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(54) **Device for determining the concentration of a substance in body liquid**

Vorrichtung zur bestimmung der Konzentration eines Stoffes in Körperflüssigkeit

Dispositif destines a determiner la concentration d'une substance dans un liquide corporel

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EP-A2- 0 298 441 WO-A-99/39627
DE-A1- 4 446 346 RU-C1- 2 088 927
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Description

Technical Field

[0001] The invention relates to a method and a device for determining the concentration of a substance in an in-vitro or in-vivo specimen containing body liquid according to the preamble of the independent claims.

Background Art

[0002] Radio wave spectroscopy has been known to provide promising potential in the in-vitro and in-vivo determination of the concentration of glucose and other substances in body fluids. In particular, this technology is of substantial interest for the determination of glucose concentration in blood and/or inter- or intracellular liquid. A device for measuring blood level glucose is disclosed in US 5 792 668, where two electrodes are brought into direct contact with the human body and the impedance is measured between them.

[0003] DE 44 46 346 describes a device for detecting a change of volume of the electrolytes in living body parts. It comprises two electrodes being sufficiently apart for the user to introduce his lower leg between them.

[0004] WO 99/39627 describes an apparatus for non-invasively monitoring of glucose including electrodes for measuring the impedance of skin tissue. It is proposed to design the apparatus in the form of a wristwatch.

[0005] Despite its potential, the technology has not yet been used in commercial devices, which is attributed to the limited accuracy of the presently known solutions.

[0006] US 5,533,802 discloses a device for determining the concentration of a substance in body liquid of a human body comprising a first electrode, a holder for fixing the first electrode to an arm or leg of a body, a signal source connected to the first electrode, a measuring circuit and a data processor for determining the concentration of the substance.

Disclosure of the Invention

[0007] Hence, it is the goal of the invention to provide a method and device that allow to increase the reliability of this type of measurement.

[0008] This goal is reached by the independent claims.

[0009] The invention is directed to a device particularly suited for in-vivo measurements of the human body. This device comprises an elongate electrode having a width much smaller than its length. A holder in the form of a wristband is provided to mount the electrode to an arm or a leg with the longitudinal axis of the electrode extending parallel thereto. In this way, a large interaction space is established, which allows to measure the desired concentration with a higher level of accuracy.

[0010] Preferably, at least two electrodes are provided, wherein the modulated voltage is applied between them.

By using two electrodes, a defined field can be established within the specimen. For best signals, it has been found advantageous to place the second electrode in electric contact with the specimen.

[0011] The measured parameter preferably depends on the electrical impedance at the electrode(s). It has been found that the concentration of various substances, in particular glucose, affects the real or imaginary part of this impedance because it changes the loss and/or dielectric constant of body fluid.

[0012] Preferably, the electrode forms part of a resonant circuit, which is operated at or close to its resonance frequency. Under such conditions, a change of the dielectric or loss properties of the specimen leads to substantial shifts in the parameters of the resonant circuit and can therefore be measured with high sensitivity.

[0013] Advantageously, the first electrode is electrically insulated from the specimen. Hence, the measured parameter does not depend on the surface conditions of the specimen. Rather, the signal is capacitively coupled to the specimen and the measured parameter depends therefore primarily on the conditions within the specimen. The parameter measured in this way can then be converted to the desired concentration, e.g. by using calibration data.

[0014] The device of the present invention has been found to be especially suited for measuring the glucose concentration in body fluid.

Brief Description of the Drawings

[0015] The invention will be better understood and objects other than those set forth above will become apparent when consideration is given to the following detailed description thereof. Such description makes reference to the annexed drawings, wherein:

Fig. 1 is a block circuit diagram of a preferred device for carrying out the invention,
 Fig. 2 is a view onto a possible embodiment of the device,
 Fig. 3 is a section along line III-III of Fig. 2,
 Fig. 4 is the device of Fig. 3 with a wristband,
 Fig. 5 shows the behavior of the relative amplitude A as a function of frequency,
 Fig. 6 is a second embodiment of the circuit,
 Fig. 7 is an alternative electrode geometry,
 Fig. 8 shows measurements at varying glucose concentrations (mmol/liter) in physiologic solution and
 Fig. 9 a third embodiment of the circuit.

Modes for Carrying Out the Invention

[0016] Fig. 1 shows a block circuit diagram of a preferred device for carrying out the invention. It comprises a voltage controlled oscillator (VCO) 1 as a signal source for generating a sine wave signal. This signal is fed to two amplifiers 2, 3. The output of first amplifier 2 is con-

nected via a resistor R1 to a first signal path 4. A resonant circuit 5 comprising an inductance L and a capacitor C in series is connected between first signal path 4 and ground. The output of second amplifier 3 is connected via a resistor R2 to a second signal path 6. Second signal path 6 is substantially identical to first signal path 4 but comprises a resistor R3 as a reference load instead of resonant circuit 5.

[0017] Both signal paths 4, 6 are fed to a measuring circuit 7, which determines the relative amplitude A of both signals as well as, optionally, their mutual phase shift ϕ . Relative amplitude A can e.g. be the amplitude of first signal path 4 in units of the amplitude of second signal path 6 (wherein the amplitudes are the peak values of the sine waves).

[0018] The output signal of measuring circuit 7 is fed to a microprocessor 8, which also controls the operation of VCO 1.

[0019] As can be seen from Fig. 1, the device in the present embodiment further comprises a temperature sensor 10, a display 11 and an input device 12 with user operatable controls, all of which are controlled by microprocessor 8.

[0020] Inductance L of the device of Fig. 1 can be generated by a coil and/or by the leads and electrodes of capacitor C. Its value is generally known with reasonable accuracy.

[0021] Capacitor C of the device of Fig. 1 is used as an antenna for probing a specimen. For this purpose, it is formed by electrodes that are arranged near the specimen. The geometry of the electrodes is selected such that the electric field generated by them extends into the specimen and the body liquid to be measured. Suitable geometries are discussed below. As mentioned above, at least one of the electrodes of the capacitor is electrically isolated such that capacitor C is primarily a capacitive load, the capacitance and loss of which depends on the electrical properties (i.e. the response) of the specimen at the frequency of VCO 1.

[0022] To measure the concentration of a substance in the body fluid of the specimen, microprocessor 8 can e.g. initiate a measurement cycle consisting of a frequency sweep of VCO 1. The sweep should start at a frequency f_{min} below the expected resonance frequency f_0 of the resonant circuit 5 and extend to a frequency f_{max} above resonance frequency f . During this sweep, the electrical properties of signal path 4 will change substantially, while those of signal path 6 will vary only slightly. The amplitude determined by measuring circuit A will therefore fall to a minimum A_0 at f_0 , as shown in Fig. 5. At the same time, phase shift ϕ crosses zero.

[0023] As can be shown, the dependence of A_0 on the dielectric constant $\epsilon(f)$ and, in particular, on the loss or conductance $p(f)$ of the fluid in the specimen is stronger than at off-resonance frequencies, which allows a sensitive measurement of the liquid's response to the electric field.

[0024] This is shown in Fig. 8, which represents meas-

urements of the type shown in Fig. 5 at glucose concentrations between 0 and 17.5 mmol/l. The vertical axis represents the ratio in dB of the signals from first signal path 4 and second signal path 6. The resonance frequency is around 35.5 MHz.

[0025] It is presently believed that the specific impedance of the body fluid, i.e. the specific conductivity $p(f)$ and the dielectric constant $\epsilon(f)$ in a frequency range between 10 MHz and 2000 MHz, and in particular between 20 MHz and 70 MHz, are a function of the properties and concentration of the salty (ionic) components of the human body. These salty components primarily include solvated sodium, potassium, calcium and other minor ions and their counter ions, the primary counter ion being chloride. Other non-ionic solvated substances, in particular substances having a similar range of size as the ion complexes, can have an impact on the impedance pattern of the salty body fluid components, provided these substances occur in sufficient concentration. In particular, glucose has a similar range of size and is present in concentrations giving rise to a well detectable variation of the amplitude A_0 at resonance frequency.

[0026] In a simple embodiment, only amplitude A_0 is measured as a parameter for the determination of the concentration. Suitable calibration data stored in microprocessor 8 is used to convert amplitude A_0 into the desired concentration level.

[0027] The effects exploited for the measurement are temperature dependent. In order to obtain high accuracy over a wide temperature range, temperature sensor 10 is brought into thermal contact with the specimen to be measured. The signals from temperature sensor 10 are used to correct the obtained result, again using calibration data obtain from calibration measurements.

[0028] A proper design of the electrodes of capacitor C allows to optimize the accuracy and sensitivity of the present device in a given application. A preferred geometry of the device for in-vivo measurements in a living body is shown in Figs. 2 and 3.

[0029] The device comprises a housing 13 closed on one side by an electrode plate 14. The display 11 is arranged opposite electrode plate 14. The electronic circuits 16 are arranged between electrode plate 14 and display 11.

[0030] Electrode plate 14 comprises an electrically insulating substrate 17 with a strip electrode 18 and a top or ring electrode 19 arranged on an outer side 20 thereof. An inner side 21 of insulating substrate 17 is covered by a bottom electrode 22. A plurality of through-contacts 23 are provided to connect ring electrode 19 to bottom electrode 22. A further through-contact 24 connects one end of strip electrode 18 to a small bond pad 25 arranged in an opening 26 of bottom electrode 22 on inner side 21.

[0031] Temperature sensor 10 is mounted to bottom electrode 22. The large number of through-contacts 23 ensure that bottom electrode 22 follows the temperature of ring electrode 18 and therefore the temperature of the specimen closely.

[0032] A typical size of electrode plate 14 is 32 mm x 21 mm. Bottom electrode 22 covers all of inner side 21 except for the small opening 26 and is therefore much larger than strip electrode 18.

[0033] Leads 28 are provided to connect bottom electrode 22, contact pad 26 and temperature sensor 10 to the electronic circuits 16.

[0034] While bottom electrode 22 and ring electrode 19 are connected to ground, strip electrode 18 is connected to inductance L of resonant circuit 5. Therefore, the capacitor C is formed between strip electrode 18 as a first electrode and ring electrode 19 and bottom electrode 22 as a second electrode. In other words, the second electrode consists of two electrode layers: a top electrode layer formed by ring electrode 19 and a bottom electrode layer formed by bottom electrode 22.

[0035] An electrically insulating cover layer 29 covers all of strip electrode 18 but not ring electrode 19. In other words, strip electrode 18 is arranged between substrate 17 and cover layer 29. Cover layer 29 is preferably of a hard, moisture- and salt-impervious material such as glass, ceramics, a polycarbonate or diamondlike carbon (DLC) of a thickness preferably between 50 and 100 μm .

[0036] As can be seen in Fig. 4, a holder or wristband 31 is attached to housing 13 for fixing the device to an arm or a leg of a human body with cover layer 29 facing the body and a longitudinal axis of strip electrode 18 parallel to the arm or leg. In this way, ring electrode 19 comes into contact with the user's skin and sets the same to ground reference potential. The electric field generated by strip electrode 18 extends into the body tissue. Since strip electrode 18 is elongate and has a width much smaller than its length and extends along the arm or leg, a comparatively large region of the body is reached by the field. This allows to obtain more sensitive and accurate measurements.

[0037] As described above, a pure sine voltage has been found to be sufficient for obtaining accurate measurements. However, other types for modulated voltages, such as square-wave voltages or pulses can be used as well. In this case, measuring circuit 7 is preferably provided with suitable filters for selectively sampling one or more frequency components. At least one measured frequency component is preferably close to the resonance frequency of resonant circuit 5 for exploiting the circuit's high sensitivity to the specimen's properties at that frequency.

[0038] The electrode geometry can be varied for adapting it to a given application. While the design of Fig. 2 is optimized for a measurement on an arm or leg, a circular design can be used for measurement on a flatter body part or an in-vitro sample.

[0039] Ring electrode 19 does not necessarily have to form a closed ring as long as it provides sufficient grounding of the body part to be measured. It can e.g. also have U-shape or consist of two stripes parallel to and laterally enclosing strip electrode 18. Ring electrode 19 can also be omitted completely or be covered by cover layer 29,

in particular for in-vitro measurements where noise is low.

[0040] Part of a further embodiment of the circuit is shown in Fig. 6. Here, no direct connection between resonant circuit 5 and measuring circuit 7 is used. Rather, an antenna electrode 33 is located in proximity to the electrodes of capacitor C, and measuring circuit 7 measures the signal returned by antenna electrode 33.

[0041] A possible arrangement of the electrodes is shown in Fig. 7. As can be seen, antenna electrode 33 is strip shaped and arranged in parallel to strip electrode 18. Both, antenna electrode 33 and strip electrode 18 are covered by cover layer 29 and therefore electrically insulated from the specimen.

[0042] The device of Figs. 6 and 7 is again sweeping VCO 1 between a frequency f_{min} below the resonance frequency f_0 of resonant circuit 5 and a frequency f_{max} above it. In contrast to Fig. 5, measuring circuit 7 now detects a maximum amplitude A_0 at f_0 , wherein the value of A_0 depends on the response, i.e. the electrical properties of the specimen at the resonance frequency f_0 . The parameter A_0 can now again be processed using calibration data as described above.

[0043] A comparison of the device of Figs. 1 and 2 with the device of Figs. 6 and 7 shows that the first embodiment measures the response of the specimen from the signal reflected to strip electrode 18. The second embodiment measures the response of the specimen from the signal transmitted from strip electrode 18 to antenna electrode 33.

[0044] It is found that the transmission and reflection show different dependencies on the concentrations of various compounds of the body fluid. Hence, a combined measurement of reflection and transmission allows a further refinement of the measurement by elimination of the influence of compounds not of interest for the quantity to be measured.

[0045] A third embodiment of a circuit is shown in Fig. 9. Here, the capacitor C formed by the electrodes is part of the resonant tank circuit of an active, self-oscillating oscillator 40. The amplitude A and frequency f_0 of the output signal of oscillator 40 depend on the capacitance and losses in capacitor C. The corresponding signal is fed to measuring circuit 7, which evaluates the parameters A and f_0 . Measuring the corresponding parameters A and f_0 again allows a sensitive measurement of the desired concentration using calibration data.

[0046] In the examples shown so far, the invention was used in a device for qualitatively or quantitatively displaying the concentration a substance (such as glucose) in body liquid. The invention can, however, e.g. also be used in devices that automatically administer medication to a body, such as an insulin pump, where the amount and/or time for administering the medication depends on the measured concentration. It can also be used in any other type of device that requires the measurement of the concentration of a substance in body fluid.

Claims

1. A device for determining the concentration of a substance in body liquid of a human body comprising an elongate first electrode (18) having a width much smaller than a length,
a holder (31) for fixing the first electrode (18) to an arm or leg of a body,
a signal source connected to the first electrode applying a modulated electrical voltage to the first electrode (18) for generating a modulated field in the specimen,
a measuring circuit (7) for measuring at least one parameter (A, ϕ , f_0) depending on a response of the specimen to the field, and
a data processor determining the concentration from the parameter,
characterized in that
said first electrode (18) has a longitudinal axis and said holder (31) is a wristband for fixing the first electrode (18) to the arm or leg with said longitudinal axis of the first electrode being parallel to the arm or leg.
2. The device of claim 1 further comprising a ring electrode (19) extending around all of said first electrode (18).
3. The device of claim 2 wherein said ring electrode (19) is connected to ground.
4. The device of one of the claims 2 or 3 wherein said ring electrode surrounds a single strip electrode with said strip electrode forming said first electrode (19).
5. The device of one of one of the preceding claims further comprising an electrically insulating substrate (17), wherein the first electrode (18) is arranged on a first side (20) of the substrate (17) between the substrate (17) and the cover layer (29).
6. The device of claim 5 further comprising a second electrode (19, 22) arranged on the substrate, wherein the signal source (2) is connected to apply the modulated electrical voltage between the first (18) and the second (19, 22) electrode.
7. The device of one of the preceding claims wherein the first electrode (18) is part of a capacitor (C) of a resonant circuit (5) comprising the capacitor (C) and an inductance (L) connected to the signal source (1).
8. The device of claim 7 wherein the capacitor (C) and the inductance (L) are arranged in series.
9. The device of one of the claims 7 or 8 wherein the measuring circuit (7) is adapted to measure a voltage over the resonant circuit (5).

10. The device of one of the claims 7 to 9 further comprising an antenna electrode (33) arranged in proximity to the first electrode (18), wherein the measuring circuit (7) is adapted to measure a signal transmitted from the first electrode (18) to the antenna electrode (33).

11. The device of any of the preceding claims wherein said first electrode (18) is a straight strip electrode.

12. The device of any of the preceding claims having two parallel strip electrodes (18, 23).

15 Patentansprüche

1. Vorrichtung zur Ermittlung der Konzentration einer Substanz in der Körperflüssigkeit eines menschlichen Körpers umfassend
eine längliche erste Elektrode (18) mit einer viel kleineren Breite als Länge,
eine Halterung (31) zur Fixierung der ersten Elektrode (18) an einem Arm oder Bein eines Körpers,
eine an der ersten Elektrode angeschlossene Signalquelle, welche eine modulierte elektrische Spannung an der ersten Elektrode (18) anlegt, zur Generierung eines modulierten Feldes im Körper,
eine Messschaltung (7) zur Messung wenigstens eines Parameters (A, ϕ , f_0) in Abhängigkeit von einer Antwort des Körpers auf das Feld, und
einen Datenprozessor, welcher die Konzentration ausgehend vom Parameter bestimmt,
dadurch gekennzeichnet, dass
die erste Elektrode (18) eine Längsachse hat und die Halterung (31) ein Armband zur Fixierung der ersten Elektrode (18) am Arm oder Bein ist, wobei die Längsachse der ersten Elektrode parallel zum Arm oder Bein ist.
2. Vorrichtung nach Anspruch 1, weiter umfassend eine Ringelektrode (19), welche sich um die gesamte erste Elektrode (18) erstreckt.
3. Vorrichtung nach Anspruch 2, wobei die Ringelektrode (19) am Nullpotential angeschlossen ist.
4. Vorrichtung nach einem der Ansprüche 2 oder 3, wobei die Ringelektrode eine einzige Streifenelektrode umschliesst, wobei die Streifenelektrode die erste Elektrode (19) bildet.
5. Vorrichtung nach einem der vorangehenden Ansprüche, weiter umfassend ein elektrisch isolierendes Substrat (17), wobei die erste Elektrode (18) auf einer ersten Seite (20) des Substrats (17) zwischen dem Substrat (17) und der Deckschicht (29) angeordnet ist.

6. Vorrichtung nach Anspruch 5, weiter umfassend eine zweite auf dem Substrat angeordnete Elektrode (19, 22), wobei die Signalquelle (2) zum Anlegen der modulierten elektrischen Spannung zwischen der ersten (18) und der zweiten (19, 22) Elektrode angeschlossen ist. 5
7. Vorrichtung nach einem der vorangehenden Ansprüche, wobei die erste Elektrode (18) Teil eines Kondensator (C) eines Schwingkreises (5), welcher den Kondensator (C) und eine an der Signalquelle (1) angeschlossene Spule (L) umfasst, ist. 10
8. Vorrichtung nach Anspruch 7, wobei der Kondensator (C) und die Spule (L) in Serie geschaltet sind. 15
9. Vorrichtung nach einem der Ansprüche 7 oder 8, wobei die Messschaltung (7) zur Messung einer Spannung am Schwingkreis (5) ausgestaltet ist. 20
10. Vorrichtung nach einem der Ansprüche 7 bis 9, weiter umfassend eine Antennenelektrode (33), welche in der Nähe der ersten Elektrode (18) angeordnet ist, wobei die Messschaltung (7) zur Messung eines von der ersten Elektrode (18) zur Antennenelektrode (33) gesendeten Signals ausgestaltet ist. 25
11. Vorrichtung nach einem der vorangehenden Ansprüche, wobei die erste Elektrode (18) eine gerade Streifenelektrode ist. 30
12. Vorrichtung nach einem der vorangehenden Ansprüche mit zwei parallelen Streifenelektroden (18, 23). 35

Revendications

1. Dispositif pour déterminer la concentration d'une substance dans un fluide corporel d'un corps humain comprenant
 - une première électrode (18) allongée et avec une largeur beaucoup plus petite qu'une longueur,
 - un support (31) pour fixer la première électrode (18) à un bras ou une jambe d'un corps,
 - une source de signal connectée à la première électrode, qui applique une tension électrique modulée à la première électrode (18), afin de générer un champs modulé dans le spécimen,
 - un circuit de mesure (7) pour mesurer au moins un paramètre (A, ϕ , f₀) dépendant d'une réponse du spécimen au champs, et
 - un processeur de données déterminant la concentration à partir du paramètre,**caractérisé en ce que**
 - ladite première électrode (18) a un axe longitudinal et ledit support (31) est un bracelet pour fixer la première électrode (18) au bras ou à la jambe avec ledit

axe longitudinal de la première électrode étant parallèle au bras ou à la jambe.

2. Dispositif selon la revendication 1, comprenant en outre une électrode annulaire (19) s'étendant autour de toute ladite première électrode (18).
3. Dispositif selon la revendication 2, ladite électrode annulaire (19) étant connectée à la terre.
4. Dispositif selon l'une des revendications 2 ou 3, ladite électrode annulaire entourant une seule électrode du type bande avec ladite électrode du type bande formant ladite première électrode (19).
5. Dispositif selon l'une des revendications précédentes, comprenant en outre un substrat d'isolation électrique (17), la première électrode (18) étant arrangée d'un premier côté (20) du substrat (17) entre le substrat (17) et la couche de couverture (29).
6. Dispositif selon la revendication 5, comprenant en outre une deuxième électrode (19, 22) arrangée sur le substrat, la source de signal (2) étant connectée afin d'appliquer la tension électrique modulée entre la première (18) et la deuxième (19, 22) électrode.
7. Dispositif selon l'une des revendications précédentes, la première électrode (18) faisant partie d'un condensateur (C) d'un circuit oscillant (5) comprenant le condensateur (C) et une inductance (L) connectée à la source de signal (1).
8. Dispositif selon la revendication 7, le condensateur (C) et l'inductance (L) étant arrangés en série.
9. Dispositif selon l'une des revendications 7 ou 8, le circuit de mesure (7) étant adapté à mesurer une tension au circuit oscillant (5).
10. Dispositif selon l'une des revendications 7 à 9, comprenant en outre une électrode d'antenne (33) arrangée près de la première électrode (18), le circuit de mesure (7) étant adapté à mesurer un signal transmis de la première électrode (18) à l'électrode d'antenne (33).
11. Dispositif selon l'une des revendications précédentes, ladite première électrode (18) étant une électrode du type bande droite.
12. Dispositif selon l'une des revendications précédentes, ayant deux électrodes du type bande (18, 23) parallèles.

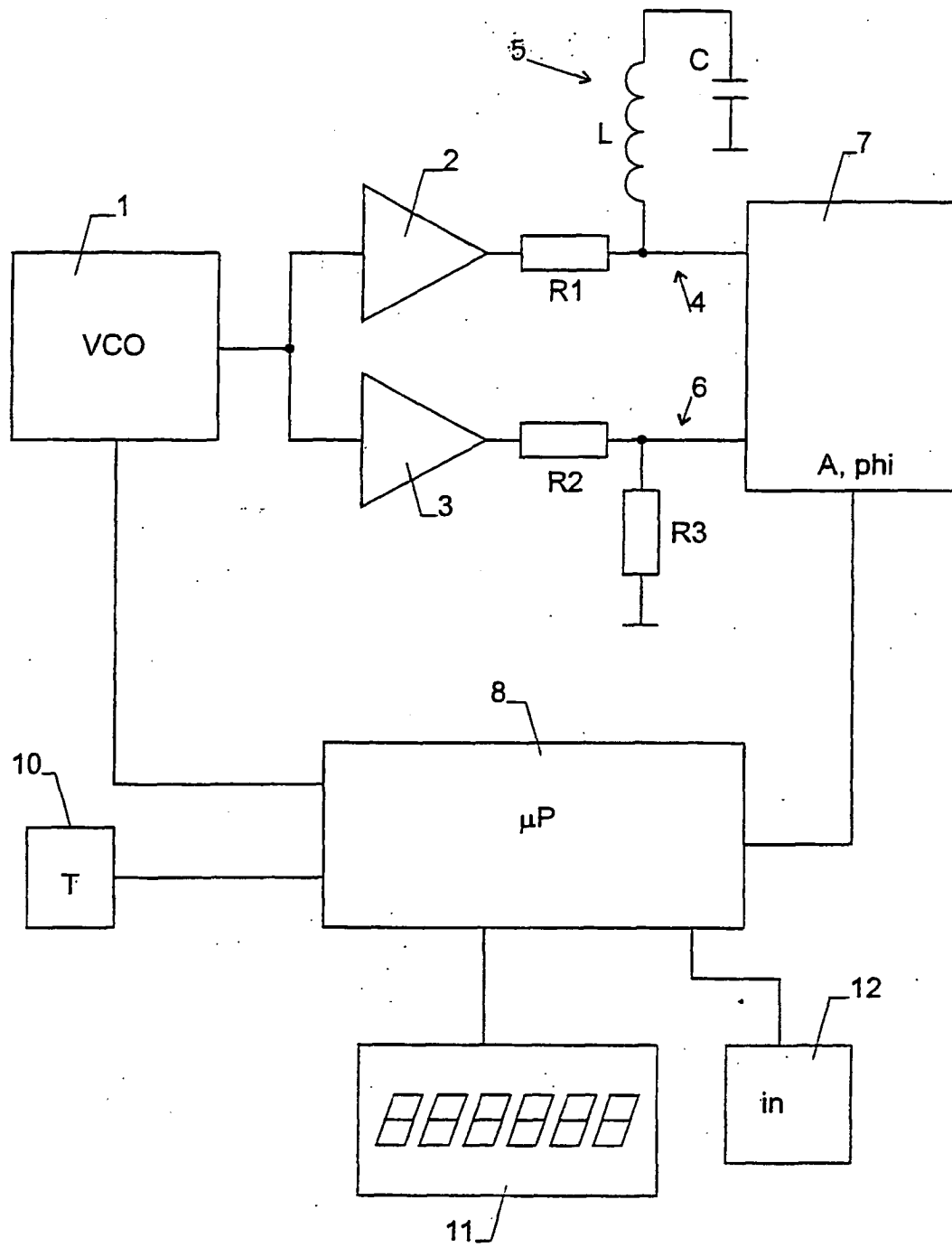
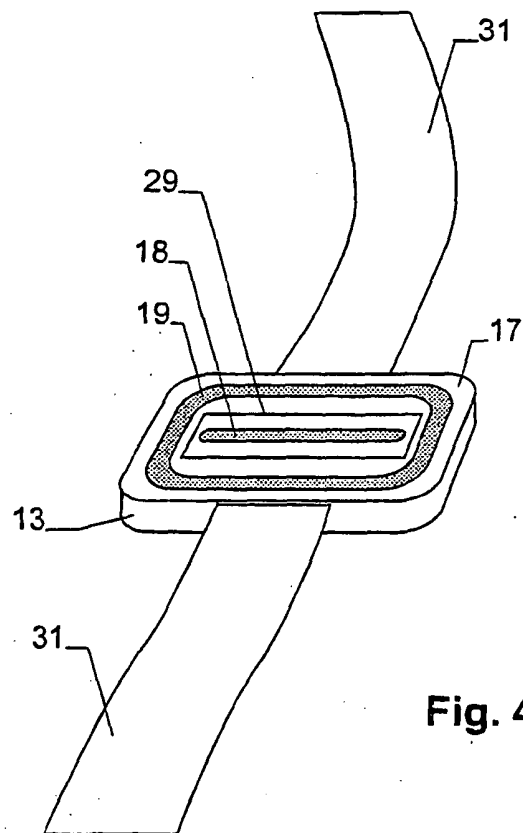
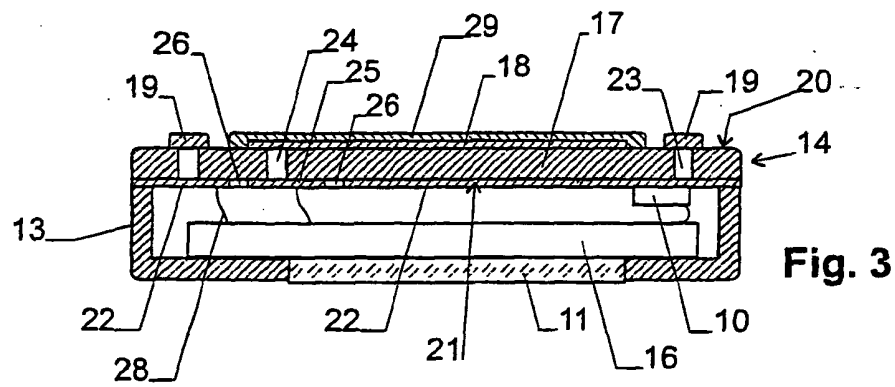
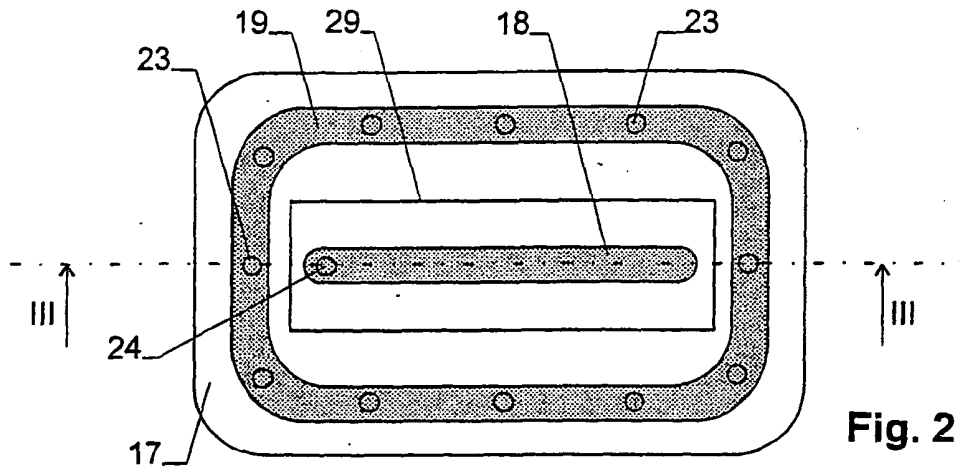


Fig. 1



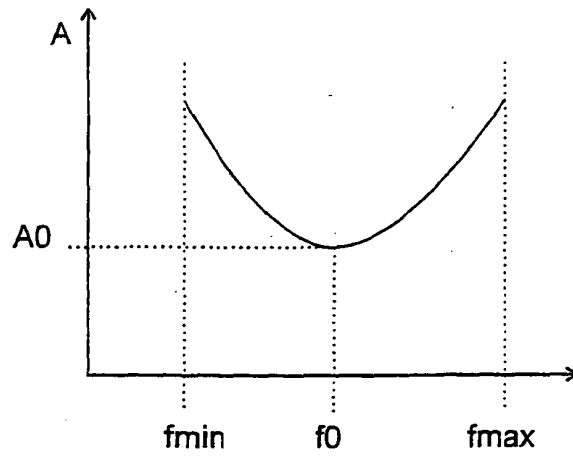


Fig. 5

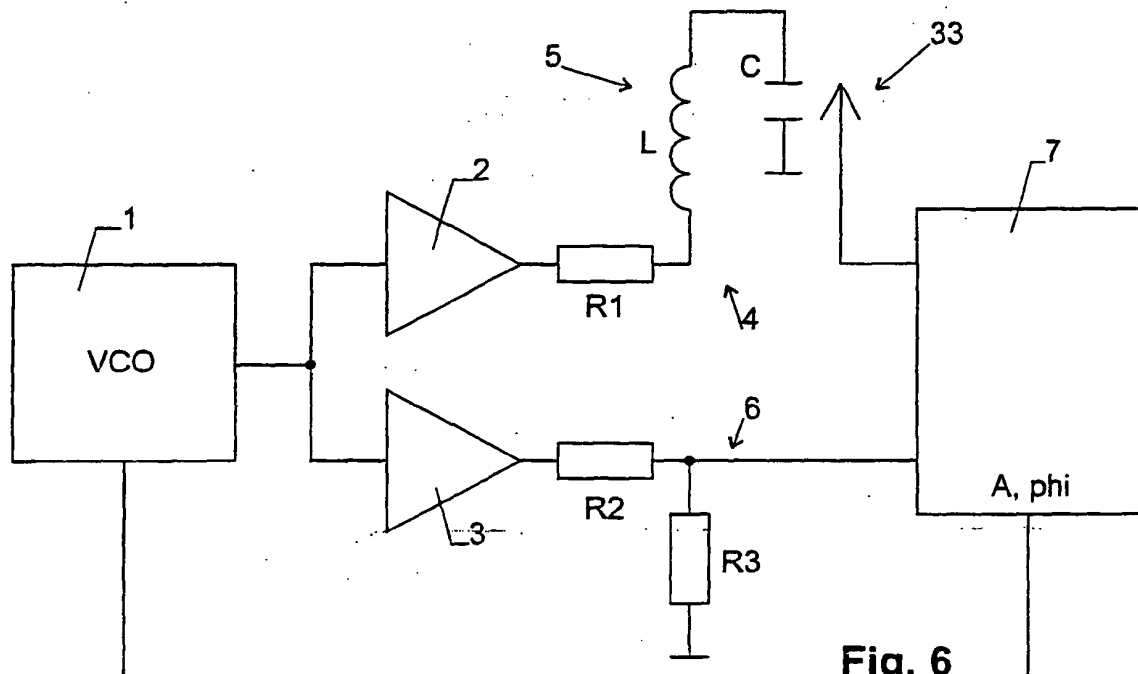


Fig. 6

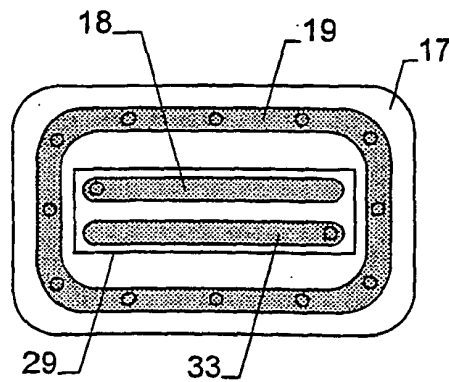


Fig. 7

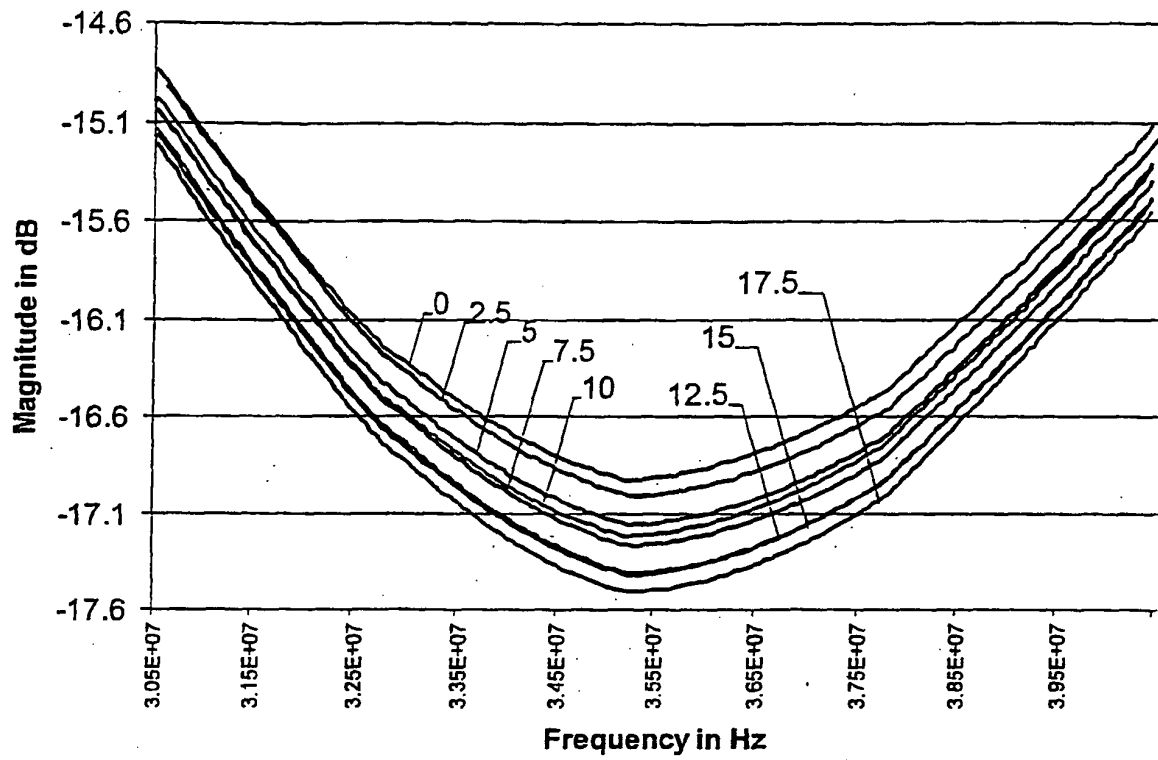


Fig. 8

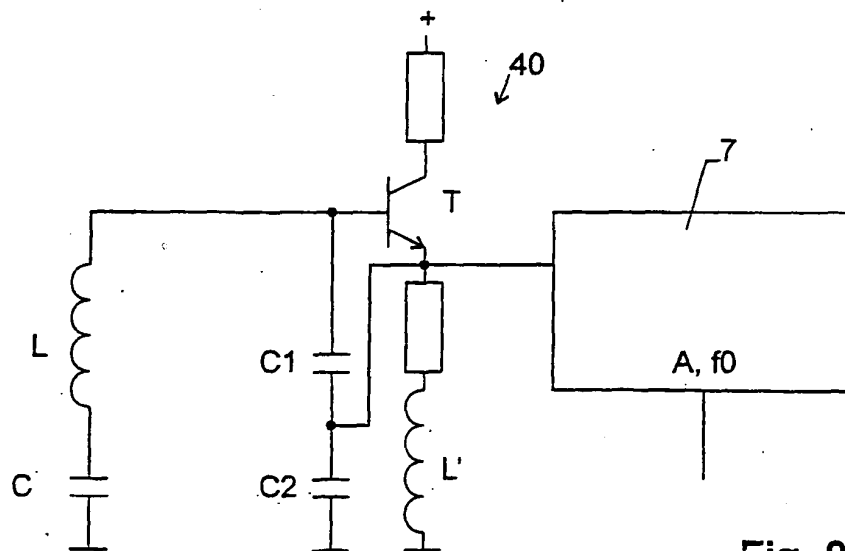


Fig. 9

REFERENCES CITED IN THE DESCRIPTION

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- WO 9939627 A [0004]
- US 5533802 A [0006]

专利名称(译)	用于确定体液中物质浓度的装置		
公开(公告)号	EP1818010B1	公开(公告)日	2012-02-29
申请号	EP2006021295	申请日	2001-03-06
申请(专利权)人(译)	SOLIANIS HOLDING AG		
当前申请(专利权)人(译)	BIOVOTION AG		
[标]发明人	SCHREPFER THOMAS W CADUFF ANDREAS HIRT ETIENNE SUSSTRUNK HEINZ		
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摘要(译)

为了测量体液中物质的浓度，例如血液或组织中的葡萄糖水平，在样本处设置条形电极（18）和环形电极（19）。环形电极（19）与样品直接电接触，而条形电极（18）与样品电绝缘。条形电极（18）平行于臂或腿布置，以获得大的相互作用长度。电极（18,19）在谐振电路中形成电容器。将接近或处于共振频率的MHz范围内的调制电压施加到电极，并测量体液的响应。该设计允许高精度的测量。

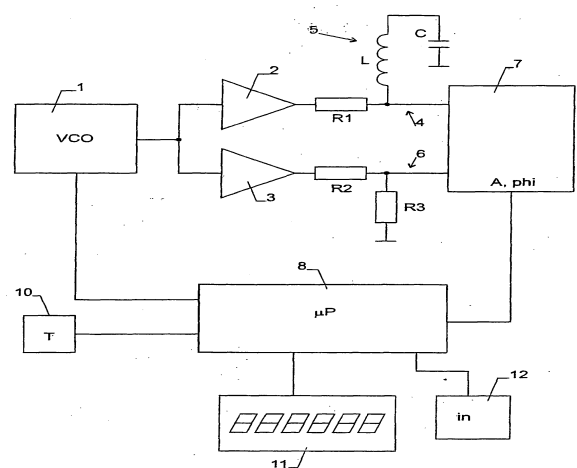


Fig. 1