement may be beneficial, ie on the aforementioned pulse or the above pulse sequence ( 4a and 4b ) Add a higher-frequency pulse with lower electromagnetic flux density B. These additional pulses may in their amplitudes (and frequencies) vary in different ways, as exemplified in the 4c to 4h is shown. They are generally from 50 to 80  $\mu$ T.

• [0031]

Advantageously, the width of a single pulse at 50 to 300 ms and the pulse width of a base at 10 to 60 ms; preferably 80 to 200 ms and 20 to 40 ms.

• [0032]

The so-called. "Intensity" or pulse intensity is physically the electromagnetic flux density B with the unit tesla.

• [0033]

The pulses generated by the device according to the invention are given periodically and ask for drawing representation in their envelopes arcuate as sine or cosine up parabola-like constructs. Within the envelope occur harmonic oscillations with the same or different amplitude, which may also overlap to anharmonic vibrations, By "envelope" is meant the curve, the maxima of the different levels of the amplitudes of a certain sequence of amplitudes affected and thus this sequence in the ascending and descending part "wrapped" (see 2). For superimposed anharmonic oscillations this always affects only the maxima of the adjacent next higher amplitude.

• [0034]

Preferably, thus corresponding to a pulse function type whose rise and fall runs of the envelopes as curved as in rectified currents.

• [0035]

The pulses are composite oscillations or waves, which are formed from a plurality of harmonics as the harmonic or anharmonic different amplitude and frequency, with the partial frequencies of  $\sim$  20 to 3000 Hz.

• [0036]

"Envelope" connects the different amplitudes of the harmonics (amplitude = max. Elongation of a partial oscillation). The **"envelope"** approximately reflects the history of the composite oscillation or wave.

• [0037]

Particularly preferred is a pulse function type for the envelope that corresponds to the type of rectified Kosinusstromes. Such a rectified cosine current is in the development of a Fourier series representation of periodic functions as follows (X) =  $I_0 \pi (1 + \pi 2 \cos x + 21 \cdot 3 \cos 2x - 23 \times 5 \cos 4x + 25 \times 7 \cos 6x - + ...)$ 

• [0038]

In graphical presentation fulfills the 1c,

• [0039]

Under "arcuate course of a curve" means a type of curve that has no turning points and is negatively curved, as exemplified in 1a . 1b and 1c is shown.

• [0040]

Examples of the superimposition of harmonic oscillations and the resulting anharmonic vibration are in 4 listed.

• [0041]

Optimal treatment results are obtained when the signal (pulse) is varied on the basis of simultaneously measured in accordance with features of the microcirculation. Here, amplitudes and frequencies of the individual pulses, pulse trains or pulse intervals or intensities can be changed. Intensities of nano-Tesla range up to milli-Tesla range are possible z. B. 50 nT to 800 mT.

• [0042]

Very good measurement results in terms of biological effects vasomotion and functional state of the microcirculation were obtained using electromagnetic flux densities in the range of 80  $\mu$ T to 150  $\mu$ T. These are always averaged amounts.

• [0043]

For the desired effects in the microcirculation is a variation of the electromagnetic flux densities compared with a variation of the pulse types, and especially of the pulse sequence is of less importance.

• [0044]

The apparatus of the invention can be used in the sense of a healthy power increase or to infections and / or stress-exposed persons in the elderly with reduced physical performance and reduced immune defense and also in case of illness. The treatment of mammals is within the scope of the invention. For prophylactic use in particular the effects on vasomotion (feature A  $_{VM}$ ) and the distribution state of the blood in the microvascular networks (characteristic nNP) of meaning and thus for improving physical performance and improved organ function due to an expansion of the microcirculatory regulation width.

• [0045]

Compared with devices in which follow impulses that exponential functions, and higher pulse sequences (higher incidence of pulses per unit of time) are applied, are obtained with the apparatus of the invention

significantly larger and much more prolonged characteristic changes in the functional state of the microcirculation.

• [0046]

For example, if pulses with exponential functions to change the feature A  $_{VM}$  from a maximum of 10% is achieved and a decay of the change occurs after about 20 minutes, signal to the invention shows a maximum of about 22%, a period of time is only slightly falling at this elevation and sounds slowly from about 50 to 60 minutes. Overall, this is a significantly improved overall effect is achieved.

• [0047]

Such, for example, peripheral circulatory disorders, diabetic microangiopathy, diabetic neuropathy, wound healing and bone healing disorders and ulcers is advantageously a (complementary-therapeutic) use of the device according to the invention in various diseases (such as in leg ulcers in the setting of chronic venous insufficiency) in multimorbid geriatric patients, inter alia,

• [0048]

The invention will be explained in more detail by examples. In the accompanying drawings:

• [0049]

1a Arch shaped pulse with a steep rise and steep drop;

• [0050]

1b Arch shaped pulse with gentle slope and shallow waste;

• [0051]

1c Pulse type rectified cosine current;

• [0052]

2 Envelope (dashed line) of a modified amplitude wave;

• [0053]

3 Superposition of three harmonic oscillations U  $_{1,}$  U  $_{2}$  and U  $_{3}$  equal amplitude and phase and frequency ratio  $\omega_{1,} \omega_{2}$  and  $\omega_{3}$  = 1: 2: 3;

• [0054]

4a preferred pulse sequence 2 for 1 minute;

• [0055]

4b Pulse sequence 1 per 3 minutes;

• [0056]

4c Intensity-time diagram with pulse train 3 per minute (150 ms and 163  $\mu$ T) with basic pulses shorter intervals and lower intensity (30 ms and 78  $\mu$ T);

• [0057]

4d Section of a pulse sequence of 1 pulse per minute (150 ms and 163  $\mu T$ ) with base pulses (30 ms and 78  $\mu T$ ) continuously;

• [0058]

4e Section of a pulse sequence of 1 pulse per minute with basic pulses stochastic intensity profile and

• [0059]

4f Section of a pulse sequence of 1 pulse per minute with basic pulses having a sinusoidal intensity pattern.

• [0060]

In the figures, the pulse widths that are only in the range of milliseconds, not shown to scale.

- Example 1
- [0061]

In a number of subjects with peripheral circulatory disorders repräsentive features of the functional state of the microcirculation by means of a vital microscopic examination unit, by reflection spectroscopy, laser micro-flow measurement and white light spectroscopy measured:

Number of blood cell-perfused nodal points in a defined microvascular network nNP, arteriolar vasomotion / area under the envelope of the amplitude-frequency spectrum of the arteriolar vasomotion A  $_{\rm VM}$ .

• [0062]

Thereafter, the use of a pulse Ratos genes are generated with the pulses which are supplied to an electromagnetic coil occurs. The coil is in contact with a skin surface (target tissue). It is provided by means of this device on impulses the target tissue at intervals of 1 day, 3 days, 6 days, 9 days and 12 days. The measurement of the above parameters was performed 10 minutes after completion of the impulse. Number of subjects: 16 Age: 55-65 years Channels: 5 per minute Pulse Type: approximately rectified sinusoidal Pulse intensity: single pulse of 180  $\mu$ T and a pulse width of 150 ms; additionally base pulse with 60  $\mu$ T and a pulse width of 30 ms Treatment duration: 2 x 25 minutes in the interval of 2 h Treatment sequence: every 2nd day

• [0063]

Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha$  = 5%.

• [0064]

The percent change for A  $_{VM}$  was on the 3rd day about 11% and increased to 12 days to about 22%.

• [0065]

The percent change for nNP was on the 3rd day about 10% and increased to 12 days to about 24%.

- Comparative Example 1
- [0066]

It has been worked in the same manner as in Example 1 with a group of 16 subjects. Channels: 30 per second Pulse type: special exponential function  $e^{\sin(x \text{ high 3})}$  according to EP 995463 Pulse intensity: 50 µT with 30 ms pulse width

• [0067]

Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha = 5\%$ .

• [0068]

The percent change for A  $_{\rm VM}$  was on the 3rd day about 3% and increased to about 4% on day 12.

• [0069]

The percent change for nNP was on the 3rd day about 4% and increased to 12 days to about 6%.

• [0070]

These changes do not represent therapeutically relevant changes and show that both pulse type nor pulse sequence involve no significant influence on the local regulatory mechanism of the microcirculation.

- Example 2
- [0071]

In a number of subjects with diabetic microangiopathy was worked in the same manner as in Example 1. Number of subjects: 14 Age: 60-70 years

• [0072]

The statistical analysis of successes with the Wilcoxon rank sum test,  $\alpha$  = 5%.

• [0073]

The percent change for A  $_{\rm VM}$  was on the 3rd day more than 9% and increased to 12 days to about 25%.

• [0074]

The percent change for nNP was on the 3rd day about 12% and increased to 12 days to about 30%.

- Comparative Example 2
- [0075]

It has been worked in the same manner as in Example 2 with a group of 14 subjects. Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha = 5\%$ .

• [0076]

The percent change for A  $_{\rm VM}$  was on the 3rd day about 5% and increased to 12 days to about 8%.

• [0077]

The percent change for nNP was on the 3rd day is around 5% and increased to 12 days to about 7%.

• [0078]

These changes do not represent therapeutically relevant changes and show that both pulse type nor pulse sequence involve no significant influence on the local regulatory mechanism of the microcirculation.

- Example 3
- [0079]

For a number of healthy elderly subjects was carried out in the same manner as in Example 1. Number of subjects: 16 Age: 55-65 years without pathological findings

• [0080]

Statistical analysis was performed using the Wilcoxon rank sum test,  $\alpha = 5\%$ .

## Revendications(7) Langue du texte original : <u>Allemand</u>

- 1. An apparatus for generating a pulsed electromagnetic field with pulse control, comprising a pulse generator which is connected with a coil for generating an electromagnetic field, **characterized** in that the pulse generator is configured in such a way that the emanating from it pulses represent periodic pulses, the arcuate ascending and descending envelopes have with harmonic or anharmonic oscillation profile within the envelope, and that the pulse sequence in the range of 1 pulse / 20 minutes to 4 pulses / 1 minute, for which pulse sequence based impulse to 90  $\mu$ T and higher individual pulses up to 180  $\mu$ T and the pulse width of the base impulses is 10-60 ms, and the width of the individual pulses is 50-300 ms; and that a control pulse train, pulse width, pulse function type and electromagnetic flux density measurement data are based, reflect characteristics of blood microcirculation using non-invasive vital microscopic, spectrometric, laser-Doppler or oxygen partial pressure measurement method of a target tissue, for the function type Such pulses are exempted exponential functions.
- 2. An apparatus according to claim 1, characterized in that the pulse function type for the envelope corresponds to the type of a rectified Kosinusstromes.
- 3. Apparatus according to claim 1, characterized in that the pulse train in the range from 1 pulse / 5 minutes to 4 pulses / minute, preferably from 1 pulse / minute to 4 pulses / minute.
- 4. Apparatus according to claim 1, characterized in that the pulse control measurement data from the blood microcirculation underlie selected from the group consisting of the venular oxygen utilization, the number of blood cell-perfused nodal points, venular stream flow, local hematocrit in a microvessel, local

hematocrit in all microvessels, the arteriolar vasomotion, number of adhering white blood cells on a defined venule inner wall, local changes of substance concentrations in tissue and a plurality of these features.

- 5. Apparatus according to claim 4, characterized in that the pulse control measurement data for the venule oxygen extraction are based.
- 6. Apparatus according to claim 4, characterized in that the pulse control measurement data for the arteriolar vasomotion underlie.
- 7. Apparatus according to claim 1, characterized in that the pulse strength is in the range from 80 to 150  $\mu T$  lies.

#### Citations de brevets

Brevet cité	Date de dépôt	Date de publication	Déposant	Titre
<u>DE3340974A1</u> *	11 nov. 1983	23 mai 1985	Werner Dipl Phys Kraus	Electrotherapy apparatus
<u>DE10304085A1</u> *	31 janv. 2003	12 août 2004	Günther, Andreas	Anordnung und Verfahren zur Durchführung einer Magnetfeldtherapie
<u>EP0594655B1</u> *	3 juil. 1992	6 mars 1996	Dr. Fischer Ag	Device for transporting ions, especially protons
<u>EP0995463B1</u> *	21 oct. 1998	16 août 2001	Wolf. A. Prof. Kafka	Device applying electric or electromagnetic signals for promoting biological processes
WO1999020345A1 *	16 oct. 1998	29 avr. 1999	Axel Muntermann	Device for magnetic field therapy

\* Cité par l'examinateur