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(54) IN-VIVO PRESSURE MONITORING SYSTEM

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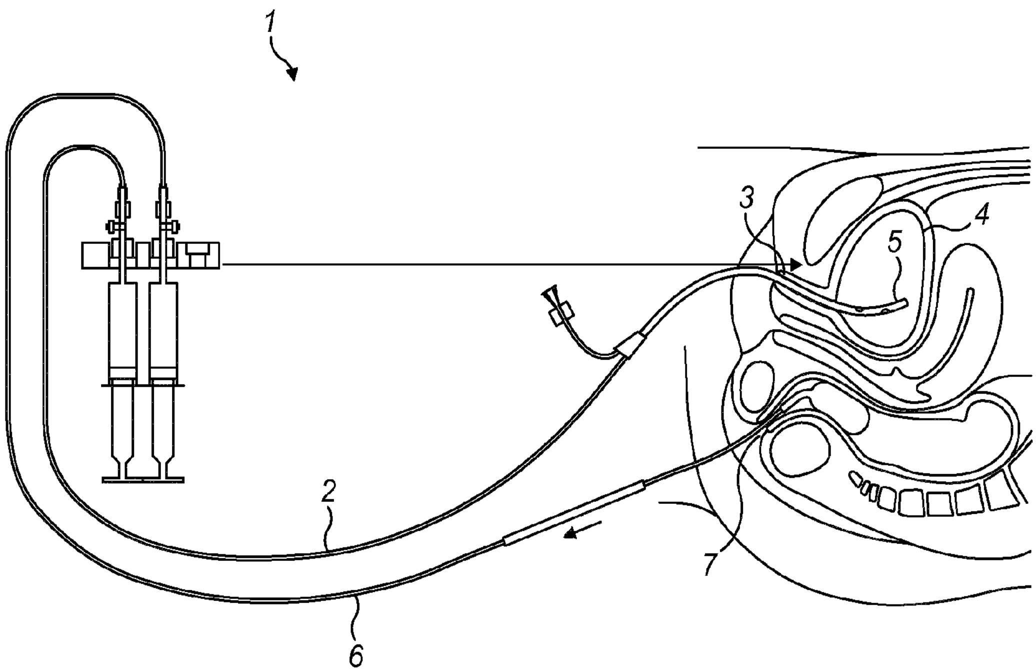
(57) **ABSTRACT**

A system for in-vivo monitoring of pressure of a body fluid. The system comprises a delivery component and an elongate sensor delivery member shaped so as to pass through the delivery component when it has been inserted in to a patient. A first pressure sensor is positioned at a distal end of the delivery member.



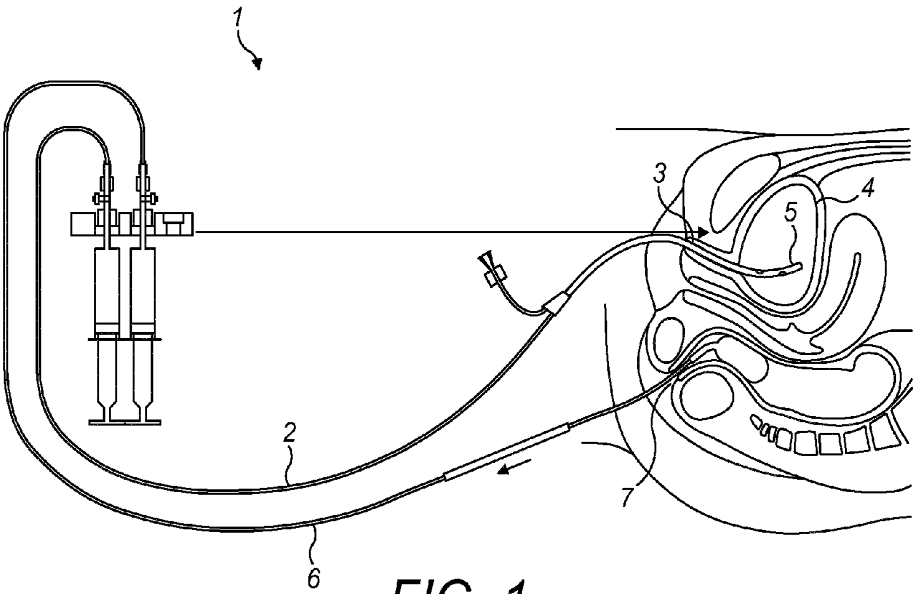


FIG. 1

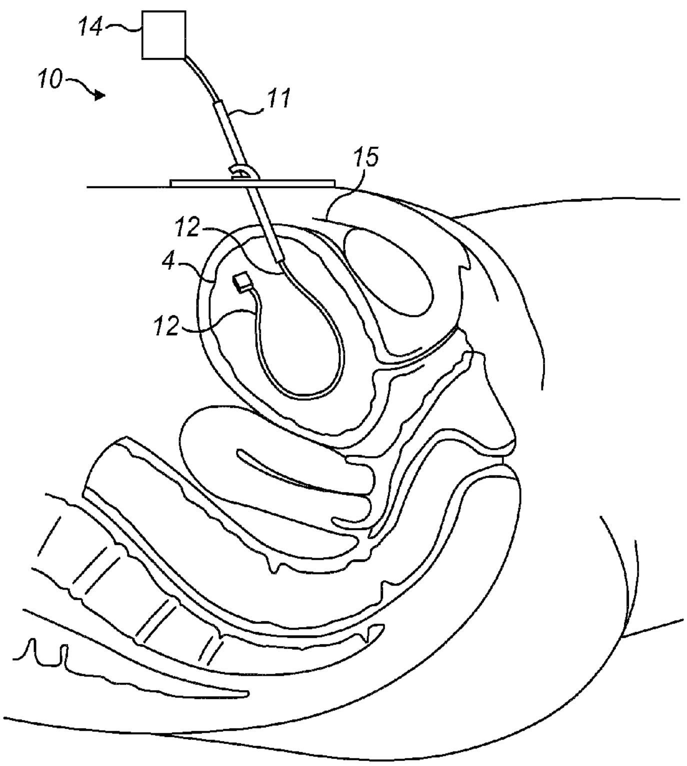


FIG. 2

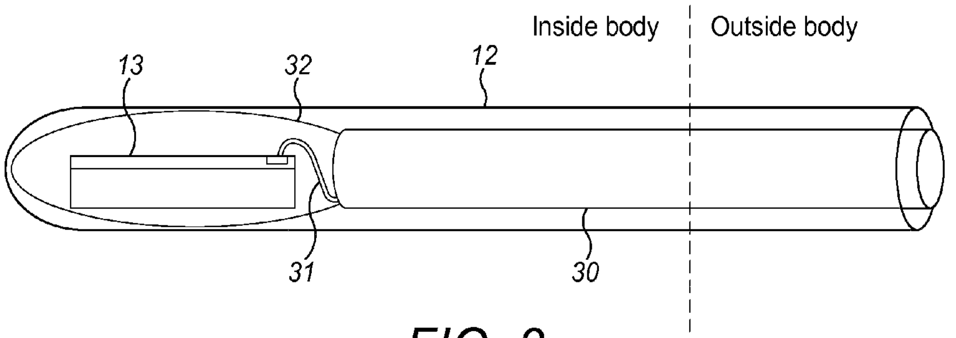


FIG. 3

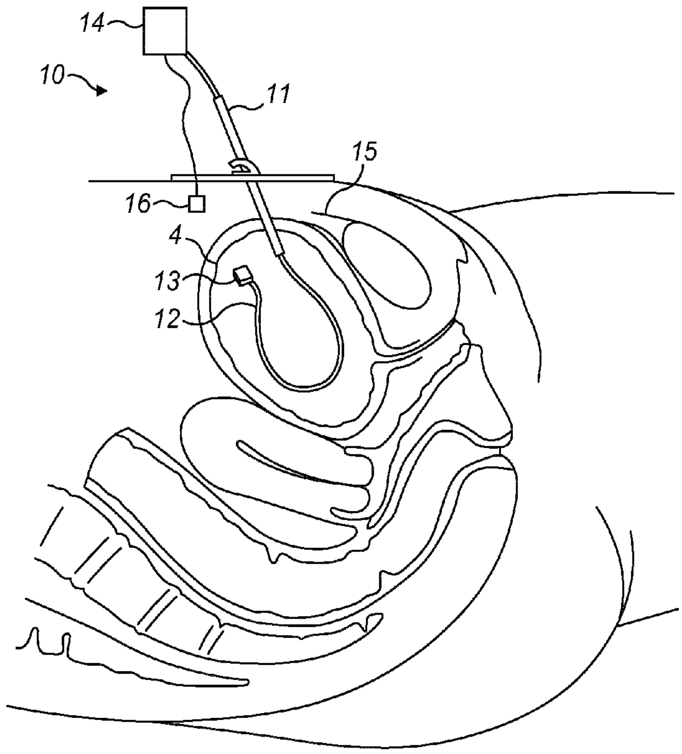


FIG. 4

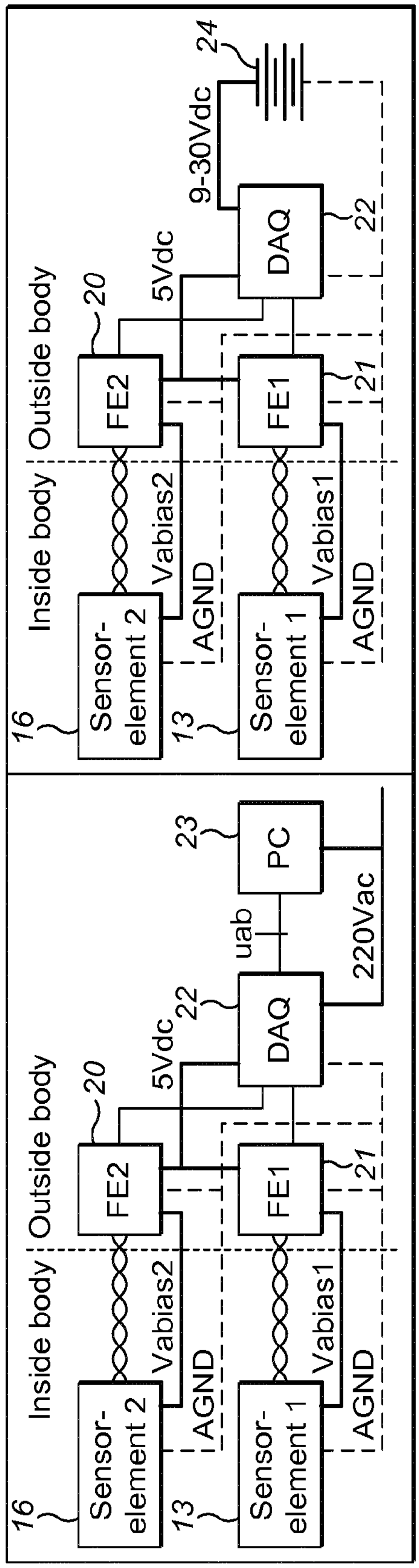

Inside body
Outside body
16
Sensor-element 2
13
Sensor-element 1
Vabias2
Vabias1
AGND
AGND
FE2
FE1
20
21
5Vdc
DAQ
22
uab
PC
23
220Vac
9-30Vdc
24

FIG. 5

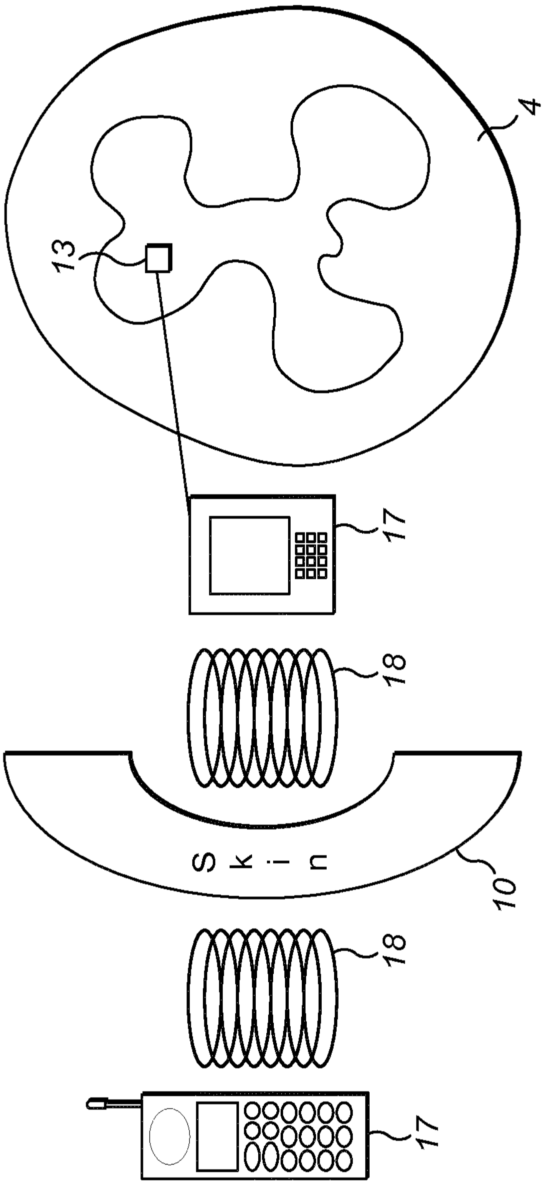


FIG. 6

IN-VIVO PRESSURE MONITORING SYSTEM

[0001] The present invention relates to an in-vivo pressure monitoring system.

[0002] There are many locations within a human or animal body where there are medical benefits in being able to monitor the ambient pressure in fluid or tissue. For example, it can be extremely beneficial in understanding the wellbeing of a patient and understanding the effectiveness of any treatment to the pressure in a patient's cranial fluid, within their bladder, muscle compartments, or within their circulatory system.

[0003] Because of the benefits of such monitoring pressure monitoring systems have been developed which can be inserted in to the body of a user to provide pressure readings.

[0004] One example is a system in which a fluid filled catheter is inserted via the urinary tract in to the bladder. The fluid in the catheter will transmit pressure to an external transducer located outside the patient. The bladder is then filled with saline with simultaneous pressure recording. A balloon attached to a fluid filled catheter is inserted into the rectum for recording of reference pressure.

[0005] Such systems have provided significant benefits in terms of improved pressure readings which a medical practitioner can then use to assess the condition of the patient. However, they also have significant disadvantages.

[0006] For example, a system of the type described above is extremely uncomfortable for a patient in that it requires insertion of a relatively large catheter, and restricts the movement of the user quite significantly whilst this Is in place. Furthermore, such systems do not necessarily provide true indication of bladder pressure, because it can only be in place for a limited period of time during which the bladder will not have been through a complete cycle of having been filled and emptied. In addition, such a system is sensitive to movement by the patient, such movement potentially generating pressure variations that the system is unable to compensate for.

[0007] Accordingly, there is a need for provision of a system which can be employed with the patient to improve the monitoring of the pressure of a bodily fluid with reduced discomfort to the patient. Furthermore, there is a need to provide a system which can provide long term monitoring so that pressure readings over an extended period of time can be provided to ensure a true representation of the fluid pressures and therefore give a better representation of the condition of a patient and the effectiveness of any treatment. In addition, there is a need to provide a system which can compensate for factors which may affect any pressure reading which are not actually directly linked to a patient's condition, such as digestion, change in body position, or movement by the patient or external pressure or temperature changes. There is also a need to provide a system which can assist in longer term monitoring of pressure and assist in treatment of a patient's condition. The present invention seeks to meet at least some of these needs.

[0008] According to the present invention there is provided a system for in-vivo monitoring of ambient pressure in a body fluid or tissue, the system comprising:

- [0009] a delivery component;
- [0010] an elongate sensor delivery member shaped so as to pass through the delivery component when it has been inserted in to a patient; and
- [0011] a first pressure sensor positioned at a distal end of the delivery member.

[0012] The delivery component may be a catheter. The system may further comprise a second pressure sensor configured to be inserted subcutaneously in to a patient in use. In such a configuration the system may further comprise means for receiving data for the second sensor and for comparing it to pressure data for the first sensor. Such a comparison provides a final signal that has been adjusted to compensate for external pressure on the fluid or tissue for which pressure is being monitored, that external pressure having been generated by patient movement or atmospheric pressure variation, for example, as such effect will have been read by both sensors.

[0013] The system may further comprise a temperature sensor such that pressure data from the first sensor can be adjusted to remove any temperature related effects.

[0014] The delivery member may have communication means and power supply means formed therein such that the sensor can be provided with power and the output of the sensor can be passed through the elongate member to external processing means. The output of the sensor(s) element can be passed through the elongate member to a subcutaneous processing means. Alternatively, the first and the second sensor element may have wireless communication means for communication with a subcutaneous processing means. The subcutaneous processing means then may have wireless communication means for communication with an external data receiving/handling device.

[0015] The system of the present invention may be connected to an alarm device to provide warning if a pressure detected by the system exceeds a predetermined amount. In addition to this, or as an alternative thereto, this can be a system configured to activate a nerve stimulation device connected to the patient to which the system is itself connected to stimulate the nervous system of a user to act in response to a pressure variation detected by the system.

[0016] With the system of the present invention, by use of a simple cannula and delivery member in combination, it is possible to insert a pressure sensor in to a patient very simply and with far less discomfort than with prior art systems. Furthermore, it is possible to provide a system which can be retained within the patient for far longer periods of time, for example days rather than hours, without reducing patient mobility. This provides the additional benefits that pressure data can be obtained over far longer periods of time providing far more reliable and consistent data for assessment for patient's condition. The system of the present invention, when provided with additional sensors also provides more accurate data that compensates for potential errors generated by variations in temperature, atmospheric pressure, or patient movement, for example.

[0017] One example of the present invention will now be described with reference to the accompanying drawings, in which:

[0018] FIG. **1** is a schematic diagram of an example prior art in-vivo pressure monitoring system;

[0019] FIG. **2** is a schematic diagram showing an example system according to the present invention;

[0020] FIG. **3** is a schematic cross-sectional view of a sensor and delivery device employed in the invention;

[0021] FIG. **4** is a schematic diagram showing a further example system according to the present invention;

[0022] FIG. **5** is a schematic diagram showing example signal processing circuitry for use in the invention and;

[0023] FIG. **6** is a schematic diagram of a yet further example of the invention in which wireless communication with the sensor is provided.

[0024] Referring to FIG. **1**, a system **1** according to the prior art comprises a catheter **2** which is passed, in use, through the urinary tract **3** and in to the bladder **4** of a patient. Positioned at the distal end of the catheter **2** is a pressure sensor **5**. A second balloon catheter **6** is provided and is passed, in use, in to the rectum **7** of the patient. In use fluid may be provided via the catheter **2** in to the bladder **4** to fill the bladder and/or the balloon catheter **6** inflated to apply pressure to the bladder **4** to retain the catheter in place. Readings are taken from the pressure sensor **5** during the generation of pressure within the bladder **4** to provide an indication of pressure levels within the bladder so that an assessment of a patient's condition can be provided.

[0025] As mentioned above, such a system has significant disadvantages. First of all, insertion of the catheter through the urinary tract **3** can cause discomfort to a patient. Furthermore, artificial generation of pressures on the bladder **4** do not necessarily provide accurate results, but in the system **1** of the type shown such artificial creation of pressures, be it through application of fluid directly to the bladder **4** or by application of pressure via the balloon catheter **6** in the rectum **7**, to retain the catheter's position, is required. This is because the invasive nature of the equipment and the discomfort generated to a patient are such that the system can only be used on a patient for a maximum of a few tens of minutes. Furthermore, in such systems there is little compensation for effects that are not directly related to the bladder **4** but which may affect the output of the sensor **5**. For example, digestion, change in body position and movement of the patient can all affect pressure within the bladder **4**, as can variations in atmospheric pressure and temperature.

[0026] FIG. **2** is a schematic diagram of a system **10** in accordance with the present invention. The system **10** of the present invention comprises a delivery component, in this example a cannula **11** and delivery catheter **12**. Positioned at a distal end of a delivery catheter **12** is a pressure sensor **13**. The sensor **13** and delivery device **12** is a micro electro mechanical system (MEMS) integrated in a hollow flexible tube made out of biocompatible material. The sensor **13** and delivery device have a diameter of less than 1.0 mm, it is possible to insert the device using a simple minimally invasive technique. FIG. **3** shows these components in more detail, they are formed from a flexible, hollow tube containing the pressure sensor element **13** connected electrically and mechanically to a flexible printed circuit board. The major part of the components, including the sensor **13**, is placed inside the subject, while the distal end is connected to an electronic front end (FE) module placed externally on the body including a signal processing component **14**.

[0027] In use the system **10** of the present invention is operated as follows. Firstly, the cannula **11** is inserted through the abdominal wall **15** and in to the bladder **4**. The delivery catheter **12** is then inserted in to the cannula and in to the bladder **4** so that the sensor **13** is positioned within the bladder **4**. The signal processing component **14** is attached to the patient also so the patient is then mobile and can move about as normal. Pressure readings can then be taken from the sensor **13** and processed by the signal processing component **14** over a significant period of time, hours or possibly even days. Accordingly, pressure data can be obtained by the signal processing component **14** over a complete emptying and filling cycle of the bladder to provide far more data to a physician than is available with any prior art system. The cannula **11** of the system **10** of the present invention is a relatively standard cannula. The sensor **13** can be one of a number of sensors, but is, for example, a sensor of the type disclosed in "I. Clausen, et al., "A miniaturized pressure sensor with inherent biofouling protection designed for in vivo applications," in 33rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Boston, Mass. USA, 2011, pp. 1880-1883.". The delivery catheter **12**, as it does not have to deliver any fluids in to the bladder, can be of a relatively narrow diameter, which simplifies insertion and reduces the size requirements of the cannula.

[0028] As will be appreciated, the example shown in FIG. **2** is inserted in to a bladder **4**. However, a similar approach could be used to insert the sensor **13** in to another body cavity or tissue for pressure sensing another part of a patient's body. It could, for example, be inserted in to the cranial fluids to measure cranial fluid pressure using a similar delivery component **11** and delivery catheter **12**. The use of cannula is not relevant in this example. Instead, the sensor **13** is integrated in the tip of the catheter, which is inserted to drain away excessive brain fluid to e.g. the abdomen.

[0029] The signal processing component **14** may further comprise an additional pressure sensor and/or temperature sensor **16** so that data can be collected to compensate for variations in atmospheric pressure and temperature to improve the accuracy of the data from the pressure sensor **13**.

[0030] FIG. **4** shows a further example system **10** according to the present invention. This example has many components in common with the example of FIG. **2**, and where this is the case, components have been numbered identically. Here however, a second pressure sensor **16** is provided with the system **10**, that pressure sensor **16** being arranged to be inserted subcutaneously in to the patient. It also connected to the processing component **14**. In this example, the second pressure sensor **16** provides data on the pressure adjacent to the bladder **4** in the abdominal wall. This pressure data is fed to the signal processing component **14** for assessment in combination with the data received from the first pressure sensor **13**.

[0031] Data from the second pressure sensor **16** can be used to compensate for pressure generated by user movement and/or the atmosphere that might affect the bladder **4** but which is not directly related to pressure of fluid within the bladder. This enables the signal processing component **14** to compensate for such movements by providing data for analysis by a physician. It can also be used to compensate for atmospheric condition variations, for example. The signal of interest is the differential signal between the first **13** and the second sensor **16**. As the atmospheric condition and also change in body position affect both signals in the same way, so in most cases no other compensation is required. FIG. **5** shows example system configurations with two sensors. The target signal from sensor **13** and the reference signal from the second sensor **16** are transmitted to two separate electronic modules **20.21** and from there further transmitted to an external data module (DAQ) **22**. Measurement data are either transferred from the DAQ module **22** via USB to a PC **23** or stored on a SD-memory card **24**.

[0032] With all of the systems of the present invention it is possible for the signal processing component **14** to be configured to issue an alarm if excessive pressure is detected either pressure sensor **13**, or if a pressure threshold is exceeded for a predetermined period of time. Such an alarm can be used to advise a physician of a serious medical condition, or can be used by a patient to remind them to empty their bladder, for example. In addition to the provision of such an alarm, or as an alternative thereto, the signal processing component **14** may be configured to trigger a nerve stimulation component under certain pressure conditions, that nerve stimulation component then stimulating a patient's nervous system to encourage it to empty the patient's bladder, for example.

[0033] FIG. **6** shows an alternative system **10** of the present invention further comprising wireless communication means **17** for receiving data from the first **13** and/or second **16** pressure sensors. The received data is then transmitted, either by wired or wireless means to the signal processing component **14**. With such a system it is possible for the sensor **13** to be left in the bladder **4** or other body cavity and the delivery catheter **12** removed, together with removal of the cannula **11**. This yet further reduces patient discomfort whilst allowing the pressure sensor to remain within the body catheter to provide long term pressure readings. With such a configuration the first and/or second sensors **12**, **16** may have their own power supply and/or maybe configured to be charged capacitively or inductively by the wireless communication component. With such configuration a number of different wireless communication techniques are possible such as inductive methods, or other methods where the signal transmitter is "short-circuiting"/changing an EM-field set up by an external power source (and data receiver).

[0034] The system of the invention is to be comprehensive in all aspects, diagnostic, monitoring and therapeutic, and can be used throughout a process treatment of a patient. In general, the first stage in the process is to explore whether there is a pressure related problem or not. If there is a suspected pressure related problem, long-term monitoring may be needed to clarify the extent and severity of the problem under physiological conditions in the second stage. The third stage will involve therapeutic intervention with feedback systems to a device releasing medication, alarm system or electrical stimulation.

[0035] The process would have a schematic progression for all stages A first stage is diagnostic evaluation with sensors placed in fluid and/or tissue connected to external recording devices. Typical recording time will be less than 60 minutes.

[0036] A second stage is monitoring during physiological conditions with sensors placed in fluid and/or tissue connected to small external recording devices adapted for ambulatory use. Typical recording time will be 24-48 hours. A next stage is therapeutic intervention with sensors placed in fluid and/or tissue and implantable recording device connected to device. Expected duration of this stage will be from weeks up to several years.

[0037] As mentioned above, the system of the present invention provides significant benefits over the prior art systems in terms of ease of insertion in to a patient, as well as the ability to provide long term measurements, and allow independent movement for a patient with which the system is used. Furthermore, it also enables for provision of a system in which a patient can be assisted in control of their own bladder movement or control of their medical condition that can be monitored based on the fluid for which pressure is being detected. Furthermore, it also enables the possibility of a system in which auto stimulation of a body function or auto triggering of a medical device can be provided in a simple and effective manner based upon the monitored pressure.

1. A system for in-vivo monitoring of pressure of a body fluid, the system comprising:

a delivery component;

an elongate sensor delivery member shaped so as to pass through the delivery component when it has been inserted in to a patient; and

a first pressure sensor positioned at a distal end of the delivery member.

2. The system of claim **1**, further comprising a signal processing component for receiving data from the first pressure sensor and providing an output to a user based upon the received data.

3. The system of claim **1**, further comprising a second pressure sensor configured to be inserted subcutaneously in to a patient in use.

4. The system of claim **3**, further comprising means for receiving data from the second sensor and for comparing it to pressure data from the first sensor to provide compensated pressure data to a user.

5. The system of claim **1** further comprising a temperature sensor such that pressure data from the first sensor can be adjusted to remove any temperature related effects by using data from the temperature sensor.

6. The system of claim **1** wherein the delivery member has communication means and power supply means formed therein such that the first pressure sensor is provided with power and the output of the first pressure sensor can be passed through the delivery member to external processing means.

7. The system of claim **1**, wherein the first pressure sensor has wireless communication means for communication with an external data receiving device.

8. The system of claim **1** further comprising an alarm device to provide warning if a pressure detected by the system meets a predetermined condition.

9. The system of claim **1** configured to activate a nerve stimulation device connected to the patient to which the system is itself connected, to stimulate the nervous system of the patient to act in response to a predetermined pressure condition detected by the system.

10. The system of claim **1**, wherein the delivery component is a cannula.

* * * * *

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[标]申请(专利权)人(译)	辛文特公司		
申请(专利权)人(译)	SINVENT AS		
当前申请(专利权)人(译)	SINVENT AS		
[标]发明人	GLOTT THOMAS INGELIN CLAUSEN		
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优先权	2013190369 2013-10-25 EP		
外部链接	Espacenet USPTO		

摘要(译)

一种用于体内监测体液压力的系统。该系统包括递送部件和细长的传感器递送构件，该细长的传感器递送构件成形为当其已经插入患者体内时穿过递送部件。第一压力传感器定位在输送构件的远端。