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DESCRIPTION

[0001] Deleted

Technical Field

[0002] The present invention relates to measurement of neural activity, and in particular relates to measurement of a compound action potential or the like by using one or more electrodes implanted proximal to neural tissue.

Background of the Invention

[0003] There are a range of circumstances in which it is desirable to obtain an electrical measurement of a compound action potential (CAP) evoked on a neural pathway by an electrical stimulus applied to the neural pathway. However, this can be a difficult task as an observed CAP signal will typically have a maximum amplitude in the range of microvolts, whereas a stimulus applied to evoke the CAP is typically several volts. Electrode artefact usually results from the stimulus, and manifests as a decaying output of several millivolts throughout the time that the CAP occurs, presenting a significant obstacle to isolating the CAP of interest. As the neural response can be contemporaneous with the stimulus and/or the stimulus artefact, CAP measurements present a difficult challenge of amplifier design. In practice, many non-ideal aspects of a circuit lead to artefact, and as these mostly have a decaying exponential characteristic which can be of either positive or negative polarity, identification and elimination of sources of artefact can be laborious.

[0004] A number of approaches have been proposed for recording a CAP, including those of King (US Patent No. 5,913,882), Nygard (US Patent No. 5,758,651) and Daly (US Patent Application No. 2007/0225767).

[0005] Evoked responses are less difficult to detect when they appear later in time than the artifact, or when the signal-to-noise ratio is sufficiently high. The artifact is often restricted to a time of 1 - 2 ms after the stimulus and so, provided the neural response is detected after this time window, data can be obtained. This is the case in surgical monitoring where there are large distances between the stimulating and recording electrodes so that the propagation time from the stimulus site to the recording electrodes exceeds 2 ms. However, to characterize the responses from the dorsal columns for example, high stimulation currents and close proximity between electrodes are required, and therefore the measurement process must overcome contemporaneous artifact directly. Similar considerations can arise in deep brain stimulation where it can be desirable to stimulate a neural structure and immediately measure the response of that structure before the neural response propagates elsewhere.

[0006] Implanted electrical stimulus devices must also provide for charge recovery in order to ensure that transient currents delivered by stimuli do not lead to a net DC injection of charge into the tissue. One approach is to provide capacitors in series on each electrode, to prevent DC transfer to tissue, and such capacitors are often a requirement of regulatory bodies in order for an active implantable device to obtain market approval. Another arrangement as shown in Figure 1 omits electrode capacitors, and instead provides switches to short circuit the stimulus and sense electrodes e1 - e4 to each other to effect charge recovery between stimuli, and also provides a star network of resistors each of a value in the range of perhaps hundreds of k Ω , permanently connecting all electrodes together in order to equilibrate charge before the device is powered on, as shown in Figure 1. However, the provision of electrode capacitors or a star network of resistors between the electrodes and the measurement amplifier can give rise to considerable effects of artefact which can interfere with attempts to measure small CAP signals.

[0007] Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

[0008] Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

[0009] In this specification, a statement that an element may be "at least one of" a list of options is to be understood that the element may be any one of the listed options, or may be any combination of two or more of the listed options.

Summary of the Invention

[0010] The invention is defined in claim 1. Further aspects and preferred embodiments are defined in the appended claims. Aspects, embodiments and examples of the present disclosure which do not fall under the scope of the appended claims do not form part of the invention and are merely provided for illustrative purposes. Furthermore, the methods presented in the present description are provided for illustrative purposes only and do not form part of the present invention.

[0011] The present invention provides an implantable device for measuring a neural response to a stimulus, the device comprising:

a plurality of electrodes including one or more nominal stimulus electrodes and one or more nominal sense electrodes;

a stimulus source for providing a stimulus to be delivered from the one or more stimulus electrodes to neural tissue in order to evoke a neural response;

a measurement amplifier for amplifying a neural response signal sensed at the one or more sense electrodes, and

a control unit configured to control application of a stimulus to the neural tissue and measurement of an evoked neural response, the control unit configured to apply an electrical stimulus from the stimulus electrodes to neural tissue, the control unit further configured to impose a delay during which the stimulus electrodes are open circuited, and the control unit further configured to, during the delay, measure a neural response signal present at the sense electrodes with the measurement amplifier, characterized in that an impedance between the sense electrodes is sufficiently large that a voltage arising on the sense electrode tissue interface in response to the stimulus is constrained to a level which permits assessment of the neural response voltage seen at the sense electrode.

[0012] It is to be noted that different embodiments may involve stimuli of varying intensity or duration, electrodes of varying geometry and size, and/or a varying spatial separation between the stimulus electrodes and the sense electrode(s). The present invention recognises that knowledge of each such parameter in an evoked response measurement system enables a determination to be made as to an expected voltage which will arise on the sense electrode(s) as a result of the electrical characteristics of the stimulus delivered. In particular, modelling the interface between the sense electrode(s) and the tissue as including a constant phase element impedance, representing the electrode-electrolyte interface capacitance and tissue capacitance, and determining the impedance of the constant phase element for the physical parameters of the implant concerned, enables an appropriate lower limit to be placed on the impedance between the sense electrodes.

[0013] The impedance between the sense electrodes is preferably chosen to be sufficiently large that the voltage arising on the sense electrode tissue interface in response to the stimulus is constrained to a level which is no more than 15 times larger than the neural response voltage seen at the sense electrode, more preferably is no more than 5 times larger than the neural response voltage seen at the sense electrode, more preferably is no more than 2 times larger than the neural response voltage seen at the sense electrode, even more preferably is no more than the same as the neural response voltage seen at the sense electrode, and most preferably is no more than half of the neural response voltage seen at the sense electrode.

[0014] Some embodiments may utilise a differential measurement of the neural response by using two sense electrodes. In such embodiments the voltage arising on the sense electrode tissue interface in response to the stimulus is to be understood to be the differential voltage arising between the two sense electrodes in response to the stimulus. The two sense

electrodes for example may be mounted upon a single implanted electrode array. Alternative embodiments may undertake a single ended measurement utilising a single sense electrode and a distal reference electrode, and in such embodiments the voltage arising on the sense electrode tissue interface in response to the stimulus is to be understood to be the differential voltage arising between the sense electrode and the reference electrode in response to the stimulus.

[0015] Some embodiments of the present invention further comprise a sense electrode capacitor provided in series between the sense electrode and the measurement amplifier, the sense electrode capacitor being chosen to have a capacitance which ensures that the voltage arising across the capacitor in response to the stimulus is constrained to a level which permits assessment of the neural response voltage seen at the sense electrode. Such embodiments may thus enable improved prevention of DC charge injection to the tissue, while nevertheless retaining neural response measurement capability. In such embodiments, the stimulus electrodes may have corresponding capacitors in order to prevent DC charge injection, and also to permit electrical reconfiguration of each electrode as either a stimulus electrode or sense electrode, as required.

[0016] In some embodiments, the input impedance to the measurement amplifier (Z_{IN}) is defined as:

$$Z_{IN} > Z_C \frac{(V_{S1} - V_{S2})}{V_E}$$

where

Z_C is the constant phase element impedance of the or each sense electrode,

$V_{S1} - V_{S2}$ is the differential voltage arising on the sense electrode tissue interface in response to the stimulus, and

V_E is the neural response voltage seen at the sense electrode.

[0017] In such embodiments Z_{IN} may comprise resistance and/or capacitance provided the above requirement is met. To give sufficient margin of V_E over $(V_{S1} - V_{S2})$, in some embodiments Z_{IN} may be limited by:

$$Z_{IN} > A \times Z_C (V_{S1} - V_{S2}) / V_E$$

A is a scalar provided to give sufficient margin of V_E over $(V_{S1} - V_{S2})$, and may for example be in the range of 2 - 5. Alternatively, in embodiments utilising artefact compensation by way of exponential subtraction, A may be in the range of 0.5 or greater while still permitting assessment of the neural response and such embodiments are thus within the scope of the present invention. Moreover, some embodiments may correlate the measurement against a filter template to extract the neural response from the measurement, in accordance with the teachings of WO2015/074121 by the present applicant, and in such embodiments A may be in the range of 0.067 or greater while still permitting assessment of the neural response and such

embodiments are thus within the scope of the present invention.

[0018] The neural response measurement may in some embodiments be conducted in the manner taught by International Patent Publication No. WO2012155183.

[0019] Methods relating to the invention may further comprise obtaining neural measurements repeatedly over time and monitoring for changes. In response to detected changes some embodiments may provide feedback control of a therapy delivered to the patient, such as an electrical stimulus therapy and/or medication. Medication may be controlled automatically by an implanted drug pump or by producing a report for a physician to alter a prescription, for example.

[0020] In some embodiments, charge on the stimulus electrodes may be recovered by connecting the stimulus electrodes to each other by either a short circuit or via an impedance, before application of the stimulus and/or after measurement of the neural response.

[0021] In some embodiments, the measurement amplifier is kept connected to the sense electrodes throughout the stimulus and measurement. In such embodiments, the measurement amplifier is preferably a wide bandwidth amplifier with sufficient common mode range to avoid saturation by the stimulus. Alternatively, the amplifier may be used in an auto-zero state in which it can zero sufficiently quickly after the stimulus to track the neural response.

Brief Description of the Drawings

[0022] An example of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 illustrates a prior art approach to neural response measurement;

Figure 2 illustrates a neural response measurement system in accordance with one embodiment of the present invention;

Figure 3 illustrates an embodiment of the invention utilising electrode capacitors;

Figure 4 is another illustration of the embodiment of Figure 3, showing the stimulus electrode shorting arrangement;

Figure 5 is a simplified model of the driving circuitry of an implantable device and the surrounding tissue;

Figure 6 is an illustrative equivalent circuit of the constant phase element at each electrode-tissue interface;

Figure 7 is a plot produced by a simulation of the model of Figure 5, showing the artifact

arising after a stimulus in the presence of various values of amplifier input impedance, both capacitive and resistive;

Figure 8 shows experimental data points, and simulation curves, of artefact arising from a stimulus when the amplifier input resistance and capacitance are varied;

Figure 9 shows the RMS artifact contribution from resistance and capacitance respectively;

Figure 10 shows artefact variation with resistance and capacitance; and

Figure 11 shows RMS artefact variation with resistance and capacitance.

Description of the Preferred Embodiments

[0023] Figure 2 illustrates a neural response measurement system in accordance with one embodiment of the present invention. Two sense electrodes each having a constant phase element (CPE) impedance of Z_C are used to detect a neural response signal V_e arising in neural tissue of an implant recipient. A stimulus applied by stimulus electrodes of the implant (shown in Figure 4) gives rise to the neural response, but also causes stimulus voltages V_{s1} and V_{s2} to be present on the sense electrodes. An input impedance of Z_{in} is present at each input of the differential measurement amplifier.

[0024] The input impedance required in this embodiment of the invention is determined by noting that noise input is comparable to stimulation voltage, and that the goal is for the stimulus to induce a voltage ($V_{s1} - V_{s2}$) on the CPE of the sense electrodes which is less than the evoked response V_E . Consequently the desired input impedance is given by:

$$Z_{IN} > Z_C \frac{(V_{s1} - V_{s2})}{V_E}$$

[0025] In one embodiment, being a spinal cord stimulator (SCS) having electrodes with an area of 14 mm², $Z_C = 20\Omega$, ($V_{s1} - V_{s2}$) ~ 1V, $V_e = 50 \mu V$, so that the above equation dictates that the minimum value of Z_{in} is 400 k Ω . To give a sufficient margin of V_e over artefact, a more desirable value of Z_{in} is larger, perhaps in the range 1-2 M Ω . In alternative embodiments such as a cochlear implant with electrode area of about 0.1 mm², being a fraction of the area of an SCS electrode, the minimum required amplifier input impedance is many times higher; 8 M Ω or for sufficient margin more preferably 20 M Ω , illustrating the difficulties of the resistance values chosen in Figure 1.

[0026] Figure 3 shows an embodiment of the present invention utilising an ASIC amplifier having a very high value of Z_{in} . Electrode capacitors are provided to block DC insertion to the

tissue, the electrode capacitors having a value of $C_{in} = 5\text{pF}$. Since the ASIC amplifier of Figure 3 automatically settles to zero during off periods there is no need for resistance to be added at the amplifier input.

[0027] Figure 4 is another illustration of the embodiment of figure 2. Electrode capacitors are provided on all electrodes to block DC. The electrode capacitors can store their own charge which in turn can produce uncontrolled current on switch-on. Accordingly, the control module closes the switches to equilibrate the stimulus electrodes prior to each stimulus. The switches are closed only in short bursts so that the equilibration current does not rise to a level which is perceivable by the implant recipient. Similar embodiments may be provided having additional resistance and/or capacitance on the inputs of the measurement amplifier, so long as the input impedance obeys the equation above.

[0028] The importance of including the constant phase element model of the electrode-to-tissue interface in figure 2 for example arises from a simplified model of the driving circuitry and saline as shown in Figure 5. The circuit consists of the spreading resistance, being a mesh of resistors that model the current through the bulk saline; the constant phase elements (CPE) where the saline meets the electrode metal; an excitation source having an output impedance including some stray capacitance; loading on each electrode and a ground connection. The saline bath has a bulk voltage point sBath. The saline bath is used to mimic tissue. In Figure 5 a single-ended measurement can be made between electrodes e1 and e2, and a differential measurement can be made between e2 and e3.

[0029] An equivalent circuit of a CPE is shown in figure 6. It consists of a set of series RC networks connected in parallel. To adequately model a saline bath, the CPE might have 20-30 RC pairs, but the simplified version of Figure 6 is shown for understanding. The RC pairs have time constants that change exponentially, in this case by a factor of $\sqrt{10}$, however the notable fact is that the time constants of each RC pair are different from all other RC pairs in the CPE. Following a stimulus, the output voltage of a CPE will change over time as charge redistributes between the capacitors, even though no net current is flowing in or out. This property is shared by a single parallel RC network, although a CPE has no R value that can be found at DC.

[0030] Unlike an RC network that shows a response characteristic of the circuit, the response of a CPE is dominated by the RC networks that have a similar time constant to that of the length of the stimulation. For example a SCS may have a stimulus pulse width in the range of 100 - 500 μs . This result is important for defining the apparent conductance of a capacitor as discussed below.

[0031] Following a stimulus, there are three mechanisms or sources of artifact that can be identified in the circuit of Figure 5. For each of these mechanisms, the load and current source impedances are considered infinite unless otherwise noted:

- The voltage on the CPE on electrode 1 changes. This can be seen in a single ended

measurement $e_2 - e_1$, or on the stimulating electrode e_1 . This is not seen in the differential measurement as this voltage is common mode between e_2 and e_3 .

- If the current source output impedance is finite, the change in the electrode 1 CPE voltage causes a current to flow through the spreading resistance. This appears differentially on electrodes e_2 and e_3 . This only occurs due to the mesh nature of the spreading resistance; if modelled by a star resistor or a single string of resistors this will not be observed.
- If the input impedance of either sense amplifier is finite, then during stimulus current will flow into this load. This will then settle.

[0032] The ability of the model of figure 5 to predict the voltage on e_4 was experimentally tested. All stimulation used 4mA 400us biphasic pulses. These were used to give rise to an artifact large enough to resolve above noise, and with a voltage on the electrodes that could be digitized without anomaly. This stimulation level delivers 1.6 uC per stimulus, which is in the upper end of the range of charge required for comfort level stimulation in a SCS. Measurements were averaged over 99 iterations. As artefact can take many different profiles of either polarity, a single artefact measure was defined as being the integral of the $V.t$ product of the signal, after resetting the DC value to a baseline.

[0033] In addition to experimental verification a simulation of Figure 5 was conducted. Figure 7 shows a simulation output showing the artifact over a selected range after the stimulus, in which the y-axis indicates RMS voltage $\times$ time, and the x-axis indicates admittance, with admittance of capacitances being calculated as $Y = C.t$, where t is the stimulus pulse width. Input impedance on the amplifier was selected to be either 330 pF, 1000 pF, 3300 pF, 330 kQ, and 100 kQ, giving rise to respective artefact waveforms 702, 704, 706, 708, 710. It is notable that capacitance and resistance give rise to artefact of opposite polarity. Although these are simple waveforms, in practice there can be several sources of artifact with different time-constants so that the actual artefact seen can be more complex than the simple monotonic decreasing curves shown.

[0034] Figure 8 shows both experimental data points and simulation curves, where the load resistance and capacitance are varied. The conductance of the capacitors, being their value divided by the length of each phase of the biphasic pulse, is a measure that has the same slope of artefact as for a resistor, and is thus preferred to using the entire length of the stimulus in Figures 8 to 11. The simulated line and the experimentally obtained data point groups having a positive slope in Figure 8 show the effect of adding resistance, while the simulated line and the experimentally obtained data point groups having a negative slope show the effect of adding capacitance to the amplifier input impedance. The slopes of the capacitive and resistive lines are very similar for all electrodes, and closely match that of the simulation, indicating that the model of Figure 5 is largely correct. The electrodes have different y-intercepts. Electrode 1 (the 'r1.txt' data points) has a peak artifact of 700 uV when a resistive load is reduced, which is a very large artefact and would certainly obscure a neural response

signal of around 10 uV. In the absence of loading, artifact can be positive or negative. The y-intercept offsets are outside the control of the electronics, and must be handled by techniques such as filtering.

[0035] While the plot of Figure 8 validates the simulation model, it also shows that there is a missing element that causes artifact in the absence of loading and causes the y-intercept offsets. The y-intercept offsets vary from one electrode to the next, and is perhaps the result of metallic contamination on each electrode surface creating a small galvanic cell and asymmetric behaviour for the phases of the biphasic pulse.

[0036] Figure 9 shows the RMS contribution to simulated artefact from resistance and capacitance respectively.

[0037] Figure 10 shows artefact variation when both resistance and capacitance are progressively changed.

[0038] Figure 11 shows artefact variation with resistance and capacitance using the above described RMS method.

[0039] In figs 10 and 11, the curve dips then rises, consistent with Figure 8. As expected, due to the DC offset, the RMS method obscures the fundamental accuracy of the model.

[0040] From the simulation model, using the above described baseline definition of artifact and a 400us pulse width, the sensitivity of artefact to resistance is 4.1×10^{-2} V.s per mho, and the sensitivity of artefact to capacitance is -2.85×10^{-2} Vs per mho. Thus for a load of R, and where the artifact is over a 1ms interval, then the voltage is

$$V(r,t) = 4.1 \times 10^{-2} / (R \times t)$$

[0041] So for example, for an amplifier input resistance of 100 KΩ, and a 1ms artefact interval:
 $V(100k, 1ms) = 400 \text{ uV}$

[0042] Further, for a capacitive load, and where the artifact is over a 1ms interval, then the voltage is:

$$V(C,t) = -7.14 \times 10^1 \times C / t$$

[0043] So for example for a 1000 pF load, artifact over 1ms, artifact = 71.4 uV.

[0044] Using this artefact calculation method, the following table shows the artifact contributions of various stray impedances which might be present in a typical SCS.

Stray Impedance	Value	Artifact Contribution for 1ms in μV
Cable	350p	25
input impedance	50k	820
Star load	270k	152
Output impedance of current source	135k	304
Reference inputs to amplifier	83.3K	492

[0045] As can be seen in the above table, appropriate adjustment and control of such impedances present in the neural measurement system can allow considerable sources of artefact to be reduced and ease the task measuring a neural signal of the order of 10 μV .

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- [US5913882A \[0004\]](#)
- [US5758651A \[0004\]](#)
- [US20070225767A \[0004\]](#)
- [WO2015074121A \[0017\]](#)
- [WO2012155183A \[0018\]](#)

Patentkrav

1. En implantérbar anordning til måling af neuralrespons på en stimulus, hvor
5 anordningen omfatter:

en pluralitet af elektroder, der omfatter én eller flere nominelle
stimuluselektroder og to eller flere nominelle registreringselektroder;
en stimuluskilde til tilvejebringelse af en stimulus, der skal overføres fra den ene
10 eller flere stimuluselektroder til neuralvæv for at frembringe en neural respons;
en målingsforstærker til forstærkelse af et neuralresponssignal, der registreres
på registreringselektroderne, og
en kontrolenhed, der er konfigureret til at kontrollere påføringen af en stimulus
på neuralvævet og måling af en frembragt neural respons, kontrolenheden er
15 konfigureret til at påføre en elektrisk stimulus fra stimuluselektroderne til
neuralvævet, kontrolenheden desuden er konfigureret til at pålægge en
forsinkelse, hvorunder stimuluselektroderne har åbent kredsløb, og
kontrolenheden desuden er konfigureret til, under forsinkelsen, at måle et
neuralresponssignal, der forekommer på registreringselektroderne, med
20 målingsforstærkeren, hvori en impedans mellem registreringselektroderne er
tilstrækkelig stor til, at en spænding, der opstår på registreringselektrodens
vævsgrænseflade som reaktion på stimulussen, er begrænset til et niveau, der
muliggør evaluering af den neuralresponsspænding, der ses på
registreringselektroderne, hvori kontrolenheden desuden er konfigureret til at
25 indhente en differentialmåling af neuralresponsen ved at bruge to
registreringselektroder, og hvori den spænding, der opstår på
registreringselektrodens vævsgrænseflade som svar på stimulussen er den
differentialspænding, der opstår mellem de to registreringselektroder som svar
på stimulussen,
30 og hvori Z_{IN} er begrænset af:

$$Z_{IN} > A \times Z_C (V_{s1} - V_{s2}) / V_E$$

hvor A er en skalar, der er angivet for at give tilstrækkelig margen på V_E over $(V_{s1} - V_{s2})$

- 5 Z_C er konstantfaseelementets impedans for hver registreringselektrode, $V_{s1} - V_{s2}$ er den differentialspænding, der opstår på registreringselektrodens vævsgrænseflade som svar på stimulussen, og V_E er spændingen af den neuralrespons, der blev set på registreringselektroden.

10

2. Anordningen i krav 1, hvori den impedans, der er angivet i målingsforstærkeren (Z_{IN}), har en værdi:

$$Z_{IN} > Z_C \frac{(V_{s1} - V_{s2})}{V_E}$$

15

3. Anordningen i krav 1, hvori A er større end 0,067.

4. Anordningen i krav 3, hvori kontrolenheden er konfigureret til at korrelere målingen med en filterskabelon for at uddrage neuralresponsen fra målingen.

20

5. Anordningen i krav 3, hvori A er større end 0,5.

6. Anordningen i krav 5, hvori kontrolenheden er konfigureret til at anvende artefaktkompensation via eksponentiel subtraktion.

25

7. Anordningen i krav 5, hvori A er større end 1.

8. Anordningen i krav 7, hvori A er større end 2.

- 9.** Anordningen i ethvert af kravene 1 til 8 omfatter desuden en registreringselektrodekondensator i serie mellem den ene eller hver registreringselektrode og målingsforstærkeren, den ene eller hver registreringselektrodekondensator har en kapacitans, der sikrer, at den spænding, der opstår via kondensatoren som svar på stimulussen, er begrænset til et niveau, der muliggør evaluering af den neuralrespons-spænding, der ses på registreringselektroden.
- 10.** Anordningen i ethvert af kravene 1 til 9 omfatter desuden en stimulouselektrodekondensator i serie mellem den ene eller hver stimulouselektrode og målingsforstærkeren, den ene eller hver stimulouselektrodekondensator har en kapacitans, der sikrer, at den spænding, der opstår via kondensatoren som svar på stimulussen, er begrænset til et niveau, der muliggør evaluering af den neuralrespons-spænding, der ses på registreringselektroden.
- 11.** Anordningen i krav 9 eller krav 10, hvori anordningen kan omkonfigureres til at muliggøre elektrisk omkonfiguration af hver elektrode som enten en stimulouselektrode eller registreringselektrode.
- 12.** Anordningen af ethvert af krav 1 til 11, hvori elektroderne er monteret på en enkelt implanteret elektrodematrice.

DRAWINGS

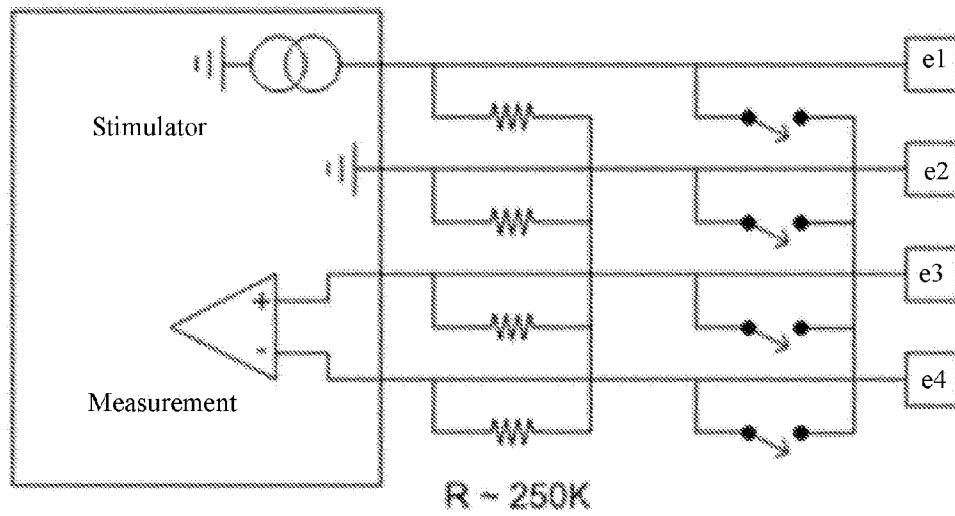


Figure 1 – Prior Art

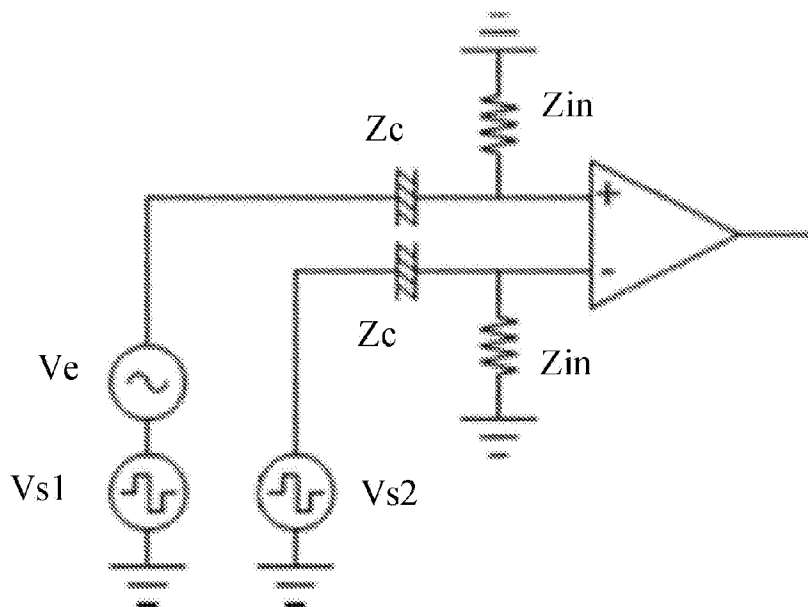


Figure 2

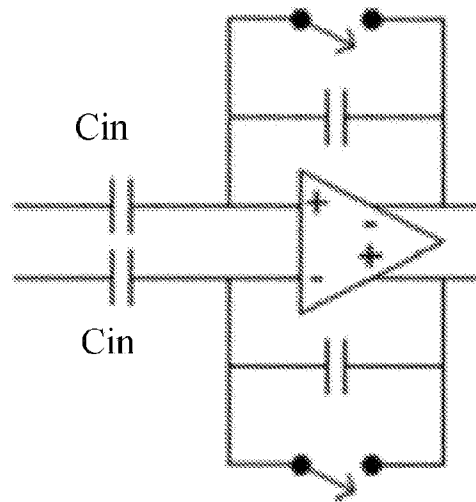


Figure 3

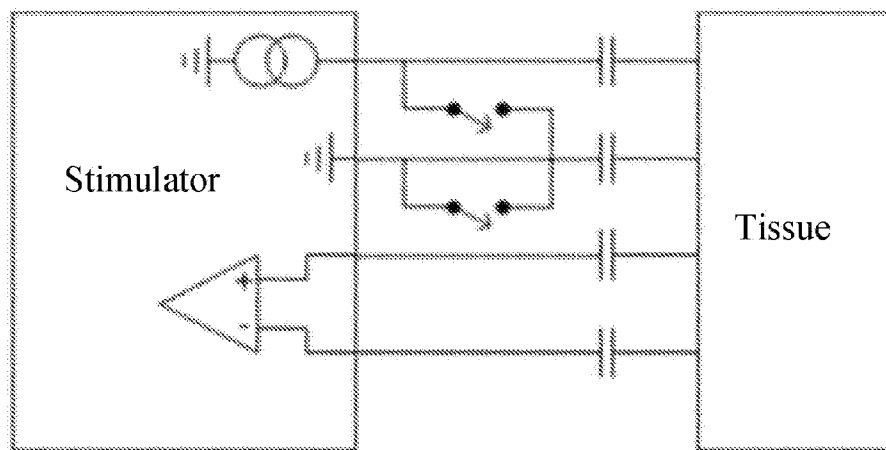
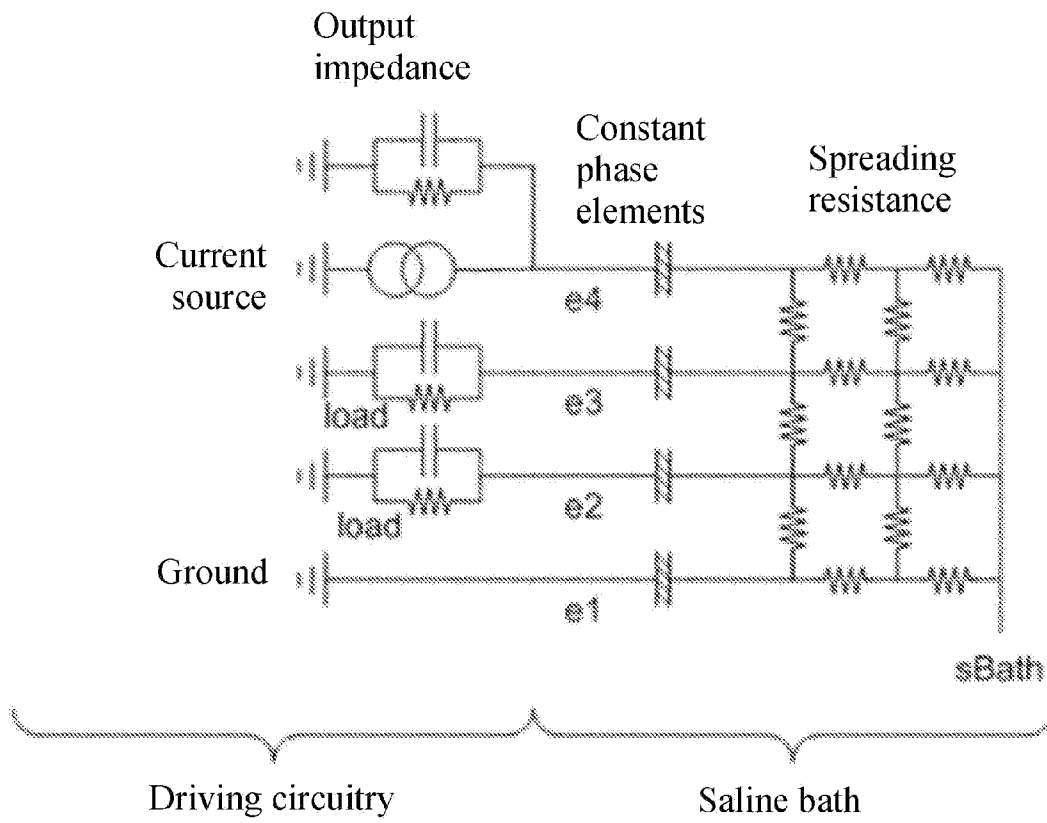
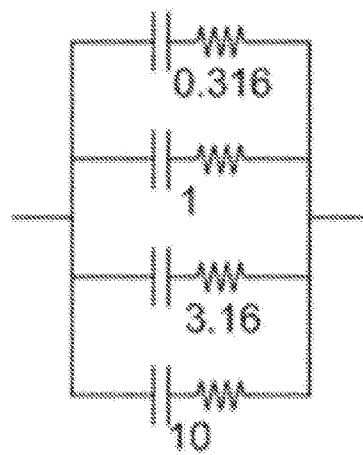


Figure 4

**Figure 5****Figure 6**

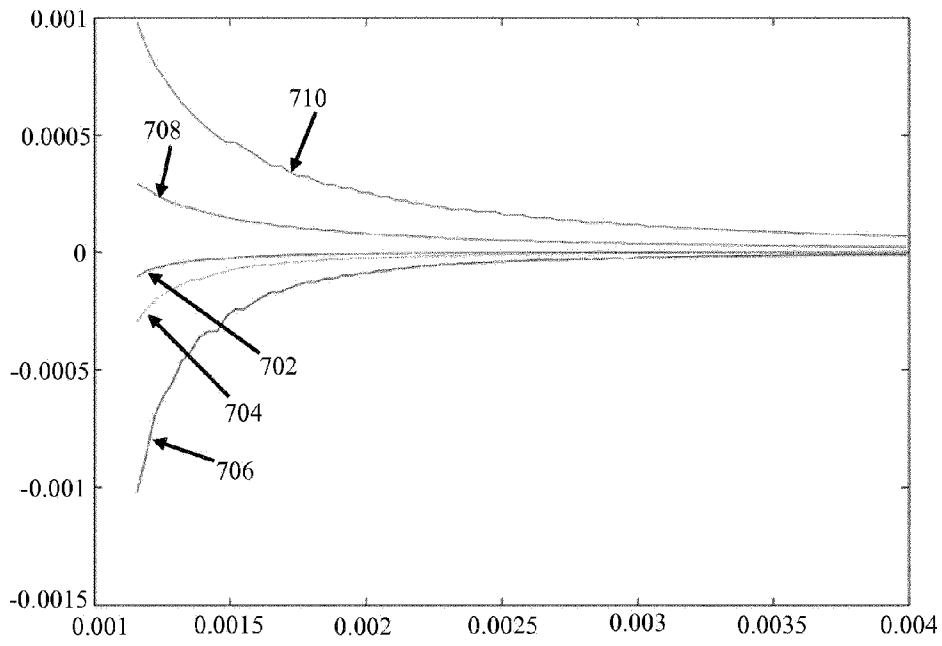


Figure 7

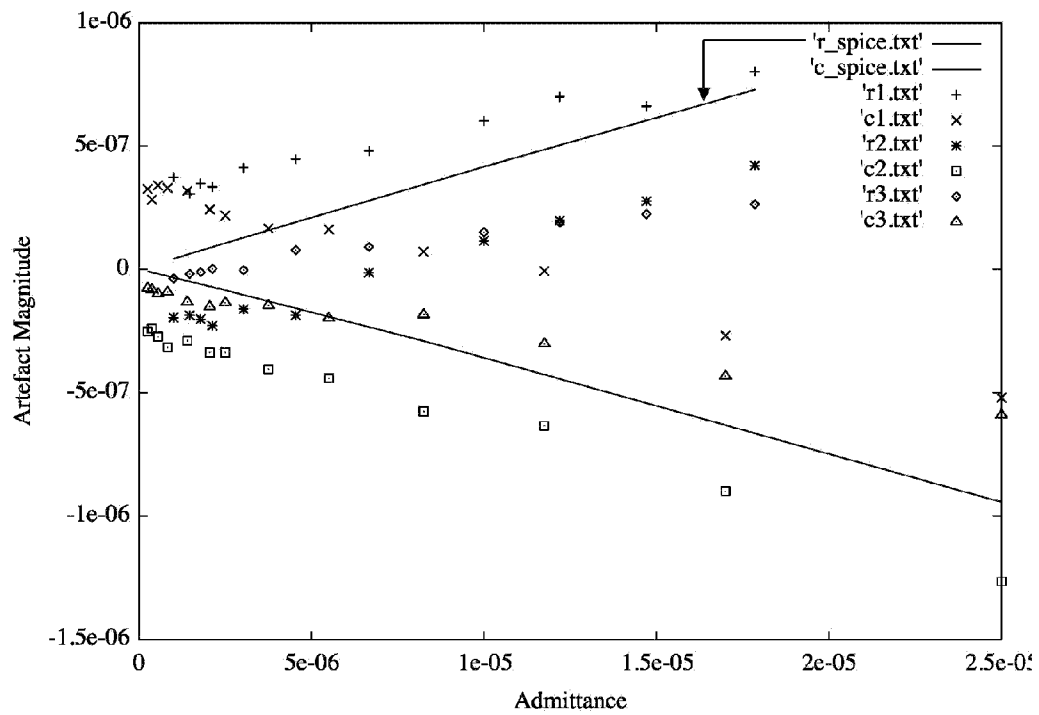
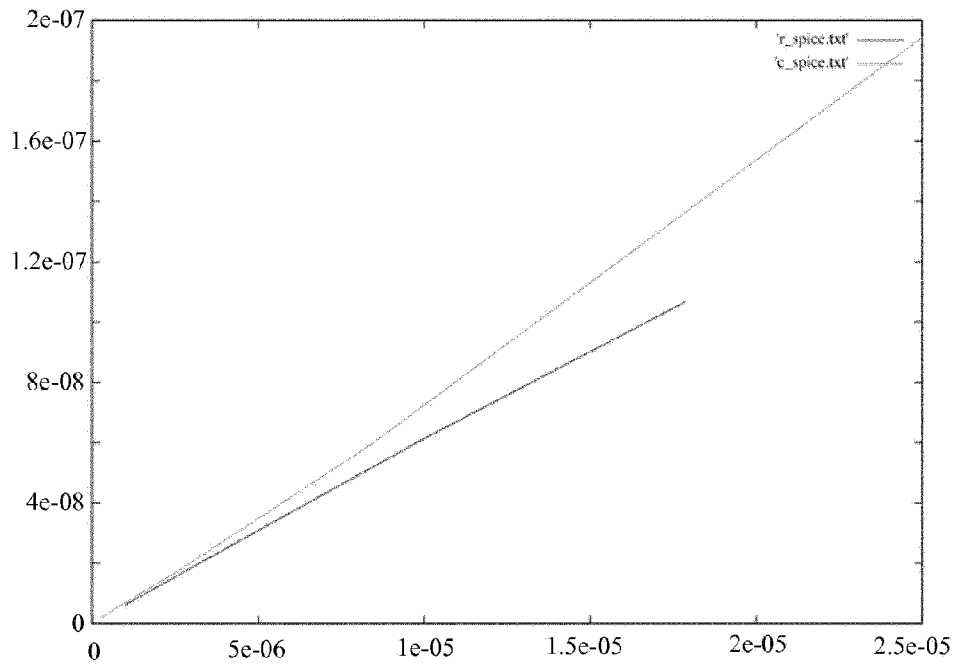
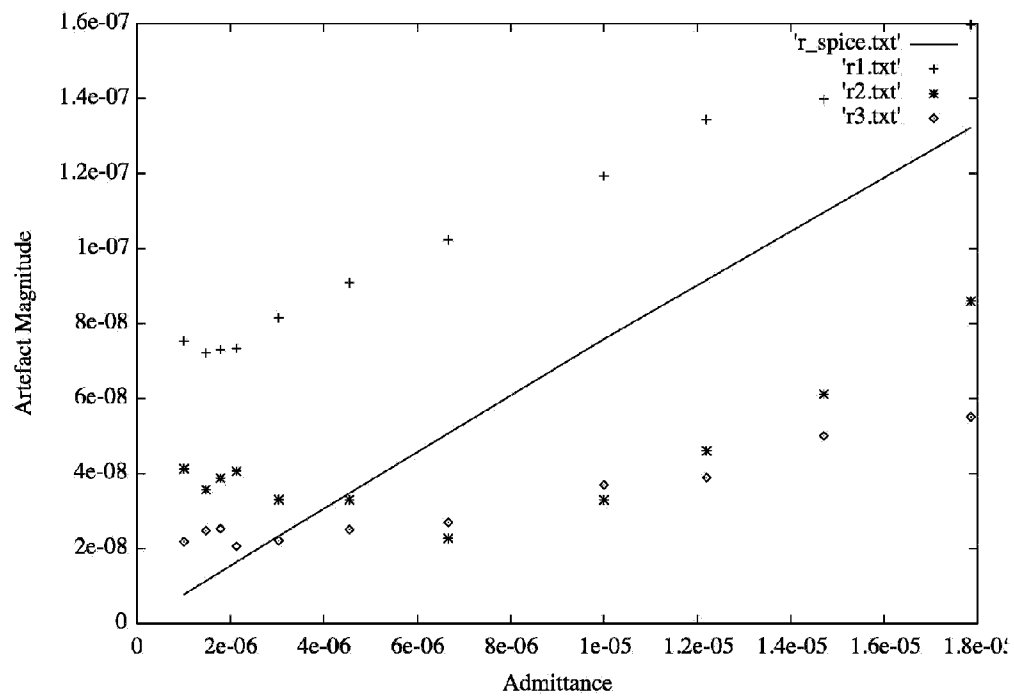
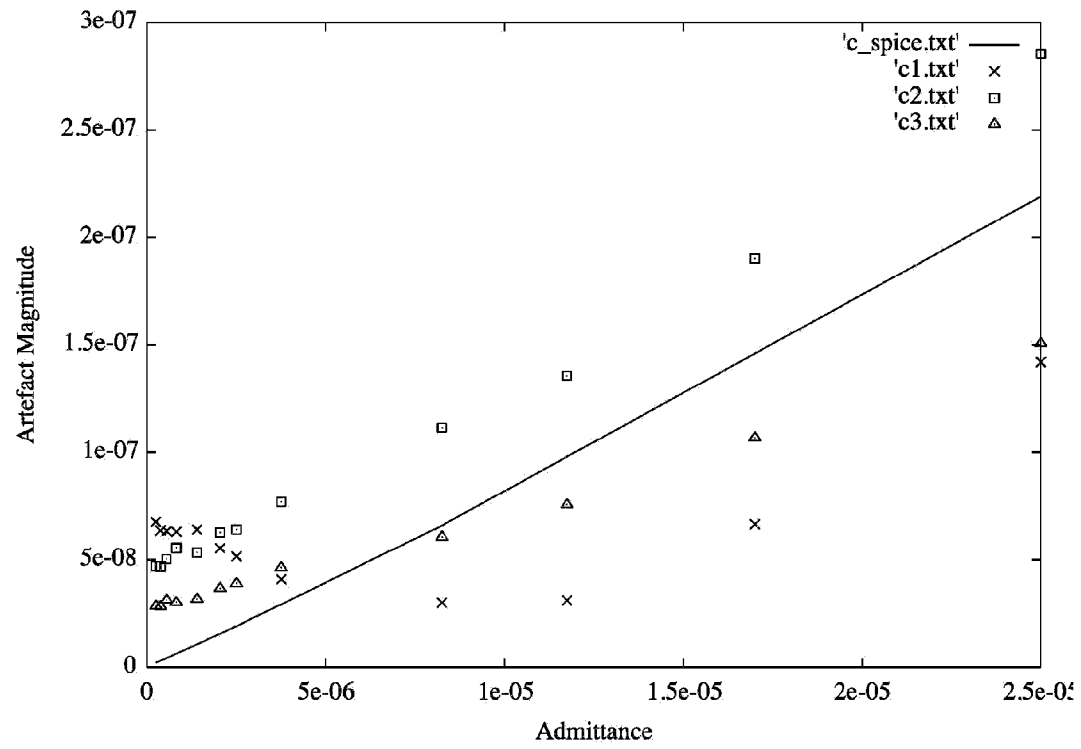


Figure 8

**Figure 9****Figure 10**

**Figure 11**