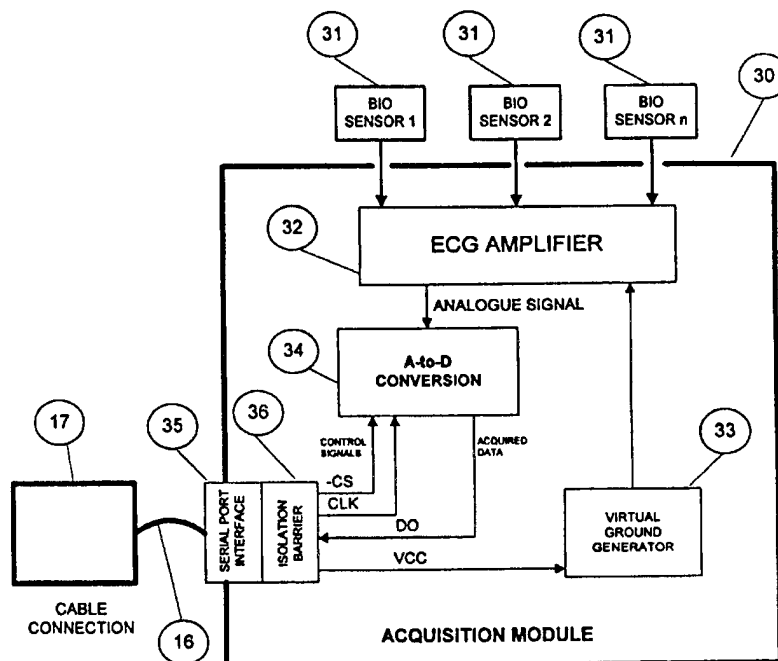




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/AU00/00404 (22) International Filing Date: 8 May 2000 (08.05.00) (30) Priority Data: PQ 0184 6 May 1999 (06.05.99) AU PQ 2257 16 August 1999 (16.08.99) AU (71) Applicant (for all designated States except US): SHELL, Allan, Michael [AU/AU]; 14/166 Belmore Road, Randwick, NSW 2031 (AU). (71)(72) Applicants and Inventors: PLATT, Harry, Louis [AU/AU]; 14/166 Belmore Road, Randwick, NSW 2031 (AU). JANKOV, Vladimir [AU/AU]; 14/166 Belmore Road, Randwick, NSW 2031 (AU). (74) Agent: YOUNG, Philip, Claude; Wilson & Young, P.O. Box 553, Alexandria, NSW 1435 (AU).		(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, 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). Published With international search report.

(54) Title: PHYSIOLOGICAL SIGNAL ACQUISITION CABLE



(57) Abstract

A physiological signal acquisition monitoring apparatus has a bio sensor (11, 31) connected by cable means (12) to an electrically isolated bio acquisition unit (13, 30) including an amplifying (14, 32) and control means (15) which is serially connected by cable means (16) to a display device (17) for displaying in real time the resulting graphically representation of the physiological signal.

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PHYSIOLOGICAL SIGNAL ACQUISITION CABLE

The present invention relates to physiological monitoring of patients and, in particular, to physiological signal acquisition cable which provides real time and/or simultaneous transmission of the acquired signals via a serial RS232 port.

5

BACKGROUND TO THE INVENTION

Shifts in patient care, practices are changing the nature of monitoring. Increasingly, hospitals are attempting to lower costs by moving high-acuity patients as quickly as possible from intensive care units (ICU) to intermediate care and general ward areas.

10 This trend has dramatically reduced the need for the high end stationary, multi-parameter monitoring systems typically employed in the ICU. This has intensified demand for a more flexible, and therefore less expensive, systems that can easily be integrated into lower-acuity areas and configured to individual patient needs.

This is particularly the case in heart rate monitoring where the ECG is the well known form of monitoring.

15 In respect of foetal monitoring, the foetal heart rate (FHR) is the primary indicator of foetal viability. Current methods utilise FHR charts and are based on the detection of the mechanical activity of the heart via active ultrasound devices and interpretation by the clinician or nurse.

Foetal heart electrical activity has been analysed since the beginning of this century.

20 However, problems associated with the small amplitude of the foetal signals and the influence of noise, have made the foetal ECG (FECG) difficult. FECG acquired from surface electrodes have a very low amplitude and the FECG data is masked by the maternal ECG (MECG). This problem results in the requirement of expensive ultrasound analysis systems for calculating the foetal heart rate.

25 Therefore it is seen that inexpensive monitoring technologies are needed to enable surveillance of all pregnancies during the second and the last trimester and, in particular, to

determine the appropriateness of intervention to minimise a potential risk to mother and foetus.

Therefore it would be advantageous to provide a physiological signal acquisition apparatus which provides real time and/or simultaneous transmission of the acquired signals which is
5 simpler and therefore less expensive than known apparatus.

OBJECT OF THE INVENTION

It is an object of the present invention to provide a physiological signal acquisition apparatus which substantially overcomes or ameliorates the above mentioned disadvantages. At the very least, the object of the invention is to provide an alternative to
10 known physiological signal acquisition apparatus.

DISCLOSURE OF THE INVENTION

According to one aspect of the present invention there is disclosed a physiological signal acquisition monitoring apparatus having a bio sensor connected by cable means to an electrically isolated bio acquisition unit including an amplifying and control means which is
15 serially connected by cable means to a display device for displaying in real time the resulting graphically representation of the physiological signal.

Preferably, the display device is a notebook PC, a palmtop PC and/or smart panel.

Preferably, the physiological signal acquisition cable monitor is used to acquire and display ECG, FECG, or to monitor blood pressure, asthma control, pacemaker monitoring,
20 monitoring oxygen saturation, diabetes measurements, heart sounds and the like.

Preferably the bio sensor is electrodes or other pickup device.

Preferably the results are recorded by the display device as well as being shown in real time.

According to one aspect of the present invention there is disclosed a portable and multipurpose medical device for biological signals acquisition, display and biological data storage, said device comprising:

a display and storage device a display and storage device comprising:

5 a first housing;

a display screen being provided on the first housing for displaying the acquired data; control means disposed within the first housing to control data acquisition options, storage of the acquired data, and other application specific functions of the medical device;

a biological signals acquisition module comprising:

10 a second housing;

a plurality of biological sensors;

an analog circuit to amplify and pre-condition biological signals from the plurality of the biological sensors;

a digital circuit for digitizing the biological signal and to send the biological data to said

15 first housing; and

connector means connecting the first and second housings.

Preferably, the connector means is a cable means serially connecting the first and second housings.

Preferably, the display device is a notebook PC, a palmtop PC and/or smart panel.

20 Preferably, the physiological signal acquisition monitoring and display device is used to simultaneously acquire and physiological signals from a plurality of sensors measuring at least one of the group including multilead ECG, FECG, EEG, EMG, oximetry, blood pressure whether detected by invasive or non-invasive means, respiration, temperature, phonocardiogram, tokolytic, blood glucose, pCO₂, pO₂ and pacemaker pulses, and
25 condition the signals and transmit data representing the signals in real time to an input/output port of the display device.

Preferably, the circuit means includes an isolated section, a non-isolated section with an isolation barrier therebetween, the isolated section being isolated from the input/output port of the display device. The isolated section receives the signals from the sensors and amplifies and preconditions the signals into data specific to the signal type prior to
5 transmitting the data through the isolation barrier.

Preferably, the non-isolated section receives the data transmitted through the isolation barrier and prepares the data for transmission to input/output port of the display device via an input/output interface in the first housing and a cable means to the input/output port of the display device which is a second housing of the apparatus.

10 BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be now be described with reference to the accompanying drawings in which:

Fig. 1 is a perspective view of a preferred embodiment of the the apparatus of the present invention,

15 Fig. 2 is a block diagram of the apparatus of Fig. 1, and

Fig. 3 is a block diagram of another preferred embodiment of the apparatus of the present invention.

BEST MODE OF CARRYING OUT THE INVENTION

One embodiment of a physiological signal acquisition cable monitoring apparatus 10 is
20 illustrated in Figs. 1 and 2 of the drawings. The apparatus 10 preferably acquires an ECG and therefore includes electrodes or bio sensor 11 connected by cable 12 to an acquisition unit 13. The unit 13 includes a bio amplifier 14 and a control unit 15. The acquisition unit 13 is serially connected by cable 16 to a laptop display and storage device 17.

The acquisition unit 13 acquires the ECG while simultaneously displaying the ECG waveform on the display of the laptop in real time. The type of display and software of the display determine the level of cardiac information to be analysed, displayed and/or recorded.

- 5 The cable 16 includes access for a power supply line 18 to the acquisition unit 13 from the laptop, a serial control data line 19 and a output serial data line 20. The cable is connected to the laptop via a RS232 serial port 21 which allows the various signals to be acquired and displayed in real time.

- The invention, however, is not limited to acquisition of ECG signals only. For example,
10 FECG, EEG, EMG, oximetry, blood pressure whether detected by invasive or non-invasive means, respiration, temperature, phonocardiogram, tokolytic, blood glucose, pCO₂, pO₂ and pacemaker pulses.

- A block diagram of another ECG acquisition module 30 is shown in Fig. 3. The ECG signal is collected via the sensors 31 and amplified by amplifier 32. The amplifier 32 is
15 DC biased by the virtual ground potential produced by a virtual ground generator 33. The amplified analogue signal is fed to the input of analogue to digital converter (ADC) 34. The ADC 12 has two control inputs (-CS and CLK) and one output (DO). Control signals -CS and CLK are supplied by the display device 17 via its serial port 21, the connector and the cable 16 to a serial port interface 35 of the ECG acquisition module 30.

- 20 The amplified analogue signal is converted into digital ECG data (DO) and sent to the display device 17 via the serial port interface 35 of the ECG acquisition module 30, the cable 16, the connector and internal circuitry of the display and storage device 17.

- Digital ECG data being stored in the display device 17 are accessible for displaying, calculations and overwriting. Control and data signals flow is defined by the display
25 device 17.

Hardware Implementation

The ECG amplifier 32 is comprised of a high input impedance front stage voltage follower (U1a, U1b), instrumentation amplifier U2, high pass filter (C3, R4), second amplification stage U1d and a low pass anti-aliasing filter (R7, C4).

- 5 Front stage voltage followers use popular LMC6464 operational amplifier from National Semiconductors with input current less than 1nA.

It is believed that the preferred embodiment as described meets AAMI/ANSI ECG recommended safety standards which will include an electrical isolation barrier 36 as seen in Fig. 3.

- 10 All digital signals are transferred via digital optical isolators. A high pass filter defines the low end of the frequency band of the acquired ECG signal at 0.05Hz. A low pass filter removes high frequency noise on the input of ADC. Frequency response of the ECG amplifier for the selected filters values is 0.05Hz – 100Hz. 100Hz high end frequency is defined by the selected sample rate of 200Hz is in a compliance with the AAMI/ANSI
- 15 ECG recommended frequency response standards.

Instrumentation amplifier INA126 from Burr-Brown Corporation is configured for a gain of 5. DC offset voltage is calculated as V_{CC}/Gain , where $V_{CC} = 5V$ and $\text{Gain} = 5$. DC offset voltage $V_{dc} = 5/5 = \pm 500mV$ is well above required by the AAMI/ANSI ECG standard of minimum of $\pm 300mV$.

- 20 The ECG acquisition module 30 uses single positive voltage derived from the display device 17 serial connector.

In order to amplify bipolar AC ECG signal without distortions, input stage voltage followers and instrumentation amplifier are referenced to AMP_REF voltage = $V_{CC}/2$ generated by the virtual ground generator U1c.

Second stage of the amplifier is referenced to AMP_REF as well in order to bring the output signal to the half of ADC reference voltage.

The gain of second amplifier stage is defined by the values R5 and R6 and set to 151. Overall gain is 755.

- 5 The foregoing 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 of the present invention.

CLAIMS

1. A physiological signal acquisition monitoring apparatus having a bio sensor connected by cable means to an electrically isolated bio acquisition unit including a amplifying and control means which is serially connected by cable means to a display
5 device for displaying in real time the resulting graphically representation of the physiological signal.
2. The physiological signal acquisition monitoring apparatus according to claim 1, wherein the display device is a notebook PC, a palmtop PC and/or smart panel.
3. The physiological signal acquisition monitoring apparatus according to claim 1,
10 wherein the physiological signal acquisition cable monitor is used to acquire and display ECG, FECG, or to monitor blood pressure, asthma control, pacemaker monitoring, monitoring oxygen saturation, diabetes measurements, heart sounds and the like.
4. The physiological signal acquisition monitoring apparatus according to claim 1, wherein the bio sensor is electrodes or another pickup device.
- 15 5. The physiological signal acquisition monitoring apparatus according to claim 1, wherein the results are recorded by the display device as well as being shown in real time.
6. A multipurpose medical device for biological signals acquisition, display and biological data storage, said device comprising:

a display and storage device a display and storage device comprising:
20 a first housing;
a display screen being provided on the first housing for displaying the acquired data;
control means disposed within the first housing to control data acquisition options, storage of the acquired data, and other application specific functions of the medical device;

a biological signals acquisition module comprising:
25 a second housing;

a plurality of biological sensors;

an analog circuit to amplify and pre-condition biological signals from the plurality of the biological sensors;

a digital circuit for digitizing the biological signal and to send the biological data to said

5 first housing; and

connector means connecting the first and second housings.

7. A multipurpose medical device for biological signals acquisition, display and biological data storage according to claim 6, wherein the connector means is a cable means serially connecting the first and second housings.

10 8. A multipurpose medical device for biological signals acquisition, display and biological data storage according to claim 6, wherein the display device is a notebook PC, a palmtop PC and/or smart panel.

9. A multipurpose medical device for biological signals acquisition, display and biological data storage according to claim 6, wherein the physiological signal acquisition
15 monitoring and display device is used to simultaneously acquire and physiological signals from a plurality of sensors measuring at least one of the group including multilead ECG, FECG, EEG, EMG, oximetry, blood pressure whether detected by invasive or non-invasive means, respiration, temperature, phonocardiogram, tokolytic, blood glucose, pCO₂, pO₂ and pacemaker pulses, and condition the signals and transmit data representing the signals
20 in real time to an input/output port of the display device.

10. A multipurpose medical device for biological signals acquisition, display and biological data storage according to claim 6, wherein the circuit means includes an isolated section, a non-isolated section with an isolation barrier therebetween, the isolated section being isolated from the input/output port of the display device.

25 11. A multipurpose medical device for biological signals acquisition, display and biological data storage according to claim 10, wherein the isolated section receives the

signals from the sensors and amplifies and preconditions the signals into data specific to the signal type prior to transmitting the data through the isolation barrier.

12. A multipurpose medical device for biological signals acquisition, display and biological data storage according to claim 11, wherein the non-isolated section receives the data transmitted through the isolation barrier and prepares the data for transmission to input/output port of the display device via an input/output interface in the first housing and a cable means to the input/output port of the display device which is a second housing of the apparatus.

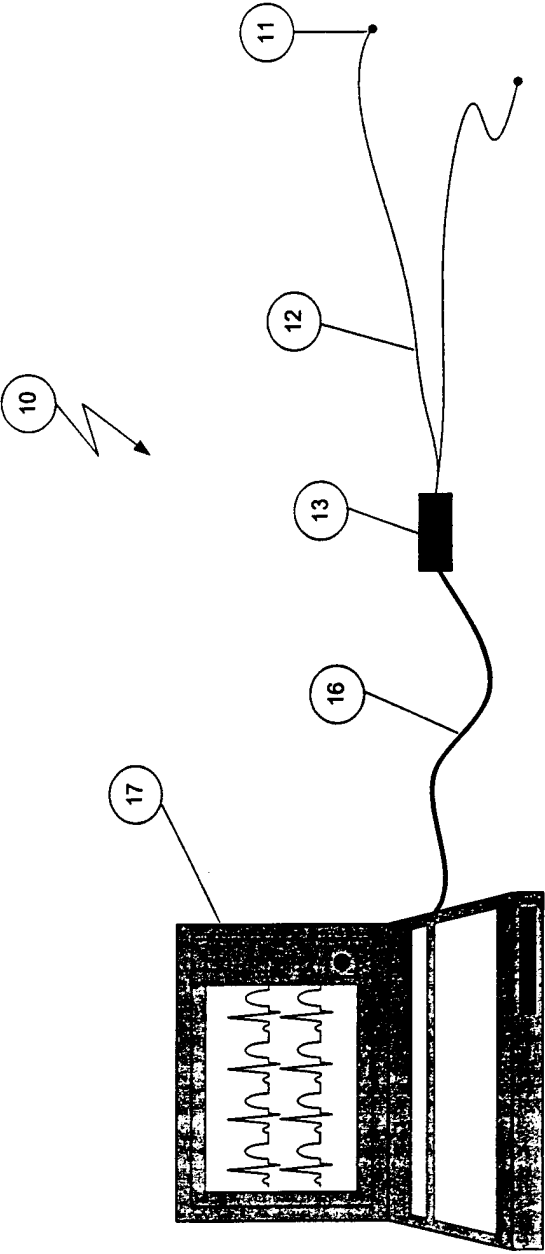
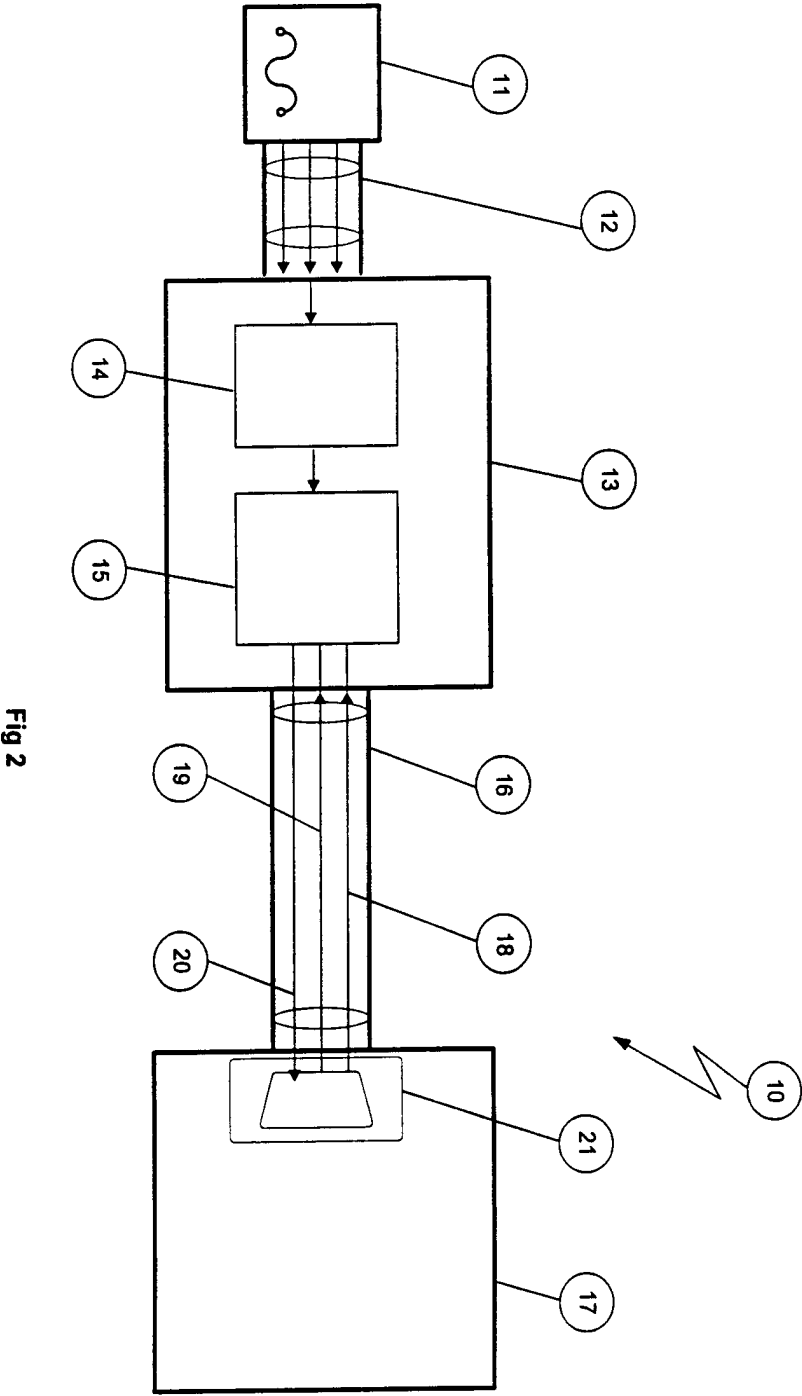


Fig 1



3/3

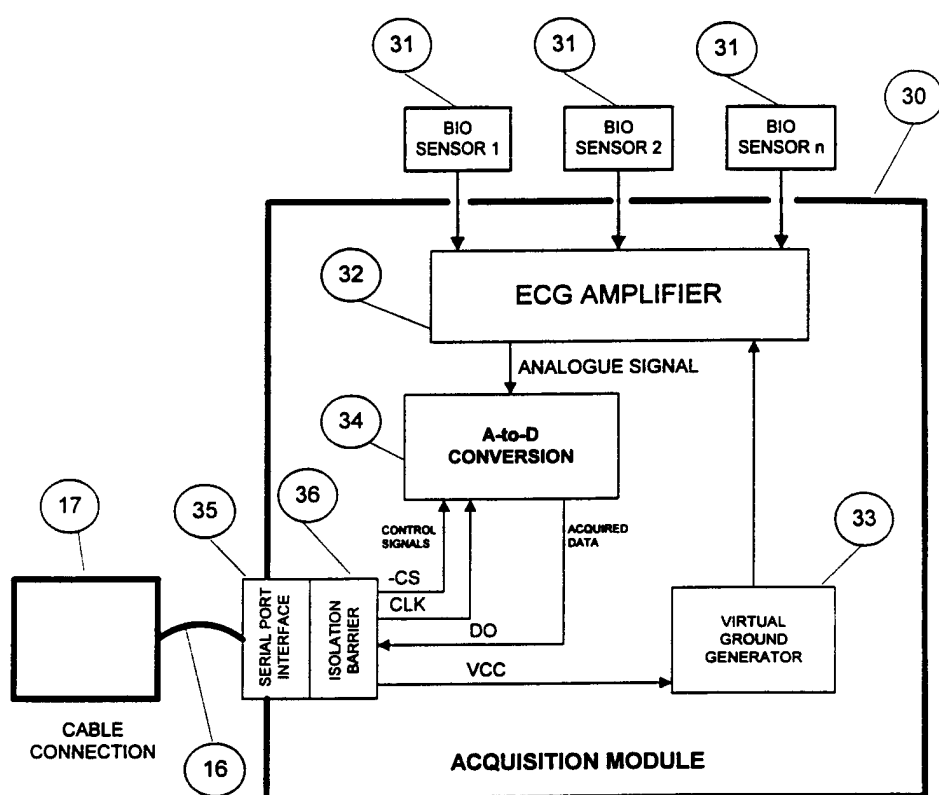


Fig 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00404

A. CLASSIFICATION OF SUBJECT MATTER																						
Int. Cl. ⁷ : A61B 5/04																						
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 G06F																						
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																						
C. DOCUMENTS CONSIDERED TO BE RELEVANT																						
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.																				
X	WO 91/02484 (BIOMETRAK CORPORATION) 7 March 1991 Page 12 line 2 to page 15 line 13	1 to 12																				
X	WO 89/02247 (SANDERS) 23 March 1989 Page 7 line 14 to page 9 line 18	1 to 12																				
X	US 5899855 (BROWN) 4 May 1999 Column 10 lines 35 to 41, figure 1	1 to 12																				
☒ Further documents are listed in the continuation of Box C ☒ See patent family annex																						
* Special categories of cited documents: <table border="0"> <tr> <td>"A"</td> <td>document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T"</td> <td>later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E"</td> <td>earlier application or patent but published on or after the international filing date</td> <td>"X"</td> <td>document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L"</td> <td>document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y"</td> <td>document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O"</td> <td>document referring to an oral disclosure, use, exhibition or other means</td> <td>"&"</td> <td>document member of the same patent family</td> </tr> <tr> <td>"P"</td> <td>document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family	"P"	document published prior to the international filing date but later than the priority date claimed		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention																			
"E"	earlier application or patent but published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone																			
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art																			
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Date of the actual completion of the international search 5 July 2000		Date of mailing of the international search report 19 JUL 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 <i>D. Melhuish</i> DAVID MELHUISE Telephone No : (02) 6283 2426																				

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00404

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 601589 (SIEMENS MEDICAL SYSTEMS, INC.) 15 June 1994 Column 15 lines 3 to 37, figure 3	1 to 12
X	US 5581369 (RIGHTER et al.) 3 December 1996 Column 3 line 46 to column 4 line 42	6 to 12

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00404

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 91/02484	AU 52801/90	US 5020540	CA 2064791	EP 489010	
WO 89/02247	AU 25302/88	CA 1326884	US 4858617		
US 5899855	AU 56088/94	CA 2148708	EP 670064	US 5307263	WO 94/11831
	US 5960403				
EP 601589					
US 5581369					
					END OF ANNEX

专利名称(译)	生理信号采集电缆		
公开(公告)号	EP1191877A4	公开(公告)日	2003-05-02
申请号	EP2000920284	申请日	2000-05-08
[标]申请(专利权)人(译)	SHELL ALLAN MICHAEL PLATT HARRY LOUIS JANKOV VLADIMIR		
申请(专利权)人(译)	SHELL , ALLAN MICHAEL 普拉特HARRY LOUIS JANKOV , VLADIMIR		
当前申请(专利权)人(译)	SHELL , ALLAN MICHAEL 普拉特HARRY LOUIS JANKOV , VLADIMIR		
[标]发明人	PLATT HARRY LOUIS JANKOV VLADIMIR		
发明人	PLATT, HARRY, LOUIS JANKOV, VLADIMIR		
IPC分类号	A61B5/00 A61B5/0402 A61B5/0428 A61B5/0444 A61B5/0476 A61B5/0488 A61B5/08 A61B5/1473 A61B5/1477 A61N1/08 A61N1/37 A61B5/04		
CPC分类号	A61B5/04282		
代理机构(译)	WHARTON , PETER ROBERT		
优先权	1999PQ2257 1999-08-16 AU 1999PQ0184 1999-05-06 AU		
其他公开文献	EP1191877A1		
外部链接	Espacenet		

摘要(译)

生理信号采集监测装置具有生物传感器 (11,31) , 其通过电缆装置 (12) 连接到电隔离的生物采集单元 (13,30) , 该生物采集单元包括放大器 (14,32) 和控制装置 (15) , 其是通过电缆装置 (16) 串联连接到显示装置 (17) , 用于实时显示生理信号的结果图形表示。