Office de la Propriété Intellectuelle du Canada
Un organisme d'Industrie Canada

Canadian Intellectual Property Office
An agency of Industry Canada

CA 2538940 A1 2006/06/22

(21) 2 538 940

(12) DEMANDE DE BREVET CANADIEN
CANADIAN PATENT APPLICATION

(13) A1

(22) Date de dépôt/Filing Date: 2006/03/03

(41) Mise à la disp. pub./Open to Public Insp.: 2006/06/22

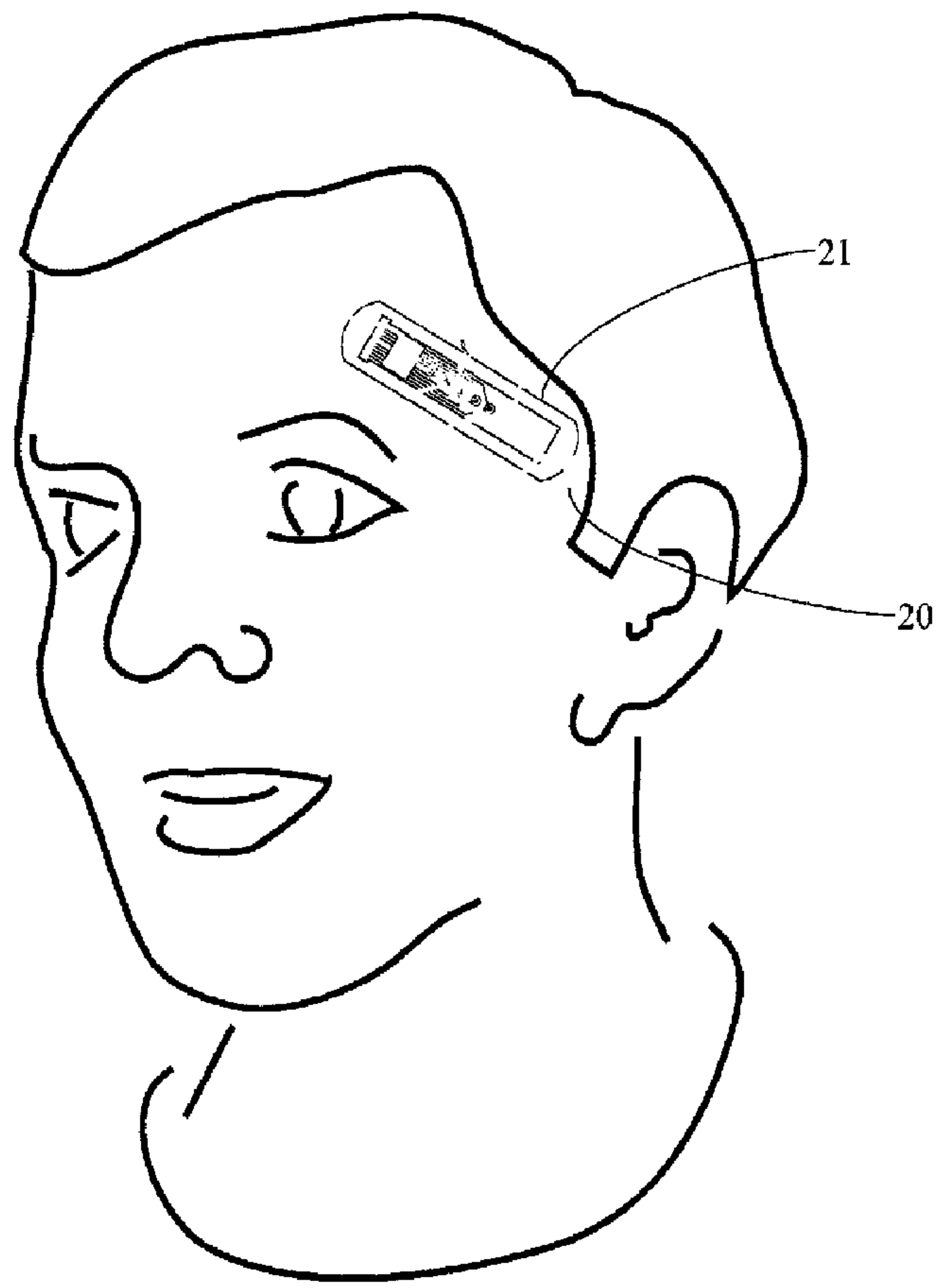
(51) Cl.Int./Int.Cl. *A61B 5/00* (2006.01), *A61B 5/01* (2006.01), *A61F 13/00* (2006.01), *A61F 13/02* (2006.01), *A61G 99/00* (2006.01)

(71) Demandeurs/Applicants:
HASLETT, JAMES W., CA;
FINVERS, IVARS, CA;
JULLIEN, GRAHAM A., CA

(72) Inventeurs/Inventors:
HASLETT, JAMES W., CA;
FINVERS, IVARS, CA;
JULLIEN, GRAHAM A., CA

(74) Agent: LAMBERT, ANTHONY R.

(54) Titre : PANSEMENT AVEC CAPTEURS
(54) Title: BANDAGE WITH SENSORS



(57) Abrégé/Abstract:
A bandage incorporates sensor arrays. The sensor arrays may measure temperature and are fixed to a person's temple in use, or other suitable body part. An estimate of core body temperature may be made using the arrays. The bandage may carry processing

(57) Abrégé(suite)/Abstract(continued):
electronics and a transmitter. Processing may be done on the bandage or remotely from the bandage. Other physiological parameters may be made depending on the type of sensor used.

ABSTRACT OF THE DISCLOSURE

A bandage incorporates sensor arrays. The sensor arrays may measure temperature and are fixed to a person's temple in use, or other suitable body part. An estimate of core body temperature may be made using the arrays. The bandage may carry processing electronics and a transmitter. Processing may be done on the bandage or remotely from the bandage. Other physiological parameters may be made depending on the type of sensor used.

BANDAGE WITH SENSORS

BACKGROUND OF THE INVENTION

[0001] Core body temperature is an important indicator of a person's health. Traditionally non-invasive measurement of body temperature is based on oral, rectal, tympanic (ear), or axial (armpit) thermometers. Typically these provide a single temperature measurement per use and are not used to provide long-term monitoring of a patient's temperature. More recently, clinical thermometers based on the measurement of skin temperature over the superficial temporal artery of the forehead have appeared. The current implementations of these thermometers are as hand-held wands that are manually scanned across the forehead region. For long term monitoring of body temperature a thermometer that is unobtrusive and can be left affixed to a patient is needed.

[0002] Temporal Artery Thermometers (TAT), as disclosed in U.S. Patent Numbers: 6,292,685; 6,499,877 B2; 6,932,775 B2, provide a non-invasive means of measuring a person's core body temperature by scanning a hand-held device with an integrated infrared temperature sensor across the superficial temporal artery on the forehead. The devices described in the above disclosures all use an infrared imager for the temperature sensor. This sensor must then be manually scanned across the forehead in order to obtain a temperature reading. As such these devices are not suited for long term monitoring of patient temperature. The methods disclosed all rely on estimating the core temperature using both a skin temperature measurement and the ambient temperature. For a bandage based thermometer, the ambient temperature may be a poor indicator of the local conditions at the bandage site (for example, if the patient's head in on a pillow), therefore the use of ambient temperature can lead to inaccurate core temperature estimates.

[0003] U.S. Patent Number 6,646,567 discloses a body temperature measurement system which provides a wireless link between the on-body temperature sensing device and a remote receiver. The device described uses a temperature probe in contact with the body whose temperature is to be measured. Since skin temperature alone is not a good indicator of core temperature, such a temperature measurement method fails to provide an accurate measurement of core body temperature when used in a bandage based temperature sensor application.

[0004] U.S. Patent Number 6,416,471 discloses a health parameter measurement system which comprises an on-body sensor band for measurement of the requisite health parameters, a wireless transmission link between the sensor band and a second on-body (or in close proximity) transceiver which retransmits the health parameter data over a second wireless link (or by a telecommunications link) to a remote monitoring station. This disclosure describes a system for wirelessly transmitting health parameter data but not the specifics of gathering that data.

[0005] U.S. Patent Number 6,929,611 discloses a head mounted body temperature measurement device, where the temperature sensor is held by a strap onto either the center of the forehead or the fontanel of an infant. This disclosure describes a method of estimating core temperature based on a single skin temperature measurement and a second environment temperature. The temperature sensor, however, is placed in the center of the forehead, which is not the optimal placement for estimating the core temperature. The temperature sensor is held in place using a strap or helmet, a much less comfortable method than a bandage.

[0006] U.S. Patent Number 6,890,096 discloses a body temperature measuring device that uses a single skin temperature measurement along with a heat flux sensor to estimate body temperature. The disclosed method is focused on reducing the time needed until a valid temperature reading is obtained once the temperature probe comes in contact with the skin. Since the bandage based thermometer is in-place for long periods of time, thermal equilibrium is reached soon after the initial attachment and thereafter no special techniques are needed to improve temporal response.

SUMMARY OF THE INVENTION

[0007] The described invention improves upon the prior state of the art in several ways. In one aspect of the invention, a device is provided to estimate the core body temperature based on multiple temperature measurements made in the temple region of the forehead without the need to manually scan the temperature sensor across this region. The core temperature may be estimated using only temperatures measured locally to the bandage. There is no need for an ambient temperature reading, thereby eliminating errors related to variation in heat flow out of the forehead due to specific environmental conditions of the space surrounding the forehead region. The temperature sensing device may be affixed to the forehead region as a small flexible bandage, eliminating the need for cumbersome straps or helmets. Only raw sensor data need be transmitted to the remote receiver, thereby minimizing the sensor module's power consumption.

[0008] According to one aspect of the invention, the device can be used for other measurements, and therefore there is also provided a measuring device, comprising: a bandage; an array of sensors attached to the bandage, the sensors of the array of sensors having exposed sensing surfaces; and the sensors of the array of sensors having an output.

[0009] According to a further aspect of the invention, there is provided a non-invasive means of estimating core body temperature using a multi-sensor thermometer that is constructed in a flexible bandage like form and affixed to the temple region of a patient's forehead.

[0010] In a further aspect of the invention, there is provided a system for measurement of core body temperature which consists of two parts: a device that is affixed to the forehead in the region of the temple, and a device to receive and process the sensor data transmitted wirelessly by the device affixed to the forehead.

[0011] According to an aspect of the invention, the device affixed to the temple region of the forehead is provided as a flexible bandage. The bandage includes two arrays of temperature sensors. The first array of temperature sensors is positioned on the bottom surface of the bandage and provides a set of measurements of temperature of the skin that is underneath each sensor. The second temperature sensor array is positioned towards the outer surface (away from the skin) of the bandage and is separated from the first temperature array by a layer of thermally insulating material. An electronic circuit is used to measure the output of each temperature sensor in each array. The sensor readings are then transmitted by wireless means to a remote receiver. A processor in the receiver converts the sensor readings into an equivalent temperature reading if this conversion is necessary and has not already been performed prior to the transmission of the data. The processor then chooses the sensor reading from the skin temperature sensing array which represents the highest skin temperature. For convenience, this reading will be designated as T_{skin}. The processor then chooses the sensor reading from the outer temperature sensor array which is in closest physical proximity to the sensor that provided T_{skin}, for convenience, this sensor reading is designated T_{outer}. The processor then estimates the core body temperature using the formula

$$T_{core} = T_{skin} + \alpha(T_{skin} - T_{outer}) \qquad (1.1)$$

where α represents an empirically determined parameter the value of which will depend on the thermal properties of the bandage.

[0012] For those skilled in the art, it is clear that the conversion of temperature sensor array measurements to an estimated core body temperature reading could equally well be performed in the device affixed to the forehead, in which case only the core temperature reading need be transmitted to the receiver. Equally, part of the conversion process could be performed in the device affixed to the forehead, and partially in the receiver.

[0013] The receiver can display the body temperature directly, as well as sending the information to other systems used to monitor and record patient medical information.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] There will now be described preferred embodiments of the invention, by reference to the figures by way of example, in which like numerals denote like elements, and in which:

[0015] Figure 1 shows a bandage thermometer positioned on the forehead in the temple region.

[0016] Figure 2 shows a bandage thermometer positioned on the forehead in the temple region along with the remote receiver.

[0017] Figure 3 shows an exploded view of one embodiment of the bandage thermometer.

[0018] Figure 4 shows an exploded view of the cross-sectional view of one embodiment of the bandage thermometer.

[0019] Figure 5 shows a cross-sectional view of one embodiment of the bandage thermometer.

[0020] Figure 6 shows a bottom view of one embodiment of the bandage thermometer.

[0021] Figure 7 shows one of the temperature sensor elements.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

[0022] In the claims, the word "comprising" is used in its inclusive sense and does not exclude other elements being present. The indefinite article "a" before a claim feature does not exclude more than one of the feature being present.

[0023] The bandage thermometer 21 is affixed to the forehead in the temple region. In this position, the bandage should overlay a portion of the superficial temporal artery 20 that lies just beneath the skin surface in this region. The bandage can be equally affixed to either the left or right temple region of a patient's forehead.

[0024] In order to estimate the core body temperature, the temperature of the skin (T_{skin}), which is preferably overlying a portion of the superficial temporal artery, is measured along with a second temperature (T_{outer}) that is used to subsequently estimate the heat flowing out of the skin in this region. By combining the two temperatures, the core body temperature can be estimated using:

$$T_{core} = T_{skin} + \alpha(T_{skin} - T_{outer}) \quad (1.2)$$

where T_{skin} preferably represents the temperature of the skin in a region in close proximity to the superficial temporal artery, T_{outer} the temperature of the outer temperature sensor which is in closest proximity to the skin temperature sensor which provided the T_{skin} measurement. The parameter, α, is an empirically determined coefficient which depends upon the physical construction and thermal characteristics of the bandage, and the physical location of the temporal artery relative to the bandage and the thermal characteristic of the tissue separating the artery from the temperature sensor. The physical and thermal characteristics of the bandage can be well controlled by its construction. The location of the artery and thermal characteristics of the overlying tissue will vary with each individual and with each particular placement of the bandage. Therefore α is best determined through the use of clinical trials using a specific implementation of the bandage.

[0025] In the preferred embodiment, multiple temperature sensors 8 are arrayed longitudinally along the bottom surface (the surface facing towards the skin) of the bandage. Although this specific embodiment shows an array of five sensors, a different number of sensors could be used. The trade-off is accuracy versus cost. Fewer sensors means that average distance between the temporal artery and the closest sensor will be increased, therefore reducing the accuracy of the body temperature estimation. More sensors increase cost. The sensors 8 are spaced approximately 10 mm apart. To extend the physical region of temperature sensing, each temperature sensor 30 is embedded within a disk 31 of material approximately 5 mm in diameter which possesses a high thermal conductivity. A flexible printed circuit board, is used to mount the sensors as well as to provide electrical connectivity between the sensors and the processor module 9. For clarity the flexible printed circuit board is shown in most figures as consisting of an upper 5 and lower 2 parts, but is constructed as a single unit which is then folded over. The processor module 9 contains the electronic circuitry necessary to provide a means of measuring the outputs of the temperature sensors, processing that information as necessary, and transmitting it by wireless 23 means to the remote receiver 22. Although shown in the diagrams as a single entity, the processor module 9 represents the grouping of individual components necessary to implement the sensor interface, data processing, and the wireless link. A thin layer of flexible material 1 is attached to the bottom surface of the flexible printed circuit board 2, and contains holes 7 through which the sensor elements protrude. The skin side of the material is covered with an adhesive which allows the bandage to be temporarily affixed to the skin. The combination of the slight protrusion of the sensor elements thorough the insulating layer, the use of the thermal conductive disk 31 to increase the surface area of the temperature sensor 30, and the adhesive properties of the bottom surface of the bandage helps ensure that the skin temperature sensors make good thermal contact with the skin, and therefore can provide an accurate measurement of the underlying skin temperature.

[0026] A second temperature sensor array 10, of similar construction to the skin temperature sensor array 8, is arranged towards the outer (away from the skin) surface of the bandage. In the preferred embodiment, the outer temperature sensor array is positioned such that the individual sensor elements of the second array 10 approximately overlay the corresponding sensor elements in the first array 8, but are separated from the first array elements by an intervening layer of material composed of two layers 3 and 4 for ease of construction. This intervening layer would typically be composed of insulating material so that a reasonable temperature difference can be measured between the first and second temperature array sensors under normal ambient conditions.

[0027] The second temperature sensor array 10 is attached to the same flexible printed circuit board 5 and 2 as the first array 8. The flexible printed circuit board is folded over so that the sensor elements of the first and second array are aligned with each other. A composition of insulating material is sandwiched between the two sensor arrays. This composition consists of two layers for ease of construction. The bottom layer 3 contains a hole to allow the folded flexible printed circuit board to pass through, and possibly a second cavity 15 to provide enough room for the processor module 9 to fit. The bottom layer ensures that the second array of sensor elements are separated from the first sensor array by a layer with well-controlled thermal properties. The upper layer 4 contains holes 14 for both the flexible printed circuit board and the processor 16, along with holes 11 for each of the temperature sensor elements of the second sensor array 10. The flexible printed circuit board also provides the electrical connectivity 12 between the sensor arrays 8 and 10 and the processor module 9 and any other components such as the battery and the antenna used for the wireless link. The components processor module also mounted on the flexible printed circuit board.

[0028] The two temperature sensor arrays 8 and 10 plus the intervening material 3 and 4 allow the heat flow through the bandage to be to be estimated. It is this heat flow estimate that allows the core body temperature, as indicated by the temperature of the blood within the temporal artery, to be estimated from the skin temperature measurement. In most of the prior art, the heat flow out of the skin is estimated by measuring the ambient temperature of the surrounding environment. This provides a much less accurate estimate of the heat flow and one prone to error due to variation in the local environment immediately surround the site at which the skin temperature measurement is made.

[0029] In order to obtain the best estimate of the core body temperature, the skin temperature sensor with the highest temperature reading is chosen to represent the skin temperature T_{skin} since this should correspond to the location where the sensor is in closest proximity to the temporal artery. Once the appropriate skin temperature sensor has been selected, the outer temperature T_{outer} can be measured from the temperature sensor in the second temperature array which is in closest physical proximity to the selected skin temperature sensor. The heat flowing out of the skin can now be estimated using

$$q_{bandage} = h_{material}(T_{skin} - T_{outer}) \qquad (1.3)$$

where $h_{material}$ is the thermal coefficient of conductivity of the material between the two temperature sensors, including that of the flexible printed circuit board 2 and that of the thermal insulating material layer 3 and 4.

[0030] Once the heat flow out of the skin is known, the heat balance equation can be solved to estimate the temperature of the underlying artery and hence the core body temperature. The heat balance law states that the heat flowing out of the body must equal the heat lost through the bandage, or

$$q_{body} = h_{tissue}(T_{core} - T_{skin}) \qquad (1.4)$$

Combining equations (1.3) and (1.4) leads to the heat balance equation

$$h_{tissue}(T_{core} - T_{skin}) = h_{material}(T_{skin} - T_{outer}) \qquad (1.5)$$

which reduces to the equation for core temperature (1.1) if

$$\alpha = \frac{h_{material}}{h_{tissue}}. \qquad (1.6)$$

[0031] The thermal conductivity coefficient $h_{material}$ can be measured experimentally and depends on the particular bandage construction and the material used. The tissue coefficient $h_{material}$ can be estimated from generally known thermal coefficients of tissue and an estimate of the average artery location. Alternately, the overall coefficient α can be determined experimentally using clinical trials, which is the preferred method.

[0032] Once the core body temperature is estimated, it is transmitted by wireless means to a remote receiver for monitoring.

[0033] In an alternate embodiment, the processor module 9 on the bandage would simple collect the raw sensor measurements and transmit that data to the remote receiver 22. At the remote receiver, the raw data would be converted into a core body temperature estimate. By preforming the majority of the data in the receiver, the power consumption of the processor on the bandage can be reduced and more sophisticated processing of the data can be implemented (error screening, averaging, etc.).

[0034] In yet another embodiment, the processing of the raw sensor data can be distributed between the bandage and the remote receiver. This allows the overall power of the bandage to be minimized by optimizing the power consumed by data processing versus power consumed by the wireless link. The more data processing is performed on the bandage the fewer bytes of data need to be transmitted. The optimum split between in the processing performed on the bandage versus the receiver will depend on the characteristics of the specific implementation of the processor module and the wireless transmission scheme used.

[0035] In order to minimize power consumption of the electronic circuitry located on the bandage, it may be desirable to transmit by wireless means all of the raw temperature sensor measurements to the remote receiver. The selection of the maximum skin temperature and corresponding outer temperature and subsequent calculation of the core temperature can then be performed by the processor at the receiver. Since the receiver can be line powered, power consumption is not a concern.

[0036] The remote receiver can have a means of entering a patient's core body temperature that was measured by some alternate means. The processor used to calculate the core body temperature can then use the alternately measured body temperature to adjust the coefficient, α, in order to calibrate a particular bandage to the specific patient. If the calculation of the core body temperature is performed on the bandage, a bidirectional wireless link 23 and 24 can be used to upload the new value of α to the bandage, where it can be Stored in some form of non-volatile memory.

[0037] An array may have any shape, and may be linear, two dimensional or three dimensional. The inner array establishes a baseline. The outer array may have the same or a different shape as compared with the first array. Preferably, the baseline is the skin temperature, and for this it is preferred that the sensors be in thermal contact with the skin. The intervening material between the two arrays can be any suitable material or materials and may comprise several layers. A processor may include a transmitter and receiver. The bandage can be any shape.

[0038] Immaterial modifications may be made to the embodiments of the invention described here without departing from the invention.

What is claimed is:

1. A measuring device, comprising:

a bandage;

an array of sensors attached to the bandage, the sensors of the array of sensors having exposed sensing surfaces; and

the sensors of the array of sensors having a first sensor output.

2. The measuring device of claim 1further comprising a processor having the first sensor output as input, the processor being configured to estimate a value representative of a physiological characteristic from the first sensor output.

3. The measuring device of claim 1 or 2 in which the bandage has a sticking surface at least partly covered with adhesive, and the exposed sensing surfaces of the sensors are surrounded by the sticking surface of the bandage.

4. The measuring device of claim 1, 2 or 3 further comprising a second array of sensors separated from the first array of sensors by a layer, the second array of sensors having a second sensor output, and the processor being configured to estimate the value representative of a physiological characteristic taking into account the second sensor output.

5. The measuring device of claim 2, 3 or 4 in which the sensors are temperature sensors and physiological characteristic is temperature.

6. The measuring device of claim 4 or 5 in which the processor uses the first sensor output as a baseline, and estimates a correction to the baseline based on a function of the first sensor output and the second sensor output to yield an estimate of the physiological parameter.

7. The measuring device of claim 4, 5 or 6 in which the processor uses equation 12 to estimate temperature of a body.

8. The measuring device of any one of claims 1-7 applied to measurement of human body core temperature.

9. The measuring device of any one of claims 1-8 further comprising a transmitter attached to the bandage, and transmitter being connected to transmit signals received directly or indirectly from the sensors to a receiver.

10. The measuring device of any one of claims 2-9 in which the processor is remote from the bandage.

11. A device for the measurement of body temperature, comprising:

a first array of temperature sensors; and

a second array of temperature sensors separated from the first array by a layer of material; and

a means of determining the highest temperature measured by the first temperature sensor array, this temperature is referred to as T_{skin}, and a means of determining a temperature measured by the sensors of the second array which corresponds to the sensor in closest physical proximity to the first sensor array, this temperature is referred to as T_{outer}; and

a data processor to estimate the core body temperature (T_{core}) using the following formula

$$T_{core} = T_{skin} + \alpha(T_{skin} - T_{outer})$$

using the two selected temperatures (T_{skin} and T_{outer}), and a scaling factor α.

12. A device for the measurement of body temperature, comprising:

an array of temperature sensors in thermal contact with the skin; and

a second array of temperature sensors separated from the first array by a layer of material ;

an electronic circuit for converting the temperature sensor output signal into a digital representation;

an electronic circuit for wirelessly transmitting the digital representation of the sensor outputs to remote receiver;

a wireless receiver to receive the temperature sensor data; and

a data processor to select the sensor data which originates from the skin sensor which measures the highest temperature, this value represents T_{skin}, and then selects the data from the second array temperature sensor which is in closest physical proximity to the selected skin sensor, this value represents T_{outer}; and

a data processor to estimate the core body temperature (T_{core}) using the following formula

$$T_{core} = T_{skin} + \alpha(T_{skin} - T_{outer})$$

using the two selected temperatures (T_{skin} and T_{outer}), and a scaling factor α.

13. A device as in Claims 11 or 12, with a means of displaying the estimated core temperature.

14. A device as in Claims 11, 12 or 13, with a means of retransmitting, by wired or wireless means, the estimated core temperature to other patient information processing/gathering system.

15. A device as in Claims 11, 12, 13 or 14, where the temperature sensor portion of device and the associated processor are incorporated in a flexible carrier and affixed to the temple region of the forehead by means of an adhesive substance.

16. A device as in any one of Claims 1 to 5 where the individual temperature sensors are each in thermal contact with a disk of material of high thermal conductivity which increases the physical region for which the temperature sensor provides a measurement.

17. A device as in any one of Claims 1 to 6 where the temperature sensor array is a matrix of temperature sensors.

18. A device as in any one of Claims 1 to 7 where the coefficient, α, is adaptively adjusted to calibrate a particular device to the patient's core body temperature which has been measured by some other means.

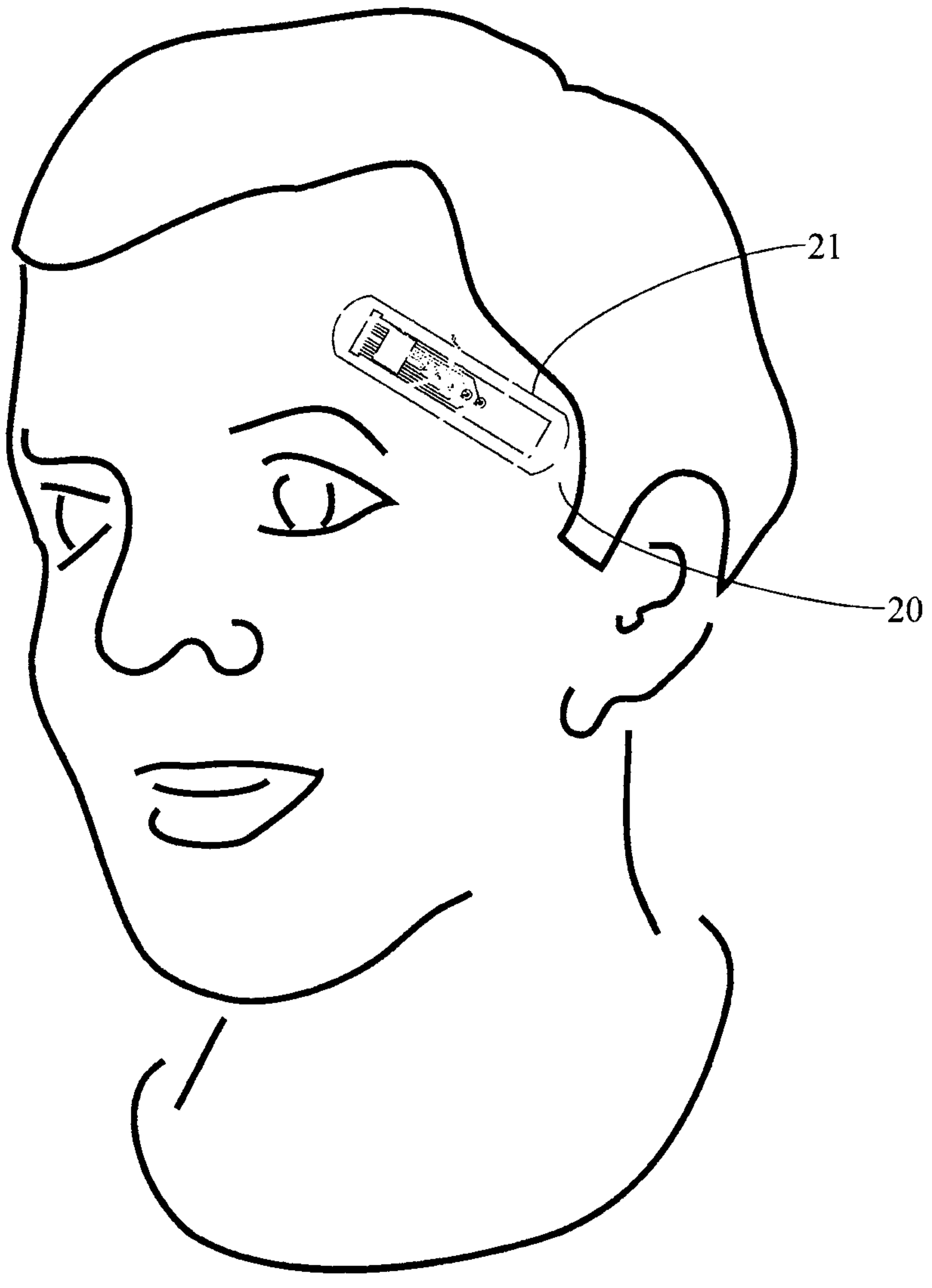


FIG. 1

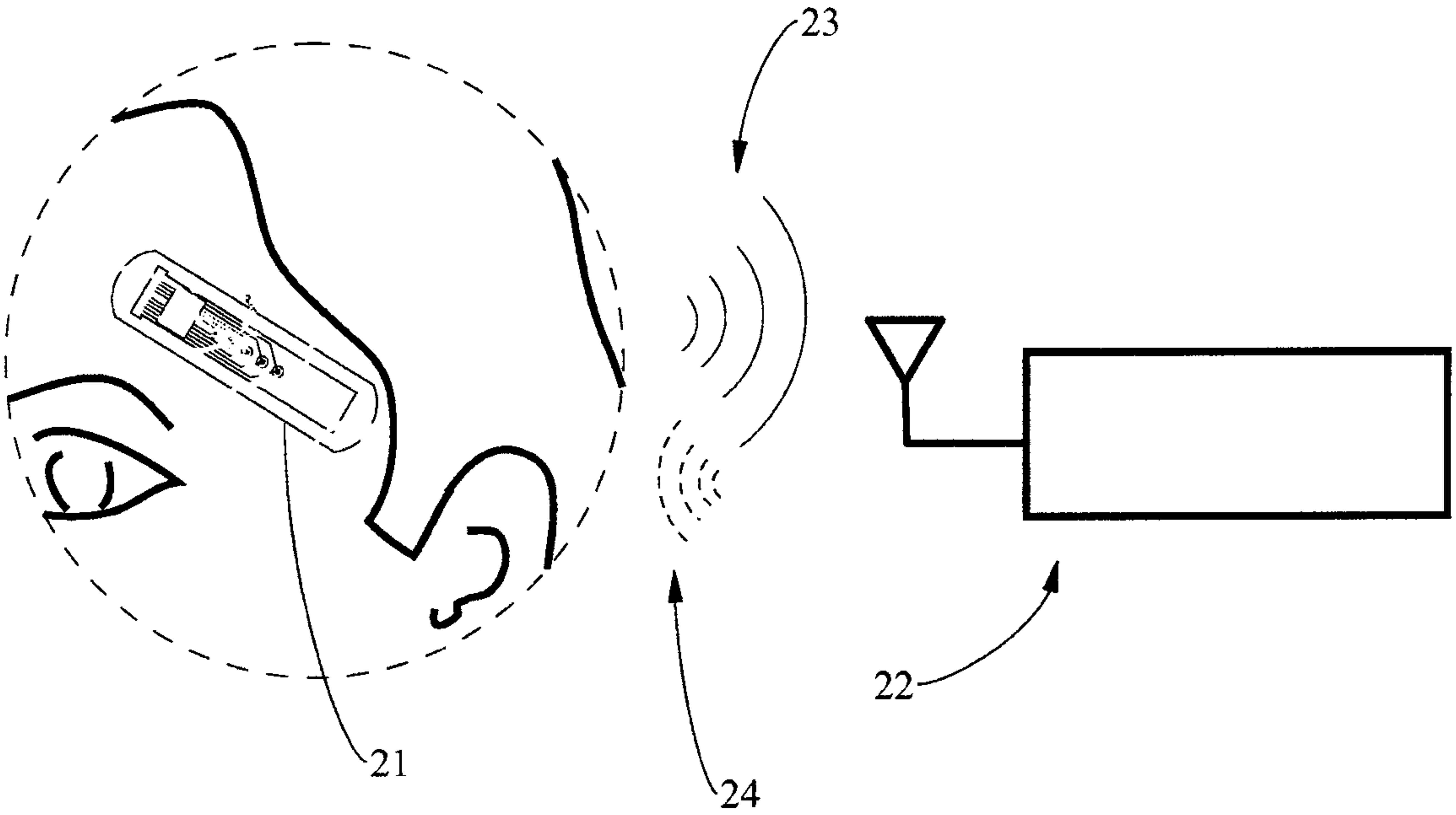


FIG. 2

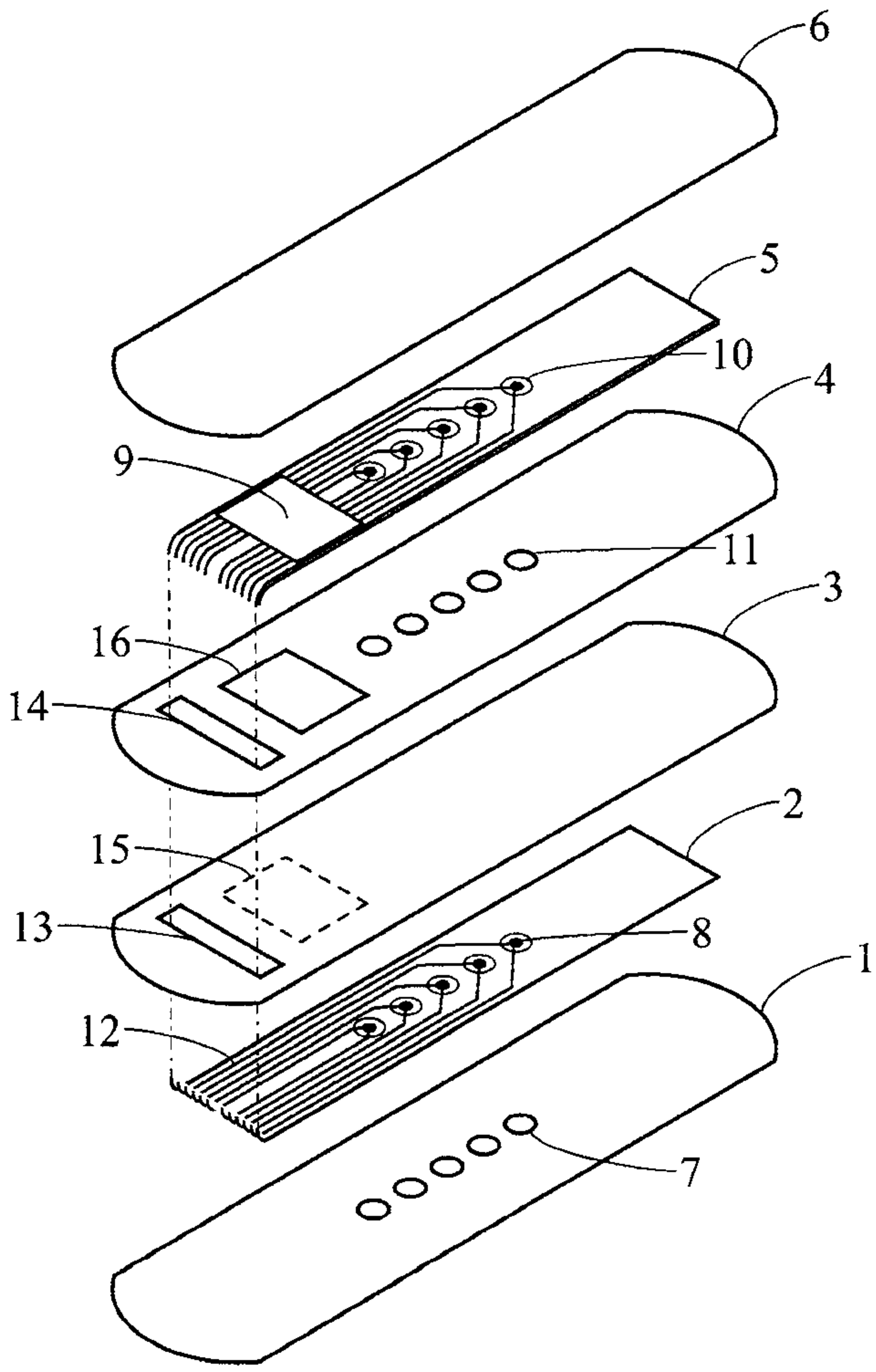


FIG. 3

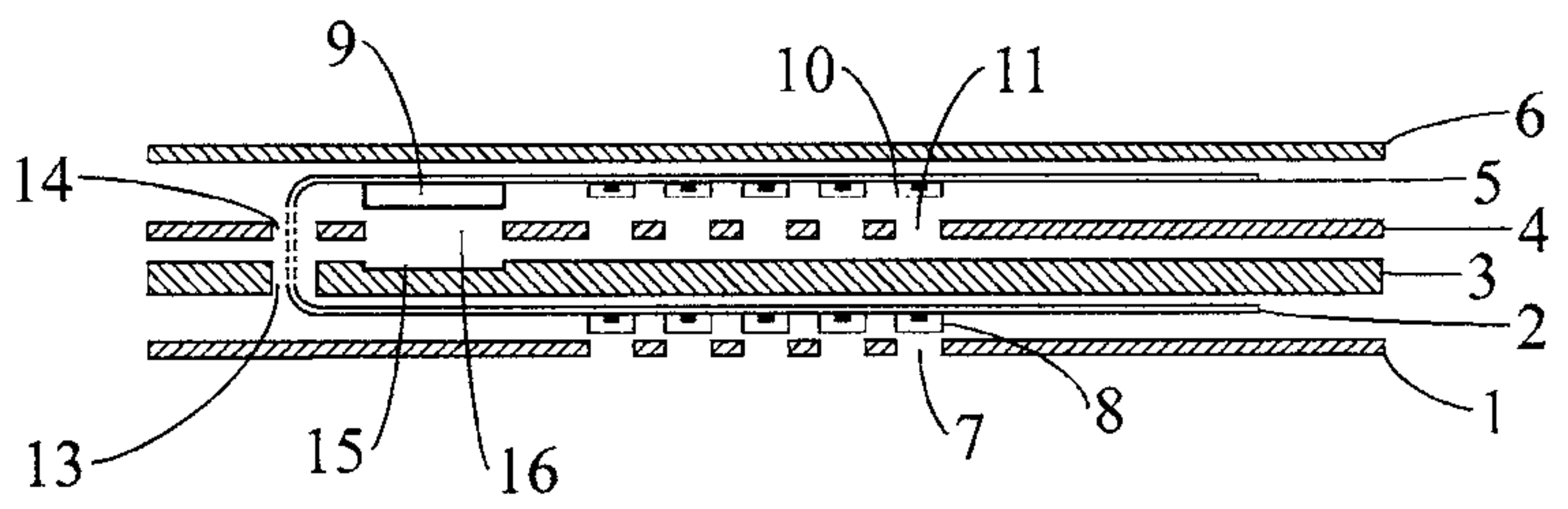


FIG. 4

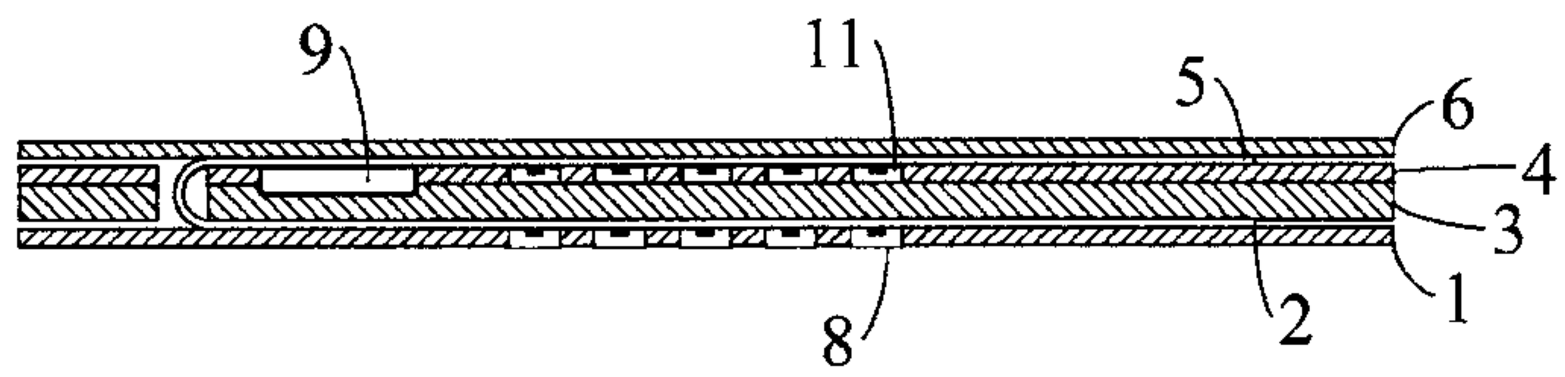


FIG. 5

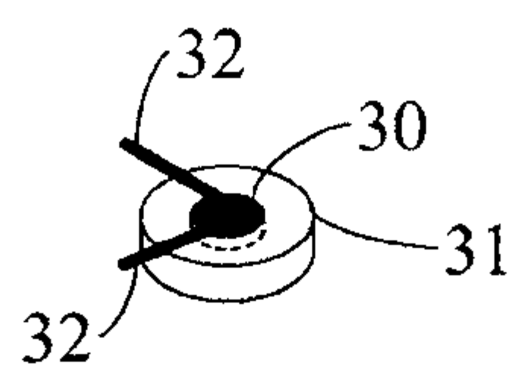


FIG. 7

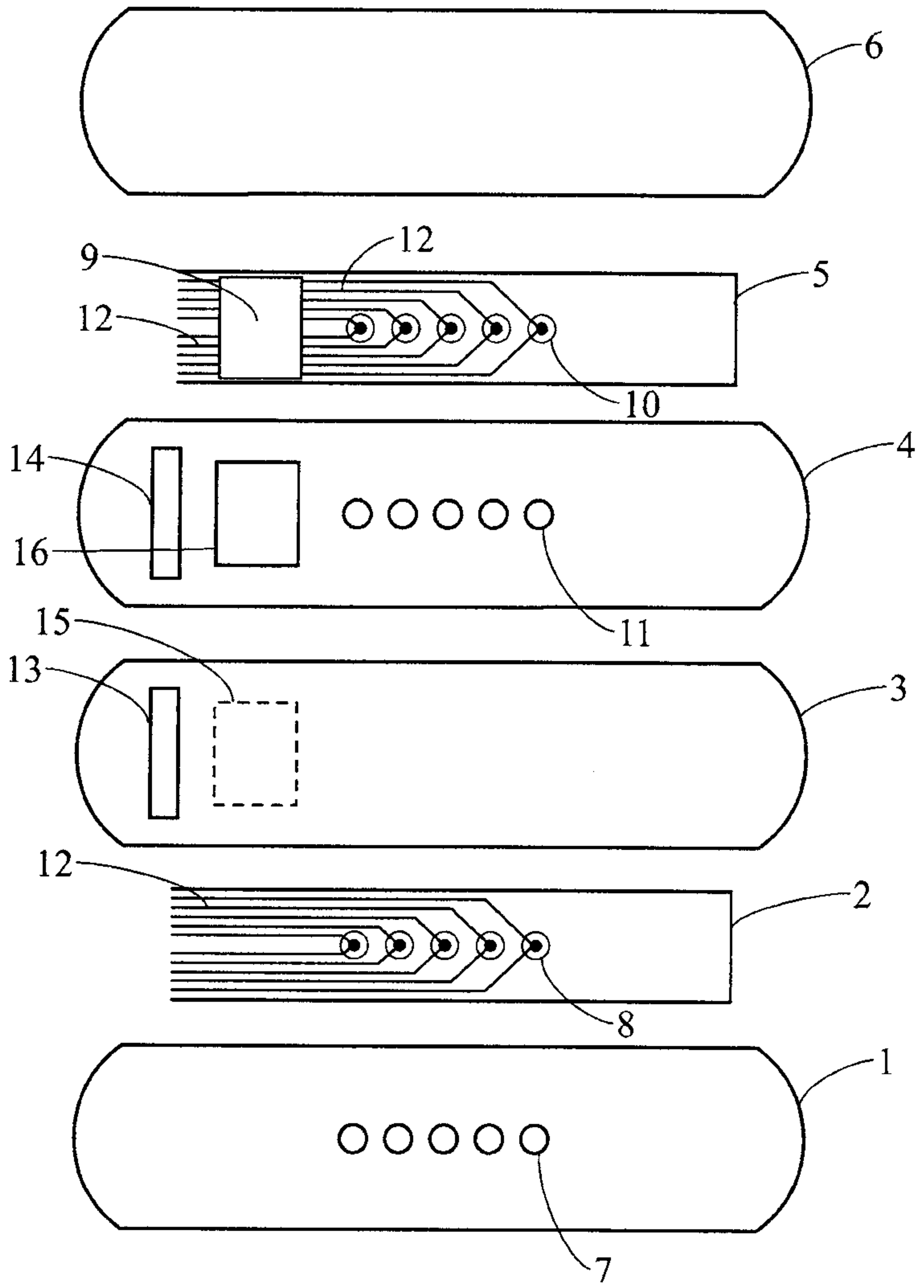
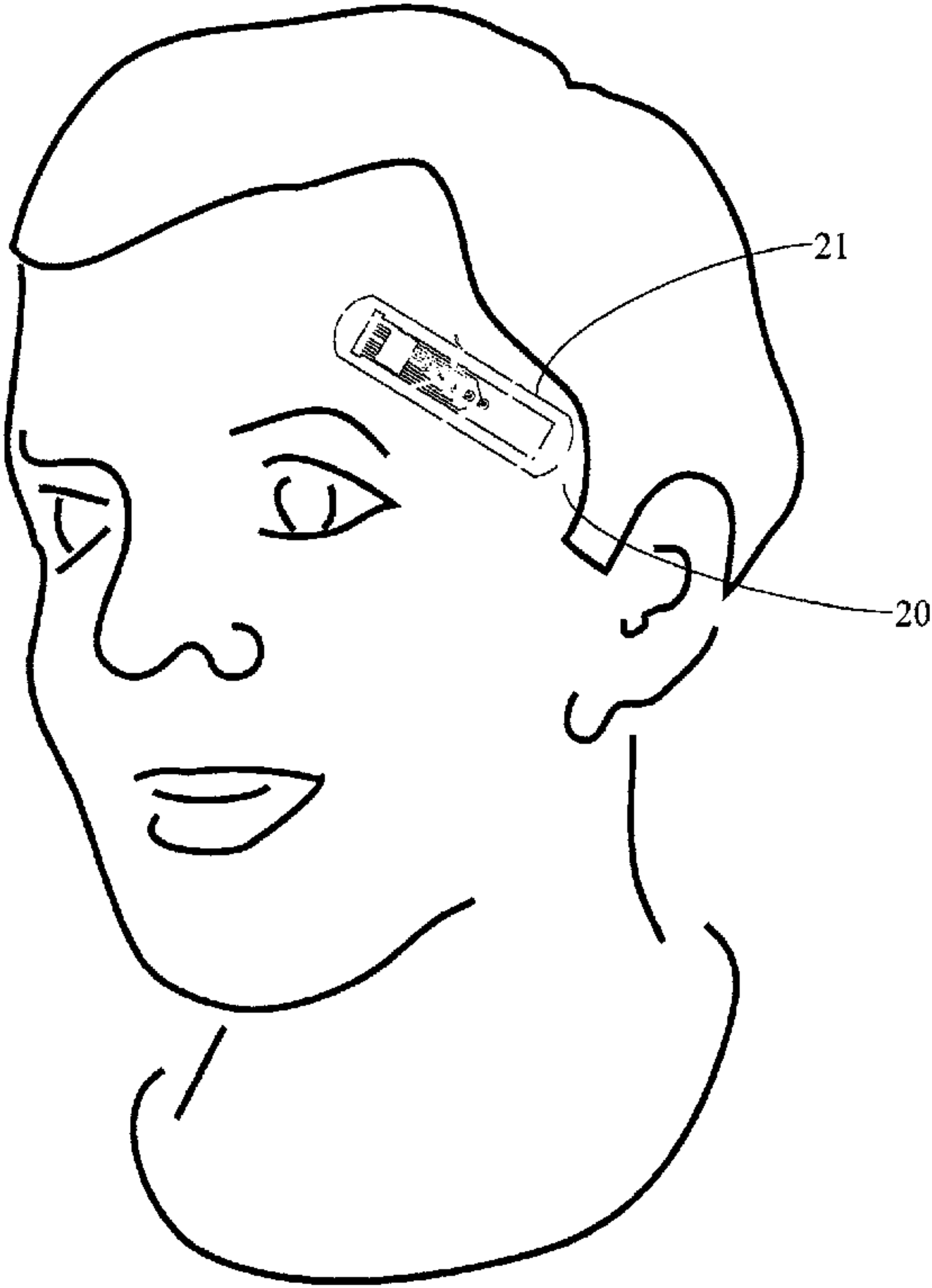


FIG. 6


21
20