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(54) Title: IMPLANTABLE VISCOSITY MONITORING DEVICE AND METHOD THEREFOR

(57) Abstract: An apparatus includes an implantable acoustic viscosity sensor configured to acoustically obtain a viscosity signal indicative of a viscosity of a fluid in contact with the viscosity sensor. A viscosity measurement circuit produces a viscosity measurement from the viscosity signal.

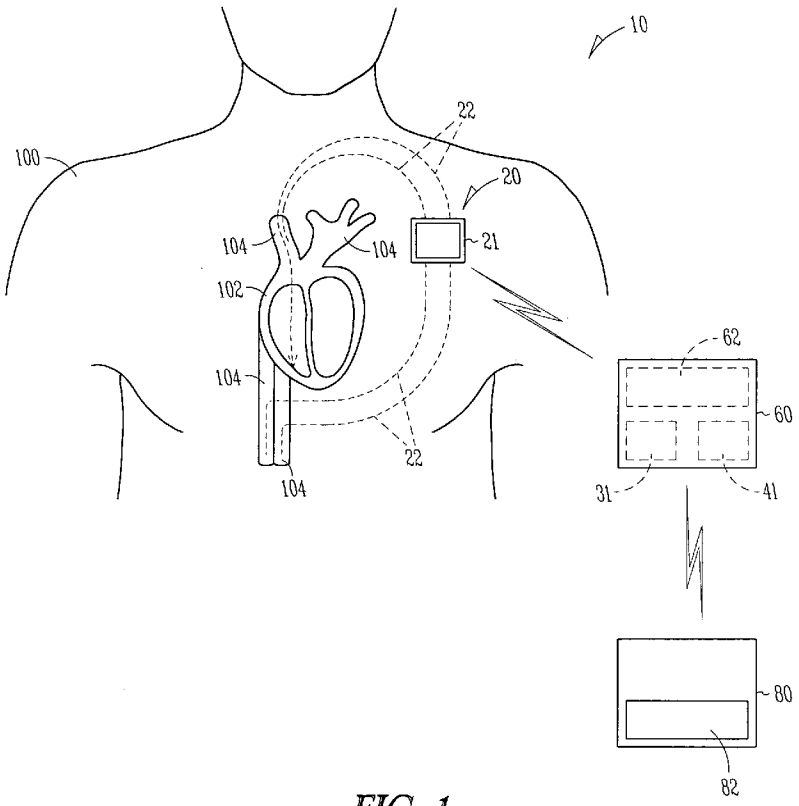

FIG. 1

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IMPLANTABLE VISCOSITY MONITORING DEVICE AND METHOD THEREFOR

CLAIM OF PRIORITY

Benefit of priority is hereby claimed to U.S. Patent Application Serial Number 11/781,769, filed July 23, 2007, which application is herein incorporated by reference.

TECHNICAL FIELD

This patent document pertains generally to an implantable viscosity monitoring device and more particularly, but not by way of limitation, to an implantable viscosity sensor for measuring viscosity of a physiological fluid, such as blood, for instance, in contact with the implanted sensor.

BACKGROUND

Implantable medical devices (IMDs) are devices designed to be implanted into a patient. Some examples of these devices include cardiac function management (CFM) devices such as implantable pacemakers, implantable cardioverter defibrillators (ICDs), cardiac resynchronization devices, and devices that include a combination of such capabilities. CFM devices are typically used to treat patients using electrical or other therapy. They can also help a physician or caregiver in diagnosing a patient by internal monitoring of the patient's condition. CFM devices may include one or more electrodes in communication with one or more sense amplifiers to monitor electrical heart activity within a patient. CFM devices often include one or more other physiological sensors to monitor one or more other internal patient parameters. Other examples of implantable medical devices include implantable diagnostic devices, implantable drug delivery systems, or implantable devices with neural stimulation capability.

Thrombosis is a serious clinical situation, which commonly occurs in patients with coronary artery disease (CAD), heart failure (HF), atrial fibrillation

(AF), stroke, and other medical situations. Some clinical interventions, such as treatment of anemia in HF patients, increase the risk of thrombosis. Other clinical interventions, such as blood thinning intervention, increase the risk of bleeding.

Prothrombin time (PT) and International Normalized Ratio (INR) are common parameters to monitor the risk of thrombosis and bleeding. PT is the time required for a blood specimen of a patient to form a clot. Thromboplastin, a phospholipid-protein preparation that activates clotting in blood specimens, is used in determining PT. PT values can vary with use of different thromboplastins and coagulation analyzers. The INR was developed as a standardized value for indicating the risk of thrombosis and bleeding, which, unlike PT values, does not vary with the use of different thromboplastins and coagulation analyzers. For patients who need anticoagulant therapy, an acceptable INR range is between 2 and 2.5. If the INR falls below 2, it could be indicative of clotting in the patient, giving rise to concerns of a clot dislodging and leading to health complications. If the INR rises above 2.5, it could be indicative of the inability of the blood of the patient to clot. For at least these reasons, it is desirable to maintain INR between 2 and 2.5.

OVERVIEW

The present inventors have recognized, among other things, that in at least such instances of clinical interventions such as blood thinning that increase the risk of bleeding, it is desirable to monitor the risk of thrombosis and bleeding in an ambulatory manner, in a chronic manner, or both in a chronic and ambulatory manner.

The present inventors have also recognized, among other things, that a blood viscosity measurement can be used as a surrogate parameter for PT and, if normalized, can be used as a surrogate parameter for INR. Certain examples of PT/INR measurement devices externally measure viscosity of a blood sample taken from a patient, however, such examples would not allow ambulatory or chronic blood INR measurements. Instead, such examples of external PT/INR measurement devices would require the patient to visit a clinic or laboratory,

which could require relatively lengthy procedure time to obtain PT/INR value, or otherwise be inconvenient.

This document describes, among other things, an apparatus includes an implantable acoustic viscosity sensor configured to acoustically obtain a viscosity signal indicative of a viscosity of a fluid in contact with the viscosity sensor. A viscosity measurement circuit produces a viscosity measurement from the viscosity signal.

Example 1 describes an apparatus. In this example, the apparatus comprises an implantable acoustic viscosity sensor configured to acoustically obtain a viscosity signal indicative of a viscosity of a fluid in contact with the viscosity sensor. A viscosity measurement circuit is in communication with the acoustic viscosity sensor, the viscosity measurement circuit producing a viscosity measurement from the viscosity signal.

In Example 2, the apparatus of Example 1 is optionally configured such that the acoustic viscosity sensor is configured to wirelessly communicate with the viscosity measurement circuit.

In Example 3, the apparatus of one or more of Examples 1-2 optionally comprises a lead connecting the acoustic viscosity sensor with the viscosity measurement circuit, wherein the acoustic viscosity sensor is configured to communicate with the viscosity measurement circuit via the lead.

In Example 4, the apparatus of one or more of Examples 1-3 is optionally configured such that the apparatus comprises an implantable cardiac function management (CFM) device.

In Example 5, the apparatus of one or more of Examples 1-4 optionally comprises a housing including an anchor configured to anchor the housing within a subject, the acoustic viscosity sensor being carried by or coupled with the housing.

In Example 6, the apparatus of one or more of Examples 1-5 optionally is configured such that the housing can be anchored within a blood vessel of the subject.

In Example 7, the apparatus of one or more of Examples 1-6 is optionally configured such that the housing can be anchored within a vein of the subject.

In Example 8, the apparatus of one or more of Examples 1-7 optionally comprises an automatic drug dispenser, in communication with the viscosity measurement circuit, the drug dispenser configured to titrate delivery of a drug to a subject using the viscosity measurement as a control input.

In Example 9, the apparatus of one or more of Examples 1-8 is optionally configured such that the viscosity measurement circuit is configured to produce an International Normalized Ratio (INR) value from the viscosity measurement.

In Example 10, the apparatus of one or more of Examples 1-9 is optionally configured such that the acoustic viscosity sensor comprises a surface acoustic wave (SAW) sensor.

In Example 11, the apparatus of one or more of Examples 1-10 is optionally configured such that the acoustic viscosity sensor comprises a microelectromechanical system (MEMS) based sensor.

In Example 12, the apparatus of one or more of Examples 1-11 optionally comprises a local or remote external interface configured to be communicatively coupled to the viscosity measurement circuit or the viscosity sensor to receive information obtained from the viscosity signal.

In Example 13, the apparatus of one or more of Examples 1-12 optionally comprises the external interface being configured to display the information obtained from the viscosity signal.

In Example 14, the apparatus of one or more of Examples 1-13 optionally comprises the external interface being configured to display an International Normalized Ratio (INR) obtained using the information from the viscosity signal.

In Example 15, the apparatus of one or more of Examples 1-14 optionally comprises a separate implantable device, in addition to the acoustic viscosity sensor, the separate implantable device configured to be communicatively coupled to the viscosity measurement circuit or the viscosity sensor to receive information obtained from the viscosity signal.

In Example 16, the apparatus of one or more of Examples 1-15 optionally comprises an implantable temperature sensor configured to obtain a temperature signal, and a temperature measurement circuit in communication with the

temperature sensor, the temperature measurement circuit producing a temperature measurement from the temperature signal.

Example 17 describes a method. In this example, the method comprises implantably acoustically generating a viscosity signal indicative of a viscosity of a physiological fluid of a subject, measuring a viscosity of the physiological fluid using information from the viscosity signal, and providing information about the measured viscosity to a user or process.

In Example 18, the method of Example 17 optionally comprises at least partially wirelessly communicating the viscosity signal to a viscosity measurement circuit.

In Example 19, the method of one or more of Examples 17-18 optionally comprises communicating the viscosity signal to a viscosity measurement circuit via using an at least partially intravascular lead.

In Example 20, the method of one or more of Examples 17-19 is optionally performed such that implantably acoustically generating a viscosity signal comprises using an acoustic viscosity sensor that is anchored within a subject.

In Example 21, the method of one or more of Examples 17-20 optionally comprises anchoring the acoustic viscosity sensor within a blood vessel of the subject.

In Example 22, the method of one or more of Examples 17-21 optionally is performed such that anchoring includes anchoring within a vein of the subject.

In Example 23, the method of one or more of Examples 17-22 optionally comprises automatically titrating drug delivery using the measured viscosity to control the titrating.

In Example 24, the method of one or more of Examples 17-23 optionally comprises producing an International Normalized Ratio (INR) value from the viscosity measurement.

In Example 25, the method of one or more of Examples 17-24 optionally comprises communicating, internally within the subject, information obtained from the viscosity signal.

In Example 26, the method of one or more of Examples 17-25 optionally comprises communicating, to a location external to the subject, information obtained from the viscosity signal.

In Example 27, the method of one or more of Examples 17-26 optionally comprises displaying the information obtained from the viscosity signal.

In Example 28, the method of one or more of Examples 17-27 optionally comprises displaying an International Normalized Ratio (INR) obtained from the viscosity signal.

In Example 29, the method of one or more of Examples 17-28 optionally comprises sensing a viscosity of a physiological fluid using a surface acoustic wave.

Example 30 describes an implantable medical device. In this example, the implantable medical device comprises means for implantably acoustically generating a signal indicative of a viscosity of a physiological fluid of a subject, means for measuring a viscosity of the physiological fluid using information from the viscosity signal, and means for providing information about the measured viscosity to a user or a process.

In Example 31, the device of Example 30 optionally comprises means for automatically titrating drug delivery using the viscosity measurement to control the titrating.

In Example 32, the device of one or more of Examples 30-31 optionally comprises means for communicating information obtained from the signal to a local or remote external location.

In Example 33, the device of one or more of Examples 30-32 optionally comprises means for communicating information obtained from the signal to a remote external location.

This overview is intended to provide an overview of subject matter of the present patent application. It is not intended to provide an exclusive or exhaustive explanation of the invention. The detailed description is included to provide further information about the present patent application.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, which are not necessarily drawn to scale, like numerals describe substantially similar components throughout the several views. Like numerals having different letter suffixes represent different instances of substantially similar components. The drawings illustrate generally, by way of example, but not by way of limitation, various embodiments discussed in the present document.

Fig. 1 illustrates portions of an example of a system including a leaded IMD having a viscosity sensor;

Fig. 2 illustrates an example of a leaded IMD having a viscosity sensor;

Fig. 3 illustrates portions of an example of a system including a leadless IMD having a viscosity sensor;

Figs. 4 and 5 illustrate affixation of an example of a leadless IMD having a viscosity sensor;

Figs. 6-8 illustrate examples of a leadless IMD having a viscosity sensor;

Fig. 9A illustrates a top view of an example of an acoustic wave sensor;

Fig. 9B illustrates a cross-sectional view of another example of an acoustic wave sensor;

Fig. 10 illustrates an example of a system to monitor blood viscosity of a subject and deliver a drug to the subject; and

Fig. 11 illustrates an example of a method for measuring viscosity of a physiological fluid.

DETAILED DESCRIPTION

Referring to Figs. 1-3, examples of an apparatus 10 include an implantable acoustic viscosity sensor 30 configured to acoustically obtain a viscosity signal indicative of a viscosity of a fluid in contact with the viscosity sensor 30, as will be described in greater detail below. At least the acoustic viscosity sensor 30 of the apparatus 10 is configured to be implanted within a subject 100. The apparatus 10 includes, in one example, an intravascular lead 22 carrying the viscosity sensor 30 (see Figs. 1 and 2) and, in another example, includes a leadless apparatus 10 (see Fig. 3). The various configurations of the apparatus 10 are described in more detail below. The apparatus 10 includes a

viscosity measurement circuit 31 in communication with the acoustic viscosity sensor 30. The viscosity measurement circuit 31 produces a viscosity measurement from the viscosity signal. In one example, the viscosity measurement circuit 31 is configured to produce an electronic representation of an International Normalized Ratio (INR) from the viscosity measurement. In one example, the viscosity measurement circuit 31 is located internally with respect to the subject 100. In another example, the viscosity measurement circuit 31 is located externally with respect to the subject 100.

Referring now to Figs. 1 and 2, an example of the leaded apparatus 10 is generally depicted, the apparatus 10 including an implantable medical device (IMD) 20 that includes an intravascular lead 22. In one example, the IMD 20 is communicatively coupled to a local external interface 60. In certain examples, the local external interface 60 can be communicatively coupled to a remote external interface 80. The IMD 20 and the local external interface 60, as well as the local external interface 60 and the remote external interface 80, can be communicatively coupled in various ways, such as over a wired or wireless telecommunications or computer network, for instance. In certain examples, the IMD 20 includes an implantable cardiac function management (CFM) device 20, such as a pacer, cardioverter, defibrillation device, cardiac resynchronization therapy (CRT) device, or combination device that combines these or other functions, such as patient monitoring, therapy control, or the like. In one example, the local external interface 60 or the remote external interface 80 is an optional element as the IMD 20 may contain all necessary hardware, circuitry, or software to perform the desired detection, processing, or therapy function(s). In another example, the local external interface 60 alone, or in combination with at least one of the remote external interface 80 and the IMD 20, performs the desired detection, processing, or therapy function(s).

In one example, the IMD 20 includes a hermetically-sealed canister or can 21. The can 21 includes, for instance, circuitry therein for coordinating operation of the IMD 20, transmitting or receiving signals, a power supply for the IMD 20, and the like. In one example, a lead 22 has a proximal end 22A coupled to the can 21, the lead 22 extending to a distal end 22B disposed at a target location within a subject 100. In one example, the acoustic viscosity

sensor 30 is carried by or coupled with the lead 22. In a further example, the acoustic viscosity sensor 30 is disposed at or near the distal end 22B of the lead 22. The lead 22 can include an anchor 24 configured to anchor the lead 22 within the subject 100. In one example, the anchor 24 is disposed at or near the distal end 22B of the lead 22 and includes flexible tines 24A which are configured to hook, grab, or otherwise help attach to anatomical structure within the subject 100. The lead 22 can include other anchor configurations, such as, but not limited to, a coil; a hook; an expandable mesh, screen, or other element; or the like.

In one example, at least the distal end 22B of the lead 22 is disposed within the vasculature of the subject 100, such as with the anchor 24 configured to anchor or otherwise attach the lead 22 thereto. The lead 22 can be introduced or anchored in various areas of the vasculature of the subject 100 (at least some of which are shown in phantom in Fig. 1). In one example, the lead 22 is anchored in a blood vessel 104 of the subject 100. Depending upon the circumstances, it is contemplated that the lead 22 can be anchored in a vein or an artery. For instance, the lead 22 can be anchored in a vein, such as the superior vena cava, the inferior vena cava, or the pulmonary vein, or an artery, such as the aorta or the pulmonary artery. In another example, the lead 22 is anchored in a heart 102 of the subject 100.

The viscosity measurement circuit 31 can be disposed within the IMD 20, for instance within the can 21. In this example, the lead 22 electrically or optically connects the acoustic viscosity sensor 30 with the viscosity measurement circuit 31, wherein the acoustic viscosity sensor 30 is configured to communicate with the viscosity measurement circuit 31 via the lead 22. In another example, the viscosity measurement circuit 31 is disposed within the local external interface 60 and the acoustic viscosity sensor 30 is configured to be in wireless communication with the viscosity measurement circuit 31.

Referring to Figs. 3-8, in another example, the leadless apparatus 10 includes a leadless IMD 120. The IMD 120 of this example includes an implantable diagnostic device 120 for measuring at least one physiological parameter, such as blood viscosity, for instance. In at least one example, the IMD 120 is communicatively coupled to a local external interface 60, which, in

turn is communicatively coupled to a remote external interface 80. The IMD 120 and the local external interface 60, as well as the local external interface 60 and the remote external interface 80, can be communicatively coupled in various ways, such as over a wired or wireless telecommunications or computer network, for instance. In one example, the local external interface 60 or the remote external interface 80 is an optional element as the IMD 120 may contain all necessary hardware, circuitry, or software to perform the desired detection, processing, or therapy function(s). In an example, the local external interface 60 alone or in combination with at least one of the remote external interface 80 and the IMD 120 performs the desired detection, processing, or therapy function(s). In one example, the IMD 120 communicates with another implantable device implanted within the subject 100, such as a CFM device, through an intra-body communication technique, such as radio frequency (RF) or acoustic energy, including audible sound energy or ultrasound. In this example, the IMD 120 can relay information obtained from the viscosity signal, as generated by the IMD 120, to the other implantable device to assist the other implantable device with performance of detection, processing, or therapy functions, for instance. As discussed in more detail below, one function of the other device can include drug delivery. In certain examples, the other device can be an intermediate communication station or a device to process at least the viscosity signal from the IMD 120 in order to integrate it to, for instance, a therapy function.

In one example, the IMD 120 includes a housing 121 including an anchor 124 configured to anchor the housing 121 within a subject 100. The acoustic viscosity sensor 30 is carried by or coupled with the housing 121. The housing 121 can be configured to be anchored within a blood vessel 104, such as a vein or an artery, of the subject 100. Various examples of anchoring configurations are contemplated.

In one example, referring to Figs. 4 and 5, the IMD 120 includes an expandable anchor 124 having the housing 121 attached thereto. In this example, the expandable anchor 124 of the IMD 120 is coupled at or near a distal end portion 90A of a catheter 90 or other IMD delivery system. As shown, the expandable anchor 124 may comprise a stent-like structure including a mesh surface that may be intravascularly delivered in a collapsed state and

expanded when implanted in a blood vessel 104. To expand the expandable anchor 124, the catheter 90 may include an inflatable balloon 92, which may be inflated once the IMD 120 is positioned as desired. Inflating the balloon 92 expands the expandable anchor 124 until the expandable anchor 124 abuts a wall of the blood vessel 104. The abutting of the expandable anchor 124 with the wall of the blood vessel 104 passively fixates the expandable anchor 124 and, in turn, the IMD 120, within the blood vessel 104. Once the expandable anchor 124 is fixated within the blood vessel 104, in one example, the balloon 92 can be deflated and the catheter 90 removed from the blood vessel 104, leaving the IMD 120 in place within the blood vessel 104. In a further example, the expandable anchor 124 can be self-expanding. In this example, the balloon of the previous example need not be used to expand the expandable anchor 124. Instead, for instance, the expandable anchor 124 can be retained in a compressed state on the catheter 90. The expandable anchor 124 can be released from the catheter 90 at a desired location, at which point the expandable anchor 124 can self-expand from its compressed state to abut the wall of the blood vessel 104 to fixate the expandable anchor 124 and, in turn, the IMD 120, within the blood vessel 104.

Referring to Fig. 6, the IMD 120 includes another example of an expandable anchor 124. In this example, the expandable anchor 124 includes a zigzag-like configuration that is in contact with an inner surface of the blood vessel 104. Additionally, the example shown in Fig. 6 includes a second attached element 126 That is, the IMD 120 includes an element in addition to housing 121 including the acoustic viscosity sensor 30. In one example, the second element 126 includes a power source, such as a battery, for instance, for powering at least the IMD 120 and the acoustic viscosity sensor 30 thereof. In another example, the second element 126 includes a temperature sensor for monitoring a blood temperature, as will be described in more detail below. In other examples, the second element 126 includes another monitoring device, such as a flow sensor for monitoring blood flow. In yet another example, the second element 126 includes a combination of devices therein. In still another example, one or more of the devices described above with respect to the second element 126 can be included within a single element, such as the housing 121.

The connection between one or more of the expandable anchor 124, the housing 121, or the second element 126 may be achieved mechanically such as using one or more crimps, adhesives, welding, or any other convenient mechanism or material.

Referring to Fig. 7, the IMD 120 includes yet another example of an expandable anchor 124. The expandable anchor 124 of this example includes two expandable portions with the housing 121 disposed therebetween.

Referring to Fig. 8, the IMD 120 includes still another example of an expandable anchor 124. The expandable anchor 124 of this example includes a coil-like configuration. Other expandable electrode configurations can be used.

The insertion of the IMD 120 of the examples shown in Figs. 6-8 into the blood vessel 104 may be performed in a variety of ways. In one example, the insertion of the IMD 120 is performed via a catheterization procedure, such as the delivery system described above and shown in Figs. 4 and 5. In such an example, the IMD 120 may be mounted on a delivery system in a compressed configuration so as to enable navigation to the desired blood vessel 104. At the desired deployment site, the expandable anchor 124 may then be allowed to expand to abut a wall of the blood vessel 104. In another example, the IMD 120 is inserted into an incision in the blood vessel 104.

As seen in the examples shown in Figs. 1-3, each of the lead-including IMD 20 and the leadless IMD 120 includes an acoustic viscosity sensor 30 for sensing viscosity of a physiological fluid, such as blood, for instance. Several types of acoustic viscosity sensors 30 are contemplated herein.

Referring to Fig. 9A, in one example, the acoustic viscosity sensor 30 comprises a piezoelectric surface acoustic wave (SAW) sensor 130. In this example, a surface 132 includes a piezoelectric layer 131 having coupled thereto input interdigitated electrodes 134, output interdigitated electrodes 136, and an insulation layer. In one example, at least the input and output electrodes 134, 136 are coupled to a top of the piezoelectric layer 131. In this example, at least one of interdigitated electrodes 134 is driven with, for instance, an alternating voltage signal to activate the SAW transducer and generate surface acoustic wave along the surface 132 at a frequency. The vibrating surface 132 is in contact with a fluid, such as blood. In this example, the viscosity of the fluid

alters the oscillation frequency of the surface 132. For instance, an increased fluid viscosity results in a lower oscillation frequency, and a decreased fluid viscosity results in a higher oscillation frequency. The fluid in contact with the surface 132 also causes resonance damping and an insertion loss due to the acoustic wave transferred to the fluid, which can be related to the viscosity of the fluid. This oscillation frequency shift or the power insertion loss can be used to create a viscosity signal, which can be converted into a viscosity measurement of the fluid. In certain examples, SAW sensors 130 have different surface acoustic wave modes by choosing different piezoelectric material orientations. For instance, in one example, the sensor 130 operates in a shear vertical surface acoustic wave (SV-SAW) mode in which transverse displacement of the SAW is normal to the surface 132. In one example, the sensor 130 operates in a shear horizontal surface acoustic wave (SH-SAW) mode in which transverse displacement of the SAW is parallel to the surface 132.

Referring to Fig. 9B, in another example, the acoustic viscosity sensor 30 comprises a bulk acoustic wave (BAW) sensor 230. Examples of BAW sensors include, for instance, a thickness shear mode (TSM) resonator and a shear-horizontal acoustic plate mode (SH-APM) sensor. In certain examples, the BAW sensor 230 includes a piezoelectric layer 231 sandwiched between top and bottom thin film electrodes 234, 236. In this example, an alternating voltage is applied to the electrodes 234, 236 to vibrate the piezoelectric layer 231 in a thickness shear mode at a frequency. Fluid, such as blood, in contact with the vibrating surface 232 mechanically interacts with the vibrating surface 232. A curve is depicted in Fig. 9B that represents displacements across a cross section of the BAW sensor 230, the fluid, and a solid-liquid interface therebetween. It is contemplated that the surface 232 is vibrated at the fundamental frequency, although it should be understood that other frequencies can be used or can result, such as harmonics. As in the example of the piezoelectric SAW sensor 130 above, the viscosity of the fluid alters the oscillation frequency of acoustic wave, with, for instance, an increased fluid viscosity resulting in a lower oscillation frequency and a decreased fluid viscosity resulting in a higher oscillation frequency. The fluid in contact with the surface 232 causes resonance damping and a frequency shift, which can be related to the viscosity of the fluid. In an

example, using the frequency change, the acoustic viscosity sensor 230 creates a signal that can be converted into a viscosity measurement of the fluid.

In one example, the acoustic viscosity sensor 30 comprises a microelectromechanical system (MEMS) based sensor. In one example, the MEMS based sensor comprises a solid-state acoustic wave transducer that is manufactured using a micro-machining process. In one example, the MEMS sensor comprises a solid-state surface acoustic wave (SAW) transducer. In another example, the MEMS sensor comprises a solid-state bulk acoustic wave (BAW) transducer. In these examples, a transducer of either of the acoustic sensors 130, 230 can be manufactured together with signal processing or conditioning electronics in one die. In another example, a transducer of either of the sensors 130, 230 can be packaged together with signal processing or conditioning electronics in one package. In another example, the acoustic viscosity sensor 30 includes only the transducer of either of the acoustic sensors 130, 230, with the signal processing or conditioning electronics located in another device, either within or outside of the subject 100. In one example, the sensor and electronics are packaged in a titanium or other biocompatible material housing or box with the sensing surface exposed. In certain examples, the sensor packaging includes a coating of a drug eluting substance. In one example, the sensor packaging includes a coating of a drug eluting substance at least at the sensing surface.

Referring again to Figs. 1-3, in other examples, the apparatus 10 includes an implantable temperature sensor 40 configured to obtain a temperature signal. In one example, the leaded IMD 20 includes the temperature sensor 40 disposed in or on the lead 22. In one example, the temperature sensor 40 is disposed at or near the distal end 22B of the lead 22. In another example, the leadless IMD 120 includes the temperature sensor 40 within the housing 121. In one example, the temperature sensor 40 is configured to sense blood temperature. A temperature measurement circuit 41 is in communication with the temperature sensor 40. As with the viscosity measurement circuit 31 described above, the temperature measurement circuit 41 can be disposed within the IMD 20, 120 or within the local external interface 60. In one example, the temperature measurement circuit 41 of the lead including IMD 20 is disposed within the can 21 and is in

communication with the temperature sensor 40 via the lead 22. In another example, the temperature measurement circuit 41 of the leadless IMD 120 is disposed within the housing 121 so as to be in direct communication with the temperature sensor 40, which is also disposed within the housing 121. In yet another example, the temperature measurement circuit 41 of the apparatus 10 is disposed within the local external interface 60 and is in wireless communication with the temperature sensor 40 of the IMD 20, 120. The temperature measurement circuit 41 is configured to produce a temperature measurement from the temperature signal. The temperature measurement obtained from the temperature sensor 40 can then be used in monitoring or therapy of the subject 100. For instance, the temperature measurement can be used in the blood viscosity assessment to take into account temperature-related changes in the viscosity measurement. In an example, the temperature measurement is used in other aspects of monitoring or therapy and is included with the IMD 20, 120 to avoid having to implant a separate temperature-sensing IMD. In other examples, the temperature measurement circuit 41 is included on the same circuit board as the viscosity measurement circuit 31 to limit manufacturing costs associated therewith and to maximize use of space within the IMD 20, 120.

Referring to Figs. 1 and 3, the apparatus 10 can optionally include the local external interface 60 and the remote external interface 80. The local external interface 60 can comprise a handheld reader, a personal digital assistant (PDA), or a desktop or laptop computer. Information derived from the viscosity signal obtained from the IMD 20, 120 can be communicated to the local external interface 60 or the remote external interface 80 to perform viscosity processing at such other locations. Moreover, such processing can include information from one or more devices, either implanted within or externally situated with respect to the subject 100. For example, a blood viscosity measurement as measured by the IMD 20, 120 can be combined with information obtained from an implantable cardiac function management device, for instance, during processing at the remote external interface 80, such as to trigger an alert or responsive therapy.

Additionally, in at least one example, at least one of the local external interface 60 and the remote external interface 80 is configured to allow a user

(for instance, the subject 100, a physician, or a caregiver) to program the IMD 20, 120. For instance, the user can program operation modes of the IMD 20, 120, such as monitoring time of the viscosity sensor 30 and the optional temperature sensor 40. Monitoring can include, but is not limited to, continuous monitoring, recurrent or periodic monitoring, or sleep/wake-up monitoring, which monitors changes in blood viscosity and, optionally, temperature during the transitional periods between sleep and wakefulness.

In certain examples, as stated above, information from the IMD 20, 120 can be communicated to the local external interface 60 or the remote external interface 80. The local external interface 60 or the remote external interface 80 can be configured to store or display the information.

In one example, the local external interface 60 is configured to receive information obtained from the viscosity signal. The local external interface 60 can be configured to display the information obtained from the viscosity signal. For instance, the local external interface 60 optionally includes a display 62 to display the information. The display 62 can take various forms, including, but not limited to, a monitor, a liquid crystal display (LCD), or a light emitting diode (LED) display. The information can be portrayed in other forms, including a printout from a printer, an audible alert or signal such as a beep or buzz, or an alert light such as a blinking light. In one example, the local external interface 60 is configured to display the International Normalized Ratio (INR) obtained using the information from the viscosity signal. In other examples, information other than the INR is displayed by the display 62 of the local external interface 60, such as the viscosity measurement, prothrombin time (PT), or blood temperature as measured by the temperature sensor 40. Additionally, the display 62 can portray other information, such as information obtained from other IMDs or other components of the IMD 20, 120; externally measured information, such as a weight measurement; or programmed settings of the IMD 20, 120.

In another example, the remote external interface 80 is configured to be communicatively coupled to receive the information obtained from the viscosity signal. The remote external interface 80 can comprise, for instance, a remote server or computer. The remote external interface 80 is configured to display the information obtained from the viscosity signal. For instance, the remote external

interface 80 optionally includes a display 82 to display the information. The display 82 can take various forms, including, but not limited to, a monitor, a liquid crystal display (LCD), or a light emitting diode (LED) display. The information can be portrayed in other forms, including a printout from a printer, an audible alert or signal such as a beep or buzz, or an alert light such as a blinking light. In one example, the remote external interface 80 is configured to display the International Normalized Ratio (INR) obtained using the information from the viscosity signal. In other examples, information other than the INR is displayed by the display 82 of the remote external interface 80, such as the viscosity measurement, prothrombin time (PT), or blood temperature as measured by the temperature sensor 40. Additionally, the display 82 can portray other information, such as information obtained from other IMDs or other components of the IMD 20, 120; externally measured information, such as a weight measurement; or programmed settings of the IMD 20, 120. The remote external interface 80 can be accessible to a physician or caregiver to receive the information obtained by the IMD 20, 120 and to allow the physician or caregiver to alter the settings of the IMD 20, 120 remotely, contact the subject 100 to discuss the information received, or contact other medical professionals (emergency medical technicians, for instance) to provide the subject 100 with medical treatment.

Referring to Fig. 10, in another example, the apparatus 10 includes an automatic drug dispenser 50 configured to titrate delivery of a drug to the subject 100 (Figs. 1 and 3) using the viscosity measurement as a control input. In one example, the automatic drug dispenser 50 is carried by the subject 100 and is communicatively coupled to the IMD 20, 120, the local external interface 60, or the remote external interface 80. In one example, if the viscosity measurement or INR reaches, falls below, or rises above a threshold value, the automatic drug dispenser 50 can be configured to increase or decrease the dosage of or otherwise administer a drug, such as an anti-coagulant or blood thinner drug, to the subject 100. The threshold is associated with or related to INR values or prothrombin time. For instance, if an INR reading of the subject 100 falls below 2, the IMD 20, 120, the local external interface 60, or the remote external interface 80 can communicate with the automatic drug dispenser 50 to deliver a

blood thinner drug to the subject 100. In this example, the IMD 20, 120 can continue monitoring blood viscosity, and, if the INR does not rise above 2, the automatic drug dispenser 50 can be operated to deliver an additional dose of the blood thinner drug. In this way, the apparatus 10 can be used to maintain the INR of the subject 100 within an acceptable range in an effort to limit negative health complications to the subject 100, such as stroke, heart failure, and other medical situations. In one example, if the viscosity measurement or INR reaches, falls below, or rises above a threshold value, the apparatus 10 provides an alert to the subject 100 to allow the subject 100 to ingest a blood thinner drug in lieu of automatic drug titration. In one example, the threshold is a range that includes an upper bound and a lower bound to assist with or guide treatment for bleeding or thrombosis risks.

Fig. 11 shows an example of a method 1000. At 1010, a viscosity signal is implantably acoustically generated to be indicative of a viscosity of a physiological fluid, such as, for instance, blood, although the present example is not intended to be limited as such. In one example, this includes sensing a viscosity of a physiological fluid using a surface acoustic wave. For instance, the viscosity signal can be generated by the acoustic viscosity sensor 30 of the IMD 20, 120. At 1020, a viscosity of the physiological fluid is measured using information from the viscosity signal. For instance, the viscosity measurement can be generated by the viscosity measurement circuit 31. In one example, the viscosity signal is wirelessly or otherwise communicated to a viscosity measurement circuit 31. In an example, the viscosity signal is communicated to a viscosity measurement circuit 31 using an at least partially intravascular lead 22.

In further examples, the method 1000 includes anchoring an acoustic viscosity sensor 30 within a subject 100. For instance, the IMD 20, 120 including the acoustic viscosity sensor 30 can be anchored within the subject 100 using an anchor 24, 124. In one example, anchoring of the acoustic viscosity sensor 30 includes anchoring within a blood vessel 104 of the subject 100. In one example, anchoring includes anchoring within a vein 104 of the subject 100. In other examples, anchoring includes anchoring within an artery 104 or heart 102 of the subject 100.

In certain examples, the method 1000 includes producing an electronic representation of an International Normalized Ratio (INR) from the viscosity measurement. In other examples, other information is produced, such as an electronic representation of prothrombin time (PT) from the viscosity measurement or a temperature measurement from a temperature signal of the temperature sensor 40. In one example, a portion of the apparatus 10, such as the viscosity measurement circuit 31, for instance, correlates the viscosity measurement with electronic representations of INR or PT values. Such electronic representations of INR or PT values can be stored in a database of a memory element of a portion of the apparatus, such as, for instance, the viscosity measurement circuit 31. In one example, the method 1000 includes communicating information obtained from the viscosity signal to an external location. For instance, the information can be communicated to the local external interface 60 or the remote external interface 80. In a further example, the method 1000 includes displaying the information obtained from the viscosity signal. For instance, the information can be displayed on the display 62 of the local external interface 60 or the display 82 of the remote external interface 80. In one example, the method 1000 includes displaying an electronic representation of the International Normalized Ratio (INR) obtained from the viscosity signal. In another example, the INR obtained from the viscosity signal is audibly communicated using one or more beeps, buzzes, or other such sounds.

In another example, the method 1000 includes titrating drug delivery using the measured viscosity to control the titrating. For instance, drug delivery can be titrated by the automatic drug dispenser 50 using at least the viscosity measurement as a control input.

Advantageously, the apparatus 10 provides for internal measurement of blood viscosity. That is, the apparatus 10 does not require the subject 100 to visit a clinic or laboratory and have a blood sample taken in order to obtain a blood viscosity measurement. Further advantageously, the apparatus 10 provides real-time measurement of blood viscosity from which PT and INR values can be derived so that the subject 100 need not wait for a relatively lengthy procedure time to obtain a PT or INR value.

Some Notes

The above detailed description includes references to the accompanying drawings, which form a part of the detailed description. The drawings show, by way of illustration, specific embodiments in which the invention can be practiced. These embodiments are also referred to herein as "examples." All publications, patents, and patent documents referred to in this document are incorporated by reference herein in their entirety, as though individually incorporated by reference. In the event of inconsistent usages between this document and those documents so incorporated by reference, the usage in the incorporated reference(s) should be considered supplementary to that of this document; for irreconcilable inconsistencies, the usage in this document controls.

In this document, the terms "a" or "an" are used, as is common in patent documents, to include one or more than one, independent of any other instances or usages of "at least one" or "one or more." In this document, the term "or" is used to refer to a nonexclusive or, such that "A or B" includes "A but not B," "B but not A," and "A and B," unless otherwise indicated. In the appended claims, the terms "including" and "in which" are used as the plain-English equivalents of the respective terms "comprising" and "wherein." Also, in the following claims, the terms "including" and "comprising" are open-ended, that is, a system, device, article, or process that includes elements in addition to those listed after such a term in a claim are still deemed to fall within the scope of that claim. Moreover, in the following claims, the terms "first," "second," and "third," etc. are used merely as labels, and are not intended to impose numerical requirements on their objects.

Method examples described herein can be computer or machine-implemented at least in part. Some examples can include a computer-readable medium or machine-readable medium encoded with instructions operable to configure an electronic device to perform methods as described in the above examples. An implementation of such methods can include code, such as microcode, assembly language code, a higher-level language code, or the like. Such code can include computer readable instructions for performing various methods. The code may form portions of computer program products. Further,

the code may be tangibly stored on one or more volatile or non-volatile computer-readable media during execution or at other times. These computer-readable media may include, but are not limited to, hard disks, removable magnetic disks, removable optical disks (e.g., compact disks and digital video disks), magnetic cassettes, memory cards or sticks, random access memories (RAM's), read only memories (ROM's), and the like.

The above description is intended to be illustrative, and not restrictive. For example, the above-described examples (or one or more aspects thereof) may be used in combination with each other. Other embodiments can be used, such as by one of ordinary skill in the art upon reviewing the above description. The Abstract is provided to comply with 37 C.F.R. §1.72(b), to allow the reader to quickly ascertain the nature of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims. Also, in the above Detailed Description, various features may be grouped together to streamline the disclosure. This should not be interpreted as intending that an unclaimed disclosed feature is essential to any claim. Rather, inventive subject matter may lie in less than all features of a particular disclosed embodiment. Thus, the following claims are hereby incorporated into the Detailed Description, with each claim standing on its own as a separate embodiment. The scope of the invention should be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

WHAT IS CLAIMED IS:

1. An apparatus, comprising:

an implantable acoustic viscosity sensor configured to acoustically obtain a viscosity signal indicative of a viscosity of a fluid in contact with the viscosity sensor; and

a viscosity measurement circuit in communication with the acoustic viscosity sensor, the viscosity measurement circuit producing a viscosity measurement from the viscosity signal.

2. The apparatus of claim 1, wherein the acoustic viscosity sensor is configured to wirelessly communicate with the viscosity measurement circuit.

3. The apparatus of claim 1, comprising a lead connecting the acoustic viscosity sensor with the viscosity measurement circuit, wherein the acoustic viscosity sensor is configured to communicate with the viscosity measurement circuit via the lead.

4. The apparatus of any of claims 1 through 3, wherein the apparatus comprises an implantable cardiac function management (CFM) device.

5. The apparatus any of claims 1 through 4, comprising a housing including an anchor configured to anchor the housing within a subject, the acoustic viscosity sensor being carried by or coupled with the housing.

6. The apparatus of claim 5, wherein the housing is configured to be anchored within a blood vessel of the subject.

7. The apparatus any of claims 5 and 6, wherein the housing is configured to be anchored within a vein of the subject.

8. The apparatus of any of claims 1 through 7, comprising an automatic drug dispenser, in communication with the viscosity measurement circuit, the

drug dispenser configured to titrate delivery of a drug to a subject using the viscosity measurement as a control input.

9. The apparatus of any of claims 1 through 8, wherein the viscosity measurement circuit is configured to produce an International Normalized Ratio (INR) value from the viscosity measurement.

10. The apparatus of any of claims 1 through 9, wherein the acoustic viscosity sensor comprises a surface acoustic wave (SAW) sensor.

11. The apparatus of any of claims 1 through 9, wherein the acoustic viscosity sensor comprises a bulk acoustic wave (BAW) sensor.

12. The apparatus of any of claims 1 through 9, wherein the acoustic viscosity sensor comprises a microelectromechanical system (MEMS) based sensor.

13. The apparatus of any of claims 1 through 12, comprising a local or remote external interface configured to be communicatively coupled to the viscosity measurement circuit or the viscosity sensor to receive information obtained from the viscosity signal.

14. The apparatus of claim 13, wherein the external interface is configured to display the information obtained from the viscosity signal.

15. The apparatus of any of claims 13 and 14, wherein the external interface is configured to display an International Normalized Ratio (INR) obtained using the information from the viscosity signal.

16. The apparatus of any of claims 1 through 15, comprising a separate implantable device, in addition to the acoustic viscosity sensor, the separate implantable device configured to be communicatively coupled to the viscosity

measurement circuit or the viscosity sensor to receive information obtained from the viscosity signal.

17. The apparatus of any of claims 1 through 16, comprising:

an implantable temperature sensor configured to obtain a temperature signal; and

a temperature measurement circuit in communication with the temperature sensor, the temperature measurement circuit producing a temperature measurement from the temperature signal.

18. A method, comprising:

implantably acoustically generating a viscosity signal indicative of a viscosity of a physiological fluid of a subject;

measuring a viscosity of the physiological fluid using information from the viscosity signal; and

providing information about the measured viscosity to a user or process.

19. The method of claim 18, comprising at least partially wirelessly communicating the viscosity signal to a viscosity measurement circuit.

20. The method of any of claims 18 and 19, comprising communicating the viscosity signal to a viscosity measurement circuit via using an at least partially intravascular lead.

21. The method of any of claims 18 through 20, wherein implantably acoustically generating a viscosity signal comprises using an acoustic viscosity sensor that is anchored within a subject.

22. The method of claim 21, comprising anchoring the acoustic viscosity sensor within a blood vessel of the subject.

23. The method of any of claims 21 and 22, wherein anchoring includes anchoring within a vein of the subject.

24. The method of any of claims 18 through 23, comprising automatically titrating drug delivery using the measured viscosity to control the titrating.

25. The method of any of claims 18 through 24, comprising producing an International Normalized Ratio (INR) value from the viscosity measurement.

26. The method of any of claims 18 through 25, comprising communicating, internally within the subject, information obtained from the viscosity signal.

27. The method of any of claims 18 through 26, comprising communicating, to a location external to the subject, information obtained from the viscosity signal.

28. The method of claim 27, comprising displaying the information obtained from the viscosity signal.

29. The method of any of claims 27 and 28, comprising displaying an International Normalized Ratio (INR) obtained from the viscosity signal.

30. The method of any of claims 18 through 29, comprising sensing a viscosity of a physiological fluid using a surface acoustic wave.

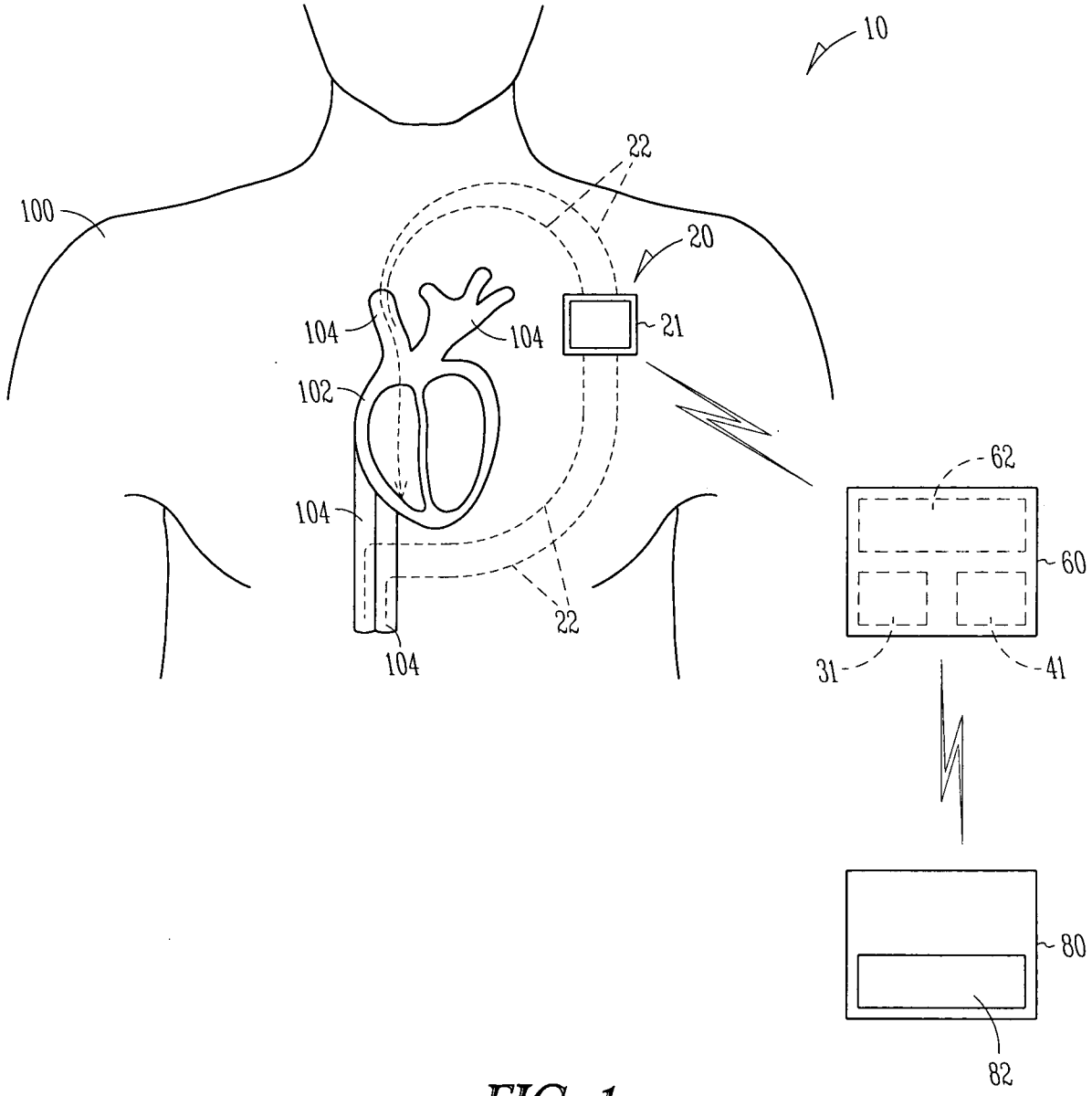
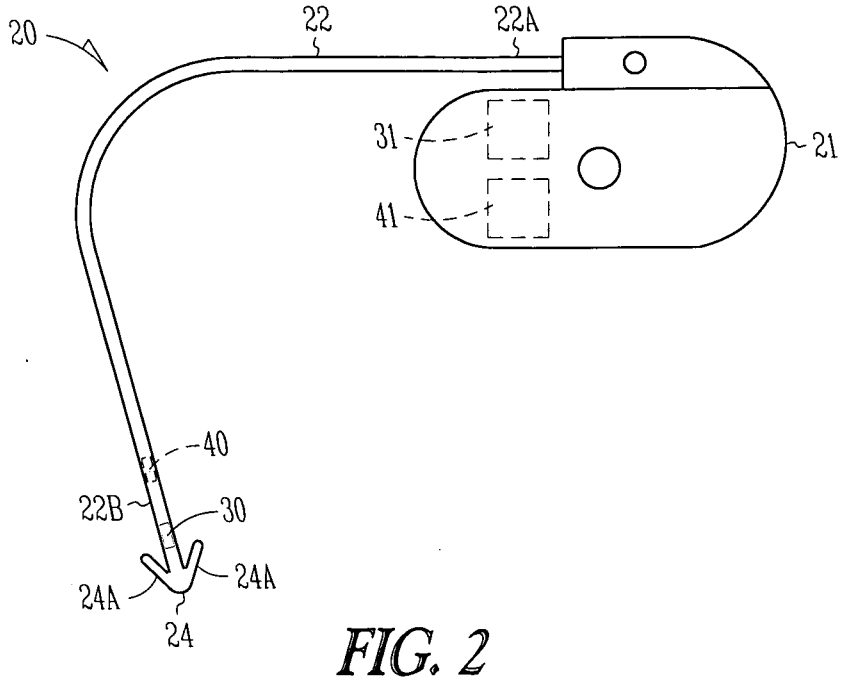


FIG. 1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22B
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24A
24A
24

FIG. 2

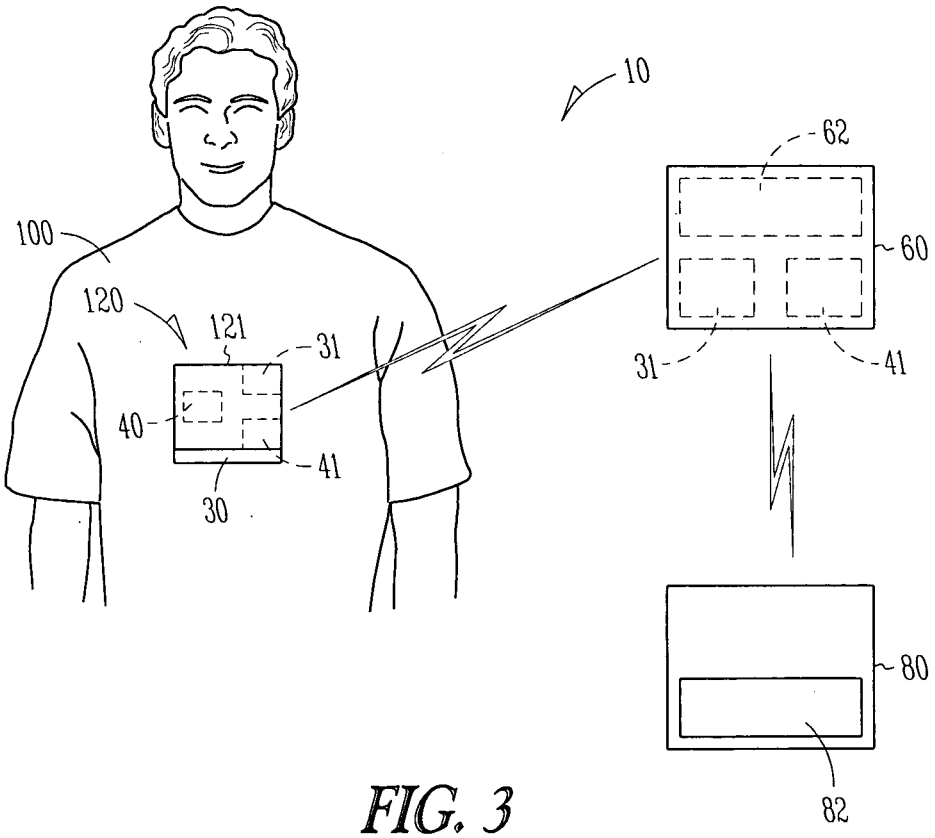
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FIG. 3

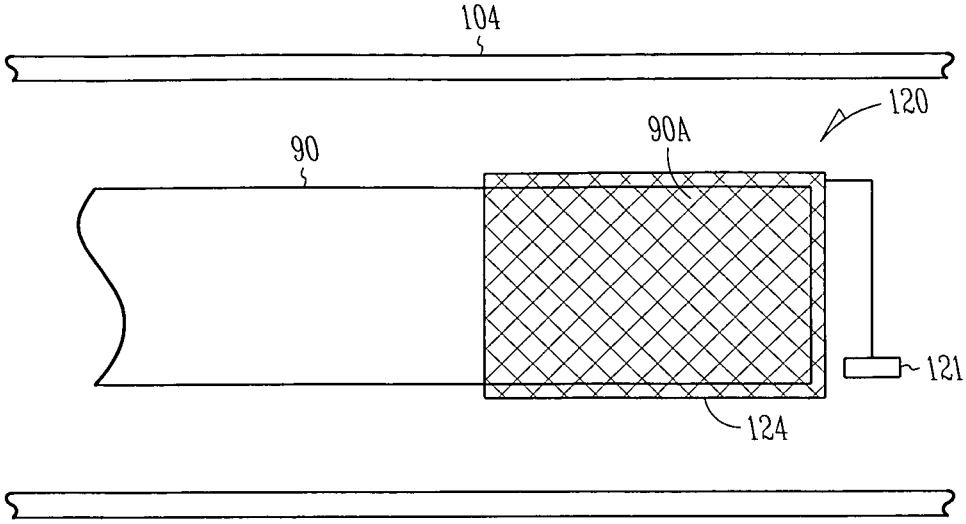

FIG. 4

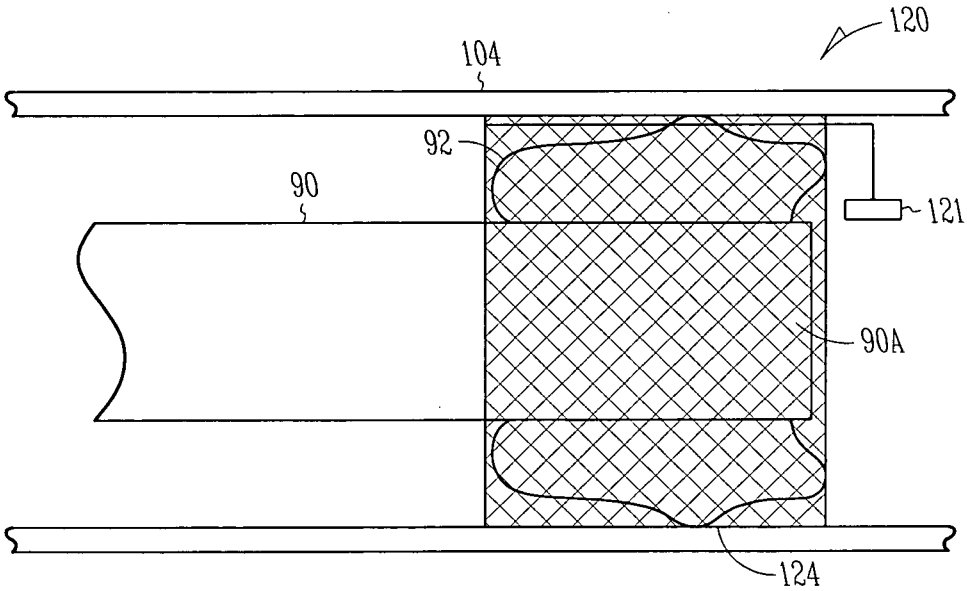

FIG. 5

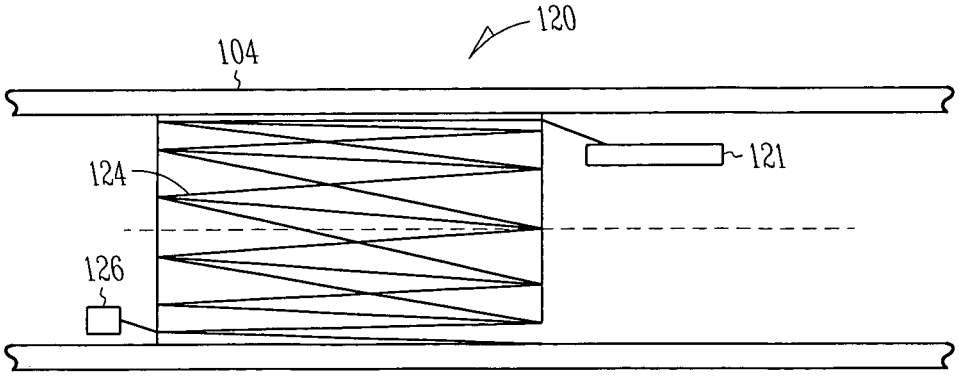

FIG. 6

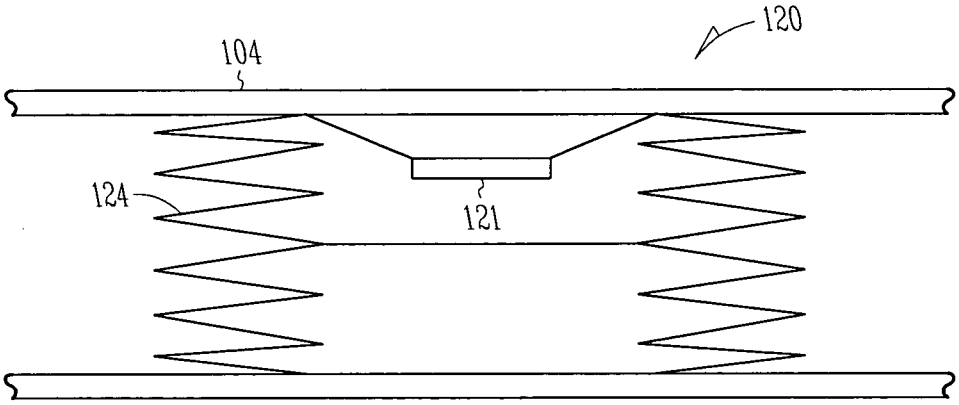

FIG. 7

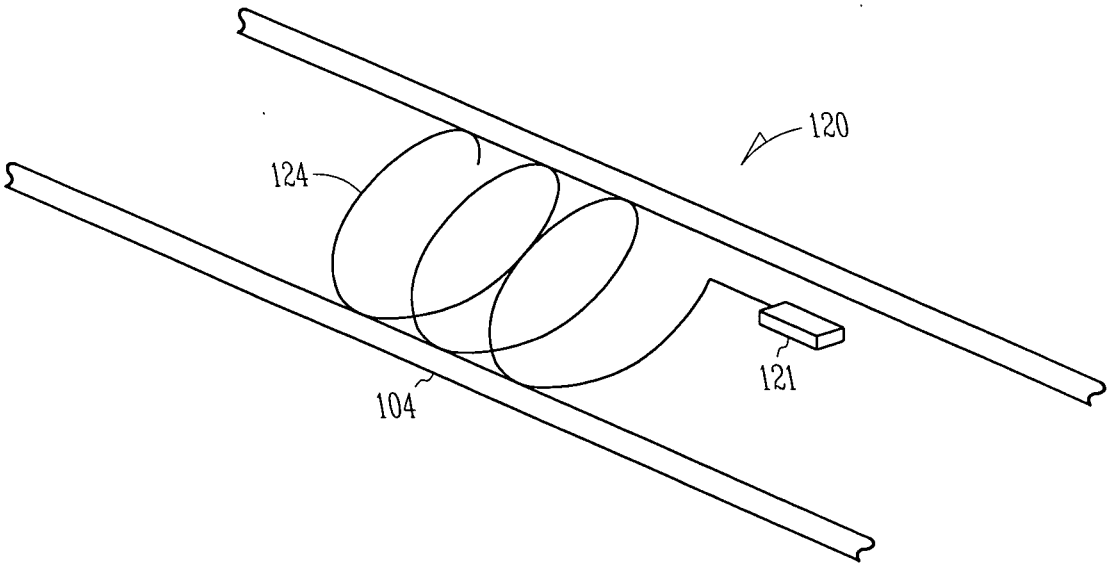

FIG. 8

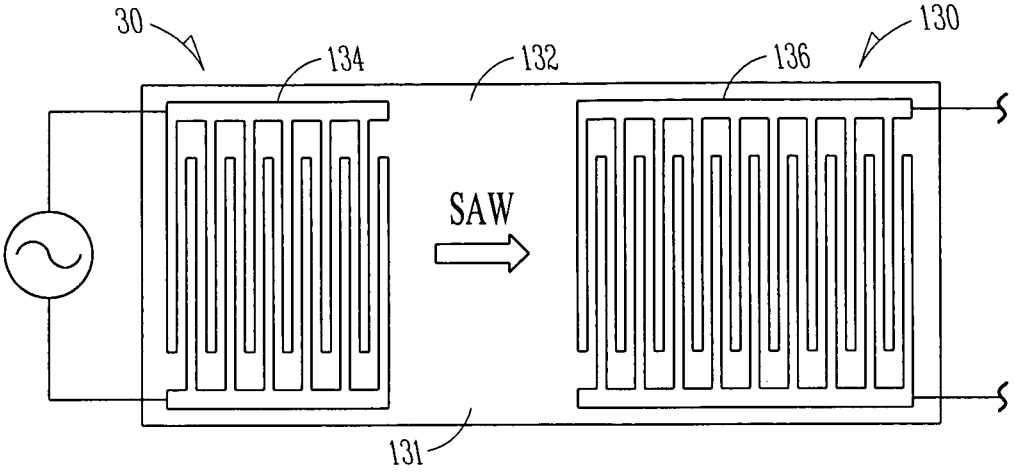

FIG. 9A

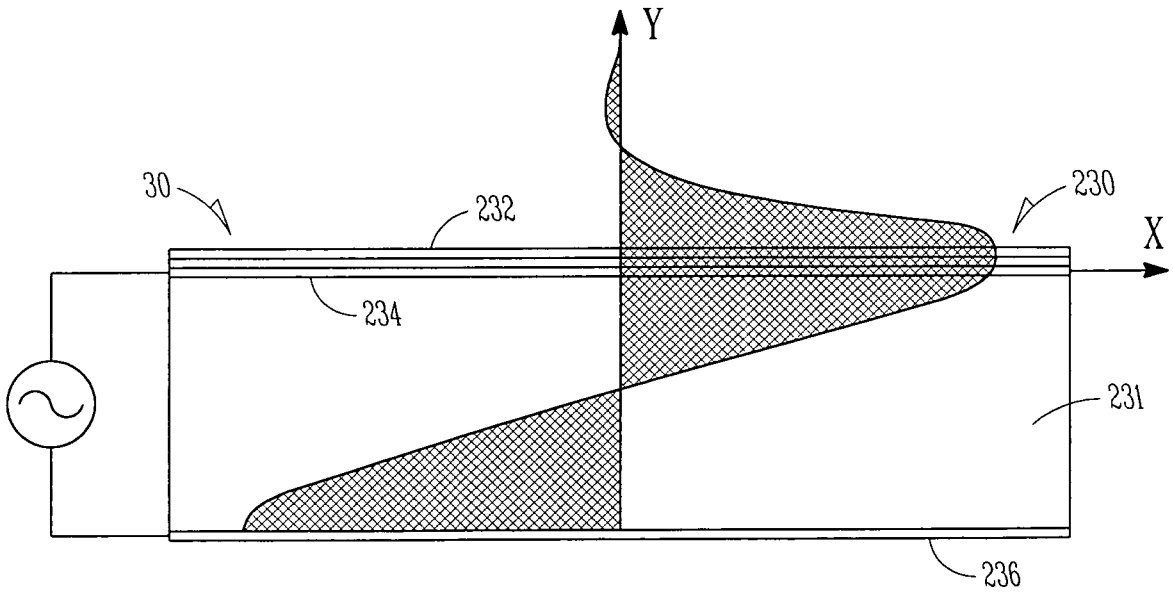

FIG. 9B

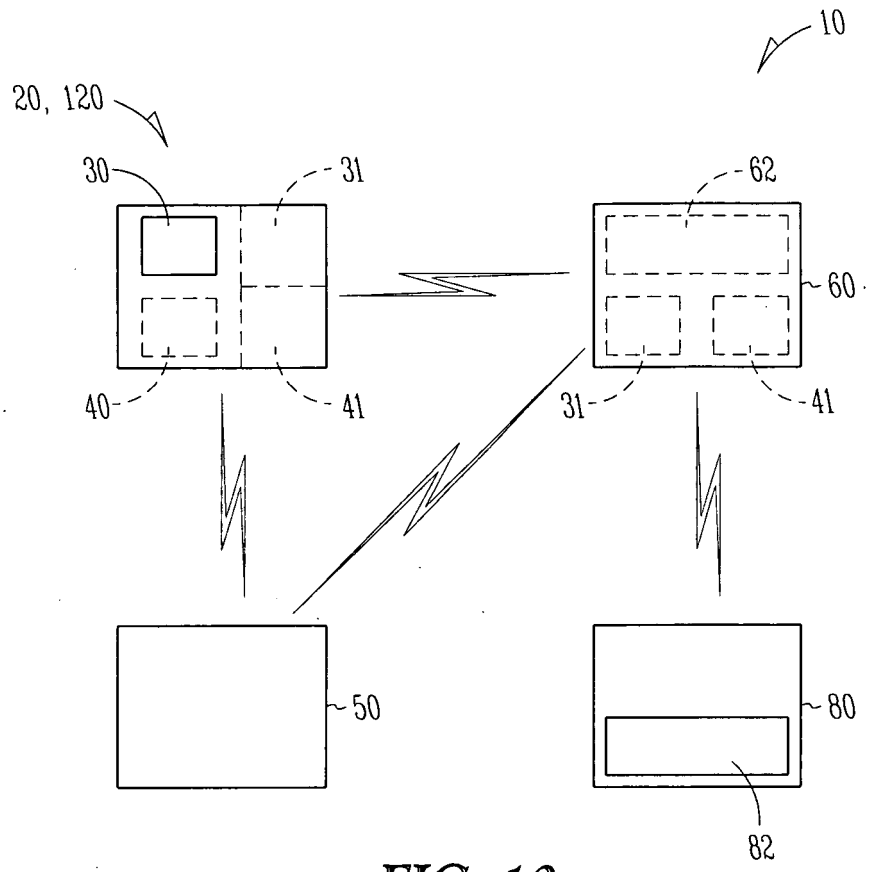
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FIG. 10

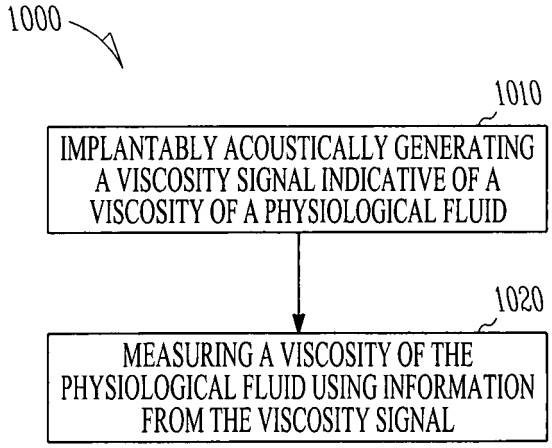
1000
1010
IMPLANTABLY ACOUSTICALLY GENERATING A VISCOSITY SIGNAL INDICATIVE OF A VISCOSITY OF A PHYSIOLOGICAL FLUID
1020
MEASURING A VISCOSITY OF THE PHYSIOLOGICAL FLUID USING INFORMATION FROM THE VISCOSITY SIGNAL

FIG. 11

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/002538

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00

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)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, INSPEC, MEDLINE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005/058166 A (IMP COLLEGE INNOVATIONS LTD [GB]; TOUMAZOU CHRISTOPHER [GB]; MCLEOD CH) 30 June 2005 (2005-06-30)	1,2,4, 10,11, 13, 16-19, 26,27,30
A		3,9,12, 14,15, 20,25, 28,29
X	WO 2006/060806 A (MEDTRONIC INC [US]; GOTTESMAN JANELL M [US]; MARKOWITZ H TOBY [US]; WI) 8 June 2006 (2006-06-08) page 10, line 5 - line 8 page 12, line 2	1-4,13, 14,17, 18,27,28
A	page 9, line 1 - line 4	8

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"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)

"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

"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

"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

"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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 July 2008	23/07/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Knüpling, Moritz

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/002538

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 2007/090159 A (MEDTRONIC INC [US]; CHEN KAIMIN [US]; SCHMIDT CRAIG L [US]; MERRITT DO) 9 August 2007 (2007-08-09) paragraphs [0100], [0109]	1-8,13, 14,18, 21,26,27
A	WO 92/15239 A (KENSEY NASH CORP [US]) 17 September 1992 (1992-09-17) page 4, line 18 - line 22	1,3,18, 20
A	WO 2004/052182 A (PROTEUS BIOMEDICAL INC [US]) 24 June 2004 (2004-06-24) paragraphs [0048], [0062]	1,5-7,18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/002538

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. [X] Claims Nos.: 22,23,24
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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 allsearchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers 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 and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/002538

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2005058166 A	30-06-2005	EP 1699359 A1	13-09-2006
		JP 2007513669 T	31-05-2007
		US 2007282172 A1	06-12-2007
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		US 2006122864 A1	08-06-2006
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		WO 2007089980 A2	09-08-2007
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WO 2004052182 A	24-06-2004	AU 2003296956 A1	30-06-2004
		CA 2508800 A1	24-06-2004
		EP 1581102 A2	05-10-2005
		JP 2006509547 T	23-03-2006
		US 2004193021 A1	30-09-2004

专利名称(译)	可植入粘度监测装置及其方法		
公开(公告)号	EP2175770A1	公开(公告)日	2010-04-21
申请号	EP2008726118	申请日	2008-02-26
[标]申请(专利权)人(译)	心脏起搏器股份公司		
申请(专利权)人(译)	心脏起搏器，INC.		
当前申请(专利权)人(译)	心脏起搏器，INC.		
[标]发明人	ZHANG YUNLONG MI BIN		
发明人	ZHANG, YUNLONG MI, BIN		
IPC分类号	A61B5/00		
CPC分类号	A61B5/0031 A61B5/6882		
优先权	11/781769 2007-07-23 US		
其他公开文献	EP2175770B1		
外部链接	Espacenet		

摘要(译)

一种装置包括可植入声学粘度传感器，其被配置为在声学上获得指示与粘度传感器接触的流体粘度的粘度信号。粘度测量电路根据粘度信号产生粘度测量值。