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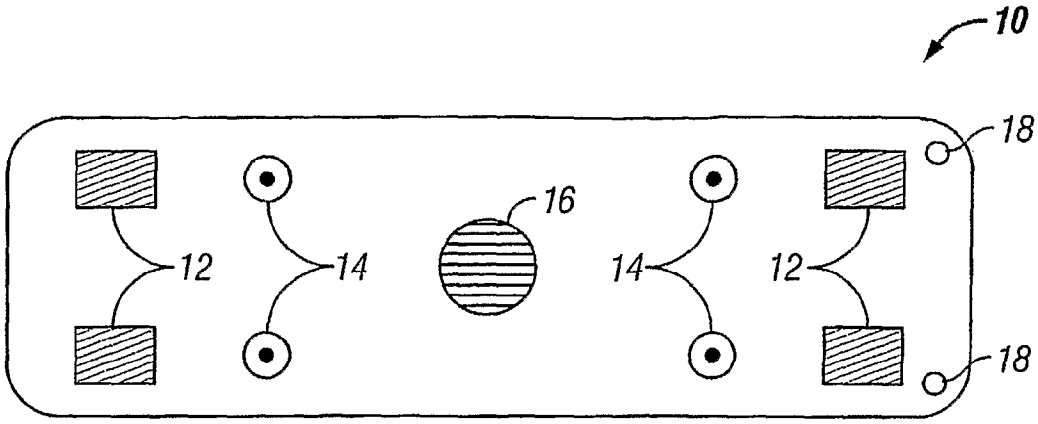
(54) Title: PORTABLE DEVICE FOR MONITORING ELECTROCARDIOGRAPHIC SIGNALS AND INDICES OF BLOOD FLOW



(57) Abstract: Embodiments of the present invention are directed to a physiological monitoring device which is configured to record signals that reflect blood flow and/or blood pressure, and which may also record ECG signals. In one embodiment, a portable monitoring device comprises a plurality of impedance electrodes configured to be coupled to a patient's body and to generate an AC current with an electrical field to detect local electrical impedance of a portion of the patient's body encompassed by the electrical field, the local electrical impedance being a surrogate measure of local blood flow of the portion of the patient's body. At least a portion of the portable monitoring device is configured to be insertable subcutaneously into the patient's body.

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PORTABLE DEVICE FOR MONITORING ELECTROCARDIOGRAPHIC SIGNALS AND INDICES OF BLOOD FLOW

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is based on and claims the benefit of U.S. Provisional Patent Application No. 60/569,551, filed May 10, 2004, the entire disclosure of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to diagnostic monitoring systems and, more particularly, to a portable diagnostic monitoring system for assessing cardiovascular hemodynamic state during the setting of a normal or abnormal heart rhythm. Advantageously, the monitoring system is capable of detecting abnormalities of blood pressure and/or flow.

[0003] Changes in cardiac output or blood pressure may be of value in diagnosis and management chronic and/or recurring disease states (e.g., congestive heart failure, hypertension, syncope). Currently, such measurements require invasive intravascular catheters with attached sensors (e.g., pressure, oxygen saturation) or an intra-arterial cannula.

[0004] Devices employing the technique of impedance plethysmography (commonly known as Impedance Cardiographs (ICG) when applied to the thorax) have been developed which are external to the body and can provide a surrogate marker of pulsatile blood volume changes and/or surrogate measure of blood flow by detection of changes in bioelectrical impedance (BEI). Typically, these devices use band or spot electrodes around the ends of the thorax and measure change in chest impedance due to altered vascular volumes corresponding to cardiac activity. Current is transmitted through the chest and seeks the path of least resistance, i.e., the blood filled aorta. With each heartbeat, the blood volume and velocity of the aorta change. Impedance plethysmography measures the corresponding change in impedance and calculates the hemodynamic parameters.

BRIEF SUMMARY OF THE INVENTION

[0005] The invention addresses the medical problem of evaluating the hemodynamic impact of a cardiac arrhythmia or suspected cardiac arrhythmia in free-living individuals. The objective may be accomplished by correlating electrocardiographic (ECG) recordings with surrogate measurements of blood pressure and/or blood flow obtained from a portable (wearable or insertable) cardiac monitor. In essence, for instances in which there is suspicion that heart rhythm disturbances are causing symptoms (e.g., dizziness, syncope, or weakness), the ability to correlate a documented arrhythmia with its hemodynamic effect will allow the physician to better assess the true impact of the arrhythmia on the patient. Additionally, some patients may exhibit hemodynamic disturbances (e.g., abrupt hypotension) without concomitant arrhythmia. Examples include certain vasodepressor faints in which the main problem is dilation of arterial blood vessels causing a fall in blood pressure, or in some individuals in association with movement from supine or seated to upright posture (e.g., orthostatic hypotension and/or orthostatic faints). In these conditions the heart rhythm may remain normal, or only relatively minor abnormalities are recorded and the heart rate may remain within the normal range; nonetheless, the blood pressure becomes abnormally low. Currently, these latter conditions are difficult to document in free-living individuals as they occur unpredictably over time, and at present there is no available portable monitor systems which can document both ECG and hemodynamic alterations over relatively long periods (e.g., weeks or months).

[0006] Embodiments of the present invention are directed to a physiological monitoring device which is configured to record signals that reflect blood flow and/or blood pressure, and which may also record ECG signals. In an exemplary embodiment, a portable diagnostic monitoring device is capable of detecting abnormal cardiac rhythms and assess their impact on blood flow, as well as detect abnormalities of blood flow that may or may not be associated with an abnormal heart rhythm. An example of clinical use is the evaluation of individuals experiencing syncope (faints) of unknown origin. The monitoring device may be worn on the body surface of the patient. A more practical embodiment of the monitoring device is of a sufficiently small size as to be insertable into the body of the patient using techniques essentially identical to placement of a conventional pacemaker generator. In the exemplary embodiment, intra-vascular access is not utilized, so that the system offers diagnostic capabilities without invading blood

vessels to insert sensors. In other embodiments, intravascular or extravascular leads may be used to enhance the diagnostic capability. In yet other embodiments, the monitoring device may be incorporated into a conventional pacemaker or implantable defibrillator (ICD) to enhance the diagnostic capability of those instruments.

[0007] In accordance with an aspect of the present invention, a portable monitoring device comprises a plurality of impedance electrodes configured to be coupled to a patient's body and to generate an AC current with an electrical field to detect local electrical impedance of a portion of the patient's body encompassed by the electrical field, the local electrical impedance being a surrogate measure of local blood flow of the portion of the patient's body. At least a portion of the portable monitoring device is configured to be insertable subcutaneously into the patient's body.

[0008] In some embodiments, the impedance electrodes are to be placed in close proximity to (e.g., within less than about 5 cm of) a target region of the patient's body to be monitored. The impedance electrodes are configured to detect local electrical impedance near an artery in the patient's body. The impedance electrodes include two electrodes that are spaced from one another in a direction generally parallel to or transversely across the artery. A temperature sensor may also be used in this device to aid in assessing local blood flow and/or monitoring for recurring disease states that may cause fever. The temperature sensor is configured to measure local tissue temperature of the patient's body near the temperature sensor. A plurality of ECG electrodes are configured to be coupled to the patient's body. A telemetry component is configured to communicate telemetrically with an external device. A warning component, which may be activated or deactivated by an external telemetry link, provides warning based on the detected information. The impedance electrodes are can-mounted surface electrodes. Auxiliary leads are coupled with the impedance electrodes.

[0009] In specific embodiments, a memory is configured to store physiological information obtained by detecting the local electrical impedance by the impedance electrodes. The memory is configured to store physiological data based on instructions delineating criteria for data to be stored. The memory has looping memory capability. The memory is configured to store data temporally proximate to an event based on information detected by the impedance electrodes or patient-activated triggering.

[0010] In accordance with another aspect of the present invention, a portable monitoring device comprises a plurality of impedance electrodes configured to be coupled to a patient's body and to generate an AC current with an electrical field to detect local electrical impedance of a portion of the patient's body encompassed by the electrical field; a plurality of ECG electrodes configured to be coupled to the patient's body; and a memory configured to store physiological information obtained by detecting the local electrical impedance by the impedance electrodes and by the ECG electrodes.

[0011] In some embodiments, the impedance electrodes and the ECG electrodes are can-mounted surface electrodes. Auxiliary leads may also be coupled with at least some of the impedance electrodes and the ECG electrodes.

[0012] In accordance with another aspect of the invention, a method of monitoring a patient comprises coupling a plurality of impedance electrodes to a patient's body to generate an AC current with an electrical field to detect local electrical impedance of a portion of the patient's body encompassed by the electrical field, the local electrical impedance being a surrogate measure of local blood flow of the portion of the patient's body; and inserting at least a portion of a portable monitoring device including the impedance electrodes subcutaneously into the patient's body.

[0013] In some embodiments, the impedance electrodes are placed in the vicinity (e.g., usually within less than about 5 cm) of a target region of the patient's body to be monitored (e.g., an artery such as the subclavian artery). The impedance electrodes may be applied to a muscle of the patient's body to be monitored. Two of the impedance electrodes may be positioned near an artery and spaced in a direction generally parallel to the artery. Local tissue temperature of the patient's body may also be measured. ECG data of the patient may also be measured. The method may further include transferring information obtained by the impedance electrodes and other sensors (e.g., temperature sensors, ECG electrodes) to an external device disposed outside the patient's body. A warning is generated based on the detected information using pre-determined criteria programmed into the device by the user (e.g., physician). The method further comprises storing physiological information obtained by detecting the local electrical impedance by the impedance electrodes. The information is stored based on instructions delineating criteria for data to be stored. The information is stored proximate to an event based on information detected by the impedance electrodes or patient-activated triggering.

[0014] In specific embodiments, the method further comprises coupling auxiliary leads to the impedance electrodes and positioning the auxiliary leads in a target location in the patient's body. The method may further comprise providing the impedance electrodes in an implantable diagnostic device.

[0015] A further configuration permits automatic telemetry of information to an external receiver/ transmitter for automatic transfer to a distant monitoring station such as by radiowaves, wireless telephony, or direct internet connection.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Fig. 1 is a plan view of a portable monitoring device according to an embodiment of the present invention.

[0017] Fig. 2 is an elevational view of the portable monitoring device of Fig. 1.

[0018] Figs. 3A-3D are simplified schematic views of the positioning of the impedance electrodes relative to an artery.

[0019] Fig. 4 is a simplified schematic view of a monitoring device incorporated in an implantable device such as a pacemaker or ICD.

[0020] Fig. 5 is a plan view of a portable monitoring device including leads according to another embodiment of the present invention.

[0021] Fig. 6 is a simplified schematic view of an external device for communicating with a monitoring device inserted into a patient.

DETAILED DESCRIPTION OF THE INVENTION

[0022] The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

[0023] Figs. 1 and 2 show a monitoring device 10 which includes a plurality of impedance electrodes 12, a plurality of ECG electrodes 14, a temperature sensor 16, and a plurality of suture ports 18. Figs. 1 and 2 show four impedance electrodes 12 that are spaced from each other and four ECG electrodes 14 that are spaced from each other, although fewer (e.g., two impedance electrodes and two ECG electrodes) or more

electrodes may be used in other embodiments. The use of four impedance electrodes 12 can eliminate electrode interface artifacts and the high electrode tissue impedance. The sensors and electrodes are depicted as protruding from the surface, but they may be flat. In the specific embodiment shown, the impedance electrodes 12, ECG electrodes 14, and temperature sensor 16 are built into the body or can of the monitoring device 10. The monitoring device 10 is desirably a stand-alone, self-powered device with a battery 20, which may be rechargeable. There is no need for intra-cardiac electrodes, although the addition of intra- or extra-cardiac electrodes may be employed to enhance the diagnostic capabilities in alternative embodiments. The monitoring device 10 is compact, typically less than half the size of a conventional modern pacemaker. It is designed to collect, store, and transmits surrogate blood pressure and/or flow data as well as ECG data. Various embodiments may include all or some of the sensors and electrodes depicted.

[0024] The impedance electrodes 12 are configured to transmit electrical signals and/or measure the resulting local electrical impedance as it is determined by the signals passing through tissue and/or blood vessels in the vicinity of the impedance electrodes 12, as encompassed by an electrical field of an AC current generated by the impedance electrodes 12. More particularly, the impedance electrodes 12 can measure surrogates of the local blood flow characteristics (e.g., blood flow volume or velocity) of the local tissue zone and, more precisely, the pulsatile blood volume change in the muscle in the local tissue zone being sampled. The impedance electrodes 12 generate an AC current with an electrical field that encompasses the local tissue zone being sampled to measure voltage drop therebetween. The voltage drop depends on the impedance corresponding to the pulsation of blood. The blood flow oscillates over time, and intermittently changes the impedance over time. For instance, the impedance may represent the relative magnitudes of blood flow (increasing or decreasing), or may be a relative measure of the blood flow (volume and/or velocity) with respect to an earlier time. The local impedance change is expected to be proportional to changes in the pulsatile blood volume change in the muscle in the tissue zone being sampled. A minimum of two impedance electrodes 12 are used. Additional impedance electrodes 12 allow different impedance or voltage drop vectors to be generated to provide a better chance of detecting changes in the blood flow characteristics.

[0025] In some embodiments, the impedance electrodes 12 are configured to be disposed near the artery or arteries being monitored, typically separated by less than about

5 cm, more desirably about 3-4 cm. The distance depends on the strength of the electrical field of the AC current being generated, and can increase with an increase in the strength of the electrical field. The artery 30 may be disposed generally parallel to the spacing between two impedance electrodes (e.g., Fig. 3A); the impedance electrodes may be disposed generally transversely across the artery on opposite sides thereof (e.g., Fig. 3B); or the impedance electrodes may be disposed at an angle relative to the artery (e.g., Figs. 3C or 3D). Measurement using the transverse arrangement may be less effective than using the longitudinal or parallel arrangement, since blood resistivity changes with flow, and decreases in the longitudinal direction and increases in the transverse direction due to the lining up of the red cells. The impedance electrodes are described as extra-vascular sensors, but may be positioned within the vascular system (intra-vascular) in other embodiments.

[0026] It is noted, however, that the impedance electrodes 12 are configured to be applied over any target region on a patient's body for detecting a surrogate marker of pulsatile blood volume changes or blood flow. The target region may be the muscle of the body or some tissue region. In that case, the impedance electrodes 12 need not be placed in the vicinity of any arteries.

[0027] The temperature sensor 16 measures local tissue temperature which may be a surrogate marker for blood pressure and/or blood flow measurement. The sensor 16 can detect flow-related temperature differences. A sensitive recording system is preferably used. For instance, an abrupt local temperature change may reasonably be interpreted as being due to acute changes in local blood flow. Slow temperature changes may reflect environmental factors, or a fever, etc. Rapid temperature changes, albeit of a small magnitude, is most likely related to blood flow alterations.

[0028] The ECG electrodes 14 increase the clinical utility of the monitoring device 10 by recording one or more ECG lead vectors. The data collected by the ECG electrodes 14 may be used to correlate with the data collected by the impedance electrodes 12 and/or the temperature sensor16 to assist physicians in distinguishing whether cardiac arrhythmias are responsible for hypotensive symptoms or other mechanisms are at fault. Other sensor may be used to detect flow change utilizing, for example, laser Doppler techniques (photophethysmography) or local detection of hemoglobin by reflectance methods.

[0029] As seen in Fig. 2, the monitoring device 10 includes a processor 22 and a memory 24 for storing data collected by the electrodes and sensor. The monitoring device 10 may be programmed to collect and process data using the processor 22 and memory 24 as desired by the user and/or manufacturer. The memory 24 may store the data temporarily or permanent. The data may be transmitted to a remote site, such as a memory device worn by the patient or a server elsewhere, after data transfer by a telemetry link with the telemetry component 26. Information may be transmitted via the telemetry component 26 between the device 10 and an external system such as a central monitoring center. Data may be transmitted automatically or after telemetry instruction from an external user such as physician or nurse. The device 10 may be programmed to store all or some of the recorded data based upon downloaded instructions delineating criteria for data storage (e.g., outside upper or lower heart rate boundaries). A warning component 28 such as a buzzer or audible alert may be incorporated in order to warn the patient of an impending problem.

[0030] In specific embodiments, the monitoring device 10 is inserted into the body of the patient under the skin, more typically under the subcutaneous tissue. For example, the monitoring device 10 may be inserted subcutaneously under the collar bone to be disposed near the subclavian artery. If the monitoring device 10 is inserted to place the impedance electrodes 12 against the pectoralis muscles, a surrogate assessment of skeletal muscle blood flow will be the target to be monitored. An insertable monitoring device is more practical than a wearable one for long term use because it eliminates the need to attach electrodes or the like onto the external skin surface of the patient. In yet another embodiment, the monitoring device 10 may be incorporated into an implantable device such as a cardiac pacemaker, an implantable defibrillator (ICD), or the like to provide additional diagnostic or hemodynamic feedback capability (see, e.g., U.S. Patent No. 5,441,525). Fig. 4 shows a simplified schematic view of monitoring device components 50 as a part of an implantable device 60.

[0031] While Figs. 1 and 2 show can-mounted surface electrodes, lead-mounted electrodes may be used. Unipolar and/or bipolar signals can be detected. One or more ECG vectors can be provided by the positioning of electrodes on the can or header, or on auxiliary leads designed to be positioned in the extra-vascular tissues, or on intra-vascular or intra-cardiac electrodes. The leads and can may both be inserted under the skin, or either or both the leads and can may be mounted on the body surface.

[0032] Fig. 5 shows another monitoring device 110 having impedance electrodes 112, ECG electrodes 114, a temperature sensor 116, and suture ports 118. Additional leads 120 are provided for remote placement. These auxiliary extra-vascular tissue leads 120 are provided for any of the electrodes 12, 14 and temperature sensor 16 to place them in closer proximity with the desired target(s) to be monitored. A needle or the like can be used to guide the leads 120 and manipulate them subcutaneously to the desired locations. In alternative embodiments, the electrodes, sensors, and/or leads may be detachable rather than fixed to the body of the device.

[0033] In specific embodiments, the memory capability of the monitoring device 10 is "looping" (first in, first out) with programmable durations of the "loop" permitting the saving of information prior to automatic or patient-activated triggering of the recordings. Programmability will be such as to permit all or only a subset of detected signals to be stored for subsequent immediate or later transmission to the body surface of the patient, and ultimately to medical personnel for interpretation (e.g., by wireless telephony). For instance, the monitoring device 10 can be programmed to save data temporally proximate certain events (just before and just after), such as an abrupt substantial change in surrogate measures of blood flow (e.g., impedance or temperature).

[0034] The patient may be offered a custom-programmed hand-held PDA (personal digital assistant) or a similar external device 200, as illustrated in Fig. 6. In Fig. 6, the monitoring device is inserted under the skin 210 of the patient. The patient may use the external device 200 to instruct the implanted or inserted monitoring device 10 to collect and/or transmit data at such times as the patient feels appropriate (e.g., real-time records recorded during a symptom event or looped records saved by transmitted after symptoms). The monitoring device 10 may also be programmed to retain and transmit data automatically when certain predetermined physiological boundaries are exceeded (e.g., blood flow surrogate or heart rate above or below preset limits). Communication may be automatic or initiated by an external user such as a physician or nurse.

[0035] The monitoring device does not require intra-vascular access. For long-term (weeks or months) cardiac monitoring, this offers previously unavailable data, ease of use, and enhanced safety compared to intra-vascular applications. The result is the ability to assess, at least qualitatively, the hemodynamic impact of heart rhythm disturbances in free-living individuals. Similarly, the monitoring device offers the potential to document

heart rhythm and tissue blood flow surrogates (e.g., tissue impedance, temperature) during periods of hypotension of non-cardiac cause, thereby helping to assess the possibility of a cardiac and/or vascular cardiac etiology during diagnostic evaluation of patients. This portable diagnostic device is capable, without use of intra-cardiac electrodes, of diagnosing hemodynamic perturbations and ascertaining whether and to what degree they are caused by cardiac rhythm disturbances. At the same time, the device can be enhanced by adding non-vascular or intra-vascular leads for placing sensors at more distance sites in the body, or can be incorporated as a diagnostic element within a conventional cardiac pacemaker, ICD, or other implanted diagnostic instrument.

[0036] It is recognized that tissue blood flow may vary with respiration, posture, altered cardiac output, or changes in vascular tone. However, for patients in whom heart monitoring of the type discussed herein is selected (i.e., those with suspected arrhythmias or syncope), an abrupt substantial change in surrogate measures of blood flow may reasonably be expected to be due to an arrhythmia or other abrupt hypotensive state. Thus, detection of suspected flow alterations, along with ECG correlation, will assist physicians in distinguishing whether cardiac arrhythmias (i.e., abnormally slow or fast heart rates) are responsible for hypotensive symptoms or whether other mechanisms (e.g., vasodepressor hypotension without arrhythmia) are at fault. In many instances, hypotension occurs without evident arrhythmia. The present monitoring device is designed to detect this type of clinical problem in free-living individuals.

[0037] From the foregoing, it will be apparent to those skilled in the art that the present invention provides, in exemplary non-limiting embodiments, a wide variety of design options for the electrodes, sensors, leads, and the like for the monitoring device. Further, those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

WHAT IS CLAIMED IS:

1. A portable monitoring device comprising:

a plurality of impedance electrodes configured to be coupled to a patient's body and to generate an AC current with an electrical field to detect local electrical impedance of a portion of the patient's body encompassed by the electrical field, the local electrical impedance being a surrogate measure of local blood flow of the portion of the patient's body; and

wherein at least a portion of the portable monitoring device is configured to be insertable subcutaneously into the patient's body.

2. The portable monitoring device of claim 1 wherein the impedance electrodes are to be placed in proximity to a target region of the patient's body to be monitored.

3. The portable monitoring device of claim 2 wherein the impedance electrodes are to be placed within less than about 5 cm of the target region of the patient's body to be monitored.

4. The portable monitoring device of claim 1 wherein the impedance electrodes are configured to detect local electrical impedance near an artery in the patient's body.

5. The portable monitoring device of claim 4 wherein the impedance electrodes include two electrodes that are spaced from one another in a direction generally parallel to the artery.

6. The portable monitoring device of claim 4 wherein the impedance electrodes include two electrodes that are spaced from one another in a direction generally transversely across the artery.

7. The portable monitoring device of claim 1 further comprising a temperature sensor configured to measure local tissue temperature of the patient's body near the temperature sensor.

8. The portable monitoring device of claim 1 further comprising a plurality of ECG electrodes configured to be coupled to the patient's body.

9. The portable monitoring device of claim 1 further comprising a battery.

10. The portable monitoring device of claim 1 further comprising a telemetry component configured to communicate telemetrically with an external device.

11. The portable monitoring device of claim 1 further comprising a warning component to provide warning based on the detected information.

12. The portable monitoring device of claim 1 wherein the impedance electrodes are can-mounted surface electrodes.

13. The portable monitoring device of claim 12 further comprising auxiliary leads coupled with the impedance electrodes.

14. The portable monitoring device of claim 1 further comprising a memory configured to store physiological information obtained by detecting the local electrical impedance by the impedance electrodes.

15. The portable monitoring device of claim 14 wherein the memory is configured to store data based on instructions delineating criteria for data to be stored.

16. The portable monitoring device of claim 14 wherein the memory has looping memory capability.

17. The portable monitoring device of claim 14 wherein the memory is configured to store data temporally proximate to an event based on information detected by the impedance electrodes or patient-activated triggering.

18. A portable monitoring device comprising:

a plurality of impedance electrodes configured to be coupled to a patient's body and to generate an AC current with an electrical field to detect local electrical impedance of a portion of the patient's body encompassed by the electrical field; and

a plurality of ECG electrodes configured to be coupled to the patient's body.

19. The portable monitoring device of claim 18 further comprising a temperature sensor configured to measure local tissue temperature of the patient's body near the temperature sensor.

20. The portable monitoring device of claim 18 further comprising a telemetry component configured to communicate telemetrically with an external device.

21. The portable monitoring device of claim 18 wherein the impedance electrodes and the ECG electrodes are can-mounted surface electrodes.

22. The portable monitoring device of claim 21 further comprising auxiliary leads coupled with at least some of the impedance electrodes and the ECG electrodes.

23. A method of monitoring a patient, the method comprising:

coupling a plurality of impedance electrodes to a patient's body to generate an AC current with an electrical field to detect local electrical impedance of a portion of the patient's body encompassed by the electrical field, the local electrical impedance being a surrogate measure of local blood flow of the portion of the patient's body; and

inserting at least a portion of a portable monitoring device including the impedance electrodes subcutaneously into the patient's body.

24. The method of claim 23 wherein the impedance electrodes are placed in proximity to a target region of the patient's body to be monitored.

25. The method of claim 24 wherein the impedance electrodes are placed within less than about 5 cm of the target region of the patient's body to be monitored.

26. The method of claim 23 wherein the impedance electrodes are applied to a muscle of the patient's body to be monitored.

27. The method of claim 23 further comprising positioning two of the impedance electrodes near an artery and spacing the impedance electrodes in a direction generally parallel to the artery.

28. The method of claim 23 further comprising positioning two of the impedance electrodes near an artery and spacing the impedance electrodes in a direction generally transverse across the artery.

29. The method of claim 23 further comprising measuring local tissue temperature of the patient's body.

30. The method of claim 23 further comprising measuring ECG data of the patient.

31. The method of claim 23 further comprising transferring information obtained by the impedance electrodes to an external device disposed outside the patient's body.

32. The method of claim 23 further comprising generating a warning based on the detected information.

33. The method of claim 23 further comprising storing physiological information obtained by detecting the local electrical impedance by the impedance electrodes.

34. The method of claim 33 wherein the information is stored based on instructions delineating criteria for data to be stored.

35. The method of claim 33 wherein the information is stored proximate to an event based on information detected by the impedance electrodes or patient-activated triggering.

36. The method of claim 23 further comprising coupling auxiliary leads to the impedance electrodes and positioning the auxiliary leads in a target location in the patient's body.

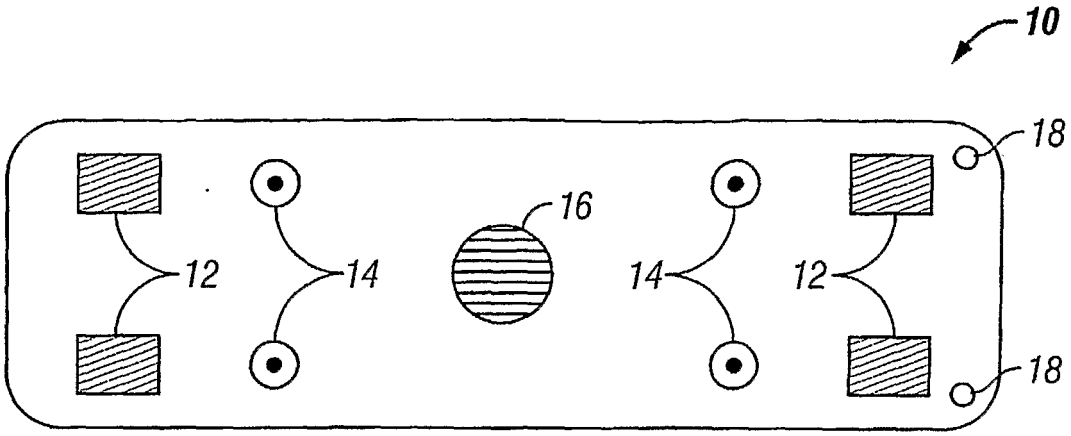
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FIG. 1

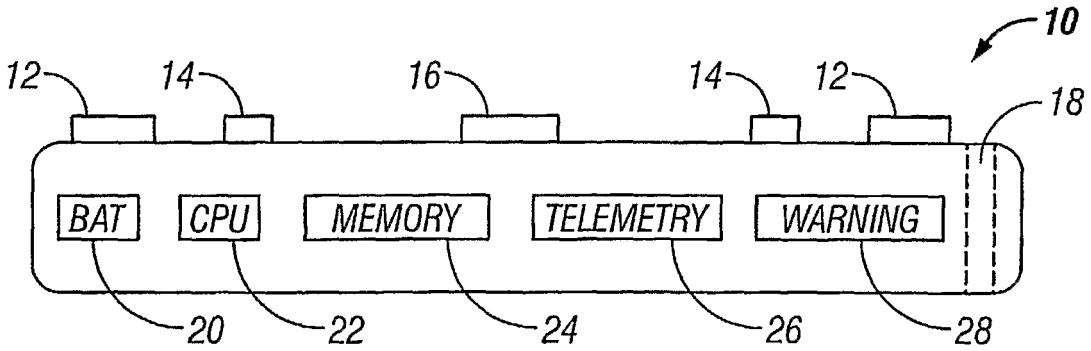
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FIG. 2

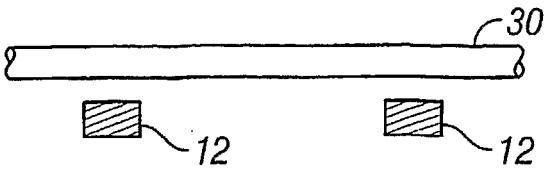

FIG. 3A

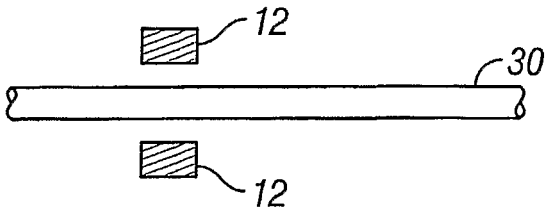

FIG. 3B

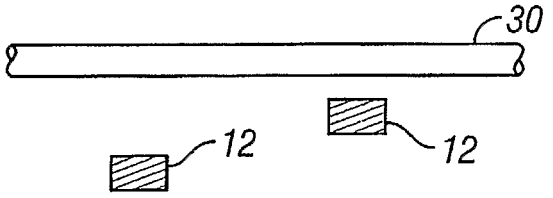

FIG. 3C

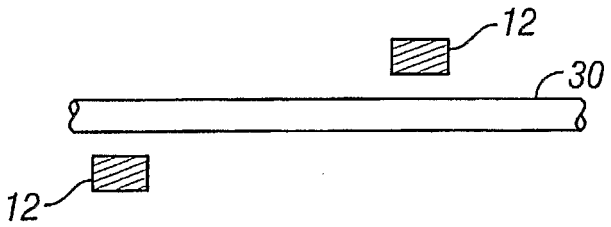

FIG. 3D

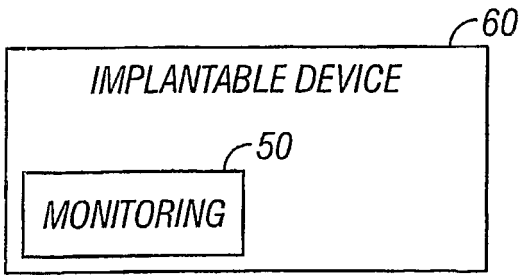

FIG. 4

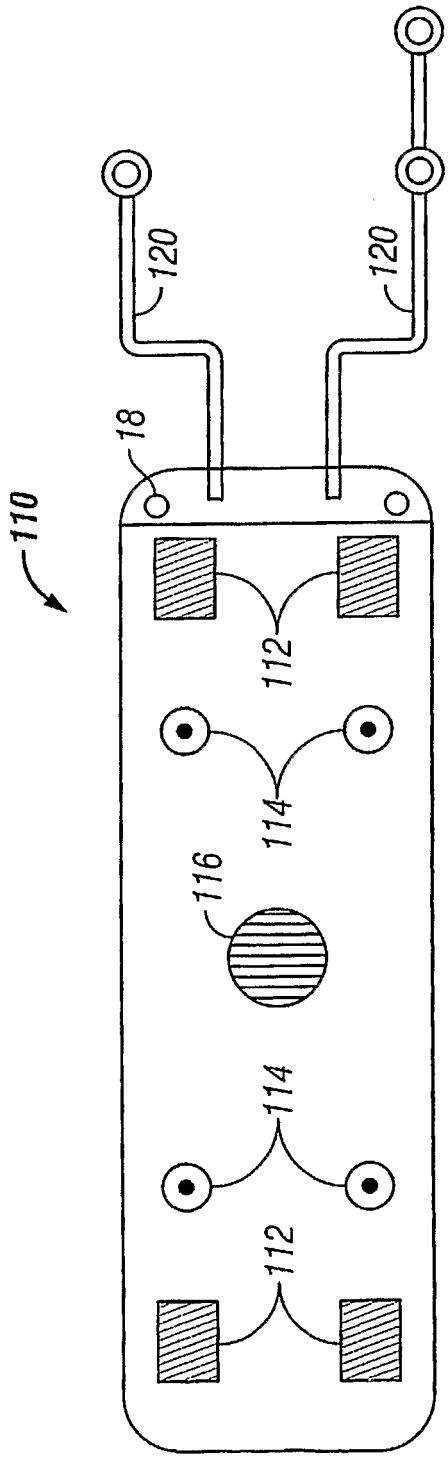

FIG. 5

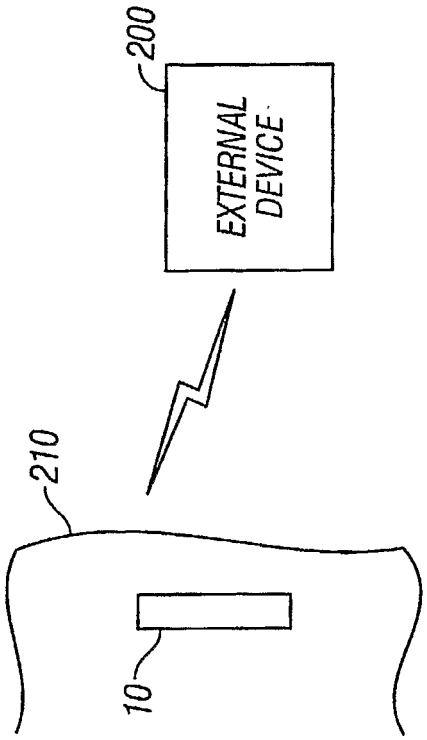

FIG. 6

专利名称(译)	用于监测心电图信号和血流指数的便携式设备		
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申请(专利权)人(译)	TRANSOMA MEDICAL，INC.		
当前申请(专利权)人(译)	明尼苏达大学校董会		
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摘要(译)

本发明的实施例涉及一种生理监测装置，其被配置为记录反映血流和/或血压的信号，并且还可以记录ECG信号。在一个实施例中，便携式监测设备包括多个阻抗电极，其被配置为耦合到患者身体并且利用电场产生AC电流以检测由电场包围的患者身体的一部分的局部电阻抗，局部电阻抗是患者身体部分局部血流的替代量度。便携式监测设备的至少一部分被配置为可皮下插入患者体内。