A pressure or force transducer (38) mounts to the headband and provides feedback on tension in the headband.

FIG. 4

FOREHEAD MOUNTED IMPEDANCE PLETHYSMOGRAPHY SYSTEM AND METHOD

Abstract: A system and method for determining changes in patient blood volume/flow are described. Electrodes are positioned on a patient's forehead and alternating current is passed through a first group of the plurality of electrodes (16a, 16d) into the patient's forehead. A voltage is detected at each of a second group of the plurality of electrodes (16c, 16b) and an impedance is calculated from the detected voltages and used to determine the patient's changes in blood volume or flow. A headband (12) having sense and drive electrodes mounted thereto is also disclosed. The sense electrodes are located between the drive electrodes and separated from one another by a distance greater than the separation between a sense electrode and an adjacent drive electrode. A pressure or force transducer (38) mounts to the headband and provides feedback on tension in the headband.
NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG,
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:
— as to applicant's entitlement to apply for and be granted a
patent (Rule 4.17(H))

Published:
— with international search report
FOREHEAD MOUNTED IMPEDANCE PLETHYSMOGRAPHY
SYSTEM AND METHOD

[001] This invention generally relates to systems and methods for determining changes in blood volume or flow from measurements of impedance, and more particularly, to determining changes in blood volume or flow from impedance measurements taken from the forehead of a patient.

[002] Impedance plethysmography is a non-invasive medical test that measures small changes in electrical resistance of the chest, calf or other regions of the body. These measurements reflect blood volume changes. This procedure provides an alternative to venography, which is invasive and requires a great deal of skill to execute adequately and interpret accurately. With impedance plethysmography, a number of electrodes need only be secured to the patient and changes in impedance measured.

[003] The current practice in impedance plethysmography is to secure the electrodes to the thorax or leg of the patient. Measurements taken in this manner are subject to artifacts due to patient movement. When cardiopulmonary resuscitation (CPR) is being administered, movement of the patient's chest is extensive and therefore impedance measurements do not adequately reflect actual blood flow, whether natural or the result of chest compressions. Placing electrodes on a patient's limbs is also impractical in emergency situations inasmuch as blood flow to the limbs is drastically reduced when a patient is in shock. Impedance measurements of a patient's limbs will therefore not accurately reflect blood perfusion induced by CPR, for example.

[004] Positioning electrodes on a patient's leg or thorax is also impractical in emergency situations inasmuch as four electrodes must be secured to the patient on opposite sides of the chest or leg. Each area to which an electrode is attached requires shaving and cleaning prior to adhesion. In addition, when the patient is being treated for cardiac arrest with a defibrillator, the defibrillator electrodes can impede or become entangled with the plethysmograph electrodes, which will in any event be a secondary consideration to the need for cardiac resuscitation. These considerations make the
current plethysmography practice impractical in emergency situations when time is critical.

[005] In view of the foregoing it would be advantageous to provide a system and method for accurately measuring blood perfusion using impedance plethysmography that is suitable for use in medical emergencies such as sudden cardiac arrest.

[006] In accordance with the principles of the present invention an apparatus is provided for determining blood volume changes in a patient. The apparatus includes a plurality of electrodes adapted to be secured to a patient's forehead. The apparatus further includes a signal driving circuit, a sensing circuit, and a processor. The signal driving circuit is coupled to at least one of the electrodes and is configured to drive an alternating signal to the patient's forehead. The sensing circuit is coupled to at least one other of the electrodes and is configured to sense from the patient's forehead electrical signals resulting from the alternating signal. The processor is coupled to the signal driving circuit and the sensing circuit and is configured to calculate impedance from the alternating signal and electrical signals sensed from the patient's forehead to determine changes in blood volume.

[007] In another aspect of the invention a plurality of electrodes are positioned on a patient's forehead. Alternating current is passed through a first group of the plurality of electrodes into the patient's forehead. A voltage is detected at each of a second group of the plurality of electrodes. The patient's change in blood volume is then measured by processing the detected voltage.

[008] In accordance with a further aspect of the present invention the first group includes first and second drive electrodes and the second group includes first and second sense electrodes located between the first and second drive electrodes. The first sense electrode is closer to the first drive electrode than to the second sense electrode.

[009] In accordance with yet another aspect of the present invention, the electrodes are mounted to a headband comprising a pressure transducer and/or force sensor and a visual indicator. A visual indication is outputted when the pressure and/or force indicated by the respective transducer falls within a range of values corresponding to
tension in the headband suitable for maintaining the electrodes in contact with the patient's forehead while not overly restricting blood flow.

[010] In the drawings:

[011] Figure 1 is an illustration of a patient wearing a headband suitable for measuring a patient's heart rate in accordance with an embodiment of the present invention.

[012] Figure 2 is a top plan view of a headband suitable for measuring a patient's blood perfusion in accordance with an embodiment of the present invention.

[013] Figure 3 is a schematic block diagram of a system for determining a patient's blood perfusion using the headband of Figures 1 and 2.

[014] Figure 4 is a top plan view of an alternative embodiment of a headband suitable for measuring a patient's blood perfusion in accordance with an embodiment of the present invention.

[015] Figure 5 is a schematic block diagram of a system for determining a patient's blood perfusion using the headband of Figure 4.

[016] Referring to Figure 1, a system 10 for measuring blood volume characteristics includes a headband 12 worn around the head of a patient 14. The headband 12 may extend completely around the patient's head, be adhered to the patient's forehead by an adhesive, or partially encircle the patient's head and be maintained in place by the elasticity of the headband or a headband strap biasing itself against the head of the patient. A plurality of electrodes 16a-16d are secured to the inner surface of the headband 12 such that they are in contact with the skin of the patient's forehead when the headband 12 is placed on the patient's head. In some embodiments, the electrodes 16a-16d include an adhesive surface for adhering the electrodes 16a-16d to the patient's head. In other embodiments, the headband 12 is omitted and the electrodes 16a-16d are secured to the patient's head only by means of adhesive in the pattern shown.

[017] The electrodes 16a, 16b are located on one side of the patient's forehead and the electrodes 16c, 16d are located on the other side of the forehead. The distance between the pairs of electrodes is preferably much greater than the separation between the electrodes within a pair. For example, the separation between the medial electrodes 16b
and 16c may be between three and fifteen times the separation between the electrodes 16a and 16b or the separation between the electrodes 16c and 16d. In a preferred embodiment, the separation between the medial electrodes 16b and 16c may be between eight and twelve times the separation between the electrodes of each pair.

[018] The electrodes 16a-16d are preferably formed of a material providing short term stability of the electrode-to-skin half-cell potential and providing overall short term stability of the interface impedance within the driving frequency of signals applied to the electrodes 16a-16d. In some embodiments, the electrodes 16a, 16d contact the skin by means of a hydrogel, such as RG 63T hydrogel.

[019] Referring to Figure 2, in a preferred embodiment, the headband 12 encircles the patient's head, as shown, and includes a fastener 18 for securing ends 20a, 20b of the headband 12 to one another. In some embodiments, the fastener 18 is a hook and loop fastening system such as VELCRO, however other fastening systems such as buckles, snaps, a knot, or the like may be used to secure the ends 20a, 20b to one another. In other embodiments, the headband 12 is a continuous loop with elastic portions to enable the headband 12 to bias itself against the patient's head. In other embodiments, the headband 12 includes both elastic portions and a fastener 18.

[020] A controller 22 is secured to the headband 12 and includes circuits for driving the electrodes 16a-16d and for detecting voltages therefrom. The controller 22 is coupled to a monitoring device 24 by means of wires or wirelessly to transmit measurements and/or to receive control signals. The device 24 may be embodied as an automatic external defibrillator (AED), CPR feedback device, or the like. A power source 26, such as a battery, is also secured to the headband 12. In an alternative embodiment, the power source 26 and controller 22 are separate from the headband 12 and are electrically coupled to the headband 12 by means of wires.

[021] In some embodiments, visual indicators 28 are positioned on the headband 12 in relation to the headband electrode pairs such that a user may determine the location of one or more of the electrodes when the electrodes 16a-16d are facing the patient's forehead. In the illustrated embodiment, the visual indicators 28 are LEDs each
positioned over one of the medial electrodes 16b, 16c. In other embodiments, the visual indicators 28 are each positioned over one of the lateral electrodes 16a, 16d. In other embodiments the visual indicators 28 are located at a position between the lateral electrode 16a and the medial electrode 16b and a position between the medial electrode 16c and the lateral electrode 16d. In other embodiments, the visual indicators 28 are marks made on the outside surface of the headband 12 rather than LEDs.

[022] Referring to Figure 3, the controller 22 in this embodiment includes a driving module 30 that generates signals coupled to some of the electrodes 16a-16d. In a preferred embodiment, the driving module 30 couples signals only to the lateral electrodes 16a, 16d. The driving module 30 couples an alternating signal to the electrodes 16a, 16d, such that the polarity of the electrodes 16a, 16d change cyclically and the direction of current flow changes cyclically. The frequency of the alternating signal is preferably between about 1 and 100 kHz and the RMS current of the signal is preferably between 10 microamperes and 1 milliampere. In some embodiments, the RMS current of the driving signal is proportional to its frequency. For example, the RMS current may be equal to about 10 microamperes times the frequency measured in kilohertz. For example, a 100kHz carrier times 10 microamps would result in a 100 times 10 µa RMS current or 1000 µa (1 mA).

[023] The controller 22 of Figure 3 includes a sensing module 32 coupled to some of the electrodes 16a-16d. In a preferred embodiment, the sensing module 32 receives signals only from the medial electrodes 16b, 16c. The sensing module 32 preferably does not draw a significant amount of current. For example, the sensing module 32 may include a voltage follower that outputs a voltage exerted at its input, but which has a high input impedance and therefore does not draw a significant amount of current. The sensing module 32 may further process the sensed voltage by demodulating the sensed voltage to remove the carrier frequency components. For example, the sensed voltage may be demodulated using the in-phase (I) and quadrature (Q) signals of the carrier frequency, as known in the art. The sensing module may further condition either
the sensed or demodulated signal by, for example, amplifying or filtering as known in the art.

[024] The controller 22 of Figure 3 includes a processing module 34 that processes the output of the sensing module 32 in order to extract information regarding blood volume changes in the patient 14. The processing module 34 may, for example, extract a measure of blood perfusion, heart rate, or the like. In some embodiments, the heart rate may be analyzed to determine breathing rate by detecting changes in the R to R interval of the cardiac cycle caused by respiration. Another method may include measurement of the amplitude modulation of the carrier caused by changes in impedance. The impedance will change as a function of respiration and this can also be measured. The processing module 34 may extract the information according to impedance plethysmography techniques known in the art, such as those used to extract blood volume change information through impedance measurements performed on the patient's thorax. In some embodiments, extraction of information regarding blood volume changes occurs in a device remote from the headband 12. In such embodiments the processing module 34 may be omitted from the headband 12.

[025] The controller 22 of Figure 3 includes a transmitting module 36. The transmitting module 36 receives an output from the sensing module 32 or processing module 34 and transmits the signal over a wire or wirelessly to a remote device. The remote device may include an automatic external defibrillator (AED), electrocardiogram (ECG) monitor, or other device for monitoring physiological attributes or vital signs. In other embodiments the controller may be integrated into the remote device.

[026] Referring to Figure 4, in this embodiment the system 10 further includes a load cell (or piezo-electric type of force sensor) 38, or pressure transducer 38, secured to the headband 12. In a preferred embodiment, the force sensor 38 is embodied as a piezoelectric film positioned on the headband 12 between the headband 12 and the patient's skin. However, other devices known in the art suitable for measuring tension in the headband 12 or pressure of the headband against the patient's forehead may be
used. The force sensor 38 may detect one or both of tension in the headband 12 and force of the headband 12 against the head of the patient 14. Monitoring one or both of tension and force helps the operator to secure the headband 12 in proper contact with the head of the patient 14 without constricting blood flow through vascular structures beneath the headband 12.

[027] Referring concurrently to Figures 4 and 5, the force sensor 38 is shown coupled to the controller 22, which is further coupled to one or more indicators 40, which may be embodied as an audible alarm or LED. The controller 22 includes a tensioning module 42 which activates one of the one or more indicators 40 when an output from the force sensor 38 indicates that the tension in the headband 12 is within a range of values found to have a high likelihood of maintaining the electrodes 16a-16d in good electrical contact with the patient's forehead without excessive constriction of blood flow. The controller 22 deactivates the indicator 40 when the tension exceeds the acceptable range of values. Alternatively, the controller 22 may activate a different indicator 40 if the tension exceeds the acceptable range of values. In yet another alternative, the controller 22 activates the same indicator when tension exceeds the acceptable range but in a different manner. For example, the controller 22 may cause an indicator 40 embodied as an LED to remain off where tension is below an acceptable range, to emit steadily if the tension lies within the acceptable range, and to emit intermittently if tension exceeds the acceptable range. The output of the force sensor 38 may be either recorded on the headband or transmitted and recorded by another device such that the tension in the headband 12 may be used to interpret data transmitted from the headband 12.

[028] In another embodiment, the indicator 40 can be omitted and the tensioning indication provided by one or both of the indicators 28. In yet another embodiment a separate force sensor 38 is associated with each pair of electrodes, monitoring the forehead contact at each electrode pair location. The indicators 28 are then used to signal the effectiveness of patient contact for each of the electrode pairs, respectively.
The various systems disclosed hereinabove enable rapid mounting of electrodes to a patient in emergency situations. Measurements taken using the disclosed systems also provide a more accurate measurement of blood volume changes in the patient in emergency situations than prior systems. Due to mounting of the electrodes on the patient's head, the impedance between the electrodes is not as affected by chest compressions as is for thorax mounted electrodes. Furthermore, due to the rigidity of the skull, changes in the volume through which current passes is not significantly affected by movement of the patient, which results in reduced motion artifacts even when the patient's head moves or CPR compressions are being applied.

Blood perfusion at the forehead is also relatively unaffected by the patient being in a state of shock. As noted above, blood flow to the limbs of a patient experiencing shock is reduced. In contrast, blood flow to the patient's head continues until the latest stages of shock. Measuring blood flow at the forehead is therefore useful for measuring blood perfusion in patients experiencing major trauma or receiving CPR.

From the foregoing it will be appreciated that, although specific embodiments of the invention have been described herein for purposes of illustration, various modifications may be made without deviating from the spirit and scope of the invention. One or more of the visual indicators of an embodiment of the invention may be substituted by audible indicators or speech processor for real time feedback, for instance. Audio or visual output signals may be transmitted either wirelessly or by wire to an audio/visual output device for direct real time feedback to a rescuer which may guide the rescuer in modifying the therapy. Other sensors may be incorporated in the headband such as one or more of those shown in concurrently filed US patent application serial number 6/ , entitled "FOREHEAD MOUNTED BIOMETRIC SENSOR WITH MOTION ARTIFACT REDUCING SYSTEM AND METHOD" which is incorporated herein by reference. Reference to modules constituting embodiments of the invention indicate structures and steps for performing the functions attributed to a module, however the structures for performing the functions attributed to a module may be operate at different times or include multiple distinct structures that
may or may not be collocated. Accordingly, the invention is not limited except as by the appended claims.
WHAT IS CLAIMED IS:

1. An apparatus for monitoring heart rate comprising:
   a headband adapted to secure to the forehead of a subject;
   a plurality of electrodes secured to the headband and positioned to be interposed
   between the headband and the forehead when the headband is secured to the forehead;
   and
   a controller including a driving circuit coupled to a first group of the plurality of
   electrodes and configured to output current through the first group, a sensing circuit
   coupled to a second group of the plurality of electrodes and configured to sense voltages
   at each of the electrodes of the second group, and a processing circuit configured to
   receive the sensed voltages from the sensing circuit and output a heart rate based on the
   sensed voltages.

2. The apparatus of claim 1, wherein the driving circuit is configured to output an alternating current through the first group of electrodes.

3. The apparatus of claim 1, wherein the first group includes first and second drive electrodes and wherein the driving circuit is further configured to alternately pass current from the first to the second drive electrode and from the second to the first drive electrode at a drive frequency and a drive RMS current.

4. The apparatus of claim 3, wherein the drive frequency is between about 1 and 100 kHz.

5. The apparatus of claim 4, wherein the drive RMS current is substantially proportional to the drive frequency.

6. The apparatus of claim 5, wherein the drive RMS current is substantially equal to 10 micro amps times the drive frequency in kilohertz.
7. The apparatus of claim 1, wherein the headband further comprises a pressure transducer or force sensor and a visual indicator, the controller configured to activate the visual indicator when an output of the pressure transducer falls within a range of values.

8. An apparatus for determining blood volume changes/flow in a patient, comprising:
   a plurality of electrodes adapted to be secured to a patient's forehead;
   a signal driving circuit coupled to at least one of the plurality of electrodes and configured to drive an alternating signal to the patient's forehead;
   a sensing circuit coupled to at least one other of the plurality of electrodes and configured to sense from the patient's forehead electrical signals resulting from the alternating signal;
   a processor coupled to the signal driving circuit and the sensing circuit, the processor configured to calculate impedance from the alternating signal and electrical signals sensed from the patient's forehead to determine patient blood flow therefrom.

9. The apparatus of claim 8 wherein the plurality of electrodes include adhesive for adhering the electrodes to the patient's forehead.

10. The apparatus of claim 8, further comprising a headband adapted to be secured to the patient's head and the plurality of electrodes are attached to the headband and are positioned against the patient's forehead.

11. The apparatus of claim 10 wherein the headband further comprises visual indicators positioned on the headband indicating locations of the plurality of electrodes.
12. The apparatus of claim 8 wherein the plurality of electrodes comprises four electrodes, two electrodes coupled to the signal driving circuit and two electrodes coupled to the sensing circuit.

13. The apparatus of claim 8 wherein the signal driving circuit is configured to drive an alternating current signal to the patient's forehead, the sensing circuit is configured to sense voltage signals resulting from the alternating signal, and the processor is configured to calculate impedance from the alternating current signal and sense voltage signals.

14. The apparatus of claim 8 wherein the processor is further configured to calculate patient heart rate from the electrical signals sensed from the patient's forehead.

15. The apparatus of claim 14 wherein the processor is further configured to determine a breathing rate from the electrical signals.

16. The apparatus of claim 13 wherein the processor is further configured to provide audio and/or visual feedback to the rescuer in real time to provide a method of changing the therapy to improve changes in blood volume/flow during CPR.
**INTERNATIONAL SEARCH REPORT**

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/024  A61B5/026  A61B5/053

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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Further documents are listed in the continuation of Box C

See patent family annex

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Date of the actual completion of the international search: 13 March 2009

Date of mailing of the international search report: 24/03/2009

Name and mailing address of the ISA:
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Authorized officer
Schindler, Martin
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