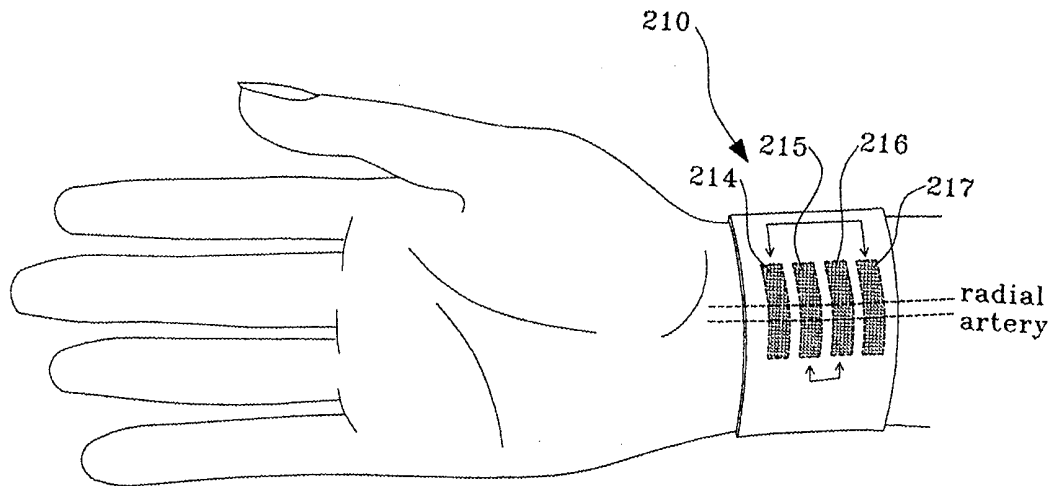




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁷ : A61B 5/0245, 5/053</p>	<p>A1</p>	<p>(11) International Publication Number: WO 00/28892 (43) International Publication Date: 25 May 2000 (25.05.00)</p>
<p>(21) International Application Number: PCT/AU99/00997 (22) International Filing Date: 12 November 1999 (12.11.99) (30) Priority Data: PP 7119 13 November 1998 (13.11.98) AU (71) Applicant (for all designated States except US): MICROMEDICAL INDUSTRIES LIMITED [AU/AU]; 11 Technology Drive, Labrador, QLD 4215 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): SATCHWELL, Bruce, Richard [AU/AU]; 127 Pebble Beach Drive, Runaway Bay, QLD 4216 (AU). WALSH, Andrew, Michael [AU/AU]; 4 Epsom Road, Rosebery, NSW 2474 (AU). (74) Agent: WALLINGTON-DUMMER; P.O. Box 297, Rydalmere, NSW 1701 (AU).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search report.</p>

(54) Title: WRIST MOUNTABLE MONITOR



(57) Abstract

A wrist mountable monitor (10) having impedance electrodes (14, 15, 16, 17) adapted for contact with a user's skin for the purpose of measuring bioimpedance; one or more of the electrodes (14, 15, 16, 17) in electrical communication with data processing means (11) which monitors a signal (13) derived from said electrodes and derives physiological information therefrom.

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WRIST MOUNTABLE MONITOR

The present invention relates to a wrist mountable monitor and, more particularly, to such a monitor adapted to monitor and display vital signs which can be derived from bioimpedance measurements.

BACKGROUND

Certain types of wrist watch-type heart monitors are known such as, for example, disclosed in US5738104 which monitors heart rate on the basis of ECG measurements. US5492127 discloses a monitor which uses microphones to detect heart rate. US5228449 utilizes photoplethysmography.

Similar wrist mounted heart rate monitors have been proposed (e.g. Bryars US5,795,300), except all others suggest either photoplethysmography or pressure sensing as a means to measure heart rate. Bryars for example, has suggested the use of two piezoelectric crystals placed across the radial artery, one to directly measure the pressure, the other to measure the background pressure that can later be subtracted out. This technique requires precise placement of the sensors directly over the radial artery. Since this location can vary from one person to another, it can be prone to placement error.

ECG based rate detectors require the user to form a circuit by touching the watch with their opposite hand (or have additional thoracic ECG electrodes). Photoplethysmography usually requires additional finger cuffs. Microphones are subject to noise.

US5795300 to Bryars (assigned to Advanced Body Metrics Corporation) particularly discusses the problem of piezoelectric monitors and the problems they have with spurious noise. This device, as with any others, is limited to only providing heart pulse rate.

There is no simple solution at present to conveniently and reliably measure pulse information together with the possibility of measuring other vital signs from a simple wrist-worn device.

It is an object of the present invention to overcome or ameliorate the abovementioned disadvantages.

BRIEF DESCRIPTION OF INVENTION

Accordingly, in one broad form of the invention there is provided a wrist mountable monitor having impedance electrodes adapted for contact with a users skin for the purpose of measuring bioimpedance; one or more of said electrodes in electrical communication with data processing means which monitors a signal derived from said electrodes and derives information therefrom.

Preferably, said electrodes comprise first and second current delivery electrodes and first and second receiver electrodes.

Preferably said current electrodes are driven by a constant amplitude current source which is modulated by a square wave signal derived from said data processing means.

Preferably said impedance electrodes communicate with an amplifier and a synchronous demodulator thereby to produce said impedance signal for input to said data processing means.

Preferably said monitor includes including predetermined data which is compared with data derived from said impedance signal; said data processing means performing a comparison operation to determine when data derived from said impedance signal moves outside a range defined by said predetermined data.

Preferably said information comprises at least heart rate or respiration rate or body motion of said user.

In a fourth broad form of the invention there is provided a method of measuring at least respiration rate of a person; said method including applying electrodes at or near the wrist of a person; said method further including driving selected ones of said electrodes with predetermined electric current; said method further comprising monitoring selected others of said electrodes thereby to determine respiration rate of said person by changes in bioimpedance at or near said wrist.

Preferably said electrodes are oriented parallel to the alignment of the radial or ulnar artery.

In an alternative preferred form said electrodes are oriented transverse to the alignment of the radial or ulnar artery.

Preferably at least a portion of said information is communicated to a display forming part of said monitor whereby a user of said monitor can observe said information on set display during use.

5 Preferably said monitor incorporates alarm means which is activated when said data moves outside said range to find the said predetermined data.

Preferably said alarm means comprises an audible output.

Preferably said alarm means comprises a visual output.

10 Preferably said alarm means communicates with telemetry means thereby to transmit an alarm signal to a remote location.

Preferably said remote location is located at less than five metres from said monitor. In an alternative said remote location is located up to two hundred metres from said monitor.

15 In a further alternative preferred form said remote location is located at greater than two hundred metres from said monitor.

Preferably said telemetry means utilizes a low frequency carrier.

20 In an alternative preferred form telemetry means utilizes a carrier in the MHz band or GHz band.

In an alternative preferred form said telemetry means utilizes a cellular mobile telephone technology for communication with said remote location.

25 BRIEF DESCRIPTION OF DRAWINGS

Embodiments of the present invention will now be described with reference to the drawings wherein:

Fig. 1 is a block diagram of a wrist mountable monitor according to a first embodiment of the invention,

30 Fig. 2 is a perspective view of the monitor in place on a wrist of a user.

Fig. 3 is a block diagram of a monitor circuit according to a second embodiment of the invention,

Fig. 4 is an end section view of the wrist of a wearer of the monitor of Fig. 3 showing a preferred electrode lay out,

Fig. 5 is a view from underneath the wrist of a wearer showing the electrode arrangement of Fig. 4,

Fig. 6 is a plan view of the monitor display of the monitor of Fig. 3,

Fig. 7 illustrates an alternative preferred electrode arrangement usable with the device of Fig. 3,

Fig. 8 shows further detail of the alternative preferred electrode arrangement of Fig. 7,

Fig. 9 is an end, section view of the wrist of a wearer where the electrode arrangement is as for Fig. 7

Fig. 10 is a block diagram of a remote monitoring system usable with the arrangement of either Fig. 1 or Fig. 3.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

A block diagram of a wrist mountable monitor 10 is illustrated in Fig. 1 and includes a microprocessor 11 which receives as primary input on primary signal input 12 an oscillating signal 13 derived from electrodes 14, 15, 16, 17 on wrist strap 18.

The entire circuit is designed with microminiature surface mount CMOS low power technology. The microprocessor 11 at output 24 generates a high frequency square wave 23 that is used to generate a constant amplitude current, from current generator 19 which in turn delivers this current across the subject's wrist via electrodes 14, 17. Twopickup electrodes 15, 16 are used to detect the impedance change in the wrist caused by a change in blood volume. The impedance change is reflected as a voltage which is amplified by amplifier 20 then rectified by the synchronous demodulator 22 then amplified again by amplifier 21. The resulting signal 13 is fed back to the microprocessor 11 where it is digitised by an A/D convertor to allow processing by microprocessor 11. An optional modulator 25 places signal 13 on a carrier for transmission to a remote site via antenna 26. The microprocessor also drives bidirectional RS 232 port 27 and an LCD display 28 to

display information such as pulse rate and respiration rate derivable from signal 13 and time.

In use the monitor 10 can display heart rate, step rate and respiration rate on LCD display 28. Microprocessor 11 can be
5 programmed to monitor preset or predetermined values of these measurements and to display or otherwise signal when the measured values fall outside these predetermined ranges.

In a particular embodiment spike 29 on waveform 13 which corresponds to or coincides with a runner's heel striking the
10 ground can be monitored and information thereby derived from this event such as, for example, distance travelled information.

With reference to Fig. 3 a more detailed block diagram of the arrangement of Fig. 1 is disclosed as a second embodiment of the invention. In Fig. 3 like components and signals are numbered as
15 for the first embodiment, but prefixed by the numeral one (100s series).

The monitor 110 according to the second embodiment of the invention relies on micro controller 111 for digital signal processing. It can be, for example, of type PIC17C756. Micro
20 controller 111 supplies high frequency square wave 123 oscillating at approximately 50 kHz via out put 124 and then through band pass filter 130 to electrode ray 131 comprising constant current supply electrodes 114, 117 supplied by constant current source 119.

25 Impedance across wrist 132 there is as a function of blood volume change in the wrist as indicated diagrammatically in Fig. 4. The impedance variation is reflected as a change in voltage across sensing electrodes 115, 116.

The detected voltage signal 133 is buffered by amplifier and
30 transformer combination 134 and so as to remove common mode noise prior to amplification and conversion to direct current by synchronize demodulator 122. The output from the synchronize demodulator 122 is a direct current which is proportional to the impedance across wrist 132 at the driving frequency (in this
35 instance 50kHz). In a preferred form, but not shown in the block diagram of Fig. 3, it is desirable to enable the synchronize

detection switch to be toggled at any point in phase of the wave form 123 in order to take into account any unwanted phase lags. Because we are interested in change of impedance across the wrist 132, a base impedance signal 135 from pulse with modulation output 5 136 is subtracted from the synchronize demodulator output 137 by amplifier arrangement 138 leaving difference input signal 113 supplied to the analogue digital conversion input 112 of micro controller 111.

The base level impedance signal 135 can be altered as the 10 input signal drifts out of range, for example by corresponding control of digitally controlled resistor 139 driven from digital output 140 of micro controller 111.

The output from the synchronous demodulator comprises DC and AC components. The former corresponds to a constant impedance Z 15 and the latter to a variable component dZ , which is due mainly to changing blood volume in the wrist. As Z is not relevant in this application, it must be removed. This would normally be achieved by AC (capacitive) coupling. However, in this application, the respiration component is of such a low frequency, that this is not 20 a very suitable method. Instead, the microcontroller outputs an analogue voltage (via the attenuator) equivalent to the DC component Z , hence cancelling it out from the input signal. If the voltage sensed by the microcontroller saturates to either voltage rail, the microcontroller can bring it back within range by 25 altering the value of the PWM output in an appropriate manner. Thus the stage is effectively DC coupled, but can easily cope with variations in the value of the constant component Z .

As for the first embodiment processed information can be displayed on LCD display 128 and can be transmitted as a telemetry 30 signal 141 via modulator/transmitter 125. The telemetry applications will be described in more detail with reference to Fig. 10.

As shown in detail in Fig. 5 the electrodes 114, 115, 116, 117 are arranged on wrist strap 118 so that, in use, they lie along the 35 direction of the radial artery and ulnar artery as seen in Fig. 4. With this orientation a typical electrode length is in the range 1

to 2 centimeters. Electrodes of this type and this orientation driven in the manner previously described provides a system which is less prone to placement error than 5 millimetre piezo electric crystals of LEDs. In addition, as the monitor 10,110 measures signals at a drive frequency, in this instance, of 50kHz rather than near DC levels (as is the case with piezo electric sensing) it is far less prone to muscle/motion artifact which tends to occur at low frequency thereby more readily affecting photoplethysmographic or pressure sensors than the sensor arrangement of the present application.

With reference to Figs. 7, 8 and 9 and alternative electrode arrangement is possible and where like components are numbered as for the first embodiment but prefixed with the numeral 2 (200 series).

In this arrangement the electrodes 214, 215, 216, 217 are arranged to lie in parallel as previously but, in this instance, are oriented at 90 degrees to the orientation of the second embodiment illustrated in Figs. 4 and 5.

The technique so far referred to effectively measure blood volume variation throughout the entire wrist, and derives physiological information directly from these measurements. It is thought that respiratory rate is derived from blood variation in the venous part of the wrist. As this is of low pressure, the volume is easily affected by motion artifact, such as that caused by muscle and tendon movement. This artifact reduces the signal to noise ratio of the measurements, making the device unsuitable for active individuals.

The variation of Figs. 7-9 is to alter the electrode array structure from laterally across the wrist (as suggested by Farg et al) to longitudinally along the wrist (Figs. 7-9). The electrodes must be smaller for this. If the electrodes are specifically placed immediately above an artery (such as the radial artery), the instrument will selectively measure blood volume change just in that artery, rather than the wrist as a whole. The arterial blood flow is influenced almost entirely by the heart pump activity, and

less so by muscle artifact or pulmonary function. Hence such a wrist monitor will be suitable for noise free measurement of heart rate in active individuals. (eg. during sport training).

In the case of the driving circuits of both of the first embodiment (fig. 1) and the second embodiment (fig. 3) a low power consumption micro controller is to be preferred thereby allowing long battery life (battery not shown in diagrams).

Because the device is battery powered no body isolation transformer is required for patient safety. In a preferred form there are no exposed metal parts except for the wrist electrodes with the body of the monitor 10, 110, 210 being made ideally from a non-conductive polymer such as ABS.

In the case of the drive circuits described it is to be noted that the drive current for the electrodes is derived from a square wave rather than a sine wave oscillator. The resulting wave form is therefore more stable and hence does away with the requirement for a reference level measurement.

With reference to fig. 10 a monitoring systems 310 is shown comprising a wrist mounted monitor 110 communicating by its telemetry signal 141 with receiver 311. Receiver 311 demodulates the telemetry signal 141 and communicates resulting information to personal computer 312 via its serial port 313.

A data logging program can thus keep track of pulse rate, respiration rate and distance travelled utilising signal information derived from the monitor 110. The telemetry may be of 3 forms:

- (i) short range eg. <5m. Such telemetry can utilise unidirectional (ie. transmit only) low frequency (eg. <10MHz carrier frequency) near field telemetry. Near field telemetry has the advantage of being somewhat resistant to interference from neighbouring units, since the field strength drops proportional to $1/r^3$, rather than conventional far field's $1/r$. This may be advantageous when used in a hospital ward, for example, where many units may be used in close proximity.
- (ii) mid range (<200m)

Such telemetry can make use of one of the ISM bands of 443/868/915 MHz utilizing one of the recently available microminiature chipsets if specially made for this purpose (eg. RF micro devices RF2905). It can also utilise the international 2.45 GHz band, for example with spread spectrum Bluetooth™ technology.

(iii) long range (>200m)

Cellular mobile phone technology (eg. GSM) can be used to provide a longer range link.

The above describes only some embodiments of the present invention and modifications, obvious to those skilled in the art, can be made thereto without departing from the scope and spirit of the present invention.

15 INDUSTRIAL APPLICABILITY

Embodiments of the present invention can be applied with advantage by users who for example wish to self-monitor physiological parameters such as respiration rate in a convenient manner.

CLAIMS

1. A wrist mountable monitor having impedance electrodes adapted for contact with a users skin for the purpose of measuring bioimpedance; one or more of said electrodes in electrical communication with data processing means which monitors a signal derived from said electrodes and derives information therefrom.
2. The monitor of claim 1 wherein said electrodes comprise first and second current delivery electrodes and first and second receiver electrodes.
3. The monitor of claim 2 wherein said current electrodes are driven by a constant amplitude current source which is modulated by a square wave signal derived from said data processing means.
4. The monitor of any one of claims 2 to 4 wherein said impedance electrodes communicate with an amplifier and a synchronous demodulator thereby to produce said impedance signal for input to said data processing means.
5. The monitor of any previous claim including predetermined data which is compared with data derived from said impedance signal; said data processing means performing a comparison operation to determine when data derived from said impedance signal moves outside a range defined by said predetermined data.
6. The monitor of any previous claim wherein said information comprises at least heart rate or respiration rate or body motion of said user.
7. The method of measuring at least respiration rate of a person; said method including applying electrodes at or near the wrist of a person; said method further including driving selected ones of said electrodes with predetermined electric current; said method further comprising monitoring selected others of said electrodes thereby to determine respiration rate of said person by changes in bioimpedance at or near said wrist.
8. The method of claim 7 wherein said electrodes are oriented parallel to the alignment of the radial or ulnar artery.
9. The method of claim 7 wherein said electrodes are oriented transverse to the alignment of the radial or ulnar artery.

10. The monitor of any one of claims 1-6 wherein at least a portion of said information is communicated to a display forming part of said monitor whereby a user of said monitor can observe said information on set display during use.
- 5 11. The monitor of claim 5 incorporating alarm means which is activated when said data moves outside said range to find the said predetermined data.
12. The monitor of claim 11 wherein said alarm means comprises an audible output.
- 10 13. The monitor of claim 11 wherein said alarm means comprises a visual output.
14. The monitor of claim 11 wherein said alarm means communicates with telemetry means thereby to transmit an alarm signal to a remote location.
- 15 15. The monitor of any one of claims 1-7 and further including telemetry means whereby at least a portion of said information is communicable to a remote location.
16. The monitor of claim 15 wherein said remote location is located at less than five metres from said monitor.
- 20 17. The monitor of claim 15 wherein said remote location is located up to two hundred metres from said monitor.
18. The monitor of claim 15 wherein said remote location is located at greater than two hundred metres from said monitor.
19. The monitor of claim 16 wherein said telemetry means utilises
25 a low frequency carrier.
20. The monitor of claim 17 wherein said telemetry means utilizes a carrier in the MHz band or GHz band.
21. The monitor of claim 18 wherein said telemetry means utilizes a cellular mobile telephone technology for communication with said
30 remote location.

2/9

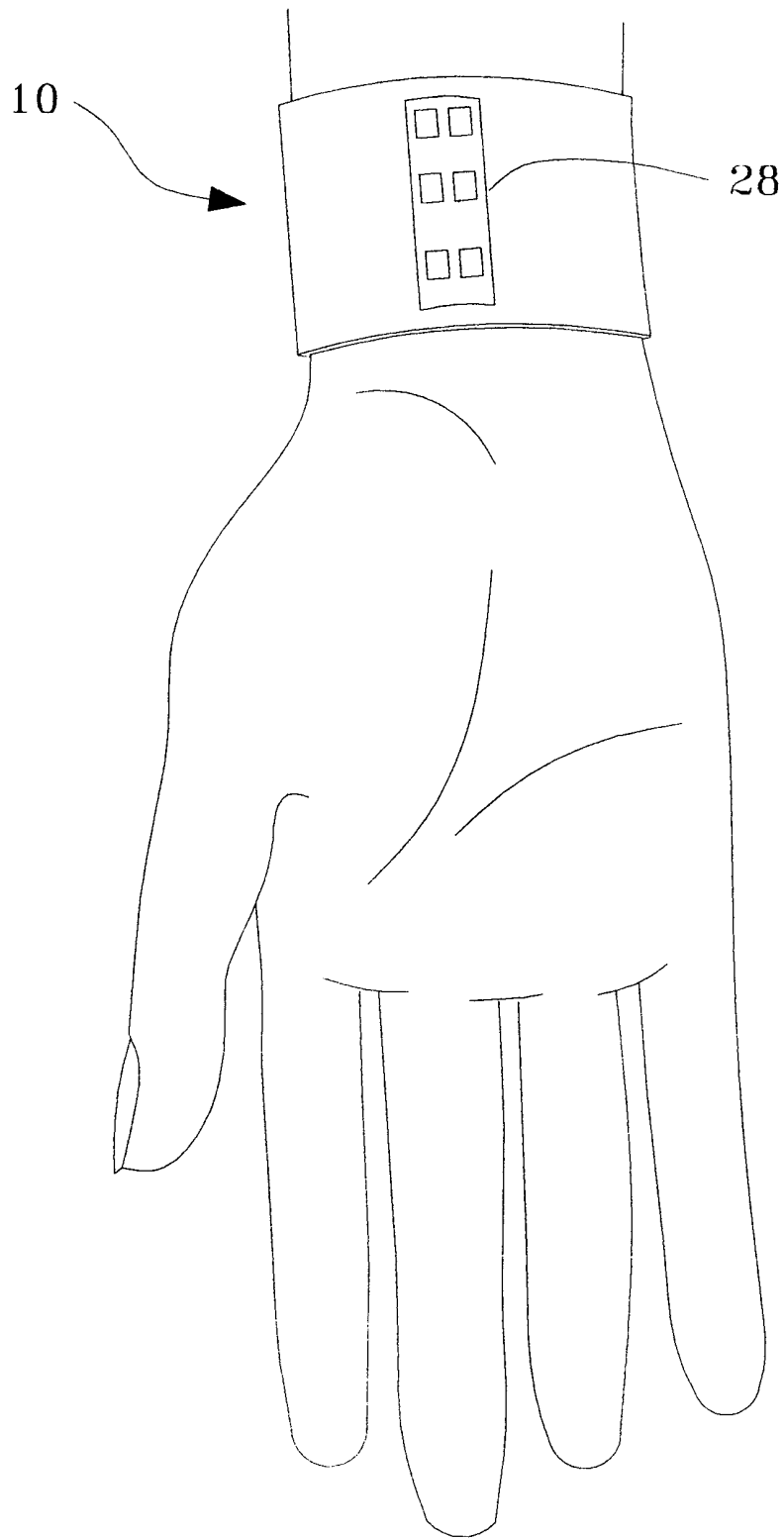


Fig. 2

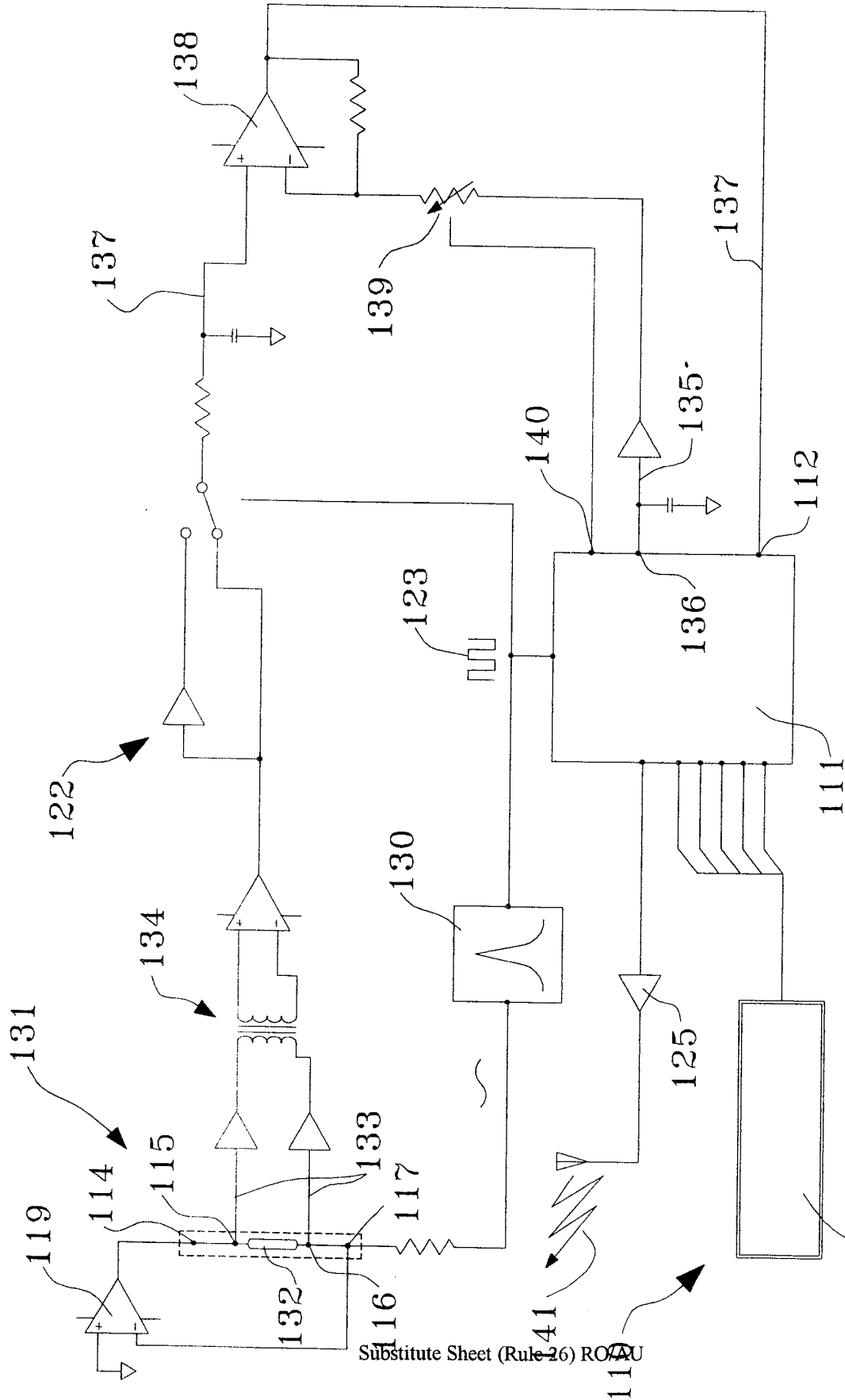


Fig. 3

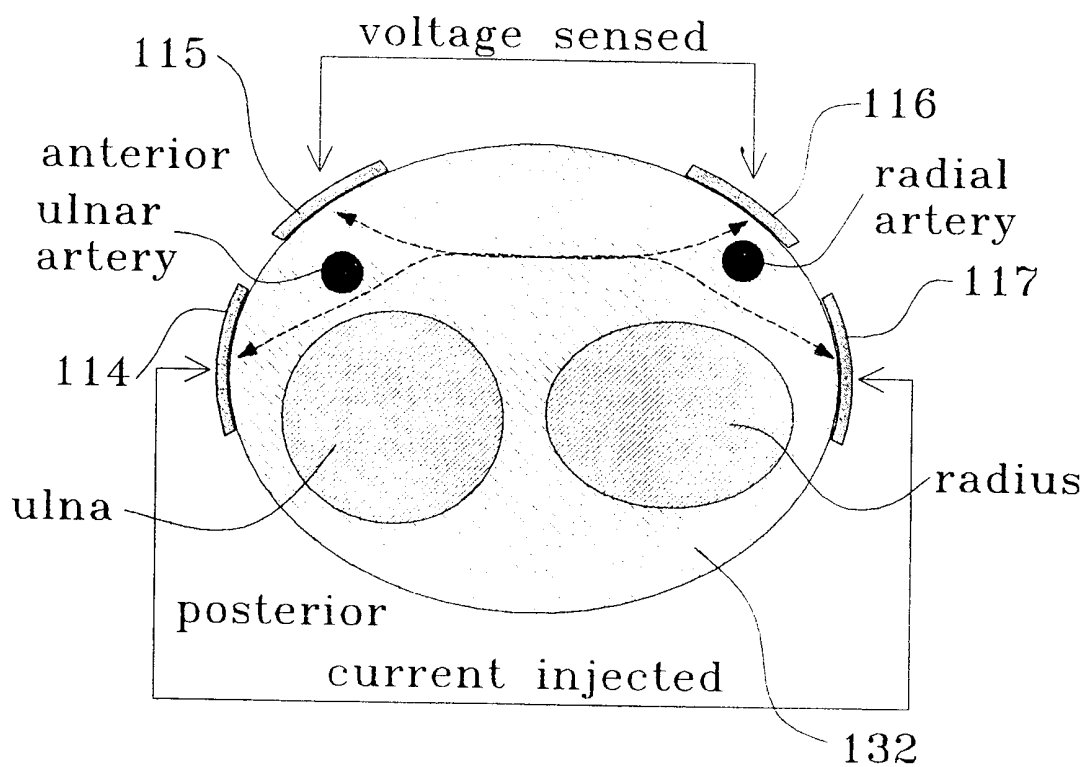


Fig. 4

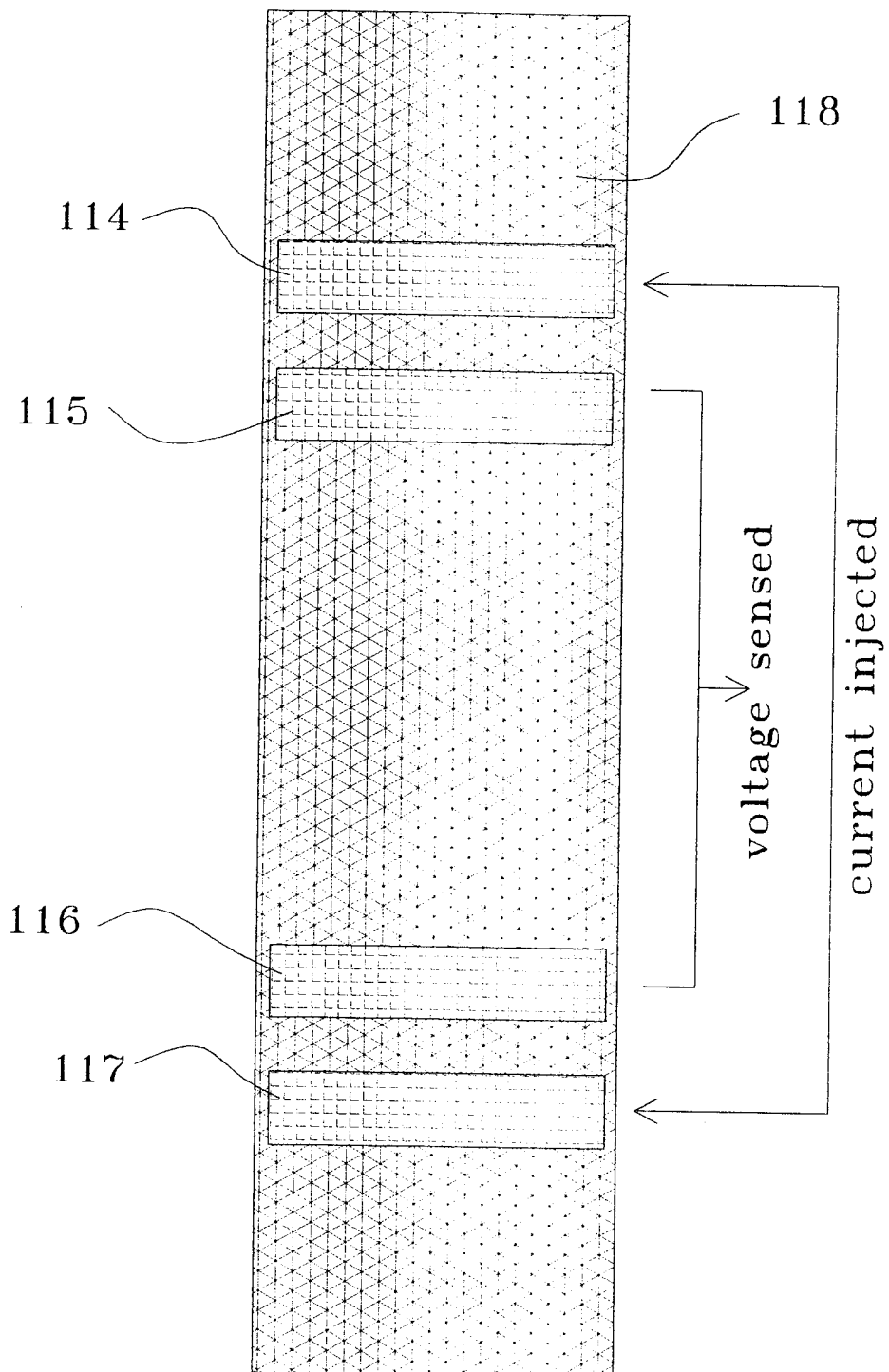


Fig. 5

6/9

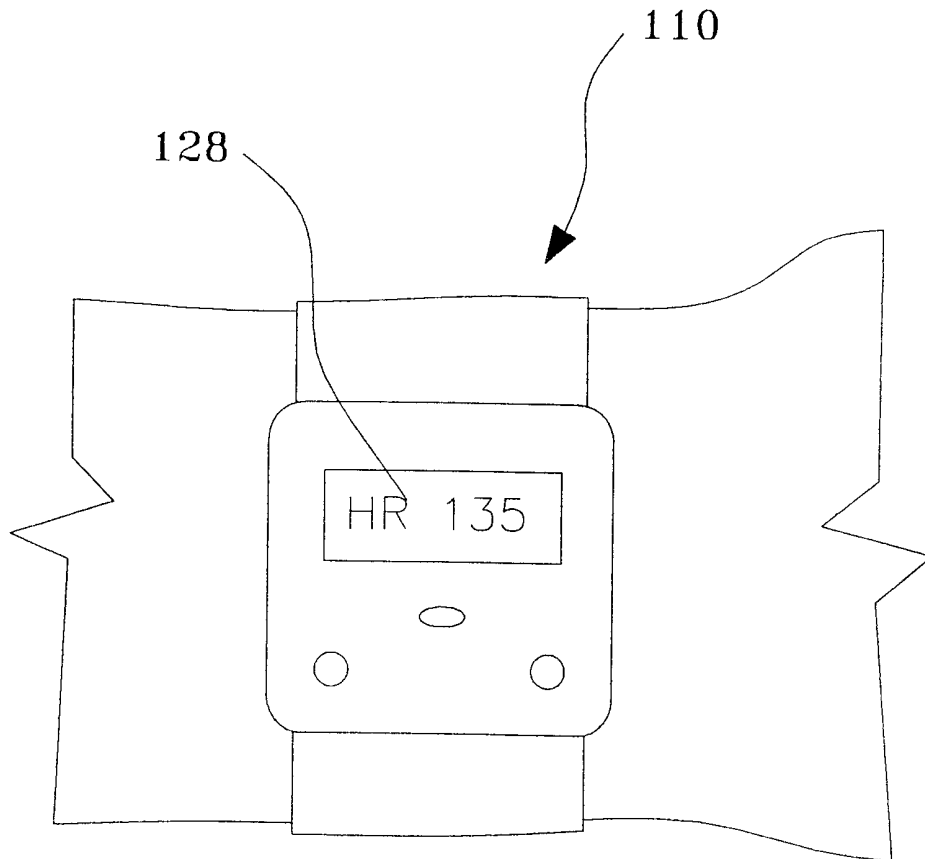


Fig. 6

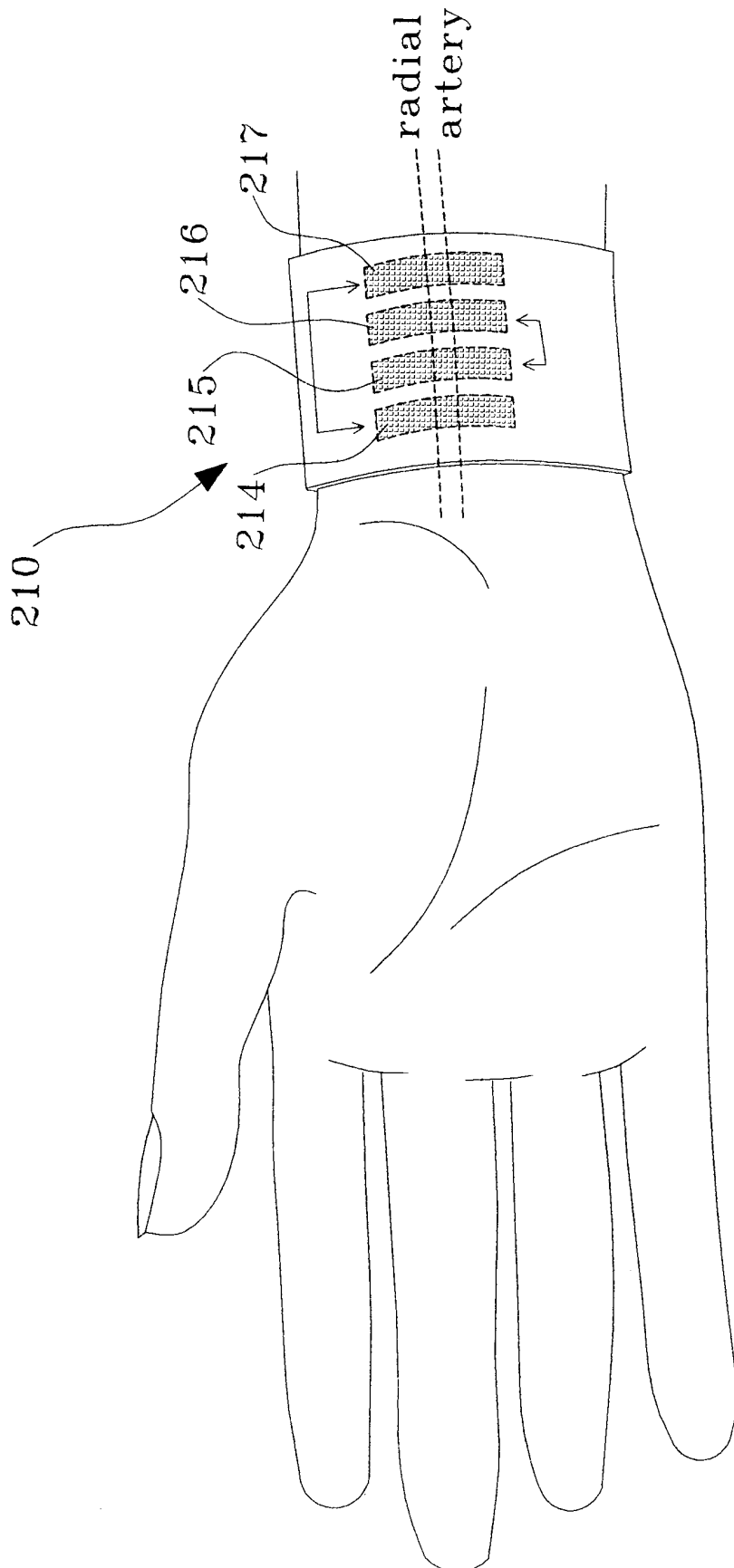


Fig. 7

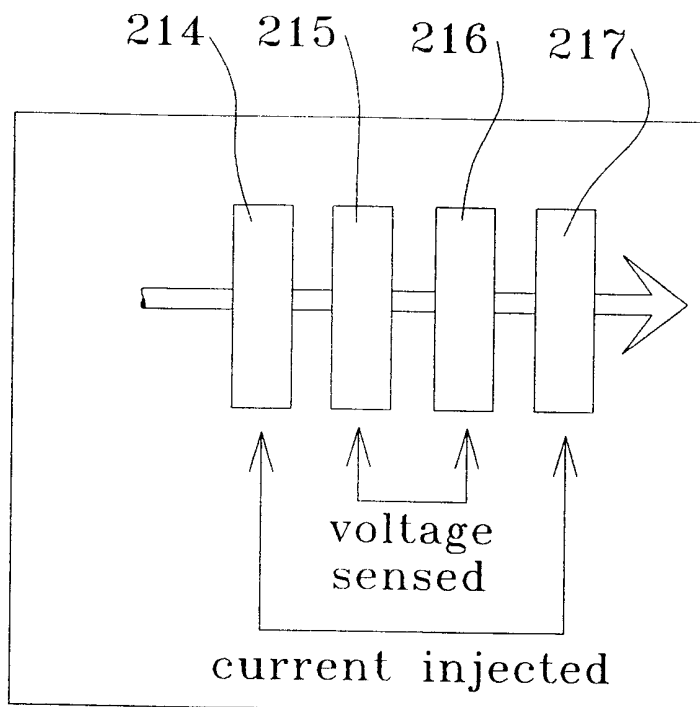


Fig. 8

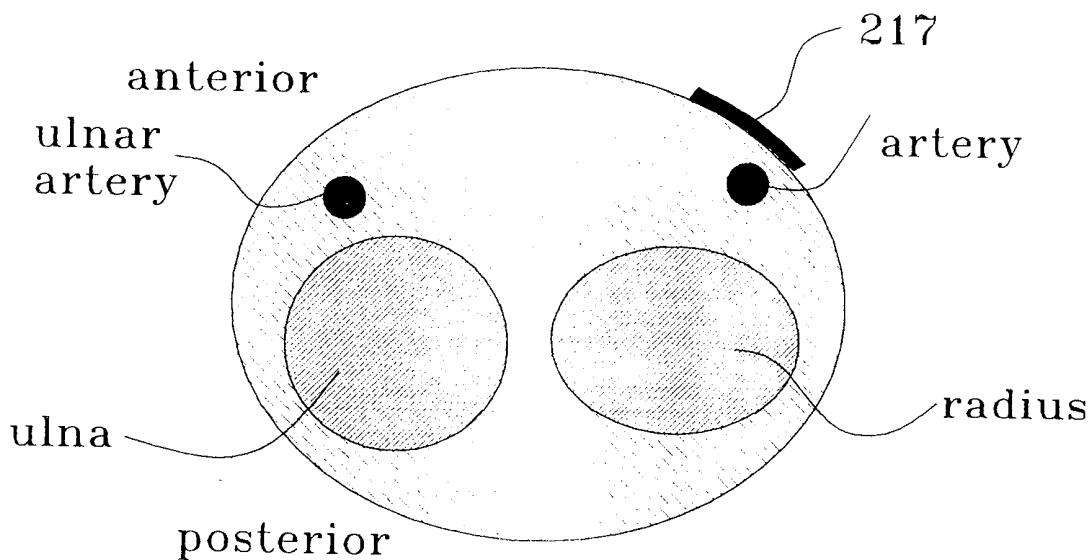


Fig. 9

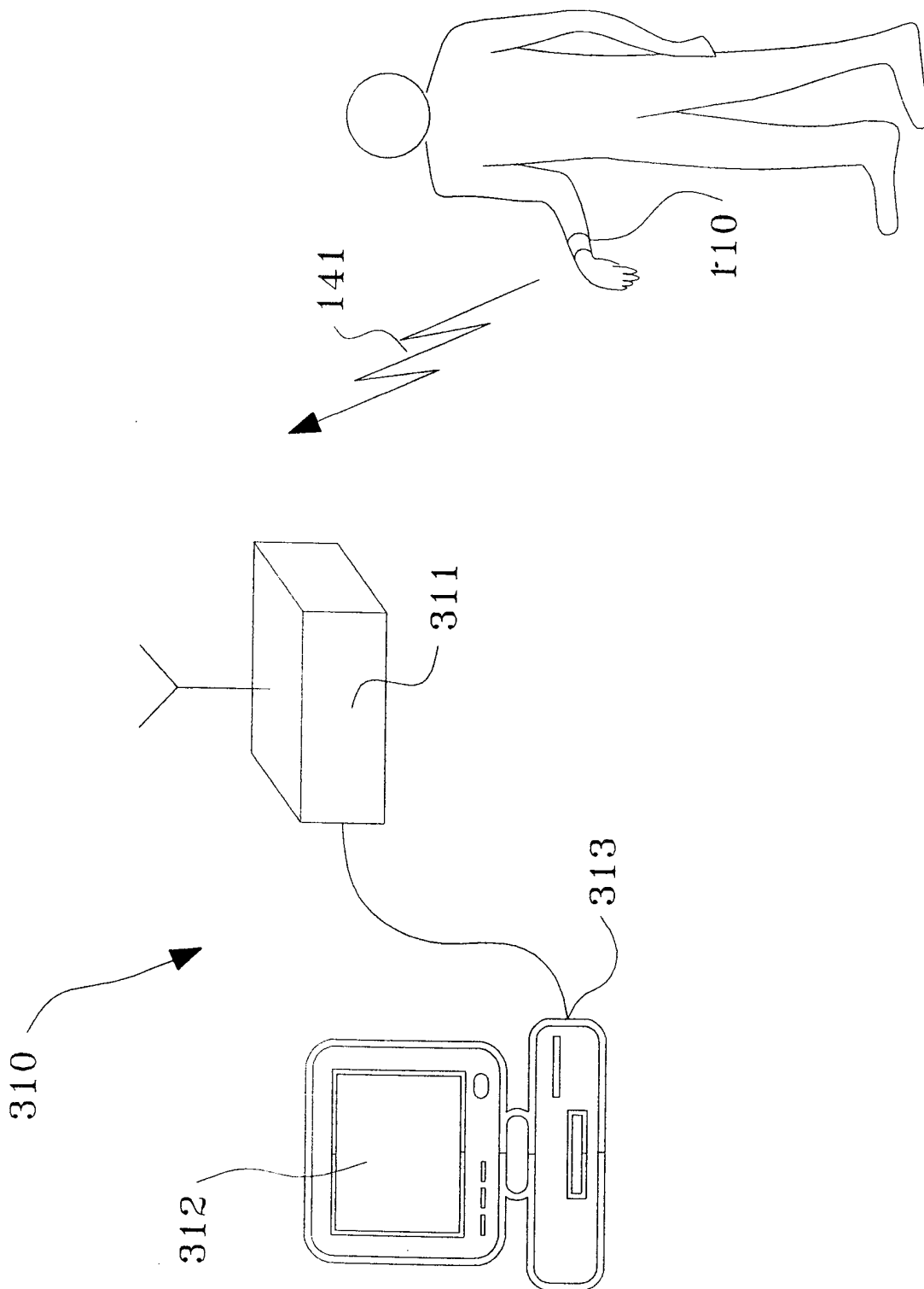


Fig. 10

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/00997

A. CLASSIFICATION OF SUBJECT MATTER				
Int Cl ⁷ : A61B 5/0245, 5/053				
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 5/-				
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 practicable, search terms used) WPAT & JAPIO + keywords (electrode, sens+, impedance, bioimpedance, resistance, conductivity, skin, wrist, arm, hand)				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	WO 93/16636 A1 (MYLLYMAKI M) 2 September 1993 page 3, lines 7-23, figures 1 & 2	1, 10-21		
X	DE 4221526 A1 (HECHT K) 20 January 1994 figure 2	1		
X	Derwent Abstract Accession No. 98-210640/19, Class W04, JP 10057355 A (OMRON KK) 3 March 1998	1		
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex				
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Date of the actual completion of the international search 2 February 2000		Date of mailing of the international search report 08 FEB 2000		
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer GEOFF SADLIER Telephone No.: (02) 6283 2114		

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/00997

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5469859 A (TSOGLIN et al.) 28 November 1995 column 8, lines 10-27 & column 5, lines 35-56	7
X	US 5685316 A (SCHOOKIN et al.) 11 November 1997 column 2, line 59-column 3, line 8	7
X,P	US 5907282 A (FERNANDEZ A) 25 May 1999 figures 1 & 2, column 3, line 59- column 4, line 24	1

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU 99/00997

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	93/16636	AT	181492	AU	35020/93	EP	630208
		FI	920896	NO	943160	US	5515858
DE	4221526						
JP	10057355						
US	5469859	EP	575984	IL	102300	JP	7031604
US	5685316	AU	24200/97	CA	2251250	CN	1221325
		EP	901342	WO	97/37591		
US	5907282						
							END OF ANNEX