

PROCESS AND APPARATUS FOR DETERMINING BLOOD FLOW RATE OR CARDIAC OUTPUT

Field of the Invention

[0001] The present invention generally relates to the field of measuring blood flow rate or cardiac output, and more particularly to a heat-exchange assembly for determining the blood flow rate or cardiac output and a catheter being equipped with such a heat-exchange assembly, and further to a process for determining the blood flow rate or cardiac output.

Background of the Invention

[0002] Coronary arteries supply the heart with oxygen-rich blood; the blood flow inside of the coronary arteries is blocked in certain coronary artery diseases. Atherosclerosis, which is also called the blockage of the arteries, narrowing of the arteries, or hardening of the arteries, is one chronic coronary artery disease obstructing the blood flow through the coronary arteries by forming plaques on the inside walls; the rupture of plaques causes heart attack or stroke. The first goal for treatment of atherosclerosis is to restore as much blood flow as possible through the affected portion of coronary arteries and to reduce the risk of plaque rupture so as to avoid heart attack or stroke.

[0003] The standard treatments for coronary artery diseases such as atherosclerosis include the balloon angioplasty and atherectomy that are catheter-based procedures. The balloon angioplasty compresses the fatty plaques onto the artery walls to make more room for blood to flow through the artery. Coronary stents are often implanted after a balloon angioplasty and/or atherectomy. Stents may also be used to restore normal blood flow in arteries that have been torn or otherwise damaged by previous treatments. Stents can be placed in arteries and veins throughout the body. The restored blood flow results in the improvement of the cardiac system and functions. The other standard treatments for coronary artery diseases are medication and bypass surgery to restore normal blood flow rate. Therefore, measuring blood flow rate is essential in these treatments to provide critical feedback and to monitor any improvements.

[0004] Attempts to measure blood flow rate or cardiac output in the prior arts have taken different principles and forms. One is to include a heating element in the catheter together with other sensors and controls; by heating a segment of blood indirectly with the heating element such

as an electric resistance heater, the temperature deviation of blood could be monitored as a function of time at a location downstream from the location at which the heating element is placed; the blood flow rate is measured by the area under the thermodilution curve based on Stewart-Hamilton Principle. However, the heating could result in adverse fever responses from the body. Another attempt is to avoid the heating by injecting a bolus of saline liquid into the blood stream, where the saline liquid has a lower temperature than that of the blood; then the blood flow rate or cardiac output is determined using the similar thermodilution techniques. Yet another is to inject indicator dye into the blood vessels to enhance X-ray images; then the blood flow rate or cardiac output can be determined by the dye-dilution curve. However, in the latter two cases, alien materials have been introduced into the blood flow; it causes safety concerns.

[0005] Therefore, there is an existing need for processes and apparatus that can measure blood flow rate or cardiac output easily and safely.

Summary of the Invention

[0006] One embodiment of the present invention provides a heat-exchange assembly adaptable to a catheter for measuring blood flow rate or cardiac output. The heat-exchange assembly comprises a flexible closed-loop heat-transfer element having two ends; one end for receiving a heat-exchange medium and another end emptying the heat-exchange medium, and at least three thermistors, at least one of the at least three thermistors being employed for monitoring the temperature of the heat-exchange medium before it enters the flexible closed-loop heat-transfer element, at least one of the at least three thermistors being employed for monitoring the temperature of the heat-exchange medium after it passes the flexible closed-loop heat-transfer element, and at least one of the at least three thermistors being employed for monitoring the temperature of blood flowing over the flexible closed-loop heat-transfer element; thereby when the heat-exchange assembly is placed at a desired position within a blood vessel, the at least three thermistors detect the temperatures of the heat-exchange medium before it enters the flexible closed-loop heat-transfer element and after it passes the flexible closed-loop heat-transfer element, and the temperature of the blood flowing over the flexible closed-loop heat-transfer element; then the temperatures acquired are used to determine the blood flow rate or cardiac output.

[0007] In another embodiment of the heat-exchange assembly, the flexible closed-loop heat-transfer element is a thermal conductive tubing with a spring-like configuration forming a thermal conductive tubing coil. In one further embodiment of the heat-exchange assembly, the thermal conductive tubing is made of thermal conductive and bio-compatible materials. In another further embodiment of the heat-exchange assembly, the thermal conductive tubing is made of stainless steel or titanium. In yet another further embodiment of the heat-exchange assembly, the thermal conductive tubing has a preferable outer diameter about 0.5 - 0.75mm, a preferable inner diameter about 0.34 - 0.45mm, and the thermal conductive tubing coil has a preferable coil outside diameter about 2.8 - 5mm, and a preferable coil pitch about two times to three times of the preferable outer diameter of the thermal conductive tubing.

[0008] In another embodiment of the heat-exchange assembly, the at least three thermistors are glass bead thermistors. In one further embodiment of the heat-exchange assembly, the beaded thermistor is preferably made of nickel alloy insulated with polyimide.

[0009] Another embodiment of the present invention provides a catheter able to determine blood flow rate or cardiac output. The catheter comprises a catheter tube with a proximal end and a distal end, a heat-exchange medium inlet port disposed at the proximal end for introducing a heat-exchange medium into the catheter from an outer source, a heat-exchange medium outlet port disposed at the proximal end for discharging the heat-exchange medium from the catheter to an outer receiver, a flexible closed-loop heat-transfer element disposed at the distal end; wherein the flexible closed-loop heat-transfer element has two ends, one end for receiving the heat-exchange medium from the heat-exchange medium inlet port and another end emptying the heat-exchange medium through the heat-exchange medium outlet port, at least three thermistors, at least one of the at least three thermistors being employed for monitoring the temperature of the heat-exchange medium before it enters the flexible closed-loop heat-transfer element, at least one of the at least three thermistors being employed for monitoring the temperature of the heat-exchange medium after it passes the flexible closed-loop heat-transfer element, and at least one of the at least three thermistors being employed for monitoring the temperature of blood flowing over the flexible closed-loop heat-transfer element; and a temperature monitoring port disposed at the proximal end for receiving the acquired temperatures by

the at least three thermistors and outputting the acquired temperatures to a display means or microprocess chip; thereby when the catheter is inserted into a blood vessel and the heat-exchange assembly is placed at a desired position within a blood vessel, the at least three thermistors detect the temperatures of the heat-exchange medium before it enters the flexible closed-loop heat-transfer element and after it passes the flexible closed-loop heat-transfer element, and the temperature of the blood flowing over the flexible closed-loop heat-transfer element; then the temperatures acquired are used to determine the blood flow rate or cardiac output.

[0010] In another embodiment of the catheter, the flexible closed-loop heat-transfer element is a thermal conductive tubing with a spring-like configuration forming a thermal conductive tubing coil. In one further embodiment of the catheter, the thermal conductive tubing is made of thermal conductive and bio-compatible materials. In another further embodiment of the catheter, the thermal conductive tubing is made of stainless steel or titanium. In yet another further embodiment of the catheter, the thermal conductive tubing has a preferable outer diameter about 0.5 - 0.75mm, a preferable inner diameter about 0.34 - 0.45mm, and the thermal conductive tubing coil has a preferable coil outside diameter about 2.8 - 5mm, and a preferable coil pitch about two times to three times of the preferable outer diameter of the thermal conductive tubing.

[0011] In another embodiment of the catheter, the at least three thermistors are glass bead thermistors. In one further embodiment of the catheter, the beaded thermistor is preferably made of nickel alloy insulated with polyimide.

[0012] In another embodiment of the catheter, the blood flow rate or cardiac output is calculated by the following equations (1)-(3).

$$[0013] \quad Q_f = m_f C_f (T_{fi} - T_{fo}) \quad (1)$$

$$[0014] \quad Q_b = m_b C_b (T_{bi} - T_{bo}) \quad (2)$$

$$[0015] \quad Q = UA(LMTD) \quad (3)$$

[0016] where, Q_f = heat transfer rate to the heat-exchange medium in the heat-transfer element; Q_b = heat transfer rate from the blood flowing over the heat-transfer element; Q = heat transfer rate through the heat-transfer element; m_f = mass flow rate of the heat-exchange medium in the heat-transfer element; m_b = mass flow rate of the blood flowing over the heat-transfer element; C_f = specific heat capacity of the heat-exchange medium in the heat-transfer element; C_b = specific heat capacity of the blood flowing over

the heat-transfer element; T_{fi} = inlet temperature of the heat-exchange medium in the heat-transfer element; T_{fo} = outlet temperature of the heat-exchange medium in the heat-transfer element; T_{bi} = inlet temperature of the blood over the heat-transfer element; T_{bo} = outlet temperature of the blood over the heat-transfer element; UA = Heat transfer coefficient x surface area of the heat-transfer element; and $LMTD$ = Log Mean Temperature Difference.

[0017] Another embodiment of the present invention provides a process for determining blood flow rate or cardiac output. The process comprises steps of placing a catheter at a desired location within a blood vessel, wherein the catheter comprises a heat-exchange assembly with a heat-transfer element, and wherein the heat-exchange assembly is able to detect the temperatures of a heat-exchange medium before/after it passes through the heat-transfer element and the temperature of the blood flowing over the heat-transfer element; acquiring the temperatures of the heat-exchange medium before/after it passes through the heat-transfer element and the temperature of the blood flowing over the heat-transfer element; and determining the blood flow rate or cardiac output employing the acquired temperatures; wherein the determining step performs the calculation by the following equations (1)-(3).

$$[0018] \quad Q_f = m_f C_f (T_{fi} - T_{fo}) \quad (1)$$

$$[0019] \quad Q_b = m_b C_b (T_{bi} - T_{bo}) \quad (2)$$

$$[0020] \quad Q = UA(LMTD) \quad (3)$$

[0021] where, Q_f = heat transfer rate to the heat-exchange medium in the heat-transfer element; Q_b = heat transfer rate from the blood flowing over the heat-transfer element; Q = heat transfer rate through the heat-transfer element; m_f = mass flow rate of the heat-exchange medium in the heat-transfer element; m_b = mass flow rate of the blood flowing over the heat-transfer element; C_f = specific heat capacity of the heat-exchange medium in the heat-transfer element; C_b = specific heat capacity of the blood flowing over the heat-transfer element; T_{fi} = inlet temperature of the heat-exchange medium in the heat-transfer element; T_{fo} = outlet temperature of the heat-exchange medium in the heat-transfer element; T_{bi} = inlet temperature of the blood over the heat-transfer element; T_{bo} = outlet temperature of the blood over the heat-transfer element; UA = Heat transfer coefficient x surface area of the heat-transfer element; and $LMTD$ = Log Mean Temperature Difference.

[0022] In another embodiment of the process, the heat-transfer element has two ends; one end for receiving a heat-exchange medium and another end emptying the heat-

exchange medium; and wherein the heat-exchange assembly further comprises of at least three thermistors, at least one of the at least three thermistors being employed for monitoring the temperature of the heat-exchange medium before it enters the flexible closed-loop heat-transfer element, at least one of the at least three thermistors being employed for monitoring the temperature of the heat-exchange medium after it passes the flexible closed-loop heat-transfer element, and at least one of the at least three thermistors being employed for monitoring the temperature of blood flowing over the flexible closed-loop heat-transfer element; thereby when the heat-exchange assembly is placed at a desired position within a blood vessel, the at least three thermistors detect the temperature of the heat-exchange medium before it enters the flexible closed-loop heat-transfer element, the temperature of the heat-exchange medium after it passes the flexible closed-loop heat-transfer element, and the temperature of the blood flowing over the flexible closed-loop heat-transfer element; then the temperatures acquired are used to determine the blood flow rate or cardiac output.

[0023] In another embodiment of the process, the heat-transfer element is a thermal conductive tubing with a spring-like configuration so as to form a thermal conductive tubing coil. In one further embodiment of the process, the thermal conductive tubing is made of thermal conductive and bio-compatible materials. In another further embodiment of the process, the thermal conductive tubing is made of stainless steel or titanium. In yet another further embodiment of the process, the thermal conductive tubing has a preferable outer diameter about 0.5 - 0.75mm, and a preferable inner diameter about 0.34 - 0.45mm, and the thermal conductive tubing coil has a preferable coil outside diameter about 2.8 - 5mm, and a preferable coil pitch about two times to three times of the preferable outer diameter of the thermal conductive tubing.

[0024] In another embodiment of the process, the at least three thermistors are glass bead thermistors. In one further embodiment of the process, the beaded thermistor is preferably made of nickel alloy insulated with polyimide.

[0025] The objectives and advantages of the invention will become apparent from the following detailed description of preferred embodiments thereof in connection with the accompanying drawings.

Brief Description of the Drawings

[0026] Preferred embodiments according to the present invention will now be described with reference to the Figures, in which like reference numerals denote like elements.

[0027] FIG 1 shows a schematic view of a catheter in accordance with one embodiment of the present invention.

[0028] FIG 2 is an isometric view of the heat-transfer element in accordance with one embodiment of the present invention.

[0029] FIG 3 is a longitude cross-section view of the heat-exchange assembly in accordance with one embodiment of the present invention.

[0030] FIG 4 is a perpendicular cross-section view in line A-A' shown in FIG 3.

[0031] FIG 5 is a longitude cross-section view of the heat-exchange assembly in accordance with another embodiment of the present invention.

[0032] FIG 6 shows an illustrative view of the application of the catheter in accordance with one embodiment of the present invention.

[0033] FIG 7 shows a prototype experimental result.

Detailed Description of the Invention

[0034] The present invention may be understood more readily by reference to the following detailed description of certain embodiments of the invention.

[0035] Throughout this application, where publications are referenced, the disclosures of these publications are hereby incorporated by reference, in their entireties, into this application in order to more fully describe the state of art to which this invention pertains.

[0036] The present invention provides a flexible catheter that measures blood flow rate or cardiac output without heating the blood or introducing alien materials into the blood. In brief, the flexible catheter in accordance with one embodiment of the present invention comprises a heat-exchange assembly with a flexible closed-loop heat-transfer element that is positioned at the distal tip of the flexible catheter. In operation, the flexible catheter is inserted through the vascular system to position the distal tip of the flexible

catheter in a location of a blood vessel where the blood flow rate or cardiac output is measured. When a pre-cooled heat-exchange medium is pumped through the catheter to the distal tip, the heat-transfer element absorbs a small amount of heat energy from the blood flowing over the heat-transfer element in the blood vessel so that the pre-cooled heat-exchange medium is warmed up within the heat-transfer element. By having a very large surface area of the heat-transfer element and a relatively lower mass flow rate of the fluid in the heat-transfer element with respect to the blood flow rate outside the heat-transfer element, the small amount of heat energy could be effectively transferred to the pre-cooled heat-exchange medium, creating an elevated temperature suitable for determining the blood flow rate or cardiac output. Once an empirical relationship between the temperature parameter and blood flow rate is established for a specific heat-transfer element, measuring the temperature change enables the blood flow rate or cardiac output to be determined through this relationship without the need for introduction of an auxiliary liquid into the patient's blood.

[0037] The flexible catheter of the present invention has advantages. For example, it measures blood flow rate or cardiac output by measuring the temperature changes of the pre-cooled heat-exchange medium within the heat-transfer element without the need to know the temperature change between the up and down streams of the blood flow; as such the apparatus can be shorter and much miniaturized. In addition, it does not inject any auxiliary liquid or dye into the blood flow; thus it allows repeated measurement and does not affect the composition of blood stream. Further, it does not heat the blood flow; thus it avoids the adverse effects caused by the use of surface-heating electrical-resistance heaters.

[0038] Now referring to FIG 1, there is provided a schematic view of a catheter in accordance with one embodiment of the present invention. The catheter 1 comprises a catheter tube 10 with a proximal end and a distal end, a temperature monitoring port 20 disposed at the proximal end for monitoring the temperature changes and outputting the temperature changes to a display means or microprocess chip, a heat-exchange medium outlet port 30 disposed at the proximal end for discharging the heat-exchange medium from the catheter to an outer receiver, a heat-exchange medium inlet port 40 disposed at the proximal end for introducing the heat-exchange medium into the catheter from an outer source, and a heat-transfer element 50 disposed at the distal end for conducting the heat-exchange between the heat-exchange medium and blood. In operation, the catheter 1 is

inserted into a blood vessel or other lumens and the distal end is positioned at one desired location so that the heat-transfer element 50 enables heat-exchange between the introduced heat-exchange medium from the heat-exchange medium inlet port 40 and the blood; the temperature change of the heat-exchange medium occurs during the heat-exchange process and is monitored by thermal sensors discussed in detail below. It is to be noted that the design of the catheter is well known in the art, and that any catheter is suitable for the present invention; thus no more details about the catheter design will be provided herein.

[0039] Now referring to FIG 2, there is provided an isometric view of the heat-transfer element in accordance with one embodiment of the present invention. The heat-transfer element 50 is configured to be a tubing coil with a spring-like configuration, being exposed to external environment (e.g., blood when in operation). The ring numbers in one heat-transfer element depend on a user's application, preferably 20-30 rings for a spring-like heat-transfer element. The materials suitable for making the tubing coil include all thermal conductive and bio-compatible materials. The preferable materials include stainless steel or titanium.

[0040] Now referring to FIG 3, there is provided a longitude cross-section view of the heat-exchange assembly in accordance with one embodiment of the present invention. The tubing has a preferable outer diameter about 0.5 – 0.75mm (a as shown in FIG 3), a preferable inner diameter about 0.34-- 0.45mm, a preferable coil outside diameter about 2.8 -- 5mm (b as shown in FIG 3), and a preferable coil pitch (p as shown in FIG 3) about 2 to 3 times of the tubing outer diameter. When a metallic tubing coil is used, the metallic tubing length before coiling is preferably about 200 – 500mm. The heat-exchange medium includes any suitable thermal conductive fluid. For the sake of safety, the heat-exchange medium is preferably the ones having no detrimental effects to the subject in case of leakage, including saline solution. The flow rate of the heat-exchange medium and its temperature before being introduced through the heat-exchange medium inlet port can be determined by routine experimental procedures; the affecting factors include the nature of the heat-exchange medium, the ring numbers of the tubing coil, the pitches of the tubing coil, the inner diameter of the tubing and the coil outer diameter. For saline solution, the flow rate is preferably about 3-10 ml/min; the temperature of the saline solution ready for heat exchange is preferably about 0 – 10°C.

[0041] Now referring to FIG 4, there is provided a perpendicular cross-section view in line A-A' shown in FIG 3. The inlet thermal sensor or thermistor 31, outlet thermistor 41 and blood stream thermistor 11 are disposed at the proximal position related to the tubing coil for monitoring the temperatures; the inlet thermal sensor or thermistor 31 monitors the temperature of the heat-exchange medium right before it enters the tubing coil; the outlet thermistor 41 monitors the temperature of the heat-exchange medium right after it exits the tubing coil; and the blood stream thermistor 11 monitors the blood temperature. The calculation of the blood flow rate or cardiac output will be discussed in detail hereinafter. The lead wires 60 allows the sensors to send their signals to the temperature monitoring port 20 for further processing. Any miniaturized thermistor is suitable for the present invention including glass bead thermistor; the beaded thermistor is preferably made of nickel alloy insulated with polyimide.

[0042] Now referring to FIG 5, there is provided a longitude cross-section view of the heat-exchange assembly in accordance with another embodiment of the present invention. In this configuration, the tubing coil is attached at the end of the catheter directly to the lumens. It is useful when the size of the catheter is critical for certain applications, e.g., the insertion of catheter into very narrow vessels. All of the important parameters have been described above.

[0043] Now referring to FIG 6, there shows an illustrative view of the application of the catheter in accordance with one embodiment of the present invention. A preliminary experiment has been conducted using a simple heat-transfer element integrated with a catheter and confirmed the application of the relationship derived through theoretically analysis based on the following equations (1)-(3).

[0044]
$$Q_f = m_f C_f (T_{fi} - T_{fo}) \quad (1)$$

[0045]
$$Q_b = m_b C_b (T_{bi} - T_{bo}) \quad (2)$$

[0046]
$$Q = UA(LMTD) \quad (3)$$

[0047] where,

[0048] Q_f = heat transfer rate to the heat-exchange medium in the heat-transfer element;

[0049] Q_b = heat transfer rate from the blood flowing over the heat-transfer element;

[0050] Q = heat transfer rate through the heat-transfer element;

[0051] m_f = mass flow rate of the heat-exchange medium in the heat-transfer element;

[0052] m_b = mass flow rate of the blood flowing over the heat-transfer element;

[0053] C_f = specific heat capacity of the heat-exchange medium in the heat-transfer element;

[0054] C_b = specific heat capacity of the blood flowing over the heat-transfer element;

[0055] T_{fi} = inlet temperature of the heat-exchange medium in the heat-transfer element;

[0056] T_{fo} = outlet temperature of the heat-exchange medium in the heat-transfer element;

[0057] T_{bi} = inlet temperature of the blood over the heat-transfer element;

[0058] T_{bo} = outlet temperature of the blood over the heat-transfer element;

[0059] UA = Heat transfer coefficient x surface area of the heat-transfer element;
and

[0060] $LMTD$ = Log Mean Temperature Difference.

[0061] $LMTD$ is a function of T_{fi} , T_{fo} , T_{bi} and T_{bo} while UA could be assumed to be constant for a specific heat transfer system. Q could be equated to the Q_f and Q_b and the mass flow rate of blood, m_b , could then be related to the outlet temperature of the heat-exchange medium, T_{fo} , leaving the heat-transfer element, by eliminating, T_{bo} , leaving the rest of the parameters in the expression. The results have demonstrated the relationship shown in FIG 7. Thus, the cardiac output and the substantial change of the cardiac output could be determined from the measurement of the heat-exchange medium temperature leaving the heat-transfer element, using this relationship.

[0062] While the present invention has been described with reference to particular embodiments, it will be understood that the embodiments are illustrative and that the invention scope is not so limited. Alternative embodiments of the present invention will become apparent to those having ordinary skill in the art to which the present invention pertains. Such alternate embodiments are considered to be encompassed within the spirit and scope of the present invention. Accordingly, the scope of the present invention is described by the appended claims and is supported by the foregoing description.

CLAIMS

What is claimed is:

1. A heat-exchange assembly adaptable to a catheter for measuring blood flow rate or cardiac output, comprising:
 - a flexible closed-loop heat-transfer element configured to have a body with an input end and an output end; wherein the input end for receiving a heat-exchange medium from an input lumen of the catheter and the output end for emptying the heat-exchange medium to an output lumen of the catheter; and wherein the body is configured to allow the heat-exchange medium to flow in file through from the input end to the output end; and
 - at least three thermistors, one of the at least three thermistors being configured at the proximity of the input end for monitoring the temperature of the heat-exchange medium before it enters the body of the flexible closed-loop heat-transfer element, one of the at least three thermistors being employed configured at the proximity of the output end for monitoring the temperature of the heat-exchange medium after it passes the body of the flexible closed-loop heat-transfer element, and one of the at least three thermistors being configured for monitoring the temperature of blood flowing over the flexible closed-loop heat-transfer element;thereby when the heat-exchange assembly is placed at a desired position within a blood vessel, the at least three thermistors detect the temperatures of the heat-exchange medium before/after it passes the body of the flexible closed-loop heat-transfer element, and the temperature of the blood flowing over the flexible closed-loop heat-transfer element; then the blood flow rate or cardiac output is determined by the detected temperatures.
2. The heat-exchange assembly of claim 1, wherein the body of the flexible closed-loop heat-transfer element is a thermal conductive tubing with a spring-like configuration forming a thermal conductive tubing coil.
3. The heat-exchange assembly of claim 2, wherein the thermal conductive tubing is made of thermal conductive and bio-compatible materials.

4. The heat-exchange assembly of claim 2, wherein the thermal conductive tubing is made of stainless steel or titanium.
5. The heat-exchange assembly of claim 2, wherein the thermal conductive tubing has a preferable outer tube diameter about 0.5 - 0.75mm, a preferable inner tube diameter about 0.34 - 0.45mm, and the thermal conductive tubing coil has a preferable outside coil diameter about 2.8 - 5mm, and a preferable coil pitch about two times to three times of the preferable outer diameter of the thermal conductive tubing.
6. The heat-exchange assembly of claim 1, wherein the at least three thermistors are glass bead thermistors.
7. The heat-exchange assembly of claim 6, wherein the beaded thermistor is preferably made of nickel alloy insulated with polyimide.
8. A catheter able to determine blood flow rate or cardiac output, comprising:
 - a catheter tube with a proximal end and a distal end;
 - a heat-exchange medium inlet port disposed at the proximal end for introducing a heat-exchange medium into the catheter from an outer source;
 - a heat-exchange medium outlet port disposed at the proximal end for discharging the heat-exchange medium from the catheter to an outer receiver;
 - a flexible closed-loop heat-transfer element disposed at the distal end; wherein the flexible closed-loop heat-transfer element configured to have a body with an input end and an output end; wherein the input end for receiving the heat-exchange medium from the heat-exchange medium inlet port and the output end emptying the heat-exchange medium through the heat-exchange medium outlet port; and wherein the body is configured to allow the heat-exchange medium to flow in file through from the input end to the output end;
 - at least three thermistors, one of the at least three thermistors being configured at the proximity of the input end for monitoring the temperature of the heat-exchange medium before it enters the body of the flexible closed-loop heat-transfer element, one of

the at least three thermistors being employed configured at the proximity of the output end for monitoring the temperature of the heat-exchange medium after it passes the body of the flexible closed-loop heat-transfer element, and one of the at least three thermistors being configured for monitoring the temperature of blood flowing over the flexible closed-loop heat-transfer element; and

a temperature monitoring port disposed at the proximal end for receiving the acquired temperatures by the at least three thermistors and outputting the acquired temperatures to a display means or microprocess chip;

thereby when the catheter is inserted into a blood vessel and the heat-exchange assembly is placed at a desired position within a blood vessel, the at least three thermistors detect the temperatures of the heat-exchange medium before/after it passes the body of the flexible closed-loop heat-transfer element, and the temperature of the blood flowing over the flexible closed-loop heat-transfer element; then the blood flow rate or cardiac output is determined by the detected temperatures.

9. The catheter of claim 8, wherein the body of the flexible closed-loop heat-transfer element is a thermal conductive tubing with a spring-like configuration forming a thermal conductive tubing coil.

10. The catheter of claim 9, wherein the thermal conductive tubing is made of thermal conductive and bio-compatible materials.

11. The catheter of claim 9, wherein the thermal conductive tubing is made of stainless steel or titanium.

12. The catheter of claim 9, wherein the thermal conductive tubing has a preferable outer tube diameter about 0.5 - 0.75mm, a preferable inner tube diameter about 0.34 - 0.45mm, and the thermal conductive tubing coil has a preferable outside coil diameter about 2.8 - 5mm, and a preferable coil pitch about two times to three times of the preferable outer diameter of the thermal conductive tubing.

13. The catheter of claim 8, wherein the at least three thermistors are glass bead thermistors.

14. The catheter of claim 13, wherein the beaded thermistor is preferably made of nickel alloy insulated with polyimide.

15. The catheter of claim 8, wherein the blood flow rate or cardiac output is calculated by the following equations (1)-(3).

$$Q_f = m_f C_f (T_{fi} - T_{fo}) \quad (1)$$

$$Q_b = m_b C_b (T_{bi} - T_{bo}) \quad (2)$$

$$Q = UA(LMTD) \quad (3)$$

where, Q_f = heat transfer rate to the heat-exchange medium in the heat-transfer element; Q_b = heat transfer rate from the blood flowing over the heat-transfer element; Q = heat transfer rate through the heat-transfer element; m_f = mass flow rate of the heat-exchange medium in the heat-transfer element; m_b = mass flow rate of the blood flowing over the heat-transfer element; C_f = specific heat capacity of the heat-exchange medium in the heat-transfer element; C_b = specific heat capacity of the blood flowing over the heat-transfer element; T_{fi} = inlet temperature of the heat-exchange medium in the heat-transfer element; T_{fo} = outlet temperature of the heat-exchange medium in the heat-transfer element; T_{bi} = inlet temperature of the blood over the heat-transfer element; T_{bo} = outlet temperature of the blood over the heat-transfer element; UA = Heat transfer coefficient x surface area of the heat-transfer element; and $LMTD$ = Log Mean Temperature Difference.

16. A process for determining blood flow rate or cardiac output, comprising steps of:
placing a catheter at a desired location within a blood vessel, wherein the catheter comprises a heat-exchange assembly with a heat-transfer element, and wherein the heat-exchange assembly is able to detect the temperatures of a heat-exchange medium before/after it passes through the heat-transfer element and the temperature of the blood flowing over the heat-transfer element;

acquiring the temperatures of the heat-exchange medium before/after it passes through the heat-transfer element and the temperature of the blood flowing over the heat-transfer element; and

determining the blood flow rate or cardiac output employing the acquired temperatures; wherein the determining step performs the calculation by the following equations (1)-(3).

$$Q_f = m_f C_f (T_{fi} - T_{fo}) \quad (1)$$

$$Q_b = m_b C_b (T_{bi} - T_{bo}) \quad (2)$$

$$Q = UA(LMTD) \quad (3)$$

where, Q_f = heat transfer rate to the heat-exchange medium in the heat-transfer element; Q_b = heat transfer rate from the blood flowing over the heat-transfer element; Q = heat transfer rate through the heat-transfer element; m_f = mass flow rate of the heat-exchange medium in the heat-transfer element; m_b = mass flow rate of the blood flowing over the heat-transfer element; C_f = specific heat capacity of the heat-exchange medium in the heat-transfer element; C_b = specific heat capacity of the blood flowing over the heat-transfer element; T_{fi} = inlet temperature of the heat-exchange medium in the heat-transfer element; T_{fo} = outlet temperature of the heat-exchange medium in the heat-transfer element; T_{bi} = inlet temperature of the blood over the heat-transfer element; T_{bo} = outlet temperature of the blood over the heat-transfer element; UA = Heat transfer coefficient x surface area of the heat-transfer element; and $LMTD$ = Log Mean Temperature Difference.

17. The process of claim 16, wherein the heat-transfer element has two ends; one end for receiving a heat-exchange medium and another end emptying the heat-exchange medium; and

wherein the heat-exchange assembly further comprises:

at least three thermistors, at least one of the at least three thermistors being employed for monitoring the temperature of the heat-exchange medium before it enters the flexible closed-loop heat-transfer element, at least one of the at least three thermistors being employed for monitoring the temperature of the heat-exchange medium after it passes the flexible closed-loop heat-transfer element, and at least one of the at least three thermistors being employed for monitoring the temperature of blood flowing over the flexible closed-loop heat-transfer element;

thereby when the heat-exchange assembly is placed at a desired position within a blood vessel, the at least three thermistors detect the temperatures of the heat-exchange medium before/after it passes the flexible closed-loop heat-transfer element, and the

temperature of the blood flowing over the flexible closed-loop heat-transfer element; then the temperatures acquired are used to determine the blood flow rate or cardiac output.

18. The process of claim 17, wherein the heat-transfer element is a thermal conductive tubing with a spring-like configuration so as to form a thermal conductive tubing coil.

19. The process of claim 18, wherein the thermal conductive tubing is made of thermal conductive and bio-compatible materials.

20. The process of claim 18, wherein the thermal conductive tubing is made of stainless steel or titanium.

21. The process of claim 18, wherein the thermal conductive tubing has a preferable outer tube diameter about 0.5 - 0.75mm, and a preferable inner tube diameter about 0.34 - 0.45mm, and the thermal conductive tubing coil has a preferable outside coil diameter about 2.8 - 5mm, and a preferable coil pitch about two times to three times of the preferable outer diameter of the thermal conductive tubing.

22. The process of claim 18, wherein the at least three thermistors are glass bead thermistors.

23. The process of claim 22, wherein the beaded thermistor is preferably made of nickel alloy insulated with polyimide.