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(54) **Method of configuring a pressure sensing catheter, and catheter sheath**

Verfahren zur Einrichtung eines Druckmesskatheters, und Katheterhülle

Procédé de configuration d'un cathéter de prise de pression, et gaine de cathéter

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Description

TECHNICAL FIELD

[0001] The present invention relates generally to pressure sensors and more specifically to a pressure sensor that may be adapted as a high resolution manometric catheter.

BACKGROUND OF THE INVENTION

[0002] The use of pressure measurements in small confined spaces is important in a number of different fields. In the field of diagnostic medicine and monitoring of patients, it is often necessary or useful to measure relatively small pressure changes inside various organs in the individual's body. A number of different devices have been constructed to measure these pressure changes. Such devices include pressure sensing catheters that may be used in coronary arteries, devices for use in the urethra, and esophageal pressure sensing instruments.

[0003] One example of a need to detect an internal organ pressure change is esophageal pressure analysis. The ability to detect and display pressure differences over time provides a tool for manometric analysis both in the esophagus and potentially other parts of the gastrointestinal tract such as the stomach, duodenum, small bowel, colon, and anorectum.

[0004] Gastrointestinal motility disorders remain significant both in terms of the number of patients having symptoms of these disorders and the health care resources required to treat these disorders. Imaging methods (including endoscopy and radiography) provide some information regarding gastrointestinal organ structure and the movement of contents within these organs. Other imaging techniques are limited to diagnosis of disorders only if the disorder is characterized by a change to the organ's appearance or conspicuous abnormalities in the movement of the contents within such organs. However if the gastrointestinal disorder is simply an abnormality in the contracting function of the organ, an alternative diagnostic method is required. Manometry provides a sensitive measure of pressure change within an elongate organ, allowing additional useful information for diagnosis, treatment or monitoring of a disorder.

[0005] A number of different devices to measure pressure (specifically within human organs) have been disclosed. For example, U.S. Pat. No. 4,887,610 discloses a manometric catheter that includes a sleeve segment having two attached metal electrodes. This design allows the simultaneous measurement from a single location of pressure and electrical events specifically in human sphincters.

[0006] U.S. Pat. No. 4,873,990 discloses a probe for measuring circumferential pressures in a body cavity. This reference discloses the measurement of urodynamic pressure for evaluating human urinary sphincter function. Along the length of the probe are a number of deformable wall sensors. These wall sensors have flexible sidewall areas and a means to modulate the signal as the wall of the probe moves under the influence of external pressure.

[0007] U.S. Pat. No. 4,739,769 discloses a pressure transducer in which a fluid circulated through a tube at a constant flow rate expands into a bubble in a catheter. Absent an external pressure a bubble expands where there is no increase in the flow resistance to the system.

[0008] U.S. Pat. No. 5,987,995 discloses a fiberoptic pressure catheter including a light source, an optical fiber coupled to receive light from the light source and the sensor head that is optically coupled to the optical fiber. The housing has an opening that is enclosed by a membrane. The membrane may move in response to pressure differences between the membrane chamber and the pressure outside a sensor head. A resilient ribbon is coupled to the chamber such that it may move in front of the optical fiber. The ribbon is also coupled to the membrane such that it is repositioned by the membrane in response to pressure changes, thereby reflecting varying amounts of light back into the optical fiber based on the amount of pressure on the membrane.

[0009] U.S. Pat. No. 5,983,727 discloses a plurality of membranes including an incompressible mount and a deformable membrane mounted over the mount such that there is a cavity between said membrane and mount surface. A non-contact transducer within the mount detects deflection of the membrane.

[0010] U.S. Patent Application Ser. No. 60/343,714, also owned by the present applicant, discloses various methods and algorithms for visualization of values, including internal pressure measurement. Such visualization includes display in a number of formats of pressure readings.

[0011] Furthermore, U.S. Pat. No. 5,836,894 discloses an apparatus for measuring mechanical parameters of the prostate and for imaging the prostate using such parameters. A pressure force sensing array is used to measure the surface stress pattern on soft tissues. The pattern of mechanical stress and the changes in the pattern as a function of the applied pressure, position of the array and time are processed to construct an image of the internal structure of the tissues. The detected parameters and processed image provide information useful in the detection and diagnosis of soft tissue pathologies such as breast and prostate tumors. The apparatus is particularly useful for mechanical imaging of the prostate and comprises a transrectal probe. The probe includes a probe shaft, a position sensor for determining the position of the tip and an array of force sensors for determining the pattern of pressure from tissue deformed by the tip.

[0012] U.S. Pat. No. 6,051,293 discloses a protective sheath (cover) for a probe for therapeutic or diagnostic use, in particular an aseptic disposable sheath aiming to protect the probe from body fluids and to protect contam-

ination, and the patient and nursing personnel from the transmission of pathogenic microorganisms.

[0013] U.S. Pat. No. 4,877,033 relates to a disposable needle guide, ultrasound probe sheath and an ultrasound cable sleeve as a single unit designed for use in conjunction with a transvaginal ultrasound probe for a method of gynecologic surgery.

[0014] U.S. Pat. No. 5,579,784 discloses a male condom wherein an elastic band is secured about the open end of the condom to fit tightly about the penis, and is mounted on a fitting ring which permits the user to hold it expanded as the condom is placed over the penis and then permits the band to be released and tightly engage the head of the penis as its end is pushed against the closed end of the condom.

[0015] There are a number of limitations of the prior art. These include the inability to provide sufficient number of solid state sensors in a sufficiently small diameter tool to allow for a pressure sensor that is able to reliably resolve the spatial characteristics of pressure waves in elongate organs. The pressure sensing catheters currently available with a higher number of pressure sensors are of the water-perfused pneumohydraulic designs. These designs are not solid state, tend to be cumbersome and expensive, and are technically challenging to use. One drawback of such designs is that to overcome gravity effects, the patient must remain supine to ensure that the external transducers are at the level of the esophagus. In addition, sterilization of these catheters is difficult.

[0016] In addition, while a sufficient number of sensor sites has been achieved using perfussed water technology, these sensor sites have highly localized "spot" sensitivity and hence render unreliable measurements in regions of physiological asymmetry such as the pharynx and the upper esophageal sphincter. The use of circumferential sensing yields reliable measurements in these regions.

[0017] In addition providing a robust, easily sterilizable and simpler to manufacture device is needed.

SUMMARY OF THE INVENTION

[0018] The invention is defined in claims 1 and 7, respectively. Particular embodiments are set out in the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019]

Fig. 1 is a perspective view of a pressure sensing catheter.

Fig. 2 is a side cross-section of an air gap pressure sensor.

Fig. 2A is a bottom (inside surface) view of the sensing membrane before assembly onto a rigid tube.

Fig. 2B is a top (outside surface) view of the sensing membrane before assembly onto a rigid tube.

Fig. 3 is a side perspective view of an air gap pressure sensor.

Fig. 4 is a cross-sectional view of a pressure sensor.

Fig. 5 is a multiplexed logic representation.

Fig. 6 is a side cross-section showing three sensors.

Fig. 7 is a side cross-section showing a venting design.

Fig. 8A is a top view of the flex harness showing the electrical pads.

Fig. 8B is a top view showing the electrical pads of a pressure sensor.

Fig. 8C is a top view of the flex harness and axial stress bearing cable ("leash").

Fig. 8D is a top view of the flex harness.

Fig. 8E is a side view of the flex harness and leash.

Figs. 9A-9D are cross-sectional views showing the process of assembling an outer sheath on the pressure sensors.

Figs. 10A-10D are front views showing an alternative process of assembling an outer sheath onto the pressure sensors.

Figs. 11A, 11B are cross sectional views of a pressure sensor and outer sleeve having a trapped air bubble completely separating the outer sleeve from the pressure sensing membrane and having the trapped air removed, respectively.

Figs. 12A, 12C, and 12E are front views of a pressure sensor having an outer sleeve that includes a reservoir tip, shown before during and after intubation.

Figs. 12B, 12D, and 12F are side views of a pressure sensor having an outer sleeve that includes a reservoir tip, shown before during and after intubation.

Figs. 13A-13D are cross sectional views of pressure sensors having various pressure sensing membrane positions or designs.

DETAILED DESCRIPTION OF THE INVENTION

[0020] The present disclosure generally may be viewed as including a few broad concepts which the present examples illustrate. The first broad concept is the connection of solid state pressure sensors each having an input and an output. The output signal is modulated indicating pressure within the sensing area. The inputs and outputs are electrically connected to a bus such that multiple sensors share a single input line and multiple sensors share an output line (i.e. an electrically conductive path). In using such a configuration the number of lines required in a device may be reduced. This allows a smaller diameter catheter with a larger number of more closely spaced pressure sensors. With such a configuration, the ability to spatially resolve pressure changes, such as contractions as they move through an organ (e.g. peristalsis) is possible.

[0021] A second concept is the use of spaced air gap pressure sensors in a pressure sensing catheter. The use of such pressure sensors, rather than a liquid pres-

sure sensor, provides a number of advantages such as increased reliability, reduced maintenance requirements and simplicity of operation. Such a solid state device also enables a robust system that produces repeatable results.

[0022] A third concept is the use of an axially rigid central cable to provide a flexible assembly that has high axial rigidity. These results and other advantages are illustrated in the following examples.

[0023] A fourth concept is the use of a deformable pressure sensing membrane mounted on a rigid structure having a coaxial electrode surface, the pressure sensing membrane mounted such that the side edges of the membrane are fixed to the rigid structure, flanking an inner facing membrane electrode. These flanking sections may be attached to the rigid structure. This allows the pressure sensor to shunt axial or bending loads.

[0024] A fifth concept is a pressure sensing catheter including a number of pressure sensors, each having an input and output, with the inputs and outputs connected to a flexible ribbon cable.

[0025] A sixth concept is a pressure sensor or pressure sensing catheter in which pressure is transduced using a deformable membrane that is coaxial with an inner metalized surface, wherein the membrane and surface are separated by a gap. The gap is in communication with an interior volume such that a gas in the air gap can move from the area between the deformable membrane and metalized surface, into the interior of the rigid structure having the metalized surface to allow the gap to be vented to a selected pressure condition, such as ambient air or a controlled pressure chamber. If the capactive pressure sensor is included in a catheter, the catheter may have a venting tube to vent to ambient air or to a pressure chamber.

[0026] A seventh concept is use of an outer biocompatible covering extending over a plurality of solid state pressure sensors. Such a biocompatible covering may be a disposable sheath, a outer compliant sleeve, or both.

[0027] A eighth concept is a deformable membrane pressure sensor in which the deformable membrane includes a plurality of slits that allow deformation of the pressure sensing membrane toward a coaxial inner conductive surface, narrowing an air gap that separates the deformable membrane from an inner surface.

[0028] A ninth concept is a capacitive pressure sensor that includes a deformable membrane that has a plurality of traces on the membrane. One trace is joined to an outer electrode on the membrane, a second allows connection to an inner electrode on a rigid substrate, and a third may be used to ground the rigid substrate and membrane to isolate the pressure sensor from ambient dielectric interference.

[0029] A tenth concept is a capacitive sensor having a rigid structure and a deformable membrane mounted on the rigid structure such that an air gap is formed between an inward facing electrode on the deformable membrane and a metalized electrode surface on said rigid structure. A raised rib on said rigid structure allows positioning of the deformable membrane such that the electrode on the deformable surface is separated from the electrode on the rigid structure by a selected distance.

[0030] Another concept is a capacitive pressure sensing catheter which includes a metal rigid solid support and an overlaying deformable membrane, the support and/or the membrane grounded to make the structure insensitive to ambient dielectric changes.

[0031] Effective representation of gastrointestinal and other motor events may be dramatically improved by increasing the number of pressure sensors to allow for sufficient number of sensors to visualize pressure changes along the entire relevant length. But this must be done with a device that still is sufficiently small in diameter to be tolerated in intubation. The various features of the present invention allow from this improvement.

[0032] Circumferential sensing allows accurate sensing in regions of asymmetry of physiological pressure such as the oropharynxs and upper esophageal sphincter. Technologies that provide only "spot" sensing at one point or region on the catheter surface give highly variable readings depending on where the sensitive region is oriented relative to the asymmetry. The operator typically has no control over this orientation and so the measurements can be unreliable. Circumferential sensing also maximizes the available capacitive electrode area (the conductive surface area on each side of the air gap) and thereby maximizes the capacitive signal (increased signal to noise ratio).

[0033] With respect to Fig. 1 a catheter 100 includes a longitudinally extending non-rigid outer tube 114 which forms the outer surface of the catheter. Tube 114 may be a silicone sleeve that is 1.27 to 0.054 mm (0.050 to 0.001 inch) thick. This material is biocompatible and should not degrade or substantially deform under the conditions within the organ in which the device is used. A material which has been certified and approved for use in implantable devices and has sufficiently high moisture barrier and mechanical compliance properties should be acceptable in this respect. In addition, physiological compatibility is enhanced by incorporating an internal structure to make the device axially rigid, as will be described herein.

[0034] As used herein, sleeve refers to a permanent structure overlaying the pressure sensors. This may be frictionally fit over the pressure sensors. If a sleeve is used alone, it must be sterilized between each use. A sheath is a thin disposable structure that may be fit onto a catheter. Such a device would be sterile, and the catheter could be simply inserted into a sheath prior to use, eliminating further need for sterilization of the device. Either a sleeve or a sheath may be used with a catheter, and preferably both a sleeve and a sheath are used.

[0035] The process of disinfecting manometric catheters presents certain difficulties both to a manufacturer and the user of these catheters. For perfused water pressure sensors, small water flow holes are often blocked

by material present within an elongated internal organ (such as mucus in esophageal measurements). Such material, if not removed from the catheter immediately, hardens and might permanently damage the device or preclude complete disinfection. Sterilization (as by autoclave) is satisfactory for disinfection or sterilization of such a device but is time consuming. Also, the high pressure and temperature of an autoclave sterilization is not generally adaptable for sterilization of solid state devices.

[0036] The solid state catheter shown in Fig. 1 is easier to disinfect using chemical agents than perfused water designs. However, such chemical disinfection must be compatible with the outer sleeve without degrading the sleeve material.

[0037] To avoid the degradation of the outer catheter sleeve (which may degrade when typical disinfectants are used) one approach is to use organic soap to remove any protein before using a suitable disinfectant. However this adds an additional time-consuming step to the disinfection process. An alternative is to simply use a sanitary disposable sheath, either alone or on top of a outer sleeve.

[0038] In Fig. 1, the outer sleeve is a one-quarter millimeter thick tube of silicone. Molded end 110 does not contain internal sensors. As such, end 110 may be a solid silicone section of a narrower diameter that abuts the terminal sensor in the internal lumen of the sleeve.

[0039] The catheter may be inserted into a sheath. Such a sheath may include a custom design string balloon. The sheath may be manufactured as a prepackaged component in a pre-sterilized enclosure with an insertion stick inside the sheath.

[0040] Figs. 9A - 9D show one insertion methodology of a sheath onto a catheter. The sheath is introduced into a tube that is slightly larger than the diameter of the sheath. A proximal end of the sheath is folded back against the tube to form a seal. The tube is then attached to a vacuum source that evacuates the space between the tube and the sheath causing the sheath to expand. The insertion stick is removed and the pressure sensors mounted on a cable are introduced into the sheath. The vacuum is then released and the sheath contracts over the catheter. The catheter is then ready for calibration and clinical use. To remove the sheath, the sheath is again sealed on the vacuum fixture and vacuum is again applied. This process is illustrated in Figs. 9A - 9D.

[0041] In Figs. 10A-10D, an alternative sheath insertion method is shown. In this embodiment the sheath is an extremely thin material (for example a thickness of 0.0254 mm (0.001 inch) or less). The sheath has a "baggy" or loose fit over the pressure sensors. It is preferred that the sheath be as thin as possible to both minimize the effect on the pressure measurements and to reduce patient discomfort. Given that the tissues of the sinuses and the throat are very sensitive to irregularities, a thinner, softer material that provides a more compliant surface is preferred. On the interior of the sheath a lubricant (e.g. talc, cornstarch, or a very light oil or silica lubricant) may be used to ensure that the catheter does not stick to the sheath during insertion or removal.

[0042] With reference to Fig. 10A, a rigid collar 300 is attached to the open end of the sheath 302. This gives a user a rigid structure to grip during insertion.

[0043] During insertion, a sliding ring 304 is slid over the sheath. The sliding ring may be made of a relatively soft foam rubber such that it is able to slightly deform. It is sized to be a relatively tight fit over the circumference of the catheter. As shown in Fig. 10B, the ring forces the air in the sheath out the open end as it moves up the catheter. It is important to remove this air between the sheath and the sensors because this can cause errors in pressure measurement (e.g. the peristaltic action of the esophagus can drive the air in a distal direction.) In addition, an air bubble that extends over multiple sensors can cause an equal pressure indication from those multiple sensors despite the fact that the physiological pressures at the corresponding locations are not the same.

[0044] In Fig. 10C, once the sliding ring 304 is at the top of the sheath 302, the closure 306 may be tightened to secure the sheath over the pressure sensors, preventing any additional air from entering the sheath. Elastic adhesive tape may be used for such a closure.

[0045] This design tolerates some remaining air in the sheath. A large air bubble trapped over the sensors could change the reading of a sensor only if the space between the sheath and the sensor were fully inflated. The pressure measured by a sensor P_s is determined by the formula $P_s = P_{sh} + P_{ph}$ where P_{sh} is the pressure gradient across the sheath from inside to outside and P_{ph} is the physiological pressure to be measured inside of an organ. Because the sheath acts as a thin membrane, P_{Sh} is negligible unless the air fully inflates the sheath membrane in this area. Thus as shown in Fig. 11B, where outer sheath 314, overlays sensor 312 such that air gap 320 does not extend around the sensor, the effect is negligible. In the case of Fig. 11A, the bubble does completely inflate the sheath resulting in error.

[0046] The design of this embodiment includes a reservoir volume, lying between the outer diameter of the catheter and the inner diameter of the sheath, which may contain small air pockets without affecting the sensed pressure. The mitigates two adverse conditions: 1. Pressure measurement errors noted above, and 2. Bubbles spanning multiple sensors (as described in relation to the insertion of the membrane.) The second instance would only occur if enough air were introduced into the outer sleeve to fully inflate the area between at least two sensors.

[0047] In Figs. 12A, 12B, the sheath 322 is shown having a reservoir 325 at the end of the sheath 322. A welded, bonded or otherwise affixed plastic stop 324 limits insertion of the catheter, but allows the air bubble to pass into a distal reservoir via openings on the sides of plastic stop 324. In Figs. 12C, 12D, the reservoir tip 325 is shown folded along the side of the body of the device during insertion of the catheter into the patient. After intubation,

the tip deploys (e.g. into the stomach) and provides a reservoir for remaining air, as seen in Figs. 12E, 12F. The peristaltic pressure within the organ into which the device is inserted may act to pump air from about the sensors into the tip.

[0048] Returning to Fig. 1, within outer sleeve 114 is pressure sensors 112. As noted below in relation to Figs. 13A-13E, the pressure sensors may be circumferential, sector pressure sensors, spot pressure sensors, or have other designs. These sensors are spaced at intervals extending back from tip 110. In the illustrated embodiment, thirty-six pressure sensors are used. Each of the pressure sensors has an input and an output. The input is connected to an input wire that provides a voltage signal to the sensor. These input wires are terminated at terminal connector 116. The terminal connector has pin, pads, or other means for connecting this device to a voltage source. Similarly an output from each sensor is attached to an output wire extending through the sensors through sleeve 114 and to terminal connector 118. Again each line (wire) may terminate at a pin, pad or other contact that allows it to be joined to an electronic device to analyze the modulation of the voltage from each sensor. While it is contemplated that any voltage modulating pressure sensor may be used, it is preferred to use capacitive sensors in which the capacitance of a sensor membrane is modulated by pressure changes. This will be described in relation to the remaining figures, which use a circumferential air gap configuration as an example.

[0049] With the design of Fig. 1, the device has pressure sensors that extend to the sphincter at the entrance to the stomach. When inserted the distal tip 110 extends into the stomach. The sensors are able to provide a real time measurement of pressure distribution (including quasi static sphincter pressure and peristaltic pressure waves as they propagate through the gastrointestinal tract. As shown in figure 1, no sheath is used.

[0050] As shown in Fig. 1, the space between sensors 122 is filled with a flexible material (e.g. silicon) and the outer sleeve 114 is supported by this material and the sensors 112. An internal flex harness provides axial stiffness.

[0051] With reference to Fig. 2, a cross-section through a pressure sensor is shown. A biocompatible outer sleeve 114 is the longitudinally extending non-rigid tube providing the outer surface of this device. It is relatively thin-walled (for example, one quarter of a millimeter thick) and biocompatible such that the device may be introduced into an internal organ of a patient. Biocompatibility is only one of the desired of the sleeve. It also should have good mechanical properties (low compression set (i.e. returns to its original shape after being compressed or stretched)) to minimize hysteresis in the pressure signal characteristic. Also for capacitance sensing

[0052] it should have very low moisture and water vapor permeability. This is because changes in humidity in the air gap will cause changes in dielectric constant of the air and hence erroneous changes in indicated pressure. It has been found that the described examples, including one mm thick silicon sleeves, work well. The sheath may be a thermal plastic elastomer to enhance moisture impermeability.

[0053] A precision-turned sensor support tube 126 forms a support structure for the pressure sensor. Such an element may be a metal "spool" which is mass-producible. A plurality of ridges 134, 132, 138, 136 extend from the outer surface of spool 126. Such ridges are annular raised structures on the surface of spool 126. Overlying these ridges is a sensing membrane 122. Epoxy strips 144 are positioned between ridges 134 and 132, and ridges 138 and 136, respectively. These epoxy strips may be precision die cut strips that allow the sensing membrane 122 to be firmly secured to spool 126 at a known height above surface 124. This height is precisely controlled by the height of the adjacent ridges of the spool. Between ridges 132 and 138 no epoxy strip is inserted. Thus there is an air gap between the sensing membrane 122 and the inner surface 124 on spool 126.

[0054] Sensing membrane 122 may be a precision laser cut membrane with a thin metalized coating that has been etched to form an appropriate electrode pattern. Vacuum metal deposition may be used to metalize a central sensing portion on the spool which is electrically connected to an output on the membrane. A thin dielectric coating on surface 124 of the spool and underlying the vacuum deposited metal portion may be used to electrically isolate the spool from the latter electrode. These two nominally parallel, coaxial surfaces, separated by an air gap thus become a capacitive sensing means. The spool is one example of the rigid support structure that may be used for such a capacitive sensor.

[0055] With reference to Fig. 2A, a flattened membrane is shown. This membrane may be affixed over the spool by epoxy spacers to secure the sensing membrane into a fixed place. In Fig. 2A, the membrane is a very thin material, such as 0.0254 mm (0.001 inch) thick polyimide. Coated onto this material is a thin 0.2 micron copper pattern. Polyimide is preferred for its mechanical properties (e.g low compression set, low hysteresis, etc.). Thicker copper would result in metal yield effects under pressure during deformation, increasing hysteresis. The copper is initially fully plated onto one side of the membrane and then is precision etched into a pattern using standard photo lithograph methods.

[0056] On the inside face, a current is introduced in input 332, providing an AC voltage to strip 330. A ground 350 is in electrical communication to interconnect tab 352, which is connected to the spool for electrical shielding. Electrode 340 is the output electrode and is connected to tab 342, which is interconnected to the metalized area on the spool. After bonding to a spool input 332, output 340 and ground 350 extend on arm 335 from the side of the sensor, allowing connection to wires or lines for remote connection to the sensor input and output. Preferably ground 350 extends to outside the membrane,

as seen in Fig. 2B, to shield the outside of the sensor from ambient dielectric changes. Arm 335 may extend to a wire bus for connection of the output and input from a sensor to the wire bus.

[0057] With reference to Fig. 3, the perspective view of the device shows sensing membrane 122 overlying spool 126. A central strip on sensing membrane 122 has longitudinally oriented slits 150 which extend entirely through the sensing membrane 132. When the outer sleeve is positioned over the sensing membrane, pressure from the circumferential area surrounding the outer sleeve is transferred to the sensing membrane which then is able to deform slightly and press into the gap towards the inner surface shown in Fig. 2.

[0058] The present design of a flexible membrane secured over a rigid substrate has a number of useful features. One is the distribution of axial load. Some forces will stress the sensor, including axial pressure from bends in the catheter as the catheter is positioned inside an elongate organ. The deformable area of the membrane and the associated metalized electrode surface on the deformable membrane are flanked on each side by an attachment region that are secured to the rigid support (e.g. spool). These non-sensing areas minimize the axial stress forces bearing on the pressure sensing membrane, reducing error.

[0059] Tab 152 extends from the side of sensing membrane 122. In practice 1, 2, 3 or more tabs may be used, which extend beyond spool 126. On the underside of tab 152 are integral electrical interconnections. With reference to Fig. 8B, sensing membrane 122 is electrically linked to an input pad 160, a ground 164, and an output 162. Input 160 has a voltage to be introduced into the device and onto the sensing membrane. Preferably this voltage is an alternating current (AC) signal. In one embodiment, the AC signal has a frequency below 250 kHz.

[0060] With reference to Fig. 2 when a pressure is introduced against the biocompatible outer sleeve 114, this is transferred to the sensing membrane 122. The slits 150 shown in Fig. 3, 8B allow membrane 122 to deflect towards inner surface 124 reducing the height of the air gap to a significantly greater degree than would occur if the membrane were continuous (i.e. without slits). This enables a greater increase in the capacitance of the capacitor effected by the membrane and spool electrodes and hence yields greater pressure sensitivity. This change in capacitance causes modulation of signal at output 162. Both the input 160, and the output 162 are joined to input and output lines (wires) as described below.

[0061] The change in voltage is read from the output wires at a terminal end by an electronic device that is not part of the catheter. The catheter may be linked to this device by electronic couplers as previously described. The conversion of the voltage modulation into a pressure reading may be done:

1. By a formula relating the change in voltage to a change in the gap between the electrodes, which correlates to the pressure of the device.
2. Calibration of the catheter. The sensing portion of the catheter may be inserted into a sealed chamber and subjected to pressure changes as the voltage modulation is measured. Individual sensors may be isolated into individual, pressure regulated compartments, or the catheter as a whole may be subject to a pressure variation.

[0062] Returning to Fig. 2, extending from sensing membrane 122 is tab 152. The inputs and outputs are connected to lines or wires in harness 170 which is joined to shielded cable 172. This is transferred by shielded cable 172 to the terminal connectors. As shown in Fig. 1 the terminal end of this cable allows connection to electronic circuitry to determine the modulation in voltage and hence the applied pressure at the membrane.

[0063] One important feature of this particular example is the minimization of the coupling of the bending and/or tensile stresses to the sensor. The use of a rigid support spool with annular ridges and epoxy strips to firmly secure the sensing membrane onto the spool on both axial sides of the free-deflecting length of the membrane, provides a very rigid structure which is minimally affected by bending and tensile loads. The bending and tensile loads are shunted to the rigid spool and thus the strain from these forces detected by the sensing membrane is very small.

[0064] A second design issue is mitigating the hysteresis effects in the applied pressure versus modulated voltage characteristic, for example, those resulting from pressure deflection elements. This may be in part effected through selection of materials and thickness of both outer sleeve and membrane. It has been found that a thermal plastic elastomer in a thickness of ten thousandths of an inch (1 inch = 2.54 cm) provides sufficient environmental protection to the sensors and has sufficiently low compression set to have minimal hysteresis effect on the transducing mechanism. It has been found also that a one thousandth of an inch thick polyimide membrane and an air gap of four thousandths of an inch resulted in relatively low hysteresis under both low pressure and full range pressure cycling conditions. In addition, in conjunction with the aforementioned slits in the membrane, this configuration provided a high output signal.

[0065] With reference to Fig. 6 a plurality of sensors without the outer sleeve are illustrated. In Fig. 6 pressure sensors 60, 62, 64 are part of a single pressure sensing device. An axial stress bearing cable 180 is positioned such that it extends through an interior area of each of the rigid spools of sensors 60, 62, 64. Component 180 may function as a safety leash that extends coaxially through the pressure sensors in the catheter. This cable-like element is flexible and may be bent, but is rigid in tension so that the sensing section cannot stretch. This cable also is sufficiently rugged that it may be used to bear a load without fatigue-related degradation as the

catheter is extended into and out of an elongate organ. The signal bearing components (ie. the sensor elements, the flex harness (electrical bus element) and the interconnections) are not subject then to the stresses of the axial loads (primarily due to design of the sensor, with the sensing membrane flanked by supporting regions of membrane on either side affixed to the rigid substrate) and hence the assembly is more reliable. Optionally a structure 183 may be linked to the axial stress bearing cable 180, although this may not be needed. It should be realized that the flexible outer sleeve, not shown in Fig. 6, extends between the pressure sensing components. This space may be filled with silicone rubber that is molded to have the same cylindrical cross-section as the sensor elements so that the assembly has a continuous outer diameter. Thus these areas between the components are less rigid and allow the catheter to bend as necessary to accommodate the shape of the internal organ into which the catheter is inserted. The input and output signals may be transferred to the sensing membranes from the signal bearing component.

[0066] Fig. 8A illustrates the electrical pads on the flexible harness, which is transmitted to the shielded wire cable. The input 250 on the flexible harness matches input 160 on the sensing membrane. Likewise ground 164 on the sensing membrane is connected to ground 252.

[0067] With reference to Fig. 4 a cross-section showing the internal cables of the system is illustrated. Axial stress bearing cable 180 extends through the interior of spool 126. Outer membrane 114 is disposed outside of spool 126. A flexible shielded cable also runs through the interior of spool 126. This cable is composed of an insulating layer 182, a first layer of conductive wires 184, a second insulating layer 186, a second layer of conductive wires 188, and a final outer layer of insulation 190. In some variations, an inner electrical ground layer, also separated on each side by insulation, may be used. In some variations an electrical ground layer lies above the first layer and below the final layer. This signal bearing ribbon provides a layer for input wires and a layer for output wires each of which are insulated both from wires in the same layer and wires in opposing layers. As shown in Fig. 6 these wires may be disposed in a signal bearing ribbon 181 that does not bear any substantial axial stress. This allows stable electrical connection of the wires to the pressure sensors 60, 62, 64. More specifically this allows connection to the pressure sensing membrane using the connection configuration shown in Figs. 8A, 8B.

[0068] In Figs. 8C, 8D, 8E further details of the leash/axial support cable, flex harness and their connection is shown. In Fig. 8C, axial stress bearing cable is axially rigid, but flexible in bending to shunt axial loads from the rest of the assembly. Flex harness 181, contains the wires bringing the signal to and from the pressure sensors. At one terminus, the leash is bonded into a stainless steel relief tube 199. The flex harness 181 is also affixed to cable 180 in this tube as shown in Fig. 8E. This configuration acts to protect the solder connections of input and output wires to the flexing structure. The disclosed wire harness also makes the device easier to manufacture and assemble.

[0069] In Fig. 8D the flex harness is shown. At the proximal ends of the harness on each side are six pad solder patterns to allow connections of at total of twelve wires (e.g. the input or output wires) to the device. The three pad patterns 278, 279, 281 interconnect to the pads on the membrane as shown in Figs. 8A, 8B. The holes 277, 276 allow the axial support cable to be threaded through the support harness.

[0070] Also shown in Fig. 4 is vent tube 192. If a vented design is used it may be as shown in Fig. 7.

[0071] A tubular structure 126 has an overlying pressure membrane 122. Between membrane 122 and a section of spool 126 is an air gap cavity 120 defined by nominally tubular pressure sensing membrane 122 and a metalized surface of spool 126. A vent hole 200 vents air gap 120 into a central space 201 within the interior spool 126. Also extending through the interior of spool 126 is vent tube 192 having an opening 203 to allow gas communication between air gap 120 and vent tube 192. Other pressure sensors are connected to the vent tube in a similar fashion with a block end of the tube at the distal end of the probe. At the proximal end of the probe, the vent tubes vent to room pressure or potentially a controlled pressure means such as a control pressure chamber or vacuum source. Also within spool 126 are cavity seals 202, 204. These seal the ends of spool 126 ensuring gas communication between air gap space 120 and vent tube 192. The primary role of these seals is to prevent the silicone that is injection molded between the sensors in subsequent operations, from entering the cavity inside the element and potentially blocking the vent tube or entering the air gap. As shown in Fig. 7 a single vent hole extends through spool 126. In other variations, a plurality of vent holes disposed through spool 126 at various locations of air gap 120 may be used.

[0072] The disclosed air gap sensors are capable of measuring pressure from a number of closely spaced locations along a sensitive length. This yields a high spatial resolution image of the region of interest. In esophageal measurements, separating sensors by 1.2 centimeters or less and having 32 sensors or more may be preferred as this allows detailed pressure profile mapping of the entire region of interest of most patients. In one variation a spacing of one centimeter and the use of 36 circumferential sensors is used.

[0073] One important aspect is the ability to use a relatively large number of sensors in a tube of relatively small dimensions. This allows the catheter to measure pressure from a spatial distribution while also providing a sufficiently small diameter to be tolerated by the patient during intubation and data collection. The reduction in the diameter is achieved in part through the use of a multiplex logic shown in Fig. 5. In Fig. 5 input wires A, B, C, D, E, and F and output wires G, H, I, J, K, and L are

used with 36 sensors. For example input A provides an input to sensors 6, 12, 18, 24, 30 and 36. Similarly, wire B provides an input signal to sensors 5, 11, 17, 23, 29 and 35; wire C provides an input to sensors 4, 10, 16, 22, 28 and 34. Input wire D provides an input to sensors 3, 9, 15, 21, 27 and 33; wire E provides an input to sensors 2, 8, 14, 20, 26 and 32; and input wire F provides a signal to sensors 1, 7, 13, 19, 25, and 31.

[0074] Output wire L transmits the output from sensors 1-6, output wire K transmits the output from sensors 7-12, output wire J transmits the output from sensors 13-18, through 18, output wire I transmits the output signal from sensors 19-24, output wire H transmits the signal from sensors 25-30, and output wire G transmits the signal from sensors 31-36. The topology of the input and output may be as shown, may be reversed, or may be reconfigured in various manners. Any configuration in which more than one sensor shares an input or an output reduces the numbers of wires required. In the example of Fig. 5, six input wires and six output wires allow use of 36 sensors in a circumferential pressure sensing catheter which reduces the number of wires required on the signal bearing ribbon. This multiplex or group of sensors with matrix interconnections minimizes the number of electrical conductors required that run through the interior of the catheter.

[0075] In the preceding illustrated concepts it should be realized that a number of the elements apply generally to pressure sensing probes. The illustrated method to multiplex a group of sensors with matrix interconnections that provide a bus to minimize the number of required electrical conductors in the body of the probe applies regardless of the number of input and output conductors used.

[0076] Each sensor has an input and an output. There are N inputs and M outputs to provide NxM unique addresses (i.e. support that many sensors uniquely). The required number of cable conductors is N+M, which is generally considerably less than NxM. In some variations the number of sensors sharing an input line and the number of sensors sharing an output line need not be the same. For the simplicity of the multiplex logic, symmetrical designs may be preferred. Those skilled in the art will realize that a number of alternative topologies may be designed. This matrix interconnection is adaptable to any pressure sensor in which a transducer converts the pressure signal to an electrical signal.

[0077] A second idea that applies generically to a variety of different pressure sensing probes is the use of the disclosed loosely routed signal cable in combination with a flexibly compliant, axially rigid cable for strain relief of the signal bearing component. This axially rigid cable makes the probe output much less sensitive to axial loads. Although the disclosed example utilizes electrical signal as the signal means, it is envisioned that such a design would be adaptable to optical or electro-optical sensors as well.

[0078] Those of skill in the art will understand that a number of different modifications and different variations may be made.

[0079] For example the pressure sensors may not be entirely circumferential. In each of Figs. 13A-13E, the rigid internal component 370 supports a deformable sensing surface 371 separated from a rigid support surface by an air gap. The sensing membrane may by circumferential (as in Fig. 13A), a sector membrane (as in Fig. 13B), or a spot membrane (as in Fig. 13C). In addition the solid support may be flat sided, as in Figs. 13D, 13E. In such instances, the sensing membrane may be positioned directly over a flat surface (as in Fig. 13D) or the sensor may be over lain with a low hysteresis medium that transmits pressure to a sensing membrane inside the outer sleeve and below media 372 (as shown in Fig. 13E).

[0080] The present design affords a number of advantages. A relatively large number of sensors (30 or more) may be accommodated in a compact design that allows for sensing over a biologically relevant length. The use of an axial stress bearing cable makes the device insensitive to positioning. The measurements from such a calibrated sensor are both repeatable and consistent. The catheter sterilization is rapid and simple. Because of rapid sterilization, there is less "down time" when the instrument would be unavailable because it is being cleaned. Because pressure measurements are made from the entire length of an organ, the diagnosis of disorders based on the pressure measurements from an entire organ are simplified.

[0081] Also, as some variations do not employ the axially rigid strain relief cable, the axial structure support for the assembly may be provided via a sufficiently rugged axial cable that also houses the electrical lines for input and output signal transmission.

[0082] In addition, the outer sleeve that extends the length of the assembly may be implemented as a piecewise sleeve covering only one or more sensors, or the design, in absence of axial slits over the sensing membrane may have the membrane surface sealed such that the sensed pressure acts directly on the membrane without a permanent out sleeve. Additionally, there may be no permanent outer sleeve in any configuration of the membrane or sensor arrangement where the disposable sheath may be in contact directly with the sensors.

Claims

1. A method of configuring a pressure-sensing catheter (308) having a proximal end portion, a distal end portion and a plurality of pressure sensors (112) disposed between the proximal end portion and the distal end portion, the method comprising:

   positioning a biocompatible sheath (302) with at least a portion of the sheath (302) over a portion of the catheter (308), wherein the sheath (302)

is made of a material having a thickness of 0.0254 mm or less, and wherein the sheath (302) comprises a rigid collar (300) attached to an open end of the sheath (302) to give a user a rigid structure to grip during insertion;
encircling the distal end portion of the catheter (308) with a sliding ring (304) having an opening extending therethrough, wherein an inner diameter of the opening is adapted to provide a relatively tight fit over the circumference of the catheter (308); and
moving the sliding ring (304) relative to the catheter (308) in a sliding motion toward the proximal end portion of the catheter (308), thereby forcing air in the sheath (302) out the open end of the sheath (302).

2. The method of claim 1, wherein the sliding ring (304) comprises a deformable soft foam rubber.

3. The method of claim 1 or 2, wherein positioning the biocompatible sheath (302) with at least a portion of the sheath (302) over a portion of the catheter (308) comprises inserting the proximal end portion of the catheter (308) into the open end of the sheath (302).

4. The method of any of claims 1 to 3, wherein the method further comprises sealing the open end of the sheath (302) against the catheter (308) after the sliding ring (304) is moved toward the proximal end portion of the catheter (308).

5. The method of claim 4, wherein the open end of the sheath (302) is sealed against the catheter (308) using an elastic closure member (306).

6. The method of any of claims 1 to 5, wherein positioning the biocompatible sheath (302) with at least a portion of the sheath (302) over a portion of the catheter (308) comprises positioning the sheath (302) with a baggy or loose fit over the pressure-sensing catheter (308).

7. A combination of components for configuring a sterile sheath (302) on a catheter (308) having a plurality of pressure sensors (112), the combination comprising:

a sterile catheter sheath (302) sized and configured to encircle the catheter (308) and extend over the plurality of pressure sensors (112), wherein the sheath (302) is made of material with a thickness of 0.0254 mm or less, and wherein the sheath (302) comprises a rigid collar (300) configured to be attached to an open end of the sheath (302) to give a user a rigid structure to grip during insertion; and
a sliding ring (304) comprising an opening which provides a relatively tight fit over the circumference of the catheter (308);
wherein the sliding ring (304) is configured to slide over the sheath (302) encircling the catheter (308) and to force the air in the sheath (302) out the open end of the sheath (302) as the sliding ring (304) moves along the catheter (308); and
wherein the sliding ring (304) comprises soft foam rubber.

8. The combination of components of claim 7, further comprising a closure (306) adapted to be tightened to secure the sheath (302) over the plurality of pressure sensors to prevent air from entering the sheath (302).

9. The combination of components of claim 7 or 8, wherein a lubricant is disposed on an inner wall of the sheath (302).

10. The combination of components of claim 7, 8 or 9, wherein the sheath (302) comprises a plastic stop (324) affixed to a distal end portion of the sheath (302) to block further insertion of the catheter (308) into the sheath (302).

11. The combination of components of any of claims 7 to 10, wherein the sheath (302) comprises a distal reservoir.

Patentansprüche

1. Verfahren zum Konfigurieren eines Druckmesskatheters (308) mit einem proximalen Endabschnitt, einem distalen Endabschnitt und einer Vielzahl von Drucksensoren (112), die zwischen dem proximalen Endabschnitt und dem distalen Endabschnitt angeordnet sind, wobei das Verfahren umfasst:

Positionieren einer biokompatiblen Hülle (302) mit zumindest einem Abschnitt der Hülle (302) über einem Abschnitt des Katheters (308), wobei die Hülle (302) aus einem Material mit einer Dicke von 0,0254 mm oder weniger gemacht ist, und wobei die Hülle (302) einen starren Kragen (300) umfasst, der an einem offenen Ende der Hülle (302) befestigt ist, um einem Benutzer während der Einführung eine starre Struktur zum Greifen zu geben;
Umgeben des distalen Endabschnitts des Katheters (308) mit einem Gleitring (304) mit einer Öffnung, die sich durch diesen erstreckt, wobei ein Innendurchmesser der Öffnung dazu ausgelegt ist, einen relativ engen Sitz über dem Umfang des Katheters (308) zu schaffen; und
Bewegen des Gleitrings (304) relativ zum Ka-

theter (308) in einer Gleitbewegung in Richtung des proximalen Endabschnitts des Katheters (308), wodurch Luft in der Hülle (302) aus dem offenen Ende der Hülle (302) gedrängt wird.

2. Verfahren nach Anspruch 1, wobei der Gleitring (304) einen verformbaren weichen Schaumgummi umfasst.

3. Verfahren nach Anspruch 1 oder 2, wobei das Positionieren der biokompatiblen Hülle (302) mit zumindest einem Abschnitt der Hülle (302) über einem Abschnitt des Katheters (308) das Einsetzen des proximalen Endabschnitts des Katheters (308) in das offene Ende der Hülle (302) umfasst.

4. Verfahren nach einem der Ansprüche 1 bis 3, wobei das Verfahren ferner das Abdichten des offenen Endes der Hülle (302) am Katheter (308) umfasst, nachdem der Gleitring (304) in Richtung des proximalen Endabschnitts des Katheters (308) bewegt wird.

5. Verfahren nach Anspruch 4, wobei das offene Ende der Hülle (302) am Katheter (308) unter Verwendung eines elastischen Verschlusselements (306) abgedichtet wird.

6. Verfahren nach einem der Ansprüche 1 bis 5, wobei das Positionieren der biokompatiblen Hülle (302) mit zumindest einem Abschnitt der Hülle (302) über einem Abschnitt des Katheters (308) das Positionieren der Hülle (302) mit einem schlotterigen oder lockeren Sitz über dem Druckmesskatheter (308) umfasst.

7. Kombination von Komponenten zum Konfigurieren einer sterilen Hülle (302) auf einem Katheter (308) mit einer Vielzahl von Drucksensoren (112), wobei die Kombination umfasst:

eine sterile Katheterhülle (302), die so bemessen und ausgelegt ist, dass sie den Katheter (308) umgibt und sich über die Vielzahl von Drucksensoren (112) erstreckt, wobei die Hülle (302) aus einem Material mit einer Dicke von 0,0254 mm oder weniger gemacht ist, und wobei die Hülle (302) einen starren Kragen (300) umfasst, der so ausgelegt ist, dass er an einem offenen Ende der Hülle (302) befestigt ist, um einem Benutzer während der Einführung eine starre Struktur zum Greifen zu geben; und
einen Gleitring (304) mit einer Öffnung, die einen relativ engen Sitz über dem Umfang des Katheters (308) schafft;
wobei der Gleitring (304) so ausgelegt ist, dass er über die Hülle (302) gleitet, die den Katheter (308) umgibt, und die Luft in der Hülle (302) aus dem offenen Ende der Hülle (302) drängt, wenn sich der Gleitring (304) entlang des Katheters (308) bewegt; und
wobei der Gleitring (304) einen weichen Schaumgummi umfasst.

8. Kombination von Komponenten nach Anspruch 7, die ferner einen Verschluss (306) umfasst, der so ausgelegt ist, dass er zugezogen wird, um die Hülle (302) über der Vielzahl von Drucksensoren zu befestigen, um zu verhindern, dass Luft in die Hülle (302) eintritt.

9. Kombination von Komponenten nach Anspruch 7 oder 8, wobei ein Gleitmittel an einer Innenwand der Hülle (302) angeordnet ist.

10. Kombination von Komponenten nach Anspruch 7, 8 oder 9, wobei die Hülle (302) einen Kunststoffanschlag (324) umfasst, der an einem distalen Endabschnitt der Hülle (302) befestigt ist, um eine weitere Einführung des Katheters (308) in die Hülle (302) zu blockieren.

11. Kombination von Komponenten nach einem der Ansprüche 7 bis 10, wobei die Hülle (302) ein distales Reservoir umfasst.

Revendications

1. Procédé de configuration d'un cathéter manométrique (308) ayant une partie d'extrémité proximale, une partie d'extrémité distale et une pluralité de capteurs de pression (112) disposés entre la partie d'extrémité proximale et la partie d'extrémité distale, le procédé comprenant les étapes consistant à :

positionner une gaine biocompatible (302) avec au moins une partie de la gaine (302) sur une partie du cathéter (308), dans lequel la gaine (302) est constituée d'un matériau ayant une épaisseur de 0,0254 mm ou moins, et dans lequel la gaine (302) comprend un collier rigide (300) fixé à une extrémité ouverte de la gaine (302) pour donner à un utilisateur une structure rigide à saisir au cours d'une insertion,
encercler la partie d'extrémité distale du cathéter (308) avec une bague coulissante (304) ayant une ouverture s'étendant à travers celle-ci, dans lequel un diamètre intérieur de l'ouverture est adapté pour permettre un ajustement relativement serré sur la circonférence du cathéter (308), et
déplacer la bague coulissante (304) par rapport cathéter (308) dans un mouvement de coulissement en direction de la partie d'extrémité proximale du cathéter (308), en forçant de cette manière l'air dans la gaine (302) à sortir de l'extré-

mité ouverte de la gaine (302).

2. Procédé selon la revendication 1, dans lequel la bague coulissante (304) comprend un caoutchouc mousse mou déformable.

3. Procédé selon la revendication 1 ou 2, dans lequel le positionnement de la gaine biocompatible (302) avec au moins une partie de la gaine (302) sur une partie du cathéter (308) comprend l'insertion de la partie d'extrémité proximale du cathéter (308) dans l'extrémité ouverte de la gaine (302).

4. Procédé selon l'une quelconque des revendications 1 à 3, où le procédé comprend en outre le fait de fermer l'extrémité ouverte de la gaine (302) par rapport au cathéter (308) après que la bague coulissante (304) a été déplacée en direction de la partie d'extrémité proximale du cathéter (308).

5. Procédé selon la revendication 4, dans lequel l'extrémité ouverte de la gaine (302) est fermée par rapport au cathéter (308) en utilisant un élément de fermeture élastique (306).

6. Procédé selon l'une quelconque des revendications 1 à 5, dans lequel le positionnement de la gaine biocompatible (302) avec au moins une partie de la gaine (302) sur une partie du cathéter (308) comprend le positionnement de la gaine (302) avec un ajustement flottant ou libre sur le cathéter manométrique (308).

7. Combinaison de composants pour configurer une gaine stérile (302) sur un cathéter (308) ayant une pluralité de capteurs de pression (112), la combinaison comprenant :

une gaine de cathéter stérile (302) dimensionnée et configurée pour encercler le cathéter (308) et s'étendre sur la pluralité de capteurs de pression (112), dans laquelle la gaine (302) est constituée d'un matériau ayant une épaisseur de 0,0254 mm ou moins, et dans laquelle la gaine (102) comprend un collier rigide (300) configuré pour être fixé à une extrémité ouverte de la gaine (302) pour donner à un utilisateur une structure rigide à saisir au cours d'une insertion, et

une bague coulissante (304) comprenant une ouverture qui permet un ajustement relativement serré sur la circonférence du cathéter (308),

dans lequel la bague coulissante (304) est configurée pour coulisser sur la gaine (302) encerclant le cathéter (308) et pour forcer l'air dans la gaine (302) à sortir de l'extrémité ouverte de la gaine (302) lorsque la bague coulissante (304) se déplace le long du cathéter (308), et dans laquelle la bague coulissante (304) comprend un caoutchouc mousse mou.

8. Combinaison de composants selon la revendication 7, comprenant en outre une fermeture (306) adaptée pour être serrée pour fixer la gaine (302) sur la pluralité de capteurs de pression pour empêcher de l'air de pénétrer dans la gaine (302).

9. Combinaison de composants selon la revendication 7 ou 8, dans laquelle un lubrifiant est disposé sur une paroi intérieure de la gaine (302).

10. Combinaison de composants selon la revendication 7, 8 ou 9, dans laquelle la gaine (302) comprend une butée en plastique (324) fixée à une partie d'extrémité distale de la gaine (302) pour bloquer une insertion plus importante du cathéter (308) dans la (302).

11. Combinaison de composants selon l'une quelconque des revendications 7 à 10, dans laquelle la gaine (302) comprend un réservoir distal.

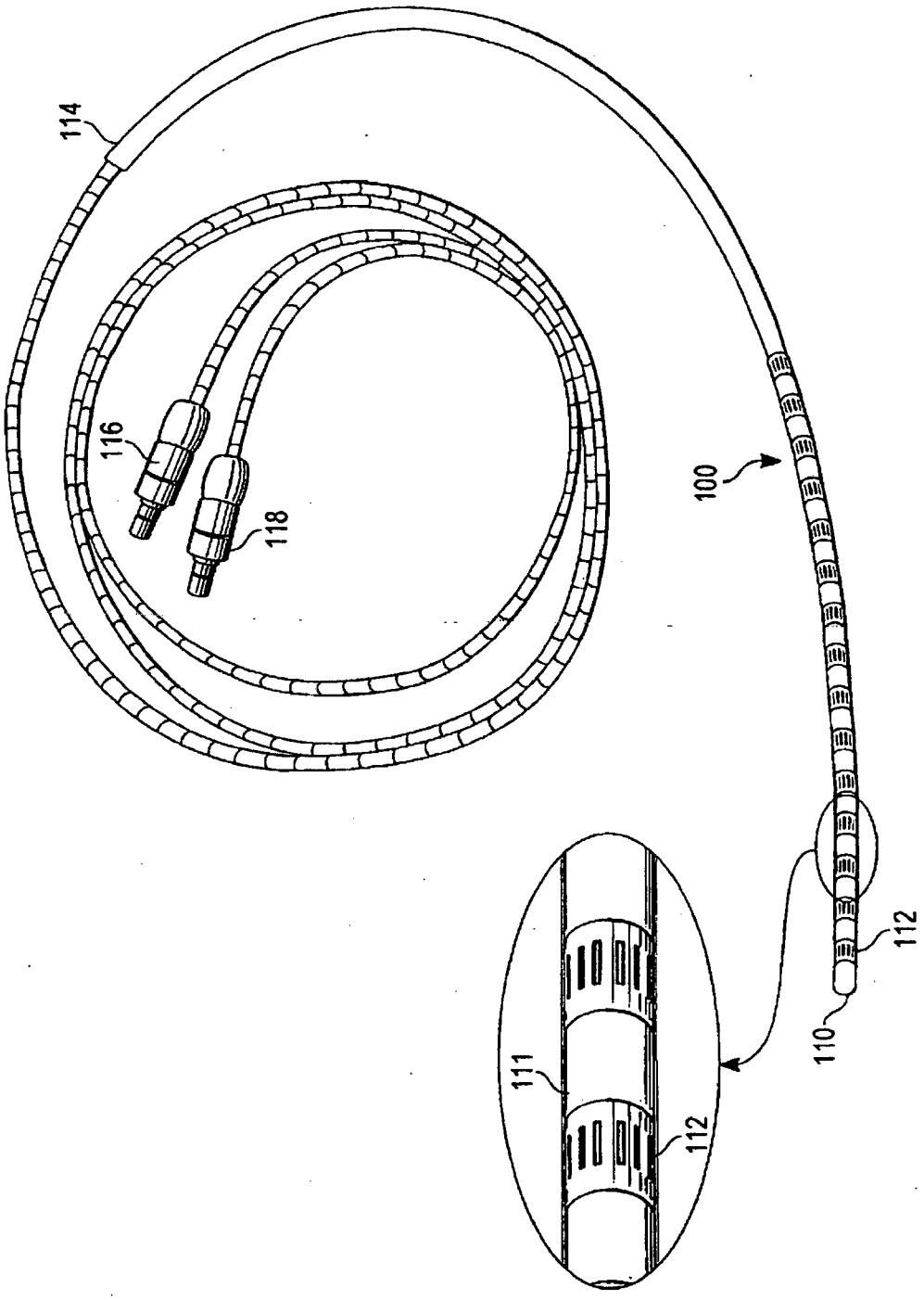


Fig. 1

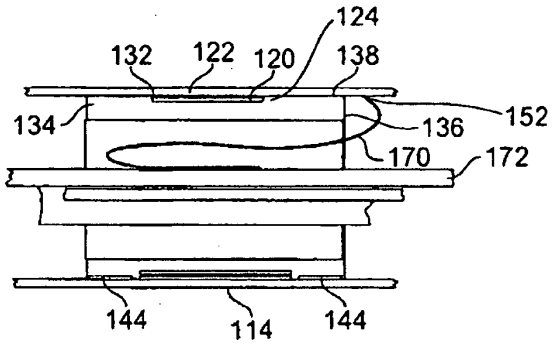


Fig._2

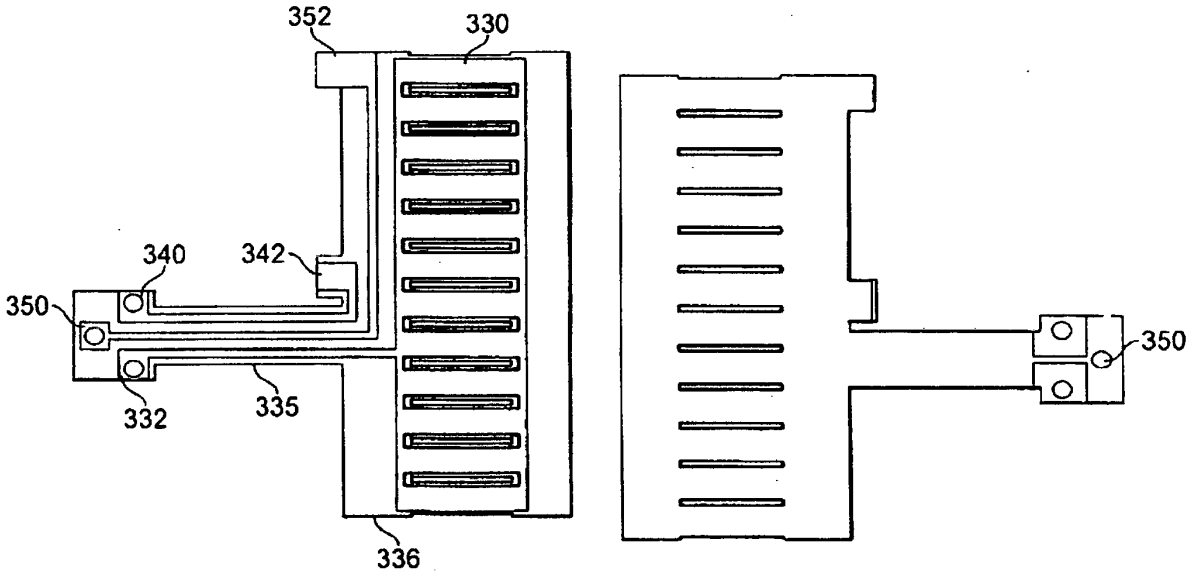


Fig._2A

Fig._2B

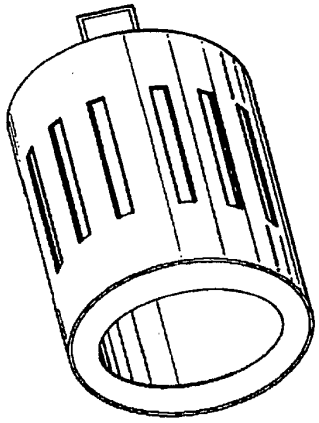


Fig._3

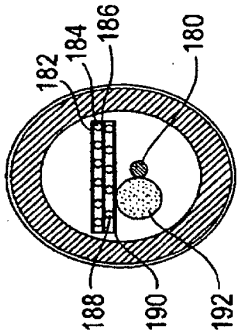


Fig._4

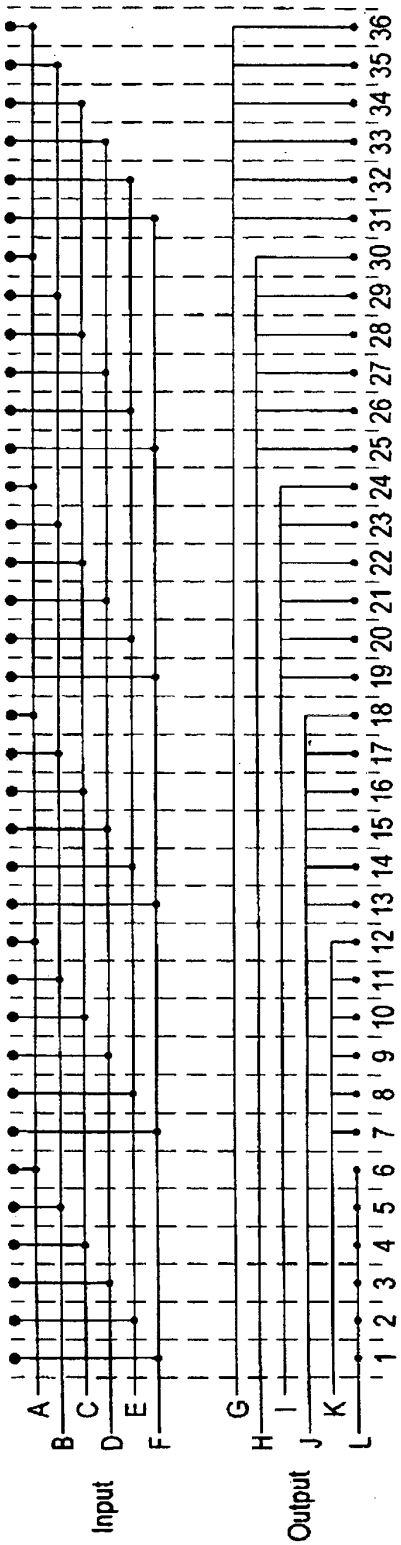


Fig._5

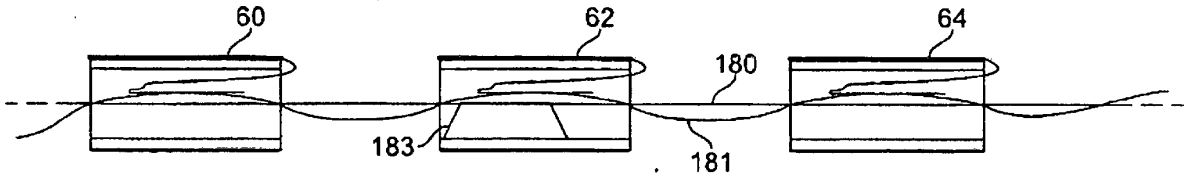


Fig._ 6

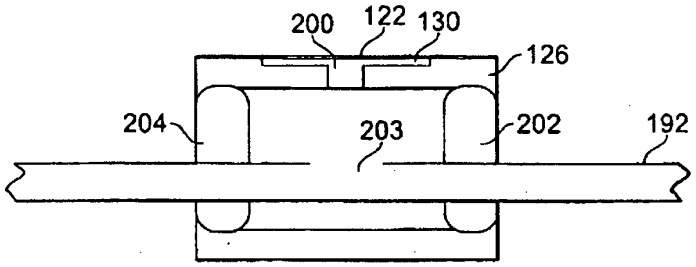


Fig._ 7

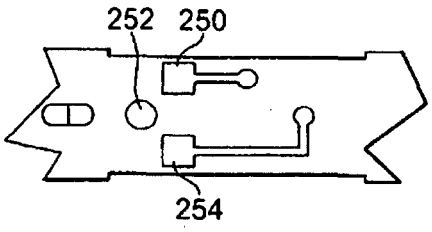


Fig._ 8A

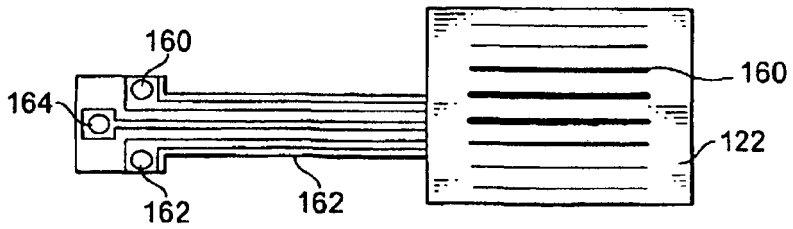


Fig._ 8B

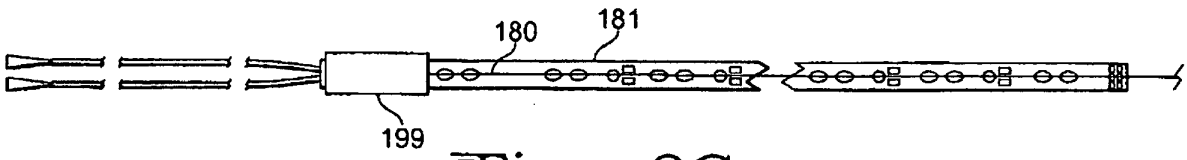


Fig._ 8C

Fig._ 8D

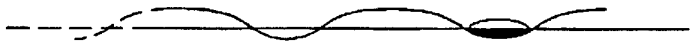


Fig._ 8E

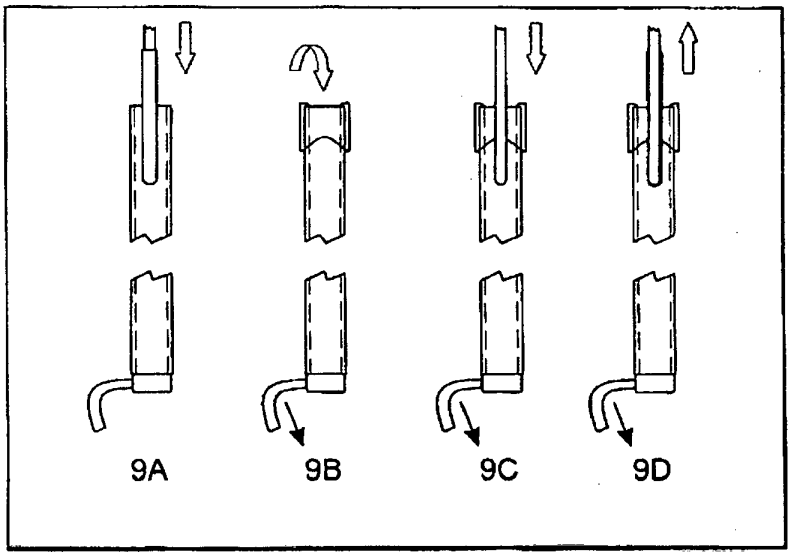


Fig._ 9

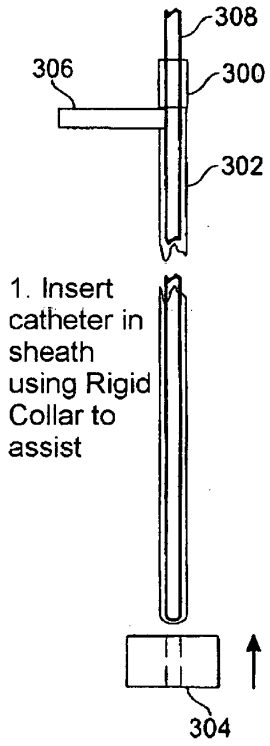


Fig._ 10A

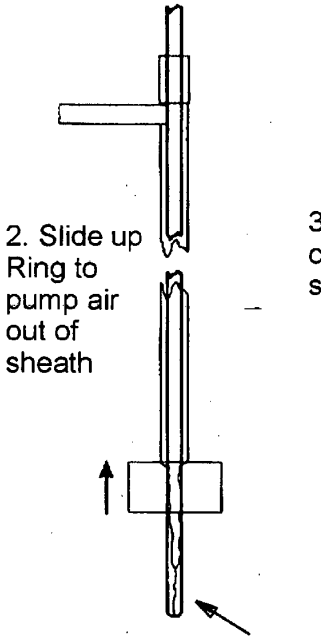


Fig._ 10B

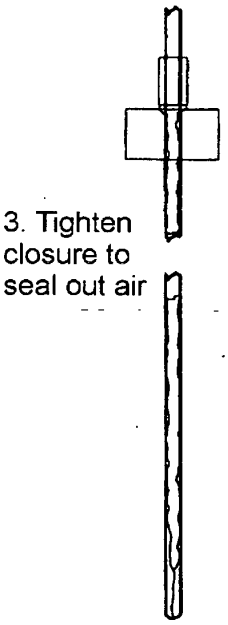


Fig._ 10C

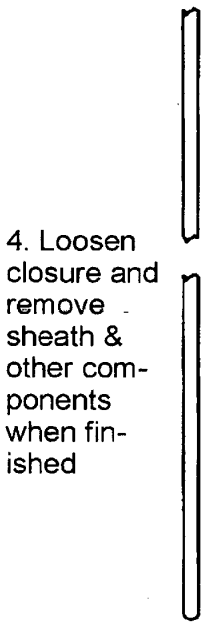


Fig._ 10D

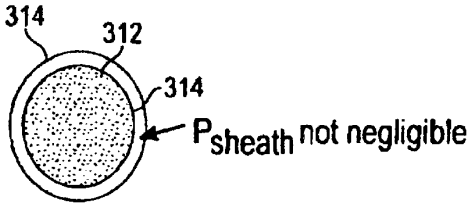


Fig._11A

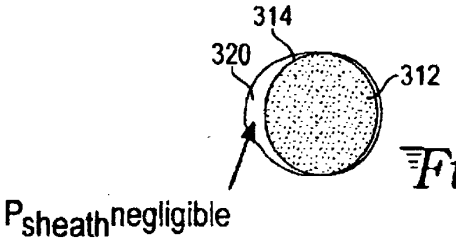


Fig._11B

Fig._12A

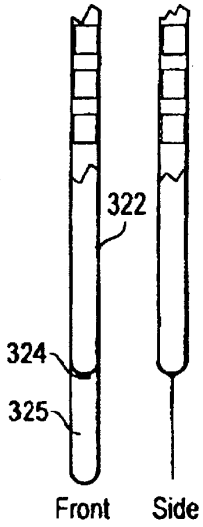


Fig._12B

Fig._12C

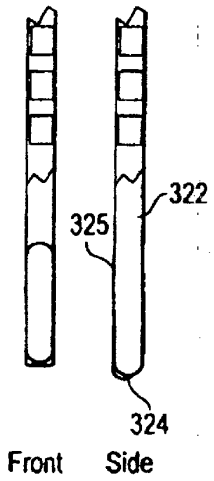


Fig._12D

Fig._12E

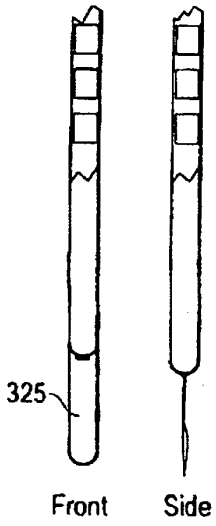
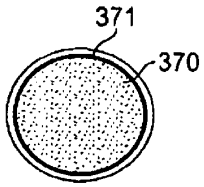


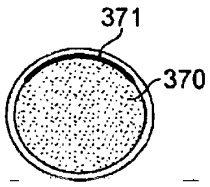
Fig._12F

Fig._ 13A

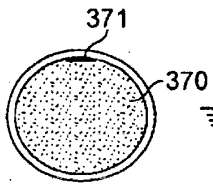


Circumferential

Fig._ 13B



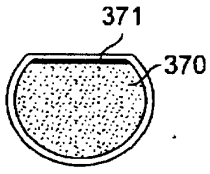
Sector



Spot

Fig._ 13C

Fig._ 13D



Flat Sided

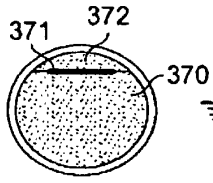


Fig._ 13E

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	配置压力传感导管的方法和导管护套		
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申请号	EP2011188400	申请日	2004-10-08
[标]申请(专利权)人(译)	SIERRA SCI INSTR		
申请(专利权)人(译)	SIERRA科学仪器，INC.		
当前申请(专利权)人(译)	基文影像（洛杉矶）有限责任公司		
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发明人	PARKS, THOMAS, R. SON, JAE, S.		
IPC分类号	A61B5/00 A61B5/02 G01L		
CPC分类号	A61B5/6852 A61B5/0215 A61B5/037 A61M2025/0002		
优先权	60/510475 2003-10-10 US		
其他公开文献	EP2417906A1		
外部链接	Espacenet		

摘要(译)

本发明提供了一种配置压力传感导管的方法，该压力传感导管具有近端部分，远端部分和设置在近端部分和远端部分之间的多个压力传感器，该方法包括：定位生物相容性护套（302）在导管的一部分上具有至少一部分护套;用滑动环（304）环绕导管的远端部分，滑动环（304）具有穿过其延伸的开口，开口的未变形内径约等于或小于导管的外径;使滑动构件（304）相对于导管以朝向导管的近端部分的滑动运动移动，从而减小护套与多个压力传感器中的一个或多个之间的气体袋的尺寸。

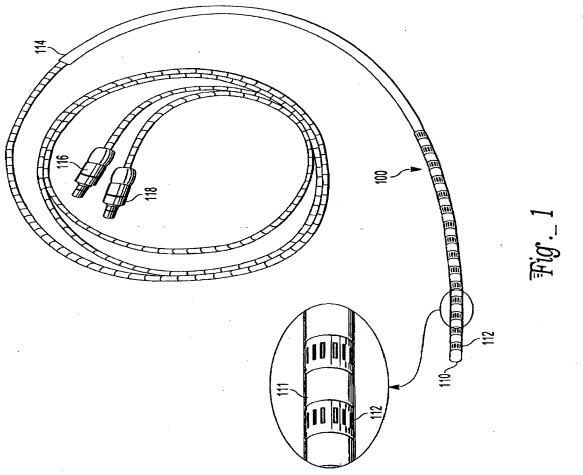

Fig. 1