PATENT ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

EPAS ID: PAT5630095

SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	RELEASE OF SECURITY INTEREST

CONVEYING PARTY DATA

Name	Execution Date
FITLINXX, INC.	07/06/2019

RECEIVING PARTY DATA

Name:	LUMIRADX UK LTD
Street Address:	3 MORE LONDON
Internal Address:	RIVERSIDE
City:	LONDON
State/Country:	UNITED KINGDOM
Postal Code:	SE1 2AQ

PROPERTY NUMBERS Total: 30

Property Type	Number
Application Number:	60180915
Patent Number:	7187924
Patent Number:	7466979
Patent Number:	7937121
Patent Number:	8150424
Patent Number:	8606338
Patent Number:	6336365
Patent Number:	8214007
Patent Number:	8630699
Patent Number:	8750974
Patent Number:	8965492
Patent Number:	9155484
Application Number:	14062242
Application Number:	60795763
Application Number:	60813846
Application Number:	13480169
Application Number:	14333601
Application Number:	11799033
Application Number:	61566528

Property Type	Number
Application Number:	13690313
Application Number:	13840098
Application Number:	14184042
Application Number:	14491441
Application Number:	14757584
Application Number:	61602819
Application Number:	14380701
Application Number:	14880413
Application Number:	14880366
Application Number:	14270971
PCT Number:	US1456532

CORRESPONDENCE DATA

Fax Number:

Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.

Phone: 2128598000
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Address Line 1: ONE NEW YORK PLAZA
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ATTORNEY DOCKET NUMBER:	5485-1
NAME OF SUBMITTER:	DANIEL STERN
SIGNATURE:	/Daniel Stern/
DATE SIGNED:	07/22/2019
	This document serves as an Oath/Declaration (37 CFR 1.63).

Total Attachments: 5
source=Lumira-FitLinxx Patent Release_Executed#page1.tif
source=Lumira-FitLinxx Patent Release_Executed#page2.tif
source=Lumira-FitLinxx Patent Release_Executed#page3.tif
source=Lumira-FitLinxx Patent Release_Executed#page4.tif
source=Lumira-FitLinxx Patent Release_Executed#page5.tif

TERMINATION AND RELEASE OF
NOTICE OF GRANT OF SECURITY INTEREST IN PATENTS

WHEREAS, pursuant to that certain Security Agreement dated as of December 1, 2016, between LumiraDx UK Ltd ("**Grantor**") and FitLinxx, Inc. ("**Secured Party**"), Grantor granted to the Secured Party a continuing security interest in and continuing lien upon the patents, patent licenses and patent applications set forth on Schedule 1 attached hereto (such patents, patent licenses and patent applications, the "**IP Collateral**").

WHEREAS, notice of that grant was recorded in the United States Patent and Trademark Office ("**USPTO**") at Reel 041038/0102 on December 20, 2016, as corrected by that certain corrective notice, which was recorded in the USPTO at Reel 043516/0799 on August 10, 2017; and

WHEREAS, Grantor has requested and Secured Party has agreed to provide a document suitable for recording in the USPTO for purposes of recording the release, relinquishment and discharge of its continuing security interest in and continuing lien upon the IP Collateral.

NOW, THEREFORE, in consideration of and in exchange for good and valuable consideration, Secured Party hereby releases, relinquishes and discharges its continuing security interest in and continuing lien upon the IP Collateral.

THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF DELAWARE APPLICABLE TO CONTRACTS MADE AND TO BE PERFORMED IN THE STATE OF DELAWARE WITHOUT REGARD TO CONFLICTS OF LAW PRINCIPLES.

IN WITNESS WHEREOF, the Secured Party has caused this Termination and Release of Notice of Grant of Security Interest in Patents to be duly executed as of July 6, 2019.

Fitlinxx, Inc., as Secured Party

By: _____

Name: David P. Monahan
Title: President and CEO

18327998

SCHEDULE 1

SCHEDULE 1

PATENTS

Country	Patent No./ App No.	Title	Filing Date	Issue Date	
U.S.	60/180,915	Intelligent Data network with power management capabilities	2/8/2000	N/A	
U.S.	7,187,924	Intelligent Data network with power management capabilities	2/8/2001	3/6/2007	
U.S.	7,466,979	Intelligent Data network with power management capabilities	4/11/2006	12/16/2008	
U.S.	7,937,121	Intelligent Data network with power management capabilities	12/5/2008	5/3/2011	
U.S.	8,150,424	Intelligent Data network with power management capabilities	4/11/2011	4/3/2012	
U.S.	8,606,338	Intelligent Data network with power management capabilities	1/17/2012	12/10/2013	
U.S.	14/062,242	Intelligent Data network with power management capabilities	10/24/2013	N/A	
U.S.	6,336,365	Low-cost accelerometer	8/24/1999	1/8/2002	
U.S.	60/795,763	Intelligent Device and Data Network	4/28/2006	N/A	
U.S.	60/813,846	Intelligent Device and Data Network	6/15/2006	N/A	
U.S.	13/480,169	Intelligent Device and Data Network	5/24/2012	N/A	
U.S.	14/333,601	Intelligent Device and Data Network	7/17/2014	N/A	
U.S.	11/799,033	Intelligent Device and Data Network	4/30/2017	N/A	

Country	Patent No./ App No.	Title	Filing Date	Issue Date	
U.S.	61/566,528	Intelligent Activity Monitoring	12/2/2011	N/A	
U.S.	13/690,313	Intelligent Activity Monitor	11/30/2012	N/A	
U.S.	13/840,098	Versatile Sensors with Data Fusion Functionality	3/15/2013	N/A	
U.S.	14/184,042	Versatile Sensors with Data Fusion Functionality	2/19/2014	N/A	
U.S.	14/491,441	Health Monitor	9/19/2014	N/A	
U.S.	14/757,584	Health Monitor	12/23/15	N/A	
U.S.	61/602,819	Intermediate Audio Link and Apparatus for Device-to-Device Communications	2/24/2012	N/A	
U.S.	14/380,701	Intermediate Audio Link and Apparatus for Device-to-Device Communications	8/22/2014	N/A	
U.S.	8,214,007	Body Worn Physiological Sensor Device Having a Disposable Electrode Module	11/1/2006	7/3/2012	
U.S.	8,630,699	Body Worn Physiological Sensor Device Having a Disposable Electrode Module	6/5/2012	1/14/2014	
U.S.	8,750,974	Body Worn Physiological Sensor Device Having a Disposable Electrode Module	12/11/2013	6/10/2014	
U.S.	8,965,492	Body Worn Physiological Sensor Device Having a Disposable Electrode Module	5/2/2014	2/24/2015	
U.S.	9,155,484	Body Worn Physiological Sensor Device Having a Disposable Electrode	1/13/2015	10/15/2015	

Country	Patent No./ App No.	Title	Filing Date	Issue Date	
		Module			
U.S.	14/880,413	Body Worn Physiological Sensor Device Having a Disposable Electrode Module	10/12/2015	N/A	
U.S.	14/880,366	Body Worn Physiological Sensor Device Having a Disposable Electrode Module	10/12/2015	N/A	
U.S.	14/270,971	Clip for Securing a Wearable Item	5/6/2014	N/A	
Europe	14769534.0	Versatile Sensor with Data Fusion Functionality	3/15/2013	N/A	
PCT	PCT/US14/56 532	Versatile Sensor with Data Fusion Functionality	9/19/2014	N/A	

UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	07/03/2012	8214007	3022036 US01	7955

88750 7590 06/13/2012

HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 491 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

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;

Change(s) applied
to document,
/C.L.F./
4/16/2012

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.

[0067]
~~[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.

[0072]
~~[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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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.

[0061]
~~[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.

[0065]
~~[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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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.

[0048]
~~[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.

[0053]
~~[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.

[0058]
~~[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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PTO/SB/08a (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
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

Change(s) applied to document
/R.M.L./
4/17/2012

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
	A	US- 5,319,363	06-07-1994	Welch et al.	
	B	US- 5,579,001	11-26-1996	Dempsey et al.	
	C	US- 5,579,775	12-03-1996	Dempsey et al.	
	D	US- 5,682,803	11-04-1997	~~Gideon et al.~~ Boianjiu	
	E	US- 5,687,734	11-18-1997	Dempsey et al.	
	F	US- 5,748,103	05-05-1998	Flach et al.	
	G	US- 5,767,791	06-16-1998	Stoop, et al.	
	H	US- 5,917,414 A	06-29-1999	Oppelt et al.	
	I	US- 6,057,758 A	05-02-2000	Dempsey et al.	
	J	US- 6,198,394 B1	03-06-2001	Jacobsen et al.	
	K	US- 6,440,067 B1	08-27-2002	DeLuca et al.	
	L	US- 6,544,171 B2	04-08-2003	Beetz et al.	
	M	US- 6,544,173	04-08-2003	West et al.	
	N	US- 6,544,174	04-08-2003	West et al.	
	O	US- 6,579,231 B1	06-17-2003	Phipps	
	P	US- 6,847,892 B2	~~06-02-2002~~ 01-2005	Zhou et al.	
	Q	US- 6,870,484 B1	03-22-2005	Brinsfield et al.	
	R	US- 7,382,247 B2	06-03-2008	Welch et al.	
	S	US- 7,439,856 B2	10-21-2008	Weiner et al.	

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	03/07/2012

*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, 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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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L./

Customer No.: 88750

FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US01	Application Number: 11/591,619
	Applicant: Steven D. Baker et al.	Confirmation No.: 7955
	Filing Date: November 1, 2006	Group Art Unit: 3762

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,515,735	5/14/1996	Sarihan			
	5,600,071	2/4/1997	Sooriakumar et al.			
	5,808,331	9/15/1998	Zhang et al.			
	5,889,211	3/30/1999	Maudie et al.			
	~~6,016,933~~	1/11/2000	Foerstner et al.		6013933	
	6,089,692	7/18/2000	Anagnostopoulos			
	6,212,944	4/10/2001	Kwun et al.			
	6,331,444	12/18/2001	Ferrari et al.			
	6,448,621	9/10/2002	Thakur			
	6,586,810	7/1/2003	Thakur			
	2004/0252031	12/16/2004	Taylor			
	6,911,727	6/28/2005	Martin et al.			
	2005/0216334	9/29/2005	Mehrabani-Farsi			
	2007/0293781	12/20/2007	Sims et al.			
	7,318,417	1/15/2008	Lang et al.			
	2009/0043185	2/12/2009	McAdams et al.			
	7,508,064	3/24/2009	Martin et al.			
	2009/0131759	5/21/2009	Sims et al.			
	7,563,632	7/21/2009	Martin et al.			
	2010/0145202	6/10/2010	McLaughlin et al.			
	2010/0160762	6/24/2010	McLaughlin et al.			
	2010/0324390	12/23/2010	McLaughlin et al.			

Change(s) applied to document, /R.M.L./ 4/17/2012

EXAMINER	/Nicole LaVert/	DATE CONSIDERED	03/07/2012

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 for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L./

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	3022036 US01	7955

TITLE OF INVENTION:

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1740	$300	$0	$2040	06/12/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Sonny Z. Zhan
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: WELCH ALLYN, INC.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): SKANEATELES FALLS, NY

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☑ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☑ Issue Fee
- ☑ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ☐ A check is enclosed.
- ☑ Payment by credit card. Form PTO-2038 is attached.
- ☑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 50-4979 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Sonny Z. Zhan/ Date 2012-06-05

Typed or printed name Sonny Z. Zhan Registration No. 62936

This collection of information is required by 37 CFR 1.311. 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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:	Sonny Zhiyu Zhan/Renee M. Boronka
Attorney Docket Number:	3022036 US01

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:				
Utility Appl issue fee	1501	1	1740	1740
Publ. Fee- early, voluntary, or normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2040**

Electronic Acknowledgement Receipt	
EFS ID:	12936132
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:	88750
Filer:	Sonny Zhiyu Zhan/Renee M. Boronka
Filer Authorized By:	Sonny Zhiyu Zhan
Attorney Docket Number:	3022036 US01
Receipt Date:	05-JUN-2012
Filing Date:	01-NOV-2006
Time Stamp:	13:28:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$2040
RAM confirmation Number	11254
Deposit Account	504979
Authorized User	ZHAN,SONNY
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	2012-06-06--Issue-Fee-Payment.pdf	87302 2372d5f6c9be599e7074659e6b4662f3a8b9a5e6	no	2
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	32179 cf579afdaa7cd1d66d50255b00c0d267c22775fe	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	119481		

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.

<u>New Applications Under 35 U.S.C. 111</u>
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.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
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.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
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.

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

NOTICE OF ALLOWANCE AND FEE(S) DUE

88750 7590 03/12/2012

HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 03/12/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	3022036 US01	7955

TITLE OF INVENTION: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1740	$300	$0	$2040	06/12/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 02/11)

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

88750 7590 03/12/2012
HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	3022036 US01	7955

TITLE OF INVENTION: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1740	$300	$0	$2040	06/12/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
LAVERT, NICOLE F	3762	600-509000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:
- ❑ Issue Fee
- ❑ Publication Fee (No small entity discount permitted)
- ❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**
- ❑ A check is enclosed.
- ❑ Payment by credit card. Form PTO-2038 is attached.
- ❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
- ❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.
- ❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 21

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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	3022036 US01	7955

88750 7590 03/12/2012

HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 03/12/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 491 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 491 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

PTOL-85 (Rev. 02/11)

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 22

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The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 11/591,619	Applicant(s) BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	

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

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the arguments submitted on April 18, 2011*.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are *1-6,8-39,41-44 and 59-61*.

4. ☐ 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 the:
      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)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date See Continuation Sheet
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Continuation of Attachment(s) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date: 5/25/11, 2/2/10, 12/29/09, 10/20/09, 6/3/08, 2/16/07.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 25

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 25, 2011 has been entered.

EXAMINER'S AMENDMENT/EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows: Claims 45-58 are cancelled

EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: The closest prior art, Stivoric in view of Fadem et al., Potts et al., Welch et al., and Merry et al., fails to disclose the claimed invention, neither in combination nor alone, since neither reference discloses a body

worn patient monitoring device comprising a disposable module including at least one series current-limiting resistor being in the form of resistive traces (e.g., see 'Arguments' pp 2).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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, Niketa Patel can be reached on 571-272-4156. 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.

/NICOLE F. LAVERT/

Examiner, Art Unit 3762

Customer No.: 88750

FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US01	Application Number: 11/591,619
	Applicant: Steven D. Baker et al.	Confirmation No.: 7955
	Filing Date: November 1, 2006	Group Art Unit: 3762

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,515,735	5/14/1996	Sarihan			
	5,600,071	2/4/1997	Sooriakumar et al.			
	5,808,331	9/15/1998	Zhang et al.			
	5,889,211	3/30/1999	Maudie et al.			
	6,016,933	1/11/2000	Foerstner et al.			
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	6,212,944	4/10/2001	Kwun et al.			
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	7,563,632	7/21/2009	Martin et al.			
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	2010/0160762	6/24/2010	McLaughlin et al.			
	2010/0324390	12/23/2010	McLaughlin et al.			

EXAMINER	/Nicole LaVert/	DATE CONSIDERED	03/07/2012

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 for next communication to the Applicant.

*Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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	Applicant: Steven D. Baker et al.	Confirmation No.: 7955
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FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 2008/142365	11/27/2008	WO				
	WO 2009/056859	5/7/2009	WO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		

EXAMINER /Nicole LaVert/	DATE CONSIDERED 03/07/2012

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PTO/SB/08a (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known	
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

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
	A	US- 5,319,363	06-07-1994	Welch et al.	
	B	US- 5,579,001	11-26-1996	Dempsey et al.	
	C	US- 5,579,775	12-03-1996	Dempsey et al.	
	D	US- 5,682,803	11-04-1997	Gideon et al.	
	E	US- 5,687,734	11-18-1997	Dempsey et al.	
	F	US- 5,748,103	05-05-1998	Flach et al.	
	G	US- 5,767,791	06-16-1998	Stoop, et al.	
	H	US- 5,917,414 A	06-29-1999	Oppelt et al.	
	I	US- 6,057,758 A	05-02-2000	Dempsey et al.	
	J	US- 6,198,394 B1	03-06-2001	Jacobsen et al.	
	K	US- 6,440,067 B1	08-27-2002	DeLuca et al.	
	L	US- 6,544,171 B2	04-08-2003	Beetz et al.	
	M	US- 6,544,173	04-08-2003	West et al.	
	N	US- 6,544,174	04-08-2003	West et al.	
	O	US- 6,579,231 B1	06-17-2003	Phipps	
	P	US- 6,847,892 B2	06-02-2002	Zhou et al.	
	Q	US- 6,870,484 B1	03-22-2005	Brinsfield et al.	
	R	US- 7,382,247 B2	06-03-2008	Welch et al.	
	S	US- 7,439,856 B2	10-21-2008	Weiner et al.	

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	03/07/2012

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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, 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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
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

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
	T	US- 7,515,043 B2	04-07-2009	Welch et al.	
	U	US- 7,515,044 B2	04-07-2009	Welch et al.	
	V	US- 2001/0023315 A1	09-20-2001	Flach et al.	
	W	US- 2005/0116820 A1	06-02-2005	Goldreich	
	X	US- 2005/0206518 A1	09-22-2005	Welch et al.	
	Y	US- 2006/0238333 A1	10-26-2006	Welch et al.	
	Z	US- 2007/0013511 A1	01-18-2007	Weiner et al.	
	AA	US- 2007/0069887 A1	03-29-2007	Welch et al.	
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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]
	BB	WO 01/89362 A2 and A3	11-29-2001	West et al.		
	CC	WO 01/97686 A1	12-27-2001	Voegeli et al.		

Examiner Signature	/Nicole LaVert/	Date Considered	03/07/2012

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1454	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/03/07 11:22
L2	637	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/03/07 11:32
L3	2475	600/509.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/03/07 11:37
L4	317	600/382.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/03/07 11:47
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S3	1	S2 and "407"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 12:39

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iRhythm, Inc. / Welch Allyn, Inc.
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S52	6084	S51 and medical	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
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S54	148	S53 and modular	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
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S59	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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S60	0	"20040176818" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:08
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S62	1241	S61 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S63	231	"I120" and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S64	102	S63 and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S65	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
S66	84	S65 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
S67	1	"11591619" and (indirect same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26

S68	1	"11591619" and (indirect same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26
S69	1	"11591619" and (direct same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:28
S70	1	"20070270678" and "30"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
S71	1	"20070270678" and strip	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
S72	0	"20070270678" and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
S73	2	"20060074284"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
S74	2	"20070270678" and substrate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:05
S75	15	"6064901"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:08

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S76	0	S75 and resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:12
S77	145267	(current same limit$4) and electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S78	1311	S77 and (disposable same electrode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S79	116	S78 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S80	10	S79 and ((current same limit$4) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:14
S81	1	"11591619" and annulus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:20
S82	0	"11591619" and Seebeek	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:22
S83	1	"11591619" and Seebeck	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:23

S84	2	"20060183434"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:40
S85	9	"6623312"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:46
S86	1	"11591619" and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:20
S87	0	"20070270678" and caridac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S88	0	"20070270678" and cardiac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S89	1	"20070270678" and heart	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S90	1	"11591619" and (pacer same detection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:30
S91	743453	external same device	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33

S92	5324	S91 and wearable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S93	3581	S92 and (wearable same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S94	1128	S93 and (cardiac or heart)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S95	101	S94 and (detect$4 same (cardiac same event))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:34
S96	3	"20060238333"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:45
S97	5	"2004084720"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S98	0	"2004084720" and (high same voltage)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S99	0	"2004084720" and (circuit same protection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13

S100	0	"2004084720" and diodes	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:15
S101	1	"2004084720" and detect$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:15
S102	0	"2004008738" and (pacer same detect$)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:43
S103	687	(pacer same detection) same circuit	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:46
S104	360	S103 and (external same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:46
S105	219	S104 and @py<="2005"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:47
S106	107019	(patient same monitor $4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:06
S107	11349	S106 and (wear$4 or garment or clothing)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:06

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S108	5925	S107 and dispos$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
S109	2609	S108 and (power same source)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
S110	2165	S109 and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
S111	244	S110 and (physiological same analysis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:08
S112	2	"20020106709"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:36
S113	2	"20050245839"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:44
S114	1	"11591619" and (communication same module)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:09
S115	1	"20050245839" and wireless	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:13

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S116	1	"20050245839" and microprocessor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:14
S117	1	"11591619" and (disposable same connector)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:14
S118	1	"11591619" and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:17
S119	231	"20050245839" andconductive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:21
S120	1	"20050245839" and conductive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:21
S121	1102	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:25
S122	533	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:51
S123	262	600/382.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 13:10

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S124	1	"20020106709" and (real same time)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 13:24
S125	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 17:45
S126	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 18:09
S127	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 22:03
S128	1275	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/17 12:45
S129	571	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/17 16:30
S130	2101	resistor same (trac$4 same substrate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:24
S131	36	S130 and (medical same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:24

S132	19	S131 and @py<="2006"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:25
S133	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:28
S134	1	S133 and trac$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:28

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L5	648	607/60.ccls.	USPAT; UPAD	OR	OFF	2012/03/07 11:50
L6	1210	600/509.ccls.	USPAT; UPAD	OR	OFF	2012/03/07 11:55
L7	419	600/372.ccls.	USPAT; UPAD	OR	OFF	2012/03/07 11:58
L8	221	600/382.ccls.	USPAT; UPAD	OR	OFF	2012/03/07 12:01

3/7/2012 12:01:52 PM
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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	11591619	BAKER ET AL.
	Examiner	**Art Unit**
	NICOLE F LAVERT	3762

ORIGINAL		INTERNATIONAL CLASSIFICATION	
CLASS	SUBCLASS	CLAIMED	NON-CLAIMED
600	372	A 6 1 N 1 / 00 (2006.01.01)	
		A 6 1 B 5 / 04 (2006.01.01)	

CROSS REFERENCE(S)					
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
607	60				
600	382	509			

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	18	33	34										
2	2	18	19	34	35										
3	3	19	20	35	36										
4	4	20	21	36	37										
5	5	21	22	37	38										
6	6	22	23	38	39										
7	8	23	24	39	41										
8	9	24	25	40	42										
9	10	25	26	41	43										
10	11	26	27	42	44										
11	12	27	28	45	59										
12	13	28	29	43	60										
13	14	29	30	44	61										
14	15	30	31												
15	16	31	32												
16	17	32	33												

NONE	3/7/12	**Total Claims Allowed:** 45	
(Assistant Examiner)	(Date)		
/NICOLE F LAVERT/ Examiner.Art Unit 3762	3/7/12	O.G. Print Claim(s) 1	O.G. Print Figure 1a
(Primary Examiner)	(Date)		

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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
ABOVE	UPDATED	7/7/2009	NFL
" "	" "	3/3/2010	NFL
" "	" "	9/7/2010	NFL
ABOVE	UPDATED	2/17/2011	NFL
ABOVE	UPDATED	3/7/2012	NFL
600	509	3/7/2012	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
Searched all classes and subclasses from the 'Searched' notes	Searched the USPGPUB, USPAT, USOCR, EPO, JPO, DERWENT. etc. databases	3/7/2012	NFL

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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
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 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
		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]
	BA	JP 11-088546	03-30-1999	NEC Corp.		

Examiner Signature	/Nicole LaVert/	Date Considered	03/07/2012

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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, 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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
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	704_049/054 (3022036 US01)

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]
	CA	Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2006-507455 (5 pages).	

Examiner Signature	/Nicole LaVert/	Date Considered	03/07/2012

*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.

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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
	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	
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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	03/07/2012

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	11591619
Filing Date	2006-11-01
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US01

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	1	20040252031		2004-12-16	Taylor	
	2	20090043185		2009-02-12	McAdams et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11591619
	Filing Date	2006-11-01
	First Named Inventor	Steven D. Baker
	Art Unit	3762
	Examiner Name	Nicole F. Lavert
	Attorney Docket Number	3022036 US01

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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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):
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☐ 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

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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.

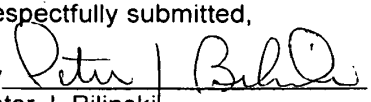
This Information Disclosure Statement is filed before the mailing date of a first Office Action on the merits as far as is known to the undersigned (37 CFR 1.97(b)(3)). Therefore, it is believed no fee is required.

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
MARJAMA & BILINSKI LLP
250 South Clinton Street
Suite 300
Syracuse, New York 13202
(315) 425-9000
Customer No. 20874

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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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
	AA	US-2003-0149349A1	08/07/2003	Jensen	
	AB	US-4,791,933	12/20/1988	Asai et al.	
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	AK1	US-6,794,990B2	09/21/2004	Tseng	

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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.		

Examiner Signature	/Nicole LaVert/	Date Considered	03/07/2012

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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

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

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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	3022036 US01

APPLICANTS

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;

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

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

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11/21/2006

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

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HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202
UNITED STATES

TITLE

Body worn physiological sensor device having a disposable electrode module

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FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US01	Application Number: 11/591,619
	Applicant: Steven D. Baker et al.	Confirmation No.: 7955
	Filing Date: November 1, 2006	Group Art Unit: 3762

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,515,735	5/14/1996	Sarihan			
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FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US01	Application Number: 11/591,619
	Applicant: Steven D. Baker et al.	Confirmation No.: 7955
	Filing Date: November 1, 2006	Group Art Unit: 3762

FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	WO 2008/142365	11/27/2008	WO				
	WO 2009/056859	5/7/2009	WO				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
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(43) International Publication Date
27 November 2008 (27.11.2008)

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(10) International Publication Number
WO 2008/142365 A1

(51) International Patent Classification:
A61B 5/0408 (2006.01) *A61B 5/0416* (2006.01)

(21) International Application Number:
PCT/GB2008/001492

(22) International Filing Date: 30 April 2008 (30.04.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0709531.8 18 May 2007 (18.05.2007) GB

(71) Applicant *(for all designated States except US)*: **SENSOR TECHNOLOGY & DEVICES LIMITED** [GB/GB]; 4 Heron Road, Belfast BT3 9LE (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MCLAUGHLIN, James, Andrew** [GB/GB]; 49 North Parade, Belfast BT7 2GH (GB). **ANDERSON, John, McCune** [GB/GB]; 16 Torrgrange, Hollywood BT18 0NG (GB). **SKILLEN, Michael** [GB/GB]; 71 Bleerick Drive, Greystone, Co. Antrim BT41 1HX (GB).

(74) Agent: **MURGITROYD & COMPANY**; 165-169 Scotland Street, Glasgow G5 8PL (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(54) Title: SENSORS

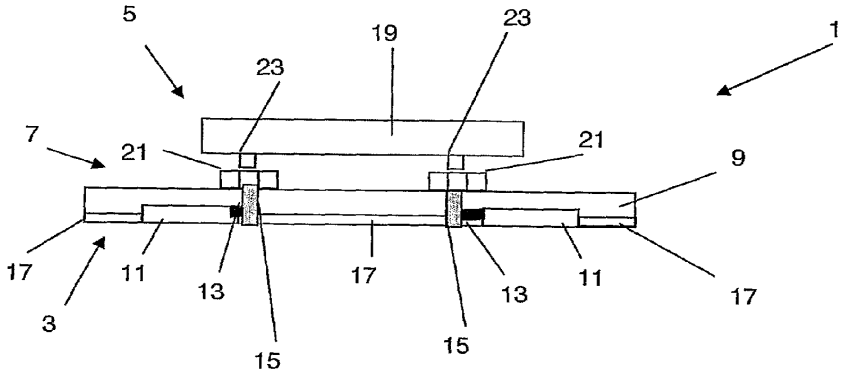


Fig. 1

(57) Abstract: A two-part sensor (1) comprising a first part comprising a sensing device (3) which senses information, a second part comprising a receiving device (5) which receives a measure of the information, and a connector (7) comprising at least one first portion (21) which is magnetic and is attached to one of the sensing device and the receiving device, and at least one second portion (23) which is magnetisable and is attached to an other of the sensing device and the receiving device, wherein the first portion and the second portion are connectable and disconnectable to connect and disconnect the sensing device and the receiving device.

WO 2008/142365 A1

Sensors

The invention relates to two-part sensors, and particularly, but not exclusively, to sensors for sensing electrical signals, for example ECG electrical signals or electrical signals produced as a result of blood flow through an artery.

A wide range of sensors exist, particularly for ECG measurement. One such sensor which is commonly used, comprises a plurality of electrodes for sensing ECG signals, a receiver for receiving the ECG signals, and a connector between each electrode and the receiver. The electrodes are typically attached to a plurality of locations of the chest of a user of the sensor. The receiver may be a unit located in the proximity of the user, or may be attached to a strap and worn around the waist of the user. The connectors are usually elongate to be able to reach between the electrodes and the receiver, and are flexible to be able to accommodate movement of the user. The connectors are connected to the electrodes by various types of connecting portions, including for example crocodile clips. It is important that good connection is achieved between the connectors and the electrodes, in order that the connection between the connectors and the electrodes is maintained, i.e. they cannot easily be inadvertently disconnected, and that good quality ECG signals may be measured. This is not always achieved with the sensors described above, and improvements in sensors are therefore desirable.

According to a first aspect of the invention there is provided a two-part sensor comprising
a first part comprising a sensing device which senses information,
a second part comprising a receiving device which receives a measure of the information, and

a connector comprising at least one first portion which is magnetic and is attached to one of the sensing device and the receiving device, and at least one second portion which is magnetisable and is attached to an other of the sensing device and the receiving device, wherein the first portion and the second portion are connectable and disconnectable to connect and disconnect the sensing device and the receiving device.

The connector first portion may be attached to the sensing device, and the connector second portion may be attached to the receiving device. Alternatively, the connector first portion may be attached to the receiving device, and the connector second portion may be attached to the sensing device.

The connector first portion and the connector second portion may be connectable by magnetic forces exerted by the first portion on the second portion. The connector second portion may be magnetisable by comprising a ferromagnetic material, for example high iron content steel. The connector second portion may be magnetic. The connector first portion and the connector second portion may be connectable by magnetic forces exerted by the first portion on the second portion and magnetic forces exerted by the second portion on the first portion. The magnetic forces may act to guide connection of the sensing device and the receiving device.

The connector first portion and the connector second portion may be connectable by magnetic forces which are configured more readily to release the receiving device from the sensing device than to release the sensing device from connection with a user of the sensor. The connector first portion and the connector second portion may be connectable by magnetic forces which are in a of range approximately 7N to

approximately 10 N. Thus a body-worn, two-part sensor is provided, the receiving device of which may be disconnected from the sensing device without disconnecting the sensing device from the body.

The connector first portion and the connector second portion may be disconnectable by force applied by a user of the sensor. The force may be in a range of approximately 7N to approximately 10 N (equivalent to approximately a 700g to approximately 1kg weight pull or attraction).

The connector may comprise a plurality of connector first portions and a plurality of connector second portions, each connector first portion being connectable and disconnectable to a connector second portion. For example, the connector may comprise two connector first portions and two connector second portions. For example, the connector may comprise three connector first portions and three connector second portions. The connector first portions and the connector second portions may be attached to the sensing and receiving devices in a polarised arrangement, such as to dictate orientation of the receiving device with respect to the sensing device. For example, the connector may comprise three connector first portions and three connector second portions, attached to the sensing and receiving devices, typically but not exclusively, in a polarised arrangement comprising a triangular arrangement. In a preferred embodiment, the three connector first portions are attached to the sensing device in a triangular arrangement, and the three connector second portions are attached to the receiving device in a triangular arrangement. Using a polarised arrangement of the connector portions prevents misconnection of the sensing and receiving devices with respect to each other, and allows easy and rapid connection of the sensing and receiving devices, as a user does not have to determine how the devices should be oriented with respect to each other. A connector comprising

three connector first portions and three connector second portions is particularly advantageous in that the connector provides secure connection and electrical safety, whilst the sensing and receiving devices may be more readily disconnected from each other than other connector portion arrangements, for example four connector first portions and four second portions arranged in a square.

The connector first portion and the connector second portion may transmit the measure of the information from the sensing device to the receiving device. For example, the measure of the information may comprise electrical signals, and the connector first portion and the connector second portion may transmit the electrical signals from the sensing device to the receiving device. The connector first portion and the connector second portion may form a low impedance path for the electrical signals. The connector first portion or the connector second portion may form a part of an electrode system of the sensor for electrical signal measurement. The connector first portion and the connector second portion may comprise chloride connector portions. Connectivity of the connector first portion and the connector second portion by magnetic forces achieves a good connection between the portions in terms of conductivity of electrical signals by the connector first portion and the connector second portion.

The connector first portion may comprise a female-type clip portion and the connector second portion may comprise a male-type stud portion, which portions mate with each other. Alternatively, the connector first portion may comprise a male-type stud portion and the connector second portion may comprise a female-type clip portion, which portions mate with each other.

The sensing device may sense information comprising movement. The movement may be caused, for example, by pulse wave velocity signals, for example, of blood in an artery of a user of the sensor. The sensing device may produce a measure of the movement information comprising electrical signals. The sensing device may comprise a material capable of sensing movement and producing electrical signals which are a measure of the movement.

The sensing device may sense information comprising electrical signals. The electrical signals may be caused, for example, by ECG signals of a user of the sensor, or respiration of a user of the sensor. The sensing device may produce a measure of the electrical signals.

The sensing device may comprise at least one electrode, capable of sensing information in the form of electrical signals and producing a measure of the electrical signals. The sensing device may comprise an array of electrodes, each capable of sensing information in the form of electrical signals and producing a measure of the electrical signals. The or each electrode may comprise a Ag/AgCl-hydrogel electrode. The or each electrode may be annulus shaped. The sensing device may comprise a polyester substrate, in which the or each electrode may be provided.

The sensing device may comprise a stud to connect the or each electrode to a connector first portion or a connector second portion attached to the sensing device. The or each stud may be magnetic. The or each stud may be provided with insulation in the form of a polyester substrate and a screen-printed dielectric ink. The or each electrode may be provided on a first surface of the sensing device, and the or each stud may form a through-hole connection to a connector first portion or a connector second

portion attached to a second, opposite, surface of the sensing device. The sensing device may comprise a track to connect the or each electrode to the or each stud. The or each track may comprise silver and may be screen-printed in the sensing device. The or each track may be provided with insulation in the form of a polyester substrate and a screen-printed dielectric ink. For the or each electrode, the electrode may be provided on a first surface of the sensing device, a track may be provided on or near the first surface of the sensing device, in connection with the electrode, and a stud may be provided which forms a through-hole connection to a connector first portion or a connector second portion attached to a second, opposite, surface of the sensing device. The electrodes (and tracks when provided) may therefore be provided on or near a first surface of the sensing device, which is a surface attached adjacent to skin of a user of the sensor, and the connector first/second portion attached to an opposite side of the sensing device. Such an arrangement eases construction of the sensing device, and lowers consumable costs and the cost of manufacture of the sensing device.

The sensing device may comprise a patch provided with pressure-sensitive adhesive, for attachment of the sensing device to a user of the sensor. The patch may comprise an arrangement of spaced adhesive portions. The spacing is preferably optimised to ensure good attachment of the patch to the user.

The sensing device may be a disposable sensing device.

The receiving device may comprise a telemetry unit, for wireless sending of the measure of the information to an acquisition system. The receiving device may be a low-profile receiving device. This is particularly desirable

when the sensor is to be worn by a user thereof. The receiving device may be a reusable receiving device.

Providing a two-part sensor in which the sensing device is a separate part from the receiving device, allows the relatively inexpensive sensing device to be disposable, whilst the relatively expensive receiving device is reusable.

Embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 comprises a schematic cross sectional view of a two-part sensor according to a first embodiment of the invention;

Figure 2 comprises a schematic representation of a two-part sensor according to a second embodiment of the invention, and

Figure 3 comprises a schematic representation of a two-part sensor according to a third embodiment of the invention.

Figure 1 illustrates a two-part sensor 1 comprising a first part comprising a sensing device 3, a second part comprising a receiving device 5 and a connector 7. The sensor 1 is intended for use by a person, for sensing information in the form of electrical signals comprising ECG signals produced by the person's heart. The sensor thus monitors vital signs of the person. It will appreciated, however, that further embodiments of the invention may sense information other than electrical signals.

The sensing device 3 is in the form of a patch, and comprises a polyester substrate 9. Three electrodes 11 (only two of which are shown) are

screen-printed, in a triangular arrangement, onto a first surface of the substrate 9, to protrude from the substrate 9, as shown. Each electrode comprises a Ag/AgCl-hydrogel electrode, in the shape of an annulus. The sensing device 3 further comprises a track 13 and a stud 15 for each electrode 11. The tracks 13 and the studs 15 are provided with insulation in the form of the polyester substrate and a screen-printed dielectric ink (not shown). Each track 13 comprises silver and is screen-printed onto the first surface of the substrate so as to be in connection with an electrode 11. Each stud 15 is magnetic, and has a first end which extends beyond the first surface of the substrate 9 and a second end at a second, opposite, surface of the substrate 9, i.e. each stud 15 forms a through-hole connection through the sensing device 3, as shown. The first end of each stud 15 is connected to a track 13, and the second end of each stud 15 is connected to the connector 7. The sensing device 3 further comprises an arrangement of spaced adhesive portions 17, comprising pressure-sensitive adhesive, provided on the first surface of the substrate 9, as shown.

The receiving device 5 comprises a telemetry unit 19. This receives the measure of the information from the sensing device, and wirelessly sends the measure of the information to an acquisition system (not shown). The receiving device 5 is designed to be low-profile.

The connector 7 comprises three connector first portions 21 (only two of which are shown), and three connector second portions 23 (only two of which are shown). The connector first portions 21 are attached to the sensing device 3 in a polarised, triangular arrangement, and the connector second portions 23 are attached to the receiving device 5 in a polarised, triangular arrangement. The triangular arrangement of the connector first portions 21 corresponds to the triangular arrangement of the electrodes

11, tracks 13 and studs 15 of the sensing device 3, and each connector first portion 21 is attached to a stud 15. The triangular arrangement of the connector first portions 21 also substantially corresponds to the triangular arrangement of the connector second portions 23. The connector first portions 21 each comprise a female-type clip portion and the connector second portions 23 each comprise a male-type stud portion, which portions mate with each other. The connector first portions 21 are each magnetic, and the connector second portions 23 are each magnetisable by comprising high iron content steel. Each pair of a connector first portion 21 and a connector second portion 23 is connectable by magnetic forces exerted by the first portion on the second portion. The magnetic forces are configured more readily to release the receiving device 5 from the sensing device 3 than to release the sensing device 3 from connection with the body of the person using the sensor 1, and are in a of range approximately 7N to approximately 10 N. Each pair of a connector first portion 21 and a connector second portion 23 transmits the measure of the information (comprising electrical signals) from the sensing device 3 to the receiving device 5, and form a low impedance path for the electrical signals.

In use, the two-part sensor 1 is positioned on the body of the person using the sensor 1. In this embodiment, the sensing device 3 is attached to the skin of the chest of the person, using the adhesive portions 17 of the sensing device 3. The first surface of the substrate 9 of the sensing device 3 is then positioned adjacent the person, and the second, opposite, surface of the substrate 9 faces away from the person. Once the sensing device 3 has been securely attached to the person, the receiving device 5 is connected to the sensing device 3, using the connector 7. Each connector second portion 23, connected to the receiving device 5, is brought into proximity with a connector first portion 21, connected to the

sensing device 3. The magnetic forces between the connector first and second portions act to guide connection of the portions, such that each male-type stud of a connector second portion 23 mates with a female-type clip of a connector first portion 21. As the three connector first portions 21 are attached to the sensing device 3 in a polarised, triangular arrangement, and the three connector second portions 23 are attached to the receiving device 5 in a polarised, triangular arrangement, the orientation of the receiving device 5 with respect to the sensing device 3 is easily determined. Such an arrangement of the connector first and second portions prevents misconnection of the sensing and receiving devices with respect to each other. The coupling between each pair of a connector first portion 21 and a connector second portion 23 is strong enough to hold the receiving device 5 to the sensing device 3 (preventing inadvertent disconnection), but weak enough to allow disconnection of the devices without detaching the sensing device 3 from the body of the person. The sensing and receiving devices are disconnectable by force applied by the person using the sensor 1. The force should be in the range of approximately 7N to approximately 10 N (equivalent to approximately 700g to approximately 1kg weight). The sensing device 3 and the receiving device 5 may thus be connectable to each other and disconnectable from each other, with ease. This is particularly advantageous as the sensing device 3 will generally be a relatively cheap item, and therefore can be disposable, whereas the receiving device 5 will generally be a relatively expensive item, and therefore will desirable be reusable.

In this embodiment, each electrode 11 of the sensing device 3 senses information in the form of electrical signals comprising ECG signals produced by the heart of the person using the sensor 1. Each electrode 11 produces a measure of the electrical signals, which comprises the

electrical signals, and transmits the signals to a track 13 connected to the electrode 11. Each track 13 transmits the electrical signals to a stud 15 attached to the track 13. Each stud 15 transmits the electrical signals to a connector first portion 21 attached thereto. Each connector first portion 21 transmits the electrical signals to a connector second portion 23 connected thereto The electrical signals are thus transmitted from the sensing device 3 to the receiving device 5, which may then transmit the signals to an acquisition unit.

Figure 2 illustrates a schematic representation of a second embodiment of a two-part sensor of the invention. The sensor comprises a sensing device in the form of a patch, as shown, and a receiving device connected to the sensing device by a connector, as shown. The sensing device senses information comprising electrical signals, caused by ECG signals of a user of the sensor, or respiration of a user of the sensor.

Figure 3 illustrates a schematic representation of a third embodiment of a two-part sensor of the invention. The sensor comprises a sensing device in the form of a patch, as shown, a receiving device connected to the sensing device by a connector, as shown, and two further patches attached to the sensor. The sensing device of this embodiment senses information comprising movement, caused, for example, by pulse wave velocity signals of blood in an artery of a user of the sensor. The sensing device produces a measure of the movement information comprising electrical signals, and comprises a material capable of sensing movement and producing electrical signals which are a measure of the movement.

The two-part sensors of the invention provide the ability to have a disposable sensing device and a reusable receiving device, are easy to use as the receiving device may be readily connected to the sensing

device using the polarised connection arrangement, and may be disconnected from the sensing device without disconnecting the sensing device from the user, are comfortable to use due to the low profile of the receiving device, provide good electrical signal acquisition due to the use of a magnetic connector, and have low construction costs due to the arrangement of the electrodes and connector on opposite sides of the sensing device.

CLAIMS

1. A two-part sensor comprising a first part comprising a sensing device which senses information, a second part comprising a receiving device which receives a measure of the information, and a connector comprising at least one first portion which is magnetic and is attached to one of the sensing device and the receiving device, and at least one second portion which is magnetisable and is attached to an other of the sensing device and the receiving device, wherein the first portion and the second portion are connectable and disconnectable to connect and disconnect the sensing device and the receiving device.

2. A two-part sensor according to claim 1, in which the connector first portion and the connector second portion are connectable by magnetic forces exerted by the first portion on the second portion.

3. A two-part sensor according to claim 1 or claim 2, in which the connector second portion is magnetic, and the connector first portion and the connector second portion are connectable by magnetic forces exerted by the first portion on the second portion and magnetic forces exerted by the second portion on the first portion.

4. A two-part sensor according to claim 2 or claim 3, in which the connector first portion and the connector second portion are connectable by magnetic forces which are configured more readily to release the receiving device from the sensing device than to release the sensing device from connection with a user of the sensor.

5. A two-part sensor according to any of claims 2 to 4, in which the connector first portion and the connector second portion are connectable

by magnetic forces which are in a of range approximately 7N to approximately 10 N.

6. A two-part sensor according to any preceding claim, in which the connector comprises a plurality of connector first portions and a plurality of connector second portions, each connector first portion being connectable and disconnectable to a connector second portion.

7. A two-part sensor according to claim 6, in which the connector first portions and the connector second portions are attached to the sensing and receiving devices in a polarised arrangement, such as to dictate orientation of the receiving device with respect to the sensing device.

8. A two-part sensor according to claim 7, in which the connector comprises three connector first portions and three connector second portions, attached to the sensing and receiving devices in a polarised arrangement comprising a triangular arrangement.

9. A two-part sensor according to any preceding claim, in which the connector first portion and the connector second portion transmit the measure of the information from the sensing device to the receiving device.

10. A two-part sensor according to any preceding claim, which senses information comprising movement.

11. A two-part sensor according to any of claims 1 to 9, which senses information comprising electrical signals.

12. A two-part sensor according to any preceding claim, in which the sensing device comprises at least one electrode, capable of sensing information in the form of electrical signals and producing a measure of the electrical signals.

13. A two-part sensor according to claim 12, in which the sensing device comprises a stud to connect the or each electrode to a connector first portion or a connector second portion attached to the sensing device.

14. A two-part sensor according to claim 13, in which the or each electrode is provided on a first surface of the sensing device, and the or each stud forms a through-hole connection to a connector first portion or a connector second portion attached to a second, opposite, surface of the sensing device.

15. A two-part sensor according to claim 13 or claim 14, in which the sensing device comprises a track to connect the or each electrode to the or each stud.

16. A two-part sensor according to any preceding claim, in which the sensing device is a disposable sensing device, and the receiving device is a reusable receiving device.

1/1

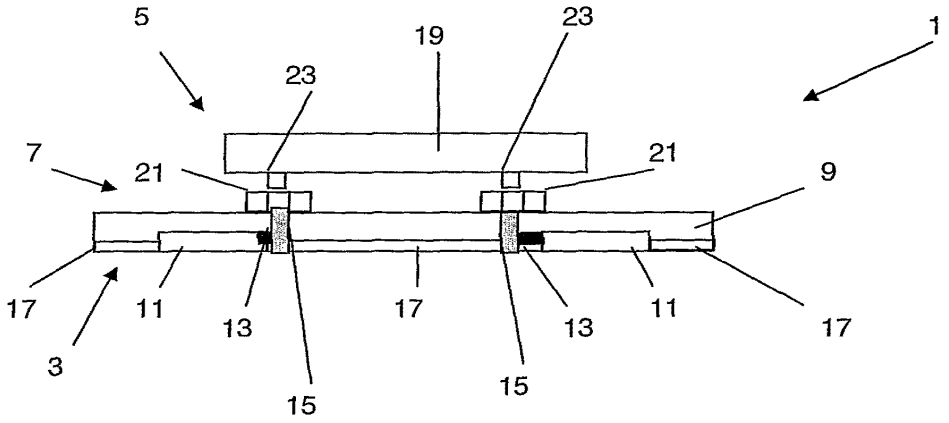


Fig. 1

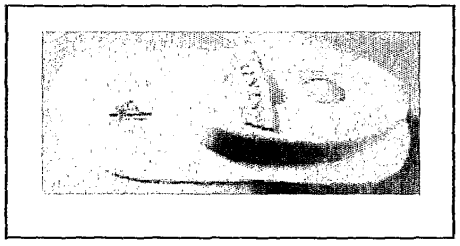


Fig. 2

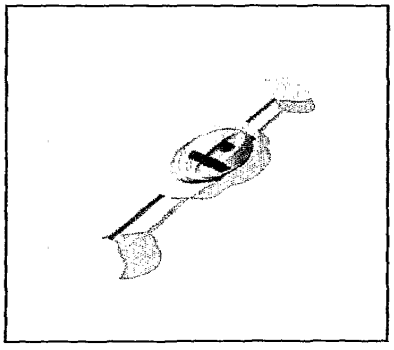


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 552 785 A (SAMSUNG ELECTRONICS CO LTD [KR]) 13 July 2005 (2005-07-13) abstract; figures 1-3 paragraph [0001] paragraph [0007] paragraph [0010] paragraph [0015] - paragraph [0017]	1-16
X	US 4 653 503 A (HEATH ROGER L [US]) 31 March 1987 (1987-03-31) abstract column 1 - column 5	1-5,9-16
X	US 4 259 965 A (FUKUDA KOTARO ET AL) 7 April 1981 (1981-04-07) abstract column 3 - column 5	1-5,9-16

☐ 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
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Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Koprinarov, Ivaylo

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1552785 A	13-07-2005	CN 1647751 A	03-08-2005
		JP 2005193058 A	21-07-2005
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(54) **Title:** MEASUREMENT OF OXYGEN SATURATION OF BLOOD HAEMOGLOBIN

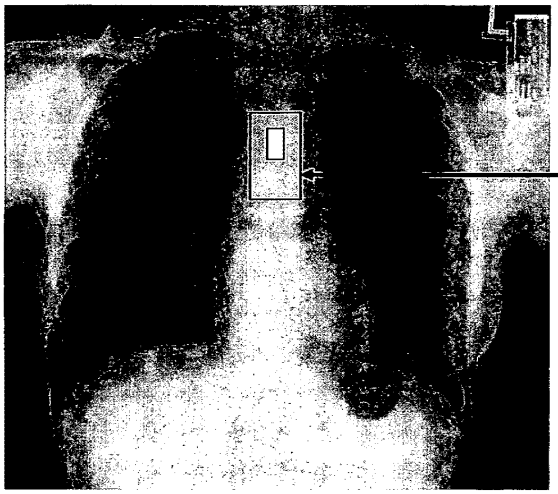


Fig 1

(57) **Abstract:** The invention provides a chest-based oximeter (1) for measuring oxygen saturation of haemoglobin in blood of the chest of a subject, comprising at least one radiation source (5,7) adapted to emit radiation onto the chest, at least one radiation detector (9) adapted to detect radiation reflected from the chest, and a pressure device (11) adapted to apply pressure to the oximeter to connect the oximeter to the chest.

WO 2009/056859 A1

Measurement of Oxygen Saturation of Blood Haemoglobin

This invention relates to the measurement of oxygen saturation of blood haemoglobin.

The oxygen saturation of haemoglobin in blood is an important indicator of the health of a subject. For example, measurements of oxygen saturation can detect hypoxia before the subject becomes cyanosed. Measurement of oxygen saturation of blood haemoglobin is therefore routinely carried out for subjects receiving medical care in hospitals, and for monitoring the health of subjects in the home.

Traditionally, oximeters are used to make measurements of oxygen saturation of blood haemoglobin at peripheral sites of the subject, such as a finger, ear or toe. Thus saturation of peripheral oxygen, commonly referred to as SpO_2, is measured. In use, an oximeter is attached to a peripheral site of the subject, in proximity to an artery, and senses the oxygen saturation of arterial blood. The oximeter comprises two radiation sources and a radiation detector. Commonly, the radiation sources are positioned on a first side of the peripheral site, e.g. on a first side of a finger, and the radiation detector is arranged on a second, opposite, side of the peripheral site. This is referred to as a transmission oximeter. Radiation from the sources is transmitted from the sources into the peripheral site. Some of the radiation is absorbed by the peripheral site, and particularly the blood in the artery of the site, and some of the radiation passes through the peripheral site. At least some of this transmitted radiation is detected by the detector. The radiation sources, usually LEDs, produce radiation at different wavelengths, the first source in the red part of the electromagnetic spectrum, and the second source in the infra red (IR) part of the electromagnetic spectrum. The level of

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iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
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absorption of red and IR radiation in blood, depends on the oxygenation level of haemoglobin in the blood. Further, for blood having a particular haemoglobin oxygenation level, the red and IR radiation will be absorbed by different amounts. By detecting radiation that is transmitted through the arterial blood, it is possible to calculate the absorption of the red and IR radiation and compute the percentage of haemoglobin in the arterial blood which is saturated with oxygen. This is usually expressed as a percentage of total saturation. The blood flow through the artery will be pulsatile in form. The oximeter is designed to detect radiation transmitted through blood in the artery, by being configured to detect pulsatile transmitted radiation. The oximeter is able to distinguish the pulsatile signals from other more static signals, e.g. signals transmitted through tissue or veins. The oximeter is able to measure the heart rate of the subject, and also to produce an indication of the quality of blood flow through the artery.

As measurement of oxygen saturation of haemoglobin in blood finds widespread application, improvements in measurement systems and techniques are constantly being sought.

According to a first aspect of the invention there is provided a chest-based oximeter for measuring oxygen saturation of haemoglobin in blood of the chest of a subject, comprising
at least one radiation source adapted to emit radiation onto the chest,
at least one radiation detector adapted to detect radiation reflected from the chest, and
a pressure device adapted to apply pressure to the oximeter to connect the oximeter to the chest.

It has been found that the signals representing radiation reflected from the chest are weaker than signals representing radiation transmitted through

the finger. Nevertheless, the chest signals are measurable, are sufficiently strong to measure accurately oxygen saturation values, oxygen perfusion trends and accurate heart rate values, and are sufficiently repeatability for good quality measurements.

The pressure device may be applied to skin of the chest of the subject. The pressure device may comprise a material which has a Young's modulus which is lower than that of the skin of the chest of the subject. The material may comprise a stretchable foam material. The pressure device may stress and apply a pressure on the oximeter towards the skin, to connect the oximeter to the chest. The difference between the Young's modulus of the skin and the Young's modulus of the pressure device material may cause the pressure device to stress and apply a pressure on the oximeter towards the skin. The pressure device may apply pressure on the oximeter which increases with time, for example as the skin absorbs moisture from the material of the pressure device.

The pressure device may be profiled to press onto the chest of the subject to apply pressure to the oximeter towards the chest, to connect the oximeter to the chest. The pressure device may comprise a suction device. The pressure device may comprise a biasing device, for example, a spring. The pressure device may comprise a finger push device. The pressure device may comprise a belt.

The pressure device may apply a pressure in the range of approximately 1 Pascal to approximately 100000 Pascal. The pressure device may be provided with a pressure sensitive adhesive.

The pressure device may optically couple the radiation from the radiation source to the chest of the subject. The pressure device may optically

couple the radiation reflected from the chest of the subject to the radiation detector.

It has been found that the amplitude of detected radiation significantly increases when a pressure is applied to the oximeter. The amplitude of the detected radiation is indicative of the quality of the measure of the oxygen saturation of haemoglobin in blood that is obtained by the oximeter. Accurate measurement of oxygen saturation by oximeters can only be achieved when an adequate pulse is present at the measurement site, i.e. the chest. Applying pressure to the oximeter will increase the strength of the measurement of the pulse and therefore oxygen saturation will be more accurately measured by the oximeter. The pressure to be applied by the pressure device may be determined by applying a range of pressure from zero pressure to heavy pressure to the oximeter, and measuring the radiation reflected from the chest. It has been found that as the pressure is gradually increased, the peak to peak values of measured signals stays approximately constant until a pressure threshold is reached, then the peak to peak values increases as the pressure continues to increase, until a cut-off pressure is reached at which the peak to peak values fall to an unmeasurable size where the quality of the signals has deteriorated significantly. The pressure range between the pressure threshold and the pressure cut-off is the optimum pressure range to use.

The chest-based oximeter may comprise an optical coupling element. This may be positioned in the oximeter to enhance coupling of radiation between the radiation source and the radiation detector and the chest of the subject.

The at least one radiation source and the at least one radiation detector may be mounted in the chest-based oximeter such that they are spaced

apart by a distance in the range of approximately 0.5mm to approximately 2cm. The at least one radiation source and the at least one radiation detector may be mounted in the chest-based oximeter such that, in use, they are positioned in the range of approximately 1cm to approximately 20cm above the chest of the subject.

The at least one radiation source may emit radiation having one or more infra red peak wavelengths. The chest-based oximeter may further comprise a second radiation source which emits radiation having one or more infra red peak wavelengths. The at least one radiation source may emit radiation having at least a first infra red peak wavelength, and the second radiation source may emit radiation having at least a second, different, infra red peak wavelength. The or each infra red peak wavelength is in the range of 600nm to 1500nm, for example 780nm, 810nm, 820nm, 830nm, 840nm, 850nm, 870nm, 880nm, 890nm, 910nm, 940nm, 970nm, 1050nm, 1070nm, 1200nm, 1300nm, 1350nm, 1450nm, 1550nm.

Infra red radiation has a wavelength range which sensitive to the measurement of oxygen saturation in blood. Using one or more radiation sources which emit radiation having infra red wavelengths therefore optimises the detection ability of the oximeter. Effects due to skin, tissue path, etc. can be filtered or monitored and subtracted in order to measure the oxygen saturation and also the heart rate of the subject.

The at least one radiation source may emit radiation having one or more visible peak wavelengths. The chest-based oximeter may further comprise a second radiation source which emits radiation having one or more visible peak wavelengths.

The at least one radiation source may emit radiation having one or more visible peak wavelengths, and the oximeter may further comprise a second radiation source which emits radiation having one or more infra red peak wavelengths.

The radiation source or radiation sources may comprise an LED or LEDs. The radiation source or radiation sources may comprise a solid state laser or solid state lasers. When the oximeter comprises two or more radiation sources, the sources may comprise LEDS, or solid state lasers, or a combination of LEDs and solid state lasers.

The chest-based oximeter may comprise one or more devices to, for example, process or amplify the radiation detected by the radiation detector. The chest-based oximeter may comprise a processor, which may receive one or more signals representing radiation detected by the radiation detector, and may use the signal or signals to provide a measure of the oxygen saturation of haemoglobin in blood of the chest. The chest-based oximeter may comprise a transmitter. The transmitter may transmit one or more signals representing the measure of the oxygen saturation of haemoglobin in blood of the chest to a remote receiver. The transmitter may relay changes in oxygen saturation in blood of the chest of the subject to, for example, a clinician even when the subject is at home. The chest-based oximeter may comprise a receiver. The receiver may receive instructions which may be used to control the operation of the chest-based oximeter.

Alternatively, the transmitter may transmit signals representing the radiation detected by the detector to a remote receiver, which comprises a processor which uses the signal or signals to provide a measure of the oxygen saturation of haemoglobin in blood of the chest.

The transmitter may wirelessly transmit the one or more signals to the remote receiver. This means that the chest-based oximeter does not require leads to connect to the remote receiver, which may otherwise impede movement of the subject.

The chest-based oximeter may comprise a hydrogel interface. The hydrogel interface may, in use, be attached to the chest of the subject. The hydrogel interface may be placed in contact with skin of the chest. The hydrogel interface may comprise adhesive, which is used to attach it to the skin. The adhesive may be a pressure-sensitive adhesive. The hydrogel interface may have substantially similar visco-elastic properties as skin. The hydrogel interface may have a Young's modulus substantially similar to that of skin. The hydrogel interface may be flexible. The hydrogel interface may be flexible to allow it to flex with movement of the subject. The hydrogel interface may be flexible to allow it to flex with movement of the subject, such that it remains attached to the chest. The hydrogel interface may be flexible to allow it to flex with movement of the subject, such that radiation from the radiation source is emitted substantially perpendicular onto the measurement site of the subject. The hydrogel interface may be flexible to allow it to flex with movement of the subject, such that motion-induced artefacts in the reflected radiation detected by the detector are reduced. The hydrogel interface may have substantially similar electrical properties as skin. This will give overall similar ionic content and therefore no potential gradients. The hydrogel interface may act as a second skin for the measurement site.

The hydrogel interface may be situated between the radiation source and radiation detector and the chest of the subject. The hydrogel interface may cover the radiation source. The hydrogel interface may cover the

radiation detector. The radiation source may emit radiation through the hydrogel interface onto the chest. The hydrogel interface may diffuse the radiation emitted from the radiation source. The diffusion of the radiation may average angles of penetration of the radiation into the chest. The diffusion may be, for example, from an approximately $1mm^2$ source to an area of approximately $1cm^2$. The hydrogel interface may provide coupling of the radiation from the source to the chest. The radiation detector may detect radiation reflected from the chest which passes through the hydrogel interface. The hydrogel interface may diffuse the radiation reflected from the chest. The diffusion of the radiation may average angles of reflection of the radiation from the chest. The diffusion may be, for example, from an approximately $1mm^2$ source to an area of approximately $1cm^2$. The hydrogel interface may provide coupling of the radiation from the chest to the radiation detector. The diffusion allows for improved averaging of the absorption of the radiation, and thus improved accuracy of the oximeter. The coupling improves the detection of the reflected radiation against background noise/artefact. This gives a cleaner and more sensitive analysis leading to higher accuracy. The optical coupling stops stray light from interfering with the detected radiation.

The hydrogel interface may be shaped to fit the chest of the subject. The hydrogel interface may comprise a film. The hydrogel interface may comprise a ball. The hydrogel interface may have a thickness in the range of approximately 0.5mm to approximately 1cm. The hydrogel interface may have an area of approximately $1cm^2$. The hydrogel interface may be up to approximately 85% water based. The hydrogel interface is preferably biocompatible. It will then have a low toxicity and sensitisation effects on the subject.

It has been found that when the chest-based oximeter is provided with a hydrogel interface, the signals produced by the radiation detector have waveforms which can be sharper and more consistent, than those produced when no hydrogel interface is used. When no hydrogel interface is used, the signals produced by the radiation detector are stronger than those produced when a hydrogel interface is used, but the signals may be more prone to influence by slight movements between the oximeter and the skin of the subject and between the skin and underlying bone.

The chest-based oximeter may have a low profile. This will make it easier to wear than conventional oximeters used on a finger, ear or toe.

The chest-based oximeter may, in use, be attached to a region of the chest above the notch sternum. Positioning of the chest-based oximeter above the notch region of the chest of the subject will ensure high coupling of the oximeter with the main heart blood paths. Positioning of the chest-based oximeter above the notch region of the chest of the subject avoids hysteresis or time delays in signals detected by the oximeter. Positioning of the chest-based oximeter above the notch region of the chest of the subject also makes the oximeter easy for the subject to wear.

The chest-based oximeter may be used to measure a wide range of oxygen saturation values. This may be tested by the subject carrying out a controlled breathing exercise, which manipulates the subject's blood oxygen saturation values, through a wide range of saturation values. It has been found that decreases in oxygen saturation values were indicated earlier at the chest than at the finger, that measurements of oxygen saturation taken at the chest fell at a faster rate than measurements of oxygen saturation taken at the finger, and that chest oxygen saturation values fell to a lower level than finger oxygen saturation values.

The chest-based oximeter may also measure carbon monoxide saturation in blood of the chest of the subject.

The chest-based oximeter may form part of a system which measures one or more vital signs of the subject. The vital signs may comprise any of heart rate, ECG, respiration rate, temperature. The system may comprise the V-patch vital signs measurement system of Sensor Technology & Devices.

According to a second aspect of the invention there is provided a method of measuring oxygen saturation of haemoglobin in blood of the chest of a subject, comprising
attaching an oximeter to the chest using a pressure device of the oximeter adapted to apply pressure thereto to connect the oximeter to the chest,
operating at least one radiation source of the oximeter to emit radiation onto the chest,
operating at least one radiation detector of the oximeter to detect radiation reflected from the chest, and
using the radiation detected by the detector to measure the oxygen saturation of haemoglobin in blood of the chest.

Embodiments of the invention will now be described by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a schematic representation of a first embodiment of an chest-based oximeter according to the invention, shown positioned on a subject's chest;

Figure 2 is a schematic representation of the chest-based oximeter of Figure 1, and

Figure 3 is a schematic representation of a second embodiment of a chest-based oximeter according to the invention.

Figure 1 shows a first embodiment of a chest-based oximeter 1 according to the invention, placed on a subject's chest. The oximeter 1 is positioned on a region of the chest above the notch sternum, as illustrated, and measures oxygen saturation of haemoglobin in blood of the region of the chest above the notch sternum.

Figure 2 shows the chest-based oximeter 1 in more detail. The oximeter 1 comprises a housing 3, two radiation sources 5, 7, a radiation detector 9 and a pressure device 11. The housing comprises a flexible substrate. The radiation sources 5, 7 and the radiation detector 9 are each mounted on a surface of the housing 3, as shown, in a reflectance measurement arrangement. The sources and the detector are spaced apart by a distance in the range of approximately 0.5mm to approximately 2cm. The radiation sources 5, 7 comprise LEDs. The radiation source 5 emits radiation having a visible peak wavelength in the red region of the visible spectrum. The radiation source 7 emits radiation having an infra red peak wavelength of 920nm or 1300nm. The radiation source 7 comprises an IR LED, such as those supplied by Roithner Lasertechnik. The radiation detector 9 comprises a photodiode, such as the TSL220 photodiode supplied by Texas Instruments.

As described, the chest-based oximeter 1 comprises a conventional arrangement of radiation sources in terms of number and wavelength. It will be appreciated that the oximeter 1 could comprise a different number

of radiation sources with different wavelengths, for example a first radiation source which emits radiation having an infra red peak wavelength of 900nm and a second radiation source which emits radiation having an infra red peak wavelength of 1300nm.

The pressure device 11 comprises a stretchable foam material, which has a Young's modulus which is lower than that of the skin of the chest of the subject. The pressure device 11 is attached at a first side thereof to the surface of the housing 3 on which the radiation sources and detector are mounted. The pressure device 11 as shown extends along the surface of the housing 3 and around the sides of the housing 3. It will be appreciated that other shapes of pressure device 11 may be used, for example, the pressure device may only extend along part of the surface of the housing 3. In use, the pressure device 11 is applied at a second side thereof to skin of the region of the chest above the notch sternum of the subject. As the Young's modulus of the skin and the Young's modulus of the pressure device material are different, this will cause the pressure device 11 to stress and apply a pressure on the oximeter towards the skin, and connect the oximeter to the chest. The pressure device 11 may apply a pressure in the range of approximately 1 Pascal to approximately 100000 Pascal on the oximeter towards the chest of the subject.

The pressure device 11 is of a thickness to position the radiation sources 5, 7 and the radiation detector 9 between approximately 1cm and approximately 20 cm above the notch region of the chest. The pressure device 11 is shaped to optically couple the radiation from the radiation sources 5, 7 to the notch region of the chest, and to optically couple the radiation reflected from the notch region of the chest to the radiation detector 9.

The chest-based oximeter 1 further comprises a power supply, a controller, a processor, a receiver, a transmitter and electronic circuitry, all located within the housing 3. The electronic circuitry connects the radiation sources 5, 7 and the radiation detector 9 to the power supply, for supply of power thereto. It will be appreciated that, alternatively, a power supply could be provided external to the oximeter 1. The electronic circuitry connects the radiation sources 5, 7 to the controller, which acts to control the operation of the sources. The electronic circuitry connects the radiation detector 9 to the processor. The processor receives signals from the radiation detector 9, and uses the signals to provide a measure of the oxygen saturation. The processor may pass measurement of the oxygen saturation to the transmitter, for transmission to a device external to the oximeter. It will appreciated that the chest-based oximeter 1 may be connected to a processor which is situated external to the oximeter. The oximeter may then transmit signals from the radiation detector 9 to a receiver of the external processor. The controller of the oximeter 1 may receive control signals via the receiver from a source external to the oximeter, to control operation of the oximeter. For example, the control signals may be generated by a physician of the subject. The transmitter and receiver of the oximeter 1 may be connected by wires or, preferably, wirelessly connected to devices external to the oximeter.

The entire chest-based oximeter 1 has a low profile. This will make it easier for the subject to wear than conventional oximeters used on a finger, ear or toe.

In use, the chest-based oximeter 1 is attached to the region of the chest above the notch sternum of the subject using the pressure device 11, and measures oxygen saturation of haemoglobin in blood of the notch region of the chest, as follows. The controller receives a signal via the receiver

causing it to activate the radiation sources 5, 7. These emit red and IR radiation onto the notch region of the chest. The radiation from the sources is transmitted into the notch region, and some of the radiation is absorbed by the notch region of the chest, and particularly haemoglobin in blood in arteries of the chest region. Some of the radiation from the sources is reflected from the notch region of the chest, and particularly haemoglobin in the blood in the arteries. The level of absorption of red and IR radiation in blood, depends on the oxygenation level of haemoglobin in the blood, and, for blood having a particular haemoglobin oxygenation level, the red and IR radiation will be absorbed by different amounts. The detector 9 detects red and IR radiation reflected from the notch region. The detector 9 produces signal representative of the reflected radiation, and passes these signals to the processor. The processor uses the signals in an analysis algorithm and calculates the absorption of the red and IR radiation, and computes a measure of the oxygen saturation of haemoglobin in blood of the arteries of the notch sternum region of the chest. This is usually expressed as a percentage of total saturation. The blood flow through the arteries will be pulsatile in form. The oximeter 1 is designed to detect radiation reflected from blood in the arteries, by being configured to detect pulsatile reflected radiation. The oximeter 1 is able to distinguish the pulsatile signals from other more static signals, e.g. signals transmitted through tissue or veins. The oximeter 1 is also able to measure the heart rate of the subject, and to produce an indication of the quality of blood flow through the arteries.

Positioning of the oximeter 1 above the notch region of the chest of the subject ensures high coupling of the oximeter 1 with the main heart blood arteries. Positioning of the oximeter 1 above the notch region of the chest also avoids hysteresis in signals detected by the oximeter 1, and makes the oximeter easy for the subject to wear.

As stated earlier, it has been found that the signals representing radiation reflected from the chest are weaker than signals representing radiation transmitted through the finger. Nevertheless, the chest signals are measurable, are sufficiently strong to measure accurately oxygen saturation values and accurate heart rate values, and are sufficiently repeatability for good quality measurements.

Figure 3 shows a second embodiment of a chest-based oximeter 21, used to measure oxygen saturation of haemoglobin in blood of a subject. The oximeter 21 comprises a housing 23, two radiation sources 25, 27, a radiation detector 29, a pressure device 30 and a hydrogel interface 31. The housing comprises a flexible substrate. The radiation sources 25, 27 and the radiation detector 29 are each mounted on a surface of the housing 23, as shown, in a reflectance measurement arrangement. The sources and the detector are spaced apart by a distance in the range of approximately 0.5mm to approximately 2cm. The radiation sources 25, 27 comprise LEDs. The radiation source 25 emits radiation having a visible peak wavelength in the red region of the visible spectrum. The radiation source 27 emits radiation having an infra red peak wavelength. As described, the chest-based oximeter 21 again comprises a conventional arrangement of radiation sources in terms of number and wavelength. It will be appreciated that the oximeter 21 could comprise a different number of radiation sources with different wavelengths, for example one or two radiation sources which emit radiation having one or more infra red peak wavelengths.

The pressure device 30 may comprise any of a finger push device, a belt, a biasing device, for example, a spring. The pressure device 30 is attached at a first side thereof to the surface of the housing 23 on which

the radiation sources and detector are not mounted. The pressure device 30 as shown extends along the surface of the housing 23 and around the sides of the housing 23. It will be appreciated that other shapes of pressure device 30 may be used, for example, the pressure device may only extend along part of the surface of the housing. In use, the oximeter 21 is applied to the region of the chest above the notch sternum of the subject. The pressure device 30 is activated and applies a pressure on the oximeter 21 towards the chest, and connects the oximeter 21 to the chest. The pressure device 11 may apply a pressure in the range of approximately 1 Pascal to approximately 100000 Pascal on the oximeter towards the chest of the subject.

The hydrogel interface 31 is shaped to fit the chest of the subject. The hydrogel interface 31 comprises a film, having a thickness in the range of approximately 0.5mm to approximately 1cm. The hydrogel interface 31 is biocompatible, to reduce toxicity and sensitisation effects on the subject.

The hydrogel interface 31 is attached at a first side thereof to the surface of the housing 23 on which the radiation sources and detector are mounted. The hydrogel interface 31 is attached at a second side thereof to the chest of the subject. The hydrogel interface 31 is placed in contact with skin of the measurement site, and comprises adhesive, which is used to attach it to the skin. The adhesive is preferably pressure-sensitive. The hydrogel interface 31 has substantially similar visco-elastic properties as skin, and a Youngs modulus substantially similar to that of skin. The hydrogel interface 31 is flexible, to allow it to flex with movement of the subject, such that it remains attached to the chest and radiation from the radiation sources is emitted substantially perpendicular onto the measurement site. Such flexibility of the hydrogel interface 31 will reduced motion-induced artefacts in the reflected radiation detected by the

detector 29. The hydrogel interface 31 preferably also has substantially similar electrical properties as skin. In effect, the hydrogel interface 31 acts as a second skin for the chest of the subject.

The hydrogel interface 31 is situated between the radiation sources 25, 27 and the radiation detector 29, and the chest of the subject, as shown. The hydrogel interface 31 thus covers the radiation sources 25, 27, which emit radiation through the hydrogel interface 31 onto the chest. The hydrogel interface 31 diffuses the radiation emitted from the radiation sources, to average angles of penetration of the radiation into the chest. The hydrogel interface 31 also provides coupling of the radiation from the sources 25, 27 to the chest. The hydrogel interface 31 also covers the radiation detector 29, which detects radiation reflected from the chest which passes through the hydrogel interface 31. The hydrogel interface 31 diffuses the radiation reflected from the chest, to average angles of reflection of the radiation from the chest. The hydrogel interface 31 also provides coupling of the radiation from the chest to the radiation detector 29.

The oximeter 21 further comprises a power supply, a controller, a processor, a receiver, a transmitter and electronic circuitry, all located within the housing 23. The electronic circuitry connects the radiation sources 25, 27 and the radiation detector 29 to the power supply, for supply of power thereto. It will be appreciated that, alternatively, a power supply could be provided external to the oximeter 21. The electronic circuitry connects the radiation sources 25, 27 to the controller, which acts to control the operation of the sources. The electronic circuitry connects the radiation detector 29 to the processor. The processor receives signals from the radiation detector 29, and uses the signals to provide a measure of the oxygen saturation. The processor may pass measurement of the oxygen saturation to the transmitter, for transmission to a device external

to the oximeter. It will appreciated that the chest-based oximeter may be connected to a processor which is situated external to the oximeter 21. The oximeter may then transmit signals from the radiation detector 29 to a receiver of the external processor. The controller of the oximeter 21 may receive control signals via the receiver from a source external to the oximeter, to control operation of the oximeter. For example, the control signals may be generated by a physician of the subject. The transmitter and receiver of the oximeter 21 may be connected by wires or, preferably, wirelessly connected to devices external to the oximeter.

In use, the oximeter 21 is attached to the chest of the subject via the hydrogel interface 31, and the pressure device 30 activated to apply pressure on the oximeter towards the chest. The region of the chest of the subject may be above the notch sternum of the chest. The controller receives a signal via the receiver causing it to activate the radiation sources 25, 27. These emit red and IR radiation onto the measurement site. The radiation from the sources is transmitted into the chest, and some of the radiation is absorbed by the chest, and particularly haemoglobin in blood in arteries of the chest. Some of the radiation from the sources is reflected from the chest, and particularly haemoglobin in the blood in the arteries. The level of absorption of red and IR radiation in blood, depends on the oxygenation level of haemoglobin in the blood, and, for blood having a particular haemoglobin oxygenation level, the red and IR radiation will be absorbed by different amounts. The detector 29 detects red and IR radiation reflected from the chest. The detector 29 produces signal representative of the reflected radiation, and passes these signals to the processor. The processor uses the signals in an analysis algorithm and calculates the absorption of the red and IR radiation, and computes a measure of the oxygen saturation of haemoglobin in blood of the arteries of the chest. This is usually expressed as a percentage of

total saturation. The blood flow through the arteries will be pulsatile in form. The oximeter 21 is designed to detect radiation reflected from blood in the arteries, by being configured to detect pulsatile reflected radiation. The oximeter 21 is able to distinguish the pulsatile signals from other more static signals, e.g. signals transmitted through tissue or veins. The oximeter 21 is also able to measure the heart rate of the subject, and to produce an indication of the quality of blood flow through the arteries.

It has been found that when the chest-based oximeter 21 is provided with a hydrogel interface 31, the signals produced by the radiation detector 29 have waveforms which are sharper and more consistent, than those produced when no hydrogel interface is used. When no hydrogel interface is used, the signals produced by the radiation detector are stronger than those produced when a hydrogel interface is used, but the signals are more prone to influence by slight movements between the oximeter and the skin of the subject and between the skin and underlying bone.

CLAIMS

1. A chest-based oximeter for measuring oxygen saturation of haemoglobin in blood of the chest of a subject, comprising
at least one radiation source adapted to emit radiation onto the chest,
at least one radiation detector adapted to detect radiation reflected from the chest, and
a pressure device adapted to apply pressure to the oximeter to connect the oximeter to the chest.

2. A chest-based oximeter according to claim 1 in which the pressure device is applied to skin of the chest of the subject, and comprises a material which has a Young's modulus which is lower than that of the skin of the chest of the subject.

3. A chest-based oximeter according to claim 2 in which the pressure device stresses and applies a pressure on the oximeter towards the skin, to connect the oximeter to the chest.

4. A chest-based oximeter according to claim 1 in which the pressure device comprises any of a biasing device, a finger push device, a belt.

5. A chest-based oximeter according to any preceding claim in which the pressure device applies a pressure in the range of approximately 1 Pascal to approximately 100000 Pascal.

6. A chest-based oximeter according to any preceding claim in which the pressure device optically couples the radiation from the radiation source to the chest of the subject, and optically couples the radiation reflected from the chest of the subject to the radiation detector.

7. A chest-based oximeter according to any preceding claim in which the at least one radiation source and the at least one radiation detector are mounted in the chest-based oximeter such that they are spaced apart by a distance in the range of approximately 0.5mm to approximately 2cm.

8. A chest-based oximeter according to any preceding claim in which the at least one radiation source and the at least one radiation detector are mounted in the chest-based oximeter such that, in use, they are positioned in the range of approximately 1cm to approximately 20cm above the chest of the subject.

9. A chest-based oximeter according to any preceding claim in which the at least one radiation source emits radiation having one or more infra red peak wavelengths.

10. A chest-based oximeter according to claim 9 which further comprises a second radiation source which emits radiation having one or more infra red peak wavelengths.

11. A chest-based oximeter according to claim 10 in which the at least one radiation source emits radiation having at least a first infra red peak wavelength, and the second radiation source emits radiation having at least a second, different, infra red peak wavelength.

12. A chest-based oximeter according to any of claims 9 to 11 in which the or each infra red peak wavelength is in the range of 600nm to 1500nm, for example 780nm, 810nm, 820nm, 830nm, 840nm, 850nm, 870nm, 880nm, 890nm, 910nm, 940nm, 970nm, 1050nm, 1070nm, 1200nm, 1300nm, 1350nm, 1450nm, 1550nm.

13. A chest-based oximeter according to any of claims 1 to 8 in which the at least one radiation source emits radiation having one or more visible peak wavelengths.

14. A chest-based oximeter according to claim 13 which further comprises a second radiation source which emits radiation having one or more visible peak wavelengths.

15. A chest-based oximeter according to any of claims 1 to 8 in which the at least one radiation source emits radiation having one or more visible peak wavelengths, and the oximeter further comprises a second radiation source which emits radiation having one or more infra red peak wavelengths.

16. A chest-based oximeter according to any preceding claim which comprises a hydrogel interface.

17. A chest-based oximeter according to any preceding claim which has a low profile.

18. A chest-based oximeter according to any preceding claim which also measures carbon monoxide saturation in blood of the chest of the subject.

19. A chest-based oximeter according to any preceding claim which forms part of a system which measures one or more vital signs of the subject, such as any of heart rate, ECG, respiration rate, temperature.

20. A method of measuring oxygen saturation of haemoglobin in blood of the chest of a subject, comprising

attaching an oximeter to the chest using a pressure device of the oximeter adapted to apply pressure thereto to connect the oximeter to the chest,

operating at least one radiation source of the oximeter to emit radiation onto the chest,

operating at least one radiation detector of the oximeter to detect radiation reflected from the chest, and

using the radiation detected by the detector to measure the oxygen saturation of haemoglobin in blood of the chest.



Fig 1

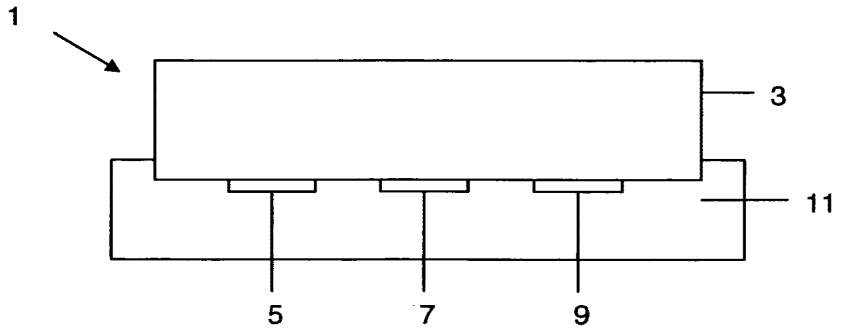


Fig 2

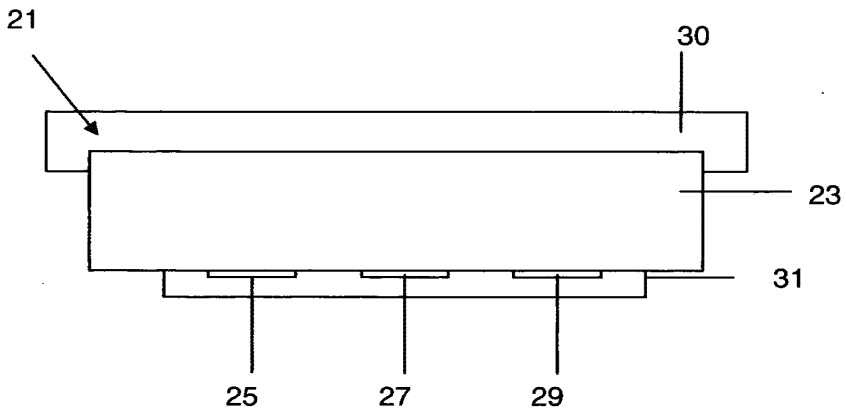


Fig 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/003708

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99/47039 A (AIHONEN JUKKA [FI]; KIRVESKARI JUHA [FI]; PENTTILAE HEIKKI [FI]; SIRKI) 23 September 1999 (1999-09-23) page 7, line 25 - page 11, line 12; figure 5	1,4,5,7, 9-13,15, 19,20
X	US 2002/124295 A1 (FENWICK LOEL [US] ET AL) 12 September 2002 (2002-09-12) paragraphs [0070] - [0072]; claims 1-4	1,4,5,8, 9,12,13, 15,17, 19,20
X	WO 96/16591 A (AIHONEN JUKKA [FI]; PENTTILAE HEIKKI [FI]; SIRKIAE JOUNI [FI]; TUOMINE) 6 June 1996 (1996-06-06) paragraphs [0020] - [0039]; claims	1,4,5, 17-20

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 February 2009	03/03/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Manschot, Jan

Form PCT/ISA/210 (second sheet) (April 2005)

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 112

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/003708

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 425 181 A (PISANI JUSTIN [GB]; HOWARD PETER [GB]; CADE DANIEL [GB]; WARD STEPHEN) 18 October 2006 (2006-10-18) page 5, paragraph 2	1,4,5, 17,19,20
X	US 2007/142715 A1 (BANET MATTHEW J [US] ET AL) 21 June 2007 (2007-06-21) paragraphs [0008], [0009]	1,20
P,X	EP 1 946 697 A (SUISSE ELECTRONIQUE MICROTECH [CH]) 23 July 2008 (2008-07-23) the whole document	1,4,5, 7-13,15, 17,20

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 113

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2008/003708

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9947039 A	23-09-1999	NONE	
US 2002124295 A1	12-09-2002	NONE	
WO 9616591 A	06-06-1996	AU 690764 B2	30-04-1998
		AU 3985095 A	19-06-1996
		EP 0796056 A1	24-09-1997
		FI 945613 A	30-05-1996
		JP 10509083 T	08-09-1998
GB 2425181 A	18-10-2006	NONE	
US 2007142715 A1	21-06-2007	NONE	
EP 1946697 A	23-07-2008	US 2008171926 A1	17-07-2008

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:	Sonny Zhiyu Zhan/Cynthia Losurdo
Attorney Docket Number:	3022036 US01
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:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	1801	1	810	810
		Total in USD ($)		**810**

Electronic Acknowledgement Receipt	
EFS ID:	10166093
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:	88750
Filer:	Sonny Zhiyu Zhan/Cynthia Losurdo
Filer Authorized By:	Sonny Zhiyu Zhan
Attorney Docket Number:	3022036 US01
Receipt Date:	25-MAY-2011
Filing Date:	01-NOV-2006
Time Stamp:	13:51:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$810
RAM confirmation Number	11142
Deposit Account	504979
Authorized User	ZHAN,SONNY
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.16 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.20 (Post Issuance fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment Submitted/Entered with Filing of CPA/RCE	2011-05-25--Resp-to-Advisory-Action-3022036US01.pdf	19359 e31b99fb5766f2498cc752f5abf32aa3907f0c0e	no	2
Warnings:					
Information:					
2	Request for Continued Examination (RCE)	2011-05-25--RCE-3022036US01.pdf	697870 8c128a82bba24dd928a336f08676ff8512ac741c	no	3
Warnings:					
Information:					
3	Transmittal Letter	2011-05-25--IDS-Transmittal-3022036US01.pdf	21869 fd3232ff2bf932a830fff47e319b25b11cc00245	no	2
Warnings:					
Information:					
4	Information Disclosure Statement (IDS) Filed (SB/08)	2011-05-25--IDS-1449-3022036US01.pdf	31275 6cd74086bde49b7060211b72e29adc6c6c30648a	no	2
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
5	Foreign Reference	WO-08142365.pdf	785248 5b528f34ba25d38b80e08fdb55c5fb95851df794	no	19
Warnings:					
Information:					
6	Foreign Reference	WO-09056859.pdf	1216726 83c18dab73830ec6752bc1e98fb62ea07426c265	no	29
Warnings:					
Information:					
7	Fee Worksheet (PTO-875)	fee-info.pdf	30310 9d45ed8f36f192054b4a1723919af47b792f765b	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2802657		

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker	Examiner:	Nicole F. Lavert
Serial No.:	11/591,619	Group Art Unit:	3762
Filed:	November 1, 2006	Docket No.:	3022036 US01
Customer No.:	88750	Confirmation No.:	7955
Title:	Body Worn Physiological Sensor Device Having a Disposable Electrode Module		

RESPONSE

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

Dear Sir:

In response to the final Office Action mailed March 2, 2011 and the Advisory Action mailed May 17, 2011, please consider and enter the following amendments and remarks.

Remarks are included with this paper.

Remarks

This is in reply to the final Office Action mailed March 2, 2011 and the Advisory Action mailed May 17, 2011. A Request for Continued Examination is enclosed herewith. The Amendment and Response filed April 18, 2011 with the Patent Office is incorporated herein by reference in its entirety and is respectfully requested to be entered. Withdrawal of the pending rejections and advancement of this application to allowance are respectfully requested.

Favorable reconsideration in the form of a Notice of Allowance is respectfully requested. Please contact the undersigned attorney with any questions regarding this application. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 50-4979.

Respectfully submitted,

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153/US
(315) 685-4397

Date: May 25, 2011

/Sonny Z. Zhan/
Name: Sonny Z. Zhan
Reg. No.: 62,936

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 121

Doc code: RCEX
Doc description: Request for Continued Examination (RCE)

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. 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 contains a valid OMB control number.

REQUEST FOR CONTINUED EXAMINATION(RCE)TRANSMITTAL
(Submitted Only via EFS-Web)

Application Number	11/591,619	Filing Date	2006-11-01	Docket Number (if applicable)	3022036 US01	Art Unit	3762
First Named Inventor	Steven D. Baker			Examiner Name	Nicole F. Lavert		

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. The Instruction Sheet for this form is located at WWW.USPTO.GOV

SUBMISSION REQUIRED UNDER 37 CFR 1.114

Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

☒ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

- ☒ Consider the arguments in the Appeal Brief or Reply Brief previously filed on 2011-04-18
- ☐ Other _____

☒ Enclosed

- ☒ Amendment/Reply
- ☒ Information Disclosure Statement (IDS)
- ☐ Affidavit(s)/ Declaration(s)
- ☐ Other _____

MISCELLANEOUS

☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of months _____
(Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

☐ Other _____

FEES

☒ **The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.**
The Director is hereby authorized to charge any underpayment of fees, or credit any overpayments, to Deposit Account No 504979

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

☒ Patent Practitioner Signature

☐ Applicant Signature

PTO/SB/30EFS (07-09)
Approved for use through 07/31/2012. 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 contains a valid OMB control number.

Signature of Registered U.S. Patent Practitioner			
Signature	/Sonny Z. Zhan/	Date (YYYY-MM-DD)	2011-05-25
Name	Sonny Z. Zhan	Registration Number	62936

This collection of information is required by 37 CFR 1.114. 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 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.

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

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker et al.	Examiner:	Nicole F. Lavert
Serial No.:	11/591,619	Group Art Unit:	3762
Filed:	November 1, 2006	Docket No.:	3022036 US01
Customer No.:	88750	Confirmation No.:	7955
Title:	Body Worn Physiological Sensor Device Having A Disposable Electrode Module		

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b))

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner.

This statement should be considered because it is submitted before the mailing of a first Office action after the filing of a request for continued examination under § 1.114. Accordingly, no fee is due for consideration of the items listed on the enclosed Form 1449.

In accordance with 37 C.F.R. §1.98(a)(2), a copy of each foreign patent and/or a copy of each publication, other than U.S. patents and U.S. patent application publications, listed on the accompanying Form 1449 is enclosed.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicant reserves the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicant does not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of the attached Form 1449, marked as being considered and initialed by the Examiner, to the undersigned with the next official communication.

Please consider this a petition for extension of time for a sufficient number of months to enter these papers or any future papers, if appropriate. The Commissioner is hereby authorized

to charge any additional fees as set forth in §§ 38 CFR 1.16 to 1.18 which may be required for entry of these papers or to credit any overpayment to Deposit Account No. 50-4979.

Respectfully submitted,
Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153/US
(315) 685-4397

Date: May 25, 2011

/Sonny Z. Zhan/
Name: Sonny Z. Zhan
Reg. No.: 62,936

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 126

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. 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.

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 05/25/2011

	(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 ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 59	Minus	** 60	= 0	X $ =		OR	X $52=	0
Independent (37 CFR 1.16(h))	* 4	Minus	***7	= 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:
/TAMARA DARKO/

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.**

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

DO NOT ENTER: /N.F.L./

05/12/2011

S/N 11/591,619 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker	Examiner:	Nicole F. Lavert
Serial No.:	11/591,619	Group Art Unit:	3762
Filed:	November 1, 2006	Docket No.:	3022036 US01
Customer No.:	88750	Confirmation No.:	7955
Title:	Body Worn Physiological Sensor Device Having a Disposable Electrode Module		

AMENDMENT AND RESPONSE

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

Dear Sir:

In response to the final Office Action mailed March 2, 2011, please consider and enter the following amendments and remarks.

An **Interview Summary** is included with this paper.

Amendments to the **Claims** are included this paper.

Remarks are included with this paper.

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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	3022036 US01	7955

88750 7590 05/17/2011

HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	
MAIL DATE	DELIVERY MODE
05/17/2011	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.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 11/591,619	**Applicant(s)** BAKER ET AL.	
	Examiner NICOLE F. LAVERT	**Art Unit** 3762	

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

THE REPLY FILED 18 April 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-6,8-39,41-44 and 59-61*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

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Continuation of 3. NOTE: The amendment to the independent claims, 1 & 59, such as the addition of at least one series current-limiting resistor being in the form of resistive traces…" will require a further search and/or a further consideration in the prior art is required.

Continuation of 11. does NOT place the application in condition for allowance because: The amendments to the claims will require a further search and/or a further consideration in the prior art is required..

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker	Examiner:	Nicole F. Lavert
Serial No.:	11/591,619	Group Art Unit:	3762
Filed:	November 1, 2006	Docket No.:	3022036 US01
Customer No.:	88750	Confirmation No.:	7955
Title:	Body Worn Physiological Sensor Device Having a Disposable Electrode Module		

AMENDMENT AND RESPONSE

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

Dear Sir:

In response to the final Office Action mailed March 2, 2011, please consider and enter the following amendments and remarks.

An **Interview Summary** is included with this paper.

Amendments to the **Claims** are included this paper.

Remarks are included with this paper.

Interview Summary

On April 5, 2011, Applicants' attorney Sonny Z. Zhan and inventor Steven D. Baker had a telephonic interview with the Examiner Nicole F. Lavert regarding this application. The items discussed included the outstanding claim rejections. Proposed claim amendments to overcome the rejections were discussed. Although no agreement was made, it is believed that these claim amendments overcome the outstanding rejections, and allowance of the pending claims is requested.

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In the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently Amended) A body worn patient monitoring device comprising:

a disposable module including a plurality of electrical connections, said 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 disposable module including a disposable module connector;

a power source to power the body worn patient monitoring device;

a communication-computation module being removable and reusable, having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector, the communication-computation module including:

a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event, and

a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver, wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module and the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient; and

at least one series current-limiting resistor configured to protect the communication-computation module, the at least one series current-limiting resistor being screened ~~in the form of resistive traces~~ on a flexible substrate, the at least one series current-limiting resistor being in the form of resistive traces.

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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.

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

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.

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

6. (Previously Presented) The body worn device of claim 5, wherein the at least one series current-limiting resistor protects the communication-computation module during a patient defibrillation event.

7. (Canceled)

8. (Previously Presented) The body worn device of claim 4, wherein the mechanical interface from the at least one series current-limiting resistor to the EGG electrode includes a filleted edge.

9. (Previously Presented) The body worn device of claim 4, wherein the mechanical interface from the at least one series current-limiting resistor to the EGG electrode comprises overlapped layers.

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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.

11. (Previously Presented) The body worn device of claim 1, further comprising an insulating material overlaying the at least one series current-limiting resistor to prevent arcing.

12. (Original) The body worn device of claim 5, wherein the EGG electrodes are formed substantially in the shape of an annulus.

13. (Original) The body worn device of claim 12, wherein the annulus comprises a conductive link.

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.

15. (Previously Presented) The body worn device of claim 1, wherein the power source is a renewable power source internal to the body worn device.

16. (Previously Presented) The body worn device of claim 1, wherein the power source comprises a rechargeable battery or a one time use battery.

17. (Previously Presented) The body worn device of claim 1, wherein the power source is a battery contained within said disposable module.

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18. (Previously Presented) The body worn device of claim 1, wherein the power source is a Seebeck device.

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).

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

21. (Previously Presented) 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.

22. (Previously Presented) The body worn device of claim 20, wherein the virtual electrode is adapted to include 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. (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.

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.

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

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.

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.

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.

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.

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

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.

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.

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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.

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

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.

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

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 pacemaker.

38. (Previously Presented) The body worn device of claim 1, wherein the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.

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.

40. (Canceled)

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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.

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.

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.

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.

45. (Withdrawn) 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

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printing the second material onto the substrate wherein at least part of the second the material overlays the first material.

46. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

49. (Withdrawn) 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

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protection resistor is electrically disposed between at least one of said plurality of electrical connections and said ECG electronics module.

50. (Withdrawn) The EGG monitor of claim 49, wherein said at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

51. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from said at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a filleted edge.

52. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from the at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a plurality of overlapped layers.

53. (Withdrawn) The EGG 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.

54. (Withdrawn) 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

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module to disable said pacer detect circuit in order to reduce said electrical load on said power source.

55. (Withdrawn) The ECG monitor of claim 54, wherein said power source is a battery.

56. (Withdrawn) 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 an 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; and

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. (Withdrawn) 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 signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

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58. (Withdrawn) 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.

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59. (Currently Amended) A body worn patient monitoring device comprising:

a disposable module including a plurality of electrical connections, the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals, the disposable module including a disposable module connector;

a power source to power the body worn patient monitoring device;

a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module including:

a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event,

a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver, and

wherein the disposable module has a mechanical and electrical coupling to the communication-computation module, forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient; and

at least one series current-limiting resistor configured to protect the communication-computation module, the at least one series current-limiting resistor being screened ~~in the form of resistive traces~~ on a flexible substrate, the at least one series current-limiting resistor being in the form of resistive traces.

60. (Previously Presented) The body worn device of claim 1, wherein the radio circuit communicates an unprocessed physiological signal.

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61. (Previously Presented) The body worn device of claim 1, wherein the radio circuit communicates a result of the physiological analysis at a predetermined time.

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Remarks

This is in reply to the final Office Action mailed March 2, 2011. Applicants wish to thank the Examiner for her careful review and consideration of this application.

In the subject Action, claims 1-6, 8-39, 41-44 and 59-61 are rejected. Claims 1 and 59 are amended to further define subject matter. No new matter has been entered hereby. Claims 1-6, 8-39 and 41-61 remain pending in the present application. In light of the foregoing amendments and the following remarks, withdrawal of the pending rejections and advancement of this application to allowance are requested.

I. Claim Rejections - 35 U.S.C. § 103

A. Claims 1, 4-5, 12-18 and 59-61

Claims 1, 4-5, 8-18 and 59-61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric et al. (hereinafter "Stivoric"), U.S. Patent Application Publication 2005/0245839, in view of Fadem et al. (hereinafter "Fadem"), U.S. Patent Application Publication 2007/0270678, Potts et al. (hereinafter "Potts"), U.S. Patent Application Publication 2002/0106709, Welch et al. (hereinafter "Welch"), U.S. Patent Application Publication 2005/0206518, and Merry et al. (hereinafter "Merry"), U.S. Patent No. 6,623,312. These rejections are respectfully traversed for at least the following reasons.

Claim 1 is amended to further clarify subject matter. Claim 1, as currently amended, recites, in part, "the at least one series current-limiting resistor being in the form of resistive traces." (emphasis added)

Some example advantages of such a body worn patient monitoring device including a series current-limiting resistor being in the form of resistive traces are described in paragraphs [0006] and [0009] of the present application. Such a body worn patient monitoring device can solve the conventional problems, for example, the physical volume of conventional power resistors is too large for use in a compact monitor application. Such a body worn patient monitoring device can advantageously, with a physically compact resistive element, protect the

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body worn device from damage caused by multiple defibrillation cycles.

Furthermore, in a non-limiting example, as further described in paragraph [0055] of the present application, resistive traces on flexible circuit board layer 101 replace the bulky power resistors needed by prior art monitors. These resistive traces 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 dissipate that portion of the potentially damaging defibrillation energy that is coupled into the monitor.

In contrast, Merry discloses, as conceded on page 9 of the Office Action, that the electrical components (resistors) 294 are actually mounted on the printed circuit board 292. See Merry, col. 7, ll. 14-15; Fig. 3. Merry fails to disclose "the at least one series current-limiting resistor being in the form of resistive traces", as required by claim 1 of the present application.

On page 10, the Office Action alleges that Ulmer (U.S. Pat. No. 6,539,613) teaches that it is well known to form resistors into a substrate via embedding and depositing said resistor into a substrate. Applicants respectfully point out that resistors disclosed in Ulmer are not in the form of resistive traces. See Ulmer, e.g., Figs. 2-8. Ulmer fails to disclose "the at least one series current-limiting resistor being in the form of resistive traces", as required by claim 1 of the present application.

Further, none of the cited references Stivoric, Fadem, Potts and Welch, alone or in combination, discloses "the at least one series current-limiting resistor being in the form of resistive traces", as required by claim 1 of the present application.

Therefore, even if it is proper to combine the cited references (which point Applicants do not concede), the combination fails to disclose or suggest all limitations of claim 1. Applicants therefore respectfully request reconsideration and withdrawal of the pending rejection. Claim 1 should be allowable. Reconsideration and allowance of claim 1, as well as claims 4-5, 8-18 and 60-61 that depend therefrom, are respectfully requested.

Claim 59, as currently amended, recites, in part, "the at least one series current-limiting resistor being in the form of resistive traces." (emphasis added) Claim 59 is therefore allowable for at least similar reasons to those provided above with respect to claim 1. Reconsideration and

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allowance of claim 59 are respectfully requested.

B. Claims 2-3 and 19-24

Claims 2-3 and 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, Welch, and Merry, in further view of Schraag, U.S. Patent No. 5,309,918. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 2-3 and 19-24 depend from claim 1. Schraag fails to remedy the shortcomings of Stivoric, Fadem, Potts, Welch, and Merry noted above. Claims 2-3 and 19-24 are therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 2-3 and 19-24 are respectfully requested.

C. Claims 25-32, 39 and 42-44

Claims 25-32, 39 and 42-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, Welch, and Merry, in further view of Jackson et al., U.S. Patent Application Publication 2005/0137489. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 25-32, 39 and 42-44 depend from claim 1. Jackson et al. fails to remedy the shortcomings of Stivoric, Fadem, Potts, Welch, and Merry noted above. Claims 25-32, 39 and 42-44 are therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 25-32, 39 and 42-44 are respectfully requested.

D. Claims 33-37

Claims 33-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, Welch, and Merry, in further view of Westra et al., U.S. Patent Application Publication 2006/0183434. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 33-37 depend from claim 1. Westra et al. fails to remedy the shortcomings of

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Stivoric, Fadem, Potts, Welch, and Merry noted above. Claims 33-37 are therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 33-37 are respectfully requested.

F. Claim 38

Claim 38 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, Welch, and Merry, in further view of Eshelman et al., U.S. Patent Application Publication 2003/0001742. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 38 depends from claim 1. Eshelman et al. fails to remedy the shortcomings of Stivoric, Fadem, Potts, Welch, and Merry noted above. Claim 38 is therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 38 are respectfully requested.

G. Claim 41

Claim 41 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, Welch, and Merry, in further view of Owen et al., U.S. Patent Application Publication 2003/0055460. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 41 depends from claim 1. Owen et al. fails to remedy the shortcomings of Stivoric, Fadem, Potts, Welch, and Merry noted above. Claim 41 is therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 41 are respectfully requested.

II. Conclusion

The remarks set forth above provide certain arguments in support of the patentability of the pending claims. There may be other reasons that the pending claims are patentably distinct over the cited references, and the right to raise any such other reasons or arguments in the future

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is expressly reserved.

Favorable reconsideration in the form of a Notice of Allowance is respectfully requested. Please contact the undersigned attorney with any questions regarding this application. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 50-4979.

Respectfully submitted,

Welch Allyn, Inc.
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(315) 685-4397

Date: April 18, 2011

/Sonny Z. Zhan/
Name: Sonny Z. Zhan
Reg. No.: 62,936

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Electronic Acknowledgement Receipt

EFS ID:	9898611
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:	88750
Filer:	Sonny Zhiyu Zhan/Cynthia Losurdo
Filer Authorized By:	Sonny Zhiyu Zhan
Attorney Docket Number:	3022036 US01
Receipt Date:	18-APR-2011
Filing Date:	01-NOV-2006
Time Stamp:	13:24:21
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		2011-04-18--Amendment-to-OA-Dated-2011-03-02.pdf	61483 dc87194454b078965b8f738e2e229a5b2501ffa4	yes	20

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment After Final	1	1
	Applicant summary of interview with examiner	2	2
	Claims	3	15
	Applicant Arguments/Remarks Made in an Amendment	16	20
Warnings:			
Information:			
	Total Files Size (in bytes):	61483	

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/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 04/18/2011

	(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))	* 59	Minus	** 60	= 0	X $ =		OR	X $52=	0
Independent (37 CFR 1.16(h))	* 4	Minus	***7	= 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:
/LINDA A. WASHINGTON/

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.**

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

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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_049/054 (3022036 US01	7955

88750 7590 04/08/2011

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SYRACUSE, NY 13202

EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
04/08/2011	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.

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

All participants (applicant, applicant's representative, PTO personnel):

(1) *NICOLE F. LAVERT*.

(2) *STEVEN D. BAKER*.

(3) *SONNY Z. ZHAN*.

(4) _____.

Date of Interview: *05 April 2011*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *1*.

Identification of prior art discussed: *Merry et al. (US 6,623,312)*.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Based on the submitted arguments and/or amendments the examiner will be required to perform another search and/or take a further consideration in the prior art cited.*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/Nicole F. LaVert/ Examiner, Art Unit 3762	

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 156

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

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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_049/054 (3022036 US01	7955

88750 7590 03/02/2011

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EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
03/02/2011	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 *13 December 2010*.

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) *1-6,8-39,41-44 and 59-61* is/are pending in the application.

4a) Of the above claim(s) *45-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-39,41-44 and 59-61* 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 *1/8/07* 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 *2/2/10, 12/29/09, 10/20/09, 6/3/08, 2/16/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

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, 4-6, 8-18 & 59-61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839) in view of Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709), Welch et al. (US 2005/0206518) and Merry et al. (US 6,623,312

Stivoric et al. discloses a body worn patient monitoring device {e.g., [0039] & (Fig 8)}: a disposable module (e.g., element 314) including a plurality of electrical connections (e.g., via disclosed sensors 120 & 125) adaptable to be coupled to a skin surface to measure physiological signals, the disposable module including a disposable module connector (e.g., [0046], [0124] & [0317]-[0138]), a power source (e.g., element 135) to power said device; and a communication-computation module which receives physiological signals from the disposable module (e.g.,

[0040]-[0041] & [0097]), the communication-computation module (e.g., element 55) being removable [e.g., 0137] including a radio circuit to communicate, upon determination of the predetermined physiological event, a result of said event (e.g., via the disclosed means of transmitting derived, i.e. determined, data related to the "trend of change" in physiological measurements that meet certain preset, i.e. predetermined, thresholds [0048]), via a radio transmission (e.g., element 72) and/or communicate an unprocessed physiological signal (e.g., via the disclosed transmission of "raw signals) to a remote radio receiver (e.g., elements 65 & 70) {e.g., , [0041], [0106], [0109] & (Fig 1)}, wherein the disposable module is mechanically and electrically coupled directly to the communication module and the body worn monitoring device including the disposable module and the communication module is adapted to be directly non-permanently affixed to the skin surface of the patient {e.g., [0137]-[0138] & (Fig 8)}.

Stivoric et al. discloses the claimed invention having a body worn patient monitoring device comprising a plurality of electrical connections adapted to measure physiological signals and a communication-computation module, except wherein at least one of said electrical connection further comprises a half cell and/or are ECG electrodes and the communication-computation module further comprises a microprocessor to perform a real-time physiological analysis of and communicate said signals from a disposable and/or reusable module and wherein said device further comprises at least one series current-limiting resistor being screened in the form of resistive traces on a flexible substrate. Fadem et al. teaches that it is known to use a disposable, sealed electronics module that is adapted to be affixed to a location of a subjects skin used for capturing ECG signals, wherein said module further comprises an electrode module (e.g., element 23) having an electrode pad (e.g., element 32) and a contact pad (e.g., element 33)

that is impregnated with a conduction enhancing substance {e.g., [0043]-[0044] & (Fig 2)}. 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). Potts et al. teaches that it is known to use a disposable, monitoring device having a microprocessor configured to receive raw signals at selected time intervals and analysis said signals (i.e., compare to parameter threshold values) in order to predict a specific physiological event (e.g., [0014]-[0015] & [0036]). Welch et al. teaches that it is known to use a wearable monitoring device that is disposable as well as reusable [e.g., 0095]. Merry et al. teaches that it is known to use an electrode structure comprising a current-limiting resistor (e.g., element 294), wherein said resistor is mounted on a printed circuit board (e.g., element 292) [e.g., (col 1, ln 7-10), (col 7, ln 32-59) & (Fig 3)]. Note that it is well known in the art that the disclosed printed circuit board (e.g., element 292) that contains said resistors (e.g., element 294) comprise some type of flexible non-conductive, substrate material used in order to properly house electrical components of a given circuit, wherein the method of mounting said resistor, i.e. via the claimed means of forming resistive traces on a flexible substrate. Therefore, 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 Stivoric et al. with the half-cell electrode module capable of measuring ECG signals as taught by Fadem et al., the microprocessor capable of performing real-time physiological analysis of measured signals as taught by Potts et al., the reusable and disposable wearable monitoring device as taught by Welch et al. and the current-limiting resistor as taught by Merry et al.,, since such a modification would provide the body worn device that is capable of

monitoring and analyzing ECG signals via flexible, conductive electrical connections that are disposable and non-permanently affixed to the skin surface of the patient, wherein the body worn patient monitoring device further comprises at least one series current limiting resistor for providing the predictable results pertaining to electrically measuring physiological signals from a patient via a means that is conductively maintained in constant contact with the skin so that the patient can move about normally and/or perform normal day-to-day activities when wearing the device [e.g., Fadem, 0044] and provide the results of adaptively determining the physiological state of the patient based on real-time measurements made from a monitoring system so as to have the capability of providing adaptive, individual-specific treatment to said patient based on the measurements (e.g., Potts, [0014]-[0015] & [0036]) and provide the results of using a wearable monitoring device that can be reapplied to another part of the body without being damaged and/or not functioning properly [e.g., Welch, 0095] and provide a means of 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).

4. **Claims 2-3 & 19-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709), Welch et al. (US 2005/0206518) and Merry et al. (US 6,623,312), as applied to claims 1, 4-6, 8-18 & 59-61 above, in further view of Schraag (US 5,309,918).

Stivoric/Fadem/Potts/Welch/Merry et al. discloses the claimed invention having a body worn monitoring device except for the device further comprising at least one indirect electrical connection to the body, wherein the electrical connection is 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 Stivoric/Fadem/Potts/Welch/Merry 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).

5. **Claims 25-32, 39 & 42-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709), Welch et al. (US 2005/0206518) and Merry et al. (US 6,623,312), as applied to claims 1, 4-6, 8-18 & 59-61 above, in further view of Jackson et al. (US 2005/0137489).

Stivoric/Fadem/Potts/Welch/Merry 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 Stivoric/Fadem/Potts/Welch/Merry 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].

6. **Claims 33-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709), Welch et al. (US 2005/0206518) and Merry et al. (US 6,623,312), as applied to claims 1, 4-6, 8-18 & 59-61 above, in further view of Westra et al. (US 2006/0183434).

Stivoric/Fadem/Potts/Welch/Merry 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 Stivoric/Fadem/Potts/Welch/Merry 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].

7. **Claim 38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709), Welch et al. (US 2005/0206518) and Merry et al. (US 6,623,312), as applied to claims 1, 4-6, 8-18 & 59-61 above, in further view of Eshelman et al. (US 2003/0001742).

Stivoric/Fadem/Potts/Welch/Merry 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 Stivoric/Fadem/Potts/Welch/Merry 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].

8. **Claim 41** is rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709), Welch et al. (US 2005/0206518) and Merry et al. (US 6,623,312), as applied to claims 1, 4-6, 8-18 & 59-61 above, in further view of Owen et al. (US 2003/0055460).

Stivoric/Fadem/Potts/Welch/Merry 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 Stivoric/Fadem/Potts/Welch/Merry 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

9. Applicant's arguments filed December 15, 2010 have been fully considered but they are not persuasive. The applicant argues that the cited references, neither alone nor in combination discloses at least one series current-limiting resistor since the modifying reference, Merry et al., only mentions that the resistor is used and has no disclosure of any embodiment of a current-limiting resistor on a flexible substrate therefore said cited references fails to disclose "the at least one series current-limiting resistor being screened in the form of resistive traces on a flexible substrate." The examiner disagrees and further points out the Merry et al. discloses the use of the resistors (e.g., 294) mounted on the printed circuit board (e.g., element 292), wherein

said resistors are used to limit the amount of current that passes through the circuit to a safe level, therefore providing a means of current-limiting via a resistive means as is instantly claimed [e.g., (col 7, ln 32-59) & (Fig 3)}.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ulmer (US 6,539,613) teaches that it is well known in the art to form resistors into a substrate via embedding and depositing said resistor into a substrate.

THIS ACTION IS MADE FINAL. 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 mailing 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, Niketa Patel can be reached on 571-272-4156. 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.

/Nicole F. LaVert/
Examiner, Art Unit 3762

/Niketa I. Patel/
Supervisory Patent 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-6,539,613 B1	04-2003	Ulmer, Kenneth R.	29/620
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	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
" "	" "	3/3/2010	NFL
" "	" "	9/7/2010	NFL
ABOVE	UPDATED	2/17/2011	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_049/054 (3022036 US01

APPLICANTS

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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		STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
❑ Yes ☑ No	❑ Yes ☑ No	/NICOLE F LAVERT/ Examiner's Signature	❑ Met after Allowance NFL Initials	OR	14	58	6

ADDRESS

HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202
UNITED STATES

TITLE

Body worn physiological sensor device having a disposable electrode module

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
3954	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

BIB (Rev. 05/07).

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L6	2101	resistor same (trac$4 same substrate)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:24
L7	36	l6 and (medical same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:24
L8	19	l7 and @py<="2006"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:25
L9	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:28
L10	1	l9 and trac$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/18 10:28
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

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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
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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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
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

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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
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

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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
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

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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
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

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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
S45	985	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:02
S46	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:09
S47	254	600/382.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:15
S48	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:29
S49	1	S48 and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:29
S50	4	"20040242976" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:32

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S51	8148	implantable same housing	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:32
S52	6084	S51 and medical	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
S53	1908	S52 and module	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
S54	148	S53 and modular	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
S55	0	"20040176818" and ECG	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:17
S56	1	"20040176818" and cardiac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:17
S57	1	"11591619" and disposable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:59
S58	5	"20040242976"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:01

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S59	0	"20040176818" and releas$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:06
S60	0	"20040176818" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:08
S61	162763	dispos$4 same electrodes	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:15
S62	1241	S61 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S63	231	"l120" and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S64	102	S63 and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S65	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
S66	84	S65 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18

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S67	1	"11591619" and (indirect same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26
S68	1	"11591619" and (indirect same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26
S69	1	"11591619" and (direct same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:28
S70	1	"20070270678" and "30"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
S71	1	"20070270678" and strip	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
S72	0	"20070270678" and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
S73	2	"20060074284"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
S74	2	"20070270678" and substrate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:05

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S75	15	"6064901"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:08
S76	0	S75 and resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:12
S77	145267	(current same limit$4) and electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S78	1311	S77 and (disposable same electrode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S79	116	S78 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S80	10	S79 and ((current same limit$4) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:14
S81	1	"11591619" and annulus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:20
S82	0	"11591619" and Seebeek	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:22

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S83	1	"11591619" and Seebeck	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:23
S84	2	"20060183434"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:40
S85	9	"6623312"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:46
S86	1	"11591619" and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:20
S87	0	"20070270678" and caridac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S88	0	"20070270678" and cardiac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S89	1	"20070270678" and heart	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S90	1	"11591619" and (pacer same detection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:30

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S91	743453	external same device	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S92	5324	S91 and wearable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S93	3581	S92 and (wearable same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S94	1128	S93 and (cardiac or heart)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S95	101	S94 and (detect$4 same (cardiac same event))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:34
S96	3	"20060238333"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:45
S97	5	"2004084720"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S98	0	"2004084720" and (high same voltage)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13

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Exhibit 1002
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S99	0	"2004084720" and (circuit same protection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S100	0	"2004084720" and diodes	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:15
S101	1	"2004084720" and detect$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:15
S102	0	"2004008738" and (pacer same detect$)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:43
S103	687	(pacer same detection) same circuit	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:46
S104	360	S103 and (external same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:46
S105	219	S104 and @py<="2005"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:47
S106	107019	(patient same monitor $4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:06

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S107	11349	S106 and (wear$4 or garment or clothing)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:06
S108	5925	S107 and dispos$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
S109	2609	S108 and (power same source)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
S110	2165	S109 and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
S111	244	S110 and (physiological same analysis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:08
S112	2	"20020106709"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:36
S113	2	"20050245839"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:44
S114	1	"11591619" and (communication same module)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:09

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S115	1	"20050245839" and wireless	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:13
S116	1	"20050245839" and microprocessor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:14
S117	1	"11591619" and (disposable same connector)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:14
S118	1	"11591619" and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:17
S119	231	"20050245839" andconductive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:21
S120	1	"20050245839" and conductive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:21
S121	1102	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:25
S122	533	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:51

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S123	262	600/382.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 13:10
S124	1	"20020106709" and (real same time)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 13:24
S125	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 17:45
S126	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 18:09
S127	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 22:03
S128	1275	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/17 12:45
S129	571	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2011/02/17 16:30

EAST Search History (Interference)

< This search history is empty>

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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
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 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
		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]
	BA	JP 11-088546	03-30-1999	NEC Corp.		

Examiner Signature	/Nicole LaVert/	Date Considered	02/17/2011

*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, 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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Sheet 2 of 2

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Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 US01)

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]
	CA	Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2006-507455 (5 pages).	

Examiner Signature	/Nicole LaVert/	Date Considered	02/17/2011

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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
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☐ 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
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MARJAMA & BILINSKI LLP
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Customer No. 20874

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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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
	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.		

Examiner Signature	/Nicole LaVert/	Date Considered	02/17/2011

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L./

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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

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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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Examiner Signature	/Nicole LaVert/	Date Considered	02/17/2011

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

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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
	AL1	US-4,141,367 A	02/27/1979	Ferreira	
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Sheet 1 of 2

Complete if Known	
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

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
	A	US- 5,319,363	06-07-1994	Welch et al.	
	B	US- 5,579,001	11-26-1996	Dempsey et al.	
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Sheet 2 of 2

Complete if Known	
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

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
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	BB	WO 01/89362 A2 and A3	11-29-2001	West et al.		
	CC	WO 01/97686 A1	12-27-2001	Voegeli et al.		

Examiner Signature	/Nicole LaVert/	Date Considered	02/17/2011

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Application Number	11591619
Filing Date	2006-11-01
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US01

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	1	20040252031		2004-12-16	Taylor	
	2	20090043185		2009-02-12	McAdams et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11591619
	Filing Date	2006-11-01
	First Named Inventor	Steven D. Baker
	Art Unit	3762
	Examiner Name	Nicole F. Lavert
	Attorney Docket Number	3022036 US01

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker	Examiner:	Nicole F. Lavert
Serial No.:	11/591,619	Group Art Unit:	3762
Filed:	November 1, 2006	Docket No.:	704_049/054 US01
Customer No.:	88750	Confirmation No.:	7955
Title:	Body Worn Physiological Sensor Device Having a Disposable Electrode Module		

AMENDMENT AND RESPONSE

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

Dear Sir:

In response to the non-final Office Action mailed September 13, 2010, please consider and enter the following amendments and remarks.

Amendments to the **Claims** are included this paper.

Remarks are included with this paper.

In the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently Amended) A body worn patient monitoring device comprising:

a disposable module including a plurality of electrical connections, said 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 disposable module including a disposable module connector;

a power source to power the body worn patient monitoring device; [[and]]

a communication-computation module being removable and reusable, having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector, the communication-computation module including:

a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event, and

a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, via a radio transmission to a remote radio receiver, wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module and the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient; and

at least one series current-limiting resistor configured to protect the communication-computation module, the at least one series current-limiting resistor being screened in the form of resistive traces on a flexible substrate.

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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.

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

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.

5. (Currently Amended) The body worn device of claim 4, wherein the ECG electrodes comprise a material screened onto [[a]] the flexible substrate.

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

7. (Canceled)

8. (Currently Amended) The body worn device of claim [[7]] 4, wherein the mechanical interface from the at least one series current-limiting resistor to the EGG electrode includes a filleted edge.

9. (Currently Amended) The body worn device of claim [[7]] 4, wherein the mechanical interface from the at least one series current-limiting resistor to the EGG electrode comprises overlapped layers.

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Page 205

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.

11. (Currently Amended) The body worn device of claim [[6]] 1, further comprising an insulating material overlaying the at least one series current-limiting resistor to prevent arcing.

12. (Original) The body worn device of claim 5, wherein the EGG electrodes are formed substantially in the shape of an annulus.

13. (Original) The body worn device of claim 12, wherein the annulus comprises a conductive link.

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.

15. (Previously Presented) The body worn device of claim 1, wherein the power source is a renewable power source internal to the body worn device.

16. (Previously Presented) The body worn device of claim 1, wherein the power source comprises a rechargeable battery or a one time use battery.

17. (Previously Presented) The body worn device of claim 1, wherein the power source is a battery contained within said disposable module.

18. (Previously Presented) The body worn device of claim 1, wherein the power source is a Seebeck device.

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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).

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

21. (Previously Presented) 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.

22. (Previously Presented) The body worn device of claim 20, wherein the virtual electrode is adapted to include 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. (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.

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.

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

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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.

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.

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.

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.

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

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.

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.

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.

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

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.

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

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 pacemaker.

38. (Previously Presented) The body worn device of claim 1, wherein the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.

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.

40. (Canceled)

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

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of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, to save power.

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.

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.

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.

45. (Withdrawn) 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.

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46. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

49. (Withdrawn) 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.

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50. (Withdrawn) The EGG monitor of claim 49, wherein said at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

51. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from said at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a filleted edge.

52. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from the at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a plurality of overlapped layers.

53. (Withdrawn) The EGG 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.

54. (Withdrawn) 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. (Withdrawn) The ECG monitor of claim 54, wherein said power source is a battery.

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56. (Withdrawn) 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 an 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; and

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. (Withdrawn) 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 signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

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58. (Withdrawn) 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.

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59. (Currently Amended) A body worn patient monitoring device comprising:

a disposable module including a plurality of electrical connections, the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals, the disposable module including a disposable module connector;

a power source to power the body worn patient monitoring device; [[and]]

a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module including:

a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event,

a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver, and

wherein the disposable module has a mechanical and electrical coupling to the communication-computation module, forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient; and

at least one series current-limiting resistor configured to protect the communication-computation module, the at least one series current-limiting resistor being screened in the form of resistive traces on a flexible substrate.

60. (Previously Presented) The body worn device of claim 1, wherein the radio circuit communicates an unprocessed physiological signal.

61. (Previously Presented) The body worn device of claim 1, wherein the radio circuit communicates a result of the physiological analysis at a predetermined time.

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Remarks

This is in reply to the non-final Office Action mailed September 13, 2010. Applicants wish to thank the Examiner for her careful review and consideration of this application.

In the Office Action, claims 1-39, 41-44 and 59-61 are rejected. Claim 7 is now canceled without prejudice or disclaimer, and subject matter from the claim is incorporated into claims 1 and 59. Claims 1 and 59 are amended to further define subject matter. Claims 5, 6, 8, 9 and 11 are amended to make some formality changes. No new matter has been entered hereby. Claims 1-6, 8-39 and 41-61 remain pending in the present application. In light of the foregoing amendments and the following remarks, withdrawal of the pending rejections and advancement of this application to allowance are requested.

I. Claim Rejections - 35 U.S.C. § 103

A. Claims 1, 4-5, 12-18 and 59-61

Claims 1, 4-5, 12-18 and 59-61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric et al. (hereinafter "Stivoric"), U.S. Patent Application Publication 2005/0245839, in view of Fadem et al. (hereinafter "Fadem"), U.S. Patent Application Publication 2007/0270678, Potts et al. (hereinafter "Potts"), U.S. Patent Application Publication 2002/0106709, and Welch et al. (hereinafter "Welch"), U.S. Patent Application Publication 2005/0206518. These rejections are respectfully traversed for at least the following reasons.

Claim 1, as currently amended, recites, in part, a body worn patient monitoring device including a communication-computation module and "at least one series current-limiting resistor configured to protect the communication-computation module, the at least one series current-limiting resistor being screened in the form of resistive traces on a flexible substrate." (emphasis added) These amendments are fully supported, for example, at paragraphs [0054]-[0058], [0066]-[0067] and [0086], and Figs. 4A-4D, 15 and 16A-6B of the originally filed Specification.

Some example advantages of such a body worn patient monitoring device including a series current-limiting resistor being screened in the form of resistive traces on a flexible

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substrate are described in paragraphs [0006] and [0009] of the present application. Such a body worn patient monitoring device can solve the conventional problems, for example, the physical volume of conventional power resistors is too large for use in a compact monitor application. Such a body worn patient monitoring device can advantageously, with a physically compact resistive element, protect the body worn device from damage caused by multiple defibrillation cycles.

As admitted in section 4 of the Office Action, none of the cited references Stivoric, Fadem, Potts and Welch, alone or in combination, discloses "at least one series current-limiting resistor". The Office Action has alleged that Merry et al. (U.S. Patent No. 6,623,312) teaches that it is known to use an electrode structure comprising a current-limiting resistor. However, Merry is directed to an electrode connector to cure misalignment problems between the connector contacts and the electrode contacts. See Merry, col. 1, ll. 34-36; col. 2, ll. 29-30. Merry discloses the resistors 294 are suitably rated to operate under normal loads. If a spike in the voltage is detected, the resistors 294 limit the amount of current that passes through the circuit to a safe level. See Merry, col. 7, ll. 38-43. Merry only mentions that a resistor is used. Merry has no disclosure of any embodiment of a current-limiting resistor on a flexible substrate. The electrical components (resistors) 294 are actually "mounted" on a lower surface of the printed circuit board 292. See Merry, col. 7, ll. 14-15. Further, Merry has no disclosure of implementing a current-limiting resistor in a small package. Therefore, Merry fails to disclose "the at least one series current-limiting resistor being screened in the form of resistive traces on a flexible substrate", as required by claim 1 of the present application.

Applicants further do not believe that there is any suggestion to combine the five (5) references as suggested by the Examiner. However, assuming *arguendo* that the five references were combined, the combination fails to disclose or suggest all limitations of claim 1. Reconsideration and allowance of claim 1, as well as claims 4-5, 12-18 and 60-61 that depend therefrom, are respectfully requested.

Claim 59 recites, in part, a body worn patient monitoring device including at least one series current-limiting resistor configured to protect the communication-computation module, the

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at least one series current-limiting resistor being screened in the form of resistive traces on a flexible substrate. Claim 59 is therefore allowable for at least similar reasons to those provided above with respect to claim 1. Reconsideration and allowance of claim 59 are respectfully requested.

B. Claims 6-11

Claims 6-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, and Welch, in further view of Merry. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

As discussed above, independent claim 1 is allowable. Thus, dependent claims 6 and 8-11 are allowable over the art of record. It is respectfully noted that claim 7 is canceled without prejudice or disclaimer, and subject matter from the claim is incorporated into claim 1. Reconsideration and allowance of claims 6 and 8-11 are respectfully requested.

C. Claims 2-3 and 19-24

Claims 2-3 and 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, and Welch, in further view of Schraag, U.S. Patent No. 5,309,918. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 2-3 and 19-24 depend from claim 1. Schraag fails to remedy the shortcomings of Stivoric, Fadem, Potts, and Welch noted above. Claims 2-3 and 19-24 are therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 2-3 and 19-24 are respectfully requested.

D. Claims 25-32, 39 and 42-44

Claims 25-32, 39 and 42-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, and Welch, in further view of Jackson et al., U.S. Patent Application Publication 2005/0137489. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

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Claims 25-32, 39 and 42-44 depend from claim 1. Jackson et al. fails to remedy the shortcomings of Stivoric, Fadem, Potts, and Welch noted above. Claims 25-32, 39 and 42-44 are therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 25-32, 39 and 42-44 are respectfully requested.

E. Claims 33-37

Claims 33-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, and Welch, in further view of Westra et al., U.S. Patent Application Publication 2006/0183434. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 33-37 depend from claim 1. Westra et al. fails to remedy the shortcomings of Stivoric, Fadem, Potts, and Welch noted above. Claims 33-37 are therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 33-37 are respectfully requested.

F. Claim 38

Claim 38 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, and Welch, in further view of Eshelman et al., U.S. Patent Application Publication 2003/0001742. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 38 depends from claim 1. Eshelman et al. fails to remedy the shortcomings of Stivoric, Fadem, Potts, and Welch noted above. Claim 38 is therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 38 are respectfully requested.

G. Claim 41

Claim 41 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, Potts, and Welch, in further view of Owen et al., U.S. Patent Application Publication

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2003/0055460. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 41 depends from claim 1. Owen et al. fails to remedy the shortcomings of Stivoric, Fadem, Potts, and Welch noted above. Claim 41 is therefore allowable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 41 are respectfully requested.

II. Conclusion

The remarks set forth above provide certain arguments in support of the patentability of the pending claims. There may be other reasons that the pending claims are patentably distinct over the cited references, and the right to raise any such other reasons or arguments in the future is expressly reserved.

Favorable reconsideration in the form of a Notice of Allowance is respectfully requested. Please contact the undersigned attorney with any questions regarding this application. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 50-4979.

Respectfully submitted,

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(315) 685-4397

Date: December 13, 2010

/Sonny Z. Zhan/
Name: Sonny Z. Zhan
Reg. No.: 62,936

Electronic Acknowledgement Receipt

EFS ID:	9021067
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:	88750
Filer:	Sonny Zhiyu Zhan/Cynthia Losurdo
Filer Authorized By:	Sonny Zhiyu Zhan
Attorney Docket Number:	704_049/054 (3022036 US01
Receipt Date:	13-DEC-2010
Filing Date:	01-NOV-2006
Time Stamp:	15:32:02
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		Amendment-to-OA-Dated-20100913.pdf	106973 71aaf242be841c527029208a849101b1bdb38823	yes	18

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	13
	Applicant Arguments/Remarks Made in an Amendment	14	18
Warnings:			
Information:			
	Total Files Size (in bytes):	106973	

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/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
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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	12/13/2010	(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))	* 59	Minus	** 60	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 7	Minus	***7	= 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:
/LASHAWN MORGAN/

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	704_049/054 (3022036 US01	7955

88750 7590 09/13/2010

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EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
09/13/2010	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 May 2010*.

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 and 59-61* 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 and 59-61* 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 *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/2/10, 12/29/09, 10/20/09, 6/3/08 & 2/16/07.

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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, 4-5, 12-18 & 59-61** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839) in view of Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709) and Welch et al. (US 2005/0206518).

Stivoric et al. discloses a body worn patient monitoring device {e.g., [0039] & (Fig 8)}: a disposable module (e.g., element 314) including a plurality of electrical connections (e.g., via disclosed sensors 120 & 125) adaptable to be coupled to a skin surface to measure physiological signals, the disposable module including a disposable module connector (e.g., [0046], [0124] & [0317]-[0138]), a power source (e.g., element 135) to power said device; and a communication-computation module which receives physiological signals from the disposable module (e.g.,

[0040]-[0041] & [0097]), the communication-computation module (e.g., element 55) being removable [e.g., 0137] including a radio circuit to communicate, upon determination of the predetermined physiological event, a result of said event (e.g., via the disclosed means of transmitting derived, i.e. determined, data related to the "trend of change" in physiological measurements that meet certain preset, i.e. predetermined, thresholds [0048]), via a radio transmission (e.g., element 72) and/or communicate an unprocessed physiological signal (e.g., via the disclosed transmission of "raw signals) to a remote radio receiver (e.g., elements 65 & 70) {e.g., , [0041], [0106], [0109] & (Fig 1)}, wherein the disposable module is mechanically and electrically coupled directly to the communication module and the body worn monitoring device including the disposable module and the communication module is adapted to be directly non-permanently affixed to the skin surface of the patient {e.g., [0137]-[0138] & (Fig 8)}.

Stivoric et al. discloses the claimed invention having a body worn patient monitoring device comprising a plurality of electrical connections adapted to measure physiological signals and a communication-computation module, except wherein at least one of said electrical connection further comprises a half cell and/or are ECG electrodes and the communication-computation module further comprises a microprocessor to perform a real-time physiological analysis of and communicate said signals from a disposable and/or reusable module. Fadem et al. teaches that it is known to use a disposable, sealed electronics module that is adapted to be affixed to a location of a subjects skin used for capturing ECG signals, wherein said module further comprises an electrode module (e.g., element 23) having an electrode pad (e.g., element 32) and a contact pad (e.g., element 33) that is impregnated with a conduction enhancing substance {e.g., [0043]-[0044] & (Fig 2)}. 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). Potts et al. teaches that it is known to use a disposable, monitoring device having a microprocessor configured to receive raw signals at selected time intervals and analysis said signals (i.e., compare to parameter threshold values) in order to predict a specific physiological event (e.g., [0014]-[0015] & [0036]). Welch et al. teaches that it is known to use a wearable monitoring device that is disposable as well as reusable [e.g., 0095]. 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 Stivoric et al. with the half-cell electrode module capable of measuring ECG signals as taught by Fadem et al., the microprocessor capable of performing real-time physiological analysis of measured signals as taught by Potts et al. and the reusable and disposable wearable monitoring device as taught by Welch et al., since such a modification would provide the body worn device that is capable of monitoring and analyzing ECG signals via flexible, conductive electrical connections that are disposable and non-permanently affixed to the skin surface of the patient for providing the predictable results pertaining to electrically measuring physiological signals from a patient via a means that is conductively maintained in constant contact with the skin so that the patient can move about normally and/or perform normal day-to-day activities when wearing the device [e.g., Fadem, 0044] and provide the results of adaptively determining the physiological state of the patient based on real-time measurements made from a monitoring system so as to have the capability of providing adaptive, individual-specific treatment to said patient based on the measurements (e.g., Potts, [0014]-[0015] & [0036]) and provide the results of using a wearable monitoring device

that can be reapplied to another part of the body without being damaged and/or not functioning properly [e.g., Welch, 0095].

4. **Claims 6-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709) and Welch et al. (US 2005/0206518)., as applied to claims 1, 4-5 & 12-18 above, in further view of Merry et al. (US 6,623,312).

Stivoric/Fadem/Potts/Welch 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 Stivoric/Fadem/Potts/Welch 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 2-3 & 19-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709) and Welch et al. (US 2005/0206518), as applied to claims 1, 4-5 & 12-18 above, in further view of Schraag (US 5,309,918).

Stivoric/Fadem/Potts/Welch et al. discloses the claimed invention having a body worn monitoring device except for the device further comprising at least one indirect electrical

connection to the body, wherein the electrical connection is 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 Stivoric/Fadem/Potts/Welch 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 Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709) and Welch et al. (US 2005/0206518), as applied to claims 1, 4-5 & 12-18 above, in further view of Jackson et al. (US 2005/0137489).

Stivoric/Fadem/Potts/Welch 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 Stivoric/Fadem/Potts/Welch 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 Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709) and Welch et al. (US 2005/0206518), as applied to claims 1, 4-5 & 12-18 above, in further view of Westra et al. (US 2006/0183434).

Stivoric/Fadem/Potts/Welch 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 Stivoric/Fadem/Potts/Welch 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 Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709) and Welch et al. (US 2005/0206518), as applied to claims 1, 4-5 & 12-18 above, in further view of Eshelman et al. (US 2003/0001742).

Stivoric/Fadem/Potts 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 Stivoric/Fadem/Potts 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 Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678), Potts et al. (US 2002/0106709) and

Welch et al. (US 2005/0206518), as applied to claims 1, 4-5 & 12-18 above, in further view of Owen et al. (US 2003/0055460).

Stivoric/Fadem/Potts/Welch 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 Stivoric/Fadem/Potts/Welch 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 1-39, 41-44 & 59-61 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendments.

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, Niketa Patel can be reached on 571-272-4156. 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.

/Niketa I. Patel/
Supervisory Patent 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

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,309,918 A	05-1994	Schraag, Martin	600/508
*	B	US-2002/0106709 A1	08-2002	Potts et al.	435/14
*	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-2005/0206518 A1	09-2005	Welch et al.	340/539.12
*	H	US-2005/0245839 A1	11-2005	Stivoric et al.	600/549
*	I	US-2006/0183434 A1	08-2006	Westra et al.	455/078
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	K	US-			
	L	US-			
	M	US-			

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*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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	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
" "	" "	3/3/2010	NFL
" "	" "	9/7/2010	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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**** CONTINUING DATA **************************

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

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11/21/2006

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

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TITLE

Body worn physiological sensor device having a disposable electrode module

FILING FEE RECEIVED		
3954	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

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 22:03
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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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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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S41	3	"20060044856"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2008/12/04 19:13
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S45	985	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:02
S46	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:09

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S47	254	600/382.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:15
S48	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:29
S49	1	S48 and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:29
S50	4	"20040242976" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:32
S51	8148	implantable same housing	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:32
S52	6084	S51 and medical	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
S53	1908	S52 and module	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
S54	148	S53 and modular	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33

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S55	0	"20040176818" and ECG	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:17
S56	1	"20040176818" and cardiac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:17
S57	1	"11591619" and disposable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:59
S58	5	"20040242976"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:01
S59	0	"20040176818" and releas$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:06
S60	0	"20040176818" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:08
S61	162763	dispos$4 same electrodes	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:15
S62	1241	S61 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16

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S63	231	"l120" and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S64	102	S63 and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S65	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
S66	84	S65 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
S67	1	"11591619" and (indirect same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26
S68	1	"11591619" and (indirect same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26
S69	1	"11591619" and (direct same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:28
S70	1	"20070270678" and "30"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39

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S71	1	"20070270678" and strip	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
S72	0	"20070270678" and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
S73	2	"20060074284"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
S74	2	"20070270678" and substrate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:05
S75	15	"6064901"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:08
S76	0	S75 and resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:12
S77	145267	(current same limit$4) and electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S78	1311	S77 and (disposable same electrode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13

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S79	116	S78 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S80	10	S79 and ((current same limit$4) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:14
S81	1	"11591619" and annulus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:20
S82	0	"11591619" and Seebeek	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:22
S83	1	"11591619" and Seebeck	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:23
S84	2	"20060183434"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:40
S85	9	"6623312"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:46
S86	1	"11591619" and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:20

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S87	0	"20070270678" and caridac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S88	0	"20070270678" and cardiac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S89	1	"20070270678" and heart	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S90	1	"11591619" and (pacer same detection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:30
S91	743453	external same device	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S92	5324	S91 and wearable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S93	3581	S92 and (wearable same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S94	1128	S93 and (cardiac or heart)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33

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S95	101	S94 and (detect$4 same (cardiac same event))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:34
S96	3	"20060238333"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:45
S97	5	"2004084720"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S98	0	"2004084720" and (high same voltage)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S99	0	"2004084720" and (circuit same protection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S100	0	"2004084720" and diodes	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:15
S101	1	"2004084720" and detect$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:15
S102	0	"2004008738" and (pacer same detect$)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:43

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S103	687	(pacer same detection) same circuit	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:46
S104	360	S103 and (external same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:46
S105	219	S104 and @py<="2005"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:47
S106	107019	(patient same monitor $4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:06
S107	11349	S106 and (wear$4 or garment or clothing)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:06
S108	5925	S107 and dispos$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
S109	2609	S108 and (power same source)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
S110	2165	S109 and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07

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S111	244	S110 and (physiological same analysis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:08
S112	2	"20020106709"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:36
S113	2	"20050245839"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:44
S114	1	"11591619" and (communication same module)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:09
S115	1	"20050245839" and wireless	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:13
S116	1	"20050245839" and microprocessor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:14
S117	1	"11591619" and (disposable same connector)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:14
S118	1	"11591619" and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:17

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S119	231	"20050245839" andconductive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:21
S120	1	"20050245839" and conductive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:21
S121	1102	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:25
S122	533	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:51
S123	262	600/382.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 13:10
S124	1	"20020106709" and (real same time)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 13:24
S125	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 17:45
S126	3	"20050206518"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/09/07 18:09

EAST Search History (Interference)

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Page 255

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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
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 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
		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]
	BA	JP 11-088546	03-30-1999	NEC Corp.		

Examiner Signature	/Nicole LaVert/	Date Considered	09/07/2010

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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
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 US01)

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]
	CA	Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2006-507455 (5 pages).	

Examiner Signature	/Nicole LaVert/	Date Considered	09/07/2010

*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.

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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
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☐ 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

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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)

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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
MARJAMA & BILINSKI LLP
250 South Clinton Street
Suite 300
Syracuse, New York 13202
(315) 425-9000
Customer No. 20874

FEB 16 2007
PATENT & TRADEMARK OFFICE

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

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
	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.		

Examiner Signature	/Nicole LaVert/	Date Considered	09/07/2010

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L./

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

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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

	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.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L./

Examiner Signature	/Nicole LaVert/	Date Considered	09/07/2010

FEB 16 2007
PATENT & TRADEMARK OFFICE

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

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV967909486US in an envelope addressed to:

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)

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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
	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	
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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	09/07/2010

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

Complete if Known	
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

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
	A	US- 5,319,363	06-07-1994	Welch et al.	
	B	US- 5,579,001	11-26-1996	Dempsey et al.	
	C	US- 5,579,775	12-03-1996	Dempsey et al.	
	D	US- 5,682,803	11-04-1997	Gideon et al.	
	E	US- 5,687,734	11-18-1997	Dempsey et al.	
	F	US- 5,748,103	05-05-1998	Flach et al.	
	G	US- 5,767,791	06-16-1998	Stoop, et al.	
	H	US- 5,917,414 A	06-29-1999	Oppelt et al.	
	I	US- 6,057,758 A	05-02-2000	Dempsey et al.	
	J	US- 6,198,394 B1	03-06-2001	Jacobsen et al.	
	K	US- 6,440,067 B1	08-27-2002	DeLuca et al.	
	L	US- 6,544,171 B2	04-08-2003	Beetz et al.	
	M	US- 6,544,173	04-08-2003	West et al.	
	N	US- 6,544,174	04-08-2003	West et al.	
	O	US- 6,579,231 B1	06-17-2003	Phipps	
	P	US- 6,847,892 B2	06-02-2002	Zhou et al.	
	Q	US- 6,870,484 B1	03-22-2005	Brinsfield et al.	
	R	US- 7,382,247 B2	06-03-2008	Welch et al.	
	S	US- 7,439,856 B2	10-21-2008	Weiner et al.	

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	09/07/2010

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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
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 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
	T	US- 7,515,043 B2	04-07-2009	Welch et al.	
	U	US- 7,515,044 B2	04-07-2009	Welch et al.	
	V	US- 2001/0023315 A1	09-20-2001	Flach et al.	
	W	US- 2005/0116820 A1	06-02-2005	Goldreich	
	X	US- 2005/0206518 A1	09-22-2005	Welch et al.	
	Y	US- 2006/0238333 A1	10-26-2006	Welch et al.	
	Z	US- 2007/0013511 A1	01-18-2007	Weiner et al.	
	AA	US- 2007/0069887 A1	03-29-2007	Welch et al.	
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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]
	BB	WO 01/89362 A2 and A3	11-29-2001	West et al.		
	CC	WO 01/97686 A1	12-27-2001	Voegeli et al.		

Examiner Signature	/Nicole LaVert/	Date Considered	09/07/2010

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	11591619
Filing Date	2006-11-01
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US01

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040252031		2004-12-16	Taylor	
	2	20090043185		2009-02-12	McAdams et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	11591619
	Filing Date	2006-11-01
	First Named Inventor	Steven D. Baker
	Art Unit	3762
	Examiner Name	Nicole F. Lavert
	Attorney Docket Number	3022036 US01

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Nicole LaVert/	Date Considered	09/07/2010

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L./

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker	Examiner:	Nicole F. Lavert
Serial No.:	11/591,619	Group Art Unit:	3762
Filed:	November 1, 2006	Docket No.:	704_049/054 US01
Customer No.:	88750	Confirmation No.:	7955
Title:	Body Worn Physiological Sensor Device Having a Disposable Electrode Module		

AMENDMENT AND RESPONSE

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

Dear Sir:

In response to the non-final Office Action mailed March 16, 2010, please consider and enter the following amendments and remarks.

Amendments to the **Claims** are included this paper.

Remarks are included with this paper.

In the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently Amended) A body worn patient monitoring device comprising:

a disposable module including a plurality of electrical connections, said 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 disposable module including a disposable module connector;

a power source to power the body worn patient monitoring device; and

a communication-computation module being removable and reusable, having a communication-computation module connector to receive physiological signals from the disposable module via said disposable module connector, the communication-computation module including:

a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event, and

a radio circuit to communicate, upon determination of the predetermined physiological event, ~~an unprocessed physiological signal or~~ a result of the physiological analysis ~~at a predetermined time or~~ on [[an]] the occurrence of [[a]] the predetermined physiological event, via a radio transmission to a remote radio receiver, wherein the disposable module is mechanically and electrically coupled directly to the communication-computation module and the body worn patient monitoring device including the disposable module and the communication-computation module is adapted to be directly non-permanently affixed to the skin surface of the patient.

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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.

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

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.

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

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.

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.

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

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

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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.

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.

12. (Original) The body worn device of claim 5, wherein the EGG electrodes are formed substantially in the shape of an annulus.

13. (Original) The body worn device of claim 12, wherein the annulus comprises a conductive link.

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.

15. (Previously Presented) The body worn device of claim 1, wherein the power source is a renewable power source internal to the body worn device.

16. (Previously Presented) The body worn device of claim 1, wherein the power source comprises a rechargeable battery or a one time use battery.

17. (Previously Presented) The body worn device of claim 1, wherein the power source is a battery contained within said disposable module.

18. (Previously Presented) The body worn device of claim 1, wherein the power source is a Seebeck device.

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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).

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

21. (Previously Presented) 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.

22. (Previously Presented) The body worn device of claim 20, wherein the virtual electrode is adapted to include 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. (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.

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.

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

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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.

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.

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.

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.

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

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.

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.

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.

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

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.

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

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 pacemaker.

38. (Previously Presented) The body worn device of claim 1, wherein the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.

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.

40. (Canceled)

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

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of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, to save power.

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.

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.

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.

45. (Withdrawn) 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.

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46. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

49. (Withdrawn) 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.

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50. (Withdrawn) The EGG monitor of claim 49, wherein said at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

51. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from said at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a filleted edge.

52. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from the at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a plurality of overlapped layers.

53. (Withdrawn) The EGG 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.

54. (Withdrawn) 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. (Withdrawn) The ECG monitor of claim 54, wherein said power source is a battery.

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56. (Withdrawn) 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 an 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; and

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. (Withdrawn) 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 signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

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58. (Withdrawn) 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.

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59. (Previously Presented) A body worn patient monitoring device comprising:

a disposable module including a plurality of electrical connections, the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals, the disposable module including a disposable module connector;

a power source to power the body worn patient monitoring device; and

a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module including:

a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event,

a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver, and

wherein the disposable module has a mechanical and electrical coupling to the communication-computation module, forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient.

60. (New) The body worn device of claim 1, wherein the radio circuit communicates an unprocessed physiological signal.

61. (New) The body worn device of claim 1, wherein the radio circuit communicates a result of the physiological analysis at a predetermined time.

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Remarks

This is in reply to the non-final Office Action mailed March 16, 2010. Applicants wish to thank the Examiner for the Examiner's careful review and consideration of this application.

In the subject Action, claims 1-39 and 41-44 are rejected. Claim 40 has previously been canceled without prejudice or disclaimer. Claims 45-58 have previously been withdrawn. Claim 1 is amended to further define subject matter. New claims 60-61 are added. No new matter has been entered hereby. Claim 59 has previously been added, but the subject Action did not make a disposition of claim 59. A disposition of claim 59 is respectfully required. Claims 1-39 and 41-61 remain pending in the present application. In light of the foregoing amendments and the following remarks, withdrawal of the pending rejections and advancement of this application to allowance are requested.

I. Claim Rejections - 35 U.S.C. § 103

A. Claims 1, 4-5 and 12-18

Claims 1, 4-5 and 12-18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric et al. (hereinafter "Stivoric"), U.S. Patent Application Publication 2005/0245839, in view of Fadem et al. (hereinafter "Fadem"), U.S. Patent Application Publication 2007/0270678, and Potts et al. (hereinafter "Potts"), U.S. Patent Application Publication 2002/0106709. These rejections are respectfully traversed for at least the following reasons.

First, claim 1, as currently amended, recites, in part, a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event. (emphasis added) Even presupposing that Stivoric, Fadem and Potts are combined, none of the cited references disclose and/or teaches this feature in claim 1. Rather, Stivoric discloses a multi component system includes a module in addition to a receiver for receiving temperature and other data measurement. See Stivoric, e.g., para. [0040]. Data may be processed by module 55 and transmitted by primary transmission 72 to a receiver. Id. at para. [0106]; Fig. 1. The module and receiver disclosed in Stivoric do not

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suggest a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, as required by claim 1 of the present application.

Fadem also fails to disclose a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event.

Potts discloses a microprocessor of controlling a sensing mechanism to obtain a series of raw signals at selected time intervals, predicting a measurement value at a further time interval, and comparing the predicted measurement value to a predetermined threshold value. See Potts, e.g., para. [0014]. Obtaining signals at selected time intervals and comparing the predicted and predetermined values disclosed in Potts do not suggest a radio circuit to communicate, upon determination of the predetermined physiological event, a result of the physiological analysis on the occurrence of the predetermined physiological event, as required by claim 1 of the present application.

Second, claim 1 recites, in part, a disposable module and a communication-computation module being removable and reusable. (emphasis added) In contrast, Stivoric fails to disclose or suggest this feature. Rather, Stivoric discloses a multi component system includes a module in addition to a receiver for receiving temperature and other data measurement. See Stivoric, e.g., para. [0040]. Stivoric discloses "FIG. 8 illustrates a fourth embodiment of module 55 which is a disposable embodiment." Id. at para. [0137]. That is, Stivoric conceives of multiple embodiments of the module where one is disposable and a completely separate embodiment is disposable. No disclosure in Stivoric suggests that a portion of the module is reusable and another portion is disposable.

Neither Fadem nor Potts discloses a disposable module and a communication-computation module being removable and reusable, as required by claim 1 of the present application.

Therefore, even if it is proper to combine the cited references, the combination fails to disclose or suggest all limitations of claim 1. Reconsideration and allowance of claim 1, as well

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as claims 4-5 and 12-18 that depend respectively therefrom, are respectfully requested.

B. Claims 6-11

Claims 6-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, and Potts, in further view of Merry et al., U.S. Patent No. 6,623,312. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 6-11 depend (directly or indirectly) from claim 1. Merry et al. fails to remedy the shortcomings of Stivoric, Fadem, and Potts noted above. Claims 6-11 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 6-11 are respectfully requested.

C. Claims 2-3 and 19-24

Claims 2-3 and 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, and Potts, in further view of Schraag, U.S. Patent No. 5,309,918. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 2-3 and 19-24 depend (directly or indirectly) from claim 1. Schraag fails to remedy the shortcomings of Stivoric, Fadem, and Potts noted above. Claims 2-3 and 19-24 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 2-3 and 19-24 are respectfully requested.

D. Claims 25-32, 39 and 42-44

Claims 25-32, 39 and 42-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, and Potts, in further view of Jackson et al., U.S. Patent Application Publication 2005/0137489. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 25-32, 39 and 42-44 depend (directly or indirectly) from claim 1. Jackson et al. fails to remedy the shortcomings of Stivoric, Fadem, and Potts noted above. Claims 25-32, 39 and 42-44 are therefore patentable for at least the same reasons as those provide above for claim

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1. Reconsideration and allowance of claims 25-32, 39 and 42-44 are respectfully requested.

E. Claims 33-37

Claims 33-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, and Potts, in further view of Westra et al., U.S. Patent Application Publication 2006/0183434. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 33-37 depend (directly or indirectly) from claim 1. Westra et al. fails to remedy the shortcomings of Stivoric, Fadem, and Potts noted above. Claims 33-37 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 33-37 are respectfully requested.

F. Claim 38

Claim 38 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, and Potts, in further view of Eshelman et al., U.S. Patent Application Publication 2003/0001742. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 38 depends from claim 1. Eshelman et al. fails to remedy the shortcomings of Stivoric, Fadem, and Potts noted above. Claim 38 is therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 38 are respectfully requested.

G. Claim 41

Claim 41 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stivoric, Fadem, and Potts, in further view of Owen et al., U.S. Patent Application Publication 2003/0055460. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 41 depends from claim 1. Owen et al. fails to remedy the shortcomings of

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Stivoric, Fadem, and Potts noted above. Claim 41 is therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 41 are respectfully requested.

II. New Claims

New claims 60-61 depend from claim 1 and further define over the art of record. Consideration and allowance of the claims are respectfully requested.

III. Conclusion

The remarks set forth above provide certain arguments in support of the patentability of the pending claims. There may be other reasons that the pending claims are patentably distinct over the cited references, and the right to raise any such other reasons or arguments in the future is expressly reserved.

Favorable reconsideration in the form of a Notice of Allowance is respectfully requested. Please contact the undersigned attorney with any questions regarding this application. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 50-4979.

Respectfully submitted,

Date: May 26, 2010

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Customer No.: 88750

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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:	Sonny Zhiyu Zhan
Attorney Docket Number:	704_049/054 (3022036 US01

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:				
Claims in excess of 20	1202	2	52	104
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**104**

Electronic Acknowledgement Receipt

EFS ID:	7693364
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:	88750
Filer:	Sonny Zhiyu Zhan
Filer Authorized By:	
Attorney Docket Number:	704_049/054 (3022036 US01
Receipt Date:	26-MAY-2010
Filing Date:	01-NOV-2006
Time Stamp:	16:10:29
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Electronic Funds Transfer
Payment was successfully received in RAM	$104
RAM confirmation Number	2461
Deposit Account	
Authorized User	

File Listing:

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

1		2010-05-26--Response-To-OA.pdf	94928 5a60a5743334646c3a4989524c7912c037f4894	yes	18

Multipart Description/PDF files in .zip description		
Document Description	**Start**	**End**
Amendment/Req. Reconsideration-After Non-Final Reject	1	1
Claims	2	13
Applicant Arguments/Remarks Made in an Amendment	14	18

Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	30081 b9ef8aebaf98dac56af8d2d1782f064d2e8cbabb	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	125009		

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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.

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/591,619	Filing Date 11/01/2006	☒ To be Mailed

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☐ RATE ($)	SMALL ENTITY ☐ FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	OTHER THAN SMALL ENTITY FEE ($)
FOR	NUMBER FILED	NUMBER EXTRA					
☐ 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 05/26/2010

	(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 ($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 60	Minus	** 58	= 2	X $ =		OR	X $52=	104
Independent (37 CFR 1.16(h))	* 7	Minus	***7	= 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	**104**

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:
/KATRINA HARLING/

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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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/591,619	11/01/2006	Steven D. Baker	704_049/054 (3022036 US01	7955

88750 7590 03/16/2010

HISCOCK & BARCLAY, LLP
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EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
03/16/2010	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 *07 December 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 and 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 and 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 *2/2/10, 12/29/09, 10/20/09, 6/3/08, 2/16/07*.
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 293

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, 4-5 & 12-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839) in view of Fadeem et al. (US 2007/0270678) and Potts et al. (US 2002/0106709).

Stivoric et al. discloses a body worn patient monitoring device {e.g., [0039] & (Fig 8)}: a disposable module (e.g., element 314) including a plurality of electrical connections (e.g., via disclosed sensors 120 & 125) adaptable to be coupled to a skin surface to measure physiological signals, the disposable module including a disposable module connector (e.g., [0046], [0124] & [0317]-[0138]), a power source (e.g., element 135) to power said device; and a communication-computation module which receives physiological signals from the disposable module (e.g.,

[0040]-[0041] & [0097]), the communication-computation module including a radio circuit to communicate an unprocessed physiological signal (e.g., via the disclosed transmission of "raw signals) or a result of event, via a radio transmission (e.g., element 72) to a remote radio receiver (e.g., elements 65 & 70) {e.g., [0041], [0106], [0109] & (Fig 1)}, wherein the disposable module is mechanically and electrically coupled directly to the communication module and the body worn monitoring device including the disposable module and the communication module is adapted to be directly non-permanently affixed to the skin surface of the patient {e.g., [0137]-[0138] & (Fig 8)}.

Stivoric et al. discloses the claimed invention having a body worn patient monitoring device comprising a plurality of electrical connections adapted to measure physiological signals and a communication-computation module, except wherein at least one of said electrical connection further comprises a half cell and/or are ECG electrodes and the communication-computation module further comprises a microprocessor to perform a real-time physiological analysis of said signals from the disposable module. Fadem et al. teaches that it is known to use a disposable, sealed electronics module that is adapted to be affixed to a location of a subjects skin used for capturing ECG signals, wherein said module further comprises an electrode module (e.g., element 23) having an electrode pad (e.g., element 32) and a contact pad (e.g., element 33) that is impregnated with a conduction enhancing substance {e.g., [0043]-[0044] & (Fig 2)}. 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). Potts et al. teaches that it is known to use a disposable, monitoring device having a microprocessor

configured to receive raw signals at selected time intervals and analysis said signals (i.e., compare to parameter threshold values) in order to predict a specific physiological event (e.g., [0014]-[0015] & [0036]). 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 Stivoric et al. with the half-cell electrode module capable of measuring ECG signals as taught by Fadem et al. and the microprocessor capable of performing real-time physiological analysis of measured signals as taught by Potts et al., since such a modification would provide the body worn device that is capable of monitoring and analyzing ECG signals via flexible, conductive electrical connections that are disposable and non-permanently affixed to the skin surface of the patient for providing the predictable results pertaining to electrically measuring physiological signals from a patient via a means that is conductively maintained in constant contact with the skin so that the patient can move about normally and/or perform normal day-to-day activities when wearing the device [e.g., Fadem, 0044] and provide the results of adaptively determining the physiological state of the patient based on real-time measurements made from a monitoring system so as to have the capability of providing adaptice, individual-specific treatment to said patient based on the measurements (e.g., [0014]-[0015] & [0036]).

4. **Claims 6-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678) and Potts et al. (US 2002/0106709), as applied to claims 1, 4-5 & 12-18 above, in further view of Merry et al. (US 6,623,312).

Stivoric/Fadem/Potts 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 Stivoric/Fadem/Potts 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 2-3 & 19-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678) and Potts et al. (US 2002/0106709), as applied to claims 1, 4-5 & 12-18 above, in further view of Schraag (US 5,309,918).

Stivoric/Fadem/Potts et al. discloses the claimed invention having a body worn monitoring device except for the device further comprising at least one indirect electrical connection to the body, wherein the electrical connection is 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 Stivoric/Fadem/Potts 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 Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678) and Potts et al. (US 2002/0106709), as applied to claims 1, 4-5 & 12-18 above, in further view of Jackson et al. (US 2005/0137489).

Stivoric/Fadem/Potts 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 Stivoric/Fadem/Potts 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 Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678) and Potts et al. (US 2002/0106709), as applied to claims 1, 4-5 & 12-18 above, in further view of Westra et al. (US 2006/0183434).

Stivoric/Fadem/Potts 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 Stivoric/Fadem/Potts 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 Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678) and Potts et al. (US 2002/0106709), as applied to claims 1, 4-5 & 12-18 above, in further view of Eshelman et al. (US 2003/0001742).

Stivoric/Fadem/Potts 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 Stivoric/Fadem/Potts 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 Stivoric et al. (US 2005/0245839), Fadeem et al. (US 2007/0270678) and Potts et al. (US 2002/0106709), as applied to claims 1, 4-5 & 12-18 above, in further view of Owen et al. (US 2003/0055460).

Stivoric/Fadem/Potts 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 Stivoric/Fadem/Potts 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 1-39 & 41-44 have been considered but are moot in view of the new ground(s) of rejection as necessitated by amendments.

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, Carl Layno can be reached at 571-272-4949. 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.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/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-2002/0106709 A1	08-2002	Potts et al.	435/14
*	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-6,623,312 B2	09-2003	Merry et al.	439/729
*	G	US-2005/0137489 A1	06-2005	Jackson et al.	600/515
*	H	US-2005/0245839 A1	11-2005	Stivoric et al.	600/549
*	I	US-2006/0074284 A1	04-2006	Juola et al.	600/372
*	J	US-2006/0136001 A1	06-2006	Ortega et al.	607/009
*	K	US-2006/0183434 A1	08-2006	Westra et al.	455/078
*	L	US-2007/0270678 A1	11-2007	Fadem et al.	600/372
	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)
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	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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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_049/054 (3022036 US01

APPLICANTS

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Thomas P. Blackadar, Natick, MA;

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

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

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

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /NICOLE F LAVERT/ Examiner's Signature	☐ Met after Allowance NFL Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		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		
3850	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

BIB (Rev. 05/07).

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
" "	" "	3/3/2010	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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EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L3	107019	(patient same monitor $4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:06
L4	11349	l3 and (wear$4 or garment or clothing)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:06
L5	5925	l4 and dispos$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
L6	2609	l5 and (power same source)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
L7	2165	l6 and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:07
L8	244	l7 and (physiological same analysis)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:08
L9	2	"20020106709"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:36

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L10	2	"20050245839"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 11:44
L11	1	"11591619" and (communication same module)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:09
L12	1	"20050245839" and wireless	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:13
L13	1	"20050245839" and microprocessor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:14
L14	1	"11591619" and (disposable same connector)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:14
L15	1	"11591619" and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:17
L16	231	"20050245839" andconductive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:21
L17	1	"20050245839" and conductive	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:21

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L18	1102	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:25
L19	533	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 12:51
L20	262	600/382.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 13:10
L21	1	"20020106709" and (real same time)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2010/03/03 13:24
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

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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

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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
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

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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
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

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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
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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S45	985	607/60.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:02
S46	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:09
S47	254	600/382.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:15
S48	1	"11591619"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:29
S49	1	S48 and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:29
S50	4	"20040242976" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:32
S51	8148	implantable same housing	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:32
S52	6084	S51 and medical	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33

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S53	1908	S52 and module	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
S54	148	S53 and modular	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 13:33
S55	0	"20040176818" and ECG	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:17
S56	1	"20040176818" and cardiac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:17
S57	1	"11591619" and disposable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 14:59
S58	5	"20040242976"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:01
S59	0	"20040176818" and releas$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:06
S60	0	"20040176818" and gel	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:08

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S61	162763	dispos$4 same electrodes	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:15
S62	1241	S61 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S63	231	"l120" and communication	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S64	102	S63 and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:16
S65	502	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
S66	84	S65 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:18
S67	1	"11591619" and (indirect same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26
S68	1	"11591619" and (indirect same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:26

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S69	1	"11591619" and (direct same connection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:28
S70	1	"20070270678" and "30"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
S71	1	"20070270678" and strip	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:39
S72	0	"20070270678" and capacit$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
S73	2	"20060074284"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 15:58
S74	2	"20070270678" and substrate	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:05
S75	15	"6064901"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:08
S76	0	S75 and resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:12

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S77	145267	(current same limit$4) and electrode	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S78	1311	S77 and (disposable same electrode)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S79	116	S78 and (ECG same monitor$4)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:13
S80	10	S79 and ((current same limit$4) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:14
S81	1	"11591619" and annulus	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:20
S82	0	"11591619" and Seebeek	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:22
S83	1	"11591619" and Seebeck	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:23
S84	2	"20060183434"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:40

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S85	9	"6623312"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/07 16:46
S86	1	"11591619" and (half same cell)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:20
S87	0	"20070270678" and caridac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S88	0	"20070270678" and cardiac	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S89	1	"20070270678" and heart	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:29
S90	1	"11591619" and (pacer same detection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:30
S91	743453	external same device	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S92	5324	S91 and wearable	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33

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S93	3581	S92 and (wearable same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S94	1128	S93 and (cardiac or heart)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:33
S95	101	S94 and (detect$4 same (cardiac same event))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:34
S96	3	"20060238333"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 15:45
S97	5	"2004084720"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S98	0	"2004084720" and (high same voltage)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S99	0	"2004084720" and (circuit same protection)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:13
S100	0	"2004084720" and diodes	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:15

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S101	1	"2004084720" and detect$4	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:15
S102	0	"2004008738" and (pacer same detect$)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:43
S103	687	(pacer same detection) same circuit	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:46
S104	360	S103 and (external same device)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:46
S105	219	S104 and @py<="2005"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2009/07/17 16:47

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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
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 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
		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]
	BA	JP 11-088546	03-30-1999	NEC Corp.		

Examiner Signature	/Nicole LaVert/	Date Considered	03/03/2010

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 2

Complete if Known	
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	704_049/054 (3022036 US01)

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]
	CA	Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2006-507455 (5 pages).	

Examiner Signature	/Nicole LaVert/	Date Considered	03/03/2010

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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.

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TRANSMITTAL FORM

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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*)

☐ 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

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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).

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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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MARJAMA & BILINSKI LLP
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iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 326

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 2

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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
	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.		

Examiner Signature	/Nicole LaVert/	Date Considered	03/03/2010

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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

	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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Examiner Signature	/Nicole LaVert/	Date Considered	03/03/2010

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FEB 16 2007
PATENT & TRADEMARK OFFICE

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

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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
	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.	
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	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.	
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	AY1	US-2006/0205171 A1	09/14/2006	Tsukada	
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FOREIGN PATENT DOCUMENTS

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Sheet 1 of 2

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Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US01

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	A	US- 5,319,363	06-07-1994	Welch et al.	
	B	US- 5,579,001	11-26-1996	Dempsey et al.	
	C	US- 5,579,775	12-03-1996	Dempsey et al.	
	D	US- 5,682,803	11-04-1997	Gideon et al.	
	E	US- 5,687,734	11-18-1997	Dempsey et al.	
	F	US- 5,748,103	05-05-1998	Flach et al.	
	G	US- 5,767,791	06-16-1998	Stoop, et al.	
	H	US- 5,917,414 A	06-29-1999	Oppelt et al.	
	I	US- 6,057,758 A	05-02-2000	Dempsey et al.	
	J	US- 6,198,394 B1	03-06-2001	Jacobsen et al.	
	K	US- 6,440,067 B1	08-27-2002	DeLuca et al.	
	L	US- 6,544,171 B2	04-08-2003	Beetz et al.	
	M	US- 6,544,173	04-08-2003	West et al.	
	N	US- 6,544,174	04-08-2003	West et al.	
	O	US- 6,579,231 B1	06-17-2003	Phipps	
	P	US- 6,847,892 B2	06-02-2002	Zhou et al.	
	Q	US- 6,870,484 B1	03-22-2005	Brinsfield et al.	
	R	US- 7,382,247 B2	06-03-2008	Welch et al.	
	S	US- 7,439,856 B2	10-21-2008	Weiner et al.	

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Examiner Signature	/Nicole LaVert/	Date Considered	03/03/2010

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	T	US- 7,515,043 B2	04-07-2009	Welch et al.	
	U	US- 7,515,044 B2	04-07-2009	Welch et al.	
	V	US- 2001/0023315 A1	09-20-2001	Flach et al.	
	W	US- 2005/0116820 A1	06-02-2005	Goldreich	
	X	US- 2005/0206518 A1	09-22-2005	Welch et al.	
	Y	US- 2006/0238333 A1	10-26-2006	Welch et al.	
	Z	US- 2007/0013511 A1	01-18-2007	Weiner et al.	
	AA	US- 2007/0069887 A1	03-29-2007	Welch et al.	
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	BB	WO 01/89362 A2 and A3	11-29-2001	West et al.		
	CC	WO 01/97686 A1	12-27-2001	Voegeli et al.		

Examiner Signature	/Nicole LaVert/	Date Considered	03/03/2010

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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, 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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Receipt date: 12/29/2009
Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (07-09)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	11591619
Filing Date	2006-11-01
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US01

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20040252031		2004-12-16	Taylor	
	2	20090043185		2009-02-12	McAdams et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
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Receipt date: 12/29/2009	Application Number	11591619
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Filing Date	2006-11-01
	First Named Inventor	Steven D. Baker
	Art Unit	3762
	Examiner Name	Nicole F. Lavert
	Attorney Docket Number	3022036 US01

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/Nicole LaVert/	Date Considered	03/03/2010

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /N.F.L.

PATENT
Attorney Docket No. 704_049/054 (3022036 US01)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker et al.	Art Unit:	3762
Serial No.:	11/591,619	Examiner:	Nicole F. Lavert
Filing Date:	November 1, 2006		
Title:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

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

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/B Form which are known by them and considered warranting disclosure under 37 C.F.R. §1.56. The best available copies of the non-patent literature documents and abstract translation for the prior art cited in the attached PTO/SB08/A/B Form are submitted herewith.

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.

As this Information Disclosure Statement is being filed (1) no later than three months from the application's filing date, (2) before the mailing date of the first Office Action on the merits and is therefore submitted as both timely and proper or (3) within three months of the mailing date of the foreign search report; thus, no fees are believed to be due.

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

February 2, 2010
Date

R. Stephen Rosenholm
Reg. No. 45,283
Customer No. 72,742
One Park Place
300 South State Street
Syracuse, NY 13202-2078
Tel: (315) 422-2131

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 335

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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
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	704_049/054 (3022036 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
		US-			
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		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]
	BA	JP 11-088546	03-30-1999	NEC Corp.		

Examiner Signature		Date Considered	

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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
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 US01)

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]
	CA	Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2006-507455 (5 pages).	

Examiner Signature		Date Considered	

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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.

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PATENT ABSTRACTS OF JAPAN

(11)Publication number : 11-088546
(43)Date of publication of application : 30.03.1999

(51)Int.Cl. H04M 11/04
A61B 5/00
G08B 25/08
G08B 25/10
H04B 7/15
H04Q 7/38
// G01S 5/14

(21)Application number : 09-267794
(22)Date of filing : 12.09.1997

(71)Applicant : NEC CORP
(72)Inventor : YAMASHITA YUKINAGA

(54) CRISIS NOTICE SYSTEM

(57)Abstract:
PROBLEM TO BE SOLVED: To obtain a portable telephone terminal that is released from a critical condition quickly and surely by sensing a rapid change in a body condition (pulses, brood pressure and body temperature or the like) and sending automatically a notice of the body condition at that point of time and an emergency message to a contact place registered in advance.
SOLUTION: In this system, a radio wave of the global positioning system is received in an emergency and latitude and altitude data at a present position are updated. Upon the receipt of an execution instruction or sensing of a rapid change in a body condition from a body condition sensor, the body condition data and the emergency message at the point of time are sent automatically to an emergency message contact place registered in advance with position data. A mobile communication network relay exchange station stores tentatively the emergency message, extracts of position data of transmission source, the data are converted into a specific area name and address and medium conversion to a voice signal is conducted. Similarly the body data and the emergency message are converted into data/voice data and the resulting data are sent to a called terminal as a voice call.

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 338

Electronic Acknowledgement Receipt

EFS ID:	6933308
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:	88750
Filer:	Robert Stephen Rosenholm/Kristen Jackson
Filer Authorized By:	Robert Stephen Rosenholm
Attorney Docket Number:	704_049/054 (3022036 US01
Receipt Date:	02-FEB-2010
Filing Date:	01-NOV-2006
Time Stamp:	16:33:17
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	Information Disclosure Statement (IDS) Filed (SB/08)	Information-Disclosure-Statement.pdf	58040 a0e515d16e3b84fc8eb3b302e0e72395e3405afc	no	1
Warnings:					
Information:					

This is not an USPTO supplied IDS fillable form					
2	Information Disclosure Statement (IDS) Filed (SB/08)	PTO-SB08A-B.pdf	144365 97f5f2fbb75f76161669e75f8ff773091e69542b	no	2
Warnings:					
Information:					
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3	NPL Documents	Japanese-Office-Action-dated-1-12-10.pdf	205987 dd57e334ac4c4db79012ec1375a4bc22678edcc2	no	5
Warnings:					
Information:					
4	Foreign Reference	Abstract-Translation-JP1188546.pdf	132925 24a44369d44abaef1dd8d6c1af4a9093a615590b	no	1
Warnings:					
Information:					
			Total Files Size (in bytes):	541317	

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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.

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<u>New International Application Filed with the USPTO as a Receiving Office</u>
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United States Patent and Trademark Office
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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_049/054 (3022036 US01

CONFIRMATION NO. 7955

88750
HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

POA ACCEPTANCE LETTER

OC000000039933405

Date Mailed: 02/01/2010

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/22/2010.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/hchristian/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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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

POWER OF ATTORNEY NOTICE

20874
MARJAMA MULDOON BLASIAK & SULLIVAN LLP
250 SOUTH CLINTON STREET
SUITE 300
SYRACUSE, NY 13202

OC000000039933369

Date Mailed: 02/01/2010

NOTICE REGARDING CHANGE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 01/22/2010.

- The Power of Attorney to you in this application has been revoked by the applicant. Future correspondence will be mailed to the new address of record(37 CFR 1.33).

/hchristian/

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REVOCATION OF POWER OF ATTORNEY WITH NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven Baker
Art Unit	3736
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 US01)

I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint the practitioners at Customer Number : 88,750

☒ Please change the correspondence address for the above-identified application to:

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OR

☐ Firm *or* Individual Name			
Address			
City		State	ZIP
Country			
Telephone		Email	

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)

SIGNATURE of Applicant or Assignee of Record

Signature			
Name	Steven D. Baker		
Date	19 Jan 2010	Telephone	503 530 7653

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 1.36. 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 3 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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Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036.US01)

I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint the practitioners at Customer Number : 88,750

☒ Please change the correspondence address for the above-identified application to:

☒ The address associated with Customer Number: 88,750

OR

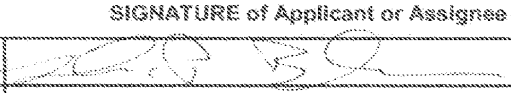
☐ Firm or Individual Name			
Address			
City		State	ZIP
Country			
Telephone		Email	

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)

SIGNATURE of Applicant or Assignee of Record

Signature			
Name	Thomas P. Blackadar		
Date	11/4/2010	Telephone	5086530583

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.

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Art Unit	3736
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 US01)

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☐ 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 of Applicant or Assignee of Record

Signature	James P Welch		
Name	James P. Welch		
Date	Dec 18, 2009	Telephone	949-632-4752

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REVOCATION OF POWER OF ATTORNEY WITH NEW POWER OF ATTORNEY AND CHANGE OF CORRESPONDENCE ADDRESS

Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3736
Examiner Name	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022036 US01)

I hereby revoke all previous powers of attorney or authorizations of agent given in the above-identified application.

☐ A Power of Attorney is submitted herewith.

OR

☒ I hereby appoint the practitioners at Customer Number : 88,750

☒ Please change the correspondence address for the above-identified application to:

☒ The address associated with Customer Number: 88,750

OR

☐ Firm *or* Individual Name			
Address			
City		State	ZIP
Country			
Telephone		Email	

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)

SIGNATURE of Applicant or Assignee of Record

Signature	S. McAdams		
Name	Eric T. McAdams		
Date	22/Dec/09	Telephone	+33(0)472438986

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.

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Page 346

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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	Nicole F. Lavert
Attorney Docket Number	704_049/054 (3022/036 US01)

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☐ Firm *or* Individual Name			
Address			
City		State	ZIP
Country			
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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)

SIGNATURE of Applicant or Assignee of Record

Signature			
Name	Norbert Ohlenbusch		
Date	12/20/2009	Telephone	978-409-9763

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Electronic Acknowledgement Receipt

EFS ID:	6864267
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:	Robert Stephen Rosenholm/Kristen Jackson
Filer Authorized By:	Robert Stephen Rosenholm
Attorney Docket Number:	704_049
Receipt Date:	22-JAN-2010
Filing Date:	01-NOV-2006
Time Stamp:	15:28:45
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	Change of Address	Baker.pdf	294333 6ab6e7f1f4760aa9971ea7b2c6e81dd530d0908b	no	1

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2	Change of Address	Blackadar.pdf	619120 bcf7e5384b83f1005e26b8dda7460d60cb4e826d	no	1
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New International Application Filed with the USPTO as a Receiving Office

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11591619
	Filing Date	2006-11-01
	First Named Inventor	Steven D. Baker
	Art Unit	3762
	Examiner Name	Nicole F. Lavert
	Attorney Docket Number	3022036 US01

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	1	20040252031		2004-12-16	Taylor	
	2	20090043185		2009-02-12	McAdams et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11591619
	Filing Date	2006-11-01
	First Named Inventor	Steven D. Baker
	Art Unit	3762
	Examiner Name	Nicole F. Lavert
	Attorney Docket Number	3022036 US01

Examiner Initials*	Cite No	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, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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EXAMINER SIGNATURE

Examiner Signature		Date Considered	

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**		
	Application Number	11591619
	Filing Date	2006-11-01
	First Named Inventor	Steven D. Baker
	Art Unit	3762
	Examiner Name	Nicole F. Lavert
	Attorney Docket Number	3022036 US01

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any 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. See 37 CFR 1.97(e)(1).

OR

☒ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/R. Stephen Rosenholm/	Date (YYYY-MM-DD)	2009-12-29
Name/Print	R. Stephen Rosenholm	Registration Number	45283

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Electronic Acknowledgement Receipt

EFS ID:	6721360
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:	Robert Stephen Rosenholm/Kristen Jackson
Filer Authorized By:	Robert Stephen Rosenholm
Attorney Docket Number:	704_049
Receipt Date:	29-DEC-2009
Filing Date:	01-NOV-2006
Time Stamp:	15:46:25
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	Information Disclosure Statement (IDS) Filed (SB/08)	US_IDS_Form__SB_08a.pdf	767220 2c8de5748c6cfd3fa55fe9a0825ca5d7dc6d040d	no	4

Warnings:	
Information:	

Total Files Size (in bytes):	767220

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National Stage of an International Application under 35 U.S.C. 371
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	11/591,619
Applicant	:	Steven D. Baker
Filed	:	November 1, 2006
Art Unit	:	3762
Examiner	:	Nicole F. Lavert
Docket No.	:	3022036 US01 (704_049/054 US01)
Confirmation No.	:	7955
Customer No.	:	88,750
Title	:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

SUPPLEMENTAL RESPONSE TO FINAL OFFICE ACTION

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

Dear Sir:

This Supplemental Response is a second reply that follows a Final Office Action mailed July 20, 2009. A timely filed first reply including a Request for Continued Examination (RCE) was submitted to the U.S. Patent and Trademark Office on October 20, 2009. As a result, no time extension is required for this second reply. Please consider and enter the following amendments and remarks.

An **Interview Summary** is included with this paper.

Amendments to the **Claims** including the previously withdrawn claims are included with this paper.

Remarks are included with this paper.

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Interview Summary

On December 1, 2009, Applicants' attorneys R. Stephen Rosenholm, Sonny Z. Zhan, and inventor Steven D. Baker had a telephonic interview with Examiner Nicole F. Lavert and her Supervisory Examiner George R. Evanisko regarding this application. The items discussed included the outstanding claim rejections. Proposed claim amendments to overcome the rejections were discussed.

An agreement was reached that the proposed claim amendments of claim 1 patentably distinguish over the cited art of record and overcome the current claim rejections, but are subject to a possible new search by the Examiner. Also, Supervisory Examiner (SPE) Evanisko stated that claim 1 appeared to be broad enough so that other prior art (not of record) could fall within the scope of claim 1 as interpreted by the SPE Evanisko. SPE Evanisko also had questions regarding the scope and intended meaning of the "body worn" claim 1 limitation and its support within the invention description of the subject patent application. SPE Evanisko stated that some prior art including wires connecting pocket resident electronics, sensory vests, defibrillation devices might fall within the scope of claim 1.

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In the Claims

This listing of claims will replace all prior versions and listings of claims in the application.

1. (Currently Amended) A body worn patient monitoring device comprising:

~~at least one~~ a disposable module including a plurality of electrical connections, said[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~~ a power source to power the body worn patient monitoring device; and

~~at least one~~ a 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~~ a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event, and

a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on an 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.

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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.

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

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.

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

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.

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.

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

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

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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.

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.

12. (Original) The body worn device of claim 5, wherein the EGG electrodes are formed substantially in the shape of an annulus.

13. (Original) The body worn device of claim 12, wherein the annulus comprises a conductive link.

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.

15. (Currently Amended) 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. (Currently Amended) 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. (Currently Amended) The body worn device of claim 1, wherein the ~~at least one~~ power source is a battery contained within said disposable module.

18. (Currently Amended) The body worn device of claim 1, wherein the ~~at least one~~ power source is a Seebeck device.

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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).

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

21. (Previously Presented) 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.

22. (Previously Presented) The body worn device of claim 20, wherein the virtual electrode is adapted to include 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. (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.

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.

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

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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.

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.

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.

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.

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

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.

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.

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.

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

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.

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

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 pacemaker.

38. (Previously Presented) The body worn device of claim 1, wherein the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.

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.

40. (Canceled)

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

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of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, to save power.

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.

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.

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.

45. (Withdrawn) 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.

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46. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

49. (Withdrawn) 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.

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50. (Withdrawn) The EGG monitor of claim 49, wherein said at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

51. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from said at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a filleted edge.

52. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from the at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a plurality of overlapped layers.

53. (Withdrawn) The EGG 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.

54. (Withdrawn) 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. (Withdrawn) The ECG monitor of claim 54, wherein said power source is a battery.

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56. (Withdrawn) 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 an 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; and

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. (Withdrawn) 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 signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

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58. (Withdrawn) 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.

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59. (New) A body worn patient monitoring device comprising:

a disposable module including a plurality of electrical connections, the electrical connections adapted for electrical coupling to a skin surface to receive physiological signals, the disposable module including a disposable module connector;

a power source to power the body worn patient monitoring device; and

a communication-computation module, having a communication-computation module connector to receive the physiological signals from the disposable module via the disposable module connector, the communication-computation module including:

a microprocessor to actively monitor a patient and to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event,

a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis, at a predetermined time or on an occurrence of a predetermined event, via a radio transmission to a remote radio receiver, and

wherein the disposable module has a mechanical and electrical coupling to the communication-computation module, forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient.

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Remarks

This Supplemental Response is a second reply that follows a Final Office Action mailed July 20, 2009. A timely filed first reply including a Request for Continued Examination (RCE) was submitted to the U.S. Patent and Trademark Office on October 20, 2009 and entered into the record for the prosecution of the subject patent application. As a result, no time extension is required for this second supplemental reply in accordance with the rules of patent examination [MPEP 710.02(e)]. However, in the event of a fee deficiency, please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 50-3010.

In this Supplemental Response, claim 1 is further amended to define the subject matter. Some editorial revisions have also been made to claims 15-18. New claim 59 is added. No new matter has been added. Claim 40 has previously been canceled without prejudice or disclaimer. Claims 45-58 have previously been withdrawn. Claims 1-39, 41-44 and 59 remain pending in the present application.

A telephonic interview was conducted between Examiners and Applicants' representatives on December 1, 2009. Within this interview, the Examiners agreed to accept entry of this Supplemental Response. The interview is summarized herein under the heading Interview Summary. Applicants wish to thank the Examiner for the Examiner's careful review and consideration of this patent application.

In light of the following remarks, withdrawal of the pending rejections and advancement of this application to allowance are requested.

I. Questions Raised in the Telephonic Interview

Within the telephonic interview, SPE Evanisko raised questions regarding the scope and meaning of the claim 1 language "body worn". With respect to "body worn", the specification of the present application states, for example, "a 'body worn' device is defined herein as a device that is directly, but non-permanently, affixed to a patient's body." See Specification, paragraph [0040]. The specification also states "[a] 'body worn monitor' is a device that can be directly

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'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" (emphasis added). See Specification, paragraph [0040].

With further respect to the "body worn" claim language, the specification states:

> [u]nlike 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. 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". (emphasis added)

See Specification, paragraph [0040].

As indicated above, monitoring prior art devices that include wires that connect to pocket resident electronics do not fall within the scope of the language "contained within in a "body worn" package", and prior art devices that include wires that connect to sensors also do not fall within the scope of the language "without the use of external wires from sensors to the device".

The body worn device recited in the claims of the present applications does not need external wires connecting to separate components, such as for example, pocket resident electronics. These external wires are more cumbersome to wear and are more vulnerable to noise as compared to the design of the Applicants' invention. Applicants respectfully suggest that the Examiner refer to the above recited specification support for interpreting the language "body worn" recited in the claims of the present application.

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II. Claim Rejections - 35 U.S.C. § 102(e) / 103(a)

Claims 1-5 and 12-18 are rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Fadem et al. (hereinafter "Fadem"), U.S. Patent Application Publication 2007/0270678. These rejections are respectfully traversed for at least the following reasons.

First, Applicants' claim 1 recites, in part, "communication-computation module including a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event, and a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on an occurrence of a predetermined event." (emphasis added)

One non-limiting example of the physiological analysis of the present application is disclosed is described on paragraphs [0094]-[0096] within the specification of the present application. For example, the physiological analysis can determine an occurrence of a physiological event such as the presence of a life threatening arrhythmias (LTA) (Paragraph [0094]). In response, the body worn device can activate transmission of full waveforms in response to an occurrence of such an LTA or atrial flutter type of physiological event (Paragraph [0094]). Further, the body worn device can also periodically send data or send data upon external request.

Conversely, Fadem discloses processing circuitry operatively configured to signal amplify and digital convert the sensed biopotential signal. The microcontroller unit 66 sets parameters for signal gain, filter settings, sampling rate, and transmission rate. See Fadem, e.g., paras. [0023]; [0046]; FIG. 8. Fadem fails to disclose or suggest a communication-computation module including a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals, said analysis determining an occurrence of a predetermined physiological event as recited by claim 1 of the present application.

In fact, there is no recitation to the phrase "physiological analysis" or to word "analysis"

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within the entire Detailed Description of the Fadem patent application. The only recitations to the word "physiological" within the Fadem entire patent application are within the phrases "physiological signals" (Abstract), "physiological conditions" (Paragraph [0003]), "physiological monitoring" (Paragraph [0007]) and "electrophysiological activity" (Paragraph [0040]). Only the "electrophysical activity" phrase is recited within the Detailed Description of Fadem. The phrases physiological "signals", "conditions" and "monitoring" are only recited within the Background section, and not recited within the Detailed Description portion of the Fadem patent application. Fadem simply does not teach "physiological analysis of a physiological signal" as recited within the Applicants' claim 1.

Further, Fadem's microcontroller unit 66 (MCU) is focused on system initialization (see, Fadem, paragraph [0046]) rather than the patient's physiological status (health and well being). There is no disclosure of a physiological analysis of portions of waveforms. Therefore, merely setting initialization parameters for a signal as disclosed in Fadem does not disclose or suggest an "analysis determining an occurrence of a predetermined physiological event" as required in claim 1 of the present application.

Repeating a portion of the claim 1 recitation above, claim 1 recites, in part, a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on an occurrence of a predetermined event (emphasis added).

Conversely, Fadem discloses the amplified voltage potentials are then either transmitted wirelessly via radio transceiver module 63 or are temporarily stored in flash memory 65 and then transmitted in short bursts to increase battery life. (See Fadem, e.g., para. [0046]). Transmitting the amplified voltage potentials in short bursts to increase battery life as disclosed in Fadem does not suggest a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on an occurrence of a predetermined event, as recited by claim 1 of the present application.

Reconsideration and allowance of claim 1, as well as claims 2-5 and 12-18 that depend respectively from claim 1, are respectfully requested.

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III. Claim Rejections - 35 U.S.C. § 103

A. Claims 6-11

Claims 6-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Merry et al., U.S. Patent No. 6,623,312. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 6-11 depend (directly or indirectly) from claim 1. Merry et al. fails to remedy the shortcomings of Fadem noted above. For example, Merry fails to teach or suggest a module including a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined physiological event, as claimed by the Applicants. As a result, claims 6-11 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 6-11 are respectfully requested.

B. Claims 19-24

Claims 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Schraag, U.S. Patent No. 5,309,918. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 19-24 depend (directly or indirectly) from claim 1. Schraag fails to remedy the shortcomings of Fadem noted above. For example, Schraag fails to teach or suggest a module including a microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined physiological event, as claimed by the Applicant. As a result, claims 19-24 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 19-24 are respectfully requested.

Furthermore, Applicants are unable to find any indication of a "reference electrode that can be used to improve common mode rejection (CMR)" as recited in claim 19 of the present application.

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C. Claims 25-32, 39 and 42-44

Claims 25-32, 39 and 42-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Jackson et al., U.S. Patent Application Publication 2005/0137489. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 25-32, 39 and 42-44 depend (directly or indirectly) from claim 1. Jackson et al. fails to remedy the shortcomings of Fadem noted above. For example, Jackson fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined physiological event, as claimed by the Applicants.

Instead, Jackson describes an implantable cardiac stimulation device that is designed to provide a prediction of impending arrhythmia and does not determine a specific occurrence of a physiological event. An implantable device is not "non-permanently affixed to the skin surface of the patient" as recited within claim 1.

As a result, claims 25-32, 39 and 42-44 which depend directly or indirectly from claim 1, are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 25-32, 39 and 42-44 are respectfully requested.

D. Claims 33-37

Claims 33-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Westra et al., U.S. Patent Application Publication 2006/0183434. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 33-37 depend (directly or indirectly) from claim 1. Westra et al. fails to remedy the shortcomings of Fadem noted above. For example, Westra fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined physiological event, as claimed by the Applicants. As a result, claims 33-37 are therefore patentable for at least the same reasons as those provide above for claim 1.

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Reconsideration and allowance of claims 33-37 are respectfully requested.

E. Claim 38

Claim 38 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Eshelman et al., U.S. Patent Application Publication 2003/0001742. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 38 depends from claim 1. Eshelman et al. fails to remedy the shortcomings of Fadem noted above. For example, Eshelman fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined physiological event, as claimed by the Applicants.

Furthermore, claim 38 recites, in part, "the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient." Applicants are unable to find any disclosure within Eshelman related to failure of contact of one of more of the electrical connections with the skin surface of the patient.

As a result, claim 38 is therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 38 are respectfully requested.

F. Claim 41

Claim 41 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Owen et al., U.S. Patent Application Publication 2003/0055460. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 41 depends from claim 1. Owen et al. fails to remedy the shortcomings of Fadem noted above. For example, Owen fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined physiological event, as claimed by the Applicants. As a result, claim 41 is therefore patentable for at least the

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same reasons as those provide above for claim 1. Reconsideration and allowance of claim 41 are respectfully requested.

Furthermore, Owen is multiple unit defibrillator having separate wired electrodes, and not a single unit body worn monitoring device like that claimed and described by the Applicant's invention. Applicants are unable to find any disclosure in Owen that describes a power saving mode timed to a specific portion of an ECG waveform, such as at the end of a "T wave" or to the beginning of a "P wave", as claimed and described by the Applicant's invention.

IV. New Claim

New claim 59 is added. New claim 59, like claim 1, recites in part, "to perform a real-time physiological analysis of the physiological signals, the analysis determining an occurrence of a predetermined ECG event" and further recites "the disposable module has a mechanical and electrical coupling to the communication-computation module, forming the body worn patient monitoring device as a single unit that is adapted to be directly and non-permanently affixed to the skin surface of the patient." (emphasis added)

New claim 59 is believed to be allowable over the art of record for at least the reasons as stated above with respect to the patentability of claim 1 above.

V. Conclusion

The remarks set forth above provide certain arguments in support of the patentability of the pending claims. There may be other arguments that support the pending claims as being patentably distinct over the cited references, and the right to raise any such other reasons or arguments in the future is expressly reserved.

Favorable reconsideration in the form of a Notice of Allowance is respectfully requested. Please contact the undersigned attorney with any questions regarding this application. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 50-3010.

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Respectfully submitted,

HISCOCK & BARCLAY, LLP

Date: December 7, 2009

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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:	Robert Stephen Rosenholm/Kristen Jackson
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:				
Independent claims in excess of 3	1201	1	220	220
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
		Total in USD ($)		**220**

Electronic Acknowledgement Receipt

EFS ID:	6586383
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:	Robert Stephen Rosenholm/Kristen Jackson
Filer Authorized By:	Robert Stephen Rosenholm
Attorney Docket Number:	704_049
Receipt Date:	07-DEC-2009
Filing Date:	01-NOV-2006
Time Stamp:	16:24:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$220
RAM confirmation Number	3131
Deposit Account	
Authorized User	

File Listing:

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

1	Amendment After Final	Supplemental-Response-filed-12-7-09.pdf	1087100 801790d1fe1d932f153601290039616128239155	no	23
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	30087 ab89d5edf5236b81bc5ccacc9cb3b25409beebae	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1117187	

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/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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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	12/07/2009	(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))	* 58	Minus	** 58	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 7	Minus	***6	= 1	X $ =		OR	X $220=	220
	☐ 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	**220**

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:
/LINDA A. WASHINGTON/

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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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 12/03/2009

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
12/03/2009	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.

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

All participants (applicant, applicant's representative, PTO personnel):

(1) *NICOLE F. LAVERT*.

(2) *GEORGE EVANISKO*.

(3)*STEVEN BAKER*.

(4)*STEPHAN ROSENHOLM*.

Date of Interview: *01 December 2009*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *1*.

Identification of prior art discussed: *FADEM ET AL. (US 2007/0270678)*.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

/George R Evanisko/ Primary Examiner, Art Unit 3762	

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Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

———

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Based on a draft amdt to the claims of the analysis determining an occurrence of a physiological event the prior art reference cited, Fadem et al.,appears not to read on the claims (although a closer reaidng is necessary. The Examiner has also agreed to allow a supplemental amendment to be submitted by the Applicant no later than Dec 7th 2009. Based on the submitted amendments and/or arguments the Examiner will have to make a further consideration and/or perform an additional search..

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PTO/SB/30 (07-09)
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Request for Continued Examination (RCE) Transmittal

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

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 (704_049/054 US01)

This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.
Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. Submission required under 37 CFR 1.114 Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

   a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.

      i. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on _____

      ii. ☐ Other _____

   b. ☑ Enclosed

      i. ☑ Amendment/Reply

      ii. ☐ Affidavit(s)/ Declaration(s)

      iii. ☑ Information Disclosure Statement (IDS)

      iv. ☐ Other _____

2. Miscellaneous

   a. ☐ Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of _____ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)

   b. ☐ Other _____

3. Fees The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.

   a. ☐ The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any overpayments, to Deposit Account No. _____.

      i. ☑ RCE fee required under 37 CFR 1.17(e)

      ii. ☐ Extension of time fee (37 CFR 1.136 and 1.17)

      iii. ☐ Other _____

   b. ☐ Check in the amount of $ _____ enclosed

   c. ☑ Payment by credit card (Form PTO-2038 enclosed)

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.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature	R. Stephen Rosenholm	Date	October 20, 2009
Name (Print/Type)	R. Stephen Rosenholm	Registration No.	45,283

CERTIFICATE OF MAILING OR TRANSMISSION

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

Signature			
Name (Print/Type)		Date	

This collection of information is required by 37 CFR 1.114. 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 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: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	11/591,619
Applicant	:	Steven D. Baker
Filed	:	November 1, 2006
Art Unit	:	3762
Examiner	:	Nicole F. Lavert
Docket No.	:	3022036 US01 (704_049/054 US01)
Confirmation No.	:	7955
Customer No.	:	88,750
Title	:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

RESPONSE TO FINAL OFFICE ACTION

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

Dear Sir:

In response to the Final Office Action mailed July 20, 2009, please consider and enter the following amendments and remarks.

Amendments to the **Claims** including the previously withdrawn claims are included with this paper.

Remarks are included with this paper.

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In the Claims

This listing of claims including the previously withdrawn claims will replace all prior versions and listings of claims in the application.

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, said analysis determining an occurrence of a predetermined event, and a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on an 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.

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.

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

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.

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

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.

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.

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

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

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.

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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.

12. (Original) The body worn device of claim 5, wherein the EGG electrodes are formed substantially in the shape of an annulus.

13. (Original) The body worn device of claim 12, wherein the annulus comprises a conductive link.

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.

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.

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.

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

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

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).

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

21. (Previously Presented) 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.

22. (Previously Presented) The body worn device of claim 20, wherein the virtual electrode is adapted to include 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. (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.

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.

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

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.

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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.

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.

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.

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

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.

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.

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.

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

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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.

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

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 pacemaker.

38. (Previously Presented) The body worn device of claim 1, wherein the communication-computation module includes circuit components configured to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.

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.

40. (Canceled)

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.

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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.

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.

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.

45. (Withdrawn) 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.

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46. (Withdrawn) 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. (Withdrawn) 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. (Withdrawn) 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.

49. (Withdrawn) 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.

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50. (Withdrawn) The EGG monitor of claim 49, wherein said at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

51. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from said at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a filleted edge.

52. (Withdrawn) The EGG monitor of claim 49, wherein a mechanical interface is defined from the at least one series current-limiting resistor to said at least one EGG electrode, said mechanical interface including a plurality of overlapped layers.

53. (Withdrawn) The EGG 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.

54. (Withdrawn) 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. (Withdrawn) The ECG monitor of claim 54, wherein said power source is a battery.

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56. (Withdrawn) 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 an 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; and

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. (Withdrawn) 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 signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

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58. (Withdrawn) 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.

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Remarks

This is in reply to the Final Office Action mailed July 20, 2009. A Request For Continued Examination is enclosed herewith. Applicants wish to thank the Examiner for the Examiner's careful review and consideration of this application.

In the subject Action, claims 1-39 and 41-44 are rejected. Claim 1 is amended. Claim 40 has previously been canceled without prejudice or disclaimer. Claims 45-58 have previously been withdrawn. Claims 1-39 and 41-44 remain pending in the present application. In light of the following remarks, withdrawal of the pending rejections and advancement of this application to allowance are requested.

I. Listing of Claims

The listing of claims including the previously withdrawn claims will replace all prior versions and listings of claims in the application.

II. Claim Rejections - 35 U.S.C. § 102(e) / 103(a)

Claims 1-5 and 12-18 are rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Fadem et al. (hereinafter "Fadem"), U.S. Patent Application Publication 2007/0270678. These rejections are respectfully traversed for at least the following reasons.

First, the Applicant's claim 1 recites, in part, "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, said analysis determining an occurrence of a predetermined event, and a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on an occurrence of a predetermined event." (Emphasis Added)

The physiological analysis is described, at least in part, within the Applicant's invention description (Paragraphs 95-97). For example, the physiological analysis can determine a likelihood of a presence of a life threatening arrhythmias (LTA) (Paragraph 95) or a presence of

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atrial flutter (Paragraph 96) and activate transmission of full waveforms in response to an occurrence of such an LTA or atrial flutter type of event (Paragraph 95).

Conversely, Fadem discloses processing circuitry operatively configured to signal amplify and digital convert the sensed biopotential signal. The microcontroller unit 66 sets parameters for signal gain, filter settings, sampling rate, and transmission rate. See Fadem, e.g., paras. [0023]; [0046]; FIG. 8. Fadem fails to disclose or suggest a 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, as recited by claim 1 of the present application.

Repeating a portion of the claim 1 recitation above, claim 1 recites, in part, 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 (emphasis added).

Rather, Fadem discloses the amplified voltage potentials are then either transmitted wirelessly via radio transceiver module 63 or are temporarily stored in flash memory 65 and then transmitted in short bursts to increase battery life. See Fadem, e.g., para. [0046]. Transmitting the amplified voltage potentials in short bursts to increase battery life as disclosed in Fadem does not suggest 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, as recited by claim 1 of the present application.

Reconsideration and allowance of claim 1, as well as claims 2-5 and 12-18 that depend respectively therefrom, are respectfully requested.

III. Claim Rejections - 35 U.S.C. § 103

A. Claims 6-11

Claims 6-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Merry et al., U.S. Patent No. 6,623,312. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

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Claims 6-11 depend (directly or indirectly) from claim 1. Merry et al. fails to remedy the shortcomings of Fadem noted above. For example, Merry fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined event, as claimed by the Applicant. As a result, claims 6-11 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 6-11 are respectfully requested.

B. Claims 19-24

Claims 19-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Schraag, U.S. Patent No. 5,309,918. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 19-24 depend (directly or indirectly) from claim 1. Schraag fails to remedy the shortcomings of Fadem noted above. For example, Schraag fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined event, as claimed by the Applicant. As a result, claims 19-24 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 19-24 are respectfully requested.

C. Claims 25-32, 39 and 42-44

Claims 25-32, 39 and 42-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Jackson et al., U.S. Patent Application Publication 2005/0137489. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 25-32, 39 and 42-44 depend (directly or indirectly) from claim 1. Jackson et al. fails to remedy the shortcomings of Fadem noted above. For example, Jackson fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an

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occurrence of a predetermined event, as claimed by the Applicant. As a result, claims 25-32, 39 and 42-44 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 25-32, 39 and 42-44 are respectfully requested.

D. Claims 33-37

Claims 33-37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Westra et al., U.S. Patent Application Publication 2006/0183434. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 33-37 depend (directly or indirectly) from claim 1. Westra et al. fails to remedy the shortcomings of Fadem noted above. For example, Westra fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined event, as claimed by the Applicant. As a result, claims 33-37 are therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claims 33-37 are respectfully requested.

E. Claim 38

Claim 38 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Eshelman et al., U.S. Patent Application Publication 2003/0001742. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 38 depends from claim 1. Eshelman et al. fails to remedy the shortcomings of Fadem noted above. For example, Eshelman fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined event, as claimed by the Applicant. As a result, claim 38 is therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 38 are respectfully requested.

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F. Claim 41

Claim 41 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Fadem in view of Owen et al., U.S. Patent Application Publication 2003/0055460. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 41 depends from claim 1. Owen et al. fails to remedy the shortcomings of Fadem noted above. For example, Owen fails to teach or suggest a module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals for determining an occurrence of a predetermined event, as claimed by the Applicant. As a result, claim 41 is therefore patentable for at least the same reasons as those provide above for claim 1. Reconsideration and allowance of claim 41 are respectfully requested.

IV. Conclusion

The remarks set forth above provide certain arguments in support of the patentability of the pending claims. There may be other arguments that support the pending claims as being patentably distinct over the cited references, and the right to raise any such other reasons or arguments in the future is expressly reserved.

Favorable reconsideration in the form of a Notice of Allowance is respectfully requested. Please contact the undersigned attorney with any questions regarding this application. Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account 50-3010.

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Page 405

Respectfully submitted,

HISCOCK & BARCLAY, LLP

Date: October 20, 2009

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iRhythm, Inc. / Welch Allyn, Inc.
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Page 406

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	11/591,619
Applicant	:	Steven D. Baker
Filed	:	November 1, 2006
Art Unit	:	3762
Examiner	:	Nicole F. Lavert
Docket No.	:	3022036 US01 (704_049/054 US01)
Confirmation No.	:	7955
Customer No.	:	88,750

INFORMATION DISCLOSURE STATEMENT

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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 constructed *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.

As this Information Disclosure Statement is being filed before the mailing of a first

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Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114. Thus, no fees are believed to be due.

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

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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
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 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
	A	US- 5,319,363	06-07-1994	Welch et al.	
	B	US- 5,579,001	11-26-1996	Dempsey et al.	
	C	US- 5,579,775	12-03-1996	Dempsey et al.	
	D	US- 5,682,803	11-04-1997	Gideon et al.	
	E	US- 5,687,734	11-18-1997	Dempsey et al.	
	F	US- 5,748,103	05-05-1998	Flach et al.	
	G	US- 5,767,791	06-16-1998	Stoop, et al.	
	H	US- 5,917,414 A	06-29-1999	Oppelt et al.	
	I	US- 6,057,758 A	05-02-2000	Dempsey et al.	
	J	US- 6,198,394 B1	03-06-2001	Jacobsen et al.	
	K	US- 6,440,067 B1	08-27-2002	DeLuca et al.	
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	R	US- 7,382,247 B2	06-03-2008	Welch et al.	
	S	US- 7,439,856 B2	10-21-2008	Weiner et al.	

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Sheet 2 of 2

Complete if Known	
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Examiner Name	Nicole F. Lavert
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	T	US- 7,515,043 B2	04-07-2009	Welch et al.	
	U	US- 7,515,044 B2	04-07-2009	Welch et al.	
	V	US- 2001/0023315 A1	09-20-2001	Flach et al.	
	W	US- 2005/0116820 A1	06-02-2005	Goldreich	
	X	US- 2005/0206518 A1	09-22-2005	Welch et al.	
	Y	US- 2006/0238333 A1	10-26-2006	Welch et al.	
	Z	US- 2007/0013511 A1	01-18-2007	Weiner et al.	
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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]
	BB	WO 01/89362 A2 and A3	11-29-2001	West et al.		
	CC	WO 01/97686 A1	12-27-2001	Voegeli et al.		

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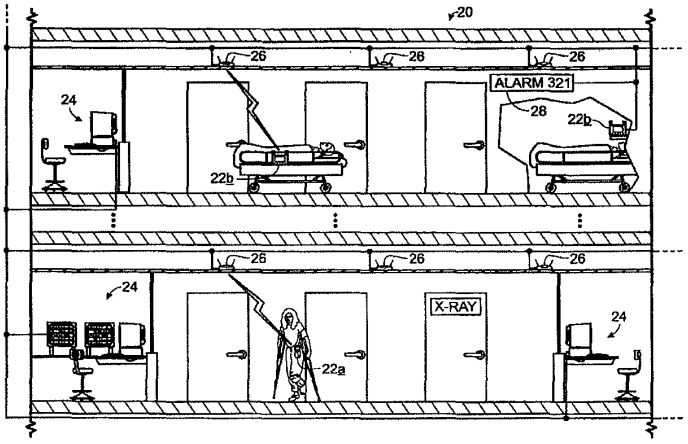
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[Continued on next page]

(54) Title: PATIENT MONITORING SYSTEM



(57) Abstract: A wireless patient monitor is adapted to communicate with any one of plural medical telemetry networks, each having one or more central stations, where each network is configured to communicate via wireless communications using one of multiple different communications settings. The monitor includes one or more sensor inputs for receiving vital signs data from a patient, a wireless transceiver; and a controller coupled to receive the vital signs data via the one or more sensor inputs and to communicate with a network via the transceiver. The monitor also includes a display device and is controllable by the controller to automatically display a notification to a user of the monitor upon establishing communications with the at least one central station. There is also a method of monitoring a patient and a wireless medical telemetry system.

WO 01/89362 A2

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

PATIENT MONITORING SYSTEM

Cross-Reference to Related Applications

This application claims priority to U.S. Provisional Patent Application Serial No. 60/205,412, filed May 19, 2000 and entitled PATIENT MONITORING SYSTEM. The subject matter of this application is incorporated herein by this reference.

Field of the Invention

The present invention relates generally to monitoring the vital signs of one or more patients, and more particularly to a system and method for monitoring patients via wireless communications.

Background

Devices for measuring various physiological parameters, or "vital signs," of a patient such as temperature, blood pressure, heart rate, heart activity, etc., have been a standard part of medical care for many years. Indeed, the vital signs of some patients (e.g., those undergoing relatively moderate to high levels of care) typically are measured on a substantially continuous basis to enable physicians, nurses and other health care providers to detect sudden changes in a patient's condition and evaluate a patient's condition over an extended period of time. However, since most hospitals and other medical facilities care for numerous patients assigned to numerous different rooms, it can be difficult for a finite number of clinicians to monitor multiple patients on a continuous basis. In an effort to alleviate this problem, some medical monitoring systems have been developed to enable the vital signs data collected from patients to be conveyed to a central location, thereby allowing one or a few clinicians to simultaneously monitor multiple patients in different locations. However, many of

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such prior systems have not allowed the monitored patients to move about the hospital. Although a few "mobile" monitoring systems have been attempted, such systems are difficult to use and prone to failure resulting in the loss of a patient's vital signs data.

Summary

A wireless patient monitor is adapted to communicate with any one of plural medical telemetry networks, each having one or more central stations, where each network is configured to communicate via wireless communications using one of multiple different communications settings. The monitor includes one or more sensor inputs for receiving vital signs data from a patient, a wireless transceiver configured to transmit and receive wireless communications; and a controller coupled to receive the vital signs data via the one or more sensor inputs and to communicate with a network via the transceiver. The controller is configured, upon initial power-up, to automatically transmit a signal to a local one of the plural networks via the transceiver to request the communications settings used by the local network, and to establish communications with at least one of the central stations on the local network using the communications settings received from the local network without intervention from a user of the patient monitor.

Another version of the invention is a wireless, patient vital signs monitor adapted to communicate with a medical telemetry network having at least one central station. The monitor includes one or more sensor input ports for receiving patient vital signs data, a controller coupled to receive the vital signs data via the one or more input ports, and a wireless transceiver controllable by the controller to communicate

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with the at least one central station. The controller is configured, when not in communication with the at least one central station, to repeatedly attempt to establish communications with the at least one central station via the wireless transceiver. A display device is also included and is controllable by the controller to automatically display a notification to a user of the monitor upon establishing communications with the at least one central station.

Yet other versions of the invention include a wireless, patient vital signs monitor, a method of monitoring a patient and a wireless medical telemetry system. The advantages of the present invention will be understood more readily after a consideration of the drawings and the Detailed Description.

Brief Description of the Drawings

Fig. 1 is a fragmentary, schematic illustration of an exemplary medical telemetry network according to the present invention in the context of a hospital.

Fig. 2 is a fragmentary, schematic diagram of a system for monitoring a plurality of patients in accordance with the present invention.

Fig. 3 is a front elevation view of an exemplary central monitoring station according to the present invention.

Fig. 4 is a schematic diagram of an exemplary system for monitoring patients according to the present invention.

Fig. 5 is a front isometric view of an exemplary patient monitor according to the present invention.

Fig. 6 is a front isometric view of another exemplary patient monitor according to the present invention.

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Fig. 7 is a schematic, functional block diagram of an exemplary patient monitor according to the present invention.

Fig. 8 is an exemplary image for display on a display screen according to the present invention.

Fig. 9 is similar to the image of Fig. 8 but modified to include a message region for display on a display screen according to the present invention.

Fig. 10 is similar to the image of Fig. 8 but modified to include a user-interface for display on a display screen according to the present invention.

Fig. 11 is a flowchart illustrating an exemplary rendezvous process according to the present invention.

Fig. 12 is a flowchart illustrating an exemplary communications configuration process according to the present invention.

Fig. 13 is an exemplary image for display on a display screen, and including a user-interface operable to select a primary central station in accordance with the present invention.

Fig. 14 is an exemplary image for display on a display screen, and including a user-interface operable to confirm a monitoring configuration in accordance with the present invention.

Fig. 15 is an exemplary image for display on a display screen, and including a user-interface operable to identify a patient being monitored in accordance with the present invention.

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Fig. 16 is an exemplary image for display on a display screen, and including a user-interface operable to select a primary central station in accordance with the present invention.

Fig. 17 is an exemplary image for display on a display screen, and including a user-interface operable to change alarm condition parameters in accordance with the present invention.

Fig. 18 is an exemplary image representing ECG data from a single electrode for display on a display screen according to the present invention.

Fig. 19 is an exemplary image representing ECG data from plural electrodes for display on a display screen according to the present invention.

Fig. 20 is an exemplary image indicating an alarm condition for display on a display screen according to the present invention.

Fig. 21 is a schematic illustration of a system for monitoring a patient at plural central stations according to the present invention.

Fig. 22 is a flowchart diagram of an exemplary method for monitoring a patient at a central location in accordance with the present invention.

Fig. 23 is a flowchart diagram of another exemplary method for monitoring a patient at a central location in accordance with the present invention.

Fig. 24 is a flowchart diagram of another exemplary method for monitoring a patient at a central location in accordance with the present invention.

Fig. 25 is a flowchart diagram of another exemplary method for monitoring a patient at a central location in accordance with the present invention.

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Fig. 26 is a flowchart diagram of another exemplary method for monitoring a patient at a central location in accordance with the present invention.

Detailed Description

From an overview, and as will be described in detail below, a system and method for monitoring patients is described that affords communication between plural patient monitors and plural central monitoring stations. The system and method is designed to allow the patient monitors to communicate with the central monitoring stations by using any known communication connection (such as to-be-described access points) located anywhere using any known communications technology (such as the IEEE 802.11 standard for wireless communication) that provides a communication channel. The to-be-described system and method also makes it possible for a clinician to view patient data on a display component of the patient monitor via any known communication channel such as the Internet. For example, the clinician could view patient data using known web browsers.

The to-be described system and method also includes a so-called "rendezvous process" of establishing communications with one or more central stations. As will be shown in connection with the description of Fig. 11, the rendezvous process may be carried out in any of a variety of different ways, and may vary depending on whether wireless or wired communications are used, as well as on whether the patient monitor is establishing a new communications connection or reestablishing prior communications which were lost or terminated.

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The patient monitors of the to-be-described system are also constructed to function both as part of a network of patient monitors and central stations, as well as stand-alone patient monitors.

Turning now to details, a system for monitoring patients according to the present invention is indicated generally at 20 in Fig 1. System 20 includes one or more patient monitors 22, each adapted to collect vital signs data from a patient. System 20 also includes one or more central monitoring stations 24 adapted to communicate with the patient monitors and receive, process and store the vital signs data. Thus, physicians, nurses and other health-care personnel (hereinafter referred to collectively as clinicians) are able to monitor a plurality of patients simultaneously and continuously from one or more central locations. As will be described in more detail below, patient monitors 22 and central stations 24 are coupled to communicate using wireless transmissions within a medical telemetry network, thereby allowing a patient to move about inside or outside a monitoring facility without loss of central monitoring.

In the exemplary embodiments shown and described herein, system 20 is configured for use in a hospital. However, it will be appreciated that system 20 also may be used in a variety of other environments including: (i) other types of medical facilities, research facilities, senior-care facilities, hospices, field hospitals, etc.; and (ii) types of non-medical facilities and environments such as patient residences, retail stores, or patient locations outdoors. Therefore, it will be understood that the description herein encompasses medical telemetry systems for use in all such environments.

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System 20 may be configured to provide patient monitoring within selected regions of a facility or throughout the facility. In the exemplary embodiment depicted in Fig. 1, system 20 is configured with patient monitors and central stations on multiple floors of a hospital. System 20 includes one or more wireless transceivers 26 disposed within the facility and configured to communicate with patient monitors 22 via wireless transmissions. The wireless transceivers are configured to convey communications between the patient monitors and the central stations. As a result, centralized patient monitoring will extend wherever wireless transceivers 26 are disposed within a facility.

Transceivers 26 may be also be characterized as transmitter/receivers 26, i.e. any device capable of transmitting and sending communication signals, whether it be a device operable for a wired application or a device operable for a wireless application. However, for purposes of the remainder of the description of the exemplary embodiment, the term transceivers will be used to describe for the wireless application being described.

Each floor may include a single central station (as shown on the upper floor in Fig. 1) or plural central stations (as shown on the lower floor). Alternatively, a single central station may be configured to monitor patients on multiple floors. In many hospitals, central stations 24 are assigned to sections within the hospital that perform different functions rather than to particular floors. For example, one or more central stations may be configured to monitor patients admitted to the Intensive Care Ward, one or more different central stations may be configured to monitor patients admitted to the Emergency Room, while one or more other central stations may be configured

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to monitor patients admitted to the Maternity Ward, etc. Regardless of how the central stations are arranged or assigned, system 20 may be configured to allow any patient monitor 22 to be monitored by any central station 24.

In addition to allowing multiple remote patients to be monitored at a central location, system 20 may also be configured to allow clinicians to view information about a patient's condition from various locations inside and/or outside the hospital. For example, in the embodiment depicted in Fig. 1, system 20 includes one or more annunciating devices 28, each having a display adapted to identify a particular patient (e.g., by name, room number, etc.) and to provide some information concerning the patient's condition. Typically, annunciating devices 28 are used to indicate alarm conditions for a monitored patient. Alternatively, the annunciating devices may be configured to indicate the condition of selected patients regardless of whether an alarm condition exists. In addition to annunciator devices 28, system 20 may also include other devices configured to enable clinicians to monitor a patient's condition at a location remote from either the patient or the central station. These other devices will be described in more detail below.

System 20 may be implemented in many different forms and configurations using various types and combinations of components to provide a variety of features and functions within the scope of the invention. For clarity, the invention will be described below primarily in the context of one particular exemplary embodiment. However, it will be understood that the scope of the invention is not limited to the particular embodiment described, but rather extends to all such embodiments, forms, configurations, types and combinations.

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Turning attention to Fig. 2, a schematic representation of exemplary system 20 is shown. The system includes a medical telemetry network 30 adapted to monitor a plurality of patients. In the exemplary embodiment, network 30 includes a physical data transport structure 32 (also referred to herein as a network) such as an Ethernet Local Area Network (LAN) system. Alternatively, network 30 may be any of the electrical and/or optical network communications structures known to those of skill in the art. Alternatively, physical data transport structure 32 may include any other suitable network structure, including a wireless structure, whether now known or later developed. In any event, physical data transport structure 32 is adapted to interconnect a plurality of network components, and to transmit data communications between the components.

Although not shown in Fig. 2, it will be appreciated by those of skill in the art that physical data transport structure 32 typically will include one or more devices adapted to connect the physical transmission lines together and route communications within the communications structure. Examples of such devices include switches, hubs, bridges, routers, and the like. Thus, as used her herein physical data transport structure 32 includes all such devices which may be necessary and/or beneficial to a particular implementation as well as the physical communication lines.

Communications transmitted within network 30 typically comply with one or more standard data communication protocols which are known to those of skill in the art. As will be described in more detail below, the components of exemplary network 30 use a variety of standard communication protocols including the Transmission Control Protocol/Internet Protocol (TCP/IP) suite, User Datagram Protocol (UDP),

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etc. Use of standard communication protocols allows a variety of different components to be connected to communicate over the network. Furthermore, use of standard communication protocols enables the use of standard routers, switches and other network devices as mentioned above. Alternatively or additionally, the components may communicate using one or more non-standardized protocols adapted for medical telemetry or a particular application.

Network 30 includes one or more central stations 24, each connected to communicate via physical data transport structure 32 and configured to monitor a plurality of patients. It will be appreciated that central stations 24 may take any one or more of a variety of different forms. In the exemplary embodiment, each central station takes the form of a computer workstation configured to communicate via physical data transport structure 32 and monitor a plurality of patients. Central stations 24 may be any suitable type of central station such as the ACUITY® central station available from Welch Allyn Protocol, Inc. of Beaverton, Oregon. The ACUITY® central station is a version of the invention claimed in U.S. Patent No. 5,319,313 to Welch et al.

One example of a central station in accordance with the present invention is shown in Fig. 3. Exemplary central station 24 includes a processing module 34 having at least one processor (not shown) and at least one data storage unit (not shown). The processor is adapted to execute software stored in the data storage unit to communicate with patient monitors, analyze patient data, etc. Central station 24 also includes a plurality of display devices such as display monitors 36. Alternatively, central station 24 may include a single display monitor. In any event, display

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monitors 36 are connected to processing module 34 and adapted to display vital signs data collected from a plurality of patients. Typically, central station 24 also includes one or more input devices 38 (e.g. keyboard, cursor control, mouse, remote control, touch-screen, etc.) operable by a user to control the central station. Central station 24 may also include one or more audio input/output (i/o) devices such as speakers, microphones, sirens, buzzers, etc., adapted to produce an audible message to a user of the central station n. Those of skill in the art will appreciate that central stations 24 may have a variety of different configurations within the scope of the invention.

Central stations 24 are typically disposed at selected centralized locations within the hospital such as at nursing stations, etc. Each central station is adapted to receive patient vital signs data from one or more patient monitors via physical data transport structure 32. The central stations are controllable by a user to display selected information concerning each monitored patient on the display monitor. This allows clinicians to view the information collected by a patient monitor at the centralized location. Additionally, central stations 24 may be configured to simultaneously display data from a plurality of patients, thereby enabling a single clinician to watch over several patients at different locations. In addition to communicating with patient monitors, central stations 24 may also be configured to communicate with other central stations within the network. Thus, for example, patient data received at one central station may be forwarded to a different central station. This allows two or more clinicians at different locations to simultaneously monitor a single patient. Communications among different central stations will be described in more detail below.

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Turning attention back to Fig. 2, network 30 may also include one or more database systems 40 configured to store patient information. Database system 40 is connected to physical data transport structure 32 and accessible by central stations 24 to store and retrieve data. Patient information stored on database system 40 may include a variety of information concerning each patient including personal information, medical history, room location, etc. Typically, the central stations are configured to access database system 40 to identify patients who are admitted to the hospital and display a list of the patients on display monitor 36. This allows a clinician to associate vital signs data received from a particular patient monitor with the corresponding patient. The central station also may be configured to store on database system 40 some or all of the vital signs data received from the patient monitors. While database system 40 is depicted in Fig. 2 as a single, separate system connected to physical data transport structure 32, it will be appreciated that other configurations are also within the scope of the invention. For example, database system 40 may be multiple databases distributed around network 30. Alternatively, database system 40 may be contained within some or all of the central stations. Typically, database system 40 is a system or network of data storage devices, some of which are contained within the central stations and others existing separately in network 30. In any event, it will be appreciated that database system 40 may be any of the various database systems or structures such as are known to those of skill in the art.

As discussed above, central stations 24 are configured to communicate with a plurality of patient monitors via physical data transport structure 32. Communications

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between the central stations and patient monitors may be via wire (i.e., transmitted over a physical line adapted to convey electrical or optical signals), or may be wireless communications. Considering first the wire communications, one or more patient monitors 22 may be connected to physical data transport structure 32 either directly (e.g., through an Ethernet connection), or indirectly through a terminal server 42 or similar device. Terminal server 42 includes a plurality of ports adapted to receive connections from the patient monitors. In addition, the terminal server is also connected to physical data transport structure 32. The terminal server is configured to receive communications from the patient monitors and forward the communications to the appropriate central station via physical data transport structure 32. Similarly, the terminal server also is configured to receive communications from the central stations via physical data transport structure 32 and convey the communications to the appropriate patient monitor. Terminal server 42 may be any of a variety of terminal servers such as are known to those of skill in the art. Any known wire or wireless communication technologies may be used to perform the functions described above.

In TCP/IP based networks, communications between central stations and patient monitors are directed to the appropriate component using network addresses such as IP addresses as well as hardware addresses. Typically, each central station is assigned a unique IP address and all communications to and from a particular central station will include the particular station's IP address. Similarly, all patient monitors which are directly connected to physical data transport structure 32 are assigned a unique IP address. In contrast, patient monitors which are connected to physical data transport structure 32 through a terminal server typically do not have a unique IP

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address. Instead, the terminal server has an IP address with which to communicate with the other components connected to physical data transport structure 32. Communications from a patient monitor are transmitted to the terminal server with the IP address of the destination component (e.g., a central station). The terminal server appends its own IP address to each communication and then forwards the communication to the appropriate component. Similarly, communications to a patient monitor are transmitted with the terminal server's address as the destination address. Upon receipt, the terminal server forwards the communications to the appropriate patient monitor.

As shown in Fig. 2, network 30 also includes one or more wireless transceivers 26, which are hereinafter referred to as access points 26. Each access point is connected to physical data transport structure 32 and configured to communicate with the other components connected to physical data transport structure 32. Each access point includes the software necessary to communicate via physical data transport structure 32 using the selected communications protocols of network 30 (e.g., TCP/IP, UDP, etc.). In the exemplary embodiment, each access point has a unique IP address that may be permanently coded into the access point, or may be assigned by a server such as described below. The access points also are configured to communicate, via wireless transmissions, with components which are not directly connected to physical data transport structure 32. Each access point includes a wireless receiver to receive wireless communications, and a wireless transmitter to transmit wireless communications.

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It will be appreciated that access points 26 may be configured to communicate using any of a variety of different wireless transmission technologies depending on the application, environment, governmental regulations, etc. In the exemplary implementation, the access points are configured to communicate with the patient monitors (described in more detail below) as well as other devices under the IEEE 802.11 standard using Frequency Hopping Spread Spectrum (FHSS) technology in the 2.4 GHz ISM (Industrial, Scientific, and Medical) band. The IEEE 802.11 communications standard is well known to those of skill in the art. Access points 26 essentially act as network bridges between the wireless components of network 30 and wired network physical data transport structure 32. Other wireless transmission, or communication, technologies known to those skilled in the art may be used including IEEE 802.11a, IEEE 802.11b, and IEEE 802.15.

Exemplary access points 26 may be any wireless transceivers adapted to communicate using the IEEE 802.11 FHSS technology. One example of a suitable access point is the SPECTRUM24 AP 3021 available from Symbol Technologies of Holtsville, New York. In other implementations and embodiments, access points 26 may be selected which are configured to communicate using other technologies. In any event, the access points usually are configured to simultaneously communicate with a plurality of patient monitors and/or other wireless devices. For example, the AP 3021 access points are adapted to simultaneously communicate with up to approximately 15 patient monitors.

Each access point typically has a range within which it can communicate with wireless devices. The range will vary depending on the power of the wireless

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transmitter, environmental conditions, etc. Typically, the access points are arranged within the hospital so that at least one access point is able to communicate with a patient monitor at any point within a defined region of the hospital. For example, if it is desired that wireless patient monitors be used on a particular floor of the hospital, then sufficient access points are provided and positioned so that every location on the particular floor is within the range of one or more access points. This ensures that a patient associated with a patient monitor can move about the hospital floor without loss of central monitoring. It will be understood that the access points may be arranged to provide wireless coverage within a defined region that is less than an entire floor of the hospital. Alternatively, the access points may be arranged to provide coverage for regions that span multiple floors (whether or not adjacent) and/or multiple buildings.

As will be discussed in more detail below, patient monitors and other wireless devices communicate over physical data transport structure 32 by first associating with an access point. Once a patient monitor has associated with a particular access point, communications between the patient monitor and components on physical data transport structure 32 are conveyed by the particular access point. However, as the patient monitor moves out of range of the particular access point and into the range of another access point, the patient monitor associates with the other access point and subsequent communications between the patient monitor and components on physical data transport structure 32 are conveyed by the other access point.

Use of FHSS technology allows access points to be positioned so that the ranges of the access points overlap. Such an arrangement provides for geographic

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redundancy in the event an access point fails. In addition, overlapping the access point ranges increases the monitoring capacity within the defined region or selected portions of the defined region. The access points typically are configured to communicate with one another to minimize or prevent interference. The access points may also be configured to manage and balance the communication loads experienced by each access point. In addition, one or more of the central stations may be configured to control the access points to balance communication loads.

It will be appreciated that in many implementations the communication of patient information by wireless transmission must be secure and confidential. These security needs may be met in any of a variety of ways known to those of skill in the art. For example, the 802.11 standard provides WEP (Wired Equivalent Privacy) which encrypts the wireless transmissions. In addition, some implementations may utilize additional security measures such as end-to-end data encryption, etc.

In the exemplary embodiment, network 30 also includes a router 44 or similar device connected to physical data transport structure 32 between a first portion 46 and a second portion 48 of physical data transport structure 32. Components connected to the first portion are assigned IP addresses corresponding to a first subnet, while components connected to the second portion are assigned IP addresses corresponding to a second subnet. First portion 46 is connected to central stations 24, database system 40, terminal server 42 and the other components of network 30 which are configured for wired communications via physical data transport structure 32. Second portion 48 is connected to access points 26. Thus, first portion 46 may be seen as a wired portion of network 30, while second portion 48 may be seen as a wireless

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portion of network 30. Use of router 44 between wired portion 46 and wireless portion 48 allows the wireless portion of the network to be isolated from the communication traffic on the wired portion of the network. Communications between patient monitors and central stations are passed by router 44 from wired portion 46 to wireless portion 48 and vice versa. However, communications between central stations and/or other components connected to wired portion 46 are not passed to wireless portion 48. Alternatively, wired portion 46 and wireless portion 48 may be directly connected to the same subnet, eliminating the need for a router.

In the exemplary embodiment, network 30 also includes at least one server system 50 connected to the wireless portion of the network. As will be discussed in more detail below, server system 50 is adapted to assign IP addresses to the patient monitors once the patient monitors associate with an access point. Server system 50 may be configured to assign IP addresses according to any suitable protocol such as the Dynamic Host Configuration Protocol (DHCP), the Bootstrap Protocol (BOOTP), etc. It will be appreciated that server system 50 is connected on the wireless portion of physical data transport structure 32 relative to router 44 to ensure that requests for IP addresses from the patient monitors are received at server system 50. Alternatively, router 44 may be configured to convey the requests for IP addresses between the wireless and wired portions, in which case server system 50 may be connected on the wired portion of the network.

Server system 50 may be a separate computer system adapted to manage and assign IP addresses only, or it may be configured to perform other functions including network management, etc. In alternative embodiments, one of central stations 24 is

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configured to perform the functions of server system 50, thereby alleviating the need for a separate server system 50. In such embodiments, the central station which is configured to assign IP addresses in the alternative embodiment should be connected to the wireless portion of network 30 unless router 44 is adapted to pass requests for an IP address to the wired portion of the network.

Network 30 may also include one or more wireless communication devices referred to herein as clinician terminals 52. The wireless clinician terminals may take any one of a variety of different forms including Personal Digital Assistants (PDA's), Internet Protocol (IP) telephones, portable computers, etc. Clinician terminals 52 include wireless transceivers (e.g., RF network cards) that are configured to associate with access points 26. The clinician terminals also include suitable software executable by the terminals to communicate with the central stations via access points 26. The clinician terminals may also be configured to perform a variety of functions such as receiving and displaying patient vital signs data from the central station, transmitting control instructions to the central station to control a selected aspect of the central station, transmitting control instructions to the central station for forwarding to a patient monitor to control selected aspects of the patient monitor, sending and receiving textual messages, receiving and acknowledging alarm signals, etc. In the exemplary embodiment, clinician terminals 52 are configured to function as quasi-central stations, by displaying patient vital signs data and providing a user-interface operable by the clinician to control the patient monitor.

Clinician terminals 52 enable physicians, nurses and others to obtain information concerning a patient from any location within the defined region of

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network 30, rather than only at the patient's location or at a central station. Thus, for example, a clinician several floors away from a patient can receive a notification of an alarm at the patient monitor associated with the patient. Further, the clinician can evaluate the patient's condition from the vital signs data without going to the patient's location. The clinician may then take appropriate action depending on the patient's condition. It will be appreciated that clinician terminals 52 enable clinicians to work more efficiently and effectively, and to care for a larger number of patients than would otherwise be possible. Furthermore, while the clinician terminals may include paging functions, the clinician terminals provide substantially more information to the clinicians than pagers.

Exemplary telemetry network 30 also is connected to the main computer network 54 of the hospital, referred to hereinafter as the secondary or non-telemetry network. Secondary network 54 typically includes a plurality of computer terminals 56, database systems 58, etc. The secondary network interconnects the hospital's administrative computers and other non-telemetry components. Typically, secondary network 54 is connected to telemetry network 30 through router 44. This isolates the telemetry network from non-telemetry communication traffic, while allowing devices connected to the non-telemetry network to access patient vital signs data. Similarly, users of central stations 24 are able to access information on the secondary network as needed. In some implementations it may be desirable to provide security measures to ensure that only authorized users of secondary network 54 are able to access telemetry network 30. Any of a variety of suitable security measures may be employed as are known to those of skill in the art.

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Network 30 may also be connected to a communications network external to the hospital such as an extranet, virtual private network, Wide Area Network (WAN), etc. In the exemplary implementation, network 30 is connected to the Internet 60. Typically, network 30 is connected to the Internet via a firewall 62 or other suitable security device to restrict access to patient data and other confidential information.

As shown in Fig. 4, the telemetry network of one hospital 64 may be connected to the telemetry network and/or the secondary network of one or more other hospitals 66 in remote locations. The telemetry network may be connected to the remote hospitals via Internet 60 or via a direct, non-public network 68 such as is known to those of skill in the art. Central stations 24 of hospital 64 may be configured to transmit patient information including vital signs data to central stations or other computers in remote hospital 66. Similarly, the central stations of hospital 64 may be configured to request and receive patient information including vital signs data from remote hospitals 66. It will be appreciated that communication of patient information between remote hospitals allows clinicians to participate in consultations with their remote colleagues more effectively and efficiently.

In the implementation described above, access points 26 were arranged within the hospital to provide wireless monitoring in a defined region of the hospital. In alternative implementations, the defined region may extend outside the hospital. For example, system 20 may include one or more access points 26 which are positioned outside of the hospital, as shown in Fig. 4. The access points are connected to Internet 60 and configured to transmit the patient vital signs data to network 30 and one or more central stations 24. This allows patients to move outside of the hospital without

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loss of continuous central monitoring. So long as the patient remains within the range of at least one access point, the patient's vital signs data may be displayed on a central station as if the patient was still in the hospital. Similarly, emergency response workers could connect a patient monitor to an accident victim so that the hospital can monitor the victim's condition while the victim is transported to the hospital.

It will be appreciated that placement of access points outside of the hospital also allows clinicians to access patient data when outside the hospital. As shown in Fig. 4, one or more clinician terminals 52 may associate with the external access points to view patient information and control the patient monitor connected to a patient. This provides clinicians with more flexibility to leave the hospital while continuing to monitor their patients at the hospital (or patients outside the hospital). Alternatively, clinicians may monitor patients using personal computers 70 or similar devices configured to connect to Internet 60 and communicate with central stations at the hospital. Computers 70 may be located anywhere a connection is available that provides a communication channel using any communication technology. For example, computers 70 may be located anywhere a connection to the Internet is available. Alternatively, computers 70 may be configured to associate with an external access point and communicate via wireless transmissions.

As discussed above, the defined region of monitoring will extend outside the hospital wherever access points 26 are positioned. In areas where the external network of access points is undeveloped, patient monitors 22 and/or clinician terminals 52 may be configured to communicate using other wireless communication technologies. For example, the implementation depicted in Fig. 4 includes a Cellular

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Digital Packet Data (CDPD) network 72, such as is currently used for cellular telephone and other communications. Patient monitors 22 and/or clinician terminals 52 may be configured to communicate with central stations in hospital 64 via CDPD network 72. Thus, for example, a patient might be discharged to go home while continuing to be monitored. It will be appreciated that this alleviates the need to have new wireless networks installed throughout a geographic region, since the components of system 20 are configured to communicate using preexisting networks. An alternate implementation (undepicted) would be to use what is known as a Global System Mobile (GSM), or any other available wide-reaching communication system.

Considering patient monitors 22 in more detail, it will be appreciated that there are a variety of different patient monitors available and suitable for use with system 20. System 20 may include one or more patient monitors of a single type, or may include multiple types of patient monitors, each configured to communicate with one or more central stations. For example, the exemplary embodiment of system 20 depicted in Figs. 1 and 2 includes a first type of patient monitor 22a adapted to be carried or worn by a patient, and a second type of patient monitor 22b adapted to be mounted on a bed, wheelchair, etc, as well as being carried. Patient monitors 22a and 22b may be configured to perform the same monitoring functions or may be configured to perform different monitoring functions. In any event, each type of patient monitor 22 is configured to collect vital signs data from a patient and communicate at least a portion of the vital signs data to a central station via physical data transport structure 32. Suitable patient monitors are available from several

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manufacturers, including the MICROPAQ and PROPAQ patient monitors available from Welch Allyn Protocol, Inc. of Beaverton, Oregon.

Turning attention now to Fig. 5, exemplary patient monitor 22a is shown in more detail. The monitor includes a portable housing 80 having one or more sensor input ports 82. The housing is sized to be held by a clinician or patient, or to be worn by the patient using a strap, belt, or similar device. Sensor input ports 82 are adapted to receive and connect to sensor cables 83. Each cable 83 is attached to one or more sensor assemblies (not shown). The sensor assemblies may include any vital signs sensor assembly adapted to detect and/or measure selected vital signs data from a patient and transmit the vital signs data via cables 83. Examples, of suitable sensor assemblies include electrocardiogram (ECG) sensor assemblies, non-invasive blood pressure sensor assemblies, invasive blood pressure sensor assemblies, temperature sensor assemblies, pulse oximetry sensor assemblies, respiration sensor assemblies, carbon dioxide sensor assemblies, etc. Suitable sensor assemblies are available from Welch Allyn Protocol, Inc. of Beaverton, Oregon. In any event, each sensor input port is adapted to receive patient vital signs data from the sensor assembly attached thereto.

Patient monitor 22a also includes a display device such as display screen 84 adapted to display the vital signs data or an image representative of the vital signs data. Exemplary display screen 84 is in the form of a liquid crystal display (LCD) device. Alternatively or additionally to display screen 84, patient monitor 22a may include any other suitable display device such as a printer, one or more indicator lights, light-emitting diodes, etc. The patient monitor also includes one or more input

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devices such as buttons 86 disposed on housing 80. Buttons 86 are operable by a user to input information into patient monitor 22a, as will be discussed in more detail below. In addition to, or in place of buttons 86, the patient monitor may include other types of input devices including switches, knobs, etc. As a further alternative, display screen 84 may be a touch-screen adapted to input information in response to contact by the user at selected locations on the screen. While the exemplary embodiment will be described below as having input devices in the form of buttons, it will be understood that any type of input device may be used.

Exemplary patient monitor 22a further includes a battery assembly 88 having one or more batteries. Battery assembly 88 is mountable in a battery compartment within housing 80. The batteries typically are rechargeable, however non-rechargeable batteries may also be used. Although not shown in Fig. 5, patient monitor 22a also includes a controller, a memory device, and an on-board wireless transceiver, all operably disposed within portable housing 80. An internal antenna 90 is mounted within the housing and coupled to the wireless transceiver. Alternatively, antenna 90 may be disposed externally to housing 80. An audio input/output device 92, (e.g., speaker, microphone, buzzer, siren, etc.) is also disposed within the housing and adapted to produce an audible notification to a clinician, patient, or other user of the monitor. An alternative to the input/output device would be a bi-directional audio device.

As shown in Fig. 6, exemplary patient monitor 22b includes a portable housing 94 adapted to attach to a bed, wheelchair or other support structure. Housing 94 includes one or more sensor input ports 82 adapted to connect to sensor cables 83 and

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receive vital signs data from one or more sensor assemblies (not shown). Similar to patient monitor 22a, patient monitor 22b includes a display device such as display screen 84 and one or more input devices such as buttons 86. Although not shown in Fig. 6, patient monitor 22b also includes a battery assembly 88, an antenna 90, and an audio output device 92. As will be described in more detail below, patient monitor 22b also includes a controller, a memory device and an on-board wireless transceiver, all operably disposed in housing 94.

Unlike patient monitor 22a, patient monitor 22b includes an output port 96 adapted to receive a hard-wired network connection cable 98 such as an Ethernet, RS-232, modem line, or similar network communications cable for connection to physical data transport structure 32 or terminal server 42. Thus, patient monitor 22b is configured to communicate with central stations 24 using either wireless communications via its on-board wireless transceiver, or wire communications via output port 96. As will be discussed in more detail below, patient monitor 22b may be configured to automatically switch between wire and wireless communications in various situations.

As mentioned above, each patient monitor 22 includes a controller disposed within the portable housing. It will be appreciated that any of a variety of different computer controllers, micro-controllers, or processors, such as are known to those of skill in the art, may be used. The controller, indicated at 100 in Fig. 7, is operably coupled to receive power from battery assembly 88. The controller may also be configured to receive power from other sources (e.g., AC line current through a wall socket, DC current through photovoltaic cells, etc.).

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Controller 100 is also connected to memory device 102. It will be appreciated that memory device 102 may be any one or a combination of devices adapted to store electronic information such as RAM, ROM, PROM, EPROM, etc. Memory device 102 may also include removable storage media such as magnetic discs and tapes, optical discs, etc. In addition to storing patient vital signs data, memory device 102 may be configured to store one or more software control programs executable by controller 100 to perform its various functions including receiving and analyzing vital signs data, presenting information to a user, etc. In addition, the software will include the necessary programs for communicating with central stations 24 (e.g., TCP/IP, DHCP, etc.) While memory device 102 has been depicted as a single device, those of skill in the art will appreciate that memory device 102 may be a plurality of either similar or different memory devices.

Controller 100 is also coupled to sensor ports 82 and configured to receive vital signs data from the sensor assemblies via the sensor ports. In addition, controller 100 may be configured to supply power and/or suitable drive signals onto one or more of the sensor ports to drive the sensor assemblies attached to the ports. In any event, vital signs data received at controller 100 may be stored in memory device 102, processed, discarded, and/or communicated immediately to a central station.

The controller is connected to control wireless transceiver 104 and communicate with central stations 24 via the transceiver. Wireless transceiver 104 may be any of a variety of wireless transceivers which are known to those of skill in the art. One example of a suitable wireless transceiver is the SPECTRUM24 LA 3021 PC card, available from Symbol Technologies of Holtsville, New York.

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Alternatively, other wireless transceivers may be used. In any event, wireless transceiver 104 is configured to communicate with access points 26 using the appropriate communications protocol of network 30. The wireless transceiver is connected to antenna 90 and transmits data received from controller 100 to access points 26. Similarly, the wireless transceiver receives transmissions from one or more access points and forwards the communications to the controller. The wireless communications between patient monitor 22 and the central stations will be discussed in more detail below.

In the case of patient monitor 22b, controller 100 is also connected to output port 96 and configured to communicate with central stations 24 via the output port rather than via wireless transceiver 104. Controller 100 may also include a network card or similar device (not shown) adapted to transmit and receive communications via output port 96. For clarity, the description below assumes that patient monitor 22 communicates with central stations 24 via wireless transceiver 104. However, it will be understood that, unless stated otherwise, and for purposes of this description, communications via output port 96 are viewed as identical to communications via the wireless transceiver, and therefore both types of communications are included within the description. A distinction between wireless and hard-wired communication is that patient location (room) is known with hard-wired communication (via the network jack to which the monitor is connected) and not known with wireless communication. However, for purposes of this description, that distinction is not seen as pertinent and that is why communications via output port 96 are viewed as identical to communications via the wireless transceiver.

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Controller 100 is also connected to receive inputs from buttons 86. The buttons are operable by a user of the patient monitor to input information to the controller, as well as to control the controller. Each button may have a single function or may have a variety of functions depending on such factors as the operating condition of the controller, status of the sensor assemblies, communications with a central station, screen displays, etc. In the exemplary embodiment, controller 100 is configured to control the function of buttons 86 and to disable the buttons under defined conditions.

Controller 100 is configured to control display screen 84 to display an image representing the vital signs data. It will be appreciated that the image displayed on display screen 84 will vary depending on the vital signs data collected by the patient monitor. Additionally, exemplary controller 100 is configured to change the display based on instructions received from the user via buttons 86. For example, the user might select between displaying a single ECG signal from a single electrode, or multiple ECG signals from multiple electrodes. Fig. 8 shows an exemplary display screen 84 on which vital signs data is being displayed. A waveform region 106 of the display shows an image representing the signal data received from an ECG sensor assembly. A numeric region 108 of the display shows images that provide numerical representations of the vital signs data (e.g., heart rate, oxygen saturation in the patient's blood, etc.). The display may also include a patient identifier 110 that uniquely identifies the patient, such as the patient's name, etc. Fig. 9 shows another exemplary display screen 84 similar to the one in Fig. 8. However, the display screen shown in Fig. 9 has been changed to include a message region 112 for displaying messages to a user. Similarly, Fig. 10 shows another exemplary display screen 84 in

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which the image has been changed to include a user-interface region 114. The user-interface region allows a user to enter information and control the patient monitor by operating buttons 86. Control of the display screen will be described in further detail below.

Controller 100 is also connected to control audio output device 92 and/or other audible indicator devices to produce audible messages or signals. The controller may be configured to control the audio output device to produce audible signals under any one or more of a variety of conditions. For example, controller 100 is typically configured to analyze at least some of the vital signs data and produce an audible alarm if the vital signs data is outside a selected nominal range. The analysis of vital signs data and detection of alarm conditions will be described in further detail below.

While one exemplary functional embodiment of patient monitors 22 has been depicted in Fig. 7 and described above, it will be appreciated that many other configurations are possible. Thus, the invention is not limited to the exemplary embodiment described, but includes any patient monitor configuration adapted to collect vital signs data from a patient and communicate the vital signs data to one or more central stations.

Typically, patient monitors 22 are configured to function as stand-alone devices capable of providing local patient monitoring regardless of whether the patient monitor is in communication with a central station. The patient monitor may be configured to begin monitoring immediately upon power-up and attachment of at least one sensor assembly. Alternatively, the patient monitor may be configured to begin monitoring upon receipt of an actuation signal.

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Patient monitors 22 are also configured to attempt to establish communications with one or more central stations and communicate the vital signs data to the central stations. In the exemplary embodiment, the patient monitors are configured to attempt to establish communications immediately at power-up and to continue the attempt until communications are established. Alternatively, one or more of the patient monitors may be configured to attempt to establish communications only in response to an instruction by a user and/or the occurrence of selected conditions. Those of skill in the art will appreciate that the process of establishing communications with one or more central stations, also referred to herein as the rendezvous process, may be carried out in any of a variety of different ways. In addition, the rendezvous process may vary depending on whether the patient monitor is communicating through wireless or wire communications, as well as on whether the patient monitor is establishing a new communications connection or reestablishing prior communications which were lost or terminated.

The rendezvous process of the exemplary embodiment is schematically illustrated in Fig. 11. The process begins with establishing a connection to physical data transport structure 32 by any one of several methods. Where patient monitor 22 is configured to communicate using only wireless communications, the patient monitor establishes a connection to physical data transport structure 32 by associating with an access point, as indicated at 200. It will be appreciated that the process of associating with an access point may vary with varying configurations of the access point and/or varying configurations of the patient monitor. In the exemplary embodiment, wireless transceiver 104 associates with a patient monitor according to

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the IEEE 802.11 standard, and the details of that standard are known to those skilled in the art. Certain features of the exemplary embodiment include that (i) the patient monitors can be used in any telemetry network described herein (such as the 802.11-standard telemetry network) without user-adjustment of the communications frequency, and (ii) the patient monitors automatically scan for access points and detect access-point configuration and synchronization information.

In addition, the wireless transceiver determines which access points are within range of the patient monitor, and the current communications load on the in-range access points. Using this information, the patient monitor selects one of the in-range access points with which to communicate, and begins the authentication process which is followed by the association process. Once the authentication and association processes are complete, the connection between the patient monitor and physical data transport structure 32 is established.

In the exemplary embodiment where communications over network 30 conform to the IP protocol, each device must have an associated IP address with which to send and receive communications. In some embodiments, patient monitor 22 may have a permanently assigned IP address stored in memory device 102. Alternatively, patient monitor 22 may not have an assigned IP address, and instead may be configured to request an IP address upon establishing a connection with physical data transport structure 32, as indicated at 202 and 204. Typically, patient monitor 22 requests an IP address by transmitting a broadcast request to server 50 using the appropriate protocol (e.g., DHCP, BOOTP, etc.). The request is answered by server 50, which responds by assigning the patient monitor an IP address from a

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store of available IP addresses, and then transmitting a notification of the assignment to the patient monitor. Alternatively, server 50 may store a pre-assigned IP address for each device, and respond with the corresponding pre-assigned IP address. Upon receiving the assigned IP address, the patient monitor is prepared to broadcast a request for communications to one or more central stations, as will be described in more detail below.

Where patient monitor 22 is adapted to communicate using either wireless or wire communications, the process for establishing a connection to physical data transport structure 32 will vary depending on whether a wireless or wire connection is established. In the former case, the process may occur as described above, i.e., first associating with an access point, and then requesting an IP address if necessary. Alternatively, if a wire connection is to be established, the patient monitor may be physically connected to a terminal server which is connected to the network, as indicated at 206. It will be appreciated that the connection indicated at 206 may alternatively take other forms, such as a modem connection to a modem server, etc. In any case, once the connection is established and any necessary hand-shaking between the patient monitor and the terminal server is completed, the patient monitor is prepared to broadcast a request for communications to one or more central stations. Patient monitor 22 will communicate using the IP address of the server, and therefore is not required to have its own IP address.

As a further alternative, the patient monitor may be directly connected to a hard-wired connection on physical data transport structure 32 with an Ethernet or similar connection technology, as indicated at 208. As with a patient monitor that is

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connected to communicate using wireless communications, a patient monitor directly connected to physical data transport structure 32 may have a permanently assigned IP address, or may request the assignment of an IP address once the physical connection is established. In any event, in the hard-wired implementation, the terminal server is then prepared to initiate a request for communications to one or more central stations.

Regardless of how a patient monitor establishes a connection with physical data transport structure 32, the patient monitor must then establish communications with a central station by broadcasting a request for communications to the central station, as indicated at 210. It will be appreciated by those of skill in the art that a patient monitor may broadcast a request for communications in any of a variety of ways. In the exemplary embodiment, the patient monitor transmits the request as a UDP broadcast to all central stations. Alternatively, other communication protocols may be used.

The UDP communications request may include a variety of parameters adapted to inform the central station about the patient monitor. For example, communications requests typically include such information as the identity, type, and/or capabilities of the patient monitor, the IP and MAC (Media Access Control) addresses of the patient monitor, the version of software installed on the patient monitor, etc. The request may also include an indicator of the type of communications desired. For example, the patient monitor may request communications to establish central monitoring of a patient, download newer versions of the patient monitoring software (discussed in more detail below), or perform network maintenance, etc. This information allows the central station to determine how to respond to the request. Unless stated otherwise,

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the description below will assume that the patient monitor's communications request is for the purposes of establishing centralized monitoring of a patient.

In the exemplary embodiment, the communications request is passed to, and received by, all central stations of network 30, as indicated at 212. Any routers or other network devices connected to physical data transport structure 32 are configured to pass on the request to the central stations as necessary. Alternatively, the request may be conveyed to fewer than all of the central stations, or to a single central station. Each central station is configured to respond to the communications request when received. Upon receiving the first response the patient monitor transmits an acknowledgement to the central station that sent the first response. The patient monitor is configured to reject subsequent responses by transmitting a "reject" message to any central station that sends a subsequent response. The central stations are configured to cease sending responses to the communications request after receiving a "reject" message, unless a new request for communications is received.

In some embodiments, the central stations may be configured to ensure that a preferred central station responds to the communications request. For example, the central stations may be configured to recognize a patient monitor that has communicated with network 30 in the past (e.g., based upon information transmitted in the communications request), and to allow the particular central station that was previously in communication with the patient monitor to respond first. Thus, in the exemplary embodiment the central stations are configured to determine if a communications request was sent by a patient monitor which was previously in communication with a particular central station within a predefined time period. If so,

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the particular central station is configured to respond to the request immediately, while the remaining central stations will wait for a relatively short period of time (e.g., 10, 15, 20, 25, or 30 seconds, etc.) before responding. This priority is based on the assumption that the patient monitor is likely still connected to the same patient as during the previous communications, and that the patient is likely to be monitored at the same central station as during the previous communications. In any event, once the patient monitor receives a first response to its communications request, the patient monitor and the central station which sent the first response (hereinafter referred to as the "provisional central station") begin communicating to configure the centralized monitoring session, as indicated at 214.

As will be described in more detail below, the particular central station which serves as the provisional central station begins the process of configuring the monitoring session. However, before the centralized monitoring begins, one of the central stations of network 30 is selected to complete the configuration process and perform the central monitoring. This selected central station is referred to herein as the "primary central station." If the provisional central station is selected to be the primary central station, then no change in communications is needed, and the provisional central station assumes the role of the primary central station. Conversely, if a different central station is selected to be the primary central station, communications with the patient monitor are transferred from the provisional central station to the selected central station, which then assumes the role of primary central station.

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As is known to those of skill in the art, wireless communications which have been established between a patient monitor and a primary central station may be lost or "dropped" for any of a variety of reasons. For example, the wireless transmissions may not be received by the access point and/or the wireless transceiver of the patient monitor because the patient monitor is moved out of the defined range of network 30 (i.e., out of range of any access point). Similarly, the transmissions may have been blocked by structures between the patient monitor and the access point, such as when the patient monitor is taken into an elevator or similar enclosure. Alternatively, a portion or device of network 30 may have failed, causing the communications to be dropped. As a further alternative, the battery in the patient monitor may have been replaced or discharged, causing the patient monitor to lose communications.

The response by patient monitor 22 and central stations 24 to communications dropouts may vary depending on the length and/or cause of the dropout. In the exemplary embodiment for example, a relatively brief dropout (e.g., less than approximately 10, 20, or 30 seconds, etc.), is treated as an interruption rather than as an actual loss of communications. Lost or incomplete transmissions due to such interruptions may be resent, discarded, or ignored according to the communications protocols used by the patient monitor and central stations. Once the interruption ends, the patient monitor and primary central station resume communicating as before.

In the event of a loss of communications that extends beyond a brief interruption, exemplary patient monitor 22 is configured to detect the loss and automatically attempt to restore the communications. If the patient monitor is no longer associated with an access point, the patient monitor attempts to establish an

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association as described in the 802.11 standard, and continues to attempt to establish an association until association with an access point is regained. Once the patient monitor re-associates with an access point (or if the patient monitor never lost the association), the patient monitor broadcasts a request for communications to the central stations, and the rendezvous process proceeds as described above. Once the patient monitor is in communication with a provisional central station, the patient monitor and provisional central station begin the process of configuring the monitoring session, as indicated at 214.

It will be appreciated that the session configuration process may proceed in any of a variety of different ways to configure a variety of different monitoring parameters. For example, the configuration process may identify which patient is being monitored, which central station will monitor the patient, which central station will control the patient monitor, what types of vital signs data should be monitored, how the vital signs data should be analyzed, what alarm conditions should be detected, how the patient monitor should function, etc. An exemplary session configuration process is indicated generally at 216 in Fig. 12. During process 216 a primary central station is selected, the monitored patient is identified, and the patient's room or other location is specified.

Referring to Fig. 12, the provisional central station first determines whether the patient monitor is still connected to the same patient as before the communications dropout. If such is the case, then the provisional central station assumes that the patient monitor is attempting to restore communications which were lost, and prior values for patient identity, etc., may be used. Alternatively, if the request is to

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establish new communications, then the central station determines the information needed to complete the configuration by querying a user of the patient monitor, as will be described in more detail below.

The provisional central station may be configured to employ a variety of different methods or mechanisms to determine whether the patient monitor is still connected to the same patient. In the exemplary embodiment for example, the provisional central station first sends a request to the patient monitor for an indication of whether the patient monitor was continuously monitoring the patient during the period the communications were lost, as indicated at 218. If the patient monitor responds affirmatively, then the patient currently being monitored is necessarily the same patient that was previously monitored.

Patient monitor 22 is configured to receive the request and detect whether it continuously monitored the same patient during the communication dropout. Typically, the patient monitor is configured to detect continuous monitoring by detecting whether the patient monitor was operational during the communications dropout, and whether vital signs data was continuously received via at least one of the sensor assemblies. For example, one exemplary ECG sensor assembly connectable to a patient is adapted to continuously send ECG vital signs data to patient monitor controller 100. If the patient monitor is disconnected from the patient during the dropout, the ECG signal will lapse. Any lapse in the ECG vital signs data is detected by the controller. Alternatively, the ECG sensor assembly, or other types of sensor assemblies, may be configured to detect actual contact with the patient. In any event, the patient monitor responds to the request by informing the provisional central station

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of whether the patient monitor has continuously monitored the same patient. It should be noted that the patient monitor may be monitoring the patient through sensor assemblies that do not continuously send vital signs data to the controller, and that do not detect contact with the patient. In which case, the patient monitor will be unable to confirm that it has continuously monitored the same patient, and will respond to the request from the central station accordingly.

If, at step 218, the patient monitor responds that it has continuously monitored the same patient, the provisional central station proceeds to perform a reconnect process, as indicated at 220 and as described below. Alternatively, if the patient monitor responds that it has not continuously monitored the same patient, the provisional central station then determines whether the patient monitor was recently connected to network 30, as indicated at 222. In other words, if the time period during which communications between the patient monitor and the primary central station were lost is less than a predetermined length of time, then the provisional central station concludes that the patient monitor is attempting to restore a recent connection, and proceeds to perform reconnect process 220. Otherwise, the provisional monitor concludes that the patient monitor is attempting to establish a new communications session. It should be noted that if the patient monitor was continuously monitoring the same patient during the communications dropout, then the provisional central station may safely assume the patient monitor is still connected to the same patient regardless of the length of the dropout.

The predetermined length of time that defines a recent connection may be set to any desired length of time as appropriate for a particular application. In the

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exemplary embodiment, the predetermined length of time is selected to be less than the minimum time period (e.g., 1, 2, 3, 4, or 5 minutes, etc.) normally needed to disconnect a patient monitor from one patient and reconnect the patient monitor to another patient. Thus, if the patient monitor was out of communication for any period of time less than that minimum disconnection/reconnection time, the provisional central station concludes that the patient monitor is still connected to the same patient. Alternatively, other time periods may be used.

The provisional central station may determine whether the patient monitor was recently connected in various ways. Typically, each central station is adapted to store patient vital signs data in database system 40. The vital signs data includes the time of collection by the patient monitor and/or receipt by the central station. Thus, the provisional central station may be configured to access database system 40 to determine the time that the last vital signs data was received from the patient monitor. Alternatively, the patient monitor may be configured to determine the length of the dropout and to inform the provisional central station, either automatically or in response to a query from the provisional central station.

In addition to the length of time during which communications were lost, the provisional central station may be configured also to evaluate other conditions at step 222. For example, if the prior communications were dropped intentionally, i.e., in response to a command by a user, the provisional central station may be configured to assume that a new patient has been connected to the patient monitor. In which case, the patient monitor is not attempting to restore a recent connection, but instead is attempting to establish a new communications connection.

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As mentioned above, the provisional central station proceeds to perform a reconnect process, indicated at 220, if the provisional central station determines either that the patient monitor continuously monitored the same patient during the dropout, or that the patient monitor was recently connected to communicate with a primary central station. During reconnect process 220 the provisional central station automatically determines which patient is being monitored by the patient monitor, and which central station served as the primary central station before the communications dropout. Typically, this information is stored by the patient monitor in memory device 102, and is communicated to the provisional central station by the patient monitor. Alternatively, the information may be stored in database system 40 and read by the provisional central station via physical data transport structure 32.

In any event, if the provisional central station is not the primary central station, then the provisional central station conveys a message to the primary central station to take over the remainder of the rendezvous process. If the primary central station is available, it begins communicating with the patient monitor via physical data transport structure 32 and conducts the remainder of the configuration process as described below. Likewise, the patient monitor transmits all subsequent communications to the primary central station, and the provisional central station ends further communications with the patient monitor.

Alternatively, if the primary central station does not respond to the provisional central station or is otherwise unavailable, the provisional central station may be configured to transmit a message to the patient monitor that the primary central station is unavailable. In the exemplary embodiment, the patient monitor controller causes

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display screen 84 to display a user-interface 114, such as shown in Fig. 13, including a message that the primary central station is unavailable. The user-interface may also include instruction elements 116 which are selectable by a user to instruct the central station to recheck the availability of the primary central station, or to try a new primary central station. The clinician or other user of the patient monitor may use buttons 86 to select the desired instruction, which the patient monitor then communicates to the provisional central station. Depending on the user's instructions, the provisional central station either sends another message to the primary central station to take over the communications, or transmits a list of central stations to the patient monitor. In the latter case, controller 100 causes the display device to display a list of central stations, from which the user may select using buttons 86. The patient monitor transmits the user's selection to the provisional central station, which sends a message to the selected central station to take over the communications. If the selected central station is not available, the provisional central station informs the patient monitor and the user either selects a different central station, or instructs the provisional central station to retry the selected central station. This process may be repeated until an available central station is selected to act as the primary central station. The selected central station then begins communicating with the patient monitor and conducts the remainder of the configuration process.

Once the primary central station takes over the communications with the patient monitor, the primary central station is configured to determine the patient identity (patient ID) of the particular patient being monitored by the patient monitor. In general, either or both the primary central station and the patient monitor may be

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configured to be involved with the determination of patient ID. For example, the primary central station may determine the patient ID by transmitting a request for the patient ID to the patient monitor. If the patient monitor cannot provide the patient ID, the primary central station then accesses database system 40 to obtain the patient ID which was stored during the patient monitor's last communication session. Once the primary central station determines the identification of the particular patient being monitored by the patient monitor, the primary central station thereafter associates all vital signs data received from the patient monitor with the particular patient. In addition, the vital signs data along with other patient information may be stored on database system 40, and then retrieved for viewing and analysis at a later time.

After the primary central station has assumed the communications with the patient monitor and determined the identity of the patient being monitored, the primary central station then determines whether the patient has been assigned to a particular location, such as a room number, bed, ward, floor, etc., as indicated at 224 in Fig. 12. This information may then be displayed on central station monitor 36 to inform the clinician of the patient's assigned location. However, in view of the portability of patient monitors 22, a particular patient may be temporarily absent from his or her assigned location even though the patient is continuously monitored at the central station. In any event, the primary central station determines whether the patient has been assigned to a particular location by sending a request for the information to the patient monitor. If the patient monitor is unable to provide an assigned location, the primary central station may be configured to search database system 40 for the information.

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If the primary central station is unable to determine the assigned location, the central station is configured to query the user of the patient monitor for the patient's assigned location, as will be described in more detail below. Otherwise, the rendezvous and configuration processes are complete, and the primary central station proceeds to confirm that no other patient monitor is monitoring the same patient, as indicated at 226. In addition to checking the other patient monitors in communication with the primary central station, the primary central station also communicates with other central stations in network 30 to ensure that the same patient is not being monitored by a different central station. In the event the primary central station determines that another patient monitor is monitoring the same patient, an alarm or other indication may be displayed at the primary central station and/or the patient monitor so that a different patient ID may be selected.

As described above, the patient monitor is adapted to automatically attempt to restore communications with its primary central station in the event the communications are lost. Upon reestablishing communication, the primary central station (or a provisional central station, if different than the primary central station) is configured to automatically determine whether the patient monitor is still connected to the same patient. The central station may use a variety of mechanisms and methods to determine whether the patient monitor is still connected to the same patient, including measuring the length of time of the communications dropout, and determining whether the patient monitor disconnected from the patient data during the dropout. If the patient monitor is still connected to the same patient, the central station then associates the patient monitor with the patient so that any vital signs data received

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from the patient monitor is also associated with the patient. It will be appreciated that the capability to automatically identify the monitored patient at the central station after a communications dropout, enables the central station to monitor a large number of patients without constant intervention by a clinician to reconfigure a patient monitor each time a dropout occurs. Furthermore, the automatic configuration ensures that centralized monitoring of the patient resumes as soon as the patient monitor restores communication with the central station.

Turning attention back to Fig. 12, if the provisional central station determines that the patient monitor is not attempting to restore lost communications, the provisional central station proceeds to configure a new monitoring session by determining the identity of the patient being monitored, the primary central station which will monitor the patient, and the patient's assigned location. When the patient monitor establishes a new communications connection with the provisional central station, the patient monitor automatically displays a notification to a user of the patient monitor on display screen 84. As will be described below, the notification typically includes a user-interface operable by a user of the patient monitor to configure the communications session.

It will be appreciated that the provisional central station may determine the identity of the monitored patient in various ways. For example, even where the patient monitor has not recently been in communication with a central station and has not been monitoring the patient continuously since its last communication with a central station, it nevertheless may be more likely than not that the patient monitor has been reconnected to monitor the same patient. In the exemplary embodiment

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therefore, the provisional central station first determines whether the identity of the previous patient monitored by the patient monitor is available, as indicated at 228.

To determine whether the patient ID of the previous patient is available, the provisional central station may be configured first to query the patient monitor. Exemplary patient monitor 22 is configured to store the ID of the previous patient in memory device 102, unless the patient ID is cleared by the user. Thus, the exemplary provisional central station transmits a request to the patient monitor for the previous patient ID. If the previous patient ID is available at the patient monitor, the patient monitor communicates the previous patient ID to the provisional central station. Otherwise, the patient monitor responds that no patient ID is available.

If the patient ID is not available at the patient monitor, the provisional central station may be configured to search database system 40 for the previous patient ID associated with the patient monitor. Alternatively, if the patient monitor is connected to physical data transport structure 32 via a hard-wired connection, the provisional central station may be configured to search the database system for the previous patient ID associated with the particular location of the hard-wired connection. This strategy is based on the likelihood that the patient who was previously in the room with the hard-wired connection has not been moved since the last communications session. In the exemplary embodiment, the provisional central station is configured to search for the patient ID associated with the patient monitor if the patient monitor is communicating via wireless transmissions, and to search for the patient ID associated with the particular location of the hardwired connection if the patient monitor is communicating via wire.

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If the previous patient ID is available (either from the patient monitor or the database system), the provisional central station communicates an instruction to the patient monitor to confirm whether the patient currently being monitored is the same as the last patient monitored, as indicated at 230. In response, controller 100 automatically causes display screen 84 to display a user-interface 114, such as illustrated in Fig. 14. The user-interface displays the previous patient's identity (i.e., the patient's name, identifying number, and/or other identifying designation) and asks the user to confirm that the patient monitor is connected to the previous patient. Exemplary user-interface 114 also includes instruction elements 116 which are selectable by the user to indicate that the patient monitor is or is not connected to the previous patient. In the exemplary embodiment, the user-interface also displays the patient's assigned location, indicated at 118, and the central station that previously monitored the patient, indicated at 120. Thus, the clinician or other user is prompted by user-interface 114 to confirm that the same patient is being monitored, and is assigned to the same location, and is to be monitored by the same central station. Alternatively, the user may indicate that a new patient is being monitored, or that the patient has been assigned to a new location, or that the patient should be monitored by a different central station. The user's selection is communicated by the patient monitor to the provisional central station.

As shown in Fig. 12, if the user confirms the previous patient, location and primary central station (i.e., by selecting the instruction element labeled "YES"), the rendezvous and configuration processes are complete, and the primary central station proceeds to confirm that no other patient monitor is monitoring the same patient, as

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indicated at 226 and as discussed above. It should be noted that if the provisional central station is not the primary central station, then the provisional central station sends a request to the primary central station to take over the communications and complete the configuration process, as described above.

Alternatively, if the user responds by selecting a different one of the instruction elements, the provisional central station proceeds to determine the necessary configuration information. For example, if the user indicates that the patient currently being monitored is not the previous patient (i.e., by selecting the instruction element labeled "NO"), the provisional central station determines whether the patient monitor is configured to display a list of patients, as indicated at 232. The provisional central station may determine whether the patient monitor is configured to display a list of patients in various ways, including by sending a query to the patient monitor for its capabilities, or by accessing database system 40 to ascertain the capabilities of the patient monitor based on the type of patient monitor. As mentioned above, the type of the patient monitor may be transmitted to the provisional central station during the initial portion of the rendezvous process.

If the patient monitor is not configured to display a list of patients, then the patient ID confirmation process is passed to the central station, as indicated at 226. The central station typically is configured to display a user-interface allowing a clinician to specify the patient ID and the patient's assigned location. In addition, the clinician may instruct the central station to transfer communications with the patient monitor to a different central station, as will be described in more detail below. If, on the other hand, the patient monitor is configured to display a list of patients, the

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central station accesses database system 40 to identify at least some of the patients admitted to the hospital, and transmits a list of those patients to the patient monitor.

As indicated at 234, exemplary controller 100 displays the list of patients on display screen 84. An exemplary display screen presenting a list of patients is illustrated in Fig. 15. Rather than identifying the patient at the patient monitor, the clinician may operate buttons 86 to instruct that the patient's ID be selected at the central station, as indicated at 236. In which case the patient ID confirmation process is passed to the central station, as indicated at 226 and as discussed above. Alternatively, the clinician may select the ID of the monitored-patient from the patient list. The patient's ID is then communicated to the central station by the patient monitor. Next, the central station transmits a list of locations to the patient monitor controller, which displays the list to the user, as indicated at 238. Once the user selects the patient's assigned location from the list, the controller communicates the information to the central station. Finally, the central station confirms the patient is not being monitored by a different patient monitor, as indicated at 226, at which point the rendezvous and configuration processes are complete.

If, at step 230, the clinician indicates that the patient has been assigned to a different location (i.e., by selecting the instruction element labeled "NEW ROOM"), the patient monitor communicates this information to the central station, which responds by sending a list of locations to the patient monitor, as described above. The clinician then selects the patient's assigned location from the list, as indicated at 238. The location assignment is communicated to the central station, which then completes

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the rendezvous and configuration processes by confirming that the patient is not being monitored by a different patient monitor.

Returning attention briefly to Fig. 14, if the central station that monitored the previous patient will not be the primary central station, the clinician requests communications with a different central station (e.g., by selecting the control element labeled "NEW UNIT"). The clinician's instruction is then communicated to the provisional central station, which responds by transmitting a list of central stations in network 30. Controller 100 displays the list of central stations on display screen 84, as indicated at 240 in Fig. 12. Figure 16 illustrates an exemplary user-interface on display screen 84, including a list of user-selectable central stations. Once the clinician selects the desired central station from the list, the selection is communicated to the provisional central station. If the provisional central station is not the selected central station, the provisional central station sends a request to the selected central station to take over the communications and configuration process. If the selected central station is available, it takes over the communications with the patient monitor and completes the configuration process. Otherwise, the provisional central station causes the patient monitor to notify the clinician that the selected central station is unavailable, as described above.

Once the a central station is selected to be the primary central station and assumes the communications with the patient monitor, the primary central station proceeds to determine the identity of the patient and the patient's assigned location. As described above, the identity of the patient and the patient's assigned location may be entered by the clinician at the patient monitor and then communicated to the

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primary central station. Alternatively, the patient ID and assigned location may be specified at the primary central station. In any event, once the primary central station has confirmed the identity and the assigned location of the patient, as indicated at 226, the rendezvous and configuration processes are complete.

As described above, exemplary configuration process 216 is adapted to automatically determine the patient's identity, etc., whenever possible. This tends to minimize the amount of effort required by the clinician to configure the patient monitor for centralized monitoring. However, it will be appreciated that the provisional central station may be configured also to determine the patient identity, primary central station, and assigned location in other ways. For example, if the patient ID is not available at step 228, then the exemplary provisional central station is configured to determine whether a list of central stations should be presented to the clinician, as indicated at 232. Typically, a list of central stations is presented whenever network 30 includes more than one central station. As indicated at 240 and described above, the provisional central station transmits the list of central stations to the patient monitor for display to the clinician. The clinician selects a desired central station to serve as the primary central station. The patient monitor communicates the selection to the provisional central station, which sends a message to the selected central station to take over the communications. If the selected central station is not available, the clinician is informed to make another selection, as described above. If, at step 242, the provisional central station determines that a list of central stations should not be presented to the user, the provisional central station becomes the primary central station and completes the remainder of the configuration process.

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Once the primary central station is in communication with the patient monitor, the primary central station queries the clinician for the patient ID and assigned location. Alternatively, the patient ID and assigned location may be specified at the primary central station. In any event, the primary central station then confirms that no other patient monitors are monitoring the same patient, thereby completing the rendezvous and configuration processes.

It will be appreciated by those of skill in the art that the exemplary rendezvous and configuration processes illustrated in Figs. 11 and 12 and described above, provide a variety of capabilities for monitoring patients via medical telemetry network 30. For example, a clinician may select which central station will monitor the patient by entering instructions at the patient monitor. The clinician's instructions are communicated to the provisional central station, which then sends a request to the selected central station to take over the communications. Alternatively, the patient monitor may send a request for communications directly to the selected central station in response to the clinician's instructions. In any event, the clinician is not required to configure the patient monitor at the central station, but instead may configure and initiate the central monitoring process without leaving the patient's location.

Furthermore, exemplary patient monitor 22 is configured to automatically attempt to establish communications with a central station beginning at power-up. The patient monitor determines, without user intervention, the communications settings needed to establish a connection and to communicate with network 30 such as transmission frequency, IP addresses, synchronization, etc. Thus, a patient monitor may be shipped from its manufacturing site to any location in the world and the

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patient monitor will automatically configure itself to begin communications with a local medical telemetry network according to the present invention. Similarly, a patient monitor used in a network at one location may be taken to a different location, where the patient monitor will configure itself to communicate with the local medical telemetry network at the different location. As a result, patient monitors 22 may be operated without specialized training or knowledge in network communications. Instead, clinicians may place a new patient monitor in immediate use simply by powering-up the patient monitor.

If communications between a patient monitor and central station are lost, the patient monitor automatically attempts to restore the communications without requiring reconfiguration. However, if the patient monitor is attempting to establish a new communications connection, the clinician or other user of the patient monitor is automatically notified once a communications connection (either wire or wireless) is established to allow the monitoring session to be configured. A user-interface for configuring the monitoring session is automatically displayed on the patient monitor display screen. The user-interface is at least partially defined by instructions received from the central station, and is operable by a user of the patient monitor to identify the monitored patient, and to select a primary central station to perform the central monitoring, etc. After a primary central station is identified and assumes communications with, and control of, the patient monitor, the patient is continuously monitored at the primary central station. In view of the capability of the patient monitors and central stations to automatically initiate and configure the centralized

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monitoring process, system 20 represents a substantial advancement in patient monitoring.

It will be appreciated by those of skill in the art that the rendezvous and configuration processes described above are just one of the many ways in which the central stations and patient monitors may be configured to establish new communications and/or restore lost communications. Many variations and modifications to the rendezvous and configuration processes are possible within the scope of the invention. Therefore, it will be understood that the invention is not limited to the particular exemplary processes described above, but includes all such processes, variations, and modifications suitable for establishing communications between a patient monitor and a central monitoring station via a communications network structure.

Once patient monitor 22 has established (or restored) communications with the primary central station, the patient monitor is configured to continuously communicate the vital signs data it collects to the central station. In the exemplary embodiment, patient monitor 22 is configured to communicate all vital signs data that is collected. Alternatively, the patient monitor may be configured to communicate only a portion of the vital signs data collected. In any event, the central station is configured to receive the vital signs data and associate it with the patient being monitored. As mentioned above, the central station typically is configured to communicate simultaneously with a plurality of patient monitors, in which case the vital signs data received from each patient monitor is associated with the particular patient connected to that patient monitor.

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Although patient monitor 22 is adapted to communicate with one or more central stations to establish central monitoring, the patient monitor is also configured to provide patient monitoring at the patient's location. As mentioned above, exemplary controller 100 is adapted to receive the vital signs data via sensor ports 82, and to display an image on display screen 84 that represents at least a portion of the vital signs data. It will be appreciated that the image may take any of a variety of different forms which will vary depending on the type of vital signs data collected. Thus, exemplary patient monitor 22 provides continuous local monitoring regardless of whether the patient monitor is in communication with a central station. Buttons 86 enable a clinician or other user to control a variety of functions including the information displayed on display screen 84, the format of the displayed image, the vital signs data collected, analysis of the vital signs data, alarm conditions, etc. For example, controller 100 may be controllable to display signals from selected sensor assemblies such as an ECG sensor assembly, or from a selected electrode of the ECG sensor assembly. In addition, the controller may be configured to analyze at least some of the collected vital signs data using one or more user-selectable parameters to provide additional information.

Similarly, controller 100 may be configured to analyze the vital signs data to detect whether the data is within certain defined nominal ranges, and to indicate an alarm condition if the controller detects that a portion of the data is not within the defined ranges. For example, if the upper and lower parameter values for heart rate are 120 and 50 beats per minute, respectively, the patient monitor will indicate an alarm if the detected heart rate is either greater than 120 or less than 50 beats per

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minute. Alternatively, any other portion of the collected vital signs data may be analyzed for alarm conditions, such as blood pressure, temperature, oxygen saturation in the patient's blood (SpO2), etc. Further, the defined nominal ranges typically are variable parameters and selectable by the user to specify particular alarm conditions for a particular patient. Fig. 17 illustrates an exemplary user-interface displayable on display screen 84, and operable by a clinician to specify the parameter values used by controller 100 to analyze the vital signs data. Alarm indications may include warning messages on display screen 84 and/or warning sounds from audio output device 92, etc.

Patient monitor 22 may also be configured to detect equipment or communications problems and provide an indication of the problem to the user. For example, controller 100 may be configured to detect a low power level in battery assembly 88, a sensor assembly that has become disconnected from the patient, a malfunction in buttons 86, lost communications, etc. The indication provided to the user may be the same as or different than the indication provided in response to the alarm conditions.

When patient monitor 22 is in communication with network 30, the primary central station may be configured to control some or all of the functions of the patient monitor. This enables a clinician to control a plurality of remotely distributed patient monitors from a single location. In addition, a central station may be configured to enable a clinician to control all patient monitors in communication with the central station to function identically. Alternatively, the clinician may control each patient monitor to function differently.

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In the exemplary embodiment, the primary central station is configured and operable to change the variable parameter values which define nominal data ranges. Thus, the clinician can set or change the detection of alarm conditions at the primary central station. Instructions entered by the clinician at the primary central station are communicated to controller 100. The controller is configured to change the specified variable value in response to the instruction, and to analyze the vital signs data using the new value. Similarly, the primary central station may be configured to communicate instructions to controller 100 specifying what portions of the vital signs data should be analyzed. For example, it is known to those of skill in the art that a patient's heart rate may be determined from ECG data or from SpO2 data. Thus, where the patient monitor is collecting both ECG data and SpO2 data from a patient, a clinician at the central station may specify which type of data the controller analyzes to determine heart rate.

In addition, since the central stations typically have greater data processing capability than the patient monitors, the primary central station may be configured to analyze the vital signs data received from the patient monitor to determine additional information. For example, the primary central station may be configured to perform ST and/or arrhythmia analysis on the ECG waveform data, whereas controller 100 may analyze the ECG waveform to determine only the patient's heart rate. If the primary central station detects an alarm condition as a result of the analysis, the alarm condition may be displayed on central station monitor 36. In addition, the primary central station may communicate the alarm condition to the patient monitor and instruct controller 100 to present an indication of the alarm condition at the patient

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monitor. By varying where the vital signs data analysis occurs (at the central station or at the patient monitor), the patient monitor's resources may be concentrated on collecting the vital signs data and presenting information to a clinician attending the patient.

The primary central station may also be configured to control both the types of information and the image displayed on display screen 84. For example, where the ECG sensor assembly includes a plurality of electrodes, the clinician at the primary central station may instruct the patient monitor to display the waveform from a particular one of the electrodes, as shown in Fig. 18. Alternatively, the clinician may instruct the patient monitor to display the waveforms from a plurality of the electrodes, as shown in Fig. 19. It will be appreciated that controller 100 may be configured to control display screen 84 to display any desired information or image format in response to instructions received from the primary central station. Alternatively, the controller may be configured to turn off a portion or all of the display screen in response to instructions from the central station.

As described above, the patient monitor and/or the primary central station may be configured to indicate an alarm condition, equipment problem, etc., with at least one of a visible indicator or an audible indicator. For example, Fig. 20 illustrates an exemplary image displayable on display screen 84 which indicates an alarm condition. Typically, the user-interface will include an icon or other indicia to specify the cause of the alarm or problem (e.g., high heart rate, high temperature, etc.).

The patient monitor and primary central station may be configured to continue presenting the indicator for a predetermined time period, or for as long as the

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condition or problem persists. Alternatively, the indicator may be terminated after a specified period of time, even if the condition or problem has not ended. In the exemplary embodiment, the indicator also may be terminated (or suspended for a defined time period) if the clinician acknowledges the indication at the patient monitor and/or the primary central station. Thus, an alarm condition detected at the primary central station and communicated to the patient monitor may be acknowledged at the patient monitor. The acknowledgement is communicated to the primary central station, which then terminates the indication. As a result, a clinician attending the patient need not leave the patient's location to return to the primary central station and acknowledge the alarm.

Once communications are established between a patient monitor and a primary central station of the exemplary embodiment, the patient monitor communicates all vital signs data to the primary central station and is controlled by the primary central station. While other central stations also may receive the vital signs data and send instructions for the patient monitor (as will be described in more detail below), the primary central station maintains control of the patient monitor and is responsible for providing the central monitoring. However, control and central monitoring of the patient monitor may be transferred to a different central station, in which case the different central station is configured to take over communications with the patient monitor and assume control of the central station.

In the exemplary embodiment, a clinician may transfer control of the patient monitor to a different central station by entering a transfer instruction at the patient monitor or at the primary central station. If the clinician is at the patient monitor,

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controller 100 transmits the transfer instruction to the primary central station, which responds by sending a list of central stations to the patient monitor. The controller displays the list on display screen 84 to allow the clinician to select the desired central station. Once the clinician makes a selection, the patient monitor communicates the selection to the primary central station, which sends a request to the selected central station to take over the communications. If the selected central station is unavailable, the primary central station sends a notification to the patient monitor so that the clinician can make another selection. Alternatively, the patient monitor may communicate with the selected central station directly. However, if the clinician is at the primary central station when transferring control, the primary central station sends a request to the selected central station to take over the communications, as described above. Once the selected central station takes over as the new primary central station, the patient monitor communicates all subsequent vital signs data to the new primary central station.

As mentioned above, communications dropouts between the patient monitor and the primary central station may occur for a variety of reasons. Once a dropout occurs, the patient monitor begins attempting to restore the communications. However, during the dropout, the patient is not monitored at the central station. Therefore, the patient monitor may be configured to detect when central monitoring has ended, and to take additional steps to minimize any disruption due to the dropout.

In the exemplary embodiment, the patient monitor is configured to function differently when out of communication with a central station. For example, controller 100 may disable buttons 86 (e.g., by disregarding inputs at the buttons) when the

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controller is in communication with a central station so that the functions of the patient monitor can only be changed at the central station. Alternatively, the controller may suppress alarm indications at the patient monitor when in communication with a central station. Similarly, the controller may turn off the display when in communication with a central station to conserve battery power. The controller may be configured to perform the above steps either automatically, or in response to an instruction from the central station. However, the controller typically is configured to activate the buttons, the display and the alarm indications when not in communication with a central station.

Furthermore, some embodiments of patient monitor 22 include a button 86 operable by the patient to request clincian assistance (i.e., a "Nurse Call" button). In such case, the patient monitor may be configured to respond differently to activation of the button depending on whether the patient monitor is in communication with a central station. For example, the patient monitor may be configured to sound an audible alarm if the patient monitor is not in communication with a central station, or to forward the request for assistance to a central station without sounding an audible alarm if the patient monitor is in communication with a central station.

Similarly, when communications between the patient monitor and central station are lost, the patient monitor may be configured to automatically switch from a centrally-monitored mode, in which the vital signs data is communicated to a central station that at least partially controls the patient monitor, to a stand-alone mode, in which the vital signs data are not communicated to a central station. Typically, the patient monitor also is configured to automatically switch from the stand-alone mode

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to the centrally-monitored mode when the communications are restored. In other words, the patient monitor may be configured to automatically relinquish at least partial control of the patient monitoring process when in communication with a central station, but to resume full control in the event communications are lost.

In addition to automatically switching between a stand-alone mode and a centrally-monitored mode, the patient monitor may also be configured to take any one or more of a variety of steps to return to the centrally-monitored mode with minimal disruption. As described above for example, the exemplary patient monitor is configured to automatically and continuously attempt to restore the communications during the dropout. Upon restoring a connection to physical data transport structure 32, the patient monitor is configured to reestablish communications with a primary central station and, where possible, to configure the monitoring session without intervention by a clinician.

Nevertheless, the vital signs data are not communicated to the central station during the dropout. As a result, further analysis at the central station of the vital signs data received during the dropout cannot be conducted, and the vital signs data cannot be stored on database system 40 for later access. Therefore, exemplary patient monitor 22 could be configured to store at least a portion of the vital signs data collected during the dropout, and then communicate the stored vital signs data to the central station once the communications are restored. The vital signs data may be stored in memory device 102 and/or some other data storage buffer. In any event, the data collected during a dropout period would not be lost.

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It will be appreciated that, depending on the length of the dropout, the vital signs data collected may exceed the patient monitor's storage capacity. Therefore, the patient monitor may be configured to store only a portion of the vital signs data collected once it detects the dropout. For example, the patient monitor may be configured to begin storing the data immediately after detecting the dropout, and then cease storing new data once the memory device is full. Alternatively, the patient monitor may be configured to begin storing the data immediately, and once the memory storage is full, to begin storing subsequent data in place of the oldest stored data. As a further alternative, the patient monitor may be configured to store only data from selected sensor assemblies rather than all sensor assemblies.

As another alternative, the patient monitor may be configured to store portions of the vital signs data which meet defined criteria. In the exemplary embodiment for example, controller 100 is configured to analyze the vital signs data received during a dropout, and to detect the occurrence of a medically-significant event based on the vital signs data. The controller only stores data that corresponds to the occurrence of a medically-significant event. Examples of typical medically-significant events include alarm conditions, arrhythmia, activation of the Nurse-Call button, etc. The amount of data stored may vary depending on the event. Typically, a continuous sequence of data is stored from a point in time several seconds or minutes before the event is detected to several seconds or minutes after the event ends. Thus, several running seconds or minutes of prior data are continuously buffered until an event is detected, at which point all or a portion of the data is stored until the event ends.

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It will be appreciated that the criteria defining a medically-significant event may vary depending on the type of event, the type of sensor assembly that collects the data, the condition of the patient, the clinician's judgment, etc. The patient monitor may be pre-programmed with the criteria defining medically-significant events. Alternatively, the criteria for medically-significant events may be programmed into the patient monitor by the clinician or received from the central station. In any event, by storing only data corresponding to the occurrence of medically-significant events, the patient monitor is able to conserve data storage capacity while ensuring that communication dropouts do not prevent the primary central station from receiving the most important vital signs data.

Alternatively, or additionally, exemplary patient monitor 22 may be configured to selectively store data under other conditions. For example, controller 100 may store data at selected time intervals, or in response to an instruction from a clinician via buttons 86, etc. Thus, it will be appreciated that the patient monitor may be configured to selectively store data under any conditions as desired for a particular application.

In the embodiments described above, patient monitor 22 communicates collected vital signs data to a single central station, referred to herein as the primary central station. Likewise, the patient monitor is controlled by the primary central station. However, in other embodiments, the patient monitor may be configured to broadcast the vital signs data it collects to a plurality of central stations, and to receive and execute instructions from a plurality of central stations. As a further alternative,

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the primary central station may be configured to convey vital signs data received from a patient monitor to one or more other central stations.

As shown in Fig. 21, exemplary primary central station 24a is configured to receive vital signs data from patient monitor 22, and to forward the vital signs data to one or more secondary central stations 24b. The vital signs data received from the patient monitor may then be displayed at the secondary central station(s) as well as at the primary central station. Typically, the secondary central station communicates a request to the primary central station to receive a particular patient's vital signs data. In response to the request, the primary central station is configured to continuously forward all vital signs data it receives that is associated with the particular patient. In addition, instructions entered at a secondary central station are communicated to the primary central station, which forwards the instructions to the patient monitor for execution. Thus, from the point of view of a clinician monitoring the patient, a secondary central station provides the same capabilities as the primary central station. However, some functions are performed only at the primary central station, such as storing or archiving the vital signs data to database system 40, performing arrhythmia analysis, etc.

It will be appreciated that communicating the vital signs data to one or more secondary central stations allows the patient's data to be monitored by clinicians at plural locations within the hospital. Thus, there is no need for a clinician to travel to a different floor, or care unit, etc., of the hospital to view the data from a particular patient. Similarly, a clinician endeavoring to monitor a particular patient is not

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restricted to a single location, but instead can monitor the patient from a variety of different locations.

In addition to providing central monitoring from multiple locations, secondary central stations 24b may also be configured to provide a failsafe in the event of a failure involving the primary central station. Thus, in the exemplary embodiment, at least one of the secondary central stations is configured to automatically attempt to take over communications with the patient monitor if communications between primary central station 24a and the patient monitor are lost. The secondary central station may be configured to detect the loss of communications from the primary central station in a variety of ways. In the exemplary embodiment, the secondary central station is configured to detect a loss of communications with the primary central station(even a sudden, catastrophic one such as loss of power). In response to the message, the secondary central station would then attempt to establish communications with the patient monitor. Additionally, the secondary central station is configured to monitor the communications it receives from the primary central station, and if the primary central station suddenly stops communicating (e.g., due to loss of power, malfunction, etc.) for a defined period of time, the secondary central station is configured to attempt to establish communications with the patient monitor. Alternatively, the patient monitor may be configured to transmit a request for communications to the secondary central station in the event the primary central station stops communicating.

Once the secondary central station establishes communications with the patient monitor, the secondary central station takes over the functions of the primary central

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station. Alternatively, the clinician may be prompted to select a new primary central station for further monitoring. Where plural secondary central stations are monitoring the patient monitor, the first secondary central station to establish communications with the patient monitor takes over as the primary central station. The new primary central station then begins forwarding the vital signs data received from the patient monitor to the remaining secondary central stations. Thus, the patient continues to be monitored at a central location staffed by clinicians, and the vital signs data collected from the patient continues to be stored for later retrieval.

As described above, patient monitor 22 and central stations 24 are configured to automatically establish and maintain communications while the patient monitor is monitoring a patient. However, patient monitor 22 may also be operable to end the communications with the central station(s). This provides an intentional and controlled termination of communications so that the patient monitor and/or the central stations do not automatically attempt to restore communications. In the exemplary embodiment, the patient monitor is operable by a clinician (e.g., using buttons 86) to transmit an end-communications signal to the primary central station. The primary central station is configured to send a confirmation of the end-communications signal to the patient monitor, which is displayed to the clinician at the patient monitor. The primary central station may also send a notification to the secondary central stations, if any.

Once the end-communications signal has been received and confirmed, the patient monitor may be powered down by the clinician without causing the primary central station to report a loss of communications. The primary central station will of

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course detect the loss of communication, but will be configured not to report this type of loss because it is expected. Alternatively, the primary central station will terminate the communications after a defined delay period even though vital signs data were still being received. If the patient monitor is still operating and collecting data after the communications are terminated, the patient monitor would be required to initiate the rendezvous process described above to resume centralized monitoring of the patient. Any monitoring parameters, alarm conditions, etc., that were changed at the patient monitor in response to an instruction from the central station would be reset to the nominal default values stored by the patient monitor. Likewise, any monitoring parameters, alarm conditions, etc., that were changed at the central station in response to an instruction from the clinician at the patient monitor, would be reset to the nominal default values stored by the central station.

As shown in Figs. 1 and 2 and described above, patient monitor 22b is configured to establish communications with a central station and communicate vital signs data via either one of output port 96 or wireless transceiver 104 (illustrated in Fig. 7). In addition, exemplary patient monitor 22b is configured to detect whether output port 96 is connected to physical data transport structure 32 (either directly or through terminal server 42), and to switch automatically between wireless communications and wire communications depending on whether the output port is connected to the network structure. For example, where patient monitor 22b is initially in communications with a central station via output port 96 and the output port is disconnected from physical data transport structure 32, then controller 100 is configured to automatically associate with an access point and continue the

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communications with the central station via wireless transceiver 104. Similarly, where patient monitor 22b is in wireless communications with a central station when output port 96 is connected to physical data transport structure 32, controller 100 is configured to automatically cease communicating via wireless transceiver 104, and instead to communicate with the central station via the output port. Thus, the clinician can select whether patient monitor 22b communicates using wire or wireless communications by connecting and disconnecting, respectively, output port 96 to physical data transport structure 32.

As mentioned above, patient monitor 22 may also be configured to establish communications with a central station to download newer versions of the control software stored in memory device 102 and executable by controller 100. It will be appreciated that the download process may be carried out in any of a variety of different ways within the scope of the invention. It should also be understood that the control software could be for any component of the patient monitor, such as by way of examples, computer cards associated with any/all of the sensor assemblies (e.g. a pulse oximetry card, an NIBP card, etc.), computer cards associated with radio telemetry, etc.

In the exemplary embodiment, patient monitor 22 is operable by a user to request a software update. In response to the user's instructions, the patient monitor attempts to establish communications with one or more central stations, and transmits a query for new versions of the software to the central stations. The query is included as a part of the request for communications which the patient monitor broadcasts to the central stations during the rendezvous process. Each central station responding to

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the request indicates the version of the software stored at the central station. The patient monitor waits a defined period (e.g., 10 seconds) to receive responses from the central stations, and then selects a central station with the newest version of the software. Thus, even where the central stations have multiple versions of the software, the patient monitor is configured to determine which central station(s) has the newest version and to download the software from the central station with the newest version. This allows a system administrator to store new versions of the software on just one or a few of the central stations, and then operate the patient monitors to automatically find and download the newest software.

Once a central station with the newest version of the software is selected, the patient monitor transmits a request to the selected central station to download the new software. The selected central station responds by transmitting the new software via either wire or wireless communications, depending on whether the patient monitor is communicating via output port 96 or wireless transceiver 104. The software download may be carried out using any of a variety of methods or protocols, such as Trivial File Transfer Protocol (TFTP), etc. Typically, the patient monitor and selected central station verify that the software was accurately received at the patient monitor using one or more of a variety of error-checking methods known to those of skill in the art. Once the patient monitor receives the new software, controller 100 updates the control software by installing the new software. The controller may carry out this updating process for control software of any of components of the patient monitor as described above.

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As described above, the invention provides a system for continuously monitoring a plurality of patients at one or more central stations using a plurality of portable patient monitors. The invention also provides a method for monitoring a patient at a central location, as indicated generally at 300 in Fig. 22. The method is implemented by software running on patient monitors 22, central stations 24, and/or other components of system 20. The method includes, at step 310 establishing wireless communications between a patient monitor and a communications network having at least one wireless transceiver and a plurality of central stations. Then communicating a list of the plural central stations to the patient monitor via the wireless transceiver, as indicated at step 320. Alternatively, the list of the plural central stations may be provided to, or stored on, the patient monitor in other ways. In any event, method 300 proceeds with selecting, at the patient monitor, one of the plural central stations, as indicated at 330. Then collecting, at the patient monitor, vital signs data from a patient, as indicated at step 340. The vital signs data are communicated to the wireless transceiver, at step 350, and then communicated from the wireless transceiver to the selected central station, at step 360.

A further method for monitoring patients according to the present invention is indicated generally at 400 in Fig. 23. Method 400 includes, at step 410, establishing communications between a wireless patient monitor and a central station adapted to receive vital signs data from a plurality of patients. Configuring the patient monitor to collect vital signs data from a particular one of the plural patients, at step 420. Communicating a list of the plural patients from the central station to the patient monitor, as indicated at step 430. Alternatively, the list of patients may be provided

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to, or stored on, the patient monitor in other ways. In any event, method 400 continues at step 440 with identifying, at the patient monitor, the particular patient. Communicating the identity of the particular patient to the central station, at step 450. Communicating the vital signs data collected from the particular patient to the central station, as indicated at step 460. Finally, associating, at the central station, the vital signs data with the particular patient, as indicated at step 470.

Another method for monitoring patients according to the present invention is indicated generally at 500 in Fig. 24. Method 500 includes, at step 510, establishing wireless communications between a patient monitor and a central station. Collecting vital signs data from a patient at the patient monitor, at step 520. Communicating the vital signs data from the patient monitor to the central station, at step 530. In the event that communications between the patient monitor and the central station are lost, detecting that loss of communications, at step 540. Storing at least a portion of the vital signs data at the patient monitor while the patient monitor is out of communications with the central station, as indicated at step 550. Restoring wireless communications between the patient monitor and the central station, at step 560. Then, communicating at least a portion of the stored vital signs data from the patient monitor to the central station, as indicated at step 570.

Another method for monitoring patients according to the present invention is indicated generally at 600 in Fig. 25, and includes establishing wireless communications between a patient monitor and a first central station, as indicated at step 610. Collecting vital signs data from a patient at the patient monitor, at step 620. Communicating the vital signs data from the patient monitor to the first central station,

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at step 630. So long as communications between the patient monitor and the first central station are maintained, the patient monitor continues to communicate the vital signs data to the first central station, as indicated at 640. However, in the event communications between the patient monitor and the first central station are lost, then wireless communications are automatically established between the patient monitor and a second central station, as indicated at step 650. Finally, communicating the vital signs data from the patient monitor to the second central station, at step 660. It should also be noted that when a clinician using the patient monitor transfers communication to a different central station, there is a transition time (presently that duration is in the range of about 5-10 seconds). During that transition time, the patient monitor could be configured to store data for later uploading to the different central station chosen by the clinician.

Another method for monitoring patients according to the present invention is indicated generally at 700 in Fig. 26. Method 700 includes, at step 710, establishing wireless communications between a patient monitor connected to a particular one of plural patients and a central station. Communicating the identity of the particular patient from the patient monitor to the central station, at step 720. As noted above in connection with the determination of patient ID, either or both the central station and the patient monitor may be involved with this determination. The patient monitor may be adapted to detect the disconnection of the particular patient from the patient monitor, and also adapted to send a patient-disconnection signal to the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost. The central station could then determine patient

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ID by associating the patient-disconnection signal with the patient monitor and received patient vital signs data from that patient monitor. Alternatively, the patient monitor could be adapted to detect the identity of the particular patient and inform the central station of the identity of that particular patient.

Collecting vital signs data from the particular patient at the patient monitor, as indicated at 730. Then, communicating the vital signs data to the central station, at step 740, and associating, at the central station, the patient monitor with the particular patient, as indicated at step 750. So long as communications between the patient monitor and the central station are maintained, the patient monitor continues to communicate the vital signs data to the central station, which associates the vital signs data with the particular patient, as indicated at 760. In the event communications between the patient monitor and the central station are lost for a period of time, reestablishing the communications between the patient monitor and the central station, at step 770. Then, automatically determining, at the central station, whether the patient monitor is still connected to the particular patient, as indicated at step 780. Finally, if the patient monitor is still connected to the particular patient, then associating the patient monitor with the particular patient.

In addition to the exemplary methods for monitoring patients described above, it will be appreciated that the configuration and operation of system 20 is not limited to the exemplary methods as many variations and modifications are possible within the scope of the invention. Further, system 20 may be configured and operated to monitor patients according to a variety of other methods within the scope of the

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invention. Therefore, it will be understood that all such methods, variations and modifications are within the scope of the invention.

It is believed that the disclosure set forth above encompasses multiple distinct inventions with independent utility. While each of these inventions has been disclosed in its preferred form, the specific embodiments thereof as disclosed and illustrated herein are not to be considered in a limiting sense as numerous variations are possible. The subject matter of the inventions includes all novel and non-obvious combinations and subcombinations of the various elements, features, functions and/or properties disclosed herein. No single feature, function, element or property of the disclosed embodiments is essential to all of the disclosed inventions. Similarly, where the claims recite "a" or "a first" element or the equivalent thereof, such claims should be understood to include incorporation of one or more such elements, neither requiring nor excluding two or more such elements.

It is believed that the following claims particularly point out certain combinations and subcombinations that are directed to one of the disclosed inventions and are novel and non-obvious. Inventions embodied in other combinations and subcombinations of features, functions, elements and/or properties may be claimed through amendment of the present claims or presentation of new claims in this or a related application. Such amended or new claims, whether they are directed to a different invention or directed to the same invention, whether different, broader, narrower or equal in scope to the original claims, are also regarded as included within the subject matter of the inventions of the present disclosure.

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WE CLAIM

1. A wireless patient monitor adapted to communicate with any one of plural medical telemetry networks, each having one or more central stations, where each network is configured to communicate via wireless communications using one of multiple different communications settings, the monitor comprising:

one or more sensor inputs for receiving vital signs data from a patient;

a wireless transceiver configured to transmit and receive wireless communications; and

a controller coupled to receive the vital signs data via the one or more sensor inputs and to communicate with a network via the transceiver;

where the controller is configured, upon initial power-up, to automatically transmit a signal to a local one of the plural networks via the transceiver to request the communications settings used by the local network, and to establish communications with at least one of the central stations on the local network using the communications settings received from the local network without intervention from a user of the patient monitor.

2. The monitor of claim 1, where the controller is configured to transmit the vital signs data to the at least one central station using the selected communications settings.

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3. The monitor of claim 2, where the controller is configured to transmit the vital signs data to the at least one central station without intervention from the user.

4. The monitor of claim 1, where the communications settings include a communications address for the monitor.

5. The monitor of claim 1, where the communications settings include a communications address for the at least one central station.

6. A wireless, patient vital signs monitor adapted to communicate with a medical telemetry network having at least one central station, the monitor comprising:

one or more sensor input ports for receiving patient vital signs data;

a controller coupled to receive the vital signs data via the one or more input ports;

a wireless transceiver controllable by the controller to communicate with the at least one central station;

where the controller is configured, when not in communication with the at least one central station, to repeatedly attempt to establish communications with the at least one central station via the wireless transceiver; and

a display device controllable by the controller to automatically display a notification to a user of the monitor upon establishing communications with the at least one central station.

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7. The monitor of claim 6, further comprising one or more user-operable input devices, and where the controller is adapted to control the display device to display a user-interface adapted to request inputs from a user via the one or more input devices.

8. The monitor of claim 7, where the controller is adapted to receive instructions from the at least one central station via the wireless transceiver, and where the user-interface is at least partially defined by the instructions.

9. The monitor of claim 8, where the medical telemetry network includes plural central stations, and where the instructions identify at least two of the plural central stations, and where the user-interface is adapted to allow a user to select one of the identified central stations via the one or more input devices.

10. The monitor of claim 9, where the controller is adapted, if not in communication with the selected central station, to attempt to establish communications with the selected central station and transmit the vital signs data to the selected central station.

11. The monitor of claim 9, where the controller is adapted to control the display device to display a notification to the user if the controller cannot establish communications with the selected central station.

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12. A wireless, patient vital signs monitor adapted to communicate with a central station, comprising:

a wireless transceiver;

a controller coupled to the wireless transceiver and configured to establish communications with the central station via the wireless transceiver; and

one or more sensor input ports for receiving patient vital signs data;

where the controller is coupled to receive the vital signs data via the one or more input ports and communicate the vital signs data to the central station via the wireless transceiver;

where the controller includes a data storage buffer for storage of the vital signs data, and where the controller is configured to automatically detect a loss of communications with the central station, and to store, in the data storage buffer, at least a portion of the vital signs data received while out of communications with the central station; and

where the controller is configured to communicate the stored vital signs data to the central station via the wireless transceiver if communications with the central station are restored.

13. The monitor of claim 12, where the controller is adapted to store only the portions of the vital signs data that meet one or more defined criteria.

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14. The monitor of claim 12, where the controller is adapted to analyze the vital signs data received while out of communications with the central station, and to detect the occurrence of a medically-significant event based on the vital signs data.

15. The monitor of claim 14, where the controller is adapted to store only those portions of the vital signs data which correspond to the occurrence of medically-significant events.

16. A method for monitoring a patient, comprising:

establishing wireless communications between a patient monitor and a central station;

collecting vital signs data from a patient at the patient monitor;

communicating the vital signs data from the patient monitor to the central station;

detecting a loss of communications between the patient monitor and the central station;

storing at least a portion of the vital signs data at the patient monitor while the patient monitor is out of communications with the central station;

restoring wireless communications between the patient monitor and the central station; and

communicating at least a portion of the stored vital signs data from the patient monitor to the central station.

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17. The method of claim 16, further comprising analyzing the vital signs data at the patient monitor while the patient monitor is out of communications with the central station to detect the occurrence of a medically-significant event, and where the step of storing includes storing only portions of the vital signs data which correspond to the occurrence of medically-significant events.

18. A wireless, patient vital signs monitor adapted to communicate with a medical telemetry network having at least one central station, the monitor comprising:

one or more sensor input ports for receiving patient vital signs data;

a wireless transceiver; and

a controller coupled to receive the vital signs data via the one or more input ports, and configured to control the wireless transceiver to establish and maintain communications with the at least one central station;

where the controller is configured to detect a loss of communications with the at least one central station, and if a loss of communications is detected, to automatically switch from a first operating mode in which the controller transmits the received vital signs data to the at least one central station, to a second operating mode in which the controller does not transmit the received vital signs data to the at least one central station.

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19. The monitor of claim 18, where the controller is adapted to attempt to reestablish communications with the at least one central station, and to automatically switch back to the first operating mode if the communications are reestablished.

20. The monitor of claim 18, further comprising an output device controllable by the controller to indicate an alarm if the vital signs data is outside one or more defined ranges, and where the controller is adapted to control the output device not to indicate the alarm when the controller is in the first operating mode.

21. The monitor of claim 18, further comprising one or more input devices operable by a user to input information to the controller, and where the controller is adapted to disregard at least some inputs by the user when the controller is in the first operating mode.

22. The monitor of claim 18, further comprising a display device controllable by the controller to display information to a user, and where the controller is adapted to control the display device not to display any information when the controller is in the first operating mode.

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23. The monitor of claim 18, further comprising an output device controllable by the controller to indicate an alarm, and an input device operable by a user to input a request for assistance to the controller, and where, if the user inputs a request for assistance, the controller is configured to communicate the request to the at least one central station if in the first operating mode, and to control the output device to indicate an alarm if in the second operating mode.

24. A wireless, patient vital signs monitor adapted to communicate with at least one central station connected to receive vital signs data via a communications network, where the communications network includes one or more hard-wired ports and one or more network transceivers, the monitor comprising:

one or more sensor input ports for receiving patient vital signs data;

an output port connectable to a hard-wired port on the network;

a wireless transceiver adapted to transmit information to, and receive information from, at least one of the one or more network transceivers; and

a controller coupled to receive the vital signs data via the one or more input ports, and configured to communicate the vital signs data to the at least one central station via a selected one of the output port or the wireless transceiver.

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25. The monitor of claim 24, where the controller is configured to communicate the vital signs data to the at least one central station via the output port if the output port is connected to a hard-wired port, and to communicate the vital signs data to the at least one central station via the wireless transceiver if the output port is not connected to a hard-wired port.

26. The monitor of claim 25, where the controller is configured to automatically switch from communicating the vital signs data via the output port to communicating the vital signs data via the wireless transceiver upon the disconnection of the output port from a hard-wired port.

27. The monitor of claim 25, where the controller is configured to automatically switch from communicating the vital signs data via the wireless transceiver to communicating the vital signs data via the output port upon the connection of the output port to a hard-wired port.

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28. A method for monitoring a patient, comprising:

providing a medical telemetry network having at least one central station connected to one or more wireless transceivers and to one or more hard-wired ports;

collecting vital signs data from a patient at a patient monitor;

automatically detecting whether the patient monitor is connected to one of the one or more hard-wired ports;

communicating the vital signs data to the central station via the wireless transceiver if the patient monitor is not connected to one of the one or more hard-wired ports.

29. The method of claim 28, further comprising, if the patient monitor is connected to one of the one or more hard-wired ports, then communicating the vital signs data to the central station via the connected hard-wired port.

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30. A wireless medical telemetry system, comprising:

a central station adapted to receive vital signs data associated with a plurality of patients; and

at least one wireless patient monitor including a controller and a wireless transceiver, where the patient monitor also includes control software executable by the controller to

monitor a particular one of the plurality of patients by collecting vital signs data from the particular patient, and

transmit the collected vital signs data to the central station via the wireless transceiver;

where the controller is adapted to receive new control software via the wireless transceiver, and to update the control software with new control software.

31. The system of claim 30, where the controller is adapted to receive the new control software from the central station.

32. The system of claim 31 wherein the at least one patient monitor includes plural components, and the controller is adapted to receive the new control software for use with any of the components.

33. The system of claim 32, where the controller is adapted to transmit a query to the central station to determine whether the new control software is available for transmission to the patient monitor.

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34. The system of claim 33, further comprising a second central station, and where the controller is adapted to transmit the query to both central stations, and where each central station is adapted to respond to the query.

35. The system of claim 34, where each of the central station and the second central station are adapted to store a different one of multiple versions of the new control software, and where each central station is adapted to inform the patient monitor of the version of the new control software it stores in response to the query, and

where the controller is adapted to determine which central station is storing a latest version of the new control software and to transmit a download request to the central station that is storing the latest version.

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36. A wireless medical telemetry system, comprising:

at least one wireless patient monitor configured to collect patient vital signs data; and

at least one central station adapted to establish communications with the at least one patient monitor via a wireless transceiver, and to receive the patient vital signs data from the at least one patient monitor;

where the at least one patient monitor is operable by a user to transmit an end-communications signal to the at least one central station; and

where the at least one central station is configured to terminate the communications with the at least one patient monitor in response to the end-communications signal.

37. The system of claim 36, where the at least one central station is configured to communicate a confirmation of the end-communications signal to the patient monitor.

38. The system of claim 37, where the at least one patient monitor includes a display device adapted to display a message to the user in response to the confirmation.

39. The system of claim 36, where the at least one central station is configured to continue receiving the vital signs data until the communications with the at least one patient monitor are terminated.

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40. A method for monitoring a patient, comprising:

establishing wireless communications between a patient monitor and a wireless transceiver connected to a remote central station;

collecting, at the patient monitor, vital signs data from a patient and communicating the vital signs data to the central station via the wireless transceiver;

communicating an end-communications signal from the patient monitor to the central station; and

terminating the communications by the central station in response to the end-communications signal.

41. The method of claim 40, further comprising communicating a confirmation of the end-communications signal from the central station to the patient monitor.

42. The method of claim 41, further comprising displaying a message to a user of the patient monitor in response to the confirmation.

43. The method of claim 40, further comprising discontinuing the step of collecting and communicating the vital signs data.

44. The method of claim 43, where the step of terminating is performed before the discontinuing.

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45. The method of claim 43, where the step of terminating is performed after the discontinuing.

46. A system for monitoring the vital signs of a patient from a selected remote location, the system comprising:

at least one wireless patient monitor adapted to collect vital signs data from a patient;

a medical telemetry network including a plurality of central stations adapted to receive vital signs data, and one or more wireless transceivers adapted to communicate with the at least one patient monitor;

where the at least one patient monitor is operable by a user to select one of the plural central stations, and to transmit a request to establish communications to the selected central station via the one or more wireless transceivers.

47. The system of claim 46, where the selected central station is adapted to establish communications with the at least one patient monitor in response to the request, and to receive the vital signs data via the one or more wireless transceivers.

48. The system of claim 46, where at least one of the plural central stations is configured to communicate a list of the plural central stations to the at least one patient monitor, and where the at least one patient monitor includes a display device adapted to display the list of plural central stations to the user.

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49. The system of claim 48, where the at least one patient monitor includes one or more input devices operable by the user to select one of the plural central stations on the list.

50. The system of claim 46, where the at least one patient monitor is operable by the user to select a different one of the plural central stations, and to transmit, to the selected central station, a request to change communications from the selected central station to the different central station.

51. The system of claim 50, where the selected central station is configured to terminate communications with the at least one patient monitor in response to the request to change communications.

52. The system of claim 51, where the different central station is configured to establish communications with the at least one patient monitor in response to the request to change communications, and to receive the vital signs data via the one or more wireless transceivers.

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53. A method for monitoring a patient, comprising:

establishing wireless communications between a patient monitor and a communications network having at least one wireless transceiver and a plurality of central stations;

selecting, at the patient monitor, one of the plural central stations;

collecting, at the patient monitor, vital signs data from a patient and communicating the vital signs data to the wireless transceiver; and

communicating the vital signs data from the wireless transceiver to the selected central station via the communications network.

54. The method of claim 53, further comprising:

communicating a list of the plural central stations to the patient monitor via the wireless transceiver; and

displaying the list to a user of the patient monitor.

55. The method of claim 54, further comprising receiving an input from the user selecting one of the plural central stations on the list.

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56. The method of claim 55, further comprising:

receiving a subsequent input from the user selecting a different one of the plural central stations;

communicating subsequently collected vital signs data to the wireless transceiver; and

communicating the subsequently collected vital signs data from the wireless transceiver to the different central station via the communications network.

57. A medical monitoring system, comprising:

a central station adapted to receive vital signs data concerning a plurality of patients;

one or more transmitter/receivers associated with the central station; and

at least one patient monitor configured to monitor a particular one of the plurality of patients by collecting vital signs data from the particular patient, and configured to establish communications with the central station and communicate the collected vital signs data to the central station via the one or more transmitter/receivers;

where the at least one patient monitor is operable by a user to identify the particular patient from the plurality of patients, and to inform the central station of the identity of the particular patient; and

where the central station is configured to associate the vital signs data received from the at least one patient monitor with the particular patient.

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58. The system of claim 57, where the central station is configured to transmit a list of the plurality of patients to the at least one patient monitor, and where the at least one patient monitor includes a display device adapted to display the list to the user.

59. The system of claim 57, where the central station is adapted to store the identity of the particular patient and, in the event that the communications with the central station are lost and then restored, to transmit a request to the at least one patient monitor for a confirmation that the at least one patient monitor is still configured to monitor the particular patient.

60. The system of claim 57, where the system, the one or more transmitter/receivers, and the at least one patient monitor is wireless.

61. The system of claim 60, where the central station is configured to transmit a list of the plurality of patients to the at least one patient monitor, and where the at least one patient monitor includes a display device adapted to display the list to the user.

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62. The system of claim 61, where the central station is adapted to store the identity of the particular patient and, in the event that the communications with the central station are lost and then restored, to transmit a request to the at least one patient monitor for a confirmation that the at least one patient monitor is still configured to monitor the particular patient.

63. A method for monitoring a patient, comprising:

establishing communications between a patient monitor and a central station via a transmitter/receiver associated with the central station, where the central station is adapted to receive vital signs data from a plurality of patients;

configuring the patient monitor to collect vital signs data from a particular one of the plural patients;

identifying, at the patient monitor, the particular patient;

communicating the identity of the particular patient to the central station;

communicating the vital signs data to the central station; and

associating, at the central station, the vital signs data with the particular patient.

64. The method of claim 63, further comprising:

communicating a list of the plural patients from the central station to the patient monitor; and

displaying the list to a user of the monitor.

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65. The method of claim 63, further comprising,

if the communications between the patient monitor and the central station are lost, then:

restoring the communications between the patient monitor and the central station;

communicating a request for confirmation from the central station to the patient monitor that the patient monitor is still configured to monitor the particular patient; and

communicating the confirmation from the patient monitor to the central station.

66. The method of claim 63, where the step of establishing communications is between a wireless patient monitor and a central station via a wireless transmitter/receiver associated with the central station, where the central station is adapted to receive vital signs data from a plurality of patients.

67. The method of claim 66, further comprising:

communicating a list of the plural patients from the central station to the patient monitor; and

displaying the list to a user of the monitor.

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68. The method of claim 66, further comprising,

if the communications between the patient monitor and the central station are lost, then:

restoring the communications between the patient monitor and the central station;

communicating a request for confirmation from the central station to the patient monitor that the patient monitor is still configured to monitor the particular patient; and

communicating the confirmation from the patient monitor to the central station.

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69. A medical monitoring system, comprising:

a central station associated with one or more transmitter/receivers, and adapted to receive vital signs data concerning a plurality of patients; and

a patient monitor having a transmitter/receiver, the patient monitor being adapted to establish communications with the central station and transmit an identity of a particular one of the plural patients, and adapted to collect vital signs data from the particular patient when connected to the particular patient and to transmit the vital signs data to the central station;

where the central station is configured to receive the identity of the particular patient and the vital signs data, and to associate the vital signs data with the particular patient when the communications are established; and

where, in the event that the communications between the patient monitor and central station are lost for a period of time and then restored, the central station is configured to automatically determine whether the patient monitor is still connected to the particular patient, and to associate the vital signs data with the particular patient if the patient monitor is still connected to the particular patient.

70. The system of claim 69, where the central station is configured to determine whether the patient monitor is still connected to the particular patient by measuring the period of time the communications are lost, and associating the vital signs data with the particular patient if the period of time is less than a predetermined length of time.

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71. The system of claim 69, where the patient monitor is adapted to detect the disconnection of the particular patient from the patient monitor, and where the patient monitor is adapted to inform the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost.

72. The system of claim 69, where the central station is configured to transmit a request to the patient monitor for a patient identity if the central station does not determine that the patient monitor is still connected to the particular patient.

73. The system of claim 69, where the system and the one or more transmitter/receivers are wireless.

74. The system of claim 73, where the central station is configured to determine whether the patient monitor is still connected to the particular patient by measuring the period of time the communications are lost, and associating the vital signs data with the particular patient if the period of time is less than a predetermined length of time.

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75. The system of claim 73, where the patient monitor is adapted to detect the disconnection of the particular patient from the patient monitor, and where the patient monitor is adapted to inform the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost.

76. The system of claim 73, where the central station is configured to transmit a request to the patient monitor for a patient identity if the central station does not determine that the patient monitor is still connected to the particular patient.

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77. A method for monitoring a patient from a central station configured to monitor a plurality of patients, where each of the plural patients has an identity, the method comprising:

establishing communications between a patient monitor connected to a particular one of the plural patients and the central station;

communicating the identity of the particular patient from the patient monitor to the central station;

collecting vital signs data from the particular patient at the patient monitor;

communicating the vital signs data to the central station;

associating, at the central station, the vital signs data with the particular patient; and

in the event communications between the patient monitor and the central station are lost for a period of time:

reestablishing the communications between the patient monitor and the central station,

automatically determining, at the central station, whether the patient monitor is still connected to the particular patient, and

if the patient monitor is still connected to the particular patient, then associating the vital signs data with the particular patient.

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78. The method of claim 77, where the step of determining includes determining that the patient monitor is still connected to the particular patient if the period of time when the communications between the patient monitor and the central station were lost was less than a predetermined length of time.

79. The method of claim 77, where the step of determining includes

detecting, at the patient monitor, if the particular patient was disconnected from the patient monitor during the period of time when the communications between the patient monitor and the central station were lost; and

informing the central station whether the particular patient was disconnected from the patient monitor during the period of time when the communications between the patient monitor and the central station were lost.

80. The method of claim 77, where the step of establishing communications involves wireless communications between a patient monitor connected to a particular one of the plural patients and the central station.

81. The method of claim 80, where the step of determining includes determining that the patient monitor is still connected to the particular patient if the period of time when the communications between the patient monitor and the central station were lost was less than a predetermined length of time.

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82. The method of claim 80, where the step of determining includes

detecting, at the patient monitor, if the particular patient was disconnected from the patient monitor during the period of time when the communications between the patient monitor and the central station were lost; and

informing the central station whether the particular patient was disconnected from the patient monitor during the period of time when the communications between the patient monitor and the central station were lost.

83. A method for monitoring a patient, comprising:

collecting, by a patient monitor, vital signs data from the patient;

establishing communications between the patient monitor and a central station;

communicating the vital signs data from the patient monitor to the central station;

analyzing the vital signs data to detect an alarm condition;

indicating the alarm condition at both the patient monitor and the central station;

receiving, at the patient monitor, an acknowledgement from a user of the patient monitor;

communicating the acknowledgement from the patient monitor to the central station; and

terminating the indication of the alarm condition at the central station in response to the acknowledgement.

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84. The method of claim 84, where the step of indicating includes indicating the alarm condition at the patient monitor, and further comprising terminating the indication of the alarm condition at the patient monitor in response to the acknowledgement.

85. The method of claim 84, where the step of indicating includes producing an audible signal at the central station, and where the step of terminating includes terminating the audible signal.

86. The method of claim 84, where the step of indicating includes producing a visible signal at the central station, and where the step of terminating includes terminating the visible signal.

87. The method of claim 84, where the step of analyzing is performed by the central station.

88. The method of claim 84, where the step of analyzing is performed by the patient monitor.

89. The method of claim 84, where the step of establishing communications involves wireless communications between the patient monitor and a central station.

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90. The method of claim 89, where the step of indicating includes indicating the alarm condition at the patient monitor, and further comprising terminating the indication of the alarm condition at the patient monitor in response to the acknowledgement.

91. The method of claim 89, where the step of indicating includes producing an audible signal at the central station, and where the step of terminating includes terminating the audible signal.

92. The method of claim 89, where the step of indicating includes producing a visible signal at the central station, and where the step of terminating includes terminating the visible signal.

93. The method of claim 89, where the step of analyzing is performed by the central station.

94. The method of claim 89, where the step of analyzing is performed by the patient monitor.

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95. A medical monitoring system, comprising:

at least one patient monitor adapted to collect vital signs data from a patient; and

a central station adapted to communicate with the at least one patient monitor via transmissions;

where the at least one patient monitor includes a controller configured to analyze the vital signs data based on one or more variable parameter values; and

where the central station is configured to communicate an instruction to the at least one patient monitor to change the value of at least one of the one or more variables to a new value, and where the controller is configured to analyze the vital signs data based on the new value in response to the instruction.

96. The system of claim 95, where the one or more variable parameter values includes a nominal data range, and where the controller is configured to analyze the vital signs data to determine whether the vital signs data is within the nominal data range and to indicate an alarm condition to a user if the vital signs data is outside the nominal data range.

97. The system of claim 96, where the vital signs data includes data indicating a heart-rate of the patient, and where the one or more variable parameter values includes a nominal range of heart-rate data.

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98. The system of claim 96, where the vital signs data includes data chosen from the group consisting of the oxygen saturation of the patient's arterial blood, the patient's blood pressure, and the amount of carbon dioxide in the patient's breath, and where the one or more variable parameter values is respectively chosen from the group consisting of a nominal range of oxygen saturation data, blood pressure data, and carbon dioxide data.

99. The system of claim 95, where the system and the at least one patient monitor are wireless, and the central station is adapted to communicate with the at least one patient monitor via wireless transmissions.

100. The system of claim 99, where the one or more variable parameter values includes a nominal data range, and where the controller is configured to analyze the vital signs data to determine whether the vital signs data is within the nominal data range and to indicate an alarm condition to a user if the vital signs data is outside the nominal data range.

101. The system of claim 100, where the vital signs data includes data indicating a heart-rate of the patient, and where the one or more variable parameter values includes a nominal range of heart-rate data.

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Page 521

102. The system of claim 100, where the vital signs data includes data chosen from the group consisting of the oxygen saturation of the patient's arterial blood, the patient's blood pressure, and the amount of carbon dioxide in the patient's breath, and where the one or more variable parameter values is respectively chosen from the group consisting of a nominal range of oxygen saturation data, blood pressure data, and carbon dioxide data.

103. A medical monitoring system, comprising:

a central station adapted to receive vital signs data concerning a plurality of patients;

one or more transmitter/receivers associated with the central station; and

at least one patient monitor configured to monitor a particular one of the plurality of patients by collecting vital signs data from the particular patient, and configured to establish communications with the central station and communicate the collected vital signs data to the central station via the one or more transmitter/receivers;

where the system is operable by plural users to identify the particular patient from the plurality of patients, and to inform the user of the identity of the particular patient; and

where the system is configured to associate the vital signs data received from the at least one patient monitor with the particular patient.

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104. The system of claim 103, where the central station is operable by a first user to identify the particular patient from the plurality of patients, and to inform a second user of the identity of the particular patient.

105. The system of claim 103, where the at least one patient monitor is operable by the second user to identify the particular patient from the plurality of patients, and to inform a second user of the identity of the particular patient.

106. The system of claim 104, where the central station is configured to maintain a list of the plurality of patients being monitored by the system.

107. The system of claim 104, where the central station is configured to transmit a list of the plurality of patients to the at least one patient monitor, and where the at least one patient monitor includes a display device adapted to display the list to the second user.

108. The system of claim 107, where the central station is adapted to store the identity of the particular patient and, in the event that the communications with the central station are lost and then restored, to transmit a request to the at least one patient monitor for a confirmation that the at least one patient monitor is still configured to monitor the particular patient.

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109. A medical monitoring system, comprising:

a central station associated with one or more transmitter/receivers, and adapted to receive vital signs data concerning a plurality of patients; and

a patient monitor having a transmitter/receiver, the patient monitor being adapted to establish communications with the central station and adapted to collect vital signs data from a particular one of the plural patients when connected to the particular patient and to transmit the vital signs data to the central station;

where the central station is configured to receive the vital signs data, and to associate the vital signs data with the particular patient when the communications are established; and

where, in the event that the communications between the patient monitor and central station are lost for a period of time and then restored, the central station is configured to automatically determine whether the patient monitor is still connected to the particular patient, and to associate the vital signs data with the particular patient if the patient monitor is still connected to the particular patient.

110. The system of claim 109, where the central station is configured to determine whether the patient monitor is still connected to the particular patient by measuring the period of time the communications are lost, and associating the vital signs data with the particular patient if the period of time is less than a predetermined length of time.

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111. The system of claim 109, where the patient monitor is adapted to detect the disconnection of the particular patient from the patient monitor, and where the patient monitor is adapted to send a patient-disconnection signal to the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost.

112. The system of claim 111, wherein the patient monitor is adapted to detect the identity of the particular patient and inform the central station of the identity.

113. The system of claim 109, where the central station is configured to transmit a request to the patient monitor for a patient identity if the central station does not determine that the patient monitor is still connected to the particular patient.

114. The system of claim 109, where the system and the one or more transmitter/receivers are wireless.

115. The system of claim 114, where the central station is configured to determine whether the patient monitor is still connected to the particular patient by measuring the period of time the communications are lost, and associating the vital signs data with the particular patient if the period of time is less than a predetermined length of time.

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116. The system of claim 114, where the patient monitor is adapted to detect the disconnection of the particular patient from the patient monitor, and where the patient monitor is adapted to send a patient-disconnection signal to the central station if the particular patient was disconnected from the patient monitor during the period of time the communications were lost.

117. The system of claim 116, wherein the patient monitor is adapted to detect the identity of the particular patient and inform the central station of the identity.

118. A wireless medical telemetry system, comprising:

at least one wireless patient monitor configured to monitor a patient by collecting vital signs data from the patient;

a first central station associated with one or more wireless transceivers, and adapted to establish communications with the at least one patient monitor and receive the vital signs data via the one or more wireless transceivers; and

a second central station associated with the one or more wireless transceivers, and adapted to receive vital signs data via the one or more wireless transceivers;

where the second central station is configured to automatically attempt to establish communications with the at least one patient monitor and receive the vital signs data in place of the first central station in the event the communications between the first central station and the at least one patient monitor are lost.

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119. The system of claim 118, where the second central station is configured to monitor the communications between the first central station and the at least one patient monitor.

120. The system of claim 119, where the second central station is configured to monitor the communications between the first central station and the at least one patient monitor by receiving the vital signs data from the first central station, and to automatically attempt to establish communications with the at least one patient monitor if the second central station stops receiving the vital signs data from the first central station.

121. The system of claim 118, where the at least one patient monitor is configured to transmit a request to establish communications to the second central station via the one or more wireless transceivers in the event the communications with the first central station are lost.

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122. The system of claim 118, further comprising a third central station associated with the one or more wireless transceivers, and adapted to receive vital signs data via the one or more wireless transceivers, and where both the second and third central stations are configured to automatically attempt to establish communications with the at least one patient monitor and receive the vital signs data in place of the first central station in the event the communications between the first central station and the at least one patient monitor are lost.

123. The system of claim 118, where the first central station is configured to communicate instructions to the at least one patient monitor to control the patient monitor, and where the second central station is configured to automatically attempt to assume control of the at least one patient monitor in the event the communications between the first central station and the at least one patient monitor are lost.

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124. A method for monitoring a patient, comprising:

establishing wireless communications between a patient monitor and a first central station;

collecting vital signs data from a patient at the patient monitor;

communicating the vital signs data from the patient monitor to the first central station; and

if communications between the patient monitor and the first central station are lost, automatically establishing wireless communications between the patient monitor and a second central station, and communicating the vital signs data from the patient monitor to the second central station.

125. The method of claim 124, further comprising monitoring, at the second central station, the communications between the patient monitor and the first central station.

126. The method of claim 125, where the step of monitoring includes receiving, at the second central station, the vital signs data from the first central station.

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127. The method of claim 124, where the step of establishing wireless communications between the patient monitor and the second central station includes detecting, at the patient monitor, a loss of communications with the first central station, and transmitting a request to establish communications from the patient monitor to the second central station.

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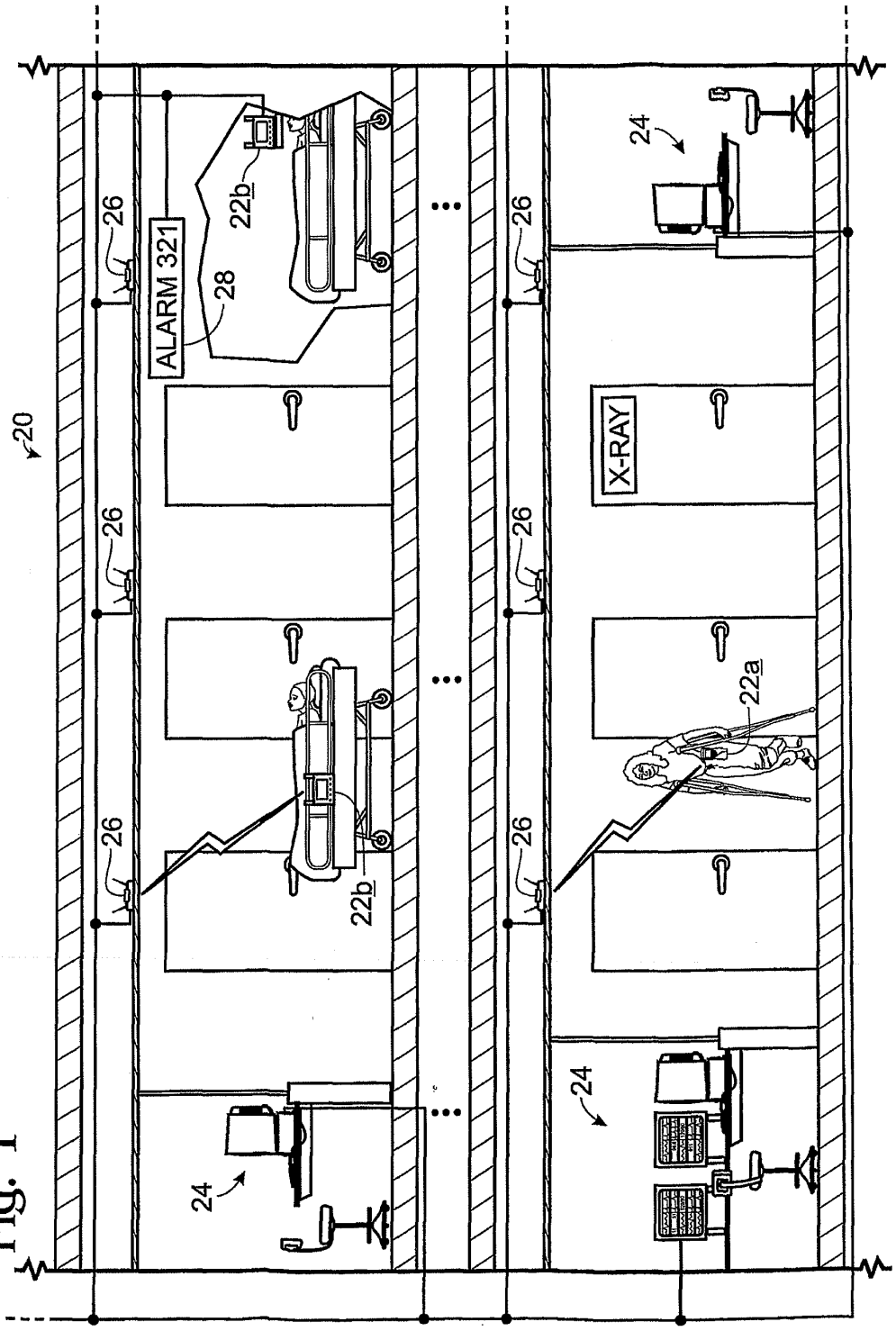


Fig. 1

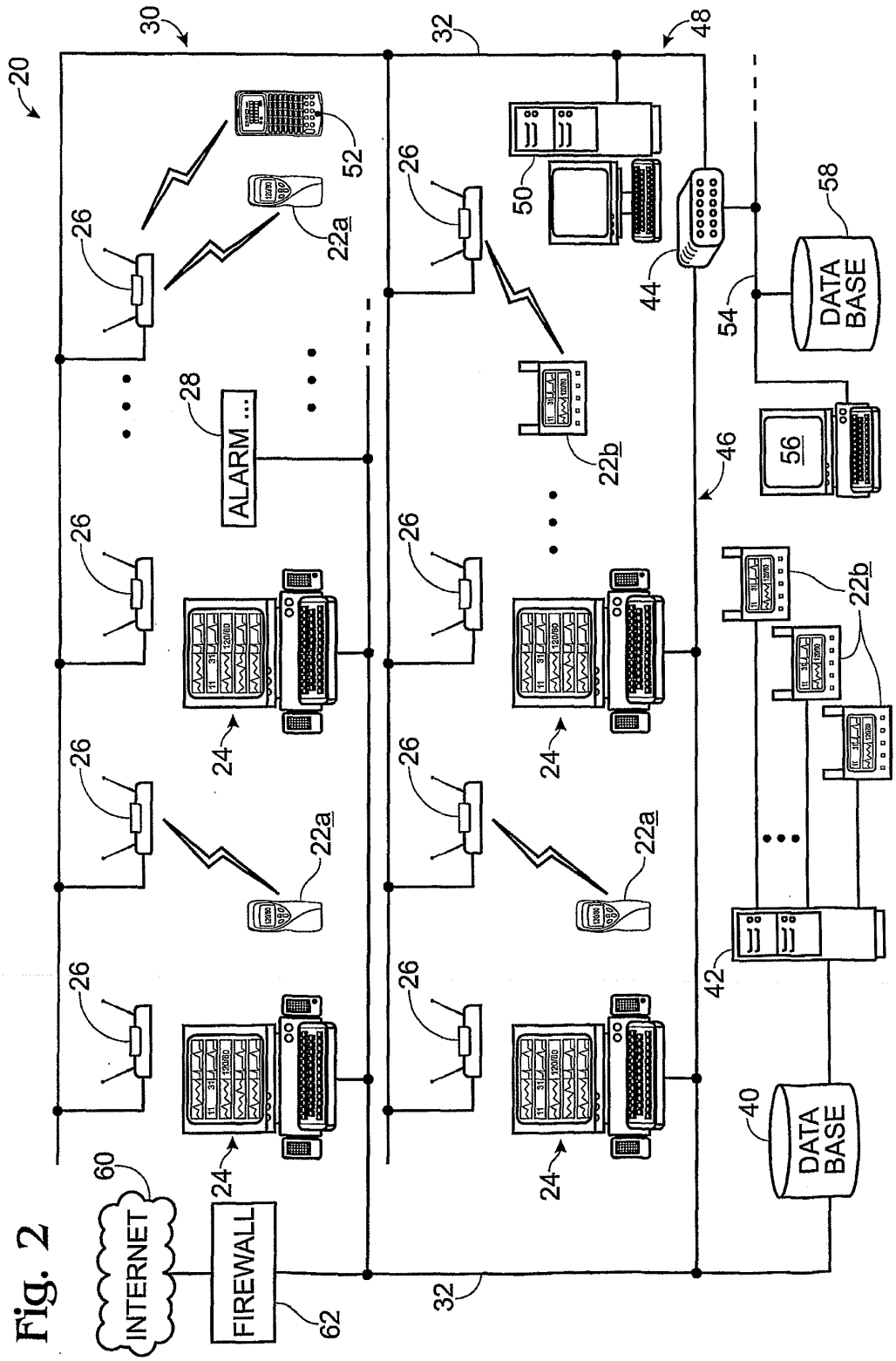

20
30
32
48
52
22a
26
50
58
DATA BASE
54
44
28
ALARM ...
22b
46
56
24
42
60
INTERNET
FIREWALL
62
40
DATA BASE

Fig. 2

Fig. 3

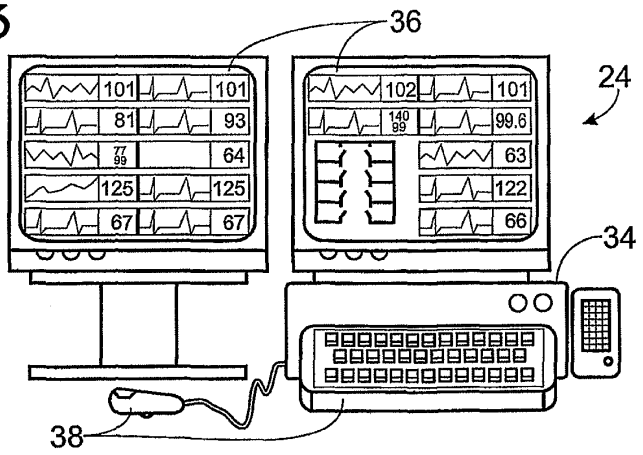

36
24
34
38
101
101
81
93
64
125
125
67
67
102
101
99.6
63
122
66

Fig. 4

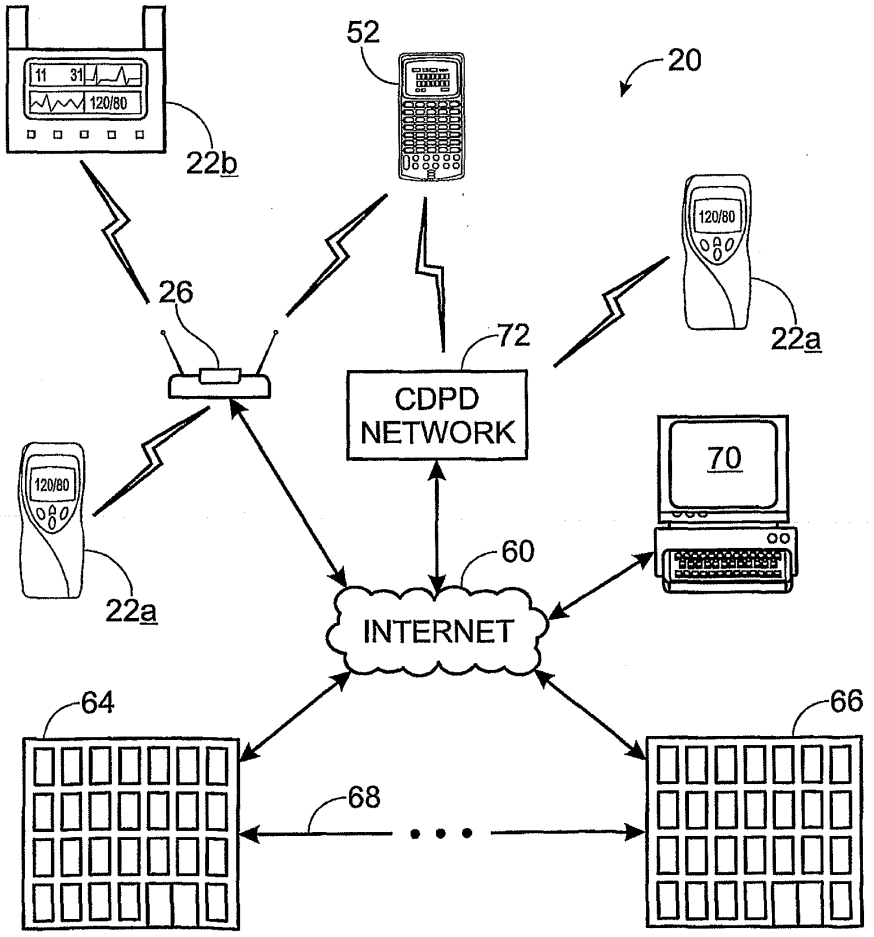

52
20
22b
26
72
22a
CDPD NETWORK
70
60
INTERNET
64
66
68
120/80

Fig. 5

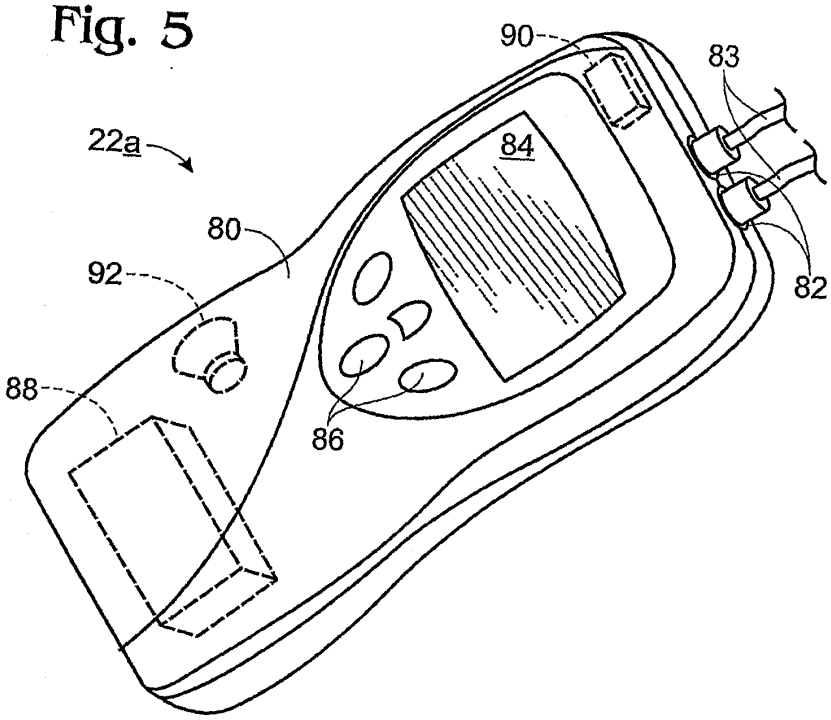


Fig. 6

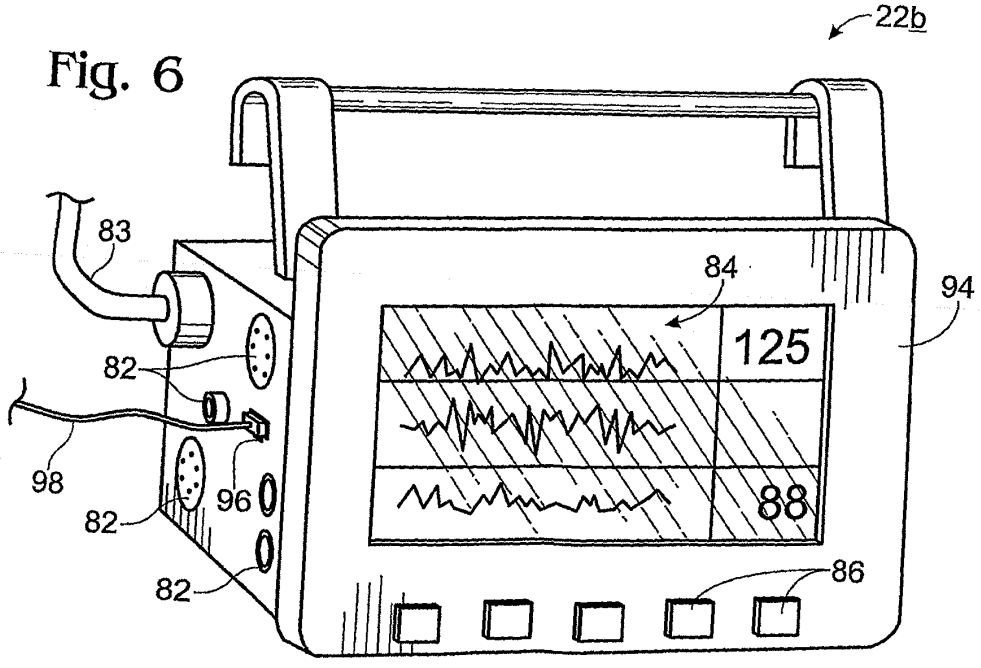


Fig. 7

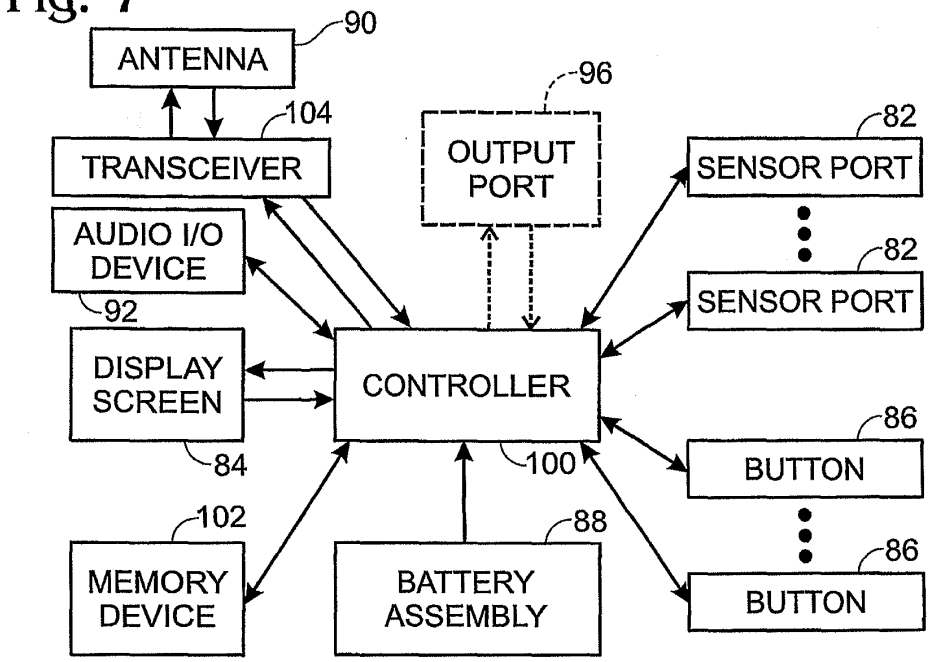

ANTENNA
90
TRANSCEIVER
104
OUTPUT PORT
96
SENSOR PORT
82
SENSOR PORT
82
AUDIO I/O DEVICE
92
DISPLAY SCREEN
84
CONTROLLER
100
BUTTON
86
BUTTON
86
MEMORY DEVICE
102
BATTERY ASSEMBLY
88

Fig. 8

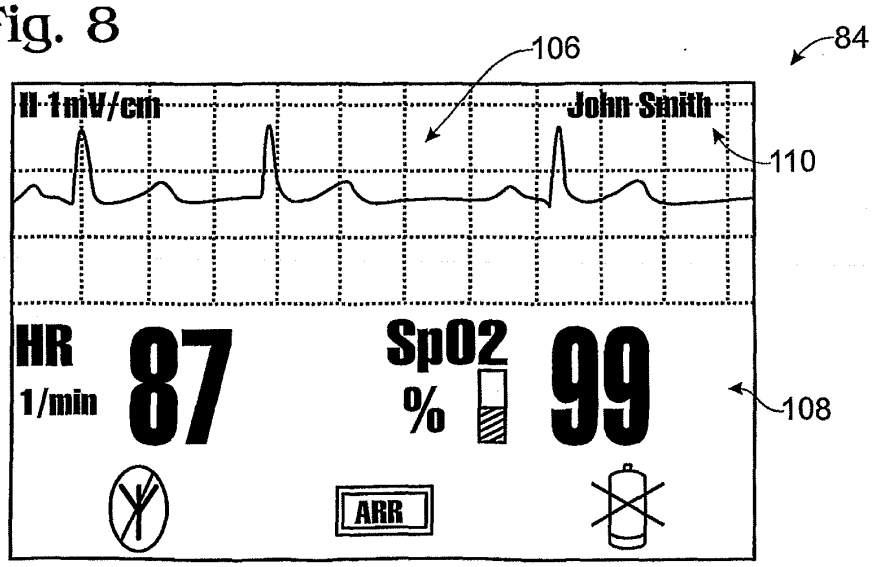

84
106
II 1mV/cm
John Smith
110
HR
1/min
87
SpO2
%
99
108
ARR

Fig. 9

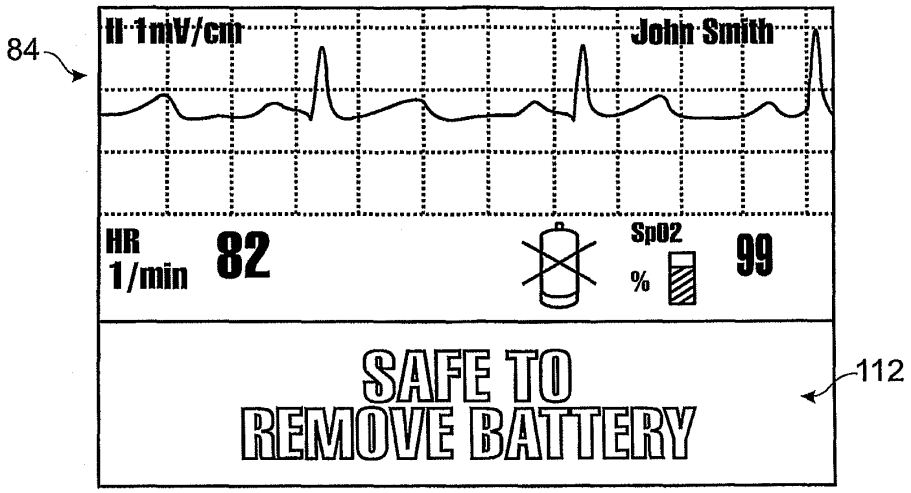

II 1mV/cm
John Smith
84
HR
1/min
82
SpO2
%
99
SAFE TO
REMOVE BATTERY
112

Fig. 10

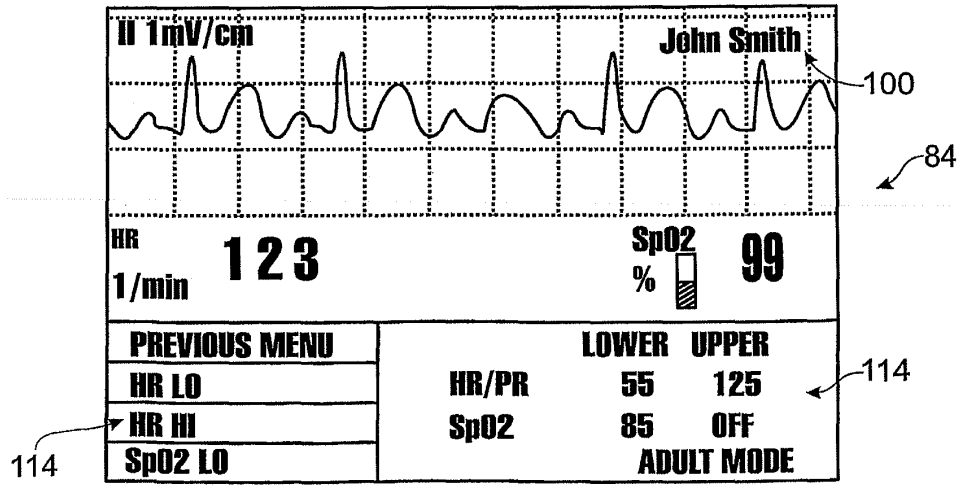

II 1mV/cm
John Smith
100
84
HR
1/min
123
SpO2
%
99
PREVIOUS MENU
HR LO
HR HI
SpO2 LO
114
LOWER UPPER
HR/PR 55 125
SpO2 85 OFF
ADULT MODE
114

Fig. 11

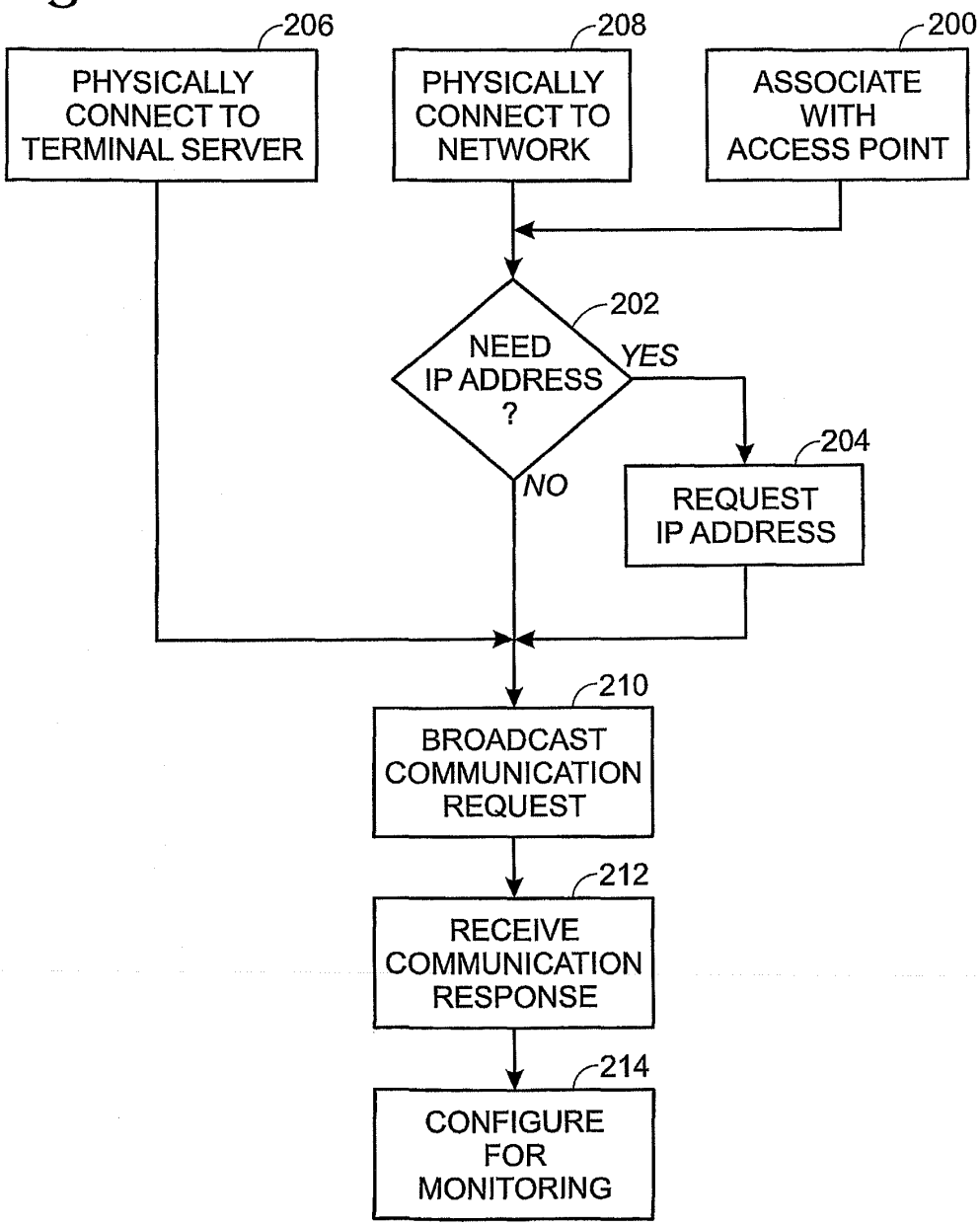

206
PHYSICALLY CONNECT TO TERMINAL SERVER
208
PHYSICALLY CONNECT TO NETWORK
200
ASSOCIATE WITH ACCESS POINT
202
NEED IP ADDRESS ?
YES
NO
204
REQUEST IP ADDRESS
210
BROADCAST COMMUNICATION REQUEST
212
RECEIVE COMMUNICATION RESPONSE
214
CONFIGURE FOR MONITORING

Fig. 12

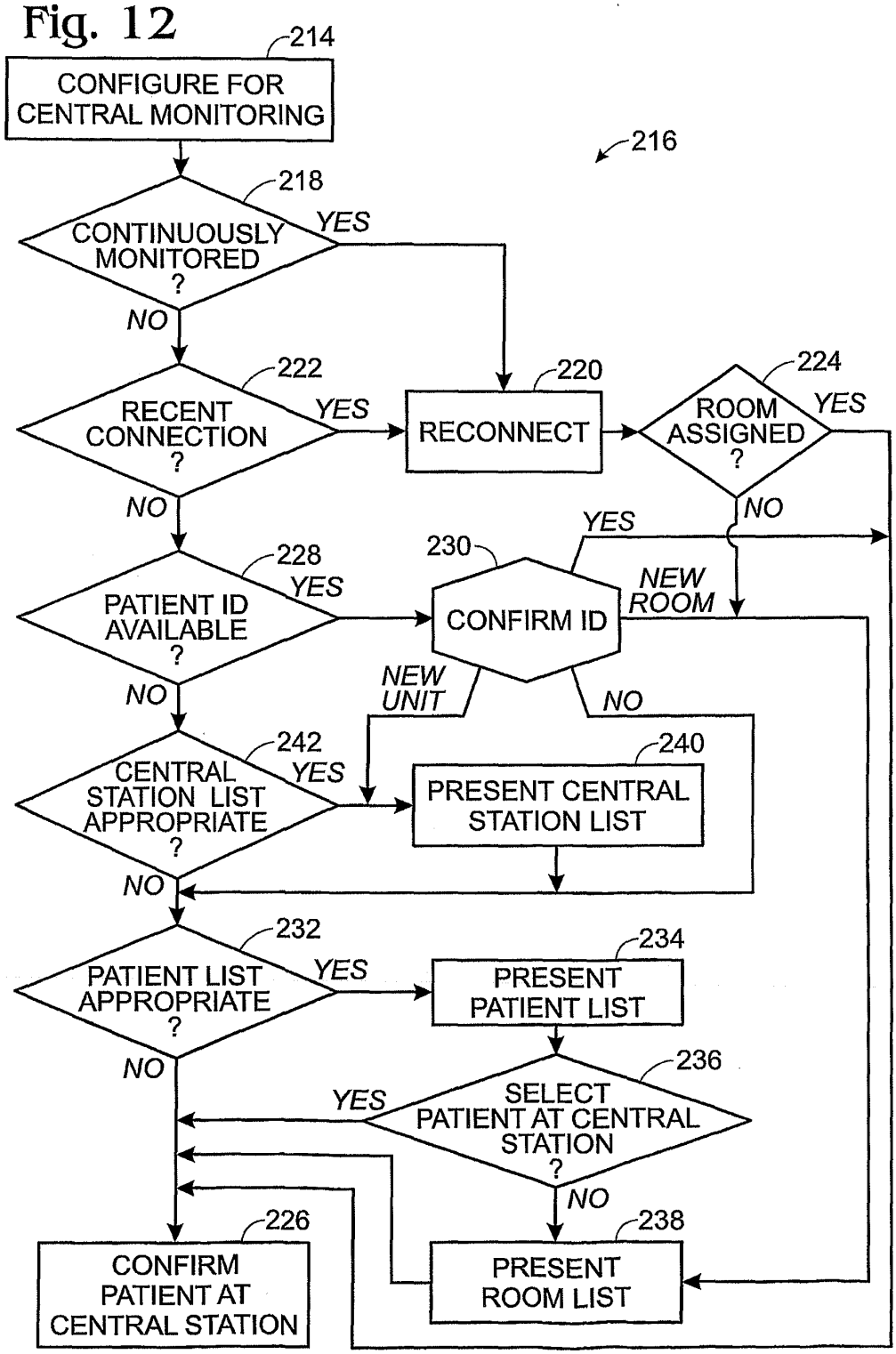

214
CONFIGURE FOR CENTRAL MONITORING
216
218
CONTINUOUSLY MONITORED ?
YES
NO
222
RECENT CONNECTION ?
YES
220
RECONNECT
224
ROOM ASSIGNED ?
YES
NO
YES
NO
228
PATIENT ID AVAILABLE ?
YES
230
CONFIRM ID
NEW ROOM
NEW UNIT
NO
NO
242
CENTRAL STATION LIST APPROPRIATE ?
YES
240
PRESENT CENTRAL STATION LIST
NO
232
PATIENT LIST APPROPRIATE ?
YES
234
PRESENT PATIENT LIST
NO
236
SELECT PATIENT AT CENTRAL STATION ?
YES
NO
226
CONFIRM PATIENT AT CENTRAL STATION
238
PRESENT ROOM LIST

Fig. 13

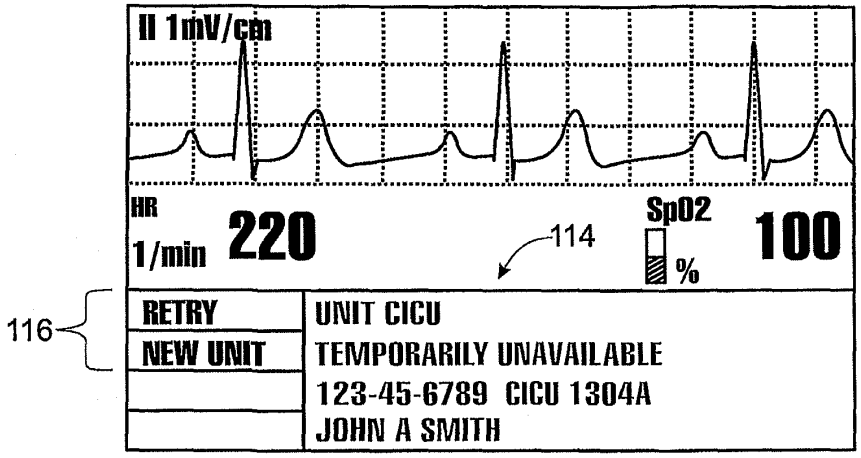

II 1mV/cm
HR
1/min
220
114
SpO2
%
100
116
RETRY
NEW UNIT
UNIT CICU
TEMPORARILY UNAVAILABLE
123-45-6789 CICU 1304A
JOHN A SMITH

Fig. 14

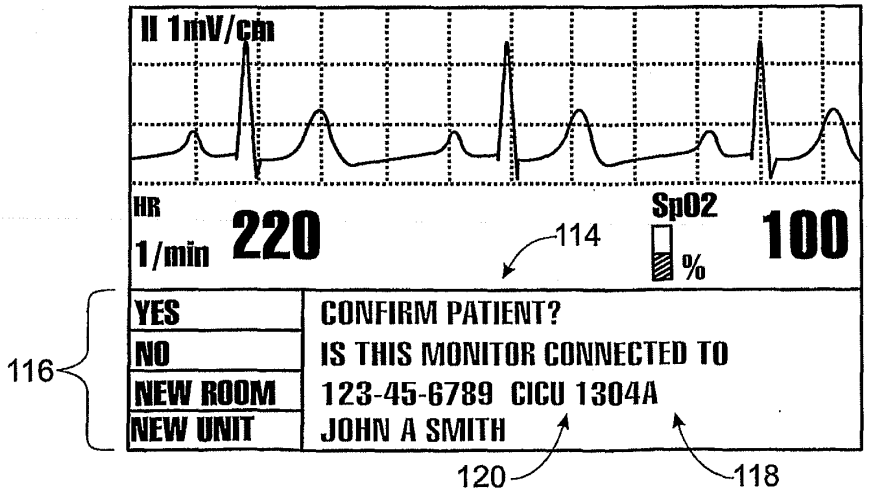

II 1mV/cm
HR
1/min
220
114
SpO2
%
100
116
YES
NO
NEW ROOM
NEW UNIT
CONFIRM PATIENT?
IS THIS MONITOR CONNECTED TO
123-45-6789 CICU 1304A
JOHN A SMITH
120
118

Fig. 15

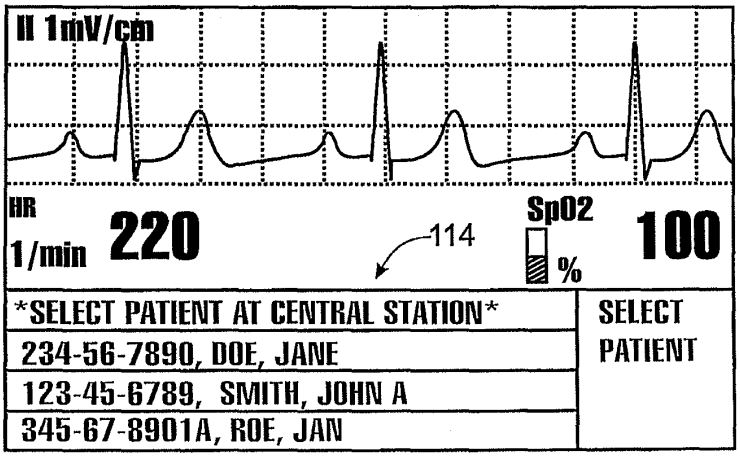

II 1mV/cm
HR
1/min 220
114
SpO2
%
100
SELECT PATIENT AT CENTRAL STATION
234-56-7890, DOE, JANE
123-45-6789, SMITH, JOHN A
345-67-8901A, ROE, JAN
SELECT
PATIENT

Fig. 16

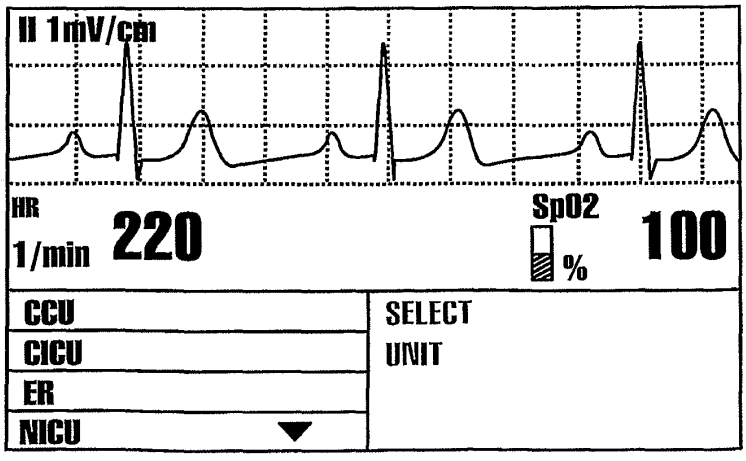

II 1mV/cm
HR
1/min 220
SpO2
%
100
CCU
CICU
ER
NICU
SELECT
UNIT

Fig. 17

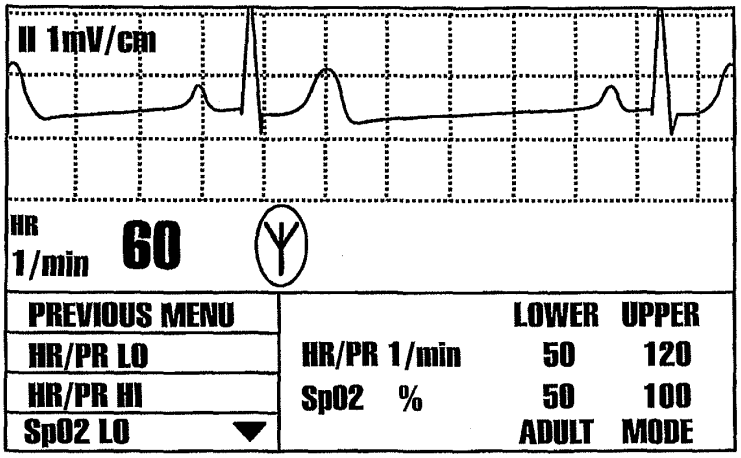

II 1mV/cm
HR
1/min
60
PREVIOUS MENU
HR/PR LO
HR/PR HI
SpO2 LO
LOWER
UPPER
HR/PR 1/min
50
120
SpO2 %
50
100
ADULT
MODE

Fig. 18

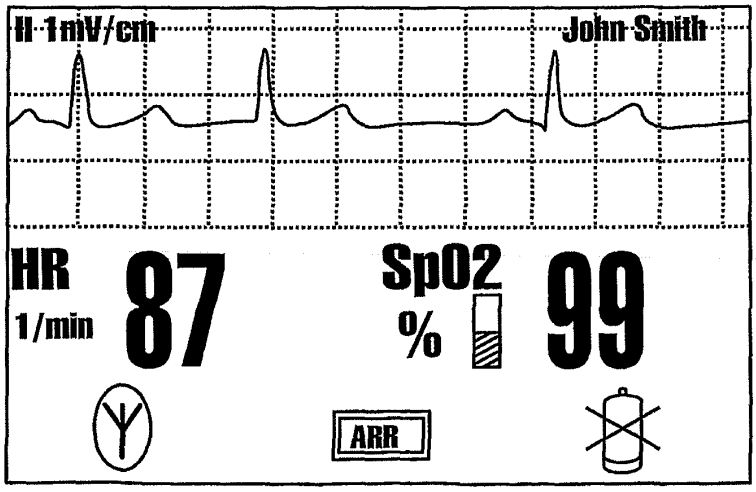

II 1mV/cm
John Smith
HR
1/min
87
SpO2
%
99
ARR

Fig. 19

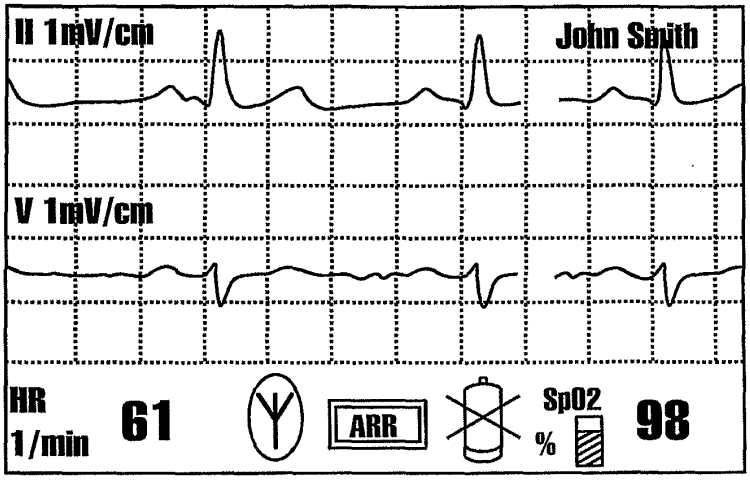

II 1mV/cm
John Smith
V 1mV/cm
HR
1/min
61
ARR
SpO2
%
98

Fig. 20

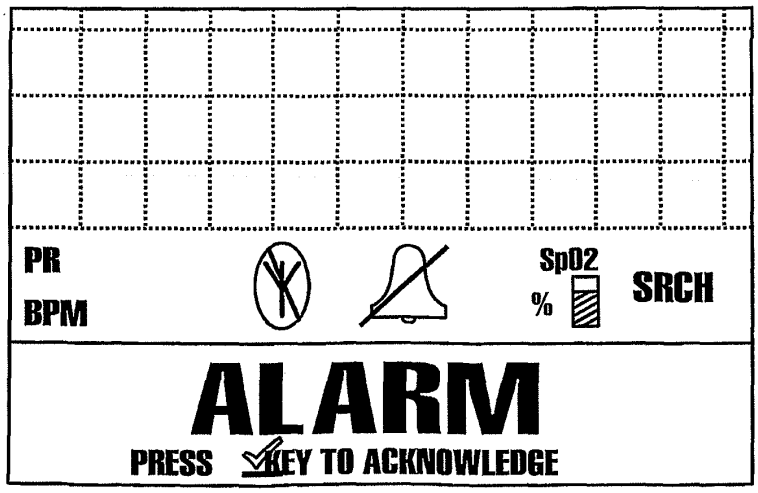

PR
BPM
SpO2
%
SRCH
ALARM
PRESS KEY TO ACKNOWLEDGE

Fig. 21

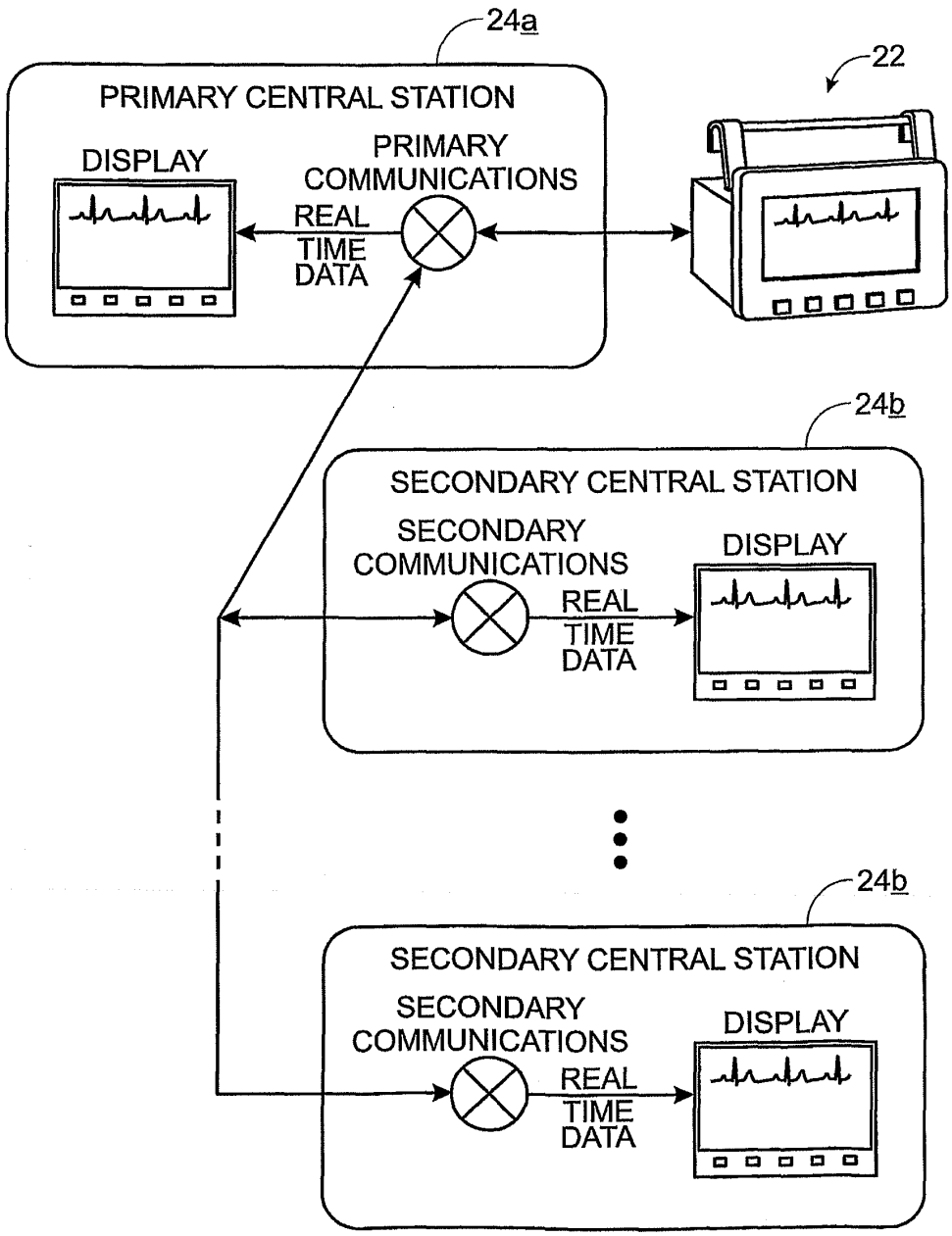

24a
22
PRIMARY CENTRAL STATION
DISPLAY
PRIMARY COMMUNICATIONS
REAL TIME DATA
24b
SECONDARY CENTRAL STATION
SECONDARY COMMUNICATIONS
DISPLAY
REAL TIME DATA
24b
SECONDARY CENTRAL STATION
SECONDARY COMMUNICATIONS
DISPLAY
REAL TIME DATA

Fig. 22

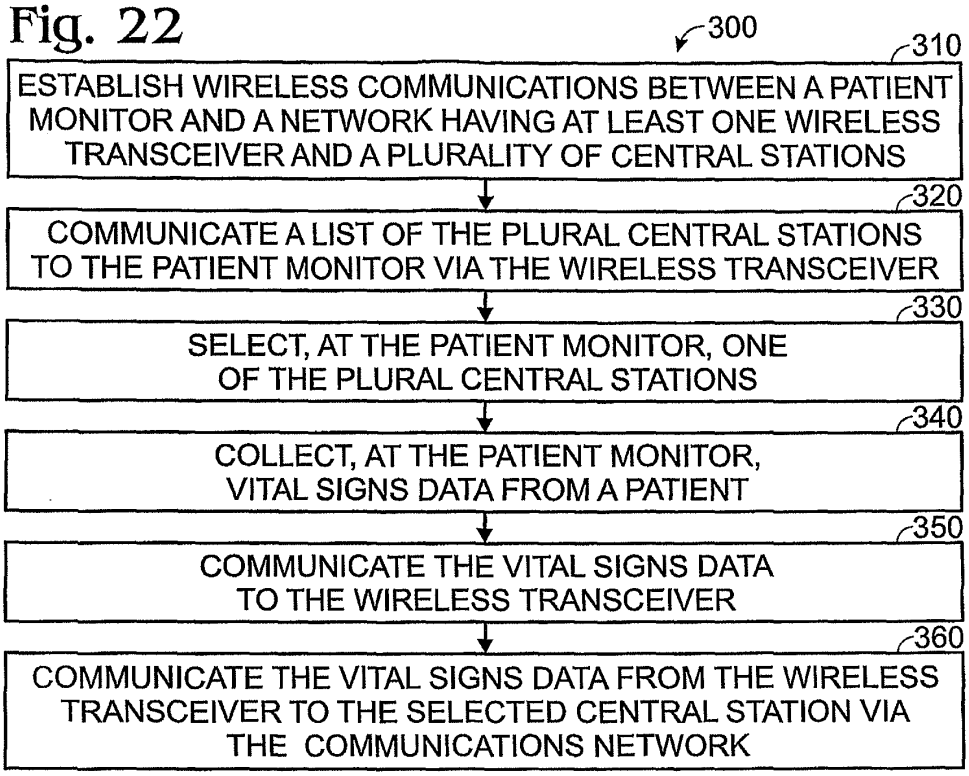

300
310
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A NETWORK HAVING AT LEAST ONE WIRELESS TRANSCEIVER AND A PLURALITY OF CENTRAL STATIONS
320
COMMUNICATE A LIST OF THE PLURAL CENTRAL STATIONS TO THE PATIENT MONITOR VIA THE WIRELESS TRANSCEIVER
330
SELECT, AT THE PATIENT MONITOR, ONE OF THE PLURAL CENTRAL STATIONS
340
COLLECT, AT THE PATIENT MONITOR, VITAL SIGNS DATA FROM A PATIENT
350
COMMUNICATE THE VITAL SIGNS DATA TO THE WIRELESS TRANSCEIVER
360
COMMUNICATE THE VITAL SIGNS DATA FROM THE WIRELESS TRANSCEIVER TO THE SELECTED CENTRAL STATION VIA THE COMMUNICATIONS NETWORK

Fig. 23

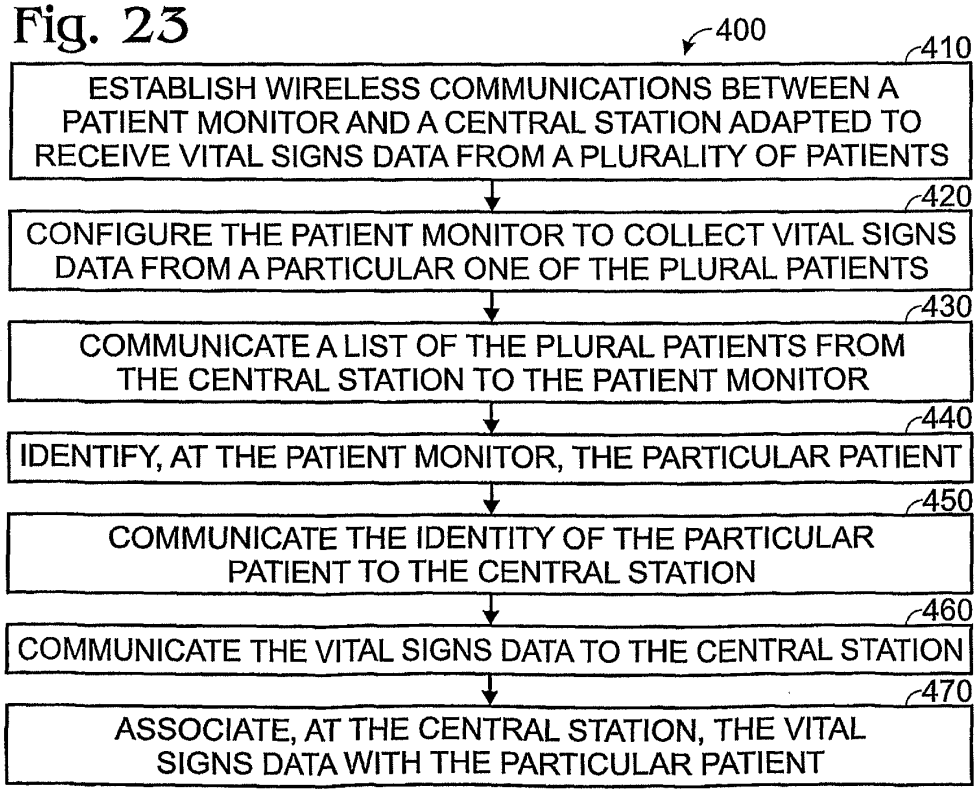

400
410
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A CENTRAL STATION ADAPTED TO RECEIVE VITAL SIGNS DATA FROM A PLURALITY OF PATIENTS
420
CONFIGURE THE PATIENT MONITOR TO COLLECT VITAL SIGNS DATA FROM A PARTICULAR ONE OF THE PLURAL PATIENTS
430
COMMUNICATE A LIST OF THE PLURAL PATIENTS FROM THE CENTRAL STATION TO THE PATIENT MONITOR
440
IDENTIFY, AT THE PATIENT MONITOR, THE PARTICULAR PATIENT
450
COMMUNICATE THE IDENTITY OF THE PARTICULAR PATIENT TO THE CENTRAL STATION
460
COMMUNICATE THE VITAL SIGNS DATA TO THE CENTRAL STATION
470
ASSOCIATE, AT THE CENTRAL STATION, THE VITAL SIGNS DATA WITH THE PARTICULAR PATIENT

Fig. 24

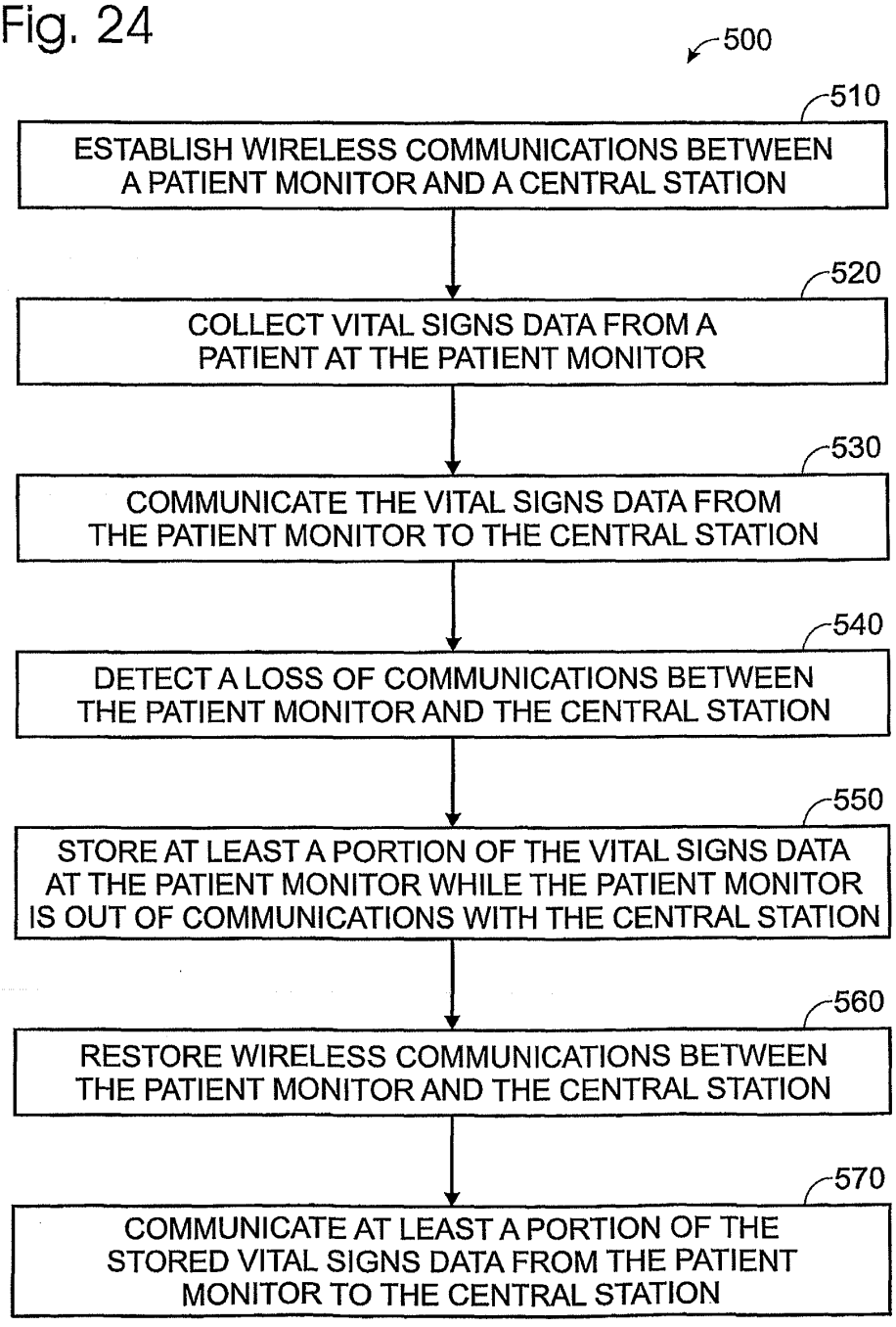

500
510
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A CENTRAL STATION
520
COLLECT VITAL SIGNS DATA FROM A PATIENT AT THE PATIENT MONITOR
530
COMMUNICATE THE VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE CENTRAL STATION
540
DETECT A LOSS OF COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE CENTRAL STATION
550
STORE AT LEAST A PORTION OF THE VITAL SIGNS DATA AT THE PATIENT MONITOR WHILE THE PATIENT MONITOR IS OUT OF COMMUNICATIONS WITH THE CENTRAL STATION
560
RESTORE WIRELESS COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE CENTRAL STATION
570
COMMUNICATE AT LEAST A PORTION OF THE STORED VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE CENTRAL STATION

Fig. 25

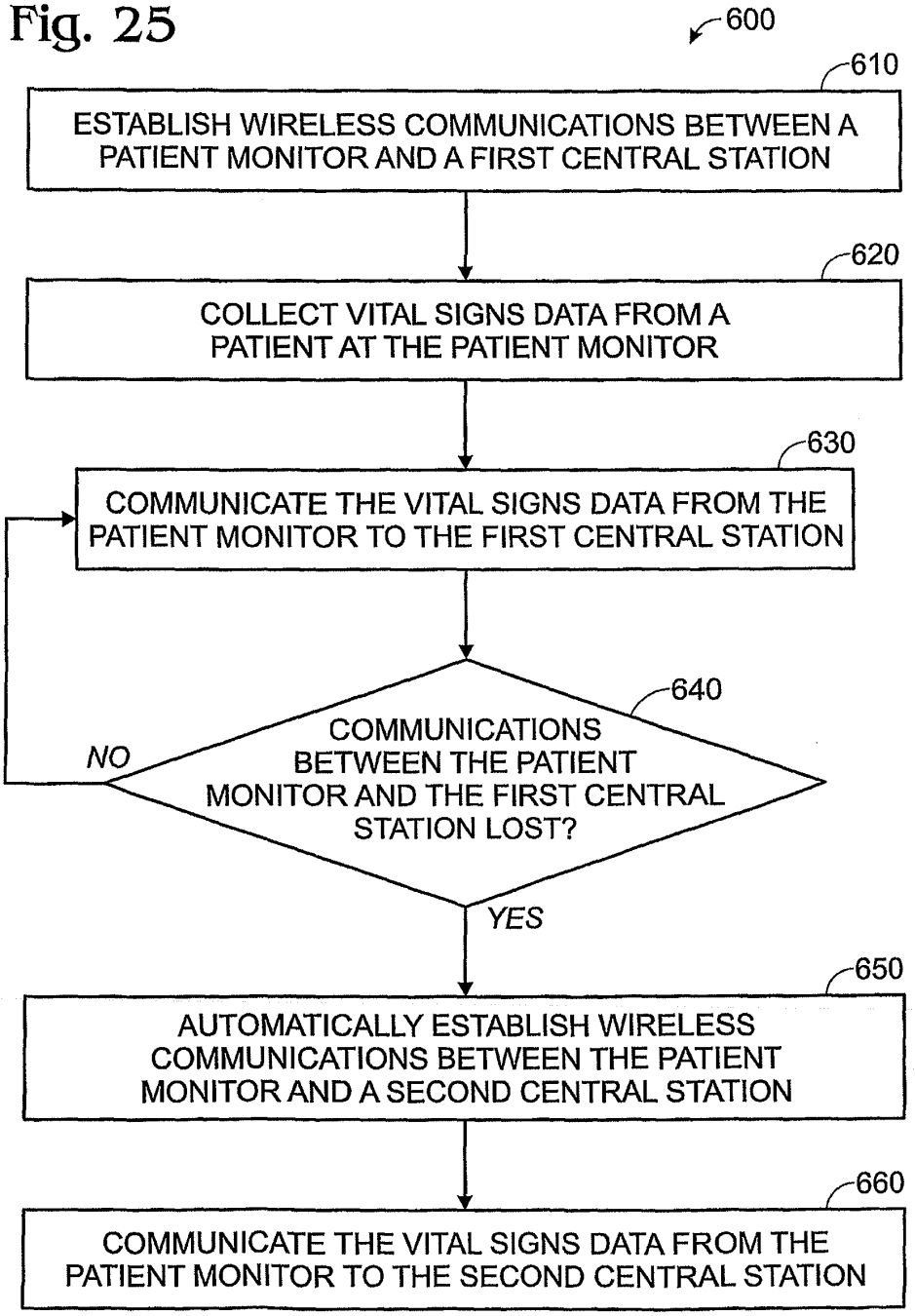
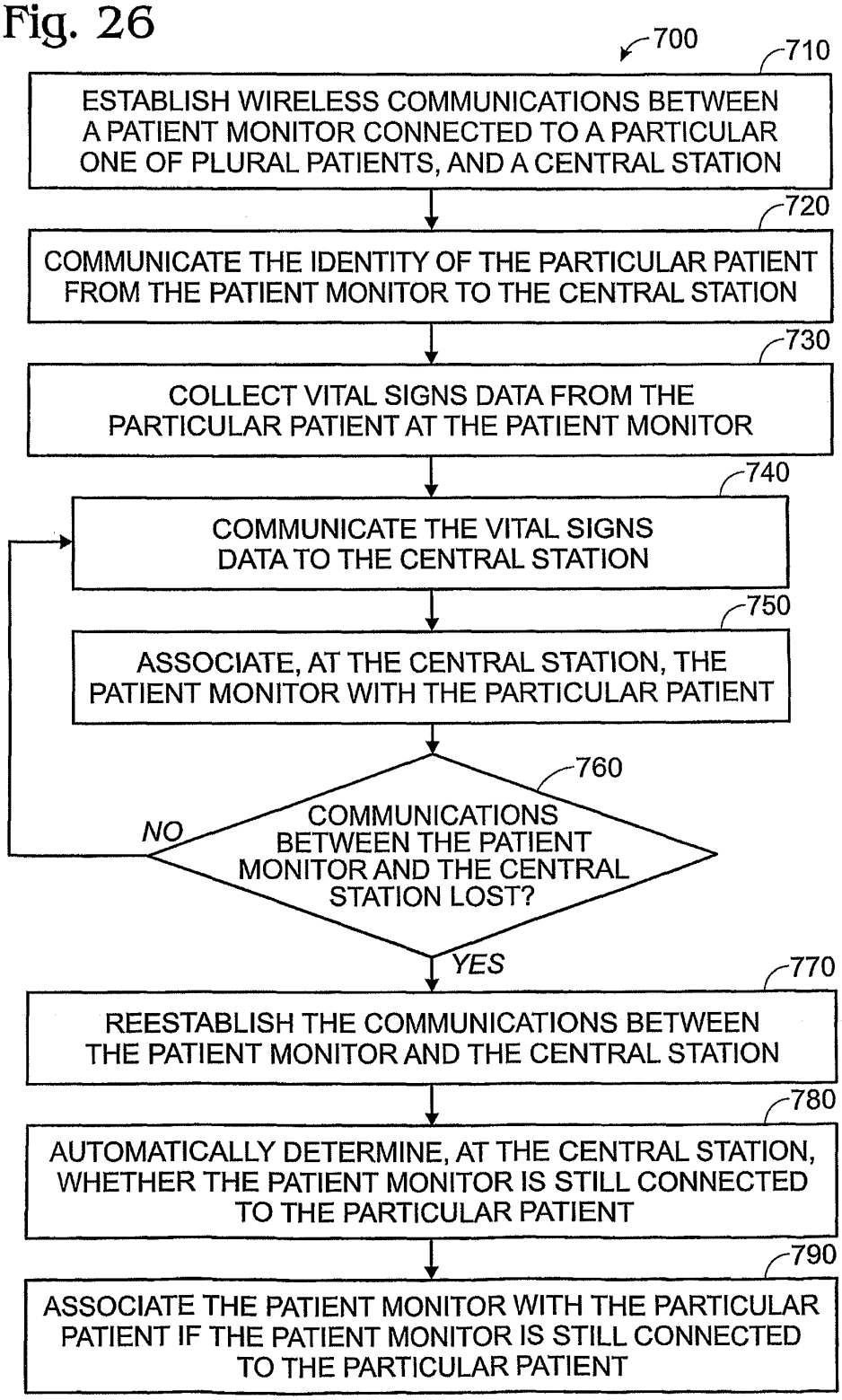

600
610
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A FIRST CENTRAL STATION
620
COLLECT VITAL SIGNS DATA FROM A PATIENT AT THE PATIENT MONITOR
630
COMMUNICATE THE VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE FIRST CENTRAL STATION
640
COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE FIRST CENTRAL STATION LOST?
NO
YES
650
AUTOMATICALLY ESTABLISH WIRELESS COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND A SECOND CENTRAL STATION
660
COMMUNICATE THE VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE SECOND CENTRAL STATION

Fig. 26


700
710
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR CONNECTED TO A PARTICULAR ONE OF PLURAL PATIENTS, AND A CENTRAL STATION
720
COMMUNICATE THE IDENTITY OF THE PARTICULAR PATIENT FROM THE PATIENT MONITOR TO THE CENTRAL STATION
730
COLLECT VITAL SIGNS DATA FROM THE PARTICULAR PATIENT AT THE PATIENT MONITOR
740
COMMUNICATE THE VITAL SIGNS DATA TO THE CENTRAL STATION
750
ASSOCIATE, AT THE CENTRAL STATION, THE PATIENT MONITOR WITH THE PARTICULAR PATIENT
760
COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE CENTRAL STATION LOST?
NO
YES
770
REESTABLISH THE COMMUNICATIONS BETWEEN THE PATIENT MONITOR AND THE CENTRAL STATION
780
AUTOMATICALLY DETERMINE, AT THE CENTRAL STATION, WHETHER THE PATIENT MONITOR IS STILL CONNECTED TO THE PARTICULAR PATIENT
790
ASSOCIATE THE PATIENT MONITOR WITH THE PARTICULAR PATIENT IF THE PATIENT MONITOR IS STILL CONNECTED TO THE PARTICULAR PATIENT

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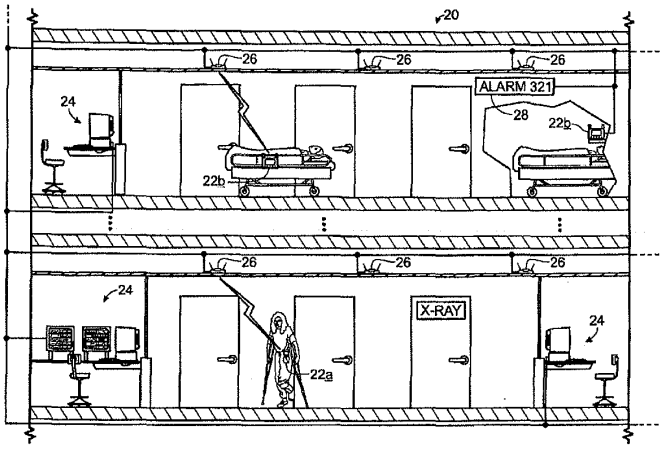
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[Continued on next page]

(54) Title: PATIENT MONITORING SYSTEM



(57) Abstract: A wireless patient monitor (22) is adapted to communicate with any one of plural medical telemetry network (30), each having one or more central stations (24), where each network is configured to communicate via wireless communications using one of multiple different communications settings. The monitor includes one or more sensor inputs for receiving vital signs data from a patient, a wireless transceiver; and a controller coupled to receive the vital signs data via the one or more sensor inputs and to communicate with a network via the transceiver. The monitor also includes a display device (84) and is controllable by the controller to automatically display a notification to a user of the monitor upon establishing communications with the at least one central station. There is also a method of monitoring a patient and a wireless medical telemetry system.

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NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A, P	US 6,225,901 B1 (Kail, IV) 01 May 2001, see entire document	1, 6, 12, 16, 18, 69, 77, 109
A, E	US 6,319,200 B1 (Lai et al) 20 November 2001, see entire document	1, 46, 53, 83, 95, 103, 118
X, E	US 6,406,426 B1 (Reuss et al.) 18 June 2002, see entire document	36-66, 83-102
A, E	US 6,440,067 B1 (DeLuca et al.) 27 August 2002, see entire document	36, 40, 46, 53, 69

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

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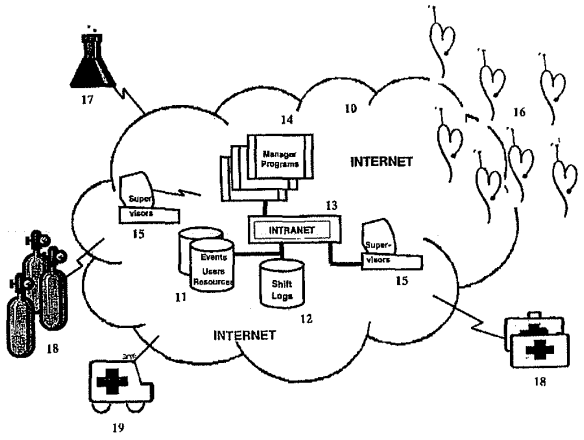
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(54) Title: SYSTEM FOR MAINTENANCE AND MANAGEMENT OF HEALTH



(57) Abstract: A Mobile Tele-Medical Maintenance system (MTMM system) applying different IT methods to perform different functions for the tele-medical maintenance of large numbers of individuals. The MTMM system includes a system kernel residing on web servers, linked to a large number of peripheral units on the individuals. The kernel containing the collection of all the "Private Medical Web Sites" and "Personal Health Plans" of the individuals. The MTMM system periphery including walk-in care offices and intelligent physio-logical sensors that can communicate directly with the kernel's programs via the Internet or similar communication networks, preferably using the user's phone and its traditional interfaces, message display plus message voice, and push-button plus voice input. The system kernel controlling directly actuators in the periphery and using message display and message voice output of the telephone to interact with the individual.

WO 01/97686 A1

System for maintenance and management of health

FIELD OF THE INVENTION

The present invention relates generally to systems for maintenance and management of health for individual patients with Communication Systems for remote monitoring and controlling of large collections of individuals, persons or devices, and to Artificial Intelligence for managing and maintaining their good status and trouble-free operation.

BACKGROUND OF THE INVENTION

In most western societies, namely in the United States and Europe, more than 30% of the population do have serious chronic health problems that challenge them in any aspects of their daily work life, and even more and worse when they leave their home to go on travel, or try to do some sports for their health. The annual medical cost in the U.S. have soared to more than 10'000 $ per non-healthy person. To bring down and control these costs, home healthcare and preventive healthcare have been launched and promoted by insurers and politicians, delivered by mostly small local care givers spread out over the country. The success of these programs was expected to be significant, especially when modern tools and methods of communication were designed, as described in earlier patents for different, interactive and interesting hardware systems and electronic data processing or EDP methods.

But all these efforts ran against the fact that life expectancy climbed faster than any corrective measures. Sooner or later it will add all of us to the group of persons who have to be constantly monitored. In these modern societies we mostly live single on our own with no mate in the home. And any retired people's home will only accept us, if we can still move around freely and do not have to stay and

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iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 553

to be served in the bed all the time, because the next weakness or dizziness can not be predicted or immediately assessed and reacted upon.

Many tele-medical systems have been designed and described in the very details, but have not really been used wide-spread and have not contributed to successful optimization of cost and services. Main reason for this is the limited application of existing technology in hardware and software by the medical caregivers and therefore only a limited range of services are conceived and delivered.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is a system for the maintenance and management of health which permits an easy and complete access to all important data of the patient to be treated.

This object of the invention is accomplished by a system with the features of Claim 1.

The main advantage of the system according to the present invention is that all important data can be retrieved immediately at any place. So the caregivers like medical doctors, first-aid men and emergency services can immediately decide which treatment or therapy should be given.

In systems used for the management of large industrial plants, e.g. to control and maintain large oil refineries, or systems for monitoring remote pump stations along pipelines latest sensor technology with high-speed communications and extensive Artificial Intelligence in the central supervision stations, are known for over 20 years. Repair and preventive maintenance cost have been reduced to lowest

optimized levels, while at the same time availability of the very complex plants was pushed up and can be guaranteed today to 100% over 30 years.

It was surprisingly found that the functions to be implemented in efficiency optimized health maintenance of large groups of individuals, spread over rural countryside are very similar to above mentioned management systems, that secure the safe and efficient operation of all the installations in a large metropolitan subway system. The medical maintenance system according to the present invention now combines the advantages of usual medical sensors and well-trained medical personnel in hospitals, doctor's offices, wide-spread walk-in stores and emergency services with the leading technical maintenance intelligence, with the most efficient and most widely used, traditional communication tool, the telephone.

These and other advantages of the invention are disclosed in the dependent claims and the following description in which an exemplified embodiment of the invention is described with respect to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 shows an overview of the elements of the present invention,

Fig. 2 shows a basic program module for monitoring and supervising,

Fig. 3 shows another module for assessing and decision making, and

Fig. 4 shows several medical sensors connected to a mobile telephone for communication with the maintenance and management system.

DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS

In the following description we define as 'Patients', 'Individuals' and 'Units' the individuals and the large number of distributed entities to be monitored, managed and maintained. They all have as a main property their 'Condition', defined by the

physiological data and measured through different parameters. We call 'Walk-ins' the devices, doctor's offices and labs, that measure and collect the 'Condition' data from the 'Patients' by 'Sensors' and feed the measured data into the management system.

We call 'Managers' the programs and 'Supervisors' and 'Caregivers' the persons who are in charge of the 'Condition' monitoring, like doctors, first-aid men and emergency services, which react on 'Events' defined as alarms, problems and the like. We call 'Resources' all the man hours, money, people, devices, energy and consumables or disposables used and spent for treatment, troubleshooting, assistance and for teaching and maintenance of the 'Units'.

We call 'Logs' all the electronically organized and recorded inputs of measurements, actions, notes and results. And finally we call 'Reports' all the information gathered over the whole time and compiled on different purposes to satisfy general and specific information needs, from administrative functions to strategic fact-finding and decision-making.

MTMM System Overview

In Figure 1 a platform of the Mobile Tele-Medical Maintenance System (MTMM) is depicted, which is a computer system with a combination of proven technology process control modules, hardware and software, with a known medical knowledge base, linked via the Internet 10 and with the telephone as communication net as backbone to the distributed peripheral entities. The system kernel consists of several large databases 11 containing all the relevant data of all Patients and Resources : A 'Personal Medical Web Site' contains the data in form of an EMR ('Electronic Medical Record') which is stored in a Condition Log in one of the databases 11. At the other hand the access to the EMR can be obtained via an Internet link. The system kernel resides normally on web servers and is linked to a large number of peripheral units on the individual patients.

A 'Personal Health Plan' shows all the doctor's prescriptions and recommendations to the Patient for medication, eating, physical activities, lifestyle, telephone calls to the doctor's office, etc. and the selected Condition monitoring with threshold values or limits and indications for corrective actions to caregivers should any values or limits be exceeded.

A further database 12 collects all the Condition measurements made and Event messages received, together with all the corrective actions or reactions taken and initiated by the Manager programs and the Supervisors and Caregivers, and links them to Cases, Users and Resources in a Shift Log. Also the Personal Health Plan is linked to the Shift Log.

The databases 11 and 12 are connected by and communicate over an internal network or intranet 13 with each other, directed by Manager modules 14 and Supervisors and Caregivers 15.

The kernel is surrounded by the peripherals, linked to the databases and the Manager Modules via the Internet: All the Patients, shown as 'Mobile Hearts' 16, the Walk-ins 17, the Caregivers 18 and emergency services 19. These peripherals have many ways to enter their Condition data into the databases, using e.g. smart Sensors, lab instruments and PC's, alarm buttons and help-phones, or just 'manual' typing or voice input in plain text on a terminal. Also scanners can be used to enter handwritten information, which can be transferred to machine-readable information by a known transposing program, into the databases 11.

Log Manager Module

In Figure 2 a Log Manager Module is shown, which is the basic program module of the MTMM system, doing Condition Monitoring and Supervision. All Conditions, i.e. measurements, alarms and other inputs, and Events 21 are entered and logged into the databases. All the necessary links 22 to Personal Health Plans are

updated, enabling fast retrieval and augmentation of knowledge stored in a knowledge database.

The Log Manager Module as a condition monitoring device assesses the data entered and, if preset limits or trends 23 have been exceeded, automatically generates alarms 24 to Supervisors, Caregivers, Patients, emergency services and other medical personnel on duty. Based on the doctors prescriptions 25 and case classifications 23 the Log Manager Module initiates calls by doctors, visits by Caregivers, medication changes by pharmacies, device exchange and maintenance by technicians, etc.

The Log Manager Module sends the orders 26 for these corrective actions also to the human shift Supervisor who may then decide on priorities and may coordinate the actions. The Log Manager Module keeps track of all the related events, of his own actions and initiations, of the Supervisors decisions, of the actions and the results feedback 27 , in a fully integrated Shift Log 28.

It is a main characteristic of the MTMM system that all the tasks can be and some have to be executed in parallel by the software Manager Modules and the human Supervisors.

The Log Manager Module is an excellent tool for any shift supervision 29, also for medical supervision. No handwritten notes are necessary, all important events are always present and can be called upon directly on-screen. The planning of shifts in care giving, in emergency telephone services, for ambulances and for hospitals, etc. becomes "easy" to manage.

Diagnostic Manager Module

In Figure 3 the Diagnostic Manager Module as an evaluating device is shown, which is a 'knowledge driven brain' of the MTMM system, doing the assessment of Conditions and Events, taking decisions and making recommendations to the

Caregivers and the Patients for troubleshooting and treatment and keeping record of the results 35 of each action.

In response to alarms 31, Condition measurements 32 and descriptions 33 of problem situations, the Diagnostic Manager Module enables Supervisors, Caregivers, emergency technicians and Patients to assess the situation 34 and to identify the appropriate corrective action quickly and accurately. This module, applying usual software technologies, combines actual 'best-practice' diagnosis guidelines with a unique knowledge base from the electronic Shift Logs 36, learning and acquiring new knowledge 37 continuously.

With this knowledge always recallable from the Diagnostic Manager, all the Supervisors, Caregivers, emergency and shift staff are learning continuously on their job 38, reducing cost of training significantly and improving the quality of their service. Internet-based teaching can be included, linked and added to the recommended procedures.

Health Plan Manager Module

This is the first program in the 'Maintenance Control Cycle' and it enables the Caregivers to tailor-made their 'Teaching and Treatment' service to the Patients' individual needs, while optimizing the deployment of their resources and reduce the cost generated. But it is also the follow-up program that enables the Caregiver and the Patient to adjust their efforts and to optimize the deviation of the Condition from 'best practice' accepted standards for the Patient's sex, age, population group, job, education, activity, etc.

All Teaching, Treatment, medications, activities, Condition monitoring parameters with devices and actions are managed and displayed to Caregiver and Patient in a Health Plan (or Disease Management) classification system. All the different sources of services (doctors, walk-ins, care givers visits) and their care and assistance given, planned and unplanned, are selected and implemented in this

'Personal Health Plan'. For this task the Health Plan Manager Module bases on the Caregivers experience and 'best practice' guidelines but also on all company internal rules and ISO certified standards.

The 'Personal Health Plan' keeps the overall picture of all the service efforts done and the resulting Condition, summarized into an integral history of the Patient's health. Transitions in his 'medical life', by going to the hospital, being released to a nursing home, moving to another area and another family doctor, changing job and health insurance, etc. can be managed without transferring the patients data in a old-fashioned, cumbersome way. In the MTMM system the 'Mobile Patient' can really leave home 'without it' and access his 'Private Patient Web site' and his 'Personal Health Plan' from any place in this world, while still being monitored, supervised and assisted like in his home town.

Service Manager Module

This is the module for the Caregiver's logistics organization. It enables them to monitor and optimize their highly complex, distributed and costly operations. It manages the collection of all service contracts and doctors prescriptions. It controls all preventive care and unscheduled troubleshooting events, and includes them into a "integral" care cycle. It allows regular preventive care work to be scheduled, planned, ordered and monitored down to the smallest consumable needed.

All services, all devices and Resources are recorded and managed in a parts classification system. This system includes all necessary information about suppliers, contracts, equipment and warranties. The same way all the patients and the care, planned and unplanned, are managed in the Health Plan Manager, the same way all peripheral entities, Devices and Resources, are maintained ready and in good condition. For this purpose the Service Manager Module also contains all the information according to ISO standards and company internal rules and specs.

While the care givers work is performed, all data about type of service, problems solved, how, with which medication and material and at what cost, are entered and a special Care Service Report is generated. Findings, conclusions and actions taken are then transferred to the Diagnostic Manager's knowledge data base.

Report Manager Module

This is the evaluation and analysis program for the management of this fully integrated Health Maintenance Process. It enables continuous and periodical monitoring and classification of the activities in the electronic Shift Log, in the service orders and in other Events. This makes transparent the patients and population group's proneness to problems just as well as the cost control, hours spent and medication and consumables used.

The Report Manager Module enables monitoring the compliance of the therapies implemented and the outcome of the therapies administered. It therefore delivers the basis to all measures to improve efficiency and quality of the Care-giving process ('Teaching and Treating') throughout the whole service industry and its market.

All the data bases are of the relational type, based on standard software. It therefore is easy to add report generators to create additional, custom made reports, as well as to implement interfaces to sophisticated Management Information Systems.

Peripherals Integration

In Figure 4 the integration of peripherals is depicted. The MTMM system uses the open architecture of Internet, telephone and the so called 'RF-Piconet', which finally enables a full integration of all types of peripherals via the easy to use, omnipresent telephone link, by wire and wireless.

The telephones, mainly the new mobile phones (also built into other devices, like watches, palm PC's), shall become the favorites in personal medical condition monitoring. Installing and assigning new peripherals is easy: New users get their phone with a world-wide private number (= device address). They can use it where ever they are and what ever telecom company's infrastructure they are based on.

The new mobile phones have become real Internet terminals, with which huge amounts of information can be downloaded and displayed, if necessary. They are used in the MTMM system as hubs for the very small network of different intelligent Sensors on the Patients body and devices nearby in the home, the "Piconet" 43. The mobile phone can poll Condition data from the Sensors, display them, pre-assess them and transmit them on to the databases in the kernel. And all Users have been comfortable for a long time with the user-friendly guidance "if you need assistance, press 0" and will also get used to high-tech voice input and voice recognition.

In most urban areas the mobile phone system enables tracking of the Patient's position down to some 50 m accuracy, an ideal tool for any Emergency Medical Service but also for caring friends and family members.

The Sensors have become 'intelligent' and can communicate over the same Internet with the central Log Manager Module. In the MTMM system they download requests and limits for bio-signal acquisition and transmission and do the Condition monitoring. They can do basic pre-assessments of the bio-signals and can give local alarms to the Patient, if limits are exceeded. They integrate RF-Piconet transceivers (like Bluetooth) that enable them to start communication with any other device, when ever they are switched on.

The MTMM system performs thus the functions of "CSACT" : Condition monitoring, Supervision, Assessment, Communication, Treatment and Teaching. It applies different methods of signal analysis in the intelligent sensors and in the kernel to assess the actual status of the individuals, it communicates the assessment to diagnosing programs and supervisory personnel and commands the actuators, assistance personnel and the individual to treat itself and to cope with the actual situation. Using standard and Artificial Intelligence software the MTMM system will do : Alarms, immediate corrective actions, reports, logs including accounting; recalls to care providers, optimized plans for preventive check-ups and care; optimized management of all personnel, material, devices and infrastructure resources of the care givers; all sorts of statistics for any level of the medical hierarchy in politics, public and private health organizations and insurers.

Fig. 4 shows such a typical 'Piconet' 43 in the MTMM system: a mobile telephone 41 with its display 42 and special display control buttons 44, its numeric keypad 45 in order to type in values from stand-alone tests, speaker and microphone for voice output and input 46. The mobile telephone 41 communicates with any server on the Internet and its built-in RF-Piconet transceiver 47 communicate with two Sensors on the Patients body, and with one tabletop device.

A heart monitor 50 senses the ECG with two electrodes 48, pre-analyzes it and stores it on a memory-card 49. It also monitors the breathing rate and breathing volume by breath sensors 52. The measured values are stored and checked for coherence between two normally independent signals. The heart monitor 50 uses the display 42 of the mobile telephone 41 to show to the patient locally his Condition with heart-rate, body temperature, breath rate and breath volume. The mobile telephone 41 transmits further the Condition data over the Internet 53 to the MTMM system and to its Log Manager Module. The heart monitor 50 and mobile telephone 41 may communicate continuously or periodically with each other, or only in case of alarms or exceeding of limits.

A non-invasive blood pressure unit 55 is used only a few times a day, according to the doctor's request. So are many other devices; when ever they are taken out of the pocket and switched on, they automatically search over transceiver 47 the area for an active 'Piconet' to hook on. The RF-Piconet transceiver 47 (like Blue-tooth) offers this type of network, like the wire-bound Ethernet.

A glucose meter 56 might be of the old fashioned strip type. With a built-in RF-Piconet transceiver 47 it will automatically call the MTMM system via the mobile telephone's access to the Internet 51 and will ask for Condition measurement schedules. If it does not have the network capability, the MTMM system will request the Patient via the mobile telephone's display 42 to do a measurement at the prescribed time and to type in the resulting value via the numeric keypad 45 of the mobile telephone 41.

It should be clear to the skilled person that instead of mobile telephones 41 also normal telephone sets or PC's with a monitor can be used.

Built-in data conversion modules in the Log Manager Module allow defined alarm and condition data formats to be transferred directly into the database. The Supervisors can assess the individual patients status 'real-time' by calling their mobile phone's "Pico-net" hub.

But also the devices leased and maintained by the Caregiver, by the ambulances and by medical personnel can be called and directed in 'real-time'. The logs of their deployment at the same time are transferred to commercial bookkeeping and invoicing systems within the company offering useful and efficient support not found in other systems.

Standard Hardware and Software

The system is standard-based, running on Windows and Unix platforms. The databases are all relational. The system is also modular. The individual modules can be used independently of one another.

5

The favorite network, fully exploiting the new WAP (Wireless Application Protocol) capabilities, is the worldwide Internet, or an Intranet in large companies, hospitals, nursing home holdings, etc. The mobile telephone can control several sensors and input devices. Bluetooth is the future standard in these "Piconets".

Claims

1. A system for maintenance and management of health care for individual patients comprising

a computer system with

a condition monitoring device, in which physiological data measured on the patient is transmitted, entered and stored together with alarm signals and event information of the patient into a Condition Log,

a supervision device, in which the alarm signals and event information are assessed and which transmits the alarm signals and event information to care givers involved in order to initiate a corrective action on the patient and to request a report about the corrective action and its results, and in which the reports are stored into a Shift Log, and

an evaluating device, in which problems and the patterns of the measurements are evaluated by comparing the problems and patterns with accumulated information in a knowledge database, thereafter selecting appropriate corrective action to be recommended to the caregivers and requesting a report of the caregivers about the corrective action and its results, which reports are entered into the database accumulating and enlarging the knowledge database, and

a communication system connected to the computer system for transmitting alarms and recommendations to a supervisor, who corrects and/or releases the alarms and recommendations, which are transmitted further to the caregivers for taking the recommended action.

2. A system according to Claim 1, whereas the communication system comprises devices for Internet access, especially Internet accessible mobile telephones, PDA's and PC's.

3. A system according to Claim 1 or 2, wherein sensors are provided for measuring the physiological data on the patient which are connected to the communication system.

4. A system according to one of Claims 1 to 3, comprising a Medical Web Site stored in the computer system, which contains a separate database containing all medical data and the medical history of each individual patient, which is accessible by express authorization of the individual patient and/or his caregiver only.

5. A system according to one of Claims 1 to 4 comprising a Personal Health Plan stored in the computer system, containing the doctor's prescriptions for medication, treatments, practicing and lifestyle of the individual patient, a schedule for the monitoring of conditions stored in the Condition Log, the selection of sensors to be used, the threshold values of the physiological data to be monitored and corrective actions, whereas the monitored data, compliance for therapies and the outcome of the therapies are attached to the Plan, which is accessible by express authorization of the individual patient and/or his caregiver only.

6. A system according to one of Claims 1 to 5 comprising a Log Manager Module for monitoring the alarm signals and the event information in the Condition Log and for supervising the reports in the Shift Log.

7. A system according to one of Claims 1 to 6, comprising a Diagnostic Manager Module for diagnosing the condition of the individual patient by means of comparing data stored in expert computer programs containing diagnosis guidelines with the accumulated data of the knowledge database.

FIG. 1

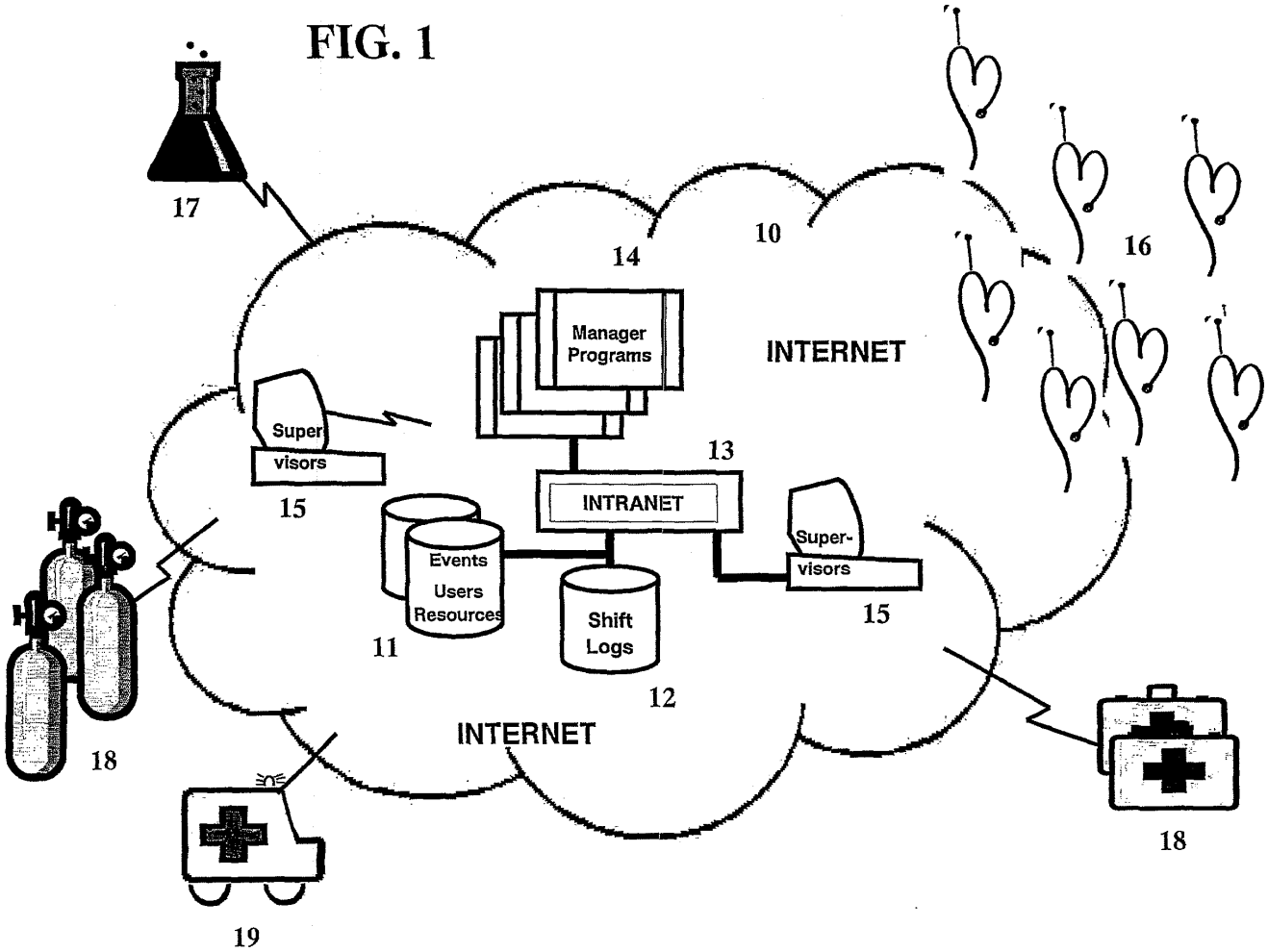

17
14
10
16
Manager Programs
INTERNET
Super visors
15
13
INTRANET
Events
Users
Resources
11
Shift Logs
12
Super-visors
15
INTERNET
18
18
19

FIG. 2

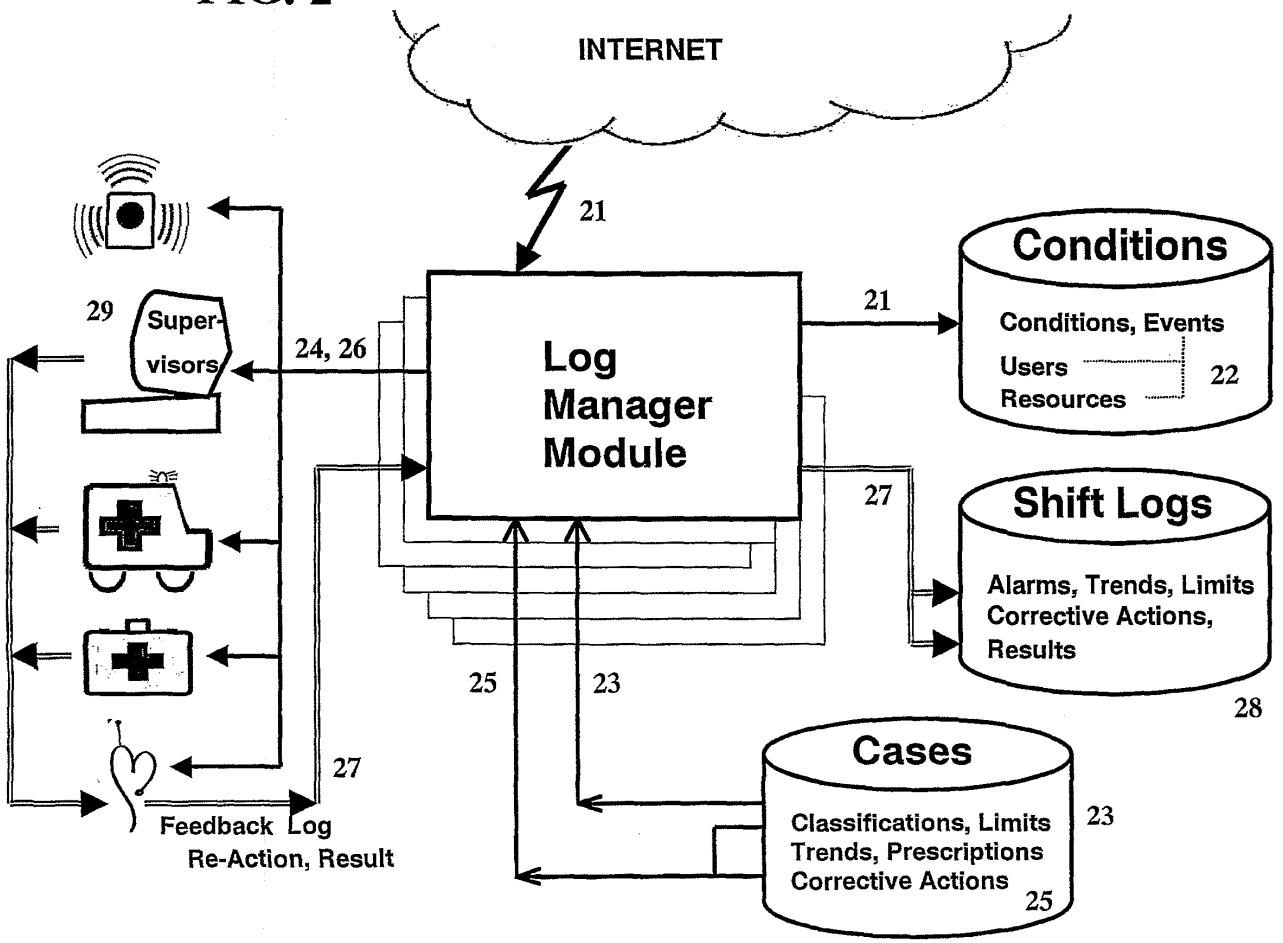
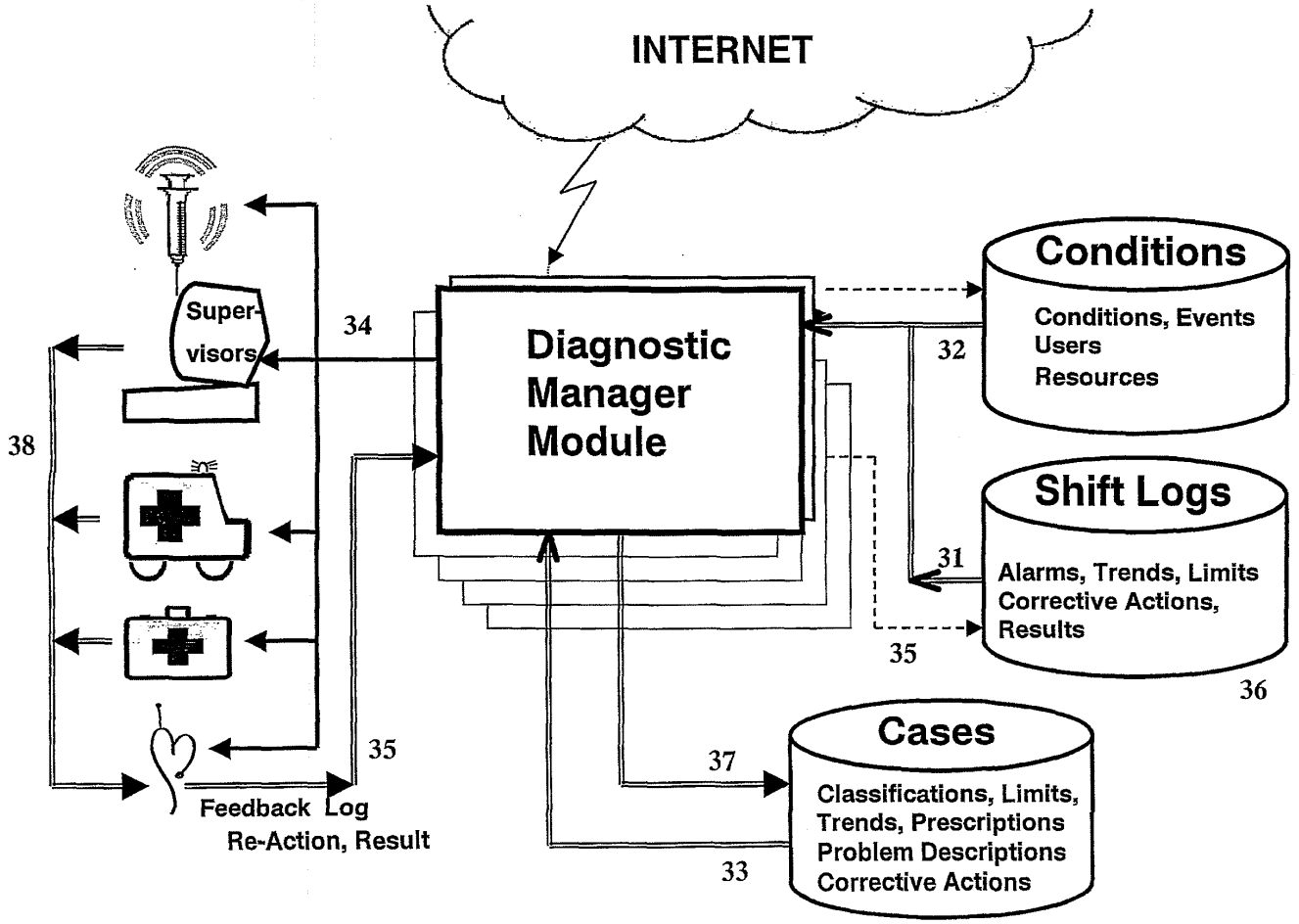

INTERNET
21
Conditions
Conditions, Events
Users
Resources
22
21
29
Super-
visors
24, 26
Log
Manager
Module
27
Shift Logs
Alarms, Trends, Limits
Corrective Actions,
Results
28
25
23
Cases
Classifications, Limits
Trends, Prescriptions
Corrective Actions
25
23
27
Feedback Log
Re-Action, Result

FIG. 3


INTERNET
Super-
visors
34
38
Diagnostic
Manager
Module
Conditions
Conditions, Events
Users
Resources
32
Shift Logs
Alarms, Trends, Limits
Corrective Actions,
Results
31
35
36
Cases
Classifications, Limits,
Trends, Prescriptions
Problem Descriptions
Corrective Actions
37
33
35
Feedback Log
Re-Action, Result

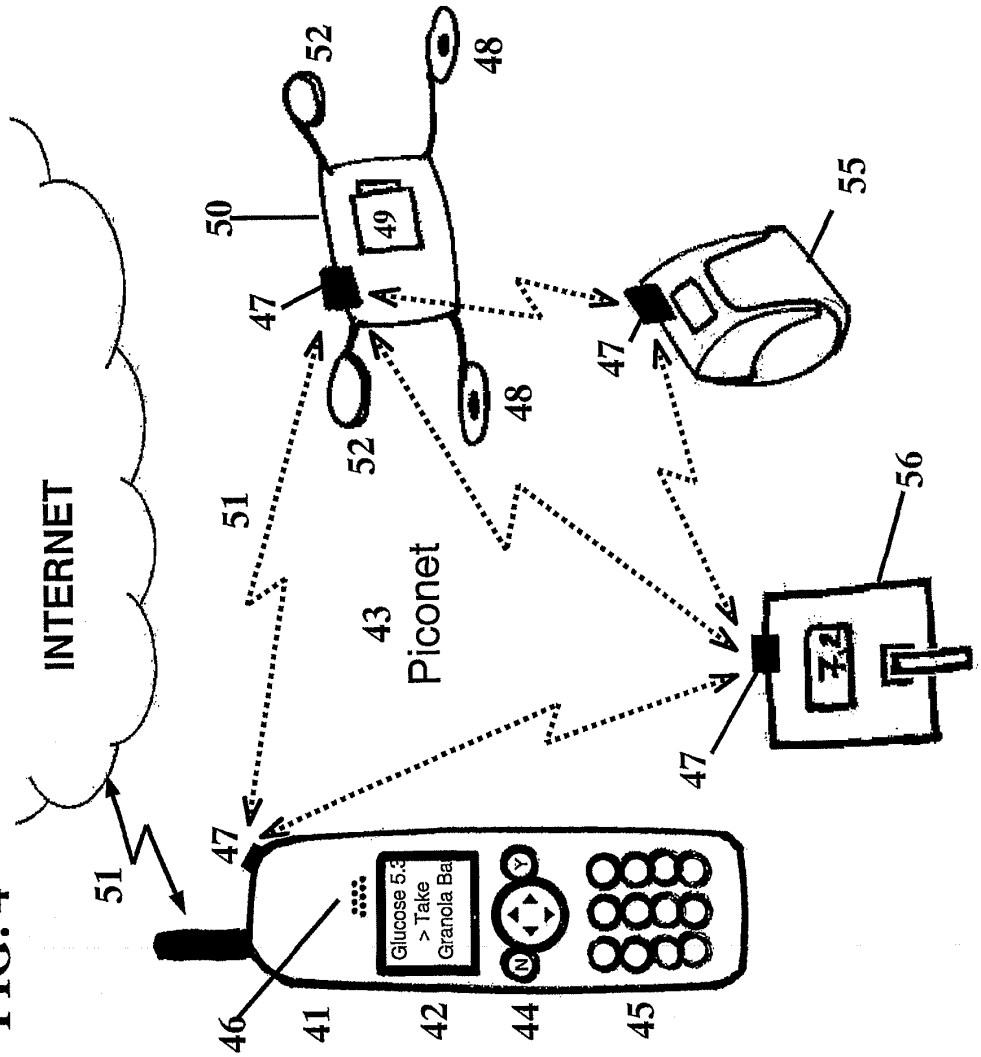

INTERNET
51
47
46
41
Glucose 5.3
> Take
Granola Ba
42
44
45
43
Piconet
51
52
48
50
49
47
52
48
47
55
47
56

FIG. 4

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/IB 01/01110

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00 G06F19/00

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)
IPC 7 A61B G06F

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 544 661 A (LONG PAUL V ET AL) 13 August 1996 (1996-08-13) column 1, line 64 -column 2, line 15 column 3, line 22 - line 31 column 8, line 62 -column 9, line 6	1-3,6,7
Y	WO 00 28459 A (STEWARD DUANE) 18 May 2000 (2000-05-18) page 8, line 8 - line 15 page 9, line 12 -page 10, line 5	1-3,6,7

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"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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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 October 2001	12/10/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Martelli, L

1

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

INTERNATIONAL SEARCH REPORT
Information on patent family members

Inte ›nal Application No
PCT/IB 01/01110

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5544661 A	13-08-1996	NONE	
WO 0028459 A	18-05-2000	AU 3098800 A	29-05-2000
		WO 0028459 A2	18-05-2000

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

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:	Robert Stephen Rosenholm/Jill Huffstater
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:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Request for continued examination	1801	1	810	810
		Total in USD ($)		**810**

Electronic Acknowledgement Receipt

EFS ID:	6296627
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:	Robert Stephen Rosenholm/Jill Huffstater
Filer Authorized By:	Robert Stephen Rosenholm
Attorney Docket Number:	704_049
Receipt Date:	20-OCT-2009
Filing Date:	01-NOV-2006
Time Stamp:	17:02:02
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$810
RAM confirmation Number	3407
Deposit Account	
Authorized User	

File Listing:

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

1	Request for Continued Examination (RCE)	2009-10-20-RCE-Transmittal.pdf	89360 2da60d476a494c354ff81655c762d0582036e8b8	no	1
Warnings:					
This is not a USPTO supplied RCE SB30 form.					
Information:					
2	Amendment After Final	2009-10-20-Response-To-OA.pdf	30760 83a8cedced627985c73a0f4809c5e8e200622ebb	no	1
Warnings:					
Information:					
3	Claims	2009-10-20-OA-Claims.pdf	492504 f9410dd6b5300d39a45356fe1ad842a96dbd209c	no	11
Warnings:					
Information:					
4	Applicant Arguments/Remarks Made in an Amendment	2009-10-20-OA-Remarks.pdf	300997 b779426eaab6ccbc2b18d2e17ab17c65a5ac2ad7	no	6
Warnings:					
Information:					
5	Miscellaneous Incoming Letter	2009-10-20-IDS-Statement.pdf	60624 3ef05054929e19f43df9354baf51f974a729c96f	no	2
Warnings:					
Information:					
6	Information Disclosure Statement (IDS) Filed (SB/08)	2009-10-20-SB08A.pdf	170997 10b9b6b2a80c39cb6f077f0a23c45aada939ce59	no	2
Warnings:					
Information:					
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7	Foreign Reference	2009-10-20-WO-0189362.pdf	6468671 ff8c5b1ee66a8c93f454ee913a669bfe335aac9b	no	141
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Information:					
8	Foreign Reference	WO-0197686.pdf	1006570 56ea6bd68702b5b8944f256ae34502ced3a92527	no	22
Warnings:					
Information:					

9	Fee Worksheet (PTO-875)	fee-info.pdf	30254 f95942f8dcbec8cd1e3e4b3e66492e981dd71b7b	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	8650737	

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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.

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PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 11/591,619	Filing Date 11/01/2006	☐ To be Mailed

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		(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 ($)	ADDITIONAL FEE ($)
	10/20/2009									
	Total (37 CFR 1.16(i))	* 57	Minus	** 58	= 0	X $ =		OR	X $52=	0
	Independent (37 CFR 1.16(h))	* 6	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:
/Ruby Johnson/

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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PTO/SB/122 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
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Application

Address to:
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P.O. Box 1450
Alexandria, VA 22313-1450

Application Number	11/591,619
Filing Date	November 1, 2006
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Lavert, Nicole F.
Attorney Docket Number	704_049/054 US01

Please change the Correspondence Address for the above-identified patent application to:

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I am the:

☐ Applicant/Inventor

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

☑ Attorney or agent of record. Registration Number 35,067.

☐ Registered practitioner named in the application transmittal letter in an application without an executed oath or declaration. See 37 CFR 1.33(a)(1). Registration Number_____.

Signature Peter J. Bilinski

Typed or Printed Name Peter J. Bilinski

Date October 6, 2009	Telephone 315-425-2700

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.

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Electronic Acknowledgement Receipt

EFS ID:	6211305
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:	Peter J Bilinski/Jill Huffstater
Filer Authorized By:	Peter J Bilinski
Attorney Docket Number:	704_049
Receipt Date:	06-OCT-2009
Filing Date:	01-NOV-2006
Time Stamp:	15:40:50
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	Change of Address	2009-10-06-Change-Of-Correspondence.pdf	62362 21229f61043f921ce041ddf4252d6430088b5bd4	no	1
Warnings:					
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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
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