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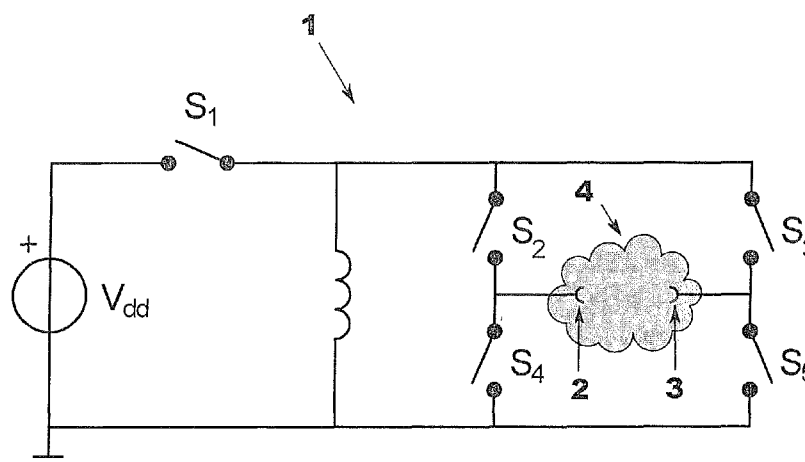
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(54) **Title:** TISSUE- OR NEUROSTIMULATOR

**FIG. 1**

(57) **Abstract:** Tissue- or neurostimulator, comprising a power supply (Vdd) and an implantable pulse generator (IPG) powered by said power supply (Vdd) to which an electrode or electrodes are connected or connectable for delivery of pulses from the pulse generator to a patient's region of interest or tissue so as to provide said region of interest or tissue with electrical stimulation, which pulse generator comprises a switching circuit providing an intermittent connection with the electrode or electrodes, wherein the pulse generator comprises at least one inductor (L) for storing of energy from the power supply (Vdd) and subsequent release to the patient's region of interest or tissue through the electrode or electrodes.

Tissue- or neurostimulator

The invention relates to a tissue- or neurostimulator, comprising a power supply, such as a battery, and an implantable pulse generator (IPG) powered by said power supply, to which pulse generator an electrode or electrodes are connected or connectable for delivery of pulses from the pulse generator to a patient's region of interest or tissue so as to provide said region of interest or tissue with electrical stimulation, and which pulse generator comprises a switching circuit providing an intermittent connection with the electrode or electrodes.

Such a tissue- or neurostimulator is disclosed in Xiao Liu ; Demosthenous, A. ; Donaldson, N., "A Miniaturized, Power-Efficient Stimulator Output Stage Based on the Bridge Rectifier Circuit", IEEE Asia Pacific Conference on Circuits and Systems, 2006. APCCAS 2006. This document discloses the use of two high frequency, current based, signals to reconstruct a traditional stimulation signal. The goal is to reduce the size of the blocking capacitors that are required for safety purposes. The switching circuit according to this document operates at a low frequency that is derived from the two high frequency signals.

According to Wikipedia in medical technology a neurostimulator, also called an implanted pulse generator (IPG) is a battery powered device designed to deliver electrical stimulation to the brain. Within the scope of the invention the stimulator can also stimulate tissue that thus indirectly entices the brain. Neurostimulators are an integral component of surgically implanted systems such as deep brain stimulation and vagus nervus stimulation or peripheral nerve stimulation, designed to treat neurological disorders. These devices are implanted within a person's body, usually beneath the clavicle.

The nervous system of the human body is an electrochemical system. Many pathologies find their origin in the nervous system (e.g. Parkinson's disease, Depression, Alzheimer Disease, Chronic Pain or Tinnitus) or can be influenced

using the nervous system (Rheumatoid arthritis, etc.). Traditionally medical technology has focused its treatment methods using drugs, thereby addressing the chemical aspect of the nervous system. This has however serious drawbacks: drugs do not work locally, but have impact on the whole body. In many cases drugs can treat a particular disease, but they will also lead to unwanted side effects. Simply said, people are getting sick of drugs.

An alternative for drug treatment is neural stimulation. This treatment method uses the electrical component of the nervous system for treatment purposes. Electrodes are implanted close to the pathological region in the nervous system and they are connected to an implantable pulse generator (IPG). In this way the pulses generated can interfere with the nervous system at the desired location and reduce pathological activity in an electrical way. The main advantage is that electrical stimulation acts locally on the nervous system. Therefore it suffers much less from side effects than traditional medical treatment by means of drugs.

US 2010/274301 discloses a tissue- or neurostimulator, comprising a power supply and an implantable pulse generator (IPG) powered by said power supply to which an electrode or electrodes are connected or connectable for delivery of pulses from the pulse generator to a patient's region of interest or tissue so as to provide said region of interest or tissue with electrical stimulation, which pulse generator comprises means for storing of energy and a switching circuit providing an intermittent connection of said means for storing of energy with the electrode or electrodes, which means for storing of energy comprises at least one inductor for storing of energy from the power supply and subsequent release of said energy to the patient's region of interest or tissue through the electrode or electrodes.

The energy required for neurostimulation usually comes from a battery integrated in the IPG and/or from energy harvested by other means (e.g. inductive coupling). Regardless of the way the energy is acquired, the components in the IPG that generate the energy (i.e. the battery or receiving coil) take up significant space and limit the implantability of the

system. Currently the size of the IPG is in general too big to be implanted close to the area of interest (e.g. inside the skull), setting the need for long electrode leads which severely decrease the reliability of the system (risk of breaking, infection and scar tissue).

It is therefore an object of the invention to improve the implantability of the IPG and to limit the required size of the energy storing element.

It is a further object of the invention to improve the power efficiency of the electrical stimulation; this efficiency should be as high as possible: from the energy used by the IPG as much as possible should be conveyed into the tissue. This is also beneficial for the purpose to limit the size of the power source.

Still a further object of the invention is to provide a solution to the problem that stimulators of the prior art usually only use part of the full range power supply voltage. When using current based stimulation, the voltage swing depends on the (highly unpredictable) tissue impedance and when using voltage stimulation the full range amplitude is almost never used. This means that 'part of the available voltage' is not used effectively thereby dramatically decreasing the power efficiency.

To address the above problems and to promote the realization of the objects of the invention, the tissue- or neurostimulator according to the invention has the features of one or more of the appended claims.

According to a first aspect of the invention during operation the switching circuit is operated at a high-frequency which, depending on the inductor's value, is selected at a level to arrange that the tissue connected to the electrodes is still at least partly charged when it gets connected to the power supply and the inductor for a period subsequent to the tissue's first connection to the power supply and the inductor. In this manner the dielectric properties of the tissue are effectively utilized by arranging that the switching frequency of the stimulator is much higher than the time constant that applies to the discharging of the tissue. In this way the tissue itself can act as an output filter to

smooth the signal from the stimulator which enables the application of relatively small components whilst effective use is made of the available energy from a regular battery.

It is remarked that within the scope of the invention a high frequency as mentioned herein should be understood as being at least 100 kHz. Suitably the operating frequency and inductor value are selected at values taken into account and making use of an average capacitor value of the tissue to be connected to the stimulator so as to arrange that said tissue essentially will function as smoothing filter for the pulses received from the pulse generator. The inductance value of the inductor of the stimulator depends on the selected switching frequency of the stimulator as well as the range of expected output currents when the stimulator is connected to the tissue. The switching frequency should be selected high enough to arrange that the capacitive properties of the tissue can be effectively utilized for stimulation of this tissue without the need to apply external components as an additional smoothing filter for the output signal of the stimulator. Within the terms of the invention sufficient filtering is achieved when the tissue voltage does not drop back to zero voltage between two subsequent intermittent connections of the tissue with the stimulator. For illustrative purposes examples of practical values are the following: For output currents in the range of 100 μ A through small electrodes with an impedance of around 100k Ω , an inductor of around 70 μ H can be chosen for a switching frequency of 10MHz. If the switching frequency is lowered to a frequency of 1MHz, the inductor needs to be chosen bigger, in the order of 700 μ H. For output currents in the range of 10mA through bigger sized electrodes with an impedance of around 1k Ω , an inductor of around 700nH can be chosen for a switching frequency of 10MHz.

It is beneficial that the switching circuit is arranged for repeatedly interrupting and restoring the inductor's connection with the power source and during said interrupting of the connection with the power source, establish a connection of the inductor with the electrode or electrodes so as to provide it with power pulses so as to retrieve the energy from the inductor and provide this energy via the elec-

trodes to the tissue being treated. Using an inductor interrupting the current through the inductor results in an upswung voltage over the inductor obviating the need to apply a power converter for transferring energy from the power supply to the stimulated tissue.

By alternately connecting and disconnecting the inductor to the power supply and to the tissue at a high frequency, which can be done either directly or via an electrical component or electronic circuit, the energy from the power supply can be transferred with a very high efficiency. Thus the fully available power range can be used to stimulate the tissue, and all of the available energy of the power supply is used to generate an appropriate electrical field for stimulation.

By adjusting the duty cycle of the repeatedly connected and disconnected power supply to the inductor and the repeatedly connected and disconnected inductor with the tissue, the average energy delivery to the tissue can be controlled (i.e. the amplitude of the stimulation). In this way no voltage headroom is wasted and a theoretical efficiency of 100% can be reached.

When the tissue or neurostimulator of the invention is arranged with plural channels for simultaneous stimulation of different tissue areas, it is preferable that the at least one inductor is shared or multiplexed by plural channels for simultaneous stimulation of said different tissue areas. In this way the use of relatively bulky components do not stand in the way to the miniaturization of the stimulator.

Preferably the high-frequency switching circuit is arranged to provide a first (voltage or current) pulse train and a second pulse train at a selectable repeat rate, wherein each first pulse train has a selectable first duration and is followed by a second pulse train of opposite polarity that has a selectable second duration. The application of the opposite polarity is important to avoid that on average over a longer period of time the stimulated tissue is subjected to electrochemical responses due to a remaining voltage over the tissue. For this purpose it may also be beneficial that said first pulse train and second pulse train are followed by a phase for

decharging the stimulated tissue. The selectable repeat rate is applied in order to be able to control the amount of stimulus that is applied to the tissue.

Preferably the first and/or second pulse train or
5 trains have a selectable frequency, preferably at least hundred kilohertz, more preferably in the megahertz range, and even more preferably about 10 MHz. The frequency is selected in order to match the requirements of the application based on for instance electrode impedance, energy loss etc.

10 The consequence of this way of stimulation is that the stimulation current will be switched on and off at this high rate as well. However the electric field which is eventually responsible for the (de)-activation of the tissue is averaged out because of the low-pass filter nature of tissue.

15 This means that by providing the frequency of the stimulation signal at a much higher level than the time constant of the tissue, a similar electric field can be generated as is done with traditional stimulation.

The invention will hereinafter be further elucidated
20 with reference to the drawing.

In the drawing:

-figure 1 shows schematically the tissue- or neurostimulator in a first embodiment of the invention connected to tissue;

25 -figure 2 shows schematically the tissue- or neurostimulator in a second embodiment of the invention connected to tissue;

-figure 3 shows an example of exciting said tissue with a constant duty cycle; and

30 -figure 4 shows in detail the excitation during a first pulse train A as shown in figure 3.

With reference first to figure 1 showing a first embodiment, and figure 2 showing a second embodiment, the tissue- or neurostimulator of the invention is generally denoted
35 with reference 1. The neurostimulator 1 of the invention comprises a power supply V_{dd} and an implantable pulse generator (IPG) S1, S2, S3, S4, S5, L powered by said power supply V_{dd} to which an electrode or electrodes 2, 3 are connected or connectable for delivery of pulses from the pulse generator to a

patient's region of interest or tissue 4 so as to provide said tissue 4 with electrical stimulation.

The pulse generator comprises a high frequency switching circuit S1, S2, S3, S4, S5 providing an intermittent connection between the power supply V_{dd} and the inductor L on the one hand, alternated by an intermittent connection between the inductor L and the electrode or electrodes 2, 3 on the other hand. The inductor L is this way used for storing of energy from the power supply V_{dd} and subsequent release of energy to the patient's region of interest 4 through the electrode or electrodes 2, 3. To have this arrangement work satisfactorily the switching circuit S1, S2, S3, S4, S5 is arranged for repeatedly interrupting and restoring the reactive component's connection with the power source V_{dd} and during said interrupting of the connection with the power source V_{dd} , to establish an intermittent connection of the inductor L with the electrode or electrodes 2, 3 so as to provide the desired power pulses to the connected tissue 4. In practice the inductance value of the inductor L of the stimulator depends on the selected switching frequency of the stimulator as well as the range of expected output currents when the stimulator is connected to the patient's region of interest 4. On the other hand the switching frequency should be selected high enough to arrange that the capacitive properties of the tissue are effectively utilized for stimulation of this tissue without the need to apply external components as an additional smoothing filter for the output signal of the stimulator. Within the terms of the invention sufficient filtering is achieved when the tissue voltage does not drop back to zero voltage between two subsequent intermittent connections of the tissue with the stimulator. Practical values are then: for output currents in the range of 100 μ A through (small) electrodes with an impedance of around 100k Ω , an inductor of around 70 μ H can be chosen for a switching frequency of 10MHz. If the switching frequency is lowered to a frequency of 1MHz, the inductor needs to have a value in the order of 700 μ H. For output currents in the range of 10mA through bigger sized electrodes with an impedance of around 1k Ω , an inductor of around 700nH can be used with a switching frequency of 10MHz.

The switches of the circuit of figure 1 operate for instance according to the following steps A-E.

A. S1 is closed, all other switches are open; the inductor L charges up to a particular current.

5 B. S2 & S5 are closed, all other switches are open; the inductor L discharges its energy through the tissue 4. It is remarked that switches S2 and S5 need to open when the current crosses 'zero' to prevent oscillations.

10 Step A and B are repeated with a predetermined and desired switching frequency for as long as the pulse of the desired polarity needs to be. After completion of the pulse, the following steps C and D are executed.

C. S1 is closed, all other switches are open; the inductor L charges up to a particular current.

15 D. S3 & S4 are closed, all other switches are open; the inductor L discharges its energy in opposite direction through the tissue 4 in comparison with step B.

20 Steps C and D are repeated with a predetermined and desired switching frequency for as long as the second pulse having its polarity opposite to the pulse according to the steps A and B needs to be.

E. Following the steps A, B, C and D, the tissue is shorted, for example by closing S4 and S5.

25 In a similar fashion as in the embodiment according to figure 1, the switches of the circuit of figure 2 operate for instance according to the following steps A-E.

A. S2 and S5 are closed, all other switches are open; the inductor L charges up to a particular current.

30 B. S5 & S1 are closed or S2 & S1 are closed, all other switches are open; the inductor L discharges its energy through the tissue 4. It is again a remark that switch S1 needs to open when the current crosses 'zero' to prevent oscillations.

35 Step A and B are repeated with a predetermined and desired switching frequency for as long as the pulse of the desired polarity needs to be. After completion of the pulse, the following steps C and D are executed.

C. S3 & S4 are closed, all other switches are open; the inductor L charges up to a particular current in opposite

direction.

D. S3 & S1 are closed or S4 & S1 are closed, all other switches are open; the inductor L is discharging its energy in opposite direction through the tissue.

5 Steps C and D are repeated with a predetermined and desired switching frequency for as long as the second pulse having its polarity opposite to the pulse according to the steps A and B needs to be.

10 E. After completion of the steps A, B, C and D, the tissue 4 is shorted, for example by just closing S1. Furthermore one of the switches S2-S5 need to be closed as well to keep the tissue at a well-defined voltage.

15 In both the embodiments of figures 1 and 2 the ratio A/B and C/D determine the duty cycle, and therefore the stimulation amplitude. This can vary during the pulse and also between the first pulse I and second pulse II as shown in figure 3 discussed hereafter. Figure 3 shows as an example an image of a signal with a constant duty cycle of approximately 50% to which the tissue 4 is subjected. The figure shows that the
20 high-frequency switching circuit S1, S2, S3, S4, S5 is arranged to provide a first pulse train I and a second pulse train B. Each first voltage pulse train I has a selectable first duration (this duration can be for instance 100 μ s) which is followed by a second voltage pulse train II of opposite polarity that has a selectable second duration (also approximately 100 μ s). The duration of the pulses can in practice vary between 0,05 msec and 0,5 msec. Both the first pulse
25 train I and the second pulse train II are for instance operated with the same frequency of 1 MHz.

30 Figure 4 shows the effect of the repeated interrupting and restoring of the reactive component's connection with the power source V_{dd} whilst during said interrupting of the connection with the power source V_{dd} , the connection of the reactive component L with the electrode or electrodes 2, 3 is
35 established or maintained so as to provide the tissue high energy and high-frequency (approximately 1 MHz) pulses.

Figure 3 and 4 both show the power trains resulting from the application of a tissue or neurostimulator which is arranged with plural channels (Channel 1 and Channel 2) for

simultaneous stimulation of different tissue areas, in which situation it is preferable that the at least one inductor L is shared or multiplexed by said plural channels 1 and 2.

5 As a caveat the inventors remark that the above description of possible embodiments of the invention are not limiting to the appended claims. The protective scope of such claims must therefore be understood in the broadest possible sense without being considered limited to the offered example, which merely serves to elucidate these claims.

CLAIMS

1. Tissue- or neurostimulator (1), comprising a power supply (V_{dd}) and an implantable pulse generator (IPG) (S1, S2, S3, S4, S5, L) powered by said power supply (V_{dd}) to which an electrode or electrodes (2, 3) are connected or connectable for delivery of pulses from the pulse generator (S1, S2, S3, S4, S5, L) to a patient's region of interest or tissue (4) so as to provide said region of interest or tissue (4) with electrical stimulation, which pulse generator (S1, S2, S3, S4, S5, L) comprises means for storing of energy (L) and a switching circuit (S1, S2, S3, S4, S5) providing an intermittent connection of said means for storing of energy (L) with the electrode or electrodes (2, 3), which means for storing of energy (L) comprises at least one inductor (L) for storing of energy from the power supply (V_{dd}) and subsequent release of said energy to the patient's region of interest or tissue (4) through the electrode or electrodes (2, 3), **characterized in that** during operation the switching circuit (S1, S2, S3, S4, S5) is operated at a high-frequency which, depending on the inductor's value, is selected at a level to arrange that the tissue connected to the electrodes (2, 3) is still at least partly charged when it gets connected to the power supply (V_{dd}) and the inductor (L) for a period subsequent to the tissue's first connection to the power supply (V_{dd}) and the inductor (L).

2. Tissue or neurostimulator (1) according to claim 1, **characterized in that** it's operating frequency and inductor value are selected at values taken into account and making use of an average capacitor value of the tissue to be connected to the stimulator so as to arrange that said tissue essentially functions as smoothing filter for the pulses received from the pulse generator (S1, S2, S3, S4, S5, L).

3. Tissue or neurostimulator (1) according to claim 1 or 2, **characterized in that** the switching circuit (S1, S2, S3, S4, S5) is arranged for repeatedly interrupting and restoring the inductor's connection with the power source (V_{dd}) and during said interrupting of the connection with the power source (V_{dd}), establish a connection of the inductor (L) with the

electrode or electrodes (2, 3) so as to provide it with power pulses.

4. Tissue- or neurostimulator in accordance with any one of the previous claims, **characterized in that** the high-frequency switching circuit (S1, S2, S3, S4, S5) is arranged to provide a first pulse train (I) and a second pulse train (II) at a selectable repeat rate, wherein each first pulse train (I) has a selectable first duration and is followed by a second pulse train (II) of opposite polarity that has a selectable second duration.

5. Tissue- or neurostimulator in accordance with claim 4, **characterized in that** said first pulse train (I) and second pulse train (II) are followed by a phase for discharging the stimulated region of interest or tissue (4).

6. Tissue- or neurostimulator in accordance with any one of the previous claims 4-5, **characterized in that** the first and/or second pulse train or trains (I, II) have a selectable frequency, preferably at least hundred kilohertz, more preferably in the megahertz range, and even more preferably about 10 MHz.

7. Tissue or neurostimulator in accordance with any one of the previous claims, **characterized in that** the at least one inductor (L) is shared or multiplexed by plural channels for simultaneous stimulation of different tissue areas.

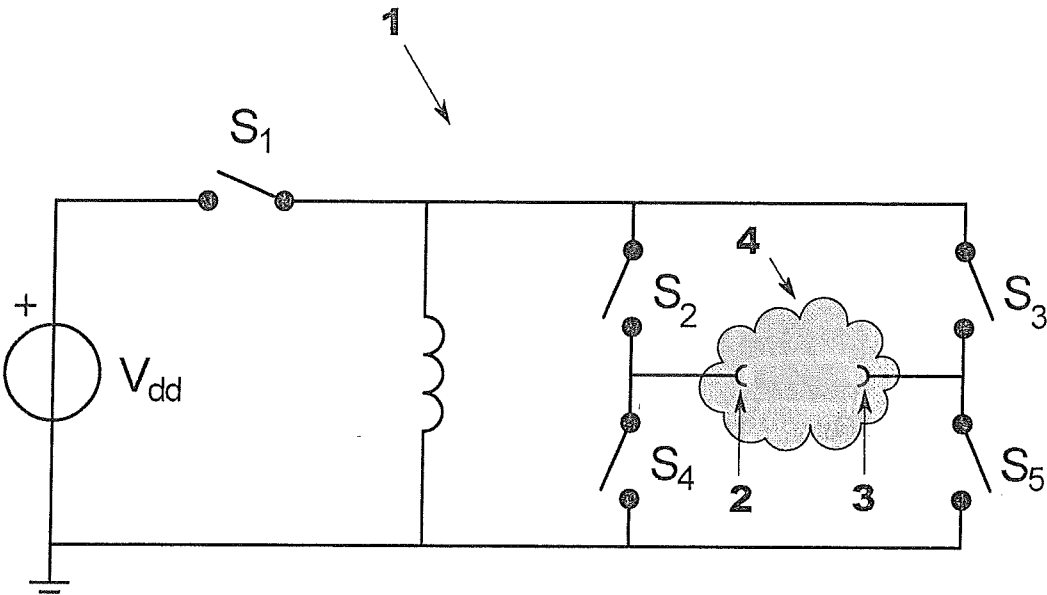


FIG. 1

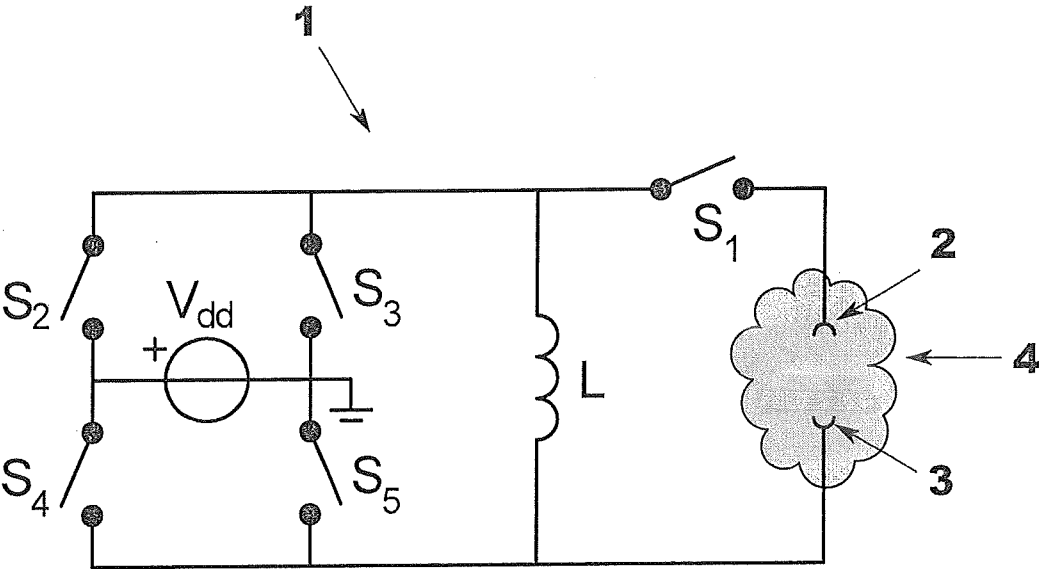


FIG. 2

3/4

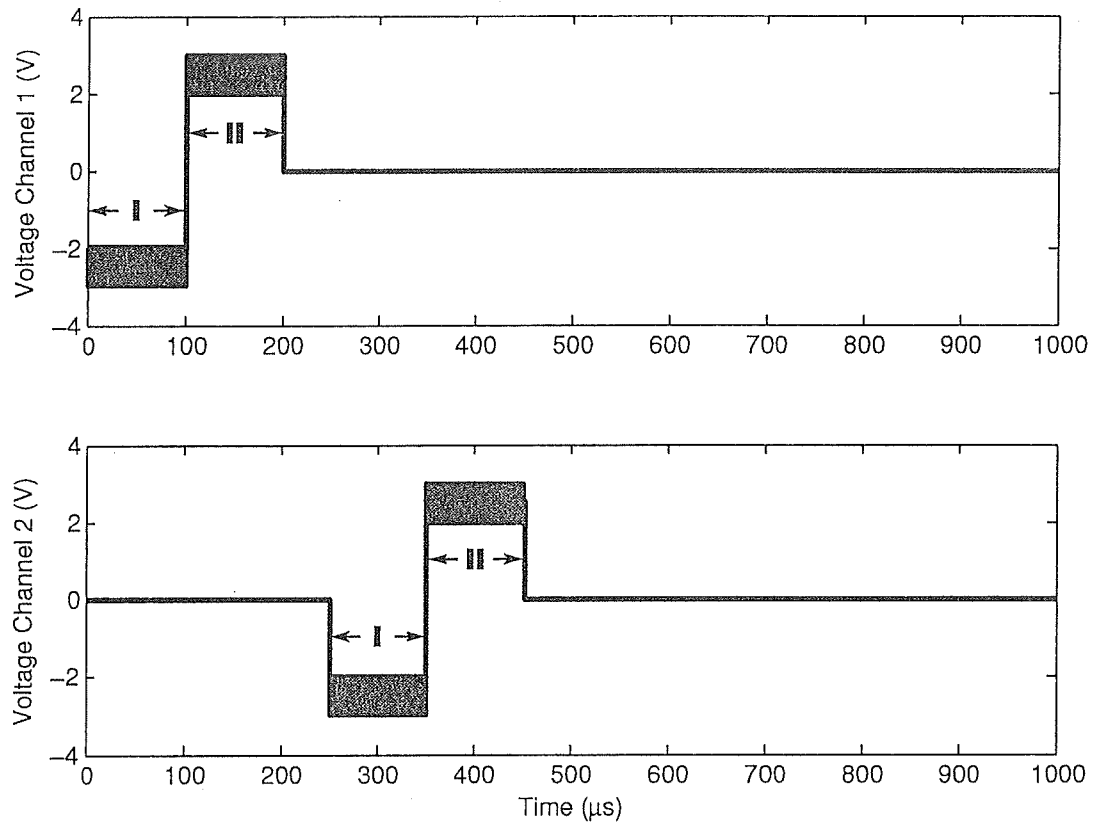


FIG. 3

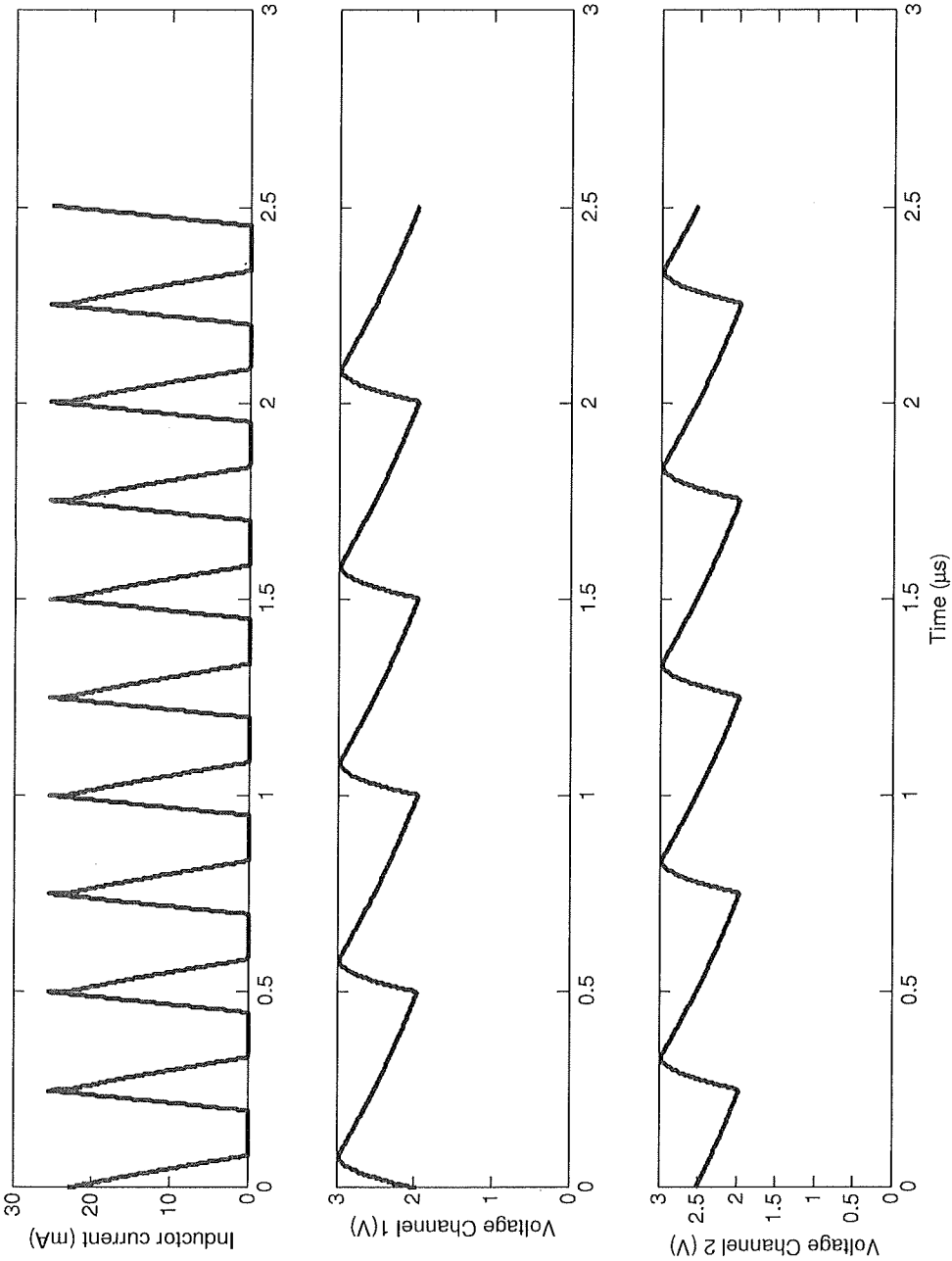


FIG. 4