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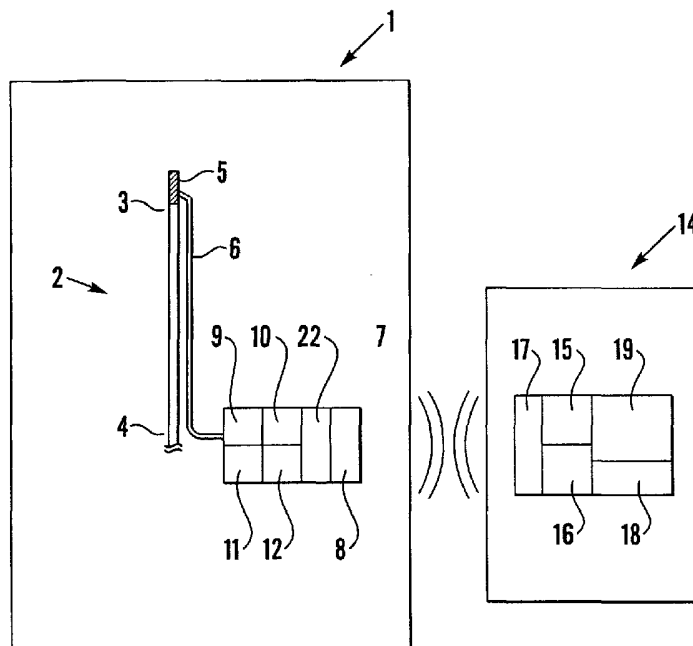
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(54) Title: SYSTEM FOR READ-OUT OF PRESSURE



(57) Abstract: The invention relates to a measuring unit (1) for measuring pressure and for wireless transmission of measuring signals, a recording unit (14) for measuring signals, and a system for measuring pressure and for wireless data and energy transmission between a measuring unit (1) and a recording unit (14), where the measuring unit (1) and the recording unit (14) can be inductively interconnected.



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System for read-out of pressure

The present invention relates to a system for passive measurement of pressure and for wireless data and energy transmission between a measuring unit and a recording unit, where the measuring unit and the recording unit can be inductively
5 interconnected by means of coils.

The invention is based on measurement of intracranial pressure in hydrocephalus patients.

Patients with hydrocephalus (water on the brain) suffer from a disparity between production and drainage of fluid from the interior of the brain. In some of these
10 patients this disparity can be so great that the suffering has to be treated by an operation. The operation usually consists in inserting a drain (ventricular catheter), thereby establishing an alternative drainage path for the brain fluid. A drainage system (shunt system) is normally inserted through a drill hole in the skull and on into the cavity of the brain. From the drill hole, the other end of the drain is then
15 passed under the skin down to a suitable drainage location for the brain fluid, which in most cases is the abdominal cavity.

Serious complications may arise, however, in cases where this surgically inserted drainage system becomes clogged, resulting in an increase in the pressure within the skull. Apart from headache, the patient will not display specific symptoms in such a
20 situation, and the doctor concerned may therefore easily be caught in a dilemma as to whether or not he/she is faced with a life-threatening situation. In order to alleviate such situations as well as avoiding unnecessary operations, therefore, from the medical point of view it would be of indispensable assistance to have a simple and reliable means to enable non-invasive measurements of the intracranial pressure
25 of these patients to be performed.

The invention proposes placing a pressure sensor in the drainage system, which, in addition to the safety aspect when there is a suspicion of drainage failure, will also be able to prevent unnecessary shunt revisions (surgical inspection and possible replacement of the drainage system).

30 Placing the sensor inside the brain's cavity, on the tip of the surgically inserted ventricular catheter, will ensure that it really is the intracranial pressure that is measured.

US 5,074,352 discloses an implantable bio-sensor for monitoring internal physiological conditions in a patient. The biosensor comprises a sensor part and a
35 transmitter part adapted for placing inside the patient's body and a receiver part which is disposed outside the patient. The sensor part is mounted on a valve body

and will thereby sense the pressure there. The device is not adapted for measuring inside the brain. Nor is such a measurement suggested in the publication.

DE 19643782 C1 discloses a device for controlled drainage of fluid from the brain to the abdomen. The device comprises a valve and a catheter with sensors for measuring the fluid pressure in the brain and in the abdomen respectively. To solve the problem of energy transmission to the valve, the use of an accumulator is proposed in this publication. The presence of such an accumulator in the patient's body will not be sufficiently satisfactory. Moreover, the publication does not indicate how the sensor is adapted for being placed inside the brain. This problem is crucial for providing a successful product, since there must be absolutely no risk of brain damage associated with the sensor. The sensor should therefore be specially adapted for such an application.

Another known pressure measurement system has been commercialized by RadionicsTM. The measurement system consists of an internal, implanted unit integrated in the drainage system, together with an external unit used for excitation and read-out of the internal unit. The internal unit including the sensor element is located on the outside of the skull, and this will not elicit satisfactory results. This is linked to the fact that the reason for drainage failure in most cases is a blockage in the part of the drainage system located within the skull. A possibility therefore exists that the measurement system may show normal pressure values, while in actual fact the intracranial pressure may be substantially heightened.

As already stated, the best place for performing pressure measurements will be on the tip of the ventricular catheter in the exact area where a dangerous excess pressure could develop, i.e. the pressure gauge must be located approximately in the middle of the cranium, 8 to 12 cm from the outside of the head. To provide a signal transmission of sufficient power from this point towards the outside will make great demands on the measuring/transmitting unit (which in addition must be small) and the receiver unit. The same argument will apply to measuring pressure in other inaccessible places in the body, such as, for example, joints, musculature or other tissue.

At the same time it is important to avoid the presence of energy sources in the patient's body, since they require maintenance and replacement, which can only be implemented by surgery.

The invention will therefore solve the above-mentioned problems in the prior art by providing a measuring unit for measuring pressure and for wireless transmission of measuring signals, which permits measurement of pressure within the brain, transmission of the measuring signals to a location outside the patient's body while simultaneously receiving energy from a location outside the patient's body, thus avoiding the need for implanted energy sources. The measuring unit cooperates with

a recording unit which is responsible for energy supply and which, as already stated, is located outside the patient's body.

5 The measuring unit comprises a catheter with a distal end and a proximal end, a device for transmitting the sensor signal to a processing and transmitting device, where the processing and transmitting device comprises an energy transmitter in the form of a coil for wireless transmission of processed measuring signals and energy supply signals. The measuring unit is characterised in that it comprises a pressure sensor mounted on the catheter's distal end.

10 The pressure sensor in the measuring unit according to the invention is specially adapted for placing in an area of the body that can withstand only very limited strain. A typical example of such an area is within the brain, and the sensor according to the invention is small in size in order to avoid damaging surrounding tissue. The space available in the catheter is approximately 2x2x4mm.

15 The sensor according to the invention is also adapted for low heat generation, thus preventing the temperature round the sensor from rising to dangerous values. At the same time the sensor is adapted for repeated precise measurement of pressure.

20 On account of the lack of space, the coil in the measuring unit will be adapted to be placed immediately under the skin in the area of the shunt valve. The total space available here is approximately 20x20x4mm. The measuring unit is flexible, thus enabling it to be laid along the cranium. From the coil and the circuit logic, wires lead into the sensor which is a silicon micromachined sensor. The sensor is manufactured by surface micromachining since surface dimensions are independent of the thickness of the substrate. The sensor can therefore be miniaturised to the submillimeter range without difficult or sophisticated procedures.

25 The recording unit according to the invention comprises a signal receiver for wireless receipt of pressure signals and an energy transmitter for wireless transmission of energy, where the transmitter and the receiver comprise an inductive coil and where the device further comprises an energy source connected to the transmitter together with a processing and display unit connected to the transmitter and to the receiver. The recording unit is adapted to receive the signals from the measuring unit.

35 Finally, the invention includes a system for measuring pressure and for wireless data and energy transmission between a measuring unit and a recording unit, where the measuring unit and the recording unit can be inductively interconnected, where the measuring unit comprises a catheter with a distal end and a proximal end, a pressure sensor mounted on the catheter's distal end, a device for transmitting the sensor signal to a processing and transmitting device, where the processing and transmitting device comprises a coil for wireless transmission of processed

measuring signals and energy supply signals, and the recording unit comprises a signal receiver for wireless receipt of pressure signals and an energy transmitter for wireless transmission of energy, where the transmitter and the receiver comprise an inductive coil, and where the device further comprises an energy source connected to the transmitter together with a processing and display unit connected to the transmitter and to the receiver.

The system in itself is inventive since both the measuring unit and the recording unit are adapted to their specific function. Taking measurements within the brain and reliable transmission of signals make demands on both the measuring unit and the recording unit.

The system will permit measurements to be taken at such high speed and with such great precision that it is possible to see the effect of the heart beats in the pressure measurements, i.e. the measurement rate is 100 measurements per second or higher.

In the following description it is assumed that the device for wireless transmission of measuring signals and energy signals is a coil, but other devices for wireless energy transmission may also be employed, such as laser devices and acoustic devices.

Preferred embodiments of the invention are indicated in the attached patent claims.

The invention offers several advantages compared with the prior art.

The measuring unit according to the invention is adapted to perform measurements directly in the relevant area of the brain, thus providing the best possible monitoring of the state of the brain. Furthermore, the pressure measurement system is installed "automatically" when installing the drain system, i.e. no extra surgical procedure is necessary.

Since the signal transmission takes place inductively, there will be no permanent feed wires through the skin, which unavoidably entail a major risk of infection as well as discomfort for the patient.

The absence of implanted energy sources will be particularly advantageous when employing the system for measuring intracranial pressure, since from a medical point of view it is undesirable to insert the components of a battery in the immediate vicinity of the brain and the central nervous system. In addition, a self-powered, battery-free unit will reduce the need for replacement of parts.

The doctor (and in many cases the patient him/herself) can obtain reliable information about the pressure within the skull. This is vital in order to make a correct diagnosis.

An embodiment of the invention will now be described in detail by means of the figures, in which:

figure 1 is a principle drawing of the system according to the invention,

5 figure 2 illustrates an embodiment of the sensor in the measuring unit according to the invention,

figures 3-4 show a general circuit diagram for inductive energy transmission between two coils,

figure 5 illustrates voltage amplitudes over an equivalent resistance as a function of the coupling coefficient k ,

10 figure 6 illustrates the expected energy transmission between the recording unit and the measuring unit,

figure 7 illustrates an extended circuit diagram of the measuring unit showing the components of the equivalent resistance,

15 figure 8 illustrates the difference in the current amplitude relative to the coupling coefficient k ,

figure 9 illustrates a circuit diagram for energy transmission between two coils,

figure 10 illustrates a circuit diagram for reading a piezoresistive sensor,

figure 11 illustrates a 12 bit DAC designed for unilateral voltage supply,

figure 12 illustrates a PCB layout for the recording unit board,

20 figure 13 illustrates a PCB layout for the measuring unit board (large coil),

figure 14 illustrates a PCB layout for the measuring unit board (small coil),

figure 15 illustrates a PCB layout for the rectifier and the stabiliser,

figure 16 illustrates a PCB layout for the readout board,

25 figure 17 illustrates a state machine for the main program in the processing and transmitting unit,

figure 18 illustrates the general structure of the system according to the invention.

30 Figure 1 is a principle drawing of the system according to the invention. The figure illustrates a schematic grouping of elements and not necessarily the real connections between them. The system comprises a measuring unit 1 for measuring pressure and transmitting pressure signals together with a recording unit 14 for receiving and further processing of the signals as well as for transmission of energy to the

measuring unit 1. Transmission of the signals between the measuring unit 1 and the recording unit 14 will be wirelessly implemented by means of an inductive coil in each of these units (8 and 17 respectively). Alternatively, as mentioned previously, laser light or acoustic signals may be employed for wireless transmission of the signals. When used for measuring intracranial pressure, for example, the units 1 and 14 will be located on each side of the patient's skin. The measuring unit 1 comprises a catheter 2 with a distal end 3 and a proximal end 4. The terms distal and proximal are employed here in relation to the location for transmission of the measuring signal and not in relation to the measuring location. In connection with the use of the invention in a system for measuring intracranial pressure, the catheter 2 will be the one used for collecting fluid in the brain ventricle and transferring it to the abdominal/arterial system. On the catheter's 2 distal end a pressure sensor 5 is mounted, which in a preferred embodiment of the invention is a piezoelectric sensor. The sensor 5 is connected via a transfer device 6 to a processing and transmitting device 7. In an embodiment of the invention the transfer device will be composed of one or more electric wires which are preferably embedded in the catheter 2.

The processing and transmitting device 7 is located near the catheter's proximal end, so that during use it is located as close as possible to the surface of the patient's skin. It poses no problems from the surgical point of view to have transmission coil 8 approximately 2x2 cm in size. Calculations and experiments show that the connection between unit 7 and unit 14 will then be good enough for energy and data transmission with a distance through the skin of 4-8 millimetres. Another advantage of this positioning will be that any replacement of parts in the implanted sensor unit will be as non-invasive as possible for the patient. As mentioned earlier, the processing and transmitting device 7 may comprise a coil 8 for wireless transmission of pressure measuring signals. In a preferred embodiment the device comprises an analog to digital converter 9 connected to the pressure sensor 5 in order to convert the sensor's measuring signals from analog measuring signals to digital pressure data signals. Digitisation should be undertaken on the part of the system that is located within the body during use, since this will mean that the wireless transmission will have the least chance of influencing the measuring signals with noise. The A/D converter 9 is connected in turn to a control unit 11, which is responsible for transmission of the pressure data signals by means of a modulation unit 10. The control unit 11 effects changes in the processing and transmitting device's 7 equivalent resistance. A change in the equivalent resistance will result in a change in the current in the coil 17 in the recording unit 14, thereby causing the pressure data signal to be transmitted between the measuring unit 1 and the recording unit 14. This will be further clarified later. The device 7 also comprises a storage unit 12 for storing control orders for the device 7 as well as other necessary parameters. Finally, the measuring unit 1 comprises a power supply

unit 22 for diverting operating voltage/current from the coil 8 to the rest of the measuring unit 1.

Figure 1 also illustrates the recording unit 14. The recording unit comprises a signal receiver 15 for receiving the pressure data signals, the signal receiver comprising a coil 17, which during read-out will be connected inductively to the coil 8 in the measuring unit 1. From the point of view of the recording unit, the measuring unit will represent an impedance that is substantially resistive. A change in the resistance in the measuring unit 1 will be transmitted to the recording unit via the coils 8 and 17, and the signal receiver 15 will be responsible for transmitting these changes (in the form of a current amplitude modulation) to a processing and display unit 19, where a digital signal processing is performed in order to recreate the digitised pressure value from the amplitude-modulated current. The recording unit 14 further comprises an energy transmitter 16 which is connected to an energy source 18. The object of the transmitter 16 is to transmit the necessary energy to the power supply unit 22 in the measuring unit 1, thus avoiding the need for batteries or other energy sources in the measuring unit 1. The energy transmission is implemented by the coils 8 and 17 acting like a standard transformer (where 17 constitutes the transformer's primary side and 8 constitutes the secondary side). The signal transmission from coil 8 to coil 17 is implemented by digital "0" and "1" causing the resistance in the unit 1 to be "high" or "low". This is reflected in the current travelling in coil 17, which at all times is the primary coil for energy transmission. While the energy transmission at all times passes from 17 to 8, 14 can receive digital data from 7 by measuring the current in 17.

It would be possible to employ two pairs of coils, one for energy transmission and a second pair for data transmission.

When employing a single pair of coils, it will be a simple matter to:

- 1) surgically insert the system, where the coil 8 is securely stitched under the skin,
- 2) place 17 on the outside of the skin, thus providing both energy and data transmission in a satisfactory manner. The processing and display unit 19 will, inter alia, control the signal and energy transmission.

The measuring unit is MR-compatible, i.e. it has a small surface and is furthermore made of metals with low magnetic susceptibility in order to limit eddy-currents caused by varying magnetic fields during MR imaging.

The pressure sensor 5 will advantageously be a piezoelectric sensor, which in an embodiment may consist of four piezoresistive resistors in a Wheatstone bridge configuration, two of which are placed on a thin membrane. This will be further clarified by means of figure 2. This configuration entails the incorporation of four independent wires (6, figure 1) in the walls of the catheter. With regard to providing reference pressure, this may be accomplished by mounting an additional pressure

sensor in the recording unit 14 in order thereby to measure the difference between the brain pressure and atmospheric pressure (relative pressure measurement).

Figure 2A illustrates a pressure sensor of this kind for use in the measuring unit according to the invention. The sensor 5 is a piezoelectric sensor with a polysilicon membrane M with two boron-doped piezoresistors PR located at the oppositely-located edges. The piezoresistors PR are connected to two polysilicon resistors (figure 2C) with the same topology in a Wheatstone bridge connection. The sensor also comprises contact pads or wires CP for transmitting signals from the sensor, and an insulating or passivating layer of PSG (phosphosilicate glass) that protects the sensor and covers the whole sensor apart from the membrane C and the wires CP. The cavity C under the membrane is formed by etching with concentrated hydrofluoric acid of the thick silicon dioxide layer formed by local oxidation of silicon. After the etching process, the membrane is sealed by depositing a layer of silicon dioxide. The pressure in the cavity C remains equal to the pressure in the depositing reactor (approximately 25Pa) during the rest of the processing.

The layer thickness is the same as for a commercial 2.5 μm CMOS process apart from poly-Si used for the membrane M and sacrificial oxide. Compression tension in the poly-Si layer is eliminated by a high-temperature alloying process used for well operation. The total technological process has 9 lithographic steps.

As mentioned earlier, the sensor is manufactured by surface machining. This process results in thinner sensors than in bulk manufacture. However, polycrystal silicon is employed in the surface technology, which results in less accuracy than can be achieved with bulk machining. The accuracy will be satisfactory for the present application, even with a surface-machined sensor, and this process has therefore been chosen.

Figure 2B illustrates a section along line B-B in figure 2A. In this section all the layers forming the sensor can be seen, which are: I. Monocrystalline silicon (670 μm), II. Polycrystalline silicon (membrane M, 0.9 μm), III. Dielectric (SiO_2 , 0.5 μm), IV. Polycrystalline silicon (boron-doped, piezoresistor PR, 0.4 μm), V. Dielectric (SiO_2 , 0.2 μm), VI. Aluminium wires (1 μm), VII. Dielectric PSG. The cavity C will be between 1.6 and 1.4 μm .

Figure 2C illustrates a sensor 5 viewed from above. As can be seen, the sensor 5 comprises piezoelectric resistors, whereof two PR_C are mounted on the membrane C and are arranged to measure the membrane's deformation and thereby pressure. Two additional sensors PR_R are connected to the sensors PR_C in a Wheatstone bridge configuration and are intended to compensate for changes in resistivity with temperature. The figure also illustrates distance pieces S provided on the side of the membrane facing the monocrystalline layer I (figure 2B). The function of the

distance pieces is to prevent the membrane from resting on the bottom of the cavity at great pressure and "sticking" to it.

Figure 2D illustrates various embodiments of sensors of the type described. In the middle of the figure square sensors can be seen with dimensions 0.7 mm. The sensors on the left of these are those that are to be used in the measuring unit according to the invention, and they are 0.7 mm long and approximately 0.2 mm wide. In this figure the wires CP for all the piezoresistive elements PR can be seen.

Figure 2E illustrates an arrangement for mechanical testing of the sensor 5. In this arrangement the cavity C in the sensor is connected to an auxiliary (dummy?) cavity DC covered by an auxiliary (dummy?) membrane DM. The dummy membrane is perforated, thus providing the dummy cavity DC and the cavity C with atmospheric pressure, and the change in the resistance of the piezoresistive elements PR is measured. The results of the test are shown in the table below.

Diaphragm diameter of sensor, um	75		60	
	Before breaking	After breaking	Before breaking	After breaking
Bridge resistance, Ohm	4244	4220	4236	4224
	4250	4227	4230	4217
	4271	4250	4215	4203
	4281	4259	4253	4240
	4257	4235	4213	4200
Resulting sensivity (approximate), mV/V/atm	5.5		3.0	

This sensor permits a design with small dimensions and simultaneously limited heat generation. The accuracy will also be satisfactory.

The system comprising the measuring unit and the recording unit has the following characteristics:

- a) measuring range: from 0 to 2 atmospheres, i.e. 0 to 202.65 kPa,
- b) accuracy: 12 bit, so that the resolution corresponding to 1 bit corresponds to 50 Pa, the lowest value 0 corresponds to 0 Pa and the highest 4095 corresponds to 204.75 kPa,
- c) dimensions 0.7x0.2x0.2 for the sensor,
- d) non-linearity 0.025 FSO, 1 LSB,
- e) hysteresis 0.025 FSO, 1 LSB,
- f) long-term stability 0.025% per annum, operating time minimum 10 years,
- g) zero point stability 0.005 per degree Celsius,
- h) sensitivity operation 0.005% per degree Celsius,
- i) temperature range 18-43°C,
- j) vibration sensitivity 0.025%
- k) resistance change in the piezoresistors at 1 atm pressure change will be 5.5 per thousand for diaphragm diameter of 75 microns and 3 per thousand for diaphragm diameter 60 microns. The latter means that for a membrane with a diameter of 75 microns and 5V drive voltage for the bridge, for 1 atm pressure change a signal of approximately 14 mV is obtained from the Wheatstone bridge before amplification, while 50 Pa pressure change gives an approximately 6.8 microvolt signal from the bridge before amplification.

As mentioned earlier, the pressure data signal transmission will be implemented by a current modulation. This will now be explained more fully by means of figures 3 and 4.

- Figure 3A illustrates a general circuit diagram for inductive energy transmission between two coils 8 and 17, i.e. a simplified equivalent circuit for the system according to the invention. The left part of the figure with component designation 1 denotes the recording unit 14, while the right part with component designation 2 denotes the measuring unit 1. The induced voltage across L2 resulting from current I1 through the coil L1 (corresponding to coil 17 in figure 1) will be proportional to the mutual inductance M together with the time-derivative of the current I1. In order to force the voltage across L2 (corresponding to coil 8 in figure 1) up to a respectable voltage level, the coil L1 must be excited by a moderate, high-frequency current. This is achieved by exciting the coil L1 in series with a condenser C1 and subsequently adapting the excitation frequency in order to obtain resonance in the measuring unit 1, i.e. $f_r = 1/2\pi\sqrt{L_1C_1}$.

- Since the series impedance of L1 and C1 ideally is zero at resonance frequency f_r , R1 will provisionally be able to be considered as a purely current-limiting resistance. In the measuring unit 1 the coil L2 is placed in parallel with the condenser C2 which together with L2 is adapted to represent an infinitely large

impedance at the resonance frequency ω_r . It will be possible to take out the voltage across C2 and L2 across the resistance R2. The resistance R2 represents a provisional equivalent to the circuit electronics in the measuring unit 1.

In figure 3B the mutual inductance between the recording unit 14 and the measuring unit 1 is divided into separate coil elements in series with the self-inductances, with the result that the origin of the induced voltage is clear in each case. Assuming a harmonic excitation of the recording unit 14 and if the circuit is described with complex impedances, it can be shown that the equivalent series impedance Z_{eq} caused by the inductive connection between the coils L1 and L2 in the external unit is given by: $Z_{eq} = \omega^2 M^2 / Z_2$. Based on this and if the excitation frequency, which is designated by ω_r is chosen so that L1 and L2 are resonantly connected, the expressions for Z1 (the total impedance in the recording unit), I1 and V1 will be:

$$Z_1 = (R_1 + k^2 R_2 \frac{L_1}{L_2}) - j\omega_r k^2 L_1 \quad (1)$$

15

$$I_1 = \frac{V_1}{Z_1} = \frac{V_1}{(R_1 + k^2 R_2 \frac{L_1}{L_2}) - j\omega_r k^2 L_1} \quad (2)$$

$$V_2 = \frac{k R_2 \sqrt{\frac{L_1}{L_2}} V_1}{(R_1 + k^2 R_2 \frac{L_1}{L_2}) - j\omega_r k^2 L_1} \quad (3)$$

20

This means that the ratio between the voltage amplitude across the resistance R2 and the amplitude of the excitation voltage V1 can be expressed by:

$$\left| \frac{V_2}{V_1} \right| = \frac{k R_2 \sqrt{\frac{L_1}{L_2}}}{\sqrt{(R_1 + k^2 R_2 \frac{L_1}{L_2})^2 + (\omega_r k^2 L_1)^2}} \quad (4)$$

25

As will be seen from the above formula, the voltage across R2 is dependent on the coupling coefficient k , and it will be possible to find a coupling coefficient resulting in the greatest possible energy transmission. The voltage across R2 decreases both for $k < k_{krit}$ and $k > k_{krit}$.

- 5 Figure 4 illustrates the circuit diagram in figure 3B, but also with coverage for the coils' inherent resistance. In order to achieve a respectable voltage value in the induced voltage V_m , it will be advantageous to increase the angular frequency ω . Thus in a non-limiting embodiment of the invention, an excitation frequency $f = 10\text{MHz}$ will be chosen. With this frequency the following values will be chosen for
10 the rest of the circuit:

TABLE 1: Specifications for the pressure sensor

Parameter	Symb.	Min*	Typ	Max*	Unit
Signal function of pressure and temperature	V (P,T)	$(S0+S1(T-25))P+Z0+Z1(T-25)$			mV/V
Sensitivity	S0	8.7	11.3	12.3	
Temp. coeff. Sensitivity operation	S1		-0.016		1%
Offset	Z0	-2.5	5.4	25	mV/V
Temp. coeff. Offset operation	Z1		-0.016		mV/V°C

- By means of the values in table 1, with the aid of Maple-based impedance calculations in the circuit illustrated in figure 4, we shall make a closer study of the
15 expected voltage amplitudes for this example. These are illustrated in figure 5. The curves display pronounced peaks, corresponding to critical connection for the different values of R2.

- Figure 6 illustrates the expected energy transmission between the recording unit 14 and the measuring unit 1 in the form of the power dissipated in R2, also taking into
20 consideration the power dissipated in the coil resistance RL2. It is important to obtain the most efficient energy transmission possible, but the power that will be dissipated in the implanted measuring unit 1 must also be considered. With an excitation frequency equal to 12 MHz, the energy deposited in the tissue will be so little that any heating of the surrounding tissue can probably be considered
25 negligible with a sensible encapsulation of the implanted circuit.

Figure 7 illustrates an extended circuit diagram of the measuring unit 1 illustrating the components of the equivalent resistance R2. The equivalent resistance R2 in

figures 2-4 is now replaced by a rectifying diode D, with a related collecting condenser Cd. These components are succeeded by two parallel-connected voltage references (shunt references). The two voltage references are intended for the role of voltage supply for the device 7 (figure 1) and are split into an analog and a digital part. With regard to the inductive data transmission which represents an important part of the invention, it will now be demonstrated how two inductively connected coils permit communication between the measuring unit 1 and the recording unit 14. Based on the circuit diagram in figure 7 and the block diagram in figure 1, we shall analyse the situation that arises when the control unit 11 cuts the current arm responsible for operation of the analog part. In this situation the considered resistance Req will increase, and in consequence the equivalent resistance R2 will also increase. This change in the equivalent resistance R2 can be used to achieve an inductive data transmission between the measuring unit 1 and the recording unit 14.

In order to see how the current amplitude I1 in the recording unit varies during the inductive current transmission, we shall replace the equivalent resistance R2 with Rx in the formula (1). The impedance Z1 in the recording unit will then be expressed by:

$$Z_1 = (R_1 + k^2 R_x \frac{L_1}{L_2}) - j\omega_r k^2 L_1 \quad (5)$$

Assuming that the coils 8 and 17 are identical, a fulfilment of $R_x^2 \gg (\omega_r L_2)^2$ will imply that $R_x^2 \gg (\omega_r L_1)^2$ is fulfilled. Thus the impedance Z1 will appear substantially resistive, and can therefore be considered as a series connection of the resistance R1 and an equivalent resistance $k^2 R_x$ originating in the measuring unit. Since the expression $k^2 R_x$ is definitely of the same order as R1 for the cases under consideration, we shall therefore also be able to substantially alter the current in the recording unit 14 by varying the coupling coefficient k or the resistance Rx. This will be one of the objects of being able to connect to and disconnect from the current arms responsible for the operation of the analog part. By varying the equivalent resistance R2 between two different resistance values, it will in fact be possible to achieve an amplitude modulation of the current in the recording unit 14. According to the invention this amplitude modulation will be able to be employed for transmitting digitised pressure values from the measuring unit 1 to the recording unit 14.

Figure 8 illustrates the difference in the current amplitude Idiff with switching coefficients k in the range 0.2-0.4 (this will be the relevant range for our example).

As can be seen in the figure, the change in the current amplitude is of the order of approximately 10mA, a difference that can easily be detected with today's technology.

5 The collecting condenser Cd (figure 7) will represent a limiting factor in the projected current modulation during connection and disconnection of the analog arm. Cd will be decisive for the length of the edges in the modulated current in the recording unit 14. The number of digital pulses and thereby the number of pressure measurements that can be performed per time unit will therefore also be determined by Cd. This will favour obtaining a value for Cd that is as low as possible.

10 However, Cd will also be able to "smooth out" ripple voltage in the voltage Vs, and should therefore be as large as possible. This is a case where a compromise has to be made.

The above-mentioned example with connection and disconnection of the analog arm is intended as an illustration of the invention, since it would be more expedient to

15 use a separate modulating resistance (as a part of the unit 10, figure 1) in the measuring unit 1 to undertake corresponding changes in the equivalent resistance R2.

A concrete embodiment of some parts of the invention will now be described in order to provide the best possible illustration of how the invention works.

20 Figure 9 is a circuit diagram for energy transmission between two coils. In the diagram it can be seen that an inductive voltage supply generates an alternating voltage which is rectified and stabilised to 3.3V and 5V. The 5V voltage source can be switched off by the digital signal "ANALOG" on 3.3V. By means of the inductive connection, the result is transmitted by power modulation in the

25 measuring unit. The signal "DATA" controls the switch SW_MOD which switches a resistance off and on.

Figure 10 illustrates a circuit diagram for reading the sensor 5. VANALOG and VDIG obtain voltage from the voltage supply in figure 9. The circuit has adjustments of offset and amplification (AD627). The signal is digitised by a 12bit

30 analog to digital converter (ADS7816). The result is Manchester encoded in the control unit, which transmits the result serially on the digital line "DATA".

Figure 11 illustrates a 12bit digital to analog converter DAC. The output signal from amplification and calibration, which varies between 0 and 5 for pressure between 0.8 and 1.8 bar, will be digitised here. By means of digitisation the result

35 becomes easier to transmit as well as being less influenced by noise. Once again it is important that the digitisation does not consume a lot of current and it has to work with unilateral voltage supply. In figure 11 the switches are PMOS BSS84

and NMOS BSN10. In order to achieve 12bit accuracy, a good operational amplifier and a comparator will be required.

Figure 12 illustrates a PCB layout for the recording unit board, while figures 13 and 14 illustrate a PCB layout for the measuring unit board, with a large and a small coil
5 respectively.

Figure 15 illustrates a PCB layout for the rectifier and the stabiliser, while figure 16 illustrates a PCB layout for the read-out board.

As mentioned previously, the processing and transmitting unit will control reading of the sensor and transmission of the result to an external receiver. The processing
10 and transmitting unit must start by itself as soon as the digital voltage is switched on. We have a one-way communication from the measuring unit to the recording unit for transmitting the pressure value. Thus there are no command signals such as, for example, a reset signal from the recording unit to the processing unit. In this embodiment of the invention the processing unit can start up in arbitrary conditions,
15 but it is also possible to design it so that it generates its own reset signal. As stated, the processing unit will control the reading and it has four phases:

- Phase 1 Start: the switch for the voltage source for the analog circuits is switched on. After the voltage source has been switched on, it and the analog
20 circuits will need a little time to stabilise. The processing unit waits 64 clock periods before transition to the next phase.
- Phase 2 Digitisation: the analog to digital converter digitises the voltage and the result is stored in a register (storage unit 12). The processing unit controls digitisation with control signals to the analog to digital converter.
- Phase 3 Start transmission: the analog voltage source is switched off again
25 and the processing unit now waits until everything is stabilised.
- Phase 4 Stop transmission: the result from the analog to digital converter is transmitted to the recording unit. After phase 4 the sequence begins anew with phase 1.

The actual VHDL program for the processing unit is divided into three bits: a main
30 program that controls the four phases, a program for the digitisation and a program for the transmission of the data. The main program consists of a status machine as illustrated in figure 17.

In addition to the status machine, the main program has a counter that is used to determine waiting period one and two in the status machine. The counter is also
35 used to make a clock signal and counter for the two other units digitisation and transmission. "DIG_RDY" in figure 17 is a Boolean signal from the VHDL unit

digitiser which is true when it is finished with a digitisation and the data are available. The same applies for "SEND_RDY" which is true when the VHDL unit transmitter has transmitted all the data. The output signal "ANALOG" is the control signal to the switch which switches the analog voltage source on or off.

5 "ANALOG" is 0V in the conditions "Start" and "Digitise", so that the analog voltage source is on in these conditions. "DIG_EN" is the signal that starts the VHDL unit digitiser, while "SEND_EN" starts the VHDL unit transmitter. The VHDL unit digitiser controls the reading of the analog to digital converter, and this converter requires two digital control signals, clock "DCLOCK" and shutdown
10 "SHDN". The converter transmits the result serially on the output "DOUT" where each bit is clocked out when the edge is falling. The VHDL unit digitiser reads in the result on the input "DIN" when the edge of the clock is rising "DCLOCK" since the signal is stable when the edge is rising.

The task of the VHDL unit transmitter is to control the transmission of the data. In
15 order to simplify the transmission to an external receiver, the data are encoded with a Manchester encoding. Manchester encoding always has level change in the middle of a bit cell, where a bit cell is the same length as the clock period with which the data are transmitted. The level change is from high to low when the data bit transmitted is "1" and level change is from low to high when "0" is transmitted. The
20 data stream that is transmitted thereby receives a guaranteed varying signal since there is always a level change in a bit cell. Level change always occurs at the same point with an interval of a clock period and an external receiver (recording unit) can thereby retrieve the clock information. The shortest level period will be a half clock period and the longest level period will be a whole clock period. It is important to
25 remember this during the modulation where we must adapt the transmitter's clock so that the shortest level period is easily visible to a receiver circuit.

The code for the main program, digitiser unit and transmitter unit can be found in the attachment at the end of the description.

With reference to figure 18, therefore, the system according to the invention will
30 comprise a measuring unit 1 and a recording unit 14, where the recording unit 14 may advantageously comprise a small hand-held instrument driven by portable batteries (energy source 18 in figure 1). These will permit excitation of the series resonance circuit in the recording unit 14 by amplifying the signal from a high-frequency oscillator 20. The coil 17 in the series resonance circuit will build up a
35 voltage over the coil 8 in the measuring unit 1. After rectification and stabilisation this voltage will be able to be employed for operation of the measuring unit 1. The measuring unit 1 will be responsible for excitation of the sensor 5, digitise the sensor's 5 measuring signals and transmit the data signals to the recording unit 14 via impedance modulation in the unit 10. The measuring unit, moreover, will be
40 able to be divided into an analog part and a digital part. The digital part comprises

the processing and transmitting device 7 for controlling the actual read-out sequence together with the data transmission. As stated, the analog part will be responsible for excitation of the sensor and for A/D conversion of the measuring signals. Subsequently (i.e. after the measurement) the analog part will be
5 disconnected and the digital pressure values will be transmitted by means of a modulation resistance 10. The modulation resistance 10 provides an amplitude modulation of the current in the recording unit 14, and this will be capable of recreating the digitised pressure value based on the current signals by means of a digital signal processing 19. The recording unit 14 will further comprise a pressure
10 sensor 21 for introducing a reference pressure.

The invention permits a transmission rate of 116 measurements per second with a resolution of 0.30 mbar.

Thus the invention will differ from the prior art by permitting inter alia measurement of the brain pressure:

- 15
1. with a micro-electro-mechanical system sensor,
 2. within the brain, and with a
 3. wireless transmission and
 4. without batteries at the measuring location.

In addition, the system according to the invention is:

- 20
5. intended for long-term use,
 6. suitable for monitoring in the home,
 7. and easily adaptable for transmitting signals (telemetry) via a mobile network to hospitals, etc.

Even though apparatus exists for wireless transmission of data without batteries at
25 the measuring location, these known systems are not suitable for measuring within the brain over a long period. The measurement within the brain has hitherto only been performed following brain surgery, in periods of up to a week, with wires through the skin, in hospital.

The invention therefore represents a clear improvement on the prior art. The
30 invention leads to greater flexibility and reliability, while simultaneously extending the area of application.

PATENT CLAIMS

1. A measuring unit (1) for measuring pressure and for wireless transmission of measuring signals, comprising a catheter (2) with a distal end (3) and a proximal end (4), a device (6) for transmitting the sensor signal to a processing and
5 transmitting device (7), where the processing and transmitting device comprises an energy transmitter in the form of a coil (8) for wireless transmission of processed measuring signals and energy supply signals,
characterised in that the measuring unit comprises a pressure sensor (5) mounted on the catheter's distal end.
- 10 2. A measuring unit according to claim 1,
characterised in that the sensor (5) is a piezoelectric or capacitive sensor.
3. A measuring unit according to one of the preceding claims,
characterised in that the processing and transmitting device is located near the catheter's proximal end (4).
- 15 4. A measuring unit according to one of the preceding claims,
characterised in that the measuring unit's processing and transmitting device (7) further comprises:
- an analog to digital converter (9) connected to the pressure sensor for converting the sensor's measuring signals,
20 - a modulation unit (10) for modulating a pressure data signal on the basis of the digital measuring signals,
- a control unit (11) for controlling read-out and conversion of the measuring signals, wireless transmission of the data signals and energy transmission,
- a storage unit (12) for storing control orders and necessary parameters,
25 - a power supply unit (22) for providing a power supply signal based on the coil's (8) energisation signal.
5. A measuring unit according to claim 4,
characterised in that the modulation unit (10) comprises an adjustable resistance (13).
- 30 6. A measuring unit according to one of the preceding claims,
characterised in that the catheter's proximal end is adapted to be placed within the brain of a mammal, preferably a person, for measuring intracranial pressure.
7. A recording unit (14) for measuring signals, comprising a signal receiver (15) for wireless receipt of pressure signals and an energy transmitter (16) for
35 wireless transmission of energy, where the transmitter (15) comprises an inductive coil (17), and the receiver (16) comprises an inductive coil (17), and where the

device further comprises an energy source (18) connected to the transmitter (15) for delivering the energy to the energy transmitter (16) together with a processing and display unit (19) connected to the transmitter and to the receiver.

8. A recording unit according to claim 7,
5 characterised in that it comprises a single coil, common to the transmitter and the receiver.

9. A system for measuring pressure and for wireless data and energy
transmission between a measuring unit (1) and a recording unit (14), where the
measuring unit (1) and the recording unit (14) can be inductively interconnected,
10 characterised in that it comprises a measuring unit (1) according to one of the
claims 1-7 and a recording unit (14) according to one of the claims 7-8.

10. A system for measuring intracranial pressure or pressure in joints,
musculature or other tissue in a mammal,
characterised in that it comprises a system according to claim 9.

15 11. A method for measuring intracranial pressure by means of a measuring
system as indicated in claim 9.

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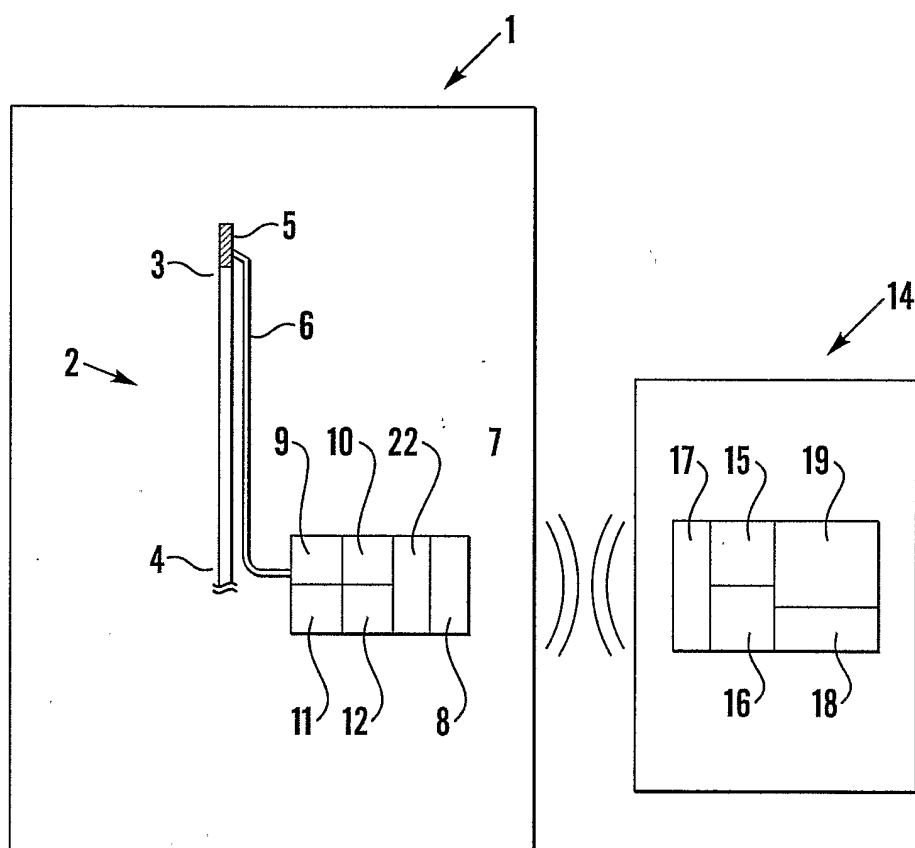


Fig. 1

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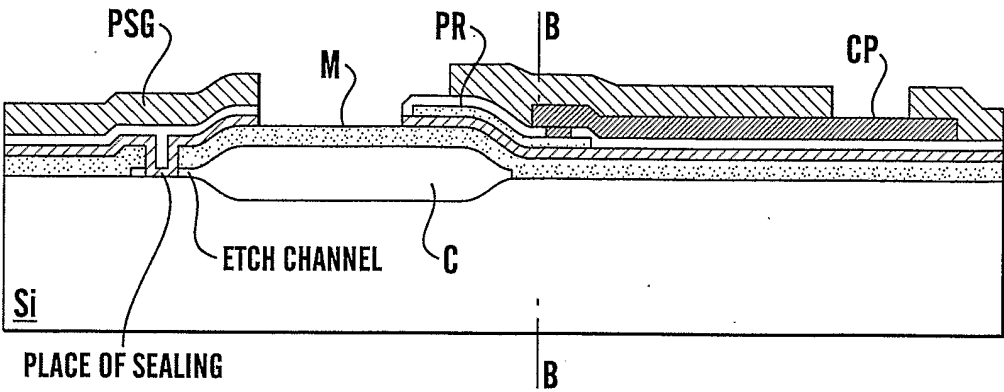


Fig.2A

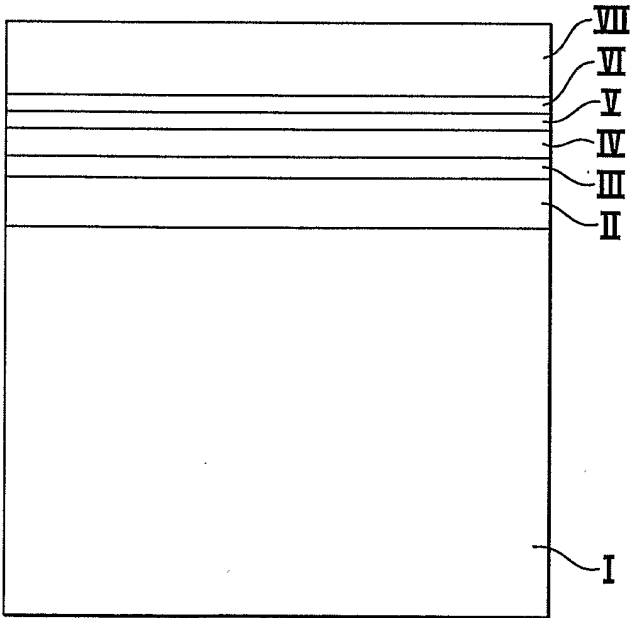


Fig.2B

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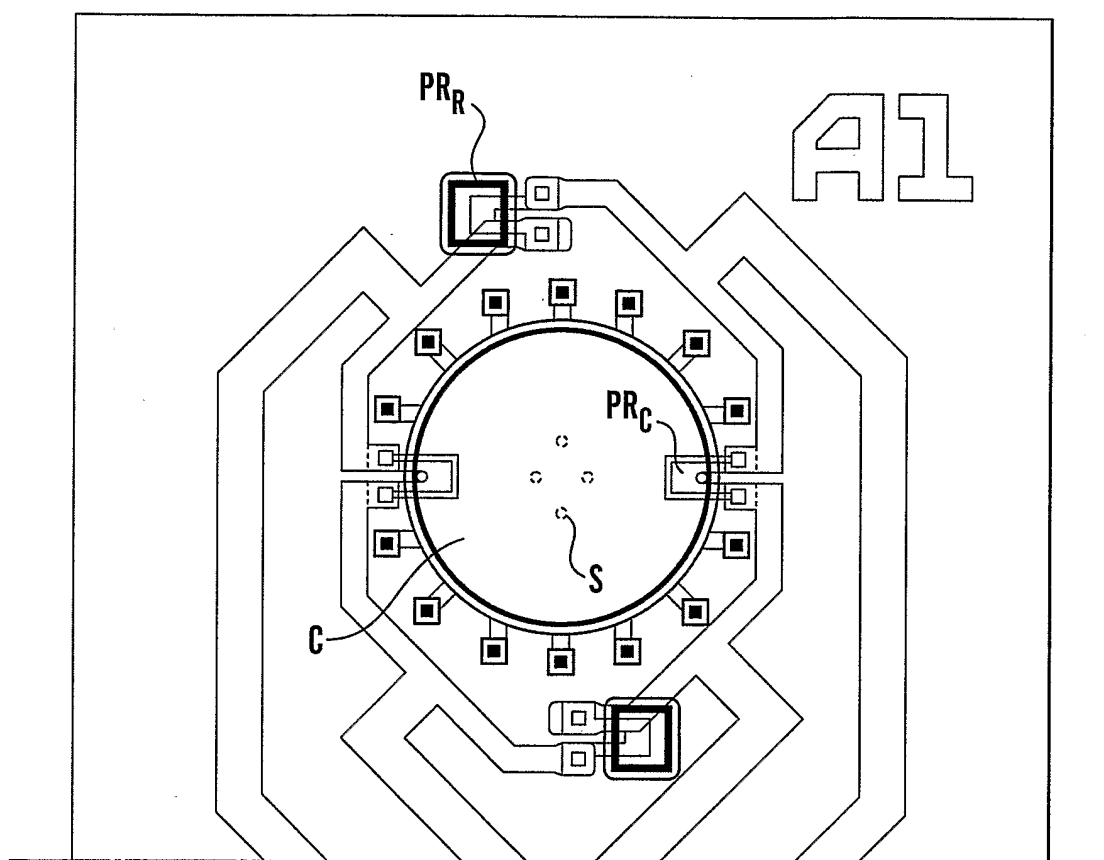


Fig.2C

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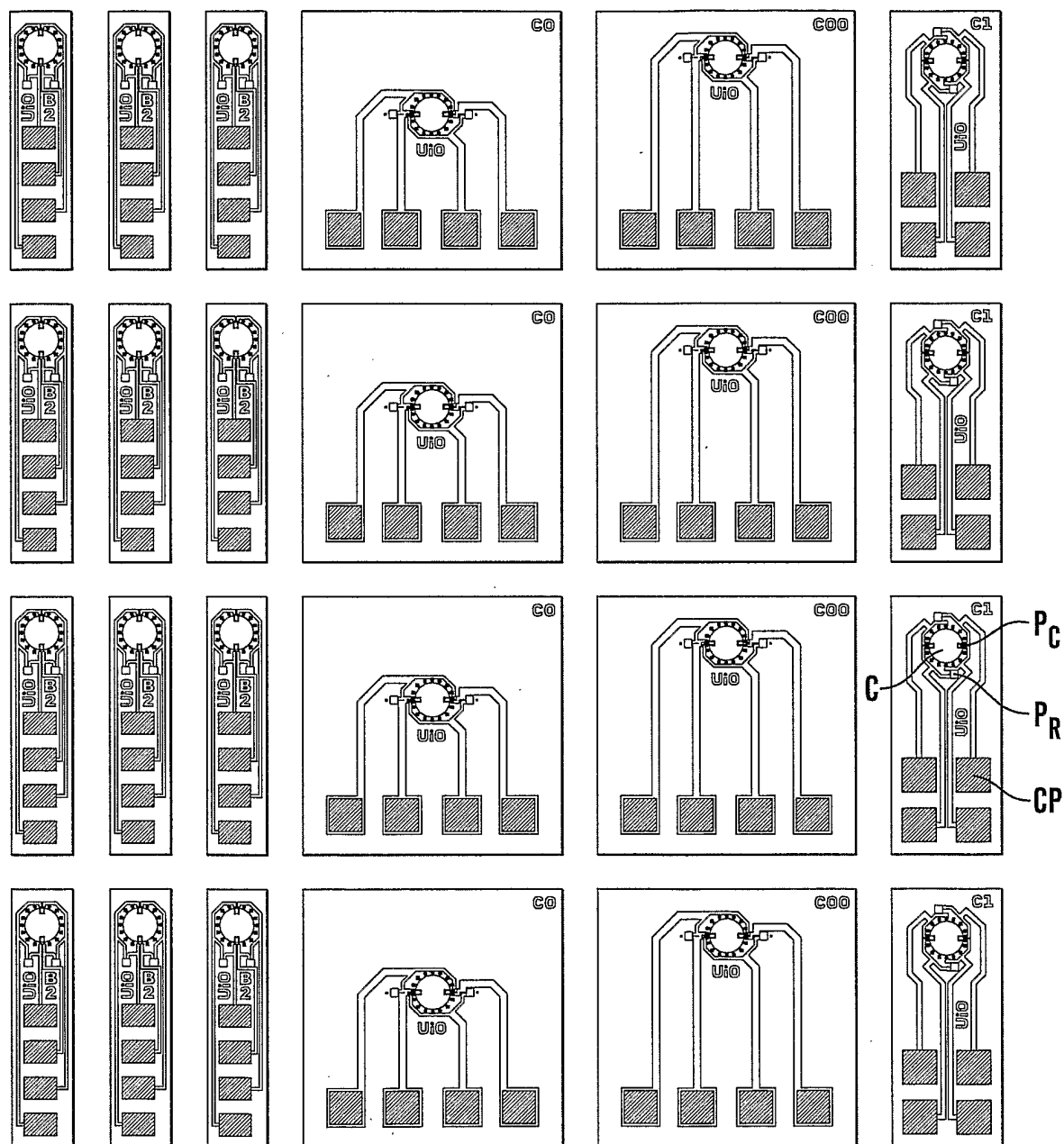


Fig. 2D

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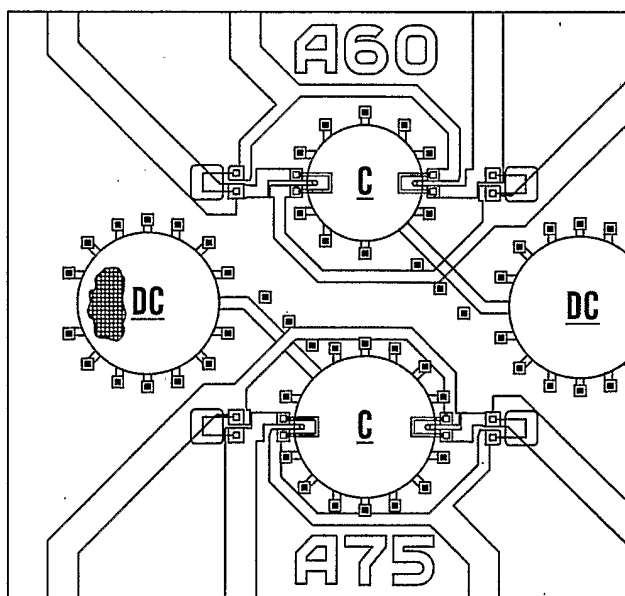
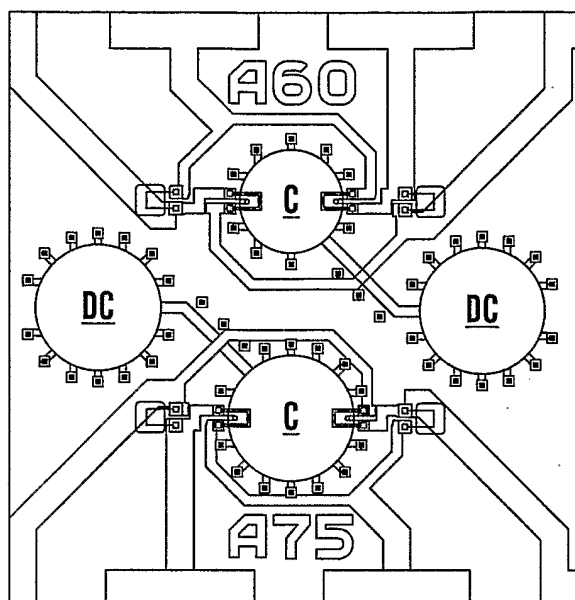


Fig.2E

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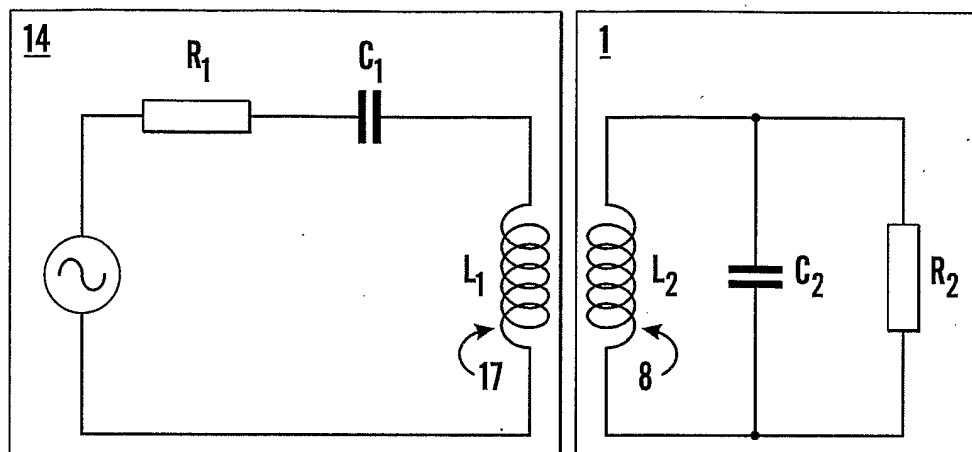


Fig. 3A

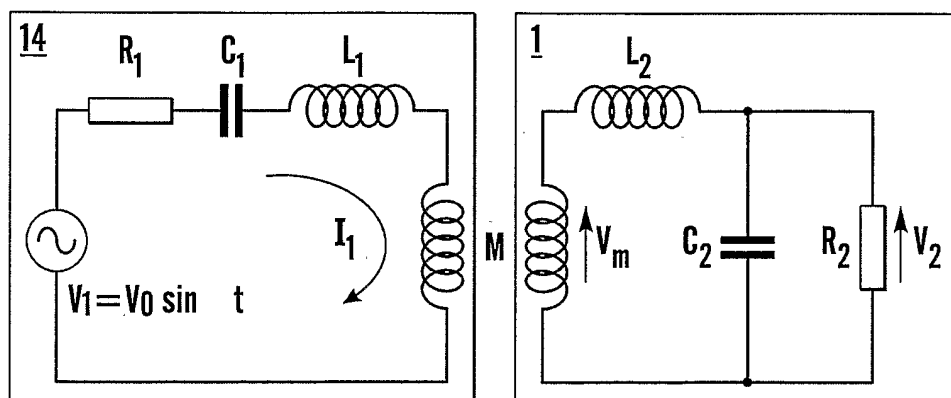


Fig. 3B

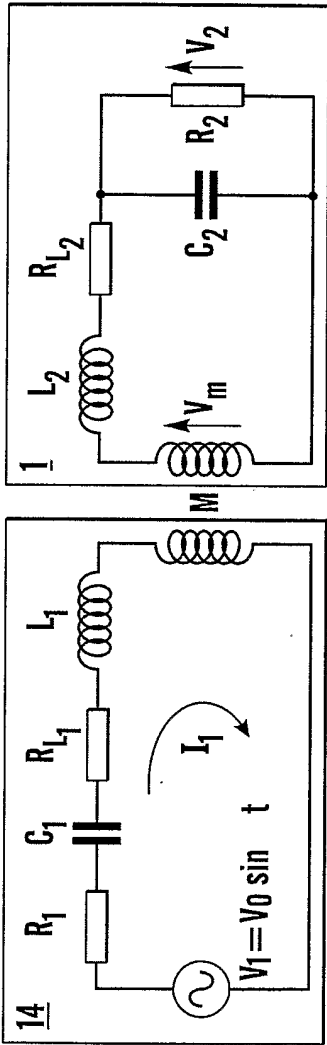


Fig. 4

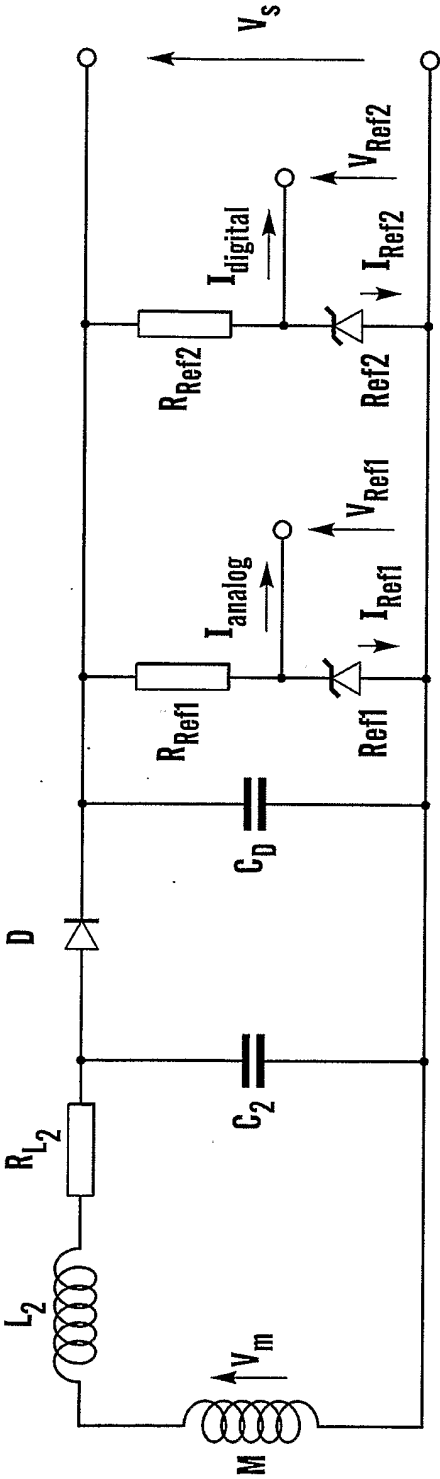


Fig. 7

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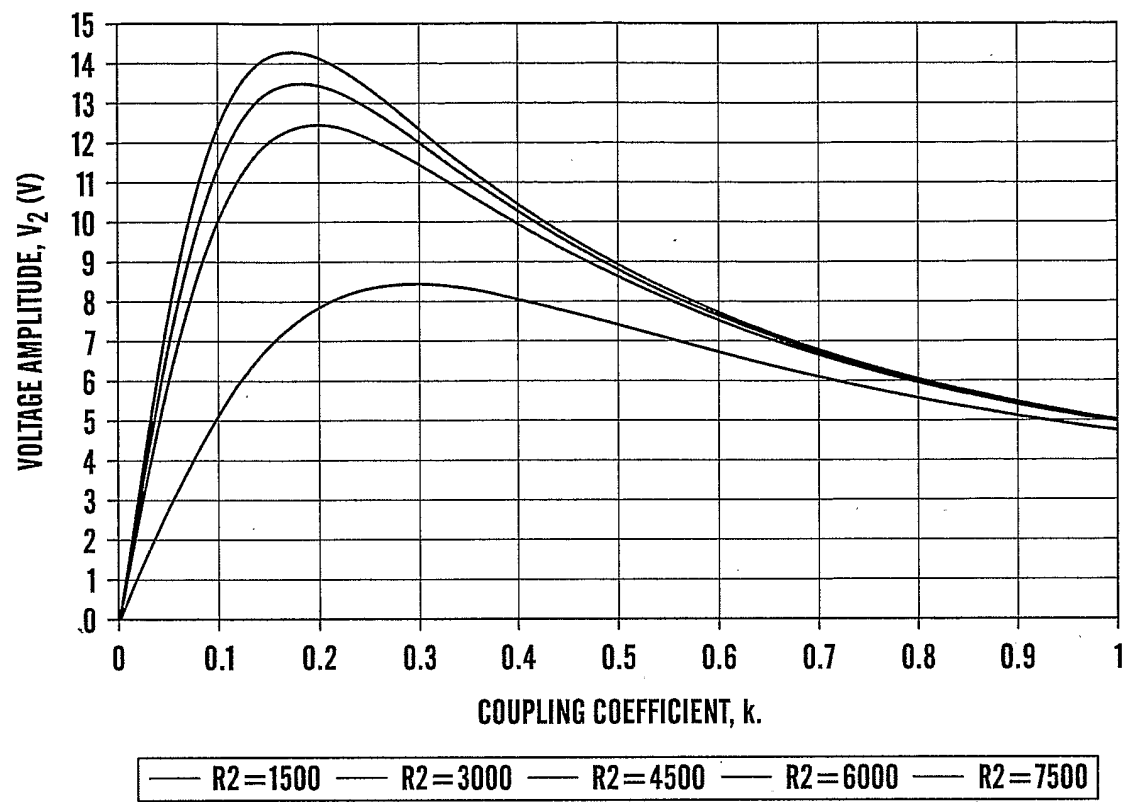


Fig.5

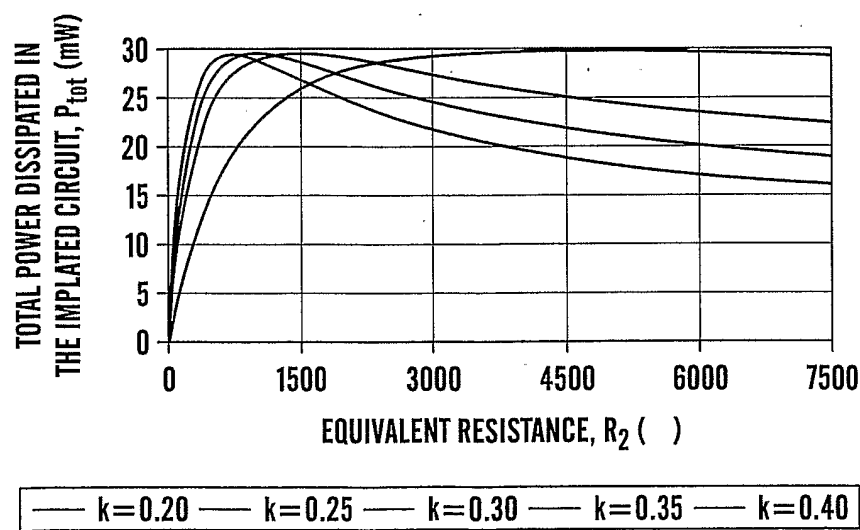


Fig.6

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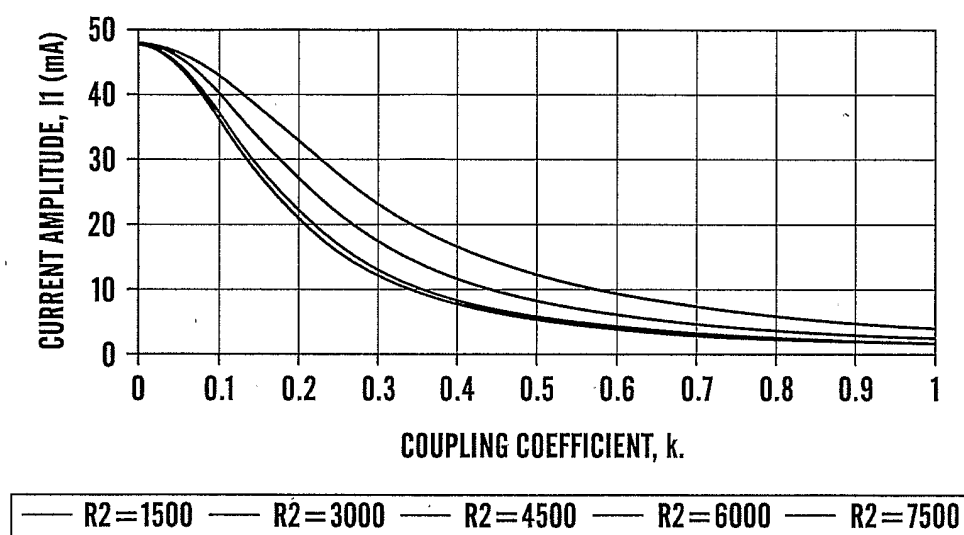


Fig.8

10/17

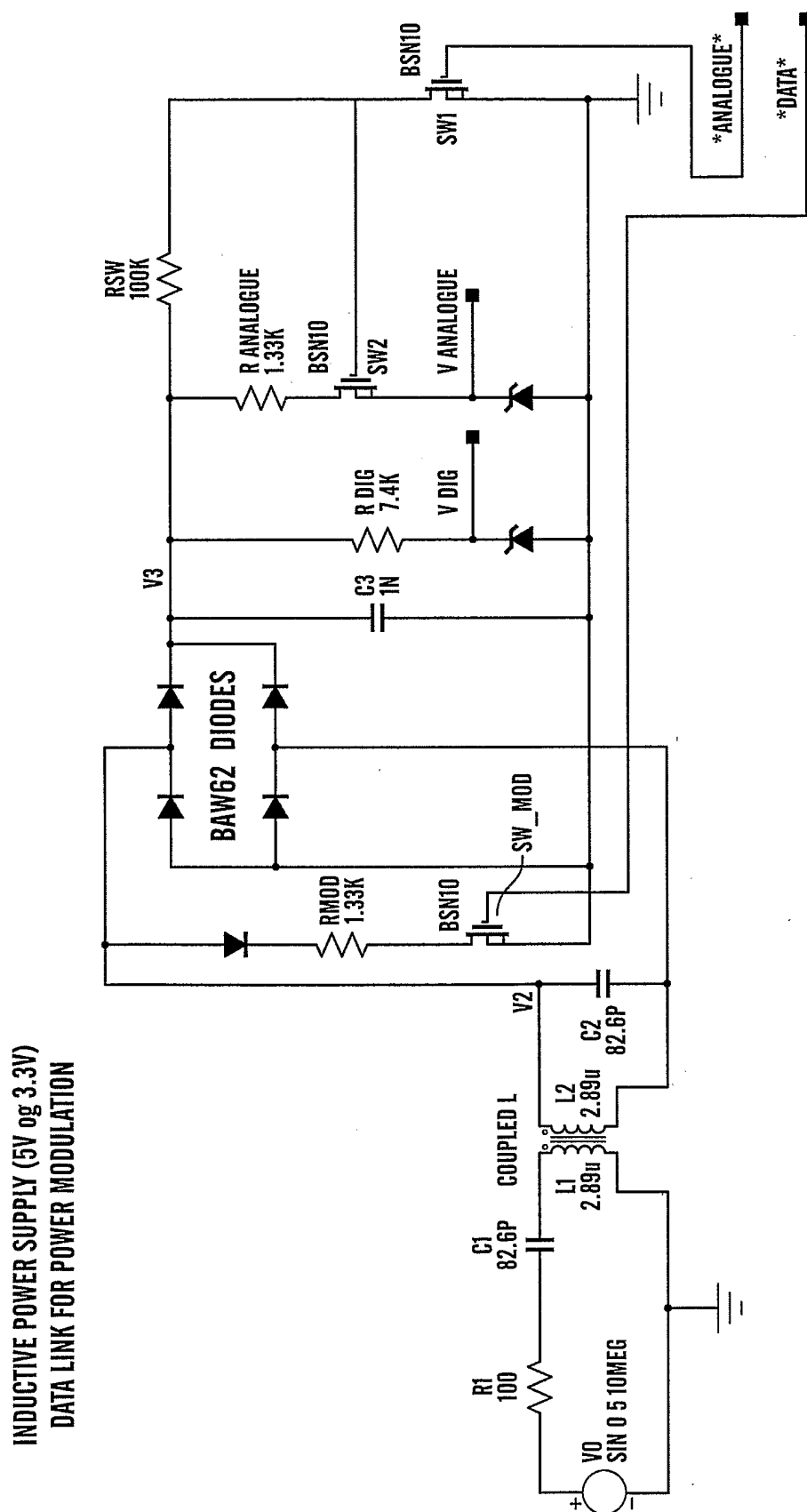


Fig. 9

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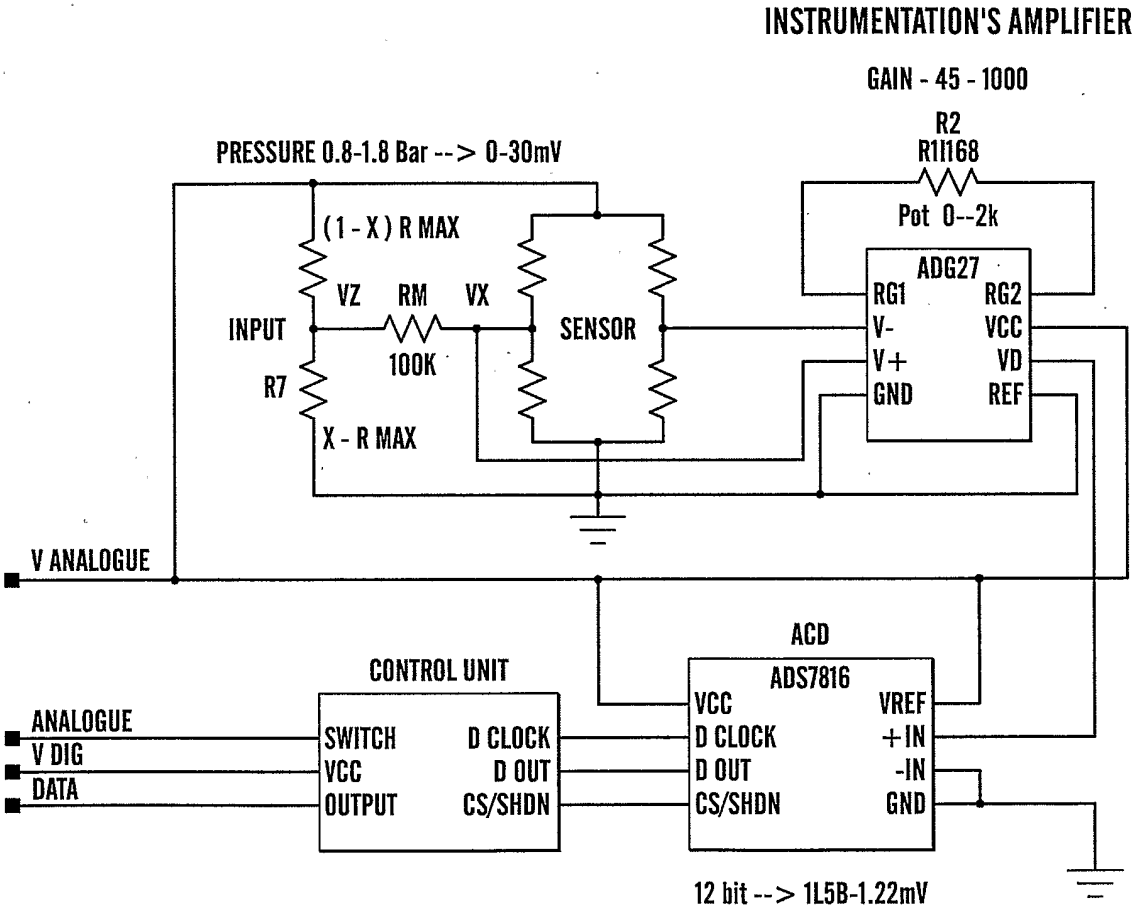


Fig.10

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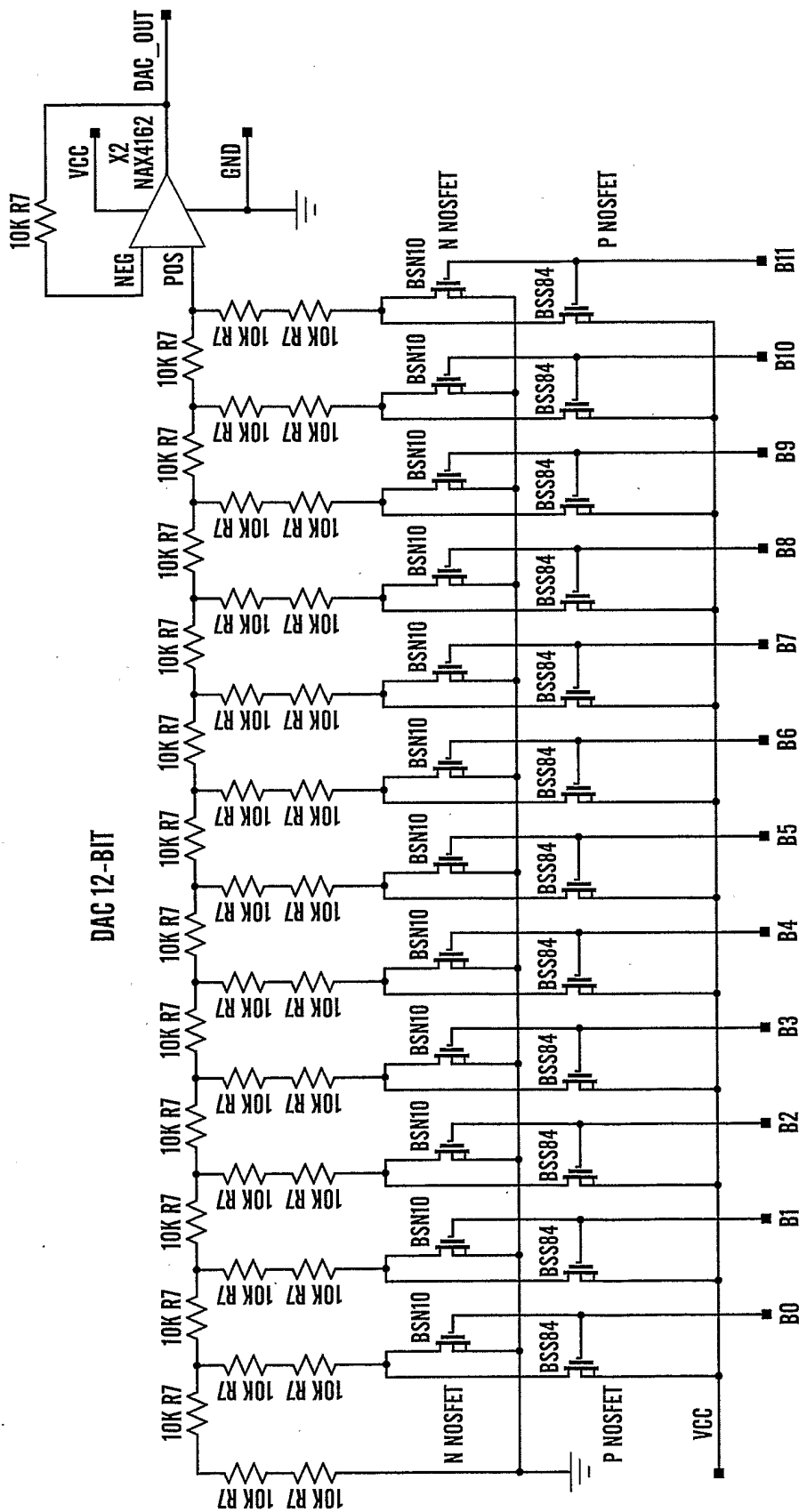


Fig.11

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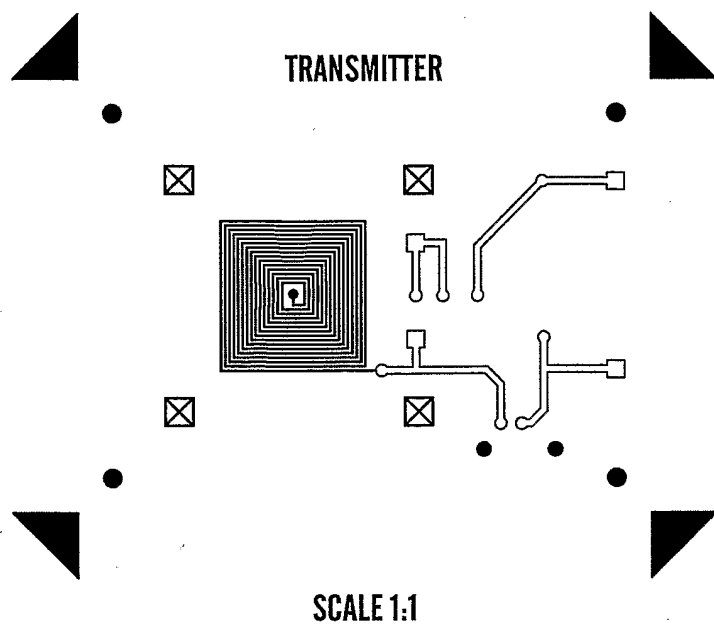


Fig. 12

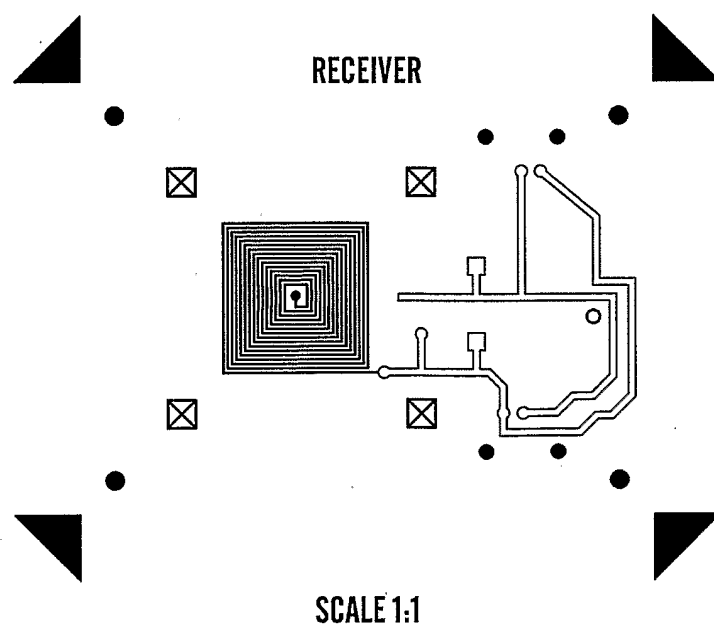


Fig. 13

14/17

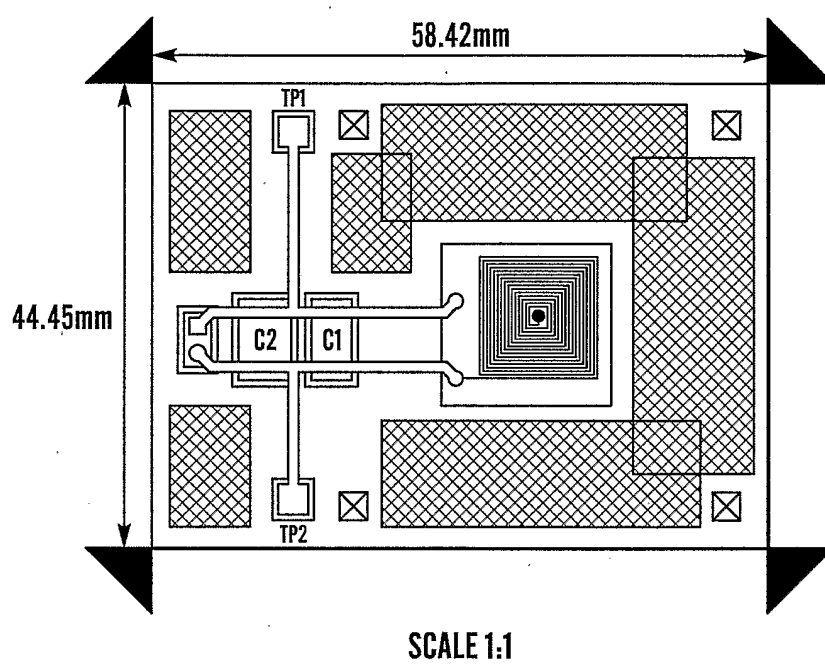


Fig. 14

15/17

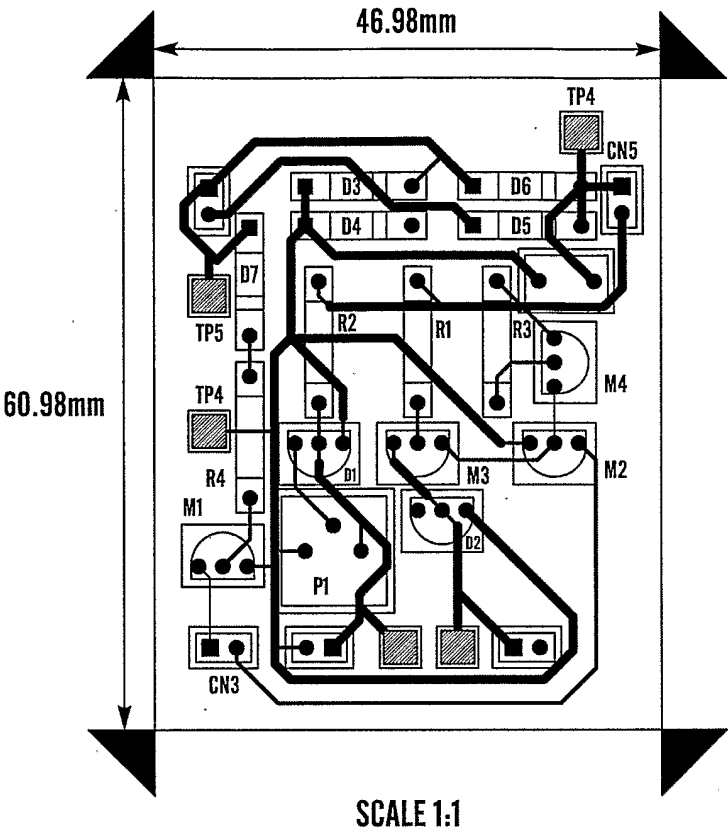


Fig. 15

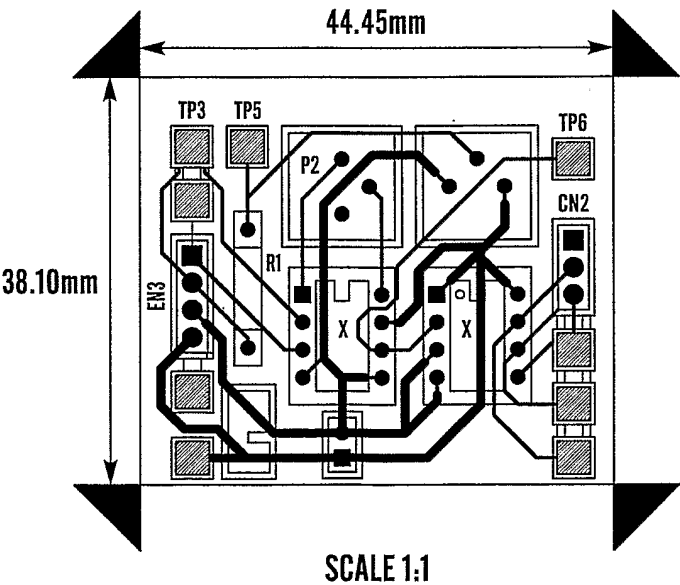
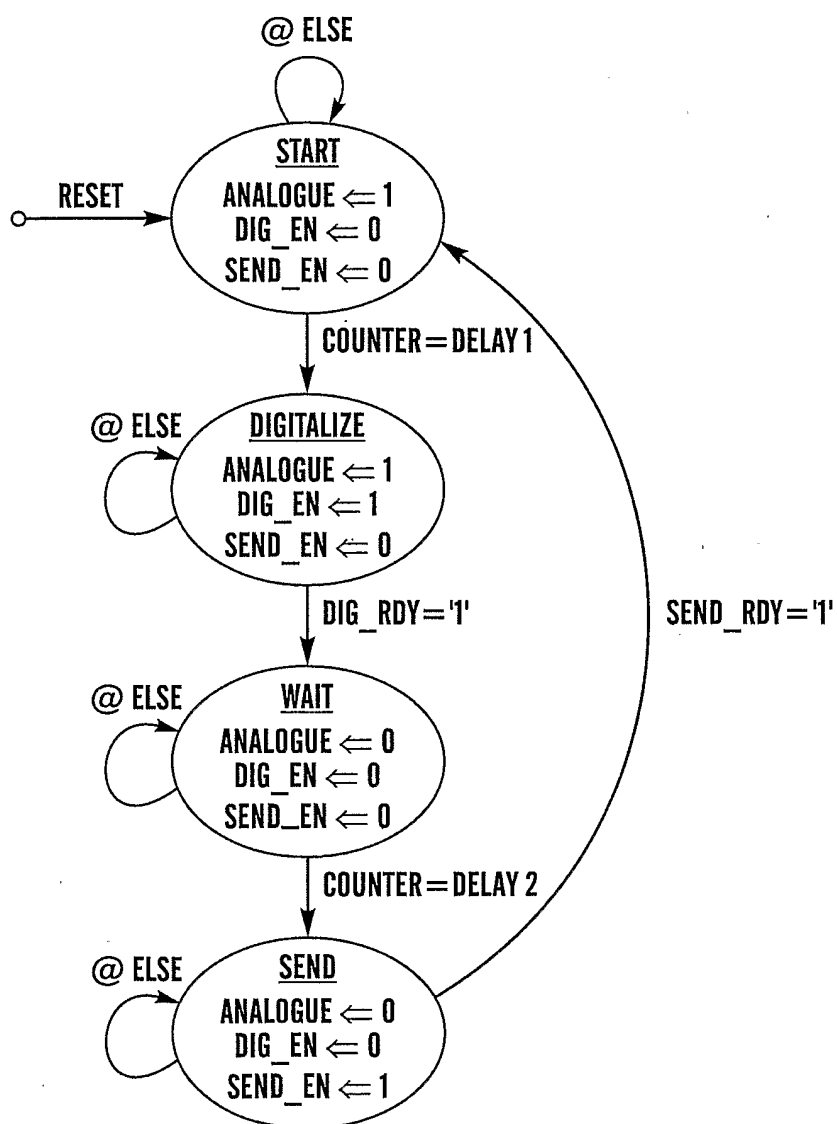


Fig. 16

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THE STATUS MACHINE, "<=" MEANS IS ASSIGNED,
WHILE "=" IS TEST THAT RETURNS FALSE OR TRUE.

Fig. 17

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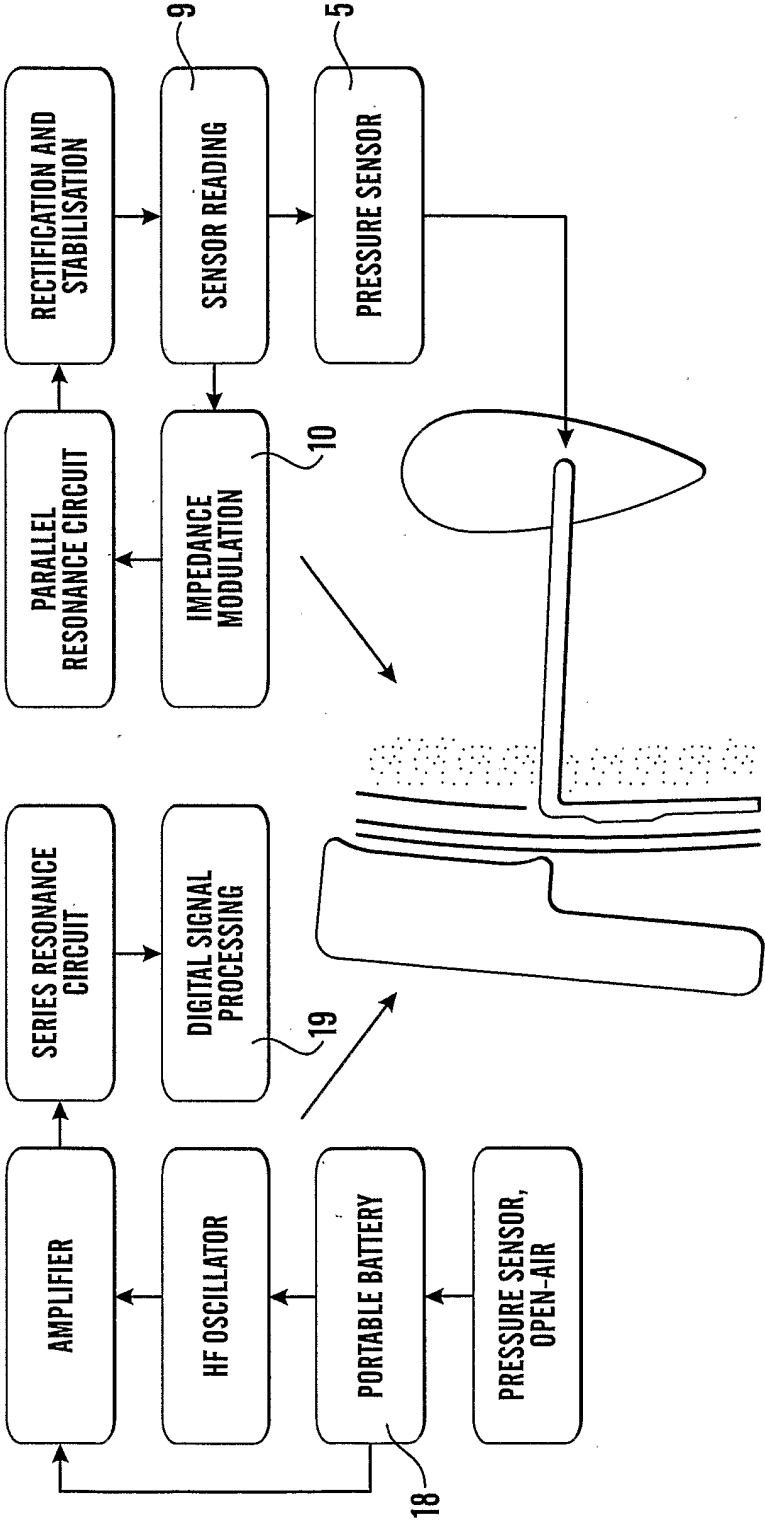


Fig. 18

INTERNATIONAL SEARCH REPORT

International application No.

PCT/NO 2003/000225

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 5/00, A61B 5/03

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)

IPC7: A61B, A61M

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

SE,DK,FI,NO classes as above

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

EPO-INTERNAL, WPI DATA, PAJ, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 19654990 A1 (LEONHART, STEFFEN ET AL), 18 June 1998 (18.06.1998), column 3, line 8 - line 59; column 6, line 33 - column 7, line 34, figures 1,2	1,3,4,6
Y	--	2,7-11

☒ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:	"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
"A" document defining the general state of the art which is not considered to be of particular relevance	"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
"E" earlier application or patent but published on or after the international filing date	"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
"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)	"&" document member of the same patent family
"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	

Date of the actual completion of the international search	Date of mailing of the international search report
5 March 2004	09-03-2004

Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Bo Gustavsson/mj Telephone No. +46 8 782 25 00
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Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/NO 2003/000225

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	T. Eggers et al "ADVANCED HYBRID INTEGRATED LOW-POWER TELEMETRIC PRESSURE MONITORING SYSTEM FOR BIOMEDICAL APPLICATIONS" CONF-Proceedings IEEE Thirteenth Annual International Conference on Micro Electro Mechanical Systems (Cat. No. 00CH36308), Proceedings IEEE Thirteenth Annual International Conference on Micro Electro Mechanical Systems, Miyazaki, Japan, 23-27 Jan. 2000 AN 6636042	2
A	--	7-11
Y	B. Flick et al "STUDY AND DEVELOPMENT OF A PORTABLE TELEMETRIC INTRACRANIAL PRESSURE MEASUREMENT UNIT" Proceedings - 19th International Conference - IEEE/EMBS 30 Oct.-2 Nov. 1997 Chicago, IL USA. Vol. 3, Pages 977-980 See the whole document	7-11
A	--	
A	WO 0105302 A1 (NEFF, SAMUEL, R.), 25 January 2001 (25.01.2001), See the whole document	1-11
A	--	
A	US 5704352 A (GERALD F. TREMBLAY ET AL), 6 January 1998 (06.01.1998), See the whole document. Cited in the application.	1-11
	-- -----	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/NO 2003/000225

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.: **11**
because they relate to subject matter not required to be searched by this Authority, namely:
see next page
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:

1. ☐ 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 fee, this Authority did not invite payment of any additional fee.
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.
☐ No protest accompanied the payment of additional search fees.

Claim 11 relates to a diagnostic method practised on the human or animal body. The method of claim 11 comprises in-vivo measurements in order to determine the intracranial pressure in a human or animal body using a telemetric implant. This necessarily requires medically skilled staff and the method is to be carried out under the responsibility of a doctor. Thus, the International Search Authority is not required to carry out an international search for these claims (Rule 39.1(iv)). Nevertheless, a search has been executed for claim 11 based on the technical features of the measuring system.

INTERNATIONAL SEARCH REPORT

Information on patent family members

24/12/2003

International application No.

PCT/NO 2003/000225

DE	19654990	A1	18/06/1998	DE	19643782	C	27/08/1998
WO	0105302	A1	25/01/2001	AU	5926600	A	05/02/2001
				CA	2378044	A	25/01/2001
				EP	1202666	A	08/05/2002
				US	6165135	A	26/12/2000
US	5704352	A	06/01/1998	NONE			