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
Email: teas@friedfrank.com
Correspondent Name: DANIEL STERN C/O FRIED FRANK ET AL
Address Line 1: ONE NEW YORK PLAZA
Address Line 4: NEW YORK, NEW YORK 10004

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

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.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/488,520	01/14/2014	8630699	3022036 US02	9601

88750 7590 12/24/2013

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 0 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, UNITED KINGDOM;
James P. Welch, Mission Viejo, CA;
Norbert Ohlenbusch, Andover, MA;
Thomas P. Blackadar, Natick, MA;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

Customer No.: 88750

FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	4,141,367 A	02/27/1979	Ferreira			
	4,791,933	12/20/1988	Asai et al.			
	4,800,894 A	01/31/1989	Milani			
	4,957,109	09/18/1990	Groeger et al.			
	4,958,645	09/25/1990	Cadell et al.			
	4,974,607	12/04/1990	Miwa			
	5,257,631	11/02/1993	Wik			
	5,294,928 A	03/15/1994	Cooper et al.			
	5,309,918 A	05/10/1994	Schraag			
	5,319,363	06/07/1994	Welch et al.			
	5,458,122	10/17/1995	Hethuin			
	~~5,515,736~~	05/14/1996	Sarihan			5,515,735
	5,538,007	07/23/1996	Gorman			
	5,544,661	08/13/1996	Davis et al.			
	5,579,001	11/26/1996	Dempsey et al.			
	5,579,775	12/03/1996	Dempsey et al.			
	5,600,071	02/04/1997	Sooriakumar et al.			
	5,682,803	11/04/1997	Gideon et al.			
	5,687,734	11/18/1997	Dempsey et al.			
	5,694,940	12/09/1997	Unger et al.			
	5,743,269	04/28/1998	Okigami et al.			
	5,748,103	05/05/1998	Flach et al.			
	5,767,791	06/16/1998	Stoop et al.			
	5,808,331	09/15/1998	Zhang et al.			
	5,832,490	11/03/1998	Riley			
	5,871,451	02/16/1999	Unger et al.			

Change(s) applied to document, /D.D./ 10/4/2013

EXAMINER /Nicole LaVert/	DATE CONSIDERED 05/11/2013

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./

FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,882,300	03/16/1999	Malinouskas et al.			
	5,889,211	03/30/1999	Maudie et al.			
	5,899,866	05/04/1999	Cyrus, et al.			
	5,916,159	06/29/1999	Kelly et al.			
	5,917,414 A	06/29/1999	Oppelt et al.			
	5,919,141	07/06/1999	Money et al.			
	5,938,597	08/17/1999	Stratbucker			
	5,966,692	10/12/1999	Langer et al.			
	5,987,519	11/16/1999	Peifer et al.			
	5,995,861	11/30/1999	Price			
	6,006,125	12/21/1999	Kelly et al.			
Change(s) applied to document, /D.D./ 10/4/2013	~~6,016,933~~	01/11/2000	Foerstner et al.			6,013,933
	6,018,705	01/25/2000	Gaudet et al.			
	6,026,321	02/15/2000	Miyata et al.			
	6,052,654	04/18/2000	Gaudet et al.			
	6,057,758 A	05/02/2000	Dempsey et al.			
	6,066,093	05/23/2000	Kelly et al.			
	6,073,046	06/06/2000	Patel et al.			
	6,076,003	06/13/2000	Rogel			
	6,089,692	07/18/2000	Anagnostopoulos			
	6,122,340	09/19/2000	Darley et al.			
	6,150,951	11/21/2000	Olejniczak			
	6,161,036	12/12/2000	Matsumura et al.			
	6,171,236 B1	01/09/2001	Avitall et al.			
	6,198,394 B1	03/06/2001	Jacobsen et al.			
	6,212,944	04/10/2001	Kwun et al.			

EXAMINER /Nicole LaVert/	DATE CONSIDERED 05/11/2013

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./

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 09/06/2013
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.
13/488,520	06/05/2012	Steven D. Baker	3022036 US02	9601

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$300	$0	$2080	12/06/2013

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 Hiscock & Barclay, LLP
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 50-3010 (enclose an extra copy of this form).

PTOL-85 (Rev. 02/11)

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29	NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
❑ Applicant asserting small entity status. See 37 CFR 1.27	NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
❑ Applicant changing to regular undiscounted fee status.	NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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 /Peter J. Bilinski/ Date December 6, 2013

Typed or printed name Peter J. Bilinski Registration No. 35,067

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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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	13/488,520
Applicant	:	Steven D. Baker et al.
Filed	:	June 5, 2012
Art Unit	:	3762
Examiner	:	Nicole F. Lavert
Docket No.	:	3022036 US02
Confirmation No.:		9601
Customer No.	:	88,750
Title	:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

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

COMMENTS ON STATEMENT FOR REASONS FOR ALLOWANCE

Sir:

Applicant acknowledges the Examiner's Reason(s) for Allowance dated September 6, 2013. Applicant respectfully notes, however, that there may be additional reasons for allowance that have not been specifically cited, and which may apply to the allowed claims, in addition to or instead of the cited Reason(s). Applicant respectfully notes that each of the allowed claims is patentable in its own right and for other reasons raised during its prosecution or as explained in the specification of the captioned application. Moreover, as the prosecution history of the claims is clear and is not limited only to the Examiner's Reason(s), the Examiner's Reason for Allowance therefore is not binding on Applicant and no acquiescence is made by Applicant to such Reason(s).

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 13

Entry of this submission into the file is respectfully requested.

Respectfully submitted,

HISCOCK & BARCLAY, LLP

/Peter J. Bilinski/

Date: December 6, 2013

Peter J. Bilinski
Reg. No. 35,067
Hiscock & Barclay, LLP
One Park Place
300 South State Street
Syracuse, NY 13202-2078
Tel: (315) 425-2856
Fax: (315) 703-7397

Electronic Patent Application Fee Transmittal

Application Number:	13488520
Filing Date:	05-Jun-2012
Title of Invention:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
First Named Inventor/Applicant Name:	Steven D. Baker
Filer:	Peter J Bilinski/Susanne Pelose
Attorney Docket Number:	3022036 US02

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	1780	1780
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**2080**

Electronic Acknowledgement Receipt	
EFS ID:	17589476
Application Number:	13488520
International Application Number:	
Confirmation Number:	9601
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:	Peter J Bilinski/Susanne Pelose
Filer Authorized By:	Peter J Bilinski
Attorney Docket Number:	3022036 US02
Receipt Date:	06-DEC-2013
Filing Date:	05-JUN-2012
Time Stamp:	14:45:13
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	$2080
RAM confirmation Number	1207
Deposit Account	503010
Authorized User	

File Listing:

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

1	Miscellaneous Incoming Letter	2013-12-06-Issue-Fee-Transmittal-Letter.pdf	197041 e74211418dfa9f9c80d34a51d573ddb07b3211df	no	1
Warnings:					
Information:					
2	Issue Fee Payment (PTO-85B)	2013-12-06-Issue-Fee-Transmittal.pdf	601056 704c8a95b624e29b3d0c2920f3753dcd16db80b0	no	2
Warnings:					
Information:					
3	Miscellaneous Incoming Letter	2013-12-06-Comments-On-Statement-For-Reasons-For-Allowance.pdf	304118 27b533ac4f7c3a3b74d0f1cc419013473877fedf	no	2
Warnings:					
Information:					
4	Fee Worksheet (SB06)	fee-info.pdf	32152 59e7bed7746882460ba2da4739536d8f7bbfe549	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1134367		

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<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.

HISCOCK & BARCLAY LLP

Peter J. Bilinski
Partner

December 6, 2013

Via Electronic Filing System (EFS)

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

Application Number:	13/488,520
Filing Date:	June 5, 2012
First Named Inventor(s):	Steven D. Baker
Art Unit:	3762
Examiner Name:	Nicole F. Lavert
Attorney Docket Number:	3022036 US02
Invention:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

In response to the Notice of Allowance and Fee(s) due, mailed September 6, 2013, Applicants submit as follows:

- This Transmittal Letter (1 page)
- Part B – Fee(s) Transmittal (PTOL-85) (1 page) and
- Comments on Statement for Reasons for Allowance (2 pages)

The Commissioner is authorized to charge the issue fee, for a large entity, in the amount of $2,080.00 to our Deposit Account 50-3010 and to charge any deficiencies or credit any excess payments to our Deposit Account No. 50-3010.

Very truly yours,

/Peter J. Bilinski/

Peter J. Bilinski
Reg. No. 35,067

PJB:scp
Enclosures

One Park Place – 300 South State Street – Syracuse, New York 13202 hblaw.com
pbilinski@hblaw.com Direct: 315.425.2856 Fax: 315.703.7397

7696580.1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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NOTICE OF ALLOWANCE AND FEE(S) DUE

88750 7590 09/06/2013
HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 09/06/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/488,520	06/05/2012	Steven D. Baker	3022036 US02	9601

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$300	$0	$2080	12/06/2013

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 ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

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)

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 20

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 09/06/2013
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.
13/488,520	06/05/2012	Steven D. Baker	3022036 US02	9601

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

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1780	$300	$0	$2080	12/06/2013

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).

PTOL-85 (Rev. 02/11)

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29	NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
❑ Applicant asserting small entity status. See 37 CFR 1.27	NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
❑ Applicant changing to regular undiscounted fee status.	NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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.

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.

PTOL-85 (Rev. 02/11) Approved for use through 08/31/2013. OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/488,520	06/05/2012	Steven D. Baker	3022036 US02	9601

88750 7590 09/06/2013

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

EXAMINER	
LAVERT, NICOLE F	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 09/06/2013

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 0 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 0 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 23

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.

Notice of Allowability	Application No. 13/488,520	Applicant(s) BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	AIA (First Inventor to File) Status No

-- 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 August 16, 2013*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
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 *8-15*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   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. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ 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).
6. ☐ 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. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/NICOLE F. LAVERT/
Primary Examiner, Art Unit 3762

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

1. The present application is being examined under the pre-AIA first to invent provisions.

DETAILED ACTION

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

EXAMINER'S AMENDMENT

2. 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 1-7 are cancelled.

EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE

3. The following is an examiner's statement of reasons for allowance: The closest prior art, Tasto, fails to disclose, suggest, and/or teach an ECG monitor that is configured for receiving and processing patient heart signals from a plurality of disposed connections (e.g., see 'Arguments').

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."

Allowable Subject Matter

4. Claims 8-15 are allowed.

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, Christopher Koharski can be reached on 571-272-7230. 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/
Primary Examiner, Art Unit 3762

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
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BIB DATA SHEET

CONFIRMATION NO. 9601

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/488,520	06/05/2012	600	3762	3022036 US02

APPLICANTS

Steven D. Baker, Beaverton, OR;
Eric T. McAdams, Whitehead, UNITED KINGDOM;
James P. Welch, Mission Viejo, CA;
Norbert Ohlenbusch, Andover, MA;
Thomas P. Blackadar, Natick, MA;

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

This application is a CON of 11/591,619 11/01/2006 PAT 8214007 *

(*)Data provided by applicant is not consistent with PTO records.

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

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ****

06/13/2012

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	15	2

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		
1250	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).

Issue Classification

Application/Control No.	Applicant(s)/Patent Under Reexamination
13488520	BAKER ET AL.
Examiner	**Art Unit**
NICOLE F LAVERT	3762

CPC				
Symbol			**Type**	**Version**
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CPC Combination Sets						
Symbol			**Type**	**Set**	**Ranking**	**Version**
	/					
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NONE (Assistant Examiner) (Date)	**Total Claims Allowed:** 8	
/NICOLE F LAVERT/ Primary Examiner.Art Unit 3762 8/25/13 (Primary Examiner) (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13488520	BAKER ET AL.
	Examiner	**Art Unit**
	NICOLE F LAVERT	3762

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION													
CLASS	SUBCLASS	CLAIMED									NON-CLAIMED				
600	509	A	6	1	B	5 / 04 (2006.0)									
CROSS REFERENCE(S)		A	6	1	B	5 / 02 (2006.01.01)									
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)														
600	372	508													

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	8	
/NICOLE F LAVERT/ Primary Examiner.Art Unit 3762	8/25/13	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13488520	BAKER ET AL.
	Examiner	**Art Unit**
	NICOLE F LAVERT	3762

☐ 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	8														
2	9														
3	10														
4	11														
5	12														
6	13														
7	14														
8	15														

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 8	
/NICOLE F LAVERT/ Primary Examiner.Art Unit 3762	8/25/13	O.G. Print Claim(s) 1	O.G. Print Figure 1
(Primary Examiner)	(Date)		

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1758	600/508.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:02
L2	3249	600/509.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:02
L3	829	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/08/25 19:03
S1	1534	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:14
S2	2846	600/509.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:16
S3	717	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
S4	38520	(eck or eckg or cardiac or heart) same monitor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
S5	3417	S4 and (electrical same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
S6	1847	S5 and (power same source)\	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S7	53826	(current same limiting) same resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S8	33	S6 and (current same limiting) same resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S9	33	S6 and ((current same limiting) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
S10	23	S9 and @py<="2005"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:27
S11	4727	(external) same ((heart or EKG or ECG) same monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:38
S12	2815	S11 and @py<="2009"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:38
S13	11	S12 and ((current same limiting) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2013/05/11 12:39

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			DERWENT; IBM_TDB			
S14	351	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:52
S15	3	"20030171743"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/07/16 10:50
S16	1	S15 and heart	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/07/16 10:51

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L4	503	600/372.ccls.	USPAT; UPAD	OR	OFF	2013/08/25 19:05
L5	1512	600/509.ccls.	USPAT; UPAD	OR	OFF	2013/08/25 19:05
L6	881	600/508.ccls.	USPAT; UPAD	OR	OFF	2013/08/25 19:05

8/25/2013 7:05:24 PM
C:\Users\nlavert\Documents\EAST\Workspaces\13488520.wsp

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	13/488,520
Applicant	:	Steven D. Baker et al.
Filed	:	June 5, 2012
Art Unit	:	3762
Examiner	:	Nicole F. Lavert
Docket No.	:	3022036 US02
Confirmation No.:		9601
Customer No.	:	88,750
Title	:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

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

RESPONSE TO OFFICE ACTION

Sir:

In response to the non-final Office Action, dated May 16, 2013, please amend the above-captioned patent application, without prejudice, as follows:

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

Amendments to the Claims are reflected in the following Listing of Claims, which begin on page 3 of this paper.

Remarks begin on page 7 of this paper.

Amendments to the Specification:

Please replace paragraph [0001] with the following amended paragraph:

This application is a continuation application of, and claims priority and benefit to, U.S. ~~patent application serial number 11/591,619,~~ Patent No. 8,214,007 B2, entitled "Body Worn Device Having a Disposable Electrode Module", filed November 1, 2006, the entirety of which is hereby incorporated by reference.

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Amendments to the Claims:

Please replace all prior listing of claims with the following Listing of Claims:

Listing of Claims

1. (Withdrawn) A method for providing high voltage circuit protection for a patient monitor, the method comprising:

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.

2. (Withdrawn) The method of claim 1, wherein both determining a print pattern and thickness of both the first and second materials comprise including a filleted section.

3. (Withdrawn) The method of claim 1, wherein both determining a print pattern and thickness of both the first and second materials comprise determining a print pattern and thickness of both the first and second materials to achieve a total resistance value.

4. (Withdrawn) The method of claim 1, wherein both determining a print pattern and thickness of both the first and second materials comprise the further steps of determining a print pattern and thickness of both the first and second materials to achieve a spacing between two or more electrical traces of the print pattern, and applying an insulating layer after the step of printing of the second material.

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5. (Withdrawn) The method of claim 1, the method further comprising:

providing an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals;

filtering the measured heartbeat signals with an analog high pass filter having an analog high pass cutoff frequency;

removing the effects of the analog high pass filter with a digital inverse filter algorithm resulting in substantially unfiltered heartbeat signals;

filtering the substantially unfiltered heartbeat signals digitally using a digital filter having a digital high pass filter cutoff frequency lower than said analog cutoff frequency.

6. (Withdrawn) The method of claim 5, wherein filtering the measured heartbeat signals with an analog high pass filter comprises filtering the measured physiological signals with an analog high pass filter having a 0.5 Hz analog high pass cutoff frequency.

7. (Withdrawn) The method of claim 5, wherein filtering the substantially unfiltered heartbeat signals digitally comprises filtering the substantially unfiltered heartbeat signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

8. (Original) 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;

a power source;

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

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an ECG electronics module, the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections,

wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.

9. (Original) The ECG monitor of claim 8, wherein the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

10. (Original) The ECG monitor of claim 8, wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge.

11. (Original) The ECG monitor of claim 8, wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers.

12. (Original) The ECG monitor of claim 11, wherein the plurality of 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.

13. (Original) The ECG monitor of claim 8, the ECG monitor further comprising a pacer detect circuit to detect the presence or absence of a pacemaker, the ECG electronics module drawing power as an electrical load on the power source wherein the pacer detect circuit, upon detection of the absence of a pacemaker signal in a patient being monitored by the ECG monitor, causes the ECG electronics module to disable the pacer detect circuit in order to reduce the electrical load on the power source.

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14. (Original) The ECG monitor of claim 13, wherein the power source is a battery.

15. (Original) The ECG monitor of claim 8, wherein the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the 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 the power source.

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REMARKS

This paper is timely filed in response to the non-final Office Action on the merits, dated May 16, 2013, in regard to the captioned patent application and having a three (3) month statutory due date of August 16, 2013.

Claims 1-15 are pending and in which claims 1-7 have been withdrawn based on a previous Restriction Requirement. Applicant previously and timely responded to the Restriction Requirement with traverse, but the Examiner has failed to indicate the finality of the Restriction Requirement, as required. Applicant therefore maintains their position that this Requirement should be withdrawn for reasons provided in their previous paper and maintains the right, in any event, to file at least divisional application based on non-elected subject matter.

As to the examined claims, claims 8-15 have been rejected under 35 U.S.C. 102(b) as being anticipated by Tasto et al. (U.S. Patent Application Publication No. 2003/0171743, "Tasto"). In addition, the specification has been objected to based on minor informalities. Applicant respectfully requests reconsideration.

Applicant gratefully acknowledges the telephonic interview granted by Examiner Nicole F. Lavert to Applicant's representative, Peter Bilinski, on July 16, 2013. The subject matter of the interview is incorporated into this response.

Section 102 Rejections – claims 8-15 (Tasto)

In order to anticipate successfully under the Patent Statute, each and every claimed feature must be found (either explicitly or inherently) in the single cited reference. Those features that are not found must be notoriously well known to one of ordinary skill in the relevant field.

The present invention claimed herein relates to an ECG monitor with various recited features that are specific to an ECG measurement of a patient and control of pulses used therewith. Tasto, on the other hand, relates to an electrocautery device used for promoting the flow of blood through vessels or to connective tissue of a patient. Though both Tasto and Applicant's monitor are used in connection with the medical field

in general and furthermore are directed to a patient, there is almost nothing else similar in terms of a comparison between these references.

Referring to the Examiner's points as raised in item 3 of the Office Action, Tasto as discussed above is NOT an ECG monitor nor can this device be configured (by one of ordinary skill) for this particular use. Paragraph [0001] of Tasto, referred to by the Examiner, merely relates to a cross-reference to other applications. No reference to an ECG monitor is made either here or any portion of this cited reference. The Examiner is therefore requested to provide a more specific reference to this recited feature. Tasto is specifically directed to an electrosurgical device that applies high frequency electrical energy to increase the flow of blood to a target tissue so as to improve the condition of a patient, for example, suffering from coronary artery disease or other similar maladies so as to offset the effects of this disease, which occludes major blood vessels. The cited device is further intended to promote blood flow to other tissue, as discussed at paragraph [0009] of Tasto, such as to connective tissue such as found in joints and tendons to relieve arthritis, bursitis and other conditions.

To that end, Tasto is configured to utilize an probe that includes an active electrode and one or more return electrodes. The active electrode is positioned in close proximity to a target site of the patient and a high frequency voltage potential is established between the active electrode and the return electrode(s). An electrically conductive fluid is used between the active electrode and the body structure enabling high frequency voltage to be applied between the active electrode and the return electrodes through a current flow path created by the conductive fluid (paragraph 0014).

In any event, the electrosurgical apparatus of Tasto is a therapeutic device while an ECG monitor utilizes a set of electrodes placed onto a patient for purposes of measuring cardiac activity (QRST and other waveforms) in a scheduled medical examination, when a patient is experiencing arrythymias or other events or when the patient has suffered a heart attack or other emergency event. During the latter, the patient may be subjected to several defibrillation cycles that can directly influence an ECG electrode assembly. The differences between each of these devices is stark and the devices described by each of Tasto and the examined claims of the present invention are

clearly not interchangeable in any way. As a general matter, therefore, an anticipatory rejection cannot be made and should be withdrawn.

Still further, ECG monitors during use can be exposed to defibrillation pulses since an ECG monitor and defibrillator would be used at the same time. To that end, the present invention includes features for protecting the life of the ECG monitor. More specifically, claim 8 requires a plurality of electrical connections, a power source, at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate and an ECG electronics module, the latter module being configured for receiving and processing patient heartbeat signals from the plurality of electrical connections. According to claim 8, the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.

Tasto fails to include an ECG electronics module that is configured for receiving and processing patient heartbeat signals from a plurality of disposed connections (electrodes). As previously noted, Tasto is used to apply electrical energy but is not configured, through any means, to receive and process heartbeat signals as measured by a set of ECG electrodes. Though a processor in general can be equipped with various software that could arguably provide waveform detection, there is no such suggestion found to make this substitution. As noted, the sole aim of Tasto is to provide high frequency electrical energy to a designated target site of a patient. Measurements, such as ECG measurements, are not contemplated by this reference in any way and there is no inherency in providing such a feature in connection with this device. The Examiner is respectfully requested to identify any applicable portion of the prior art that includes or otherwise suggests the above-noted missing feature at a minimum.

Because claim 8 includes at least one feature entirely missing from the cited art of record, there can be no anticipation under the Statute. Claims 9-15 are allowable for the same reasons, since each of these dependent claims minimally include the features of claim 8. Reconsideration and withdrawal of this rejection is respectfully requested.

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As to the specification objections, paragraph [0001] has been amended to provide updated patent numbers for the referenced patent application, as requested. No new matter has been added. Entry and favorable consideration is respectfully requested.

In summary, the above-captioned patent application is now in an allowable condition and such allowance is earnestly solicited.

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

No fees are due and owing for the filing of this paper, since this correspondence is timely filed in advance of the three (3) month deadline of August 16, 2013. However and in the event that Applicants have overlooked the need for an extension of time, additional extension of time, payment of fee, or additional payment of fee, the Director is authorized to charge Applicants Deposit Account No.: 50-3010 and to credit any overpayments thereto.

Respectfully submitted,

HISCOCK & BARCLAY, LLP

/Peter J. Bilinski/

Date: August 16, 2013

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Electronic Acknowledgement Receipt	
EFS ID:	16613644
Application Number:	13488520
International Application Number:	
Confirmation Number:	9601
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:	Peter J Bilinski/Susanne Pelose
Filer Authorized By:	Peter J Bilinski
Attorney Docket Number:	3022036 US02
Receipt Date:	16-AUG-2013
Filing Date:	05-JUN-2012
Time Stamp:	15:54:18
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	2013-08-16-Transmittal-Form.pdf	413980 737bf75c3c8efb61874baf864e5c43b98c06f246	no	1
Warnings:					
Information:					

2		2013-08-16-Amendment.pdf	2352742 0730d5f973c91cbddfb091f17b92cee9f7ef2c92	yes	10

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Claims	2	6
	Applicant Arguments/Remarks Made in an Amendment	7	10

Warnings:	
Information:	
Total Files Size (in bytes):	2766722

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.

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	11

Application Number	13/488,520
Filing Date	June 5, 2012
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US02

ENCLOSURES *(Check all that apply)*

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

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Hiscock & Barclay, LLP		
Signature	/Peter J. Bilinski/		
Printed name	Peter J. Bilinski		
Date	August 16, 2013	Reg. No.	35,067

CERTIFICATE OF TRANSMISSION/MAILING

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

Signature			
Typed or printed name		Date	

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

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/488,520	06/05/2012	Steven D. Baker	3022036 US02	9601

88750 7590 07/22/2013

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

EXAMINER	
LAVERT, NICOLE F	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
07/22/2013	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@hblaw.com

Applicant-Initiated Interview Summary	**Application No.** 13/488,520	**Applicant(s)** BAKER ET AL.	
	Examiner NICOLE F. LAVERT	**Art Unit** 3762	

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

(1) *NICOLE F. LAVERT*. (3)_____.

(2) *PETER J. BILINSKI*. (4)_____.

Date of Interview: *16 July 2013*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

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

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *8-15*.

Identification of prior art discussed: *Tasto*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Based on the arguments the examiner agrees with the applicant in that the cited prior art reference, Tasto, fails to disclose the claimed invention. Based on the submitted arguments the Examiner will be required to perform another search.

Applicant recordation instructions: 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

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☐ Attachment

/NICOLE F. LAVERT/ 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/488,520	06/05/2012	Steven D. Baker	3022036 US02	9601

88750 7590 05/16/2013

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

EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
05/16/2013	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@hblaw.com

Office Action Summary	Application No. 13/488,520	Applicant(s) BAKER ET AL.	
	Examiner NICOLE F. LAVERT	Art Unit 3762	AIA (First Inventor to File) Status No

-- 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 March 2013*.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

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

3)☐ 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.

4)☐ 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

5)☒ Claim(s) *1-15* is/are pending in the application.

5a) Of the above claim(s) *1-7* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *8-15* is/are rejected.

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

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

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

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

11)☒ The drawing(s) filed on *05 June 2012* 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).

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).

Certified copies:

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)).

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

Interim copies:

a)☐ All b)☐ Some c)☐ None of the: Interim copies of the priority documents have been received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/7/12*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

iRhythm, Inc. / Welch Allyn, Inc.
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Page 51

DETAILED ACTION

Election/Restrictions

1. Claims 1-7 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 26, 2013.

Specification

The disclosure is objected to because of the following informalities: Any application numbers listed in the disclosure should be updated to reflect their patent status (e.g. pending, patented, abandoned) and publication numbers should be provided for any applications that have been published. Specifically, paragraphs [e.g., 0001] needs to be corrected. Furthermore, any reference to attorney docket numbers appearing therein should be removed.

Claim Rejections - 35 USC § 102

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

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

3. **Claims 8-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Tasto et al. (US 2003/0171743).

Tasto et al. disclose an ECG monitor comprising [e.g., 0001]: a plurality of electrical connections including at least one electrode, the electrical connections being couplable to a skin surface to measure patient heartbeat signals; a power source (e.g., element 14); at least one

current-limiting defibrillation protection resistor (e.g., via the element 48), the at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and an ECG electronic module, the ECG electronic module (e.g., via the disclosed processor 18) receiving and processing patient heartbeat signals from the plurality of electrical connections, wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module {e.g., [0018], [0025] & (Figs 1-2)}.

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, Christopher Koharski can be reached on 571-272-7230. 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/
Primary Examiner, Art Unit 3762

Notice of References Cited	Application/Control No. 13/488,520	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-2008/0139953 A1	06-2008	Baker et al.	600/509
	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.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1534	600/508.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:14
L2	2846	600/509.CCLS.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:16
L3	717	600/372.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
L4	38520	(eck or eckg or cardiac or heart) same monitor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
L5	3417	l4 and (electrical same connections)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:25
L6	1847	l5 and (power same source)\	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
L7	53826	(current same limiting) same resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
L8	33	l6 and (current same limiting) same resistor	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
L9	33	l6 and ((current same limiting) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:26
L10	23	l9 and @py<="2005"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:27
L11	4727	(external) same ((heart or EKG or ECG) same monitor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:38
L12	2815	l11 and @py<="2009"	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:38
L13	11	l12 and ((current same limiting) same resistor)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:39
L14	351	607/7.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2013/05/11 12:52

EAST Search History (Interference)

<This search history is empty>

5/11/2013 12:54:55 PM

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 56

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Customer No.: 88750

FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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EXAMINER /Nicole LaVert/	DATE CONSIDERED 05/11/2013

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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U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2010/0145202	06/10/2010	McLaughlin et al.			
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						YES	NO
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EXAMINER /Nicole LaVert/	DATE CONSIDERED 05/11/2013

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	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2006-507455 (5 pages).
		International Search Report/Written Opinion for PCT/US07/83156 dated May 15, 2008 (16 pages).

EXAMINER /Nicole LaVert/	DATE CONSIDERED 05/11/2013

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./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13488520	BAKER ET AL.
	Examiner	Art Unit
	NICOLE F LAVERT	3762

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
600	508-509 & 372	5/11/2013	NFL

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor Search (EDAN)	5/11/2013	NFL
EAST Search (see attachment)	5/11/2013	NFL
Consulted Search notes	5/11/2013	NFL

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	13/488,520
Applicant	:	Steven D. Baker et al.
Filed	:	June 5, 2012
Art Unit	:	3762
Examiner	:	Nicole F. Lavert
Docket No.	:	3022036 US02
Confirmation No.:		9601
Customer No.	:	88,750
Title	:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

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

RESPONSE TO RESTRICTION REQUIREMENT WITH TRAVERSE

Sir:

In response to the Restriction Requirement, dated March 13, 2013 and pursuant to 35 USC §121 and MPEP §818, Applicants herein provisionally elect, with traverse, to prosecute Group II, claims 8-15.

Applicants retain the right to file divisional applications to any non-elected subject matter.

Amendments to the Claims are reflected in the following Listing of Claims, which begin on page 2 of this paper.

Remarks begin on page 6 of this paper.

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Exhibit 1002
Page 65

Amendments to the Claims:

Please replace all prior listing of claims with the following Listing of Claims:

Listing of Claims

1. (Withdrawn) A method for providing high voltage circuit protection for a patient monitor, the method comprising:

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.

2. (Withdrawn) The method of claim 1, wherein both determining a print pattern and thickness of both the first and second materials comprise including a filleted section.

3. (Withdrawn) The method of claim 1, wherein both determining a print pattern and thickness of both the first and second materials comprise determining a print pattern and thickness of both the first and second materials to achieve a total resistance value.

4. (Withdrawn) The method of claim 1, wherein both determining a print pattern and thickness of both the first and second materials comprise the further steps of determining a print pattern and thickness of both the first and second materials to achieve a spacing between two or more electrical traces of the print pattern, and applying an insulating layer after the step of printing of the second material.

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5. (Withdrawn) The method of claim 1, the method further comprising:

providing an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals;

filtering the measured heartbeat signals with an analog high pass filter having an analog high pass cutoff frequency;

removing the effects of the analog high pass filter with a digital inverse filter algorithm resulting in substantially unfiltered heartbeat signals;

filtering the substantially unfiltered heartbeat signals digitally using a digital filter having a digital high pass filter cutoff frequency lower than said analog cutoff frequency.

6. (Withdrawn) The method of claim 5, wherein filtering the measured heartbeat signals with an analog high pass filter comprises filtering the measured physiological signals with an analog high pass filter having a 0.5 Hz analog high pass cutoff frequency.

7. (Withdrawn) The method of claim 5, wherein filtering the substantially unfiltered heartbeat signals digitally comprises filtering the substantially unfiltered heartbeat signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

8. (Original) 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;

a power source;

at least one current-limiting defibrillation protection resistor, the at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and

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an ECG electronics module, the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections,

wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.

9. (Original) The ECG monitor of claim 8, wherein the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

10. (Original) The ECG monitor of claim 8, wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge.

11. (Original) The ECG monitor of claim 8, wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers.

12. (Original) The ECG monitor of claim 11, wherein the plurality of 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.

13. (Original) The ECG monitor of claim 8, the ECG monitor further comprising a pacer detect circuit to detect the presence or absence of a pacemaker, the ECG electronics module drawing power as an electrical load on the power source wherein the pacer detect circuit, upon detection of the absence of a pacemaker signal in a patient being monitored by the ECG monitor, causes the ECG electronics module to disable the pacer detect circuit in order to reduce the electrical load on the power source.

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14. (Original) The ECG monitor of claim 13, wherein the power source is a battery.

15. (Original) The ECG monitor of claim 8, wherein the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the 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 the power source.

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REMARKS

As noted above and in response to the Restriction Requirement, dated March 13, 2013, Applicants herein provisionally elect, with traverse, to prosecute Group II, claims 8-15 of the above-captioned utility application pursuant to 35 USC §121 and 37 CFR §1.142.

Applicants respectfully traverse this Restriction Requirement since the subject matter of all of the pending claims – is sufficiently related that a thorough and complete search for the subject matter of the elected claims would necessarily encompass a thorough and complete search for the subject matter of the non-elected claims. Thus, it is respectfully submitted that search and examination of the entire application could be made without serious burden. See MPEP §803 in which it is clearly stated that "[i]f the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits." It is respectfully submitted that this policy should apply in the present application in order to avoid unnecessary delay and expense to Applicants and improper duplicative examination by the Patent Office.

More specifically, the subject matter of claims 1-7 commonly relate to that of the elected claims as to the provision of at least one current-limiting defibrillation protection resistor and the construction of same, including resistor print patterns and use of same as part of an ECG monitor. As a result, there would be no additional burden placed on the Office in terms of searching or examination to warrant restriction. Reconsideration of this Requirement is respectfully requested.

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

In the event this Requirement is maintained, Applicants herein reserve the right to file at least one divisional patent application based on any non-elected subject matter.

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

No fees are due and owing for the filing of this paper, since this correspondence is timely filed in advance of the one (1) month deadline of April 13, 2013. However and in the event that Applicants have overlooked the need for an extension of time, additional extension of time, payment of fee, or additional payment of fee, the Director is authorized to charge Applicants Deposit Account No.: 50-3010 and to credit any overpayments thereto.

Respectfully submitted,

HISCOCK & BARCLAY, LLP

/Peter J. Bilinski/

Date: March 26, 2013

Peter J. Bilinski
Reg. No. 35,067
One Park Place
300 South State Street
Syracuse, NY 13202-2078
Tel: (315) 425-2856
Fax: (315) 703-7397

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 71

Electronic Acknowledgement Receipt

EFS ID:	15350751
Application Number:	13488520
International Application Number:	
Confirmation Number:	9601
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:	Peter J Bilinski/Susanne Pelose
Filer Authorized By:	Peter J Bilinski
Attorney Docket Number:	3022036 US02
Receipt Date:	26-MAR-2013
Filing Date:	05-JUN-2012
Time Stamp:	09:07:26
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Miscellaneous Incoming Letter	2013-03-26-Transmittal-Form.pdf	423355 9ea164ab13180ba17c2098c15f515c041136f138	no	1
Warnings:					
Information:					

2		2013-03-26-Response-to-Restriction-Requirement.pdf	1512654 c4f36904250eac35f4996f7fc33f426c5c730d5f	yes	7

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response to Election / Restriction Filed	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	7

Warnings:	
Information:	
Total Files Size (in bytes):	1936009

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.

Doc Code: TRAN.LET

Document Description: Transmittal Letter

PTO/SB/21 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission	8

Application Number	13/488,520
Filing Date	June 5, 2012
First Named Inventor	Steven D. Baker
Art Unit	3762
Examiner Name	Nicole F. Lavert
Attorney Docket Number	3022036 US02

ENCLOSURES *(Check all that apply)*

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

Remarks

Response to Restriction Requirement dated March 13, 2013

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Hiscock & Barclay, LLP		
Signature	/Peter J. Bilinski/		
Printed name	Peter J. Bilinski		
Date	March 26, 2013	Reg. No.	35,067

CERTIFICATE OF TRANSMISSION/MAILING

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

Signature			
Typed or printed name		Date	

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

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PTO/SB/06 (09-11)
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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875	Application or Docket Number 13/488,520	Filing Date 06/05/2012	☐ To be Mailed

ENTITY: ☒ LARGE ☐ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	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 $310 ($155 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	

APPLICATION AS AMENDED – PART II

AMENDMENT	03/26/2013	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 15	Minus	** 20	= 0	X $80 =	0
	Independent (37 CFR 1.16(h))	* 2	Minus	***3	= 0	X $420 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

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

LIE
/JOSEPH BROOKS/

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.

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.
13/488,520	06/05/2012	Steven D. Baker	3022036 US02	9601

88750 7590 03/13/2013

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

EXAMINER	
LAVERT, NICOLE F	
ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
03/13/2013	ELECTRONIC

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.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@hblaw.com

Office Action Summary	Application No.	Applicant(s)	
	13/488,520	BAKER ET AL.	
	Examiner	Art Unit	
	NICOLE F. LAVERT	3762	

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

Period for Reply

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

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

Status

1)☒ Responsive to communication(s) filed on *05 June 2012*.

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

3)☐ 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.

4)☐ 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

5)☒ Claim(s) *1-15* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☐ Claim(s) _____ is/are rejected.

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

9)☒ Claim(s) *1-15* are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

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

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

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

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

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) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

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

I. Claims 1-7, drawn to a method, classified in class 600, subclass 372.

II. Claims 8-15, drawn to an ECG monitor, classified in class 600, subclass 508.

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method as claimed can be used by another and materially different apparatus such as a neurological monitor that senses EEG signals from the brain and/or spine versus an ECG monitor as is instantly claimed.

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

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

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

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

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

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

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

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

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

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/

Primary Examiner, Art Unit 3762

2.

UNITED STATES PATENT AND TRADEMARK OFFICE

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/488,520	06/05/2012	Steven D. Baker	3022036 US02

CONFIRMATION NO. 9601

88750
HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

PUBLICATION NOTICE

OC000000056652793

Title:BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

Publication No.US-2012-0238890-A1
Publication Date:09/20/2012

NOTICE OF PUBLICATION OF APPLICATION

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

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Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/488,520

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	380
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	620
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	250
TOTAL CLAIMS (37 CFR 1.16(i))	15 minus 20 =	*			OR	x 60 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 250 =	0.00
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 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).						0.00
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							0.00
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	1250

APPLICATION AS AMENDED - PART II

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	Total (37 CFR 1.16(i))	*	Minus	**	=	x =		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	

		(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	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 found in the appropriate box in column 1.

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/488,520	06/05/2012	3735	1250	3022036 US02	15	2

CONFIRMATION NO. 9601

88750
HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

FILING RECEIPT

OC000000054828203

Date Mailed: 06/15/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Steven D. Baker, Beaverton, OR;
Eric T. McAdams, Whitehead, UNITED KINGDOM;
James P. Welch, Mission Viejo, CA;
Norbert Ohlenbusch, Andover, MA;
Thomas P. Blackadar, Natick, MA;

Assignment For Published Patent Application

WELCH ALLYN, INC., Skaneateles Falls, NY

Power of Attorney: The patent practitioners associated with Customer Number 88750

Domestic Priority data as claimed by applicant

This application is a CON of 11/591,619 11/01/2006 PAT 8214007 *
(*)Data provided by applicant is not consistent with PTO records.

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)

If Required, Foreign Filing License Granted: 06/13/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/488,520**

Projected Publication Date: 09/20/2012

Non-Publication Request: No

Early Publication Request: No

Title

BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

Preliminary Class

600

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Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

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APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/488,520	06/05/2012	Steven D. Baker	3022036 US02

CONFIRMATION NO. 9601

88750
HISCOCK & BARCLAY, LLP
ONE PARK PLACE, 300 S. STATE ST.
SYRACUSE, NY 13202

POA ACCEPTANCE LETTER

OC000000054828402

Date Mailed: 06/15/2012

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/05/2012.

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.

/dpham/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

Customer No.: 88750

FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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EXAMINER	DATE CONSIDERED
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FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
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EXAMINER	DATE CONSIDERED
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.	

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FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

U.S. PATENT DOCUMENTS						
EXAMINER INITIAL	DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	2010/0145202	06/10/2010	McLaughlin et al.			
	2010/0160762	06/24/2010	McLaughlin et al.			
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FOREIGN PATENT DOCUMENTS							
	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
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	0910985 A1	04/28/1999	EP				
	11042214	02//16/1999	JP			✓	
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	0197686 A1	12/27/2001	WO				
	2008142365	11/27/2008	WO				
	2009056859	05/07/2009	WO				

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FORM 1449* **INFORMATION DISCLOSURE STATEMENT** **IN AN APPLICATION** (Use several sheets if necessary)	Docket Number: 3022036 US02	Application Number: 13/488,520
	Applicant: Steven D. Baker et al.	Confirmation No.: 9601
	Filing Date: June 5, 2012	Group Art Unit: Not Yet Assigned

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
		Japanese Office Action dated January 12, 2010 for Japanese Patent Application No. 2006-507455 (5 pages).
		International Search Report/Written Opinion for PCT/US07/83156 dated May 15, 2008 (16 pages).

EXAMINER	DATE CONSIDERED
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(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

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

(12) # EUROPEAN PATENT APPLICATION

(21) Application number: 86109450.6

(22) Date of filing: 10.07.86

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

(30) Priority: 25.07.85 IT 6768785

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

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

(71) Applicant: Rossi, Paolo
Via Verdi, 18
28100 Novara(IT)

(72) Inventor: Rossi, Paolo
Via Verdi, 18
28100 Novara(IT)

(74) Representative: Prato, Roberto et al,
c/o Ing. Carlo e Mario Torta Via Viotti 9
I-10121 Torino(IT)

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

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

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

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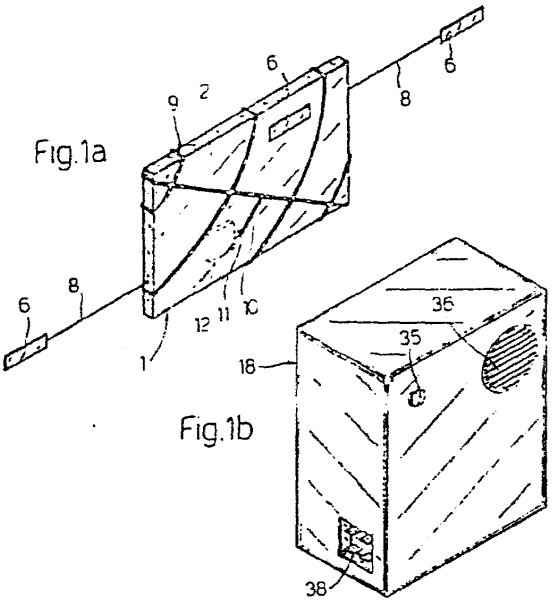


Fig.1a

Fig.1b

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

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

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

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

critical conditions and activating an alarm.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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CLAIMS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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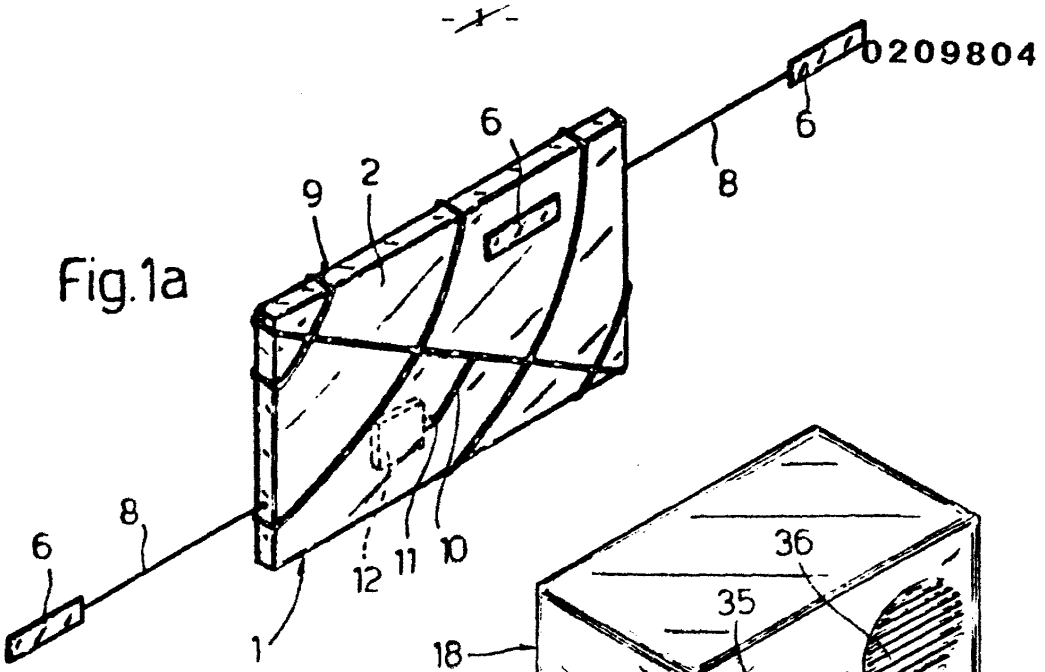


Fig.1a

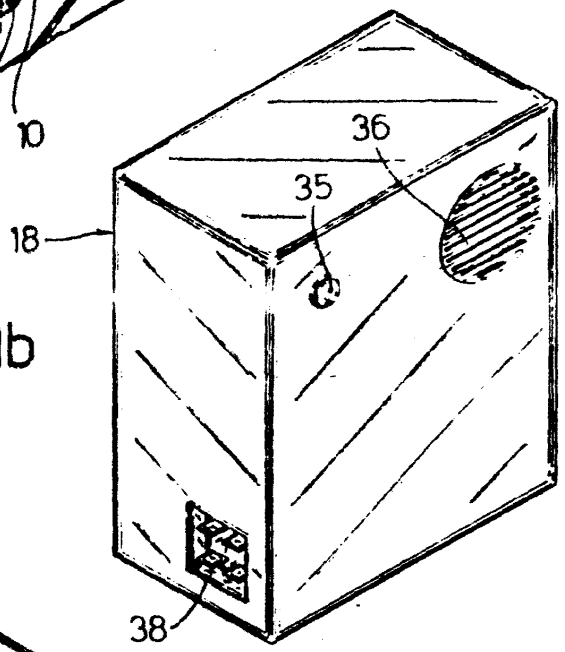


Fig.1b

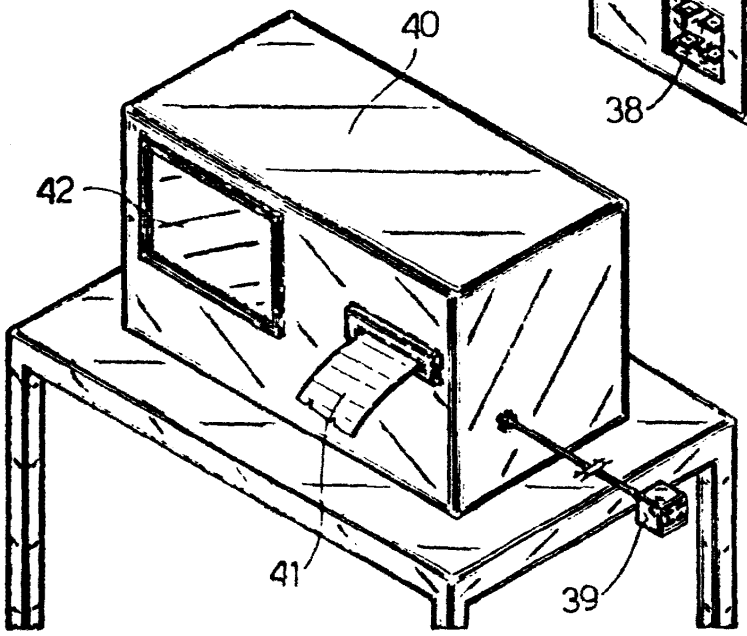


Fig.1c

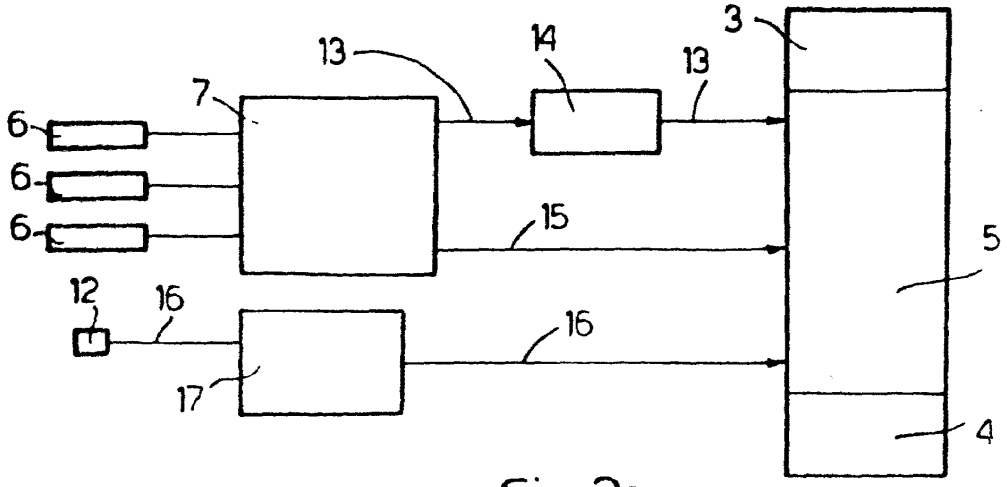

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Fig.2a

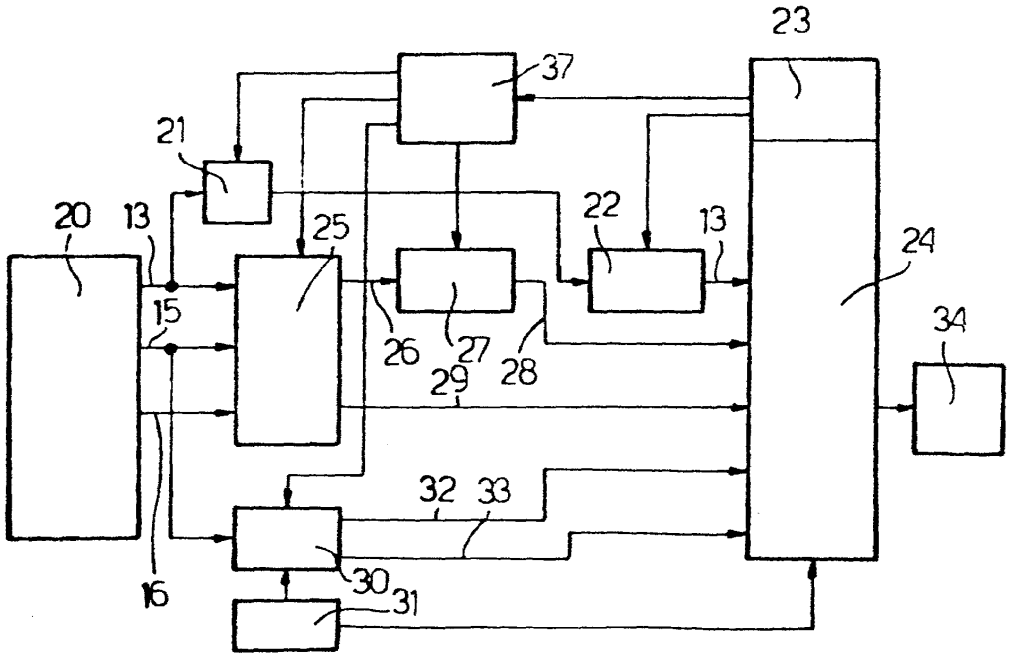

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Fig.2b

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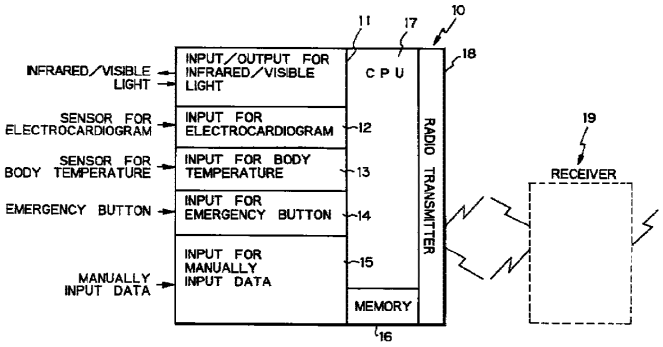
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(54) Apparatus for monitoring patients

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

Fig. 1



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Description

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

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

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

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

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

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

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

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

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

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shape memory material.

Fig. 1 is a block diagram illustrating the internal mechanism of the first embodiment of the patient monitoring apparatus in accordance with the present invention.

Fig. 2 is a perspective view of the first embodiment of the patient monitoring apparatus in accordance with the present invention.

Fig. 3 is a view of the reverse side that directly touches the patient's skin of the first embodiment of the patient monitoring apparatus in accordance with the present invention.

Fig. 4 is a cross sectional view of the second embodiment, worn into an external acoustic meatus, of the patient monitoring apparatus in accordance with the present invention.

Fig. 5 is a (partially transparent) perspective view of the second embodiment of the patient monitoring apparatus in accordance with the present invention.

Fig. 6 is a block diagram illustrating the internal mechanism of the second embodiment of the patient monitoring apparatus in accordance with the present invention.

Preferred embodiments of the present invention will now be described by referring to the attached drawings. Referring to Fig. 1, a block diagram illustrating the internal mechanism of the first embodiment of the patient monitoring apparatus 10 in accordance with the present invention is provided. The patient monitoring apparatus 10 is in the form of a wrist watch and directly attached to a part of the patient's body, for example, on his/her wrist, ankle, finger, or arm by means of a band. The patient monitoring apparatus 10 comprises an infrared/visible light input/output for transmitting/receiving infrared light and visible light to measure the pulse, pulse waves and S_pO_2 of the patient; an input 12 from an electrocardiographic sensor; an input 13 from a body temperature sensor; input 14 from an emergency button; and an input 15 for manually inputting data such as results of urine examination and blood glucose values, etc. Each of these inputs 11-15 is connected to the central processing unit (CPU) 17, which is provided with infrared and visible light for measurement and a plurality of measured data from the above-mentioned input and then which supplies the data, after processing them or as they are, to the parental unit or receiving unit 19 via the radio transmitter 18.

The receiving unit 19, which is a "home unit" disclosed in the above incorporated Japanese application, is installed at the patient's house and has a computer incorporated therein so as to automatically function to transmit data via an appropriate modem. The data received by the unit 19 is transmitted through transmission medium to a center unit (not shown) installed at the medical institute which is in charge of the area. If the patient is being taken care of at a hospital and a patient monitoring apparatus 10 is attached to him/her, the receiving unit 19 is also installed at the hospital and transmits the processed or raw data to a center unit at the same hospital or at the central medical institute in charge of said hospital.

The CPU 17 is capable of, if necessary, having the input data and processed results temporarily stored in the memory 16. The CPU 17 calculates the blood pressure on the basis of the pulse and electrocardiographic data obtained via infrared detection and/or compares each of the input data with the reference value predetermined by a physician. If any of the input data is not within the predetermined range, the CPU 17 produces resultant information indicative of the result of the comparison. Whether the input data is to be transmitted as it is or after processed is selectively determined by means of the mode setting-up button 22. When desired, the processed results will be displayed on the display 20 by the CPU 17.

Referring to Fig. 2, a front perspective view of the first embodiment of the present patient monitoring apparatus 10 is shown, and is attached like a wrist watch. The button switch 22 is a mode set-up button used to switch between various modes. Each of a plurality of button switches 23 is used for the patient wearing this apparatus to manually input data such as blood glucose values, body weight, and results of urine examination. The emergency button switch 21, when activated by the patient in a medical emergency, have an emergency signal wirelessly or optically transmitted.

Next, referring to Fig. 3, the reverse side that directly touches the patient's skin in the first embodiment of the present patient monitoring apparatus 10 is shown. The infrared light produced by the infrared light transmitting unit 25 passes through a portion of the patient's body and after being reflected and/or diffused, it is measured by the infrared light detecting sensor 26. The light emitted from the visible light transmitting unit 27 also passes through a portion of the patient's body and is measured by the visible light detecting sensor 28. The CPU 17 calculates the oxygen saturation of arterial blood (S_pO_2), pulse and pulse wave from these data. The electrocardiographic sensor 29 detects the electrocardiogram of the patient. The detected electrocardiogram is amplified and its noise is removed at the electrocardiograph input unit 12 and CPU 17. Data indicative of the body temperature of the portion in touch with the body temperature sensor 30 is sent to the CPU 17 via the body temperature input unit 13.

Since all the sensors described above are mounted on the reverse side surface and the measurement of the various data is automatically performed, the patient is not physically restricted during detection of medical data and sending the detected data to the receiving unit 19 via an appropriate medium such as infrared light under a computer (CPU 17).

Notification of a medical emergency by the present apparatus comprises in two stages. In the first stage, the patient can notify medical staff at a medical institute with a center unit installed of his/her condition by activating the emergency button switch 21 on the apparatus 10. In response to the activation of this switch 21, an

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emergency signal is transmitted to the receiving unit by way of the wireless or optical communication function equipped with this apparatus 10. On receipt of this emergency signal from the patient, the medical institute will take emergency measures to cope with the situation.

The second stage, in accordance with this apparatus 10 already disclosed in the above mentioned Japanese patent application, and involves continuous detection of the patient's vital signs. However, in this case, vital signs are automatically and continuously detected by using the wrist watch type apparatus 10 rather than the more cumbersome means provided by the foregoing application. In order to more fully realize the vital sign detection function than in the case of the above first stage, the apparatus 10 continuously detects the patient's vital signs on a twenty-four hour basis. Preferably, vital signs to be detected include the pulse detected in the patient's wrist. As far as any predetermined vital sign can be detected in an ordinary manner, electrical signals continue to be transmitted from the monitoring apparatus 10. If the patient stays within a predetermined distance from the home (receiving) unit 19, the home unit 19 is capable of receiving signals. The CPU incorporated in the home unit will not take any action as long as the electrical signals continue since the continuous detection of signals assumes that the patient is in a normal condition. However, once signals cease to be detected, the home unit will immediately transmit an emergency signal to the medical institute and notify the medical staff there of the occurrence of an emergency without any investigation of the patient's physical condition. Although signal failure may be due to an electrical fault in the apparatus 10 or any other extraordinary event as well as the occurrence of a physical disorder, the present apparatus 10 will without exception, decide on a general fail-safe principle that a medical emergency has occurred, thus enabling a critical response to be taken.

The pendant type apparatus belonging to the prior art can be effective only if the patient actuates the switch him/herself by pulling the strong attached thereto, for example. Whereas the present apparatus will always be effective even if the occurrence of medical emergency is so sudden and unexpected that the patient him/herself does not have the chance or strength to pull the switch. Thus the present apparatus 10 is more reliable than the prior art apparatuses which require the activation of a switch by the patient.

In order to facilitate this function, the home unit can be set to an absent mode to avoid an emergency signal being wrongly transmitted to the center unit, or the emergency notification function can be turned off.

Depending on the patient's condition, $ETCO_2$ can be detected as a vital sign, wherein the internal mechanism will be the same except for a difference in the detector thereof.

Referring to Fig. 4, which illustrates a cross sectional view of the second embodiment of the patient monitoring apparatus in accordance with the present invention. another type of the present apparatus will be described. As shown in the figure, the apparatus 110 is shaped like an earplug and worn in an external acoustic meatus of the patient. Preferably, in order to maintain the hearing capacity, the apparatus 110 has a hollow portion 112 passing through at the center of this cylindrical-shaped apparatus 110. The outside surface of the apparatus 110 consists of a flexible and soft material to prevent discomfort while the sensors and transducers mounted on the surface comfortably contact the skin in the external acoustic meatus of the patient.

Fig. 5 is a (partially transparent) perspective view of this earplug type second embodiment of the present patient monitoring apparatus. On the surface of the apparatus 110 in touch with the skin in the external acoustic meatus, electrodes 114, 115 for the detection of the electrocardiograph, a transducer 116 for the detection of pulse wave (pressure) and a sensor 117 for the body temperature are mounted.

In addition, the infrared light emitted by the infrared light transmitting unit 118 passes through a portion of the patient's body and after being reflected and/or diffused, returned light is measured by the infrared light detecting sensor 119. Similarly the light emitted from the visible light transmitting unit 120 also passes through a portion of the patient's body and is measured by the visible light detecting sensor 121. The sensors 114, 115, 117, 119, 121 and transducer 116 are located on the surface of such a portion 122 of the apparatus 110 inserted into the ear. The surface of this inserted portion on which the plurality of sensors are mounted is preferably smooth so that the patient wearing the apparatus is not subject to any discomfort. The sensors and transducer are connected to the control and transmitting unit 123 via an lead 124 on which the detected data will be transferred.

Fig. 6 is a block diagram illustrating the internal mechanism of this second embodiment. As shown, the electrocardiographic signal detected with the electrocardiogram detection electrodes 114, 115 is provided to the processor 132 via the electrocardiogram input unit 125. The pulse wave signal (by way of pressure) detected with the pressure transducer 116 is provided to the processor 132 via pressure input unit 126. The temperature signal detected with the temperature sensor 117 is provided to the processor via the temperature input unit 127. The infrared light is emitted from the infrared light output unit 128 and then the emission unit so as for the oxygen saturation of arterial blood (S_pO_2), pulse wave and blood pressure to be measured. The emitted infrared light returns from the patient's body and is measured by the infrared light detecting sensor 119. Similarly the visible light emitted from the visible light transmitting unit 120 also passes through a portion of the patient's body and is measured by the visible light detecting sensor 121. On the basis of the received amount of the infrared and/or visible light, S_pO_2, pulse wave and blood pressure are calculate.

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In detecting and measuring the electrocardiogram, in particular, it may be preferable to attach an appropriate electrode in each of the patient's external acoustic meatuses and to connect them each other so as to correlate the data from both of them.

The processor 132 is powered by an exchangeable Lithium battery and has a microprocessor (not shown) incorporated therein and the microprocessor performs the above described calculation using the data detected. Incidentally by performing the measurement by this apparatus 110 continuously and/or once in every predetermined time period, it is possible to collect a series of medical data and construct a medical database about a specific group of patients over some time period. The obtained data will be wirelessly sent to the home unit.

Although the apparatus 110 has a hollow portion at the center of its cylindrical portion, it may be possible that the hearing capacity of the person wearing it will be worse than otherwise. In such a case, conventional technique employed in an earplug type hearing aid will also be used in the apparatus 110. For example, a small microphone is mounted to transmit sound wave signals and to amplify them.

The emergency notification function of this earplug type second embodiment of the present invention is constructed similarly to the case with the first embodiment.

While several embodiments of the present invention have been shown and described, alternate embodiments will be apparent to those skilled in the art and are within the intended scope of the present invention. Therefore, the invention is to be limited only by the following claims.

Claims

1. A monitoring apparatus wirelessly attached to a portion of a person's body for automatically obtaining the medical data of the person and transmitting the thus obtained data to a receiver, comprising:

   means for non-invasively detecting, as the person's vital sign, said data including one or a combination of the pulse, pulse wave, electrocardiogram, temperature, blood pressure and/or S_pO_2 of the person via the interfacing surface between the apparatus and the contacted portion on the person's body, and
   means for transmitting said detected data to said receiver by means of wireless or optical communication medium such as infrared rays.

2. The apparatus recited in claim 1 further comprising means for comparing said detected data with a set of reference values indicative of the person's normal bodily condition and for displaying on a display of the apparatus or notifying said receiver of whether said detected data is within a normal range of the values.

3. The apparatus recited in claim 1 wherein said non-invasive detecting means comprises means for measuring S_pO_2 of the person by emitting infrared rays and/or visible light to a portion on the body and detecting a return consisting of the reflected and diffused rays and light.

4. The apparatus recited in claim 1 wherein said vital sign continues to be detected and further comprising means for automatically transmitting an emergency signal to said receiver upon detecting the abnormality of the vital sign or upon an intentional activation of a switch by the person.

5. The apparatus recited in claim 1 further comprising means for manually inputting additional medical data such as the result of a urine examination, weight and blood glucose value.

6. The apparatus recited in any one of claims 1 to 5 wherein said apparatus is appropriately formed so as to be attached to a wrist, ankle, finger or arm of the person's body.

7. The apparatus recited in any one of claims 1 to 5 wherein said apparatus is appropriately formed so as to be inserted into one or both of external acoustic meatuses of the person's body.

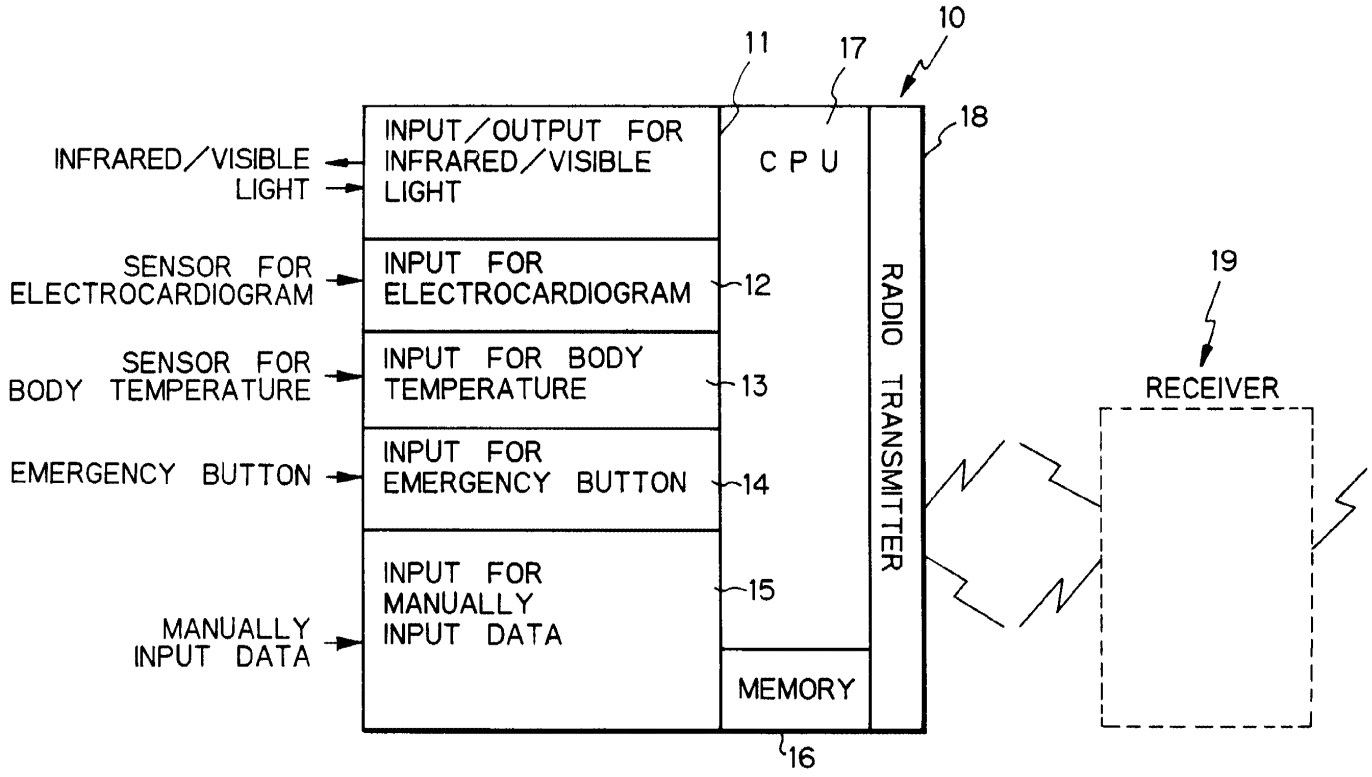
8. The apparatus recited in claim 7 wherein the apparatus is shaped as an earplug that has a hollow structure passing through the apparatus so that the person's hearing ability is maintained and said detecting means comprises one or more sensors or transducers mounted on the surface of the apparatus.

9. The apparatus recited in claim 8 further comprising means for enhancing the hearing ability by amplifying the sounds coming into the external acoustic meatus.

10. The apparatus recited in any one of claims 7 to 9 wherein the apparatus is formed from a soft and flexible or shape memory material.

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Fig. 1



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Fig. 2

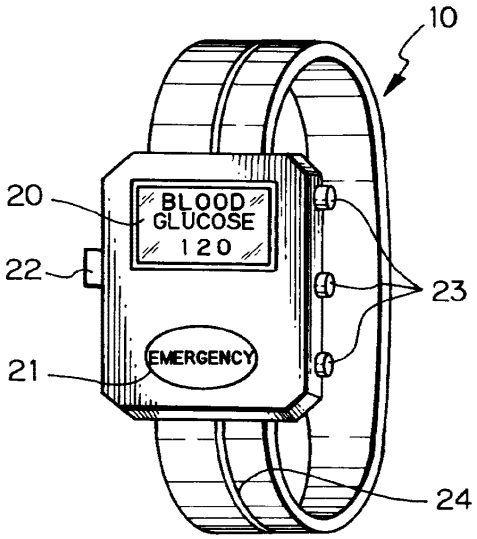
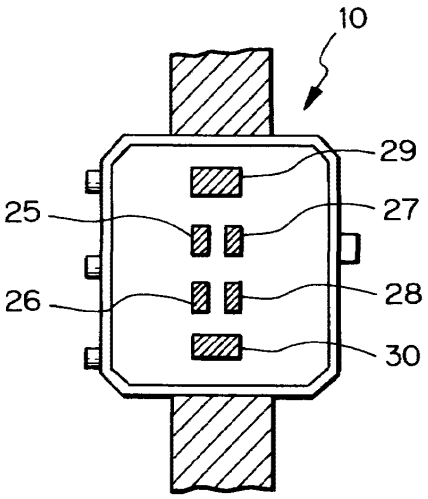


Fig. 3



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Fig. 4

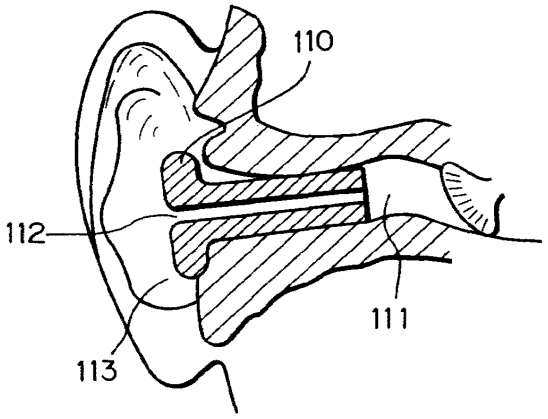
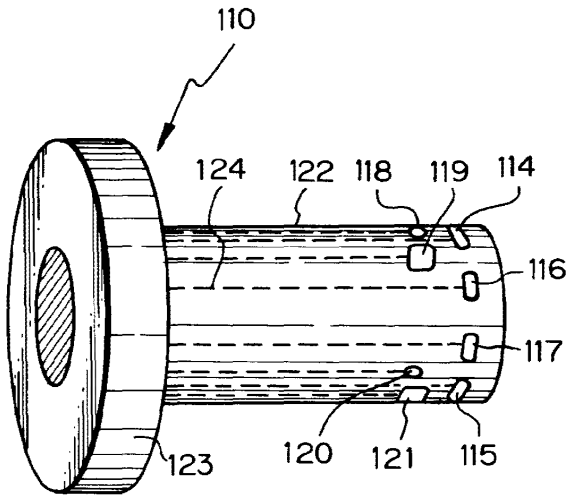
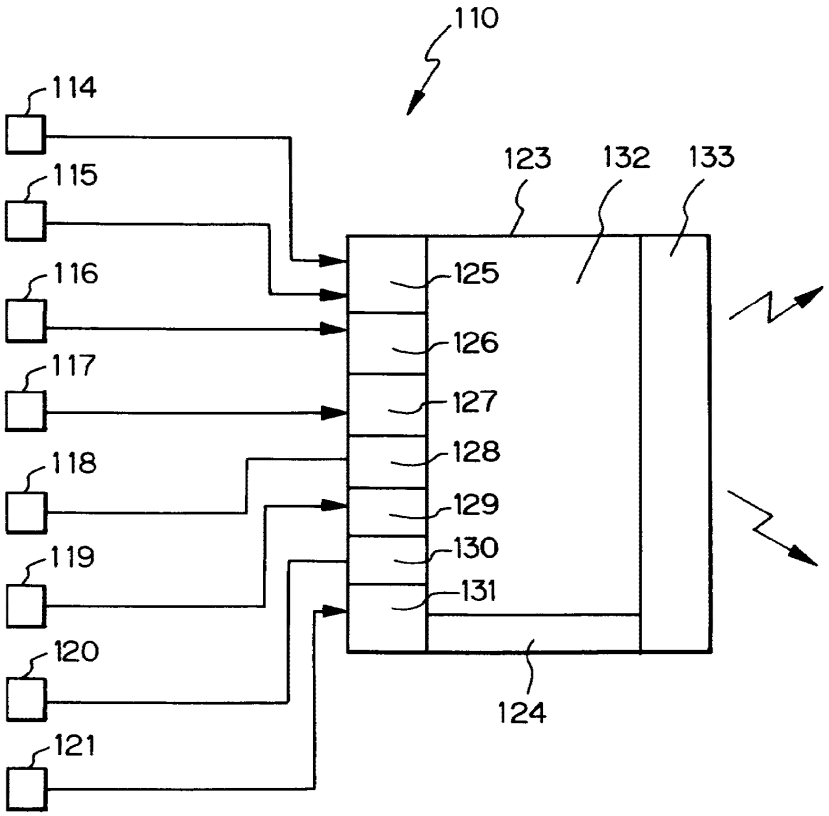


Fig. 5



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Fig. 6



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European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 11 5041

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
X	WO-A-95 07048 (BESSON ET AL.) 16 March 1995 * page 32, line 10 - page 33, line 2 * * page 38, line 20 - page 44, line 17 * * figures 1-6 *	1	A61B5/00
A		3,6	
X	FR-A-2 686 497 (ARGAMAKOFF) 30 July 1993 * page 2, line 5 - page 3 * * page 6, line 20 - page 7, line 27 * * figures 1-8 *	1	
A		2-4,6	
A	GB-A-2 243 691 (PAYNE ET AL.) 6 November 1991 * page 7, line 7 - page 13, line 19 * * figures 1A-4 *	1,2,4,6	
A	US-A-5 213 099 (TRIPP, JR.) 25 May 1993 * column 4, line 51 - column 5, line 39 * * figures *	3,7,10	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A	US-A-4 312 358 (BARNEY) 26 January 1982 * column 4, line 15 - column 5, line 32 * * column 7, line 48 - column 9, line 61 * * figures 1,2 *	5,7	A61B
A	WO-A-91 15989 (KINGSTON) 31 October 1991 * page 3, line 12 - page 5, line 26 * * figures *	4	
A	WO-A-89 00024 (MICROMEDICAL INDUSTRIES PTY LIMITED) 12 January 1989 * abstract * * page 3, line 33 - page 6, line 29 * * page 8, line 26 - line 33 * * figures 1,2 *	5	

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	4 February 1997	Chen, A

EPO FORM 1503 03.82 (P04C01)

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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EUROPEAN SEARCH REPORT

Application Number
EP 96 11 5041

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	EP-A-0 104 924 (MINNESOTA MINING AND MANUFACTURING COMPANY) 4 April 1984 * page 7, line 22 - page 11, line 18 * * figures 1,2 * ---	8,10	
A	GB-A-2 162 325 (ELECTRONIC IDENTIFICATION SYSTEMS SILKEBORG A S) 29 January 1986 * abstract * * page 1, line 5 - line 88 * * figure 1 * -----	1,7,8	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)

The present search report has been drawn up for all claims

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(54) Electrocardiograph bioelectric interface system and method of use

(57) A bioelectric interface (3) provides three Einthoven triangle equivalent lead forming electrodes positioned on a subject's chest so as to provide a Wilson common terminal (WCT) voltage essentially equivalent to that provided by an Einthoven triangle formed using leads positioned conventionally on a subject's limbs. Wilson common terminal (WCT) forming resistors can be of fixed values or variable to allow adjustment of a produced Wilson common terminal (WCT) voltage. Additional precordial electrodes are also typically present. Electrodes can consist of single elements or groups of electrode elements, and are present in locational regions of the bioelectric interface (3) which allow a single size system to fit to patients with various sized bodies. The presence of an "undulated" outer periphery bounbary (UOPB) comprised of a plurality of curves facilitates conformation to a subject's body, and removal of the bioelectric interface (3), in use.

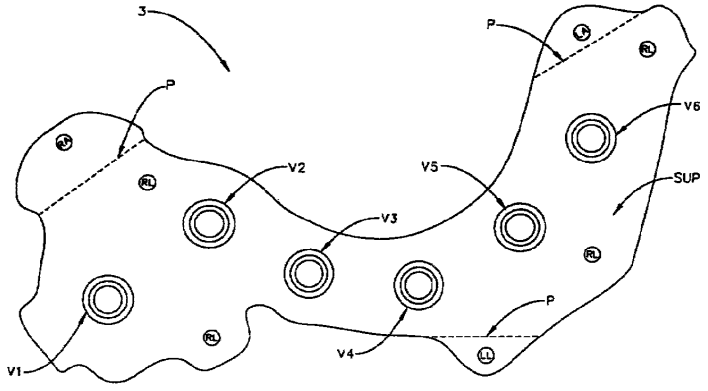


FIG. 7c

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Description

TECHNICAL FIELD

[0001] The present invention relates to systems of electrodes for use in bioelectric interfacing. More particularly, the present invention is a system, and method of use, which provides all electrodes required by electrocardiograph systems, including equivalent Einthoven triangle limb electrodes, on a common subject chest mounted support sheet.

BACKGROUND

[0002] Conventional medical analysis and therapy often involves use of a plurality of individual electrodes, each applied independently to an appropriate location on a subject's body by way of electrically conductive paste, and securing means such as a skin compatible adhesive. A relevant example of use is in the monitoring of Electrocardiogram (ECG) signals at precordial; and at left and right arm, and left leg locations by independent electrodes in an Einthoven triangle configuration.

[0003] Further, it is known to apply individual non-invasive precordial electrodes to a subject's chest to allow not only the acquiring of ECG data, but to allow defibrillation of fibrillating hearts and to allow the pacing of arrested hearts and the like.

[0004] A problem which presents in the use of such independent electrodes, however, is that reliable, repeatable placement upon a subject's body is difficult. For instance, it is generally accepted that a majority of the errors encountered in acquiring ECG data is caused by improper electrode placement by medical technical staff.

[0005] Of relatively recent development are flexible electrode pads which comprise a multiplicity of electrodes affixed thereto in an appropriate pattern for use in medical analysis and/or therapy. For instance, a Patent to Manoli, No, 4,583,549 describes an ECG electrode pad in which six conductive discs are plated and etched on a flexible adhesive pad in a clinically conventional predetermined pattern effective for precordial ECG electrode placement. Reproducible attachment of said six electrodes to a subject's chest in the proper arrangement for use with standard ECG machines is thus made possible by a single application of an electrode pad of an appropriate size for use with any subject. However, it would seem that the Manoli system would require a host of numerous sized electrode pads to accommodate subjects of different sizes as the Claims recite rather strict electrode placement criteria which are referenced with respect to a subject's body. A single electrode pad would not meet said requirements on subjects of different sizes. A Patent, No, 4,121,575 to Mills et al. describes a multiple electrode device for application to a subject's chest, formed in stretchable non-conductive material having apertures in the V1-V6 positions. The capability for stretching the material is held to allow accurate positioning of V1-V6 electrodes on subjects of differing body size. A Patent to Groeger et al., No. 4,957,109 describes an electrode assembly comprising right and left arm and leg leads, and precordial leads all affixed to a common structure. The arm and leg leads do not affix to a subject's chest during use. The Mills et al. and Groeger et al. systems do not serve to maintain a relatively fixed positioning of electrodes therein during use, and it is noted that movement between electrodes during use frequently causes confounding noise generation in electrocardiography systems. Another Patent, No. 5,327,888 to Imran describes a precordial electrode strip which is supplied with detachable RA, LA and LL limb leads, which detachable limb leads are applied to subject limbs in use.

[0006] Patents to Way et al., Nos 4,955,381 and 5,080,099 describe multiple conductive polymer pad containing electrodes for performing multiple electrical physiological functions from a set of electrodes with respect to a subject, at or about the same time, such as defibrillation, pacing and monitoring. Other Patents which disclose multiple electrode assemblies are Patent No. 4,328,814 to Arkans and Patent No. 5,191,886 to Paeth et al. These Patents each describe a plurality of electrodes configured in a physically seriesed configuration with conductive leads to various physically seriesed contacts, present at one end thereof. In addition, a Patent to Collins, No, 3,612,061 describes a porous sheet of elastic material which supports an array of electrodes adapted to contact a wearer's skin, and Patent No. 5,184,620 to Cudahy et al. describes an electrode pad system comprised of a multiplicity of electrodes which are utilized in defibrillation and pacing scenarios as directed by an on-line computer driven analysis and electrical energy application system, which system distributes electrical energy to appropriate sets of said multiplicity electrodes in response to subject needs.

[0007] Continuing, it is to be understood that particularly appropriate materials in which to form an electrode pad with a plurality of ECG monitoring electrodes present therein are hydropolymers. This is because hydropolymers can be pliable, self-adhesive and compatible with maintaining the requisite hydration of subject skin to which they affix during prolonged use. The pliable property makes hydropolymers exceptionally well suited for application to unpredictable irregularities of various subject's chests and the self-adhesive property negates the need to apply adhesive material to affix the present invention to a subject's body during use. As well, the need to apply electrically conductive paste to electrically conducting areas of electrodes becomes unnecessary.

[0008] A Patent, No. 5,331,959 to Imran, describes a low impedance dry conforming contact member in which are present rods or filaments which are cured into material such as a silicon-based material, such that

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when configured as an electrode provide impedance reducing projections which protrude into the pores of a subject's skin during use. Said rods or filaments reduce the need to use conductive paste. Another Patent, No. 4,524,087 to Engel, describes a conductive electrode application comprising an adhesive, swellable, dermally-nonirritating, conformable, ionic hydropolymer biomedical electrode fabricated by a claimed process.

[0009] Continuing, three Patents to Keusch et al, Nos. 4,706,680, 4,989,607 and 5,143,071 describe hydrogels which are caused to be highly conductive by the inclusion of an essentially uniformly distributed active electrolyte therein. Said Patents state that to form the hydrogels a polymeric mixture is caused to become cross-linked by exposure to radiant energy. This causes a gel-like solid to form which is sufficiently tacky and adhesive to adhere to subject's skin and which is substantially non-stringy and non-aggressive so that subject comfort is protected.

[0010] A Patent to Highe et al., No 5,289,822 describes an electrode formed of a dry-conductive material having an outer surface for placement in contact with a subject's skin. A composition is deposited on at least a portion of the surface of the dry-electrode which comprises a plurality of water-containing vesicles. The purpose of said water-containing vesicles being to effect an immediate lowering of subject skin resistance upon the application of the electrode. It is stated that a period of approximately four minutes is otherwise required for moisture from a subject's skin to naturally occur at the electrode.

[0011] A Patent to Schmid, No. 5,124,107 describes a process for manufacturing a body electrode which comprises one or more galvanically active sensors which are combined with a first layer capable of adhering to a subject's skin, on a body contact side thereof. A second covering or supporting layer is also present on the opposite side of the body electrode. The process for manufacture provides that the two layers are sequentially cast in a mold which provides intended shape and size. The procedure avoids manufacturing problems encountered where electrodes are stamped from a preformed sheet. A potential problem of using such an electrode as provided by the Schmid 107 Patent is that it provides a laterally oriented conductive path between said galvanically active sensors through the first layer thereof. Electrically anisotropic conducting hydropolymers would be preferable.

[0012] Continuing, a Patent to Suyama et al, No. 5,132,058 describes a process for producing an anisotropically electroconductive sheet having a plurality of electroconductive portions extending in the direction of the thickness of the sheet. Application of an anisotropic magnetic field is utilized to draw electroconductive particles into a molding material such that said electroconductive particles gather where said electromagnetic field is applied. Another Patent which describes a similar system to that achieved by practice of the Suyama et al. Patent is No. 4,778,635 to Hechtman et al. A Patent to Kashiro et al,. No. 4,209,481 describes an anisotropically electroconductive sheet in which electroconductive wires are formed into patterned groupings, which patterned groupings are in turn formed into patterns. The wires are parallel in the direction of the sheet thickness, and spaced apart by non-electroconductive elastomer. Another Patent, No. 5,045,249 to Jin et al., describes electrical interconnections made by means of a layer or sheet medium comprising chains of magnetically aligned, electrically conductive particles in a non-conducting medium. End particles of chains protrude from a surface of the medium to effect electrical contact. A Patent to Abraham et al. describes an electrode for use with electrosurgical apparatus which provides capacitive coupling with the skin of a subject. The electrode includes a conductive plate connected to the electrosurgical apparatus with an insulating layer disposed in contact with the conductive plate and on the opposite face of the insulator there is provided conductive material in the form of a plurality of discrete islands of conductive adhesive material which contact the skin of a subject during use. Another Patent, No. 5,232,639 to Reitz et al. describes a process for forming articles with anisotropic void distributions therein.

[0013] It is also established that electrode configuration can be important in determining the accuracy of monitored signals. For instance, the use of a Bulls-eye shaped electrode, which comprises a central electrode surrounded by one or more annular ring electrodes, can provide signals which focus upon a specific region of a subject's heart, which focus is not available when a simple electrode geometry is utilized. As well, Bulls-eye shaped electrodes allow determination of derivatives of detected signals in use.

[0014] An article by He et al. titled "Body Surface Laplacian Mapping of Cardiac Electrical Activity" published in The American J. of Cardiology, Vol. 70, Dec. 15, 1992 describes the use of Bulls-eye shaped electrodes to map derivatives of cardiogenic signals.

[0015] Patents which describe unusual geometrical electrode configurations are, for instance, a Patent to Clare et al., No. 5,295,482 which discloses a large surface area electrode in which a central portion is surrounded by two surrounding ring portions., said central and two surrounding ring portions being separated from one another by annular regions. This Patent states that during use current density is found to be greater at the outer edge of an electrode than it is at a more central location. The purpose of the described system is disclosed as being to effect a more uniform distribution of current density over the effective large surface area of the disclosed electrode during use, by providing multiple "outer-edge" providing portions. Other references which describe the "edge-effect" are a Patent to Dahl et al., No. 5,063,932 and a Canadian Patent No. 1,219,642. In addition, two articles also treat the subject, said articles being: "Optimal Electrode Designs for

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Electrosurgery, Defibrillation, and External Cardiac Pacing", by Kim et al., which appeared in Transactions On Biomedical Engineering, Vol. BME-33, No. 9, September 1986; and "Analysis and Control of the Dispersive Current Distribution under Circular Dispersive Electrodes", by Wiley and Webster, which appeared in the IEEE Transactions On Biomedical Engineering, Vol. BME-29, No. 5, in May 1982.

[0016] Even in view of the above cited literature, need remains for a convenient to utilize bioelectric interface which is suitable for application to subjects of differing body sizes, which bioelectric interface comprises equivalent Einthoven triangle limb electrodes on a common subject chest mounted support sheet, which preferably comprises an electrically anisotropic conducting hydropolymer self adhesive material, which provides electrodes of a geometry appropriate for optimizing electrical contact to a subject, which allows accurately monitored signals to be obtained thereform during use, and which facilitates external cardiac pacing, cardiac defibrillation, electro surgery, electro-ablation processes, and impedance cardiography.

DISCLOSURE OF THE INVENTION

[0017] The present invention concerns the practice of electrocardiography wherein a number of electrical signals, which are diagnostic of myocardial function, are acquired via electrodes placed upon a subject's body. As regards this use, subject contacting electrodes can be spatially oriented in lead configurations such as Einthoven triangle, Frank, McFee, Schmidt, twelve-lead configurations etc., and in array patterns for use in mapping, etc. The present invention bioelectric interface is a system which provides Right-Arm (RA), Left-Arm (LA) and Left-Leg (LL) electrodes which form, when applied to a subject's chest in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern, said pattern being determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. The present invention bioelectric interface further provides all necessary electrodes, appropriately configured for mounting to a subject's chest, for use with electrocardiograph systems.

[0018] As demonstrated in the Background Section of this Disclosure, multiple electrode systems are not unknown. However, said known systems do not provide all electrodes for use with a twelve-lead electrocardiogram (ECG) system conveniently positioned on a bioelectric interface which can be easily, accurately and repeatably applied to a subject's chest in a desired anatomical orientation. A twelve-lead (ECG) system, by conventional practice, requires that electrodes be placed on a subject's Right (RA) and Left (LA) arms and Left leg (LL), and that six precordial electrodes (V1, V2, V3, V4, V5, and V6), be placed upon the subject's chest. The locations of the V1-V6 electrodes are:

V1--in the region of the fourth intercostal space at the right sternal border;
V2--in the region of fourth intercostal space at the left sternal border;
V4--in the region of fifth intercostal space at the left mid-clavicular line;
V3--in the region of the midpoint between the V2 and V4 electrodes;
V5--in the region of the fifth intercostal space at the left anterior axillary line;
V6--in the region of the fifth intercostal space in the left mid-axillary line.

[0019] No known reference, however, suggests that arm and leg equivalent electrodes should be placed at chest locations relatively near the precordial electrodes. The present invention teaches that said arm and leg equivalent electrodes are to be so placed. The location of said arm and leg equivalent electrodes is best understood by reference to the Drawings which are discussed in the Detailed Description of this Disclosure, however, verbally their positioning can be generally described as:

Right Arm--generally in the region of the second intercostal space to the right of the sternum;

Left Arm-generally in the region of left fourth intercostal space at the mid-axillary line; and

Left Leg--generally in the region of the inferior costal margin in the left mid-clavicular line.

[0020] In addition, the present invention teaches the optional use of multiple electrode element electrodes, (eg. "Bulls-eye" shaped electrodes), for instance, in a multiple electrode element electrode system. Use of single electrode element "Button" electrodes is conventional, and in use each such Button electrode serves to measure an electrical signal between it and a common or reference electrode, (typically termed uni-polar electrodes), or a smaller button electrode (typically termed Bi-polar electrodes). When multiple electrode element (eg. Bulls-eye), electrodes are utilized, however, signals are generated between two components of a single electrode. Continuing, a Bulls-eye shaped electrode is typically configured like a "target". That is, typically a Button electrode will be centrally located within an outer annular shaped electrode. The benefits provided by such, multi-electrode element electrodes are the ability to achieve greater resolution of signals generated in a specific area of a subject's heart, and it is noted, that the signals measured are representative of the derivatives of electrical signal activity produced by a subject's

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heart. That is, the signal provided between a Button and First Annulus is proportional to a derivative of a signal generated by a subject's heart. Additional annular ring electrodes can also be present and signals measure thereby are proportional to higher order derivatives. Use of Bulls-eye" electrode geometry then allows investigation of High Frequency aspects of electrical activity generated by a subject's heart. It is noted that a limitation is associated with the use of Bulls-eye electrodes in that the smaller they are dimensioned, although enabling increased resolution and investigation of electrical signals generated in smaller regions in a heart, the smaller the magnitude of signal they provide. In a multiple electrode setting then, where relative motion between electrodes can create confounding electrical noise, it than becomes increasingly important to prevent relative motion between electrodes and components of Bulls-eye electrodes, when Bulls-eye electrodes are present. (Note, it is emphasized that it is possible to achieve a result similar to that provided by "Bulls-eye" electrodes with outer multiple element electrodes, and for the purposes of this Disclosure any functionally similar electrode is to be considered as included by the terminology "Bulls-eye" whether a closed annulus is present or not).

[0021] It is also to be understood that a present invention electrode can consist of a plurality of electrode elements, (eg. a plurality of button shaped electrode elements), configured in a region of the bioelectric interface which, in use, aligns with an anatomical location appropriate for use in a twelve-lead (ECG) system.

[0022] With the forgoing in mind, it is then to be appreciated that the system of the present invention is a bioelectric interface comprised of a plurality of electrodes which are affixed to a support sheet in a desired spatially separated pattern, such that in use said electrodes are essentially fixed in location with respect to one another. It is noted that fixing said relative position between electrodes, and between electrode elements, serves to reduce electrical noise which can be generated when, in use, electrodes move with respect to one another. Again, it is to be understood that the electrodes can be of single electrode element, or multiple electrode element Button or Bulls-eye, (or other), geometry.

[0023] Continuing, a typical present invention bioelectric interface has an adhesive material present over at least a portion of a surface thereof which contacts a subject in use. The adhesive material of the present invention can have the properties of simultaneously demonstrating essentially electrically anisotropicity, but isotropic mechanical (eg. pliability and adhesion), properties. That is, the specific impedance across the adhesive material can be significantly different from that laterally directed, but the mechanical properties such as adhesion and pliability are typically essentially consistent. (Note, the term "specific impedance" is used to refer to the regional bulk property of the adhesive material, rather than properties resulting from dimensions of sheets fabricated therefrom). In the preferred embodiment, the adhesive material is a hydropolymer sheet which demonstrates a tackiness on a subject skin contact side thereof. Hydropolymers are particularly applicable in realization of the present invention as they are electrically conductive, relatively nonirritating to a subject's skin, and they demonstrate excellent adhesive qualities. Commercially available hydropolymer sheets with isotropic electrical properties, are available from Promeon of Boston, MA under the product designation RG-60 Series Hydrogels. Lec-Tec of Minneapolis, MN also markets hydrogels. The present invention provides that such adhesive hydropolymer sheet material can be utilized, if "slits" or hydropolymer discontinuity effecting "voids", are entered thereto at appropriate locations to effect electrical anisotropicity between electrodes present at various laterally offset locations. It is noted that hydropolymer sheets do not typically demonstrate a rigidity sufficient to maintain a spatially stable relationship between electrodes affixed thereto, but particularly when slits and/or voids are formed therein, hence, the present invention requires that a support sheet carrier matrix be present to which electrodes and said adhesive sheet attach. That is, the system of the present invention will then comprise a support sheet carrier matrix to which are attached, at desired spatially offset locations, electrodes, over which configuration said hydropolymer is placed so that said electrodes are sandwiched between sand carrier matrix and hydropolymer. At locations between the various electrodes said "slits" and/or "voids" are then caused to be present by, typically, a mechanical process. It is noted that in practice said "slits" need not be of a degree to provide complete discontinuity between various regions of the resulting hydropolymer system to provide a sufficiently anisotropic specific impedance system, but that use of disconuity affecting "voids" is within the scope of the present invention. The Background Section also identifies various electrically anisotropic adhesive materials. The present invention, in addition, teaches that an essentially electrically anisotropic adhesive material sheet can be provided by a "Scrim" material comprising a number of channels therethrough, which channels are caused to be filled with an electrically conductive adhesive material, (preferably a hydropolymer), such that "island channels" of conductive material exist across the resultant sheet, but such that electrically nonconductive scrim exists between laterally oriented islands of conductive material. The "Scrim" can be electrically conductive carbon fibers, and/or electrically non-conducting plastic filaments, as required to provide a desired electrical anisotropicity.

[0024] Continuing, the present invention, in its preferred embodiment, teaches that one size of multiple electrode bioelectrical interface should be sufficient for use with all subjects, regardless of body size. The present invention teaches that do accomplish placement of electrodes, such as defined infra for twelve-lead systems, on subject's bodies of various size, that

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groups of electrode elements should be available in the region of for instance, the fourth intercostal space at the right sternal border, (ie. the location for a V1 lead). In use then, regardless of a subject body size, one electrode element in a group of electrode elements in the region of the fourth intercostal space at the right sternal border, will provide an optimum result. Which electrode element in a group of electrode elements provides said optimum result, will of course be subject specific. Prior art has failed to recognize the need to provide a group of electrode elements in the region of a specific electrode placement location so that a user can select, manually or automatically, an appropriately placed electrode element for a specific subject.

[0025] It is also noted that as the relative spatial separation of various electrodes is essentially fixed by the present invention, and as their position on a subject's body is typically secured by an adhesive sheet, is it possible to conduct activities such as cardio-pulmonary-resuscitation (CPR) on a subject to which the present invention bioelectric interface is applied, without removal thereof. Such is essentially impossible where individual leads are utilized in an (ECG) system. As well, the present invention teaches that the means for making electrical contact to the electrodes should be available on the outer, non-subject contact, surface of the bioelectrical interface. For instance, snaps might be provided so that leads from any (ECG) system can easily attach thereto, or so that conductive tracks can be employed to bring signals to a manifold or connector means for convenient electrical access.

[0026] It is also emphasized that the electrodes in the bioelectric interface, being electrically conductive, enable, in an emergency, the application of defibrillation paddle-type electrodes to said interface means for making intimate electrical contact to said electrodes without removing the present invention bioelectrical interface from the subject. And, because the present invention is firmly affixed to a subject, the defibrillation shock will be safely transmitted to the subject with little, or no attenuation. It is also emphasized that in use, first and second conventional paddles of a defibrillation system can be caused to contact first and second spatially separated groups of electrodes in the bioelectric interface, press contacted electrodes into good electrical contact with the subject, and deliver electrical defibrillating pulse energy therethrough. Further, the presence of multiple electrodes, (and even multiple electrode elements within an electrode), within a defibrillation paddle-sized cluster of electrodes, through which defibrillation electrical energy can be delivered to a subject, serve to reduce adverse edge effects associated with applying defibrillation electrical energy through single element paddle, (or pad), electrodes. Special electrodes can be specifically designed which serve to reduce edge effects, and use thereof in the present invention Bioelectric interace is within the scope of the present invention.

[0027] One can also utilize one or more electrodes in the present invention bioelectric interface for heart pacing, electrosurgery, electro ablation and impedance cardiography.

[0028] The present invention bioelectric interface can be better described, in its most basic form, as comprising a support sheet in functional combination with at least three (3) spatially separated electrocardiogram system electrodes, with each of said at least three (3) spatially separated electrocardiogram system electrodes being a single electrical electrode element or a group of electrically independent electrode elements. Each of said spatially separated electrocardiogram system electrodes is affixed to said support sheet in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin. Three (3) of said at least three (3) electrocardiogram system electrodes being configured in an RA, LA, LL electrocardiogram system electrode pattern. The positioning of said three (3) electrocardiogram system electrodes as applied to a subject's chest during use can be described as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

[0029] Further, said electrodes RA, LA and LL form, when applied to a subject's body in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern which is determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. Said user selected range of voltage deviation can be selected to be less than one (1.0) millivolt, one (1.0) millivolt, or greater than one (1.0) millivolt.

[0030] The present invention bioelectric interface can further comprise an equivalent electrocardiogram system RL electrode, and said RA, LA, LL and RL electrodes can be present in the support sheet such that performations allow easy detachment of said equivalent electrocardiogram RA, LA, LL and RL electrodes, in use, thereby allowing them to be automatically positioned at a location in contact with a subject's chest, or by manual manipulation, in conventional subject limb positions.

[0031] The present invention bioelectric interface sup-

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port sheet is typically at least partially covered with an adhesive material on a subject contacting side thereof, and said adhesive material can present with electrical conductive properties which can be isotropic, or regionally anisotropic such that the specific impedance through said adhesive material is less that in a laterally oriented direction. Said regional anisotropic electrical conductive properties of said adhesive material can be effected, as described infra herein, by the presence of an electrically conductive and/or nonconductive scrim patterned therein so as to form channel regions of electrically conductive adhesive material through said adhesive material bordered by said scrim material, such that adhesive material in one channel region does not contact that in other regions. An alternative approach to effecting said regional anisotropic electrical conductive properties of the adhesive material involves the placing of slits and/or voids therein. Said adhesive material can be a hydropolymer and it can be caused to cover essentially the entire subject contacting surface of said support sheet.

[0032] As mentioned, at least one of said spatially separated electrocardiogram system electrodes can be of a construction consisting of a group of electrically independent electrode elements, and said elements can be configured in, for instance, Bulls-eye and multiple button shaped electrode elements patterns.

[0033] It is further disclosed that the present invention bioelectric interface can present with "holes" therethrough in regions between spatially separated electrodes so as to allow viewing of, and access to a subject's skin. As well, the outer edge of the present invention can have an "undulated" shape which can be described as a series of "curved tabs". As used here, the term "undulate" means an essentially repeating curved shape effected upon an outer edge of a present invention bioelectric interface, which undulated shape is not absolutely necessary, and the benefits of which are not, without trial an error experimentation, readily obvious. It has been found by the Inventor, however, that said present invention bioelectric interface outer edge shape allows achieving better conformation to a subject's body in use, and facilitates easy removal of a present invention bioelectric interface from a subject's body, by allowing relatively easy grasping of a "curve tab" between a thumb and first fingers. That is, where an outer edge of a present invention bioelectric interface does not have an "undulated", plurality of "curved tabs" shape, removal of a present invention bioelectric interface has been found to be more difficult.

[0034] A prefered bioelectric interface embodiment comprises a support sheet in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially spearated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements). Each of said spatially separated electrocardiogram system electrodes is affixed to said support sheet in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin. Nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern, such that said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as recited infra herein. Said prefered bioelectric interface further comprises an electocardiogram system RL electrode; and additionally further comprises perforations in said support sheet which allow easy detachment and deployment of at least one of said electrocardiogram RA, LA, LL and RL electrodes, thereby allowing positioning at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position). Said prefered embodiment further includes a fold enhancing impression and/or perforations located between at least two electrodes selected from the group consisting of: (V1 and V2; V2 and V3; V3 and V4; V4 and V5; V5 and V6; RA and V1; V4 and LL; LA and V6). As with other embodiments said prefered embodiment support sheet is at least partially covered with an adhesive material on a subject contacting side thereof, and said adhesive material can present with electrical conductive properties selected from the group consisting of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that the regional specific impedance through said adhesive material is less than in a laterally oriented dimension direction therealong). As well, said adhesive material can be selected from the group consisting of: (hydrophillic and non-hydrophillic). Said prefered embodiment can further comprise at least one hole present through said support sheet at a location between electrodes, which hole allows access to a subject's skin in use, and at least one hole can be present at a location selected from the group consisting of: (the level of the second intercostal space adjacent to said RA electrode, and the level of the fourth intercostal space adjacent to said V1 electrode, and between said RA and V2 electrodes, and between said V4 and V5 electrodes). Said prefered embodiment has a fold enhancing impression and/or perforations located between V3 and V4 electrodes, and between RA and V1 electrodes, and an undulated outer perimeter boundary shape.

[0035] A method of providing an Einthoven triangle equivalent RA, LA, LL pattern of electrodes on the chest of a subject, utilizing the present invention bioelectric interface, can comprise the steps of:

a. Providing a present invention bioelectric interface comprising a support sheet in functional combination with at least three (3) spatially separated electrocardiogram system electrodes as already

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described, wherein at least one (1) of said at least three (3) spatially separated electrocardiogram system electrodes is of a construction consisting of a group of electrically independent electrode elements. As described above, each of said spatially separated electrocardiogram system electrodes is affixed to said support sheet in a manner such the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin. Three (3) of said at least three (3) electrocardiogram system electrodes are configured in an RA, LA, LL electrocardiogram system electrode pattern, such that said three (3) electrocardiogram system electrodes are applied on a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

Also as described above, said electrodes RA, LA and LL form, when applied to a subject's body in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern which is determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. Said user selected range of voltage deviation can be selected to be less than one (1.0) millivolt, one (1.0) millivolt, or greater than one (1.0) millivolt;

b. Applying said bioelectric interface to a subject;

c. Selecting at least one electrically independent element in each of said at least one electrocardiogram system RA, LA and LL electrode(s) consisting of a group of electrically independent electrode elements;

d. Connecting said selected electrocardiogram system electrically independent element(s) in each of said RA, LA and LL electrode(s) to appropriate inputs of an electrocardiogram system.

[0036] Continuing, a preferred embodiment of the present invention bioelectric interface comprises a support sheet in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes. Each of said at least nine (9) spatially separated electrocardiogram system electrodes being a single electrical electrode element or a group of electrically independent electrode elements. Each of said spatially separated electrocardiogram system electrodes is affixed to said support sheet in a manner such the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, with nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern. In use, said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

Said electrodes RA, LA and LL form as described infra herein, when applied to a subject's body in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern which is determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. Said user selected range of voltage deviation can be selected to be less than one (1.0) millivolt, one (1.0) millivolt, or greater than one (1.0) millivolt.

[0037] The V1, V2, V3, V4, V5, V6 electrocardiogram system precordial electrode pattern is formed as:

electrode V1 in the region of the fourth intercostal space at the right sternal border;

electrode V2 in the region of the fourth intercostal space at the left sternal border;

electrode V4 in the region of the fifth intercostal space at the left mid-clavicular line;

electrode V3 in the region of the midpoint between electrode groups V2 and V4;

electrode V5 in the region of the fifth intercostal

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space in the left anterior axillary line; and

electrode V6 in the region of the fifth intercostal space in the left mid-axillary line.

[0038] The described preferred embodiment of the present invention can also further comprise an equivalent electrocardiogram system RL electrode, and perforations can be present in said support sheet to allow easy detachment and deployment of said equivalent electrocardiogram RA, LA, LL and RL electrodes, in use, so that they can be positioned in contact with a subject's chest, or in conventional subject limb position.

[0039] As described above, the presently described present invention bioelectric interface support sheet is also typically et least partially covered with an adhesive material on a subject contacting side thereof, which adhesive material presents with electrical conductive properties which can be isotropic or regionally anisotropic such that the specific impedance through said adhesive material is less than that in a laterally oriented direction. As also already discussed, a preferred adhesive material is hydropolymer which covers essentially the entire subject contacting surface of said support sheet.

[0040] Also as discussed above, each of the electrodes can be of a construction consisting of a group of electrically independent electrode elements, such as a Bulls-eye pattern, and multiple button shaped electrode elements.

[0041] A method of acquiring electrocardiographic data can comprise the steps of:

a. Providing a bioelectric interface comprising a support sheet in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, as just described;
b. Affixing said bioelectric interface to a subject as described above, and causing electrodes therein to be electrically attached to an electrocardiographic system such that familiar electrocardiographic data is obtained.

[0042] Said method of acquiring electrocardiographic data said method of acquiring electrocardiographic data can further include the step of removing and deploying said electrodes RA, LA and LL configured in an Einthoven frontal triangle equivalent LA, RA, LL pattern, utilizing perforations in said support sheet, and affixing said RA, LA and LL electrodes to conventional subject limb locations.

[0043] A method of utilizing any present invention bioelectric interface during formation of an Einthoven triangle equivalent or during acquisition of electrocardiographic data, can further comprise the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing;
d. electro surgery;
e. electro-ablation; and
f. impedance cardiography.

on said subject without removing said bioelectric interface.

[0044] Where defibrillation is performed, two conventional defibrillation paddles are positioned so that a first conventional defibrillation paddle contacts at least two of said electrocardiogram system electrodes, and a second said conventional defibrillation paddles contacts at least two of said electrocardiogram system electrodes, said two at least electrodes contacted by said first conventional defibrillation paddle being different than, and spatially separated from, said at least two electrodes contacted by said second conventional defibrillation paddle. In use, electrodes contacted by defibrillation paddles are caused to be pressed firmly into good contact with a subject. The result of the presence of multiple electrodes being that defibrillation pulse current distribution electrode edge effects are reduced.

[0045] It is further noted that the voltage present at a formed Wilson common terminal can be a root-mean-square value of a selected portion of a subject electrocardiogram system monitored electrocardiogram cycle, such as the QRS complex.

[0046] It is also noted that a conventional Wilson common terminal is a central "Y" interconnection point of fixed value, (eg. 10,000 ohm), resistors attached to RA, LA and LL electrodes. The present invention provides that at least one of said resistors can be variable and can, in use, be adjusted and thereby set a Wilson common terminal voltage produced by use of a present invention Bioelectric Interface, to a desired value. The application of variable resistors in forming a Wilson common terminal in combination with a present invention Bioelectric Interface, to effect production of a Wilson common terminal voltage which is within a desired deviation value with respect to a similar voltage which would be obtained utilizing conventional limb positioned electrodes, is not, to the inventor's knowledge, obviated in any known reference or combination of references.

[0047] Finally, it is noted that it might be possible to configure a Wilson common terminal utilizing two Limb electrodes selected from the group consisting of RA, LA and LL, and a third electrode selected from the group of precordial electrodes consisting of V1, V2, V3, V4, V5 and V6. The present invention includes such a configuration.

[0048] The present invention will be better understood by reference to the Detailed Description Section in conjunction with the accompanying Drawings.

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SUMMARY OF THE INVENTION

[0049] It is a primary purpose of the present invention to teach that electrodes configured in an RA, LA, LL electrocardiogram system electrode pattern in a bioelectric interface should be applied to a subject's chest during use, the positioning of said electrocardiogram system electrodes being:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space at the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

said electrodes RA, LA and LL forming an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern which is determined as acceptable by presentation of a voltage with respect to ground at a formed Wilson common terminal, which voltage with respect to ground is within a selected range of deviation from a voltage with respect to ground presented at a conventionally formed Wilson common terminal using conventional subject limb positioning of RA, LA and LL electrodes. (Said user selected range of voltage deviation can be selected to be less than one (1.0) millivolt, one (1.0) millivolt, or greater than one (1.0) millivolt).

[0050] It is another purpose of the present invention to teach that six precordial electrodes (V1, V2, V3, V4, V5, and V6) in said bioelectric interface, should also be placed upon the subject's chest in combination with said RA, LA and LL electrodes. The locations of the V1-V5 electrodes being:

V1--in the region of the fourth intercostal space at the right sternal border;
V2--in the region of fourth intercostal space at the left sternal border;
V4--in the region of fifth intercostal space at the left mid-clavicular line;
V3--in the region of the midpoint between the V2 and V4 electrodes;
V5--in the region of the fifth intercostal space at the left anterior axillary line;
V6--in the region of the fifth intercostal space in the left mid-axillary line.

[0051] It is yet another purpose of the present invention to teach the use of multiple electrode element electrodes, (eg. "Bulls-eye" shaped electrodes), as well as single electrode element "Button" electrodes in a bioelectric interface.

[0052] It is still yet another purpose of the present invention to teach a bioelectric interface which has an adhesive material present over at least a portion of a surface thereof which contacts a subject in use.

[0053] It is yet still another purpose of the present invention to teach a bioelectric interface in which the adhesive material is a hydropolymer.

[0054] It is another purpose of the present invention to teach a bioelectric interface in which the adhesive material demonstrates anisotropic specific impedance, such as effected by the presence of a slit or slits therein.

[0055] It is yet another purpose of the present invention to teach a method of utilizing any present invention bioelectric interface during formation of an Einthoven triangle equivalent or during acquisition of electrocardiographic data, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing;
d. electro surgery;
e. electro-ablation; and
f. impedance cardiography.

on said subject without removing said bioelectric interface.

[0056] It is still yet another purpose of the present invention to teach a bioelectric interface comprised of a plurality of electrodes which are affixed to a support sheet in a desired spatially separated pattern, such that in use said electrodes are essentially fixed in location with respect to one another such that confounding noise signals resulting from relative motion between said electrodes are reduced in use.

[0057] It is another purpose of the present invention to teach the use of variable resistor(s) in formation of a Wilson common terminal. The purpose thereof being to allow adjustment of a voltage appearing at a Wilson common terminal formed utilizing present invention Bioelectric Interface RA, LA and LL electrodes, so that it is within a desired range of deviation from a Wilson common terminal voltage obtained utilizing conventionally placed limb electrodes.

[0058] It is yet another purpose of the present invention to teach the presence of impression(s) and/or perforations in a bioelectric interface to facilitate easy removal of electrodes, (eg. RA,LA, RL and LL), and to make enhance folding capability for packaging, shipping and storage purposes.

[0059] It is another purpose yet of the present invention to teach the presence of holes in, an undulated outer periphery boundary of, a bioelectric interface to enhance conformation to a subject's body contoures in use.

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BRIEF DESCRIPTION OF THE DRAWINGS

[0060]

Fig. 1 shows a side elevational view of a bioelectric interface showing an electrode "sandwiched" by an adhesive sheet and a carrier matrix.

Fig. 2 shows a view of a two electrode bioelectric interface with a common adhesive sheet applied thereto, in which common adhesive sheet is present an electrically anisotropic property causing slit present between.

Figs. 3a and 3b show top and side elevation views respectively of a novel electrically anisotropic adhesive sheet.

Figs. 4a and 4b show various designs for electrodes.

Fig. 4c shows the electrodes of Figs. 4a and 4b sandwiched between a carrier matrix and an adhesive sheet.

Fig. 5a shows a multi-element electrode configured in a Bulls-eye pattern.

Fig. 5b shows a multi-element electrode pattern configured from button electrodes.

Fig. 6a shows a partial frontal view of a human torso, with formation of a Wilson Common Terminal from standard RA, LA and LL electrodes indicated.

Fig. 6b shows a partial frontal view of a human torseau, with formation of an equivalent Wilson Common Terminal indicated, as formed from equivalent RA, LA and LL electrodes of the present invention bioelectric interface.

Fig. 7a shows a bioelectric interface configured for use with a twelve lead (ECG) system. Shown are groups of electrodes which serve to allow a "one-size-fits-all" result. Also shown is an exemplary presence of a multi-element Bulls-eye electrode, and the presence of "slits" in an adhesive sheet to effect electrical anisotropic properties therein.

Fig. 7b shows a bioelectric interface configured for use with a twelve lead (ECG) system. Shown are groups of electrodes made of a plurality of electrode elements as shown in Fig. 5b, which serve to allow a "one-size-fits-all" result. Shown also are perforations in a continuous support sheet for use in detaching leads used in forming an Einthoven triangle equivalent Left Arm, Right Arm and Left Leg pattern.

Fig. 7c shows a bioelectric interface configured for use with a twelve lead (ECG) system. Shown are groups of electrodes made of a plurality of electrode elements configured as shown in Fig. 5a, which serve to allow high frequency investigation and mapping. Shown also are perforations in a continuous support sheet for use in detaching leads used in forming an Einthoven triangle equivalent Left Arm, Right Arm and Left Leg pattern.

Fig. 7d shows a bioelectric interface configured for use with a twelve lead (ECG) system. Indicated are electrodes positioned beneath paddles of a defibrillating system.

Fig. 7e shows a bioelectric interface with an undulated curved tab shaped outer edge in combination with the presence of strategically placed holes through said bioelectric interface.

DETAILED DESCRIPTION

[0061] Turning now to the Drawings, there is shown in Fig. 1 a side elevational cross-sectional view of a single electrode (E) in a bioelectric interface (1) system comprising a Support Sheet (SUP) and an adhesive material (AS). Note that the electrode (E) is "sandwiched" between the Support Sheet (SUP) and adhesive material (AS). This is a typical arrangement, but where an adhesive material can provide sufficient spatial positioning integrity it is to be understood that the Support Sheet (SUP) can become unnecessary.

[0062] Fig. 2 shows a bioelectric interface system (2) comprised of two electrodes (E1) and (E2) looking from the surface thereof upon which is present an adhesive material (AS), (ie. that surface which will contact a subject's skin in practice). Note that a "slit" (S) is shown as present between said electrodes (E1) and (E2). In the case where the adhesive material is made of an electrically isotropic material, (eg. commercially available hydropolymers in sheet form for instance), it has been found that providing a slit (S) between two electrodes (E1) and (E2) effects essentially electrically anisotropic properties thereto. That is, a lower specific impedance will be measured from an electrode through the adhesive material than between two electrodes. In the case that an adhesive material provides such anisotropic electrical specific impedance properties, said slit (S) typically becomes unnecessary. It is noted that the reason the adhesive material should provide anisotropic electrical properties is that in an (ECG) setting, for instance, if the adhesive material is electrically isotropic, signals which should be present in one electrode in a bioelectric interface, will to some extent be present in other electrodes as well, as a result of lateral current flow through said adhesive material, and many prior multiple electrode systems therefore, enter an artifact to (ECG) data as a result. As well, adhesive material elec-

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trical anisotropicity allows use of higher resolution electrode geometry, (discussed supra) because lateral current flow is limited.

[0063] It will he noted that the adhesive material (AS) in Fig. 2 is not completely bisected by the slit (8). This is a preferred, but not limiting practice, because complete electrode isolation is not always optimum. For instance, in (ECG) system settings it is common to inject a noise compensating signal to a Right Leg electrode via a driver circuit, which signal is to be imposed upon all electrodes. This practice is well known by practitioners in the (ECG) field, with noise compensating current flow normally being through a subject's skin, but it has been found that allowing some electrical path through the adhesive material does not noticeably degrade acquired (ECG) data. With that thought in mind it is noted that a goal of the present invention is to provide a very firm affixation to a subject's body such that spatial separation between electrodes is maintained constant and such that good electrical contact between electrodes and a subject's skin is effected, via said adhesive material. Hence, the more surface area of the present invention bioelectric interface upon which the adhesive material remains present, the better.

[0064] Fig. 3a shows a present invention system for providing electrically anisotropic specific impedance in an "adhesive sheet". Shown is an electrically non-conductive "Scrim" (SM) present in a form which provides numerous channel regions, said channel regions being filled with electrically isotropic conductive adhesive material (A).

[0065] Turning now to Figs. 4a and 4b, there are shown preferred shapes (E3) and (E4) for electrodes. Note that there are regions of said electrodes which will tend to project into an adhesive material (AS) placed in contact therewith. The effect of said projection is to provide a thinning of the adhesive material (AS) and effect an electrically anisotropic character to the adhesive material (AS) as viewed in cross section. That is, electrical impedance from an electrode (E3) or (E4) through said adhesive material (AS) will be caused to be less than that between electrodes (E3) and (E4) through said adhesive material (AS), because of a thinning effect at the projecting edges of said electrodes. Fig. 4c demonstrates the adhesive material (AS) thinning effect. Any electrode shape effecting a similar effect is to be considered equivalent. Fig 4c also shows the presence of external device electrical connector means (EC).

[0066] Fig. 5a shows an example of a multi-element electrode (E5) with a "Bulls-eye" geometry. As described in the Disclosure of the Invention Section of herein, use of said multiple element electrodes allows investigation of high frequency components in (ECG) signals, and allows better spatial resolution of the sources of monitored (EGG) signals. (It is to be understood that the "Bulls-eye" shape is an example of a multi-element electrode, and that any functionally similar multi-element electrode configuration is to be considered as included within the term "Bulls-eye"). The underlying distinction between multi-element electrodes and single element electrodes being that multiple single element electrodes typically utilize a single common electrode as a reference, whereas multi-element electrodes provide their own reference point. It will be appreciated that electrical anisotropicity can become very important in view of the higher resolution capability of "Bulls-eye" electrodes, when signals are being monitored from closely positioned points of, for instance a human heart muscle. That is, greater resolution capability is of no consequence if the signal reaching a sensing electrode is effected by lateral current flow through an attached adhesive material, which signal was originated by a distal source. Fig. 5b shows a plurality of "Button" electrode elements (B1), (B2), (B3), (B4) and (B5) which comprise an electrode (E6). Such an arrangement is beneficially utilized in a present invent in Bioelectric Interface meant for use in Defibrillation. The well known "Edge" effect which results in uneven current distribution over the region of an electrode can be reduced by such a configuration.

[0067] Fig. 6a shows a partial human torso with RA, LA and LL electrodes placed on the limbs. Also shown is an Einthoven triangle Wilson Common Terminal (WCT) formed by attaching resistors to said RA, LA and LL electrodes, which resistors have a common central connection so as to form a "Y" circuit.

[0068] Fig. 6b shows a partial human torso with RA, LA and LL electrodes placed on the chest as is effected by the present invention Bioelectric Interface (3). Also shown is an Einthoven equivalent frontal I II, III lead triangle, Wilson Common Terminal (WCT) formed by attaching resistors (r1), (r2) and (r3) to said RA, LA and LL electrodes, which resistors have a common central connection so as to form a "Y" circuit.

[0069] It is the result of the present invention that voltages which appear at Wilson Common Terminals shown in Figs. 6a and 6b, each with respect to ground, are essentially equivalent, if the present invention RA, LA and LL electrodes are appropriately positioned within the Fig. 6b demonstrated bioelectric interface. A method of accomplishing this can be aided by causing at least one of the RA, LA and LL electrodes to be comprised of a plurality of electrically independent electrode elements, (as demonstrated in Fig. 7b). A user can, manually or via automation, optimally select an element in each RA, LA and LL electrode. As described in the Disclosure of the Invention Section, appropriate placement of the present invention RA, LA and LL electrodes in a present invention biointerface as applied to a subject, is achieved when a voltage present at a Wilson Common Terminal as shown in Fig. 6b, is essentially the same as the voltage present at a Wilson Common Terminal as shown in Fig. 6a within some user selected voltage deviation range, (eg. less than one (1.0) millivolt).

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[0070] Turning now to Fig. 7a there is shown an approximately "actual size" typical present invention biolelectric interface system (3) with electrodes present therein and appropriately spatially distributed and positioned for use with a twelve lead (ECG) system. Fig. 7a shows the surface of the present invention bioelectric interface (3) opposite to that upon which is typically present an adhesive material which contacts a subject's skin in use. In use the bioelectric interface system (3) will typically be placed upon a subject's chest with the various precordial V1-V6 electrodes, and electrode groups, placed as follows:

electrode V1--in the region of the fourth intercostal space at the right sternal border.
electrode Y2--in the region of the fourth intercostal space at the left sternal border;
electrode V4--in the region of the fifth intercostal space at the left mid-clavicular line;
electrode V3--in the region half way between electrodes V2 and V4;
electrode V5-in the region of the fifth intercostal space at the left anterior axillary line; and
electrode V6--in the region of the fifth intercostal space at the left mid-axillary line.

[0071] Note that electrodes V4, V5 and V6 are each shown as a group of electrode elements. The present invention provides for any of the electrodes V1-V6 and any other electrodes which might be present, to be present as a group thereof. The reason for this is that the present invention bioelectric interface is truely a "single size fits all system". That is, even though subject's body sizes vary greatly one to another, the present invention can be applied to essentially any non-deformed subject and an electrode within a group of electrodes in the region of an appropriate location will be found to be properly positioned for use, within an error which exists even if individual electrodes are utilized, (said error originating from improper application of a single electrode). It is emphasized that while only V4, V5 and V6 precordial electrodes are shown as groups of electrode elements in Fig. 7a, any electrode shown, or any other configuration of electrode elements utilized, can be present as a group of electrodes as necessary to effect the "one-size-fits-all" feature of the present invention bioelectric interface system. The reason that Fig. 7a shows electrodes V1, V2 and V6 as single electrodes and electrodes V4, V5 and V6 as shown as groups of electrode elements is that, in practice, application of the present invention bioelectric interface system to a subject's body will proceed in a manner that typically assures appropriate positioning of electrodes V1, V2 and V3 on a subject's chest. The remaining electrodes will then make contact with the subject's body at locations based upon the size and shape of the bioelectric interface (3), which for any specific electrode might or might not be at the generally accepted locations recited infra. Where a group of electrodes is present, however, it should be appreciated that one of the electrodes in the group will be found to be more appropriately positioned than the others of the group. It is also noted that where groups of electrodes are present, unused electrodes in a group can be utilized as, for instance, electrodes to effect cardiac pacing. As well, if one electrode in a group becomes inoperable, another can be substituted and still allow acquisition of reasonable (ECG) data. (See Fig. 7b and 7c for other non-limiting examples). Also, multiple electrodes can be combined in a parallel configuration to allow greater current carrying capability during, for instance, defibrillation procedures.

[0072] Shown also in Fig. 7a are also the Right Arm (RA), Left Leg (LL) and Left Arm (LA) electrodes, positioned as appropriate for use as an Einthoven triangle equivalent configuration pattern, and for use as Right Arm (RA), Left Leg (LL) and Left Arm (LA) equivalent electrodes in the present invention bioelectric interface. Said electrodes are positioned as:

electrode (RA)--in the general region of the second intercostal space to the right of the sternam;
electrode (LA)--in the general region of the left fourth intercostal space at the mid-axillary line; and
electrode (LL)--in the general region of the inferior costal margin at the right or left mid-clavicular line.

(Note, multiple electrodes designated Right Leg (RL) are also present. As alluded to above, the Right Leg (RL) electrode in (ECG) settings is typically utilized to inject an out-of-phase noise compensating signal, which can be functionally applied to many electrodes. It has been determined that said noise compensating signal can be injected at any essentially any location on the present invention bioelectric interface without degradation of the results).

[0073] Also note that slits (S) in an electrically isotropic adhesive material are shown in broken lines. As viewed, said adhesive material would be present on a lower surface of the shown present invention bioelectric interface (3), hence are shown as viewed through the adhesive material and indicated Support Sheet (SUP). Said slits (S) will be less necessary, and probably unnecessary, where an adhesive material constructed from an inherently electrically anisotropic material, such as demonstrated by Figs. 3a and 3b, is utilized. In such systems the scrim (SM) can provide structural integrity, while the present electrically conductive adhesive can provide sufficient adhesive contact and electrical conductivity.

[0074] Also note that Fig. 7a shows one of the V6 electrodes as a "Bulls-eye" electrode with a central Button (B1) and outer annular ring (B2) present. Again, this is demonstrative, and in effect all electrodes could be of a multi-element construction. The conductive polymer will typically, though not necessarily, be discontinuous between the element of a multi-element electrode. Note

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than the central Button (B1) can still serve as a standard Button electrode. In use, one could also interconnect the V6 (B1) and (B2) elements, or all the electrodes in a group, (for instance, if it became necessary to defibrillate a subject while a present invention bioelectric interface is in place). Conventional practice would require removal of any such electrode providing system. However, where the present invention bioelectric interface (3) is present, a defibrillation paddle could be positioned to effectively form a single electrode from electrodes in the V4, V5 and V6 groups. (Note said defibrillation paddle could contact external contact means (EC) such as shown in Fig. 4c). A second defibrillation paddle could likewise be simultaneously applied to the V1, V2 and V3 electrodes, or group of electrodes should alternatives be present at V1, V2 and V3 electrode locations. (See Fig. 7d for indication of Defibrillation Paddles in use).

[0075] Again, Fig. 7a provides a non-limiting example of a Bioelectric Interface (3) of the present invention. The present invention is, however, in the combination of the various disclosed elements thereof, in their various forms, as well as in electrode positioning.

[0076] Continuing, Fig. 7b shows a present invention Bioelectric Interface (3) with electrodes consisting of a Fig. 5b electrode element arrangement present at all V1, V2, V3, V4, V5, and V6 locations in the Support Sheet (SUP). RA, LA and LL electrodes are also shown to comprise multiple electrode elements. As in Fig. 7a, the Bioelectric Interface is viewed from the non-subject contacting side, and indications of the presence, and positioning of electrodes electrically accessible from both the shown, and subject contacting sides is present. The dotted lines surrounding each of said V1, V2, V3, V4, V5 and V6 locations is to indicate that the Fig. 5b electrode element arrangement is to be taken in combination as an electrode. Also note that Fig. 7b shows Perforations (P) present in the Support Sheet (SUP) at electrode RA, LA, and LL, (eg. Right Arm, Left Arm and Left Leg) locations. Said Perforations (P) allow easy removal of the RA, LA, and LL electrodes when it is desired to deploy and place said electrodes at conventional subject limb locations in use.

[0077] Fig. 7c shows a present invention Bioelectric Interface (3) with Fig. 5a Bulls-eye electrodes present at V1, V2, V3, V4, V5 and V6 locations in the Support Sheet (SUP). As in Figs. 7a and 7b, the Bioelectric Interface is viewed from the non-subject contacting side, and indications of the presence, and positioning of electrodes electrically accessible from both the shown, and subject contacting sides is present. Also note that Fig. 7c, as did Fig. 7b, shows Perforations (P) present in the Support Sheet (SUP) at electrode RA, LA, and LL (eg. Right Arm, Left Arm and Left Leg) locations. Said Perforations (P) allow easy removal of the RA, LA, and LL electrodes when it is desired to deploy and place said electrodes at, for instance, conventional limb locations in use.

[0078] Fig. 7d shows a present invention Bioelectric Interface (3) with simple single Button electrodes present at V1, V2, V3, V4, V5 and V6 locations in the Support Sheet (SUP). As in Figs. 7a, 7b and 7c, the Bioelectric Interface is viewed from the non-subject contacting side, and indications of the presence, and positioning of electrodes electrically accessible from both the shown, and subject contacting sides is present. Also shown are outline representations of First (DF1) and Second (DF2) Defibrillation Paddles placed over the RA, LA, LL, V1, V2, V3, V4, V5 and V6 electrodes of the present invention Bioelectric Interface (3), as said First (DF1) and Second (DF2) Defibrillation Paddles would be positioned in use. Note that First (PD1) Defibrillation Paddle electrically contacts electrodes RA, V1, V2, and V3, while Second (DF2) Defibrillation Paddle electrically contacts electrodes LA, LL, V4, V5, and V6. The multiple points of supply of electrical energy to the body of a subject wearing the present invention Bioelectric Interface (3) serves to reduce uneven current flow caused by electrode "Edge" effect. It should be appreciated that were First (DF1) and Second (DF2) Defibrillation Paddles shown applied to Figs. 7b or 7c, even more separate electrode elements would be contacted, and the "Edge" effect would be even more reduced.

[0079] Turning now to Fig. 7e, there is shown a prefered embodiment of the present invention bioelectric interface (3). Shown are a support sheet (SUP) in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially separated electrocardiogram system electrodes, which can be of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements). Each of said spatially separated electrocardiogram system electrode is affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin. Nine (9) of said at least nine (9) electrocardiogram system electrodes are configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern much as described with respect to Figs. 7a - 7d. The prefered embodiment is shown to also include an electrocardiogram system RL electrode. In particular it should be noted that the Fig. 7e embodiment further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of at least one of said electrocardiogram RA, LA, LL and RL electrodes, thereby allowing positioning at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position). Further note that fold enhancing impression and/or perforations are shown as present between V3 and V4 electodes, and between RA and V1 electrodes. Such fold enhancing impression and/or perforations can be present between essentially any at two electrodes such as between V1 and V2; V2 and V3; V3 and V4; V4 and V5; V5 and V6; RA and V1; V4 and LL;

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LA and V6. As with other embodiments in said Fig. 7e prefered embodiment, the support sheet is at least partially covered with an adhesive material on a subject contacting side thereof, and said adhesive material can present with electrical conductive properties selected from the group consisting of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that the regional specific impedance through said adhesive material is less than in a laterally oriented dimension direction therealong). Also, said adhesive material can be hydrophillic and non-hydrophillic. Note also that the bioelectric interface in Fig. 7e has at least one hole (H) present through said support sheet at a location between electrodes, which hole allows access to a subject's skin in use. Holes (H) are shown at location of the level of the second intercostal space adjacent to said RA electrode, and at the level of the fourth intercostal space adjacent to said V1 electrode, and between said RA and V2 electrodes, and between said V4 and V5 electrodes. Such holes make the bioelectric interface more compliant and able to conform to a subject's body contours. Also note that the Fig. 7e bioelectric interface has an "undulated" outer perimeter boundary shape. This is prefered as it further enhances conformation to a subject's body contours in use, and said "undulations" allow relatively easy grasping between a thumb and first finger, thereby facilitating removal of a bioelectric interface from a subject, (which has proven a bit difficult with some bioelectric interfaces without an "undulated" outer perimeter boundary.

[0080] As a general comment regarding Figs. 7a, 7b, 7c, 7d and 7e, the electrodes are shown positioned in each Bioelectric Interface (3), as viewed from the non-subject contacting side thereof. Fig. 4c demonstrates the typically only an external device electrical connector means (EC) is visible as so viewed, with a typically larger electrode area present on the subject contacting side. Hence, Figs. 7a, 7b, 7c and 7d should be viewed as demonstrating the positioning of electrodes, and elements which comprise them, in a present invention Bioelectric Interface, rather than being accurate representations of the size of said electrodes, as viewed.

[0081] As another general comment, it is to be appreciated that the present invention bioelectric interface system provides a means by which many electrodes can be applied to a subject by a simple, error limiting procedure. As it is generally accepted that improper application of electrodes is the most common reason for faulted (ECG) data acquisition, this is significant. As well, the present invention bioelectric interface provides a rather significant body contact surface area, said surface area being, typically, essentially covered with an adhesive material. This serves to ensure that electrodes, once applied to a subject, will not vary from the positions in which they are applied, and should not vary with respect to one another. It is known that relative motion between electrodes accounts for production of noise in acquired (ECG) data. The present invention greatly limits problems associated with noise generated by this effect. In fact, it is generally possibly to perform cardio-pulmonary-resuscitation on subjects wearing the present invention bioelectric interface while continuing to acquire (ECG) data. It is also mentioned that when the adhesive material is a hydropolymer, subject discomfort is minimized, and moisture resulting from sweating etc. actually serves to improve the adhesion properties.

[0082] While not shown, it is possible to form arrays of electrodes in a present invention bioelectric interface, for use in cardiac mapping. In such arrays, electrode arrangement is typically rectangular with, for instance, sixteen, twenty-four, thirty-six, sixty-four etc. electrodes present. The electrodes present can be of Button or Bulls-eye geometry, or, in other embodiments of the present invention, can be of any functional geometrical shape. It is also noted that it is possible to affix alternative embodiments of the present invention bioelectric interface to the back of a subject as well as to the chest thereof.

[0083] It is also noted that primary evidence that a Wilson Common Terminal (WCT) Voltage produced utilizing a present invention Bioelectric Interface is equivalent to that produced when conventionally placed limb leads are utilized, is essential equivalence of monitored ECG lead outputs from both said systems. In that light it is to be understood that a conventional Wilson Common Terminal is constructed utilizing resistors of equal value, (eg. 10,000 ohms each). Again referring to Figs. 6a and 6b, this is equivalent to considering Resistors (r1), (r2) and (r3) to be of equivalent values. Where this is the case, placement of the Right Arm (RA), Left Arm (LA) and Left Leg (LL) electrodes alone, in a Fig. 6b setting, provides for realizing a voltage at the Fig. 6b Wilson Common Terminal (WCT) which is in a desired relationship to that present at the Wilson Common Terminal (WCT) formed utilizing electrodes positioned on limbs, as shown in Fig. 6a. However, it should be appreciated that if resistors (r1), (r2) and (r3) are available, then adjusting their values can also have an effect on the voltage which appears at a Wilson Common Terminal (WCT). The present invention provides for use of variable (r1) and/or (r2) and/or (r3) resistor(s) such that in use, adjustment of one or more of said variable (r1) and/or (r2) and/or (r3) resistor(s) allows "setting" a voltage at the Wilson Common Terminal (WCT) to essentially any value at, or anywhere between, the voltages present at any of the Right Arm (RA), Left Arm (LA) and Left Leg (LL) electrodes. Thus, the present invention can include as a Method of Use step, adjustment of the values of the resistors which form the Wilson Common Terminal (WCT), after a Fig. 6b Bioelectric Interface (3) is placed upon a subject's chest. (Note that Operational Amplifiers with adjustable gain can be utilized in place of the described variable resistors and are to be considered functionally equivalent and within the scope of the

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terminology "variable resistor". Op-Amps beneficially provide light input impedance.)

[0084] It will be apparent to those skilled in the art that some redundancy exists in any Einthoven-like lead system which lies largely in a single subject body plane, such as the frontal plane. Some minor efficiencies might be achieved, at the expense of redundance, if for example, two mutually perpendicular leads were created and used exclusively to define the frontal plane in electrocardiology. Furthermore, other mathematically derived leads are commonly employed to provide additional information, (eg "augmented" frontal plane leads). However, it is to be understood that new heart related information can not be created simply by the mathematical manipulation of redundant information. Therefore, where appropriate, the Claims are to be interpreted to include mathematically equivalent lead placement systems. In particular, the language, "generally in the region of" should be interpreted sufficiently broadly to include both an Einthoven equivalent triangle and an orthogonal lead configuration formed by a shifting of a lead position, which identified lead configurations provide mathematically essentially equivalent information.

[0085] It is specifically stated, as it is difficult to otherwise describe, that for the purposes of this disclosure the term "undulate" is defined as indicating a sequence of curves in said a bioelectric interface "undulated" outer perimeter boundary (UOPB), as shown in Fig. 7e. This is best understood by comparison to a bioelectric interface outer perimeter boundary with a relatively "smoothed" shape, as is shown in Figs. 7a - 7d.

[0086] Finally, it is noted that the terminology "Wilson Common Terminal" has been used throughout this Disclosure, whereas many references utilize the terminology "Wilson Central Terminal". The term "Common" is used to imply application in an instrumentation setting, but for most purposes it can be read as "Central" without loss of accuracy.

[0087] Having hereby disclosed the subject matter of the present invention, it should be obvious that many modifications, substitutions, and variations of the present teachings are possible in view of the teachings. It is therefore to be understood that the present invention may be practiced other than as specifically described, and should be limited in breadth and scope only by the Claims.

Claims

1. A bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least three spatially separated electrocardiogram system electrodes, each of said at least three spatially separated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, three of said at least three electrocardiogram system electrodes being configured in an RA, LA, LL electrocardiogram system electrode pattern, such that said three electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

said RA, LA and LL electrodes forming, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern presenting with a voltage with respect to ground at a Wilson common terminal formed from "Y" connected resistors from each of said RA, LA and LL electrodes, said resistors each being selected from the group consisting of: (fixed and variable), said voltage with respect to ground being within a selected range of deviation from a similarly obtained voltage with respect to ground which would present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) milivolt, thereby enabling familiar ECG data acquisition.

2. A bioelectric interface (3) as in Claim 1 which further comprises an electrocardiogram system RL electrode.

3. A bioelectric interface (3) as in Claim 2 which further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of said electrocardiogram RL electrode can, in use, be positioned at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position).

4. A bioelectric interface (3) as in Claim 1 which further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of said Einthoven triangle equivalent RA, LA and LL electrodes therefrom so that said Einthoven triangle equivalent RA, LA, and LL electrodes can,

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in use, be positioned at locations selected from the group consisting of: (in contact with a subject's chest, and in conventional Einthoven triangle subject limb positions).

5. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, which adhesive (AS) material presents with electrical conductive properties selected from the group consisitng of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that regional specific impedance through said adhesive (AS) material is less that in a laterally oriented direction therealong).

6. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, the electrical conductive properties of said adhesive (AS) material being regionally anisotropic, said anisotropic electrical conductive properties of said adhesive (AS) material resulting from the presence of an electrically nonconductive scrim patterned therein so as to form channel regions of electrically conductive adhesive (AS) material through said adhesive (AS) material bordered by said scrim material, such that adhesive (AS) material in one channel region does not contact that in other regions.

7. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject containing side thereof, the electrical conductive properties of said adhesive (AS) material being regionally anisotropic, said anisotropic electrical conductive properties of the adhesive (AS) material resulting from the presence of slits/voids formed therein.

8. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, said adhesive (AS) material being a hydropolymer with isotropic electrical conductive properties.

9. A bioelectric interface (3) as in Claim 8, in which the hydropolymer adhesive (AS) material covers essentially the entire subject contacting surface of said support sheet (SUP).

10. A bioelectric interface (3) as in Claim 1, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, said adhesive (AS) material being a hydropolymer with regional anisotropic electrical conductive properties.

11. A bioelectric interface (3) as in Claim 10, in which the hydropolymer adhesive (AS) material covers essentially the entire subject contacting surface of said support sheet (SUP).

12. A bioelectric interface (3) as in Claim 1, in which at least one of said spatially separated electrocardiogram system electrodes is of a construction consisting of a group of electrically independent electrode elements.

13. A bioelectric interface (3) as in Claim 12, in which said electrically independent electrode elements are configured in a pattern selected from the group consisting of: (a Bulls-eye pattern, and multiple button shaped electrode elements).

14. A method of providing an Einthoven triangle equivalent RA, LA, LL pattern of electrodes on the chest of a subject comprising the steps of:

a. providing a bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least three spatially separated electrocardiogram system electrodes, at least one (1) of said at least three spatially separated electrocardiogram system electrodes being of a construction consisting of a group of electrically independent electrode elements, each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, three of said at least three electrocardiogram system electrodes being configured in an RA, LA, LL electrocardiogram system electrode pattern, said RA, LA and LL electrodes forming, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern presenting with a voltage with respect to ground at a Wilson common terminal formed from "Y" connected resistors from each of said RA, LA and LL electrodes, said resistors each being selected from the group consisting of: (fixed and variable), said voltage with respect to ground being within a selected range of deviation from a similarly obtained voltage with respect to ground which would be present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) millivolt, thereby enabling familiar ECG data acquisition;

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b. applying said bioelectric interface (3) to a subject;

c. selecting at least one electrically independent element in each of said at least one electrocardiogram system RA, LA and LL electrode(s) consisting of a group of electrically independent electrode elements to constitute the electrode of which it is an electrically independent element;

d. connecting said electrocardiogram system RA, LA and LL electrodes to appropriate inputs of an electrocardiogram system.

15. A method of providing an Einthoven triangle equivalent RA, LA, LL pattern of electrodes on the chest of a subject as in Claim 14, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing;
d. electro surgery;
e. electro-ablation; and
f. impedance cardiography.

on said subject without removing said biolelectric interface (3) .

16. A bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially separated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern, such that said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;

said electrodes RA, LA and LL being positioned so as to form, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern presenting with a voltage with respect to ground at a Wilson common terminal formed from "Y" connected resistors from each of said RA, LA and LL electrodes, said resistors each being selected from the group consisting of: (fixed and variable), said voltage with respect to ground being within a selected range of deviation from a voltage respect to ground which would present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) millivolt, thereby enabling familiar ECG data acquisition;

electrode V1 in the region of the fourth intercostal space at the right sternal border;

electrode V2 in the region of the fourth intercostal space at the left sternal border;

electrode V4 in the region of the fifth intercostal space at the left mid-clavicular line;

electrode V3 in the region of the midpoint between electrode groups V2 and V4;

electrode V5 in the region of the fifth intercostal space in the left anterior axillary line; and

electrode V6 in the region of the fifth intercostal space in the left mid-axillary line.

17. A bioelectric interface (3) as in Claim 16 which further comprises an electocardiogram system RL electrode.

18. A bioelectric interface (3) as in Claim 17 which further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of said electrocardiogram RL electrode can, in use, be positioned at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position).

19. A bioelectric interface (3) as in Claim 16 which further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of said Einthoven triangle equivalent RA, LA and LL electrodes therefrom so that said Einthoven

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triangle equivalent RA, LA, and LL electrodes can, in use, be positioned at locations selected from the group consisting of: (in contact with a subject's chest, and in conventional Einthoven triangle subject limb positions).

20. A bioelectric interface (3) as in Claim 16, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, which adhesive (AS) material presents with electrical conductive properties selected from the group consisitng of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that the regional specific impedance through said adhesive (AS) material is less than in a laterally oriented dimension direction therealong).

21. A bioelectric interface (3) as in Claim 16 in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, the electrical conductive properties of said adhesive (AS) material being anisotropic, said anisotropic electrical conductive properties of said adhesive (AS) material resulting from the presence of an electrically nonconductive scrim patterned therein so as to form channel regions of electrically conductive adhesive (AS) material through said adhesive (AS) material bordered by said scrim material, such that adhesive (AS) material in one channel region does not contact that in other regions.

22. A bioelectric interface (3) as in Claim 16, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, the electrical conductive properties of said adhesive (AS) material being anisotropic, said anisotropic electrical conductive properties of the adhesive (AS) material resulting from the presence of slits/voids formed therein.

23. A bioelectric interface (3) as in Claim 16, in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, said adhesive (AS) material being a hydropolymer with isotropic electrical conductive properties.

24. A bioelectric interface (3) as in Claim 23, in which the hydropolymer adhesive (AS) material covers essentially the entire subject contacting surface of said support sheet (SUP).

25. A bioelectric interface (3) as in Claim 16 in which the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, said adhesive (AS) material being a hydropolymer with regional anisotropic electrical conductive properties.

26. A bioelectric interface (3) as in Claim 25, in which the hydropolymer adhesive (AS) material covers essentially the entire subject contacting surface of said support sheet (SUP).

27. A bioelectric interface (3) as in Claim 16, in which at least one of said spatially separated electrocardiogram system electrodes is of a construction consisting of a group of electrically independent electrode elements.

28. A bioelectric interface (3) as in Claim 27, in which said electrically independent electrode elements are configured in a pattern selected from the group consisting of: (a Bulls-eye pattern, and multiple button shaped electrode elements).

29. A method of acquiring electrocardiographic data comprising the steps of:

a. providing a bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially separated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern, such that said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrodes RA, LA and LL positioned so as to form, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern presenting with a voltage with respect to ground at a Wilson common terminal formed from "Y" connected resistors from each of said RA, LA and LL electrodes, said resistors each being selected from the group consisting of: (fixed and variable), said voltage with respect to ground being within a selected range of deviation from a voltage respect to ground which would

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present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) milivolt, thereby enabling familiar ECG data acquisition;

electrode V1 in the region of the fourth intercostal space at the right sternal border;

electrode V2 in the region of the fourth intercostal space at the left sternal border;

electrode V4 in the region of the fifth intercostal space at the left mid-clavicular line;

electrode V3 in the region of the midpoint between electrode groups V2 and V4;

electrode V5 in the region of the fifth intercostal space in the left anterior axillary line; and

electrode V6 in the region of the fifth intercostal space in the left mid-axillary line;

b. affixing said bioelectric interface (3) to a subject and causing electrodes therein to be electrically attached to an electrocardiographic system such that familiar electrocardiographic data is obtained.

30. A method of acquiring electrocardiographic data as in Claim 29 which further comprises the step of selecting at least one of the Wilson common terminal forming "Y" connected resistors from said RA, LA and LL electrodes to be variable, and the adjusting the value of at least one of said at least one of the Wilson common terminal forming "Y" connected resistors to place the Wilson common terminal voltage within a selected range of deviation from a similarly obtained voltage which would present at a Wilson common terminal formed using conventional subject limb positioning of RA, LA and LL electrodes, said selected range of voltage deviation being on the order of one (1.0) milivolt, thereby enabling familiar ECG data acquisition;.

31. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing a bioelectric interface (3) includes providing perforation in said support sheet (SUP) such that said three electrodes configured in an Einthoven triangle equivalent RA, LA, and LL pattern can be easily removed therefrom; said method of acquiring electrocardiographic data further including the step of removing said electrodes RA, LA and LL configured in an Einthoven frontal lead triangle equivalent LA, RA, LL pattern and affixing them to conventional subject limb locations.

32. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing a bioelectric interface (3) includes providing an adhesive (AS) material present over at least a portion of a subject contacting side of said support sheet (SUP).

33. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing said bioelectric interface (3) comprises the step of causing at least some of said electrodes to comprise a group of electrically independent electrode elements configured in a pattern selected from the group consisting of: (a Bulls-eye pattern, and multiple button shaped electrode elements).

34. A method of acquiring electrocardiographic data as in Claim 29, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing;
d. electro surgery;
e. electro-ablation; and
f. impedance cardiography.

on said subject without removing said bioelectric interface (3) .

35. A method of acquiring electrocardiographic data as in Claim 29, which further comprises the simultaneous step of performing cardiac defibrillation utilizing two conventional defibrillation paddles, in which a first conventional defibrillation paddle contacts at least two of said at least nine electrocardiogram system electrodes, and in which a second said conventional defibrillation paddles contacts at least two of said at least nine electrocardiogram system electrodes, said at least two electrodes contacted by said first conventional defibrillation paddle being different than and sread apart from said at least two electrodes contacted by said second conventional defibrillation paddle; with the result being that in use said electrodes contacted by said defibrillation paddles are caused to be pressed into firm contact with a subject and defibrillation pulse current delivered thereto with current distribution electrode perimeter boundary effects being reduced.

36. A bioelectric interface (3) as in Claim 1, in which the voltage present at a formed Wilson common terminal is a root-mean-square value of a selected

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portion of a subject electrocardiogram system monitored electrocardiogram cycle.

37. A bioelectric interface (3) as in Claim 36, in which the selected portion of a subject electrocardiogram system monitored electrocardiogram cycle is the QRS complex.

38. A bioelectric interface (3) as in Claim 16, in which the voltage present at a formed Wilson common terminal is a root-mean-square value of a selected portion of a subject electrocardiogram system monitored electrocardiogram cycle.

39. A bioelectric interface (3) as in Claim 38, in which the selected portion of a subject electrocardiogram system monitored electrocardiogram cycle is the QRS complex.

40. A bioelectric interface (3) comprising an adhesive (AS) material in functional combination with at least two spacially separated electrodes, which adhesive (AS) material simultaneously presents with essentially anisotropic specific impedance properties and essentially isotropic mechanical pliability and adhesion properties, said electrodes being affixed to said adhesive (AS) material in a manner such that their relative positions with respect to one another are essentially fixed, and such that the specific impedance from each said electrode directly through said adhesive (AS) material, is less than that between any said electrodes through said adhesive (AS) material, said bioelectric interface (3) having an undulated outer perimeter boundary shape.

41. A bioelectric interface (3) as in Claim 40, in which the adhesive (AS) material is comprised of electrically conductive polymer.

42. A bioelectric interface (3) as in Claim 41, in which the electrically conductive polymer is hydrophillic, and thereby particularly well suited for application to human skin.

43. A bioelectric interface (3) as in Claim 40, in which the electrodes are each of a construction such that contact with the adhesive (AS) material is essentially continuous over the dimension of each said electrode.

44. A bioelectric interface (3) as in Claim 40, in which at least one of said electrodes is of a multiple-piece construction such that each of said multiple pieces contacts the adhesive (AS) material independently and essentially continuously over the dimension of each said multiple pieces.

45. A bioelectric interface (3) as in Claim 44, in which the multipiece construction configures a Bulls-eye pattern.

46. A bioelectric interface (3) as in Claim 40, which further comprises a carrier matrix affixed thereto so as to sandwich said electrodes between said carrier matrix and said adhesive (AS) material, the purpose being to improve the integrity of the spacial separation between said electrodes.

47. A bioelectric interface (3) as in Claim 40, which further comprises means for electrically connecting said electrodes to external devices.

48. A bioelectric interface (3) comprising an adhesive (AS) material in functional combination with at least two spacially separated groups of electrode(s), at least one of which spacially separated group of electrode(s) can consist of more than one electrode, which adhesive (AS) material simultaneously presents with essentially anisotropic specific impedance properties and essentially isotropic pliability and adhesion mechanical properties, electrodes in said spacially separated groups of electrode(s) being affixed to said adhesive (AS) material in a manner such the relative positions of electrodes present with respect to one another are essentially fixed, and such that the specific impedance from each electrode in said groups of spacially separated electrode(s) directly through said adhesive (AS) material, is less than that between any two electrodes in different spacially separated groups of electrodes through said adhesive (AS) material, said bioelectric interface (3) having an undulated outer perimeter boundary shape.

49. A bioelectric interface (3) as in Claim 38, in which the adhesive (AS) material is comprised of electrically conductive polymer.

50. A bioelectric interface (3) as in Claim 39, in which the electrically conductive polymer is hydrophillic, and thereby particularly well suited for application to human skin.

51. A bioelectric interface (3) as in Claim 58, in which the electrodes in the groups of electrode(s) are each of a construction such that contact with the adhesive (AS) material is essentially continuous over the dimension of each said electrode.

52. A bioelectric interface (3) as in Claim 59, in which at least one if said electrodes in said groups of electrode(s) is of a multiple-piece construction such that each of said multiple pieces contacts the adhesive (AS) material independently and essentially continuously over the dimension of each said

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multiple pieces.

53. A bioelectric interface (3) as in Claim 52, in which the multipiece construction configures a Bulls-eye pattern.

54. A bioelectric interface (3) as in Claim 48, which further comprises a carrier matrix affixed thereto so as to sandwich said electrodes in said groups of electrode(s) between said carrier matrix and said adhesive (AS) material, the purpose being to improve the integrity of the spacial separation between said electrodes.

55. A bioelectric interface (3) as in Claim 48, which further comprises means for electrically connecting said electrodes in said groups of electrode(s) to external devices.

56. A bioelectric interface (3) as in Claim 48, in which the number of groups of electrode(s) is three, said bioelectric interface (3) being configured and sized so as to place said three groups of electrodes in an essentially congruent Einthoven triangle equivalent Left Arm, Right Arm, Left Leg pattern, such that in use all said groups of electrodes contact a patient's chest.

57. A bioelectric interface (3) as in Claim 48, in which
the number of groups of electrode(s) is nine, said nine groups of electrode(s) being configured in an I, II, III, V1, V2, V3, V4, V5, V6 twelve lead electrocardiogram system electrode pattern, such that said nine groups of electrode(s) are positioned on a patient's chest during use as follows:

electrode group I in the region of the second intercostal space to the right of the sternum;

electrode group II in the region of the left fourth intercostal space at the mid-axillary line;

electrode group III in the region of the inferior costal margin in the mid-clavicular line;

electrode group V1 in the region of the fourth intercostal space at the right sternal border;

electrode group V2 in the region of the fourth intercostal space at the left sternal border;

electrode group V4 in the region of the fifth intercostal space at the mid-clavicular line;

electrode group V3 in the region of the midpoint between electrode groups V2 and V4;

electrode group V5 in the region of the fifth intercostal space in the anterior axillary line; and

electrode group V6 in the region of the fifth intercostal space in the mid-axillary line;

such that during use one electrode from each group of electrode(s) will be found to be more appropriately situated for a specific patient depending upon the patient's body size.

58. A bioelectric interface (3) as in Claim 50, which further comprises three additional groups of electrode(s) which are configured and sized so as to place said additional three groups of electrodes in an essentially congruent Einthoven triangle equivalent Left Arm, Right Arm, Left Leg pattern, such that in use all said groups of electrodes contact a patient's chest.

59. A bioelectric interface (3) as in Claim 40, in which there are present a multiplicity of electrodes configured in an essentially rectangular shaped matrix such that in use said bioelectric interface (3) is affixed to one of the group consisting of a patient's chest and back, said bioelectric interface (3) being appropriate for use in electrocardiographic mapping.

60. A bioelectric interface (3) as in Claim 45, in which there are present a multiplicity of electrodes configured in an essentially rectangular shaped matrix such that in use said bioelectric interface (3) is affixed to one of the group consisting of a patient's chest and back, said bioelectric interface (3) being appropriate for use in electrocardiographic mapping.

61. A method of acquiring electrocardiographic data comprising the steps of:

a. providing a bioelectric interface (3) comprising at least two spacially separated groups of electrode(s), at least one of which spacially separated group of electrode(s) can consist of more than one electrode, which adhesive (AS) material presents with essentially anisotropic specific impedance properties but essentially isotropic mechanical properties, said spatially separated groups of electrode(s) being affixed to said adhesive (AS) material in a manner such that their relative positions with respect to one another remain essentially fixed, and such that the specific impedance from each electrode in said groups of spatially separated electrode(s) directly through said adhesive (AS) material, is less than that between any two

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electrodes in different spacially separated groups of electrodes through said adhesive (AS) material, said bioelectric interface (3) having an undulated outer perimeter boundary shape, in which bioelectric interface (3) the number of groups of electrode(s) is nine, said nine groups of electrode(s) being configured in an I, II, III, V1, V2, V3, V4, V5, V6 twelve lead electrocardiogram system electrode pattern, such that said nine groups of electrode(s) are positioned on a patient's chest during use as follows:

electrode group I in the region of the second intercostal space to the right of the sternum;

electrode group II in the region of the left fourth intercostal space at the mid-axillary line;

electrode group III in the region of the inferior costal margin in the mid-clavicular line;

electrode group V1 in the region of the fourth intercostal space at the right sternal border;

electrode group V2 in the region of the fourth intercostal space at the left sternal border;

electrode group V4 in the region of the fifth intercostal space at the mid-clavicular line;

electrode group V3 in the region of the midpoint between electrode groups V2 and V4;

electrode group V5 in the region of the fifth intercostal space in the anterior axillary line; and electrode group V6 in the region of the fifth intercostal space in the mid-axillary line;

such that during use one electrode from each group of electrode(s) will be found to be more appropriately situated for a specific patient depending upon the patient's body size;

b. affixing said bioelectric interface (3) to a patient and causing the electrodes therein to be electrically attached to an electrocardiographic system such that electrocardiographic data is obtained.

62. A method of acquiring electrocardiographic data as in Claim 61, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing; and
d. electro surgery.

on said patient without removing said bioelectric interface (3) .

63. A method of acquiring electrocardiographic data as in Claim 61, which further comprises the simultaneous step of causing at least some some of said electrodes to have a multiple component configuration.

64. A method of performing cardiac mapping comprising the steps of:

a. providing a bioelectric interface (3) comprising an adhesive (AS) material in functional combination with at least two spacially separated electrodes, which adhesive (AS) material presents with essentially anisotropic specific impedance properties but essentially isotropic mechanical properties, said electrodes being affixed to said adhesive (AS) material in a manner such that their relative positions with respect to one another remain essentially fixed, and such that the specific impedance from each said electrode directly through said adhesive (AS) material, is less than that between any said electrodes through said adhesive (AS) material, said electrical anisotropic specific impedance properties of said adhesive (AS) material being the result of a slit/void or slits/voids therein, which slit/void or slits/voids are positioned between groups of electrodes, in which bioelectric interface (3) there are present a multiplicity of electrodes configured in an essentially rectangular shaped matrix such that in use said bioelectric interface (3) is affixed to one of the group consisting of a patient's chest and back, said bioelectric interface (3) being appropriate for use in electrocardiographic mapping;

b. affixing said bioelectric interface (3) to a patient on one of the elements in the group consisting of a patient's chest and back, and causing said electrides to be connected to an electrocardiograph mapping system.

65. A method of acquiring electrocardiographic data as in Claim 64, which further comprises the simultaneous step of performing a procedure selected from the group consisting of;

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a. cardio-pulmonary resuscitation
b. cardiac defibrillation;
c. cardiac pacing; and
d. electro surgery.

66. A method of acquiring electrocardiographic data as in Claim 64, which further comprises the simultaneous step of causing at least some of said electrodes to have a multiple component configuration.

67. A bioelectric interface (3) as in Claim 1, having an undulated outer perimeter boundary shape.

68. A bioelectric interface (3) as in Claim 67, having at least one hole present through said bioelectric interface (3) at a location between electrodes.

69. A method of providing an Einthoven triangle equivalent RA, LA, LL pattern of electrodes on the chest of a subject, as in Claim 14, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having an undulated outer perimeter boundary shape.

70. A method of acquiring electrocardiographic data as in Claim 69, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having at least one hole present through said bioelectric interface (3) at a location between electrodes.

71. A bioelectric interface (3) as in Claim 16, having an undulated outer perimeter boundary shape.

72. A bioelectric interface (3) as in Claim 71, having at least one hole present through said bioelectric interface (3) at a location between electrodes.

73. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having an undulated outer perimeter boundary shape.

74. A method of acquiring electrocardiographic data as in Claim 73, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having at least one hole present through said bioelectric interface (3) at a location between electrodes.

75. A bioelectric interface (3) as in Claim 40, wherein at least one hole is present through said bioelectric interface (3) adhesive (AS) material at a location between electrodes.

76. A bioelectric interface (3) as in Claim 40, wherein said electrical anisotropic specific impedance properties of said adhesive (AS) material are the result of a slit/void or slits/voids therein, which slit/void or slits/voids are positioned between electrodes.

77. A bioelectric interface (3) as in Claim 40, wherein at least one hole is present through said bioelectric interface (3) adhesive (AS) material at a location between electrodes.

78. A bioelectric interface (3) as in Claim 48, wherein said electrical anisotropic specific impedance properties of said adhesive (AS) material are the result of a slit/void or slits/voids therein, which slit/void or slits/voids are positioned between groups of electrodes.

79. A bioelectric interface (3) as in Claim 48, wherein at least one hole is present through said bioelectric interface (3) adhesive (AS) material at a location between electrodes.

80. A method of acquiring electrocardiographic data as in Claim 61 in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having an undulated outer perimeter boundary shape.

81. A method of acquiring electrocardiographic data as in Claim 80, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interface (3) having at least one hole present through said bioelectric interface (3) at a location between electrodes.

82. A bioelectric interface (3) as in Claim 16, which further comprises fold enhancing perforations located between said V3 and V4 electrodes.

83. A method of acquiring electrocardiographic data as in Claim 29, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interace with fold enhancing perforations located between said V3 and V4 electrodes.

84. A method of acquiring electrocardiographic data as in Claim 61, in which the step of providing a bioelectric interface (3) includes providing a bioelectric interace with fold enhancing perforations located between said V3 and V4 electrodes.

85. A bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least nine (9) spatially separated electrocardiogram system electrodes, each of said at least nine (9) spatially separated electrocardiogram system electrodes being of a construction selected from a

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group consisting of: (a single electrical electrode element and a group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin, nine (9) of said at least nine (9) electrocardiogram system electrodes being configured in an RA, LA, LL, V1, V2, V3, V4, V5, V6 electrocardiogram system electrode pattern, such that said nine (9) electrocardiogram system electrodes are applied to a subject's chest during use as follows:

electrode RA being generally in the region of the second intercostal space to the right of the sternum;

electrode LA being generally in the region of the left fourth intercostal space in the mid-axillary line;

electrode LL being generally in the region of the inferior costal margin in the left mid-clavicular line;
said electrodes RA, LA and LL being positioned so as to form, in use, an Einthoven frontal lead triangle with an equivalent I, II, III lead pattern;

electrode V1 in the region of the fourth intercostal space at the right sternal border;

electrode V2 in the region of the fourth intercostal space at the left sternal border;

electrode V4 in the region of the fifth intercostal space at the left mid-clavicular line;

electrode V3 in the region of the midpoint between electrode groups V2 and V4;

electrode V5 in the region of the fifth intercostal space in the left anterior axillary line; and

electrode V6 in the region of the fifth intercostal space in the left mid-axillary line;
which bioelectric interface (3) further comprises an electrocardiogram system RL electrode;
which bioelectric interface (3) further comprises perforations in said support sheet (SUP) which allow easy detachment and deployment of at least one of said electrocardiogram RA, LA, LL and RL electrodes, thereby allowing positioning at a location selected from the group consisting of: (in contact with a subject's chest, and in conventional subject limb position);
which bioelectric interface (3) further includes a fold enhancing impression and/or perforations located between at least two electrodes selected from the group consisting of: (V1 and V2; V2 and V3; V3 and V4; V4 and V5; V5 and V6; RA and V1; V4 and LL; LA and V6);
in which said bioelectric interface (3) the support sheet (SUP) is at least partially covered with an adhesive (AS) material on a subject contacting side thereof, which adhesive (AS) material presents with electrical conductive properties selected from the group consisitng of: (isotropic electrical conductive properties, and anisotropic electrical conductive properties such that the regional specific impedance through said adhesive (AS) material is less than in a laterally oriented dimension direction therealong); said adhesive (AS) material being selected from the group consisting of: (hydrophillic and non-hydrophillic).

86. A bioelectric interface (3) as in Claim 85, further comprises at least one hole present through said support sheet (SUP) at a location between electrodes, which hole allows access to a subject's skin in use.

87. A bioelectric interface (3) as in Claim 86, in which at least one hole is present at a location selected from the group consisting of: (the level of the second intercostal space adjacent to said RA electrode, and the level of the fourth intercostal space adjacent to said V1 electrode, and between said RA and V2 electrodes, and between said V4 and V5 electrodes).

87. A bioelectric interface (3) as in Claim 85, in which fold enhancing impression(s) and/or perforations are located between V3 and V4 electodes, and between RA and V1 electrodes.

88. A bioelectric interface (3) as in Claim 85, which has an undulated outer perimeter boundary shape.

89. A bioelectric interface (3) as in Claim 85, in which at least one electrode is comprised of a group of electrically independent electrode elements are present and configured in a bulls-eye.

90. A bioelectric interface (3) comprising a support sheet (SUP) in functional combination with at least three spatially separated electrocardiogram system electrodes, each of said at least three spatially separated electrocardiogram system electrodes being of a construction selected from a group consisting of: (a single electrical electrode element and a

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group of electrically independent electrode elements), each of said spatially separated electrocardiogram system electrodes being affixed to said support sheet (SUP) in a manner such that the relative positions of said electrocardiogram system electrodes with respect to one another are essentially fixed therewithin; two of said at least three electrocardiogram system electrodes being selected from a group of electrodes consisting of equivalent RA, LA, LL and RL electrocardiogram system electrodes, and one of said at least three electrocardiogram system electrodes being selected from a group of electrocardiogram system electrodes consisting of V1, V2, V3, V4, V5, and V6 precordial electrodes.

91. A bioelectric interface suitable for monitoring electrocardiographic signals from a subject, said bioelectric interface comprising subject chest mounted right-arm (RA), left arm (LA) and left-leg (LL) electrodes which, in use, configure an equivalent Einthoven frontal I, II, III limb lead pattern.

92. A bioelectric interface suitable for monitoring electrocardiographic signals from a subject, said bioelectric interface comprising subject chest mounted precordial V1, V2, V3, V4, V5, and V6 electrodes.

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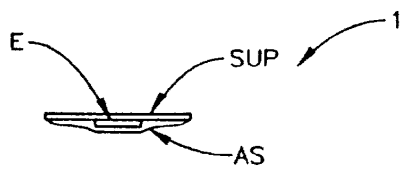


FIG. 1a

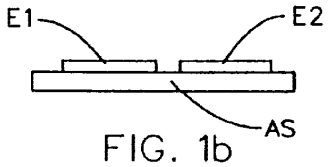


FIG. 1b

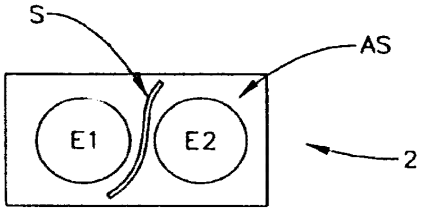


FIG. 2



FIG. 4a

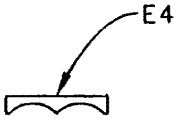


FIG. 4b

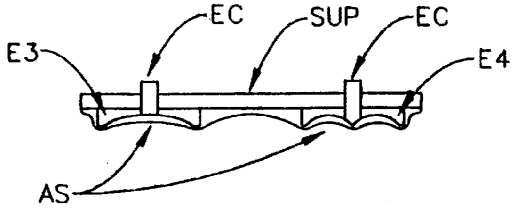


FIG. 4c

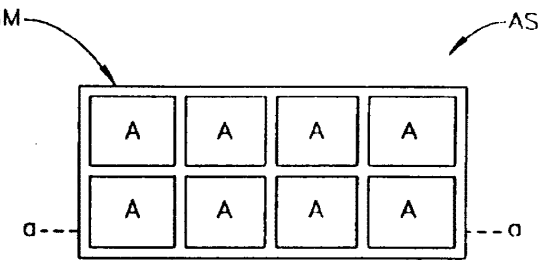


FIG. 3a

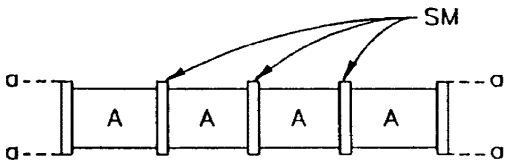


FIG. 3b

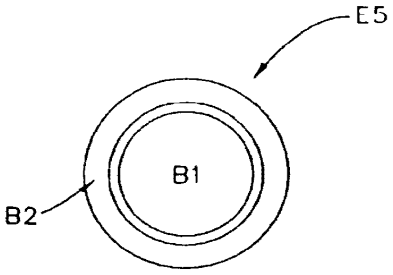


FIG. 5a

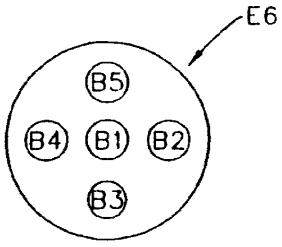


FIG. 5b

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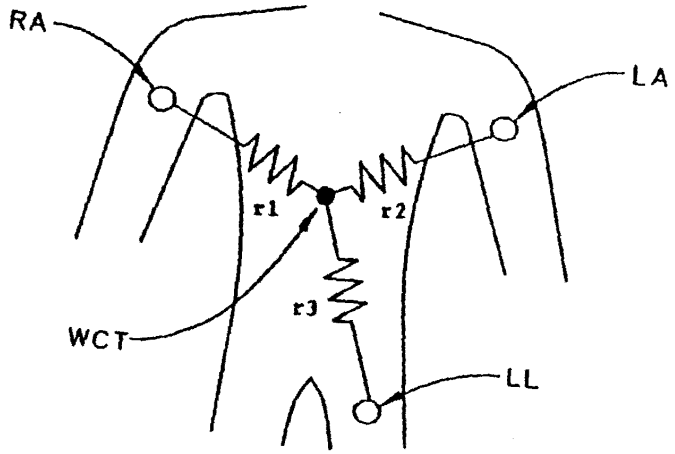


FIG. 6a

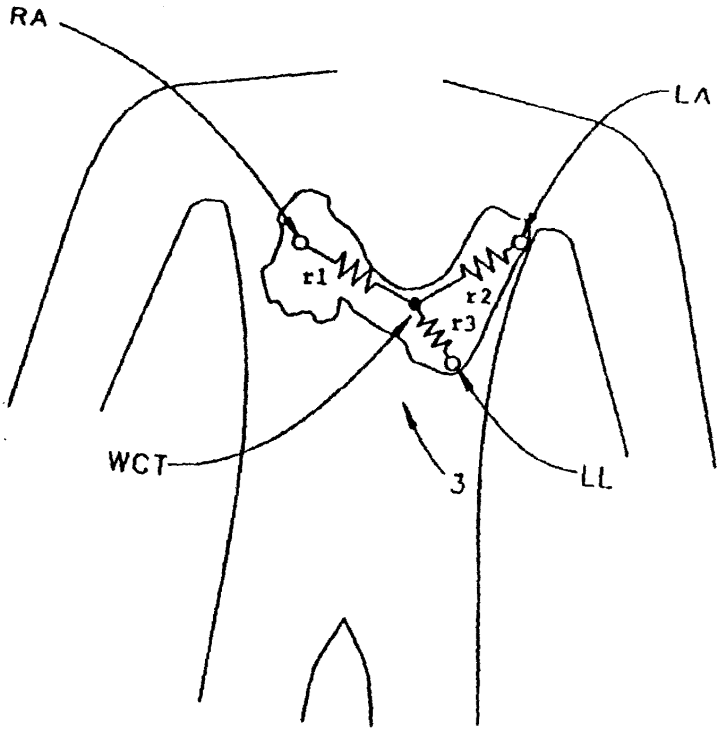


FIG. 6b

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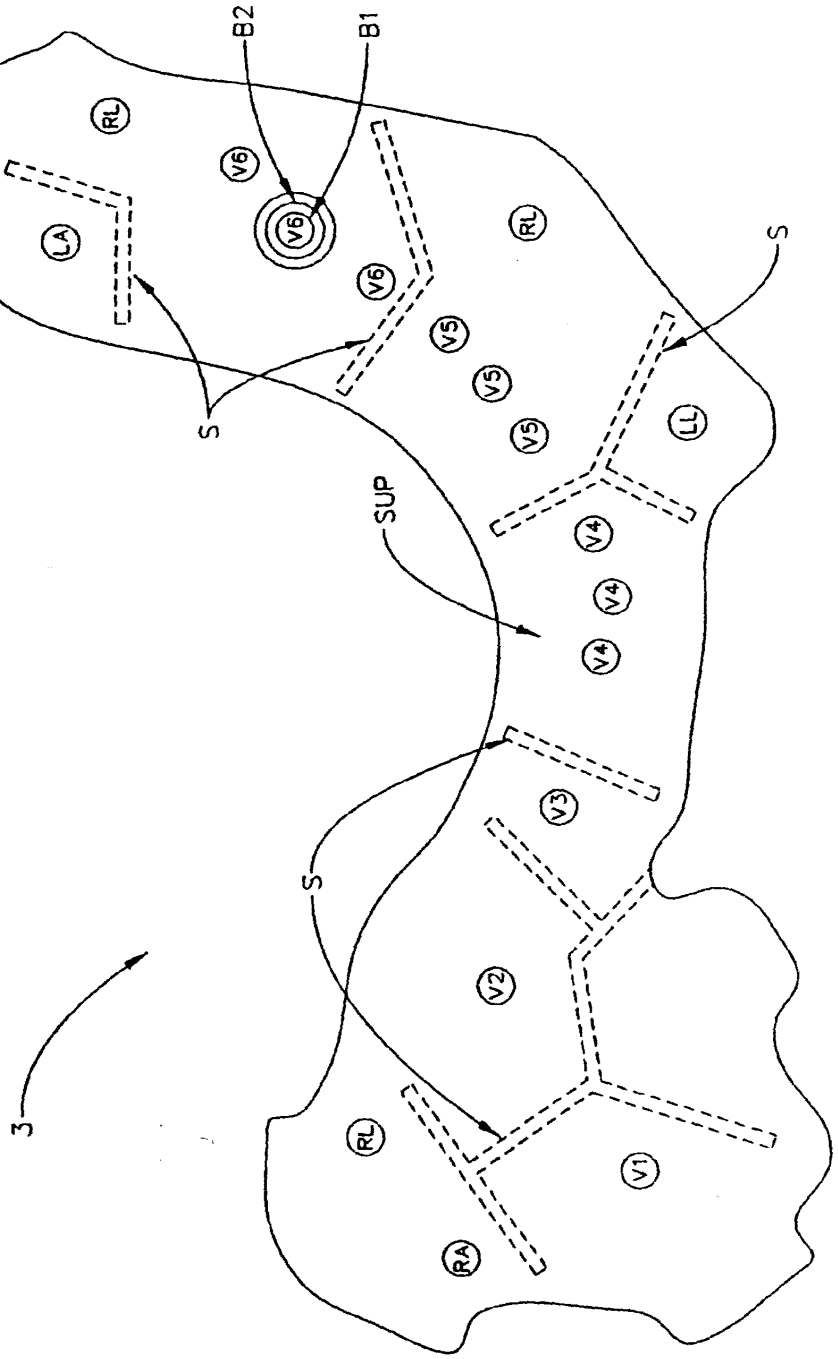


FIG. 7a

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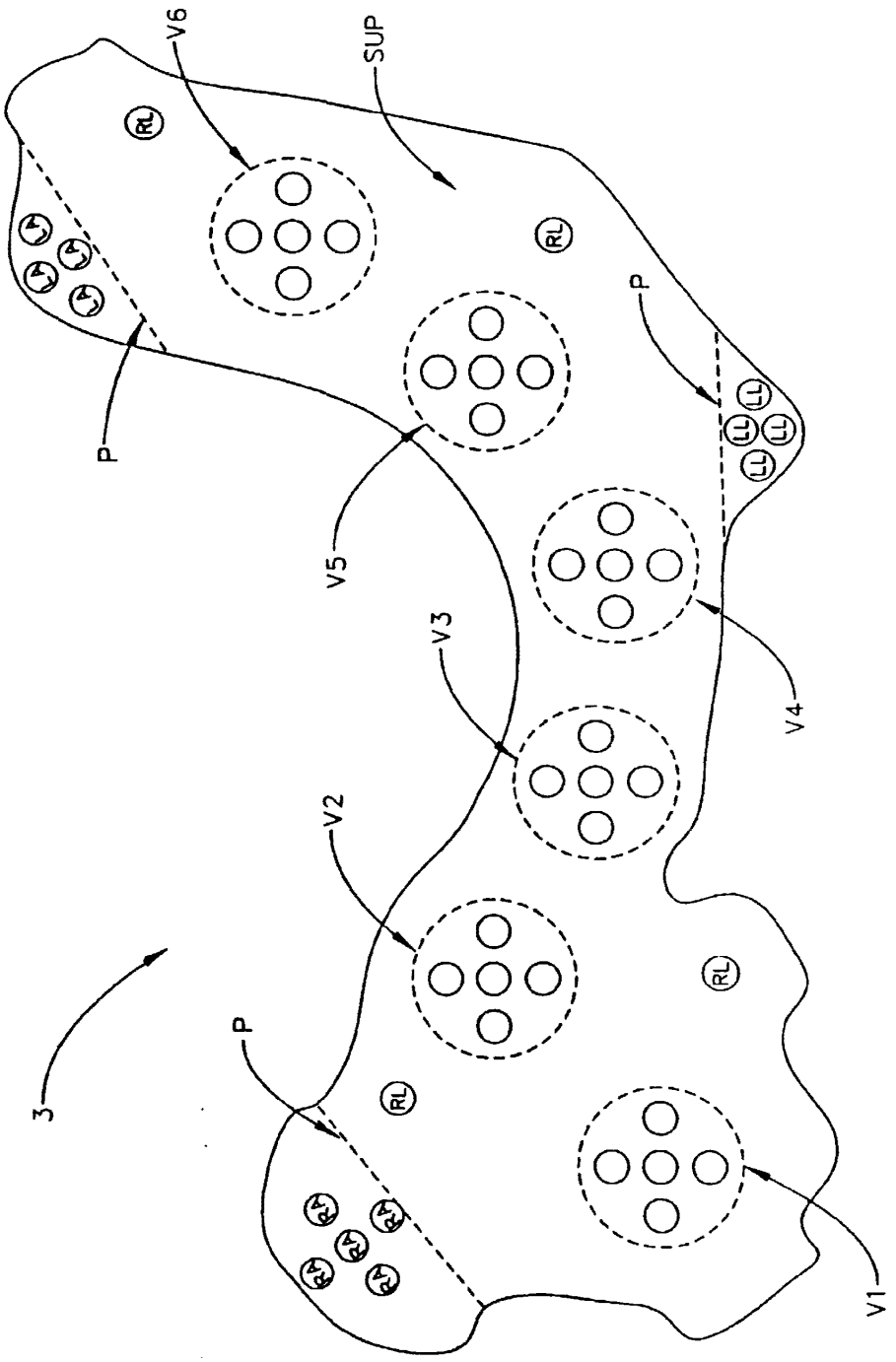


FIG. 7b

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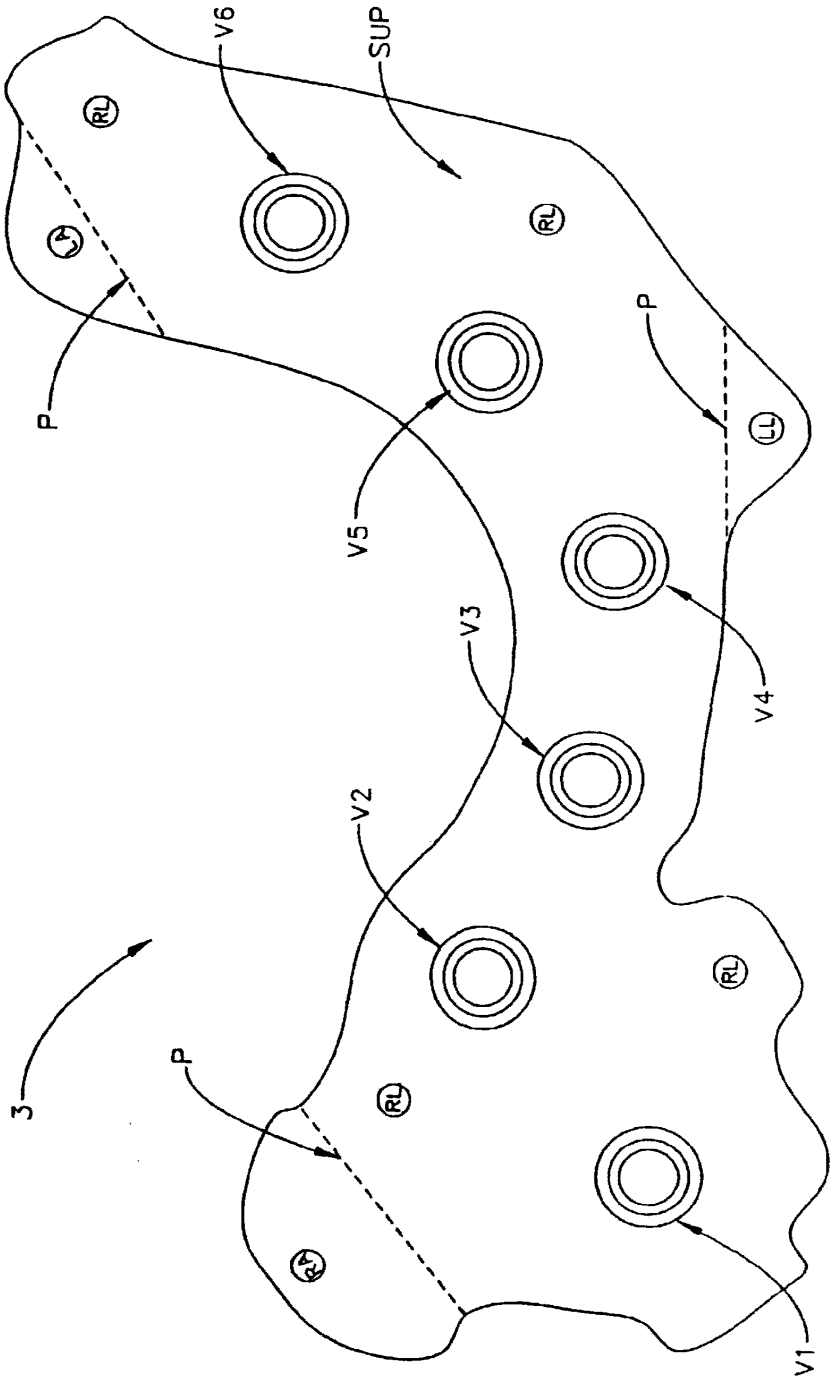


FIG. 7c

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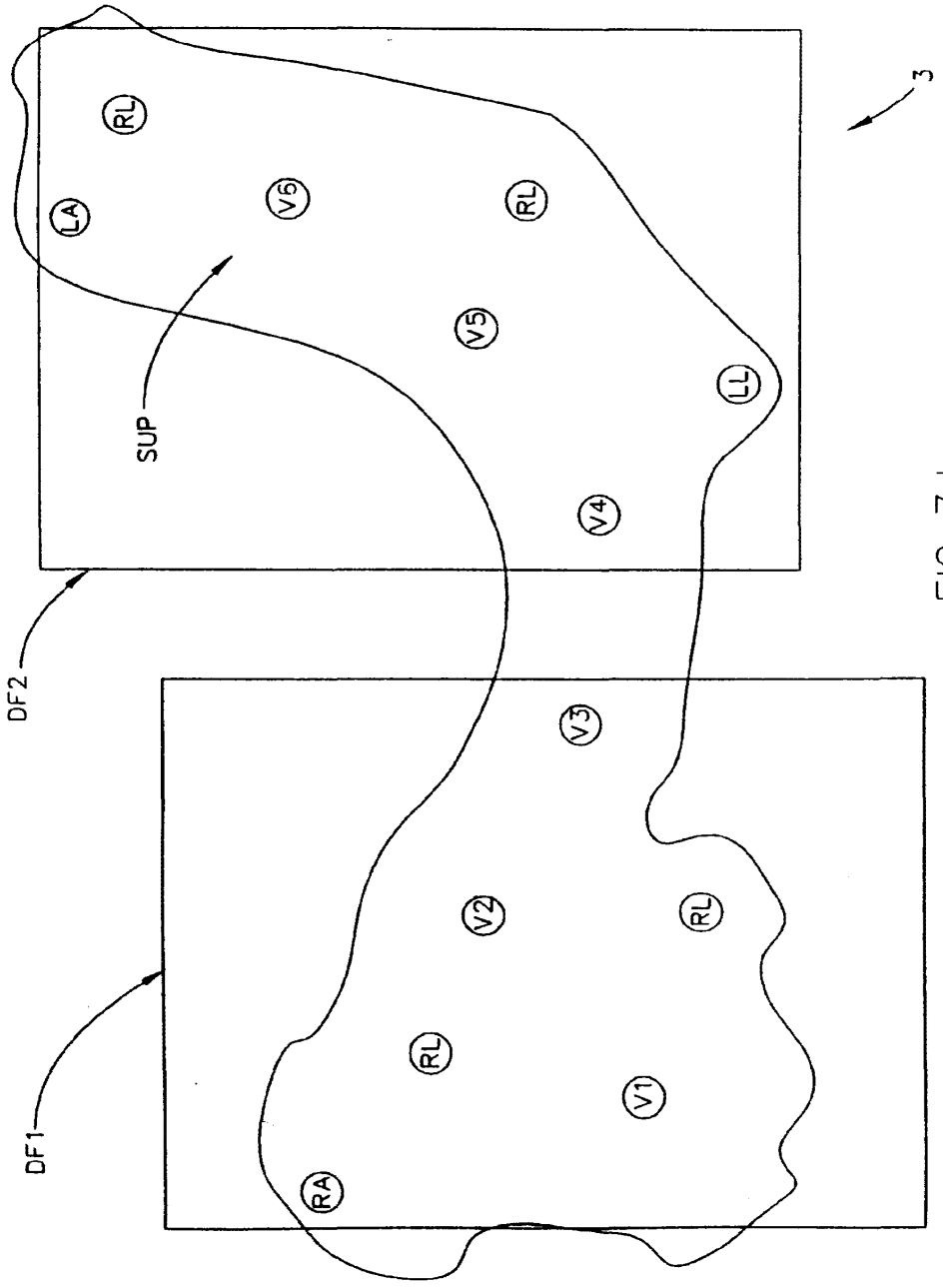


FIG. 7d

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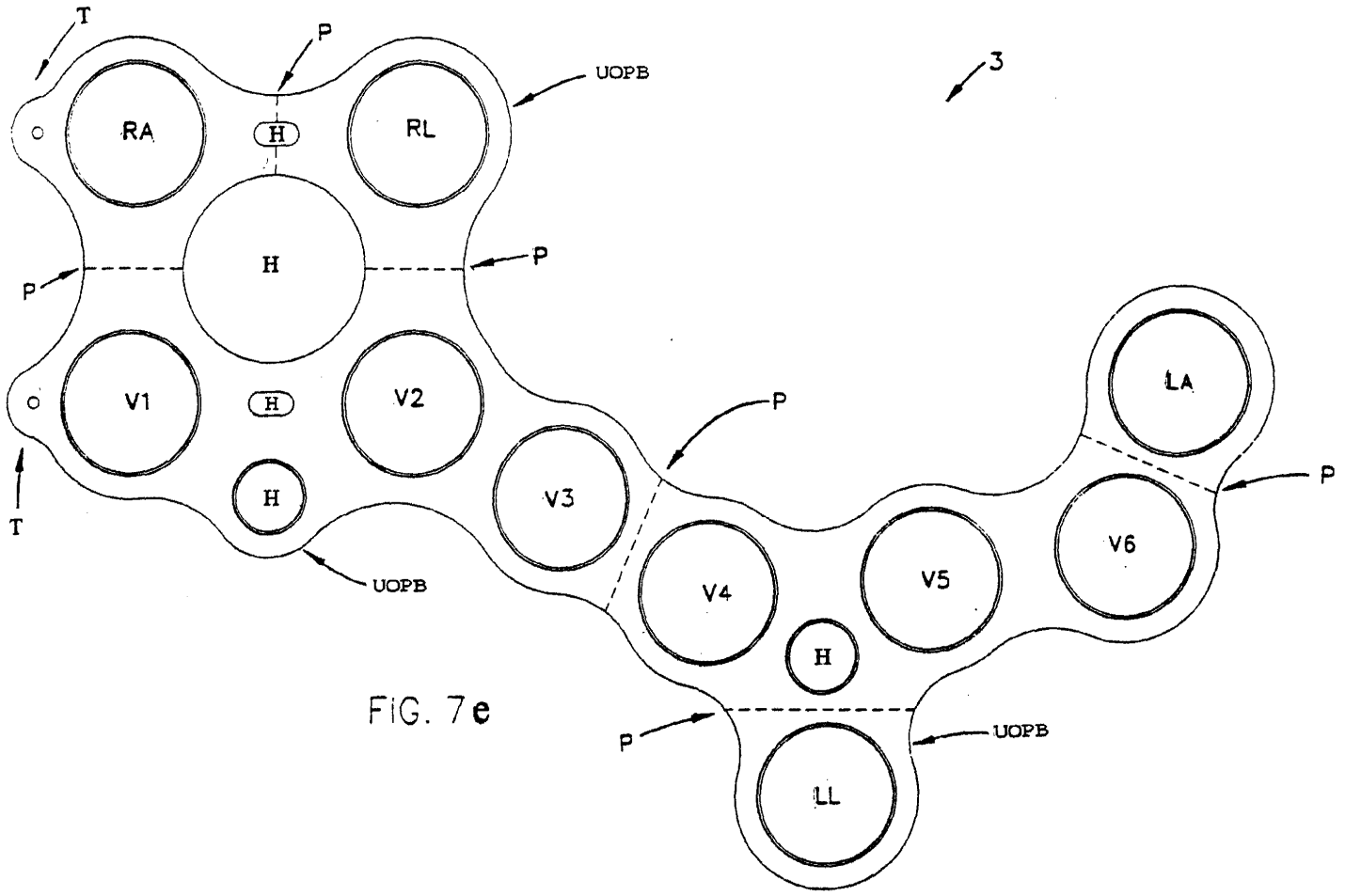


FIG. 7e

European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

which under Rule 45 of the European Patent Convention shall be considered, for the purposes of subsequent proceedings, as the European search report

Application Number EP 97 30 8319

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
E	US 5 678 545 A (STRATBUCKER) * the whole document * ---	1-92	A61B5/0408
X,D	EP 0 509 689 A (PHYSIO-CONTROL CORPORATION) * the whole document * ---	1-5,8, 12, 16-20, 23,27, 85,90-92	
X	WO 94 01039 A (SEGALOWITZ) * the whole document * ---	1,2,5, 12,16, 17,20, 27,90-92 85	
X,D	US 5 184 620 A (MARQUETTE ELECTRONICS) * column 5, line 43 - column 8, line 47 * --- -/--	1,5,12, 16,20, 27,90-92 82,85, 87,89	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61B

INCOMPLETE SEARCH

The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims.

Claims searched completely :

1-13,16-28,36-39,67,68,71,72,82,85-92

Claims searched incompletely :

Claims not searched :

14,15,29-35,61-66,69,70,73,74,80,81,83,84

Reason for the limitation of the search:

Article 52(4) EPC

Place of search	Date of completion of the search	Examiner
THE HAGUE	8 April 1998	LEMERCIER, D

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C07)

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European Patent Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 97 30 8319

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X,D	WO 90 01898 A (GROEGER) * page 3, line 14 - page 4, line 23; figure 1 * ---	1,2,5,8,9,12,16,17,20,23,24,27,67,71,90-92 85,88	
A	WO 90 09143 A (SEGALOWITZ) * the whole document * ---	1,2,5-11,16,17,20-26,36-39,85,90-92	TECHNICAL FIELDS SEARCHED (Int.Cl.6)
A,D	DE 36 37 956 A (CHERNE INDUSTRIES) * column 11, line 11 - column 15, line 35 * -----	1,5,8,16,20,23,68,72,85-87,90-92	

EPO FORM 1503 03.82 (P04C10)

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European Patent Office

Application Number
EP 97 30 8319

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☒ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-13,16-28,36-39,67,68,71,72,82,85-92

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European Patent Office

LACK OF UNITY OF INVENTION SHEET B

Application Number
EP 97 30 8319

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-13,16-28,36-39,67,68,71,72,82,85-92

   bioelectric interface comprising a support sheet for electrodes.

2. Claims: 40-60,75-79

   bioelectric interface comprising an adhesive.

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Espacenet

Bibliographic data: JP11042214 (A) — 1999-02-16

PORTABLE WIRELESS ELECTROCARDIOGRAM MONITOR

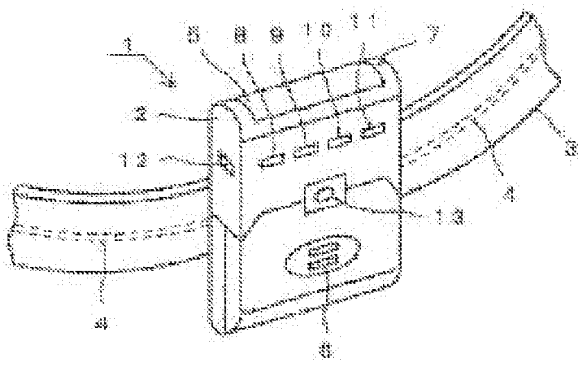
Inventor(s):	IDO TERUO ±	
Applicant(s):	IDO TERUO ±	
Classification:	**- international:**	***A61B5/00; G06F19/00; G06Q50/00; G08B25/04;*** (IPC1-7): A61B5/00; G06F19/00; G08B25/04
	- European:	
Application number:	JP19970214178 19970723	
Priority number(s):	JP19970214178 19970723	

Abstract of JP11042214 (A)

PROBLEM TO BE SOLVED: To obtain heartbeat data and electrocardiogram data of a patient automatically and carry out reliable finding and life-saving even if an abnormality occurs to the patient while he is out, in home medical care. SOLUTION: A portable wireless electrocardiogram monitor 1 is mounted on the waist of a patient, and a breast-mounted wireless electrocardiograph is mounted on the breast or preferably near the heart of the patient. Heart rate data and electrocardiogram data obtained from the instruments are transmitted by radio automatically to a medical institution periodically or when an abnormality occurs. If the medical institution finds an abnormality from the analysis of the data, it sends medical advice to the patient by sound or text if his condition is less serious. If it is considered that an emergency has occurred, it dispatches a care vehicle or ambulance equipped with a car navigation system for finding and life-saving of the patient on the basis of position information of the patient obtained from the instrument 1.

Last updated: 14.03.2012 Worldwide Database 5.7.38; 93p

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(19)日本国特許庁（ＪＰ）　(12) **公開特許公報（Ａ）**　(11)特許出願公開番号

特開平11－42214

(43)公開日　平成11年(1999)２月16日

(51)Int.Cl.[6]	識別記号	ＦＩ	
Ａ６１Ｂ　5/00	１０２	Ａ６１Ｂ　5/00	１０２Ｃ
Ｇ０６Ｆ　19/00		Ｇ０８Ｂ　25/04	Ｋ
Ｇ０８Ｂ　25/04		Ｇ０６Ｆ　15/42	Ｅ

審査請求　未請求　請求項の数４　ＦＤ　（全　７　頁）

(21)出願番号　特願平9－214178

(22)出願日　平成９年(1997)７月23日

(71)出願人　597050129
井戸　照夫
静岡県浜松市高丘町655－４

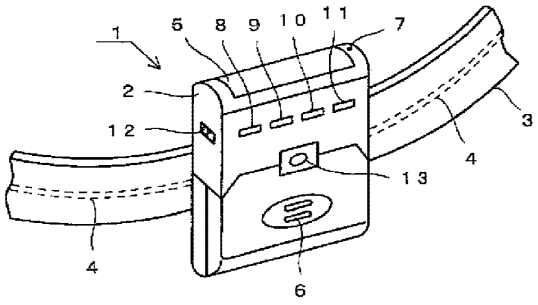
(72)発明者　井戸　照夫
静岡県浜松市高丘町655－４

(54)【発明の名称】　携帯型無線心電監視装置

(57)【要約】

【課題】　在宅医療において、患者の心拍数データや心電図データ等を自動的に得ると共に、外出中の患者に異常が発生した場合でも確実な発見および救助を行う。

【解決手段】　患者の腰部に携帯型無線心電監視装置を装着し、さらに患者の胸部好ましくは心臓付近に胸当て無線心電計を装着する。該装置より得られる心拍数データや心電図データ等を、定期検診時または異常時にはその都度、自動的に無線により医療機関に送信する。医療機関では前記データを解析し異常が見られた場合、程度の軽いものであれば音声または文字による医療アドバイスを患者宛てに送信する。また、緊急事態が発生していると判断した場合は、カーナビゲーションシステムを搭載した介護車または救急車を出動させ、前記装置より得られる患者の位置情報等により患者の発見および救助を行う。



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【特許請求の範囲】
【請求項１】　本体とベルトで構成され、本体内には無線データ送受信手段、データ表示手段、音声入出力手段、警報手段、制御手段、スイッチからの信号を入力するインターフェース手段等を内蔵し、ベルト内にアンテナを内蔵した装置を患者に所持させ、外部無線心電計から送信される心電データを演算処理して得られたデータを簡易無線により定期的に医療機関に送信したり、該データに対する医療機関からの指示を受信する機能を有することを特徴とした、携帯型無線心電監視装置。
【請求項２】　無線データ送受信手段としてＧＰＳ信号を受信する機能とＤ－ＧＰＳ対応のＦＭ多重放送を受信する機能とを有し、患者が外出先で倒れたり徘徊等により行方不明になった場合に、前記ＧＰＳより送信される位置情報等から患者の所在位置を認識して、異常状況と所在位置を医療機関に送信することで患者の救出を容易に行う機能を有することを特徴とした、請求項１に記載の携帯型無線心電監視装置。
【請求項３】　無線データ送受信手段と別置の衛星通信送受信手段を経由することにより通信衛星との間で通信を行う機能を有し、簡易無線で通信不可能な遠隔地にある医療機関と通信を行うことができる機能を有することを特徴とした、請求項１および請求項２に記載の携帯型無線心電監視装置。
【請求項４】　医療機関からの指示を受信する場合において、着信を音声や警報または振動等で患者に知らせる機能と、指示に対する反応がなく患者が危険な状態であると判断した場合に警報および発光手段により、患者の周辺者に注意を促し救助を受けることができることを特徴とした、請求項１、請求項２および請求項３に記載の携帯型無線心電監視装置。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、医療機関と患者がそれぞれ保有する無線心電監視装置により心拍数データや心電図データ等の医療情報を遠隔監視し適宜医療アドバイスを行う在宅医療と、異常時において患者に意識がない場合でも自動的に救急通報を発信することのできる機能を有して患者を救助することができる、無線心電監視装置に関するものである。
【０００２】
【従来の技術】心臓疾患のある患者や高齢者または独居老人を対象とした在宅医療として、訪問看護婦による定期検診が行われている。また近年、通信技術の発達により電話回線を用いて携帯型心電図記憶装置で心電図データを医療機関に送信し、心電図解析等を行う在宅医療支援システムが稼動され始めている。また、心拍数データを簡易型携帯電話（以後、ＰＨＳという。）を利用して医療機関に送信し、患者を遠隔監視する在宅医療支援システムも検討され始めている。
【０００３】
【発明が解決しようとする課題】しかしながら、従来のような訪問看護婦による定期検診では検診時における患者の様子をみるだけであり、定期検診時以外の患者の様子を把握することができないという問題があった。また、定期検診時以外の時に患者の容体に変化または異常が起きた場合は患者本人や周辺者からの通報により救助を行っているが、前記異常時に患者本人が外出していたり自宅内にいても家族等が外出して患者独りの場合において、意識がなく動けない場合には通報することができないという問題があった。また、意識があり動ける場合であっても外出時等においては正確な所在位置を通報できないことも多い。この結果、患者の発見が遅れ医療上の手遅れを招くという問題もあった。
【０００４】また、電話回線を用いて携帯型心電図記憶装置で心電図データを医療機関に送信し、心電図解析等を行う在宅医療支援システムにおいても、前述と同様にその時点での患者の様子をみるだけであり、患者の容体に変化または異常が起きた場合、その時点の状況を把握することができなかった。しかも、電話回線を用いる方式のため外出先から容易にデータを送信することができなかった。
【０００５】また、ＰＨＳを利用して心拍数データを医療機関に送信し、患者を遠隔監視する在宅医療支援システムにおいては、患者の状態を常時監視できるものの、地方の小都市を始め高齢者の多い山間地や過疎地域まで含めたＰＨＳの通話可能領域を拡大する等の社会的基盤の拡充を計るには多大な設備投資と長期に渡る施工期間が必要であり、ＰＨＳ利用の在宅医療支援システムの運用にはこれらの整備拡充を待たなければならないという問題がある。さらに、電話回線を使用するためデータ送受信毎に通話料金が課金され、運用経費がかさむという問題もある。
【０００６】また、ＰＨＳは在宅医療支援システムで使用されるよりも一般通話を目的として使用される場合が圧倒的に多い。ＰＨＳのように不特定多数によって運用される無線周波数では、その中から特定の発信元のみを検出し受信時点における電界強度または電力強度の変移によって発信される電波の方位を探索することは識別処理が困難でかつ時間も要する。このため、患者に意識がなく連絡できない場合にＰＨＳからの電波を検出して患者の所在位置を正確に探索することは困難となるという問題もある。
【０００７】本発明はこのような問題点に鑑み、専用周波数を用いた簡易無線により外出時でも定期的に心拍数データや心電図データ等を自動送信し、しかも患者の容体に変化または異常が起きた場合には異常信号を自動送信し、患者の早期発見および早期救助を行うことを目的に発明されたものである。
【０００８】

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【課題を解決するための手段】上記の目的を達成するために、患者の胸部には図１にあるような携帯型無線心電監視装置１を装着する。該携帯型無線心電監視装置１は本体２とベルト３で構成される。本体２の上部にはモードスイッチ８、設定スイッチ９、警報リセットスイッチ１０、バックライトスイッチ１１、電源スイッチ１２、マイクロホン７およびＬＣＤ５が、本体２の中央部はスピーカ６および発光ランプ１３が設けられる。ベルト３内にはアンテナ４を内蔵する。図２は本発明の携帯型無線心電監視装置を構成するブロック図である。アンテナ４、データ送受信部１４、ＦＭ波受信部１５、ＣＰＵ１６、ＬＣＤ駆動部１７、ＬＣＤ５、データメモリ部１８、タイマ部１９、音声出力部２０、音声入力部２１、バイブレータ２２、インターフェース部２３、電源ユニット２４、およびバッテリ２５で構成される。インターフェース部２３にはモードスイッチ８、設定スイッチ９、警報リセットスイッチ１０およびバックライトスイッチ１１を接続し、さらに振動センサ（図示せず）および発光ランプ１３を接続する。また、音声出力部２０にはスピーカ６を、音声入力部２１にはマイク７を接続する。

【０００９】患者の胸部には図３にあるような胸当て無線心電計２６を装着する。該胸当て無線心電計２６は本体２７とベルト２８で構成される。本体２７の内側には心電センサ（図示せず）が、外側には制御部およびバッテリ３８が、さらに本体２７の上部には電源スイッチ３１が設けられる。制御部内にはアンテナ２９を内蔵する。また、本体２７とベルト２８を固定部３０で留める。図４は本発明の胸当て無線心電計を構成するブロック図である。アンテナ２９、データ送受信部３２、ＣＰＵ３３、タイマ部３４、バイブレータ３５、インターフェース部３６、電源ユニット３７およびバッテリ３８で構成される。インターフェース部３６には心電センサを接続する。

【００１０】また、遠隔地と通信するために通信衛星を中継する衛星通信を行うには図５にあるような衛星通信コンバータ３９および専用パラボラアンテナ４３を用い、携帯型無線心電監視装置１からの信号を前記衛星通信コンバータ３９および専用パラボラアンテナ４３を中継して行う。図６は本発明の衛星通信コンバータを構成するブロック図である。アンテナ４０、データ送受信部４９、ＣＰＵ５０、コンバータ５１、データ送受信部５２、データメモリ部５３、タイマ部５４、インターフェース部５５、電源ユニット５６およびバッテリ４３で構成される。インターフェース部５５にはモードスイッチ４１およびモニタランプ４２を接続する。専用パラボラアンテナ４３は反射器４４、導波管４５、支柱４６および固定台４７で構成され、衛星通信コンバータ３９と同軸ケーブル４８で接続する。

【００１１】

【発明の実施の形態】本発明の実施の形態を図を用いて詳しく説明する。図１は本発明の携帯型無線心電監視装置の斜視図である。該携帯型無線心電監視装置１は外観上は万歩計と同様であり、本体２とベルト３で構成される。本体２の上面にはＬＣＤ５およびマイク７を有し、本体２の上部正面にはモードスイッチ８、設定スイッチ９、警報リセットスイッチ１０、バックライトスイッチ１１を有し、本体２の上部側面には電源スイッチ１２を有し、中央部正面にはスピーカ６および発光ランプ１３を有する。また、ベルト３内にはアンテナ４を内蔵する。バッテリ２５は充電可能な２次電池で、外部ＡＣアダプタより電源ユニット２４を経由して充電される。図２は本発明の携帯型無線心電監視装置を構成するブロック図である。モードスイッチ８、設定スイッチ９、警報リセットスイッチ１０、バックライトスイッチ１１、発光ランプ１３およびバイブレータ２２がインターフェース部２３を経由してＣＰＵ１６に接続される。また、本体２に内蔵された振動センサ（図示せず）も同様にインターフェース部２３を経由してＣＰＵ１６に接続される。該振動センサは携帯型無線心電監視装置１の振動や傾きを検出し、胸当て無線心電計２６と合わせて患者の状態（緊急事態であるか携帯型無線心電監視装置１を外している状態であるかなど）を判断するために使用される。ＣＰＵ１６では胸当て無線心電計２６からの心電データを演算処理し１分間の心拍数データや心電図データを算出すると共にサンプリングを行い、データメモリ部１８にサンプリングデータを蓄積する。また、タイマ部１９はＣＰＵ１６の基準クロックになると共に時計機能として時刻データを生成する。そして、前記心拍数データや心電図データおよび時刻データをＬＣＤ駆動部１７を経由してＬＣＤ５に表示する。

【００１２】予め設定された定期検診時刻になった場合は前記心拍数データや心電図データ等をデータ送受信部１４を経由してアンテナ４より電波として発射する。また、該データが異常値と判断した場合にはその都度異常信号として同様にデータ送受信部１４を経由してアンテナ４より電波として発射する。該電波の送信出力は１Ｗ以上あり、半径３Ｋｍ以上のゾーンをカバーする能力がある。

【００１３】近年、電波を含む電磁波の人体への影響が懸念されている。本発明の携帯型無線心電監視装置１においてベルト３内にアンテナ４を内蔵し、また、胸当て無線心電計２６において本体２７内にアンテナ２９を内蔵し電波を発射しているが、ベルト３の裏面や本体２７とアンテナ２９の間にカーボン材等でできた電磁波吸収帯や電磁波遮蔽帯（図示せず）等を接着もしくは挿入することで人体側への磁束密度を減少させることができ、人体への影響を回避することが可能である。また、ペースメーカー等の医療機器の誤動作を引き起こす可能性も問題視されているが、同様にカーボン材等でできた電磁

波吸収肌着や電磁波遮蔽肌着（図示せず）等を着ることで、ペースメーカー等の医療機器への影響を回避することが可能である。

【００１４】ＣＰＵ１６には音声出力部２０を経由してスピーカ６が接続され、音声入力部２１を経由してマイク７が接続される。上述のように予め設定された時刻に収集された定期検診データに異常が見られた場合や異常信号が発信された場合、医療機関は医療アドバイスとして音声信号またはメッセージ信号を送信する。携帯型無線心電監視装置１は該信号を受信し、音声信号の場合は音声出力部２０を経由してスピーカ６より音声メッセージや警報を吹鳴する。メッセージ信号の場合はＬＣＤ駆動部１７を経由してＬＣＤ５に文字メッセージを表示する。これらのメッセージに対する応答としてモードスイッチ８および設定スイッチ９で応答を返したり、直接マイク７に向かって話してもよい。応答がない場合は患者に緊急事態が発生していると判断し、スピーカ６より警報を吹鳴したり発光ランプ１３を点滅させ周辺者に注意を促し救助を受けることが可能となる。なお、前記医療アドバイスの受信時にスピーカ６を吹鳴させたくない場合には、モードスイッチ８および設定スイッチ９でバイブレータ２２，３５を選択することにより振動で受信を知ることが可能である。

【００１５】また、図３は本発明の胸当て無線心電計の斜視図であり、本体２７とベルト２８で構成される。本体２７の内側には心電センサ（図示せず）を有し、外側には制御部を有する。該制御部内には制御回路のほかにバッテリ３８やアンテナ２９を内蔵する。バッテリ３８は充電可能な２次電池で、外部ＡＣアダプタより電源ユニット３７を経由して充電される。さらに本体２７の上部には電源スイッチ３１を有する。また、本体２７とベルト２８を固定部３０で留める。図４は本発明の胸当て無線心電計を構成するブロック図である。心電センサ（図示せず）がインターフェース部３６を経由してＣＰＵ３３に接続される。該ＣＰＵ３３では心電センサからの信号を演算処理し心電データとしてデータ送受信部３２を経由しアンテナ２９より携帯型無線心電監視装置１に対し電波として発射する。

【００１６】さらに、図５の本発明の衛星通信コンバータおよび専用パラボラアンテナの斜視図にあるように、別置の衛星通信コンバータ３９および専用パラボラアンテナ４３を経由することにより通信衛星との間で通信を行う機能を有し、簡易無線で通信不可能な遠隔地にある医療機関と通信を行うことができる。図６は、本発明の衛星通信コンバータを構成するブロック図である。携帯型無線心電監視装置１より送信された電波信号はアンテナ４０に入りデータ送受信部４９を経由して信号処理した後ＣＰＵ５０に入力される。該ＣＰＵ５０では信号処理を行いコンバータ５１およびデータ送受信部５２を経由し専用パラボラアンテナ４３より電波として発射する。ＣＰＵ５０には前記信号を蓄積するためのデータメモリ部５３や該ＣＰＵ５０の基準クロックを生成するタイマ部５４が接続される。また該衛星通信コンバータ３９のモードを設定するモードスイッチ４１や通信状態を監視するモニタランプ４２がインターフェース部５５を経由して接続される。電源ユニット５６は交流電源および直流電源が入力可能で、商用電源やカーバッテリー等に接続することができる。電源ユニット５６の２次側にはバッテリ５７が接続され常時充電を行っており、前記電源の取れない場所においても使用可能である。

【００１７】

【実施例】本発明の実施例を図を用いて説明する。図１は本発明の携帯型無線心電監視装置の斜視図で、図３は本発明の胸当て無線心電計の斜視図である。在宅看護の必要のある患者に、携帯型無線心電監視装置１をベルト３により腰部に装着させ、また、胸当て無線心電計２６をベルト２８により胸部好ましくは心臓付近に装着させる。胸当て無線心電計２６からは携帯型無線心電監視装置１に対し患者の心電データを微弱無線により送信する。携帯型無線心電監視装置１は胸当て無線心電計２６からの心電データを演算処理し１分間の心拍数データや心電図データを算出すると共にサンプリングを行い、データメモリ部１８にサンプリングデータを蓄積する。

【００１８】通常、携帯型無線心電監視装置１は医療機関に対し予め設定された定期検診時刻に、心拍数データ，心電図データ，患者ＩＤ番号，地域ＩＤ番号および患者の位置データ等を自動送信する。また、前記データに異常が見られた場合には異常信号としてその都度自動送信する。

【００１９】携帯型無線心電監視装置１の上面にはＬＣＤ５があり、前記心拍数データや心電図データおよび時刻データを表示することができる。なお、周囲が暗くなった場合にはバックライトスイッチ１１をＯＮにしてＬＣＤ５の裏面のバックライトを点灯し、ＬＣＤ５を見やすくすることができる。

【００２０】携帯型無線心電監視装置１より医療機関に送信された定期検診データまたは異常信号は担当医および予め設置されている情報処理システムにより直ちに解析される。そこで何らかの異常が見られた場合、程度の軽いものであれば医療アドバイスとして音声信号またはメッセージ信号を患者の所持する携帯型無線心電監視装置１に送信する。患者は、該携帯型無線心電監視装置１の表面にあるスピーカ６の吹鳴や本体２に内蔵のバイブレータ２２または胸当て無線心電計２６の本体２７に内蔵のバイブレータ３５による振動で医療アドバイス信号の受信を確認することができる。なお、スピーカ６の吹鳴またはバイブレータ２２，３５の振動のどちらの動作にするかはモードスイッチ９および設定スイッチ１０で選択することができる。なお、スピーカ６の吹鳴時に吹鳴を止めたい場合には警報リセットスイッチ１０をＯＮ

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にして吹鳴を止めることができる。
【００２１】音声信号の場合はスピーカ６より音声メッセージを吹鳴する。また、メッセージ信号の場合はＬＣＤ５に文字メッセージを表示する。これらのメッセージに対する応答としてマイク７に向かって直接担当医と話をしたり、モードスイッチ８および設定スイッチ９で応答を返してもよい。心電データが変動している状態で応答がない場合は患者に緊急事態が発生していると判断し、スピーカ６より警報を吹鳴したり発光ランプ１３を点滅させ周辺者に注意を促し救助を受けることが可能である。
【００２２】また、前述のデータの解析結果において既に緊急事態が発生していると判断した場合は、医療メッセージの代りに直ちにスピーカ６より警報を吹鳴したり発光ランプ１３を点滅させ周辺者に注意を促し救助を受ける態勢に入る。さらに医療機関では患者を救助するために介護車または救急車を出動させる。該介護車または救急車に搭載されているＧＰＳカーナビゲーションシステムと患者の所持する携帯型無線心電監視装置１より送信される患者の位置データ等により患者の位置を探索し、患者の元に急行することができる。該カーナビゲーションシステムはＤ－ＧＰＳ対応としＦＭ多重放送を受信して位置補正をすることにより患者の位置を高精度（誤差数メートル以内）に探索することができる。
【００２３】また、図5は本発明の衛星通信コンバータおよび専用パラボラアンテナの斜視図であるが、このような別置の衛星通信コンバータ３９と専用パラボラアンテナ４３を用いることにより携帯型無線心電監視装置１から発射される電波の届かないような遠隔地にある医療機関との間でも在宅医療が可能となる。該携帯型無線心電監視装置１から発射された電波は衛星通信コンバータ３９のアンテナ４０に入り、信号変換した後専用パラボラアンテナ４３より通信衛星に向けて電波を発射する。遠隔地（国外も含む）にある医療機関は該電波を受信することにより最先端の医療対応により処置情報を患者に最寄りの医療機関に伝達したり、患者への医療メッセージを送信する等の遠隔在宅医療が可能である。なお、携帯型無線心電監視装置１から発射される電波の届かないような遠隔地にある医療機関との間で通信を行う方法として、携帯型無線心電監視装置１の電波のゾーン内に複数の無線中継局を配置して信号を中継する方法もあるが、どちらの方法を用いても構わない。
【００２４】
【発明の効果】以上述べたように、本発明の携帯型無線心電監視装置を在宅医療に採用することにより以下のような効果を奏することができる。
患者が携帯型無線心電監視装置および胸当て無線心電計を常時身に付けることにより心拍数データや心電図データ等のデータが得られ、該データを定期的または異常時にはその都度自動送信できるため、在宅医療の遠隔監視ができる。
患者が携帯型無線心電監視装置および胸当て無線心電計を常時身に付けることにより通院が困難な在宅患者の状態把握が容易にできる。
外出中の患者でも所在位置が容易に探索できるため、異常時でも容易に救出することができる。このため、患者の外出制限が緩和され要注意患者の生活環境を変えることができる。
携帯型無線心電監視装置より送信される定期検診データまたは異常信号の内容に応じ医療機関から医療アドバイスとして音声メッセージや文字メッセージを受信できるため本人または周辺者による適切な応急処置を取ることができる。
患者の在宅介護化が容易になり、個人や保険機関の通院・入院費負担や、医療機関の要員費・入院設備費が軽減できる。
別置の衛星通信コンバータおよび専用パラボラアンテナを中継することにより遠隔地の医療機関と通信を行うことができ、最先端の遠隔在宅医療が可能となる。
【図面の簡単な説明】
【図１】本発明の携帯型無線心電監視装置の斜視図である。
【図２】本発明の携帯型無線心電監視装置を構成するブロック図である。
【図３】本発明の胸当て無線心電計の斜視図である。
【図４】本発明の胸当て無線心電計を構成するブロック図である。
【図５】本発明の衛星通信コンバータおよび専用パラボラアンテナの斜視図である。
【図６】本発明の衛星通信コンバータを構成するブロック図である。
【符号の説明】
１　携帯型無線心電監視装置
２　本体
３　ベルト
４　アンテナ
５　ＬＣＤ
６　スピーカ
７　マイク
８　モードスイッチ
９　設定スイッチ
１０　警報リセットスイッチ
１１　バックライトスイッチ
１２　電源スイッチ
１３　発光ランプ
１４　データ送受信部
１５　ＦＭ波受信部
１６　ＣＰＵ
１７　ＬＣＤ駆動部
１８　データメモリ部

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１９　タイマ部
２０　音声出力部
２１　音声入力部
２２　バイブレータ
２３　インターフェース部
２４　電源ユニット
２５　バッテリ
２６　胸当て無線心電計
２７　本体
２８　ベルト
２９　アンテナ
３０　固定部
３１　電源スイッチ
３２　データ送受信部
３３　ＣＰＵ
３４　タイマ部
３５　バイブレータ
３６　インターフェース部
３７　電源ユニット
３８　バッテリ

【図１】

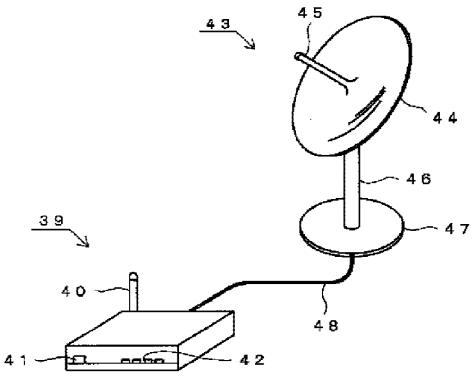
３９　衛星通信コンバータ
４０　アンテナ
４１　モードスイッチ
４２　モニタランプ
４３　専用パラボラアンテナ
４４　反射器
４５　導波管
４６　支柱
４７　固定台
４８　同軸ケーブル
４９　データ送受信部
５０　ＣＰＵ
５１　コンバータ
５２　データ送受信部
５３　データメモリ部
５４　タイマ部
５５　インターフェース部
５６　電源ユニット
５７　バッテリ

【図２】

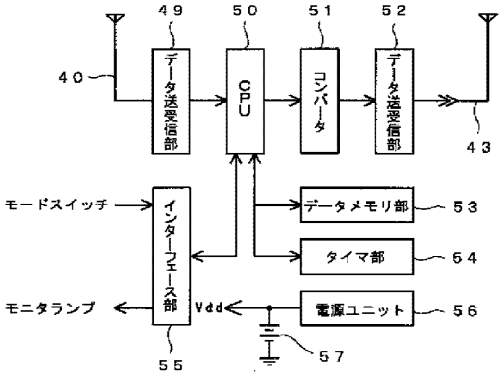
【図３】

【図４】

【図５】


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【図６】


49
50
51
52
40
データ送受信部
CPU
コンバータ
データ送受信部
43
モードスイッチ
インターフェース部
データメモリ部
53
タイマ部
54
モニタランプ
Vdd
電源ユニット
56
55
57

Espacenet

Bibliographic data: JP11088546 (A) — 1999-03-30

CRISIS NOTICE SYSTEM

Inventor(s):	YAMASHITA YUKINAGA ±	
Applicant(s):	NEC CORP ±	
Classification:	**- international:**	***A61B5/00; G01S19/17; G08B25/08; G08B25/10; H04B7/15; H04M11/04; H04Q7/38;*** (IPC1-7): A61B5/00; G01S5/14; G08B25/08; G08B25/10; H04B7/15; H04M11/04; H04Q7/38
	- European:	
Application number:	JP19970267794 19970912	
Priority number(s):	JP19970267794 19970912	

Abstract of JP11088546 (A)

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.

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25/10		25/10	Ｄ	
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(54)【発明の名称】　危機通知システム

(57)【要約】
【課題】緊急通報の伝達方法において、音声を媒体とした情報で、既存の固定電話網、移動体通信網の電話端末へ伝達させ、多くの人々が利用できる機会を作ること。緊急通報を身体状態の急激変化を契機に自動的に行うシステム及び装置Ｎ提供。
【解決手段】緊急通報発信位置をＧＰＳにて判別し具体的な住所に翻訳した後、音声化して、緊急メッセージと合成し、既存の固定電話網及び移動体通信網配下の電話端末に音声で送信する。また、緊急メッセージは、体調（血圧、脈拍、体温）を監視し、急激な状態変化の検知により発信する。

【特許請求の範囲】
【請求項１】身体の状態変化、すなわち脈拍、血圧、体温などの急激変化、を感知し、その時点での身体の状態の通知と緊急メッセージとを、予め登録しておいた緊急メッセージ連絡先に自動的に発信する手段を備えたことを特徴とする携帯電話端末装置。
【請求項２】前記緊急メッセージの発信を手動で実行する手段を備えたことを特徴とする請求項１記載の携帯電話端末装置。
【請求項３】携帯端末装置において、
緊急メッセージを記憶する緊急メッセージ蓄積部と、
前記緊急メッセージの送信先電話番号を記憶する緊急メッセージ送信先アドレス蓄積部と、
身体の体調状態を感知するための体調状態測定センサと、
体調状態を監視し、異常検出時、前記緊急メッセージの発信の判断を下す体調監視手段と、
前記体調監視手段による判定により、移動体通信網へ前記緊急メッセージを発信するために通信回線を接続する制御を行う緊急メッセージ発信制御手段と、
ＧＰＳとの交信を自動的に実行し、発信地点の緯度、経度、距離、方角を取得し、前記緊急メッセージと共に位置データとして前記移動体通信網に発信する手段と、
を含むことを特徴とする携帯端末装置。
【請求項４】請求項１乃至３記載の携帯端末装置において急メッセージ発信時に、全世界衛星測位システム（Ｇｌｏｂａｌ　Ｐｏｓｉｔｉｏｎｉｎｇ　Ｓｙｓｔｅｍ、以下「ＧＰＳ」という）との交信を自動的に実行し、発信地点の緯度、経度、距離、方角を受信し、前記緊急メッセージと共に位置データとして移動体通信網に発信し、
移動体通信網の中継交換局において、該当する緊急メッセージを抽出して一時的に蓄積し、
発信地点の位置データを抽出し、具体的な住所、居住地名、ビル名を検索、割り出し、データ・音声へのメディア変換を施すと共に、身体の状態変化データについても同様に、データ・音声へのメディア変換を施し、一時的に蓄積していた前記緊急メッセージと音声合成して、最終着信地点まで、緊急メッセージと身体状態を音声呼として送信する機能を有する移動体通信システム。
【請求項５】前記移動体通信網の中継交換局では、前記緊急メッセージ、緊急メッセージ発信地点位置情報、及び身体状態変化情報は音声とともに、前記緊急メッセージの端末形態を参照し、最終着信地点の端末に合わせて、テキストデータによる電子メール形態、及び／又は、ファクシミリ端末への送信文書形態に、メディア変換を施す手段を備えたことを特徴とする請求項４記載の移動体通信システム。
【請求項６】携帯端末装置が緊急通報メッセージ発信時、発信位置をＧＰＳにて取得し、該位置データを該緊急メッセージと共に移動体通信網に発信し、
前記移動体通信網の中継交換局において、前記発信元の位置データを具体的な住所データに翻訳した後、該住所データを音声化して、受信した前記緊急メッセージと合成し、既存の固定電話網及び移動体通信網配下の電話端末に音声で送信することを特徴とする緊急通知システム。
【請求項７】緊急メッセージを記憶する緊急メッセージ蓄積部と、
前記緊急メッセージの送信先電話番号、あるいは、メールアドレスを記憶する緊急メッセージ送信先アドレス蓄積部と、
身体の状態として血圧、脈拍、体温を測定する体調状態測定センサと、
体調状態測定センサからのデータを収集、蓄積し、緊急メッセージを発信するか否かを判断する体調監視手段と、
緊急メッセージをユーザ自身の手で発信するための緊急メッセージ手動発信手段と、
緊急メッセージ発信時に動作制御を管理する緊急メッセージ発信制御手段と、
緊急メッセージを発信した現在地点を特定するため、ＧＰＳ衛星に対して現在位置情報取得要求を行うＧＰＳ信号発信制御手段と、
ＧＰＳからの現在位置情報を受信するＧＰＳ信号受信制御手段と、
ＧＰＳ向けの無線信号を送信信号／受信信号に分解するＧＰＳ送受分波手段と、
ＧＰＳ通信か移動体通信網との通信かによって選択する周波数を変えるための周波数選択手段と、
緊急メッセージ送信先アドレス蓄積部に格納された送信先アドレスデータと、ＧＰＳ信号受信制御手段で取得した位置情報データと、前記体調監視手段で取得した体調データをテキストデータとして合成する送信データ合成手段と、
を携帯端末機能に加えて具備したことを特徴とする携帯端末装置。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は、危機通知に好適なシステムに関し、特に、通信装置におけるメッセージの蓄積、自動発呼、メディア変換、発信地点位置情報検出を実現する装置及びシステムに関する。
【０００２】
【従来の技術】ＧＰＳシステムを利用して、緊急通信を発した移動体通信機の位置情報を取得し、更に特定した発信元位置を地図画面上に表示させる表示手段を持つ緊急通信発信元確認システムが、例えば特開平８－３１７０８５号公報に提案されている。
【０００３】また、ユーザが携帯端末装置の緊急通報ボ

タンを押すことにより、緊急通報を発信し通知する緊急通信支援サービス方式が、例えば特開平８－１８０２８６号公報に提案されている。

【０００４】

【発明が解決しようとする課題】しかしながら、上記した従来技術は下記記載の問題点を有してる。

【０００５】第１の問題点は、緊急通報を発信した移動体通信機の表現方法が、地図上という視覚情報に限定されている、ということである。

【０００６】その理由は、例えば上記特開平８－３１７０８５号公報記載のような表示手段を備えていれば問題は無いが、世間一般に普及している固定電話網の電話端末、ファクシミリ端末等との通信ができず、このため、多数の人がこのシステムを利用できる機会を妨げている。

【０００７】第２の問題点は、ユーザがボタン操作しなければ緊急通報が発信できない、ということである。

【０００８】その理由は、例えば、上記特開平８－１８０２８６号公報記載のように、常に利用者が操作することが可能な状態であれば問題は無いが、突発的な事件、事故への遭遇や急病発症時には、操作ボタンすら押せない状況下も予想され、緊急通報を発信できないまま絶命してしまうことも考えられる。

【０００９】したがって、本発明は、上記問題点に鑑みてなされたものであって、その目的は、緊急メッセージ発信位置情報をＧＰＳにより明確化した後、例えば発信位置情報を具体的な住所に翻訳し、住所データを音声にメディア変換することにより、一般に普及している固定電話網、携帯電話等へ音声による緊急通報を実現可能とするシステムを提供することにある。

【００１０】また、本発明は、緊急メッセージの発信契機については、突発的な事件、事故、急病の発症により、能動的な操作が出来ない場合、或いは周囲に救助を求める人間が居ない状況下においても、急激な体調変化を感知することにより、緊急メッセージを発信することが可能とし、より迅速かつ、より確実に危機状態から離脱させ得る、携帯端末装置およびシステムを提供することにある。

【００１１】

【課題を解決するための手段】前記目的を達成するため、本発明の携帯端末装置は、身体の状態変化、すなわち脈拍、血圧、体温などの急激変化、を感知し、その時点での身体の状態の通知と緊急メッセージとを、予め登録しておいた緊急メッセージ連絡先に自動的に発信する手段を備えたことを特徴とする。

【００１２】また、本発明の携帯端末装置は、前記緊急メッセージの発信を手動で実行する手段を備える。

【００１３】また、本発明の移動体通信システムは、上記携帯電話端末装置において緊急メッセージ発信時に、全世界衛星測位システム（Ｇｌｏｂａｌ　Ｐｏｓｉｔｉｏｎｉｎｇ　Ｓｙｓｔｅｍ、以下「ＧＰＳ」という）との交信を自動的に実行し、発信地点の緯度、経度、距離、方角を受信し、前記緊急メッセージと共に位置データとして移動体通信網に発信し、移動体通信網の中継交換局において、該当する緊急メッセージを抽出して一時的に蓄積し、発信地点の位置データを抽出し、具体的な住所、居住地名、ビル名を検索、割り出し、データ・音声へのメディア変換を施すと共に、身体の状態変化データについても同様に、データ・音声へのメディア変換を施し、一時的に蓄積していた前記緊急メッセージと音声合成して、最終着信地点まで、緊急メッセージと身体状態を音声呼として送信する機能を有する。

【００１４】本発明の移動体通信システムは、前記移動体通信網の中継交換局では、前記緊急メッセージ、緊急メッセージ発信地点位置情報、及び身体状態変化情報は音声とともに、前記緊急メッセージの端末形態を参照し、最終着信地点の端末に合わせて、テキストデータによる電子メール形態、及び／又は、ファクシミリ端末への送信文書形態に、メディア変換を施す手段を備えたことを特徴とする。

【００１５】［発明の概要］本発明の概要について説明する。本発明においては、緊急メッセージ発信位置情報をＧＰＳにより、テキストデータとして取得した後、具体的な住所に翻訳し、住所のテキストデータを音声にメディア変換するための機能とし、移動体通信網の中継管轄局の交換機（図１の１３１）に、該当する緊急メッセージからＧＰＳによる位置情報を抽出する緊急メッセージ抽出部（図１の１３３）と、具体的住所情報検索部（図１の１３４）と、住所のテキストデータから音声データへ変換し移動体通信網に再送信するメディア変換部（図１の１３５）を有する。

【００１６】また、突発的な事件、事故、急病の発症により、能動的な操作が出来ない場合、或いは周囲に救助を求める人間が居ない状況下において、急激な体調変化を感知することにより緊急メッセージを発信する機能は、身体に体調状態（血圧、脈拍、体温）を感知するための体調状態測定センサ部（図１の１１８）と、体調状態を監視し、発信する判断を下す体調監視部（図１の１１９）と、体調監視部による判定により実際に移動体通信網へ緊急メッセージを発信するために通信回線を接続する制御を行う緊急メッセージ発信制御部（図１の１１７）を携帯端末装置に備えて構成される。

【００１７】本発明による、緊急メッセージ発信位置情報をＧＰＳにより、テキストデータとして取得した後、具体的な住所に翻訳し、住所のテキストデータを音声にメディア変換する機能を有することで、緊急メッセージを一般に普及している固定電話網、携帯電話等へ音声で伝達する。これにより、緊急メッセージを受信する側が既存の通信端末で対応可能となり、同種の危機通知システム及び緊急通報システムを、より多くの人が利用でき

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る。

【００１８】また、急激な体調変化を感知し緊急メッセージを自動的に発信する機能を有することで、突発的な事件、事故の遭遇、及び急病の発症時に、人間が行う電話の発信操作を代行する。これにより、周囲に救助を求める人間が居ない状況下においても、緊急メッセージを発信することが可能となり、危機状態からいち早く離脱できる可能性が高まる。

【００１９】

【発明の実施の形態】本発明の実施の構成について図面を参照にして説明する。

【００２０】図１は、本発明の実施の形態に係る危機通知システムの構成を機能ブロック図にて示したものである。図１を参照すると、本発明の実施の形態の危機通知システムは、移動体通信網及びＧＰＳとエアインタフェースをもつアンテナ部（１０１）と、移動体通信網との通信か、ＧＰＳとの通信かによって異なる無線周波数帯を選択し切り替えて発信する周波数選択部（１０２）を備える。

【００２１】周波数選択部（１０２）で移動体通信網との通信が選択された場合の無線信号は、送受分波部（１０３）にて送信信号／受信信号に分解される。移動体通信網からの受信信号については、復調部（１０４）で元の信号周波数に復調され、復号化部（１０５）で復号されて、音声データは受信音声制御部（１０７）へ、制御信号は受信制御信号部（１０６）へ送られる。受信音声制御部（１０７）は、受話部（１０８）に対して音声データを音声に変換して伝達する。受信制御信号部（１０６）からの受信信号は発着信制御部（１１４）に送られ、着信があることをユーザに通知する。

【００２２】移動体通信網への送信については、通常呼発信部（１１５）にて回線接続要求を発着信制御部（１１４）に送出する。送信先電話番号はダイヤル部（１１６）にて入力する。送話部（１１３）から入力された音声は、送信音声制御部（１１２）でサンプリングされ、符号化部（１１０）に送信されてディジタル信号化される。発着信制御部（１１４）からの送信制御信号は送信制御信号部（１１１）に送出され、サンプリングされた音声データと共に符号化部（１１０）でディジタル信号化される。変調部（１０９）はディジタル信号を所定の搬送波に重畳し、送受分波部（１０３）、アンテナ部（１０１）を経て移動体通信網へ送信される。

【００２３】本発明の実施の形態において、携帯端末装置は、これら従来の携帯電話の機能ブロックに加え、緊急メッセージを記憶する緊急メッセージ蓄積部（１２２）と、緊急メッセージの送信先電話番号、或いは、メールアドレスを記憶する緊急メッセージ送信先アドレス蓄積部（１２１）と、身体に密着させ、血圧、脈拍、体温を測定する体調状態測定センサ部（１１８）と、体調状態測定センサ部（１１８）からのデータを収集、蓄積し、緊急メッセージを発信するか否かを判断する体調監視部（１１９）と、緊急メッセージをユーザ自身の手で発信する緊急メッセージ手動発信部（１２０）と、緊急メッセージ発信時に動作制御を管理する緊急メッセージ発信制御部（１１７）と、を備えている。

【００２４】これらの緊急メッセージ発信用機能ブロックに加え、緊急メッセージを発信した現在地点を特定するため、ＧＰＳ衛星（１２７）に対して現在位置情報取得要求を行うＧＰＳ信号発信制御部（１２４）と、ＧＰＳからの現在位置情報を受信するＧＰＳ信号受信制御部（１２５）と、ＧＰＳ向けの無線信号を送信信号／受信信号に分解するＧＰＳ送受分波部（１２３）と、を備えている。

【００２５】ＧＰＳとの通信時は周波数選択部（１０２）でＧＰＳ送受分波部（１２３）との接続を実現する。

【００２６】緊急メッセージ発信制御部（１１７）からの要求により、発信された緊急メッセージは、緊急メッセージ蓄積部（１２２）に格納されている音声データと、緊急メッセージ送信先アドレス蓄積部（１２１）に格納された送信先アドレスデータと、ＧＰＳ信号受信制御部（１２５）で取得した位置情報データと、体調監視部（１１９）で取得した体調データから構成されるが、ディジタル送信データ合成部（１２６）で音声以外の位置情報データと送信先アドレスデータと体調データを合成する。

【００２７】移動体通信網に送出された緊急メッセージは、既存の基地局アンテナ（１２８）、基地局（１２９）、中継局（１３０）を経て、本システムのユーザを一括管理する管轄中継局交換機（１３１）に転送される。

【００２８】管轄中継局交換機（１３１）には、転送された緊急メッセージを選択し蓄積する網内緊急メッセージ蓄積部（１３２）と、網内緊急メッセージ蓄積部（１３２）で保持された緊急メッセージから、送信先アドレスデータと位置情報データと体調データを抽出する緊急メッセージ抽出部（１３３）と、位置情報データを元に具体的な重著（所番地、ビル名、通称名等）に翻訳する具体的住所情報検索部（１３４）と、具体的住所情報検索部（１３４）のデータと体調データを音声情報に変換するメディア変換部（１３５）と、網内緊急メッセージ蓄積部（１３２）で保持した緊急メッセージと、音声化された具体的住所データと体調データを再度、音声として合成し管轄中継局交換機（１３１）に戻す緊急メッセージ再合成部（１３６）を接続する。

【００２９】全て音声化された緊急メッセージは、網内緊急メッセージ蓄積部（１３２）で既に格納している、ユーザが緊急メッセージ送信先アドレス蓄積部（１２１）に予め登録した送信先アドレスを元に、固定電話網（１３７）を経由して送信先アドレスの電話端末（１３

８）とのリンクが確立された後、送信される。或いは、そのまま移動体通信網（１４２）を経由して他の移動体端末（１３９）とのリンクが確立された後、送信される。

【００３０】なお、メディア変換部（１３５）では、ユーザの希望により、ファクシミリ端末（１４０）への送信、或いは、電子メール形態（１４１）の送信を実現するためのメディア変換も行う。

【００３１】図２及び図３は、本発明の実施の形態に係る危機通知システムの動作を示すフローチャートである。なお、図２及び図３は単に図面作成の都合で分図されたものである。本発明の実施の形態の動作について図１及び図２を参照して説明する。

【００３２】まず、送話部（１１３）から緊急メッセージ蓄積部（１２２）に対し、緊急メッセージ登録を行う（ステップ２０１）。この時、緊急メッセージ発信制御部（１１７）では緊急メッセージ登録の有無を確認する。

【００３３】その後、ダイヤル部（１１６）から緊急メッセージ送信先アドレス蓄積部（１２１）に対し、緊急メッセージ送信先アドレス登録を行う（ステップ２０２）。この時、緊急メッセージ発信制御部（１１７）では緊急メッセージ送信先アドレス登録の有無を確認する。

【００３４】緊急メッセージの発信時動作は、緊急メッセージ発信制御部（１１７）で、体調監視部（１１９）及び緊急メッセージ手動発信部（１２０）からの緊急メッセージ発信要求を受信する（ステップ２０３）。

【００３５】緊急メッセージ発信要求の受信後、登録フェーズで行った緊急メッセージと緊急メッセージ送信先アドレスの存在確認を行う（ステップ２０４）。存在が確認されなければ、ステップ２０３の緊急メッセージ登録待ちの状態に戻る。

【００３６】一方、ステップ２０４で緊急メッセージの存在が確認されれば、緊急メッセージ発信制御部（１１７）は、発信位置データ取得要求をＧＰＳ信号発信制御部（１２４）に送る（ステップ２０５）。

【００３７】ＧＰＳ信号発信制御部（１２４）では、ＧＰＳから位置データを収集し、収集データをＧＰＳ信号受信制御部（１２５）を経由しディジタル信号データ合成部（１２６）に格納する。位置データが収集不可の場合には（ステップ２０６）、ステップ２０５の発信位置データ取得要求の状態に戻る。

【００３８】ステップ２０６において位置データ取得後、緊急メッセージ発信制御部（１１７）は、体調データ取得要求を体調監視部（１１９）に送る（ステップ２０７）。

【００３９】体調監視部（１１９）では、体調状態測定センサ部（１１８）から取得要求時の血圧、脈拍、体温等のデータを収集し、収集データをディジタル信号データ合成部（１２６）に格納する。体調データ収集不可の場合には（ステップ２０８）、ステップ２０７の体調データ取得要求の状態に戻る。

【００４０】全ての情報取得終了後、緊急メッセージ発信制御部（１１７）は、緊急メッセージ送信先アドレスと体調データと位置データの合成要求をディジタル信号データ合成部（１２６）に送る（ステップ２０９）。

【００４１】合成完了後、送信先アドレスに向けて緊急メッセージを発信するため、まず管轄中継局とのリンクを確立する。リンクが確立されない場合は確立するまでこの動作を行う（ステップ２１０）。

【００４２】リンク確立後、緊急メッセージ発信制御部（１１７）はディジタル送信データ合成部（１２６）及び送信音声制御部（１１２）に対し、緊急メッセージと収集データの送出要求を行う（ステップ２１１）。

【００４３】移動体通信網の管轄中継局（１３１）では、送信された緊急メッセージと収集データを一時的に保持し（ステップ２１２）、緊急メッセージ抽出部（１３３）へ送る。

【００４４】緊急メッセージ抽出部（１３３）では、保持されたデータから、位置データの抽出（ステップ２１３）、体調データの抽出（ステップ２１４）、送信先アドレスデータの抽出（ステップ２１５）を行う。

【００４５】ステップ２１３で抽出された位置データは、具体的住所情報検索部（１３４）で実在の住所情報に翻訳される（ステップ２１６）。

【００４６】翻訳された住所、及び、抽出された体調データは、メディア変換部（１３５）でデータ→音声に変換される（ステップ２１７）。

【００４７】音声に変換された住所データと体調データは、緊急メッセージ再合成部（１３６）で音声のまま合成される（ステップ２１８）。

【００４８】管轄中継局（１３１）では、合成を確認した後、既に抽出し保持している送信先アドレスを基に、最終送信先端末を呼び出す（ステップ２１９）。

【００４９】応答があった場合（ステップ２２０）、ステップ２１８で合成した緊急メッセージを送出する（ステップ２２１）。

【００５０】一方、応答が無い場合には最終送信先端末の呼び出し状態に戻り（ステップ２１９）、応答するまで繰り返す（２２０）。

【００５１】

【実施例】上記した本発明の実施の形態について更に詳細に説明すべく、本発明の一実施例について図面を参照して以下に説明する。本発明は、従来の携帯電話端末及び移動体通信網に対して適用することが可能である。

【００５２】図１に示した機能ブロックにおいて、アンテナ部（１０１）、送受分波部（１０３）、復調部（１０４）、復号化部（１０５）、受信音声制御部（１０７）、受信制御信号部（１０６）、受話部（１０８）、

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通常呼発信部（１１５）、発着信制御部（１１４）、ダイヤル部（１１６）、送話部（１１３）、送信音声制御部（１１２）、符号化部（１１０）、及び、送信制御信号部（１１１）は、従来の携帯電話装置の機能ブロックに対応する。

【００５３】また、緊急メッセージを記憶する緊急メッセージ蓄積部（１２２）と、緊急メッセージの送信先電話番号、或いは、メールアドレスを記憶する緊急メッセージ送信先アドレス蓄積部（１２１）についても、従来の携帯電話装置に付加されているメモ機能を、緊急メッセージ用として、独立に確保することにより、実現することができる。

【００５４】本発明の一実施例の携帯端末装置は、これら従来機能に、身体に密着させ、血圧、脈拍、体温を測定する体調状態測定センサ部（１１８）と、体調状態測定センサ部（１１８）からのデータを収集、蓄積し、緊急メッセージを発信するか否かを判断する体調監視部（１１９）と、緊急メッセージをユーザ自身の手で発信する緊急メッセージ手動発信部（１２０）と、緊急メッセージ発信時に動作制御を管理する緊急メッセージ発信制御部（１１７）からなる緊急メッセージ発信用機能ブロックを加え、更に、緊急メッセージを発信した現在地点を特定するため、ＧＰＳ衛星（１２７）に対して、現在位置情報取得要求を行うＧＰＳ信号発信制御部（１２４）と、ＧＰＳからの現在位置情報を受信するＧＰＳ信号受信制御部（１２５）とＧＰＳ向けの無線信号を送信信号／受信信号に分解するＧＰＳ送受分波部（１２３）と、ＧＰＳ通信か移動体通信網との通信かによって選択する周波数を変えるための周波数選択部（１０２）と、ＧＰＳ送受分波部（１２３）と、緊急メッセージ送信先アドレス蓄積部（１２１）に格納された送信先アドレスデータと、ＧＰＳ信号受信制御部（１２５）で取得した位置情報データと、体調監視部（１１９）で取得した体調データをテキストデータとして合成する、ディジタル送信データ合成部（１２６）の機能を追加することにより実現できる。

【００５５】また、移動体通信網側は、既存の管轄中継局の交換機（１３１）に、転送された緊急メッセージを選択し蓄積する網内緊急メッセージ蓄積部（１３２）と、網内緊急メッセージ蓄積部（１３２）で保持された緊急メッセージ（音声＋テキストデータ）から、テキストデータである、送信先アドレスデータと位置情報データと体調データを抽出する緊急メッセージ抽出部（１３３）と、位置情報データを元に具体的な住所（所番地、ビル名、通称名等）に翻訳する具体的住所情報検索部（１３４）と、具体的住所情報検索部（１３４）のデータと体調データを音声に変換するメディア変換部（１３５）と、網内緊急メッセージ蓄積部（１３２）で保持した緊急メッセージと、音声化された具体的住所データと体調データを再度、音声として合成し管轄中継局交換機（１３１）に戻すメディア変換部（ユーザの希望によりファクシミリ端末（１４０）への送信、或いは電子メール形態（１４１）の送信も実現する）（１３５）を接続することで実現可能となる。

【００５６】図４及び図５は、本発明の一実施例の動作の一例を示すフローチャートである。なお、図４及び図５は単に図面作成の都合で分図されたものである。本発明の一実施例の動作について図１、図４及び図５を参照して説明する。

【００５７】まず、通常の携帯電話として使用している状態（図４のステップ３０１）において、送話部（１１３）から、一例として「緊急事態発生、至急救助願います」の緊急メッセージを録音する（ステップ３０２）。この緊急メッセージは緊急メッセージ蓄積部（１２２）に格納される（ステップ３０３）。

【００５８】その後、ダイヤル部（１１６）から、先の緊急メッセージを連絡したい送信先アドレスである「０３－１２３４－５６７８」（例）を投入する（ステップ３０４）。

【００５９】この送信先アドレスは、緊急メッセージ送信先アドレス蓄積部（１２１）に格納される（ステップ３０５）。

【００６０】この緊急メッセージの発信は、身体に装着している体調状態測定センサ部（１１８）にて、随時測定される体調データを、体調監視部（１１９）で監視し、身体が危険な状態に陥ったことを検知した場合（ステップ３０６）、或いは、緊急メッセージ手動発信部（１２０）に対し、手動で発信操作が行われた場合（ステップ３０７）に限り、緊急メッセージ発信要求（３０８）が緊急メッセージ発信制御部（１１７）に送られる。緊急メッセージの登録、発信以外の場合は、通常の携帯電話として継続使用できる状態を保持する（ステップ３０１）。

【００６１】緊急メッセージ発信要求（ステップ３０８）後、緊急メッセージ発信制御部（１１７）は、発信動作を行った場所を特定するため、発信位置データ取得要求をＧＰＳ信号発信制御部（１２４）に送る（ステップ３０９）。

【００６２】ＧＰＳ信号発信制御部（１２４）では、ＧＰＳから位置データとして緯度、経度、高さ、包囲（北緯ＸＸ度ＹＹ分ＺＺ秒、東経ｘｘ度ｙｙ分ｚｚ秒、海抜Ｈｍ、方位Ｒ度）を収集し、ＧＰＳ信号受信制御部（１２５）を経由しディジタル信号データ合成部（１２６）にテキストデータ化して格納する（ステップ３１１）。位置データが収集不可の場合には（ステップ３１０）、ステップ３０９の発信位置データ取得要求の状態に戻る。

【００６３】位置データ取得後、緊急メッセージ発信制御部（１１７）は、体調データ取得要求を体調監視部（１１９）に送る（ステップ３１２）。

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【００６４】体調監視部（１１９）では、体調状態測定センサ部（１１８）から取得要求時の血圧、脈拍、体温（最高血圧ＨＨ、最低血圧ＬＬ、脈拍数Ｐ、体温ＴＴ度ｔ分、変動量ＡＡ、ＢＢ、ＣＣ）のデータを収集し、収集データをディジタル信号データ合成部（１２６）にテキストデータ化して格納する（図５のステップ３１４）。

【００６５】体調データ収集不可の場合には（図４のステップ３１３）、ステップ３１２の体調データ取得要求の状態に戻る。

【００６６】この２つの情報取得終了後、緊急メッセージ発信制御部（１１７）は、送信すべき緊急メッセージを構築するため、テキストデータ化された送信先アドレスと体調データと位置データはディジタル信号データ合成部（１２６）で合成される（図５のステップ３１５）。

【００６７】合成完了後、送信先アドレスに向けて、緊急メッセージを発信するため、まず管轄中継局とのリンクを確立する。リンクが確立されない場合は確立するまでこの動作を繰り返す（ステップ３１６）。

【００６８】リンク確立後、緊急メッセージ発信制御部（１１７）は、ディジタル送信データ合成部（１２６）に対し、ステップ３１５で合成された位置データ、送信先アドレス、体調データのテキストデータ（「０３－１２３４－５６７８」＋「北緯ＸＸ度ＹＹ分ＺＺ秒、東経ｘｘ度ｙｙ分ｚｚ秒、海抜Ｈｍ、方位Ｒ度」＋「最高血圧ＨＨ、最低血圧ＬＬ、脈拍数Ｐ、体温ＴＴ度ｔ分、変動量ＡＡ、ＢＢ、ＣＣ」）と、送信音声制御部（１１２）に対して、緊急メッセージ蓄積部（１２２）に格納済みの緊急メッセージ（「緊急事態発生、至急救助願います」）とを、確立した通信リンクに送出する（ステップ３１７）。

【００６９】移動体通信網の管轄中継局（１３１）では、送信された緊急メッセージと収集データを受信・保持し（ステップ３１８）、緊急メッセージ抽出部（１３３）へ送る。

【００７０】緊急メッセージ抽出部（１３３）では、保持されたデータから、位置データの抽出（ステップ３１９）、体調のデータ抽出（ステップ３２０）、送信先アドレスデータの抽出（ステップ３２１）の処理を行う。

【００７１】抽出された位置データ（北緯ＸＸ度ＹＹ分ＺＺ秒、東経ｘｘ度ｙｙ分ｚｚ秒、海抜Ｈｍ、方位Ｒ度）（３１９）は、具体的住所情報検索部（１３４）で実在の住所情報（東京都港区．．．．．○○ビル５Ｆ等）に翻訳される（ステップ３２２）。

【００７２】ステップ３２２で翻訳され住所、ステップ３２０で抽出された体調データはメディア変換部（１３５）でデータ→音声に変換される（ステップ３２３）。

【００７３】音声に変換された住所データと体調データは、緊急メッセージ再合成部（１３３）で「緊急事態発生、至急救助願います、現在地は東京都港区…○○ビル５Ｆ、現在の体調は最高血圧ＨＨ、最低血圧ＬＬ、脈拍数Ｐ、体温ＴＴ度ｔ分」というように合成音声化される（ステップ３２４）。

【００７４】管轄中継局（１３１）では、ステップ３２４での合成音声の確認後、既に抽出して保持している送信先アドレス（「０３－１２３４－５６７８」）（３２１）を元に、最終送信先端末を呼び出す（ステップ３２５）。

【００７５】応答があった場合、ステップ３２４で合成した緊急メッセージを送出する（ステップ３２６）。一方、応答が無い場合には、ステップ３２５の最終送信先端末の呼び出し状態に戻り、応答するまで繰り返す。

【００７６】本発明の別の実施例として、緊急メッセージ送信先を複数設定しておき、緊急メッセージを各設定済み送信先にラウンドロビン方式で発信することで、緊急メッセージの伝達率を高め、危機状態からの迅速な離脱を支援する構成としてもよい。

【００７７】

【発明の効果】以上説明したように、本発明によれば、緊急メッセージ発信位置情報をＧＰＳにより明確化した後、具体的な住所に翻訳し、その住所を音声に変換することにより、一般に普及している固定電話網、携帯電話等への緊急通報を実現する、という効果を奏するものであり、危機通知、緊急通報を多くの人が利用できる機会を与えるものである。

【００７８】また、本発明によれば、緊急メッセージの発信契機については、突発的な事件、事故、急病の発症により、能動的な操作が出来ない場合、或いは周囲に救助を求める人間が居ない状況下においても、急激な体調変化を感知することにより、緊急メッセージを発信することができる、という効果を奏するものであり、より迅速かつ、より確実に危機状態から離脱させることを可能としている。

【図面の簡単な説明】

【図１】本発明の実施の形態の構成を示す機能ブロック図である。

【図２】本発明の実施の形態の動作を説明するためのフローチャートである。

【図３】本発明の実施の形態の動作を説明するためのフローチャートである。

【図４】本発明の一実施例の動作を説明するためのフローチャートである。

【図５】本発明の一実施例の動作を説明するためのフローチャートである。

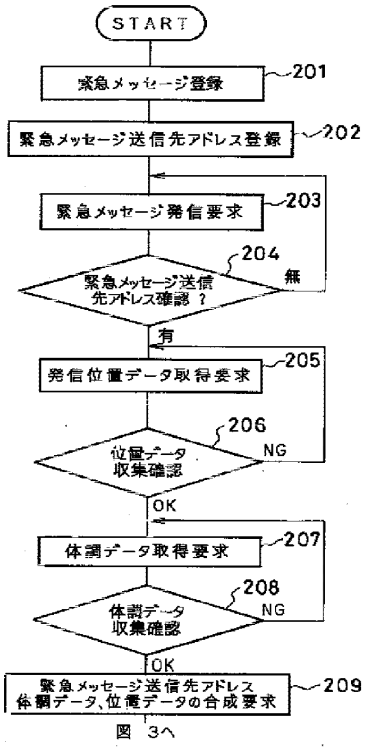
【符号の説明】

１０１　アンテナ部
１０２　周波数選択部
１０３　送受分波部
１０４　復調部

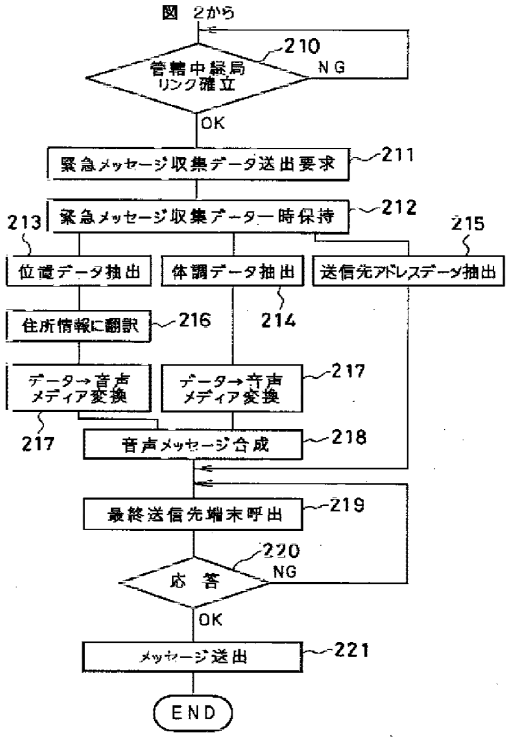
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１０５　復号化部
１０６　受信制御信号部
１０７　受信音声制御部
１０８　受話部
１１０　符号化部
１１１　送信制御信号部
１１２　送信音声制御部
１１３　送話部
１１４　発着信制御部
１１５　通常呼発信部
１１６　ダイヤル部
１１７　緊急メッセージ発信制御部
１１８　体調状態測定センサ部
１１９　体調監視部
１２０　緊急メッセージ手動発信部
１２２　緊急メッセージ蓄積部
１２１　緊急メッセージ送信先アドレス蓄積部
１２３　ＧＰＳ送受分波部
１２４　ＧＰＳ信号発信制御部
１２５　ＧＰＳ信号受信制御部
１２６　ディジタル送信データ合成部
１２７　ＧＰＳ衛星
１３１　交換機
１３２　網内緊急メッセージ蓄積部
１３３　緊急メッセージ抽出部
１３４　具体的住所情報検索部
１３５　メディア変換部
１４０　ファクシミリ端末

【図２】

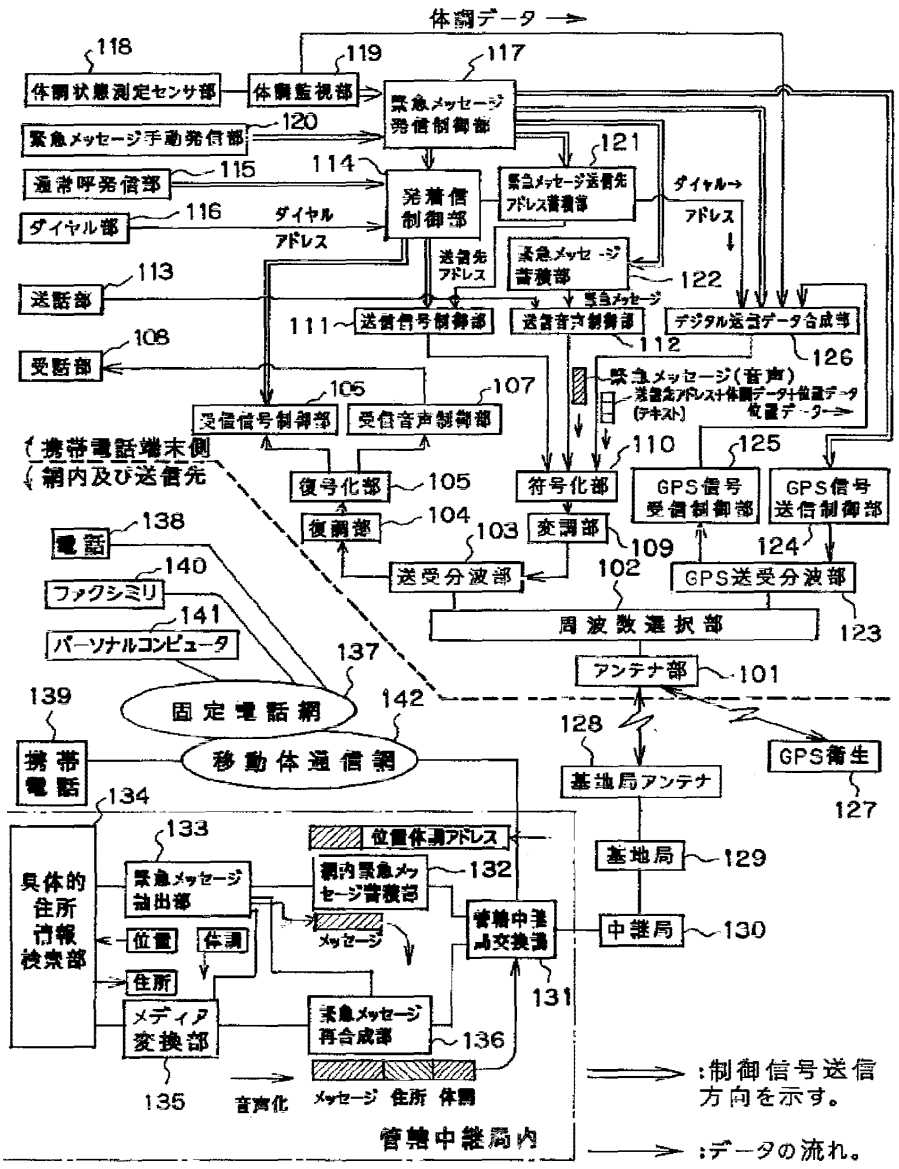


【図３】

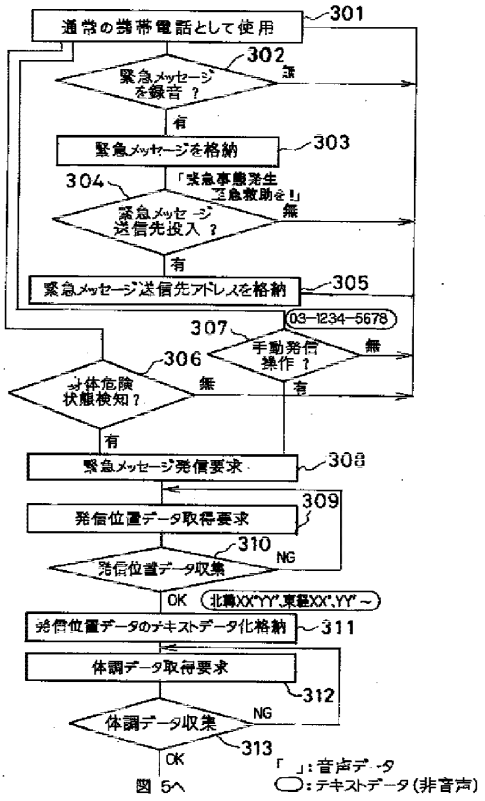


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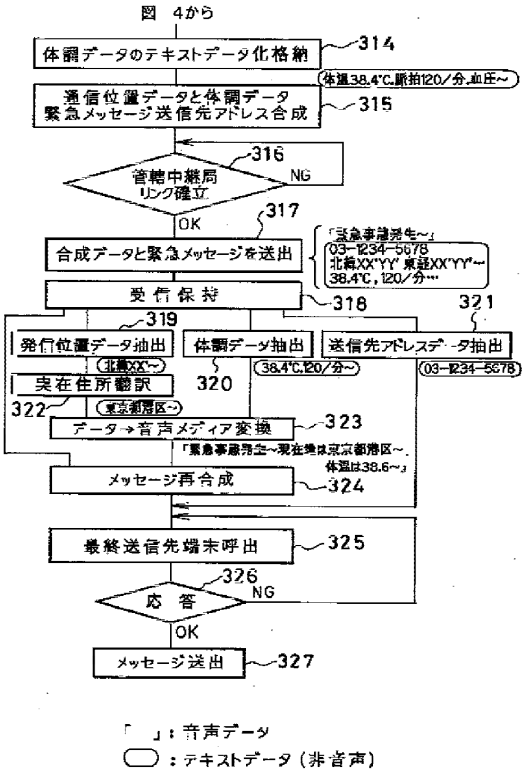
【図１】


体調データ
118
体調状態測定センサ部
119
体調監視部
117
緊急メッセージ発信制御部
緊急メッセージ手動発信部
120
通常呼発信部
115
114
発着信制御部
121
緊急メッセージ送信先アドレス蓄積部
ダイヤル→アドレス
ダイヤル部
116
ダイヤルアドレス
送信先アドレス
緊急メッセージ蓄積部
122
送話部
113
緊急メッセージ
111
送信信号制御部
送信音声制御部
112
デジタル送信データ合成部
126
受話部
108
緊急メッセージ（音声）
送信先アドレス＋体調データ＋位置データ
（テキスト）
位置データ
105
受信信号制御部
107
受信音声制御部
携帯電話端末側
網内及び送信先
110
125
復号化部
105
符号化部
GPS信号受信制御部
GPS信号送信制御部
138
電話
104
復調部
103
変調部
109
124
140
ファクシミリ
送受分波部
102
GPS送受分波部
141
パーソナルコンピュータ
周波数選択部
123
137
アンテナ部
101
139
固定電話網
142
128
携帯電話
移動体通信網
基地局アンテナ
GPS衛生
127
134
位置体調アドレス
133
具体的住所情報検索部
緊急メッセージ抽出部
網内緊急メッセージ蓄積部
132
基地局
129
位置
体調
メッセージ
管轄中継局交換機
中継局
130
住所
131
メディア変換部
緊急メッセージ再合成部
136
135
音声化
メッセージ 住所 体調
管轄中継局内
：制御信号送信方向を示す。
：データの流れ。

【図４】



【図５】



フロントページの続き

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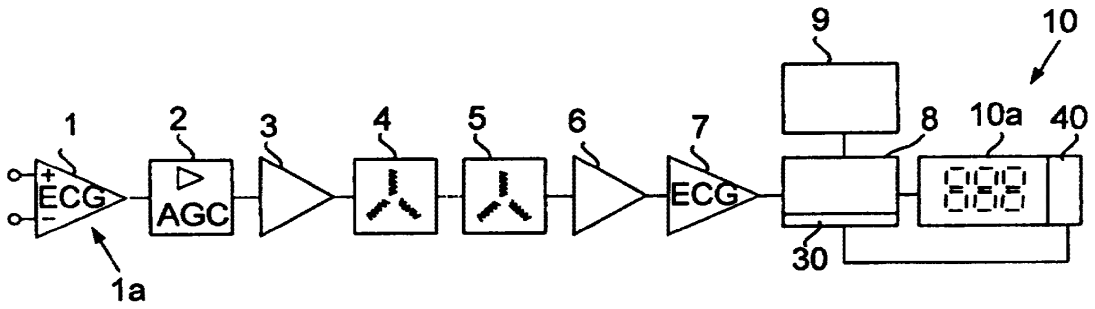
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(54) Title: METHOD AND APPARATUS IN CONNECTION WITH MEASURING THE HEARTBEAT RATE OF A PERSON



(57) Abstract

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

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

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

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

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

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

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

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

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

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

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

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

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

Figure 2 shows a heartbeat rate variation graph during exertion,

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

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

Figure 5 shows the display of a heartbeat rate monitor,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

rate monitor simultaneously both graphically and digitally.

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

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

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

Claims

1. A method in connection with measuring the heartbeat rate of a person, characterized by the following steps:

- measuring, with a heartbeat rate monitor, the ECG signal of the person and the timing moment of at least one ECG signal waveform, such as the QRS complex,
- calculating the average heartbeat rate frequency of the heartbeat rate from the ECG signal, and
- providing, by means of a mathematical function, heartbeat rate variation information proportional to the magnitude of the heartbeat rate variation or to that of the total or partial power of a spectrum derived from the heartbeat rate, said heartbeat rate variation information being displayed on the display of the heartbeat rate monitor.

2. A method according to claim 1, characterized in that in the method, the heartbeat rate variation is indicated on the display of the heartbeat rate monitor simultaneously with the average heartbeat rate frequency.

3. A method according to claim 1, characterized in that in the method, the heartbeat rate variation information is indicated on the display of the heartbeat rate monitor graphically and/or digitally.

4. A method according to claim 3, characterized in that in the method, the heartbeat rate variation information is indicated on the display of the heartbeat rate monitor simultaneously both graphically and digitally.

5. A method according to claim 1, characterized in that the heartbeat rate variation information is indicated on such a common display element that is used for indicating the modes and set conditions

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

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

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

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

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

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

- means (1- 4) for detecting and transmitting heartbeat rate signals,

- a heartbeat rate monitor (5 - 10; 11) for receiving, calculating and measuring heartbeat rate signals, and for registering the timing moment of at least one ECG signal waveform contained by a heartbeat rate signal, for instance the QRS complex,

- means (8; 12) for calculating the average heartbeat rate frequency of the heartbeat rate on the

basis of the ECG signal,

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

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

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

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

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

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

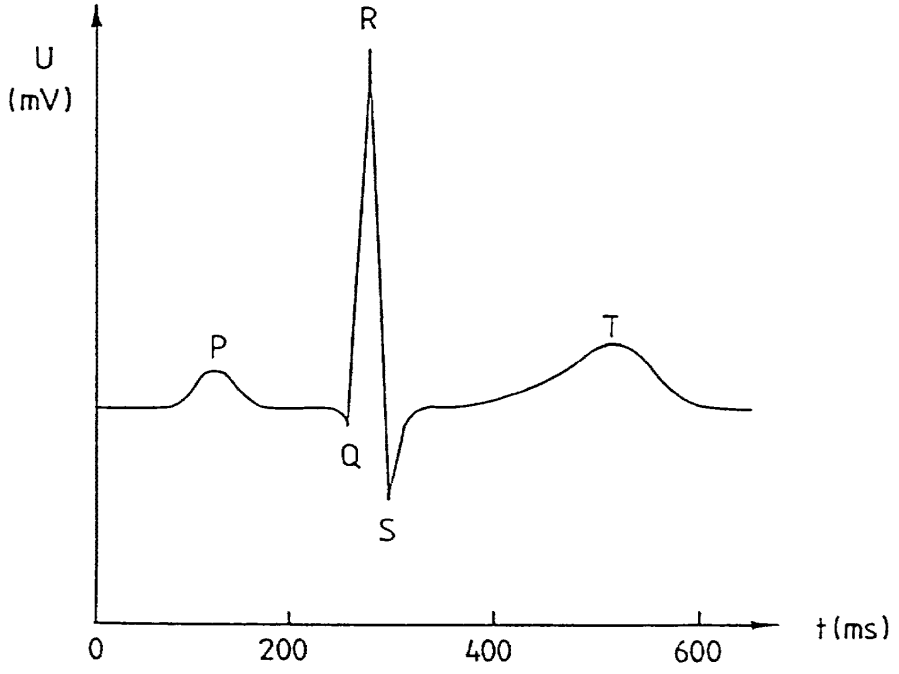


FIG. 1

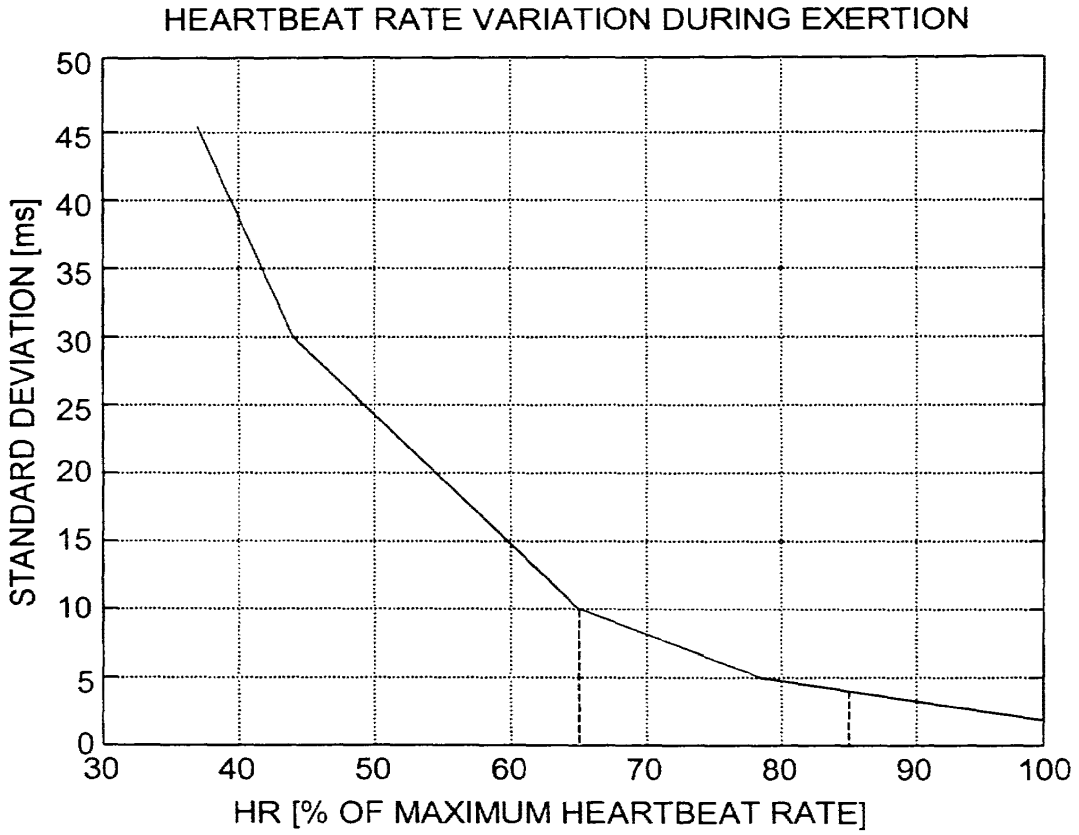

HEARTBEAT RATE VARIATION DURING EXERTION
STANDARD DEVIATION [ms]
50
45
40
35
30
25
20
15
10
5
0
30
40
50
60
70
80
90
100
HR [% OF MAXIMUM HEARTBEAT RATE]

FIG. 2

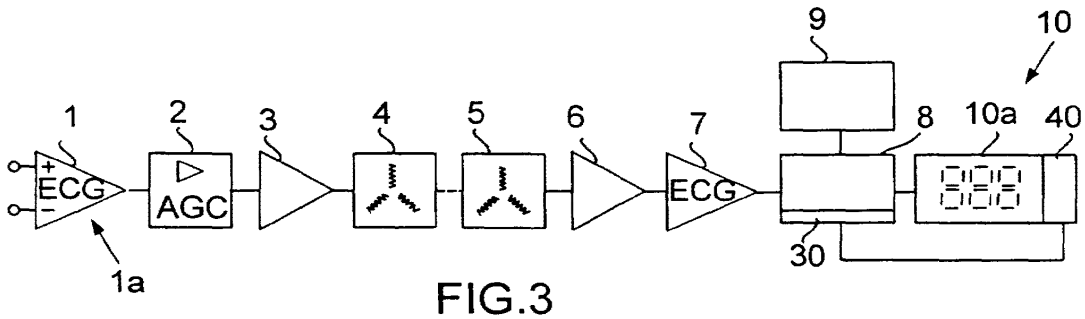

1
2
3
4
5
6
7
8
9
10
10a
40
30
ECG
AGC
ECG
1a

FIG.3

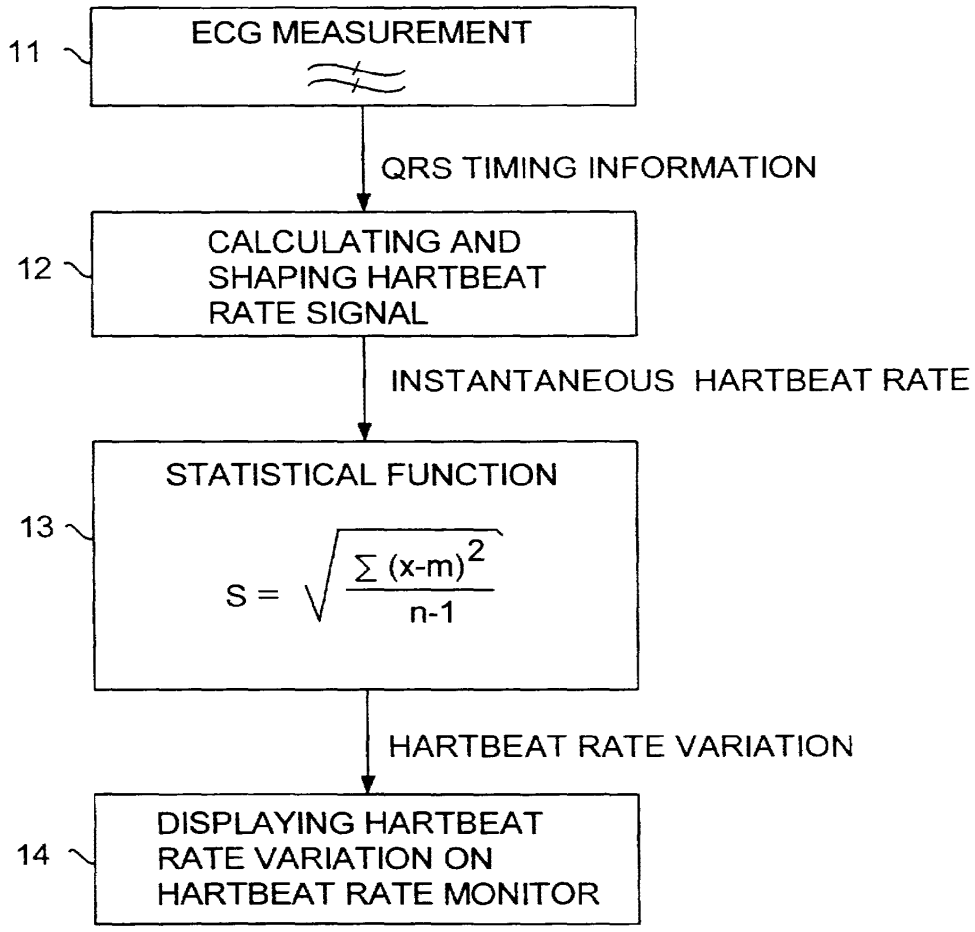

11
ECG MEASUREMENT
QRS TIMING INFORMATION
12
CALCULATING AND SHAPING HARTBEAT RATE SIGNAL
INSTANTANEOUS HARTBEAT RATE
13
STATISTICAL FUNCTION
$S = \sqrt{\frac{\sum (x-m)^2}{n-1}}$
HARTBEAT RATE VARIATION
14
DISPLAYING HARTBEAT RATE VARIATION ON HARTBEAT RATE MONITOR

FIG. 4

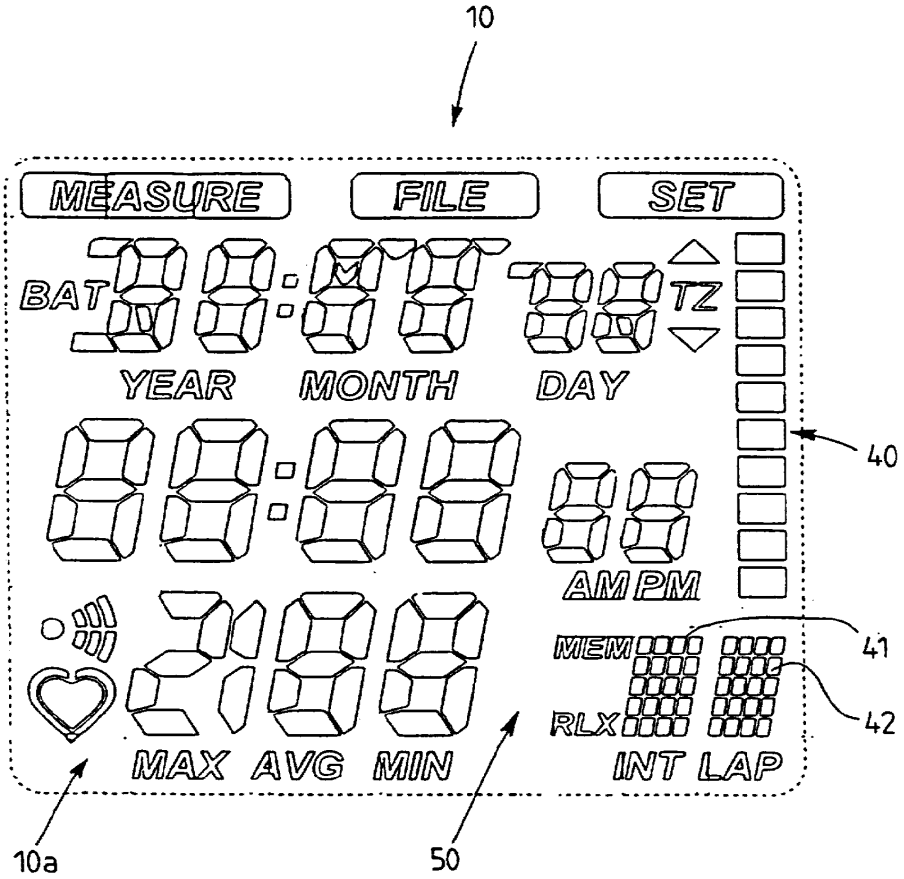

10
MEASURE
FILE
SET
BAT
TZ
YEAR
MONTH
DAY
AM PM
MEM
RLX
MAX AVG MIN
INT LAP
40
41
42
10a
50

FIG. 5

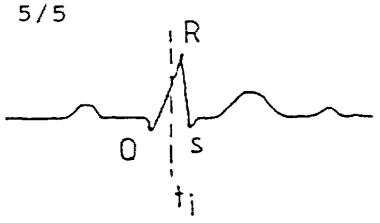


FIG. 6a

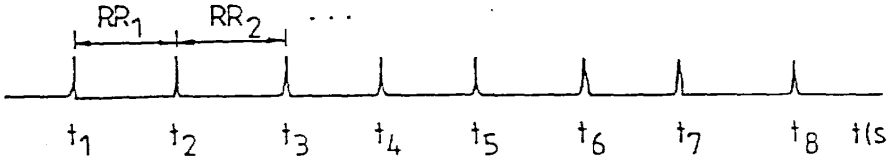


FIG. 6b

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

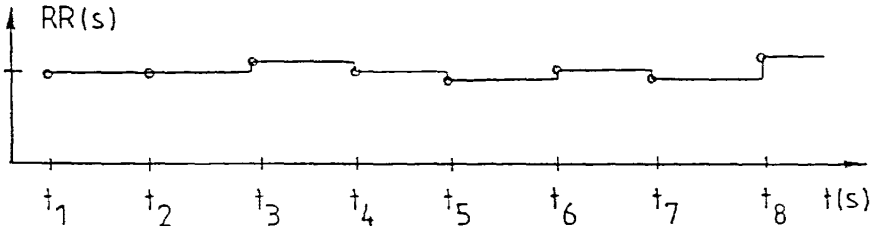


FIG. 6c

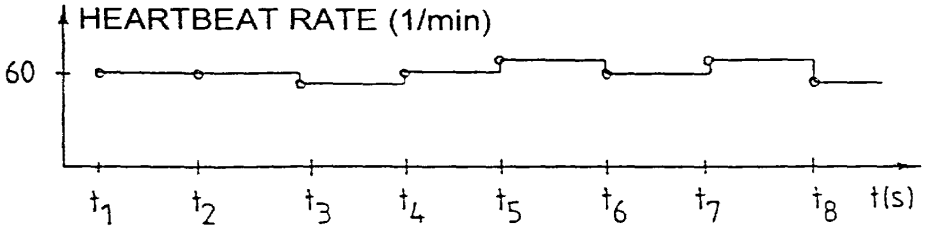


FIG. 6d

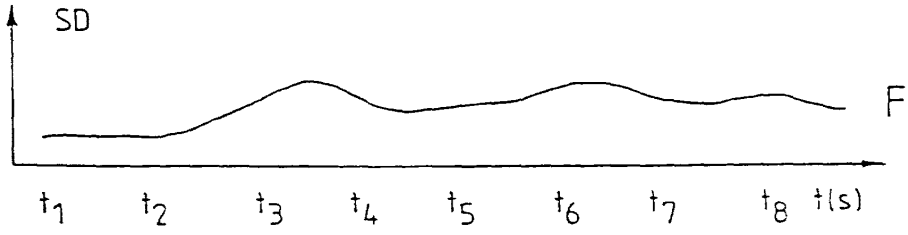


FIG. 6e

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 95/00714

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61B 5/024
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B

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

SE,DK,FI,NO classes as above

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

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"P" document published prior to the international filing date but later than the priority date claimed
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"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

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

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

INTERNATIONAL SEARCH REPORT
Information on patent family members

05/02/96

International application No.
PCT/FI 95/00714

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

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

Espacenet

Bibliographic data: WO9629005 (A1) — 1996-09-26

PULSE RATE METER

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Classification:	**- international:**	***A61B5/00; A61B5/024; A61B5/0245; A61B5/22;*** (IPC1-7): A61B5/0245
	- European:	A61B5/00B3B; A61B5/0245; A61B5/024F; A61B5/22B2; A61B5/68B1H; A61B5/68B3B

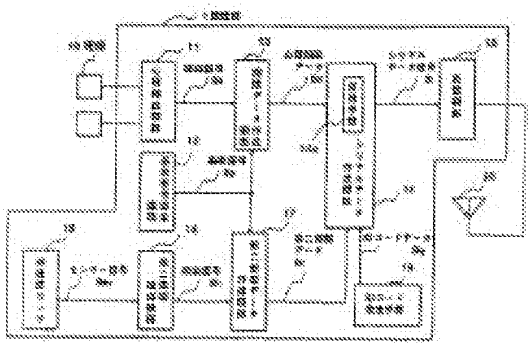
Application number:	WO1996JP00661 19960315
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Abstract of WO9629005 (A1)

This invention aims at improving a method of carrying out communication between a transmission unit and a reception unit in a pulse rate meter and providing a pulse rate meter not influenced by noise. To achieve these objects, the present invention provides a pulse rate meter comprising a transmission unit provided with a detecting circuit for detecting an electrocardiographic signal obtained from a pair of electrodes fixed to the portion of a human body which is in the vicinity of the heart (2), and generating a detected signal (3), an interval data preparation circuit for counting the generation interval of the detected signals by a signal of a predetermined cycle and generating interval data (4), a serial data preparation circuit for converting the interval date into a serial signal and generating serial data signal (5), a transmission circuit for modulating the serial data signal and transmit the resultant signal as a ratio signal (6), and a battery as a power source (7), and a reception unit provided with a reception circuit for receiving the radio signal from the transmission unit, demodulating the resultant signal and generating a reception signal (8), a data decoding circuit for decoding the reception signal and generating electrocardiographic interval data (9), an operation circuit for calculating a heart rate on the basis of the electrocardiographic

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interval data, and a display for indicating a heart rate thereon. According to the present invention, even when the reception circuit receives noise or a signal having no relation with a heart rate, which does not constitute correct data in this case, it cannot be decoded correctly by the decoding circuit, and the data received normally in the preceding time are displayed. Therefore, erroneous heart rates are not displayed.



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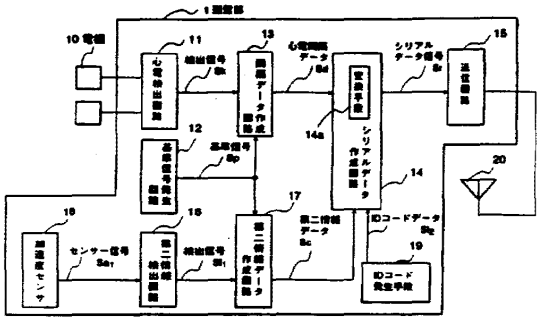
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(54) **Title : PULSE RATE METER**

(54) 発明の名称　心拍計

(57) **Abstract :**

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



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（５７）要約

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

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

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

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

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						VN	ヴィエトナム

明　細　書

心拍計

技術分野

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

背景技術

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

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

発明の開示

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

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

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

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

図面の簡単な説明

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

発明を実施するための最良の形態

以下図面に基づいて本発明の実施例を詳述する。

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

図１は本発明による心拍計の送信部の一実施例のブロック図である。

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

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

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

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

一方、第二情報検出回路１６は、加速度センサー１８により加速度の変化の電気的信号であるセンサー信号$Ｓａ_{1}$を検出、増幅し、センサー信号$Ｓａ_{1}$に同期したパルス信号である検出信号$Ｓ１_{1}$を出力し、第二情報データ作成回路１７は、検出信号$Ｓ１_{1}$の発生間隔を基準信号発生回路１２から出力される基準信号Ｓｐで計数しその計数値を第二情報データである走行ピッチデータＳｃとして出力する。

また、ＩＤコード発生手段１９は、所定のＩＤコードを発生し、シリアルデータ作成回路１４が処理可能なＩＤコードデータ$Ｓ１_{2}$に変換し出力する。

シリアルデータ作成回路１４は、心電間隔データＳｄと第二情報データＳｃとＩＤコードデータ$Ｓ１_{2}$とを変換手段１４ａで結合した後シリアルデータに変換し、Ｔｊ秒毎にシリアルデータ信号Ｓｒを出力する。送信回路１５は、シリアルデータ信号Ｓｒが入力される毎に該シリアルデータ信号Ｓｒを変調して無線信号としてアンテナ２０から送信する。

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

図２は本発明による心拍計の受信部の一実施例のブロック図である。

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

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り構成されている。

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

データデコード回路３２は、受信信号Ｓｊをデコードし、データ分離手段３２ａから心電間隔データＳｎと第二情報データSm_1とＩＤコードデータSm_2とを分離出力する。心電間隔データＳｎは前記送信部１の心電間隔データＳｄと同じ信号であり、第二情報データSm_1は前記送信部１の第二情報データ$S1_1$と同じ信号であり、ＩＤコードデータSm_2は前記送信部１のＩＤコードデータ$S1_2$と同じ信号である。また、データデコード回路３２は心電間隔データＳｎと第二情報データSm_1とＩＤコードデータSm_2のデコードが正常に行われると、ワンショット信号であるデコード終了信号Ｓｅを出力する。受信制御回路３３はデコード終了信号Ｓｅが入力されると、一定幅のパルス信号である受信制御信号Ｓｓを出力する。受信制御信号Ｓｓのパルス幅は前記送信部１から送信される無線信号の間隔Ｔｊ秒よりも短い信号である。デコード終了信号Ｓｅと受信制御信号Ｓｓは消費電力低減のために必要とする信号であるが、その動作説明については後述する。

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

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

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

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

上記構成を有する、本発明による心拍計の動作を説明する。

まず図１において、送信部１の動作を説明する。

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

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

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

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

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

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

次に図２において、受信部２の動作を説明する。

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

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

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

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

次に受信制御回路３３の動作を説明する。

図３は受信制御回路３３の動作を説明するためのタイムチャートである。

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

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

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

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

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

図４は、本発明による心拍計の一実施例の装着状態を示す図である。

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

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

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

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

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

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

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

図６は本発明による心拍計の受信部の一実施例の外観図である。

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

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

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

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

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

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

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

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

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

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

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

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

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

産業上の利用可能性

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

請　求　の　範　囲

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

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

から成ることを特徴とする心拍計。

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

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

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

ことを特徴とする請求の範囲第１項または第２項に記載の心拍計。

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

前記ＩＤコード比較判定手段は、分離した間隔データの前方に連結されていた

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

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

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

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

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

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

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

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

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

ことを特徴とする請求の範囲第５項に記載の心拍計。

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

図1

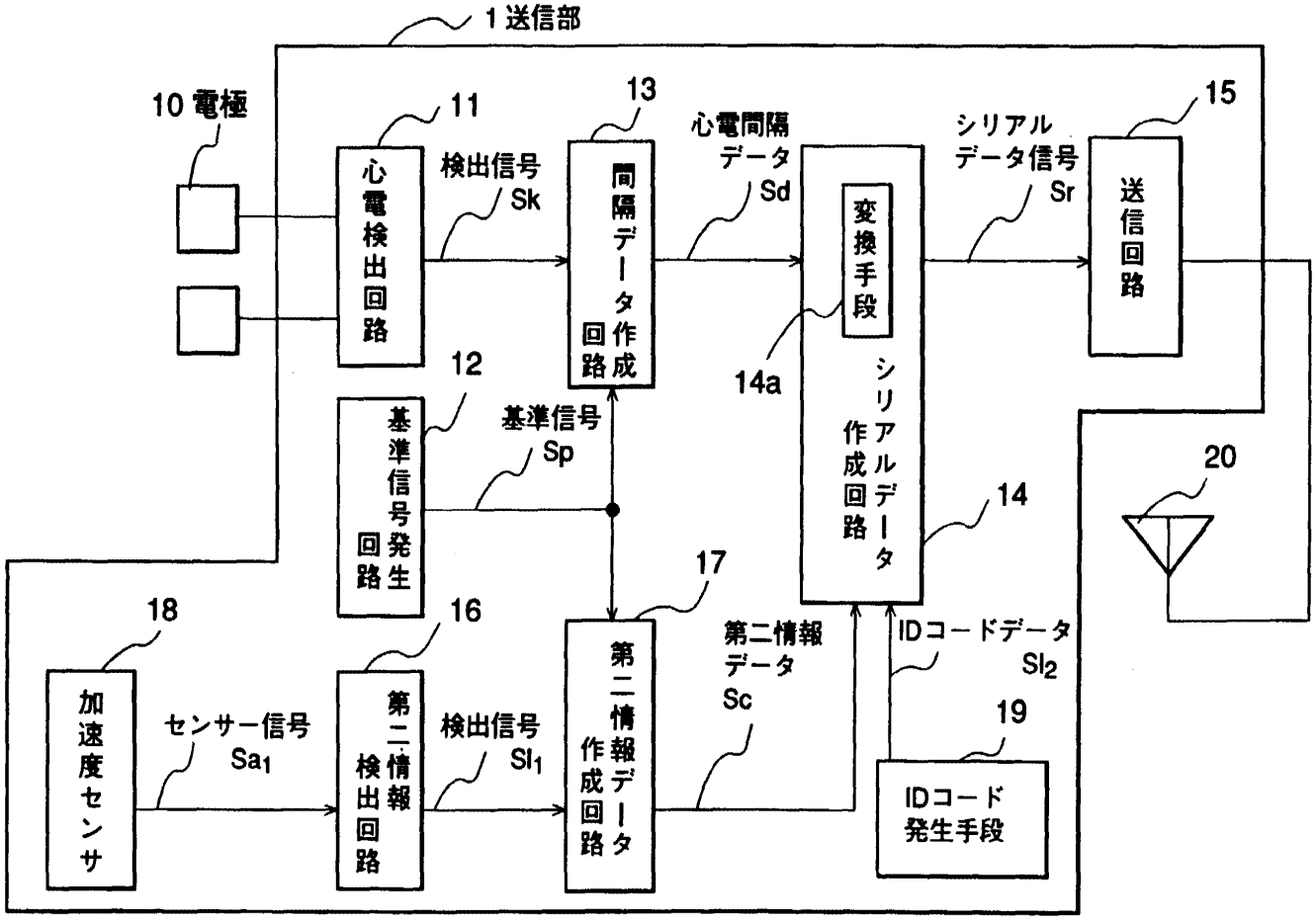

1 送信部
10 電極
11
心電検出回路
検出信号 Sk
13
間隔データ作成回路
心電間隔データ Sd
変換手段
14a
シリアルデータ作成回路
14
シリアルデータ信号 Sr
15
送信回路
20
12
基準信号発生回路
基準信号 Sp
17
第二情報データ作成回路
第二情報データ Sc
IDコードデータ SI_2
19
IDコード発生手段
18
加速度センサ
センサー信号 Sa_1
16
第二情報検出回路
検出信号 SI_1

図2

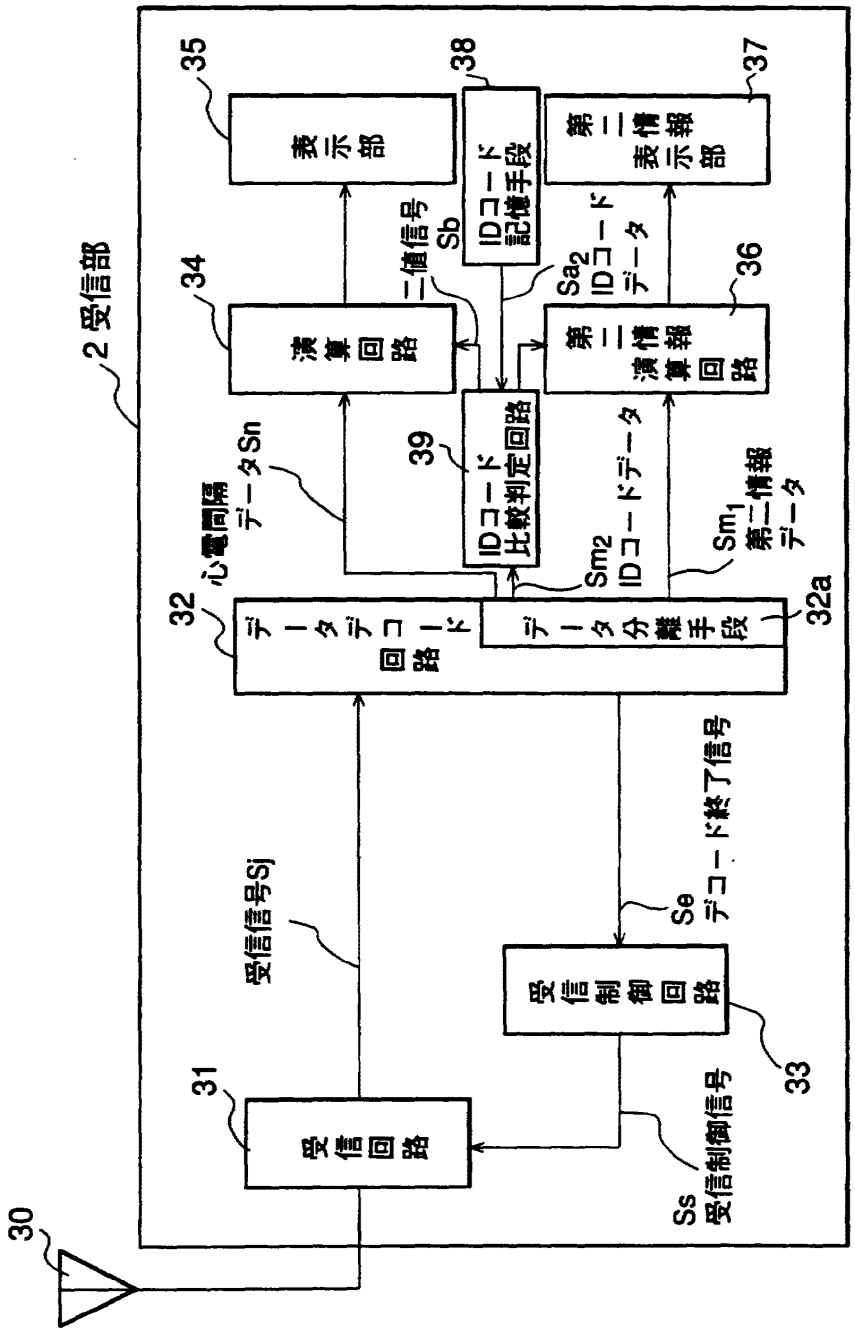

2 受信部
30
31
受信回路
受信信号Sj
32
データデコード回路
32a
データ分離手段
心電間隔データSn
Sm2 IDコードデータ
Sm1 第二情報データ
33
受信制御回路
Se デコード終了信号
Ss 受信制御信号
34
演算回路
二値信号Sb
35
表示部
36
第二情報演算回路
Sa2 IDコードデータ
37
第二情報表示部
38
IDコード記憶手段
39
IDコード比較判定回路

図3

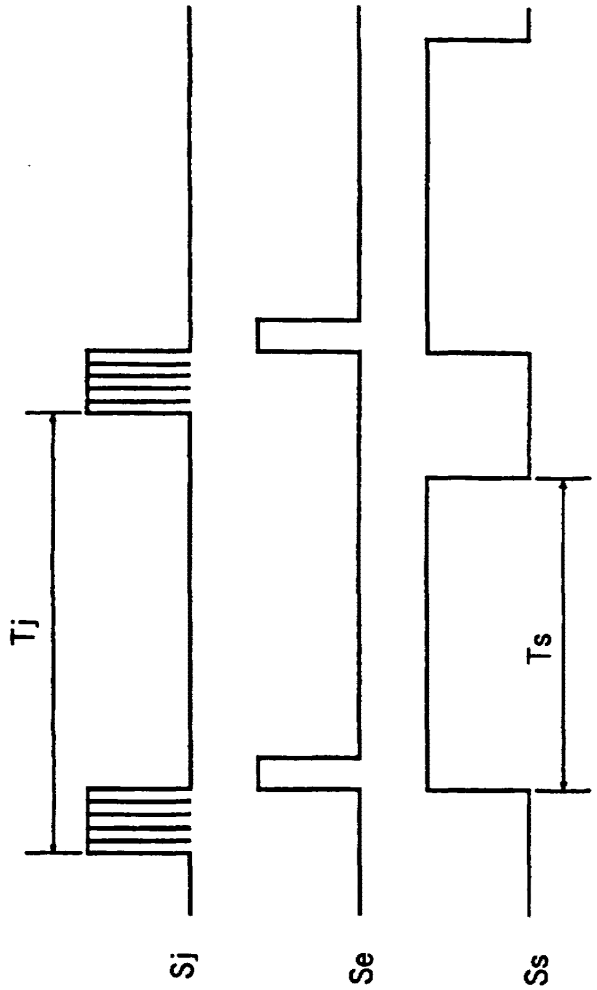
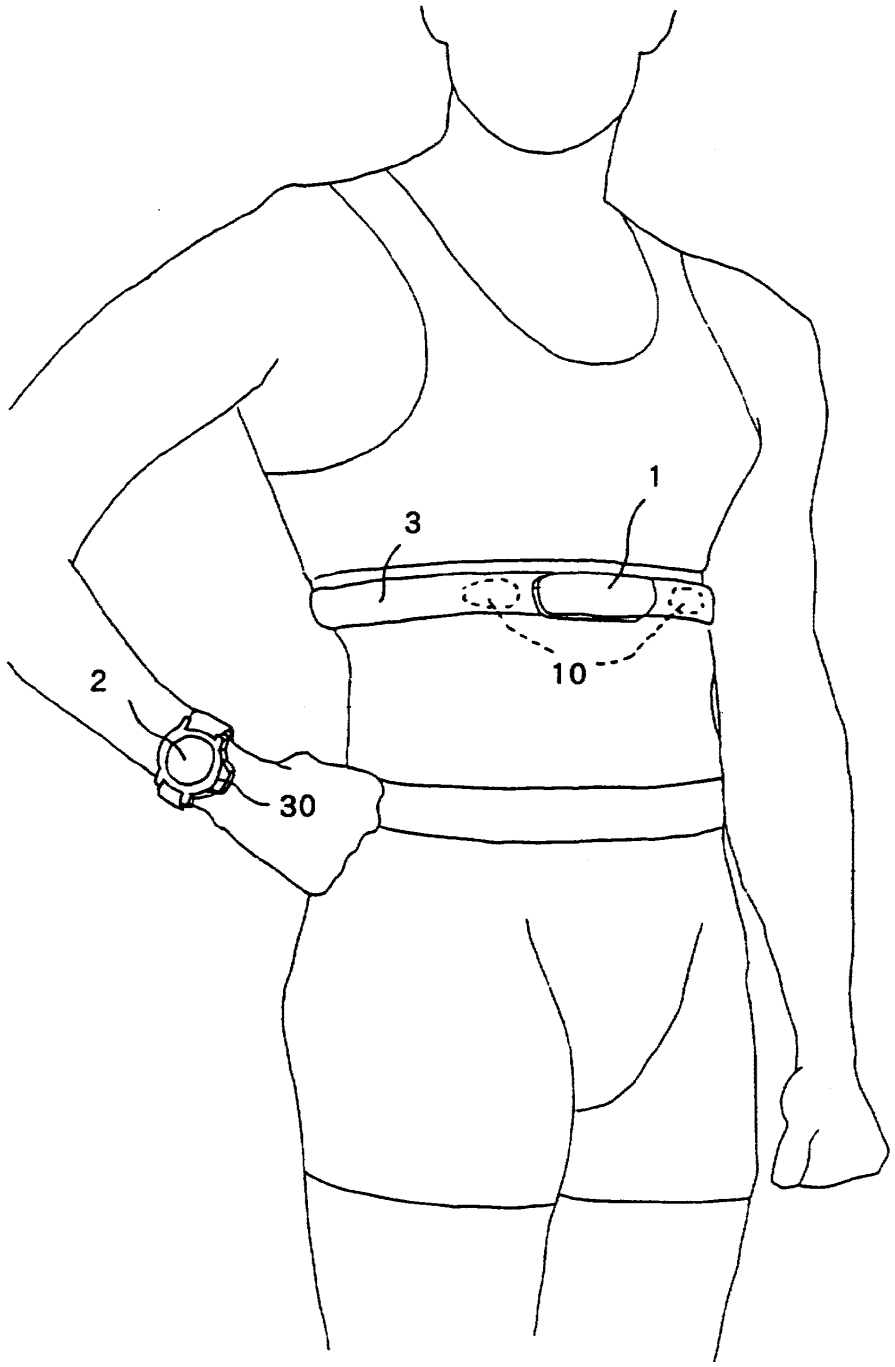


図4



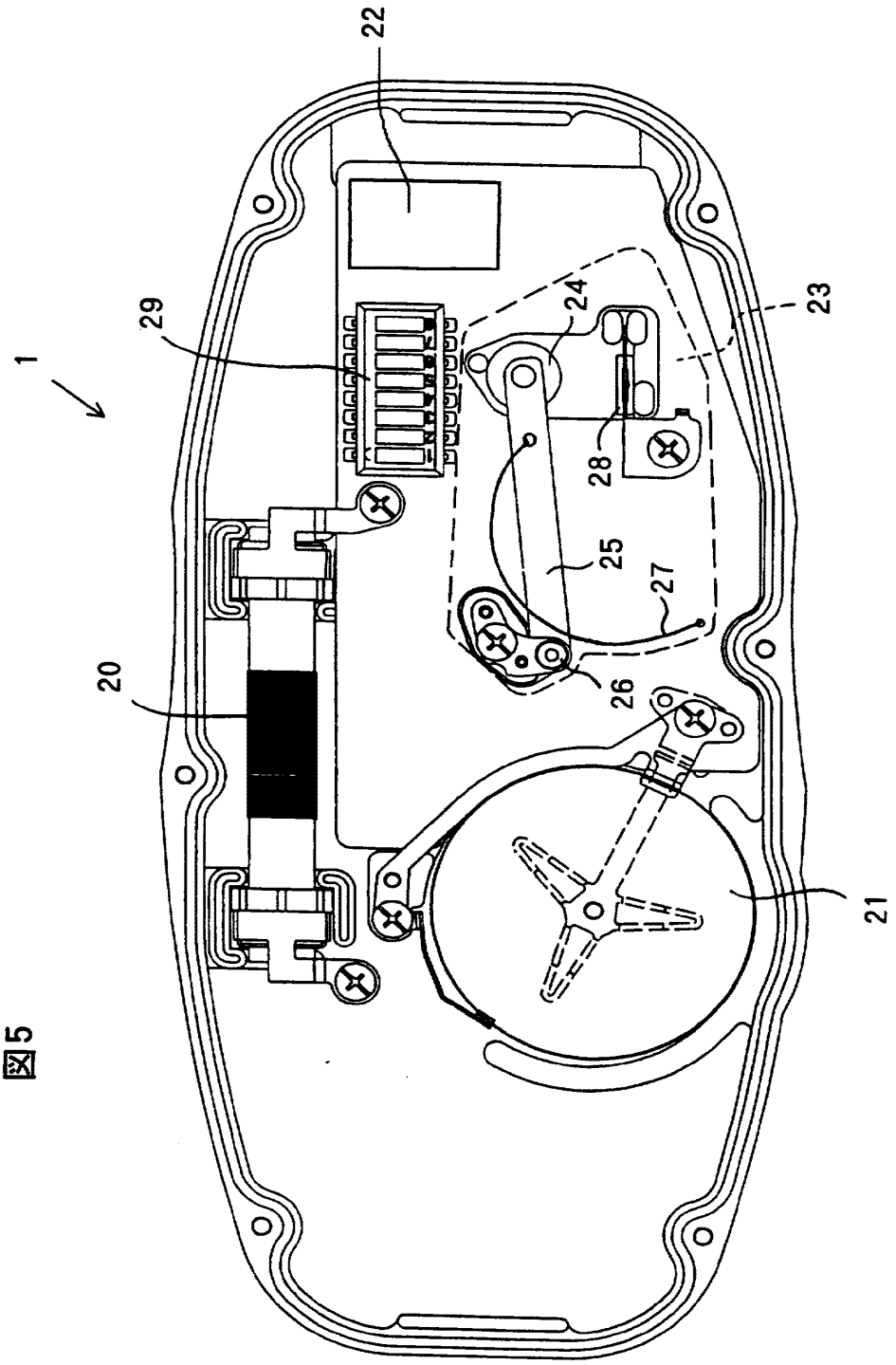


図5

WO 96/29005 PCT/JP96/00661

図6

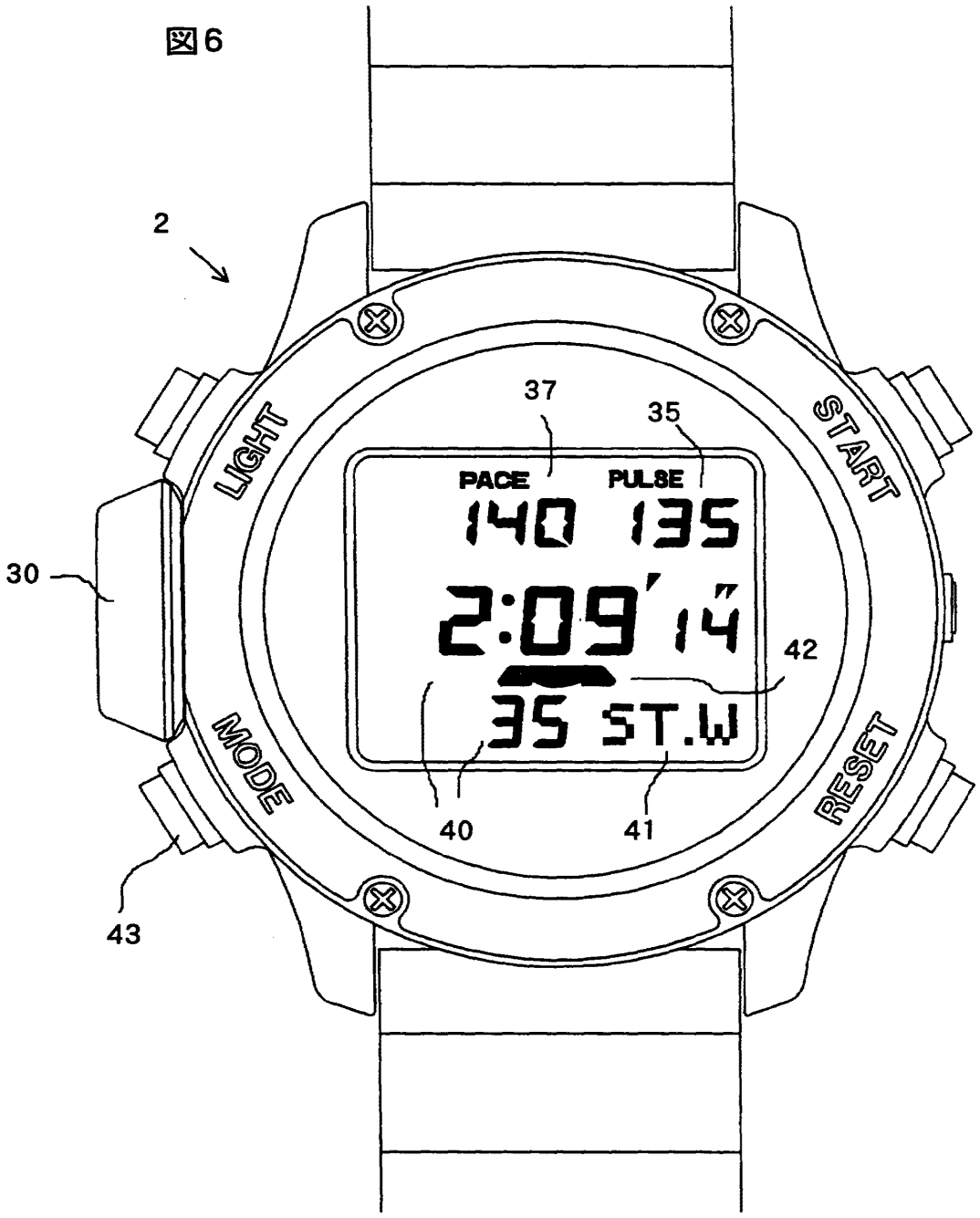
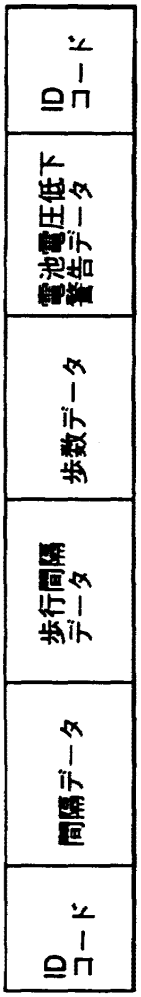


図7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP96/00661

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

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
Int. Cl^6 A61B5/0245, A61B5/00, B61B5/04

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

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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
"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
April 30, 1996 (30. 04. 96)	May 14, 1996 (14. 05. 96)
Name and mailing address of the ISA/ Japanese Patent Office Facsimile No.	Authorized officer Telephone No.

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP96/00661

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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

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

国際調査報告	国際出願番号　ＰＣＴ／ＪＰ９６／００６６１

A.　発明の属する分野の分類（国際特許分類（ＩＰＣ））

Int.Cl[6]　　Ａ６１Ｂ５／０２４５

B.　調査を行った分野

調査を行った最小限資料（国際特許分類（ＩＰＣ））

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

最小限資料以外の資料で調査を行った分野に含まれるもの

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

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

C.　関連すると認められる文献

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

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

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３０．０４．９６	14.05.96

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

様式ＰＣＴ／ＩＳＡ／２１０（第２ページ）（１９９２年７月）

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国際調査報告	国際出願番号　ＰＣＴ／ＪＰ９６／００６６１

Ｃ（続き）．　関連すると認められる文献

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

様式ＰＣＴ／ＩＳＡ／２１０（第２ページの続き）（１９９２年７月）

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(71) Applicant: DATA CRITICAL CORP. [US/US]; Suite 2200, 100 North Broadway, Oklahoma City, OK 73102 (US).

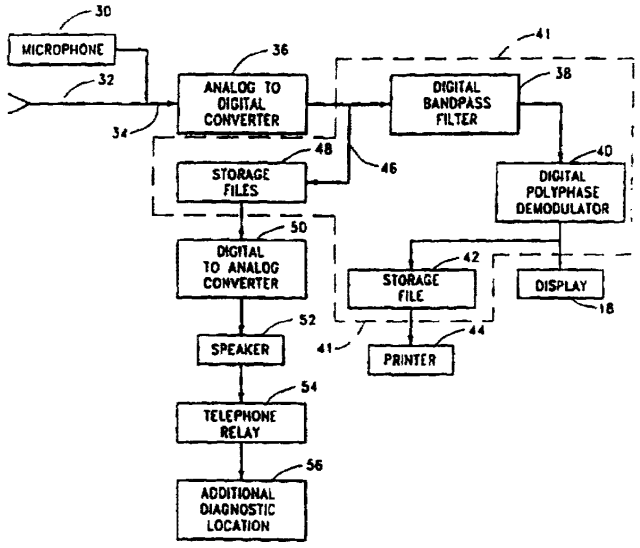
(72) Inventors: ALBERT, David, E.; 801 Northwest 40th Street, Oklahoma City, OK 73118 (US). SMITH, Landgrave, T.; P.O. Box 19346, Oklahoma City, OK 73152 (US). RIEGER, Carl, J.; 1005 Riviera Drive, Ponca City, OK 74601 (US). CUMMING, Colin, J.; 2801 South Fox Ledge Drive, Stillwater, OK 74074 (US). HOY, Leslie, D.; 313 Hardwicke Drive, Knoxville, TN 37923 (US).

(74) Agents: LaBRIE, Michael, J. et al.; Dougherty, Hessin, Beavers & Gilbert, Suite 1400, Two Leadership Square, 211 North Robinson, Oklahoma City, OK 73102 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: METHOD AND HAND-HELD APPARATUS FOR DEMODULATING AND VIEWING FREQUENCY MODULATED BIOMEDICAL SIGNALS



(57) Abstract

This invention is a method and apparatus for transmission of biomedical waveform data from a patient to an attending physician, wherein the waveform data audio signal (30) is frequency modulated for subsequent wire line or wireless transmission to a remote hand-held computer that functions to digitize (36), record (42), and demodulate (40) the frequency modulated signal for display (18) on the computer, for permanent print-out, or for further retransmission.

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METHOD AND HAND-HELD APPARATUS FOR DEMODULATING AND VIEWING FREQUENCY MODULATED BIOMEDICAL SIGNALS

BACKGROUND OF THE INVENTION

1. Field of the Invention.

The invention relates generally to improved method and apparatus for monitoring a patient's biomedical waveform data and, more particularly, but not by way of limitation, it relates to an improved method and apparatus for monitoring a patient's electrocardiogram (ECG) data using a hand-held computer in association with a wireline or wireless telephone system.

2. Description of the Prior Art.

The prior art includes numerous systems wherein ECG data or the like is transmitted from a patient to a particular doctor's office or health service center. U.S. Patent No. 4,938,229 discloses an earlier form of monitoring system which includes apparatus for demodulating a constant amplitude audio FM ECG signal. The analog FM signal is processed through a zero crossing counter which generates a digital pulse for every crossing. The time intervals between pulses are then averaged to produce a digital ECG signal at a predetermined sample rate. This procedure differs from the present invention as it does not digitize the audio FM signal, nor does it utilize such as a polyphase demodulator to derive the ECG data in digital form. U.S. Patent No. 4,531,527 discloses another system for trans-telephonic ECG monitoring; however, this system requires special hardware considerations and differs in may other aspects from Applicants' method and apparatus.

U.S. Patent No. 4,409,984 discloses a method for square pulse frequency modulation and demodulation of ECG data in a multiple patient monitoring system. The system does not employ polyphase demodulation since it processes a constant amplitude FM signal to detect zero crossings, and neither does it provide portable storage and display of ECG data in the manner of the present invention. The similar digital FM demodulator is taught in the U.S. Patents Nos. 4,027,146 and 3,909,599, but there is no teaching of the digitization of an FM data signal nor of

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possible retransmitting of the FM signal. In addition, these patents all require hardware of specialized design for carrying out specific circuit functions.

The U.S. Patents Nos. 5,365,935; 5,191,891; and 5,333,616 all relate to an ECG monitoring system that utilizes wrist-worn transtelephonic ECG recorders and transmitters. The disclosure does not deal with any form of signal demodulation and display or any storage and retransmission capabilities. The present invention would be compatible for use to receive, display, store and/or retransmit biomedical signals derived by the teachings of these patents.

ECG data is usually transmitted directly from the patient to the analyzing location and one such system, available from Instromedix, Inc. of Hillsboro, Oregon, utilizes a Heart Card to provide a recording of the ECG signal from thirty seconds upward to five minutes. This system provides for transmission via a wired or wireless telephone system of such recorded or realtime ECG data in the form of a frequency modulated audio signal. The transmitted FM audio signal is then demodulated at the doctor's office or health service center for viewing of the actual ECG data whereupon the patient's personal doctor is alerted if a problem is seen in the data. Further, the actual ECG data waveform may be sent via facsimile to the attending doctor.

SUMMARY OF THE INVENTION

The present invention relates to an improved communication system for conveying ECG data or other biomedical waveform data more directly between the patient and an attending doctor's location. The patient employs a Heart Card-type of device that converts the patient's ECG signal into a frequency modulated audio signal that may then be analyzed by audio inputting via a telephone system to a selected hand-held computer device that functions to digitize, record and demodulate the frequency modulated signal for presentation and viewing on the hand-held computer display screen. Also, the operator has the option of printing out the demodulated biomedical signal for further viewing separate from the hand-held computer. There is still

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further an option of retransmitting the stored ECG audio signal via telephone, either wireline or wireless, to a designated doctor's office; or, if no one answers, the call may be forwarded to another nurse or doctor as designated. At any of the first or forwarded receiver stations, the attendant may also have a programmed hand-held computer that can receive the audio FM biomedical signal for digitization, recording and demodulation for viewing. The hand-held computer is one with integrated microphone, audio analog to digital converter, digital to analog converter, speaker, and central processing unit with memory for performing various computational, data storage and signal processing tasks.

Therefore, it is an object of the present invention to provide a highly accurate and portable biomedical signal monitor for use with a telephone system, either wireline or wireless.

It is also an object of the present invention to provide a highly accurate and reliable patient monitoring system that allows the doctor to interface directly over a telephone system with the patient at anytime or anywhere.

It is yet further an object of the present invention to provide a patient monitor system that may be quickly and reliably deployed in monitoring operation.

It is still further an object of the present invention to provide a reliable and accurate patient ECG monitoring system with first hand communication between doctor (or other healthcare provider) and patient.

Finally, it is an object of the invention to provide a hand-held computer with proprietary software that combines with a telephone system to provide remote monitoring of a patient's electrocardiogram (ECG).

Other objects and advantages of the invention will be evident from the following detailed description when read in conjunction with the accompanying drawings that illustrate the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an idealized block diagram of an ECG monitoring system;

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FIG. 2 is a functional block diagram of a preferred form of signal processing circuitry as effected by a hand-held computer;

FIG. 3 is an idealized block diagram of a monitoring relay link for further transmission of ECG data;

FIG. 4 is a functional block diagram of an alternative form of patient monitoring circuitry as effected by a programmed hand-held computer;

FIG. 5 is a diagram of a programmed signal process as utilized in the preferred form of circuitry;

FIG. 6 is a diagram illustrating cycle accumulation between filtered data and decimated data output;

FIGS. 7, 8 and 9 are a flow diagram for the demodulation procedure carried out by the Rhythm-Stat SX software; and

FIG. 10 is a top plan view of a Psion 3a hand-held computer.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. 1, a patient monitoring system 10 consists of a Heart Card 12 disposed on the patient and capable of detecting and recording the electrocardiogram signal (ECG) for a predetermined time and then actuable to transmit the ECG as a frequency modulated audio band signal 14. The Heart Card 12 is a commercially available device that functions to sense the ECG data for a predetermined time period and, after the period, the Heart Card 12 can be actuated to transmit the audio frequency modulated ECG data. Such Heart Card sensor/transmitters may be obtained from such as Instromedix, Inc. of Hillsboro, Oregon. Other devices that perform the same or similar functions (i.e., recording the ECG and transmitting over a phone system as a frequency modulated audio signal) are available from Instromedix, Inc. and other vendors.

The frequency modulated audio signal 14 may then be transmitted via telephone, either wireline or wireless; or, the frequency modulated audio signal 14 may be played directly into the audio microphone of a palmtop computer 16 which includes resident software that processes the biomedical data contained in the frequency modulated audio signal and displays the data

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on the computer screen 18. In most cases, the patient and Heart Card 12 will be remote from the palmtop computer 16 and the attending physician or diagnostician. In this situation the Heart Card 12 need only transmit the frequency modulated audio into the receiver 20 of telephone 22 which is connected via a suitable telephone system 24, either wireline or wireless, to a telephone 26 at the attending physician's office whereupon the telephone transmitter 28 can direct frequency modulated audio data 14 into the microphone of the palmtop computer 16 to complete the information relay.

A preferred embodiment of the invention uses a Psion 3a palmtop personal computer with proprietary software as will be further described. The hand-held computer 16 must have an integrated microphone or direct audio electrical jack that can interface to a wireline or wireless phone. A laptop computer could be used for the present invention; however, it does not have the portability feature that makes the hand-held version preferred.

The preferred form of the invention is illustrated in the functional block diagram of FIG. 2 which illustrates the functional components of the programmed Psion 3a palmtop computer 16. The frequency modulated audio biomedical data may be input directly to microphone 30 or, in some cases, it may be received directly through a connector jack 32 to input lead 34 to analog/digital converter 36. The output from analog to digital converter 36 is then applied to a digital band-pass filter 38, e.g., over the band of 0.05 Hz to 40 Hz, and then to a digital polyphase demodulator 40. The dash-line 41 outlines the central processing unit and memory components of the palmtop computer 16 (FIG. 1). The demodulator 40 employs two simultaneous filters which have been optimized for integer operation using a micropower microprocessor. The output from demodulator 40 may then be applied directly to display 18, or the filtered digital signal can be applied directly to a storage file 42 for selected output via printer 44.

Alternatively, the digital biomedical FM data signal output from analog to digital converter 36 may be applied via lead 46 to a storage file 48. Selected data from storage file 48 may

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then be played back into digital to analog converter 50 and the analog signal can then be applied to a loud speaker 52 and/or further telephone or facsimile relay 54 to a remote diagnostic location for further demodulation, review and opinion. As shown in FIG. 3, the original receiving phone 26 and handset 28 may be used to relay the data via telephone system link 53 to yet another phone 26R and handset 28R as located at another remote location. Such further transfer may be necessitated by a need for second opinion or additional comparison data. The hand-held computer 16 may be operated to emit the audible ECG data from handset 18 for transmission via telephone interconnect 53 to the remote phone 26R whereupon handset 28R provides audible input to another hand-held computer 16R for processing and display of the ECG data.

FIG. 4 illustrates an alternative design of the invention utilizing a palmtop computer of the type having a PCMCIA interface slot for signal processing and display. A received frequency modulated audio signal is fed either via microphone 30 or connector 32 to input lead 34 to the analog FM demodulator 58. The FM demodulator 58 may be such as a IC phase locked loop, Exar type 215. The analog FM demodulator 58 then applies output to an analog to digital converter 60 which provides digital output via the palmtop PCMCIA interface to the palmtop's CPU for digital filtering (40), storage and display. Optionally, a band-pass filter 62 may be interconnected between the demodulator 58 and the analog to digital converter 60. The output from digital filter 38, having a pass-band of 0.05 Hz to 40 Hz., may then be applied to output display 18, or, it may be placed in storage file 42 for subsequent recall to printer 44. The demodulator 58, converter 60 and bandpass filters 62 and 40 are all contained in the PCMCIA card.

Referring to the preferred embodiment of FIG. 2, it is an objective of the Rhythm-Stat program to demodulate a frequency modulated audio signal and to decimate the output for storage and plotting purposes. The Psion 3a computer 16 records sound files at an 8,000 samples per second rate and uses an A-Law analog to digital transformation. Therefore, the program used to demodulate a frequency modulated ECG or biomedical signal

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must perform three functions. As shown in FIG. 5, these functions are (1) an A-Law decoder 64, (2) a band-pass filter 66, and (3) a frequency estimator 68 which includes a residue estimator 70 and a cycle accumulator 69. The A-Law decoder 64 functions as an expander which reverses the action of the A-Law compressor in the Psion. The A-Law encoding is a standard approximation to the logarithmic compression as established by CCITT, the European standards body. The output of the A-Law compander is defined by

$$F(x) = sgn(x)^* A|x|/(1+\ln(A)) \qquad 0 \le |x| < 1/A \qquad (1)$$

$$F(x) = sgn(x)^* (1+\ln(A|x|))/(1+\ln(A)) \qquad 1/A \le |x| \le 1 \qquad (2)$$

where x is the analog input, F(x) is the A-Law compander output, sgn(x) is the sign (+/-) of x, and A is the compression parameter. Since the Psion 3a computer 16 records the sound file in A-Law encoded format (12-bit data stored in 8 bits, all at 8000 samples per second), these values need to be decoded in order to band-pass filter and demodulate the signal. The decoding is accomplished by using a look-up table. The range of A-Law encoded values is -128 to 127, therefore, an array of length 256 is initialized to contain the A-Law decoded values. The array is indexed from zero to 255 as the decoded value contained at indexed zero corresponds to the A-Law value of -128, and the decoded value contained at index 255 corresponds to the A-Law value of 127. Therefore, to decode any A-Law value, 128 is added to the A-Law value and the result is used to index into the array.

The digital band-pass filter 66 is utilized to remove unwanted signal introduced when recording with the Psion 3a. The equation used to realize the band-pass filter is

$$a_0y(n)=b_0x(n)+b_1x(n-1)+b_2x(n-2)+a_1y(n-1)+a_2y(n-2) \qquad (3)$$

where x(n) is the input data, y(n) is the output data, and a_x, b_x are constant coefficients. For data that is sampled at 8000 Hz, to obtain a band-pass filter with a Q=2 and a center frequency of 2000 Hz, the coefficients are set to

$a_0 = 1$
$a_1 = 0$
$a_2 = -0.5$
$b_0 = 1$
$b_1 = 0$

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$b_2 = -1$

This realizes a band-pass filter with a transfer function

$$H(z) = (1-z^{-2})/(1+0.5z^{-2}) \quad (4)$$

This portion of the demodulation procedure is implemented directly after the A-Law decoder 64 and before the cycle counting procedure.

The frequency estimator 68 functions by windowing the input data and counting the number of complete cycles contained within the window. The phase of the incomplete cycle located at the end of each window is estimated by using the arctangent function. Therefore, the frequency estimator 68 contains two sections which are (1) the cycle accumulator and (2) a residue estimator. See FIG. 6. The cycle accumulator consists of two overlapping windows and FIG. 6 shows the relationship between the two windows. The filtered data appears on line 72 with 40 unit graduations while the decimated output data appears along line 74. The size of each window determines the amount of decimation in the demodulation procedure. Choosing a window size of 80 decimates the data from 80 input points to 1 (80:1), however, with two overlapping windows the final output is decimated by 40:1. Thus, with an original sampling of 8000 samples per second, the output is resampled to 200 samples per second after decimation. For a frequency estimate, each window counts the number of complete cycles of 80 band-pass filtered data points. For each complete cycle, 256 (corresponding to 2 π radians) is added to the window counters. After determining the number of complete cycles contained in 80 data points, a window calls the residue estimator passing the 79th and 80th

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data points to determine the amount of the incomplete cycle on the end of the window.

Using the last two data points of the cycle accumulator window, the residue estimator 70 determines the amount of an incomplete cycle by using a look-up table technique. The look-up table contains arctangent values for every possible point in the first quadrant of a sine wave. The values are scaled to range from zero to 64 (corresponding to 0-$\pi/2$ radians). Using the sign of the two points passed from the cycle counter, the residue estimator 70 determines in which quadrant the points are located. These points are then scaled so that both are less than 64 in order to index into the arctangent look-up table. The quadrant determination with the arctangent value, determines the output of the residue estimator as follows:

1st quadrant: Residue Estimate = arctangent value

2nd quadrant: Residue Estimate = 128 -arctangent value

3rd quadrant: Residue Estimate = 128 +arctangent value

4th quadrant: Residue Estimate = 256 -arctangent value

The residue estimate is added to the window calling the residue estimator 70 and thus is used as an output point. The window counter is then reset to 256 minus residue estimate to include an estimate of the incomplete cycle located at the beginning of the next 80 filtered data points.

FIGS. 7, 8 and 9 are a flow diagram of the demodulation procedure that is carried out under the system program, i.e., the Rhythm-Stat XL software, as will be further described below. In FIG. 7, the process begins at START 100 whereupon variables are initialized in flow stage 102 and the input and output files

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are readied at stage 104. The flow stage 106 then reads the *.WVE file header information and the number of samples in the file is stored at flow stage 108. Flow stage 108 then proceeds to stage 110 which sees reading of eighty input samples after which decision stage 112 tests to see whether or not end of file (EOF) has been encountered. If end of file does appear, then the affirmative output proceeds to END stage 114 and completion of the program operation. If end of file is not yet reached, the negative output passes flow to stage 116 which functions to A-Law decode the samples. The A-Law decoding expands the A-Law encoded values to the original value.

Data handling proceeds to flow stage 118 which effects bandpass filtering and subsequent flow stage 120 functions to assign samples in accordance with polarity of the last sign. Continuing on to FIG. 8, the line 122 connects from Terminal B to flow stage 124 which points to first sample with data flow on line 126 to a series of decision stages. A first decision stage 128 tests for whether or not the sample is positive with a negative response by-passing on line 130, and an affirmative response proceeding to the subsequent decision stage 132 which queries for last sign negative. A negative response directs flow to by-pass line 130 and an affirmative response continues process to stage 134 which adds 256 to cyclecount 1 and cyclecount 2. A flow stage 136 then assigns a lastsign the sign (+/-) of the sample being processed.

Flow line 138 then proceeds to stage 140 which functions to point to the next sample prior to decision stage 142 which queries whether the sample is the forty-first sample in the

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sequence. If negative, and the sample is other than the forty-first sample, flow recycles via line 143 to the decision stage 128 which tests whether or not the sample is positive; but, if stage 142 is affirmative, flow proceeds to stage 144 wherein the look-up cycle residue is estimated. That is, a value is obtained from the arctangent table for samples thirty-nine and forty as flow proceeds to stage 146 which adds the estimate to cyclecount 1. A next flow stage 148 sees output to file of cyclecount 1 with flow stage 150 resetting the cyclecount 1 before proceeding on line 152 for connection to the C terminal at FIG. 9.

The line 152 leads to a series of decision stages wherein stage 154 tests for a positive sample and, if negative, cycles ahead via line 156, and, if affirmative, query is made of the next decision stage 158 as to whether or not the last sign was negative. If not, cycle ahead via lead 156 is made or, if affirmative, flow proceeds to stage 160 which adds 256 to each of cyclecount 1 and cyclecount 2.

Flow proceeds from stage 160 as well as by-pass line 156 to a stage 162 which functions to assign the lastsign or previous sample sign. Thereafter, flow stage 164 points to the next sample as indication proceeds via line 166 to a decision stage 168 which queries whether the sample is the eighty-first sample in the succession. If not, flow proceeds via line 170 to recycle through stages 154 and 158 and succeeding stages; however, if the decision is affirmative (the eighty-first sample) then stage 172 establishes the look-up cycle residue estimate, i.e., samples 79 and 80 from the arctangent look-up

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table. The estimate is added to the cyclecount 2 in flow stage 174 and output to file in flow stage 176 prior to the reset of cyclecount 2 in stage 178. Flow then proceeds through terminal A back to FIG. 7 for recycle through flow stage 110 which reads the next eighty input samples. Eventually, when end of file is encountered as at flow stage 112, the affirmative output proceeds to END 114 to terminate the process.

The program for controlling the Psion 3a hand-held computer 16 is termed the Rhythm-Stat XL software and it functions to acquire frequency modulated biomedical data, e.g., ECG data, as generated by an Instromedix™ recording device known as the Heart Card 12 or other similar medical data recording device. The Psion 3a computer 16 is programmed with the Rhythm-Stat XL program that functions with the Psion floating point emulator. Data files with a *.WVE extension must be first placed in the ECG data directory, and these are Psion sound files that will be decoded, demodulated, and displayed by the Rhythm-Stat XL program as an ECG rhythm strip.

On start up (see FIG. 10), the program displays a title screen, and pressing the ESCAPE key 76 continues operation with an empty graphics grid as the program title will appear on display screen 18. The MENU key 78 may then be depressed to access the program menus and selected hot keys will be shown to the right of the listed menu items. In order to use an item, it is necessary to hold down the Psion special key 80 while pressing the desired character key. As shown in FIG. 10, the white keys are the standard Qwerty keys while the black keys are various function and control keys. The ECG data scaling,

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keyboard display controls, and data acquisition and relay are summarized below.

The initial display represents a 12.5 mm/second scale that is divided into 200 ms graduations. Up to three 9.6 second periods of ECG totalling 28.8 seconds of ECG rhythm, may be displayed. Expanded scales of 25 and 50 mm per second are available.

The y scale is calibrated to show millivolts of signal value. During demodulation, and after the processing is completed, and the data replotted, a square calibration pulse will appear on the left of the first segment of ECG data to provide signal calibration. An additional calibration pulse may be found at the end of a data set and these calibration pulses are nominally 1 millivolt on the y axis. A control key selects display scales of 25 or 50 mm per second and selected arrow keys 86 may be used to select ECG epochs for display. When the ECG is expanded on the x axis, the y scale is 0.5 millivolts per graduation, and left and right arrow keys 96 and 98 will scroll the expanded display by one epoch at the selected scale. The user may increase or decrease the waveform amplitude by a factor of two with selected gain controls at any scale. The waveform may be shifted up or down in 0.5 mv increments with up and down arrow keys of key group 86 for expanded displays, and also with the shifted up and down arrow keys in the initial 12.5 mm per second display.

The Rhythm-Stat XL program records, decodes and displays acoustic frequency modulated ECG data that is generated by such as the Instromedix Heart Card or other heart watch device, or

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by another Psion 3a computer that is equipped with Rhythm-Stat XL program, as shown in FIG. 3. Recording of the acoustic data may be direct, or it may be done with ordinary telephones across a wireline or wireless phone system.

A more detailed operation description of menu options, keyboard controls, and ECG recording and relay procedures for this program follows. A first option in the FILES menu is the "open ECG file" which functions to display a list of files in the reverse/ECG directory. Left and right arrow keys 96 and 98 at the files display will present the file names. The only valid file types are *.RXL, *.RST and *.WVE files, and if other files are in the ECG directory, they will be shown. The program has no provision for user interruption of WVE input file processing, which takes about 30 seconds, or of ECG data recording or playback, which takes 35 seconds. If necessary, a user may terminate the application during file processing or recording by holding down the Psion control key 80 while depressing the ESCAPE key 76.

The Rhythm-Stat XL program is intended to record and display frequency modulated acoustic ECG data, and taking the record option will produce a file name selection dialogue. When the desired file name is entered, a screen will tell the user that Rhythm-Stat XL program is ready to record and will begin when the "ENTER" key 82 is depressed.

At this point, the user can place the output speaker on the Heart Card 12 as close to the Psion microphone opening (square opening at bottom right edge of the case) as possible. If recording over the telephone, place the Heart Card 12 (FIG. 1)

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on the sender's handset microphone 20 with the receiver's handset speaker 28 as close to the Psion microphone opening as possible. The user can then initiate the playback and recording as close to simultaneously as possible. The Heart Card 12 has a nominal 30 second playback period while the Psion 3a records 35 seconds of sound. The difference will accommodate a few seconds of variance in user synchronization of playback and recording.

Note that there is no progress indicated for the recording and the program, and when Rhythm-Stat XL program completes its recording, an annunciator chirps, and a third screen appears to tell the user that the recording is complete. The new WVE file will then be found among the file names offered in the files plus open menu option for processing and display.

Another files menu item, playback ECG, appears in the Rhythm-Stat XL program. Thus, the program may be used to relay the FM ECG data to another Psion equipped with the Rhythm-Stat XL program, by playing back the *.WVE ECG data file. Taking the playback option will produce a file name selection dialogue. Once the file name is selected, a second screen will tell the user that Rhythm-Stat XL is ready to play back the ECG data file, and will begin when the ENTER key 82 is depressed. The receiving Psion must be prepared for recording with the output speaker on the sending Psion as close to the microphone opening of the receiving Psion as is conveniently possible. If relaying the data over a phone system, the sending Psion speaker should be placed closely over the handset microphone with the receiving handset speaker as close to the related Psion opening as

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possible. Once again, the playback and recording is initiated as close to simultaneously as possible and a high frequency warble of the frequency modulated ECG data will be audible and ceasing upon completion of playback. An annunciator chirp tells the user when the transfer has been accomplished.

The remaining files menu items are "SAVE ECG AS", "DELETE", and "EXIT" and the last two items are self-explanatory. However, the "SAVE AS" item provides for automatic conversion of WVE files to RST files. The data output remains the same, but the RST files are 1k to 5k as compared to 250k for the WVE files. It is useful to be able to process the same WVE file in different ways in order to examine development options.

In addition to the files menu, there is a waveform menu which controls certain display parameters. A first "EXPAND ON X" refers to selection of 25 or 50 mm/second displays. Note that pressing the "z" key 94 will have the same effect. When "EXPAND ON X" item is first activated, a 4.8 second epoch will be highlighted on the main 12 x 5 mm/second display screen. Pressing "z" key 94 again will then toggle the selection box back and forth between the 4.8 second epoch (25 mm/second) and a 2.4 second epoch (50 mm/second). The selection block may be moved around with selected arrow keys 86. Pressing "ENTER" key 82 will display the epoch at the selected mm/second x-axis scale, and pressing the "z" key 94 will toggle the expanded or zoom selection, from 25 mm/second to 50 mm/second and back. The time period in the waveform and the scale are displayed in a text window at the top of the display screen 18. While in a 25 or 50 mm/second screen, the left and right arrow keys 96 and 98

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will scroll the display to the left or right; and, a shifted left or right arrow will increment or decrement the display one complete epoch to the left or right. Depression of control key 88 plus a left or right arrow of keys 86 will initiate continuous scrolling that may be terminated with the "ESCAPE" key 76.

If not scrolling continuously, the "ESCAPE" key 76 will return the user to the 2.5 mm/second main display screen for alternative epoch selection. While zoomed, the dual function Home keys 96 and end key 98 (the Psion plus left arrow and Psion plus right arrow of keys 86) will display the first and last epoch at the scale selected. The up and down arrow keys of the group 86 will shift the zero volt baseline up or down.

Since the nominal recording and playback periods for Rhythm-Stat XL are 35 seconds, additional ECG data, beyond the 28.8 seconds shown on the initial 12.5 mm/second screen, may be available. In such case, that data may be accessed easily by selecting the last epoch on the 12.5 mm/second screen, pressing enter, and scrolling to the right to the end of the data set. Should the user make a recording synchronization error, an additional 1 millivolt calibration pulse may be found at the end of the data set.

Waveform gain selection is accomplished using the Psion key 80 plus the + key 90 to increase the current waveform amplitude by a factor of 2. The waveform amplitude can be halved by depressing the Psion key 80 plus the - key 92. It should be noted that reducing the gain, and then increasing the gain, may cause loss of detail resolution. Similarly, increasing the gain

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may produce values that are detrimental to ECG feature resolution; however, the file may be processed again to regain an original waveform for further manipulation.

There is a waveform menu for moving the ECG up and down on the display screen 18. In a zoomed screen, the menu selection, or an up or down arrow of keys 86 will move the waveform up or down on the display adjusting the position of the zero millivolt baseline. This function is useful on occasions where a low frequency component places a portion of the ECG off the screen in the 25 or 50 mm/second display. In the 12.5 mm/second screen, the same effect may be obtained by the menu selection of the Psion control key 80 plus a shifted up or down arrow key of the key group 86.

The complete program of source code files for Rhythm-Stat XL version 0.2.8 alpha is included with the present application as Exhibit A. A list of the major software routines with functional description is as follows:

```
! read me
Source Code files for Rhythm-Stat XL

ABOUT.C
Title and About screen

Common.C
These are variables and structures for global reference

DeMod. Asm
Assembly module for demodulation of acoustic FM ECG signal,
Requires pointers to ALAW decoding and Arctangent tables; Called
by Process_WVE_File () in WVE_File.C.

Dlg_Ctl.C
file dialog control

File_Ctl.C
UBYTE Open Sound File (UBYTE File Name []);
VOID Close Sound File (VOID);
UBYTE Read Sound Header (SndFile sFileHead);
```


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```
INT Read Sound Segment (UBYTE FileBuf [], UINT Size);

G_SCROLL.C
Scrolls graphics plotting rectangle, one 200 ms window at a
time, right or left

GRID_CTL.C
Entire screen is MainRcl.
Application screen AppRel is the MainRcl, less border
Plotting area is PltRcl, which is AppRcl less axes and caption,
x and y values are in absolute screen coordinates

MISC.C
Miscellaneous functions and procedures

NOTIFY.C
Procedures for posting model and non-model message boxes for
user.

PLOT_CTL.C
Procedures for plotting epochs, and entire data set on the 12.6
mm.sec screen.

PPP_Dec.C
Procedures to decimate (downsample) data, while locating and
preserving peak information in the waveform.  External call is
made to PPP_Decimate_into_Buffers () from WVE_File.C

PPP_Dec.H
Include file for module PPP_Dec.C

Notify.C
Procedures for posting model and non-model message boxes for
user

PLOT_CTL.C
Procedures for plotting epochs, and the entire data set on 12.5
mm/sec screen

PPP_Dec.C
Procedures to decimate (downsample) data, while locating and
preserving peak information in waveform.  External call is made
to PPP_Decimate_Into_ Buffers () from WVE_File.C

PPP_Dec.H
Include file for module PPP_Dec.C

PVTYPES.H
Include file for module RST_File.C

RST_File.C
Procedures to read and process a *.RST file format.  The *.RST
file format is a variation on the *.CMF file format used in
other Data Critical medical information files.
```


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RSTAT_XL.H
Include file for Rhythm-Stat XL modules

WVE_File.C
Procedure to decode and demodulate the FM ECG signal, received as sound data

Wnd_Ctrl.C
The entire screen is MainRcl. The Application Screen, AppRcl, is the MainRcl, less the border. The plotting area is PltRcl, which is AppRcl, less axes and Caption. X and Y values are in absolute screen coordinates

Str_Fn.C
String manipulation functions and utilities

Sound_10.C
Procedures to record and playback the FM modulated ECG data in the form of Psion WVE sound files

The foregoing discloses a novel method and apparatus using a programmed palmtop computer that enables a patient to monitor his own biomedical data for dial-up phone relay to his primary doctor or other diagnostician. The patient can detect and record up to 5 minutes of a selected ECG rhythm sequence for transmission via frequency modulated audio signal to the programmed computer which then functions to digitize and demodulate the rhythm sequence for print-out on the palmtop computer display or printing device.

The present invention removes intervention of a third party in the monitoring service and allows a medical attendant familiar with the patient to interface directly with that patient. In other words, an attending doctor or medical provider can offer more personal and more rapid attention to each case.

The present device enables a virtual arrythmia monitoring service whereby an attending physician can receive and review transtelephonic ECG data using only a hand-held computer and a phone, either wireline or wireless.

Changes may be made in the combination and arrangement of elements as heretofore set forth in the specification and shown in the drawings; it being understood that changes may be made in the embodiments disclosed without departing from the spirit and scope of the invention as defined in the following claims.

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```
----------*/

UINT Newline2Null(char *p, UINT curpos, UINT len)
{ UINT i=0;
 for(i=curpos; i<len; i++)
   { if(*(p+i) == '\n') { *(p+i) = '\0'; return (i); } };
 return 1;
}

/*****************************************************************************/
// copy string2 to string1 up to newline char in string2
// Terminate string1 with null instead newline
/*****************************************************************************/
INT StrCpyNL( TEXT *String1, TEXT *String2)
{ INT i;
 i = 0;
 while ((*String1++ = *String2++) != '\n') { i++; }
 String1--;              // backup one to point to newline char
 *String1 = '\0';        // pointer is now pointing to end of string
 return i;
}
/*****************************************************************************
  reversed error logic because it sounded better
----------*/
INT RecTypeIsValid(UBYTE RecType)
{ if((RecType >= MIN_REC_CODE) && (RecType <= MAX_REC_CODE)) return 1;
 else return 0;
}
/*****************************************************************************
 Looks up the record type - jump table
----------*/
INT RecExists(UBYTE RecType)
{ INT i;
 i = (int)RecType;
 // toc.reclist[i].type != RecType ||
 if( (toc.reclist[i].type ==  0 ) ||
    (toc.reclist[i].type == -1 )
   )
   { return -1; }
 else
   { return 0;};
}
/*****************************************************************************
----------*/
INT InvalidFileSignature( VOID )
{ INT len; TEXT fsignature[FILE_SIG_SIZE];
 len = p_read(sFcb, fsignature, FILE_SIG_SIZE);
 if(len < FILE_SIG_SIZE) return -1;
 fsignature[4]='\0';
 if(p_scmp(fsignature, PV_FILE_SIG)) return -1;
 return 0;
}
```


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```
/*****************************************************************************
                    RStat_XL.C
                Main Program Module
            R-Stat XL version 0.2.8
        Copyright Data Critical Inc., 1996.
    United States and international patents pending

-----------------------------------------------------------------------------*/
#include "RStat_XL.H"
TEXT    sTitle[] =
      {"Rhythm-Stat XL (c)Data Critical 1996. v0.2.8 alpha"};

extern  VOID *DatCommandPtr;


extern  INT     ACTION;
extern  TEXT    LocalDir[];
extern  TEXT    FileSpec[];
extern  INT     ret;
extern  VOID    *sFcb;

extern  TEXT    PlotCaption[];

extern  DATACTL  mm12;
extern  DATACTL  mm25;
extern  DATACTL  mm50;
extern  EPOCHCTL Epoch;
extern  PLOTCTL  Plot;

extern  INT     n_Seg;
extern  INT     n_Xseg;
extern  INT     n_Yseg;

extern  TEXT    usermsg[];
      INT     Y_shft =0;
GLREF_D UWORD  _UseFullScreen;  /* For uCommonInit() */
GLREF_D UWORD  *_GreyLines;     /* Points to underline masks */

      UINT    hWndMain;       /* ID of main window */

      UINT    modepos = 0;    /* Current mode */
LOCAL_D UWORD  Menu1Pos;       /* Remembers position in menu bar 1 */
LOCAL_D UWORD  Lines[16];      /* Menu underline masks */
#define N_MODES       3
#define FILES_ITEMS    6
#define PROC_ITEMS     6
#define ITEMS_BEFORE_FILES 0
#define ITEMS_BEFORE_PROC  FILES_ITEMS

INT nModes = N_MODES;
/* Menu card 1 titles */
LOCAL_D H_MENU_DATA mdata1[]=
{ "Files",     FILES_ITEMS,
  "Waveform",  PROC_ITEMS,
```


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```
  NULL
};
/*** Text and accelerators of menu bar 1 ***/
LOCAL_D TEXT   *cmds1[]=
{ "oOpen ECG File", "rRecord ECG",   "pPlayBack ECG",
  "sSave ECG As",  "dDelete File",  "xExit RhythmStat",
  "zExpand on X",  "+Gain+  2.00",  "-Gain-  0.50",
  "qMove ECG Up",  "wMove ECG Down", "cClear Screen",
  NULL
};
GLDEF_D TEXT      **_cmds = (&cmds1[0]);   /* Points to commands */
GLDEF_D H_MENU_DATA *_mdata = (&mdata1[0]); /* Points to menu cards */

BYTE      First = TRUE;
UINT      hWndTemp;
G_GC      TmpGc;
G_FONT_INFO TmpFontInfo;


GLDEF_C VOID main             ( VOID );
LOCAL_C VOID SpecificInit      ( VOID );
LOCAL_C VOID MainLoop          ( VOID );
LOCAL_C VOID ServiceUserInput    ( VOID );
LOCAL_C VOID TryExecuteCommand   ( INT e);
LOCAL_C VOID ProcessSystemCommand ( VOID );

LOCAL_C VOID Service_Zoom_Request ( VOID );
LOCAL_C VOID ZoomAmplitude       ( BYTE Gain );
LOCAL_C VOID AdjustZero          ( BYTE offset);
LOCAL_C VOID Replot              ( VOID );
LOCAL_C VOID IdentifyLastEpoch   ( VOID );
LOCAL_C VOID CurrentEpoch        ( VOID );
LOCAL_C VOID SelectEpoch_Right   ( VOID );
LOCAL_C VOID SelectEpoch_Left    ( VOID );
LOCAL_C VOID SelectEpoch_Up      ( VOID );
LOCAL_C VOID SelectEpoch_Down    ( VOID );
LOCAL_C VOID PlotEpochRight      ( VOID );
LOCAL_C VOID PlotEpochLeft       ( VOID );
LOCAL_C UBYTE ScrollOneDivRight   ( VOID );
LOCAL_C UBYTE ScrollOneDivLeft    ( VOID );

LOCAL_C BYTE  RecordECG          ( TEXT filename[] );
LOCAL_C BYTE  PlayECG            ( TEXT filename[] );

LOCAL_C VOID SizeCopyRightWindow  ( VOID );
LOCAL_C VOID CopyRightScreen      ( VOID );


/*****************************************************************************
                    Main()
 ---------------------------------------------------------------------------- */
GLDEF_C VOID main(VOID)
{ _UseFullScreen = TRUE;   /* Use the full extent of the 3a screen */
  uCommonInit();           /* Do some common intialization */
```


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```
 SpecificInit();
 MainLoop();
}
/*****************************************************************************
 Initialisation
 ---------------------------------------------------------------------- */
LOCAL_C VOID SpecificInit(VOID)
{
 p_mkdir("M:\\ECG"); // p_setpth("M:\\ECG");
 _GreyLines = &Lines[0];          /* Point to underline masks OK */
 uEnableGrey();                   /* Grey please */

 hWndMain = uFindMainWid();      /* Get handle */
 CreateMainGC();                  /* Create graphics context */
 ToggleStatusWindow();
 SizeRectangles();               /* Initialise main screen, get status window */
 wsSetList(W_STATUS_WINDOW_ICON,NULL,0);      /* Initialise w. Icon */

 About_RStatXL();

 BufferGrid();

 InsertCaption(sTitle,CJustify);
 p_scpy(PlotCaption, sTitle);


 // Structure Initialization
 EvaluateArrayPointers();
 InitializeStartingValues();

 ACTION = IDLE;  First = TRUE;
}

LOCAL_D WS_EV event;
/*****************************************************************************
  Main loop, asynchronous form
 ---------------------------------------------------------------------- */
LOCAL_C VOID MainLoop(VOID)
{ WORD wactive = FALSE;

 OpenTimer ( 1 );
 wactive=FALSE;

 FOREVER
  { if(wactive) { wFlush(); }
    else       { wGetEvent(&event); wactive=TRUE; }
    p_iowait();

    if(event.type==E_FILE_PENDING) // if no keystroke
     {
      if(ACTION==SCROLL_RIGHT)
       { if(!ScrollOneDivRight())
          { ACTION = IDLE; p_sound((UINT)1,(UINT)320);
            Epoch.iSelected = 1;
```


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```
        }
      }
     if(ACTION==SCROLL_LEFT)
      { if(!ScrollOneDivLeft())
        { ACTION = IDLE; p_sound((UINT)1,(UINT)320);
          Epoch.iSelected = n_Xseg*n_Yseg; // Epoch.Last;
        }
      }
     ResetTimer( 1 );
     continue;   // leaves wactive TRUE
    }

   else  // this takes us to the main keyborad loop
    { wactive = FALSE;
     if(event.type==WM_KEY)     // Keystroke - service it
      {
       ServiceUserInput();
       wCancelGetEvent();
      }
    }

  } // endForever
}

/*****************************************************************************
        Keyboard service
 ---------------------------------------------------------------------- */
LOCAL_C VOID ServiceUserInput( VOID )
{ ret = FALSE;

 if(event.p.key.keycode & W_EVENT_KEY)
  { switch (event.p.key.keycode)
    { case CONS_EVENT_COMMAND:          /*  The shell has spoken  */
        ProcessSystemCommand();      /*  Obey the shell  */
    }
  }
 else if(event.p.key.keycode & W_SPECIAL_KEY)     /* Psion key pressed */
     { TryExecuteCommand(event.p.key.keycode & (~W_SPECIAL_KEY));}
 else
  { switch (event.p.key.keycode)
    {
     case W_KEY_HOME:
        if(Epoch.iSelected && Epoch.bPlotted )
         { Epoch.iSelected = 1;
          Plot_Epoch( Epoch.iSelected);
         }
        break;
     case W_KEY_END:
        if(Epoch.iSelected && Epoch.bPlotted )
         { Epoch.iSelected = Epoch.Last;
          Plot_Epoch(Epoch.iSelected);
         }
        break;
     case W_KEY_UP:
```


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```
    if(Epoch.iSelected && !Epoch.bPlotted)
     { if( event.p.key.modifiers & W_SHIFT_MODIFIER )
       { AdjustZero( (BYTE)-(Plot.sz_ydiv) ); }
      else
       { SelectEpoch_Up();};
     }
    else
     { AdjustZero( (BYTE)-(Plot.sz_ydiv) ); }
    break;
  case W_KEY_DOWN:
    if(Epoch.iSelected && !Epoch.bPlotted)
     { if( event.p.key.modifiers & W_SHIFT_MODIFIER )
       { AdjustZero( (BYTE)Plot.sz_ydiv ); }
      else
       { SelectEpoch_Down(); }
     }
    else
     { AdjustZero( (BYTE)Plot.sz_ydiv ); }
    break;
  case '+':
    ZoomAmplitude ( 2 );
    break;
  case '-':
    ZoomAmplitude ( -2 );
    break;
  case 'z':
    Service_Zoom_Request();
    break;
  case W_KEY_TAB:
    if( event.p.key.modifiers & W_SHIFT_MODIFIER )
     { PlotEpochLeft(); }
    else
     { PlotEpochRight(); }
    break;
  case W_KEY_LEFT:
    if(Epoch.iSelected)
     { if( !Epoch.bPlotted )
       { SelectEpoch_Left();
       }
      else // epoch is plotted
       { if( event.p.key.modifiers & W_SHIFT_MODIFIER )
         { PlotEpochLeft();
         }
        else
         { if( event.p.key.modifiers & W_CTRL_MODIFIER )
           { if((ACTION==IDLE) && Epoch.bPlotted)
             { ACTION=SCROLL_RIGHT; }
           }
          else
           { ScrollOneDivRight();
           }
         };
       };
     }
```


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```
    break;
case W_KEY_RIGHT:
    if(Epoch.iSelected )
     { if( !Epoch.bPlotted )
       { SelectEpoch_Right();
       }
      else
       { if( event.p.key.modifiers & W_SHIFT_MODIFIER )
         { PlotEpochRight();
         }
        else
         { if( event.p.key.modifiers & W_CTRL_MODIFIER )
           { if((ACTION==IDLE) && Epoch.bPlotted)
             { ACTION=SCROLL_LEFT;}
           }
          else
           { ScrollOneDivLeft();
           }
         };
       };
     }
    break;

case W_KEY_RETURN:
    if(Epoch.iSelected && !Epoch.bPlotted)
     { if(Epoch.iSelected <= Epoch.Last)
       { Epoch.bPlotted = Plot_Epoch ( Epoch.iSelected);}
     }
    break;
case W_KEY_ESCAPE:
    if( ACTION )  // interrupt any extended process
     { ACTION = IDLE; p_sleep(2);
     }
    else
     { if( Epoch.iSelected )
       { if(!Epoch.bPlotted)  // invalidate epoch selection
         { InvertSegColor(Epoch.iSelected);
           Epoch.iSelected = 0;
         }
        else              // back up from plotted epoch
         { Epoch.bPlotted = FALSE;
           if(Epoch.iSelected == Epoch.Last)
             { Epoch.iSelected = n_Xseg*n_Yseg;}
           Replot();
           n_Seg = NSEG;
         }
       }
     }
    break;
case W_KEY_MENU:                /* Menu key pressed  */
    ret = uPresentMenus();      /*  Display the menu  */
    if(ret > 0){ TryExecuteCommand(ret);}
    break;
```


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```
      default:
         break;
      } // endswitch

   } // endelse(!event.p.key.keycode & W_EVENT_KEY)
}
/*****************************************************************************
 Manage the menu command selected in view 1
 ----------------------------------------------------------------------------*/
LOCAL_C VOID ManageCommand1(INT index)
{ BYTE Ack;
 switch (index)
  { case ITEMS_BEFORE_FILES:       // oOpen
      // Filename to open may be *.WVE, *.FMD, or *.RST
      GetExistingFileName( &FileSpec[0] );
      if(FileSpec[0])
       { InsertCaption("Data Critical Remote Telephonic ECG",CJustify);
        if(Epoch.iSelected){Epoch.iSelected=0;Epoch.bPlotted=0;}
        if(!First) BufferGrid();
        if( (p_ssubi(&FileSpec[0],".WVE")) >= 0 )
         { ACTION = DEMODULATE;
          Process_WVE_File ( &FileSpec[0] ); First = FALSE;
          ACTION = IDLE;
         }
        if( (p_ssubi(&FileSpec[0],".RST")) >= 0 )
         { Process_RST_File ( &FileSpec[0] ); First = FALSE;
         }
        Y_shft =0;
        // OK now plot data if any
        if(mm12.Pts)
         { Epoch.iSelected = 0; Plot_Buffer ( );
          Plot.mm_sec = 12;
         }
       }
      break;
    case ITEMS_BEFORE_FILES +1:    // rRecord
      if(EnoughSpace(281))
       { if(GetNewFileName(&FileSpec[0]))
         { ACTION = RECORD;
          ret = (INT)Record_FM_ECG_1 ( &FileSpec[0]);
          ACTION = IDLE;
          if( ret )
           { if(Epoch.iSelected){Epoch.iSelected=0;Epoch.bPlotted=0;}
            if(!First)BufferGrid();
            ACTION=DEMODULATE;
            Process_WVE_File ( &FileSpec[0] );
            ACTION = IDLE; First=FALSE;
            // OK now plot data if any
            if(mm12.Pts)
             { Epoch.iSelected = 0; Plot_Buffer ( );
              Plot.mm_sec = 12;
             }
           }
          else
```


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```
            { InsertCaption(PlotCaption, CJustify);
            }
          }
        }
      break;
  case ITEMS_BEFORE_FILES +2:    // pPlayBack
     if(GetExistingFileName(&FileSpec[0]))
      { if( (p_ssubi(&FileSpec[0],".WVE")) >= 0 )
         { ACTION = PLAYBACK;
          Playback_FM_ECG_1 ( &FileSpec[0]);
          ACTION = IDLE;
          InsertCaption(PlotCaption,CJustify);
         }
        else
         { GetCopyOfFileName(usermsg, FileSpec );
          if(usermsg[0])
           { p_scat(&usermsg[p_slen(usermsg)]," is Not a .Wve File");
            p_sound((UINT)4,(UINT)320);
            Notify(usermsg);
           }
         }
      }
     break;
  case ITEMS_BEFORE_FILES +3:    // sSave As
     // GetNewFileName ( &FileSpec[0] );
     // SaveRTMfile( &FileSpec[0] );
     break;
  case ITEMS_BEFORE_FILES +4:    // dDelete
     if(GetExistingFileName(&FileSpec[0]))
      { p_scpy(usermsg,"Delete ");
       GetCopyOfFileName(&usermsg[p_slen(usermsg)],FileSpec);
       p_scat(usermsg,"?");
       Notify_2(&Ack, usermsg);
       if(Ack) p_delete ( &FileSpec[0] );
      }
     break;
  case ITEMS_BEFORE_FILES +5:    // xExit
     p_exit(0);
  case ITEMS_BEFORE_PROC:        // zZoom X 25 or 50
     Service_Zoom_Request();
     break;
  case ITEMS_BEFORE_PROC + 1:    // Gain +1.50
     ZoomAmplitude ( 2 );
     break;
  case ITEMS_BEFORE_PROC + 2:    // Gain - 0.66
     ZoomAmplitude ( -2 );
     break;
  case ITEMS_BEFORE_PROC + 3:    // Shift Zero Up
     AdjustZero ( (BYTE)-(Plot.sz_ydiv));
     break;
  case ITEMS_BEFORE_PROC + 4:    // Shift Zero Down
     AdjustZero ( (BYTE)Plot.sz_ydiv );
     break;
  case ITEMS_BEFORE_PROC + 5:    // cClear
```


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```
        BufferGrid();
        mm50.Pts =0; mm25.Pts =0; mm12.Pts =0;
        Epoch.iSelected = 0; Epoch.bPlotted = FALSE;
        p_scpy(usermsg,sTitle);
        InsertCaption(usermsg,CJustify);
        p_scpy(PlotCaption, usermsg);
        break;
    }
}
/*****************************************************************************
 ---------------------------------------------------------------------- */
VOID Service_Zoom_Request ( VOID )
{ if(!mm12.Pts) return;

 if(Epoch.iSelected && !Epoch.bPlotted)
   { InvertSegColor ( Epoch.iSelected ); }

 // if 12, make it 25, if 25 make it 50, if 50, make it 25
 if(Plot.mm_sec==12)
   { Plot.mm_sec = 25;   n_Seg = NSEG;
   }
 else
   { if(Plot.mm_sec==25)
      { Plot.mm_sec = 50;   n_Seg = NSEG*2;
        if(Epoch.iSelected)Epoch.iSelected = Epoch.iSelected*2-1;
      }
     else
      { if(Plot.mm_sec==50)
         { Plot.mm_sec = 25;  n_Seg = NSEG;
           if(Epoch.iSelected)
             { if(Epoch.iSelected >1)
                { if(!(Epoch.iSelected%2))
                   { Epoch.iSelected = Epoch.iSelected/2;}
                  else
                   { Epoch.iSelected = Epoch.iSelected/2+1;}
                }
             }
         }
      };
   }

 n_Xseg = n_Seg/N_YSEG;  // 6/3=2 or 12/3=4
 SizeSegments();         // uses only N_YSEG

 // Identify the last epoch containing data
 IdentifyLastEpoch();
 n_Yseg = Epoch.Last / n_Xseg;
 if( n_Yseg < N_YSEG ) { if ((Epoch.Last%n_Xseg)) n_Yseg++; }
 // p_atos(usermsg,"last %d, nX %d, nY %d", Epoch.Last, n_Xseg, n_Yseg); Notify(usermsg);

 // Restructure Display
 if( Epoch.iSelected)
   { if(Epoch.iSelected > n_Seg) Epoch.iSelected=n_Seg;
     if(Epoch.bPlotted)
```


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```
      { Plot_Epoch ( Epoch.iSelected );
      }
    else
      { InvertSegColor  ( Epoch.iSelected );
      }
   }
  else
   { Epoch.iSelected = 1;
     InvertSegColor ( Epoch.iSelected );
   }
}
/*****************************************************************************
 ---------------------------------------------------------------------- */
LOCAL_C VOID SelectEpoch_Up ( VOID )
{ INT iNewSelection = Epoch.iSelected - n_Xseg;
 if(iNewSelection < 1 )
   { // wrap around
     iNewSelection +=(n_Xseg*n_Yseg);
   }
 if(iNewSelection <= Epoch.Last)
   { InvertSegColor(Epoch.iSelected); // To Bl on Wh
     Epoch.iSelected = iNewSelection;
     InvertSegColor(Epoch.iSelected); // To Wh on Bl
   }
}
/*****************************************************************************
 This not an inversion of SelectEpochUp() because Epoch.Last may
 exceed n_Xseg * n_Yseg, yet access to Epoch.Last via zoomed epoch
 shifts and scrolling is to be preserved..
 ---------------------------------------------------------------------- */
LOCAL_C VOID SelectEpoch_Down ( VOID )
{ INT iNewSelection = Epoch.iSelected + n_Xseg;

 if( iNewSelection > (n_Xseg*n_Yseg) )
   { iNewSelection -= (n_Xseg*n_Yseg);
   }
 if(iNewSelection >= 1)
   {
     InvertSegColor(Epoch.iSelected); // To Bl on Wh
     Epoch.iSelected = iNewSelection;
     InvertSegColor(Epoch.iSelected); // To Wh on Bl
   }
}
/*****************************************************************************
 ---------------------------------------------------------------------- */
LOCAL_C VOID SelectEpoch_Right ( VOID )
{ InvertSegColor(Epoch.iSelected);  // To Bl on Wh
 if( !(Epoch.iSelected % n_Xseg) )
   { Epoch.iSelected = Epoch.iSelected -(n_Xseg-1);
   }
 else
   { Epoch.iSelected = Epoch.iSelected +1;
     if(Epoch.iSelected > (n_Xseg*n_Yseg))
       { Epoch.iSelected=((Epoch.iSelected-1)/n_Xseg)*n_Xseg+1;}
```


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```
 }
 InvertSegColor(Epoch.iSelected); // To Wh on Bl
}
/*****************************************************************************
 ---------------------------------------------------------------- */
LOCAL_C VOID SelectEpoch_Left ( VOID )
{ InvertSegColor(Epoch.iSelected); // To Bl on Wh
 if( (Epoch.iSelected % n_Xseg)==1 )
   { Epoch.iSelected = Epoch.iSelected +(n_Xseg-1);
    while(Epoch.iSelected > Epoch.Last)Epoch.iSelected--;
   }
 else
   { Epoch.iSelected = Epoch.iSelected -1; }
 InvertSegColor(Epoch.iSelected); // to Wh on Bl
}
/*****************************************************************************
 Plot.X_shft is reset to zero in Plot_Epoch(), and is updated in
 PlotXdivRight() and PlotXdivLeft() in module G_Scroll.C
 ---------------------------------------------------------------- */
LOCAL_C UBYTE ScrollOneDivLeft ( VOID )
{ if(ScrollLeft())
   { UpdateTenthSecs( 2 );
    if( Plot.X_shft >= ( Plot.n_xdiv ) )
      { Epoch.iSelected++;
       //CurrentEpoch();
       Plot.X_shft =0;
      }
    UpdateEpochCaption();
    return TRUE;
   }
 else
   { return FALSE;
   }
}
/*****************************************************************************
 Plot.X_shft is reset to zero in Plot_Epoch(), and is updated in
 PlotXdivRight() and PlotXdivLeft() in module G_Scroll.C
 ---------------------------------------------------------------- */
LOCAL_C UBYTE ScrollOneDivRight ( VOID )
{ if(ScrollRight())
   { UpdateTenthSecs( (-2) );
    if( Plot.X_shft <= ( -Plot.n_xdiv ) )
      { Epoch.iSelected--;
       //CurrentEpoch();
       Plot.X_shft =0;
      }
    UpdateEpochCaption();
    return TRUE;
   }
 else
   { return FALSE;
   }
}
/*****************************************************************************
```


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```
  Replot one zoomed screen to left
 ---------------------------------------------------------------------- */
LOCAL_C VOID PlotEpochLeft ( VOID )
{ if(Epoch.iSelected > 1)
   { Epoch.iSelected --;  Plot_Epoch ( Epoch.iSelected );
    // Caption updated in Plot_Epoch();
   }
}
/*************************************************************************
  Replot one zoomed screen to right
 ---------------------------------------------------------------------- */
LOCAL_C VOID PlotEpochRight ( VOID )
{ if(Epoch.iSelected < Epoch.Last)
   { Epoch.iSelected ++;  Plot_Epoch ( Epoch.iSelected );
    // Caption updated in Plot_Epoch();
   }
}
/*************************************************************************
  Return the number of the last epoch containing data
 ---------------------------------------------------------------------- */
LOCAL_C VOID IdentifyLastEpoch ( VOID )
{ if(Plot.mm_sec == 50)
   { Epoch.Last = mm50.Pts/FSX;  if(mm50.Pts%FSX) Epoch.Last++;
   }
 else // Plot.mm_sec == 25
   { Epoch.Last = mm25.Pts/FSX;  if(mm25.Pts%FSX) Epoch.Last++;
   }
}
/*************************************************************************
 ----------------------------------------------------------------------*/
LOCAL_C VOID CurrentEpoch ( VOID )
{ INT CurrentMidPoint = Plot.Lptr + ( (Plot.Rptr - Plot.Lptr) / 2 );
 if(Plot.mm_sec==50)
   { Epoch.iSelected = (CurrentMidPoint / 480) + 1; }
 else // Plot.mm_sec==25)
   { Epoch.iSelected = (CurrentMidPoint / 960) + 1; }

}
/*************************************************************************
  Increase or decrease buffer amplitude and replot
 ---------------------------------------------------------------------- */
LOCAL_C VOID ZoomAmplitude ( BYTE Gain )
{ // check gain limits
 if(Gain>0)
   { if (Y_shft >  0)  { p_sound((UINT)4,(UINT)180); return; }
    else           { Y_shft++; }
   }
 if(Gain<0)
   { if (Y_shft < 0)   { p_sound((UINT)4,(UINT)180); return; }
    else           { Y_shft--; }
   }
 PostRescaling();
 if(Plot.Pts==mm50.Pts)
   { AdjustBufferAmplitude( &mm50.Buf[0], mm50.Pts, Gain );
```


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```
    Replot();
    AdjustBufferAmplitude( &mm25.Buf[0], mm25.Pts, Gain );
    AdjustBufferAmplitude( &mm12.Buf[0], mm12.Pts, Gain );
   }
 if(Plot.Pts==mm25.Pts)
   { AdjustBufferAmplitude( &mm25.Buf[0], mm25.Pts, Gain );
    Replot();
    AdjustBufferAmplitude( &mm50.Buf[0], mm50.Pts, Gain );
    AdjustBufferAmplitude( &mm12.Buf[0], mm12.Pts, Gain );
   }
 if(Plot.Pts==mm12.Pts)
   { AdjustBufferAmplitude( &mm12.Buf[0], mm12.Pts, Gain );
    Replot();
    AdjustBufferAmplitude( &mm50.Buf[0], mm50.Pts, Gain );
    AdjustBufferAmplitude( &mm25.Buf[0], mm25.Pts, Gain );
   }
}
/*****************************************************************************
  Move vectors up or down on screen
 ---------------------------------------------------------------------------- */
VOID AdjustZero ( BYTE offset )
{
 if(Plot.Pts==mm50.Pts)
   { AdjustBufferZero ( mm50.Buf, mm50.Pts, offset);
    Replot();
    AdjustBufferZero ( mm25.Buf, mm25.Pts, offset);
    AdjustBufferZero ( mm12.Buf, mm12.Pts, offset);
   }
 if(Plot.Pts==mm25.Pts)
   { AdjustBufferZero ( mm25.Buf, mm25.Pts, offset);
    Replot();
    AdjustBufferZero ( mm50.Buf, mm50.Pts, offset);
    AdjustBufferZero ( mm12.Buf, mm12.Pts, offset);
   }
 if(Plot.Pts==mm12.Pts)
   { AdjustBufferZero ( mm12.Buf, mm12.Pts, offset);
    Replot();
    AdjustBufferZero ( mm50.Buf, mm50.Pts, offset);
    AdjustBufferZero ( mm25.Buf, mm25.Pts, offset);
   }
}
/*****************************************************************************
  Replot Entire buffer, or the previously plotted epoch
 ---------------------------------------------------------------------------- */
LOCAL_C VOID Replot ( VOID )
{ if(!Epoch.bPlotted)
   { Plot_Buffer( );
    if(Epoch.iSelected)InvertSegColor(Epoch.iSelected);
   }
  else
   { ReplotCurrentSegment();
   }
}
/*****************************************************************************
```


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```
  Look up the selected command and manage appropriately
 ---------------------------------------------------------------------- */
LOCAL_C VOID TryExecuteCommand(INT keycode)
{ if (modepos == N_MODES) return;
  keycode = uLocateCommand(keycode);
  if (keycode >= 0) { ManageCommand1(keycode); }
}
/*****************************************************************************
  Listen to the shell
 ---------------------------------------------------------------------- */
LOCAL_C VOID ProcessSystemCommand(VOID)
{ TEXT buf[P_FNAMESIZE + 2];
  wGetCommand((UBYTE *)&buf[0]);
  if (buf[0] == 'X') p_exit(0);
}
/*****************************************************************************
  Diamond is pressed - if changing to background, surrender the
  screen and interrogate the Advisor every 30 seconds or so.
 ---------------------------------------------------------------------- */
LOCAL_C VOID SwitchMode(VOID)
{ modepos++;   modepos %= (N_MODES-1);
  wsSelectList(modepos);
  if (modepos)
     { _cmds = (&cmds1[0]);  _mdata = (&mdata1[0]);  }
}
```


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```
/*****************************************************************************
                RStat_XL.H
          R-Stat XL, version 0.2.8
       Copyright Data Critical Inc., 1996.
   United States and international patents pending

        Inlude file for R-Stat XL modules
-----------------------------------------------------------------------------*/
#include <p_std.h>
#include <p_file.h>
#include <p_serial.h>
#include <p_math.h>
#include <epoc.h>
#include <wlib.h>
#include <hwif.h>
#include <stdio.h>
#include <string.h>


// Program activity constants
#define IDLE          00
#define SCROLL_RIGHT   01
#define SCROLL_LEFT    02
#define DEMODULATE     10
#define RECORD         20
#define PLAYBACK       21

// Error codes
#define NO_PAGES    0
#define OPEN_TIMER  1
#define OPEN_PORT   2
#define ADV_HAND    3
#define FILE_SAVE   4
#define FILE_OPEN   5
#define INC_READ    6

// Program control constants
#define  M6PT            12  // offset to monospaced 6pt font
#define  M8PT             3  // offset to monospaced 8pt font
#define  M10PT            0  // offset to monospaced 10pt font

// Processing array size constants
#define  ALAW_SZ         256 // integers
#define  ATAN_SZ        4096 // integers
#define  ECG_BUF_SZ     7168 // bytes
#define  PLOT_BUF_SZ    7168 // bytes

#define  BUF_MARGIN        2

// Graphics constants
#define  INPUT_SAMP_SEC    125
#define  PLOT_SAMP_SEC     200
#define  WVE_SAMP_SEC      200
#define  RST_SAMP_SEC      125
```


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```
#define FSX             480
#define FSY             160
#define X_BORD            1
#define Y_BORD            3
#define DSP_SEC          29

#define NSEG             6
#define N_XDIV          24
#define SZ_XDIV         20
#define N_YDIV           7
#define SZ_YDIV         20
#define N_MINDIV         5
#define N_YSEG           3
#define PIX_SEC_10      50
#define PIX_SEC_25      100
#define PIX_SEC_50      200


// Fonts
#define F6PTY            7
#define F8PTY            9
#define F10PTY           11
// Font control constants
#define INVERT           3
#define INVERT_LEFT_INDENT   5
#define INVERT_CLEAR       0
#define INVERT_SET         1
#define MONOSPACED         2
#define LJustify         G_TEXT_ALIGN_LEFT
#define RJustify         G_TEXT_ALIGN_RIGHT
#define CJustify         G_TEXT_ALIGN_CENTRE

typedef struct PtrStructure
 { INT  *pALaw;
   INT  **ppATanSeg;
   INT  *pCycleAccum;
   INT  *pBPFilter;
   INT  *pLastSign;
 } DMODPARM;

typedef struct
{ BYTE    *Buf;         // 7168 bytes for 35.8 sec of data @ 200 Hz
  INT     Pts;
  INT     Sec;
  INT     Smp_sec;
} DATACTL;

typedef struct
{ INT     nEpoch;
  INT     Last;         // the last epoch with data
  INT     iSelected;    // epoch number selected
  UBYTE   bPlotted;     // status
}EPOCHCTL;
```


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```
typedef struct
{ BYTE *Buf;  INT  Pts; // 3840 bytes, for 35.8 sec of data @ 100 Hz
 INT  mm_sec; INT  iPt_Px;
 BYTE iY_zero; BYTE iY_scale; INT  iMinY;  INT  iMaxY;
 INT  last_x; INT  last_y;
 INT  n_xdiv; INT  sz_xdiv; INT  sz_minxdiv;
 INT  n_ydiv; INT  sz_ydiv; INT  sz_minydiv;
 INT  Lptr;  INT  Rptr;  INT  X_shft;
 INT  L_Sec;  INT  L_Tenths; INT  R_Sec;  INT  R_Tenths;
 P_DTOB d2bformat;
} PLOTCTL;

//------- In ReadRsc.C ---------
VOID LoadTables          ( VOID );

// ------ In About.C ------------
VOID About_RStatXL       ( VOID );

// ------ In DEMOD.ASM = DEMOD.OBJ, masm output
void cdecl demod         ( INT iOutput[],
                   BYTE cinput[],
                   DMODPARM *DeModParam );

// ------ In Common.C ----------
VOID EvaluateArrayPointers   ( VOID );
VOID InitializeStartingValues ( VOID );

// ------ In PPPick.C ----------
VOID PPP_Decimate_Into_Buffers   ( VOID );

// ------ In Sound_IO.C --------
BYTE Record_FM_ECG_1     ( TEXT filename[] );
BYTE Record_FM_ECG_2     ( TEXT filename[] );
BYTE Playback_FM_ECG_1    ( TEXT filename[] );
BYTE Playback_FM_ECG_2    ( TEXT filename[] );

// ------ In WndCtrl.C --------
VOID InsertCaption       ( TEXT *Capt, INT Justify );
VOID SizeRectangles      ( VOID );
VOID CreateMainGC        ( VOID );
VOID ToggleStatusWindow   ( VOID );
VOID InvertSegColor      ( INT index );
VOID SizeSegments        ( VOID );
VOID CreateIndicator     ( VOID );
VOID UpdateIndicator     ( ULONG current, ULONG total );
VOID ClearPlotSpace      ( VOID );

// ------ In Grid_Ctl.C --------
VOID BufferGrid          ( VOID );
VOID EpochGrid           ( VOID );
VOID Dotted_X            ( INT y, INT x_st, INT x_nd,
                   UBYTE draw, UBYTE blank );
VOID Dotted_Y            ( INT x, INT y_st, INT y_nd,
                   UBYTE draw, UBYTE blank );
```


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```
// ------ In G_Scroll.C
UBYTE ScrollLeft        ( VOID );
UBYTE ScrollRight       ( VOID );

// ------ In File_Ctl.C ------
BYTE  EnoughSpace       ( UINT Minimum_K );
UBYTE OpenInputFile     ( TEXT *FileName );
UBYTE OpenBinaryInputFile ( TEXT *FileName );

UBYTE OpenOutputFile    ( TEXT FileName[] );
VOID  CloseInputFile    ( VOID );
UBYTE ReadWVEHeader     ( SndFile *sFileHead );
INT   ReadWVESegment    ( UBYTE FileBuf[], UINT Size, LONG OffSet );
VOID  GetCopyOfFileName ( TEXT *filename, TEXT *filespec );

// ------ In RST_File.C ------
BYTE  Process_RST_File      ( TEXT FileName[] );

// ------ In WVE_File.C ------
BYTE  Process_WVE_File    (TEXT FileName[] );

// ------ In Plot_Ctl.C ------
VOID  Plot_Buffer           ( VOID );
BYTE  Plot_Epoch            ( INT epoch );
VOID  ReplotCurrentSegment  ( VOID );
VOID  Clip_and_Plot         ( INT  ix, INT iy, INT *Lx, INT *Ly,
                      INT iMax, INT iMin );
VOID  Calculate_Plot_MinMax   ( VOID );

//------- In Dlg_Ctl.C ---------
BYTE  GetExistingFileName  ( TEXT *FileSpec );
BYTE  GetNewFileName       ( TEXT *FileSpec );
BYTE  GetFilterName        ( TEXT *FilterSpec );

// ------ In Err_Hndl.C --------
VOID  ReportError         ( INT func, INT error );

//------- In Notify.C  ---------
VOID  Notify              ( TEXT *Msg );
VOID  Notify_2            ( BYTE *ack, TEXT *Msg );
VOID  About_FM_ECG        ( VOID );

//------- In Str_fn.C  ---------
VOID  lShfStr             ( TEXT *str, INT n );
VOID  rShfStr             ( TEXT *str, INT  n);
INT   scat_n              ( TEXT *dst, TEXT *src, INT n );
INT   ch_index            ( UBYTE Str[], UBYTE ch );

//------ In Misc.C -------------
VOID  AdjustBufferAmplitude ( BYTE Buffer[], INT Ln, BYTE gain );
VOID  AdjustBufferZero    ( BYTE Buffer[], INT Ln, BYTE gain );
BYTE  Convert_RemECG_To_RST ( BYTE Output[], INT InOut,
                    BYTE Input[],  INT InIn   );
```


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```
VOID  OpenTimer          ( INT interval );
VOID  ResetTimer         ( INT interval );
VOID  CancelTimer        ( VOID );
VOID  CloseTimer         ( VOID );
VOID  CalcSeconds        ( VOID );
VOID  UpdateTenthSecs    ( INT amount );
VOID  UpdateEpochCaption ( VOID );
VOID  PostRescaling      ( VOID );
VOID  IShfInt            ( INT *data, INT *len, INT n );
```


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```
/*****************************************************************************
                    WVE_File.C
            R-Stat XL, version 0.2.8
        Copyright Data Critical Inc., 1996
    United States and international patents pending

  Procedure to decode and demodulate the FM ECG signal, recieved
  as sound data.

  Process_WVE_File() requires 28.0 seconds to execute, up to the call
  to PPP_Decimate_Into_Buffers(). Time is distributed as follows:

  Loading the ALAW decoding and ArcTangent tables..... 0.6
  Reading the file 3,200+ times, @ 80 bytes each..... 10.2
  Demodulating the 80 byte reads, and decimating to 200 Hz.... 14.5
  Applying a plotting zero correction and gain..... 0.4
  Filtering to remove spikes and attenuating the baseline..... 0.4
  Plotting the data as it is read and processed..... 1.9

  The call to Decimate into the 100 Hz and 50 Hz buffers
  requires an additional 2 seconds.
 ----------------------------------------------------------------------------*/
#include "RStat_XL.H"
extern INT    ACTION;
extern TEXT   LocalDir[];
extern TEXT   LocalFileName[];
extern TEXT   InputFile[];
extern VOID   *sFcb;
extern INT    ret;
extern TEXT   usermsg[];

extern DMODPARM DeModParam;
extern DATACTL  mm50;
extern DATACTL  mm25;
extern DATACTL  mm12;
extern INT     *DecIn;
extern INT     *DecOut;
     INT     Input_Pts = 0;
     INT     CalFound  = 0;

extern PLOTCTL Plot;
extern P_RECT  PltRcl;

extern INT    *iAlaw;
extern INT    *iAtan;
extern INT    *pAtanSeg[];

     UBYTE   *bFileBuf;
extern SndFile sFileHead;
extern SndFile *psFileHead;


LOCAL_C INT   CalPulse              ( VOID );
LOCAL_C VOID  Initialize_Incoming_Plot ( VOID );
```


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```
LOCAL_C VOID  Plot_Incoming        ( INT Buffer[], INT Pts );

/*************************************************************************
 -------------------------------------------------------------------------*/
BYTE Process_WVE_File (TEXT FileName[])
{ INT   i,k, readsz, bytes, iGain, iZero;

 INT   iDemodData[2];
 BYTE  cDataInAlaw[82];
 INT   iBandPassFilter[2] = {0, 0};
 INT   iLastSign = {1};
 INT   iCycleAccum[2] = {0, 2560};

 /***       BEGIN     ***/
 readsz =   80;
 iGain  =    6;
 iZero  = 5143;  // mean of 384 pts from ts022896.wve is 5143.679
 CalFound =  0;

 /**** Make sure pointers are correct     ****/
 EvaluateArrayPointers();
 InitializeStartingValues();

 /**** Get ALAW decoding and Arctangent   ****/
 /**** tables from imbedded resource file.****/
 LoadTables( );

 /**** Initialize demodulation parameter structure  ****/
 DeModParam. pALaw       = &iAlaw[0];
 DeModParam. ppATanSeg   = pAtanSeg;
 DeModParam. pCycleAccum  = &iCycleAccum[0];
 DeModParam. pBPFilter    = &iBandPassFilter[0];
 DeModParam. pLastSign    = &iLastSign;
 k=0; for(i=0;i<4096;i+=64) {pAtanSeg[k]=&iAtan[i];k++;}

 /****  Open the WVE file as a binary stream  ***/
 if(!OpenBinaryInputFile(FileName))return FALSE;

 /****  Read header information ******************/
 ReadWVEHeader(psFileHead);
 mm50.Sec = (INT)(sFileHead.Samples/8000);
 mm50.Pts = mm50.Sec * WVE_SAMP_SEC;
 mm50.Smp_sec = WVE_SAMP_SEC;

 /**** Post filename and seconds of ECG **********/
 GetCopyOfFileName(LocalFileName,FileName);
 p_atos(usermsg,"Demodulating %s: %d seconds, 200 ms/dv",
          LocalFileName, mm50.Sec );
 InsertCaption(usermsg,CJustify);

 /****  Read And Demodulate  WVE Data *********/
 Initialize_Incoming_Plot ();
 p_bfil(DecIn, 14336, 0x00);  Input_Pts = 0;
 bytes = p_read( sFeb, &cDataInAlaw[0], (UINT)readsz );
```


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```
do
 { /*** Read readsz btes from WVE file ****/
  bytes = p_read( sFcb, &cDataInAlaw[0], (UINT)readsz );
  if(bytes<readsz) break;

  /*** Decode, Filter, & Demodulate buffer ****/
  demod( &iDemodData[0], &cDataInAlaw[0], &DeModParam );
  DecIn[Input_Pts++] = (BYTE)-((iDemodData[0]-iZero)/iGain);
  DecIn[Input_Pts++] = (BYTE)-((iDemodData[1]-iZero)/iGain);

  /*** while less than 3 seconds of data, check for cal pulse ***/
  if( (Input_Pts<3000) && !CalFound ) CalFound  = CalPulse ();

  /**** Plot buffer here, step 4 (50 Hz) ****/
  if((Input_Pts) > (Plot.Rptr + Plot.iPt_Px))
   { Plot_Incoming ( DecIn, (Input_Pts-1) ); }

 }while (bytes);
CloseInputFile();
Input_Pts --;              // Correct for last increment

if(CalFound)
 { DecIn     += CalFound;  // Increment pointer to Cal pulse
  Input_Pts -= CalFound;  // Decrement count for Cal pulse
 }
else
 { Notify("Advisory - Leading calibration pulse not recognized.");
 }

mm50.Pts = Input_Pts;
mm50.Sec = mm50.Pts/WVE_SAMP_SEC;
mm50.Pts = mm50.Sec*WVE_SAMP_SEC;  // This reconciles any truncation error

/*** Decimate into 100Hz and 50Hz buffers & collapse 200 Hz buffer **/
PPP_Decimate_Into_Buffers();  p_sound((UINT)1,(UINT)320);

return TRUE;
}
/*****************************************************************************
To find leading edge of Cal Pulse.
Cal pulse is about 30 data points wide, and - 40 tall.
Rise "time" is about 3 data points.
-----------------------------------------------------------------------*/
LOCAL_C INT CalPulse ( VOID )
{ INT slope=0; INT j; INT i = Input_Pts -1;
 // back index up 23
 i-=23; if (i<0) return 0;
 for(j=0;j<10;j++) { slope += ( DecIn[i+1] - DecIn[i] );  i++; }
 if( (slope/10) !=0 ) return 0;
 slope=0;
 for(j=0;j<3; j++) { slope += ( DecIn[i+1] - DecIn[i] );  i++; }
 if( (slope/3) > (-10) ) return 0;
 slope=0;
 for(j=0;j<10;j++) { slope += ( DecIn[i+1] - DecIn[i] );  i++; }
```


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```
 if( (slope/10) !=0 ) return 0;
 return ( i-20 );
}
/*************************************************************************
 Plots a single datum from the incoming decoded and demodulated data
 The screen is at 12.5 mm/sec, and the plot steps down on Y when the
 edge of the screen is reaced to plot the entire data set as 3 rows.
 ------------------------------------------------------------------*/
LOCAL_C VOID Plot_Incoming ( INT Buffer[], INT Pts )
{
 INT iY = Buffer[Pts]/Plot.iY_scale + Plot.iY_zero;

 if(Plot.iY_zero>PltRcl.br.y)return;
 if(((Plot.last_x+1)>PltRcl.br.x)||((Plot.last_x+1)<PltRcl.tl.x)) return;

 // Clip on Y if needed
 if(iY <= Plot.iMinY)  { iY=Plot.iMinY;}
 else                  { if(iY >= Plot.iMaxY) iY=Plot.iMaxY; };

 // Plot it
 gDrawLine(Plot.last_x, Plot.last_y, Plot.last_x+1, iY );

 Plot.last_x++;
 Plot.last_y = iY;
 Plot.Rptr = Pts;

 if(!(Plot.last_x%(FSX-1))) // step down one row on screen
  { //BYTE Dy = (BYTE)((float)(PltRcl.br.y - PltRcl.tl.y)/4.5);
   //Plot.iY_zero = Plot.iY_zero + Dy;
   Plot.iY_zero = Plot.iY_zero + (BYTE)(SZ_YDIV*2);
   Plot.last_x  = PltRcl.tl.x;
   Plot.last_y  = (int)Plot.iY_zero;
   Calculate_Plot_MinMax();
  }
}

/*************************************************************************
 ------------------------------------------------------------------*/
LOCAL_C VOID Initialize_Incoming_Plot ( VOID )
{ Plot.iY_scale  = 3;
 Plot.iY_zero   = (BYTE)(PltRcl.tl.y + SZ_YDIV);
 Plot.last_x    = PltRcl.tl.x;  Plot.last_y = (int)Plot.iY_zero;
 Plot.iPt_Px    = WVE_SAMP_SEC/PIX_SEC_10;
 Plot.Rptr      = 0;
 Calculate_Plot_MinMax();
}
```

```
/*****************************************************************
                Wnd_Ctrl.C
          R-Stat XL, version 0.2.8
       Copyright Data Critical Inc., 1996.
  United States and international patents pending

 The Entire Screen is MainRcl.
 The Application Screen, AppRcl, is the MainRcl, less the border.
 The Plotting area is PltRcl, which is AppRcl, less axes and Caption.
 X and Y values are in absolute screen coordinates
 ----------------------------------------------------------------*/
#include "RStat_XL.H"
/* in EcgSound.H
#define FSX    480
#define FSY    160
#define F6PTY    7
#define F8PTY    9
#define F10PTY   11
*/
// In Common.C
extern TEXT      usermsg[];
extern UINT      hWndMain;       /* ID of main window */
extern P_RECT    MainRcl;
extern P_RECT    AppRcl;
extern P_RECT    CptRcl;
extern P_RECT    IndRcl;
extern P_RECT    PltRcl;
extern P_RECT    PltSpc;         // in internal coordinates
extern P_RECT    ScrollRcl;
extern P_RECT    SegRcl[];

/* Now defines
extern INT       X_Bord_Off;
extern INT       Y_Bord_Off;
extern INT       SZ_Xdiv;
extern INT       N_Xdiv;
extern INT       N_Ydiv;
extern INT       SZ_Ydiv;
extern INT       n_Yseg;
*/
extern INT       n_Xseg;
extern INT       n_Seg;

    G_GC      Mgc;
extern INT       nModes;
    INT      CurrentStatusWindowExtent = W_STATUS_WINDOW_BIG;
    P_EXTENT   StatusExtent;
    G_FONT_INFO FontInfo;

FLOAT  fIndicator_rng_x   = 0.0;
P_RECT  FillRcl;

LOCAL_C VOID SizeMainWindow       ( VOID );
LOCAL_C VOID SizeAppRectangle     ( VOID );
```


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```
LOCAL_C VOID SizeCaptionRectangle   ( VOID );
LOCAL_C VOID SizeIndicatorRectangle ( VOID );
LOCAL_C VOID SizePlotSpace          ( VOID );
LOCAL_C VOID ClearMainRectangle     ( VOID );
LOCAL_C VOID ClearAppRectangle      ( VOID );
LOCAL_C VOID ClearCaption           ( VOID );
LOCAL_C VOID ClearIndicator         ( VOID );
LOCAL_C VOID ShowRectangles         ( VOID );

/*****************************************************************
 Sizes all windows relative to status window and font size
 ----------------------------------------------------------------*/
VOID SizeRectangles( VOID )
{ SizeMainWindow();
 SizeAppRectangle();
 SizeCaptionRectangle();
 SizeIndicatorRectangle();
 SizePlotSpace();
 // ShowRectangles();
}

/*****************************************************************
          Insert the plot caption
 ----------------------------------------------------------------*/
VOID InsertCaption( TEXT *Capt, INT Justify )
{ ClearCaption();
 gPrintBoxText(&CptRcl, FontInfo.height-1, Justify,
          FontInfo.ascent, Capt, p_slen(Capt));
 return;
}

/*****************************************************************
   Create and box the indicator window
 ----------------------------------------------------------------*/
VOID CreateIndicator ( VOID )
{ ClearIndicator();
 gDrawBox(&IndRcl);
 fIndicator_rng_x =  (float)(IndRcl.br.x - IndRcl.tl.x);
 FillRcl.tl.y     =  IndRcl.tl.y;
 FillRcl.br.y     =  IndRcl.br.y;
 FillRcl.tl.x     =  IndRcl.tl.x;
}
/*****************************************************************
   Update the indicator by adding to previous x and drawing
   a vertical line at each intervening pixel column up
   through the current x.
 ----------------------------------------------------------------*/
VOID UpdateIndicator ( ULONG current, ULONG total )
{ // find proportion current is of total
 FLOAT pX = (float)((float)current/(float)total);
 // multiply by the width of the indicator & add to left edge
 FillRcl.br.x = IndRcl.tl.x + (INT)(fIndicator_rng_x * pX);
 // If current value is greater than previous, fill up the space
 if( FillRcl.br.x > FillRcl.tl.x )
```


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```
    { gClrRect(&FillRcl, G_TRMODE_SET);
      FillRcl.tl.x = FillRcl.br.x;
    }
}
/*****************************************************************
 Return the size of the Application window, equal to the
 Main window less the border.
   mode 1 = tl.x 7, tl.y 9, br.x 409, br.y 153
   mode 2 = tl.x 7, tl.y 9, br.x 441, br.y 153
   mode 3 = tl.x 7, tl.y 9, br.x 473, br.y 153
   p_atos( usermsg, "tl.x %d, tl.y %d, br.x %d, br.y %d",
         AppRcl.tl.x, AppRcl.tl.y, AppRcl.br.x, AppRcl.br.y);
   Notify(usermsg);
-----------------------------------------------------------------*/
LOCAL_C VOID SizeAppRectangle( VOID )
{ AppRcl.tl.x  =  X_BORD/2;
  AppRcl.tl.y  =  Y_BORD;
  AppRcl.br.x  =  MainRcl.br.x - X_BORD-1;
  AppRcl.br.y  =  MainRcl.br.y - Y_BORD;

}
/*****************************************************************
 Return the size of the Caption Rectangle
 Sized and located at TOP of App window
  6 pt = tl.x 8, tl.y 10, br.x 406, br.y 18
  8 pt = tl.x 8, tl.y 10, br.x 408, br.y 20
-----------------------------------------------------------------*/
LOCAL_C VOID SizeCaptionRectangle( VOID )
{ CptRcl.tl.x  =  AppRcl.tl.x +1;
  CptRcl.tl.y  =  AppRcl.tl.y +1;
  CptRcl.br.x  =  AppRcl.br.x -1;
  CptRcl.br.y  =  CptRcl.tl.y + FontInfo.height;// -5;
}
/*****************************************************************
 Return the size of the Progress Indicator Rectangle,
 nested inside the caption window
-----------------------------------------------------------------*/
LOCAL_C VOID SizeIndicatorRectangle( VOID )
{                       // char width * (filename size+4)
  IndRcl.tl.x  =  CptRcl.tl.x  + (FontInfo.max_width * (12+3));
  IndRcl.tl.y  =  CptRcl.tl.y  + 1;
  IndRcl.br.x  =  CptRcl.br.x  - 4;
  IndRcl.br.y  =  CptRcl.br.y  - 1;
}

/*****************************************************************
 Return the size of the Plot Space, Which is to be the
 Application window, less the caption at top
 NOTE!! To gain a little vertical space, we are encroaching on
 the caption window. Hence, if the caption is changed, the
 plot must be redone, though the reverse is not true.
 mode 1, 6pt tl.x 8, tl.y 28, br.x 408, br.y 152
 mode 1, 8pt tl.x 8, tl.y 30, br.x 408, br.y 152
 mode 2, 6pt tl.x 8, tl.y 28, br.x 440, br.y 152
```


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```
mode 2, 8pt tl.x 8, tl.y 30, br.x 440, br.y 152
mode 3, 6pt tl.x 8, tl.y 28, br.x 472, br.y 152
mode 3, 8pt tl.x 8, tl.y 30, br.x 472, br.y 152
-------------------------------------------------------------*/
LOCAL_C VOID SizePlotSpace( VOID )
{ INT margin, sz_X, sz_Y;

 // X dimension
 sz_X = SZ_XDIV * N_XDIV; // + 1;
 margin = (AppRcl.br.x - AppRcl.tl.x) - sz_X ;
 if(margin<0)margin=0;

 PltRcl.tl.x = AppRcl.tl.x + (margin/2);
 PltRcl.br.x = PltRcl.tl.x + sz_X;

 // Y dimension
 sz_Y = SZ_YDIV * N_YDIV;
 margin = (AppRcl.br.y - (AppRcl.tl.y + CptRcl.br.y)) - sz_Y;
 PltRcl.tl.y = AppRcl.tl.y + CptRcl.br.y + (margin/2);
 PltRcl.br.y = PltRcl.tl.y + sz_Y;

 PltSpc.tl.x = 0; PltSpc.tl.y = 0;
 PltSpc.br.x = PltRcl.br.x-PltRcl.tl.x;
 PltSpc.br.y = PltRcl.br.y-PltRcl.tl.y;

 /*
 p_atos(usermsg," App_X %u, PlotSpace Sized: %d x %d",
    AppRcl.br.x,
    PltRcl.br.x - PltRcl.tl.x, PltRcl.br.y - PltRcl.tl.y );
 Notify(usermsg);
 */

 // define the NSEG segments of the plot space
 SizeSegments ( );
}
/*********************************************************************
        Define the plot segments
   These rectangles allow the use of inversion for highlighting
 one of the six EKG epochs displayed as 2 across and 3 down.
   Segment 1 == SegRcl[0]    Segment 2 == SegRcl[1]
   Segment 3 == SegRcl[2]    Segment 2 == SegRcl[3]
   Segment 5 == SegRcl[4]    Segment 2 == SegRcl[5]

 -------------------------------------------------------------*/
VOID SizeSegments( VOID )
{ INT i,rx;
 INT siz_x = PltSpc.br.x / n_Xseg;
 INT siz_y = SZ_YDIV * (N_YSEG-1);
 INT ry   = 0;
 for(i=0; i<n_Seg; i++)
    { rx = i%n_Xseg;
     SegRcl[i].tl.x = PltRcl.tl.x +   (siz_x*rx) +1 ;
     SegRcl[i].br.x = SegRcl[i].tl.x +  siz_x    -1 ;
     if(!i)
```

```
      { SegRcl[i].tl.y = PltRcl.tl.y +1; }
    else
      { if(i%n_Xseg)
          { SegRcl[i].tl.y = SegRcl[i-1].tl.y; }
        else
          { SegRcl[i].tl.y = SegRcl[i-1].br.y; }
      }
    SegRcl[i].br.y = SegRcl[i].tl.y + siz_y;
    if(rx) { ry++;  if(ry>(N_YSEG-1))ry=0;};
   }
}
/*****************************************************************
        Invert colors in a rectangle
 ----------------------------------------------------------------*/
VOID InvertSegColor_1( INT index )
{ gClrRect( &SegRcl[index - 1], G_TRMODE_INV );
}
/*****************************************************************
        Frames a rectangle
 ----------------------------------------------------------------*/
VOID InvertSegColor( INT index )  // SelectSegment()
{ P_RECT TmpRcl;
 p_bcpy(&TmpRcl,&SegRcl[index - 1], sizeof(P_RECT));

 if(!(index%n_Xseg)) TmpRcl.br.x --;
 // frame
 gClrRect( &TmpRcl, G_TRMODE_INV );
 // content
 TmpRcl.tl.x += 4;  TmpRcl.br.x -= 4;
 TmpRcl.tl.y += 3;  TmpRcl.br.y -= 3;
 gClrRect( &TmpRcl, G_TRMODE_INV );
}

/*****************************************************************
        Clear the Main window
 ----------------------------------------------------------------*/
LOCAL_C VOID ClearMainRectangle(VOID)
{ gClrRect( &MainRcl, G_TRMODE_CLR);
}
/*****************************************************************
        Clear Application window
 ----------------------------------------------------------------*/
LOCAL_C VOID ClearAppRectangle( VOID )
{ gClrRect( &AppRcl, G_TRMODE_CLR);
}
/*****************************************************************
        Clear Caption window
 ----------------------------------------------------------------*/
LOCAL_C VOID ClearCaption( VOID )
{ gClrRect( &CptRcl, G_TRMODE_CLR);
}
/*****************************************************************
        Clear Indicator window
 ----------------------------------------------------------------*/
```


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```
LOCAL _C VOID ClearIndicator( VOID )
{ gClrRect( &IndRcl, G_TRMODE_CLR);
}
/*****************************************************************
        Clear Plot window
 ----------------------------------------------------------*/
VOID ClearPlotSpace( VOID )
{ gClrRect( &PltRcl, G_TRMODE_CLR);
}
/*****************************************************************
  Size the main window, border it and display
  Status Window according to current size
  W_WIN_BACK_CLR
 ----------------------------------------------------------*/
VOID SizeMainWindow( VOID )
{ W_WINDATA MainWinData;
 wInquireStatusWindow(CurrentStatusWindowExtent, &StatusExtent);
 MainWinData.extent.tl.x  = 0;
 MainWinData.extent.tl.y  = 0;
 MainWinData.extent.width  = FSX - StatusExtent.width;
 MainWinData.extent.height = FSY;
 wSetWindow(hWndMain, W_WIN_EXTENT, &MainWinData);
 MainRcl.tl.x = 0;
 MainRcl.tl.y = 0;
 MainRcl.br.x = FSX - StatusExtent.width;
 MainRcl.br.y = FSY;
 ClearMainRectangle();
 wStatusWindow(CurrentStatusWindowExtent);
 gBorder2(W_BORDER_TYPE_0,
W_BORD_CORNER_I|W_BORD_SHADOW_ON|W_BORD_SHADOW_D);
}
/*****************************************************************************
 Work out the next version of the Status Window
 ----------------------------------------------------------------------------*/
VOID ToggleStatusWindow( VOID )
{ CurrentStatusWindowExtent++;
 CurrentStatusWindowExtent %= nModes;
}
/*****************************************************************************
 Create a graphics context
 WS_FONT_BASE+12 is a tiny   6 point monospace, x = 6, y = 6;
 WS_FONT_BASE+ 3 is a smaller 8 point monospace, x = 8, y = 8;
 WS_FONT_BASE+ 0 is default, 10 point monospace, x = 6, y = 8;
 ----------------------------------------------------------------------------*/
VOID CreateMainGC(VOID)
{ UINT fieldset; INT hgc;
  Mgc.gmode   = G_TRMODE_SET;        // default
  Mgc.textmode = G_TRMODE_REPL;      // replacement!
  Mgc.style   = G_STY_NORMAL;        // default
  Mgc.flags   = G_GC_FLAG_BOTH_PLANES; // default??
  Mgc.font    = WS_FONT_BASE+M8PT;    // M8PT = +3, M10PT = +0
  fieldset    = G_GC_MASK_FONT;
  hgc = gCreateGC(hWndMain,fieldset,&Mgc);
  gFontInfo(Mgc.font,Mgc.style,&FontInfo);
```


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```
 if (hgc < 0)  p_exit(hgc);
}

/*****************************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID ShowRectangles (VOID)
 {
  // FONT
  p_atos( usermsg, "Font: Index %d, X %d Y %d",
        Mgc.font, FontInfo.max_width, FontInfo.height);
  Notify(usermsg);
  // APPLICATION
  p_atos( usermsg, "Appl: tl.x %d, tl.y %d, br.x %d, br.y %d",
        AppRcl.tl.x, AppRcl.tl.y, AppRcl.br.x, AppRcl.br.y);
  Notify(usermsg);
  // CAPTION
  p_atos( usermsg, "Capt: tl.x %d, tl.y %d, br.x %d, br.y %d",
        CptRcl.tl.x, CptRcl.tl.y, CptRcl.br.x, CptRcl.br.y);
  Notify(usermsg);
  // PLOT
  p_atos( usermsg, "Plot: tl.x %d, tl.y %d, br.x %d, br.y %d",
        PltRcl.tl.x, PltRcl.tl.y, PltRcl.br.x, PltRcl.br.y);
  Notify(usermsg);
 }
```


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```
/*****************************************************************************
                Str_Fn.C

        R-Stat XL, version 0.2.8
     Copyright Data Critical Inc., 1996.
  United States and international patents pending

   String manipulation functions and utilities
-----------------------------------------------------------------------*/
#include "RStat_XL.H"

/*****************************************************************
 Left-shifts the string str by n characters, and pads str to
 the end (null) with nulls.
 ---------------------------------------------------------------*/
VOID lShfStr( TEXT *str, INT n)
{ int i,j;
 if(!str[0])return;
 i=0;
 for(j=n;str[j];j++){ str[i]=str[j]; i++; };
 for(  ;str[i];i++)  str[i]=0x00;
}
/*****************************************************************
 Right-shifts the string by n characters, padding with spaces
 This is can be very dangerous if the caller is not attending
 to the length of the string.
 ---------------------------------------------------------------*/
VOID rShfStr( TEXT *str, INT  n)
{ int i,j;
 if(!str[0])return;
 i=p_slen(str);    // i points to trailing null
 j=i+n;            // j points to target offset
 for(  ;i>0;i--) { str[j]=str[i]; j--; };
 str[j]=str[i];
 do { j--; str[j]=0x20; } while (j);  // pad on left with spaces
}
/*****************************************************************************
 Concatenates n bytes from the source string onto the destination
 string, and enforces a null termination, returning the index to the
 trailing null.
 ---------------------------------------------------------------*/
INT scat_n ( TEXT *dst, TEXT *src, INT n )
{ INT j = 0; INT i = p_slen( dst );
  for(j=0;j<n;j++) dst[i++]=src[j]; dst[i]=0x00; return i;
}
/*****************************************************************************
  Returns the index to the first instance of the character ch,
  or a minus one if ch is not found
 ---------------------------------------------------------------*/
INT ch_index ( UBYTE Str[], UBYTE ch )
{ INT i = 0;
  if(!Str[0]) return -1;
  while(Str[i]) { if(Str[i]==ch) break; else i++; };
  if(Str[i]==ch) return i;
```


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```
else        return -1;
}
```


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```
/*****************************************************************************
                Sound_IO.C
          R-Stat XL, version 0.2.8
       Copyright Data Critical Inc., 1996.
   United States and international patents pending

 Procedures to record and play back the FM modulated ECG data in
 the form of PSION WVE sound files
 *****************************************************************************/
#include <p_sys.h>
#include "RStat_XL.H"

#define TRUE      1
#define FALSE     0

#define PENDING     E_FILE_PENDING

extern TEXT   LocalFileName[];
extern TEXT   usermsg[];
extern INT    ret;

LOCAL_D VOID  *pTim;
LOCAL_D WORD  TmStat;
      VOID  *pCom;        // extern in Err_Hndl.C for showserial
LOCAL_D WORD  WrStat;
LOCAL_D WORD  RdStat;

LOCAL_C BYTE  SetUpSoundIO     ( TEXT filename[], TEXT *Type );

LOCAL_C VOID  QueueTimer       ( ULONG timeout );
LOCAL_C VOID  CancelTimer      ( VOID );
LOCAL_C VOID  CancelSerialWrite ( VOID );
LOCAL_C VOID  CancelSerialRead  ( VOID );

/*****************************************************************************
 ---------------------------------------------------------------------- */
 BYTE Record_FM_ECG_1 ( TEXT filename[] )
{ INT i;
  if(!SetUpSoundIO ( filename, "Recording" )) return FALSE;
  ret = p_recordsoundw( filename, 137);
  if(!ret)
    { for(i=0;i<2;i++)
        { p_sound((UINT)2,(UINT)320);p_sound((UINT)1,(UINT)100);}
      ret = 1;
    }
  else
    { if(ret==-37)
        { p_atos(usermsg,"Insufficient free space for recording    ",\
                 "    Delete one or more *.WVE files");}
      else
        { p_atos(usermsg,"Error %d in p_recordsoundw()",ret);}
      ret = 0;
      for(i=0;i<4;i++)
        { p_sound((UINT)2,(UINT)320);p_sound((UINT)1,(UINT)100);}
```


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```
  }
 if(!ret) Notify(usermsg);
 return ((BYTE)ret);
}
/*****************************************************************************
 ---------------------------------------------------------------------- */
 BYTE Record_FM_ECG_2 ( TEXT filename[] )
{ WORD RecStat =0;
  WORD elapsed_time=0;
  WORD total_time = 36;  // seconds


  if(!SetUpSoundIO ( filename, "Recording" )) return FALSE;
  // get current time
  // start a timer
  // start recording
  p_recordsounda(filename, 137, &RecStat);

  while ( RecStat == -46 )
    { // check the time
      UpdateIndicator( (ULONG) elapsed_time, (ULONG)total_time );
      // check the keyboard

    };
  p_sound((UINT)4,(UINT)220);
  Notify("Recording Complete, Press Esc to Continue");
  // RestoreContent of Text Window

  if( RecStat == 0 ) return TRUE;
  else               return FALSE;
}
/*****************************************************************************
   Should complete with ret = 0, unless file invalid type or not found
 ---------------------------------------------------------------------- */
 BYTE Playback_FM_ECG_1 ( TEXT filename[] )
{ INT i;
  if(!SetUpSoundIO ( filename, "Playback" )) return FALSE;

  ret = p_playsoundw( filename, (UINT)0, (UINT)0 );

  for(i=0;i<2;i++)
     { p_sound((UINT)2,(UINT)320);p_sound((UINT)1,(UINT)100);}

  // Restore Text Window
  if( ret == 0 ) return TRUE;
  else           return FALSE;

}
/*****************************************************************************
 ---------------------------------------------------------------------- */
 BYTE Playback_FM_ECG_2 ( TEXT filename[] )
{ WORD RecStat = 0;
  WORD elapsed_time =0;
  WORD total_time = 36;
```


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```
if(!SetUpSoundIO ( filename, "Playback" )) return FALSE;

// get current time
// start a timer
// start recording
p_playsounda( filename, (UINT)0, (UINT)0, &RecStat);

while ( RecStat == -46 )
  { // check the time
   UpdateIndicator( (ULONG)elapsed_time, (ULONG)total_time );
/*
   // check the keyboard
   for(;;)
     { wGetEventWait( &event );

       if( event.type==WM_KEY )
        { p_atos( &bb[0],"Key code: %d", event.p.key.keycode );
          gPrintBoxText ( &box,
                    50,
                    G_TEXT_ALIGN_CENTRE,
                    0,
                    &bb[0],
                    p_slen(&bb[0]));
          wInvalidateWin ( wid );
          if( event.p.key.keycode==W_KEY_RETURN ) break;

        }
     };
*/
  };
 p_sound((UINT)4,(UINT)220);
 // Restore Text Window

 if( RecStat == 0 ) return TRUE;
 else           return FALSE;

}
/*****************************************************************************
 ---------------------------------------------------------------------------- */
LOCAL_C BYTE SetUpSoundIO ( TEXT filename[], TEXT *Type )
{ BYTE Ack = TRUE;

  GetCopyOfFileName( LocalFileName, filename);
  p_atos(usermsg,"%s: ", LocalFileName);
  // Capture content of text window & stash it
  InsertCaption(usermsg,LJustify);
  CreateIndicator();
  p_atos(usermsg,"Enter to Begin %s      Else Esc to Cancel",Type);
  Notify_2(&Ack, usermsg);
  if(Ack) return TRUE;
  else    return FALSE;

 }
```


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```
/*****************************************************************************
 *****************************************************************************/
LOCAL_C VOID QueueTimer(ULONG timeout)
{ p_ioc(pTim, P_FREAD, &TmStat, &timeout);
}
/*****************************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID CancelSerialWrite(VOID)
{ p_iow(pCom, P_FCANCEL);
 p_waitstat(&WrStat);
}
/*****************************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID CancelSerialRead(VOID)
{ p_iow(pCom, P_FCANCEL);
 p_waitstat(&RdStat);
}
/*****************************************************************************
 ----------------------------------------------------------------*/
LOCAL_C VOID CancelTimer(VOID)
{ p_iow(pTim, P_FCANCEL);
 p_waitstat(&TmStat);
}
```


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What is claimed is:

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1. A hand-held computer device for monitoring a patient's ECG signal in the form of a frequency modulated audio signal, comprising:

a digital computer having integral microphone, analog to digital converter, speaker, display, digital to analog converter and CPU/memory;

software controlling said digital computer to digitize and demodulate said frequency modulated audio ECG signal; and

means indicating said digitized audio ECG signal on said display.

2. A hand-held computer device as set forth in claim 1 wherein said software controlling said digital computer further comprises:

means to convert said frequency modulated audio ECG signal to a digital frequency modulated ECG signal;

means to demodulate said digital frequency modulated ECG signal to produce a digital ECG signal; and

means to display said digital ECG signal.

3. A hand-held computer device as set forth in claim 1 which further comprises:

means to demodulate said frequency modulated audio ECG signal;

means to digitize said audio ECG signal; and

means to display said digital ECG signal.

4. A hand-held computer device for patient monitoring, comprising:

means for receiving a frequency modulated audio signal indicating a selected, continuously variable biomedical parameter of a patient's physical condition;

analog to digital converter means changing the frequency modulated audio signal to a digital signal;

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means for band-pass filtering said de-modulated digital signal to produce a filtered digital signal having a low frequency pass-band;

a digital polyphase demodulator receiving said digital signal for transformation to a de-modulated digital signal; and

means for displaying the filtered digital signal for a selected time interval.

5. A hand-held computer device as set forth in claim 4 which further includes:

means receiving said filtered digital signal to file in storage.

6. A hand-held computer device as set forth in claim 5 which further includes:

means conducting selected digital signal from said storage for direct print-out.

7. A hand-held computer device as set forth in claim 5 which further includes:

means conducting selected digital signal from said storage via a telephone facsimile system.

8. A hand-held computer device as set forth in claim 4 which further includes:

file means receiving said digital signals from said analog to digital converter means for storage of selected digital signals;

digital-to-analog converter means receiving stored digital signals from the file means to produce a selected time analog signal; and

speaker means for annunciating said time analog signal for pickup and relay via a telephone connection to an auxiliary hand-held computer device.

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9. A hand-held computer device as set forth in claim 4 wherein said means for receiving comprises:

a receptacle receiving electrical signal input of said frequency modulated audio signal.

10. A hand-held computer device as set forth in claim 4 wherein said means for receiving comprises:

a microphone receiving said frequency modulated audio signal.

11. A personal cardiac monitoring system, comprising:

a hand-held computer having integral microphone, audio analog to digital converter, digital to analog converter, speaker, display screen, and central processing unit with associated memory, and further comprising:

means detecting and audibly reproducing a patient's ECG segment for a predetermined time interval as frequency modulated audio for input to said computer microphone; and

software controlling analog to digital signal conversion of said frequency modulated audio input, and controlling the demodulation of the digital signals for output to a display screen.

12. A personal cardiac monitoring system as set forth in claim 11 which further includes:

a low frequency band-pass filter receiving said converted digital signal and outputting to said demodulating stage.

13. A personal cardiac monitoring system as set forth in claim 11 which further includes:

means receiving said low frequency band-pass filter output for audible output from said hand-held computer speaker; and

an associated telephone for pick-up of said audible

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output to provide a relay extension.

14. A hand-held computer device for patient monitoring, comprising:

means for receiving a frequency modulated audio signal indicating a selected biomedical parameter of a patient's physical condition;

means for demodulating said audio signal to produce a time analog signal;

analog to digital converter means changing said time analog signal to a digital signal; and

output means for storage and display of the digitized signal indicating said physical condition.

15. A hand-held computer device as set forth in claim 14 which further includes:

a first band-pass filter applied at the frequency modulation center frequency to the received frequency modulated audio signal.

16. A hand-held computer device as set forth in claim 14 which further includes:

a low frequency band-pass filter applied to said converted digital signal.

17. A hand-held computer device as set forth in claim 15 which further includes:

a low frequency band-pass filter applied to said converted digital signal.

18. A hand-held computer device as set forth in claim 15 wherein:

the first band-pass filter is centered at about 1950 Hz.

19. A hand-held computer device as set forth in claim 16 wherein:

said low frequency band-pass filter extends from .05

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Hz to 40 Hz.

20. A hand-held computer device as set forth in claim 17 which further includes:

means for audibly replaying the frequency modulated audio signal.

21. A hand-held computer device as set forth in claim 14 which further includes:

means for detecting and recording a time segment of a patient's heartbeat for input to said means for receiving.

22. A hand-held computer device as set forth in claim 21 which further includes:

means for frequency modulating the detected heartbeat time segment.

23. A hand-held computer device as set forth in claim 14 which further includes:

a device for detecting, frequency modulating and storing a selected time segment of a patient's heartbeat for subsequent transmission to said means for receiving.

24. A hand-held computer device as set forth in claim 21 which further includes:

a first band-pass filter applied at the frequency modulation center frequency to the received frequency modulated audio signal.

25. A hand-held computer device as set forth in claim 21 which further includes:

a low frequency band-pass filter applied to said converted digital signal.

26. A hand-held computer device as set forth in claim 23 which further includes:

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a low frequency band-pass filter applied to said converted digital signal.

27. A hand-held computer device as set forth in claim 25 wherein:

said first band-pass filter is centered about 1950 Hz and said low frequency band-pass filter extends from about .05 Hz to 40 Hz.

28. A hand-held computer device for patient monitoring, comprising:

means for receiving a frequency modulated audio signal indicating a selected biomedical parameter of a patient's physical condition;

means for digitizing and A-Law compressing said audio signal to provide an A-Law digital output;

A-Law decoder means receiving and expanding said A-Law digital output;

a band-pass filter receiving said expanded digital output to produce a filtered digital output;

a frequency estimator means receiving said filtered digital output; and

means for displaying said filtered digital output.

29. A hand-held computer device as set forth in claim 28 wherein said frequency estimator means comprises:

a cycle accumulator receiving said filtered digital output and producing an accumulator signal; and

a residue estimator receiving said accumulator signal to produce said filtered digital output.

30. A hand-held computer device as set forth in claim 29 wherein:

said selected biomedical parameter is a patient's ECG rhythm strip.

31. A method for using a hand-held computer for monitoring a patient's biomedical signals that relate to a selected

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physical condition, comprising:

receiving a frequency modulated audio signal replica of said biomedical signals;

demodulating said audio signal to produce a time analog signal;

converting said time analog signal to a digital signal representation; and

displaying said digital signal representation as a time analog graphic display.

32. The method for using a hand-held computer as set forth in claim 31 wherein such a system is housed in a PCMCIA card device as received in said hand-held computer.

33. A method for monitoring a patient's ECG signal, comprising:

developing a frequency modulated audio ECG signal from the patient;

inputting the frequency modulated audio ECG signal via telephone to a hand-held, programmed digital computer at a medical diagnostics site;

converting said frequency modulated audio ECG signal to a digital frequency modulated ECG signal;

demodulating said digital frequency modulated ECG signal to produce a digital ECG signal; and

displaying said digital ECG signal as a time analog indication.

34. A method for using a hand-held computer for monitoring a patient's ECG signals, comprising:

developing a frequency modulated audio ECG signal from the patient;

inputting the frequency modulated audio ECG signal via telephone to a hand-held, programmed digital computer at a medical diagnostics site;

companding said frequency modulated audio ECG signal by transforming with an A-Law encoder and decoder to produce an A-Law digital signal

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counterpart;

filtering said digital signal counterpart with a selected bandpass; and

deriving a frequency estimate of the digital signal counterpart for display of the ECG signals.

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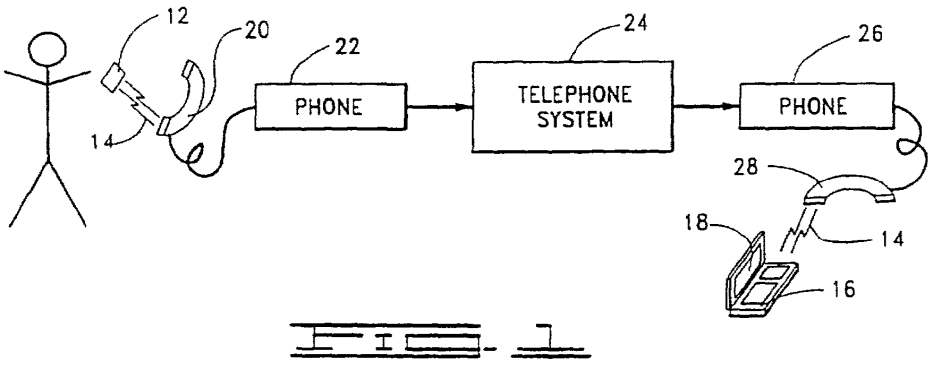

12
20
22
24
26
PHONE
TELEPHONE SYSTEM
PHONE
14
28
18
14
16

FIG. 1

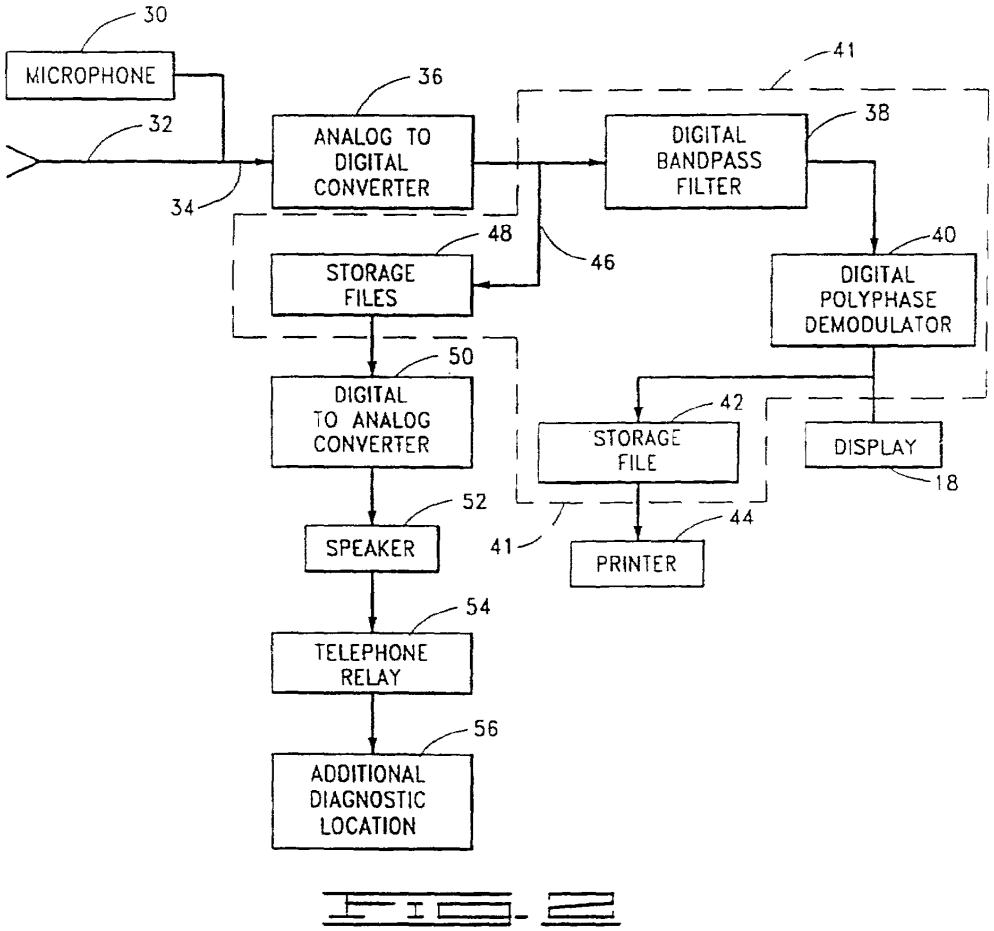

30
MICROPHONE
32
34
36
ANALOG TO DIGITAL CONVERTER
41
38
DIGITAL BANDPASS FILTER
48
STORAGE FILES
46
40
DIGITAL POLYPHASE DEMODULATOR
50
DIGITAL TO ANALOG CONVERTER
42
STORAGE FILE
DISPLAY
18
52
SPEAKER
41
44
PRINTER
54
TELEPHONE RELAY
56
ADDITIONAL DIAGNOSTIC LOCATION

FIG. 2

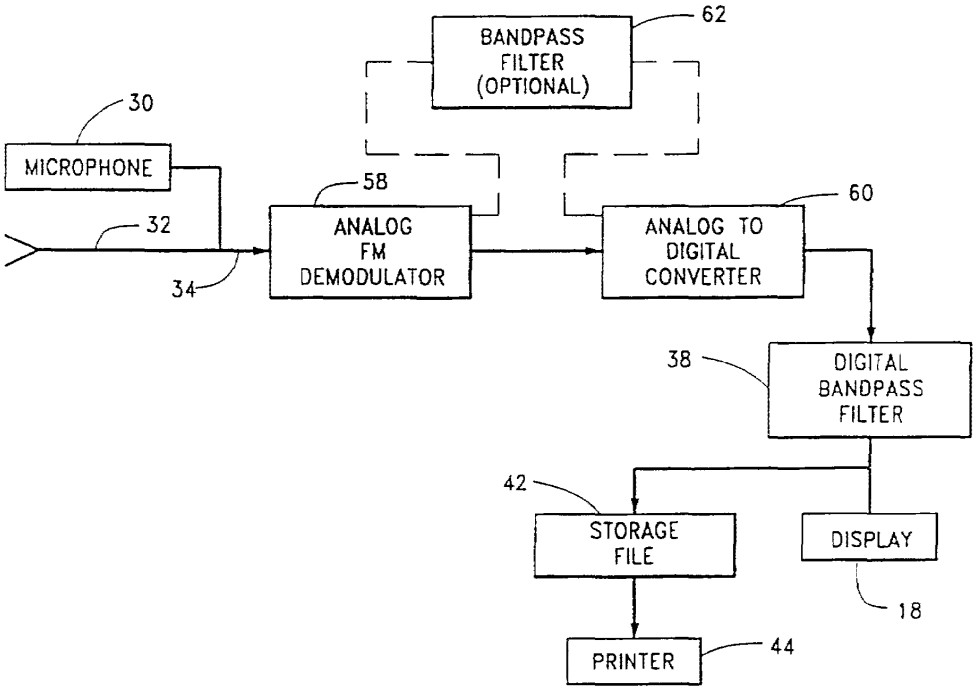

BANDPASS FILTER (OPTIONAL)
62
30
MICROPHONE
58
ANALOG FM DEMODULATOR
60
ANALOG TO DIGITAL CONVERTER
32
34
38
DIGITAL BANDPASS FILTER
42
STORAGE FILE
DISPLAY
18
PRINTER
44

FIG. 4

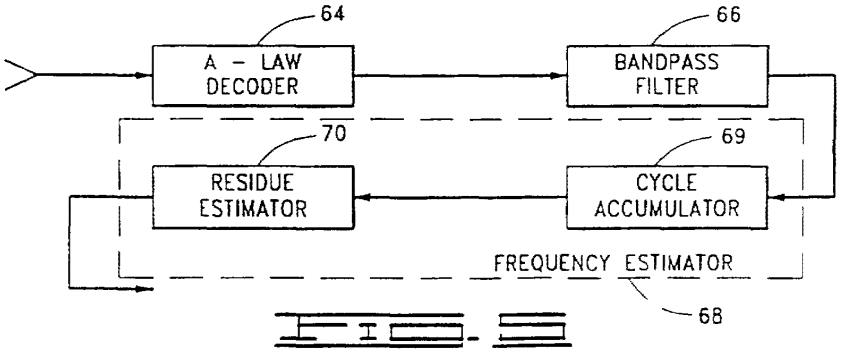

64
A - LAW DECODER
66
BANDPASS FILTER
70
RESIDUE ESTIMATOR
69
CYCLE ACCUMULATOR
FREQUENCY ESTIMATOR
68

FIG. 5

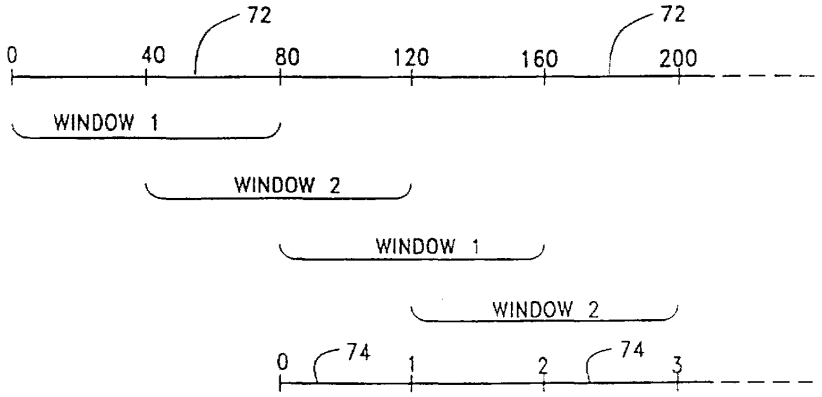

72
72
0
40
80
120
160
200
WINDOW 1
WINDOW 2
WINDOW 1
WINDOW 2
0
74
1
2
74
3

FIG. 5

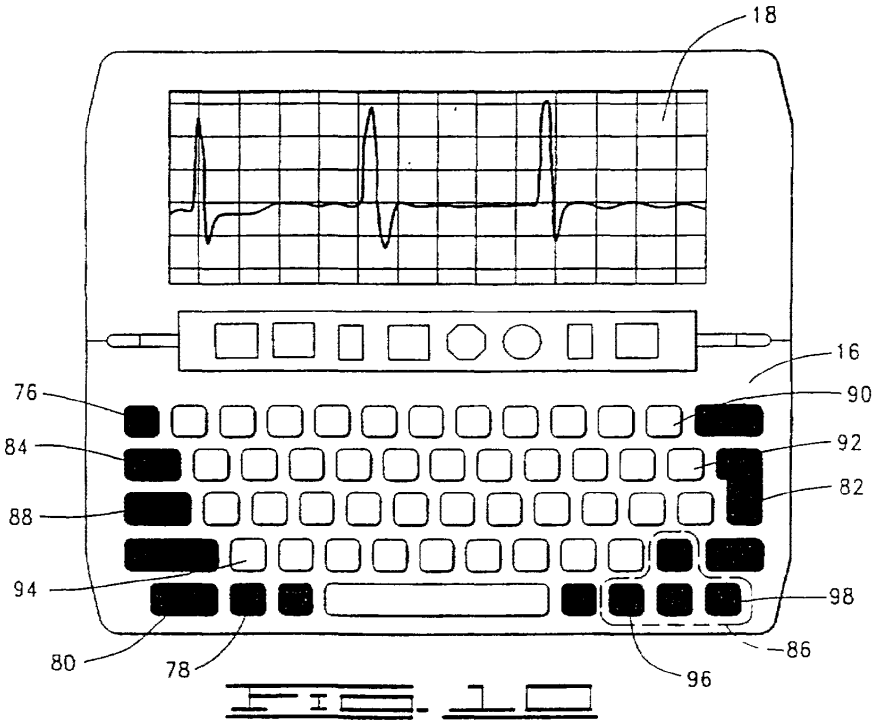

18
16
76
90
84
92
82
88
94
98
86
80
78
96

FIG. 6

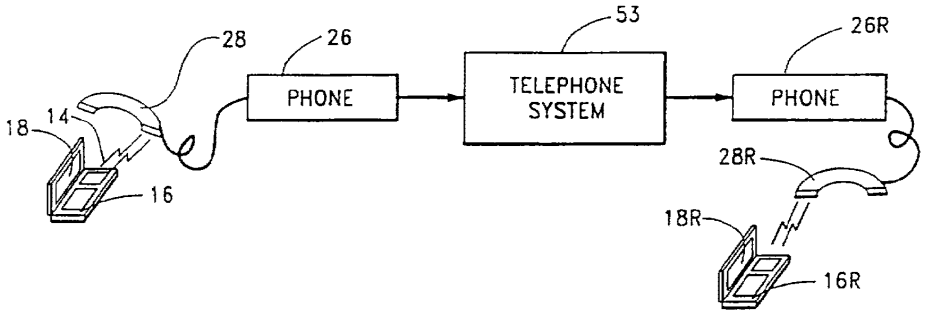

28
26
53
26R
PHONE
TELEPHONE SYSTEM
PHONE
18
14
16
28R
18R
16R

FIG. 3

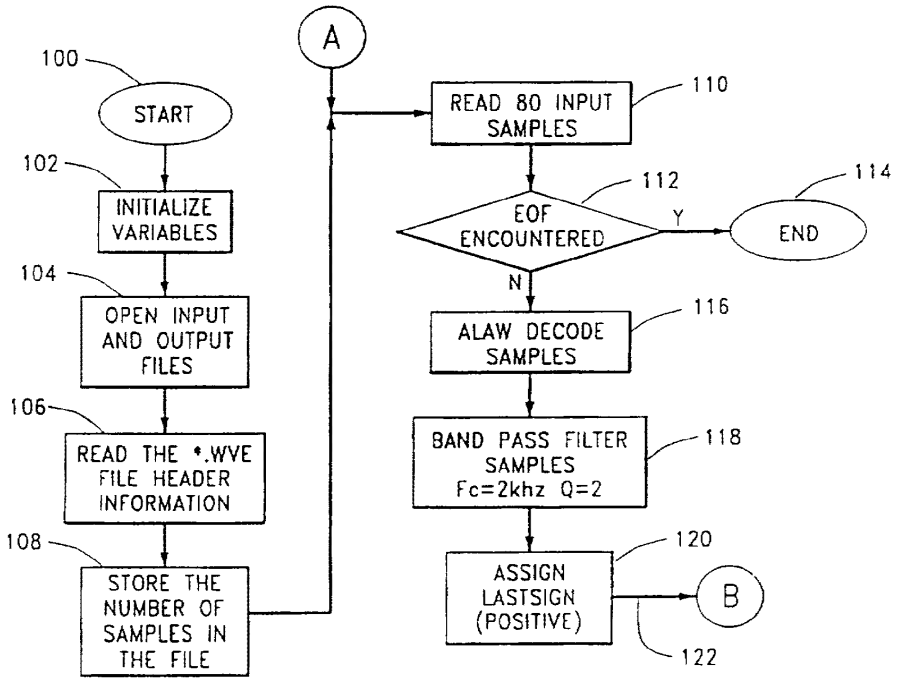
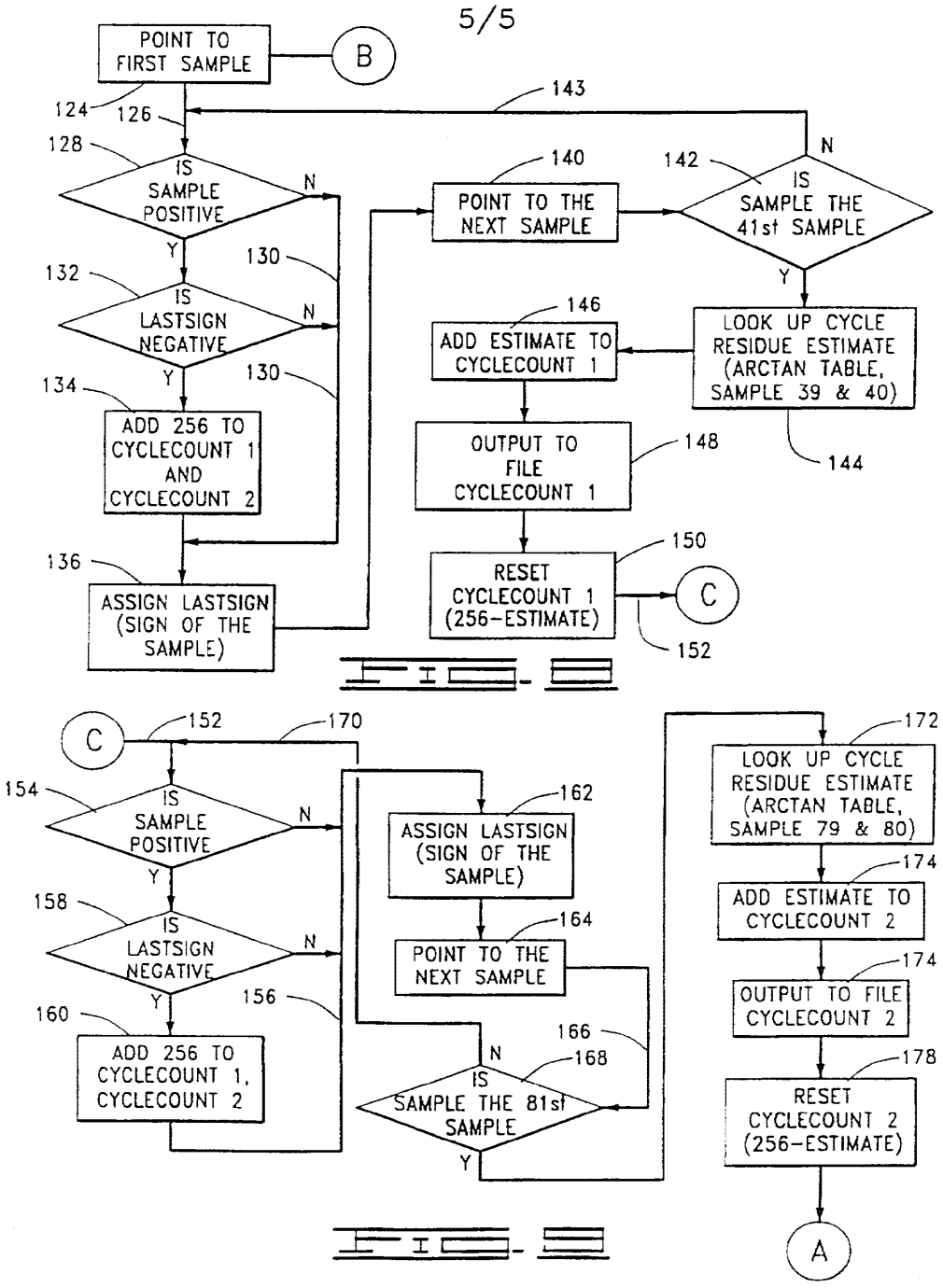

A
100
START
102
INITIALIZE VARIABLES
104
OPEN INPUT AND OUTPUT FILES
106
READ THE *.WVE FILE HEADER INFORMATION
108
STORE THE NUMBER OF SAMPLES IN THE FILE
110
READ 80 INPUT SAMPLES
112
EOF ENCOUNTERED
Y
114
END
N
116
ALAW DECODE SAMPLES
118
BAND PASS FILTER SAMPLES Fc=2khz Q=2
120
ASSIGN LASTSIGN (POSITIVE)
B
122

FIG. 7


POINT TO FIRST SAMPLE
B
124
126
143
128
IS SAMPLE POSITIVE
N
Y
130
132
IS LASTSIGN NEGATIVE
N
Y
130
134
ADD 256 TO CYCLECOUNT 1 AND CYCLECOUNT 2
136
ASSIGN LASTSIGN (SIGN OF THE SAMPLE)
140
POINT TO THE NEXT SAMPLE
142
IS SAMPLE THE 41st SAMPLE
N
Y
146
ADD ESTIMATE TO CYCLECOUNT 1
LOOK UP CYCLE RESIDUE ESTIMATE (ARCTAN TABLE, SAMPLE 39 & 40)
144
OUTPUT TO FILE CYCLECOUNT 1
148
RESET CYCLECOUNT 1 (256-ESTIMATE)
150
C
152
C
152
170
154
IS SAMPLE POSITIVE
N
Y
158
IS LASTSIGN NEGATIVE
N
Y
160
ADD 256 TO CYCLECOUNT 1, CYCLECOUNT 2
156
162
ASSIGN LASTSIGN (SIGN OF THE SAMPLE)
164
POINT TO THE NEXT SAMPLE
166
N
168
IS SAMPLE THE 81st SAMPLE
Y
172
LOOK UP CYCLE RESIDUE ESTIMATE (ARCTAN TABLE, SAMPLE 79 & 80)
174
ADD ESTIMATE TO CYCLECOUNT 2
174
OUTPUT TO FILE CYCLECOUNT 2
178
RESET CYCLECOUNT 2 (256-ESTIMATE)
A

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/09174

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/0432
US CL :128/696
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/696, 710, 711, 904; 607/032, 060

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,336,245 A (ADAMS et al.) 09 August 1994, entire document.	1, 2, 4-13, 28-30, 33, 34
Y	US 5,433,736 A (NILSSON) 18 July 1995, Fig. 1.	1, 2, 4-13, 28-30, 33, 34
Y	US 4,567,883 A (LANGER et al.) 04 February 1986, entire document.	28-30, 34
Y	US 5,466,246 A (SILVIAN) 14 November 1995, entire document.	2, 4-13, 28-30, 33, 34
Y	US 3,731,311 A (WILLIAMS) 01 May 1973, col. 1, lines 35-40.	4-10

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

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Date of the actual completion of the international search 19 AUGUST 1997	Date of mailing of the international search report 29 AUG 1997
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Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/09174

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,503,158 A (COPPOCK et al.) 02 April 1996, entire document.	1, 3, 14, 20-23, 31, 32

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

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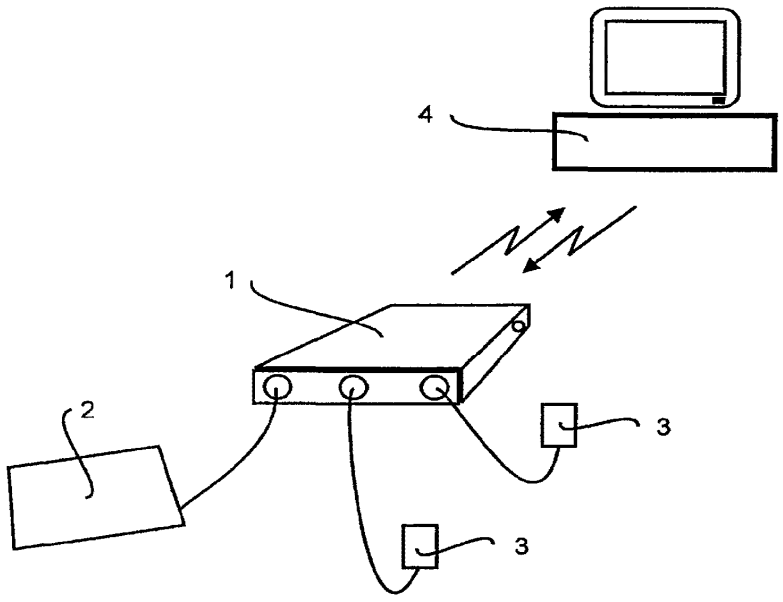
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(54) Title: A MEDICAL MEASURING SYSTEM

(57) Abstract

In a medical measurement system, measurements can be carried out at a distance from a hospital. Thus the patient is connected to a measuring system comprising measuring sensors and a unit for collecting data comprising a transmitter. The system also comprises a centrally located surveillance unit. The measuring sensors sense various physical and physiological parameters, for example brain activities, actions of the heart, respiration, blood pressure, blood values/tests and body movements. The sensed signals are transmitted to a portable small device of low weight for collecting and/or analysing data, which is connected to a central surveillance unit, for example via the public switched telephone network (PSTN), a radio system, in particular a cellular radio system, or via a satellite communication. In a preferred embodiment the measuring sensors comprise a preamplifier having an identification circuit. The identification circuit is used for providing each preamplifier with a unique identity. In yet another preferred embodiment a measuring pad for measuring physical and physiological parameters is provided. The measuring pad comprises a film having piezo and/or pyro electrical characteristics, for example a PVF–film (Poly Vinyl Fluoride), or any other sensor having similar properties. By using such a film, which can convert movements into an electrical signal several advantages are achieved.



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A MEDICAL MEASURING SYSTEM

TECHNICAL FIELD

The present invention relates to a medical measuring system and in particular to a method and a system for portable measurement, surveillance, transmission recording and analysis of physical, physiological and other functions and parameters.

BACKGROUND OF THE INVENTION AND PRIOR ART

In various medical areas it is sometimes necessary to perform measurements and surveillance during long periods of time. Examples of such medical areas could be neurology, cardiology, telemedicine, long-term nursing and home nursing. During such long-term measurements, which typically last for days, the patient must at all time be connected to the measuring equipment in order for a continuous measurement to occur.

Furthermore, in most cases such measurements must be supervised by qualified personnel in order to prevent interruptions in the measurements and to check that the condition of the patient does not worsen. The latter is very important since measurements of the kind mentioned above often are included in treatment as follow-up examinations or in investigations for establishing a diagnosis. Thus, it is common that the person responsible for correctly carrying out the measurements is a doctor.

These long term measurements must therefore be carried out using ambulatory measurement equipment, since the patient can hardly be expected to remain in bed during the long periods required for obtaining a continuous series of measurements. Further, the measuring equipment must be located at a hospital in order to there be supervised by a doctor in charge.

This is of course expensive for the payer of the hospital care and not particularly comfortable for the patient who

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 307

cannot leave the hospital despite the fact that he/she is not in any need of hospitalization at the movement.

SUMMARY

It is an object of the present invention to reduce the costs resulting from long-term measurements.

It is another object of the present invention to improve the environment and reduce the difficulties for patients who need to undergo long-term measurements.

It is yet another object of the present invention to provide a measuring pad for measurements of physical and physiological parameters, which is very sensitive and which therefore can be located at a fairly long distance from a patient, for example beneath a thick mattress or even under a bed.

It is a further object of the present invention to provide a pre-amplifier, which is easy to handle and which produces or eliminates the risk for erroneous handling, and which is suited to be used together with the measuring equipment.

These objects and others are obtained by means of a method and system by means of which the measurements can be carried out at a distance from a hospital. Thus the patient is connected to a measuring system comprising measuring sensors and a unit for collecting data comprising a transmitter. The unit for collecting data preferably also comprises means for performing different analyses. The system also comprises a centrally located surveillance unit.

The measuring sensors sense various physical and physiological parameters, for example brain activities, actions of the heart, respiration, blood pressure, blood values/tests and body movements. The sensed signals are transmitted to a portable small device of low weight for collecting and/or analysing data, which is connected to a

central surveillance unit, for example via the public switched telephone network (PSTN), a radio system, in particular a cellular radio system, or via a satellite communication. The central surveillance unit is monitored by qualified personnel which can follow the measurements and also in certain cases reprogram the unit for collecting and analysing data during an ongoing measurement.

In a preferred embodiment the measuring sensors comprise a preamplifier having an identification circuit. The identification circuit is used for providing each preamplifier with a unique identity. The fact that each pre-amplifier is given a unique identity makes it possible for the unit collecting and analysing data to automatically check if the correct pre-amplifier has been attached to the correct input terminal and, if that is not the case, either correct the error or give a signal indicating that an erroneous connection has been made.

In yet another preferred embodiment a measuring pad for measuring physical and physiological parameters is provided. The measuring pad comprises a film having piezo and/or pyro electrical characteristics, for example a PVF-film (Poly Vinyl Fluoride), or any other sensor having similar properties. By using such a film, which can convert movements into an electrical signal several advantages are achieved. Thus, a measuring pad comprising such a film is easy to fold together and can be made very sensitive, whereby it can be placed beneath the mattress or even under the bed in which the patient is lying.

Furthermore, the signals transmitted to/ from the central surveillance unit can be image/video signals (if a camera is connected to the system), audio signals (such as speech), text signals (for transmission of prescriptions etc.) as well as biological signals. In this manner the personnel at the surveillance end of the system can have full access to information required for providing the patient with proper medical treatment at distance.

The use of the system as described herein provides a number of advantages compared to the prior art. Thus, the patient no longer needs to be in a hospital but can instead be at home or at an another suitable location. Hence, by using the system the cost for hospital care is reduced or eliminated. Furthermore the patient can move around freely due to the fact that the measuring system and auxiliary equipment used for collecting data are made small and of low weight.

BRIEF DESCRIPTION OF THE DRAWINGS

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

- Figure 1 is a schematic view of an ambulatory medical measuring system.
- Figure 2 is a schematic diagram of a unit for collecting and analysing data.
- Figure 3 is a schematic diagram of a preamplifier used in the medical measuring system shown in figure 1.
- Figure 4 is a section through a measuring pad for use together with the medical measuring system shown in figure 1.

DETAILED DESCRIPTION

In figure 1 a schematic diagram of an ambulatory medical measuring system is shown. Thus a unit 1 for collecting and analysing data is connected to a measuring pad 2 and a pre-amplifier 3. The measuring pad 2 and the preamplifiers 3 sense different physical and physiological parameters and are described in more detail below in conjunction with figure 3 and figure 4. These signals are transmitted to the unit 1 for collecting and analysing data.

In the unit 1 the signals provided by the measuring pad 2 and the preamplifiers 3 are A/D-converted and stored and analysed. The digital data stored in the unit 1 can then be output from the unit 1 to an external computer 4.

The transmission of data to the external computer 4 can be carried out in a number of different ways. In a preferred embodiment the transmission is carried out using an infrared

IR-interface. Such an arrangement has the advantage that the patient can be connected to the measuring equipment when data is transmitted from the unit 1 to the computer 4 without being physically connected to the computer 4. Thus, the risk for electrical current to be transmitted from the computer 4 to the patient is eliminated.

In another preferred embodiment the unit 1 is also provided with, e.g., a PCMCIA-card or PC-card or a similar device by means of which the unit 1 can connect to a telephone or data network. The computer 4 then does not need to be in the same room as the unit 1 when data is transmitted from the unit 1 to the computer 4. For example, the unit 1 can be located together with the patient at home and the computer 4 can be located at the hospital.

A doctor or another qualified person at the hospital can then connect to the unit 1 at any time and transmit measurements data from the unit 1 via for example the public switched telephone network or a cellular network to the computer 4. In such an arrangement the patient does not need to be disturbed or even know about when the unit 1 transmits data and must hence not be bothered by this.

In yet another preferred embodiment the unit 1 can in itself analyse the collected measurement data. Examples of analyses which the unit 1 can perform are comparisons between measured signals and threshold values corresponding to such signals.

Thus, an alarm can be activated in the unit 1 if such a threshold value is crossed either from above or from below and the computer 4 can be automatically contacted via the telephone or data network in order for the doctor or qualified personnel monitoring the computer 4 to immediately have access to all measurement data, in particular the data causing the triggering of the alarm.

In this manner an important event in the series of measured data can be spotted quickly, transmitted and possibly taken

care of. For example, the information transmitted can form the basis for moving the patient to a hospital in order to perform more thorough investigations and tests or that an emergency alarm is issued and that actions required are performed.

Another advantage achieved with such an arrangement is that it is possible to perform adjustments in the settings at distance. Thus, if the doctor or qualified personnel for one reason or another wants to measure some another physical or physiological parameter, which at present is not being measured, information thereof can be transmitted from the computer 4 to the unit 1 and collection of the new desired parameter can start in the unit 1.

In yet another preferred embodiment data regarding the patients earlier conditions and possible treatment can also be stored and transmitted to/from the unit 1. The unit 1 may also be equipped with a GPS-navigation system for continuous surveillance of the movements of the patient and in order to locate the patient quickly in the case an alarm signal is transmitted and the patient must be located quickly.

In fig. 2 a schematic block diagram of the unit 1 is shown. Thus, the unit 1 comprises an input terminal 10 for analogue signals and an input terminal 12 for digital signals. The analogue input terminal is connected to a unit 14 wherein the signal is amplified and filtered. The output signal from the unit 14 is fed to an A/D-converter 16 wherein the signal from the unit 14 is converted into a digital format.

The output signal from the A/D-converter is fed to a computation and control unit 18. The signals input at the terminal 12 are also connected to the unit 18. The unit 18 is connected to a memory 20 in which information can be stored and from which the unit 18 can read information. The unit 18 is also connected to a unit 22 arranged to transmit and receive information from outside the unit 1. . The unit 22 can for example be a wireless modem or another suitable

interface.

The unit 1 can further comprise a power supply unit 24, for example a rechargeable or replaceable battery. In a preferred embodiment the power supply unit comprises a back-up function so that a battery can be charged or replaced without having to interrupt an ongoing measurement.

The unit 1 may also have an input terminal 26 to which equipment for control, calibration or analysis of the unit 1 can be connected.

In Fig. 3, a schematic block diagram of the pre-amplifier 3 is shown. Thus, the pre-amplifier 3 comprises a first amplifier 103, which is connected to a number of input terminals arranged to receive plug-in contacts for electrodes, which are attached to a person from whom measured data are collected.

The amplifier 103 is connected to a digital filter 105. The filter 105 filters the signals using a suitable filter. The filter may by different for different types of signals as described below.

The filter 105 is in turn connected to a second amplifier 107 wherein the signals are amplified a second time to a suitable output amplitude. The amplifier 107 is connected to an output terminal through which the pre-amplifier 3 can be connected to the unit 1. The pre-amplifier 3 can also be equipped with a wireless interface towards the unit 1. If such an arrangement is employed the need for cables and input/output terminals can be dispensed with.

Furthermore, the pre-amplifier 3 comprises an identification and calibration unit 109. The unit 109 can communicate with the unit 1 or with another external unit via a bi-directional data communication line. Thus, the unit 1 can read a unique ID-number and also, in a preferred embodiment, read calibration data stored in the unit 109.

In a preferred embodiment the ID-number and the calibration data can be read continuously or every time the pre-amplifier is connected to the unit 1.

IN another preferred embodiment the pre-amplifier 3 can be informed of which type of signal which is to be measured. This is accomplished by means of a special protocol, which informs the pre-amplifier that a particular type of signals are to be measured, for example heart or brain signals.

Since the pre-amplifier is informed of which type of signals that are to be measured the filter 105 can be adjusted for that type of signals and also the amplifiers 103 and 107 can be set to levels, which are suitable for the type of signals to be measured.

Since each pre-amplifier 3 is given a unique identity the unit 1 can sense if the correct pre-amplifier has been connected to the corresponding input terminal of the unit 1. If this is not the case, the unit 1 can correct the mistake or give a signal informing the user of his/her mistake.

Furthermore, since the unit 1 and/or the pre-amplifier 3 has knowledge of which type of signal that is to be measured, an alarm signal can be issued if the wrong type of signal is measured.

In Fig 4, a section through the measuring pad 2 is shown. The pad 2 comprises a pressure sensitive element 201 made of a material such as a PVF-film or another type of film, which generates an electrical voltage in response to physical movements or pressure changes. Around the element 201 a protective coating 202 is arranged.

The coating 202 isolates the element 201 from static voltages and other electrical noise. The pad 2 is preferably further provided with a shock absorbing material 3, which protects the element 201 from impacts. The material 3 is preferably a rubber material or another suitable flexible and robust

material.

The pad 1 has an outer coating made of a water resistant material 204, which prevents liquid from getting into contact with the pressure sensitive element 201. The element 201 can further communicate with the unit 1 via a cable 205, which is connected to the unit 1 and to the element 201. The cable 205 is passed through the outer coating 204 of the pad 2 through a watertight passage.

In another preferred embodiment the interface between the unit 1 and the pad 2 is wireless. The element 201 then emits signals to the unit 1 via a wireless modem or via infrared (IR) light, or in any other suitable manner.

A portable system as described herein can be made of very low weight and the measuring parts of the system, i.e. the electrodes and its pre-amplifier(s), and the measuring pad, are therefore easy to bring along when a patient using them wants to move around. This gives the patient much more freedom than what can be achieved with the prior art.

WHAT IS CLAIMED IS:

1. A medical portable measuring system comprising:
- sensors for measuring physical and/or physiological parameters of a patient, said sensors being arranged to emit signals to a data collecting unit, wherein the data collecting unit is arranged to communicate with a surveillance unit located at distance from the data collecting unit.

2. A system according to claim 1, wherein the data collecting unit is connected to the surveillance unit via a wireless interface.

3. A system according to claim 1, wherein the data collecting unit comprises means for analysing collected data.

4. A system according to claim 3, wherein means for issuing an alarm signal are connected to the analysing means.

5. A system according to claim 1, wherein the surveillance unit is arranged to transmit control and set-up signals to the data collecting unit.

6. A system according to claim 1, wherein the collecting unit comprises a GPS-transmitter.

7. A system according to claim 1, comprising a signal amplifier device connected to the data collecting unit having an identification circuit for automatic identification of the amplifier.

8. A system according to claim 7, wherein the amplifier device has means for storing calibration data.

9. A system according to claim 7, wherein the amplifier device comprises a signal filter, the parameters of which can be controlled in response to control signals.

10. A system according to claim 1, comprising a pressure sensitive element made of a film arranged to convert pressure changes into an electrical signal and which is connected to the data collecting unit.

11. A system according to claim 10, wherein an elastic material is arranged around the film.

12. A system according to claim 10, wherein the film is made of PVF (Poly Vinyl Fluoride).

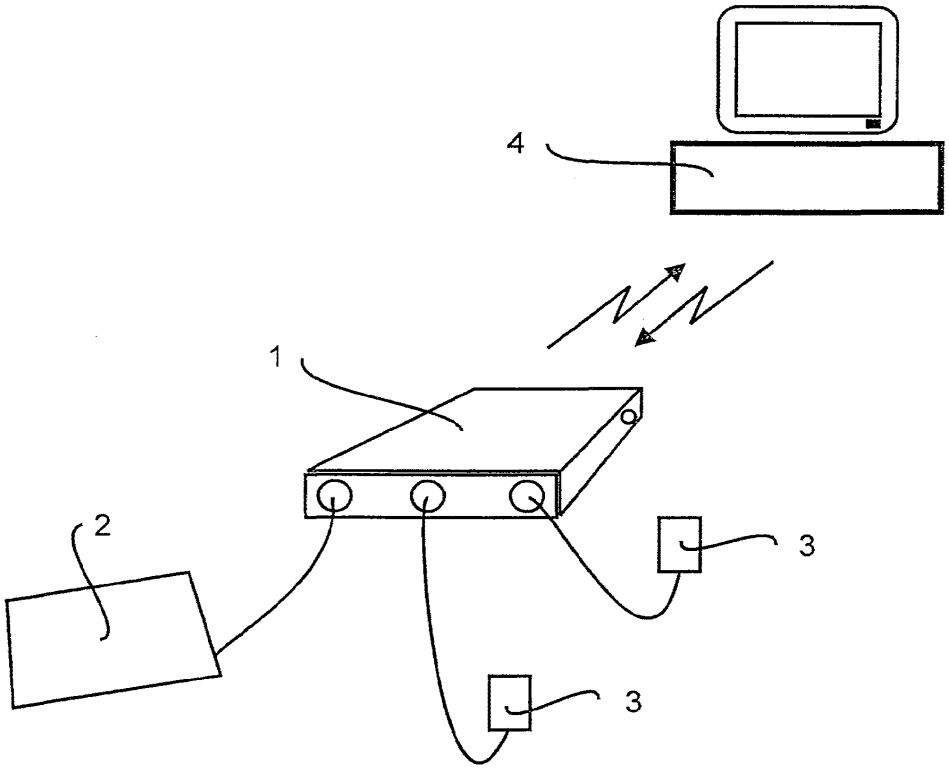


Fig. 1

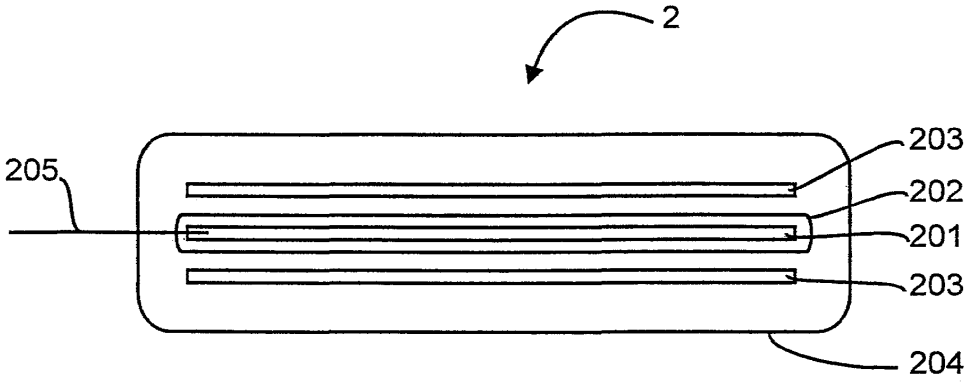


Fig. 4

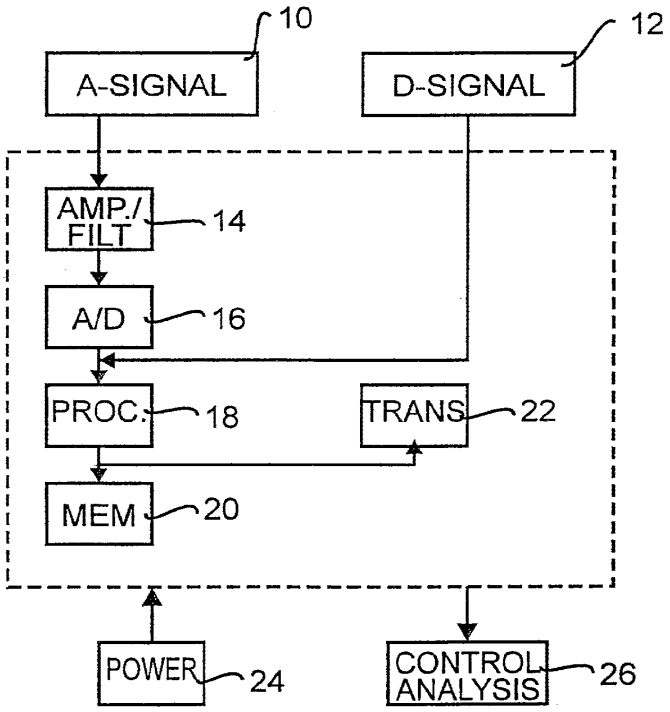

10
12
A-SIGNAL
D-SIGNAL
AMP./ FILT
14
A/D
16
PROC.
18
TRANS
22
MEM
20
POWER
24
CONTROL ANALYSIS
26

Fig. 2

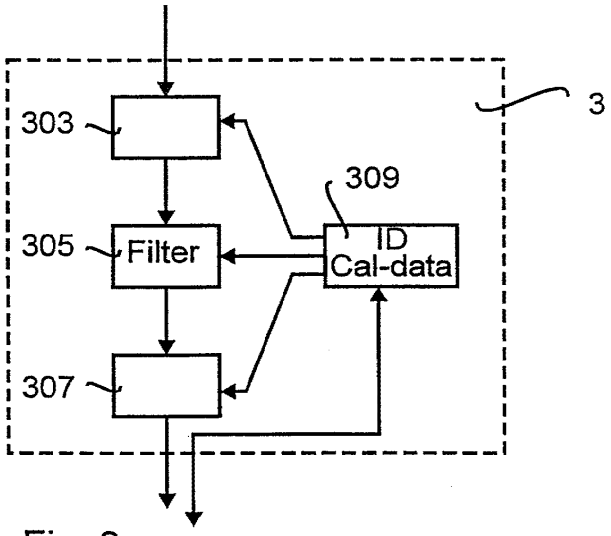

3
303
309
305
Filter
ID
Cal-data
307

Fig. 3

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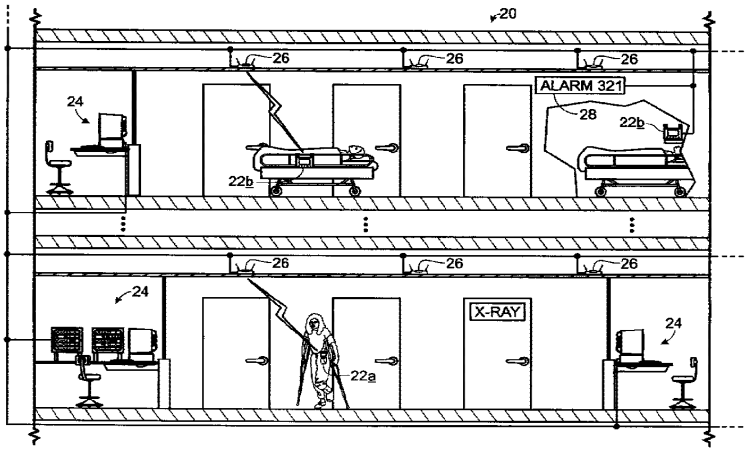
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(54) Title: PATIENT MONITORING SYSTEM



(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.

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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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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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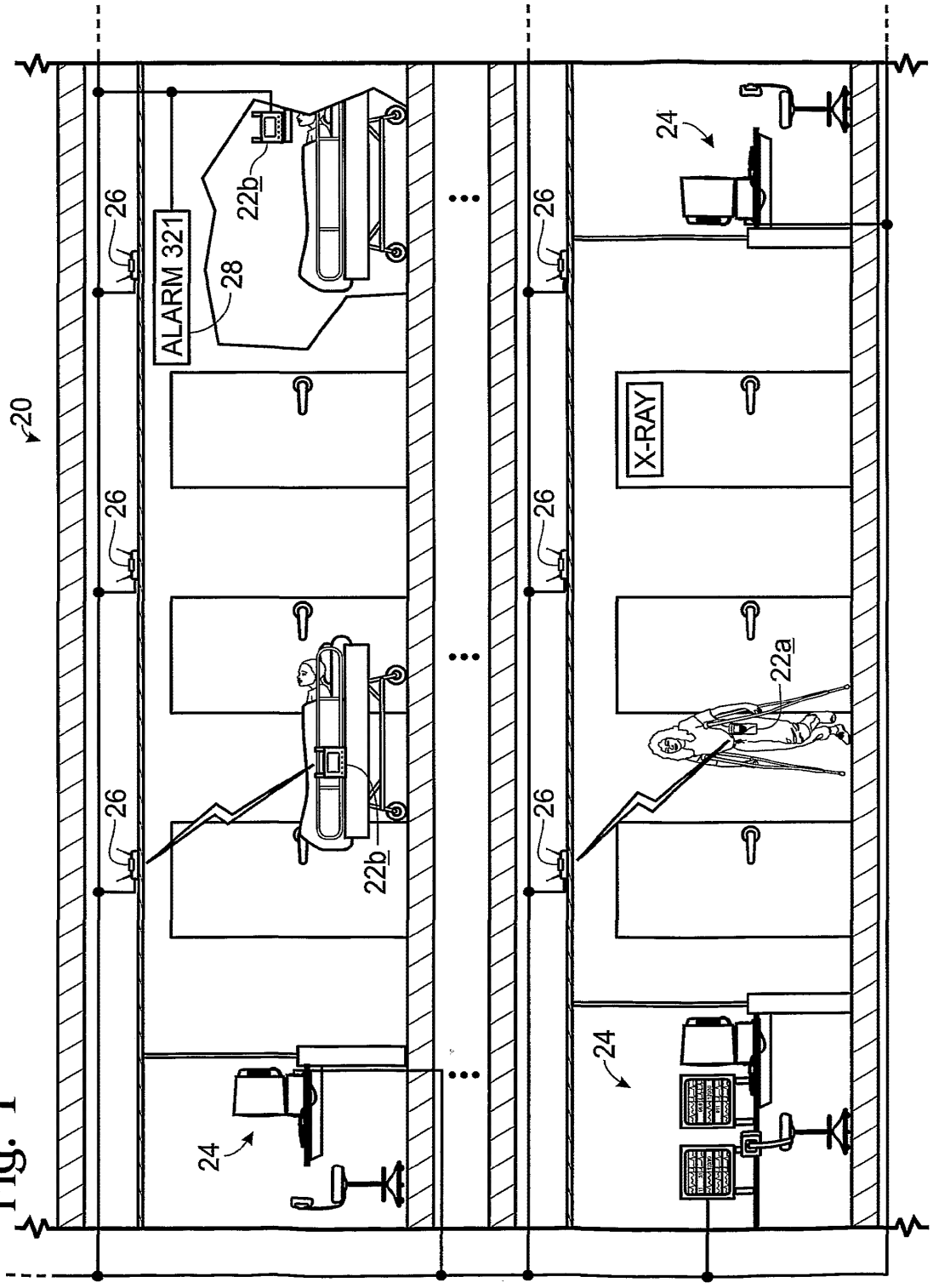


Fig. 1

Fig. 2

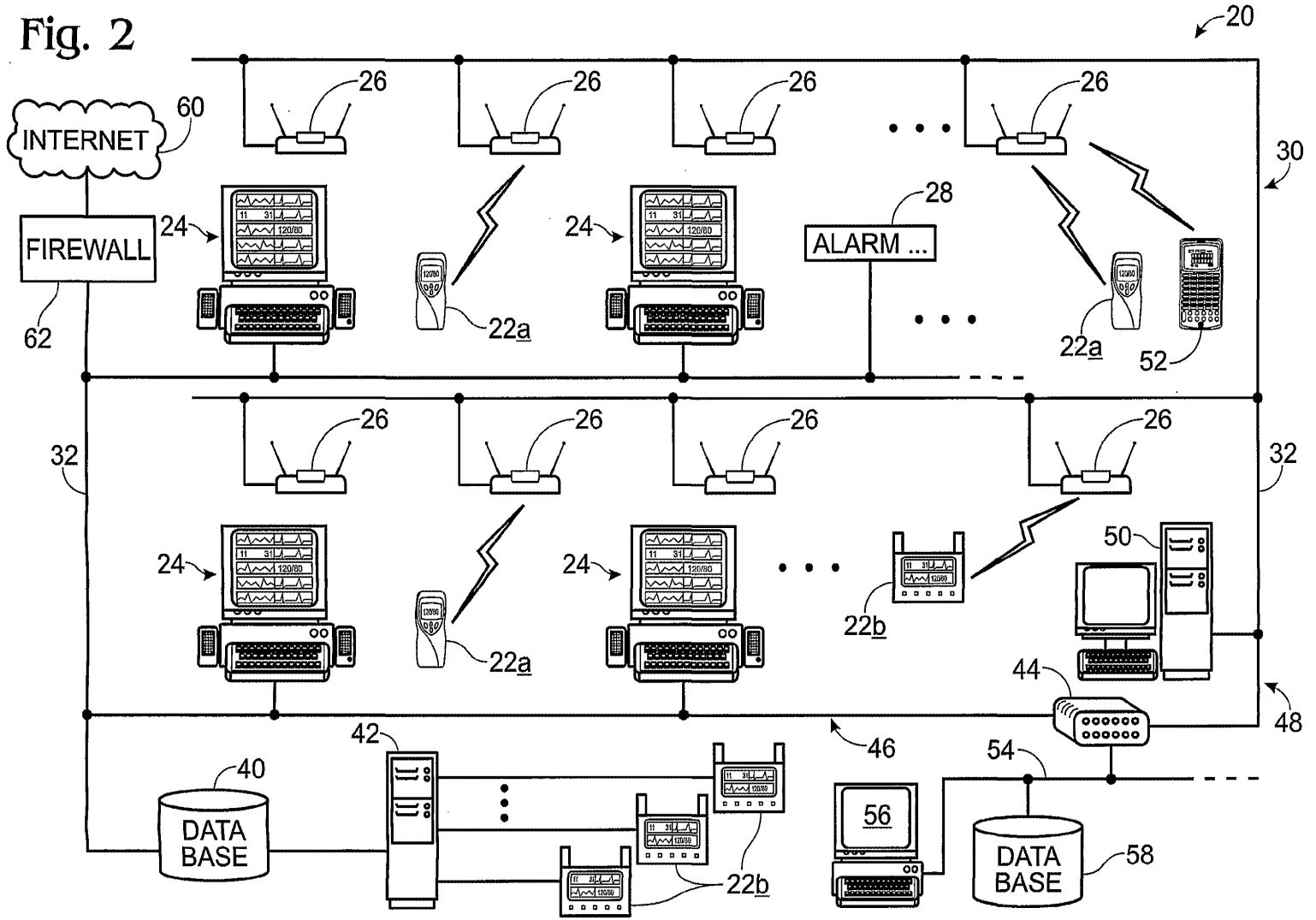

20
INTERNET
60
FIREWALL
62
26
24
22a
22b
28
ALARM ...
30
32
50
52
40
DATA BASE
42
44
46
48
54
56
58

Fig. 3

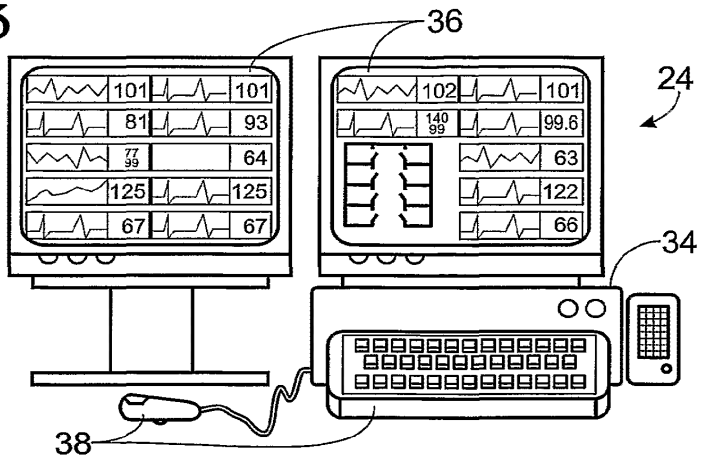

36
24
34
38
101
101
81
93
64
125
125
67
67
102
101
140
99
99.6
63
122
66

Fig. 4

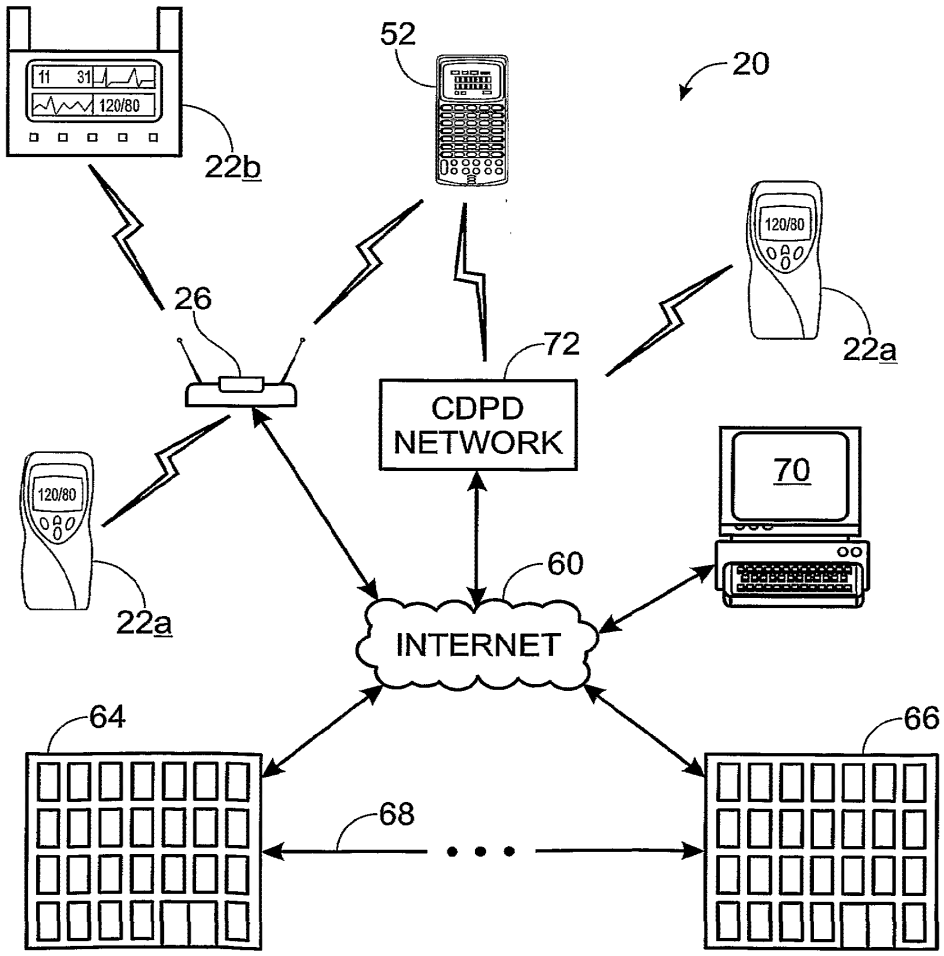

52
20
22b
26
72
22a
CDPD
NETWORK
70
60
22a
INTERNET
64
66
68
120/80
120/80

Fig. 5

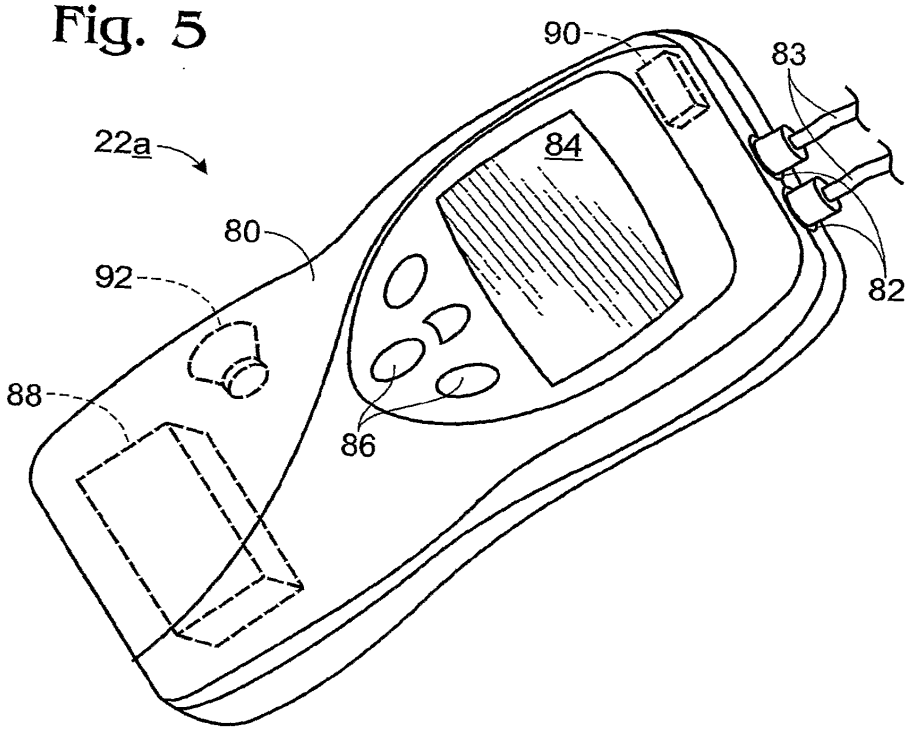


Fig. 6

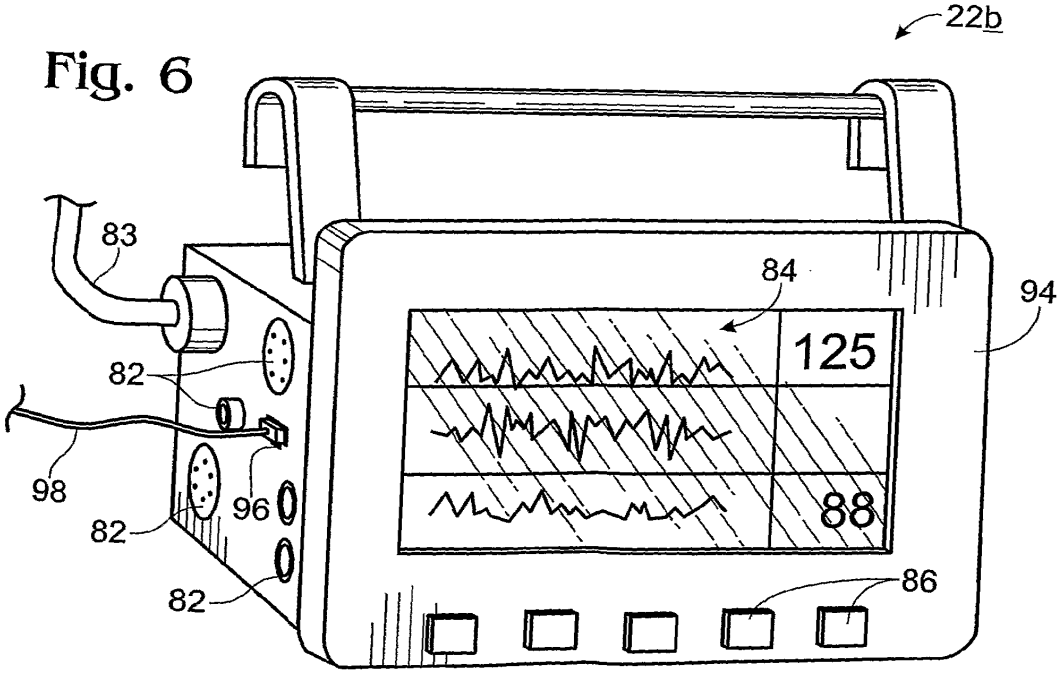


Fig. 7

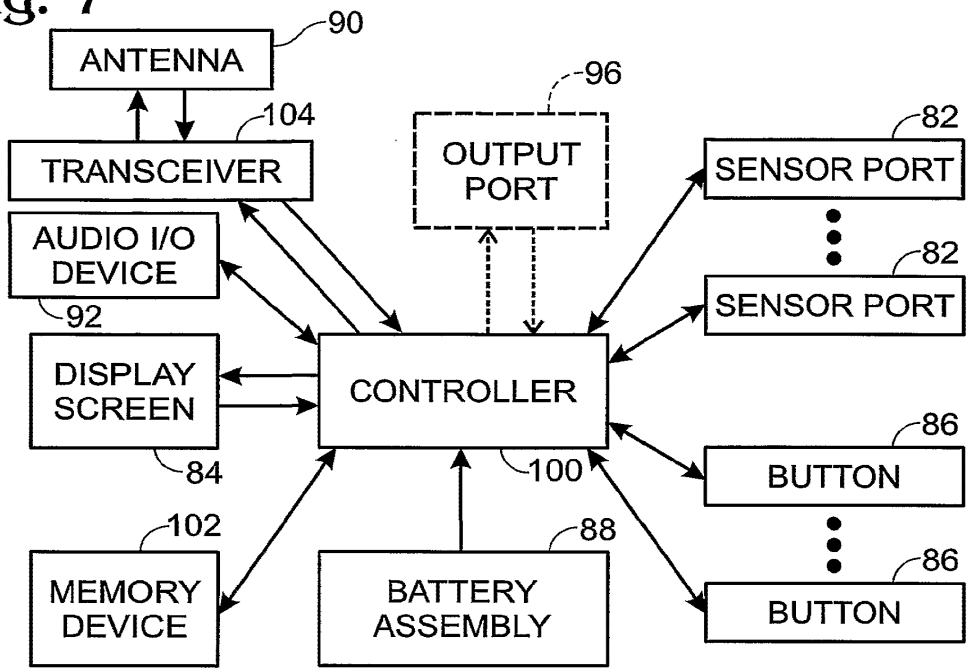

ANTENNA
90
TRANSCEIVER
104
OUTPUT PORT
96
SENSOR PORT
82
SENSOR PORT
82
AUDIO I/O DEVICE
92
DISPLAY SCREEN
84
CONTROLLER
100
BUTTON
86
BUTTON
86
MEMORY DEVICE
102
BATTERY ASSEMBLY
88

Fig. 8

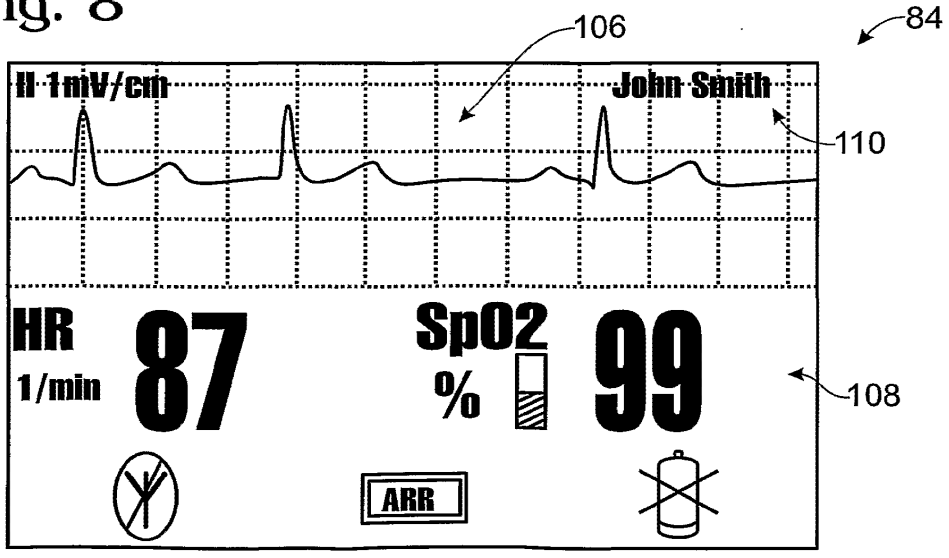

II 1mV/cm
John Smith
106
84
110
HR
1/min
87
SpO2
%
99
108
ARR

Fig. 9

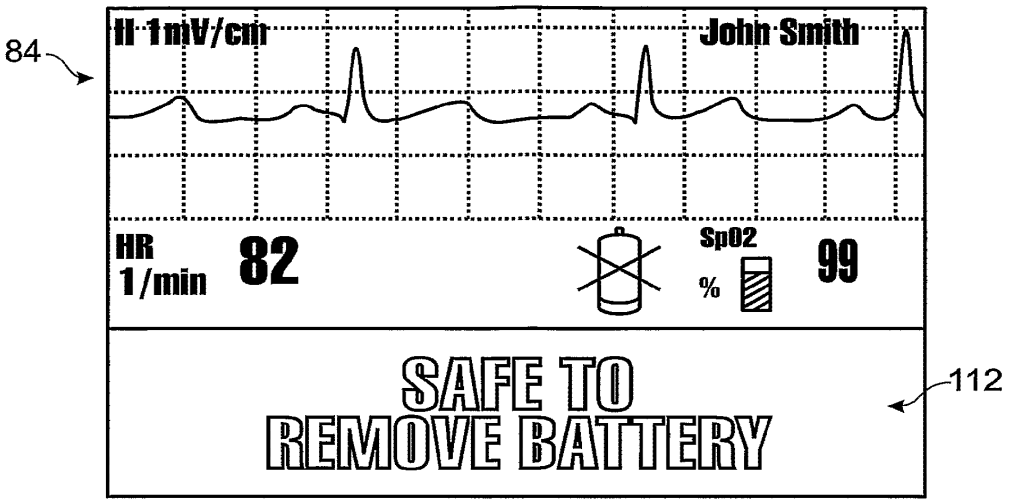

84
II 1mV/cm
John Smith
HR
1/min
82
SpO2
%
99
SAFE TO
REMOVE BATTERY
112

Fig. 10

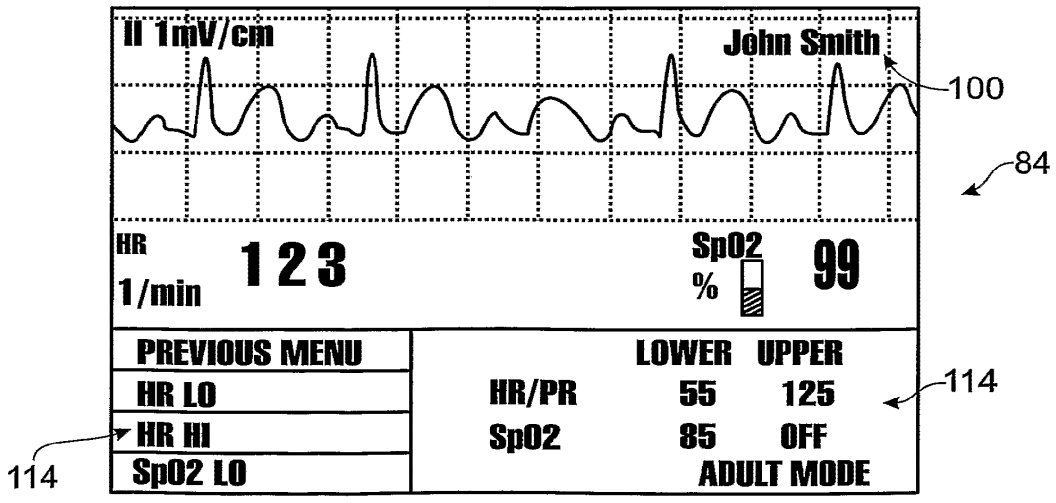

II 1mV/cm
John Smith
100
84
HR
1/min
123
SpO2
%
99
PREVIOUS MENU
HR LO
HR HI
SpO2 LO
114
LOWER UPPER
HR/PR 55 125
SpO2 85 OFF
ADULT MODE
114

Fig. 11

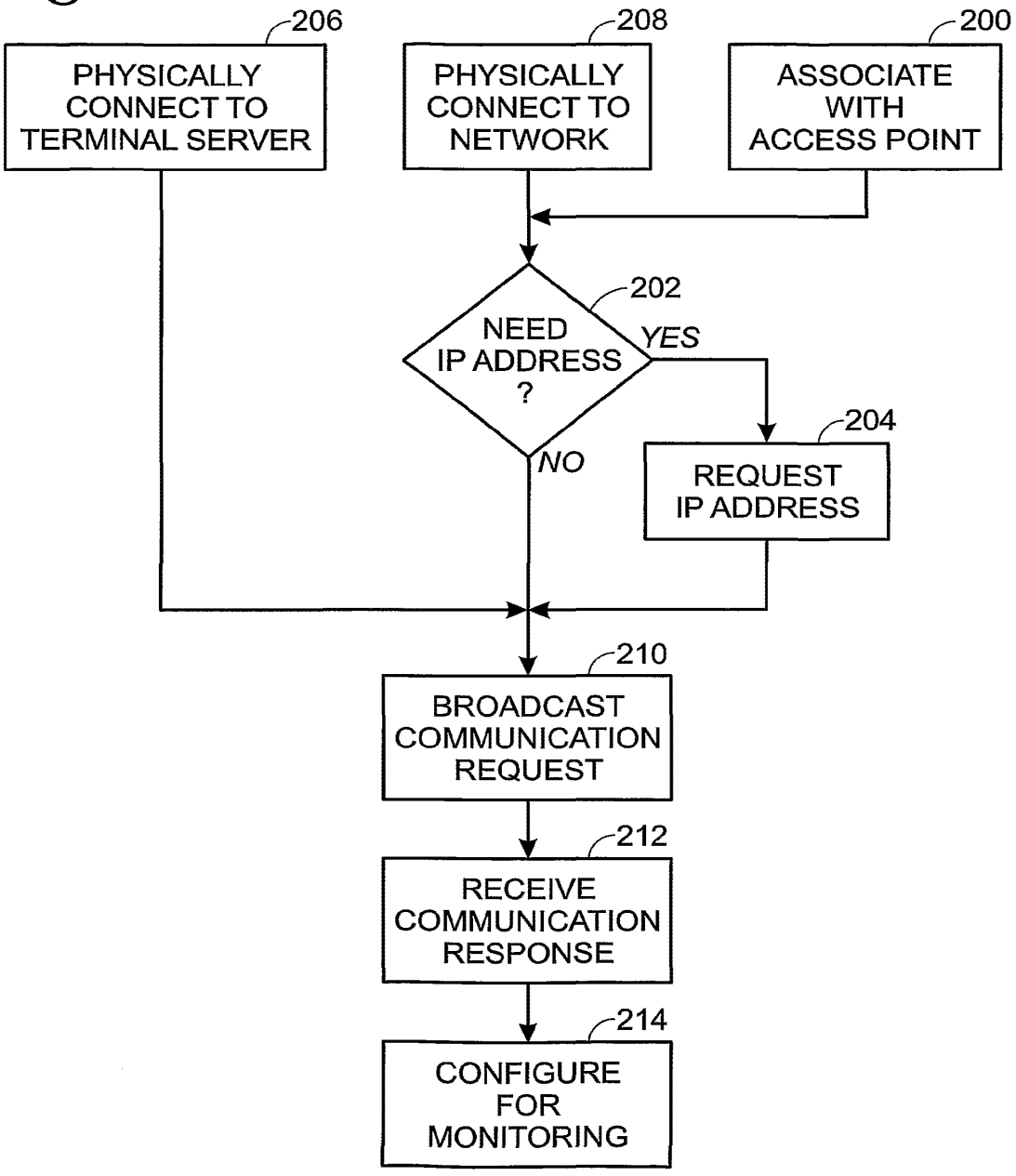

206
PHYSICALLY CONNECT TO TERMINAL SERVER
208
PHYSICALLY CONNECT TO NETWORK
200
ASSOCIATE WITH ACCESS POINT
202
NEED IP ADDRESS ?
YES
NO
204
REQUEST IP ADDRESS
210
BROADCAST COMMUNICATION REQUEST
212
RECEIVE COMMUNICATION RESPONSE
214
CONFIGURE FOR MONITORING

Fig. 12

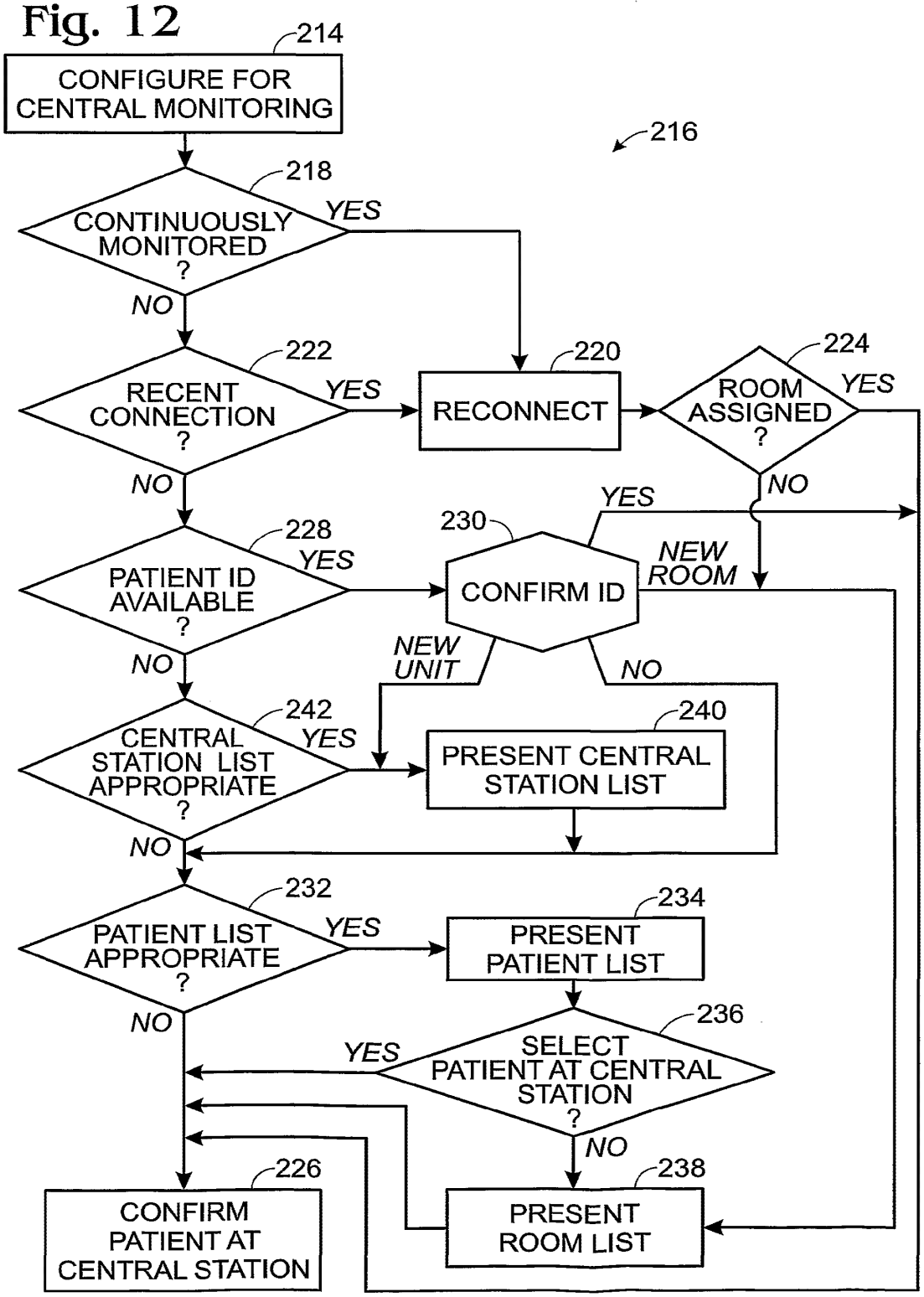

214
CONFIGURE FOR CENTRAL MONITORING
216
218
CONTINUOUSLY MONITORED ?
YES
NO
222
RECENT CONNECTION ?
YES
220
RECONNECT
224
ROOM ASSIGNED ?
YES
NO
YES
230
CONFIRM ID
NEW ROOM
228
PATIENT ID AVAILABLE ?
YES
NO
NEW UNIT
NO
242
CENTRAL STATION LIST APPROPRIATE ?
YES
240
PRESENT CENTRAL STATION LIST
NO
232
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

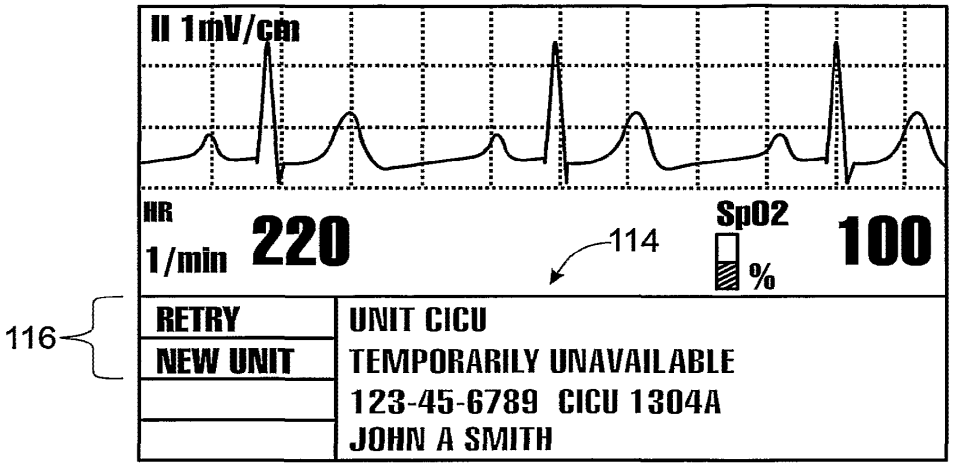

II 1mV/cm
HR
1/min
220
114
SpO2
%
100
116
RETRY
NEW UNIT
UNIT CICU
TEMPORARILY UNAVAILABLE
123-45-6789 CICU 1304A
JOHN A SMITH

Fig. 14

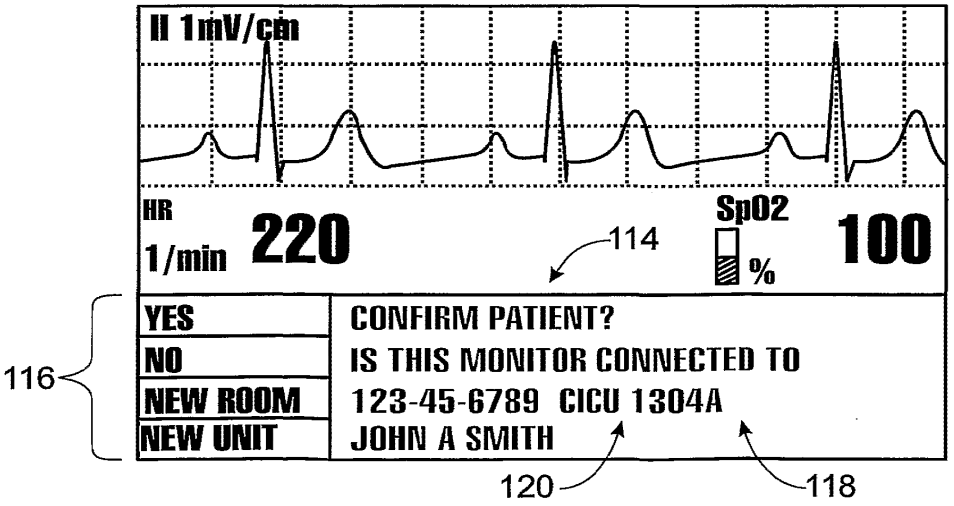

II 1mV/cm
HR
1/min
220
114
SpO2
%
100
116
YES
NO
NEW ROOM
NEW UNIT
CONFIRM PATIENT?
IS THIS MONITOR CONNECTED TO
123-45-6789 CICU 1304A
JOHN A SMITH
120
118

Fig. 15

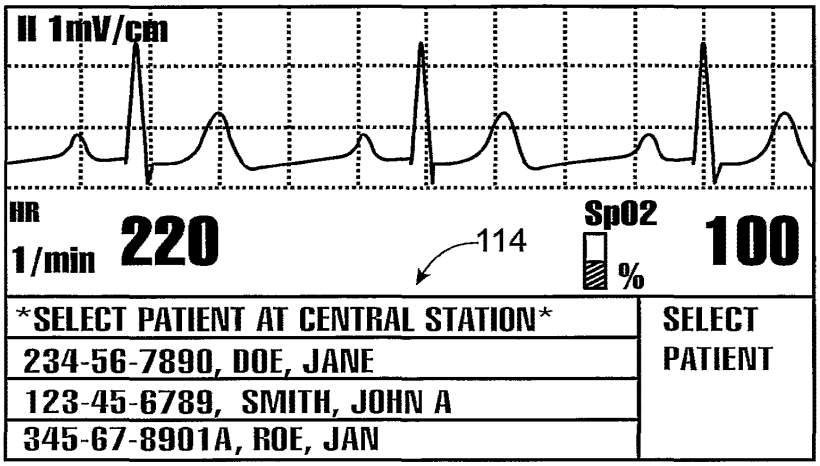

II 1mV/cm
HR
1/min 220
114
SpO2
%
100
SELECT PATIENT AT CENTRAL STATION
234-56-7890, DOE, JANE
123-45-6789, SMITH, JOHN A
345-67-8901A, ROE, JAN
SELECT
PATIENT

Fig. 16

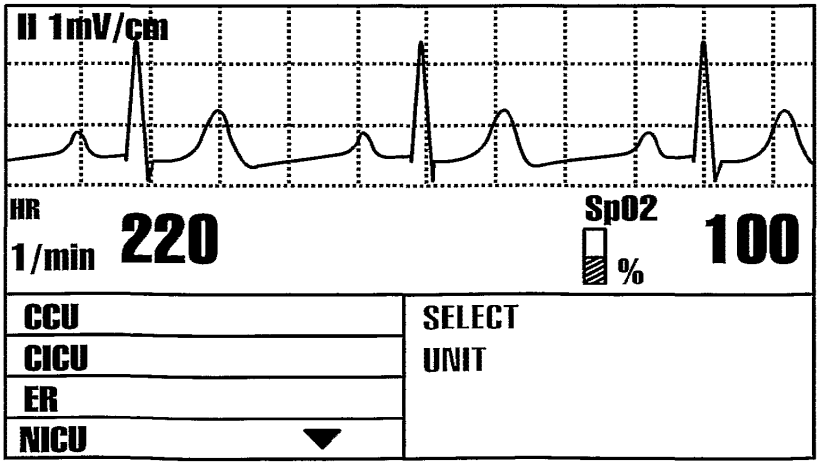

II 1mV/cm
HR
1/min 220
SpO2
%
100
CCU
CICU
ER
NICU
SELECT
UNIT

Fig. 17

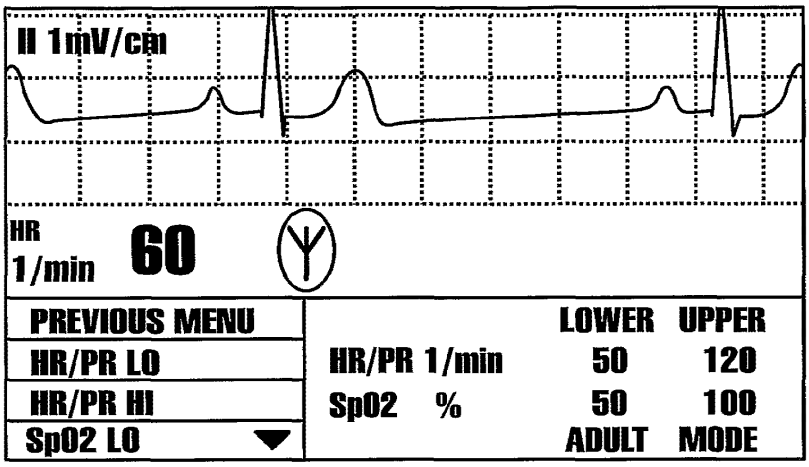

II 1mV/cm
HR
1/min
60
PREVIOUS MENU
HR/PR LO
HR/PR HI
SpO2 LO
LOWER
UPPER
HR/PR 1/min
50
120
SpO2 %
50
100
ADULT
MODE

Fig. 18

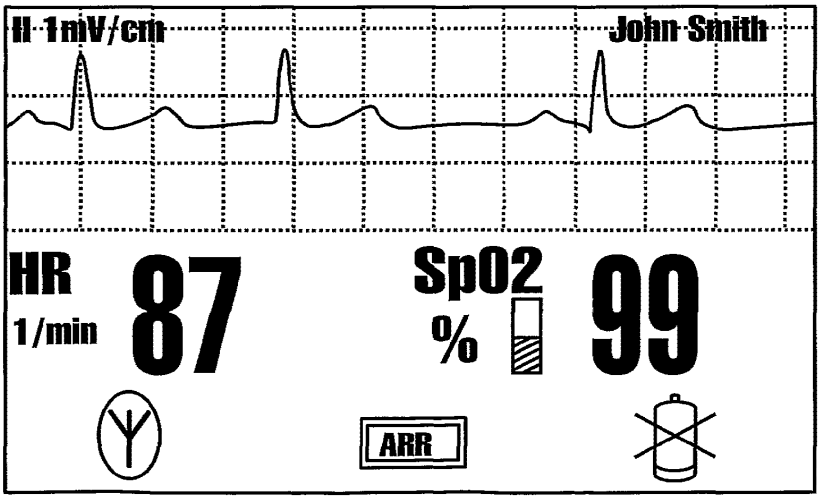

II 1mV/cm
John Smith
HR
1/min
87
SpO2
%
99
ARR

Fig. 19

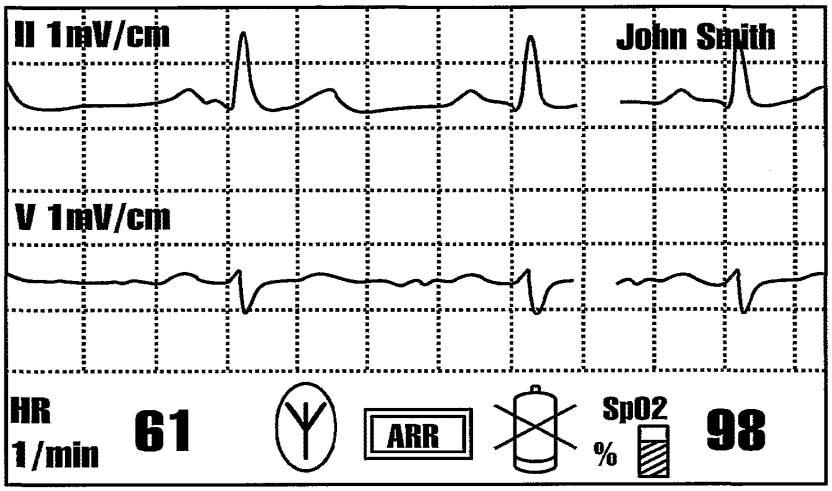

II 1mV/cm
John Smith
V 1mV/cm
HR
1/min
61
ARR
SpO2
%
98

Fig. 20

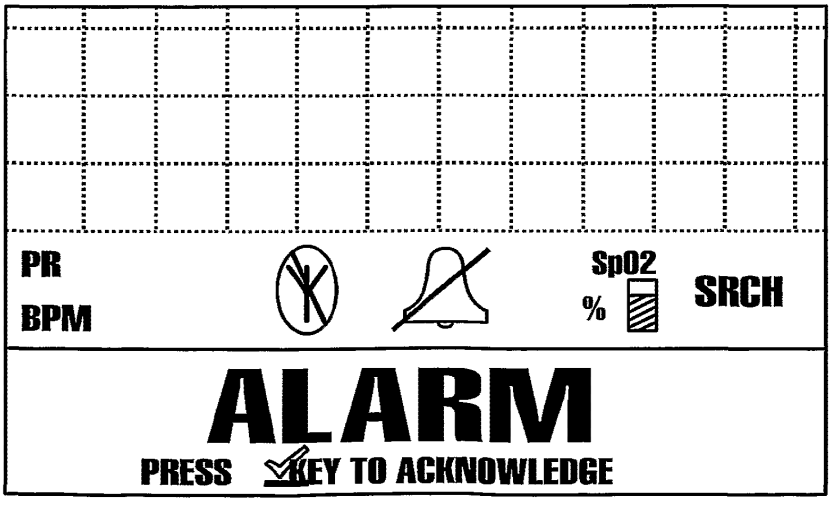

PR
BPM
SpO2
%
SRCH
ALARM
PRESS KEY TO ACKNOWLEDGE

Fig. 21

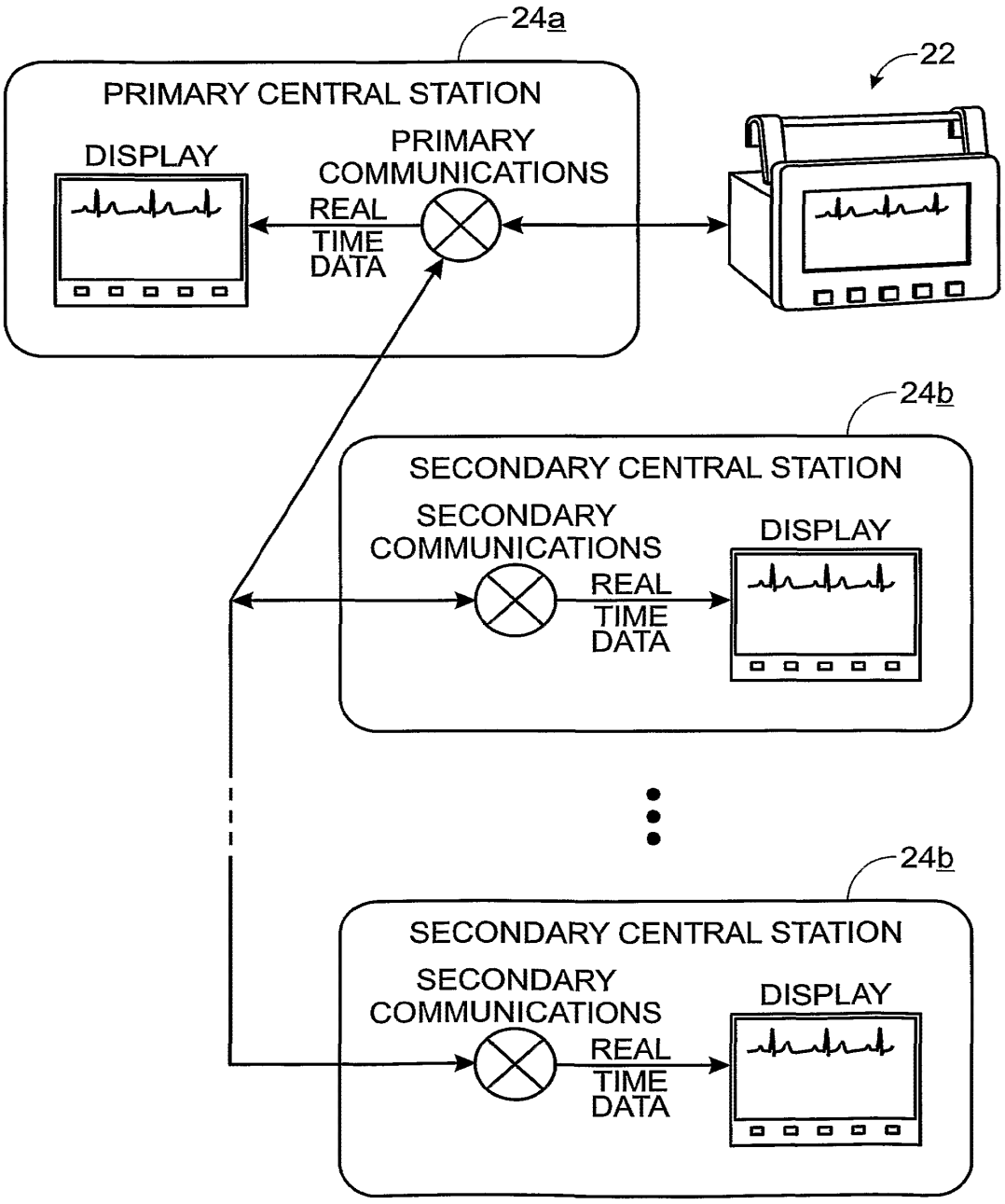

24a
22
PRIMARY CENTRAL STATION
DISPLAY
PRIMARY COMMUNICATIONS
REAL TIME DATA
24b
SECONDARY CENTRAL STATION
SECONDARY COMMUNICATIONS
DISPLAY
REAL TIME DATA
24b
SECONDARY CENTRAL STATION
SECONDARY COMMUNICATIONS
DISPLAY
REAL TIME DATA

Fig. 22

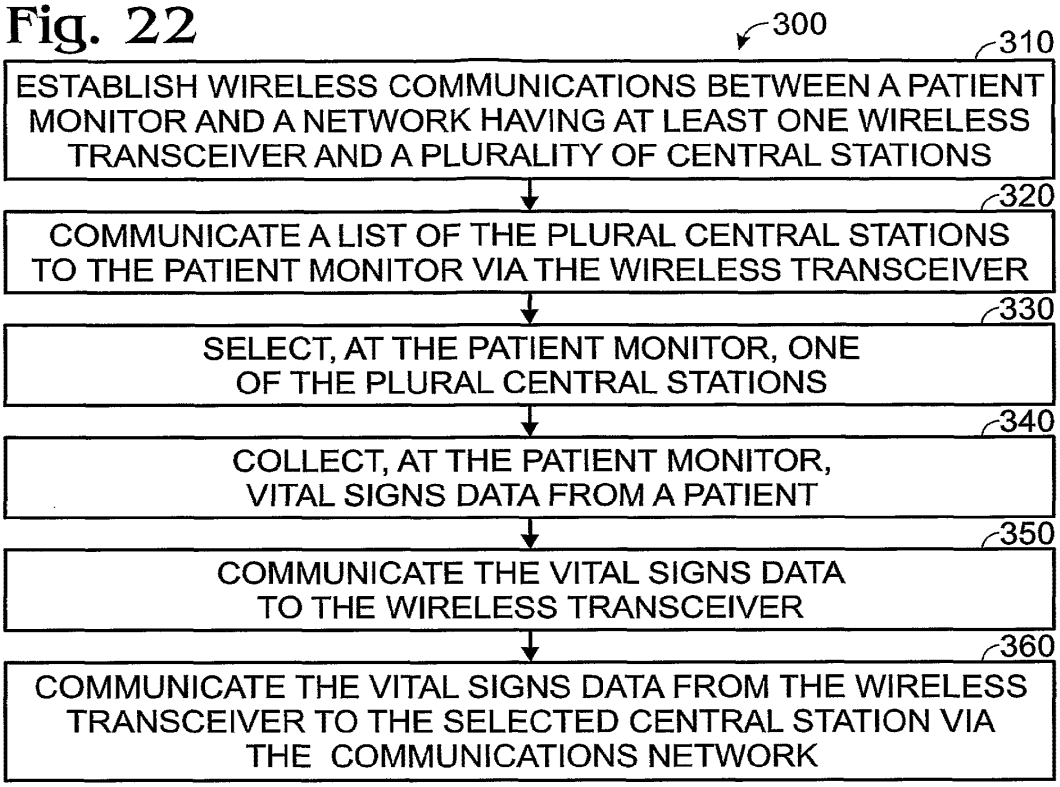

300
310
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A NETWORK HAVING AT LEAST ONE WIRELESS TRANSCEIVER AND A PLURALITY OF CENTRAL STATIONS
320
COMMUNICATE A LIST OF THE PLURAL CENTRAL STATIONS TO THE PATIENT MONITOR VIA THE WIRELESS TRANSCEIVER
330
SELECT, AT THE PATIENT MONITOR, 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

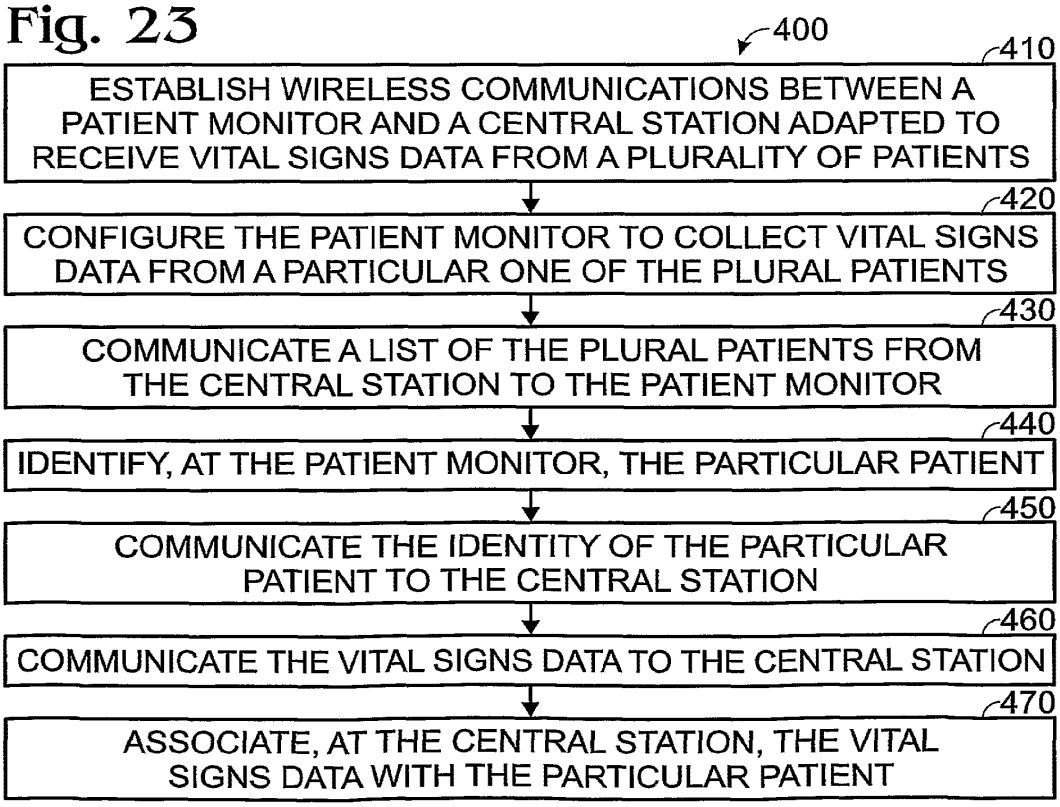

400
410
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A CENTRAL STATION ADAPTED TO RECEIVE VITAL SIGNS DATA FROM A PLURALITY OF PATIENTS
420
CONFIGURE THE PATIENT MONITOR TO COLLECT VITAL SIGNS DATA FROM A PARTICULAR ONE OF THE PLURAL PATIENTS
430
COMMUNICATE A LIST OF THE PLURAL PATIENTS 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

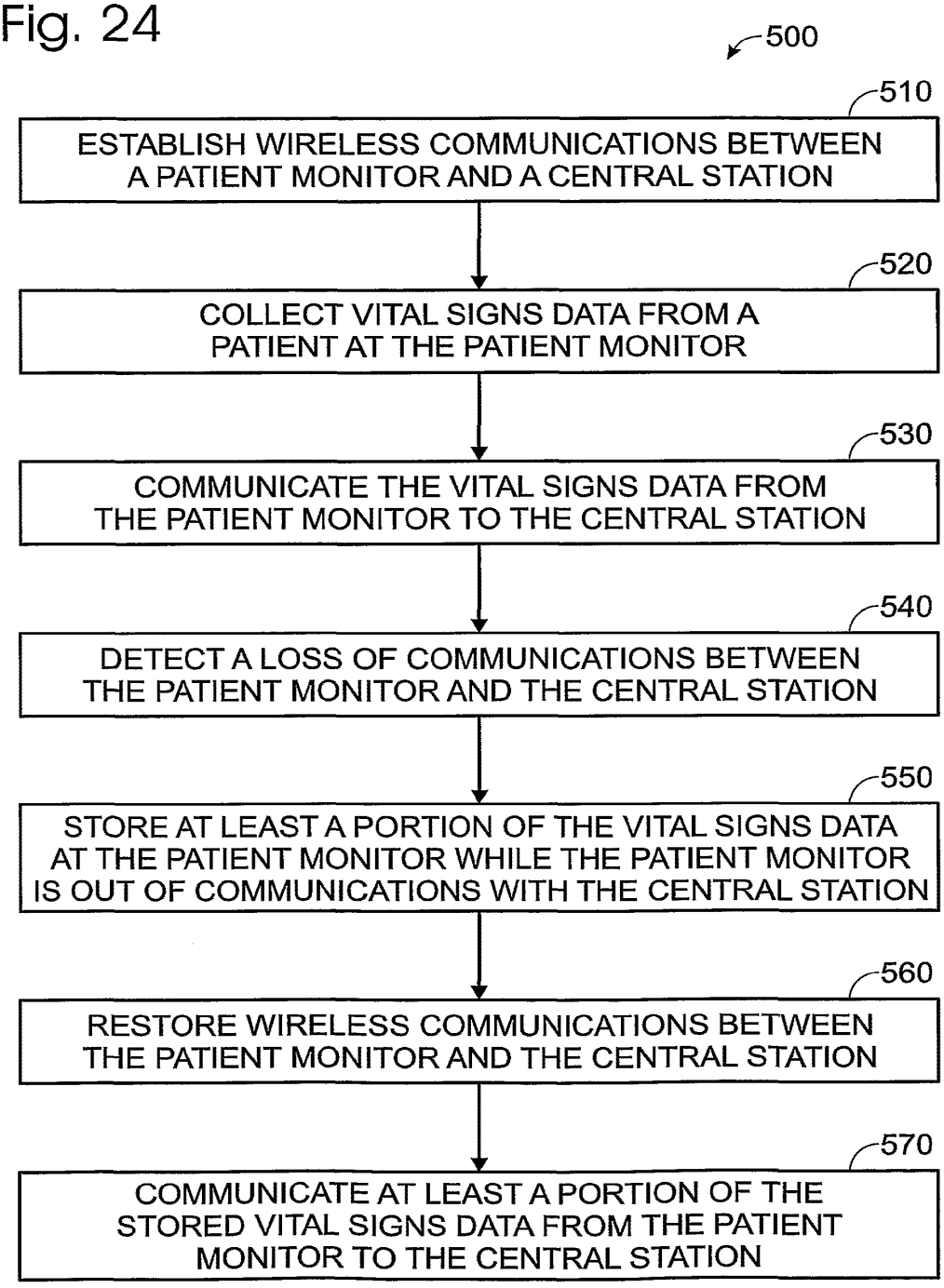

500
510
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A CENTRAL STATION
520
COLLECT VITAL SIGNS DATA FROM A PATIENT AT THE PATIENT MONITOR
530
COMMUNICATE THE VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE CENTRAL STATION
540
DETECT A LOSS OF COMMUNICATIONS BETWEEN THE PATIENT MONITOR 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

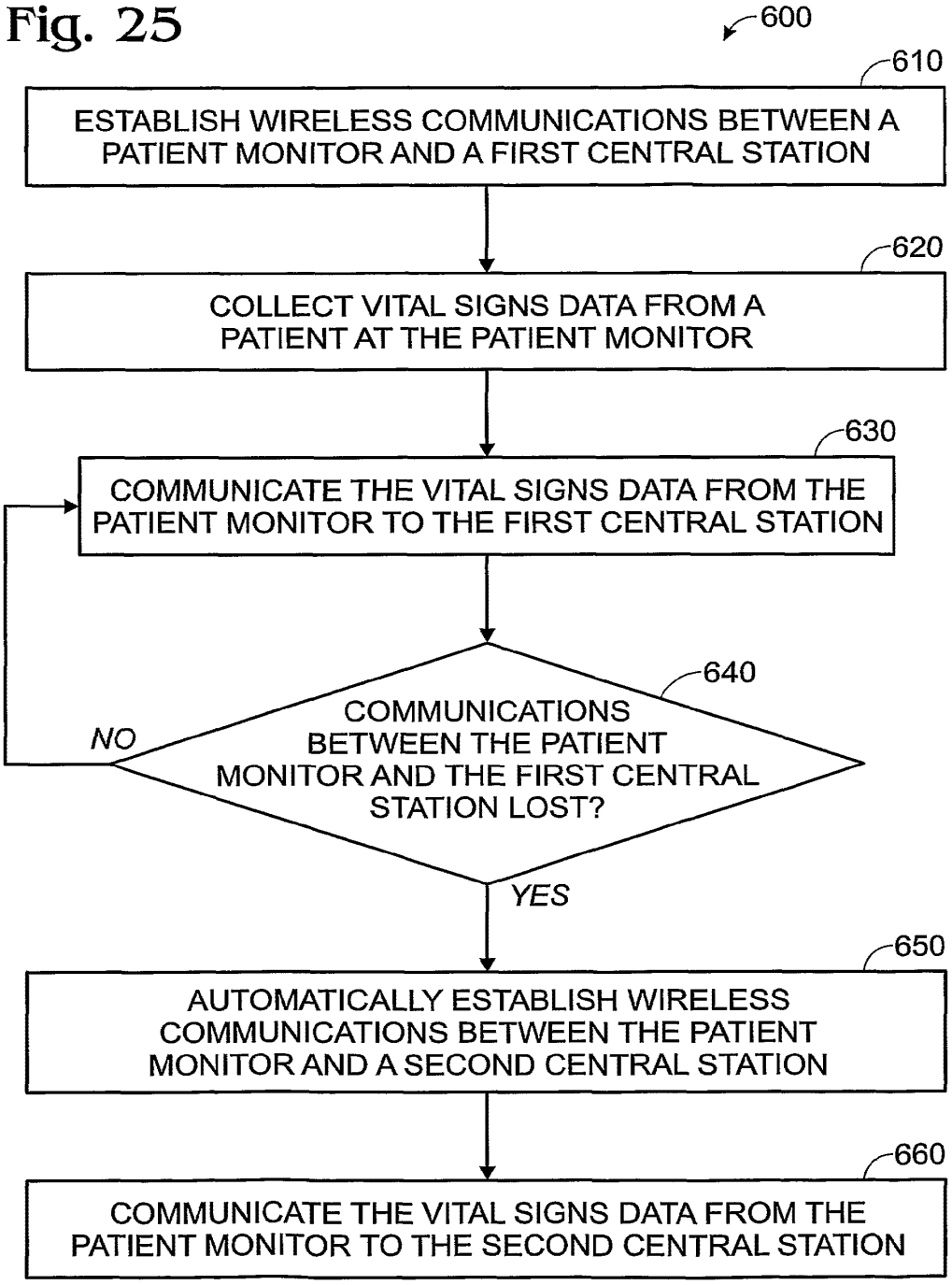
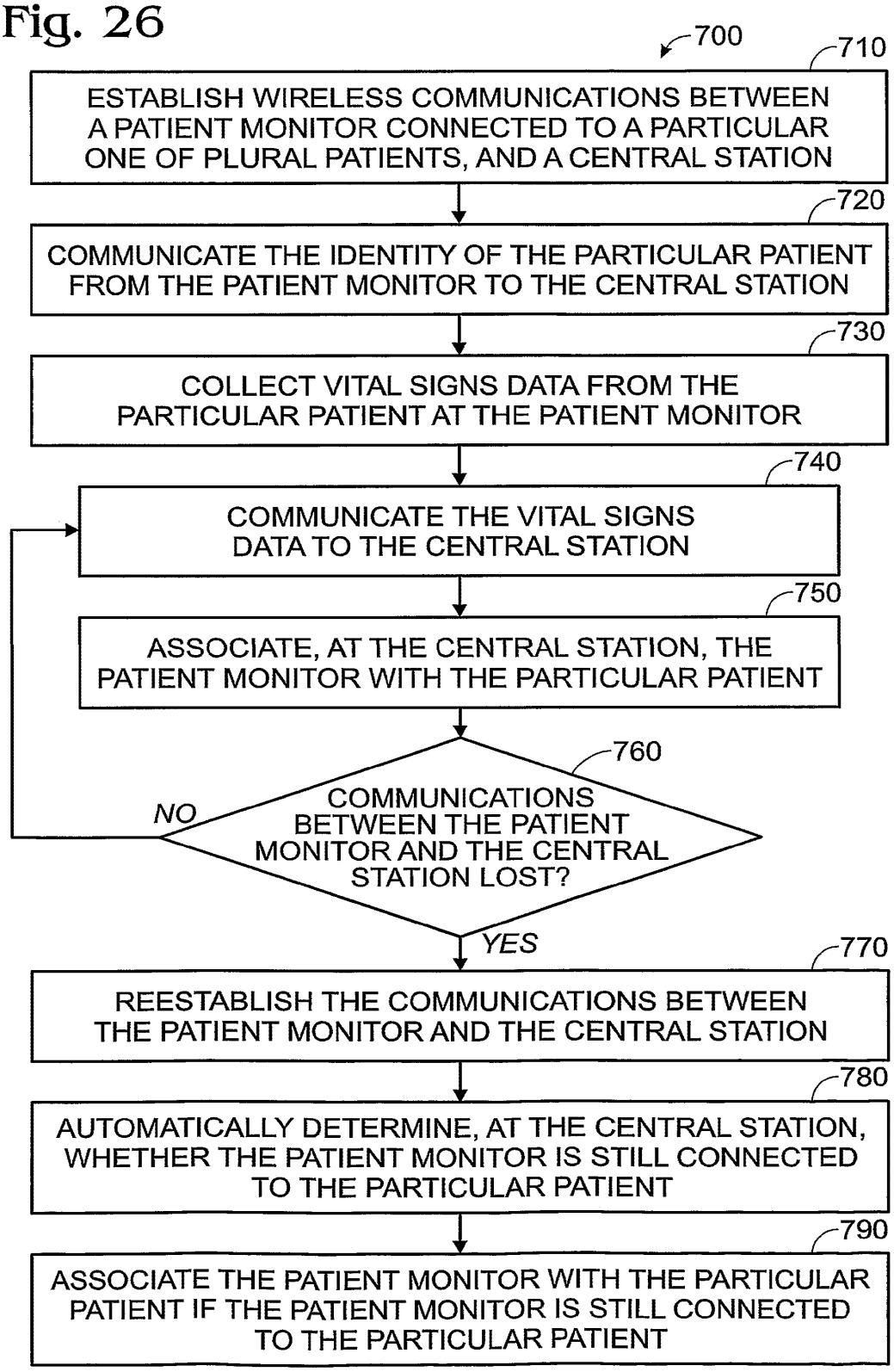

600
610
ESTABLISH WIRELESS COMMUNICATIONS BETWEEN A PATIENT MONITOR AND A FIRST CENTRAL STATION
620
COLLECT VITAL SIGNS DATA FROM A PATIENT AT THE PATIENT MONITOR
630
COMMUNICATE THE VITAL SIGNS DATA FROM THE PATIENT MONITOR TO THE FIRST CENTRAL STATION
640
COMMUNICATIONS BETWEEN THE PATIENT MONITOR 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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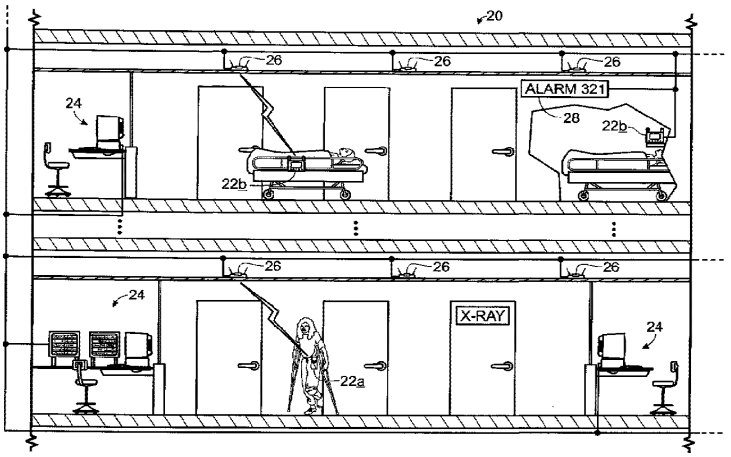
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

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Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

[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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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.

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International application No.
PCT/US01/16042

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/00
US CL : 600/300

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : Please See Continuation Sheet

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
West 2.1

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

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Date of the actual completion of the international search
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Date of mailing of the international search report
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Continuation of B. FIELDS SEARCHED Item 1:
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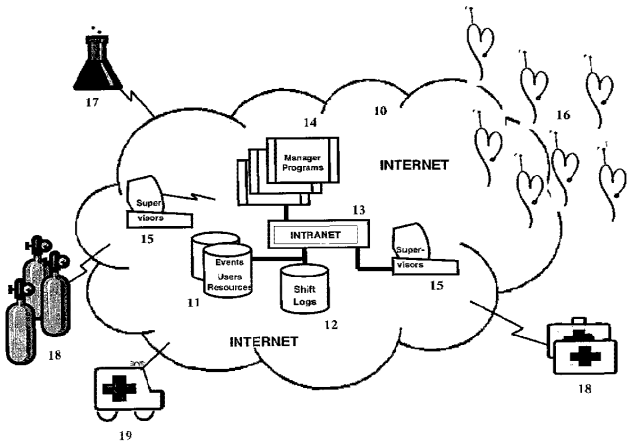
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(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

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.

(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 462

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

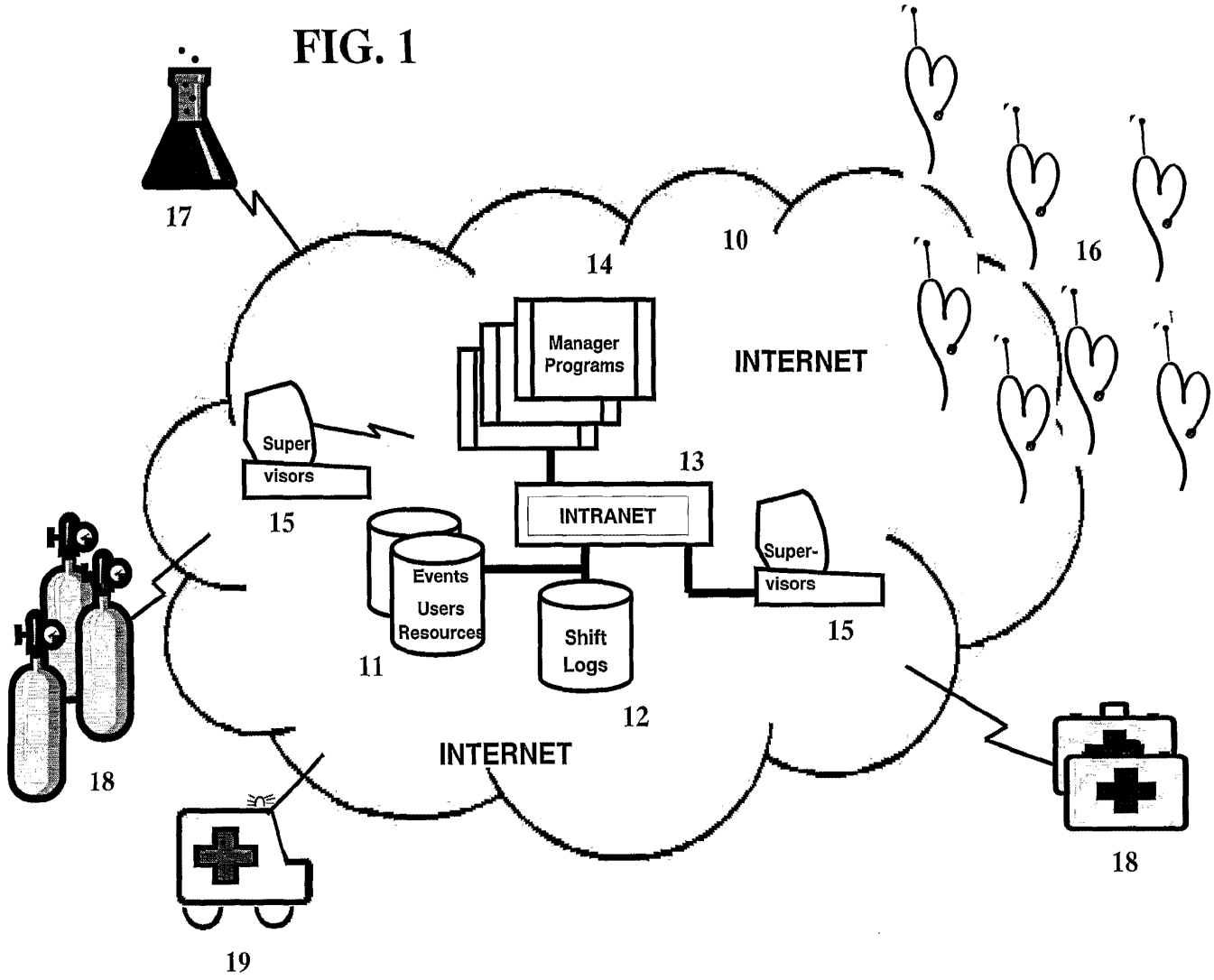

17
14
10
16
Manager Programs
INTERNET
Super visors
15
13
INTRANET
Events
Users
Resources
11
Shift Logs
12
Super- visors
15
INTERNET
18
18
19

FIG. 2

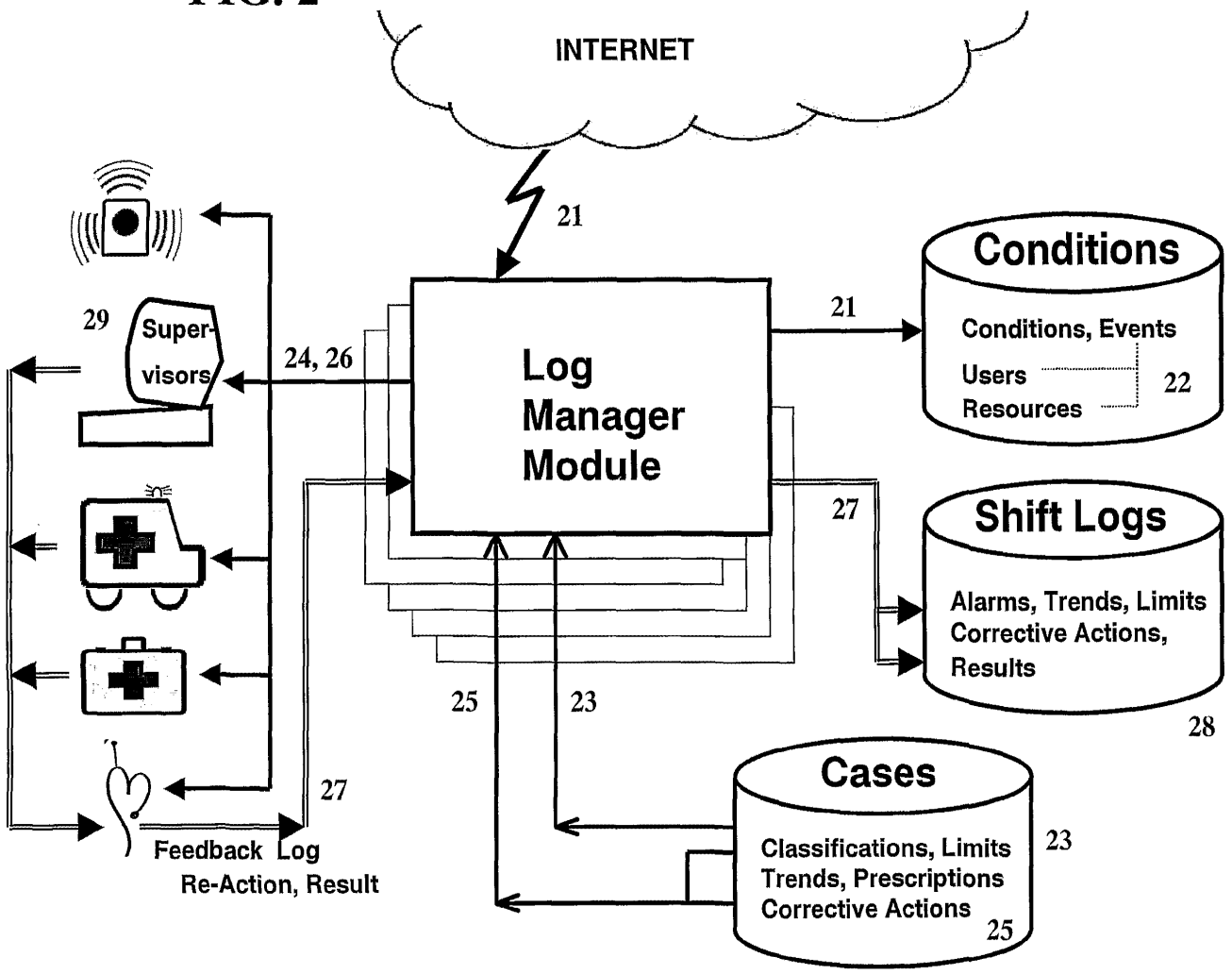

INTERNET
21
Conditions
Conditions, Events
Users
Resources
22
21
29
Super-
visors
24, 26
Log
Manager
Module
27
Shift Logs
Alarms, Trends, Limits
Corrective Actions,
Results
28
25
23
Cases
Classifications, Limits
Trends, Prescriptions
Corrective Actions
25
23
27
Feedback Log
Re-Action, Result

FIG. 3

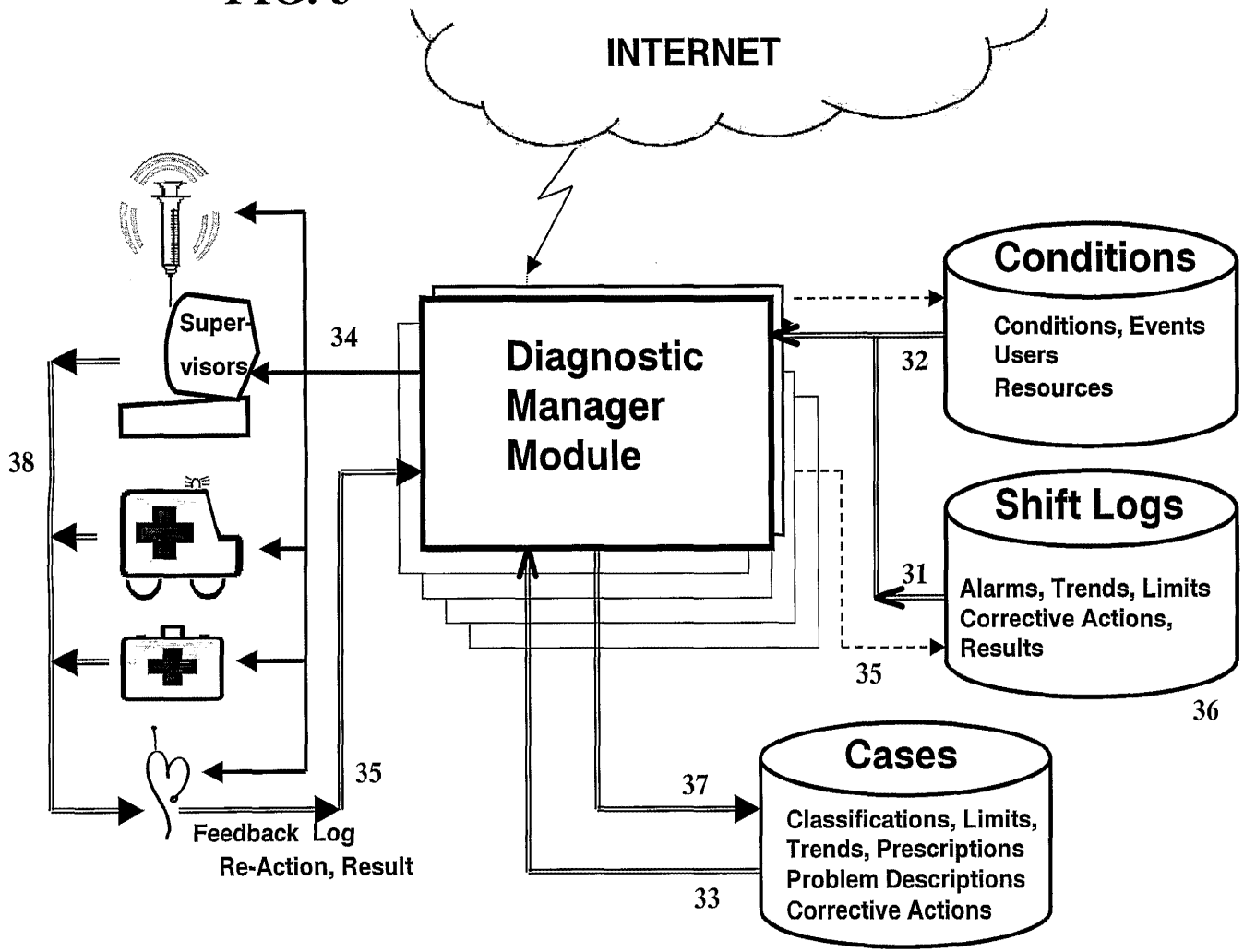
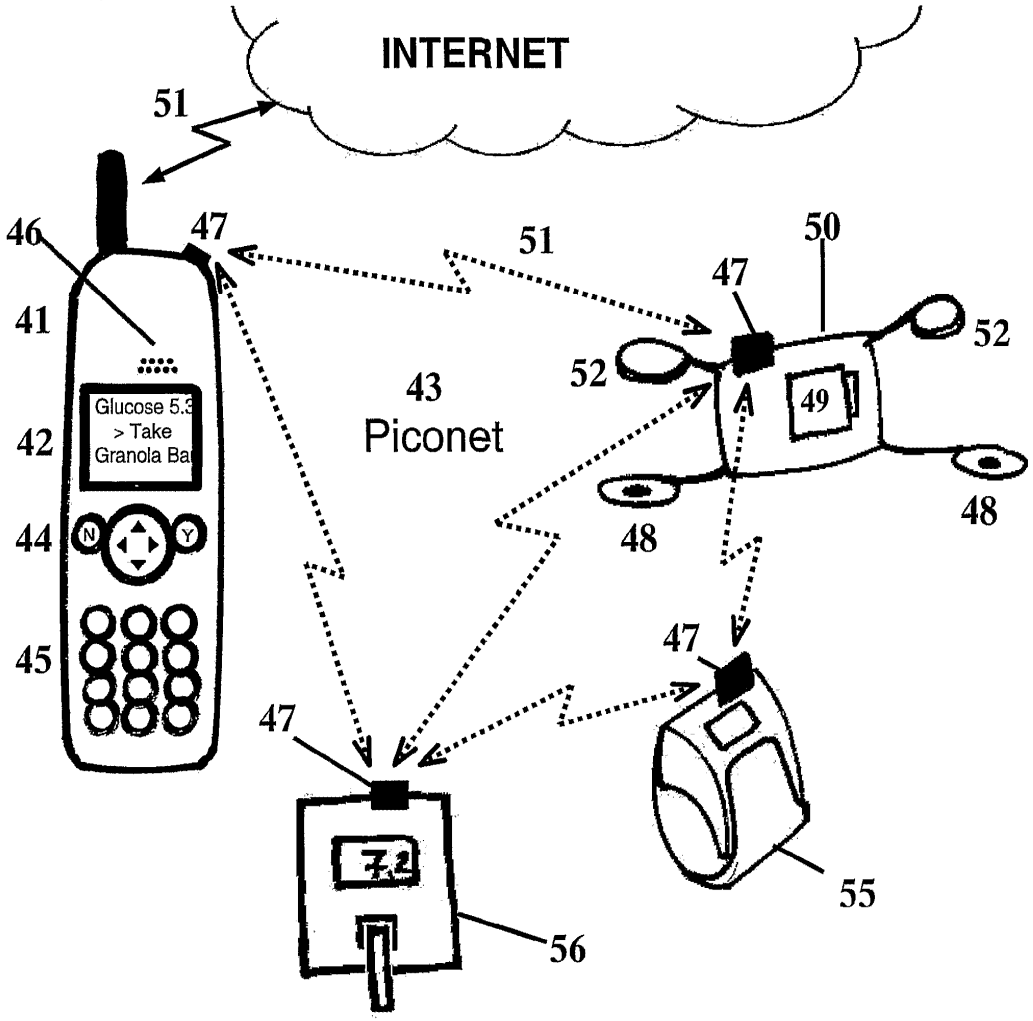

INTERNET
Super-
visors
34
38
Diagnostic
Manager
Module
Conditions
Conditions, Events
Users
Resources
32
Shift Logs
Alarms, Trends, Limits
Corrective Actions,
Results
31
35
36
Cases
Classifications, Limits,
Trends, Prescriptions
Problem Descriptions
Corrective Actions
37
33
35
Feedback Log
Re-Action, Result

FIG. 4


INTERNET
51
46
47
41
42
44
45
Glucose 5.3
> Take
Granola Ba
51
50
47
52
52
43
Piconet
49
48
48
47
47
7.2
56
55

INTERNATIONAL SEARCH REPORT

Inte nal Application No
PCT/IB 01/01110

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B. FIELDS SEARCHED

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

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

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"O" document referring to an oral disclosure, use, exhibition or other means

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5544661 A	13-08-1996	NONE	
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		WO 0028459 A2	18-05-2000

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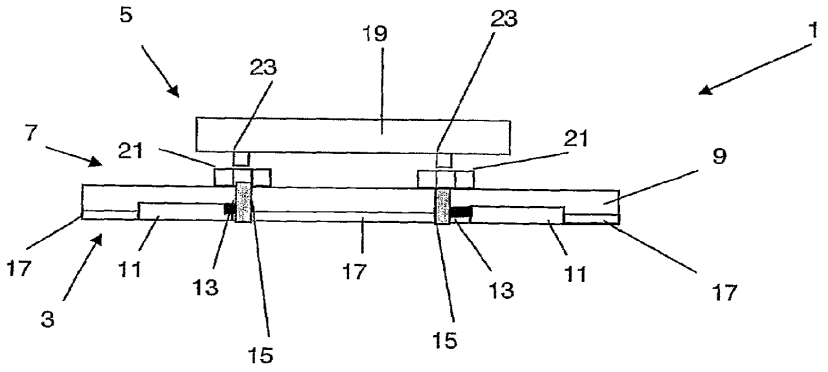


Fig. 1

(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.

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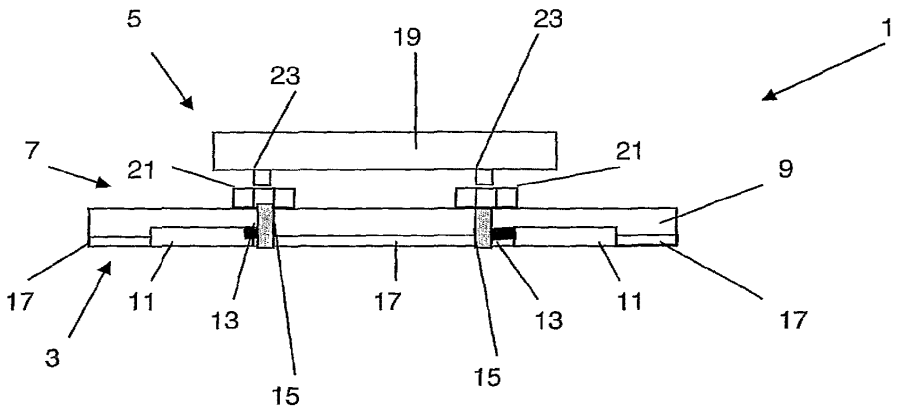


Fig. 1

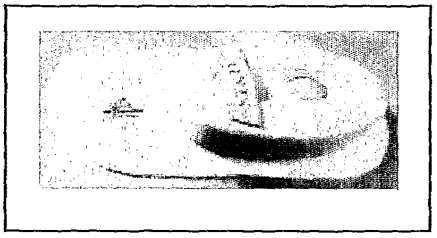


Fig. 2

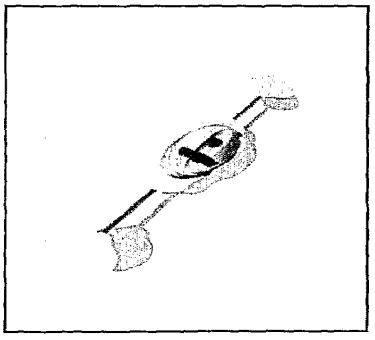


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/001492

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/0408 A61B5/0416

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

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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
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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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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.

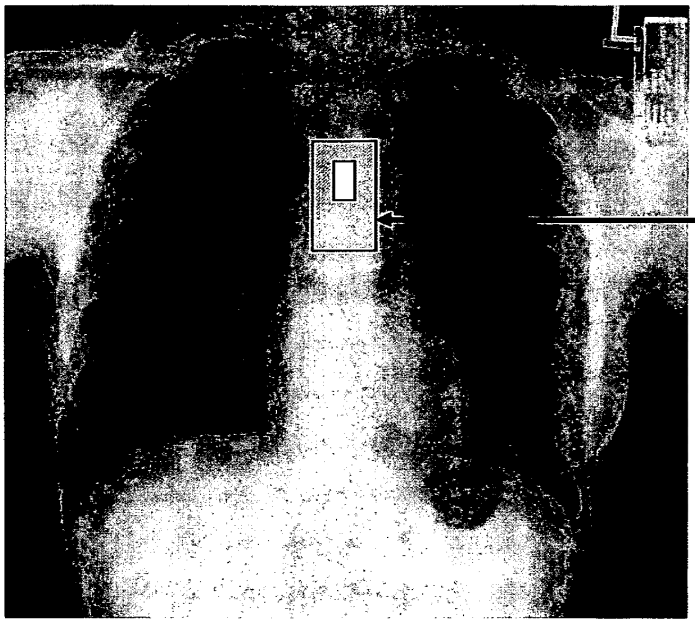


Fig 1

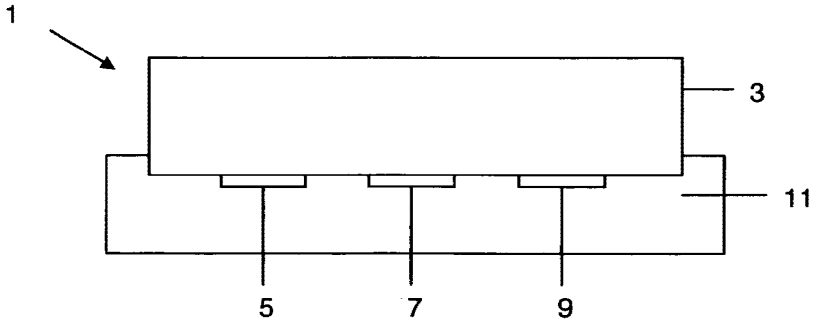


Fig 2

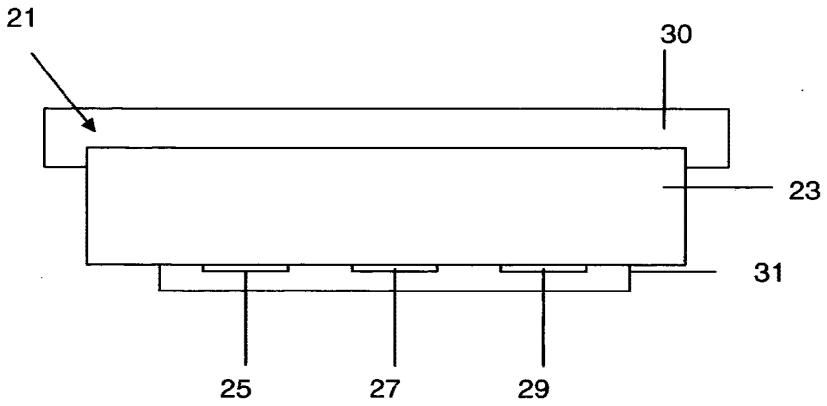


Fig 3

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

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Page 528

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 529

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2008/003708

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PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

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Applicant's or agent's file reference 3022036 WO01	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 07/83156	International filing date *(day/month/year)* 31 October 2007 (31.10.2007)	(Earliest) Priority Date *(day/month/year)* 01 November 2006 (01.11.2006)
Applicant WELCH ALLYN, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No. 1A

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

HISCOCK & BARCLAY, LLP
FILE NO. 3022036 WO01
DUE DATE AC= 7/15/08 C2-9/1/08
FINAL 30 MO DL BY: SYR CA
5/1/09

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 531

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 07/83156

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Group 1: Claims 1-44 are directed to the special technical feature of a disposable module, a communication-computation module, and specific structural connectors to structurally and operatively connect the disposable module to the communication-computational module.
Group 2: Claims 45-48 are directed to the special technical feature of a method of providing high voltage circuit protection including the steps of determining the print patterns and thicknesses of a first material with a first resistivity and second material with a second resistivity, the first and second materials to be printed on a substrate.
Group 3: Claims 49-53 are directed to the special technical feature of a current-limiting defibrillation protection resistor screened onto a substrate.
Group 4: Claims 54-55 are directed to the special technical feature of ECG montior having a pacer detect circuit to detect the presence or absence of a pacemaker, where upon detection of a pacemaker signal in a patient the pacer detect circuit is disabled to reduce electrical load.

--- Continued on extra sheets at back of form --

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
1-44, 49-55, and 58

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

iRhythm, Inc. / Welch Allyn, Inc.
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Page 532

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 07/83156

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/04 (2008.01)
USPC - 600/509
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(8): A61B 5/04 (2008.01)
USPC: 600/509

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
IPC(8): A61B 5/04 (2008.01)
USPC: 600/509; 600/301, 481, 508

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
USPTO WEST (USPT, PGPUB, EPAB, JPAB); body, wear, worn, monitor$, dispos$, electric$, connect$, skin, power, source, processor, microprocessor, signal, remote, receiver, affix$, attach$, disposable, ECG, electrode, series, resistor, screen$, substrate, 'electrodes', defibrillat$, fillet$, carbon, layer, conduc
Google Scholar

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 2004/0242976 A1 (ABREU) 02 December 2004 (02.12.2004), [Abstract], [0016], [0075], [0095], [0119], [0341], [0393], [0398], [0481], [0482], [0488], [0502], Fig. 77A	1-3, 15-18 ----- 4-14, 19-44
X --- Y	US 2003/0055460 A1 (OWEN, et al.) 20 March 2003 (20.03.2003), [Abstract], para[0017], [0077]-[0079], [0082], [0089], [0090], [0094], [0115], [0126], [0139], [0175], [0176], claims 12, 31, 34	49, 50, 52, 53 ----- 4-14, 20-24, 30-32, 41-44, 51, 54, 55, 58
Y	US 5,309,918 A (SCHRAAG) 10 May 1994 (10.05.1994), [Abstract], col 4, ln 15-22; col 7, ln 63-65	19-24
Y	US 2006/0136001 A1 (ORTEGA, et al.) 22 June 2006 (22.06.2006), para[0098], [0105]	23, 25-29, 37, 54, 55
Y	US 2006/0183434 A1 (WESTRA, et al.) 17 August 2006 (17.08.2006), [Abstract], para[0014]	33-37
Y	US 2003/0001742 A1 (ESHELMAN, et al.) 02 January 2003 (02.01.2003), para[0029]	38
Y	US 2006/0044856 A1 (BIRD, et al.) 02 March 2006 (02.03.2006), para[0038]	39
Y	US 5,294,928 A (COOPER, et al.) 15 March 1994 (15.03.1994), [Abstract]	40, 54, 55, 58
Y	US 2006/0205171 A1 (TSUKADA) 14 September 2006 (14.09.2006), para[0051]	8, 51
Y	US 2002/0122519 A1 (DOUGLAS, et al.) 05 September 2002 (05.09.2002), para[0030])	35, 42
Y	US 2004/0113806 A1 (NEYKOV) 17 June 2004 (17.06.2004), para[0009]	43

☒ Further documents are listed in the continuation of Box C. ☐

* 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 application or patent 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 April 2008 (17.04.2008)	15 MAY 2008

Name and mailing address of the ISA/US	Authorized officer:
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

HISCOCK & BARCLAY, LLP
FILE NO. 3042036 W001
DUE DATE AC- 7/15/08 C2-9/1/08
FINAL 30 MO D/L BY: SYR
5/1/09

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 07/83156

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0189976 A1 (KARNI, et al.) 24 August 2006 (24.08.2006), para[0002]	21
Y	US 4,141,367 A (FERREIRA) 27 February 1979 (27.02.1979), col 8, ln 15-29	37
Y	US 4,800,894 A (MILANI) 31 January 1989 (31.01.1989), col 1, ln 40-43	42

Form PCT/ISA/210 (continuation of second sheet) (April 2007)

-- Continued from Box III. --

Group 5: Claims 56-57 are directed to the special technical feature of method of high pass filtering including filtering measured heartbeat signals with an analog high pass filter having an analog high pass cutoff frequency, removing the effects of the analog high pass filter with a digital inverse filter algorithm resulting in substantially unfiltered heartbeat signals, and filtering the substantially unfiltered heartbeat signals digitally using a digital filter having a high pass filter cutoff frequency lower than said analog cutoff frequency.
Group 6: Claim 58 are directed to the special technical feature of an algorithm that causes an ECG monitor to enter a low power mode that disables at least one circuit from the end of a "T wave" at the end of one heartbeat to the beginning of a "P wave" of the next heartbeat.

None of these technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, accordingly, unity of invention is lacking under PCT Rule 13.1.
Where two or more of the Groups share one or more substantial technical features, you must show those technical features to be known (i.e. not ?special?) in order to distinguish them. In some cases, this may require prior art to show that the common technical feature(s) was/were known and therefore not ?special.?

iRhythm, Inc. / Welch Allyn, Inc.
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Page 536

PATENT COOPERATION TREATY

RECEIVED
MAY 19 2008

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
JOSEPH M. GELLER
HISCOCK & BARCLAY, LLP
ONE PARK PLACE
300 SOUTH STATE STREET
SYRACUSE, NY 13202-2078

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	15 MAY 2008
Applicant's or agent's file reference 3022036 WO01	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 07/83156	31 October 2007 (31.10.2007)	01 November 2006 (01.11.2006)

International Patent Classification (IPC) or both national classification and IPC
IPC(8) - A61B 5/04 (2008.01)
USPC - 600/509

Applicant WELCH ALLYN, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US	Date of completion of this opinion	Authorized officer:
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	17 April 2008 (17.04.2008)	Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/237 (cover sheet) (April 2007)

HISCOCK & BARCLAY, LLP
FILE NO. 3022036 WO01
DUE DATE AC-7/15/08 C2-9/1/08
FINAL 30 MOD/L BY: SYR CL
5/1/09

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/83156

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed.

   ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

iRhythm, Inc. / Welch Allyn, Inc.
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/83156

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the appicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

Group 1: Claims 1-44 are directed to the special technical feature of a disposable module, a communication-computation module, and specific structural connectors to structurally and operatively connect the disposable module to the communication-computational module.
Group 2: Claims 45-48 are directed to the special technical feature of a method of providing high voltage circuit protection including the steps of determining the print patterns and thicknesses of a first material with a first resistivity and second material with a second resistivity, the first and second materials to be printed on a substrate.
Group 3: Claims 49-53 are directed to the special technical feature of a current-limiting defibrillation protection resistor screened onto a substrate.
Group 4: Claims 54-55 are directed to the special technical feature of ECG montior having a pacer detect circuit to detect the presence or absence of a pacemaker, where upon detection of a pacemaker signal in a patient the pacer detect circuit is disabled to reduce electrical load.
Group 5: Claims 56-57 are directed to the special technical feature of method of high pass filtering including filtering measured heartbeat signals with an analog high pass filter having an analog high pass cutoff frequency, removing the effects of the analog high pass filter with a digital inverse filter algorithm resulting in substantially unfiltered heartbeat signals, and filtering the substantially unfiltered heartbeat signals digitally using a digital filter having a high pass filter cutoff frequency lower than said analog cutoff frequency.
Group 6: Claim 58 are directed to the special technical feature of an algorithm that causes an ECG monitor to enter a low power mode that disables at least one circuit from the end of a "T wave" at the end of one heartbeat to the beginning of a "P wave" of the next heartbeat.

None of these technical features are common to the other groups, nor do they correspond to a special technical feature in the other groups. Therefore, accordingly, unity of invention is lacking under PCT Rule 13.1.
Where two or more of the Groups share one or more substantial technical features, you must show those technical features to be known (i.e. not .special.) in order to distinguish them. In some cases, this may require prior art to show that the common technical feature(s) was/were known and therefore not .special..

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-44, 49-55, and 58

Form PCT/ISA/237 (Box No. IV) (April 2007)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/83156

Box No. V **Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	4-14, 19-44, 49-55, 58	YES
	Claims	1-3, 15-18	NO
Inventive step (IS)	Claims	NONE	YES
	Claims	1-44, 49-53, 54, 55, 58	NO
Industrial applicability (IA)	Claims	1-44, 49-53, 54, 55, 58	YES
	Claims	NONE	NO

2. Citations and explanations:

Claims 1-3 and 15-18 lack novelty under PCT Article 33(2) as being anticipated by US 2004/0242976 A1 (Abreu).

As per claim 1, Abreu discloses a body worn patient monitoring device ([Abstract]) comprising: at least one disposable module 1730 including a plurality of electrical connections 1590 (para[0502], Fig. 77A), the electrical connections 1590 couplable to a skin surface to measure physiological signals (para[0502]), the at least one disposable module 1730 including a disposable module connector 1590 (para[0502], Fig. 77A); at least one internal 1594 or external power source to power the body worn patient monitoring device (para[0502], Fig. 77A); and at least one communication-computation module 1596, having a communication-computation module connector 1590/1592 to receive physiological signals from the at least one disposable module 1730 via said disposable module connector 1590 (para[0502], Fig. 77A), the communication-computation module 1596 including at least one microprocessor 1592 to actively monitor the patient (para[0502], Fig. 77A) and perform real-time physiological analysis of the physiological signals (para[0488]) and a radio circuit 1592 ([Abstract], para[0502], Fig. 77A) 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 (para[0095]), via a radio transmission to a remote radio receiver ([Abstract]), wherein the at least one disposable module 1730 is mechanically 1598 and electrically coupled 1590/1592 directly to the at least one communication-computation module 1596 and the body worn patient monitoring device 1591 ([Abstract], para[0502], Fig. 77A) including the at least one disposable module 1730 and the at least one communication-computation module 1596 is directly non-permanently affixed to the skin surface of the patient (para[0502], Fig. 77A).

As per claim 2, Abreu discloses the device of claim 1 and further discloses wherein the plurality of electrical connections 1590 to the body (para[0502], Fig. 77A) comprise at least one of direct electrical connections to the body (para[0016]) and indirect electrical connections to the body (para[0075]).

As per claim 3, Abreu discloses the device of claim 2 and further discloses wherein the indirect electrical connections to the body (para[0075]) comprise capacitive connections to the body (para[0075]).

As per claim 15, Abreu discloses the device of claim 1 and further discloses wherein the at least one power source 1594 (para[0502], Fig. 77A) is a renewable power source internal to the body worn device (para[0341]).

As per claim 16, Abreu discloses the device of claim 1 and further discloses wherein the at least one power source 1594 (para[0502], Fig. 77A) comprises a rechargeable battery (para[0341]) or a one time use battery.

As per claim 17, Abreu discloses the device of claim 1 and further discloses wherein the at least one power source 1594 (para[0502], Fig. 77A) is a battery contained within (para[0341]) said disposable module 1730 (para[0502], Fig. 77A).

As per claim 18, Abreu discloses the device of claim 1 and further discloses wherein the at least one power source 1594 (para[0502], Fig. 77A) is a Seebeck device (para[0398]).

Claims 49, 50, 52 and 53 lack an inventive step under PCT Article 33(3) as being obvious over US 2003/0055460 A1 to Owen, et al. (hereinafter Owen).

As per claim 49, Owen suggests an ECG monitor (para[0094]) comprising: a plurality of electrical connections including at least one electrode ([Abstract]), the electrical connections being couplable to a skin surface ([Abstract]) to measure patient heartbeat signals (para[0017]); at least one internal or external power source ([Abstract]) to power the ECG monitor (para[0094]); at least one current-limiting defibrillation protection resistor (para[0139]), said at least one current-limiting defibrillation protection resistor comprising a resistor (para[0139]) that could be screened onto a substrate (para[0077], [0078]); and an ECG electronics module (para[0017]), to receive and process patient heartbeat signals from said plurality of electrical connections (para[0017]), wherein said at least one current-limiting defibrillation protection resistor (para[0139]) could be electrically disposed between the at least one of said plurality of electrical connections ([Abstract]) and said ECG electronics module (para[0017]). It would have been obvious to a person of ordinary skill in the art to derive claim 49 provided Owen as a reference since Owen discloses that a conductor could be screened on a flexible substrate (para[0077], [0078]) and the resistors disclosed by Owen (para[0139]) could replace the conductors and instead be screened on a flexible substrate (para[0077], [0078]). Also, the current-limiting resistor disclosed by Owen (para[0139]) could be readily integrated into various circuit configurations by a person of ordinary skill in the art.

-***-Continued on Supplemental Page-***-

iRhythm, Inc. / Welch Allyn, Inc.
Exhibit 1002
Page 540

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box No. V:
-Continued from Citations and Explanations:

As per claim 50, Owen further suggests wherein said at least one current-limiting defibrillation protection resistor could comprise a resistor (para[0139]) screened onto a flexible substrate (para[0077], [0078]). It would have been obvious to a person of ordinary skill in the art to derive claim 50 provided Owen as a reference since Owen discloses that a conductor could be screened on a flexible substrate (para[0077], [0078]) and the resistors disclosed by Owen (para[0139]) could replace the conductors and instead be screened on a flexible substrate (para[0077], [0078]).

As per claim 52, Owen further suggests wherein the mechanical interface from the at least one series current-limiting resistor (para[0139]) to the one ECG electrode (para[0094]) could comprise a plurality of overlapped layers (para[0077], [0078]). It would have been obvious to a person of ordinary skill in the art to derive claim 52 provided Owen as a reference since the overlapped layers (para[0077], [0078]) disclosed by Owen could be readily incorporated into the mechanical interface from the resistor to the ECG electrode.

As per claim 53, Owen further suggests wherein said plurality of overlapped layers (para[0077], [0078]) could comprise a carbon resistive layer (para[0078], [0082]) that could be screened over (para[0077], [0078]) a conductive surface (para[0078], [0082]), the carbon resistive layer (para[0078], [0082]) having substantially the same shape as said conductive surface (para[0078], [0082]). It would have been obvious to a person of ordinary skill in the art to derive claim 53 provided Owen as a referece since the overlapped layers (para[0077], [0078]) disclosed by Owen could be readily incorporated into the mechanical interface from the resistor to the ECG electrode and a conductor could be screened on a flexible substrate (para[0077], [0078]) and the resistors disclosed by Owen (para[0139]) could replace the conductors and instead be screened on a flexible substrate (para[0077], [0078]).

Claims 4-7, 9-14, 30-32, 41 and 44 lack an inventive step under PCT Article 33(3) as being obvious over Abreu in view of Owen.

As per claim 4, Abreu discloses the device of claim 1 and Owen further discloses wherein the body worn patient monitoring device comprises an ECG monitor (para[0094]) and at least two of the electrical connections are ECG electrodes (para[0094]). It would have been obvious to a person of ordinary skill in the art to derive claim 4 provided Abreu and Owen as references since a body worn device incorporating and ECG monitor is able to determine whether the heart of a patient is functioning within normal ranges as compared to a body worn device without an ECG monitor.

As per claim 5, Abreu and Owen, in combination, disclose the device of claim 4 and Owen further discloses wherein the ECG electrodes (para[0094]) comprise a material screened onto a flexible substrate (para[0077], [0078]).

As per claim 6, Abreu and Owen, in combination, disclose the device of claim 5 and Owen suggests further comprising at least one series current-limiting resistor (para[0139]) to protect the communication-computation module during a patient defibrillation event (para[0139]).

As per claim 7, Abreu and Owen, in combination, disclose the device of claim 6 and Owen further suggests wherein the at least one series current-limiting resistor (para[0139]) could comprise a resistor (para[0139]) that could be screened on the flexible substrate (para[0077], [0078]). It would have been obvious to a person of ordinary skill in the art to derive claim 7 provided Abreu and Owen as references since Owen discloses that a conductor could be screened on a flexible substrate (para[0077], [0078]) and the resistors disclosed by Owen (para[0139]) could replace the conductors and instead be screened on a flexible substrate (para[0077], [0078]).

As per claim 9, Abreu and Owen, in combination, disclose the device of claim 7 and Owen further suggests wherein the mechanical interface from the at least one series current-limiting resistor (para[0139]) to the ECG electrode (para[0094]) could comprise overlapped layers (para[0077], [0078]). It would have been obvious to a person of ordinary skill in the art to derive claim 9 provided Abreu and Owen as references since the overlapped layers (para[0077], [0078]) disclosed by Owen could be readily incorporated into the mechanical interface from the resistor to the ECG electrode.

As per claim 10, Abreu and Owen, in combination, disclose the device of claim 9 and Owen further suggests wherein the overlapped layers (para[0077], [0078]) could comprise a carbon resistive layer (para[0078], [0082]) that could be screened over (para[0077], [0078]) a conductive surface (para[0078], [0082]), the carbon resistive layer (para[0078], [0082]) having the same shape as the conductive surface (para[0078], [0082]).

As per claim 11, Abreu and Owen, in combination, disclose the device of claim 6 and Owen suggests further comprising an insulating material that could overlay (para[0079]) the at least one series current-limiting resistor to prevent arcing (para[0139]). It would have been obvious to a person of ordinary skill in the art to derive claim 11 provided Abreu and Owen as references since an insulating material could be readily applied to a resistor positioned in series.

As per claim 12, Abreu and Owen, in combination, disclose the device of claim 5 and Owen further discloses wherein the ECG electrodes are formed substantially in the shape of an annulus (para[0090]).

As per claim 13, Abreu and Owen, in combination, disclose the device of claim 12 and Owen further suggests wherein the annulus (para[0090]) could comprise a conductive ink (para[0077], [0078]).

As per claim 14, Abreu and Owen, in combination, disclose the device of claim 5 and Owen further suggests wherein the substrate (para[0077], [0078]) is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors (para[0094]) while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal (para[0115]).

-***-Continued on Supplemental Page-***-

iRhythm, Inc. / Welch Allyn, Inc.
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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
Box No. V:
-Continued from Citations and Explanations:

As per claim 30, Abreu discloses the device of claim 1 and Owen further suggests wherein the body worn device could include circuit protection (para[0139]) that could allow the device to survive multiple defibrillation cycles of at least 360 joules (claim 31).

As per claim 31, Abreu and Owen, in combination, disclose the device of claim 30 and Owen further suggests wherein the circuit protection (para[0139]) could comprise a gas discharge tube or a plurality of diodes (claims 14, 34) to clamp or limit the signals from the electrical connections (para[0139], claims 14, 34).

As per claim 32, Abreu and Owen, in combination, disclose the device of claim 30 and Abreu further discloses wherein a plurality of circuitry components 1590/1592/1594 are distributed between the disposable module 1730 and the communication-computation module 1596 (para[0502], Fig. 77A). Abreu does not explicitly disclose the components of the circuit protection. Owen does suggest the components of the circuit protection (para[0139]).

As per claim 41, Abreu discloses the device of claim 1 and Owen further suggests 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 (para[0175], [0176]), that could be 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 (para[0175], [0176]). It would have been obvious to a person of ordinary skill in the art to derive claim 41 provided Abreu and Owen as references since Owen discloses that the low-power mode for the processor could be controlled to last for any particular duration (para[0175], [0176]), which could include the period of time 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.

As per claim 44, Abreu discloses the device of claim 1 and Owen further suggests wherein a plurality of diodes that could be disposed between circuitry (claims 14, 34) and an electronics common (ground) (claim 12) and that could protect one or more internal circuits of the circuitry (para[0139]) from a defibrillation pulse (para[0139], claim 31). Owen does not explicitly disclose the physiological sensors and the communication-computation module. Abreu does disclose the physiological sensors 1590 and the communication-computation module 1596 ([Abstract], para[0502], Fig. 77A).

Claim 19 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu in view of US 5,309,918 A (Schraag).

As per claim 19, Abreu discloses the device of claim 1 and Schraag further discloses wherein one of the electrical connections is a reference electrode that can be used to improve common mode rejection (CMR) ([Abstract]). It would have been obvious to a person of ordinary skill in the art to derive claim 19 provided Abreu and Schraag as references since reference electrodes can be engineered specifically to improve the common mode rejection (CMR) in ECG electrodes.

Claims 25-29 lack an inventive step under PCT Article 33(3) as being obvious over Abreu in view of US 2006/0136001 A1 to Ortega, et al. (hereinafter Ortega).

As per claim 25, Abreu discloses the device of claim 1 and further discloses the communication-computation module 1596 (para[0502], Fig. 77A). Abreu does not explicitly disclose a pacer detection circuit. Ortega does disclose a pacer detection circuit (para[0105]). It would have been obvious to a person of ordinary skill in the art to derive claim 25 provided Abreu and Ortega as references since a module applied externally to the skin of a patient that is capable of communicating with a pacemaker can provide more functions to a user as compared to attachable devices without pacemaker communication functions.

As per claim 26, Abreu and Ortega, in combination, disclose the device of claim 25 and Ortega further suggests wherein the pacer detection circuit could be capable of generating a microprocessor interrupt to inform the microprocessor that a pacer event occurred (para[0105]). Ortega does not explicitly disclose the microprocessor. Abreu does disclose the microprocessor 1592 (para[0502], Fig. 77A).

As per claim 27, Abreu and Ortega, in combination, disclose the device of claim 26 and Abreu further discloses wherein the microprocessor interrupt is used to mark a corresponding physiological signal in time (para[0481]). Abreu does not explicitly disclose related to a pacer event. Ortega does disclose related to a pacer event (para[0105]).

As per claim 28, Abreu and Ortega, in combination, disclose the device of claim 26 and Ortega further suggests wherein the device could automatically determine if a patient has a pacemaker and could only enable the pacer detect circuit when a pacemaker is present (para[0105]). It would have been obvious to a person of ordinary skill in the art to derive claim 28 provided Abreu and Ortega as references since Ortega discloses an external signaling device in communication with an implanted pacemaker (para[0105]) and such a device could be capable of performing the functions stated in claim 28.

As per claim 29, Abreu and Ortega, in combination, disclose the device of claim 26 and Abreu further suggests wherein the device is configured by an external input to enable or disable a function (para[0482], [0502]). Abreu does not explicitly disclose the pacer detect circuit. Ortega does disclose the pacer detect circuit (para[0105]).

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Claims 33, 34 and 36 lack an inventive step under PCT Article 33(3) as being obvious over Abreu in view of US 2006/0183434 A1 to Westra, et al. (hereinafter Westra).

As per claim 33, Abreu discloses the device of claim 1 and further comprising filtering (para[0393]) the physiological signals ([Abstract]). Abreu does not explicitly disclose a high pass filter with a selectable corner frequency. Westra does disclose a high pass filter with a selectable corner frequency (para[0014]). It would have been obvious to a person of ordinary skill in the art to derive claim 33 provided Abreu and Westra as references since a physiological signal measuring device with a high pass filter is able to effectively eliminate any unwanted low frequency signals from being processed as compared to a device without a filter.

As per claim 34, Abreu and Westra, in combination, disclose the device of claim 33 and Westra further discloses wherein the corner frequency is selected by a switch selectable resistance (para[0014]).

As per claim 36, Abreu and Westra, in combination, disclose the device of claim 33 and Abreu further suggests software that could run on the microprocessor (para[0119]). Abreu does disclose wherein the high pass filter is implemented (para[0014]). It would have been obvious to a person of ordinary skill in the art to derive claim 36 provided Abreu and Westra as references since the high pass filter disclosed by Westra could be readily integrated into the software disclosed by Abreu.

Claim 38 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu in view of US 2003/0001742 A1 to Eshelman, et al. (hereinafter Eshelman).

As per claim 38, Abreu discloses the device of claim 1 and further discloses wherien the communication-computation module 1596 includes circuit components 1592 of the electrical connections 1590 with the skin surface of the patient (para[0502], Fig. 77A). Abreu does not explicitly disclose to detect failure of contact. Eshelman does disclose to detect failure of contact (para[0029]). It would have been obvious to a person of ordinary skill in the art to derive claim 38 provided Abreu and Eshelman as references since a physiological sensor capable of detecting a failure of contact with a skin surface can alert a patient or user of an unattached sensor component.

Claim 39 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu in view of US 2006/0044856 A1 to Bird, et al. (hereinafter Bird).

As per claim 39, Abreu discloses the device of claim 1 and further discloses the communication-computation module 1596 (para[0502], Fig. 77A). Abreu does not explicitly disclose protection from external high energy signals by electro-surgical isolation suppression circuits. Bird does suggest protection from external high energy signals by electro-surgical isolation suppression circuits (para[0038]). It would have been obvious to a person of ordinary skill in the art to derive claim 39 provided Abreu and Bird as references since a physiological sensor device having an integrated isolation suppression circuit can more effectively protect the various modules from undesirable external high energy signals that could intefere with other electrical signals.

Claim 40 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu in view of US 5,294,928 A to Cooper, et al. (hereinafter Cooper).

As per claim 40, Abreu discloses the device of claim 1 and further discloses the digital circuits on the body worn device ([Abstract]). Abreu does not explicitly disclose wherein the microprocessor automatically enters a sleep mode during a conversion cycle of an analog to digital converter (ADC) to minimize noise pickup. Cooper does disclose wherein the microprocessor automatically enters a sleep mode during a conversion cycle of an analog to digital converter (ADC) to minimize noise pickup ([Abstract]). It would have been obvious to a person of ordinary skill in the art to derive claim 40 provided Abreu and Cooper as references a physiological sensor having a microprocessor capable of automatically entering a sleep mode could greatly reduce undesirable noise that could interfere with other signals.

Claim 51 lacks an inventive step under PCT Article 33(3) as being obvious over Owen in view of US 2006/0205171 A1 (Tsukada).

As per claim 51, Owen obviates the monitor of claim 49 and Tsukada further discloses wherein the mechanical interface from the resistor to the electrode includes a filleted edge (para[0051]). Tsukada does not explicitly disclose the at least one series current-limiting resistor and the ECG electrode. Owen does disclose the at least one series current-limiting resistor (para[0139]) and the ECG electrode (para[0094]). It would have been obvious to a person of ordinary skill in the art to derive claim 51 provided Owen and Tsukada as references since a filleted edge is one of a multitude of designs that could be selected for the mechanical interface between a resistor and an electrode in an ECG system.

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Claim 58 lacks an inventive step under PCT Article 33(3) as being obvious over Owen in view of Cooper.

As per claim 58, Owen suggests an ECG monitor (para[0094]) comprising: a plurality of electrical connections ([Abstract]), said electrical connections being couplable to a skin surface ([Abstract]) to measure patient heartbeat signals (para[0017]); at least one internal or external power source ([Abstract]) to power the ECG monitor (para[0094]); and an ECG electronics module (para[0017]) to receive and process heartbeat signals from said plurality of electrical connections (para[0017]), said ECG electronics module (para[0017]) drawing power as an electrical load on said power source ([Abstract]), said ECG electronics module including a microprocessor to process (para[0018]) heartbeat signals (para[0017]), wherein an algorithm running on said microprocessor could cause the ECG monitor to enter a low power mode that could disable at least one circuit of the ECG electronics module (para[0175], [0176]), that could be 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 (para[0175], [0176]). Cooper also suggests a microprocessor with an algorithm capable of entering a "sleep mode" ([Abstract]) that could be used in order to reduce an electrical load on a power source. It would have been obvious to a person of ordinary skill in the art to derive claim 58 provided Owen and Cooper as references since Owen discloses that the low-power mode for the processor could be controlled to last for any particular duration (para[0175], [0176]), which could include the period of time 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.

Claim 8 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu and Owen and further in view of Tsukada.

As per claim 8, Abreu and Owen, in combination, disclose the device of claim 7 and Tsukada further discloses wherein the mechanical interface from the resistor to the electrode includes a filleted edge (para[0051]). Tsukada does not explicitly disclose the at least one series current-limiting resistor and the ECG electrode. Owen does disclose the at least one series current-limiting resistor (para[0139]) and the ECG electrode (para[0094]). It would have been obvious to a person of ordinary skill in the art to derive claim 8 provided Abreu, Owen and Tsukada as references since a filleted edge is one of a multitude of designs that could be selected for the mechanical interface between a resistor and an electrode in an ECG system.

Claims 20, 22 and 24 lack an inventive step under PCT Article 33(3) as being obvious over Abreu and further in view of Owen and Schraag.

As per claim 20, Abreu discloses the device of claim 1 and Owen discloses further comprising a virtual electrode (para[0089]). Owen does not explicitly disclose a reference electrode to improve CMR. Schraag does disclose a reference electrode to improve CMR ([Abstract]). It would have been obvious to a person of ordinary skill in the art to derive claim 20 provided Abreu, Owen and Schraag as references since the methods of creating a virtual electrode and a reference electrode to improve CMR are well-known in the field of biomedical engineering and a virtual electrode could be utilized as a reference electrode to improve CMR in an ECG device.

As per claim 22, Abreu, Owen and Schraag, in combination, disclose the device of claim 20 and Abreu further suggests wherein an electrode 1590 comprises a capacitive coupling of a body of the communication-computation module 1596 to the skin surface of the patient (para[0502], Fig. 77A). Abreu does not explicitly disclose the virtual electrode and to reduce power line frequency interference. Owen does disclose the virtual electrode (para[0089]). Schraag does suggest to reduce power line frequency interference (col 7, ln 63-65).

As per claim 24, Abreu, Owen and Schraag, in combination, disclose the device of claim 20 and Schraag further discloses wherein the reference electrode is a passive electrical connection or the reference electrode is actively driven (col 4, ln 15-22).

Claim 35 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu and Westra and further in view of US 2002/0122519 A1 to Douglas, et al. (hereinafter Douglas).

As per claim 35, Abreu and Westra, in combination, disclose the device of claim 33 and Westra further suggests wherein the corner frequency could be selected by one or more switching capacitors switched at a rate higher (para[0014]). Westra does not explicitly disclose the corner frequency of a low pass anti-aliasing filter. Douglas does disclose a rate of a corner frequency of a low pass anti-aliasing filter (para[0030]). It would have been obvious to a person of ordinary skill in the art to derive claim 35 provided Abreu, Westra and Douglas as references since a physiological signal measurement device with a high pass filter having a switching rate higher than that of a low pass filter allows for more accurate and rapid adjustment of high pass filter settings.

Claim 43 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu and further in view of Owen and US 2004/0113806 A1 (Neykov).

As per claim 43, Abreu discloses the device of claim 1 and Neykov further suggests wherein neon bulbs connect in a circuit to an electronics common (ground) to protect one or more internal circuits (para[0009]). Neykov does not explicitly disclose the physiological sensors of the communication-computation module from a defibrillation pulse. Abreu does disclose the physiological sensors 1590 of the communication-computation module 1596 ([Abstract], para[0502], Fig. 77A). Owen does disclose a defibrillation pulse (para[0139], claim 31). It would have been obvious to a person of ordinary skill in the art to derive claim 43 provided Abreu, Owen and Neykov as references since the incorporation of neon bulbs between sensors and a ground within a physiological sensing device could protect the device circuits from harmful energy, including defribillation pulses.

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Claims 54 and 55 lack an inventive step under PCT Article 33(3) as being obvious over Owen and further in view of Ortega and Cooper.

As per claim 54, Owen discloses an ECG monitor (para[0094]) comprising: a plurality of electrical connections ([Abstract]), said plurality of electrical connections being couplable to a skin surface ([Abstract]) to measure patient heartbeat signals (para[0017]); at least one internal or external power source ([Abstract]) to power the ECG monitor (para[0094]); and an ECG electronics module (para[0017]) to receive and process patient heartbeat signals from said plurality of electrical connections (para[0017]), said ECG electronics module (para[0017]) drawing power as an electrical load on said power source ([Abstract]) wherein a patient being monitored by the ECG monitor (para[0094]), causes said ECG electronics module (para[0017]). Owen does not explicitly disclose a pacer detect circuit to detect the presence or absence of a pacemaker wherein said pacer detect circuit, upon detection of the absence of a pacemaker signal in a patient being monitored, causes circuitry to disable said pacer detect circuit in order to reduce said electrical load on said power source. Ortega does suggest a pacer detect circuit (para[0105]) that could be configured to detect the presence or absence of a pacemaker (para[0105]) wherein said pacer detect circuit, upon detection of the absence of a pacemaker signal in a patient being monitored (para[0105]). Cooper and Owen, in combination, do suggest could cause circuity to disable a circuit in order to reduce said electrical load on said power source (Cooper, [Abstract]; Owen, para[0175], [0176]). It would have been obvious to a person of ordinary skill in the art to derive claim 54 provided Owen, Ortega and Cooper as references since an ECG monitor containing circuitry capable of disabling a circuit upon the detection of an absence of a pacemaker could greatly reduce the amount of power utilized by such a device.

As per claim 55, Owen, Ortega and Cooper, in combination, disclose the monitor of claim 54 and Owen further discloses wherein the power source is a battery (para[0126]).

Claim 21 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu, Owen and Schraag and further in view of US 2006/0189976 A1 to Karni, et al. (hereinafter Karni).

As per claim 21, Abreu, Owen and Karni, in combination, disclose the device of claim 20 and Karni further discloses wherein the virtual electrode is an electrode situated near the skin of the patient, but not directly connected to the skin (para[0002]). It would have been obvious to a person of ordinary skill in the art to derive claim 21 provided Abreu, Owen, Schraag and Karni as references since and ECG device incorporating a virtual electrode that is not directly connected to the skin could reduce certain types of signal interference.

Claim 23 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu, Owen and Schraag and further in view of Ortega.

As per claim 23, Abreu, Owen and Schraag, in combination, disclose the device of claim 20 and Ortega further discloses including a reference electrode switch for selectively choosing between various electrodes as the reference electrode and a directly connected electrode as the reference electrode and wherein when the reference electrode switch selects another electrode, the direclty connected electrode can be used as an additional ECG electrode (para[0098]). Ortega does not explicitly disclose the virtual electrode. Owen does disclose the virtual electrode (para[0089]). It would have been obvious to a person of ordinary skill in the art to derive claim 23 provided Abreu, Owen, Schraag and Ortega as references since an ECG device that allows for switching between different reference electrodes permits multiple configurations of the ECG electrodes to be achieved.

Claim 37 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu in further view of Ortega, Westra and US 4,141,367 A (Ferreira).

As per claim 37, Abreu discloses the device of claim 1 and Ferreira further suggests wherein the body worn device could self check a pacer circuit by injecting a simulated pacer pulse into a circuit to stimulate the pacer circuit by simulating the presence of a patient's pacemaker (col 8, ln 15-29). Ferreira does not explicitly disclose a pacer detection circuit and into a front end amplifier. Ortega does disclose a pacer detection circuit (para[0105]). Westra does disclose a front end amplifier ([Abstract]). It would have been obvious to a person of ordinary skill in the art to derive claim 37 provided Abreu, Ortega, Westra and Ferreira as references since a pacemaker detection device with a circuit-checking system can ensure the proper functioning of the device prior to its use.

Claim 42 lacks an inventive step under PCT Article 33(3) as being obvious over Abreu and Owen and further in view of Douglas and US 4,800,894 A (Milani).

As per claim 42, Abreu and Owen, in combination, disclose the device of claim 4 and Douglas further suggests having a low enough corner frequency such that the energy from a pulse could be recorded by at least one sample, even though the pulse itself is of small duration compared to the sample rate and the pulse could occur between samples (para[0030]). Douglas does not explicitly disclose including an ESIS filter and a pacer pulse is recorded. Owen does disclose a pacer pulse is recorded (para[0017]). Milani does disclose including an ESIS filter (col 1, ln 40-43). It would have been obvious to a person of ordinary skill in the art to derive claim 42 provided Abreu, Owen, Douglas and Milani as references since Douglas discloses low pass filter with an adjustable corner frequency that could be adjusted to a low enough frequency such that a pulse could be recorded by at least one sample (para[0030]). Also, an ECG device incorporating an ESIS low pass filter with an adjustable corner frequency could enhance the reliability with which varying pulses could be recorded.

Claims 1-44, 49-55 and 58 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.

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NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;

(ii) the claim is cancelled;

(iii) the claim is new;

(iv) the claim replaces one or more claims as filed;

(v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers, claims 30, 33 and 36 unchanged; new claims 49 to 51 added."

2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."

3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."

4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.

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Electronic Acknowledgement Receipt

EFS ID:	12960526
Application Number:	13488520
International Application Number:	
Confirmation Number:	9601
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 Boronka
Filer Authorized By:	Sonny Zhiyu Zhan
Attorney Docket Number:	3022036 US02
Receipt Date:	07-JUN-2012
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Application Type:	Utility under 35 USC 111(a)

Payment information:

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Transmittal Letter	2012-06-07_IDS-Transmittal.pdf	19207 38cc5d04b47f272554ab7716365c0a83398f aad5	no	2
Warnings:					
Information:					

2	Information Disclosure Statement (IDS) Form (SB08)	2012-06-07_IDS-1449.pdf	61976 38d96e7f06210a16ecc1662c0b68c575557 05aa7	no	6
Warnings:					
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3	Foreign Reference	EP0209804A2.pdf	722218 859bd969a4b7fcb2410438886110d0b4700 9c8f7	no	18
Warnings:					
Information:					
4	Foreign Reference	EP0770349A1.pdf	533091 ca4a0b37c16633824a282cd188c6ff645fac0 887	no	11
Warnings:					
Information:					
5	Foreign Reference	EP0910985A1.pdf	2351142 af0644e7be8ed48853b44e570ef00e0cd9c 5b288	no	37
Warnings:					
Information:					
6	Foreign Reference	JP11042214A.pdf	629648 c017727eee26ec693f971d4ec473685471e 6c967	no	9
Warnings:					
Information:					
7	Foreign Reference	JP11088546A.pdf	840724 e13de325b7c130db8c461d9b70c2ea4a56c 93362	no	12
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Information:					
8	Foreign Reference	WO9620641A1.pdf	710087 42423795ffbc282dd50838a0a02b68b41e4 b40fd	no	21
Warnings:					
Information:					
9	Foreign Reference	WO9629005A1.pdf	1486040 411afaf9cda82b70c1e04d1e4e70550d92f7 db10	no	29
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Information:					
10	Foreign Reference	WO9746156A1.pdf	2337888 c3d947e1ff33fdf7a49a85047ec31ec05e48e 657	no	75

Warnings:					
Information:					
11	Foreign Reference	WO9959460A2.pdf	582086 0a59d2d9071083d2f042afa2729029ae3d160c8e	no	15
Warnings:					
Information:					
12	Foreign Reference	WO0189362A2.pdf	5573126 638e8a3be34b56e0ea27fb62449459348b869be6	no	137
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13	Foreign Reference	WO0189362A3.pdf	145567 61ce2ab9b5ef241f2b2993127f50d3cd2bb713a7	no	4
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14	Foreign Reference	WO0197686A1.pdf	886341 e5436c70b42cb51402675bf207436b9b98f6ca35	no	22
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Information:					
15	Foreign Reference	WO2008142365A1.pdf	790518 4875ef60c67f68cdf477e25a5e78207c20be1cc2	no	19
Warnings:					
Information:					
16	Foreign Reference	WO2009056859A1.pdf	1222455 524d87e2a1335800bf98a5159b6ab181013be533	no	29
Warnings:					
Information:					
17	Non Patent Literature	NPL1_JP2006507455.pdf	205954 30687bcc961a1512c84071a79b181d9a821a1501	no	5
Warnings:					
Information:					
18	Non Patent Literature	NPL2_ISRWO.pdf	1162945 f5b270044ca40192ad058340b8b9f58428b94834	no	16
Warnings:					
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		Total Files Size (in bytes):	20261013		

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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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker et al.	Examiner:	TBA
Serial No.:	13/488,520	Group Art Unit:	TBA
Filed:	June 5, 2012	Docket No.:	3022036 US02
Customer No.:	88750	Confirmation No.:	9601
Title:	Body Worn Physiological Sensor Device Having a Disposable Electrode Module		

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 within three months of the filing date of the above-identified application, which is not an application under 37 C.F.R. § 1.53(d). 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, Applicants do 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: June 7, 2012

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

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PTO/SB/14 (11-08)
Approved for use through 06/30/2010. 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 contains a valid OMB control number.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3022036 US02
	Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information:

Applicant 1 Remove

Applicant Authority	◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Steven	D.	Baker	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Beaverton	State/Province	OR	Country of Residence [i]	US

Citizenship under 37 CFR 1.41(b) [i]	US

Mailing Address of Applicant:

Address 1	c/o Welch Allyn, Inc., Attn.: Legal Dept.		
Address 2	4341 State Street Road		
City	Skaneateles Falls	State/Province	NY
Postal Code	13153-0220	Country [i]	US

Applicant 2 Remove

Applicant Authority	◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	Eric	T.	McAdams	

Residence Information (Select One) ○ US Residency ◉ Non US Residency ○ Active US Military Service

City	Whitehead	Country Of Residence [i]	UK

Citizenship under 37 CFR 1.41(b) [i]	GB

Mailing Address of Applicant:

Address 1	c/o Welch Allyn, Inc., Attn.: Legal Dept.		
Address 2	4341 State Street Road		
City	Skaneateles Falls	State/Province	NY
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Applicant 3 Remove

Applicant Authority	◉ Inventor	○ Legal Representative under 35 U.S.C. 117	○ Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	James	P.	Welch	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Mission Viejo	State/Province	CA	Country of Residence [i]	US

PTO/SB/14 (11-08)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3022036 US02
	Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE	

Citizenship under 37 CFR 1.41(b) i	US				
Mailing Address of Applicant:					
Address 1	c/o Welch Allyn, Inc., Attn.: Legal Dept.				
Address 2	4341 State Street Road				
City	Skaneateles Falls	**State/Province**	NY		
Postal Code	13153-0220	**Country**i	US		

Applicant 4 Remove

Applicant Authority (•) Inventor ( ) Legal Representative under 35 U.S.C. 117 ( ) Party of Interest under 35 U.S.C. 118

Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	Norbert		Ohlenbusch	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Andover	**State/Province**	MA	**Country of Residence** i	US
Citizenship under 37 CFR 1.41(b) i	US				
Mailing Address of Applicant:					
Address 1	c/o Welch Allyn, Inc., Attn.: Legal Dept.				
Address 2	4341 State Street Road				
City	Skaneateles Falls	**State/Province**	NY		
Postal Code	13153-0220	**Country**i	US		

Applicant 5 Remove

Applicant Authority (•) Inventor ( ) Legal Representative under 35 U.S.C. 117 ( ) Party of Interest under 35 U.S.C. 118

Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**
	Thomas	P.	Blackadar	

Residence Information (Select One) (•) US Residency ( ) Non US Residency ( ) Active US Military Service

City	Natick	**State/Province**	MA	**Country of Residence** i	US
Citizenship under 37 CFR 1.41(b) i	US				
Mailing Address of Applicant:					
Address 1	c/o Welch Allyn, Inc., Attn.: Legal Dept.				
Address 2	4341 State Street Road				
City	Skaneateles Falls	**State/Province**	NY		
Postal Code	13153-0220	**Country**i	US		

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	88750

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3022036 US02
	Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE	

Email Address	ipdocket@hblaw.com	Add Email	Remove Email

Application Information:

Title of the Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		
Attorney Docket Number	3022036 US02	**Small Entity Status Claimed** ☐	
Application Type	Nonprovisional		
Subject Matter	Utility		
Suggested Class (if any)		**Sub Class (if any)**	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	14	**Suggested Figure for Publication (if any)**	1A

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing.

Please Select One:	◉ Customer Number	○ US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	88750		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a)(2) or CFR 1.78(a)(4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)
	Continuation of	11591619	2006-11-01

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

PTO/SB/14 (11-08)
Approved for use through 06/30/2010. OMB 0651-0032
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3022036 US02
	Application Number	
Title of Invention	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE	

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Remove

Application Number	Country [i]	Parent Filing Date (YYYY-MM-DD)	Priority Claimed
			◯ Yes ◯ No

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Assignee Information:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

Assignee 1 Remove

If the Assignee is an Organization check here. ☒

Organization Name	Welch Allyn, Inc.		
Mailing Address Information:			
Address 1	4341 State Street Road		
Address 2			
City	Skaneateles Falls	**State/Province**	NY
Country [i] US		Postal Code	13153-0220
Phone Number		Fax Number	
Email Address			

Additional Assignee Data may be generated within this form by selecting the **Add** button. Add

Signature:

A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.

Signature	/Sonny Z. Zhan/			Date (YYYY-MM-DD)	2012-06-05
First Name	Sonny Z.	Last Name	Zhan	Registration Number	62936

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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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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.

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S/N **T**o **B**e **A**ssigned PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Steven D. Baker et al.	Examiner:	TBA
Serial No.:	TBA	Group Art Unit:	TBA
Filed:	On even date herewith	Docket No.:	3022036 US02
Customer No.:	88750	Confirmation No.:	TBA
Title:	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE		

AUTHORIZATION FOR EXTENSION OF TIME ALL REPLIES

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

Dear Sir:

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.

Please further charge any additional fees required to enter these papers or any future papers, or credit any overpayment of fees, to Deposit Account No. 50-4979.

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

Date: June 5, 2012

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

BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation application of, and claims the priority and benefit to, U.S. patent application serial number 11/591,619, entitled "Body Worn Physiological Sensor Device Having a Disposable Electrode Module," filed November 1, 2006, the entirety of which is hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] This invention relates generally to a physiological monitor and more particularly to a body worn physiological monitor.

BACKGROUND OF THE INVENTION

[0003] Measurements of various physiological parameters are important to the study of the human condition. Physiological measurements can be particularly important in a health care setting, such as in a hospital. One of the more important physiological measurements performed on a patient is the electrocardiogram (ECG), showing the condition of the human heart.

[0004] Portable patient monitors have evolved that allow patients to enjoy at least some mobility. Typically a battery operated monitor can be hung on a belt, shoulder strap, or carried by a patient using some other similar hanging arrangement. Sensors, such as ECG electrodes, are affixed to the patient's body, such as with tape, and connected to the battery operated monitor by wires. After a fixed interval of time, or at a low battery indication, the batteries can be replaced or recharged. One example of a portable patient monitor is the Micropaq wireless patient monitor, manufactured by Welch Allyn, Inc., that permits multi-parameter monitoring and patient alarm capabilities built in a small, rugged, lightweight, patient-wearable device.

[0005] Another version of a portable physiological monitor is the heart rate monitor typically used by individuals engaged in an athletic activity. The monitor includes a sensor, which generally makes direct or indirect contact with an individual's chest to monitor heart beats and then by wires, or by wireless techniques, the sensor transmits the sensed heart beat to a nearby microcomputer based monitor and display. Such units generally measure only heart beat and are not capable of doing any of the traditional ECG analysis functions.

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[0006] A recurrent problem with the portable monitors typically used in healthcare applications is the need for wires from sensors situated on the patient's body to the portable unit. These wires can become tangled and cause discomfort or become unplugged when inadvertently pulled or tugged on. In addition, wire motion can increase ECG noise due to the triboelectric effect. Muscle movement can also increase ECG noise, due to the typical placement of ECG electrodes over major muscles. Moreover, portable monitor battery maintenance (e.g. battery recharging or replacement) can be time consuming and costly.

[0007] Another problem is related to the requirement that a medical grade monitor survive multiple defibrillation cycles of at least 360 joules. Conventionally, this requirement has been met by one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor. The problem is that the physical volume of conventional power resistors is too large for use in a compact monitor application.

[0008] Another shortcoming of small sensor devices is that these devices lack the intelligence to vary the amount and type of data transmitted, depending on patient condition. Exercise heart monitors do not transmit a full patient waveform for clinical analysis while medical monitors measure and transmit the full patient waveform, even when the patient is healthy. While transmitting the full patient waveform is the preferred solution from a purely clinical standpoint, such transmission requires significant power to transmit large amounts of data and restricts the design from being small and inexpensive.

[0009] Yet another problem is that arrhythmia analysis is a computationally intensive operation not well-suited to existing small portable monitors that presently have no ability to perform arrhythmia analysis.

[0010] Therefore, there is a need for a body worn combined physiological sensor and monitor having a disposable sensor, but used and worn by a patient as a single unit directly and non-permanently affixed to a patient's body. Also, what is needed is a physically compact resistive element for protecting a body worn device from damage caused by multiple defibrillation cycles. Also, what is needed is a medical-grade monitor that can intelligently measure and transmit data only as required to alert clinicians that the patient needs additional attention. What is also needed is a body-worn device capable of running arrhythmia analysis through computationally efficient algorithms.

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SUMMARY OF THE INVENTION

[0011] According to one aspect, a body worn patient monitoring device comprises at least one disposable module including a plurality of electrical connections to the body. The electrical connections are coupled to a skin surface of the patient to measure physiological signals of the patient. The at least one disposable module includes a disposable module connector. The body worn patient monitoring device includes at least one internal or external power source to power the body worn patient monitoring device. The body worn patient monitoring device also includes at least one communication-computation module, having a communication-computation module connector to receive physiological signals from the at least one disposable module via said disposable module connector. The communication-computation module also includes at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals and a radio circuit to communicate a raw physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module. The body worn patient monitoring device, including the at least one disposable module and the at least one communication-computation module, is directly non-permanently affixed to the skin surface of the patient.

[0012] According to another aspect, a method of providing high voltage circuit protection for a body worn monitor comprises the steps of: providing a substrate that supports one or more electrical connections to a patient's body; determining a print pattern and thickness of a first material having a first resistivity to be printed on the substrate; determining a print pattern and thickness of a second material having a second resistivity to be printed on the substrate; printing the first material onto the substrate; and printing the second material onto the substrate wherein at least part of the second material overlays the first material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] For a further understanding of these and objects of the invention, reference will be made to the following Detailed Description which is to be read in connection with the accompanying drawings, in which:

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[0014] FIG. 1A shows an exemplary body worn physiological monitor having a disposable electrode module;

[0015] FIG. 1B shows a partially unassembled side view of the body worn physiological monitor of FIG. 1A;

[0016] FIG. 1C shows an assembled side view of the body worn physiological monitor of FIG. 1A;

[0017] FIG. 1D shows a bottom view of the body worn physiological monitor of FIG. 1A;

[0018] FIG. 2 shows an exploded perspective view of an exemplary body worn physiological monitor;

[0019] FIG. 3 shows an exploded perspective view of an exemplary computation and communication module;

[0020] FIG. 4A shows an exemplary disposable unit flexible circuit board;

[0021] FIG. 4B shows a partial enlarged view of a portion of the flexible circuit board of FIG. 4A, further showing an exemplary resistive trace having a fillet;

[0022] FIG. 4C shows a partial side elevated view of a portion of the flexible circuit board of FIG. 4A, further showing an exemplary conductive surface overlaying a resistive material;

[0023] FIG. 4D shows a partial side elevational view of the circuit board of FIG. 4A, further showing an exemplary conductive surface having a snap receptacle;

[0024] FIG. 5 shows a block diagram of one embodiment of a body worn physiological monitor having a power source in a disposable unit;

[0025] FIG. 6 shows a block diagram of one embodiment of a body worn physiological monitor having a power source in or connected to the computation and communication module;

[0026] FIG. 7A shows a schematic diagram of a direct connected reference electrode used in conjunction with a body worn physiological monitor;

[0027] FIG. 7B shows a schematic diagram of a virtual reference electrode as used in conjunction with a body worn physiological monitor;

[0028] FIG. 8 shows a schematic diagram depicting one embodiment of an analog switching arrangement provided on a body worn physiological monitor to select a reference electrode configuration;

[0029] FIG. 8A shows an exemplary driven lead circuit topology for use with electrodes of a body worn physiological monitor;

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[0030] FIG. 9 shows an exemplary ESIS filter circuit topology with circuit protection;

[0031] FIG. 10 shows an alternative circuit protection to that depicted in FIG. 9;

[0032] FIG. 11 shows a flow chart for an algorithm utilized by a body worn physiological monitor to detect whether a patient has a pace maker;

[0033] FIG. 12 shows a circuit topology of a high pass filter useful for baseline restoration;

[0034] FIG. 13 shows seven graphs of amplitudes plotted versus frequency to illustrate exemplary operation of the circuit of FIG. 12;

[0035] FIG. 14 shows two exemplary positions for a body worn ECG monitor to be non-permanently affixed directly to a patient's body;

[0036] FIG. 15 shows a block diagram of a setup for simulating the effect of patient defibrillation on resistive traces;

[0037] FIG. 16A symbolically shows resistive dots silk screened on a tray;

[0038] FIG. 16B shows a histogram of an exemplary resistive distribution of baked resistive dots; and

[0039] FIG. 17 shows an exemplary ECG waveform.

[0040] Package styling varies slightly between the drawings. Such minor differences, e.g. the case styling of computation and communication module 102, illustrate minor variations in mechanical packaging suitable for use as body worn monitors. Drawings are not necessarily shown to scale.

DETAILED DESCRIPTION

[0041] A "body worn" device is described herein with regard to certain exemplary embodiments. A "body worn" device is defined herein as a device that is directly, but non-permanently, affixed to a patient's body. A "body worn monitor" is a device that can be directly "worn" on the patient's body as a single unit, including one or more physiological sensors and a communications and computation module to perform at least initial processing of one or more physiological measurements made using one or more physiological sensors. Unlike prior art patient-wearable devices, at least one sensor can be incorporated into the device that makes a direct or indirect (such as by capacitive coupling) electrical connection with the patient's body without the use of external wires from sensors to the device. In addition and unlike athletic heart monitors, a "body worn" monitor can be a full functioning medical grade monitor, e.g. meeting the requirements of European Unions' Medical Device Directive and other applicable industry

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standards, such as EC-13 for an electrocardiograph. The body worn medical-grade monitor can include a device, for example, such as a pulse oximeter, CO_2monitor, 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.

[0042] FIGS. 1A-1D depict various views of an exemplary body worn physiological monitor 100 having a communication and computation module 102 and a disposable electrode module 110. In this exemplary embodiment, physiological monitor 100 is designed for use as an electrocardiogram (ECG) monitor for obtaining and recording and/or transmitting ECG information, including ECG waveforms and alarms for a person, such as a patient, wearing body worn physiological monitor 100.

[0043] FIG. 1A shows an exemplary top view of body worn physiological monitor 100. A crescent shape allows the body worn physiological monitor 100 to be placed on the chest of a patient, and more specifically around the pectoralis major, to allow measurement of lead configuration I, II, or III, or to be placed on the patient's side allowing measurement using a V-lead configuration. Though not shown, multiple body worn physiological monitor 100 units can be used to effectively provide multiple leads. By placing electrodes around the body so that they are not situated directly atop major muscles, both motion noise artifacts and muscle noise artifacts can be prevented. Moreover, by eliminating cables, noise due to cable motion or compression (i.e. triboelectric effect) can be eliminated.

[0044] FIG. 1B shows a side elevated view of physiological monitor 100 having an exemplary attachment mechanism, such as a retention clip 104, to mechanically attach communications and computation module 102 to the top surface of the disposable electrode module 110. Flexible printed circuit layer 101 can be made from a thin insulating material, such as according to this embodiment, a 75 micron thick layer of Mylar®. Typically electrical traces (not shown in FIGS. 1A-1D) on flexible printed circuit layer 101 can be further protected by an insulating covering, analogous to a conformal coating. A formed plastic layer or a cloth with adhesive on one side thereof can be used to cover and protect flexible printed circuit layer 101,

as well as to provide an aesthetic outer layer to make the body worn monitor 100 visually appealing.

[0045] FIG. 1C shows a side view of physiological monitor 100 in which the communications and computation module 102 has been affixed to disposable electrode module 110. FIG. 1D depicts a view of the underside of exemplary physiological monitor 100 showing one embodiment of disposable electrode module 110 having electrodes 109. In this embodiment, each electrode 109 comprises electrode gel 103 and conductive surface 404 (FIG. 4). Together, electrode gel 103 and conductive surface 404 create a half cell, such as, for example, a Silver/Silver Chloride half cell. Also and according to this embodiment, conductive surface 404 can directly accept the electrode gel 103.

[0046] FIG. 2 shows an exploded assembly view of the exemplary body worn physiological monitor 100. As noted with regard to FIGS. 1A-1D, the body worn physiological monitor 100 includes a removable and reusable communications and computation module 102 and a disposable electrode module 110, the later including electrode gels 103 for ECG monitoring and batteries 204 to power communications and computation module 102. A flat planar insulating/adhesive member 105 includes a plurality of openings that are each sized to receive electrode gels 103. The insulating member 105 provides a bottom side cover for the flexible printed circuit layer 101 and augments adhesion to the human body. Electrode gel 103, when attached to an appropriate substrate such as silver-silver-chloride or other substrate, can be used to establish a relatively low impedance electrical connection between conductive surface 404 (FIG. 4) and the patient's skin.

[0047] Electrode gels 103 can adhere to a patient's skin. While electrode gel 103 is typically an adhesive electrode gel, the adhesion offered by electrode gels 103 alone might not give a sufficient holding force for non-permanently affixing body worn physiological monitor 100 to a patient. To achieve a better adhesion of body worn monitor 100 to a patient's skin, insulating/adhesive member 105 can be used to non-permanently affix body worn physiological monitor 100 to a patient. Thus, body worn monitor 100 can be applied to a patient in the same way an adhesive strip is applied, such as for example, those adhesive strips sold under the brand name "BAND-AID®". One exemplary type of foam adhesive suitable for affixing a flexible circuit board to a patient is 1.6 mm adhesive foam from Scapa Medical of Bedfordshire, UK. As shown in FIGS. 1B and 1C (although not to scale), each of the electrode gels 103 extend

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sufficiently below adhesive layer 105 in order to ensure good electrical connection with a patient's skin surface (not shown). Tab 106, FIG. 1A, allows for easy removal of a protective backing 111 from adhesive layer 105.

[0048] Flexible printed circuit layer 101 can include contacts, such as battery clips (not shown), to receive and connect to batteries 204. (It is contemplated that in some future embodiments, a single battery can provide sufficient electrical power.) In the exemplary embodiment, as shown in FIG. 2, batteries 204 can be mounted under respective battery flaps 205 arranged on opposite sides of the flexible printed circuit layer 101. Alternatively, battery clips (not shown) or battery holders (not shown) can be used to provide both mechanical support and electrical connections for each of the batteries 204. One type of battery holder suitable for such use, for example, is the model 2990 battery holder, manufactured by the Keystone Electronics Corp. of Astoria, N.Y. Battery cover 107 provides protection for batteries 204 as well as a surface to press upon when applying electrodes 103 to conductive surface 404. Retention clips 104 can comprise, for example, a plurality of spring fingers with latching clips. Retention clip 104, affixed to disposable electrode module 110, can be used to secure reusable communications and computation module 102 to disposable package 110. Reusable communications and computation module 102 is herein illustrated in a simplified representation, including cover 201, communications and computation printed circuit board assembly 202, and base 203.

[0049] FIG. 3 shows a mechanical view of an exemplary reusable communications and computation module 102, as well as a preferred method for making an electrical connection between flexible printed circuit layer 101 in disposable electrical module 110 and communications and computation printed circuit board assembly 202 situated in reusable communications and computation module 102. In this exemplary embodiment, communications and computation printed circuit board assembly 202 can include a plurality of press fit and/or soldered conductive sockets 301 for receiving electrical plug 302, the plug having a corresponding plurality of conductive pins. Each conductive pin shown in plug 302 can correspond to an electrical connection pad on flexible printed circuit layer 101. A row of mechanical sockets 303 can receive the multi-pin row of plug 302. Thus, an electrical connection can be made between each pad of flexible printed circuit layer 101 having a conductive post on plug 302 and each corresponding conductive socket 301 on communications

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and computation printed circuit board assembly 202. Posts 304 can align and secure each of the cover 201, communications and computation printed circuit board assembly 202, and base 203. Note that in FIG. 3, a simplified drawing of cover 201 omits slots to receive retention clip 104 to affix communications and computation module 102 to disposable package 110. A body worn monitor 100 would typically also include retention clip 104 FIG. 2, or other suitable type of mechanical clip(s), in order to provide a secure mechanical connection between communications and computation module 102 and disposable electrode module 110.

[0050] FIG. 4A shows one embodiment of flexible circuit board 101 in an expanded (e.g. unassembled) view. Flexible circuit board 101 is formed on a substrate 406. Substrate 406 can be cut, for example, from a Mylar sheet of suitable thickness. In this embodiment, one battery 204 can be mounted adjacent to a conductive surface 404. Conductive gel 103 (not shown in FIG. 4) can be mounted on the exposed conductive side of a conductive surface 404.

[0051] Conductive surface 404 can also be viewed as the electrode portion of a half cell and electrode gel 103 can be considered to be the electrolyte portion of a half cell. In conventional terms of art, the combination of electrode and electrolyte and ECG electrode is typically referred to as a half cell. For example, the combination of a conductive surface 404 and an electrolyte layer (e.g., electrode gel 103) forms a half cell. For convenient quick reference to a half cell structure, the term "electrode" (assigned reference designator "109") is used interchangeably with "half cell" herein. It is understood that in typical embodiments, electrode 109 comprises conductive surface 404 and electrode gel 103.

[0052] Typically, electrodes make use of a circular or square conductive surface. Increasing the ratio of the perimeter of the surface to the area of the surface affects current density distribution and defibrillation recovery.

[0053] For convenience, we define the term "annulus" herein and throughout as the region between two simple curves. A simple curve is a closed curve that does not cross itself. Under this definition, an annulus can include substantially square shapes, substantially rectangular shapes, substantially circular shapes, substantially oval shapes, as well as substantially rectangular shapes with rounded corners. Further we include in the definition of annulus, the case of a substantially "U" shaped surface as described by a single closed curve.

[0054] One exemplary electrode gel 103 suitable for such use on a body worn monitor is type LT00063 hydrogel supplied by Tyco Healthcare of Prague, Czech Republic. Typically, a

conductive surface 404 creates the electrode portion of the half cell. By increasing the ratio of perimeter to area of the circular electrode portion of the half cell, the signal to noise ratio of the input ECG signal can be increased.

[0055] As depicted herein on the exemplary circuit layout, two batteries 304 can be connected in series, with one polarity being made available at connection pad 407 from battery connection 402, battery connection 401 creating the series connection between the two batteries, and connection pad 410 providing the second polarity of the series connected batteries. Note that in some embodiments, a single battery alternatively may be used in lieu of the exemplary arrangement or two batteries can be also wired in parallel, depending on the voltage requirements of a particular communications and computation module 102.

[0056] Connection pads 408 and 409 electrically couple the signals from electrode gels 103 (not shown in FIGS. 4A-4D) via conductive surface 404 and resistive traces 412 to electrical plug 302 (not shown in FIGS. 4A-4D). Electrode contact pad 405 can be connected via resistive trace 413 to connection pad 411 to provide a direct-connected reference electrode (not shown in FIGS. 4A-4D). Traces 412 extending between conductive surface 404 and connection pads 408 and 409 and trace 413 extending between conductive surface 405 and connection pad 411 can be made from resistive materials including resistive metals, carbon, silver ink, powders, paints, or other material of determinable electrical resistance.

[0057] Resistive traces on flexible circuit board layer 101 replace the bulky power resistors needed by prior art monitors, having electrodes or sensors connected by wires or leads. These resistive traces should survive multiple defibrillation cycles such that body worn monitor 100 remains functional even after one or more attempts to re-start a patient's heart. In order to survive defibrillation, the resistive traces should dissipate that portion of the potentially damaging defibrillation energy that is coupled into the monitor. This fractional portion of the defibrillation energy typically enters body worn monitor 100 from electrodes 109, FIG. 1D (electrodes 109 including conductive surface 404 and electrode gel 103).

[0058] It is desirable that the resistances of the protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms. Below 1 kilo ohm, depending on the resistive material used, it can be more likely that the resistance of the resistive traces 412 and 413 will increase with each successive defibrillation pulse. Above 10 kilo ohms, a high resistance impairs the signal to noise ratio, specifically due to thermal noise, which has a mean square value of

4*k*T*R*BW, where "k" is Boltzmann's constant, "T" is temperature measured in degrees Kelvin, "R" is resistance in ohms, and "BW" is bandwidth, in Hz, which becomes significant relative to the EC-13 requirement that the noise referred to input be less than 30 μV peak-to-valley.

[0059] Power dissipation in the herein described traces can be calculated by E^2/R, in which E refers to the potential across the trace and R is the resistance of the trace. R can be calculated by ρ*L/A, where ρ is the resistivity of the material used to form the trace, L is the length of the trace, and A is the cross-sectional area of the trace.

[0060] In developing resistive traces for use on a flexible printed circuit layer 101, typically formed on a Mylar substrate 406, such as shown in FIG. 4A, various materials were tested. Silver, including silver inks, while useable, was found to be less desirable, because it was difficult to achieve sufficiently thin silver traces on Mylar to achieve high enough resistances. Carbon, including carbon pastes and carbon inks, was also tried and found to be suitable. In order to use carbon however, several additional problems had to be solved. At 1 kilo ohm, the power dissipated by the resistors caused them to degrade across multiple defibrillation cycles. The solution was to make carbon traces in the range of about 8 to 10 kilo ohms. 10 kilo ohm resistances proved to be a good compromise between noise levels, power dissipation by the resistors, and manufacturing tolerances for depositing carbon ink on a Mylar substrate to dissipate the power from multiple defibrillation cycles. To achieve the desired resistance of about 10 kilo ohms (interchangeably represented herein as "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] Another problem associated with carbon traces was arcing at the interface between the carbon and conductive traces. Arcing was particularly problematic at the abrupt connection between the carbon trace and conductive surface 404. Arcing was also observed to occur

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between the end section of the carbon trace and conductive surface 404. (Electrode gels 103 create the conductive path to the patient through conductive surface 404 and a layer of conductive gel.)

[0062] According to one solution to the above noted arcing problem, as shown in FIG. 4B, a rounded (fillet) section 430 of carbon trace can be added at the interface to conductive surface 404. A fillet or "tear drop" shape causes the carbon trace to become gradually wider as it connects to conductive surface 404 and relieves the electrical potential stress at the interface.

[0063] An alternative solution to the arcing problem is shown in FIG. 4C, wherein carbon can be laid down beyond the trace (412) to include a pattern of conductive surface 404 formed from carbon. A carbon annulus pattern can be deposited before the conductive surface 404 is deposited. Conductive surface 404 can then be deposited as an overlay over the earlier formed carbon annulus shape. Finally, conductive gel 103 can be attached to the conductive surface layer (the carbon layer residing between conductive surface 404 and the Mylar substrate used as flexible circuit board 101). Both of the aforementioned arcing solutions can be used together. It should also be noted that conductive surface 404 can be formed from suitable materials other than silver, including, for example, materials such as silver chloride.

[0064] Arcing can also occur between the resistive traces and other (typically silver) conductive traces on the flexible circuit board 101. Trace to trace arcing can be suppressed by allowing sufficient spacing between the traces. Generally a minimum spacing of about 3 mm/kV, as required by ASNI/AAMI DF80:2003 57.10 BB, has been found to be sufficient to prevent trace to trace arcing from a defibrillation event. Closer trace spacing, as close as 0.01 mm/kV, can be employed successfully by first applying an insulating dielectric layer, similar to a conformal coating, over the surface of flexible circuit board 101 that covers most of the substrate and traces. The insulating dielectric layer can be prevented from forming or adhering to conductive surface 404, such as by use of a mask during application of the insulating layer.

[0065] In an alternate embodiment, as depicted in FIG. 4D, a snap device can be added to conductive surface 404 to accept a manufacture snap-on electrode (not shown), such as, for example, the ConMed Cleartrace line of ECG electrodes including the model 1700 Cleartrace electrode manufactured by the ConMed Corp. of Utica, N.Y. or similar type electrodes made by the 3M Corp. of St. Paul, Minn. When designed to accept a snap-on electrode, the conductive surface 404 is typically smaller than in the previous embodiment. A receptacle snap 432 for

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receiving the commercial snap-on electrode can be inserted by any suitable method, such as by press fitting or other fastening method, into conductive surface 404, typically also penetrating through substrate 406. In this embodiment, arcing can be similarly suppressed in this embodiment by adding a fillet to the carbon-conductive surface interface and/or deposing a conductive surface 404 over a carbon layer as previously described.

[0066] Example: Resistive traces and an annulus were tested on a substrate formed from CT3 heat stabilized treated polyester (75 microns thick), such as manufactured by the MacDermid Autotype Corp. of Schaumburg, Ill. Resistive traces were silk screened onto the substrate using 7102 carbon paste conductor from the DuPont Corporation of Wilmington, Del. The carbon paste conductor was deposited through a 43T silk screen mesh. The substrate containing the paste deposit was then cured inside a fan assisted air circulated oven at 120°C for a period of 5 minutes. The traces formed were about 55 mm long and 2 mm wide, having an overall thickness of about 7.5 microns. The initial measured resistance of each trace was about 14 kilo ohms. After each trace was subjected to 3 defibrillation cycles, the measured resistance increased to about 15 kilo ohms. Over a 3 mm length, the trace widens to about 5 mm, terminating into a carbon annulus with an outer diameter of about 20 mm and an inner diameter of about 10 mm. A silver layer of PF-410 silver ink from the Norcote Corp. of Eastleigh Hampshire, UK was then deposited over the carbon annulus, also to an overall thickness of about 7.5 microns. The deposition of the silver layer was via the silk screen printing method, in which a 90T silk screen mesh was used. The substrate containing the deposited silver ink was then cured inside a fan assisted air circulated oven at 120°C for a period of 15 minutes. A third dielectric insulating layer comprising SD2460, components A & B (dielectric and hardener), manufactured by Lackwerke Peters GmbH + Co KG of Kempen, Germany, and having a thickness of approximately 13 microns was then deposited over the traces and substrate, but not over the annulus. (The electrodes were formed by attaching a conductive gel to the annulus. The conductive gel used was LT00063 hydrogel from Tyco Healthcare of Prague, Czech Republic.) Again, the silk screen printing process was used to deposit the dielectric layer through a 90T screen mesh. The substrate was placed again into a fan assisted air circulated oven at 120°C for a period of 30 minutes.

[0067] Example: Silver traces for use as conductive (not resistive) traces on a body worn monitor circuit substrate were formed from a silver paste that was silk screened onto a Mylar

substrate. 45 mm long traces had a measured resistance in a range of 3.5 to 6 ohms, 75 mm traces had a measured resistance in a range of 6.5 to 13 ohms, and 105 mm traces had a measured resistance in a range of 10 to 16 ohms. The deposition of the silver layer was performed via the silk screen printing method in which a 90T silk screen mesh was used. The substrate containing the deposited silver ink was then cured inside a fan assisted air circulated oven at 120°C for a period of 15 minutes.

[0068] FIG. 15 diagrammatically depicts an exemplary test setup used to simulate the effect of a patient defibrillation on resistive traces. Defibrillator 1501 was used to apply multiple defibrillation shocks of 360 Joules each to the 100 ohm resistor 1502. The 100 ohm resistor according to this setup simulated a patient's body. Note that most of the defibrillation energy goes into the patient's body by design, to restart the patient's heart. Resistive traces 1503 and 1504 were wired across resistor 1502, also as shown in FIG. 15, in order to simulate the electrical circuit that would be formed between the resistive traces in a body worn monitor situated on a patient undergoing defibrillation. Neon bulbs 1506 were used as part of the protection circuitry that can be used with resistive traces in a body worn monitor. 400 ohm safety resistor 1505 was present as a precaution to limit short circuit current in the event of a test setup failure. Both the 100 ohm resistor (simulating human skin resistance) and the 400 ohm safety resistor were used in accordance with medical specification AAMI EC-13. Following 3 defibrillation shocks of 360 Joules each, the measured resistance of the 10 k carbon track changed from 10 k to 11 k following the first shock, to 13.1 k following the second shock, and to 13.2 k following the third shock. The measured resistance of the 9.7 k trace changed from 9.7 k to 11.6 k following the first shock, to 13.0 k following the second shock, and finally to 13.2 k, following the third shock. In a subsequent related test, the 100 ohm resistor was replaced by a closer simulation in the form of a fresh (dead) chicken. The setup otherwise remained the same as shown in FIG. 15. In this case, the resistance as measured on each of the test resistive traces changed from 10.7 k to 10.25 k, and from 8.5 k to 9.4 k, following multiple defibrillations. During testing, it was also noted that the change in measured resistance of the resistive traces was generally consistent. It was also noted that as a given resistive trace was increased, the (delta R {caused by defibrillation}/R {net trace resistance}) can be minimized.

[0069] 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

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

[0070] FIG. 5 shows a block diagram representative of one embodiment of the body worn physiological monitor 100. Physiological sensors 501 (such as electrodes 109 in FIG. 1D) can be electrically coupled to electromechanical connector 502 (as by the resistive traces 412 shown in FIG. 4). Connector 502 serves to electrically couple communications and computation module 102 to a disposable electrode module 110 (FIG. 2). Secondary connector 503 can also electrically couple one or more additional sensors, which can be situated both on and off of disposable electrode module 110, to electromechanical connector 502 for electrical coupling along with physiological sensor signals 501 to communications and computation module 102 (shown in FIG. 1) via electromechanical connector 505. Signals received by the communications and computation module 102 can be electrically coupled into communications

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and computation module 102 via electronic protection circuits 506 and/or filters, such as ESIS filters 507.

[0071] Signals can be limited or clipped in amplitude, as needed, by protection circuit 506, and filtered by filter 507. One or more analog amplifiers 508 can be used to amplify the amplitude limited and filtered signals. In the exemplary body worn ECG monitor, amplifiers 508 can advantageously be differential amplifiers to amplify the difference signal (e.g. the ECG "vector") between two ECG electrodes. The electrical output of amplifiers 508 can be electrically coupled to both PACER circuits 509 and ECG circuits 510. PACER circuits 509 are described further below. ECG circuits 510 perform several functions, including "trace restore", low pass filtering (anti-aliasing), high pass filtering, and amplification (gain). Low pass filtering filters signals according to the Nyquist criterion to avoid aliasing later when the signals are digitized by analog to digital converter (ADC) 516. The high pass filter causes the input to be AC coupled from a roll off frequency of about 0.05 Hz, as specified by industry ECG standards. Gain is required to cause the small pre-amplified potentials from physiological sensors (such as electrodes 109) to more closely match the available dynamic range of the digitizing ADC 516. Note that ADC 516 can be a dedicated ADC chip or can be included in a microcomputer integrated circuit, such as a microcomputer serving as microprocessor 512.

[0072] A microprocessor, such as microprocessor 512, is defined herein as synonymous and interchangeable with the terms "microcomputer", "microcontroller", and "microprocessor". Such microprocessors are also interchangeably represented herein as "μ P" or "μ C". Further, any microprocessor disclosed herein can be replaced by any integrated device that can perform the function of a microprocessor, such as, but not limited to, a field programmable gate array ("FPGA") programmed to perform the functions of a microprocessor.

[0073] Typically, one or more differential amplifiers can be dedicated to particular difference voltages associated with physiological sensors 501 or 504, but it should be noted that one or more amplifiers 508 can also be multiplexed by techniques as known in the art, to serve multiple physiological sensors using a lesser number of amplifiers. Similarly, one or more ADCs 516 can serve two or more signals from physiological sensors 501 or 504 using techniques such as multiplexing in time that is digitizing one physiological sensor difference signal at a time sending a digital result to a next stage one after the other. ECG circuits 510 and PACER circuits

509 are referred to in the plural, since there can be individual circuits for each measured physiological signal, such as for each measured ECG vector.

[0074] Electrical power from power source 515 can be regulated by regulator 514 and distributed as regulated voltage 517 to most function blocks (as represented herein by the label "POWER"). Each of these function blocks also has a control ("CTRL") input 511 from microprocessor 512, allowing these circuits to be disabled, when not needed, in order to save battery power. When viewed over time, most of the ECG waveform does not contain useful information since there is significant "dead time" between heart beats. Therefore, for example, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heartbeat, circuits can be powered down (in a device "sleep mode") to save on the order of 60% of the energy stored in the power source that would have otherwise been used during this dead time.

[0075] FIG. 17 shows an exemplary ECG waveform. In brief, the P wave can be related to the electrical current causing atrial contraction. The QRS complex can be related to ventricular contraction of the left and right ventricles. The Q wave can be related to electrical current traveling through the intraventricular septum, while the R and S waves can be related to the ventricles contracting. The T-wave is due to the re-polarization of the ventricles. Usually, atrial re-polarization occurs atop the QRS complex, and being much smaller than the QRS complex, is not seen. The ST segment connects the QRS complex to the T-wave. Irregular or missing waves may be indicators of cardiac issues including: ischemic tissue, e.g. due to myocardial infarction, bundle branch block, atrial problems (specifically P-wave abnormalities), pericarditis, and electrolyte disturbance.

[0076] Generally, power source 515 can include one or more "button" cells typically disposed on disposable electrode module 110; however, the block diagram of FIG. 6 shows an embodiment of a body worn physiological monitor 100 where power is supplied by a power source located on, or connected to communications and computation module 102 instead of residing within disposable electrode module 110.

[0077] Beyond power saving considerations, it can also be desirable in some embodiments of body worn physiological monitor 100 to put the microcontroller and/or other circuits, including particularly digital circuits, into a sleep mode during an ADC conversion cycle to minimize pickup of self generated electrical noise and to minimize power use. Preferably, the A/D circuit

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can acquire multiple samples and buffer the samples, before awakening the microprocessor, which then can batch-process the data. Buffering can be set to match the patient's heart rate, as there is no significant clinical benefit to analyzing every sample as it is taken.

[0078] Turning back to the input circuits, typically amplifiers 508 are differential or instrumentation amplifiers useful to selectively amplify desired difference signals between connector terminals (such as an ECG vector), while rejecting common mode signals (such as interfering signals that appear simultaneously on both connector terminals). Beyond using a differential amplifier, other techniques can be advantageously used to further reduce common mode pickup (CMR) and thus to improve the common mode rejection ratio (CMRR) of the input amplifier stages of body worn physiological monitor 100. CMR is of particular concern with regard to body worn physiological monitor 100 because of the proliferation of potentially interfering electromagnetic fields, such as from 50 Hz or 60 Hz AC power line distribution throughout a hospital. For example, many fluorescent ceiling lamp fixtures generate strong 60 Hz alternating current (AC) electromagnetic fields that can appear as common mode signals on physiological sensors 501, such as ECG electrodes 109.

[0079] FIG. 7A shows one embodiment in which body worn physiological sensor 501 comprises a plurality of ECG electrodes 109 and 701. Two electrodes 109 generate an ECG difference potential for patient 703. A third electrode, reference electrode 701 can be electrically coupled to electronics common 704 (or other potential level) and can be used to improve CMR. In this embodiment, the electronics common 704 (shown as the negative terminal of the battery in FIG. 7A) can be directly tied to the patient in the vicinity of electrodes 109. Thus, the electronics common of the electronic circuits in communications and computation module 102 can be made to more closely follow any change in potential in the vicinity of electrodes 109. Reference electrode 701 can be particularly helpful to ensure that inputs 109 remain within a reasonably narrow common mode range, such as by reducing a 60 Hz potential that would otherwise appear to move the electronics common 704 at 60 Hz with respect to electrodes 109.

[0080] In another embodiment as shown in FIG. 7B, virtual electrode 702 performs a similar function as previously described with regard to reference electrode 701. In this embodiment, instead of creating a DC-coupled reference electrode, electrode 701 is replaced by the capacitive coupling between flexible printed circuit layer 101 and the patient 703, resulting in a virtual electrode 702 with an AC coupled common. Such AC coupling increases with decreased

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distance between flexible printed circuit layer 101 and the patient and can advantageously reduce 60 Hz common mode signals (AC signals).

[0081] In yet another version of a directly connected electrode 701, as shown in FIG. 8A, electrode 701 can be actively driven by an electrical output from communications and computation module 102. Typically, an operational amplifier (OpAmp) or other type of amplifier can be used to create a "driven lead". Driven lead circuits can be used to further improve CMR over passive electrodes 701 as shown in FIG. 7A. An exemplary circuit suitable for use to drive an electrode 701 is shown in FIG. 8A. Amplifiers (OpAmps) 810 and 811 buffer the high impedance signals from electrode 1 and 2 (exemplary electrodes 109). Difference amplifier 508 conveys the difference signal (such as an ECG vector) as previously described. The two 10 kilo ohm resistors provide an average of the common mode signals appearing simultaneously at the inputs of buffer amplifiers 810 and 811. The inverting low pass filter built around OpAmp 812 inverts the averaged common mode pickup signal (at electrodes 1 and 2) and applies that signal out of phase (180°phase shifted) to a directly connected driven electrode (such as electrode 701). By applying the average common mode signal to the driven electrode, amplifier 812 effectively suppresses common mode signals at electrodes 1 and 2 within the effective bandwidth of the negative feedback loop by active noise cancellation. In theory, a virtual electrode 702 could be similarly driven, but the voltage requirements to drive a capacitively coupled common electrode are high enough to make a "driven virtual electrode" a less practical option. Thus, it can be seen that a reference electrode can be a passive connection or an actively driven connection.

[0082] It can also be desirable to have more than one CMR technique available. For example, in a low noise environment, a lower power reference electrode might be used for CMR. Then if the noise increases to a level where the reference electrode provides insufficient CMR, the body worn monitor can switch to a driven lead more suitable for CMR in a high noise environment. In this embodiment, a particular CMR configuration can be selected by electronic switching. FIG. 8 shows one such exemplary switching block represented as reference electrode switch 801. Microprocessor μP) 512 can control reference electrode switch 801 to select direct connected electrode 701, virtual electrode 702, or directly connected electrode 701 additionally driven by a driven lead circuit 802. It should also be noted that in the embodiment of FIG. 8, when virtual

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electrode 702 provides sufficient CMR, electrode 701 can be used as a third electrode, thus allowing body worn monitor 100 to simultaneously measure two different heart vectors.

[0083] FIG. 9 shows one embodiment of an exemplary defibrillation protection circuit (506) and ESIS filter 507. As shown in FIG. 9, electrodes 109 can be connected via input resistors R91 and R92. Gas discharge tubes, such as neon bulbs L1 and L2, can be used for over voltage protection by firing at a designed voltage to prevent large potentials from appearing at the input leads to amplifier 508. The gas discharge tubes can be disposed on either disposable electrode module 110 or on the communication and computation module 102. Defibrillation protection resistors R91 and R92 can further reside in disposable electrode module 110, such as in the form of the resistance of traces 412.

[0084] ESIS filters 507 can be used to satisfy AAMI standard EC13 on Electrosurgical Interference Suppression (ESIS). Standard EC13 addresses the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used. Without such suppression, the high RF output of an electrosurgical device can render ECG monitoring impossible and or render the monitor unusable. Resistors R93 to R98 and capacitors C91 to C96 form cascaded low pass filter sections (e.g. R93-C1). Three cascaded single pole filters are shown on each input leg of amplifier 508 as an example; more or less stages can also be used. It is also not necessary for each section of the cascaded filter to have identical values or roll off points in the frequency domain to create a specific response, e.g., Bessel, Chebychev, or other filter response known to those skilled in the art. Also, ESIS filters are not limited to cascaded single pole filters and can take other forms as known in the art.

[0085] Test circuit 906 can provide a relatively sharp transient signal for testing the PACER circuit described below as part of a body worn monitor 100 "power on self test ". Resistors R99 and R100 can pull the output of the differential amplifier 508 allowing the microcontroller (512) to detect which electrode, if any, has detached, much as a "lead failed" detection is accomplished by ECG monitors having leads. Body worn monitor 100 does not use leads, but it is still possible for one or both of the physiological sensors to move free of a patient's body. Such disconnects can occur in situations in which body worn monitor 100 partially moves away from the body to which it is non-permanently affixed. The input impedance at one or both of the electrodes 109 changes in a sensor off (sensor disconnect) event. When a patient is attached, amplifier 508

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typically has an output voltage of near zero volts. However, if one of the electrodes 109 comes off, resistors R99 or R100 cause the output of amplifier 508 to move to a most positive output ("positive rail") or to a most negative output ("negative rail"). Note that the negative rail can be a small voltage near zero, in the case of single supply circuit operation, and that both inputs could be pulled to the same rail. Lead-fail detection can also be analyzed to determine when the device is attached to the patient and then to automatically enter full operational mode. Such analysis can be done at a low frequency.

[0086] The ESIS filter 507 also can cause a stretching in the time domain of a pacer pulse so that the event is recorded by at least one sample, even though the pacer pulse itself is of small duration compared to the ADC sample rate and the pacer pulse is likely to occur between samples.

[0087] FIG. 10 shows an alternative circuit to accomplish over voltage protection, such as is required during defibrillation. In FIG. 10, diodes 1001 prevent the electrode potentials from going much more than one diode voltage drop above Vcc or below ground and resistors R91 and R92 limit current. Using circuit protection, such as gas discharge tubes L1 and L2 (FIG. 9) and/or diodes 1001 (FIG. 10) combined with resistances R91 and R92, typically in the form of resistive traces 412, a body worn device can survive multiple defibrillation cycles of at least 360 joules.

[0088] PACER circuit 509 detects pacemaker pulses. One reason to detect a pacemaker is to prevent the ECG circuitry from inadvertently registering the regular pulses from a pacemaker as an actual heart rhythm. Separation of a pacemaker signal from signals generated by the heart is important both to generate accurate ECG analysis results as well as to correctly detect the absence of an actual heart rhythm. For example, a pacemaker continues to function even where a human heart has completely failed.

[0089] A pacer event (pacemaker signal) is typically a narrow pulse typically less than 100 microseconds wide. Because of the capacitance between the pacer in a patient and an ECG circuit, an otherwise relatively square pacer pulse as administered at the patient's heart by a pacemaker, can appear to an ECG monitor as a pulse with a negative undershoot and an exponential return to zero that could inadvertently mimic a QRS signal. A pacer signal, however, can be recognized by an analog differentiator and alert microprocessor 512 to the presence of a pacer and to disregard the refractory period of the corresponding R-C recovery due

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to the pacer signal. The pacer detection circuit or PACER circuit can generate a microprocessor interrupt to inform the microprocessor that a pacer event occurred and to mark a corresponding physiological signal in time as related to a pacer event. PACER circuit 509 can also cause one or more pacer related circuits to automatically power down for power saving, where it is determined that a patient is not using a pacemaker.

[0090] FIG. 11 shows an algorithm useful to determine if the pacer circuit should be enabled. A typical PACER detection circuit uses a significant percentage of the energy available from a power source such as batteries 204. If a PACER signal is not detected, such as at power up of body worn monitor 100, the pacer circuit can be automatically disabled allowing for a longer battery life. Since typical PACER circuits can use several amplifiers (OpAmps), they can consume up to one third of the analog power, therefore securing the PACER circuits when they are not needed (i.e. the patient does not have a pace maker) can cause a significant improvement in battery life. The algorithm also can also provide checks to determine if a demand type pace maker begins operation (which might be inactive at power up of body worn monitor 100) by analyzing beat variability. While it can be advantageous to have the body worn device automatically sense the presence of a pacemaker and to enable the PACER detection circuit, the choice as to whether to enable or disable the PACER circuit can also be done by externally configuring the body worn device. Such external configuration can be done through a hardwired communication connection cable or via communications and computation module 102, in which communications and computation module 102 is a two-way radio transceiver communication device capable of receiving a configuration command sent for a remote radio transceiver. The radio could be 802.11 compliant, but generally would use a lighter-weight (simpler) protocol that can be more energy efficient. A suitable lighter weight protocol could be proprietary, or standards-based, such as ZigBee or Bluetooth. A body worn physiological monitor 100 is particularly well suited for use in hospital environment as part of an integrated wireless monitoring network. The details of such monitoring networks are disclosed in U.S. patent application Ser. No. 11/031,736 entitled, "Personal Status Physiological Monitor System and Architecture and Related Monitoring Methods", which is incorporated by reference herein in its entirety.

[0091] FIG. 12 shows a high pass filter (HPF) suitable for use in ECG circuits block 510. An advantage of a 0.5 Hz HPF is faster recovery from DC offsets due to patient movement,

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defibrillation, electrocuatery, etc. However ST segment analysis is negatively impacted if HPF cutoff is greater than about 0.05 Hz. Thus, it is preferable to have the ability to change between a 0.5 and 0.05 Hz cutoff frequency. The high pass filter of FIG. 12 is implemented by a low pass filter configured as an inverting amplifier in a negative feedback circuit to give a net effective high pass transfer function from circuit input to output. The corner frequency of the composite filter can be adjusted by switching in resistor R2'. Alternatively, S1 can be switched at a periodic rate to place a duty cycle on C. Note that the frequency of switching of SI should be fast with respect to the corner frequency of the anti-aliasing low pass filter. The graphs A-D of FIG. 13 further illustrate the performance of the exemplary filter of FIG. 12. These graphs show normalized amplitude on the vertical axis plotted against frequency on the horizontal axis. FIG. 13, graph A represents a raw input signal. FIG. 13, graphs B and C are Bode Plots representing the high and low-pass filter sections. After applying filter responses B & C to input Data A, filtered data D is the result. The HPF cutoff can be 0.5 Hz or some lower value depending on whether R2' is switching in or if C is duty cycled.

[0092] Another method to achieve this frequency change is to use digital filters implemented on Microprocessor 512 to reverse the effects of the 0.5 Hz HPF, then implement a digital HPF at a lower cutoff frequency, 0.05 Hz, for example. The response of the 0.5 Hz filter should be known to implement the inverse filter. This response can be measured using microprocessor 512 to trigger the test circuit 906 to create an impulse, H(s). The inverse response is the [1-H(s)] (FIG. 13, graph E) and this inverse filter can be digitally implemented by methods familiar to those skilled in the art. H'(s) is the frequency response of the new HPF with lower cutoff frequency, nominally 0.05 Hz. The digital filter for H'(s) is digitally generated (F) and applied along with [1-H(s)] (FIG. 13, graph E), resulting in the frequency response displayed in FIG. 13, graph G. A high pass filter suitable for use in ECG circuits block 510 can be implemented in full or in part by software that can run on microprocessor 512.

[0093] FIG. 14 shows how a body worn monitor 100 configured as an ECG monitor can be situated on a patient in at least two different orientations to measure different heart vectors. A primary heart vector is measured by orientation from the patient's right shoulder to the left hip, as shown by position 1401. An alternative position 1402 can be more suitable where there is injury or where patient anatomy is such that it causes the preferred position 1401 to be less desirable. Also, body worn monitor 100 can be affixed to the side of patient 703 (similar to a measurement

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made by a conventional ECG "V" lead) or back of a patient 703 (such as where a patient needs to sleep on their stomach) to monitor still other ECG vectors (not shown). In effect, a body worn monitor 100 can be placed to pick a particular vector that can be traversed by the electrodes 109. For example at least the first three primary heart vectors, i.e. I, II, and III, can be made conveniently available in this manner.

[0094] While illustrated with an internal battery, it is important to note that a body worn physiological monitor 100 can be powered by either an internal power source only, an external power source only, or by an internal or an external power source. An internal power source can be a renewable power source, such as a rechargeable battery.

[0095] Another type of internal power source is a Peltier device operated in reverse, also called a Seebeck device. Seebeck discovered that a conductor generates a voltage when subjected to a temperature gradient. Thermoelectric couples are solid-state devices capable of generating electrical power from a temperature gradient, known as the Seebeck effect. (By contrast, the Peltier effect refers to the situation where electrical energy is converted into a temperature gradient.) A Seebeck device "couple" consists of one N-type and one P-type semiconductor pellet. The temperature differential causes electron flow from hot to cold in the N-type couple and hole flow from hot to cold in the P-type couple. To create an electromotive force (EMF), the following connections are made: On the cold side (i.e. the side that is exposed to room temperature) the pellets are joined and on the hot side (i.e. the patient side), the pellets are connected to a load, such as the computation and communication module 102. The open circuit voltage of a Seebeck device is given by $V=S \Delta T$, in which S is the Seebeck coefficient in volts/°K and ΔT is the temperature difference between the hot and cold sides. It is a challenge today to completely power the computation and communication module 102 from a Seebeck device that is of the same size as the computation and communication module 102. Presently, a Seebeck device may only provide supplementary power, but as electronics migrate toward lower power and Seebeck coefficients and thermocouple densities improve, a Seebeck device can be a viable long-term power solution for a patient-worn monitor. Other methods of generating energy, such as mechanical (as is used in some wrist watches) and solar, can also be viable methods for providing a renewable self-contained power source for a body worn monitor.

[0096] Turning to analysis routines suitable for use on a body worn monitor, typically, ECG beat picking, such as by using wavelet or Fourier transforms and/or matched filter analysis in the

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time domain can be computationally expensive. Modeling the QRS pulse as three triangles with alternating polarities creates a rough matched filter for the QRS pulse. Taking the second derivative results in impulse functions at the peaks of the triangles (where the first derivative is discontinuous), and all other points are zero. The second derivative method also makes the convolution with incoming data extremely efficient as most of the multiplies have a 0 as the multiplicand and requires minimal computation. The result can then be integrated twice to produce a matched-filter output, which can be fed into the beat-picking algorithm that provides fiducial marks. Using a second matched filter that is sinusoidal in shape and with appropriate discriminators, the system can provide indications of Life Threatening Arrhythmias (LTA); that is, Asystole, Vfib, and Vtach. While the accuracy of this system is less competitive with a high-end Arrhythmia solutions such as those provided, for example, by Mortara, the filters can be tuned to err toward false positives and upon a positive LTA response, activate transmission of full waveforms.

[0097] Research has also shown that analysis of the R-R portion of the ECG waveform interval statistics can provide a method to predict atrial flutter. Applying this and other low-computational cost methods can allow a body worn monitor device to begin transmitting full waveforms for either clinical or algorithmic analysis by a more powerful engine, when the probability of other arrhythmias is high. Transmitting only the R-R intervals of ECG waveforms is an example of a lossy data compression method. R-R intervals comprise a string of data and the string of data can also be compressed. Lossless or lossy data compression of the entire waveform can be implemented to save battery life, including not transmitting (or perhaps not even sampling) data between the T and the P wave. Because data compression results in less data to transmit, the power saved may offset the computation cost of the data compression.

[0098] While we have referred often to ECG applications herein, the application of low-intensity computational methods as a power saving measure apply equally well to other types of low power-sensors, including, but not limited to EEG, SPO_2, temperature, and invasive or non-invasive blood pressure measurements. Whether the body-worn medical-grade monitor performs complex analysis or simply compares a single numeric value to a single numeric limit, the device can function in a low-power radio state until a predetermined threshold is exceeded. A body worn monitor can also periodically send data or send data upon external request. Additionally, external devices can send commands to modify the operating parameters and thresholds.

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[0099] Turning to other communication matters, it may be that adverse events occur in which no uplink is available. In a case of no uplink (failed communications), the body worn monitor can buffer time-stamped waveforms corresponding to any adverse events. The buffers can also store waveforms for later analysis in which this storage is triggered by the patient when the patient recognizes a condition, such as chest pain. In the case of an alarm that occurs when there is no uplink, alarms can be configured to be latched until confirmed by a clinician. Preferably, non-continuous data are marked (time stamp, sample number) to allow correlation of non-continuous data with continuous data and data are also marked to indicate when an alarm was initiated for later data analysis, including algorithm performance analysis.

[00100] In those instances in which many body worn monitor devices are used in close proximity to one another, there can be concern that the reports from one body worn monitor might be interchanged with reports from another body worn monitor. The body worn monitor presented herein, can be configured with a patient context (i.e. name, room number, patient ID, age, etc) and can maintain that context for as long as the monitor is connected to the patient to avoid such problems. The body worn monitor can determine the status of its connection to the patient via a continuous vital signs monitor, pressure, temperature, galvanic response, or similar input. Upon detection of a loss of connection with a patient, the device can, depending upon different variable settings, either erase the patient context or when re-connected to the patient, require the care giver to confirm the patient context. When the body worn monitor is initially powered up or connected to a patient, it can have a time holdoff for alarms to prevent false alarms (e.g. low heart rate, lead-fail detection) while the system stabilizes.

[00101] Regarding firmware updates, where there are large numbers of body worn monitors in a hospital, it can be problematic to keep them all updated with the latest version of firmware. One solution to this problem is to provide a wireless update ability for downloading and installing new firmware and/or configurations into all of the body worn monitors.

[00102] While the present invention has been particularly shown and described with reference to the preferred mode as illustrated in the drawings, it will be understood by one skilled in the art that various changes in detail may be effected therein without departing from the spirit and scope of the invention as defined by the following claims. It is further understood that several aspects of the invention, including, but not limited to, defibrillation protection resistors, pacer detect

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circuit disabling, methods for ECG signal high pass filtering, and various other low power modes are not limited to body worn monitors, and can be used in ECG monitors of any type.

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What is claimed is:

1. A method for providing high voltage circuit protection for a patient monitor, the method comprising:

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.

2. The method of claim 1, wherein both determining a print pattern and thickness of both the first and second materials comprise including a filleted section.

3. The method of claim 1, wherein both determining a print pattern and thickness of both the first and second materials comprise determining a print pattern and thickness of both the first and second materials to achieve a total resistance value.

4. The method of claim 1, wherein both 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.

5. The method of claim 1, the method further comprising:

providing an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals;

filtering the measured heartbeat signals with an analog high pass filter having an analog high pass cutoff frequency;

removing the effects of the analog high pass filter with a digital inverse filter algorithm resulting in substantially unfiltered heartbeat signals;

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filtering the substantially unfiltered heartbeat signals digitally using a digital filter having a digital high pass filter cutoff frequency lower than said analog cutoff frequency.

6. The method of claim 5, wherein filtering the measured heartbeat signals with an analog high pass filter comprises filtering the measured physiological signals with an analog high pass filter having a 0.5 Hz analog high pass cutoff frequency.

7. The method of claim 5, wherein filtering the substantially unfiltered heartbeat signals digitally comprises filtering the substantially unfiltered heartbeat signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

8. 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;

a power source;

at least one current-limiting defibrillation protection resistor, the at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and

an ECG electronics module, the ECG electronics module receiving and processing patient heartbeat signals from the plurality of electrical connections,

wherein the at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of the plurality of electrical connections and the ECG electronics module.

9. The ECG monitor of claim 8, wherein the at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

10. The ECG monitor of claim 8, wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a filleted edge.

11. The ECG monitor of claim 8, wherein a mechanical interface is defined from the at least one series current-limiting resistor to the at least one ECG electrode, the mechanical interface including a plurality of overlapped layers.

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12. The ECG monitor of claim 11, wherein the plurality of 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.

13. The ECG monitor of claim 8, the ECG monitor further comprising a pacer detect circuit to detect the presence or absence of a pacemaker, the ECG electronics module drawing power as an electrical load on the power source wherein the pacer detect circuit, upon detection of the absence of a pacemaker signal in a patient being monitored by the ECG monitor, causes the ECG electronics module to disable the pacer detect circuit in order to reduce the electrical load on the power source.

14. The ECG monitor of claim 13, wherein the power source is a battery.

15. The ECG monitor of claim 8, wherein the ECG electronics module includes a microprocessor to process the heartbeat signals, wherein an algorithm running on the 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 the power source.

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ABSTRACT

A method for providing high voltage circuit protection for a patient monitor. The method includes providing a substrate that supports one or more electrical connections to a patient's body. The method further includes 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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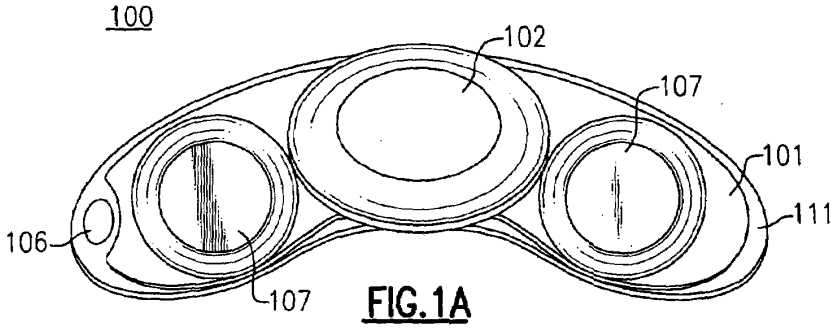


FIG.1A

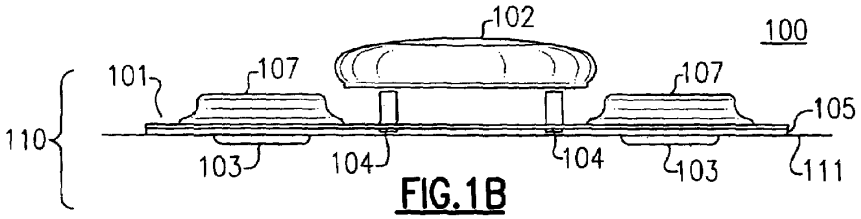


FIG.1B

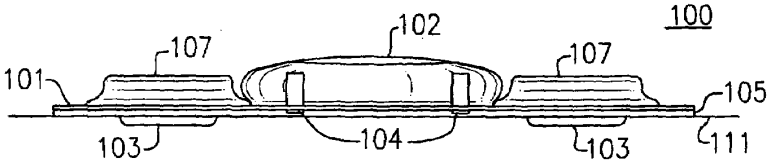


FIG.1C

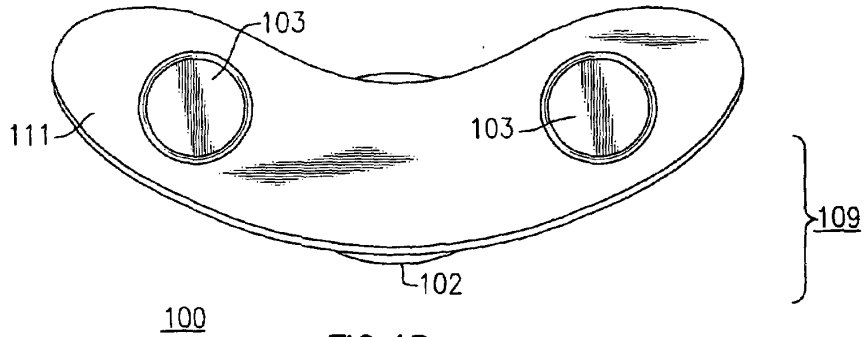


FIG.1D

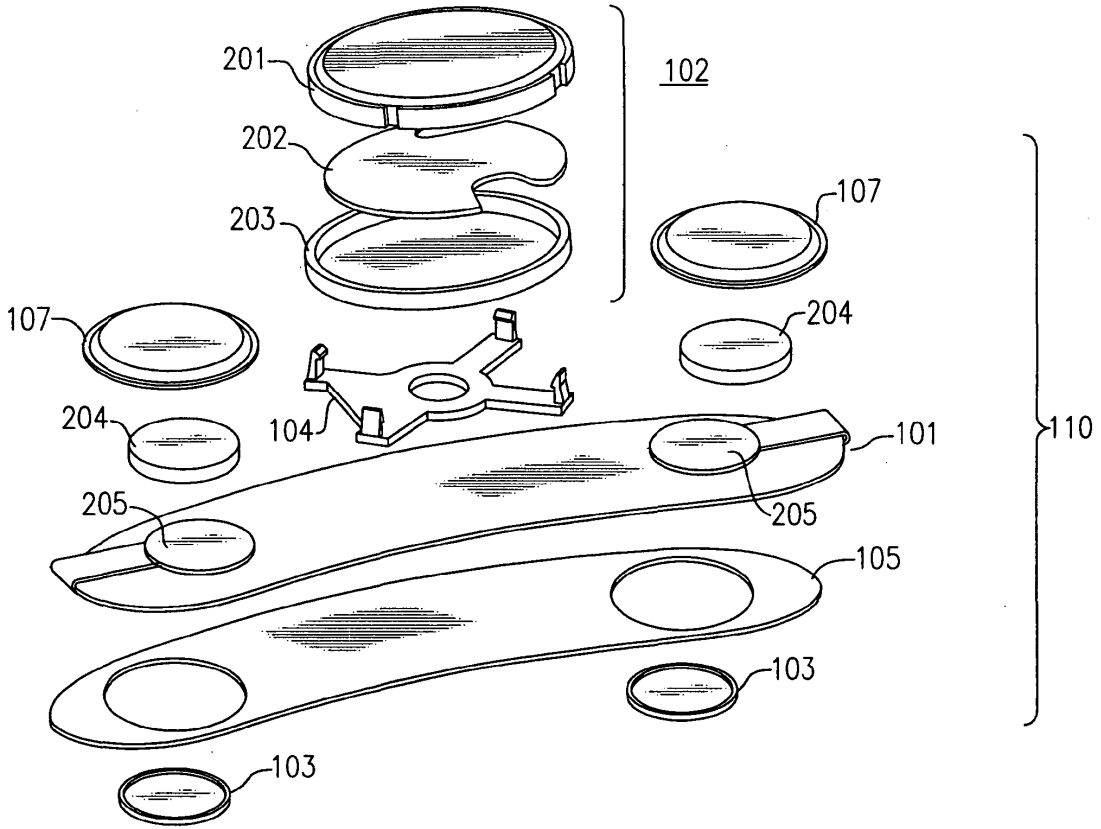


FIG.2

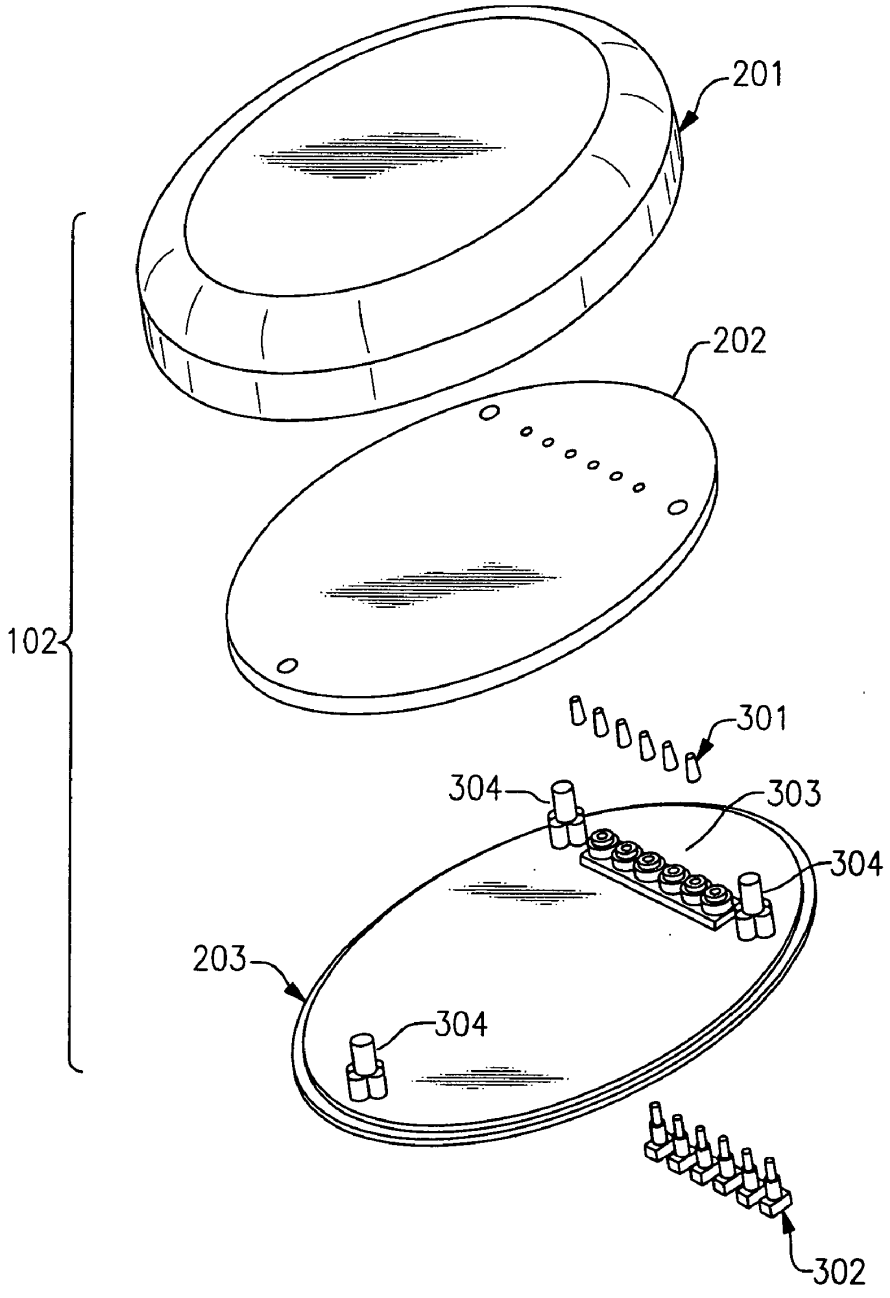


FIG.3

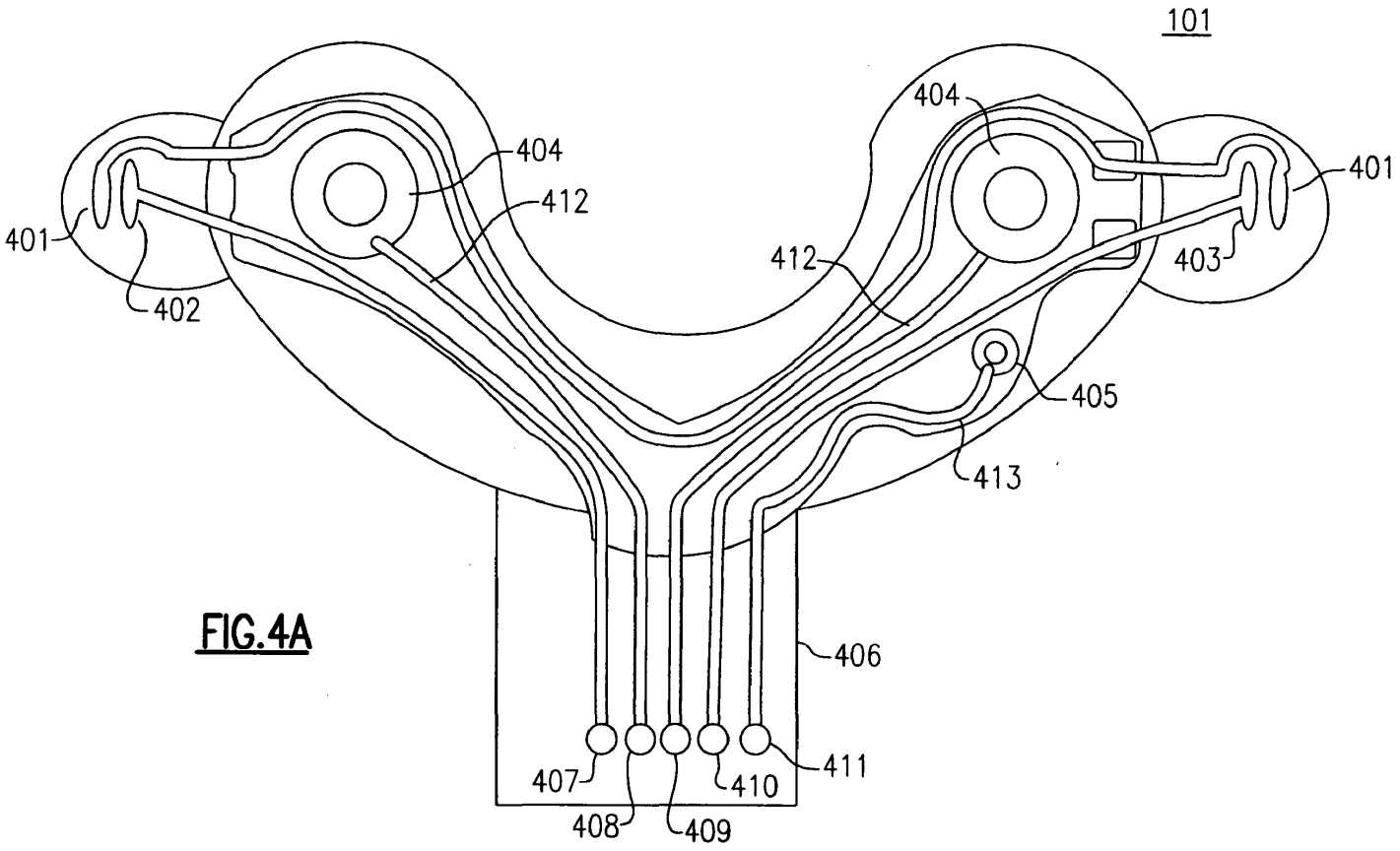

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FIG.4A

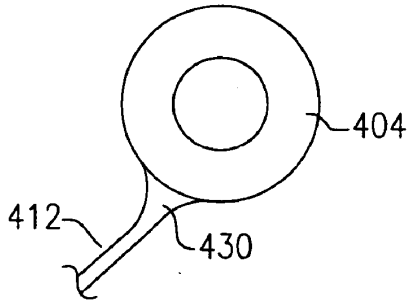


FIG.4B

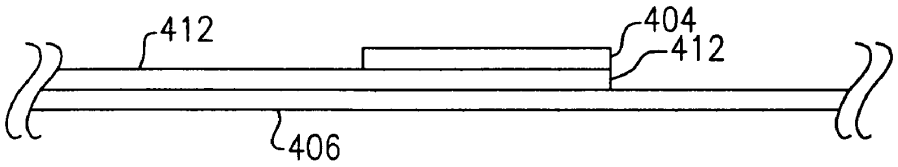


FIG.4C

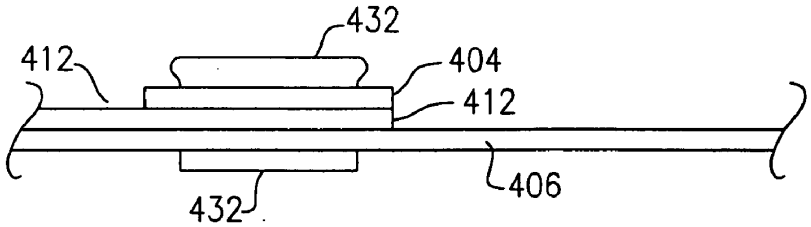


FIG.4D

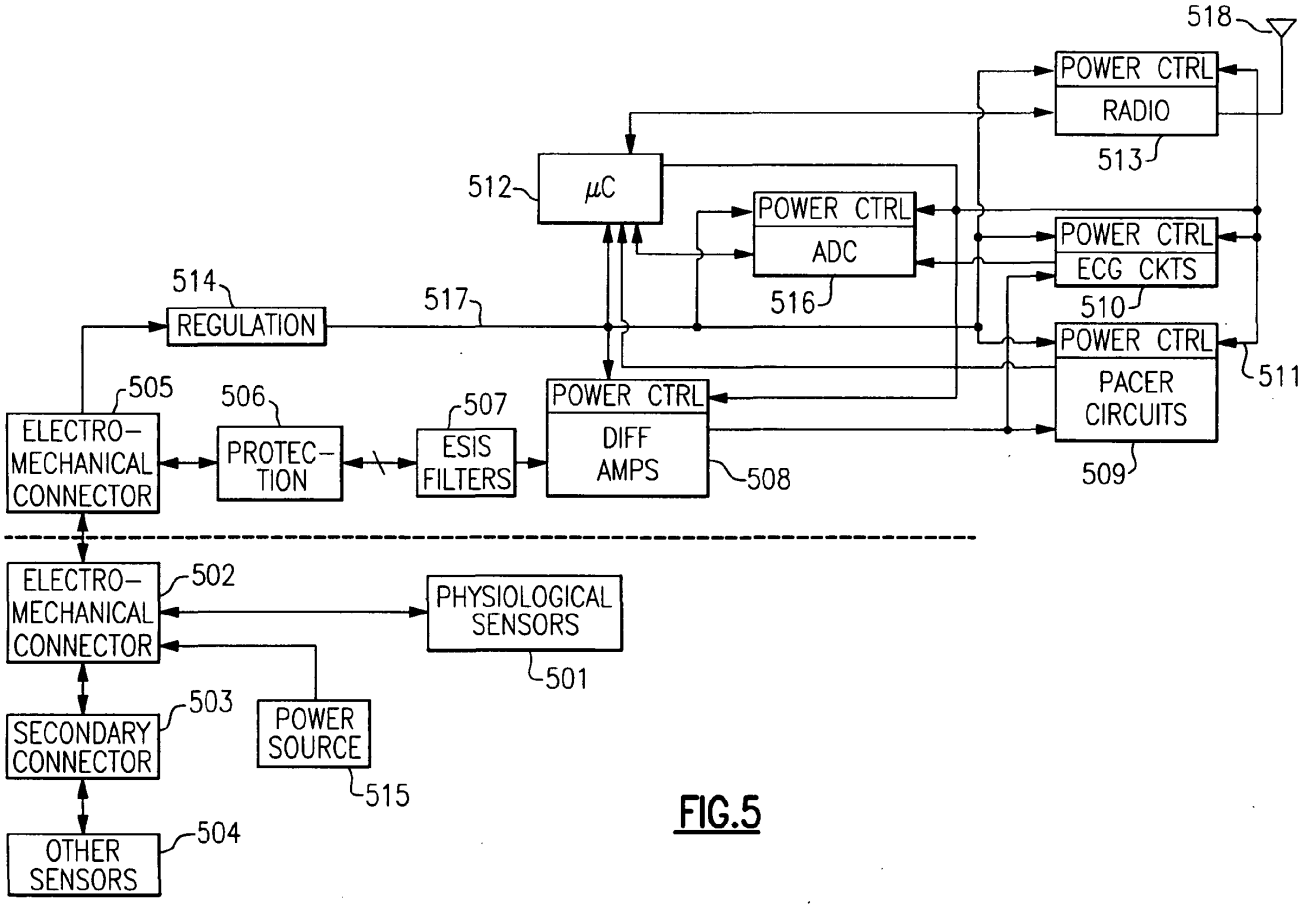

518
POWER CTRL
RADIO
513
512
μC
POWER CTRL
ADC
516
POWER CTRL
ECG CKTS
510
POWER CTRL
PACER CIRCUITS
511
509
514
REGULATION
517
505
ELECTRO-MECHANICAL CONNECTOR
506
PROTEC-TION
507
ESIS FILTERS
POWER CTRL
DIFF AMPS
508
ELECTRO-MECHANICAL CONNECTOR
502
PHYSIOLOGICAL SENSORS
501
SECONDARY CONNECTOR
503
POWER SOURCE
515
OTHER SENSORS
504

FIG.5

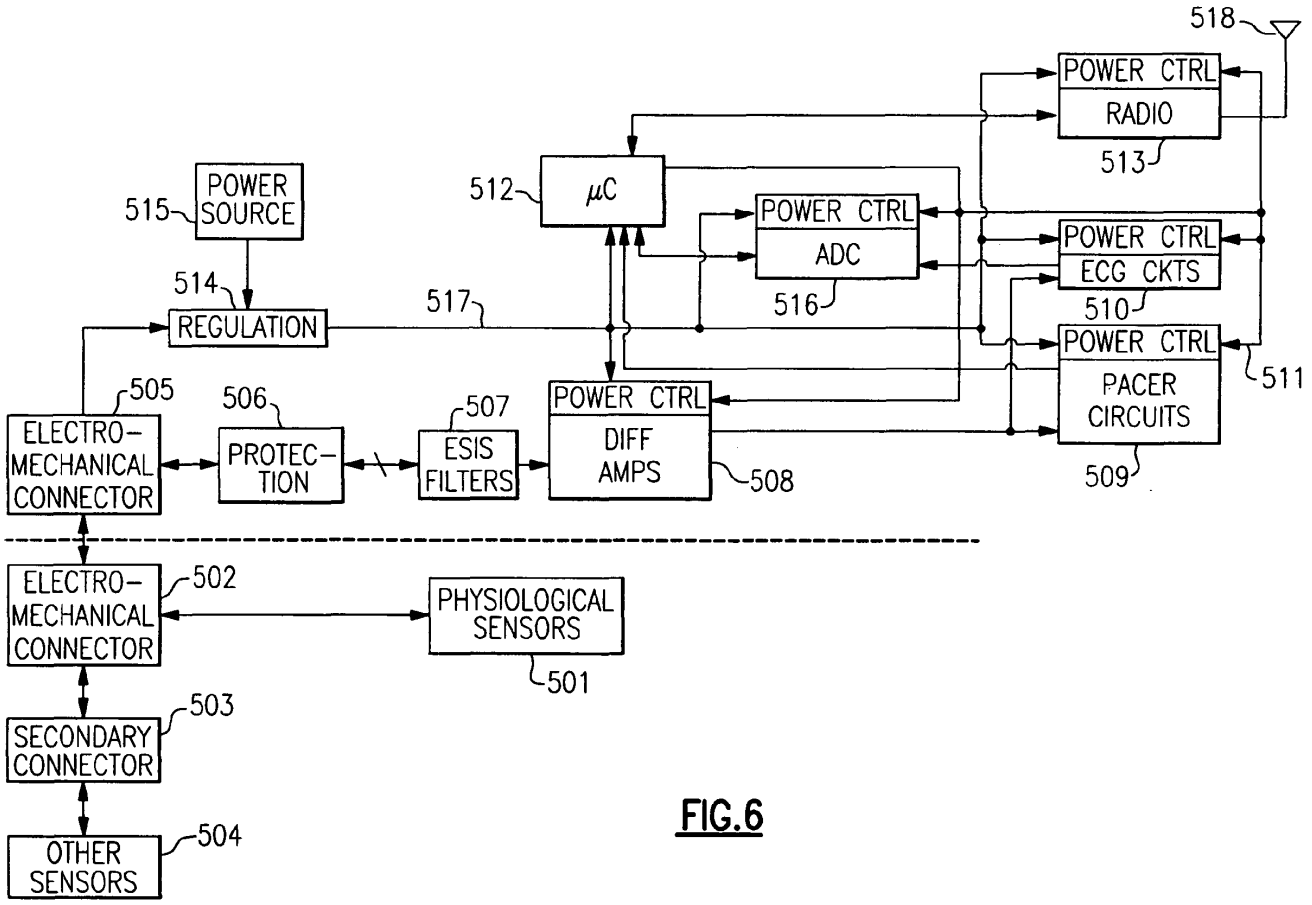

518
POWER CTRL
RADIO
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μC
POWER CTRL
ADC
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POWER CTRL
ECG CKTS
510
POWER CTRL
PACER CIRCUITS
511
509
515
POWER SOURCE
514
REGULATION
517
505
ELECTRO-MECHANICAL CONNECTOR
506
PROTEC-TION
507
ESIS FILTERS
POWER CTRL
DIFF AMPS
508
502
ELECTRO-MECHANICAL CONNECTOR
PHYSIOLOGICAL SENSORS
501
503
SECONDARY CONNECTOR
504
OTHER SENSORS

FIG.6

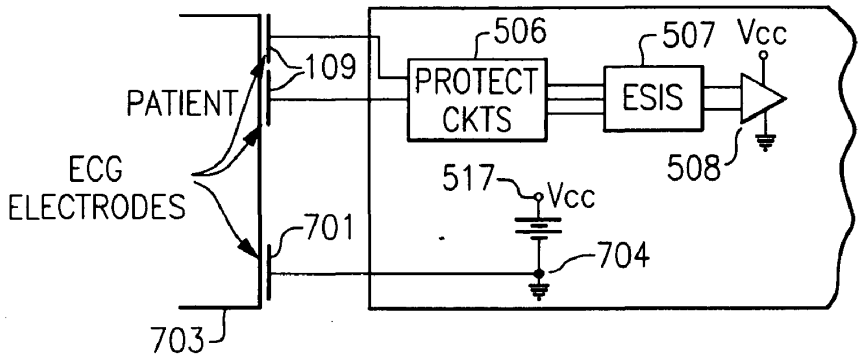

506
507
Vcc
109
PROTECT
CKTS
ESIS
PATIENT
ECG
ELECTRODES
508
517
Vcc
701
704
703

FIG.7A

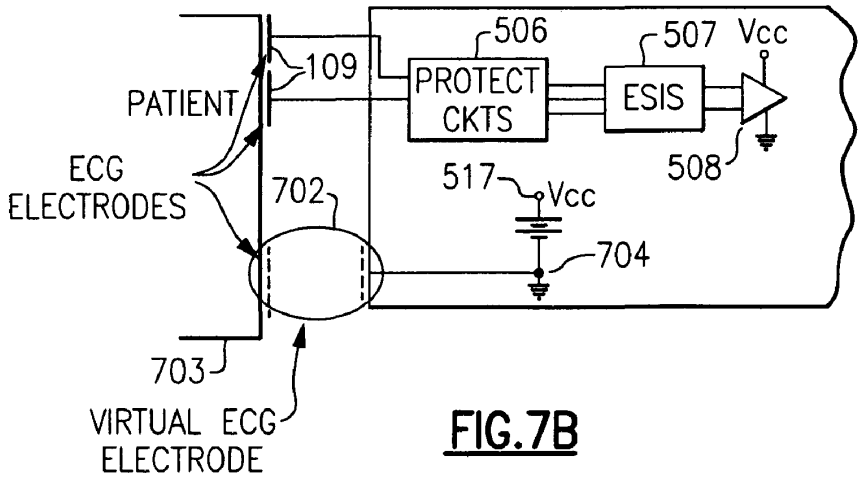

506
507
Vcc
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PROTECT
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ESIS
PATIENT
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ELECTRODES
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517
Vcc
702
704
703
VIRTUAL ECG
ELECTRODE

FIG.7B

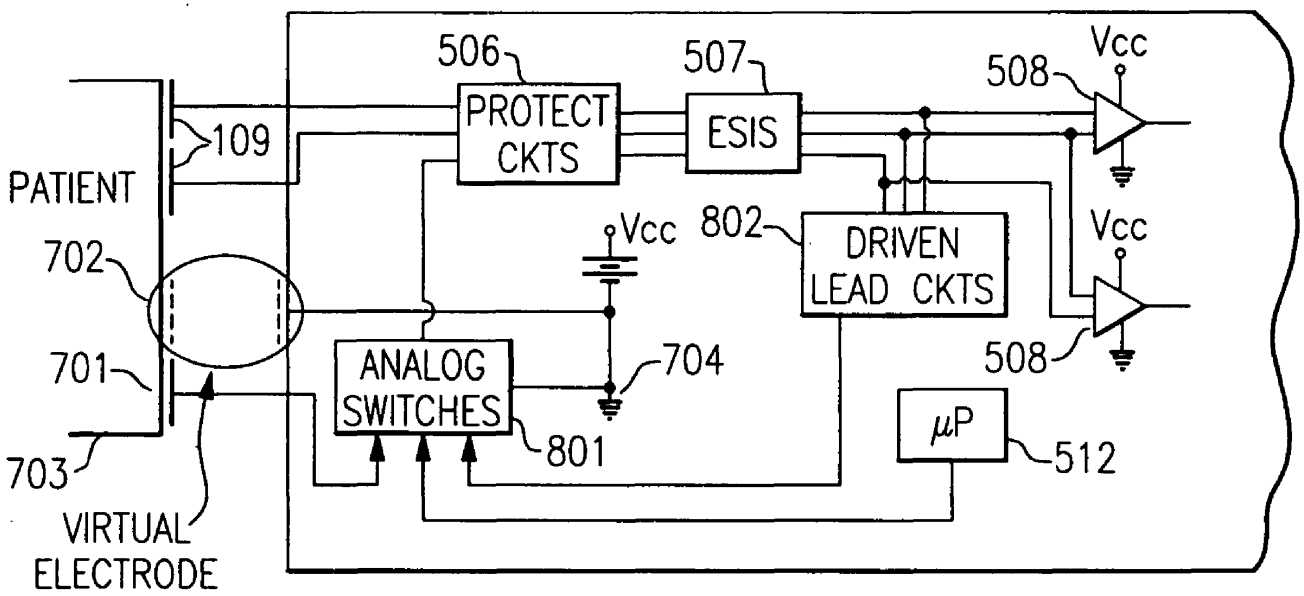

506
PROTECT CKTS
507
ESIS
508
Vcc
109
PATIENT
Vcc
802
DRIVEN LEAD CKTS
Vcc
702
701
ANALOG SWITCHES
704
508
801
μP
512
703
VIRTUAL ELECTRODE

FIG.8

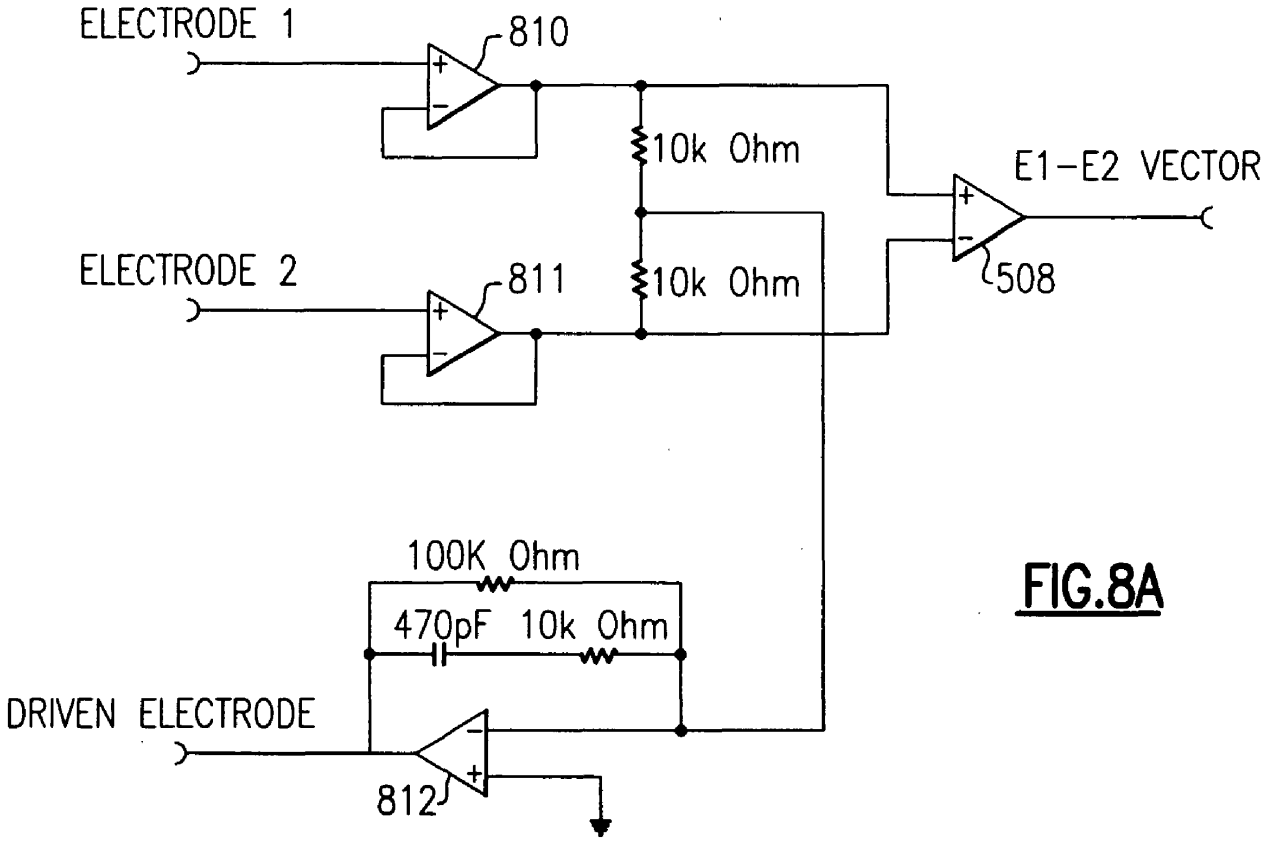

ELECTRODE 1
810
10k Ohm
E1-E2 VECTOR
ELECTRODE 2
811
10k Ohm
508
100K Ohm
470pF 10k Ohm
DRIVEN ELECTRODE
812

FIG.8A

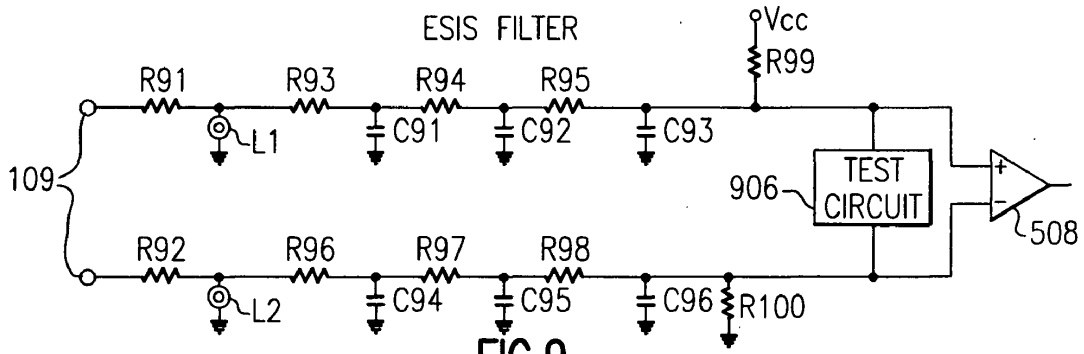

ESIS FILTER
Vcc
R99
R91
R93
R94
R95
L1
C91
C92
C93
109
906
TEST CIRCUIT
508
R92
R96
R97
R98
L2
C94
C95
C96
R100

FIG.9

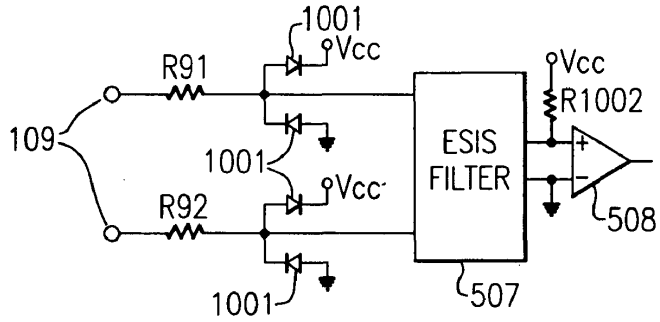

1001
Vcc
R91
109
1001
Vcc
R92
1001
ESIS FILTER
507
Vcc
R1002
508

FIG.10

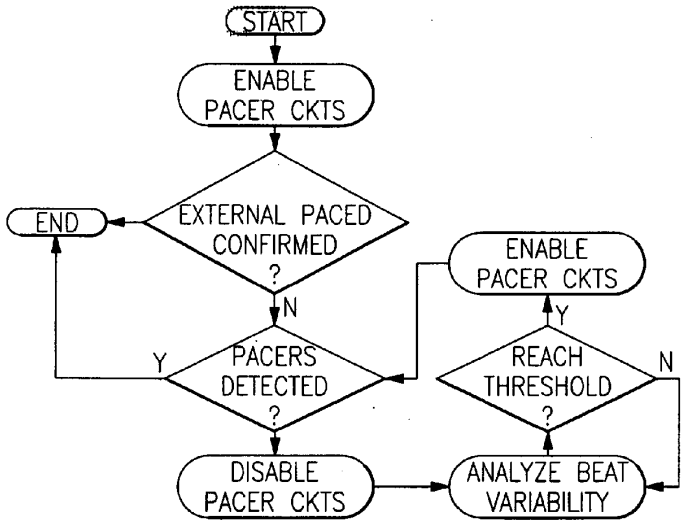


FIG.11

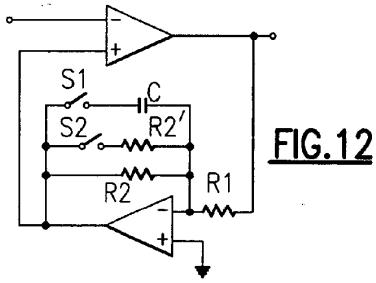


FIG.12

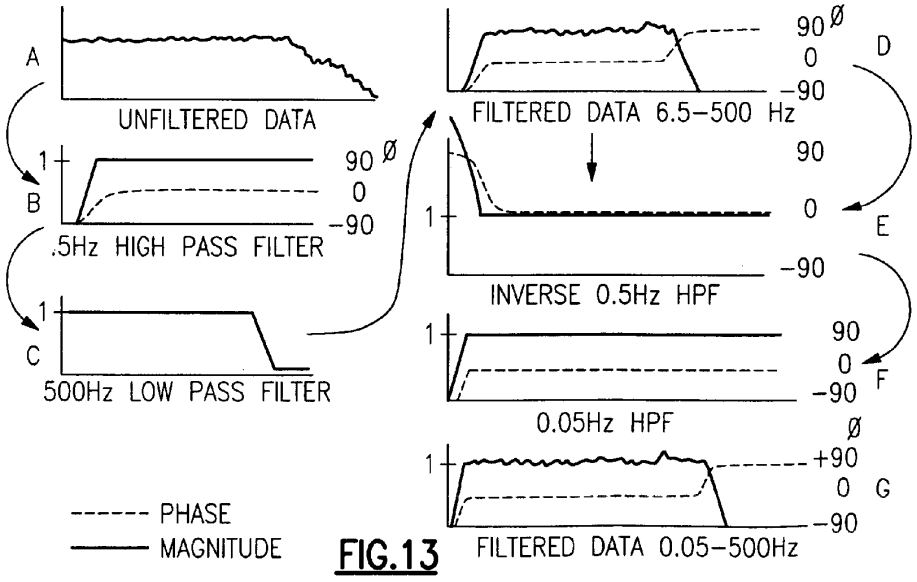


FIG.13

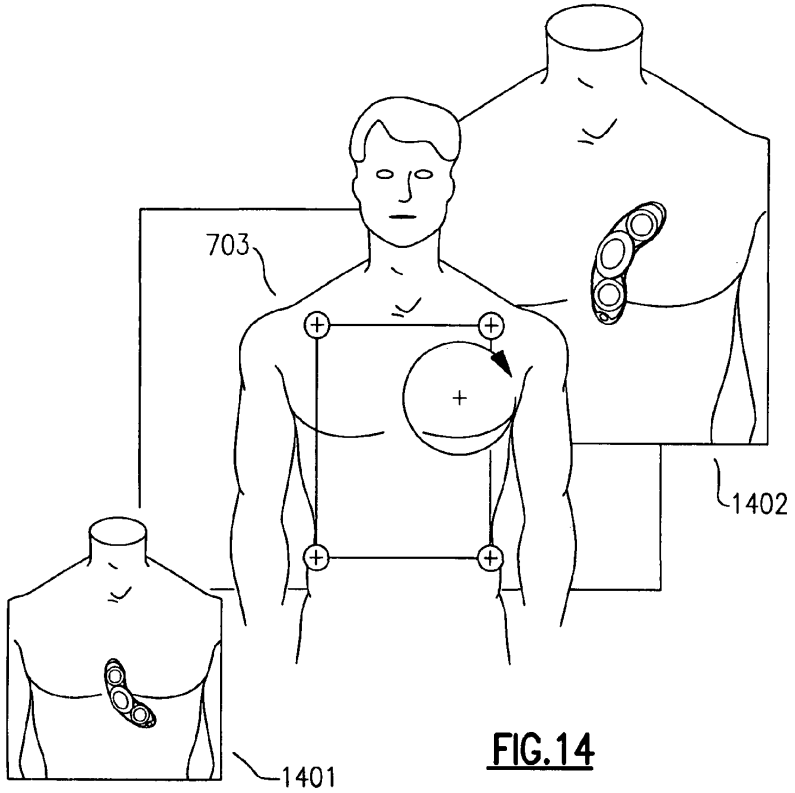

703
1402
1401

FIG.14

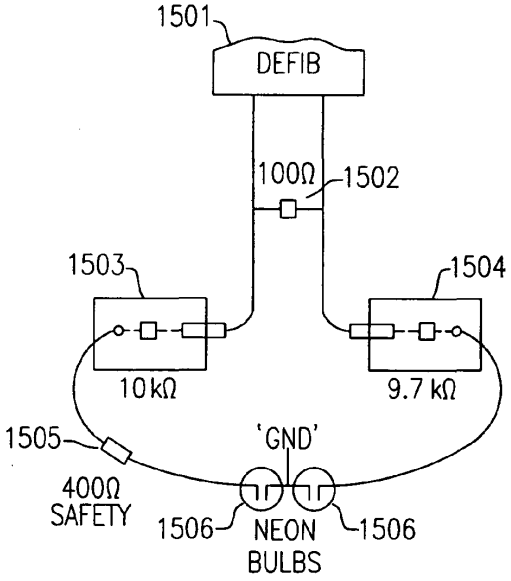

1501
DEFIB
100Ω
1502
1503
1504
10kΩ
9.7 kΩ
1505
'GND'
400Ω
SAFETY
1506
NEON
BULBS
1506

FIG.15

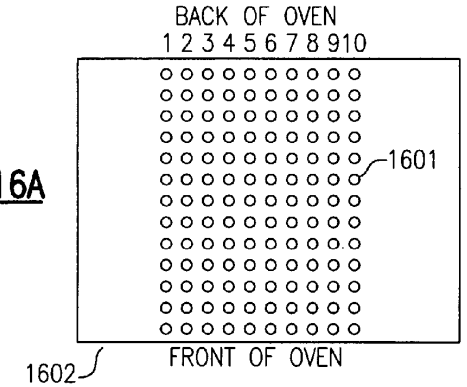


FIG.16A

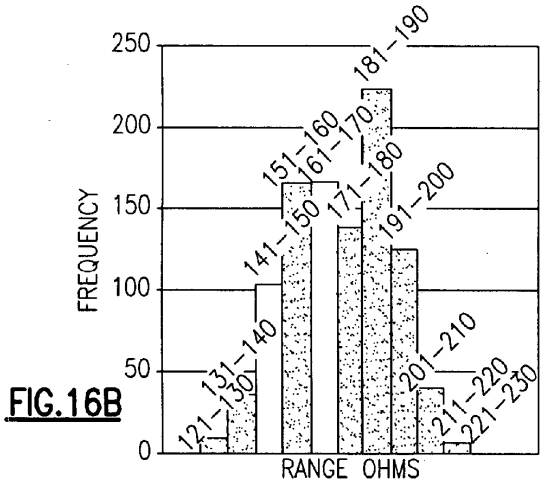


FIG.16B

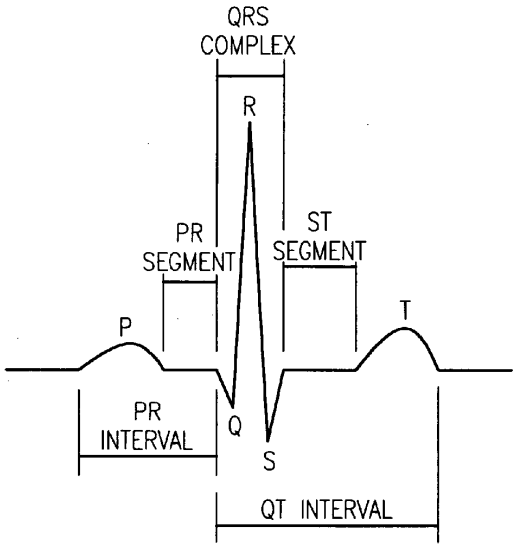


FIG.17

OIPE
JAN 19 2007
PATENT & TRADEMARK OFFICE

DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION, POWER OF ATTORNEY (37 CFR 1.32)and CORRESPONDENCE ADDRESS INDICATION FORM (37 CFR 1.32)		
	Application Number	11/591,619
	Filing Date	November 1, 2006
	First Named Inventor	Steven D. Baker
	Title	BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE
	Group Art Unit	3736
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	704_049
	Express Mail Label No.	EV969121569US

DECLARATION

This declaration is directed to:

☐ The attached application, or

☒ Application No. 11/591,619, filed on November 1, 2006, ☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

My residence, mailing address, and citizenship are as stated below next to my name;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

All statements made herein of my/our own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

Each of the undersigned hereby grants to any duly empowered legal representative the power to insert on this document any further information which may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office or with the rules of any other national or international Patent Office.

FOREIGN PRIORITY CLAIMS

I/we hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on _____ supplemental priority data sheet(s) attached hereto.

DESIGNATION OF POWER OF ATTORNEY

The following individual(s) is/are hereby appointed by the applicant(s) as my/our attorney(s) or agent(s) to prosecute the application identified above, and any additional applications based substantially on the disclosure contained therein, including applications under the Patent Cooperation Treaty, and to transact all business before any patent granting agency, including the United States Patent and Trademark Office, connected therewith:

Designation under 37 CFR § 1.32(c)(2)
All patent practitioners associated with the **Customer Number 20874**.
Please recognize or change the correspondence address for the above-identified application to the address associated with **Customer Number 20874**.

The undersigned is/are

☒ the Applicant(s)/Inventor(s)

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

SIGNATURE(S) OF APPLICANT(S) OR ASSIGNEE OF RECORD

NAME OF SOLE OR FIRST INVENTOR:			☐ **A petition has been filed for this unsigned inventor**
Steven D. **Given Name (first and middle [if any])**			Baker **Family Name or Surname**
Inventor's Signature			03/14/2007 **Date:**
Residence: **City** Beaverton	**State** OR	**Country** US	**Citizenship** US
Mailing Address 7623 SW Crisp Drive			
City Beaverton	**State** OR	**ZIP** 97007	**Country** US

NAME OF SECOND INVENTOR:			☐ **A petition has been filed for this unsigned inventor**
Eric T. **Given Name (first and middle [if any])**			McAdams **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Whitehead	**State** Antrim	**Country** UK	**Citizenship** GB
Mailing Address 52 Cable Road			
City Whitehead	**State** Antrim	**ZIP** BT389PZ	**Country** Northern Ireland (UK)

☐ **Additional inventors are being named on the second supplemental Additional Inventor(s) sheet(s) attached hereto.**

☐ Additional foreign application numbers are listed on _____ supplemental priority data sheet(s) attached hereto.

DESIGNATION OF POWER OF ATTORNEY

The following individual(s) is/are hereby appointed by the applicant(s) as my/our attorney(s) or agent(s) to prosecute the application identified above, and any additional applications based substantially on the disclosure contained therein, including applications under the Patent Cooperation Treaty, and to transact all business before any patent granting agency, including the United States Patent and Trademark Office, connected therewith:

Designation under 37 CFR § 1.32(c)(2)
All patent practitioners associated with the **Customer Number 20874**.
Please recognize or change the correspondence address for the above-identified application to the address associated with **Customer Number 20874**.

The undersigned is/are

☒ the Applicant(s)/Inventor(s)

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

SIGNATURE(S) OF APPLICANT(S) OR ASSIGNEE OF RECORD

NAME OF SOLE OR FIRST INVENTOR:	☐ **A petition has been filed for this unsigned inventor**
Steven D. **Given Name (first and middle [if any])**	Baker **Family Name or Surname**

Inventor's Signature		**Date:**

Residence: City Beaverton	**State** OR	**Country** US	**Citizenship** US
Mailing Address 7623 SW Crisp Drive			
City Beaverton	**State** OR	**ZIP** 97007	**Country** US

NAME OF SECOND INVENTOR:	☐ **A petition has been filed for this unsigned inventor**
Eric T. **Given Name (first and middle [if any])**	McAdams **Family Name or Surname**

Inventor's Signature		**Date:**

Residence: City Whitehead	**State** Antrim	**Country** UK	**Citizenship** GB
Mailing Address 52 Cable Road			
City Whitehead	**State** Antrim	**ZIP** BT389PZ	**Country** Northern Ireland (UK)

☐ **Additional inventors are being named on the second supplemental Additional Inventor(s) sheet(s) attached hereto.**

NAME OF THIRD INVENTOR:			☐ A petition has been filed for this unsigned inventor
James P. **Given Name (first and middle [if any])**			Welch **Family Name or Surname**
Inventor's Signature	James C Welch		**Date:** 1/15/07
Residence: **City** Mission Viejo	**State** CA	**Country** US	**Citizenship** US
Mailing Address 22381 Bayberry			
City Mission Viejo	**State** CA	**ZIP** 92692	**Country** US

NAME OF FOURTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Norbert **Given Name (first and middle [if any])**			Ohlenbusch **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Andover	**State** MA	**Country** US	**Citizenship** US
Mailing Address 9 Whispering Pines Drive			
City Andover	**State** MA	**ZIP** 01810	**Country** US

NAME OF FIFTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Thomas P. **Given Name (first and middle [if any])**			Blackadar **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Natick	**State** MA	**Country** US	**Citizenship** US
Mailing Address 5 Lupine Road			
City Natick	**State** MA	**ZIP** 01760	**Country** US

NAME OF THIRD INVENTOR:			☐ A petition has been filed for this unsigned inventor
James P. **Given Name (first and middle [if any])**			Welch **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Laguna Niguel	**State** CA	**Country** US	**Citizenship** US
Mailing Address 24446 Kathleen Drive			
City Laguna Niguel	**State** CA	**ZIP** 92677	**Country** US

NAME OF FOURTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Norbert **Given Name (first and middle [if any])**			Ohlenbusch **Family Name or Surname**
Inventor's Signature	Norbert Ohlenbusch		4/10/2007 **Date:**
Residence: **City** Andover	**State** MA	**Country** US	**Citizenship** US
Mailing Address 9 Whispering Pines Drive			
City Andover	**State** MA	**ZIP** 01810	**Country** US

NAME OF FIFTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Thomas P. **Given Name (first and middle [if any])**			Blackadar **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Natick	**State** MA	**Country** US	**Citizenship** US
Mailing Address 5 Lupine Road			
City Natick	**State** MA	**ZIP** 01760	**Country** US

NAME OF THIRD INVENTOR:			☐ A petition has been filed for this unsigned inventor
James P. **Given Name (first and middle [if any])**			Welch **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Laguna Niguel	**State** CA	**Country** US	**Citizenship** US
Mailing Address 24446 Kathleen Drive			
City Laguna Niguel	**State** CA	**ZIP** 92677	**Country** US

NAME OF FOURTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Norbert **Given Name (first and middle [if any])**			Ohlenbusch **Family Name or Surname**
Inventor's Signature			**Date:**
Residence: **City** Andover	**State** MA	**Country** US	**Citizenship** US
Mailing Address 9 Whispering Pines Drive			
City Andover	**State** MA	**ZIP** 01810	**Country** US

NAME OF FIFTH INVENTOR:			☐ A petition has been filed for this unsigned inventor
Thomas P. **Given Name (first and middle [if any])**			Blackadar **Family Name or Surname**
Inventor's Signature			**Date:** 1/10/07
Residence: **City** Natick	**State** MA	**Country** US	**Citizenship** US
Mailing Address 5 Lupine Road			
City Natick	**State** MA	**ZIP** 01760	**Country** US

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
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 US02

Filed as Large Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility application filing	1011	1	380	380
Utility Search Fee	1111	1	620	620
Utility Examination Fee	1311	1	250	250
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1250**

Electronic Acknowledgement Receipt	
EFS ID:	12933819
Application Number:	13488520
International Application Number:	
Confirmation Number:	9601
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 US02
Receipt Date:	05-JUN-2012
Filing Date:	
Time Stamp:	10:42:54
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1250
RAM confirmation Number	9144
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)	

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Application Data Sheet	2012-06-05--ADS-3022036-US02.pdf	1104596 9ab0e3c73a195e7d994428aa73162e8b34c3c4b4	no	5
Warnings:					
Information:					
2	Extension of Time	2012-06-05_EOT--Fees-Paid--All-Replies-3022036_US02.pdf	15986 21a2aea018fc8699bf6c3dfb0d398820b366757c	no	1
Warnings:					
Information:					
3		2012-06-05_Application_3022036_US02.pdf	163514 1b64abcb313fdb1050f98040824f4034ae59f974	yes	31

Multipart Description/PDF files in .zip description

Document Description	Start	End
Specification	1	27
Claims	28	30
Abstract	31	31

Warnings:					
Information:					
4	Drawings-only black and white line drawings	2012-06-05--Drawings-3022036-US02.pdf	253701 770ce4deee5b8e53369f686800bc6d22010ebadd	no	14
Warnings:					
Information:					
5	Oath or Declaration filed	2012-06-05--Declaration.pdf	236637 2626fc37d5a3110c90caf5fd6c67839ffcc1138e	no	6
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	33266 3be3900149b684520eb7e876b03ff8c9fbdc13ab	no	2
Warnings:					

Information:	
Total Files Size (in bytes):	1807700

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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.

PTO/SB/80 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☑ Practitioners associated with the Customer Number: 88750

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☑ The address associated with Customer Number: 88750

OR

☐ Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

Assignee Name and Address:

WELCH ALLYN, INC.
4341 STATE STREET ROAD
SKANEATELES FALLS, NEW YORK 13153-0220

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature	Chris Horacek	Date	9/9/11
Name	Chris Horacek	Telephone	315.685.4558
Title	Vice President		

This collection of information is required by 37 CFR 1.31, 1.32 and 1.33. 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.**

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

Electronic Acknowledgement Receipt

EFS ID:	12934252
Application Number:	13488520
International Application Number:	
Confirmation Number:	9601
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 US02
Receipt Date:	05-JUN-2012
Filing Date:	
Time Stamp:	11:16:31
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	Assignee showing of ownership per 37 CFR 3.73(b).	2012-06-05--3-73B-3022036-US02.pdf	425238 78d21ae37450815656ee7d88f00c51c8df38e34c	no	2
Warnings:					
Information:					

2	Power of Attorney	2012-06-05--POA.pdf	69921 d7359e24362db2d6f39d9d1444d997825cb927d7	no	1

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Total Files Size (in bytes):	495159

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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.

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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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STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Steven D. Baker et al.

Application No./Patent No.: 13/488,520 Filed/Issue Date: June 5, 2012

Titled: BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

Welch Allyn, Inc. , a corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.

states that it is:

1. [X] the assignee of the entire right, title, and interest in;

2. [ ] an assignee of less than the entire right, title, and interest in (The extent (by percentage) of its ownership interest is _____ %); or

3. [ ] the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

A. [X] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 024363, Frame 0586, or for which a copy therefore is attached.

OR

B. [ ] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

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[ ] Additional documents in the chain of title are listed on a supplemental sheet(s).

[ ] As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (*i.e.*, a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Sonny Z. Zhan/ 2012-06-05

Signature Date

Sonny Z. Zhan Corporate Counsel - IP

Printed or Typed Name Title

This collection of information is required by 37 CFR 3.73(b). 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: 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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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.
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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.