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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	704_049	7955

20874 7590 07/20/2009

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EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
07/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/591,619	BAKER ET AL.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39 & 41-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39 & 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/3/08 & 2/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. **Claims 1-5 & 12-18** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fadem et al. (US 2007/0270678).

Fadem et al. discloses a body worn patient monitoring device {e.g., [0002] & (Fig 1, 10) comprising; at least one disposable module (35) including a plurality of electrical connections (33), comprising at least one half cell (32/33) adapted to be couplable to a skin surface and a disposable module connector {e.g., [0042]-[0044] & (Figs 2 & 8)}; at least one internal power source to power said device (e.g., Fig 1, 24); and at least one communication-computation module (23) including at least one microprocessor (66) and a radio circuit (63), wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one

communication-computation module and the body worn patient monitoring device, in which are adapted to be directly non-permanently affixed to the skin surface of the patient {e.g., [0020]-[0023], [0046] & (Fig 8)}. Note that the Examiner is interpreting the reference contact (32) electrically coupled to the reference conductive adhesive pad (33) as being the at least one disposable module having at least one electrical connections comprising a half cell as is instantly claimed (e.g., Fig 2).

In the alternative, Fadem et al. discloses the claimed invention having a body worn patient monitoring device with at least one disposable module including a plurality of electrical connections consisting of a reference contact (32) and reference conductive adhesive pad 33) electrically coupled together except wherein said electrical connections comprise a half cell. It would have been obvious to one having ordinary skill in the art to have modified the device with the use of electrical connections comprising a half cell, since it is known in the art that said electrical connection comprising a half cell is used to provide the predictable results pertaining to providing an electrode structure that makes an efficient electrical contact with a patient's skin and enhances the skin's conduction so as to properly capture physiological measurements for said patient [e.g., 0044].

4. **Claims 6-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fadem et al. (US 2007/0270678) in view of Merry et al. (US 6,623,312)

Fadem et al. discloses the claimed invention having a body worn patient monitoring device except wherein said device further comprises at least one series current-limiting resistor. Merry et al. teaches that it is known to use an electrode structure comprising a current-limiting

resistor [e.g., (col 1, ln 7-10), (col 7, ln 32-59) & (Fig 3, 294)]. It would have been obvious to one having ordinary skill in the art to have modified the device as taught by Fadem et al. with the current-limiting resistor as taught by Merry et al., since such a modification would provide the body worn patient monitoring device with at least one series current-limiting resistor for providing the predictable results pertaining to limiting the amount of current that passes through the electrode's circuit to a predetermined, safe level, so as to prevent high loads from reaching the sensing device (e.g., Merry, col 7, ln 32-59).

5. **Claims 19-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fadem et al. (US 2007/0270678) in view of Schraag (US 5,309,918).

Fadem et al. discloses the claimed invention having a body worn monitoring device except for the device further comprising at least one electrical connection being a reference electrode that can be used to improve common mode rejection (CMR). Schraag teaches that it is known to use an transducer further comprising a reference electrode incorporated as an electrical contact, which improves the common-mode rejection ratio of the transducer [e.g., (col 1, ln 17-20), (col 7, ln 17-34) & (col 8, ln 27-37)]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn monitoring device as taught by Fadem et al. with the reference electrode incorporated as an electrical contact as taught by Schraag, since such a modification would provide the predictable results pertaining to improving the common mode rejection ratio achieved by utilizing a reference electrode so as to properly obtain electrical, physiological measurements by way of making electrical contact with the skin of a patient (e.g., Schraag, col 8, ln 27-37).

6. **Claims 25-32, 39 & 42-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fadem et al. (US 2007/0270678) in view of Jackson et al. (US 2005/0137489).

Fadem et al. discloses the claimed invention having a body worn monitoring device except wherein said device further comprises a pacer detection circuit and a circuit protection component allowing said device to survive multiple defibrillation cycles. Jackson et al. teaches that it is known to use a method of predicting a cardiac event by utilizing an external monitoring device that further comprises a microcontroller (224) used to control and operate a pacing timing and control circuitry (212) and a defibrillation control circuitry (230) {e.g., [0012], [0031] & (Fig 2)}. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Fadem et al. with the external monitoring system having a pacing timing and control circuitry and a defibrillation control circuitry as taught by Jackson et al., since such a modification would provide the body worn monitoring device with a pacer detection circuit and a circuit protection component allowing said device to survive multiple defibrillation cycles for providing the predictable results pertaining to detecting a particular cardiac event and providing a pacing therapy based on said event, wherein if said pacing therapy requires high voltage cardioversion and/or defibrillation pulses a means for controlling said high voltage treatment is set into place so as to initiate and/or terminate the high voltage therapy based on the monitored high voltage being compared to a predetermined value [Jackson, 0031].

7. **Claims 33-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fadem et al. (US 2007/0270678) in view Westra et al. (US 2006/0183434).

Fadem et al. discloses the claimed invention having a body worn monitoring device except for a device further comprising a high pass filter with a selectable corner frequency. Westra et al. teaches that it is known to use an electronic communication system comprising a high pass filter additionally having a tunable corner frequency (e.g., [0012] & [0014]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn device as taught by Fadem et al. with the high pass filter having a tunable corner frequency as taught by Westra et al., since such a modification would provide the predictable results pertaining to selectively filtering out unwanted information so as to filter physiological signals monitored by said body worn device [e.g., Westra, 0014].

8. **Claim 38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fadem et al. (US 2007/0270678) in view of Eshelman et al. (US 2003/0001742).

Fadem et al. discloses the claimed invention having a body worn monitoring device comprising a communication-computation module except for a device further comprising circuit components to detect failure of contact of one or more of the electrical connections with the skin surface of the patient. Eshelman et al. teaches that is known to use an invention relating to assisting people with disabilities further comprising a biosensors in which includes a skin contact detector capable or monitoring biological processes measurable on the user's skin {e.g., [0029] & (Fig 2, 27)}. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the body worn device as taught by Fadem et al. with the skin contact detector as taught by Eshelman et al., since such a modification would provide the predictable results pertaining to monitoring biological processes measurable on the user's skin,

such as detecting danger zones in a parameter space so as to effectively determine if there is an contact failure between said device and a patient's skin [e.g., Eshelman, 0029].

9. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fadem et al. (US 2007/0270678) in view of Owen et al. (US 2003/0055460).

Fadem et al. discloses the claimed invention having a body worn monitoring device except for the body monitoring device further comprising an algorithm running on a microprocessor in the device, causing the device to enter a low power mode that disables at least one circuit of the device to save power. Owen et al. teaches that it is known to use a personable wearable cardiac device further comprising a power saving feature by way of a processor that is capable of operating in different modes, such as a low-power mode, during which the processor consumes different amounts of power (e.g., [0175]-[0176]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn monitoring device as taught by Fadem et al. with the processor having a power saving feature capable of operating in different modes as taught by Owen et al., since such modification would provide the predictable results pertaining to operating a device in different power-saving modes, such as a low-power mode, in order to consume efficient amounts of power [e.g., Owen, 0175].

Response to Arguments

10. Applicant's arguments with respect to claims 1-44 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendments.

11. Applicant's arguments, filed 24 March 2009, with respect to the §101 rejections of the claims and the objections to the drawings and specification have been fully considered and are persuasive and have been withdrawn.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (alt. fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762

Notice of References Cited	Application/Control No. 11/591,619	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,294,928 A	03-1994	Cooper et al.	341/142
*	B	US-5,309,918 A	05-1994	Schraag, Martin	600/508
*	C	US-2003/0001742 A1	01-2003	Eshelman et al.	340/573.1
*	D	US-2003/0055460 A1	03-2003	Owen et al.	607/5
*	E	US-6,623,312 B2	09-2003	Merry et al.	439/729
*	F	US-2005/0137489 A1	06-2005	Jackson et al.	600/515
*	G	US-2006/0074284 A1	04-2006	Juola et al.	600/372
*	H	US-2006/0136001 A1	06-2006	Ortega et al.	607/009
*	I	US-2006/0183434 A1	08-2006	Westra et al.	455/078
*	J	US-2007/0270678 A1	11-2007	Fadem et al.	600/372
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11591619	BAKER ET AL.
	Examiner	Art Unit
	NICOLE F LAVERT	3762

SEARCHED			
Class	Subclass	Date	Examiner
607	60	12/4/2008	NFL
600	372 & 382	12/4/2008	NFL
ABOVE	UPDATED	7/7/2009	NFL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Search (EDAN)	12/4/2008	NFL
EAST Search (see attachment)	12/4/2008	NFL

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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BIB DATA SHEET

CONFIRMATION NO. 7955

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/591,619	11/01/2006 RULE	600	3762	704_049

APPLICANTS

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James P. Welch, Laguna Niguel, CA;
Norbert Ohlenbusch, Andover, MA;
Thomas P. Blackadar, Natick, MA;

**** CONTINUING DATA **************************

**** FOREIGN APPLICATIONS **************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****
11/21/2006

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☑ No	/NICOLE F LAVERT/ Examiner's Signature	☐ NFL Initials	OR	14	58	6

ADDRESS

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UNITED STATES

TITLE

Body worn physiological sensor device having a disposable electrode module

FILING FEE RECEIVED		
3630	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	985	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:02
L3	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:09
L4	254	600/382.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:15
L5	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:29
L6	1	l5 and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:29
L8	4	"20040242976" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:32
L9	8148	implantable same housing	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:32

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L10	6084	l9 and medical	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
L11	1908	l10 and module	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
L12	148	l11 and modular	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
L13	0	"20040176818" and ECG	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:17
L14	1	"20040176818" and cardiac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:17
L15	1	"11591619" and disposable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:59
L16	5	"20040242976"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:01
L17	0	"20040176818" and releas$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:06

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L18	0	"20040176818" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:08
L19	162763	dispos$4 same electrodes	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:15
L20	1241	l19 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
L21	231	"l120" and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
L22	102	l21 and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
L23	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
L24	84	l23 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
L25	1	"11591619" and (indirect same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26

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L26	1	"11591619" and (indirect same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26
L27	1	"11591619" and (direct same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:28
L28	1	"20070270678" and "30"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
L29	1	"20070270678" and strip	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
L30	0	"20070270678" and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
L31	2	"20060074284"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
L32	2	"20070270678" and substrate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:05
L33	15	"6064901"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:08

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L34	0	l33 and resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:12
L35	145267	(current same limit$4) and electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
L36	1311	l35 and (disposable same electrode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
L37	116	l36 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
L38	10	l37 and ((current same limit$4) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:14
L39	1	"11591619" and annulus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:20
L40	0	"11591619" and Seebeek	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:22
L41	1	"11591619" and Seebeck	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:23

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Page 600

L42	2	"20060183434"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:40
L43	9	"6623312"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:46
S1	916	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:17
S2	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:39
S3	1	S2 and "407"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:39
S4	0	S2 and "403"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:40
S5	1	S2 and "504"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:50
S6	1	S2 and "511"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:51

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Page 601

S7	0	S2 and "513"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:54
S8	1	S2 and radio	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:54
S9	0	S2 and "518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:55
S10	1	S2 and "514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:55
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S12	1	S2 and "802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:59
S13	0	S2 and "1002"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:02
S14	0	S2 and "R1002"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:02

iRhythm, Inc. / Welch Allyn, Inc.
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Page 602

S15	1	S2 and "1601"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:05
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S18	499	607/36.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:10
S19	3959	600/300.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:24
S20	472	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:25
S21	2	S17 and (ECG or heart)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 14:11
S22	2	"20030055460"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 14:13

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Page 603

S23	7	"5309918"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 17:39
S24	2	"20060189976"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 17:44
S25	2	"20060136001"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 17:48
S26	2	"20060183434"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:10
S27	2	"20060136001"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:13
S28	2	"20020122519"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:16
S29	31	"4141367"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:18
S30	2	"20030001742"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:19

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Exhibit 1002
Page 604

S31	3	"20060044856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:48
S32	47	"5294928"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:51
S33	2	"20040113806"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:53
S34	6	"4800894"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:55
S35	12373	external same (medical same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:06
S36	1683	S35 and (worn or wearable)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:06
S37	832	S36 and (power same source)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:06
S38	748	S37 and (electrodes or sensors)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:07

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S39	132	S38 and (capacitors and substrate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:07
S40	3	"20060205171"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:11
S41	3	"20060044856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:13
S42	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/05 11:13
S43	5	"20040242976"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/05 11:16
S44	3	"5309918" and (mode same rejection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/05 13:49

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Page 606

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	7	Application Number	11/591,619-Conf. #7955
		Filing Date	November 1, 2006
		First Named Inventor	Steven D. Baker
		Art Unit	3736
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	704_049

ENCLOSURES (*Check all that apply*)

☐ Fee Transmittal Form	☐ Drawing(s)	☐ After Allowance Communication to TC
☐ Fee Attached	☐ Licensing-related Papers	☐ Appeal Communication to Board of Appeals and Interferences
☐ Amendment/Reply	☐ Petition	☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brie.)
☐ After Final	☐ Petition to Convert to a Provisional Application	☐ Proprietary Information
☐ Affidavits/declaration(s)	☐ Power of Attorney, Revocation Change of Correspondence Address	☐ Status Letter
☐ Extension of Time Request	☐ Terminal Disclaimer	☒ Other Enclosure(s) (please Identify below):
☐ Express Abandonment Request	☐ Request for Refund	Form PTO/SB08/A/B (2 pgs); Return Mailroom Postcard; foreign references BA-BH; Certificate of Mailing (IDS)
☒ Information Disclosure Statement	☐ CD, Number of CD(s) _____	
☐ Certified Copy of Priority Document(s)	☐ Landscape Table on CD	
☐ Reply to Missing Parts/ Incomplete Application	Remarks	
☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MARJAMA & BILINSKI LLP		
Signature	Peter J. Bilinski		
Printed name	Peter J. Bilinski		
Date	February 16, 2007	Reg. No.	35,067

Transmittal

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV967909486US, on the date shown below in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 16, 2007 Signature: Cheryl M Nichols (Cheryl Nichols)



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Dated: February 16, 2007 Signature: (Cheryl Nichols)

Docket No.: 704_049
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Steven D. Baker et al.

Application No.: 11/591,619 Confirmation No.: 7955

Filed: November 1, 2006 Art Unit: 3736

For: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)). Therefore, it is believed no fee is required.

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant herein submits English language versions and/or Abstracts for each of the attached foreign documents, pursuant to 37 CFR 1.97(c) and (e)(1) or (b)(3).

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0289, under Order No. 704_049. A duplicate copy of this paper is enclosed.

Dated: February 16, 2007

Respectfully submitted,

By _____

Peter J. Bilinski
Registration No.: 35,067
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Suite 300
Syracuse, New York 13202
(315) 425-9000
Customer No. 20874

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	11/591,619-Conf. #7955
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/N.F.L/	AA	US-2003-0149349A1	08/07/2003	Jensen	
	AB	US-4,791,933	12/20/1988	Asai et al.	
	AC	US-4,957,109	09/18/1990	Groeger et al.	
	AD	US-4,958,645	09/25/1990	Cadell et al.	
	AE	US-4,974,607	12/04/1990	Miwa	
	AF	US-5,257,631	11/02/1993	Wik	
	AG	US-5,458,122	10/17/1995	Hethuin	
	AH	US-5,538,007	07/23/1996	Gorman	
	AI	US-5,544,661	08/13/1996	Davis et al.	
	AJ	US-5,694,940	12/09/1997	Unger et al.	
	AK	US-5,743,269	04/28/1998	Okigami et al.	
	AL	US-5,832,490	11/03/1998	Riley	
	AM	US-5,871,451	02/16/1999	Unger et al.	
	AN	US-5,882,300	03/16/1999	Malinouskas et al.	
	AO	US-5,899,866	05/04/1999	Cyrus et al.	
	AP	US-5,916,159	06/29/1999	Kelly et al.	
	AQ	US-5,919,141	07/06/1999	Money et al.	
	AR	US-5,938,597	08/17/1999	Stratbucker	
	AS	US-5,966,692	10/12/1999	Langer et al.	
	AT	US-5,987,519	11/16/1999	Peifer et al.	
	AU	US-5,995,861	11/30/1999	Price	
	AV	US-6,006,125	12/21/1999	Kelly et al.	
	AW	US-6,018,705	01/25/2000	Gaudet et al.	
	AX	US-6,026,321	02/15/2000	Miyata et al.	
	AY	US-6,052,654	04/18/2000	Gaudet et al.	
	AZ	US-6,066,093	05/23/2000	Kelly et al.	
	AA1	US-6,073,046	06/06/2000	Patel et al.	
	AB1	US-6,076,003	06/13/2000	Rogel	
	AC1	US-6,122,340	09/19/2000	Darley et al.	
	AD1	US-6,150,951	11/21/2000	Olejniczak	
	AE1	US-6,161,036	12/12/2000	Matsumura et al.	
	AF1	US-6,171,237B1	01/09/2001	Avitall et al.	
	AG1	US-6,298,314B1	10/02/2001	Blackadar et al.	
	AH1	US-6,336,365B1	01/08/2002	Blackadar et al.	
	AI1	US-6,357,147B1	03/19/2002	Darley et al.	
	AJ1	US-6,493,652B1	12/10/2002	Ohlenbusch et al.	
	AK1	US-6,794,990B2	09/21/2004	Tseng	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
/N.F.L/	BA	EP 0209804 A2	01-28-1987	Rossi, Paolo		
	BB	WO 9620641 A1	07-11-1996	Polar Electro Oy		
	BC	WO 9629005 A1	09-26-1996	Citizen Watch Co. Ltd.		

Examiner Signature	/Nicole LaVert/	Date Considered	07/07/2009

PTO/SB/08A/B (09-06)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	11/591,619-Conf. #7955
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049

/N.F.I/	BD	EP 0770349 A1	05-02-1997	Akasaka, Noboru		
	BE	WO 9746156 A1	12-11-1997	Data Critical Corp.		
	BF	JP 11042214	02-16-1999	Ido Teruo		
	BG	EP 0910985 A1	04-28-1999	Stratbucker, Robert Allen		
	BH	WO 9959460 A2	11-25-1999	Biosys AB		

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

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[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Nicole LaVert/	Date Considered	07/07/2009



Application No. (if known): 11/591,619 Attorney Docket No.: 704_049

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Registration Number, if applicable

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IDS (Citation) by Applicant (45 References) (2 pages)

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 1

Complete if Known	
Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049 US01

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/N.F.L/	AL1	US-4,141,367 A	02/27/1979	Ferreira	
	AM1	US-4,800,894 A	01/31/1989	Milani	
	AN1	US-5,294,928 A	03/15/1994	Cooper, et al.	
	AO1	US-5,309,918 A	05/10/1994	Schraag	
	AP1	US-2002/0122519 A1	09/05/2002	Douglas, et al.	
	AQ1	US-2003/0001742 A1	01/02/2003	Eshelman, et al.	
	AR1	US-2003/0055460 A1	03/20/2003	Owen, et al.	
	AS1	US-2004/0113806 A1	06/17/2004	Neykov	
	AT1	US-2004/0242976 A1	12/02/2004	Abreu	
	AU1	US-2006/0044856 A1	03/02/2006	Bird, et al.	
	AV1	US-2006/0136001 A1	06/22/2006	Ortega, et al.	
	AW1	US-2006/0183434 A1	08/17/2006	Westra, et al.	
	AX1	US-2006/0189976 A1	08/24/2006	Karni, et al.	
	AY1	US-2006/0205171 A1	09/14/2006	Tsukada	
		US-			
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		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] - Number[4] - Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	/Nicole LaVert/	Date Considered	07/07/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	11/591,619
Applicant	:	Steven D. Baker
Filed	:	November 1, 2006
Art Unit	:	3762
Examiner	:	Nicole F. Lavert
Docket No.	:	3022036 US01
Confirmation No.:		7955
Customer No.	:	72742
Title	:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE

Sir:

In response to an Office Action mailed December 12, 2008, please amend the above-captioned patent application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims begin on page 6 of this paper.

Remarks begin on page 12 of this paper.

AMENDMENTS TO THE SPECIFICATION:

Please replace the following paragraphs with the following amended paragraphs:

[0043] FIG. 1B shows a side elevated view of physiological monitor 100 having an exemplary attachment mechanism, such as a retention clip 104, to mechanically attach communications and computation module 102 to the top surface of the disposable electrode module 110. Flexible printed circuit layer 101 can be made from a thin insulating material, such as according to this embodiment, a 75 micron thick layer of ~~Mylar~~ MYLAR®. Typically electrical traces (not shown in FIGS. 1A-1D) on flexible printed circuit layer 101 can be further protected by an insulating covering, analogous to a conformal coating. A formed plastic layer or a cloth with adhesive on one side thereof can be used to cover and protect flexible printed circuit layer 101, as well as to provide an aesthetic outer layer to make the body worn monitor 100 visually appealing.

[0049] FIG. 4A shows one embodiment of flexible circuit board 101 in an expanded (e.g. unassembled) view. Flexible circuit board 101 is formed on a substrate 406. Substrate 406 can be cut, for example, from a ~~Mylar~~ MYLAR® sheet of suitable thickness. In this embodiment, one battery 204 can be mounted adjacent to an conductive surface 404. Conductive gel 103 (not shown in FIG. 4) can be mounted on the exposed conductive side of a conductive surface 404.

[0054] As depicted herein on the exemplary circuit layout, two batteries 304 can be connected in series, with one polarity being made available at connection pad 407 from battery connection 402, battery connection 401 creating the series connection between the two batteries, and connection pad 410, from battery connection 403, providing the second polarity of the series connected batteries. Note that in some embodiments, a single battery alternatively may be used in lieu of the exemplary arrangement or two batteries can be also wired in parallel, depending on the voltage requirements of a particular communications and computation module 102.

[0059] In developing resistive traces for use on a flexible printed circuit layer 101, typically formed on a ~~Mylar~~ MYLAR® substrate 406, such as shown in FIG. 4A, various materials were tested. Silver, including silver inks, while useable, was found to be less desirable, because it was

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difficult to achieve sufficiently thin silver traces on ~~Mylar~~ MYLAR® to achieve high enough resistances. Carbon, including carbon pastes and carbon inks, was also tried and found to be suitable. In order to use carbon however, several additional problems had to be solved. At 1 kilo ohm, the power dissipated by the resistors caused them to degrade across multiple defibrillation cycles. The solution was to make carbon traces in the range of about 8 to 10 kilo ohms. 10 kilo ohm resistances proved to be a good compromise between noise levels, power dissipation by the resistors, and manufacturing tolerances for depositing carbon ink on a ~~Mylar~~ MYLAR® substrate to dissipate the power from multiple defibrillation cycles. To achieve the desired resistance of about 10 kilo ohms (interchangeably represented herein as "10 k" or "10 kΩ"), for a given resistivity of the carbon paste, and given trace width and thickness (height), the length of the trace is then defined. In some cases, such as for traces 412, the length needed for a trace run, as between conductive surface 404 and connection point 409, might be longer than the length defined for a particular trace resistance (typically 10 k). In this case, traces can be extended by lengths of silver conductive traces. There can be a short overlay distance, on the order of 5 to 10 mm, in which a silver trace overlaps the carbon trace to provide a more robust connection between the resistive and conductive portions of the traces. Where overlap is used, the overall length of the resistive portion can be adjusted slightly to maintain the desired overall resistance.

[0062] An alternative solution to the arcing problem is shown in FIG. 4C, wherein carbon can be laid down beyond the trace (412) to include a pattern of conductive surface 404 formed from carbon. A carbon annulus pattern can be deposited before the conductive surface 404 is deposited. Conductive surface 404 can then be deposited as an overlay over the earlier formed carbon annulus shape. Finally, conductive gel 103 can be attached to the conductive surface layer (the carbon layer residing between conductive surface 404 and the ~~Mylar~~ MYLAR® substrate used as flexible circuit board 101). Both of the aforementioned arcing solutions can be used together. It should also be noted that conductive surface 404 can be formed from suitable materials other than silver, including, for example, materials such as silver chloride.

[0066] Example: Silver traces for use as conductive (not resistive) traces on a body worn monitor circuit substrate were formed from a silver paste that was silk screened onto a ~~Mylar~~ MYLAR® substrate. 45 mm long traces had a measured resistance in a range of 3.5 to 6 ohms,

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75 mm traces had a measured resistance in a range of 6.5 to 13 ohms, and 105 mm traces had a measured resistance in a range of 10 to 16 ohms. The deposition of the silver layer was performed via the silk screen printing method in which a 90T silk screen mesh was used. The substrate containing the deposited silver ink was then cured inside a fan assisted air circulated oven at 120° C. for a period of 15 minutes.

[0068] The screen printing technique for laying down resistive traces was further investigated by printing a plurality of small carbon resistive dots 1601 of about 20 mm in diameter using a 7102 carbon ink applied by a screen printer (not shown). The carbon dots 1601 were laid out on a tray 1602 as shown in FIG. 16A, for baking in an oven. A manually operated squeegee (not shown) was used to apply the resistive dots 1601 to the tray 1602 through a mask (not shown). It was determined that control of thickness during application was one important factor for controlling the distribution of resistance. It was noted that during manual application, the variation of resistance depended upon the distance between the plurality of dots 1601 and the person applying the resistive paste, and that the pressure applied using the squeegee could also affect the final resistance by a factor of two. It was further noted that "even" heating across the tray 1602 was advantageous during oven drying, although this factor was found to have less effect on the final dot resistance distribution. A resistance distribution of the baked and measured dots 1601 is shown in the histogram of FIG. 16B. This testing indicated that production traces laid down on a substrate, such as ~~Mylar~~ MYLAR®, for use in a body worn monitor should preferably be printed using a semi-automatic screen print process, such as by a screen printing mechanical roller process. A digital multimeter ("DMM") with probes placed at each edge of a dot 1601 was used to measure the resistance from one edge of the dot to the other. It was found that uniform application of ink was important to keeping a tight distribution of resistance, with even heating having a smaller influence on the distribution of the resistance of the test dots. Since a trace with too low a resistance has a greater $\Delta R/R$, and higher probability of failing and very high resistance traces result in worse S/N ratio, it is important to have a reasonably tight tolerance on the trace resistance.

[0073] Electrical power from power source 515 can be regulated by regulator 514 and distributed as regulated voltage 517 to most function blocks (as represented herein by the label

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"POWER"), such as including the function block radio 513 which is electrically coupled to antenna 518. Each of these function blocks also has a control ("CTRL") input 511 from microprocessor 512, allowing these circuits to be disabled, when not needed, in order to save battery power. When viewed over time, most of the ECG waveform does not contain useful information since there is significant "dead time" between heart beats. Therefore, for example, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, circuits can be powered down (in a device "sleep mode") to save on the order of 60% of the energy stored in the power source that would have otherwise been used during this dead time.

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AMENDMENTS TO THE CLAIMS:

Claim 1 (currently amended): A body worn patient monitoring device comprising:

at least one disposable module including a plurality of electrical connections, the electrical connections adapted to be couplable to a skin surface to measure physiological signals, at least one of said electrical connections comprising a half cell, the at least one disposable module including a disposable module connector;

at least one internal or external power source to power the body worn patient monitoring device; and

at least one communication-computation module, having a communication-computation module connector to receive physiological signals from the at least one disposable module via said disposable module connector, the communication-computation module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals and a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module and the body worn patient monitoring device including the at least one disposable module and the at least one communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient.

Claim 2 (original): The body worn device of claim 1, wherein the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body.

Claim 3 (original): The body worn device of claim 2, wherein the indirect electrical connections to the body comprise capacitive connections to the body.

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Claim 4 (original): The body worn device of claim 1, wherein the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes.

Claim 5 (original): The body worn device of claim 4, wherein the ECG electrodes comprise a material screened onto a flexible substrate.

Claim 6 (original): The body worn device of claim 5, further comprising at least one series current-limiting resistor to protect the communication-computation module during a patient defibrillation event.

Claim 7 (original): The body worn device of claim 6, wherein the least one series current-limiting resistor comprises a resistor screened on the flexible substrate.

Claim 8 (original): The body worn device of claim 7, wherein the mechanical interface from the at least one series current-limiting resistor to the ECG electrode includes a filleted edge.

Claim 9 (original): The body worn device of claim 7, wherein the mechanical interface from the at least one series current-limiting resistor to the ECG electrode comprises overlapped layers.

Claim 10 (original): The body worn device of claim 9, wherein the overlapped layers comprise a carbon resistive layer screened over a conductive surface, the carbon resistive layer having substantially the same shape as the conductive surface.

Claim 11 (original): The body worn device of claim 6, further comprising an insulating material overlaying the at least one series current-limiting resistor to prevent arcing.

Claim 12 (original): The body worn device of claim 5, wherein the ECG electrodes are formed substantially in the shape of an annulus.

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Claim 13 (original): The body worn device of claim 12, wherein the annulus comprises a conductive ink.

Claim 14 (original): The body worn device of claim 5, wherein the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal.

Claim 15 (original): The body worn device of claim 1, wherein the at least one power source is a renewable power source internal to the body worn device.

Claim 16 (original): The body worn device of claim 1, wherein the at least one power source comprises a rechargeable battery or a one time use battery.

Claim 17 (original): The body worn device of claim 1, wherein the at least one power source is a battery contained within said disposable module.

Claim 18 (original): The body worn device of claim 1, wherein the at least one power source is a Seebeck device.

Claim 19 (original): The body worn device of claim 1, wherein one of the electrical connections is a reference electrode that can be used to improve common mode rejection (CMR).

Claim 20 (original): The body worn device of claim 1, further comprising a virtual electrode as a reference electrode to improve CMR.

Claim 21 (currently amended): The body worn device of claim 20, wherein the virtual electrode is an electrode adapted to be situated near the skin of the patient, but not directly connected to the skin.

Claim 22 (currently amended): The body worn device of claim 20, wherein the virtual electrode is adapted to include ~~comprises~~ a capacitive coupling of a body of the communication-

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computation module to the skin surface of the patient to reduce power line frequency interference.

Claim 23 (original): The body worn device of claim 20, including a reference electrode switch for selectively choosing between using the virtual electrode as the reference electrode and a directly connected electrode as the reference electrode and wherein when the reference electrode switch selects the virtual electrode, the directly connected electrode can be used as an additional ECG electrode.

Claim 24 (original): The body worn device of claim 20, wherein the reference electrode is a passive electrical connection or the reference electrode is actively driven.

Claim 25 (original): The body worn device of claim 1, wherein the communication-computation module includes a pacer detection circuit.

Claim 26(original): The body worn device of claim 25, wherein the pacer detection circuit generates a microprocessor interrupt to inform the microprocessor that a pacer event occurred.

Claim 27 (original): The body worn device of claim 26, wherein the microprocessor interrupt is used to mark a corresponding physiological signal in time as related to a pacer event.

Claim 28 (original): The body worn device of claim 26, wherein the device automatically determines if a patient has a pacemaker and only enables the pacer detect circuit when a pacemaker is present.

Claim 29 (original): The body worn device of claim 26, wherein the device is configured by an external input to enable or disable the pacer detect circuit.

Claim 30 (original): The body worn device of claim 1, wherein the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules.

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Claim 31 (original): The body worn device of claim 30, wherein the circuit protection comprises a gas discharge tube or a plurality of diodes to clamp or limit the signals from the electrical connections.

Claim 32 (original): The body worn device of claim 30, wherein a plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module.

Claim 33 (original): The body worn device of claim 1, further comprising a high pass filter with a selectable corner frequency to filter the physiological signals.

Claim 34 (original): The body worn device of claim 33, wherein the corner frequency is selected by a switch selectable resistance.

Claim 35 (original): The body worn device of claim 33, wherein the corner frequency is selected by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter.

Claim 36 (original): The body worn device of claim 33, wherein the high pass filter is implemented in software running on the microprocessor.

Claim 37 (original): The body worn device of claim 1, wherein the body worn device self checks a pacer detection circuit by injecting a simulated pacer pulse into a front end amplifier to stimulate the pacer detection circuit by simulating the presence of a patient's pace maker.

Claim 38 (currently amended): The body worn device of claim 1, wherein the communication-computation module includes circuit components <u>configured</u> to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.

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Claim 39 (original): The body worn device of claim 1, wherein the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits.

Claim 40 (canceled): The body worn device of claim 1, wherein the microprocessor automatically enters a sleep mode during a conversion cycle of an analog to digital converter (ADC) to minimize noise pickup from digital circuits on the body worn device.

Claim 41 (original): The body worn device of claim 1, wherein an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, to save power.

Claim 42 (original): The body worn device of claim 4, including an ESIS filter having a low enough corner frequency such that the energy from a pacer pulse is recorded by at least one sample, even though the pacer pulse itself is of small duration compared to the sample rate and the pacer pulse occurs between samples.

Claim 43 (original): The body worn device of claim 1, wherein neon bulbs connected from the physiological sensors to an electronics common (ground) protect one or more internal circuits of the communication-computation module from a defibrillation pulse.

Claim 44 (original): The body worn device of claim 1, wherein a plurality of diodes disposed between the physiological sensors and an electronics common (ground) protect one or more internal circuits of the communication-computation module from a defibrillation pulse.

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REMARKS

A Request for a One (1) Month Extension of Time pursuant to 37 CFR 1.136(a) is attached hereto.

All claims stand rejected. Claims 1-39 and 41-44 remain in this application. Claims 1-44 have been rejected under 35 U.S.C. §101. Claims 1-3 and 15-18 have been rejected under 35 U.S.C. §102. The Examiner did not expressly reject claims 8, 42, or 43. Applicants request that the Examiner indicate if these claims would be allowable. Claims 4-7, 9-14, 19-29, 30-38, 40-41 and 44 have been rejected under 35 U.S.C. §103. Claims 1, 21, 22, and 38 have been amended to overcome the §101 rejection. Claim 40 is canceled without prejudice. Claim 1 has been amended to include a half cell. A half cell can be created by an electrode gel and conductive surface. (Specification, paragraph [0044]). Support for the claim 1 amendment can be found at paragraph [0044]. No new matter has been added.

1. Claim Rejections 35 U.S.C. §101

The Examiner suggests that claim language such as "... adapted to be attached to" the skin of a patient would avoid the impression that Applicants intended to positively claim a part of the human body as a claim element. Applicants thank the Examiner for this helpful suggestion. Claims 1, 21, 22, and 38 have been so amended. No new matter has been added.

2. Claim Rejections 35 U.S.C. §102

The Examiner has rejected claims 1-3 and 15-18 under 35 U.S.C. §102(b) as being anticipated by Abreu, U.S. Published Patent Application No. 2004/0242976 (hereinafter "Abreu").

It is well known that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.

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Applicants respectfully traverse the Examiner's rejection as inapplicable to claim 1 as amended. Claim 1 calls for "at least one disposable module including a plurality of electrical connections, the electrical connections adapted to be couplable to a skin surface to measure physiological signals, *at least one of said electrical connections comprising a half cell*". (Claim 1, italics added for emphasis). A half cell, such as can be created by an electrode gel and conductive surface, forms one type of electrical connection useful in physiological measurements such as for taking ECG data. (Specification, paragraph [0044]). Nowhere in Abreu, does Abreu describe a half cell as called for by claim 1. Therefore Abreu cannot anticipate claim 1 or any of the claims which depend from claim 1.

3. Claim Rejections 35 U.S.C. §103

The Examiner has rejected claims 4-7 and 9-14 under 35 U.S.C. §103 as in the Examiner's view being unpatentable over Abreu in view of Owen, et al.'s U.S. Published Patent Application No. 2003/0055460 (hereinafter "Owen").

The Examiner alleges that one skilled in the art of patient monitors, in the Examiner's view, would have combined Abreu's face mounted thermal sensor, a thermal detector for receiving radiation energy from the skin at a brain tunnel, with a prior art ECG monitor to arrive at the instant invention. As explained in more detail below, the combination of Abreu, a face worn temperature measurement, and Owen, a prior art multiple-unit portable defibrillator having separate wired electrodes, does not result in the "single unit" body worn monitor of the instant invention.

Abreu teaches that human physiological monitoring can be done based temperature measurements at a "brain tunnel", at a place on the face, where the eye nears the nose that yields temperature data related to brain temperature. Owen describes a prior art multiple unit portable wearable defibrillator where ECG electrodes 31 (Owen FIG. 3) are coupled by a wiring harness (separate wires) to a wearable defibrillator 10 (FIG. 2). Owen's electrodes, wiring harness,

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connector that couple the wires from the wiring harness into defibrillator 10, and power source (e.g. power supply 20) are physically separate components.

By contrast, claim 1 of the instant body worn monitor calls for a body worn patient monitoring device comprising at least one disposable module including a plurality of electrical connections, the electrical connections adapted to be couplable to a skin surface to measure physiological signals, at least one of said electrical connections comprising a half cell, the at least one disposable module including a disposable module connector ... wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module and the body worn patient monitoring device including the at least one disposable module and the at least one communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient.

The instant invention addresses in part the need for a body worn combined physiological sensor and monitor having a disposable sensor, but used and worn by a patient as a *single unit* directly and non-permanently affixed to a patient's body. (Specification, paragraph [0009]). For example, a recurrent problem with the portable monitors typically used in healthcare applications is the need for wires from sensors situated on the patient's body to the portable unit. These wires can become tangled and cause discomfort or become unplugged when inadvertently pulled or tugged on. In addition, wire motion can increase ECG noise due to the triboelectric effect. (Specification, paragraph [0005]). The at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module in the instant body worn monitor. Owen's prior art wiring harness teaches a conventional wired sensor approach having multiple physical units not directly mechanically coupled to each other. Thus it can be seen that a combination of Owen (which teaches away from the single unit, non-wired (no wire harness) solution of the instant invention) and Abreu does not result in a single-unit body worn monitor of the instant invention.

Specifically regarding claim 4, combining Owen with Abreu does not result in an ECG monitor wherein the at least one disposable module is mechanically and electrically coupled

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directly to the at least one communication-computation module without need a conventional ECG wiring harness.

Regarding claims 5 and 6, the instant screened electrodes and series current-limiting resistor are components of the "single unit" body worn monitor of claims 1 and 4. Regarding claim 7, a resistor screened on the flexible substrate, as compared to relatively large protective bulk resistors of the prior art, is one aspect of the instant body worn monitor that makes possible a single compact structure as opposed to Owen's conventional wiring harness approach. As indicated by the complete absence of disclosure regarding Owen's protection for sensitive ECG signal input circuitry, Owen is wholly unaware of an integral protection resistor approach, especially that which protects the sensitive electronics during a defibrillation event. Owen alludes to bulk discharge/protection components and switches in Owen's FIG. 8, block 67, however Owen is wholly devoid of description regarding any non-bulk integral component protection, such as the screened resistances of the instant invention. Owen's prior art "identification" bulk resistors appear to serve a different function (cable identification). Therefore, regarding claims 5 and 6, the proffered combination of Owen and Abreu does not result in the single-unit body worn monitor of the instant invention.

Regarding claims 9 and 10, there can be a short overlay distance, on the order of 5 to 10 mm, in which a silver trace overlaps the carbon trace to provide a more robust connection between the resistive and conductive portions of the traces. Where overlap is used, the overall length of the resistive portion can be adjusted slightly to maintain the desired overall resistance. (Specification, paragraph [0059]). Thus the claimed mechanical interface from the at least one series current-limiting resistor to the ECG electrode can comprise overlapped layers and claimed overlapped layers that comprise a carbon resistive layer screened over a conductive surface, the carbon resistive layer having substantially the same shape as the conductive surface, are yet more aspects of the inventive integral protection resistor screened on the flexible substrate and electrodes that make possible a "single unit" body worn monitor as compared with Owen's conventional wire harness approach. Similarly, regarding claim 11, the insulating material overlaying the at least one series current-limiting resistor to prevent arcing, claims yet another aspect of the "single unit" body worn monitor solution which no longer requires large bulk

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protection resistors typically used for wire harness connected electrodes of the prior art (e.g. Owen). Claims 12 and 13 claim embodiments having ECG electrodes that are formed substantially in the shape of an annulus, neither of which are disclosed nor contemplated by Owen. Therefore, regarding claims 9 and 10, the proffered combination of Owen and Abreu does not result in the single-unit body worn monitor of the instant invention.

Regarding claims 4-7 and 9-14, the Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn patient monitoring device as taught by Abreu with the wearable ECG-based flexible pads and sensing electrodes as taught by Owen, since such a modification, in the Examiner's view, would provide the body worn patient monitoring device with an ECG monitor and ECG electrodes for providing, in the Examiner's view, the predictable results pertaining to monitoring a patient's conditions, detecting shockable or paceable arrhythmias and/or administering therapy to a patient. (Office Action, page 5). Specifically regarding claim 14, claim 14 calls for "The body worn device of claim 5, wherein the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal." Applicants are unable to find any disclosure regarding a substrate that is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal in either Owen or Abreu. Applicants request that the Examiner cite to specific lines in either of the references that disclose such a substrate having a particular shape to provide the structure and features recited in claim 14. Applicants therefore respectfully suggest that, regarding claims 4-7 and 9-14, the proffered combination of Owen and Abreu does not result in the single-unit body worn monitor of the instant invention.

Regarding claims 30-32, 39 and 44, the Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn monitoring device as taught by Abreu with the discharge/protection switches used to control defibrillation energy delivered as taught by Owen, since such modification, in the Examiner's view, would provide the body worn monitoring device comprising a discharge/protection switches for providing, in the Examiner's view, the predictable results

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pertaining to controlling the delivery of defibrillation energy. (Office Action, page 6). As discussed above, Abreu describes a thermal measurement of the brain tunnel at an eye near a "brain tunnel".

Applicants also respectfully note the Owen patent describes a defibrillator system having some rudimentary monitoring capability, not a patient monitor. One important difference is that the Owen defibrillator by definition "knows" when a charge is going to be delivered to a patient and can actively switch off or otherwise actively protect its rudimentary ECG functionality without any detection means. By contrast, a "single unit" body worn monitor ECG structure has an ECG measurement functionality that continues through a defibrillator event typically without any information as to when such an event might occur. Also, regarding claim 39, it is believed that defibrillators do not use ESIS filters, since a defibrillator of the type described by Owen would not be present during surgery, such as where electrocautery might be used. Therefore, regarding claims 30-32, 39 and 44, the proffered combination of Owen and Abreu does not result in the single-unit body worn monitor of the instant invention.

Regarding claim 41, the Examiner alleges that it would have been obvious to one having ordinary skill in the art, in the Examiner's view, at the time the invention was made to modify the body worn monitoring device as taught by Abreu with the processor having a power saving feature capable of operating in different modes as taught by Owen, since, such modification would provide, in the Examiner's view, the predictable results pertaining to operating a device in different power-saving modes, such as a low-power mode, in order to consume efficient amounts of power [e.g., Owen, 0175]. (Office Action, page 7). Applicants are unable to find any disclosure in the cited sections of Owen that disclose power saving modes timed to specific portions of an ECG waveform, such as to the end of a "T wave" or to the beginning of a "P wave". Therefore, the combination of Owen's defibrillator and Abreu's temperature measurement does not appear to achieve the "single unit" body worn monitor ECG structure wherein an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, to save power.

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The Examiner has rejected claims 19-24 under 35 U.S.C. §103 as in the Examiner's view being unpatentable over Abreu in view of U.S. Patent No. 5,309,918 to Schraag (hereinafter "Schraag"). The Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made, in the Examiner's view, to modify the body worn monitoring device as taught by Abreu with the reference electrode incorporated as an electrical contact as taught by Schraag, since, in the Examiner's view, such a modification would provide the predictable results pertaining to improving the common mode rejection ratio achieved by utilizing a reference electrode (e.g., Schraag, col. 8, in 27-37). (Office Action, page 7). Moreover, claims 20-24 call for a virtual electrode as a reference electrode to improve CMR, whereas Schraag appears to disclose only a reference electrode in electrical contact.

> **The capacitance of transformer 37 is only about 3 pF, which leads to a basic CMRR of approximately 91 dB. If an additional rejection of 20 dB is obtained with a common-mode amplifier, a CMRR of 111 dB is obtained; another 9 dB may easily be achieved by additional electronic measures or a reference electrode. The crucial point is that, even if a reference electrode is used, the 9 dB rejection can be obtained without electrode gel. The reference electrode may be incorporated as an electrical contact at the bottom side of box 24 (e.g., a ground plate GP). (Schraag, col. 8, lines 27-39).**

It can be seen from Schraag's description above and Schraag FIG. 5 that Schraag achieves CMR via conventional galvanic isolation using a transformer to create a "floating" front end. Schraag's only passing reference to use of a reference electrode, is to an electrode *in electrical contact* with a patient's body, possibly in the absence of gel, not to a virtual electrode (note that direct contact without gel does not describe a virtual "non-contact" electrode). Applicants are unable to find any indication of a virtual electrode used for CMRR anywhere in Schraag. Therefore, the combination of Abreu and Schraag does not produce the structures claimed by claims 19-24.

The Examiner has rejected claims 25-29 under 35 U.S.C. §103 as in the Examiner's view being unpatentable over Abreu in view of Ortega, et al.'s U.S. Published Patent Application No. 2006/0136001 (hereinafter "Ortega"). The Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention, in the Examiner's view, was made to modify the body worn monitoring device as taught by Abreu with the pacing-detection technology, based on wireless network switching functions as taught by Ortega, since, in the

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Examiner's view, such a modification would provide the predictable results pertaining to controlling the automatic pacing of an implantable cardiac device so as to effectively provide electrical stimulating therapy [e.g., Ortega, 0105]. (Office Action, page 8).

> **As is customary with implantable pulse generators, the device may be programmable to achieve either conventional bipolar or unipolar stimulation or to achieve the stimulation of the present invention through an external programmer or controlled automatically by the device. The selection can be based on user preference or be driven by physiological factors such as widths of the patient's QRS complex or the conduction interval between the stimulus to a far away region in the heart. In addition switching between the pacing of the present invention and conventional pacing can also be determined by the percentage of pacing with a preference for a higher percentage with the pacing of the present invention. Further, the switching from the conventional pacing to the present invention pacing can be used when there exists an exit block or the pacing electrode is located in infracted myocardium when conventional pacing can not effect the depolarization of the myocardium at the high output level. The automatic determination can be effected through the deployment of any automatic capture detection technology that exists in the prior art. Additionally, wireless network enabled switching function for therapy optimization can also be implemented with the present invention. In such case, certain patient physiologic data are gathered by the implantable device and sent to a remote server/monitor through a wireless communication network. (Ortega, paragraph [0105]).**

In citing Ortega, paragraph [0105], the Examiner appears to somehow equate communications of an actual pacer electrically directly wired to a person's heart and communicating via a wireless communication network to a body worn monitor detecting the presence or not of a pacer via electrodes on the outer surface of the skin of a patient's body. Applicants can only assume that there is some confusion regarding what Applicants are claiming by claims 25-29. Claims 25-29 claim a "single unit" body worn monitor with at least one half cell that can detect and react to the presence or absence of a heart pacer in a patient. By contrast, Ortega describes a pacer instrument that makes intimate electrical contact with a heart to provide a pacer function. For example, in claim 28 of the instant application, the body worn monitor automatically determines if a patient has a pacemaker and only enables the pacer detect circuit when a pacemaker is present, thus accomplishing significant power savings. It is respectfully suggested that the Ortega published patent application is inapplicable to Applicants' claims 25-29 and that the proffered combination of Abreu and Ortega does not yield the claimed structures of claims 25-29.

The Examiner has rejected claims 33-37 under 35 U.S.C. §103 as in the Examiner's view being unpatentable over Abreu in view of U.S. Published Patent Application No. 2006/0183434

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by Westra, et al. (hereinafter "Westra"). The Examiner alleges that it would have been obvious to one having ordinary skill in the art at the time the invention was made, in the Examiner's view, to modify the body worn device as taught by Abreu with the high pass filter having a tunable comer frequency as taught by Westra, since, in the Examiner's view, such a modification would provide the predictable results. (Office Action, page 8). Claims 33 to 36 claim an "input" filter to filter the physiological signals and have nothing to do with the radio portion of the computing and communication module. The corner frequency of the high pass filter can be selected by a switch selectable resistance (claim 34) or by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter (claim 35), or the high pass filter is implemented in software running on the microprocessor (claim 36). The location of the corner frequency (e.g. in the feedback path of FIG. 12), is selected based on a desired bandwidth for efficient and accurate ECG monitoring. The filters of Applicants' claims 33-36 have no relation to radio transceivers and thus it is respectfully suggested that a rejection based on Ortega is improper.

Also, Ortega appears to have no disclosure regarding body worn device that self checks a pacer detection circuit by injecting a simulated pacer pulse into a front end amplifier to stimulate the pacer detection circuit by simulating the presence of a patient's pace maker (claim 37). The rejection as to claim 37 is traversed as improper. Applicants believe this rejection was possibly an Examiner oversight and respectfully request that the Examiner specifically cite to applicable prior art or to indicate allowability of claim 37.

The Examiner has rejected claim 38 under 35 U.S.C. §103 as in the Examiner's view being unpatentable over Abreu in view of U.S. Published Patent Application No. 2003/0001742 by Eshelman, et al. (hereinafter "Eshelman"). The Examiner alleges that it would have been obvious to one of ordinary skill in the art at the time the invention was made, in the Examiner's view, to modify the body worn device as taught by Abreu with the skin contact detector as taught by Eshelman, since, in the Examiner's view such a modification would provide the predictable results pertaining to monitoring biological processes measurable on the user's skin, such as detecting danger zones in a parameter space [e.g., Eshelman, 0029]. (Office Action, page 9). Claim 38 claims a body worn device wherein the communication-computation module includes

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circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient. Eshelman discloses a dedicated skin contact sensor. Eshelman's dedicated skin contact sensor is not used or otherwise usable to measure one or more physiological parameters. By contrast, the failure of contact detection mechanism of the instant invention makes use of otherwise active physiological sensor electrodes that can also detect a loss of skin contact. Applicants are unable to find any disclosure in Eshelman related to failure of contact of one or more of the electrical connections of a body worn monitor with the skin surface of the patient. Applicants respectfully request that the Examiner specifically cite to where Eshelman describes this technical feature.

The Examiner has rejected claim 40 under 35 U.S.C. §103 as in the Examiner's view being unpatentable over Abreu in view in view of U.S. Patent No. 5,294,928 to Cooper, et al. (hereinafter "Cooper"). Claim 40 has been canceled without prejudice.

4. Objection to the Drawings:

The Examiner objects to the drawings as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference characters not mentioned in the description: The following reference numbers are not discussed in the specification: "403" of Figure 4 and "513 & 518" of Figures 5 & 6.

An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of error in the specification, but also the appropriate correction. *In re Odd*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). (MPEP §2163.07 (II) Amendments to Application Which Are Supported in the Original Description, Obvious Errors).

The specification has been amended at paragraph [0054] "connection pad 410, from battery connection 403, providing …". One skilled in the art can readily see from the original drawing of FIG. 4 that reference designator 403 is a battery connection of the same type as

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described with regard to reference designators 401 and 402 and using the same electro-mechanical symbol. The symbol designated as 403 is expressly shown in FIG. 4 as electrically coupled to connection pad 410, the same as "connection pad 407 from battery connection 402" is described and shown in FIG. 4. The phrase "from battery connection 403," corrects an obvious error that does not constitute new matter since one skilled in the art would easily recognize in FIG. 4, the existence of the error (omission of reference designator 403) in the specification. No new matter has been added.

Similarly, regarding reference designators 513 and 518 in FIG. 5 and FIG. 6, the specification has been amended to add the phrase, "such as including the function block radio 513 which is electrically coupled to antenna 518". Block 513 is labeled in text in both the original FIG. 5 and the original FIG. 6 as "RADIO". Also, one skilled in the art would recognize the electronic symbol labeled 518 as a radio antenna. The phrase "such as including the function block radio 513 which is electrically coupled to antenna 518" corrects an obvious error that does not constitute new matter since one skilled in the art would easily recognize in FIG. 5 and FIG. 6, the existence of the error (omission of reference designators 513 and 518) in the specification. No new matter has been added.

5. Objection to the Specification:

The Examiner requested that Applicants replace the trademark named Mylar® with a capitalized word, MYLAR® and wherever MYLAR® appears in the specification, to accompany the trademark term with a generic terminology. Applicants so amend the specification. No new matter has been added.

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6. Conclusion

Applicants have amended the specification and claims as suggested by the Examiner to overcome the Examiner's objections. Applicants believe that Abreu does not anticipate claim 1 as amended, thus overcoming all §102 rejections. Regarding the §103 rejections and as explained in detail above, the Abreu reference, a thermal measurement of a brain tunnel made on the face near an eye, cannot credibly be combined with any of the other cited prior art elements, such as Owen's prior art portable defibrillator, according to known methods to yield the instant single unit body worn monitor including a half cell as a predictable result. The combination of Abreu, a face worn temperature measurement, and Owen, a prior art multiple-unit portable defibrillator having separate wired electrodes, does not result in a "single unit" body worn monitor of the instant invention. Therefore Applicants believe they have also overcome all §103 rejections.

If the Examiner wishes to expedite disposition of this matter, he/she is invited to contact Applicants' representative at the telephone number listed below.

Applicants believe that the fee for a one month extension of time is due on account of submission of this paper. Applicants are paying the required fee in conjunction with the submission of this paper. In the event that Applicants may have overlooked the need for an additional fee, the Director is conditionally authorized to charge Deposit Account No: 50-3010.

Respectfully submitted,

HISCOCK & BARCLAY, LLP



Date: March 24, 2009

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Page 636

Electronic Patent Application Fee Transmittal

Application Number:	11591619
Filing Date:	01-Nov-2006
Title of Invention:	Body worn physiological sensor device having a disposable electrode module
First Named Inventor/Applicant Name:	Steven D. Baker
Filer:	Thomas J. Wall/Jill Kirby
Attorney Docket Number:	704_049

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with $0 paid	1251	1	130	130

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**130**

Electronic Acknowledgement Receipt

EFS ID:	5024257
Application Number:	11591619
International Application Number:	
Confirmation Number:	7955
Title of Invention:	Body worn physiological sensor device having a disposable electrode module
First Named Inventor/Applicant Name:	Steven D. Baker
Customer Number:	20874
Filer:	Thomas J. Wall/Jill Kirby
Filer Authorized By:	Thomas J. Wall
Attorney Docket Number:	704_049
Receipt Date:	24-MAR-2009
Filing Date:	01-NOV-2006
Time Stamp:	15:06:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$130
RAM confirmation Number	438
Deposit Account	503010
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Miscellaneous Incoming Letter	2009-03-24-Transmittal-Amendment-Response.pdf	71621 3ffbeebebf0d42dd54b77e99a40b1386a0591a6b	no	1
Warnings:					
Information:					
2	Extension of Time	2009-03-24-Petition-For-Extension.pdf	71213 2f8efe283f388c9cb38f3c98c9e212d6f0eec491	no	1
Warnings:					
Information:					
3	Amendment/Req. Reconsideration-After Non-Final Reject	2009-03-24-Amendment-And-Response.pdf	30124 b9a4cadbc4c7a2adbf084289f53d02b7a7cfa5a4	no	1
Warnings:					
Information:					
4	Specification	2009-03-24-Specification-Amendments.pdf	239105 870e4c618df0bc940b051c1496376509f8286352	no	4
Warnings:					
Information:					
5	Claims	2009-03-24-Claims-Amendments.pdf	294234 85bc9583e958a769248f215daa6c954c02a7a7a4	no	6
Warnings:					
Information:					
6	Applicant Arguments/Remarks Made in an Amendment	2009-03-24-Remarks.pdf	751948 e97eaace156229f21108dc54afee4403bf9b703e	no	12
Warnings:					
Information:					
7	Fee Worksheet (PTO-06)	fee-info.pdf	30075 1bfee23862558470a1b464313843f91d5ea4a5c4	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1488320		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (12-08)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	25

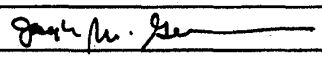
Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US01

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☐ Other Enclosure(s) (please identify below):

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Hiscock & Barclay, LLP		
Signature			
Printed name	Joseph M. Geller		
Date	March 24, 2009	Reg. No.	48,144

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/22 (02-09)
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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) **FY 2009** *(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)*	Docket Number (Optional) 3022036 US01
Application Number 11/591,619	Filed November 1, 2006
For BODY WORK PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE	
Art Unit 3762	Examiner Nicole F. Lavert

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	Fee	Small Entity Fee	
☑ One month (37 CFR 1.17(a)(1))	$130	$65	$ 130.00
☐ Two months (37 CFR 1.17(a)(2))	$490	$245	$
☐ Three months (37 CFR 1.17(a)(3))	$1110	$555	$
☐ Four months (37 CFR 1.17(a)(4))	$1730	$865	$
☐ Five months (37 CFR 1.17(a)(5))	$2350	$1175	$

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☑ The Director has already been authorized to charge fees in this application to a Deposit Account.

☑ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 50-3010.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).

☑ attorney or agent of record. Registration Number 48,144

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature	March 24, 2009 Date
Joseph M. Geller Typed or printed name	(315) 768-7284 Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☑ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.136(a). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 6 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/06 (07-06)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
11/591,619	11/01/2006	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 03/24/2009	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 43	Minus	** 58	= 0	X $ =		OR	X $52=	0
Independent (37 CFR 1.16(h))	* 1	Minus	***6	= 0	X $ =		OR	X $220=	0
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	0

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/GAIL D. D. WOOTEN/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	704_049	7955

20874 7590 12/12/2008

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EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
12/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/591,619	BAKER ET AL.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 January 2007* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/3/08 & 2/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Claims 45-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 November 2008.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: The following reference numbers are not discussed in the specification; "403" of Figure 4 and "513 & 518" of Figures 5 & 6. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The use of the trademark Mylar® has been noted in this application [e.g., 0043]. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-44 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In regards to claim 1, the phrase, "…communication-computation module is directly non-permanently affixed to the skin surface of the patient," is directed to non-statutory subject matter since the claim limitations positively recites a part of the human body. It is suggested to use such claim language as "...adapted to be attached..." or "...for attachment to..." or in some similar way which does not positively set forth the human body or portion thereof as part of the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. **Claims 1-3 & 15-18** rejected under 35 U.S.C. 102(b) as being anticipated by Abreu (US 2004/0242976).

In regards to **claims 1-3 & 15-18** Abreu discloses, a body worn patient monitoring device comprising {e.g., [0017] & (Fig 16A-C, 180)}: at least one disposable module (e.g., Fig 77A, 1590) including a plurality of electrical connections (e.g., Fig 77A, 1730) the electrical connections couplable to a skin surface to measure physiological signals, the at least one disposable module including a disposable module connector; at least one internal or external power source (e.g., Fig 77A, 1594) to power the body worn patient monitoring device; and at least one communication-computation module (e.g., Fig 77A, 1596), having a communication-computation module connector to receive physiological signals from the at least one disposable module via said disposable module connector, the communication-computation module including at least one microprocessor to actively monitor the patient (e.g., Fig 77A, 1592) and to perform a real-time physiological analysis of the physiological signals and a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module and the body worn patient monitoring device including the at least one disposable module and the at least one communication-computation module is directly non-permanently affixed to the skin surface of the patient {e.g., [0095], [0488], [0502] & (Fig 77A)}.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 4-7 & 9-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2004/0242976) in view of Owen et al. (US 2003/0055460).

In regards to **claims 4-7 & 9-14**, Abreu discloses the claimed invention having a body worn patient monitoring device except for a body worn monitoring device comprising a ECG monitor and at least two of the of the electrical connection being ECG electrodes. Owen et al. teaches that it is known to use a personal wearable pacer/cardioverter/defibrillator flexible pads and sensing electrodes {e.g., [0003], [0094] & (Fig 31, 22/24 & 31)}. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn patient monitoring device as taught by Abreu with the wearable ECG-based flexible pads and sensing electrodes as taught by Owen et al., since such a modification would provide the body worn patient monitoring device with an ECG monitor and ECG electrodes for providing the predictable results pertaining to monitoring a patient's conditions, detecting shockable or paceable arrhythmias and/or administering therapy to a patient.

9. **Claims 30-32, 39 & 44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2004/0242976) in view of Owen et al. (US 2003/0055460).

In regards to claims 30-32 & 44, Abreu discloses the claimed invention having a body worn monitoring device except for the body worn monitoring device further including a circuit protection, allowing said device to survive multiple defibrillation cycles. Owen et al. teaches that it is known to use a personable wearable cardiac device further comprising a resistor-capacitor configuration controlled by discharge/protection switches, which are used to control the waveform of the defibrillation energy delivered (e.g., [0139]-[0140]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn monitoring device as taught by Abreu with the discharge/protection switches used to control defibrillation energy delivered as taught by Owen et al., since such modification would provide the body worn monitoring device comprising a discharge/protection switches for providing the predictable results pertaining to controlling the delivery of defibrillation energy [e.g., Owen, 0140].

10. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2004/0242976) in view of Owen et al. (US 2003/0055460).

Abreu discloses the claimed invention having a body worn monitoring device except for the body monitoring device further comprising an algorithm running on a microprocessor in the device, causing the device to enter a low power mode that disables at least one circuit of the device to save power. Owen et al. teaches that it is known to use a personable wearable cardiac device further comprising a power saving feature by way of a processor that is capable of operating in different modes, such as a low-power mode, during which the processor consumes

different amounts of power (e.g., [0175]-[0176]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn monitoring device as taught by Abreu with the processor having a power saving feature capable of operating in different modes as taught by Owen et al., since such modification would provide the predictable results pertaining to operating a device in different power-saving modes, such as a low-power mode, in order to consume efficient amounts of power [e.g., Owen, 0175].

11. **Claim 19-24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2004/0242976) in view of Schraag (US 5,309,918).

Abreu discloses the claimed invention having a body worn monitoring device except for the device further comprising at least one electrical connections being an reference electrode that can be used to improve common mode rejection (CMR). Schraag teaches that it is known to use an ECG transducer further comprising a reference electrode incorporated as an electrical contact, which improves the common-mode rejection ratio of the ECG transducer [e.g., (col 1, ln 17-20), (col 7, ln 17-34) & (col 8, ln 27-37)]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn monitoring device as taught by Abreu with the reference electrode incorporated as an electrical contact as taught by Schraag, since such a modification would provide the predictable results pertaining to improving the common mode rejection ratio achieved by utilizing a reference electrode (e.g., Schraag, col 8, ln 27-37).

12. **Claims 25-29** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2004/0242976) in view of Ortega et al. (US 2006/0136001).

Abreu discloses the claimed invention having a body worn monitoring device comprising a communication-computation except for the device further comprising a pacer detection circuit. Ortega et al. teaches that it is known to use a method and apparatus for treating a condition of a patient's heart comprising a programmable device having the capability of switching between pacing configurations in which said pacing is controlled by an automatic determination autocapture detection technology, based on wireless network enabled switching functions [e.g., 0105]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn monitoring device as taught by Abreu with the pacing-detection technology, based on wireless network switching functions as taught by Ortega et al., since such a modification would provide the predictable results pertaining to controlling the automatic pacing of an implantable cardiac device so as to effectively provide electrical stimulating therapy [e.g., Ortega, 0105].

13. **Claims 33-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2004/0242976) in view of Westra et al. (US 2006/0183434).

Abreu discloses the claimed invention having a body worn monitoring device except for a device further comprising a high pass filter with a selectable corner frequency. Westra et al. teaches that it is known to use an electronic communication system comprising a high pass filter additionally having a tunable corner frequency (e.g., [0012] & [0014]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn device as taught by Abreu with the high pass filter having a tunable corner frequency as taught by Westra et al., since such a modification would provide the predictable results

pertaining to selectively filtering out unwanted information so as to filter physiological signals monitored by said body worn device [e.g., Westra, 0014].

14. **Claim 38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2004/0242976) in view of Eshelman et al. (US 2003/0001742).

Abreu discloses the claimed invention having a body worn monitoring device comprising a communication-computation module except for a device further comprising circuit components to detect failure of contact of one or more of the electrical connections with the skin surface of the patient. Eshelman et al. teaches that is known to use an invention relating to assisting people with disabilities further comprising a biosensors in which includes a skin contact detector capable or monitoring biological processes measurable on the user's skin {e.g., [0029] & (Fig 2, 27)}. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the body worn device as taught by Abreu with the skin contact detector as taught by Eshelman et al., since such a modification would provide the predictable results pertaining to monitoring biological processes measurable on the user's skin, such as detecting danger zones in a parameter space [e.g., Eshelman, 0029].

15. **Claim 40** is rejected under 35 U.S.C. 103(a) as being unpatentable over Abreu (US 2004/0242976) in view of Cooper et al. (US 5,294,928)

Abreu discloses the claimed invention having a body worn monitoring device comprising a microprocessor except for the device further comprising a microprocessor that automatically enters sleep mode a during conversion cycle of an analog to digital converter. Cooper et al. teaches that it is known to use a microcontroller having analog to digital conversion (ADC) capabilities in which the sleep mode of the analog to digital converter is enabled when the

microcontroller is asleep (e.g., col 3, ln 8-12). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the body worn device as taught by Abreu with the microcontroller having an enabled sleep mode for an ADC as taught by Cooper et al., since such a modification would provide the predictable results pertaining to minimizing noise pickup from digital circuits on said body worn device

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762

Notice of References Cited	Application/Control No. 11/591,619	Applicant(s)/Patent Under Reexamination BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,294,928 A	03-1994	Cooper et al.	341/142
*	B	US-5,309,918 A	05-1994	Schraag, Martin	600/508
*	C	US-2002/0122519 A1	09-2002	Douglas et al.	375/376
*	D	US-2003/0001742 A1	01-2003	Eshelman et al.	340/573.1
*	E	US-2003/0055460 A1	03-2003	Owen et al.	607/5
*	F	US-2004/0242976 A1	12-2004	Abreu, Marcio Marc	600/315
*	G	US-2006/0044856 A1	03-2006	Bird et al.	363/131
*	H	US-2006/0136001 A1	06-2006	Ortega et al.	607/009
*	I	US-2006/0183434 A1	08-2006	Westra et al.	455/078
*	J	US-2006/0189976 A1	08-2006	Karni et al.	606/041
*	K	US-2006/0205171 A1	09-2006	Tsukada, Torayuki	438/382
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11591619	BAKER ET AL.
	Examiner	Art Unit
	NICOLE F LAVERT	3762

SEARCHED			
Class	Subclass	Date	Examiner
607	60	12/4/2008	NFL
600	372 & 382	12/4/2008	NFL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Search (EDAN)	12/4/2008	NFL
EAST Search (see attachment)	12/4/2008	NFL

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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BIB DATA SHEET

CONFIRMATION NO. 7955

SERIAL NUMBER	FILING or 371(c) DATE / RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
11/591,619	11/01/2006	600	3762	704_049

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**** CONTINUING DATA **************************

**** FOREIGN APPLICATIONS **************************

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****
11/21/2006

Foreign Priority claimed	35 USC 119(a-d) conditions met	Verified and Acknowledged	Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ Yes ☑ No	☐ Yes ☑ No	/NICOLE F LAVERT/ Examiner's Signature	☐ NFL Initials	OR	14	58	6

ADDRESS

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TITLE

Body worn physiological sensor device having a disposable electrode module

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
3630	No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	7	"5309918"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 17:39
L2	2	"20060189976"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 17:44
L3	2	"20060136001"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 17:48
L4	2	"20060183434"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:10
L5	2	"20060136001"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:13
L6	2	"20020122519"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:16
L7	31	"4141367"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:18

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L8	2	"20030001742"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:19
L9	3	"20060044856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:48
L10	47	"5294928"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:51
L11	2	"20040113806"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:53
L12	6	"4800894"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 18:55
L13	12373	external same (medical same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:06
L14	1683	l13 and (worn or wearable)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:06
L15	832	l14 and (power same source)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:06

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L16	748	l15 and (electrodes or sensors)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:07
L17	132	l16 and (capacitors and substrate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:07
L18	3	"20060205171"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:11
L19	3	"20060044856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:13
S1	916	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:17
S2	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:39
S3	1	S2 and "407"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:39
S4	0	S2 and "403"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:40

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S5	1	S2 and "504"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:50
S6	1	S2 and "511"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:51
S7	0	S2 and "513"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:54
S8	1	S2 and radio	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:54
S9	0	S2 and "518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:55
S10	1	S2 and "514"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:55
S11	1	S2 and "801"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:59
S12	1	S2 and "802"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:59

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 663

S13	0	S2 and "1002"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:02
S14	0	S2 and "R1002"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:02
S15	1	S2 and "1601"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:05
S16	1	S2 and "1602"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:05
S17	5	"20040242976"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:09
S18	499	607/36.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:10
S19	3959	600/300.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:24
S20	472	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 13:25

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 664

S21	2	S17 and (ECG or heart)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 14:11
S22	2	"20030055460"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 14:13

12/4/2008 7:17:51 PM
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iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 665

OIPE IAP20
FEB 16 2007
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2-20-07

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	7	Application Number	11/591,619-Conf. #7955
		Filing Date	November 1, 2006
		First Named Inventor	Steven D. Baker
		Art Unit	3736
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	704_049

ENCLOSURES (*Check all that apply*)

☐ Fee Transmittal Form	☐ Drawing(s)	☐ After Allowance Communication to TC
☐ Fee Attached	☐ Licensing-related Papers	☐ Appeal Communication to Board of Appeals and Interferences
☐ Amendment/Reply	☐ Petition	☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brie.)
☐ After Final	☐ Petition to Convert to a Provisional Application	☐ Proprietary Information
☐ Affidavits/declaration(s)	☐ Power of Attorney, Revocation Change of Correspondence Address	☐ Status Letter
☐ Extension of Time Request	☐ Terminal Disclaimer	☒ Other Enclosure(s) (please Identify below):
☐ Express Abandonment Request	☐ Request for Refund	Form PTO/SB08/A/B (2 pgs); Return Mailroom Postcard; foreign references BA-BH; Certificate of Mailing (IDS)
☒ Information Disclosure Statement	☐ CD, Number of CD(s) _____	
☐ Certified Copy of Priority Document(s)	☐ Landscape Table on CD	
☐ Reply to Missing Parts/ Incomplete Application	Remarks	
☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	MARJAMA & BILINSKI LLP		
Signature	Peter J. Bilinski		
Printed name	Peter J. Bilinski		
Date	February 16, 2007	Reg. No.	35,067

Transmittal

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV967909486US, on the date shown below in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: February 16, 2007 Signature: Cheryl M Nichols (Cheryl Nichols)

FEB 16 2007
PATENT & TRADEMARK OFFICE

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Dated: February 16, 2007 Signature: (Cheryl Nichols)

Docket No.: 704_049
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Steven D. Baker et al.

Application No.: 11/591,619 Confirmation No.: 7955

Filed: November 1, 2006 Art Unit: 3736

For: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

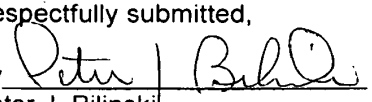
This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)). Therefore, it is believed no fee is required.

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant herein submits English language versions and/or Abstracts for each of the attached foreign documents, pursuant to 37 CFR 1.97(c) and (e)(1) or (b)(3).

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0289, under Order No. 704_049. A duplicate copy of this paper is enclosed.

Dated: February 16, 2007

Respectfully submitted,

By 

Peter J. Bilinski
Registration No.: 35,067
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250 South Clinton Street
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Customer No. 20874

PATENT & TRADEMARK OFFICE
FEB 1 6 2007

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	11/591,619-Conf. #7955
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/N.F.L./	AA	US-2003-0149349A1	08/07/2003	Jensen	
	AB	US-4,791,933	12/20/1988	Asai et al.	
	AC	US-4,957,109	09/18/1990	Groeger et al.	
	AD	US-4,958,645	09/25/1990	Cadell et al.	
	AE	US-4,974,607	12/04/1990	Miwa	
	AF	US-5,257,631	11/02/1993	Wik	
	AG	US-5,458,122	10/17/1995	Hethuin	
	AH	US-5,538,007	07/23/1996	Gorman	
	AI	US-5,544,661	08/13/1996	Davis et al.	
	AJ	US-5,694,940	12/09/1997	Unger et al.	
	AK	US-5,743,269	04/28/1998	Okigami et al.	
	AL	US-5,832,490	11/03/1998	Riley	
	AM	US-5,871,451	02/16/1999	Unger et al.	
	AN	US-5,882,300	03/16/1999	Malinouskas et al.	
	AO	US-5,899,866	05/04/1999	Cyrus et al.	
	AP	US-5,916,159	06/29/1999	Kelly et al.	
	AQ	US-5,919,141	07/06/1999	Money et al.	
	AR	US-5,938,597	08/17/1999	Stratbucker	
	AS	US-5,966,692	10/12/1999	Langer et al.	
	AT	US-5,987,519	11/16/1999	Peifer et al.	
	AU	US-5,995,861	11/30/1999	Price	
	AV	US-6,006,125	12/21/1999	Kelly et al.	
	AW	US-6,018,705	01/25/2000	Gaudet et al.	
	AX	US-6,026,321	02/15/2000	Miyata et al.	
	AY	US-6,052,654	04/18/2000	Gaudet et al.	
	AZ	US-6,066,093	05/23/2000	Kelly et al.	
	AA1	US-6,073,046	06/06/2000	Patel et al.	
	AB1	US-6,076,003	06/13/2000	Rogel	
	AC1	US-6,122,340	09/19/2000	Darley et al.	
	AD1	US-6,150,951	11/21/2000	Olejniczak	
	AE1	US-6,161,036	12/12/2000	Matsumura et al.	
	AF1	US-6,171,237B1	01/09/2001	Avitall et al.	
	AG1	US-6,298,314B1	10/02/2001	Blackadar et al.	
	AH1	US-6,336,365B1	01/08/2002	Blackadar et al.	
	AI1	US-6,357,147B1	03/19/2002	Darley et al.	
	AJ1	US-6,493,652B1	12/10/2002	Ohlenbusch et al.	
	AK1	US-6,794,990B2	09/21/2004	Tseng	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
/N.F.L./	BA	EP 0209804 A2	01-28-1987	Rossi, Paolo		
	BB	WO 9620641 A1	07-11-1996	Polar Electro Oy		
	BC	WO 9629005 A1	09-26-1996	Citizen Watch Co. Ltd.		

Examiner Signature	/Nicole LaVeri/	Date Considered	12/04/2008

PTO/SB/08A/B (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	11/591,619-Conf. #7955
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049

/N.F.L./	BD	EP 0770349 A1	05-02-1997	Akasaka, Noboru		
	BE	WO 9746156 A1	12-11-1997	Data Critical Corp.		
	BF	JP 11042214	02-16-1999	Ido Teruo		
	BG	EP 0910985 A1	04-28-1999	Stratbucker, Robert Allen		
	BH	WO 9959460 A2	11-25-1999	Biosys AB		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Nicole LaVert/	Date Considered	12/04/2008



Application No. (if known): 11/591,619 Attorney Docket No.: 704_049

Certificate of Express Mailing Under 37 CFR 1.10

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MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

on February 16, 2007
Date

Cheryl M. Nichols
Signature

Cheryl Nichols
Typed or printed name of person signing Certificate

Registration Number, if applicable

(315) 425-9000
Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

IDS (Citation) by Applicant (45 References) (2 pages)

PTO/SB/08A (09-06)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049 US01

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/N.F.L./	AL1	US-4,141,367 A	02/27/1979	Ferreira	
	AM1	US-4,800,894 A	01/31/1989	Milani	
	AN1	US-5,294,928 A	03/15/1994	Cooper, et al.	
	AO1	US-5,309,918 A	05/10/1994	Schraag	
	AP1	US-2002/0122519 A1	09/05/2002	Douglas, et al.	
	AQ1	US-2003/0001742 A1	01/02/2003	Eshelman, et al.	
	AR1	US-2003/0055460 A1	03/20/2003	Owen, et al.	
	AS1	US-2004/0113806 A1	06/17/2004	Neykov	
	AT1	US-2004/0242976 A1	12/02/2004	Abreu	
	AU1	US-2006/0044856 A1	03/02/2006	Bird, et al.	
	AV1	US-2006/0136001 A1	06/22/2006	Ortega, et al.	
	AW1	US-2006/0183434 A1	08/17/2006	Westra, et al.	
	AX1	US-2006/0189976 A1	08/24/2006	Karni, et al.	
	AY1	US-2006/0205171 A1	09/14/2006	Tsukada	
		US-			
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		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] - Number[4] - Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature	/Nicole LaVert/	Date Considered	12/04/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	11/591,619
Applicant	:	Steven D. Baker, et al.
Filed	:	November 1, 2006
Art Unit	:	3762
Examiner	:	Nicole F. Lavert
Docket No.	:	704_049 (3022036US01)
Confirmation No.:		7955
Customer No.	:	72742
Title	:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO RESTRICTION REQUIREMENT

Sir:

In response to the Restriction Requirement, dated November 6, 2008 and pursuant to 35 USC §121 and MPEP §818, Applicants herein provisionally elect, without traverse, to prosecute Group I, claims 1-44.

Applicant retains the right to file divisional applications to the non-elected subject matter.

Remarks begin on page 2 of this paper.

REMARKS

As noted above and in response to the Restriction Requirement, dated November 15, 2007, Applicants herein provisionally elect, without traverse, to prosecute Group I, claims 1-44 of the above-captioned utility application pursuant to 35 USC §121 and 37 CFR §1.142.

Applicants herein reserve the right to file divisional patent application(s) based on the non-elected embodiments.

Entry of this response and expedited examination of the elected embodiment is respectfully requested at this time.

If the Examiner wishes to expedite disposition of the above-captioned design patent application, he is invited to contact Applicants representative at the telephone number below.

In the event that Applicants have overlooked the need for an extension of time, additional extension of time, payment of fee, or additional payment of fee, Applicants hereby conditionally petition therefor and authorize that any charges be made to Deposit Account No.: 50-3010.

Respectfully submitted,

HISCOCK & BARCLAY, LLP

Date: November 26, 2008

Joseph M. Geller
Reg. No. 48,144
One Park Place
300 South State Street
Syracuse, NY 13202-2078
Tel: (315) 768-7284
Fax: (315) 703-7369

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 674

Electronic Acknowledgement Receipt

EFS ID:	4361558
Application Number:	11591619
International Application Number:	
Confirmation Number:	7955
Title of Invention:	Body worn physiological sensor device having a disposable electrode module
First Named Inventor/Applicant Name:	Steven D. Baker
Customer Number:	20874
Filer:	Thomas J. Wall/Jill Kirby
Filer Authorized By:	Thomas J. Wall
Attorney Docket Number:	704_049
Receipt Date:	26-NOV-2008
Filing Date:	01-NOV-2006
Time Stamp:	14:15:14
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	2008-11-26-Transmittal-Response-To-Restriction-Requirement.pdf	68644 320903c0ad412be56a310b6db968a1433b7e456e	no	1
Warnings:					
Information:					

2	Response to Election / Restriction Filed	2008-11-26-Response-To-Restriction-Requirement.pdf	65808 664cf3ade5908b9958f67e58f86e9fef90ea9ba6	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	134452	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (11-08)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	3

Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US01

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):
  Response to Restriction Requirement

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Hiscock & Barclay, LLP		
Signature	Joseph M. Geller		
Printed name	Joseph M. Geller		
Date	November 26, 2008	Reg. No.	48,144

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name		Date	

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	704_049	7955

20874 7590 11/06/2008

MARJAMA MULDOON BLASIAK & SULLIVAN LLP
250 SOUTH CLINTON STREET
SUITE 300
SYRACUSE, NY 13202

EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
11/06/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/591,619	BAKER ET AL.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 679

DETAILED ACTION

1. A telephone call was made to John M. Geller on 20 October 2008 to request an oral election to the above restriction requirement, but did not result in an election being made.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-44, drawn to a body worn patient monitoring device, classified in class 607, subclass 60.

   II. Claims 45-48, drawn to a method of making high voltage circuit protection for a body worn monitor, classified in class 29, subclass 1.

   III. Claims 49-53, drawn to an ECG monitor, classified in class 600, subclass 509.

   IV. Claims 54-55 & 58, drawn to ECG monitor, classified in class 508.

   V. Claims 56-57, drawn to method to improve ECG signal high pass filtering, classified in class 600, subclass 513.

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus claimed can be used by another and materially different process such as a method for treating physiological disorders by sensing physiological parameter utilizing a body worn monitor versus a method of providing high voltage circuit protection for a body worn monitor as instantly claimed.

3. Inventions I and III are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as a body worn patient monitoring device not requiring the use of a defibrillation protection resistor. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. Inventions I and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination I has separate utility such as not requiring the use of an ECG electronics module. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP

§ 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

5. fInventions V and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus claimed can be used by another and materially different process such as a method for treating physiological disorders by sensing physiological parameter utilizing a body worn monitor versus a method to improve ECG signal high pass filtering as instantly claimed.

6. Inventions II and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus claimed can be used by another and materially different process such as a method for treating physiological disorders by sensing physiological parameter utilizing a ECG monitor versus a method of providing high voltage circuit protection for a body worn monitor as instantly claimed.

7. Inventions II and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to

practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used by another and materially different process such as method of treating and monitoring cardiac disorders versus a method of providing high voltage circuit protection for a body worn monitor as is instantly claimed.

8. Inventions II and V are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination IV has separate utility such as a method of improving ECG signal filtering utilized in order to remove unwanted effects such as signal noise and artifacts, providing more efficient ECG data. See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

9. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant

case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the use of a pacer detect circuit. The subcombination has separate utility such as the capability of disabling said ECG monitoring device in order to reduce the electrical load of a power source.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

10. Inventions V and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus claimed can be used by another and materially different process such as a method for treating physiological disorders by sensing physiological parameter utilizing a body worn monitor versus a method to improve ECG signal high pass filtering as instantly claimed.

11. Inventions V and IV are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to

practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus claimed can be used by another and materially different process such as a method for treating physiological disorders by sensing physiological parameter utilizing a body worn monitor versus a method to improve ECG signal high pass filtering as instantly claimed.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE F. LAVERT whose telephone number is (571)270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Nicole F. LaVert/
Examiner, Art Unit 3762

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APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/591,619	11/01/2006	Steven D. Baker	704_049

CONFIRMATION NO. 7955

20874
MARJAMA MULDOON BLASIAK & SULLIVAN LLP
250 SOUTH CLINTON STREET
SUITE 300
SYRACUSE, NY13202

Title: Body worn physiological sensor device having a disposable electrode module

Publication No. US-2008-0139953-A1
Publication Date: 06/12/2008

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Pre-Grant Publication Division, 703-605-4283

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker et al.	Art Unit:	3736
Serial No.:	11/591,619	Examiner:	Not Yet Assigned
Filing Date:	November 1, 2006		
Title:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §1.97, Applicants and their legal representatives hereby make of record the references on the attached PTO/SB/08A Form which are known by them and considered warranting disclosure under 37 C.F.R. §1.56.

Applicant(s) have become aware of the following documents, cited in an International Search Report issued May 15, 2008, during the prosecution of International Application No. PCT/US07/83156, which relates to the above referenced application, hereby submit(s) these documents for the Examiner's consideration. These documents are cited on the enclosed PTO Form SB/08A, and a copy of the International Search Report/Written Opinion are enclosed as well.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Applicants and their legal representatives hereby indicate that, as required by 37 C.F.R. § 1.97(e)(1), that at least one item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.

Also, as this Information Disclosure Statement is being filed (1) no later than three months from the application's filing date or (2) before the mailing date of the first Office Action on the merits and is therefore submitted as both timely and proper; thus, no fees are believed to be due.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 689

However, in the event of a fee deficiency, the Director is authorized to charge any underpayment or credit any overpayment to our Deposit Account No. 50-3010.

Respectfully submitted,

HISCOCK & BARCLAY, LLP

June 3, 2008
Date

Joseph M. Geller
Reg. No. 48,144
One Park Place
300 South State Street
Syracuse, NY 13202-2078
Tel: (315) 422-2131
Fax: (315) 472-3059

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 690

PTO/SB/08A (09-06)
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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049 US01

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.[1]	Document Number Number - Kind Code[2] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AL1	US-4,141,367 A	02/27/1979	Ferreira	
	AM1	US-4,800,894 A	01/31/1989	Milani	
	AN1	US-5,294,928 A	03/15/1994	Cooper, et al.	
	AO1	US-5,309,918 A	05/10/1994	Schraag	
	AP1	US-2002/0122519 A1	09/05/2002	Douglas, et al.	
	AQ1	US-2003/0001742 A1	01/02/2003	Eshelman, et al.	
	AR1	US-2003/0055460 A1	03/20/2003	Owen, et al.	
	AS1	US-2004/0113806 A1	06/17/2004	Neykov	
	AT1	US-2004/0242976 A1	12/02/2004	Abreu	
	AU1	US-2006/0044856 A1	03/02/2006	Bird, et al.	
	AV1	US-2006/0136001 A1	06/22/2006	Ortega, et al.	
	AW1	US-2006/0183434 A1	08/17/2006	Westra, et al.	
	AX1	US-2006/0189976 A1	08/24/2006	Karni, et al.	
	AY1	US-2006/0205171 A1	09/14/2006	Tsukada	
		US-			
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		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] - Number[4] - Kind Code[5] (*if known*)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	3396265
Application Number:	11591619
International Application Number:	
Confirmation Number:	7955
Title of Invention:	Body worn physiological sensor device having a disposable electrode module
First Named Inventor/Applicant Name:	Steven D. Baker
Customer Number:	20874
Filer:	Thomas J. Wall/Jill Kirby
Filer Authorized By:	Thomas J. Wall
Attorney Docket Number:	704_049
Receipt Date:	03-JUN-2008
Filing Date:	01-NOV-2006
Time Stamp:	15:41:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes) /Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	2008-05-03-IDS-Transmittal.pdf	70921 5322ea2771153d6c5b6d4011ced33172c41b5b6c	no	1

Warnings:	
Information:	

2	Information Disclosure Statement Letter	2008-05-03-Supplemental-IDS.pdf	73619 7c6ce3ff855cfd2aad9ed3e597cb925283b8f35a	no	2
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Filed	2008-05-03-PTOSB08A.pdf	88825 3f17d6b850f14cc4a9e079246e74ef5545a3036d	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Miscellaneous Incoming Letter	2008-05-03-PCT-Written-Opinion.pdf	1162456 87ae8311f774d37c12548de3fce7a47280786712	no	16
Warnings:					
Information:					
		Total Files Size (in bytes):	1395821		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/21 (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
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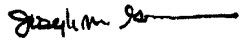
Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049 US01

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  PTO/SB/08A
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Remarks

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Date	June 3, 2008	Reg. No.	48,144

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Total Number of Pages in This Submission	7	Application Number	11/591,619-Conf. #7955
		Filing Date	November 1, 2006
		First Named Inventor	Steven D. Baker
		Art Unit	3736
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	704_049

ENCLOSURES (*Check all that apply*)

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- [ ] Certified Copy of Priority Document(s)
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Printed name	Peter J. Bilinski		
Date	February 16, 2007	Reg. No.	35,067

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Docket No.: 704_049
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Steven D. Baker et al.

Application No.: 11/591,619 Confirmation No.: 7955

Filed: November 1, 2006 Art Unit: 3736

For: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
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Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)). Therefore, it is believed no fee is required.

In accordance with 37 CFR 1.98(a)(2)(ii), Applicant has not submitted copies of U.S. patents and U.S. patent applications. Applicant herein submits English language versions and/or Abstracts for each of the attached foreign documents, pursuant to 37 CFR 1.97(c) and (e)(1) or (b)(3).

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0289, under Order No. 704_049. A duplicate copy of this paper is enclosed.

Dated: February 16, 2007

Respectfully submitted,

By Peter J. Bilinski

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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-2003-0149349A1	08/07/2003	Jensen	
	AB	US-4,791,933	12/20/1988	Asai et al.	
	AC	US-4,957,109	09/18/1990	Groeger et al.	
	AD	US-4,958,645	09/25/1990	Cadell et al.	
	AE	US-4,974,607	12/04/1990	Miwa	
	AF	US-5,257,631	11/02/1993	Wik	
	AG	US-5,458,122	10/17/1995	Hethuin	
	AH	US-5,538,007	07/23/1996	Gorman	
	AI	US-5,544,661	08/13/1996	Davis et al.	
	AJ	US-5,694,940	12/09/1997	Unger et al.	
	AK	US-5,743,269	04/28/1998	Okigami et al.	
	AL	US-5,832,490	11/03/1998	Riley	
	AM	US-5,871,451	02/16/1999	Unger et al.	
	AN	US-5,882,300	03/16/1999	Malinouskas et al.	
	AO	US-5,899,866	05/04/1999	Cyrus et al.	
	AP	US-5,916,159	06/29/1999	Kelly et al.	
	AQ	US-5,919,141	07/06/1999	Money et al.	
	AR	US-5,938,597	08/17/1999	Stratbucker	
	AS	US-5,966,692	10/12/1999	Langer et al.	
	AT	US-5,987,519	11/16/1999	Peifer et al.	
	AU	US-5,995,861	11/30/1999	Price	
	AV	US-6,006,125	12/21/1999	Kelly et al.	
	AW	US-6,018,705	01/25/2000	Gaudet et al.	
	AX	US-6,026,321	02/15/2000	Miyata et al.	
	AY	US-6,052,654	04/18/2000	Gaudet et al.	
	AZ	US-6,066,093	05/23/2000	Kelly et al.	
	AA1	US-6,073,046	06/06/2000	Patel et al.	
	AB1	US-6,076,003	06/13/2000	Rogel	
	AC1	US-6,122,340	09/19/2000	Darley et al.	
	AD1	US-6,150,951	11/21/2000	Olejniczak	
	AE1	US-6,161,036	12/12/2000	Matsumura et al.	
	AF1	US-6,171,237B1	01/09/2001	Avitall et al.	
	AG1	US-6,298,314B1	10/02/2001	Blackadar et al.	
	AH1	US-6,336,365B1	01/08/2002	Blackadar et al.	
	AI1	US-6,357,147B1	03/19/2002	Darley et al.	
	AJ1	US-6,493,652B1	12/10/2002	Ohlenbusch et al.	
	AK1	US-6,794,990B2	09/21/2004	Tseng	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document: Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	BA	EP 0209804 A2	01-28-1987	Rossi, Paolo		
	BB	WO 9620641 A1	07-11-1996	Polar Electro Oy		
	BC	WO 9629005 A1	09-26-1996	Citizen Watch Co. Ltd.		

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First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049

	BD	EP 0770349 A1	05-02-1997	Akasaka, Noboru		
	BE	WO 9746156 A1	12-11-1997	Data Critical Corp.		
	BF	JP 11042214	02-16-1999	Ido Teruo		
	BG	EP 0910985 A1	04-28-1999	Stratbucker, Robert Allen		
	BH	WO 9959460 A2	11-25-1999	Biosys AB		

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European Patent Office
Office européen des brevets

(11) Publication number: **0 209 804**
A2

(12) EUROPEAN PATENT APPLICATION

(21) Application number: 86109450.6

(22) Date of filing: 10.07.86

(51) Int. Cl.⁴: A 61 B 5/07
A 61 B 5/04, A 61 B 5/02

(30) Priority: 25.07.85 IT 6768785

(43) Date of publication of application:
28.01.87 Bulletin 87/5

(84) Designated Contracting States:
AT BE CH DE FR GB LI NL SE

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(54) Unit with a subcutaneous pick-up for continuously monitoring physiological cardiorespiratory variables.

(57) Unit for continuously monitoring and detecting variations in physiological cardiorespiratory variables, such as electrocardiogram signals (QRS-T), heart rate, ventilation/minute (VE), breathing rate, systolic output (SO), cardiac output (CO) and arterial pressure (AP).

The said unit comprises a first subcutaneous part (1) having means (6, 9, 12) for detecting first physiological parameters, such as the difference in potential between electrodes, transthoracic impedance and subcutaneous blood pressure, and means for handling first signals, depending on the said physiological parameters, and for transmitting them, by radio-frequency, to a second part (18) outside the body; the latter part having means for receiving the said physiological variables, which are then processed for detecting critical conditions and activating alarm means (35, 36).

EP 0 209 804 A2

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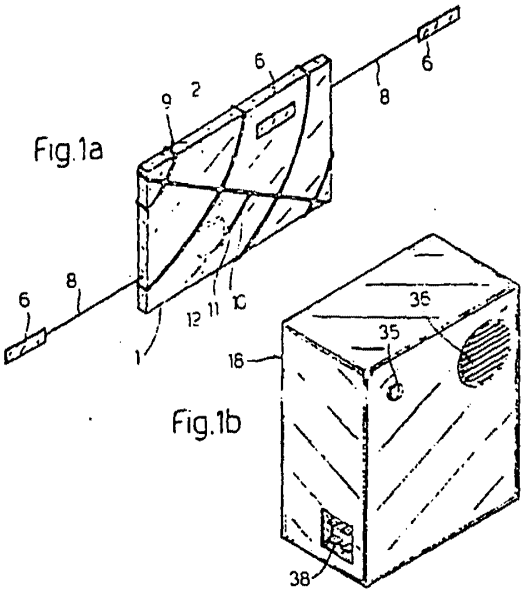


Fig.1a

Fig.1b

UNIT WITH A SUBCUTANEOUS PICK-UP FOR CONTINUOUSLY MONITORING PHYSIOLOGICAL CARDIORESPIRATORY VARIABLES

The present invention relates to a unit with a subcutaneous pick-up for continuously monitoring physiological cardiorespiratory variables.

For continuously monitoring the cardiorespiratory condition of patients, essentially by means of an electrocardiogram signal, such control is currently known to be conducted using external equipment, the pick-up electrodes of which are arranged on the outside of the patient's body. This limits, not only the scope of the control itself, which may only be performed for limited periods of time, but also the activity of the patient, on account of the pick-up equipment being applied to the outside of the patient's body.

The aim of the present invention is to provide a unit for continuously monitoring cardiorespiratory functions, which involves no limitation in the activity of the patient, and which provides for automatically detecting

critical conditions and activating an alarm.

Further aims and advantages of the unit according to the present invention will be disclosed in the following description.

With this aim in view, the present invention relates to a unit for continuously monitoring physiological cardio-respiratory variables, characterised by the fact that it comprises a first subcutaneous part having means for detecting first physiological parameters, and means for handling the said first parameters and transmitting relative first signals to a second part outside the patient's body; the latter part having means for handling the said first signals, and means for processing the said second physiological variables and/or variations in the same, received from the said handling means, for detecting critical conditions and activating alarm means.

A non-limiting arrangement of the present invention will now be described with reference to the attached drawings in which :

- Fig.s 1a, 1b and 1c show views in perspective of three parts on the unit according to the present invention;
- Fig.s 2a and 2b show respective block diagrams of the parts shown in Fig.s 1a and 1b.

Fig.1a shows a first part 1 of the unit according to the present invention, the said part consisting of a rectangular case 2 conveniently titanium-plated, a few centimetres in length and width, a few millimetres thick and containing : circuitry described in more detail later on with reference to Fig. 2a, a solid-state, conveniently lithium battery 3 having a supply life of a few years

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for supplying the circuitry on part 1, a quartz clock 4 and a radio-frequency transmitter 5. The said first part 1 presents three electrodes 6 connected to an internal circuit block 7. Of the said three electrodes 6, one is affixed to case 2 and may conveniently be formed from a portion of the same, whereas the other two are connected by 7-10 cm long wires 8 through case 2, with organic liquid sealing portions conveniently formed of silicone. About case 2 is wound a wide-mesh network 9 of glycerine-filled, intercommunicating teflon tubes, one branch 10 of which fits inside case 2, with an organic liquid insulating zone 11, so as to communicate hydraulically with an electric pressure microtransducer 12 inside part 1. The latter is inserted under the skin, conveniently in the left armpit or mammary region, between the third and fifth rib space, the said electrode 6 affixed to case 2 being arranged facing the ribs, and the other two electrodes 6 being positioned so as to pick up an electrocardiogram signal from the front and lower-rear surfaces of the heart. Block 7 (Fig. 2a) detects the difference in potential between each of the two detached electrodes 6 and the one affixed to case 2, so as to pick up an electrocardiogram signal from two simultaneous branches. These are then processed and sent, in the form of electrocardiogram signal 13, to an amplifying block 14 the output signal of which is then sent to transmitting block 5. Block 7 also detects variations in transthoracic impedance between two of the said three electrodes 6, and supplies a signal 15 also to transmitter 5. As described in more detail later on, variations in transthoracic impe-

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dance signal 15 are used for measuring variations in respiratory ventilation/minute (VE) (breathing rate times current volume) and in systolic output (SO). These two parameters, in fact, differ as to frequency and length : impedance variations caused by breathing are slow and independant of cardiac activity, whereas those caused by systolic output are synchronous with the QRS section on the electrocardiogram signal. Microtransducer 12, which may be a piezoelectric crystal or electromagnetic induction type, supplies a signal 16 depending on the pressure and pressure variations of network 9. Via an amplifying block 17, the said signal 16 is supplied to transmitting block 5 which also comprises a transmission band and time constant selecting circuit. The said transmission band may conveniently range from 5 to 1000 Hertz, in that the frequency of electrocardiogram signal section QRS ranges from 40 to 100 Hertz, that of section S-T from 5 to 40 Hertz, whereas transthoracic impedance may vary by as much as 10 Hertz.

The unit according to the present invention also comprises a second part 18 (Fig. 1b) in the form of a portable pocket box and having internal circuitry as shown on the block diagram in Fig. 2b. The latter shows a receiving block 20 for receiving, even over a distance of a few metres, the signals transmitted by transmitting block 5 on part 1, which separates, by means of frequency band selection, electrocardiogram signal 13, transthoracic impedance variation signal 15 and pressure signal 16. Via a level regulating circuit 21, signal 13 is

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sent to block 22 which, controlled by microprocessor 23 via known identification algorithms, compares the QRS-T sections on in-coming electrocardiogram signals with those considered to be normal, rejects those within the normal range, and sends to a processing and memorising block 24, controlled by microprocessor 23, any abnormal electrocardiogram signals indicating atrial or ventricular arrythmia, dynamic or temporary ischemic alterations (S-T section up or down), and second or third degree atrio-ventricular failure.

Electrocardiogram signal 13 and transthoracic impedance variation signal 15 are sent to block 25, which analyses the said impedance variation synchronous with electrocardiogram section QRS, to give a systolic output variation signal 26. As the reference systolic output value may be set individually, given real cardiac output (CO) measured simultaneously and directly (the best non-invasive method, in terms of accuracy and automation, is a CO_2 measurement), signal 26, via circuit block 27, supplies a signal 28 proportional to cardiac output and which is also sent to processing and memorising block 24. Signal 16 is also sent to block 25 which, by working out the value of the said signal synchronous with section QRS of electrocardiogram signal 13, gives a signal 29, as a function of tissue perfusion pressure, which is also sent to processing block 24.

Variations in transthoracic impedance signal 15 associated with breathing activity depend on breathing rate and current volume. Breathing rate times current volume gives ventilation/minute. The said signal 15 is therefore also

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sent to a processing block 30, which also receives a signal from a clock 31, and which detects the distance between peak breathing points to give a first signal 32, depending on breathing rate and expressing the number of breaths per minute, and a second signal 33 proportional to ventilation/minute and obtained by means of an integral function over one minute of the breathing impedance curve. Both signals 32 and 33 are sent to processing block 24, which also receives the signal from clock 31. The said processing block 24, controlled by microprocessor 23, analyses the in-coming signals relative to the said physiological variables, distinguishes between physiological and pathological variations, identifies various critical conditions, as described in more detail later on, activates an alarm block 34 which, as shown in Fig.1b, may comprise both optical and acoustic alarm means, 35 and 36, and memorises the values of the said critical physiological variables so detected. Furthermore, it may automatically clear the memory of any non-pathological physiological variables. Block 24 may conveniently provide for minimum seven days' data storage, the said second part 18 being supplied by a renewable or rechargeable long-life supply system. The said second part 18 also comprises a circuit block 37 comprising setting circuits and circuits for automatically scanning the signal reference values of the various physiological variables being controlled. The said block 37 controls blocks 21, 25, 30 and 27 and may conveniently be controlled by microprocessor 23. Processing block 24 therefore receives signals 13, 28, 32 and 33, which may be set for supplying real physiological variable

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values. Signal 29, however, proportional to tissue perfusion pressure, cannot be used for setting purposes, when compared with pressure measured by a sphygmomanometer on the humeral artery. Variations in the said signal 29, together with other in-coming data relative to other physiological variables, are used, however, for monitoring physiological behaviour (rise in perfusion pressure, caused by physical strain, alongside increased heart rate and cardiac output or vice versa) and for detecting pathological variations, such as : fall in perfusion pressure despite a simultaneous increase in heart rate (tachyarrythmia), fall in perfusion pressure with severe bradycardia, rise in perfusion pressure with no accompanying increase in physical activity.

The control algorithm performed by processing block 24, for detecting critical conditions, is based on a number of syndromic associations useful in making the following diagnoses.

Physiological sinus tachycardia develops gradually, during muscular activity, and is proportional to work done, oxygen consumption, ventilation/minute, cardiac output and arterial pressure. Ventilation/minute increases along side an increase in both breathing rate and current volume.

Sinus tachycardia resulting from neuropsychic stimulation is independent of motorial activity or oxygen consumption, is unaccompanied by increased ventilation/minute, but may be accompanied by increased breathing rate alone, or also increased arterial pressure. Cardiac output remains unchanged.

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Supraventricular tachycardia develops and ceases rapidly, with no change in ventilation/minute or breathing rate. No change or a fall is registered in cardiac output (with a heart rate of over 150) and in arterial pressure.

Ventricular tachycardia is accompanied by a fall in cardiac output and arterial pressure; ventilation/minute remains unchanged, whereas breathing rate may increase in relation to cardiac insufficiency.

Ventricular fibrillation is accompanied by a sharp, massive fall in cardiac output and arterial pressure, followed, a few seconds later, by ventilation arrest. Unlike ventricular fibrillation, asystolia resulting from heart failure silences the signal.

In view of the foregoing considerations, the alarm conditions detected by processing block 24 are therefore determined by : severe arrythmia, myocardiac ischemia, acute left ventricular failure, each of which may either develop gradually or appear suddenly. Each critical condition is classified by block 24 according to one of three danger levels : level one : pre-alarm; level two: alarm; level three : critical alarm; the signal issued by optical and acoustic alarms 35 and 36 being differentiated accordingly.

Pre-alarm arrythmias are : highly frequent, polymorphous, premature ventricular pulsations in pairs or clusters, and second degree atrio-ventricular failure.

Alarm arrythmias are : ventricular tachycardias, unsustained or sustained up to 30 seconds, within a frequency range of 130-180 beats/minute, and asystolias of three

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seconds or over, caused by sino-atrial or atrio-ventricular failure.

Critical alarm arrythmias are : sustained ventricular tachycardias of over 180 beats/minute, ventricular fibrillations and asystolias lasting over five seconds.

Myocardiac ischemia triggers the pre-alarm when section S-T of electrocardiogram signal 13 rises or falls by 2 mm or more, for at least 15 seconds, on either branch of electrodes 6.

An ischemia alarm is triggered when the rise or fall in the said section S-T persists for over 15 seconds. The critical alarm is triggered when the said rise or fall in section S-T exceeds 4 mm, or when the said rise or fall is accompanied by first and second degree ventricular arrythmia and/or left ventricular failure. Pre-alarm conditions may also include changes in heart rate and arterial pressure accompanied by or preceding a rise or fall of even less than 2 mm in section S-T.

Left ventricular failure may be detected at the presymptomatic stage (level one alarm) by :

1) A sustained increase of over two minutes, as compared with reference values, in sinus heart rate (over 20 beats/minute), arterial pressure (over 30%) and breathing rate (over 5 breaths/minute) during resting hours (recorded by clock 31).
2) A sustained increase of over two minutes in breathing rate (over 5 breaths/minute) accompanied by a fall in cardiac output (over 10%).
3) An increase in heart rate accompanied by a fall in cardiac output during physical activity.

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4) An increase in breathing rate unaccompanied by increased cardiac output in patients suffering from bradyarrythmia.

Left ventricular failure alarms of the second or third level are triggered by : persistent sinus tachycardia (over 110 beats/minute), tachypnea with no increase in volume/minute (over 20 breaths/minute), rise or fall in arterial pressure, and a fall in cardiac output as compared with reference values.

The said second part 18 also presents a socket 38 into which may be plugged a connector 39 on a third part 40, the latter being a unit installable, for example, in a hospital control centre and being, for example, a dynamic electrocardiogram reader designed to :

- receive the data stored in the memory on processing block 24;
- collect the said data on real-time tables or graphs;
- print out any interesting data on paper 41;
- monitor the signal from receiver 20 on fluorescent screen 42 for checking any misread physiological variables (false positives or negatives) or wrongly-formulated alarms;
- tune into the radio-frequency signal transmitted by transmitter 5 on first part 1, for checking and real-time setting each signal via microprocessor 23 on setting circuit 37.

The advantages of the unit according to the present invention will be clear from the foregoing description. In particular, the said first part 1 remains permanently inserted under the skin for continuously transmitting sig-

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nals to a portable pocket part, with no restriction in the activity of the patient whose conditions is thus controlled continuously and who is informed immediately, via alarm means on the portable pocket part, of any critical conditions, as early as the pre-alarm stage, thus enabling appropriate remedial or preventive action to be taken. Periodically transferring the data stored in the portable pocket part to the unit at the control centre enables an in-depth trend analysis to be conducted of the physiological cardiorespiratory variables being controlled. The unit according to the present invention also provides for greater efficiency in detecting critical conditions, on account of it detecting, not only an electrocardiogram signal, but also other physiological variables, such as ventilation/minute, systolic output, cardiac output and arterial pressure.

In addition to patients requiring constant care and observation, the unit according to the present invention may also be applied to subjects performing physical activities under particularly gruelling conditions, e.g. astronauts.

To those skilled in the art it will be clear that changes may be made to the embodiment as described herein without, however, departing from the scope of the present invention. For example, a few of the circuits for picking up basic signals 13, 15 and 16, from which to obtain signals 28, 29, 32 and 33 representing the physiological variables being controlled, may be formed on second part 18 instead of first part 1.

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CLAIMS

1) - Unit for continuously monitoring physiological cardiorespiratory variables, characterised by the fact that it comprises a first subcutaneous part (1) having means (6, 9, 12) for detecting first physiological parameters, and means (7, 14, 17) for handling the said first parameters and transmitting relative first signals (13, 15, 16) to a second part (18) outside the patient's body; the latter part (18) having means (25, 30, 27, 22) for handling the said first signals (13, 15, 16), and means (24) for processing the said second physiological variables and/or variations in the same, received from the said handling means (25, 30, 27, 22), for detecting critical conditions and activating alarm means (34, 35, 36).

2) - Unit according to Claim 1, characterised by the fact that the said first part (1) comprises means (5) for radio-frequency transmitting the said first signals (13, 15, 16) to receiving means (20) on the said second part (18).

3) - Unit according to Claim 1 or 2, characterised by the fact that the said means for detecting the said first physiological parameters comprise at least two electrodes (6) for detecting a difference in potential and so providing a characteristic electrocardiogram signal (13), and for detecting transthoracic impedance for providing at least a few of the said second physiological variables.

4) - Unit according to Claim 3, characterised by the fact that it comprises three electrodes (6).

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5) - Unit according to Claim 3 or 4, characterised by the fact that the said means for detecting the said first physiological parameters comprise means (9, 12) for detecting a pressure outside the said first part (1).

6) - Unit according to Claim 5, characterised by the fact that the said pressure detecting means comprise an electric pressure microtransducer (12) housed in the said first part (1) and connected hydraulically to a network of fluid-filled tubes (9) arranged about the said first part (1).

7) - Unit according to one of the foregoing Claims, characterised by the fact that the said first part (1) comprises an extremely long-life supply battery (3) and is housed in a titanium-plated case (2).

8) - Unit according to one of the foregoing Claims, characterised by the fact that the said second part (18) is pocket-portable.

9) - Unit according to one of the foregoing Claims, characterised by the fact that the said second physiological variables comprise at least some of the following : a characteristic electrocardiogram signal (QRS-T), ventilation/minute (VE), breathing rate, systolic output (SO), cardiac output (CO) and arterial pressure (AP).

10) - Unit according to one of the foregoing Claims, characterised by the fact that the said means (7, 17, 14, 25, 30, 27, 22) for handling the said first physiological parameters for obtaining the said second physiological variables are housed at least partially or totally in the said first (1) and/or the said second (18) part.

11) - Unit according to one of the foregoing Claims, cha-

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racterised by the fact that the said processing means (24) on the said second part (18) comprise a microprocessor (23) and timing means (31).

12) - Unit according to one of the foregoing Claims, characterised by the fact that the said second part (18) comprises memory means controlled by the said processing means (24).

13) - Unit according to one of the foregoing Claims, characterised by the fact that the said processing means (24) are designed to establish critical conditions of different levels, and to differentiate activation of the said alarm means (34, 35, 36) accordingly.

14) - Unit according to one of the foregoing Claims, characterised by the fact that it comprises a third part (40) to which the said second part (18) may be connected for transferring a large number of the said second physiological variables stored in the said second part (18).

15) - Unit according to Claim 14, characterised by the fact that the said third part (40) comprises means for processing and/or analysing and/or printing (41) and/or monitoring on a screen (42) the said second physiological variables received from the said second part (18).

16) - Unit according to Claim 14 or 15, characterised by the fact that the said third part (40) comprises means for receiving the said signals from the said first part (1) and for automatically setting the said handling means (21, 25, 30, 27).

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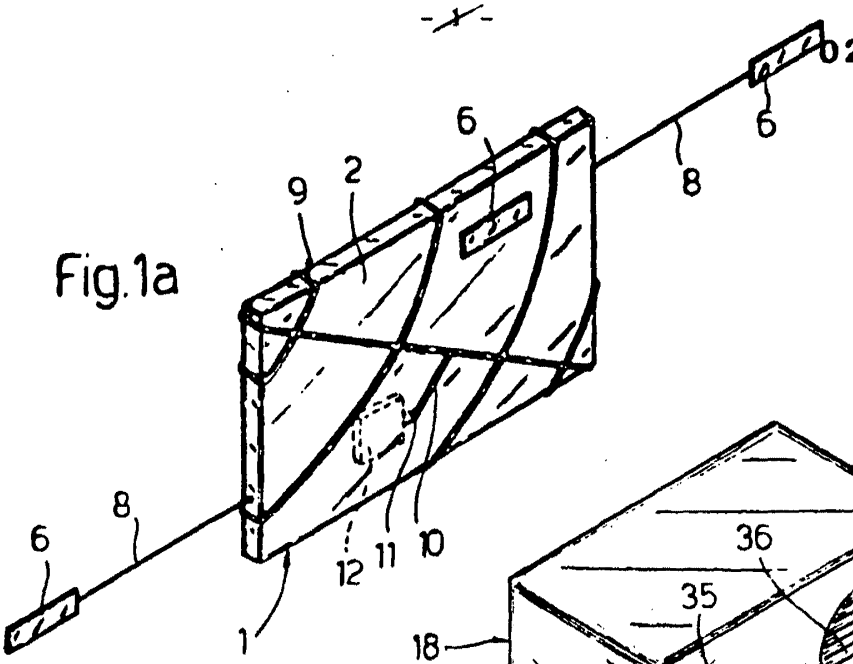


Fig.1a

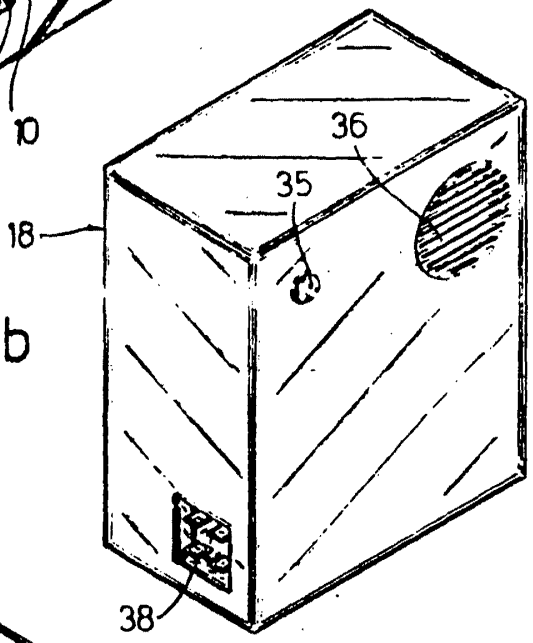


Fig.1b

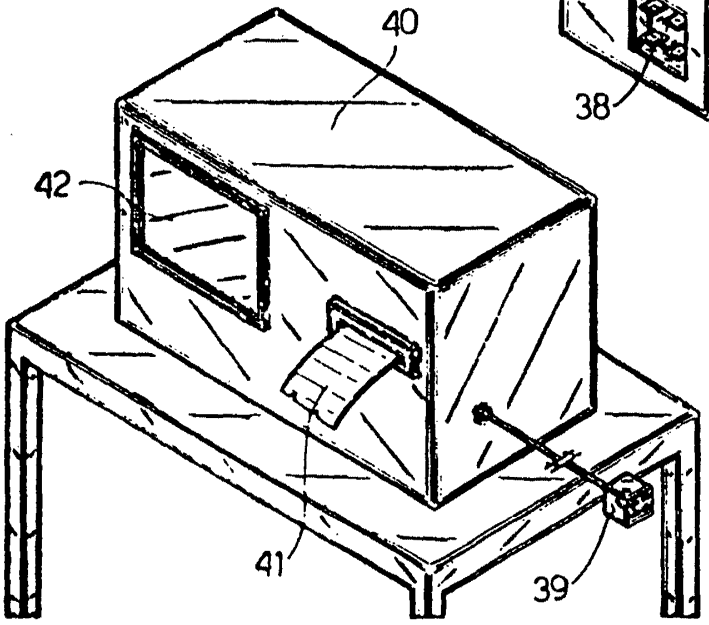


Fig.1c

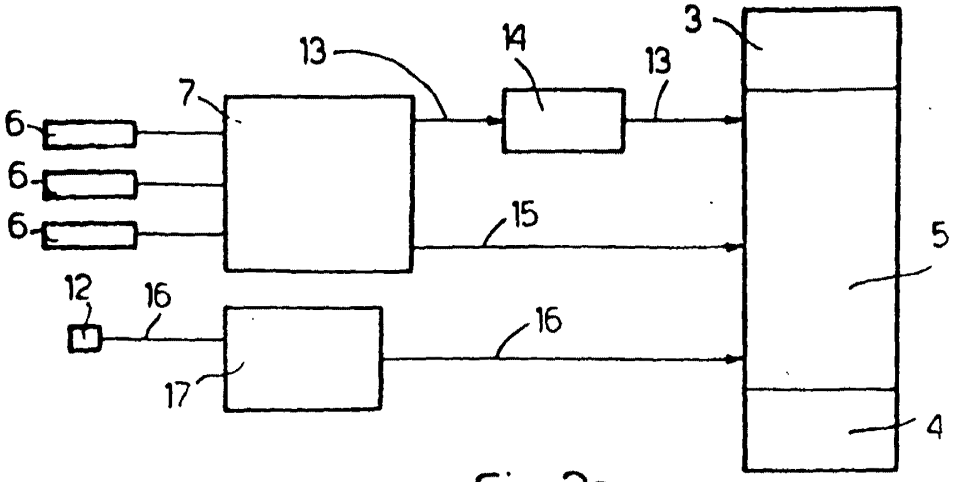

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Fig. 2a

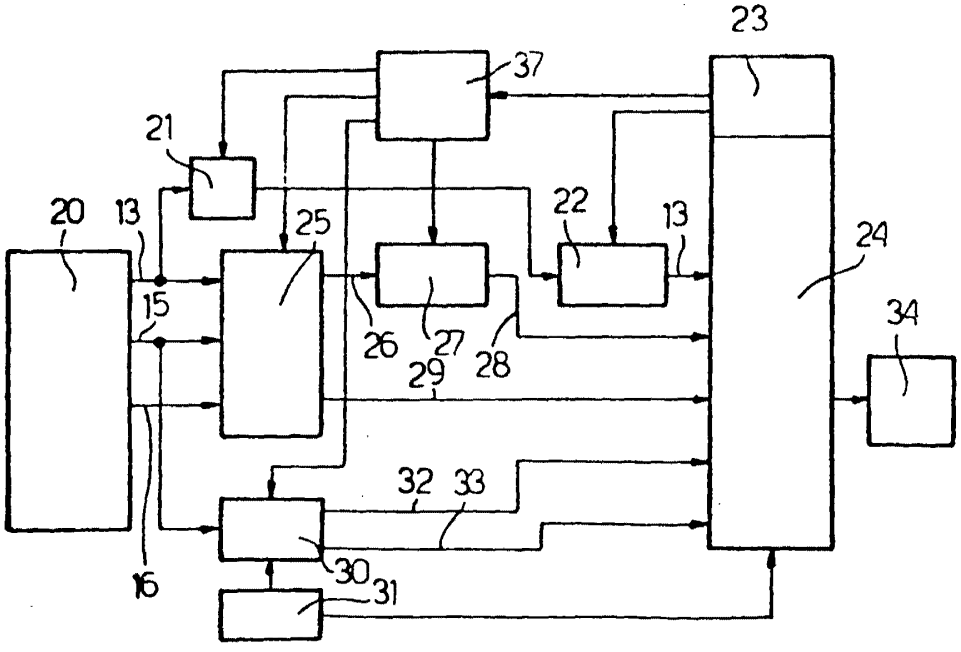

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Fig. 2b

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 5/024

A1

(11) International Publication Number: WO 96/20641

(43) International Publication Date: 11 July 1996 (11.07.96)

(21) International Application Number: PCT/FI95/00714

(22) International Filing Date: 28 December 1995 (28.12.95)

(30) Priority Data:

946164	29 December 1994 (29.12.94)	FI
952656	31 May 1995 (31.05.95)	FI

(81) Designated States: DE, GB, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

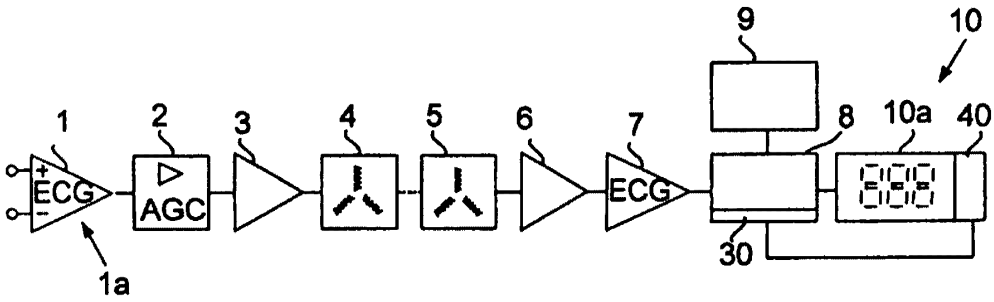
Published
With international search report.
In English translation (filed in Finnish).

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(54) Title: METHOD AND APPARATUS IN CONNECTION WITH MEASURING THE HEARTBEAT RATE OF A PERSON



(57) Abstract

The present invention relates to a method and apparatus in connection with measuring the heartbeat rate of a person. In the method, the ECG signal of the person and the timing moment of at least one ECG signal waveform, such as the QRS complex, are measured with a heartbeat rate monitor. The average heartbeat rate frequency of the heartbeat rate is calculated from the ECG signal. Heartbeat rate variation information proportional to the magnitude of the heartbeat rate variation or to that of the total or partial power of a spectrum derived from the heartbeat rate is provided by means of a mathematical function, said heartbeat rate variation information being displayed on the display (10) of the heartbeat rate monitor together with the average heartbeat rate frequency.

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Method and apparatus in connection with measuring the heartbeat rate of a person

The present invention relates to a method and apparatus in connection with measuring the heartbeat rate of a person.

Heartbeat rate measurement is based on monitoring cardiac function. When contracting, a heart produces a series of electric pulses, which can be measured in a body. The measurement and analysis of such a signal is referred to as electrocardiography (ECG). The actual signal is referred to as an ECG signal. In an ECG signal, it is possible to distinguish phases resulting from different operational stages of the heart. These portions are the so-called P, Q, R, S, T and U-waves.

In known solutions, a heartbeat rate monitor shows on its display mainly average heartbeat rate frequency information only, which is calculated as an average from a suitable number of single pulsations. However, there is need to render the heartbeat rate monitors more versatile. In existing heartbeat rate monitors which filter heartbeat rate, the averaging which levels instantaneous heartbeat rate variation prevents the heartbeat rate measurement information from being analyzed in more detail. In signal processing, averaging means low pass filtering, which as used in this connection cuts the fast variation signal away from the heartbeat rate signal. The known solutions do not provide sufficiently multi-faceted information.

Due to the variation in the sympathetic-parasympathetic balance of the autonomic nervous system, variations around the average heartbeat rate level occur constantly in heartbeat rate. The variation in heartbeat rate is caused by the function of the cardiovascular control system. The main reasons for the variation are

respiratory arrhythmia, variation caused by blood pressure control, and variation caused by the heat balance control of the system. Among these, the most significant and causing the greatest variation is respiratory arrhythmia. The transmitting nervous systems of heartbeat rate variation can be distinguished by means of heartbeat rate variation frequency analysis. At the present time, the sympathetic nervous system is considered to be slow; it is hardly capable of transmitting frequencies higher than 0.15 Hz. Instead, the operation of the parasympathetic nervous system is fast, wherefore frequencies higher than the above-mentioned threshold frequency are transmitted through the parasympathetic nervous system.

The object of the present invention is to provide a new type of method and apparatus, with the use of which the problems associated with the known solutions are avoided.

The invention is characterized by what is defined in the claims below.

Many advantages are achieved with the invention. Measuring heartbeat rate variation and showing the measurement result on the display of the heartbeat rate monitor provide important additional information on the operation of a human body and nervous system, especially on the degree of relaxation of a human. By using heartbeat rate variation according to the invention for defining the degree of relaxation, it is possible to implement individual monitoring which is sufficiently multi-faceted and accurate for the needs of a person. The invention thus enables real-time and wireless monitoring of heartbeat rate variation, whereby the invention provides us with more information without difficult measurements carried out in laboratories. A great heartbeat rate variation is an indication that the parasympathetic nervous system functions, which generally corresponds to a relaxed state

of a system. As for a small value, it indicates that the sympathetic nervous system is active, which is related to physical or mental stress. Thus, by measuring heartbeat rate variation, it is possible to monitor the state of the autonomic nervous system.

In the following, the invention will be described in more detail by means of examples with reference to the accompanying drawings, in which

Figure 1 shows the shape of an ECG signal caused by heartbeat rate,

Figure 2 shows a heartbeat rate variation graph during exertion,

Figure 3 shows a general view of the apparatus of the invention,

Figure 4 shows a functional diagram of the apparatus according to an embodiment of the invention,

Figure 5 shows the display of a heartbeat rate monitor,

Figures 6a - 6e show the forming of a heartbeat rate variation signal from an ECG signal.

Figure 1 shows a typical ECG signal caused by heartbeat rate as presented in a time-voltage coordinate system. The above-mentioned P, Q, R, S, and T-waves can be distinguished in each signal by an accurate measurement. The highest value R represents the maximum point of an ECG signal, and the pulsation defined by the points Q, R and S, i.e. the QRS complex, represents the most easily distinguishable part of the ECG signal. The interval between two successive R peak values is often referred to as the R-R interval of the ECG signal. A P-wave is caused by the contraction of the atria. When the atria contract, the ventricles are filled with blood. The QRS complex formed by the peaks of three waves, defining the shape of the R peak of the ECG signal, is produced when the ventricles contract. The right ventricle thus pumps blood

from veins to the lungs, and the left ventricle pumps blood from the lungs to arteries. The repolarization of the ventricle muscles causes a T-wave, which is lower and more even than the R peak. The periods between the waves depend on the speed of propagation of the nervous stimulus in the heart.

In a healthy human, the ECG signal is between 1 and 2mV in amplitude as measured on the skin. For instance, the amplitude value and duration given for an R peak in literature are 1.6 mV and 90ms, whereas the corresponding values for a P-wave are 0.25 mV and 110 ms. When the heartbeat rate accelerates as a result of exertion, the durations and amplitudes of the different components of the ECG signal remain almost unchanged. It is thus known that the accurate measurement of heartbeat rate and related phenomena is possible by analyzing the ECG signal of heartbeat rate.

The easiest starting point for determining the timing point of an ECG signal accurately is the detection of the QRS complex. In a disturbance-free situation, the QRS complex can be detected in a fairly simple manner by means of a peak value detector. To reduce the number of disturbances occurring in practical situations, some type of filtering is used in accurate analyses. The filtering may take place by using a band-pass filter, adapted filter, or pattern recognition.

Figure 2 shows the behaviour of heartbeat rate variation according to the level of exertion. The graph is drawn on the basis of standard deviations calculated from 100 successive R-R intervals. The figure shows a distinct non-linear decrease in the variation when the exertion is increased.

In the method of the invention, an ECG signal is measured at the chest or some other body part of a person engaged in exercise, and this signal is transmitted to a

receiver as in existing heartbeat rate monitors. The resolution of the heartbeat rate transmitter in defining the timing information of successive ECG signals is at least in the range of 1 ms. The heartbeat rate of the exercising person is constantly monitored during the entire performance. The heartbeat rate monitor measures, as deviating from averaging monitors, some unambiguous timing point of each ECG signal, for instance the R-R interval obtained from QRS complexes, and calculates the standard deviation of the heartbeat rate or some other variation index from the collected intervals. The heartbeat rate monitor constantly monitors the development of the variation.

Figure 3 shows a schematic view of the exemplifying apparatus of the invention. In the telemetric heartbeat rate monitor shown in Figure 3, ECG electrodes 1a are connected to the differential input poles of an ECG pre-amplifier 1. The heartbeat rate signal provided by the pre-amplifier 1 is amplified in an AGC amplifier 2, which is used for controlling a power amplifier 3, in which is produced a heartbeat rate signal controlling coils 4, the interval between the pulses of the signal being the same as the interval between the heart pulsations. A magnetic field varying with the rhythm of the heartbeat rate is thus generated in the coils 4. The blocks 1 - 4 of Figure 1 preferably constitute a telemetric transmitter unit, such as a transmitter belt, which a person wears against his skin, for instance against his chest.

In Figure 3, the other blocks, beginning from block 5, constitute a telemetric receiver unit, which is preferably for instance a receiver wristband worn on the wrist. The magnetic field received from the coils 4, detected by receiving coils 5, is amplified in a sensitive pre-amplifier 6, whereafter the signal is applied to a signal amplifier 7. The output signal of the amplifier is

processed in a microcomputer 8, which calculates from a desired number of previous pulses an average heartbeat rate frequency, which is indicated, i.e. displayed, on a display 10, such as a liquid crystal display 10 in a display element 10a. The average heartbeat rate frequency can also be stored in a memory 9. As regards the above-mentioned elements 1 - 10, the apparatus corresponds to known apparatuses.

The most essential part of the invention is a block 30 and a display element 40, to which the block 30 is connected. The block 30 is a means for calculating the heartbeat rate variation. The means 30 can be implemented as a program segment of the microcomputer 8. The means 30 calculates the heartbeat rate variation data and indicates the heartbeat rate variation in the display element 40. In practise, the display element 10a for indicating the average heartbeat rate and the display element 40 for indicating the heartbeat rate variation are different display elements included in the same display unit 10, such as a liquid crystal display.

Figure 4 shows a functional diagram of the apparatus according to an embodiment of the invention. The functions according to the diagram are preferably included in the software of the microcomputer 8 of the heartbeat rate monitor. The purpose is to determine the heartbeat rate variation of a person engaged for instance in exercise or sports training. In Figure 4, the heartbeat rate measurement which is the basis of the operation is carried out in block 11. By means of the heartbeat rate monitor 5- 10, the heartbeat rate of a person and the timing moment of at least one waveform of the ECG signal, for instance the QRS complex, are measured during the training period.

Thereafter, instantaneous heartbeat rate is calculated in block 12 on the basis of corresponding ECG

signal waveform distances, and a possible shaping is carried out for instance with a suitable digital filter. The heartbeat rate signal can be preferably high pass filtered in this connection to remove slow processes distorting the result, these processes being due for instance to sudden changes in load levels.

A heartbeat rate variation value proportional to the magnitude of the heartbeat rate variation or to that of the total or partial power of a spectrum derived from the heartbeat rate is provided by means of a statistical function 13, i.e. by the formula of the standard deviation S in this example. The heartbeat rate variation can also be calculated for instance by means of the height or width of the heartbeat rate variation distribution pattern or by means of a quantity provided by a statistical function derived from the height and width. The block 13 of Figure 4 corresponds to the block 30 in Figure 3.

The heartbeat rate variation values calculated during the training period are registered, i.e. stored, in the memory 9 in a block 14 as a time function, and the heartbeat rate variation information is also displayed on the display element 40 of the display 10. The heartbeat rate monitor of the invention thus comprises a heartbeat rate variation calculation unit 30 and a display element 40, which displays, on a real-time basis, an index number and/or a graphic indicator proportional to the heartbeat rate variation, for instance a bar 40, the height of which is in some manner proportional to the calculated heartbeat rate variation. Figures 6a - 6e show examples of how a heartbeat rate variation signal is derived from an ECG signal. The starting point is the measured ECG signal according to Figure 1, in which a suitable timing point t_i (Figure 6a) is determined on the basis of R pulses. Figure 6b shows the determination of instantaneous heartbeat rate on the basis of the timing points $t_1 \ldots t_n$ of R-R intervals.

The instantaneous heartbeat rate is shown as a continuous signal in an R-R time domain in Figure 6c and in a heartbeat rate time domain in Figure 6d, the heartbeat rate equalling 60/RR in the heartbeat rate time domain. Figure 6e shows a heartbeat rate variation graph, which can be calculated directly from the R-R intervals (Figure 6b) as a recursively floating standard deviation, or as a moving height or width determined from the shape of the distribution pattern, or as a value of the partial or total power of a spectrum derived from the signals of Figure 6c or 6d.

In the apparatus of the invention, the heartbeat rate variation display 40, i.e. a so-called relaxation display 40, preferably consists of a bar comprising for instance 10 parts. The height of the bar directly represents the standard deviation of pulsation intervals. The higher the bar, the greater the standard deviation and correspondingly the degree of relaxation.

In the preferred embodiment of the invention, the heartbeat rate variation is indicated on the display 10 of the heartbeat rate monitor simultaneously with the average heartbeat rate frequency in the method. The user is thus able to detect both the average heartbeat rate frequency and the heartbeat rate variation at the same time at a single glance, the heartbeat rate variation thus indicating the degree of relaxation of the person.

In the preferred embodiment of the invention, the heartbeat rate variation information is indicated on the display of the heartbeat rate monitor graphically and/or digitally in the method. The graphic display is implemented for instance with a bar-like display element. The digital display can be implemented with display elements 41 - 42.

In the method, the heartbeat rate variation information is indicated on the display of the heartbeat

rate monitor simultaneously both graphically and digitally.

The heartbeat rate variation information is indicated on such a common display element that is also used for indicating the modes and set conditions of the heartbeat rate monitor.

In the method, an indicator 50 indicates whether the common display element 40 displays heartbeat rate variation information or modes and set conditions.

Even if the invention has been described above with reference to the examples according to the accompanying drawings, it will be apparent that the invention is not so restricted, but it can modified in various ways within the scope of the inventive concept disclosed in the appended claims.

Claims

1. A method in connection with measuring the heartbeat rate of a person, c h a r a c t e r i z e d by the following steps:

- measuring, with a heartbeat rate monitor, the ECG signal of the person and the timing moment of at least one ECG signal waveform, such as the QRS complex,

- calculating the average heartbeat rate frequency of the heartbeat rate from the ECG signal, and

- providing, by means of a mathematical function, heartbeat rate variation information proportional to the magnitude of the heartbeat rate variation or to that of the total or partial power of a spectrum derived from the heartbeat rate, said heartbeat rate variation information being displayed on the display of the heartbeat rate monitor.

2. A method according to claim 1, c h a r a c - t e r i z e d in that in the method, the heartbeat rate variation is indicated on the display of the heartbeat rate monitor simultaneously with the average heartbeat rate frequency.

3. A method according to claim 1, c h a r a c - t e r i z e d in that in the method, the heartbeat rate variation information is indicated on the display of the heartbeat rate monitor graphically and/or digitally.

4. A method according to claim 3, c h a r a c - t e r i z e d in that in the method, the heartbeat rate variation information is indicated on the display of the heartbeat rate monitor simultaneously both graphically and digitally.

5. A method according to claim 1, c h a r a c - t e r i z e d in that the heartbeat rate variation information is indicated on such a common display element that is used for indicating the modes and set conditions

of the heartbeat rate monitor in addition to indicating the heartbeat rate variation information.

6. A method according to claim 5, c h a r a c t e r i z e d in that in the method, an indicator (50) indicates whether the common display element (40) displays heartbeat rate variation information or modes and set conditions.

7. A method according to claim 1, c h a r a c t e r i z e d in that the heartbeat rate variation information is calculated by means of a statistical function (13) which provides the standard deviation of the heartbeat rate as a result.

8. A method according to claim 1, c h a r a c t e r i z e d in that the heartbeat rate variation information is calculated by means of a statistical function which provides the height or width of the distribution pattern of an instantaneous heartbeat rate signal or R-R signal as a result.

9. A method according to claim 1, c h a r a c t e r i z e d in that the heartbeat rate variation information is calculated by means of a function which provides the total or partial power of a power spectrum of a continuous heartbeat rate signal as a result.

10. An apparatus in connection with measuring the heartbeat rate of a person, c h a r a c t e r i z e d in that the apparatus comprises:

- means (1- 4) for detecting and transmitting heartbeat rate signals,
- a heartbeat rate monitor (5 - 10; 11) for receiving, calculating and measuring heartbeat rate signals, and for registering the timing moment of at least one ECG signal waveform contained by a heartbeat rate signal, for instance the QRS complex,
- means (8; 12) for calculating the average heartbeat rate frequency of the heartbeat rate on the

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
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basis of the ECG signal,

- means (8; 13) for providing heartbeat rate variation information proportional to the magnitude of the heartbeat rate variation or to that of the total or partial power of a spectrum derived from the heartbeat rate by means of a mathematical function, and

- means (40, 41- 42) for indicating the heartbeat rate variation information on the heartbeat rate monitor.

11. An apparatus according to claim 10, c h a r a c t e r i z e d in that the means (40, 41- 42) for indicating the heartbeat rate variation information on the heartbeat rate monitor comprise a display element (40, 41- 42) on the same display (10) which comprises a display element (10a) for indicating the average heartbeat rate information.

12. An apparatus according to claim 10, c h a r a c t e r i z e d in that the means for indicating the heartbeat rate variation information comprise a graphic and/or digital display element (40 and/or 41- 42).

13. An apparatus according to claim 10, c h a r a c t e r i z e d in that the means (40) for indicating the heartbeat rate variation information consist of the same display element (40) which indicates modes and set conditions on the heartbeat rate monitor.

14. An apparatus according to claim 10, c h a r a c t e r i z e d in that the apparatus comprises a high pass filter (11) for filtering a heartbeat rate signal.

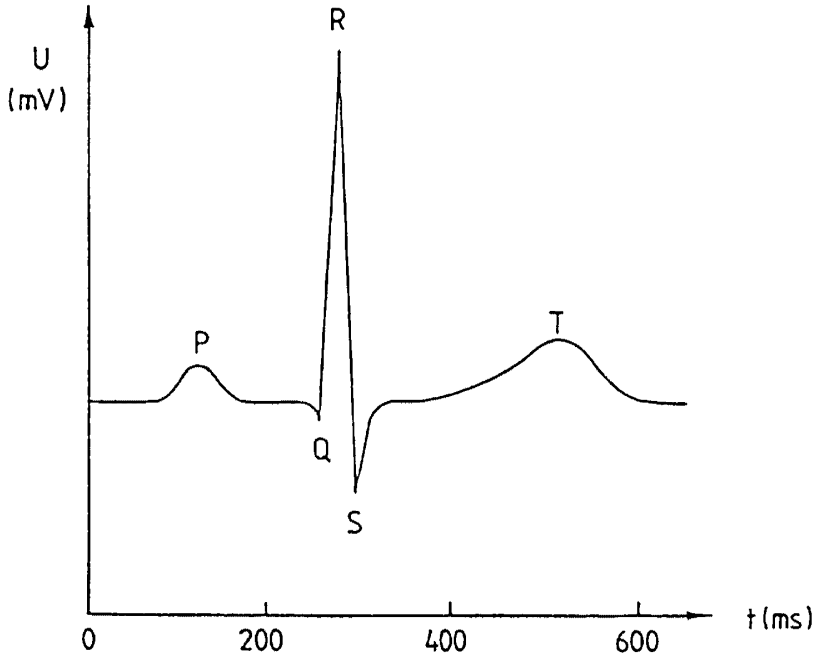


FIG. 1

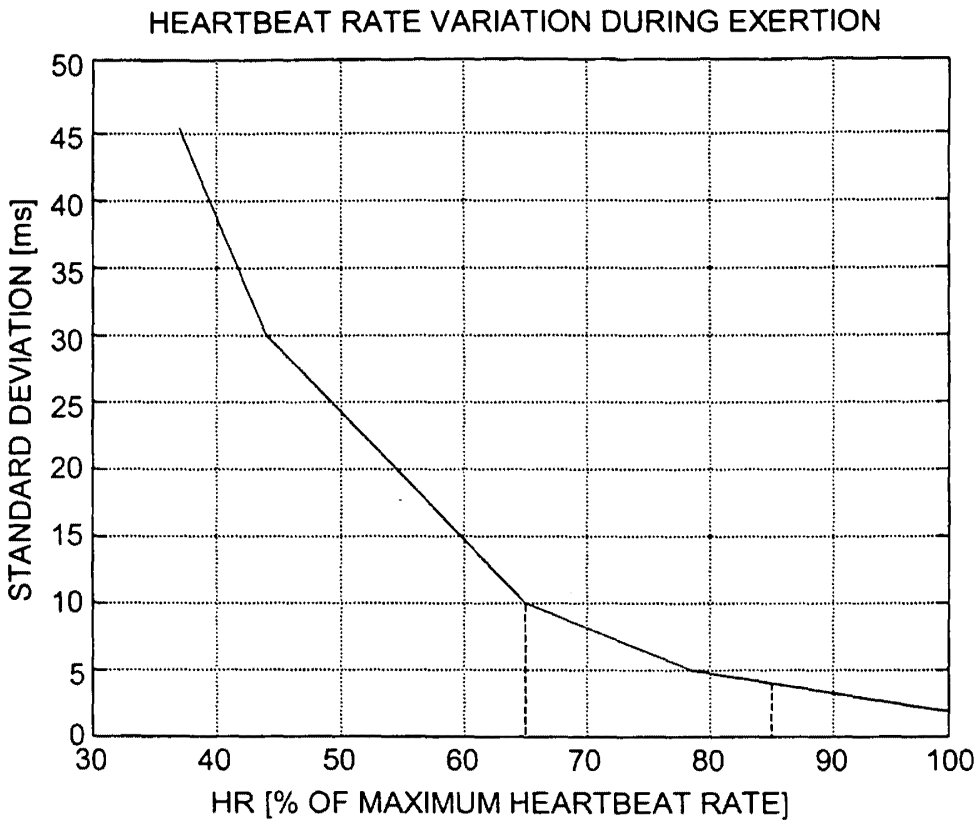

HEARTBEAT RATE VARIATION DURING EXERTION
STANDARD DEVIATION [ms]
50
45
40
35
30
25
20
15
10
5
0
30
40
50
60
70
80
90
100
HR [% OF MAXIMUM HEARTBEAT RATE]

FIG. 2

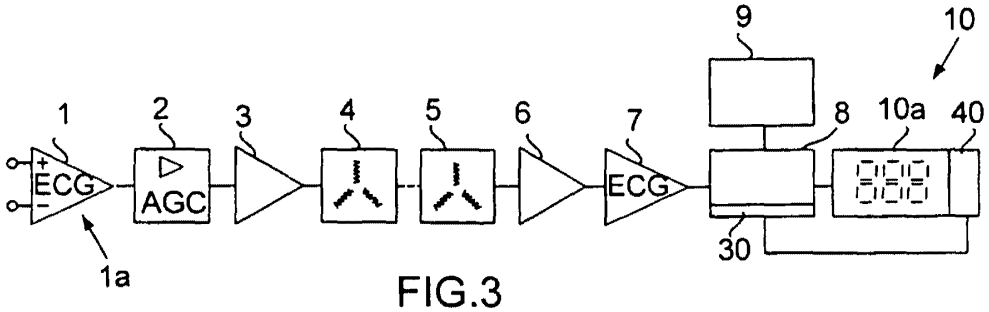

9
10
1
2
3
4
5
6
7
8
10a
40
ECG
AGC
ECG
30
1a

FIG.3

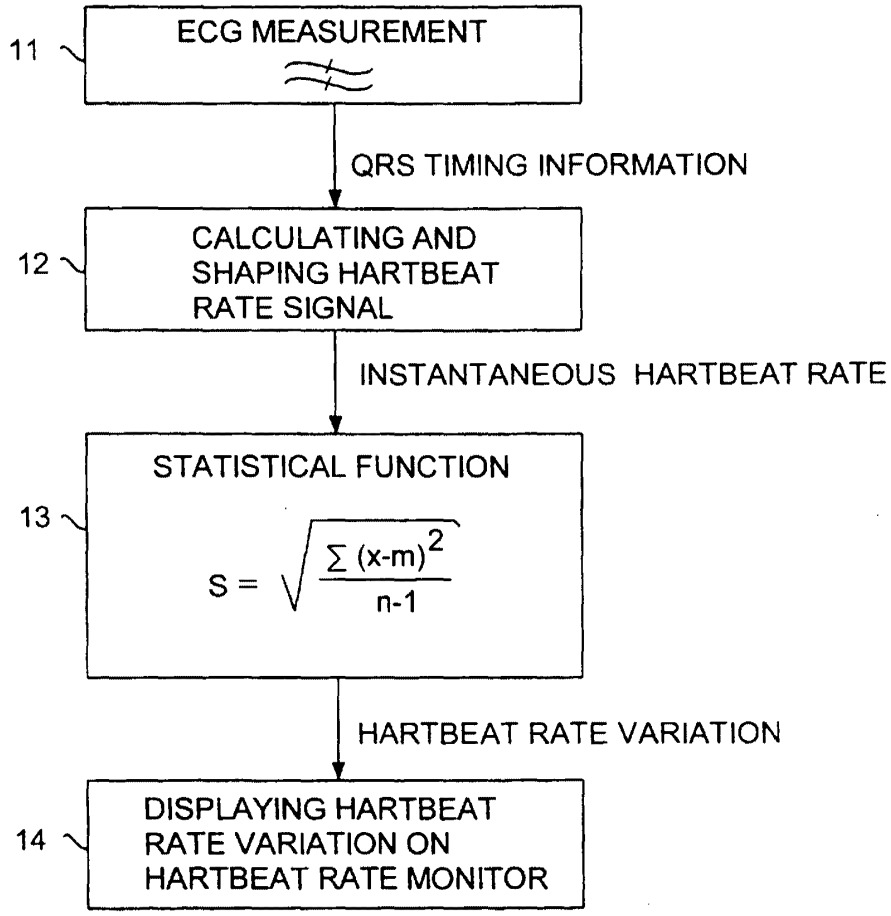

11
ECG MEASUREMENT
QRS TIMING INFORMATION
12
CALCULATING AND SHAPING HARTBEAT RATE SIGNAL
INSTANTANEOUS HARTBEAT RATE
13
STATISTICAL FUNCTION
$S = \sqrt{\frac{\sum (x-m)^2}{n-1}}$
HARTBEAT RATE VARIATION
14
DISPLAYING HARTBEAT RATE VARIATION ON HARTBEAT RATE MONITOR

FIG. 4

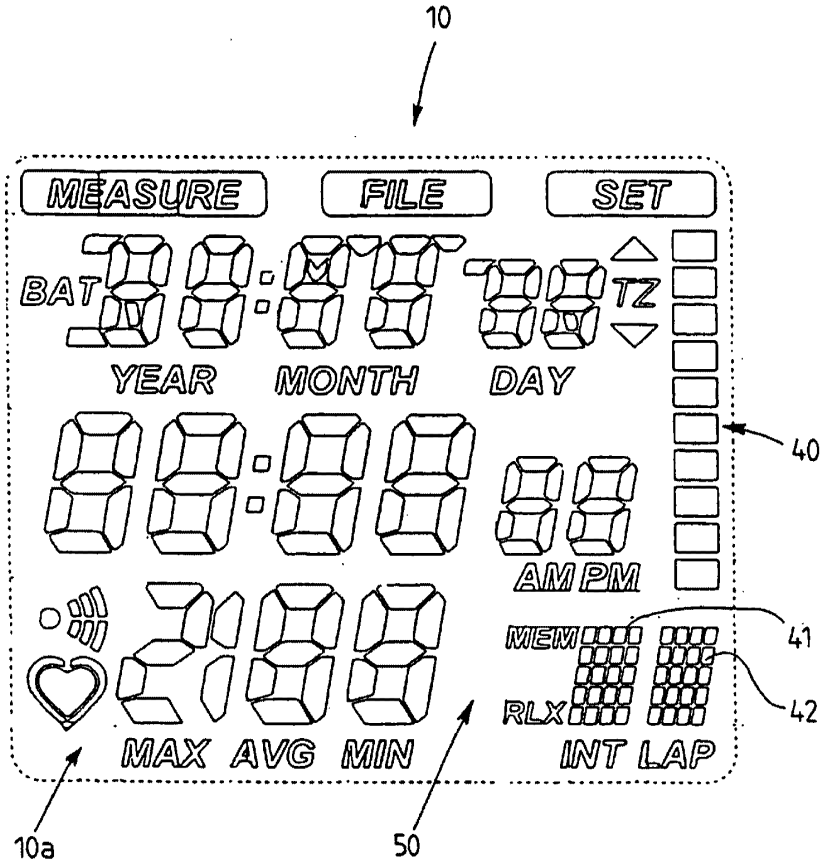

10
MEASURE
FILE
SET
BAT
TZ
YEAR
MONTH
DAY
40
AM PM
MEM
41
RLX
42
MAX AVG MIN
INT LAP
10a
50

FIG. 5

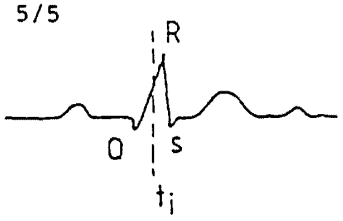


FIG. 6a

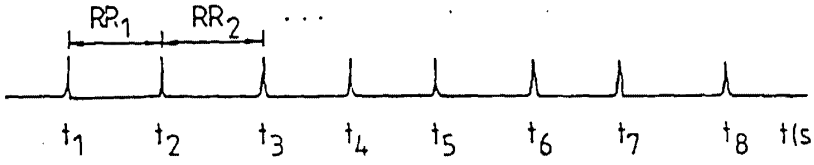


FIG. 6b

$RR_1 = t_2 - t_1$, $RR_2 = t_3 - t_2$, ...

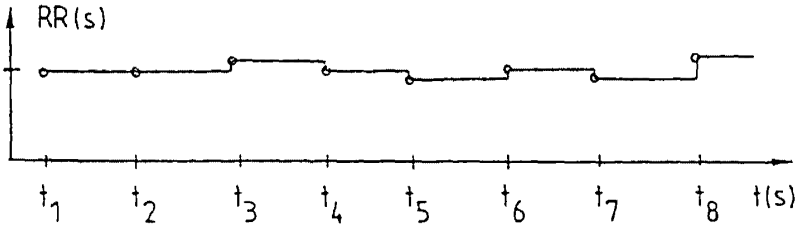


FIG. 6c

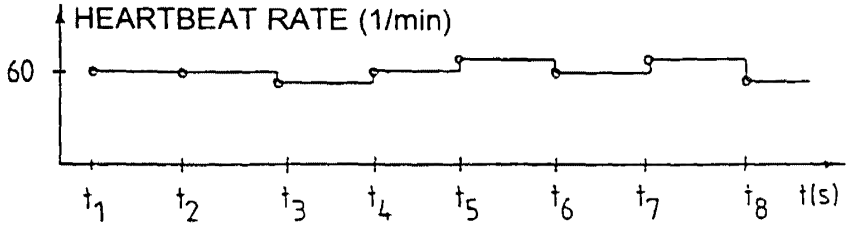


FIG. 6d

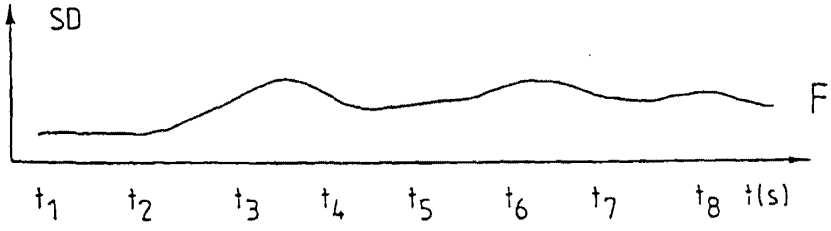


FIG. 6e

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 95/00714

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/024
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)

IPC6: A61B

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

SE,DK,FI,NO classes as above

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	DE 3209850 C2 (DORNIER SYSTEM GMBH), 28 March 1985 (28.03.85), column 3, line 19 - line 62, figures 1, 2	1,10
Y	US 5339822 A (L.A. TAYLOR ET AL), 23 August 1994 (23.08.94), claims 1,4	1,10
A	US 4566461 A (M. LUBELL ET AL), 28 January 1986 (28.01.86), abstract	1-14
A	US 5117833 A (D.E. ALBERT ET AL), 2 June 1992 (02.06.92), abstract	1-14

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
2 April 1996	10/04/96
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Vilho Juvonen Telephone No. +46 8 782 25 00

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INTERNATIONAL SEARCH REPORT
Information on patent family members

05/02/96

International application No.
PCT/FI 95/00714

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-C2- 3209850	28/03/85	NONE	
US-A- 5339822	23/08/94	NONE	
US-A- 4566461	28/01/86	EP-A,A,A 0117330 JP-A- 59149128	05/09/84 27/08/84
US-A- 5117833	02/06/92	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

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特許協力条約に基づいて公開された国際出願

(51) 国際特許分類6		(11) 国際公開番号	WO96/29005
A61B 5/0245	A1	(43) 国際公開日	1996年9月26日(26.09.96)

(21) 国際出願番号 PCT/JP96/00661
(22) 国際出願日 1996年3月15日(15.03.96)

(30) 優先権データ

特願平7/57871	1995年3月17日(17.03.95)	JP
特願平7/202971	1995年8月9日(09.08.95)	JP
特願平7/202972	1995年8月9日(09.08.95)	JP

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JP, US, 欧州特許(AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

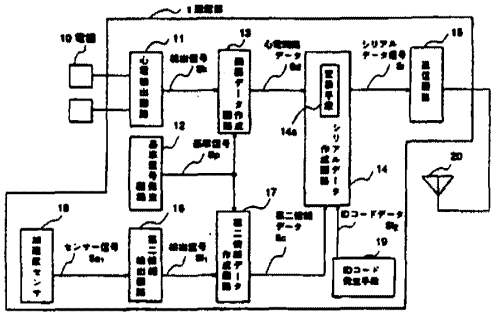
添付公開書類　国際調査報告書

(54) Title : PULSE RATE METER

(54) 発明の名称　心拍計

(57) Abstract :

This invention aims at improving a method of carrying out communication between a transmission unit and a reception unit in a pulse rate meter and providing a pulse rate meter not influenced by noise. To achieve these objects, the present invention provides a pulse rate meter comprising a transmission unit provided with a detecting circuit for detecting an electrocardiographic signal obtained from a pair of electrodes fixed to the portion of a human body which is in the vicinity of the heart (2), and generating a detected signal (3), an interval data preparation circuit for counting the generation interval of the detected signals by a signal of a predetermined cycle and generating interval data (4), a serial data preparation circuit for converting the interval date into a serial signal and generating serial data signal (5), a transmission circuit for modulating the serial data signal and transmit the resultant signal as a ratio signal (6), and a battery as a power source (7), and a reception unit provided with a reception circuit for receiving the radio signal from the transmission unit, demodulating the resultant signal and generating a reception signal (8), a data decoding circuit for decoding the reception signal and generating electrocardiographic interval data (9), an operation circuit for calculating a heart rate on the basis of the electrocardiographic interval data, and a display for indicating a heart rate thereon. According to the present invention, even when the reception circuit receives noise or a signal having no relation with a heart rate, which does not constitute correct data in this case, it cannot be decoded correctly by the decoding circuit, and the data received normally in the preceding time are displayed. Therefore, erroneous heart rates are not displayed.



1 ... transmission unit
10 ... electrode
11 ... electro-cardiographic detecting circuit
12 ... reference signal generating circuit
13 ... interval data preparation circuit
14 ... serial data preparation circuit
14a ... conversion means
15 ... transmission circuit
16 ... second information detecting circuit
17 ... second information data preparation circuit
18 ... acceleration sensor
19 ... ID code generating means
S_m ... sensor signal
S_c ... second information data
S_d ... electrocardiographic interval data
S_s ... detected signal
$S_{s'}$ ... detected signal
$S_{i'}$ ... ID code data
S_p ... reference signal
S_r ... serial data signal

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（５７）要約

本発明は、心拍計の送信部と受信部との通信方法を改善し、ノイズの影響を受けない心拍計を提供することを目的とする。

本発明はこの目的を達成するために、人体における心臓の近傍に装着された一対の電極から得られる心電信号を検出して検出信号を発生する検出回路と、該検出信号の発生間隔を一定周期の信号で計数して間隔データを発生する間隔データ作成回路と、該間隔データをシリアル信号に変換してシリアルデータ信号を発生するシリアルデータ作成回路と、該シリアルデータ信号を変調して無線信号として送信する送信回路と、電源としての電池とを備えた送信部と、該送信部からの無線信号を受信して復調し受信信号を発生する受信回路と、前記受信信号をデコードして心電間隔データを発生するデータデコード回路と、心電間隔データから心拍数を算出する演算回路と、心拍数を表示する表示部とを備えた受信部とから心拍計を構成する。

本発明によれば、受信回路がノイズや無関係の信号を受信しても、この場合には正しいデータではないためデータデコード回路が正常にデコードできず、前回の正しい受信の際のデータを表示するので、誤った心拍数を表示してしまうことがない。

情報としての用途のみ
ＰＣＴに基づいて公開される国際出願をパンフレット第一頁にＰＣＴ加盟国を同定するために使用されるコード

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明 細 書

心拍計

技術分野

本発明は心電信号を検出しその情報を無線にて送出し、その情報を受信することで離れた場所で心拍数を表示する心拍計に関する。

背景技術

従来、心臓の近傍に装着された一対の電極から得られる心電信号を検出してその情報を無線信号で送信する送信部と、その無線信号を受信し演算することで心拍数を表示できる腕時計などに組み込まれた小形の情報機器である受信部とにより、離れたところでも心拍数を観測することができるという提案がたとえば実開平３－５４０５号公報においてなされている。

上述の従来の心拍計では送信部にて心電信号を検出するたびに無線信号を送信し、それを受信部で受信するようにしており、すなわち、受信のタイミングが心拍のタイミングであった。このため、たとえば電車の踏切の音を鳴らすための電磁ノイズなど様々なノイズを誤って受信してしまい、受信すべき心拍のタイミングとは狂ってしまい、誤った心拍数を表示してしまうといった問題があった。

発明の開示

本発明の目的は、従来の心拍計の問題点を解決し、送信部と受信部との通信方法を改善しノイズの影響を受けない心拍計を提供することにある。

上記目的を達成するための本発明の構成は、人体における心臓の近傍に装着された一対の電極から得られる心電信号を検出して検出信号を発生する検出回路と、該検出信号の発生間隔を一定周期の信号で計数して間隔データを発生する間隔データ作成回路と、該間隔データをシリアル信号に変換してシリアルデータ信号を発生するシリアルデータ作成回路と、該シリアルデータ信号を変調して無線信号として送信する送信回路と、電源としての電池とを備えた送信部と、該送信

部からの無線信号を受信して復調し受信信号を発生する受信回路と、前記受信信号をデコードして心電間隔データを発生するデータデコード回路と、心電間隔データから心拍数を算出する演算回路と、心拍数を表示する表示部とを備えた受信部とから成ることを特徴とする。

上記構成により本発明は、受信回路がノイズや無関係の信号を受信しても、この場合には正しいデータではないためデータデコード回路が正常にデコードできず、前回の正しい受信の際のデータを表示するので、誤った心拍数を表示してしまうことがない。

図面の簡単な説明

図１は本発明による心拍計の送信部の一実施例のブロック図、図２は本発明による心拍計の受信部の一実施例のブロック図、図３は受信制御回路の動作を説明するためのタイムチャート、図４は本発明による心拍計の一実施例の装着状態を示す図、図５は本発明による心拍計の送信部の一実施例の外観図であり内部が見えるように蓋を取り外したところを示す図、図６は本発明による心拍計の受信部の一実施例の外観図、図７は送信部から受信部に対して送信する信号のフォーマットの一例を示す図である。

発明を実施するための最良の形態

以下図面に基づいて本発明の実施例を詳述する。

なお、本実施例における心拍計では、心電信号以外の信号による情報（以下「第二情報」という）を受信部に表示することもでき、この第二情報としては、たとえば、送信部を装着した人の１分当たりの歩行数や総歩行数であり、また、送信部の電池電圧低下の警告である。

図１は本発明による心拍計の送信部の一実施例のブロック図である。

本実施例では、第二情報は走行ピッチすなわち１分当たりの歩行数の場合を想定する。

１０は電極であり、人体における心臓の近傍に装着される。１８は加速度センサーであり、この送信部に内蔵してある。１は送信部であり、心電検出回路１１

と、基準信号発生回路１２と、間隔データ作成回路１３と、シリアルデータ作成回路１４と、送信回路１５と、第二情報検出回路１６と、第二情報データ作成回路１７と、ＩＤコード発生手段１９とにより構成されている。

心電検出回路１１は、電極１０により検出された心電信号を検出、増幅し、心電信号に同期したパルス信号である検出信号Ｓｋを出力する。間隔データ作成回路１３は、検出信号Ｓｋの発生間隔を基準信号発生回路１２から出力される基準信号Ｓｐで計数しその計数値を心電間隔データＳｄとして出力する。

一方、第二情報検出回路１６は、加速度センサー１８により加速度の変化の電気的信号であるセンサー信号$Ｓａ_1$を検出、増幅し、センサー信号$Ｓａ_1$に同期したパルス信号である検出信号$Ｓ１_1$を出力し、第二情報データ作成回路１７は、検出信号$Ｓ１_1$の発生間隔を基準信号発生回路１２から出力される基準信号Ｓｐで計数しその計数値を第二情報データである走行ピッチデータＳｃとして出力する。

また、ＩＤコード発生手段１９は、所定のＩＤコードを発生し、シリアルデータ作成回路１４が処理可能なＩＤコードデータ$Ｓ１_2$に変換し出力する。

シリアルデータ作成回路１４は、心電間隔データＳｄと第二情報データＳｃとＩＤコードデータ$Ｓ１_2$とを変換手段１４ａで結合した後シリアルデータに変換し、Ｔｊ秒毎にシリアルデータ信号Ｓｒを出力する。送信回路１５は、シリアルデータ信号Ｓｒが入力される毎に該シリアルデータ信号Ｓｒを変調して無線信号としてアンテナ２０から送信する。

本実施例においては、Ｔｊ秒毎にシリアルデータ信号Ｓｒを無線信号として送出しているが、心拍や走行ピッチの変動に追従できる程度の時間（１秒、５秒、１０秒等）であればよい。

図２は本発明による心拍計の受信部の一実施例のブロック図である。

２は受信部であり、受信回路３１と、データデコード回路３２と、受信制御回路３３と、演算回路３４と、表示部３５と、第二情報演算回路３６と、第二情報表示部３７と、ＩＤコード記憶手段３８と、ＩＤコード記憶判定回路３９とによ

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り構成されている。

受信回路３１は、アンテナ３０から受信された送信部１からの無線信号を増幅、検波、復調し、受信信号Ｓｊを出力する。また、受信回路３１は受信制御回路３３から受信制御信号Ｓｓが入力されるとその機能を停止する。受信信号Ｓｊは前記送信部１のシリアルデータ信号Ｓｒと同じ信号である。

データデコード回路３２は、受信信号Ｓｊをデコードし、データ分離手段３２ａから心電間隔データＳｎと第二情報データSm_1とＩＤコードデータSm_2とを分離出力する。心電間隔データＳｎは前記送信部１の心電間隔データＳｄと同じ信号であり、第二情報データSm_1は前記送信部１の第二情報データSl_1と同じ信号であり、ＩＤコードデータSm_2は前記送信部１のＩＤコードデータSl_2と同じ信号である。また、データデコード回路３２は心電間隔データＳｎと第二情報データSm_1とＩＤコードデータSm_2のデコードが正常に行われると、ワンショット信号であるデコード終了信号Ｓｅを出力する。受信制御回路３３はデコード終了信号Ｓｅが入力されると、一定幅のパルス信号である受信制御信号Ｓｓを出力する。受信制御信号Ｓｓのパルス幅は前記送信部１から送信される無線信号の間隔Ｔｊ秒よりも短い信号である。デコード終了信号Ｓｅと受信制御信号Ｓｓは消費電力低減のために必要とする信号であるが、その動作説明については後述する。

ＩＤコード記憶手段３８は各心拍計が固有に持っているＩＤコードを記憶しており、その値は送信側のＩＤコードと同じである。また、ＩＤコード記憶手段３８はその記憶しているＩＤコードデータを電気信号Sa_2として出力する。

ＩＤコード比較判定回路３９は、データデコード回路３２がデコードしたＩＤコードデータSm_2とＩＤコード記憶手段３８の出力するＩＤコードデータSa_2とを比較判定しその結果として二値信号Ｓｂを演算回路３４および第二情報演算回路３６に出力する。

演算回路３４は心電間隔データＳｎを演算して心拍数に変換し、その心拍数を表示部３５に表示する。また、第二情報演算回路３６は第二情報データSm_1を

演算して表示可能なデータ、たとえば、走行ピッチに変換し第二情報表示部３７に表示する。

上記構成を有する、本発明による心拍計の動作を説明する。

まず図１において、送信部１の動作を説明する。

電極１０により検出された心電信号は心電検出回路１１により検出信号Ｓｋに変換される。間隔データ作成回路１３は、検出信号Ｓｋの間隔を基準信号発生回路１２によって出力される基準信号Ｓｐによって計数するが、ここで基準信号Ｓｐの周波数を６００Ｈｚとする。たとえば、心拍数が８０の場合、検出信号Ｓｋの間隔が７５０ｍｓとなり、計数値は４５０となる。

第二情報検出回路１６では、走行時に生じる加速度の周期的な変化を加速度センサー１８が検出した上で電気信号$Ｓａ_1$に変換する。その検出信号$Ｓａ_1$を増幅し、走行ピッチに同期して第二情報検出信号$Ｓ１_1$が出力される。第二情報データ作成回路１７は、第二情報検出信号$Ｓ１_1$の間隔を基準信号発生回路１２によって出力される基準信号Ｓｐによって計数する。１分間のピッチ数が１２０の場合、第二情報検出信号$Ｓ１_1$の間隔が５００ｍｓとなり、計数値は３００となる。

間隔データ作成回路１３の計数値４５０は心電間隔データＳｄとして、第二情報検出回路１６の計数値３００は第二情報データＳｃとしてシリアルデータ作成回路１４に送られる。

一方、ＩＤコード発生手段１９はたとえば「Ｎｏ．１０」というＩＤコードを発生するものとする。ＩＤコード発生手段１９はこの「Ｎｏ．１０」というＩＤコードをシリアルデータ作成回路１４が処理可能な「１０」という数値のＩＤコードデータ$Ｓ１_2$に変換しシリアルデータ作成回路１４に出力する。

シリアルデータ作成回路１４では変換手段１４ａで心電間隔データＳｄと第二情報データＳｃとＩＤコードデータ$Ｓ１_2$とを連結したうえでＴｊ秒毎にシリアルデータであるシリアルデータ信号Ｓｒに変換し、シリアルデータ信号Ｓｒは送信回路１５により無線信号としてアンテナ１９を介して送信される。

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シリアルデータ信号ＳｒはＴｊ秒毎に無線信号として送出されている。従来方式では、心拍の検出毎に送信を行なっていたため、毎秒数十回送信を行なう必要があった。対して、本方式は、数～数十秒毎に一回送信を行なうのみである。従って、単位時間あたりの送信回数は大幅に減少でき、送信部１の消費電力を大幅に低減できる。

次に図２において、受信部２の動作を説明する。

送信部１より送信された無線信号はアンテナ３０を介して受信回路３１に入力され、受信回路３１は受信信号Ｓｊを出力する。受信信号Ｓｊはシリアル信号であり、データデコード回路３２によって心電間隔データＳｎと第二情報データSm_1 ＩＤコードデータSm_2 とにデコードされる。

ここで、前記送信部１の心電間隔データＳｄの値が例示したごとく４５０であった場合、心電間隔データＳｎの値は同様に４５０となる。４５０という値は、心電信号の間隔を６００Ｈｚで計数した値であるので、演算回路３４は３６０００／Ｓｎを計算することで１分間の心拍数を得、この心拍数を表示部３５に表示する。同様に、前記送信部１の第二情報データＳｃの値が３００の場合走行ピッチである第二情報データSm_1 は３００となる。３００という値は、心電信号の間隔を６００Ｈｚで計数した値であるので、第二情報演算回路３６は３６０００／Sm_1 を計算することで１分間の走行ピッチを得、この走行ピッチを第二情報表示部３７に表示する。

一方、ＩＤコード比較判定回路３９は、データデコード回路３２がデコードしたＩＤコードデータSm_2 とＩＤコード記憶手段３８が記憶しているＩＤコードデータSa_2 との比較を行う。本来、送信部１と受信部２のＩＤコードは同一であるから、受信が成功していればSm_2 とSa_2 とは一致するはずである。もし、不一致の場合は混信などの理由により受信が失敗した場合であり、この場合心電間隔データＳｎや第二情報データSm_1 も信頼性に乏しいため、演算回路３４および第二情報演算回路３６での演算処理は行わず、表示も前回の受信が成功したときの演算結果の表示を継続するべきである。そこで、ＩＤコード比較判

定回路３９は、比較を行った結果の一致／不一致の二値信号Ｓｂを演算回路３４および第二情報演算回路３６に出力する。演算回路３４および第二情報演算回路３６では、この二値信号Ｓｂの結果が一致の場合は上述のように演算と表示を行うが、Ｓｂの結果が不一致の場合は演算は行われず、表示部３５および第二情報表示部３７の表示は前回の演算結果を保持する。

次に受信制御回路３３の動作を説明する。

図３は受信制御回路３３の動作を説明するためのタイムチャートである。

無線信号が受信回路３１によって受信され受信信号Ｓｊが出力される。データデコード回路３２は受信信号Ｓｊをデコードし、データ分離手段３２ａで心電間隔データＳｎと第二情報データ$Ｓｍ_1$とＩＤコードデータ$Ｓｍ_2$とを出力するが、デコードが正常に終了したときデコード終了信号Ｓｅを出力する。

受信制御回路３３はデコード終了信号Ｓｅが入力されるとパルス幅Ｔｓ秒の受信制御信号Ｓｓを出力し、Ｔｓ秒だけ受信回路３１の動作を停止させる。この間、受信回路３１は非動作状態となるため受信回路３１で消費していた電力は格段に小さくなる。

送信部１からは無線信号はＴｊ秒間隔で送られてくるが、受信回路３１が受信制御信号Ｓｓによって停止されている時間Ｔｓ秒の方がＴｊ秒よりも短いためＴｊ秒後に送られてくる次の無線信号の受信に影響を与えない。また、初期の状態で一回も無線信号を受信していない状態では受信制御信号Ｓｓは出力されないため、受信回路３１は常時動作状態であり最初の無線信号の受信ができないということは起こらない。さらに、ノイズや無関係の信号を受信回路３１が受信して誤った検出信号Ｓｋを出力したとしても正しいデータではないためデータデコード回路３２が正常にデコードできずデコード終了信号Ｓｅが出力されず、受信制御信号Ｓｓによって受信回路３１の動作が停止することはない。

通常動作状態において、上述したごとく受信回路３１はＴｊ秒中のＴｓ秒の間は停止しているため、見かけ上受信回路３１の消費電力はＴｓ／Ｔｊになることになる。受信部２の中で一番消費電力が大きいのは唯一のアナログ回路である受

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信回路３１であるので、受信回路３１の消費電力を見かけ上小さくすることで、受信部２の消費電力を大幅に小さくすることができる。そして、心電間隔データＳｎ以外に第二情報データSm_1および$IDコードデータSm_2$を付加した場合でも受信時間としては第二情報データSm_1および$IDコードデータSm_2$のデータ長分長くなるだけであり、送信間隔Ｔｊとデータ長との関係を適切に設定しておけば消費電力の著しい上昇は防げる。

図４は、本発明による心拍計の一実施例の装着状態を示す図である。

送信部１は、ベルト３により胸部に固定され、このとき電極１０の一方が心臓の近傍にくるようにする。電極１０はたとえば導電ゴムによって形成され、素肌に直接触れるようにする。受信部２は、たとえば時計機能を兼ね備え、通常の腕時計と同様に腕に装着する。

図５は本発明による心拍計の送信部の一実施例の外観図である。図５においては内部が見えるように蓋を取り外したところを図示してある。

２０は受信部２に対して無線信号を送信するためのアンテナ、２１は電源としての電池、２２は各処理を実現したＩＣ、２３は図１に示した加速度センサー１８の一例としての歩行検出機構、２９は図１に示したＩＤコード発生手段１９の一例としてのディップスイッチである。

歩行検出機構２３は、重り２４と腕２５と支点２６とバネ２７と接点２８とを有する。通常は、バネ２７の力によって腕２５とともに重り２４が引き上げられ、重り２４と接点２８とが接しない状態にある。そして、送信部１を装着した人が歩行すると、人が歩行するときに生じる上下動により、支点２６を中心にして重り２４が揺動し、歩行の一歩毎に重り２４と接点２８とが接することになる。たとえば、重り２４や接点２８等は導体で構成されており、重り２４と接点２８とが接することにより電流が流れ、歩行の一歩一歩を検出することができる。

なお、上述した図１および図２の説明では、第二情報が走行ピッチの場合について説明したが、本発明における第二情報はこれに限られるものではなく、たと

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えば、電池２１の電圧の低下や歩行検出機構２３で検出した総歩行数を送信部１から受信部２に対して通知するものであってもよい。

ディップスイッチ２９は設定を変更することにより様々なＩＤコードを発生することができ、ディップスイッチ２９で設定したＩＤコードと同じＩＤコードを受信部２のＩＤコード記憶手段３８に記憶させるようにすればよい。

図６は本発明による心拍計の受信部の一実施例の外観図である。

受信部２は腕時計型であり、時計機能を兼ね備える。受信部２の脇には送信部１からの無線信号を受信するためのアンテナ３０が備えられ、受信部２の表面には、１分辺りの心拍数を表示する表示部３５と、たとえば１分辺りの歩行数を表示する第二情報表示部３７と、たとえば時刻を表示する時刻表示部４０と、モード変更ボタン４３を押すことによって変更することができる現在のモードを表示するモード表示部４１と、送信部１からの受信状態を表示する受信状態表示部４２とが備えられている。

図６において、表示部３５は１分辺りの心拍数が１３５回であることを示し、第二情報表示部３７は１分辺りの歩行数が１４０歩であることを示し、モード表示部４１はストップウオッチモードであることを示し、時刻表示部４０にはストップウオッチで計測した時間が２時間９分１４秒３５であることを示している。また、受信状態表示部４２は、図６のようにマークが表示されているときには現在受信状態にあることを示す。

モード変更ボタン４３を押すと、たとえば、第二情報表示部３７に表示する情報を１分辺りの歩行数から総歩行数に変更することができ、また、時刻表示部４０に表示する情報をストップウオッチで計測した時間から現在時刻に変更することができる。

また、第二情報として、送信部１内の電池２１の電圧低下警告を送信部１から受信したときには、モード表示部４１で、現在のモードの「ＳＴ．ｗ」と、送信部１側の電池電圧低下を意味する「ＢＴ．ｔ」とを交互表示させる。一方、受信部２内の電源電圧の低下を検出したときには、モード表示部４１で、現在のモー

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ドの「ＳＴ．ｗ」と、受信部２側の電池電圧低下を意味する「ＢＴ．ｗ」とを交互表示させる。

ところで、上述した図１および図２の説明では、ＩＤコード比較判定回路３９において、データデコード回路３２がデコードしたＩＤコードデータSm_2とＩＤコード記憶手段３８の出力するＩＤコードデータSa_2とを比較判定しその結果信号Ｓｂを演算回路３４および第二情報演算回路３６に出力するようにしたが、本発明はこれに限らず、たとえば、送信部１から受信部２に対して送信する信号を図７に示すようなフォーマットにし、より正確な比較判定を行うようにしてもよい。以下に、この場合の動作について説明する。

図１に示したシリアルデータ作成回路１４の変換手段１４ａでは、ＩＤコードSl_2、心電間隔データＳｄ、第二情報データＳｃ、ＩＤコードSl_2の順にデータを連結しシリアルデータ信号Ｓｒを作成する。

図２に示したデータデコード回路３２のデータ分離手段３２ａでは、受信信号ＳｊからＩＤコードSm_2、心電間隔データＳｎ、第二情報データSm_1、ＩＤコードSm_2を分離する。その後、ＩＤコード比較判定回路３９では、受信信号Ｓｊから分離したＩＤコードデータSm_2とＩＤコード記憶手段３８の出力するＩＤコードデータSa_2とを比較判定するとともに、受信信号Ｓｊの先端に連結されていたＩＤコードSm_2と、受信信号Ｓｊの後端に連結されていたＩＤコードSm_2とを比較判定し、その結果である二値信号Ｓｂを演算回路３４および第二情報演算回路３６に出力する。

すなわち、演算回路３４および第二情報演算回路３６では、この二値信号Ｓｂの結果が一致の場合は上述のように演算と表示を行うが、Ｓｂの結果が不一致の場合は演算は行われず、表示部３５および第二情報表示部３７の表示は前回の演算結果を保持する。このようにすることにより、受信信号Ｓｊの信頼性を高めることができる。

上記のごとく本発明によれば、心拍のデータをデータにして一定間隔Ｔｊ秒毎に送信するが、時間Ｔｊ秒を適切な値に調整することにより送信部１の消費電力

を大幅に小さくすることができる。また、受信部２の受信回路３１を受信制御回路３３で制御することにより、受信部２の受信回路３１の消費電力をＴｓ／Ｔｊにすることができる。従って、送信部１および受信部２全体の消費電力を大幅に小さくでき、電池の消耗を抑えて電池寿命を長くすることができ電池交換の頻度を低くすることができる。受信部２を腕時計のように小形の携帯電子機器に組み込む場合でも小さい電池で長時間駆動することが可能となり、電池交換の頻度を低くすることで、より利便性の高い心拍計を提供できる。

また、本発明によれば、送信機側に心電間隔データ以外の第二情報データの検出機能と両データを結合しシリアルデータとする機能とを設け、受信機側にシリアルデータを心電間隔データと第二情報データとにデコードする機能と各データの処理の可能な演算回路と表示部とを設けることにより、心拍計に心拍計測以外の付加機能を持たせることができた。これにより、心拍計の機能向上を図ることができる。

さらに、本発明によれば、送信機側にＩＤコード設定機能と、心電間隔データとＩＤコードデータとを結合しシリアルデータとする機能とを設け、受信側にシリアルデータを心電間隔データとＩＤコードデータとにデコードする機能と、ＩＤコード記憶機能と、送信されてきたＩＤコードと記憶されているＩＤコードとを比較判定できる機能とを設けることにより、心拍計に、混信などによる誤った心拍データを受信し演算してしまうのを防ぐ機能を持たせることができた。これにより、心拍計の受信の信頼性向上を図ることができる。

産業上の利用可能性

本発明は、心拍計の受信部と時計機能とを一体化するのに限らず、たとえば高度計機能を備えることにより、登山の際に高度や心拍数が一目でわかる電子機器を提供することができる。

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請 求 の 範 囲

1． 人体における心臓の近傍に装着された一対の電極から得られる心電信号を検出して検出信号を発生する検出回路と、該検出信号の発生間隔を一定周期の信号で計数して間隔データを発生する間隔データ作成回路と、該間隔データをシリアル信号に変換してシリアルデータ信号を発生するシリアルデータ作成回路と、該シリアルデータ信号を変調して無線信号として送信する送信回路と、電源としての電池とを備えた送信部と、

該送信部からの無線信号を受信して復調し受信信号を発生する受信回路と、前記受信信号をデコードして心電間隔データを発生するデータデコード回路と、心電間隔データから心拍数を算出する演算回路と、心拍数を表示する表示部とを備えた受信部と

から成ることを特徴とする心拍計。

2． 前記送信回路からの無線信号は、一定間隔の間欠無線信号であることを特徴とする請求の範囲第1項に記載の心拍計。

3． 前記送信部は識別用のＩＤコードを発生するＩＤコード発生手段を有し、前記シリアルデータ作成回路は前記間隔データと前記ＩＤコードとを連結してシリアル信号に変換してシリアルデータ信号を発生し、

前記受信部は、ＩＤコードを記憶するＩＤコード記憶手段と、前記シリアルデータに基づいて前記間隔データと前記ＩＤコードとに分離するデータ分離手段と、前記ＩＤコード記憶手段のＩＤコードと分離したＩＤコードとを比較し比較結果に基づいて分離した間隔データの採用可否を判定するＩＤコード比較判定手段とを有する

ことを特徴とする請求の範囲第1項または第2項に記載の心拍計。

4． 前記シリアルデータ作成回路は、前記間隔データの前後両方に前記ＩＤコードを連結してシリアル信号に変換してシリアルデータ信号を発生し、

前記ＩＤコード比較判定手段は、分離した間隔データの前方に連結されていた

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ＩＤコードと、分離した間隔データの後方に連結されていたＩＤコードとを比較し比較結果に基づいて分離した間隔データの採用可否を判定する
ことを特徴とする請求の範囲第３項に記載の心拍計。

５．　前記送信部は、心電信号とは異なる第二情報を検出する第二情報検出手段と、該第二情報検出手段からの検出信号に基づいて第二情報データを作成する第二情報データ作成回路と、前記間隔データと前記第二情報データとを連結してシリアルデータに変換するシリアルデータ作成回路とを有し、

前記受信部は、前記シリアルデータに基づいて前記間隔データと前記第二情報データとに分離するデータ分離手段と、分離した第二情報データを演算処理する第二情報演算手段とを有する
ことを特徴とする請求の範囲第１項または第２項に記載の心拍計。

６．　前記第二情報検出手段が歩行検出手段を有する歩数計であり、前記第二情報データが歩数データであることを特徴とする請求の範囲第５項に記載の心拍計。

７．　前記第二情報検出手段が、歩行を検出して歩行検出信号を発生する歩行検出手段と、該歩行検出信号の発生間隔を一定周期の信号で計数して歩行間隔データを発生する歩行間隔データ作成回路とであり、前記第二情報データが該歩行間隔データであることを特徴とする請求の範囲第５項に記載の心拍計。

８．　前記第二情報検出手段が電池の電圧検出回路であり、前記第二情報データが電池電圧低下警告データであることを特徴とする請求の範囲第５項に記載の心拍計。

９．　前記送信部は識別用のＩＤコードを発生するＩＤコード発生手段を有し、前記シリアルデータ作成回路は、前記間隔データと前記第二情報データとを連結して検出データとし、該検出データの前後両方に前記ＩＤコードを連結してシリアル信号に変換してシリアルデータ信号を発生し、

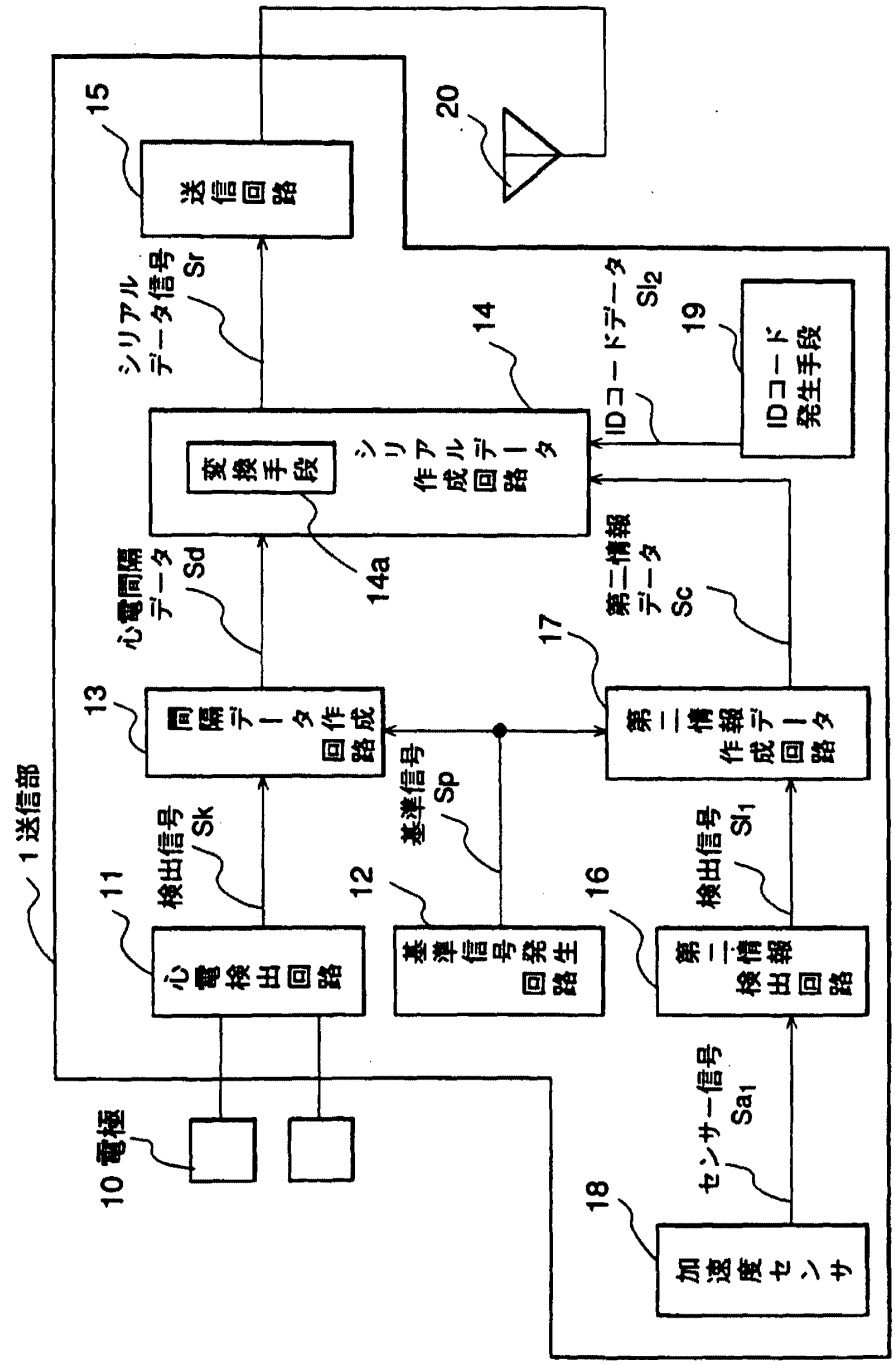
前記受信部は、ＩＤコードを記憶するＩＤコード記憶手段と、前記シリアルデータに基づいて前記検出データと前記ＩＤコードとに分離するとともに該分離

した検出データに基づいて前記間隔データと前記第二情報データとに分離するデータ分離手段と、前記ＩＤコード記憶手段のＩＤコードと分離したＩＤコードとを比較し比較結果に基づいて分離した間隔データおよび第二情報データの採用可否を判定するとともに分離した検出データの前方に連結されていたＩＤコードと、分離した検出データの後方に連結されていたＩＤコードとを比較し比較結果に基づいて分離した間隔データおよび第二情報データの採用可否を判定するＩＤコード比較判定手段とを有する

ことを特徴とする請求の範囲第５項に記載の心拍計。

１０．　前記一対の電極を結ぶ線に対して、前記歩行検出手段の検出動作方向がほぼ直交していることを特徴とする請求の範囲第６項または第７項に記載の心拍計。

図1



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図2

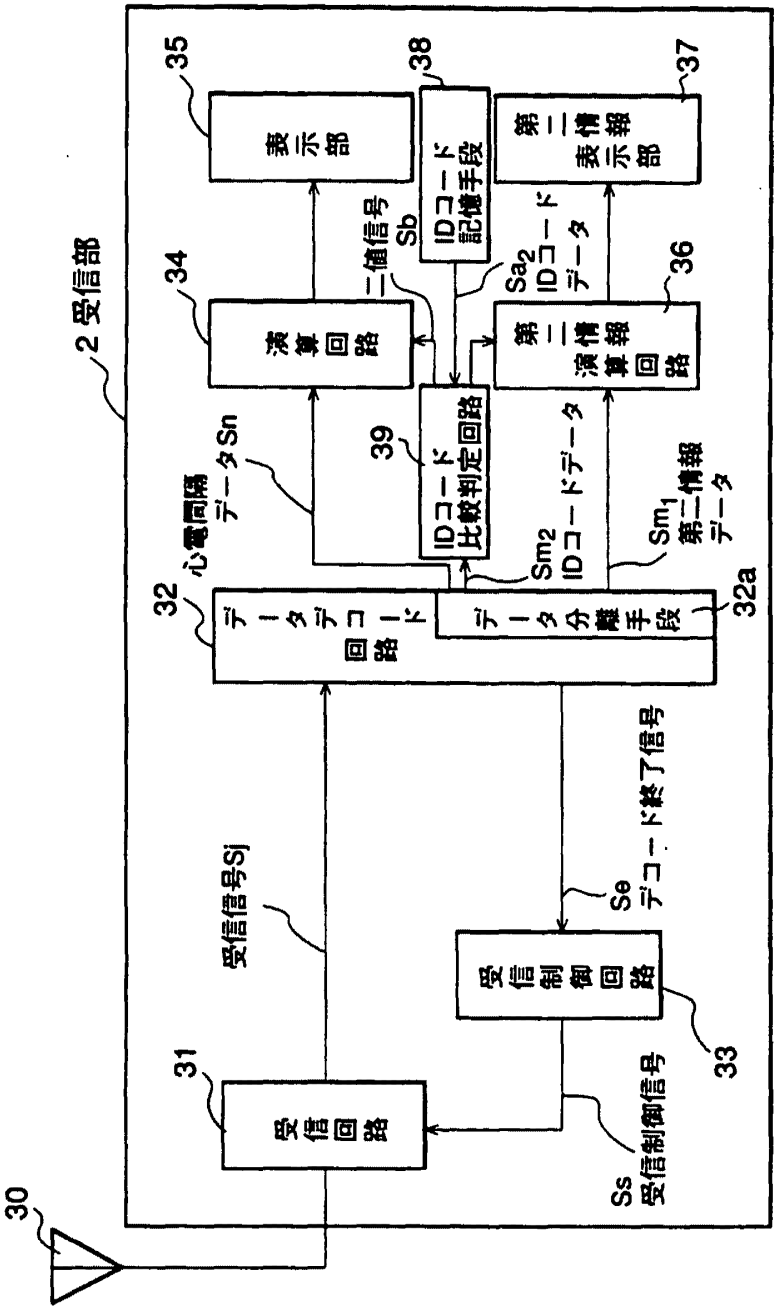

2 受信部
35
表示部
38
IDコード記憶手段
37
第二情報表示部
二値信号 Sb
Sa2 IDコードデータ
34
演算回路
36
第二情報演算回路
39
IDコード比較判定回路
心電間隔データ Sn
Sm2 IDコードデータ
Sm1 第二情報データ
32
データデコード回路
データ分離手段
32a
受信信号Sj
Se デコード終了信号
受信制御回路
33
31
受信回路
Ss 受信制御信号
30

図3

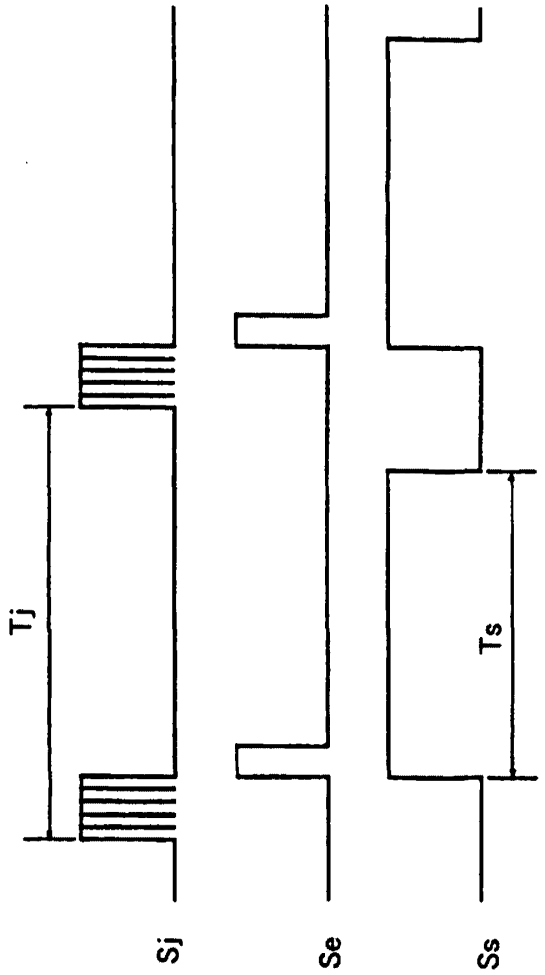
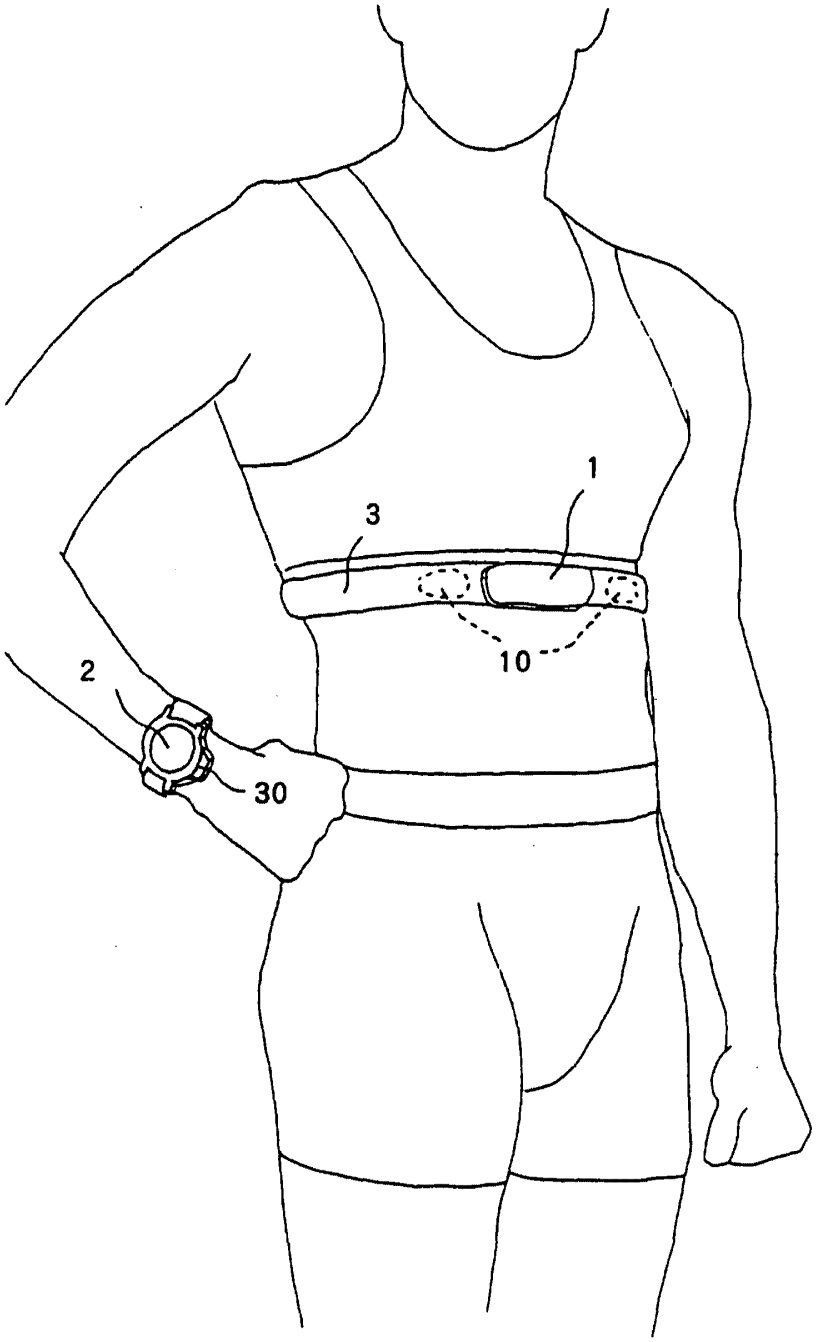


図4



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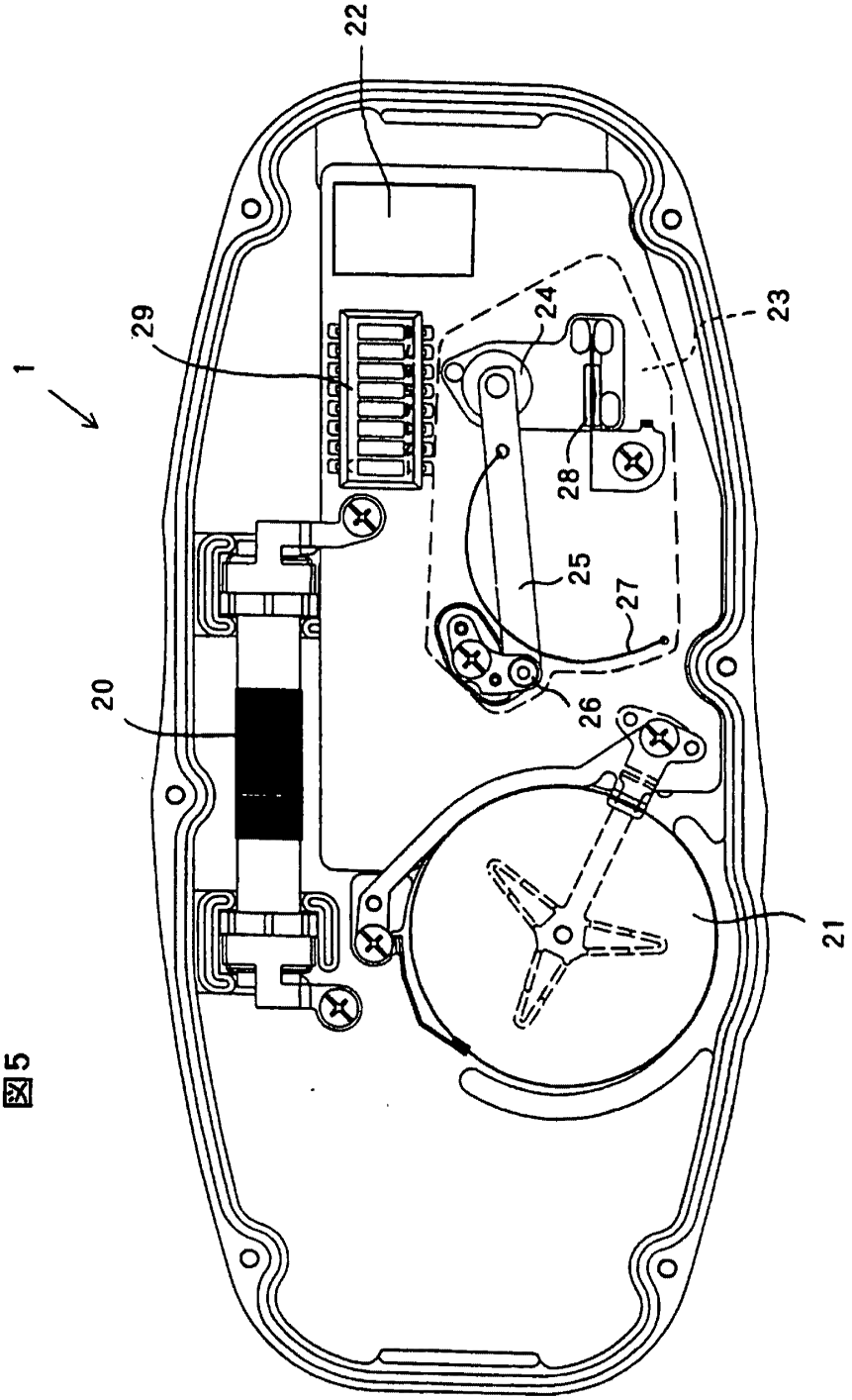


図5

図6

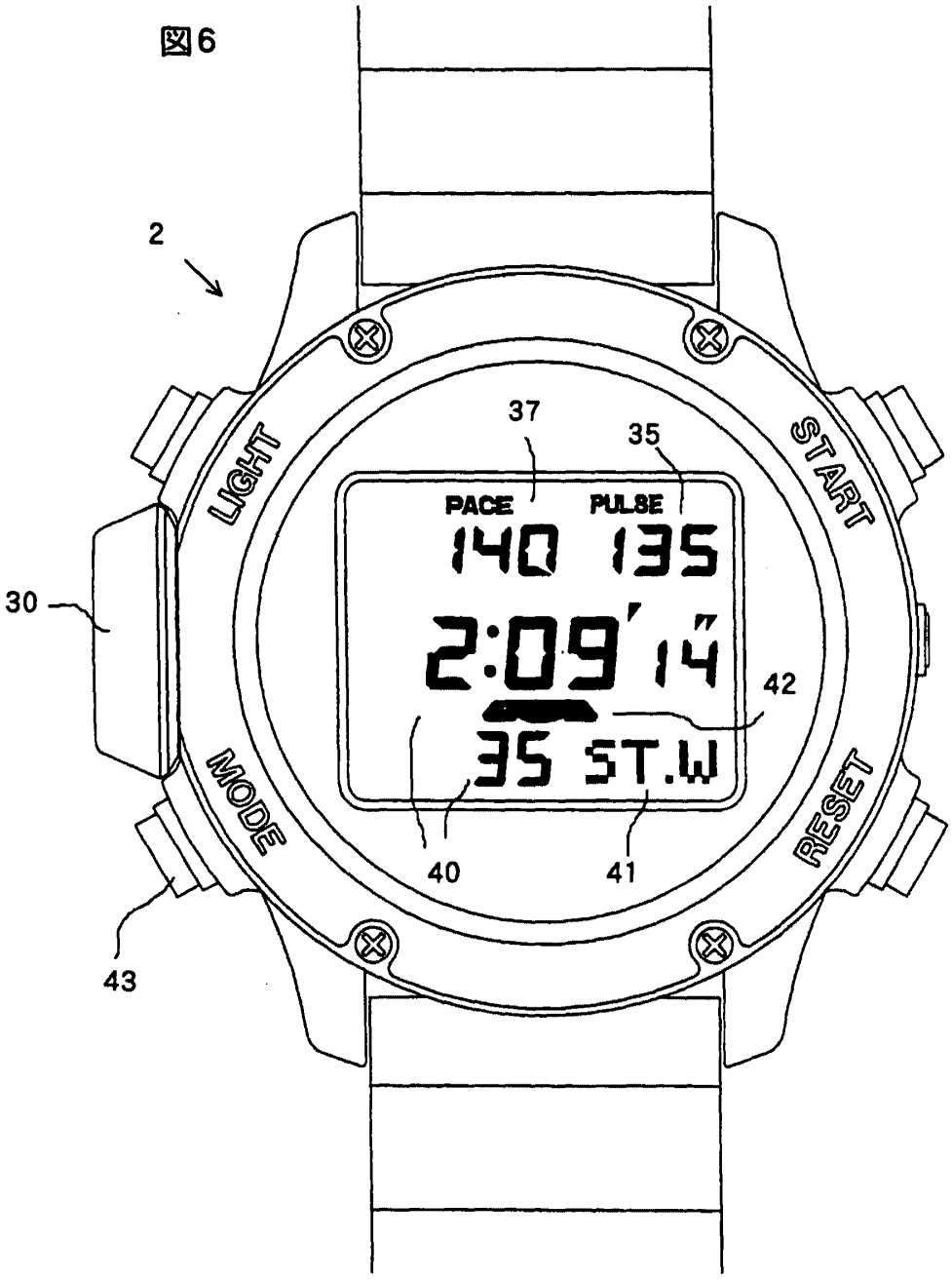
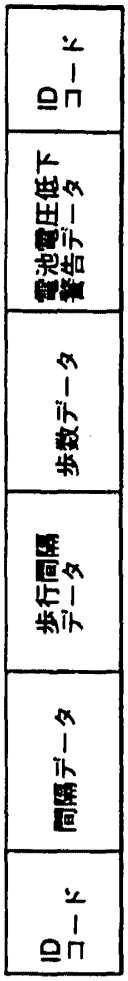

2
LIGHT
START
MODE
RESET
30
37
35
PACE
PULSE
140
135
2:09'14"
35 ST.W
42
40
41
43

図7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP96/00661

A. CLASSIFICATION OF SUBJECT MATTER
Int. Cl^6 A61B5/0245

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)
Int. Cl^6 A61B5/0245, A61B5/00, B61B5/04

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Jitsuyo Shinan Koho 1945 - 1995
Kokai Jitsuyo Shinan Koho 1971 - 1995

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Microfilm of the Japanese Utility Model Application No. 90728/1986 (Laid-open No. 202804/1987)(Matsushita Eelctric Works, Ltd.), December 24, 1987 (24. 12. 87)(Family: none)	1, 2
Y		3 - 10
Y	Microfilm of the Japanese Utility Model Application No. 36816/1989 (Laid-open No. 130605/1990)(Nippon Koden Kogyo K.K.), October 29, 1990 (29. 10. 90)(Family: none)	3, 4
Y	JP, 6-105817, A (NEC San-ei Instruments, Ltd.), April 19, 1994 (19. 04. 94)(Family: none)	5 - 10
Y	JP, 5-161611, A (NEC San-ei Instruments, Ltd.), June 29, 1993 (29. 09. 93)(Family: none)	5 - 10
Y	JP, 4-161143, A (Nippon Koden Kogyo K.K.), June 4, 1992 (04. 06. 92)(Family: none)	6, 7, 10
Y	JP, 5-76503, A (Casio Computer Co., Ltd.),	6, 7, 10

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents:
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"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
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"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	Date of mailing of the international search report
April 30, 1996 (30. 04. 96)	May 14, 1996 (14. 05. 96)
Name and mailing address of the ISA/ Japanese Patent Office Facsimile No.	Authorized officer Telephone No.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP96/00661

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	March 30, 1993 (30. 03. 93)(Family: none)	
Y	Microfilm of the Japanese Utility Model Application No. 9894/1988 (Laid-open No. 117310/1989)(Omron Corp.), August 8, 1989 (08. 08. 89)(Family: none)	8
A	JP, 5-317278, A (Suzuken Co., Ltd.), Decmeber 3, 1993 (03. 12. 93)(Family: none)	1 - 10

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

国際調査報告	国際出願番号　PCT／JP96／00661

A.　発明の属する分野の分類（国際特許分類（IPC））

Int.Cl[6]　A61B5／0245

B.　調査を行った分野

調査を行った最小限資料（国際特許分類（IPC））

Int.Cl[6]　A61B5／0245　A61B5／00　A61B5／04

最小限資料以外の資料で調査を行った分野に含まれるもの

日本国実用新案公報　1945－1995年
日本国公開実用新案公報　1971－1995年

国際調査で使用した電子データベース（データベースの名称、調査に使用した用語）

C.　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求の範囲の番号
X	実願昭61－90728号（実開昭62－202804号）のマイクロフィルム（松下電工株式会社）24．12月．1987（24．12．87）（ファミリーなし）	1、2
Y		3－10
Y	実願平1－36816号（実開平2－130605号）のマイクロフィルム（日本光電工業株式会社）29．10月．1990（29．10．90）（ファミリーなし）	3、4
Y	JP，6－105817，A（日本電気三栄株式会）19．4月．1994（19．04．94）（ファミリーなし）	5－10
Y	JP，5－161611，A（日本電気三栄株式会社）29．6月．1993（29．09．93）（ファミリーなし）	5－10
Y	JP，4－161143，A（日本光電工業株式会社）4．6月．1992（04．06．92）（ファミリーなし）	6、7、10

☐ C欄の続きにも文献が列挙されている。　☐ パテントファミリーに関する別紙を参照。

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「O」口頭による開示、使用、展示等に言及する文献
「P」国際出願日前で、かつ優先権の主張の基礎となる出願の日の後に公表された文献
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「&」同一パテントファミリー文献

国際調査を完了した日	国際調査報告の発送日
30．04．96	14.05.96

国際調査機関の名称及びあて先	特許庁審査官（権限のある職員）	2J	7638
日本国特許庁（ISA／JP） 郵便番号100 東京都千代田区霞が関三丁目4番3号	山本　春樹　印		
	電話番号　03－3581－1101　内線　3251		

様式PCT／ISA／210（第2ページ）（1992年7月）

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国際調査報告	国際出願番号　ＰＣＴ／ＪＰ９６／００６６１

Ｃ（続き）．　関連すると認められる文献

引用文献のカテゴリー＊	引用文献名　及び一部の箇所が関連するときは、その関連する箇所の表示	関連する請求の範囲の番号
Ｙ	ＪＰ，５－７６５０３，Ａ（カシオ計算機株式会社）３０．３月．１９９３（３０．０３．９３）（ファミリなし）	６、７、１０
Ｙ	実願昭６３－９８９４号（実開平１－１１７３１０号）のマイクロフィルム（立石電機株式会社）８．８月．１９８９（０８．０８．８９）（ファミリーなし）	８
Ａ	ＪＰ，５－３１７２７８，Ａ（株式会社スズケン）３．１２月．１９９３（０３．１２．９３）（ファミリーなし）	１－１０

様式ＰＣＴ／ＩＳＡ／２１０（第２ページの続き）（１９９２年７月）

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Exhibit 1002
Page 768

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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 770 349 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
02.05.1997 Bulletin 1997/18

(51) Int. Cl.[6]: **A61B 5/00**

(21) Application number: **96115041.4**

(22) Date of filing: **19.09.1996**

(84) Designated Contracting States:
DE FR GB

(30) Priority: **19.09.1995 JP 240125/95**
30.10.1995 JP 281862/95

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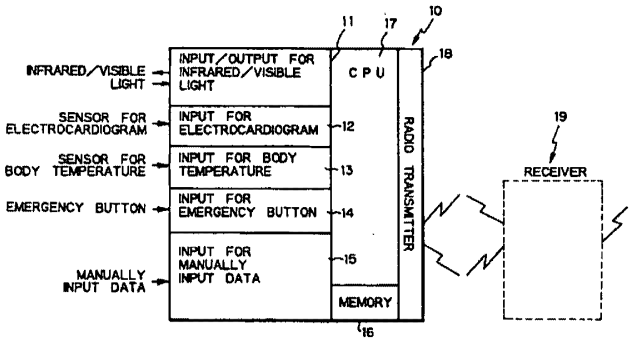
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(54) Apparatus for monitoring patients

(57) A monitoring apparatus (10,110) is wirelessly attached to a portion of a person's body for automatically obtaining the medical data of the person and transmitting the thus obtained data to a receiver. The apparatus (10,110) comprises means for non-invasively detecting, as the person's vital sign, said data including one or a combination of the pulse, pulse wave, electrocardiogram, temperature, blood pressure and S_pO_2 of the person via the interfacing surface between the apparatus and the contacted portion on the person's body, and means (18) for transmitting said detected data to said receiver (19) by means of wireless or optical communication medium such as infrared rays.

Fig. 1



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Description

The present invention relates to an apparatus for remotely monitoring the physical condition of a patient who is at home or being taken care of in a hospital, and also for monitoring the health of elderly people. More particularly, the present invention relates to an apparatus attached to a part of a patient's body to enable remote monitoring by means of radio or optical transmission by for example radio or infrared rays.

As the ratio of elderly people in the population increases along with incumbent medical expenses, an apparatus for remotely monitoring the physical condition of a patient regardless of whether the patient is at home or is being taken care of at a hospital while keeping to a minimum the burden both on the patient's side and on the medical institute's side, is desired.

As prior art apparatuses, a bed-side type apparatus for use in a hospital or a transport type apparatus for use in an ambulance, which is in reality said bed-side type apparatus taken into and used in an emergency vehicle, are known. Though it may be possible to wirelessly transmit data by using these prior art monitoring apparatuses, electrodes of an electrocardiographic sensor, wires that connect said sensor to the electrodes, or various apparatuses as a tube for a sphygmomanometer must still be attached to a patient's body, thus restricting his/her activity and sometimes causing and discomfort. Accordingly, a patient monitoring apparatus is strongly desired that does not restrict overly a patient's activity and that enables the patient to live as normal a life as possible with his/her physical conditions being appropriately monitored.

A portable pendant-type apparatus is also known that is used to transmit an emergency signal that indicates the occurrence of a medical emergency. This type of apparatus, however, is designed on the premise that the patient can activate a switch by pulling it down. Thus if a medical emergency occurs suddenly and a patient is unable to operate a switch, the apparatus will not function at all. The present invention is aimed at remedying such a defect.

Japanese Patent Application No. 203,369/1995 discloses an invention called Medical System for Patients-at-Home. In accordance with the thus disclosed invention, a system which comprises a network formed from a group of home units each of which is set up at a plurality of patients' homes with at least one central unit being provided at a medical institute which functions as a local center for the patients-at-home in the community. The home unit as well as the central unit consists of a computer equipped with a high speed microprocessor (CPU) and an appropriate modem which allows bi-directional communication between each of the home units and the medical center, thereby exchanging information on a real time basis so that a physician or a nurse can provide the patient-at-home with instructions appropriate to his/her specific bodily condition, based on the medical information acquired via the system. This application is herein incorporated by reference.

In the above system, medical information is provided to the home unit from various measurement apparatus. The present invention is analogous to this system in that it relates to a measurement apparatus or monitoring apparatus that is attached to some portion of the patient's body without restricting his/her bodily activities and that it is capable of measuring/monitoring various bodily data in an appropriate and integrated manner. The present invention includes, among other things that are not included in the above incorporated system, an interface means by which medical data can be collected from the patient's body and which couples the acquired data to the home unit placed in the patient's home.

An object of the present invention is to provide a patient monitoring apparatus which minimizes restrictions to patient's movement and also discomfort caused by the apparatus and yet enables effective measurement of bodily data, thereby making it possible for an appropriate and integrated diagnosis to be made and, if necessary, for medical treatment to be initiated at an early stage.

In accordance with one feature of the present invention, a monitoring apparatus is provided which is wirelessly attached to a part of a person's body for automatically obtaining the medical data of the person and transmitting the thus obtained data to a receiver. The apparatus comprises means for non-invasively detecting, as the person's vital signs, said data including one or a combination of the pulse, pulse wave, electrocardiogram, temperature, blood pressure and S_pO_2 of the person via the interfacing surface between the apparatus and the contacted portion on the person's body, and means for transmitting said detected data to said receiver by means of wireless or optical communication medium such as infrared rays. The apparatus may further comprises means for comparing said detected data with a set of reference values indicative of the person's normal bodily condition and for displaying on a display of the apparatus or notifying said receiver of whether said detected data is within a normal range. In this apparatus, said non-invasive detecting means may comprise means for measuring S_pO_2 of the person by emitting infrared rays and/or visible light to a part of the body and detecting a return consisting of the reflected and diffused rays.

In accordance with another feature of the present invention, the above-mentioned apparatus may be appropriately formed so as to be inserted into one or both of external acoustic meatuses of the person's body. In this case, the apparatus is shaped as an earplug that has a hollow structure passing through the apparatus so that the person's hearing ability is maintained and said detecting means comprises one or more sensors or transducers mounted on the surface of the apparatus. The apparatus may further comprise means for enhancing the hearing ability by amplifying the sounds coming into the external acoustic meatus. The apparatus may be formed from a soft and flexible or

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shape memory material.

Fig. 1 is a block diagram illustrating the internal mechanism of the first embodiment of the patient monitoring apparatus in accordance with the present invention.

Fig. 2 is a perspective view of the first embodiment of the patient monitoring apparatus in accordance with the present invention.

Fig. 3 is a view of the reverse side that directly touches the patient's skin of the first embodiment of the patient monitoring apparatus in accordance with the present invention.

Fig. 4 is a cross sectional view of the second embodiment, worn into an external acoustic meatus, of the patient monitoring apparatus in accordance with the present invention.

Fig. 5 is a (partially transparent) perspective view of the second embodiment of the patient monitoring apparatus in accordance with the present invention.

Fig. 6 is a block diagram illustrating the internal mechanism of the second embodiment of the patient monitoring apparatus in accordance with the present invention.

Preferred embodiments of the present invention will now be described by referring to the attached drawings. Referring to Fig. 1, a block diagram illustrating the internal mechanism of the first embodiment of the patient monitoring apparatus 10 in accordance with the present invention is provided. The patient monitoring apparatus 10 is in the form of a wrist watch and directly attached to a part of the patient's body, for example, on his/her wrist, ankle, finger, or arm by means of a band. The patient monitoring apparatus 10 comprises an infrared/visible light input/output for transmitting/receiving infrared light and visible light to measure the pulse, pulse waves and S_pO_2 of the patient; an input 12 from an electrocardiographic sensor; an input 13 from a body temperature sensor; input 14 from an emergency button; and an input 15 for manually inputting data such as results of urine examination and blood glucose values, etc. Each of these inputs 11-15 is connected to the central processing unit (CPU) 17, which is provided with infrared and visible light for measurement and a plurality of measured data from the above-mentioned input and then which supplies the data, after processing them or as they are, to the parental unit or receiving unit 19 via the radio transmitter 18.

The receiving unit 19, which is a "home unit" disclosed in the above incorporated Japanese application, is installed at the patient's house and has a computer incorporated therein so as to automatically function to transmit data via an appropriate modem. The data received by the unit 19 is transmitted through transmission medium to a center unit (not shown) installed at the medical institute which is in charge of the area. If the patient is being taken care of at a hospital and a patient monitoring apparatus 10 is attached to him/her, the receiving unit 19 is also installed at the hospital and transmits the processed or raw data to a center unit at the same hospital or at the central medical institute in charge of said hospital.

The CPU 17 is capable of, if necessary, having the input data and processed results temporarily stored in the memory 16. The CPU 17 calculates the blood pressure on the basis of the pulse and electrocardiographic data obtained via infrared detection and/or compares each of the input data with the reference value predetermined by a physician. If any of the input data is not within the predetermined range, the CPU 17 produces resultant information indicative of the result of the comparison. Whether the input data is to be transmitted as it is or after processed is selectively determined by means of the mode setting-up button 22. When desired, the processed results will be displayed on the display 20 by the CPU 17.

Referring to Fig. 2, a front perspective view of the first embodiment of the present patient monitoring apparatus 10 is shown, and is attached like a wrist watch. The button switch 22 is a mode set-up button used to switch between various modes. Each of a plurality of button switches 23 is used for the patient wearing this apparatus to manually input data such as blood glucose values, body weight, and results of urine examination. The emergency button switch 21, when activated by the patient in a medical emergency, have an emergency signal wirelessly or optically transmitted.

Next, referring to Fig. 3, the reverse side that directly touches the patient's skin in the first embodiment of the present patient monitoring apparatus 10 is shown. The infrared light produced by the infrared light transmitting unit 25 passes through a portion of the patient's body and after being reflected and/or diffused, it is measured by the infrared light detecting sensor 26. The light emitted from the visible light transmitting unit 27 also passes through a portion of the patient's body and is measured by the visible light detecting sensor 28. The CPU 17 calculates the oxygen saturation of arterial blood (S_pO_2), pulse and pulse wave from these data. The electrocardiographic sensor 29 detects the electrocardiogram of the patient. The detected electrocardiogram is amplified and its noise is removed at the electrocardiograph input unit 12 and CPU 17. Data indicative of the body temperature of the portion in touch with the body temperature sensor 30 is sent to the CPU 17 via the body temperature input unit 13.

Since all the sensors described above are mounted on the reverse side surface and the measurement of the various data is automatically performed, the patient is not physically restricted during detection of medical data and sending the detected data to the receiving unit 19 via an appropriate medium such as infrared light under a computer (CPU 17).

Notification of a medical emergency by the present apparatus comprises in two stages. In the first stage, the patient can notify medical staff at a medical institute with a center unit installed of his/her condition by activating the emergency button switch 21 on the apparatus 10. In response to the activation of this switch 21, an

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emergency signal is transmitted to the receiving unit by way of the wireless or optical communication function equipped with this apparatus 10. On receipt of this emergency signal from the patient, the medical institute will take emergency measures to cope with the situation.

The second stage, in accordance with this apparatus 10 already disclosed in the above mentioned Japanese patent application, and involves continuous detection of the patient's vital signs. However, in this case, vital signs are automatically and continuously detected by using the wrist watch type apparatus 10 rather than the more cumbersome means provided by the foregoing application. In order to more fully realize the vital sign detection function than in the case of the above first stage, the apparatus 10 continuously detects the patient's vital signs on a twenty-four hour basis. Preferably, vital signs to be detected include the pulse detected in the patient's wrist. As far as any predetermined vital sign can be detected in an ordinary manner, electrical signals continue to be transmitted from the monitoring apparatus 10. If the patient stays within a predetermined distance from the home (receiving) unit 19, the home unit 19 is capable of receiving signals. The CPU incorporated in the home unit will not take any action as long as the electrical signals continue since the continuous detection of signals assumes that the patient is in a normal condition. However, once signals cease to be detected, the home unit will immediately transmit an emergency signal to the medical institute and notify the medical staff there of the occurrence of an emergency without any investigation of the patient's physical condition. Although signal failure may be due to an electrical fault in the apparatus 10 or any other extraordinary event as well as the occurrence of a physical disorder, the present apparatus 10 will without exception, decide on a general fail-safe principle that a medical emergency has occurred, thus enabling a critical response to be taken.

The pendant type apparatus belonging to the prior art can be effective only if the patient actuates the switch him/herself by pulling the strong attached thereto, for example. Whereas the present apparatus will always be effective even if the occurrence of medical emergency is so sudden and unexpected that the patient him/herself does not have the chance or strength to pull the switch. Thus the present apparatus 10 is more reliable than the prior art apparatuses which require the activation of a switch by the patient.

In order to facilitate this function, the home unit can be set to an absent mode to avoid an emergency signal being wrongly transmitted to the center unit, or the emergency notification function can be turned off.

Depending on the patient's condition, $ETCO_2$ can be detected as a vital sign, wherein the internal mechanism will be the same except for a difference in the detector thereof.

Referring to Fig. 4, which illustrates a cross sectional view of the second embodiment of the patient monitoring apparatus in accordance with the present invention. another type of the present apparatus will be described. As shown in the figure, the apparatus 110 is shaped like an earplug and worn in an external acoustic meatus of the patient. Preferably, in order to maintain the hearing capacity, the apparatus 110 has a hollow portion 112 passing through at the center of this cylindrical-shaped apparatus 110. The outside surface of the apparatus 110 consists of a flexible and soft material to prevent discomfort while the sensors and transducers mounted on the surface comfortably contact the skin in the external acoustic meatus of the patient.

Fig. 5 is a (partially transparent) perspective view of this earplug type second embodiment of the present patient monitoring apparatus. On the surface of the apparatus 110 in touch with the skin in the external acoustic meatus, electrodes 114, 115 for the detection of the electrocardiograph, a transducer 116 for the detection of pulse wave (pressure) and a sensor 117 for the body temperature are mounted.

In addition, the infrared light emitted by the infrared light transmitting unit 118 passes through a portion of the patient's body and after being reflected and/or diffused, returned light is measured by the infrared light detecting sensor 119. Similarly the light emitted from the visible light transmitting unit 120 also passes through a portion of the patient's body and is measured by the visible light detecting sensor 121. The sensors 114, 115, 117, 119, 121 and transducer 116 are located on the surface of such a portion 122 of the apparatus 110 inserted into the ear. The surface of this inserted portion on which the plurality of sensors are mounted is preferably smooth so that the patient wearing the apparatus is not subject to any discomfort. The sensors and transducer are connected to the control and transmitting unit 123 via an lead 124 on which the detected data will be transferred.

Fig. 6 is a block diagram illustrating the internal mechanism of this second embodiment. As shown, the electrocardiographic signal detected with the electrocardiogram detection electrodes 114, 115 is provided to the processor 132 via the electrocardiogram input unit 125. The pulse wave signal (by way of pressure) detected with the pressure transducer 116 is provided to the processor 132 via pressure input unit 126. The temperature signal detected with the temperature sensor 117 is provided to the processor via the temperature input unit 127. The infrared light is emitted from the infrared light output unit 128 and then the emission unit so as for the oxygen saturation of arterial blood (S_pO_2), pulse wave and blood pressure to be measured. The emitted infrared light returns from the patient's body and is measured by the infrared light detecting sensor 119. Similarly the visible light emitted from the visible light transmitting unit 120 also passes through a portion of the patient's body and is measured by the visible light detecting sensor 121. On the basis of the received amount of the infrared and/or visible light, S_pO_2, pulse wave and blood pressure are calculate.

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In detecting and measuring the electrocardiogram, in particular, it may be preferable to attach an appropriate electrode in each of the patient's external acoustic meatuses and to connect them each other so as to correlate the data from both of them.

The processor 132 is powered by an exchangeable Lithium battery and has a microprocessor (not shown) incorporated therein and the microprocessor performs the above described calculation using the data detected. Incidentally by performing the measurement by this apparatus 110 continuously and/or once in every predetermined time period, it is possible to collect a series of medical data and construct a medical database about a specific group of patients over some time period. The obtained data will be wirelessly sent to the home unit.

Although the apparatus 110 has a hollow portion at the center of its cylindrical portion, it may be possible that the hearing capacity of the person wearing it will be worse than otherwise. In such a case, conventional technique employed in an earplug type hearing aid will also be used in the apparatus 110. For example, a small microphone is mounted to transmit sound wave signals and to amplify them.

The emergency notification function of this earplug type second embodiment of the present invention is constructed similarly to the case with the first embodiment.

While several embodiments of the present invention have been shown and described, alternate embodiments will be apparent to those skilled in the art and are within the intended scope of the present invention. Therefore, the invention is to be limited only by the following claims.

Claims

1. A monitoring apparatus wirelessly attached to a portion of a person's body for automatically obtaining the medical data of the person and transmitting the thus obtained data to a receiver, comprising:

   means for non-invasively detecting, as the person's vital sign, said data including one or a combination of the pulse, pulse wave, electrocardiogram, temperature, blood pressure and/or S_pO_2 of the person via the interfacing surface between the apparatus and the contacted portion on the person's body, and
   means for transmitting said detected data to said receiver by means of wireless or optical communication medium such as infrared rays.

2. The apparatus recited in claim 1 further comprising means for comparing said detected data with a set of reference values indicative of the person's normal bodily condition and for displaying on a display of the apparatus or notifying said receiver of whether said detected data is within a normal range of the values.

3. The apparatus recited in claim 1 wherein said non-invasive detecting means comprises means for measuring S_pO_2 of the person by emitting infrared rays and/or visible light to a portion on the body and detecting a return consisting of the reflected and diffused rays and light.

4. The apparatus recited in claim 1 wherein said vital sign continues to be detected and further comprising means for automatically transmitting an emergency signal to said receiver upon detecting the abnormality of the vital sign or upon an intentional activation of a switch by the person.

5. The apparatus recited in claim 1 further comprising means for manually inputting additional medical data such as the result of a urine examination, weight and blood glucose value.

6. The apparatus recited in any one of claims 1 to 5 wherein said apparatus is appropriately formed so as to be attached to a wrist, ankle, finger or arm of the person's body.

7. The apparatus recited in any one of claims 1 to 5 wherein said apparatus is appropriately formed so as to be inserted into one or both of external acoustic meatuses of the person's body.

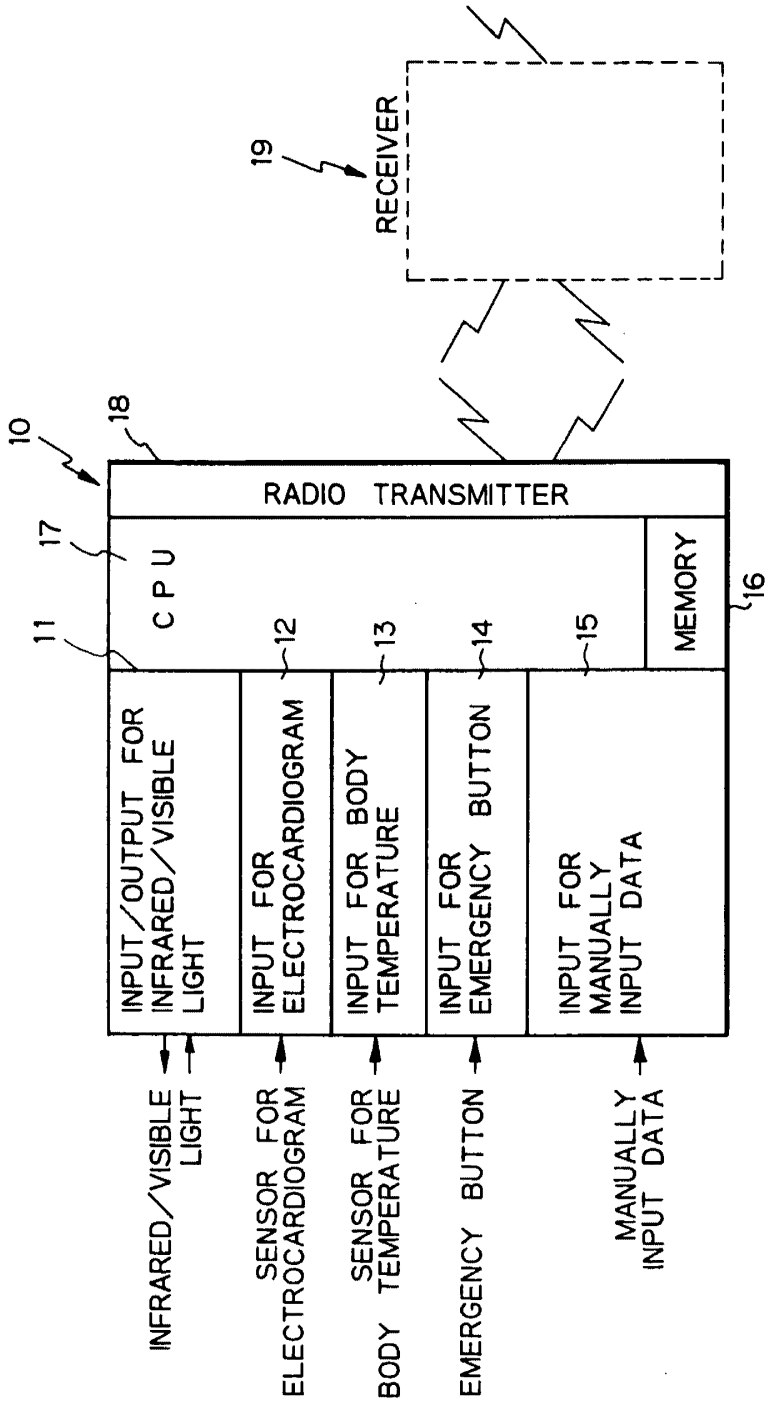
8. The apparatus recited in claim 7 wherein the apparatus is shaped as an earplug that has a hollow structure passing through the apparatus so that the person's hearing ability is maintained and said detecting means comprises one or more sensors or transducers mounted on the surface of the apparatus.

9. The apparatus recited in claim 8 further comprising means for enhancing the hearing ability by amplifying the sounds coming into the external acoustic meatus.

10. The apparatus recited in any one of claims 7 to 9 wherein the apparatus is formed from a soft and flexible or shape memory material.

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Fig. 1



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Fig. 2

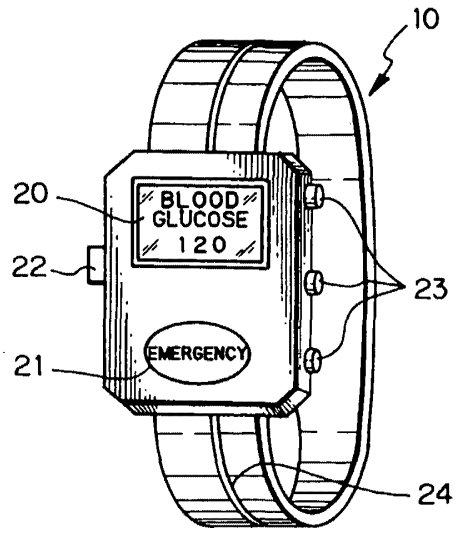
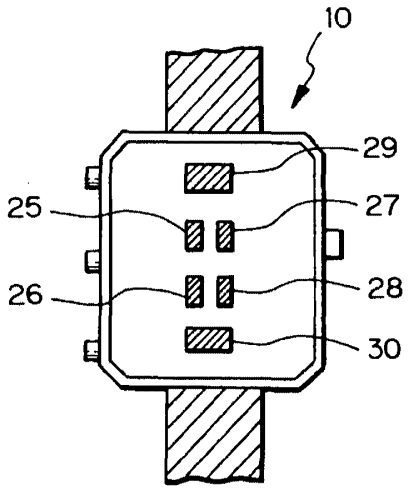


Fig. 3



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Fig. 4

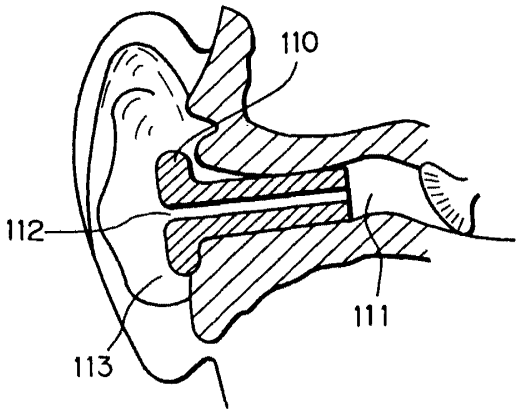
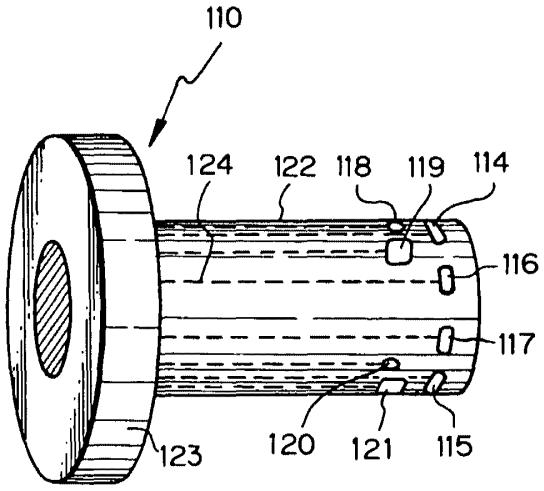
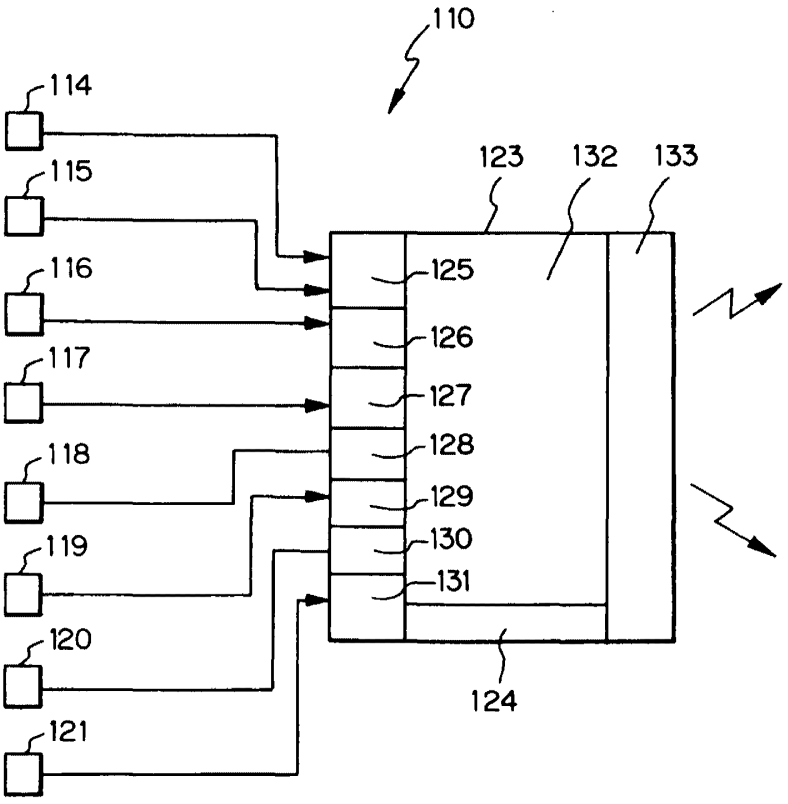


Fig. 5



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Fig. 6



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EUROPEAN SEARCH REPORT

Application Number
EP 96 11 5041

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO-A-95 07048 (BESSON ET AL.) 16 March 1995 * page 32, line 10 - page 33, line 2 * * page 38, line 20 - page 44, line 17 * * figures 1-6 *	1	A61B5/00
A		3,6	
X	FR-A-2 686 497 (ARGAMAKOFF) 30 July 1993 * page 2, line 5 - page 3 * * page 6, line 20 - page 7, line 27 * * figures 1-8 *	1	
A		2-4,6	
A	GB-A-2 243 691 (PAYNE ET AL.) 6 November 1991 * page 7, line 7 - page 13, line 19 * * figures 1A-4 *	1,2,4,6	
A	US-A-5 213 099 (TRIPP, JR.) 25 May 1993 * column 4, line 51 - column 5, line 39 * * figures *	3,7,10	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	US-A-4 312 358 (BARNEY) 26 January 1982 * column 4, line 15 - column 5, line 32 * * column 7, line 48 - column 9, line 61 * * figures 1,2 *	5,7	A61B
A	WO-A-91 15989 (KINGSTON) 31 October 1991 * page 3, line 12 - page 5, line 26 * * figures *	4	
A	WO-A-89 00024 (MICROMEDICAL INDUSTRIES PTY LIMITED) 12 January 1989 * abstract * * page 3, line 33 - page 6, line 29 * * page 8, line 26 - line 33 * * figures 1,2 *	5	

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	4 February 1997	Chen, A

CATEGORY OF CITED DOCUMENTS

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EUROPEAN SEARCH REPORT

Application Number
EP 96 11 5041

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	EP-A-0 104 924 (MINNESOTA MINING AND MANUFACTURING COMPANY) 4 April 1984 * page 7, line 22 - page 11, line 18 * * figures 1,2 * ---	8,10	
A	GB-A-2 162 325 (ELECTRONIC IDENTIFICATION SYSTEMS SILKEBORG A S) 29 January 1986 * abstract * * page 1, line 5 - line 88 * * figure 1 * -----	1,7,8	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)

The present search report has been drawn up for all claims

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 5/0432 — A1

(11) International Publication Number: **WO 97/46156**

(43) International Publication Date: 11 December 1997 (11.12.97)

(21) International Application Number: PCT/US97/09174

(22) International Filing Date: 4 June 1997 (04.06.97)

(30) Priority Data:
08/658,236 4 June 1996 (04.06.96) US

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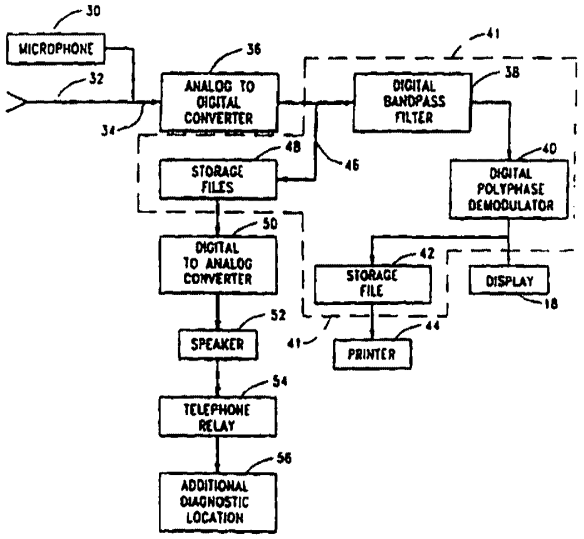
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(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: METHOD AND HAND-HELD APPARATUS FOR DEMODULATING AND VIEWING FREQUENCY MODULATED BIOMEDICAL SIGNALS



(57) Abstract

This invention is a method and apparatus for transmission of biomedical waveform data from a patient to an attending physician, wherein the waveform data audio signal (30) is frequency modulated for subsequent wire line or wireless transmission to a remote hand-held computer that functions to digitize (36), record (42), and demodulate (40) the frequency modulated signal for display (18) on the computer, for permanent print-out, or for further retransmission.

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METHOD AND HAND-HELD APPARATUS FOR DEMODULATING AND VIEWING FREQUENCY MODULATED BIOMEDICAL SIGNALS

BACKGROUND OF THE INVENTION

1. Field of the Invention.

The invention relates generally to improved method and apparatus for monitoring a patient's biomedical waveform data and, more particularly, but not by way of limitation, it relates to an improved method and apparatus for monitoring a patient's electrocardiogram (ECG) data using a hand-held computer in association with a wireline or wireless telephone system.

2. Description of the Prior Art.

The prior art includes numerous systems wherein ECG data or the like is transmitted from a patient to a particular doctor's office or health service center. U.S. Patent No. 4,938,229 discloses an earlier form of monitoring system which includes apparatus for demodulating a constant amplitude audio FM ECG signal. The analog FM signal is processed through a zero crossing counter which generates a digital pulse for every crossing. The time intervals between pulses are then averaged to produce a digital ECG signal at a predetermined sample rate. This procedure differs from the present invention as it does not digitize the audio FM signal, nor does it utilize such as a polyphase demodulator to derive the ECG data in digital form. U.S. Patent No. 4,531,527 discloses another system for trans-telephonic ECG monitoring; however, this system requires special hardware considerations and differs in may other aspects from Applicants' method and apparatus.

U.S. Patent No. 4,409,984 discloses a method for square pulse frequency modulation and demodulation of ECG data in a multiple patient monitoring system. The system does not employ polyphase demodulation since it processes a constant amplitude FM signal to detect zero crossings, and neither does it provide portable storage and display of ECG data in the manner of the present invention. The similar digital FM demodulator is taught in the U.S. Patents Nos. 4,027,146 and 3,909,599, but there is no teaching of the digitization of an FM data signal nor of

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possible retransmitting of the FM signal. In addition, these patents all require hardware of specialized design for carrying out specific circuit functions.

The U.S. Patents Nos. 5,365,935; 5,191,891; and 5,333,616 all relate to an ECG monitoring system that utilizes wrist-worn transtelephonic ECG recorders and transmitters. The disclosure does not deal with any form of signal demodulation and display or any storage and retransmission capabilities. The present invention would be compatible for use to receive, display, store and/or retransmit biomedical signals derived by the teachings of these patents.

ECG data is usually transmitted directly from the patient to the analyzing location and one such system, available from Instromedix, Inc. of Hillsboro, Oregon, utilizes a Heart Card to provide a recording of the ECG signal from thirty seconds upward to five minutes. This system provides for transmission via a wired or wireless telephone system of such recorded or realtime ECG data in the form of a frequency modulated audio signal. The transmitted FM audio signal is then demodulated at the doctor's office or health service center for viewing of the actual ECG data whereupon the patient's personal doctor is alerted if a problem is seen in the data. Further, the actual ECG data waveform may be sent via facsimile to the attending doctor.

SUMMARY OF THE INVENTION

The present invention relates to an improved communication system for conveying ECG data or other biomedical waveform data more directly between the patient and an attending doctor's location. The patient employs a Heart Card-type of device that converts the patient's ECG signal into a frequency modulated audio signal that may then be analyzed by audio inputting via a telephone system to a selected hand-held computer device that functions to digitize, record and demodulate the frequency modulated signal for presentation and viewing on the hand-held computer display screen. Also, the operator has the option of printing out the demodulated biomedical signal for further viewing separate from the hand-held computer. There is still

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further an option of retransmitting the stored ECG audio signal via telephone, either wireline or wireless, to a designated doctor's office; or, if no one answers, the call may be forwarded to another nurse or doctor as designated. At any of the first or forwarded receiver stations, the attendant may also have a programmed hand-held computer that can receive the audio FM biomedical signal for digitization, recording and demodulation for viewing. The hand-held computer is one with integrated microphone, audio analog to digital converter, digital to analog converter, speaker, and central processing unit with memory for performing various computational, data storage and signal processing tasks.

Therefore, it is an object of the present invention to provide a highly accurate and portable biomedical signal monitor for use with a telephone system, either wireline or wireless.

It is also an object of the present invention to provide a highly accurate and reliable patient monitoring system that allows the doctor to interface directly over a telephone system with the patient at anytime or anywhere.

It is yet further an object of the present invention to provide a patient monitor system that may be quickly and reliably deployed in monitoring operation.

It is still further an object of the present invention to provide a reliable and accurate patient ECG monitoring system with first hand communication between doctor (or other healthcare provider) and patient.

Finally, it is an object of the invention to provide a hand-held computer with proprietary software that combines with a telephone system to provide remote monitoring of a patient's electrocardiogram (ECG).

Other objects and advantages of the invention will be evident from the following detailed description when read in conjunction with the accompanying drawings that illustrate the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an idealized block diagram of an ECG monitoring system;

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FIG. 2 is a functional block diagram of a preferred form of signal processing circuitry as effected by a hand-held computer;

FIG. 3 is an idealized block diagram of a monitoring relay link for further transmission of ECG data;

FIG. 4 is a functional block diagram of an alternative form of patient monitoring circuitry as effected by a programmed hand-held computer;

FIG. 5 is a diagram of a programmed signal process as utilized in the preferred form of circuitry;

FIG. 6 is a diagram illustrating cycle accumulation between filtered data and decimated data output;

FIGS. 7, 8 and 9 are a flow diagram for the demodulation procedure carried out by the Rhythm-Stat SX software; and

FIG. 10 is a top plan view of a Psion 3a hand-held computer.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, a patient monitoring system 10 consists of a Heart Card 12 disposed on the patient and capable of detecting and recording the electrocardiogram signal (ECG) for a predetermined time and then actuable to transmit the ECG as a frequency modulated audio band signal 14. The Heart Card 12 is a commercially available device that functions to sense the ECG data for a predetermined time period and, after the period, the Heart Card 12 can be actuated to transmit the audio frequency modulated ECG data. Such Heart Card sensor/transmitters may be obtained from such as Instromedix, Inc. of Hillsboro, Oregon. Other devices that perform the same or similar functions (i.e., recording the ECG and transmitting over a phone system as a frequency modulated audio signal) are available from Instromedix, Inc. and other vendors.

The frequency modulated audio signal 14 may then be transmitted via telephone, either wireline or wireless; or, the frequency modulated audio signal 14 may be played directly into the audio microphone of a palmtop computer 16 which includes resident software that processes the biomedical data contained in the frequency modulated audio signal and displays the data

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on the computer screen 18. In most cases, the patient and Heart Card 12 will be remote from the palmtop computer 16 and the attending physician or diagnostician. In this situation the Heart Card 12 need only transmit the frequency modulated audio into the receiver 20 of telephone 22 which is connected via a suitable telephone system 24, either wireline or wireless, to a telephone 26 at the attending physician's office whereupon the telephone transmitter 28 can direct frequency modulated audio data 14 into the microphone of the palmtop computer 16 to complete the information relay.

A preferred embodiment of the invention uses a Psion 3a palmtop personal computer with proprietary software as will be further described. The hand-held computer 16 must have an integrated microphone or direct audio electrical jack that can interface to a wireline or wireless phone. A laptop computer could be used for the present invention; however, it does not have the portability feature that makes the hand-held version preferred.

The preferred form of the invention is illustrated in the functional block diagram of FIG. 2 which illustrates the functional components of the programmed Psion 3a palmtop computer 16. The frequency modulated audio biomedical data may be input directly to microphone 30 or, in some cases, it may be received directly through a connector jack 32 to input lead 34 to analog/digital converter 36. The output from analog to digital converter 36 is then applied to a digital band-pass filter 38, e.g., over the band of 0.05 Hz to 40 Hz, and then to a digital polyphase demodulator 40. The dash-line 41 outlines the central processing unit and memory components of the palmtop computer 16 (FIG. 1). The demodulator 40 employs two simultaneous filters which have been optimized for integer operation using a micropower microprocessor. The output from demodulator 40 may then be applied directly to display 18, or the filtered digital signal can be applied directly to a storage file 42 for selected output via printer 44.

Alternatively, the digital biomedical FM data signal output from analog to digital converter 36 may be applied via lead 46 to a storage file 48. Selected data from storage file 48 may

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then be played back into digital to analog converter 50 and the analog signal can then be applied to a loud speaker 52 and/or further telephone or facsimile relay 54 to a remote diagnostic location for further demodulation, review and opinion. As shown in FIG. 3, the original receiving phone 26 and handset 28 may be used to relay the data via telephone system link 53 to yet another phone 26R and handset 28R as located at another remote location. Such further transfer may be necessitated by a need for second opinion or additional comparison data. The hand-held computer 16 may be operated to emit the audible ECG data from handset 18 for transmission via telephone interconnect 53 to the remote phone 26R whereupon handset 28R provides audible input to another hand-held computer 16R for processing and display of the ECG data.

FIG. 4 illustrates an alternative design of the invention utilizing a palmtop computer of the type having a PCMCIA interface slot for signal processing and display. A received frequency modulated audio signal is fed either via microphone 30 or connector 32 to input lead 34 to the analog FM demodulator 58. The FM demodulator 58 may be such as a IC phase locked loop, Exar type 215. The analog FM demodulator 58 then applies output to an analog to digital converter 60 which provides digital output via the palmtop PCMCIA interface to the palmtop's CPU for digital filtering (40), storage and display. Optionally, a band-pass filter 62 may be interconnected between the demodulator 58 and the analog to digital converter 60. The output from digital filter 38, having a pass-band of 0.05 Hz to 40 Hz., may then be applied to output display 18, or, it may be placed in storage file 42 for subsequent recall to printer 44. The demodulator 58, converter 60 and bandpass filters 62 and 40 are all contained in the PCMCIA card.

Referring to the preferred embodiment of FIG. 2, it is an objective of the Rhythm-Stat program to demodulate a frequency modulated audio signal and to decimate the output for storage and plotting purposes. The Psion 3a computer 16 records sound files at an 8,000 samples per second rate and uses an A-Law analog to digital transformation. Therefore, the program used to demodulate a frequency modulated ECG or biomedical signal

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must perform three functions. As shown in FIG. 5, these functions are (1) an A-Law decoder 64, (2) a band-pass filter 66, and (3) a frequency estimator 68 which includes a residue estimator 70 and a cycle accumulator 69. The A-Law decoder 64 functions as an expander which reverses the action of the A-Law compressor in the Psion. The A-Law encoding is a standard approximation to the logarithmic compression as established by CCITT, the European standards body. The output of the A-Law compander is defined by

$$F(x) = \mathrm{sgn}(x)^{*} A|x|/(1+\ln(A)) \qquad 0 \le |x| < 1/A \qquad (1)$$

$$F(x) = \mathrm{sgn}(x)^{*} (1+\ln(A|x|))/(1+\ln(A)) \qquad 1/A \le |x| \le 1 \qquad (2)$$

where x is the analog input, F(x) is the A-Law compander output, sgn(x) is the sign (+/-) of x, and A is the compression parameter. Since the Psion 3a computer 16 records the sound file in A-Law encoded format (12-bit data stored in 8 bits, all at 8000 samples per second), these values need to be decoded in order to band-pass filter and demodulate the signal. The decoding is accomplished by using a look-up table. The range of A-Law encoded values is -128 to 127, therefore, an array of length 256 is initialized to contain the A-Law decoded values. The array is indexed from zero to 255 as the decoded value contained at indexed zero corresponds to the A-Law value of -128, and the decoded value contained at index 255 corresponds to the A-Law value of 127. Therefore, to decode any A-Law value, 128 is added to the A-Law value and the result is used to index into the array.

The digital band-pass filter 66 is utilized to remove unwanted signal introduced when recording with the Psion 3a. The equation used to realize the band-pass filter is

$$a_0 y(n) = b_0 x(n) + b_1 x(n-1) + b_2 x(n-2) + a_1 y(n-1) + a_2 y(n-2) \qquad (3)$$

where x(n) is the input data, y(n) is the output data, and a_x, b_x are constant coefficients. For data that is sampled at 8000 Hz, to obtain a band-pass filter with a Q=2 and a center frequency of 2000 Hz, the coefficients are set to

$a_0 = 1$
$a_1 = 0$
$a_2 = -0.5$
$b_0 = 1$
$b_1 = 0$

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$b_2 = -1$

This realizes a band-pass filter with a transfer function

$$H(z) = (1-z^{-2})/(1+0.5z^{-2}) \quad (4)$$

This portion of the demodulation procedure is implemented directly after the A-Law decoder 64 and before the cycle counting procedure.

The frequency estimator 68 functions by windowing the input data and counting the number of complete cycles contained within the window. The phase of the incomplete cycle located at the end of each window is estimated by using the arctangent function. Therefore, the frequency estimator 68 contains two sections which are (1) the cycle accumulator and (2) a residue estimator. See FIG. 6. The cycle accumulator consists of two overlapping windows and FIG. 6 shows the relationship between the two windows. The filtered data appears on line 72 with 40 unit graduations while the decimated output data appears along line 74. The size of each window determines the amount of decimation in the demodulation procedure. Choosing a window size of 80 decimates the data from 80 input points to 1 (80:1), however, with two overlapping windows the final output is decimated by 40:1. Thus, with an original sampling of 8000 samples per second, the output is resampled to 200 samples per second after decimation. For a frequency estimate, each window counts the number of complete cycles of 80 band-pass filtered data points. For each complete cycle, 256 (corresponding to 2 π radians) is added to the window counters. After determining the number of complete cycles contained in 80 data points, a window calls the residue estimator passing the 79th and 80th

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data points to determine the amount of the incomplete cycle on the end of the window.

Using the last two data points of the cycle accumulator window, the residue estimator 70 determines the amount of an incomplete cycle by using a look-up table technique. The look-up table contains arctangent values for every possible point in the first quadrant of a sine wave. The values are scaled to range from zero to 64 (corresponding to $0-\pi/2$ radians). Using the sign of the two points passed from the cycle counter, the residue estimator 70 determines in which quadrant the points are located. These points are then scaled so that both are less than 64 in order to index into the arctangent look-up table. The quadrant determination with the arctangent value, determines the output of the residue estimator as follows:

1st quadrant: Residue Estimate = arctangent value

2nd quadrant: Residue Estimate = 128 -arctangent value

3rd quadrant: Residue Estimate = 128 +arctangent value

4th quadrant: Residue Estimate = 256 -arctangent value

The residue estimate is added to the window calling the residue estimator 70 and thus is used as an output point. The window counter is then reset to 256 minus residue estimate to include an estimate of the incomplete cycle located at the beginning of the next 80 filtered data points.

FIGS. 7, 8 and 9 are a flow diagram of the demodulation procedure that is carried out under the system program, i.e., the Rhythm-Stat XL software, as will be further described below. In FIG. 7, the process begins at START 100 whereupon variables are initialized in flow stage 102 and the input and output files

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are readied at stage 104. The flow stage 106 then reads the *.WVE file header information and the number of samples in the file is stored at flow stage 108. Flow stage 108 then proceeds to stage 110 which sees reading of eighty input samples after which decision stage 112 tests to see whether or not end of file (EOF) has been encountered. If end of file does appear, then the affirmative output proceeds to END stage 114 and completion of the program operation. If end of file is not yet reached, the negative output passes flow to stage 116 which functions to A-Law decode the samples. The A-Law decoding expands the A-Law encoded values to the original value.

Data handling proceeds to flow stage 118 which effects bandpass filtering and subsequent flow stage 120 functions to assign samples in accordance with polarity of the last sign. Continuing on to FIG. 8, the line 122 connects from Terminal B to flow stage 124 which points to first sample with data flow on line 126 to a series of decision stages. A first decision stage 128 tests for whether or not the sample is positive with a negative response by-passing on line 130, and an affirmative response proceeding to the subsequent decision stage 132 which queries for last sign negative. A negative response directs flow to by-pass line 130 and an affirmative response continues process to stage 134 which adds 256 to cyclecount 1 and cyclecount 2. A flow stage 136 then assigns a lastsign the sign (+/-) of the sample being processed.

Flow line 138 then proceeds to stage 140 which functions to point to the next sample prior to decision stage 142 which queries whether the sample is the forty-first sample in the

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sequence. If negative, and the sample is other than the forty-first sample, flow recycles via line 143 to the decision stage 128 which tests whether or not the sample is positive; but, if stage 142 is affirmative, flow proceeds to stage 144 wherein the look-up cycle residue is estimated. That is, a value is obtained from the arctangent table for samples thirty-nine and forty as flow proceeds to stage 146 which adds the estimate to cyclecount 1. A next flow stage 148 sees output to file of cyclecount 1 with flow stage 150 resetting the cyclecount 1 before proceeding on line 152 for connection to the C terminal at FIG. 9.

The line 152 leads to a series of decision stages wherein stage 154 tests for a positive sample and, if negative, cycles ahead via line 156, and, if affirmative, query is made of the next decision stage 158 as to whether or not the last sign was negative. If not, cycle ahead via lead 156 is made or, if affirmative, flow proceeds to stage 160 which adds 256 to each of cyclecount 1 and cyclecount 2.

Flow proceeds from stage 160 as well as by-pass line 156 to a stage 162 which functions to assign the lastsign or previous sample sign. Thereafter, flow stage 164 points to the next sample as indication proceeds via line 166 to a decision stage 168 which queries whether the sample is the eighty-first sample in the succession. If not, flow proceeds via line 170 to recycle through stages 154 and 158 and succeeding stages; however, if the decision is affirmative (the eighty-first sample) then stage 172 establishes the look-up cycle residue estimate, i.e., samples 79 and 80 from the arctangent look-up

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table. The estimate is added to the cyclecount 2 in flow stage 174 and output to file in flow stage 176 prior to the reset of cyclecount 2 in stage 178. Flow then proceeds through terminal A back to FIG. 7 for recycle through flow stage 110 which reads the next eighty input samples. Eventually, when end of file is encountered as at flow stage 112, the affirmative output proceeds to END 114 to terminate the process.

The program for controlling the Psion 3a hand-held computer 16 is termed the Rhythm-Stat XL software and it functions to acquire frequency modulated biomedical data, e.g., ECG data, as generated by an Instromedix™ recording device known as the Heart Card 12 or other similar medical data recording device. The Psion 3a computer 16 is programmed with the Rhythm-Stat XL program that functions with the Psion floating point emulator. Data files with a *.WVE extension must be first placed in the ECG data directory, and these are Psion sound files that will be decoded, demodulated, and displayed by the Rhythm-Stat XL program as an ECG rhythm strip.

On start up (see FIG. 10), the program displays a title screen, and pressing the ESCAPE key 76 continues operation with an empty graphics grid as the program title will appear on display screen 18. The MENU key 78 may then be depressed to access the program menus and selected hot keys will be shown to the right of the listed menu items. In order to use an item, it is necessary to hold down the Psion special key 80 while pressing the desired character key. As shown in FIG. 10, the white keys are the standard Qwerty keys while the black keys are various function and control keys. The ECG data scaling,

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keyboard display controls, and data acquisition and relay are summarized below.

The initial display represents a 12.5 mm/second scale that is divided into 200 ms graduations. Up to three 9.6 second periods of ECG totalling 28.8 seconds of ECG rhythm, may be displayed. Expanded scales of 25 and 50 mm per second are available.

The y scale is calibrated to show millivolts of signal value. During demodulation, and after the processing is completed, and the data replotted, a square calibration pulse will appear on the left of the first segment of ECG data to provide signal calibration. An additional calibration pulse may be found at the end of a data set and these calibration pulses are nominally 1 millivolt on the y axis. A control key selects display scales of 25 or 50 mm per second and selected arrow keys 86 may be used to select ECG epochs for display. When the ECG is expanded on the x axis, the y scale is 0.5 millivolts per graduation, and left and right arrow keys 96 and 98 will scroll the expanded display by one epoch at the selected scale. The user may increase or decrease the waveform amplitude by a factor of two with selected gain controls at any scale. The waveform may be shifted up or down in 0.5 mv increments with up and down arrow keys of key group 86 for expanded displays, and also with the shifted up and down arrow keys in the initial 12.5 mm per second display.

The Rhythm-Stat XL program records, decodes and displays acoustic frequency modulated ECG data that is generated by such as the Instromedix Heart Card or other heart watch device, or

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by another Psion 3a computer that is equipped with Rhythm-Stat XL program, as shown in FIG. 3. Recording of the acoustic data may be direct, or it may be done with ordinary telephones across a wireline or wireless phone system.

A more detailed operation description of menu options, keyboard controls, and ECG recording and relay procedures for this program follows. A first option in the FILES menu is the "open ECG file" which functions to display a list of files in the reverse/ECG directory. Left and right arrow keys 96 and 98 at the files display will present the file names. The only valid file types are *.RXL, *.RST and *.WVE files, and if other files are in the ECG directory, they will be shown. The program has no provision for user interruption of WVE input file processing, which takes about 30 seconds, or of ECG data recording or playback, which takes 35 seconds. If necessary, a user may terminate the application during file processing or recording by holding down the Psion control key 80 while depressing the ESCAPE key 76.

The Rhythm-Stat XL program is intended to record and display frequency modulated acoustic ECG data, and taking the record option will produce a file name selection dialogue. When the desired file name is entered, a screen will tell the user that Rhythm-Stat XL program is ready to record and will begin when the "ENTER" key 82 is depressed.

At this point, the user can place the output speaker on the Heart Card 12 as close to the Psion microphone opening (square opening at bottom right edge of the case) as possible. If recording over the telephone, place the Heart Card 12 (FIG. 1)

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on the sender's handset microphone 20 with the receiver's handset speaker 28 as close to the Psion microphone opening as possible. The user can then initiate the playback and recording as close to simultaneously as possible. The Heart Card 12 has a nominal 30 second playback period while the Psion 3a records 35 seconds of sound. The difference will accommodate a few seconds of variance in user synchronization of playback and recording.

Note that there is no progress indicated for the recording and the program, and when Rhythm-Stat XL program completes its recording, an annunciator chirps, and a third screen appears to tell the user that the recording is complete. The new WVE file will then be found among the file names offered in the files plus open menu option for processing and display.

Another files menu item, playback ECG, appears in the Rhythm-Stat XL program. Thus, the program may be used to relay the FM ECG data to another Psion equipped with the Rhythm-Stat XL program, by playing back the *.WVE ECG data file. Taking the playback option will produce a file name selection dialogue. Once the file name is selected, a second screen will tell the user that Rhythm-Stat XL is ready to play back the ECG data file, and will begin when the ENTER key 82 is depressed. The receiving Psion must be prepared for recording with the output speaker on the sending Psion as close to the microphone opening of the receiving Psion as is conveniently possible. If relaying the data over a phone system, the sending Psion speaker should be placed closely over the handset microphone with the receiving handset speaker as close to the related Psion opening as

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possible. Once again, the playback and recording is initiated as close to simultaneously as possible and a high frequency warble of the frequency modulated ECG data will be audible and ceasing upon completion of playback. An annunciator chirp tells the user when the transfer has been accomplished.

The remaining files menu items are "SAVE ECG AS", "DELETE", and "EXIT" and the last two items are self-explanatory. However, the "SAVE AS" item provides for automatic conversion of WVE files to RST files. The data output remains the same, but the RST files are 1k to 5k as compared to 250k for the WVE files. It is useful to be able to process the same WVE file in different ways in order to examine development options.

In addition to the files menu, there is a waveform menu which controls certain display parameters. A first "EXPAND ON X" refers to selection of 25 or 50 mm/second displays. Note that pressing the "z" key 94 will have the same effect. When "EXPAND ON X" item is first activated, a 4.8 second epoch will be highlighted on the main 12 x 5 mm/second display screen. Pressing "z" key 94 again will then toggle the selection box back and forth between the 4.8 second epoch (25 mm/second) and a 2.4 second epoch (50 mm/second). The selection block may be moved around with selected arrow keys 86. Pressing "ENTER" key 82 will display the epoch at the selected mm/second x-axis scale, and pressing the "z" key 94 will toggle the expanded or zoom selection, from 25 mm/second to 50 mm/second and back. The time period in the waveform and the scale are displayed in a text window at the top of the display screen 18. While in a 25 or 50 mm/second screen, the left and right arrow keys 96 and 98

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will scroll the display to the left or right; and, a shifted left or right arrow will increment or decrement the display one complete epoch to the left or right. Depression of control key 88 plus a left or right arrow of keys 86 will initiate continuous scrolling that may be terminated with the "ESCAPE" key 76.

If not scrolling continuously, the "ESCAPE" key 76 will return the user to the 2.5 mm/second main display screen for alternative epoch selection. While zoomed, the dual function Home keys 96 and end key 98 (the Psion plus left arrow and Psion plus right arrow of keys 86) will display the first and last epoch at the scale selected. The up and down arrow keys of the group 86 will shift the zero volt baseline up or down.

Since the nominal recording and playback periods for Rhythm-Stat XL are 35 seconds, additional ECG data, beyond the 28.8 seconds shown on the initial 12.5 mm/second screen, may be available. In such case, that data may be accessed easily by selecting the last epoch on the 12.5 mm/second screen, pressing enter, and scrolling to the right to the end of the data set. Should the user make a recording synchronization error, an additional 1 millivolt calibration pulse may be found at the end of the data set.

Waveform gain selection is accomplished using the Psion key 80 plus the + key 90 to increase the current waveform amplitude by a factor of 2. The waveform amplitude can be halved by depressing the Psion key 80 plus the - key 92. It should be noted that reducing the gain, and then increasing the gain, may cause loss of detail resolution. Similarly, increasing the gain

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may produce values that are detrimental to ECG feature resolution; however, the file may be processed again to regain an original waveform for further manipulation.

There is a waveform menu for moving the ECG up and down on the display screen 18. In a zoomed screen, the menu selection, or an up or down arrow of keys 86 will move the waveform up or down on the display adjusting the position of the zero millivolt baseline. This function is useful on occasions where a low frequency component places a portion of the ECG off the screen in the 25 or 50 mm/second display. In the 12.5 mm/second screen, the same effect may be obtained by the menu selection of the Psion control key 80 plus a shifted up or down arrow key of the key group 86.

The complete program of source code files for Rhythm-Stat XL version 0.2.8 alpha is included with the present application as Exhibit A. A list of the major software routines with functional description is as follows:

```
! read me
Source Code files for Rhythm-Stat XL

ABOUT.C
Title and About screen

Common.C
These are variables and structures for global reference

DeMod. Asm
Assembly module for demodulation of acoustic FM ECG signal,
Requires pointers to ALAW decoding and Arctangent tables; Called
by Process_WVE_File () in WVE_File.C.

Dlg_Ctl.C
file dialog control

File_Ctl.C
UBYTE Open Sound File (UBYTE File Name []);
VOID Close Sound File (VOID);
UBYTE Read Sound Header (SndFile sFileHead);
```


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INT Read Sound Segment (UBYTE FileBuf [], UINT Size);

G_SCROLL.C
Scrolls graphics plotting rectangle, one 200 ms window at a time, right or left

GRID_CTL.C
Entire screen is MainRcl.
Application screen AppRel is the MainRcl, less border
Plotting area is PltRcl, which is AppRcl less axes and caption, x and y values are in absolute screen coordinates

MISC.C
Miscellaneous functions and procedures

NOTIFY.C
Procedures for posting model and non-model message boxes for user.

PLOT_CTL.C
Procedures for plotting epochs, and entire data set on the 12.6 mm.sec screen.

PPP_Dec.C
Procedures to decimate (downsample) data, while locating and preserving peak information in the waveform. External call is made to PPP_Decimate_into_Buffers () from WVE_File.C

PPP_Dec.H
Include file for module PPP_Dec.C

Notify.C
Procedures for posting model and non-model message boxes for user

PLOT_CTL.C
Procedures for plotting epochs, and the entire data set on 12.5 mm/sec screen

PPP_Dec.C
Procedures to decimate (downsample) data, while locating and preserving peak information in waveform. External call is made to PPP_Decimate_Into_ Buffers () from WVE_File.C

PPP_Dec.H
Include file for module PPP_Dec.C

PVTYPES.H
Include file for module RST_File.C

RST_File.C
Procedures to read and process a *.RST file format. The *.RST file format is a variation on the *.CMF file format used in other Data Critical medical information files.

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RSTAT_XL.H
Include file for Rhythm-Stat XL modules

WVE_File.C
Procedure to decode and demodulate the FM ECG signal, received as sound data

Wnd_Ctrl.C
The entire screen is MainRcl. The Application Screen, AppRcl, is the MainRcl, less the border. The plotting area is PltRcl, which is AppRcl, less axes and Caption. X and Y values are in absolute screen coordinates

Str_Fn.C
String manipulation functions and utilities

Sound_10.C
Procedures to record and playback the FM modulated ECG data in the form of Psion WVE sound files

The foregoing discloses a novel method and apparatus using a programmed palmtop computer that enables a patient to monitor his own biomedical data for dial-up phone relay to his primary doctor or other diagnostician. The patient can detect and record up to 5 minutes of a selected ECG rhythm sequence for transmission via frequency modulated audio signal to the programmed computer which then functions to digitize and demodulate the rhythm sequence for print-out on the palmtop computer display or printing device.

The present invention removes intervention of a third party in the monitoring service and allows a medical attendant familiar with the patient to interface directly with that patient. In other words, an attending doctor or medical provider can offer more personal and more rapid attention to each case.

The present device enables a virtual arrythmia monitoring service whereby an attending physician can receive and review transtelephonic ECG data using only a hand-held computer and a phone, either wireline or wireless.

Changes may be made in the combination and arrangement of elements as heretofore set forth in the specification and shown in the drawings; it being understood that changes may be made in the embodiments disclosed without departing from the spirit and scope of the invention as defined in the following claims.

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```
----------*/

UINT Newline2Null(char *p, UINT curpos, UINT len)
{ UINT i=0;
 for(i=curpos; i<len; i++)
   { if(*(p+i) == '\n') { *(p+i) = '\0'; return (i); } };
 return 1;
}

/*****************************************************************************/
// copy string2 to string1 up to newline char in string2
// Terminate string1 with null instead newline
/*****************************************************************************/
INT StrCpyNL( TEXT *String1, TEXT *String2)
{ INT i;
 i = 0;
 while ((*String1++ = *String2++) != '\n') { i++; }
 String1--;              // backup one to point to newline char
 *String1 = '\0';         // pointer is now pointing to end of string
 return i;
}
/*****************************************************************************
  reversed error logic because it sounded better
----------*/
INT RecTypeIsValid(UBYTE RecType)
{ if((RecType >= MIN_REC_CODE) && (RecType <= MAX_REC_CODE)) return 1;
 else return 0;
}
/*****************************************************************************
 Looks up the record type - jump table
----------*/
INT RecExists(UBYTE RecType)
{ INT i;
 i = (int)RecType;
 // toc.reclist[i].type != RecType ||
 if( (toc.reclist[i].type ==  0 ) ||
    (toc.reclist[i].type == -1 )
   )
   { return -1; }
 else
   { return 0;};
}
/*****************************************************************************
----------*/
INT InvalidFileSignature( VOID )
{ INT len; TEXT fsignature[FILE_SIG_SIZE];
 len = p_read(sFcb, fsignature, FILE_SIG_SIZE);
 if(len < FILE_SIG_SIZE) return -1;
 fsignature[4]='\0';
 if(p_scmp(fsignature, PV_FILE_SIG)) return -1;
 return 0;
}
```


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```
/*****************************************************************
                    RStat_XL.C
                Main Program Module
            R-Stat XL, version 0.2.8
        Copyright Data Critical Inc., 1996.
    United States and international patents pending

-----------------------------------------------------------------*/
#include "RStat_XL.H"
TEXT    sTitle[] =
     {"Rhythm-Stat XL (c)Data Critical 1996. v0.2.8 alpha"};

extern  VOID *DatCommandPtr;


extern  INT     ACTION;
extern  TEXT    LocalDir[];
extern  TEXT    FileSpec[];
extern  INT     ret;
extern  VOID    *sFcb;

extern  TEXT    PlotCaption[];

extern  DATACTL  mm12;
extern  DATACTL  mm25;
extern  DATACTL  mm50;
extern  EPOCHCTL Epoch;
extern  PLOTCTL  Plot;

extern  INT     n_Seg;
extern  INT     n_Xseg;
extern  INT     n_Yseg;

extern  TEXT    usermsg[];
     INT     Y_shft =0;
GLREF_D UWORD  _UseFullScreen;  /* For uCommonInit() */
GLREF_D UWORD  *_GreyLines;     /* Points to underline masks */

     UINT   hWndMain;        /* ID of main window */

     UINT   modepos = 0;     /* Current mode */
LOCAL_D UWORD  Menu1Pos;        /* Remembers position in menu bar 1 */
LOCAL_D UWORD  Lines[16];       /* Menu underline masks */
#define N_MODES       3
#define FILES_ITEMS   6
#define PROC_ITEMS    6
#define ITEMS_BEFORE_FILES 0
#define ITEMS_BEFORE_PROC  FILES_ITEMS

INT nModes = N_MODES;
/* Menu card 1 titles */
LOCAL_D H_MENU_DATA mdata1[]=
{ "Files",     FILES_ITEMS,
  "Waveform",  PROC_ITEMS,
```


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```
  NULL
};
/*** Text and accelerators of menu bar 1 ***/
LOCAL_D TEXT  *cmds1[]=
{ "oOpen ECG File", "rRecord ECG",  "pPlayBack ECG",
  "sSave ECG As",  "dDelete File",  "xExit RhythmStat",
  "zExpand on X",  "+Gain+  2.00",  "-Gain-  0.50",
  "qMove ECG Up",  "wMove ECG Down", "cClear Screen",
  NULL
};
GLDEF_D TEXT     **_cmds = (&cmds1[0]);   /* Points to commands */
GLDEF_D H_MENU_DATA *_mdata = (&mdata1[0]);  /* Points to menu cards */

BYTE     First = TRUE;
UINT     hWndTemp;
G_GC     TmpGc;
G_FONT_INFO TmpFontInfo;


GLDEF_C VOID main            ( VOID );
LOCAL_C VOID SpecificInit    ( VOID );
LOCAL_C VOID MainLoop        ( VOID );
LOCAL_C VOID ServiceUserInput   ( VOID );
LOCAL_C VOID TryExecuteCommand  ( INT e);
LOCAL_C VOID ProcessSystemCommand ( VOID );

LOCAL_C VOID Service_Zoom_Request ( VOID );
LOCAL_C VOID ZoomAmplitude      ( BYTE Gain );
LOCAL_C VOID AdjustZero         ( BYTE offset);
LOCAL_C VOID Replot             ( VOID );
LOCAL_C VOID IdentifyLastEpoch  ( VOID );
LOCAL_C VOID CurrentEpoch       ( VOID );
LOCAL_C VOID SelectEpoch_Right  ( VOID );
LOCAL_C VOID SelectEpoch_Left   ( VOID );
LOCAL_C VOID SelectEpoch_Up     ( VOID );
LOCAL_C VOID SelectEpoch_Down   ( VOID );
LOCAL_C VOID PlotEpochRight     ( VOID );
LOCAL_C VOID PlotEpochLeft      ( VOID );
LOCAL_C UBYTE ScrollOneDivRight  ( VOID );
LOCAL_C UBYTE ScrollOneDivLeft   ( VOID );

LOCAL_C BYTE  RecordECG         ( TEXT filename[] );
LOCAL_C BYTE  PlayECG           ( TEXT filename[] );

LOCAL_C VOID SizeCopyRightWindow  ( VOID );
LOCAL_C VOID CopyRightScreen      ( VOID );


/*************************************************************************
                    Main()
 ------------------------------------------------------------------------ */
GLDEF_C VOID main(VOID)
{ _UseFullScreen = TRUE;   /* Use the full extent of the 3a screen */
  uCommonInit();           /* Do some common intialization */
```


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```
 SpecificInit();
 MainLoop();
}
/*************************************************************************
 Initialisation
 ------------------------------------------------------------------------ */
LOCAL_C VOID SpecificInit(VOID)
{
 p_mkdir("M:\\ECG"); // p_setpth("M:\\ECG");
 _GreyLines = &Lines[0];          /* Point to underline masks OK */
 uEnableGrey();                   /* Grey please */

 hWndMain  =  uFindMainWid();     /* Get handle */
 CreateMainGC();                  /* Create graphics context */
 ToggleStatusWindow();
 SizeRectangles();                /* Initialise main screen, get status window */
 wsSetList(W_STATUS_WINDOW_ICON,NULL,0);      /* Initialise w. Icon */

 About_RStatXL();

 BufferGrid();

 InsertCaption(sTitle,CJustify);
 p_scpy(PlotCaption, sTitle);


 // Structure Initialization
 EvaluateArrayPointers();
 InitializeStartingValues();

 ACTION = IDLE;  First = TRUE;
}

LOCAL_D WS_EV event;
/*************************************************************************
  Main loop, asynchronous form
 ------------------------------------------------------------------------ */
LOCAL_C VOID MainLoop(VOID)
{ WORD wactive = FALSE;

 OpenTimer ( 1 );
 wactive=FALSE;

 FOREVER
  { if(wactive) { wFlush(); }
    else       { wGetEvent(&event); wactive=TRUE; }
    p_iowait();

    if(event.type==E_FILE_PENDING) // if no keystroke
     {
      if(ACTION==SCROLL_RIGHT)
       { if(!ScrollOneDivRight())
          { ACTION = IDLE; p_sound((UINT)1,(UINT)320);
            Epoch.iSelected = 1;
```


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```
        }
      }
     if(ACTION==SCROLL_LEFT)
      { if(!ScrollOneDivLeft())
        { ACTION = IDLE; p_sound((UINT)1,(UINT)320);
          Epoch.iSelected = n_Xseg*n_Yseg; // Epoch.Last;
        }
      }
     ResetTimer( 1 );
     continue;   // leaves wactive TRUE
    }

   else  // this takes us to the main keyborad loop
    { wactive = FALSE;
     if(event.type==WM_KEY)     // Keystroke - service it
      {
       ServiceUserInput();
       wCancelGetEvent();
      }
    }

  } // endForever
}

/*****************************************************************************
        Keyboard service
 ---------------------------------------------------------------------- */
LOCAL_C VOID ServiceUserInput( VOID )
{ ret = FALSE;

 if(event.p.key.keycode & W_EVENT_KEY)
  { switch (event.p.key.keycode)
    { case CONS_EVENT_COMMAND:          /* The shell has spoken */
        ProcessSystemCommand();      /* Obey the shell */
    }
  }
 else if(event.p.key.keycode & W_SPECIAL_KEY)     /* Psion key pressed */
     { TryExecuteCommand(event.p.key.keycode & (~W_SPECIAL_KEY));}
 else
  { switch (event.p.key.keycode)
    {
     case W_KEY_HOME:
        if(Epoch.iSelected && Epoch.bPlotted )
         { Epoch.iSelected = 1;
          Plot_Epoch( Epoch.iSelected);
         }
        break;
     case W_KEY_END:
        if(Epoch.iSelected && Epoch.bPlotted )
         { Epoch.iSelected = Epoch.Last;
          Plot_Epoch(Epoch.iSelected);
         }
        break;
     case W_KEY_UP:
```


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```
    if(Epoch.iSelected && !Epoch.bPlotted)
     { if( event.p.key.modifiers & W_SHIFT_MODIFIER )
       { AdjustZero( (BYTE)-(Plot.sz_ydiv) ); }
      else
       { SelectEpoch_Up();};
     }
    else
     { AdjustZero( (BYTE)-(Plot.sz_ydiv) ); }
    break;
  case W_KEY_DOWN:
    if(Epoch.iSelected && !Epoch.bPlotted)
     { if( event.p.key.modifiers & W_SHIFT_MODIFIER )
       { AdjustZero( (BYTE)Plot.sz_ydiv ); }
      else
       { SelectEpoch_Down(); }
     }
    else
     { AdjustZero( (BYTE)Plot.sz_ydiv ); }
    break;
  case '+':
    ZoomAmplitude ( 2 );
    break;
  case '-':
    ZoomAmplitude ( -2 );
    break;
  case 'z':
    Service_Zoom_Request();
    break;
  case W_KEY_TAB:
    if( event.p.key.modifiers & W_SHIFT_MODIFIER )
     { PlotEpochLeft(); }
    else
     { PlotEpochRight(); }
    break;
  case W_KEY_LEFT:
    if(Epoch.iSelected)
     { if( !Epoch.bPlotted )
       { SelectEpoch_Left();
       }
      else // epoch is plotted
       { if( event.p.key.modifiers & W_SHIFT_MODIFIER )
         { PlotEpochLeft();
         }
        else
         { if( event.p.key.modifiers & W_CTRL_MODIFIER )
           { if((ACTION==IDLE) && Epoch.bPlotted)
             { ACTION=SCROLL_RIGHT; }
           }
          else
           { ScrollOneDivRight();
           }
         };
       };
     }
```


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```
    break;
case W_KEY_RIGHT:
    if(Epoch.iSelected )
     { if( !Epoch.bPlotted )
       { SelectEpoch_Right();
       }
      else
       { if( event.p.key.modifiers & W_SHIFT_MODIFIER )
         { PlotEpochRight();
         }
        else
         { if( event.p.key.modifiers & W_CTRL_MODIFIER )
           { if((ACTION==IDLE) && Epoch.bPlotted)
             { ACTION=SCROLL_LEFT;}
           }
          else
           { ScrollOneDivLeft();
           }
         };
       };
     }
    break;

case W_KEY_RETURN:
    if(Epoch.iSelected && !Epoch.bPlotted)
     { if(Epoch.iSelected <= Epoch.Last)
       { Epoch.bPlotted = Plot_Epoch ( Epoch.iSelected);}
     }
    break;
case W_KEY_ESCAPE:
    if( ACTION ) // interrupt any extended process
     { ACTION = IDLE; p_sleep(2);
     }
    else
     { if( Epoch.iSelected )
       { if(!Epoch.bPlotted) // invalidate epoch selection
         { InvertSegColor(Epoch.iSelected);
           Epoch.iSelected = 0;
         }
        else            // back up from plotted epoch
         { Epoch.bPlotted = FALSE;
           if(Epoch.iSelected == Epoch.Last)
             { Epoch.iSelected = n_Xseg*n_Yseg;}
           Replot();
           n_Seg = NSEG;
         }
       }
     }
    break;
case W_KEY_MENU:              /* Menu key pressed */
    ret = uPresentMenus();    /* Display the menu */
    if(ret > 0){ TryExecuteCommand(ret);}
    break;
```


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```
      default:
         break;
      } // endswitch

   } // endelse(!event.p.key.keycode & W_EVENT_KEY)
}
/*****************************************************************************
 Manage the menu command selected in view 1
 ----------------------------------------------------------------------------*/
LOCAL_C VOID ManageCommand1(INT index)
{ BYTE Ack;
 switch (index)
  { case ITEMS_BEFORE_FILES:      // oOpen
      // Filename to open may be *.WVE, *.FMD, or *.RST
      GetExistingFileName( &FileSpec[0] );
      if(FileSpec[0])
       { InsertCaption("Data Critical Remote Telephonic ECG",CJustify);
        if(Epoch.iSelected){Epoch.iSelected=0;Epoch.bPlotted=0;}
        if(!First) BufferGrid();
        if( (p_ssubi(&FileSpec[0],".WVE")) >= 0 )
         { ACTION = DEMODULATE;
          Process_WVE_File ( &FileSpec[0] ); First = FALSE;
          ACTION = IDLE;
         }
        if( (p_ssubi(&FileSpec[0],".RST")) >= 0 )
         { Process_RST_File ( &FileSpec[0] ); First = FALSE;
         }
        Y_shft =0;
        // OK now plot data if any
        if(mm12.Pts)
         { Epoch.iSelected = 0; Plot_Buffer ( );
          Plot.mm_sec = 12;
         }
       }
      break;
    case ITEMS_BEFORE_FILES +1:    // rRecord
      if(EnoughSpace(281))
       { if(GetNewFileName(&FileSpec[0]))
         { ACTION = RECORD;
          ret = (INT)Record_FM_ECG_1 ( &FileSpec[0]);
          ACTION = IDLE;
          if( ret )
           { if(Epoch.iSelected){Epoch.iSelected=0;Epoch.bPlotted=0;}
            if(!First)BufferGrid();
            ACTION=DEMODULATE;
            Process_WVE_File ( &FileSpec[0] );
            ACTION = IDLE; First=FALSE;
            // OK now plot data if any
            if(mm12.Pts)
             { Epoch.iSelected = 0; Plot_Buffer ( );
              Plot.mm_sec = 12;
             }
           }
          else
```


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```
            { InsertCaption(PlotCaption, CJustify);
            }
          }
        }
      break;
  case ITEMS_BEFORE_FILES +2:   // pPlayBack
      if(GetExistingFileName(&FileSpec[0]))
       { if( (p_ssubi(&FileSpec[0],".WVE")) >= 0 )
          { ACTION = PLAYBACK;
            Playback_FM_ECG_1 ( &FileSpec[0]);
            ACTION = IDLE;
            InsertCaption(PlotCaption,CJustify);
          }
         else
          { GetCopyOfFileName(usermsg, FileSpec );
            if(usermsg[0])
             { p_scat(&usermsg[p_slen(usermsg)]," is Not a .Wve File");
               p_sound((UINT)4,(UINT)320);
               Notify(usermsg);
             }
          }
       }
      break;
  case ITEMS_BEFORE_FILES +3:   // sSave As
      // GetNewFileName ( &FileSpec[0] );
      // SaveRTMfile( &FileSpec[0] );
      break;
  case ITEMS_BEFORE_FILES +4:   // dDelete
      if(GetExistingFileName(&FileSpec[0]))
       { p_scpy(usermsg,"Delete ");
         GetCopyOfFileName(&usermsg[p_slen(usermsg)],FileSpec);
         p_scat(usermsg,"?");
         Notify_2(&Ack, usermsg);
         if(Ack) p_delete ( &FileSpec[0] );
       }
      break;
  case ITEMS_BEFORE_FILES +5:   // xExit
      p_exit(0);
  case ITEMS_BEFORE_PROC:       // zZoom X 25 or 50
      Service_Zoom_Request();
      break;
  case ITEMS_BEFORE_PROC + 1:   // Gain +1.50
      ZoomAmplitude ( 2 );
      break;
  case ITEMS_BEFORE_PROC + 2:   // Gain - 0.66
      ZoomAmplitude ( -2 );
      break;
  case ITEMS_BEFORE_PROC + 3:   // Shift Zero Up
      AdjustZero ( (BYTE)-(Plot.sz_ydiv));
      break;
  case ITEMS_BEFORE_PROC + 4:   // Shift Zero Down
      AdjustZero ( (BYTE)Plot.sz_ydiv );
      break;
  case ITEMS_BEFORE_PROC + 5:   // cClear
```


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```
        BufferGrid();
        mm50.Pts =0; mm25.Pts =0; mm12.Pts =0;
        Epoch.iSelected = 0; Epoch.bPlotted = FALSE;
        p_scpy(usermsg,sTitle);
        InsertCaption(usermsg,CJustify);
        p_scpy(PlotCaption, usermsg);
        break;
    }
}
/*****************************************************************************
 ---------------------------------------------------------------- */
VOID Service_Zoom_Request ( VOID )
{ if(!mm12.Pts) return;

 if(Epoch.iSelected && !Epoch.bPlotted)
   { InvertSegColor ( Epoch.iSelected ); }

 // if 12, make it 25, if 25 make it 50, if 50, make it 25
 if(Plot.mm_sec==12)
   { Plot.mm_sec = 25;   n_Seg = NSEG;
   }
 else
   { if(Plot.mm_sec==25)
       { Plot.mm_sec = 50;   n_Seg = NSEG*2;
         if(Epoch.iSelected)Epoch.iSelected = Epoch.iSelected*2-1;
       }
     else
       { if(Plot.mm_sec==50)
           { Plot.mm_sec = 25;  n_Seg = NSEG;
             if(Epoch.iSelected)
               { if(Epoch.iSelected >1)
                   { if(!(Epoch.iSelected%2))
                       { Epoch.iSelected = Epoch.iSelected/2;}
                     else
                       { Epoch.iSelected = Epoch.iSelected/2+1;}
                   }
               }
           }
       };
   }

 n_Xseg = n_Seg/N_YSEG;  // 6/3=2 or 12/3=4
 SizeSegments();        // uses only N_YSEG

 // Identify the last epoch containing data
 IdentifyLastEpoch();
 n_Yseg = Epoch.Last / n_Xseg;
 if( n_Yseg < N_YSEG ) { if ((Epoch.Last%n_Xseg)) n_Yseg++; }
 // p_atos(usermsg,"last %d, nX %d, nY %d", Epoch.Last, n_Xseg, n_Yseg); Notify(usermsg);

 // Restructure Display
 if( Epoch.iSelected)
   { if(Epoch.iSelected > n_Seg) Epoch.iSelected=n_Seg;
     if(Epoch.bPlotted)
```


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```
    { Plot_Epoch ( Epoch.iSelected );
    }
   else
    { InvertSegColor ( Epoch.iSelected );
    }
  }
 else
  { Epoch.iSelected = 1;
   InvertSegColor ( Epoch.iSelected );
  }
}
/*****************************************************************************
 ---------------------------------------------------------------------- */
LOCAL_C VOID SelectEpoch_Up ( VOID )
{ INT iNewSelection = Epoch.iSelected - n_Xseg;
 if(iNewSelection < 1 )
  { // wrap around
   iNewSelection +=(n_Xseg*n_Yseg);
  }
 if(iNewSelection <= Epoch.Last)
  { InvertSegColor(Epoch.iSelected); // To Bl on Wh
   Epoch.iSelected = iNewSelection;
   InvertSegColor(Epoch.iSelected); // To Wh on Bl
  }
}
/*****************************************************************************
 This not an inversion of SelectEpochUp() because Epoch.Last may
 exceed n_Xseg * n_Yseg, yet access to Epoch.Last via zoomed epoch
 shifts and scrolling is to be preserved..
 ---------------------------------------------------------------------- */
LOCAL_C VOID SelectEpoch_Down ( VOID )
{ INT iNewSelection = Epoch.iSelected + n_Xseg;

 if( iNewSelection > (n_Xseg*n_Yseg) )
  { iNewSelection -= (n_Xseg*n_Yseg);
  }
 if(iNewSelection >= 1)
  {
   InvertSegColor(Epoch.iSelected); // To Bl on Wh
   Epoch.iSelected = iNewSelection;
   InvertSegColor(Epoch.iSelected); // To Wh on Bl
  }
}
/*****************************************************************************
 ---------------------------------------------------------------------- */
LOCAL_C VOID SelectEpoch_Right ( VOID )
{ InvertSegColor(Epoch.iSelected); // To Bl on Wh
 if( !(Epoch.iSelected % n_Xseg) )
  { Epoch.iSelected = Epoch.iSelected -(n_Xseg-1);
  }
 else
  { Epoch.iSelected = Epoch.iSelected +1;
   if(Epoch.iSelected > (n_Xseg*n_Yseg))
    { Epoch.iSelected=((Epoch.iSelected-1)/n_Xseg)*n_Xseg+1;}
```


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```
  ;
 InvertSegColor(Epoch.iSelected); // To Wh on Bl
}
/*****************************************************************************
 ---------------------------------------------------------------------- */
LOCAL_C VOID SelectEpoch_Left ( VOID )
{ InvertSegColor(Epoch.iSelected); // To Bl on Wh
 if( (Epoch.iSelected % n_Xseg)==1 )
  { Epoch.iSelected = Epoch.iSelected +(n_Xseg-1);
   while(Epoch.iSelected > Epoch.Last)Epoch.iSelected--;
  }
 else
  { Epoch.iSelected = Epoch.iSelected -1; }
 InvertSegColor(Epoch.iSelected); // to Wh on Bl
}
/*****************************************************************************
 Plot.X_shft is reset to zero in Plot_Epoch(), and is updated in
 PlotXdivRight() and PlotXdivLeft() in module G_Scroll.C
 ---------------------------------------------------------------------- */
LOCAL_C UBYTE ScrollOneDivLeft ( VOID )
{ if(ScrollLeft())
  { UpdateTenthSecs( 2 );
   if( Plot.X_shft >= ( Plot.n_xdiv ) )
    { Epoch.iSelected++;
     //CurrentEpoch();
     Plot.X_shft =0;
    }
   UpdateEpochCaption();
   return TRUE;
  }
 else
  { return FALSE;
  }
}
/*****************************************************************************
 Plot.X_shft is reset to zero in Plot_Epoch(), and is updated in
 PlotXdivRight() and PlotXdivLeft() in module G_Scroll.C
 ---------------------------------------------------------------------- */
LOCAL_C UBYTE ScrollOneDivRight ( VOID )
{ if(ScrollRight())
  { UpdateTenthSecs( (-2) );
   if( Plot.X_shft <= ( -Plot.n_xdiv ) )
    { Epoch.iSelected--;
     //CurrentEpoch();
     Plot.X_shft =0;
    }
   UpdateEpochCaption();
   return TRUE;
  }
 else
  { return FALSE;
  }
}
/*****************************************************************************
```


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```
  Replot one zoomed screen to left
 ---------------------------------------------------------------------- */
LOCAL_C VOID PlotEpochLeft ( VOID )
{ if(Epoch.iSelected > 1)
   { Epoch.iSelected --;  Plot_Epoch ( Epoch.iSelected );
    // Caption updated in Plot_Epoch();
   }
}
/*************************************************************************
  Replot one zoomed screen to right
 ---------------------------------------------------------------------- */
LOCAL_C VOID PlotEpochRight ( VOID )
{ if(Epoch.iSelected < Epoch.Last)
   { Epoch.iSelected ++;  Plot_Epoch ( Epoch.iSelected );
    // Caption updated in Plot_Epoch();
   }
}
/*************************************************************************
  Return the number of the last epoch containing data
 ---------------------------------------------------------------------- */
LOCAL_C VOID IdentifyLastEpoch ( VOID )
{ if(Plot.mm_sec == 50)
   { Epoch.Last = mm50.Pts/FSX;  if(mm50.Pts%FSX) Epoch.Last++;
   }
 else // Plot.mm_sec == 25
   { Epoch.Last = mm25.Pts/FSX;  if(mm25.Pts%FSX) Epoch.Last++;
   }
}
/*************************************************************************
 ----------------------------------------------------------------------*/
LOCAL_C VOID CurrentEpoch ( VOID )
{ INT CurrentMidPoint = Plot.Lptr + ( (Plot.Rptr - Plot.Lptr) / 2 );
 if(Plot.mm_sec==50)
   { Epoch.iSelected = (CurrentMidPoint / 480) + 1; }
 else // Plot.mm_sec==25)
   { Epoch.iSelected = (CurrentMidPoint / 960) + 1; }

}
/*************************************************************************
  Increase or decrease buffer amplitude and replot
 ---------------------------------------------------------------------- */
LOCAL_C VOID ZoomAmplitude ( BYTE Gain )
{ // check gain limits
 if(Gain>0)
   { if (Y_shft >  0)  { p_sound((UINT)4,(UINT)180); return; }
     else          { Y_shft++; }
   }
 if(Gain<0)
   { if (Y_shft < 0)  { p_sound((UINT)4,(UINT)180); return; }
     else          { Y_shft--; }
   }
 PostRescaling();
 if(Plot.Pts==mm50.Pts)
   { AdjustBufferAmplitude( &mm50.Buf[0], mm50.Pts, Gain );
```


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```
    Replot();
    AdjustBufferAmplitude( &mm25.Buf[0], mm25.Pts, Gain );
    AdjustBufferAmplitude( &mm12.Buf[0], mm12.Pts, Gain );
   }
  if(Plot.Pts==mm25.Pts)
   { AdjustBufferAmplitude( &mm25.Buf[0], mm25.Pts, Gain );
    Replot();
    AdjustBufferAmplitude( &mm50.Buf[0], mm50.Pts, Gain );
    AdjustBufferAmplitude( &mm12.Buf[0], mm12.Pts, Gain );
   }
  if(Plot.Pts==mm12.Pts)
   { AdjustBufferAmplitude( &mm12.Buf[0], mm12.Pts, Gain );
    Replot();
    AdjustBufferAmplitude( &mm50.Buf[0], mm50.Pts, Gain );
    AdjustBufferAmplitude( &mm25.Buf[0], mm25.Pts, Gain );
   }
}
/*************************************************************************
  Move vectors up or down on screen
 ------------------------------------------------------------------------ */
VOID AdjustZero ( BYTE offset )
{
 if(Plot.Pts==mm50.Pts)
  { AdjustBufferZero ( mm50.Buf, mm50.Pts, offset);
   Replot();
   AdjustBufferZero ( mm25.Buf, mm25.Pts, offset);
   AdjustBufferZero ( mm12.Buf, mm12.Pts, offset);
  }
 if(Plot.Pts==mm25.Pts)
  { AdjustBufferZero ( mm25.Buf, mm25.Pts, offset);
   Replot();
   AdjustBufferZero ( mm50.Buf, mm50.Pts, offset);
   AdjustBufferZero ( mm12.Buf, mm12.Pts, offset);
  }
 if(Plot.Pts==mm12.Pts)
  { AdjustBufferZero ( mm12.Buf, mm12.Pts, offset);
   Replot();
   AdjustBufferZero ( mm50.Buf, mm50.Pts, offset);
   AdjustBufferZero ( mm25.Buf, mm25.Pts, offset);
  }
}
/*************************************************************************
  Replot Entire buffer, or the previously plotted epoch
 ------------------------------------------------------------------------ */
LOCAL_C VOID Replot ( VOID )
{ if(!Epoch.bPlotted)
  { Plot_Buffer( );
   if(Epoch.iSelected)InvertSegColor(Epoch.iSelected);
  }
 else
  { ReplotCurrentSegment();
  }
}
/*************************************************************************
```


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```
  Look up the selected command and manage appropriately
 ---------------------------------------------------------------------- */
LOCAL_C VOID TryExecuteCommand(INT keycode)
{ if (modepos == N_MODES) return;
  keycode = uLocateCommand(keycode);
  if (keycode >= 0) { ManageCommand1(keycode); }
}
/*************************************************************************
  Listen to the shell
 ---------------------------------------------------------------------- */
LOCAL_C VOID ProcessSystemCommand(VOID)
{ TEXT buf[P_FNAMESIZE + 2];
  wGetCommand((UBYTE *)&buf[0]);
  if (buf[0] == 'X') p_exit(0);
}
/*************************************************************************
  Diamond is pressed - if changing to background, surrender the
  screen and interrogate the Advisor every 30 seconds or so.
 ---------------------------------------------------------------------- */
LOCAL_C VOID SwitchMode(VOID)
{ modepos++;   modepos %= (N_MODES-1);
  wsSelectList(modepos);
  if (modepos)
    { _cmds = (&cmds1[0]); _mdata = (&mdata1[0]); }
}
```


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```
/*****************************************************************************
                    RStat_XL.H
              R-Stat XL, version 0.2.8
          Copyright Data Critical Inc., 1996.
     United States and international patents pending

          Inlude file for R-Stat XL modules
-----------------------------------------------------------------------------*/
#include <p_std.h>
#include <p_file.h>
#include <p_serial.h>
#include <p_math.h>
#include <epoc.h>
#include <wlib.h>
#include <hwif.h>
#include <stdio.h>
#include <string.h>


// Program activity constants
#define IDLE          00
#define SCROLL_RIGHT   01
#define SCROLL_LEFT    02
#define DEMODULATE     10
#define RECORD         20
#define PLAYBACK       21

// Error codes
#define NO_PAGES    0
#define OPEN_TIMER  1
#define OPEN_PORT   2
#define ADV_HAND    3
#define FILE_SAVE   4
#define FILE_OPEN   5
#define INC_READ    6

// Program control constants
#define  M6PT            12  // offset to monospaced 6pt font
#define  M8PT             3  // offset to monospaced 8pt font
#define  M10PT            0  // offset to monospaced 10pt font

// Processing array size constants
#define  ALAW_SZ         256 // integers
#define  ATAN_SZ        4096 // integers
#define  ECG_BUF_SZ     7168 // bytes
#define  PLOT_BUF_SZ    7168 // bytes

#define  BUF_MARGIN        2

// Graphics constants
#define  INPUT_SAMP_SEC    125
#define  PLOT_SAMP_SEC     200
#define  WVE_SAMP_SEC      200
#define  RST_SAMP_SEC      125
```


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```
#define FSX             480
#define FSY             160
#define X_BORD            1
#define Y_BORD            3
#define DSP_SEC          29

#define NSEG             6
#define N_XDIV          24
#define SZ_XDIV         20
#define N_YDIV           7
#define SZ_YDIV         20
#define N_MINDIV         5
#define N_YSEG           3
#define PIX_SEC_10      50
#define PIX_SEC_25     100
#define PIX_SEC_50     200


// Fonts
#define F6PTY            7
#define F8PTY            9
#define F10PTY          11
// Font control constants
#define INVERT           3
#define INVERT_LEFT_INDENT   5
#define INVERT_CLEAR     0
#define INVERT_SET       1
#define MONOSPACED       2
#define LJustify         G_TEXT_ALIGN_LEFT
#define RJustify         G_TEXT_ALIGN_RIGHT
#define CJustify         G_TEXT_ALIGN_CENTRE

typedef struct PtrStructure
{ INT *pALaw;
  INT **ppATanSeg;
  INT *pCycleAccum;
  INT *pBPFilter;
  INT *pLastSign;
} DMODPARM;

typedef struct
{ BYTE   *Buf;        // 7168 bytes for 35.8 sec of data @ 200 Hz
  INT    Pts;
  INT    Sec;
  INT    Smp_sec;
} DATACTL;

typedef struct
{ INT    nEpoch;
  INT    Last;        // the last epoch with data
  INT    iSelected;   // epoch number selected
  UBYTE  bPlotted;    // status
}EPOCHCTL;
```


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```
typedef struct
{ BYTE *Buf;  INT  Pts; // 3840 bytes, for 15.8 sec of data @ 100 Hz
 INT  mm_sec; INT  iPt_Px;
 BYTE iY_zero; BYTE iY_scale; INT  iMinY;  INT  iMaxY;
 INT  last_x; INT  last_y;
 INT  n_xdiv; INT  sz_xdiv; INT  sz_minxdiv;
 INT  n_ydiv; INT  sz_ydiv; INT  sz_minydiv;
 INT  Lptr;  INT  Rptr;  INT  X_shft;
 INT  L_Sec;  INT  L_Tenths; INT  R_Sec;  INT  R_Tenths;
 P_DTOB d2bformat;
} PLOTCTL;

//------- In ReadRsc.C ---------
VOID LoadTables          ( VOID );

// ------ In About.C ------------
VOID About_RStatXL       ( VOID );

// ------ In DEMOD.ASM = DEMOD.OBJ, masm output
void cdecl demod         ( INT iOutput[],
                   BYTE cInput[],
                   DMODPARM *DeModParam );

// ------ In Common.C ----------
VOID EvaluateArrayPointers   ( VOID );
VOID InitializeStartingValues ( VOID );

// ------ In PPPick.C ----------
VOID PPP_Decimate_Into_Buffers   ( VOID );

// ------ In Sound_IO.C --------
BYTE Record_FM_ECG_1     ( TEXT filename[] );
BYTE Record_FM_ECG_2     ( TEXT filename[] );
BYTE Playback_FM_ECG_1   ( TEXT filename[] );
BYTE Playback_FM_ECG_2   ( TEXT filename[] );

// ------ In WndCtrl.C --------
VOID InsertCaption       ( TEXT *Capt, INT Justify );
VOID SizeRectangles      ( VOID );
VOID CreateMainGC        ( VOID );
VOID ToggleStatusWindow  ( VOID );
VOID InvertSegColor      ( INT index );
VOID SizeSegments        ( VOID );
VOID CreateIndicator     ( VOID );
VOID UpdateIndicator     ( ULONG current, ULONG total );
VOID ClearPlotSpace      ( VOID );

// ------ In Grid_Ctl.C --------
VOID BufferGrid          ( VOID );
VOID EpochGrid           ( VOID );
VOID Dotted_X            ( INT y, INT x_st, INT x_nd,
                   UBYTE draw, UBYTE blank );
VOID Dotted_Y            ( INT x, INT y_st, INT y_nd,
                   UBYTE draw, UBYTE blank );
```


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```
// ------ In G_Scroll.C
UBYTE ScrollLeft        ( VOID );
UBYTE ScrollRight       ( VOID );

// ------ In File_Ctl.C ------
BYTE  EnoughSpace       ( UINT Minimum_K );
UBYTE OpenInputFile     ( TEXT *FileName );
UBYTE OpenBinaryInputFile ( TEXT *FileName );

UBYTE OpenOutputFile    ( TEXT FileName[] );
VOID  CloseInputFile    ( VOID );
UBYTE ReadWVEHeader     ( SndFile *sFileHead );
INT   ReadWVESegment    ( UBYTE FileBuf[], UINT Size, LONG OffSet );
VOID  GetCopyOfFileName ( TEXT *filename, TEXT *filespec );

// ------ In RST_File.C ------
BYTE  Process_RST_File      ( TEXT FileName[] );

// ------ In WVE_File.C ------
BYTE  Process_WVE_File    (TEXT FileName[] );

// ------ In Plot_Ctl.C ------
VOID  Plot_Buffer           ( VOID );
BYTE  Plot_Epoch            ( INT epoch );
VOID  ReplotCurrentSegment  ( VOID );
VOID  Clip_and_Plot         ( INT  ix, INT iy, INT *Lx, INT *Ly,
                      INT iMax, INT iMin );
VOID  Calculate_Plot_MinMax   ( VOID );

//------- In Dlg_Ctl.C ---------
BYTE  GetExistingFileName  ( TEXT *FileSpec );
BYTE  GetNewFileName       ( TEXT *FileSpec );
BYTE  GetFilterName        ( TEXT *FilterSpec );

// ------ In Err_Hndl.C --------
VOID  ReportError         ( INT func, INT error );

//------- In Notify.C ---------
VOID  Notify              ( TEXT *Msg );
VOID  Notify_2            ( BYTE *ack, TEXT *Msg );
VOID  About_FM_ECG        ( VOID );

//------- In Str_fn.C ---------
VOID  lShfStr             ( TEXT *str, INT n );
VOID  rShfStr             ( TEXT *str, INT  n);
INT   scat_n              ( TEXT *dst, TEXT *src, INT n );
INT   ch_index            ( UBYTE Str[], UBYTE ch );

//------ In Misc.C ------------
VOID  AdjustBufferAmplitude ( BYTE Buffer[], INT Ln, BYTE gain );
VOID  AdjustBufferZero    ( BYTE Buffer[], INT Ln, BYTE gain );
BYTE  Convert_RemECG_To_RST ( BYTE Output[], INT InOut,
                    BYTE Input[], INT InIn  );
```


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```
VOID  OpenTimer          ( INT interval );
VOID  ResetTimer         ( INT interval );
VOID  CancelTimer        ( VOID );
VOID  CloseTimer         ( VOID );
VOID  CalcSeconds        ( VOID );
VOID  UpdateTenthSecs    ( INT amount );
VOID  UpdateEpochCaption ( VOID );
VOID  PostRescaling      ( VOID );
VOID  IShfInt            ( INT *data, INT *len, INT n );
```


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```
/*****************************************************************
                    WVE_File.C
            R-Stat XL, version 0.2.8
        Copyright Data Critical Inc., 1996.
    United States and international patents pending

    Procedure to decode and demodulate the FM ECG signal, recieved
    as sound data.

    Process_WVE_File() requires 28.0 seconds to execute, up to the call
    to PPP_Decimate_Into_Buffers(). Time is distributed as follows:

    Loading the ALAW decoding and ArcTangent tables..... 0.6
    Reading the file 3,200+ times, @ 80 bytes each..... 10.2
    Demodulating the 80 byte reads, and decimating to 200 Hz.... 14.5
    Applying a plotting zero correction and gain..... 0.4
    Filtering to remove spikes and attenuating the baseline..... 0.4
    Plotting the data as it is read and processed..... 1.9

    The call to Decimate into the 100 Hz and 50 Hz buffers
    requires an additional 2 seconds.
    ----------------------------------------------------------------*/
#include "RStat_XL.H"
extern INT    ACTION;
extern TEXT   LocalDir[];
extern TEXT   LocalFileName[];
extern TEXT   InputFile[];
extern VOID   *sFcb;
extern INT    ret;
extern TEXT   usermsg[];

extern DMODPARM DeModParam;
extern DATACTL  mm50;
extern DATACTL  mm25;
extern DATACTL  mm12;
extern INT    *DecIn;
extern INT    *DecOut;
    INT    Input_Pts = 0;
    INT    CalFound  = 0;

extern PLOTCTL Plot;
extern P_RECT  PltRcl;

extern INT    *iAlaw;
extern INT    *iAtan;
extern INT    *pAtanSeg[];

    UBYTE  *bFileBuf;
extern SndFile sFileHead;
extern SndFile *psFileHead;


LOCAL_C INT  CalPulse          ( VOID );
LOCAL_C VOID Initialize_Incoming_Plot ( VOID );
```


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```
LOCAL_C VOID Plot_Incoming        ( INT Buffer[], INT Pts );

/*****************************************************************
 ----------------------------------------------------------------*/
BYTE Process_WVE_File (TEXT FileName[])
{ INT  i,k, readsz, bytes, iGain, iZero;

 INT  iDemodData[2];
 BYTE cDataInAlaw[82];
 INT  iBandPassFilter[2] = {0, 0};
 INT  iLastSign = {1};
 INT  iCycleAccum[2] = {0, 2560};

 /***     BEGIN    ***/
 readsz =  80;
 iGain  =  6;
 iZero  = 5143;  // mean of 384 pts from ts022896.wve is 5143.679
 CalFound = 0;

 /**** Make sure pointers are correct    ****/
 EvaluateArrayPointers();
 InitializeStartingValues();

 /**** Get ALAW decoding and Arctangent  ****/
 /**** tables from imbedded resource file.****/
 LoadTables( );

 /**** Initialize demodulation parameter structure  ****/
 DeModParam. pALaw      = &iAlaw[0];
 DeModParam. ppATanSeg  = pAtanSeg;
 DeModParam. pCycleAccum  = &iCycleAccum[0];
 DeModParam. pBPFilter    = &iBandPassFilter[0];
 DeModParam. pLastSign    = &iLastSign;
 k=0; for(i=0;i<4096;i+=64) {pAtanSeg[k]=&iAtan[i];k++;}

 /****  Open the WVE file as a binary stream  ***/
 if(!OpenBinaryInputFile(FileName))return FALSE;

 /****  Read header information ******************/
 ReadWVEHeader(psFileHead);
 mm50.Sec = (INT)(sFileHead.Samples/8000);
 mm50.Pts = mm50.Sec * WVE_SAMP_SEC;
 mm50.Smp_sec = WVE_SAMP_SEC;

 /**** Post filename and seconds of ECG **********/
 GetCopyOfFileName(LocalFileName,FileName);
 p_atos(usermsg,"Demodulating %s: %d seconds, 200 ms/dv",
          LocalFileName, mm50.Sec );
 InsertCaption(usermsg,CJustify),

 /****  Read And Demodulate .WVE Data *********/
 Initialize_Incoming_Plot ();
 p_bfil(Decln, 14336, 0x00);  Input_Pts = 0;
 bytes = p_read( sFcb, &cDataInAlaw[0], (UINT)readsz );
```


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```
do
 { /*** Read readsz btes from WVE file ****/
  bytes = p_read( sFeb, &cDataInAlaw[0], (UINT)readsz );
  if(bytes<readsz) break;

  /*** Decode, Filter, & Demodulate buffer ****/
  demod( &iDemodData[0], &cDataInAlaw[0], &DeModParam );
  DecIn[Input_Pts++] = (BYTE)-((iDemodData[0]-iZero)/iGain);
  DecIn[Input_Pts++] = (BYTE)-((iDemodData[1]-iZero)/iGain);

  /*** while less than 3 seconds of data, check for cal pulse ***/
  if( (Input_Pts<3000) && !CalFound ) CalFound  = CalPulse ();

  /**** Plot buffer here, step 4 (50 Hz) ****/
  if((Input_Pts) > (Plot.Rptr + Plot.iPt_Px))
   { Plot_Incoming ( DecIn, (Input_Pts-1) ); }

 }while (bytes);
CloseInputFile();
Input_Pts --;            // Correct for last increment

if(CalFound)
 { DecIn    += CalFound;  // Increment pointer to Cal pulse
  Input_Pts -= CalFound;  // Decrement count for Cal pulse
 }
else
 { Notify("Advisory - Leading calibration pulse not recognized.");
 }

mm50.Pts = Input_Pts;
mm50.Sec = mm50.Pts/WVE_SAMP_SEC;
mm50.Pts = mm50.Sec*WVE_SAMP_SEC;  // This reconciles any truncation error

/*** Decimate into 100Hz and 50Hz buffers & collapse 200 Hz buffer **/
PPP_Decimate_Into_Buffers();  p_sound((UINT)1,(UINT)320);

return TRUE;
}
/*************************************************************************
To find leading edge of Cal Pulse.
Cal pulse is about 30 data points wide, and - 40 tall.
Rise "time" is about 3 data points.
-------------------------------------------------------------------------*/
LOCAL_C INT CalPulse ( VOID )
{ INT slope=0; INT j; INT i = Input_Pts -1;
 // back index up 23
 i-=23; if (i<0) return 0;
 for(j=0;j<10;j++) { slope += ( DecIn[i+1] - DecIn[i] );  i++; }
 if( (slope/10) !=0 ) return 0;
 slope=0;
 for(j=0;j<3; j++) { slope += ( DecIn[i+1] - DecIn[i] );  i++; }
 if( (slope/3) > (-10) ) return 0;
 slope=0;
 for(j=0;j<10;j++) { slope += ( DecIn[i+1] - DecIn[i] );  i++; }
```


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```
 if( (slope/10) !=0 ) return 0;
 return ( i-20 );
}
/*****************************************************************
 Plots a single datum from the incoming decoded and demodulated data
 The screen is at 12.5 mm/sec, and the plot steps down on Y when the
 edge of the screen is reaced to plot the entire data set as 3 rows.
 ----------------------------------------------------------------*/
LOCAL_C VOID Plot_Incoming ( INT Buffer[], INT Pts )
{
 INT iY = Buffer[Pts]/Plot.iY_scale + Plot.iY_zero;

 if(Plot.iY_zero>PltRcl.br.y)return;
 if(((Plot.last_x+1)>PltRcl.br.x)||((Plot.last_x+1)<PltRcl.tl.x)) return;

 // Clip on Y if needed
 if(iY <= Plot.iMinY)  { iY=Plot.iMinY;}
 else                  { if(iY >= Plot.iMaxY) iY=Plot.iMaxY; };

 // Plot it
 gDrawLine(Plot.last_x, Plot.last_y, Plot.last_x+1, iY );

 Plot.last_x++;
 Plot.last_y = iY;
 Plot.Rptr = Pts;

 if(!(Plot.last_x%(FSX-1))) // step down one row on screen
   { //BYTE Dy = (BYTE)((float)(PltRcl.br.y - PltRcl.tl.y)/4.5);
     //Plot.iY_zero = Plot.iY_zero + Dy;
     Plot.iY_zero = Plot.iY_zero + (BYTE)(SZ_YDIV*2);
     Plot.last_x  = PltRcl.tl.x;
     Plot.last_y  = (int)Plot.iY_zero;
     Calculate_Plot_MinMax();
   }
}

/*****************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID Initialize_Incoming_Plot ( VOID )
{ Plot.iY_scale  = 3;
 Plot.iY_zero   = (BYTE)(PltRcl.tl.y + SZ_YDIV);
 Plot.last_x    = PltRcl.tl.x;  Plot.last_y = (int)Plot.iY_zero;
 Plot.iPt_Px    = WVE_SAMP_SEC/PIX_SEC_10;
 Plot.Rptr      = 0;
 Calculate_Plot_MinMax();
}
```

```
/*****************************************************************
                Wnd_Ctrl.C
          R-Stat XL, version 0.2.8
       Copyright Data Critical Inc., 1996.
   United States and international patents pending

  The Entire Screen is MainRcl.
  The Application Screen, AppRcl, is the MainRcl, less the border.
  The Plotting area is PltRcl, which is AppRcl, less axes and Caption.
  X and Y values are in absolute screen coordinates
  ---------------------------------------------------------------*/
#include "RStat_XL.H"
/* in EcgSound.H
#define FSX    480
#define FSY    160
#define F6PTY    7
#define F8PTY    9
#define F10PTY   11
*/
// In Common.C
extern TEXT      usermsg[];
extern UINT      hWndMain;       /* ID of main window */
extern P_RECT    MainRcl;
extern P_RECT    AppRcl;
extern P_RECT    CptRcl;
extern P_RECT    IndRcl;
extern P_RECT    PltRcl;
extern P_RECT    PltSpc;         // in internal coordinates
extern P_RECT    ScrollRcl;
extern P_RECT    SegRcl[];

/* Now defines
extern INT       X_Bord_Off;
extern INT       Y_Bord_Off;
extern INT       SZ_Xdiv;
extern INT       N_Xdiv;
extern INT       N_Ydiv;
extern INT       SZ_Ydiv;
extern INT       n_Yseg;
*/
extern INT       n_Xseg;
extern INT       n_Seg;

    G_GC      Mgc;
extern INT       nModes;
    INT       CurrentStatusWindowExtent = W_STATUS_WINDOW_BIG;
    P_EXTENT  StatusExtent;
    G_FONT_INFO FontInfo;

FLOAT  findicator_rng_x  = 0.0;
P_RECT FillRcl;

LOCAL_C VOID SizeMainWindow      ( VOID );
LOCAL_C VOID SizeAppRectangle    ( VOID );
```


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```
LOCAL_C VOID SizeCaptionRectangle   ( VOID );
LOCAL_C VOID SizeIndicatorRectangle ( VOID );
LOCAL_C VOID SizePlotSpace          ( VOID );
LOCAL_C VOID ClearMainRectangle     ( VOID );
LOCAL_C VOID ClearAppRectangle      ( VOID );
LOCAL_C VOID ClearCaption           ( VOID );
LOCAL_C VOID ClearIndicator         ( VOID );
LOCAL_C VOID ShowRectangles         ( VOID );

/*****************************************************************
 Sizes all windows relative to status window and font size
 ----------------------------------------------------------------*/
VOID SizeRectangles( VOID )
{ SizeMainWindow();
 SizeAppRectangle();
 SizeCaptionRectangle();
 SizeIndicatorRectangle();
 SizePlotSpace();
 // ShowRectangles();
}

/*****************************************************************
          Insert the plot caption
 ----------------------------------------------------------------*/
VOID InsertCaption( TEXT *Capt, INT Justify )
{ ClearCaption();
 gPrintBoxText(&CptRcl, FontInfo.height-1, Justify,
          FontInfo.ascent, Capt, p_slen(Capt));
 return;
}

/*****************************************************************
   Create and box the indicator window
 ----------------------------------------------------------------*/
VOID CreateIndicator ( VOID )
{ ClearIndicator();
 gDrawBox(&IndRcl);
 fIndicator_rng_x =  (float)(IndRcl.br.x - IndRcl.tl.x);
 FillRcl.tl.y     =  IndRcl.tl.y;
 FillRcl.br.y     =  IndRcl.br.y;
 FillRcl.tl.x     =  IndRcl.tl.x;
}
/*****************************************************************
   Update the indicator by adding to previous x and drawing
   a vertical line at each intervening pixel column up
   through the current x.
 ----------------------------------------------------------------*/
VOID UpdateIndicator ( ULONG current, ULONG total )
{ // find proportion current is of total
 FLOAT pX = (float)((float)current/(float)total);
 // multiply by the width of the indicator & add to left edge
 FillRcl.br.x = IndRcl.tl.x + (INT)(fIndicator_rng_x * pX);
 // If current value is greater than previous, fill up the space
 if( FillRcl.br.x > FillRcl.tl.x )
```


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```
    { gClrRect(&FillRcl, G_TRMODE_SET);
      FillRcl.tl.x = FillRcl.br.x;
    }
}
/*****************************************************************
 Return the size of the Application window, equal to the
 Main window less the border.
   mode 1 = tl.x 7, tl.y 9, br.x 409, br.y 153
   mode 2 = tl.x 7, tl.y 9, br.x 441, br.y 153
   mode 3 = tl.x 7, tl.y 9, br.x 473, br.y 153
   p_atos( usermsg, "tl.x %d, tl.y %d, br.x %d, br.y %d",
         AppRcl.tl.x, AppRcl.tl.y, AppRcl.br.x, AppRcl.br.y);
   Notify(usermsg);
-----------------------------------------------------------------*/
LOCAL_C VOID SizeAppRectangle( VOID )
{ AppRcl.tl.x  =  X_BORD/2;
  AppRcl.tl.y  =  Y_BORD;
  AppRcl.br.x  =  MainRcl.br.x - X_BORD-1;
  AppRcl.br.y  =  MainRcl.br.y - Y_BORD;

}
/*****************************************************************
 Return the size of the Caption Rectangle
 Sized and located at TOP of App window
  6 pt = tl.x 8, tl.y 10, br.x 406, br.y 18
  8 pt = tl.x 8, tl.y 10, br.x 408, br.y 20
 -----------------------------------------------------------------*/
LOCAL_C VOID SizeCaptionRectangle( VOID )
{ CptRcl.tl.x  =  AppRcl.tl.x +1;
  CptRcl.tl.y  =  AppRcl.tl.y +1;
  CptRcl.br.x  =  AppRcl.br.x -1;
  CptRcl.br.y  =  CptRcl.tl.y + FontInfo.height;// -5;
}
/*****************************************************************
 Return the size of the Progress Indicator Rectangle,
 nested inside the caption window
 -----------------------------------------------------------------*/
LOCAL_C VOID SizeIndicatorRectangle( VOID )
{                    // char width * (filename size+4)
  IndRcl.tl.x  =  CptRcl.tl.x  + (FontInfo.max_width * (12+3));
  IndRcl.tl.y  =  CptRcl.tl.y  + 1;
  IndRcl.br.x  =  CptRcl.br.x  - 4;
  IndRcl.br.y  =  CptRcl.br.y  - 1;
}

/*****************************************************************
 Return the size of the Plot Space, Which is to be the
 Application window, less the caption at top
 NOTE!! To gain a little vertical space, we are encroaching on
 the caption window. Hence, if the caption is changed, the
 plot must be redone, though the reverse is not true.
 mode 1, 6pt tl.x 8, tl.y 28, br.x 408, br.y 152
 mode 1, 8pt tl.x 8, tl.y 30, br.x 408, br.y 152
 mode 2, 6pt tl.x 8, tl.y 28, br.x 440, br.y 152
```


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```
mode 2, 8pt tl.x 8, tl.y 30, br.x 440, br.y 152
mode 3, 6pt tl.x 8, tl.y 28, br.x 472, br.y 152
mode 3, 8pt tl.x 8, tl.y 30, br.x 472, br.y 152
-------------------------------------------------------------*/
LOCAL_C VOID SizePlotSpace( VOID )
{ INT margin, sz_X, sz_Y;

 // X dimension
 sz_X = SZ_XDIV * N_XDIV; // + 1;
 margin = (AppRcl.br.x - AppRcl.tl.x) -  sz_X ;
 if(margin<0)margin=0;

 PltRcl.tl.x  =  AppRcl.tl.x  + (margin/2);
 PltRcl.br.x  =  PltRcl.tl.x  + sz_X;

 // Y dimension
 sz_Y = SZ_YDIV * N_YDIV;
 margin = (AppRcl.br.y - (AppRcl.tl.y + CptRcl.br.y)) -  sz_Y;
 PltRcl.tl.y  =  AppRcl.tl.y + CptRcl.br.y + (margin/2);
 PltRcl.br.y  =  PltRcl.tl.y  + sz_Y;

 PltSpc.tl.x  =  0;  PltSpc.tl.y  =  0;
 PltSpc.br.x  =  PltRcl.br.x-PltRcl.tl.x;
 PltSpc.br.y  =  PltRcl.br.y-PltRcl.tl.y;

 /*
 p_atos(usermsg," App_X %u,  PlotSpace Sized: %d x %d",
    AppRcl.br.x,
    PltRcl.br.x - PltRcl.tl.x,  PltRcl.br.y - PltRcl.tl.y );
 Notify(usermsg);
 */

 // define the NSEG segments of the plot space
 SizeSegments ( );
}
/*************************************************************
        Define the plot segments
   These rectangles allow the use of inversion for highlighting
 one of the six EKG epochs displayed as 2 across and 3 down.
    Segment 1 == SegRcl[0]     Segment 2 == SegRcl[1]
    Segment 3 == SegRcl[2]     Segment 2 == SegRcl[3]
    Segment 5 == SegRcl[4]     Segment 2 == SegRcl[5]

 -------------------------------------------------------------*/
VOID SizeSegments( VOID )
{ INT i,rx;
  INT siz_x =  PltSpc.br.x / n_Xseg;
  INT siz_y =  SZ_YDIV * (N_YSEG-1);
  INT ry    =  0;
  for(i=0; i<n_Seg; i++)
    { rx = i%n_Xseg;
      SegRcl[i].tl.x = PltRcl.tl.x +   (siz_x*rx) +1 ;
      SegRcl[i].br.x = SegRcl[i].tl.x +  siz_x    -1 ;
      if(!i)
```

```
    { SegRcl[i].tl.y = PltRcl.tl.y +1; }
   else
    { if(i%n_Xseg)
       { SegRcl[i].tl.y = SegRcl[i-1].tl.y; }
      else
       { SegRcl[i].tl.y = SegRcl[i-1].br.y; }
    }
   SegRcl[i].br.y = SegRcl[i].tl.y + siz_y;
   if(rx) { ry++; if(ry>(N_YSEG-1))ry=0;};
  }
}
/*****************************************************************
        Invert colors in a rectangle
-----------------------------------------------------------------*/
VOID InvertSegColor_I( INT index )
{ gClrRect( &SegRcl[index - 1], G_TRMODE_INV );
}
/*****************************************************************
        Frames a rectangle
-----------------------------------------------------------------*/
VOID InvertSegColor( INT index ) // SelectSegment()
{ P_RECT TmpRcl;
 p_bcpy(&TmpRcl,&SegRcl[index - 1], sizeof(P_RECT));

 if(!(index%n_Xseg)) TmpRcl.br.x --;
 // frame
 gClrRect( &TmpRcl, G_TRMODE_INV );
 // content
 TmpRcl.tl.x += 4; TmpRcl.br.x -= 4;
 TmpRcl.tl.y += 3; TmpRcl.br.y -= 3;
 gClrRect( &TmpRcl, G_TRMODE_INV );
}

/*****************************************************************
        Clear the Main window
-----------------------------------------------------------------*/
LOCAL_C VOID ClearMainRectangle(VOID)
{ gClrRect( &MainRcl, G_TRMODE_CLR);
}
/*****************************************************************
        Clear Application window
-----------------------------------------------------------------*/
LOCAL_C VOID ClearAppRectangle( VOID )
{ gClrRect( &AppRcl, G_TRMODE_CLR);
}
/*****************************************************************
        Clear Caption window
-----------------------------------------------------------------*/
LOCAL_C VOID ClearCaption( VOID )
{ gClrRect( &CptRcl, G_TRMODE_CLR);
}
/*****************************************************************
        Clear Indicator window
-----------------------------------------------------------------*/
```


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```
LOCAL _C VOID ClearIndicator( VOID )
{ gClrRect( &IndRcl, G_TRMODE_CLR);
}
/*****************************************************************
        Clear Plot window
 ----------------------------------------------------------------*/
VOID ClearPlotSpace( VOID )
{ gClrRect( &PltRcl, G_TRMODE_CLR);
}
/*****************************************************************
   Size the main window, border it and display
   Status Window according to current size
   W_WIN_BACK_CLR
 ----------------------------------------------------------------*/
VOID SizeMainWindow( VOID )
{ W_WINDATA MainWinData;
 wInquireStatusWindow(CurrentStatusWindowExtent, &StatusExtent);
 MainWinData.extent.tl.x  = 0;
 MainWinData.extent.tl.y  = 0;
 MainWinData.extent.width  = FSX - StatusExtent.width;
 MainWinData.extent.height = FSY;
 wSetWindow(hWndMain, W_WIN_EXTENT, &MainWinData);
 MainRcl.tl.x = 0;
 MainRcl.tl.y = 0;
 MainRcl.br.x = FSX - StatusExtent.width;
 MainRcl.br.y = FSY;
 ClearMainRectangle();
 wStatusWindow(CurrentStatusWindowExtent);
 gBorder2(W_BORDER_TYPE_0,
W_BORD_CORNER_I|W_BORD_SHADOW_ON|W_BORD_SHADOW_D);
}
/*****************************************************************
 Work out the next version of the Status Window
 ----------------------------------------------------------------*/
VOID ToggleStatusWindow( VOID )
{ CurrentStatusWindowExtent++;
 CurrentStatusWindowExtent %= nModes;
}
/*****************************************************************
 Create a graphics context
 WS_FONT_BASE+12 is a tiny   6 point monospace, x = 6, y = 6;
 WS_FONT_BASE+ 3 is a smaller 8 point monospace, x = 8, y = 8;
 WS_FONT_BASE+ 0 is default, 10 point monospace, x = 6, y = 8;
 ----------------------------------------------------------------*/
VOID CreateMainGC(VOID)
{ UINT fieldset; INT hgc;
  Mgc.gmode   = G_TRMODE_SET;        // default
  Mgc.textmode = G_TRMODE_REPL;      // replacement!
  Mgc.style   = G_STY_NORMAL;        // default
  Mgc.flags   = G_GC_FLAG_BOTH_PLANES; // default??
  Mgc.font    = WS_FONT_BASE+M8PT;   // M8PT = +3, M10PT = +0
  fieldset    = G_GC_MASK_FONT;
  hgc = gCreateGC(hWndMain,fieldset,&Mgc);
  gFontInfo(Mgc.font,Mgc.style,&FontInfo);
```


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```
 if (hgc < 0)  p_exit(hgc);
}

/*****************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID ShowRectangles (VOID)
 {
  // FONT
  p_atos( usermsg, "Font: Index %d, X %d Y %d",
        Mgc.font, FontInfo.max_width, FontInfo.height);
  Notify(usermsg);
  // APPLICATION
  p_atos( usermsg, "Appl: tl.x %d, tl.y %d, br.x %d, br.y %d",
        AppRcl.tl.x, AppRcl.tl.y, AppRcl.br.x, AppRcl.br.y);
  Notify(usermsg);
  // CAPTION
  p_atos( usermsg, "Capt: tl.x %d, tl.y %d, br.x %d, br.y %d",
        CptRcl.tl.x, CptRcl.tl.y, CptRcl.br.x, CptRcl.br.y);
  Notify(usermsg);
  // PLOT
  p_atos( usermsg, "Plot: tl.x %d, tl.y %d, br.x %d, br.y %d",
        PltRcl.tl.x, PltRcl.tl.y, PltRcl.br.x, PltRcl.br.y);
  Notify(usermsg);
 }
```


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```
/*****************************************************************
                Str_Fn.C

        R-Stat XL. version 0.2.8
     Copyright Data Critical Inc., 1996.
  United States and international patents pending

   String manipulation functions and utilities
-----------------------------------------------------------------*/
#include "RStat_XL.H"

/*****************************************************************
 Left-shifts the string str by n characters, and pads str to
 the end (null) with nulls.
 -----------------------------------------------------------------*/
VOID lShfStr( TEXT *str, INT n)
{ int i,j;
 if(!str[0])return;
 i=0;
 for(j=n;str[j];j++){ str[i]=str[j]; i++; };
 for(  ;str[i];i++)  str[i]=0x00;
}
/*****************************************************************
 Right-shifts the string by n characters, padding with spaces
 This is can be very dangerous if the caller is not attending
 to the length of the string.
 -----------------------------------------------------------------*/
VOID rShfStr( TEXT *str, INT  n)
{ int i,j;
 if(!str[0])return;
 i=p_slen(str);    // i points to trailing null
 j=i+n;            // j points to target offset
 for(  ;i>0;i--) { str[j]=str[i]; j--; };
 str[j]=str[i];
 do { j--; str[j]=0x20; } while (j);  // pad on left with spaces
}
/*****************************************************************
 Concatenates n bytes from the source string onto the destination
 string, and enforces a null termination, returning the index to the
 trailing null.
 -----------------------------------------------------------------*/
INT scat_n ( TEXT *dst, TEXT *src, INT n )
{ INT j = 0; INT i = p_slen( dst );
  for(j=0;j<n;j++) dst[i++]=src[j]; dst[i]=0x00; return i;
}
/*****************************************************************
  Returns the index to the first instance of the character ch,
  or a minus one if ch is not found
 -----------------------------------------------------------------*/
INT ch_index ( UBYTE Str[], UBYTE ch )
{ INT i = 0;
  if(!Str[0]) return -1;
  while(Str[i]) { if(Str[i]==ch) break; else i++; };
  if(Str[i]==ch) return i;
```


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```
else        return -1;
}
```


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```
/*****************************************************************
                Sound_IO.C
          R-Stat XL, version 0.2.8
       Copyright Data Critical Inc., 1996.
  United States and international patents pending

 Procedures to record and play back the FM modulated ECG data in
 the form of PSION WVE sound files
 *****************************************************************/
#include <p_sys.h>
#include "RStat_XL.H"

#define TRUE      1
#define FALSE     0

#define PENDING    E_FILE_PENDING

extern TEXT   LocalFileName[];
extern TEXT   usermsg[];
extern INT    ret;

LOCAL_D VOID  *pTim;
LOCAL_D WORD  TmStat;
     VOID  *pCom;        // extern in Err_Hndl.C for showserial
LOCAL_D WORD  WrStat;
LOCAL_D WORD  RdStat;

LOCAL_C BYTE  SetUpSoundIO    ( TEXT filename[], TEXT *Type );

LOCAL_C VOID  QueueTimer      ( ULONG timeout );
LOCAL_C VOID  CancelTimer     ( VOID );
LOCAL_C VOID  CancelSerialWrite ( VOID );
LOCAL_C VOID  CancelSerialRead  ( VOID );

/*****************************************************************
 ---------------------------------------------------------------- */
 BYTE Record_FM_ECG_1 ( TEXT filename[] )
{ INT i;
  if(!SetUpSoundIO ( filename, "Recording" )) return FALSE;
  ret = p_recordsoundw( filename, 137);
  if(!ret)
    { for(i=0;i<2;i++)
        { p_sound((UINT)2,(UINT)320);p_sound((UINT)1,(UINT)100);}
      ret = 1;
    }
  else
    { if(ret==-37)
        { p_atos(usermsg,"Insufficient free space for recording    ",\
                 "   Delete one or more *.WVE files");}
      else
        { p_atos(usermsg,"Error %d in p_recordsoundw()",ret);}
      ret = 0;
      for(i=0;i<4;i++)
        { p_sound((UINT)2,(UINT)320);p_sound((UINT)1,(UINT)100);}
```


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```
  }
 if(!ret) Notify(usermsg);
 return ((BYTE)ret);
}
/*************************************************************************
 ------------------------------------------------------------------- */
BYTE Record_FM_ECG_2 ( TEXT filename[] )
{ WORD RecStat =0;
 WORD elapsed_time=0;
 WORD total_time = 36;  // seconds


 if(!SetUpSoundIO ( filename, "Recording" )) return FALSE;
 // get current time
 // start a timer
 // start recording
 p_recordsounda(filename, 137, &RecStat);

 while ( RecStat == -46 )
  { // check the time
    UpdateIndicator( (ULONG) elapsed_time, (ULONG)total_time );
    // check the keyboard

  };
 p_sound((UINT)4,(UINT)220);
 Notify("Recording Complete, Press Esc to Continue");
 // RestoreContent of Text Window

 if( RecStat == 0 ) return TRUE;
 else               return FALSE;
}
/*************************************************************************
  Should complete with ret = 0, unless file invalid type or not found
 ------------------------------------------------------------------- */
BYTE Playback_FM_ECG_1 ( TEXT filename[] )
{ INT i;
 if(!SetUpSoundIO ( filename, "Playback" )) return FALSE;

 ret = p_playsoundw( filename, (UINT)0, (UINT)0 );

 for(i=0;i<2;i++)
   { p_sound((UINT)2,(UINT)320);p_sound((UINT)1,(UINT)100);}

 // Restore Text Window
 if( ret == 0 ) return TRUE;
 else           return FALSE;

}
/*************************************************************************
 ------------------------------------------------------------------- */
BYTE Playback_FM_ECG_2 ( TEXT filename[] )
{ WORD RecStat = 0;
  WORD elapsed_time =0;
  WORD total_time = 36;
```


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```
if(!SetUpSoundIO ( filename, "Playback" )) return FALSE;

// get current time
// start a timer
// start recording
p_playsounda( filename, (UINT)0, (UINT)0, &RecStat);

while ( RecStat == -46 )
  { // check the time
    UpdateIndicator( (ULONG)elapsed_time, (ULONG)total_time );
/*
    // check the keyboard
    for(;;)
      { wGetEventWait( &event );

        if( event.type==WM_KEY )
          { p_atos( &bb[0],"Key code: %d", event.p.key.keycode );
            gPrintBoxText ( &box,
                        50,
                        G_TEXT_ALIGN_CENTRE,
                        0,
                        &bb[0],
                        p_slen(&bb[0]));
            wInvalidateWin ( wid );
            if( event.p.key.keycode==W_KEY_RETURN ) break;

          }
      };
*/
  };
 p_sound((UINT)4,(UINT)220);
 // Restore Text Window

 if( RecStat == 0 ) return TRUE;
 else           return FALSE;

}
/*****************************************************************************
---------------------------------------------------------------- */
LOCAL_C BYTE SetUpSoundIO ( TEXT filename[], TEXT *Type )
{ BYTE Ack = TRUE;

 GetCopyOfFileName( LocalFileName, filename);
 p_atos(usermsg,"%s: ", LocalFileName);
 // Capture content of text window & stash it
 InsertCaption(usermsg,LJustify);
 CreateIndicator();
 p_atos(usermsg,"Enter to Begin %s      Else Esc to Cancel",Type);
 Notify_2(&Ack, usermsg);
 if(Ack) return TRUE;
 else   return FALSE;

}
```


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```
/*****************************************************************
 *****************************************************************/
LOCAL_C VOID QueueTimer(ULONG timeout)
{ p_ioc(pTim, P_FREAD, &TmStat, &timeout);
}
/*****************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID CancelSerialWrite(VOID)
{ p_iow(pCom, P_FCANCEL);
 p_waitstat(&WrStat);
}
/*****************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID CancelSerialRead(VOID)
{ p_iow(pCom, P_FCANCEL);
 p_waitstat(&RdStat);
}
/*****************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID CancelTimer(VOID)
{ p_iow(pTim, P_FCANCEL);
 p_waitstat(&TmStat);
}
```


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What is claimed is:

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1. A hand-held computer device for monitoring a patient's ECG signal in the form of a frequency modulated audio signal, comprising:

a digital computer having integral microphone, analog to digital converter, speaker, display, digital to analog converter and CPU/memory;

software controlling said digital computer to digitize and demodulate said frequency modulated audio ECG signal; and

means indicating said digitized audio ECG signal on said display.

2. A hand-held computer device as set forth in claim 1 wherein said software controlling said digital computer further comprises:

means to convert said frequency modulated audio ECG signal to a digital frequency modulated ECG signal;

means to demodulate said digital frequency modulated ECG signal to produce a digital ECG signal; and

means to display said digital ECG signal.

3. A hand-held computer device as set forth in claim 1 which further comprises:

means to demodulate said frequency modulated audio ECG signal;

means to digitize said audio ECG signal; and

means to display said digital ECG signal.

4. A hand-held computer device for patient monitoring, comprising:

means for receiving a frequency modulated audio signal indicating a selected, continuously variable biomedical parameter of a patient's physical condition;

analog to digital converter means changing the frequency modulated audio signal to a digital signal;

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means for band-pass filtering said de-modulated digital signal to produce a filtered digital signal having a low frequency pass-band;

a digital polyphase demodulator receiving said digital signal for transformation to a de-modulated digital signal; and

means for displaying the filtered digital signal for a selected time interval.

5. A hand-held computer device as set forth in claim 4 which further includes:

means receiving said filtered digital signal to file in storage.

6. A hand-held computer device as set forth in claim 5 which further includes:

means conducting selected digital signal from said storage for direct print-out.

7. A hand-held computer device as set forth in claim 5 which further includes:

means conducting selected digital signal from said storage via a telephone facsimile system.

8. A hand-held computer device as set forth in claim 4 which further includes:

file means receiving said digital signals from said analog to digital converter means for storage of selected digital signals;

digital-to-analog converter means receiving stored digital signals from the file means to produce a selected time analog signal; and

speaker means for annunciating said time analog signal for pickup and relay via a telephone connection to an auxiliary hand-held computer device.

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9. A hand-held computer device as set forth in claim 4 wherein said means for receiving comprises:

a receptacle receiving electrical signal input of said frequency modulated audio signal.

10. A hand-held computer device as set forth in claim 4 wherein said means for receiving comprises:

a microphone receiving said frequency modulated audio signal.

11. A personal cardiac monitoring system, comprising:

a hand-held computer having integral microphone, audio analog to digital converter, digital to analog converter, speaker, display screen, and central processing unit with associated memory, and further comprising:

means detecting and audibly reproducing a patient's ECG segment for a predetermined time interval as frequency modulated audio for input to said computer microphone; and

software controlling analog to digital signal conversion of said frequency modulated audio input, and controlling the demodulation of the digital signals for output to a display screen.

12. A personal cardiac monitoring system as set forth in claim 11 which further includes:

a low frequency band-pass filter receiving said converted digital signal and outputting to said demodulating stage.

13. A personal cardiac monitoring system as set forth in claim 11 which further includes:

means receiving said low frequency band-pass filter output for audible output from said hand-held computer speaker; and

an associated telephone for pick-up of said audible

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output to provide a relay extension.

14. A hand-held computer device for patient monitoring, comprising:

means for receiving a frequency modulated audio signal indicating a selected biomedical parameter of a patient's physical condition;

means for demodulating said audio signal to produce a time analog signal;

analog to digital converter means changing said time analog signal to a digital signal; and

output means for storage and display of the digitized signal indicating said physical condition.

15. A hand-held computer device as set forth in claim 14 which further includes:

a first band-pass filter applied at the frequency modulation center frequency to the received frequency modulated audio signal.

16. A hand-held computer device as set forth in claim 14 which further includes:

a low frequency band-pass filter applied to said converted digital signal.

17. A hand-held computer device as set forth in claim 15 which further includes:

a low frequency band-pass filter applied to said converted digital signal.

18. A hand-held computer device as set forth in claim 15 wherein:

the first band-pass filter is centered at about 1950 Hz.

19. A hand-held computer device as set forth in claim 16 wherein:

said low frequency band-pass filter extends from .05

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Hz to 40 Hz.

20. A hand-held computer device as set forth in claim 17 which further includes:

means for audibly replaying the frequency modulated audio signal.

21. A hand-held computer device as set forth in claim 14 which further includes:

means for detecting and recording a time segment of a patient's heartbeat for input to said means for receiving.

22. A hand-held computer device as set forth in claim 21 which further includes:

means for frequency modulating the detected heartbeat time segment.

23. A hand-held computer device as set forth in claim 14 which further includes:

a device for detecting, frequency modulating and storing a selected time segment of a patient's heartbeat for subsequent transmission to said means for receiving.

24. A hand-held computer device as set forth in claim 21 which further includes:

a first band-pass filter applied at the frequency modulation center frequency to the received frequency modulated audio signal.

25. A hand-held computer device as set forth in claim 21 which further includes:

a low frequency band-pass filter applied to said converted digital signal.

26. A hand-held computer device as set forth in claim 23 which further includes:

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a low frequency band-pass filter applied to said converted digital signal.

27. A hand-held computer device as set forth in claim 25 wherein:

said first band-pass filter is centered about 1950 Hz and said low frequency band-pass filter extends from about .05 Hz to 40 Hz.

28. A hand-held computer device for patient monitoring, comprising:

means for receiving a frequency modulated audio signal indicating a selected biomedical parameter of a patient's physical condition;

means for digitizing and A-Law compressing said audio signal to provide an A-Law digital output;

A-Law decoder means receiving and expanding said A-Law digital output;

a band-pass filter receiving said expanded digital output to produce a filtered digital output;

a frequency estimator means receiving said filtered digital output; and

means for displaying said filtered digital output.

29. A hand-held computer device as set forth in claim 28 wherein said frequency estimator means comprises:

a cycle accumulator receiving said filtered digital output and producing an accumulator signal; and

a residue estimator receiving said accumulator signal to produce said filtered digital output.

30. A hand-held computer device as set forth in claim 29 wherein:

said selected biomedical parameter is a patient's ECG rhythm strip.

31. A method for using a hand-held computer for monitoring a patient's biomedical signals that relate to a selected

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physical condition, comprising:

receiving a frequency modulated audio signal replica of said biomedical signals;

demodulating said audio signal to produce a time analog signal;

converting said time analog signal to a digital signal representation; and

displaying said digital signal representation as a time analog graphic display.

32. The method for using a hand-held computer as set forth in claim 31 wherein such a system is housed in a PCMCIA card device as received in said hand-held computer.

33. A method for monitoring a patient's ECG signal, comprising:

developing a frequency modulated audio ECG signal from the patient;

inputting the frequency modulated audio ECG signal via telephone to a hand-held, programmed digital computer at a medical diagnostics site;

converting said frequency modulated audio ECG signal to a digital frequency modulated ECG signal;

demodulating said digital frequency modulated ECG signal to produce a digital ECG signal; and

displaying said digital ECG signal as a time analog indication.

34. A method for using a hand-held computer for monitoring a patient's ECG signals, comprising:

developing a frequency modulated audio ECG signal from the patient;

inputting the frequency modulated audio ECG signal via telephone to a hand-held, programmed digital computer at a medical diagnostics site;

companding said frequency modulated audio ECG signal by transforming with an A-Law encoder and decoder to produce an A-Law digital signal

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counterpart;

filtering said digital signal counterpart with a selected bandpass; and

deriving a frequency estimate of the digital signal counterpart for display of the ECG signals.

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Page 848

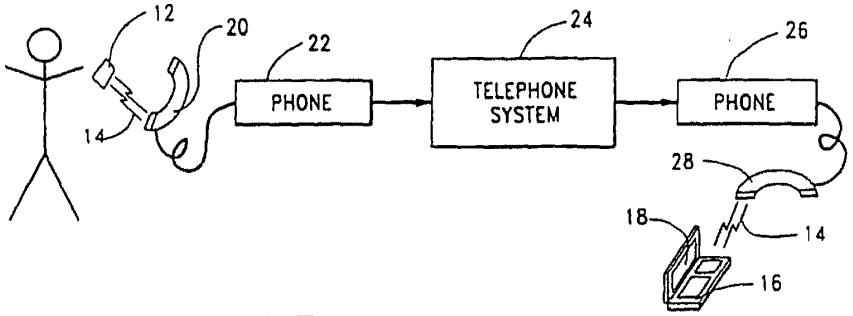

12
20
22
24
26
PHONE
TELEPHONE SYSTEM
PHONE
14
28
18
14
16

FIG. 1

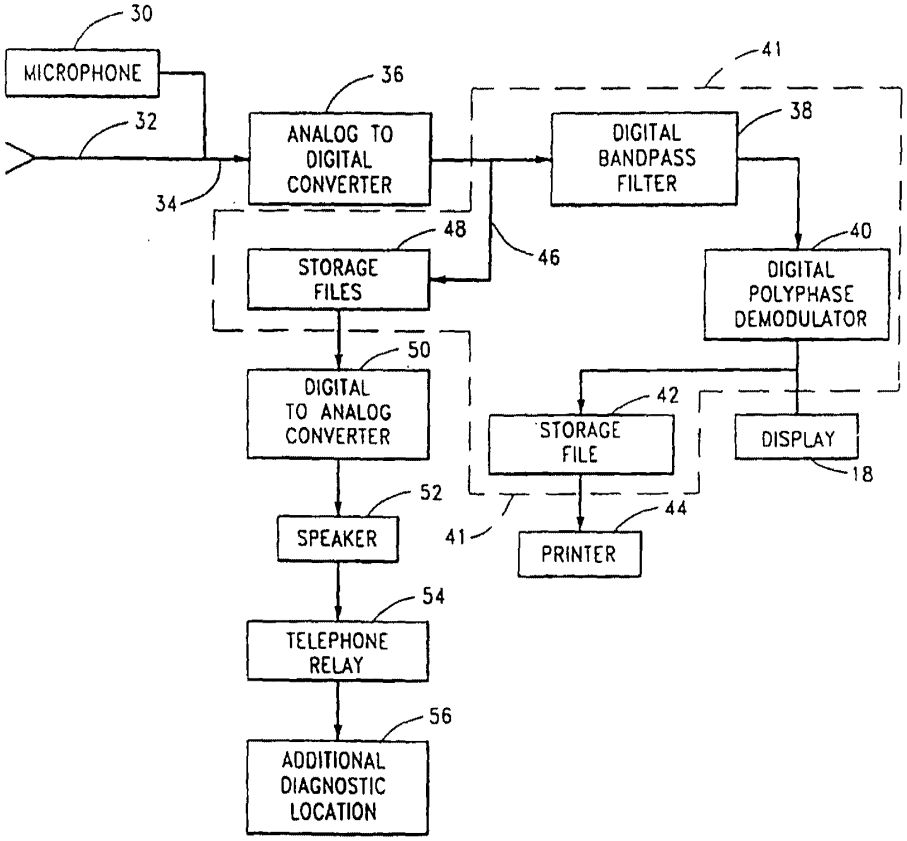

30
MICROPHONE
32
34
36
ANALOG TO DIGITAL CONVERTER
41
38
DIGITAL BANDPASS FILTER
48
STORAGE FILES
46
40
DIGITAL POLYPHASE DEMODULATOR
50
DIGITAL TO ANALOG CONVERTER
42
STORAGE FILE
DISPLAY
18
52
SPEAKER
41
44
PRINTER
54
TELEPHONE RELAY
56
ADDITIONAL DIAGNOSTIC LOCATION

FIG. 2

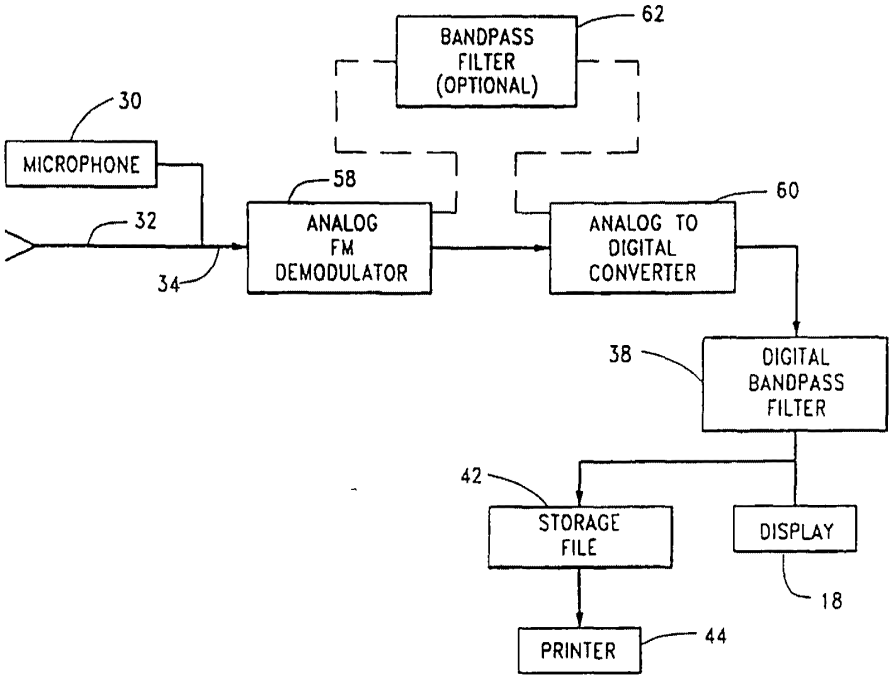

BANDPASS FILTER (OPTIONAL)
62
30
MICROPHONE
58
ANALOG FM DEMODULATOR
60
ANALOG TO DIGITAL CONVERTER
32
34
38
DIGITAL BANDPASS FILTER
42
STORAGE FILE
DISPLAY
18
PRINTER
44

FIG. 4

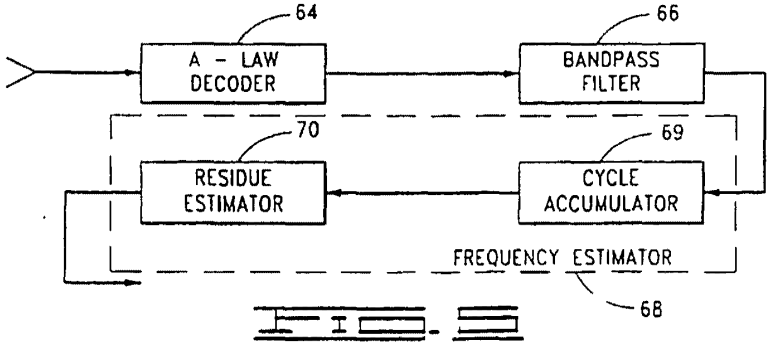

64
A - LAW DECODER
66
BANDPASS FILTER
70
RESIDUE ESTIMATOR
69
CYCLE ACCUMULATOR
FREQUENCY ESTIMATOR
68

FIG. 5

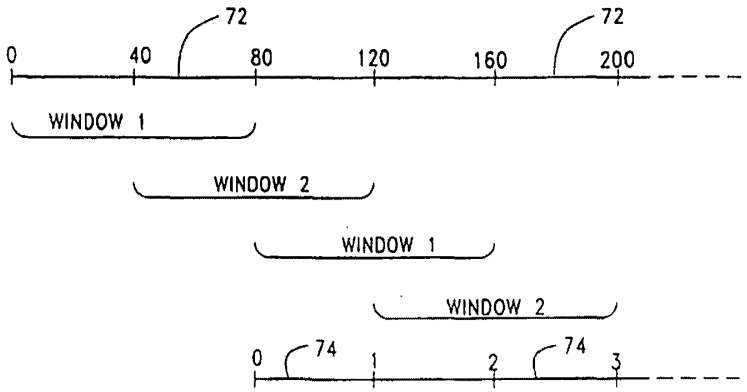

72
72
0
40
80
120
160
200
WINDOW 1
WINDOW 2
WINDOW 1
WINDOW 2
0
74
1
2
74
3

FIG. 8

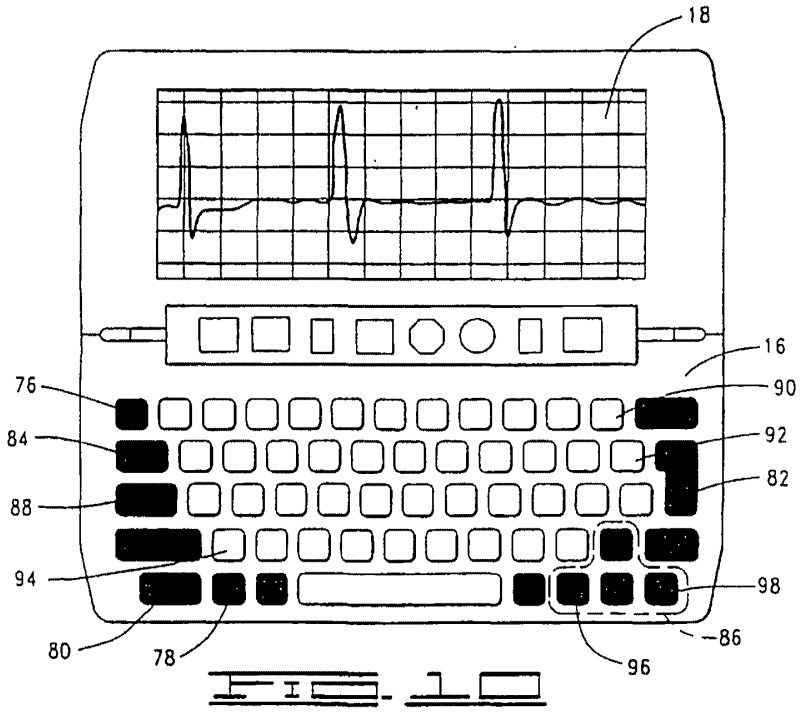

18
16
76
90
84
92
82
88
94
98
86
80
78
96

FIG. 9

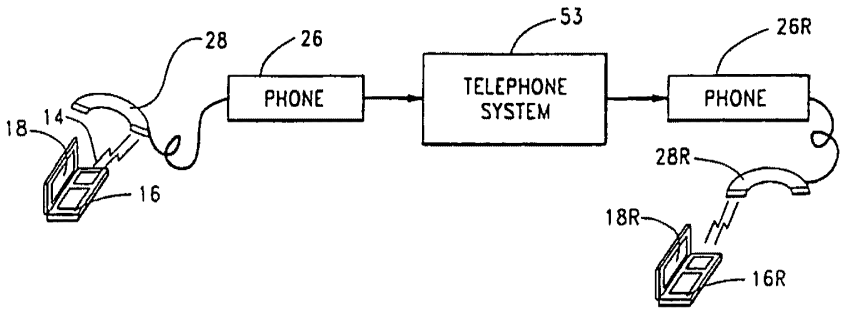

28
26
53
26R
PHONE
TELEPHONE SYSTEM
PHONE
18
14
16
28R
18R
16R

FIG. 3

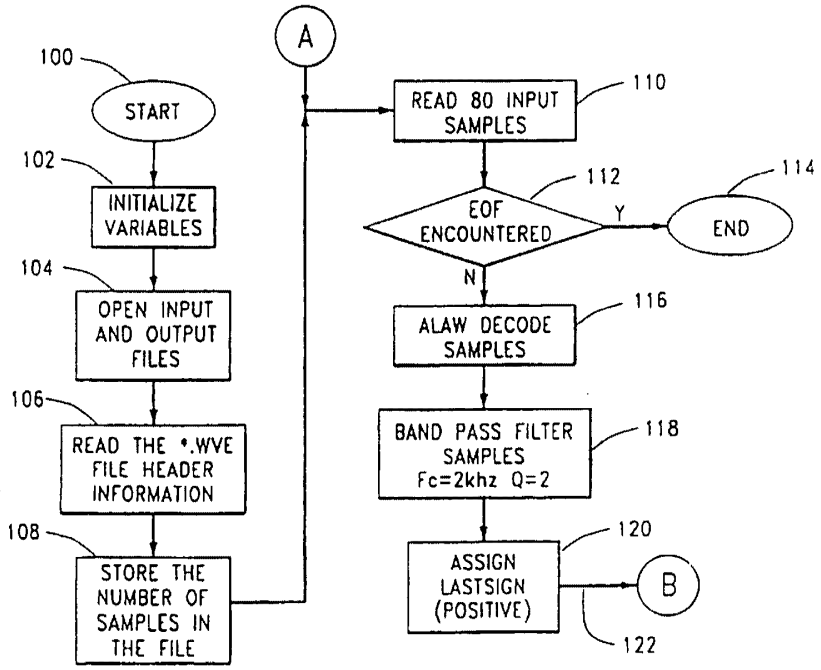

A
100
START
102
INITIALIZE VARIABLES
104
OPEN INPUT AND OUTPUT FILES
106
READ THE *.WVE FILE HEADER INFORMATION
108
STORE THE NUMBER OF SAMPLES IN THE FILE
110
READ 80 INPUT SAMPLES
112
EOF ENCOUNTERED
Y
114
END
N
116
ALAW DECODE SAMPLES
118
BAND PASS FILTER SAMPLES Fc=2khz Q=2
120
ASSIGN LASTSIGN (POSITIVE)
B
122

FIG. 2

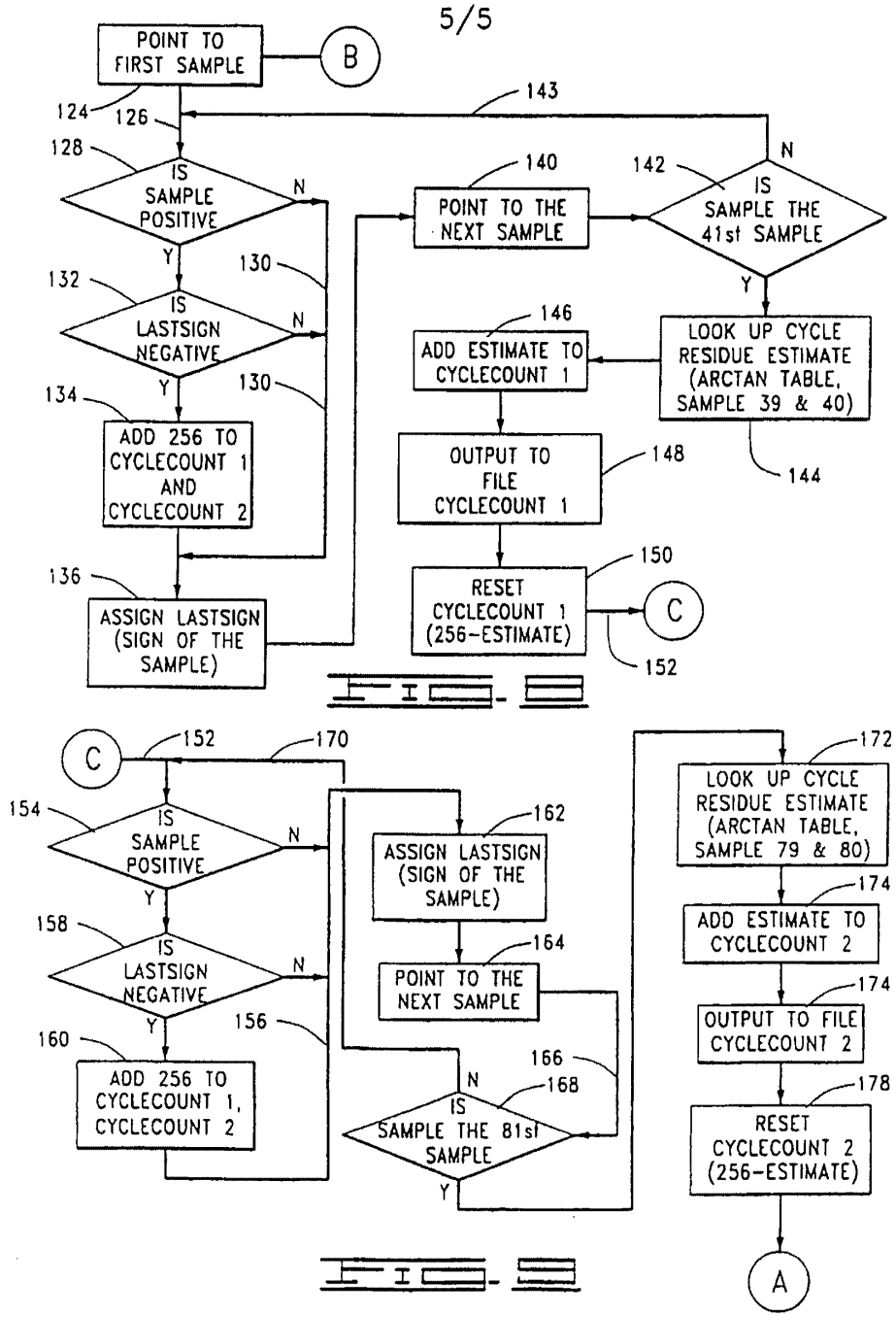

POINT TO FIRST SAMPLE
B
124
126
143
128
IS SAMPLE POSITIVE
N
Y
130
132
IS LASTSIGN NEGATIVE
N
Y
130
134
ADD 256 TO CYCLECOUNT 1 AND CYCLECOUNT 2
136
ASSIGN LASTSIGN (SIGN OF THE SAMPLE)
140
POINT TO THE NEXT SAMPLE
142
IS SAMPLE THE 41st SAMPLE
N
Y
LOOK UP CYCLE RESIDUE ESTIMATE (ARCTAN TABLE, SAMPLE 39 & 40)
144
146
ADD ESTIMATE TO CYCLECOUNT 1
148
OUTPUT TO FILE CYCLECOUNT 1
150
RESET CYCLECOUNT 1 (256-ESTIMATE)
C
152
C
152
170
154
IS SAMPLE POSITIVE
N
Y
158
IS LASTSIGN NEGATIVE
N
Y
160
ADD 256 TO CYCLECOUNT 1, CYCLECOUNT 2
156
162
ASSIGN LASTSIGN (SIGN OF THE SAMPLE)
164
POINT TO THE NEXT SAMPLE
166
N
168
IS SAMPLE THE 81st SAMPLE
Y
172
LOOK UP CYCLE RESIDUE ESTIMATE (ARCTAN TABLE, SAMPLE 79 & 80)
174
ADD ESTIMATE TO CYCLECOUNT 2
174
OUTPUT TO FILE CYCLECOUNT 2
178
RESET CYCLECOUNT 2 (256-ESTIMATE)
A

FIG. 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/09174

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/0432
US CL :128/696

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)

U.S. : 128/696, 710, 711, 904; 607/032, 060

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)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,336,245 A (ADAMS et al.) 09 August 1994, entire document.	1, 2, 4-13, 28-30, 33, 34
Y	US 5,433,736 A (NILSSON) 18 July 1995, Fig. 1.	1, 2, 4-13, 28-30, 33, 34
Y	US 4,567,883 A (LANGER et al.) 04 February 1986, entire document.	28-30, 34
Y	US 5,466,246 A (SILVIAN) 14 November 1995, entire document.	2, 4-13, 28-30, 33, 34
Y	US 3,731,311 A (WILLIAMS) 01 May 1973, col. 1, lines 35-40.	4-10

[X] 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	Date of mailing of the international search report
19 AUGUST 1997	29 AUG 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer JEFFREU R. JASTRZAB Telephone No. (703) 308-2097

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/09174

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 5,503,158 A (COPPOCK et al.) 02 April 1996, entire document.	1, 3, 14, 20-23, 31, 32

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PATENT ABSTRACTS OF JAPAN

(11)Publication number : 11-042214
(43)Date of publication of application : 16.02.1999

(51)Int.Cl. A61B 5/00
G06F 19/00
G08B 25/04

(21)Application number : 09-214178
(22)Date of filing : 23.07.1997

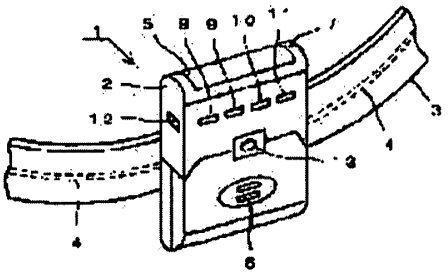
(71)Applicant : IDO TERUO
(72)Inventor : IDO TERUO

(54) PORTABLE WIRELESS ELECTROCARDIOGRAM MONITOR

(57)Abstract:

PROBLEM TO BE SOLVED: To obtain heartbeat data and electrocardiogram data of a patient automatically and carry out reliable finding and life-saving even if an abnormality occurs to the patient while he is out, in home medical care.

SOLUTION: A portable wireless electrocardiogram monitor 1 is mounted on the waist of a patient, and a breast-mounted wireless electrocardiograph is mounted on the breast or preferably near the heart of the patient. Heart rate data and electrocardiogram data obtained from the instruments are transmitted by radio automatically to a medical institution periodically or when an abnormality occurs. If the medical institution finds an abnormality from the analysis of the data, it sends medical advice to the patient by sound or text if his condition is less serious. If it is considered that an emergency has occurred, it dispatches a care vehicle or ambulance equipped with a car navigation system for finding and life-saving of the patient on the basis of position information of the patient obtained from the instrument 1.



LEGAL STATUS

[Date of request for examination]

[Date of sending the examiner's decision of rejection]

[Kind of final disposal of application other than the examiner's decision of rejection or application converted registration]

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[Date of final disposal for application]

[Patent number]

[Date of registration]

[Number of appeal against examiner's decision of rejection]

[Date of requesting appeal against examiner's decision of rejection]

[Date of extinction of right]

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CLAIMS

[Claim(s)]
[Claim 1] It consists of a body and a belt. In a body A wireless data transceiver means, a data display means, A voice-input/output means, an alarm means, a control means, an interface means to input the signal from a switch, etc. are built in. Transmit periodically the data obtained by carrying out data processing of the electrocardio data which a patient is made to possess the equipment which contained the antenna in the belt, and are transmitted from an external wireless electrocardiograph to a medical institution with simplicity radio, or Pocket mold wireless electrocardio supervisory equipment characterized by having the function to receive the directions from the medical institution to these data.
[Claim 2] It has the function to receive a GPS signal as a wireless data transceiver means, and the function to receive the FM multiplex broadcast of a D-GPS response. When a patient breaks down from a going-out place or goes missing by wandering etc., a patient's location location is recognized from the positional information transmitted from said GPS. Pocket mold wireless electrocardio supervisory equipment according to claim 1 characterized by having the function to rescue a patient easily by transmitting an abnormal situation and a location location to a medical institution.
[Claim 3] Claim 1 characterized by having the function which communicates between communication satellites by going via a wireless data transceiver means and a separate-type satellite communication transceiver means, and having the function which can communicate with the medical institution in the remote place which cannot communicate with simplicity radio, and pocket mold wireless electrocardio supervisory equipment according to claim 2.
[Claim 4] Claim 1 and claim 2 which there are not a function to tell a patient about arrival of the mail by voice, an alarm or an oscillation, etc. when receiving the directions from a medical institution, and a reaction to directions, and were characterized by the ability to be able to demand caution from a patient's circumference person and able to receive rescue with an alarm and a luminescence means when a patient judges that it is in a dangerous condition, and pocket mold wireless electrocardio supervisory equipment according to claim 3.

[Translation done.]

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Page 859

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DETAILED DESCRIPTION

[Detailed Description of the Invention]
[0001]
[Field of the Invention] This invention relates to the wireless electrocardio supervisory equipment which has to a patient the function which can send an emergency report automatically even when unconscious at the remote medical treatment with which a medical institution and a patient do the remote monitor of the medical information, such as heart rate data and electrocardiogram data, with the wireless electrocardio supervisory equipment held, respectively, and perform medical advice suitably, and the time of abnormalities, and can rescue a patient.
[0002]
[Description of the Prior Art] As a remote medical treatment for a patient, elderly people, or old people living alone with cardiopathy, the periodic medical examination by the visiting nurse is performed. Moreover, electrocardiogram data are transmitted to a medical institution with a pocket mold electrocardiogram store using the telephone line by development of communication technology, and the remote medical treatment support system which performs electrocardiogram analysis etc. is beginning to work in recent years. Moreover, heart rate data are transmitted to a medical institution using personal handy phone (it is henceforth called PHS.), and the remote medical treatment support system which carries out the remote monitor of the patient is also beginning to be examined.
[0003]
[Problem(s) to be Solved by the Invention] However, in the periodic medical examination by visiting nurse like before, the appearance of the patient at the time of a medical checkup is only seen, and there was a problem that the appearance of patients other than the time of a periodic medical examination could not be grasped. moreover, the case where change or abnormalities occur in a patient's condition at the times other than the time of a periodic medical examination -- a patient -- although rescued with the report from a principal or a circumference person -- the time of said abnormalities -- a patient -- even if the principal was out or it was in the house, the family etc. went out, and when there was nothing about consciousness in the case of one patient and it was not able to move, there was a problem that it could not report. Moreover, even if it is the case where it is about consciousness and can move, in the time of going out etc., an exact location location cannot be notified in many cases. Consequently, there was also a problem that discovery of a patient caused too late on delay medical care.
[0004] Moreover, when electrocardiogram data are transmitted to a medical institution with a pocket mold electrocardiogram store using the telephone line, the appearance of the patient in the event is only seen like the above-mentioned also in the remote medical treatment support system which performs electrocardiogram analysis etc. and change or abnormalities occur in a patient's condition, the situation at the event has not been grasped. And data were not able to be easily transmitted from a going-out place because of the method using the telephone line.
[0005] Moreover, transmit heart rate data to a medical institution using PHS, and a patient is set to the remote medical treatment support system which carries out a remote monitor. The construction period over plant-and-equipment investment and the long period of time of expanding the field of PHS included to the gap ground with many elderly people or an underpopulation area including the local small city which can be talked over the telephone, although a patient's condition can be monitored continuously great for measuring expansion of a social base is required. There is a problem that it must wait for these maintenance expansion in employment of the remote medical treatment support system of PHS utilization. Furthermore, in order to use the telephone line, phonecall charges are charged for every data transmission and reception, and there is also a problem that employment expense increases.
[0006] Moreover, PHS is overwhelmingly used for the purpose of a general call in many cases rather than it is used with a remote medical treatment support system. Discernment processing is difficult for searching bearing of the electric wave which detects only specific dispatch origin out of it, and is sent by conversion of the field strength at the

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reception event, or power reinforcement, and the radio frequency employed by many and unspecified persons like PHS also takes time amount. For this reason, when a patient does not have consciousness and cannot be contacted, detecting the electric wave from PHS and searching a patient's location location to accuracy also has the problem of becoming difficult.

[0007] This invention transmits heart rate data, electrocardiogram data, etc. automatically periodically also in the time of going out with the simplicity radio using an exclusive frequency in view of such a trouble, when change or abnormalities moreover occur in a patient's condition, it transmits an abnormality signal automatically, and it is invented for the purpose of performing a patient's early detection and early rescue.

[0008]

[Means for Solving the Problem] A patient's thorax is equipped with pocket mold wireless electrocardio supervisory equipment 1 which is shown in drawing 1 in order to attain the above-mentioned object. This pocket mold wireless electrocardio supervisory equipment 1 consists of a body 2 and a belt 3. As for the center section of the body 2, a loudspeaker 6 and the luminescence lamp 13 are formed for a mode switch 8, a configuration switch 9, the alarm reset switch 10, a backup light switch 11, an electric power switch 12, a microphone 7, and LCD5 in the upper part of a body 2. An antenna 4 is built in in a belt 3. Drawing 2 is a block diagram which constitutes the pocket mold wireless electrocardio supervisory equipment of this invention. It consists of an antenna 4, the data transceiver section 14, FM wave receive section 15, CPU16, the LCD actuator 17, LCD5, the data memory section 18, the timer section 19, the voice output section 20, the voice input section 21, vibrator 22, the interface section 23, a power supply unit 24, and a dc-battery 25. A mode switch 8, a configuration switch 9, the alarm reset switch 10, and a backup light switch 11 are connected to the interface section 23, and a sway sensor (not shown) and the luminescence lamp 13 are connected further. Moreover, a loudspeaker 6 is connected to the voice output section 20, and a microphone 7 is connected to the voice input section 21.

[0009] A patient's thorax is equipped with the breastplate wireless electrocardiograph 26 which is shown in drawing 3 . This breastplate wireless electrocardiograph 26 consists of a body 27 and a belt 28. Inside a body 27, outside a control section and a dc-battery 38 are formed, and an electric power switch 31 is further formed for an electrocardio sensor (not shown) in the upper part of a body 27. An antenna 29 is built in in a control section. Moreover, a body 27 and a belt 28 are stopped by the fixed part 30. Drawing 4 is a block diagram which constitutes the breastplate wireless electrocardiograph of this invention. It consists of an antenna 29, the data transceiver section 32, CPU33, the timer section 34, vibrator 35, the interface section 36, a power supply unit 37, and a dc-battery 38. An electrocardio sensor is connected to the interface section 36.

[0010] Moreover, in order to communicate with a remote place, using the satellite communication converter 39 and the exclusive parabolic antenna 43 which are at drawing 5 to perform satellite communication which relays a communication satellite, said satellite communication converter 39 and the exclusive parabolic antenna 43 are relayed, and the signal from pocket mold wireless electrocardio supervisory equipment 1 is performed. Drawing 6 is a block diagram which constitutes the satellite communication converter of this invention. It consists of an antenna 40, the data transceiver section 49, CPU50, a converter 51, the data transceiver section 52, the data memory section 53, the timer section 54, the interface section 55, a power supply unit 56, and a dc-battery 43. A mode switch 41 and the monitor lamp 42 are connected to the interface section 55. The exclusive parabolic antenna 43 consists of a reflector 44, a waveguide 45, a stanchion 46, and standing ways 47, and is connected with the satellite communication converter 39 with a coaxial cable 48.

[0011]

[Embodiment of the Invention] The gestalt of operation of this invention is explained in detail using drawing. Drawing 1 is the perspective view of the pocket mold wireless electrocardio supervisory equipment of this invention. This pocket mold wireless electrocardio supervisory equipment 1 of an exterior is the same as that of pedmeter, and consists of a body 2 and a belt 3. In the top face of a body 2, it has LCD5 and a microphone 7, has a mode switch 8, a configuration switch 9, the alarm reset switch 10, and a backup light switch 11 in the up transverse plane of a body 2, has an electric power switch 12 in the up side face of a body 2, and has a loudspeaker 6 and the luminescence lamp 13 in a center-section transverse plane. Moreover, an antenna 4 is built in in a belt 3. A dc-battery 25 is the rechargeable battery which can charge, and is charged via a power supply unit 24 from an external AC adapter. Drawing 2 is a block diagram which constitutes the pocket mold wireless electrocardio supervisory equipment of this invention. A mode switch 8, a configuration switch 9, the alarm reset switch 10, a backup light switch 11, the luminescence lamp 13, and vibrator 22 are connected to CPU16 via the interface section 23. Moreover, the sway sensor (not shown) built in the body 2 is similarly connected to CPU16 via the interface section 23. This sway sensor detects an oscillation of pocket mold wireless electrocardio supervisory equipment 1 and an inclination, and it is used in order to judge a patient's

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conditions -- whether it is emergency or it is in the condition of having removed pocket mold wireless electrocardio supervisory equipment 1 -- together with the breastplate wireless electrocardiograph 26. In CPU16, it samples, while carrying out data processing of the electrocardio data from the breastplate wireless electrocardiograph 26 and computing heart rate data and electrocardiogram data for 1 minute, and sampling data are accumulated in the data memory section 18. Moreover, the timer section 19 generates time-of-day data as a clock function while becoming the reference clock of CPU16. And said heart rate data and electrocardiogram data, and time-of-day data are displayed on LCD5 via the LCD actuator 17.

[0012] When the periodic medical examination time of day set up beforehand comes, said heart rate data, electrocardiogram data, etc. are discharged as an electric wave from an antenna 4 via the data transceiver section 14. Moreover, when these data judge it as outlying observation, it discharges as an electric wave from an antenna 4 via the data transceiver section 14 similarly as an abnormality signal each time. The transmitting output of this electric wave has the capacity which covers those or more [1] with W, and a zone with a radius of 3km or more.

[0013] In recent years, we are anxious about the effect of the body on an electromagnetic wave including an electric wave. Although the antenna 4 was built in in the belt 3 in the pocket mold wireless electrocardio supervisory equipment 1 of this invention, and the antenna 29 was built in in the body 27 in the breastplate wireless electrocardiograph 26 and the electric wave is discharged It is possible to be able to decrease the flux density by the side of the body by pasting up or inserting the electromagnetic wave absorption band made in carbon material etc., an electromagnetic wave electric shielding band (not shown), etc. between the rear face of a belt 3, a body 27, and an antenna 29, and to avoid the effect on the body. Moreover, although possibility of causing malfunction of medical equipment, such as a pace maker, is also regarded as questionable, it is possible to avoid the effect of the medical equipment on a pace maker etc. by wearing the electromagnetic wave absorption underwear similarly made in carbon material etc., an electromagnetic wave electric shielding underwear (not shown), etc.

[0014] A loudspeaker 6 is connected to CPU16 via the voice output section 20, and a microphone 7 is connected via the voice input section 21. When the case where abnormalities are seen, and an abnormality signal are sent to the periodic medical examination data collected at the time of day set up beforehand as mentioned above, a medical institution transmits a sound signal or a message signal as medical advice. Pocket mold wireless electrocardio supervisory equipment 1 receives this signal, and, in the case of a sound signal, sounds a voice-told message and an alarm from a loudspeaker 6 via the voice output section 20. In the case of a message signal, an alphabetic character message is displayed on LCD5 via the LCD actuator 17. A response may be returned by the mode switch 8 and the configuration switch 9 as a response to these messages, or you may talk toward the direct microphone 7. When there is no response, it judges that emergency has occurred to the patient, and an alarm is sounded from a loudspeaker 6 or it becomes possible to blink the luminescence lamp 13, to demand caution from a circumference person, and to receive rescue. In addition, it is possible by choosing vibrator 22 and 35 by the mode switch 8 and the configuration switch 9 to get to know reception by oscillation to sound a loudspeaker 6 at the time of reception of said medical advice.

[0015] Moreover, drawing 3 is the perspective view of the breastplate wireless electrocardiograph of this invention, and consists of a body 27 and a belt 28. Inside a body 27, it has an electrocardio sensor (not shown), and, outside, has a control section. In this control section, the dc-battery 38 and antenna 29 other than a control circuit are built in. A dc-battery 38 is the rechargeable battery which can charge, and is charged via a power supply unit 37 from an external AC adapter. Furthermore in the upper part of a body 27, it has an electric power switch 31. Moreover, a body 27 and a belt 28 are stopped by the fixed part 30. Drawing 4 is a block diagram which constitutes the breastplate wireless electrocardiograph of this invention. An electrocardio sensor (not shown) is connected to CPU33 via the interface section 36. Data processing of the signal from an electrocardio sensor is carried out, and it considers as electrocardio data, and discharges from an antenna 29 as an electric wave to pocket mold wireless electrocardio supervisory equipment 1 via the data transceiver section 32 in this CPU33.

[0016] Furthermore, as shown in the perspective view of the satellite communication converter of this invention of drawing 5 , and an exclusive parabolic antenna, by going via the separate-type satellite communication converter 39 and the separate-type exclusive parabolic antenna 43, it has the function which communicates between communication satellites, and can communicate with the medical institution in the remote place which cannot communicate with simplicity radio. Drawing 6 is a block diagram which constitutes the satellite communication converter of this invention. After the electric-wave signal transmitted from pocket mold wireless electrocardio supervisory equipment 1 goes into an antenna 40 and carries out signal processing via the data transceiver section 49, it is inputted into CPU50. In this CPU50, signal processing is performed and it discharges as an electric wave from the exclusive parabolic antenna 43 via a converter 51 and the data transceiver section 52. The timer section 54 which generates the reference clock of the data memory section 53 for accumulating said signal or this CPU50 is connected to CPU50. Moreover, the

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monitor lamp 42 which supervises the mode switch 41 which sets up the mode of this satellite communication converter 39, and a communication link condition is connected via the interface section 55. A power supply unit 56 can input AC power supply and DC power supply, and can be connected to a source power supply, a car dc-battery, etc. A dc-battery 57 is connected to the secondary of a power supply unit 56, and it is always charging, and is usable also in the location which cannot take said power source.

[0017]

[Example] The example of this invention is explained using drawing. Drawing 1 is the perspective view of the pocket mold wireless electrocardio supervisory equipment of this invention, and drawing 3 is the perspective view of the breastplate wireless electrocardiograph of this invention. a patient with the need for home health care is equipped with pocket mold wireless electrocardio supervisory equipment 1 with a belt 3 at the lumbar part -- making -- moreover, the breastplate wireless electrocardiograph 26 -- a belt 28 -- a thorax -- it is made to equip near the heart preferably From the breastplate wireless electrocardiograph 26, a patient's electrocardio data are transmitted by feeble wireless to pocket mold wireless electrocardio supervisory equipment 1. Pocket mold wireless electrocardio supervisory equipment 1 samples while it carries out data processing of the electrocardio data from the breastplate wireless electrocardiograph 26 and computes heart rate data and electrocardiogram data for 1 minute, and it accumulates sampling data in the data memory section 18.

[0018] Usually, pocket mold wireless electrocardio supervisory equipment 1 transmits heart rate data, electrocardiogram data, a patient ID number, a local ID number, a patient's location data, etc. automatically at the periodic medical examination time of day beforehand set up to the medical institution. Moreover, when abnormalities are looked at by said data, it transmits automatically as an abnormality signal each time.

[0019] There is LCD5 in the top face of pocket mold wireless electrocardio supervisory equipment 1, and said heart rate data and electrocardiogram data, and time-of-day data can be displayed. In addition, when a perimeter becomes dark, a backup light switch 11 is turned ON, the back light of the rear face of LCD5 can be turned on, and LCD5 can be made legible.

[0020] The periodic medical examination data or the abnormality signal transmitted to the medical institution from pocket mold wireless electrocardio supervisory equipment 1 is promptly analyzed by the doctor in charge and the information processing system currently installed beforehand. Then, when a certain abnormalities are seen, if it is the light thing which is extent, a sound signal or a message signal will be transmitted to the pocket mold wireless electrocardio supervisory equipment 1 which a patient possesses as medical advice. A patient can check reception of a medical advice signal by sounding of the loudspeaker 6 in the front face of this pocket mold wireless electrocardio supervisory equipment 1, or the oscillation by the vibrator 22 of built-in on a body 2, or the vibrator 35 of built-in on the body 27 of the breastplate wireless electrocardiograph 26. In addition, it can be chosen by the mode switch 9 and the configuration switch 10 whether it is made which actuation of sounding or vibrator 22 of a loudspeaker 6, and an oscillation of 35. In addition, the alarm reset switch 10 can be turned ON and sounding can be stopped to stop sounding at the time of sounding of a loudspeaker 6.

[0021] In the case of a sound signal, a voice-told message is sounded from a loudspeaker 6. Moreover, in the case of a message signal, an alphabetic character message is displayed on LCD5. As a response to these messages, toward a microphone 7, it may talk to a direct doctor in charge, or a response may be returned by the mode switch 8 and the configuration switch 9. It is possible to judge that emergency has occurred to the patient when there is no response in the condition of changing electrocardio data, to sound an alarm from a loudspeaker 6, or to blink the luminescence lamp 13, to demand caution from a circumference person, and to receive rescue.

[0022] Moreover, when it is judged that emergency has already occurred in the analysis result of the above-mentioned data, an alarm is promptly sounded instead of [loudspeaker / 6] a medical message, or it goes into the attitude of blinking the luminescence lamp 13, demanding caution from a circumference person, and receiving rescue. In order to rescue a patient, a care vehicle or an ambulance is made to mobilize furthermore in a medical institution. The location data of the patient transmitted from the GPS car-navigation system carried in this care vehicle or the ambulance and the pocket mold wireless electrocardio supervisory equipment 1 which a patient possesses etc. can search for a patient's location, and it can hasten to a patient's origin. This car-navigation system can search a patient's location to high degree of accuracy (less than several m error) by considering as a D-GPS response, receiving an FM multiplex broadcast and carrying out location amendment.

[0023] Moreover, although drawing 5 is the perspective view of the satellite communication converter of this invention, and an exclusive parabolic antenna, the remote medical treatment of it becomes possible also among the medical institutions in a remote place which the electric wave discharged from pocket mold wireless electrocardio supervisory equipment 1 does not reach by using such the separate-type satellite communication converter 39 and the

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separate-type exclusive parabolic antenna 43. The electric wave discharged from this pocket mold wireless electrocardio supervisory equipment 1 goes into the antenna 40 of the satellite communication converter 39, and after carrying out signal transformation, it discharges an electric wave towards a communication satellite from the exclusive parabolic antenna 43. The remote medical treatment of transmitting treatment information to a nearby medical institution according to the latest medical response at a patient, or transmitting the medical message to a patient is possible for the medical institution in a remote place (outside the country is included) by receiving this electric wave. In addition, which approach may be used although there is also a method of arranging two or more radio relay stations, and relaying a signal in the zone of the electric wave of pocket mold wireless electrocardio supervisory equipment 1 as an approach of communicating among the medical institutions in a remote place which the electric wave discharged from pocket mold wireless electrocardio supervisory equipment 1 does not reach.

[0024]

[Effect of the Invention] As stated above, the following effectiveness can be done so by adopting the pocket mold wireless electrocardio supervisory equipment of this invention as a remote medical treatment.

** When a patient always attaches pocket mold wireless electrocardio supervisory equipment and a breastplate wireless electrocardiograph to the body, data, such as heart rate data and electrocardiogram data, are obtained, and periodical or since it can transmit automatically each time at the time of abnormalities, the remote monitor of a remote medical treatment can do these data.

** When a patient always attaches pocket mold wireless electrocardio supervisory equipment and a breastplate wireless electrocardiograph to the body, condition grasp of an in-home patient with difficult going to hospital regularly can be performed easily.

** Since the patient or location location under going out can search easily, it can rescue easily also in the time of abnormalities. For this reason, a going-out limit of a patient is eased and the living environment of a patient requiring special attention can be changed.

** Since a voice-told message and an alphabetic character message are receivable as medical advice from a medical institution according to the content of the periodic medical examination data transmitted from pocket mold wireless electrocardio supervisory equipment, or the abnormality signal, the suitable first-aid treatment by the principal or the circumference person can be adopted.

** A patient's home care-ization becomes easy and going-to-hospital-regularly / hospitalization expense burden of an individual or an insurance engine, and the personnel expense and the hospitalization installation cost of a medical institution can be mitigated.

** By relaying a separate-type satellite communication converter and a separate-type exclusive parabolic antenna, it can communicate with the medical institution of a remote place, and the latest remote medical treatment becomes possible.

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TECHNICAL FIELD

[Field of the Invention] This invention relates to the wireless electrocardio supervisory equipment which has to a patient the function which can send an emergency report automatically even when unconscious at the remote medical treatment with which a medical institution and a patient do the remote monitor of the medical information, such as heart rate data and electrocardiogram data, with the wireless electrocardio supervisory equipment held, respectively, and perform medical advice suitably, and the time of abnormalities, and can rescue a patient.

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PRIOR ART

[Description of the Prior Art] As a remote medical treatment for a patient, elderly people, or old people living alone with cardiopathy, the periodic medical examination by the visiting nurse is performed. Moreover, electrocardiogram data are transmitted to a medical institution with a pocket mold electrocardiogram store using the telephone line by development of communication technology, and the remote medical treatment support system which performs electrocardiogram analysis etc. is beginning to work in recent years. Moreover, heart rate data are transmitted to a medical institution using personal handy phone (it is henceforth called PHS.), and the remote medical treatment support system which carries out the remote monitor of the patient is also beginning to be examined.

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EFFECT OF THE INVENTION

[Effect of the Invention] As stated above, the following effectiveness can be done so by adopting the pocket mold wireless electrocardio supervisory equipment of this invention as a remote medical treatment.
** When a patient always attaches pocket mold wireless electrocardio supervisory equipment and a breastplate wireless electrocardiograph to the body, data, such as heart rate data and electrocardiogram data, are obtained, and periodical or since it can transmit automatically each time at the time of abnormalities, the remote monitor of a remote medical treatment can do these data.
** When a patient always attaches pocket mold wireless electrocardio supervisory equipment and a breastplate wireless electrocardiograph to the body, condition grasp of an in-home patient with difficult going to hospital regularly can be performed easily.
** Since the patient or location location under going out can search easily, it can rescue easily also in the time of abnormalities. For this reason, a going-out limit of a patient is eased and the living environment of a patient requiring special attention can be changed.
** Since a voice-told message and an alphabetic character message are receivable as medical advice from a medical institution according to the content of the periodic medical examination data transmitted from pocket mold wireless electrocardio supervisory equipment, or the abnormality signal, the suitable first-aid treatment by the principal or the circumference person can be adopted.
** A patient's home care-ization becomes easy and going-to-hospital-regularly / hospitalization expense burden of an individual or an insurance engine, and the personnel expense and the hospitalization installation cost of a medical institution can be mitigated.
** By relaying a separate-type satellite communication converter and a separate-type exclusive parabolic antenna, it can communicate with the medical institution of a remote place, and the latest remote medical treatment becomes possible.

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TECHNICAL PROBLEM

[Problem(s) to be Solved by the Invention] However, in the periodic medical examination by visiting nurse like before, the appearance of the patient at the time of a medical checkup is only seen, and there was a problem that the appearance of patients other than the time of a periodic medical examination could not be grasped. moreover, the case where change or abnormalities occur in a patient's condition at the times other than the time of a periodic medical examination -- a patient -- although rescued with the report from a principal or a circumference person -- the time of said abnormalities -- a patient -- even if the principal was out or it was in the house, the family etc. went out, and when there was nothing about consciousness in the case of one patient and it was not able to move, there was a problem that it could not report. Moreover, even if it is the case where it is about consciousness and can move, in the time of going out etc., an exact location location cannot be notified in many cases. Consequently, there was also a problem that discovery of a patient caused too late on delay medical care.
[0004] Moreover, when electrocardiogram data are transmitted to a medical institution with a pocket mold electrocardiogram store using the telephone line, the appearance of the patient in the event is only seen like the above-mentioned also in the remote medical treatment support system which performs electrocardiogram analysis etc. and change or abnormalities occur in a patient's condition, the situation at the event has not been grasped. And data were not able to be easily transmitted from a going-out place because of the method using the telephone line.
[0005] Moreover, transmit heart rate data to a medical institution using PHS, and a patient is set to the remote medical treatment support system which carries out a remote monitor. The construction period over plant-and-equipment investment and the long period of time of expanding the field of PHS included to the gap ground with many elderly people or an underpopulation area including the local small city which can be talked over the telephone, although a patient's condition can be monitored continuously great for measuring expansion of a social base is required. There is a problem that it must wait for these maintenance expansion in employment of the remote medical treatment support system of PHS utilization. Furthermore, in order to use the telephone line, phonecall charges are charged for every data transmission and reception, and there is also a problem that employment expense increases.
[0006] Moreover, PHS is overwhelmingly used for the purpose of a general call in many cases rather than it is used with a remote medical treatment support system. Discernment processing is difficult for searching bearing of the electric wave which detects only specific dispatch origin out of it, and is sent by conversion of the field strength at the reception event, or power reinforcement, and the radio frequency employed by many and unspecified persons like PHS also takes time amount. For this reason, when a patient does not have consciousness and cannot be contacted, detecting the electric wave from PHS and searching a patient's location location to accuracy also has the problem of becoming difficult.
[0007] This invention transmits heart rate data, electrocardiogram data, etc. automatically periodically also in the time of going out with the simplicity radio using an exclusive frequency in view of such a trouble, when change or abnormalities moreover occur in a patient's condition, it transmits an abnormality signal automatically, and it is invented for the purpose of performing a patient's early detection and early rescue.
[0008]

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MEANS

[Means for Solving the Problem] A patient's thorax is equipped with pocket mold wireless electrocardio supervisory equipment 1 which is shown in drawing 1 in order to attain the above-mentioned object. This pocket mold wireless electrocardio supervisory equipment 1 consists of a body 2 and a belt 3. As for the center section of the body 2, a loudspeaker 6 and the luminescence lamp 13 are formed for a mode switch 8, a configuration switch 9, the alarm reset switch 10, a backup light switch 11, an electric power switch 12, a microphone 7, and LCD5 in the upper part of a body 2. An antenna 4 is built in in a belt 3. Drawing 2 is a block diagram which constitutes the pocket mold wireless electrocardio supervisory equipment of this invention. It consists of an antenna 4, the data transceiver section 14, FM wave receive section 15, CPU16, the LCD actuator 17, LCD5, the data memory section 18, the timer section 19, the voice output section 20, the voice input section 21, vibrator 22, the interface section 23, a power supply unit 24, and a dc-battery 25. A mode switch 8, a configuration switch 9, the alarm reset switch 10, and a backup light switch 11 are connected to the interface section 23, and a sway sensor (not shown) and the luminescence lamp 13 are connected further. Moreover, a loudspeaker 6 is connected to the voice output section 20, and a microphone 7 is connected to the voice input section 21.

[0009] A patient's thorax is equipped with the breastplate wireless electrocardiograph 26 which is shown in drawing 3 . This breastplate wireless electrocardiograph 26 consists of a body 27 and a belt 28. Inside a body 27, outside a control section and a dc-battery 38 are formed, and an electric power switch 31 is further formed for an electrocardio sensor (not shown) in the upper part of a body 27. An antenna 29 is built in in a control section. Moreover, a body 27 and a belt 28 are stopped by the fixed part 30. Drawing 4 is a block diagram which constitutes the breastplate wireless electrocardiograph of this invention. It consists of an antenna 29, the data transceiver section 32, CPU33, the timer section 34, vibrator 35, the interface section 36, a power supply unit 37, and a dc-battery 38. An electrocardio sensor is connected to the interface section 36.

[0010] Moreover, in order to communicate with a remote place, using the satellite communication converter 39 and the exclusive parabolic antenna 43 which are at drawing 5 to perform satellite communication which relays a communication satellite, said satellite communication converter 39 and the exclusive parabolic antenna 43 are relayed, and the signal from pocket mold wireless electrocardio supervisory equipment 1 is performed. Drawing 6 is a block diagram which constitutes the satellite communication converter of this invention. It consists of an antenna 40, the data transceiver section 49, CPU50, a converter 51, the data transceiver section 52, the data memory section 53, the timer section 54, the interface section 55, a power supply unit 56, and a dc-battery 43. A mode switch 41 and the monitor lamp 42 are connected to the interface section 55. The exclusive parabolic antenna 43 consists of a reflector 44, a waveguide 45, a stanchion 46, and standing ways 47, and is connected with the satellite communication converter 39 with a coaxial cable 48.

[0011]

[Embodiment of the Invention] The gestalt of operation of this invention is explained in detail using drawing. Drawing 1 is the perspective view of the pocket mold wireless electrocardio supervisory equipment of this invention. This pocket mold wireless electrocardio supervisory equipment 1 of an exterior is the same as that of pedmeter, and consists of a body 2 and a belt 3. In the top face of a body 2, it has LCD5 and a microphone 7, has a mode switch 8, a configuration switch 9, the alarm reset switch 10, and a backup light switch 11 in the up transverse plane of a body 2, has an electric power switch 12 in the up side face of a body 2, and has a loudspeaker 6 and the luminescence lamp 13 in a center-section transverse plane. Moreover, an antenna 4 is built in in a belt 3. A dc-battery 25 is the rechargeable battery which can charge, and is charged via a power supply unit 24 from an external AC adapter. Drawing 2 is a block diagram which constitutes the pocket mold wireless electrocardio supervisory equipment of this invention. A mode switch 8, a configuration switch 9, the alarm reset switch 10, a backup light switch 11, the luminescence lamp 13, and

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vibrator 22 are connected to CPU16 via the interface section 23. Moreover, the sway sensor (not shown) built in the body 2 is similarly connected to CPU16 via the interface section 23. This sway sensor detects an oscillation of pocket mold wireless electrocardio supervisory equipment 1 and an inclination, and it is used in order to judge a patient's conditions -- whether it is emergency or it is in the condition of having removed pocket mold wireless electrocardio supervisory equipment 1 -- together with the breastplate wireless electrocardiograph 26. In CPU16, it samples, while carrying out data processing of the electrocardio data from the breastplate wireless electrocardiograph 26 and computing heart rate data and electrocardiogram data for 1 minute, and sampling data are accumulated in the data memory section 18. Moreover, the timer section 19 generates time-of-day data as a clock function while becoming the reference clock of CPU16. And said heart rate data and electrocardiogram data, and time-of-day data are displayed on LCD5 via the LCD actuator 17.

[0012] When the periodic medical examination time of day set up beforehand comes, said heart rate data, electrocardiogram data, etc. are discharged as an electric wave from an antenna 4 via the data transceiver section 14. Moreover, when these data judge it as outlying observation, it discharges as an electric wave from an antenna 4 via the data transceiver section 14 similarly as an abnormality signal each time. The transmitting output of this electric wave has the capacity which covers those or more [1] with W, and a zone with a radius of 3km or more.

[0013] In recent years, we are anxious about the effect of the body on an electromagnetic wave including an electric wave. Although the antenna 4 was built in in the belt 3 in the pocket mold wireless electrocardio supervisory equipment 1 of this invention, and the antenna 29 was built in in the body 27 in the breastplate wireless electrocardiograph 26 and the electric wave is discharged It is possible to be able to decrease the flux density by the side of the body by pasting up or inserting the electromagnetic wave absorption band made in carbon material etc., an electromagnetic wave electric shielding band (not shown), etc. between the rear face of a belt 3, a body 27, and an antenna 29, and to avoid the effect on the body. Moreover, although possibility of causing malfunction of medical equipment, such as a pace maker, is also regarded as questionable, it is possible to avoid the effect of the medical equipment on a pace maker etc. by wearing the electromagnetic wave absorption underwear similarly made in carbon material etc., an electromagnetic wave electric shielding underwear (not shown), etc.

[0014] A loudspeaker 6 is connected to CPU16 via the voice output section 20, and a microphone 7 is connected via the voice input section 21. When the case where abnormalities are seen, and an abnormality signal are sent to the periodic medical examination data collected at the time of day set up beforehand as mentioned above, a medical institution transmits a sound signal or a message signal as medical advice. Pocket mold wireless electrocardio supervisory equipment 1 receives this signal, and, in the case of a sound signal, sounds a voice-told message and an alarm from a loudspeaker 6 via the voice output section 20. In the case of a message signal, an alphabetic character message is displayed on LCD5 via the LCD actuator 17. A response may be returned by the mode switch 8 and the configuration switch 9 as a response to these messages, or you may talk toward the direct microphone 7. When there is no response, it judges that emergency has occurred to the patient, and an alarm is sounded from a loudspeaker 6 or it becomes possible to blink the luminescence lamp 13, to demand caution from a circumference person, and to receive rescue. In addition, it is possible by choosing vibrator 22 and 35 by the mode switch 8 and the configuration switch 9 to get to know reception by oscillation to sound a loudspeaker 6 at the time of reception of said medical advice.

[0015] Moreover, drawing 3 is the perspective view of the breastplate wireless electrocardiograph of this invention, and consists of a body 27 and a belt 28. Inside a body 27, it has an electrocardio sensor (not shown), and, outside, has a control section. In this control section, the dc-battery 38 and antenna 29 other than a control circuit are built in. A dc-battery 38 is the rechargeable battery which can charge, and is charged via a power supply unit 37 from an external AC adapter. Furthermore in the upper part of a body 27, it has an electric power switch 31. Moreover, a body 27 and a belt 28 are stopped by the fixed part 30. Drawing 4 is a block diagram which constitutes the breastplate wireless electrocardiograph of this invention. An electrocardio sensor (not shown) is connected to CPU33 via the interface section 36. Data processing of the signal from an electrocardio sensor is carried out, and it considers as electrocardio data, and discharges from an antenna 29 as an electric wave to pocket mold wireless electrocardio supervisory equipment 1 via the data transceiver section 32 in this CPU33.

[0016] Furthermore, as shown in the perspective view of the satellite communication converter of this invention of drawing 5 , and an exclusive parabolic antenna, by going via the separate-type satellite communication converter 39 and the separate-type exclusive parabolic antenna 43, it has the function which communicates between communication satellites, and can communicate with the medical institution in the remote place which cannot communicate with simplicity radio. Drawing 6 is a block diagram which constitutes the satellite communication converter of this invention. After the electric-wave signal transmitted from pocket mold wireless electrocardio supervisory equipment 1 goes into an antenna 40 and carries out signal processing via the data transceiver section 49, it is inputted into CPU50.

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In this CPU50, signal processing is performed and it discharges as an electric wave from the exclusive parabolic antenna 43 via a converter 51 and the data transceiver section 52. The timer section 54 which generates the reference clock of the data memory section 53 for accumulating said signal or this CPU50 is connected to CPU50. Moreover, the monitor lamp 42 which supervises the mode switch 41 which sets up the mode of this satellite communication converter 39, and a communication link condition is connected via the interface section 55. A power supply unit 56 can input AC power supply and DC power supply, and can be connected to a source power supply, a car dc-battery, etc. A dc-battery 57 is connected to the secondary of a power supply unit 56, and it is always charging, and is usable also in the location which cannot take said power source.

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EXAMPLE

[Example] The example of this invention is explained using drawing. Drawing 1 is the perspective view of the pocket mold wireless electrocardio supervisory equipment of this invention, and drawing 3 is the perspective view of the breastplate wireless electrocardiograph of this invention. a patient with the need for home health care is equipped with pocket mold wireless electrocardio supervisory equipment 1 with a belt 3 at the lumbar part -- making -- moreover, the breastplate wireless electrocardiograph 26 -- a belt 28 -- a thorax -- it is made to equip near the heart preferably From the breastplate wireless electrocardiograph 26, a patient's electrocardio data are transmitted by feeble wireless to pocket mold wireless electrocardio supervisory equipment 1. Pocket mold wireless electrocardio supervisory equipment 1 samples while it carries out data processing of the electrocardio data from the breastplate wireless electrocardiograph 26 and computes heart rate data and electrocardiogram data for 1 minute, and it accumulates sampling data in the data memory section 18.

[0018] Usually, pocket mold wireless electrocardio supervisory equipment 1 transmits heart rate data, electrocardiogram data, a patient ID number, a local ID number, a patient's location data, etc. automatically at the periodic medical examination time of day beforehand set up to the medical institution. Moreover, when abnormalities are looked at by said data, it transmits automatically as an abnormality signal each time.

[0019] There is LCD5 in the top face of pocket mold wireless electrocardio supervisory equipment 1, and said heart rate data and electrocardiogram data, and time-of-day data can be displayed. In addition, when a perimeter becomes dark, a backup light switch 11 is turned ON, the back light of the rear face of LCD5 can be turned on, and LCD5 can be made legible.

[0020] The periodic medical examination data or the abnormality signal transmitted to the medical institution from pocket mold wireless electrocardio supervisory equipment 1 is promptly analyzed by the doctor in charge and the information processing system currently installed beforehand. Then, when a certain abnormalities are seen, if it is the light thing which is extent, a sound signal or a message signal will be transmitted to the pocket mold wireless electrocardio supervisory equipment 1 which a patient possesses as medical advice. A patient can check reception of a medical advice signal by sounding of the loudspeaker 6 in the front face of this pocket mold wireless electrocardio supervisory equipment 1, or the oscillation by the vibrator 22 of built-in on a body 2, or the vibrator 35 of built-in on the body 27 of the breastplate wireless electrocardiograph 26. In addition, it can be chosen by the mode switch 9 and the configuration switch 10 whether it is made which actuation of sounding or vibrator 22 of a loudspeaker 6, and an oscillation of 35. In addition, the alarm reset switch 10 can be turned ON and sounding can be stopped to stop sounding at the time of sounding of a loudspeaker 6.

[0021] In the case of a sound signal, a voice-told message is sounded from a loudspeaker 6. Moreover, in the case of a message signal, an alphabetic character message is displayed on LCD5. As a response to these messages, toward a microphone 7, it may talk to a direct doctor in charge, or a response may be returned by the mode switch 8 and the configuration switch 9. It is possible to judge that emergency has occurred to the patient when there is no response in the condition of changing electrocardio data, to sound an alarm from a loudspeaker 6, or to blink the luminescence lamp 13, to demand caution from a circumference person, and to receive rescue.

[0022] Moreover, when it is judged that emergency has already occurred in the analysis result of the above-mentioned data, an alarm is promptly sounded instead of [loudspeaker / 6] a medical message, or it goes into the attitude of blinking the luminescence lamp 13, demanding caution from a circumference person, and receiving rescue. In order to rescue a patient, a care vehicle or an ambulance is made to mobilize furthermore in a medical institution. The location data of the patient transmitted from the GPS car-navigation system carried in this care vehicle or the ambulance and the pocket mold wireless electrocardio supervisory equipment 1 which a patient possesses etc. can search for a patient's location, and it can hasten to a patient's origin. This car-navigation system can search a patient's location to high degree

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of accuracy (less than several m error) by considering as a D-GPS response, receiving an FM multiplex broadcast and carrying out location amendment.

[0023] Moreover, although drawing 5 is the perspective view of the satellite communication converter of this invention, and an exclusive parabolic antenna, the remote medical treatment of it becomes possible also among the medical institutions in a remote place which the electric wave discharged from pocket mold wireless electrocardio supervisory equipment 1 does not reach by using such the separate-type satellite communication converter 39 and the separate-type exclusive parabolic antenna 43. The electric wave discharged from this pocket mold wireless electrocardio supervisory equipment 1 goes into the antenna 40 of the satellite communication converter 39, and after carrying out signal transformation, it discharges an electric wave towards a communication satellite from the exclusive parabolic antenna 43. The remote medical treatment of transmitting treatment information to a nearby medical institution according to the latest medical response at a patient, or transmitting the medical message to a patient is possible for the medical institution in a remote place (outside the country is included) by receiving this electric wave. In addition, which approach may be used although there is also a method of arranging two or more radio relay stations, and relaying a signal in the zone of the electric wave of pocket mold wireless electrocardio supervisory equipment 1 as an approach of communicating among the medical institutions in a remote place which the electric wave discharged from pocket mold wireless electrocardio supervisory equipment 1 does not reach.

[Translation done.]

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3.In the drawings, any words are not translated.

DESCRIPTION OF DRAWINGS

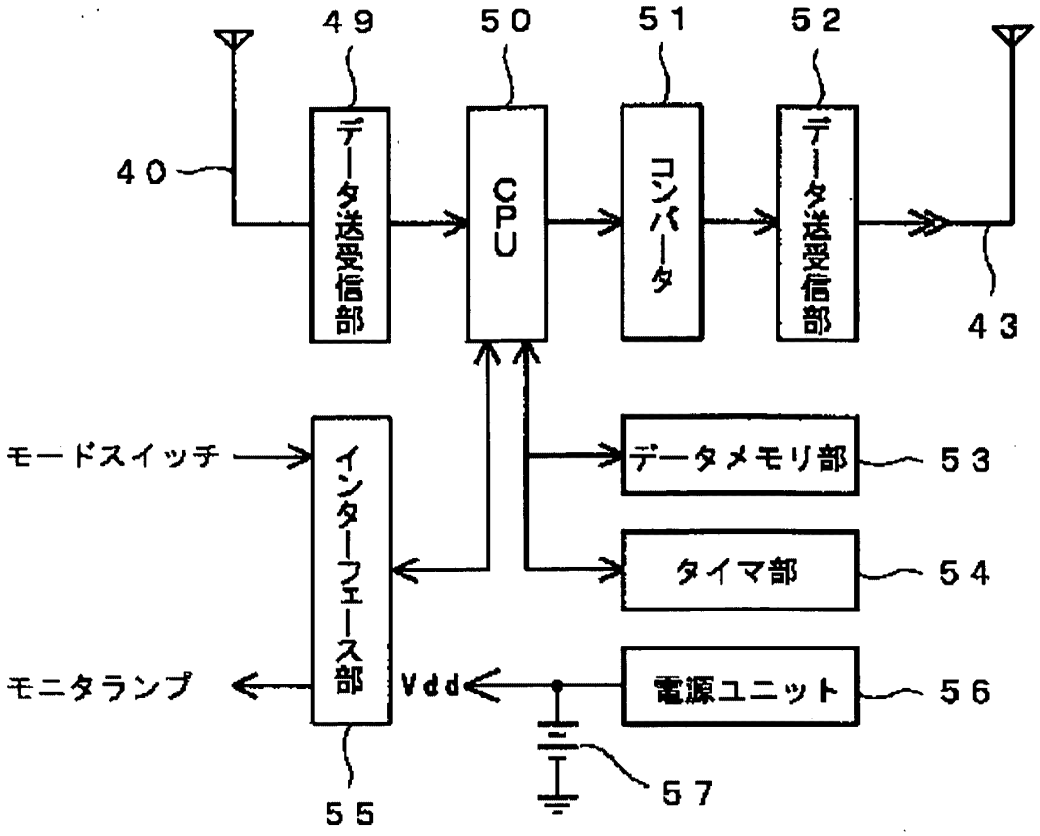
[Brief Description of the Drawings]
[Drawing 1] It is the perspective view of the pocket mold wireless electrocardio supervisory equipment of this invention.
[Drawing 2] It is the block diagram which constitutes the pocket mold wireless electrocardio supervisory equipment of this invention.
[Drawing 3] It is the perspective view of the breastplate wireless electrocardiograph of this invention.
[Drawing 4] It is the block diagram which constitutes the breastplate wireless electrocardiograph of this invention.
[Drawing 5] It is the perspective view of the satellite communication converter of this invention, and an exclusive parabolic antenna.
[Drawing 6] It is the block diagram which constitutes the satellite communication converter of this invention.
[Description of Notations]
1 Pocket Mold Wireless Electrocardio Supervisory Equipment
2 Body
3 Belt
4 Antenna
5 LCD
6 Loudspeaker
7 Microphone
8 Mode Switch
9 Configuration Switch
10 Alarm Reset Switch
11 Backup Light Switch
12 Electric Power Switch
13 Luminescence Lamp
14 Data Transceiver Section
15 FM Wave Receive Section
16 CPU
17 LCD Actuator
18 Data Memory Section
19 Timer Section
20 Voice Output Section
21 Voice Input Section
22 Vibrator
23 Interface Section
24 Power Supply Unit
25 Dc-battery
26 Breastplate Wireless Electrocardiograph
27 Body
28 Belt
29 Antenna
30 Fixed Part
31 Electric Power Switch

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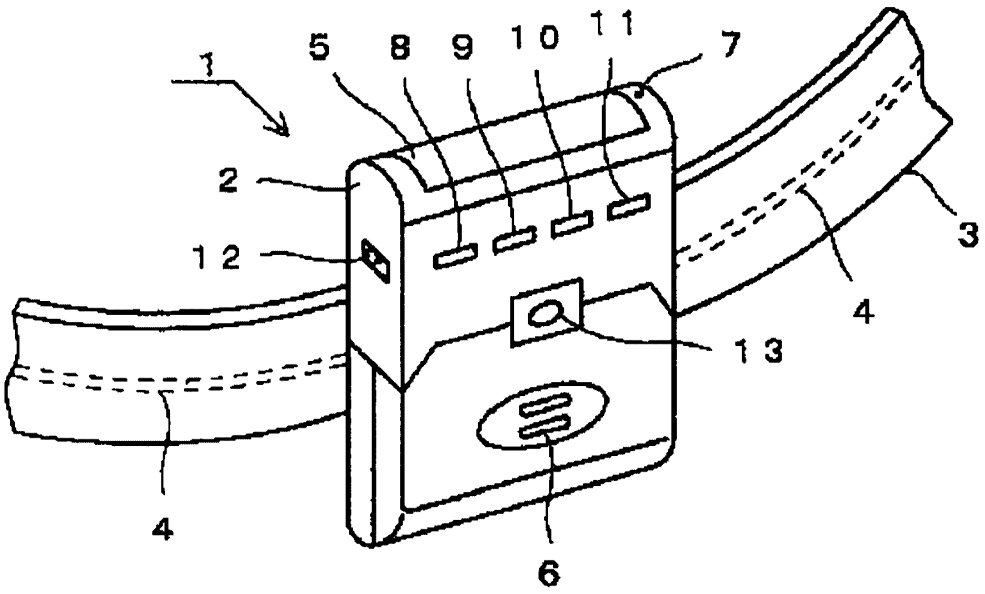
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34 Timer Section
35 Vibrator
36 Interface Section
37 Power Supply Unit
38 Dc-battery
39 Satellite Communication Converter
40 Antenna
41 Mode Switch
42 Monitor Lamp
43 Exclusive Parabolic Antenna
44 Reflector
45 Waveguide
46 Stanchion
47 Standing Ways
48 Coaxial Cable
49 Data Transceiver Section
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51 Converter
52 Data Transceiver Section
53 Data Memory Section
54 Timer Section
55 Interface Section
56 Power Supply Unit
57 Dc-battery

[Translation done.]

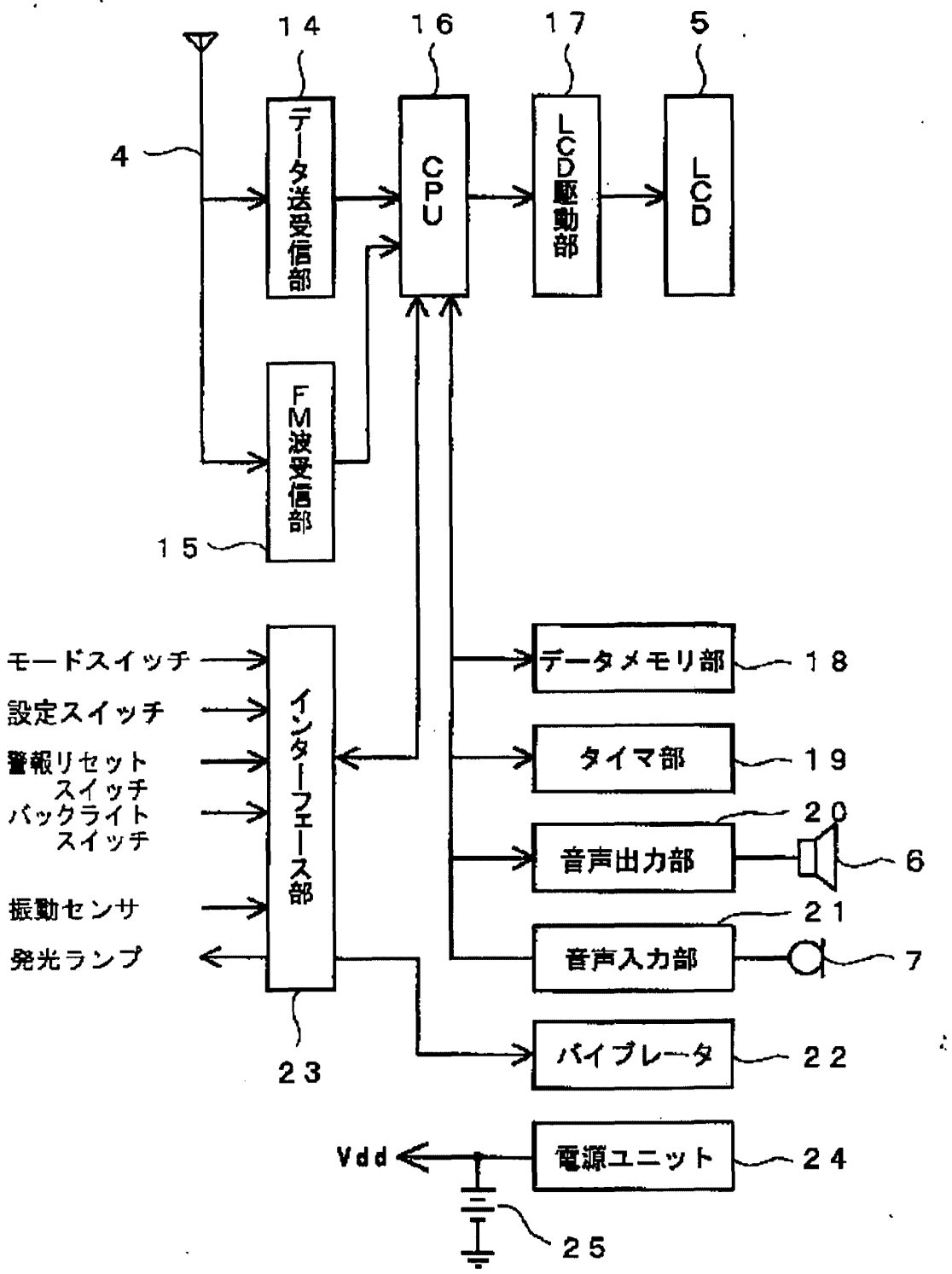
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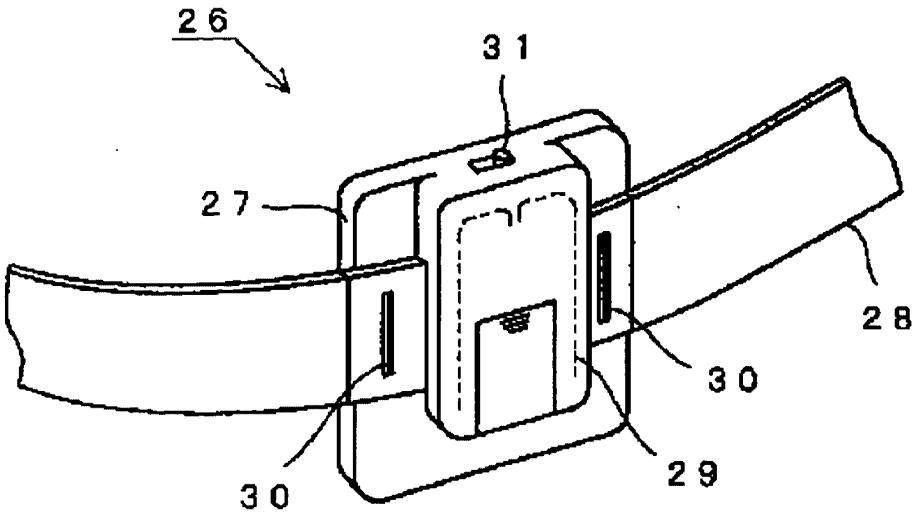
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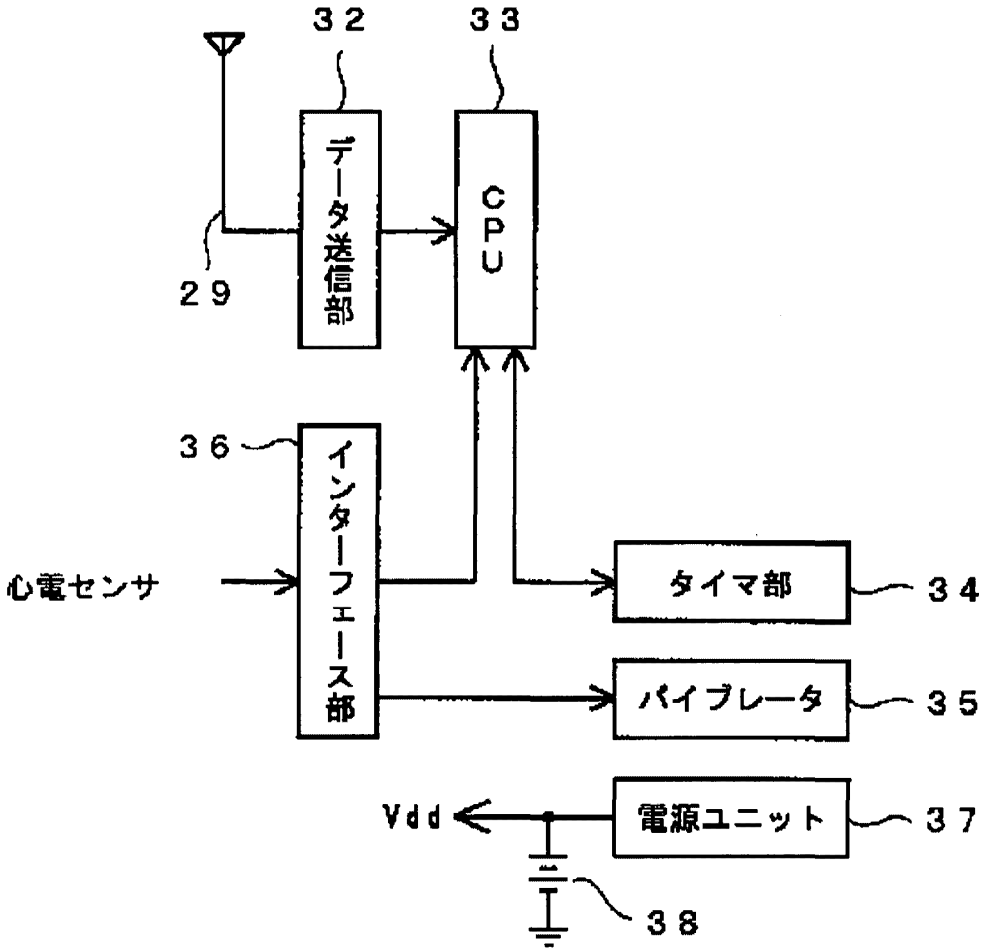
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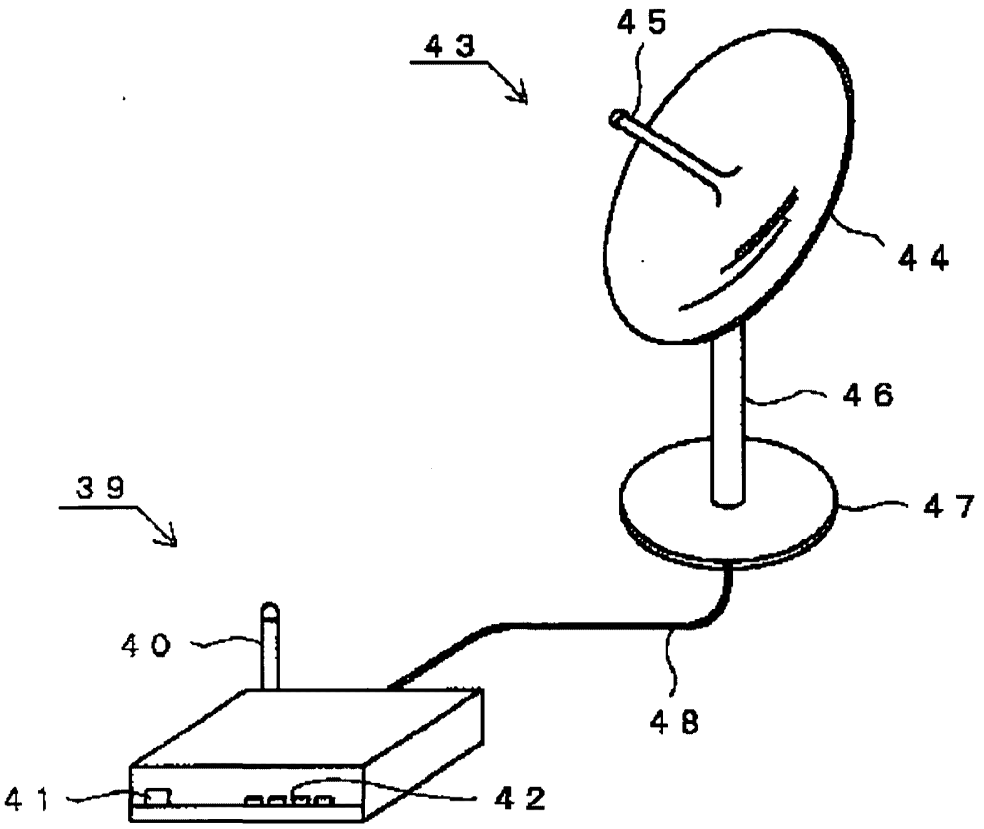
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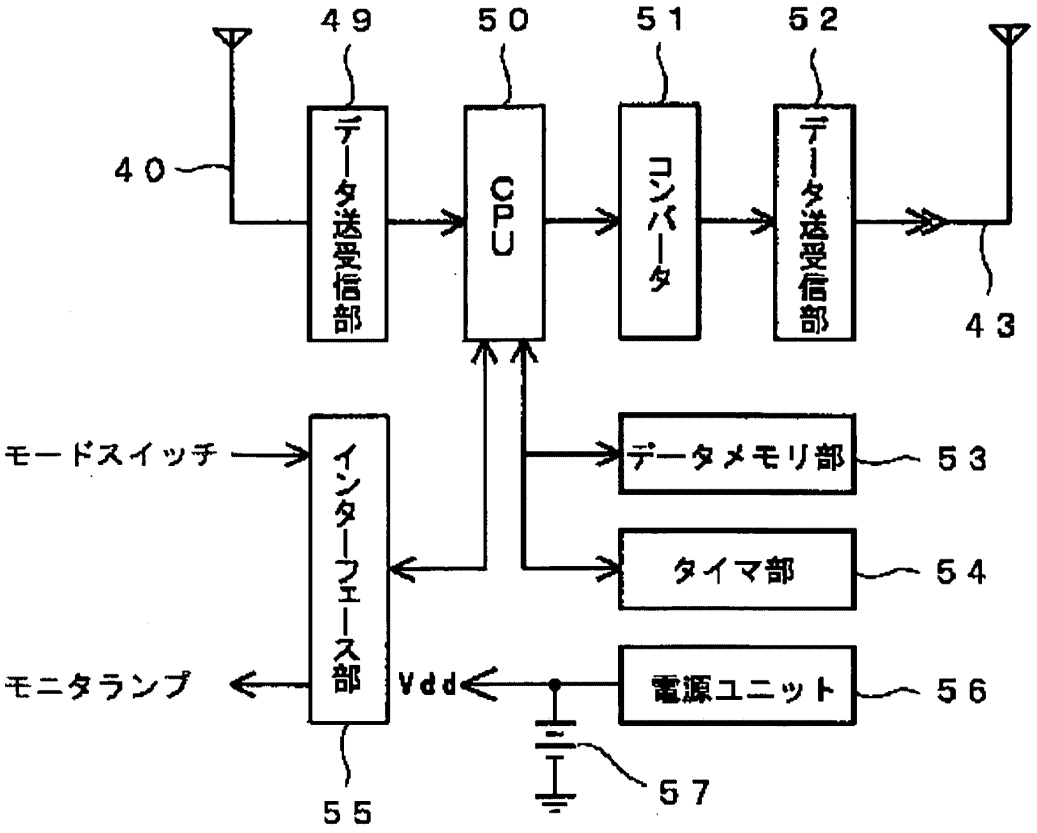
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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 910 985 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
28.04.1999 Bulletin 1999/17

(51) Int. Cl.[6]: **A61B 5/0408**

(21) Application number: **97308319.9**

(22) Date of filing: **20.10.1997**

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE
Designated Extension States:
AL LT LV RO SI

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(54) Electrocardiograph bioelectric interface system and method of use

(57) A bioelectric interface (3) provides three Einthoven triangle equivalent lead forming electrodes positioned on a subject's chest so as to provide a Wilson common terminal (WCT) voltage essentially equivalent to that provided by an Einthoven triangle formed using leads positioned conventionally on a subject's limbs. Wilson common terminal (WCT) forming resistors can be of fixed values or variable to allow adjustment of a produced Wilson common terminal (WCT) voltage. Additional precordial electrodes are also typically present. Electrodes can consist of single elements or groups of electrode elements, and are present in locational regions of the bioelectric interface (3) which allow a single size system to fit to patients with various sized bodies. The presence of an "undulated" outer periphery bounbary (UOPB) comprised of a plurality of curves facilitates conformation to a subject's body, and removal of the bioelectric interface (3), in use.

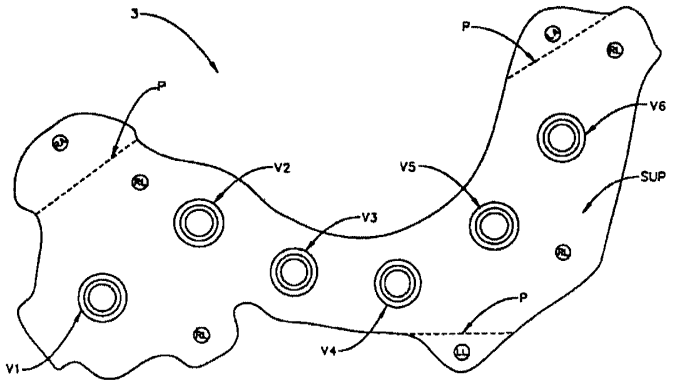


FIG. 7c

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Description

TECHNICAL FIELD

[0001] The present invention relates to systems of electrodes for use in bioelectric interfacing. More particularly, the present invention is a system, and method of use, which provides all electrodes required by electrocardiograph systems, including equivalent Einthoven triangle limb electrodes, on a common subject chest mounted support sheet.

BACKGROUND

[0002] Conventional medical analysis and therapy often involves use of a plurality of individual electrodes, each applied independently to an appropriate location on a subject's body by way of electrically conductive paste, and securing means such as a skin compatible adhesive. A relevant example of use is in the monitoring of Electrocardiogram (ECG) signals at precordial; and at left and right arm, and left leg locations by independent electrodes in an Einthoven triangle configuration.

[0003] Further, it is known to apply individual non-invasive precordial electrodes to a subject's chest to allow not only the acquiring of ECG data, but to allow defibrillation of fibrillating hearts and to allow the pacing of arrested hearts and the like.

[0004] A problem which presents in the use of such independent electrodes, however, is that reliable, repeatable placement upon a subject's body is difficult. For instance, it is generally accepted that a majority of the errors encountered in acquiring ECG data is caused by improper electrode placement by medical technical staff.

[0005] Of relatively recent development are flexible electrode pads which comprise a multiplicity of electrodes affixed thereto in an appropriate pattern for use in medical analysis and/or therapy. For instance, a Patent to Manoli, No, 4,583,549 describes an ECG electrode pad in which six conductive discs are plated and etched on a flexible adhesive pad in a clinically conventional predetermined pattern effective for precordial ECG electrode placement. Reproducible attachment of said six electrodes to a subject's chest in the proper arrangement for use with standard ECG machines is thus made possible by a single application of an electrode pad of an appropriate size for use with any subject. However, it would seem that the Manoli system would require a host of numerous sized electrode pads to accommodate subjects of different sizes as the Claims recite rather strict electrode placement criteria which are referenced with respect to a subject's body. A single electrode pad would not meet said requirements on subjects of different sizes. A Patent, No, 4,121,575 to Mills et al. describes a multiple electrode device for application to a subject's chest, formed in stretchable non-conductive material having apertures in the V1-V6 positions. The capability for stretching the material is held to allow accurate positioning of V1-V6 electrodes on subjects of differing body size. A Patent to Groeger et al., No. 4,957,109 describes an electrode assembly comprising right and left arm and leg leads, and precordial leads all affixed to a common structure. The arm and leg leads do not affix to a subject's chest during use. The Mills et al. and Groeger et al. systems do not serve to maintain a relatively fixed positioning of electrodes therein during use, and it is noted that movement between electrodes during use frequently causes confounding noise generation in electrocardiography systems. Another Patent, No. 5,327,888 to Imran describes a precordial electrode strip which is supplied with detachable RA, LA and LL limb leads, which detachable limb leads are applied to subject limbs in use.

[0006] Patents to Way et al., Nos 4,955,381 and 5,080,099 describe multiple conductive polymer pad containing electrodes for performing multiple electrical physiological functions from a set of electrodes with respect to a subject, at or about the same time, such as defibrillation, pacing and monitoring. Other Patents which disclose multiple electrode assemblies are Patent No. 4,328,814 to Arkans and Patent No. 5,191,886 to Paeth et al. These Patents each describe a plurality of electrodes configured in a physically seriesed configuration with conductive leads to various physically seriesed contacts, present at one end thereof. In addition, a Patent to Collins, No, 3,612,061 describes a porous sheet of elastic material which supports an array of electrodes adapted to contact a wearer's skin, and Patent No. 5,184,620 to Cudahy et al. describes an electrode pad system comprised of a multiplicity of electrodes which are utilized in defibrillation and pacing scenarios as directed by an on-line computer driven analysis and electrical energy application system, which system distributes electrical energy to appropriate sets of said multiplicity electrodes in response to subject needs.

[0007] Continuing, it is to be understood that particularly appropriate materials in which to form an electrode pad with a plurality of ECG monitoring electrodes present therein are hydropolymers. This is because hydropolymers can be pliable, self-adhesive and compatible with maintaining the requisite hydration of subject skin to which they affix during prolonged use. The pliable property makes hydropolymers exceptionally well suited for application to unpredictable irregularities of various subject's chests and the self-adhesive property negates the need to apply adhesive material to affix the present invention to a subject's body during use. As well, the need to apply electrically conductive paste to electrically conducting areas of electrodes becomes unnecessary.

[0008] A Patent, No. 5,331,959 to Imran, describes a low impedance dry conforming contact member in which are present rods or filaments which are cured into material such as a silicon-based material, such that

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when configured as an electrode provide impedance reducing projections which protrude into the pores of a subject's skin during use. Said rods or filaments reduce the need to use conductive paste. Another Patent, No. 4,524,087 to Engel, describes a conductive electrode application comprising an adhesive, swellable, dermally-nonirritating, conformable, ionic hydropolymer biomedical electrode fabricated by a claimed process.

[0009] Continuing, three Patents to Keusch et al, Nos. 4,706,680, 4,989,607 and 5,143,071 describe hydrogels which are caused to be highly conductive by the inclusion of an essentially uniformly distributed active electrolyte therein. Said Patents state that to form the hydrogels a polymeric mixture is caused to become cross-linked by exposure to radiant energy. This causes a gel-like solid to form which is sufficiently tacky and adhesive to adhere to subject's skin and which is substantially non-stringy and non-aggressive so that subject comfort is protected.

[0010] A Patent to Highe et al., No 5,289,822 describes an electrode formed of a dry-conductive material having an outer surface for placement in contact with a subject's skin. A composition is deposited on at least a portion of the surface of the dry-electrode which comprises a plurality of water-containing vesicles. The purpose of said water-containing vesicles being to effect an immediate lowering of subject skin resistance upon the application of the electrode. It is stated that a period of approximately four minutes is otherwise required for moisture from a subject's skin to naturally occur at the electrode.

[0011] A Patent to Schmid, No. 5,124,107 describes a process for manufacturing a body electrode which comprises one or more galvanically active sensors which are combined with a first layer capable of adhering to a subject's skin, on a body contact side thereof. A second covering or supporting layer is also present on the opposite side of the body electrode. The process for manufacture provides that the two layers are sequentially cast in a mold which provides intended shape and size. The procedure avoids manufacturing problems encountered where electrodes are stamped from a preformed sheet. A potential problem of using such an electrode as provided by the Schmid 107 Patent is that it provides a laterally oriented conductive path between said galvanically active sensors through the first layer thereof. Electrically anisotropic conducting hydropolymers would be preferable.

[0012] Continuing, a Patent to Suyama et al, No. 5,132,058 describes a process for producing an anisotropically electroconductive sheet having a plurality of electroconductive portions extending in the direction of the thickness of the sheet. Application of an anisotropic magnetic field is utilized to draw electroconductive particles into a molding material such that said electroconductive particles gather where said electromagnetic field is applied. Another Patent which describes a similar system to that achieved by practice of the Suyama et al. Patent is No. 4,778,635 to Hechtman et al. A Patent to Kashiro et al,. No. 4,209,481 describes an anisotropically electroconductive sheet in which electroconductive wires are formed into patterned groupings, which patterned groupings are in turn formed into patterns. The wires are parallel in the direction of the sheet thickness, and spaced apart by non-electroconductive elastomer. Another Patent, No. 5,045,249 to Jin et al., describes electrical interconnections made by means of a layer or sheet medium comprising chains of magnetically aligned, electrically conductive particles in a non-conducting medium. End particles of chains protrude from a surface of the medium to effect electrical contact. A Patent to Abraham et al. describes an electrode for use with electrosurgical apparatus which provides capacitive coupling with the skin of a subject. The electrode includes a conductive plate connected to the electrosurgical apparatus with an insulating layer disposed in contact with the conductive plate and on the opposite face of the insulator there is provided conductive material in the form of a plurality of discrete islands of conductive adhesive material which contact the skin of a subject during use. Another Patent, No. 5,232,639 to Reitz et al. describes a process for forming articles with anisotropic void distributions therein.

[0013] It is also established that electrode configuration can be important in determining the accuracy of monitored signals. For instance, the use of a Bulls-eye shaped electrode, which comprises a central electrode surrounded by one or more annular ring electrodes, can provide signals which focus upon a specific region of a subject's heart, which focus is not available when a simple electrode geometry is utilized. As well, Bulls-eye shaped electrodes allow determination of derivatives of detected signals in use.

[0014] An article by He et al. titled "Body Surface Laplacian Mapping of Cardiac Electrical Activity" published in The American J. of Cardiology, Vol. 70, Dec. 15, 1992 describes the use of Bulls-eye shaped electrodes to map derivatives of cardiogenic signals.

[0015] Patents which describe unusual geometrical electrode configurations are, for instance, a Patent to Clare et al., No. 5,295,482 which discloses a large surface area electrode in which a central portion is surrounded by two surrounding ring portions., said central and two surrounding ring portions being separated from one another by annular regions. This Patent states that during use current density is found to be greater at the outer edge of an electrode than it is at a more central location. The purpose of the described system is disclosed as being to effect a more uniform distribution of current density over the effective large surface area of the disclosed electrode during use, by providing multiple "outer-edge" providing portions. Other references which describe the "edge-effect" are a Patent to Dahl et al., No. 5,063,932 and a Canadian Patent No. 1,219,642. In addition, two articles also treat the subject, said articles being: "Optimal Electrode Designs for

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Electrosurgery, Defibrillation, and External Cardiac Pacing", by Kim et al., which appeared in Transactions On Biomedical Engineering, Vol. BME-33, No. 9, September 1986; and "Analysis and Control of the Dispersive Current Distribution under Circular Dispersive Electrodes", by Wiley and Webster, which appeared in the IEEE Transactions On Biomedical Engineering, Vol. BME-29, No. 5, in May 1982.

[0016] Even in view of the above cited literature, need remains for a convenient to utilize bioelectric interface which is suitable for application to subjects of differing body sizes, which bioelectric interface comprises equivalent Einthoven triangle limb electrodes on a common subject chest mounted support sheet, which preferably comprises an electrically anisotropic conducting hydropolymer self adhesive material, which provides electrodes of a geometry appropriate for optimizing electrical contact to a subject, which allows accurately monitored signals to be obtained thereform during use, and which facilitates external cardiac pacing, cardiac defibrillation, electro surgery, electro-ablation processes, and impedance cardiography.

DISCLOSURE OF THE INVENTION

[0017] The present invention concerns the practice of electrocardiography wherein a number of electrical signals, which are diagnostic of myocardial function, are acquired via electrodes placed upon a subject's body. As regards this use, subject contacting electrodes can be spatially oriented in lead configurations such as Einthoven triangle, Frank, McFee, Schmidt, twelve-lead configurations etc., and in array patterns for use in mapping, etc. The present invention bioelectric interface is a system which provides Right-Arm (RA), Left-Arm (LA) and Left-Leg (LL) electrodes which form, when applied to a subject's chest in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern, said pattern being determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. The present invention bioelectric interface further provides all necessary electrodes, appropriately configured for mounting to a subject's chest, for use with electrocardiograph systems.

[0018] As demonstrated in the Background Section of this Disclosure, multiple electrode systems are not unknown. However, said known systems do not provide all electrodes for use with a twelve-lead electrocardiogram (ECG) system conveniently positioned on a bioelectric interface which can be easily, accurately and repeatably applied to a subject's chest in a desired anatomical orientation. A twelve-lead (ECG) system, by conventional practice, requires that electrodes be placed on a subject's Right (RA) and Left (LA) arms and Left leg (LL), and that six precordial electrodes (V1, V2, V3, V4, V5, and V6), be placed upon the subject's chest. The locations of the V1-V6 electrodes are:

V1--in the region of the fourth intercostal space at the right sternal border;
V2--in the region of fourth intercostal space at the left sternal border;
V4--in the region of fifth intercostal space at the left mid-clavicular line;
V3--in the region of the midpoint between the V2 and V4 electrodes;
V5--in the region of the fifth intercostal space at the left anterior axillary line;
V6--in the region of the fifth intercostal space in the left mid-axillary line.

[0019] No known reference, however, suggests that arm and leg equivalent electrodes should be placed at chest locations relatively near the precordial electrodes. The present invention teaches that said arm and leg equivalent electrodes are to be so placed. The location of said arm and leg equivalent electrodes is best understood by reference to the Drawings which are discussed in the Detailed Description of this Disclosure, however, verbally their positioning can be generally described as:

Right Arm--generally in the region of the second intercostal space to the right of the sternum;

Left Arm-generally in the region of left fourth intercostal space at the mid-axillary line; and

Left Leg--generally in the region of the inferior costal margin in the left mid-clavicular line.

[0020] In addition, the present invention teaches the optional use of multiple electrode element electrodes, (eg. "Bulls-eye" shaped electrodes), for instance, in a multiple electrode element electrode system. Use of single electrode element "Button" electrodes is conventional, and in use each such Button electrode serves to measure an electrical signal between it and a common or reference electrode, (typically termed uni-polar electrodes), or a smaller button electrode (typically termed Bi-polar electrodes). When multiple electrode element (eg. Bulls-eye), electrodes are utilized, however, signals are generated between two components of a single electrode. Continuing, a Bulls-eye shaped electrode is typically configured like a "target". That is, typically a Button electrode will be centrally located within an outer annular shaped electrode. The benefits provided by such, multi-electrode element electrodes are the ability to achieve greater resolution of signals generated in a specific area of a subject's heart, and it is noted, that the signals measured are representative of the derivatives of electrical signal activity produced by a subject's

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heart. That is, the signal provided between a Button and First Annulus is proportional to a derivative of a signal generated by a subject's heart. Additional annular ring electrodes can also be present and signals measure thereby are proportional to higher order derivatives. Use of Bulls-eye" electrode geometry then allows investigation of High Frequency aspects of electrical activity generated by a subject's heart. It is noted that a limitation is associated with the use of Bulls-eye electrodes in that the smaller they are dimensioned, although enabling increased resolution and investigation of electrical signals generated in smaller regions in a heart, the smaller the magnitude of signal they provide. In a multiple electrode setting then, where relative motion between electrodes can create confounding electrical noise, it than becomes increasingly important to prevent relative motion between electrodes and components of Bulls-eye electrodes, when Bulls-eye electrodes are present. (Note, it is emphasized that it is possible to achieve a result similar to that provided by "Bulls-eye" electrodes with outer multiple element electrodes, and for the purposes of this Disclosure any functionally similar electrode is to be considered as included by the terminology "Bulls-eye" whether a closed annulus is present or not).

[0021] It is also to be understood that a present invention electrode can consist of a plurality of electrode elements, (eg. a plurality of button shaped electrode elements), configured in a region of the bioelectric interface which, in use, aligns with an anatomical location appropriate for use in a twelve-lead (ECG) system.

[0022] With the forgoing in mind, it is then to be appreciated that the system of the present invention is a bioelectric interface comprised of a plurality of electrodes which are affixed to a support sheet in a desired spatially separated pattern, such that in use said electrodes are essentially fixed in location with respect to one another. It is noted that fixing said relative position between electrodes, and between electrode elements, serves to reduce electrical noise which can be generated when, in use, electrodes move with respect to one another. Again, it is to be understood that the electrodes can be of single electrode element, or multiple electrode element Button or Bulls-eye, (or other), geometry.

[0023] Continuing, a typical present invention bioelectric interface has an adhesive material present over at least a portion of a surface thereof which contacts a subject in use. The adhesive material of the present invention can have the properties of simultaneously demonstrating essentially electrically anisotropicity, but isotropic mechanical (eg. pliability and adhesion), properties. That is, the specific impedance across the adhesive material can be significantly different from that laterally directed, but the mechanical properties such as adhesion and pliability are typically essentially consistent. (Note, the term "specific impedance" is used to refer to the regional bulk property of the adhesive material, rather than properties resulting from dimensions of sheets fabricated therefrom). In the preferred embodiment, the adhesive material is a hydropolymer sheet which demonstrates a tackiness on a subject skin contact side thereof. Hydropolymers are particularly applicable in realization of the present invention as they are electrically conductive, relatively nonirritating to a subject's skin, and they demonstrate excellent adhesive qualities. Commercially available hydropolymer sheets with isotropic electrical properties, are available from Promeon of Boston, MA under the product designation RG-60 Series Hydrogels. Lec-Tec of Minneapolis, MN also markets hydrogels. The present invention provides that such adhesive hydropolymer sheet material can be utilized, if "slits" or hydropolymer discontinuity effecting "voids", are entered thereto at appropriate locations to effect electrical anisotropicity between electrodes present at various laterally offset locations. It is noted that hydropolymer sheets do not typically demonstrate a rigidity sufficient to maintain a spatially stable relationship between electrodes affixed thereto, but particularly when slits and/or voids are formed therein, hence, the present invention requires that a support sheet carrier matrix be present to which electrodes and said adhesive sheet attach. That is, the system of the present invention will then comprise a support sheet carrier matrix to which are attached, at desired spatially offset locations, electrodes, over which configuration said hydropolymer is placed so that said electrodes are sandwiched between sand carrier matrix and hydropolymer. At locations between the various electrodes said "slits" and/or "voids" are then caused to be present by, typically, a mechanical process. It is noted that in practice said "slits" need not be of a degree to provide complete discontinuity between various regions of the resulting hydropolymer system to provide a sufficiently anisotropic specific impedance system, but that use of disconuity affecting "voids" is within the scope of the present invention. The Background Section also identifies various electrically anisotropic adhesive materials. The present invention, in addition, teaches that an essentially electrically anisotropic adhesive material sheet can be provided by a "Scrim" material comprising a number of channels therethrough, which channels are caused to be filled with an electrically conductive adhesive material, (preferably a hydropolymer), such that "island channels" of conductive material exist across the resultant sheet, but such that electrically nonconductive scrim exists between laterally oriented islands of conductive material. The "Scrim" can be electrically conductive carbon fibers, and/or electrically non-conducting plastic filaments, as required to provide a desired electrical anisotropicity.

[0024] Continuing, the present invention, in its preferred embodiment, teaches that one size of multiple electrode bioelectrical interface should be sufficient for use with all subjects, regardless of body size. The present invention teaches that do accomplish placement of electrodes, such as defined infra for twelve-lead systems, on subject's bodies of various size, that

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groups of electrode elements should be available in the region of for instance, the fourth intercostal space at the right sternal border, (ie. the location for a V1 lead). In use then, regardless of a subject body size, one electrode element in a group of electrode elements in the region of the fourth intercostal space at the right sternal border, will provide an optimum result. Which electrode element in a group of electrode elements provides said optimum result, will of course be subject specific. Prior art has failed to recognize the need to provide a group of electrode elements in the region of a specific electrode placement location so that a user can select, manually or automatically, an appropriately placed electrode element for a specific subject.

[0025] It is also noted that as the relative spatial separation of various electrodes is essentially fixed by the present invention, and as their position on a subject's body is typically secured by an adhesive sheet, is it possible to conduct activities such as cardio-pulmonary-resuscitation (CPR) on a subject to which the present invention bioelectric interface is applied, without removal thereof. Such is essentially impossible where individual leads are utilized in an (ECG) system. As well, the present invention teaches that the means for making electrical contact to the electrodes should be available on the outer, non-subject contact, surface of the bioelectrical interface. For instance, snaps might be provided so that leads from any (ECG) system can easily attach thereto, or so that conductive tracks can be employed to bring signals to a manifold or connector means for convenient electrical access.

[0026] It is also emphasized that the electrodes in the bioelectric interface, being electrically conductive, enable, in an emergency, the application of defibrillation paddle-type electrodes to said interface means for making intimate electrical contact to said electrodes without removing the present invention bioelectrical interface from the subject. And, because the present invention is firmly affixed to a subject, the defibrillation shock will be safely transmitted to the subject with little, or no attenuation. It is also emphasized that in use, first and second conventional paddles of a defibrillation system can be caused to contact first and second spatially separated groups of electrodes in the bioelectric interface, press contacted electrodes into good electrical contact with the subject, and deliver electrical defibrillating pulse energy therethrough. Further, the presence of multiple electrodes, (and even multiple electrode elements within an electrode), within a defibrillation paddle-sized cluster of electrodes, through which defibrillation electrical energy can be delivered to a subject, serve to reduce adverse edge effects associated with applying defibrillation electrical energy through single element paddle, (or pad), electrodes. Special electrodes can be specifically designed which serve to reduce edge effects, and use thereof in the present invention Bioelectric interace is within the scope of the present invention.

[0027] One can also utilize one or more electrodes in the present invention bioelectric interface for heart pacing, electrosurgery, electro ablation and impedance cardiography.

[0028] The present invention bioelectric interface can be better described, in its most basic form, as comprising a support sheet in functional combination with at least three (3) spatially separated electrocardiogram system electrodes, with each of said at least three (3) spatially separated electrocardiogram system electrodes being a single electrical electrode element or a group of electrically independent electrode elements. Each of said spatially separated electrocardiogram system electrodes is affixed to said support sheet in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin. Three (3) of said at least three (3) electrocardiogram system electrodes being configured in an RA, LA, LL electrocardiogram system electrode pattern. The positioning of said three (3) electrocardiogram system electrodes as applied to a subject's chest during use can be described as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

[0029] Further, said electrodes RA, LA and LL form, when applied to a subject's body in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern which is determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. Said user selected range of voltage deviation can be selected to be less than one (1.0) millivolt, one (1.0) millivolt, or greater than one (1.0) millivolt.

[0030] The present invention bioelectric interface can further comprise an equivalent electrocardiogram system RL electrode, and said RA, LA, LL and RL electrodes can be present in the support sheet such that performations allow easy detachment of said equivalent electrocardiogram RA, LA, LL and RL electrodes, in use, thereby allowing them to be automatically positioned at a location in contact with a subject's chest, or by manual manipulation, in conventional subject limb positions.

[0031] The present invention bioelectric interface sup-

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port sheet is typically at least partially covered with an adhesive material on a subject contacting side thereof, and said adhesive material can present with electrical conductive properties which can be isotropic, or regionally anisotropic such that the specific impedance through said adhesive material is less that in a laterally oriented direction. Said regional anisotropic electrical conductive properties of said adhesive material can be effected, as described infra herein, by the presence of an electrically conductive and/or nonconductive scrim patterned therein so as to form channel regions of electrically conductive adhesive material through said adhesive material bordered by said scrim material, such that adhesive material in one channel region does not contact that in other regions. An alternative approach to effecting said regional anisotropic electrical conductive properties of the adhesive material involves the placing of slits and/or voids therein. Said adhesive material can be a hydropolymer and it can be caused to cover essentially the entire subject contacting surface of said support sheet.

[0032] As mentioned, at least one of said spatially separated electrocardiogram system electrodes can be of a construction consisting of a group of electrically independent electrode elements, and said elements can be configured in, for instance, Bulls-eye and multiple button shaped electrode elements patterns.

[0033] It is further disclosed that the present invention bioelectric interface can present with "holes" therethrough in regions between spatially separated electrodes so as to allow viewing of, and access to a subject's skin. As well, the outer edge of the present invention can have an "undulated" shape which can be described as a series of "curved tabs". As used here, the term "undulate" means an essentially repeating curved shape effected upon an outer edge of a present invention bioelectric interface, which undulated shape is not absolutely necessary, and the benefits of which are not, without trial an error experimentation, readily obvious. It has been found by the Inventor, however, that said present invention bioelectric interface outer edge shape allows achieving better conformation to a subject's body in use, and facilitates easy removal of a present invention bioelectric interface from a subject's body, by allowing relatively easy grasping of a "curve tab" between a thumb and first fingers. That is, where an outer edge of a present invention bioelectric interface does not have an "undulated", plurality of "curved tabs" shape, removal of a present invention bioelectric interface has been found to be more difficult.

[0034] A prefered bioelectric interface embodiment comprises a support sheet in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially spearated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements). Each of said spatially separated electrocardiogram system electrodes is affixed to said support sheet in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin. Nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern, such that said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as recited infra herein. Said prefered bioelectric interface further comprises an electocardiogram system RL electrode; and additionally further comprises perforations in said support sheet which allow easy detachment and deployment of at least one of said electrocardiogram RA, LA, LL and RL electrodes, thereby allowing positioning at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position). Said prefered embodiment further includes a fold enhancing impression and/or perforations located between at least two electrodes selected from the group consisting of: (V1 and V2; V2 and V3; V3 and V4; V4 and V5; V5 and V6; RA and V1; V4 and LL; LA and V6). As with other embodiments said prefered embodiment support sheet is at least partially covered with an adhesive material on a subject contacting side thereof, and said adhesive material can present with electrical conductive properties selected from the group consisting of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that the regional specific impedance through said adhesive material is less than in a laterally oriented dimension direction therealong). As well, said adhesive material can be selected from the group consisting of: (hydrophillic and non-hydrophillic). Said prefered embodiment can further comprise at least one hole present through said support sheet at a location between electrodes, which hole allows access to a subject's skin in use, and at least one hole can be present at a location selected from the group consisting of: (the level of the second intercostal space adjacent to said RA electrode, and the level of the fourth intercostal space adjacent to said V1 electrode, and between said RA and V2 electrodes, and between said V4 and V5 electrodes). Said prefered embodiment has a fold enhancing impression and/or perforations located between V3 and V4 electrodes, and between RA and V1 electrodes, and an undulated outer perimeter boundary shape.

[0035] A method of providing an Einthoven triangle equivalent RA, LA, LL pattern of electrodes on the chest of a subject, utilizing the present invention bioelectric interface, can comprise the steps of:

a. Providing a present invention bioelectric interface comprising a support sheet in functional combination with at least three (3) spatially separated electrocardiogram system electrodes as already

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described, wherein at least one (1) of said at least three (3) spatially separated electrocardiogram system electrodes is of a construction consisting of a group of electrically independent electrode elements. As described above, each of said spatially separated electrocardiogram system electrodes is affixed to said support sheet in a manner such the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin. Three (3) of said at least three (3) electrocardiogram system electrodes are configured in an RA, LA, LL electrocardiogram system electrode pattern, such that said three (3) electrocardiogram system electrodes are applied on a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

Also as described above, said electrodes RA, LA and LL form, when applied to a subject's body in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern which is determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. Said user selected range of voltage deviation can be selected to be less than one (1.0) millivolt, one (1.0) millivolt, or greater than one (1.0) millivolt;

b. Applying said bioelectric interface to a subject;

c. Selecting at least one electrically independent element in each of said at least one electrocardiogram system RA, LA and LL electrode(s) consisting of a group of electrically independent electrode elements;

d. Connecting said selected electrocardiogram system electrically independent element(s) in each of said RA, LA and LL electrode(s) to appropriate inputs of an electrocardiogram system.

[0036] Continuing, a preferred embodiment of the present invention bioelectric interface comprises a support sheet in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes. Each of said at least nine (9) spatially separated electrocardiogram system electrodes being a single electrical electrode element or a group of electrically independent electrode elements. Each of said spatially separated electrocardiogram system electrodes is affixed to said support sheet in a manner such the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, with nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern. In use, said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

Said electrodes RA, LA and LL form as described infra herein, when applied to a subject's body in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern which is determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. Said user selected range of voltage deviation can be selected to be less than one (1.0) millivolt, one (1.0) millivolt, or greater than one (1.0) millivolt.

[0037] The V1, V2, V3, V4, V5, V6 electrocardiogram system precordial electrode pattern is formed as:

electrode V1 in the region of the fourth intercostal space at the right sternal border;

electrode V2 in the region of the fourth intercostal space at the left sternal border;

electrode V4 in the region of the fifth intercostal space at the left mid-clavicular line;

electrode V3 in the region of the midpoint between electrode groups V2 and V4;

electrode V5 in the region of the fifth intercostal

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space in the left anterior axillary line; and

electrode V6 in the region of the fifth intercostal space in the left mid-axillary line.

[0038] The described preferred embodiment of the present invention can also further comprise an equivalent electrocardiogram system RL electrode, and perforations can be present in said support sheet to allow easy detachment and deployment of said equivalent electrocardiogram RA, LA, LL and RL electrodes, in use, so that they can be positioned in contact with a subject's chest, or in conventional subject limb position.

[0039] As described above, the presently described present invention bioelectric interface support sheet is also typically et least partially covered with an adhesive material on a subject contacting side thereof, which adhesive material presents with electrical conductive properties which can be isotropic or regionally anisotropic such that the specific impedance through said adhesive material is less than that in a laterally oriented direction. As also already discussed, a preferred adhesive material is hydropolymer which covers essentially the entire subject contacting surface of said support sheet.

[0040] Also as discussed above, each of the electrodes can be of a construction consisting of a group of electrically independent electrode elements, such as a Bulls-eye pattern, and multiple button shaped electrode elements.

[0041] A method of acquiring electrocardiographic data can comprise the steps of:

a. Providing a bioelectric interface comprising a support sheet in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, as just described;

b. Affixing said bioelectric interface to a subject as described above, and causing electrodes therein to be electrically attached to an electrocardiographic system such that familiar electrocardiographic data is obtained.

[0042] Said method of acquiring electrocardiographic data said method of acquiring electrocardiographic data can further include the step of removing and deploying said electrodes RA, LA and LL configured in an Einthoven frontal triangle equivalent LA, RA, LL pattern, utilizing perforations in said support sheet, and affixing said RA, LA and LL electrodes to conventional subject limb locations.

[0043] A method of utilizing any present invention bioelectric interface during formation of an Einthoven triangle equivalent or during acquisition of electrocardiographic data, can further comprise the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation

b. cardiac defibrillation;

c. cardiac pacing;

d. electro surgery;

e. electro-ablation; and

f. impedance cardiography.

on said subject without removing said bioelectric interface.

[0044] Where defibrillation is performed, two conventional defibrillation paddles are positioned so that a first conventional defibrillation paddle contacts at least two of said electrocardiogram system electrodes, and a second said conventional defibrillation paddles contacts at least two of said electrocardiogram system electrodes, said two at least electrodes contacted by said first conventional defibrillation paddle being different than, and spatially separated from, said at least two electrodes contacted by said second conventional defibrillation paddle. In use, electrodes contacted by defibrillation paddles are caused to be pressed firmly into good contact with a subject. The result of the presence of multiple electrodes being that defibrillation pulse current distribution electrode edge effects are reduced.

[0045] It is further noted that the voltage present at a formed Wilson common terminal can be a root-mean-square value of a selected portion of a subject electrocardiogram system monitored electrocardiogram cycle, such as the QRS complex.

[0046] It is also noted that a conventional Wilson common terminal is a central "Y" interconnection point of fixed value, (eg. 10,000 ohm), resistors attached to RA, LA and LL electrodes. The present invention provides that at least one of said resistors can be variable and can, in use, be adjusted and thereby set a Wilson common terminal voltage produced by use of a present invention Bioelectric Interface, to a desired value. The application of variable resistors in forming a Wilson common terminal in combination with a present invention Bioelectric Interface, to effect production of a Wilson common terminal voltage which is within a desired deviation value with respect to a similar voltage which would be obtained utilizing conventional limb positioned electrodes, is not, to the inventor's knowledge, obviated in any known reference or combination of references.

[0047] Finally, it is noted that it might be possible to configure a Wilson common terminal utilizing two Limb electrodes selected from the group consisting of RA, LA and LL, and a third electrode selected from the group of precordial electrodes consisting of V1, V2, V3, V4, V5 and V6. The present invention includes such a configuration.

[0048] The present invention will be better understood by reference to the Detailed Description Section in conjunction with the accompanying Drawings.

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SUMMARY OF THE INVENTION

[0049] It is a primary purpose of the present invention to teach that electrodes configured in an RA, LA, LL electrocardiogram system electrode pattern in a bioelectric interface should be applied to a subject's chest during use, the positioning of said electrocardiogram system electrodes being:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space at the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

said electrodes RA, LA and LL forming an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern which is determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. (Said user selected range of voltage deviation can be selected to be less than one (1.0) millivolt, one (1.0) millivolt, or greater than one (1.0) millivolt).

[0050] It is another purpose of the present invention to teach that six precordial electrodes (V1, V2, V3, V4, V5, and V6) in said bioelectric interface, should also be placed upon the subject's chest in combination with said RA, LA and LL electrodes. The locations of the V1-V5 electrodes being:

V1--in the region of the fourth intercostal space at the right sternal border;
V2--in the region of fourth intercostal space at the left sternal border;
V4--in the region of fifth intercostal space at the left mid-clavicular line;
V3--in the region of the midpoint between the V2 and V4 electrodes;
V5--in the region of the fifth intercostal space at the left anterior axillary line;
V6--in the region of the fifth intercostal space in the left mid-axillary line.

[0051] It is yet another purpose of the present invention to teach the use of multiple electrode element electrodes, (eg. "Bulls-eye" shaped electrodes), as well as single electrode element "Button" electrodes in a bioelectric interface.

[0052] It is still yet another purpose of the present invention to teach a bioelectric interface which has an adhesive material present over at least a portion of a surface thereof which contacts a subject in use.

[0053] It is yet still another purpose of the present invention to teach a bioelectric interface in which the adhesive material is a hydropolymer.

[0054] It is another purpose of the present invention to teach a bioelectric interface in which the adhesive material demonstrates anisotropic specific impedance, such as effected by the presence of a slit or slits therein.

[0055] It is yet another purpose of the present invention to teach a method of utilizing any present invention bioelectric interface during formation of an Einthoven triangle equivalent or during acquisition of electrocardiographic data, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing;
d. electro surgery;
e. electro-ablation; and
f. impedance cardiography.

on said subject without removing said bioelectric interface.

[0056] It is still yet another purpose of the present invention to teach a bioelectric interface comprised of a plurality of electrodes which are affixed to a support sheet in a desired spatially separated pattern, such that in use said electrodes are essentially fixed in location with respect to one another such that confounding noise signals resulting from relative motion between said electrodes are reduced in use.

[0057] It is another purpose of the present invention to teach the use of variable resistor(s) in formation of a Wilson common terminal. The purpose thereof being to allow adjustment of a voltage appearing at a Wilson common terminal formed utilizing present invention Bioelectric Interface RA, LA and LL electrodes, so that it is within a desired range of deviation from a Wilson common terminal voltage obtained utilizing conventionally placed limb electrodes.

[0058] It is yet another purpose of the present invention to teach the presence of impression(s) and/or perforations in a bioelectric interface to facilitate easy removal of electrodes, (eg. RA,LA, RL and LL), and to make enhance folding capability for packaging, shipping and storage purposes.

[0059] It is another purpose yet of the present invention to teach the presence of holes in, an undulated outer periphery boundary of, a bioelectric interface to enhance conformation to a subject's body contoures in use.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0060]

Fig. 1 shows a side elevational view of a bioelectric interface showing an electrode "sandwiched" by an adhesive sheet and a carrier matrix.

Fig. 2 shows a view of a two electrode bioelectric interface with a common adhesive sheet applied thereto, in which common adhesive sheet is present an electrically anisotropic property causing slit present between.

Figs. 3a and 3b show top and side elevation views respectively of a novel electrically anisotropic adhesive sheet.

Figs. 4a and 4b show various designs for electrodes.

Fig. 4c shows the electrodes of Figs. 4a and 4b sandwiched between a carrier matrix and an adhesive sheet.

Fig. 5a shows a multi-element electrode configured in a Bulls-eye pattern.

Fig. 5b shows a multi-element electrode pattern configured from button electrodes.

Fig. 6a shows a partial frontal view of a human torso, with formation of a Wilson Common Terminal from standard RA, LA and LL electrodes indicated.

Fig. 6b shows a partial frontal view of a human torseau, with formation of an equivalent Wilson Common Terminal indicated, as formed from equivalent RA, LA and LL electrodes of the present invention bioelectric interface.

Fig. 7a shows a bioelectric interface configured for use with a twelve lead (ECG) system. Shown are groups of electrodes which serve to allow a "one-size-fits-all" result. Also shown is an exemplary presence of a multi-element Bulls-eye electrode, and the presence of "slits" in an adhesive sheet to effect electrical anisotropic properties therein.

Fig. 7b shows a bioelectric interface configured for use with a twelve lead (ECG) system. Shown are groups of electrodes made of a plurality of electrode elements as shown in Fig. 5b, which serve to allow a "one-size-fits-all" result. Shown also are perforations in a continuous support sheet for use in detaching leads used in forming an Einthoven triangle equivalent Left Arm, Right Arm and Left Leg pattern.

Fig. 7c shows a bioelectric interface configured for use with a twelve lead (ECG) system. Shown are groups of electrodes made of a plurality of electrode elements configured as shown in Fig. 5a, which serve to allow high frequency investigation and mapping. Shown also are perforations in a continuous support sheet for use in detaching leads used in forming an Einthoven triangle equivalent Left Arm, Right Arm and Left Leg pattern.

Fig. 7d shows a bioelectric interface configured for use with a twelve lead (ECG) system. Indicated are electrodes positioned beneath paddles of a defibrillating system.

Fig. 7e shows a bioelectric interface with an undulated curved tab shaped outer edge in combination with the presence of strategically placed holes through said bioelectric interface.

DETAILED DESCRIPTION

[0061] Turning now to the Drawings, there is shown in Fig. 1 a side elevational cross-sectional view of a single electrode (E) in a bioelectric interface (1) system comprising a Support Sheet (SUP) and an adhesive material (AS). Note that the electrode (E) is "sandwiched" between the Support Sheet (SUP) and adhesive material (AS). This is a typical arrangement, but where an adhesive material can provide sufficient spatial positioning integrity it is to be understood that the Support Sheet (SUP) can become unnecessary.

[0062] Fig. 2 shows a bioelectric interface system (2) comprised of two electrodes (E1) and (E2) looking from the surface thereof upon which is present an adhesive material (AS), (ie. that surface which will contact a subject's skin in practice). Note that a "slit" (S) is shown as present between said electrodes (E1) and (E2). In the case where the adhesive material is made of an electrically isotropic material, (eg. commercially available hydropolymers in sheet form for instance), it has been found that providing a slit (S) between two electrodes (E1) and (E2) effects essentially electrically anisotropic properties thereto. That is, a lower specific impedance will be measured from an electrode through the adhesive material than between two electrodes. In the case that an adhesive material provides such anisotropic electrical specific impedance properties, said slit (S) typically becomes unnecessary. It is noted that the reason the adhesive material should provide anisotropic electrical properties is that in an (ECG) setting, for instance, if the adhesive material is electrically isotropic, signals which should be present in one electrode in a bioelectric interface, will to some extent be present in other electrodes as well, as a result of lateral current flow through said adhesive material, and many prior multiple electrode systems therefore, enter an artifact to (ECG) data as a result. As well, adhesive material elec-

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trical anisotropicity allows use of higher resolution electrode geometry, (discussed supra) because lateral current flow is limited.

[0063] It will he noted that the adhesive material (AS) in Fig. 2 is not completely bisected by the slit (8). This is a preferred, but not limiting practice, because complete electrode isolation is not always optimum. For instance, in (ECG) system settings it is common to inject a noise compensating signal to a Right Leg electrode via a driver circuit, which signal is to be imposed upon all electrodes. This practice is well known by practitioners in the (ECG) field, with noise compensating current flow normally being through a subject's skin, but it has been found that allowing some electrical path through the adhesive material does not noticeably degrade acquired (ECG) data. With that thought in mind it is noted that a goal of the present invention is to provide a very firm affixation to a subject's body such that spatial separation between electrodes is maintained constant and such that good electrical contact between electrodes and a subject's skin is effected, via said adhesive material. Hence, the more surface area of the present invention bioelectric interface upon which the adhesive material remains present, the better.

[0064] Fig. 3a shows a present invention system for providing electrically anisotropic specific impedance in an "adhesive sheet". Shown is an electrically non-conductive "Scrim" (SM) present in a form which provides numerous channel regions, said channel regions being filled with electrically isotropic conductive adhesive material (A).

[0065] Turning now to Figs. 4a and 4b, there are shown preferred shapes (E3) and (E4) for electrodes. Note that there are regions of said electrodes which will tend to project into an adhesive material (AS) placed in contact therewith. The effect of said projection is to provide a thinning of the adhesive material (AS) and effect an electrically anisotropic character to the adhesive material (AS) as viewed in cross section. That is, electrical impedance from an electrode (E3) or (E4) through said adhesive material (AS) will be caused to be less than that between electrodes (E3) and (E4) through said adhesive material (AS), because of a thinning effect at the projecting edges of said electrodes. Fig. 4c demonstrates the adhesive material (AS) thinning effect. Any electrode shape effecting a similar effect is to be considered equivalent. Fig 4c also shows the presence of external device electrical connector means (EC).

[0066] Fig. 5a shows an example of a multi-element electrode (E5) with a "Bulls-eye" geometry. As described in the Disclosure of the Invention Section of herein, use of said multiple element electrodes allows investigation of high frequency components in (ECG) signals, and allows better spatial resolution of the sources of monitored (EGG) signals. (It is to be understood that the "Bulls-eye" shape is an example of a multi-element electrode, and that any functionally similar multi-element electrode configuration is to be considered as included within the term "Bulls-eye"). The underlying distinction between multi-element electrodes and single element electrodes being that multiple single element electrodes typically utilize a single common electrode as a reference, whereas multi-element electrodes provide their own reference point. It will be appreciated that electrical anisotropicity can become very important in view of the higher resolution capability of "Bulls-eye" electrodes, when signals are being monitored from closely positioned points of, for instance a human heart muscle. That is, greater resolution capability is of no consequence if the signal reaching a sensing electrode is effected by lateral current flow through an attached adhesive material, which signal was originated by a distal source. Fig. 5b shows a plurality of "Button" electrode elements (B1), (B2), (B3), (B4) and (B5) which comprise an electrode (E6). Such an arrangement is beneficially utilized in a present invent in Bioelectric Interface meant for use in Defibrillation. The well known "Edge" effect which results in uneven current distribution over the region of an electrode can be reduced by such a configuration.

[0067] Fig. 6a shows a partial human torso with RA, LA and LL electrodes placed on the limbs. Also shown is an Einthoven triangle Wilson Common Terminal (WCT) formed by attaching resistors to said RA, LA and LL electrodes, which resistors have a common central connection so as to form a "Y" circuit.

[0068] Fig. 6b shows a partial human torso with RA, LA and LL electrodes placed on the chest as is effected by the present invention Bioelectric Interface (3). Also shown is an Einthoven equivalent frontal I II, III lead triangle, Wilson Common Terminal (WCT) formed by attaching resistors (r1), (r2) and (r3) to said RA, LA and LL electrodes, which resistors have a common central connection so as to form a "Y" circuit.

[0069] It is the result of the present invention that voltages which appear at Wilson Common Terminals shown in Figs. 6a and 6b, each with respect to ground, are essentially equivalent, if the present invention RA, LA and LL electrodes are appropriately positioned within the Fig. 6b demonstrated bioelectric interface. A method of accomplishing this can be aided by causing at least one of the RA, LA and LL electrodes to be comprised of a plurality of electrically independent electrode elements, (as demonstrated in Fig. 7b). A user can, manually or via automation, optimally select an element in each RA, LA and LL electrode. As described in the Disclosure of the Invention Section, appropriate placement of the present invention RA, LA and LL electrodes in a present invention biointerface as applied to a subject, is achieved when a voltage present at a Wilson Common Terminal as shown in Fig. 6b, is essentially the same as the voltage present at a Wilson Common Terminal as shown in Fig. 6a within some user selected voltage deviation range, (eg. less than one (1.0) millivolt).

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[0070] Turning now to Fig. 7a there is shown an approximately "actual size" typical present invention biolelectric interface system (3) with electrodes present therein and appropriately spatially distributed and positioned for use with a twelve lead (ECG) system. Fig. 7a shows the surface of the present invention bioelectric interface (3) opposite to that upon which is typically present an adhesive material which contacts a subject's skin in use. In use the bioelectric interface system (3) will typically be placed upon a subject's chest with the various precordial V1-V6 electrodes, and electrode groups, placed as follows:

electrode V1--in the region of the fourth intercostal space at the right sternal border.
electrode Y2--in the region of the fourth intercostal space at the left sternal border;
electrode V4--in the region of the fifth intercostal space at the left mid-clavicular line;
electrode V3--in the region half way between electrodes V2 and V4;
electrode V5-in the region of the fifth intercostal space at the left anterior axillary line; and
electrode V6--in the region of the fifth intercostal space at the left mid-axillary line.

[0071] Note that electrodes V4, V5 and V6 are each shown as a group of electrode elements. The present invention provides for any of the electrodes V1-V6 and any other electrodes which might be present, to be present as a group thereof. The reason for this is that the present invention bioelectric interface is truely a "single size fits all system". That is, even though subject's body sizes vary greatly one to another, the present invention can be applied to essentially any non-deformed subject and an electrode within a group of electrodes in the region of an appropriate location will be found to be properly positioned for use, within an error which exists even if individual electrodes are utilized, (said error originating from improper application of a single electrode). It is emphasized that while only V4, V5 and V6 precordial electrodes are shown as groups of electrode elements in Fig. 7a, any electrode shown, or any other configuration of electrode elements utilized, can be present as a group of electrodes as necessary to effect the "one-size-fits-all" feature of the present invention bioelectric interface system. The reason that Fig. 7a shows electrodes V1, V2 and V6 as single electrodes and electrodes V4, V5 and V6 as shown as groups of electrode elements is that, in practice, application of the present invention bioelectric interface system to a subject's body will proceed in a manner that typically assures appropriate positioning of electrodes V1, V2 and V3 on a subject's chest. The remaining electrodes will then make contact with the subject's body at locations based upon the size and shape of the bioelectric interface (3), which for any specific electrode might or might not be at the generally accepted locations recited infra. Where a group of electrodes is present, however, it should be appreciated that one of the electrodes in the group will be found to be more appropriately positioned than the others of the group. It is also noted that where groups of electrodes are present, unused electrodes in a group can be utilized as, for instance, electrodes to effect cardiac pacing. As well, if one electrode in a group becomes inoperable, another can be substituted and still allow acquisition of reasonable (ECG) data. (See Fig. 7b and 7c for other non-limiting examples). Also, multiple electrodes can be combined in a parallel configuration to allow greater current carrying capability during, for instance, defibrillation procedures.

[0072] Shown also in Fig. 7a are also the Right Arm (RA), Left Leg (LL) and Left Arm (LA) electrodes, positioned as appropriate for use as an Einthoven triangle equivalent configuration pattern, and for use as Right Arm (RA), Left Leg (LL) and Left Arm (LA) equivalent electrodes in the present invention bioelectric interface. Said electrodes are positioned as:

electrode (RA)--in the general region of the second intercostal space to the right of the sternam;
electrode (LA)--in the general region of the left fourth intercostal space at the mid-axillary line; and
electrode (LL)--in the general region of the inferior costal margin at the right or left mid-clavicular line.

(Note, multiple electrodes designated Right Leg (RL) are also present. As alluded to above, the Right Leg (RL) electrode in (ECG) settings is typically utilized to inject an out-of-phase noise compensating signal, which can be functionally applied to many electrodes. It has been determined that said noise compensating signal can be injected at any essentially any location on the present invention bioelectric interface without degradation of the results).

[0073] Also note that slits (S) in an electrically isotropic adhesive material are shown in broken lines. As viewed, said adhesive material would be present on a lower surface of the shown present invention bioelectric interface (3), hence are shown as viewed through the adhesive material and indicated Support Sheet (SUP). Said slits (S) will be less necessary, and probably unnecessary, where an adhesive material constructed from an inherently electrically anisotropic material, such as demonstrated by Figs. 3a and 3b, is utilized. In such systems the scrim (SM) can provide structural integrity, while the present electrically conductive adhesive can provide sufficient adhesive contact and electrical conductivity.

[0074] Also note that Fig. 7a shows one of the V6 electrodes as a "Bulls-eye" electrode with a central Button (B1) and outer annular ring (B2) present. Again, this is demonstrative, and in effect all electrodes could be of a multi-element construction. The conductive polymer will typically, though not necessarily, be discontinuous between the element of a multi-element electrode. Note

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than the central Button (B1) can still serve as a standard Button electrode. In use, one could also interconnect the V6 (B1) and (B2) elements, or all the electrodes in a group, (for instance, if it became necessary to defibrillate a subject while a present invention bioelectric interface is in place). Conventional practice would require removal of any such electrode providing system. However, where the present invention bioelectric interface (3) is present, a defibrillation paddle could be positioned to effectively form a single electrode from electrodes in the V4, V5 and V6 groups. (Note said defibrillation paddle could contact external contact means (EC) such as shown in Fig. 4c). A second defibrillation paddle could likewise be simultaneously applied to the V1, V2 and V3 electrodes, or group of electrodes should alternatives be present at V1, V2 and V3 electrode locations. (See Fig. 7d for indication of Defibrillation Paddles in use).

[0075] Again, Fig. 7a provides a non-limiting example of a Bioelectric Interface (3) of the present invention. The present invention is, however, in the combination of the various disclosed elements thereof, in their various forms, as well as in electrode positioning.

[0076] Continuing, Fig. 7b shows a present invention Bioelectric Interface (3) with electrodes consisting of a Fig. 5b electrode element arrangement present at all V1, V2, V3, V4, V5, and V6 locations in the Support Sheet (SUP). RA, LA and LL electrodes are also shown to comprise multiple electrode elements. As in Fig. 7a, the Bioelectric Interface is viewed from the non-subject contacting side, and indications of the presence, and positioning of electrodes electrically accessible from both the shown, and subject contacting sides is present. The dotted lines surrounding each of said V1, V2, V3, V4, V5 and V6 locations is to indicate that the Fig. 5b electrode element arrangement is to be taken in combination as an electrode. Also note that Fig. 7b shows Perforations (P) present in the Support Sheet (SUP) at electrode RA, LA, and LL, (eg. Right Arm, Left Arm and Left Leg) locations. Said Perforations (P) allow easy removal of the RA, LA, and LL electrodes when it is desired to deploy and place said electrodes at conventional subject limb locations in use.

[0077] Fig. 7c shows a present invention Bioelectric Interface (3) with Fig. 5a Bulls-eye electrodes present at V1, V2, V3, V4, V5 and V6 locations in the Support Sheet (SUP). As in Figs. 7a and 7b, the Bioelectric Interface is viewed from the non-subject contacting side, and indications of the presence, and positioning of electrodes electrically accessible from both the shown, and subject contacting sides is present. Also note that Fig. 7c, as did Fig. 7b, shows Perforations (P) present in the Support Sheet (SUP) at electrode RA, LA, and LL (eg. Right Arm, Left Arm and Left Leg) locations. Said Perforations (P) allow easy removal of the RA, LA, and LL electrodes when it is desired to deploy and place said electrodes at, for instance, conventional limb locations in use.

[0078] Fig. 7d shows a present invention Bioelectric Interface (3) with simple single Button electrodes present at V1, V2, V3, V4, V5 and V6 locations in the Support Sheet (SUP). As in Figs. 7a, 7b and 7c, the Bioelectric Interface is viewed from the non-subject contacting side, and indications of the presence, and positioning of electrodes electrically accessible from both the shown, and subject contacting sides is present. Also shown are outline representations of First (DF1) and Second (DF2) Defibrillation Paddles placed over the RA, LA, LL, V1, V2, V3, V4, V5 and V6 electrodes of the present invention Bioelectric Interface (3), as said First (DF1) and Second (DF2) Defibrillation Paddles would be positioned in use. Note that First (PD1) Defibrillation Paddle electrically contacts electrodes RA, V1, V2, and V3, while Second (DF2) Defibrillation Paddle electrically contacts electrodes LA, LL, V4, V5, and V6. The multiple points of supply of electrical energy to the body of a subject wearing the present invention Bioelectric Interface (3) serves to reduce uneven current flow caused by electrode "Edge" effect. It should be appreciated that were First (DF1) and Second (DF2) Defibrillation Paddles shown applied to Figs. 7b or 7c, even more separate electrode elements would be contacted, and the "Edge" effect would be even more reduced.

[0079] Turning now to Fig. 7e, there is shown a prefered embodiment of the present invention bioelectric interface (3). Shown are a support sheet (SUP) in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially separated electrocardiogram system electrodes, which can be of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements). Each of said spatially separated electrocardiogram system electrode is affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin. Nine (9) of said at least nine (9) electrocardiogram system electrodes are configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern much as described with respect to Figs. 7a - 7d. The prefered embodiment is shown to also include an electrocardiogram system RL electrode. In particular it should be noted that the Fig. 7e embodiment further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of at least one of said electrocardiogram RA, LA, LL and RL electrodes, thereby allowing positioning at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position). Further note that fold enhancing impression and/or perforations are shown as present between V3 and V4 electodes, and between RA and V1 electrodes. Such fold enhancing impression and/or perforations can be present between essentially any at two electrodes such as between V1 and V2; V2 and V3; V3 and V4; V4 and V5; V5 and V6; RA and V1; V4 and LL;

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LA and V6. As with other embodiments in said Fig. 7e prefered embodiment, the support sheet is at least partially covered with an adhesive material on a subject contacting side thereof, and said adhesive material can present with electrical conductive properties selected from the group consisting of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that the regional specific impedance through said adhesive material is less than in a laterally oriented dimension direction therealong). Also, said adhesive material can be hydrophillic and non-hydrophillic. Note also that the bioelectric interface in Fig. 7e has at least one hole (H) present through said support sheet at a location between electrodes, which hole allows access to a subject's skin in use. Holes (H) are shown at location of the level of the second intercostal space adjacent to said RA electrode, and at the level of the fourth intercostal space adjacent to said V1 electrode, and between said RA and V2 electrodes, and between said V4 and V5 electrodes. Such holes make the bioelectric interface more compliant and able to conform to a subject's body contours. Also note that the Fig. 7e bioelectric interface has an "undulated" outer perimeter boundary shape. This is prefered as it further enhances conformation to a subject's body contours in use, and said "undulations" allow relatively easy grasping between a thumb and first finger, thereby facilitating removal of a bioelectric interface from a subject, (which has proven a bit difficult with some bioelectric interfaces without an "undulated" outer perimeter boundary.

[0080] As a general comment regarding Figs. 7a, 7b, 7c, 7d and 7e, the electrodes are shown positioned in each Bioelectric Interface (3), as viewed from the non-subject contacting side thereof. Fig. 4c demonstrates the typically only an external device electrical connector means (EC) is visible as so viewed, with a typically larger electrode area present on the subject contacting side. Hence, Figs. 7a, 7b, 7c and 7d should be viewed as demonstrating the positioning of electrodes, and elements which comprise them, in a present invention Bioelectric Interface, rather than being accurate representations of the size of said electrodes, as viewed.

[0081] As another general comment, it is to be appreciated that the present invention bioelectric interface system provides a means by which many electrodes can be applied to a subject by a simple, error limiting procedure. As it is generally accepted that improper application of electrodes is the most common reason for faulted (ECG) data acquisition, this is significant. As well, the present invention bioelectric interface provides a rather significant body contact surface area, said surface area being, typically, essentially covered with an adhesive material. This serves to ensure that electrodes, once applied to a subject, will not vary from the positions in which they are applied, and should not vary with respect to one another. It is known that relative motion between electrodes accounts for production of noise in acquired (ECG) data. The present invention greatly limits problems associated with noise generated by this effect. In fact, it is generally possibly to perform cardio-pulmonary-resuscitation on subjects wearing the present invention bioelectric interface while continuing to acquire (ECG) data. It is also mentioned that when the adhesive material is a hydropolymer, subject discomfort is minimized, and moisture resulting from sweating etc. actually serves to improve the adhesion properties.

[0082] While not shown, it is possible to form arrays of electrodes in a present invention bioelectric interface, for use in cardiac mapping. In such arrays, electrode arrangement is typically rectangular with, for instance, sixteen, twenty-four, thirty-six, sixty-four etc. electrodes present. The electrodes present can be of Button or Bulls-eye geometry, or, in other embodiments of the present invention, can be of any functional geometrical shape. It is also noted that it is possible to affix alternative embodiments of the present invention bioelectric interface to the back of a subject as well as to the chest thereof.

[0083] It is also noted that primary evidence that a Wilson Common Terminal (WCT) Voltage produced utilizing a present invention Bioelectric Interface is equivalent to that produced when conventionally placed limb leads are utilized, is essential equivalence of monitored ECG lead outputs from both said systems. In that light it is to be understood that a conventional Wilson Common Terminal is constructed utilizing resistors of equal value, (eg. 10,000 ohms each). Again referring to Figs. 6a and 6b, this is equivalent to considering Resistors (r1), (r2) and (r3) to be of equivalent values. Where this is the case, placement of the Right Arm (RA), Left Arm (LA) and Left Leg (LL) electrodes alone, in a Fig. 6b setting, provides for realizing a voltage at the Fig. 6b Wilson Common Terminal (WCT) which is in a desired relationship to that present at the Wilson Common Terminal (WCT) formed utilizing electrodes positioned on limbs, as shown in Fig. 6a. However, it should be appreciated that if resistors (r1), (r2) and (r3) are available, then adjusting their values can also have an effect on the voltage which appears at a Wilson Common Terminal (WCT). The present invention provides for use of variable (r1) and/or (r2) and/or (r3) resistor(s) such that in use, adjustment of one or more of said variable (r1) and/or (r2) and/or (r3) resistor(s) allows "setting" a voltage at the Wilson Common Terminal (WCT) to essentially any value at, or anywhere between, the voltages present at any of the Right Arm (RA), Left Arm (LA) and Left Leg (LL) electrodes. Thus, the present invention can include as a Method of Use step, adjustment of the values of the resistors which form the Wilson Common Terminal (WCT), after a Fig. 6b Bioelectric Interface (3) is placed upon a subject's chest. (Note that Operational Amplifiers with adjustable gain can be utilized in place of the described variable resistors and are to be considered functionally equivalent and within the scope of the

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terminology "variable resistor". Op-Amps beneficially provide light input impedance.)

[0084] It will be apparent to those skilled in the art that some redundancy exists in any Einthoven-like lead system which lies largely in a single subject body plane, such as the frontal plane. Some minor efficiencies might be achieved, at the expense of redundance, if for example, two mutually perpendicular leads were created and used exclusively to define the frontal plane in electrocardiology. Furthermore, other mathematically derived leads are commonly employed to provide additional information, (eg "augmented" frontal plane leads). However, it is to be understood that new heart related information can not be created simply by the mathematical manipulation of redundant information. Therefore, where appropriate, the Claims are to be interpreted to include mathematically equivalent lead placement systems. In particular, the language, "generally in the region of" should be interpreted sufficiently broadly to include both an Einthoven equivalent triangle and an orthogonal lead configuration formed by a shifting of a lead position, which identified lead configurations provide mathematically essentially equivalent information.

[0085] It is specifically stated, as it is difficult to otherwise describe, that for the purposes of this disclosure the term "undulate" is defined as indicating a sequence of curves in said a bioelectric interface "undulated" outer perimeter boundary (UOPB), as shown in Fig. 7e. This is best understood by comparison to a bioelectric interface outer perimeter boundary with a relatively "smoothed" shape, as is shown in Figs. 7a - 7d.

[0086] Finally, it is noted that the terminology "Wilson Common Terminal" has been used throughout this Disclosure, whereas many references utilize the terminology "Wilson Central Terminal". The term "Common" is used to imply application in an instrumentation setting, but for most purposes it can be read as "Central" without loss of accuracy.

[0087] Having hereby disclosed the subject matter of the present invention, it should be obvious that many modifications, substitutions, and variations of the present teachings are possible in view of the teachings. It is therefore to be understood that the present invention may be practiced other than as specifically described, and should be limited in breadth and scope only by the Claims.

Claims

1. A bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least three spatially separated electrocardiogram system electrodes, each of said at least three spatially separated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, three of said at least three electrocardiogram system electrodes being configured in an RA, LA, LL electrocardiogram system electrode pattern, such that said three electrocardiogram system electrodes are applied to a subject's chest during use as follows:

> electrode RA being generally in the region of the second intercostal space to the right of the sternum;
>
> electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;
>
> electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

said RA, LA and LL electrodes forming, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern presenting with a voltage with respect to ground at a Wilson common terminal formed from "Y" connected resistors from each of said RA, LA and LL electrodes, said resistors each being selected from the group consisting of: (fixed and variable), said voltage with respect to ground being within a selected range of deviation from a similarly obtained voltage with respect to ground which would present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) milivolt, thereby enabling familiar ECG data acquisition.

2. A bioelectric interface (3) as in Claim 1 which further comprises an electrocardiogram system RL electrode.

3. A bioelectric interface (3) as in Claim 2 which further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of said electrocardiogram RL electrode can, in use, be positioned at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position).

4. A bioelectric interface (3) as in Claim 1 which further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of said Einthoven triangle equivalent RA, LA and LL electrodes therefrom so that said Einthoven triangle equivalent RA, LA, and LL electrodes can,

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in use, be positioned at locations selected from the group consisting of: (in contact with a subject's chest, and in conventional Einthoven triangle subject limb positions).

5. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, which adhesive (AS) material presents with electrical conductive properties selected from the group consisitng of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that regional specific impedance through said adhesive (AS) material is less that in a laterally oriented direction therealong).

6. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, the electrical conductive properties of said adhesive (AS) material being regionally anisotropic, said anisotropic electrical conductive properties of said adhesive (AS) material resulting from the presence of an electrically nonconductive scrim patterned therein so as to form channel regions of electrically conductive adhesive (AS) material through said adhesive (AS) material bordered by said scrim material, such that adhesive (AS) material in one channel region does not contact that in other regions.

7. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject containing side thereof, the electrical conductive properties of said adhesive (AS) material being regionally anisotropic, said anisotropic electrical conductive properties of the adhesive (AS) material resulting from the presence of slits/voids formed therein.

8. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, said adhesive (AS) material being a hydropolymer with isotropic electrical conductive properties.

9. A bioelectric interface (3) as in Claim 8, in which the hydropolymer adhesive (AS) material covers essentially the entire subject contacting surface of said support sheet (SUP).

10. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, said adhesive (AS) material being a hydropolymer with regional anisotropic electrical conductive properties.

11. A bioelectric interface (3) as in Claim 10, in which the hydropolymer adhesive (AS) material covers essentially the entire subject contacting surface of said support sheet (SUP).

12. A bioelectric interface (3) as in Claim 1, in which at least one of said spatially separated electrocardiogram system electrodes is of a construction consisting of a group of electrically independent electrode elements.

13. A bioelectric interface (3) as in Claim 12, in which said electrically independent electrode elements are configured in a pattern selected from the group consisting of: (a Bulls-eye pattern, and multiple button shaped electrode elements).

14. A method of providing an Einthoven triangle equivalent RA, LA, LL pattern of electrodes on the chest of a subject comprising the steps of:

a. providing a bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least three spatially separated electrocardiogram system electrodes, at least one (1) of said at least three spatially separated electrocardiogram system electrodes being of a construction consisting of a group of electrically independent electrode elements, each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, three of said at least three electrocardiogram system electrodes being configured in an RA, LA, LL electrocardiogram system electrode pattern, said RA, LA and LL electrodes forming, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern presenting with a voltage with respect to ground at a Wilson common terminal formed from "Y" connected resistors from each of said RA, LA and LL electrodes, said resistors each being selected from the group consisting of: (fixed and variable), said voltage with respect to ground being within a selected range of deviation from a similarly obtained voltage with respect to ground which would be present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) millivolt, thereby enabling familiar ECG data acquisition;

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b. applying said bioelectric interface (3) to a subject;

c. selecting at least one electrically independent element in each of said at least one electrocardiogram system RA, LA and LL electrode(s) consisting of a group of electrically independent electrode elements to constitute the electrode of which it is an electrically independent element;

d. connecting said electrocardiogram system RA, LA and LL electrodes to appropriate inputs of an electrocardiogram system.

15. A method of providing an Einthoven triangle equivalent RA, LA, LL pattern of electrodes on the chest of a subject as in Claim 14, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing;
d. electro surgery;
e. electro-ablation; and
f. impedance cardiography.

on said subject without removing said biolelectric interface (3).

16. A bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially separated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern, such that said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;
said electrodes RA, LA and LL being positioned so as to form, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern presenting with a voltage with respect to ground at a Wilson common terminal formed from "Y" connected resistors from each of said RA, LA and LL electrodes, said resistors each being selected from the group consisting of: (fixed and variable), said voltage with respect to ground being within a selected range of deviation from a voltage respect to ground which would present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) millivolt, thereby enabling familiar ECG data acquisition;

electrode V1 in the region of the fourth intercostal space at the right sternal border;

electrode V2 in the region of the fourth intercostal space at the left sternal border;

electrode V4 in the region of the fifth intercostal space at the left mid-clavicular line;

electrode V3 in the region of the midpoint between electrode groups V2 and V4;

electrode V5 in the region of the fifth intercostal space in the left anterior axillary line; and

electrode V6 in the region of the fifth intercostal space in the left mid-axillary line.

17. A bioelectric interface (3) as in Claim 16 which further comprises an electocardiogram system RL electrode.

18. A bioelectric interface (3) as in Claim 17 which further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of said electrocardiogram RL electrode can, in use, be positioned at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position).

19. A bioelectric interface (3) as in Claim 16 which further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of said Einthoven triangle equivalent RA, LA and LL electrodes therefrom so that said Einthoven

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triangle equivalent RA, LA, and LL electrodes can, in use, be positioned at locations selected from the group consisting of: (in contact with a subject's chest, and in conventional Einthoven triangle subject limb positions).

20. A bioelectric interface (3) as in Claim 16, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, which adhesive (AS) material presents with electrical conductive properties selected from the group consisitng of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that the regional specific impedance through said adhesive (AS) material is less than in a laterally oriented dimension direction therealong).

21. A bioelectric interface (3) as in Claim 16 in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, the electrical conductive properties of said adhesive (AS) material being anisotropic, said anisotropic electrical conductive properties of said adhesive (AS) material resulting from the presence of an electrically nonconductive scrim patterned therein so as to form channel regions of electrically conductive adhesive (AS) material through said adhesive (AS) material bordered by said scrim material, such that adhesive (AS) material in one channel region does not contact that in other regions.

22. A bioelectric interface (3) as in Claim 16, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, the electrical conductive properties of said adhesive (AS) material being anisotropic, said anisotropic electrical conductive properties of the adhesive (AS) material resulting from the presence of slits/voids formed therein.

23. A bioelectric interface (3) as in Claim 16, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, said adhesive (AS) material being a hydropolymer with isotropic electrical conductive properties.

24. A bioelectric interface (3) as in Claim 23, in which the hydropolymer adhesive (AS) material covers essentially the entire subject contacting surface of said support sheet (SUP).

25. A bioelectric interface (3) as in Claim 16 in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, said adhesive (AS) material being a hydropolymer with regional anisotropic electrical conductive properties.

26. A bioelectric interface (3) as in Claim 25, in which the hydropolymer adhesive (AS) material covers essentially the entire subject contacting surface of said support sheet (SUP).

27. A bioelectric interface (3) as in Claim 16, in which at least one of said spatially separated electrocardiogram system electrodes is of a construction consisting of a group of electrically independent electrode elements.

28. A bioelectric interface (3) as in Claim 27, in which said electrically independent electrode elements are configured in a pattern selected from the group consisting of: (a Bulls-eye pattern, and multiple button shaped electrode elements).

29. A method of acquiring electrocardiographic data comprising the steps of:

a. providing a bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially separated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern, such that said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrodes RA, LA and LL positioned so as to form, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern presenting with a voltage with respect to ground at a Wilson common terminal formed from "Y" connected resistors from each of said RA, LA and LL electrodes, said resistors each being selected from the group consisting of: (fixed and variable), said voltage with respect to ground being within a selected range of deviation from a voltage respect to ground which would

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present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) milivolt, thereby enabling familiar ECG data acquisition;

electrode V1 in the region of the fourth intercostal space at the right sternal border;

electrode V2 in the region of the fourth intercostal space at the left sternal border;

electrode V4 in the region of the fifth intercostal space at the left mid-clavicular line;

electrode V3 in the region of the midpoint between electrode groups V2 and V4;

electrode V5 in the region of the fifth intercostal space in the left anterior axillary line; and

electrode V6 in the region of the fifth intercostal space in the left mid-axillary line;

b. affixing said bioelectric interface (3) to a subject and causing electrodes therein to be electrically attached to an electrocardiographic system such that familiar electrocardiographic data is obtained.

30. A method of acquiring electrocardiographic data as in Claim 29 which further comprises the step of selecting at least one of the Wilson common terminal forming "Y" connected resistors from said RA, LA and LL electrodes to be variable, and the adjusting the value of at least one of said at least one of the Wilson common terminal forming "Y" connected resistors to place the Wilson common terminal voltage within a selected range of deviation from a similarly obtained voltage which would present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) milivolt, thereby enabling familiar ECG data acquisition;.

31. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing a bioelectric interface (3) includes providing perforation in said support sheet (SUP) such that said three electrodes configured in an Einthoven triangle equivalent RA, LA, and LL pattern can be easily removed therefrom; said method of acquiring electrocardiographic data further including the step of removing said electrodes RA, LA and LL configured in an Einthoven frontal lead triangle equivalent LA, RA, LL pattern and affixing them to conventional subject limb locations.

32. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing a bioelectric interface (3) includes providing an adhesive (AS) material present over at least a portion of a subject contacting side of said support sheet (SUP).

33. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing said bioelectric interface (3) comprises the step of causing at least some of said electrodes to comprise a group of electrically independent electrode elements configured in a pattern selected from the group consisting of: (a Bulls-eye pattern, and multiple button shaped electrode elements).

34. A method of acquiring electrocardiographic data as in Claim 29, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing;
d. electro surgery;
e. electro-ablation; and
f. impedance cardiography.

on said subject without removing said bioelectric interface (3) .

35. A method of acquiring electrocardiographic data as in Claim 29, which further comprises the simultaneous step of performing cardiac defibrillation utilizing two conventional defibrillation paddles, in which a first conventional defibrillation paddle contacts at least two of said at least nine electrocardiogram system electrodes, and in which a second said conventional defibrillation paddles contacts at least two of said at least nine electrocardiogram system electrodes, said at least two electrodes contacted by said first conventional defibrillation paddle being different than and sread apart from said at least two electrodes contacted by said second conventional defibrillation paddle; with the result being that in use said electrodes contacted by said defibrillation paddles are caused to be pressed into firm contact with a subject and defibrillation pulse current delivered thereto with current distribution electrode perimeter boundary effects being reduced.

36. A bioelectric interface (3) as in Claim 1, in which the voltage present at a formed Wilson common terminal is a root-mean-square value of a selected

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portion of a subject electrocardiogram system monitored electrocardiogram cycle.

37. A bioelectric interface (3) as in Claim 36, in which the selected portion of a subject electrocardiogram system monitored electrocardiogram cycle is the QRS complex.

38. A bioelectric interface (3) as in Claim 16, in which the voltage present at a formed Wilson common terminal is a root-mean-square value of a selected portion of a subject electrocardiogram system monitored electrocardiogram cycle.

39. A bioelectric interface (3) as in Claim 38, in which the selected portion of a subject electrocardiogram system monitored electrocardiogram cycle is the QRS complex.

40. A bioelectric interface (3) comprising an adhesive (AS) material in functional combination with at least two spacially separated electrodes, which adhesive (AS) material simultaneously presents with essentially anisotropic specific impedance properties and essentially isotropic mechanical pliability and adhesion properties, said electrodes being affixed to said adhesive (AS) material in a manner such that their relative positions with respect to one another are essentially fixed, and such that the specific impedance from each said electrode directly through said adhesive (AS) material, is less than that between any said electrodes through said adhesive (AS) material, said bioelectric interface (3) having an undulated outer perimeter boundary shape.

41. A bioelectric interface (3) as in Claim 40, in which the adhesive (AS) material is comprised of electrically conductive polymer.

42. A bioelectric interface (3) as in Claim 41, in which the electrically conductive polymer is hydrophillic, and thereby particularly well suited for application to human skin.

43. A bioelectric interface (3) as in Claim 40, in which the electrodes are each of a construction such that contact with the adhesive (AS) material is essentially continuous over the dimension of each said electrode.

44. A bioelectric interface (3) as in Claim 40, in which at least one of said electrodes is of a multiple-piece construction such that each of said multiple pieces contacts the adhesive (AS) material independently and essentially continuously over the dimension of each said multiple pieces.

45. A bioelectric interface (3) as in Claim 44, in which the multipiece construction configures a Bulls-eye pattern.

46. A bioelectric interface (3) as in Claim 40, which further comprises a carrier matrix affixed thereto so as to sandwich said electrodes between said carrier matrix and said adhesive (AS) material, the purpose being to improve the integrity of the spacial separation between said electrodes.

47. A bioelectric interface (3) as in Claim 40, which further comprises means for electrically connecting said electrodes to external devices.

48. A bioelectric interface (3) comprising an adhesive (AS) material in functional combination with at least two spacially separated groups of electrode(s), at least one of which spacially separated group of electrode(s) can consist of more than one electrode, which adhesive (AS) material simultaneously presents with essentially anisotropic specific impedance properties and essentially isotropic pliability and adhesion mechanical properties, electrodes in said spacially separated groups of electrode(s) being affixed to said adhesive (AS) material in a manner such the relative positions of electrodes present with respect to one another are essentially fixed, and such that the specific impedance from each electrode in said groups of spacially separated electrode(s) directly through said adhesive (AS) material, is less than that between any two electrodes in different spacially separated groups of electrodes through said adhesive (AS) material, said bioelectric interface (3) having an undulated outer perimeter boundary shape.

49. A bioelectric interface (3) as in Claim 38, in which the adhesive (AS) material is comprised of electrically conductive polymer.

50. A bioelectric interface (3) as in Claim 39, in which the electrically conductive polymer is hydrophillic, and thereby particularly well suited for application to human skin.

51. A bioelectric interface (3) as in Claim 58, in which the electrodes in the groups of electrode(s) are each of a construction such that contact with the adhesive (AS) material is essentially continuous over the dimension of each said electrode.

52. A bioelectric interface (3) as in Claim 59, in which at least one if said electrodes in said groups of electrode(s) is of a multiple-piece construction such that each of said multiple pieces contacts the adhesive (AS) material independently and essentially continuously over the dimension of each said

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multiple pieces.

53. A bioelectric interface (3) as in Claim 52, in which the multipiece construction configures a Bulls-eye pattern.

54. A bioelectric interface (3) as in Claim 48, which further comprises a carrier matrix affixed thereto so as to sandwich said electrodes in said groups of electrode(s) between said carrier matrix and said adhesive (AS) material, the purpose being to improve the integrity of the spacial separation between said electrodes.

55. A bioelectric interface (3) as in Claim 48, which further comprises means for electrically connecting said electrodes in said groups of electrode(s) to external devices.

56. A bioelectric interface (3) as in Claim 48, in which the number of groups of electrode(s) is three, said bioelectric interface (3) being configured and sized so as to place said three groups of electrodes in an essentially congruent Einthoven triangle equivalent Left Arm, Right Arm, Left Leg pattern, such that in use all said groups of electrodes contact a patient's chest.

57. A bioelectric interface (3) as in Claim 48, in which
the number of groups of electrode(s) is nine, said nine groups of electrode(s) being configured in an I, II, III, V1, V2, V3, V4, V5, V6 twelve lead electrocardiogram system electrode pattern, such that said nine groups of electrode(s) are positioned on a patient's chest during use as follows:

electrode group I in the region of the second intercostal space to the right of the sternum;

electrode group II in the region of the left fourth intercostal space at the mid-axillary line;

electrode group III in the region of the inferior costal margin in the mid-clavicular line;

electrode group V1 in the region of the fourth intercostal space at the right sternal border;

electrode group V2 in the region of the fourth intercostal space at the left sternal border;

electrode group V4 in the region of the fifth intercostal space at the mid-clavicular line;

electrode group V3 in the region of the midpoint between electrode groups V2 and V4;

electrode group V5 in the region of the fifth intercostal space in the anterior axillary line; and

electrode group V6 in the region of the fifth intercostal space in the mid-axillary line;

such that during use one electrode from each group of electrode(s) will be found to be more appropriately situated for a specific patient depending upon the patient's body size.

58. A bioelectric interface (3) as in Claim 50, which further comprises three additional groups of electrode(s) which are configured and sized so as to place said additional three groups of electrodes in an essentially congruent Einthoven triangle equivalent Left Arm, Right Arm, Left Leg pattern, such that in use all said groups of electrodes contact a patient's chest.

59. A bioelectric interface (3) as in Claim 40, in which there are present a multiplicity of electrodes configured in an essentially rectangular shaped matrix such that in use said bioelectric interface (3) is affixed to one of the group consisting of a patient's chest and back, said bioelectric interface (3) being appropriate for use in electrocardiographic mapping.

60. A bioelectric interface (3) as in Claim 45, in which there are present a multiplicity of electrodes configured in an essentially rectangular shaped matrix such that in use said bioelectric interface (3) is affixed to one of the group consisting of a patient's chest and back, said bioelectric interface (3) being appropriate for use in electrocardiographic mapping.

61. A method of acquiring electrocardiographic data comprising the steps of:

a. providing a bioelectric interface (3) comprising at least two spacially separated groups of electrode(s), at least one of which spacially separated group of electrode(s) can consist of more than one electrode, which adhesive (AS) material presents with essentially anisotropic specific impedance properties but essentially isotropic mechanical properties, said spatially separated groups of electrode(s) being affixed to said adhesive (AS) material in a manner such that their relative positions with respect to one another remain essentially fixed, and such that the specific impedance from each electrode in said groups of spatially separated electrode(s) directly through said adhesive (AS) material, is less than that between any two

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electrodes in different spacially separated groups of electrodes through said adhesive (AS) material, said bioelectric interface (3) having an undulated outer perimeter boundary shape, in which bioelectric interface (3) the number of groups of electrode(s) is nine, said nine groups of electrode(s) being configured in an I, II, III, V1, V2, V3, V4, V5, V6 twelve lead electrocardiogram system electrode pattern, such that said nine groups of electrode(s) are positioned on a patient's chest during use as follows:

electrode group I in the region of the second intercostal space to the right of the sternum;

electrode group II in the region of the left fourth intercostal space at the mid-axillary line;

electrode group III in the region of the inferior costal margin in the mid-clavicular line;

electrode group V1 in the region of the fourth intercostal space at the right sternal border;

electrode group V2 in the region of the fourth intercostal space at the left sternal border;

electrode group V4 in the region of the fifth intercostal space at the mid-clavicular line;

electrode group V3 in the region of the midpoint between electrode groups V2 and V4;

electrode group V5 in the region of the fifth intercostal space in the anterior axillary line; and electrode group V6 in the region of the fifth intercostal space in the mid-axillary line;

such that during use one electrode from each group of electrode(s) will be found to be more appropriately situated for a specific patient depending upon the patient's body size;

b. affixing said bioelectric interface (3) to a patient and causing the electrodes therein to be electrically attached to an electrocardiographic system such that electrocardiographic data is obtained.

62. A method of acquiring electrocardiographic data as in Claim 61, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing; and
d. electro surgery.

on said patient without removing said bioelectric interface (3).

63. A method of acquiring electrocardiographic data as in Claim 61, which further comprises the simultaneous step of causing at least some some of said electrodes to have a multiple component configuration.

64. A method of performing cardiac mapping comprising the steps of:

a. providing a bioelectric interface (3) comprising an adhesive (AS) material in functional combination with at least two spacially separated electrodes, which adhesive (AS) material presents with essentially anisotropic specific impedance properties but essentially isotropic mechanical properties, said electrodes being affixed to said adhesive (AS) material in a manner such that their relative positions with respect to one another remain essentially fixed, and such that the specific impedance from each said electrode directly through said adhesive (AS) material, is less than that between any said electrodes through said adhesive (AS) material, said electrical anisotropic specific impedance properties of said adhesive (AS) material being the result of a slit/void or slits/voids therein, which slit/void or slits/voids are positioned between groups of electrodes, in which bioelectric interface (3) there are present a multiplicity of electrodes configured in an essentially rectangular shaped matrix such that in use said bioelectric interface (3) is affixed to one of the group consisting of a patient's chest and back, said bioelectric interface (3) being appropriate for use in electrocardiographic mapping;

b. affixing said bioelectric interface (3) to a patient on one of the elements in the group consisting of a patient's chest and back, and causing said electrides to be connected to an electrocardiograph mapping system.

65. A method of acquiring electrocardiographic data as in Claim 64, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

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a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing; and
d. electro surgery.

66. A method of acquiring electrocardiographic data as in Claim 64, which further comprises the simultaneous step of causing at least some of said electrodes to have a multiple component configuration.

67. A bioelectric interface (3) as in Claim 1, having an undulated outer perimeter boundary shape.

68. A bioelectric interface (3) as in Claim 67, having at least one hole present through said bioelectric interface (3) at a location between electrodes.

69. A method of providing an Einthoven triangle equivalent RA, LA, LL pattern of electrodes on the chest of a subject, as in Claim 14, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having an undulated outer perimeter boundary shape.

70. A method of acquiring electrocardiographic data as in Claim 69, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having at least one hole present through said bioelectric interface (3) at a location between electrodes.

71. A bioelectric interface (3) as in Claim 16, having an undulated outer perimeter boundary shape.

72. A bioelectric interface (3) as in Claim 71, having at least one hole present through said bioelectric interface (3) at a location between electrodes.

73. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having an undulated outer perimeter boundary shape.

74. A method of acquiring electrocardiographic data as in Claim 73, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having at least one hole present through said bioelectric interface (3) at a location between electrodes.

75. A bioelectric interface (3) as in Claim 40, wherein at least one hole is present through said bioelectric interface (3) adhesive (AS) material at a location between electrodes.

76. A bioelectric interface (3) as in Claim 40, wherein said electrical anisotropic specific impedance properties of said adhesive (AS) material are the result of a slit/void or slits/voids therein, which slit/void or slits/voids are positioned between electrodes.

77. A bioelectric interface (3) as in Claim 40, wherein at least one hole is present through said bioelectric interface (3) adhesive (AS) material at a location between electrodes.

78. A bioelectric interface (3) as in Claim 48, wherein said electrical anisotropic specific impedance properties of said adhesive (AS) material are the result of a slit/void or slits/voids therein, which slit/void or slits/voids are positioned between groups of electrodes.

79. A bioelectric interface (3) as in Claim 48, wherein at least one hole is present through said bioelectric interface (3) adhesive (AS) material at a location between electrodes.

80. A method of acquiring electrocardiographic data as in Claim 61 in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having an undulated outer perimeter boundary shape.

81. A method of acquiring electrocardiographic data as in Claim 80, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having at least one hole present through said bioelectric interface (3) at a location between electrodes.

82. A bioelectric interface (3) as in Claim 16, which further comprises fold enhancing perforations located between said V3 and V4 electrodes.

83. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interace with fold enhancing perforations located between said V3 and V4 electrodes.

84. A method of acquiring electrocardiographic data as in Claim 61, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interace with fold enhancing perforations located between said V3 and V4 electrodes.

85. A bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially separated electrocardiogram system electrodes being of a construction selected from a

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group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern, such that said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;
said electrodes RA, LA and LL being positioned so as to form, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern;

electrode V1 in the region of the fourth intercostal space at the right sternal border;

electrode V2 in the region of the fourth intercostal space at the left sternal border;

electrode V4 in the region of the fifth intercostal space at the left mid-clavicular line;

electrode V3 in the region of the midpoint between electrode groups V2 and V4;

electrode V5 in the region of the fifth intercostal space in the left anterior axillary line; and

electrode V6 in the region of the fifth intercostal space in the left mid-axillary line;
which bioelectric interface (3) further comprises an electrocardiogram system RL electrode;
which bioelectric interface (3) further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of at least one of said electrocardiogram RA, LA, LL and RL electrodes, thereby allowing positioning at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position);
which bioelectric interface (3) further includes a fold enhancing impression and/or perforations located between at least two electrodes selected from the group consisting of: (V1 and V2; V2 and V3; V3 and V4; V4 and V5; V5 and V6; RA and V1; V4 and LL; LA and V6);
in which said bioelectric interface (3) the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, which adhesive (AS) material presents with electrical conductive properties selected from the group consisitng of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that the regional specific impedance through said adhesive (AS) material is less than in a laterally oriented dimension direction therealong); said adhesive (AS) material being selected from the group consisting of: (hydrophillic and non-hydrophillic).

86. A bioelectric interface (3) as in Claim 85, further comprises at least one hole present through said support sheet (SUP) at a location between electrodes, which hole allows access to a subject's skin in use.

87. A bioelectric interface (3) as in Claim 86, in which at least one hole is present at a location selected from the group consisting of: (the level of the second intercostal space adjacent to said RA electrode, and the level of the fourth intercostal space adjacent to said V1 electrode, and between said RA and V2 electrodes, and between said V4 and V5 electrodes).

87. A bioelectric interface (3) as in Claim 85, in which fold enhancing impression(s) and/or perforations are located between V3 and V4 electodes, and between RA and V1 electrodes.

88. A bioelectric interface (3) as in Claim 85, which has an undulated outer perimeter boundary shape.

89. A bioelectric interface (3) as in Claim 85, in which at least one electrode is comprised of a group of electrically independent electrode elements are present and configured in a bulls-eye.

90. A bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least three spatially separated electrocardiogram system electrodes, each of said at least three spatially separated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a

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group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin; two of said at least three electrocardiogram system electrodes being selected from a group of electrodes consisting of equivalent RA, LA, LL and RL electrocardiogram system electrodes, and one of said at least three electrocardiogram system electrodes being selected from a group of electrocardiogram system electrodes consisting of V1, V2, V3, V4, V5, and V6 precordial electrodes.

91. A bioelectric interface suitable for monitoring electrocardiographic signals from a subject, said bioelectric interface comprising subject chest mounted right-arm (RA), left arm (LA) and left-leg (LL) electrodes which, in use, configure an equivalent Einthoven frontal I, II, III limb lead pattern.

92. A bioelectric interface suitable for monitoring electrocardiographic signals from a subject, said bioelectric interface comprising subject chest mounted precordial V1, V2, V3, V4, V5, and V6 electrodes.

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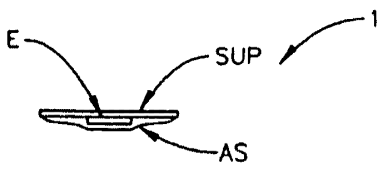


FIG. 1a

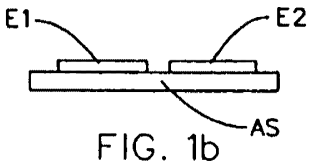


FIG. 1b

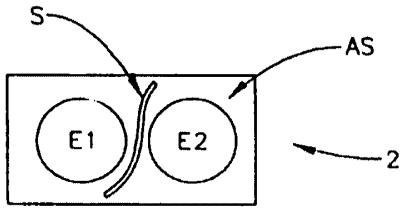


FIG. 2



FIG. 4a

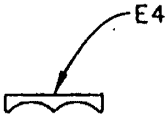


FIG. 4b

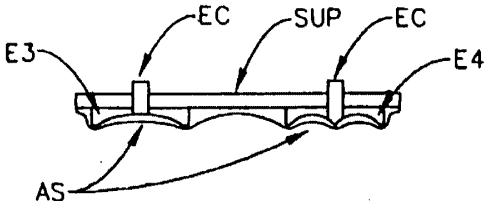


FIG. 4c

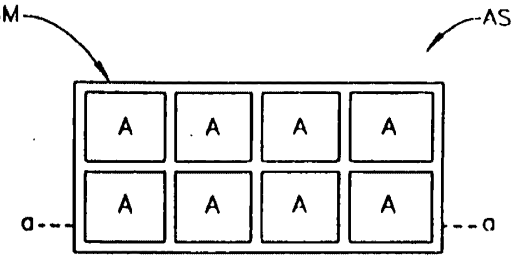


FIG. 3a

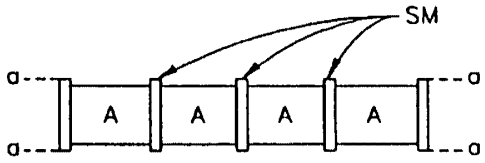


FIG. 3b

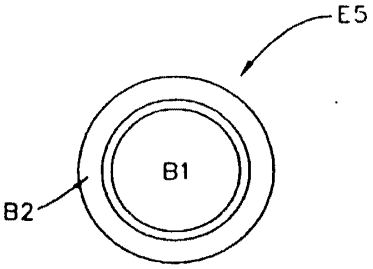


FIG. 5a

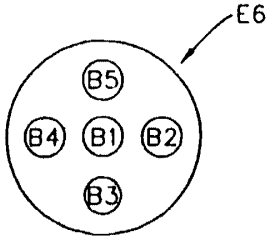


FIG. 5b

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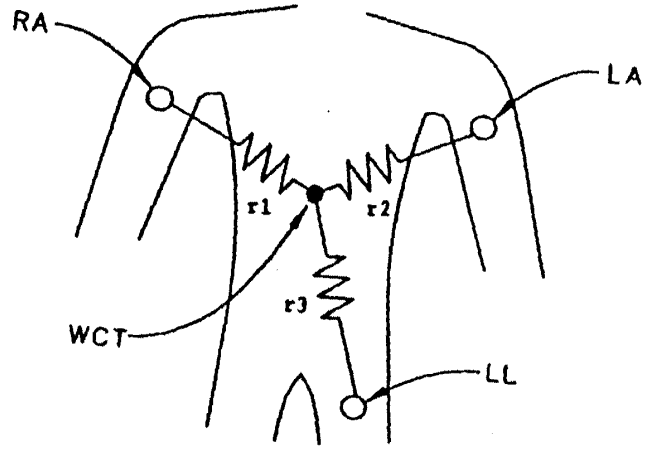


FIG. 6a

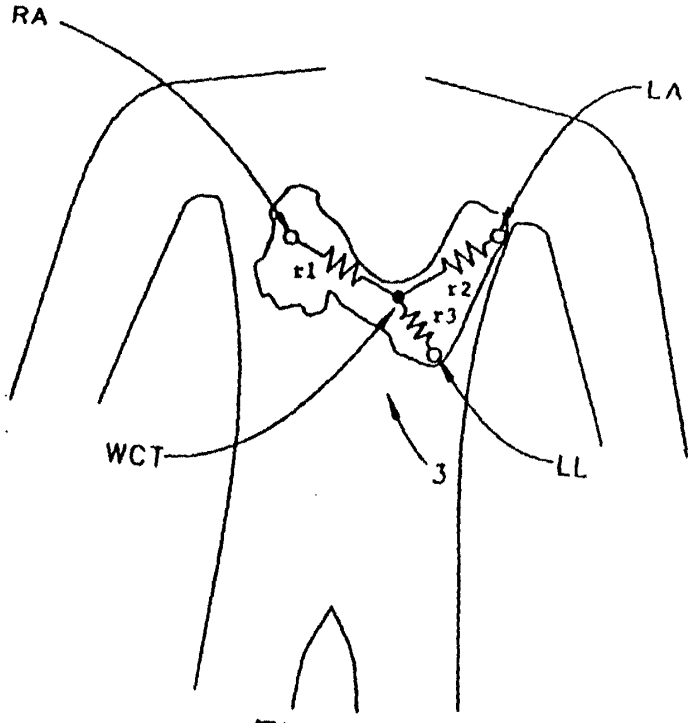


FIG. 6b

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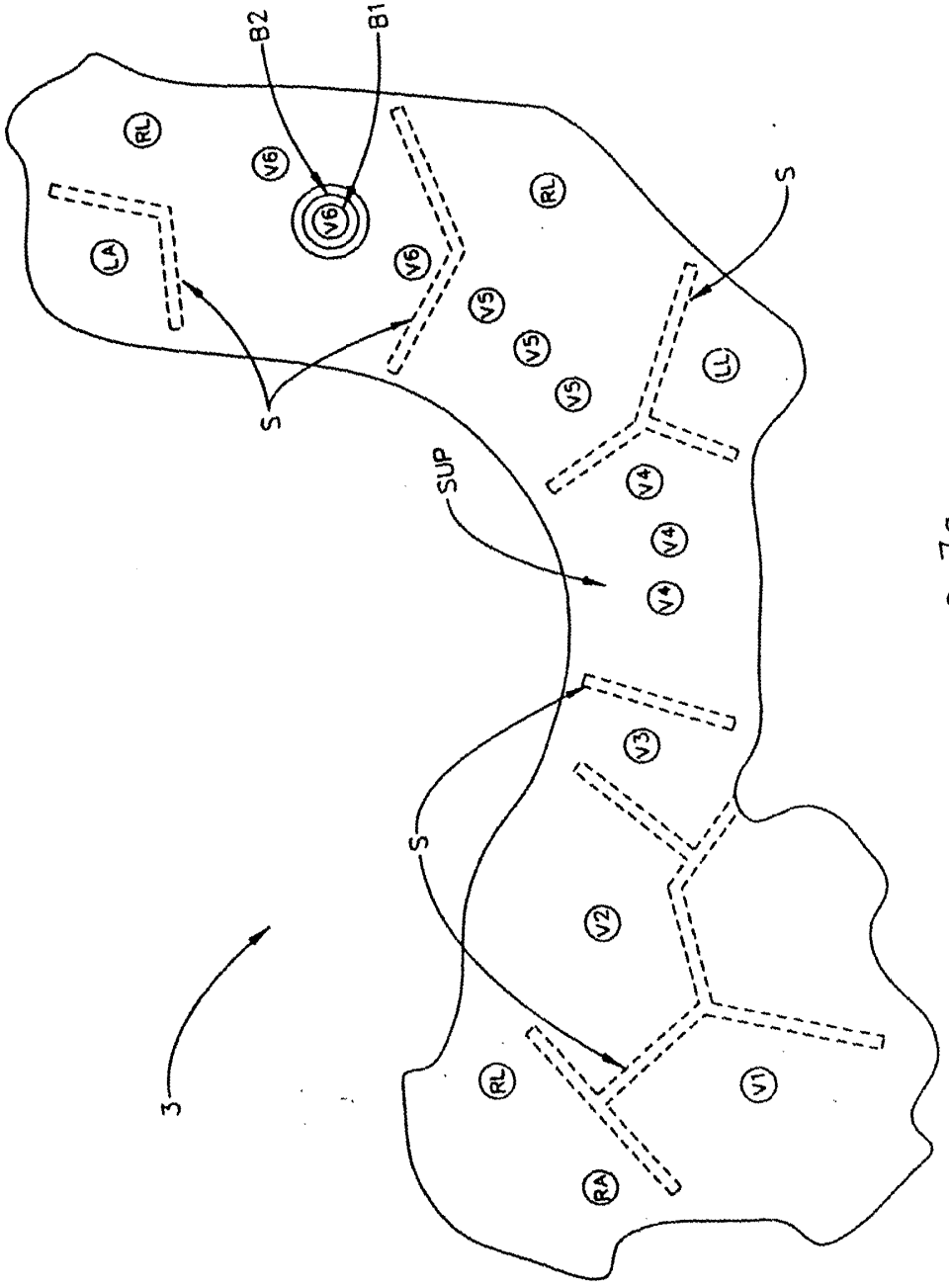


FIG. 7a

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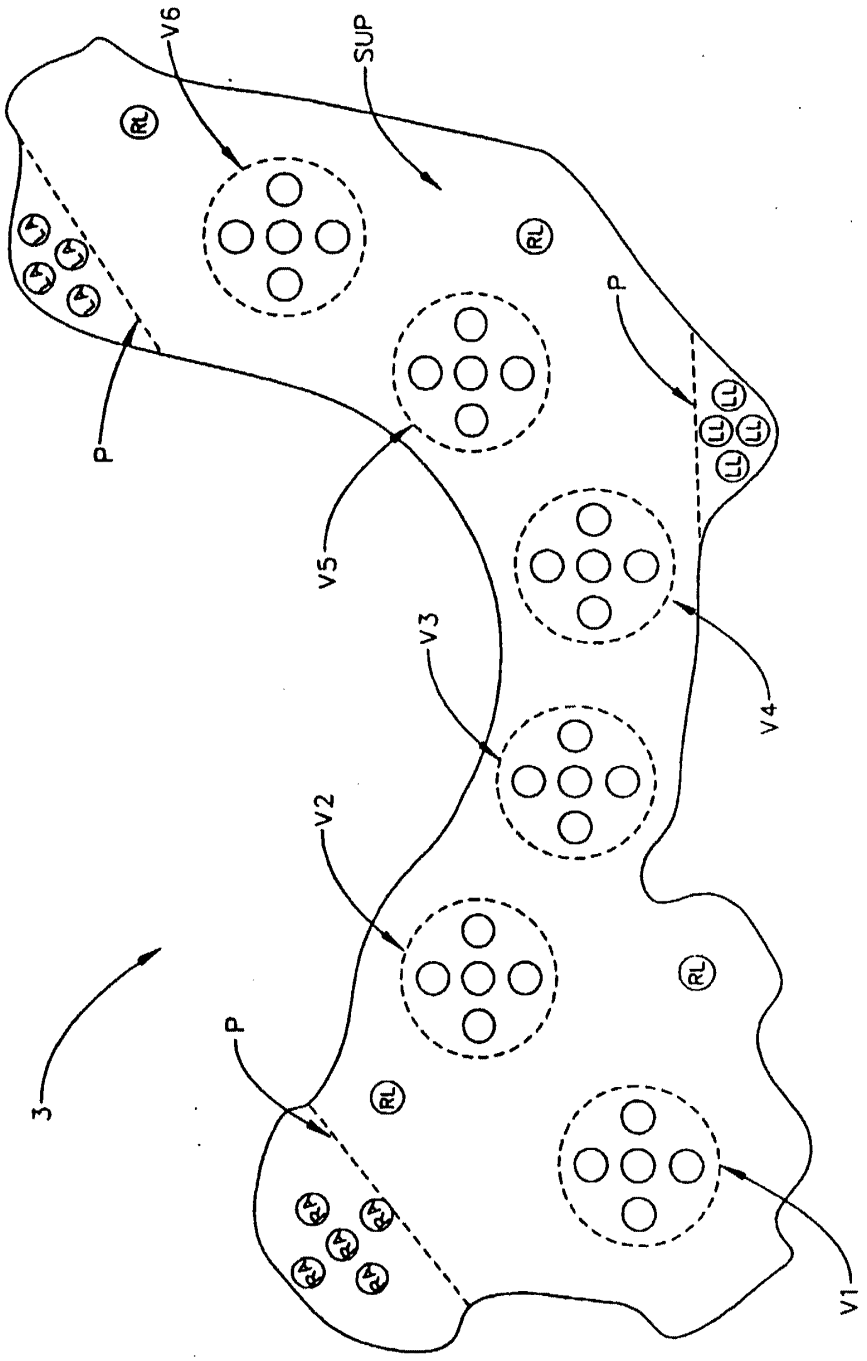


FIG. 7b

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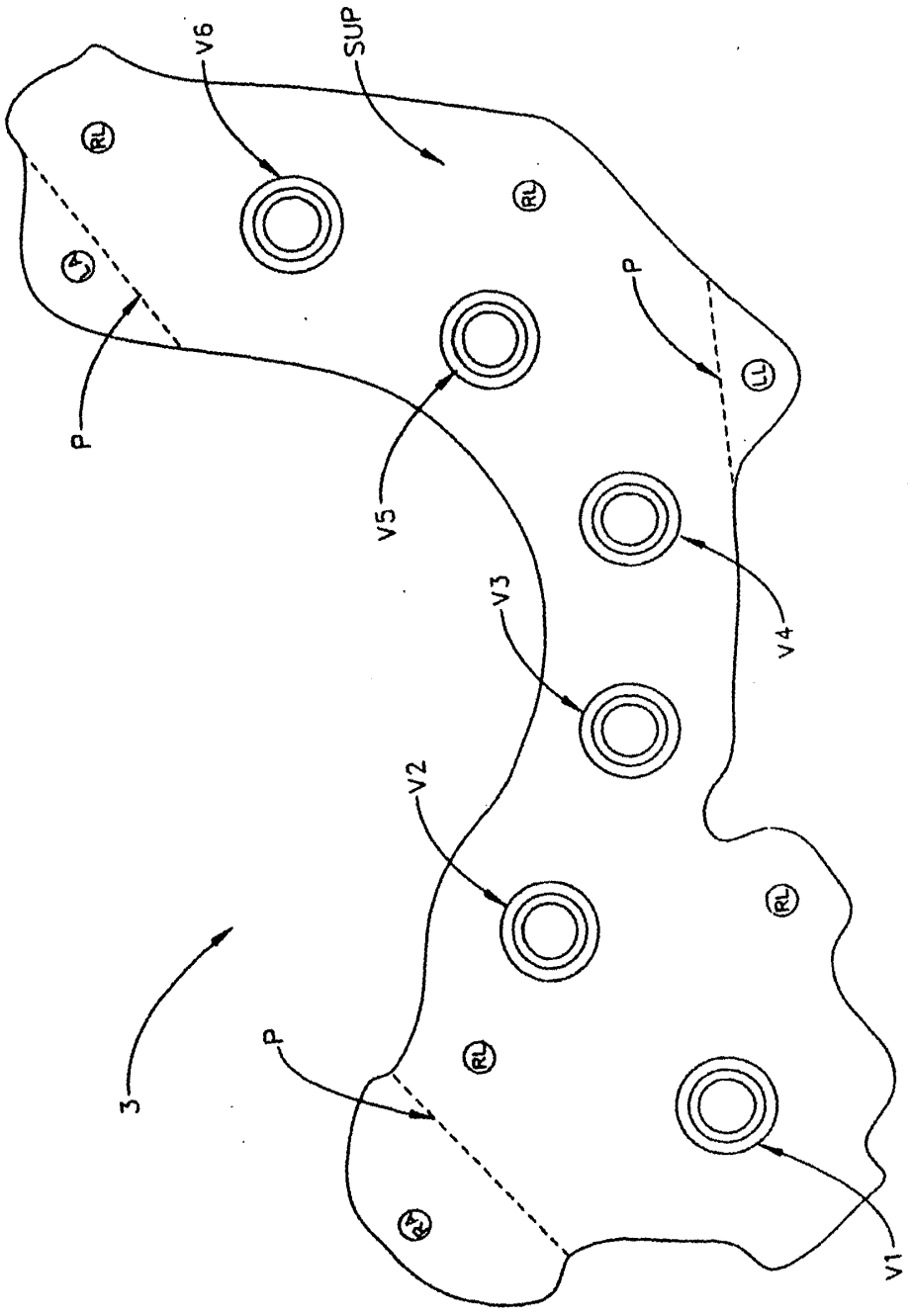


FIG. 7c

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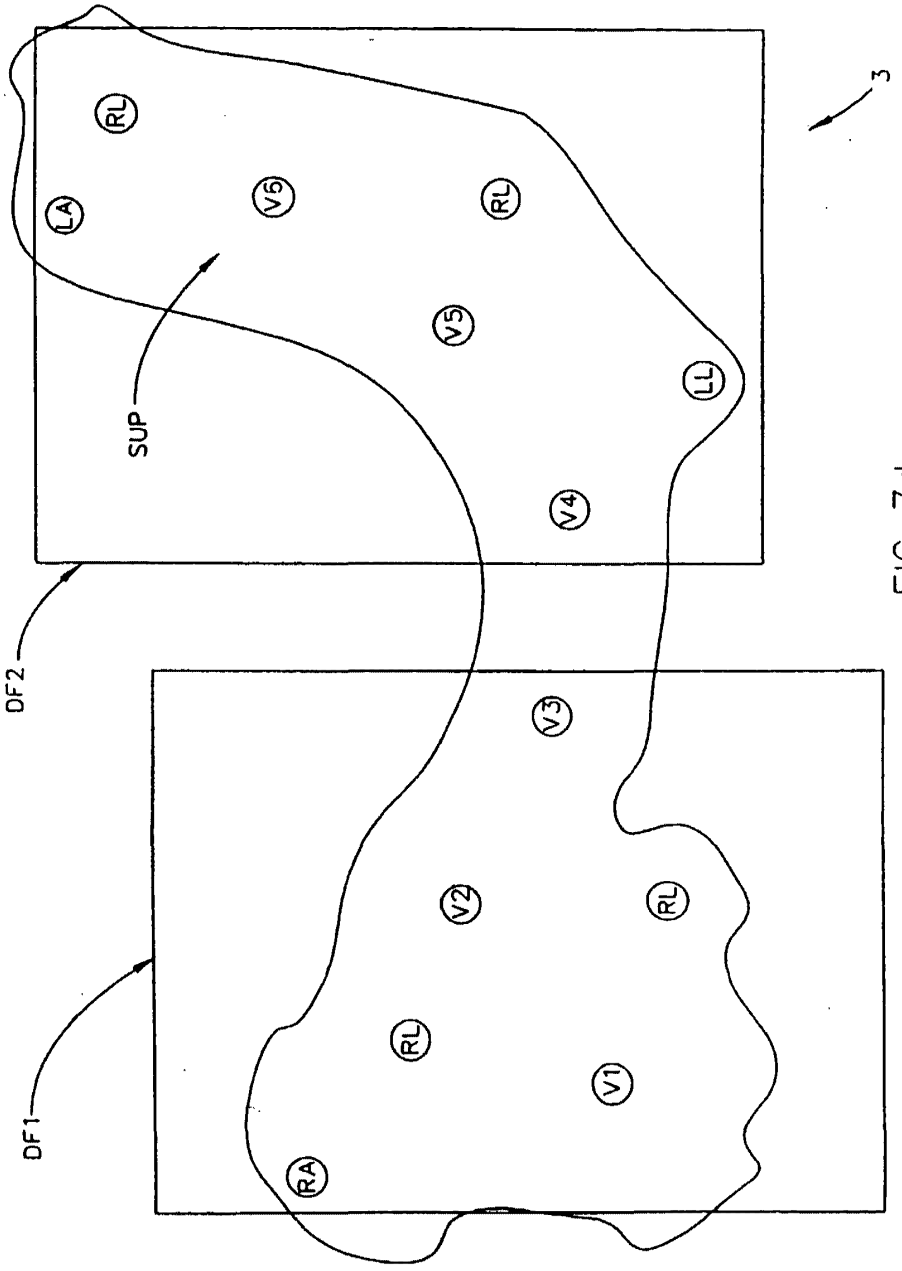


FIG. 7d

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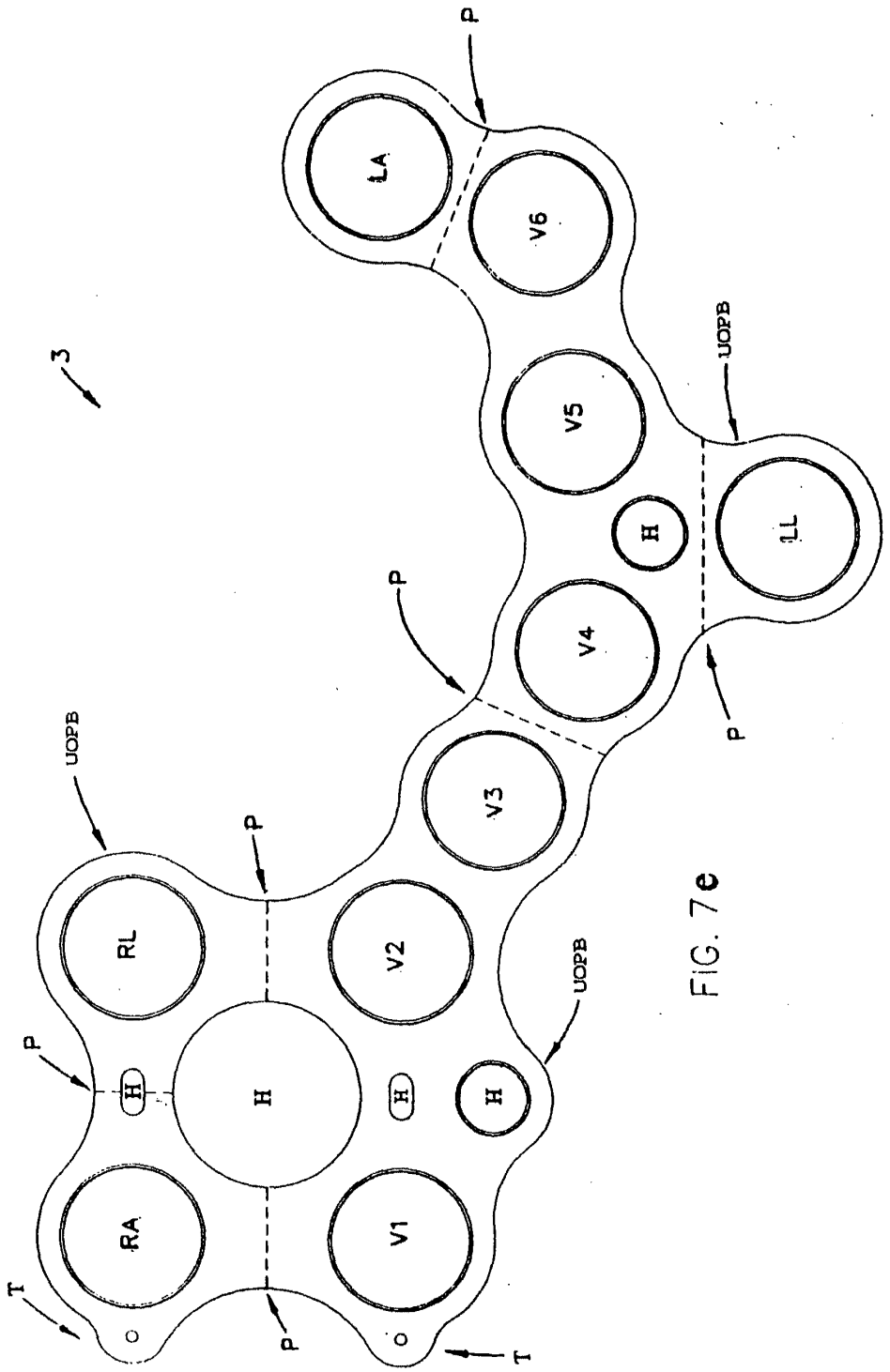


FIG. 7e

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European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 97 30 8319

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
E	US 5 678 545 A (STRATBUCKER) * the whole document * ---	1-92	A61B5/0408
X,D	EP 0 509 689 A (PHYSIO-CONTROL CORPORATION) * the whole document * ---	1-5,8,12,16-20,23,27,85,90-92	
X	WO 94 01039 A (SEGALOWITZ) * the whole document * ---	1,2,5,12,16,17,20,27,90-92 85	
X,D	US 5 184 620 A (MARQUETTE ELECTRONICS) * column 5, line 43 - column 8, line 47 * --- -/--	1,5,12,16,20,27,90-92 82,85,87,89	TECHNICAL FIELDS SEARCHED (Int.Cl.6) A61B

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :
1-13,16-28,36-39,67,68,71,72,82,85-92

Claims searched incompletely :

Claims not searched :
14,15,29-35,61-66,69,70,73,74,80,81,83,84

Reason for the limitation of the search:
Article 52(4) EPC

Place of search	Date of completion of the search	Examiner
THE HAGUE	8 April 1998	LEMERCIER, D

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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PARTIAL EUROPEAN SEARCH REPORT

Application Number
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DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X,D	WO 90 01898 A (GROEGER)	1,2,5,8, 9,12,16, 17,20, 23,24, 27,67, 71,90-92	
A	* page 3, line 14 - page 4, line 23; figure 1 *	85,88	

A	WO 90 09143 A (SEGALOWITZ)	1,2, 5-11,16, 17, 20-26, 36-39, 85,90-92	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
	* the whole document *		

A,D	DE 36 37 956 A (CHERNE INDUSTRIES)	1,5,8, 16,20, 23,68, 72, 85-87, 90-92	
	* column 11, line 11 - column 15, line 35 *		

EPO FORM 1503 03.82 (P04C10)

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Application Number
EP 97 30 8319

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-13,16-28,36-39,67,68,71,72,82,85-92

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LACK OF UNITY OF INVENTION
SHEET B

Application Number
EP 97 30 8319

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-13,16-28,36-39,67,68,71,72,82,85-92

   bioelectric interface comprising a support sheet for electrodes.

2. Claims: 40-60,75-79

   bioelectric interface comprising an adhesive.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B

A2

(11) International Publication Number: **WO 99/59460**

(43) International Publication Date: 25 November 1999 (25.11.99)

(21) International Application Number: PCT/SE99/00834

(22) International Filing Date: 17 May 1999 (17.05.99)

(30) Priority Data:

9801722-1	15 May 1998 (15.05.98)	SE
9802100-9	12 June 1998 (12.06.98)	SE
9802101-7	12 June 1998 (12.06.98)	SE

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(74) Agents: SANDSTRÖM, Staffan et al.; Bergenstråhle & Lindvall AB, P.O. Box 17704, S-118 93 Stockholm (SE).

(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, 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, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, 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).

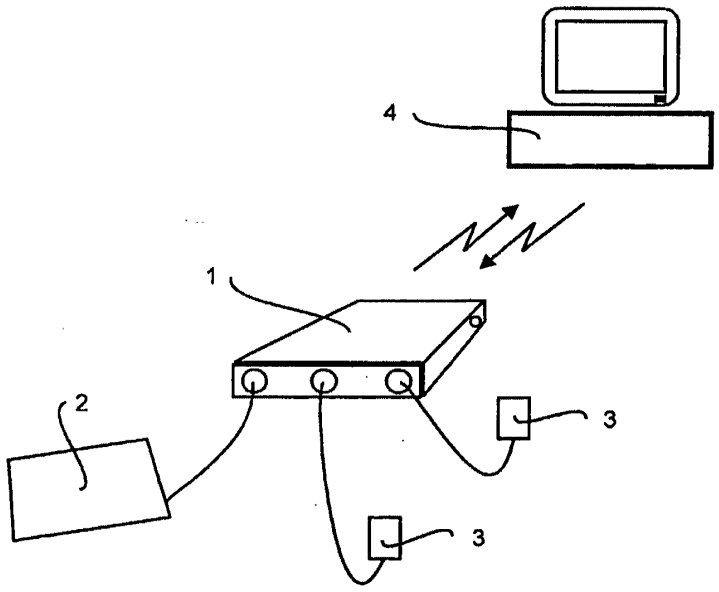
Published

Without international search report and to be republished upon receipt of that report.

(54) Title: A MEDICAL MEASURING SYSTEM

(57) Abstract

In a medical measurement system, measurements can be carried out at a distance from a hospital. Thus the patient is connected to a measuring system comprising measuring sensors and a unit for collecting data comprising a transmitter. The system also comprises a centrally located surveillance unit. The measuring sensors sense various physical and physiological parameters, for example brain activities, actions of the heart, respiration, blood pressure, blood values/tests and body movements. The sensed signals are transmitted to a portable small device of low weight for collecting and/or analysing data, which is connected to a central surveillance unit, for example via the public switched telephone network (PSTN), a radio system, in particular a cellular radio system, or via a satellite communication. In a preferred embodiment the measuring sensors comprise a preamplifier having an identification circuit. The identification circuit is used for providing each preamplifier with a unique identity. In yet another preferred embodiment a measuring pad for measuring physical and physiological parameters is provided. The measuring pad comprises a film having piezo and/or pyro electrical characteristics, for example a PVF-film (Poly Vinyl Fluoride), or any other sensor having similar properties. By using such a film, which can convert movements into an electrical signal several advantages are achieved.



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A MEDICAL MEASURING SYSTEM

TECHNICAL FIELD

The present invention relates to a medical measuring system and in particular to a method and a system for portable measurement, surveillance, transmission recording and analysis of physical, physiological and other functions and parameters.

BACKGROUND OF THE INVENTION AND PRIOR ART

In various medical areas it is sometimes necessary to perform measurements and surveillance during long periods of time. Examples of such medical areas could be neurology, cardiology, telemedicine, long-term nursing and home nursing. During such long-term measurements, which typically last for days, the patient must at all time be connected to the measuring equipment in order for a continuous measurement to occur.

Furthermore, in most cases such measurements must be supervised by qualified personnel in order to prevent interruptions in the measurements and to check that the condition of the patient does not worsen. The latter is very important since measurements of the kind mentioned above often are included in treatment as follow-up examinations or in investigations for establishing a diagnosis. Thus, it is common that the person responsible for correctly carrying out the measurements is a doctor.

These long term measurements must therefore be carried out using ambulatory measurement equipment, since the patient can hardly be expected to remain in bed during the long periods required for obtaining a continuous series of measurements. Further, the measuring equipment must be located at a hospital in order to there be supervised by a doctor in charge.

This is of course expensive for the payer of the hospital care and not particularly comfortable for the patient who

cannot leave the hospital despite the fact that he/she is not in any need of hospitalization at the movement.

SUMMARY

It is an object of the present invention to reduce the costs resulting from long-term measurements.

It is another object of the present invention to improve the environment and reduce the difficulties for patients who need to undergo long-term measurements.

It is yet another object of the present invention to provide a measuring pad for measurements of physical and physiological parameters, which is very sensitive and which therefore can be located at a fairly long distance from a patient, for example beneath a thick mattress or even under a bed.

It is a further object of the present invention to provide a pre-amplifier, which is easy to handle and which produces or eliminates the risk for erroneous handling, and which is suited to be used together with the measuring equipment.

These objects and others are obtained by means of a method and system by means of which the measurements can be carried out at a distance from a hospital. Thus the patient is connected to a measuring system comprising measuring sensors and a unit for collecting data comprising a transmitter. The unit for collecting data preferably also comprises means for performing different analyses. The system also comprises a centrally located surveillance unit.

The measuring sensors sense various physical and physiological parameters, for example brain activities, actions of the heart, respiration, blood pressure, blood values/tests and body movements. The sensed signals are transmitted to a portable small device of low weight for collecting and/or analysing data, which is connected to a

central surveillance unit, for example via the public switched telephone network (PSTN), a radio system, in particular a cellular radio system, or via a satellite communication. The central surveillance unit is monitored by qualified personnel which can follow the measurements and also in certain cases reprogram the unit for collecting and analysing data during an ongoing measurement.

In a preferred embodiment the measuring sensors comprise a preamplifier having an identification circuit. The identification circuit is used for providing each preamplifier with a unique identity. The fact that each pre-amplifier is given a unique identity makes it possible for the unit collecting and analysing data to automatically check if the correct pre-amplifier has been attached to the correct input terminal and, if that is not the case, either correct the error or give a signal indicating that an erroneous connection has been made.

In yet another preferred embodiment a measuring pad for measuring physical and physiological parameters is provided. The measuring pad comprises a film having piezo and/or pyro electrical characteristics, for example a PVF-film (Poly Vinyl Fluoride), or any other sensor having similar properties. By using such a film, which can convert movements into an electrical signal several advantages are achieved. Thus, a measuring pad comprising such a film is easy to fold together and can be made very sensitive, whereby it can be placed beneath the mattress or even under the bed in which the patient is lying.

Furthermore, the signals transmitted to/ from the central surveillance unit can be image/video signals (if a camera is connected to the system), audio signals (such as speech), text signals (for transmission of prescriptions etc.) as well as biological signals. In this manner the personnel at the surveillance end of the system can have full access to information required for providing the patient with proper medical treatment at distance.

The use of the system as described herein provides a number of advantages compared to the prior art. Thus, the patient no longer needs to be in a hospital but can instead be at home or at an another suitable location. Hence, by using the system the cost for hospital care is reduced or eliminated. Furthermore the patient can move around freely due to the fact that the measuring system and auxiliary equipment used for collecting data are made small and of low weight.

BRIEF DESCRIPTION OF THE DRAWINGS

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

- Figure 1 is a schematic view of an ambulatory medical measuring system.
- Figure 2 is a schematic diagram of a unit for collecting and analysing data.
- Figure 3 is a schematic diagram of a preamplifier used in the medical measuring system shown in figure 1.
- Figure 4 is a section through a measuring pad for use together with the medical measuring system shown in figure 1.

DETAILED DESCRIPTION

In figure 1 a schematic diagram of an ambulatory medical measuring system is shown. Thus a unit 1 for collecting and analysing data is connected to a measuring pad 2 and a pre-amplifier 3. The measuring pad 2 and the preamplifiers 3 sense different physical and physiological parameters and are described in more detail below in conjunction with figure 3 and figure 4. These signals are transmitted to the unit 1 for collecting and analysing data.

In the unit 1 the signals provided by the measuring pad 2 and the preamplifiers 3 are A/D-converted and stored and analysed. The digital data stored in the unit 1 can then be output from the unit 1 to an external computer 4.

The transmission of data to the external computer 4 can be carried out in a number of different ways. In a preferred embodiment the transmission is carried out using an infrared

IR-interface. Such an arrangement has the advantage that the patient can be connected to the measuring equipment when data is transmitted from the unit 1 to the computer 4 without being physically connected to the computer 4. Thus, the risk for electrical current to be transmitted from the computer 4 to the patient is eliminated.

In another preferred embodiment the unit 1 is also provided with, e.g., a PCMCIA-card or PC-card or a similar device by means of which the unit 1 can connect to a telephone or data network. The computer 4 then does not need to be in the same room as the unit 1 when data is transmitted from the unit 1 to the computer 4. For example, the unit 1 can be located together with the patient at home and the computer 4 can be located at the hospital.

A doctor or another qualified person at the hospital can then connect to the unit 1 at any time and transmit measurements data from the unit 1 via for example the public switched telephone network or a cellular network to the computer 4. In such an arrangement the patient does not need to be disturbed or even know about when the unit 1 transmits data and must hence not be bothered by this.

In yet another preferred embodiment the unit 1 can in itself analyse the collected measurement data. Examples of analyses which the unit 1 can perform are comparisons between measured signals and threshold values corresponding to such signals.

Thus, an alarm can be activated in the unit 1 if such a threshold value is crossed either from above or from below and the computer 4 can be automatically contacted via the telephone or data network in order for the doctor or qualified personnel monitoring the computer 4 to immediately have access to all measurement data, in particular the data causing the triggering of the alarm.

In this manner an important event in the series of measured data can be spotted quickly, transmitted and possibly taken

care of. For example, the information transmitted can form the basis for moving the patient to a hospital in order to perform more thorough investigations and tests or that an emergency alarm is issued and that actions required are performed.

Another advantage achieved with such an arrangement is that it is possible to perform adjustments in the settings at distance. Thus, if the doctor or qualified personnel for one reason or another wants to measure some another physical or physiological parameter, which at present is not being measured, information thereof can be transmitted from the computer 4 to the unit 1 and collection of the new desired parameter can start in the unit 1.

In yet another preferred embodiment data regarding the patients earlier conditions and possible treatment can also be stored and transmitted to/from the unit 1. The unit 1 may also be equipped with a GPS-navigation system for continuous surveillance of the movements of the patient and in order to locate the patient quickly in the case an alarm signal is transmitted and the patient must be located quickly.

In fig. 2 a schematic block diagram of the unit 1 is shown. Thus, the unit 1 comprises an input terminal 10 for analogue signals and an input terminal 12 for digital signals. The analogue input terminal is connected to a unit 14 wherein the signal is amplified and filtered. The output signal from the unit 14 is fed to an A/D-converter 16 wherein the signal from the unit 14 is converted into a digital format.

The output signal from the A/D-converter is fed to a computation and control unit 18. The signals input at the terminal 12 are also connected to the unit 18. The unit 18 is connected to a memory 20 in which information can be stored and from which the unit 18 can read information. The unit 18 is also connected to a unit 22 arranged to transmit and receive information from outside the unit 1. . The unit 22 can for example be a wireless modem or another suitable

interface.

The unit 1 can further comprise a power supply unit 24, for example a rechargeable or replaceable battery. In a preferred embodiment the power supply unit comprises a back-up function so that a battery can be charged or replaced without having to interrupt an ongoing measurement.

The unit 1 may also have an input terminal 26 to which equipment for control, calibration or analysis of the unit 1 can be connected.

In Fig. 3, a schematic block diagram of the pre-amplifier 3 is shown. Thus, the pre-amplifier 3 comprises a first amplifier 103, which is connected to a number of input terminals arranged to receive plug-in contacts for electrodes, which are attached to a person from whom measured data are collected.

The amplifier 103 is connected to a digital filter 105. The filter 105 filters the signals using a suitable filter. The filter may by different for different types of signals as described below.

The filter 105 is in turn connected to a second amplifier 107 wherein the signals are amplified a second time to a suitable output amplitude. The amplifier 107 is connected to an output terminal through which the pre-amplifier 3 can be connected to the unit 1. The pre-amplifier 3 can also be equipped with a wireless interface towards the unit 1. If such an arrangement is employed the need for cables and input/output terminals can be dispensed with.

Furthermore, the pre-amplifier 3 comprises an identification and calibration unit 109. The unit 109 can communicate with the unit 1 or with another external unit via a bi-directional data communication line. Thus, the unit 1 can read a unique ID-number and also, in a preferred embodiment, read calibration data stored in the unit 109.

In a preferred embodiment the ID-number and the calibration data can be read continuously or every time the pre-amplifier is connected to the unit 1.

IN another preferred embodiment the pre-amplifier 3 can be informed of which type of signal which is to be measured. This is accomplished by means of a special protocol, which informs the pre-amplifier that a particular type of signals are to be measured, for example heart or brain signals.

Since the pre-amplifier is informed of which type of signals that are to be measured the filter 105 can be adjusted for that type of signals and also the amplifiers 103 and 107 can be set to levels, which are suitable for the type of signals to be measured.

Since each pre-amplifier 3 is given a unique identity the unit 1 can sense if the correct pre-amplifier has been connected to the corresponding input terminal of the unit 1. If this is not the case, the unit 1 can correct the mistake or give a signal informing the user of his/her mistake.

Furthermore, since the unit 1 and/or the pre-amplifier 3 has knowledge of which type of signal that is to be measured, an alarm signal can be issued if the wrong type of signal is measured.

In Fig 4, a section through the measuring pad 2 is shown. The pad 2 comprises a pressure sensitive element 201 made of a material such as a PVF-film or another type of film, which generates an electrical voltage in response to physical movements or pressure changes. Around the element 201 a protective coating 202 is arranged.

The coating 202 isolates the element 201 from static voltages and other electrical noise. The pad 2 is preferably further provided with a shock absorbing material 3, which protects the element 201 from impacts. The material 3 is preferably a rubber material or another suitable flexible and robust

material.

The pad 1 has an outer coating made of a water resistant material 204, which prevents liquid from getting into contact with the pressure sensitive element 201. The element 201 can further communicate with the unit 1 via a cable 205, which is connected to the unit 1 and to the element 201. The cable 205 is passed through the outer coating 204 of the pad 2 through a watertight passage.

In another preferred embodiment the interface between the unit 1 and the pad 2 is wireless. The element 201 then emits signals to the unit 1 via a wireless modem or via infrared (IR) light, or in any other suitable manner.

A portable system as described herein can be made of very low weight and the measuring parts of the system, i.e. the electrodes and its pre-amplifier(s), and the measuring pad, are therefore easy to bring along when a patient using them wants to move around. This gives the patient much more freedom than what can be achieved with the prior art.

WHAT IS CLAIMED IS:

1. A medical portable measuring system comprising:
- sensors for measuring physical and/or physiological parameters of a patient, said sensors being arranged to emit signals to a data collecting unit, wherein the data collecting unit is arranged to communicate with a surveillance unit located at distance from the data collecting unit.

2. A system according to claim 1, wherein the data collecting unit is connected to the surveillance unit via a wireless interface.

3. A system according to claim 1, wherein the data collecting unit comprises means for analysing collected data.

4. A system according to claim 3, wherein means for issuing an alarm signal are connected to the analysing means.

5. A system according to claim 1, wherein the surveillance unit is arranged to transmit control and set-up signals to the data collecting unit.

6. A system according to claim 1, wherein the collecting unit comprises a GPS-transmitter.

7. A system according to claim 1, comprising a signal amplifier device connected to the data collecting unit having an identification circuit for automatic identification of the amplifier.

8. A system according to claim 7, wherein the amplifier device has means for storing calibration data.

9. A system according to claim 7, wherein the amplifier device comprises a signal filter, the parameters of which can be controlled in response to control signals.

10. A system according to claim 1, comprising a pressure sensitive element made of a film arranged to convert pressure changes into an electrical signal and which is connected to the data collecting unit.

11. A system according to claim 10, wherein an elastic material is arranged around the film.

12. A system according to claim 10, wherein the film is made of PVF (Poly Vinyl Fluoride).

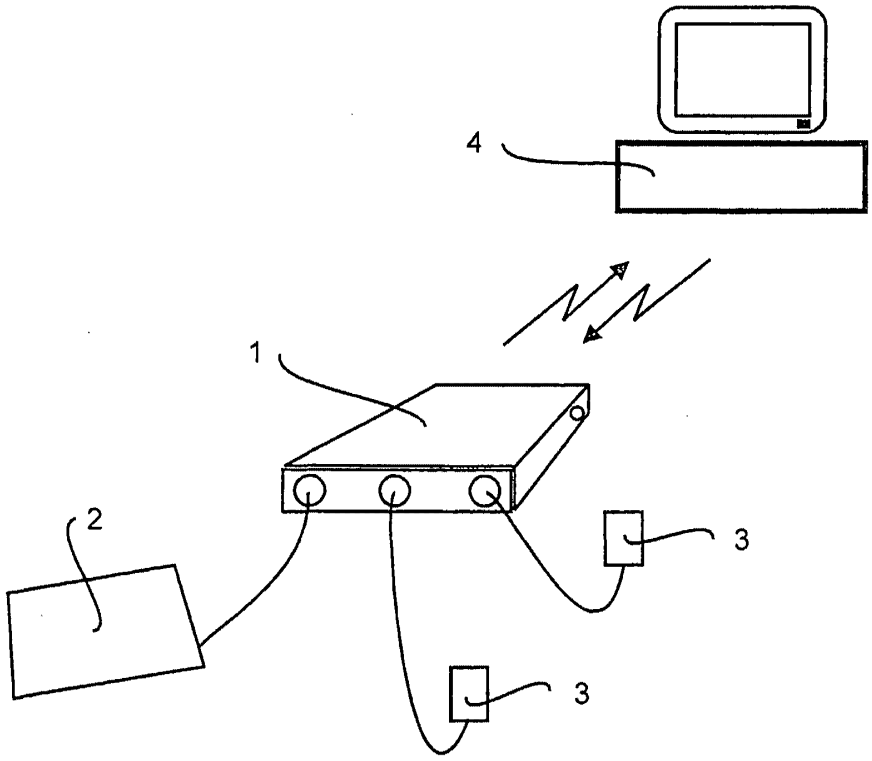


Fig. 1

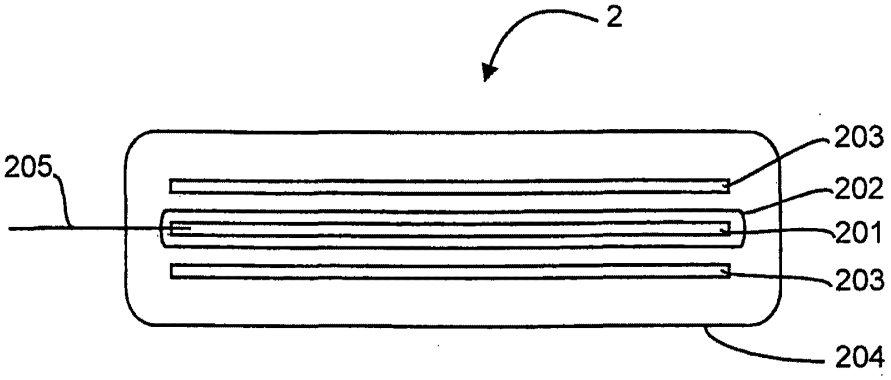


Fig. 4

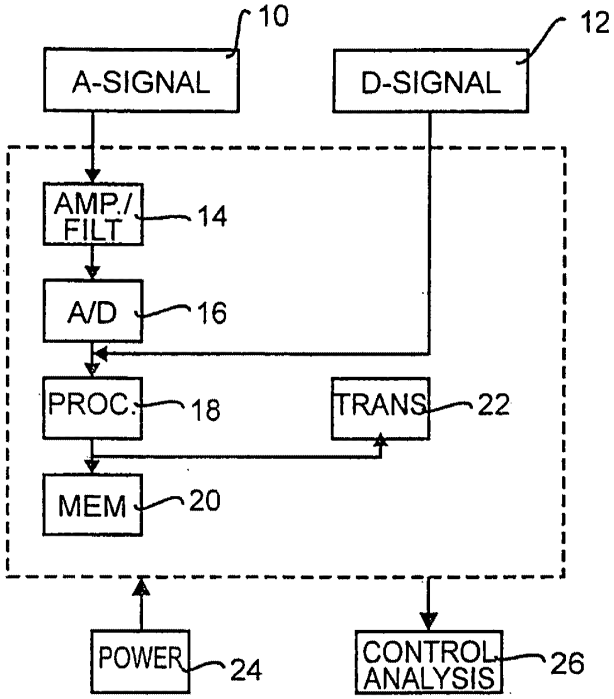

10
12
A-SIGNAL
D-SIGNAL
AMP./ FILT
14
A/D
16
PROC.
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TRANS
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MEM
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POWER
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CONTROL ANALYSIS
26

Fig. 2

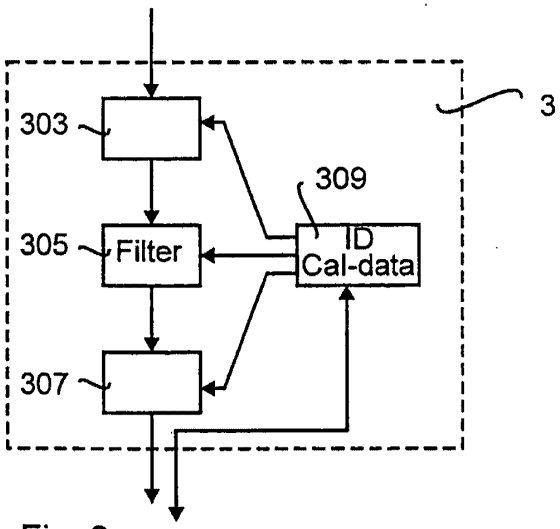

3
303
309
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Filter
ID Cal-data
307

Fig. 3

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
11/591,619	11/01/2006	3736	3630	704_049	14	58	6

CONFIRMATION NO. 7955

UPDATED FILING RECEIPT

20874
WALL MARJAMA & BILINSKI
250 SOUTH CLINTON STREET
SUITE 300
SYRACUSE, NY13202

Date Mailed: 02/01/2007

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Steven D. Baker, Beaverton, OR;
Eric T. McAdams, Whitehead, NIR, UNITED KINGDOM;
James P. Welch, Laguna Niguel, CA;
Norbert Ohlenbusch, Andover, MA;
Thomas P. Blackadar, Natick, MA;

Assignment For Published Patent Application

Welch Allyn, Inc., Skaneateles Falls, NY

Power of Attorney: The patent practitioners associated with Customer Number 20874

Domestic Priority data as claimed by applicant

Foreign Applications

If Required, Foreign Filing License Granted: 11/21/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US11/591,619**

Projected Publication Date: 05/01/2008

Non-Publication Request: No

Early Publication Request: No

Title

Body worn physiological sensor device having a disposable electrode module

Preliminary Class

600

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under

37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

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Norbert Ohlenbusch, Andover, MA;
Thomas P. Blackadar, Natick, MA;

Assignment For Published Patent Application

Welch Allyn, Inc., Skaneateles Falls, NY

Power of Attorney: None

Domestic Priority data as claimed by applicant

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Non-Publication Request: No

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/591,619	11/01/2006	Steven D. Baker	704_049

CONFIRMATION NO. 7955

20874
WALL MARJAMA & BILINSKI
101 SOUTH SALINA STREET
SUITE 400
SYRACUSE, NY 13202

FORMALITIES LETTER

Date Mailed: 11/22/2006

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Adjustment date: 01/23/2007 MTEKLEMI
01/22/2007 BABRAHA1 00000040 500289 11591619
01 FC:1051 130.00 CR

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

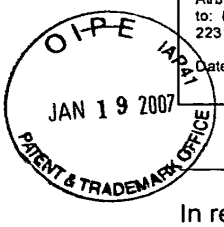
The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings submitted to the Office are not electronically reproducible. Drawing sheets must be submitted on paper, which is flexible, strong, white, smooth, non-shiny, and durable (see 37 CFR 1.84(e)). See Figure(s) 2, 14, 16B.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

01/18/2007 EHAILE1 00000050 11591619
01 FC:1051 130.00 DA



I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV969121569US, on the date shown below in an envelope addressed to: MS Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: January 19, 2007 Signature: Susanne C. Pelose
(Susanne C. Pelose)

Docket No.: 704_049
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Steven D. Baker et al.

Application No.: 11/591,619

Filed: November 1, 2006

For: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

Confirmation No.: 7955

Art Unit: 3736

Examiner: Not Yet Assigned

RESPONSE TO NOTICE TO FILE MISSING PARTS OF APPLICATION

MS Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notice to File Missing Parts of Application – Filing Date Granted mailed November 22, 2006, Applicant respectfully submits a Combined Declaration and Power of Attorney and Part 2 Copy of Notice.

Please charge our Deposit Account No. 50-0289 in the amount of $130.00 covering the fee set forth in 37 CFR 1.16(f). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our

Deposit Account No. 50-0289, under Order No. 704_049. A duplicate copy of this paper is enclosed.

Dated: January 19, 2007

Respectfully submitted,

By Peter J. Bilinski

Peter J. Bilinski
Registration No.: 35,067
WALL MARJAMA & BILINSKI LLP
250 South Clinton Street
Suite 300
Syracuse, New York 13202
(315) 425-9000
Attorney for Applicant

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 943

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PTO/SB/21 (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	18

Application Number	11/591,619-Conf. #7955
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Attorney Docket Number	704_049

ENCLOSURES (*Check all that apply*)

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [x] Reply to Missing Parts/ Incomplete Application
  - [x] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) (please Identify below):

Copy of Notice to File Missing Parts (2 pgs.); Declaration (6 pgs.); Supplemental ADS (5 pgs.) and Return Mailroom Postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	WALL MARJAMA & BILINSKI LLP		
Signature	Peter J Bilinski		
Printed name	Peter J. Bilinski		
Date	January 19, 2007	Reg. No.	35,067

Transmittal

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EV969121569US, on the date shown below in an envelope addressed to:
MS Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: January 19, 2007 Signature: Susanne C Pelose (Susanne C. Pelose)

OIPE JAN 19 2007 PATENT & TRADEMARK OFFICE

PTO/SB/17 (07-06)
Approved for use through 01/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 130.00

Complete if Known	
Application Number	11/591,619-Conf. #7955
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Examiner Name	Not Yet Assigned
Art Unit	3736
Attorney Docket No.	704_049

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 50-0289 Deposit Account Name: Wall Marjama & Bilinski LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	**Fee ($)**	**Fee ($)**	**Fee ($)**	**Fee ($)**	**Fee ($)**	**Fee ($)**	**Fees Paid ($)**
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	**Fee ($)**	**Small Entity Fee ($)**
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims	**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
_____ - =	_____ x	_____ =	_____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	**Extra Claims**	**Fee ($)**	**Fee Paid ($)**
_____ - =	_____ x	_____ =	_____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims

Fee ($)	**Fee Paid ($)**

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	**Extra Sheets**	**Number of each additional 50 or fraction thereof**	**Fee ($)**	**Fee Paid ($)**
_____ - 100 =	_____ /50	_____ (round up to a whole number) x	_____ =	_____

4. OTHER FEE(S) **Fees Paid ($)**

Non-English Specification, $130 fee (no small entity discount)

Other (e.g., late filing surcharge): 1051 Surcharge-Late oath or declaration 130.00

SUBMITTED BY					
Signature	Peter J. Bilinski	Registration No. (Attorney/Agent)	35,067	Telephone	(315) 425-9000
Name (Print/Type)	Peter J. Bilinski			Date	January 19, 2007

Fee Transmittal

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01-22-07

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/591,619	11/01/2006	Steven D. Baker	704_049

OIPE IAP41 JAN 19 2007 PATENT & TRADEMARK OFFICE

CONFIRMATION NO. 7955

FORMALITIES LETTER

20874
WALL MARJAMA & BILINSKI
101 SOUTH SALINA STREET
SUITE 400
SYRACUSE, NY 13202

Date Mailed: 11/22/2006

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

01/22/2007 BABRAHA1 00000040 500289 11591619

01 FC:1051 130.00 DA

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings submitted to the Office are not electronically reproducible. Drawing sheets must be submitted on paper, which is flexible, strong, white, smooth, non-shiny, and durable (see 37 CFR 1.84(e)). See Figure(s) 2, 14, 16B.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$130** for a non-small entity

- **$130** Surcharge.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
PART 2 - COPY TO BE RETURNED WITH RESPONSE

OIPE
JAN 19 2007
PATENT & TRADEMARK OFFICE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION, POWER OF ATTORNEY (37 CFR 1.32)and CORRESPONDENCE ADDRESS INDICATION FORM (37 CFR 1.32)	**Application Number**	11/591,619
	Filing Date	November 1, 2006
	First Named Inventor	Steven D. Baker
	Title	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
	Group Art Unit	3736
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	704_049
	Express Mail Label No.	EV969121569US

DECLARATION

This declaration is directed to:

☐ The attached application, or

☒ Application No. 11/591,619, filed on November 1, 2006, ☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

My residence, mailing address, and citizenship are as stated below next to my name;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

All statements made herein of my/our own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Each of the undersigned hereby grants to any duly empowered legal representative the power to insert on this document any further information which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office or with the rules of any other national or international Patent Office.

FOREIGN PRIORITY CLAIMS

I/we hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on _____ supplemental priority data sheet(s) attached hereto.

DESIGNATION OF POWER OF ATTORNEY

The following individual(s) is/are hereby appointed by the applicant(s) as my/our attorney(s) or agent(s) to prosecute the application identified above, and any additional applications based substantially on the disclosure contained therein, including applications under the Patent Cooperation Treaty, and to transact all business before any patent granting agency, including the United States Patent and Trademark Office, connected therewith:

Designation under 37 CFR § 1.32(c)(2)
All patent practitioners associated with the **Customer Number 20874**.
Please recognize or change the correspondence address for the above-identified application to the address associated with **Customer Number 20874**.

The undersigned is/are

☒ the Applicant(s)/Inventor(s)

☐ the Assignee of record of the entire interest. See 37 CFR 3.71. (*Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).)*

SIGNATURE(S) OF APPLICANT(S) OR ASSIGNEE OF RECORD

NAME OF SOLE OR FIRST INVENTOR:			☐ **A petition has been filed for this unsigned inventor**
Steven D. **Given Name (first and middle [if any])**			Baker **Family Name or Surname**
Inventor's Signature			03/14/2007 **Date:**
Residence: **City** Beaverton	**State** OR	**Country** US	**Citizenship** US
Mailing Address 7623 SW Crisp Drive			
City Beaverton	**State** OR	**ZIP** 97007	**Country** US

NAME OF SECOND INVENTOR:			☐ **A petition has been filed for this unsigned inventor**
Eric T. **Given Name (first and middle [if any])**			McAdams **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Whitehead	**State** Antrim	**Country** UK	**Citizenship** GB
Mailing Address 52 Cable Road			
City Whitehead	**State** Antrim	**ZIP** BT389PZ	**Country** Northern Ireland (UK)

☐ **Additional inventors are being named on the second supplemental Additional Inventor(s) sheet(s) attached hereto.**

☐ Additional foreign application numbers are listed on _____ supplemental priority data sheet(s) attached hereto.

DESIGNATION OF POWER OF ATTORNEY

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Designation under 37 CFR § 1.32(c)(2)
All patent practitioners associated with the **Customer Number 20874**.
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The undersigned is/are

☒ the Applicant(s)/Inventor(s)

☐ the Assignee of record of the entire interest. See 37 CFR 3.71. *(Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).)*

SIGNATURE(S) OF APPLICANT(S) OR ASSIGNEE OF RECORD

NAME OF SOLE OR FIRST INVENTOR:	☐ **A petition has been filed for this unsigned inventor**
Steven D. **Given Name (first and middle [if any])**	Baker **Family Name or Surname**

Inventor's Signature		**Date:**

Residence: City Beaverton	**State** OR	**Country** US	**Citizenship** US
Mailing Address 7623 SW Crisp Drive			
City Beaverton	**State** OR	**ZIP** 97007	**Country** US

NAME OF SECOND INVENTOR:	☐ **A petition has been filed for this unsigned inventor**
Eric T. **Given Name (first and middle [if any])**	McAdams **Family Name or Surname**

Inventor's Signature		**Date:**

Residence: City Whitehead	**State** Antrim	**Country** UK	**Citizenship** GB
Mailing Address 52 Cable Road			
City Whitehead	**State** Antrim	**ZIP** BT389PZ	**Country** Northern Ireland (UK)

☐ **Additional inventors are being named on the second supplemental Additional Inventor(s) sheet(s) attached hereto.**

NAME OF THIRD INVENTOR:			☐ A petition has been filed for this unsigned inventor
James P. **Given Name (first and middle [if any])**			Welch **Family Name or Surname**
Inventor's Signature	James C Welch		**Date:** 1/15/07
Residence: **City** Mission Viejo	**State** CA	**Country** US	**Citizenship** US
Mailing Address 22381 Bayberry			
City Mission Viejo	**State** CA	**ZIP** 92692	**Country** US

NAME OF FOURTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Norbert **Given Name (first and middle [if any])**			Ohlenbusch **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Andover	**State** MA	**Country** US	**Citizenship** US
Mailing Address 9 Whispering Pines Drive			
City Andover	**State** MA	**ZIP** 01810	**Country** US

NAME OF FIFTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Thomas P. **Given Name (first and middle [if any])**			Blackadar **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Natick	**State** MA	**Country** US	**Citizenship** US
Mailing Address 5 Lupine Road			
City Natick	**State** MA	**ZIP** 01760	**Country** US

NAME OF THIRD INVENTOR:			☐ A petition has been filed for this unsigned inventor
James P. **Given Name (first and middle [if any])**			Welch **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Laguna Niguel	**State** CA	**Country** US	**Citizenship** US
Mailing Address 24446 Kathleen Drive			
City Laguna Niguel	**State** CA	**ZIP** 92677	**Country** US

NAME OF FOURTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Norbert **Given Name (first and middle [if any])**			Ohlenbusch **Family Name or Surname**
Inventor's Signature	Norbert Ohlenbusch		4/10/2007 **Date:**
Residence: **City** Andover	**State** MA	**Country** US	**Citizenship** US
Mailing Address 9 Whispering Pines Drive			
City Andover	**State** MA	**ZIP** 01810	**Country** US

NAME OF FIFTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Thomas P. **Given Name (first and middle [if any])**			Blackadar **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Natick	**State** MA	**Country** US	**Citizenship** US
Mailing Address 5 Lupine Road			
City Natick	**State** MA	**ZIP** 01760	**Country** US

NAME OF THIRD INVENTOR:			☐ A petition has been filed for this unsigned inventor
James P. Given Name (first and middle [if any])			Welch Family Name or Surname
Inventor's Signature			Date:
Residence: City Laguna Niguel	State CA	Country US	Citizenship US
Mailing Address 24446 Kathleen Drive			
City Laguna Niguel	State CA	ZIP 92677	Country US

NAME OF FOURTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Norbert Given Name (first and middle [if any])			Ohlenbusch Family Name or Surname
Inventor's Signature			Date:
Residence: City Andover	State MA	Country US	Citizenship US
Mailing Address 9 Whispering Pines Drive			
City Andover	State MA	ZIP 01810	Country US

NAME OF FIFTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Thomas P. Given Name (first and middle [if any])			Blackadar Family Name or Surname
Inventor's Signature			Date: 1/10/07
Residence: City Natick	State MA	Country US	Citizenship US
Mailing Address 5 Lupine Road			
City Natick	State MA	ZIP 01760	Country US



Express Mail Label No. EV 969121569 US

Application Data Sheet

Application Information

Application number::	11/591,619
Filing Date::	November 1, 2006
Application Type::	Regular
Subject Matter::	Utility
Suggested classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R??::	
Number of CD disks::	
Number of copies of CDs::	
Sequence Submission::	
Computer Readable Form (CRF)?::	
Number of copies of CRF::	
Title::	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
Attorney Docket Number::	704_049
Request for Early Publication::	No
Request for Non-Publication::	No
Suggested Drawing Figure::	1A
Total Drawing Sheets::	18
Small Entity?::	No
Latin name::	
Variety denomination name::	
Petition included?::	No
Petition Type::	
Licensed US Govt. Agency::	
Contract or Grant Numbers One::	
Secrecy Order in Parent Appl.::	No

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 954

Applicant Information

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Steven
Middle Name::	D.
Family Name::	Baker
Name Suffix::	
City of Residence::	Beaverton
State or Province of Residence::	OR
Country of Residence::	US
Street of Mailing Address::	7623 SW Crisp Drive
City of Mailing Address::	Beaverton
State or Province of Mailing Address::	OR
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	97007

Applicant Authority Type::	Inventor
Primary Citizenship Country::	GB
Status::	Full Capacity
Given Name::	Eric
Middle Name::	T.
Family Name::	McAdams
Name Suffix::	
City of Residence::	Whitehead
State or Province of Residence::	Antrim
Country of Residence::	Northern Ireland (UK)
Street of Mailing Address::	52 Cable Road
City of Mailing Address::	Whitehead
State or Province of Mailing Address::	Antrim
Country of Mailing Address::	Northern Ireland (UK)
Postal or Zip Code of Mailing Address::	BT389PZ

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 955

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	James
Middle Name::	P.
Family Name::	Welch
Name Suffix::	
City of Residence::	Laguna Niguel
State or Province of Residence::	CA
Country of Residence::	US
Street of Mailing Address::	24446 Kathleen Drive
City of Mailing Address::	Laguna Niguel
State or Province of Mailing Address::	CA
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	92677

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Norbert
Middle Name::	
Family Name::	Ohlenbusch
Name Suffix::	
City of Residence::	Andover
State or Province of Residence::	MA
Country of Residence::	US
Street of Mailing Address::	9 Whispering Pines Drive
City of Mailing Address::	Andover
State or Province of Mailing Address::	MA
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	01810

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Thomas
Middle Name::	P.
Family Name::	Blackadar
Name Suffix::	
City of Residence::	Natick
State or Province of Residence::	MA
Country of Residence::	US
Street of Mailing Address::	5 Lupine Road
City of Mailing Address::	Natick
State or Province of Mailing Address::	MA
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	01760

Correspondence Information

Correspondence Customer Number:: 20874

Representative Information

Representative Customer Number::	20874

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::

Foreign Priority Information

Country::	Application number::	Filing Date::	Priority Claimed::

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 957

Assignee Information

Assignee Name::	Welch Allyn, Inc.
Street of mailing address::	4341 State Street Road
City of mailing address::	Skaneateles Falls
State or Province of mailing address::	NY
Country of mailing address::	US
Postal or Zip Code of mailing address::	13153

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 958

01-09-07

OIPE IAP68
JAN 08 2007
PATENT & TRADEMARK OFFICE

PTO/SB/21 (09-04)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Not Yet Assigned
Total Number of Pages in This Submission: 18	Attorney Docket Number: 704_049

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☒ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☒ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to Technology Center (TC)
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:

Return Mailroom Postcard; copy of Notice to File Missing Parts (2 pgs)

Remarks **The Commissioner is authorized to charge any additional fees to Deposit Account No. 50-0289.**

Express Mail Label No. EV969121590US

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Wall Marjama & Bilinski LLP Joseph M. Geller Reg. No. 48,144
Signature	Joseph M. Geller
Date	January 8, 2007

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service using the Express Mail Post Office To Addressee service per 37 CFR 1.10 under Express Mail No. EV969121590US addressed to **Mail Stop Missing Parts, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450** on January 8, 2007.

Typed or printed name	Cheryl M. Nichols		
Signature	Cheryl M. Nichols	Date	January 8, 2007

OIPE
JAN 08 2007
IAP66
PATENT & TRADEMARK OFFICE

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/591,619	11/01/2006	Steven D. Baker	704_049

CONFIRMATION NO. 7955

FORMALITIES LETTER

20874
WALL MARJAMA & BILINSKI
101 SOUTH SALINA STREET
SUITE 400
SYRACUSE, NY 13202

Date Mailed: 11/22/2006

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01/10/2007 EHAILE1 00000050 11591619
01 FC:1051 130.00 DA

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- **$130** Surcharge.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
PART 2 - COPY TO BE RETURNED WITH RESPONSE

OIPE IAP66
JAN 08 2007
PATENT & TRADEMARK OFFICE

REPLACEMENT SHEET

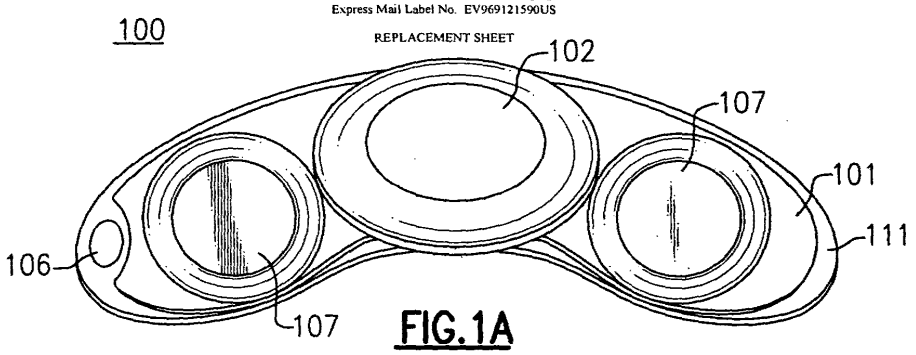


FIG.1A

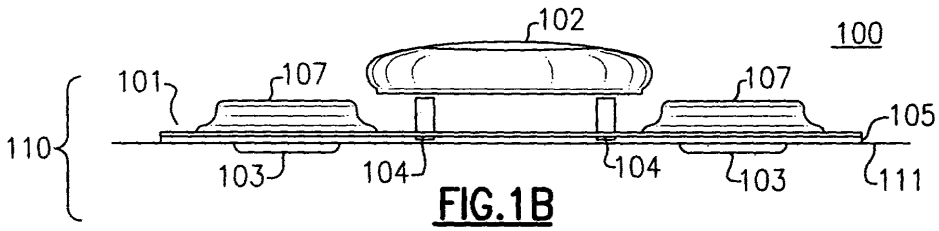


FIG.1B

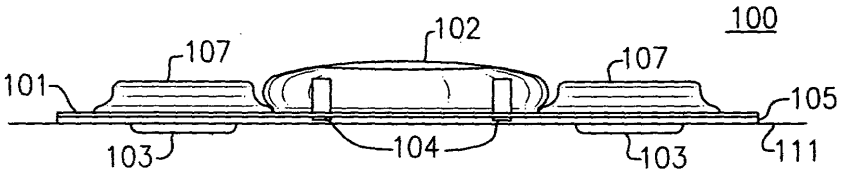


FIG.1C

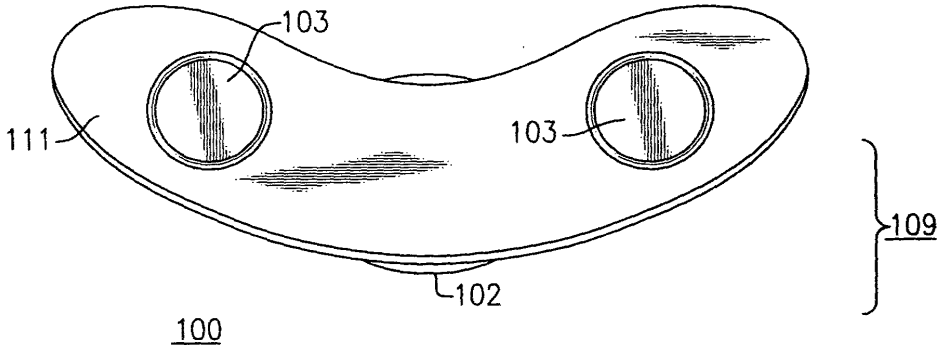


FIG.1D

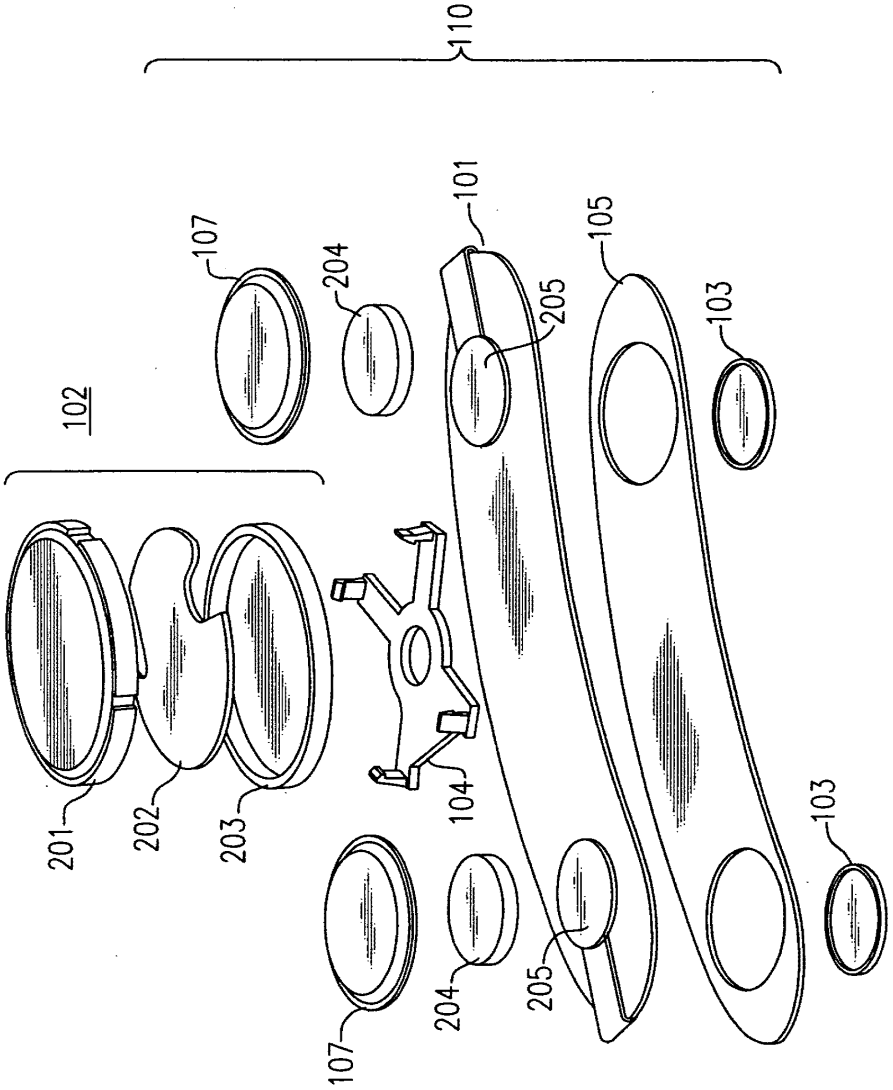


FIG.2

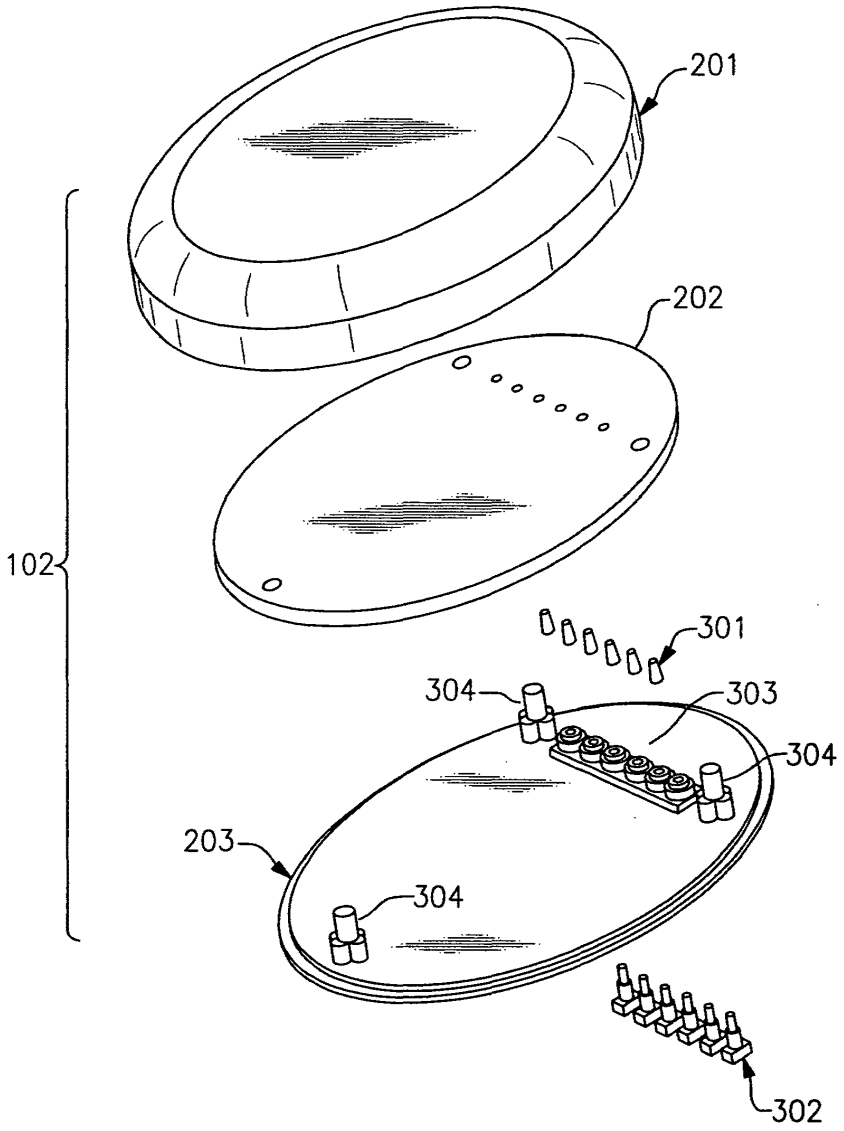


FIG.3

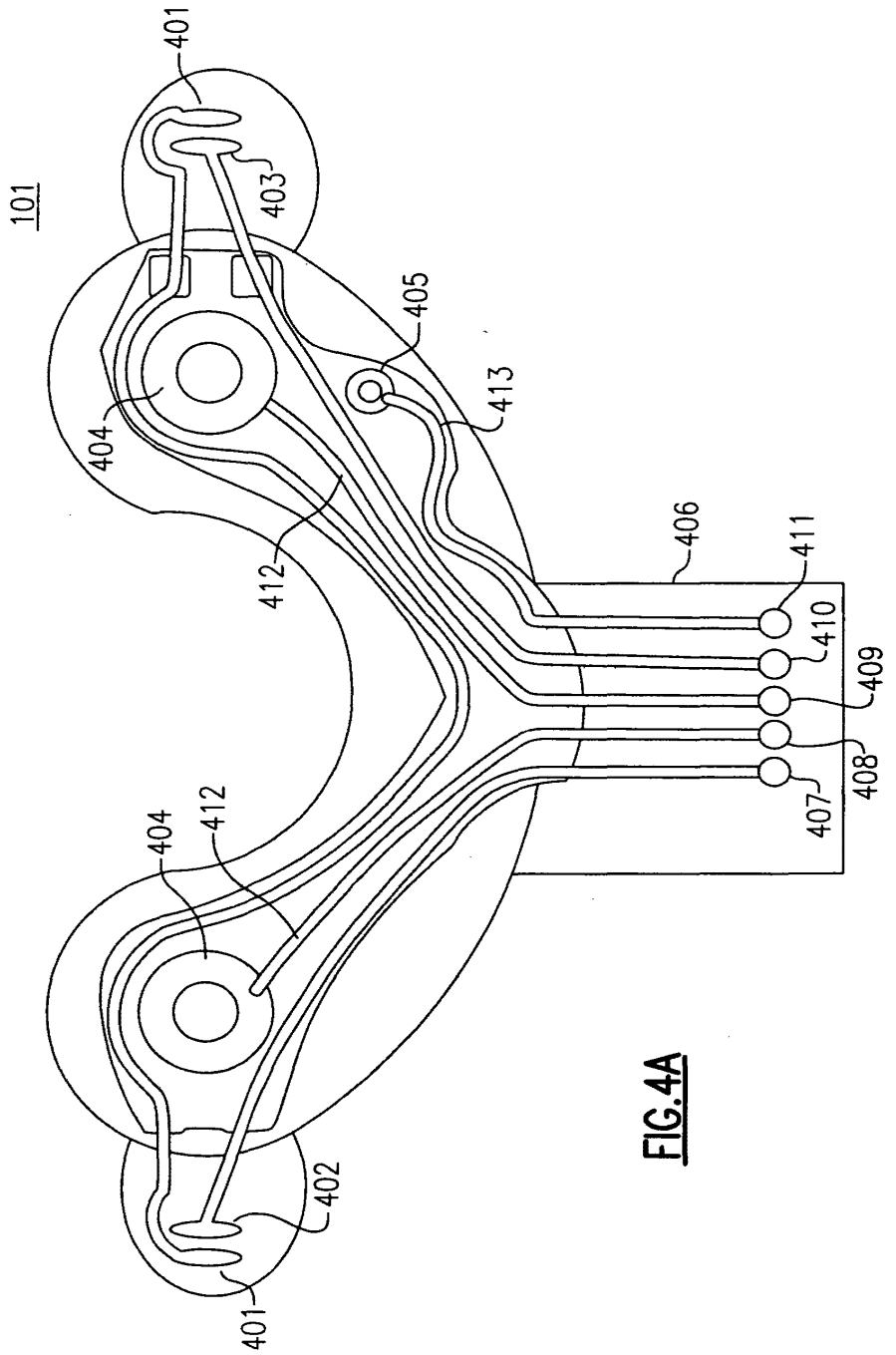

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401
403
405
413
404
412
406
411
410
409
408
407
404
412
402
401

FIG.4A

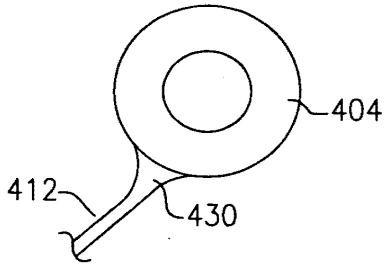


FIG.4B



FIG.4C

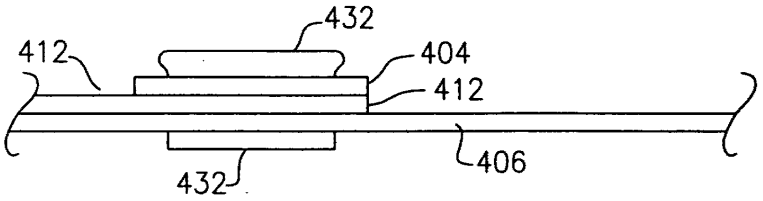


FIG.4D

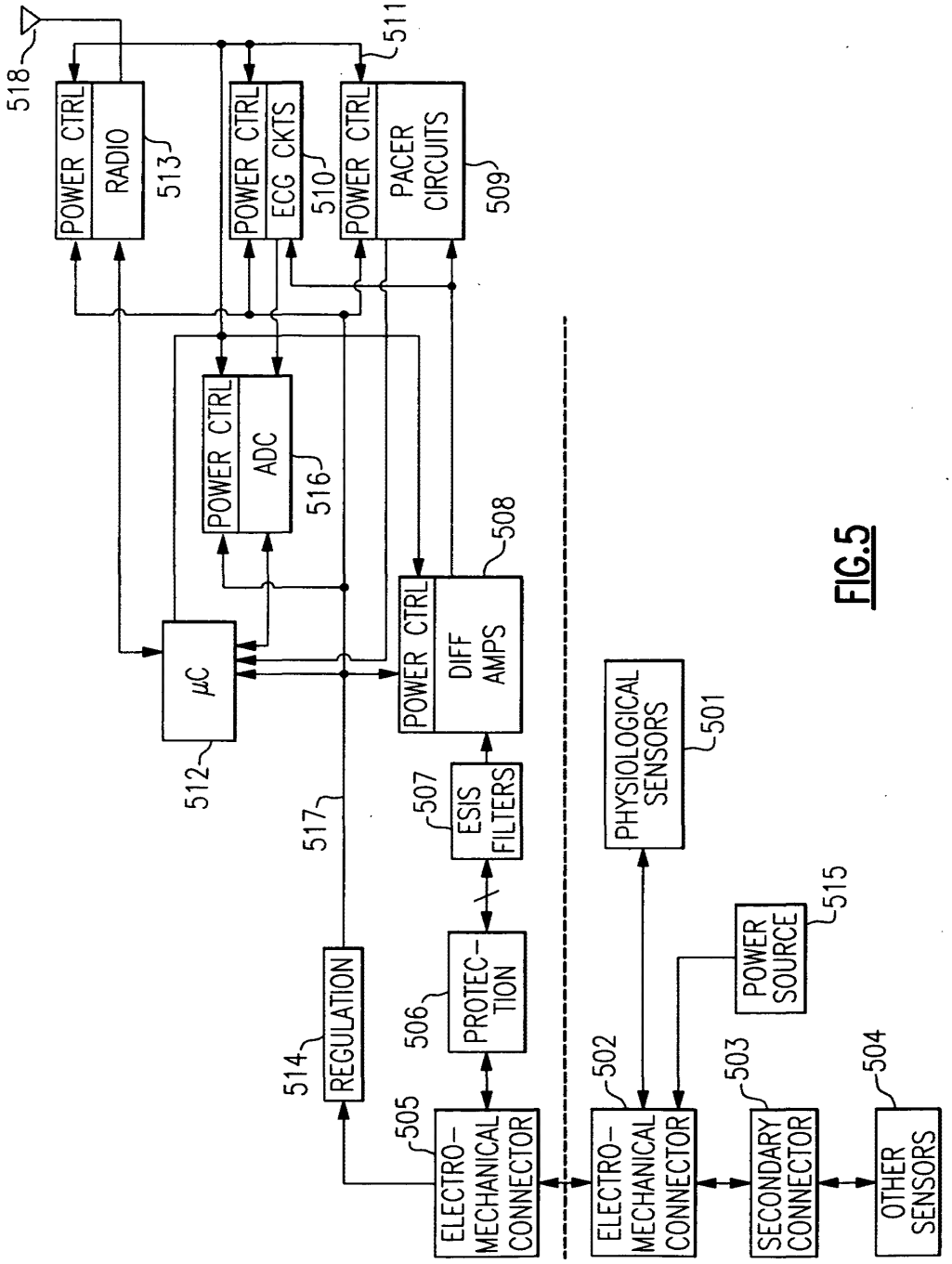

518
POWER CTRL
RADIO
513
POWER CTRL
ECG CKTS
510
POWER CTRL
PACER CIRCUITS
509
511
POWER CTRL
ADC
516
508
POWER CTRL
DIFF AMPS
µC
512
517
507
ESIS FILTERS
PHYSIOLOGICAL SENSORS
501
515
POWER SOURCE
514
REGULATION
506
PROTEC-TION
505
ELECTRO-MECHANICAL CONNECTOR
502
ELECTRO-MECHANICAL CONNECTOR
503
SECONDARY CONNECTOR
504
OTHER SENSORS

FIG.5

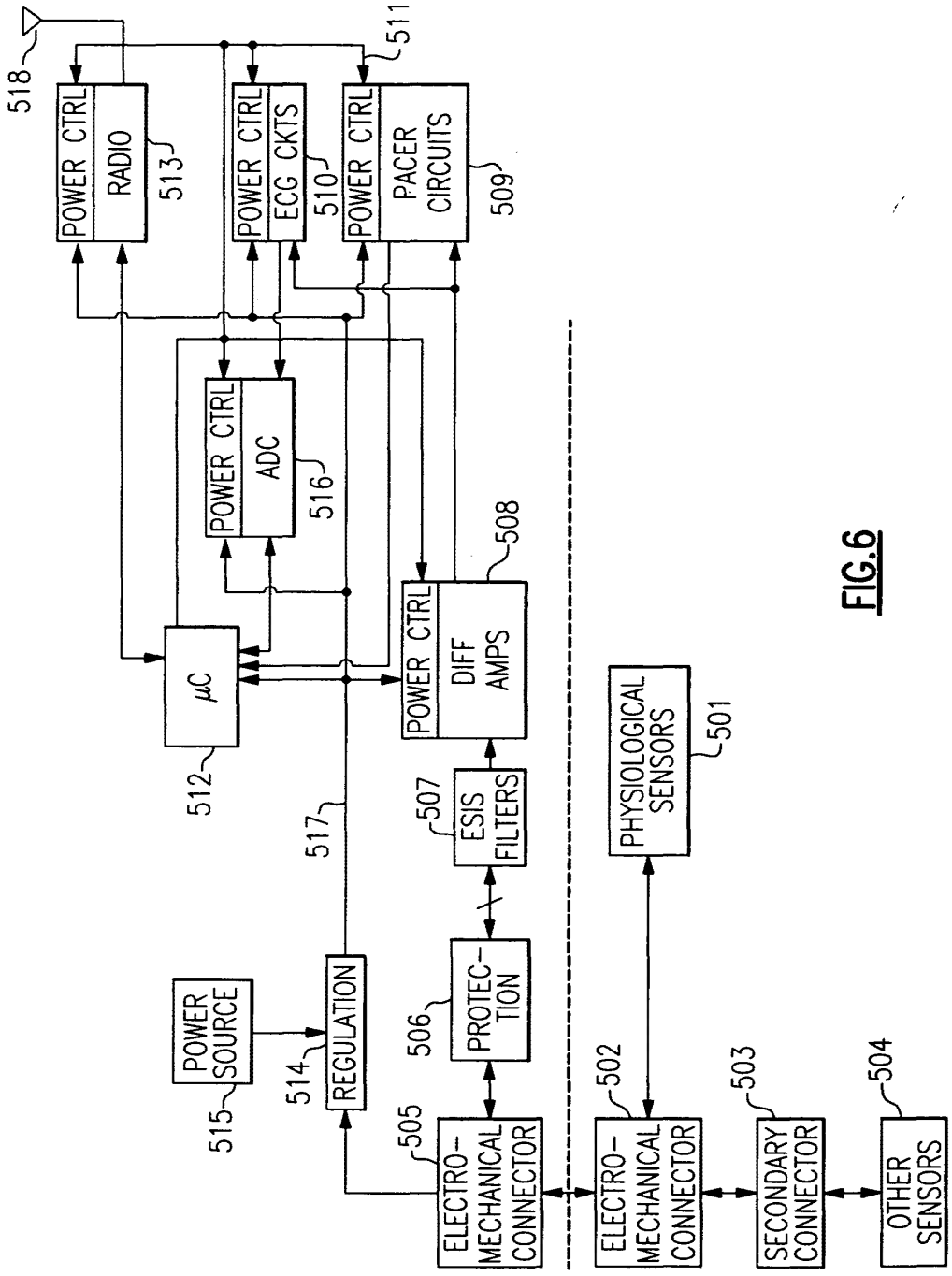

518
POWER CTRL
RADIO
513
POWER CTRL
ECG CKTS
510
511
POWER CTRL
PACER CIRCUITS
509
POWER CTRL
ADC
516
508
POWER CTRL
DIFF AMPS
µC
512
517
507
ESIS FILTERS
PHYSIOLOGICAL SENSORS
501
POWER SOURCE
515
514
REGULATION
506
PROTEC-TION
505
ELECTRO-MECHANICAL CONNECTOR
502
ELECTRO-MECHANICAL CONNECTOR
503
SECONDARY CONNECTOR
504
OTHER SENSORS

FIG.6

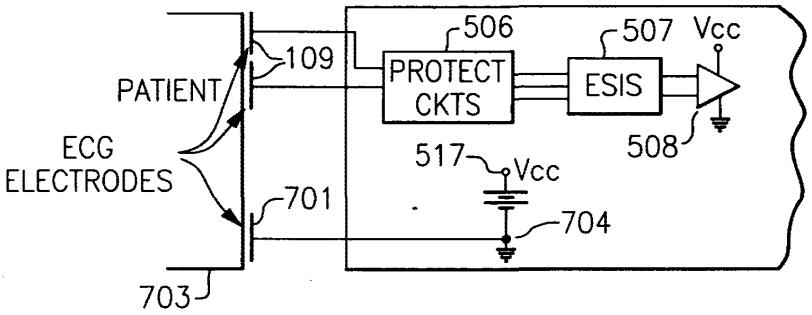

506
507
Vcc
109
PATIENT
PROTECT CKTS
ESIS
ECG ELECTRODES
517
Vcc
508
701
704
703

FIG.7A

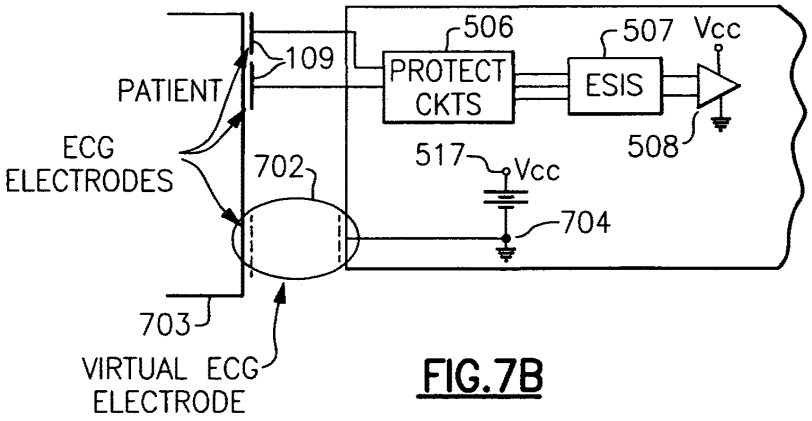

506
507
Vcc
109
PATIENT
PROTECT CKTS
ESIS
ECG ELECTRODES
517
Vcc
508
702
704
703
VIRTUAL ECG ELECTRODE

FIG.7B

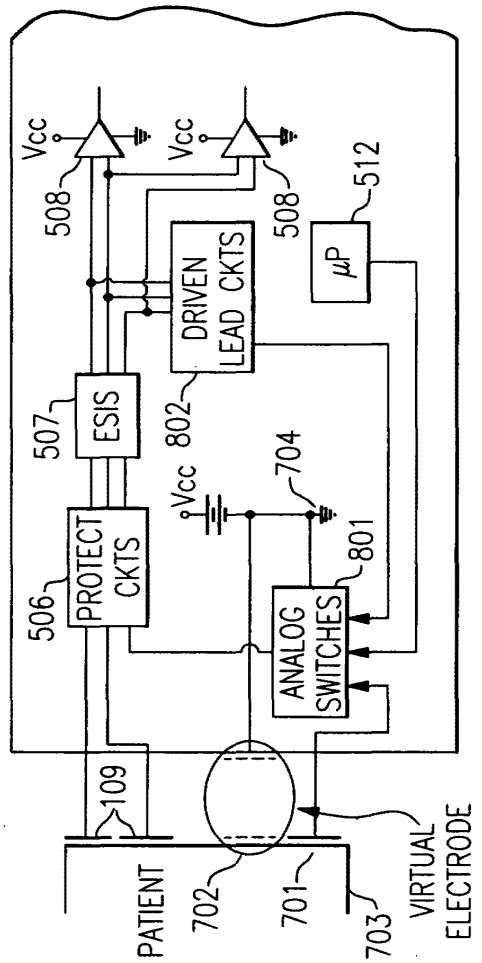

Vcc
508
Vcc
508
512
μP
DRIVEN LEAD CKTS
802
507
ESIS
Vcc
704
801
506
PROTECT CKTS
ANALOG SWITCHES
109
PATIENT
702
701
703
VIRTUAL ELECTRODE

FIG.8

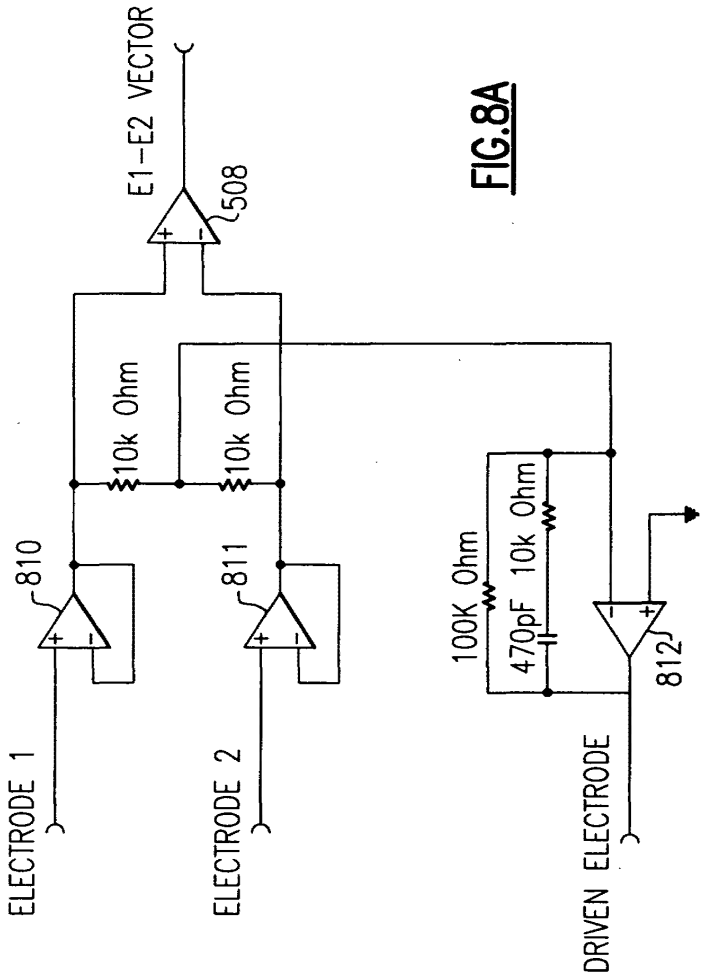

E1-E2 VECTOR
508
10k Ohm
10k Ohm
810
811
100K Ohm
470pF
10k Ohm
812
ELECTRODE 1
ELECTRODE 2
DRIVEN ELECTRODE

FIG.8A

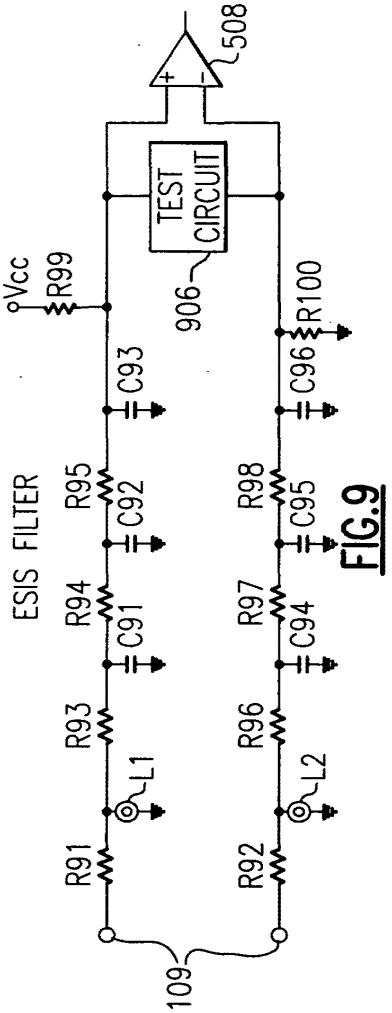

508
TEST CIRCUIT
906
°Vcc
R99
R100
C93
C96
ESIS FILTER
R95
C92
R98
C95
R94
C91
R97
C94
R93
L1
R96
L2
R91
R92
109

FIG.9

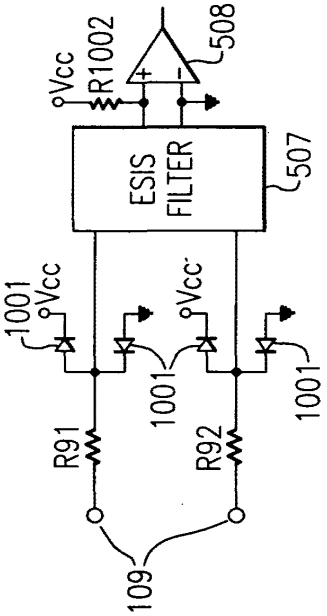

°Vcc
R1002
508
ESIS FILTER
507
1001
°Vcc
°Vcc
1001
1001
R91
R92
109

FIG.10

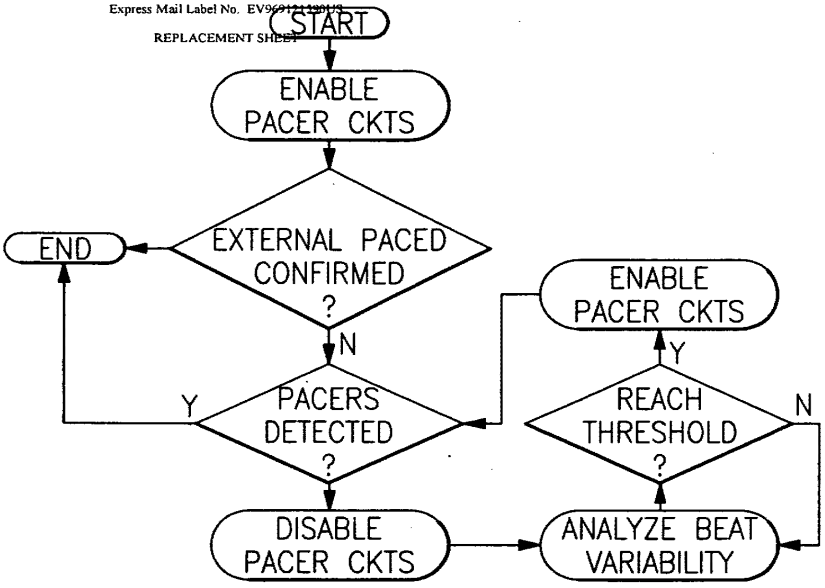


FIG.11

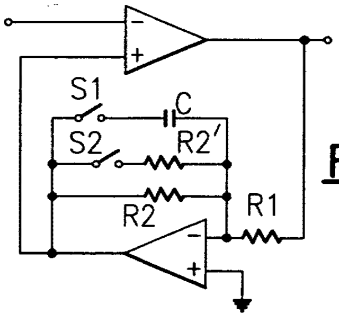


FIG.12

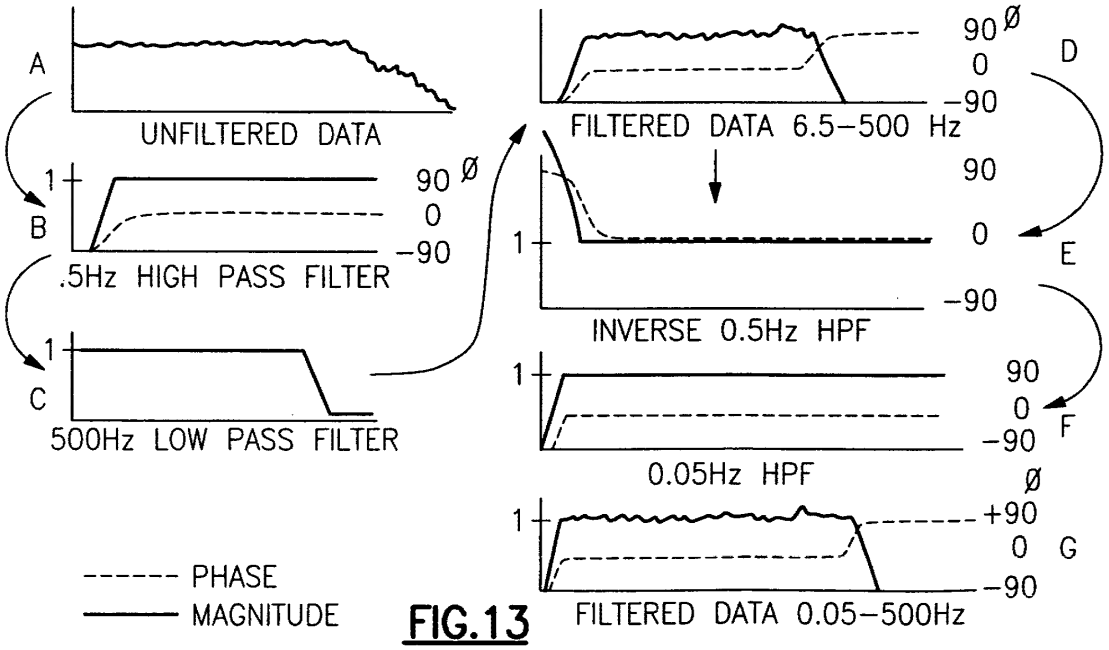


FIG.13

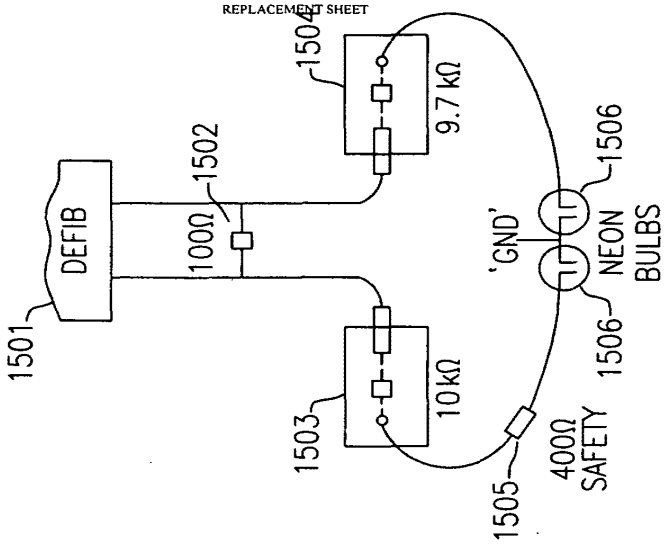

1504
9.7 kΩ
1502
100Ω
DEFIB
1501
1503
10kΩ
'GND'
1506
NEON BULBS
1506
400Ω SAFETY
1505

FIG.15

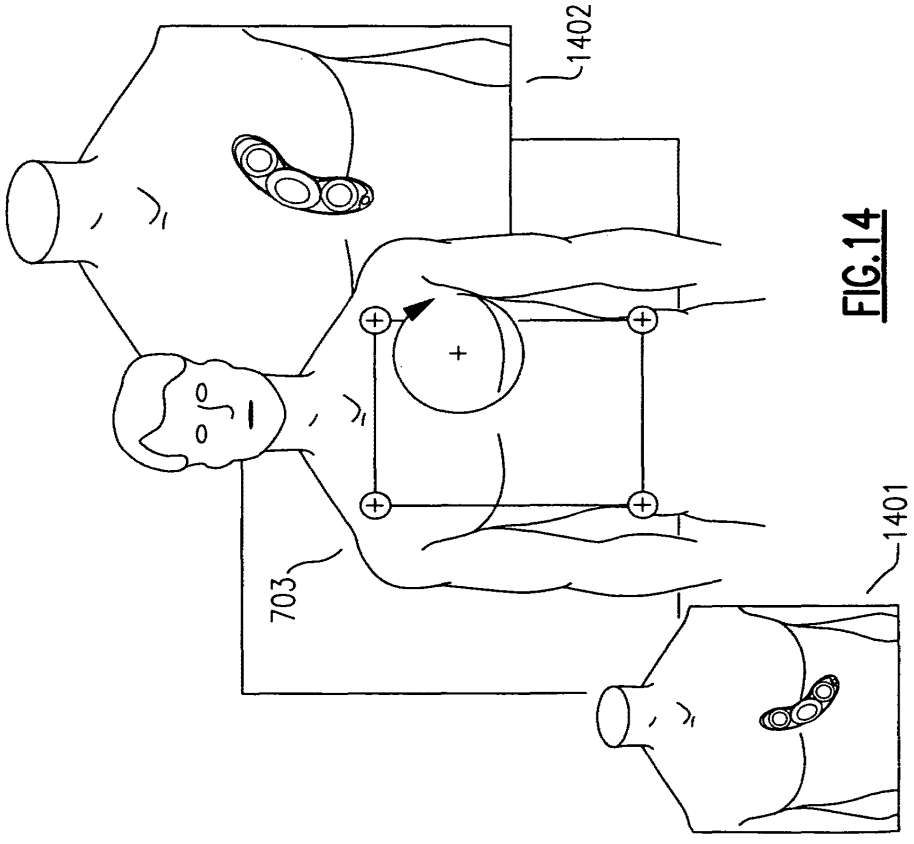

1402
703
1401

FIG.14

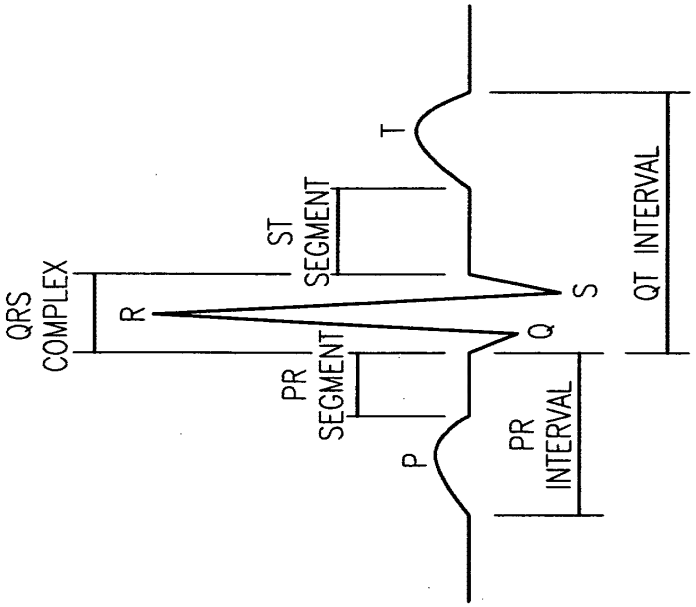


FIG.17

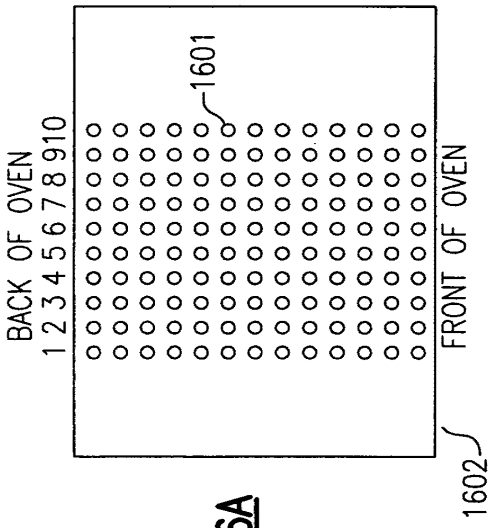


FIG.16A

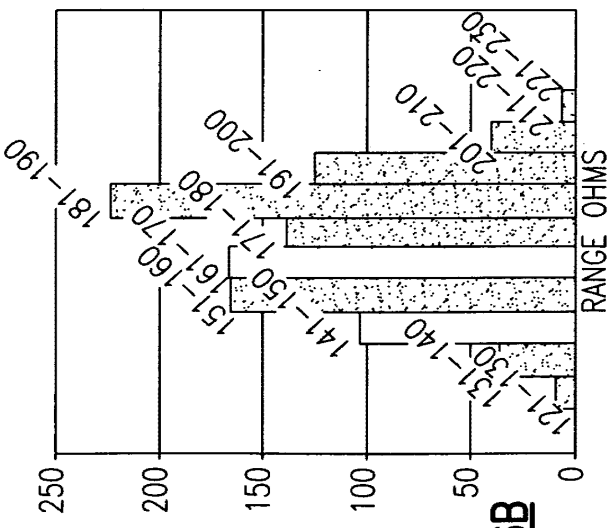


FIG.16B

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
11/591,619	11/01/2006	3736	3500	704_049	18	58	6

CONFIRMATION NO. 7955

20874
WALL MARJAMA & BILINSKI
101 SOUTH SALINA STREET
SUITE 400
SYRACUSE, NY13202

FILING RECEIPT

Date Mailed: 11/22/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Steven D. Baker, Beaverton, OR;
Eric T. McAdams, Whitehead, NIR, UNITED KINGDOM;
James P. Welch, Laguna Niguel, CA;

Assignment For Published Patent Application

Welch Allyn, Inc., Skaneateles Falls, NY

Power of Attorney: None

Domestic Priority data as claimed by applicant

Foreign Applications

If Required, Foreign Filing License Granted: 11/21/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US11/591,619**

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

Body worn physiological sensor device having a disposable electrode module

Preliminary Class

600

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/591,619	11/01/2006	Steven D. Baker	704_049

CONFIRMATION NO. 7955

20874
WALL MARJAMA & BILINSKI
101 SOUTH SALINA STREET
SUITE 400
SYRACUSE, NY 13202

FORMALITIES LETTER

Date Mailed: 11/22/2006

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
  Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
  - The drawings submitted to the Office are not electronically reproducible. Drawing sheets must be submitted on paper, which is flexible, strong, white, smooth, non-shiny, and durable (see 37 CFR 1.84(e)). See Figure(s) 2, 14, 16B.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

• To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of $130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **$130** for a non-small entity

- **$130** Surcharge.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199, or 1-800-972-6382
PART 3 - OFFICE COPY

17364 U.S. PTO
110106

PTO/SB/05 (05-05)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	704_049
First Inventor	Steven D. Baker
Title	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
Express Mail Label No.	EV885920445US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [X] **Fee Transmittal Form** (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [ ] **Applicant claims small entity status.** See 37 CFR 1.27.
3. [X] **Specification** [*Total Pages* 41]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. [X] **Drawing(s)** *(35 U.S.C. 113)* [*Total Sheets* 18]
5. **Oath or Declaration** [*Total Sheets*]
   a. [ ] Newly executed (original or copy)
   b. [ ] A copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional with Box 18 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. [X] **Application Data Sheet.** See 37 CFR 1.76
7. [ ] **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   [ ] Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission** *(if applicable, items a. – c. are required)*
   a. Computer Readable Form (CRF)
      i. [ ] Computer Readable Form (CRF)
      ii. [ ] Transfer Request (37 CFR 1.821(e))
   b. Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria, VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. [ ] **Assignment Papers** (cover sheet & document(s))
   Name of Assignee:
10. [ ] **37 CFR 3.73(b) Statement** *(when there is an assignee)* [ ] **Power of Attorney**
11. [ ] **English Translation Document** *(if applicable)*
12. [ ] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of foreign patent documents, publications, & other information.
13. [ ] **Preliminary Amendment**
14. [X] **Return Receipt Postcard** (MPEP 503) *(Should be specifically itemized)*
15. [ ] **Certified Copy of Priority Document(s)** *(if foreign priority is claimed)*
16. [ ] **Nonpublication Request** under 35 U.S.C.122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. [X] Other: **Check in the amount of $3,500.00**

112948 U.S. PTO
11/591619
110106

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*
    [ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No.: _____
    Prior application information: Examiner _____ *Art Unit:* _____

19. CORRESPONDENCE ADDRESS

[X] The address associated with Customer Number: **20874** *OR* [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email Address	

Signature	Joseph M. Geller	Date	November 1, 2006
Name (Print/Type)	Joseph M. Geller	Registration No. (Attorney/Agent)	48,144

PTO/SB/17 (01-06)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

17364 U.S. PTO
110106

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2006

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Examiner Name	Not Yet Assigned
Art Unit	Not Yet Assigned
Attorney Docket No.	704_049

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT $3,500.00

Express Mail Label No. EV885920445US

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): ____

☒ Deposit Account Deposit Account Number: 50-0289 Deposit Account Name: Wall Marjama & Bilinski LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	1,000.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims		Fee ($)		Fee Paid ($)	Multiple Dependent Claims	
58	- 20 or HP =	38	x	$50.00	=	$1,900.00	Fee ($)	Fee Paid ($)

HP= highest paid number of total claims paid for, if greater than 20

Indep. Claims		Extra Claims		Fee ($)		Fee Paid ($)		
6	- 3 or HP =	3	x	$200.00	=	$600.00		

HP =highest number of independent claims paid for, if greater than 3

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a) (1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof		Fee ($)		Fee Paid ($)
59	- 100 =	-0-	/ 50 =	-0- (round up to a whole number)	x	-0-	=	-0-

4. OTHER FEES

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g.. late filing surcharge): ____	

SUBMITTED BY

Signature	Joseph M. Geller	Registration No. 48,144 (Attorney/Agent)	Telephone 315-425-9000
Name (Print/Type)	Joseph M. Geller		Date November 1, 2006

17364 U.S. PTO
110106

PTO/SB/05 (05-05)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	704_049
First Inventor	Steven D. Baker
Title	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
Express Mail Label No.	EV885920445US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. [X] **Fee Transmittal Form** (e.g., PTO/SB/17) *(Submit an original and a duplicate for fee processing)*
2. [ ] **Applicant claims small entity status.** See 37 CFR 1.27.
3. [X] **Specification** [*Total Pages* 41]
   Both the claims and abstract must start on a new page
   (For information on the preferred arrangement, see MPEP 608.01(a))
4. [X] **Drawing(s)** *(35 U.S.C. 113)* [*Total Sheets* 18]
5. **Oath or Declaration** [*Total Sheets*]
   a. [ ] Newly executed (original or copy)
   b. [ ] A copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional with Box 18 completed)*
      i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. [X] **Application Data Sheet.** See 37 CFR 1.76
7. [ ] **CD-ROM or CD-R** in duplicate, large table or Computer Program *(Appendix)*
   [ ] Landscape Table on CD
8. **Nucleotide and/or Amino Acid Sequence Submission** *(if applicable, items a. – c. are required)*
   a. Computer Readable Form (CRF)
      i. [ ] Computer Readable Form (CRF)
      ii. [ ] Transfer Request (37 CFR 1.821(e))
   b. Specification Sequence Listing on:
      i. [ ] CD-ROM or CD-R (2 copies); or
      ii. [ ] Paper
   c. [ ] Statements verifying identity of above copies

ADDRESS TO: **Commissioner for Patents**
P.O. Box 1450
Alexandria, VA 22313-1450

ACCOMPANYING APPLICATION PARTS

9. [ ] **Assignment Papers** (cover sheet & document(s))
   Name of Assignee:
10. [ ] **37 CFR 3.73(b) Statement** *(when there is an assignee)* [ ] **Power of Attorney**
11. [ ] **English Translation Document** *(if applicable)*
12. [ ] **Information Disclosure Statement** (PTO/SB/08 or PTO-1449)
    [ ] Copies of foreign patent documents, publications, & other information.
13. [ ] **Preliminary Amendment**
14. [X] **Return Receipt Postcard** (MPEP 503) *(Should be specifically itemized)*
15. [ ] **Certified Copy of Priority Document(s)** *(if foreign priority is claimed)*
16. [ ] **Nonpublication Request** under 35 U.S.C.122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or equivalent.
17. [X] Other: **Check in the amount of $3,500.00**

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18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*
    [ ] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No.: _____
    Prior application information: Examiner _____ *Art Unit:* _____

19. CORRESPONDENCE ADDRESS

[X] The address associated with Customer Number: **20874** *OR* [ ] Correspondence address below

Name					
Address					
City		State		Zip Code	
Country		Telephone		Email Address	

Signature	Joseph M. Geller	Date	November 1, 2006
Name (Print/Type)	Joseph M. Geller	Registration No. (Attorney/Agent)	48,144

PTO/SB/17 (01-06)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number

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110106

Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2006

Complete if Known	
Application Number	Not Yet Assigned
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Examiner Name	Not Yet Assigned
Art Unit	Not Yet Assigned
Attorney Docket No.	704_049

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	$3,500.00

Express Mail Label No. EV885920445US

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): ____

☒ Deposit Account Deposit Account Number: 50-0289 Deposit Account Name: Wall Marjama & Bilinski LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
Application Type	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fee ($)	Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	1,000.00
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims		Fee ($)		Fee Paid ($)	Multiple Dependent Claims	
58	- 20 or HP =	38	x	$50.00	=	$1,900.00	Fee ($)	Fee Paid ($)

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Non-English Specification, $130 fee (no small entity discount)	
Other (e.g.. late filing surcharge): _____	

SUBMITTED BY

Signature	Joseph M. Geller	Registration No. 48,144 (Attorney/Agent)	Telephone 315-425-9000
Name (Print/Type)	Joseph M. Geller		Date November 1, 2006

Express Mail Label No. EV885920445US
PATENT
Attorney Docket No. 704_049

BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

Field of the Invention

[0001] This invention relates generally to a physiological monitor and more particularly to a body worn physiological monitor.

Background of the Invention

[0002] Measurements of various physiological parameters are important to the study of the human condition. Physiological measurements can be particularly important in a health care setting, such as in a hospital. One of the more important physiological measurements performed on a patient is the electrocardiogram (ECG), showing the condition of the human heart.

[0003] Portable patient monitors have evolved that allow patients to enjoy at least some mobility. Typically a battery operated monitor can be hung on a belt, shoulder strap, or carried by a patient using some other similar hanging arrangement. Sensors, such as ECG electrodes, are affixed to the patient's body, such as with tape, and connected to the battery operated monitor by wires. After a fixed interval of time, or at a low battery indication, the batteries can be replaced or recharged. One example of a portable patient monitor is the Micropaq wireless patient monitor, manufactured by Welch Allyn, Inc., that permits multi-parameter monitoring and patient alarm capabilities built in a small, rugged, lightweight, patient-wearable device.

[0004] Another version of a portable physiological monitor is the heart rate monitor typically used by individuals engaged in an athletic activity. The monitor includes a sensor, which generally makes direct or indirect contact with an individual's chest to monitor heart beats and then by wires, or by wireless techniques, the sensor transmits the sensed heart beat to a nearby microcomputer based monitor and display. Such units generally measure only heart beat and are not capable of doing any of the traditional ECG analysis functions.

[0005] A recurrent problem with the portable monitors typically used in healthcare applications is the need for wires from sensors situated on the patient's body to the portable unit. These wires can become tangled and cause discomfort or become unplugged when inadvertently pulled or tugged on. In addition, wire motion can increase ECG noise due to the triboelectric effect. Muscle movement can also increase ECG noise, due to the typical placement of ECG electrodes over major muscles. Moreover, portable monitor battery maintenance (e.g. battery recharging or replacement) can be time consuming and costly.

[0006] Another problem is related to the requirement that a medical grade monitor survive multiple defibrillation cycles of at least 360 joules. Conventionally, this requirement has been met by one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor. The problem is that the physical volume of conventional power resistors is too large for use in a compact monitor application.

[0007] Another shortcoming of small sensor devices is that these devices lack the intelligence to vary the amount and type of data transmitted, depending on patient condition. Exercise heart monitors do not transmit a full patient waveform for clinical analysis while medical monitors measure and transmit the full patient waveform, even when the patient is healthy. While transmitting the full patient waveform is the preferred solution from a purely clinical standpoint, such transmission requires significant power to transmit large amounts of data and restricts the design from being small and inexpensive.

[0008] Yet another problem is that arrhythmia analysis is a computationally intensive operation not well-suited to existing small portable monitors that presently have no ability to perform arrhythmia analysis.

[0009] Therefore, there is a need for a body worn combined physiological sensor and monitor having a disposable sensor, but used and worn by a patient as a single unit directly and non-permanently affixed to a patient's body. Also, what is needed is a physically compact resistive element for protecting a body worn device from damage caused by multiple defibrillation cycles. Also, what is needed is a medical-grade monitor that can intelligently measure and transmit data only as

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required to alert clinicians that the patient needs additional attention. What is also needed is a body-worn device capable of running arrhythmia analysis through computationally efficient algorithms.

Summary of the Invention

[0010] According to one aspect, a body worn patient monitoring device comprises at least one disposable module including a plurality of electrical connections to the body. The electrical connections are coupled to a skin surface of the patient to measure physiological signals of the patient. The at least one disposable module includes a disposable module connector. The body worn patient monitoring device includes at least one internal or external power source to power the body worn patient monitoring device. The body worn patient monitoring device also includes at least one communication-computation module, having a communication-computation module connector to receive physiological signals from the at least one disposable module via said disposable module connector. The communication-computation module also includes at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals and a radio circuit to communicate a raw physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module. The body worn patient monitoring device, including the at least one disposable module and the at least one communication-computation module, is directly non-permanently affixed to the skin surface of the patient.

[0011] According to another aspect, a method of providing high voltage circuit protection for a body worn monitor comprises the steps of: providing a substrate that supports one or more electrical connections to a patient's body; determining a print pattern and thickness of a first material having a first resistivity to be printed on the substrate; determining a print pattern and thickness of a second material having a second resistivity to be printed on the substrate; printing the first

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material onto the substrate; and printing the second material onto the substrate wherein at least part of the second material overlays the first material.

Brief Description of the Drawings

[0012] For a further understanding of these and objects of the invention, reference will be made to the following Detailed Description which is to be read in connection with the accompanying drawings, in which:

[0013] FIG. 1A shows an exemplary body worn physiological monitor having a disposable electrode module;

[0014] FIG. 1B shows a partially unassembled side view of the body worn physiological monitor of FIG. 1A;

[0015] FIG. 1C shows an assembled side view of the body worn physiological monitor of FIG. 1A;

[0016] FIG. 1D shows a bottom view of the body worn physiological monitor of FIG. 1A;

[0017] FIG. 2 shows an exploded perspective view of an exemplary body worn physiological monitor;

[0018] FIG. 3 shows an exploded perspective view of an exemplary computation and communication module;

[0019] FIG. 4A shows an exemplary disposable unit flexible circuit board;

[0020] FIG. 4B shows a partial enlarged view of a portion of the flexible circuit board of FIG. 4A, further showing an exemplary resistive trace having a fillet;

[0021] FIG. 4C shows a partial side elevated view of a portion of the flexible circuit board of FIG. 4A, further showing an exemplary conductive surface overlaying a resistive material;

[0022] FIG. 4D shows a partial side elevational view of the circuit board of FIG. 4A, further showing an exemplary conductive surface having a snap receptacle;

[0023] FIG. 5 shows a block diagram of one embodiment of a body worn physiological monitor having a power source in a disposable unit;

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[0024] FIG. 6 shows a block diagram of one embodiment of a body worn physiological monitor having a power source in or connected to the computation and communication module;

[0025] FIG. 7A shows a schematic diagram of a direct connected reference electrode used in conjunction with a body worn physiological monitor;

[0026] FIG. 7B shows a schematic diagram of a virtual reference electrode as used in conjunction with a body worn physiological monitor;

[0027] FIG. 8 shows a schematic diagram depicting one embodiment of an analog switching arrangement provided on a body worn physiological monitor to select a reference electrode configuration;

[0028] FIG. 8A shows an exemplary driven lead circuit topology for use with electrodes of a body worn physiological monitor;

[0029] FIG. 9 shows an exemplary ESIS filter circuit topology with circuit protection;

[0030] FIG. 10 shows an alternative circuit protection to that depicted in FIG. 9;

[0031] FIG. 11 shows a flow chart for an algorithm utilized by a body worn physiological monitor to detect whether a patient has a pace maker;'

[0032] FIG. 12 shows a circuit topology of a high pass filter useful for baseline restoration;

[0033] FIG. 13 shows seven graphs of amplitudes plotted versus frequency to illustrate exemplary operation of the circuit of FIG. 12;

[0034] FIG. 14 shows two exemplary positions for a body worn ECG monitor to be non-permanently affixed directly to a patient's body;

[0035] FIG. 15 shows a block diagram of a setup for simulating the effect of patient defibrillation on resistive traces;

[0036] FIG. 16A symbolically shows resistive dots silk screened on a tray;

[0037] FIG. 16B shows a histogram of an exemplary resistive distribution of baked resistive dots; and

[0038] FIG. 17 shows an exemplary ECG waveform.

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[0039] Package styling varies slightly between the drawings. Such minor differences, e.g. the case styling of computation and communication module 102, illustrate minor variations in mechanical packaging suitable for use as body worn monitors. Drawings are not necessarily shown to scale.

Detailed Description

[0040] A "body worn" device is described herein with regard to certain exemplary embodiments. A "body worn" device is defined herein as a device that is directly, but non-permanently, affixed to a patient's body. A "body worn monitor" is a device that can be directly "worn" on the patient's body as a single unit, including one or more physiological sensors and a communications and computation module to perform at least initial processing of one or more physiological measurements made using one or more physiological sensors. Unlike prior art patient-wearable devices, at least one sensor can be incorporated into the device that makes a direct or indirect (such as by capacitive coupling) electrical connection with the patient's body without the use of external wires from sensors to the device. In addition and unlike athletic heart monitors, a "body worn" monitor can be a full functioning medical grade monitor, e.g. meeting the requirements of European Unions' Medical Device Directive and other applicable industry standards, such as EC-13 for an electrocardiograph. The body worn medical-grade monitor can include a device, for example, such as a pulse oximeter, CO_2 monitor, respiration monitor, or can function as an ECG monitor, incorporating physiological sensors, front end analog electronic signal conditioning circuits, and a microcomputer based computation unit with wireless reporting of measured physiological data, all contained within in a "body worn" package that can be non-permanently affixed directly to a patient's body. A body-worn medical-grade monitor can also include additional measurement capabilities beyond those mentioned here.

[0041] FIGs. 1A-1D depict various views of an exemplary body worn physiological monitor 100 having a communication and computation module 102 and a disposable electrode module 110. In this exemplary embodiment, physiological monitor 100 is designed for use as an electrocardiogram (ECG)

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monitor for obtaining and recording and/or transmitting ECG information, including ECG waveforms and alarms for a person, such as a patient, wearing body worn physiological monitor 100.

[0042] FIG. 1A shows an exemplary top view of body worn physiological monitor 100. A crescent shape allows the body worn physiological monitor 100 to be placed on the chest of a patient, and more specifically around the pectoralis major, to allow measurement of lead configuration I, II, or III, or to be placed on the patient's side allowing measurement using a V-lead configuration. Though not shown, multiple body worn physiological monitor 100 units can be used to effectively provide multiple leads. By placing electrodes around the body so that they are not situated directly atop major muscles, both motion noise artifacts and muscle noise artifacts can be prevented. Moreover, by eliminating cables, noise due to cable motion or compression (i.e. triboelectric effect) can be eliminated.

[0043] FIG. 1B shows a side elevated view of physiological monitor 100 having an exemplary attachment mechanism, such as a retention clip 104, to mechanically attach communications and computation module 102 to the top surface of the disposable electrode module 110. Flexible printed circuit layer 101 can be made from a thin insulating material, such as according to this embodiment, a 75 micron thick layer of Mylar®. Typically electrical traces (not shown in FIGs. 1A-1D) on flexible printed circuit layer 101 can be further protected by an insulating covering, analogous to a conformal coating. A formed plastic layer or a cloth with adhesive on one side thereof can be used to cover and protect flexible printed circuit layer 101, as well as to provide an aesthetic outer layer to make the body worn monitor 100 visually appealing.

[0044] FIG. 1C shows a side view of physiological monitor 100 in which the communications and computation module 102 has been affixed to disposable electrode module 110. FIG. 1D depicts a view of the underside of exemplary physiological monitor 100 showing one embodiment of disposable electrode module 110 having electrodes 109. In this embodiment, each electrode 109 comprises electrode gel 103 and conductive surface 404 (FIG. 4). Together, electrode gel 103 and conductive surface 404 create a half-cell, such as, for example, a Silver/Silver

Chloride half cell. Also and according to this embodiment, conductive surface 404 can directly accept the electrode gel 103.

[0045] FIG. 2 shows an exploded assembly view of the exemplary body worn physiological monitor 100. As noted with regard to FIGs. 1A-1D, the body worn physiological monitor 100 includes a removable and reusable communications and computation module 102 and a disposable electrode module 110, the later including electrode gels 103 for ECG monitoring and batteries 204 to power communications and computation module 102. A flat planar insulating/adhesive member 105 includes a plurality of openings that are each sized to receive electrode gels 103. The insulating member 105 provides a bottom side cover for the flexible printed circuit layer 101 and augments adhesion to the human body. Electrode gel 103, when attached to an appropriate substrate such as silver-silver-chloride or other substrate, can be used to establish a relatively low impedance electrical connection between conductive surface 404 (FIG. 4) and the patient's skin.

[0046] Electrode gels 103 can adhere to a patient's skin. While electrode gel 103 is typically an adhesive electrode gel, the adhesion offered by electrode gels 103 alone might not give a sufficient holding force for non-permanently affixing body worn physiological monitor 100 to a patient. To achieve a better adhesion of body worn monitor 100 to a patient's skin, insulating/adhesive member 105 can be used to non-permanently affix body worn physiological monitor 100 to a patient. Thus, body worn monitor 100 can be applied to a patient in the same way an adhesive strip is applied, such as for example, those adhesive strips sold under the brand name "BAND-AID®". One exemplary type of foam adhesive suitable for affixing a flexible circuit board to a patient is 1.6mm adhesive foam from Scapa Medical of Bedfordshire, UK. As shown in FIGs. 1B and 1C (although not to scale), each of the electrode gels 103 extend sufficiently below adhesive layer 105 in order to ensure good electrical connection with a patient's skin surface (not shown). Tab 106, FIG. 1A, allows for easy removal of a protective backing 111 from adhesive layer 105.

Flexible printed circuit layer 101 can include contacts, such as battery clips (not shown), to receive and connect to batteries 204. (It is contemplated that in

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some future embodiments, a single battery can provide sufficient electrical power.) In the exemplary embodiment, as shown in FIG. 2, batteries 204 can be mounted under respective battery flaps 205 arranged on opposite sides of the flexible printed circuit layer 101. Alternatively, battery clips (not shown) or battery holders (not shown) can be used to provide both mechanical support and electrical connections for each of the batteries 204. One type of battery holder suitable for such use, for example, is the model 2990 battery holder, manufactured by the Keystone Electronics Corp. of Astoria, NY. Battery cover 107 provides protection for batteries 204 as well as a surface to press upon when applying electrodes 103 to conductive surface 404. Retention clips 104 can comprise, for example, a plurality of spring fingers with latching clips. Retention clip 104, affixed to disposable electrode module 110, can be used to secure reusable communications and computation module 102 to disposable package 110. Reusable communications and computation module 102 is herein illustrated in a simplified representation, including cover 201, communications and computation printed circuit board assembly 202, and base 203.

[0047] FIG. 3 shows a mechanical view of an exemplary reusable communications and computation module 102, as well as a preferred method for making an electrical connection between flexible printed circuit layer 101 in disposable electrical module 110 and communications and computation printed circuit board assembly 202 situated in reusable communications and computation module 102. In this exemplary embodiment, communications and computation printed circuit board assembly 202 can include a plurality of press fit and/or soldered conductive sockets 301 for receiving electrical plug 302, the plug having a corresponding plurality of conductive pins. Each conductive pin shown in plug 302 can correspond to an electrical connection pad on flexible printed circuit layer 101. A row of mechanical sockets 303 can receive the multi-pin row of plug 302. Thus, an electrical connection can be made between each pad of flexible printed circuit layer 101 having a conductive post on plug 302 and each corresponding conductive socket 301 on communications and computation printed circuit board assembly 202. Posts 304 can align and secure each of the cover 201, communications and

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computation printed circuit board assembly 202, and base 203. Note that in FIG. 3, a simplified drawing of cover 201 omits slots to receive retention clip 104 to affix communications and computation module 102 to disposable package 110. A body worn monitor 100 would typically also include retention clip 104 FIG. 2, or other suitable type of mechanical clip(s), in order to provide a secure mechanical connection between communications and computation module 102 and disposable electrode module 110.

[0048] FIG. 4A shows one embodiment of flexible circuit board 101 in an expanded (e.g. unassembled) view. Flexible circuit board 101 is formed on a substrate 406. Substrate 406 can be cut, for example, from a Mylar sheet of suitable thickness. In this embodiment, one battery 204 can be mounted adjacent to an conductive surface 404. Conductive gel 103 (not shown in FIG. 4) can be mounted on the exposed conductive side of a conductive surface 404.

[0049] Conductive surface 404 can also be viewed as the electrode portion of a half cell and electrode gel 103 can be considered to be the electrolyte portion of a half cell. In conventional terms of art, the combination of electrode and electrolyte and ECG electrode is typically referred to as a half cell. For example, the combination of a conductive surface 404 and an electrolyte layer (e.g., electrode gel 103) forms a half cell. For convenient quick reference to a half cell structure, the term "electrode" (assigned reference designator "109") is used interchangeably with "half cell" herein. It is understood that in typical embodiments, electrode 109 comprises conductive surface 404 and electrode gel 103.

[0050] Typically, electrodes make use of a circular or square conductive surface. Increasing the ratio of the perimeter of the surface to the area of the surface affects current density distribution and defibrillation recovery.

[0051] For convenience, we define the term "annulus" herein and throughout as the region between two simple curves. A simple curve is a closed curve that does not cross itself. Under this definition, an annulus can include substantially square shapes, substantially rectangular shapes, substantially circular shapes, substantially oval shapes, as well as substantially rectangular shapes with rounded corners.

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Further we include in the definition of annulus, the case of a substantially "U" shaped surface as described by a single closed curve.

[0052] One exemplary electrode gel 103 suitable for such use on a body worn monitor is type LT00063 hydrogel supplied by Tyco Healthcare of Prague, Czech Republic. Typically, a conductive surface 404 creates the electrode portion of the half-cell. By increasing the ratio of perimeter to area of the circular electrode portion of the half cell, the signal to noise ratio of the input ECG signal can be increased.

[0053] As depicted herein on the exemplary circuit layout, two batteries 304 can be connected in series, with one polarity being made available at connection pad 407 from battery connection 402, battery connection 401 creating the series connection between the two batteries, and connection pad 410 providing the second polarity of the series connected batteries. Note that in some embodiments, a single battery alternatively may be used in lieu of the exemplary arrangement or two batteries can be also wired in parallel, depending on the voltage requirements of a particular communications and computation module 102.

[0054] Connection pads 408 and 409 electrically couple the signals from electrode gels 103 (not shown in FIGs. 4A-4D) via conductive surface 404 and resistive traces 412 to electrical plug 302 (not shown in FIGs 4A-4D). Electrode contact pad 405 can be connected via resistive trace 413 to connection pad 411 to provide a direct-connected reference electrode (not shown in FIGs. 4A-4D). Traces 412 extending between conductive surface 404 and connection pads 408 and 409 and trace 413 extending between conductive surface 405 and connection pad 411 can be made from resistive materials including resistive metals, carbon, silver ink, powders, paints, or other material of determinable electrical resistance.

[0055] Resistive traces on flexible circuit board layer 101 replace the bulky power resistors needed by prior art monitors, having electrodes or sensors connected by wires or leads. These resistive traces should survive multiple defibrillation cycles such that body worn monitor 100 remains functional even after one or more attempts to re-start a patient's heart. In order to survive defibrillation, the resistive traces should dissipate that portion of the potentially damaging defibrillation energy that is

coupled into the monitor. This fractional portion of the defibrillation energy typically enters body worn monitor 100 from electrodes 109, FIG. 1D (electrodes 109 including conductive surface 404 and electrode gel 103).

[0056] It is desirable that the resistances of the protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms. Below 1 kilo ohm, depending on the resistive material used, it can be more likely that the resistance of the resistive traces 412 and 413 will increase with each successive defibrillation pulse. Above 10 kilo ohms, a high resistance impairs the signal to noise ratio, specifically due to thermal noise, which has a mean square value of 4*k*T*R*BW, where "k" is Boltzmann's constant, "T" is temperature measured in degrees Kelvin, "R" is resistance in ohms, and "BW" is bandwidth, in Hz, which becomes significant relative to the EC-13 requirement that the noise referred to input be less than 30 μV peak-to-valley.

[0057] Power dissipation in the herein described traces can be calculated by E^2/R, in which E refers to the potential across the trace and R is the resistance of the trace. R can be calculated by $\rho*L/A$, where ρ is the resistivity of the material used to form the trace, L is the length of the trace, and A is the cross-sectional area of the trace.

[0058] In developing resistive traces for use on a flexible printed circuit layer 101, typically formed on a Mylar substrate 406, such as shown in FIG. 4A, various materials were tested. Silver, including silver inks, while useable, was found to be less desirable, because it was difficult to achieve sufficiently thin silver traces on Mylar to achieve high enough resistances. Carbon, including carbon pastes and carbon inks, was also tried and found to be suitable. In order to use carbon however, several additional problems had to be solved. At 1 kilo ohm, the power dissipated by the resistors caused them to degrade across multiple defibrillation cycles. The solution was to make carbon traces in the range of about 8 to 10 kilo ohms. 10 kilo ohm resistances proved to be a good compromise between noise levels, power dissipation by the resistors, and manufacturing tolerances for depositing carbon ink on a Mylar substrate to dissipate the power from multiple defibrillation cycles. To achieve the desired resistance of about 10 kilo ohms

(interchangeably represented herein as "10k" or "10 kΩ"), for a given resistivity of the carbon paste, and given trace width and thickness (height), the length of the trace is then defined. In some cases, such as for traces 412, the length needed for a trace run, as between conductive surface 404 and connection point 409, might be longer than the length defined for a particular trace resistance (typically 10k). In this case, traces can be extended by lengths of silver conductive traces. There can be a short overlay distance, on the order of 5 to 10 mm, in which a silver trace overlaps the carbon trace to provide a more robust connection between the resistive and conductive portions of the traces. Where overlap is used, the overall length of the resistive portion can be adjusted slightly to maintain the desired overall resistance.

[0059] Another problem associated with carbon traces was arcing at the interface between the carbon and conductive traces. Arcing was particularly problematic at the abrupt connection between the carbon trace and conductive surface 404. Arcing was also observed to occur between the end section of the carbon trace and conductive surface 404. (Electrode gels 103 create the conductive path to the patient through conductive surface 404 and a layer of conductive gel.)

[0060] According to one solution to the above noted arcing problem, as shown in FIG. 4B, a rounded (fillet) section 430 of carbon trace can be added at the interface to conductive surface 404. A fillet or "tear drop" shape causes the carbon trace to become gradually wider as it connects to conductive surface 404 and relieves the electrical potential stress at the interface.

[0061] An alternative solution to the arcing problem is shown in FIG. 4C, wherein carbon can be laid down beyond the trace (412) to include a pattern of conductive surface 404 formed from carbon. A carbon annulus pattern can be deposited before the conductive surface 404 is deposited. Conductive surface 404 can then be deposited as an overlay over the earlier formed carbon annulus shape. Finally, conductive gel 103 can be attached to the conductive surface layer (the carbon layer residing between conductive surface 404 and the Mylar substrate used as flexible circuit board 101). Both of the aforementioned arcing solutions can be used together. It should also be noted that conductive surface 404 can be formed

from suitable materials other than silver, including, for example, materials such as silver chloride.

[0062] Arcing can also occur between the resistive traces and other (typically silver) conductive traces on the flexible circuit board 101. Trace to trace arcing can be suppressed by allowing sufficient spacing between the traces. Generally a minimum spacing of about 3 mm/kV, as required by ASNI/AAMI DF80:2003 57.10 BB, has been found to be sufficient to prevent trace to trace arcing from a defibrillation event. Closer trace spacing, as close as 0.01 mm/kV, can be employed successfully by first applying an insulating dielectric layer, similar to a conformal coating, over the surface of flexible circuit board 101 that covers most of the substrate and traces. The insulating dielectric layer can be prevented from forming or adhering to conductive surface 404, such as by use of a mask during application of the insulating layer.

[0063] In an alternate embodiment, as depicted in FIG. 4D, a snap device can be added to conductive surface 404 to accept a manufacture snap-on electrode (not shown), such as, for example, the ConMed Cleartrace line of ECG electrodes including the model 1700 Cleartrace electrode manufactured by the ConMed Corp. of Utica, NY or similar type electrodes made by the 3M Corp. of St. Paul, MN. When designed to accept a snap-on electrode, the conductive surface 404 is typically smaller than in the previous embodiment. A receptacle snap 432 for receiving the commercial snap-on electrode can be inserted by any suitable method, such as by press fitting or other fastening method, into conductive surface 404, typically also penetrating through substrate 406. In this embodiment, arcing can be similarly suppressed in this embodiment by adding a fillet to the carbon-conductive surface interface and/or deposing a conductive surface 404 over a carbon layer as previously described.

[0064] **Example:** Resistive traces and an annulus were tested on a substrate formed from CT3 heat stabilized treated polyester (75 microns thick), such as manufactured by the MacDermid Autotype Corp. of Schaumburg, IL. Resistive traces were silk screened onto the substrate using 7102 carbon paste conductor from

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the DuPont Corporation of Wilmington, DE. The carbon paste conductor was deposited through a 43T silk screen mesh. The substrate containing the paste deposit was then cured inside a fan assisted air circulated oven at 120°C for a period of 5 minutes. The traces formed were about 55 mm long and 2 mm wide, having an overall thickness of about 7.5 microns. The initial measured resistance of each trace was about 14 kilo ohms. After each trace was subjected to 3 defibrillation cycles, the measured resistance increased to about 15 kilo ohms. Over a 3 mm length, the trace widens to about 5 mm, terminating into a carbon annulus with an outer diameter of about 20 mm and an inner diameter of about 10 mm. A silver layer of PF-410 silver ink from the Norcote Corp. of Eastleigh Hampshire, UK was then deposited over the carbon annulus, also to an overall thickness of about 7.5 microns. The deposition of the silver layer was via the silk screen printing method, in which a 90T silk screen mesh was used. The substrate containing the deposited silver ink was then cured inside a fan assisted air circulated oven at 120°C for a period of 15 minutes. A third dielectric insulating layer comprising SD2460, components A & B (dielectric and hardener), manufactured by Lackwerke Peters GmbH + Co KG of Kempen, Germany, and having a thickness of approximately 13 microns was then deposited over the traces and substrate, but not over the annulus. (The electrodes were formed by attaching a conductive gel to the annulus. The conductive gel used was LT00063 hydrogel from Tyco Healthcare of Prague, Czech Republic.) Again, the silk screen printing process was used to deposit the dielectric layer through a 90T screen mesh. The substrate was placed again into a fan assisted air circulated oven at 120°C for a period of 30 minutes.

[0065] **Example:** Silver traces for use as conductive (not resistive) traces on a body worn monitor circuit substrate were formed from a silver paste that was silk screened onto a Mylar substrate. 45 mm long traces had a measured resistance in a range of 3.5 to 6 ohms, 75 mm traces had a measured resistance in a range of 6.5 to 13 ohms, and 105 mm traces had a measured resistance in a range of 10 to 16 ohms. The deposition of the silver layer was performed via the silk screen printing method in which a 90T silk screen mesh was used. The substrate containing the deposited

silver ink was then cured inside a fan assisted air circulated oven at 120°C for a period of 15 minutes.

[0066] FIG. 15 diagrammatically depicts an exemplary test setup used to simulate the effect of a patient defibrillation on resistive traces. Defibrillator 1501 was used to apply multiple defibrillation shocks of 360 Joules each to the 100 ohm resistor 1502. The 100 ohm resistor according to this setup simulated a patient's body. Note that most of the defibrillation energy goes into the patient's body by design, to restart the patient's heart. Resistive traces 1503 and 1504 were wired across resistor 1502, also as shown in FIG. 15, in order to simulate the electrical circuit that would be formed between the resistive traces in a body worn monitor situated on a patient undergoing defibrillation. Neon bulbs 1506 were used as part of the protection circuitry that can be used with resistive traces in a body worn monitor. 400 ohm safety resistor 1505 was present as a precaution to limit short circuit current in the event of a test setup failure. Both the 100 ohm resistor (simulating human skin resistance) and the 400 ohm safety resistor were used in accordance with medical specification AAMI EC-13. Following 3 defibrillation shocks of 360 Joules each, the measured resistance of the 10k carbon track changed from 10k to 11k following the first shock, to 13.1k following the second shock, and to 13.2k following the third shock. The measured resistance of the 9.7k trace changed from 9.7k to 11.6k following the first shock, to 13.0k following the second shock, and finally to 13.2k, following the third shock. In a subsequent related test, the 100 ohm resistor was replaced by a closer simulation in the form of a fresh (dead) chicken. The setup otherwise remained the same as shown in FIG. 15. In this case, the resistance as measured on each of the test resistive traces changed from 10.7k to 10.25k, and from 8.5k to 9.4k, following multiple defibrillations. During testing, it was also noted that the change in measured resistance of the resistive traces was generally consistent. It was also noted that as a given resistive trace was increased, the (delta R {caused by defibrillation}/R {net trace resistance}) can be minimized.

[0067] The screen printing technique for laying down resistive traces was further investigated by printing a plurality of small carbon resistive dots 1601 of

about 20 mm in diameter using a 7102 carbon ink applied by a screen printer (not shown). The carbon dots 1601 were laid out on a tray 1602 as shown in FIG. 16A, for baking in an oven. A manually operated squeegee (not shown) was used to apply the resistive dots 1601 to the tray 1602 through a mask (not shown). It was determined that control of thickness during application was one important factor for controlling the distribution of resistance. It was noted that during manual application, the variation of resistance depended upon the distance between the plurality of dots 1601 and the person applying the resistive paste, and that the pressure applied using the squeegee could also affect the final resistance by a factor of two. It was further noted that "even" heating across the tray 1602 was advantageous during oven drying, although this factor was found to have less effect on the final dot resistance distribution. A resistance distribution of the baked and measured dots 1601 is shown in the histogram of FIG. 16B. This testing indicated that production traces laid down on a substrate, such as Mylar, for use in a body worn monitor should preferably be printed using a semi-automatic screen print process, such as by a screen printing mechanical roller process. A digital multimeter ("DMM") with probes placed at each edge of a dot 1601 was used to measure the resistance from one edge of the dot to the other. It was found that uniform application of ink was important to keeping a tight distribution of resistance, with even heating having a smaller influence on the distribution of the resistance of the test dots. Since a trace with too low a resistance has a greater $\Delta R/R$, and higher probability of failing and very high resistance traces result in worse S/N ratio, it is important to have a reasonably tight tolerance on the trace resistance.

[0068] FIG. 5 shows a block diagram representative of one embodiment of the body worn physiological monitor 100. Physiological sensors 501 (such as electrodes 109 in FIG. 1D) can be electrically coupled to electromechanical connector 502 (as by the resistive traces 412 shown in FIG. 4). Connector 502 serves to electrically couple communications and computation module 102 to a disposable electrode module 110 (FIG. 2). Secondary connector 503 can also electrically couple one or more additional sensors, which can be situated both on and

off of disposable electrode module 110, to electromechanical connector 502 for electrical coupling along with physiological sensor signals 501 to communications and computation module 102 (shown in FIG. 1) via electromechanical connector 505. Signals received by the communications and computation module 102 can be electrically coupled into communications and computation module 102 via electronic protection circuits 506 and/or filters, such as ESIS filters 507.

[0069] Signals can be limited or clipped in amplitude, as needed, by protection circuit 506, and filtered by filter 507. One or more analog amplifiers 508 can be used to amplify the amplitude limited and filtered signals. In the exemplary body worn ECG monitor, amplifiers 508 can advantageously be differential amplifiers to amplify the difference signal (e.g. the ECG "vector") between two ECG electrodes. The electrical output of amplifiers 508 can be electrically coupled to both PACER circuits 509 and ECG circuits 510. PACER circuits 509 are described further below. ECG circuits 510 perform several functions, including "trace restore", low pass filtering (anti-aliasing), high pass filtering, and amplification (gain). Low pass filtering filters signals according to the Nyquist criterion to avoid aliasing later when the signals are digitized by analog to digital converter (ADC) 516. The high pass filter causes the input to be AC coupled from a roll off frequency of about 0.05 Hz, as specified by industry ECG standards. Gain is required to cause the small pre-amplified potentials from physiological sensors (such as electrodes 109) to more closely match the available dynamic range of the digitizing ADC 516. Note that ADC 516 can be a dedicated ADC chip or can be included in a microcomputer integrated circuit, such as a microcomputer serving as microprocessor 512.

[0070] A microprocessor, such as microprocessor 512, is defined herein as synonymous and interchangeable with the terms "microcomputer", "microcontroller", and "microprocessor". Such microprocessors are also interchangeably represented herein as "μP" or "μC". Further, any microprocessor disclosed herein can be replaced by any integrated device that can perform the function of a microprocessor, such as, but not limited to, a field programmable gate array ("FPGA") programmed to perform the functions of a microprocessor.

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[0071] Typically, one or more differential amplifiers can be dedicated to particular difference voltages associated with physiological sensors 501 or 504, but it should be noted that one or more amplifiers 508 can also be multiplexed by techniques as known in the art, to serve multiple physiological sensors using a lesser number of amplifiers. Similarly, one or more ADCs 516 can serve two or more signals from physiological sensors 501 or 504 using techniques such as multiplexing in time that is digitizing one physiological sensor difference signal at a time sending a digital result to a next stage one after the other. ECG circuits 510 and PACER circuits 509 are referred to in the plural, since there can be individual circuits for each measured physiological signal, such as for each measured ECG vector.

[0072] Electrical power from power source 515 can be regulated by regulator 514 and distributed as regulated voltage 517 to most function blocks (as represented herein by the label "POWER"). Each of these function blocks also has a control ("CTRL") input 511 from microprocessor 512, allowing these circuits to be disabled, when not needed, in order to save battery power. When viewed over time, most of the ECG waveform does not contain useful information since there is significant "dead time" between heart beats. Therefore, for example, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, circuits can be powered down (in a device "sleep mode") to save on the order of 60% of the energy stored in the power source that would have otherwise been used during this dead time.

[0073] FIG. 17 shows an exemplary ECG waveform. In brief, the P wave can be related to the electrical current causing atrial contraction. The QRS complex can be related to ventricular contraction of the left and right ventricles. The Q wave can be related to electrical current traveling through the intraventricular septum, while the R and S waves can be related to the ventricles contracting. The T-wave is due to the re-polarization of the ventricles. Usually, atrial re-polarization occurs atop the QRS complex, and being much smaller than the QRS complex, is not seen. The ST segment connects the QRS complex to the T-wave. Irregular or missing waves may be indicators of cardiac issues including: ischemic tissue, e.g. due to

myocardial infarction, bundle branch block, atrial problems (specifically P-wave abnormalities), pericarditis, and electrolyte disturbance.

[0074] Generally, power source 515 can include one or more "button" cells typically disposed on disposable electrode module 110; however, the block diagram of FIG. 6 shows an embodiment of a body worn physiological monitor 100 where power is supplied by a power source located on, or connected to communications and computation module 102 instead of residing within disposable electrode module 110.

[0075] Beyond power saving considerations, it can also be desirable in some embodiments of body worn physiological monitor 100 to put the microcontroller and/or other circuits, including particularly digital circuits, into a sleep mode during an ADC conversion cycle to minimize pickup of self generated electrical noise and to minimize power use. Preferably, the A/D circuit can acquire multiple samples and buffer the samples, before awakening the microprocessor, which then can batch-process the data. Buffering can be set to match the patient's heart rate, as there is no significant clinical benefit to analyzing every sample as it is taken.

[0076] Turning back to the input circuits, typically amplifiers 508 are differential or instrumentation amplifiers useful to selectively amplify desired difference signals between connector terminals (such as an ECG vector), while rejecting common mode signals (such as interfering signals that appear simultaneously on both connector terminals). Beyond using a differential amplifier, other techniques can be advantageously used to further reduce common mode pickup (CMR) and thus to improve the common mode rejection ratio (CMRR) of the input amplifier stages of body worn physiological monitor 100. CMR is of particular concern with regard to body worn physiological monitor 100 because of the proliferation of potentially interfering electromagnetic fields, such as from 50 Hz or 60 Hz AC power line distribution throughout a hospital. For example, many fluorescent ceiling lamp fixtures generate strong 60 Hz alternating current (AC) electromagnetic fields that can appear as common mode signals on physiological sensors 501, such as ECG electrodes 109.

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[0077] FIG. 7A shows one embodiment in which body worn physiological sensor 501 comprises a plurality of ECG electrodes 109 and 701. Two electrodes 109 generate an ECG difference potential for patient 703. A third electrode, reference electrode 701 can be electrically coupled to electronics common 704 (or other potential level) and can be used to improve CMR. In this embodiment, the electronics common 704 (shown as the negative terminal of the battery in FIG. 7A) can be directly tied to the patient in the vicinity of electrodes 109. Thus, the electronics common of the electronic circuits in communications and computation module 102 can be made to more closely follow any change in potential in the vicinity of electrodes 109. Reference electrode 701 can be particularly helpful to ensure that inputs 109 remain within a reasonably narrow common mode range, such as by reducing a 60 Hz potential that would otherwise appear to move the electronics common 704 at 60 Hz with respect to electrodes 109.

[0078] In another embodiment as shown in FIG. 7B, virtual electrode 702 performs a similar function as previously described with regard to reference electrode 701. In this embodiment, instead of creating a DC-coupled reference electrode, electrode 701 is replaced by the capacitive coupling between flexible printed circuit layer 101 and the patient 703, resulting in a virtual electrode 702 with an AC coupled common. Such AC coupling increases with decreased distance between flexible printed circuit layer 101 and the patient and can advantageously reduce 60 Hz common mode signals (AC signals).

[0079] In yet another version of a directly connected electrode 701, as shown in FIG. 8A, electrode 701 can be actively driven by an electrical output from communications and computation module 102. Typically, an operational amplifier (OpAmp) or other type of amplifier can be used to create a "driven lead". Driven lead circuits can be used to further improve CMR over passive electrodes 701 as shown in FIG. 7A. An exemplary circuit suitable for use to drive an electrode 701 is shown in FIG. 8A. Amplifiers (OpAmps) 810 and 811 buffer the high impedance signals from electrode 1 and 2 (exemplary electrodes 109). Difference amplifier 508 conveys the difference signal (such as an ECG vector) as previously described. The two 10 kilo ohm resistors provide an average of the common mode signals appearing

simultaneously at the inputs of buffer amplifiers 810 and 811. The inverting low pass filter built around OpAmp 812 inverts the averaged common mode pickup signal (at electrodes 1 and 2) and applies that signal out of phase (180 degree phase shifted) to a directly connected driven electrode (such as electrode 701). By applying the average common mode signal to the driven electrode, amplifier 812 effectively suppresses common mode signals at electrodes 1 and 2 within the effective bandwidth of the negative feedback loop by active noise cancellation. In theory, a virtual electrode 702 could be similarly driven, but the voltage requirements to drive a capacitively coupled common electrode are high enough to make a "driven virtual electrode" a less practical option. Thus, it can be seen that a reference electrode can be a passive connection or an actively driven connection.

[0080] It can also be desirable to have more than one CMR technique available. For example, in a low noise environment, a lower power reference electrode might be used for CMR. Then if the noise increases to a level where the reference electrode provides insufficient CMR, the body worn monitor can switch to a driven lead more suitable for CMR in a high noise environment. In this embodiment, a particular CMR configuration can be selected by electronic switching. FIG. 8 shows one such exemplary switching block represented as reference electrode switch 801. Microprocessor (μP) 512 can control reference electrode switch 801 to select direct connected electrode 701, virtual electrode 702, or directly connected electrode 701 additionally driven by a driven lead circuit 802. It should also be noted that in the embodiment of FIG. 8, when virtual electrode 702 provides sufficient CMR, electrode 701 can be used as a third electrode, thus allowing body worn monitor 100 to simultaneously measure two different heart vectors.

[0081] FIG. 9 shows one embodiment of an exemplary defibrillation protection circuit (506) and ESIS filter 507. As shown in FIG. 9, electrodes 109 can be connected via input resistors R91 and R92. Gas discharge tubes, such as neon bulbs L1 and L2, can be used for over voltage protection by firing at a designed voltage to prevent large potentials from appearing at the input leads to amplifier 508. The gas discharge tubes can be disposed on either disposable electrode module 110

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or on the communication and computation module 102. Defibrillation protection resistors R91 and R92 can further reside in disposable electrode module 110, such as in the form of the resistance of traces 412.

[0082] ESIS filters 507 can be used to satisfy AAMI standard EC13 on Electrosurgical Interference Suppression (ESIS). Standard EC13 addresses the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used. Without such suppression, the high RF output of an electrosurgical device can render ECG monitoring impossible and or render the monitor unusable. Resistors R93 to R98 and capacitors C91 to C96 form cascaded low pass filter sections (e.g. R93-C1). Three cascaded single pole filters are shown on each input leg of amplifier 508 as an example; more or less stages can also be used. It is also not necessary for each section of the cascaded filter to have identical values or roll off points in the frequency domain to create a specific response, e.g., Bessel, Chebychev, or other filter response known to those skilled in the art. Also, ESIS filters are not limited to cascaded single pole filters and can take other forms as known in the art.

[0083] Test circuit 906 can provide a relatively sharp transient signal for testing the PACER circuit described below as part of a body worn monitor 100 "power on self test". Resistors R99 and R100 can pull the output of the differential amplifier 508 allowing the microcontroller (512) to detect which electrode, if any, has detached, much as a "lead failed" detection is accomplished by ECG monitors having leads. Body worn monitor 100 does not use leads, but it is still possible for one or both of the physiological sensors to move free of a patient's body. Such disconnects can occur in situations in which body worn monitor 100 partially moves away from the body to which it is non-permanently affixed. The input impedance at one or both of the electrodes 109 changes in a sensor off (sensor disconnect) event. When a patient is attached, amplifier 508 typically has an output voltage of near zero volts. However, if one of the electrodes 109 comes off, resistors R99 or R100 cause the output of amplifier 508 to move to a most positive output ("positive rail") or to a most negative output ("negative rail"). Note that the negative rail can be a small

voltage near zero, in the case of single supply circuit operation, and that both inputs could be pulled to the same rail. Lead-fail detection can also be analyzed to determine when the device is attached to the patient and then to automatically enter full operational mode. Such analysis can be done at a low frequency.

[0084] The ESIS filter 507 also can cause a stretching in the time domain of a pacer pulse so that the event is recorded by at least one sample, even though the pacer pulse itself is of small duration compared to the ADC sample rate and the pacer pulse is likely to occur between samples.

[0085] FIG. 10 shows an alternative circuit to accomplish over voltage protection, such as is required during defibrillation. In FIG. 10, diodes 1001 prevent the electrode potentials from going much more than one diode voltage drop above Vcc or below ground and resistors R91 and R92 limit current. Using circuit protection, such as gas discharge tubes L1 and L2 (FIG. 9) and/or diodes 1001 (FIG. 10) combined with resistances R91 and R92, typically in the form of resistive traces 412, a body worn device can survive multiple defibrillation cycles of at least 360 joules.

[0086] PACER circuit 509 detects pacemaker pulses. One reason to detect a pacemaker is to prevent the ECG circuitry from inadvertently registering the regular pulses from a pacemaker as an actual heart rhythm. Separation of a pacemaker signal from signals generated by the heart is important both to generate accurate ECG analysis results as well as to correctly detect the absence of an actual heart rhythm. For example, a pacemaker continues to function even where a human heart has completely failed.

[0087] A pacer event (pacemaker signal) is typically a narrow pulse typically less than 100 microseconds wide. Because of the capacitance between the pacer in a patient and an ECG circuit, an otherwise relatively square pacer pulse as administered at the patient's heart by a pacemaker, can appear to an ECG monitor as a pulse with a negative undershoot and an exponential return to zero that could inadvertently mimic a QRS signal. A pacer signal, however, can be recognized by an analog differentiator and alert microprocessor 512 to the presence of a pacer and to disregard the refractory period of the corresponding R-C recovery due to the pacer

signal. The pacer detection circuit or PACER circuit can generate a microprocessor interrupt to inform the microprocessor that a pacer event occurred and to mark a corresponding physiological signal in time as related to a pacer event. PACER circuit 509 can also cause one or more pacer related circuits to automatically power down for power saving, where it is determined that a patient is not using a pacemaker.

[0088] FIG. 11 shows an algorithm useful to determine if the pacer circuit should be enabled. A typical PACER detection circuit uses a significant percentage of the energy available from a power source such as batteries 204. If a PACER signal is not detected, such as at power up of body worn monitor 100, the pacer circuit can be automatically disabled allowing for a longer battery life. Since typical PACER circuits can use several amplifiers (OpAmps), they can consume up to one third of the analog power, therefore securing the PACER circuits when they are not needed (i.e. the patient does not have a pace maker) can cause a significant improvement in battery life. The algorithm also can also provide checks to determine if a demand type pace maker begins operation (which might be inactive at power up of body worn monitor 100) by analyzing beat variability. While it can be advantageous to have the body worn device automatically sense the presence of a pacemaker and to enable the PACER detection circuit, the choice as to whether to enable or disable the PACER circuit can also be done by externally configuring the body worn device. Such external configuration can be done through a hardwired communication connection cable or via communications and computation module 102, in which communications and computation module 102 is a two-way radio transceiver communication device capable of receiving a configuration command sent for a remote radio transceiver. The radio could be 802.11 compliant, but generally would use a lighter-weight (simpler) protocol that can be more energy efficient. A suitable lighter weight protocol could be proprietary, or standards-based, such as ZigBee or Bluetooth. A body worn physiological monitor 100 is particularly well suited for use in hospital environment as part of an integrated wireless monitoring network. The details of such monitoring networks are disclosed in U.S. Patent Application Serial No. 11/031,736 entitled, "*Personal Status*

Physiological Monitor System and Architecture and Related Monitoring Methods", which is incorporated by reference herein in its entirety.

[0089] FIG 12 shows a high pass filter (HPF) suitable for use in ECG circuits block 510. An advantage of a 0.5 Hz HPF is faster recovery from DC offsets due to patient movement, defibrillation, electrocuatery, etc. However ST segment analysis is negatively impacted if HPF cutoff is greater than about 0.05 Hz. Thus, it is preferable to have the ability to change between a 0.5 and 0.05 Hz cutoff frequency. The high pass filter of FIG 12 is implemented by a low pass filter configured as an inverting amplifier in a negative feedback circuit to give a net effective high pass transfer function from circuit input to output. The corner frequency of the composite filter can be adjusted by switching in resistor R2'. Alternatively, S1 can be switched at a periodic rate to place a duty cycle on C. Note that the frequency of switching of S1 should be fast with respect to the corner frequency of the anti-aliasing low pass filter. The graphs A-D of FIG. 13 further illustrate the performance of the exemplary filter of FIG. 12. These graphs show normalized amplitude on the vertical axis plotted against frequency on the horizontal axis. FIG. 13, graph A represents a raw input signal. FIG. 13, graphs B and C are Bode Plots representing the high and low-pass filter sections. After applying filter responses B & C to input Data A, filtered data D is the result. The HPF cutoff can be 0.5 Hz or some lower value depending on whether R2' is switching in or if C is duty cycled.

[0090] Another method to achieve this frequency change is to use digital filters implemented on Microprocessor 512 to reverse the effects of the 0.5 Hz HPF, then implement a digital HPF at a lower cutoff frequency, 0.05 Hz, for example. The response of the 0.5 Hz filter should be known to implement the inverse filter. This response can be measured using microprocessor 512 to trigger the test circuit 906 to create an impulse, H(s). The inverse response is the [1-H(s)] (FIG. 13, graph E) and this inverse filter can be digitally implemented by methods familiar to those skilled in the art. H'(s) is the frequency response of the new HPF with lower cutoff frequency, nominally 0.05 Hz. The digital filter for H'(s) is digitally generated (F) and applied along with [1-H(s)] (FIG. 13, graph E), resulting in the frequency

response displayed in FIG. 13, graph G. A high pass filter suitable for use in ECG circuits block 510 can be implemented in full or in part by software that can run on microprocessor 512.

[0091] FIG. 14 shows how a body worn monitor 100 configured as an ECG monitor can be situated on a patient in at least two different orientations to measure different heart vectors. A primary heart vector is measured by orientation from the patient's right shoulder to the left hip, as shown by position 1401. An alternative position 1402 can be more suitable where there is injury or where patient anatomy is such that it causes the preferred position 1401 to be less desirable. Also, body worn monitor 100 can be affixed to the side of patient 703 (similar to a measurement made by a conventional ECG "V" lead) or back of a patient 703 (such as where a patient needs to sleep on their stomach) to monitor still other ECG vectors (not shown). In effect, a body worn monitor 100 can be placed to pick a particular vector that can be traversed by the electrodes 109. For example at least the first three primary heart vectors, i.e. I, II, and III, can be made conveniently available in this manner.

[0092] While illustrated with an internal battery, it is important to note that a body worn physiological monitor 100 can be powered by either an internal power source only, an external power source only, or by an internal or an external power source. An internal power source can be a renewable power source, such as a rechargeable battery.

[0093] Another type of internal power source is a Peltier device operated in reverse, also called a Seebeck device. Seebeck discovered that a conductor generates a voltage when subjected to a temperature gradient. Thermoelectric couples are solid-state devices capable of generating electrical power from a temperature gradient, known as the Seebeck effect. (By contrast, the Peltier effect refers to the situation where electrical energy is converted into a temperature gradient.) A Seebeck device "couple" consists of one N-type and one P-type semiconductor pellet. The temperature differential causes electron flow from hot to cold in the N-type couple and hole flow from hot to cold in the P-type couple. To create an electromotive force (EMF), the following connections are made: On the

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cold side (i.e. the side that is exposed to room temperature) the pellets are joined and on the hot side (i.e. the patient side), the pellets are connected to a load, such as the computation and communication module 102. The open circuit voltage of a Seebeck device is given by $V = S \Delta T$, in which S is the Seebeck coefficient in volts/°K and ΔT is the temperature difference between the hot and cold sides. It is a challenge today to completely power the computation and communication module 102 from a Seebeck device that is of the same size as the computation and communication module 102. Presently, a Seebeck device may only provide supplementary power, but as electronics migrate toward lower power and Seebeck coefficients and thermocouple densities improve, a Seebeck device can be a viable long-term power solution for a patient-worn monitor. Other methods of generating energy, such as mechanical (as is used in some wrist watches) and solar, can also be viable methods for providing a renewable self-contained power source for a body worn monitor.

[0094] Turning to analysis routines suitable for use on a body worn monitor, typically, ECG beat picking, such as by using wavelet or Fourier transforms and/or matched filter analysis in the time domain can be computationally expensive. Modeling the QRS pulse as three triangles with alternating polarities creates a rough matched filter for the QRS pulse. Taking the second derivative results in impulse functions at the peaks of the triangles (where the first derivative is discontinuous), and all other points are zero. The second derivative method also makes the convolution with incoming data extremely efficient as most of the multiplies have a 0 as the multiplicand and requires minimal computation. The result can then be integrated twice to produce a matched-filter output, which can be fed into the beat-picking algorithm that provides fiducial marks. Using a second matched filter that is sinusoidal in shape and with appropriate discriminators, the system can provide indications of Life Threatening Arrhythmias (LTA); that is, Asystole, Vfib, and Vtach. While the accuracy of this system is less competitive with a high-end Arrhythmia solutions such as those provided, for example, by Mortara, the filters can be tuned to err toward false positives and upon a positive LTA response, activate transmission of full waveforms.

[0095] Research has also shown that analysis of the R-R portion of the ECG waveform interval statistics can provide a method to predict atrial flutter. Applying this and other low-computational cost methods can allow a body worn monitor device to begin transmitting full waveforms for either clinical or algorithmic analysis by a more powerful engine, when the probability of other arrhythmias is high. Transmitting only the R-R intervals of ECG waveforms is an example of a lossy data compression method. R-R intervals comprise a string of data and the string of data can also be compressed. Lossless or lossy data compression of the entire waveform can be implemented to save battery life, including not transmitting (or perhaps not even sampling) data between the T and the P wave. Because data compression results in less data to transmit, the power saved may offset the computation cost of the data compression.

[0096] While we have referred often to ECG applications herein, the application of low-intensity computational methods as a power saving measure apply equally well to other types of low power-sensors, including, but not limited to EEG, SPO_2, temperature, and invasive or non-invasive blood pressure measurements. Whether the body-worn medical-grade monitor performs complex analysis or simply compares a single numeric value to a single numeric limit, the device can function in a low-power radio state until a predetermined threshold is exceeded. A body worn monitor can also periodically send data or send data upon external request. Additionally, external devices can send commands to modify the operating parameters and thresholds.

[0097] Turning to other communication matters, it may be that adverse events occur in which no uplink is available. In a case of no uplink (failed communications), the body worn monitor can buffer time-stamped waveforms corresponding to any adverse events. The buffers can also store waveforms for later analysis in which this storage is triggered by the patient when the patient recognizes a condition, such as chest pain. In the case of an alarm that occurs when there is no uplink, alarms can be configured to be latched until confirmed by a clinician. Preferably, non-continuous data are marked (time stamp, sample number) to allow correlation of non-continuous data with continuous data and data are also marked to

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indicate when an alarm was initiated for later data analysis, including algorithm performance analysis.

[0098] In those instances in which many body worn monitor devices are used in close proximity to one another, there can be concern that the reports from one body worn monitor might be interchanged with reports from another body worn monitor. The body worn monitor presented herein, can be configured with a patient context (i.e. name, room number, patient ID, age, etc) and can maintain that context for as long as the monitor is connected to the patient to avoid such problems. The body worn monitor can determine the status of its connection to the patient via a continuous vital signs monitor, pressure, temperature, galvanic response, or similar input. Upon detection of a loss of connection with a patient, the device can, depending upon different variable settings, either erase the patient context or when re-connected to the patient, require the care giver to confirm the patient context. When the body worn monitor is initially powered up or connected to a patient, it can have a time holdoff for alarms to prevent false alarms (e.g. low heart rate, lead-fail detection) while the system stabilizes.

[0099] Regarding firmware updates, where there are large numbers of body worn monitors in a hospital, it can be problematic to keep them all updated with the latest version of firmware. One solution to this problem is to provide a wireless update ability for downloading and installing new firmware and/or configurations into all of the body worn monitors.

[00100] While the present invention has been particularly shown and described with reference to the preferred mode as illustrated in the drawings, it will be understood by one skilled in the art that various changes in detail may be effected therein without departing from the spirit and scope of the invention as defined by the following claims. It is further understood that several aspects of the invention, including, but not limited to, defibrillation protection resistors, pacer detect circuit disabling, methods for ECG signal high pass filtering, and various other low power modes are not limited to body worn monitors, and can be used in ECG monitors of any type.

We Claim:

1. A body worn patient monitoring device comprising:

at least one disposable module including a plurality of electrical connections, the electrical connections couplable to a skin surface to measure physiological signals, the at least one disposable module including a disposable module connector;

at least one internal or external power source to power the body worn patient monitoring device; and

at least one communication-computation module, having a communication-computation module connector to receive physiological signals from the at least one disposable module via said disposable module connector, the communication-computation module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals and a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module and the body worn patient monitoring device including the at least one disposable module and the at least one communication-computation module is directly non-permanently affixed to the skin surface of the patient.

2. The body worn device of claim 1, wherein the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body.

3. The body worn device of claim 2, wherein the indirect electrical connections to the body comprise capacitive connections to the body.

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4. The body worn device of claim 1, wherein the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes.

5. The body worn device of claim 4, wherein the ECG electrodes comprise a material screened onto a flexible substrate.

6. The body worn device of claim 5, further comprising at least one series current-limiting resistor to protect the communication-computation module during a patient defibrillation event.

7. The body worn device of claim 6, wherein the least one series current-limiting resistor comprises a resistor screened on the flexible substrate.

8. The body worn device of claim 7, wherein the mechanical interface from the at least one series current-limiting resistor to the ECG electrode includes a filleted edge.

9. The body worn device of claim 7, wherein the mechanical interface from the at least one series current-limiting resistor to the ECG electrode comprises overlapped layers.

10. The body worn device of claim 9, wherein the overlapped layers comprise a carbon resistive layer screened over a conductive surface, the carbon resistive layer having substantially the same shape as the conductive surface.

11. The body worn device of claim 6, further comprising an insulating material overlaying the at least one series current-limiting resistor to prevent arcing.

12. The body worn device of claim 5, wherein the ECG electrodes are formed substantially in the shape of an annulus.

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13. The body worn device of claim 12, wherein the annulus comprises a conductive ink.

14. The body worn device of claim 5, wherein the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal.

15. The body worn device of claim 1, wherein the at least one power source is a renewable power source internal to the body worn device.

16. The body worn device of claim 1, wherein the at least one power source comprises a rechargeable battery or a one time use battery.

17. The body worn device of claim 1, wherein the at least one power source is a battery contained within said disposable module.

18. The body worn device of claim 1, wherein the at least one power source is a Seebeck device.

19. The body worn device of claim 1, wherein one of the electrical connections is a reference electrode that can be used to improve common mode rejection (CMR).

20. The body worn device of claim 1, further comprising a virtual electrode as a reference electrode to improve CMR.

21. The body worn device of claim 20, wherein the virtual electrode is an electrode situated near the skin of the patient, but not directly connected to the skin.

22. The body worn device of claim 20, wherein the virtual electrode comprises a capacitive coupling of a body of the communication-computation module to the skin surface of the patient to reduce power line frequency interference.

23. The body worn device of claim 20, including a reference electrode switch for selectively choosing between using the virtual electrode as the reference electrode and a directly connected electrode as the reference electrode and wherein when the reference electrode switch selects the virtual electrode, the directly connected electrode can be used as an additional ECG electrode.

24. The body worn device of claim 20, wherein the reference electrode is a passive electrical connection or the reference electrode is actively driven.

25. The body worn device of claim 1, wherein the communication-computation module includes a pacer detection circuit.

26. The body worn device of claim 25, wherein the pacer detection circuit generates a microprocessor interrupt to inform the microprocessor that a pacer event occurred.

27. The body worn device of claim 26, wherein the microprocessor interrupt is used to mark a corresponding physiological signal in time as related to a pacer event.

28. The body worn device of claim 26, wherein the device automatically determines if a patient has a pacemaker and only enables the pacer detect circuit when a pacemaker is present.

29. The body worn device of claim 26, wherein the device is configured by an external input to enable or disable the pacer detect circuit.

30. The body worn device of claim 1, wherein the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules.

31. The body worn device of claim 30, wherein the circuit protection comprises a gas discharge tube or a plurality of diodes to clamp or limit the signals from the electrical connections.

32. The body worn device of claim 30, wherein a plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module.

33. The body worn device of claim 1, further comprising a high pass filter with a selectable corner frequency to filter the physiological signals.

34. The body worn device of claim 33, wherein the corner frequency is selected by a switch selectable resistance.

35. The body worn device of claim 33, wherein the corner frequency is selected by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter.

36. The body worn device of claim 33, wherein the high pass filter is implemented in software running on the microprocessor.

37. The body worn device of claim 1, wherein the body worn device self checks a pacer detection circuit by injecting a simulated pacer pulse into a front end amplifier to stimulate the pacer detection circuit by simulating the presence of a patient's pace maker.

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38. The body worn device of claim 1, wherein the communication-computation module includes circuit components to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.

39. The body worn device of claim 1, wherein the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits.

40. The body worn device of claim 1, wherein the microprocessor automatically enters a sleep mode during a conversion cycle of an analog to digital converter (ADC) to minimize noise pickup from digital circuits on the body worn device.

41. The body worn device of claim 1, wherein an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, to save power.

42. The body worn device of claim 4, including an ESIS filter having a low enough corner frequency such that the energy from a pacer pulse is recorded by at least one sample, even though the pacer pulse itself is of small duration compared to the sample rate and the pacer pulse occurs between samples.

43. The body worn device of claim 1, wherein neon bulbs connected from the physiological sensors to an electronics common (ground) protect one or more internal circuits of the communication-computation module from a defibrillation pulse.

44. The body worn device of claim 1, wherein a plurality of diodes disposed between the physiological sensors and an electronics common (ground) protect one

or more internal circuits of the communication-computation module from a defibrillation pulse.

45. A method of providing high voltage circuit protection for a body worn monitor comprising the steps of:

providing a substrate that supports one or more electrical connections to a patient's body;

determining a print pattern and thickness of a first material having a first resistivity to be printed on the substrate;

determining a print pattern and thickness of a second material having a second resistivity to be printed on the substrate;

printing the first material onto the substrate; and

printing the second material onto the substrate wherein at least part of the second the material overlays the first material.

46. The method of claim 45, wherein both of the steps of determining a print pattern and thickness of both the first and second materials comprise the additional steps of determining a print pattern and thickness of both the first and second materials, including a filleted section.

47. The method of claim 45, wherein both of the steps of determining a print pattern and thickness of both the first and second materials comprise the further steps of determining a print pattern and thickness of both the first and second materials to achieve a total resistance value.

48. The method of claim 45, wherein both of the steps of determining a print pattern and thickness of both the first and second materials comprise the further steps of determining a print pattern and thickness of both the first and second materials to achieve a spacing between two or more electrical traces of the print pattern, and applying an insulating layer after the step of printing of the second material.

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49. An ECG monitor comprising:

a plurality of electrical connections including at least one electrode, the electrical connections being couplable to a skin surface to measure patient heartbeat signals;

at least one internal or external power source to power the ECG monitor;

at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and

an ECG electronics module, to receive and process patient heartbeat signals from said plurality of electrical connections, wherein said at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of said plurality of electrical connections and said ECG electronics module.

50. The ECG monitor of claim 49, wherein said at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

51. The ECG monitor of claim 49, wherein a mechanical interface is defined from said at least one series current-limiting resistor to said at least one ECG electrode, said mechanical interface including a filleted edge.

52. The ECG monitor of claim 49, wherein a mechanical interface is defined from the at least one series current-limiting resistor to said at least one ECG electrode, said mechanical interface including a plurality of overlapped layers.

53. The ECG monitor of claim 52, wherein said plurality of overlapped layers comprise a carbon resistive layer screened over a conductive surface, the carbon resistive layer having substantially the same shape as said conductive surface.

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54. An ECG monitor comprising:

a plurality of electrical connections, said plurality of electrical connections being couplable to a skin surface to measure patient heartbeat signals;

at least one internal or external power source to power the ECG monitor; and

an ECG electronics module to receive and process patient heartbeat signals from said plurality of electrical connections and including a pacer detect circuit to detect the presence or absence of a pacemaker, said ECG electronics module drawing power as an electrical load on said power source wherein said pacer detect circuit, upon detection of the absence of a pacemaker signal in a patient being monitored by the ECG monitor, causes said ECG electronics module to disable said pacer detect circuit in order to reduce said electrical load on said power source.

55. The ECG monitor of claim 54, wherein said power source is a battery.

56. A method to improve ECG signal high pass filtering including the steps of:

providing an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals;

filtering said measured heartbeat signals with an analog high pass filter having a analog high pass cutoff frequency;

removing the effects of said analog high pass filter with a digital inverse filter algorithm resulting in substantially unfiltered heartbeat signals;

filtering said substantially unfiltered heartbeat signals digitally using a digital filter having a digital high pass filter cutoff frequency lower than said analog cutoff frequency.

57. The method of claim 56, wherein the step of filtering said measured heartbeat signals with an analog high pass filter comprises the step of filtering said measured physiological signals with an analog high pass filter having a 0.5 Hz analog high pass cutoff frequency, and the step of filtering said substantially unfiltered heartbeat signals digitally comprises the step of filtering said substantially unfiltered heartbeat

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signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

58. An ECG monitor comprising:

a plurality of electrical connections, said electrical connections being couplable to a skin surface to measure patient heartbeat signals;

at least one internal or external power source to power the ECG monitor; and

an ECG electronics module to receive and process heartbeat signals from said plurality of electrical connections, said ECG electronics module drawing power as an electrical load on said power source, said ECG electronics module including a microprocessor to process heartbeat signals, wherein an algorithm running on said microprocessor causes the ECG monitor to enter a low power mode that disables at least one circuit of the ECG electronics module, from the end of a "T wave" at the end of one heartbeat to the beginning of a "P wave" at the beginning of the next heartbeat, in order to reduce said electrical load on said power source.

Abstract:

A body worn patient monitoring device includes at least one disposable module including a plurality of electrical connections to the body. The body worn patient monitoring device also includes at least one communication-computation module, the communication-computation module having at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals. A radio circuit communicates a raw physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module. The body worn patient monitoring device, including the at least one disposable module and the at least one communication-computation module, is directly non-permanently affixed to the skin surface of the patient.

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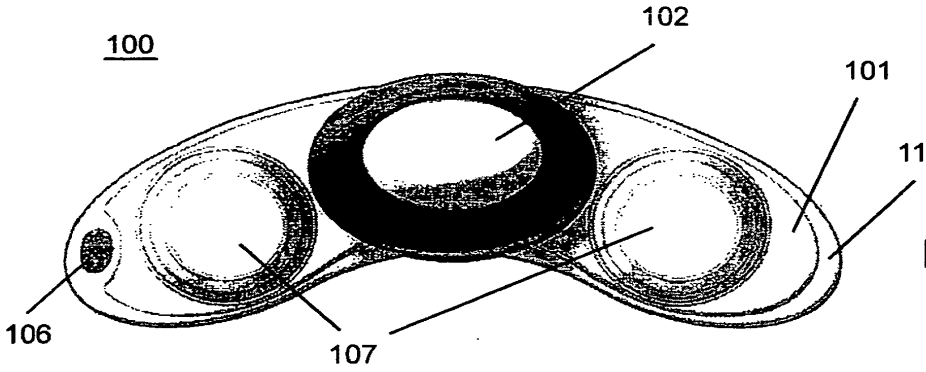


FIG. 1A

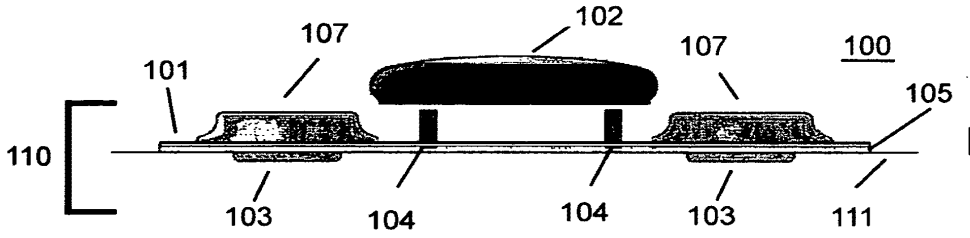


FIG. 1B

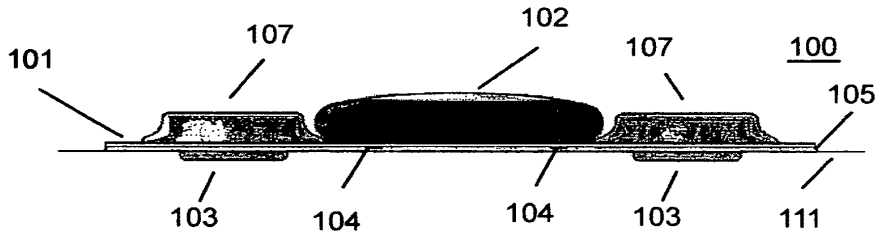


FIG.1C

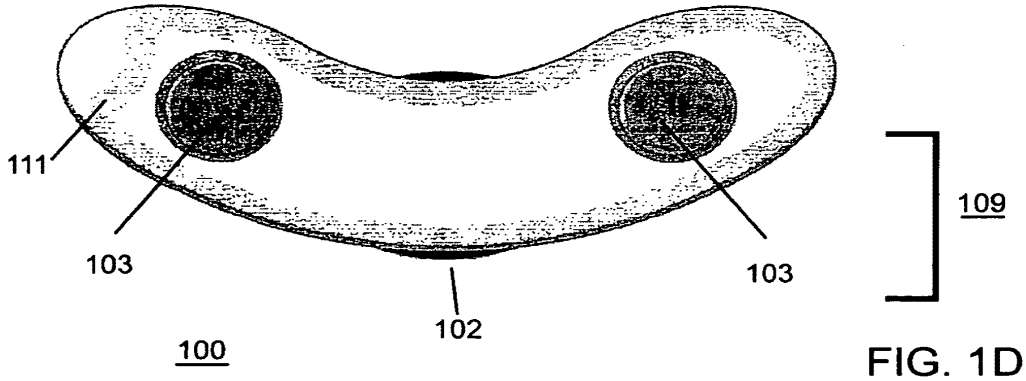


FIG. 1D

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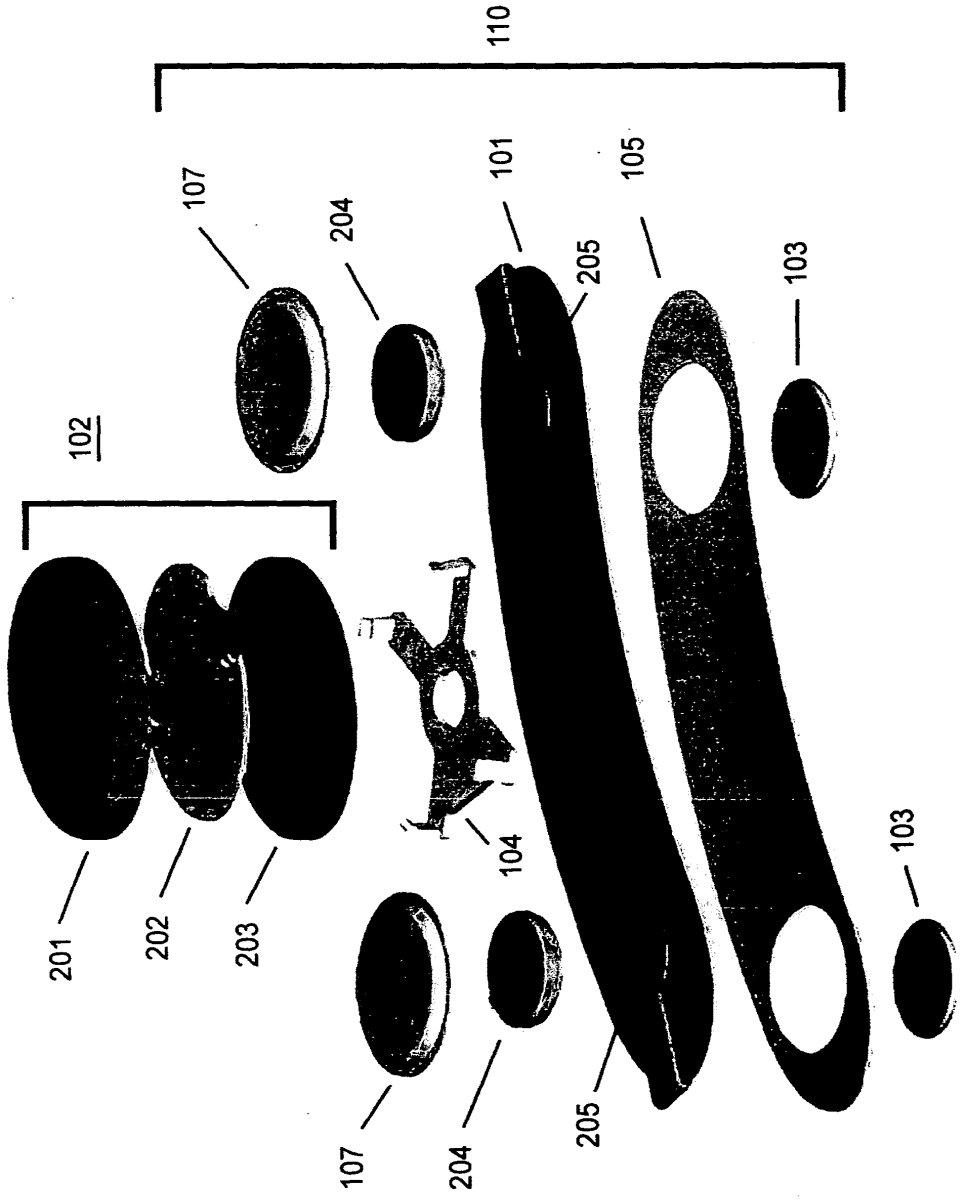


FIG. 2

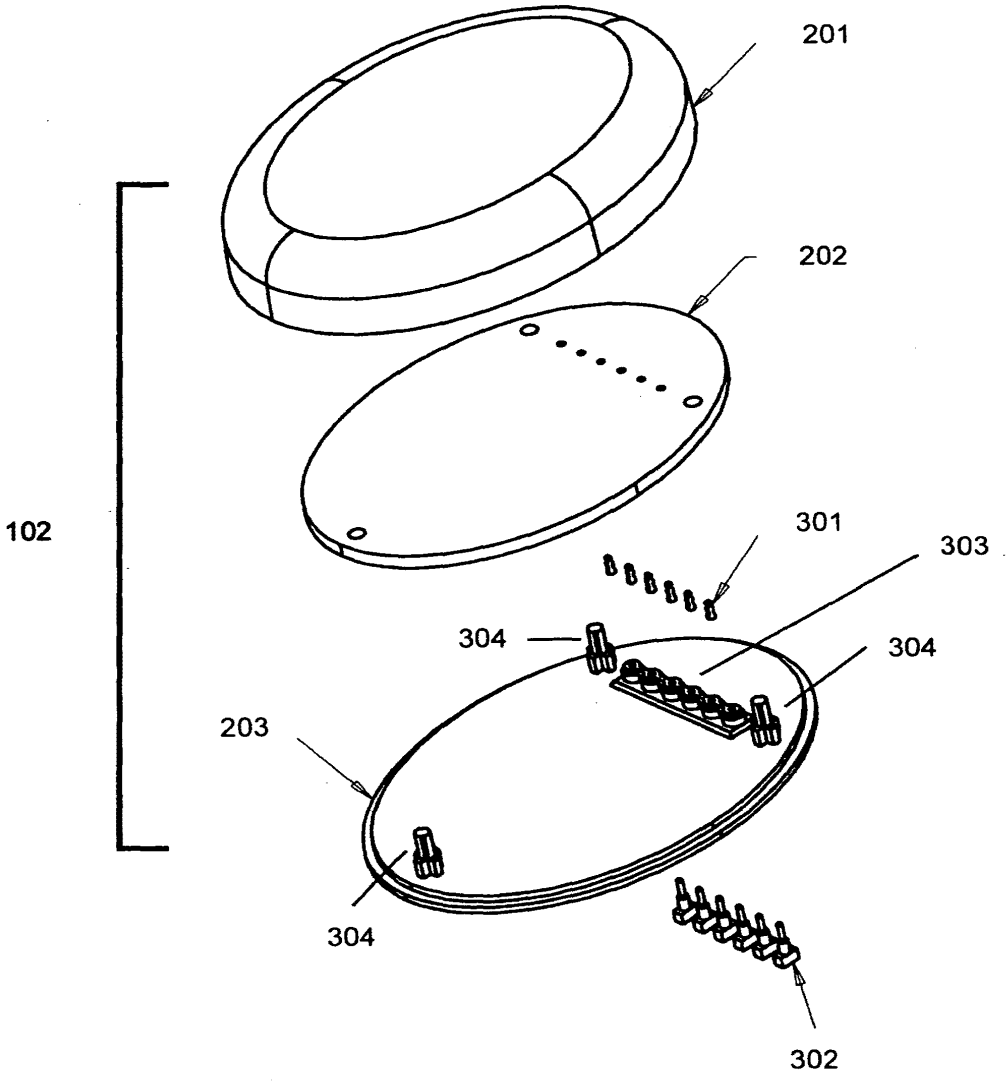


FIG. 3

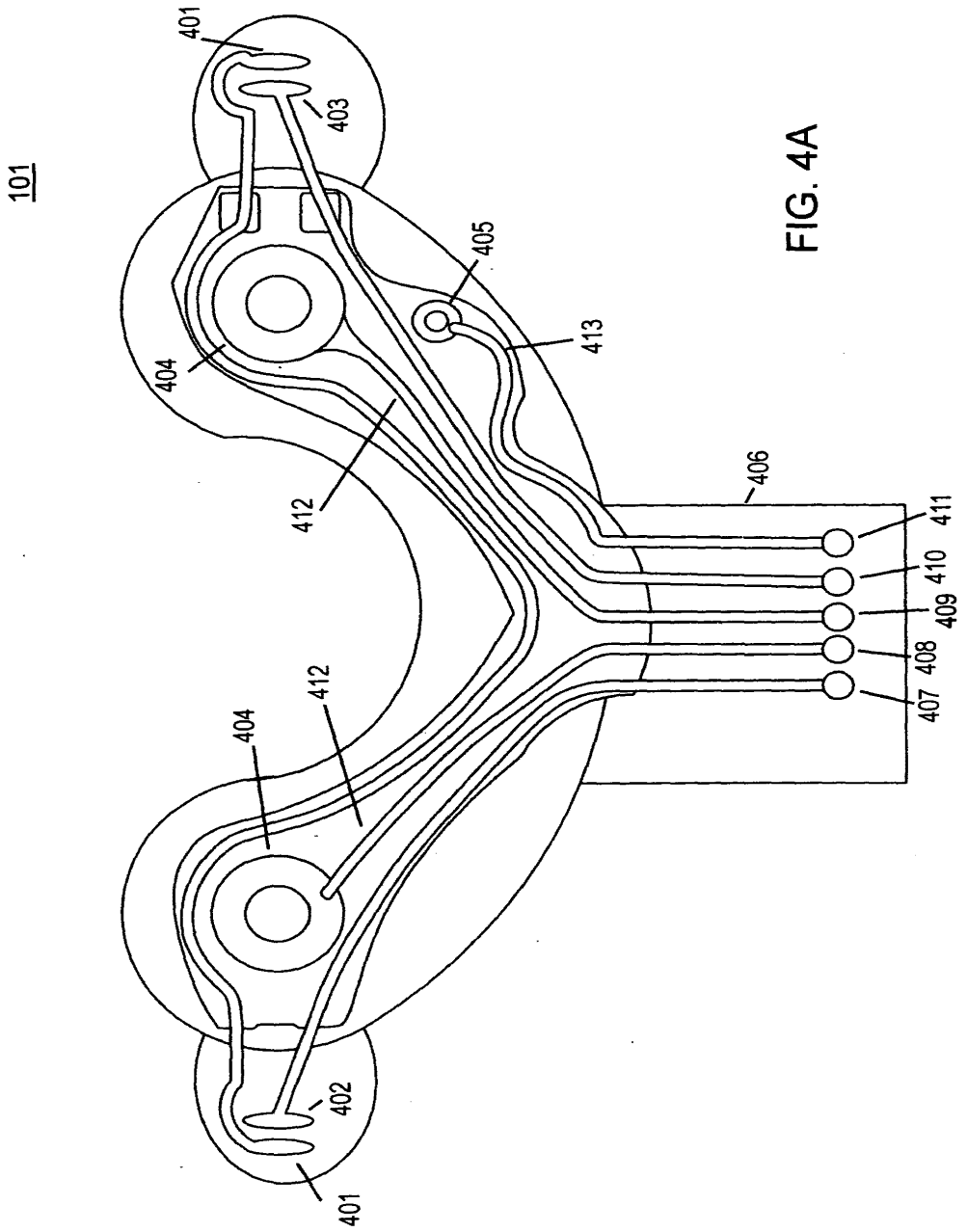

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FIG. 4A

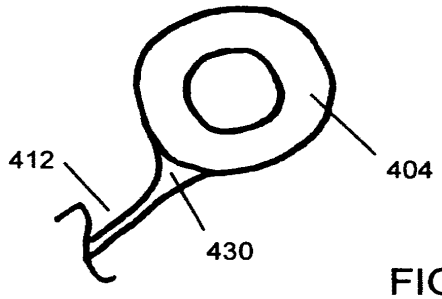


FIG. 4B

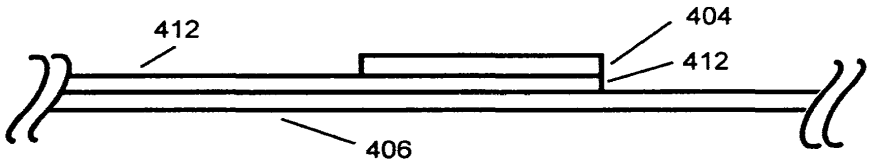


FIG. 4C

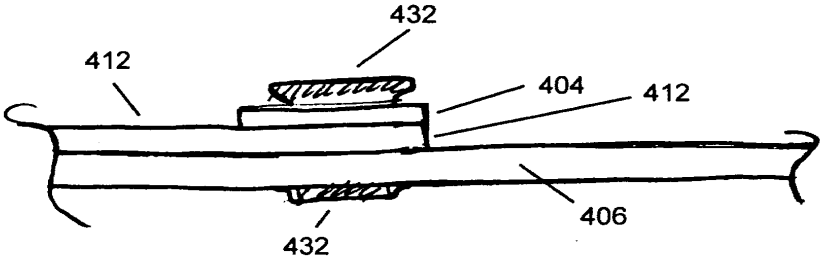


FIG. 4D

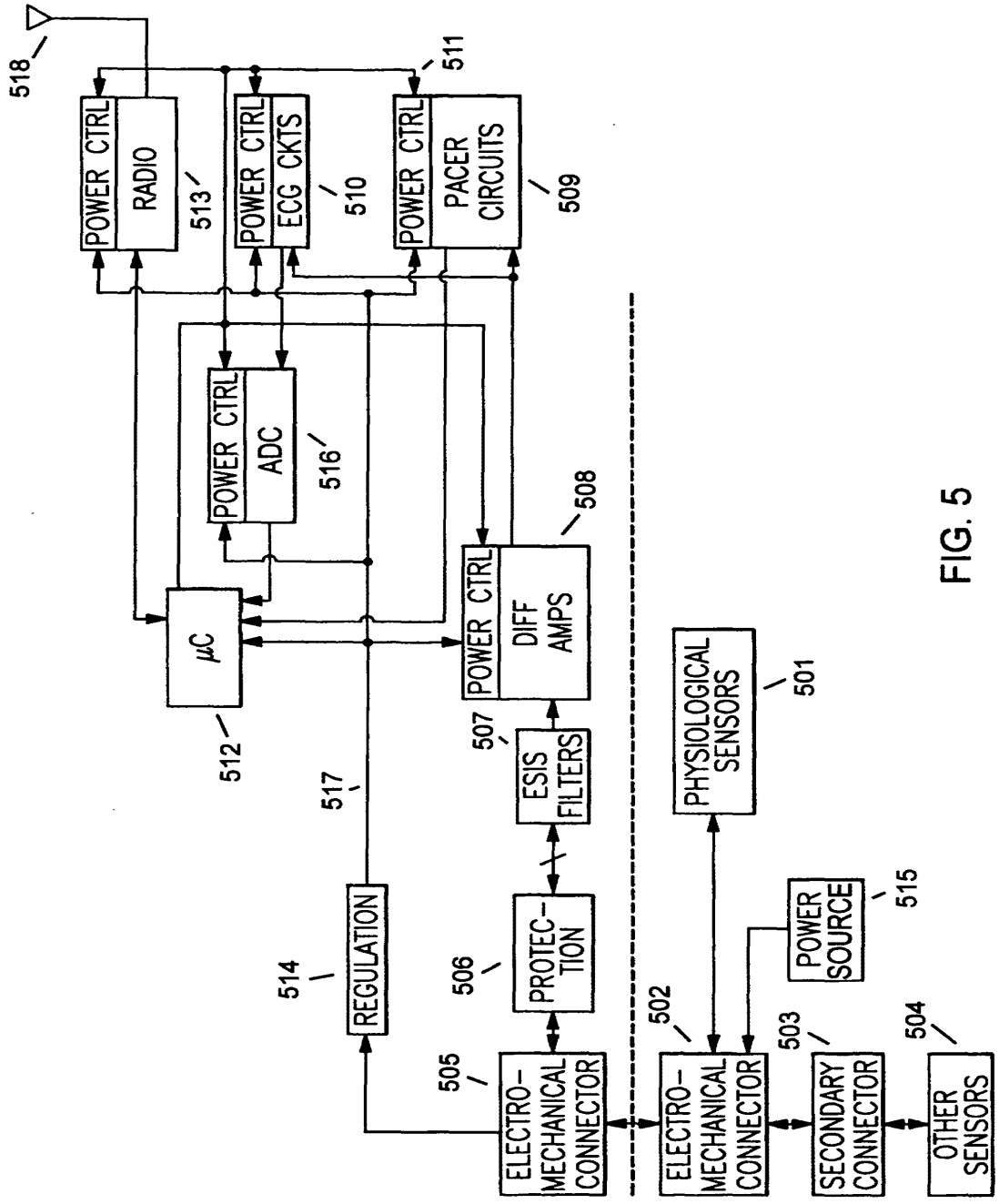

518
POWER CTRL
RADIO
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POWER CTRL
ECG CKTS
510
POWER CTRL
PACER CIRCUITS
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511
POWER CTRL
ADC
516
µC
512
POWER CTRL
DIFF AMPS
508
507
ESIS FILTERS
517
REGULATION
514
PROTEC-TION
506
505
ELECTRO-MECHANICAL CONNECTOR
PHYSIOLOGICAL SENSORS
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POWER SOURCE
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502
ELECTRO-MECHANICAL CONNECTOR
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SECONDARY CONNECTOR
504
OTHER SENSORS

FIG. 5

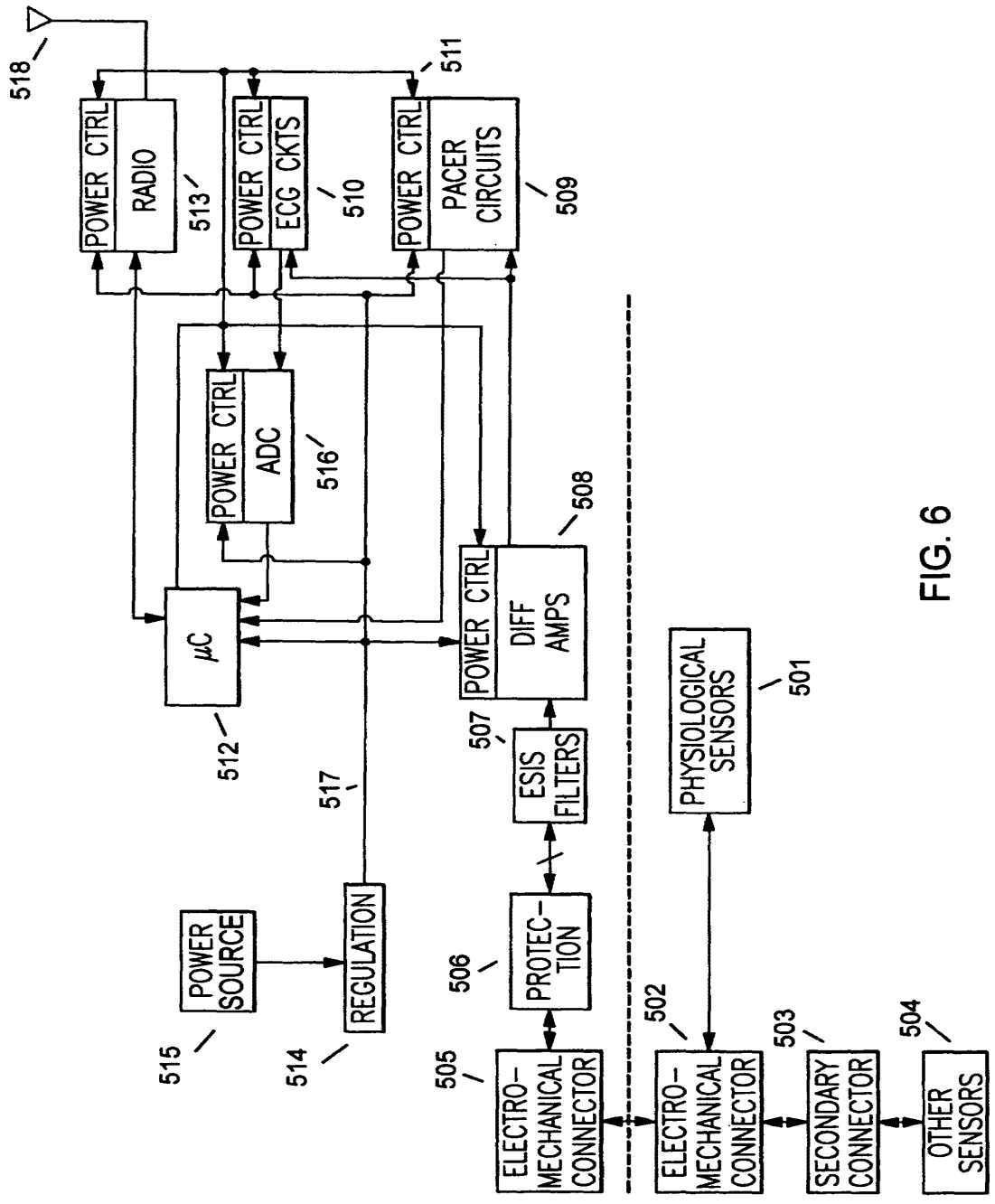

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OTHER SENSORS

FIG. 6

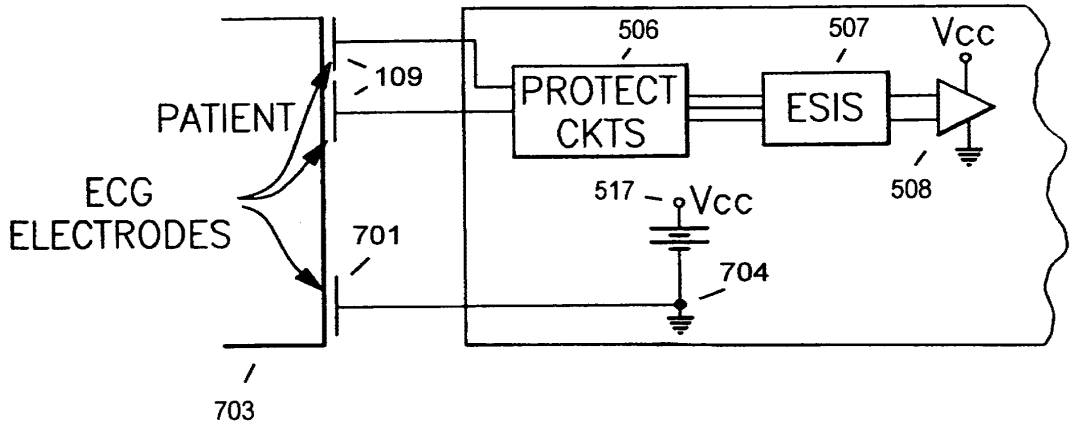

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PROTECT CKTS
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FIG. 7A

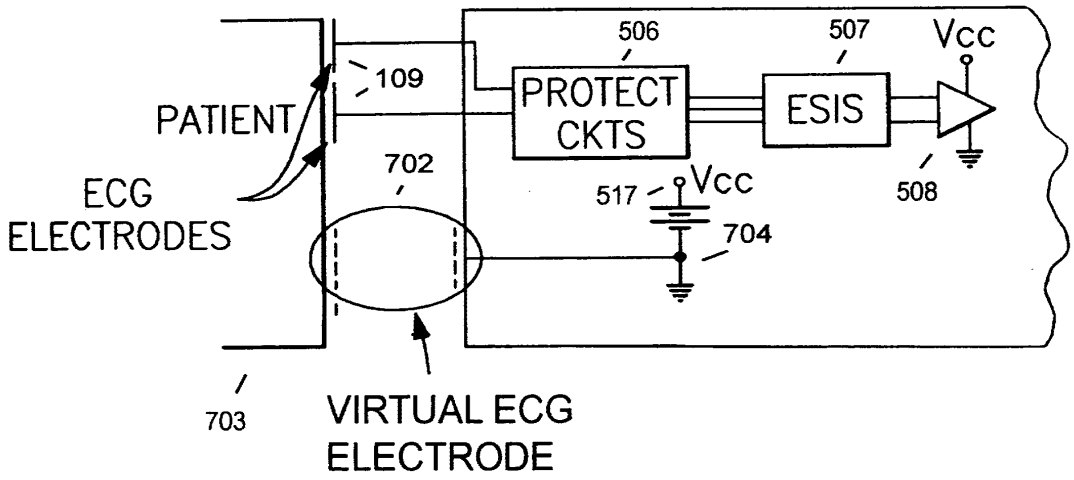

506
507
Vcc
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PROTECT CKTS
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ECG ELECTRODES
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VIRTUAL ECG ELECTRODE

FIG. 7B

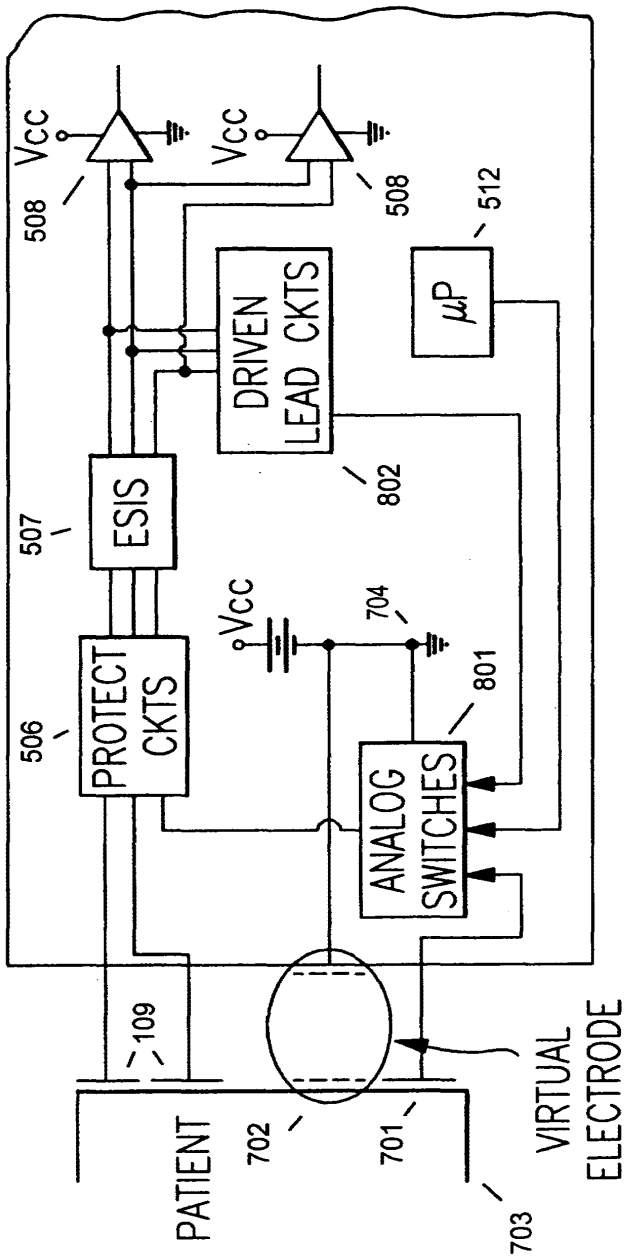

Vcc
Vcc
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508
512
DRIVEN LEAD CKTS
μP
802
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ESIS
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PROTECT CKTS
ANALOG SWITCHES
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PATIENT
702
701
703
VIRTUAL ELECTRODE

FIG. 8

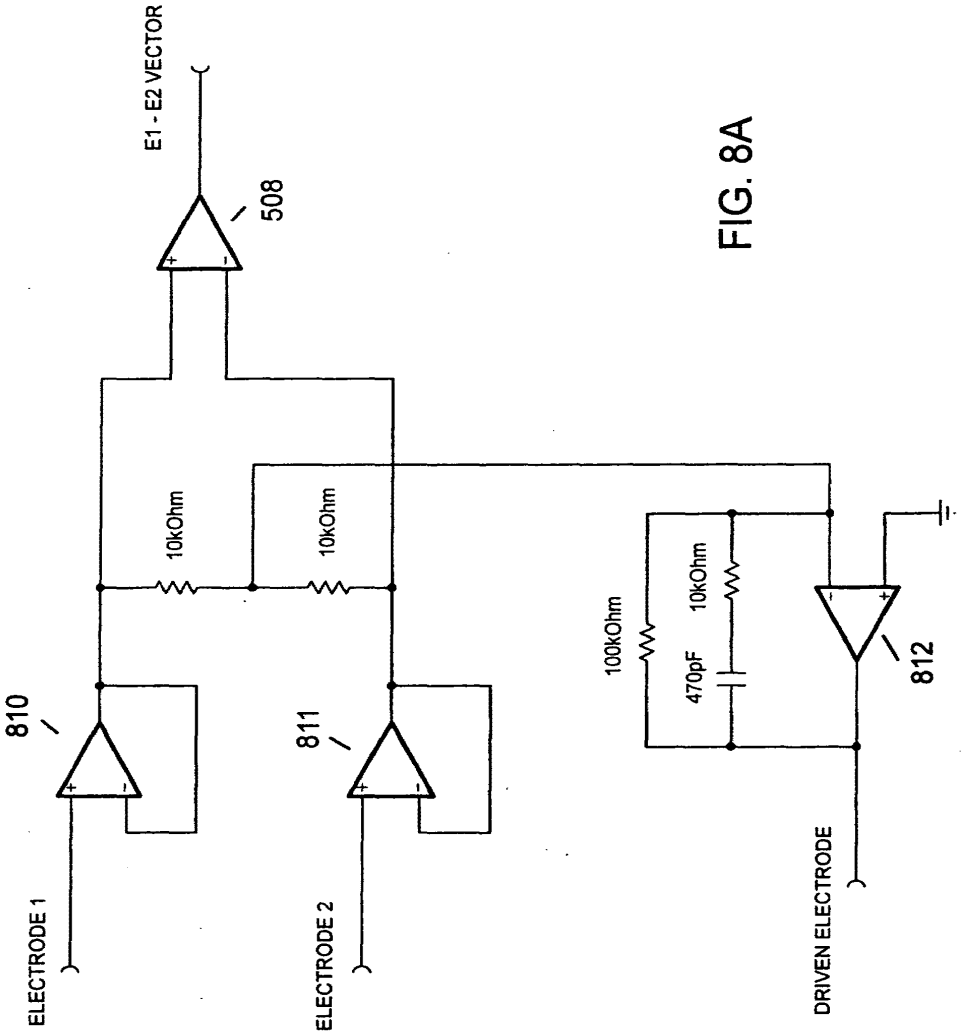

E1 - E2 VECTOR
508
10kOhm
10kOhm
810
811
812
100kOhm
10kOhm
470pF
ELECTRODE 1
ELECTRODE 2
DRIVEN ELECTRODE

FIG. 8A

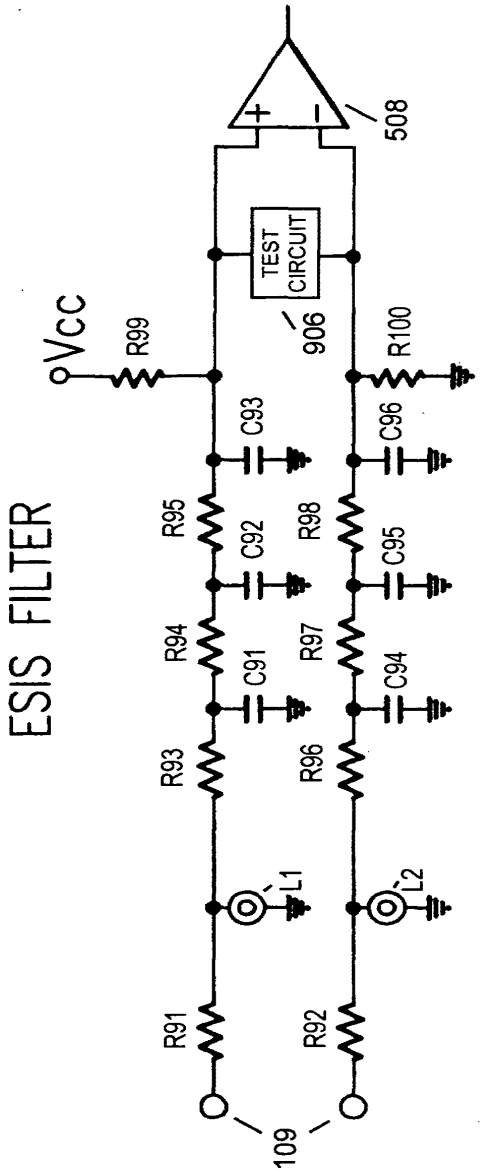

ESIS FILTER
Vcc
R99
R100
TEST CIRCUIT
906
508
C93
C96
R95
C92
R98
C95
R94
C91
R97
C94
R93
R96
L1
L2
R91
R92
109

FIG. 9

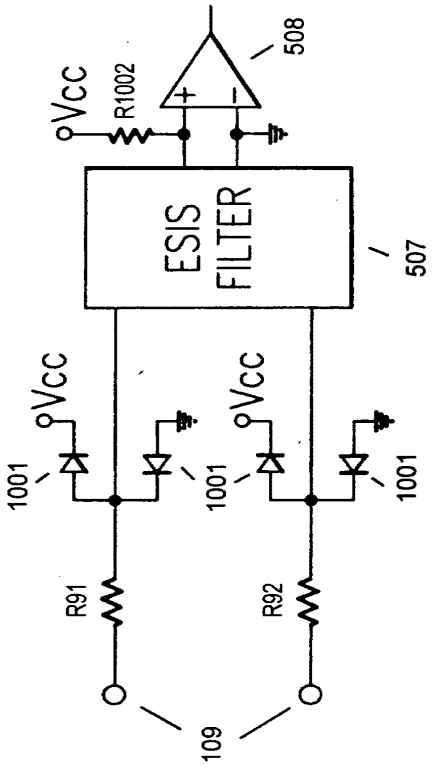

508
Vcc
R1002
+
-
ESIS
FILTER
507
Vcc
Vcc
1001
1001
1001
R91
R92
109

FIG. 10

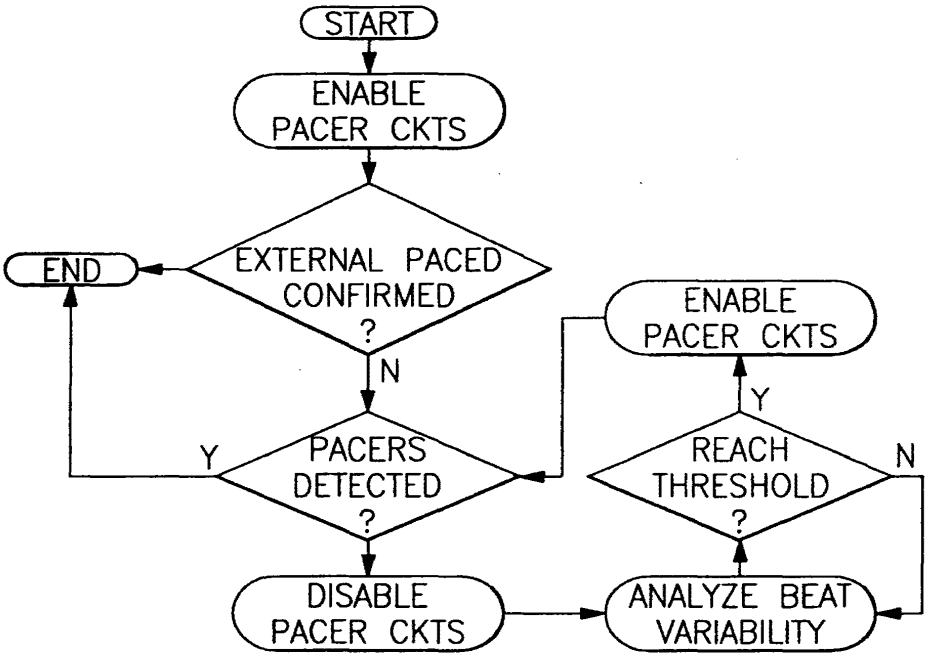

START
ENABLE PACER CKTS
EXTERNAL PACED CONFIRMED ?
END
N
Y
PACERS DETECTED ?
Y
ENABLE PACER CKTS
REACH THRESHOLD ?
N
DISABLE PACER CKTS
ANALYZE BEAT VARIABILITY

FIG. 11

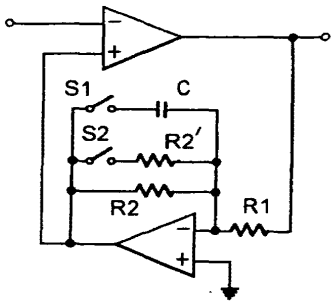

S1
C
S2
R2'
R2
R1

FIG. 12

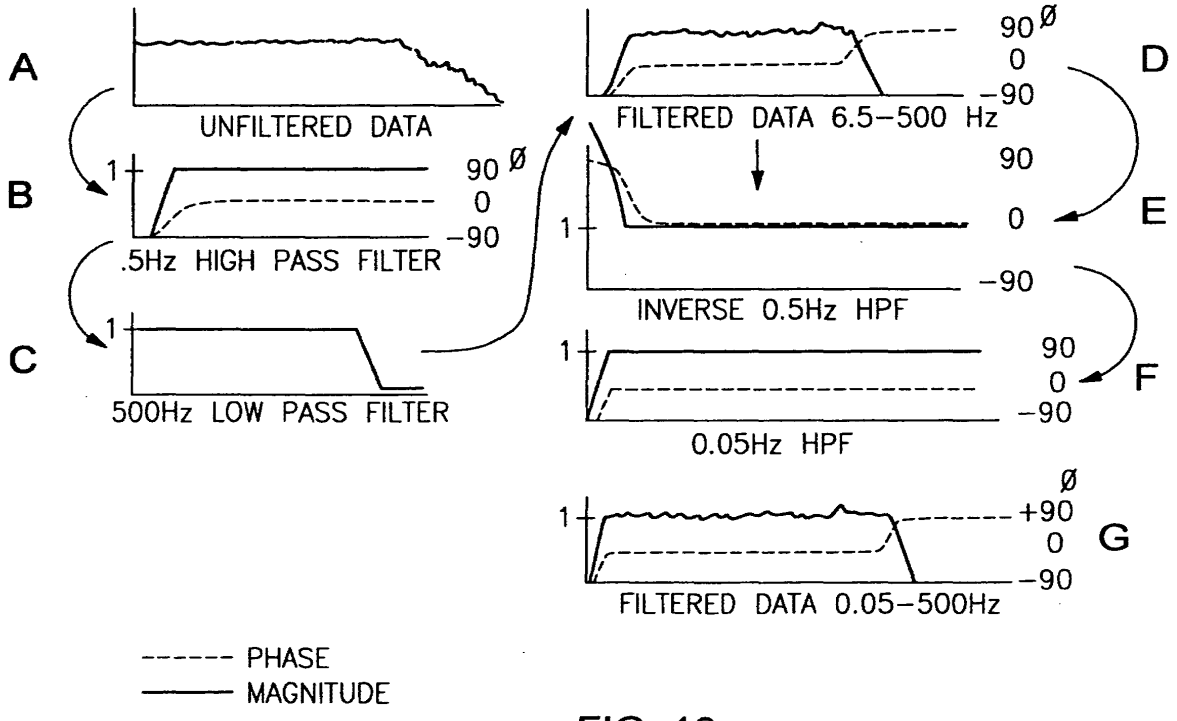

A
UNFILTERED DATA
B
1
90 Ø
0
-90
.5Hz HIGH PASS FILTER
C
1
500Hz LOW PASS FILTER
D
90 Ø
0
-90
FILTERED DATA 6.5-500 Hz
E
90
0
-90
1
INVERSE 0.5Hz HPF
F
1
90
0
-90
0.05Hz HPF
G
1
Ø
+90
0
-90
FILTERED DATA 0.05-500Hz
------ PHASE
——— MAGNITUDE

FIG. 13

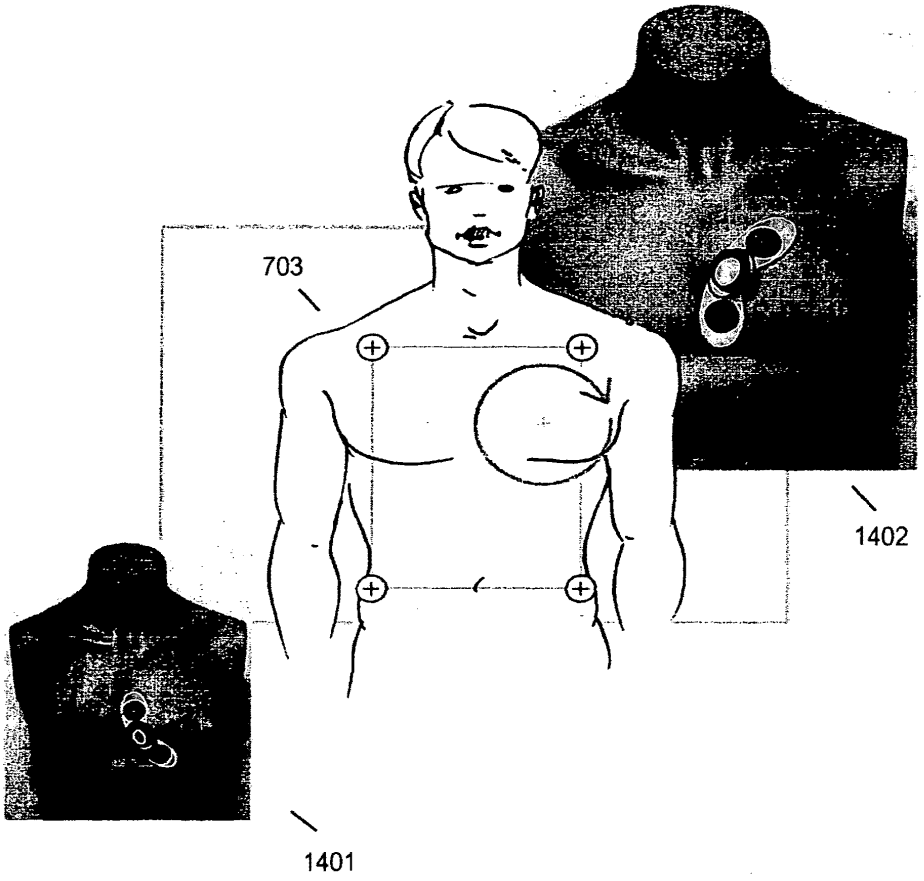


FIG. 14

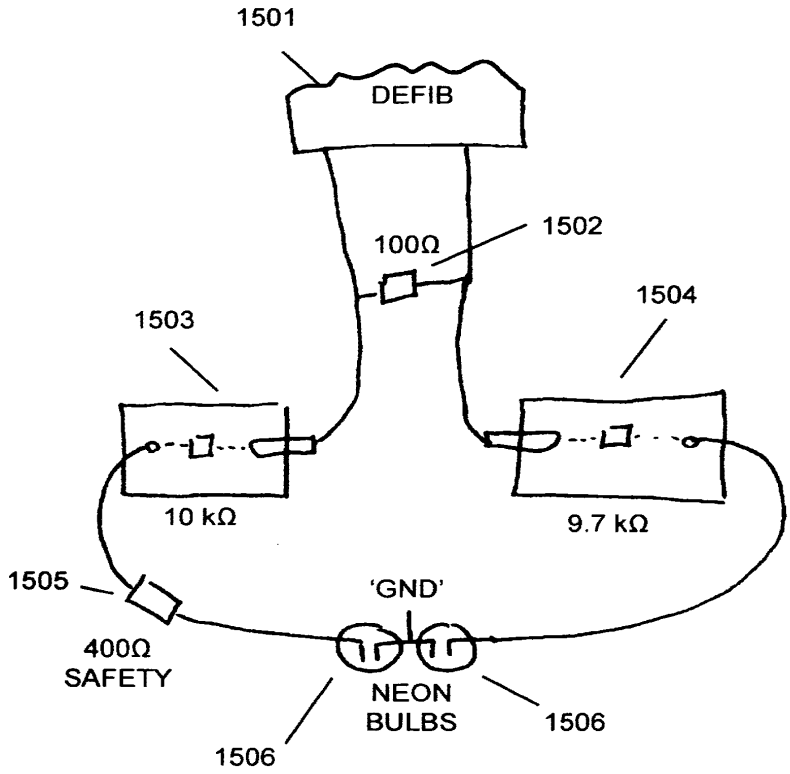

1501
DEFIB
100Ω
1502
1503
1504
10 kΩ
9.7 kΩ
1505
'GND'
400Ω
SAFETY
NEON
BULBS
1506
1506

FIG. 15

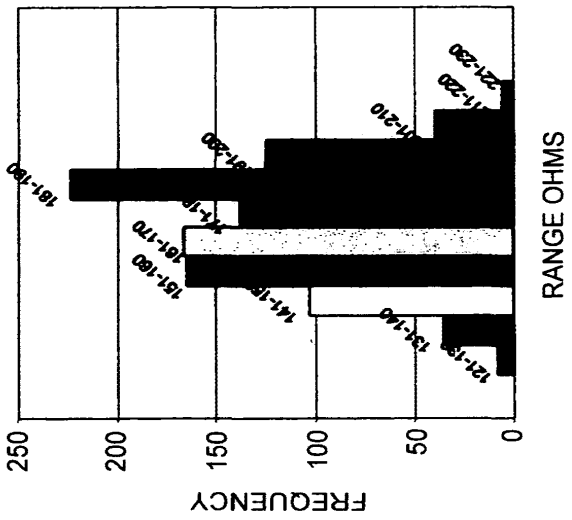


FIG. 16B

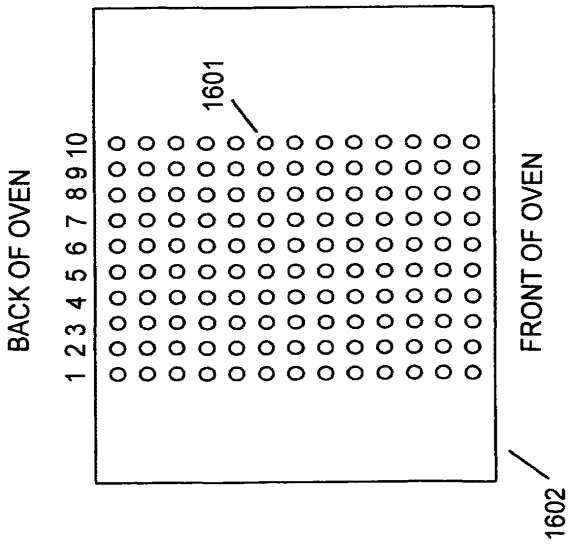


FIG. 16A

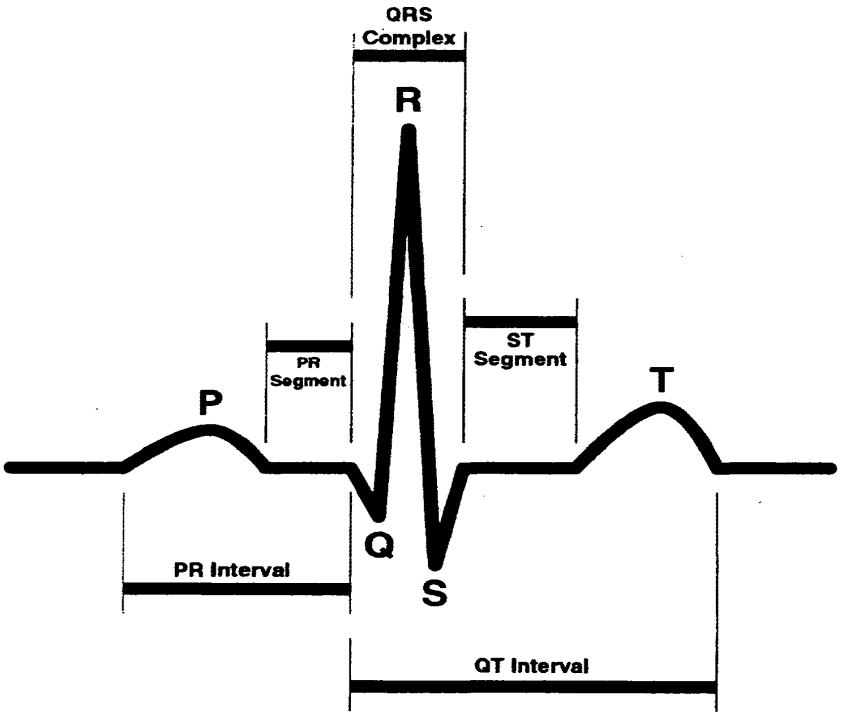

QRS
Complex
R
PR
Segment
ST
Segment
P
T
Q
S
PR Interval
QT Interval

FIG. 17

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PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

11/03/2006 CNGUYEN2 00000059 11591619

01 FC:1011	300.00 OP
02 FC:1111	500.00 OP
03 FC:1311	200.00 OP
04 FC:1202	1900.00 OP
05 FC:1201	600.00 OP

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 460-267/60033

PTO/SB/06 (12-04)
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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875 Effective December 8, 2004

Application or Docket Number: 11591619

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	150.00		N/A	300.00
SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A	$250		N/A	$500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	$100		N/A	$200
TOTAL CLAIMS (37 CFR 1.16(i))	58 minus 20 =	38	X$ 25 =		OR	X$50 =	1900
INDEPENDENT CLAIMS (37 CFR 1.16(h))	6 minus 3 =	3	X100 =		OR	X200 =	600
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			+180=			+360=	
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	2500

APPLICATION AS AMENDED – PART II

1,145,49
54,56,58

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	SMALL ENTITY ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)	OR	RATE ($)	ADDITIONAL FEE ($)
AMENDMENT B	Total (37 CFR 1.16(i))	*	Minus	**	=	X$ 25 =		OR	X$50 =	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X100 =		OR	X200 =	
	Application Size Fee (37 CFR 1.16(s))									
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))					+180=		OR	+360=	
						TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

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*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

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Application Data Sheet

Application Information

Application number::	Not Yet Assigned
Filing Date::	November 1, 2006
Application Type::	Regular
Subject Matter::	Utility
Suggested classification::	
Suggested Group Art Unit::	
CD-ROM or CD-R??::	
Number of CD disks::	
Number of copies of CDs::	
Sequence Submission::	
Computer Readable Form (CRF)?::	
Number of copies of CRF::	
Title::	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
Attorney Docket Number::	704_049
Request for Early Publication::	No
Request for Non-Publication::	No
Suggested Drawing Figure::	1A
Total Drawing Sheets::	18
Small Entity?::	No
Latin name::	
Variety denomination name::	
Petition included?::	No
Petition Type::	
Licensed US Govt. Agency::	
Contract or Grant Numbers One::	
Secrecy Order in Parent Appl.::	No

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 1047

Applicant Information

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	Steven
Middle Name::	D.
Family Name::	Baker
Name Suffix::	
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State or Province of Residence::	OR
Country of Residence::	US
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City of Mailing Address::	Beaverton
State or Province of Mailing Address::	OR
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	97007

Applicant Authority Type::	Inventor
Primary Citizenship Country::	GB
Status::	Full Capacity
Given Name::	Eric
Middle Name::	T.
Family Name::	McAdams
Name Suffix::	
City of Residence::	Whitehead
State or Province of Residence::	Antrim
Country of Residence::	Northern Ireland (UK)
Street of Mailing Address::	52 Cable Road
City of Mailing Address::	Whitehead
State or Province of Mailing Address::	Antrim
Country of Mailing Address::	Northern Ireland (UK)
Postal or Zip Code of Mailing Address::	BT389PZ

Applicant Authority Type::	Inventor
Primary Citizenship Country::	US
Status::	Full Capacity
Given Name::	James
Middle Name::	P.
Family Name::	Welch
Name Suffix::	
City of Residence::	Laguna Niguel
State or Province of Residence::	CA
Country of Residence::	US
Street of Mailing Address::	24446 Kathleen Drive
City of Mailing Address::	Laguna Niguel
State or Province of Mailing Address::	CA
Country of Mailing Address::	US
Postal or Zip Code of Mailing Address::	92677

Correspondence Information

Correspondence Customer Number:: 20874

Representative Information

Representative Customer Number::	20874

Domestic Priority Information

Application::	Continuity Type::	Parent Application::	Parent Filing Date::

Foreign Priority Information

Country::	Application number::	Filing Date::	Priority Claimed::

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 1049

Assignee Information

Assignee Name::	Welch Allyn, Inc.
Street of mailing address::	4341 State Street Road
City of mailing address::	Skaneateles Falls
State or Province of mailing address::	NY
Country of mailing address::	US
Postal or Zip Code of mailing address::	13153