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(54) **Title**: IMPLANTATABLE, ELECTRODE DEVICE, IN PARTICULAR FOR A CARDIAC PACEMAKER

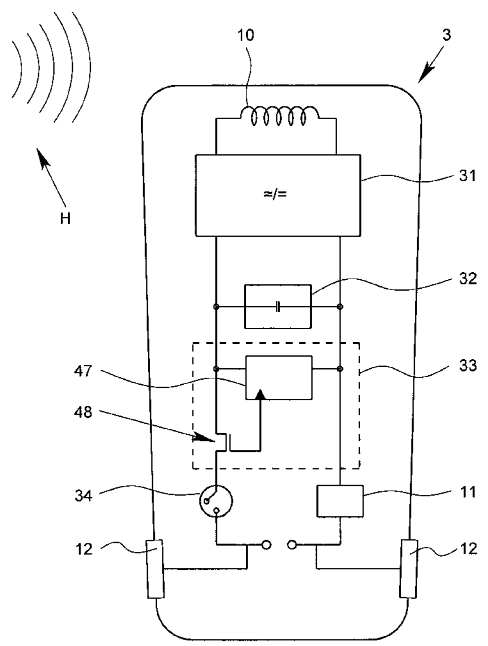

Fig. 15

(57) **Abstract**: An implantable electrode device, in particular for a cardiac pacemaker, a corresponding stimulation system and a method for operating at least two implantable electrode devices are proposed. A simplified implantation, an efficient construction and reliable control are enabled by the electrode device being supplied with energy, and preferably controlled, in an exclusively wireless manner via a time-variable magnetic field. The magnetic field is generated by an preferably implanted control device.

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Implantable electrode device, in Particular for a Cardiac Pacemaker

The present invention relates to an implantable electrode device, a stimulation system and a method for operating at least two implantable electrode devices.

In the following description of the invention, the focus is primarily on a cardiac pacemaker. However, the present invention is not restricted to this particular solution, but in general can be applied to other stimulation devices which operate electrically and in particular deliver electrical impulses for stimulation.

Cardiac pacemakers stimulate the heart beat by means of electrical impulses which are introduced into the muscle tissue of the heart. For this purpose, a cardiac pacemaker is usually implanted, for example, near the shoulder of the thoracic cage, at least one probe or electrical lead being guided from the implanted cardiac pacemaker via a vein into the atrium or the chambers of the heart and anchored there. The electrical lead is problematical or disadvantageous. This runs over a length of about 30 cm in the blood circulation system and can thereby cause undesirable or even fatal physical reactions. Furthermore, the risk of failure of the probes or leads due to material fatigue as a result of the severe mechanical stressing during body movements is particularly high. Another complication frequently encountered is dislocation of the probes triggered by movements of the patient.

Stimulation by magnetic impulses has been proposed, for example, in US 5,170,784 A in order to avoid the electrical lead and the electrode. However, purely magnetic stimulation does not function satisfactorily so that magnetically stimulating cardiac pacemakers have not been generally accepted.

US 5,411,535 A discloses a cardiac pacemaker with an implantable control device and a separate electrode device. Electrical signals of 10 MHz to a few GHz in particular are transmitted without wires between the control device and the electrode device for controlling the electrode device. The actual power supply of the electrode device is provided via a battery integrated in the electrode device. Such cardiac pacemakers with a separate electrode device have not been widely accepted so far. This may be because the electrode device is of a considerable size and has a limited operating time because of the battery.

The article "A Surgical Approach to the Management of Heart-Block Using an Inductive Coupled Artificial Cardiac Pacemaker" by L.D. Abrams et.al., published in the journal "The Lancet", 25th June 1960, pages 1372 to 1374, describes a method for stimulating a heart where an external control device comprising a coil to be located externally on the body is inductively coupled to a coil implanted between the skin and the ribs. Two electrical leads led from the implanted coil to two electrodes in the heart muscle. Apart from the fact that an external control device is generally problematical and not desirable, the wiring between the implanted coil and the electrodes at a distance therefrom results in the same problems as in the usual cardiac pacemaker described above where at least one electrode is connected to the implanted cardiac pacemaker via an electrical lead through a vein. Furthermore, the implantation of a pacemaker system requires opening the thoracic cage and involves an open-heart operation. Moreover, the implanted coil is very sensitive to external electromagnetic fields so that undesirable interfering voltages are induced and appear at the electrodes.

JP 06 079 005 A discloses an implantable cardiac pacemaker whose battery can be inductively recharged from outside via a coil.

US 5,405,367 A discloses an implantable microstimulator. The microstimulator comprises a receiving coil, an integrated circuit and electrodes. It can be supplied with energy and with control information via an external magnetic field generated by an external coil having an allocated oscillator and an allocated stimulation control device. Such a microstimulator is not suitable for cardiac stimulator or as a cardiac pacemaker since it is relatively large for sufficient capacity and requires an external energy supply.

WO 2006/045075 A1 relates to various configurations of systems that employ leadless electrodes to provide pacing therapy. In particular, a single magnetic pulse is used to generate an electrical pulse in an electrode device. This is problematic, in particular due to magnetic saturation.

US 2009/0024180 A1 discloses a stimulation system comprising an implantable electrode device. The electrode device is supplied with energy and controlled in an exclusively wireless manner via a time-variable magnetic field generated by an implanted control device.

Stimulation systems comprising a wireless transmission of energy known in the art are limited in performance by their power consumption. Furthermore, these systems may suffer from a low stimulation efficiency.

The object of the present invention is to provide an electrode device, a stimulation system or a method, wherein the reliability, efficiency and/or effectivity can be improved.

The above mentioned object is achieved by an implantable electrode device for a stimulation system according to claim 1, by a stimulation system according to claim 12 or by a method for operating at least two implantable electrode devices according to claim 16. Advantageous embodiments are subject of the subclaims.

According to a first aspect of the present invention, an implantable electrode device for a stimulation system, preferably a cardiac pacemaker, is provided. The electrode device is adapted for generating electrical impulses, wherein the electrode device is configured as a wireless and/or compact structure unit and can be supplied with energy and/or controlled by means of a time-varying magnetic field. Particularly preferably, the electrode device can be controlled by means of the time-varying magnetic field additionally or alternatively to the supply of energy by such a field.

In the sense of the present invention, the term "magnetic field" preferably covers electro-magnetic fields or waves. Hence, fields, waves or the like with any kind of magnetic component can be "magnetic fields" in the sense of the present invention as well.

The electrode device comprises a rectifier, wherein, preferably, the rectifier comprises semiconductor switches with a control port for commutation. Preferably, these semiconductor switches with control ports are transistors, in particular

MOSFETs, wherein the control port an be their gate. Alternatively or additionally, it is possible that semiconductor switches are IGBTs, four-layer-elements or any kind of semiconductor devices with controllable impedance. Preferably, the rectifier comprises semiconductor switches in a (H-) bridge configuration. The term "commutation" preferably is understood as switching an output from one to another (input-) phase, e.g. connecting an output port from a first to a second input port, in particular if a potential difference of the input is zero, in the area of zero-crossing or the like. Using a rectifier comprising semiconductor switches leads to an efficient rectifying i.e. low losses, as semiconductor switches can provide a low impedance, in particular at low operation voltages.

Alternatively or additionally, the electrode device comprises a delay means for generating a delay between reception of energy and the generation and/or delivery of at least one of the electrical impulses. Thus, a time for generating and/or for emitting and/or delivering an electrical impulse can be defined more precisely. This is advantageous for an exact and reliable stimulation.

Alternatively or additionally, the electrode device comprises a protection means to prevent or block generation or delivery of electrical impulses for a time span after a first electrical impulse has been generated. Hence, it is possible to prevent the system from generating and/or emitting electrical impulses when it is not intended. In particular, it is possible to prevent errors caused by possible disturbance or interference, in particular by undesired strong magnetic or electromagnetic fields.

A second aspect of the present invention, that can be realized independently as well, relates to a stimulation system, in particular a cardiac pacemaker, comprising an implantable control device and at least a first implantable electrode device according to the first aspect of the present invention. Such a stimulation system can be much more efficient and reliable, in particular benefiting from the advanced electrode device. With improvements in efficiently, portable systems can provide an extended life time until recharge is necessary. In addition, a better and/or more powerful stimulation can be reached.

Preferably, the stimulation system can comprise at least a second electrode device which may be an electrode device according to the first aspect of the present invention also, but does not need to. In particular, the second electrode device is implantable and configured as a wireless and/or compact structure unit an can be supplied with energy and, preferably, controlled by means of a vary magnetic field. With at least two electrode devices it is possible to realize a much more efficient stimulation, in particular by stimulating different areas. It can be useful to realize a time delay between electrical impulses of the different electrode devices. Hence, it can be particularly advantageous to make use of the delay means of the at least one electrode device according to a first aspect of the present invention.

In a third aspect of the present invention, that can be realized independently as well, a method for operating at least two implantable electrode devices is provided. These devices preferably are used in a cardiac pacemaker system and/or for generating electrical impulses. According to this method, the electrode devices are supplied with energy exclusively in a wireless manner, and electrical impulses are generated by the electrode devices with a particular time delay. The time delay is controlled and/or modified by means of the magnetic field, in particular wherein the electrode devices are triggered by magnetic fields of different strength. Controlling or modifying the time delay between the electrical impulses generated by each of the electrode devices can lead to an optimized stimulation result. Furthermore, it is advantageous to trigger the electrode devices by magnetic fields of different strength, as these magnetic fields can be generated easily, in particular without additional hardware.

According to the present invention, it is possible to combine any of the above mentioned aspects and/or alternatives. It is pointed out that it can be extraordinary advantageous, if an implantable electrode device comprises a delay means as well as protection means, wherein both of them can make use of a common switch in series with the electrode, preferably a semiconductors switch, in particular a MOSFET. Furthermore, a supervisory component can be adapted to control the switch for the delay and/or the protection functions. Nevertheless, the delay means and/or the protection means can be realized separately, too.

Another aspect of the present invention resides in the fact that the implantable electrode device for generating electrical impulses can be supplied with energy and/or preferably directly controlled in an exclusively wireless or leadless manner by means of a time-varying magnetic field. This permits a very simple and compact structure of the electrode device, whereby in particular no wiring of the electrode device is required so that implantation is simplified and the risk of failure of an electrical lead is avoided and in particular, whereby the use of an energy storage device such as a rechargeable battery, a battery or similar in the electrode device can be avoided. Furthermore, substantially greater freedom in the placement of the electrode device is obtained.

The magnetic field is preferably generated by an, in particular implantable, control device so that an external controller can be avoided. This is particularly desirable when the stimulation system is used as a cardiac pacemaker and is substantially more reliable in use than control by an external, i.e. non-implanted, control device.

The electrode device is particularly preferably controlled directly by the time-varying magnetic field. "Direct" control is to be understood in the present patent application in that the electrical impulses are generated in direct dependence on the magnetic field, for example, depending on the magnitude of the magnetic field, the polarity of the magnetic field and/or the rate of change of the magnetic field, in particular without any active electronic component being interposed in the electrode device. Consequently, in the preferred direct control, electrical impulses or stimulations are generated so that they are only temporally correlated to the magnetic field. This also permits a very simple and in particular compact structure of the electrode device and/or a very reliable defined control.

Another aspect of the present invention includes configuring the electrode device such that an electrical impulse is only generated when a minimum field strength of the magnetic field is exceeded. This very simply measure permits reliable control which in particular is not sensitive to interference when the minimum field strength is selected as suitably high, since strong magnetic fields occur very rarely but alternating electromagnetic fields having various frequencies are very common.

In particular, a first electrode device can be configured to generate and electrical impulse, if a first, minimum field strength of the magnetic field is exceeded and a second electrode device is configured to generate an electrical impulse, if a second minimum field strength of the magnetic field is exceeded. Preferably, the first and the second minimum field strength can be different such that the electrical impulses can be controlled independently using magnetic fields of different strength. Thus, a time delay between two or more electrical impulses of different electrode devices can be obtained and/or controlled.

According to a further aspect of the present invention, the electrode device must first be activated before a further electrical impulse can be generated. This activation is effected in particular by another signal, preferably by the opposite field direction of the magnetic field, shortly before triggering and generating the next electrical impulse. Thus, two-stage triggering or signal generation is required to generate an electrical impulse by means of the electrode device. This two-stage property results in particularly reliable triggering, i.e., not sensitive to interference. Alternatively or additionally, the protection means can be used to prevent or block the generation and/or delivering of an electrical impulse, in particular by deactivating a trigger function, by decoupling electrodes or the like.

The aforesaid triggering safety can be further improved or enhanced whereby the activation of the electrode device always takes place shortly before the generation of the next electrical impulse. Accordingly, the possibility that an electrical impulse as a result of an interference signal (external magnetic field with corresponding field orientation and exceeding the minimum field strength) can lead to undesirable or premature triggering of the next electrical impulse is so minimal that there is no risk for a patient.

According to another aspect of the present invention, a coil device having a high number of turns, that is a coil having many turns, is used to generate an electrical impulse having a high voltage of at least 0.5 V, preferably substantially 1 V or more and having a relatively long duration of at least 0.05 to 2 ms. In this case, the coil device can in particular have a soft-magnetic or ultrasoft magnetic core. The high number of turns, in particular at least 1,000 turns, of a suitably insulated wire made of, for example, Cu, Ag or Al in particular having a diameter of about 0.01 to 0.1 mm permits the generation of a strong and long electrical impulse in said sense.

According to a further aspect of the present invention, when the magnetic field is switched on, no continuous or persistent, for example, sawtooth-shaped ascending magnetic field pulse is generated by the control device but a plurality of short magnetic field pulses, in particular so that the core of the coil device or electrode device always varies its magnetization far below the saturation state. Thus, a minimal energy consumption can be achieved, in particular if the largest possible temporal flux variation takes place in the core of the coil device or electrode device throughout the entire duration of the stimulating pulse (optionally a contiguous sequence of electrical impulses of the electrode device; in the present invention, this sequence is considered as a single electrical impulse for stimulation). This can be achieved by short magnetic field pulses.

The magnetic field pulses can be unipolar or bipolar when using soft-magnetic core material. When using bistable materials (in particular Wiegand or pulsed wires), bipolar magnetic fields must be used.

According to an additional further aspect of the present invention, instead of an electrode device, direct electrical stimulation by a magnetisable element can take place. This magnetisable element can comprise a rectifier comprising semiconductor switches and/or a delay means and/or a protection means as well. The element in particular comprises a coil core without coil or the like. This means that a coil for transforming the magnetic field into electric current can be omitted. Instead, the magnetisable element generates directly the desired electric impulse for stimulation.

Accordingly, an implantable stimulation device comprises the magnetisable, preferably ferromagnetic element, the magnetization of the element being varied by an external or varying magnetic field so that the magnetic leakage flux of the element results in the desired electrical stimulation or generation of an electrical impulse in the surrounding tissue. This permits a particularly simple structure where electrical contact electrodes are omitted and the associated problems can be avoided.

The proposed electrode device or another electrode device can be used alternatively or additionally to convert the self-action of the heart, in particular a movement of the heart and/or electrical activity of the heart, into a magnetic impulse or another, in particular, electrical signal which can preferably be detected by the stimulation system or another receiving unit.

As has already been explained, the implantable electrode device is used in particular for generating electrical signals to stimulate the heart. However, the present invention is not restricted to this. Rather, the electrode device can generally generate any type of electrical impulse(s) or electrical signals in the human or animal body. The terms "electrode device" and "stimulation system" should accordingly be understood in a very general sense so that other applications and uses, such as for example to influence the brain, can also be understood.

The preceding is a simplified summary of the invention to provide an understanding of some aspects of the invention. This summary is neither an extensive nor exhaustive overview of the invention and its various embodiments. It is intended neither to identify key or critical elements of the invention nor to delineate the scope of the invention but to present selected concepts of the invention in a simplified form as an introduction to the more detailed description presented below. As will be appreciated, other embodiments of the invention are possible utilizing, alone or in combination, one or more of the features set forth above or described in detail below.

Further advantages, properties, features and aspects of the present invention are obtained from the following description of preferred exemplary embodiments with reference to the drawings.

Brief Description of the Figures

In the figures:

Fig. 1 is a schematic diagram of a proposed stimulation system comprising a control device and an electrode device in the implanted state according to this invention;

Fig. 2 is a schematic view of the control device according to this invention;

Fig. 3 is a schematic view of the electrode device according to this invention;

Fig. 4 is a block diagram of the electrode device according to this invention;

Fig. 5 is a schematic section view of a core element of the electrode device according to this invention;

Fig. 6 is a schematic diagram of a magnetization curve of a coil device of the electrode device according to this invention;

Fig. 7 is a schematic diagram of the time profile of a magnetic field and an induced voltage according to this invention;

Fig. 8 is a schematic section of another electrode device according to this invention;

Fig. 9 is a schematic section of another stimulation or electrode device according to this invention;

Fig. 10 is a schematic block diagram of a further proposed stimulation system comprising control device and electrode device as well as comprising a charging device according to this invention;

Fig. 11a-c is a schematic diagram of the time profile of trigger pulses, a generated magnetic field and a generated electrical impulse according to this invention;

Fig. 12 illustrates an example of preferred magnetization according to this invention;

Fig. 13 is a diagram for choosing optimized operation parameters;

Fig. 14 is a schematic diagram of a preferred circuit of the electrode device according to the present invention;

Fig. 15 is a block diagram of the electrode device;

Fig. 16 is a rectifier circuit of the electrode device;

Fig. 17 is a schematic of a rectifier circuit of the electrode device;

Fig. 18 is a block diagram of the electrode device;

Fig. 19 is a block diagram of the electrode device; and

Fig. 20 is a timing diagram for the supervisory component.

In the figures the same reference numerals are used for the same parts or parts of the same type, components and the like, where corresponding or similar advantages and properties are obtained even if a repeated description is omitted.

Figure 1 is a schematic sectional view of a proposed stimulation system 1 which is in particular configured as or works as a cardiac pacemaker in the example shown. However, the present invention is not restricted to this. For example, the stimulation system 1 can additionally or alternatively operate as a defibrillator or be used for other purposes and at other locations in the human or animal body.

The stimulation system 1 preferably comprises an implantable control device 2 and an implantable electrode device 3 separate therefrom. In the example shown, the control device 2 is implanted, in particular in the thoracic cage between the skin 4 and the ribs 5.

The control device 2 can be implanted as in present-day cardiac pacemakers. However, it is not absolutely essential to implant the control device 2. In principle, the control device 2 can also be used in the non-implanted state, that is, as an external device for controlling the electrode device 3.

Depending on the configuration, the electrode device 3 can also be used independently of the control device 2. For example, it is possible in principle that the electrode device 3 can be supplied with energy and/or controlled by another device, optionally even by a nuclear spin tomograph or the like, with suitable matching. Thus, further possible uses are obtained which go substantially beyond the possible uses of conventional cardiac pacemakers or other stimulation systems.

The electrode device 3 is preferably implanted in the heart 6 or the heart muscle of the patient, who is shown only schematically and in part. The electrode device 3 can be implanted, for example, as described in US 5,411,535 A.

Figure 2 is a schematic sectional view of the control device 2. In the example shown the control device 2 comprises a coil 7 for generating a magnetic field H, a control 8 and preferably an energy storage device 9 such as a rechargeable battery. The coil 7 can optionally be provided with a ferromagnetic, soft-magnetic or ultrasoft magnetic core or a half-sided cladding or another shoe or conducting element to concentrate the magnetic flux.

The control device 2 or control 8 can preferably receive or take up the required heart information via means not shown and/or via the coil 7 so that the generation of electrical impulses by the electrode device 3 to stimulate the heart 6 can be controlled in the desired manner. For example, reference is also made here to US 5,411,535 A. For example, electrodes, not shown, can also be connected directly to the control device 2, in particular to detect ECG signals or the like.

If necessary, the control device 2 or its energy storage device 9 can be inductively recharged in the implanted state. Thus, in particular when the energy consumption is high, an otherwise necessary operation to change the battery or changing the control device 2 can be avoided. The coil 7 provides a way to generate the magnetic field H, and is preferably used for the inductive charging. However, another induction device not shown can also be used for charging.

Figure 3 shows the proposed electrode device 3 in a schematic sectional view. The electrode device 3 in particular can be constructed only of passive structural elements and/or without an energy storage device such as a battery. Nevertheless, in a preferred alternative, the electrode device 3 comprises an energy buffer, preferably for storing energy received in wireless manner, in particular a capacitor. In the example shown, the electrode device preferably comprises a coil device 10, an optional pulse forming device 11 and preferably at least one electrode 12, preferably at least two electrodes 12, as well as preferably a common housing 13. The components and electrodes 12 are preferably integrated in the electrically insulated housing 13 or attached thereon.

The electrode device 3 is very compact and in particular is configured as substantially rod-shaped or cylindrical. In the example shown, the length is 10 to 20 mm, in particular substantially 15 mm or less. The diameter is preferably at most 5 mm, in particular substantially 4 mm or less. A retaining device can be attached to the electrode device 3, preferably an anchor or a screw which allows the electrode device 3 to be anchored in the heart muscle.

The electrode device 3 is configured to generate electrical impulses for the desired stimulation or signal generation. The electrical impulses are delivered, for example, via the electrodes 12. In the example shown, the electrodes 12 are located on opposite sides. However, the electrodes 12 can also be arranged concentrically or otherwise, for example, at one end or at the opposite ends of the electrode device 3 or the housing 13.

Figure 4 shows a schematic block diagram of the electrode device 3 according to the described and preferred exemplary embodiment. In this case, the pulse forming device 11 preferably comprises an energy buffer, in particular in the form of a capacitor 14, and a resistance 15. Additionally or alternatively, an inductance not shown, such as a coil can also be used for pulse forming.

The pulse forming device 11 is used for forming or reforming a pulse-like induction voltage which is generated or delivered under certain circumstances, as will be described in further detail hereinafter, by the induction or coil device 10. The reformed electrical impulse can then be output directly for stimulation via the connected electrodes 12.

Further structural elements are not required in principle but are possible. The electrode device 3 preferably comprises a rectifier for rectifying energy received by the coil device 10, a delay means for generating a delay between reception of the energy and generation of the electrical impulse, and/or a protection means to prevent or block generation or delivery of electrical impulses when delivery is not intended. Furthermore, the electrode device 3 can also be implemented by other structural elements having a corresponding function.

The induction or coil device 10 is preferably configured such that a pulse-like induction voltage is generated when a minimum field strength of the, i.e., external magnetic field acting on the electrode device 3 or coil device 10 is exceeded. For this purpose, the coil device 10 particularly preferably has a coil core 16 which exhibits an abrupt change in the magnetization, i.e. bistable magnetic properties, when the minimum field strength is exceeded. This abrupt change in magnetization or magnetic polarization results in the desired pulse-like induction voltage in an allocated coil 17. Alternatively or additionally, a reed relay in series with at least one electrode 12 can be used for generation and/or delivery of the electrical impulse.

In order to achieve the aforesaid bistable magnetic behavior of the coil core 16, as shown in the diagram according to Fig. 6 as an example, in the example shown the coil core 16 is preferably constructed of at least one core element 18, preferably of a plurality of core elements 18.

The core elements 18 preferably run parallel to one another so that the coil core 16 has a bundle-like structure of the core elements 18. If necessary, however, only a single core element 18 can be used to form the coil core 16, especially if the energy of the electrical impulse to be generated is relatively low or a different arrangement, for example, comprising a plurality of coil devices 10 is used.

Figure 5 shows a preferred exemplary embodiment of the core element 18 in a sectional schematic view. The core element 18 is preferably configured as wire-like.

The coil core 16 and/or the core element 18 preferably have a layer arrangement of soft and hard magnetic material. In the example shown, an inner layer such as the core 19 and an outer layer such as the cladding 20 comprise of at least magnetically different materials, namely soft magnetic material on the one hand and hard magnetic material on the other hand. The differences therefore lie in the coactive field or in different hysteresis curves of the (magnetically) different materials. The coupling as a result of the layer structure then results in the desired magnetically bistable behavior or the desired abrupt change in the magnetization of the core element 18 or all the core elements 18 and therefore the coil core 16.

The individual core elements 18 preferably have a diameter of about 50 to 500 μm, in particular substantially 100 μm and/or a length of 5 to 20 mm, in particular substantially 15 mm.

The core elements 18 are particularly preferably so-called Wiegand wires as described in US 3,820,090 and/or supplied by HID Corp., 333 St. Street, North, Heaven, CT 06473, USA under the trade name "Wiegand Effect Sensors" or so-called impulse wires as supplied by Tyco Electronics AMP GmbH, Siemenstrasse 13, 67336 Speyer, Germany. In the Wiegand wires the soft and hard magnetic layers are formed of the same material, the different magnetic properties being achieved in particular by mechanical reforming.

With regard to the possible structure and/or the materials used, reference is made supplementarily, additionally or alternatively to the article "Power Generating Device Using Compound Magnetic Wire" by A. Matsushita et al. published in the journal "Journal of Applied Physics", Vol 87, No. 9, 1st May 2000, page 6307 to 6309 and to the article "A Soft Magnetic Wire for Sensor Applications" by M. Vàzquez et al. published in the journal "J. Phys. D: Appl. Phys.", Vol. 29, 1996, pages 939 and 949, which are introduced as additional disclosure.

Various properties, features and operating modes of the proposed method, the proposed electrode device 3 and the proposed stimulation system 1 are explained in detail hereinafter.

The electrode device 3 for generating electrical impulses is preferably supplied with energy and/or controlled by means of a magnetic field H which can be generated in particular by the control device 2 in an exclusively wireless manner. In particular, the electrode device 3 requires no energy storage device such as a battery which restricts the lifetime of usability of the electrode device 3. Nevertheless, the electrode device 3 may comprise an energy buffer such as a capacitor for short term storage of energy, preferably transferred in a wireless manner. Such a energy buffer may be adapted for storing energy for five electrical impulses or less, in particular for one electrical impulse only. In particular, further energy storing devices as capacitors or inductors may be used for filtering purposes, pulse forming or the like.

The electrode device 3 is configured such that an electrical impulse is only generated and delivered when a (first) minimum field strength of the magnetic field is exceeded. Furthermore, this or another pulse generation or triggering is preferably only made possible after respective previous activation.

The impulse generation and triggering preferably takes place as a result of the external magnetic field H acting on the coil device being varied in time so that when the first minimum magnetic field strength H1 is exceeded, an abrupt change in the magnetization of the core elements 18 or the coil 16 takes as shown in the schematic magnetization curve according to Fig. 6. As a result of the inverse Wiedemann effect, this abrupt change in the magnetization results in a pulse-shaped induction voltage (pulse P in Fig. 7) in the allocated coil 11. This first minimum field strength H1 is therefore a switching threshold. Alternatively or additionally, a delay means, in particular a reed relay, and/or a protection means may be activated or controlled by the first minimum magnetic field strength H1.

The induced voltage pulses P can have an amplitude of up to about 5 V and are about 5 to 100 μs long. In order to achieve a preferably longer pulse duration, as is usual for cardiac stimulation, the optional pulse forming device 11 is preferably used. The induced voltage pulse P can thus in particular be stretched in time. Alternatively or additionally, a longer pulse duration can also be achieved by bundling a plurality of core elements 18 in the coil 17, in particular so that the pulse forming device 11 can be completely omitted.

Additional core elements 18 can be provided in the coil core 16 to increase the pulse power. Alternatively or additionally, a plurality of coil devices 10 can be connected in parallel or in series to increase the pulse power.

Alternatively or additionally, other magnetic, in particular permanent-magnetic elements can be used in the coil core 16 to achieve the respectively desired magnetic properties of the coil core 16.

The magnitude of the minimum field strength H1 depends on various factors, in particular the manufacturing conditions of the core elements 18. The minimum field strength H1 is preferably between 0.5 and 20 mT, in particular between 1 to 10 mT and is quite particularly preferably about 2 mT. These values are already substantially above the values for magnetic fields usually permissible in public so that any triggering of an electrical impulse by interference fields usually expected is eliminated.

The individual core elements 18 or the coil core 16 having the bistable magnetic properties, in particular in the preferred but not absolutely essential structure of layers having alternately soft and hard magnetic properties, can be used in various ways. In the example shown, preferably asymmetrical behavior is achieved on running through the magnetization curve or hysteresis. For resetting or attaining the starting point, that is activation for the triggering of the next impulse, the polarity of the coil core 16 is (completely) reversed by the external magnetic field H having the opposite direction when the second minimum field strength H2 is exceeded, as can be deduced from the magnetization curve in Fig. 6. It should be noted that in said processes in each case only the polarity of the soft magnetic material layers is reversed whilst the magnetization of the hard magnetic material layers is thus retained. In principle, however higher magnetic fields H can also be used to reverse the polarity of the hard magnetic layers if required.

In the example shown, the external magnetic field H, in particular generated by the control device 2, is used both for controlling (triggering) the generation and delivery of an electrical impulse by the electrode device 3 and also for supplying the electrode device 3 with the energy necessary for generating the electrical impulse. In addition, the magnetic field H is preferably also used for said activation of the electrode device 3 for the possible generation of the next electrical impulse. However, this can be also be effected in another manner or by another signal.

The external magnetic field H preferably runs at least substantially parallel to the longitudinal direction of the coil core 16 or the core elements 18.

Figure 7 shows schematically a preferred time profile V1 of the external magnetic field H acting on the electrode device 3 and the corresponding time profile V2 of the voltage U induced in the electrode device 3 or its coil 17.

The magnetic field H is preferably generated intermittently and/or as an alternating field. The magnetic field H preferably has a switch-on ratio of less than 0.5, in particular less than 0.25, particularly preferably substantially 0.1 or less.

The field strength of the magnetic field H has a substantially ramp-shaped or sawtooth-shaped time profile, at least during the switch-on times as indicated in Fig. 7.

The magnetic field H is alternately generated with an opposite field direction for alternate generation of an electrical impulse and activation of the electrode device 3 before generation of the next electrical impulse. The activation preferably takes place only shortly before generating the next electrical impulse, as indicated in Fig. 7.

The frequency of the magnetic field H is preferably only a few Hz, in particular less than 3 Hz and corresponds in particular to the desired frequency of the electrical impulses to be generated.

The ramp-shaped increase in the field strength of the magnetic field H is preferably relatively steep in order to achieve only short switch-on times and only a low switch-on ratio. This is advantageous in regard to minimizing the required energy and a defined triggering with few interfering influences.

According to the minimum field strength to be achieved, the maximum field strength of the magnetic field H in the region of the electrode device 3 preferably reaches substantially 1 to 20 mT, in particular 2 to 10 mT.

It can be seen from Fig. 7 that the negative magnetic field ramps on reaching the second minimum field strength H2 in each case only induce a very small electrical impulse which is negligible compared to the pulses P at the abrupt change in magnetization. The magnitude of these small pulses depends substantially on the rate of change in the magnetization during resetting, that is during the activation of the electrode device 3 for generation of the next electrical impulse.

According to a further development not shown, a plurality of electrode devices 3 can be used which in particular can be controlled and supplied with energy by a common control device 2. The electrode devices 3 can then be implanted at different locations, for example. As a result of different first minimum field strengths H1, different coil devices 10 and/or pulse forming devices 11 or the like, desired phase shifts, energy differences or the like can then be achieved in the electrical impulses or signals delivered by the individual electrode devices 3. In particular, the delay means can be used for synchronizing the electrode device 3.

It should be noted that the preferred synchronization of the stimulation of the heart 6 with the heat beat can be achieved, for example, by evaluating the electric voltage induced in the coil 7 of the control device 2 by the movement of the electrode device 3, optionally in conjunction with the ECG voltage which can be detected galvanically via the housing of the control device 2 or a relevant electrode.

Particular advantages of the invention reside in the possibility that the wireless electrode device 3 can be implanted in more suitable regions for stimulation, in particular, of the heart muscle, than is possible with wire-bound electrodes. Moreover, a plurality of electrode devices 3 can be implanted at different locations whereby improved stimulation and in particular better cardiac dynamics can be achieved.

Figure 8 is a schematic section of a further embodiment of the proposed electrode device 3. In this case, the coil device 10 can comprise a coil core 16 or core elements 18 made of a soft magnetic material or ultrasoft magnetic material, for example in the form of wires or strips. Such a material has a very low coactive field strength which corresponds to the minimum field strength H1 and in particular is less than 0.1 mT. The saturation field strengths of the material are less than about 0.01 to 3 mT. The coil core 16 consists of non-magnetic or completely or partially of said soft magnetic or ultrasoft magnetic material or a combination of various such magnetic materials.

In this case, the electrode device 3 or coil device 10 comprises a coil 17 preferably having a high number of turns, in particular at least 1,000 turns, particularly preferably 2,000 turns or more. In the example shown, the coil 17 has substantially 3,000 turns or more.

In the example shown, the coil inside diameter D10 is preferably 1 to 3 mm, the coil outside diameter D20 is preferably 2 to 6 mm and the coil length L1 is preferably 10 to 30 mm.

In general, ferrites or ferromagnetic metal powder materials can be used as core materials or soft magnetic materials. An advantage is that as a result of the poor electrical conductivity, these materials only exhibit low eddy current losses.

In general, the bobbin-like coil shown in Fig. 8 or its core 16 or only the central rod or only a rod-shaped core 16 or a plurality of core elements 18 can be constructed of soft or ultrasoft materials in the form of a stack of films electrically insulated from one another to reduce the transverse conductivity, to minimize eddy current losses. The same applies to the use of ferrites or other materials having corresponding properties.

The proposed electrode device 3 or coil device 10 permits the generation of relatively strong electrical impulses, in particular an impulse having a voltage of at least 1 V and a time duration of substantially 0.1 ms or more. This can be achieved in particular by the bobbin-like coil configuration shown and/or by the high number of turns. In particular, this relatively strong and relatively long-lived electrical impulse can also be achieved with the soft magnetic core material. A magnetic resetting pulse as with the Wiegand wires or the like is not absolutely necessary. However, a combination with the other magnetic materials or structures is possible.

As a result of the special RLC properties (impedance) of the primary coil 7 of the control device 2, the exciting magnetic field H can only increase relatively slowly (typically from 0 to a maximum of, for example, 0.1 to 2 mT in 0.1 to 5 ms). In the proposed coil device 10 of the electrode device 3 and under loading with a characteristic resistance for the heart muscle of, for example, about 1 kOhm, a relatively broad or long-lived impulse having a duration of at least 0.1 ms, in particular of substantially 0.25 to 2 ms, can be generated. This can possibly be attributed to the alternating current properties of the LRC arrangement (or the coil device 10, high inductance and high winding capacity of the coil) and/or to the retroactive effect of the coil current on the core 16.

The electrode device 3 described hereinbefore is preferably again combined with the control device 2 already described or another control device 2 and/or is controlled and/or supplied with energy preferably exclusively by means of an external or varying magnetic field H, as already described.

Figure 9 shows another embodiment of the proposed electrode device 3. More precisely, this is not an electrode device 3 but a stimulation device 21 since no electrodes 12 are required as in the preceding embodiments. However, the stimulation device 21 can be used instead of the electrode device 3 or for the stimulation system 1 described previously. The reasoning so far relating to the use and insertion of the electrode device 3 therefore fundamentally apply accordingly for the stimulation device 21.

The stimulation device 21 has a magnetisable element 22 which is preferably surrounded by an optional cladding 23. Electrodes 12 or the like as in the electrode device 3 are preferably not required.

The element 22 can be magnetized by an external or varying magnetic field H, in particular, the magnetic field H is generated by the control device 2 or in another suitable manner.

Variation of the magnetic field H causes a change in the magnetization of the element 22. Accordingly, the magnetic leakage flux of the element 22 in the tissue surrounding the stimulation device 21 in the implanted state, such as the heart 6, varies in time so that an electrical field strength or an electrical stimulation is generated. Consequently, an electrical stimulation or an electrical impulse is generated in the tissue, such as the heart 6, without electrodes 12.

The element 22 is preferably ferromagnetic, in particular at least substantially or exclusively made of ferromagnetic material. Alternatively or additionally, the element 22 can also be constructed as described with reference to Fig. 5 and/or it can be constructed as a Wiegand wire or the like and/or from a plurality or a bundle of core elements 18.

The stimulation device 21 in particular brings about an amplification of the external magnetic field H at the location of the stimulation device 21, that is at the implanted site. This makes it possible to achieve specific electrical stimulation in the desired area and/or depending on the magnetic field H.

Figure 10 shows another embodiment of the proposed stimulation system 1 comprising the control device 2, the electrode device 3 and an external charging device 24 in a schematic diagram similar to a block diagram. In this embodiment a plurality of short magnetic field pulses are generated as a sequence by the control device 2 during the switch-on time of the magnetic field H, i.e. during the switch-on phases. In particular, it is thus achieved that the coil arrangement 10 or its coil core 16 always changes its magnetization far below the saturation state. Thus, a minimum energy consumption can be achieved since the largest possible flux variation in the core of the coil arrangement 10 of the electrode device 3 is present or produced during the entire switch-on time of the magnetic field H and therefore substantially during the generation of the electrical impulse.

The magnetic field pulses can be unipolar or bipolar when using soft magnetic core materials. Bipolar magnetic field pulses are used when using bistable materials.

In the example shown according to Fig. 10, bipolar magnetic field pulses are preferably generated by means of a bridge of switching transistors M1 to M4 (e.g. MOSFETS, also in complementary design) or other switching semiconductor components. Also indicated in Fig. 10 are the coil 7, the control 8 and the energy storage device 9 of the control device 2. The control 8 can, for example, comprise one or two signal generators V2 and V4. Preferably connected in parallel to the energy storage device 9 is a smoothing capacitor 25. In addition, separating electronics 26 such as a switch or the like can be provided.

The control device 2 or its coil 7 is preferably configured such that the control device 2 or its energy storage device 9 can be inductively charged in the implanted state, in particular via the coil 7. For generating the required electromagnetic field during charging the charging device 24 is equipped with a suitable coil 27 and a corresponding power supply, in particular an alternating current supply 28.

Preferably, multiple magnetic field pulses are used to control the electrode device 3 and to generate the respectively desired electrical impulses, i.e. multiple magnetic field pulses form one single electric pulse for one stimulation.

Preferably, the electrode device 3 comprises a rectifier (in Fig. 10 formed by the shown diodes or any other components, in particular with a means for smoothing the resulting electrical voltage, here in the form of a capacitance). Thus, a single electrical impulse can be generated as desired, in particular as discussed in the following with regard to Fig. 11.

Figure 11a) is a schematic diagram showing a possible pulse sequence (voltage over time t) generated by the control 8 and allowing optimum triggering of the bridge. The trigger pulses, in this case for the bridge of switching transistors, are preferably only generated during the switch-on time t_{on} to t_{off}, i.e. when the magnetic field H is switched on. For example, the trigger pulses each last less than 50 μs. After a first pulse 1 (shown by the continuous line) and a certain delay time of, for example, Δt_1 of about 1 to 10 μs, an opposite pulse 2 then follows for the duration t_2 which in particular corresponds to the first duration t_1, and which reverse the primary coil voltage (voltage of the coil 7) via the bridge. This alternating generation of trigger pulses is repeated n times until a sufficient number of pulses consisting of positive and negative paired single pulses has been delivered.

As a result of the inductance of the coil 7, the trigger pulses or pulse sequences shown results in a sequence of in particular at least substantially sawtooth-shaped, preferably bipolar magnetic field pulses (shown as current through the coil 7 over time t in Fig. 11 b) which act on the electrode device 3 or its coil device 10 (secondary coil) as the magnetic field H in the sense of the present invention and there bring about the generation of an electrical impulse (or a sequence of electrical impulses for each single stimulation) for stimulation. Figure 11c) shows an electrical impulse (in particular a superposition of partially smoothed individual impulses) generated by the magnetic field pulses or the pulse-like varying magnetic field H as a schematic diagram of voltage over time t. In particular, the length of the electrical impulse depends on the length of the switch-on time of the trigger pulses or the magnetic field pulse and substantially corresponds particularly preferably to the switch-on time. Alternatively or additionally, energy transmitted via one or more magnetic fields pulses can be buffered using an energy buffer of the electrode device 3.

Similar behavior can be achieved with a unipolar sequence of magnetic field pulses. In this case, for example, the left part of the bridge and the generator V2 in Fig. 10 as well as the dashed pulse sequence 2 in Fig. 11 c) can be omitted.

The duration between two trigger pulses Δt should be selected so that the second pulse is triggered when the primary coil current which initially decreases quasi-linearly towards zero, reaches the zero level. This time interval depends both on the R/L value of the coil 7 and on the R/L value of the secondary circuit, in particular the coil arrangement 10. For the primary circuit (control device 2) substantially the winding resistance and the inductance of the coil device 10 determine the R/L ratio whilst the resistance of the coil device 10 is determined by the winding resistance and the loading resistance (tissue resistance of the stimulated part of the heart muscle or the like which is present at the electrodes 12) and the inductance is determined by the winding inductance taking into account the preferably ferromagnetic core 16. Here R designates the electrical resistance in general and L designates the inductance.

As has been explained, the impulses induced in the coil device 10 at times t or t' have different signs, i.e. a pulse sequence of bipolar pulses is obtained (both in the case of unipolar and bipolar excitation by magnetic field pulses). Unipolar electrical impulses are preferably required and generated for stimulation. These are rectified by a rectifier, in particular a bridge or diode rectifier, in the electrode device 3. Particularly preferably the rectifier comprises semiconductor switches as described in further detail later with regards to Fig. 16 and 17. The rectifier is preferably connected between the connections of the coil device 10 and the electrodes 12, as indicated in Fig. 10. This results in unipolar sequences of electrical impulses with peak values. Between the peak values the voltages can be close to zero. A small energy buffer, in particular smoothing capacitor C2 (of, for example, 1 to 200 nF) connected in parallel to the stimulation electrodes can smooth this pulsating voltage sequence if necessary. The capacitance can be optimally matched to the properties of the entire system.

With regard to Fig. 10, it should be noted that the electrode device 3 is preferably only constructed of passive, in particular, few components such as one or a plurality of diodes, in particular Schottky diodes D2, D5, D8, D9 to form the rectifier and/or the capacitor C2. The diodes may be replaced by semiconductor switches as discussed later.

The duration of the respective electrical impulse (a single stimulation) generated by the electrode device 3 depends on the respective switch-on time of the magnetic field H, in particular on the number of trigger pulses generated in a sequence and thus on the number of magnetic field pulses generated by the control device 2. Consequently, the control device 2 controls the generation of the electrical impulse or the electrode device 3 by the magnetic field H directly in the initially specified sense of the present invention.

The schematic diagram according to Fig. 11 c) shows the influence of the rectifier and the R/L ratio of the coil device 10 of the electrode device 3. When the R/L ratio is large (e.g. very small L), the coil voltage follows the derivative of the primary coil current dI/dt, which preferably increases or decreases quasi-linearly here as a consequence of the smaller R/L ratio of the primary coil (coil 7) when the polarity of the primary coil voltage is reversed. When the R/L ratio of the coil device 10 is small (including the tissue resistance present at the electrodes 12), as is realistic on account of the preferred high number of turns (in particular about 1,000 turns or more) and the preferred presence of the ferromagnetic core 16, the induced coil voltage (measured as the voltage at the load resistance of the coil 17 – in particular therefore at the tissue resistance present at the electrodes 12) only increases relatively slowly.

The proposed method of using relatively short, closely following, rectified electrical impulses as a result of a sequence of short magnetic field pulses or trigger pulses according to Fig. 11 in order to generate an electrical impulse for stimulating a single heart beat or the like, offers the possibility of adapting the stimulation pulse duration (the total length of the electrical impulse during a switch-on time of the magnetic field H, substantially the switch-on time t_{on} to t_{off}) to the needs of a particular patient by suitably adjusting the number n of pulse pairs of the trigger pulses by acting externally on the control 8 equipped with at least one suitable sensor. However, other electrical or electrotechnical design solutions are also possible.

Fig. 12 shows a B(H) curve (schematic). ΔH corresponds to the current variation through the primary coil produced by applying a voltage pulse to its leads. Symmetry to H=0 is achieved by using a sequence of a positive and a negative voltage pulse of equal amplitudes (cf. Fig. 11). This is advantageous to the case of using a unipolar voltage pulse producing the same ΔH since dB/dH is monotonically decreasing along the hysteresis curve. Hysteresis effects have been omitted in the drawing since core materials with very small hysteresis are to be preferred to avoid BH-losses.

A constant voltage suddenly applied to the primary coil results in a monotonically increasing current through the coil (equ.1) and hence a proportionally increasing magnetic field at the site of the electrode device 3 the rate governed by the time constant L/R of the coil circuit.

$$i=U/R\cdot(1-e^{\frac{-t}{L/R}})\ \text{(equ.1)}$$

Since the induced voltage in the coil device 10 of the electrode device 3 is proportional to the change of the induction dB/dt in the core element 18 which is a function of magnetic field strength, the induced voltage decreases with time during the time the voltage pulse at coil 7 is on. This means a reduction of the efficiency of conversion of the electric power consumed by coil 7 into a voltage occurring at the posts 12 the longer the voltage is applied to coil 7. Therefore, for optimal efficiency, magnetic field strength needs to be kept small which is reached by switching off or reversing the voltage applied to coil 7 by using short pulse duration times.

The amplitude and duration of the induced voltage pulse in the coil device 10 is adjusted by choosing a proper pulse voltage applied to coil 7, a suitable pulse duration and frequency. A very high frequency becomes undesirable to one part because of an increased impedance of the stimulator coil (Z=ωxL), resulting in reduced pacing pulse amplitudes. For a given design of the coil 7 and the electrode device 3 at a given mutual geometric arrangement (including the distance of the electrode device 3 from the plane of the coil 7, the angle between the coil axis and the distance of the electrode device 3 from the axis of the coil 7) details of the burst pulse sequence are optimized for minimal energy consumption at a desired pacing pulse shape. The energy consumption is given by

$$E = \frac{1}{2} C(U_1^2 - U_2^2)$$

where U_1 is the voltage at the charging capacitor C before firing a pulse burst and U_2 the voltage after firing a pulse burst after the power supply has been disconnected from C.

Since the electronic properties of the electrode device are strongly non-linear and only approximately known *a priori,* the optimal operation parameters of the pacing system have to be determined experimentally. This is performed for a single pacing pulse preferably according to the diagram shown in Fig. 13.

The timing sequence of the voltage pulses comprising a burst applied to the coil 7 can be chosen to produce almost arbitrary pacing pulse shapes. For instance, a ramp-like increase of the pacing pulse is obtained with sequentially increased voltage pulse amplitudes.

Especially, the pacing pulse can be made to change sign for some arbitrary fraction of time. This may be achieved by using a one-way rectifier 29 or diode D1 instead of the bridge rectifier depicted in Fig. 11 and attaching / connecting a Zener diode 30 (or other devices exhibiting a breakdown characteristic like four-layer-diodes, thyristors etc.) parallel to the rectifying diode D1 with an adequate Zener voltage larger than that of the normal rectifying diode, as shown in a preferred exemplary embodiment in Fig. 14. Whenever the induced voltage now with an opposite sign as compared the normal pulse is increased beyond the Zener breakdown voltage (or the Off–State Voltage of the mentioned other types of semiconductors) a reversed pulse polarity is obtained. This requires to produce an asymmetrical rate of current increase or decrease through the coil 7, i.e. producing di/dt values differing in sign and amplitude. Hence the amplitudes of positive and negative induction voltages in the electrode 3 will be different, enabling the selective application of positive or negative pacing pulses. The differing di/dt values are obtained by applying voltage pulses U (cf. equ.1) of different amplitudes and polarities to the coil 7. The described possibility might be of advantage since the pacing voltage is reported to increase with time when pacing with unipolar pulses. This potentially undesirable effect is largely reduced by employing a bipolar pacing pulse. The possibility to produce arbitrary bipolar pacing pulses persists when the normal diode D1 is omitted, using the forward and breakdown characteristics of the Zener diode.

In Fig. 15 a preferred implantable electrode device 3 is shown. This electrode device 3 can be used for a stimulation system, preferably a cardiac pacemaker. The electrode device 3 can be supplied with energy by means of a varying magnetic field H. The electrode device 3 preferably comprises means for reception of energy from the varying magnetic field H, in particular a coil device 10 or the like. Using the energy transmitted in a wireless manner, an electrical impulse can be provided by the implantable electrode device 3 via electrodes 12. In particular, the electrical impulse can advantageous be provided between two or more electrodes 12 leading to a current flowing trough an object to be stimulated.

The electrode device 3 can comprise a rectifier 31 and/or an energy buffer 32, in particular a capacitor, and/or a delay means 33 for generating a delay between reception of energy and the generation of at least one electrical impulse. The electrode device 3 further can comprise a protection means 34 for preventing or blocking generation of electrical impulses, in particular for a time span after a first electrical impulse has been generated. Moreover, the electrode device 3 may comprise a pulse forming device 11 for forming or shaping the electrical impulse to be delivered by the electrode device 3.

In the following, the electrode device 3 as well as its components will be described in further detail.

As already explained in the beginning, the coil device 10 can be provided with energy in a wireless manner, in particular by the time-varying magnetic field H. Preferably, a current is induced in the coil device 10 by the time-varying magnetic field H. Alternatively or additionally, the coil device 10 may comprise an antenna and/or is adapted for receiving energy from electromagnetic waves or the like. Preferably, the term "time-varying magnetic field" in the sense of the present invention in corporates any field or wave comprising a magnetic component, e.g. electromagnetic waves or the like.

Energy received by the coil element 10 preferably is transmitted to the rectifier 31. The rectifier 31 is adapted to transform energy from a time-varying or alternating nature to a substantially continuous one. In particular, an alternating current or voltage is rectified.

Typically, diods in a bridge configuration are use for rectifying. As shown in Fig. 16, a rectifier 31 preferably comprises semiconductor switches 35 to 38 with a control port for commutation instead or additionally. These can be configured to switch already in the area of a zero-crossing, preferably in contrast to diods having a threshold voltage of about 0.4 to 0.8 Volt. Particularly preferably, the semiconductor switches 35 to 38, in particular MOSFETs or the like, of the rectifier 31 have a threshold voltage of about zero and/or are biased at about threshold, preferably the threshold voltage and/or an biasing offset from threshold is less than ±200 mV, in particular less than ±100 mV or ±50mV. By this measure, a voltage drop across the devices forming the rectifier 31 can be minimized and/or avoided. Thus, the rectifier 31 with semiconductor switches 35 to 38 can allow for reduced power losses and/or more efficient rectifying.

In the following, an example for operating the rectifier 31 is given. If the potential of node K1 is higher than the potential of node K2, semiconductor switch 36, preferably a n-channel-MOSFET, is conducting and connects node K3 to node K2. Furthermore, semiconductor switch 37, preferably a p-channel-MOSFET, is conducting and connects node K4 to node K1. Semiconductor switches 35 and 38 are non-conducting or having a high resistance and/or impedance as long as the potential of node K1 is higher than the potential of node K2.

If potential of node K2 is higher than the potential of node K1, semiconductor switches 35 and 38 are conducting and semiconductor switches 36 and 37 having a high resistance behavior. Thus, node K3 preferably is always connected to the one of the nodes of K1 and K2 with the higher potential and node K4 always this connected to the one of the note of K1 and K2 with the lower potential leading to the rectifying behavior.

The control ports or steering ports, in particular gates, of the semiconductor switches 35 to 38 can be connected and/or contacted via inductive elements 43 to 46 as shown in Fig. 17. Typically, semiconductor switches comprise a capacitive behavior at their control ports that can be compensated for using the inductive elements 43 to 46. Furthermore, Zehner diods 39 to 42 may be used to prevent over-voltage at the control ports of semiconductor switches 35 to 38.

After rectifying has been performed, the energy can be stored in the energy buffer 32, in particular a capacitor. Preferably, the energy buffer 32 is adapted for storing the energy needed for five electric impulses or less, in particular for generating only one single electrical impulse. Thus, the energy buffer 32 can be very small, in particular much smaller than a storing device as a battery or the like.

The electrode device 3 preferably comprises a protection means 33, in particular with a supervisory component 47 and/or a semiconductor switch 48. The semiconductor switch 48 can be controlled by the supervisory component 47. The semiconductor switch 48 preferably connects the rectifier 31 and/or the storing element 32 to at least one of the electrodes 12. The semiconductor switch 48 can be provided in series with at least one of the electrodes 12. Thus, generating an electrical impulse and/or delivery of the electrical impulse can be blocked by semiconductor switch 48. Preferably, the semiconductor switch 48 has a high resistance state for blocking electrical impulse as well as a low resistance state for generating an electrical impulse or for enabling its generation.

The supervisory component 47 preferably is a circuit, in particular an integrated circuit, a microcontroller or the like. The supervisory component 47 preferably comprises a timer. For example, energy is transmitted to the electrode device 3 and a first electrical impulse is generated and/or delivered. As long as this first electrical impulse is generated, the semiconductor switch 48 is conducting and/or the supervisory component 47 generates a corresponding signal that leads to a conducting semiconductor switch 48. After delivery of the first electrical impulse, the supervisory component 47 generates a signal controlling the semiconductor switch 48 such that it changes from a low resistance state to a high resistance state for blocking generation and/or delivery of further electrical impulses.

Preferably, the supervisory components 47 holds this state for particular time span. Afterwards, the supervisory component 47 can change the control signal in order to switch the semiconductor switch 48 into a low resistance state and the next electrical impulse can be generated and/or delivered. By this measure, any generation or delivery of an electrical impulse caused by a disturbance or the like can be prevented.

Preferably, the protection means 34 is adapted to prevent generation and/or to block delivery of electrical impulses for time span greater than 0.5 ms, preferably greater than 1 ms and/or less than 100 ms, preferably less than 20 ms in particular 10 ms or less.

Alternatively or additionally, supervisory component 47 and/or semiconductor switch 48 can provide or act as a means for generating a delay between reception of the energy and the generating of at least one of the electrical impulses. If energy is received and preferably rectified, the supervisory component 47 may control the semiconductor switch 48 to get into its high resistance state directly. Afterwards, the energy delivered to the electrode device 3 can be stored in the energy buffer 32 for a particular time span. Afterwards, the semiconductor switch 38 can be switched into its low resistance state, in particular by the supervisory component 47, and the electrical impulse can be generated and/or delivered. Thus, the protection means 33 alternatively or additionally can provide the functionality of a delay means as well. Preferably, the supervisory component 47 can be programmed in advanced and/or by signals transmitted by the magnetic field H accordingly.

The supervisory component 47 can comprise a decoding means for decoding a signal provided by the time varying magnetic field H. Therefore, the magnetic field H may comprise modulated information that can be demodulated by the supervisory component 47 and can be used for programming and/or controlling the supervisory component 47.
Alternatively or additionally, the electrode device 3 may comprise a delay means 34, in particular a reed-switch as shown in Fig. 17. This delay means can block generating and/or delivering the electrical impulse until a particular field strength

or minimum field strength H1 of the magnetic field H is reached. The delay means 34 preferably is placed in series with at least one electrode 12.

For example, the time-varying magnetic field H can provide energy to the electrode device 3 using field strengths lower than that needed for controlling or triggering the delay means 34. At the time, the electrical impulse has to be delivered, the magnetic field H can reach or exceed the minimum field strength H1.

The supervisory component 47 can be supplied by the energy delivered to the electrode device 3 in a wireless manner and, in particular, stored in the energy buffer 31. Therefore, it is preferred to use a supervisory component 47 with a low power consumption, in particular in the nW regime. Fig. 20A to 20C show a typical timing diagrams of the supervisory component 47. VCC can correspond to the rectified voltage delivered by the rectifier 31. Preferably, the voltage delivered by rectifier 31 is smoothed by energy buffer 32. Fig. 20A shows an example for the rectified voltage and/or for a voltage associated with the energy buffer 32, which in the following will be called process voltage. As soon as the energy transmission by means of the time-varying magnetic field H starts, the process voltage rises up exceeding the pinch off voltage V_{TH} of the supervisory component 47 i.e. its minimum operation voltage. Fig. 20B and 20C are showing an inverted and an non-inverted reset signal, respectively. The supervisory component 47 is configured such that the reset signal shown in Fig. 20B keeps low although the process voltage exceeds the pinch of voltage V_{TH} leading to an active reset. As shown in Fig. 20C, the non-inverted reset signal has a high level, leading to an active reset, too. Thus, for the time span of t_{RP}, starting from the time when the process voltage exceeds V_{TH}, the reset for the supervisory component 47 keeps active. Thus, disturbance of initialization of the supervisory component 47 can be prevented. Afterwards, the non-inverted reset signal switches to high and/or the inverted reset signal switches to low such that the supervisory component 47 starts working. Thus, the supervisory component 47 can block and/or keep blocking the delivery of an electrical impulse for a particular time span for generating a time delay, preferably by (keep) opening the semiconductor switch 48, and/or the supervisory component 47 can permit generating the electrical impulse, in particular by closing the semiconductor switch 48, and/or the supervisory component 47 can prevent generation of additional electrical impulses for a particular time span after a first electrical impulse has been generated by blocking delivery of the electrical impulse, in particular by opening the semiconductor switch 48.

A stimulation system 1, for example a cardiac pacemaker, comprising the implantable control device 3 and, preferably, the electrode device 3 comprising a rectifier 32 with semiconductor switches 35 to 38 and/or the delay means 34 and/or a protection means 33 is shown in Fig. 1. In addition, the stimulation system can comprise a second electrode device for generating impulses, that can preferably, but does not need to, comprise a rectifier 32 comprising semiconductor switches 35 to 38 and/or the delay means and/or a protection means 33. Using more than one electrode device 3 in a stimulation system 1 can advantageously lead to a better, more efficient and/or adaptive stimulation.

Preferably, different electrode devices 3 in the stimulation system 1 are placed in some distance, in particular in a distance greater than 1 cm, preferably greater than 2 cm and/or less than 20 cm, preferably less than 15 cm. It is particularly preferred that at least one of the electrode devices 3 comprises a delay means 34 for generating a delay between reception of the energy and the generation of at least one of the electrical impulses. Thus, different electrode devices 3 can generate electrical impulses with a time lack between a first electrical impulse generated by the first electrode device 3 and a second electrical impulse generated by the second electrode device 3 which preferably comprises the delay means 34 in this example. Thus, a common, additive stimulation can be adapted to the natural behavior of an object to be stimulated, e.g. a heart 6 can be stimulated at a first position and, after a short delay, at a second position, preferably according to its typical activation and/or stimulation. Therefore the second electrode device may 3comprise a reed relay as delay means 33 that can block the output and/or generation of the electrical impulse for the particular time span until a minimum field strength H1 for triggering is exceeded. In a stimulation system with more than two electrode devices 3, it is particularly preferred that all electrode devices 3 or at least one less than the number of electrode devices 3 actually used comprise delay means 34, in particular (micro-) reed relays. Then, different electrode devices 3 can be triggered independently, in particular if, as preferred, I the different reed relays of different electrode devices 3 comprising different thresholds, i.e. different minimum magnetic field strengths H1 for triggering.

The protection means preferably is adapted to prevent generation and/or to block delivery of electrical impulses for time span greater than 0.5 ms, preferably greater than 1.0 ms and/or less than 100 ms, preferably less than 20 ms, in particular 10 ms or less. Thus, generation and/or delivery of an electrical impulse can be prevented or blocked during a short time span that has been found to be sufficient for preventing unwanted electrical impulses that may occur due to a disturbance event, and at the same time a generation of a following electrical impulse is not affected.

The induction pacemaker technology described can also be used in combination with conventional cardiac pacemaker technology. In this connection, the use for left-ventricular stimulation within the framework of resynchronization therapy is particularly appropriate.

In particular, the following aspects of the present invention can be realized independently or in any combination:

The present invention makes use of energy recovery by the magnetic field.

The present invention uses parameters and operations such that core magnetic saturation in the electrode 3 is avoided. This reduces energy consumption significantly.

The pulse shape can be adjusted arbitrary for the most effective stimulation with respect to the pacing pulse height and width by using a programmable sequence of amplitudes, durations and delay times of the individual burst pulse voltages (voltage source 9, our Fig. 10) applied to the primary coil. The importance of choosing an optimal pulse shape has been described in US 5,782,880 A.

This very flexible design also provides the possibility to generate bipolar pacing pulses by controlling the di/dt rate and sign of the current sent through the primary coil7 and making use of Zener diodes or other rectifiers with selectable breakthrough voltages.

The burst-pulse sequence is optimized with respect to duration, repetition rate and time delay to achieve minimal energy consumption for a given pacing pulse amplitude an duration. If, e.g., the delay times Δt_1 or Δt_2 are too small, the energy consumption can increase dramatically.

Use of Cu cladded Al strand (Litz) wire in the primary coil is preferred and of advantage for significantly reducing the weight of the coil of the electrode device. It also provides –as also does Cu strand wire– a large degree of mechanical flexibility. Due to the skin effect present because of the alternating current sent through coil 7 the effect of the smaller conductivity of the Al as compared that of Cu is reduced but the weight is determined largely by the aluminum. In an experiment, the energy consumption using the Co cladded Al Litz wire was close to that of using pure Cu Litz wire with similar dimensions.

Metallic soft or ultrasoft magnetic cores might preferably be used for the electrode device and provide a larger saturation magnetization as compared to ferrite. Accordingly, a lower exciting magnetic field will be needed. Due to the transients of the magnetic field pulses eddy current losses occur in the core material. They are essentially reduced by lamination of metallic cores which is preferred.

Magnetically soft cores can be achieved in particular by lamination of multiple isolated layers. Magnetically ultra-soft cores can be achieved in particular by using amorphous or nanocrystalline magnetic materials.

Only one cap at the side of the stimulator that points toward the primary coil on the core instead of two, making it smaller and only slightly less efficient.

It is preferred to use energy recovery of the magnetic field by using high capacity buffering (supercaps) of the power supply together with fast switching diodes parallel to the MOSFETs comprising the H-bridge (cf. Fig. 10) in case these are not already implemented in the MOSFETs. This also extends the lifetime of the batteries since the large peak currents are delivered by the supercaps instead of the battery.

The control device 2 is preferably in a flexible housing as it should be implanted directly above the heart near the thoracic wall. To achieve this flexibility the control device can be embedded in a silicon cushion, however other soft materials can also be used.

For magnetic field concentration towards the electrode 3 a flux concentrator might be used contained within the interior of the inner surface of the preferably soft housing, preferably silicon cushion. Experiments had shown an increase in magnetic field strength at the pacing site when the coil 7 was halfway surrounded by a thin Mumetal cover the collar of which pointing to the pacing site. Other shapes might be used.

To guarantee flexibility the power supply should be preferably provided by tailor made, flexible, lithium polymer batteries. However also other types of power supplies might be used (thermoelectric using body heat, fuel cells, cells using body fluids).

Preferably, the electrode devices 3 comprises a flexible housing and/or means for magnetic field concentration at the inner surface of the housing as described above.

According to one aspect of the present invention, stimulation system 1 can be provided, in particular a cardiac pacemaker, comprising an implantable control device 2 and an implantable electrode device 3 for generating electrical impulses, which can be supplied with energy and/or controlled by the control device 2 in an exclusively wireless manner by means of a time-varying magnetic field H, the control device 2 being configured such that the field strength of the magnetic field, at least during switch-on times, has a substantially ramp- H1, H2 or sawtooth-shaped time profile or is bipolar or pulsed.

The control device can be configured such that the magnetic field H is generated intermittently and/or wherein the control device is configured such that the magnetic field H has a switch-on ratio of less than 0.5, in particular less than 0.25, particularly preferably substantially 0.1 or less.

Furthermore, the control device 2 can be configured in such a manner that the magnetic field H is alternately generated with an opposite field direction for the alternate generation of an electrical impulse and activating the electrode device 3 before generating the next electrical impulse, in particular wherein the activation takes place shortly before generation of the next electrical impulse.

The frequency of the magnetic field can be less than 3 Hz, in particular corresponds to the desired frequency of the electrical impulses to be generated.

Preferably, the stimulation system 1 is configured in such a manner that in the switched-on state the magnetic field H is formed by a plurality of unipolar or bipolar magnetic field pulses and/or that the respective switch-on duration of the magnetic field H controls or determines the length of each electrical impulse of a stimulation generated by the electrode device 3 and/or the magnetic field H is utilized for energy recovery.

The control device 2 in particular is configured in such a manner that the field strength of the magnetic field H in the region of the electrode device 3 is substantially 1 to 20 mT, in particular 2 to 10 mT. The control device 2 in the implanted state can be charged inductively from outside.

Alternatively or additionally, an implantable electrode device 3 for a stimulation system, specifically a cardiac pacemaker, for generating electrical impulses is provided, wherein the electrode device 3 is configured as a wireless and/or compact structural unit and can be supplied with energy and directly controlled exclusively by means of a varying magnetic field H, the electrode device 3 comprising only passive components and a rectifier.

The electrode device 3 preferably is configured in such a manner that an electrical impulse is only generated when a first minimum field strength H1 of the magnetic field H is exceeded, preferably wherein the electrode device is configured in such a manner that it generates and delivers an electrical impulse each time the minimum field strength H1 is exceeded, preferably only after a respective preceding activation.

In particular, the electrode device 3 is configured in such a manner that an electrical impulse can be generated in each case only following previous activation, in particular by exceeding a second minimum field strength H2 of the magnetic field having the opposite field direction to the field direction for the generation of an electrical impulse, in particular wherein the second minimum field strength H2 is greater than the first minimum field strength H1. Preferably the minimum field H2 strength is substantially 0.5 to 20 mT, in particular 1 to 10 mT.

The electrode device 3 may comprise a coil device 10 which generates a pulse-like induction voltage when a first minimum field strength H1 of the magnetic field is exceeded, in particular wherein the coil device 10 has a coil core 16 or a core element 18 having a magnetization which varies abruptly depending on the acting magnetic field strength and/or having an, in particular, wire-like layer arrangement of soft and hard magnetic material.

Alternatively or additionally, the electrode device 3 comprises a coil device 10, wherein an electrical impulse having a voltage of at least 0.5 V and a time duration of at least 0.05 ms can be generated by the coil device 10 by an external and/or varying magnetic field H having a field strength in the region of the electrode device of at most 10 mT, in particular substantially 2 mT or less and/or wherein the coil device 10 comprises more than 100 turns, at least 1,000 turns.

The electrode device in particular comprises only a passively operating pulse forming device 11, in particular having an inductance, a capacitance and/or a resistance, and/or that the electrode device 3 is configured as battery-less and/or amplifier-less, and/or that the electrode device 3 comprises a coil device 10 with a magnetic core 19, the core 19 being magnetically soft or ultra-soft.

Further, the electrode device 3 can be configured such that each pulse-like induction voltage is output as an electrical impulse, in particular, via integrated electrodes 12.

According to one aspect of the present invention, an implantable stimulation device 21 for a stimulation system 1, in particular a cardiac pacemaker, for electrical stimulation can be provided, wherein the stimulation device 21 can be exclusively supplied with energy and in particular controlled by means of an external and/or varying magnetic field H and/or wherein the stimulation device 21 comprises a magnetisable, preferably coil-free element 22 whose magnetization and magnetic leakage flux can be varied by variation of the magnetic field H for indirect, in particular electrode-less electrical stimulation. Preferably, the element 22 is ferromagnetic or has a magnetization which varies abruptly depending on the acting magnetic field strength. Preferably, the element 22 comprises an, in particular, wire-like layer arrangement of soft and hard-magnetic material.

Further, a method for operating an implantable electrode device 3, in particular a cardiac pacemaker, for generating electrical impulses can be provided, wherein the electrode device 3 is supplied with energy and directly controlled by means of a magnetic field H to generate the electrical impulses, wherein the magnetic field H in the switched-on state is formed by a plurality of unipolar or bipolar magnetic field pulses and that the respective switch-on time of the magnetic field H controls or determines the length of the electrical impulse respectively generated by the electrode device 3 or during a contiguous sequence of electrical impulses.

The number of magnetic field H impulses can be varied for variation of the duration of each electrical impulse or a contiguous sequence of electrical impulses and/or that the magnetic impulses have a substantially sawtooth-shaped profile.

The field strength of the magnetic field H, at least during switch-on times, can have a substantially ramp- or sawtooth-shaped time profile.

The magnetic field H can have a switch-on ratio of less than 0.5, in particular less than 0.25, particularly preferably substantially 0.1 or less.

A method for generating an electrical impulse in tissue, in particular for operating a cardiac pacemaker can be provided, wherein the magnetization of a magnetisable, preferably ferromagnetic element 22 is varied by an external or varying magnetic field H in order to vary the magnetic leakage flux of the element 22 for direct electrical stimulation or generation of the electrical impulse.

According to another aspect, a stimulation system 1, in particular a cardiac pacemaker is provided. The stimulation system 1 preferably comprising an implantable control device 2 and an implantable electrode device 3 for generating electrical impulses, which can be supplied with energy and/or controlled by the control device 2 in an exclusively wireless manner by means of a time-varying magnetic field H, at least one of the control device 2 and electrode device 3 comprising a flexible housing.

Individual features, aspects and elements of the individual embodiments and variants can be arbitrarily combined with one another or used in other stimulation systems or electrode devices.

Reference List

1 stimulation system
2 control device
3 electrode device
4 skin
5 ribs
6 heart
7 coil (control device)
8 control
9 energy storage device (control device)
10 coil device (electrode device)
11 pulse forming device
12 electrode
13 housing (electrode device)
14 capacitor (electrode device)
15 resistance
16 coil core
17 coil
18 core element
19 core
20 cladding
21 stimulation device
22 magnetisable element
23 cladding
24 charging device
25 smoothing capacitor
26 electronics
27 coil
28 current supply
29 one-way rectifier
30 Zener diode
31 rectifier
32 energy buffer
33 delay means
34 protection means
35 MOSFET
36 MOSFET
37 MOSFET
38 MOSFET
39 ZEHNER diode
40 ZEHNER diode
41 ZEHNER diode
42 ZEHNER diode
43 inductive element
44 inductive element
45 inductive element
46 inductive element
47 supervisory component
48 semiconductor switch
C2 capacitor
D1 rectifying diode
D2 Schottky diode
D5 Schottky diode
D8 Schottky diode
D9 Schottky diode
D10 diameter
D20 diameter
H magnetic field
H1 minimum field strength
H2 minimum field strength
K1 node
K2 node
K3 node
K4 node
L1 coil length
M1 transistor
M2 transistor
M3 transistor
M4 transistor
V1 time profile
V2 signal generator
V4 signal generator

Claims:

1. An implantable electrode device (3) for a stimulation system (1), preferably a cardiac pacemaker, for generating electrical impulses, wherein the electrode device (3) is configured as a wireless unit and can be supplied with energy by means of a varying magnetic field (H); wherein the electrode device (3) comprises at least one of:

a rectifier (31) comprising semiconductor switches (35, 36, 37, 38) with a control port for commutation;

a delay means (33) for generating a delay between reception of the energy and the generation of at least one of the electrical impulses; and

a protection means (34) to prevent or block the generation of the electrical impulses for a time span after a first electrical impulse has been generated.

2. The implantable electrode device according to claim 1, wherein the electrode device (3) is adapted to be controlled by means of a varying magnetic field (H).

3. The implantable electrode device according to claim 1 or 2, wherein the rectifier (31) is connected to a coil device (10) for receiving energy in a wireless manner.

4. The implantable electrode device according to any one of claims 1 to 3, wherein the rectifier (31) comprises semiconductor switches (35, 36, 37, 38), preferably MOSFETS, in particular in a bridge configuration.

5. The implantable electrode device according to any one of the preceding claims, wherein the semiconductor switches (35, 36, 37, 38) of the rectifier (31) having a threshold voltage of about zero and/or are biased at about threshold.

6. The implantable electrode device according to any one of the preceding claims, wherein the control ports of the semiconductor switches (35, 36, 37, 38), in particular the gates of the MOSFETs, are connected and/or contacted via inductors.

7. The implantable electrode device according any one of the preceding claims, wherein the electrode device (3) comprises an energy buffer (32) in particular a capacitor, for storing energy supplied to the electrode device (3), preferably after rectifying.

8. The implantable electrode device according to any one of the preceding claims, wherein the delay means (33) comprises a reed relays in series with an electrode (12) of the electrode device (3), in particular with a minimum magnetic field strength (H1) as a threshold for switching, wherein, preferably, the minimum magnetic field strength (H1) is higher than the field strength used for supplying with energy.

9. The implantable electrode device according to any one of the preceding claims, comprising a semiconductor switch (48), preferably associated with the protection means (34) and/or the delay means (33), in particular a MOSFET, in series with an electrode (12) of the electrode device (3) is adapted for blocking delivery and/or preventing generation of an electrical impulse.

10. The implantable electrode device according claim 8, comprising a supervisory component (47), in particular a controller, adapted to control the semiconductor switch (48), in particular for generating the delay and/or protection function.

11. The implantable electrode device according to any one of the preceding claims, wherein protection means (34), in particular the supervisory component (47) and/or the semiconductor switch (48), is adapted to prevent generation and/or to block delivery of electrical impulses for a time span greater than 0.5 ms, preferably greater than 1 ms and/or less than 100 ms, preferably less than 20 ms, in particular 10 ms or less after a first electrical impulse has been generated and/or delivered.

12. A stimulation system, in particular a cardiac pacemaker, comprising a preferably implantable control device (2) and at least a first implantable electrode device (3) according to any one of the preceding claims.

13. The stimulation system according to claim 12, comprising at least a second electrode device (3) for generating electrical impulses, wherein the second electrode device (3) is configured as a wireless and/or compact structural unit and can be supplied with energy by means of a time-varying magnetic field (H), in particular according to any one of the claims 1 to 10.

14. The stimulation system according to claim 12 or 13, wherein the first electrode device (3) comprises a delay means (33) configured for delaying generation of an electrical impulse with reference to generation of an electrical impulse by the second one.

15. The stimulation system according to claim 12 to 14, wherein the first and second electrode devices (3) comprise reed relays with different switching thresholds.

16. A method for operating at least two implantable electrode devices, in particular in a cardiac pacemaker system, for generating electrical impulses, wherein the electrode devices (3) are supplied with energy exclusively in a wireless manner, and wherein electrical impulses are generated by the electrode devices (3) with a particular time delay, wherein the time delay is controlled and/or modified by means of the magnetic field (H), in particular wherein the electrode devices are triggered by magnetic fields (H) of different strength.

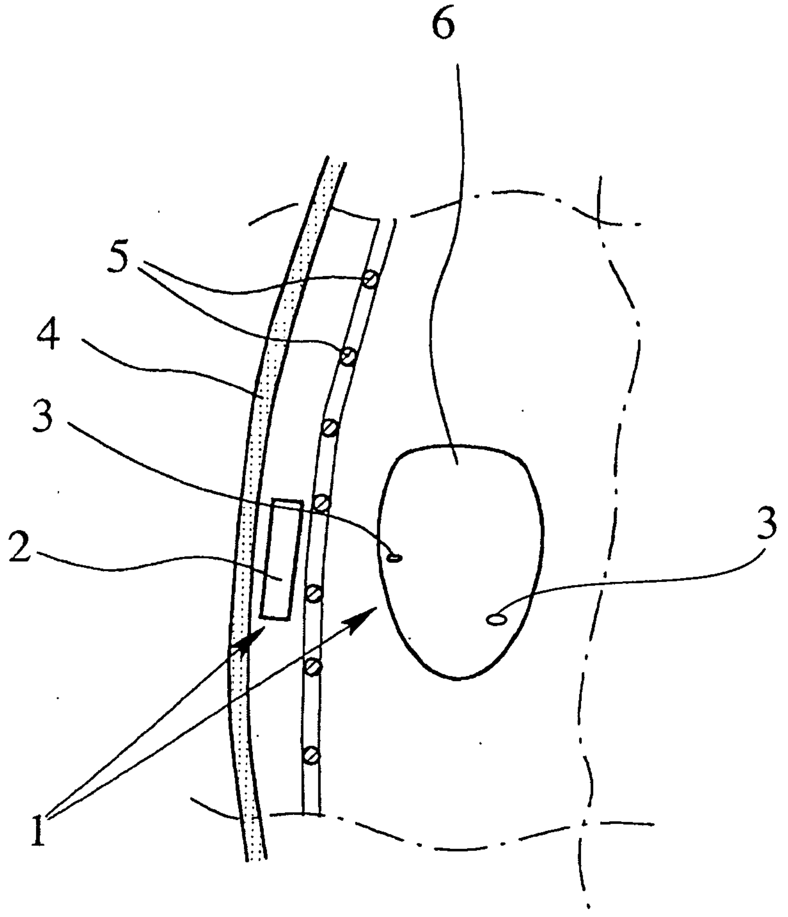


Fig. 1

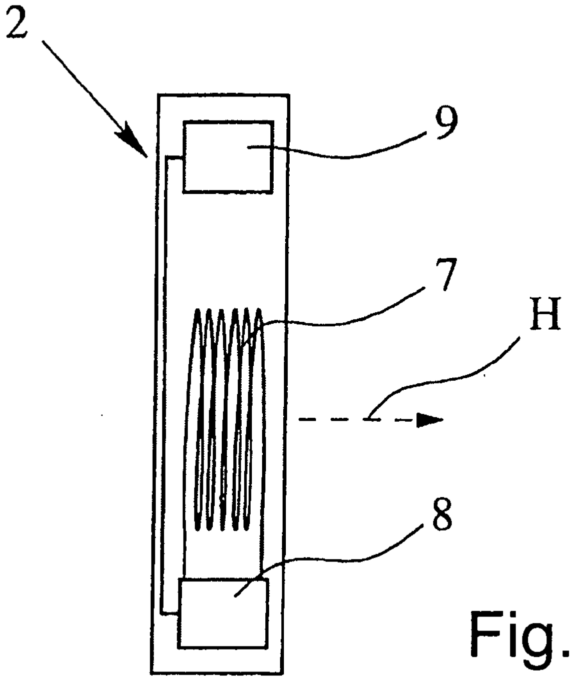


Fig. 2

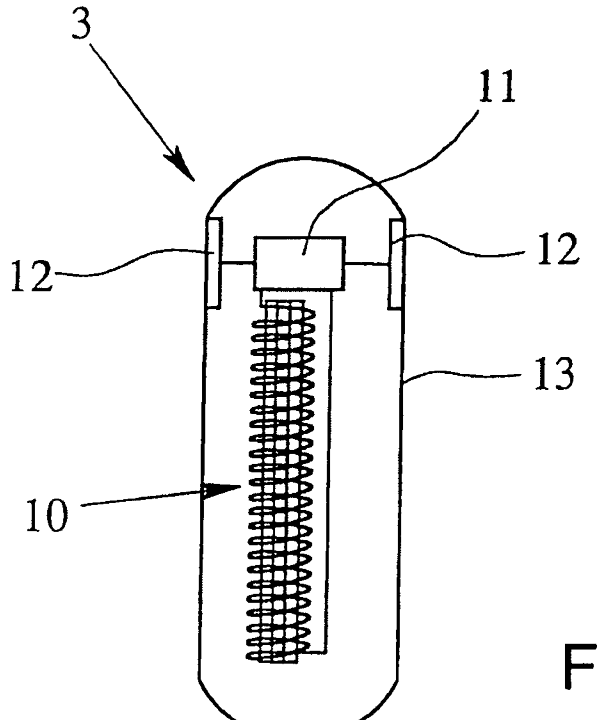


Fig. 3

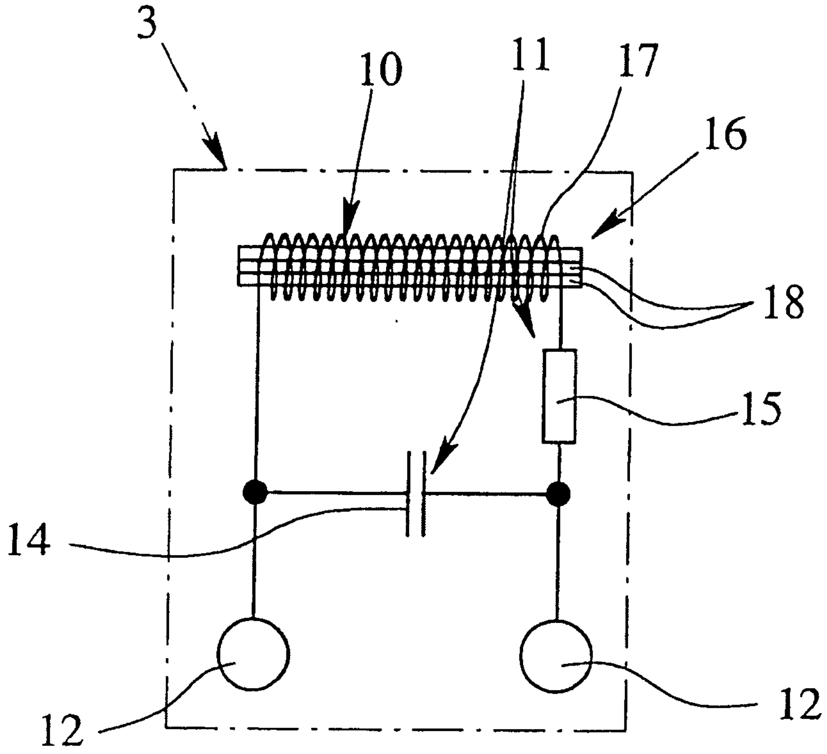


Fig. 4

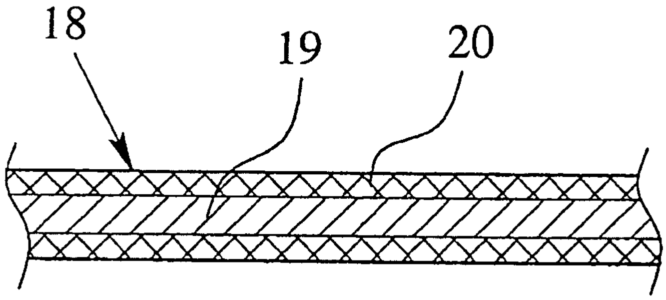


Fig. 5

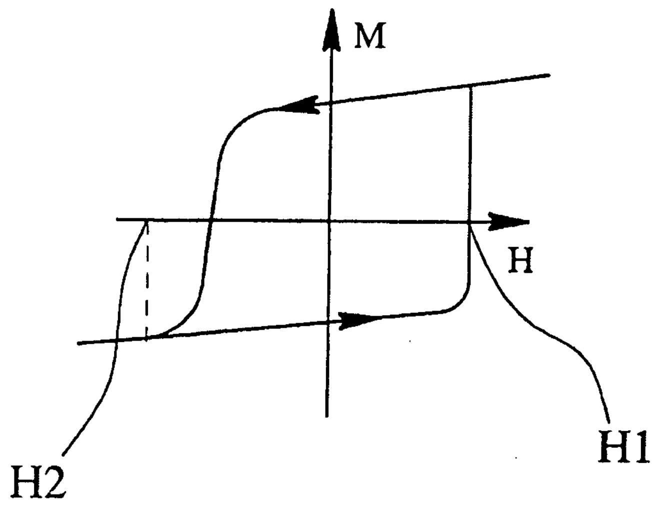


Fig. 6

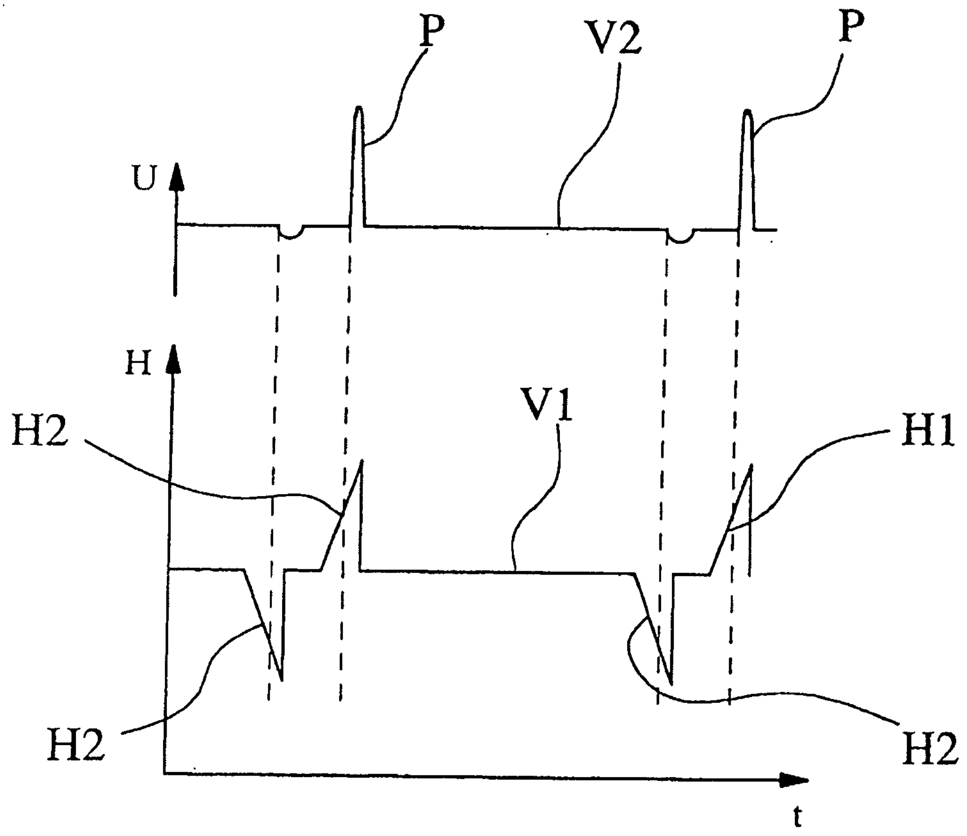


Fig. 7

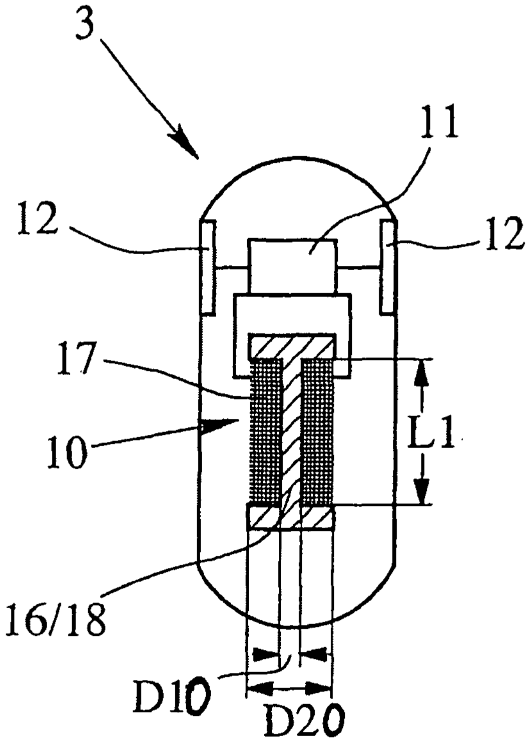


Fig. 8

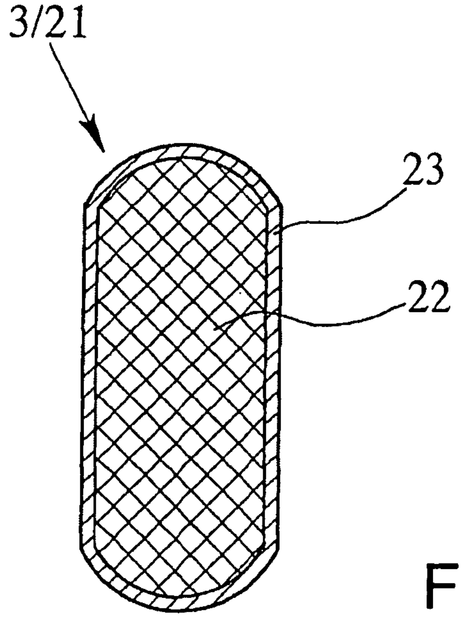
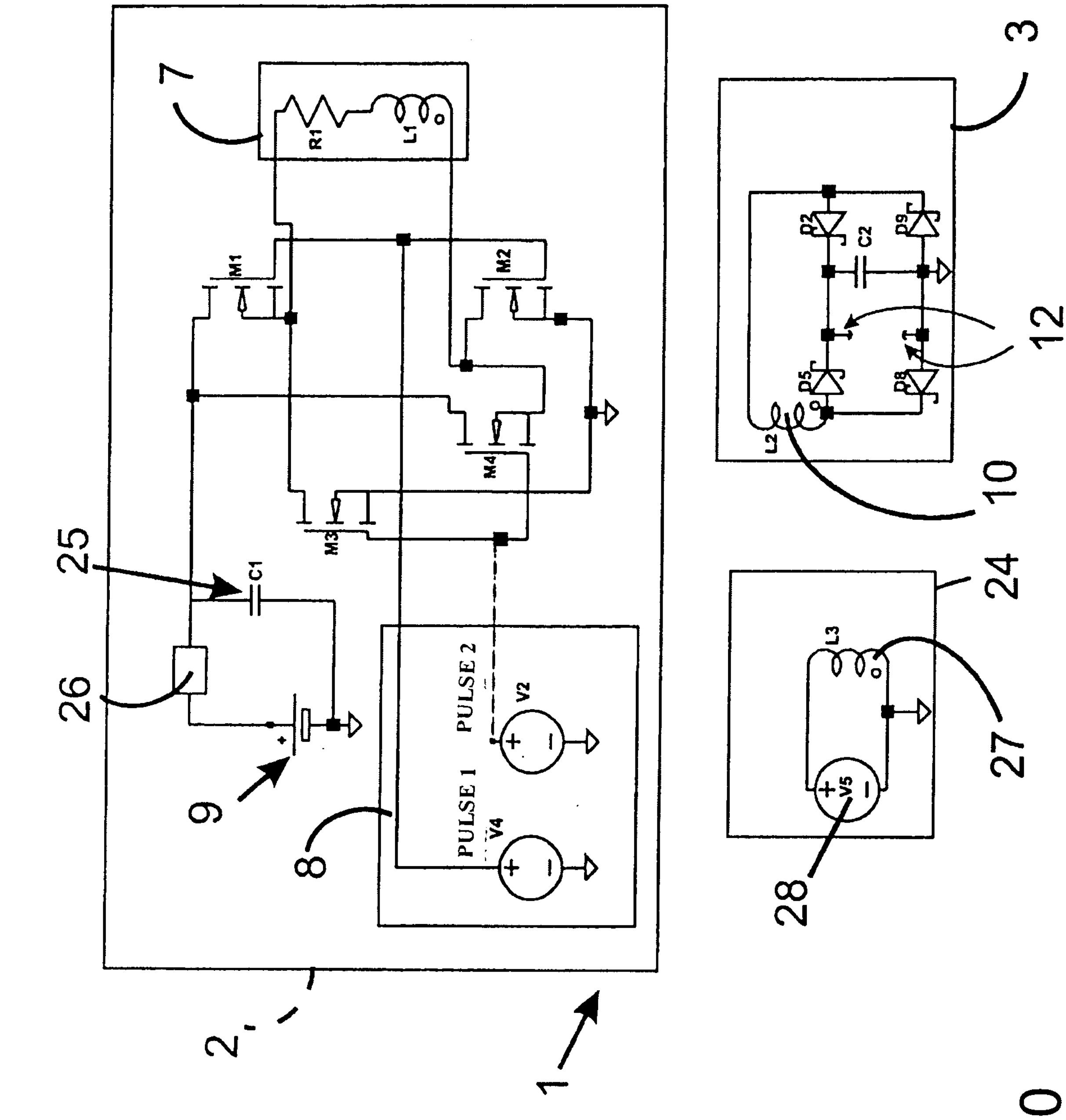


Fig. 9


R1
L1
M1
M2
M3
M4
C1
PULSE 1
PULSE 2
V4
V2
L2
D2
D5
D8
D9
C2
L3
V5
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2
3
7
8
9
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12
24
25
26
27
28

Fig. 10

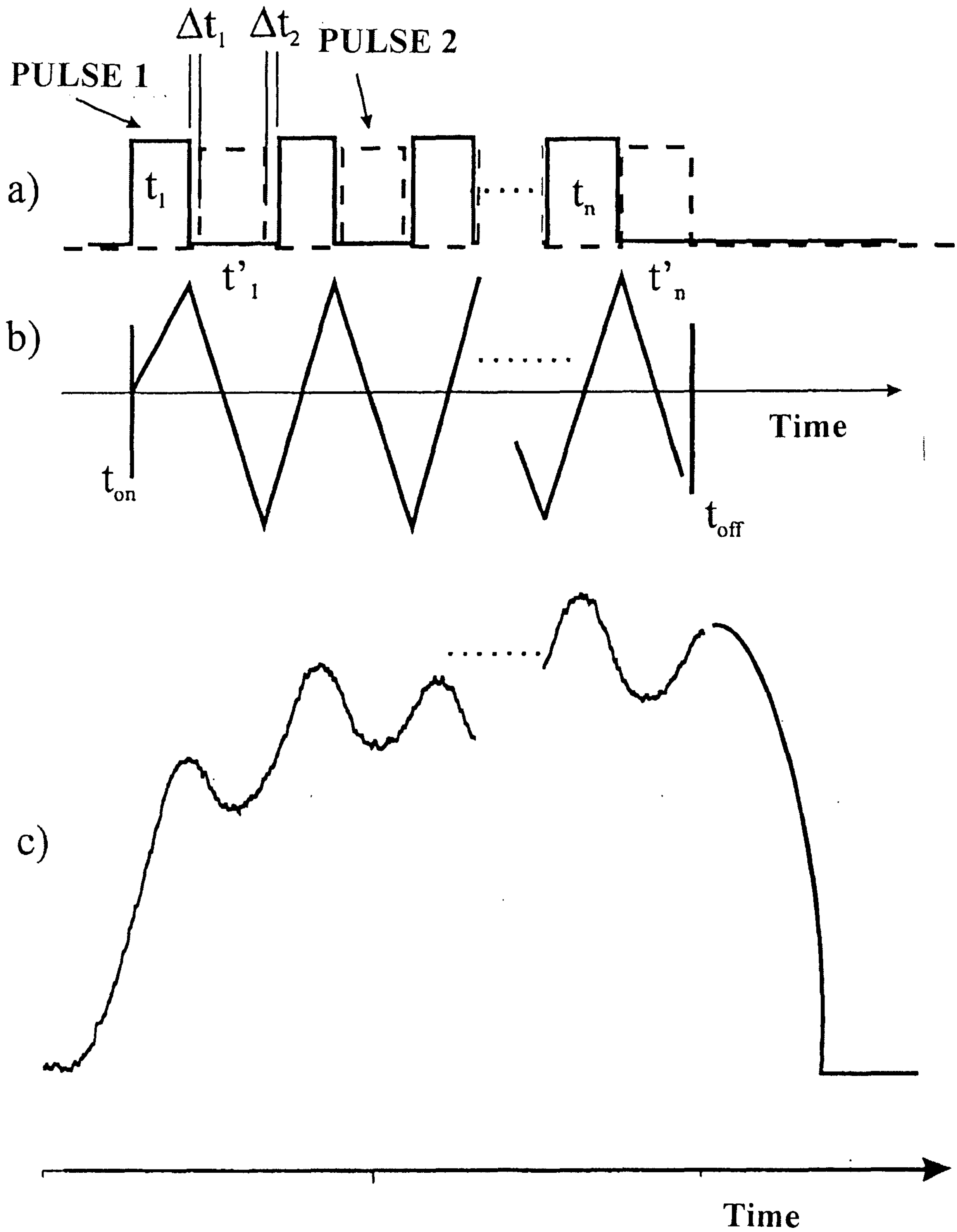

Fig. 11

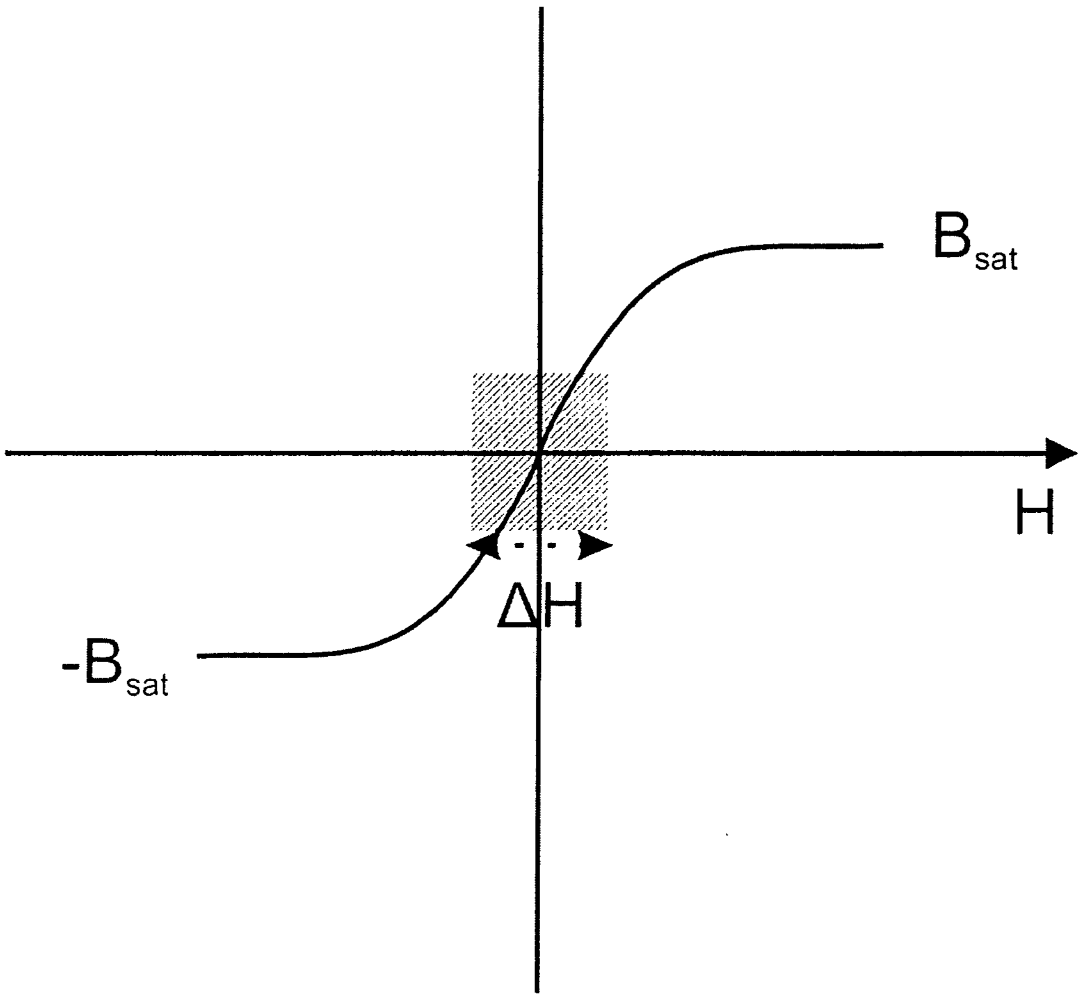

Fig. 12

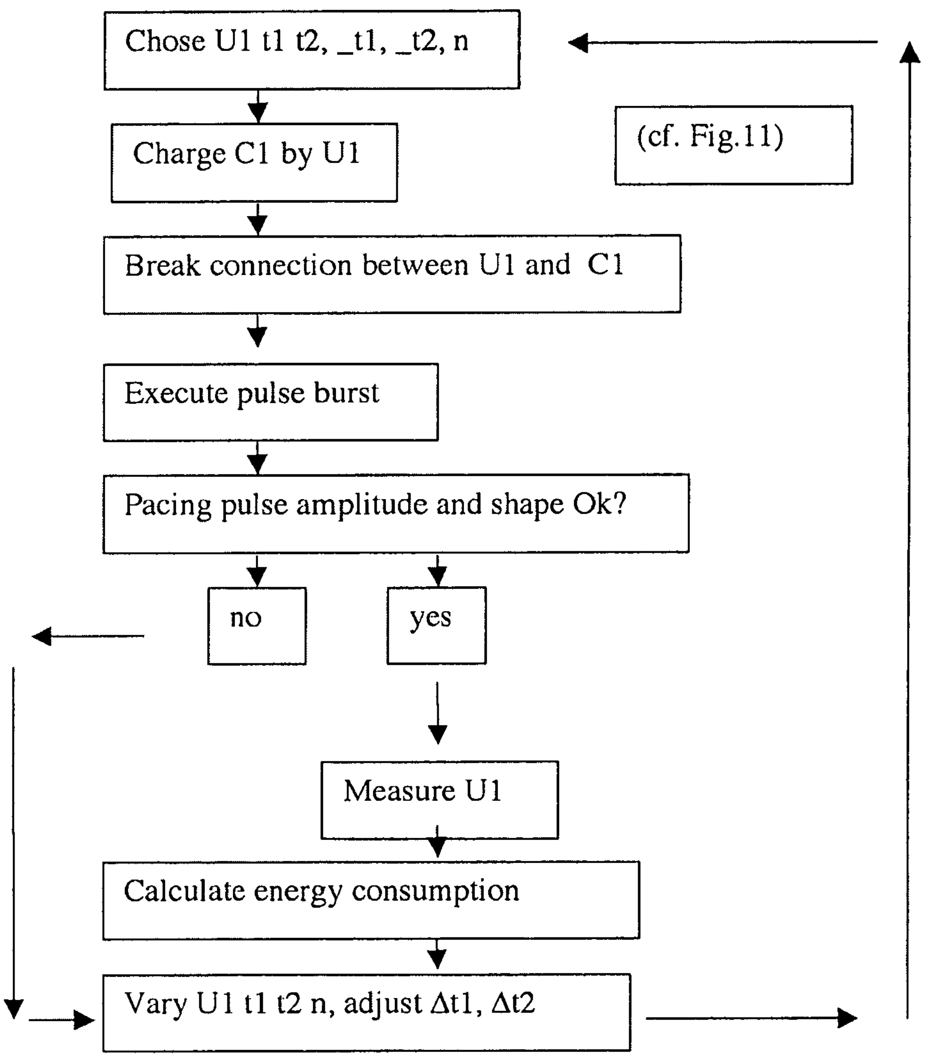
Chose U1 t1 t2, _t1, _t2, n
(cf. Fig.11)
Charge C1 by U1
Break connection between U1 and C1
Execute pulse burst
Pacing pulse amplitude and shape Ok?
no
yes
Measure U1
Calculate energy consumption
Vary U1 t1 t2 n, adjust Δt1, Δt2

Fig. 13

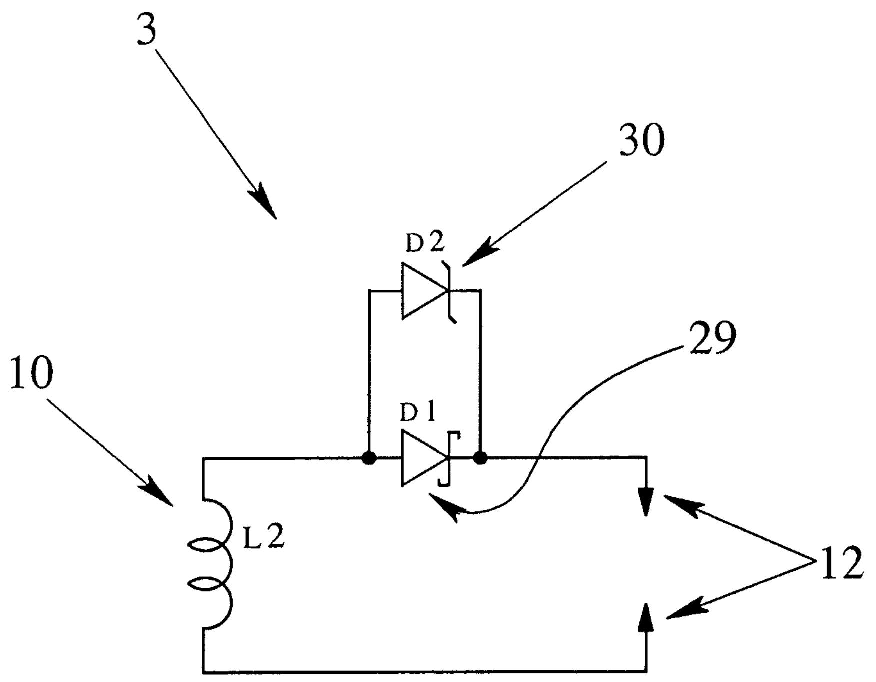

Fig. 14

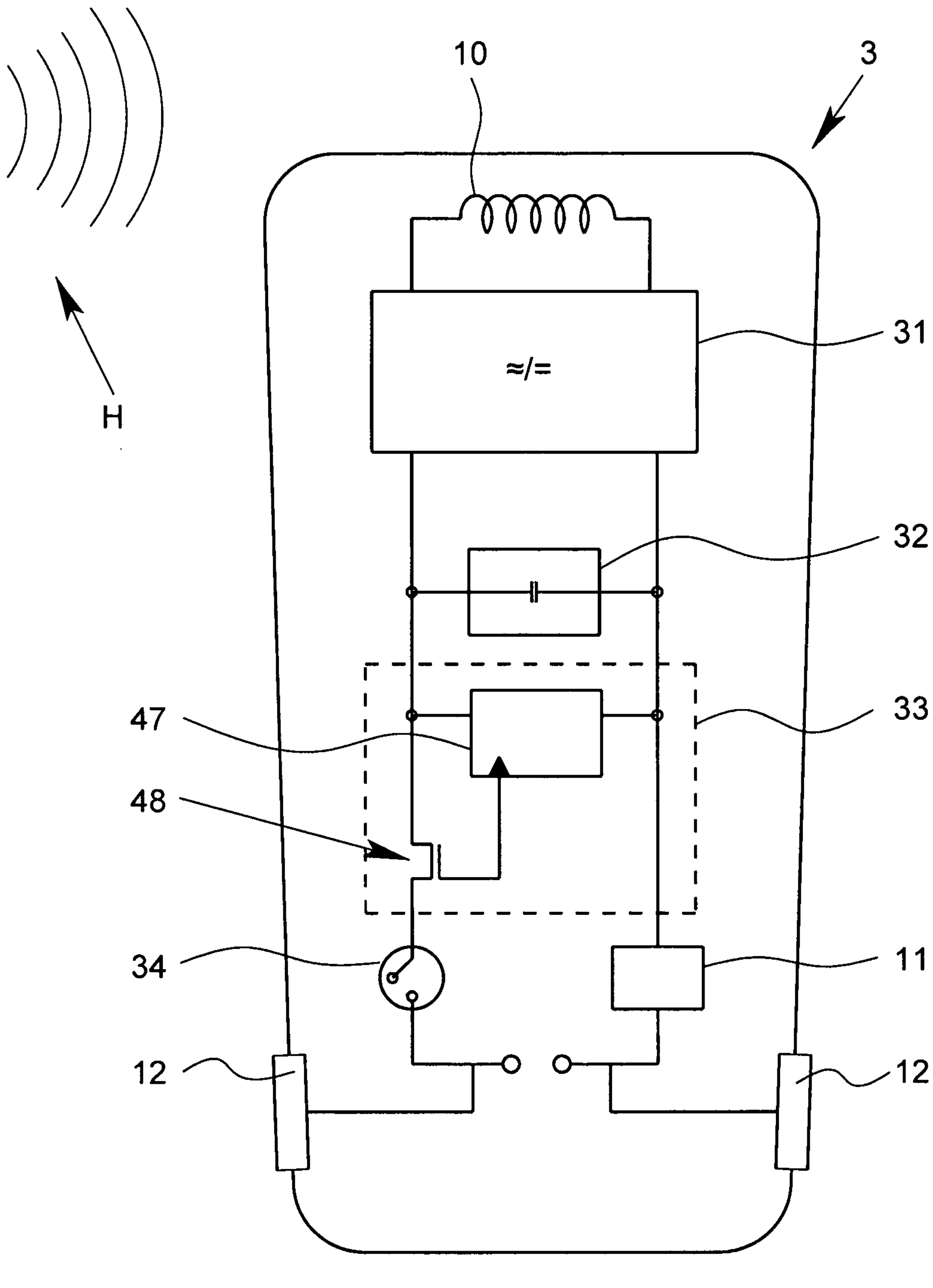

Fig. 15

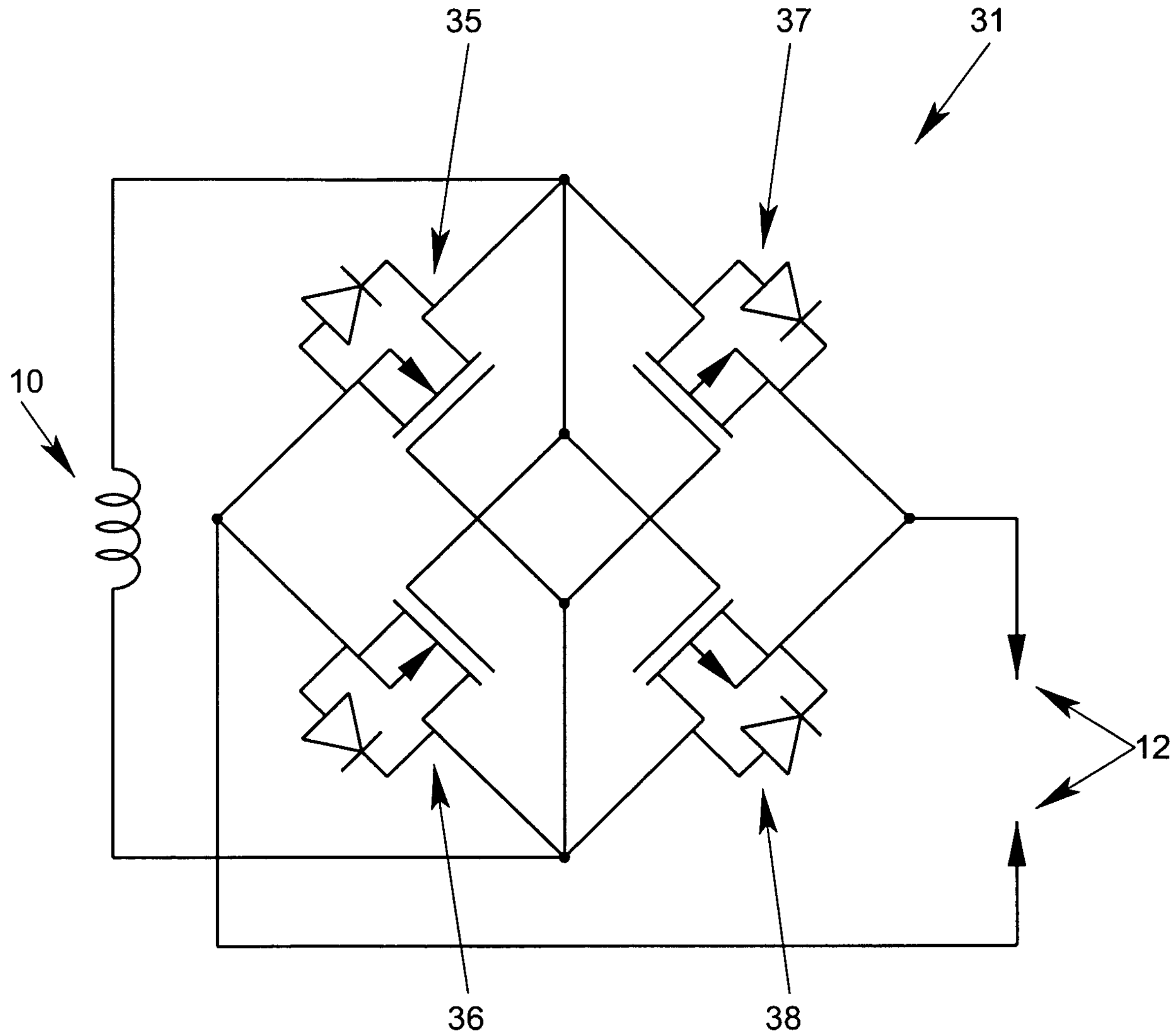

Fig. 16

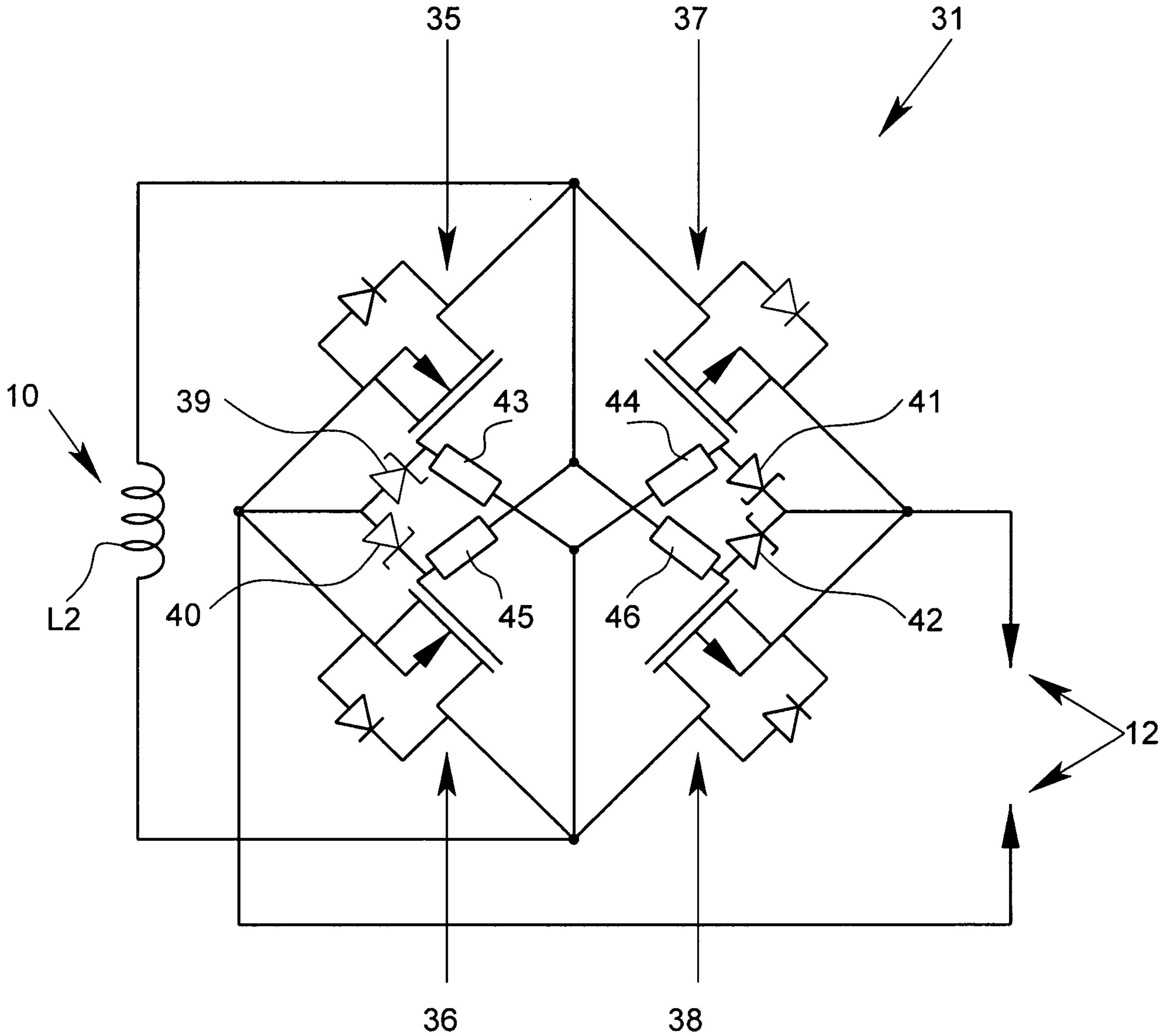

Fig. 17

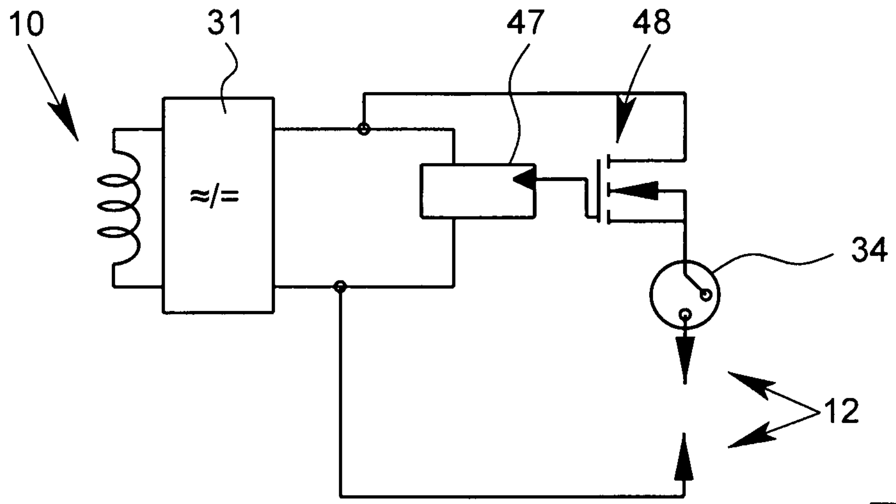

Fig. 18

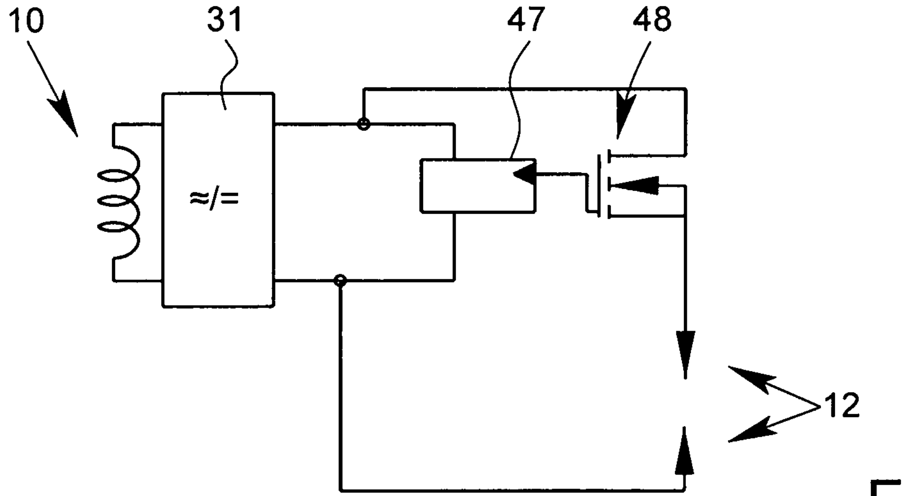

Fig. 19

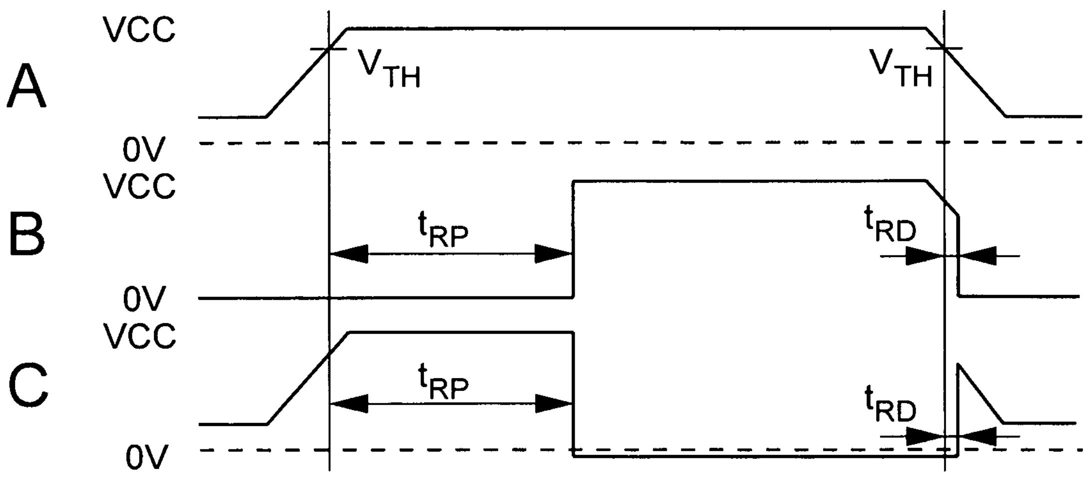

Fig. 20

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/004586

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N1/378 H02M3/335
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N H02M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2009/024180 A1 (KISKER ERHARD [DE] ET AL) 22 January 2009 (2009-01-22) the whole document	1-3,7, 12-15 6,8
X	US 5 713 939 A (NEDUNGADI ASHOK P [US] ET AL) 3 February 1998 (1998-02-03) the whole document	1,4,5, 9-11
Y	US 6 084 792 A (CHEN WEI [US] ET AL) 4 July 2000 (2000-07-04) the whole document	6
Y	US 5 769 877 A (BARRERAS SR FRANCISCO JOSE [US]) 23 June 1998 (1998-06-23) column 10, line 46 - line 61	8

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 May 2011	25/05/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Schöffmann

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/004586

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 275 739 A (FISCHELL ROBERT E) 30 June 1981 (1981-06-30) column 3, line 58 - column 4, line 47; figure 1	1-15
A	US 4 857 822 A (TABISZ WOJCIECH A [US] ET AL) 15 August 1989 (1989-08-15) column 14, line 52 - column 16, line 68	1,6,8
X	US 2006/085041 A1 (HASTINGS ROGER N [US] ET AL) 20 April 2006 (2006-04-20) paragraphs [0010], [0049], [0072], [0073], [0077]; claim 1; figures 1,5	16
A	US 2007/088398 A1 (JACOBSON PETER M [US]) 19 April 2007 (2007-04-19) paragraphs [0076] - [0097]; figures 1-6	16
A	US 2009/018599 A1 (HASTINGS ROGER N [US] ET AL) 15 January 2009 (2009-01-15) paragraph [0056]	16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2010/004586

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [ ] Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15

   implantable electrode device configured as a wireless unit and configured to receive energy by means of a varying magnetic field comprising at least one of a rectifier, means for generating a delay bewteen reception of energy and generation of electrical pulses, or a protection means for blocking the generation of electrical pulses;

   ---

2. claim: 16

   method of operating at least two implantable electrode devices supplied with energy in a wireless manner, wherein the electrical pulses are generated by the electrode devices with a particular time delay;

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2010/004586

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009024180 A1	22-01-2009	EP 1971399 A1	24-09-2008
		WO 2007087875 A1	09-08-2007
US 5713939 A	03-02-1998	CA 2266680 A1	19-03-1998
		EP 0935483 A1	18-08-1999
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