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(54) **SINGLE HEAT FLUX SENSOR ARRANGEMENT**

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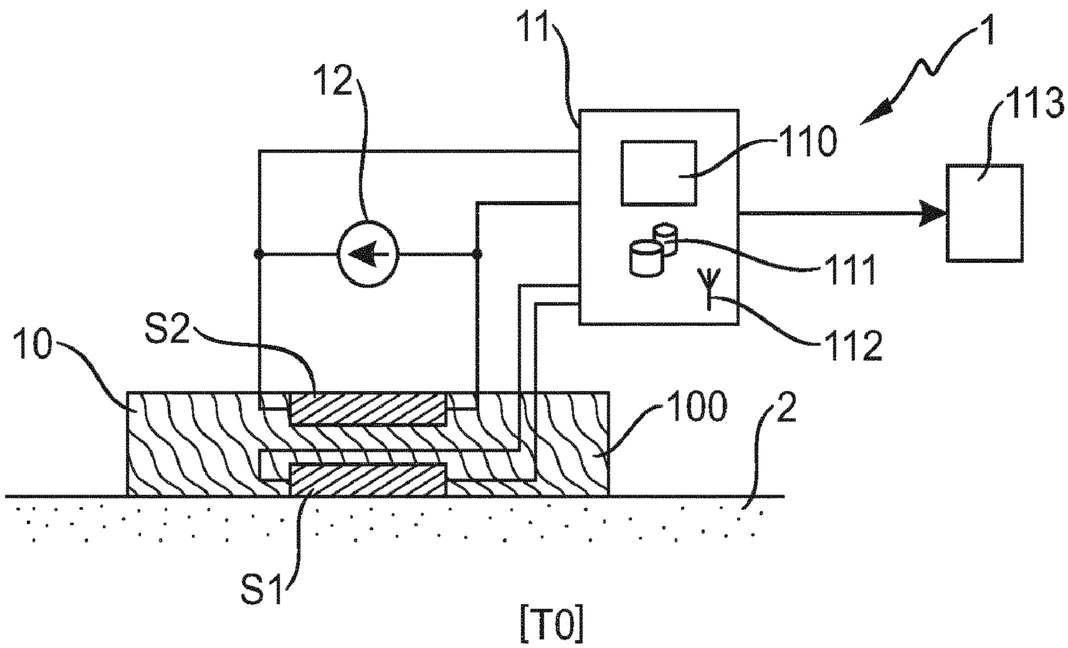
(57) **ABSTRACT**

The invention describes a single heat flux sensor arrangement (**1**) comprising a sensor (**10**) comprising a layer (**100**) of thermally insulating material, an inner temperature measurement means (S**1**) arranged at an inner region of the insulating layer (**100**) and an outer temperature measurement means (S**2**) arranged at an outer region of the insulating layer (**100**); an evaluation unit (**11**) adapted to receive a temperature input from the inner **5** temperature measurement means (S**1**) and to receive a temperature input from the outer temperature measurement means (S**2**); and a heating means (**12**, S**2**) realized to deliberately raise the temperature of a region of the insulating layer (**100**). The invention further describes a non-invasive method of measuring a core body temperature (T**0**) of a subject (**3**).



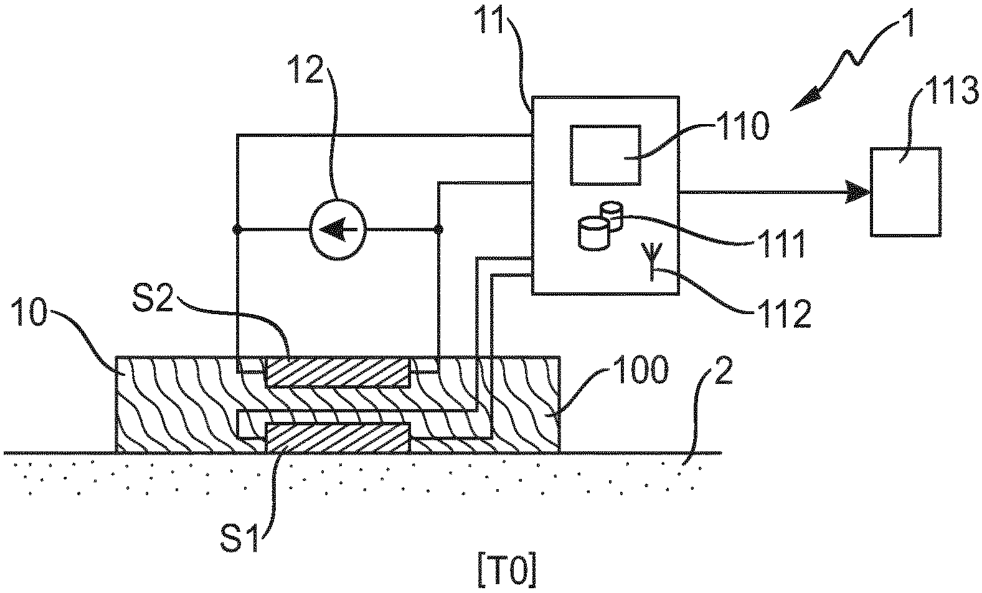


FIG. 1

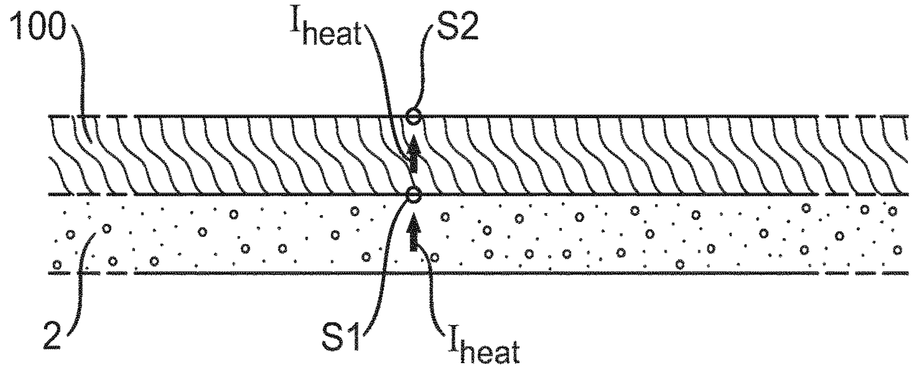


FIG. 2

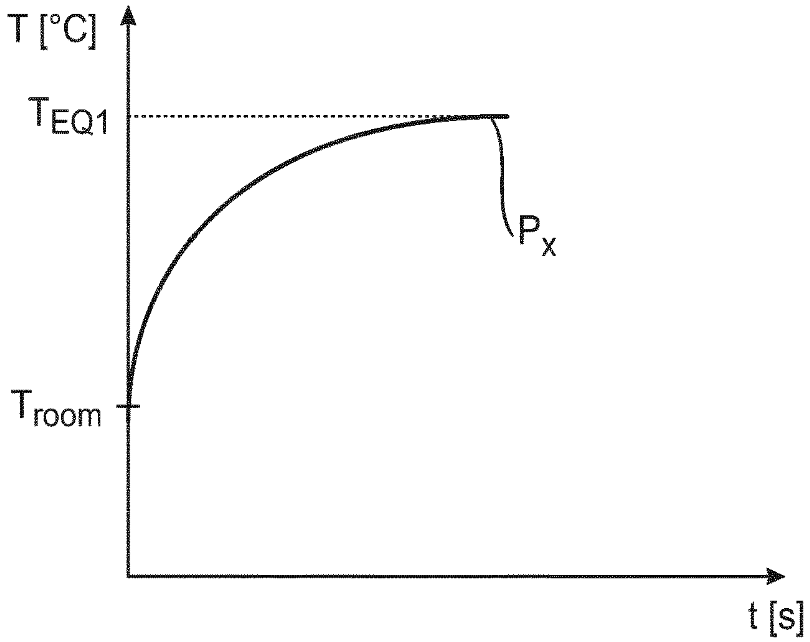


FIG. 3A

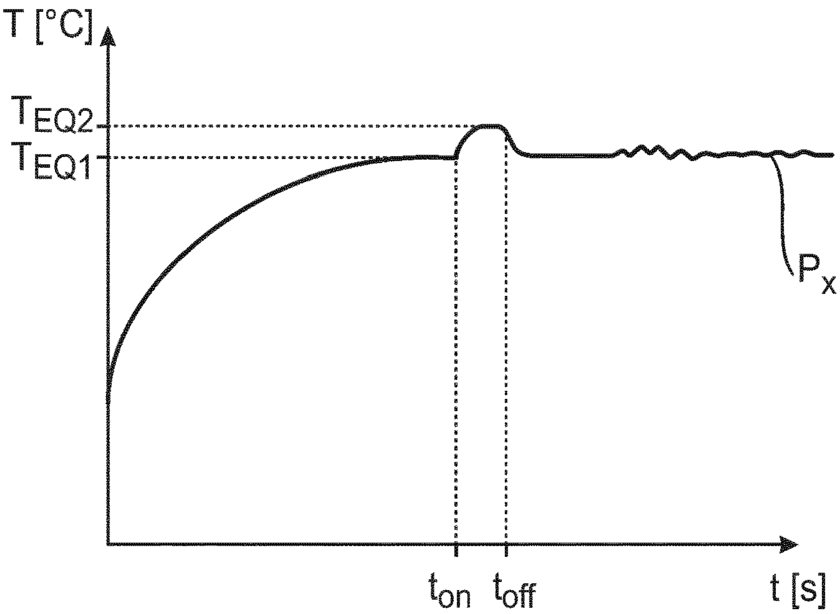


FIG. 3B

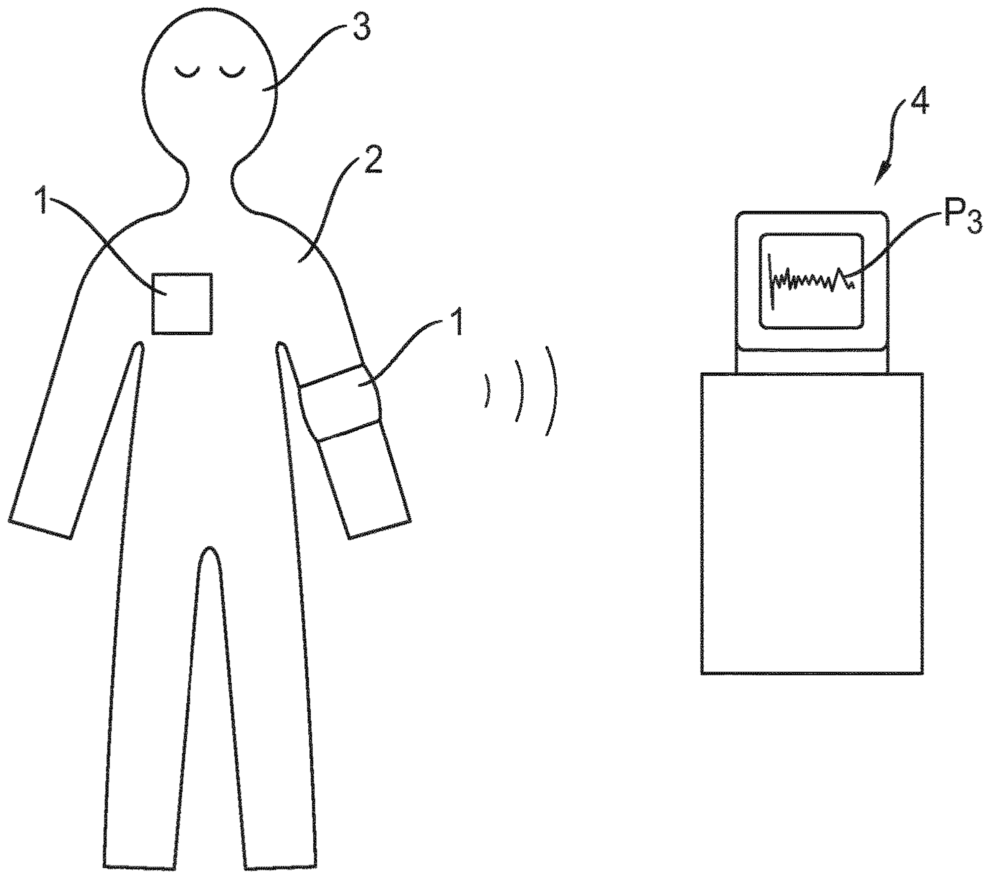


FIG. 4

SINGLE HEAT FLUX SENSOR ARRANGEMENT

FIELD OF THE INVENTION

[0001] The invention describes a single heat flux sensor arrangement and a method of measuring a core body temperature of a subject.

BACKGROUND OF THE INVENTION

[0002] In a healthcare environment, it is often necessary to accurately monitor the core body temperature of a patient. The core body temperature may be understood to be the temperature of blood through the vital organs such as the heart and brain. Its measurement is of great importance in hospital care. This is especially evident for patients undergoing long surgical procedures in cooled operating rooms, since a patient under anesthetic cannot regulate his or her body temperature. This can be a serious problem, and it is estimated that up to 50% of all surgical patients suffer from hypothermia following a surgical procedure.

[0003] One way of monitoring the core body temperature is to use an invasive probe, for example an esophageal probe, a rectal probe, etc. Since the core body temperature must be monitored over an extended period of time, such probes are generally perceived as very uncomfortable by the conscious patient. A non-invasive temperature monitoring device can be based on the concept of zero heat flux. However, such a sensor requires a control loop and heating elements to actively achieve "zero heat flow", making this kind of sensor difficult to integrate in a wearable sensor application.

[0004] Measurement of core body temperature is also possible using passive sensing. There are two main approaches in performing passive core body temperature measurement. One approach requires only two temperature measuring devices separated by an insulating material. It is assumed that the thermal resistivity of the insulating materials is known, while the skin thermal resistivity is estimated, usually taking an average value that is assumed to apply to any patient of any age. Once an equilibrium is reached (the temperature reported by a temperature measuring device has reached a constant level) the heat flow between the two temperature measuring devices can be calculated, and the core body temperature is then determined. The advantages of a passive "single heat flux sensor" are its simple geometry, a thin realization, straightforward calculations, and the fact that only two temperature measuring devices are needed. However, even disregarding the slight inaccuracy owing to the fact that heat flow is not limited to the outward direction only, a more serious inaccuracy can arise from assuming a value for the skin thermal resistivity. A patient may have a skin thermal resistivity that is not the same as the average value, so that the core body temperature for that patient will not be reported correctly. Furthermore, the skin thermal resistivity can vary even for one patient, and can be different at the forehead, arm, chest, etc.

[0005] An alternative passive approach measures two heat flows. In such a "dual heat flux sensor", the sensor pad has two layers of different thickness, and at least four temperature measuring devices. The sensor can estimate core body temperature without making any assumptions regarding the skin thermal resistivity. The advantage of a passive dual heat flux sensor is that it delivers a more accurate temperature reading. However, a dual heat flux sensor has a more complex geometry and is more expensive to manufacture; is significantly more bulky; needs at least four temperature measuring devices; requires complex calculations to be performed; has a long heating time to reach equilibrium; and is prone to error.

[0006] Therefore, it is an object of the invention to provide an improved single heat flux sensor for measuring the core temperature of a subject.

SUMMARY OF THE INVENTION

[0007] The object of the invention is achieved by the single heat flux sensor arrangement of claim **1**; and by the method of claim **13** of measuring a core body temperature of a subject.

[0008] According to the invention, the single heat flux sensor arrangement comprising a sensor comprising a layer of thermally insulating material, an inner temperature measurement means arranged at an inner region of the insulating layer and an outer temperature measurement means arranged at an outer region of the insulating layer; an evaluation unit adapted to receive a temperature input from the inner temperature measurement means and to receive a temperature input from the outer temperature measurement means; and a heating means realized to deliberately raise the temperature of a region of the insulating layer, for example to raise the temperature of one of the thermistors. The evaluation unit can then calculate a value of thermal resistivity for the subject, and can use this information to accurately determine the core body temperature of the subject.

[0009] An advantage of the inventive single heat flux sensor arrangement is that it combines the advantages of a single heat flux sensor and a dual heat flux sensor, i.e. it has the simple construction of a single heat flux sensor but achieves the better measurement accuracy of a dual heat flux sensor. By also comprising the heating means to deliberately raise the temperate of the sensor, it is possible, as will be explained below, to determine the thermal resistivity of the subject. Because this thermal resistivity is calculated instead of simply being estimated as in the conventional approach the accuracy of the temperature measurement can be significantly improved. The manufacturing costs of the inventive sensor compare favorably to conventional single heat flow sensors, and are significantly lower than dual heat flow sensors.

[0010] According to the invention, the non-invasive method of measuring a core body temperature of a subject comprises the steps of attaching such a single heat flux sensor arrangement to a subject; determining a first equilibrium temperature and subsequently activating the heating means to heat the outer region of the insulating layer of the sensor; determining a second equilibrium temperature; determining a value of thermal resistivity for that subject; and calculating the core body temperature of the subject on the basis of the thermal resistivity value and an equilibrium temperature.

[0011] The inventive method allows a more precise computation of the subject's core temperature, since it also includes a step of determining the thermal resistivity for that subject. This compares favorably with conventional single heat flux temperature sensing methods that rely on an estimated thermal resistivity value for the subject.

[0012] The dependent claims and the following description disclose particularly advantageous embodiments and features of the invention. Features of the embodiments may be combined as appropriate. Features described in the context of one claim category can apply equally to another claim category.

[0013] The terms "heat flux" and "heat flow" are understood to be synonymous, and are used interchangeably in the following. The inventive single heat flux sensor arrangement can be used to measure the temperature of any subject for which it is not practicable to determine the subject's thermal resistivity. In the following, but without restricting the invention in any way, it may be assumed that the subject is a human patient, and that the temperature to be observed is the patient's core body temperature.

[0014] A temperature measurement means can comprise any suitable type of temperature sensor. Thermistors are often used in small-scale devices to measure temperature on account of their favorably small size, their sensitivity, accuracy and the ability to easily incorporate them into an electrical circuit. Therefore, it may be assumed in the following that a temperature measurement means is a thermistor.

[0015] The thermally insulating layer or sensor pad can comprise any suitable material such as polymer foam. It may be assumed that a value of the thermal resistivity of the material can be obtained from the manufacturer of the thermally insulating material. Alternatively it is relatively straightforward to determine this value, as will be known to the skilled person.

[0016] The evaluation unit preferably comprises a suitable interface that allows it to receive a signal from each thermistor. For example, a thermistor can be connected in the overall circuit to deliver a voltage signal that is indicative of the temperature at the location of the thermistor. When the sensor is placed on the patient's skin, the temperature of the thermistors will alter in response to the heat flow through the sensor pad. To interpret the incoming information, the evaluation unit preferably comprises a suitable processing unit. The processing unit can be a microprocessor with a number of suitable interfaces, and can be realized to perform any necessary computations in order to determine an equilibrium temperature condition of the sensor. Such an equilibrium condition is attained when each thermistor reports a stable value over time.

[0017] For example, the processing unit can continuously compare the thermistor input signals, and when each of these has remained essentially constant or unchanging for an appropriate length of time (e.g. a few seconds), the processing unit can assume that a first equilibrium temperature has been reached. At this point, the processing unit can record a first temperature value for the inner thermistor and a first temperature value for the outer thermistor, and then subsequently activates the heating means.

[0018] The heating means could be realized as a wire loop embedded in the sensor pad. This could be heated from an external source, for example by passing a current through the wire. Instead of a resistive wire loop, one or more resistors can be implemented in the sensor pad to achieve the desired heating function. In a particularly preferred embodiment of the invention, the outer thermistor itself is used to raise the temperature of the sensor at the outer region, using the fact that a thermistor is essentially a resistive component. This advantageous realization eliminates the need for a separate heating element. In that preferred embodiment of the invention, a current is passed through the thermistor to raise its temperature. To this end, the heating means of the inventive single heat flux sensor arrangement comprises a current source.

[0019] The evaluation unit is preferably realized to activate the heating means in response to a first equilibrium temperature condition of the sensor, for example by issuing a trigger signal to the current source. As long as the heating means is active, the processing unit continues to compare the thermistor input signals, and when these have been essentially equal for an appropriate length of time (e.g. a few seconds), the processing unit can assume that a second thermal equilibrium condition has been reached. At this point, the processing unit can record a second temperature value for the inner thermistor and a second temperature value for the outer thermistor.

[0020] With the information collected by the evaluation unit, namely the first and second temperature values for each thermistor, and the known thermal resistivity value of the sensor pad insulating material, it is possible to calculate the skin thermal resistivity. This then allows the evaluation unit to calculate a more precise core body temperature during the subsequent temperature monitoring procedure. The method stages and the relevant mathematical equations will be explained in more detail with the aid of the diagrams.

[0021] After the second equilibrium condition has been determined, the heating means can be turned off. Alternatively, in a further preferred embodiment of the invention, the heating source is not switched off after reaching the second thermal equilibrium but remains turned on. In this embodiment, the level of heating is chosen to essentially minimize the thermal flux through the sensor pad. The resulting state resembles that of zero heat flux. In that state, the fraction that must be added to (or subtracted from) the temperature measured by the first thermistor to obtain the core temperature becomes small. The error associated with that fraction also becomes small.

[0022] Preferably, the inventive sensor arrangement is equipped with a suitable memory module that can record a temperature profile for the core body temperature of the patient. This can be displayed as visual feedback in a display unit, for example. In a further preferred embodiment of the invention, the sensor arrangement is realized as a wearable device, for example to be worn as a cuff on the patient's arm, or to be attached by an adhesive patch to the patient's chest, etc. The display unit could be an integral part of the wearable device. Alternatively or in addition, the sensor arrangement might be equipped with a wireless interface that can transmit core body temperate values, or an entire temperature profile, at intervals to a remote monitoring station.

[0023] The single flux sensor arrangement according to the invention can be in place on a patient throughout a perioperative period, as well as during transport of a patient to and from the operating room. It may also be useful for monitoring patients in a general hospital ward or in an intensive care unit.

[0024] Other objects and features of the present invention will become apparent from the following detailed descriptions considered in conjunction with the accompanying drawings. It is to be understood, however, that the drawings are designed solely for the purposes of illustration and not as a definition of the limits of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] FIG. **1** shows a block diagram of the single heat flow sensor according to the invention;

[0026] FIG. **2** shows a simplified diagram of an ideal single heat flux sensor;

[0027] FIG. **3**A illustrates a first stage in the method according to the invention;

[0028] FIG. **3**B illustrates a second stage in the method according to the invention;

[0029] FIG. **4** shows an embodiment of the single heat flow sensor according to the invention.

[0030] In the drawings, like numbers refer to like objects throughout. Objects in the diagrams are not necessarily drawn to scale.

DETAILED DESCRIPTION OF THE EMBODIMENTS

[0031] FIG. **1** shows an exemplary embodiment of the inventive single heat flow sensor arrangement **1**. The sensor arrangement **1** comprises a sensor **10**, which mainly consists of a thermal insulation layer **100** or pad **100**. The pad **100** is applied to the skin **2** of a patient, and the sensor arrangement **1** will be used to determine the patient's core body temperature.

[0032] The sensor **10** has an inner thermistor S**1** arranged at or close to an inner surface of the pad **100**, and an outer thermistor S**2** arranged at or close to an outer surface of the pad **100**. An evaluation unit **11** is electrically connected to the thermistors and can evaluate the electrical signals that it receives in order to determine a temperature T**1** at the inner region of the pad **100** and a temperature T**2** at the outer region of the pad **100**. To this end, the evaluation unit **11** can comprise a suitable microprocessor, FPGA, etc.

[0033] In this exemplary embodiment, the single heat flow sensor **1** has a memory module **111** for recording a temperature profile, and is also equipped with a transmitter **112** for sending a temperature profile and/or recorded temperature measurements to a remote monitoring station. The diagram also indicates that the single heat flow sensor **1** can be connected to or equipped with a display unit **113** (for example in the manner of a smart watch) for showing a temperature profile to a user, for example the patient or a caregiver.

[0034] The inventive sensor arrangement **1** has a heating means **12** realized to raise the temperature of the outer thermistor S**2**. In this exemplary embodiment, the heating means **12** is a current source **12**, and is controlled by the evaluation unit **11** to apply a current through the outer thermistor S**2** for a predefined duration. This allows additional information to be collected, so that the thermal resistivity of the skin **2** can be determined, as will be explained in the following.

[0035] FIG. **2** illustrates the principle of operation of a single heat flux sensor applied to the skin **2** of a person. This relatively simple sensor construction uses only two temperature sensors S**1**, S**2** separated by the layer of insulating material **100**. The heat flow I_{heat} through the skin **2** and through the sensor pad **100** will be the same, and can be expressed as

$$I_{heat} = \frac{T1 - T2}{R1} = \frac{T0 - T1}{R0} \tag{1}$$

where T**1** is the temperature at the inner sensor S**1**, T**2** is the temperature at the outer sensor S**2**, R**1** is the thermal resistivity of the insulating material **100**, and R**0** is the skin thermal resistivity. The thermal resistivity R**1** of the insulating material may be presumed to be known. An expression for the core body temperature can be obtained by re-arranging equation (1):

$$T0 = T1 + \frac{(T1 - T2)R0}{R1} \tag{2}$$

[0036] Equations (1) and (2) are based on the presumption that the material layers **2**, **100** are infinitely wide, so that the heat can be presumed to flow only in the vertical direction, as indicated by the arrows. In a practical application, there will also be a lateral heat flow component which will detract from the accuracy of the measurement results. Furthermore, only the thermal resistivity R**1** of the sensor pad is known, and the skin thermal resistivity R**0** must be estimated. This can significantly detract from the accuracy of the measurement results, since the skin thermal resistivity can vary depending on which part of the body the sensor is attached to, and values of skin thermal resistivity can vary significantly between people depending on various factors such as age, physiology, etc.

[0037] The inventive sensor can overcome this limitation of the conventional sensors by actually measuring the skin thermal resistivity. FIGS. **3**A and **3**B will be used to explain the stages of the method. Initially a thermistor of the sensor **10** may be assumed to have ambient or room temperature T_{room}. After attaching the sensor **10** to the skin **2**, heat flow from the patient's body will raise the temperature of the sensor pad **100**, so that the thermistors also report rising temperatures. A temperature profile P_x for one of the thermistors in the first stage of the method is shown in FIG. **3**A. Ultimately, the temperature of the thermistor will reach an equilibrium temperature T_{EQ1}. At this point, using equation (2) above, the core body temperature can be expressed as

$$T0 = T11 + \frac{(T11 - T21)R0}{R1} \tag{3}$$

where T**11** is the initial inner thermistor temperature value and T**21** is the initial outer thermistor temperature value. As explained above, R**1** is a known quantity, and T**11**, T**21** are measured values. The remaining unknowns are the skin thermal resistivity R**0** and the core body temperature T**0**.

[0038] In the second stage, the outer thermistor S**2** is heated for a brief duration by turning on the heating means at time t_{on} to apply a current through this thermistor S**2**. The heating arrangement can be controlled such that the temperature at the outer thermistor S**2** is only slightly raised, i.e. so that it will not be raised above core body temperature level. A new equilibrium temperature TEQ2 is reached after a while, as illustrated in FIG. **3**B. The thermistor temperatures are recorded and current is switched off at time t_{off}. Again, using equation (2) above, the core body temperature can be expressed as

$$T0 = T12 + \frac{(T12 - T22)R0}{R1} \quad (4)$$

where T**11** is the second inner thermistor temperature value; T**21** is the second outer thermistor temperature value T**21**. In this case also, R**1** is a known quantity; T**11**, T**21** are measured values, and the remaining unknowns are the skin resistivity R**0** and the core body temperature T**0**. By reversing the thermal flux, T**22** will be higher than T**12**, so that equation (4) describes a core temperature value that is lower than T**12**.

[0039] The inventive method allows the skin thermal resistivity R**0** to be expressed in terms of the measured quantities, by equating equations (3) and (4) above and solving for skin thermal resistivity R**0** to give:

$$R0 = \frac{T12 - T11}{T11 - T21 + T22 - T12} \cdot R1 \quad (5)$$

[0040] Instead of assuming that the patient's skin resistivity is the same as an average value, the patient's skin resistivity R**0** has been measured to a satisfactory degree of accuracy and is now patient-specific as well as location-specific. This allows equation (2) to be used throughout the temperature monitoring procedure to accurately report the patient's core body temperature. In this way, the core body temperature of the patient can be accurately estimated in an entirely non-invasive manner.

[0041] FIG. **4** shows the inventive single heat flow sensor **1** realized as a wearable device **1**, and indicates two of several possible locations, namely on the chest or around the arm. In each case, the sensor pad has been attached to the skin **2** of a patient **3**. A visual readout of the patient's core body temperature T**0**, as computed using the method explained above, can be shown as a temperature profile P_3. The wearable device might include a small display so that the patient or caregiver can observe the core body temperature development. Alternatively, the wearable device can send the information to a remote monitoring station **4** where the temperature profile P_3 may be shown on a display.

[0042] Although the present invention has been disclosed in the form of preferred embodiments and variations thereon, it will be understood that numerous additional modifications and variations could be made thereto without departing from the scope of the invention.

[0043] For the sake of clarity, it is to be understood that the use of "a" or "an" throughout this application does not exclude a plurality, and "comprising" does not exclude other steps or elements. The mention of a "unit" or a "module" does not preclude the use of more than one unit or module.

1. A single heat flux sensor arrangement for measuring a core body temperature of a subject, comprising:

a sensor comprising only two temperature sensors separated by a layer of thermally insulating material, wherein the sensor comprises an inner temperature sensor arranged at an inner region of the insulating layer and an outer temperature sensor arranged at an outer region of the insulating layer;

a heating means realized to deliberately raise the temperature in a region of the insulating layer; and

an evaluation unit adapted to receive a temperature input from the inner temperature, to receive a temperature input from the outer temperature, to calculate a value of thermal resistivity for that subject from the temperature values and the thermal resistivity of the insulating material according to

$$R0 = \frac{T12 - T11}{T11 - T21 + T22 - T12} \cdot R1$$

and to calculate the core body temperature of the subject on the basis of the calculated thermal resistivity.

2. A single heat flux sensor arrangement according to claim **1**, wherein the evaluation unit is realized to determine an equilibrium temperature condition of the sensor, wherein an equilibrium temperature condition is attained when each temperature sensor reports a stable value over time.

3. A single heat flux sensor arrangement according to claim **2**, wherein the evaluation unit is realized to activate the heating means in response to a first equilibrium temperature condition of the sensor.

4. A single heat flux sensor arrangement according to claim **2**, wherein the evaluation unit is realized to deactivate the heating means in response to a second equilibrium temperature condition of the sensor.

5. A single heat flux sensor arrangement according to claim **1**, wherein the heating means is realized to raise the temperature of the outer region of the insulating layer.

6. A single heat flux sensor arrangement according to claim **1**, wherein a temperature measurement means comprises a thermistor.

7. A single heat flux sensor arrangement according to claim **6**, wherein the heating means is realized to apply an electric current through the outer thermistor.

8. A single heat flux sensor arrangement according to claim **1**, wherein the heating means comprises a current source.

9. A single heat flux sensor arrangement according to claim **1**, comprising a memory module realized to record temperature-related data collected by the single heat flux sensor arrangement.

10. A single heat flux sensor arrangement according to claim **1**, realized as a wearable device.

11. A single heat flux sensor arrangement according claim **1**, comprising a display unit realized to display a temperature profile for the core body temperature of the subject.

12. A single heat flux sensor arrangement according to claim **1**, comprising a wireless interface for communication with a remote monitoring station.

13. A method of measuring a core body temperature of a subject, comprising the steps of:

attaching a single heat flux sensor arrangement according to claim **1** to the subject;

determining a first equilibrium temperature and subsequently activating the heating means to heat the outer region of the insulating layer of the sensor arrangement;

determining a second equilibrium temperature;

calculating a value of thermal resistivity for that subject;

calculating the core body temperature of the subject on the basis of the calculated thermal resistivity value and the equilibrium temperatures.

14. A method according to claim **13**, comprising a step of de-activating the heating means after determining the second equilibrium temperature.

15. A method according to claim **13**, wherein the single heat flux sensor arrangement is attached to the skin of a human subject, and a value of skin thermal resistivity is determined.

* * * * *

专利名称(译)	单热通量传感器配置		
公开(公告)号	US20190142280A1	公开(公告)日	2019-05-16
申请号	US16/300108	申请日	2017-05-18
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	BONGERS EDWIN GERARDUS JOHANNUS MARIA BLOM ANTONIUS HERMANUS MARIA		
发明人	BONGERS, EDWIN GERARDUS JOHANNUS MARIA BLOM, ANTONIUS HERMANUS MARIA		
IPC分类号	A61B5/01 A61B5/00 G01K13/00 G01K1/16		
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优先权	2016170086 2016-05-18 EP		
外部链接	Espacenet USPTO		

摘要(译)

本发明描述了一种单个热通量传感器装置（ 1 ），其包括传感器（ 10 ），其包括一层（ 100 ）的绝热材料，内部温度测量装置（ S ）布置在绝缘层的内部区域（ 100 ）和外部温度测量装置（ S 2 ）布置在绝缘层的外部区域（ 100 ）;评估单元（ 11 ），适用于接收来自内部 5 温度测量装置（ S 1 ）的温度输入并接收温度输入来自外部温度测量装置（ S 2 ）;并且实现加热装置（ 12 2 ），以有意地升高绝缘层区域的温度（ 100 ）。本发明进一步描述了测量受试者的核心体温（ T ）的非侵入性方法（ 3 ）。