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(54) **IMPLANTABLE PRESSURE SENSOR**

IMPLANTIERBARER DRUCKSENSOR

CAPTEUR DE PRESSION IMPLANTABLE

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Description**Related Application**

[0001] This application claims priority from U.S. Provisional Patent Application Serial No. 61/643,988, filed 08 May 2012.

Field of the Invention

[0002] The present invention relates to systems and methodologies for diagnosis of medical conditions, and, in particular, is directed to systems and methods in vivo pressure measurement.

Background of the Invention

[0003] Physiological pressure measurements are useful for medical diagnosis and monitoring in many medical disciplines, such as cardiology, pulmonology, gastroenterology, and urology. Blood pressure is one of the few physiological pressures that can be measured noninvasively with a sphygmomanometer, but other pressures are typically measured via catheters, either connected to transducers outside the body or by micro-transducers mounted on the tip.

[0004] "Wireless micromanometer system for chronic bladder pressure monitoring", Paul C Fletter et al, 2009 Sixth International Conference on Networked Sensing Systems (INSS 2009), 17 June 2009, describes a wireless system to monitor urinary bladder pressure comprising an implantable device with an external receiver and wireless battery charger. "Low-Power Wireless Micromanometer System for Acute and Chronic Bladder-Pressure Monitoring", Steve J A Majerus et al, 2011 IEEE Transactions on biomedical engineering, 1 March 2011, describes an implantable bladder pressure sensing system with details of dynamic powering of the implanted sensor elements.

Summary of the Invention

[0005] In accordance with an aspect of the present invention, there is provided an in vivo sensor assembly according to claim 1.

[0006] In accordance with another aspect of the present invention, there is provided a pressure monitoring system according to claim 9.

[0007] In accordance with yet another aspect of the present invention, there is provided a method according to claim 14.

Brief Description of the Drawings

[0008] The foregoing and other features of the present invention will become apparent to those skilled in the art to which the present invention relates upon reading the following description with reference to the accompanying

drawings, in which:

FIG. 1 illustrates a pressure sensing system in accordance with an aspect of the present invention; FIG. 2 illustrates one implementation of a sensor assembly in accordance with an aspect of the present invention;

FIG. 3 illustrates an exemplary amplifier assembly in accordance with an aspect of the present invention;

FIG. 4 is a chart illustrating power control signals for various components of an implanted device as a function of time over a one millisecond active interval; and

FIG. 5 illustrates a signal-processing method for use in monitoring an output of an in vivo pressure sensor for one or more predetermined events in accordance with an aspect of the present invention.

Detailed Description of the Invention

[0009] FIG. 1 illustrates a pressure sensing system 10 in accordance with an aspect of the present invention. The system 10 comprises an external base unit 20, comprising a radio frequency (RF) receiver 22, a signal processor 24, and a recharger 26 for transmitting RF energy, and an implanted device 30. The RF receiver 22 is configured to receive data communicated from the implanted device, and is specifically configured to capture very short transmission pulses from the implanted device. It will be appreciated that the external base unit 20 can include further devices (e.g., for detecting pressure in the ambient environment) that are not shown in FIG. 1.

[0010] The signal processor 24 evaluates the received pressure data to extract useful information from electrical and biological noise. The recharger 26 uses a Class-E amplifier and a tuned transmitting coil to inductively transmit RF energy to the implanted device 30. In one implementation, the recharger 26 uses less than ten watts of external RF power to provide, at a maximum separation of twenty centimeters, seven hundred microwatts of power to the implanted device 30. The base unit 20 uses inductive antennas to receive pressure telemetry from the implanted device 30 and to send power and commands to an implanted battery 32 and a power control unit 34, respectively. In one implementation, the receiver 22 is portable and battery powered, but wireless recharging through the recharger 26 utilizes alternating current (AC) line power.

[0011] The implanted device 30 can include devices for implementation with body tissue, such as organ walls, or within fluid filled cavities, such as the bladder, vertebral discs, or the subsrachnoid space. The implanted device 30 includes a pressure sensor 36 configured to determine a pressure in the region in which the device is implanted. In one implementation, the pressure sensor 36 is implemented as a microelectromechanical systems (MEMS) transducer. A signal conditioning component 38 ampli-

fies the output of the pressure sensor 36 and converts the pressure sensor output into a digital signal. An RF transmitter 39 packetizes the digital signal and transmits it to the RF receiver 22. In one implementation, each of the signal conditioning component 38, the RF transmitter 39, and the power control unit 34 are implemented on a single application-specific integrated circuit (ASIC) chip.

[0012] In accordance with an aspect of the present invention, the power control unit 34 can dynamically allocate power throughout the implanted device. Unlike standard low-duty-cycle sampling methods, the power control unit 34 does not simply gate power to the instrumentation and telemetry system, but instead operates as a "sample conveyer", in which various functions are provided with power only at points in an acquire/process/transmit cycle when they are needed to acquire, process, or transmit the data sample. It will be appreciated that this differs from a standard sleep mode, as various components are selectively deprived of power even during the active time of the device. Use of the "sample conveyer" technique greatly reduces the power consumption of the system, since circuits like the pressure sensor 36 and an analog-to-digital converter and front-end amplifier associated with the signal conditioning component 38 can be disabled after the sampled information has been passed to a next processing stage. The power usage of the system is dynamic, but the time-averaged current draw is far less than the peak.

[0013] It will be appreciated that receiving and processing a wireless signal from a low-power, *in vivo* device is not trivial even when the device is continuously transmitting in full-power mode. The pulse transmissions that are transmitted intermittently from an implanted device 30 in accordance with an aspect of the present invention provide an additional challenge. Accordingly, the receiver 22 has been designed to use a quadrature detector instead of a phase-locked loop as well as an intermediate frequency limiting amplifier with very fast signal strength detection. The receiver 22 can therefore lock onto a carrier tone in a few microseconds. Demodulation and decoding of the received signal is performed by a complex programmable logic device that checks for edges and glitches and uses majority vote algorithms for clock and data recovery. A microcontroller provides an interface to the event detector 24. In one implementation, the event detector 24 is implemented as machine executable instructions stored on a non-transitory computer readable medium and executed by an associated processor. For example, software running on a general purpose computer can be used to detect events as well as to store and display received signals.

[0014] In accordance with another aspect of the present invention, to improve the power-transfer efficiency, the sensing system 10 incorporates power status feedback. The recharge rate of the system 10 is determined by the amount of received energy. If the received energy is too large, the circuitry must dissipate the excess in the form of heat to avoid damage to the battery. Power

status feedback would enable the external recharger 26 to continuously know how much RF energy is actually making it to the implantable device, such that it would not transmit more energy than is needed. To this end, the power control unit 34 can determine if sufficient energy is being received to allow for a successful battery recharge and convey this information to the signal conditioning component 38. A single bit is provided into outgoing telemetry packets from the transmitter 39 to indicate whether the implant is receiving enough external RF power for successful battery recharge. If the received power is too low, the power status bit would be 0, indicating that the external RF recharger 26 should increase its transmitted power. If the power status bit remains at 1 for a predetermined length of time, the transmitted power can be gradually lowered until a 0 is received. This system functions automatically to maximize the efficiency of the wireless recharge method while minimizing patient exposure to strong electromagnetic fields.

[0015] In one implementation, the implanted device 30 is intended for long-term monitoring pressure within a bladder, either for diagnostic purposes or for providing feedback for various treatments, such as electrical stimulation, radiation, or pharmacology. For example, the system 10 can provide bladder pressure feedback for electrical stimulation bladder control systems as part of treatment for voiding dysfunction or urinary incontinence. This is particularly advantageous for spinal cord injured patients and other patient populations, such as those with multiple sclerosis, who have neurogenic bladder complications of neurological conditions. It is important for chronic bladder monitoring that the device not become a nidus for urinary stones, so in such implementations the implanted device can be being implanted submucosally into the wall of the bladder where it can monitor bladder pressures continuously and over the long term. In such a case, the implanted device 30 can include thin packaging and a flat broad shape.

[0016] In another implementation, the system 10 can be used during short-term monitoring of the bladder. The implanted device 30 would be inserted during an office visit, and the patient would go home with it and participate in activities of daily living that cause the incontinence and/or voiding dysfunction. The device would record data or transmit the data to a recorder worn outside the body continuously or when initiated by patient activation. The patient would then return to the doctor's office in a few days or a week to have the device extracted and the data read. It is likely that any submucosal implant will irritate the bladder for a few days or a week after implantation. Therefore a short-term implant whose purpose is diagnostic should not be implanted submucosally as it will change the state of the bladder it is intended to measure and diagnose. Since it is in the bladder for such a short duration, it is not likely to become a nidus for stones in that time.

[0017] In a short-duration diagnostic implementation of the system, the implanted device is configured to float

in the bladder so as to not become a plug during voiding. One embodiment of the short-duration device would not have a battery on the device itself but would be powered by an external device that would also record the data. The housing for the electronics in the short-duration device would be designed to increase buoyancy of the device. The device itself could be inflated with a lighter than water substance after insertion through the urethra, or it could be constructed of a material that would expand after insertion through the urethra. One configuration of the short-duration pressure monitoring device would include measurement of bladder volume, which may assist in diagnosis of type of incontinence and/or voiding dysfunction and could better guide treatment.

[0018] Both the chronic and the short-duration devices are envisioned to be implanted using a cystoscope, standard in urology clinics and hospitals. The short-duration device would be extracted also using a cystoscope. The material used to inflate the balloon could be extracted and the device extracted once reduced in size. Alternatively, material that expanded after insertion could be contracted once again, and the device would be extracted through the urethra using the cystoscope. An alternate embodiment would utilize an application-specific insertion and extraction device which could be developed to meet the specific needs of either the chronic or short-duration device.

[0019] FIG. 2 illustrates one implementation of a sensor assembly 50 in accordance with an aspect of the present invention. In the illustrated implementation, the sensor assembly 50 is intended for submucosal implantation within a human bladder, although it will be appreciated that systems in accordance with the present invention can be suitable for use in other organs, as well as in non-humans or other closed systems. The illustrated sensor assembly 50 includes a microbattery 52 and associated circuitry so that it can be recharged wirelessly and wirelessly transmit continuous pressure telemetry. The sensor 50 is sized so it can be inserted into a human bladder via the urethra and implanted into a submucosal location with either a cystoscope or an application specific insertion tool. After healing, the mucosal layer is strong enough to securely retain the sensor assembly 50, and lumen pressure can be accurately measured through the urothelium. The applications for pressure monitors are multiple and include diagnosis as well as monitoring and feedback to various treatments, such as electrical stimulation, radiation, or pharmacology. In one implementation, the sensor assembly 50 can provide bladder pressure feedback for electrical stimulation bladder control systems.

[0020] Electrical stimulation of nerves can arrest unwanted reflex bladder contractions in spinal cord injury patients. Open-loop continuous electrical stimulation can inhibit overactive bladder activity and several devices are approved by the FDA. However, patients must frequently return to the doctor to have their stimulation system adjusted when its effectiveness wanes due to habituation

or accommodation to an electrical stimulation signal that is always on. Conditional or closed-loop stimulation that only stimulates when triggered to do so is more effective than open-loop continuous stimulation, resulting in greater bladder capacity and utilizing less power. However, conditional stimulation is presently only utilized acutely for research purposes using catheter-based pressure-sensing systems since a chronic bladder sensor is not available. The illustrated sensor assembly 50 represents a miniature, wireless, catheter-free, battery-powered, rechargeable pressure monitor for chronic submucosal implantation which could provide feedback for chronic conditional stimulation.

[0021] To this end, the proposed sensor assembly 50 runs primarily from the microbattery 52 and is charged inductively via a recharge component 54 during six-hour periods, for example, when the user is sleeping. In the illustrated implementation, the battery 52 and associated recharger 54 consume more than half of the volume of the sensor assembly 50, as the active circuitry of the system is implemented on a custom application-specific integrated circuit (ASIC) 60. It will be appreciated that the recharge component 54 can include some signal processing capabilities to receive a set of prespecified commands from the base unit.

[0022] A pressure transducer 62 provides an electrical signal representative of an ambient pressure of the environment in which the sensor assembly 50 is implanted. In one example, the pressure transducer 62 can be implemented as a piezoresistive transducer, although it will be appreciated that other implementations can be used within the spirit of the present invention. The signal from the pressure transducer 62 is provided to a programmable gain (PG) instrumentation amplifier (INA) assembly 64 to amplify the transducer output signal before analog-to-digital conversion.

[0023] In accordance with an aspect of the present invention, the amplifier architecture provides a low input-referred noise and a small die layout area while maintaining a high input impedance. FIG. 3 illustrates an exemplary amplifier assembly 90 in accordance with an aspect of the present invention. The amplifier assembly 90 includes a chopper-stabilized, continuous time, fully differential operational preamplifier (FDOA) 92 feeding a differential correlated-double-sampling (CDS) amplifier arrangement 94. CDS switched-capacitor amplifiers 94 obtain low 1/f noise by sampling the signal twice and subtracting the amplifier noise before amplification.

[0024] The thermal noise floor of a CDS amplifier 94 is often limited by the size of the input sampling capacitors; large capacitors yield low noise but require huge area and reduce the input impedance of the amplifier. Because the implantable pressure sensing system intermittently acquires samples, large input capacitance is undesirable because it would require longer settling times for the pressure transducer. This would increase the time per sample, which would require more power. In the illustrated amplifier assembly, the chopped pream-

plifier 92 provides a small amount of gain to the input of the CDS amplifier 94 to allow for the use of capacitors of a practical size and capacity for a low power, in vivo device, while maintaining a high quality signal. The chopping at the input of the preamplifier 92 effectively cancels the 1/f noise that it might otherwise add to the signal.

[0025] Returning the FIG. 2, the amplified signal is provided to an analog-to-digital converter (ADC) 66 that digitizes the amplifier signal. In the illustrated implementation, the ADC 66 is implemented as a successive approximation register (SAR) ADC. The digitized signal is then provided to a packet generation component 68. The packet generation component 68 arranges the digitized pressure measurements into an appropriate transmission format and provides them to the transmitter 70 for transmission to an associated base unit (not shown).

[0026] In accordance with an aspect of the present invention, the sensor assembly 50 includes an offset removal component 72 employing a low-power, area-efficient method for removing slow pressure changes which might be caused by postural changes by the patient, device orientation shifts, or atmospheric pressure changes. Specifically, the offset removal component 72 calculates a correction factor, as function of an average of a predetermined number of previous samples, to be applied to future measurements. The offset removal component 72 can operate in two modes, automatic and forced. In the automatic mode, the offset removal component 72 seeks to maximize a sensing dynamic range by maintaining the average pressure readings in the center of the instrumentation circuitry. A forced offset calibration is initiated by wirelessly sending a command to the device over the RF recharge link. Once the command is received, the system 50 runs around three hundred times faster than normal to very quickly calculate the average pressure offset and subtract it from the pressure transducer, essentially nulling the system. The forced calibration does not maximize dynamic range, but allows a user or clinician to set the zero level to any reference pressure. Forced calibration automatically ends when the pressure output is less than eight ADC codes, and the system slows down by a factor of three hundred to conserve power.

[0027] Whether in automatic or forced mode, the offset removal component 72 operates in substantially the same manner. In one implementation, the offset removal component 72 can include an accumulator to maintain a running average of a predetermined number of previous samples. In one implementation, a twenty-one bit accumulator is used to maintain an average of the last eight thousand samples. A correction value can be calculated as a difference between the full scale range and the average in the automatic mode or a difference between one-half of the full scale range and the average in the forced mode. The correction value represents a pressure offset that is subtracted from the pressure transducer 62 by a bipolar, current-output DAC. The offset cancellation component 72 can also include one or more coarse offset

removal current sources. In one implementation, the current-output DAC can be an eight-bit DAC, such that the full scale range is two hundred fifty-five and one-half the full scale range is one hundred twenty-eight.

5 **[0028]** A power control unit 76 dynamically controls the provision of power to the circuitry 62, 64, 66, 68, 70, and 72. In the illustrated implementation, the implanted battery 52 has a capacity of about three milliamp-hours (mAh), so power management is important in chronic implantations. A six-hour recharge session can replenish 0.6 mAh of capacity, and the sensor system 50 is intended to run for at least forty-eight hours between charges. Accordingly, the time-averaged current consumption for the sensor system 50 must be less than around twelve 10 microamps.

15 **[0029]** Achieving such a small current draw for a continuously running implantable telemetry system is not feasible, but the power-control unit 76 leverages the speed ratio between bladder pressure changes and the 20 instrumentation capability. In the illustrated system, for example, bladder pressure is sampled at a rate of between twenty and one hundred hertz, even though instrumentation and telemetry circuits can provide significantly higher sample rates. The power control unit 76 is 25 thus implemented as a suite of very low power circuits that are always running in the background. During normal operation, the device is active for ten millisecond intervals each second. When the device is not active, only the power control unit 76 is consuming power. According to 30 the invention, when the device is active, the power control unit 76 selectively provides power to the vital instrumentation and telemetry circuits such that a sample can be provided with the minimum possible power expenditure. Specifically, each of the components needed to generate 35 and transmit a pressure reading 62, 64, 66, 68, 70, and 72 are provided with power only when their particular function is necessary, such that a given component can be inactive during an active interval of the sensor assembly 50. Without the power control unit 76, the implant 40 consumes over one milliamp from the battery, but when the power control unit is utilized, the time-averaged current is less than nine microamps and the power consumption of the transducer and instrumentation and telemetry circuits is greatly reduced.

45 **[0030]** FIG. 4 is a chart 100 illustrating power control signals 102-106 for various components of an implanted device as a function of time, represented on a horizontal axis 108, over a one millisecond active interval. Each power control signal 102-106 is illustrated in FIG. 2 as either "off," represented by a baseline level at which each signal begins, and "on", represented as a signal raised above the baseline. The power control signals 102-106 are complex because they successively turn on circuits 50 as the sampled voltage moves through the instrumentation and telemetry chain. This technique accounts for "warm-up" periods required by certain circuits before they 55 can accurately function, represented by a shaded region in FIG. 4.

[0031] It will be noted that the power control signal for the transmitter 102 and the amplifier 103 are on for most of the active cycle, although it will be appreciated that, for many applications, there may be as few as ten such millisecond cycles each second, such that the system is on a minimal stand-by power much of the time. The power control signals for the ADC 104, pressure transducer 105, and offset removal component 106, however, are powered during only a small portion of the active interval, in accordance with the invention, specifically that portion of the active cycle in which they are acquiring or processing the signal. Accordingly, a significant power savings can be realized.

[0032] For neuromodulation applications, an implantable device in accordance with an aspect of the present invention can transmit pressure to an external neural stimulator, with hardware associated with the stimulator monitoring the pressure signals and determining if they are abnormal and require stimulation. FIG. 5 illustrates a signal-processing method 150 for use in monitoring an output of an in vivo pressure sensor for one or more predetermined events in accordance with an aspect of the present invention. It will be appreciated that each of the steps of this method can occur at the event detector 24 of FIG. 1. The method of FIG. 5 is specifically designed to recognize pressure readings representing bladder leaks or unwanted urge spasms for the bladder, but the same concepts could be adapted for control of other organs or for responses other than neural stimulation, such as drug release or similar applications. The signal processing algorithm for pressure monitoring is capable of online real-time identification of bladder and motion events in the presence of noise, amenable to efficient implementation in a microcontroller or digital signal processor, and adaptive to accommodate for variations in event signature, both from subject to subject as well as with time in the same subject. In one implementation, the method of FIG. 5 is implemented using a low-power, sixteen-bit microcontroller in a stimulator.

[0033] At 152, windowing is applied to isolate a portion of a signal representing series of pressure measurements. For example, the window can include a predetermined time interval of the signal ending with a most recent measurement. Alternatively, some form of preprocessing, such as a thresholding process, can be used to identify portions of the signal likely to represent events, and an appropriate window can be defined around the identified potential event. At 154, the isolated signal can be upsampled to a desired upsampling frequency.

[0034] At 156, a multi-resolution wavelet analysis to is applied to the signal to de-noise the recorded signal. The applied wavelet analysis has been found to efficiently remove background electrical and biological noise and facilitate localization of specific bladder activities. Unlike a Fourier transform, which uses a fixed basis function, wavelet decomposition uses a custom basis function satisfying a set of mathematical constraints that can efficiently identify events in a signal. Time-frequency anal-

ysis using a wavelet transform helps distinguish bladder activities from motion events even in situations in which the inventors have found time- and frequency-domain methods fail to distinguish between events. Wavelet transforms are also amenable to on-chip implementation since they can be realized as a bank of high-pass and low-pass filters.

[0035] At 158, hyperclusters are identified in the wavelet transform domain and extracted as classification features. For example, the hyperclusters can be identified via a thresholding process applied to the transformed data. At 160, the extracted features are used to classify the signal into one of a plurality of event classes. For example, the events can include bladder voiding, stress, motion, bladder leaks, unwanted urge spasms, and other events of interest.

[0036] From the above description of the invention, those skilled in the art will perceive improvements, changes, and modifications. Such improvements, changes, and modifications within the skill of the art are intended to be covered by the appended claims.

Claims

25

1. An in vivo sensor assembly (30) comprising:

a pressure sensor (36) configured to provide an analog signal representing pressure;
a signal conditioning component (38) configured to convert the pressure sensor output into a digital signal;
a transmitter (39) configured to transmit the digital signal to an external base unit (20); and
a power control unit (34) configured to dynamically allocate power throughout the implantable sensor assembly, such that during an active interval of the implantable sensor assembly, each of the pressure sensor (36), the signal conditioning component (38), and the transmitter (39) are powered only for a portion of the active interval necessary to perform a related function, the portion of the active interval being less than all of the active interval, such that each of the signal conditioning component (38), and the transmitter (39) are not powered for at least part of the active interval.

2. The in vivo sensor assembly (30) of claim 1, wherein the active interval has a duration of approximately one millisecond, and the power control unit (34) being further configured to provide the active interval with a frequency between twenty and one hundred hertz.

3. The in vivo sensor assembly (30) of claim 1, wherein the signal conditioning component (38) comprises:

- a preamplifier (92) that amplifies an output of the pressure sensor (36); and
a differential correlated double-sampling amplifier arrangement (94) that amplifies the output of the preamplifier (92). 5
4. The in vivo sensor assembly (30) of claim 3, wherein the preamplifier (92) is a chopper-stabilized, continuous time fully differential operational preamplifier. 10
5. The in vivo sensor assembly (30) of claim 1, wherein the signal conditioning component (38) comprises an offset removal component (72) configured to calculate a correction value for the output of the pressure sensor (36) as a function of an average of a predetermined number of previous samples. 15
6. The in vivo sensor assembly (30) of claim 5, wherein the offset removal component (72) calculates the correction value as a difference between the a full-scale range of a digital-to-analog converter associated with the transmitter (39) and an average of a predetermined number of previous samples to maximize a sensing dynamic range of the in vivo sensor assembly (30). 20
7. The in vivo sensor assembly (30) of claim 5, wherein the signal conditioning component (38) comprises an offset removal component (72) responsive to an external command, the offset removal component (72) being configured to, in response to the external command, instruct the sensor (36) to take a plurality of measurements over a short period of time, the signal offset component calculating a correction value as an average of the plurality of measurements as to null the system. 25
8. The in vivo sensor assembly (30) of claim 1, wherein each of the signal conditioning component (38), the transmitter (39), and the power control unit (34) are implemented as a single application-specific integrated circuit chip. 30
9. A pressure monitoring system (10) comprising:
the in vivo sensor assembly (30) of claim 1; and
the external base unit (20), the external base unit (20) comprising:
a receiver (22) configured to receive the digital signal from the transmitter (39); and
an event detection component (24) configured to at least one predetermined physiological events in the received digital signal. 40
10. The pressure monitoring system (10) of claim 9, the event detection component (24) being configured to apply a multi-resolution wavelet analysis to the received digital signal to provide a transformed signal in a transform domain, identify clusters within the transform domain, and classify the digital signal into one of a plurality of event classes according to the identified clusters. 45
11. The pressure monitoring system (10) of claim 9, wherein the external base unit (20) comprises a recharger (26) configured to transmit radio frequency (RF) energy, and the in vivo sensor assembly (30) further comprises a microbattery (52) and a recharge component (54) configured to inductively charge the microbattery (52) in the presence of the transmitted RF energy. 50
12. The pressure monitoring system (10) of claim 11, wherein a transmitted power of the recharger (26) is responsive to the digital signal. 55
13. The pressure monitoring system (10) of claim 12, wherein the power control unit (34) is configured to determine if the recharge component (54) is receiving sufficient energy from the recharger (26), and the signal conditioning component (38) being configured to encode a first binary value into a bit of the digital signal if sufficient power is being received, and a second binary value into the bit if sufficient power is not being received.
14. A method for determining a pressure from the in vivo sensor assembly (30) of claim 1, the method comprising:
receiving a digital signal from the in vivo sensor (30);
applying a windowing function to the digital signal to isolate a portion of the digital signal representing a series of pressure measurements;
applying a multi-resolution wavelet analysis to the isolated portion of the digital signal to provide a transformed signal;
extracting classification features from the transformed signal; and
classifying the signal into one of a plurality of event classes according to the extracted classification features;
the method further comprising transmitting the digital signal during an active interval of the in vivo sensor (30) such that power is dynamically allocated during the active interval of the implantable sensor assembly (30), with each of a pressure sensor assembly (30), a signal conditioning component (38), and a transmitter (39) of the in vivo sensor (30) powered only for a portion of the active interval necessary to perform a related function, the portion of the active interval being less than all of the active interval, such that each of the signal conditioning components

ponent (38), and the transmitter (39) are not powered for at least part of the active interval.

Patentansprüche

1. In-vivo-Sensoranordnung (30), umfassend:

einen Drucksensor (36), der konfiguriert ist, um ein analoges Signal bereitzustellen, das den Druck darstellt;
 eine Signalkonditionierungskomponente (38), die konfiguriert ist, um die Drucksensorausgabe in ein digitales Signal umzuwandeln;
 einen Sender (39), der konfiguriert ist, um das digitale Signal an eine externe Basiseinheit (20) zu senden; und
 eine Leistungssteuereinheit (34), die konfiguriert ist, um überall in der implantierbaren Sensoranordnung dynamisch Leistung zuzuweisen, so dass während eines aktiven Intervalls der implantierbaren Sensoranordnung der Drucksensor (36), die Signalkonditionierungskomponente (38) als auch der Sender (39) jeweils nur für einen Teil des erforderlichen aktiven Intervalls mit Energie versorgt werden um eine zugehörige Funktion auszuführen, wobei der Teil des aktiven Intervalls kleiner als das gesamte aktive Intervall ist, so dass sowohl die Signalkonditionierungskomponente (38) als auch der Sender (39) für mindestens einen Teil des aktiven Intervalls nicht mit Energie versorgt werden.

2. In-vivo-Sensoranordnung (30) nach Anspruch 1, wobei das aktive Intervall eine Dauer von etwa einer Millisekunde hat und die Leistungssteuereinheit (34) ferner konfiguriert ist, um das aktive Intervall mit einer Frequenz zwischen zwanzig und einhundert Hertz bereitzustellen.

3. In-vivo-Sensoranordnung (30) nach Anspruch 1, wobei die Signalkonditionierungskomponente (38) umfasst:

einen Vorverstärker (92), der eine Ausgabe des Drucksensors (36) verstärkt; und
 eine differentielle korrelierte Verstärkeranordnung (94) mit doppelter Abtastung, die die Ausgabe des Vorverstärkers (92) verstärkt.

4. In-vivo-Sensoranordnung (30) nach Anspruch 3, wobei der Vorverstärker (92) ein Chopper-stabilisierter, zeitkontinuierlicher, vollständig differentiell arbeitender Vorverstärker ist.

5. In-vivo-Sensoranordnung (30) nach Anspruch 1, wobei die Signalkonditionierungskomponente (38) eine Offset-Entfernungskomponente (72) umfasst, die

dafür konfiguriert ist, einen Korrekturwert für die Ausgabe des Drucksensors (36) als eine Funktion eines Durchschnitts einer vorbestimmten Anzahl von vorherigen Abtastungen zu berechnen.

6. In-vivo-Sensoranordnung (30) nach Anspruch 5, wobei die Offset-Entfernungskomponente (72) den Korrekturwert als eine Differenz zwischen dem vollständigen Bereich eines Digital-Analog-Wandlers, der dem Sender (39) zugeordnet ist, und einen Mittelwert einer vorbestimmten Anzahl vorheriger Proben berechnet, um einen Erfassungsdynamikbereich der In-vivo-Sensoranordnung (30) zu maximieren.

7. In-vivo-Sensoranordnung (30) nach Anspruch 5, wobei die Signalkonditionierungskomponente (38) eine Offset-Entfernungskomponente (72) umfasst, die auf einen externen Befehl anspricht, wobei die Offset-Entfernungskomponente (72) dafür konfiguriert ist, dass sie als Reaktion auf den externen Befehl den Sensor (36) anweist, eine Vielzahl von Messungen über eine kurze Zeitdauer durchzuführen, wobei die Signal-Offset-Komponente einen Korrekturwert als einen Durchschnitt der Vielzahl von Messungen berechnet, um das System auf null zu stellen.

8. In-vivo-Sensoranordnung (30) nach Anspruch 1, wobei die Signalkonditionierungskomponente (38), der Sender (39) und die Leistungssteuereinheit (34) jeweils als ein einzelner anwendungsspezifischer integrierter Schaltungschip implementiert sind.

9. Drucküberwachungssystem (10), umfassend:

die In-vivo-Sensoranordnung (30) nach Anspruch 1; und
 die externe Basiseinheit (20), wobei die externe Basiseinheit (20) umfasst:

einen Empfänger (22), der konfiguriert ist, um das digitale Signal von dem Sender (39) zu empfangen; und
 eine Ereigniserfassungskomponente (24), die für mindestens ein vorbestimmtes physiologisches Ereignis in dem empfangenen digitalen Signal konfiguriert ist.

10. Drucküberwachungssystem (10) nach Anspruch 9, wobei die Ereigniserkennungskomponente (24) konfiguriert ist, um eine Mehrfachauflösungs-Wavelet-Analyse auf das empfangene digitale Signal anzuwenden, um ein transformiertes Signal in einer Transformationsdomäne bereitzustellen, um Cluster innerhalb der Transformationsdomäne zu identifizieren, und um das Digitalsignal in eine Vielzahl von Ereignisklassen gemäß den identifizierten Clustern zu klassifizieren.

11. Drucküberwachungssystem (10) nach Anspruch 9, wobei die externe Basiseinheit (20) ein Wiederaufladegerät (26) umfasst, das zum Übertragen von Hochfrequenz(HF)-Energie konfiguriert ist, und die In-vivo-Sensoranordnung (30) ferner eine Mikrobatterie (52) und eine Wiederaufladekomponente (54) umfasst, die konfiguriert ist, um die Mikrobatterie (52) in Gegenwart der übertragenen HF-Energie induktiv zu laden.

12. Drucküberwachungssystem (10) nach Anspruch 11, wobei eine Sendeleistung des Wiederaufladers (26) auf das digitale Signal anspricht.

13. Drucküberwachungssystem (10) nach Anspruch 12, wobei die Leistungssteuereinheit (34) konfiguriert ist, um zu bestimmen, ob die Wiederaufladekomponente (54) ausreichend Energie von dem Wiederaufladegerät (26) empfängt, und die Signalkonditionierungskomponente (38) konfiguriert ist, um einen ersten Binärwert in ein Bit des digitalen Signals zu codieren, wenn ausreichend Leistung empfangen wird, und einen zweiten Binärwert in das Bit zu codieren, wenn nicht ausreichend Leistung empfangen wird.

14. Verfahren zum Bestimmen eines Drucks von der In-vivo-Sensoranordnung (30) nach Anspruch 1, wobei das Verfahren umfasst:

Empfangen eines digitalen Signals vom In-vivo-Sensor (30);
 Anwenden einer Fensterfunktion auf das Digitalsignal, um einen Teil des Digitalsignals zu isolieren, der eine Reihe von Druckmessungen darstellt;
 Anwenden einer Mehrfachauflösungs-Wavelet-Analyse auf den isolierten Teil des Digitalsignals, um ein transformiertes Signal bereitzustellen;
 Extrahieren von Klassifizierungsmerkmalen aus dem transformierten Signal; und
 Klassifizieren des Signals in eine einer Vielzahl von Ereignisklassen gemäß den extrahierten Klassifikationsmerkmalen; wobei das Verfahren ferner das Übertragen des digitalen Signals während eines aktiven Intervalls des In-vivo-Sensors (30) umfasst, so dass Energie während des aktiven Intervalls der implantierbaren Sensoranordnung (30) dynamisch zugeteilt wird, wobei jeweils eine einer Drucksensoranordnung (30), einer Signalkonditionierungskomponente (38) und eines Senders (39) des In-vivo-Sensors (30) nur für einen Teil des aktiven Intervalls mit Energie versorgt wird, die zum Durchführen einer entsprechenden Funktion erforderlich ist, wobei der Teil des aktiven Intervalls kleiner als der gesamte aktive

Intervall ist, so dass sowohl die Signalkonditionierungskomponente (38) als auch der Sender (39) für mindestens einen Teil des aktiven Intervalls nicht mit Energie versorgt werden.

Revendications

1. Ensemble capteur in vivo (30) comprenant :

un capteur de pression (36) configuré pour délivrer un signal analogique représentant une pression,

un composant de conditionnement du signal (38) configuré pour convertir la sortie du capteur de pression en un signal numérique,
 un émetteur (39) configuré pour transmettre le signal numérique à une unité de base extérieure (20), et

une unité de commande d'alimentation (34) configurée pour allouer dynamiquement de l'énergie à travers l'ensemble capteur implantable, de telle manière que, durant un intervalle actif de l'ensemble capteur implantable, le capteur de pression (36), le composant de conditionnement du signal (38) et l'émetteur (39) ne sont alimentés que pendant une partie de l'intervalle actif nécessaire pour exécuter une fonction associée, la partie de l'intervalle actif étant inférieure à la totalité de l'intervalle actif, de telle sorte que le composant de conditionnement du signal (38) et l'émetteur (39) ne sont pas alimentés pendant au moins une partie de l'intervalle actif.

2. Ensemble capteur in vivo (30) selon la revendication 1, dans lequel l'intervalle actif a une durée d'environ une milliseconde, et l'unité de commande d'alimentation (34) est configurée en outre pour procurer l'intervalle actif à une fréquence entre vingt et cent hertz.

3. Ensemble capteur in vivo (30) selon la revendication 1, dans lequel le composant de conditionnement du signal (38) comprend :

un préamplificateur (92) qui amplifie une sortie du capteur de pression (36), et
 un dispositif d'amplificateur différentiel à double échantillonnage corrélaté (94) qui amplifie la sortie du préamplificateur (92).

4. Ensemble capteur in vivo (30) selon la revendication 3, dans lequel le préamplificateur (92) est un préamplificateur opérationnel entièrement différentiel à temps continu, stabilisé par découpage.

5. Ensemble capteur in vivo (30) selon la revendication 1, dans lequel le composant de conditionnement du

- signal (38) comprend un composant de suppression du décalage (72) configuré pour calculer une valeur de correction pour la sortie du capteur de pression (36) en fonction d'une moyenne d'un nombre prédéterminé d'échantillons précédents.
6. Ensemble capteur in vivo (30) selon la revendication 5, dans lequel le composant de suppression du décalage (72) calcule la valeur de correction sous forme d'une différence entre la plage d'échelle entière d'un convertisseur numérique-analogique associé à l'émetteur (39) et une moyenne d'un nombre prédéterminé d'échantillons précédents pour maximiser une plage dynamique de détection de l'ensemble capteur in vivo (30).
7. Ensemble capteur in vivo (30) selon la revendication 5, dans lequel le composant de conditionnement du signal (38) comprend un composant de suppression du décalage (72) réactif à une commande externe, le composant de suppression du décalage (72) étant configuré pour, en réponse à la commande externe, donner des instructions au capteur (36) pour prendre une pluralité de mesures sur une courte période de temps, le composant de décalage de signal calculant une valeur de correction sous forme d'une moyenne de la pluralité des mesures de façon à mettre à zéro le système.
8. Ensemble capteur in vivo (30) selon la revendication 1, dans lequel chacun du composant de conditionnement du signal (38), de l'émetteur (39) et de l'unité de commande d'alimentation (34) est réalisé sous forme d'une puce unique à circuit intégré spécifique à une application.
9. Système de surveillance de pression (10) comprenant :
- l'ensemble capteur in vivo (30) selon la revendication 1, et
 - l'unité de base extérieure (20), l'unité de base extérieure (20) comprenant :
- un récepteur (22) configuré pour recevoir le signal numérique de l'émetteur (39), et
- un composant de détection d'événement (24) configuré pour au moins un événement physiologique prédéterminé dans le signal numérique reçu.
10. Système de surveillance de pression (10) selon la revendication 9, le composant de détection d'événement (24) étant configuré pour appliquer une analyse d'ondelettes à multi-résolution au signal numérique reçu pour fournir un signal transformé dans un domaine de transformée, d'identifier des groupes dans le domaine de transformée, et de classifier le signal numérique dans l'une parmi une pluralité de classes d'événement selon les groupes identifiés.
- 5 11. Système de surveillance de pression (10) selon la revendication 9, dans lequel l'unité de base extérieure (20) comprend un chargeur (26) configuré pour transmettre une énergie de radiofréquence (RF), et l'ensemble capteur in vivo (30) comprend en outre une micro-batterie (52) et un composant de recharge (54) configuré pour charger par induction la micro-batterie (52) en présence de l'énergie RF transmise.
- 10 12. Système de surveillance de pression (10) selon la revendication 11, dans lequel une énergie transmise du chargeur (26) est réactive au signal numérique.
- 15 13. Système de surveillance de pression (10) selon la revendication 12, dans lequel l'unité de commande d'alimentation (34) est configurée pour déterminer si le composant de recharge (54) reçoit une énergie suffisante du chargeur (26), et le composant de conditionnement du signal (38) est configuré pour coder une première valeur binaire sous forme d'un bit du signal numérique si de l'énergie suffisante est reçue, et une deuxième valeur sous forme d'un bit si l'énergie reçue n'est pas suffisante.
- 20 14. Procédé pour déterminer une pression à partir de l'ensemble capteur in vivo (30) selon la revendication 1, le procédé comprenant :
- la réception d'un signal numérique du capteur in vivo (30),
- l'application d'une fonction de fenêtrage au signal numérique pour isoler une partie du signal numérique représentant une série de mesures de pression,
- l'application d'une analyse d'ondelettes à multi-résolution à la partie isolée du signal numérique pour fournir un signal transformé,
- l'extraction de caractéristiques de classification à partir du signal transformé, et
- la classification du signal dans l'une parmi une pluralité de classes d'événement selon les caractéristiques de classification extraites,
- le procédé comprenant en outre la transmission du signal numérique durant un intervalle actif du capteur in vivo (30) de telle manière que de l'énergie est allouée dynamiquement durant l'intervalle actif de l'ensemble capteur implantable (30), un ensemble capteur de pression (30), un composant de conditionnement du signal (38) et un émetteur (39) du capteur in vivo (30) n'étant chacun alimentés que pendant une partie de l'intervalle actif nécessaire pour exécuter une fonction associée, la partie de l'intervalle actif étant inférieure à la totalité de l'intervalle actif, de telle sorte que le composant de condi-
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tionnement du signal (38) et l'émetteur (39) ne sont pas alimentés pendant au moins une partie de l'intervalle actif.

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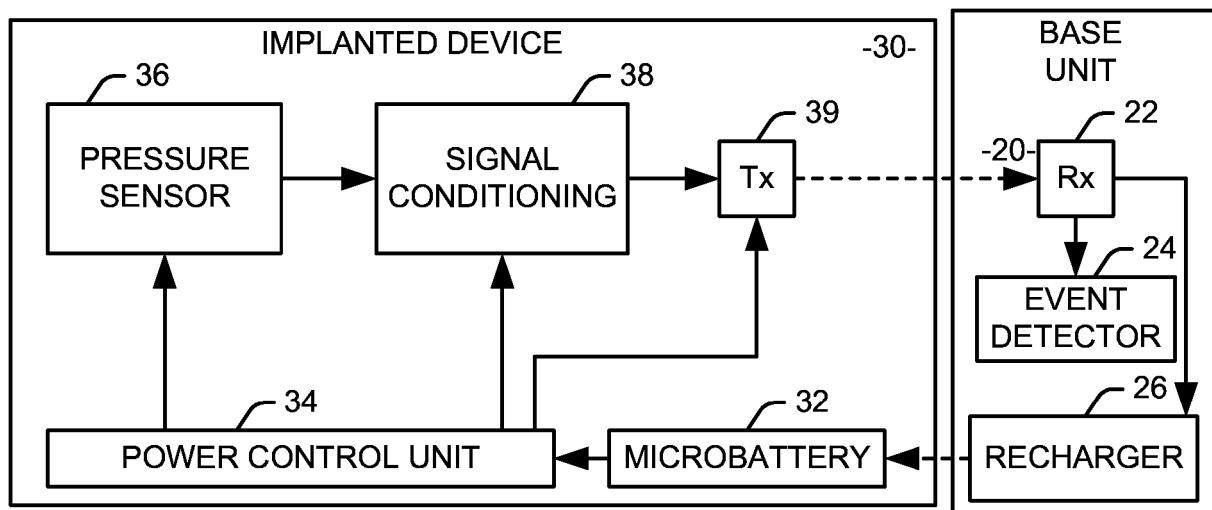


FIG. 1

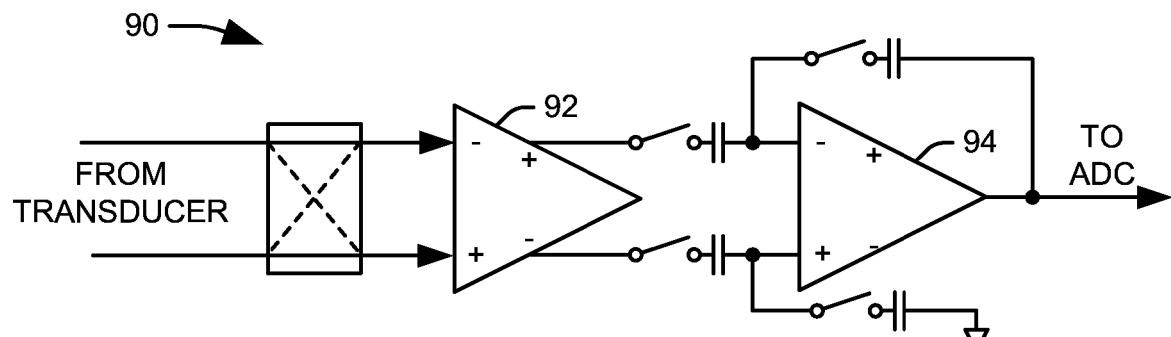


FIG. 3

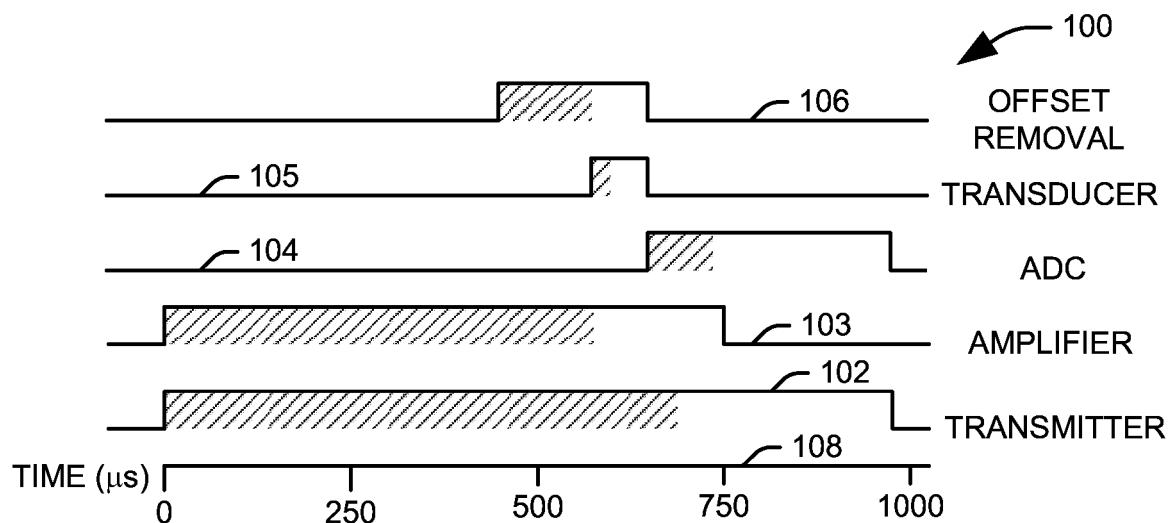


FIG. 4

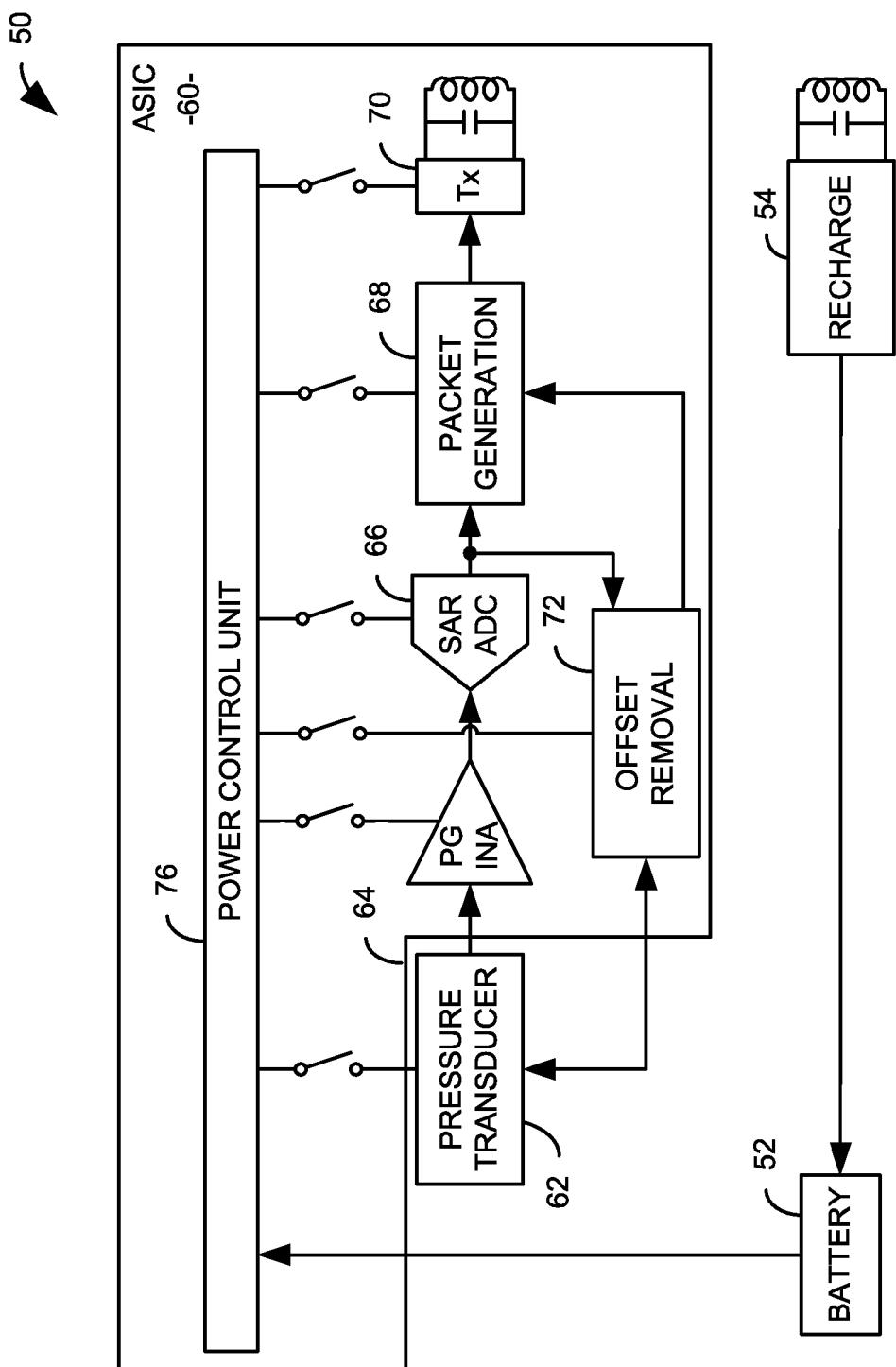


FIG. 2

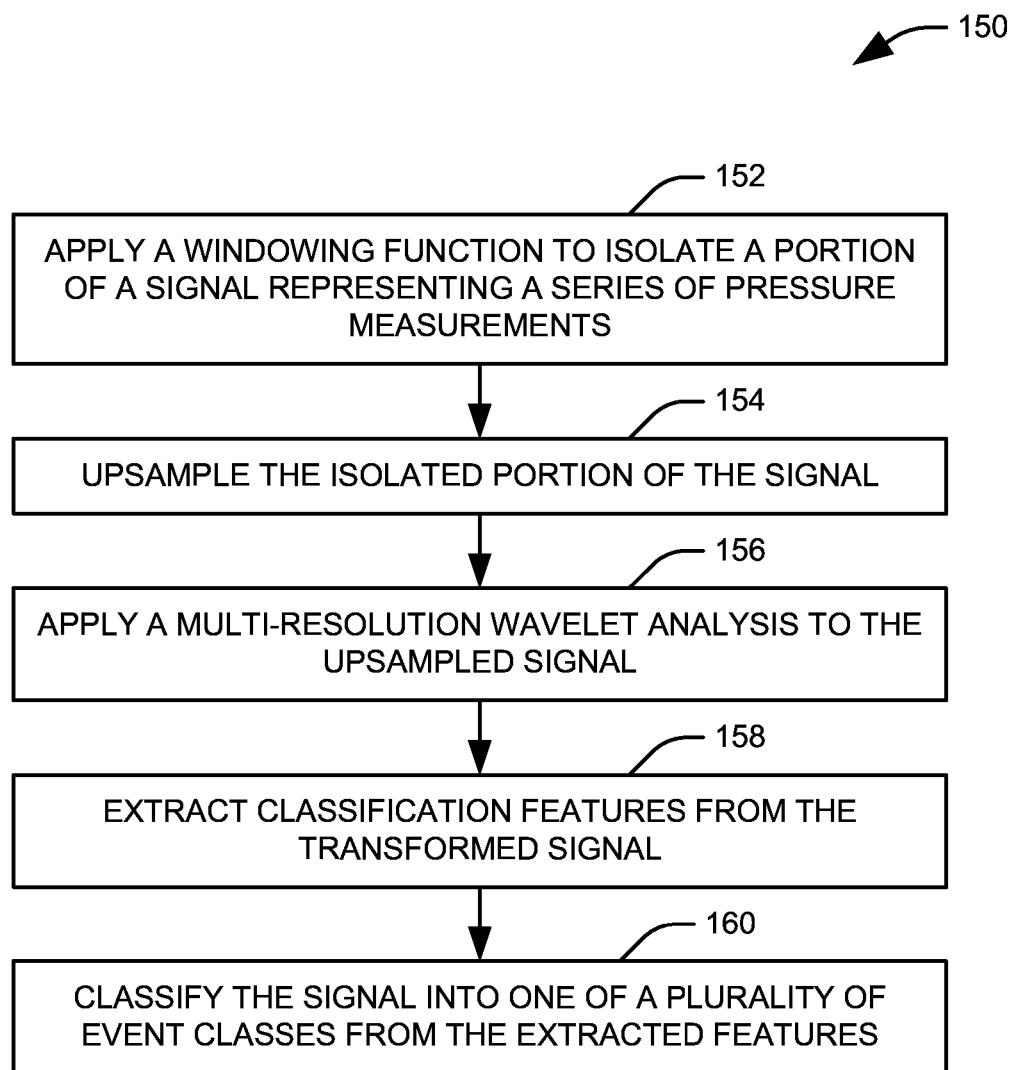


FIG. 5

REFERENCES CITED IN THE DESCRIPTION

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