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(54) Title: IMPLANTABLE PRESSURE MONITOR

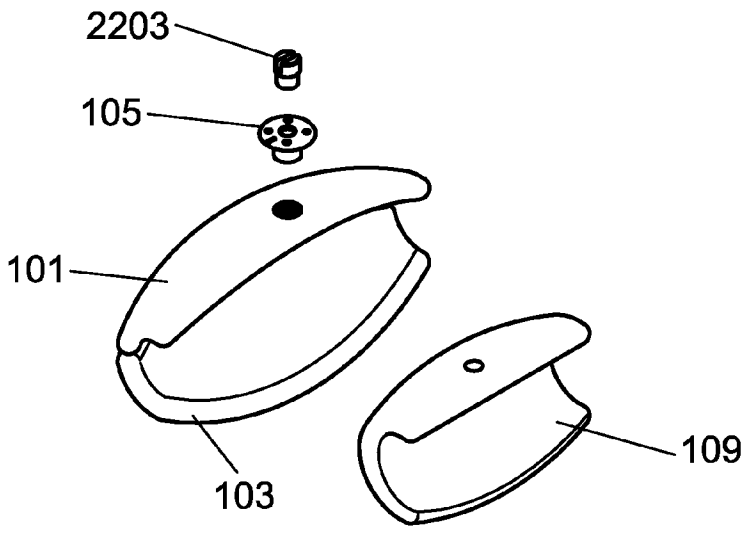

Fig. 7

(57) Abstract: There is provided an implantable pressure monitor having a fluid sack in contact with a body part of a patient where the fluid sack is retained to the body part by a pressure monitor housing that may have various attachment means. The fluid sack is filled with a liquid such as silicone oil The pressure monitor housing has an opening that provides access to a fistula with a fluid valve that terminates through the fluid sack. A fiber optic pressure sensor is in contact with the liquid in the fluid sack by way of the fistula and fluid valve. In some embodiments of the present invention, an electronics module is incorporated with the implantable pressure monitor to provide telemetry, power, and the like.

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IMPLANTABLE PRESSURE MONITOR

TECHNICAL FIELD

The present invention relates generally to medical devices, and more particularly to an implantable pressure monitor that has a variety of applications such as blood pressure monitoring, aneurism monitoring, and the like.

BACKGROUND ART

The ability to monitor pressure in a living organism such as an animal or a human has numerous applications ranging from blood pressure monitoring to monitoring medical conditions such as aneurisms and the like. While monitoring blood pressure through the skin, for example, is known, the accuracy of such devices may be questionable. Targeted pressure monitoring of a medical condition such as an aneurism requires a precise and reliable device. Such a device should be non-invasive to the vessel itself to prevent problems associated with penetration of the blood vessel.

While monitoring of blood pressure or other pressure within a body is often done on a transitory basis, there are situations that require comprehensive continuous monitoring. For example, an aneurism may require continuous monitoring to ensure that it does not continue to grow in size and rupture. The ability to continuously monitor an aneurism, and provide the patient or a medical practitioner with real-time information related to their condition is something that has heretofore been unknown. Such continuous real-time monitoring allows immediate action to be taken in the event that the patient becomes at risk. Currently, aneurism monitoring involves regular surveillance imaging that requires a visit to a medical practitioner for each check of the condition of the aneurism. There is no real-time monitoring system that could provide pressure readouts on an instrument that could, for example, be worn on a patient's wrist, or provide the data to a remote monitoring device by way of a computer network, a wireless network, or the like.

It is thus an object of the present invention to provide an implantable pressure monitor that is non-invasive to the vessel or body part to which pressure is being monitored. It is another object of the present invention to provide an implantable pressure monitor that can provide data to a remote device such as a hospital monitor, smart phone, or other such electronic device. It is another object of the present invention to provide an implantable pressure monitor that provides real time status on medical conditions such as aneurisms. It is yet another object of the present invention to provide an implantable pressure monitor that provides real time blood pressure data. It is a further object of the present invention to provide an above skin blood pressure monitor. These and other objects of the present invention are not to be considered comprehensive or

exhaustive, but rather, exemplary of objects that may be ascertained after reading this specification and claims in view of the accompanying drawings.

DISCLOSURE OF THE INVENTION

In accordance with the present invention, there is provided an implantable pressure monitor comprising a pressure monitor housing, a fluid sack retained by the pressure monitor housing, a liquid contained within the fluid sack, a fistula with a fluid valve that terminates through the fluid sack, an opening in the pressure monitor housing for access to the fistula, and a fiber optic pressure sensor in contact with the fluid by way of the fistula and fluid valve.

The foregoing paragraph has been provided by way of introduction, and is not intended to limit the scope of the invention as described by this specification, claims and the attached drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described by reference to the following drawings, in which like numerals refer to like elements, and in which:

Figure 1 is a perspective view of a wrap around pressure monitor on a vessel;

Figure 2 is a plan view of the wrap around pressure monitor of Figure 1;

Figure 3 is a rotated plan view of the wrap around pressure monitor of Figure 1;

Figure 4 is a rotated perspective view of the wrap around pressure monitor of Figure 1;

Figure 5 is a perspective view of the wrap around pressure monitor of Figure 1 without the fiber optic sensor;

Figure 6 is a perspective view of the wrap around pressure monitor of Figure 1 in the open position;

Figure 7 is an exploded view of the wrap around pressure monitor of Figure 1 in the open position;

Figure 8 is a perspective view of a strap based pressure monitor on a vessel;

Figure 9 is a rotated perspective view of the strap based pressure monitor of Figure 8;

Figure 10 is a rotated plan view of the strap based pressure monitor of Figure 8;

Figure 11 is a top perspective view of the strap based pressure monitor of Figure 8;

Figure 12 is an exploded perspective view of the strap based pressure monitor of Figure 8;

Figure 13 is a perspective view of the strap based pressure monitor of Figure 8 without the fiber optic pressure sensor;

Figure 14 is a plan view of the strap based pressure monitor of Figure 8 without the fiber optic pressure sensor;

Figure 15 is a plan view of the strap based pressure monitor cut along line A-A of Figure 14;

Figure 16 is an end view of the strap based pressure monitor of Figure 8 without the fiber optic sensor;

Figure 17 is a perspective view of a suture tab pressure monitor on a vessel;

Figure 18 is a side plan view of the suture tab pressure monitor of Figure 17;

Figure 19 is a perspective view of the suture tab pressure monitor of Figure 17;

Figure 20 is a top plan view of the suture tab pressure monitor of Figure 17;

Figure 21 is a plan view of the suture tab pressure monitor cut along line A-A of Figure 20;

Figure 22 is a perspective view of a fistula of the present invention;

Figure 23 is a side plan view of a fistula of the present invention;

Figure 24 is a top plan view of a fistula of the present invention; and

Figure 25 is a chart recording of micro movements of a patient's skin over the external carotid artery expressed as pressure vs. time.

The present invention will be described in connection with a preferred embodiment, however, it will be understood that there is no intent to limit the invention to the embodiment described. On the contrary, the intent is to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by this specification, claims and drawings attached hereto.

BEST MODE FOR CARRYING OUT THE INVENTION

The implantable pressure monitor of the present invention may have various embodiments, some of which are described herein, and others of which may be inferred from or otherwise envisioned based on the disclosure contained herein.

The implantable pressure monitor makes use of small changes in a body part (human or animal) to determine pressure. For example, a blood vessel experiences small "micro" movements as blood travels through the blood vessel. These movements can be correlated to blood pressure. In a similar way, pressure buildup in an organ or other body part can be detected by the implantable pressure monitor, providing an alert to a pending medical emergency. The implantable pressure monitor relies on the use of a fiber optic pressure sensor and a novel pressure sensing structure. The fiber optic pressure sensor may, in one embodiment of the present invention, be structured as a Fabry-Perot Interferometer such as the one disclosed in United States Patent 7,684,657 to Donlagic et al. and entitled "Single Piece Fabry-Perot Optical Sensor And Method of Manufacturing Same", the entire disclosure of which is incorporated herein by reference in it's entirety. Other fiber optic pressure sensors may also be employed, and may, in some embodiments of the present invention, contain a moveable structure such as a diaphragm that changes position in relation to a reference (such as the end of the optical fiber) under varying pressure conditions to in turn provide pressure measurements through, for example, optical means. An example of a suitable fiber optic pressure sensor is the model FOP-F125 Pressure Sensor manufactured by FISO Technologies, Inc. of Quebec, Canada. The pressure sensing structure comprises a fluid filled sack that makes contact with the body part of which pressure is to be monitored. The fiber optic pressure sensor is in communication with the liquid contained in the fluid sack. This arrangement allows for sensing of small movements across a greater surface area, as opposed to what would essentially be a point source with the fiber optic pressure sensor alone. The fluid sack is in turn attached to the body part, for example a blood vessel like the aorta, by way of an accommodating and suitably shaped pressure monitor housing. The fiber optic pressure sensor may then be run outside the body to appropriate instrumentation to provide pressure readings, alerts, and the like. In some embodiments of the present invention, the fiber optic pressure sensor may terminate with an electronics module that

is contained with the implantable pressure monitor. The electronics module in turn provides telemetry data to a hospital monitor, a smart phone, or other such electronic device that can provide pressure readings, alerts, alarms, and the like.

Several embodiments of the present invention will be described by way of the figures where figures 1-7 describe a first embodiment, figures 8-16 describe a second embodiment, and figures 17-21 describe a third embodiment. The embodiments described and depicted herein are intended primarily for use with a blood vessel and related pressure measurements. One can envision after reading this disclosure an implantable pressure monitor that has a different shape and size to accommodate pressure monitoring of other anatomical parts such as, for example, internal organs. Such changes being considered within the spirit and broad scope of the present invention as described and depicted herein. In addition, an external, non-implantable pressure monitor using the fiber optic pressure sensor and the techniques described herein is also to be considered within the spirit and scope of the present invention. An output chart of such an embodiment of the present invention being depicted in Figure 25.

A first embodiment of the present invention, as depicted in Figures 1-7, attaches to a blood vessel by way of several retention parts that fold or hinge together. Figure 1 is a perspective view of a wrap around pressure monitor on a vessel. A fluid sack 109 can be seen in contact with the blood vessel. The fluid sack 109 may be made from, for example, a metal foil, such as an aluminum foil, with suitable biocompatible coatings as necessary. The fluid sack 109 may also be made from a biocompatible cloth such as polyethylene terephthalate, also with suitable coatings as necessary. The fluid sack 109 contains a liquid such as, for example, silicone oil, that serves to transmit small movements of the blood vessel that correspond to pressure changes. Other liquids may also be employed such as a saline solution, water, or the like. Higher viscosity fluids are preferred due to their ability to transmit small pressure changes, but the present invention is not limited to such fluids. In fact, in some embodiments of the present invention, the fluid sack 109 may instead contain a gas, a gel, or the like. The fluid sack 109 may be of a shape conformal to the first retention part 101 and the second retention part 103. A fistula 105 having a fluid valve terminates through the fluid sack 109 so as to provide a liquid (or gas or gel) tight seal when the fiber optic pressure sensor 107 is placed through the fistula 105 and into the liquid, gas or gel contained in the fluid sack 109. The fistula 105 is made from a biocompatible material such as a stainless steel, a biocompatible plastic such as Polyethylene,

Polysulfone, Polypropylene, or the like. A fistula, as used herein, refers to any opening, device, apparatus, seal, or structure that provides access to the inside of the fluid sack while keeping to contents of the fluid sack contained within. The fistula may, in some embodiments of the present invention, contain a fluid valve, seal, gasket, fitting, or similar structure to ensure a complete seal once the fiber optic pressure sensor is inserted into the fluid sack. The fistula may also simply be a pass through or via and may have suitable sealing material to ensure a leak free fit. The fistula 105 may be made by machining, casting, molding, or the like. An example of a suitable fistula can be seen in Figures 22-24. The fistula 105 seals to the fluid sack 109 using mechanical and sealant means, and also may contain a valve that may be a membrane or similar structure for sealing the liquid, gas or gel to the confines of the fluid sack 109 when the fiber optic pressure sensor 107 is inserted through the fistula 105 into the fluid sack 109. The fistula 105 passes through the pressure monitor housing by way of an opening in the first retention part 101 or the second retention part 103. To hold the fluid sack 109 against the blood vessel, a pressure monitor housing can be seen comprising a first retention part 101 and a second retention part 103. The first retention part 101 and the second retention part 103 may be made from a biocompatible material such as a stainless steel, a biocompatible plastic such as Polyethylene, Polysulfone, Polypropylene, or the like. The first retention part 101 and the second retention part 103 may be made by machining, casting, molding, or the like. Such an arrangement can be hinged, pinned, or otherwise connected so that the first retention part 101 and the second retention part 103 close around the fluid sack 109 in such a way that proper communication of small movements in the vessel are sent through the fluid contained in the fluid sack 109 to the fiber optic pressure sensor 107. The first retention part 101 and the second retention part 103 may, in some embodiments of the present invention, be one and the same (a single structure). For placement around vessels, the first retention part 101 and the second retention part 103 have a generally cylindrical inner cavity or surface to accommodate a vessel such as an artery or the like. In some embodiments of the present invention, the first retention part 101 and the second retention part 103 are of a similar shape and geometry and may be curved or otherwise shaped to conform to a vessel. In other embodiments of the present invention, the first retention part 101 and the second retention part 103 are of differing shape and geometry and may have areas where the fluid sack 109 is exposed or otherwise free from the first retention part 101 or the second retention part 103. The fiber optic pressure sensor 107 may, in one embodiment of the present

invention, be structured as a Fabry-Perot Interferometer or otherwise contain a moveable structure such as a diaphragm that changes position in relation to a reference such as the end of the optical fiber under varying pressure conditions to in turn provide pressure measurements through, for example, optical means. A light source (not depicted) may be provided in optical communication with the fiber optic pressure sensor to provide an optical signal to the fiber optic pressure sensor, and a fiber optic receiver may be employed to receive the optical signal from the fiber optic pressure sensor. The received optical signal containing information that correlates with pressure readings, as seen, for example, in Figure 25.

The first retention part 101 and the second retention part 103 do not necessarily wrap completely around the blood vessel. Figure 2 is a plan view of the wrap around pressure monitor of Figure 1 showing a generally open side with the fluid sack 109.

Figure 3 is a rotated plan view of the wrap around pressure monitor of the present invention and Figure 4 is a rotated perspective view of the wrap around pressure monitor of the present invention. The fiber optic pressure sensor 807 can be seen exiting the fistula 105. The overall shape of the pressure monitor of the present invention may be, for example, a prolate spheroid or other similar geometry. Preferably, the shape of the pressure monitor should be devoid of sharp edges when implanted to avoid surgical complications. Various coatings may be applied to the pressure monitor such as drug eluting coatings and the like. In some embodiments of the present invention, the housing of the pressure monitor also serves to attach the pressure monitor to an anatomical part, either as a function of it's overall geometry, or as a function of features such as, for example, suture tabs, clamps, pins, and the like.

Figure 5 is a perspective view of the wrap around pressure monitor without the fiber optic sensor. Figure 6 is a perspective view of the wrap around pressure monitor of Figure 1 in the open position, and Figure 7 is an exploded view of the wrap around pressure monitor in the open position showing clearly the fluid sack 109 within the pressure monitor housing. The embodiment depicted by way of Figures 1-7 may be useful, for example, with laboratory animals such as rats. The fiber optics will leave the body of the laboratory animal or human through a suitable fistula, and be connected to an appropriate interface that generates and reads the optical signals necessary to drive the fiber optic pressure sensor.

For applications that include use with humans, the overall pressure monitor should preferably be small in relation to the blood vessel or organ to which pressure is to be monitored.

In addition, while in some clinical applications it may be acceptable to have the fiber optics leave the body through a suitable fistula, it oftentimes will be desirable to have electronics that provide the pressure data via telemetry to a receiving unit such as a hospital monitor, a smart phone, or other such electronic device that can provide pressure readings, alerts, alarms, and the like. These electronics may be integral with, or attached to, the pressure monitor, or may otherwise be in physical proximity to the pressure monitor of the present invention.

Figures 8-16 describe a second embodiment of the implantable pressure monitor where the pressure monitor housing 801 is attached to the vessel, organ, or other anatomical part by way of a strap 803 as seen in the perspective view of Figure 8. The strap 803 may be made from a suitable biocompatible material such as, for example, a biocompatible cloth such as, for example, polyethylene terephthalate. The strap 803 is an attachment structure for placing the pressure monitor on a body part. Other attachment structures such as hooks, pins, mesh, and the like may also be employed.

Figure 8 is a perspective view of the strap based pressure monitor on a blood vessel. A fluid sack is contained within the pressure monitor housing 801 such that it makes contact with the blood vessel. The fluid sack can be seen in the cutaway view of Figure 15 (see 1501). The fluid sack may be made from a metal foil, such as an aluminum foil, with suitable biocompatible coatings as necessary. The fluid sack may also be made from a biocompatible cloth such as polyethylene terephthalate, also with suitable coatings as necessary. The fluid sack contains a liquid such as, for example, silicone oil, that serves to transmit small movements of the blood vessel that correspond to pressure changes. Other liquids may also be employed such as a saline solution, water, or the like. Higher viscosity fluids are preferred due to their ability to transmit small pressure changes, but the present invention is not limited to such fluids. In fact, in some embodiments of the present invention, the fluid sack may instead contain a gas, a gel, or the like. A fistula 805 having a fluid valve terminates through the fluid sack so as to provide a liquid (or gas or gel) tight seal when the fiber optic pressure sensor 807 is placed through the fistula 805 and into the liquid, gas or gel contained in the fluid sack. The fistula 805 is made from a biocompatible material such as a stainless steel, a biocompatible plastic such as Polyethylene, Polysulfone, Polypropylene, or the like. A fistula, as used herein, refers to any opening, device, apparatus, seal, or structure that provides access to the inside of the fluid sack while keeping to contents of the fluid sack contained within. The fistula may, in some embodiments of the present

invention, contain a fluid valve, seal, gasket, fitting, or similar structure to ensure a complete seal once the fiber optic pressure sensor is inserted into the fluid sack. The fistula may also simply be a pass through or via and may have suitable sealing material to ensure a leak free fit. The fistula 805 may be made by machining, casting, molding, or the like. An example of a suitable fistula can be seen in Figures 22-24. The fistula 805 seals to the fluid sack using mechanical and sealant means, and also may contain a valve that may be a membrane or similar structure for sealing the liquid, gas or gel to the confines of the fluid sack when the fiber optic pressure sensor 807 is inserted through the fistula 805 into the fluid sack. The fistula 805 passes through the pressure monitor housing by way of an opening. To hold the fluid sack against the blood vessel, a pressure monitor housing 801 can be seen. The pressure monitor housing 801 may be made from a biocompatible material such as a stainless steel, a biocompatible plastic such as Polyethylene, Polysulfone, Polypropylene, or the like. The pressure monitor housing 801 may be made by machining, casting, molding, or the like. The pressure monitor housing 801 encompasses the fluid sack in such a way that proper communication of small movements in the vessel are sent through the fluid contained in the fluid sack to the fiber optic pressure sensor 807. The fiber optic pressure sensor 807 may, in one embodiment of the present invention, be structured as a Fabry-Perot Interferometer or otherwise contain a moveable structure such as a diaphragm that changes position in relation to a reference such as the end of the optical fiber under varying pressure conditions to in turn provide pressure measurements through, for example, optical means. Other attributes and components from the pressure monitor disclosed by way of Figures 1-7 may also be incorporated with the embodiment depicted in Figures 8-16.

Figure 9 is a rotated perspective view of the strap based pressure monitor. It should be noted that the strap 803 is shown as not completely encompassing the blood vessel or anatomical part The overall geometry of the strap 803 including it's length and width may vary based on the application, and in some embodiments of the present invention, the strap 803 may fully encompass the blood vessel or anatomical part.

Figure 10 is a rotated plan view of the strap based pressure monitor. Shown in Figure 10 is an electronics module 1001 that contains telemetry circuitry and power circuitry. The electronics module 1001 employs miniaturization techniques such as microelectronic design and packaging, hybrid circuit design and packaging, and the like. The electronics module 1001 contains an energy storage device that may be a battery, or may be a capacitor such as an

ultracapacitor or the like. Suitable batteries include, but are not limited to, lithium ion implantable batteries or other microbatteries that are implantable. To charge the energy storage device, a charging coil may be employed that provides inductively coupled charging from an external source of electromagnetic radiation. Such an arrangement is described in United States Patent Application Publication US2009/0289595 A1 to Chen et al. and entitled "Wireless Charging Module and Electronic Apparatus", the entire disclosure of which is incorporated herein by reference. The charging coil (not shown) is made from a conductive material such as copper, and may be coiled or formed as a spiral. The conductive material may further be a wire, flat stock, printed conductive film, or the like. In addition, in some embodiments of the present invention, an energy harvesting device such as a MEMS device or a piezoelectric device to convert kinetic energy of the body into electrical energy is used to charge the energy storage device. The energy storage device contained within the electronics module 1001 provides power to the telemetry circuitry. The telemetry circuitry includes a fiber optic receiver with appropriate fiber optic terminations to receive the distal end of the fiber optic pressure sensor, which may, in some embodiments of the present invention, be contained within the pressure monitor housing 801. The telemetry circuitry contains both optical transmit and receive functionality as well as logic and related circuits to convert the optical signals from the fiber optic pressure sensor 807 into pressure data that is in turn transmitted from the electronics module 1001 to an external receiving unit such as a hospital monitor, smart phone, computer, or the like. The electronics module 1001 contains a radiofrequency transmitter capable of sending the pressure data, or may, in some embodiments of the present invention, contain circuitry capable of being interrogated by an external device and send the pressure data on demand. Figure 11 is a top perspective view of the strap based pressure monitor. Figure 12 is an exploded perspective view of the strap based pressure monitor depicting the fluid sack and related pressure monitor housing. Figure 13 is a perspective view of the strap based pressure monitor without the fiber optic pressure sensor visible. As stated previously, the fiber optic pressure sensor may be terminated within the pressure monitor housing to the electronics module 1001 in some embodiments of the present invention.

Figure 14 is a plan view of the strap based pressure monitor without the fiber optic sensor visible and Figure 15 is a plan view of the strap based pressure monitor cut along line A-A of Figure 14. The internal fluid sack 1501 and internal fluid can be seen as the crosshatched area

depicted. Figure 16 is an end view of the strap based pressure monitor without the fiber optic sensor visible.

Similar to Figures 8-16 except for the mounting structure, Figures 17-21 describe a third embodiment of the implantable pressure monitor where the pressure monitor housing 1701 is attached to the vessel, organ, or other anatomical part by way of suture tabs such as the first suture tab 1703 and the second suture tab 1705 as seen in the perspective view of Figure 17. The suture tabs are an attachment structure for placing the pressure monitor on a body part. Other attachment structures such as hooks, pins, mesh, and the like may also be employed. The suture tabs may be made from a biocompatible material such as a stainless steel, a biocompatible plastic such as Polyethylene, Polysulfone, Polypropylene, or the like. The suture tabs may be made by machining, casting, molding, or the like, and may be cast, molded, machined, or otherwise formed with the pressure monitor housing 1701. Other attributes and components from the pressure monitor disclosed by way of Figures 1-7 and Figures 8-16 may also be incorporated with the embodiment depicted in Figures 17-21.

Figure 17 is a perspective view of a suture tab pressure monitor on a blood vessel. A fluid sack is contained within the pressure monitor housing 1701 such that it makes contact with the blood vessel. The fluid sack can be seen in the cutaway view of Figure 21 (see 2101). The fluid sack may be made from a metal foil, such as an aluminum foil, with suitable biocompatible coatings as necessary. The fluid sack may also be made from a biocompatible cloth such as polyethylene terephthalate, also with suitable coatings as necessary. The fluid sack contains a liquid such as, for example, silicone oil, that serves to transmit small movements of the blood vessel that correspond to pressure changes. Other liquids may also be employed such as a saline solution, water, or the like. Higher viscosity fluids are preferred due to their ability to transmit small pressure changes, but the present invention is not limited to such fluids. In fact, in some embodiments of the present invention, the fluid sack may instead contain a gas, a gel, or the like. A fistula 1707 having a fluid valve terminates through the fluid sack so as to provide a liquid (or gas or gel) tight seal when the fiber optic pressure sensor (not shown) is placed through the fistula 1707 and into the liquid, gas or gel contained in the fluid sack. The fistula 1707 is made from a biocompatible material such as a stainless steel, a biocompatible plastic such as Polyethylene, Polysulfone, Polypropylene, or the like. A fistula, as used herein, refers to any opening, device, apparatus, seal, or structure that provides access to the inside of the fluid sack

while keeping to contents of the fluid sack contained within. The fistula may, in some embodiments of the present invention, contain a fluid valve, seal, gasket, fitting, or similar structure to ensure a complete seal once the fiber optic pressure sensor is inserted into the fluid sack. The fistula may also simply be a pass through or via and may have suitable sealing material to ensure a leak free fit. The fistula 1707 may be made by machining, casting, molding, or the like. An example of a suitable fistula can be seen in Figures 22-24. The fistula 1707 seals to the fluid sack using mechanical and sealant means, and also may contain a valve that may be a membrane or similar structure for sealing the liquid, gas or gel to the confines of the fluid sack when the fiber optic pressure sensor is inserted through the fistula 1707 into the fluid sack. The fistula 1707 passes through the pressure monitor housing by way of an opening. To hold the fluid sack against the blood vessel, a pressure monitor housing 1701 can be seen. The pressure monitor housing 1701 may be made from a biocompatible material such as a stainless steel, a biocompatible plastic such as Polyethylene, Polysulfone, Polypropylene, or the like. The pressure monitor housing 1701 may be made by machining, casting, molding, or the like. The pressure monitor housing 1701 encompasses the fluid sack in such a way that proper communication of small movements in the vessel are sent through the fluid contained in the fluid sack to the fiber optic pressure sensor. The fiber optic pressure sensor may, in one embodiment of the present invention, be structured as a Fabry-Perot Interferometer or otherwise contain a moveable structure such as a diaphragm that changes position in relation to a reference such as the end of the optical fiber under varying pressure conditions to in turn provide pressure measurements through, for example, optical means.

Also depicted in Figure 17 is an electronics module 1709 that contains telemetry circuitry and power circuitry. The electronics module 1709 employs miniaturization techniques such as microelectronic design and packaging, hybrid circuit design and packaging, and the like. The electronics module 1709 contains an energy storage device that may be a battery, or may be a capacitor such as an ultracapacitor or the like. Suitable batteries include, but are not limited to, lithium ion implantable batteries or other microbatteries that are implantable. To charge the energy storage device, a charging coil may be employed that provides inductively coupled charging from an external source of electromagnetic radiation. Such an arrangement is described in United States Patent Application Publication US2009/0289595 A1 to Chen et al. and entitled "Wireless Charging Module and Electronic Apparatus", the entire disclosure of which is

incorporated herein by reference. The charging coil (not shown) is made from a conductive material such as copper, and may be coiled or formed as a spiral. The conductive material may further be a wire, flat stock, printed conductive film, or the like. In addition, in some embodiments of the present invention, an energy harvesting device such as a MEMS device or a piezoelectric device to convert kinetic energy of the body into electrical energy is used to charge the energy storage device. The energy storage device contained within the electronics module 1709 provides power to the telemetry circuitry. The telemetry circuitry includes a fiber optic receiver with appropriate fiber optic terminations to receive the distal end of the fiber optic pressure sensor, which may, in some embodiments of the present invention, be contained within the pressure monitor housing 1701. The telemetry circuitry contains both optical transmit and receive functionality as well as logic and related circuits to convert the optical signals from the fiber optic pressure sensor into pressure data that is in turn transmitted from the electronics module 1709 to an external receiving unit such as a hospital monitor, smart phone, computer, or the like. The electronics module 1709 contains a radiofrequency transmitter capable of sending the pressure data, or may, in some embodiments of the present invention, contain circuitry capable of being interrogated by an external device and send the pressure data on demand.

Figure 18 is a side plan view of the suture tab pressure monitor in use on a blood vessel. Figure 19 is a perspective view of the suture tab pressure monitor showing the suture tabs used to hold the pressure monitor in place. Figure 20 is a top plan view of the suture tab pressure monitor. Figure 21 is a plan view of the suture tab pressure monitor cut along line A-A of Figure 20 showing the fluid sack 2101 and internal fluid by way of the cross hatched area.

Figures 22-24 depict an exemplary fistula of the present invention. Figure 22 is a perspective view of a fistula 2201. The fiber optic pressure sensor port 2203 can be seen. Figure 23 is a side plan view of the fistula 2201 where a valve 2401 can be seen. The valve 2401 provides a liquid (or gas or gel) tight seal when the fiber optic pressure sensor is placed through the fistula and into the liquid, gas or gel contained in the fluid sack. The valve 2401 may be made from a membrane, a flexible silicone rubber, a mechanical fixture, or the like. The fistula 2201 is made from a biocompatible material such as a stainless steel, a biocompatible plastic such as Polyethylene, Polysulfone, Polypropylene, or the like. A fistula, as used herein, refers to any opening, device, apparatus, seal, or structure that provides access to the inside of the fluid sack while keeping to contents of the fluid sack contained within. The fistula may, in some

embodiments of the present invention, contain a fluid valve, seal, gasket, fitting, or similar structure to ensure a complete seal once the fiber optic pressure sensor is inserted into the fluid sack. The fistula may also simply be a pass through or via and may have suitable sealing material to ensure a leak free fit. The fistula 2201 may be made by machining, casting, molding, or the like. The fiber optic pressure sensor port 2203 is depicted as a slot, but other embodiments of the present invention use varying geometries. In addition, the overall geometry of the fistula 2201 may vary from one embodiment to another. Figure 24 is a top plan view of a fistula of the present invention.

Figure 25 is a chart recording of micro movements of a patient's skin over the external carotid artery expressed as pressure vs. time. An above the skin version of the present invention contains the fiber optic pressure sensor in direct contact with the skin above a monitoring point such as the external carotid artery. Small movements of the skin can be directly correlated with pressure changes. The chart in Figure 25, for example, depicts pressure changes in the range of 120 to 149 millimeters of mercury. The chart in Figure 25 has a y-axis range from zero to 150.0. The scale is thus millimeters of mercury (mm. Hg). In some embodiments of the present invention, a fluid sack, such as the fluid sack previously described herein, is placed between the patient's skin and the fiber optic pressure sensor. Such an arrangement may be packaged in a suitable housing, and may contain electronics to transmit the pressure information to a receiving device for subsequent display or storage. The receiving device may be worn on the patient's wrist, or it may be a device that is connected to a computer network for subsequent data transmission, display, and storage.

To use the implantable pressure monitor, the fluid sack is placed against the blood vessel, organ, or anatomical part of interest. The pressure monitor housing containing the fluid sack is then attached by way of a strap, sutures, retention parts, or the like. The fiber optic pressure sensor is then either guided outside the body or terminated with the electronics module.

While the pressure monitor described herein is suitable for implantation, the use of the novel pressure sensing structure (fluid sack and related fixtures) and fiber optic pressure sensor in above skin applications is also to be considered within the spirit and broad scope of the present invention.

It is, therefore, apparent that there has been provided, in accordance with the various objects of the present invention, an implantable pressure monitor.

While the various objects of this invention have been described in conjunction with preferred embodiments thereof, it is evident that many alternatives, modifications, and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of this specification, claims, and drawings appended herein.

What is claimed is:

1. An implantable pressure monitor comprising:
a pressure monitor housing;
a fluid sack retained by the pressure monitor housing;
a liquid contained within the fluid sack;
a fistula with a fluid valve that terminates through the fluid sack;
an opening in the pressure monitor housing for access to the fistula; and
a fiber optic pressure sensor in communication with the liquid by way of the fistula and fluid valve.

2. The implantable pressure monitor of claim 1, wherein the pressure monitor housing comprises a first retention part and a second retention part mechanically joined together.

3. The implantable pressure monitor of claim 1, wherein the pressure sensor is a Fabry-Perot Interferometer.

4. The implantable pressure monitor of claim 1, further comprising an electronics module coupled to the pressure sensor.

5. The implantable pressure monitor of claim 1, wherein the liquid contained within the fluid sack is a high viscosity liquid.

6. The implantable pressure monitor of claim 1, wherein the pressure monitor housing has the general shape of a prolate spheroid.

7. A pressure monitor comprising:
a pressure monitor housing;
a fluid sack retained by the pressure monitor housing;

an opening in the pressure monitor housing to allow the fluid sack to make contact with a body part of a patient;

a liquid contained within the fluid sack;

a fistula with a fluid valve that terminates through the fluid sack; and

a fiber optic pressure sensor in communication with the liquid by way of the fistula and fluid valve.

8. The pressure monitor of claim 7, further comprising an electronics module coupled to the pressure sensor.

9. The pressure monitor of claim 7, wherein the pressure sensor is a Fabry-Perot Interferometer.

10. The pressure monitor of claim 7, further comprising an electronics module coupled to the pressure sensor.

11. The pressure monitor of claim 7, wherein the liquid contained within the fluid sack is a high viscosity liquid.

12. An implantable pressure monitor comprising:

a pressure monitor housing;

an attachment structure mechanically affixed to the pressure monitor housing;

a fluid sack retained by the pressure monitor housing;

a liquid contained within the fluid sack;

a fistula with a fluid valve that terminates through the fluid sack;

an opening in the pressure monitor housing for access to the fistula; and

a fiber optic pressure sensor in communication with the liquid by way of the fistula and fluid valve.

13. The implantable pressure monitor of claim 12, wherein the pressure sensor is a Fabry-Perot Interferometer.

14. The implantable pressure monitor of claim 12, further comprising an electronics module coupled to the pressure sensor.

15. The implantable pressure monitor of claim 12, wherein the liquid contained within the fluid sack is a high viscosity liquid.

17. The implantable pressure monitor of claim 12, wherein the attachment structure is a strap.

18. The implantable pressure monitor of claim 12, wherein the attachment structure is a suture tab.

19. The implantable pressure monitor of claim 12, wherein the attachment structure is a plurality of suture tabs.

20. The implantable pressure monitor of claim 12, wherein the pressure monitor housing is open on one side to allow the fluid sack to contact a body part.

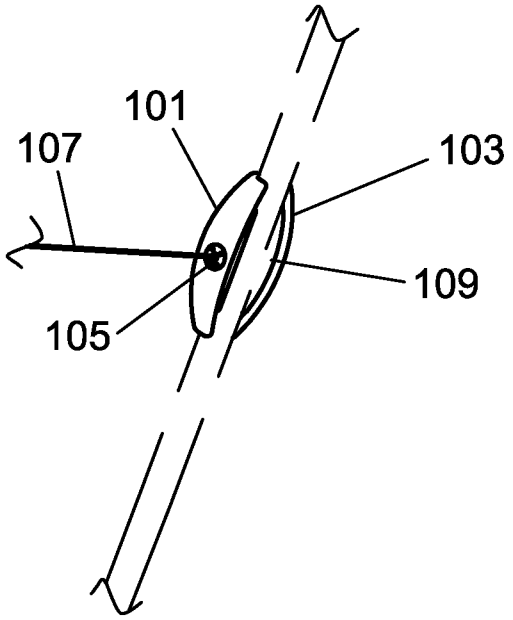


Fig. 1

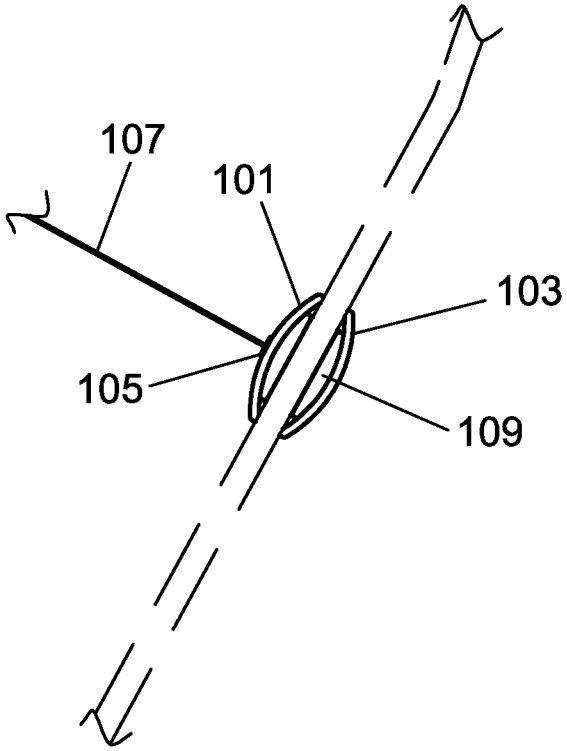


Fig. 2

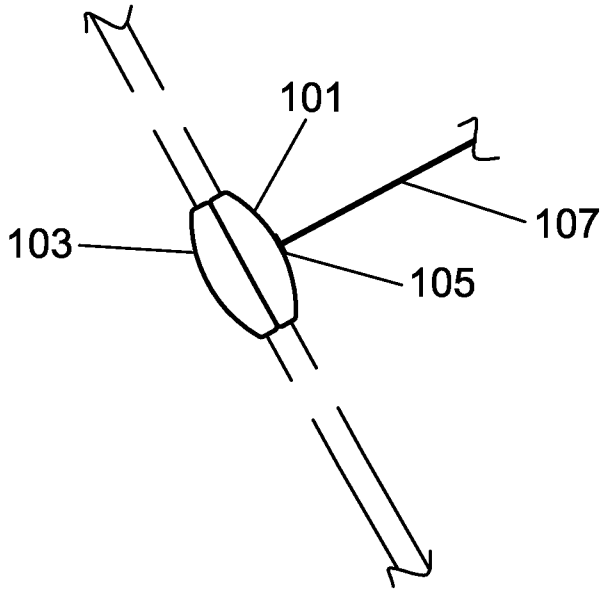


Fig. 3

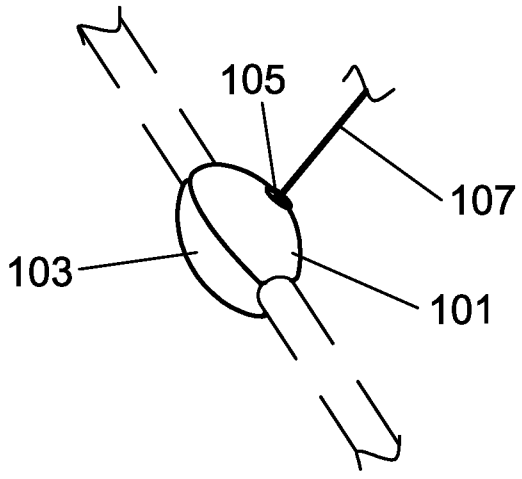


Fig. 4

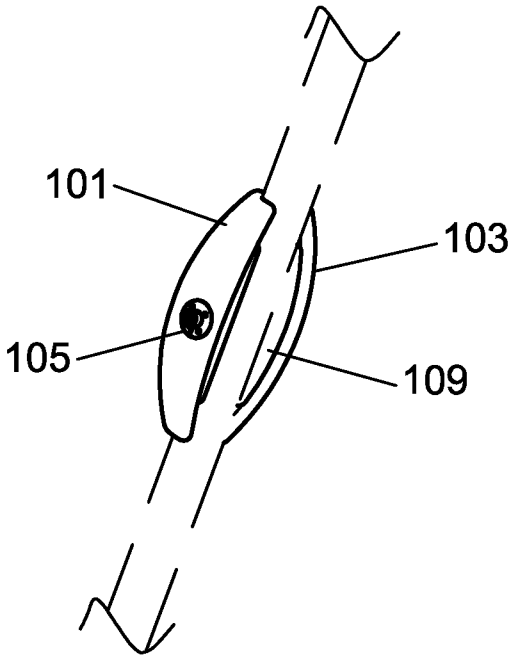


Fig. 5

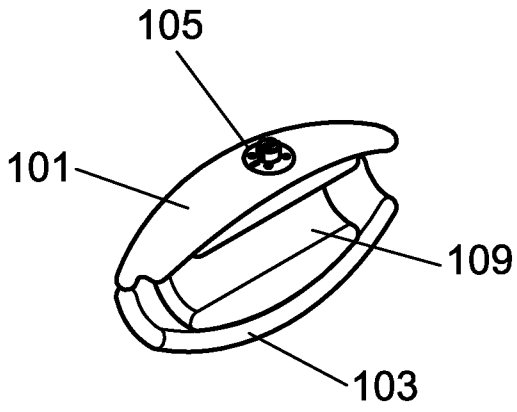


Fig. 6

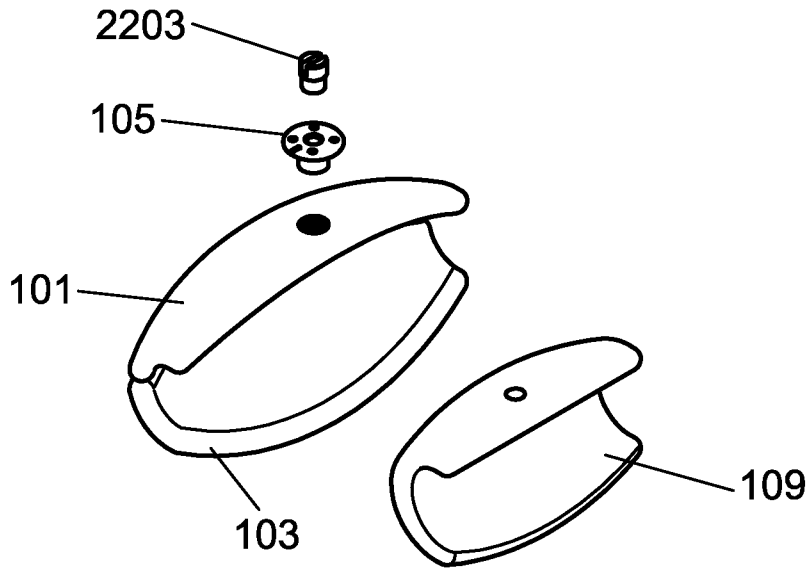


Fig. 7

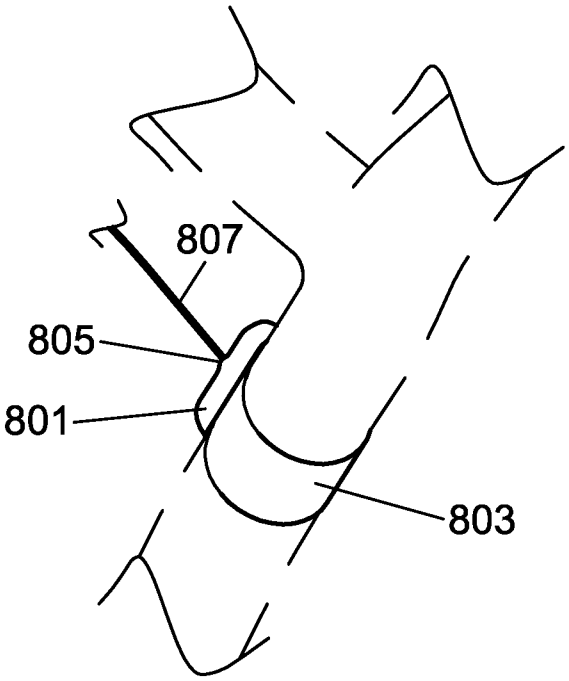


Fig. 8

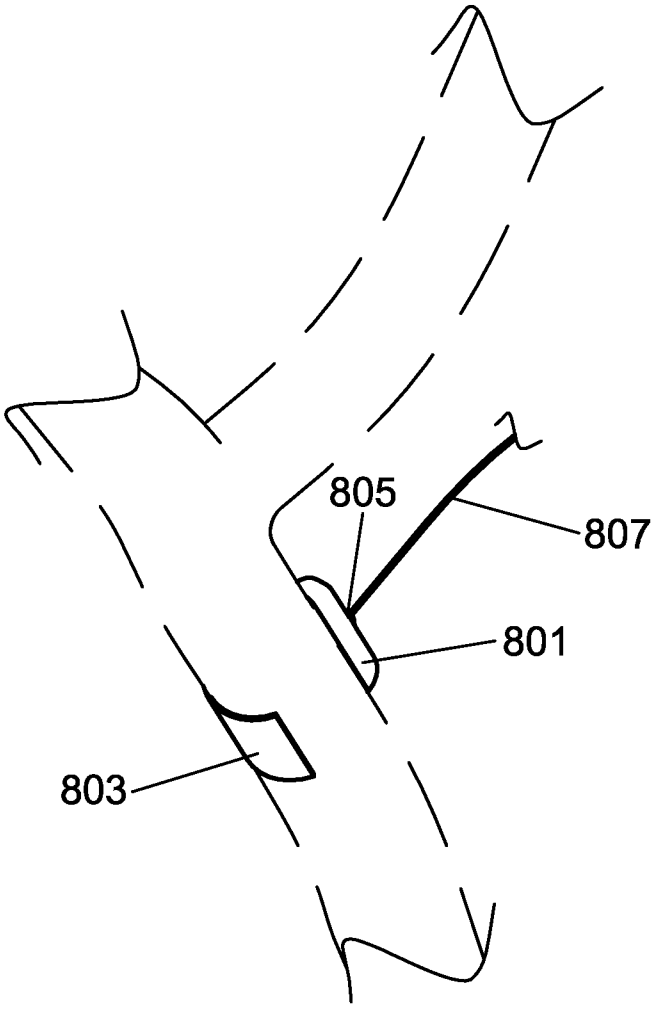


Fig. 9

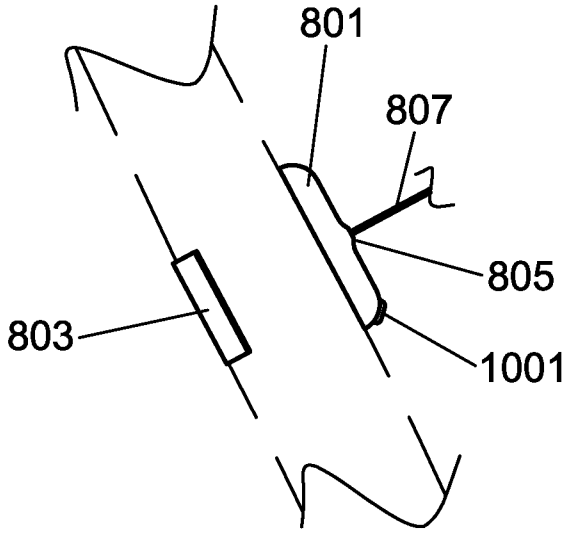


Fig. 10

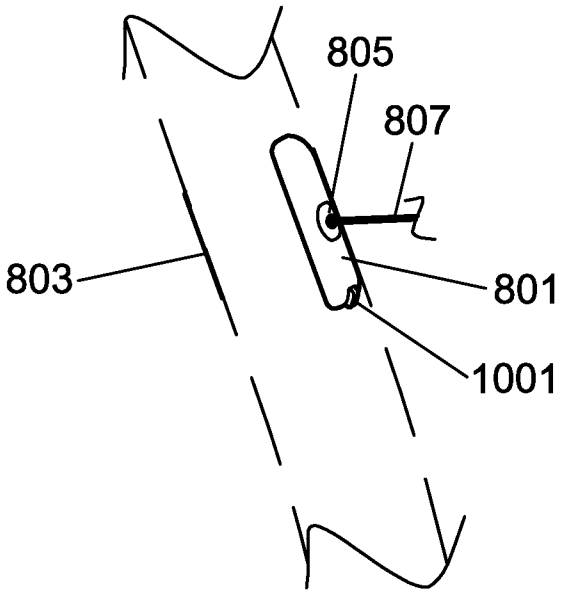


Fig. 11

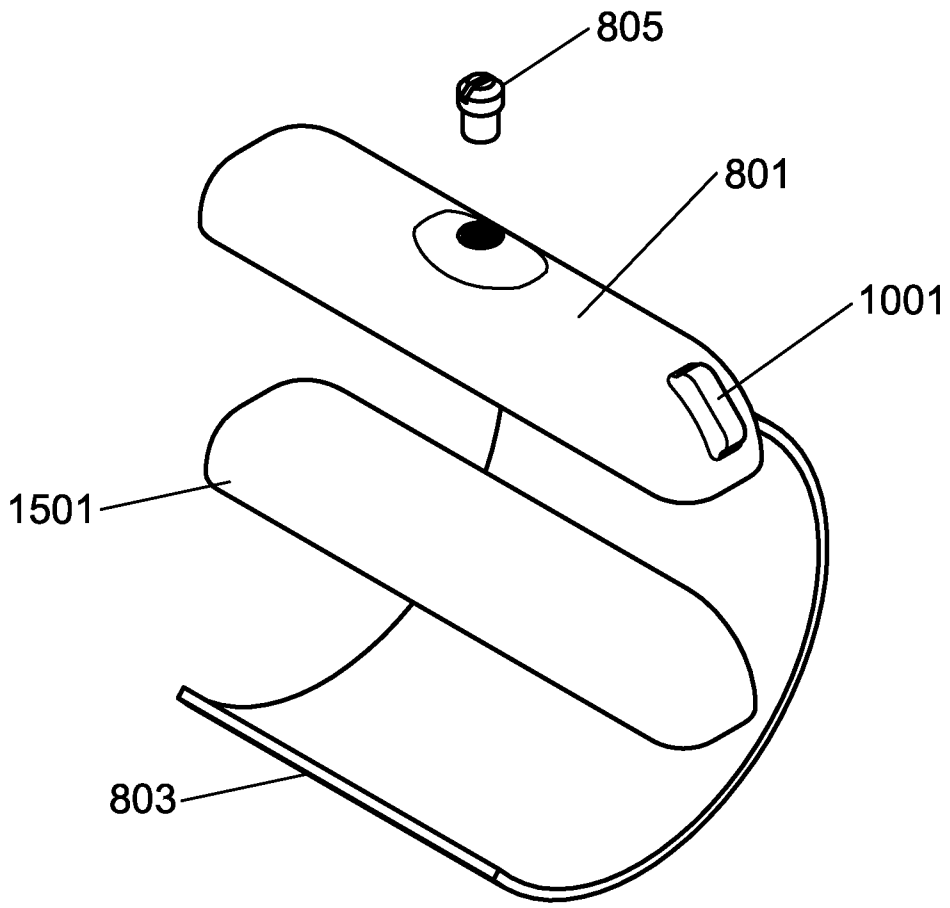


Fig. 12

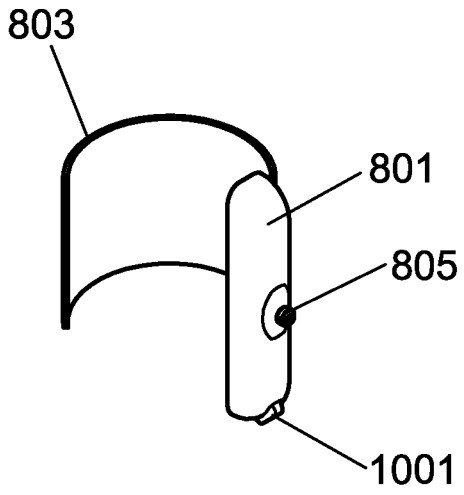


Fig. 13

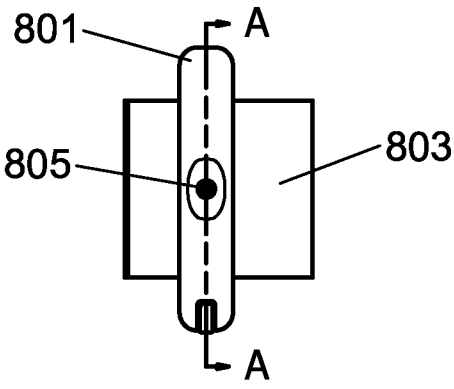


Fig. 14

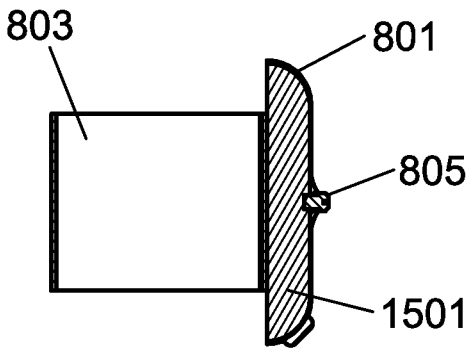


Fig. 15

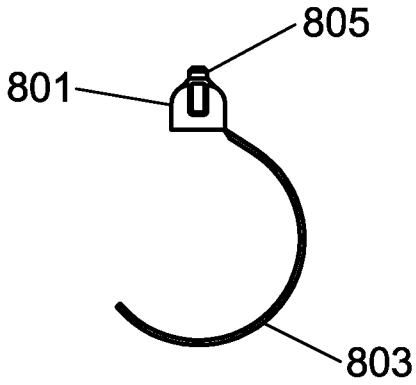


Fig. 16

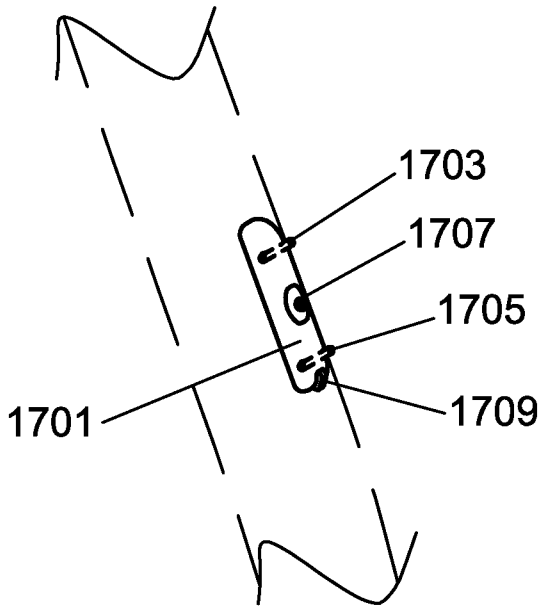


Fig. 17

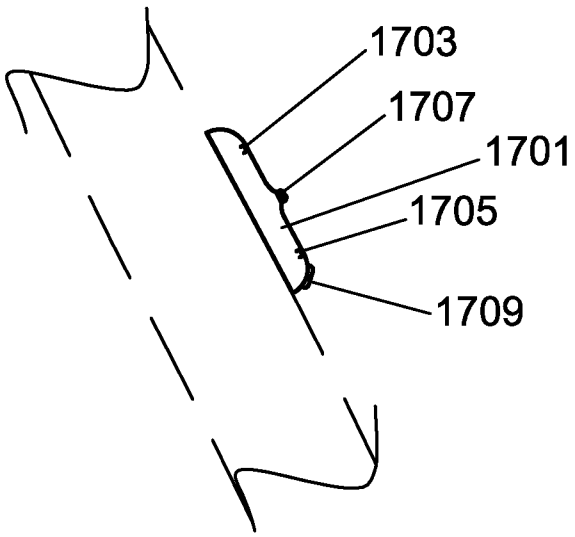


Fig. 18

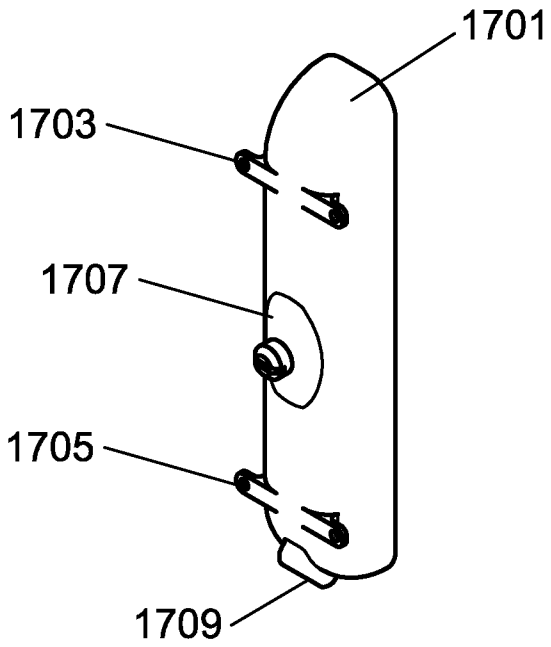


Fig. 19

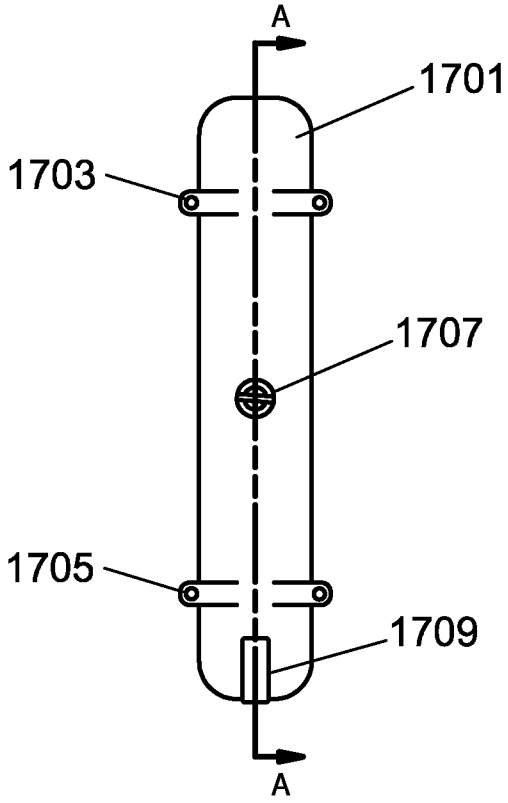


Fig. 20

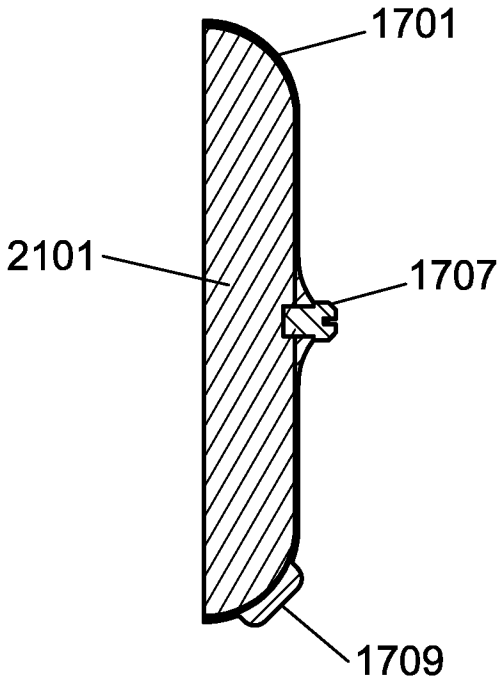


Fig. 21

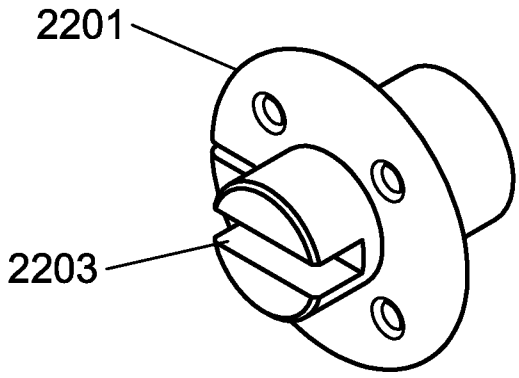


Fig. 22

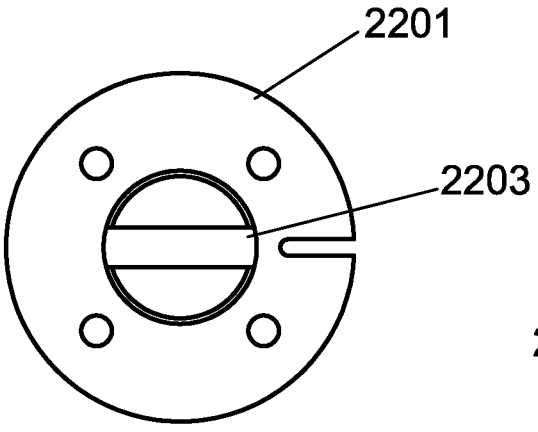


Fig. 23

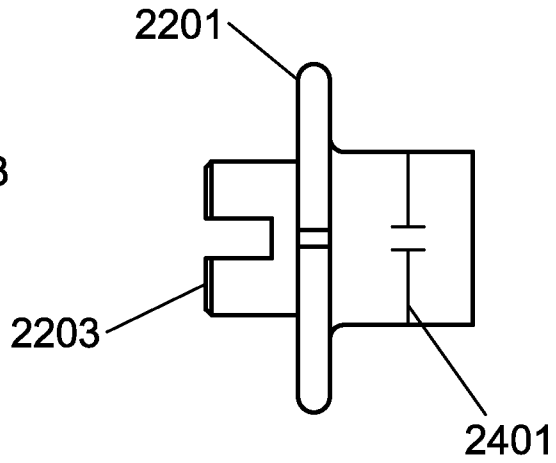
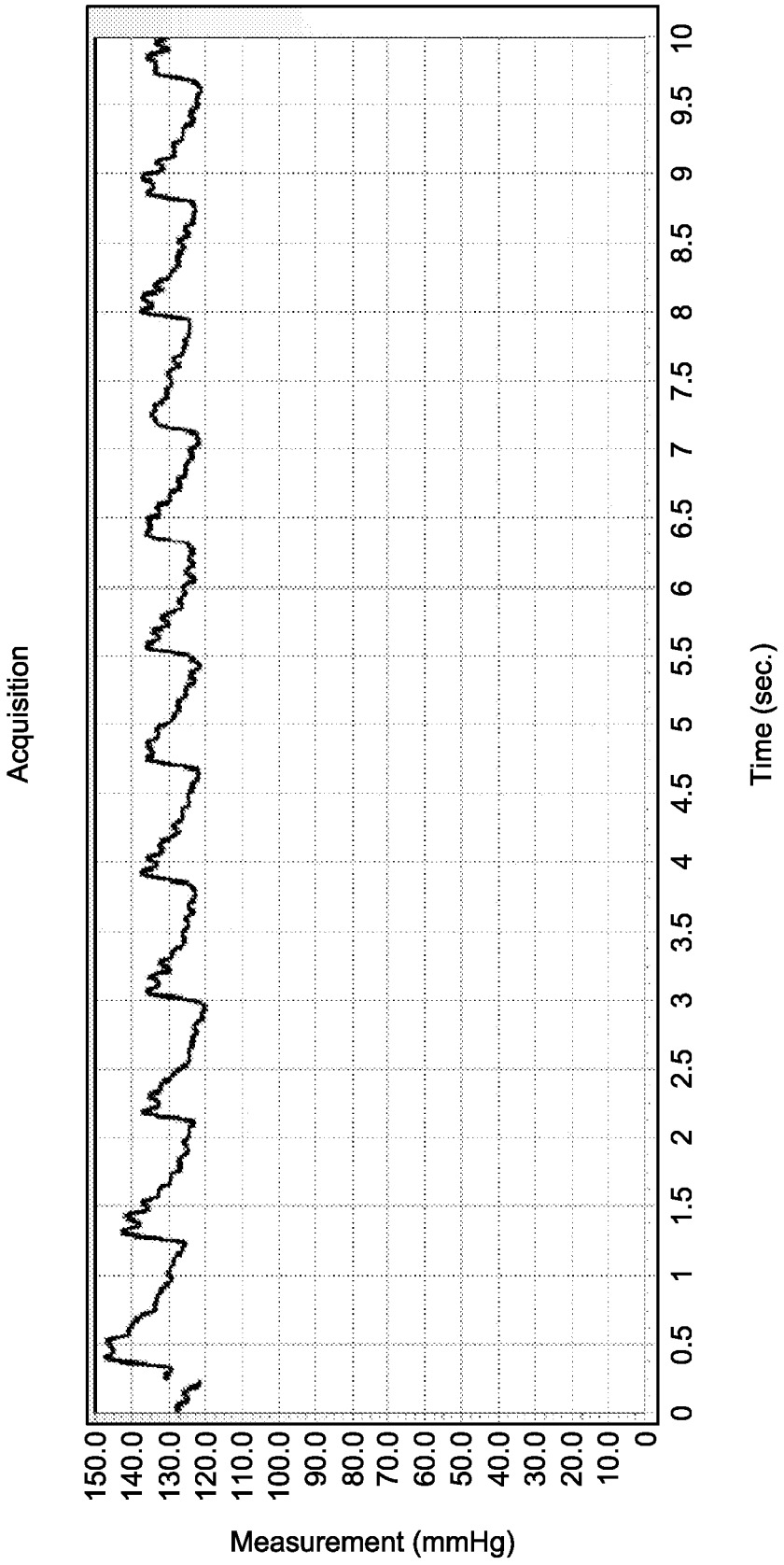


Fig. 24


Acquisition
Time (sec.)
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0.5
1
1.5
2
2.5
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3.5
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7
7.5
8
8.5
9
9.5
10
150.0
140.0
130.0
120.0
110.0
100.0
90.0
80.0
70.0
60.0
50.0
40.0
30.0
20.0
10.0
0
Measurement (mmHg)

Fig. 25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/071757

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/0215(2006.01)i

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 5/0215; A61N 1/378; A61B 5/021; A61F 2/06; A61M 25/00; A61B 5/02; G01M 7/00; A61B 5/0404; A61B 5/0408

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: blood pressure, fiber optic pressure sensor, fluid sack, liquid, water, gel, oil, gas

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	JP 2010-233883 A (NIPPON ZEON CO., LTD.) 21 October 2010 See abstract, paragraphs [0015], [0039]-[0043], claim 1 and figures 5-6.	1-15,17-20
Y	JP 2011-234884 A (OLYMPUS CORP. et al.) 24 November 2011 See abstract, paragraphs [0022], [0032], [0041], [0065], claim 1 and figures 1, 6.	1-15,17-20
A	US 2010-0298720 A1 (JOSEPH ALLEN POTKAY) 25 November 2010 See abstract, paragraphs [0073]-[0075], claim 1 and figure 1.	1-15,17-20
A	US 2003-0037591 A1 (TIM ASHTON et al.) 27 February 2003 See abstract, paragraphs [0031]-[0032], claim 1 and figure 3.	1-15,17-20
A	KR 10-2010-0126107 A (Korea Advanced Institute of Science and Technology) 01 December 2010 See abstract, paragraphs [0036]-[0044], claim 1 and figures 1-2.	1-15,17-20

☐ Further documents are listed in the continuation of Box C.

☒ 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 application or patent 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
10 March 2014 (10.03.2014)	**11 March 2014 (11.03.2014)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
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Authorized officer
KANG, Hee Gok
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/071757

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 16
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:
Claim 16 does not comply with PCT Rule 6.1(b), because claim 16 is missing in this application.

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 addtional search fees were timely paid by the applicant, this international search report covers all searchable claims.

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

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest 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/US2013/071757

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
JP 2010-233883 A	21/10/2010	JP 5347656 B2	20/11/2013
JP 2011-234884 A	24/11/2011	None	
US 2010-0298720 A1	25/11/2010	None	
US 2003-0037591 A1	27/02/2003	EP 1273261 A1 JP 2003-126126 A	08/01/2003 07/05/2003
KR 10-2010-0126107 A	01/12/2010	US 2010-0298687 A1 US 8428683 B2	25/11/2010 23/04/2013

专利名称(译)	植入式压力监测仪		
公开(公告)号	EP2925218A1	公开(公告)日	2015-10-07
申请号	EP2013859236	申请日	2013-11-25
[标]申请(专利权)人(译)	罗彻斯特大学		
申请(专利权)人(译)	罗切斯特大学		
当前申请(专利权)人(译)	罗切斯特大学		
[标]发明人	HUANG JASON HAITAO DAYAWANSA SAMANTHA		
发明人	HUANG, JASON, HAITAO DAYAWANSA, SAMANTHA		
IPC分类号	A61B5/0215 A61B5/00 A61B5/0235		
CPC分类号	A61B5/02241 A61B5/02154 A61B5/02255 A61B5/0235 A61B5/6883 A61B5/6884		
优先权	61/731742 2012-11-30 US		
其他公开文献	EP2925218B1 EP2925218A4		
外部链接	Espacenet		

摘要(译)

提供了一种可植入压力监测器，其具有与患者身体部分接触的流体袋，其中流体袋通过压力监测器壳体保持在身体部分上，该压力监测器壳体可具有各种连接装置。流体袋填充有诸如硅油的液体。压力监测器壳体具有开口，该开口提供通向流体袋的瘘管的通路，该流体阀终止于流体袋。光纤压力传感器通过瘘管和流体阀与流体袋中的液体接触。在本发明的一些实施例中，电子模块与可植入压力监测器结合以提供遥测，电力等。