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(54) **FLUID TEMPERATURE AND FLOW SENSOR APPARATUS AND SYSTEM FOR CARDIOVASCULAR AND OTHER MEDICAL APPLICATIONS**

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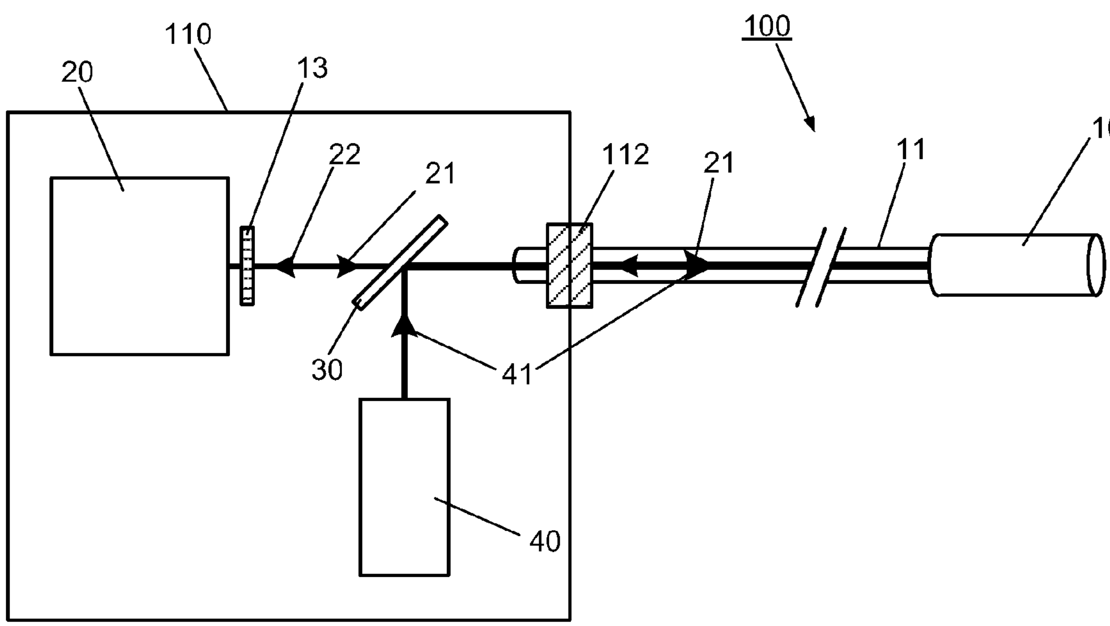
USPC **600/478**

(57) **ABSTRACT**

Apparatus (**100**) is provided comprising an optical micro-sensor (**10**) for directly measuring a fluid temperature and flow by thermoconvection, which suitable for medical applications, e.g. using minimally-invasive cardiovascular techniques. A multi-sensor apparatus (**100**) may take the form of a micro-catheter or steerable guidewire, equipped with a plurality of miniaturized optical sensors (**10**) arranged along a length of the distal end (**101**), each coupled via optical fibers (**11**) to a proximal end (**102**) comprising an input/output connector (**112**) to the control system (**110**), without the need for electrical connections. This enables direct measurement of blood flow, temperature and/or blood pressure simultaneously at several locations within the blood vessels or the heart, including transvalvular measurements. Preferably, the distal end portion has a diameter of 0.89 mm (0.035") or less, and more preferably 0.46 mm (0.018") or less, so that there is negligible effect on valve movement, transvalvular pressure gradient and flow during measurement.



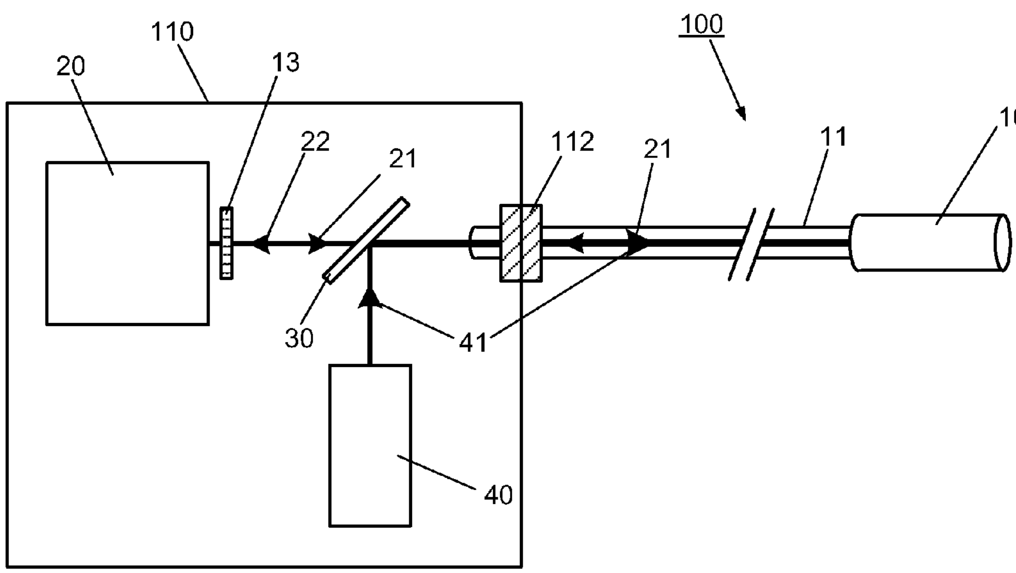


FIG. 1

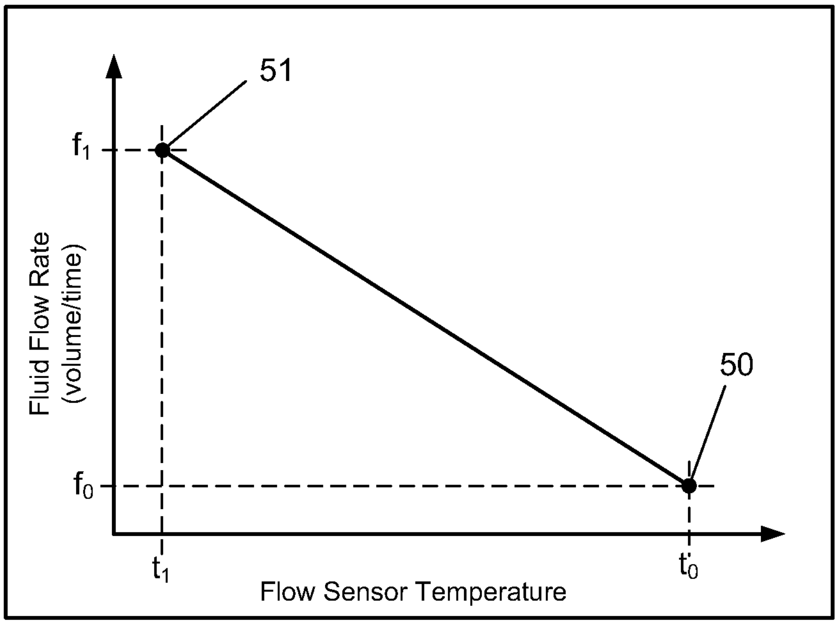

51
f1
Fluid Flow Rate (volume/time)
50
f0
t1
t0
Flow Sensor Temperature

FIG. 2

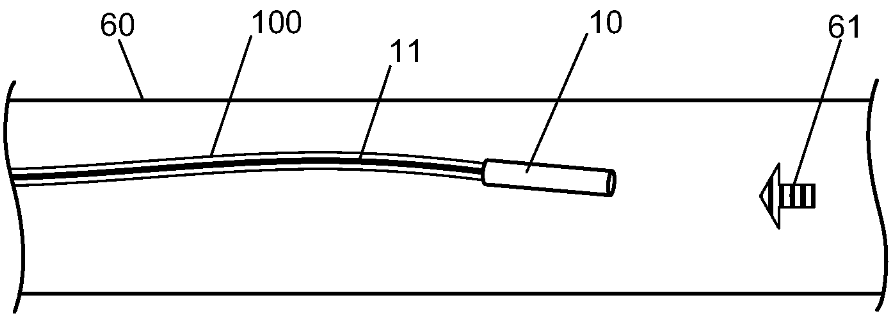


FIG. 3

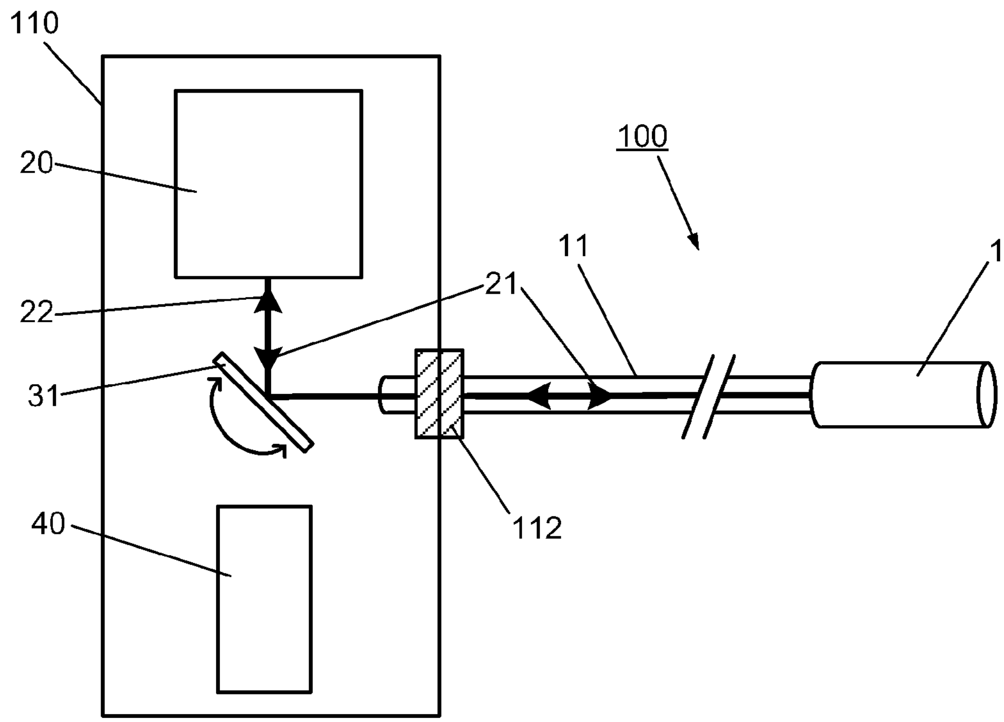


FIG. 4A

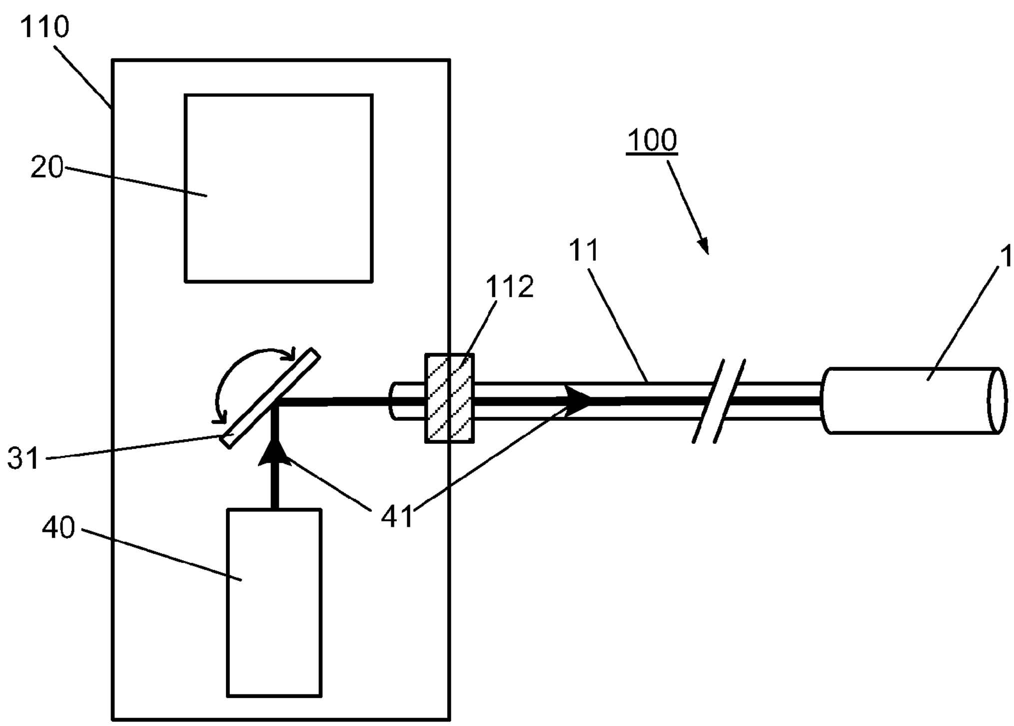


FIG. 4B

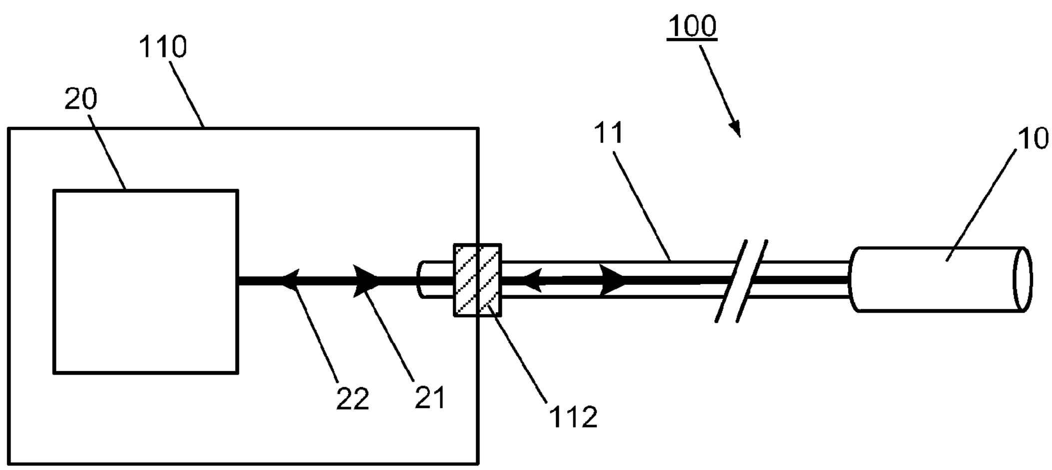


FIG. 5

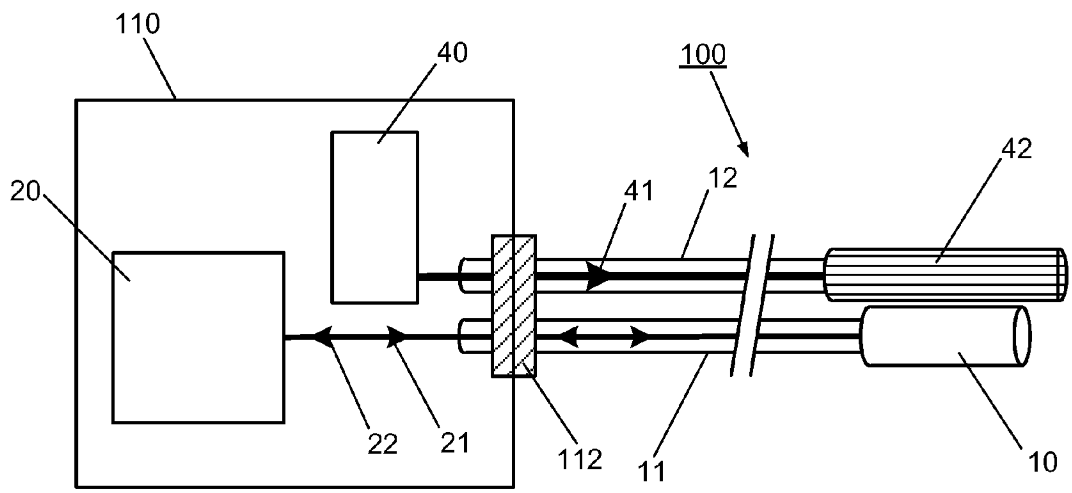

110
40
100
42
20
41
12
22
21
112
11
10

FIG. 6A

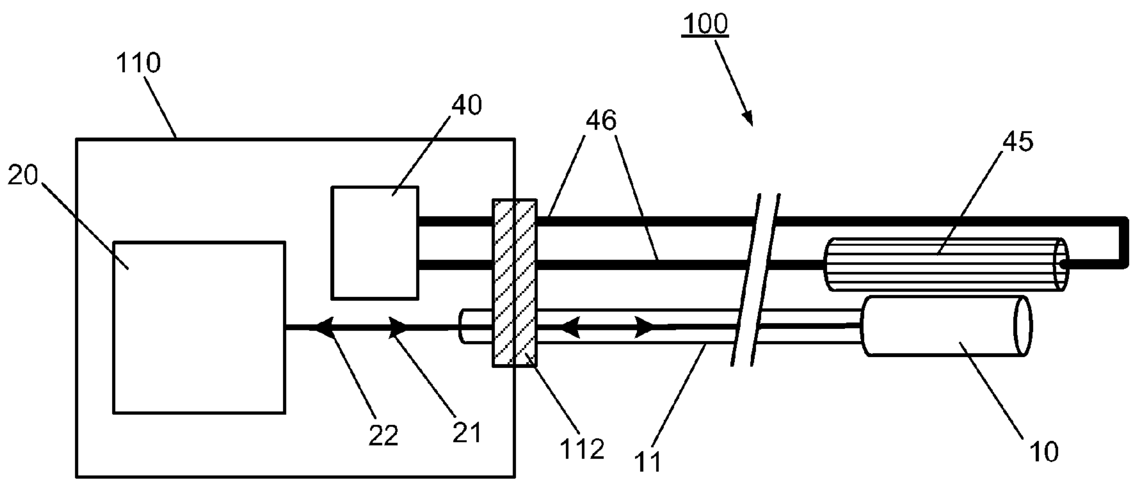

100
110
40
46
45
20
22
21
112
11
10

FIG. 6B

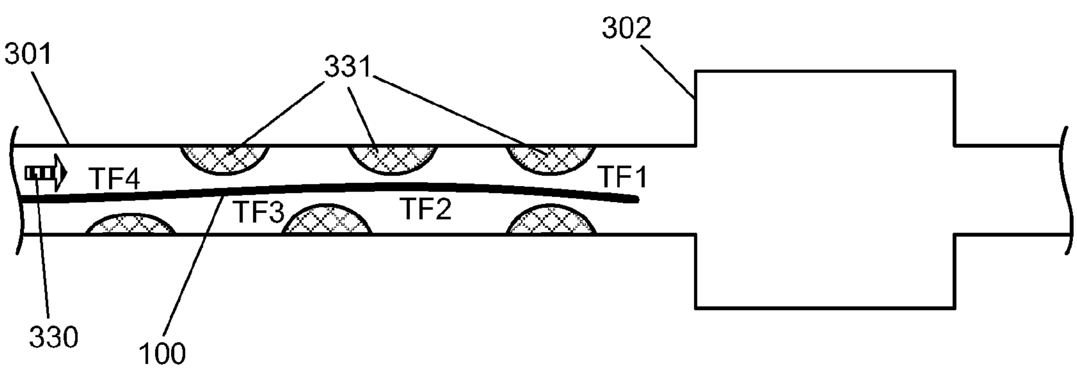


FIG. 7

FLUID TEMPERATURE AND FLOW SENSOR APPARATUS AND SYSTEM FOR CARDIOVASCULAR AND OTHER MEDICAL APPLICATIONS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. provisional patent application No. 61/552,787 entitled "Fluid temperature and flow sensor apparatus and system for cardiovascular and other medical applications", filed Oct. 28, 2011, and from U.S. provisional patent application No. 61/552,778 entitled "Apparatus, system and methods for measuring a blood pressure gradient", filed Oct. 28, 2011, both of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

[0002] This invention relates to sensor apparatus, systems and methods for measuring fluid temperature and flow for medical applications, and in particular, relates to measurement of blood flow within the heart or blood vessels, including measurement of transvalvular blood flow.

BACKGROUND ART

[0003] As described in the above referenced related patent application entitled "Apparatus, system and methods for measuring a blood pressure gradient", cardiac catheterization allows for minimally invasive procedures to obtain direct measurement of cardiovascular parameters such as blood pressure, pressure gradients and flow, to assess heart function. For example, it may be desirable to assess heart valve function to diagnose heart valve disease, or to monitor valve function after heart valve repair or replacement surgery.

[0004] For medical applications, micro-devices are available for measuring the pressure or flow of a fluid using electrical sensors or Micro-Electro-Mechanical Systems (MEMS) devices. For example, a conventional thermoconvection flow sensor uses a temperature sensitive resistor. It is based on a principle similar to a hot wire anemometer, i.e. the resistor is electrically heated, and fluid flowing past the resistor has a cooling effect. A relationship can be obtained between the temperature, the resistance of the wire, and the flow. Local flow can be measured, for example, by determining an initial temperature, and then applying a constant power to heat the resistor and detecting a change in temperature indicative of flow. Alternatively, a change in power needed to maintain a constant temperature of the resistance can be used as a measure of flow.

[0005] A micro-sensor may be introduced into a blood vessel using a micro-catheter or guidewire. One type of commercially available sensor equipped guidewire, Pressure Wire Certus from St. Jude Medical, uses a MEMS device that includes a piezoresistor and diaphragm, e.g. as described in U.S. Pat. Nos. 6,343,514 and 6,615,667 to Smith (Radi Medical Systems AB) entitled "Combined flow pressure and temperature sensor". Deformation of the diaphragm, caused by a pressure change, is read using resistance values. Flow and temperature are read using resistance values of a temperature sensitive resistor.

[0006] A problem with guidewires equipped with sensors based on electrical signals is that multiple, long electrical connections to each sensor are required. The length of a guidewire may be more than 1 metre. Use of microelectronics and long electric wires, particularly when used in humid biological conditions, tends to cause reliability issues with measurement of small electrical signals, e.g. from parasitic capacitances, noise and electromagnetic interference (EMI), and limits the ability to integrate multiple electrical sensors within a guidewire to measure pressure gradient and flow. Furthermore, there may be significant risks involved with the use of microelectronics and electrical connections, in vivo, particularly in the region of the heart, where electrical activity may disrupt normal heart function.

[0007] Additionally, a guidewire is fabricated to provide the required flexibility and torque characteristics to enable the guidewire to be steered and positioned. Thus, the guidewire usually includes torque steering components comprising a central wire or mandrel, and external coil, i.e. a fine spiral metal coil, and a J-shaped tip (pre-shaped or manually shaped).

[0008] A guidewire used for cardiology may typically have a gauge of between 0.89 mm (0.035") to 0.25 mm (0.010") for introduction into small blood vessels. Note: the catheter gauge may also be specified in French units: 1 French=0.333 mm diameter (0.013"). It will be appreciated that there is a limit to the number of electrical wires, sensors and steering components that can physically fit within the required diameter guidewire.

[0009] The electronic drift of MEMS sensors integrated in guidewires remains a limitation. For example, in one study, it was reported that measured blood pressures dropped >5 mmHg/hour due to drift, therefore causing pressure gradient over estimation (*Coronary Pressure*, Authors: Nico Pijls and Bernard de Bruyne, pages **125-127**).

[0010] In addition, MEMS sensors along with their long electrical connections significantly increase the complexity of the manufacturing assembly processes of guidewires using electrical sensors, and therefore significantly increasing their manufacturing costs. Typically, guidewires for medical use are fabricated to be disposable, i.e. for single use only, and are significantly expensive.

[0011] To avoid the need for wires for electrical connections entirely, optical pressure and temperature sensors are known, which are optically coupled to the control unit by optical fibers.

[0012] Optical sensors for measuring pressure are known that use a Micro-Opto-Mechanical-Systems (MOMS) device, which comprises a Fabry-Pérot optical cavity, where one of the two mirrors is a diaphragm. Low coherence light is sent to the cavity via an optical fiber. Diaphragm motions are measured from spectral changes of the reflected light.

[0013] Miniaturized pressure sensors of this type are described, for example, in U.S. Pat. No. 7,684,657 to Donlagic (Fiso Technologies Inc.) entitled "Single Piece Fabry-Pérot Optical Sensor and Method of Manufacturing the Same" and also in U.S. Pat. No. 7,689,07 to Belleville et al. (Opsens Inc.) entitled "Fiber optic pressure sensor for catheter use". The use of this type of MOMS sensor for cardiovascular applications is relatively recent.

[0014] Fiber optic micro-sensors for measuring temperature are known, which use a material with temperature sensitive optical properties coupled to an optical fiber, such as the OTG-M170 GaAs-based fiber optic temperature sensor manufactured by Opsens Inc. This device uses the temperature dependence of the shift in band gap absorption edge of the GaAs material to measure temperature.

[0015] These optical sensors, which may be optically coupled to a control system, e.g. via optical fibers or other flexible light guides, avoid issues of electromagnetic parasitic interferences and noise that exist with electrical sensor equipped guidewires, and are substantially immune to humid conditions. Moreover, optical sensors can be manufactured with much smaller dimensions, e.g. with an outside diameter of 170 micrometres, or less, compared to MEMS sensors. Each optical sensor usually requires coupling via a single optical fiber only, rather than multiple wires required for MEMS sensors.

[0016] However, optical micro-sensors to measure the flow of a fluid using optical technology only, i.e. without electrical connections to the sensor, are currently not available. Thus, there is a need for systems, apparatus and methods for direct measurement and monitoring of fluid flow using sensors, which are optically coupled to the control unit by optical fibers, and in particular, for measurement of blood flow within the heart and the vascular system, and more specifically for measurement of transvalvular blood flow.

SUMMARY OF INVENTION

[0017] The present invention seeks to mitigate one or more disadvantages of known systems, apparatus and methods, or at least provide an alternative.

[0018] Aspects of the invention provide a sensor apparatus, system and methods comprising an optical micro-sensor for directly measuring a temperature and local flow of a fluid by a thermoconvection effect, which is suitable for medical applications. A miniaturized optical temperature and flow sensor may be integrated into a micro-catheter or guidewire, for example, for cardiovascular applications using minimally invasive techniques. The optical thermoconvection sensor comprises a sensor element which has a temperature dependent optical characteristic and which may be optically heated, and input/output means for optically coupling the sensor element to control means for detecting said optical characteristic indicative of temperature and for heating the sensor element. A control system preferably comprises an optical controller, comprising optical source and detection means for measuring temperature based on the optical characteristic, and for optically heating the sensor element to allow flow velocity to be determined by a thermoconvection effect.

[0019] In some embodiments, the sensor apparatus may comprise multiple optical micro-sensors to allow for measuring fluid temperature and flow at multiple locations simultaneously. Optionally, one or more other sensors, such as pressure sensors, may be provided for measuring other parameters. A multi-sensor apparatus may take the form of a multi-sensor wire, i.e. an assembly of sensors integrated within a micro-catheter or steerable guidewire. The multi-sensor wire may be equipped with a plurality of miniaturized optical sensors arranged along a length of the distal end portion, each sensor being coupled via an optical fiber to a control system, without the need for electrical connections. This type of multi-sensor apparatus provides for directly measuring blood flow, temperature and/or blood pressure simultaneously at several locations within the blood vessels or the heart, including transvalvular measurements. Preferably the distal end portion has a diameter 0.89 mm (0.035") or less, and preferably 0.46 mm (0.018") or less, so that there is minimal or negligible effect on the movement of the valve and minimal disruption to the transvalvular pressure gradient and flow during measurement.

[0020] A first aspect of the invention provides a sensor apparatus for directly measuring a fluid temperature and flow by a thermoconvection effect, comprising: optical flow sensor means comprising a sensor element capable of being optically heated and having a temperature dependent optical characteristic, and input/output means for optically coupling the sensor element to control means for detecting said optical characteristic indicative of temperature and for optically heating the sensor element.

[0021] The sensor apparatus may comprise an assembly of a plurality of said flow sensors and a plurality of optical fibers, each sensor element being coupled by a respective individual optical fiber to the input/output means. The sensor apparatus may be integrated within a micro-catheter or guidewire.

[0022] The apparatus may further comprise a control system for coupling to said input/output means, the control system comprising an optical controller for measuring said optical characteristic indicative of temperature, optically heating the sensor element, and detecting a change in temperature of the sensor element indicative of a flow.

[0023] The apparatus may comprise a plurality of flow sensors, and may further comprise one or more pressure sensors, which are preferably optical pressure sensors. Each optical sensor may be optically coupled, to a proximal end of the micro-catheter or guidewire by an optical fiber, or other flexible light guide. Preferably, the distal end portion has an outside diameter of 0.89 mm (0.035") or less, and more preferably 0.46 mm (0.018") or less.

[0024] Another aspect of the invention provides an apparatus for measuring a fluid flow comprising: a sensor assembly comprising a distal end portion having a diameter suitable for introduction intravascularly or intraluminally through small vessels; and the distal end portion comprising optical sensor means comprising an optical thermoconvection sensor element having a temperature dependent optical characteristic and capable of being optically heated, the sensor element being optically coupled to input/output means at a proximal end of the sensor assembly for heating the sensor element and optically detecting a change in temperature of the sensor element indicative of a flow.

[0025] In particular, the sensor means may comprise a plurality of optical flow sensors arranged at a distal end of the sensor assembly. Each optical sensor element is preferably optically coupled by a respective optical fiber to input/output means, i.e. in the form of a suitable connector, at the proximal end of the micro-catheter or guidewire. The distal end portion comprising the sensors preferably has an outside diameter of 0.89 mm or less, and more preferably 0.46 mm or less.

[0026] Each sensor element may comprise a semiconductor material having a temperature sensitive band gap, e.g. bulk GaAs, or a semiconductor layer structure, or a quantum well layer structure having a temperature dependent optical characteristic, and which may be heated by exposure to high intensity light. Alternatively, the flow sensor element may be a MOMS sensor, such as a Fabry-Pérot sensor that may be optically heated and has a temperature sensitive cavity length.

[0027] The optical input/output means preferably further provides for coupling to an optical heating source, such as an optical controller having a high intensity light source.

[0028] The sensor means may further comprise one or more pressure sensors, which may be optical pressure sensors which are optically coupled to said input/output means at the proximal end of the sensor assembly. The optical pressure sensors preferably comprise MOMS pressure sensors, and more preferably comprise Fabry-Pérot MOMS sensors, such as described in the above referenced, related co-pending patent application.

[0029] In an embodiment, for intravalvular measurements, for example, the apparatus comprises a plurality of sensors provided along a length of 4 cm to 7 cm of the distal end portion, for example, four temperature and/or flow sensors arranged at intervals along said length of the distal end portion and optionally, one or more optical pressure sensors.

[0030] The apparatus may comprise an outer layer or covering layer, for example, in the form of a micro-catheter surrounding the sensor means and the plurality of optical fibers, the micro-catheter extending from the proximal end portion to a tip at the distal end, and the micro-catheter having apertures in the distal end portion adjacent each sensor. An aperture is provided in the covering layer adjacent each sensor to allow for contact of the sensor with surrounding fluid during measurements.

[0031] The covering layer or micro-catheter comprises, for example, a polymer tubing, which may be polyimide or PTFE, for example, or other suitable flexible, bio-compatible or hemo-compatible material, with appropriate mechanical properties. In some embodiments, the covering layer comprises a multilayer tubing. Preferably the outside diameter of the polymer tubing surrounding at least said length of the distal end portion has a diameter of 0.89 mm or less. More preferably, the diameter is 0.46 mm or less. An outer protective jacket may be provided around the proximal end portion of the apparatus.

[0032] In some preferred embodiments, the apparatus further comprises torque steering components, e.g. a mandrel extending axially along the length of the sensor assembly and a covering layer comprising a coil. The latter may have an external diameter along the length of the distal end portion of <0.89 mm and preferably 0.46 mm or less, and optionally may comprise a J-tip.

[0033] A connector, at the proximal end provides for coupling input/output means of the sensor assembly to a control system, e.g. optical coupling of each optical sensor, and optionally provides an electrical connection for an electrical sensor or heat source. The input/output means may further provide for wireless connectivity with the control system.

[0034] The apparatus may further comprise a control system which comprises an optical controller for optically heating the sensor element and for measuring a change in the optical characteristic indicative of a temperature change.

[0035] Another aspect of the invention provides a control system for a sensor apparatus comprising one or more optical temperature and flow sensors, wherein the control system comprises an optical controller, comprising a light source means and detection means for coupling to each of the optical sensors for detecting a change in the optical characteristic, indicative of a temperature change, and preferably for optically heating the sensor elements.

[0036] Alternatively, the heating means may comprise means for electrically heating the optical temperature and flow sensor, while optically detecting changes in optical characteristics or parameters indicative of temperature and/or flow values.

[0037] The system may further comprise processing means, i.e. hardware and/or software, for processing optical data, indicative of temperature and flow values, and optionally pressure and pressure gradient when the apparatus includes pressure sensors, and deriving temperature and flow values therefrom.

[0038] In a preferred embodiment, the system may further comprise processing means, comprising hardware and/or software, for graphically displaying temperature and/or flow data for one or more time intervals, and during one or more cardiac cycles.

[0039] Yet another aspect of the invention provides a method for measuring fluid temperature and/or flow, comprising: providing a sensor apparatus comprising, at a distal end, an optical temperature and flow sensor comprising a sensor element having a temperature dependent optical property, which is optically coupled to a proximal end of the sensor apparatus; introducing and advancing the distal end portion of the sensor wire into the region in which flow is to be monitored; and activating the optical temperature and flow sensor, measuring a temperature by detecting an optical parameter, indicative of temperature, heating the sensor element and detecting a change in an optical parameter, indicative of a change in temperature, and deriving therefrom a flow value.

[0040] Preferably, the step of heating the sensor element comprises optically heating the sensor element, e.g. from a high intensity light source coupled to the sensor element, so that electrical connections are not required.

[0041] Where the sensor device also comprises one or more optical pressure sensors, the method may further comprise obtaining pressure, temperature and flow data, and optionally, may further comprise gathering one or more of: blood pressure, blood pressure gradient, temperature and flow data, over one or more cardiac cycles.

[0042] Thus, a small gauge integrated sensor apparatus, e.g. in the form of a micro-catheter or guidewire, is provided that allows for direct measurement of a blood temperature and flow. The device may allow for the comparison of real-time, direct, temperature, flow and optionally, also pressure measurements at several locations simultaneously, e.g. within ventricles of the heart, arteries and/or veins during a minimally-invasive intravascular intervention. In particular, a multi-sensor apparatus having a diameter of 0.89 mm (0.035") or less, and preferably 0.46 mm (0.018") or less provides for transvalvular pressure gradient measurements with minimal or negligible disruption of the heart valve function.

[0043] In addition, if the diameter of the aorta is known, a multi-sensor wire capable of simultaneously measuring flow and pressure gradients allows for evaluation of the cardiac output, and as a consequence, estimation of, for example valve area or lumen area.

[0044] The multi-sensor apparatus, according to preferred embodiments, therefore provides for novel methods for directly and precisely measuring cardiovascular parameters using all optical micro sensors.

[0045] It will also be appreciated that apparatus, systems and methods using the sensor apparatus have primary applications for the cardiovascular system. A similar multi-sensor apparatus and system may also have applications in other systems of the body, i.e. for directly measuring a fluid temperature and/or flow in other biological fluids, liquid or gas, within both human and animal subjects, during a minimally-invasive procedure.

[0046] Thus, apparatus, systems and methods are provided that overcome problems with known methods and apparatus for measuring temperature and flow within the body, and in particular, provide for direct measurement of intravascular or transvalvular blood temperature and flow.

[0047] The foregoing and other objects, features, aspects and advantages of the present invention will become more apparent from the following detailed description, taken in conjunction with the accompanying drawings, of embodiments of the invention, which description is by way of example only.

BRIEF DESCRIPTION OF THE DRAWINGS

[0048] In the drawings, identical or corresponding elements in the different Figures have the same reference numeral.

[0049] FIG. **1** illustrates schematically a system comprising an optical sensor apparatus for measurement of temperature and flow according to a first embodiment of the present invention;

[0050] FIG. **2** shows a chart illustrating a linear relationship between the stabilized sensor temperature and the fluid flow;

[0051] FIG. **3** illustrates a sensor measuring the flow of a fluid flowing within a blood vessel;

[0052] FIGS. **4**A and **4**B illustrate operation of a system comprising a combined optical temperature and flow sensor, according to the first embodiment of the present invention, comprising a galvo mirror for coupling an optical heating source to the sensor;

[0053] FIG. **5** illustrates schematically a system comprising an optical temperature and flow sensor and an optical controller, according to a second embodiment of the present invention, wherein an optical heating source is integrated into the optical controller;

[0054] FIG. **6**A illustrates schematically a system comprising an optical temperature and flow sensor, according to a third embodiment of the present invention, comprising an optical heating source;

[0055] FIG. **6**B illustrates schematically a system comprising an optical temperature and flow sensor, according to a fourth embodiment of the present invention, comprising an electrical heating source; and

[0056] FIG. **7** illustrates schematically the positioning of a multi-sensor wire in the form of a micro-catheter or guidewire comprising multiple optical temperature and flow sensors during measurement of the blood flow velocity, by a method according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0057] As illustrated schematically in FIG. **1**, an optical micro-sensor apparatus **100** for measuring temperature and flow, according to a first embodiment, comprises a sensor **10** comprising, at least in part, a material that has a temperature sensitive optical property, e.g. a temperature sensitive band gap. The sensor element **10** is optically coupled to a distal end of a single optical fiber **11**, which may be integrated into a micro-catheter or guidewire (not shown), for example, either alone or with other optical sensors. The fiber **11** couples the sensor **10** via a suitable input/output connector **112** to a control system **110**, which includes an optical controller **20** comprising an optical source for sending low intensity reference light **21** to the sensor **10** and detection means for detecting a change in light received back **22** from the sensor **10**, e.g. a change in band gap indicative of a temperature. The control system **110** also includes a heating means for optically heating the sensor, which in this embodiment, comprises a high intensity light source **40** which is coupled via an optical element **30** comprising a beam splitter, 2×2 optical coupler or galvo mirror to send continuous or pulsed light **41** to the sensor **10** at a wavelength that is absorbed by the sensor material to cause a temperature increase. Using a principle similar to a resistive thermoconvection sensor, the micro sensor element **10** may be introduced into a flowing fluid, e.g. blood flow within an artery, for example, by introducing the sensor through a guide catheter. The sensor element may be used with optical controller **20** to detect a temperature, and then the sensor element **10** is heated by the light **41** and subsequently a change in temperature resulting from the cooling effect of the blood flow is monitored. Thus, an all-optical temperature and flow sensor apparatus **100** is provided.

[0058] The sensor element **10** may be similar or slightly larger in diameter to the optical fiber **11**, and may therefore be about 170 microns in diameter, for example using a sensor such as the OTG-M170 GaAs-based fiber optic temperature sensor from Opsens Inc. Thus, the optical temperature and flow micro sensor apparatus may be assembled with multiple other optical micro-sensors and optical fibers, in a micro-catheter or guidewire, e.g. for measuring blood pressure, a blood pressure gradient as well as blood temperature and flow.

[0059] As illustrated in FIG. **1**, the optical controller **20** transmits low intensity light **21** to the optical temperature sensor **10** at a power that does not significantly heat the optical sensor. The optical temperature sensor **10** reflects back light **22** to the optical controller **20**. A presently preferred optical temperature sensor element **10** comprises a material with temperature-dependent optical characteristics, for example, the material could be a bulk semiconductor crystal, such as GaAs, for which the optical absorption edge wavelength is temperature dependant. Alternatively, instead of a bulk material, the sensor element may comprise a semiconductor layered structure, or a structured material, such as layers of semiconductor materials forming quantum wells, wherein the optical characteristics of the quantum wells vary with temperature. Alternatively, the sensor **10** could be a miniature optical device such as Fabry-Pérot interferometer designed to measure temperature, i.e. wherein a change in temperature causes a change in cavity length which is optically detectable.

[0060] Where the sensor element comprises a material with a temperature dependent band gap, the optical controller **20**, transmits to the sensor element **10** a reference beam of light **21** with known spectral characteristics, and detects the change in spectrum of the reflected light beam **22**, from which to calculate the temperature of sensor **10**. Therefore, the optical controller **20** is a specialized spectrophotometer with additional computing capability and electronic circuitry in order to extract the temperature information from the beam of light coming from the sensor **22**. The algorithm to calculate the temperature from the sensor spectrum response is specific to the sensor **10** characteristics and technology.

[0061] The optical heating source **40** generates a heating beam of light **41**, at a different wavelength which is absorbed by the sensor element **10** and has enough power to heat the optical temperature sensor element **10** to increase its temperature by a measurable amount. The heating light beam **41** and reference light beam **21** are coupled to the optical fiber **11** via the optical beam splitter **30**. Then the light beams **21** and **41**

propagate through the same optical fiber **11** to the temperature sensor **10**. The optical beam splitter **30** could be implemented by a dichroic beam splitter, a semi-reflective mirror, a 2×2 optical coupler, or any other optical solution that can couple both light beams **21** and **41** into the optical fiber **11**.

[0062] If required, a band pass filter **13** may optionally be provided, to stop the reflected heating light **41** getting back to the optical detector into the optical controller **20**.

[0063] When the optical temperature sensor **10** is immersed in a flowing fluid, and the optical heating source **40** has been deactivated for a certain period of time, the sensor **10** provides the temperature of the fluid. Activating the optical heating source **40** optically heats the sensor **10** and increases its temperature. The rise in temperature is related to the cooling capacity of the fluid flow. When the optical heating source **40** has been activated for a certain period of time, the steady state temperature of the sensor **10** may be measured. The chart in FIG. **2** shows a linear relationship between the steady state temperature of the sensor **10** and the flow, i.e. the flow rate (volume/time), of the flowing fluid. The slope of the line depends on the cooling effect of the fluid flow. When located within a slowly moving fluid, i.e. low flow conditions (point **50** on the FIG. **2**), the steady state temperature of the sensor **10** heated by the light beam **41** stabilizes at a higher temperature compared to high flow conditions (point **51** on the FIG. **2**). The flowing fluid cools the sensor **10** heated by the light beam **41**. When the temperature sensor **10** is located in a specific fluid with known flow conditions, such as a blood vessel, the exact mathematical formula to precisely compute the flow rate of the fluid from the stabilized temperature (i.e. steady state temperature) of the sensor **10** heated by the light beam **41** can be experimentally determined. The optical controller **20** is then calibrated for a specific fluid under specific flow conditions. When properly calibrated, the optical controller **20** measures the flow rate of a fluid by monitoring the temperature of the sensor **10** heated by the light beam **41**, relative to the temperature without heating.

[0064] FIG. **3** illustrates a typical application sensor apparatus as illustrated in FIG. **1**, where the temperature sensor **10** is introduced through a micro-catheter **15** into a blood vessel, e.g. an artery, for measuring flow of blood **61** within a blood vessel **60**. The optical controller **20** estimates the blood flow **61** by assessing the temperature change after heating the optical temperature sensor **10** located within the blood vessel **60**.

[0065] For medical applications, the optical temperature sensor **10** would typically have an operating range of about 20 to 45 degrees Celsius with an accuracy of ±0.3 degree Celsius. The sensor would preferably have an outside diameter of 0.170 mm or less. By way of example, it may be a OTG-M170 GaAs-based fiber optic temperature sensor manufactured by Opsens Inc. It will be appreciated that the temperature sensitivity of the optical sensor element **10** should provide a detectable change in an optical characteristic during heating such that excessive local heating within a blood vessel is not required to measure a typical range of flow values within a blood vessel.

[0066] In apparatus according to an alternative embodiment, illustrated in FIGS. **4**A and **4**B, the beam splitter **30** is replaced by an optical switch, e.g. a galvo mirror **31**. In this embodiment, the temperature sensor **10** is sequentially and periodically exposed to reference light beam **21** and heating light beam **41**. In FIG. **4**A, with the galvo mirror in the first position the sensor **10** is exposed to the reference light beam **21** from the optical controller **20**. In FIG. **4**B, the sensor **10** is exposed to the heating light beam **41** coming from the optical heating source **40**.

[0067] In apparatus according to a second embodiment, illustrated in FIG. **5**, the light source **20** of the optical controller **20** also operates as an optical heating source **40**. A low intensity reference beam **21** is propagated through optical fiber **11** for initial measurement of temperature, and then a higher intensity light beam **41** is propagated from the optical controller **20** during heating of the sensor **10** through the optical fiber **11** to determine flow.

[0068] Apparatus according to these preferred embodiments therefore provides for all-optical coupling of sensors, and avoids the need for electrical connections.

[0069] In apparatus according to a third embodiment illustrated in FIG. **6**A, two fibers are integrated into the optical micro-sensor apparatus **100**, so that one fiber **11** carries the reference light and detected light from the optical controller **20** and another fiber **12** carries the heating light beam **41** to the distal optical heat source **42**. The distal optical heat source **42** is located at the distal end of the micro-sensor apparatus **100**, next to the temperature sensor **10**. In this alternative embodiment, the optical sensor **10** is heated by element **42**, while the flowing fluid cools the sensor **10** to allow the flow to be determined. It will be appreciated that the distal optical heat source **42** should have superior light-absorbing characteristics than the sensor **10** to cause a faster temperature increase.

[0070] While it is preferred to avoid electrical connections entirely, in apparatus according to a fourth embodiment, the optical heating source **40** is replaced by an electrical heat source **45**, as illustrated in FIG. **6**B. The electrical heat source **45** is located at the distal end **101** of the guidewire next to the temperature sensor **10** and electrically connected to the optical controller **20** through a pair of electrical wires **46**. However, the electrical connections **46** are used only for heating the element **45**, while the temperature change of the optical sensor **10** is measured optically as in the previously described embodiments. In this alternative embodiment, the optical sensor **10** is heated by the element **45**, while the flowing fluid cools the sensor **10** to allow the flow to be determined. The temperature change is measured optically, so there is no need to measure small changes in electrical signals which are sensitive to electrical interference. The electrical connection is only used for heating the element **45**, and is therefore less sensitive to electrical interference or other electrical issues.

Multi-Sensor Apparatus

[0071] Multi-sensor apparatus and systems may be provided that comprise one or more temperature and flow sensors and optionally may also comprise one or more pressure sensors. The apparatus and methods may have applications for measure fluid pressures, pressure gradients and temperature and flow in the cardiovascular system and other fluid systems of the body, such as the urinary tract.

[0072] Thus, apparatus may be provided comprising a plurality of optical flow micro-sensors **10** in the form of a multi-sensor wire which may be introduced through a micro-catheter or as a sensor equipped steerable guidewire. Such apparatus may be configured to measure fluid flow simultaneously at several locations along a length of a distal end portion of the multi-sensor wire, as shown schematically in FIG. **7**. For example, several temperature/flow sensors **10** might be assembled in a multi-sensor apparatus in the form of a micro-catheter or guidewire **100** to measure the blood flow characteristics within coronary arteries.

[0073] The apparatus comprises an outer layer, or covering layer, e.g. in the form of a micro-catheter. The covering layer comprises, for example, a polymer tubing, which may be polyimide or PTFE, for example, or other suitable flexible, bio-compatible or hemo-compatible material, with appropriate mechanical properties. In some embodiments, the covering layer may comprise a multilayer tubing. In some embodiments, the multi-sensor apparatus may take the form of a steerable guide wire, comprising a mandrel and outer coil, in which the coil acts as the covering layer.

[0074] It will also be appreciated that the multi-sensor sensor apparatus and system may further comprise pressure sensors, for example, as described in the above referenced related patent application, entitled "Apparatus, system and methods for measuring a blood pressure gradient". Thus, alternative embodiments of the apparatus and methods may also have applications for measuring fluid pressures, gradients and flows in the cardiovascular system and other fluid systems of the body, such as the urinary tract, biliary tract or venous system.

[0075] The length and diameter of the multi-sensor wire may be selected dependent on the application for which flow, temperature or pressure is to be measured. For example, for cardiovascular applications, such as transvalvular measurements, sensors may be arranged along a length of about 4 cm to 7 cm of the distal end portion of the sensor wire, and preferably the distal portion of the sensor wire has a diameter of 0.89 mm or less, and preferably 0.46 mm or less, to minimize disruption to normal valve operation.

[0076] In preferred embodiments, all optical micro-sensors for measurement of both pressure and flow are used to avoid the need for electrical connections altogether, which reduce issues of electromagnetic noise and interference and signal reliability. Also, optical pressure sensors are not susceptible to electronic drift that has been reported for some MEMS sensors. In other embodiments, optical and electrical sensors may be combined.

[0077] Systems, apparatus and methods, according to embodiments of the invention, may be used for measurements with any type of subject, whether human or animal, or for measurements to enable assessment of prosthetic devices such as artificial hearts.

[0078] It will also be apparent that systems and apparatus comprising the optical temperature and flow micro-sensor, may also have other applications for measuring and monitoring fluid flow and temperature in liquids and gases in other small scale fluid containing lumens, vessels, catheters, tubing, and/or remote or inaccessible locations where small diameter optical fibers can be introduced and/or where it is desirable to avoid long electrical connections and/or for single use applications and/or for other biocompatible applications.

INDUSTRIAL APPLICABILITY

[0079] Systems, apparatus and methods, according to embodiments of the invention, are provided for measuring fluid temperature and flow using an optical micro-sensor, and suitable for use within a micro-catheter or guidewire for minimally-invasive procedures. Apparatus may be provided with multiple optical temperature and flow sensors and optionally, pressure sensors, to allow for measurements of blood pressure gradients and flow to be made within the heart and blood vessels such as coronary arteries. The cardiologist is provided with a tool for more quickly, simply and reliably measuring and monitoring cardiovascular parameters.

[0080] In particular, by using an apparatus with multiple micro-sensors within a micro-catheter or guidewire of diameter of 0.89 mm (0.035") or less, and preferably 0.46 mm or less, for example, it is possible for a cardiologist to measure simultaneously, the flow at several points along a blood vessel or in the region of a heart valve.

[0081] The optical micro-sensor apparatus may alternatively be used to measure flow of a fluid, i.e. a gas or liquid, e.g. in other fluid systems of the body, or where long electrical connections are undesirable.

[0082] Although embodiments of the invention have been described and illustrated in detail, it is to be clearly understood that the same is by way of illustration and example only, and not to be taken by way of limitation, the scope of the present invention being limited only by the appended claims.

1. Sensor apparatus for measuring a fluid temperature and flow by a thermoconvection effect, comprising:
- optical flow sensor means, integrated within a microcatheter or a guidewire, comprising an optical fiber coupled at a distal end to a Micro-Opto-Mechanical-System (MOMS) sensor element capable of being optically heated and having a temperature dependent optical characteristic, and optical input/output means at a proximal end of the optical fiber for optically coupling the sensor element to a control means for detecting said optical characteristic indicative of temperature, for optically heating the sensor element, and for detecting a change in temperature of the MOMs sensor element indicative of fluid flow.

2. Sensor apparatus according to claim **1** comprising an assembly of a plurality of MOMs sensor elements and a plurality of optical fibers integrated within the microcatheter or guidewire, each MOMS sensor element coupled by a respective individual optical fiber to the optical input/output means.

3. Sensor apparatus according to claim **1** wherein the MOMS sensor element comprises a Fabry-Pérot MOMS sensor having a temperature dependent cavity length.

4. Sensor apparatus according to claim **1**, wherein the control means comprises an optical source and detection means for detecting the temperature dependent optical characteristic of the MOMS sensor element, an optical heating means for heating the MOMS sensor element, and processing means comprising hardware and/or software for processing optical data indicative of temperature and flow values to derive therefrom fluid temperature and fluid flow measurements.

5. An apparatus for measuring a cardiovascular temperature and flow by thermoconvection comprising:
- a sensor assembly integrated within a micro-catheter or a guidewire comprising a distal end portion and a distal tip having a diameter suitable for introduction intravascularly or intraluminally through small vessels; and
- the sensor assembly comprising optical sensor means within the distal end portion comprising at least one optical sensor element having a temperature dependent optical characteristic and capable of being optically heated for measurement of flow by thermoconvection, an aperture in the micro-catheter or guidewire adjacent each sensor element for fluid contact, and each sensor element being optically coupled by a respective indi-

vidual optical fiber to optical input/output means at a proximal end of the sensor assembly for connection to a control system for detecting said optical characteristic indicative of temperature, for heating the sensor element and optically detecting a change in temperature of the sensor element indicative of a flow.

6. An apparatus according to claim **5**, wherein distal end portion has an outside diameter of 0.89 mm (0.035") or less.

7. An apparatus according to claim **5**, wherein the distal end portion has an outside diameter of 0.46 mm (0.018") or less.

8. (canceled)

9. (canceled)

10. An apparatus according to claim **5** wherein each sensor element comprises a semiconductor material having a temperature dependent bandgap, and wherein the semiconductor material comprises one of: a bulk direct-bandgap material, a multilayer semiconductor structure and a multiquantum well structure.

11. (canceled)

12. An apparatus according to claim **5** wherein each sensor element comprises a MOMS sensor.

13. An apparatus according to claim **12** wherein the MOMS sensors comprise Fabry-Pérot MOMS sensors having a temperature dependent cavity length.

14. An apparatus according to claim **5**, wherein a plurality of said sensor elements are provided along a length of 4 cm to 7 cm of the distal end portion.

15. (canceled)

16. (canceled)

17. (canceled)

18. An apparatus according to claim **5** wherein the sensor assembly is integrated within a guidewire further comprising torque steering components for guiding the sensor assembly.

19. An apparatus according to claim **18** wherein the torque steering components comprise a mandrel extending axially along the length of the sensor assembly and an outer layer comprising a coil of the guidewire having an external diameter along the length of the distal end portion of 0.89 mm (0.035") or less, and preferably has a diameter of 0.46 mm (0.018") or less.

20. An apparatus according to claim **19** wherein wherein the distal tip comprises a J-tip.

21. (canceled)

22. An apparatus according to claim **5** wherein the optical input/output means comprises a connector for removably coupling the sensor assembly and the control system.

23. (canceled)

24. (canceled)

25. An apparatus according to claim **22** wherein the connector provides for an electrical connection for electrically heating the sensor element.

26. An apparatus according to claim **22** wherein the control system comprises:

an optical controller for optically heating each sensor element and for measuring a change in the optical characteristic indicative of a temperature change.

27. A control system for the apparatus of claim **5**, wherein the control system comprises a heating means, and a light source and detection means for coupling to each of the optical sensors for measuring the optical characteristic.

28. A control system according to claim **27** wherein the heating means comprises an optical heating means.

29. A control system according to claim **27** further comprising processing means comprising hardware and/or software for processing optical data indicative of temperature and flow values to derive therefrom temperature and flow measurements.

30. (canceled)

31. (canceled)

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