US008190223C1

(12) EX PARTE REEXAMINATION CERTIFICATE (9610th)

United States Patent

Al-Ali et al.

(10) Number: US 8,190,223 C1

(45) Certificate Issued: Apr. 24, 2013

(54) **NONINVASIVE MULTI-PARAMETER PATIENT MONITOR**

(75) Inventors: **Ammar Al-Ali**, Tustin, CA (US); **Joe Kiani**, Laguna Niguel, CA (US); **Mohamed Diab**, Mission Viejo, CA (US); **Greg Olsen**, Irvine, CA (US); **Roger Wu**, Irvine, CA (US); **Rick Fishel**, Orange, CA (US)

(73) Assignee: **Cercacor Laboratories, Inc.**, Irvine, CA (US)

Reexamination Request:
No. 90/012,559, Sep. 13, 2012

Reexamination Certificate for:

Patent No.:	**8,190,223**
Issued:	**May 29, 2012**
Appl. No.:	**11/367,033**
Filed:	**Mar. 1, 2006**

Certificate of Correction issued Nov. 13, 2012

Related U.S. Application Data

(60) Provisional application No. 60/657,596, filed on Mar. 1, 2005, provisional application No. 60/657,281, filed on Mar. 1, 2005, provisional application No. 60/657,268, filed on Mar. 1, 2005, provisional application No. 60/657,759, filed on Mar. 1, 2005.

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **600/300**; 600/323; 600/324

(58) **Field of Classification Search** ..... None
See application file for complete search history.

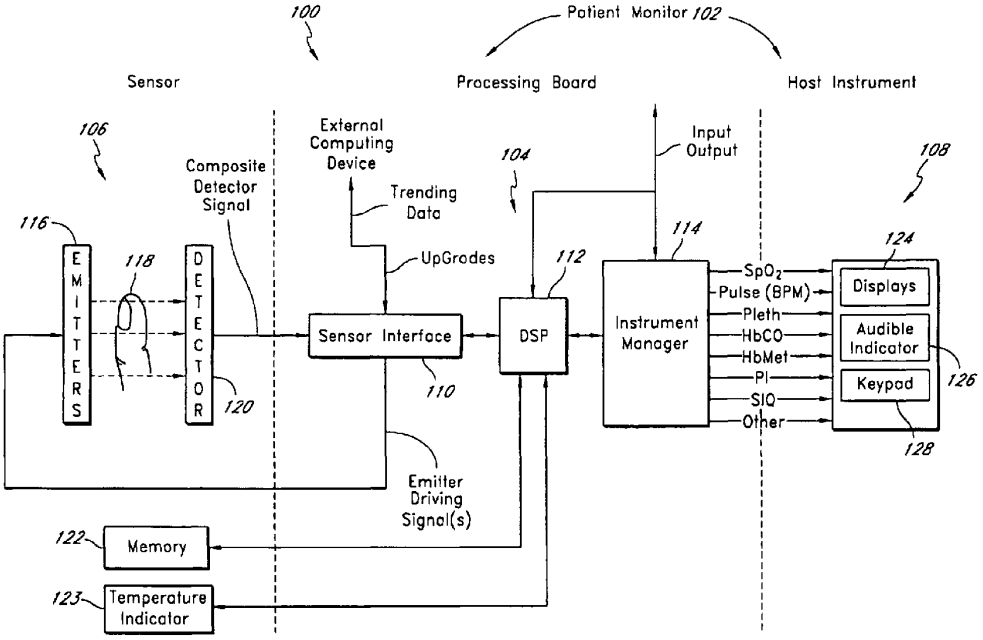
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 90/012,559, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner — Robert Nasser

(57) **ABSTRACT**

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.



APPLE 1020

EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **21-26** is confirmed.

Claims **1**, **3**, **7**, **13**, **15**, **18**, **27-28** and **45** are determined to be patentable as amended.

Claims **2**, **4-6**, **8-12**, **14**, **16-17**, **19-20**, **29-44** and **46-47**, dependent on an amended claim, are determined to be patentable.

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area **[**changes from displaying**]** *, the display of* one of the measured values of the first or second physiological parameter **[**to displaying**]** *is replaced with* the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

3. The patient monitor of claim **1**, wherein activation of a user input causes the common display area to **[**change from displaying**]** *replace* one of the measured value of the first or second physiological parameter **[**to displaying**]** *with* the other of the measured value of the first or second physiological parameter.

7. **[**The patient monitor of claim **1]** *A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient*, wherein the measured value of the first physiological parameter comprises glucose.

13. **[**The patient monitor of claim 11**]** *A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters*, wherein the aspect that changes comprises a display size.

15. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area **[**changes from displaying**]**, *the display of* one of the measured values of the first or second physiological parameters **[**to displaying**]** *is replaced with* the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area **[**changes from displaying**]**, *the display of* one of the measured values of the first or second physiological parameters **[**to displaying**]** *is replaced with* the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which **[**causes**]** *replaces* the display **[**to change from displaying**]** *of* the measured value of the first blood parameter **[**to displaying**]** *with* the measured value of the second blood parameter, wherein the display **[**also changes from displaying**]** *of* the measured value of the first blood parameter **[**to displaying**]** *is replaced by* the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a

noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

28. [The patient monitor of claim **27**] *A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:*

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,

wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

45. [The patient monitor of claim **27**] *A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:*

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,

wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

* * * * *

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/012,559	09/13/2012	8190223	403381US104RX	6710

20995 7590 03/05/2013

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
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EXAMINER	
NASSER, ROBERT L	
ART UNIT	**PAPER NUMBER**
3992	

MAIL DATE	DELIVERY MODE
03/05/2013	PAPER

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

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

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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Tia D. Fenton

OBLON, SPIVAK, ET AL.

1940 Duke Street

Alexandria, Virginia 22314

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/012,559*.

PATENT NO. *8190223*.

ART UNIT *3992*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

PTOL-465 (Rev.07-04)

Notice of Intent to Issue a Reexamination Certificate

A this action addresses amended claims 1-47 of US Patent 8,190,223 to Al-Ali et al (the '223 patent), for which a substantial new question of patentability was deemed to have been raised by the request for Ex Parte Reexamination, filed 9/13/2012. This action is being issued following Patent Owner's response of 1/28/2013.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

Claims 1-47 define over the art of record.

Claims 1-6, 8-12, 14-27, 29-44, all define over the art in that none of the art replaces the display of a first measured value with a second measured value when a change in the measurement of the second value indicates a worsening of the patient's condition. Al-Ali does not replace the first value, but switches from displaying the first value to displaying first and second values. The request asserts that while Al-Ali does not replace the value, this is nothing more than trivial and obvious substitution of design elements. The examiner disagrees, noting that there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. In addition, when an alarm condition is detected, Al-Ali switches from displaying one parameter to displaying all of the parameters to allow the user to better view the conditions that caused the alarm (see Al-Ali paragraph [0095]). As such, there would be no motivation to simply replace the first parameter with the second, as it would contradict the direct teaching in the reference of allowing the user to

see the entirety of the patient's condition. No other art of record teaches this feature. As such, claims 1-6, 8-12, 14-27, 29-44 define over the art of record.

Claim 7 defines over the art of record in that none of the art measures glucose and another parameter, and switches the display, as claimed. The request cites Lepper, which is an optical glucose measuring device. The request asserts that it would have been obvious to modify Al-Ali to measure glucose, as it is the substitution of one known measurement element for another. The examiner disagrees. Al-Ali is a multi-parameter device that measures oxygen status of a patient. The entire disclosure is directed to measuring oxygen status. While Lepper teaches that optical methods can measure glucose, the request has made no connection between glucose and oxygen status of a patient and provided no reasons why one would measure glucose in an oxygen status monitoring device. Therefore, at best, the art establishes that one of ordinary skill can measure glucose optically, but provides no motivation or rationale to measure glucose in the device of Al-Ali. No other art of record teaches this feature. As such, claim 7 defines over the art of record.

Claim 13 defines over the art of record in that none of the art changes the display size to indicate a change in the severity of the parameters. The request states that it would be a simple matter of design choice to change the size rather than the color. However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, based on the evidence presented in the request, claim 13 defines over the art of record.

Claim 28 defines over the art in that none of the art shifts a position of the display of the second parameter with respect to the first parameter. The request again proposes that this is

merely the trivial and obvious substitution of design elements. However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, based on the evidence presented in the request, claim 28 defines over Al-Ali alone, as presented in the request.

Claims 45-47 define over the art of record in that none of the art has the user activate a change for a predetermined duration with a first activation type and a undetermined duration with a second activation type. The request states that it would have been a matter of design choice to alter the length of display depending on the type of activation. However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, claims 45-47 define over the proposed combination.

Any comments considered necessary by PATENT OWNER regarding the above statement must be submitted promptly to avoid processing delays. Such submission by the patent owner should be labeled: "Comments on Statement of Reasons for Patentability and/or Confirmation" and will be placed in the reexamination file.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Fischer can be reached on 571 272-6779. 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.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3992

/FOF/
/Alexander J Kosowski/
Supervisory Patent Examiner, Art Unit 3992

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	90012559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
reviewed prosecution history of US Patent 8190223	10/11/2012	nasser
reviewed references of record	10/11/2012	nasser
reviewed references of record	11/15/2012	nasser
reviewed references of record	2/14/2013	nasser

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

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BIB DATA SHEET

CONFIRMATION NO. 6710

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
90/012,559	09/13/2012 RULE	600	3992	403381US104RX

APPLICANTS

8190223, Residence Not Provided;
CERCACOR LABORATORIES, INC.(OWNER), IRVINE, CA;
TIA D. FENTON(3RD.PTY.REQ.), ALEXANDRIA, VA;
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P., ALEXANDRIA, VA

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

This application is a REX of 11/367,033 03/01/2006 PAT 8,190,223
which claims benefit of 60/657,596 03/01/2005
and claims benefit of 60/657,281 03/01/2005
and claims benefit of 60/657,268 03/01/2005
and claims benefit of 60/657,759 03/01/2005

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

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

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /ROBERT L NASSER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
				47	5

ADDRESS

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614
UNITED STATES

TITLE

NONINVASIVE MULTI-PARAMETER PATIENT MONITOR

FILING FEE RECEIVED		
4694	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

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Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	90012559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

CPC		
Symbol	Type	Version

CPC Combination Sets				
Symbol	Type	Set	Ranking	Version

US ORIGINAL CLASSIFICATION		INTERNATIONAL CLASSIFICATION										
CLASS	SUBCLASS	CLAIMED					NON-CLAIMED					
600	300	A	6	1	B	5 / 00 (2006.01.01)						
CROSS REFERENCE(S)												
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)											
600	323	324										

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	47	
/ROBERT NASSER/ Primary Examiner.Art Unit 3992	02/14/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office — Part of Paper No. 20130214

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	90012559	8190223
	Examiner	**Art Unit**
	ROBERT NASSER	3992

NONE (Assistant Examiner)	(Date)	**Total Claims Allowed:** 47	
/ROBERT NASSER/ Primary Examiner.Art Unit 3992 (Primary Examiner)	02/14/2013 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

U.S. Patent and Trademark Office

Part of Paper No. 20130214

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	90012559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

☒ 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

NONE (Assistant Examiner)	(Date)	Total Claims Allowed: 47	
/ROBERT NASSER/ Primary Examiner.Art Unit 3992 (Primary Examiner)	02/14/2013 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

U.S. Patent and Trademark Office Part of Paper No. 20130214

Reexamination	**Application/Control No.**	**Applicant(s)/Patent Under Reexamination**
	90012559	8190223
	Certificate Date	**Certificate Number**
		C1

Requester Correspondence Address: ☐ **Patent Owner** ☒ **Third Party**
KNOBBE MARTENS OLSON & BEAR, LLP 2040 MAIN STREET, FOURTEENTH FLOOR IRVINE, CALIFORNIA 92614

LITIGATION REVIEW ☒	nasser (examiner initials)	02/14/2013 (date)
Case Name		Director Initials
none		

COPENDING OFFICE PROCEEDINGS	
TYPE OF PROCEEDING	**NUMBER**
1. none	

Notice of Intent to Issue Ex Parte Reexamination Certificate	Control No.	Patent Under Reexamination
	90/012,559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

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

1. ☒ Prosecution on the merits is (or remains) closed in this *ex parte* reexamination proceeding. This proceeding is subject to reopening at the initiative of the Office or upon petition. *Cf.* 37 CFR 1.313(a). A Certificate will be issued in view of
   (a) ☒ Patent owner's communication(s) filed: *28 January 2013*.
   (b) ☐ Patent owner's failure to file an appropriate timely response to the Office action mailed: _____.
   (c) ☐ Patent owner's failure to timely file an Appeal Brief (37 CFR 41.31).
   (d) ☐ The decision on appeal by the ☐ Board of Patent Appeals and Interferences ☐ Court dated _____
   (e) ☐ Other: _____.
2. The Reexamination Certificate will indicate the following:
   (a) Change in the Specification: ☐ Yes ☒ No
   (b) Change in the Drawing(s): ☐ Yes ☒ No
   (c) Status of the Claim(s):
      (1) Patent claim(s) confirmed: *21-26*.
      (2) Patent claim(s) amended (including dependent on amended claim(s)): *1-20 and 27-47*
      (3) Patent claim(s) canceled: _____.
      (4) Newly presented claim(s) patentable: _____.
      (5) Newly presented canceled claims: _____.
      (6) Patent claim(s) ☐ previously ☐ currently disclaimed: _____
      (7) Patent claim(s) not subject to reexamination: _____.
3. ☒ Note the attached statement of reasons for patentability and/or confirmation. Any comments considered necessary by patent owner regarding reasons for patentability and/or confirmation must be submitted promptly to avoid processing delays. Such submission(s) should be labeled: "Comments On Statement of Reasons for Patentability and/or Confirmation."
4. ☐ Note attached NOTICE OF REFERENCES CITED (PTO-892).
5. ☐ Note attached LIST OF REFERENCES CITED (PTO/SB/08 or PTO/SB/08 substitute).
6. ☐ The drawing correction request filed on _____ is: ☐ approved ☐ disapproved.
7. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   ☐ been received.
   ☐ not been received.
   ☐ been filed in Application No. _____.
   ☐ been filed in reexamination Control No. _____.
   ☐ been received by the International Bureau in PCT Application No. _____.

   * Certified copies not received: _____.
8. ☐ Note attached Examiner's Amendment.
9. ☐ Note attached Interview Summary (PTO-474).
10. ☐ Other: _____.

All correspondence relating to this reexamination proceeding should be directed to the **Central Reexamination Unit** at the mail, FAX, or hand-carry addresses given at the end of this Office action.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit: 3992

cc: Requester (if third party requester)

US008190223B2

(12) **United States Patent**
Al-Ali et al.

(10) **Patent No.: US 8,190,223 B2**
(45) **Date of Patent: May 29, 2012**

(54) **NONINVASIVE MULTI-PARAMETER PATIENT MONITOR**

(75) Inventors: **Ammar Al-Ali**, Tustin, CA (US); **Joe Kiani**, Laguna Niguel, CA (US); **Mohamed Diab**, Mission Viejo, CA (US); **Greg Olsen**, Irvine, CA (US); **Roger Wu**, Irvine, CA (US); **Rick Fishel**, Orange, CA (US)

(73) Assignee: **Masimo Laboratories, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1661 days.

(21) Appl. No.: **11/367,033**

(22) Filed: **Mar. 1, 2006**

(65) **Prior Publication Data**

US 2006/0226992 A1 Oct. 12, 2006

Related U.S. Application Data

(60) Provisional application No. 60/657,596, filed on Mar. 1, 2005, provisional application No. 60/657,281, filed on Mar. 1, 2005, provisional application No. 60/657,268, filed on Mar. 1, 2005, provisional application No. 60/657,759, filed on Mar. 1, 2005.

(51) **Int. Cl.**
A61B 5/1455 (2006.01)

(52) **U.S. Cl.** **600/310**; 600/323; 600/324; 600/326

(58) **Field of Classification Search** 600/309–344
See application file for complete search history.

(56) **References Cited**

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EP	0 569 670	2/1993
EP	0569670	11/1993

(Continued)

OTHER PUBLICATIONS

International Search Report for PCT/US2006/007516, mailed on Jan. 11, 2007, in 4 pages.

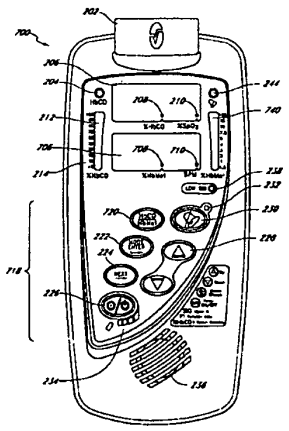
(Continued)

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(57) **ABSTRACT**

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.

47 Claims, 18 Drawing Sheets



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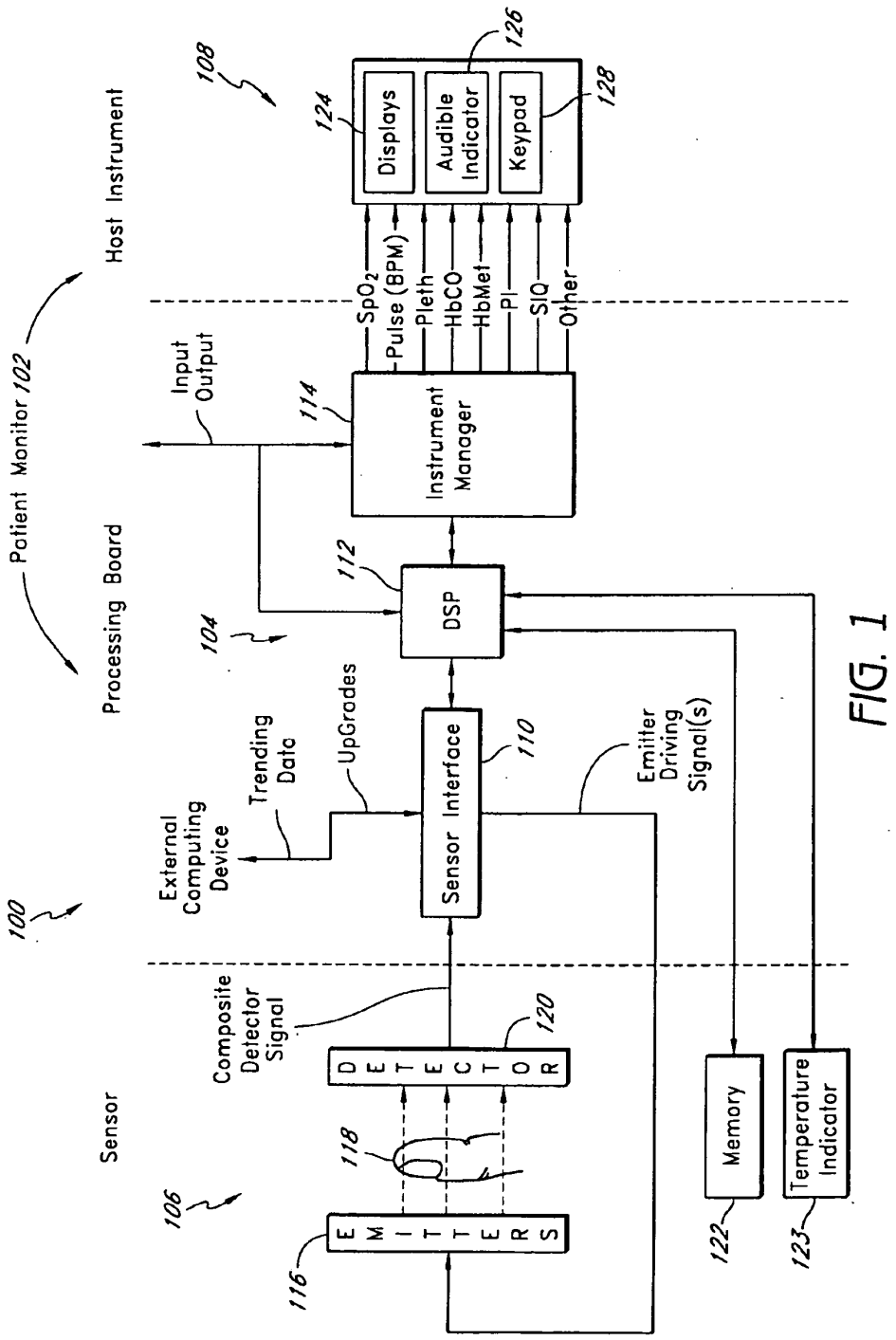

Patient Monitor 102
Host Instrument
Processing Board
Sensor
100
108
124
Displays
126
Audible Indicator
128
Keypad
SpO2
Pulse (BPM)
Pleth
HbCO
HbMet
PI
SIQ
Other
Input
Output
114
Instrument Manager
112
DSP
104
Trending Data
UpGrades
110
Sensor Interface
Emitter Driving Signal(s)
External Computing Device
Composite Detector Signal
120
DETECTOR
118
106
EMITTERS
116
Memory
122
Temperature Indicator
123

FIG. 1

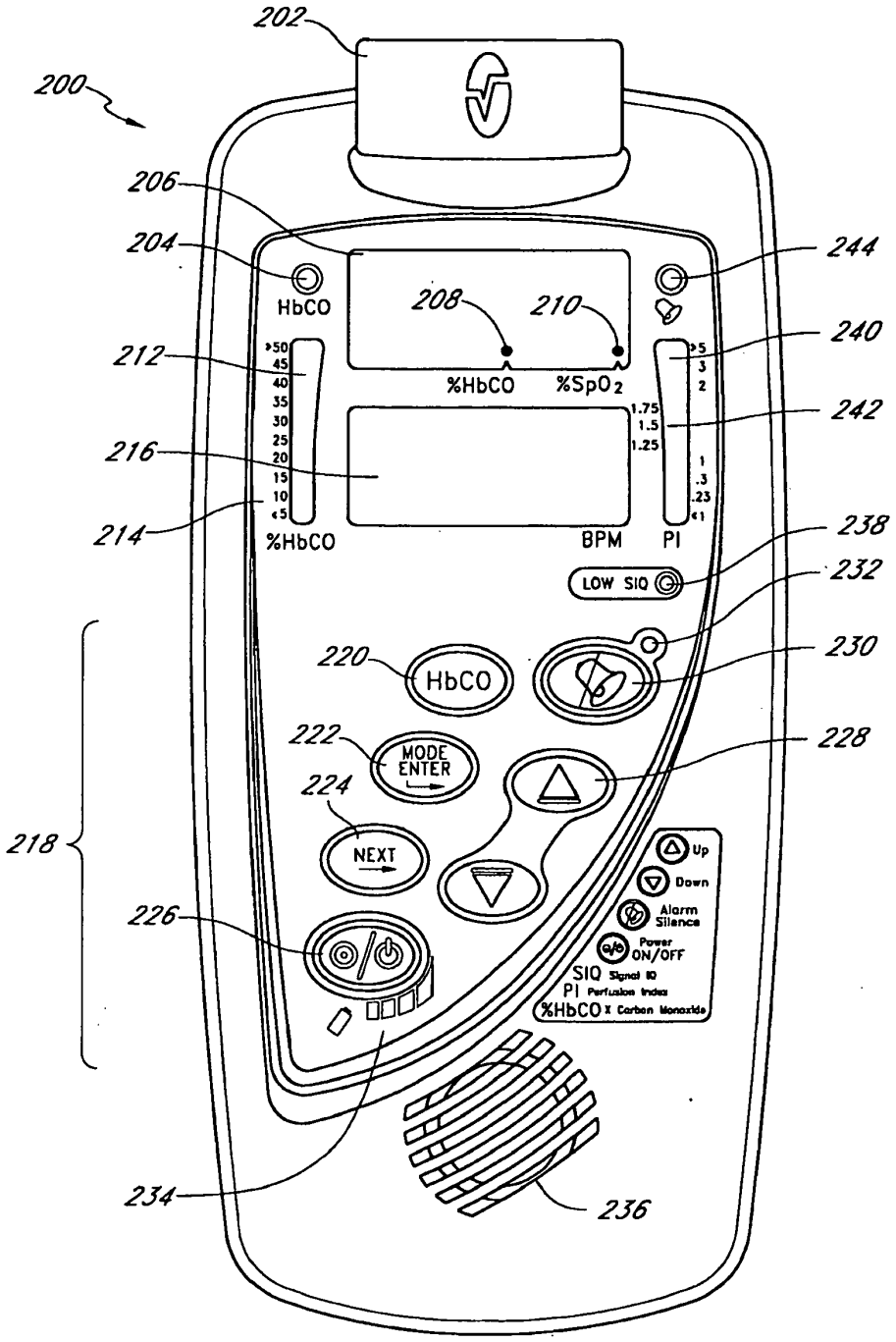

202
200
206
204
244
HbCO
208
210
240
212
%HbCO
%SpO2
242
216
BPM
PI
214
%HbCO
238
LOW SIQ
232
220
HbCO
230
222
MODE ENTER
228
224
NEXT
218
226
Up
Down
Alarm Silence
Power ON/OFF
SIQ Signal IQ
PI Perfusion Index
%HbCO Carbon Monoxide
234
236

FIG. 2

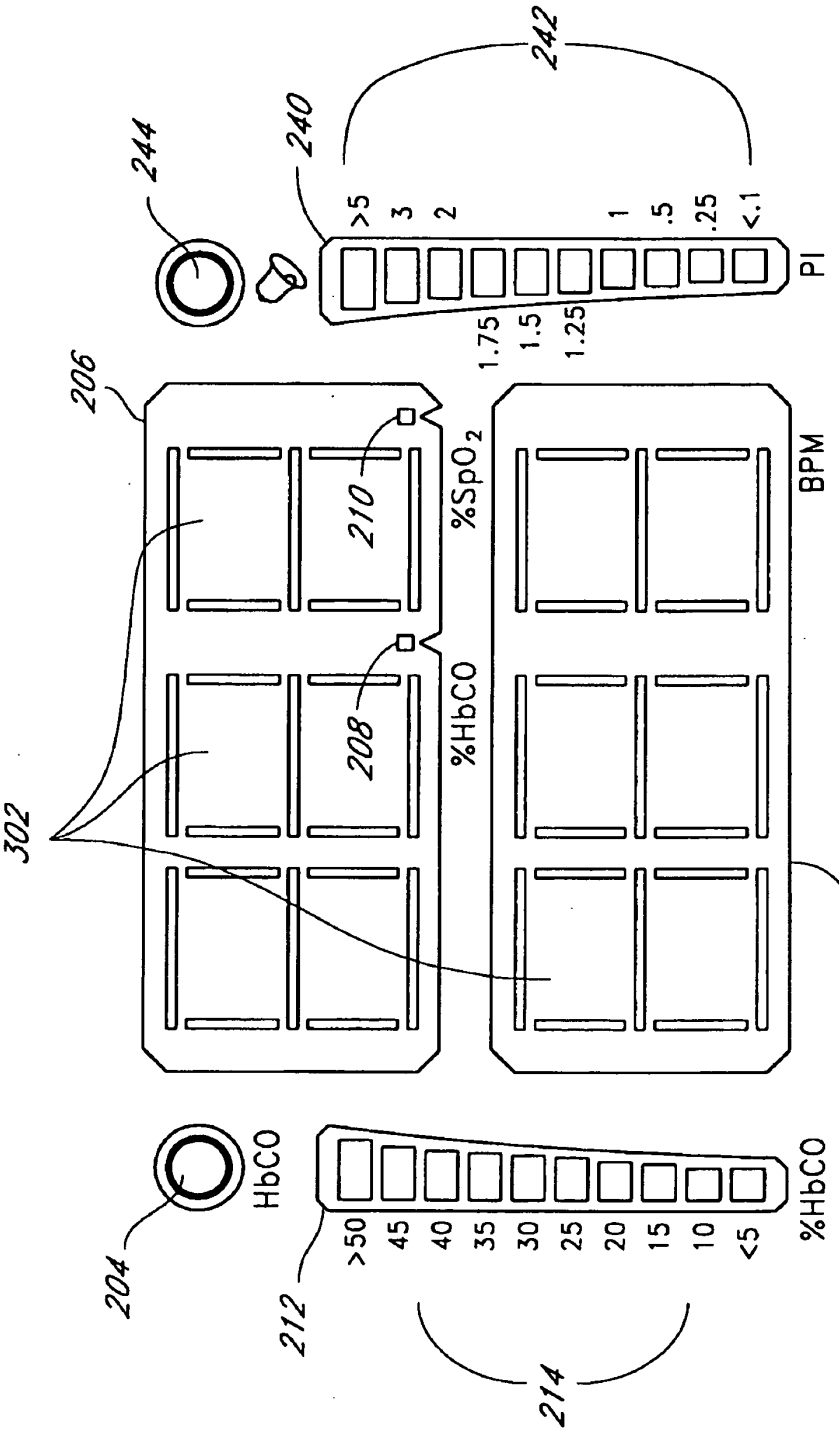

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240
244
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.5
.25
<.1
PI
1.75
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1.25
206
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BPM
208
%HbCO
302
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HbCO
%HbCO
204
212
>50
45
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35
30
25
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15
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<5
214

FIG. 3

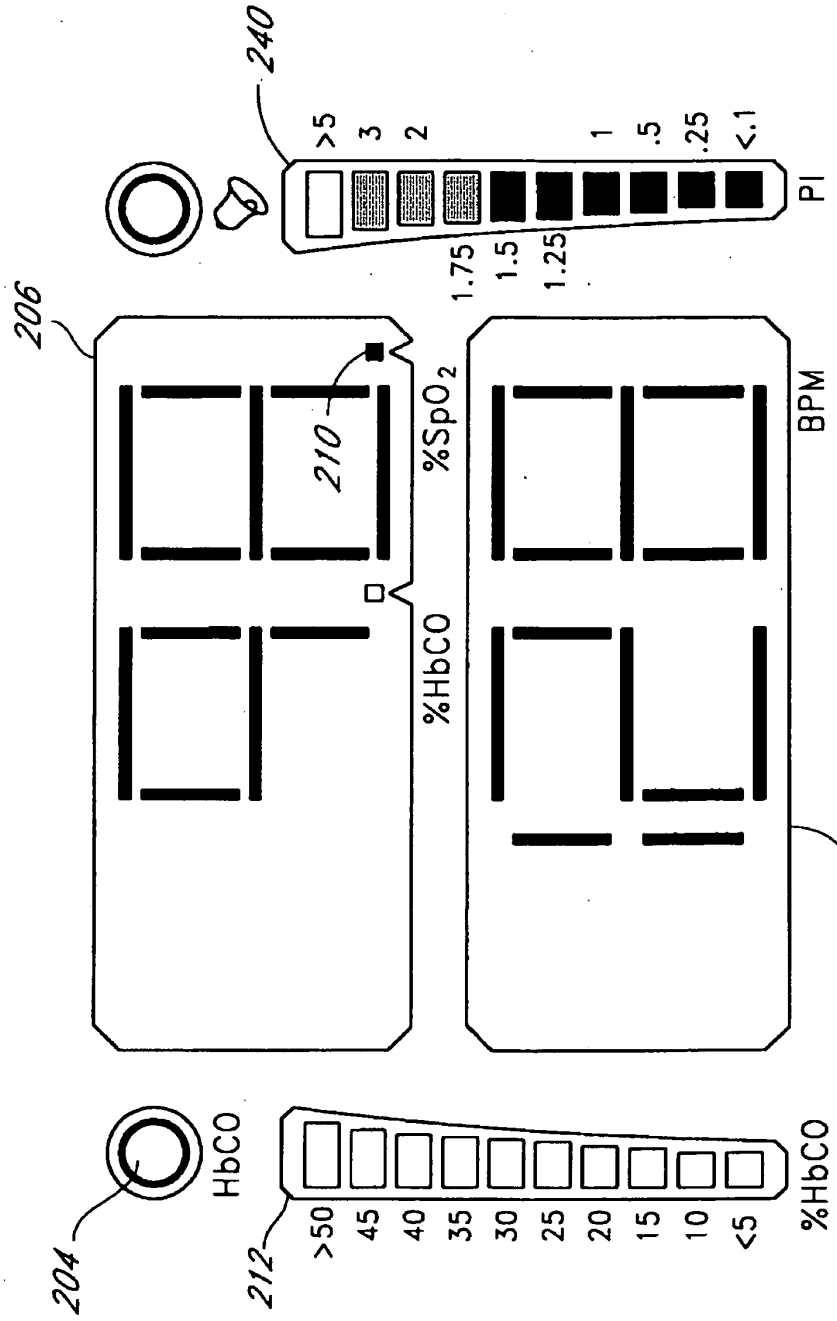

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<.1
PI
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1.5
1.25
206
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BPM
%HbCO
216
HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 4

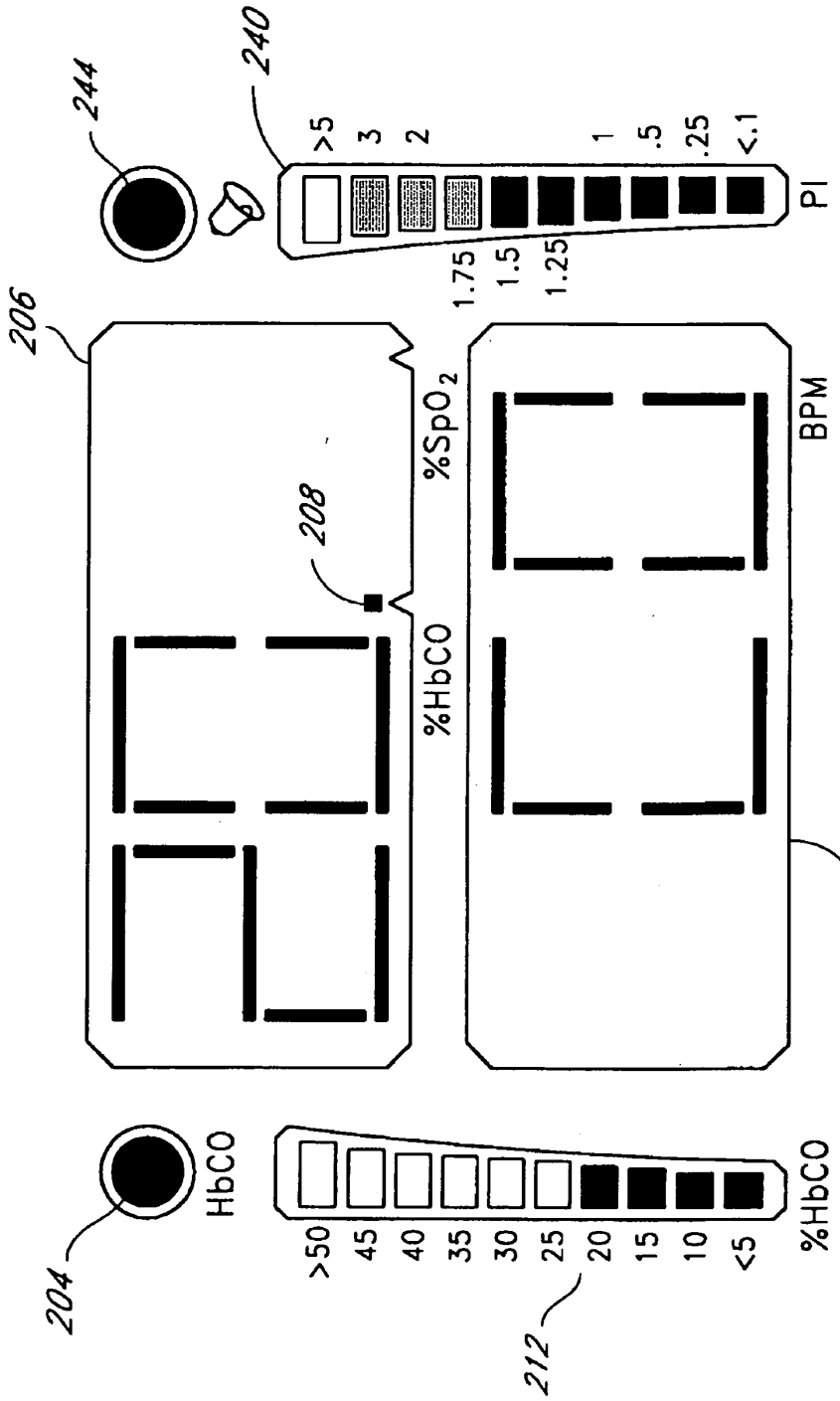

244
240
>5
3
2
1
.5
.25
<.1
PI
1.75
1.5
1.25
206
%SpO2
BPM
208
%HbCO
216
HbCO
204
>50
45
40
35
30
25
20
15
10
<5
%HbCO
212

FIG. 5

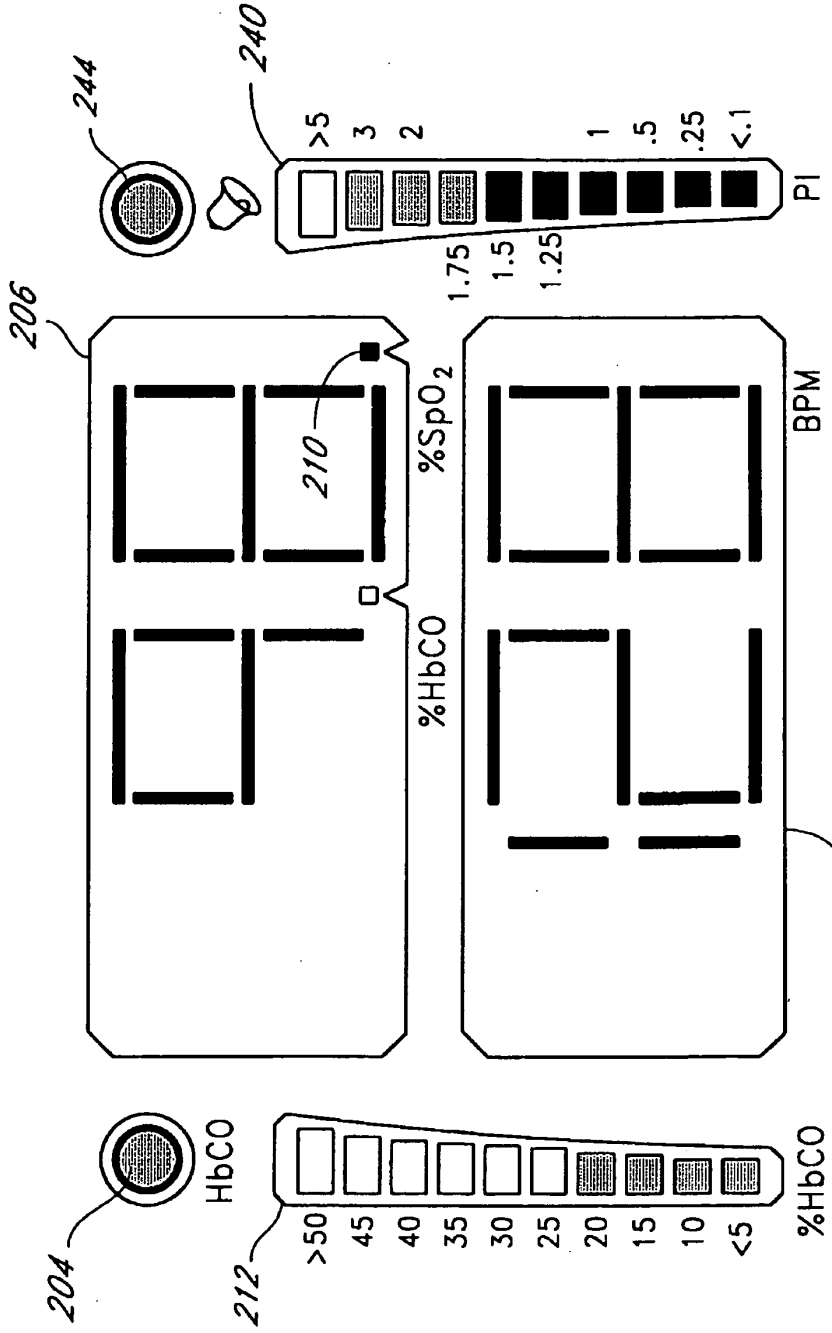

240
244
>5
3
2
1
.5
.25
<.1
PI
1.75
1.5
1.25
206
210
%SpO2
BPM
%HbCO
216
HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 6

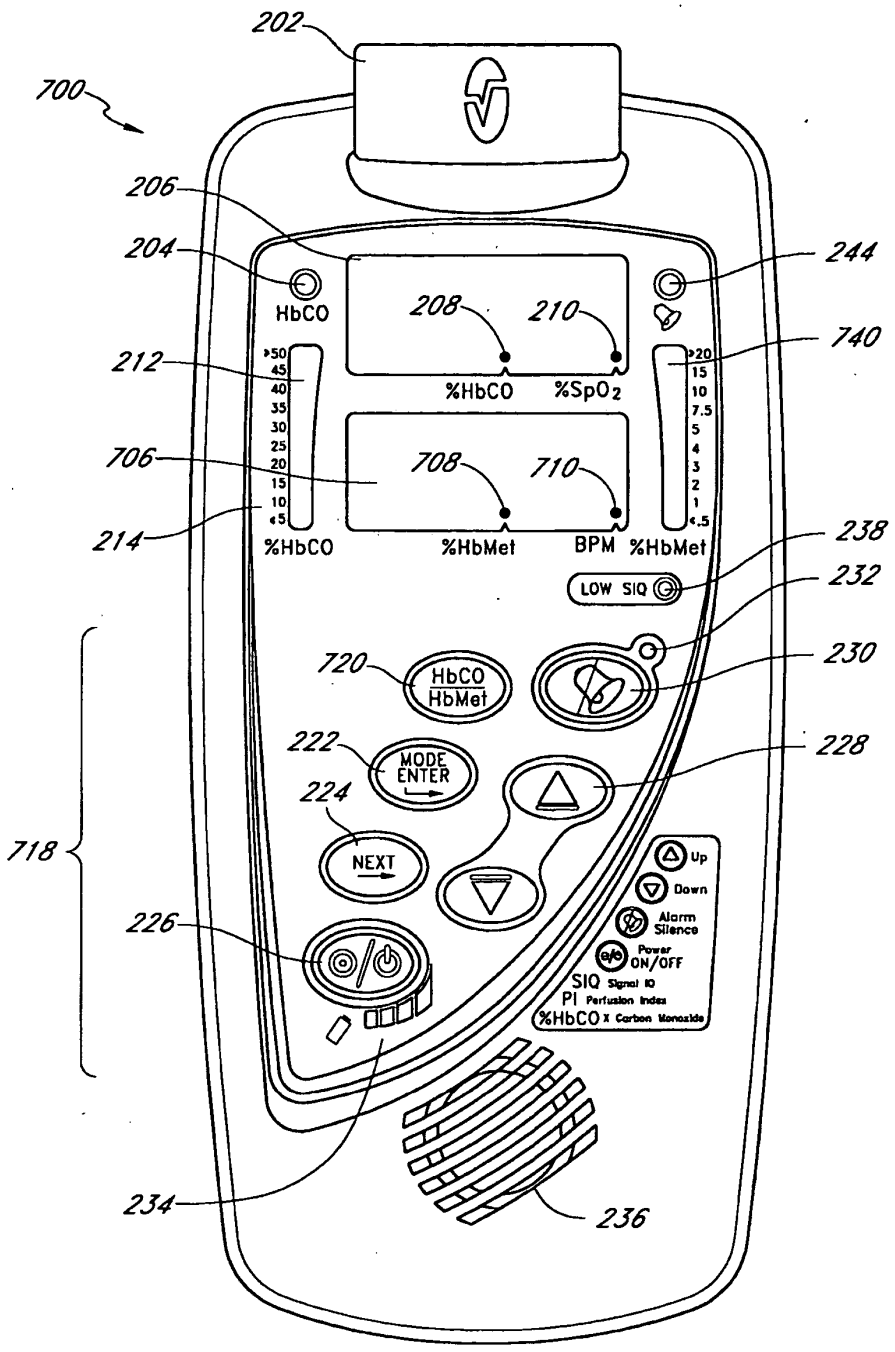

202
700
206
204
244
HbCO
208
210
740
212
%HbCO
%SpO2
706
708
710
214
%HbCO
%HbMet
BPM
%HbMet
238
LOW SIQ
232
720
HbCO
HbMet
230
222
MODE
ENTER
228
224
NEXT
718
Up
Down
Alarm
Silence
Power
ON/OFF
SIQ
PI
%HbCO
226
234
236

FIG. 7

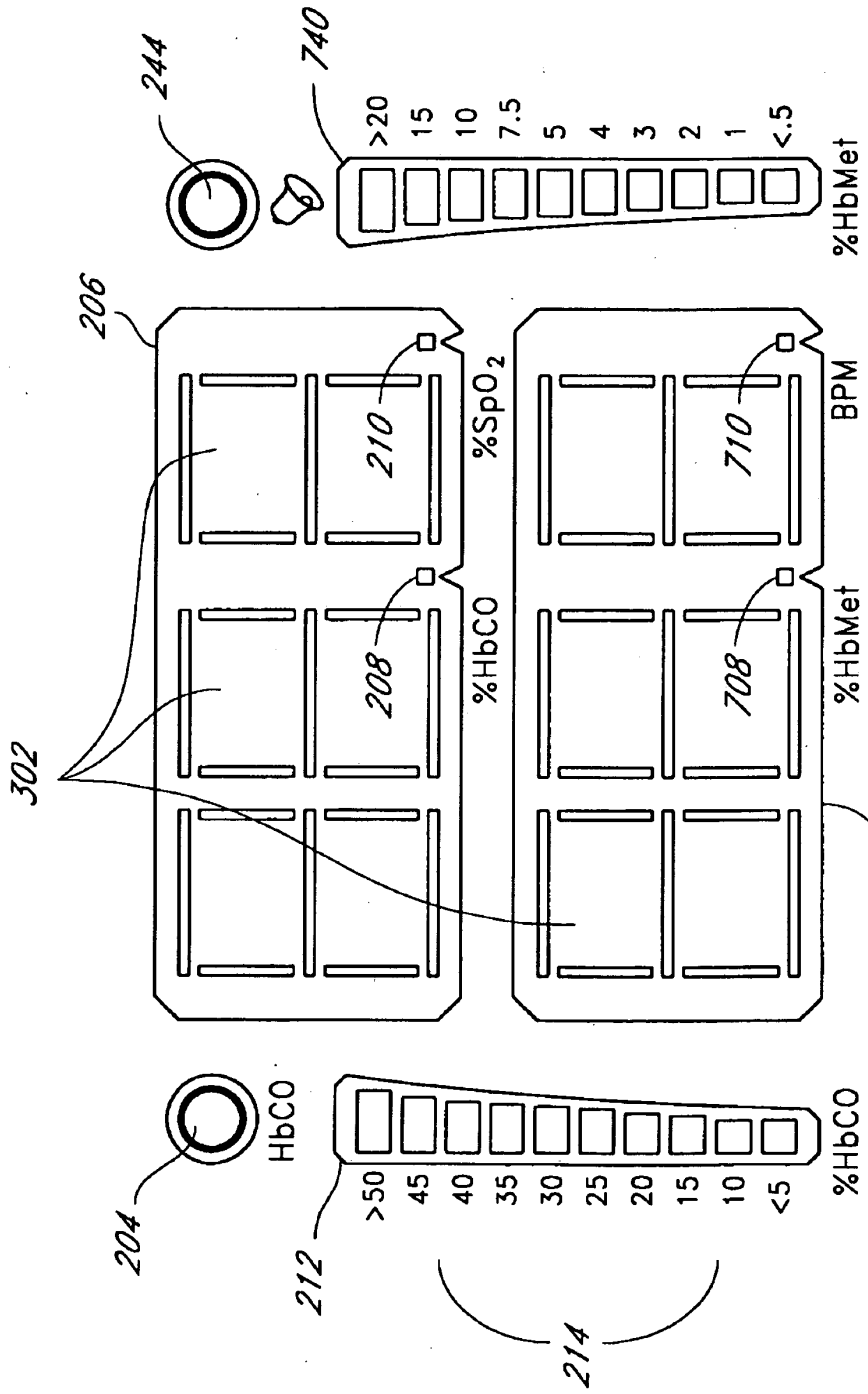

244
740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
710
BPM
208
%HbCO
708
%HbMet
302
706
HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO
214

FIG. 8

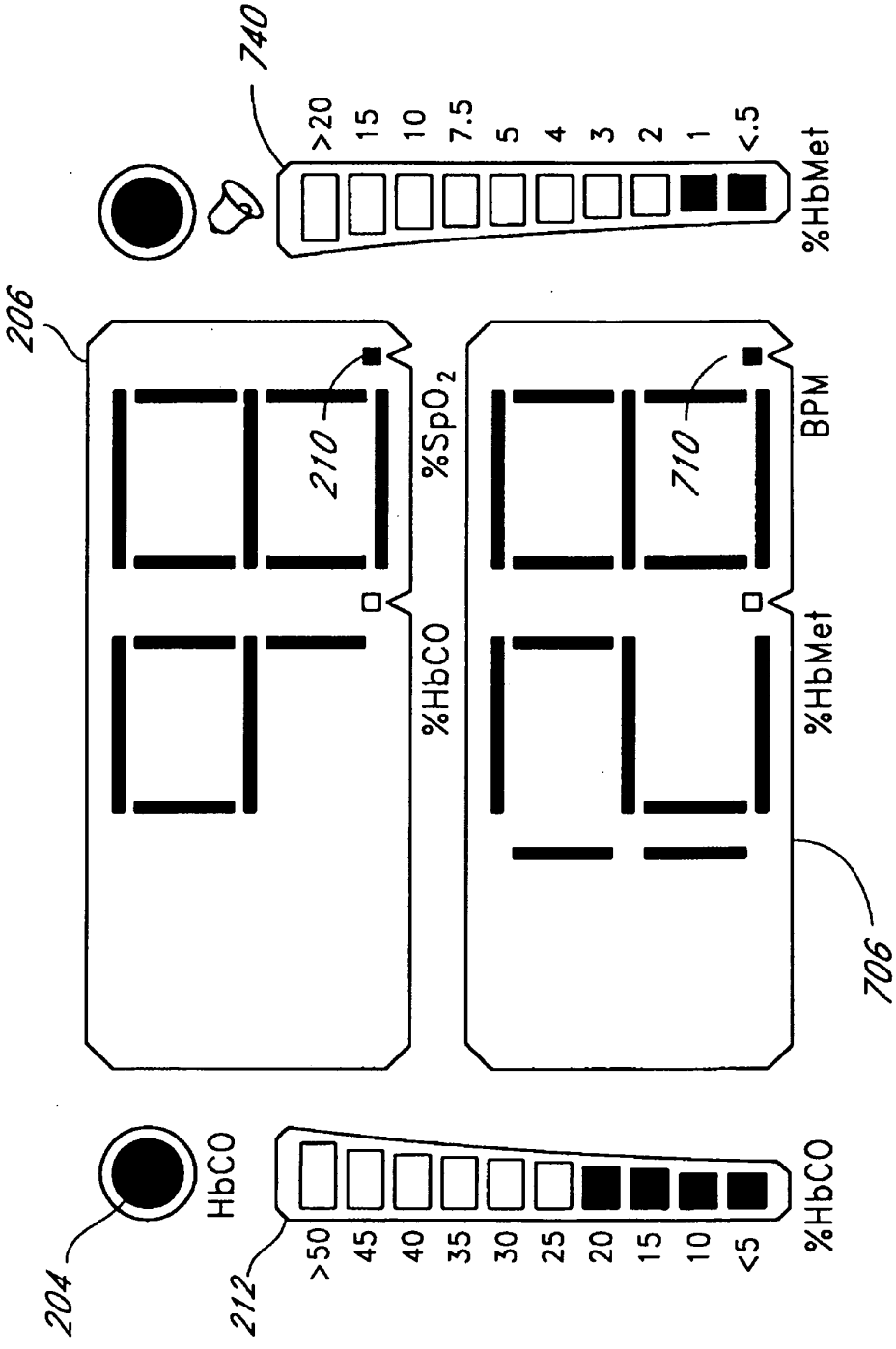

740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
%HbCO
710
BPM
%HbMet
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 9

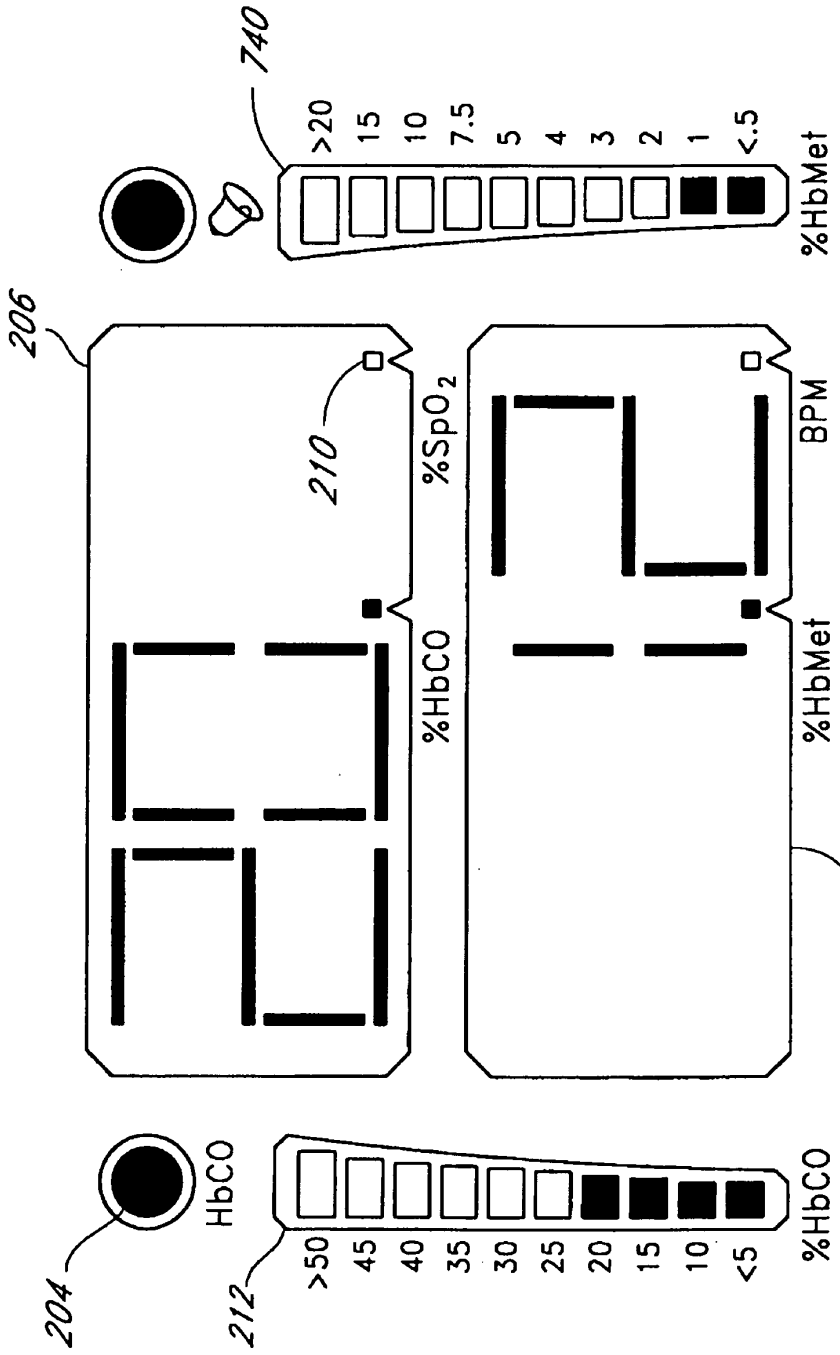

740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
%HbCO
BPM
%HbMet
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 10

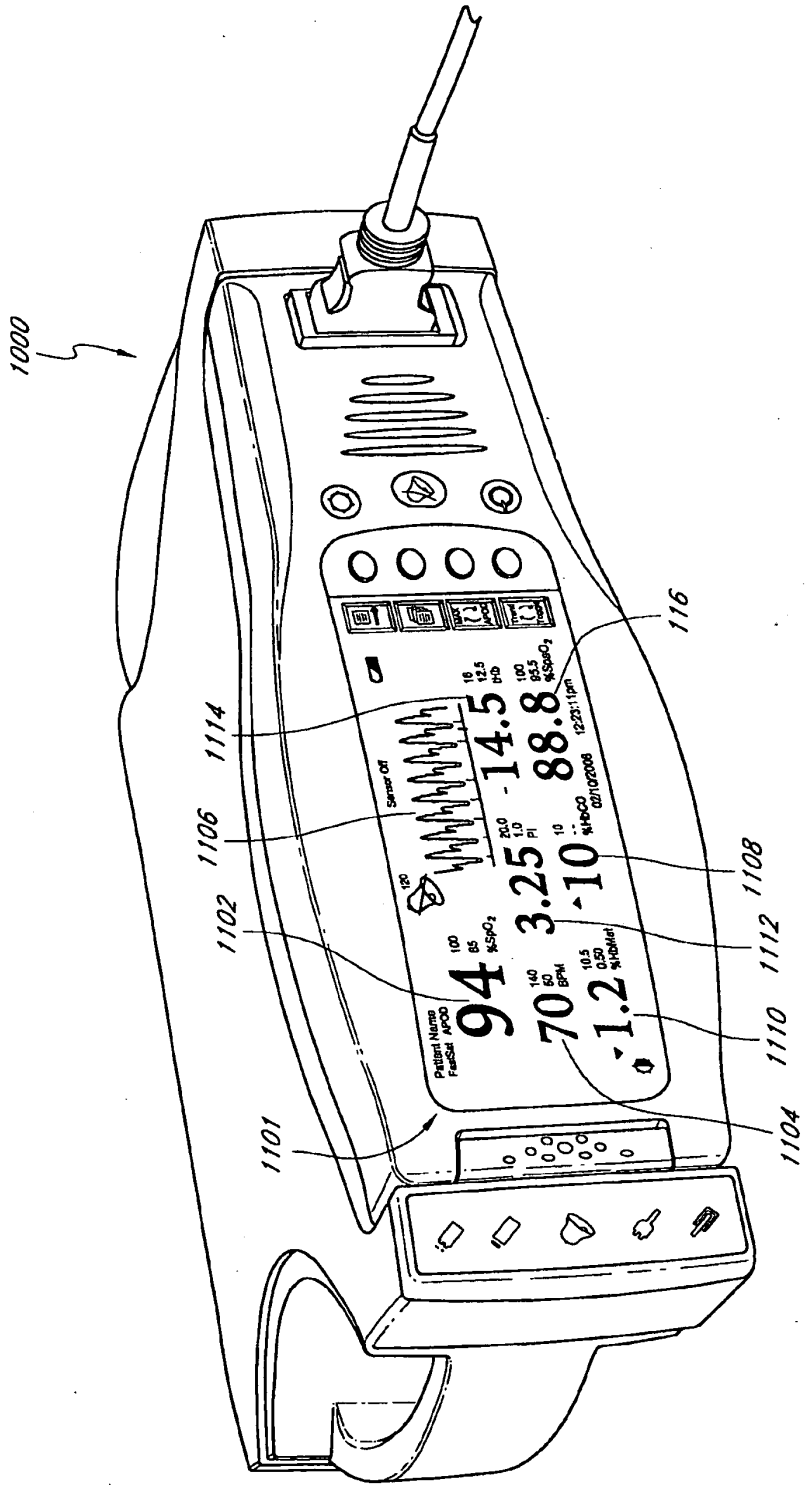

1000
1101
1102
1104
1106
1108
1110
1112
1114
116
94
70
3.25
-10
-14.5
88.8
-1.2

FIG. 11A

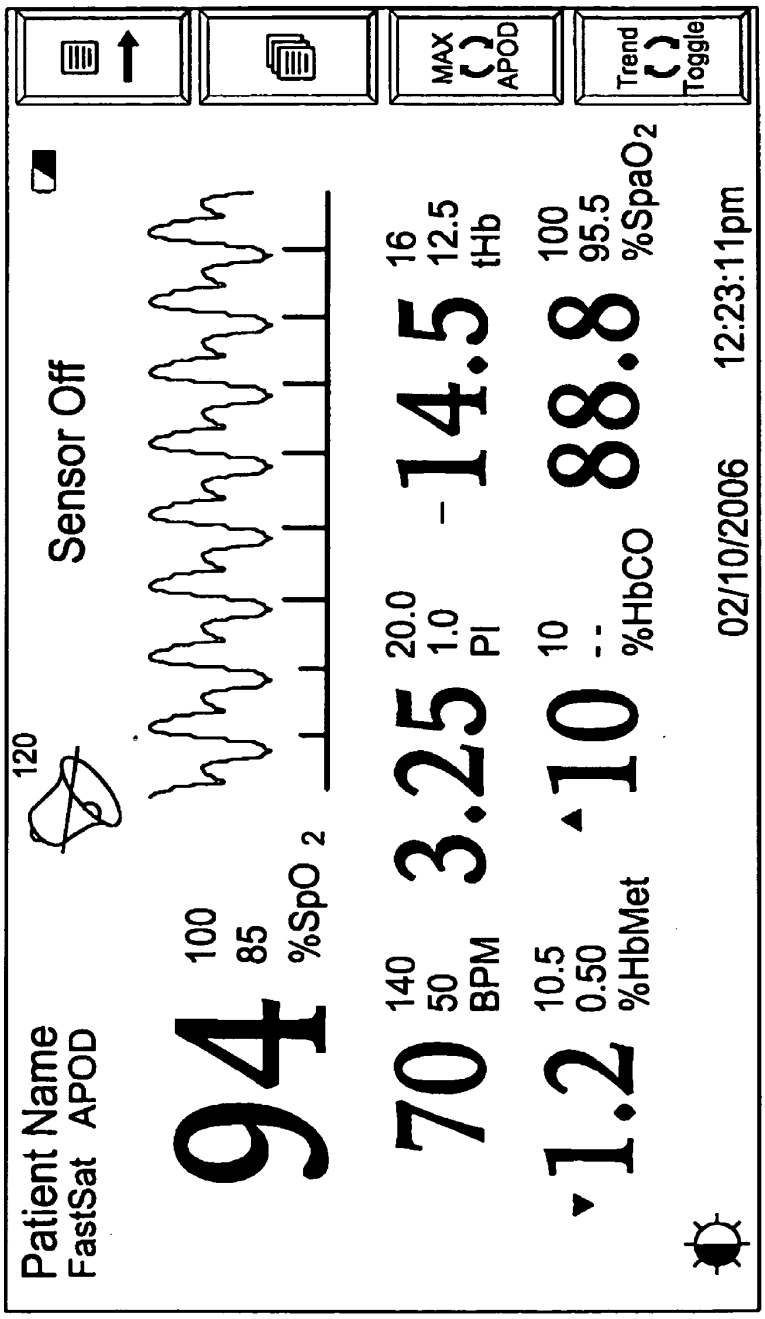

MAX APOD
Trend Toggle
Sensor Off
120
Patient Name
FastSat APOD
94
100
85
%SpO 2
70
140
50
BPM
3.25
20.0
1.0
PI
14.5
16
12.5
tHb
1.2
10.5
0.50
%HbMet
10
10
--
%HbCO
88.8
100
95.5
%SpaO2
02/10/2006
12:23:11pm

FIG. 11B

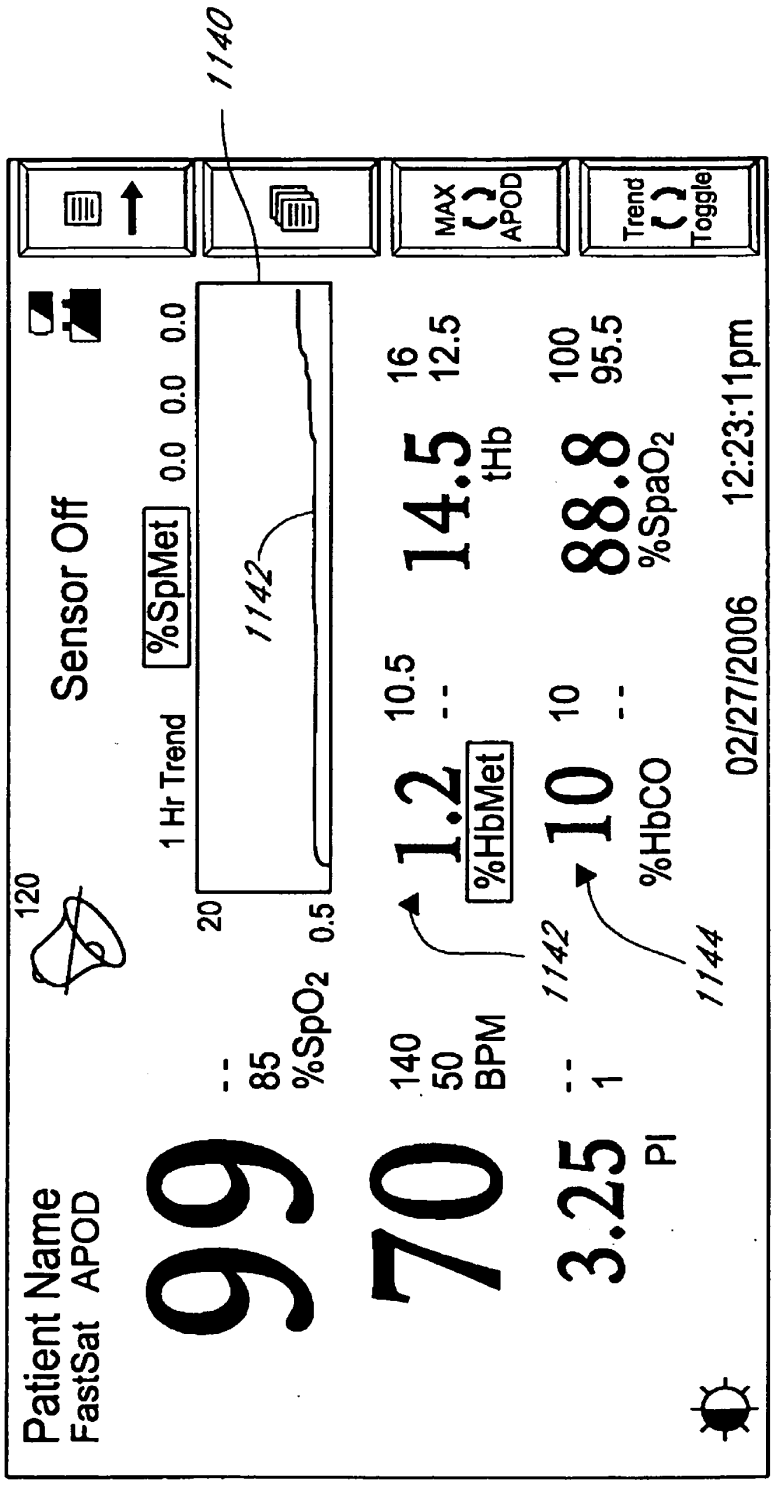

1140
MAX APOD
Trend Toggle
Sensor Off
1 Hr Trend
%SpMet
0.0 0.0 0.0
1142
20
0.5
120
Patient Name
FastSat APOD
99
-- 85
%SpO2
70
140 50
BPM
1.2
10.5 --
%HbMet
1142
3.25
-- 1
PI
10
10 --
%HbCO
1144
14.5
16 12.5
tHb
88.8
100 95.5
%SpaO2
02/27/2006
12:23:11pm

FIG. 11C

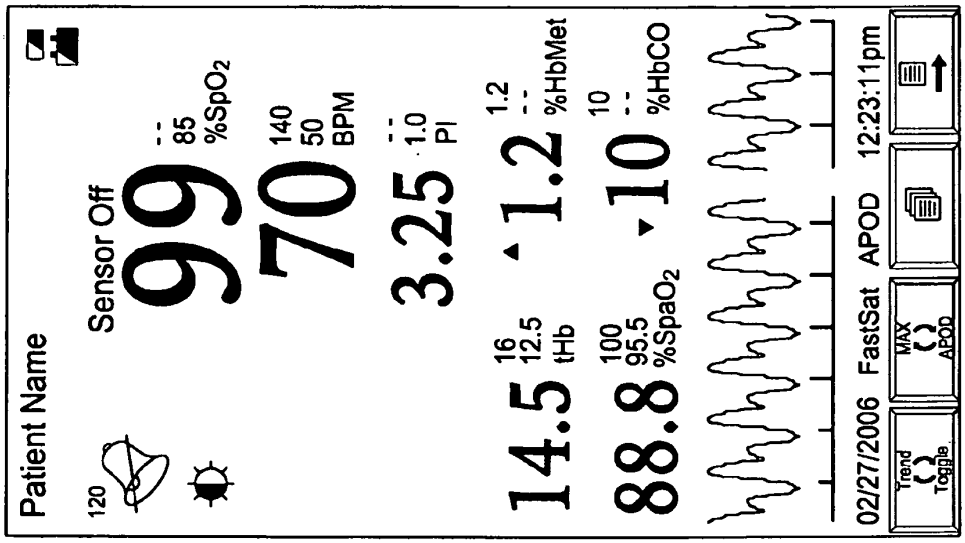

Patient Name
120
Sensor Off
99
85
%SpO2
70
140
50
BPM
3.25
1.0
PI
14.5
16
12.5
tHb
1.2
1.2
%HbMet
88.8
100
95.5
%SpaO2
10
10
%HbCO
02/27/2006
FastSat
APOD
12:23:11pm
Trend
Toggle
MAX
APOD

FIG. 11D

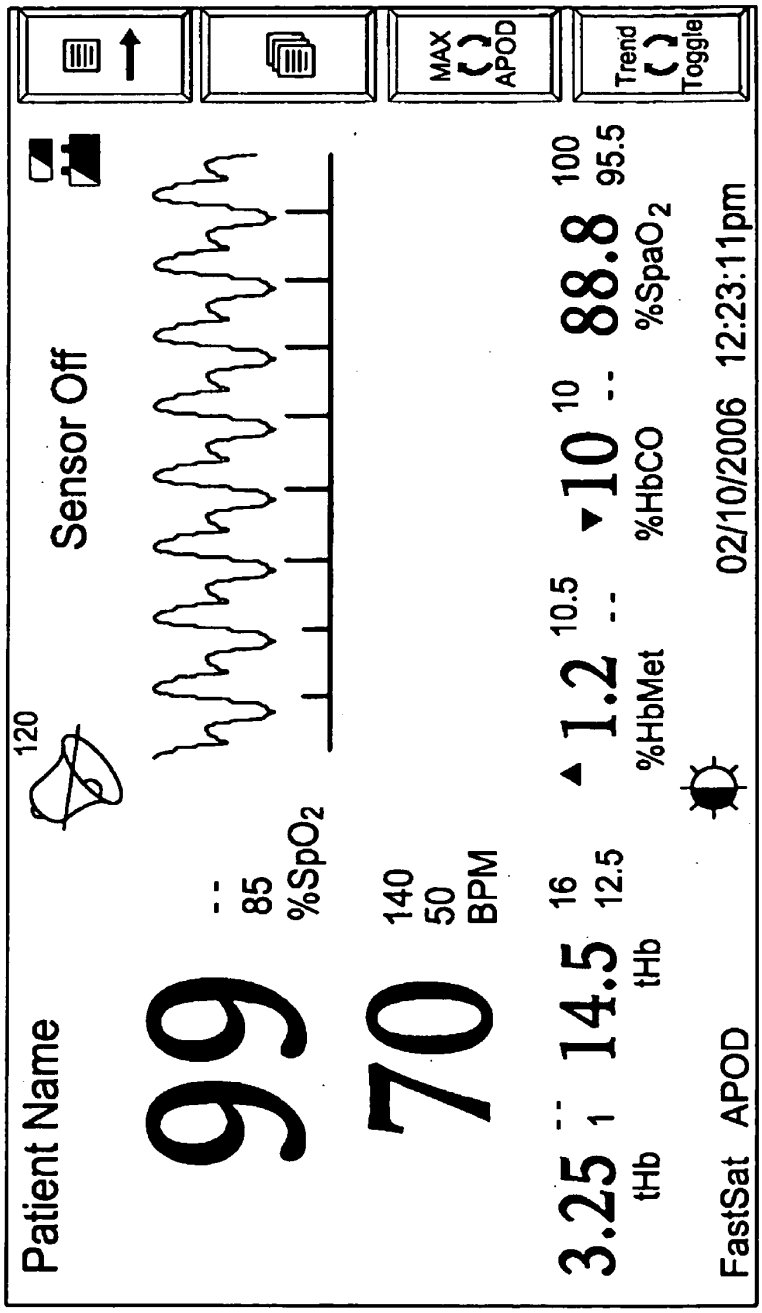

MAX APOD
Trend Toggle
Sensor Off
Patient Name
120
99
%SpO2
85
--
70
BPM
140
50
3.25
tHb
14.5
tHb
16
12.5
1.2
%HbMet
10.5
--
10
%HbCO
10
--
88.8
%SpaO2
100
95.5
02/10/2006 12:23:11pm
FastSat APOD

FIG. 11E

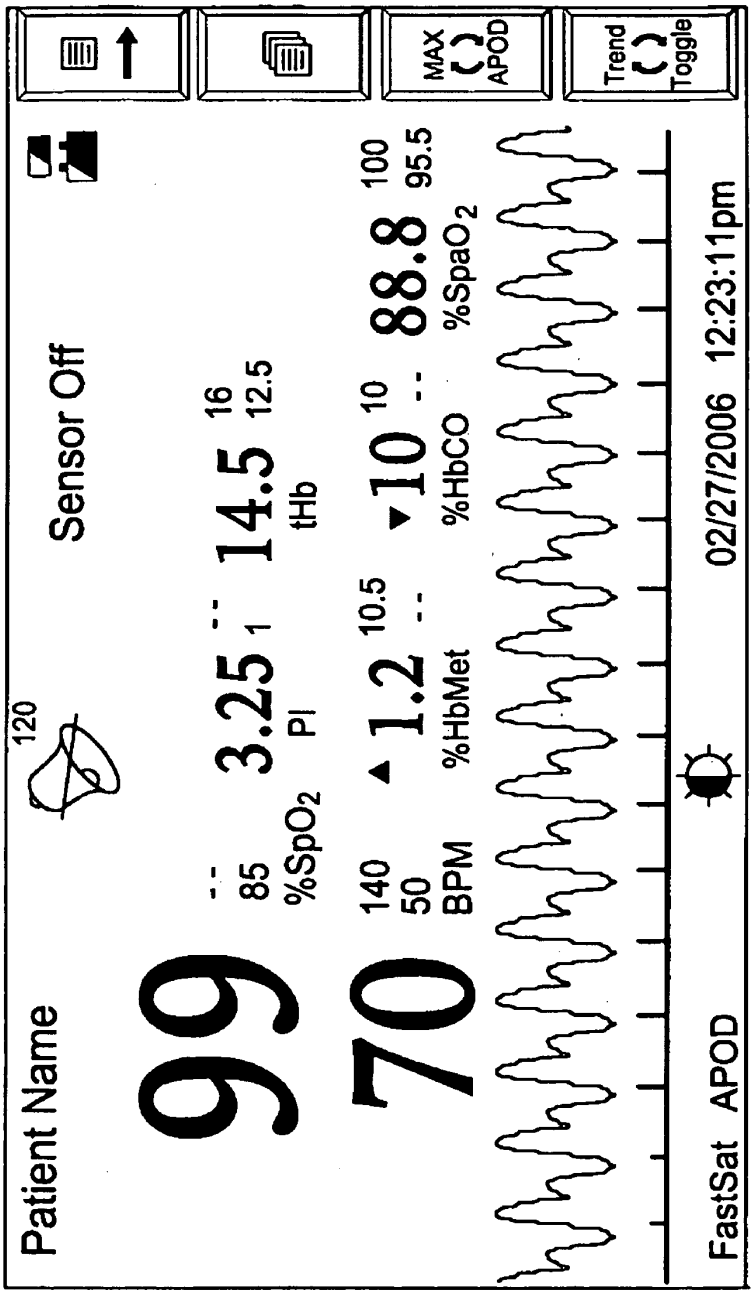

MAX APOD
Trend Toggle
Patient Name
120
Sensor Off
99
%SpO2
85
--
3.25
PI
1
--
14.5
tHb
16
12.5
70
BPM
140
50
1.2
%HbMet
10.5
--
10
%HbCO
10
--
88.8
%SpaO2
100
95.5
FastSat APOD
02/27/2006 12:23:11pm

FIG. 11F

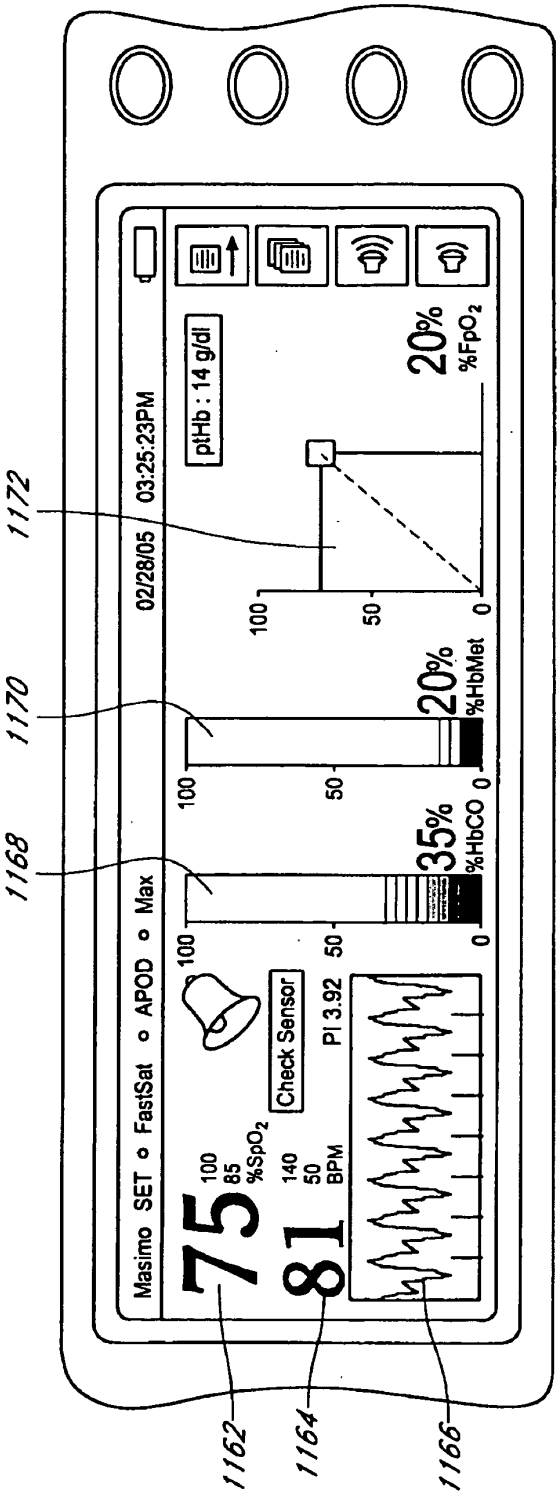

1172
1170
1168
1162
1164
1166
Masimo SET ○ FastSat ○ APOD ○ Max
02/28/05 03:25:23PM
ptHb : 14 g/dl
20% %FpO2
20% %HbMet
35% %HbCO
Check Sensor
PI 3.92
75
81
%SpO2
BPM

FIG. 11G

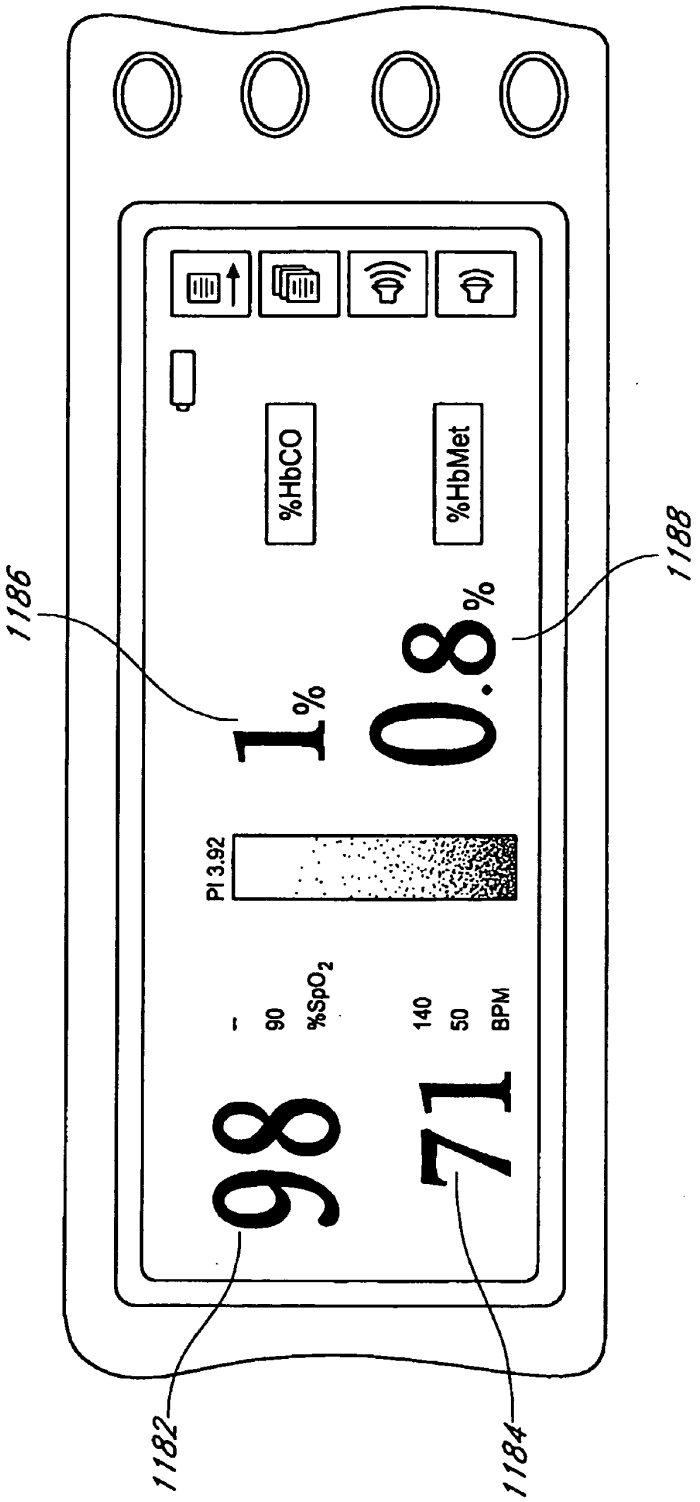

%HbCO
%HbMet
1%
0.8%
PI 3.92
90
%SpO2
98
140
50
BPM
71
1186
1188
1182
1184

FIG. 11H

NONINVASIVE MULTI-PARAMETER PATIENT MONITOR

PRIORITY CLAIM TO RELATED PROVISIONAL APPLICATIONS

The present application claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 60/657,596, filed Mar. 1, 2005, entitled "Multiple Wavelength Sensor," No. 60/657,281, filed Mar. 1, 2005, entitled "Physiological Parameter Confidence Measure," No. 60/657,268, filed Mar. 1, 2005, entitled "Configurable Physiological Measurement System," and No. 60/657,759, filed Mar. 1, 2005, entitled "Noninvasive Multi-Parameter Patient Monitor." The present application incorporates the foregoing disclosures herein by reference.

INCORPORATION BY REFERENCE OF RELATED UTILITY APPLICATIONS

The present application is related to the following copending U.S. utility applications:

	App. Sr. No.	Filing Date	Title	Atty Dock.
1	11/367,013	Mar. 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
2	11/366,995	Mar. 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/366,209	Mar. 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/366,210	Mar. 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/366,833	Mar. 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/366,997	Mar. 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/367,034	Mar. 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/367,036	Mar. 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/367,014	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
10	11/366,208	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

The present application incorporates the foregoing disclosures herein by reference.

FIELD OF THE DISCLOSURE

The present disclosure relates to the field of noninvasive patient monitors. More specifically, the disclosure relates to monitors displaying measurements derived using signals from optical sensors.

BACKGROUND

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ, the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{0,\lambda}} \quad (1)$$

$$\mu_{0,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{0,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve Equations 1-2 are the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2, pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785. Read which are owned by Masimo, and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY OF THE DISCLOSURE

Despite the success of read through motion oximeter systems, there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to SpO_2, plethysmograph waveforms, or pulse rates. For example, in accessing a patient's condition, caregivers often desire knowledge of other blood constituents, including for example, a percent value for arterial carbon monoxide saturation ("HbCO") or a percent value for methemogobin saturation ("HbMet") or the like. For example, in an embodiment, the display advantageously displays one or more of the following: pulse rate, plethysmograph waveform data, perfusion index, values of blood constituents in body tissue, including for example, HbCO, HbMet, total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In other embodiments, the monitor may advantageously and accurately determine values for one or more of HbO_2, Hb, blood glucose,

water, the presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide ("CO_2") or oxygen ("O"), ph levels, bilirubin, perfusion quality, signal quality or the like. Accordingly, the present disclosure includes a multi-parameter patient monitor capable of determining one or more of the foregoing parameters, other than or in addition to, SpO_2, plethysmograph waveforms, or perfusion quality index.

In an embodiment, the display of a noninvasive multi-parameter patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display area or real estate. In an embodiment, a user may cycle different parameter values through an area of the display common to both parameters even when one parameter is shifted, through, for example, actuation of a user input key. The patient monitor may also display different parameters as color-coded. For example, when the following measured parameters are within "normal" ranges, SpO_2 may be displayed red, pulse rate (BPM) may be displayed green, HbCO may be displayed orange, HbMet may be displayed blue, or the like. In an embodiment, measured values of SpO_2 may be displayed in white, BPM may be displayed in yellow green or aquamarine, PI™ may be displayed in violet, Hbt may be displayed in grass green, HbMet may be displayed in blue or light blue, HbCO may be displayed in orange, and $SpaO_2$ may be displayed in electric blue.

Moreover, parameter trend data may also be displayed using the same or similar color coding, especially when multiple trends are displayed on one or more display graphs. In addition, more coarse or gross parameter indications may be displayed for quick reference to indicate to a caregiver whether any of a variety of monitored parameters, such as, for example, SpO_2, HbCO or HbMet is within acceptable ranges. The monitor may advantageously include additional display information, such as, for example, parametric displays where one parameter is displayed as a function of another, three dimensional displays (for example, extending a parametric display along time or an additional parameter), directional indicators predicting where a parameter is likely heading or reporting a general direction a parameters has been trending, or the like.

In addition to the foregoing, caregivers often desire to more closely monitor parameters that are close to, approaching, or beyond normal safe thresholds. In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical monitored parameters. In alternative embodiments, the patient monitor automatically changes display modes to show parameters moving closer to or beyond normal thresholds.

In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the monitor may determine how many wavelengths a particular attached sensor will emit through communication with memory devices associated with the attached sensor or cable.

Additional embodiments include audio or visual alarms for each of multiple monitored parameters, combinations of parameters, an indication of perfusion in the tissue of the measurement site, an indication of the confidence the signal processing has in its output measurements, or the like.

For purposes of summarization, certain aspects, advantages and novel features are described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features need to be present in any particular embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings and the associated descriptions are provided to illustrate embodiments of the disclosure and not to limit the scope of the claims.

FIG. **1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system including a sensor and a multi-parameter patient monitor.

FIG. **2** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO, such as, for example, the patient monitor of FIG. **1**.

FIG. **3** illustrates an exemplary display of the patient monitor of FIG. **2**.

FIG. **4** illustrates the display of FIG. **3** showing measured values of SpO_2, BPM, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **5** illustrates the display of FIG. **3** showing measured values of HbCO, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **6** illustrates the display of FIG. **3** showing measured values of SpO_2, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. **1**.

FIG. **8** illustrates an exemplary display of the patient monitor of FIG. **7**.

FIG. **9** illustrates the display of FIG. **8** showing measured values of SpO_2, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **10** illustrates the display of FIG. **8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **11A** illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor such as, for example, the patient monitor of FIG. **1**.

FIGS. **11B-11H** illustrate display screens of the patient monitor of FIG. **11A**.

DETAILED DESCRIPTION OF PREFERRED AND ALTERNATIVE EMBODIMENTS

Embodiments of the present disclosure include a portable or other multi-parameter patient monitor capable of determining multiple physiological parameters from one or more signals output from one or more light sensitive detectors capable of detecting light attenuated by body tissue carrying pulsing blood. For example, in an embodiment, the monitor advantageously and accurately determines a wide variety of physiological parameters or other calculations as discussed above.

In an embodiment, the display of patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate. For example, the patient monitor may include one or more user input keys capable of toggling through measurement data. In an embodiment, the displays include mode indicators providing caregivers easily identifiable visual queues, such as LED's, text, icons, or other indicia providing readily identifiable queues as to which parameter is being displayed. In an embodiment, the display may shift, may be parameter color-coded, or the like to further ensure

quick comprehension of which measured parameter is the displayed parameter. For example, in an embodiment, the monitor displays SpO_2 in white, pulse rate (BPM) in green, HbCO in orange, and HbMet in blue when the respective measured parameter is within a "normal" range.

In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical or time sensitive measured parameters, specific caregiver selected parameters, or the like. For example, the patient monitor may advantageously sound audio or visual alarms that alert the caregiver to particular one or more of worsening parameters, parameters changing in a predetermined pattern or rate, parameters stabilizing below user defined or safe thresholds, caregiver selected parameters, or the like. The monitor may also use alerts that provide audio or visual indications of the severity of the condition, severity of the change, or the like. In alternative embodiments, the patient monitor may automatically change display modes when a particular parameter crosses one or more thresholds. For example, a patient monitor may be displaying a first parameter, such as a plethysmograph, and upon determining measurements indicating that HBMet is trending toward an alarm condition, the monitor may automatically switch from displaying the first parameter to the alarming parameter, or in this case, a trend of the alarming parameter.

In an embodiment, a switch is provided to allow a user to switch displays to view an alarming measurement. In an embodiment, during an alarm condition, a parameter display may switch to a trend graph in the same or different color, line weight, flash, flash rate, intensity, size, or the like.

The patient monitor may also include one or more displays capable of displaying trend data for any one or more of the monitored or derived patient parameters. For example, the trend data may be displayed in graph form, may include multiple trend lines, each representing a different monitored or derived patient parameter. Moreover, each trend line may be color-coded to facilitate quick comprehension of which trend line represents which measured parameter. However, an artisan will recognize from the disclosure herein a large number of identification techniques including color-coding, identifying text, or the like. Additionally, user input may toggle displayed trend data, may select which parameters to display simultaneously, or the like.

In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the patient monitor may provide a particular audio or visual indication, such as a beep, LED activation, graphic activation, text messages, voice messages, or the like, to indicate communication with or connection to an approved sensor, patient cable, combination, or the like. In an embodiment, the indication may change based on the manufacturer, type of sensor recognized or not recognized, type of patient, type of physiological parameters measurable with the attached sensor, or the like. Additional embodiments include an indication of perfusion in the tissue of the measurement site and an indication of the confidence the signal processing has in its output measurements or input signal quality.

To facilitate an understanding of the disclosure, the remainder of the description references exemplary embodiments illustrated in the drawings. Moreover, in this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported herein in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

FIG. **1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system **100**. As shown in FIG. **1**, the system **100** includes a patient monitor **102** comprising a processing board **104** and a host instrument **108**. The processing board **104** communicates with a sensor **106** to receive one or more intensity signal(s) indicative of one or more parameters of tissue of a patient. The processing board **104** also communicates with a host instrument **108** to display determined values calculated using the one or more intensity signals. According to an embodiment, the board **104** comprises processing circuitry arranged on one or more printed circuit boards capable of installation into the monitor **102**, or capable of being distributed as some or all of one or more OEM components for a wide variety of host instruments monitoring a wide variety of patient information. In an embodiment, the processing board **102** comprises a sensor interface **110**, a digital signal processor and signal extractor ("DSP" or "processor") **112**, and an instrument manager **114**. In general, the sensor interface **110** converts digital control signals into analog drive signals capable of driving sensor emitters, and converts composite analog intensity signal(s) from light sensitive detectors into digital data.

In an embodiment, the sensor interface **110** manages communication with external computing devices. For example, in an embodiment, a multipurpose sensor port (or input/output port) is capable of connecting to the sensor **106** or alternatively connecting to a computing device, such as a personal computer, a PDA, additional monitoring equipment or networks, or the like. When connected to the computing device, the processing board **104** may upload various stored data for, for example, off-line analysis and diagnosis. The stored data may comprise trend data for any one or more of the measured parameter data, plethysmograph waveform data acoustic sound waveform, or the like. Moreover, the processing board **104** may advantageously download from the computing device various upgrades or executable programs, may perform diagnosis on the hardware or software of the monitor **102**. In addition, the processing board **104** may advantageously be used to view and examine patient data, including raw data, at or away from a monitoring site, through data uploads/downloads, or network connections, combinations, or the like, such as for customer support purposes including software maintenance, customer technical support, and the like. Upgradable sensor ports are disclosed in copending U.S. application Ser. No. 10/898,680, filed on Jul. 23, 2004, titled "Multipurpose Sensor Port," incorporated by reference herein.

As shown in FIG. **1**, the digital data is output to the DSP **112**. According to an embodiment, the DSP **112** comprises a processing device based on the Super Harvard ARChitecture ("SHARC"), such as those commercially available from Analog Devices. However, a skilled artisan will recognize from the disclosure herein that the DSP **112** can comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In particular, the DSP **112** includes program instructions capable of receiving multiple channels of data related to one or more intensity signals representative of the absorption (from transmissive or reflective sensor systems) of

a plurality of wavelengths of emitted light by body tissue. In an embodiment, the DSP **112** accepts data related to the absorption of eight (8) wavelengths of light, although an artisan will recognize from the disclosure herein that the data can be related to the absorption of two (2) to sixteen (16) or more wavelengths.

FIG. **1** also shows the processing board **104** including the instrument manager **114**. According to an embodiment, the instrument manager **114** may comprise one or more microcontrollers controlling system management, including, for example, communications of calculated parameter data and the like to the host instrument **108**. The instrument manager **114** may also act as a watchdog circuit by, for example, monitoring the activity of the DSP **112** and resetting it when appropriate.

The sensor **106** may comprise a reusable clip-type sensor, a disposable adhesive-type sensor, a combination sensor having reusable and disposable components, or the like. Moreover, an artisan will recognize from the disclosure herein that the sensor **106** can also comprise mechanical structures, adhesive or other tape structures, Velcro wraps or combination structures specialized for the type of patient, type of monitoring, type of monitor, or the like. In an embodiment, the sensor **106** provides data to the board **104** and vice versa through, for example, a patient cable. An artisan will also recognize from the disclosure herein that such communication can be wireless, over public or private networks or computing systems or devices, or the like.

As shown in FIG. **1**, the sensor **106** includes a plurality of emitters **116** irradiating the body tissue **118** with differing wavelengths of light, and one or more detectors **120** capable of detecting the light after attenuation by the tissue **118**. In an embodiment, the emitters **116** comprise a matrix of eight (8) emission devices mounted on a flexible substrate, the emission devices being capable of emitting eight (8) differing wavelengths of light. In other embodiments, the emitters **116** may comprise twelve (12) or sixteen (16) emitters, although other numbers of emitters are contemplated, including two (2) or more emitters. As shown in FIG. **1**, the sensor **106** may include other electrical components such as, for example, a memory device **122** comprising an EPROM, EEPROM, ROM, RAM, microcontroller, combinations of the same, or the like. In an embodiment, other sensor components may include a temperature determination device **123** or other mechanisms for, for example, determining real-time emission wavelengths of the emitters **116**.

The memory **122** may advantageous store some or all of a wide variety data and information, including, for example, information on the type or operation of the sensor **106**; type or identification of sensor buyer or distributor or groups of buyer or distributors, sensor manufacturer information, sensor characteristics including the number of emitting devices, the number of emission wavelengths, data relating to emission centroids, data relating to a change in emission characteristics based on varying temperature, history of the sensor temperature, current, or voltage, emitter specifications, emitter drive requirements, demodulation data, calculation mode data, the parameters for which the sensor is capable of supplying sufficient measurement data (e.g., HpCO, HpMet, HbT, or the like), calibration or parameter coefficient data, software such as scripts, executable code, or the like, sensor electronic elements, whether the sensor is a disposable, reusable, multisite, partially reusable, partially disposable sensor, whether it is an adhesive or non-adhesive sensor, whether the sensor is a reflectance, transmittance, or transreflectance sensor, whether the sensor is a finger, hand, foot, forehead, or ear sensor, whether the sensor is a stereo sensor or a two-headed sensor, sensor life data indicating whether some or all sensor components have expired and should be replaced, encryption information, keys, indexes to keys or hash functions, or the like, monitor or algorithm upgrade instructions or data, some or all of parameter equations, information about the patient, age, sex, medications, and other information that may be useful for the accuracy or alarm settings and sensitivities, trend history, alarm history, or the like. In an embodiment, the monitor may advantageously store data on the memory device, including, for example, measured trending data for any number of parameters for any number of patients, or the like, sensor use or expiration calculations, sensor history, or the like.

FIG. **1** also shows the patient monitor **102** including the host instrument **108**. In an embodiment, the host instrument **108** communicates with the board **104** to receive signals indicative of the physiological parameter information calculated by the DSP **112**. The host instrument **108** preferably includes one or more display devices **124** capable of displaying indicia representative of the calculated physiological parameters of the tissue **118** at the measurement site. In an embodiment, the host instrument **108** may advantageously comprise a handheld housing capable of displaying one or more of a pulse rate, plethysmograph data, perfusion quality such as a perfusion quality index ("PI™"), signal or measurement quality ("SQ"), values of blood constituents in body tissue, including for example, SpO_2, HbCO, HbMet, Hbt, or the like. In other embodiments, the host instrument **108** is capable of displaying values for one or more of Hbt, Hb, blood glucose, bilirubin, or the like. The host instrument **108** may be capable of storing or displaying historical or trending data related to one or more of the measured values, combinations of the measured values, plethysmograph data, or the like. The host instrument **108** also includes an audio indicator **126** and user input device **128**, such as, for example, a keypad, touch screen, pointing device, voice recognition device, or the like.

In still additional embodiments, the host instrument **108** includes audio or visual alarms that alert caregivers that one or more physiological parameters are falling below predetermined safe thresholds. The host instrument **108** may include indications of the confidence a caregiver should have in the displayed data. In a further embodiment, the host instrument **108** may advantageously include circuitry capable of determining the expiration or overuse of components of the sensor **106**, including, for example, reusable elements, disposable elements, or combinations of the same.

Although described in terms of certain embodiments, other embodiments or combination of embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **102** may comprise one or more monitoring systems monitoring parameters, such as, for example, vital signs, blood pressure, ECG or EKG, respiration, glucose, bilirubin, or the like. Such systems may combine other information with intensity-derived information to influence diagnosis or device operation. Moreover, the monitor **102** may advantageously include an audio system, preferably comprising a high quality audio processor and high quality speakers to provide for voiced alarms, messaging, or the like. In an embodiment, the monitor **102** may advantageously include an audio out jack, conventional audio jacks, headphone jacks, or the like, such that any of the display information disclosed herein may be audiblized for a listener. For example, the monitor **102** may include an audible transducer input (such as a microphone, piezoelectric sensor, or the like) for collecting one or more of heart sounds, lung sounds, trachea sounds, or other body sounds and such

sounds may be reproduced through the audio system and output from the monitor **102**. Also, wired or wireless communications (such as Bluetooth or WiFi, including IEEE 801.11a, b, or g), mobile communications, combinations of the same, or the like, may be used to transmit the audio output to other audio transducers separate from the monitor **102**.

For example, patterns or changes in the continuous noninvasive monitoring of intensity-derived information may cause the activation of other vital sign measurement devices, such as, for example, blood pressure cuffs.

FIG. **2** illustrates a perspective view of an exemplary handheld noninvasive multi-parameter patient monitor **200**, such as, for example, the patient monitor **102** of FIG. **2**. Patient monitors **200** exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57c." As shown in FIG. **1**, the monitor **200** includes a patient cable connector **202** capable of mechanical mating with a patient cable to establish communication between the board **104** and the sensor **106**. In an embodiment, the connector **202** comprises a multipurpose cable connector such as that disclosed in the incorporated U.S. application Ser. No. 10/898,680, titled "Multipurpose Sensor Port," disclosing communication between the board **104** and an external computing device.

The monitor **200** also comprises a HbCO indicator **204** advantageously providing a visual queue that a HbCO capable sensor is properly connected through the connector **202**. For example, the HbCO indicator **204** may advantageously activate when a sensor is connected that communicates sufficient information to determine HbCO, such as, for example, a sensor capable of emitting sufficient different wavelengths of light, a sensor storing sufficient data on the memory **122**, a sensor having appropriate encryption data or key, combinations of the same, or the like. For example, in an embodiment, the processor **112** may receive information from a memory **122** indicating a number of available LED wavelengths for the attached sensor. Based on the number of wavelengths, or other information stored on the memory **122**, the processor **112** may determine whether an HbCO-ready sensor has been attached to the monitor **200**. An artisan will also recognize from the disclosure herein that the HbCO indicator **204** may advantageously comprise a HbMet indicator, Hbt indicator, or the like, which activates to a predetermined color associated with a parameter, or any color, or deactivates the same, to convey a type of attached sensor. Moreover, the artisan will recognize from the disclosure herein other parameters that may use other sensor components and the monitor **200** may include indicators capable of indicating communication with those types of sensors.

In an embodiment, the monitor **200** may also audibly indicate the type of sensor connected. For example, the monitor **200** may emit predetermined number or frequency of beeps associated with recognition of a particular sensor, a particular manufacturer, failure to recognize the sensor, or the like. Moreover, the sensor type may be indicative of the componentry, such as, for example, whether the sensor produces sufficient data for the determination of HbCO, HbMet, Hbt and SpO_2, SpO_2 only, SpO_2 and HbMet, any combination of the foregoing or other parameters, or the like. Additionally, the sensor type may be indicative of specific sensors designed for a type of patient, type of patient tissue, or the like. In other embodiments, the monitor **200** may announce the type of connector through speaker **236**.

An artisan will also recognize from the disclosure herein that other mechanical (such as keys), electrical, or combination devices may inform the monitor **200** of the type of attached sensor. In an embodiment, the processor **112** also may select to drive less emitters that are currently available, such as, for example, in the presence of low noise and when power consumption is an issue.

The monitor **200** also comprises a multi-mode display **206** capable of displaying, for example, measurements of SpO_2 and HbCO (or alternatively, HbMet). In an embodiment, the display **206** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **200**. Thus, the multi-mode display **206** may advantageously cycle through two or more measured parameters in an area common to both parameters even when shifted. In such embodiments, the monitor **200** may also advantageously include parameter indicators **208**, **210**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **206** displays measured values of SpO_2 that are normal, the numbers may advantageously appear in green, while normal measured values of HbCO may advantageously appear in orange, and normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **206** flashes at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

The monitor **200** also comprises a HbCO bar **212** where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. For example, the bar **212** is lowest when the dangers from carbon monoxide poisoning are the least, and highest when the dangers are the greatest. The bar **212** includes indicia **214** that provide an indication of the severity of carbon monoxide saturation in a patient's blood. As shown in FIG. **2**, the bar **212** and the indicia **214** continuously indicate the concentration of HbCO in about 5% increments. The indicia **214** indicate a measurement of HbCO saturation percentage between about 0 and about 50% with a granularity of about 5%. However, an artisan will also recognize from the disclosure herein a wide variety of ranges and granularities could be used, the indicia **214** could be electronically displayed in order to straightforwardly increase or decrease resolution, or the like. For example, HbCO may advantageously be displayed with greater resolution than ± about %5 in a lower portion of the scale. For example, an HbCO bar may advantageously include a scale of about <3%, about 6%, about 9%, about 12%, about 15%, about 20%, about 25%, about 30%, about 35%, and about >40%.

As is known in the art, carbon monoxide in the blood can lead to serious medical issues. For example and depending upon the particular physiology of a patient, about 10% carbon monoxide saturation can lead to headaches, about 20% can lead to throbbing headaches, or dyspnea on exertion, about 30% can lead to impaired judgment, nausea, dizziness and/or vomiting, visual disturbance, or fatigue, about 40% can lead to confusion and syncope, and about 50% and above can lead to comas, seizures, respiratory failure and even death.

In an embodiment, the bar **212** is the same or similar color as the multi-mode display **206** when displaying HbCO. In other embodiments, the bar **212** is lowest and green when the dangers from carbon monoxide poisoning are the least, and highest and red when the dangers are the greatest. In an embodiment, as HbCO increases, the entire bar **212** may advantageously change color, such as, for example, from green to red, to provide a clear indication of deepening severity of the condition. In other embodiments, the bar **212** may advantageously blink or flash, an audio alarm may beep or

provide a continuation or rise in pitch or volume, or the like to alert a caregiver of deepening severity. Moreover, straightforward to complex alarm rules may be implemented to reduce false alarms based on, for example, knowledge of the physiological limitations on the rate of change in HbCO or the like.

Additionally, the monitor **200** may be capable of storing and outputting historical parameter data, display trend traces or data, or the like. Although the foregoing bar **212** has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

FIG. **2** also shows the monitor **200** including a pulse display **216** displaying measured pulse rate in beats per minute ("BPM"). In an embodiment, the display **212** flashes when searching for a pulse. The pulse display **216** advantageously displays measured pulse rates from about zero (0) to about two hundred and forty (240) BPM. Moreover, when the measured pulse rates are considered normal, the pulse display **216** is advantageously green. Similar to other displays associated with the monitor **200**, the pulse display **216** may employ a variety of color changes, audio alarms, or combinations of the same to indicate measured BPM below predetermined safe thresholds. In an embodiment, the pulse rate display **216** displays the measured pulse rate during the display of SpO_2 and displays message data during the display of other parameters. For example, during the display of HbCO, the display **216** may advantageously display the term "CO." In an embodiment, the display of the message data may be in the same or similar color as the other displays. For example, in an embodiment, the multi-mode display **206**, the bar **212**, and the pulse display **216** may all display data or messages in orange when the multi-mode display **206** displays measured HbCO values.

FIG. **2** also illustrates the monitor **200** comprising user input keys **218**, including a HbCO button **220**, mode/enter button **222**, next button **224**, power on/off button **226**, up/down button **228**, and alarm silence button **230**. In an embodiment, activation of the HbCO button **220** toggles the measured value displayed in the multi-mode display **206**. For example, activation of the HbCO button **220** toggles the multi-mode display **206** from displaying measured values of SpO_2 to HbCO for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **206** back to SpO_2. A skilled artisan will also recognize that activation of the HbCO button **220** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO_2, may remain displayed until further activation of the button **220**, or the like.

Activation of the mode/enter button **222** cycles through various setup menus allowing a caregiver to select or activate certain entries within the menu setup system, including alarm threshold customizations, or the like. Activation of the next button **224** can move through setup options within the menu setup system and in an embodiment is not active during normal patient monitoring. For example, a caregiver may activate the mode/enter button **222** and the next button **224** to specify high and low alarm thresholds for one or more of the measured parameters, to specify device sensitivity, trend settings, display customizations, color code parameters, or the like. In an embodiment, the high alarm setting for SpO_2 can range from about two percent (2%) to about one hundred percent (100%) with a granularity of about one percent (1%). The low alarm setting for SpO_2 can range from about one percent (1%) to about one hundred percent (100%) with a granularity of about one percent (1%). Moreover, the high alarm setting for pulse rate can range from about thirty (30) BPM to about two hundred and forty (240) BPM with a granularity of about five (5) BPM. The low alarm setting for pulse rate can range from about twenty five (25) BPM to about two hundred and thirty five (235) BPM with a granularity of about five (5) BPM. Other high and low ranges for other measured parameters will be apparent to one of ordinary skill in the art from the disclosure herein.

In a further embodiment, a caregiver may activate the mode/enter button **222** and the next button **224** to specify device sensitivity, such as, for example, device averaging times, probe off detection, whether to enable fast saturation calculations, or the like. Various embodiments of fast saturation calculations are disclosed in U.S. patent application Ser. No. 10/213,270, filed Aug. 5, 2002, titled "Variable Indication Estimator" and incorporated by reference herein. Using the menus, a caregiver may also advantageously enter appropriate information governing trend collection on one or more of the measured parameters, input signals, or the like.

FIG. **2** also shows the power on/off button **226**. Activation of the power on/off button **226** activates and deactivates the monitor **200**. In an embodiment, press-and-hold activation for about two (2) seconds shuts the monitor **200** off. In an additional embodiment, activation of the on/off button **226** advantageously initiates detection of a type of attached sensor. For example, activation of the on/off button **226** may advantageously cause the monitor **200** to read information from a memory on an attached sensor and determine whether sufficient wavelengths exist on the sensor to determine one or more the physiological parameters discussed in the foregoing.

An artisan will recognize from the disclosure herein that the on/off button **226** may advantageously cause an electronic determination of whether to operate in at powers consisted with the U.S. (60 Hz) or another nationality (50 Hz). In an embodiment, such automatic determination and switching is removed from the monitor **200** in order to reduce a likelihood of problematic interfering crosstalk caused by such power switching devices.

Activation of the up/down button **228** may advantageously adjust the volume of the pulse beep tone. Additionally, activation of the up/down button **228** within the menu setup system, causes the selection of values with various menu options.

Moreover, activation of the alarm silence button **230** temporarily silences audio alarms for a predetermined period, such as, for example, about one hundred and twenty (120) seconds. A second activation of the alarm silence button **230** mutes (suspends) the alarm indefinitely, while a third activation returns the monitor **200** to standard alarm monitoring. FIG. **2** also shows the alarm silence button **230** includes an alarm silenced indicator **232**. The alarm silenced indicator **232** may advantageously flash to indicate one or more alarms are temporarily silenced, may illuminate solid to indicate the alarms have been muted, or the like. Moreover, an artisan will recognize from the disclosure herein a wide variety of alarm silencing methodologies.

The monitor **200** also includes a battery level indicator **234** indicating remaining battery life. In the illustrated embodiment, four LED's indicate the status of the battery by incrementally deactivating to indicate proportionally decreasing battery life. In an embodiment, the four LED's may also change color as the battery charge decreases, and the final LED may begin to flash to indicate that the caregiver should replace the batteries.

FIG. **2** also shows the monitor **200** including an audio transducer or speaker **236**. The speaker **236** advantageously

provides audible indications of alarm conditions, pulse tone and feedback for key-presses, or the like. Moreover, the monitor **200** includes a low signal quality indicator ("SQ" or "SIQ™") **238**. The signal IQ indicator **238** activates to inform a caregiver that a measured value of the quality of the incoming signal is below predetermined threshold values. For example, in an embodiment, the measured value for signal IQ is at least partially based on an evaluation of the plethysmograph data's correspondence to predetermined models or characteristics of physiological signals. In an embodiment, the signal IQ indicator **238** output may be associated with the displayed parameter. For example, the output may be associated with one threshold for the display of SpO_2 and another for the display of other parameter data.

The monitor **200** also comprises a perfusion quality index ("PI™") bar **240** (which quantifies the measure of perfusion of the patient) where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. In one embodiment, the PI™ bar **240** shows a static value of perfusion for a given time period, such as, for example, one or more pulses. In another embodiment, or functional setting, the PI™ bar **240** may advantageously pulse with a pulse rate, may hold the last reading and optionally fade until the next reading, may indicate historical readings through colors or fades, or the like. Additionally, the PI™ bar **240** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

The PI™ bar **240** can be used to simply indicate inappropriate occlusion due, for example, to improper attachment of the sensor **106**. The PI™ bar **240** can also be used as a diagnostic tool during low perfusion for the accurate prediction of illness severity, especially in neonates. Moreover, the rate of change in the PI™ bar **240** can be indicative of blood loss, sleep arousal, sever hypertension, pain management, the presence or absence of drugs, or the like. According to one embodiment, the PI™ bar **240** values may comprise a measurement of the signal strength of the arterial pulse as a percentage of the total signal received. For example, in one preferred embodiment, the alternating portion of at least one intensity signal from the sensor **106** may advantageously be divided by the static portion of the signal. For example, an infrared intensity signal may advantageously be used as it is less subjective to noise.

In an embodiment, a measurement below about 1.25% may indicate medical situations in need of caregiver attention, specifically in monitored neonates. Because of the relevance of about 1.25%, the PI™ bar **240** may advantageously include level indicia **242** where the indicia **242** swap sides of the PI™ bar **240**, thus highlighting any readings below about that threshold. Moreover, behavior of the PI™ bar **240**, as discussed above, may advantageously draw attention to monitored values below such a threshold.

As discussed above, the monitor **200** may include output functionality that outputs, for example, trend perfusion data, such that a caregiver can monitor measured values of perfusion over time. Alternatively or additionally, the monitor **200** may display historical trace data on an appropriate display indicating the measured values of perfusion over time. In an embodiment, the trend data is uploaded to an external computing device through, for example, the multipurpose sensor connector **202** or other input output systems such as USB, serial or parallel ports or the like.

The monitor **200** also includes an alarm indicator **244** capable of providing visual queues of the status of one or more of the measured parameters. For example, the alarm indicator **244** may advantageously be green when all of the measured parameters are within normal conditions, may gradually fade to red, may flash, increasing flash, or the like, as one or more of the measured values approaches or passes predetermined thresholds. In an embodiment, the alarm indicator **244** activates when any parameter falls below an associated threshold, thereby advantageously informing a caregiver that perhaps a nondisplayed parameters is at an alarm condition. In another embodiment, the alarm indicator **244** may indicate the status of the parameter displayed on the multi-mode display **206**. In an embodiment, the speaker **236** may sound in conjunction with and/or in addition to the indicator **244**. Moreover, in an embodiment, an alarming parameter may automatically be displayed, may be emphasized, flashed, colored, combinations of the same or the like to draw a user's attention to the alarming parameter.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

FIG. **3** illustrates an exemplary display of the patient monitor **200**. As shown in FIG. **3**, the display includes the multi-mode display **206**, the pulse rate display **216**, parameter indicators **208**, **210**, the HbCO bar **212** and indicator **204**, the PI™ bar **240**, and the alarm indicator **244**. In an embodiment, the multi-mode display **206** and the pulse rate display **216** each comprise a plurality of seven segment displays **302** capable of displaying alpha-numeric information. As disclosed in the foregoing, the exemplary display may advantageously include color-coded parameter displays. Moreover, the exemplary display may include color progressions, flashing, flashing progressions, audible alarms, audible progressions, or the like, indicating worsening measured values of physiological data. In addition, in an embodiment, some or all of the displays may flash at a first rate to indicate attempts to acquire data when actual measured values are unavailable. Moreover, some or all of the display may flash at a second rate to indicate low signal quality where confidence is decreasing that the measured values reflect actual physiological conditions.

FIG. **4** illustrates the display of FIG. **3** showing measured values of SpO_2, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **4**, the multi-mode display **206** is displaying a percentage value of SpO_2, and the pulse rate display **216** is displaying a pulse rate in beats per minute. Accordingly, the parameter indicator **210** is activated to confirm the display of measured values of SpO_2. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** is red, indicating blood oxygen measurements while the pulse rate display **216** is green, indicating normal values of a patient's pulse.

FIG. **4** also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the HbCO indicator **204** is showing communication with a sensor producing insufficient data to determine measured values of additional parameters, such as, HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about two (2) different wavelengths, may comprise sensors with insufficient data stored on a memory associated therewith, or the like.

FIG. **5** illustrates the display of FIG. **3** showing measured values of HbCO, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **5**, the multi-mode display **206** is displaying a percentage value of HbCO, and the pulse rate display **216** is displaying an appropriate message indicating the HbCO measurement, such as, for example, "CO". Also, the multi-mode display **206** has shifted the data to the left to quickly and

efficiently indicate that the displayed parameter is other than SpO_2. Accordingly, the parameter indicator **208** is also activated to confirm the display of measured values of HbCO. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** and pulse rate display message **216** are orange.

FIG. **5** also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about eight (8) or more different wavelengths; however, such sensors may comprise about two (2) or more different wavelengths. Moreover, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. **5** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

FIG. **6** illustrates the display of FIG. **3** showing measured values of SpO_2, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. In contrast to FIG. **4**, FIG. **6** shows that the monitor **200** is communicating with a sensor capable of producing sufficient data to determine measured values of HbCO, even though the displayed values are that of SpO_2 and BPM. Thus, FIG. **6** shows the activation of the HbCO indicator **204**, and the continuous monitoring of HbCO by the HbCO bar **212**. FIG. **6** also shows a high value of HbCO, and therefore, the indication of an alarm condition by activation of the alarm indicator **244**. In an embodiment, upon determination of an alarm condition on a nondisplayed parameter, the monitor **200** may advantageously provide an alarm indication through speaker and alarm indicator activation, automatic toggle to the nondisplayed parameter on the multi-mode display **206** for a defined or undefined time, or the like.

FIG. **7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor **700** capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. **1**. Patient monitors exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57 cm." As shown in FIG. **7**, the monitor **700** comprises a monitor similar to monitor **200** disclosed with reference to FIG. **2**. Moreover, monitor **700** further includes a multi-mode display **706** capable of displaying, for example, measurements of HbMet and BPM. In an embodiment, the display **706** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **700**. Thus, the multi-mode display **706** may advantageously cycle through two or more measured parameters. In such embodiments, the monitor **700** may also advantageously include parameter indicators **708**, **710**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display **706** may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **706** displays measured values of BPM that are normal, the numbers may advantageously appear in green, while normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **706** may flash at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

FIG. **7** also illustrates the monitor **700** comprising user input keys **718**, including an HbCO/HbMet button **220**. In an embodiment, activation of the HbCO/HbMet button **720** toggles the measured value displayed in the multi-mode display **706**. For example, activation of the HbCO/HbMet button **720** toggles the multi-mode display **206** from displaying measured values of SpO_2 and BPM, to HbCO and HbMet for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **706** back to SpO_2 and BPM. A skilled artisan will also recognize that activation of the HbCO/HbMet button **720** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO_2 and BPM, may remain displayed until further activation of the button **720**, or the like.

The monitor **700** also comprises a coarser indication of HbMet through an HbMet bar **740**. In an embodiment, a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value, with increments at about 0.5%, about 1%, about 2%, about 3%, about 4%, about 5%, about 7.5%, about 10%, about 15% and greater than about 20%, although an artisan will recognize from the disclosure herein other useful delineations. Additionally, the HbMet bar **740** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

Although disclosed with reference to the HbMet bar **740**, and artisan will recognize from the disclosure herein other coarse or even gross indications of HbMet, or any measured parameter. For example, a single LED may advantageously show green, yellow, and red, to indicate worsening coarse values of HbMet. Alternatively, a single LED may simply light to indicate an alarm or approaching alarm condition.

FIG. **8** illustrates an exemplary display of the patient monitor **700** of FIG. **7**. As shown in FIG. **8**, the display includes the multi-mode displays **206**, **706**, parameter indicators **208**, **210**, **708**, **710**, the HbCO bar **212** and indicator **204**, the HbMet bar **740**, and the alarm indicator **244**. In an embodiment, the multi-mode display **706** is similar to multi-mode display **206**, comprising a plurality of seven segment displays **302** capable of displaying alpha-numeric information, and capable of altering its display characteristics or aspects in a wide variety of configurations discussed with reference to the display **206**.

FIG. **9** illustrates the display of FIG. **8** showing measured values of SpO_2, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**. FIG. **9** also shows the HbMet bar **740** near the bottom and corresponding to about 1%, representing acceptable HbMet, while the HbCO bar **212** hovers at a dangerous near 20%. In addition, the HbCO indicator **204** is showing communication with a sensor producing sufficient data to determine measured values of additional parameters, such as, HbMet, HbCO or the like. In an embodiment, such sensors may comprise sensors capable of emitting light of more than two (2) different wavelengths, preferably more than four (4) different wavelengths, and more preferably eight (8) or more different wavelengths.

FIG. **10** illustrates the display of FIG. **8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **10**, the multi-mode display **706** is displaying a percentage value of HbMet that is shifted using the parameter indicator **708**. The data has been advantageously shifted to the left to quickly and efficiently indicate that the displayed parameter is other than BPM. Accordingly, the parameter indicator **708** is also activated to confirm the display of mea-

sured values of HbMet. As disclosed in the foregoing, in an embodiment, the multi-mode display **706** is blue.

FIG. **10** also shows the HbMet bar **740** nearly empty, representing acceptable HbMet. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. **10** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

FIG. **11**A illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor **1100**, such as, for example, the patient monitor of FIG. **1**. Moreover, FIGS. **11**B-**11**E illustrate exemplary display screens of the patient monitor of FIG. **11**A. As shown in FIGS. **11**A-**11**B, an embodiment of the monitor **1100** includes a display **1101** showing a plurality of parameter data. For example, the display may advantageously comprise a CRT or an LCD display including circuitry similar to that available on oximeters commercially available from Masimo Corporation of Irvine, Calif. sold under the name Radical™, and disclosed in the U.S. patents referenced above and incorporated above. However, an artisan will recognize from the disclosure herein many commercially available display components capable of displaying multiple parameter data along with the ability to display graphical data such as plethysmographs, trend traces, and the like.

In an embodiment, the display includes a measured value of SpO_2 **1102**, a measured value of pulse rate **1104** in BPM, a plethysmograph **1106**, a measured value of HbCO **1108**, a measured value of HbMet **1110**, a measured value of a perfusion quality **1112**, a measured value of Hbt **1114**, and a derived value of fractional saturation "$SpaO_2$" **116**. In an embodiment, $SpaO_2$ comprises HbO_2 expressed as a percentage of the four main hemoglobin species, i.e., HbO_2, Hb, HbCO, and HbMet.

In an embodiment, one or more of the foregoing parameter includes trending or prediction indicators **1118** showing the current trend or prediction for that corresponding parameter. In an embodiment, the indicators **1118** may advantageously comprise an up arrow, a down arrow, and a hyphen bar to indicate up trending/prediction, down trending/prediction, or neutral trending/prediction.

FIG. **11**C illustrates an exemplary display screen showing trend graph **1140** including trend line **1142** for HbMet. In an embodiment, the trend line **1142** may be advantageously colored for quick straightforward recognition of the trending parameter, may be associated with any one or more of the foregoing alarm attributes, may include trending lines for other parameters, or the like. The display screen also shows trending directional indicators **1142**, **1144** for many of the displayed physiological parameters. In an embodiment, the directional indicators **1142**, **1144** may advantageously comprises arrows showing the recent trend, predicted trend, user-customizable trend, combinations thereof, or the like for the associated parameters. In an embodiment, the directional indicators **1142**, **1144** comprises an up arrow indicating a rising trend/predicted trend, a middle bar indicating a somewhat stable trend/predicted trend, and a down arrow indicating a lowering trend/predicted trend. An artisan will recognize a wide variety of other directional indicators **1142**, **1144** from the disclosure herein.

FIG. **11**D shows an exemplary display screen in vertical format. Such vertical format could be user actuated or based on a gravity switch. FIGS. **11**E-**11**F illustrate additional displays of various physiological parameters similar to those discussed in the foregoing. being As shown in FIG. **11**G, the display includes a measured value of SpO_2 **1162**, a measured value of pulse rate **1164** in BPM, a plethysmograph **1166**, a HbCO bar **1168**, and a HbMet bar **1170**. In an embodiment, the HbCO bar **1168** and HbMet bar **1170** may advantageously behave the same or similarly to the HbCO bar **212** and HbMet bar **712**. Moreover, similar bars may advantageously display any of the physiological parameters discussed herein using display indicia appropriate to that parameter. For example, a SpO_2 or $SpaO_2$ bar may advantageously range from about 0% to about 100%, and more preferably range from about 50% to about 100%, while a Hbt bar may advantageously range from about 0 to about 30.

Moreover, similar to the disclosure above, the measured value of SpO_2 **1162** may advantageously toggle to measured values of HbCO, HbMet, Hbt, or the like based on, for example, actuation of user input keys, or the like.

In addition to the foregoing, the display may also include graphical data showing one or more color-coded or other identifying indicia for traces of trend data. Moreover, other graphical presentations may advantageously provide readily identifiable indications of monitored parameters or combinations of monitored parameters of the patient. For example, in an embodiment, the display includes a $SpaO_2$ graph **1172**. The $SpaO_2$ graph **1172** plots SpO_2 as a function of other blood analytes (1-$SpaO_2$), where $SpaO_2$ comprises HbO_2 expressed as a percentage of the four main hemoglobin species, i.e., HbO_2, Hb, HbCO, and HbMet. Thus, as shown in FIG. **11**C, as the slope of the displayed line or arrow increases, the caregiver can readily note that the majority of hemoglobin carriers are being used to carry oxygen, and not, for example, harmful carbon monoxide. On the other hand, as the slope decreases, the caregiver can readily and advantageously note that the number of hemoglobin species available to carry oxygen is decreasing, regardless of the current value of SpO_2. Moreover, the length of the arrow or line also provides an indication of wellness, e.g., the higher the line the more oxygen saturation, the lower the line, the more likely there may be desaturation event, or the like.

Thus, the $SpaO_2$ graph **1172** provides the caregiver with the ability to recognize that even though the measured value of SpO_2 may be within acceptable ranges, there are potentially an unacceptable number of hemoglobin carriers unavailable for carrying oxygen, and that other potential problems may exist, such as, for example, harmful carbon monoxide levels, or the like. In an embodiment, various alarm conditions may cause the graph **1172** to change color, flash, or any combination of alarm indications discussed in the foregoing. Moreover, FIG. **11** illustrates yet an additional display of the foregoing parameters.

An embodiment may also include the monitor **1000** advantageously defining regions of wellness/severity of the monitored patient. For example, because the graph **1172** comprises two dimensions, the monitor **1000** may advantageously define regions where the patient's measured physiological parameters are considered acceptable, regions where the patient is considered at risk, regions where the patient is critical, and the like. For example, one region of acceptability may include a high SpO_2 and a low 1-$SpaO_2$, another region of risk may include a high SpO_2 and a high 1-$SpaO_2$, and another critical region may include a low SpO_2 and a high 1-$SpaO_2$. Moreover, an artisan will recognize from the dis-

closure herein that different parameters may also be combined to provide readily identifiable indications of patient wellness.

In addition to or as an alternative to the two dimensional $SpaO_2$ graph **1172**, the monitor **1000** may also include a three dimensional graph, such as, for example, extending the graph **1172** along the variable of time. In this embodiment, the forgoing regions advantageously become three dimensional surfaces of wellness. Moreover, trend data may also be advantageously added to the surface to provide a history of when particular monitored parameters dipped in and out of various surfaces of wellness, risk, criticality, or the like. Such trend data could be color-coded, text identified, or the like. An artisan will also recognize that such surfaces may be dynamic. For example, measurements of HbCO> about 5 may dictate that trend data showing SpO_2< about 90% should be considered critical; however, measurements of HbCO< about 5 may dictate only SpO_2< about 85% would be critical. Again, an artisan will recognize from the disclosure herein other parameter combinations to create a wide variety of wellness/critical regions or surfaces that provide readily available visual or audio indications of patient well being, trigger specific alarms, or the like.

Moreover, the monitor **1000** may advantageously employ enlargement or reorganization of parameter data based on, for example, the severity of the measurement. For example, the monitor **1000** may display values for HbCO in a small portion of the screen or in the background, and when HbCO begins to approach abnormal levels, the small portion may advantageously grown as severity increases, even in some embodiments to dominate the display. Such visual alarming can be combined with audio alarms such as announcements, alarms, rising frequencies, or the like, and other visual alarms such as flashing, coloration, or the like to assist a caregiver in noticing the increasing severity of a monitored parameter. In an embodiment, a location of the display of an alarming value is changed to be displayed in a larger display area, such as **1102**, so as to be readily noticeable and its display values readily ascertainable.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **100** may advantageously be adapted to monitor or be included in a monitor capable of measuring physiological parameters other than those determined through absorption spectroscopy, such as, for example, blood pressure, ECG, EKG, respiratory rates, volumes, inputs for blood pressure sensors, acoustical sensors, and the like. Moreover, the monitor **100** may be adapted for wireless communication to and from the sensor **106**, and/or to and from other monitoring devices, such as, for example, multi-parameter or legacy monitoring devices.

Also, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

What is claimed is:

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

2. The patient monitor of claim **1**, wherein the first display area and the second display area comprise the common display area.

3. The patient monitor of claim **1**, wherein activation of a user input causes the common display area to change from displaying one of the measured value of the first or second physiological parameter to displaying the other of the measured value of the first or second physiological parameter.

4. The patient monitor of claim **1**, wherein the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.

5. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an invasively measured value.

6. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises a non-invasively measured value.

7. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises glucose.

8. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

9. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

10. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

11. The patient monitor of claim **1**, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters.

12. The patient monitor of claim **11**, wherein the aspect that changes comprises a display color.

13. The patient monitor of claim **11**, wherein the aspect that changes comprises a display size.

14. The patient monitor of claim **11**, wherein the aspect that changes comprises a display intensity.

15. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values

of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

16. The patient monitor of claim **15**, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters.

17. The patient monitor of claim **16**, wherein the aspect that changes comprises a display color.

18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

19. The patient monitor of claim **18**, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.

20. The patient monitor of claim **18**, wherein at least one of measured physiological parameters is determined noninvasively.

21. A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

displaying a measured value of a first physiological parameter in a display location of an electronic display; and

replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.

22. The method of claim **21**, wherein the indication of the worsening state comprises an alarm condition.

23. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an invasively measured value.

24. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

25. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

26. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

28. The patient monitor of claim **27**, wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

29. The patient monitor of claim **27**, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.

30. The patient monitor of claim **27**, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.

31. The patient monitor of claim **27**, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.

32. The patient monitor of claim **27**, wherein the attached sensor can provide data through the output signal and through a memory device.

33. The patient monitor of claim **27**, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.

34. The patient monitor of claim **27**, further comprising a memory for storing trend data on one or more of the first and second blood parameters.

35. The patient monitor of claim **27**, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.

36. The patient monitor of claim **27**, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.

37. The patient monitor of claim **36**, wherein the alarm comprises at least one of an audio or visual alarm.

38. The patient monitor of claim **27**, further comprising an additional display indicating perfusion through the body tissue.

39. The patient monitor of claim **27**, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.

40. The patient monitor of claim **39**, comprising an additional display capable of indicating the percent carbon monoxide saturation.

41. The patient monitor of claim 39, comprising an additional display capable of indicating the percent methemoglobin saturation.

42. The patient monitor of claim 27, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate.

43. The patient monitor of claim 42, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.

44. The patient monitor of claim 42, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

45. The patient monitor of claim 27, wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

46. The patient monitor of claim 45, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.

47. The patient monitor of claim 45, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,190,223 B2
APPLICATION NO. : 11/367033
DATED : May 29, 2012
INVENTOR(S) : Ammar Al-Ali et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Title Page 2 (Item 56), Column 1, Line 15 (Approx.), Under U.S. Patent Documents, below "Martin" insert --4,854,328 |08-1989 |Pollack--.

On Title Page 4 (Item 56), Column 1, Line 75, Under U.S. Patent Documents, change "Chin et al." to --O'Neil et al.--.

In Column 18, Line 54, change "11" to --11**H**--.

Signed and Sealed this
Thirteenth Day of November, 2012

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Ammar Al-Ali, et al.
Patent No.		8,190,223
Contr. No.	:	90/012,559
Filed	:	September 13, 2012
For	:	*NONINVASIVE MULTI-PARAMETER PATIENT MONITOR*
Examiner	:	Robert L. Nasser
Art Unit	:	3992
Conf No.	:	6710

CERTIFICATE OF EFS WEB TRANSMISSION

I hereby certify that this correspondence, and any other attachment noted on the automated Acknowledgement Receipt, is being transmitted from within the Pacific Time zone to the Commissioner for Patents via the EFS Web server on:

January 28, 2013
(Date)

John M. Grover, Reg. No. 42,610

RESPONSE TO OFFICE ACTION OF DECEMBER 3, 2012

Mail Stop *Ex Parte* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the pending Office Action of December 3, 2012, the Patentee respectfully requests the above-identified reexamination application be amended as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Status of the Claims is reflected on page 16 of this paper.

Remarks begin on page 20 of this paper.

AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior versions thereof. In accordance with 37 C.F.R. §§ 1.530(d) and (f) and M.P.E.P § 2250, changes to the claims are shown below in highlighted form, where insertions appear as underlined text (e.g., insertions) while deletions appear between double brackets (e.g., **[**deletions**]**).

1. (**Currently amended**) A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein in the common display area, the display of **[**changes from displaying**]** one of the measured values of the first or second physiological parameter is replaced with **[**to displaying**]** the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

2. (**Original**) The patient monitor of claim 1, wherein the first display area and the second display area comprise the common display area.

3. (**Currently amended**) The patient monitor of claim 1, wherein activation of a user input causes the common display area to replace **[**change from displaying**]** one of the measured value of the first or second physiological parameter with **[**to displaying**]** the other of the measured value of the first or second physiological parameter.

4. (**Original**) The patient monitor of claim 1, wherein the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.

5. (**Original**) The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an invasively measured value.

6. (**Original**) The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises a non-invasively measured value.

7. (**Currently amended**) **[**The patient monitor of claim 1**]** A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient, wherein the measured value of the first physiological parameter comprises glucose.

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8. (**Original**) The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

9. (**Original**) The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

10. (**Original**) The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

11. (**Original**) The patient monitor of claim 1, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters.

12. (**Original**) The patient monitor of claim 11, wherein the aspect that changes comprises a display color.

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13. (**Currently amended**) **[**The patient monitor of claim 11**]** A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters, wherein the aspect that changes comprises a display size.

14. (**Original**) The patient monitor of claim 11, wherein the aspect that changes comprises a display intensity.

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15. (**Currently amended**) A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein in the common display area, the display of **[**changes from displaying**]** one of the measured values of the first or second physiological parameters is replaced with **[**to displaying**]** the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

16. (**Original**) The patient monitor of claim 15, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters.

17. (**Original**) The patient monitor of claim 16, wherein the aspect that changes comprises a display color.

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18. (**Currently amended**) A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein in the common display area, the display of [changes from displaying] one of the measured values of the first or second physiological parameters is replaced with [to displaying] the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

19. (**Original**) The patient monitor of claim 18, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.

20. (**Original**) The patient monitor of claim 18, wherein at least one of measured physiological parameters is determined noninvasively.

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21. (**Original**) A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

displaying a measured value of a first physiological parameter in a display location of an electronic display; and

replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.

22. (**Original**) The method of claim 21, wherein the indication of the worsening state comprises an alarm condition.

23. (**Original**) The method of claim 21, wherein the measured value of the first physiological parameter comprises an invasively measured value.

24. (**Original**) The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

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25. (**Original**) The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

26. (**Original**) The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

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27. (**Currently amended**) A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which **[**causes**]** replaces the display **[**to change from displaying**]** of the measured value of the first blood parameter **[**to displaying**]** with the measured value of the second blood parameter, wherein the display **[**also changes from displaying**]** of the measured value of the first blood parameter **[**to displaying**]** is replaced by the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

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28. (**Currently amended**) **[**The patient monitor of claim 27**]** A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,

wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

29. (**Original**) The patient monitor of claim 27, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.

30. (**Original**) The patient monitor of claim 27, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.

31. (**Original**) The patient monitor of claim 27, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.

32. (**Original**) The patient monitor of claim 27, wherein the attached sensor can provide data through the output signal and through a memory device.

33. (**Original**) The patient monitor of claim 27, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.

34. (**Original**) The patient monitor of claim 27, further comprising a memory for storing trend data on one or more of the first and second blood parameters.

35. (**Original**) The patient monitor of claim 27, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.

36. (**Original**) The patient monitor of claim 27, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.

37. (**Original**) The patient monitor of claim 36, wherein the alarm comprises at least one of an audio or visual alarm.

38. (**Original**) The patient monitor of claim 27, further comprising an additional display indicating perfusion through the body tissue.

39. (**Original**) The patient monitor of claim 27, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.

40. (**Original**) The patient monitor of claim 39, comprising an additional display capable of indicating the percent carbon monoxide saturation.

41. (**Original**) The patient monitor of claim 39, comprising an additional display capable of indicating the percent methemoglobin saturation.

42. (**Original**) The patient monitor of claim 27, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate.

43. (**Original**) The patient monitor of claim 42, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.

44. (**Original**) The patient monitor of claim 42, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

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45. (**Currently amended**) [The patient monitor of claim 27] A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,

wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

46. (**Original**) The patient monitor of claim 45, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.

47. (**Original**) The patient monitor of claim 45, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button.

STATUS AND SUPPORT OF THE CLAIMS

In accordance with 37 C.F.R. § 1.530(e) and M.P.E.P § 2250, the following status of claims (*i.e.*, pending or canceled) and support for claim changes are provided below. As required, when there is an amendment to any claim, the Patentee provides herein an explanation of the support in the disclosure accompanying that claim's status.

1. (**Pending**) Support for the additions and deletions of "in the common display area, the display of [changes from displaying] one of the measured values of the first or second physiological parameter is replaced with [to displaying]" can be found at least in FIGS. 3–5, element 206; 11A, element 1101; col. 10:4–12; col. 14:20–27, 39–44, 60–67; col. 15: 1–5, 33–38; col. 19:24–39. The Patentee also asserts that the deletions when coupled with the amendments do not broaden claim scope. Rather, the deleted "[changes from displaying] ... [to displaying]" language is amended to "the display of ... is replaced with". In the context of the present disclosure, "replaced" can be thought of as a specific narrower species of the broader genus "changed."

2. (**Pending**).

3. (**Pending**) Support for the additions and deletions of "replace **[**change from displaying**]** ... with **[**to displaying**]**", can be found at least in the citations provided with respect to Claim 1 and at col. 11:37–50 (reciting "toggle[ing] between displays"). Also, similar to Claim 1, the Patentee asserts that the deletions when coupled with the amendments do not broaden the claim scope.

4. (**Pending**).

5. (**Pending**).

6. (**Pending**).

7. (**Pending**) The Office Action confirmed the patentability of dependent Claim 7. The Patentee amended Claim 7 herein to include the limitations of its base claim, patented independent Claim 1.

8. (**Pending**).

9. (**Pending**).

10. (**Pending**).

11. (**Pending**).

12. (**Pending**).

13. (**Pending**) The Office Action confirmed the patentability of dependent Claim 13. The Patentee amended Claim 13 herein to include the limitations of its base and intervening claims, Claims 1 and 11.

14. (**Pending**).

15. (**Pending**) Support for the additions and deletions of "in the common display area, the display of [changes from displaying] one of the measured values of the first or second physiological parameter is replaced with [to displaying]" can be found at least in the citations provided with respect to Claim 1. Also, similar to Claim 1, the Patentee asserts that the deletions when coupled with the amendments do not broaden the claim scope.

16. (**Pending**).

17. (**Pending**).

18. (**Pending**) Support for the additions and deletions of "in the common display area, the display of [changes from displaying] one of the measured values of the first or second physiological parameter is replaced with [to displaying]" can be found at least in the citations provided with respect to Claim 1. Also, similar to Claim 1, the Patentee asserts that the deletions when coupled with the amendments do not broaden the claim scope.

19. (**Pending**).

20. (**Pending**).

21. (**Pending**).

22. (**Pending**).

23. (**Pending**).

24. (**Pending**).

25. (**Pending**).

26. (**Pending**).

27. (**Pending**) Support for the additions and deletions of

> "the activation of which **[**causes**]** replaces the display **[**to change from displaying**]** of the measured value of the first blood parameter **[**to displaying**]** with the measured value of the second blood parameter, wherein the display **[**also changes from displaying**]** of the measured value of the first blood parameter **[**to displaying**]** is replaced by the measured value"

can be found at least in the citations provided with respect to Claim 1, and at col. 11:34–50. Also, similar to Claim 1, the Patentee asserts that the deletions when coupled with the amendments do not broaden the claim scope.

28. (**Pending**) The Office Action confirmed the patentability of dependent Claim 28. The Patentee amended Claim 28 herein to include the limitations of its base claim, patented independent Claim 27.

29. (**Pending**).

30. (**Pending**).

31. (**Pending**).

32. (**Pending**).

33. (**Pending**).

34. (**Pending**).

35. (**Pending**).

36. (**Pending**).

37. (**Pending**).

38. (**Pending**).

39. (**Pending**).

40. (**Pending**).

41. (**Pending**).

42. (**Pending**).

43. (**Pending**).

44. (**Pending**).

45. (**Pending**) The Office Action confirmed the patentability of dependent Claim 45. The Patentee amended Claim 45 herein to include the limitations of its base claim, patented independent Claim 27.

46. (**Pending**).

47. (**Pending**).

REMARKS

The Patentee thanks Examiner Robert L. Nasser for his careful and thoughtful examination of the present reexamination application. The Patentee also thanks Examiners Nasser and Fischer and S.P.E. Rubin for the telephone interview conducted January 22, 2012, summarized in a separate paper submitted herewith.

By way of overview, Claims 1-47 of U.S. Patent No. 8,190,223 are subject to reexamination. The Office Action confirmed the patentability of Claims 7, 13, 21–26, 28, and 45–47, and rejected Claims 1–6, 8–12, 14–20, 27, and 29–44. By this paper, the Patentee amended Claims 1, 3, 7, 13, 15, 18, 27–28, and 45, without prejudice or disclaimer to earlier versions thereof. Claims 1–47 remain pending for consideration.

Confirmation Of The Patentability Of Claims 21-26

The Office Action confirmed the patentability of independent Claim 21 and its corresponding dependent Claims 22-26 over any combinations of the cited art of record.

Confirmation Of The Patentability Of Claims 7, 13, 28, and 45-47

The Office Action confirmed the patentability of dependent Claims 7, 13, 28, and 45-47 over any combinations of the cited art of record. The Patentee amended Claim 7 to incorporate the subject matter of patented independent Claim 1, amended Claim 13 to incorporate the subject matter of patented independent Claim 1 and patented dependent Claim 11, amended Claim 28 to incorporate the subject matter of patented independent Claim 27, and amended Claim 45 to incorporate the subject matter of patented independent Claim 27. As such, the Patentee requests the patentability of independent Claims 7, 13, 28, and 45, and dependent Claims 26-27 and 46-47 be confirmed.

Confirmation Of The Patentability Of Claims 1-6, 8-12, 14-20, 27, and 29-44

The Office Action rejected independent Claims 1, 15, 18, and 27 and dependent Claims 2–4, 6, 19-20, 29, 31–38, and 42–44, under 35 U.S.C. § 103 as allegedly being

obvious over U.S. Pat. App. Pub. No. 2002/0082488, to Al-Ali et al. ("**Ali**"), in view of U.S. Pat. No. 6,658,276, issued to Kiani et al. ("**Kiani**"). The Office Action rejected dependent Claims 8–10 and 39–41, under 35 U.S.C. § 103 as allegedly being obvious over Ali, in view of Kiani, and further in view of U.S. Pat. No. 5,842,979, issued to Jarman. The Office Action rejected dependent Claims 11–12, 14, 16–17, and 30, under 35 U.S.C. § 103 as allegedly being obvious over Ali, in view of Kiani, and further in view of U.S. Pat. No. 4,051,522, issued to Healy. The Office Action rejected dependent Claim 5[1], under 35 U.S.C. § 103 as allegedly being obvious over Ali, in view of Kiani, and further in view of U.S. Pat. App. Pub. No. 2003/0120164, to Nielsen.

The Patentee respectfully traverses these rejections, the characterizations of the claims and the cited references and each and every implicit and/or explicit potential for reliance on Official Notice because Ali, alone or in combination with Kiani, Jarman, Healy or Nielsen fails to teach or suggest the elements of the claims. See M.P.E.P. § 2143 (stating that in order to establish a *prima facie* case of obviousness for a claim, the prior art references must teach or suggest all the claim limitations).

Ali teaches a stereo pulse oximeter system 100 including a plurality of oximeter sensors 114, 124, 134, each attached to various measurement sites, including digits or the hand on each side of an infant, and, for example, through a foot. *Fig. 1A*. In embodiments disclosed with reference to Figures. 16A-B, reproduced in part herein, Ali teaches,

> [0094] FIG. 16A illustrates detail of a **single-site display screen** 180 for the stereo pulse oximeter. ... The graphical display portion 1660 displays a plethysmograph 1662 for the corresponding tissue site, which can be displayed as a single waveform or an accumulated multiple of overlayed waveforms that may reveal a waveform trend. A push button or menu selection allows the user to switch to a display of data from any single one of the multiple tissue sites to which a sensor is attached.

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[1] The Office Action listed Claim 23 with Claim 5. However, Claim 23 is dependent upon Claim 21, where Claim 21's patentability was confirmed. Moreover, Claim 23's patentability was confirmed. *See Summary of the Action, item 3; Pg. 7 (recounting "Statement of Reasons for Patentability And/Or Confirmation")*. Thus, the Patentee will assume Claim 23's inclusion here was a typographical oversight.

[0095] FIG. 16B illustrates detail of a **multi-site display screen** 180 for the stereo pulse oximeter. The numerical display portion 1610 displays a value for ... a first tissue site. Also displayed is a value for ... 1634 for a second tissue site. ... The graphical display portion 1660 displays a first plethysmograph 1664 and a second plethysmograph 1666 corresponding to the first and second tissue sites, respectively. A push button, menu selection allows the user to manually switch between the single site display (FIG. 16A) and the multi-site display (FIG. 16B). Also, a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display, enabling the user better view the conditions that caused the triggering event.

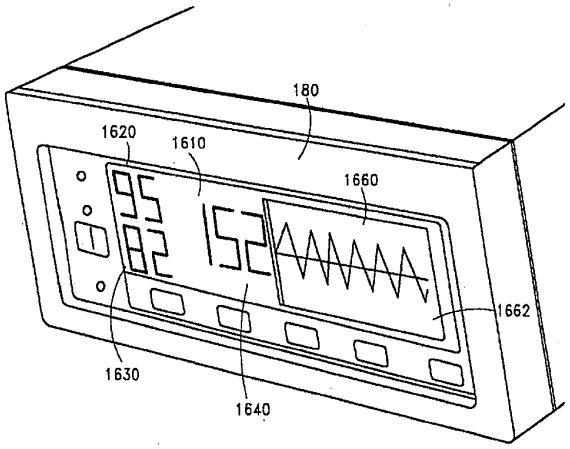


FIG. 16A

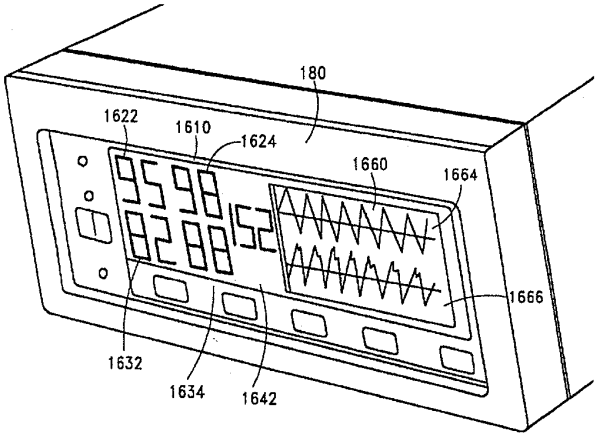


FIG. 16B

The Office Action points to the change from a display showing a single site plethysmograph 1662 in Figure 16A to a display showing multiple plethysmographs 1664, 1666 in Figure 16B. In Figure 16A, the display data is from a single monitoring site and in Figure 16B, the display data is from multiple monitoring sites.

Pending Claim 21 of the present patent recites, among other things,

21. A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device ..., the method comprising:

displaying a measured value of a first physiological parameter in a display location of an electronic display; and

> replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location ... .

The Office Action stated,

> Claim[] 21 ... define[s] over the art in that none of the art replaces the display of a first measured value with a second measured value ... . As noted above ... Al-Ali does not replace the first value, but switches from .. the first value to ... first and second values. [T]he request asserts that while Al-Ali does not replace the value, this is nothing more than trivial and obvious substitution of design elements. The Examiner disagrees, noting that there is not sufficient evidence to support this position. The only support is the statement by the requestor. Bald assertions are insufficient to establish obviousness. As such, claim 21 ... define[s] over Al-Ali ... as presented in the request. *Pg. 7.*

The Patentee agrees with the Office Action that the elements of Claim 21 are not taught or suggested by Ali. The Patentee herein amended independent Claims 1, 15, 18 and 27 to more specifically claim a first display element is being replaced by a second display element, similar to Claim 21 above. Accordingly, the Patentee asserts that Ali does not teach or suggest the elements of independent Claims 1, 15, 18 and 27.

Kiani appears to be used for the teaching of alarm thresholds, which, without commenting on whether Kiani supports those specific teachings or the appropriateness of any combination, Kiani does not remedy the lack of teaching or suggestion in Ali for replacing a first display element with a second display element. Therefore, the Patentee asserts that Ali, alone or combined with Kiani, fails to teach or suggest the elements of independent Claims 1, 15, 18 and 27. Based on at least the foregoing, the Patentee requests confirmation that independent Claims 1, 15, 18 and 27 are patentable.

Jarman appears to be used for the teaching of specific parameters to be monitored, Healy appears to be used to for the teaching of thresholds for alarms, and Nielsen appears to be used for the teaching of non-invasive blood pressure. Without commenting on whether those documents support those specific teachings or the appropriateness of any combination, similar to Kiani, Jarman, Healy and Nielsen do not

remedy the lack of teaching or suggestion in Ali for replacing a first display element with a second display element. Therefore, the Patentee asserts that the cited art of record, alone or combined, fails to teach or suggest the elements of the dependent claims based on their dependency and based on the specific elements recited therein. Based on at least the foregoing, the Patentee requests confirmation that the dependent claims are patentable.

For at least the reasons discussed above, the Patentee requests confirmation of the patentability of pending Claims 1-47.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Patentee is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Patentee reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Patentee has made any disclaimers or disavowals of any subject matter supported by the present application.

Conclusion

By focusing on specific claims and claim recitations in the discussion above, the Patentee does not intend to imply that other claim recitations are disclosed or rendered obvious by the art of record. In addition, the Patentee makes no admission that any of the cited references are properly combinable. Rather, the Patentee submits that even if the references are combined, the references still do not teach or render obvious the claimed invention.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 28, 2013

By: _____

John M. Grover
Registration No. 42,610
Attorney of Record
Customer No. 64,735
(949) 760-0404

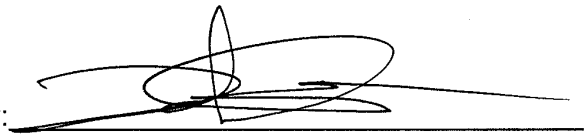
Certificate of Service

I hereby certify on January 28, 2013, that a true and correct copy of this "*RESPONSE TO OFFICE ACTION OF DECEMBER 3, 2012*" submission was mailed by first class mail, postage paid, to:

Tia D. Fenton
OBLON, SPIVAK, MCCELLAND, MAIER & NEUSTADT LLP
1940 Duke Street
Alexandria, VA 22314

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 28, 2013

By: 

John M. Grover
Attorney of Record
(949) 760-0404

14693601

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor	:	Ammar Al-Ali, et al.
Patent No.	:	8,190,223
App. No.		90/012,559
Filed	:	September 13, 2012
For	:	*NONINVASIVE MULTI-PARAMETER PATIENT MONITOR*
Examiner	:	Robert L. Nasser
Art Unit	:	3992
Conf No.	:	6710

CERTIFICATE OF EFS WEB TRANSMISSION

I hereby certify that this correspondence, and any other attachment noted on the automated Acknowledgement Receipt, is being transmitted from within the Pacific Time zone to the Commissioner for Patents via the EFS Web server on:

January 28, 2013
(Date)

John M. Grover, Reg. No. 42,610

INTERVIEW SUMMARY OF JANUARY 22, 2013

Mail Stop *Ex Parte* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the interview of January 22, 2013, the Patentee respectfully submits this *Interview Summary* in the above-identified reexamination application.

SUMMARY OF INTERVIEW

The Patentee thanks Examiners Nasser and Fischer, and S.P.E. Rubin for the telephone interview extended to the Patentee's counsel of Record, John M. Grover, on January 22, 2013. The following is a summary of the discussion.

Type of Interview, Date and Attendees

The interview was conducted telephonically on January 22, 2013, and attended by Examiners Robert L. Nasser and Margaret R. Rubin and S.P.E. Andrew J. Fischer, for the Patent Office, and John M. Grover (Reg. No. 42,610) and Daniel Gibson (Reg. No. 68,329) for the Patentee.

Identification of Claims Discussed

The participants discussed independent Claims 1, 15, 18, and 27, and dependent Claims 3, 7, 13, 28, and 45.

Identification of Prior Art Discussed

The participants discussed primarily the Al-Ali reference.

Results of Interview

The Patentee discussed with the Examiners amendments to the rejected claims relating to the subject matter of the claims where patentability is confirmed. The Examiners agreed that the proposed amendments would overcome all of the open issues in the present reexamination.

The Patentee thanks the Examiners for their professionalism and for the productive Examiner Interview.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 28, 2013

By: _____

John M. Grover
Registration No. 42,610
Attorney of Record
Customer No. 64,735
(949) 760-0404

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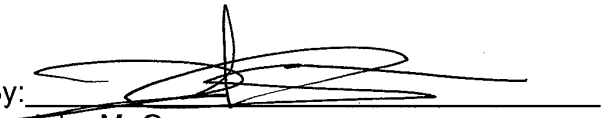
Certificate of Service

I hereby certify on January 28, 2013, that a true and correct copy of this "*INTERVIEW SUMMARY OF JANUARY 22, 2013"* submission was mailed by first class mail, postage paid, to:

Tia D. Fenton
OBLON, SPIVAK, MCCELLAND, MAIER & NEUSTADT LLP
1940 Duke Street
Alexandria, VA 22314

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: January 28, 2013

By: 

John M. Grover
Attorney of Record
(949) 760-0404

Electronic Acknowledgement Receipt	
EFS ID:	14805381
Application Number:	90012559
International Application Number:	
Confirmation Number:	6710
Title of Invention:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
First Named Inventor/Applicant Name:	8190223
Customer Number:	20995
Filer:	John M. Grover/Christine Showalter
Filer Authorized By:	John M. Grover
Attorney Docket Number:	403381US104RX
Receipt Date:	28-JAN-2013
Filing Date:	13-SEP-2012
Time Stamp:	14:22:18
Application Type:	Reexam (Third Party)

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		MLR_012X1_Response.pdf	986811 cf2f2aee9a16398b9150ad6a55ecab87f7f6ce2f	yes	26

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Response after non-final action-owner timely	1	25
	Reexam Certificate of Service	26	26

Warnings:					
Information:					
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	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Reexam Miscellaneous Incoming Letter	1	3
	Reexam Certificate of Service	4	4

Warnings:	
Information:	
Total Files Size (in bytes):	1071233

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

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

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

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/012,559	09/13/2012	8190223	403381US104RX	6710

20995 7590 01/25/2013

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
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IRVINE, CA 92614

EXAMINER	
NASSER, ROBERT L	
ART UNIT	PAPER NUMBER
3992	

MAIL DATE	DELIVERY MODE
01/25/2013	PAPER

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

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

UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office
P.O. Box 1450
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(THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS)

Tia D. Fenton

OBLON, SPIVAK, ET AL.

1940 Duke Street

Alexandria, Virginia 22314

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. *90/012,559*.

PATENT NO. *8190223*.

ART UNIT *3992*.

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified *ex parte* reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

PTOL-465 (Rev.07-04)

Ex Parte Reexamination Interview Summary	Control No.	Patent Under Reexamination
	90/012,559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

All participants (USPTO personnel, patent owner, patent owner's representative):

(1) *ROBERT NASSER*	(3) *Margaret Rubin USPTO*
(2) *Andrew Fischer, USPTO*	(4) *John Grover and Dan Gibson, Patent Owner*

Date of Interview: *22 January 2013*

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal (copy given to: 1)☐ patent owner 2)☐ patent owner's representative)

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

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.
Any other agreement(s) are set forth below under "Description of the general nature of what was agreed to…"

Claim(s) discussed: *all*.

Identification of prior art discussed: _____.

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:
Patent Owner proposed rewriting the confirmed claims into independent form to overcome the rejections .

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

A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION MUST INCLUDE PATENT OWNER'S STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. (See MPEP § 2281). IF A RESPONSE TO THE LAST OFFICE ACTION HAS ALREADY BEEN FILED, THEN PATENT OWNER IS GIVEN **ONE MONTH** FROM THIS INTERVIEW DATE TO PROVIDE THE MANDATORY STATEMENT OF THE SUBSTANCE OF THE INTERVIEW (37 CFR 1.560(b)). THE REQUIREMENT FOR PATENT OWNER'S STATEMENT CAN NOT BE WAIVED. **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

/Robert L. Nasser Jr/ Primary Examiner, Art Unit 3992		

cc: Requester (if third party requester)

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/012,559	09/13/2012	8190223	403381US104RX	6710

20995 7590 12/03/2012

KNOBBE MARTENS OLSON & BEAR LLP
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EXAMINER	
NASSER, ROBERT L	
ART UNIT	PAPER NUMBER
3992	

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12/03/2012	PAPER

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Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the *ex parte* reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

PTOL-465 (Rev.07-04)

Office Action in Ex Parte Reexamination	Control No. 90/012,559	Patent Under Reexamination 8190223
	Examiner ROBERT NASSER	Art Unit 3992

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

a☐ Responsive to the communication(s) filed on _____ . b☐ This action is made FINAL.
c☒ A statement under 37 CFR 1.530 has not been received from the patent owner.

A shortened statutory period for response to this action is set to expire 2 month(s) from the mailing date of this letter. Failure to respond within the period for response will result in termination of the proceeding and issuance of an *ex parte* reexamination certificate in accordance with this action. 37 CFR 1.550(d). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).** If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Information Disclosure Statement, PTO/SB/08.
3. ☐ Interview Summary, PTO-474.
4. ☐ _____.

Part II SUMMARY OF ACTION

1a. ☒ Claims 1-47 are subject to reexamination.
1b. ☐ Claims _____ are not subject to reexamination.
2. ☐ Claims _____ have been canceled in the present reexamination proceeding.
3. ☒ Claims 7,13,21-26,28 and 45-47 are patentable and/or confirmed.
4. ☒ Claims 1-6, 8-12, 14-20, 27, 29-44 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ The drawings, filed on _____ are acceptable.
7. ☐ The proposed drawing correction, filed on _____ has been (7a)☐ approved (7b)☐ disapproved.
8. ☐ Acknowledgment is made of the priority claim under 35 U.S.C. § 119(a)-(d) or (f).
   a)☐ All b)☐ Some* c)☐ None of the certified copies have
   1☐ been received.
   2☐ not been received.
   3☐ been filed in Application No. _____ .
   4☐ been filed in reexamination Control No. _____.
   5☐ been received by the International Bureau in PCT application No. _____.
   * See the attached detailed Office action for a list of the certified copies not received.
9. ☐ Since the proceeding appears to be in condition for issuance of an *ex parte* reexamination certificate 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.
10. ☐ Other: _____

cc: Requester (if third party requester)

Non-Final Rejection

This action addresses claims 1-47 of US Patent 8,190,223 to (Al-Ali et al (the '223 patent), for which a substantial new question of was deemed to have been raised by the request for Ex Parte Reexamination, filed 9/13/2012. This action is being issued in response to a voice mail received from Mr. Jerome Kessler on October 23, 2012, in which the Patent Owner verbally waived of Patent Owner Statement.

Interview Summary

Jerome Kessler left a voice mail for the examiner on 10/23/2012 indicating that the Patent Owner would waive the Patent Owner Statement.

Prior Art

U.S. Patent Application Publication 2002/0082488, filed December 21, 2001 and published June 27, 2002 to Al-Ali et al. ("A1-Ali").

U.S. Patent No. 6,658,276, filed February 12, 2002 and issued December 2, 2003 to Kianl et al.("Kianl").

U.S. Patent No. 5,842,979, filed February 14, 1997 and issued December 1, 1998 to Jarman ("Jarman").

U.S. Patent No. 4,051,522, filed May 5, 1975 and issued September 27, 1977 to Healy et al. ("Healy").

U.S. Patent Application Publication 2003/0120164, filed December 20, 2001 and published June 26, 2003 to Nielsen ("Nielsen").

U.S. Patent No. 5,743,262, filed June 7, 1995 and issued April 28, 1998 to Lepper et al. ("Lepper").

Relevant Statutes

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.

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

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

Rejections

A. Claims 1-4 and 6, 15, 18-20, 27, 29, 31-38, and 42-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Al-Ali et al in view of Kiani.

As to claims 1 and 27, Al-Ali shows a pulse oximeter that measures parameters at multiple sites. Figures 16a and 16b show the display formats for the device of Al-Ali. Specifically, there is a first display area displaying the numerical values 1622 and 1632 of the parameters from the first site and a second display area displaying the values 1624 and 1634 from the second site. As seen in figure 16a, in single site display mode, the parameters from any one of the sites is displayed. The first and second display areas further include a common display area, the graphical display portion 1660. The display area switches from single site mode, displaying one of the parameters, to

multiple site mode displaying the other parameter, in response to an alarm condition (see paragraph [0095]). The examiner notes that the claim that the display area changes from displaying one value to the other value based on an event, while Al-Ali changes form displaying one value to both values. The claim is written in open format, and as such, the claim is met if more than what in the claim is in the reference. Here, the reference changes from one parameter to the other parameter and additional display material, e.g. the first parameter. As such, it is the examiner's position that the claim is met. Finally, Al-Ali teaches that the switch in the display can be triggered by an alarm, which indicates a worsening of a patient's condition (e.g. moving from a non-alarm state to an alarm state). Al-Ali does not state that the alarm is based off of a threshold. However, Kiani teaches sounding an alarm when an upper or lower saturation threshold is exceeded. As such, it would have been obvious to modify Al-Ali to base the alarm on a threshold being exceeded, as it is merely the use of a well-known condition for such an alarm in an identical device.

The rejections of claims 2-6, 36, 42, and 43 are incorporated by reference herein, as presented on pages 19-21 of the request.

As to claim 15 and 18, the request notes the switch in the display is triggered based on an "alarm based on multiple site oxygen status parameters." Claim 15 requires that the switch be based on one of the parameters alarming and claim 18 requires that the switch be based on one parameter being more critical than the other. It is unclear whether the alarm in Al-Ali is based on a single parameter, or some combination of all of the parameters. However, Kiani teaches sounding alarms when

the oxygen saturation exceeds a threshold, e.g. for individual parameters. As such, it would have been obvious to at least sound an oxygen saturation alarm at each site, to prevent injury and ensure that proper care is received.

The rejections of claims 19 and 20 are incorporated by reference herein, as presented on page 24 of the request.

The rejections of claims 29, 31-35, 37, 38, and 44 are incorporated by reference herein, as presented on pages 33-40 of the request.

B. Claims 8-10 and 39-41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Al-Ali et al in view of Kiani, as applied to claims 1-4 and 6, 15, 18-20, 27, 29, 31-38, and 42-44, and further in view of Jarman.

Claims 8-10 and 39-41 are rejected in that it would have been obvious to modify Al-Ali and Kiani to also measure and display carbon monoxide and percent methomeglobin, for the reasons given on pages 43-49 of the request, which reasons are hereby incorporated by reference herein.

C. Claims 11, 12, 14, 16, 17, and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Al-Ali et al in view of Kiani, as applied to claims 1-4 and 6, 15, 18-20, 27, 29, 31-38, and 42-44, and further in view of Healy.

The rejections of claims 11, 12, 14, 16, 17, and 30 are incorporated by reference herein, as presented on pages 50-55 of the request.

D. Claims 5 and 23 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Al-Ali et al in view of Kiani, as applied to claims 1-4 and 6, 15, 18-20, 27, 29, 31-38, and 42-44, and further in view of Nielsen.

The rejections of claims 5 and 23 are incorporated by reference herein, as presented on pages 55-57 of the request, noting that Nielsen teaches measures oxygen saturation (spo2) together with invasive blood pressure.

STATEMENT OF REASONS FOR PATENTABILITY AND/OR CONFIRMATION

The following is an examiner's statement of reasons for patentability and/or confirmation of the claims found patentable in this reexamination proceeding:

Claims 7, 13, 21-26, 28, and 45-47 define over the art of record.

Claim 7 defines over the art of record in that none of the art measures glucose an another parameter, and switches the display, as claimed. The request cites Lepper, which is an optical glucose measuring device. The request asserts that it would have been obvious to modify Al-Ali to measure glucose, as it is the substitution of one known measurement element for another. The examiner disagrees. Al-Ali is a multi-parameter device that measures oxygen status of a patient. The entire disclosure is directed to measuring oxygen status. While Lepper teaches that optical methods can measure glucose, the request has made no connection between glucose and oxygen status of a patient and provided no reasons why one would measure glucose in an oxygen status monitoring device. Therefore, at best, the art establishes that one of ordinary skill can measure glucose optically, but provides no motivation or rationale to measure glucose in the device of Al-Ali. As such, claim 7 defines over the proposed rejection.

Claim 13 defines over the art of record in that none of the art changes the display size to indicate a change in the severity of the parameters. The request states that it

would be a simple matter of design choice to change the size rather than the color. However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, claim 13 defines over the art of record.

Claims 21-26 define over the art in that none of the art replaces the display of a first measured value with a second measured value when a change in the measurement of the second value indicates a worsening of the patient's condition. As noted above, Al-Ali does not replace the first value, but switches from displaying the first value to displaying first and second values. He request asserts that while Al-Ali does not replace the value, this is nothing more than trivial and obvious substitution of design elements. The examiner disagrees, noting that there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, claim 21, and its dependent claims 22-26, define over Al-Ali alone, as presented in the request.

Claim 28 defines over the art in that none of the art shifts a position of the display of the second parameter with respect to the first parameter. The request again proposes that this is merely the trivial and obvious substitution of design elements. However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, claim 28 defines over Al-Ali alone, as presented in the request.

Claims 45-47 define over the art of record in that none of the art has the user activate a change for a predetermined duration with a first activation type and a

undetermined duration with a second activation type. The request states that it would have been a matter of design choice to alter the length of display depending on the type of activation. However, there is not sufficient evidence to support this position. The only support is a statement by the requester. Bald assertions are insufficient to establish obviousness. As such, claims 45-47 define over the proposed combination.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 11/16/2012 and 11/19/2012 have been considered by the examiner. Documents which fail to constitute patents or printed publications or which are labeled "undated" on the SB/08B form have been lined through on the Form PTO/SB/08 (or PTO-1449) so as not to be published on the reexamination certificate. Those references initialed have been considered by the examiner to the extent noted below.

Per MPEP 2256, where patents, publications, and other such items of information are submitted by a party (patent owner or third party requester) in compliance with the requirements of the rules, the requisite degree of consideration to be given to such information will normally be limited by the degree to which the party filing the information citation has explained the content and relevance of the information. The initials of the examiner placed adjacent the citations on the form PTO/SB/08A and 08B or its equivalent, without an indication to the contrary in the record, do not signify that the information has been considered by the examiner any further than to the extent noted above.

Amendment in Reexamination Proceedings

Patent Owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c).

In order to ensure full consideration of any amendments, affidavits or declarations, or other documents as evidence of patentability, such documents must be submitted in response to this Office action. Submissions after the next Office action, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, after final rejection and 37 CFR 41.33 after appeal, which will be strictly enforced. See MPEP § 2250(IV) for examples to assist in the preparation of proper proposed amendments in reexamination proceedings.

Service of Papers

After filing of a request for ex parte reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. The document must reflect service or the document may be refused consideration by the Office. See 37 CFR 1.550(f).

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Litigation Reminder

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a) to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 8,190,223 throughout the course of this reexamination proceeding. The third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

By **U.S. Postal Service Mail** to:

Mail Stop *Ex Parte* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

By EFS: Registered users may submit via the electronic filing system EFS-Web, at https://efs.uspto.gov/efile/myportal/efs-registered.

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

For EFS-Web transmissions, 37 CFR 1.8(a)(1)(i) (C) and (ii) states that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if (a) it is transmitted via the Office's electronic filing system in accordance with 37 CFR 1.6(a)(4), and (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

/Robert L. Nasser Jr./
Robert L. Nasser
CRU Examiner
AU 3992
(571) 272-4731

Conferee ___/FOF/_____

/Alexander J Kosowski/

Supervisory Patent Examiner, Art Unit 3992

Reexamination	Application/Control No. 90012559	Applicant(s)/Patent Under Reexamination 8190223
	Certificate Date	Certificate Number

Requester Correspondence Address: ☐ Patent Owner ☒ Third Party
KNOBBE MARTENS OLSON & BEAR, LLP 2040 MAIN STREET, FOURTEENTH FLOOR IRVINE, CALIFORNIA 92614

LITIGATION REVIEW ☒	nasser (examiner initials)	11/15/2012 (date)
Case Name		Director Initials
none		/AJK/ for IY

COPENDING OFFICE PROCEEDINGS	
TYPE OF PROCEEDING	NUMBER

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	90012559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
reviewed prosecution history of US Patent 8190223	10/11/2012	nasser
reviewed references of record	10/11/2012	nasser
reviewed references of record	11/15/2012	nasser

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 1 OF 5	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	1	EP 0352923 A1	01-31-1990	BAXTER INT		
	2	DE 3328862 A1	02-28-1985	SIEMENS AG		
	3	EPO 0104771 B1	04-04-1984	NELLCOR INC		
	4	EPO 645117 A	03-29-1995	SEIKO EPSON CORP		
	5	WO 95/21567	08-17-1995	INCREA OY		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	6	Declaration of Perry D. Oldham in Support of Masimo Opposition to Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 7,215,984, Volume 1, Doc. 556, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	7	Declaration of Perry D. Oldham in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 7,215,984, Volume 2, Doc. 558, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	8	Masimo Corporation's Answering Brief in Opposition to Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent. No. 7,215,984, Doc. 555, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	9	Philip's Opening Brief in Support of Defendant's Motion for Summary Judgment of Invalidity and Nonnigringement of U.S. Patent No. 7,215,984, Doc. 442, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/21/12. (Redacted)	
	10	Philip Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 7,215,984, Doc. 394, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12.	
	11	Reply Brief in Support of Defendants' Motion for Summary Judgment of invalidity and Noninfringement of U.S. Patent. No. 7,216,984, Doc. 609, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 10/26/12. (Redacted)	

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

T[1] - Place a check mark in this area when an English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /B.N./

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 2 OF 5	Attorney Docket No.	MLR.012X1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	12	Declaration of Gail Baura, Ph.D. in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 7,215,984, Doc. 561, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	13	Declaration of Gail Baura, Ph.D. in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,632,272, Doc. 554, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	14	Declaration of Perry D. Oldham in Support of Masimo Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,632,272, Doc. 553, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	15	Masimo Corporation's Answering Brief in Opposition to Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272, Doc. 552, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	16	Opening Brief in Support of Defendants' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272, Doc. 444, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/21/12. (Redacted)	
	17	Defendants' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272, Doc. 402, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12	
	18	Reply Brief in Support of Defendants' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272, Doc. 614, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 10/26/12 (Redacted)	
	19	Declaration of Mohammed K. Diab in Support of Masimo's Oppositions to Defendants' Motions for Summary Judgment of Invalidity and Noninfringement of U.S. Patent Nos. 5,632,272 and 7,215,984, Doc. 563, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12 (Redacted)	
	20	Declaration of Perry D. Oldham in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 550, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12 (Redacted)	
	21	Masimo Corporation's Answering Brief in Opposition to Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 549, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12 (Redacted)	
	22	Philips' Opening Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 413, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12	

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 3 OF 5	Attorney Docket No.	MLR.012X1

NON PATENT LITERATURE DOCUMENTS			
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	23	Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 410, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12	
	24	Reply Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 613, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 10/26/12 (Redacted)	
	25	Declaration of Gail Baura, Ph.D. in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 551, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	26	V. Ya. Volkov, "Enhancing the Reliability and Accuracy of Pulse Oximetry with a Built-In Expert System," *Biomedical Engineering*, Vol. 27, No. 3 (May-June 1993) (translated from Russian)	
	27	Declaration of Gail Baura, Ph.D. in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 508, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/21/12.	
	28	Opening Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 445, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/21/12. (Redacted)	
	29	Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 406, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12.	
	30	Reply Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 610, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 10/26/12. (Redacted)	
	31	Declaration of Perry D. Oldham in Support of Masimo Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 548, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	32	Scharf, "Optimization of Portable Pulse Oximetry Through Fourier Analysis"	
	33	Scharf, "Pulse Oximetry Through Spectral Analysis"	
	34	Rusch, "Master's Thesis," Graduate School University of South Florida, Tampa, Florida (Dec., 1994)	
	35	Philips' Response to Masimo Corporation's Objections to the Report and Recommendation Regarding Claim Construction, Doc. 230, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/24/11	

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 4 OF 5	Attorney Docket No.	MLR.012X1

NON PATENT LITERATURE DOCUMENTS			
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	36	Masimo Corporation's Objections to the Report and Recommendation Regarding Claim Construction, Doc. 219, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/8/11	
	37	Defendants' Objections to Magistrate Judge Thynge's Report and Recommendation Regarding Claim Construction, Doc. 218, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/7/11	
	38	Report and Recommendation Regarding Claim Construction, Doc. 210, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 2/18/11	
	39	Memorandum Order Adopting Report and Recommendation Regarding Claim Construction, Doc. 319, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 1/17/11	
	40	Masimo Corporation's Response to Defendants' Objections to the Report and Recommendation Regarding Claim Construction, Doc. 232, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/24/11	
	41	V. Ya. Volkov, "Principles and Algroithms for Determining Blood Oxygenation Level by Pulse Oximetry," *Biomedical Engineering*, Vol. 27, No. 1 (Jan.-Feb. 1993) (translated from Russian)	
	42	Supplemental Expert Report of Dr. Robert Stone Regarding the invalidity of Masimo's Patents-in-Suit (U.S. Patent No. 5,632,272, U.S. Patent No. 6,263,222, U.S. Patent No. 7,215,984, and U.S. Patent No. 6,699,194, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/18/12	
	43	Appendixes for Expert Report of Dr. Robert Stone Regarding the invalidity of Masimo's Patents-in-Suit (U.S. Patent No. 5,632,272, U.S. Patent No. 6,263,222, U.S. Patent No. 7,215,984, and U.S. Patent No. 6,699,194, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/7/12	
	44	Expert Report of Dr. Robert Stone Regarding the invalidity of Masimo's Patents-in-Suit (U.S. Patent No. 5,632,272, U.S. Patent No. 6,263,222, U.S. Patent No. 7,215,984, and U.S. Patent No. 6,699,194, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/7/12	
	45	Revised Expert Report of Dr. Robert Stone Regarding the invalidity of Masimo's Patents-in-Suit (U.S. Patent No. 5,632,272, U.S. Patent No. 6,263,222, U.S. Patent No. 7,215,984, and U.S. Patent No. 6,699,194, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/7/12	
	46	Wukitsch, et al., "Knowing Your Monitoring Equipment," *Journal of Clinical Monitoring*, Vol. 4, No. 4 (Oct. 1998)	
	47	Second Amended Complaint for Patent Infringement, Doc. 42, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 4/25/12	

Examiner Signature	Date Considered
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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 5 OF 5	Attorney Docket No.	MLR.012X1

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	48	Masimo's Answer to Philips' Counterclaims, Doc. 28, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 12/30/11	
	49	Defendants' Answer and Philips Electronics North America Corp.'s Counterclaims to Masimo's First Amended Complaint, Doc. 11, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 11/7/11	
	50	Masimo's Answer to Philips' Counterclaims to Masimo's Second Amended Complaint, Doc. 358, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 6/4/12	
	51	Defendants' Answer and Philips Electronics North America Corp.'s Counterclaims to Masimo's Second Amended Complaint, Doc. 43, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 5/11/12	

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Examiner Signature	/Robert Nasser/	Date Considered	11/27/2012

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Diab, et al.
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L
SHEET 1 OF 5	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	4,051,522	9/27/1977	Healy	
	2	4,085,378	4/18/1978	Ryan	
	3	4,623,248	11/18/1986	Sperinde	
	4	4,653,498	3/31/1987	New	
	5	4,745,398	5/17/1988	Abel	
	6	4,765,340	8/23/1988	Sakai	
	7	4,800,495	1/24/1999	Smith	
	8	4,802,486	2/7/1989	Goodman	
	9	4,863,265	9/5/1989	Flower	
	10	4,911,167	3/27/1990	Corenman	
	11	4,942,877	7/24/1990	Sakai	
	12	4,955,379	9/11/1990	Hall	
	13	5,003,252	3/26/1991	Nystrom	
	14	5,188,108	2/23/1993	Secker	
	15	5,190,038	3/2/1993	Polson	
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	17	5,226,417	7/13/1993	Swedlow	
	18	5,246,002	9/21/1993	Prosser	
	19	5,259,381	11/9/1993	Cheung	
	20	5,307,284	4/26/1994	Brunfeldt	
	21	5,345,510	9/6/1994	Singhi	
	22	5,355,882	10/18/1994	Ukawa	
	23	5,368,224	11/29/1994	Richardson	
	24	5,406,952	4/18/1995	Barnes	
	25	5,421,329	6/6/1995	Casciani	
	26	5,438,983	8/8/1995	Flacone	
	27	5,442,940	8/22/1995	Secker	
	28	5,448,991	9/12/1995	Polson	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Diab, et al.
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L
SHEET 2 OF 5	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	29	5,503,148	4/2/1996	Pologe	
	30	5,542,421	8/6/1996	Erdman	
	31	5,575,284	11/19/1996	Athan	
	32	5,652,566	7/29/1997	Lambert	
	33	5,720,293	2/24/1998	Quinn	
	34	5,743,262	4/28/1998	Lepper	
	35	5,782,237	7/21/1998	Casciani	
	36	5,820,267	10/13/1998	Bryars	
	37	5,842,979	12/1/1998	Jarman	
	38	5,853,364	12/29/1998	Baker Jr. et al.	
	39	5,865,736	12/29/1998	Baker Jr. et al.	
	40	5,891,023	4/6/1999	Lynn	
	41	5,921,921	7/13/1999	Potratz et al.	
	42	5,950,139	9/7/1999	Korycan	
	43	5,987,343	11/16/1999	Kinast	
	44	6,047,203	4/4/2000	Sackner et al.	
	45	6,064,910	5/16/2000	Andersson et al.	
	46	6,083,172	7/4/2000	Baker Jr. et al.	
	47	6,119,026	9/12/2000	McNulty et al.	
	48	6,135,952	10/24/2000	Coetzee	
	49	6,157,850	12/5/2000	Diab et al.	
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	51	6,519,486	2/11/2003	Edgar, Jr. et al.	
	52	6,584,336	6/24/2003	Al Ali et al.	
	53	6,658,276	2/2/2003	Kianl et al.	
	54	6,822,564	11/23/2004	Al-Ali	
	55	6,970,792	11/29/2005	Diab	
	56	7,215,984	5/8/2007	Diab et al.	

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Diab, et al.
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L
SHEET 3 OF 5	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	57	7,496,393	2/24/2009	Diab et al.	
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	59	2002/0161291	10/31/2002	Kiani	
	60	2003/0000522	1/2/2003	Lynn	
	61	2003/0018241	1/23/2003	Mannheimer	
	62	2003/0073890	4/17/2003	Hanna	
	63	2003/0120164	6/26/2003	Nielsen	
	64	RE 33,643	7/23/1991	Isaacson	
	65	RE 38,492	4/6/2004	Diab	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	66	EP 0352923	01/31/1990	Baxter International Inc.		
	67	EP 0659384	06/28/1995	Seiko Instruments Inc.		
	68	EP 0645117	03/29/1995	Seiko Epson Corp.		
	69	WO 84/03032	08/16/1984	Arrhythmia Research Technology Inc.		
	70	WO 92/11803	07/23/1992	Baxter International Inc.		
	71	WO 92/15955	09/17/1992	Vital Signals, Inc.		
	72	WO 92/20273	11/26/1992	Chance		
	73	WO 98/43071	10/1/1998	Nellcor Puritan Bennett Inc.		

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	74	U.S. Patent Application Serial No. 90/012,403, filed July 23, 2012, requesting *ex parte* reexamination of Patent No. 6,263,222, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	75	U.S. Patent Application Serial No. 90/012,409, filed August 17, 2012, requesting *ex parte* reexamination of Patent No. 6.699,194, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	

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	76	U.S. Patent Application Serial No. 90/012,463, filed September 5, 2012, requesting *ex parte* reexamination of of Patent No. 7,215,984, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	77	U.S. Patent Application Serial No. 90/012,532, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,499,835, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	78	U.S. Patent Application Serial No. 90/012,534, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,962,188, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	79	U.S. Patent Application Serial No. 90/012,538, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,377,899, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	80	U.S. Patent Application Serial No. 90/012,541, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,899,507, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	81	U.S. Patent Application Serial No. 90/012,542, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 8,180,420, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	82	U.S. Patent Application Serial No. 90/012,543, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 6,850,787, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	83	U.S. Patent Application Serial No. 90/012,546, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,438,683, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	84	U.S. Patent Application Serial No. 90/012,548, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,880,606, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	85	U.S. Patent Application Serial No. 90/012,.551, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 6,970,792, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	86	U.S. Patent Application Serial No. 90/012,.553, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,024,233, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	87	U.S. Patent Application Serial No. 90/012.555, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,440,787, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	88	U.S. Patent Application Serial No. 90/012,557, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 8,150,487, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	89	U.S. Patent Application Serial No. 90/012,561, filed September 14, 2012, requesting *ex parte* reexamination of Patent No. 8,019400, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	90	U.S. Patent Application Serial No. 90/012,562, filed September 14, 2012 requesting *ex parte* reexamination of Patent No. 6,463,311, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Diab, et al.
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L
SHEET 5 OF 5	Attorney Docket No.	MLR.012X1

NON PATENT LITERATURE DOCUMENTS			
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	91	U.S. Patent Application Serial No. 90/012,566, filed September 14, 2012, requesting *ex parte* reexamination of Patent No. 7,530,955, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	92	U.S. Patent Application Serial No. 90/012,567, filed September 14, 2012, requesting *ex parte* reexamination of Patent No. 6,684,090, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	93	U.S. Patent Application Serial No. 90/012,568, filed September 14, 2012, requesting *ex parte* reexamination of Patent No. 8,128,572, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	94	U.S. Patent Application Serial No. 90/012,699, filed October 4, 2012, requesting *ex parte* reexamination of Patent No. 6,002,952, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	95	U.S. Patent Application Serial No. 95/002,183, filed Sept. 12, 2012, requesting *inter partes* reexamination of Patent No. 7,530,955, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.913 and 35 U.S.C. § 311.	
	96	Blitt, Casey D., Monitoring in Anesthesia and Critical Care Medicine, (2d ed. 1990)	
	97	Boualem Boashash, *Estimating and Interpreting the Instantaneous Frequency of a Signal-Part I: Fundamentals*, Proceedings of the IEEE, Vol. 80, No. 4 (April, 1992)	
	98	Boualem Boashash, *Note on the Use of the Wigner Distribution for Time-Frequency Signal Analysis*, IEEE Transactions on Acoustics, Speech, and Signal Processing, Vol. 36, No. 9 (Sept. 1988)	
	99	Business Wire, "Mallinckrodt Announces the Nellcor N-395 Pulse Oximeter With Oxismart XL and SatSeconds," October 7, 1999	
	100	Edward Bedrosian, *The Analytic Signal Representation of Modulating Waveforms* (1962)	
	101	Hanzo et al., "A Portable Multimedia Communicator Scheme", *Multimedia Technologies and Future Applications: Proceedings of the IEEE International Symposium* (1994)	
	102	Maciej Niedzwiecki et al. "Smoothing of Discontinuous Signals: The Competitive Approach," *IEEE Transactions on Signal Processing*, Vol. 43, No. 1, January 1995, pp. 1-13.	
	103	Steven W. Smith, *The Scientist and Engineer's Guide to Digital Signal Processing*, § 8 (1st ed. 1997)	

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Examiner Signature	/Robert Nasser/	Date Considered	11/27/2012

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 1 OF 2	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	4,623,248	11-18-1986	Sperinde	
	2	4,863,265	09-05-1989	Flower et al.	
	3	4,870,588	11-26-1989	Merhav	
	4	4,911,167	03-27-1990	Corenman et al.	
	5	4,934,372	06-19-1990	Corenman et al.	
	6	4,955,379	09-11-1990	Hall	
	7	4,965,840	10-23-1990	Subbarao	
	8	5,170,791	12-15-1992	Boos et al.	
	9	5,193,124	03-09-1993	Subbarao	
	10	5,270,942	12-14-1993	Reed	
	11	5,331,394	07-19-1994	Shalon et al.	
	12	5,353,356	10-04-1994	Waugh et al.	
	13	5,355,882	10-18-1994	Ukawa et al.	
	14	5,357,965	10-25-1994	Hall et al.	
	15	5,384,451	01-24-1995	Smith et al.	
	16	5,398,003	03-14-1995	Heyl et al.	
	17	5,404,003	04-04-1995	Smith	
	18	5,442,940	08-22-1995	Secker et al.	
	19	5,481,620	01-02-1996	Vaidyanathan	
	20	5,549,111	08-27-1996	Wright et al.	
	21	5,575,284	11-19-1996	Athan et al.	
	22	5,588,435	12-31-1996	Weng et al.	
	23	5,608,820	03-04-1997	Vaidyanathan	
	24	5,610,996	03-11-1997	Eller	
	25	5,632,272	05-27-1997	Diab et al.	
	26	6,002,952	12-14-1999	Diab et al.	
	27	6,122,535	09-19-2000	Kaestle et al.	
	28	6,157,850	12-05-2000	Diab et al.	
	29	6,263,222	07-17-2001	Diab et al.	

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	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 2 OF 2	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
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	30	6,334,065	12-25-2001	Al-Ali et al.	
	31	6,650,917	11-18-2003	Diab et al.	
	32	6,699,194	03-02-2004	Diab et al.	
	33	6,745,060	06-01-2004	Diab et al.	
	34	6,770,028	08-03-2004	Ali et al.	
	35	7,215,984	05-08-2007	Diab et al.	
	36	7,489,958	02-10-2009	Diab et al.	
	37	7,499,741	03-03-2009	Diab et al.	
	38	7,509,154	03-24-2009	Diab et al.	
	39	7,530,949	05-12-2009	Al-Ali et al.	
	40	RE33,643	07-23-1991	Isaacson et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]

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Examiner Signature	/Robert Nasser/	Date Considered	11/27/2012

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SHEET 1 OF 5	Attorney Docket No.	MLR.012X1

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Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	1	EP 0352923 A1	01-31-1990	BAXTER INT		
	2	DE 3328862 A1	02-28-1985	SIEMENS AG		
	3	EPO 0104771 B1	04-04-1984	NELLCOR INC		
	4	EPO 645117 A	03-29-1995	SEIKO EPSON CORP		
	5	WO 95/21567	08-17-1995	INCREA OY		

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	6	Declaration of Perry D. Oldham in Support of Masimo Opposition to Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 7,215,984, Volume 1, Doc. 556, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	7	Declaration of Perry D. Oldham in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 7,215,984, Volume 2, Doc. 558, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	8	Masimo Corporation's Answering Brief in Opposition to Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent. No. 7,215,984, Doc. 555, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	9	Philip's Opening Brief in Support of Defendant's Motion for Summary Judgment of Invalidity and Nonnigringement of U.S. Patent No. 7,215,984, Doc. 442, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/21/12. (Redacted)	
	10	Philip Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 7,215,984, Doc. 394, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12.	
	11	Reply Brief in Support of Defendants' Motion for Summary Judgment of invalidity and Noninfringement of U.S. Patent. No. 7,216,984, Doc. 609, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 10/26/12. (Redacted)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
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SHEET 2 OF 5	Attorney Docket No.	MLR.012X1

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	12	Declaration of Gail Baura, Ph.D. in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 7,215,984, Doc. 561, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	13	Declaration of Gail Baura, Ph.D. in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,632,272, Doc. 554, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	14	Declaration of Perry D. Oldham in Support of Masimo Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 5,632,272, Doc. 553, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	15	Masimo Corporation's Answering Brief in Opposition to Defendant's Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272, Doc. 552, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	16	Opening Brief in Support of Defendants' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272, Doc. 444, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/21/12. (Redacted)	
	17	Defendants' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272, Doc. 402, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12	
	18	Reply Brief in Support of Defendants' Motion for Summary Judgment of Invalidity and Noninfringement of U.S. Patent No. 5,632,272, Doc. 614, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 10/26/12 (Redacted)	
	19	Declaration of Mohammed K. Diab in Support of Masimo's Oppositions to Defendants' Motions for Summary Judgment of Invalidity and Noninfringement of U.S. Patent Nos. 5,632,272 and 7,215,984, Doc. 563, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12 (Redacted)	
	20	Declaration of Perry D. Oldham in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 550, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12 (Redacted)	
	21	Masimo Corporation's Answering Brief in Opposition to Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 549, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12 (Redacted)	
	22	Philips' Opening Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 413, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 3 OF 5	Attorney Docket No.	MLR.012X1

NON PATENT LITERATURE DOCUMENTS			
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	23	Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 410, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12	
	24	Reply Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 613, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 10/26/12 (Redacted)	
	25	Declaration of Gail Baura, Ph.D. in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,263,222, Doc. 551, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	26	V. Ya. Volkov, "Enhancing the Reliability and Accuracy of Pulse Oximetry with a Built-In Expert System," *Biomedical Engineering*, Vol. 27, No. 3 (May-June 1993) (translated from Russian)	
	27	Declaration of Gail Baura, Ph.D. in Support of Masimo's Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 508, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/21/12.	
	28	Opening Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 445, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/21/12. (Redacted)	
	29	Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 406, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 8/14/12.	
	30	Reply Brief in Support of Defendants' Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 610, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 10/26/12. (Redacted)	
	31	Declaration of Perry D. Oldham in Support of Masimo Opposition to Defendant's Motion for Summary Judgment of Invalidity of U.S. Patent No. 6,699,194, Doc. 548, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 9/28/12. (Redacted)	
	32	Scharf, "Optimization of Portable Pulse Oximetry Through Fourier Analysis"	
	33	Scharf, "Pulse Oximetry Through Spectral Analysis"	
	34	Rusch, "Master's Thesis," Graduate School University of South Florida, Tampa, Florida (Dec., 1994)	
	35	Philips' Response to Masimo Corporation's Objections to the Report and Recommendation Regarding Claim Construction, Doc. 230, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/24/11	

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	First Named Inventor	Ammar Al-Ali
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	36	Masimo Corporation's Objections to the Report and Recommendation Regarding Claim Construction, Doc. 219, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/8/11	
	37	Defendants' Objections to Magistrate Judge Thynge's Report and Recommendation Regarding Claim Construction, Doc. 218, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/7/11	
	38	Report and Recommendation Regarding Claim Construction, Doc. 210, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 2/18/11	
	39	Memorandum Order Adopting Report and Recommendation Regarding Claim Construction, Doc. 319, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 1/17/11	
	40	Masimo Corporation's Response to Defendants' Objections to the Report and Recommendation Regarding Claim Construction, Doc. 232, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/24/11	
	41	V. Ya. Volkov, "Principles and Algroithms for Determining Blood Oxygenation Level by Pulse Oximetry," *Biomedical Engineering*, Vol. 27, No. 1 (Jan.-Feb. 1993) (translated from Russian)	
	42	Supplemental Expert Report of Dr. Robert Stone Regarding the invalidity of Masimo's Patents-in-Suit (U.S. Patent No. 5,632,272, U.S. Patent No. 6,263,222, U.S. Patent No. 7,215,984, and U.S. Patent No. 6,699,194, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/18/12	
	43	Appendixes for Expert Report of Dr. Robert Stone Regarding the invalidity of Masimo's Patents-in-Suit (U.S. Patent No. 5,632,272, U.S. Patent No. 6,263,222, U.S. Patent No. 7,215,984, and U.S. Patent No. 6,699,194, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/7/12	
	44	Expert Report of Dr. Robert Stone Regarding the invalidity of Masimo's Patents-in-Suit (U.S. Patent No. 5,632,272, U.S. Patent No. 6,263,222, U.S. Patent No. 7,215,984, and U.S. Patent No. 6,699,194, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/7/12	
	45	Revised Expert Report of Dr. Robert Stone Regarding the invalidity of Masimo's Patents-in-Suit (U.S. Patent No. 5,632,272, U.S. Patent No. 6,263,222, U.S. Patent No. 7,215,984, and U.S. Patent No. 6,699,194, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:09-cv-00080 (LPS/MPT) dated 3/7/12	
	46	Wukitsch, et al., "Knowing Your Monitoring Equipment," *Journal of Clinical Monitoring*, Vol. 4, No. 4 (Oct. 1998)	
	47	Second Amended Complaint for Patent Infringement, Doc. 42, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 4/25/12	

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

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 5 OF 5	Attorney Docket No.	MLR.012X1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	48	Masimo's Answer to Philips' Counterclaims, Doc. 28, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 12/30/11	
	49	Defendants' Answer and Philips Electronics North America Corp.'s Counterclaims to Masimo's First Amended Complaint, Doc. 11, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 11/7/11	
	50	Masimo's Answer to Philips' Counterclaims to Masimo's Second Amended Complaint, Doc. 358, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 6/4/12	
	51	Defendants' Answer and Philips Electronics North America Corp.'s Counterclaims to Masimo's Second Amended Complaint, Doc. 43, Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 1:11-cv-00742 (LPS/MPT) dated 5/11/12	

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Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 1 OF 2	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	4,623,248	11-18-1986	Sperinde	
	2	4,863,265	09-05-1989	Flower et al.	
	3	4,870,588	11-26-1989	Merhav	
	4	4,911,167	03-27-1990	Corenman et al.	
	5	4,934,372	06-19-1990	Corenman et al.	
	6	4,955,379	09-11-1990	Hall	
	7	4,965,840	10-23-1990	Subbarao	
	8	5,170,791	12-15-1992	Boos et al.	
	9	5,193,124	03-09-1993	Subbarao	
	10	5,270,942	12-14-1993	Reed	
	11	5,331,394	07-19-1994	Shalon et al.	
	12	5,353,356	10-04-1994	Waugh et al.	
	13	5,355,882	10-18-1994	Ukawa et al.	
	14	5,357,965	10-25-1994	Hall et al.	
	15	5,384,451	01-24-1995	Smith et al.	
	16	5,398,003	03-14-1995	Heyl et al.	
	17	5,404,003	04-04-1995	Smith	
	18	5,442,940	08-22-1995	Secker et al.	
	19	5,481,620	01-02-1996	Vaidyanathan	
	20	5,549,111	08-27-1996	Wright et al.	
	21	5,575,284	11-19-1996	Athan et al.	
	22	5,588,435	12-31-1996	Weng et al.	
	23	5,608,820	03-04-1997	Vaidyanathan	
	24	5,610,996	03-11-1997	Eller	
	25	5,632,272	05-27-1997	Diab et al.	
	26	6,002,952	12-14-1999	Diab et al.	
	27	6,122,535	09-19-2000	Kaestle et al.	
	28	6,157,850	12-05-2000	Diab et al.	
	29	6,263,222	07-17-2001	Diab et al.	

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

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Ammar Al-Ali
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L.
SHEET 2 OF 2	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	30	6,334,065	12-25-2001	Al-Ali et al.	
	31	6,650,917	11-18-2003	Diab et al.	
	32	6,699,194	03-02-2004	Diab et al.	
	33	6,745,060	06-01-2004	Diab et al.	
	34	6,770,028	08-03-2004	Ali et al.	
	35	7,215,984	05-08-2007	Diab et al.	
	36	7,489,958	02-10-2009	Diab et al.	
	37	7,499,741	03-03-2009	Diab et al.	
	38	7,509,154	03-24-2009	Diab et al.	
	39	7,530,949	05-12-2009	Al-Ali et al.	
	40	RE33,643	07-23-1991	Isaacson et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	**T**[1]

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

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111912

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT

Inventor	:	Ammar Al-Ali
App. No.	:	90/012559
Filed	:	September 13, 2012
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Nasser, Robert L
Art Unit	:	3992
Conf. No.	:	6710

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

Enclosed for filing in the above-identified application are two PTO/SB/08 Equivalents, a first listing patents and printed publications, the second listing other types of documents. Of the 91 references listed, 51 are uploaded to the EFS Web server concurrently with the present filing. The references are being submitted pursuant to 37 C.F.R. § 555, M.P.E.P. §§ 2001.06(c), 2202, 2206, 2208 and 2280, in that U.S. Patent Nos. 8019400; 7215984; 7530955; 8128572; 6002952; 6263222; and 6699194 are currently involved in litigation, namely, *Masimo Corp. v. Philips Elecs. North America Corp.*, No. 1:11-cv-00742-LPS-MPT (D. Del. Filed Aug. 19, 2011). The listed patents are part of (23) twenty-three third party reexamination requests simultaneously filed against patents owned by Masimo Corporation, or it's related company, Cercacor Laboratories, Inc. (formerly, Masimo Laboratories, Inc.). To the best of the undersigned's understanding, the references submitted herewith represent documents or document portions that are non-confidential as defined by any protective order governing information exchanged between the parties to the Masimo litigation mentioned above.

The Applicants understand that the Examiner has access to sophisticated online Patent Office computing systems that provide ready access to, for example, specification and drawings, publications, pending claims, and complete file histories, including, for example, cited art, office actions, responses, and notices of allowance. Thus, the Applicants have not enclosed copies of

these documents. However, if the Examiner would like copies provided, the Applicants would be pleased to provide these references at any time upon request.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 19, 2012

By: /John M. Grover/
John M. Grover
Registration No. 42,610
Attorney of Record
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Certificate of Service
I hereby certify on November 19, 2012, that a true and correct copy of this submission was mailed by first class mail, postage paid, to:

Tia Fenton
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1940 Duke Street
Alexandria, VA 22314

/John M. Grover/
John M. Grover

14372697

Electronic Acknowledgement Receipt	
EFS ID:	14270063
Application Number:	90012559
International Application Number:	
Confirmation Number:	6710
Title of Invention:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
First Named Inventor/Applicant Name:	8190223
Customer Number:	20995
Filer:	John M. Grover/Jessica Egigian
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Attorney Docket Number:	403381US104RX
Receipt Date:	19-NOV-2012
Filing Date:	13-SEP-2012
Time Stamp:	21:26:25
Application Type:	Reexam (Patent Owner)

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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Foreign Reference	EP0352923.PDF	1099258 d426c0fb3252496bf6452ff8c6426cea2376737d	no	11
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2	Foreign Reference	DE3328862.pdf	1289427 dbf57b02236e3ac2a02ca23e7407be0920d223b7	no	19
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47	Non Patent Literature	042-Second-Amended-Complaint.pdf	12961921 15e4d6e8fdc9e49883111646deca53c777b96960	no	265
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		Total Files Size (in bytes):	137390019		

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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
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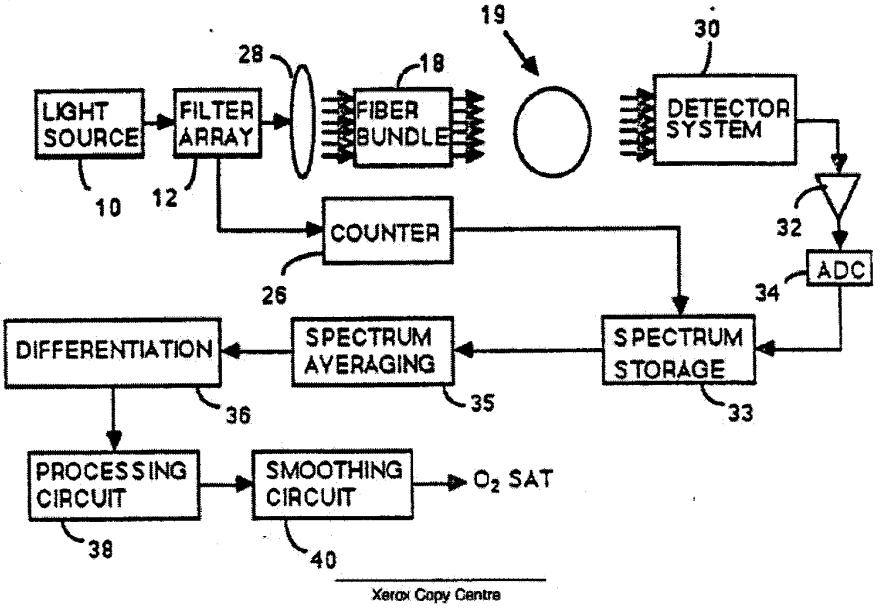
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(54) Spectrophotometric apparatus and method for monitoring oxygen saturation.

(57) A continuous spectrum of light (10) in a selected wavelength (12) band is transmitted through selected tissue. The spectral distribution of light transmitted through the selected tissue is monitored and differentiated (36) with respect to wavelength. The differentiated spectral data is processed (38) to determine the oxygen saturation in the tissue. The spectral data may be digitized (34) and stored in a storage device (33) that correlates the transmitted intensity with the wavelength. The intensity values for a predetermined number of spectra may be averaged (35) to smooth the spectral data. The first derivative of the averaged spectral data is then determined at predetermined wavelengths and processed (38) with an algorithm to determine the oxygen saturation.



EP 0 352 923 A1

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SPECTROPHOTOMETRIC APPARATUS AND METHOD FOR MONITORING OXYGEN SATURATION

BACKGROUND OF THE INVENTION

This invention relates generally to measurement of oxygen saturation in living tissue and particularly to non-invasive techniques for such measurements. Still more particularly, this invention relates to noninvasive spectrophotometric measurement of oxygen saturation of blood in body organs such as the brain.

Oxygen sufficiency and metabolism are parameters of fundamental importance in assessing the function of any body organ. In the absence of sufficient oxygen, provision of energy for tissue functions becomes impaired and is accompanied by a corresponding impairment in organ functioning. In case of extensive oxygen deprivation over a period of time, the organ looses viability, which may cause severe illness or even death.

Although all oxygen insufficiency adversely effects all body organs, the effect is most acute for the brain because of the brain's sensitivity with respect to oxygen demand and its dependance upon oxidative metabolism for proper functioning and viability. For example, it is known that hypoxia or anoxia of the brain for more than about a dozen seconds produces dysfunction, and an absence of oxygen for longer than a few minutes causes irreversible brain damage. A less acute impairment of oxygen availability causes a gradual loss in brain function, particularly in the higher centers of the cerebral cortex.

Because of the role that oxygen sufficiency plays in human physiology, intensive efforts have been made over the years to measure oxygenation in various organs. Brain and heart oxygenation are particularly important in this regard. However, it is difficult to obtain a direct measurements of oxygen saturation by a non-invasive technique except by means of pulse oximetry, which measures arterial oxygen saturation. Conway, *et al.* "A new approach for the estimation of body composition: infrared interactance.", Am. J. Clin. Nutr. 40: 1123-1130, 1984, reports that O_2 dependent organs such as the brain and heart regulate their O_2 delivery independently of changes in arterial O_2 content. Therefore, the effects of spontaneous changes in systemic O_2 availability for these organs cannot be measured by pulse oximetry.

Previous methods have used secondary effects, such as electroencephalographic and electrocardiographic changes to detect hypoxia. Electroencephalographic recordings indicating dysfunction are mainly useful for diagnosis of severe hypoxic or anoxic conditions in the brain. Electrocardiograph recordings are used to establish an oxygen deficiency in the heart muscle. However, these methods are diagnostic only in far advanced cases, and both the organs and the patient are in a precarious state of health before these signals become indicative of pathology.

It is commonly assumed that either insufficient blood circulation or ventilation is the main cause of inadequate oxygen delivery to cerebral and myocardial tissue. Although this assumption is probably correct in the majority of cases, blood flow measurements are indirect global measurements of organ oxygen delivery and are incapable of distinguishing adequate regional blood flow. Similarly, pulse oximetry is a global measurement of ventilation and oxygen delivery and is incapable of distinguishing regional ventilation and perfusion

It is known that the human body and its organs are relatively pervious to low level, non-hazardous light energy in the near infrared region of the spectrum. A beam of relatively low intensity radiation in the wavelength region of about 700 to 900 nm can penetrate and propagate through a relatively long optical path in any selected portion of a human or animal body that includes both bone and soft tissue. In particular, low intensity radiation in the 700 to 900 nm wavelength range will penetrate and propagate through a subject's skull and brain tissue with an intensity sufficient for detection with a conventional photodetector. Both hemoglobin and oxyhemoglobin absorb light in the 700 to 900 nm wavelength range. Therefore, the spectrum of such light transmitted through a subject's head may be analyzed to determine the level of oxygenation in brain tissue.

Considerable work has been done to develop techniques for non-invasively and atraumatically measuring blood oxygenation in particular, optical measurement techniques have been the subject of extensive research. The patents and publications discussed subsequently are representative of the prior art.

U.S. Patents 3,994,592 to Lardon *et al.*; 4,273,442 to Lubbers; 4,086,915 to Kofsky *et al.* and RE 31,879 to Lubbers *et al.* disclose spectral photometry apparatus that may be used for hemoglobin oxygenation testing. All four of these patents discuss or disclose differentiation of the signal at various wavelengths with respect to time. However, none of these patents discloses differentiation with respect to wavelength

U.S. Patent 3,994,592 to Lardon *et al.* is directed to a method for determining the ratio of the

concentration of two substances in a mixture of substances having adjacent absorption bands such that the radiation absorption of the mixture has a minimum between the absorption bands. Measuring absorption in three narrow spectral regions of the radiation transmitted through the mixture determines the concentration. The differences between the transmitted intensities in the three bands are used to determine the concentration ratio.

U.S. Patent 4,086,915 to Kofsky *et al.* is directed to an ear oximetry process and apparatus that uses light of two or more discrete wavelengths. Kofsky directs light of a first wavelength on an area of the subject's skin and detects the transmitted intensity. Light of a second wavelength is then directed upon the same area of the subject's skin and the transmitted intensity is again measured. Electrical signals indicative of the transmitted light intensities at the two wavelengths are time differentiated. The differentiated signals are processed with a set of predetermined coefficients to obtain the arterial oxygen saturation of the blood.

U.S. Patent 4,273,442 to Lubbers is concerned with the display of hemoglobin spectra derived from use of a spectrophotometer on the surface of body tissue. Lubbers discloses a spectral photometer that emits light toward a subject and detects the light reflected back from the subject. Successive maxima of the spectral distribution are detected, and the distances between successive maxima are calculated.

U.S. Patents 4,281,645 and 4,223,680 to Jobsis are directed to a spectrophotometric method and apparatus for making non-invasive *n vivo* measurements of local metabolism of a body organ such as the brain. Jobsis discloses selecting an optical path intersecting the organ and extending for several centimeters between points of light entry and exit on the surface of the body. Jobsis also discloses placing a plurality of near infrared light sources outside the body to provide light emissions of different wavelength in the 700 to 1300 nanometer spectral range. The light emissions have intensities below the level damaging to the body and the organ but sufficient to be detectable by a light sensor after transmission along the optical path. Jobsis discloses optical emissions including at least one measuring wavelength and at least one reference wavelength within the spectral range. Each measuring wavelength is selected such that the organ *n vivo* exhibits a selective absorption. The absorption depends upon a specific state of metabolic activity of the organ *n vivo*.

Both of these two Jobsis patents disclose directing measuring and reference wavelengths sequentially along the path and through the organ and receiving the transmitted light emissions at a light sensor. An electric circuit means produces an electrical signal representing the difference in absorption of the measuring and reference wavelengths by the organ as a function of the state of the metabolic activity *n vivo* The electrical signals are indicative of the particular state of metabolic activity of the organ. The method disclosed by Jobsis for determining qualitative changes in oxygen concentration depends upon the light absorbing characteristics of the enzyme cytochrome a, a_3, which is also known as cytochrome c oxidase.

The key element of Jobsis is the measurement of qualitative changes in oxygen concentration. Probes are placed on a subject's head to establish a baseline or reference point. Changes from the baseline are not calibrated.

U.S.Patent 4,510,938 to Jobsis relates to techniques for directing light to the head of a subject.

Stauffer *et al.*, Derivative Spectroscopy, Applied Optics, Vol. 7, No. 1, pp. 61-65, January, 1968 discloses that derivative spectroscopy has been used to enhance the detectability of overlapping spectral bands. The paper points out that derivative spectroscopy suppresses background radiation, reduces effects of instrumentally scattered radiation and suppresses atmospheric turbulence effects.

Ewalt *et al.*, Derivative Spectrometer, IBM Technical Disclosure Bulletin, Vol. 20, No. 3, pp. 1137-1140, August 1977 discloses that measuring the derivative with respect to wavelength of the usual transmission curve can improve the detection limit by an order of magnitude. This paper states that the derivative output signal is directly proportional to the concentration of absorbers in the sample path. The paper discusses a derivative spectrometer that uses a repetitive scan of a narrow wavelength band centered on the line or band peak of interest.

U.S.Patent 4,463,762 to Rubens discloses a technique for measuring oxygen absorption. Rubens uses a tourniquet to form a region of occlusion. Light of two different wavelengths is directed onto the skin tissue of the subject, and the amount of each wavelength absorbed is measured. Rubens determines the rate of change of the absorption of one wavelength relative to the other for producing a signal that indicates the rate of oxygen utilization in the tissue.

U.S.Patent 4,213,462 to Sato is directed to the detection of abnormalities such as cancerous growths. Tissue being tested is subjected to a first predetermined pressure and then exposed to light. The radiation reflected or absorbed is measured, and then the tissue is subjected to a second predetermined pressure and again exposed to the light. The difference in the absorption or reflectance characteristics for the different pressures indicates whether the tissue contains an abnormality.

U.S.Patent 4,548,505 to Ono is directed to a sensor for a spectral analyzer. The purpose of the Ono patent is to provide means for obtaining data as soon as the tip of the bundle of fibers contacts the tissue and before any change occurs in the tissue. A second purpose of this invention is to provide constant pressure on the tissue when data is taken to maintain a local hemostatic effect.

U.S.Patent 4,017,192 to Rosenthal relates to a technique for optical analysis of biomedical specimens where three interference filters are used to selectively pass light of a particular frequency through a biological sample. Rosenthal is particularly directed to automatic detection of abnormalities, such as cancer. Transmittance or reflectance data over a large number of wavelengths are correlated by multiple linear regression analysis with conventional clinical results to select test wavelengths and constants for a correlation equation. The correlation equation is applied to the spectral data to determine quantitatively the presence of the abnormality.

SUMMARY OF THE INVENTION

The present invention provides an improved apparatus and method for non-invasively and atraumatically quantitatively determining the oxygen saturation in living tissue. This invention has the advantages of using only a single light source and permitting continuous measurements of the spectrum transmitted through the tissue of interest.

An apparatus for measuring oxygen saturation in living tissue according to the present invention comprises means for directing a continuous spectrum of light in a selected wavelength band through selected tissue, means for determining the spectral distribution of light transmitted through the selected tissue, means for determining the first derivative of the spectral distribution of the light transmitted through the selected tissue with respect to wavelength, and means for processing the first derivative to determine the oxygen saturation in the tissue.

The means for determining the spectral distribution of light transmitted through the tissue preferably includes light detecting means for producing signals indicative of the light intensity transmitted through the tissue, and means for correlating the transmitted intensity with the wavelength of light incident on the tissue.

The apparatus according to the present invention may further include means for digitizing the signal output from the light detecting means, storage means for storing digitized intensity data as a function of wavelength, and means for averaging the intensity values for a predetermined number of spectra. The differentiating means is preferably configured to determine the first derivative of the averaged spectral data at predetermined wavelengths. The differentiating means is preferably configured to determine the oxygen saturation in the tissue by calculating a linear combination of the first derivatives of the spectral data at predetermined wavelengths.

A method according to the present invention for measuring oxygen saturation in living tissue, comprises the steps of directing a continuous spectrum of light in a selected wavelength band through selected tissue, determining the spectral distribution of light transmitted through the selected tissue, determining the first derivative of the spectral distribution of the light transmitted through the selected tissue with respect to wavelength, and processing the first derivative to determine the oxygen saturation in the tissue.

The step of determining the spectral distribution of light transmitted through the tissue preferably includes the steps of producing signals indicative of the light intensity transmitted through the tissue and correlating the transmitted intensity with the wavelength of light incident on the tissue.

The method according to the present invention also preferably includes the steps of digitizing the signal output from the light detecting means; storing digitized intensity data as a function of wavelength, and averaging the intensity values for a predetermined number of spectra. The method may also further include the step of forming the differentiating means to determine the first derivative of the averaged spectral data at predetermined wavelengths. The method may include the step of calculating the oxygen saturation using the algorithm

$$[O_2]_{SAT} = A\frac{\partial I_a}{\partial \lambda} + B\frac{\partial I_b}{\partial \lambda} + C\frac{\partial I_c}{\partial \lambda} + D$$

$$= A\frac{\partial I_a/\partial \lambda}{I_b/\partial \lambda} + B\frac{\partial I_c}{\partial \lambda} + C$$

where A, B, C and D are constants; a, b and c represent selected points in the transmitted spectrum and λ the wavelength. Another algorithm that may be used in the method of the invention is where the constants have been previously defined.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram of the apparatus of the invention;

Figure 2 illustrates a filter structure that may be used to obtain a continuous spectrum in a selected wavelength range;

Figure 3 graphically illustrates the logarithm of the reciprocal of spectral data obtained using the apparatus and methods of the present invention; and

Figure 4 graphically illustrates the first derivative of the logarithm of the reciprocal of the spectral data of Figure 3.

DESCRIPTION OF THE PREFERED EMBODIMENT

Referring to the block diagram of Figure 1, a light source 10 provides light to an optical filter assembly 12. The light source may be either a white light source or an infrared lamp that produces wideband light in a selected wavelength range. The wavelength range preferably includes wavelengths of about 700 to 900 nm.

A filter assembly suitable for use in the present invention is described in U.S Patent 4,017,192 to Rosenthal, which is hereby incorporated by reference into this disclosure. Referring to Figure 2, the filter assembly 12 is preferably in the form of a paddle wheel 16 mounted for rotation about an axis perpendicular to the light path between the lamp 10 and a fiber optic bundle 18. The paddle wheel 16 is typically driven at about 3 revolutions per second. In a preferred embodiment, three narrow bandwidth plate-shaped optical interference filters 22 are mounted on a hexagonal axle 24. The planes of the filters 22 are equally separated by angles of about 120°. The filters 22 extend radially from the axle 24 in planes that intersect approximately in a line coincident with the axis of rotation of the paddle wheel 16. The filters 22 preferably extend equal radial distances from the axis. The cross sectional configuration of the filters 22 on the axle 24 thus resembles the letter Y. This arrangement of a single light source and three rotating filters 22 provides a continuous spectral range in the near infrared region of the spectrum between the wavelengths of about 700 nm and 1000 nm.

Referring to Figures 1 and 2, a signal indicative of the angle of rotation of the filter assembly 12 is passed through a digital counter circuit 26 that is set to provide control signals corresponding to selected angles of rotation of the paddle wheel 16. Since the angle of rotation is related to the wavelength output of the filter assembly 12, the control signals also indicate the wavelength of light that is being applied to the subject. A counter circuit suitable for use in the present invention is disclosed in U.S. Patent No. 3,861,788 to Webster, the disclosure of which is hereby incorporated by reference into the present disclosure. An optical interrupter may be used to correlate the wavelength and intensity so that spectral data comprising intensity as a function of wavelength may be measured.

The light beam output from the filter assembly 12 may then impinge upon a lens system 28 that focuses the light onto the fiber optic bundle 18. The fiber optic bundle 18 is convenient for directing the light to a portion of a subject's body such as the head, where tissue hemoglobin oxygenation is to be measured. The lens system 28 preferably is designed to provide a wide beam of essentially uniform intensity over the fiber bundle 18. The fiber optic bundle 18 is preferably an assembly of multimode optical fibers (not shown) having a numerical aperture suitable for receiving light input from the lens system 28. Such fiber optic bundles are well-known in the art and are therefore not described in detail herein. The light is typically input to the subject's forehead or to the top of the head. Applying the light to the top of the subject's head permits direct measurements of hemoglobin saturation in the sagittal sinus, which is where venous blood pools in the top of a person's head.

A detector system 30 that includes at least one photodetector (not shown) detects the waves output from the tissue and forms an electrical signal indicative of the detected light intensity. When the detector system includes a single photodetector, the output of the detector system 30 is amplified by an amplifier 32, which may be a logarithmic amplifier if the range of the electrical output of the detector is sufficiently broad. The analog output of the amplifier 32 is then converted to a digital signal by an analog to digital

converter (ADC) 34.

More than one detector may be used to determine the saturation in various parts of the head. If multiple detectors are used then, there will be an amplifier (not shown) and an ADC (not shown) for each detector. For example, a detector may be placed within one to two centimeters of the light source for measuring the saturation of the skull and skin. A second detector may be used to measure the far field at distances greater than three centimeters from the source. This far field detector may be used to measure the average saturation of the skin, skull and brain. The spectral difference between the far field and near field detectors then are indicative of the brain saturation.

The output of the detector 30 is sampled at enough wavelengths to obtain data that can be processed to obtain at least a first derivative of the absorption of oxyhemoglobin with respect to wavelength. A spectrum storage device 33 stores the sampled detector output. The counter circuit 26 has its control signal output connected to the storage device 32 to correlate the detected and stored intensity data with the wavelength incident on the tissue. A spectrum averaging circuit 35 averages the spectral data and provides the averaged output to a differentiator 36. A signal processing device 40 then applies an algorithm to the smoothed derivative to determine the O_2 saturation in the tissue.

The spectral data from about 700 nm to 1000 nm is divided and stored in 300 wavelength intervals of unequal spectral bandwidth. In order o enhance the signal to noise ratio, a number of spectra may be stored and time averaged to produce the spectra shown in Figure 3. For example, the light source and associated electronics may be used to obtain three spectra per second. Each measured spectrum is stored in the storage device 33. Spectrum averaging circuit 34 averages a selected number of spectra. Figure 3 is a plot of the logarithm of the reciprocal of the intensity for 100 averaged spectra.

The first derivative of the spectral data is preferably calculated at 766, 835 and 865 nm although other wavelengths in the 700 to 1000 nm range have been shown to give similar results. In order to enhance the spectral features of interest, the calculation of the derivative preferably involves an averaging process rather than merely subtracting successive intensity values and dividing by the change in wavelength. For example, the spectral data may be divided into 300 intensity intervals or segments. In order to find the derivative of the thirteenth segment, the average value (I_{1-10})for the first ten segments may be calculated and stored. The next five segments (I_{11-15}) may then skipped. The average intensity for the next ten segments 16-25 (I_{16-25}))is then calculated. The derivative is then found by dividing the difference of the intensity averages by the change in wavelength. The number of segments averaged is referred to as the segment size and the number of segments skipped is referred to as the gap. Figure 4 shows the derivative of the spectral data of Figure 3 for a segment size of 10 and a gap of 1.

A preferred algorithm for calculating the oxygen saturation uses a constant plus a linear combination of the first derivatives of the spectral data. For example the oxygen saturation may be found from the thirteenth, twenty-seventh and ninetieth data points so that

$$[O_2]_{SAT} = A\frac{\partial I_{13}}{\partial \lambda} + B\frac{\partial I_{27}}{\partial \lambda} + C\frac{\partial I_{90}}{\partial \lambda} + D.$$

The oxygen saturation may also be written as

$$[O_2]_{SAT} = A\frac{\partial I_a/\partial \lambda}{\partial I_b/\partial \lambda} + B\,\partial I_c/\partial \lambda + C.$$

Referring to Figures 3 and 4, one set of preferred data points and the corresponding wavelengths are: segment 30 = 766 nm; segment 164 = 835 nm and segment 235 = 865 nm. Therefore the oxygen saturation is

$$[O_2]_{SAT} = A\frac{\partial I_{30}/\partial \lambda}{\partial I_{164}/\partial \lambda} + B\,\partial I_{235}/\partial \lambda + C.$$

The constants are determined in the calibration of each instrument. For one instrument that has been used A = 4.046; B = 519.546 and C = 26.488. Other algorithms may be used to calculate the oxygen

saturation. In some cases it may be desirable to use a plurality of different algorithms to obtain the saturation. The saturations may then be averaged. If there is reason to believe that one algorithm may be more reliable than another, appropriate weighting factors may be used in the averaging process.

The derivative of the spectral data may be smoothed before processing by a CPU 38 with an algorithm that produces a quantitative measurement of the hemoglobin oxygenation in the tissue. The smoothing circuitry may include digital filter circuitry for calculating a weighted average of the previous signal and the new signal. For example, the output of the smoothing circuit may be 90% of the previous value plus 10% of the new value. The saturation output may be expressed as

$SAT_{OUT} = 0.1\ SAT_{CUR} + 0.9SAT_{PREV}$.

Both methods of smoothing prevent the signal input to the processor from changing too rapidly.

The method of the invention may also include means for calculating the second and higher derivatives of the spectral data curve with respect to wavelength. Using the derivatives of the spectral data to calculate the oxygen saturation eliminates errors caused by nonspecific absorptions and light scattering by the skull, scalp and dura. The second derivative may be obtained numerically from the first derivative in the same manner that the first derivative is obtained from the spectral data.

The apparatus of the present invention may be used to make a tomographic map of a selected portion of a subject's body such as the brain or heart. Localized changes is cellular oxidative metabolism are indicative of conditions such as stroke, infarction, oligemia and ischemia. The transmitted spectrum is processed as described above for light paths in different planes through the organ of interest. The data for making a tomographic map may be obtained by moving the fiber optic bundle and the detector relative to the organ. The use of more than one detector according to the invention at a time may permit the data to be obtained in less time than would be required with the use of a single source and detector.

Claims

1. Apparatus for measuring oxygen saturation in living tissue, comprising:
means for directing a continuous spectrum of light in a selected wavelength band through selected tissue;
means for determining the spectral distribution of light transmitted through the selected tissue;
means for determining a derivative with respect to wavelength of the spectral distribution of the light transmitted through the selected tissue; and
means for processing the derivative to determine the oxygen saturation in the tissue.

2. The apparatus of claim 1, wherein the means for determining the spectral distribution of light transmitted through the tissue includes: light detecting means for producing signals indicative of the light intensity transmitted through the tissue; and
means for correlating the transmitted intensity with the wavelength of light incident on the tissue.

3. The apparatus of claim 2, further including:
means for digitizing the signal output from the light detecting means;
storage means for storing digitized intensity data as a function of wavelength; and
means for averaging the intensity values for a predetermined number of spectra.

4. The apparatus of claim 3 wherein the differentiating means is configured to determine the first derivative of the averaged spectral data at predetermined wavelengths.

5. The apparatus of claim 4, further including means for determining the oxygen saturation in the tissue by calculating a linear combination of the first derivatives of the spectral data at the predetermined wavelengths.

6. The apparatus of claim 1 wherein the continuous spectrum includes wavelengths ranging from 700 nm to 1000 nm.

7. The apparatus of claim 2, further including:
a first photodetector for detecting signals indicative of the oxygen saturation of the skin and bones adjacent the tissue;
a second photodetector for detecting signals indicative of the oxygen saturation of the tissue and the skin and bones adjacent the tissue; and
means for processing signals output from the first and second photodetectors to determine the oxygen saturation of the tissue.

8. A method for measuring oxygen saturation in living tissue, comprising the steps of:
directing a continuous spectrum of light in a selected wavelength band through selected tissue;
determining the spectral distribution of light transmitted through the selected tissue;
determining the first derivative of the spectral distribution of the light transmitted through the selected tissue

with respect to wavelength; and
processing the first derivative to determine the oxygen saturation in the tissue.

9. The apparatus of claim 5, wherein, the means for determining oxygen saturation uses the formula

$$[O_2]_{SAT} = A\frac{\partial I_a}{\partial \lambda} + B\frac{\partial I_b}{\partial \lambda} + C\frac{\partial I_c}{\partial \lambda} + D$$

where A, B, C and D are constants; a, b and c represent selected points in the transmitted spectrum and λ is the wavelength.

10. The apparatus of claim 9 wherein

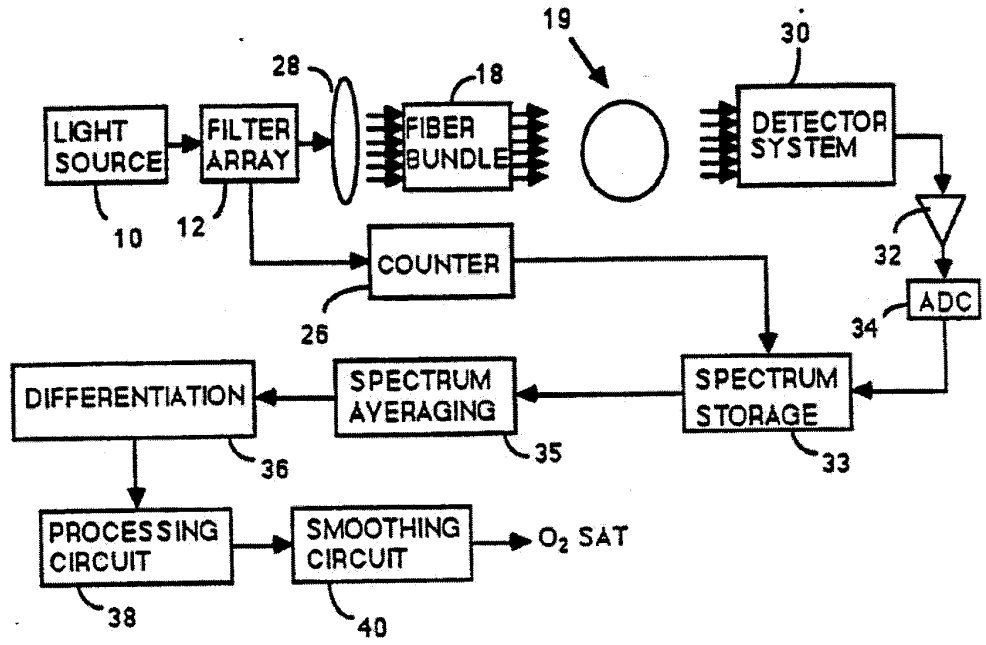
$$[O_2]_{SAT} = A\frac{\partial I_a}{\partial \lambda} + B\frac{\partial I_b}{\partial \lambda} + C\frac{\partial I_c}{\partial \lambda}$$

$$+ D = = A\frac{\partial I_a/\partial \lambda}{\partial I_b/\partial \lambda} + B\,\partial I_c/\partial \lambda + C.$$

11. The apparatus of claim 10 wherein

$$[O_2]_{SAT} = A\frac{\partial I_{766}/\partial \lambda}{\partial I_{835}/\partial \lambda} + B$$

where I_{766} is the intensity at a wavelength of 766 nm, I_{835} is the intensity at a wavelength of 835 nm and I_{865} is the intensity at a wavelength of 865 nm.


LIGHT SOURCE
FILTER ARRAY
FIBER BUNDLE
DETECTOR SYSTEM
COUNTER
ADC
SPECTRUM STORAGE
SPECTRUM AVERAGING
DIFFERENTIATION
PROCESSING CIRCUIT
SMOOTHING CIRCUIT
O_2 SAT
10
12
18
19
26
28
30
32
33
34
35
36
38
40

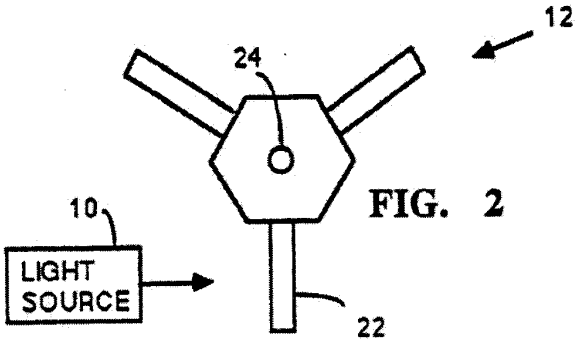

12
24
10
LIGHT SOURCE
22

FIG. 2

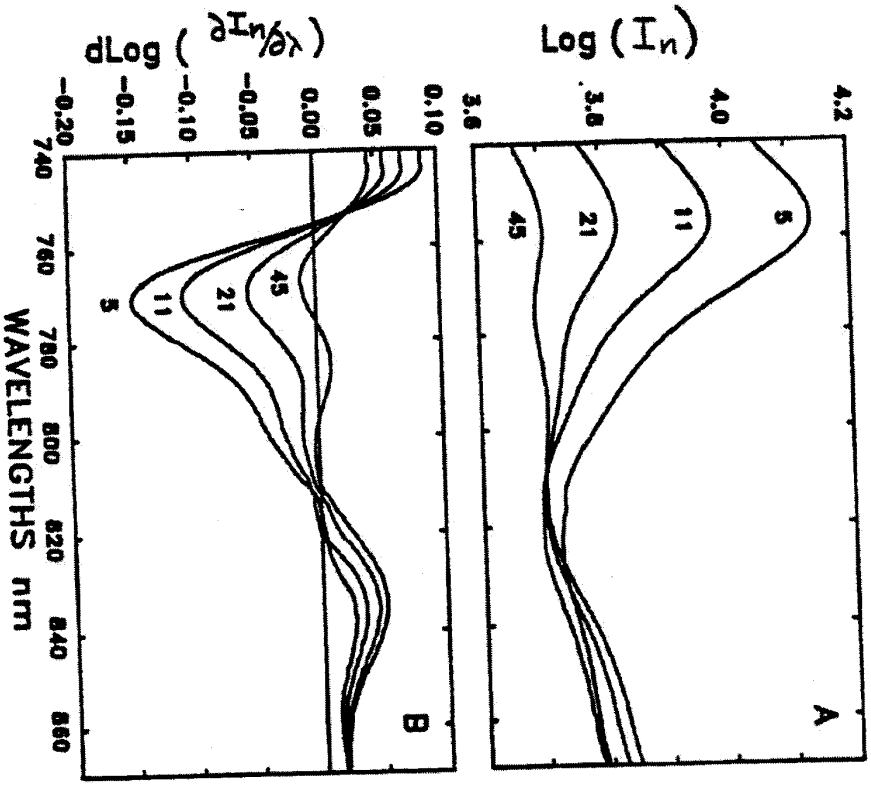

Log (I_n)
3.6
3.8
4.0
4.2
5
11
21
45
A

FIG. 3

dLog ($\partial I_n/\partial\lambda$)
−0.20
−0.15
−0.10
−0.05
0.00
0.05
0.10
740
760
780
800
820
840
860
WAVELENGTHS nm
5
11
21
45
B

FIG. 4

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 30 6879

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.5)
Y	EP-A-0 046 601 (HELLIGE GMBH) * abstract; page 9, line 21 - page 14, line 13; figure 1 *	1	A 61 B 5/00 G 01 N 21/31
A		2,4,5,8,9	
Y	EP-A-0 063 431 (M. KONOMI) * abstract; page 9, line 18 - page 21, line 7, figures 4,13 *	1	
A		2,3,6	
A,D	US-A-4 086 915 (H. I. KOFSKY et al.) * abstract; column 3, line 57 - column 4, line 25; figure 1 *	1-5	
A,D	IBM TECHNICAL DISCLOSURE BULLETIN vol. 20, no. 3, August 1977, pages 1137-1140, New York, USA; A. B. EWALT et al.: "Derivative Spectrometer" * whole document *	1-3	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 B 5/00
A 61 B 5/14
G 01 N 21/31

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	17-10-1989	WEIHS J.A.

CATEGORY OF CITED DOCUMENTS

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EPO FORM 1503 03.82 (P0401)

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Tissue photometry method and device, in particular for quantatively determining the blood oxygen saturation from photometric measurements

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Applicant(s): SIEMENS AG [DE] + (SIEMENS AG)

Classification: - international: ***A61B5/00; G01J3/28; G01N33/48;*** *G01J3/12; G01N21/78;* (IPC1-7): G01J3/28; G01N21/25; G01N33/48

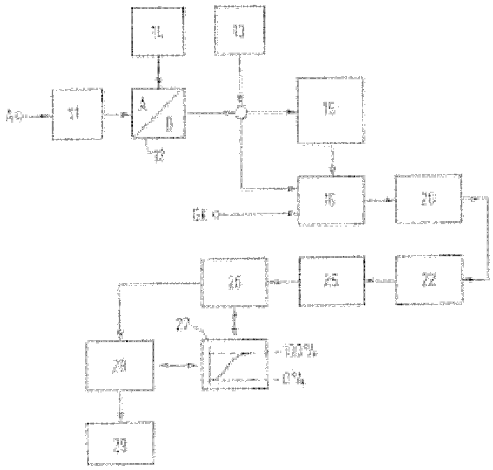
- Euro: A61B5/1455N; G01J3/28; G01N33/48

Application number: DE19833328862 19830810

Priority number(s): DE19833328862 19830810; DE19823234388 19820916

Abstract of DE3328862 (A1)

The invention relates to a tissue photometry method and device, in particular for quantitatively determining the blood oxygen saturation from photometric measurements periodically obtained using a photometer having a monochromator. Hitherto it was possible to draw essentially only qualitative conclusions from photometric spectra. According to the invention, a first spectrum is extracted from the periodic signal sequence, a specified number of further spectra are chosen on the basis of a selectable quality criterion, a Fourier transformation of the spectr into the frequency space is undertaken and, on the basis of signals in the Fourier spectrum, the characteristic value of a test sample, in particular the blood oxygen saturation, is determined by comparison with a given calibration curve. The associated device and its evaluation circuit comprise at least one



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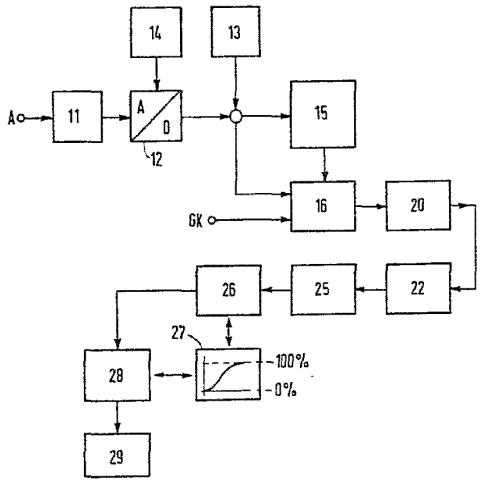
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Behördeneigentum

(54) Verfahren und Vorrichtung zur Gewebefotometrie, insbesondere zur quantitativen Ermittlung der Blut-Sauerstoff-Sättigung aus fotometrischen Meßwerten

Die Erfindung bezieht sich auf ein Verfahren und eine Vorrichtung zur Gewebefotometrie, insbesondere zur quantitativen Ermittlung der Blut-Sauerstoff-Sättigung aus fotometrischen Meßwerten, welche mittels eines Fotometers mit Monochromator periodisch gewonnen werden. Bisher konnten aus fotometrischen Spektren im wesentlichen nur qualitative Aussagen abgeleitet werden. Gemäß der Erfindung wird aus der periodischen Signalfolge ein erstes Spektrum herausgegriffen, anhand eines wählbaren Gütekriteriums eine vorgegebene Anzahl weiterer Spektren ausgewählt, eine Fourier-Transformation der Spektren in den Frequenzraum vorgenommen und anhand von Signalen im Fourier-Spektrum durch Vergleich mit einer vorgegebenen Eichkurve der charakteristische Wert einer Meßprobe, insbesondere die Blutsauerstoffsättigung ermittelt. Die zugehörige Vorrichtung mit einer Auswerteschaltung umfaßt dabei wenigstens eine Auswahleinheit, eine Einheit zur Fourier-Transformation und einen Signalselektor.



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Patentansprüche

1. Verfahren zur Gewebefotometrie, insbesondere zur quantitativen Ermittlung der Blut-Sauerstoff-Sättigung aus fotometrischen Meßwerten, welche bei einer Meßprobe mittels eines Fotometers mit Monochromator periodisch gewonnen werden, dadurch gekennzeichnet, daß

a) aus der periodischen Signalfolge ein erstes Spektrum herausgegriffen wird,

b) anhand eines wählbaren Gütekriteriums eine vorgegebene Anzahl weiterer Spektren ausgewählt wird,

c) eine Fourier-Transformation der Spektren in den Frequenzraum vorgenommen wird und

d) anhand von Signalmerkmalen im Fourier-Spektrum durch Vergleich mit einer vorgegebenen Eichkurve der charakteristische Wert der Meßprobe, insbesondere die Blutsauerstoffsättigung, ermittelt wird.

2. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß für den Verfahrensschritt a) das erste Spektrum mittels eines Triggerimpulses abgeleitet wird.

3. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß das Gütekriterium bei Verfahrensschritt b) einen Formvergleich der Spektren beinhaltet.

4. Verfahren nach Anspruch 3, dadurch gekennzeichnet, daß der Formvergleich nach Digitalisierung der Spektrendaten erfolgt.

5. Verfahren nach Anspruch 4, dadurch gekennzeichnet, daß die Digitalisierung vom Monochromator wellenlängenabhängig gesteuert ist.

6. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß das Meßsignal einer Störungsreduktion unterzogen wird.

7. Verfahren nach Anspruch 6, dadurch gekennzeichnet, daß die Störungsreduktion mittels selektiver Addition und anschließender Mittelung (sog. averaging) erfolgt.

8. Verfahren nach Anspruch 7, dadurch gekennzeichnet, daß für die selektive Addition zwischen 15 und 60 Spektren, vorzugsweise 30 Spektren, ausgewählt werden.

9. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß für Verfahrensschritt d) als Signalmerkmal die Amplituden bestimmter Frequenzen bzw. Frequenzbereiche herausgegriffen werden.

10. Verfahren nach Anspruch 9, dadurch gekennzeichnet, daß die Amplitude eines Maximums herausgegriffen wird.

11. Verfahren nach Anspruch 9, dadurch gekennzeichnet, daß das Verhältnis der Summen der Amplituden solcher Frequenzen die oberhalb eines vorgegebenen Signalminimums liegen, zur Summe

der Amplituden derjenigen Frequenzen, die unterhalb des Minimums liegen, als Signalmerkmal herangezogen wird.

12. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß die Eichkurve durch Korrelation mit einer oxygenierten und einer desoxygenierten Probe ermittelt wird.

13. Vorrichtung zur Durchführung des Verfahrens nach Anspruch 1 oder einem der Ansprüche 2 bis 12, dadurch gekennzeichnet, daß die Auswerteschaltung wenigstens eine Auswahleinheit (11 - 16) für die Spektren, eine Einheit zur Fourier-Transformation (25) und einen Signalselektor (26) zum Vergleich der selektierten Merkmale mit einer vorgegebenen Eichkurve umfaßt.

14. Vorrichtung nach Anspruch 13, dadurch gekennzeichnet, daß die Auswahleinheit (11 - 16) Mittel zum Selektieren der Meßspektren anhand vorgegebener Gütekritieren aufweist.

15. Vorrichtung nach Anspruch 13, dadurch gekennzeichnet, daß zusätzliche eine Einheit zur Störungsreduktion (20) vorhanden ist.

16. Vorrichtung nach Anspruch 15, dadurch gekennzeichnet, daß die Einheit zur Störungsreduktion (20) ein Mittelwertbildner ist.

17. Vorrichtung nach Anspruch 13, dadurch gekennzeichnet, daß ein Speicher (15) vorhanden ist, in welchem die aufgenommenen Spektren zur weiteren Verarbeitung zwischengespeichert werden.

18. Vorrichtung nach Anspruch 13, d a d u r c h g e k e n n z e i c h n e t , daß dem Signalselektor (26) eine Einheit (27) zur rechnerischen Festlegung der Eichkurve zugeordnet ist.

19. Vorrichtung nach Ansruch 13, d a d u r c h g e k e n n z e i c h n e t , daß vor der Einheit zur Fourier-Transformation (25) eine Einrichtung (22) zur Spiegelung und/oder Entzerrung der Meßspektren eingeschaltet ist.

20. Vorrichtung nach Anspruch 13, d a d u r c h g e k e n n z e i c h n e t , daß ein Digital-Rechner zur Auswertung vorhanden ist.

21. Vorrichtung nach Anspruch 20, d a d u r c h g e k e n n z e i c h n e t , daß als Digital-Rechner ein Mikroprozessor mit zugehörigem Speicher verwendet wird.

3328862

SIEMENS AKTIENGESELLSCHAFT
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Unser Zeichen
VPA 82 P 8527 01 DE

Verfahren und Vorrichtung zur Gewebefotometrie, insbesondere zur quantitativen Ermittlung der Blut-Sauerstoff-Sättigung aus fotometrischen Meßwerten

Die Erfindung bezieht sich auf ein Verfahren und eine Vorrichtung zur Gewebefotometrie, insbesondere zur quantitativen Ermittlung der Blut-Sauerstoff-Sättigung aus fotometrischen Meßwerten, gemäß dem Oberbegriff des Patentanspruchs 1.

Für die Sauerstoffversorgung in Körpergeweben spielt der Oxygenierungsgrad des Sauerstoffträgers Hämoglobin im Kapillarnetz des Gewebes eine maßgebliche Rolle. Mit Hilfe der Reflexionsspektroskopie kann aufgrund des unterschiedlichen Absorptionsverhaltens von oxygeniertem und desoxygeniertem Hämoglobin prinzipiell eine Aussage über den momentanen Oxygenierungsgrad in den oberflächlich verlaufenden Kapillaren getroffen werden. Es ist bereits bekannt, Reflexionsspektroskopie als Gewebefotometrie "in vivo" durchzuführen. Dabei wird insbesondere durch den Einsatz von flexiblen Lichtleitern die Untersuchung in kleinen Arealen möglich, wobei Artefakte durch Bewegungen der Gewebeoberflächen durch kurze Aufnahmezeiten verhindert werden sollen.

Es sind Lichtleiter-Fotometer vorgeschlagen worden, mit denen Signalspektren einer Gewebeprobe in Abhängigkeit von der Wellenlänge ermittelt werden können. Aus dem Amplitudenverlauf eines einzelnen Spektrums kann ein Sachverständiger Aussagen über die Oxygenierung der Gewebeprobe ableiten.

Wht 2 Rl / 02.08.1983

Allerdings blieben die Aussagen bisher weitgehend auf eine qualitative Deutung der Spektren beschränkt. Aufgabe der Erfindung ist es daher, ein Verfahren anzugeben sowie eine zugehörige Vorrichtung zu schaffen, mit denen quantitative Aussagen über charakteristische Größen von Meßproben gemacht werden können.

Die Aufgabe ist erfindungsgemäß durch die kennzeichnenden Merkmale des Verfahrenshauptanspruches 1 sowie des darauf zurückbezogenen Vorrichtungsanspruches 13 gelöst. Vorteilhafte Weiterbildungen der Erfindung sind in den Unteransprüchen angegeben.

Mit der Erfindung lassen sich in überraschend einfacher Weise die bei der Gewebefotometrie periodisch anfallenden Spektren auswerten. Es können nunmehr auch genaue quantitative Aussagen insbesondere über den Oxygenierungsgrad von Hämoglobin beliebiger Meßproben gemacht werden. Damit ist nun ein Weg aufgezeigt, mit dem der Einsatz des beschriebenen Verfahrens in die klinische Praxis entscheidend erleichtert wird.

Weitere Vorteile und Einzelheiten der Erfindung ergeben sich aus der nachfolgenden Figurenbeschreibung anhand der Zeichnung in Verbindung mit den übrigen Unteransprüchen.

Es zeigen:

Fig. 1 den schematischen Aufbau eines Fotometers mit Spektrometer,

Fig. 2 eine Originalkurve zur Gewebefotometrie, die mit dem verwendeten Spektrometer gemessen wurde,

Fig. 3 das Ergebnis einer Vorverarbeitung für eine oxygenierte und eine desoxygenierte Meßprobe,

Fig. 4 die zugehörigen Kurven im Frequenzraum,

Fig. 5 derartige Kurven zur Darstellung der Kinetik des Desoxygenierungsvorganges,

Fig. 6 blockschaltbildmäßig eine Vorrichtung zur Durchführung der anhand der Figuren 2 bis 5 dargestellten Verfahrensschritte.

In der Figur 1 besteht ein Mikro-Lichtleiter-Fotometer im wesentlichen aus einer Lichtquelle 1, die durch eine Xenon-Höchstdrucklampe realisiert ist. Von der Lichtquelle 1 wird das Licht über ein Filtersystem 2 auf eine Lichtleitfaser 3 von 70 µm Durchmesser als Sendelichtleiter Gewebeprobe P geleitet. Das reflektierte Licht wird über sechs Fasern, die ringförmig um den Sendelichtleiter angeordnet und pauschal mit 4 bezeichnet sind, zu einem Wellenlängenselektor geführt. Letzterer besteht aus einer mittels eines Motors 6 rotierbaren Verlaufsinterferenzfilterscheibe 5 als Monochromator, bei der in Abhängigkeit vom Drehwinkel Licht unterschiedlicher Wellenlänge zwischen 495 nm und 615 nm selektiert wird. Die Interferenzfilterscheibe 5 läßt an der Meßstelle M in Abhängigkeit vom Drehwinkel das Licht verschiedener Wellenlängen passieren, wobei bei einem Drehwinkel von 0 bis 180° der Wellenlängenbereich zwischen 495 und 615 nm in aufsteigender Folge und im Bereich von 180 bis 360° in umgekehrter Richtung durchlaufen wird. Die Intensität des transmittierten Lichtes wird von einem Fotomultiplier 7 gemessen und in Form eines analogen Spannungssignals zwecks Auswertung und weiterer Verrechnung ausgegeben. Das Spannungssignal ge-

langt dazu auf eine vorzugsweise digital arbeitende Auswertevorrichtung 10, die weiter unten im einzelnen beschrieben wird. Bei jeder Scheibenumdrehung des Monochromators 5 kann ein Triggerimpuls für die Auswertung abgeleitet werden.

Es ist auch möglich, ein Spektrometer zu verwenden, bei dem das eingestrahlte Licht monochromatisiert und dann das Spektrum periodisch abgescannt wird. Durch Ableitung weiterer Triggerpulse können bestimmte Wellenlängen markiert werden, um die Digitalisierung der Meßsignale wellenlängenabhängig zu steuern.

Der Aufbau der Auswertevorrichtung 10 wird anhand der Figur 6 beschrieben; aus den Figuren 2 bis 5 ergibt sich zunächst im wesentlichen die verfahrensmäßige Behandlung der Meßsignale.

Figur 2 zeigt einerseits, daß das Meßsignal periodisch mit der Rotation der Interferenz-Filterscheibe 5 verläuft und andererseits, daß es von einem starken Rauschen überlagert wird. Zur weiteren Signalverarbeitung müssen die Signale in einzelne Perioden getrennt werden. Dabei besteht die Schwierigkeit, daß einerseits die Periodenlänge unbekannt ist und andererseits die Längen verschiedener Perioden nicht identisch sind. Letzteres kann beispielsweise durch Schwankungen der Rotationsgeschwindigkeit der Verlaufsinterferenzfilterscheibe 5 bewirkt werden.

Bei dem vorgeschlagenen Verfahren wird zunächst ein "Referenz-Spektrum" ermittelt. Als Kriterium für die Güte eines solchen Spektrums können u.a. das Signal/Rausch-Verhältnis , die Signalhöhe oder andere Signal-

eigenschaften herangezogen werden. Durch Vergleich einzelner Spektren anhand der Gütekriterien werden andere geeignete Abschnitte für die Auswertung gefunden. Beispielsweise werden zunächst eine "Referenz-Periode" ermittelt und mittels Korrelation die ähnlichsten Abschnitte gefunden. Dabei kann auch genutzt werden, daß die Interferenzfilterscheibe 5 unabhängig vom Meßsignal bereits eine periodische Grundfunktion erzeugt, deren Maxima bzw. Minima zur Periodenfindung dienen.

Es werden also mit obigem Verfahren aus den Meßspektren einander ähnliche Abschnitte aufgefunden. Zwar ist die Korrelationslänge im wesentlichen durch die Länge des Referenzspektrums bestimmt; es lassen sich aber unterschiedliche Periodenlängen durch Überlappung der Korrelationsfelder kompensieren. Durch letzteren Verfahrensteilschritt kann man also vom Triggerimpuls der Filterscheibe unabhängig werden.

Es ergibt sich somit die Möglichkeit, anhand von Gütekriterien aus der großen Anzahl von vorhandenen Spektren eine bestimmte Anzahl Einzelspektren auszuwählen. Diese Einzelspektren können aber noch Störungen, beispielsweise Signalrauschen, aufweisen.

Eine Störungsunterdrückung kann im allgemeinen durch eine gewichtete Mittelung (sog. averaging) erreicht werden. Man kann zeigen, daß eine Mittelung von mehr als 15 Perioden bereits zu einem guten Ergebnis führt. Beispielsweise sind in der Figur 3 zwei Frequenzspektren dargestellt, die nach dem vorher beschriebenen Verfahrensschritt vorverarbeitet und einer Mittelung über 30 Perioden unterzogen wurden. Dabei ist das erste Spektrum von einer oxygenierten und das zweite Spektrum von einer desoxygenierten Probe gewonnen worden.

Da die vorverarbeiteten Signale periodisch und bandbegrenzt sind, können sie mit Hilfe der Fourier-Transformation in den Frequenzraum transformiert werden. Die Transformation führt zu einer Darstellung der Wellenlängenfunktionen als Amplituden-Frequenzdiagramme und ist in der Figur 4 für beide Proben dargestellt.

Der Aufbau der Interferenz-Filterscheibe 5 bedingt bei hohen Rotationsgeschwindigkeiten einen über den Wellenlängenbereich nahezu symmetrischen Signalverlauf, was insbesondere aus Figur 3 ersichtlich ist. Die Signalverarbeitungsgeschwindigkeit kann dadurch erhöht werden, daß jeweils nur eine Periodenhälfte gemessen und anschließend gespiegelt wird. Bei hohen Rotationsgeschwindigkeiten ist ein theoretischer Informationsverlust vernachlässigbar.

Änderungen der Hämoglobin-Oxygenierung bewirken eine deutliche Veränderung der korrespondierenden Amplituden-Frequenzdiagramme, wobei durch eine Oxygenierung eine Zunahme der Amplituden bewirkt wird.

Es hat sich gezeigt, daß kleine Änderungen in der Oxygenierung zwar nur solche geringen Änderungen im Signalverlauf bewirken, die visuell kaum bzw. gar nicht erkennbar sind; im Frequenzraum ergibt sich jedoch ein deutlicher Unterschied, der zur weiteren Auswertung herangezogen wird.

Die Figur 5 zeigt nun eine Reihe derartiger Spektren, die ausgehend von einer oxygenierten Probe in Zwischenschritten bis zu einer desoxygenierten Probe gewonnen wurden und die Kinetik solcher Vorgänge zeigen. Als Parameter ist die Zeit in 10s-Schritten eingetragen, wobei die Oxygenierung mit der Zeit abnimmt. Derartige

Spektren können sich beispielsweise bei der Stickstoffbegasung einer vorher oxygenierten Meßprobe ergeben, wobei dieser kinetische Vorgang reversibel ist.

Es bietet sich an, für die Spektren folgende Parameter zu ermitteln:

a) m (t) : entspricht einer Probe mit unbekannter Oxygenierung

b) h (t) : entspricht der Probe mit dem am stärksten oxygenierten Spektrum

c) l (t) : entspricht der Probe mit dem am stärksten desoxygenierten Spektrum

Der Anteil von h (t) an m (t) ergibt sich aufgrund folgender Korrelationsbeziehung:

$$m(t) = \alpha \cdot h(t) + \beta \cdot l(t) \qquad (1)$$

Der Faktor α stellt ein Maß für den oxygenierten und β ein Maß für den desoxygenierten Anteil im Spektrum dar. Insbesondere der interessierende Faktor α kann nun derart ermittelt werden, daß Gleichung (1) sowohl mit dem Spektrum einer voll oxygenierten Probe als auch dem Spektrum einer voll desoxygenierten Probe korreliert wird. Damit ist die Möglichkeit gegeben, eine quantitative Aussage im Rahmen der Gewebefotometrie zu treffen.

Messungen haben gezeigt, daß sich der Anteil der hohen Frequenzen am Meßsignal in charakteristischer Weise speziell mit der Oxygenierung ändert. Diese Signalmerkmale können also als quantitatives Maß für den Oxygenie-

runsgrad betrachtet werden, wobei nach Vorgabe einer Eichkurve aus diesem Merkmal sofort der Oxygenierungsgrad einer unbekannten Meßprobe ermittelt werden kann.

In der Figur 6 bedeutet A das Analogsignal des Fotomultipliers 7. Dieses wird über einen Filter 11 zur Bandbegrenzung und einen A/D-Wandler 12 mit hoher Abtastfrequenz digital gewandelt und anschließend einem Speicher 15 zwecks Zwischenspeicherung zugeführt. Über einen Triggersignalgeber 13 können Impulse aus der Drehung der Monochromatorscheibe 5 abgeleitet werden, welche charakteristisch für den Spektrentakt sind und als Start- sowie Resetimpulse verwendet werden können. Vorteilhafterweise kann die Digitalisierung von einer Takteinheit 14 entsprechend der aktuell vorliegenden Wellenlänge der Interferenzfilterscheibe 5 nach Fig. 1 gesteuert sein.

Nach Vorgabe eines Gütekriteriums GK im bereits beschriebenen Sinne lassen sich bei einer Vielzahl aufgenommener und zwischengespeicherter Spektren die geeigneten herausgreifen. Im vorliegenden Fall dient der Triggerimpuls speziell zur Anwahl eines ersten Referenzspektrums. In einer Vergleichseinheit 16 wird die "Referenz-Periode" mit den im Speicher 15 zwischengespeicherten Spektren verglichen. Aus der großen Anzahl der gespeicherten Meßwerte wird damit durch Vergleich eine vorgegebene Anzahl weiterer Spektren bestimmt, die zusammen der Einheit 20 zur Störungsunterdrückung zugeführt werden.

Zur Störungsunterdrückung wird anschließend in einer nachgeschalteten Einheit 20 eine selektive Aufaddition und Mittelwertbildung (sog. "averaging") durchgeführt, was einer Filterung der Spektren gleichkommt. Damit ist das Signal weitgehend rauschfrei, so daß es einer Einheit 25 zur Fourier-Transformation zugeführt werden kann.

Es hat sich als zweckmäßig erwiesen, vor der Fourier-Transformation eine Entzerrung der Spektren vorzunehmen. Eine dazu vorgesehene Einheit 22 dient gleichermaßen zur oben erläuterten Signalspiegelung.

Aus dem fourier-transformierten Spektrum wählt ein Signalselektor 26 als Merkmalsextrahierer die für die Oxygenierung signifikanten Frequenzen bzw. Frequenzbereiche aus. Solche Merkmale sind wie erwähnt der Anteil der hohen Frequenzen: Zur quantitativen Erfassung können entweder direkt die Amplituden bei den Maxima verwendet werden; es kann zur genauen Messung auch das Verhältnis der Summe der Amplituden solcher Frequenzen, die oberhalb eines vorgegebenen Minimums liegen, zur Summe der Amplituden der Frequenzen, die unterhalb des Minimums liegen, ermittelt werden. In der Figur 4 sind die zugehörigen Flächen durch Schraffur angedeutet.

Dem Signalselektor 26 zur Gewinnung der Signalmerkmale ist eine Eicheinheit 27 zugeordnet. Durch Vergleichen der Meßwerte mit einer vorgegebenen Kennlinie in einer Analyseeinheit 28 wird die Oxygenierung unbekannter Proben bestimmt und auf einer Anzeigeeinheit 29 digital oder analog angezeigt. Zusätzlich können die Daten rechnerkompatibel abgespeichert werden.

Das beschriebene Verfahren und die zugehörige Vorrichtung sind außer für eine allgemeine Gewebefotometrie speziell zur quantitativen Ermittlung der Blut-Sauerstoff-Sättigung im Gewebe geeignet. Die vorgeschlagene Meßmethode kann dazu auch bei sich ändernden Hämoglobin-Konzentrationen angewendet werden. Neben der Untersuchung des Hämoglobins können mit dem gleichen Ver-

fahren auch andere absorbierende und fluoreszierende Farbstoffe gewebefotometrisch erfaßt werden, sofern ein frequenzabhängiges Verhalten vorliegt. Hier ergeben sich bisher ungenutzte Möglichkeiten für eine quantitative Auswertung.

21 Patentansprüche
6 Figuren

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Anmeldetag: 10. August 1983
Offenlegungstag: 28. Februar 1985

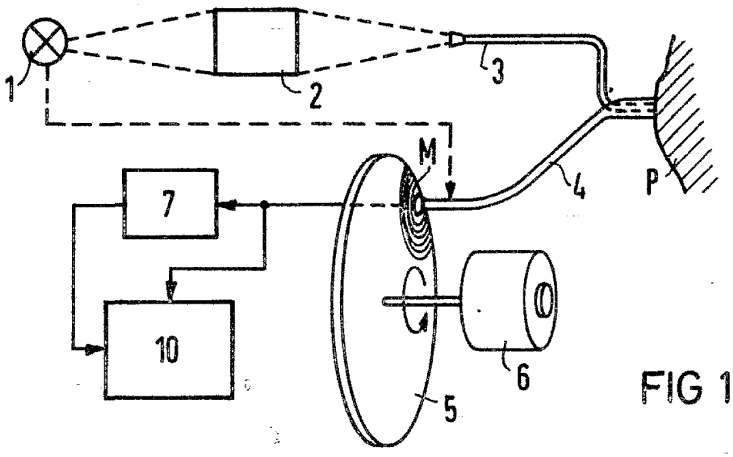


FIG 1

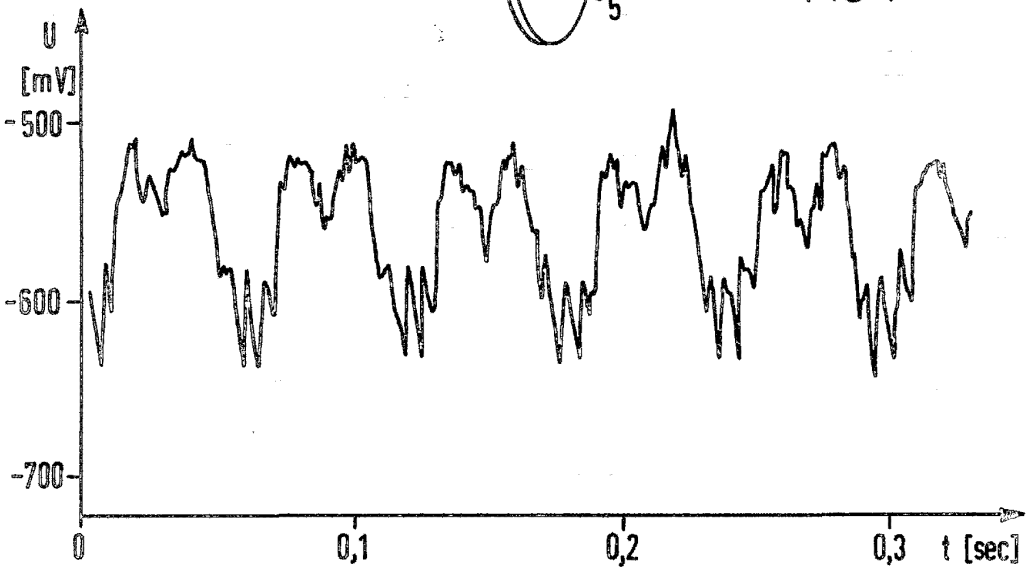


FIG 2

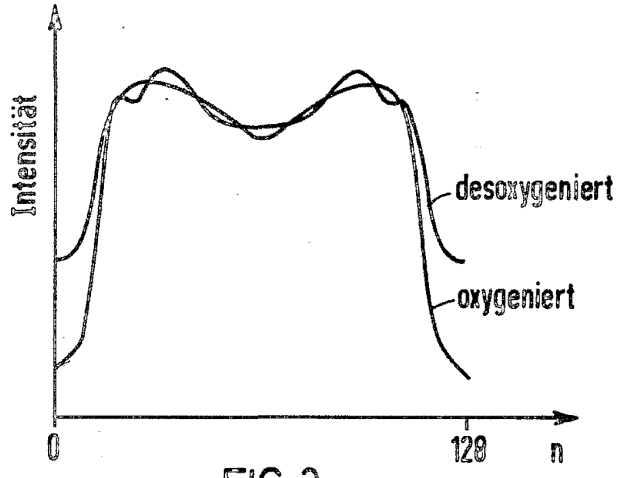


FIG 3

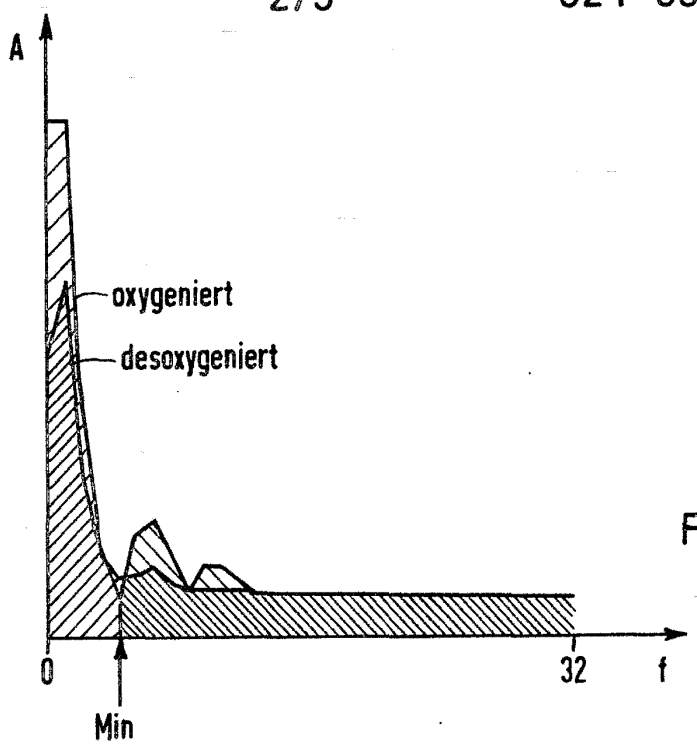

A
oxygeniert
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0
32
f
Min

FIG 4

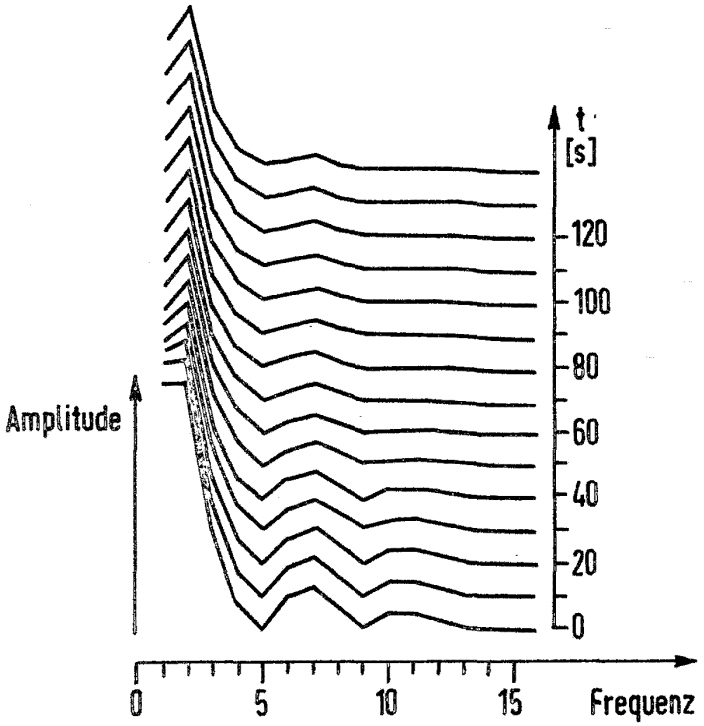

t
[s]
120
100
80
60
40
20
0
Amplitude
0
5
10
15
Frequenz

FIG 5

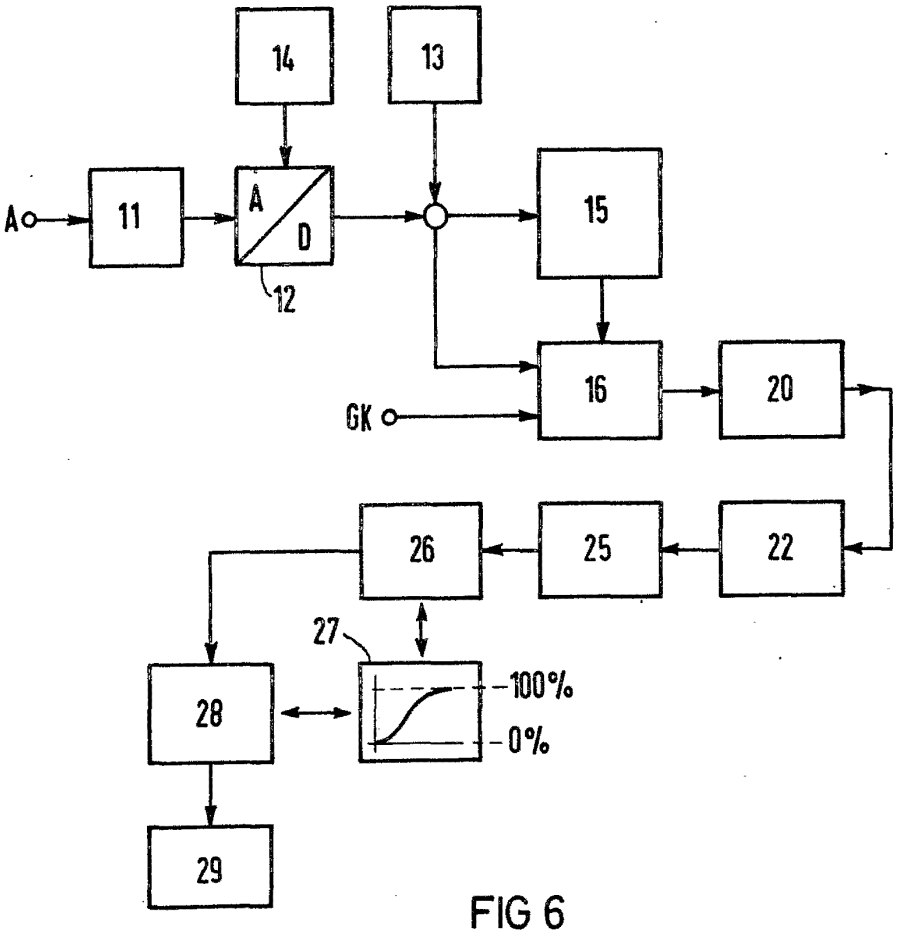


FIG 6

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(54) Pulse oximeter monitor.

(57) A pulse oximeter wherein light of two different wavelengths is passed through body tissue, such as a finger, an ear or the scalp, so as to be modulated by the pulsatile component of arterial blood therein and thereby indicate oxygen saturation. A tonal signal is emitted having a pitch proportional to the ratio of oxygen saturation and a sequential repetition proportional to pulse. A visual cue consisting of an array of strobed light emitting diodes is flashed having a total light output proportional to the magnitude of the pulse and a sequential flashing rate proportional to pulse rate. A systematic rejection of extraneous or irregular detected data prevents undue sounding of alarms.

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PULSE OXIMETER MONITOR

This invention relates to a pulse oximeter and a process for receiving and processing data from an oximeter.

Electronic, non-invasive techniques for determination of oxygen content are known. U.S. Patent No. 2,706,927 to Wood disclosed the computation of oxygen saturation from measurement of light absorption of body tissue at two wavelengths. A "bloodless" measurement was first taken in which as much blood as possible was squeezed from the area where measurement was taken. Thereafter, arterial blood was allowed to flow into the tissue as the condition of normal blood flow was restored. A comparison of the light absorption in the two states provided information on the arterial oxygen saturation of the subject. A series of devices and procedures have been founded using this technology.

In procedures based on this technology, difficulty has been experienced in reliably determining the "bloodless" parameters; due in part to geometrical distortion due to the compression of the tissue; imperfect measurement of this parameter gave imperfect results.

The transmission of light of each wavelength is a function of the thickness, colour, and structure of skin, flesh, bone, blood and other material through which the light passes. This attenuation in transmission has been asserted to have a logarithmic characteristic, in accordance with Lambert-Beers Law.

In a pulse oximeter, the primary material of interest is pulsatile arterial blood. Arterial blood is the only material whose quantity in the tissue varies with time in synchrony with the beating of the heart. Variations in light transmission therefore indicate

variations in blood flow permitting direct optical recording of the pulsatile component of arterial blood flow. This ability to separate out the light absorption of arterial blood is especially convenient; since the oxyhemoglobin component of blood is a substance for which the absorption coefficients can be determined, the fraction of any oxyhemoglobin in arterial blood can be determined.

Optical plethysmographs are well known. Such instruments measure pulse rate and provide information on the quantity of blood forced into the tissues on each heart beat. These instruments generally utilize a light frequency near or at the isobestic point where measurement of pulsatile flow is made independent of oxygen saturation. Consequently, they intentionally eliminate information on oxygen saturation.

Following the Wood 2,706,927 patent, numerous attempts have been directed at eliminating the difficulties connected with arterial saturation measurements using light absorption where the analysis requires the comparing the "bloodless" measurement either artificially induced or naturally occuring during the rest state of the heart cycle with the measurement of fresh arterial blood when fresh arterial blood enters the tissue. For example, the signal received has been divided into its "AC" and "DC" components and passed through a log amplifier before digital analysis of the signal occurs. See Koneshi et al., U.S. Patent 3,998,550. Likewise, a generation at both wavelengths of subtraction outputs has been utilized before digital analysis. Subtraction outputs have been used to eliminate the DC component and to approximate the logarithmic response of the prior art.

See Hamaguri, U.S. Patent 4,266,554. Simply stated, because the pulsatile component constitutes a small portion of the total signal of transmitted light, numerous manipulations based on logarithms have been attempted to screen out the unchanging component of the resultant signal before analysis.

U.S. Patent 3,704,706 to Herczfeld et al disclosed use of a single coherent red light source, preferably a laser. Use of a single light source is unable to separate information dealing with the arterial flow component from that dealing with the arterial oxygen component. The output of such a single red light source instrument can only be an indication of the product of blood flow the saturation level present. Neither blood flow alone or saturation alone can be known.

In all of the above schemes for the measurement of pulse rate, pulse flow and oxygen saturation the variant or AC component is a small portion of the total absorption occurring. In such circumstances, discrimination of the signal from other possible sources must occur. When it is remembered that measurements of unconscious, partially anesthetized and otherwise non-responsive patients must occur, and such patients have random and irregular movements (and heart beats), the establishment of thresholds for the reception and analysis of data is critical.

An oximeter according to one embodiment of the invention has light means wherein light of two different wavelengths is passed through body tissue, such as a finger, an ear or the scalp, so as to be modulated by the pulsatile component of arterial blood therein and thereby indicate oxygen saturation. The embodiment first receives and compares signal to parameters to check for a pulse like signal. Assuming that a pulse like signal is detected a tonal signal is emitted having a pitch proportional the ratio of oxygen saturation and a sequential repetition proportional to pulse. A visual cue consisting of an array of strobed light emitting diades is flashed having the number of lights strobed increase with increasing magnitude of the pulse and having a sequential flashing rate proportional to pulse rate. A systematic rejection of extraneous or irregular detected data prevents undue sounding of alarms.

The embodiment can simultaneously trace and indicate the pulse as well as the degree of oxygen saturation of the individual. At least one of the wavelengths of light, preferably infrared, is monitored for slope change. A signal is emitted proportional to and typically synchronous with the slope change rate to indicate heart rate. A second signal is emitted containing pulse rate and oxygen saturation information.

An advantage of this feature of the embodiment is that each pulsatile component is individually analyzed. The heat beat and arterial oxygen level of the patient is continually monitored.

The embodiment emits a series of audible signals which convey pulse rate and oxygen saturation. Pulse rate is indicated by emitting sequential tones at time intervals corresponding to the rate of

negative slope reversals (indicating pulse wave maximum). Oxygen saturation is indicated by having pitch decrease proportional to decreasing oxygen saturation.

An advantage of this feature of the embodiment is that the human ear is particularly sensitive to both changes in frequency of sequential sound signals and tonal variations in sequential sound signals. A simple beating signal can make all in the immediate vicinity well aware of both the pulse rate and oxygen saturation of the patient.

Yet another feature of this embodiment is that it emits a visual signal conveying similar information. In this arrangement, a column of light emitting diades flashes in height proportional to pulse magnitude and flashes in frequency proportional to pulse rate. As the eye is particularly sensitive to changes in both flashing rate and angular dimension or height of the flashing LED array, an indication of pulse quality is given.

Yet another feature of this embodiment is that it has a plurality of alarms, which alarms can all be individually set in accordance with the current condition of the patient. According to this feature of the embodiment, high pulse rate, low pulse rate and oxygen saturation levels can all be utilized as an alarm limit.

An advantage of this feature of the embodiment is that the parameter of the patient's warning limits can be tailored by the anesthesiologist or other attending physicians. Individual adjustment can be made to the particular physiology present.

Yet another feature of this embodiment is that it has an arrangement for rejecting extraneous data. Remembering that patients are often in an

unconscious or semi-conscious state when this instrument is used, it can be realised that the instrument does not operate in a perfect environment. Shaking or moving the sensor head or even local variations in the patients pulsatile profile could unnecessarily trigger alarms. According to this feature, incoming processed data is compared to confidence factors. If the data falls within expected levels, confidence factors remain unchanged or are upgraded to the highest level. Where data falls without the anticipated confidence levels, the data itself may be rejected. The confidence levels are eroded or opened in the range of data that can be processed. This process occurs until data consistent with the confidence limits is received. When data consistent with the confidence factor is received, it is compared to the alarm limit.

An advantage of this feature of the embodiment is that small local variations in the received signal do not trigger the alarms.

Yet another feature of this embodiment is that a totality of data is utilized for tracking the pulse. According to this feature of the embodiment, the points of maximum light transmission (commencement of inflowing pulse) and maximum light absorption (end of arterial pulse) are tracked for at least one wavelength. A maximum negative slope intermediate the maxima and minima is plotted for avoidance of the dicrotic notch. Finally, the percent of oxygen saturation is determined by comparison of light transmission at both frequencies.

All of these data are analyzed against the confidence limits for reception. Where three out of the six data values are outside the limits, the entirety of the data is rejected. Where four or more of the data values are within, the data is received and the

confidence limits under the acceptable catagories upgraded or maintained at the narrowest limit. Confidence limits of unacceptable data are eroded or opened.

An advantage of this feature of the embodiment is that interruption of data often occurs at more than one parameter. With such interruption, the entire data block may be averaged to prevent the premature sounding of alarms.

A further feature of this embodiment is that it has a simplified control for adjusting alarm limits. According to this feature, adjustment occurs to a shaft encoder directly coupled to an alarm limit adjustment knob. The alarm limit to be set is selected by pressing at least one selector button. Thereafter, turning of the alarm limit adjuster knob updates the limit by sign - depending upon direction of turn - and in limit - depending upon amount of turns. The current alarm limit being changed is shown in the visual display. If the alarm limit does not change for a preset period, that is, the knob is no longer being turned, the knob to the alarm limit is disconnected and the knob is again connected to its original connection and the display returns to its original status.

An advantage of this feature of the embodiment is that alarm limit control is easily and simply adjusted. The complex environment of the operating room and intensive care unit is provided with a useful instrument having simplified adjustment. In particular, the alarms can be controlled by one hand, important in some aspects of patient care. It is not necessary to manually reset the instrument to its original status of displaying saturation or pulse rate.

An embodiment of the invention will now be described by way of example with reference to the attached drawings in which:

Fig. 1 is a perspective view of the instrument of this invention illustrating the instrument housing and attachment of a sensor to the digit of a patient;

Fig. 2 is an overall circuit schematic of this invention;

Fig. 3 is a circuit schematic in the vicinity of the microprocessor;

Fig. 4. is a circuit schematic in the vicinity of the read only memory or ROM of this invention;

Fig. 5 is a circuit schematic in the vicinity of the read only memory or RAM of this invention;

Fig. 6 is a circuit schematic of the memory select;

Fig. 7 is a circuit schematic of the input/ output select;

Fig. 8 is a circuit schematic of the counter of this invention;

Fig. 9 is a circuit schematic of the comparator circuit wherein 12 bit digital to analog conversion occurs;

Fig. 10 is a circuit schematic of the sample - hold circuitry of this invention.

Fig. 11 is a circuit schematic of the offset amplifier circuit of this invention;

Fig. 12 is a circuit schematic of the detector of this invention;

Fig. 13 is a detail of a clock circuit having an output for powering the light emitting diodes;

Fig. 14 is a detail of circuitry for powering the light emitting diodes, the diodes being switched at a point proximate to the detector;

Fig. 15 is a circuit schematic illustrating the operation of the optically coupled adjustment knob;

Fig. 16. is a view of the control button circuitry of this invention;

Fig. 17 is a view of L.E.D. circuitry outputs; and

Fig. 18 is a view of the audio output circuitry.

Fig. 19 is a block logic diagram of the numerical process steps which result in the instrument output.

Referring to Fig. 1, the instrument housing 26 of this invention is illustrated. Outwardly, the housing includes a digit display 1, circuitry select button array 2 through 5, alarm status lights 6 through 9, an optically coupled adjustment knob 10, sync status light 11, LED digital viewmeter 12, and power switch 13. A speaker 15 is placed under and in the instrument housing.

From a connector (not shown) in housing 26 there extends leader wires 27. Wires 27 extend to a detector probe 29. Detector 29 is placed upon the finger 14 of a patient 28. Utilizing the placement of the detector 29 at the finger 14, all of the readings in this invention are made possible.

Oximeter Operation

A broader view of the operation of this instrument can be made by considering carefully the circuit schematic of Figure 2.

Referring to Fig. 2, conventional microprocessor 16 has a bus 17 extending therefrom. Bus 17 has connected thereto conventional ROM 18 and RAM 19. An LED display 20 is schematically illustrated having a select latch 21 and a digit designation latch 22. The circuit select button array 2-5 and optically coupled control knob 10 previously illustrated are gated through controls generally denominated 24.

Having set forth the more or less conventional portions of the microprocessor, attention will now be directed to the analog portions of the circuitry.

Finger 14 of patient 28 is illustrated with detector 29 having schematic detection circuitry. First light emitting diode 32 in the red range and a second light emitting diode 30 in the infrared range are sequentially pulsed to emit light in their respective frequencies by amplifiers 31,33. Typically, LED 32 is in the 6600 angstrom range with LED 30 being in the 9400 angstrom range.

It is necessary that all the light from the active light emitting diode go through the flesh in finger 14. Therefore, a light impervious barrier 36 is placed between photosensor 38 and finger 14. Barrier 36, terminating in contact with the flesh of finger 14, makes the path between the respective light emitting diodes 30, 32 and the light receiving diode 38 occur only through the flesh of finger 14.

In the instrument herein we utilize two discrete frequencies. These frequencies are 670 nanometers (red) and 940 nanometers (infrared). A small amount of discussion related to these parameters is in order.

First, the frequencies are chosen so that they are far enough apart so that the transmission of light appreciably varies with changes in oxygen saturation.

Secondly, the frequencies are chosen so that the same tissue is sampled. For example, a frequency in the ultraviolet would not sample the same tissue due to scattering.

While frequencies extremely close could be used, we have chosen not to do so. We find that drifting of light source frequency can occur with accompanying problems.

Signal received from the respective light emitting diodes first passes through a pre-amplifier 40. This signal is thereafter amplified in parallel at amplifiers 41, 42. As amplified, the signal is passed in parallel from each amplifier through respective phase detectors 43, 44. Passage through respective low pass filters 45, 46 thereafter occurs. Amplification at offset amplifiers 47, 48 then takes place. The pulsatile component is passed to multiplexer 50.

Multiplexer 50 has output to a comparator 52. Comparator 52 is ramped in half steps by a 12 bit digital to analog converter (hereinafter DAC) 54. DAC 54 places a comparison signal divided in one part from 4096 parts with the comparator outputting to bus 17.

The reader will recognize that not all human fingers and appendages are the same. Specifically, the difference between the races, skin pigment, weight, age, maturity and other factors all can lead to different signals being sensed at photosensor 38, even though the frequency and intensity of the light signal output at each of the diodes 30, 32 is the same.

Accordingly, microprocessor 16 is programmed to receive signal from photosensor 38 within an optimum range. Utilizing a second operating phase of DAC 54, and communicating signal to a sample hold 57, the individual LED's 30, 32 are given voltage outputs 60, 61. These voltage outputs 60, 61 are adjusted so that in each case photosensor 38 looks at a signal well withing the range of the DAC.

Clock 70 controls the sequential output of light from the light emitting diodes 30, 32 to a duty cycle of at least 1 in 4. This is schematically illustrated by signals Ø1 through Ø4. Reception of signal at detector 43 occurs during time periods Ø1 and Ø2 and reception of signal occurs at detector 44 during time periods Ø3 and Ø4.

It can be immediately realized that during respective time periods Ø1, Ø3 active signal from the light emitting diodes 30, 32 is being received. During the time periods Ø2 and Ø4 no signal and only noise is being received. As will hereinafter become apparent, by amplifying the negative signal before passage through the low pass filter, noise can be subtracted out utilizing the illustrated 1 in 4 duty cycle.

Having given the reader an overview of the circuitry utilized with this invention, the invention will now be discussed in detail.

Referring to Figure 3, the microprocessor 100 is illustrated having an attached crystal 104. This crystal, in combination with clock circuitry incorporated within the microprocessor 100, generate the clock signals required by the microprocessor chip itself as well as providing clock pulses to the rest of the oximeter circuitry through output 102.

Microprocessor 100 is an 8085A CPU integrated circuit chip available from Intel Corporation of Santa Clara, California. The family identification suffixes of the remaining IC components are listed on the drawing and the components are readily available from various manufacturers.

An address bus 103 includes address lines A0 through A15. To accommodate the eight bit processor, lines A0 through A7 on the address bus are latched from microprocessor pins AD0 through AD7 so that during the address time state these lines may be read. During an alternate time state, lines ADØ through AD7 become output

data lines 104, ODØ through OD7, which lines as here configured are only capable of outputting data.

Referring to Fig. 4, the ROM configuration is seen to be standard. The ROM is addressed with a conventional address bus including lines A0 to A10 addressing in parallel ROMs 106, 107 and 108. These respective ROMs are enabled by three decoded address bits from lines A11-A13 (see Fig. 6). As will hereinafter be set forth with respect to Fig. 6, enabling outputs for reading of the ROMs include read enable 110 (see Figs. 3, 4) and specific ROM addresses including ROM 0 address 111, ROM 1 address 112, and ROM 2 address 114. The particular ROMs here utilized are of the optically erasable programmable read only memory variety and include an output data bus 115.

Referring to Fig. 5, two conventional RAMs 120, 121 are shown addressed in parallel at address bits A0 through A9 at bussing 125. These RAMs write and read over eight bits with four bus lines AD0 to AD3 at bus 127 addressing RAM 120 and AD4-AD7 addressing RAM 121 at bussing 128. RAMs 120, 121 are read when enabled through enable ports 129 in the absence of a write signal on port 130. These RAMs are written when enabled by port 129 in the presence of a write signal through write ports 130. As each of the RAMs connect to four separate data bits, individual enabling of each of the RAMs is not required.

Referring to Fig. 6, the memory select circuit of this invention is illustrated. The memory select has a three bit input 140 at lines A11-A13. Output occurs when memory is selected at ROM 0 enable 111, ROM 1 enable 112, ROM 2 enable 114. A RAM enable 141 passes through an inverter and NAND gate to enable reading of RAMs 120, 121 for either reading or writing.

Referring to Fig. 8, a counter used as a divider is illustrated. Referring briefly back to Fig. 3, it will be seen that the microprocessor 100 is provided with a clock running at 2.5 Mhz generally denominated 102. The CPU clock outputs at 102 to a counter 172 (see Fig.

8.) Counter 172 divides signal 102 by the number 171 and outputs to binary counter 173 in order to generate an LED clock frequency of 1.827kHz, which is unrelated to room light frequencies. Counter 173 outputs signals LED A 191, LED B 192, LED CLK 190 and DCLK 189. This circuit in cooperation with the circuit of Fig. 13, effects light and detector switching to enable signal phasing.

Having set forth in generality the microprocessor, it will be realized that much of that disclosed is already known in the art. Specifically, complete descriptions of the wiring of this microprocessor can be found in the MCS-8085 Family Users Manual, published October 1979 by Intel Corporation. Those having skill in the art are referred to this publication should question arise about the circuitry thus far described.

Referring briefly back to Fig. 8, LED clock outputs 190, 191, 192 are inputed to the clock divider 194 of Fig. 13. Divider 194 outputs four sequential duty cycle states denominated Ø1' through Ø4'. Complements of signals Ø1 and Ø3 are outputed directly at clock driver outputs 196. It will be noted that all four signals Ø1'-Ø4' are outputed at 198 for timing purposes hereinafter discussed.

Having set forth the timer, the remainder of this disclosure will be broken down into five discrete parts. First, timing for the light emission of the LED's will be discussed. Emphasis will be placed on the fact that the diodes are switched locally.

Second, light reception will be set forth. With respect to the reception, emphasis will be made to the fact that the signal is digitally extracted without any analog treatment whatsoever. The pure digital signal is thereafter processed and utilized to create the light curves herein. Effort is made to eliminate all variables present, including those in the flesh analyzed as well as ambient light noise.

Thirdly, and in view of variant light transmission qualities of human flesh, the light level adjustment

circuit of this invention will be traced. It will be pointed out that the adjustment of the emitted light occurs so that the sensor receives an amount appropriate for the amplification circuitry.

Fourth, setting of the alarm limits will be analyzed. Illustration will be made.

Fifth, and finally, the program alarm will be discussed. Specifically, the utilization of "confidence limits" and a totality of data received in the monitoring program will be disclosed as screening extraneous data yet permitting a timely alarm to ward off catastrophe.

Referring to Fig. 14, and assuming that sufficient voltage is present across leads 301, 302, current of an appropriate level will be emitted to each of the light emitting diodes 31, 33. The diodes here are illustrated schematically across a connector 305 and are shown being switched by respective transistors 307, 309. Specifically, when a negation pulse is received at each of the transistors, the transistors open, voltage appears across the respective diodes 31, 33, and light is emitted.

Assuming light is transmitted, it is passed to the flesh of the digit 14 and is thereafter received at the receiving photosensor 38.

Referring to Fig. 12, photosensor 38 is illustrated. It is coupled across a connector 305. Connector 305 in turn passes its signal through amplifier 40. The signal is then split and passed to voltage amplifiers 41, 42, the amplification here occurring in parallel, allowing differences in gain between red and infrared signal processing. Respective phase detectors 43, 44 are clocked at inputs Ø1' - Ø4' from the clock circuit of Fig. 13. Remembering that a 1 in 4 duty cycle is here utilized with each of the signals Ø1, Ø2, Ø3, Ø4 being clock periods, it is seen that the signal is gated. Specifically, and during the Ø1 time period, negative amplification of the total light signal, including pulsatile component and noise, occurs at amplifier 201 with passage of the resultant signal through the low pass filter 45.

Referring to Figure 14, in the next sequential time period, and due to the signal Ø1 no longer appearing to close transistor 309, transistor 31 will be shunted to ground. At the same time, during time period Ø2 gate 43 will open to amplify the positive component received. This component received, however, will have no light emission whatsoever; it instead will represent pure electronic or optical noise. The timing of this circuit will therefore yield on equal bases first light containing the pulsatile component and noise and thereafter just noise. Amplifier 201 amplifies one signal positively and the other signal negatively in equal amounts. It will be seen that integrated over the full four periods of the clock, through amplifier 201 the instrument sees equal components of noise which cancel and unequal components of signal which do not cancel. By the expedient of taking the respective intermittent pulses and passing them through the low pass filter 45, there results a signal out containing valid signal only; noise cancels.

The remaining channel is analogous. Specifically, during time period Ø3, noise and light signal are amplified negatively and passed through low pass filter 46. During time period Ø4, noise only is positively amplified and cancelled in passage through the low pass filter 46.

The emitted signals V_A and V_B can be described as having two components. The first component is constant. It is that element of light which remains essentially invariant. This signal includes an absorption component because of skin pigment, bone, flesh and venous blood. The second component represents the pulsatile inflow of arterial blood.

The ratio of that second component to the first component is what is sought by the instrument. What is sought is the ratio of the arterial and pulsatile component of the blood to that of the total absorbing tissue. The color of the arterial component of the blood produces the differential light absorption that is dependant upon

the oxygen saturation of the hemoglobin. The instrument must isolate this component.

Referring to Figure 11, amplification of the signal to an idealized state is illustrated. Specifically, in taking respective signals VA', VB', an offset voltage VOFF introduced. This signal is a constant voltage which subtracts out part of the constant portion of the received light signal which relates to passage through the non-variant portions of the flesh. Since it is known that the pulsatile component is always very small with respect to the total signal, an improvement on the accuracy of digital conversion can be obtained by this subtraction. It is necessary, however, for the microprocessor program to mathematically reinsert this subtracted voltage prior to processing the signal. This subtraction and amplification occurs at the respective amplifiers 330, 331 with passage of the signals VA' and VB' from the network.

With digital to analog conversion of these signals, a combination of the pulsatile component and the remainder of the constant component is then required. This can best be seen through the circuitry of Figure 9.

Referring to Fig. 9, a multiplexor 50 is illustrated. During the analytical operation here shown, this multiplexor samples signals VA' and VB'. Signal is passed to the negative side of comparator 52. Signal for driving the multiplexor passes through lines OD4 - OD6 in the DAC high latch 360. The DAC low latch 362 is thereafter actuated in sequence responsive to enabling signals on enabling line 363. Output occurs to a digital to analog converter 54 on a twelve bit basis. Division to one part in 4096 occurs.

Typically, the signal is compared in halves. Output of DAC 54 occurs over lead 365 to comparator 52. The DAC output 366 is passed to the microprocessor. Depending upon whether a high or low signal is received, stepping of the twelve bit DAC 54 occurs in halves, enabling the twelve bit division to occur rapidly. Consequently, the output level of the voltage of the

receiving photosensor is rapidly determined with the result that the pulsatile component can be rapidly followed. This process is repeated for both signals VA' and VB' at a rate that allows the microprocessor to faithfully track both signals.

Having set forth the light reception circuitry of this invention, attention will now be directed to the level of light adjustment.

It will be remembered that each of the patients, due to flesh, skin pigment, skin thickness, bone, venous blood present and other invariants, will present his own factor of constant light absorption at both wavelengths. This being the case, it is necessary to adjust the level of current applied. This is done through the DAC circuit of Fig. 9 and the sample hold circuit of Fig. 10.

The sampling of the light signals by the microprocessor was described above. In the case where the signals are not within the useful range of the conversion circuitry, the light level must be adjusted up or down as required to restore the signal level to the voltage range acceptable to the analog to digital conversion. Referring to Figure 9, the program will output a code corresponding to the desired voltage level through its data bus into latches 362 and 360, setting the DAC 54 output to a voltage corresponding to desired LED current. Note that this is only done during a time period when the DAC is not used for input conversion. The program will then output using the same bus a bit corresponding to the selected LED into latch 370 of Fig. 10. This bit, or selection signal, is converted to a compatible voltage by voltage converter 371 and applied to one of eight analog switches 372 and 374. These have the effect of applying the voltage from the DAC, corresponding to the desired LED current level, to a storage capacitor which will latch this voltage after the input has been removed. This voltage is buffered by amplifiers 375 and 376 and applied to the LED circuitry. Thus, dependant upon the intensity of the signal received by the photosensor, the

respective light emitting diodes can be driven with greater or lesser voltage to produce the optimum voltage output.

It is noted that only two of the available eight channels of this sample hold circuitry are required to adjust the LED intensities. The remaining channels provide a general purpose analog output from the microprocessor for a variety of unrelated functions. The output of amplifier 377 provides the fixed offset for the offset amplifiers described above; VVOL, the output of amplifier 378, provides a volume control for the alarm; outputs of amplifiers 601, 602, and 603 provide external outputs for an optional chart recorder; and the output of amplifier 604 provides a control for the pitch of the alarm.

Monitor Operation

The manner in which the signal information derived by the oximeter apparatus is presented to the attendant physician through the oximeter monitor of this invention will now be discussed.

Referring to Figure 1, when the instrument power is turned on via power switch 13, digit display 1 and LED digital viewmeter 12 both flash momentarily until microprocessor 16 begins its operation. Speaker 15 also emits a beep. As soon as the microprocessor 16 takes control of the instrument, which is on the order of a millisecond, the digit display 1 is cleared, with zeros flashing on digits 794-796. On power up, the oximeter default is for the audio alarm to be inhibited so that LED alarm inhibit light 9 begins flashing. Synchronization of the patient's 28 pulse rate through detector probe 29 is not yet established. Therefore, the sync status light 11 flashes, indicating no sync. Microprocessor 16 begins to sample the photosensor's 38 signals until it determines that valid pulses are being received, at which point digits 794-796 of digit display 1 indicate

in decimal numbers the percentage of oxygen saturation in the patient's 28 blood. Digits 797-799 numerically indicate the pulse rate. The LED digital viewmeter 12 begins to flash synchronously with the pulse rate with the vertical height of each flash being proportional to the strength of the received pulse. After about 4 or 5 valid pulses have been received no-sync LED light 11 is disabled and switches off. The alarm, which operates when triggered through speaker 15, may be manually enabled by the user at this point, through alarm button 5. When button 5 is pressed, alarm inhibit light 9 ceases to flash. The alarm will sound when the alarm limits are exceeded as discussed in detail below.

When pulse synchronization is achieved, speaker 15 begins emitting beep tones at a frequency synchronous with that of the perceived pulse rate and at a pitch proportional to oxygen saturation. Defaults provide an initial volume and pitch to these signals.

The information is updated from the microprocessor 16 on a continual and regular basis, modified only by a digital filter which serves the purpose of averaging recent pulse history with present information. This simply serves to smooth out transient small deviations in pulse rate and oxygen saturation due to physiologic and artifactual noise variations.

The microprocessor 16 continues to sample data and compare it to the current alarm limits in the instrument. Upon power up, in the presently performed embodiment the alarm limits are defaulted to an 85% lower oxygen saturation limit, a lower pulse rate limit of 55 and an upper pulse rate limit of 140.

The alarm limit defaults and the audio signal from speaker 15 may be changed in the following manner. The volume of the beep tone from speaker 15 can be set by the user by turning optically coupled control knob 10. Turning control knob 10 clockwise will enable volume to be maximized; turning knob 10 counter-clockwise can

enable the audio output of speaker 15 to be totally inhibited.

To alter an alarm limit parameter, one of buttons 2-4 is pressed. For example, when saturation limit button 2 is pushed, the current saturation level alarm limit is displayed on digit 794-796. Initially, that will be the defaulted limit of 85. Optical knob 10 is then enabled for adjustment of oxygen saturation limit. By turning knob 10 in either direction, that limit may be changed anywhere from 0 to 100%, depending on what the clinician decides is an appropriate saturation alarm for the patient's 28 situation. After about two seconds of inactivity on knob 10, knob 10 will automatically be disabled for saturation limit adjustment and will return to the volume adjustment mode. Concurrently, the display 1 is switched back to show the current oxygen saturation level and the current pulse rate. High pulse rate limit button 3 and low pulse rate button 4 work in an analogous fashion. Alarm status indicator lights 6, 7 and 8 flash when their respective alarm limits are exceeded. Lights 6-8 flash irrespective of whether the audio alarm is enabled or disabled by alarm inhibit button 5.

Recall that in the absence of parameters exceeding alarm limits, speaker 15 is emitting a pulsed tone whose frequency of repetition equals the patient's pulse rate and whose pitch is proportional to oxygen saturation. When the alarm is enabled by button 5, should any parameter exceed its respective alarm limit, speaker 15 emits a continuous tone of constant pitch until either the alarm is disabled or the parameter comes back within the set boundary. Again, when the alarm is inhibited LED 9 flashes to indicate to the user that audio alarms will not sound.

A more detailed understanding of the oximeter monitor operation discussed so far can be had by reference to the circuitry of figures 15-18. Further understanding may be had by reference to the program listing contained on the microfiche appendix.

Figure 15 is a circuit schematic illustrating operation of the optically coupled control knob 10. Shaft of knob 10 is connected to a shaft encoder 793. Shaft encoder 793 is pierced at regular intervals by windows 790. LED-photosensor pairs are placed in proximity to each other on opposite sides of encoder 793. Pair 791 is shown optically coupled through a window 790 while pair 792 is blocked by encoder 793. The width of each slot is half of the interval between them. Each pair is also equipped with a narrow slit to improve resolutions. The relationship between LED-phototransistor pair 791 and 792 is such that they are separated by an angle representing 25% of the slot-to-slot angle, a relationship known as quadrature.

Were encoder 793 to be rotated in a clockwise direction, pair 791 would remain occluded at the point in time when 792 became occluded, whereas if rotated counter clockwise the opposite would be true, that is 791 would be non-occluded when 792 became occluded. A similar non-ambiguous relationship exists between the two pairs of LED-photodetectors for each edge of each window. In such manner, signals may be sent to microprocessor 16 which indicate the direction of rotation and step of knob 10.

Signals from optically coupled pairs, such as pair 791, are presented to comparators 720 and 721. Through control logic 722, both the direction of turn and the step of knob 10 is presented to the microprocessor. Signal on output DIR 724 enables the microprocessor 16 to calculate direction of turn and signal on output STEP 725 enables determination of step. The advantage of this particular arrangement is that the absolute position of the knob 10 becomes immaterial. Only when the microprocessor 16 is receiving signals from a changing knob position does the position of the knob 10 have any import.

Referring to figure 16, direction 724 and step 725 signals are passed to input gate 732. Chip 732 is enabled through control logic 734. Inputs from buttons

2-5, in combination with direction signal 724 and step signal 725, output through bus AD0-A07 to give, in turn, direction and amount of alarm limit correction in RAM memory.

Referring to figure 17, the LED display circuitry is therein illustrated. Digit selection data presented on data lines OD0-OD7 enters latch 701 enabled by display select DSPSEL 717. The data is outputed to driver 702 and driver 711 to derive numerical digit select signals SEL 0 through SEL 7, 705-710. SEL 0 through SEL 5 enable 7 segment LED decimal numerical displays 794-799.

Data representing the numerical values to be displayed on digits 794-799 enters latch 703, enabled by a display digit DSPDIG 718. The outputs of latch 703 are inputed to drivers 704 and 714. The output of drivers 704 and 714, bit 0 through bit 7, switch on segments of the individually selected standard 7 segment LED display, presenting 1 decimal digit of the current oxygen saturation level or limit, or the current pulse rate level or limit. The other digits are displayed, in turn, in similar fashion.

SEL 7 715 and SEL 6 716 each operate 8 LEDs per chip of LED chips 712, 713. The number of LEDs per chip lit is determined by bit 0 through bit 7. The number of LEDs lit will be proportional to the pulse strength and the rate of flashing of displays 712, 713 is synchronous to heart rate, as discussed above.

Finally, figure 18 illustrates control of the audio output of speaker 15. Voltage levels VVOL 378 and VBEEP 604 (see fig. 10) correspond to desired volume and desired pitch, respectively. Passing VBEEP 604 to timer 740 and transistor 743 to speaker 15 via connector 741, results in a modulated pitch and tone repetition rate. Passing VVOL 378 to transistor 742 and connector 741 to speaker 15 modulates the volume of the tone.

THEORY OF OPERATION

The method of operations involves taking measurements of light transmission in tissue at two distinct wavelengths (red and infrared) at two arbitrary points in time, these points in time being but a small fraction of the time for a complete pulse. The wave form of a pulse of blood in the human flesh is digitally plotted. By considering the change in the transmission of light due to inflowing arterial blood, a measurement is made.

Regarding this transmission, as blood flows in, light is absorbed. Consequently the resident detector of light, photosensor 38, sees less light. Thus, it is the drop in light received at the photosensor that indicates the pulsatile component.

Assuming that the ambient transmission (approximately 99% of the signal) is represented by the letter I and the change in transmission during the pulse is defined by the letter ΔI then the equation for representing the change in transmission relative to the unchanging matter in the flesh to be integrated is represented by the equation:

(1)

$$\frac{\Delta I}{I} \alpha \Delta M$$

where ΔM is the change in material in the flesh during the pulse.

Interposing a constant to produce an equation yields the form:

(2)

$$\frac{\Delta I}{I} = K\Delta M$$

where K is a constant of proportionality in the resultant equation.

Realizing that the change in mass is composed of blood whose optical absorption is larger than the tissue and that this blood includes two forms of hemo-

globin: oxy-hemoglobin (hemoglobin with appended oxygen) and reduced hemoglobin (hemoglobin without oxygen), this equation can be expanded for two variants of matter thus:

(3)

$$\frac{\Delta I}{I} = K_A \Delta M_A + K_B \Delta M_B$$

where K_A is a constant for oxy-hemoglobin; ΔM_A is the amount of matter due to the influx of oxy-hemoglobin; K_B is a constant for reduced hemoglobin and ΔM_B is the change in reduced hemoglobin.

It will be remembered, that we are conducting our examination at two discrete wavelengths. This being the case, the above relation can be expanded to include the applicable constants at each wavelength thus:

(4a)

$$\left.\frac{\Delta I}{I}\right|_{\lambda 1} = K_{A1}\, \Delta M_A + K_{B1}\, \Delta M_B$$

(4b)

$$\left.\frac{\Delta I}{I}\right|_{\lambda 2} = K_{A2}\, \Delta M_A + K_{B2}\, \Delta M_B$$

where K_{A1} and K_{B1} are the respective oxy-hemoglobin and reduced hemoglobin constants at a first wavelength $\lambda 1$ (say the red wavelength) and K_{A2} and K_{B2} are the constants at a second wavelength $\lambda 2$;

It will be appreciated that each of the constants having the form K_{xy} is a constant that relates the relation of the change of light absorption to the total light absorption for a particular color and change of matter due to pulsatile flow.

Realizing that we are after the fraction S (saturation) of oxy-hemoglobin to total hemoglobin then we know that:

(5a)

$$\Delta M_A = S\ \Delta M$$

(5b)

$$\Delta M_B = (1-S)\Delta M \text{ where } \Delta M = \Delta M_A + \Delta M_B \quad (6)$$

where S equals the saturation and (1-S) equals the fractional presence of the reduced hemoglobin. Placing this into the previous equation yields the results:

(6a)

$$\frac{\Delta I}{I}\Big|_{\lambda 1} = K_{A1}\ S\ \Delta M + K_{B1}\ (1-S)\ \Delta M$$

(6b)

$$\frac{\Delta I}{I}\Big|_{\lambda 2} = K_{A2}\ S\ \Delta M + K_{B2}\ (1-S)\ \Delta M$$

It can be seen from the above equations that one saturation is determined, solution for blood perfusion (ΔM) is trivial.

At this juncture, we surprisingly define a ratio related to the light transmission at two different wavelengths. In defining this ratio, the reader will realize that we avoid manipulation in accordance with logarithmic proportionality. Specifically, we define the ratio between light transmitted and received at the wavelength $\lambda 1$ and at the wavelength $\lambda 2$ as follows:

(7)

$$R = \frac{\frac{\Delta I}{I}\Big|_{\lambda 1}}{\frac{\Delta I}{I}\Big|_{\lambda 2}}$$

Substituting the values of change of light absorption over total light transmission yields:

(8)

$$R = \frac{K_{A1}\ S + K_{B1} - S\ K_{B1}}{K_{A2}\ S + K_{B2} - S\ K_{B2}}$$

Likewise, substituting for S yields:

(9)

$$S = \frac{K_{B1} - RK_{B2}}{R(K_{A2} - K_{B2}) - (K_{A1} - K_{B1})}$$

Thus, it can be seen that a relationship exists for both the ratio R and the saturation S.

Those in the medical arts will realize that the numbers sought to be determined electronically by the absorption of light, are also capable of laboratory tests. Specifically, there are a number of laboratory protocols and tests whose accepted results yields saturation. This being the case, a procedure for the calibration of all instruments becomes immediately apparent.

Specifically, by taking laboratory arterial oxygen saturations from individuals at differing saturations S_1, S_2, S_3, and S_4, we can measure specific transmission ratios R_1, R_2, R_3, and R_4. To reliably obtain these ratios R_i, the present instrument itself is used, in particular the portion of the device related to obtaining reliable measurements at hand herein. We thereafter can make an initial guess as to coefficients for both oxy-hemoglobin and reduced hemoglobin.

Taking one of the aforementioned constants K_{A1}, this constant can be broken down into two discrete components. First, one component can come from a previously determined value and be denominated C_{A1}. Secondly, and for each instrument, this constant will of necessity change. This change will be due to the conditions of observation, individual instrument electronics and the like. This value can be express ΔC_{A1}. Each of the four constants in the above equation can likewise be expanded in the same way.

(10)

$$(C_{A2} + \Delta C_{A2})(S_iR_i) + (C_{B2} + \Delta C_{B2})(R_i - S_iR_i) =$$

$$(C_{A1} + \Delta C_{A1})((S_i) + (C_{B1} + \Delta C_{B1})(1-S_i)$$

where i is an index related to at least four measured saturations and transmission ratios.

Those skilled in math and instrument calculation can now see that the ΔC quantities in all states and wavelengths can be simultaneously solved provided that four independent saturations are utilized. Therefore, a set of constants is attained, which constants can be utilized for programming individually produced instruments at all values of S.

The aforegoing relations can be alternatively stated. We have found that the relation of R (the ratio of transmission) to S (saturation of the hemoglobin with oxygen) is capable of simple curve fitting. Specifically, for at least human beings a constant and predictable curve of S with respect to R results. By utilizing this relationship in a look-up table, one may quickly compute the saturation of a patient.

Note that in our device, unlike in the prior art, a light source of isobestic wavelength is not used, nor is apparatus for taking logarithms necessary (see equation 7).

The reader will realize that the disclosed pulse oximeter or plethysmograph is targeted for use typically on a human digit. It should be realized that the disclosed pulse oximeter works equally well on any number of cutaneous locations. Idealized and a preferred use of the extremely small and local sensor of this invention is on the scalp of children being born. Avoidance of oxygen poor conditions during birth resulting in cerebral palsy is contemplated. Likewise, any other cutaneous location will suffice, e.g. the nasal septum.

THEORY OF MONITOR CONFIDENCE LIMITS

In order to provide an "intelligent" separation of the patient's pulses from noise and motion artifacts, a method of storing expected pulse characteristics and comparison to potential pulse wave forms is employed. This method requires five "vectors" or lists of parameters.

These parameters are $\Delta I_{\lambda 1}$, $I_{\lambda 1}$, $\Delta I_{\lambda 2}$, $I_{\lambda 2}$, and the pulse rate and are shown schematically in memory 400 of Fig. 19. It should be noted that these parameters are the same as the transmission parameters described above with scaling appropriate to 16-bit binary arithmetic.

A set of historical values for each parameter is stored in RAM, the history list. Each of these lists is five elements long in the present application, but could be shortened or expanded as required. The history lists are used as references for the current parameters being tested, also stored in RAM. This comparison yields a set of differences, which are similarly stored in coded form as difference codes. Associated with each parameter is also a "confidence" code which is, in essence, a tolerance level for each current parameter, as will be described below.

The first step in the confidence checking is to store the current parameters and then to compare the value of these parameters with the values stored in the history list. Note that the contents of the history list presumably contain the previous good pulse parameters. In the start up condition these pulse parameters are loaded with arbitrary initial values, and associated with a low confidence code admitting wide variations of data. Here, the parameter of total light transmission $I_{\lambda 1}$ is illustrated stored in memory 402.

Once the difference codes have been computed and placed in memory 403, they are compared with the corresponding stored confidence codes in memory 404. These confidence codes, which have the same range as the difference codes, are a description of how close the current parameter must be to the historical value to be considered acceptable. Both the difference codes and the confidence codes are coded in such a way that a code of 0 represents a difference or tolerance of 0-12%, 1 represents 13-25%, 2 represents 26-37%, and so forth, to the code of 8 which represents a 100% mismatch.

The meaning of this code with respect to this difference is that simply the ratio of the current parameter to the historical parameter, and with respect to the confidence codes, represents the tolerance for the parameter.

Once the confidence codes have been computed for each parameter, they are then summed at register 405 to generate a confidence score for the set of parameters. This total score is then compared to a threshold or a maximum acceptable score. It should be noted that a low score represents a close match to the expected value, and activates an enable 407 which allows data reception.

If the total confidence score is below the threshold, then the program assumes that the pulse is indeed a good pulse and takes a branch to update the confidence codes and exits to process the pulse. If the confidence code is above the threshold all data is rejected.

The confidence codes are individually adjusted by comparing the confidence code with the difference code for each parameter. If the difference code is smaller, then the confidence code is decremented by one count, expressing a higher level of confidence for the next text. If the difference code is larger, reflecting a parameter that was not within tolerance, although the total was satisfactory as a set, then that individual confidence code is incremented, representing an eroded confidence level. This process of incrementing or decrementing is repeated twice if the pulse was successful so that the confidence codes quickly converge on good pulses.

In the event that the score was not acceptable, the program retests all of the parameters except for the pulse period, this being the parameter most likely to go out of bounds from motion induced artifact. Assuming that it still fails, the confidence codes are re-adjusted once as described above in order to erode the confidence levels somewhat in preparation for the next trial.

The program then makes one last check with these updated confidence codes before exiting and rejecting the pulse. The reason for this last check is that the confidence codes which will be applied to the next pulse might as well be applied to the current pulse as well, in the event that the pulse is only slightly outside the acceptable window. This technique provides a good response to changing pulse conditions.

The above description outlines in a general way the confidence code processing used in the oximeter to provide an intelligent processor for physiologically based signals.

The reader will appreciate that the disclosed process is an intermediate step in the indication of the measurement.

In addition, the reader will appreciate that for the purposes of determining the calibration of the instrument in human subjects, the technique of determining measurements of R_i with high levels of confidence use the instrument itself to determine the calibration parameters as outlined herein.

In summary, it can be seen that the pulse oximeter monitor of the present invention provides a wide variety of essential information to attending physicians and in a variety of visual and audio forms. While the above provides a full and complete disclosure of the preferred embodiments of the invention, various modifications, alternate constructions, and equivalents may be employed without departing from the true spirit and scope of the invention. For example, high oxygen saturation limits are needed on applications involving newborn infants to prevent bronchopulmonary dysplasia and retrolental fibroplasia. Provision of an additional alarm limit for high oxygen saturation is well within the scope of this invention.

CLAIMS:

1. An oximeter comprising light means addressed to the flesh of a patient characterised in that the light means comprises first and second light sources; and by at least one light sensor also addressed to the flesh to define a light path through the flesh between the light sources and light sensor; means for detecting the light signal received by the light sensor and for separating the pulsatile signal from the sensor; audio emitter means arranged to emit an audibly perceptible sequential tone signal synchronous to change in the relation reception of light at said light source due to the pulsatile flow of blood, so that sequential tone signals synchronous to heart pulse rate are emitted and means arranged to change the tonal frequency of the audio emitter means proportionate to a difference in light signals received at said sensor of light from the first and second light sources so that change in oxygen saturation of the blood of the patient is indicated by change in tonal frequency of said tone signals synchronous to heart rate.

2. An oximeter according to Claim 1 and wherein said tonal frequency of the tone signal is arranged to decrease with decreasing oxygen saturation.

3. An oximeter comprising light means addressed to the flesh of a patient characterised in that the light means comprises at least one light source, and by a light sensor and means for determing pulse rate and intensity, and by: an array of lights; circuit means arranged to flash the lights in synchrony with pulse rate; and circuit means arranged to vary the number of the lights flashed in relation to the pulse intensity.

4. A process for receiving and processing signal data from an oximeter characterised by comprising

in combination: providing an alarm; setting a predetermined alarm limit for at least one of the parameters of pulse rate and oxygen saturation; receiving data; applying a confidence limit to the received data to narrow the range of the received data as the data is received; opening the confidence limit responsive to data received outside the narrow range; closing the confidence limit responsive to data received within the range; calculating at least one of the parameters of pulse rate and oxygen saturation only in accordance with data which is within the range; and eminating a two portion signal perceptible to the human senses, using the confidence levels, having a first portion proportional to the pulse rate and a second portion proportional to either blood perfusion rate and/or oxygen saturations.

5. A process according to Claim 4 wherein the signal includes a flashing light or lights proportional in number to a blood perfusion amount.

6. A process according to Claim 4 or 5 wherein the signal includes a tonal signal proportional in frequency to instrument detected oxygen saturation.

7. A pulse oximeter comprising light means addressed to the flesh of a patient, characterised in that the light means includes at least two light sources; and by at least one sensor; means arranged to process the signals from the light sensor including sensing means arranged to determine the maxima of absorption, the minimum of absorption and the difference in absorption between the two light sources to determine the parameters of pulse and oxygen saturation; means arranged to record the maximum absorption of each light source, the minimum of absorption of each light source and the oxygen saturation and pulse rate; means arranged to apply

a confidence limit to each of a maxima, minima, pulse rate and oxygen saturation; a corresponding confidence factor to each maxima, minima oxygen saturation and pulse rate; means arranged to reject all the signals when less than some preselected portion of the signals are received; and means arranged to receive data within the confidence limits when more than some preselected portion of the signals are received within confidence limits.

8. An oximeter of the type including means for determining oxygen saturation of blood characterised by means arranged to emit an audibly perceptible sequential tone signal; and means arranged to change the tonal frequency of the tone signal corresponding to changes in oxygen saturation.

9. An oximeter according to Claim 8 wherein said tonal frequency of said tone signal decreases with decreasing oxygen saturation.

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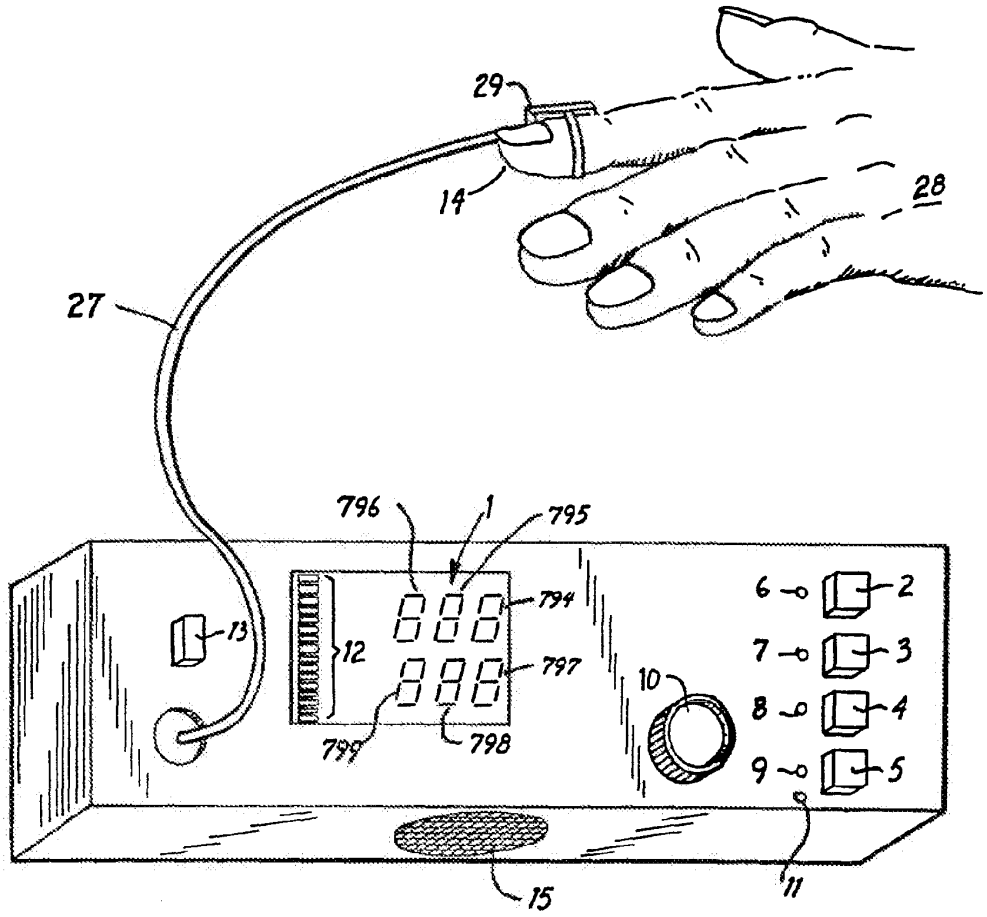


FIG. 1.

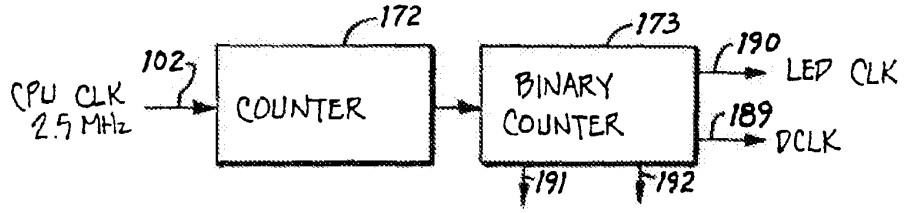


FIG. 8.

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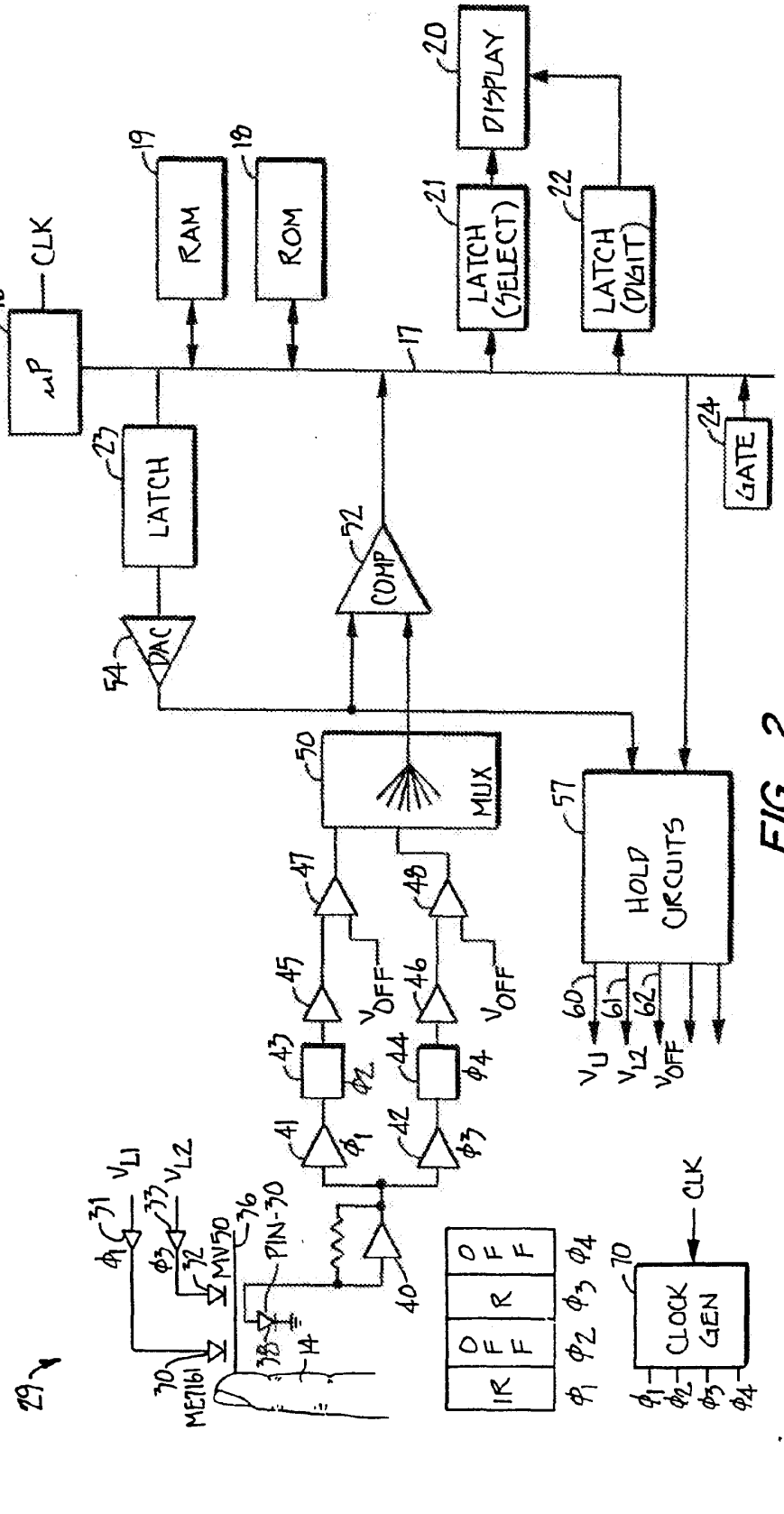


FIG. 2.

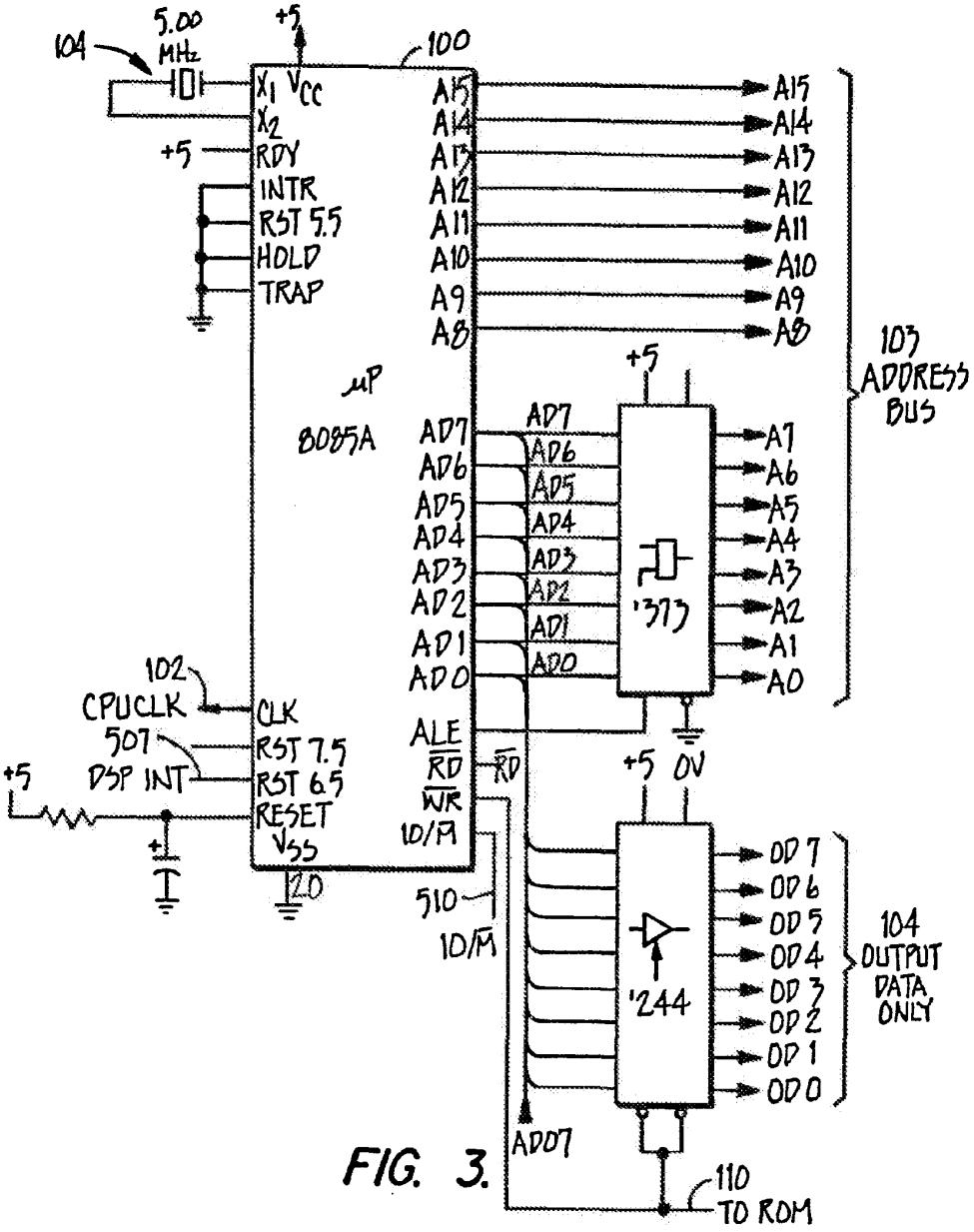

5.00 MHz
104
+5
100
X1
X2
VCC
RDY
INTR
RST 5.5
HOLD
TRAP
μP
8085A
A15
A14
A13
A12
A11
A10
A9
A8
AD7
AD6
AD5
AD4
AD3
AD2
AD1
AD0
ALE
RD
WR
IO/M
CLK
RST 7.5
RST 6.5
RESET
VSS
102
CPUCLK
507
DSP INT
510
IO/M
'373
'244
103 ADDRESS BUS
104 OUTPUT DATA ONLY
110 TO ROM
0V

FIG. 3.

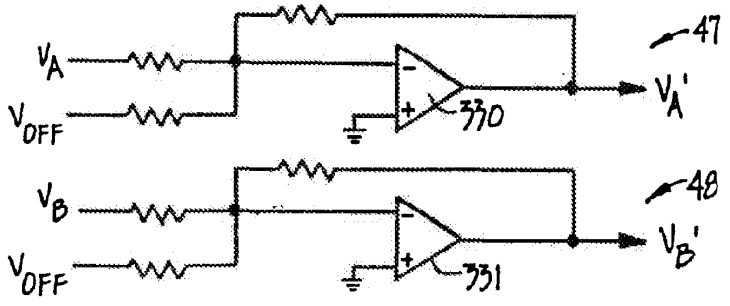

VA
VOFF
330
VA'
47
VB
VOFF
331
VB'
48

FIG. 11.

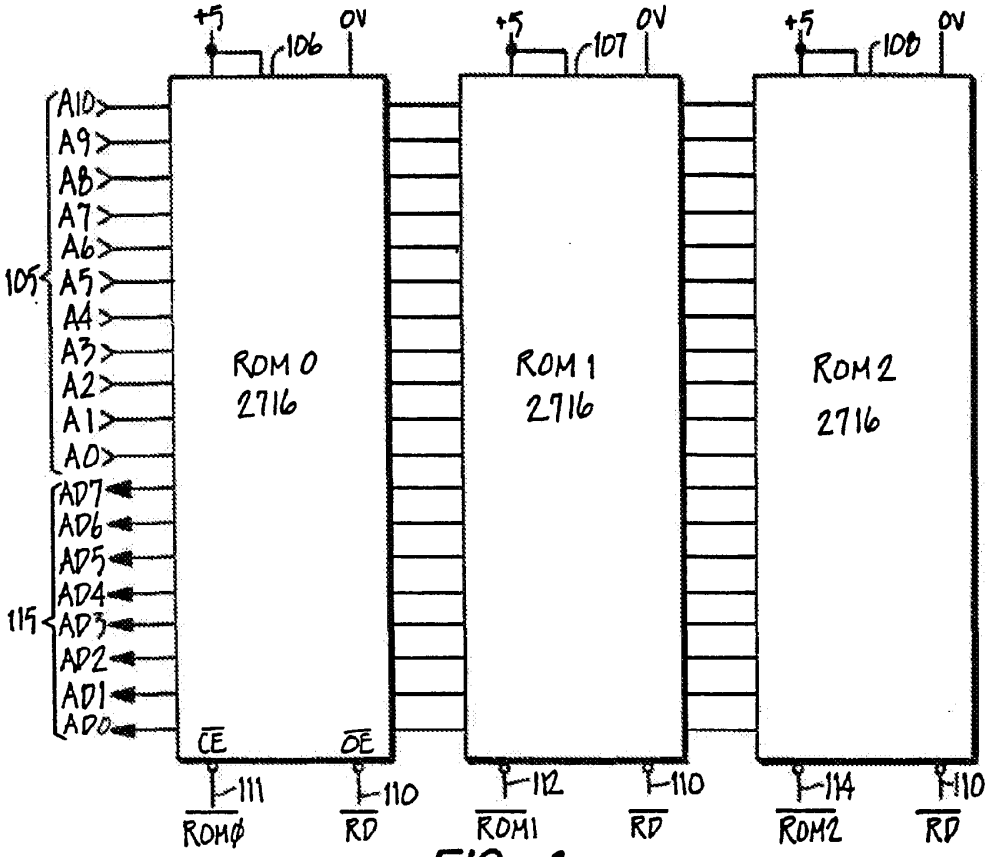

+5
106
0V
+5
107
0V
+5
108
0V
A10
A9
A8
A7
A6
A5
A4
A3
A2
A1
A0
105
AD7
AD6
AD5
AD4
AD3
AD2
AD1
AD0
115
ROM 0
2716
ROM 1
2716
ROM 2
2716
CE
OE
111
110
112
110
114
110
ROMØ
RD
ROM1
RD
ROM2
RD

FIG. 4.

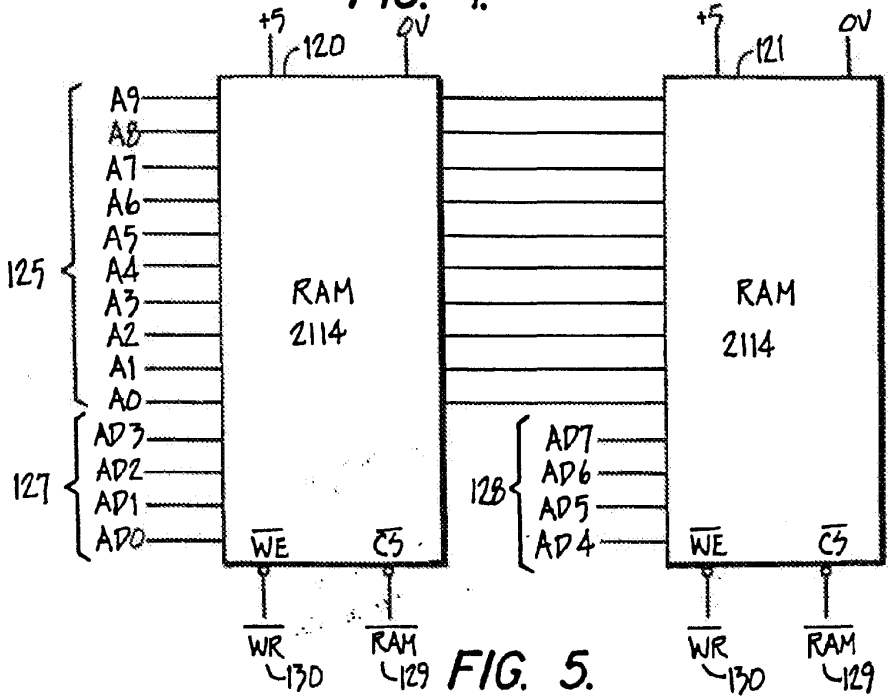

+5
120
0V
+5
121
0V
A9
A8
A7
A6
A5
A4
A3
A2
A1
A0
125
RAM
2114
RAM
2114
AD3
AD2
AD1
AD0
127
AD7
AD6
AD5
AD4
128
WE
CS
WE
CS
WR
130
RAM
129
WR
130
RAM
129

FIG. 5.

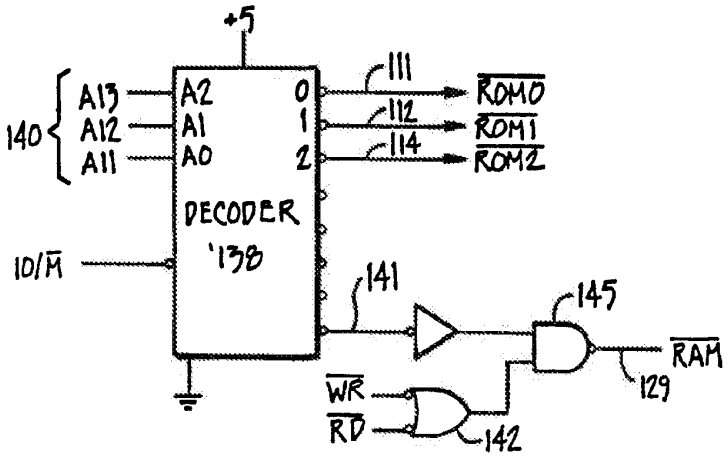


FIG. 6.

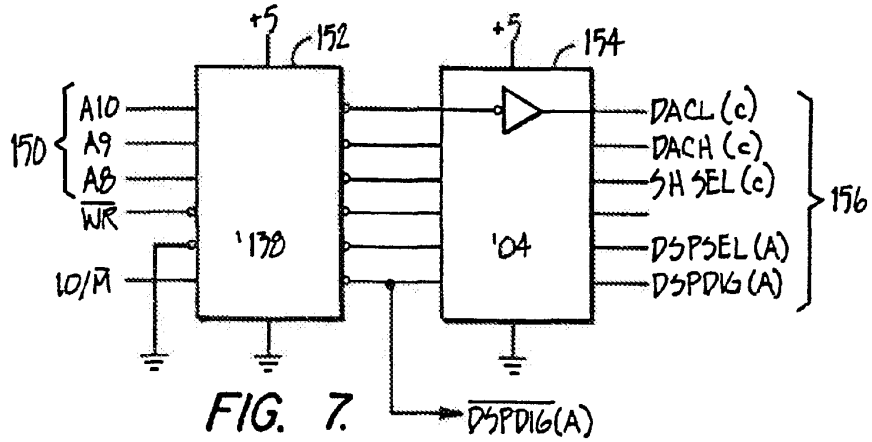


FIG. 7.

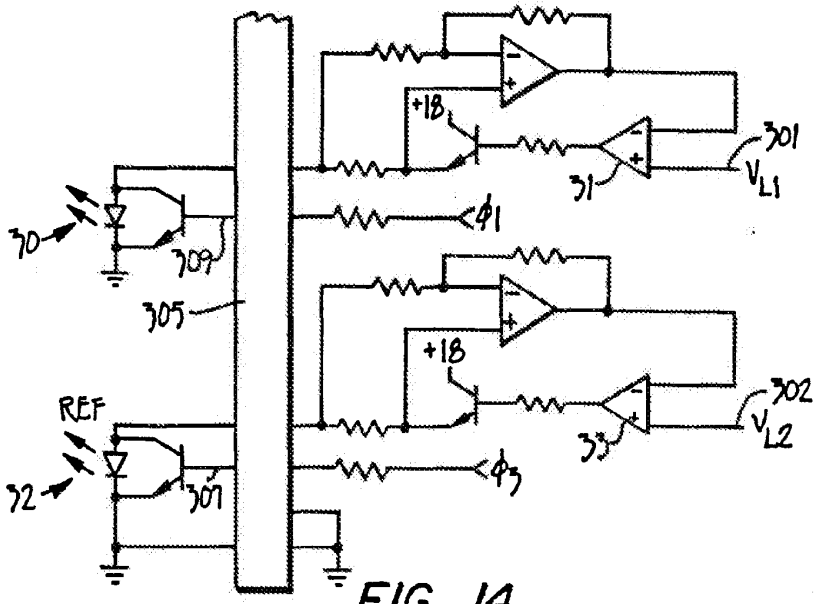


FIG. 14.

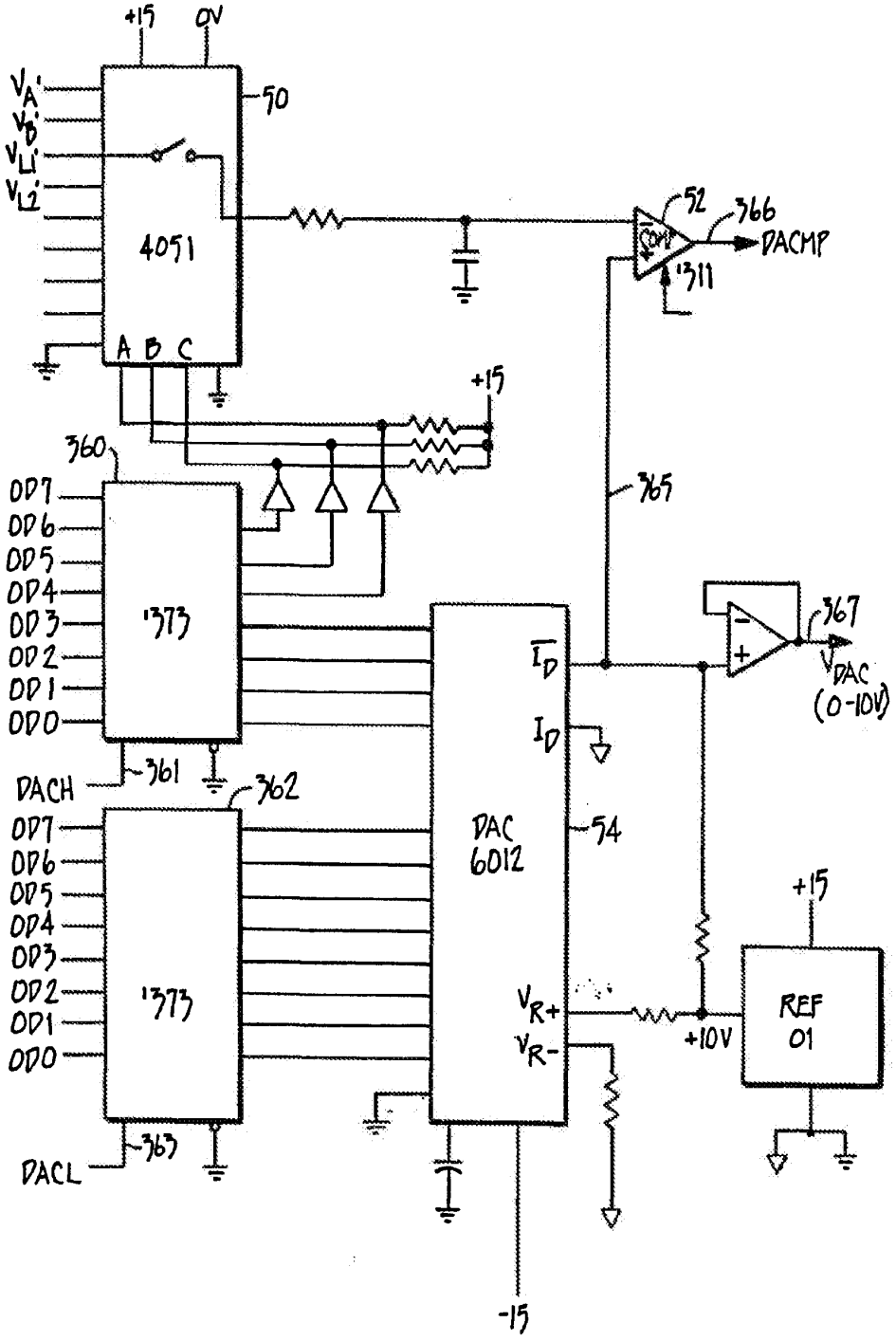

+15
0V
50
4051
A B C
V_A'
V_B'
V_{L1}'
V_{L2}'
52
366
DACMP
1311
+15
360
365
OD7
OD6
OD5
OD4
OD3
OD2
OD1
OD0
1373
367
V_{DAC}
(0-10V)
$\overline{I_D}$
I_D
DACH
361
362
DAC
6012
54
OD7
OD6
OD5
OD4
OD3
OD2
OD1
OD0
1373
+15
V_{R+}
V_{R-}
+10V
REF
01
DACL
363
-15

FIG. 9.

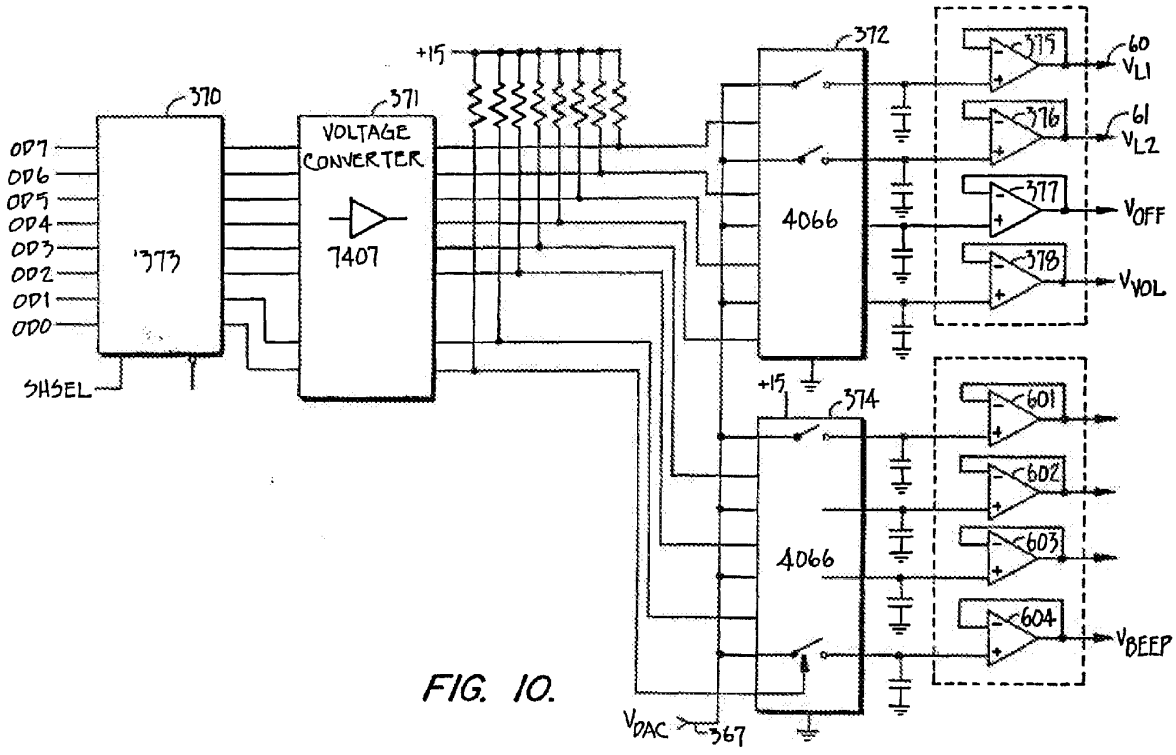


FIG. 10.

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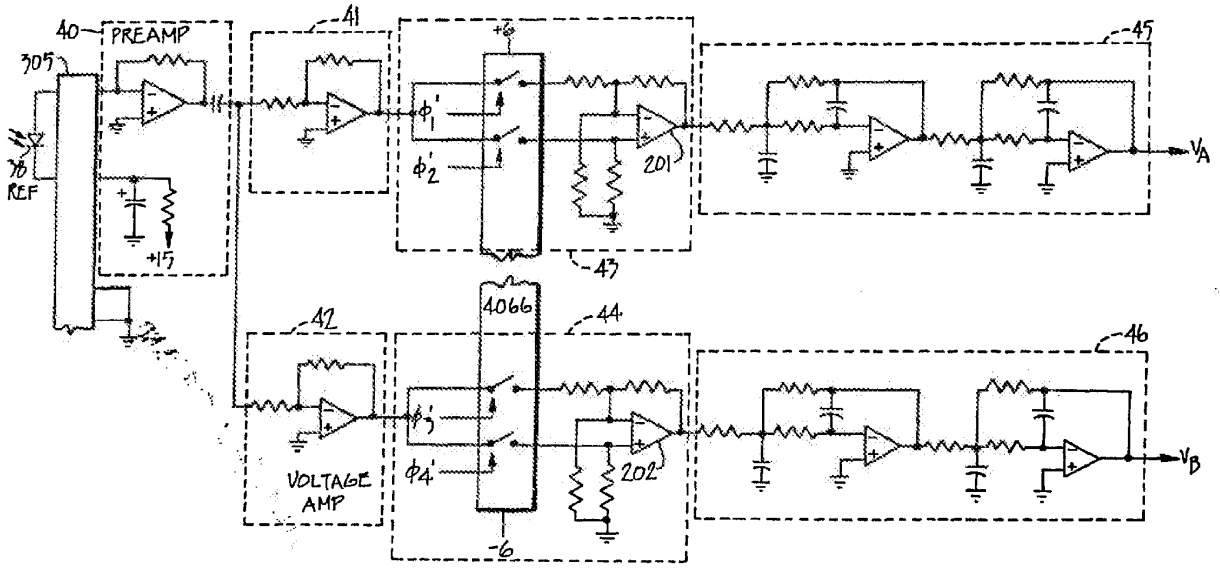

40
PREAMP
305
76
REF
+15
41
42
VOLTAGE
AMP
4066
43
44
45
46
201
202
V_A
V_B

FIG. 12.

0104771

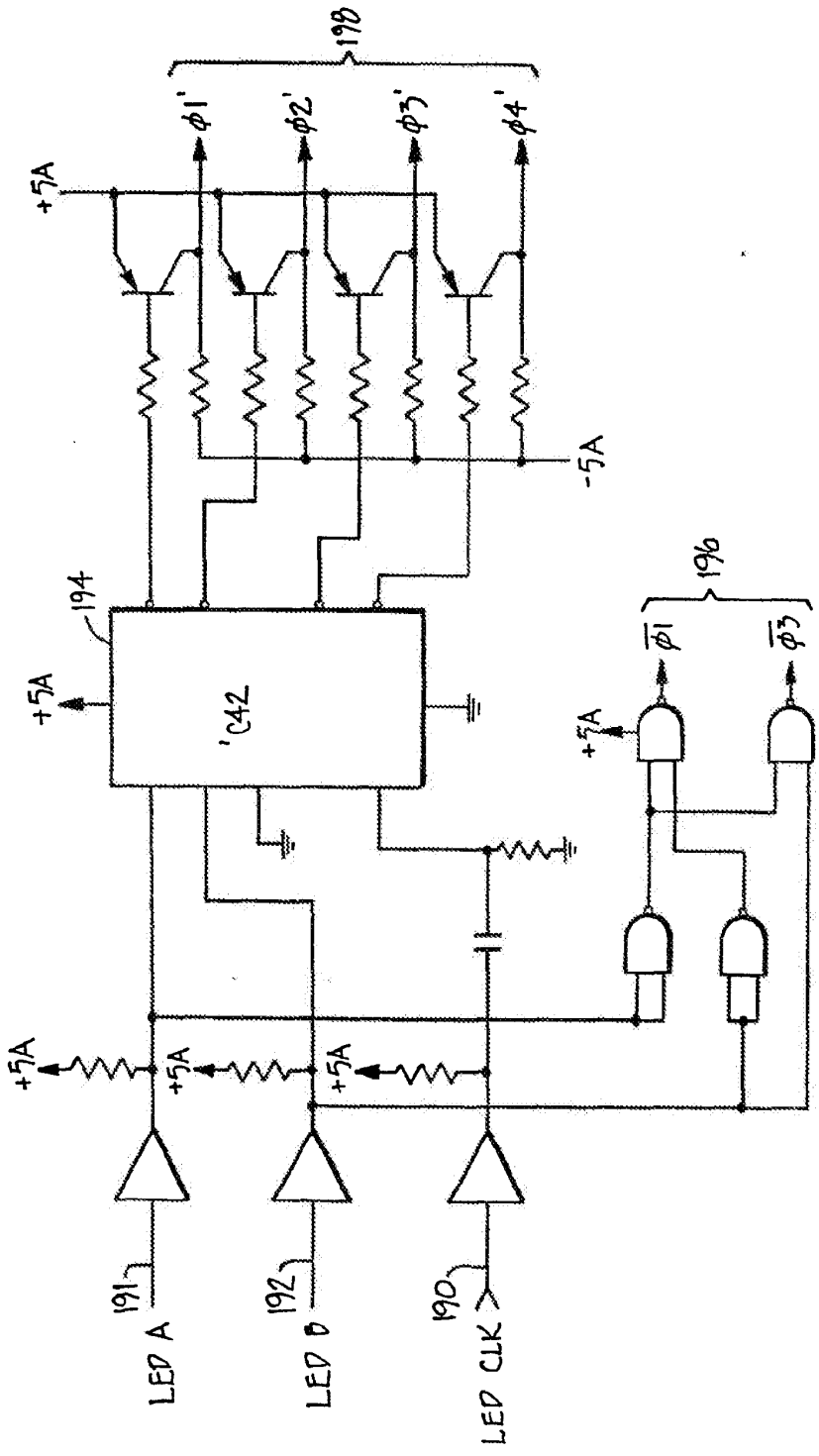


FIG. 13.

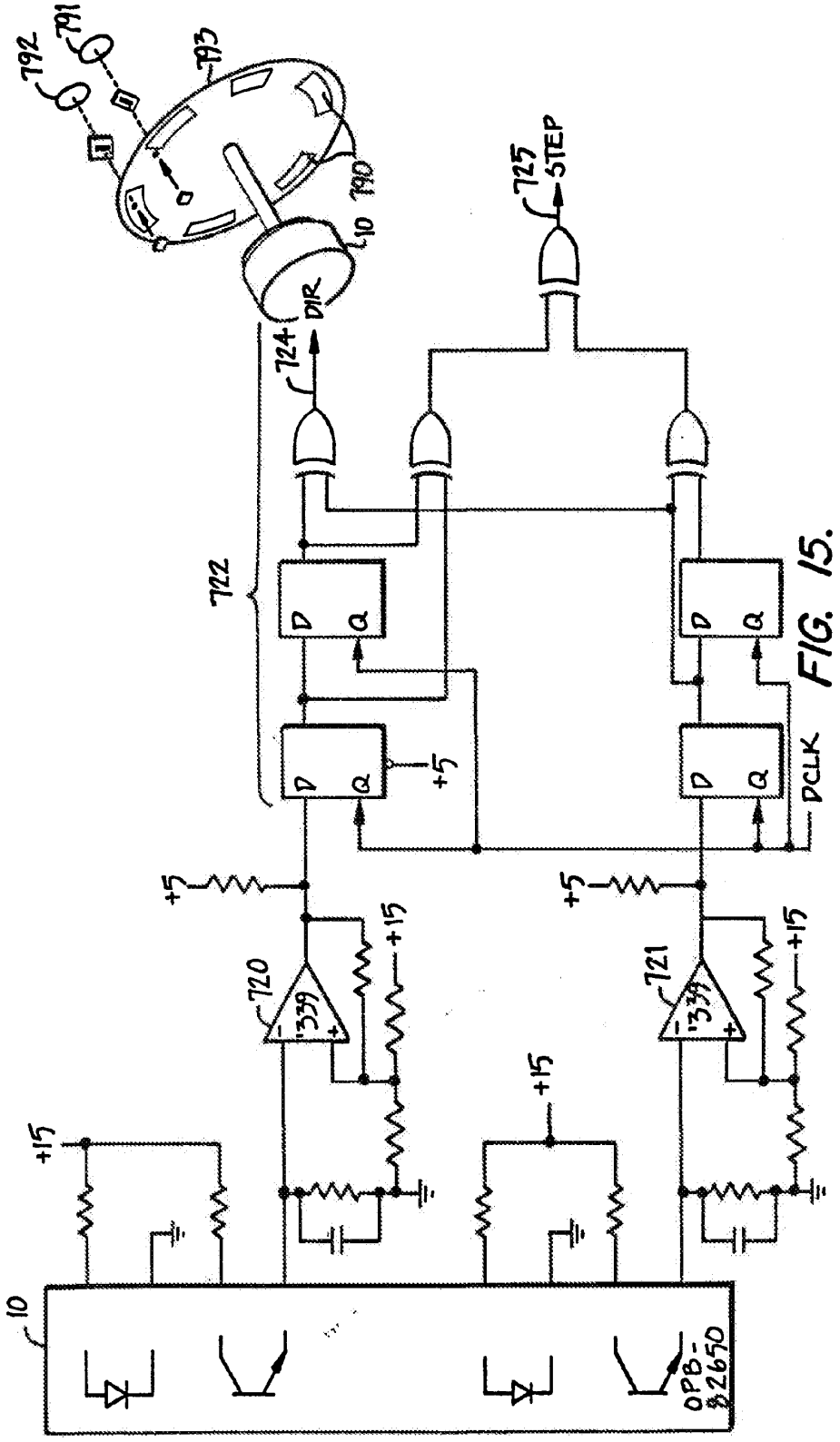

792
791
793
790
10
DIR
724
725
STEP
722
D
Q
+5
PCLK
+15
720
721
1339
10
OPB-
82650

FIG. 15.

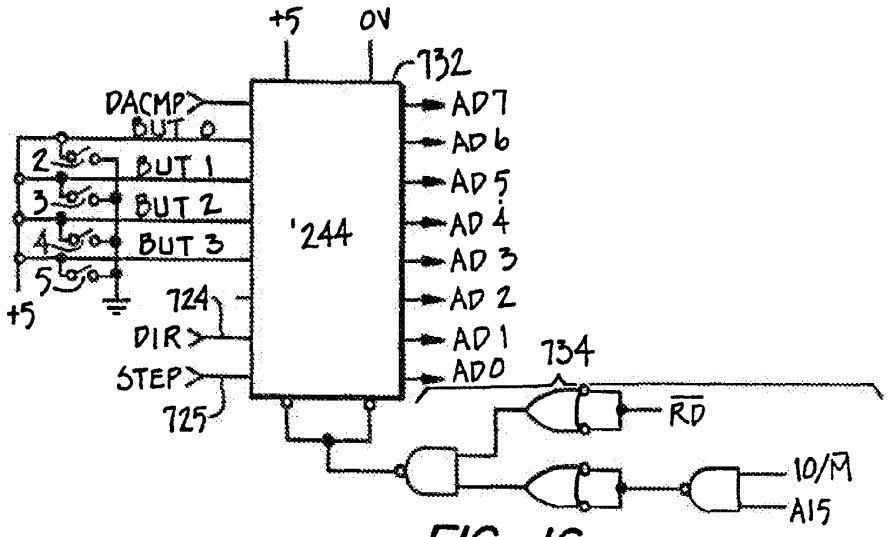

+5
0V
732
DACMP
BUT 0
BUT 1
BUT 2
BUT 3
'244
AD7
AD6
AD5
AD4
AD3
AD2
AD1
AD0
724
DIR
STEP
725
734
RD
IO/M
A15

FIG. 16.

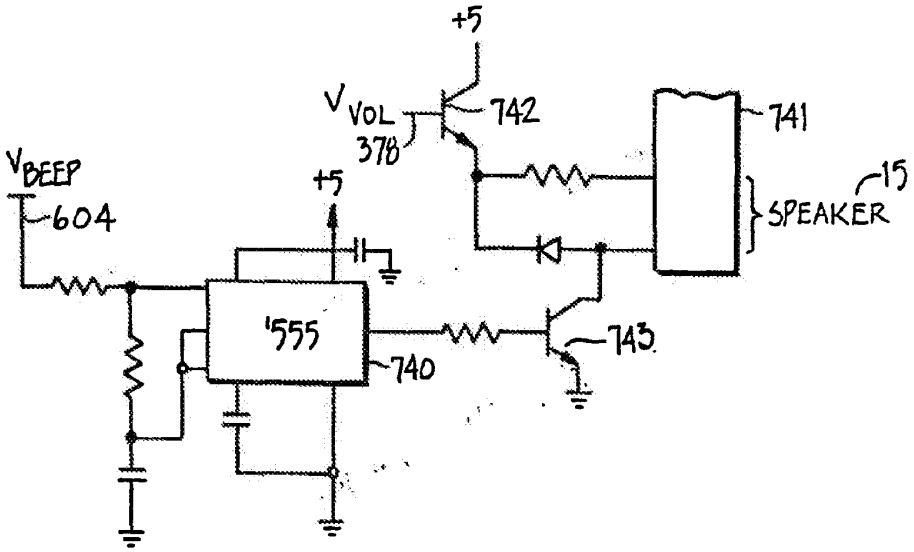

+5
V VOL
378
742
741
V BEEP
604
+5
15
SPEAKER
'555
740
743

FIG. 18.

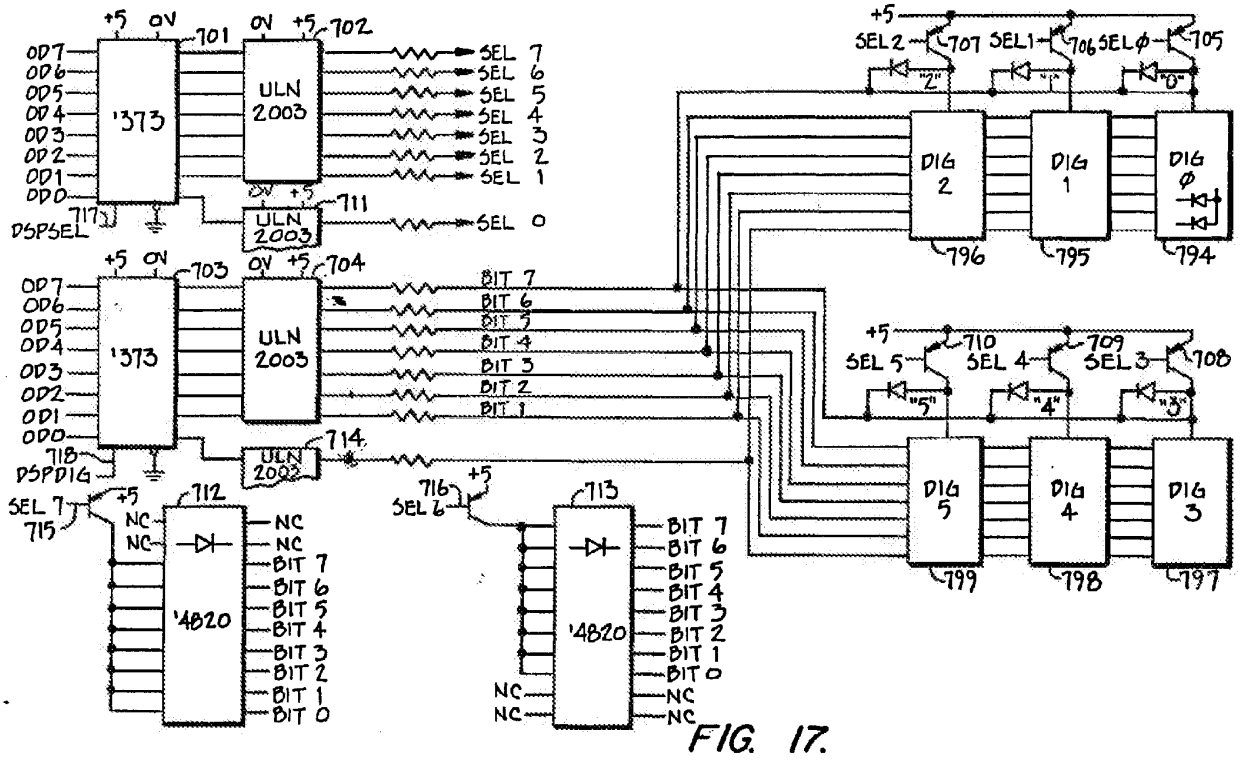

+5
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702
OD7
OD6
OD5
OD4
OD3
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OD1
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'373
ULN 2003
SEL 7
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SEL 5
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711
717
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704
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718
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ULN 2002
714
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BIT 6
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SEL 6
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SEL 2
707
SEL 1
706
SEL 0
705
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DIG 1
DIG 0
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795
794
SEL 5
710
SEL 4
709
SEL 3
708
"5"
"4"
"3"
DIG 5
DIG 4
DIG 3
799
798
797

FIG. 17.

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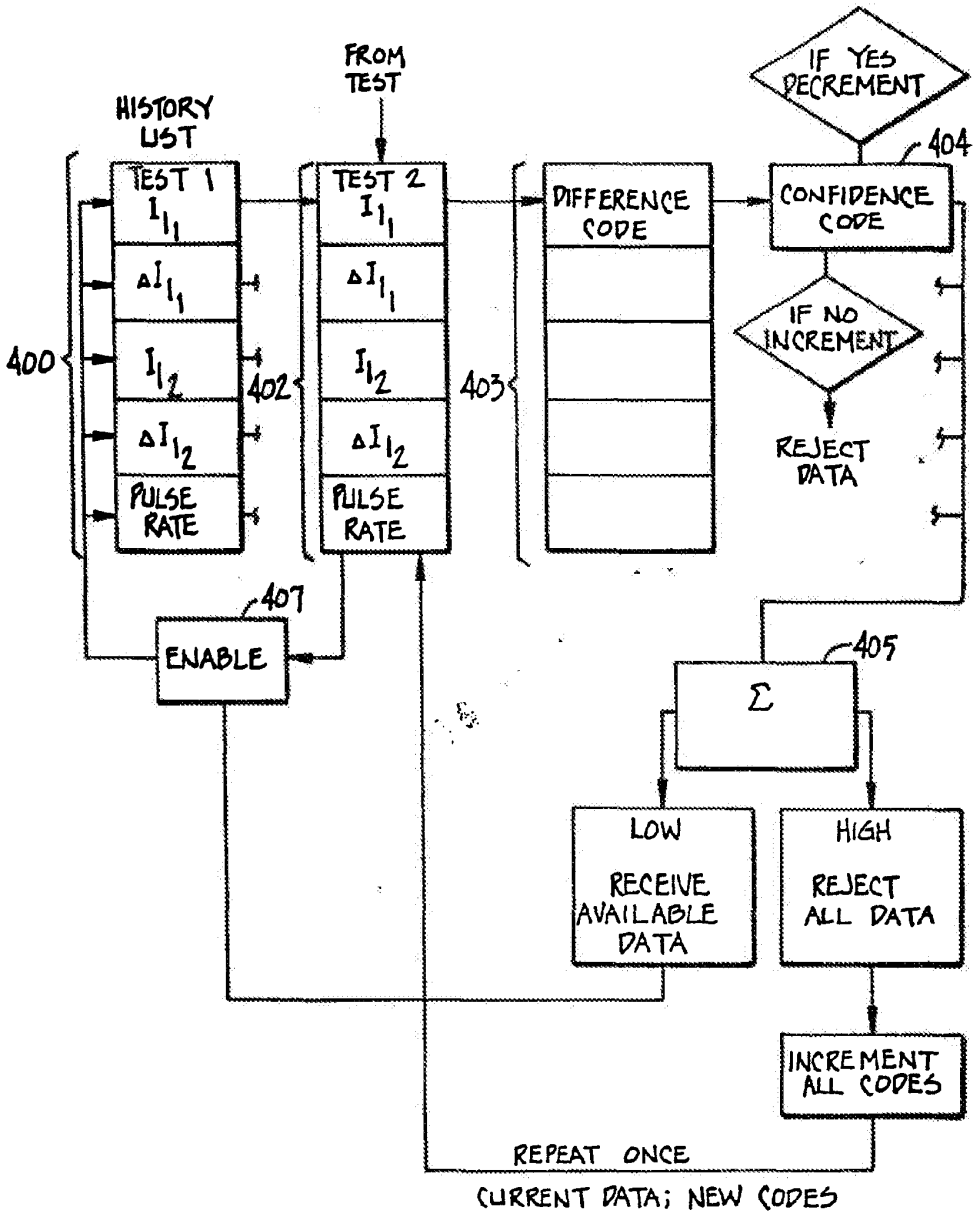


FIG. 19.

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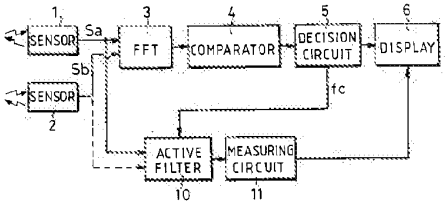
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(54) Blood pulse wave detecting apparatus and motion intensity measuring apparatus.

(57) An apparatus for detecting pulse waves and motion intensity of a living body in motion is disclosed. The apparatus has photosensors (1, 2) of the photocoupler type, for typically wavelengths of 660 nm and 940 nm, respectively. The sensors (1, 2) are attached to a person under examination, and provide output signals Sa and Sb which include a blood pulse signal as well as body motion components superimposed on the blood pulse signal. These signals Sa and Sb are subjected to Fourier transformation in a fast Fourier transformation circuit (3), and then applied to a comparator (4) which in turn compares amplitudes of major frequency components (components associated with pulse waves and body motion) to one another. According to the comparison result, a decision circuit (5) discriminates the pulse wave from the body motion. A display unit (6) displays the pulse rate corresponding to the fundamental frequency of the detected pulse wave. The display unit (6) also displays the change in motion intensity detected by the decision circuit (5). Thus, the present invention allows the detection of the change in motion intensity during the exercise of a person under the examination.

FIG.1.



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The present invention relates to a blood pulse wave detecting apparatus and motion intensity measuring apparatus. In particular, but not exclusively, the present invention performs accurate and reliable detection of the blood pulse rate, blood pulse waves, or motion intensity of a living body which is even in motion.

There are various types of known apparatus for detecting the blood pulse rate or blood pulse waves of a living body. However, most of these apparati can provide accurate detection only when a living body is at rest. This is because if the living body moves, a mixture of blood pulse wave and body movement is detected and it is impossible to extract the blood pulse wave.

The detection of the blood pulse rate or blood pulse waves of a living body is very important for control of excersizing or for health care. Therefore, there is a great need to achieve accurate blood pulse detection of a living body in motion.

One of the conventional blood pulse rate detectors is disclosed in Japanese Patent Publication No. 63-34731. When a pulse, showing a deviation from an average value, by an amount greater than an allowable limit is detected, the detection is cancelled so that only normal pulses can be detected. With this apparatus, extraordinary pulses arising, when a living body moves slightly for a short time, can be effectively cancelled, and thus only normal pulses can be detected.

In the conventional apparatus, however, if the living body makes continuous motions, the pulse will change very often and thus the detection will be cancelled so often that accurate detection of pulses will become impossible.

If the motion intensity of a living body in motion, in particular of a human body, can be measured, it will be possible to advantageously control the amount of motion. However, conventional techniques cannot measure the intensity of motion.

In view of the above, it is an object of the present invention to provide a blood pulse wave detecting apparatus which can distinguish blood pulses from body motion.

It is another object of the present invention to provide a motion intensity detecting apparatus for detecting the motion intensity of a living body.

According to a first aspect of the present invention to achieve the above objects, there is provided a blood pulse wave detecting apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; and discrimination means for making comparison of amplitudes of frequency components associated with each wavelength wherein the frequency components are included in a detected signal provided by the light detecting means, thereby discriminating a blood pulse wave of the living organism from its body motion wave according to the relationships between the ratios of the amplitudes of frequency components.

According to a second aspect of the present invention, there is provided a motion intensity measuring apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; discrimination means for making comparison of amplitudes of frequency components associated with each wavelength wherein the frequency components are included in a detected signal provided by the light detecting means, thereby discriminating a blood pulse wave of the living organism from its body motion wave according to the relationships between the ratios of the amplitudes of frequency components; and measuring means for making comparison of amplitudes of body motion associated with the different wavelengths wherein the amplitudes have been discriminated by the discrimination means, thereby measuring the motion intensity of the living organism according to the change in the ratio of the amplitudes of body motion.

According to a third aspect of the present invention, there is provided a motion intensity measuring apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; discrimination means for making comparison of amplitudes of frequency components associated with each wavelength wherein the frequency components are included in a detected signal provided by the light detecting means, thereby discriminating a blood pulse wave of the living organism from its body motion wave according to the relationships between the ratios of the amplitudes of frequency components; and measuring means for making comparison of the amplitude of the body motion to the amplitude of the blood pulse wave wherein the amplitudes of the body motion and blood pulse wave have been discriminated by the discrimination means, thereby measuring the motion intensity of the living organism according to the change in the ratio between the amplitudes.

According to a fourth aspect of the present invention, there is provided a motion intensity measuring apparatus based on the second or third aspect, wherein light having such a wavelength at which the absorbance of oxygen haemoglobin is equal to that of reduced haemoglobin is used as one of the light having different wavelengths, and wherein the measuring means employs the amplitude of a blood pulse wave included in a detected signal associated with this light as a refer-

ence value, and compares the amplitude of a blood pulse wave included in a detected signal associated with another light to the reference value, thereby measuring the motion intensity of a living organism.

According to a fifth aspect of the present invention, there is provided a motion intensity measuring apparatus based on the second, third, or fourth aspect, wherein at least one of means including the light detecting means, the discrimination means and the measuring means is adapted to be supplied with electric power only when measurement is carried out.

According to a sixth aspect of the present invention, there is provided a motion intensity measuring apparatus based on the second, third, or fourth aspect, wherein at least one of means including the light detecting means, the discrimination means and the measuring means is adapted to be supplied with electric power only when measurement is carried out at measurement timing which has been set in an intermittent fashion.

According to a seventh aspect of the present invention, there is provided a motion intensity measuring apparatus based on the fifth or sixth aspect, wherein the electric power is supplied in a pulse current form.

According to an eighth aspect of the present invention, there is provided a blood pulse wave detecting apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; frequency analyzing means for performing frequency analysis on a detected signal provided by the light detecting means, for each of light having the different wavelengths; and blood pulse frequency identifying means for identifying the blood pulse frequency of the living organism by determining which one of predefined modes the analysis result provided by the frequency analyzing means belongs to.

According to a ninth aspect of the present invention, there is provided a blood pulse wave detecting apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; Fourier transformation means for performing Fourier transformation on a detected signal provided by the light detecting means for each of the light having different wavelengths; and blood pulse frequency identifying means for identifying the blood pulse frequency of the living organism by comparing spectra provided by the Fourier transformation means for the respective different wavelengths thereby determining which one of predefined modes the comparison result belongs to.

According to a tenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; Fourier transformation means for performing Fourier transformation on a detected signal provided by the light detecting means for each of the light having different wavelengths; blood pulse frequency identifying means for identifying the blood pulse frequency of the living organism by comparing spectra provided by the Fourier transformation means for the respective different wavelengths thereby determining which one of predefined modes the comparison result belongs to; and filtering means for passing only the frequency component identified by the blood pulse frequency identifying means and its harmonics included in the detected signal provided by the light detecting means.

According to an eleventh aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on any one of the eighth through tenth aspects, further including: storage means for storing the identification result provided by the blood pulse frequency identifying means; and display means for displaying the content stored in the storage means.

According to a twelfth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the tenth aspect, further including: waveform storing means for storing an output waveform provided by the filtering means; and display means for displaying the content stored in the waveform storing means.

According to a thirteenth aspect of the present invention, there is provided a motion intensity measuring apparatus based on any one of the second through seventh aspects, further including: motion intensity storing means for storing a measurement result provided by the measuring means; and display means for displaying the measurement result stored in the motion intensity storing means.

According to a fourteenth aspect of the present invention, there is provided a motion intensity measuring apparatus based on any one of the second through fourth aspects, wherein the light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by the respective plurality of light emitting means, the plurality of light emitting means and the plurality of light receiving means being arranged in the lateral direction of a finger.

According to a fifteenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the first, eighth, ninth, or tenth aspect, wherein the light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by the respective plurality of light emitting means, the plurality of light emitting means and the plurality of light receiving means being arranged in the lateral direction of a finger.

According to a sixteenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the first, eighth, ninth or tenth aspect, wherein at least one of means including the light detecting means and the discrimination means is adapted to be supplied with electric power only when measurement is carried out.

According to a seventh aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the first, eighth, ninth, or tenth aspect, wherein at least one of means including the light detecting means and the discrimination means is adapted to be supplied with electric power only when measurement is carried out at measurement timing which has been set in an intermittent fashion.

According to an eighteenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the sixteenth or seventeenth aspect, wherein the electric power is supplied in a pulse current form.

According to a nineteenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the first, eighth, ninth, or tenth aspect, wherein the light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by the respective plurality of light emitting means, the plurality of light emitting means and the plurality of light receiving means being arranged in the lateral direction of a finger.

The apparatus according to the present invention operates as follows: When a living organism is illuminated with light having different wavelengths, the amount of light transmitted through or reflected from the living organism depends on absorbance of oxygen haemoglobin included in arterial blood and also depends on reduced haemoglobin included in venous blood. Furthermore, the absorbances of both oxygen haemoglobin and reduced haemoglobin depend on the wavelength of light in different conditions. When a living body is in motion, the body motion is superimposed on both arterial blood and venous blood. Therefore, the amount of light detected by the light detecting means is influenced by the absorbance, which is dependent on the wavelength, as well as the body motion. Thus, if the amplitudes of frequency components included in a signal detected by the light detecting means are compared to one another for each wavelength, the blood pulse wave can be discriminated from the body motion wave according to the relationships between the ratios of amplitudes (the first aspect).

The absorbance of reduced haemoglobin varies depending on its oxygen content, that is, on the motion intensity. Therefore, if the body motion wave is discriminated from the blood pulse wave, and furthermore the amplitudes of body motion waves are compared between different wavelengths, then the motion intensity of a living body can be measured according to the change in the ratio of the amplitudes (the second aspect). The motion intensity can also be measured according to the change in the ratio of the amplitude of the body motion wave to the amplitude of the blood pulse wave (the third aspect).

If light having a wavelength at which the absorbance of oxygen haemoglobin is equal to that of reduced haemoglobin is employed as one of measuring light rays, then the amount of received light associated with this light can be used as a reference value (the fourth aspect).

The blood pulse wave can also be identified by performing frequency analysis on a signal detected by the light detecting means and determining which one of predefined modes the analysis result belongs to (the fifth aspect).

The blood pulse frequency can be determined by performing Fourier transformation, which is one of ways to perform frequency analysis, and comparing the resultant spectra (the sixth aspect).

The blood pulse wave can be detected by using filter means which passes only a specific frequency component and its harmonics (the seventh aspect).

Embodiments of the present invention will now be described with reference to the accompanying drawings, of which:

Figure 1 is a block diagram illustrating the configuration of an embodiment of the present invention;

Figure 2 is a schematic diagram illustrating sensors for use in the embodiment, wherein the sensors are attached to a finger;

Figure 3 is a schematic representation of the "Lambert's" law;

Figure 4 is a schematic representation of an absorbance distribution of a human blood vessel illuminated with light;

Figure 5 is a graph illustrating the change in blood pulses as a function of distance from a heart from the left ventricle to the large vein;
Figure 6 is a graph illustrating absorbance characteristics of oxygen haemoglobin and reduced haemoglobin;
Figure 7 is a schematic diagram illustrating amplitudes of detected signal components corresponding to blood pulses and body motion, respectively, for both cases where the detection is carried out with light having wavelengths 660 nm and 940 nm;
Figure 8 is a schematic diagram illustrating the relationships of absorbance between arterial blood and venous blood for both cases where the detection is carried out with light having wavelengths 660 nm and 940 nm;
Figure 9 is a schematic diagram illustrating the method of determining the correspondence between two frequency components detected with two light rays having wavelengths of 660 nm, 940 nm and their origins to determine blood pulses and body motion;
Figure 10 is a graph illustrating frequency spectra of signals detected with light having wavelengths of 660 nm and 940 nm; and
Figure 11 is a schematic diagram illustrating an example of an actual measurement result regarding the change in the ratio of the amplitude associated with frequency 0_s to the amplitude associated with frequency 0_M wherein the measurement was carried out using light with a wavelength of 660 nm.

Detection Principle of the Invention

In the present invention, a pulse wave and motion intensity is detected according to the following principle:

(a) The Principle of Detecting Pulses via Light

First, the principle of detection of blood pulses via light will be described. When a thin film is illuminated with light, the ratio of the intensity of transmitted light to that of incident light will decreases depending on the density of matter and on the optical length. This fact is known well as the "Lambert's" law.

According to this law, the density of matter can be determined as follows: As shown in Figure 3(a), if the density of matter M is represented by C, a small optical length by 0L, the amount of incident light by I_{in}, the absorption factor of the matter M by k, then the following equation holds.

$$I_{out}/I_{in} = 1 - kC\Delta L \quad (1)$$

If the optical path is increased by a factor of 5 as shown in Figure (b), equation 1 becomes:

$$I_{out}/I_{in} = (1 - kC\Delta L)^5 \quad (2)$$

In Figure 3(a), for example, when the amount of incident light I_{in} is 10 and the amount of transmitted light is 9, then in the case of Figure 3(b), when the amount of incident light I_{in} is 10, the amount of transmitted light will be 10×0.9^5, or $I_{out}/I_{in} = 0.9^5$. i.e. $I_{out} = 5.9$.

The relationship between the amount of incident light and the amount of transmitted light for an arbitrary distance L can be obtained by integrating equation 1, thus:

$$\log(I_{out}/I_{in}) = (-kCL) \quad (3)$$

Equation 3 can be rewritten as:

$$I_{out} = I_{in} \times \exp(-kCL) \quad (4)$$

As can be seen from the above equation, if the amount of incident light I_{in}, the absorption factor k, and the optical length L are all maintained constant, then it is possible to measure the change in density of matter M by detecting the amount of transmitted light I_{out}.

Instead of detecting the amount of transmitted light, it is also possible to measure the change in density by detecting the amount of the light reflected from the matter M according to the same principle.

When a human blood vessel is illuminated with external light, the distribution of the absorption factor will be such as that shown in Figure 4. In the figure, I_2 represents the absorption caused by tissue, I_3 represents the absorption caused by venous blood, and I_4 represents the absorption caused by arterial blood.

Because the density of tissue does not change, the absorption I_2 caused by tissue is constant. The absorption I_3 by venous blood is also constant. This is because there is no pulsation in venous blood and therefore there is no change in its density. This can be seen apparently from Figure 5, which shows the decay of pulsation of blood sent from a heart compared to the distance from the heart. When blood reaches a vein, pulsation no longer occurs.

On the other hand, the absorption I_4 by arterial blood shows a change corresponding to the change in density induced by pulses. This means that pulses can be detected by illuminating a blood vessel with light and detecting the change in the amount of reflected or transmitted light. The above-described detection principle is also disclosed in Japanese Patent Laid-Open No. 2-44534.

If a human body is in motion, the body movement influences the flow of blood through the vessels including veins. As a result, the flow of venous blood becomes dynamic. This produces a change in light absorption of venous blood. Similarly, when arms or legs are in a swinging motion, vibrations of tissue also produce a change in its light absorption. Therefore, when a human body is in motion, simple detection of the amount of light reflected from or transmitted through a vessel cannot detect pulses.

(b) The Principle of Detecting Pulse Waves of a Living Body in Motion

The principle of detecting the pulse rate of a living body in motion will be described below.

Curves C1 and C2 in Figure 6 represent the absorption spectrum of haemoglobin. Haemoglobin combined with a sufficient amount of oxygen will be referred to as oxygen haemoglobin hereafter and which is provided by a heart. Reduced haemoglobin is that returning to the heart through a vein: the oxygen of which has been consumed by a body. As shown in Figure 6, the absorbance depends on the wavelength of light. The oxygen haemoglobin shows strong absorption of light in an infrared range (with a peak at 940 nm), and the reduced haemoglobin shows strong absorption of light in a red range (with a peak at 660 nm). Both types of haemoglobin have similar absorbance for light near 805 nm.

The difference in absorption characteristics between the two types of haemoglobin results from the difference in the amount of oxygen. The absorption spectrum changes from curve C1 to C2 with the consumption of oxygen.

When a human body is in motion, it consumes a greater amount of oxygen than when it is at rest. Therefore, the absorption characteristic of reduced haemoglobin varies depending on the amount of consumed oxygen. In contrast, it is known that the oxygen content combined with haemoglobin in arterial blood (or oxygen saturation ratio of arterial blood) is maintained constant regardless of the motion intensity. Therefore, if absorption is measured for different wavelengths, the motion intensity of a living body can be determined by comparing the results obtained at different wavelengths. In this technique, if the measurement is carried out for example at 940 nm and 660 nm, it is possible to achieve emphasized detection of motion intensity.

When a living body is in motion, because the body movement influences the flow of blood, the light transmitted through or reflected from a vessel includes pulses produced by the body movement superimposed on normal pulses. These body movement components should be distinguished. Otherwise, it would be impossible to detect either normal pulses or motion intensity. This point will be further discussed below.

The detection of pulse waves of a living body at rest by means of light can be represented by the following equation:

The amount of received light =
The amount of emitted light
- The amount of light absorbed by tissue
- K_{artery}•(Artery DC component + Pulse amplitude•$F(\theta_M)$)
- K_{vein}•Vein level (5)

where K_{artery} is the absorbance of arterial blood, K_{vein} is the absorbance of venous blood, Artery DC component is the DC component (constant component) of arterial blood, Vein level is the flow rate of venous blood (which has no pulse component as described above). Furthermore, $F(\theta_M)$ is the AC component of arterial blood, or a periodic function representing an amplitude (pulse amplitude) of the amount of haemoglobin which varies in an AC fashion at frequency θ_M.

When the living body is in motion, pulse components induced by the body movement are superimposed on both artery and vein blood flow. The amount of light which is received when the living body is in motion can be represented by adding these components to equation 5. For example, when an arm is in swing motion, the following equation holds:

The amount of received light =
The amount of emitted light
- The amount of light absorbed by tissue
- K_{artery}•(Artery DC component + Pulse amplitude•$F(0_M)$ + Arm amplitude•$F'(\theta_s)$)
- K_{vein}•(Vein level + Arm amplitude•$F'(\theta_s)$ (6)

In this equation, arm amplitude•$F'(\theta_s)$ is a periodic function having an amplitude (arm amplitude) of an AC component corresponding to the variation in the amount of haemoglobin induced by strokes of an arm and having a frequency of θ_s.

The amount of received light represented by equation 6 can be further modified, as shown in the following equations, for the case where the detection is done at two different wavelengths (660 nm and 940 nm in this example).

The amount of received light (660) =
The amount of emitted light (660)
- The amount of light absorbed by tissue (660)
- $K_{artery660}$•(Artery DC component + Pulse amplitude•$F(\theta_M)$ + Arm amplitude•$F'(\theta_s)$)
- $K_{vein660}$•(Vein level + Arm amplitude•$F'(\theta_s)$ (7)

The amount of received light (940) =
The amount of emitted light (940)
- The amount of light absorbed by tissue (940)
- $K_{artery940}$•(Artery DC component + Pulse amplitude•$F(\theta_M)$ + Arm amplitude•$F'(\theta_s)$)
- $K_{vein940}$•(Vein level + Arm amplitude•$F'(\theta_s)$ (8)

In the above equations 7 and 8, subscripts 660 and 940 represent wavelengths at which the detection is done, and the terms or coefficients having the subscripts represent the values at the corresponding wavelengths.

The amount of light given by equation 7 or 8, which will be referred to as a "received signal" hereafter, is a periodic function represented in the time domain. If each received signal is subjected to Fourier transformation, amplitudes of frequency components included in each received signal can be detected. In Figure 7(a), for example, the amplitude corresponding to $K_{artery660}$•Pulse amplitude, or the amplitude of the frequency component associated with pulses of arterial blood, is detected at frequency 0_M for the wavelength of 660 nm, and the amplitude corresponding to ($K_{artery660}$ + $K_{vein660}$)Arm amplitude or the amplitude of the frequency component associated with strokes of an arm superimposed on both vein and artery is detected at frequency 0_s. As shown in Figure 7(b), similar amplitudes are also detected at the same frequencies in the case of the wavelength of 940 nm.

If the absorbance characteristics shown in Figure 6 are taken into accounts, the relationships in absorbance between arterial blood and venous blood for respective wavelengths are such as those shown in Figure 8, or represented by the following inequalities:

$$K_{artery660} < K_{vein660},\ K_{artery940} > K_{vein940} \quad (9)$$

For example, as shown in Figure 9, when amplitudes of components at frequencies f_1 and f_2 are a and b, respectively, for the wavelength of 660 nm, and c and d, respectively, for the wavelength of 940 nm, if (a/b) < (c/d) or (c/a) > (d/b), then it is concluded that f_1 is the frequency corresponding to arterial blood pulses, and f_2 is the frequency corresponding to arm swinging.

Once the frequency which corresponds to arterial blood pulses has been detected, the pulse rate can be determined by converting the frequency to a number of pulses per minute. In this way, the pulse rate of a living body in motion can be detected.

Figure 10 illustrates one example of experimental results, wherein Figures 10(a) and 10(b) frequency spectra of signals detected for wavelengths of 660 nm and 940 nm, respectively. In this experiment, a man under examination swung his arms at a constant rate in synchronism with a metronome as in running, and the pulses were measured by an electrocardiograph for verification. In Figures 10(a) and 10(b), S1 denotes a fundamental frequency of arm strokes (body motion), S2 denotes the second-order harmonic of the arm strokes, and M1 denotes the fundamental frequency of blood pulses (that is, the pulse rate).

If the ratio of M1 to S1 is compared between the ratio shown in Figure 10(a) and the ratio shown in Figure 10(b), it is concluded from the above relationships that M1 represents pulses. The pulse ratio obtained in this way shows good agreement with that obtained by the electrocardiograph.

(c) The Principle of Detecting Motion Intensity

If the arterial blood pulse frequency and the body motion frequency are discriminated, the motion intensity of a living body can be detected by comparing amplitudes of these frequency components. In Figures 9(a) and 9(b), the amplitude of the frequency component 0_s representing the body motion (strokes) depends on the light absorbance of arterial and venous blood. The absorbance of arterial blood is constant regardless of the change in motion intensity, while the absorbance of venous blood varies depending on the motion intensity (the amount of oxygen consumption). As a result, the motion intensity can be determined as follows:

(1) The amplitude at frequency 0_s associated with the wavelength of 660 nm or 940 nm is sampled in a proper manner. The change in motion intensity of a living body in motion can be detected from the change in the sampled value which reflects the motion intensity.

(2) If the comparison of the ratio of the amplitude at frequency 0_s to the amplitude at frequency 0_M is made between wavelengths of 660 nm and 940 nm, the ratio reflects the motion intensity because the amplitude at frequency 0_M is independent of the motion intensity. From the change in this ratio, therefore, it is possible to detect the change in motion intensity of a living body. If the relationship between the above ratio and the motion intensity has been examined and stored in memory, the motion intensity can be determined by referring to the information stored in the memory.

Figure 11 illustrates actually-measured data with respect to the ratio of the amplitude at frequency 0_s to the amplitude at frequency 0_M - (corresponding to the ratio a/b in Figure 9) for the wavelength of 660 nm. In this measurement, a man under examination was forced to do

continuous motion, and the amplitudes at various frequencies were measured. The ratios of amplitudes are plotted as a function of the pulse rate. As represented by the alternate long and short dash line in Figure 11, the plotted points show a tendency to increase with the pulse rate. An increase in pulse rate can be regarded as an increase in motion intensity. An increase in motion intensity results in an increase in oxygen consumption of blood, and thus results in an increase in light absorbance. As a result, the amplitude at frequency 0_s (which corresponds to "b" in Figure 9) decreases with increasing motion intensity, and thus the ratio a/b increases. Therefore, the motion intensity can be detected from the change in ratio a/b.

(3) Light having a wavelength of about 805 nm is used to give a reference value of an amount received light. At this wavelength, both oxygen haemoglobin and reduced haemoglobin have constant absorbance, as shown in Figure 6. Therefore, the received signal associated with light having such a wavelength can be used to give a reference value which is compared to the amplitude of a component having a frequency of 0_s included in a received signal associated with light having another wavelength. From the change of this ratio, the motion intensity can be detected.

(d) The Principle of Detecting the Pulse Waveform of a Living Body in Motion

If the frequency reflecting artery blood pulses can be distinguished in the above-described manner, it is possible to detect a pulse waveform by using a filter which can pass this frequency and its harmonics.

A pulse wave consists of a fundamental wave and various orders of harmonics. If these components are extracted using a filter which can pass these components but which cannot pass the other frequency components, the pulse wave associated with a living body in motion is detected.

B: The Construction of Embodiments

Figure 1 is a block diagram illustrating the construction of one embodiment of this invention. In this figure, reference numerals 1 and 2 denote photosensors of the photo-coupler type for wavelengths 660 nm and 940 nm, respectively. As shown in Figure 2(a), these sensors 1 and 2 are disposed in a proper cap. The cap is adapted to be attached to the end portion of a finger in such a manner that sensors 1 and 2 are arranged in the longitudinal direction of the finger. Otherwise, the cap may also be adapted such that the sensors 1 and 2 are arranged in the lateral direction of a finger when the cap is attached to the finger.

The light beams emitted by the sensors 1 and 2 are reflected from blood vessels or tissue, and detected by photo-sensing elements of the sensors 1 and 2. As shown in Figure 1, the detected signals are applied as signals Sa and Sb, respectively, to a fast Fourier transformation circuit 3. The fast Fourier transformation circuit 3 performs Fourier transformation on signals Sa and Sb, and provides frequency spectra associated with these signals. The frequency spectra provided by the fast Fourier transformation circuit 3 are applied to a comparator 4. The comparator 4 stores the frequency spectra temporarily, and compares the magnitudes of major lines included in the spectra with one another. For example, the magnitudes of S1 and M1 shown in Figure 10(a) are compared. Similarly, the magnitudes of S1 and M1 shown in Figure 10(b) are compared. The comparison results are supplied to a decision circuit 5. Referring to comparison result patterns stored in advance, the decision circuit 5 determines which frequency corresponds to pulses and which one corresponds to body motion.

As described above, if the amplitudes a, b, c, and d of frequency components f_1 and f_2 shown in Figure 9 satisfy the relationship (a/b) < (c/d) or (c/a) > (d/b), then it is decided that frequency f_1 corresponds to arterial blood pulses, and that frequency f_2 corresponds to arm strokes. According to the decision made by the decision circuit 5, a display unit 6 including a liquid crystal display element or the like converts the frequency fc, which has been considered to correspond to the pulse rate, into a frequency per minute, and displays it on the display element.

According to the comparison results provided by the comparator 4, the decision circuit 5 detects the change in motion intensity from the ratio of the amplitude at frequency S1 to the amplitude at frequency at M1 associated with the wavelength of 660 nm or 940 nm, and outputs a signal representing the detection result to the display unit 6. The display unit 6 displays the change of motion intensity in a numerical or graphic fashion.

An active filter 10 extracts the frequency fc considered to correspond to blood pulses and its harmonics (for example, up to fifth- or sixth-order harmonics) from the output signal Sa or Sb outputted by the sensor 1 or 2. Therefore, the output signal of the active filter 10 consists of a pure pulse wave signal containing no stroke components (body motion components).

A measuring circuit 11 performs various kinds of measurement on the basis of the pulse wave signal provided by the active filter 10. For example, experiments have revealed that the ratio of the amplitude of the second-order harmonic to the am-

plitude of the third-order harmonic reflects the stress. It is also known that the mental and physical status can be measured from characteristic features of pulse waves. Thus, the measuring circuit 11 analyzes the pulse waves according to predetermined analytic methods, and outputs a signal representing the result to the display unit 6. The display unit 6 displays the measured result according to the output signal of the measuring circuit 11.

C: The Operation of the Embodiment

First, a person to be examined attaches the cap shown in Figure 2 to one of his or her fingers, and then exercises (runs, for example). Signals Sa and Sb including a blood pulse wave and body motion components superposed on it are obtained. These signals Sa and Sb are subjected to Fourier transformation in the fast Fourier transformation circuit 3. Then, amplitudes of major frequency components are compared to one another by the comparator 4. According to the comparison result, the decision circuit 5 discriminates the pulse wave and the body motion. The display unit 6 displays a pulse rate corresponding to the fundamental frequency of the pulse wave. The display unit 6 stores the pulse rate, and continues displaying this stored value until the pulse rate has been updated. The display unit 6 also displays the change of motion intensity detected by the decision circuit 5. Thus, during the exercise, it is possible to observe the change in motion intensity of the person under examination.

The active filter 10 extracts only pulse wave components and outputs them to the measuring circuit 11, which in turn performs measurement. In this way, the pulse wave of the person in motion is detected, and his (her) mental and physical status is detected from the pulse wave form. The detected results are displayed on the display unit 6 so that the mental and physical status (stress, for example) can be observed during his (her) exercising.

In the above example, the comparator 4 makes comparison of amplitudes between the fundamental wave of a pulse wave and the fundamental wave of body motion. However, the invention is not limited only to such comparison. The comparator 4 may also compare for example the fundamental wave of a pulse wave to the second-order harmonic of body motion, or compare the second-order harmonic of the pulse wave to the fundamental wave of body motion. Basically, any waves which can be discriminated clearly can be designated to be used in comparison. In some cases, body motion of a person under examination does not have periodicity. In this case, since major frequency components obtained by the Fourier transformation all result from blood pulses, it is much easier to discriminate the pulse wave. In the comparator 4 of this embodiment, when the output signal of the fast Fourier transformation circuit 3 contains only one fundamental wave and its harmonics, it is concluded that only blood pulse wave are detected, and its fundamental wave is regarded as blood pulses.

D: Modifications

The aforegoing description has been given by way of example only and it will be appreciated by a person skilled in the art that modifications can be made without departing from the scope of the present invention.

The above-described embodiment can be modified as follows:

(1) In the above embodiment, sensors are attached to the end portion of a finger to detect pulse waves at the end of the finger. Alternatively, the sensors may also be attached in such a manner that pulse waves at the root portion of a finger can be detected. Furthermore, the sensors may also be attached to detect blood pulses at a radius of a limb or at an ear. In addition to those described above, the sensors may be attached to an arbitrary portion as long as an artery and vein passing through that portion can be illuminated with light.

(2) In the above embodiment, sensors are attached with a cap (refer to Figure 2). However, the sensors may also be attached in a different manner. For example, a glove, band, tape, or the like may be used to attach the sensors to a portion to be detected.

(3) In the above embodiment, the Fourier transformation is utilized to perform frequency analysis on a sensed signal. Alternatively, discrete Fourier transformation or maximum entropy scheme may be employed. Basically, any method, which can extract frequency components included in a sensed signal and can compare amplitudes of these components to one another, can be employed.

(4) In the above embodiment, light beams having wavelengths of 660 nm and 940 nm are used for measurement. However, the wavelength is not limited only to those. Arbitrary wavelengths which lead to a difference in absorbance between oxygen haemoglobin and reduced haemoglobin may be employed.

(5) Furthermore, a light ray having a wavelength of 805 nm can be used as a reference light ray for measurement. At this wavelength, as shown in Figure 6, there is no difference in absorbance between oxygen haemoglobin and reduced haemoglobin. Therefore, the received signal associated with the light having this wavelength

can be used to give a reference value which is compared to the amplitude of a component having a frequency of θ_s included in a received signal associated with light having another wavelength. From the change of this ratio, the absolute value of the motion intensity can be detected.

(6)According to the above embodiment, it is possible to detect the frequency of body motion. Therefore, arm strokes during walking or running can be detected. Because the arm strokes correspond to the pitch of walking or running, the detection of body motion frequency allows the detection of the sum of step number. That is, the embodiment of this invention can also be used as a pedometer.

(7) The measuring circuit 11 may be adapted to include a pulse wave memory to store pulse waves outputted by the active filter 10, and pulse waves stored in the pulse wave memory may be displayed on the display unit 6. This arrangement allows visual recognition of the pulse wave form. This facilitates a grasp of the mental and physical status of a person under examination.

(8) There may be provided a motion intensity memory for temporarily storing the motion intensity detected by the decision circuit 5, and the motion intensity (or the change in motion intensity) stored in the motion intensity memory may be displayed on the display unit 6. This arrangement allows visual recognition of the motion intensity (or the change in motion intensity). This facilitates a grasp of more detailed mental and physical status of a person under examination.

(9) There may be provided a switch for performing on-off control of electric power thereby supplying the power to the entire circuit shown in Figure 1 or a specific part of the circuit only when measurement is carried out.

Furthermore, the above embodiment can be modified such that measurement is carried out at predetermined times. That is to say, electric power is intermittently supplied to the entire circuit or a specific part of the circuit only at the predetermined times for the measurement. In this case, the measurement timing can be set using a timer implemented in a hardware circuit or can be programmed in a microcomputer.

Furthermore, in either case where the electric power is supplied in on-off switching fashion or intermittent fashion, the power may be supplied in the form of a pulse current, thereby achieving a great reduction in power consumption.

According to the present invention, as described above, it is possible to perform accurate and reliable detection of the pulse ratio or the pulse wave of a living body which is even in continuous motion. Furthermore, it is also possible to detect the motion intensity during the motion of a living body.

Claims

1. A blood pulse wave detecting apparatus characterised by comprising:

   light detecting means (1,2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; and

   discrimination means (3, 4, 5, 10, 11) for making comparison of amplitudes of frequency components associated with each said wavelength wherein said frequency components are included in a detected signal provided by said light detecting means, thereby discriminating a blood pulse wave of said living organism from its body motion wave according to the relationships between the ratios of said amplitudes of frequency components.

2. A motion intensity measuring apparatus characterised by comprising:

   light detecting means (1, 2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

   discrimination means (3, 6, 10, 11) for making comparison of amplitudes of frequency components associated with each said wavelength wherein said frequency components are included in a detected signal provided by said light detecting means, thereby discriminating a blood pulse wave of said living organism from its body motion wave according to the relationships between the ratios of said amplitudes of frequency components; and

   measuring means (4) for making comparison of amplitudes of body motion associated with said different wavelengths wherein said amplitudes have been discriminated by said discrimination means,thereby measuring the motion intensity of said living organism according to the change in the ratio of said amplitudes of body motion.

3. A motion intensity measuring apparatus characterised by comprising:

   light detecting means (1,2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

   discrimination means (3, 5, 10, 11) for making comparison of amplitudes of frequency components associated with each said

wavelength wherein said frequency components are included in a detected signal provided by said light detecting means, thereby discriminating a blood pulse wave of said living organism from its body motion wave according to the relationships between the ratios of said amplitudes of frequency components; and

measuring means (14) for making comparison of the amplitude of the body motion to the amplitude of the blood pulse wave wherein the amplitudes of the body motion and blood pulse wave have been discriminated by said discrimination means, thereby measuring the motion intensity of said living organism according to the change in the ratio between the amplitudes.

4. A motion intensity measuring apparatus according to Claim 2 or 3, wherein light having such a wavelength at which the absorbance of oxygen haemoglobin is equal to that of reduced haemoglobin is used as one of said light having different wavelengths, and wherein said measuring means employs the amplitude of a blood pulse wave included in a detected signal associated with this light as a reference value, and compares the amplitude of a blood pulse wave included in a detected signal associated with another light to said reference value, thereby measuring said motion intensity of a living organism.

5. A motion intensity measuring apparatus according to Claim 2, 3, or 4 wherein at least one of means including said light detecting means, said discrimination means and said measuring means is adapted to be supplied with electric power only when measurement is carried out.

6. A motion intensity measuring apparatus according to Claim 2, 3, or 4 wherein at least one of means including said light detecting means, said discrimination means and said measuring means is adapted to be supplied with electric power only when measurement is carried out at measurement timing which has been set in an intermittent fashion.

7. A motion intensity measuring apparatus according to Claim 5 or 6 wherein said electric power is supplied in a pulse current form.

8. A blood pulse wave detecting apparatus characterised by comprising:

light detecting means (1,2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

frequency analyzing (3) means for performing frequency analysis on a detected signal provided by said light detecting means, for each of light having said different wavelengths; and

blood pulse frequency identifying means (5) for identifying the blood pulse frequency of said living organism by determining which one of predefined modes the analysis result provided by said frequency analyzing means belongs to.

9. A blood pulse wave detecting apparatus characterised by comprising:

light detecting means (1, 2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

Fourier transformation means (3) for performing Fourier transformation on a detected signal provided by said light detecting means for each of said light having different wavelengths; and

blood pulse frequency identifying means (5) for identifying the blood pulse frequency of said living organism by comparing spectra provided by said Fourier transformation means for said respective different wavelengths thereby determining which one of predefined modes the comparison result belongs to.

10. A blood pulse wave detecting apparatus characterised by comprising:

light detecting means (1, 2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

Fourier transformation means (3) for performing Fourier transformation on a detected signal provided by said light detecting means for each of said light having different wavelengths;

blood pulse frequency identifying means (5) for identifying the blood pulse frequency of said living organism by comparing spectra provided by said Fourier transformation means for respective said different wavelengths thereby determining which one of predefined modes the comparison result belongs to; and

filtering means (10) for passing only the frequency component identified by said blood pulse frequency identifying means and its harmonics included in the detected signal provided by said light detecting means.

11. A blood pulse wave detecting apparatus according to any one of Claims 8 through 10, further including:

storage means for storing the identification result provided by said blood pulse frequency identifying means; and

display means for displaying the content stored in said storage means.

12. A blood pulse wave detecting apparatus according to Claim 10, further including:

waveform storing means for storing an output waveform provided by said filtering means; and

display means for displaying the content stored in said waveform storing means.

13. A motion intensity measuring apparatus according to any one of Claims 2 through 7, further including:

motion intensity storing means for storing a measurement result provided by said measuring means; and

display means for displaying the measurement result stored in said motion intensity storing means.

14. A motion intensity measuring apparatus according to any one of Claims 2 through 4, wherein said light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by respective said plurality of light emitting means, said plurality of light emitting means and said plurality of light receiving means being arranged in the lateral direction of a finger.

15. A blood pulse wave detecting apparatus according to Claim 1, 8, 9, or 10, wherein said light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by respective said plurality of light emitting means, said plurality of light emitting means and said plurality of light receiving means being arranged in the lateral direction of a finger.

16. A blood pulse wave detecting apparatus according to Claim 1, 8, 9 or 10 wherein at least one of means including said light detecting means and said discrimination means is adapted to be supplied with electric power only when measurement is carried out.

17. A blood pulse wave detecting apparatus according to Claim 1, 8, 9 or 10 wherein at least one of means including said light detecting means and said discrimination means is adapted to be supplied with electric power only when measurement is carried out at measurement timing which has been set in an intermittent fashion.

18. A blood pulse wave detecting apparatus according to Claim 16 or 17 wherein said electric power is supplied in a pulse current form.

19. A blood pulse wave detecting apparatus according to Claim 1, 8, 9 or 10, wherein said light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by respective said plurality of light emitting means, said plurality of light emitting means and said plurality of light receiving means being arranged in the lateral direction of a finger.

FIG.1.

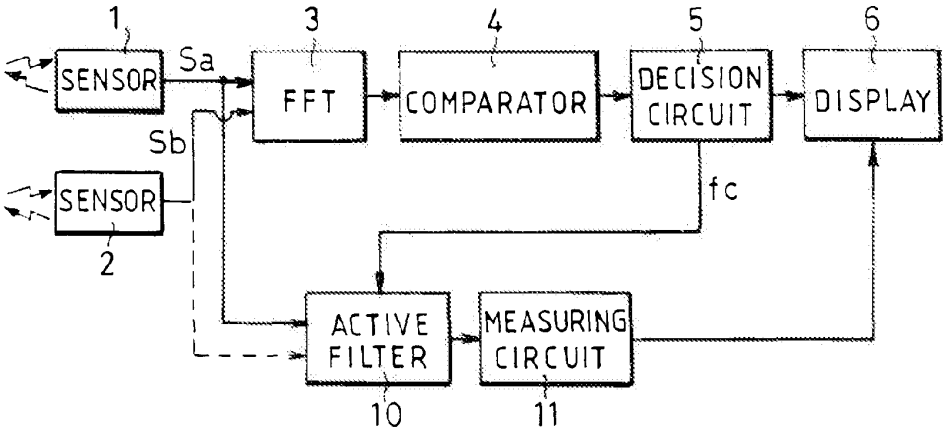
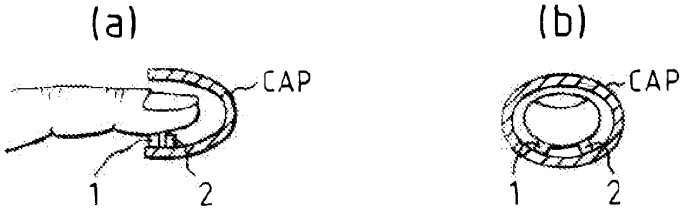
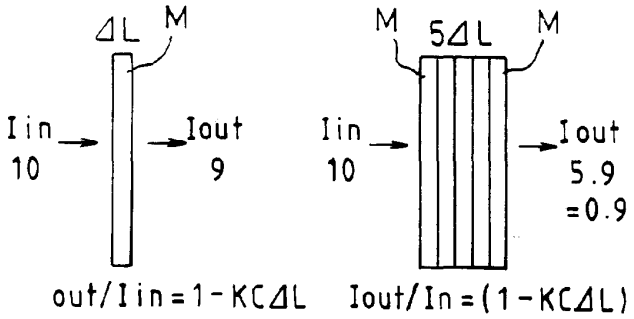

1
3
4
5
6
SENSOR
Sa
FFT
COMPARATOR
DECISION CIRCUIT
DISPLAY
Sb
SENSOR
2
fc
ACTIVE FILTER
MEASURING CIRCUIT
10
11

FIG.2


(a)
(b)
CAP
CAP
1
2
1
2



K:ABSORPTION FACTOR
L:OPTICAL LENGTH

SCHEMATIC REPRESENTATION OF THE LAMBERT'S LAW

FIG. 3

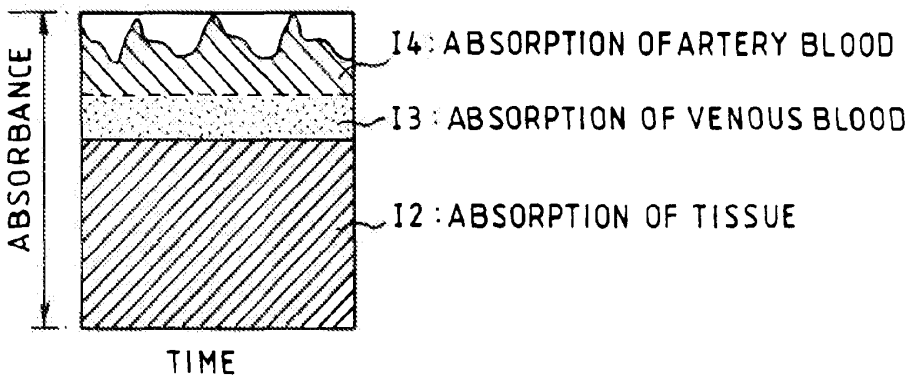


FIG. 4

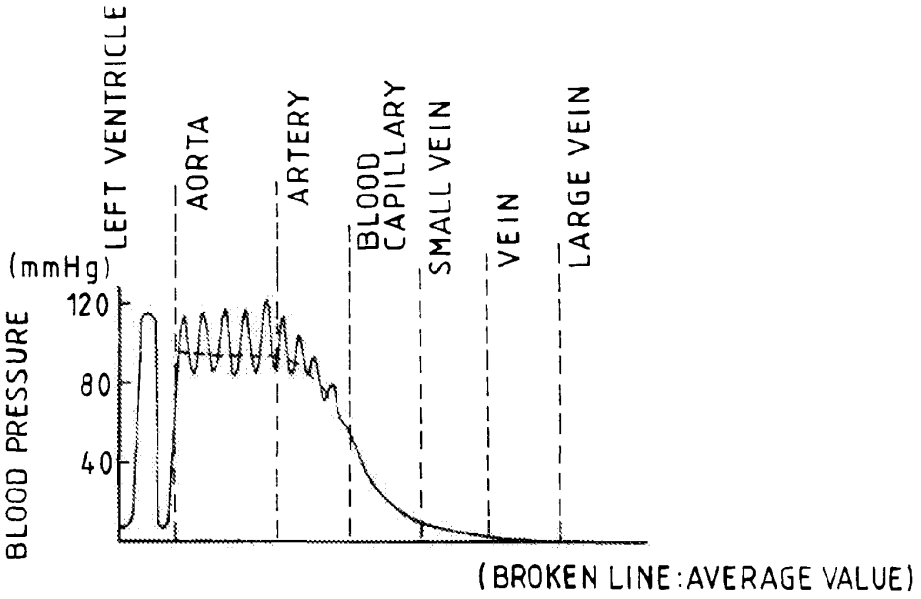
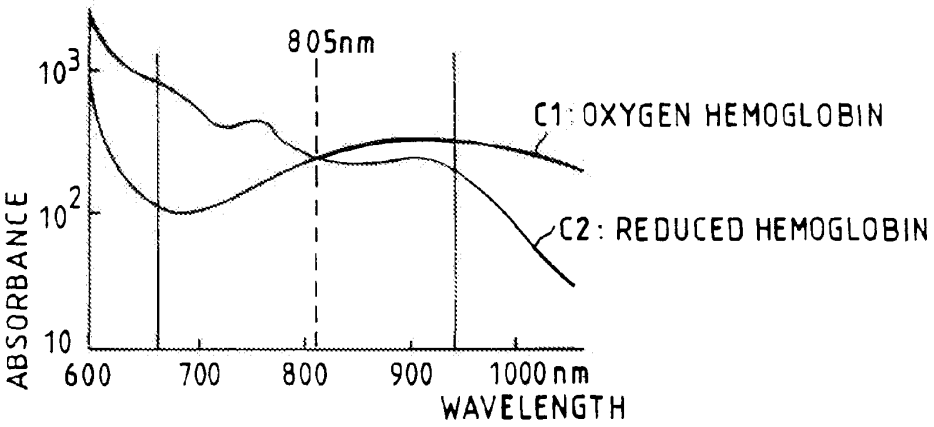


FIG.5



ABSORPTION SPECTRA OF REDUCED HEMOGLOBIN AND OXYGEN HEMOGLOBIN

FIG.6

FIG.7

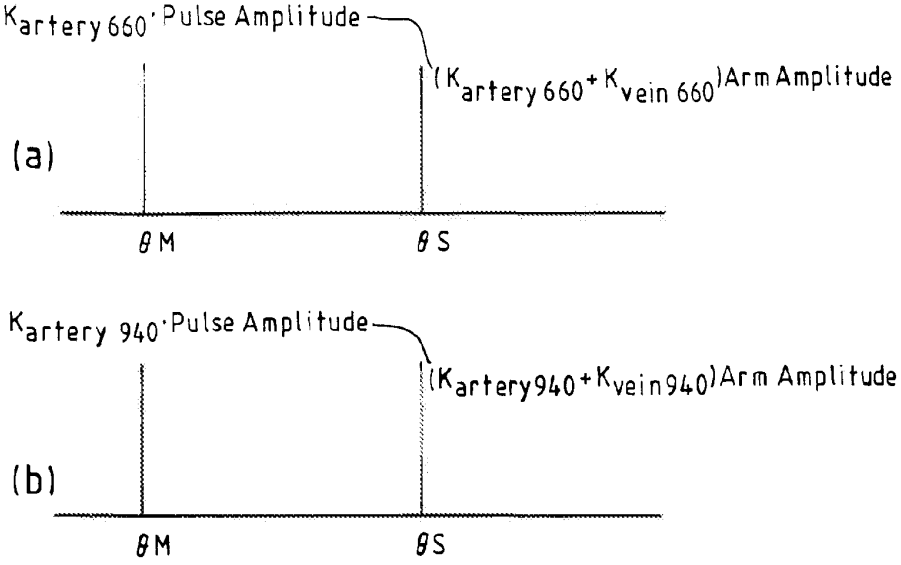

Kartery 660·Pulse Amplitude
(Kartery 660+Kvein 660)Arm Amplitude
(a)
θM
θS
Kartery 940·Pulse Amplitude
(Kartery940+Kvein940)Arm Amplitude
(b)
θM
θS

FIG.8

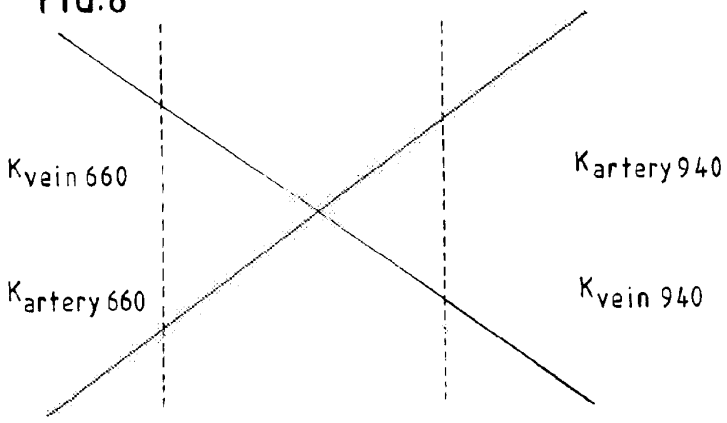
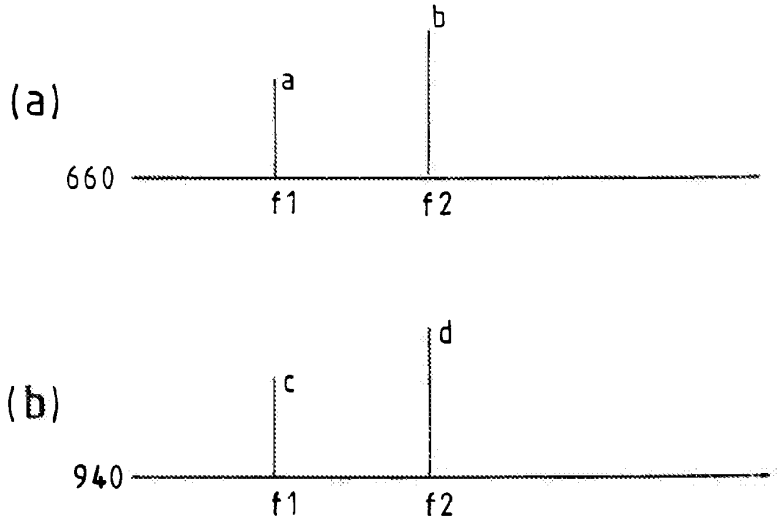

Kvein 660
Kartery 940
Kartery 660
Kvein 940

FIG.9



$(a/b) < (c/d)$ or $(c/a) > (d/b)$

Then f1 corresponds to pulses and f2 corresponds to strokes

FIG.10

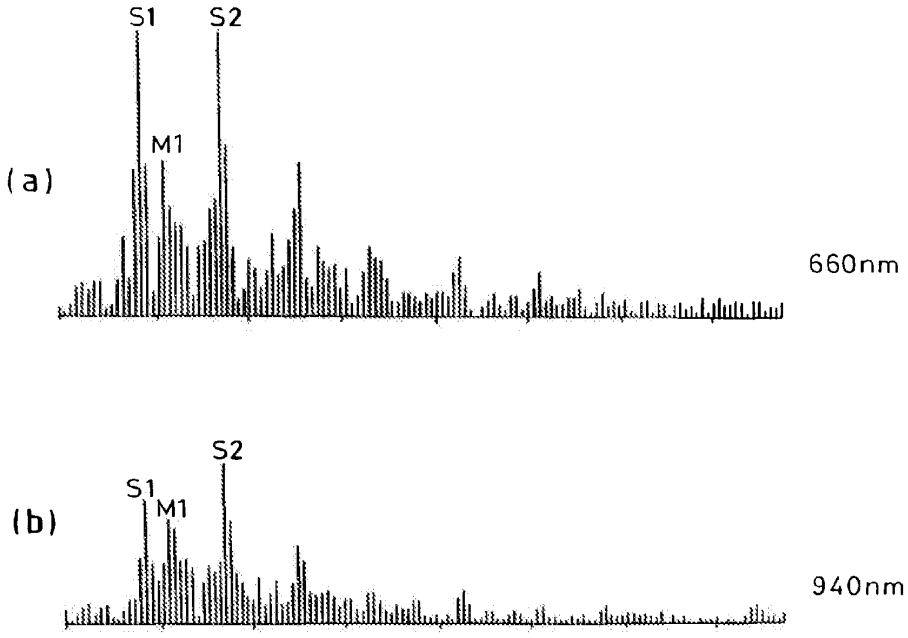
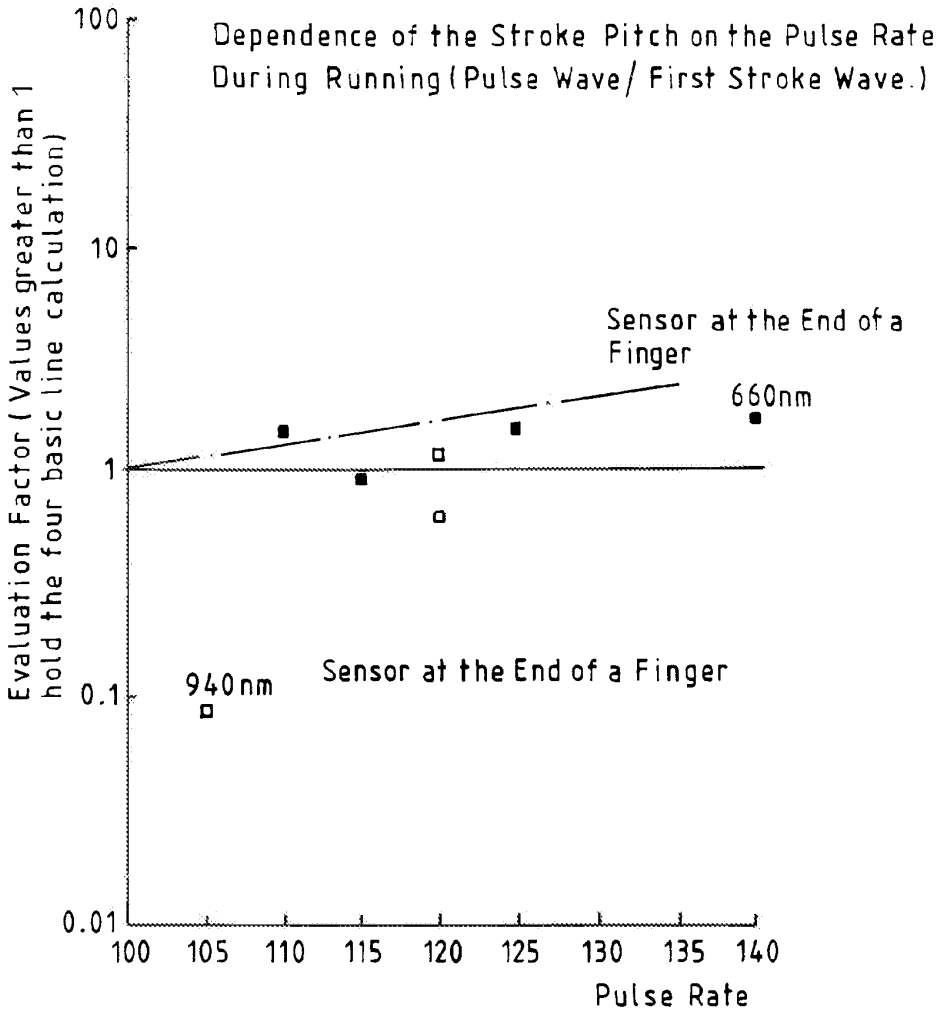


FIG.11


Dependence of the Stroke Pitch on the Pulse Rate
During Running (Pulse Wave/ First Stroke Wave.)
Evaluation Factor (Values greater than 1
hold the four basic line calculation)
100
10
1
0.1
0.01
Sensor at the End of a
Finger
660nm
940nm
Sensor at the End of a Finger
100
105
110
115
120
125
130
135
140
Pulse Rate

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Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT

EP 94307001.1

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
Y	EP - A - 0 379 140 (SUMITOMO) * Totality * --	1-8	A 61 B 5/0245 A 61 B 5/026 A 61 B 5/0285 A 61 B 5/11
Y	. --	9-19	
Y	DE - A - 3 150 925 (HONEYWELL) * Totality * --	1-8	
Y	DE - A - 4 001 574 (WALZ) * Claims; figs. * --	9-19	
A	US - A - 4 911 427 (MATSUMOTO) * Claims; figs. * --	1-3, 8-10	TECHNICAL FIELDS SEARCHED (Int. Cl. 6)
A	EP - A - 0 410 658 (SEIKO) * Claims; figs. * ----	1-3, 8-10	A 61 B 5/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	28-02-1995	NARDAI

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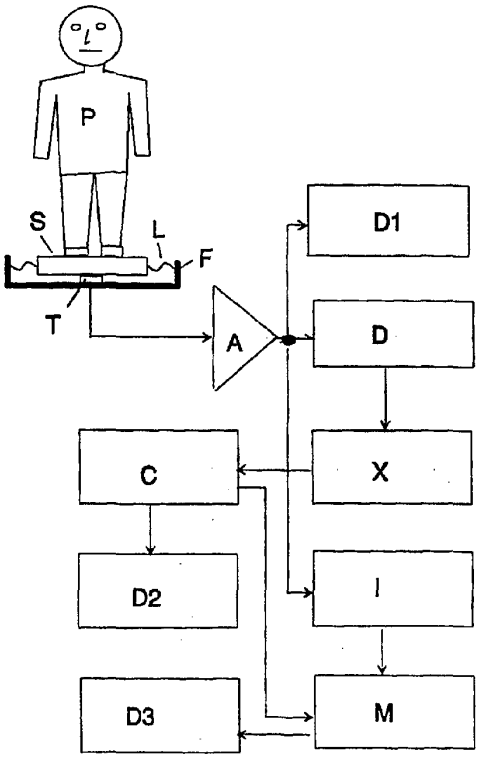
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(54) Title: METHOD AND APPARATUS FOR MEASURING PHYSICAL CONDITION

(57) Abstract

A method and an apparatus for measuring quantities relating to a person's cardiac activity, such as for example quantities proportional to heart rate, cardiac stroke volume and cardiac output. A person is positioned on a measuring support (S), so that a blood flow pulse caused by a stroke of heart is matched by a change in a person's weight (G). Said change of weight is recorded and the recorded changes of weight are used for deriving information about a person's cardiac activity, such as for example about stroke volume and cardiac output as well as heart rate.



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Method and apparatus for measuring physical condition.

The present invention relates to a method and apparatus for measuring quantities relating to the cardiac activity and physical condition of a person, including quantities correlating to the stroke volume and cardiac output which relate to the heart rate and a person's weight and cardiac blood circulation, and for using the measuring results for calculating an index representing the physical condition of a person.

The cardiac pulse rate or heart rate HR, whose unit is pulses per minute as measured in conditions of rest and various stresses, provides e.g. a representation of the physical condition of a person being examined. HR increases not only as a result of mental and physical stress but also various illnesses, for example fever. At rest, HR of a person in a good condition is typically lower than HR of a person in a poor condition.

In the evaluation of the cardiac activity, the measurement of HR only provides highly superficial information. It is also important to know the cardiac stroke volume SV, whose unit is liter, and the cardiac output CO, whose unit is liters per minute. CO is obtained for example by multiplying HR and the average SV with each other.

It is prior known to measure HR by recording electric cardiac activity, a so-called ECG-signal, used for identifying e.g. so-called QRS-complexes. The heart rate is obtained by measuring the time between successive QRS-complexes, whereby the inverse value of said time indicates HR. Devices based on this principle are manufactured for athletes and fitness enthusiasts e.g. by Polar Electro OY, Finland. A drawback in these devices is

the necessity of attaching electrodes to the body. Neither does the ECG-signal provide any information about SV or CO.

It is also prior known to measure HR by utilizing variations of electrical impedance and light transmission. Light transmission can be measured e.g. from the earlobe and finger. An HR measuring device for athletes based on light transmission is manufactured e.g. by Casio, Japan. A drawback in this type of methods is that a necessary transducer must be in a good optical contact with a person being examined. With persons in poor condition or in a cold environment, the blood circulation in a finger or an ear may be so weak that the required signal cannot be produced. The light transmission variations caused by peripheral blood circulation do not include information about SV or CO. On the other hand, the CO meters based on electrical impedance variation require that several electrodes be attached to the body.

A person being examined in a ballistiocardiographic apparatus lies on a responsive support and mechanical oscillations resulting from cardiac activity are recorded. In principle, the SV and CO values can be calculated from the amplitude of oscillations. In practice, the results have shown a poor absolute accuracy but measurements at different times on one person are relatively well reproducible. An inconvenience in this method is e.g. the provision of a sufficiently responsive bed for a patient in order to obtain sufficiently accurate measuring results.

It is further known to place a pad underneath a person being examined for producing a piezoelectric signal or some other electric quantity for measuring a person's

HR. Such measurements do not provide information about the CO or SV values of a person.

The prior known methods and equipment are neither capable of measuring HR, SV and CO values in a simple manner nor of producing simple indices for monitoring the condition of a person.

The present invention provides a solution for eliminating the deficiencies of prior art and for designing equipment which provide information not only about HR but also about the SV and CO values and the weight of a person. The quantities measured by means of methods and equipment of the invention can be used for producing index numbers for monitoring the progress of a person's condition. In order to achieve this, a method of the invention and apparatus based thereon are characterized by what is set forth in the characterizing sections of the annexed claims.

The most important benefits of the invention include simple operation and inexpensive design and particularly the information provided by methods of the invention and corresponding apparatus about the physical condition of a person.

The invention is illustrated in the accompanying drawings, in which

fig. 1 is a schematic view of forces developing in the circulatory system as a result of cardiac activity,

fig. 2 shows a block diagram for an apparatus of the invention,

fig. 3 shows two different transducer designs,

fig. 4 shows a block diagram for digital signal processing electronics in an apparatus of the invention,

fig. 5 shows one apparatus of the invention in a top and a side view.

Fig. 1A illustrates schematically those parts of a human circulatory system that are essential in view of understanding the working of the invention. The left ventricle of the heart H of a person P pumps on each stroke a pulse of bloodflow into the aorta AO, which results in a change of blood flow BF. The bloodstream turns in the aorta curve AC, which in turn produces a force FO directed towards the head of P as shown in fig. 1B. Fig. 1C is a graphic representation of the changes of BF and the corresponding variations of weight G as a function of time t.

Fig. 2 illustrates an apparatus of the invention, wherein a person P stands on a measuring support S, which is suspended on a frame F by means of sensing elements L, e.g. springs. Support S is fitted with a transforming element T, e.g. a strain gage transducer or a piezo-electric crystal or ceramics for recording the movements of S which depend on the weight of P and the compliance of L. It should be noted that a similar signal is obtained if a person is set in a sitting position on S which is provided for example with a chair-like stand. A sitting position is feasible e.g. for poorly fit or handicapped persons or if long-term recording is desired. The output signal of T is amplified by means of an amplifier A, whose output is thus dependent on the weight of P and can be shown on a display D1. The output signal of A is carried to a derivator D, from whose output signal a pulse shaper X produces a pulse which corresponds to each fast weight

change of P and which is forwarded to a central processor C, whose output provides HR shown on a display D2. X may also be provided with a detected-pulse indicator, a sound signal or a light signal or both. Another conceivable arrangement is such that the operator can select the type and intensity of an indicator signal at will or switch it off completely. Integration of the change of the output signal of A with an integrator I provides a result proportional to stroke volume SV and multiplication of this with HR by a multiplier M provides a result proportional to cardiac output CO, which is shown on a display D3.

Transducer T may comprise several separate transducers. Several transducers may be used e.g. for reducing the fluctuation caused by the swaying of a standing person. An apparatus intended for the examination of a sitting person may include a chair-like measuring support and therebelow four weight transducers, whose signals are added together. Furthermore, it may be beneficial to use a plurality of transducers such that a first transducer primarily records the weight of a person and a second transducer records variations of the weight of a person. This type of transducer circuit is chematically illustrated in fig. 3. In the case of fig. 3a, a force G' proportional to the weight of a patient applies to a sensing element L which is fitted with a transforming element Tw, possibly e.g. a strain gage transducer. Typically, this type of transducer includes two elements, whose resistance changes in the opposite directions as sensing element L flexes as a result of force G'. These transducer elements are connected to an amplifier Aw, whose output signal Sw is proportional to force G'. The current bathroom scales employ a circuit, wherein the frequency of an oscillator is altered under the control of a transforming element Tw

and this frequency is used for the derivation of weight. This type of solution, both electrical and mechanical, is included e.g. in the Hanson Hi-Tech (Bathroom scale, model 881) scale, manufactured by Hanson Industries Limited, Ireland. If such a circuit is to be maintained, it is preferable to employ another transducer solution for recording the variations of weight. Such other transducer solution is schematically shown in fig. 3b. A transducer Tb is positioned e.g. on a measuring support S, such it will be subjected to the direct or indirect action of a person's weight G. One preferred embodiment for transducer Tb involves the use of piezoelectric materials. Piezoelectric ceramic components are manufactured e.g. by N. V. Philips Gloeilampenfabrieken, Eindhoven, Holland. Applications of these have been described e.g. in the publication Piezoelectric Ceramic, Designer's Guide, Philips Component Division 1989. Transducer Tb is preferably designed e.g. by using a component consisting of two piezoelectric ceramic elements (piezoelectric bimorph). An advantage offered by such element is a relatively low electrical and mechanical impedance, which makes it particularly suitable for recording relatively low-frequency variables. The described-type of piezo-electric transducer can be included, as shown in fig. 3a, in a flexible sensing element L and the obtained signal is forwarded to an amplifier Ab, whose output signal Sb is delivered to signal processing electronics. Another way of using a piezoelectric material is to provide support S with a layer of piezoelectric material, such as PVDF-film manufactured e.g. by Pennwalt Corp., PA, U.S.A and marketed on the tradename Kynar Piezo Film.

Fig. 2 shows just one block diagram for an apparatus of the invention. For example, a quantity proportional to CO is obtained more accurately by averaging the values of SV

and HR. Thus, the apparatus must be provided with appropriate means for this purpose. In order to calculate an index representing physical condition or fitness, the above results can be converted e.g. into a digital form and a desired index can be calculated therefrom by means of a microprocessor. Thus, the apparatus must be provided with appropriate means for this purpose. The required A/D converters are manufactured e.g. by Motorola Inc. and Linear Technology Corp., USA and suitable microprocessors by Intel Corp., USA. The obtained result or results may be stored in a memory and used later as a reference in assessing the progress of a person's fitness. The recording means may comprise e.g. a semiconductor memory or a magnetic, optical or magneto-optical disc, a magnetic tape or a so-called smart card or even a punched card or tape. A suitable microprocessor assembly, which is compatible with so-called IBM PC equipment, is manufactured e.g. by Dover Electronics Manufacturing West, USA. The apparatus is of type ESP8680 and the necessary interface equipment is available therefor. In mass production, it is of course necessary to design a solution for the apparatus, which is economical in terms of production.

Instead of the embodiment shown in fig. 2, the invention can be implemented by utilizing the spectral information included in a signal coming from the transducer. After transducer T and amplifier A, the signal is converted to a digital form and it is transformed in to frequency domain for example by using FFT algorith or so-called autoregressive algorithms (Autoregreesive algorithms and other analyzing methods, which are applicable when the number of samples picked up from the signal is small, have been described e.g. in the reference: Kay et al: Proceedings of IEEE, vol. 69, No. 11, 1981). This can be

handily carried out in said PC equipment but dedicated signal processing circuits are also available. The resulting spectrum includes an intense peak correlating to the heart rate (i.e. HR) and multiples thereof. A simple program searches a suitable HR range for a maximum, which is HR at a given time. A suitable spectral range is 0.5 - 4 Hz, which corresponds to heart rates of 30 - 240 strokes/minute. This method is quick and not easily disturbed by the movements of a person. The periodicity of a signal can also be analyzed by using a correlation function. This type of solutions have been used in the analysis of periodical signals.

The aspects associated with spectral calculation and signal processing have been studied in a number of publications, including for example Proakis J. G. and Manolakis D. G.: Introduction to digital signal processing, Macmillan Publishing Company, New York, 1988 as well as Oppenheim A.V. and Schafer R.W.: Discrete-Time Signal Processing, Prentice-Hall International Inc., Englewood Cliffs, New Jersey, 1989.

Several prior known solutions can be applied in the apparatus, whose main principles have been described for example in the publication Tompkins W.J. and Webster J.G.: Design of microcomputer-based medical instrumentation, Prentice-Hall Inc., Englewood Cliffs, New Jersey, 1981. Fig. 4 illustrates a block diagram for an apparatus wherein a signal STR, coming from a transducer and, if necessary, amplified in a preamplifier, is forwarded to a filter FBP, from there to an A/D converter ADC and then to a processor DSP, whose output is advanced to a display DD. Filter FBP is a band pass filter which, when analyzing cardiac activity, eliminates the frequencies which do not include significant information or which include

disturbing signals produced e.g. by the swaying of a person. The conducted tests have indicated that a preferred frequency range is 6 - 15 Hz if the purpose is to record HR. It is preferred that the filter eliminates as effectively as possible low frequency (< 1 Hz) components. The filter may be designed using the components and concepts of analog electronies or at least some of the filtering may be effected digitally by means of processor DSP.

A number of prior known principles may be applied in transducer solutions. Since the quantity to be measured is a person's weight G, which is essentially a force produced by a person's mass and the acceleration of earth gravity, the changes of weight caused by cardiac activity can be measured in a number of ways. The above description has primarily related to piezoelectric and piezoresistive transducer elements. It is prior known to measure variations of force by means of sensing elements, such that transformations (number of transformations, rate of transformations) of sensing elements are measured by using capacitive, inductive, optical and acoustic methods. These principles are described e.g. in publications: Allocca J.A. and Stuart A.: Transducers: Theory and Application, Reston Publishing Company, Inc., Reston, 1984 as well as Cobbold R.S.C.: Transducers for Biomedical Measurements, John Wiley & Sons, New York, 1974. Combinations of prior known transducer principles may be used for implementing apparatus of the invention in a variety of ways. The selection of transducer principles depends on several factors, such as manufacturing costs, accuracy requirements and power consumption. In the simplest, so-called bathroom equipment, it is quite likely that the most preferred transducers are piezoresistive or piezoelectric. When recording changes of weight, a

piezoelectric transducer produces a powerful signal which, on the other hand, depends e.g. on the ambient temperature. However, the solution may be preferable if the purpose is to record HR.

The results and calculated indices or a summary of results and calculated indices can be printed on paper numerically and also graphically in the form of curves for thus supplying a person with a detailed representation of his or her progress. The apparatus can also be provided with signaling means, light or sound, which informs of the detection of heartbeat. As mentioned above, these means may be coupled to the pulse shaper. The apparatus may be fitted with or it may be connected to a necessary printing means, for example a matrix or laser printer. Suitable printers are manufactured for example by Canon Inc., Japan.

For example, the monitoring of physical fitness can be effected e.g. by using indices R calculated as follows:

$$R = c/(HR*G), \text{ or}$$

$$R = 1/(HR * G),$$

wherein c is a number proportional to a person's SV or CO and derived from the measuring results. It is preferred that the values used for SV and CO as well as HR are averages obtained during a period of several heartbeats. As a long term result of physical conditioning, the rest-measured HR of the heart decreases and SV increases quite rapidly but the changes of weight generally occur slowly. As a person's physical condition improves, R calculated as above rises rapidly, this being a more responsive indicator of the direction of progress than mere body

weight. Thus, R can be used as a support for weight-losing diets and fitness programs. An index indicating rapidly improving fitness improves considerably motivation for training and dieting.

The above describes just one simple way of using measured quantities for calculating an index indicating the progress or status of condition. The index formula may be adapted to include e.g. a target weight, whereby the index progress and approach towards the target are clearly discernible. Also, different quantities may be given different emphases depending on the target of a tarining or weight-losing program.

Depending on the versatility of signal processing, the calculated indices may be personal reference numbers, whereby the indices of different persons cannot be directly compared. If the signal processing is sufficiently versatile and the positioning of a person is handled carefully, it is possible to derive indices and measuring results that may be used for the relative comparison of different persons. The positioning can be assisted by using e.g. a chair-like measuring support, whose back rest is tiltable for thus finding the maximal change of weight caused by cardiac activity. The reason for this is that the direction of aorta curve relative to the body is different in different persons.

The invention may be applied e.g. in domestic (bathroom) scales. In its simplest form, such a scale would display the weight and HR of a person. For such a scale, it is possible to develop a custom-specific integrated circuit. Separate displays are not required but HR and weight may automatically alternate on the display or the display may be selected e.g. with a separate switch, remote control or

a like.

One such an apparatus is depicted on Fig. 5. Fig. 5a illustrates the top view of the apparatus. Fig. 5b. is a side view of the apparatus. The measuring support S is in the frame F. The realization of the transducer means affects on the construction of the apparatus. Mechanically the construction of the apparatus may be similar than the construction of the above mentioned Hanson scale if e.g. strain gage transducer is utilized. In the display means DD there are indicators for HR and W display modes. In the HR mode the HR indicator is lighted up and the display shows HR e.g. in beats per minute. Correspondingly, in the W mode the display shows the weight of the person in kg:s or lbs and the W indicator is lighted up. The indicators may be e.g. light emitting diodes (LED:s) or specific signs in a liquid crystal display. One benefit of the alternating display described above is the reduction of manufacturing costs. The alternating display saves also space and the figures in the display may be designed to be of large size.

The display may also be fitted on a stand or be mechanically separated from F. The communication between the display unit and the electronics near or in F may take place via wires, infrared light, (ultra)sound, capacitive or inductive coupling or radio waves. A benefit of this kind of remote display is that the person does not need to bow as he or she reads the display. The bowing movement changes the posture of the thorax and affects on the values of the possibly measured quantities related to SV and CO.

The more elaborated devices of the invention calculate fitness indices for a person and may display quantities proportional to CO and SV. Such devices are useful for

exercisers, athletes and may be available in private homes, health spas, gyms etc. Devices intended for public use may be provided with a coin mechanism or a card reader for controlling the use.

In more demanding use, more attention must be paid to the positioning of a person being examined and a good solution is a chair-like measuring support, having more than one transducers (for example 3 or 4) therebelow. The support may be provided with a tiltable back rest as well braces for setting a person repeatedly in the same position. The back rest and other braces must be provided with scales or the like, whose readings are marked down or recorded in the memory of such apparatus for future measurements. Such braces may be motorized and the motors may be controlled by the computer of the apparatus to measuring positions e.g. on the basis of a personal identification code. Naturally, a method of the invention and corresponding devices may be used in many types of psycho-physical tests, in monitoring the treatment of illnesses etc.

Monitoring SV and CO has been found beneficial when observing the treatment of atrial fibrillation and the effect of a by-pass operation. Likewise, it is conceivable to use the changes of SV and CO for assessing the treatment of cardiac insufficiency. A method of the invention and devices based thereon are capable performing this easily and economically.

The above only describes a few embodiments of the invention. The invention can be subjected to a plurality of modifications within the scope of the inventional concept defined in appended claims.

Claims

1. A method for measuring quantities relating to a person's cardiac activity, such as for example quantities proportional to heart rate (HR), cardiac stroke volume (SV) and cardiac output (CO), c h a r a c t e r i z e d in that a person is positioned on a measuring support (S), so that a blood flow pulse caused by a stroke of heart is matched by a change in a person's weight (G), said change being recorded and the recorded changes of weight being used for deriving information about a person's cardiac activity, such as for example about stroke volume and cardiac output (SV, CO) as well as heart rate (HR).

2. A method as set forth in claim 1, c h a r a c t e r - i z e d in that a person is standing on a measuring support (S).

3. A method as set forth in claim 1, c h a r a c t e r - i z e d in that a person is sitting on a measuring support (S).

4. A method as set forth in any of the preceding claims, c h a r a c t e r i z e d in that it comprises calculating a frequency spectrum for the changes of weight (G).

5. A method as set forth in any of the preceding claims, c h a r a c t e r i z e d in that it comprises calculating a correlation function for the changes of weight (G).

6. A method as set forth in any of the preceding claims, c h a r a c t e r i z e d in that the calculation of quantities proportional to heart rate (MR), stroke volume

(SV) and cardiac output (CO) is effected by using quantities proportional to the time integral of the changes of weight (G).

7. A method as set forth in any of the preceding claims, c h a r a c t e r i z e d in that it comprises recording a person's weight (G).

8. A method as set forth in any of the preceding claims, c h a r a c t e r i z e d in that the measuring results are utilized for calculating an index (R) representing the physical fitness of a person.

9. A method as set forth in claim 8, c h a r a c t e r - i z e d in that said index (R) representing a person's condition includes a correlation to a person's weight (G).

10. A method as set forth in claim 8 or 9, c h a r a c - t e r i z e d in that said index (R) representing a person's fitness includes a correlation to a person's heart rate (HR).

11. A method as set forth in any of claims 8 - 10, c h a r a c t e r i z e d in that said index (R) representing a person's condition includes a correlation to a person's cardiac stroke volume (SV).

12. An apparatus for measuring variables relating to a person's cardiac activity, such as for example variables proportional to heart rate (HR), cardiac stroke volume (SV) and cardiac output (CO), c h a r a c t e r i z e d in that it comprises a measuring support (S) for positioning a person thereon, so that a blood flow pulse caused by a stroke of heart is matched by a change in a person's weight (G), means for recording this change of

weight (T, L) as well as means for deriving quantities relating to a person's cardiac activity by utilizing the recorded change of weight (G).

13. An apparatus as set forth in claim 12, c h a r a c - t e r i z e d in that a person is positioned on measuring support (S) in a standing position.

14. An apparatus as set forth in claim 12, c h a r a c - t e r i z e d in that a person is positioned on measuring support (S) in a sitting position.

15. An apparatus as set forth in any of claims 12 - 14, c h a r a c t e r i z e d in that said transducer means (T) include means, such as for example a so-called strain gage, whose electrical impedance changes depending on a person's weight (G) and its changes.

16. An apparatus as set forth in any of claims 12 - 15, c h a r a c t e r i z e d in that said transducer means (T) include means, such as for example a piezoelectric crystal or a plastic film, which produce a voltage depending on a person's weight (G) or its changes.

17. An apparatus as set forth in any of claims 12 - 16, c h a r a c t e r i z e d in that it includes amplifier means and filtering means for using the output signal of transducer means (T) to derive therefrom a signal proportional to the changes of weight (G) relating to a person's cardiac activity.

18. An apparatus as set forth in any of claims 12 - 17, c h a r a c t e r i z e d in that it includes means for calculating quantities proportional to the time integral of the changes of weight (G).

19. An apparatus as set forth in any of claims 12 - 18, c h a r a c t e r i z e d in that it includes means for calculating a frequency spectrum for the changes of weight (G).

20. An apparatus as set forth in any of claims 12 - 19, c h a r a c t e r i z e d in that it includes elements for calculating the correlation of the changes of weight (G).

21. An apparatus as set forth in any of claims 12 - 20, c h a r a c t e r i z e d in that it includes means for calculating an index (R) representing a person's physical condition.

22. An apparatus as set forth in any of claims 12 - 21, c h a r a c t e r i z e d in that it includes means for recording the measuring results and the calculated, condition-representing indices.

23. An apparatus as set forth in any of claims 12 - 22, c h a r a c t e r i z e d in that it includes means for printing the measuring results and the calculated, condition-representing indices for example on paper numerically or in a graphic form.

24. An apparatus as set forth in any of claims 12 - 23, c h a r a c t e r i z e d in that said measuring support (S) is provided with a plurality of transducers (T).

25. An apparatus as set forth in claim 24, c h a r a c - t e r i z e d in that some of transducer means (T) record especially weight (G) and some of the transducer means record especially changes of weight (G).

26. An apparatus as set forth in claim 25, c h a r a c t e r i z e d in that the means recording especially changes of weight (G) are so-called piezoelectric transducers, such as for example a piezoelectric ceramics or a plastic film.

27. An apparatus as set forth in any of claims 12 - 26, c h a r a c t e r i z e d in that it includes display means (D1, D2, D3), such as for example an electro-luminescence, light-emitting diode, liquid crystal or cathode-ray tube display.

28. An apparatus as set forth in claim 27, which can be used the same way as a so-called bathroom scale, c h a r a c t e r i z e d in that it includes display means (D1, D2) for displaying a person's weight (G) and heart rate (HR).

29. An apparatus as set forth in any of claims 12 - 27, c h a r a c t e r i z e d in that it includes means for controlling use of the apparatus, such as for example a coin mechanism or a card reader.

30. An apparatus as set forth in any of claims 12 - 29, c h a r a c t e r i z e d in that it includes means to indicate the detection of a change of weight, such as for example a light or sound signal device.

31. An apparatus as set forth in any of claims 12 - 30, c h a r a c t e r i z e d in that it includes means for improving the repeatability of a person's position, such as for example back and arm rests.

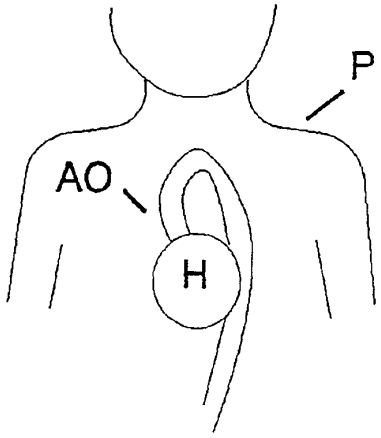


FIG . 1A

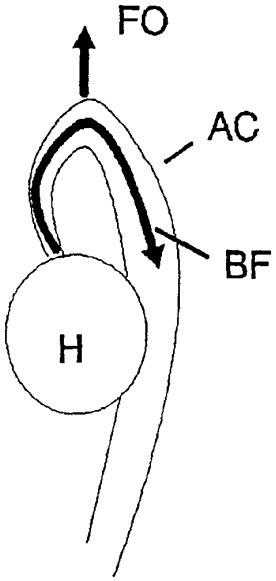


FIG. 1B

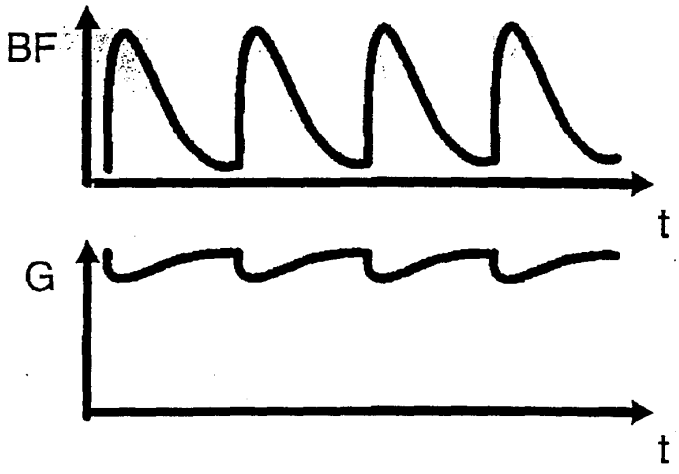


FIG. 1C

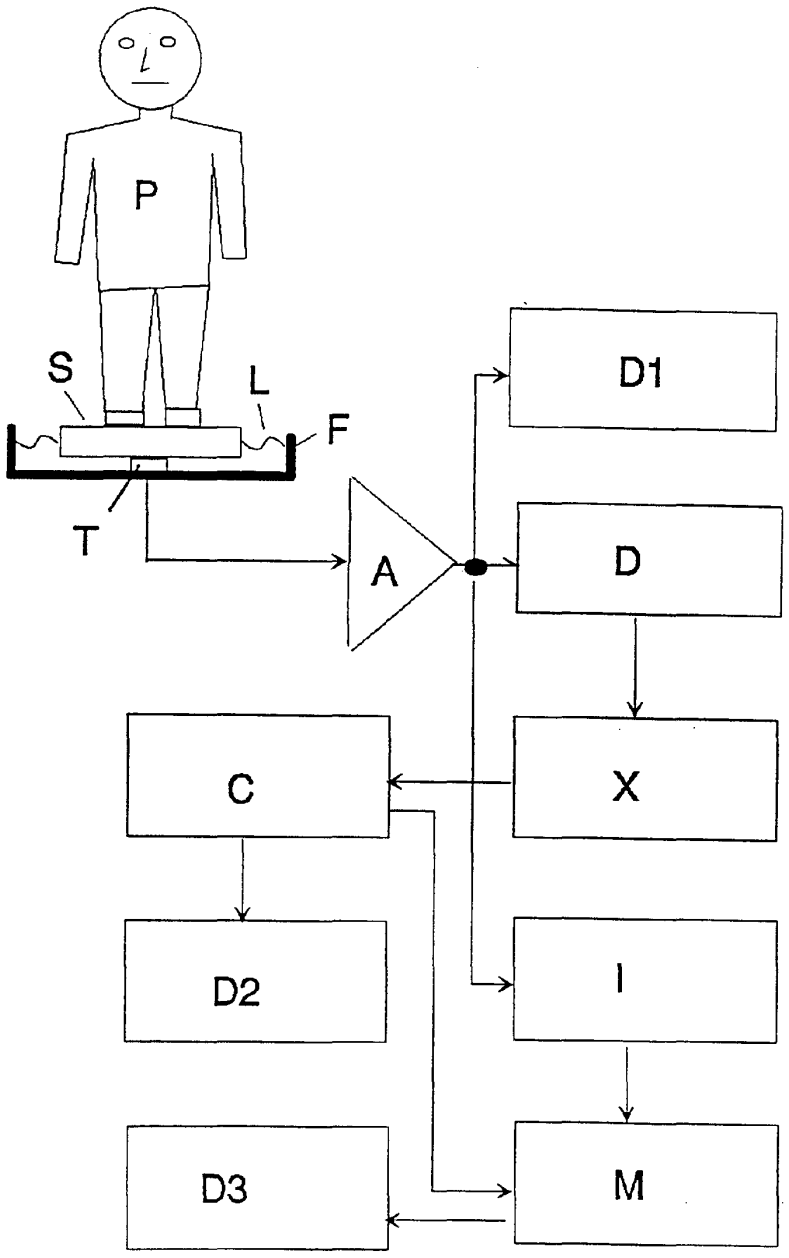


FIG. 2

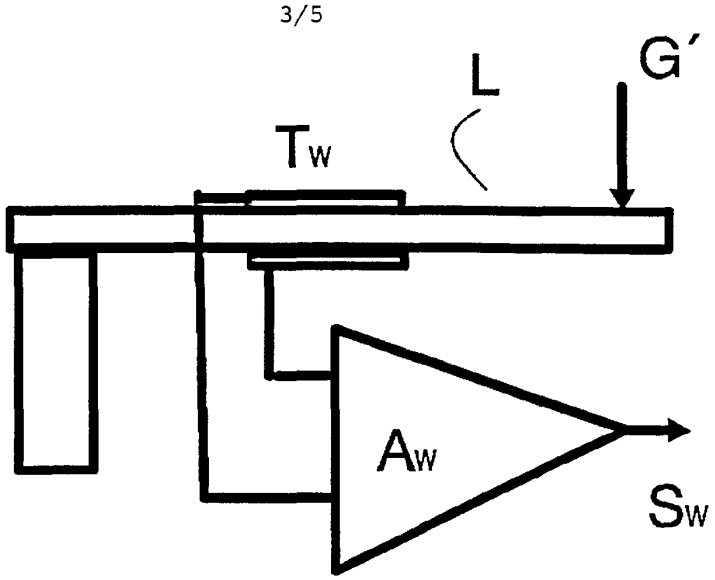


FIG. 3a

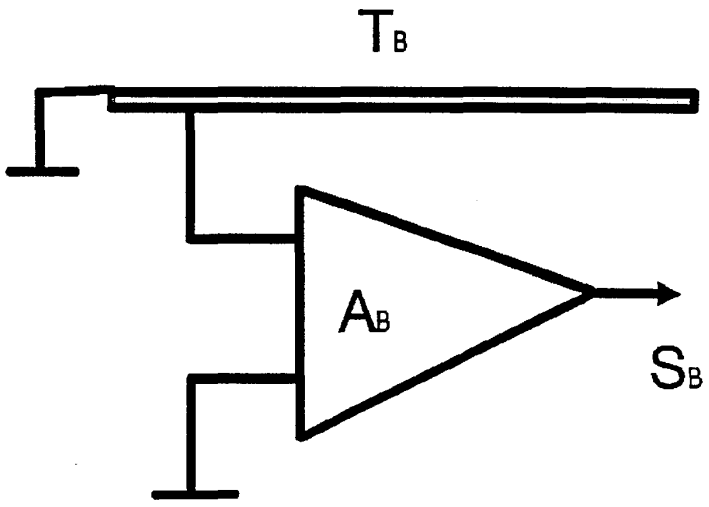


FIG. 3b

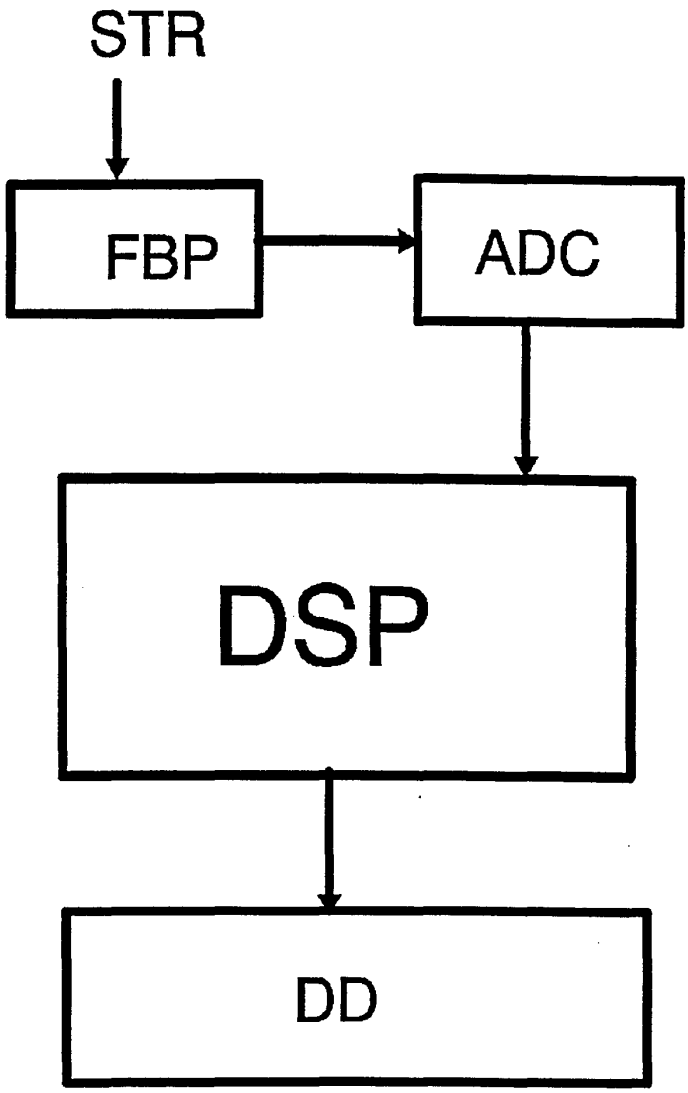


FIG. 4

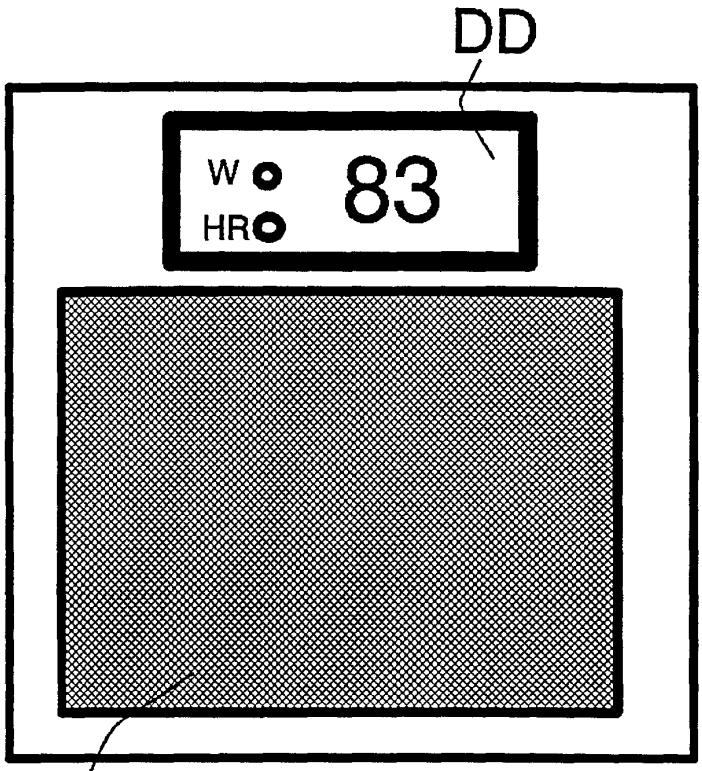


FIG. 5a

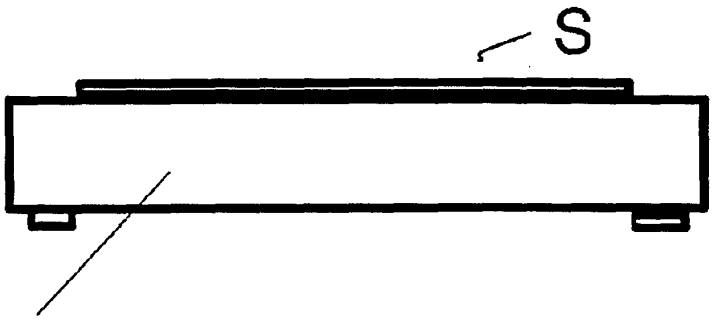


FIG. 5b

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 94/00057

A. CLASSIFICATION OF SUBJECT MATTER

IPC[5]: A61B 5/024, A61B 5/029
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[5]: 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.
E,X	WO, A1, 9406348 (INCREA OY), 31 March 1994 (31.03.94) --	1-31
X	US, A, 2141246 (A.B. JACOBUS ET AL), 27 December 1938 (27.12.38), page 1, column 1, line 1 - line 4; page 2, column 1, line 57 - line 69, figures 1,2	1,2,3,7,12, 13,14,23
Y	--	12,16,17
Y	US, A, 3465747 (V.L. ROGALLO), 9 Sept 1969 (09.09.69), column 1, line 12 - line 28; column 5, line 16 - line 31, figure 3 --	12,16,17

[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" erlier 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
28 Sept 1994	03 -10- 1994
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 Lars Jakobsson Telephone No. +46 8 782 25 00

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/FI 94/00057

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4831527 (LLOYD D. CLARK), 16 May 1989 (16.05.89), figures 1,2, abstract --	1,8-11
A	US, A, 4299233 (JEROME H. LEMELSON), 10 November 1981 (10.11.81), figure 4, abstract --	12,16
A	US, A, 4836215 (ARNOLD ST. J. LEE), 6 June 1989 (06.06.89), figures 1-3, abstract --	12,31
A	Derwent's abstract, No 90-191160/25, week 9025, ABSTRACT OF SU, 1502007 (KAZAN MEDICINE INST), 25 June 1987 (25.06.87) -- --------	1-31

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

INTERNATIONAL SEARCH REPORT

27/08/94

International application No.
PCT/FI 94/00057

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 9406348	31/03/94	NONE	
US-A- 2141246	27/12/38	NONE	
US-A- 3465747	09/09/69	NONE	
US-A- 4831527	16/05/89	NONE	
US-A- 4299233	10/11/81	NONE	
US-A- 4836215	06/06/89	US-A- 4679569	14/07/87
		US-A- 4681098	21/07/87
		US-A- 4817610	04/04/89
		US-A- 4848350	18/07/89
		US-A- 4889123	26/12/89
		US-A- 4889130	26/12/89
		US-A- 4893633	16/01/90
		US-A- 4895155	23/01/90
		US-A- 4926866	22/05/90

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

PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Diab, et al.
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L
SHEET 1 OF 5	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	1	4,051,522	9/27/1977	Healy	
	2	4,085,378	4/18/1978	Ryan	
	3	4,623,248	11/18/1986	Sperinde	
	4	4,653,498	3/31/1987	New	
	5	4,745,398	5/17/1988	Abel	
	6	4,765,340	8/23/1988	Sakai	
	7	4,800,495	1/24/1999	Smith	
	8	4,802,486	2/7/1989	Goodman	
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	11	4,942,877	7/24/1990	Sakai	
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	13	5,003,252	3/26/1991	Nystrom	
	14	5,188,108	2/23/1993	Secker	
	15	5,190,038	3/2/1993	Polson	
	16	5,218,962	6/15/1993	Mannheimer	
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	18	5,246,002	9/21/1993	Prosser	
	19	5,259,381	11/9/1993	Cheung	
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	28	5,448,991	9/12/1995	Polson	

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

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PTO/SB/08 Equivalent

INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Diab, et al.
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L
SHEET 2 OF 5	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	29	5,503,148	4/2/1996	Pologe	
	30	5,542,421	8/6/1996	Erdman	
	31	5,575,284	11/19/1996	Athan	
	32	5,652,566	7/29/1997	Lambert	
	33	5,720,293	2/24/1998	Quinn	
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	55	6,970,792	11/29/2005	Diab	
	56	7,215,984	5/8/2007	Diab et al.	

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	90/012559
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	First Named Inventor	Diab, et al.
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SHEET 3 OF 5	Attorney Docket No.	MLR.012X1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number *Number - Kind Code (if known)* Example: 1,234,567 B1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
	57	7,496,393	2/24/2009	Diab et al.	
	58	2002/0082488	6/27/2002	Al-Ali	
	59	2002/0161291	10/31/2002	Kiani	
	60	2003/0000522	1/2/2003	Lynn	
	61	2003/0018241	1/23/2003	Mannheimer	
	62	2003/0073890	4/17/2003	Hanna	
	63	2003/0120164	6/26/2003	Nielsen	
	64	RE 33,643	7/23/1991	Isaacson	
	65	RE 38,492	4/6/2004	Diab	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No.	Foreign Patent Document *Country Code-Number-Kind Code* Example: JP 1234567 A1	Publication Date MM-DD-YYYY	Name of Patentee or Applicant	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	T[1]
	66	EP 0352923	01/31/1990	Baxter International Inc.		
	67	EP 0659384	06/28/1995	Seiko Instruments Inc.		
	68	EP 0645117	03/29/1995	Seiko Epson Corp.		
	69	WO 84/03032	08/16/1984	Arrhythmia Research Technology Inc.		
	70	WO 92/11803	07/23/1992	Baxter International Inc.		
	71	WO 92/15955	09/17/1992	Vital Signals, Inc.		
	72	WO 92/20273	11/26/1992	Chance		
	73	WO 98/43071	10/1/1998	Nellcor Puritan Bennett Inc.		

NON PATENT LITERATURE DOCUMENTS			
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	74	U.S. Patent Application Serial No. 90/012,403, filed July 23, 2012, requesting *ex parte* reexamination of Patent No. 6,263,222, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	75	U.S. Patent Application Serial No. 90/012,409, filed August 17, 2012, requesting *ex parte* reexamination of Patent No. 6.699,194, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	

Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		
	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Diab, et al.
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L
SHEET 4 OF 5	Attorney Docket No.	MLR.012X1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	76	U.S. Patent Application Serial No. 90/012,463, filed September 5, 2012, requesting *ex parte* reexamination of of Patent No. 7,215,984, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	77	U.S. Patent Application Serial No. 90/012,532, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,499,835, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	78	U.S. Patent Application Serial No. 90/012,534, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,962,188, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	79	U.S. Patent Application Serial No. 90/012,538, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,377,899, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	80	U.S. Patent Application Serial No. 90/012,541, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,899,507, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	81	U.S. Patent Application Serial No. 90/012,542, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 8,180,420, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	82	U.S. Patent Application Serial No. 90/012,543, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 6,850,787, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	83	U.S. Patent Application Serial No. 90/012,546, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,438,683, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	84	U.S. Patent Application Serial No. 90/012,548, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,880,606, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	85	U.S. Patent Application Serial No. 90/012,.551, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 6,970,792, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	86	U.S. Patent Application Serial No. 90/012,.553, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,024,233, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	87	U.S. Patent Application Serial No. 90/012.555, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 7,440,787, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	88	U.S. Patent Application Serial No. 90/012,557, filed September 13, 2012, requesting *ex parte* reexamination of Patent No. 8,150,487, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	89	U.S. Patent Application Serial No. 90/012,561, filed September 14, 2012, requesting *ex parte* reexamination of Patent No. 8,019400, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	90	U.S. Patent Application Serial No. 90/012,562, filed September 14, 2012 requesting *ex parte* reexamination of Patent No. 6,463,311, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT	Application No.	90/012559
	Filing Date	September 13, 2012
	First Named Inventor	Diab, et al.
	Art Unit	3992
(Multiple sheets used when necessary)	Examiner	Nasser, Robert L
SHEET 5 OF 5	Attorney Docket No.	MLR.012X1

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[1]
	91	U.S. Patent Application Serial No. 90/012,566, filed September 14, 2012, requesting *ex parte* reexamination of Patent No. 7,530,955, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	92	U.S. Patent Application Serial No. 90/012,567, filed September 14, 2012, requesting *ex parte* reexamination of Patent No. 6,684,090, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	93	U.S. Patent Application Serial No. 90/012,568, filed September 14, 2012, requesting *ex parte* reexamination of Patent No. 8,128,572, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	94	U.S. Patent Application Serial No. 90/012,699, filed October 4, 2012, requesting *ex parte* reexamination of Patent No. 6,002,952, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.510 and 35 U.S.C. § 302.	
	95	U.S. Patent Application Serial No. 95/002,183, filed Sept. 12, 2012, requesting *inter partes* reexamination of Patent No. 7,530,955, including accompanying Reexam Request, claim charts, and other documentation filed under 37 C.F.R. § 1.913 and 35 U.S.C. § 311.	
	96	Blitt, Casey D., Monitoring in Anesthesia and Critical Care Medicine, (2d ed. 1990)	
	97	Boualem Boashash, *Estimating and Interpreting the Instantaneous Frequency of a Signal-Part I: Fundamentals*, Proceedings of the IEEE, Vol. 80, No. 4 (April, 1992)	
	98	Boualem Boashash, *Note on the Use of the Wigner Distribution for Time-Frequency Signal Analysis*, IEEE Transactions on Acoustics, Speech, and Signal Processing, Vol. 36, No. 9 (Sept. 1988)	
	99	Business Wire, "Mallinckrodt Announces the Nellcor N-395 Pulse Oximeter With Oxismart XL and SatSeconds," October 7, 1999	
	100	Edward Bedrosian, *The Analytic Signal Representation of Modulating Waveforms* (1962)	
	101	Hanzo et al., "A Portable Multimedia Communicator Scheme", *Multimedia Technologies and Future Applications: Proceedings of the IEEE International Symposium* (1994)	
	102	Maciej Niedzwiecki et al. "Smoothing of Discontinuous Signals: The Competitive Approach," *IEEE Transactions on Signal Processing*, Vol. 43, No. 1, January 1995, pp. 1-13.	
	103	Steven W. Smith, *The Scientist and Engineer's Guide to Digital Signal Processing*, § 8 (1st ed. 1997)	

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Electronic Acknowledgement Receipt	
EFS ID:	14256316
Application Number:	90012559
International Application Number:	
Confirmation Number:	6710
Title of Invention:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
First Named Inventor/Applicant Name:	8190223
Customer Number:	20995
Filer:	John M. Grover/ThuyQuyen Nguyen
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Attorney Docket Number:	403381US104RX
Receipt Date:	16-NOV-2012
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Time Stamp:	23:49:53
Application Type:	Reexam (Patent Owner)

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	Foreign Reference	EP_0352923.PDF	1099258 d426c0fb3252496bf6452ff8c6426cea2376737d	no	11
Warnings:					
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2	Foreign Reference	EP_0659384.PDF	865788 9f4752ea998d1c284aa30c24c98aaaac6dedeaf8	no	23
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5	Foreign Reference	WO_92_11803.PDF	1417370 c9246a302c785c9206206a14672d8593b4b1ec10	no	35
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7	Foreign Reference	WO_92_20273.PDF	4115639 6cd87e7a816cc78084b67c0afd8441bcf771bbc8	no	102
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Information:					
8	Foreign Reference	WO_98_43071_.PDF	960189 6658e7ad07f291787fcf119f2dd326308a857ffd	no	27
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9	Non Patent Literature	Blitt.PDF	5000535 90d9f578e7dd82bc7bf14a66e5c83d4ebf860241	no	20
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Information:					
10	Non Patent Literature	Boashash_Estimating_and_Interpreting.PDF	1303358 bccc1eee1473b1170948deeff11486db03462f8f	no	19
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11	Non Patent Literature	Boashash_Note_on_the_Use.PDF	268731 c5ee3308ee5413ec730f13ca2b660eac66ccfa1	no	4
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Information:					
13	Non Patent Literature	Bedrosian.PDF	666312 18465b24d8328a5e2e587a3de30ea5a32fbc3e04	no	28
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14	Non Patent Literature	Hanzo_.PDF	1406355 b28c15810f51667087e7485b20ddb92bc25a0136	no	28
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15	Non Patent Literature	Niedzwiecki.PDF	817247 939dbc986ff4ec0033fc29f01734ce58f53bebb7	no	13
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16	Non Patent Literature	Smith.PDF	1552981 7d3be54b425427c1386691962bfa1219de383eb3	no	28
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17	Transmittal Letter	IDS.pdf	126097 ee8ac8b853a971282b55e63670f50ac6c45e7dd7	no	4
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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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(19) Europäisches Patentamt
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(11) Publication number: **0 352 923 A1**

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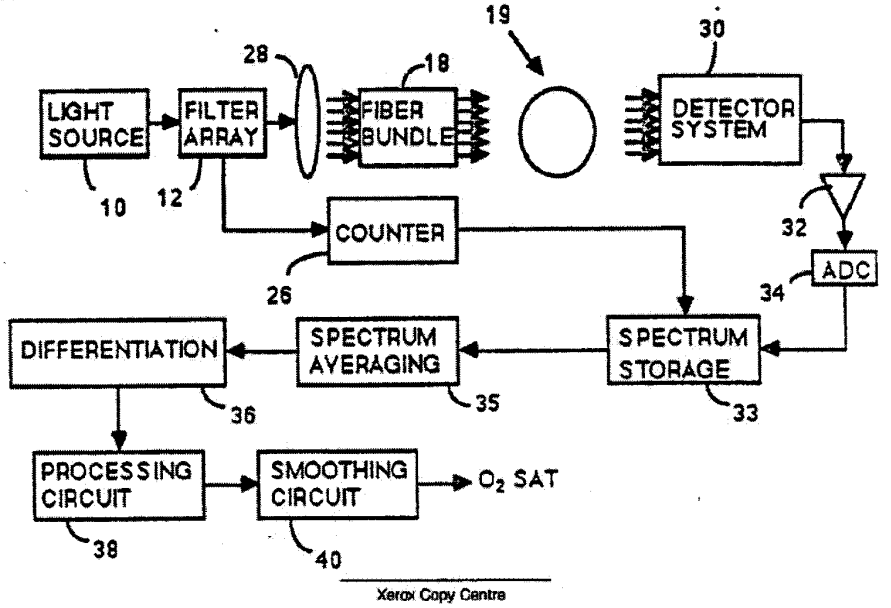
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(54) Spectrophotometric apparatus and method for monitoring oxygen saturation.

(57) A continuous spectrum of light (10) in a selected wavelength (12) band is transmitted through selected tissue. The spectral distribution of light transmitted through the selected tissue is monitored and differentiated (36) with respect to wavelength. The differentiated spectral data is processed (38) to determine the oxygen saturation in the tissue. The spectral data may be digitized (34) and stored in a storage device (33) that correlates the transmitted intensity with the wavelength. The intensity values for a predetermined number of spectra may be averaged (35) to smooth the spectral data. The first derivative of the averaged spectral data is then determined at predetermined wavelengths and processed (38) with an algorithm to determine the oxygen saturation.



EP 0 352 923 A1

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SPECTROPHOTOMETRIC APPARATUS AND METHOD FOR MONITORING OXYGEN SATURATION

BACKGROUND OF THE INVENTION

This invention relates generally to measurement of oxygen saturation in living tissue and particularly to non-invasive techniques for such measurements. Still more particularly, this invention relates to noninvasive spectrophotometric measurement of oxygen saturation of blood in body organs such as the brain.

Oxygen sufficiency and metabolism are parameters of fundamental importance in assessing the function of any body organ. In the absence of sufficient oxygen, provision of energy for tissue functions becomes impaired and is accompanied by a corresponding impairment in organ functioning. In case of extensive oxygen deprivation over a period of time, the organ looses viability, which may cause severe illness or even death.

Although all oxygen insufficiency adversely effects all body organs, the effect is most acute for the brain because of the brain's sensitivity with respect to oxygen demand and its dependance upon oxidative metabolism for proper functioning and viability. For example, it is known that hypoxia or anoxia of the brain for more than about a dozen seconds produces dysfunction, and an absence of oxygen for longer than a few minutes causes irreversible brain damage. A less acute impairment of oxygen availability causes a gradual loss in brain function, particularly in the higher centers of the cerebral cortex.

Because of the role that oxygen sufficiency plays in human physiology, intensive efforts have been made over the years to measure oxygenation in various organs. Brain and heart oxygenation are particularly important in this regard. However, it is difficult to obtain a direct measurements of oxygen saturation by a non-invasive technique except by means of pulse oximetry, which measures arterial oxygen saturation. Conway, *et al.* "A new approach for the estimation of body composition: infrared interactance.", Am. J. Clin. Nutr. 40: 1123-1130, 1984, reports that O_2 dependent organs such as the brain and heart regulate their O_2 delivery independently of changes in arterial O_2 content. Therefore, the effects of spontaneous changes in systemic O_2 availability for these organs cannot be measured by pulse oximetry.

Previous methods have used secondary effects, such as electroencephalographic and electrocardiographic changes to detect hypoxia. Electroencephalographic recordings indicating dysfunction are mainly useful for diagnosis of severe hypoxic or anoxic conditions in the brain. Electrocardiograph recordings are used to establish an oxygen deficiency in the heart muscle. However, these methods are diagnostic only in far advanced cases, and both the organs and the patient are in a precarious state of health before these signals become indicative of pathology.

It is commonly assumed that either insufficient blood circulation or ventilation is the main cause of inadequate oxygen delivery to cerebral and myocardial tissue. Although this assumption is probably correct in the majority of cases, blood flow measurements are indirect global measurements of organ oxygen delivery and are incapable of distinguishing adequate regional blood flow. Similarly, pulse oximetry is a global measurement of ventilation and oxygen delivery and is incapable of distinguishing regional ventilation and perfusion

It is known that the human body and its organs are relatively pervious to low level, non-hazardous light energy in the near infrared region of the spectrum. A beam of relatively low intensity radiation in the wavelength region of about 700 to 900 nm can penetrate and propagate through a relatively long optical path in any selected portion of a human or animal body that includes both bone and soft tissue. In particular, low intensity radiation in the 700 to 900 nm wavelength range will penetrate and propagate through a subject's skull and brain tissue with an intensity sufficient for detection with a conventional photodetector. Both hemoglobin and oxyhemoglobin absorb light in the 700 to 900 nm wavelength range. Therefore, the spectrum of such light transmitted through a subject's head may be analyzed to determine the level of oxygenation in brain tissue.

Considerable work has been done to develop techniques for non-invasively and atraumatically measuring blood oxygenation in particular, optical measurement techniques have been the subject of extensive research. The patents and publications discussed subsequently are representative of the prior art.

U.S. Patents 3,994,592 to Lardon *et al.*; 4,273,442 to Lubbers; 4,086,915 to Kofsky *et al.* and RE 31,879 to Lubbers *et al.* disclose spectral photometry apparatus that may be used for hemoglobin oxygenation testing. All four of these patents discuss or disclose differentiation of the signal at various wavelengths with respect to time. However, none of these patents discloses differentiation with respect to wavelength

U.S. Patent 3,994,592 to Lardon *et al.* is directed to a method for determining the ratio of the

concentration of two substances in a mixture of substances having adjacent absorption bands such that the radiation absorption of the mixture has a minimum between the absorption bands. Measuring absorption in three narrow spectral regions of the radiation transmitted through the mixture determines the concentration. The differences between the transmitted intensities in the three bands are used to determine the concentration ratio.

U.S. Patent 4,086,915 to Kofsky *et al.* is directed to an ear oximetry process and apparatus that uses light of two or more discrete wavelengths. Kofsky directs light of a first wavelength on an area of the subject's skin and detects the transmitted intensity. Light of a second wavelength is then directed upon the same area of the subject's skin and the transmitted intensity is again measured. Electrical signals indicative of the transmitted light intensities at the two wavelengths are time differentiated. The differentiated signals are processed with a set of predetermined coefficients to obtain the arterial oxygen saturation of the blood.

U.S. Patent 4,273,442 to Lubbers is concerned with the display of hemoglobin spectra derived from use of a spectrophotometer on the surface of body tissue. Lubbers discloses a spectral photometer that emits light toward a subject and detects the light reflected back from the subject. Successive maxima of the spectral distribution are detected, and the distances between successive maxima are calculated.

U.S. Patents 4,281,645 and 4,223,680 to Jobsis are directed to a spectrophotometric method and apparatus for making non-invasive *n vivo* measurements of local metabolism of a body organ such as the brain. Jobsis discloses selecting an optical path intersecting the organ and extending for several centimeters between points of light entry and exit on the surface of the body. Jobsis also discloses placing a plurality of near infrared light sources outside the body to provide light emissions of different wavelength in the 700 to 1300 nanometer spectral range. The light emissions have intensities below the level damaging to the body and the organ but sufficient to be detectable by a light sensor after transmission along the optical path. Jobsis discloses optical emissions including at least one measuring wavelength and at least one reference wavelength within the spectral range. Each measuring wavelength is selected such that the organ *n vivo* exhibits a selective absorption. The absorption depends upon a specific state of metabolic activity of the organ *n vivo*.

Both of these two Jobsis patents disclose directing measuring and reference wavelengths sequentially along the path and through the organ and receiving the transmitted light emissions at a light sensor. An electric circuit means produces an electrical signal representing the difference in absorption of the measuring and reference wavelengths by the organ as a function of the state of the metabolic activity *n vivo* The electrical signals are indicative of the particular state of metabolic activity of the organ. The method disclosed by Jobsis for determining qualitative changes in oxygen concentration depends upon the light absorbing characteristics of the enzyme cytochrome a, a_3, which is also known as cytochrome c oxidase.

The key element of Jobsis is the measurement of qualitative changes in oxygen concentration. Probes are placed on a subject's head to establish a baseline or reference point. Changes from the baseline are not calibrated.

U.S.Patent 4,510,938 to Jobsis relates to techniques for directing light to the head of a subject.

Stauffer *et al.*, Derivative Spectroscopy, Applied Optics, Vol. 7, No. 1, pp. 61-65, January, 1968 discloses that derivative spectroscopy has been used to enhance the detectability of overlapping spectral bands. The paper points out that derivative spectroscopy suppresses background radiation, reduces effects of instrumentally scattered radiation and suppresses atmospheric turbulence effects.

Ewalt *et al.*, Derivative Spectrometer, IBM Technical Disclosure Bulletin, Vol. 20, No. 3, pp. 1137-1140, August 1977 discloses that measuring the derivative with respect to wavelength of the usual transmission curve can improve the detection limit by an order of magnitude. This paper states that the derivative output signal is directly proportional to the concentration of absorbers in the sample path. The paper discusses a derivative spectrometer that uses a repetitive scan of a narrow wavelength band centered on the line or band peak of interest.

U.S.Patent 4,463,762 to Rubens discloses a technique for measuring oxygen absorption. Rubens uses a tourniquet to form a region of occlusion. Light of two different wavelengths is directed onto the skin tissue of the subject, and the amount of each wavelength absorbed is measured. Rubens determines the rate of change of the absorption of one wavelength relative to the other for producing a signal that indicates the rate of oxygen utilization in the tissue.

U.S.Patent 4,213,462 to Sato is directed to the detection of abnormalities such as cancerous growths. Tissue being tested is subjected to a first predetermined pressure and then exposed to light. The radiation reflected or absorbed is measured, and then the tissue is subjected to a second predetermined pressure and again exposed to the light. The difference in the absorption or reflectance characteristics for the different pressures indicates whether the tissue contains an abnormality.

U.S.Patent 4,548,505 to Ono is directed to a sensor for a spectral analyzer. The purpose of the Ono patent is to provide means for obtaining data as soon as the tip of the bundle of fibers contacts the tissue and before any change occurs in the tissue. A second purpose of this invention is to provide constant pressure on the tissue when data is taken to maintain a local hemostatic effect.

U.S.Patent 4,017,192 to Rosenthal relates to a technique for optical analysis of biomedical specimens where three interference filters are used to selectively pass light of a particular frequency through a biological sample. Rosenthal is particularly directed to automatic detection of abnormalities, such as cancer. Transmittance or reflectance data over a large number of wavelengths are correlated by multiple linear regression analysis with conventional clinical results to select test wavelengths and constants for a correlation equation. The correlation equation is applied to the spectral data to determine quantitatively the presence of the abnormality.

SUMMARY OF THE INVENTION

The present invention provides an improved apparatus and method for non-invasively and atraumatically quantitatively determining the oxygen saturation in living tissue. This invention has the advantages of using only a single light source and permitting continuous measurements of the spectrum transmitted through the tissue of interest.

An apparatus for measuring oxygen saturation in living tissue according to the present invention comprises means for directing a continuous spectrum of light in a selected wavelength band through selected tissue, means for determining the spectral distribution of light transmitted through the selected tissue, means for determining the first derivative of the spectral distribution of the light transmitted through the selected tissue with respect to wavelength, and means for processing the first derivative to determine the oxygen saturation in the tissue.

The means for determining the spectral distribution of light transmitted through the tissue preferably includes light detecting means for producing signals indicative of the light intensity transmitted through the tissue, and means for correlating the transmitted intensity with the wavelength of light incident on the tissue.

The apparatus according to the present invention may further include means for digitizing the signal output from the light detecting means, storage means for storing digitized intensity data as a function of wavelength, and means for averaging the intensity values for a predetermined number of spectra. The differentiating means is preferably configured to determine the first derivative of the averaged spectral data at predetermined wavelengths. The differentiating means is preferably configured to determine the oxygen saturation in the tissue by calculating a linear combination of the first derivatives of the spectral data at predetermined wavelengths.

A method according to the present invention for measuring oxygen saturation in living tissue, comprises the steps of directing a continuous spectrum of light in a selected wavelength band through selected tissue, determining the spectral distribution of light transmitted through the selected tissue, determining the first derivative of the spectral distribution of the light transmitted through the selected tissue with respect to wavelength, and processing the first derivative to determine the oxygen saturation in the tissue.

The step of determining the spectral distribution of light transmitted through the tissue preferably includes the steps of producing signals indicative of the light intensity transmitted through the tissue and correlating the transmitted intensity with the wavelength of light incident on the tissue.

The method according to the present invention also preferably includes the steps of digitizing the signal output from the light detecting means; storing digitized intensity data as a function of wavelength, and averaging the intensity values for a predetermined number of spectra. The method may also further include the step of forming the differentiating means to determine the first derivative of the averaged spectral data at predetermined wavelengths. The method may include the step of calculating the oxygen saturation using the algorithm

$$[O_2]_{SAT} = A\frac{\partial I_a}{\partial \lambda} + B\frac{\partial I_b}{\partial \lambda} + C\frac{\partial I_c}{\partial \lambda} + D$$

$$= A\frac{\partial I_a/\partial \lambda}{I_b/\partial \lambda} + B\frac{\partial I_c}{\partial \lambda} + C$$

where A, B, C and D are constants; a, b and c represent selected points in the transmitted spectrum and λ the wavelength. Another algorithm that may be used in the method of the invention is where the constants have been previously defined.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram of the apparatus of the invention;

Figure 2 illustrates a filter structure that may be used to obtain a continuous spectrum in a selected wavelength range;

Figure 3 graphically illustrates the logarithm of the reciprocal of spectral data obtained using the apparatus and methods of the present invention; and

Figure 4 graphically illustrates the first derivative of the logarithm of the reciprocal of the spectral data of Figure 3.

DESCRIPTION OF THE PREFERED EMBODIMENT

Referring to the block diagram of Figure 1, a light source 10 provides light to an optical filter assembly 12. The light source may be either a white light source or an infrared lamp that produces wideband light in a selected wavelength range. The wavelength range preferably includes wavelengths of about 700 to 900 nm.

A filter assembly suitable for use in the present invention is described in U.S Patent 4,017,192 to Rosenthal, which is hereby incorporated by reference into this disclosure. Referring to Figure 2, the filter assembly 12 is preferably in the form of a paddle wheel 16 mounted for rotation about an axis perpendicular to the light path between the lamp 10 and a fiber optic bundle 18. The paddle wheel 16 is typically driven at about 3 revolutions per second. In a preferred embodiment, three narrow bandwidth plate-shaped optical interference filters 22 are mounted on a hexagonal axle 24. The planes of the filters 22 are equally separated by angles of about 120°. The filters 22 extend radially from the axle 24 in planes that intersect approximately in a line coincident with the axis of rotation of the paddle wheel 16. The filters 22 preferably extend equal radial distances from the axis. The cross sectional configuration of the filters 22 on the axle 24 thus resembles the letter Y. This arrangement of a single light source and three rotating filters 22 provides a continuous spectral range in the near infrared region of the spectrum between the wavelengths of about 700 nm and 1000 nm.

Referring to Figures 1 and 2, a signal indicative of the angle of rotation of the filter assembly 12 is passed through a digital counter circuit 26 that is set to provide control signals corresponding to selected angles of rotation of the paddle wheel 16. Since the angle of rotation is related to the wavelength output of the filter assembly 12, the control signals also indicate the wavelength of light that is being applied to the subject. A counter circuit suitable for use in the present invention is disclosed in U.S. Patent No. 3,861,788 to Webster, the disclosure of which is hereby incorporated by reference into the present disclosure. An optical interrupter may be used to correlate the wavelength and intensity so that spectral data comprising intensity as a function of wavelength may be measured.

The light beam output from the filter assembly 12 may then impinge upon a lens system 28 that focuses the light onto the fiber optic bundle 18. The fiber optic bundle 18 is convenient for directing the light to a portion of a subject's body such as the head, where tissue hemoglobin oxygenation is to be measured. The lens system 28 preferably is designed to provide a wide beam of essentially uniform intensity over the fiber bundle 18. The fiber optic bundle 18 is preferably an assembly of multimode optical fibers (not shown) having a numerical aperture suitable for receiving light input from the lens system 28. Such fiber optic bundles are well-known in the art and are therefore not described in detail herein. The light is typically input to the subject's forehead or to the top of the head. Applying the light to the top of the subject's head permits direct measurements of hemoglobin saturation in the sagittal sinus, which is where venous blood pools in the top of a person's head.

A detector system 30 that includes at least one photodetector (not shown) detects the waves output from the tissue and forms an electrical signal indicative of the detected light intensity. When the detector system includes a single photodetector, the output of the detector system 30 is amplified by an amplifier 32, which may be a logarithmic amplifier if the range of the electrical output of the detector is sufficiently broad. The analog output of the amplifier 32 is then converted to a digital signal by an analog to digital

converter (ADC) 34.

More than one detector may be used to determine the saturation in various parts of the head. If multiple detectors are used then, there will be an amplifier (not shown) and an ADC (not shown) for each detector. For example, a detector may be placed within one to two centimeters of the light source for measuring the saturation of the skull and skin. A second detector may be used to measure the far field at distances greater than three centimeters from the source. This far field detector may be used to measure the average saturation of the skin, skull and brain. The spectral difference between the far field and near field detectors then are indicative of the brain saturation.

The output of the detector 30 is sampled at enough wavelengths to obtain data that can be processed to obtain at least a first derivative of the absorption of oxyhemoglobin with respect to wavelength. A spectrum storage device 33 stores the sampled detector output. The counter circuit 26 has its control signal output connected to the storage device 32 to correlate the detected and stored intensity data with the wavelength incident on the tissue. A spectrum averaging circuit 35 averages the spectral data and provides the averaged output to a differentiator 36. A signal processing device 40 then applies an algorithm to the smoothed derivative to determine the O_2 saturation in the tissue.

The spectral data from about 700 nm to 1000 nm is divided and stored in 300 wavelength intervals of unequal spectral bandwidth. In order o enhance the signal to noise ratio, a number of spectra may be stored and time averaged to produce the spectra shown in Figure 3. For example, the light source and associated electronics may be used to obtain three spectra per second. Each measured spectrum is stored in the storage device 33. Spectrum averaging circuit 34 averages a selected number of spectra. Figure 3 is a plot of the logarithm of the reciprocal of the intensity for 100 averaged spectra.

The first derivative of the spectral data is preferably calculated at 766, 835 and 865 nm although other wavelengths in the 700 to 1000 nm range have been shown to give similar results. In order to enhance the spectral features of interest, the calculation of the derivative preferably involves an averaging process rather than merely subtracting successive intensity values and dividing by the change in wavelength. For example, the spectral data may be divided into 300 intensity intervals or segments. In order to find the derivative of the thirteenth segment, the average value (I_{1-10})for the first ten segments may be calculated and stored. The next five segments (I_{11-15}) may then skipped. The average intensity for the next ten segments 16-25 (I_{16-25}))is then calculated. The derivative is then found by dividing the difference of the intensity averages by the change in wavelength. The number of segments averaged is referred to as the segment size and the number of segments skipped is referred to as the gap. Figure 4 shows the derivative of the spectral data of Figure 3 for a segment size of 10 and a gap of 1.

A preferred algorithm for calculating the oxygen saturation uses a constant plus a linear combination of the first derivatives of the spectral data. For example the oxygen saturation may be found from the thirteenth, twenty-seventh and ninetieth data points so that

$$[O_2]_{SAT} = A\frac{\partial I_{13}}{\partial \lambda} + B\frac{\partial I_{27}}{\partial \lambda} + C\frac{\partial I_{90}}{\partial \lambda} + D.$$

The oxygen saturation may also be written as

$$[O_2]_{SAT} = A\frac{\partial I_a/\partial \lambda}{\partial I_b/\partial \lambda} + B\,\partial I_c/\partial \lambda + C.$$

Referring to Figures 3 and 4, one set of preferred data points and the corresponding wavelengths are: segment 30 = 766 nm; segment 164 = 835 nm and segment 235 = 865 nm. Therefore the oxygen saturation is

$$[O_2]_{SAT} = A\frac{\partial I_{30}/\partial \lambda}{\partial I_{164}/\partial \lambda} + B\,\partial I_{235}/\partial \lambda + C.$$

The constants are determined in the calibration of each instrument. For one instrument that has been used A = 4.046; B = 519.546 and C = 26.488. Other algorithms may be used to calculate the oxygen

saturation. In some cases it may be desirable to use a plurality of different algorithms to obtain the saturation. The saturations may then be averaged. If there is reason to believe that one algorithm may be more reliable than another, appropriate weighting factors may be used in the averaging process.

The derivative of the spectral data may be smoothed before processing by a CPU 38 with an algorithm that produces a quantitative measurement of the hemoglobin oxygenation in the tissue. The smoothing circuitry may include digital filter circuitry for calculating a weighted average of the previous signal and the new signal. For example, the output of the smoothing circuit may be 90% of the previous value plus 10% of the new value. The saturation output may be expressed as

$SAT_{OUT} = 0.1\ SAT_{CUR} + 0.9SAT_{PREV}$.

Both methods of smoothing prevent the signal input to the processor from changing too rapidly.

The method of the invention may also include means for calculating the second and higher derivatives of the spectral data curve with respect to wavelength. Using the derivatives of the spectral data to calculate the oxygen saturation eliminates errors caused by nonspecific absorptions and light scattering by the skull, scalp and dura. The second derivative may be obtained numerically from the first derivative in the same manner that the first derivative is obtained from the spectral data.

The apparatus of the present invention may be used to make a tomographic map of a selected portion of a subject's body such as the brain or heart. Localized changes is cellular oxidative metabolism are indicative of conditions such as stroke, infarction, oligemia and ischemia. The transmitted spectrum is processed as described above for light paths in different planes through the organ of interest. The data for making a tomographic map may be obtained by moving the fiber optic bundle and the detector relative to the organ. The use of more than one detector according to the invention at a time may permit the data to be obtained in less time than would be required with the use of a single source and detector.

Claims

1. Apparatus for measuring oxygen saturation in living tissue, comprising:
means for directing a continuous spectrum of light in a selected wavelength band through selected tissue;
means for determining the spectral distribution of light transmitted through the selected tissue;
means for determining a derivative with respect to wavelength of the spectral distribution of the light transmitted through the selected tissue; and
means for processing the derivative to determine the oxygen saturation in the tissue.

2. The apparatus of claim 1, wherein the means for determining the spectral distribution of light transmitted through the tissue includes: light detecting means for producing signals indicative of the light intensity transmitted through the tissue; and
means for correlating the transmitted intensity with the wavelength of light incident on the tissue.

3. The apparatus of claim 2, further including:
means for digitizing the signal output from the light detecting means;
storage means for storing digitized intensity data as a function of wavelength; and
means for averaging the intensity values for a predetermined number of spectra.

4. The apparatus of claim 3 wherein the differentiating means is configured to determine the first derivative of the averaged spectral data at predetermined wavelengths.

5. The apparatus of claim 4, further including means for determining the oxygen saturation in the tissue by calculating a linear combination of the first derivatives of the spectral data at the predetermined wavelengths.

6. The apparatus of claim 1 wherein the continuous spectrum includes wavelengths ranging from 700 nm to 1000 nm.

7. The apparatus of claim 2, further including:
a first photodetector for detecting signals indicative of the oxygen saturation of the skin and bones adjacent the tissue;
a second photodetector for detecting signals indicative of the oxygen saturation of the tissue and the skin and bones adjacent the tissue; and
means for processing signals output from the first and second photodetectors to determine the oxygen saturation of the tissue.

8. A method for measuring oxygen saturation in living tissue, comprising the steps of:
directing a continuous spectrum of light in a selected wavelength band through selected tissue;
determining the spectral distribution of light transmitted through the selected tissue;
determining the first derivative of the spectral distribution of the light transmitted through the selected tissue

with respect to wavelength; and
processing the first derivative to determine the oxygen saturation in the tissue.

9. The apparatus of claim 5, wherein, the means for determining oxygen saturation uses the formula

$$[O_2]_{SAT} = A\frac{\partial I_a}{\partial \lambda} + B\frac{\partial I_b}{\partial \lambda} + C\frac{\partial I_c}{\partial \lambda} + D$$

where A, B, C and D are constants; a, b and c represent selected points in the transmitted spectrum and λ is the wavelength.

10. The apparatus of claim 9 wherein

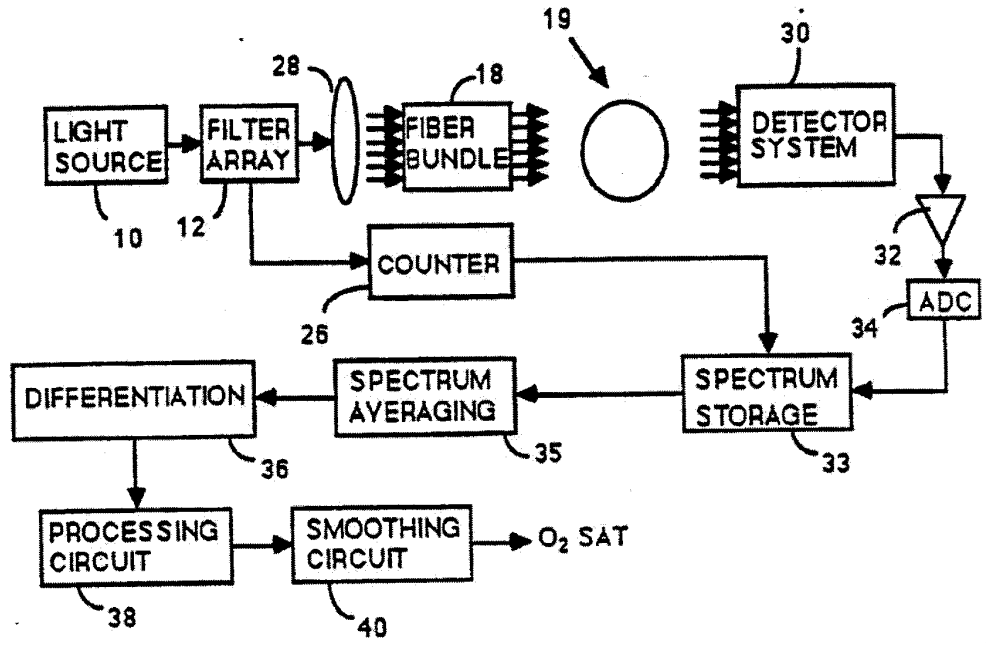
$$[O_2]_{SAT} = A\frac{\partial I_a}{\partial \lambda} + B\frac{\partial I_b}{\partial \lambda} + C\frac{\partial I_c}{\partial \lambda}$$

$$+ D = = A\frac{\partial I_a/\partial \lambda}{\partial I_b/\partial \lambda} + B\,\partial I_c/\partial \lambda + C.$$

11. The apparatus of claim 10 wherein

$$[O_2]_{SAT} = A\frac{\partial I_{766}/\partial \lambda}{\partial I_{835}/\partial \lambda} + B$$

where I_{766} is the intensity at a wavelength of 766 nm, I_{835} is the intensity at a wavelength of 835 nm and I_{865} is the intensity at a wavelength of 865 nm.


LIGHT SOURCE
FILTER ARRAY
FIBER BUNDLE
DETECTOR SYSTEM
COUNTER
ADC
SPECTRUM STORAGE
SPECTRUM AVERAGING
DIFFERENTIATION
PROCESSING CIRCUIT
SMOOTHING CIRCUIT
O_2 SAT
10
12
18
19
26
28
30
32
33
34
35
36
38
40

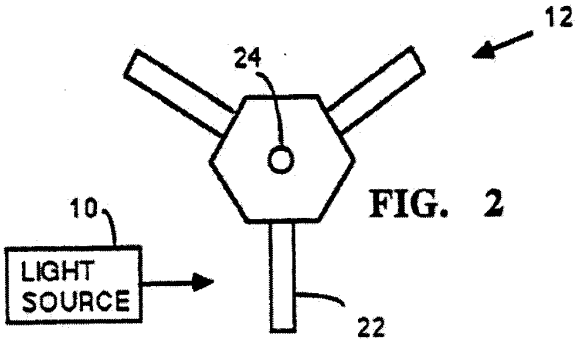

12
24
10
LIGHT SOURCE
22

FIG. 2

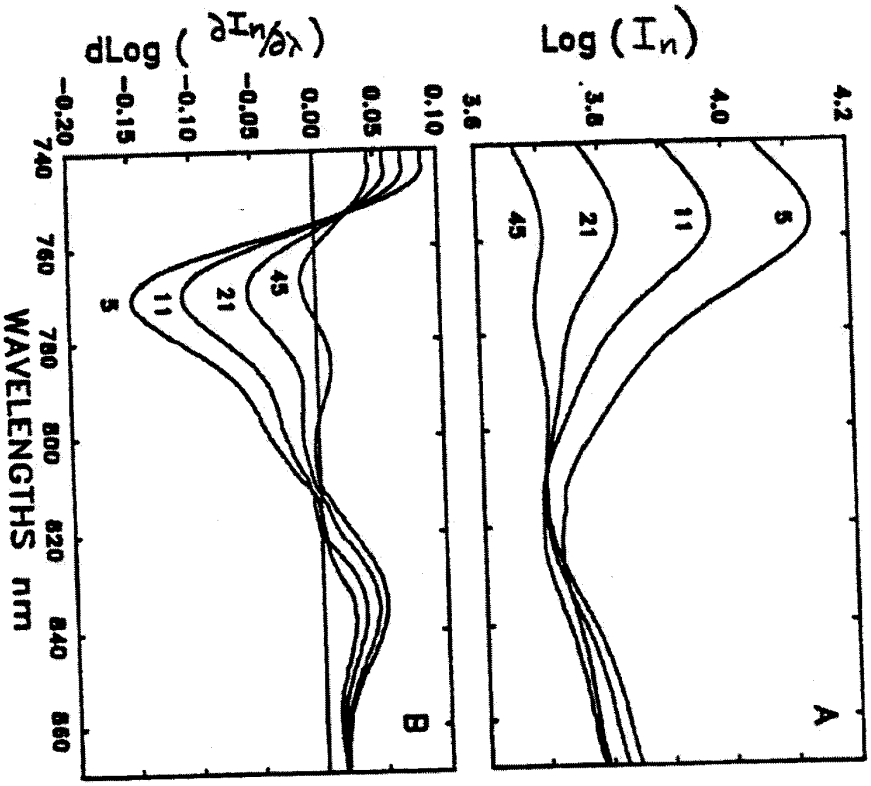

Log (I_n)
3.6
3.8
4.0
4.2
5
11
21
45
A

FIG. 3

dLog ($\partial I_n/\partial\lambda$)
−0.20
−0.15
−0.10
−0.05
0.00
0.05
0.10
740
760
780
800
820
840
860
WAVELENGTHS nm
5
11
21
45
B

FIG. 4

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 89 30 6879

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.5)
Y	EP-A-0 046 601 (HELLIGE GMBH) * abstract; page 9, line 21 - page 14, line 13; figure 1 *	1	A 61 B 5/00 G 01 N 21/31
A		2,4,5,8,9	
Y	EP-A-0 063 431 (M. KONOMI) * abstract; page 9, line 18 - page 21, line 7, figures 4,13 *	1	
A		2,3,6	
A,D	US-A-4 086 915 (H. I. KOFSKY et al.) * abstract; column 3, line 57 - column 4, line 25; figure 1 *	1-5	
A,D	IBM TECHNICAL DISCLOSURE BULLETIN vol. 20, no. 3, August 1977, pages 1137-1140, New York, USA; A. B. EWALT et al.: "Derivative Spectrometer" * whole document *	1-3	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 B 5/00
A 61 B 5/14
G 01 N 21/31

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
BERLIN	17-10-1989	WEIHS J.A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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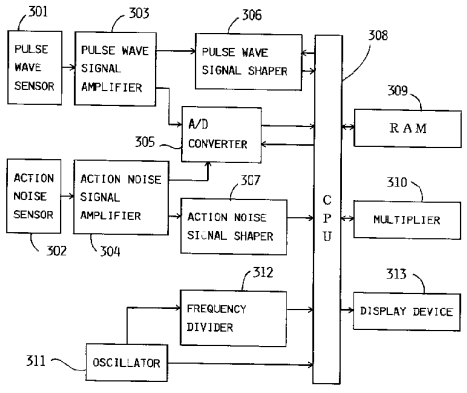
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(54) Pulse rate monitor.

(57) The pulse rate monitor is arranged by employing pulse wave component extracting means for extracting pulse wave components from frequency-analyzing results of a pulse wave sensor (301) which senses the pulse of a body and an action noise sensor (302) which senses movement of the body and pulse rate calculating means for calculating a pulse rate per 1 minute from the pulse wave components extracted from data from the pulse wave (301) and action noise sensor (302) by the pulse wave component extracting means, so that the pulse rate is displayed (313). Furthermore, there is employed an action noise signal confirming means (304,307) for judging whether or not an action noise is present, and also calculation changing means for changing a calculation method of the pulse rate based on the output signal from the action noise signal confirming means. As a result, the amount of calculation is reduced and power consumption is suppressed, so that calculation time can be shortened.

FIG. 3



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The present invention relates to a pulse rate monitor mounted on a portion of a human or other biological body.

In many circumstances it is desirable to be provided with an indication of the pulse rate of a human or other biological body. For example, during exercise, such as running, a person may wish to monitor their pulse rate in order to obtain an indication of their physical fitness and/or the vigorousness of the excercise. However, the movement/actions of the body make it difficult to accurately determine the pulse rate.

Figure 11 is a functional block diagram representing the construction of the conventional pulse wave detecting apparatus. The pule wave detecting means 1101 detects a pulse wave signal, and outputs a detected pulse wave signal to a frequency analyzing means 1103. The action noise detecting means 1102 detects an action noise signal and outputs a detected action noise signal to the frequency analyzing means 1103. The display means 1104 displays the frequency-analyzed result made by the frequency analyzing means 1103. The control means 1105 controls the frequency analyzing means 1103 and the display means 1104.

The above-described pulse wave analyzing apparatus is disclosed in Japanese Laid-Open Patent No. 60-259239.

However, the conventional pulse rate monitor merely displays both the frequency analyzed result of the pulse wave sensor and the frequency analyzed result of the action noise sensor on the output display unit. As a result, either the pulse wave frequency, or the pulse rate, must be determined by the user by observing the respective result representations on the output display unit. Also, the same signal processing system is used to determine the pulse wave frequency-analyzed and action noise frequency-analyzed results when the user is stationary and moving and thus, unnecessary parts of the signal processing unit are operated under the stationary condition.

It is an object of the present invention to provide a pulse rate monitor capable of displaying as an output a pulse rate representation even when the user is moving. Furthermore, another object of the present invention is to provide a pulse rate monitor capable of suppressing power consumption by reducing the amount by which signals are processed under a stationary condition, thereby shortening calculation time and saving power.

According to one aspect of the invention, there is provided a pulse rate monitor comprising a pulse wave sensor for sensing variations in blood pressure of a body and generating a signal indicative thereof, and a movement sensor for sensing movement of the body and generating a signal indicative thereof, characterised by processing means for calculating the pulse rate of the body based on the generated signals.

The pulse wave sensor and/or movement sensor may be mounted on or in a head, wrist, waist or leg band or the like. The sensors may be mounted on or in separate items or the same item. One or more of the sensors may be included in a watch wrist strap. In any event, the pulse wave sensor should be mounted on the body such that it can detect a pulse.

According to another aspect of the invention, there is provided a movement characteristic determining means. This may consist of an action pitch monitor. A movement sensor/action noise detection means is provided for supplying signals to a processor to determine a movement characteristic/action pitch.

A pulse rate monitor may be arranged by employing pulse wave component extracting means for extracting pulse wave components from frequency analyzing results of a pulse wave sensor and an action noise sensor; and pulse rate calculating means for calculating a pulse rate per one minute based on the pulse wave components extracted from the pulse wave component extracting means. Further, the pulse rate monitor may be arranged to confirm whether or not the action noise signal exists by action noise detecting means; and for changing the calculation method by calculation changing means when no action noise signal exists during a predetermined period of time. As a result, the calculation amount can be reduced and the power consumption can be suppressed, so that the calculation time can be shortened and power can be saved.

For a better understanding of the invention, embodiments of the invention will now be described by way of example with reference to the accompanying drawings, in which:-

Figure 1 is a functional block diagram for representing an example of the arrangement of a pulse rate monitor;

Figure 2 is a functional block diagram for representing another example of the arrangement of a pulse rate monitor;

Figure 3 is a functional block diagram for showing a pulse rate monitor according to an embodiment of the present invention;

Figure 4 is a flow chart for showing an operation concept of CPU in the pulse rate monitor according to the embodiment of the present invention;

Figure 5A shows an example of a waveform to be FFT-processed;

Figure 5B indicates a result of the FFT-processed waveform;

Figure 6A shows a result of the FFT-processed output signal of the pulse wave sensor;

Figure 6B indicates a result of the FFT-processed output signal of the action noise sensor;

Figure 6C represents such a pulse wave component obtained by subtracting the result of Figure 6B from the result of Figure 6A;

Figure 7 is a flow chart for indicating one example of the method for specifying the pulse wave component of the pulse rate monitor;

Figure 8 is a flow chart for indicating another example of the method for specifying the pulse wave component of the pulse rate monitor;

Figure 9 is a flow chart for indicating another example of the method for specifying the pulse wave component of the pulse rate monitor;

Figure 10 is a flow chart for indicating another example of the method for specifying the pulse wave component of the pulse rate monitor;

Figure 11 is a functional block diagram for indicating the arrangement of the conventional pulse rate monitor;

Figures 12A-12C are explanatory diagrams for indicating examples of outer appearance of the pulse rate monitor; Figure 12A shows a pulse rate monitor having the pulse wave sensor in a finger sack; Figure 12B indicates a pulse rate monitor having the action noise sensor assembled into a belt; and Figure 12C indicates a pulse rate monitor having the pulse wave sensor and the action noise sensor assembled into a watch strap;

Figure 13 represents a result of the FFT-processed output signal from the action noise sensor; and

Figure 14 indicates an example of a functional structural diagram of a motion pitch monitor.

Figure 1 is a functional block diagram representing one example of a pulse rate monitor.

The pulse wave detecting means 101 detects a pulse wave from a human or animal body, for example, and outputs the detected signal to the frequency analyzing means 103. The action noise detecting means 102 detects movement of the body and outputs the detected signal to the frequency analyzing means 103. The frequency analyzing means 103 frequency-analyzes the output signals from the pulse wave detecting means 101 and the action noise detecting means 102. To perform the frequency analysis, for instance, the Fast Fourier Transform (FFT) is employed.

The pulse wave component extracting means 104 specifies a pulse wave component corresponding to a pulse rate frequency from the frequency-analyzed results output from the pulse wave detecting means 101 and the action noise detecting means 102, and outputs the specified pulse wave component to the pulse rate calculating means 105. The pulse rate calculating means 105 calculates a pulse rate per minute from the frequency component of the pulse rate specified by the pulse wave component extracting means 104. The display means 106 displays the pulse rate calculated by the pulse rate calculating means 105.

Figure 2 is a functional view for representing another example of the arrangement of a pulse rate monitor. Pulse wave signal converting means 203 converts an analog pulse wave voltage signal of a human body, detected by the pulse wave detecting means 201, into a digital signal. The converted digital signal is output into pulse wave signal storing means 205.

The action noise converting means 204 converts an analog voltage signal proportional to a magnitude of the action noise, detected by the action noise detecting means 202, into a digital signal. The converted digital signal is output into action noise signal storing means 206. The pulse wave signal storing means 205 stores therein the pulse wave signal converted into the digital signal. The action noise signal storing means 206 stores therein the action noise signal converted into the digital signal.

Pulse wave signal calculating means 207 sequentially reads out the pulse wave signals stored in the pulse wave signal storing means 205 and frequency-analyzes the read pulse wave signals, thereby outputting the frequency-analyzed result into pulse wave component extracting means 209. Action noise signal calculating means 208 sequentially reads out the action noise signals stored in the action noise signal storing means 206 and performs a frequency analysis of the read action noise signal, thereby outputting the frequency-analyzed result into the pulse wave component extracting means 209. The pulse wave component extracting means 209 extracts only the pulse wave components from the frequency-analyzed results by the pulse wave signal calculating means 207 and the action noise signal calculating means 208, thereby outputting these extracted pulse wave components to calculation changing means 210.

Timing means 211 counts a time period during which there is no action noise signal that has been shaped into rectangular waves by the action noise detecting means 202), and indicates that the counted time period exceeds a predetermined time period to the calculation changing means 210. Upon receipt of the no action noise signal issued from the timing means 211, the calculation changing means 210 outputs the pulse wave signal (which has been shaped into rectangular waves by the pulse wave detecting means 201) into pulse rate calculating means 212. At the same time, the calculation changing means 210 stops the operations of the pulse wave signal converting means 203, pulse wave signal storing means 205, pulse wave signal calculating means 207, action noise signal converting means 204, action noise signal storing means 206, action noise signal calculating means 208, and pulse wave component extracting means 209.

While the calculation changing means 210 outputs the rectangular shaped pulse wave signal to the pulse rate calculating means 212, when the action noise is detected by the action noise detecting means

202, the calculation changing means 210 immediately restarts the operations of the above-described pulse wave signal converting means 203, pulse wave signal storing means 205, pulse wave signal calculating means 207, action noise signal converting means 204, action noise signal storing means 206, action noise signal calculating means 208, and pulse wave component extracting means 209, and also changes into the output signal of the pulse wave component extracting means 209.

In the pulse rate calculating means 212, a pulse rate per minute is calculated from either the frequency component of the pulse wave extracted by the pulse wave component extracting means 209, or the periodic data of the pulse wave which has been shaped by the pulse wave detecting means 201, and the calculation result is output to the display means 213.

Figure 3 is a functional block diagram representing a pulse rate monitor according to a first embodiment of the present invention. A pulse wave sensor 301 senses a pulse wave from a biological body, and outputs the sensed pulse wave signal to a pulse wave signal amplifier 303. An action noise sensor 302 senses movement of the biological body and outputs the sensed action noise signal to an action noise signal amplifier 304.

As the pulse wave sensor, for instance, a piezoelectric microphone is employed.

As the action noise sensor, an acceleration sensor is utilized, for example.

The pulse wave signal amplifier 303 amplifies the pulse wave signal and outputs the amplified pulse wave signal to an A/D converter 305 and a pulse wave shaper 306. The action noise signal amplifier 304 amplifies the action noise signal and outputs the amplified action noise signal to the A/D converter 305 and an action noise signal shaper 307. The A/D converter 305 converts both the pulse wave signal and the action noise signal to output the A/D-converted pulse wave signal and action noise signal to a CPU 308. The pulse wave signal shaper 306 shapes the pulse wave signal into rectangular waves (square waves) to output the shaped pulse wave signal to the CPU 308. The action noise signal shaper 307 shapes the action noise signal into rectangular waves (square waves) to output the shaped action noise signal to the CPU 308.

Figure 4 is a flow chart for representing such a sequential operation in which a confirmation is made as to whether or not the action noise signal is present, the calculation method for the pulse wave signal is changed, and the pulse rate is calculated and then is displayed. In Figure 3 and Figure 4, the CPU 308 confirms whether or not the action noise signal is present in response to the output signal issued from the action noise signal shaper 307, and then switches the calculation method (S402). When the existence of the action noise signal is confirmed (S402: YES), the CPU 308 performs an FFT process (S405) to the A/D-converted pulse wave signal (S403) and also A/D-converted action noise signal (S404); and further extracts the pulse wave frequency components (S406).

When the existence of the action noise signal is not confirmed (S402:NO), the pulse wave is detected (S407) and the pulse waveform is shaped (S409). During this process operation, another confirmation is made once or more as to whether or not the action noise signal is present (S408). When there is still no action noise signal (S408:NO), the pulse rate is calculated directly from the rectangular wave (S410). At this time, in Figure 3, since both the pulse wave signal and the action noise signal are no longer required for the A/D conversion, the operation of the A/D converter 305 is stopped and also the operation of the multiplier 310 is stopped which is required to perform the FFT process. Furthermore, the process operation required to extract the pulse wave component executed in the CPU 308 is stopped, so that the total power consumption can be lowered.

When there is the action noise signal (S408:YES), the frequency analysis is carried out by the FFT process operation (S405), and the pulse rate is calculated from the extracted pulse wave component (S410).

In Figures 5A and 5B, there is shown the result (Figure 5B) of FFT-processing a signal (Figure 5A) to which a frequency component fA and a frequency component fB, equal to a half of the amplitude of the frequency component fA, have been added. The lowest frequency obtained from the FFT-processed result is determined by calculating the inverse of the analyzing period of time. Assuming now that the analyzing period is 16 seconds, the line spectrum resolution becomes 1/16 seconds or 62.5 ms in period. As a consequence, the signal to be analyzed is resolved into harmonic components being equal to 16 Hz multiplied by an integer. The magnitudes (power) of the respective harmonic components are denoted by a height in ordinate. In Figure 5B, it is represented that the power of the frequency component fB is equal to a half of the power of the frequency component fA.

Figures 6A-6C show an example of results obtained by FFT-processing the output signals of the pulse wave sensor and the action noise sensor under action condition. Figure 6A represents a pulse wave spectrum "fmg", Figure 6B indicates an action noise spectrum "fsg", Figure 6C denotes a spectrum obtained by subtracting the action noise spectrum from the pulse wave spectrum, i.e. extracted pulse wave components "fM". In Figure 6A both of the frequency components of the pulse waveform and the frequency components of the signal produced by the action are superimposed. The result shown in Figure 6A is produced by FFT-processing the output signals of the pulse wave sensor. The result shown in Figure 6B is produced by the action noise sensor, and, since the action noise sensor responds only to the action of the

biological body, frequency components of the signal produced only by the action are obtained. The spectrum fsg is subtracted from the spectrum fmg, so that among the remaining line spectrum (as shown in Figure 6C), the maximum line spectrum is specified as the pulse wave frequency component. Based upon the frequency component of this pulse wave signal, the pulse rate is calculated (Figure 4, S410) and the calculated pulse rate is output to such a display element as an LCD panel (S411).

The above-described method for specifying the pulse wave component is shown in Figure 7. At a step S703, the action noise is subtracted from the pulse wave (fM = fmg - fsg), whereby frequency components contained only in the pulse wave signal are derived. The maximum frequency components among the derived pulse wave components fM is specified. The specified fMmax is the frequency component of the pulse wave.

Actually, there are some difficult cases in such a subtracting method for simply subtracting those signal components. When the respective sensor output waveforms are frequency-analyzed, adverse influences are produced by the harmonic signals. As a consequence, a method for specifying a pulse wave will now be described in detail.

In Figure 8, there is shown such a processing method for specifying a pulse wave component after an action noise component is extracted from a signal of the action noise sensor, and the action noise component is eliminated from a frequency-analyzed result of a pulse wave signal. The second harmonic fs2 of the action noise sensor, which is relatively easy to detect as the action noise component, is specified at steps S801, S802 and S803. Assuming now that the action is "running", fmin of step S802 becomes 2 Hz, corresponding to the lower limit frequency of the second harmonic appearing in the "running". Symbol "fmax" is a frequency determined by the sampling rate for the A/D conversion. Assuming now that the sampling frequency is 8 Hz, the maximum frequency at which the original waveform can be reproduced from the sampling theory is automatically determined as 4 Hz. Within a range from this fmax to fmin, the maximum line spectrum is specified as the second harmonic of the action noise component. As a step S804, the fundamental harmonic fs1 of the action noise component is obtained.

At the subsequent steps S805, S806, S807 and S808, pulse wave components coincident with the fundamental harmonic (fs1), the second harmonic (2 x fs1), and the third harmonic (3 x fs1) of the action noise component are eliminated, and the maximum frequency component among the remaining components is specified as a pulse wave "fm" at a step S809. Normally, the action noise frequency is 1 to 2 Hz. As a result, when the maximum frequency component fmax is equal to 4 Hz, it is sufficient to check the harmonics up to the third harmonic.

Now a description will be made of the reason why the maximum action noise component in the frequency region from 2 Hz to 4 Hz is extracted, and then this frequency is handled as the second harmonic of the action noise component in the above-described embodiment.

Figure 13 schematically reprsents results obtained by FFT-processing the outputs of the action noise sensor. Generally speaking, under action conditions, especially, under a running condition, as illustrated in Figure 13, a higher power of the second harmonic is obtained, as compared with that of the fundamental harmonic (i.e. 3 to 10 times higher than the fundamental harmonic during normal running). There are three sensing factors of the action noise sensor under running conditions.

That is to say,

(1) up/down movement under running conditions,

(2) fundamental harmonic of arm swings, and

(3) second harmonic leg of arm swings.

As the factor (1), since the up/down movement is equally performed when the right leg is stepped and the left leg is stepped, it becomes the second harmonic of the action noise components.

As to the factor (2), it is directed to such pendulum motion that the arm's pushing motion and the arm's pulling motion constitute one pertiod. However, in practice the arm swings under normal running are not made as a smooth pendulum motion, and therefore power of this component is weakened.

As to the factor (3), since acceleration is instantaneously applied to the arm's pushing motion and the arm's pulling motion, the power of the second harmonic becomes higher than that of the fundamental harmonic. As a consequence, the second harmonic component among the action noise frequency component is emphasized.

Under normal running conditions, when the frequency range is selected from 2 Hz to 4 Hz, the range where the second harmonic appears can be covered, even if the running pace is increased and/or decreased. Therefore, the precision of detection may be increased by extracting the second harmonic component with the featured portion while limited to this frequency range.

In Figure 9, there is shown a process method for specifying a pulse wave component after the harmonics waves of an action noise signal are specified. At a step S901, a line spectrum fs having a maximum power "P" is obtained from the frequency analayzing result of the action noise signal. Subsequently, a check is made as to whether or not an action noise component P(fs/2) higher than a predetermined value Th exists at a frequency equal to a half of fs (S902). When the line spectrum fs/2 is present (S902:YES), fs is specified as the second harmonic wave (HMC = 2) (S903). When the line spectrum fs/2 is not present

(S902:NO), another check is done as to whether or not an action noise component P(fs/3) higher than a predetermined value Th exists at a frequency equal to one third of fs at a step S904. When there is such an action noise component P(fs/3) (S904:YES), fs is specified as the third harmonic wave (HMC = 3) (S905). If there is no action noise component P(fs/3) (S904:NO), then fs is specified as the fundamental harmonic fs1 (S906).

Since it could be specified in the above-described process operations that fs corresponds to one of the higher harmonics, the fundamental harmonic fs1 of the action noise signal is obtained at a step S907. Then, at a step S908, the frequency components fm are successively compared with the action noise frequency in the order of the line spectrum with the higher power P from the frequency-analyzing results of the pulse waves. A check is done as to whether or not this frequency component is coincident with the fundamental harmonic (fs1) of the action noise signal, the second harmonic (2 x fs1), and the third harmonic (3 x fs1) (steps S908, S909, S910 and S911). With this process operation, the maximum pulse wave frequency component fm which is not coincident with the action noise components can be extracted at a step S912.

Figure 10 is a flow chart for representing such a sequential operation in which a confirmation is made as to whether or not there is an action noise signal; when such a condition that the action noise signal is not confirmed exceeds a predetermined time "T", the calculation method is changed; and a pulse rate is calculated based on a rectangular-shaped signal of pulse wave, and displayed. In Figure 3 and Figure 10, the CPU 308 makes a confirmation as to whether or not the action noise signal is present based on the output signal derived from the action noise signal shaper 307 (S1002). While the action noise signal is being confirmed (S1002:YES), a change over signal is set to OFF (S1003) so that accumulation time "Rt" for no action noise signal is set to zero (S1004). Thereafter, both the A/D converted action noise signal and pulse wave signal are FFT-processed to extract a pulse wave (S1007). Subsequently, a pulse rate is calculated (S1012) to be output to a display device 313 (S1013).

When no action noise signal is confirmed (S1002:NO), the time counting operation is commenced based on the output signal derived from an oscillator 311 and a frequency divider 312, so that elapsed time Rt is accumulated (S1008). When the accumulated time Rt exceeds a certain constant time T which is determined by either the sampling period of the signal used in the FFT process, or the sampling number (S1009:YES), the method for calculating the pulse rate is changed (S1010), the operations of the A/D conversion and the FFT process are stopped, and the pulse wave signal shaped by the pulse wave signal shaper 306 is input to the CPU 308 to calculate the pulse rate (S1012). Then, the calculated pulse rate is output to the display device 313 (S1013).

As described above, there has been explained an embodiment in which the maximum pulse wave frequency component which is not coincident with the action noise component is specified to realize the pulse rate monitor.

Alternatively, it is possible to construct a high-precision action pitch monitor which employs the same structure as above. In Figure 14, there is shown a functional block diagram of an arrangement of an action pitch monitor. The frequency component of the action pitch is specified by action noise extracting means 1405. This specifying method may be readily realized by way of the methods previously described with reference to Figure 8 and Figure 9. In accordance with the action pitch monitor, running pitches, for example, corresponding to useful information for a runner can be correctly obtained. Also, it may be possible to calculate a running distance based on the running pitches and the length of steps.

Figures 12A-12C are explanatory diagrams for indicating an example of the outer appearance of a pulse rate monitor or action pitch monitor. Figure 12A indicates a type of pulse rate monitor in which the pulse wave sensor is provided in a finger sack. Figure 12B shows a type of pulse rate monitor in which an action noise sensor 1202 is provided on a belt 1203. Figure 12C indicates a type of pulse wave monitor in which both a pulse wave sensor 1204 and an action noise sensor 1205 are assembled into a wrist watch band in an integral form.

As described above, a pulse wave component extracting means is employed which extracts the pulse wave components from the respective frequency-analyzed results of the pulse wave sensor and the action noise sensor, so that the pulse rate during motion condition can be displayed. Furthermore, under a no motion condition, where the frequency analyzing process operation is not required, the operations of the A/D converter and the calculating circuit (which have a relatively high power consumption) can be stopped. Accordingly, the power consumption can be reduced. Also, since a constant time required to perform the frequency analysis is prepared from the stationary condition until the calculation method is switched, so that non-contradictory process operation may be carried out and thus a correct pulse rate can be displayed.

Claims

1. A pulse rate monitor comprising a pulse wave sensor (101,201,301) for sensing variation in blood pressure of a body and generating a signal indicative thereof, and a movement sensor

(102,202,302) for sensing movement of the body and generating a signal indicative thereof, characterised by processing means (103-5, 203-12, 308) for calculating the pulse rate of the body based on the generated signals.

2. A pulse rate monitor according to claim 1, comprising frequency analysing means (104,203-8, 308) for resolving the pulse wave indicative signal and movement indicative signal into frequency components (fmg, fsg); and pulse wave component extracting means (104,209,308) for determining the pulse rate of the body from the pulse wave frequency components and movement frequency components.

3. A pulse rate monitor as claimed in claim 2, wherein said pulse wave component extracting means (104,209,308) comprises:

subtracting means for calculating a subtraction between the pulse wave frequency components and the movement frequency components; and

pulse wave maximum component extracting means for extracting the typical pulse rate of the body having a maximum power spectrum from pulse wave components obtained by said subtracting means.

4. A pulse rate monitor as claimed in claim 2 or 3 wherein said frequency analyzing means (104,203-8,308) comprises:

pulse wave signal converting means (203) for converting the pulse wave indicative signal into a digital signal;

movement indicative signal converting means (204) for converting the movement indicative signal into a digital signal;

pulse wave signal storing means (205) for storing the digital signal converted by said pulse wave signal converting means (203);

movement indicative signal storing means (206) for storing the digital signal converted by said movement indicative signal converting means (204);

pulse wave signal calculating means (207) for analyzing the digital signal stored in said pulse wave signal storing means (205) to obtain the pulse wave components representing frequency and power spectrum of the pulse wave signal; and

movement indicative signal calculating means (208) for analyzing the digital signal stored in said movement indicative signal storing means (206) to obtain the movement indicative components representing frequency and power spectrum of the movement indicative signal;

and wherein said pulse wave component extracting means (104,209,308) receives the pulse wave components by said pulse wave signal calculating means (207) and the movement indicative components by said movement indicative signal calculating means (208).

5. A pulse rate monitor as claimed in claim 4, wherein said pulses wave component extracting means (104,209,308) comprises:

movement indicative components eliminating means for eliminating the movement indicative components from the pulse wave components output from said pulse wave signal calculating means (207); and

pulse wave maximum component extracting means for extracting the typical pulse wave component having a maximum power spectrum from pulse wave components obtained by said movement indicative components eliminating means.

6. A pulse rate monitor as claimed in claim 4 or 5, wherein said pulse wave component extracting means (104,209,308) comprises:

movement indicative maximum component extracting means for extracting a typical movement indicative component having a maximum power spectrum from the movement indicative noise components obtained by said movement indicative signal calculating means (208);

harmonic specifying means for discriminating to which order of harmonic the typical movement indicative component obtained by said movement indicative maximum component extracting means corresponds, including the fundamental harmonic, and for specifying harmonic components including fundamental harmonic component of the movement indicative components;

movement indicative component eliminating means for eliminating all of harmonic components specified by said harmonic specifying means from the pulse wave components obtained by said pulse wave signal calculating means (207); and

pulse wave maximum component extracting means for extracting a typical pulse wave component having a maximum power spectrum from the pulse wave components obtained by said movement indicative component eliminating means.

7. A pulse rate monitor as claimed in claims 4, 5 or 6, wherein said pulse wave component extracting means (104,209,308) comprises:

movement indicative maximum component extracting means for extracting a typical movement indicative component having a maxi-

mum power spectrum from the movement indicative components obtained by said movement indicative signal calculating means (208);

harmonic specifying means for identifying the typical movement indicative component obtained by said movement indicative maximum component extracting means as a second order harmonic, and for specifying harmonic components including the fundamental harmonic components of the movement indicative components;

movement indicative component eliminating means for eliminating all of harmonic components specified by said harmonic specifying means from the pulse wave components obtained by said pulse wave signal calculating means (207); and

pulse wave maximum component extracting means for extracting a typical pulse wave component having a maximum power spectrum from the pulse wave components obtained by said movement indicative component eliminating means.

8. A pulse rate monitor as claimed in claims 4, 5, 6 or 7, wherein said pulse wave signal calculating means (207) and said movement indicative signal calculating means (208) both perform Fast Fourier Transform operations.

9. A pulse rate monitor as claimed in any preceding claim, further comprising:

timing means (211) for counting and accumulating elapsed time under a condition of no movement indicative signal being detected, and for outputting a change over signal when the elapsed time exceeds a predetermined time period; and

calculation changing means (210) for changing an input signal to said processing means from the typical pulse wave component to the pulse wave signal output by said pulse wave sensor in response to the change over signal obtained by said timing means (211).

10. A pulse rate monitor comprising:

pulse wave detecting means having a pulse wave sensor for detecting a pulse from a biological body, and for outputting a pulse wave signal;

action noise detecting means having an action noise sensor for detecting an action noise corresponding to a biological body action, and for outputting an action noise signal;

frequency analyzing means for resolving the pulse wave signal and the action noise signal into frequency components as pulse wave components and action noise components;

pulse wave component extracting means for extracting typical pulse wave component from the pulse wave components and the action noise components by said frequency analyzing means; and

pulse rate calculating means for calculating pulse rate per predetermined period, of the biological body based on the typical pulse wave component extracted by said pulse wave component extracting means.

11. An action pitch monitor comprising:

action noise detecting means (1401) having an action noise sensor for detecting an action noise corresponding to a biological body action, and for outputting an action noise signal;

action noise signal converting means (1402) for converting the action noise signal into a digital signal;

action noise signal storing means (1403) for storing the digital signal converted by said action noise signal converting means (1402);

action noise signal calculating means (1404) for processing the digital signal stored in said action noise signal storing means (1403) to obtain the action noise components representing frequency and power spectrum of the action noise signal;

action noise component extracting means (1405) for extracting a typical action noise component from the action noise components; and

action pitch calculating means (1406) for calculating action pitch, per predetermined period, of the biological body based on the typical action noise components extracted by said action noise component extracting means (1405)

FIG. 1

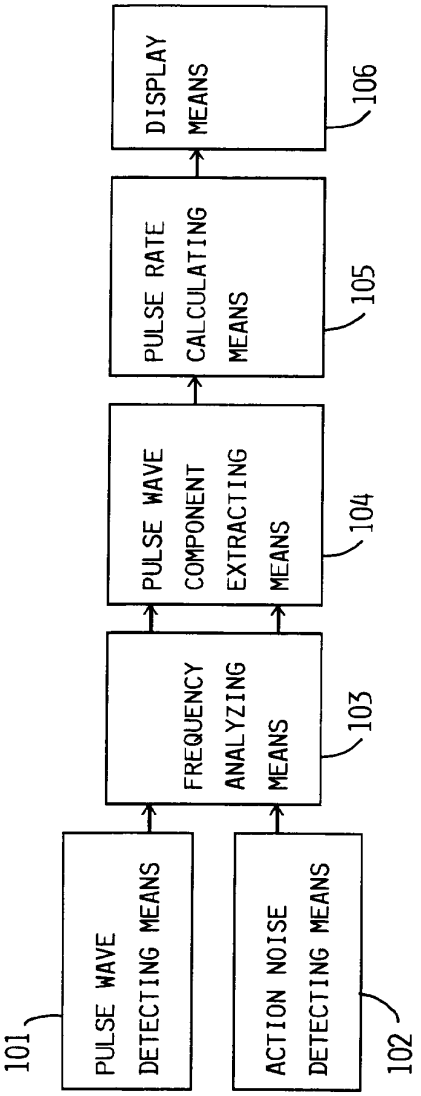

PULSE WAVE DETECTING MEANS
101
ACTION NOISE DETECTING MEANS
102
FREQUENCY ANALYZING MEANS
103
PULSE WAVE COMPONENT EXTRACTING MEANS
104
PULSE RATE CALCULATING MEANS
105
DISPLAY MEANS
106

FIG. 2

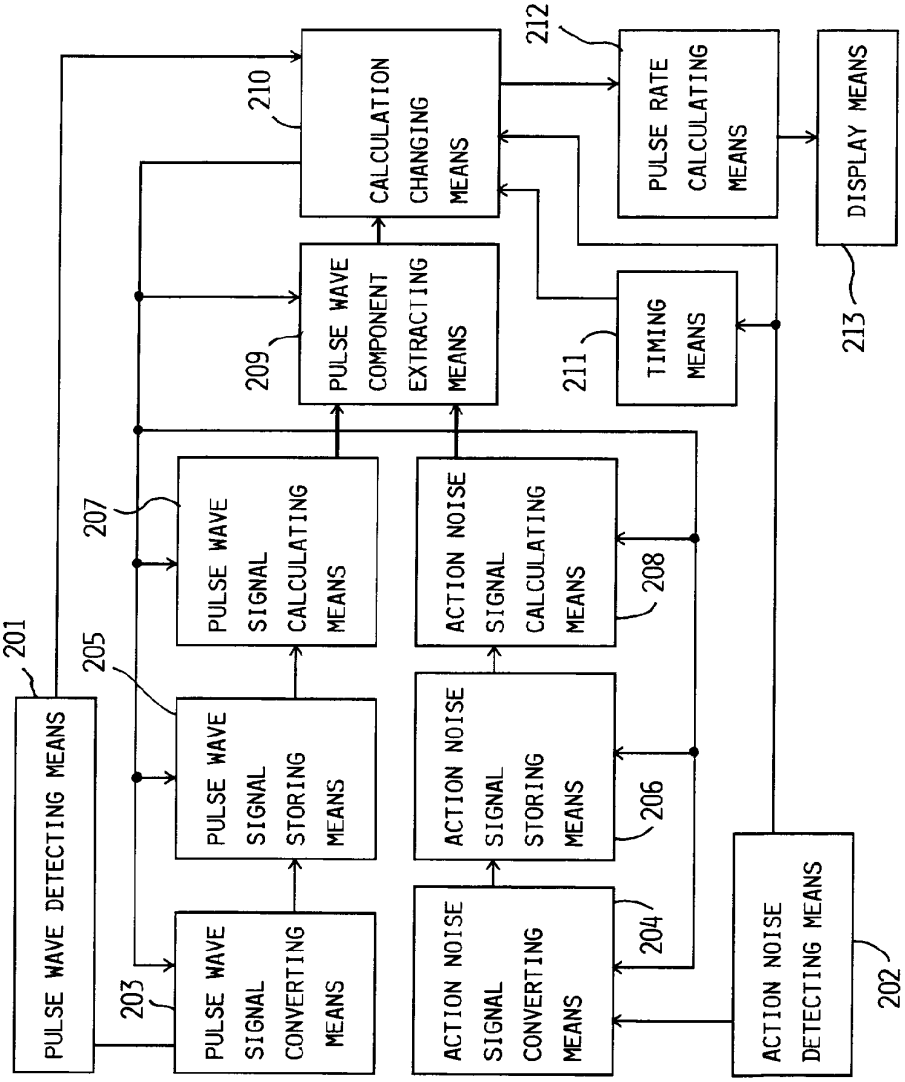

PULSE WAVE DETECTING MEANS
201
PULSE WAVE SIGNAL CONVERTING MEANS
203
PULSE WAVE SIGNAL STORING MEANS
205
PULSE WAVE SIGNAL CALCULATING MEANS
207
ACTION NOISE SIGNAL CONVERTING MEANS
204
ACTION NOISE SIGNAL STORING MEANS
206
ACTION NOISE SIGNAL CALCULATING MEANS
208
ACTION NOISE DETECTING MEANS
202
PULSE WAVE COMPONENT EXTRACTING MEANS
209
CALCULATION CHANGING MEANS
210
TIMING MEANS
211
PULSE RATE CALCULATING MEANS
212
DISPLAY MEANS
213

FIG. 3

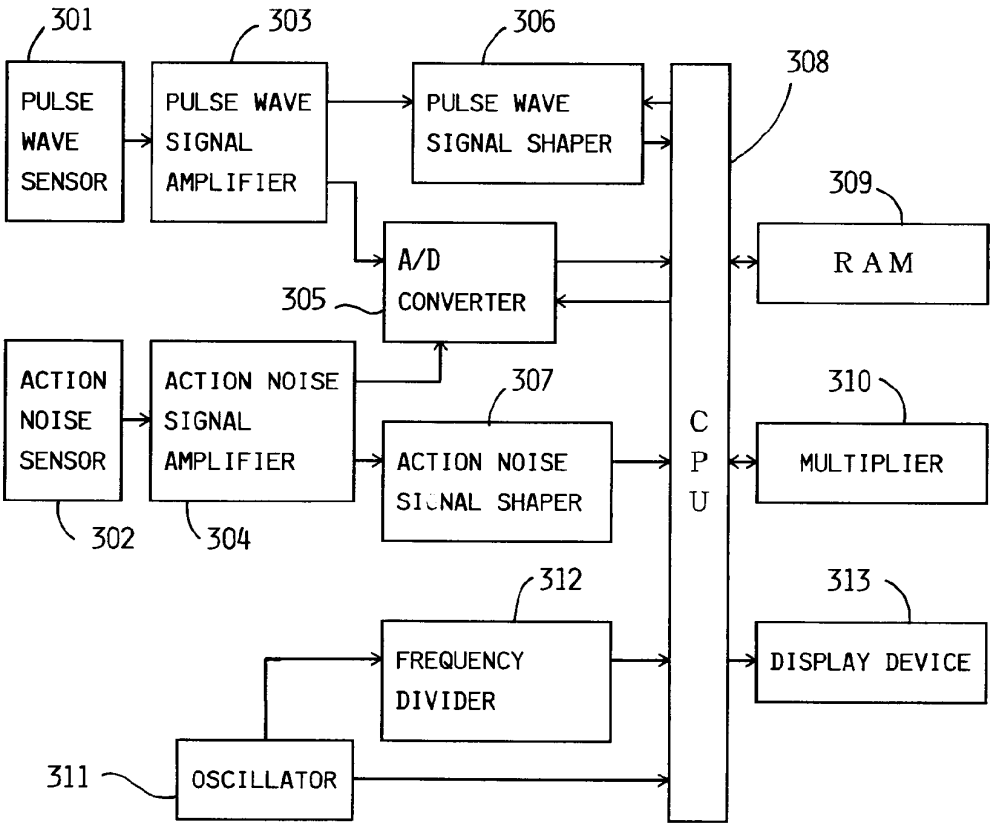
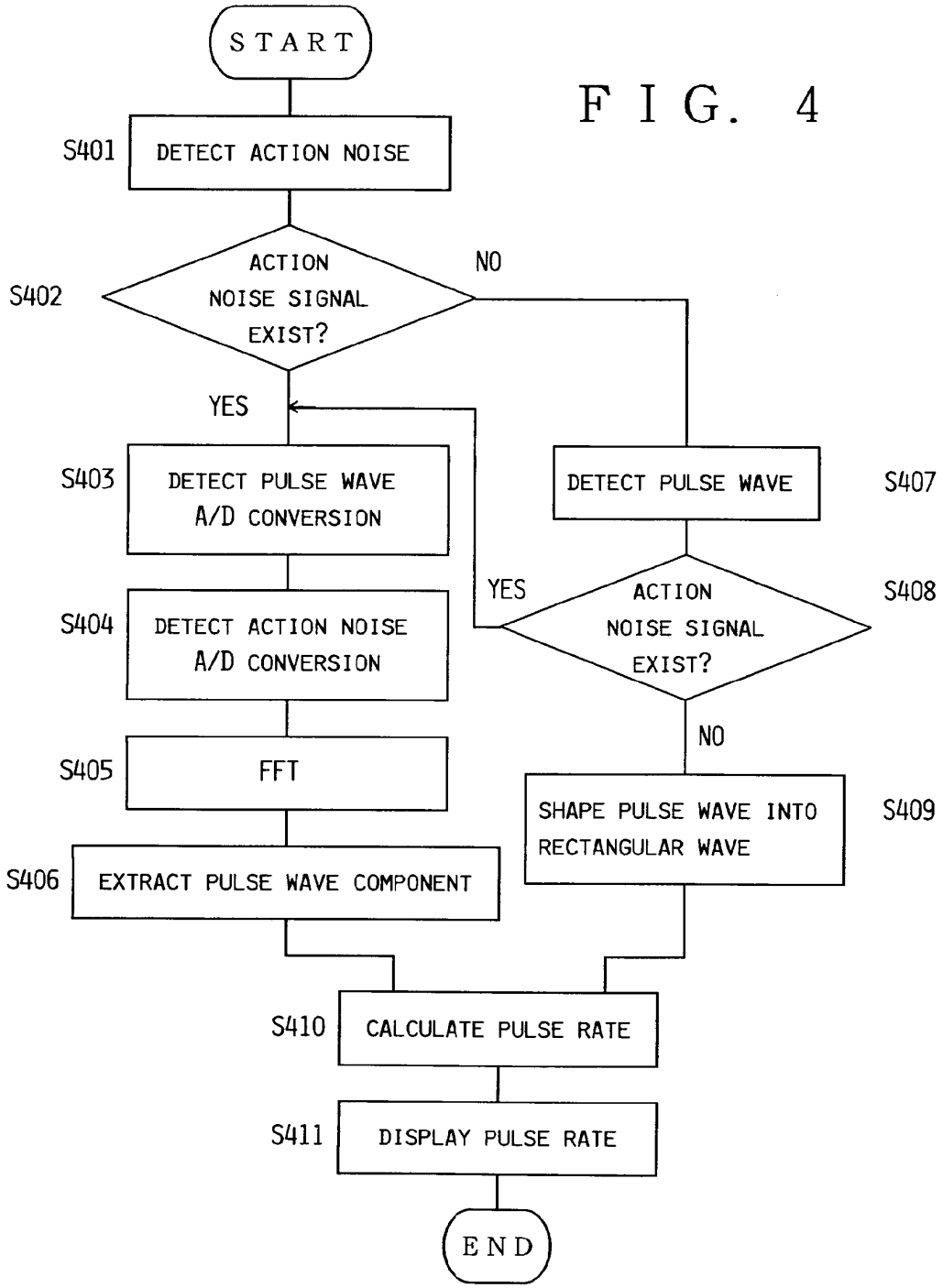

301
PULSE WAVE SENSOR
303
PULSE WAVE SIGNAL AMPLIFIER
306
PULSE WAVE SIGNAL SHAPER
308
309
RAM
A/D CONVERTER
305
ACTION NOISE SENSOR
302
ACTION NOISE SIGNAL AMPLIFIER
304
307
ACTION NOISE SIGNAL SHAPER
C P U
310
MULTIPLIER
312
FREQUENCY DIVIDER
313
DISPLAY DEVICE
311
OSCILLATOR

FIG. 4


START
S401
DETECT ACTION NOISE
S402
ACTION NOISE SIGNAL EXIST?
NO
YES
S403
DETECT PULSE WAVE A/D CONVERSION
S404
DETECT ACTION NOISE A/D CONVERSION
S405
FFT
S406
EXTRACT PULSE WAVE COMPONENT
S407
DETECT PULSE WAVE
S408
ACTION NOISE SIGNAL EXIST?
YES
NO
S409
SHAPE PULSE WAVE INTO RECTANGULAR WAVE
S410
CALCULATE PULSE RATE
S411
DISPLAY PULSE RATE
END

12

FIG. 5A

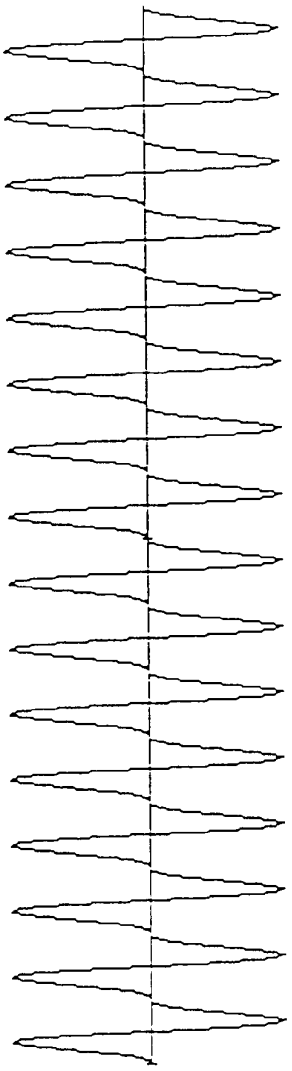


FIG. 5B

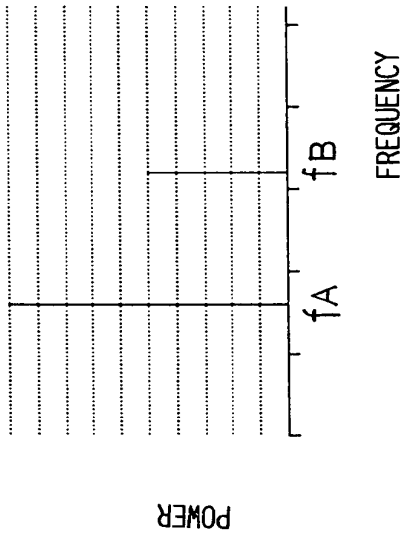


FIG. 6A

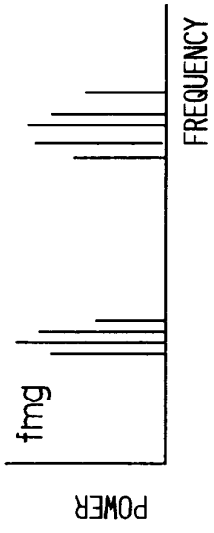


FIG. 6B

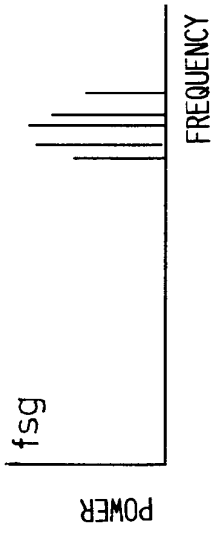


FIG. 6C

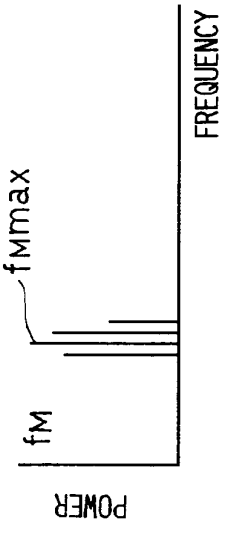


FIG. 7

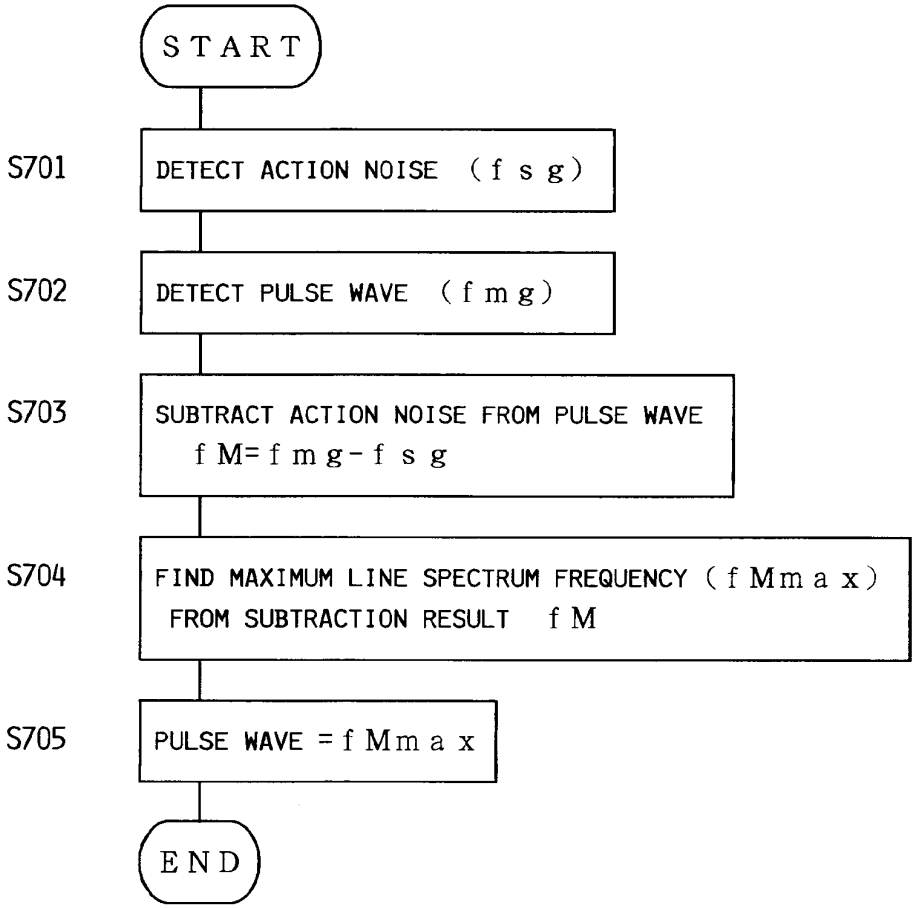

START
S701
DETECT ACTION NOISE (f s g)
S702
DETECT PULSE WAVE (f m g)
S703
SUBTRACT ACTION NOISE FROM PULSE WAVE
f M= f m g - f s g
S704
FIND MAXIMUM LINE SPECTRUM FREQUENCY (f Mm a x)
FROM SUBTRACTION RESULT f M
S705
PULSE WAVE = f Mm a x
END

FIG. 8

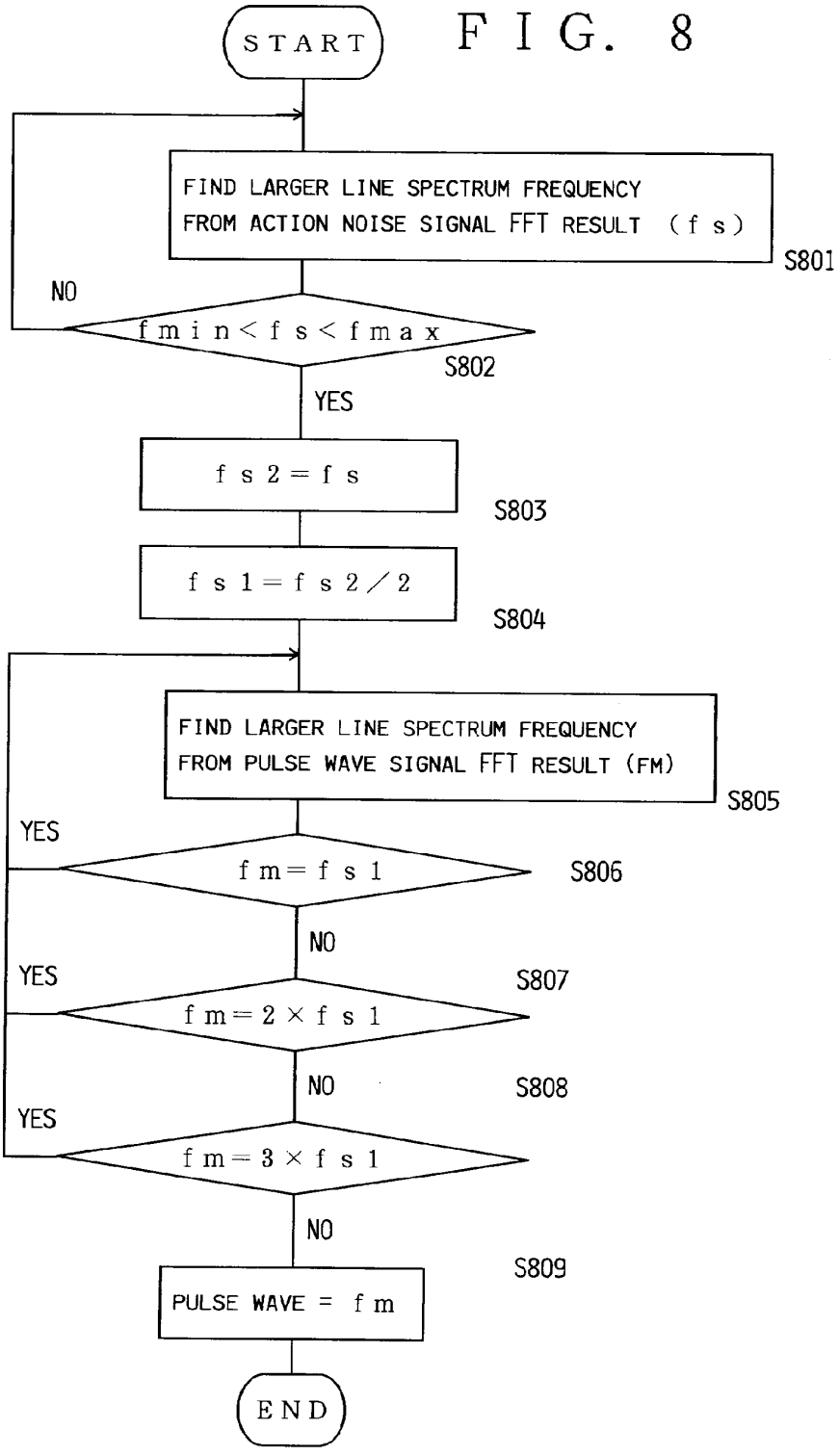

START
FIND LARGER LINE SPECTRUM FREQUENCY FROM ACTION NOISE SIGNAL FFT RESULT (fs)
S801
NO
fmin < fs < fmax
S802
YES
fs2 = fs
S803
fs1 = fs2 / 2
S804
FIND LARGER LINE SPECTRUM FREQUENCY FROM PULSE WAVE SIGNAL FFT RESULT (FM)
S805
YES
fm = fs1
S806
NO
YES
fm = 2 × fs1
S807
NO
YES
fm = 3 × fs1
S808
NO
PULSE WAVE = fm
S809
END

FIG. 9

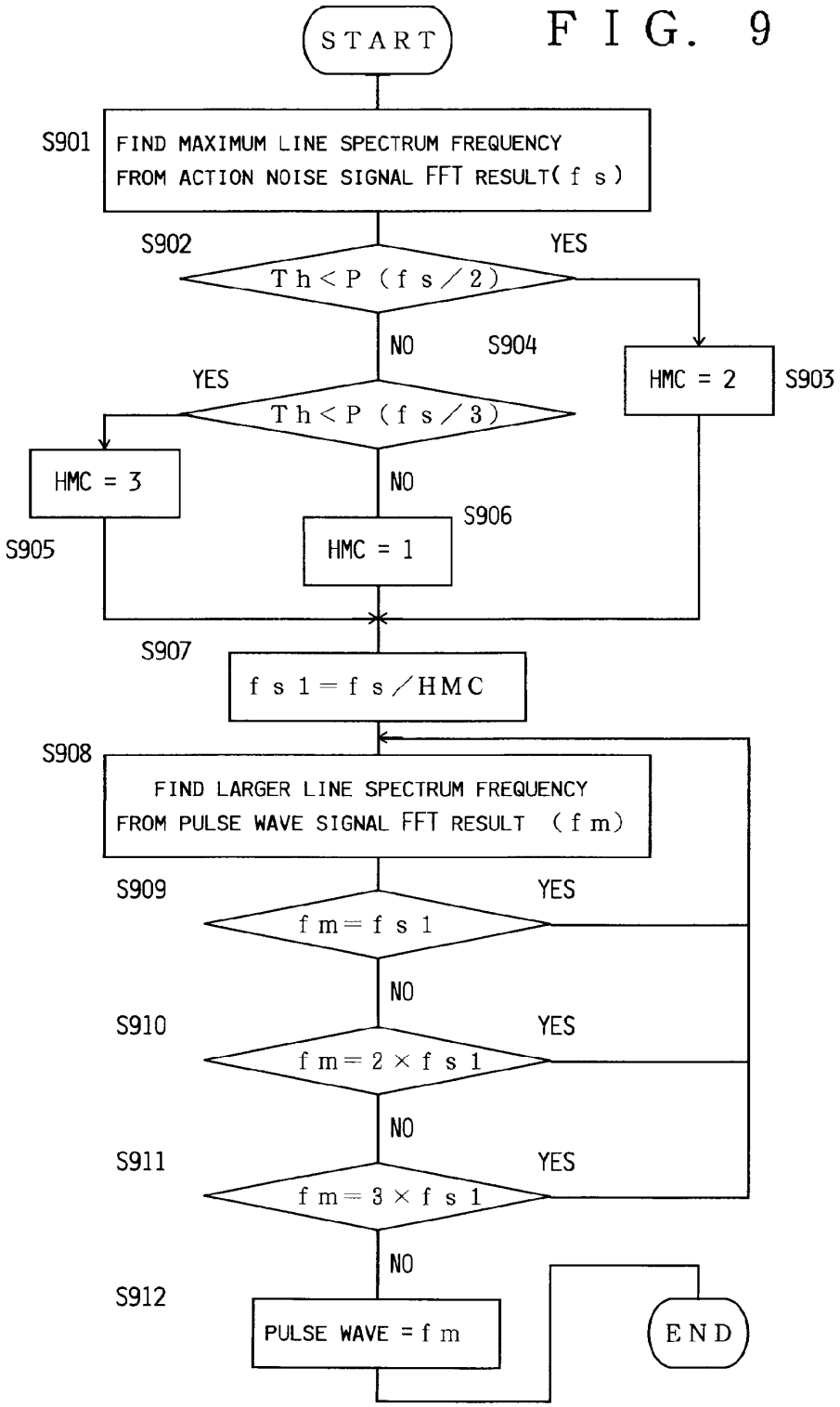

START
S901
FIND MAXIMUM LINE SPECTRUM FREQUENCY FROM ACTION NOISE SIGNAL FFT RESULT(f s)
S902
Th < P (f s / 2)
YES
HMC = 2
S903
NO
S904
Th < P (f s / 3)
YES
HMC = 3
S905
NO
S906
HMC = 1
S907
f s 1 = f s / HMC
S908
FIND LARGER LINE SPECTRUM FREQUENCY FROM PULSE WAVE SIGNAL FFT RESULT (f m)
S909
f m = f s 1
YES
NO
S910
f m = 2 × f s 1
YES
NO
S911
f m = 3 × f s 1
YES
NO
S912
PULSE WAVE = f m
END

FIG. 10

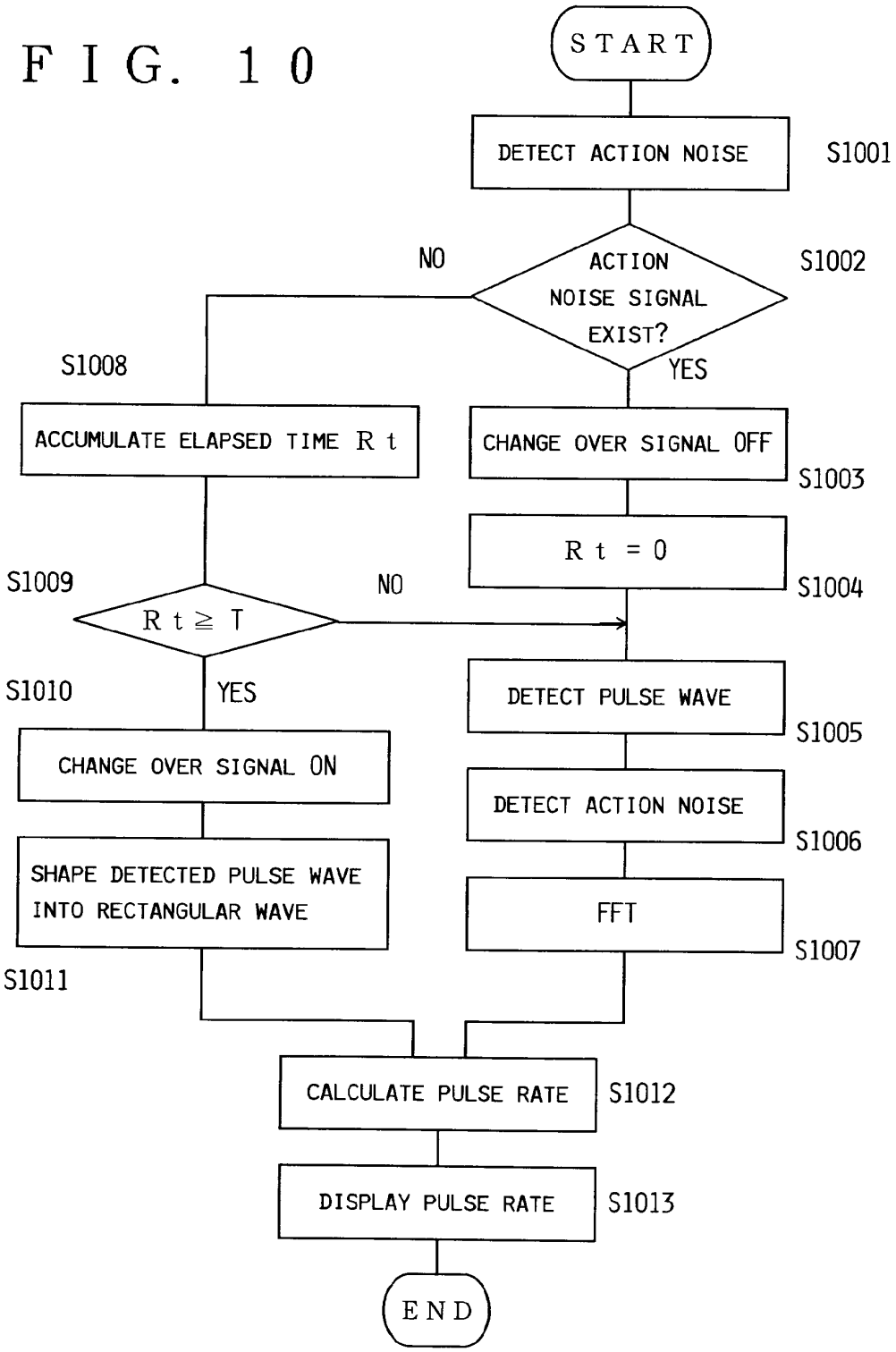

START
DETECT ACTION NOISE
S1001
ACTION NOISE SIGNAL EXIST?
S1002
NO
YES
S1008
ACCUMULATE ELAPSED TIME R t
CHANGE OVER SIGNAL OFF
S1003
R t = 0
S1004
S1009
R t ≥ T
NO
S1010
YES
DETECT PULSE WAVE
S1005
CHANGE OVER SIGNAL ON
DETECT ACTION NOISE
S1006
SHAPE DETECTED PULSE WAVE INTO RECTANGULAR WAVE
FFT
S1007
S1011
CALCULATE PULSE RATE
S1012
DISPLAY PULSE RATE
S1013
END

FIG. 11 PRIOR ART

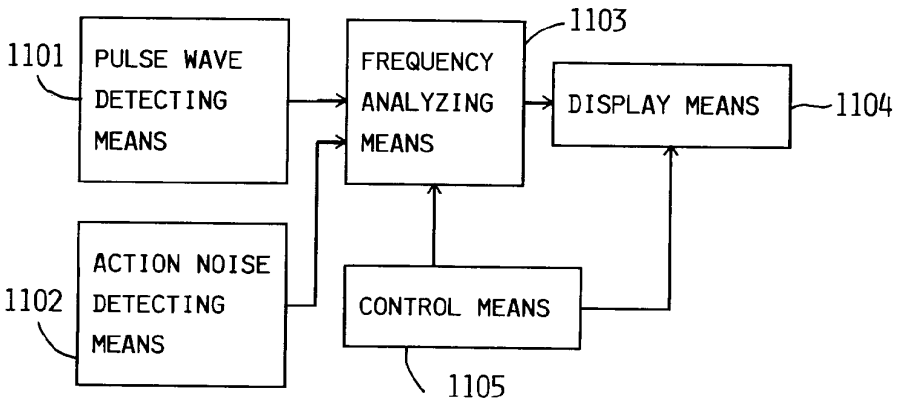


FIG. 12A

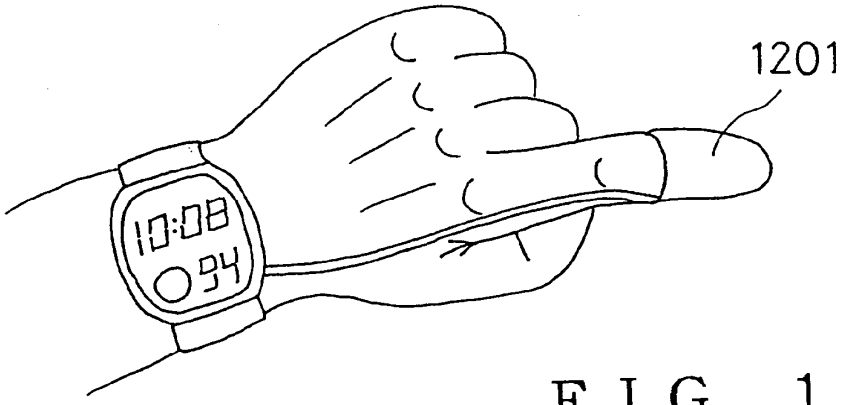


FIG. 12C

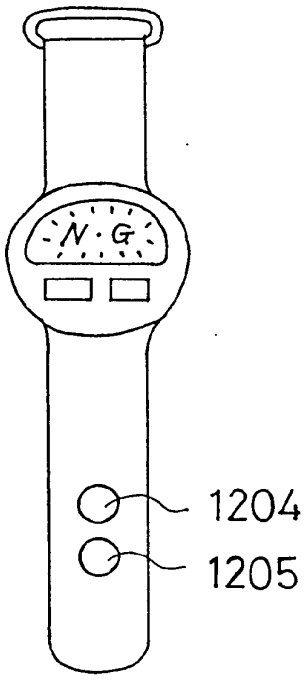


FIG. 12B

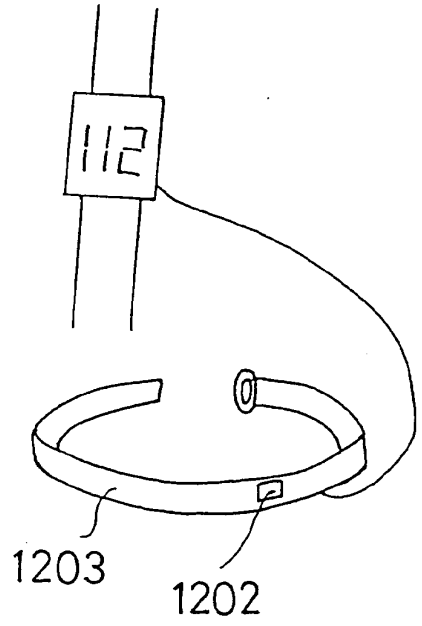


FIG. 13

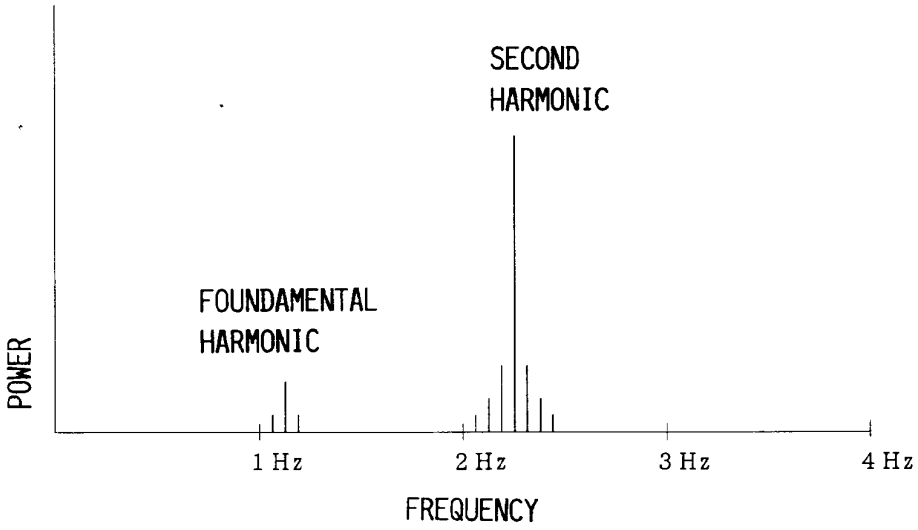
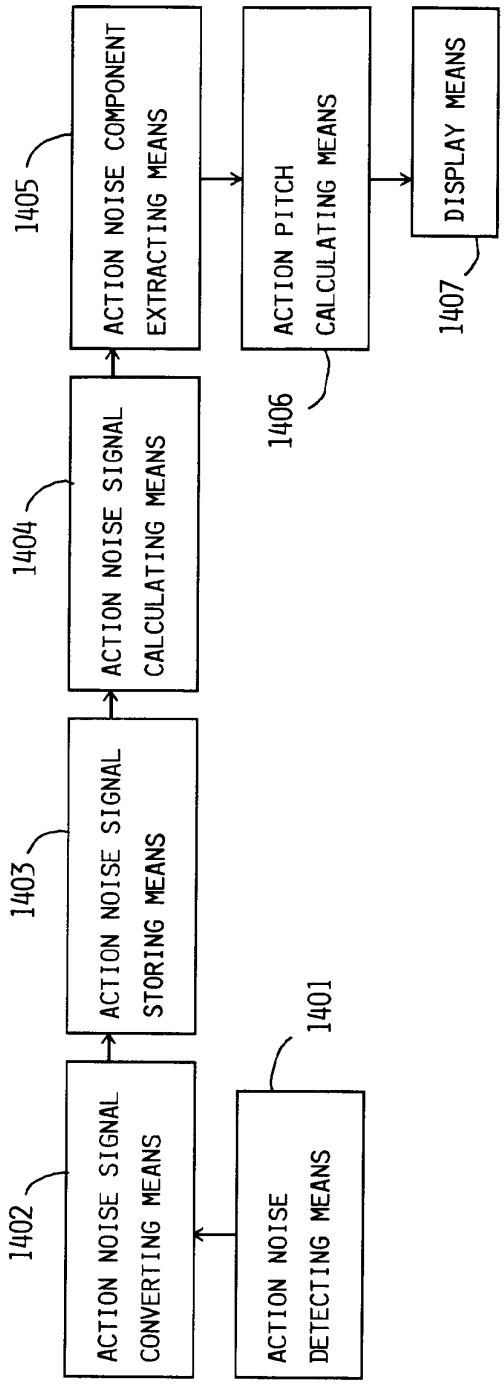

SECOND
HARMONIC
FOUNDAMENTAL
HARMONIC
POWER
1 Hz
2 Hz
3 Hz
4 Hz
FREQUENCY

FIG. 14


ACTION NOISE DETECTING MEANS
1401
ACTION NOISE SIGNAL CONVERTING MEANS
1402
ACTION NOISE SIGNAL STORING MEANS
1403
ACTION NOISE SIGNAL CALCULATING MEANS
1404
ACTION NOISE COMPONENT EXTRACTING MEANS
1405
ACTION PITCH CALCULATING MEANS
1406
DISPLAY MEANS
1407

European Patent Office

EUROPEAN SEARCH REPORT

Application Number EP 94309563.8

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	DE - A - 3 150 925 (HONEYWELL) * Totality *	1	A 61 B 5/0245
Y	--	2-11	
Y	US - A - 5 243 992 (ECKERLE) * Claims; figs. *	2-7, 9-11	
Y	-- DE - A - 4 001 574 (WALZ) * Abstract; figs. *	8	
A	-- US - A - 4 911 427 (MATSUMOTO) * Claims; figs. *	1,10, 11	

TECHNICAL FIELDS SEARCHED (Int. Cl. 6)

A 61 B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	22-02-1995	NARDAI

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

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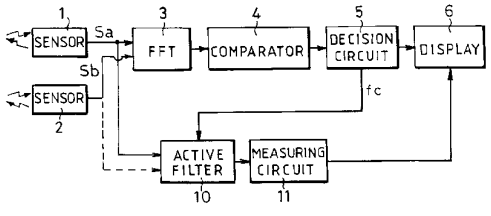
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(54) Blood pulse wave detecting apparatus and motion intensity measuring apparatus.

(57) An apparatus for detecting pulse waves and motion intensity of a living body in motion is disclosed. The apparatus has photosensors (1, 2) of the photocoupler type, for typically wavelengths of 660 nm and 940 nm, respectively. The sensors (1, 2) are attached to a person under examination, and provide output signals Sa and Sb which include a blood pulse signal as well as body motion components superimposed on the blood pulse signal. These signals Sa and Sb are subjected to Fourier transformation in a fast Fourier transformation circuit (3), and then applied to a comparator (4) which in turn compares amplitudes of major frequency components (components associated with pulse waves and body motion) to one another. According to the comparison result, a decision circuit (5) discriminates the pulse wave from the body motion. A display unit (6) displays the pulse rate corresponding to the fundamental frequency of the detected pulse wave. The display unit (6) also displays the change in motion intensity detected by the decision circuit (5). Thus, the present invention allows the detection of the change in motion intensity during the exercise of a person under the examination.

FIG.1.



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The present invention relates to a blood pulse wave detecting apparatus and motion intensity measuring apparatus. In particular, but not exclusively, the present invention performs accurate and reliable detection of the blood pulse rate, blood pulse waves, or motion intensity of a living body which is even in motion.

There are various types of known apparatus for detecting the blood pulse rate or blood pulse waves of a living body. However, most of these apparati can provide accurate detection only when a living body is at rest. This is because if the living body moves, a mixture of blood pulse wave and body movement is detected and it is impossible to extract the blood pulse wave.

The detection of the blood pulse rate or blood pulse waves of a living body is very important for control of excersizing or for health care. Therefore, there is a great need to achieve accurate blood pulse detection of a living body in motion.

One of the conventional blood pulse rate detectors is disclosed in Japanese Patent Publication No. 63-34731. When a pulse, showing a deviation from an average value, by an amount greater than an allowable limit is detected, the detection is cancelled so that only normal pulses can be detected. With this apparatus, extraordinary pulses arising, when a living body moves slightly for a short time, can be effectively cancelled, and thus only normal pulses can be detected.

In the conventional apparatus, however, if the living body makes continuous motions, the pulse will change very often and thus the detection will be cancelled so often that accurate detection of pulses will become impossible.

If the motion intensity of a living body in motion, in particular of a human body, can be measured, it will be possible to advantageously control the amount of motion. However, conventional techniques cannot measure the intensity of motion.

In view of the above, it is an object of the present invention to provide a blood pulse wave detecting apparatus which can distinguish blood pulses from body motion.

It is another object of the present invention to provide a motion intensity detecting apparatus for detecting the motion intensity of a living body.

According to a first aspect of the present invention to achieve the above objects, there is provided a blood pulse wave detecting apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; and discrimination means for making comparison of amplitudes of frequency components associated with each wavelength wherein the frequency components are included in a detected signal provided by the light detecting means, thereby discriminating a blood pulse wave of the living organism from its body motion wave according to the relationships between the ratios of the amplitudes of frequency components.

According to a second aspect of the present invention, there is provided a motion intensity measuring apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; discrimination means for making comparison of amplitudes of frequency components associated with each wavelength wherein the frequency components are included in a detected signal provided by the light detecting means, thereby discriminating a blood pulse wave of the living organism from its body motion wave according to the relationships between the ratios of the amplitudes of frequency components; and measuring means for making comparison of amplitudes of body motion associated with the different wavelengths wherein the amplitudes have been discriminated by the discrimination means, thereby measuring the motion intensity of the living organism according to the change in the ratio of the amplitudes of body motion.

According to a third aspect of the present invention, there is provided a motion intensity measuring apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; discrimination means for making comparison of amplitudes of frequency components associated with each wavelength wherein the frequency components are included in a detected signal provided by the light detecting means, thereby discriminating a blood pulse wave of the living organism from its body motion wave according to the relationships between the ratios of the amplitudes of frequency components; and measuring means for making comparison of the amplitude of the body motion to the amplitude of the blood pulse wave wherein the amplitudes of the body motion and blood pulse wave have been discriminated by the discrimination means, thereby measuring the motion intensity of the living organism according to the change in the ratio between the amplitudes.

According to a fourth aspect of the present invention, there is provided a motion intensity measuring apparatus based on the second or third aspect, wherein light having such a wavelength at which the absorbance of oxygen haemoglobin is equal to that of reduced haemoglobin is used as one of the light having different wavelengths, and wherein the measuring means employs the amplitude of a blood pulse wave included in a detected signal associated with this light as a refer-

ence value, and compares the amplitude of a blood pulse wave included in a detected signal associated with another light to the reference value, thereby measuring the motion intensity of a living organism.

According to a fifth aspect of the present invention, there is provided a motion intensity measuring apparatus based on the second, third, or fourth aspect, wherein at least one of means including the light detecting means, the discrimination means and the measuring means is adapted to be supplied with electric power only when measurement is carried out.

According to a sixth aspect of the present invention, there is provided a motion intensity measuring apparatus based on the second, third, or fourth aspect, wherein at least one of means including the light detecting means, the discrimination means and the measuring means is adapted to be supplied with electric power only when measurement is carried out at measurement timing which has been set in an intermittent fashion.

According to a seventh aspect of the present invention, there is provided a motion intensity measuring apparatus based on the fifth or sixth aspect, wherein the electric power is supplied in a pulse current form.

According to an eighth aspect of the present invention, there is provided a blood pulse wave detecting apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; frequency analyzing means for performing frequency analysis on a detected signal provided by the light detecting means, for each of light having the different wavelengths; and blood pulse frequency identifying means for identifying the blood pulse frequency of the living organism by determining which one of predefined modes the analysis result provided by the frequency analyzing means belongs to.

According to a ninth aspect of the present invention, there is provided a blood pulse wave detecting apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; Fourier transformation means for performing Fourier transformation on a detected signal provided by the light detecting means for each of the light having different wavelengths; and blood pulse frequency identifying means for identifying the blood pulse frequency of the living organism by comparing spectra provided by the Fourier transformation means for the respective different wavelengths thereby determining which one of predefined modes the comparison result belongs to.

According to a tenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus comprising: light detecting means for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; Fourier transformation means for performing Fourier transformation on a detected signal provided by the light detecting means for each of the light having different wavelengths; blood pulse frequency identifying means for identifying the blood pulse frequency of the living organism by comparing spectra provided by the Fourier transformation means for the respective different wavelengths thereby determining which one of predefined modes the comparison result belongs to; and filtering means for passing only the frequency component identified by the blood pulse frequency identifying means and its harmonics included in the detected signal provided by the light detecting means.

According to an eleventh aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on any one of the eighth through tenth aspects, further including: storage means for storing the identification result provided by the blood pulse frequency identifying means; and display means for displaying the content stored in the storage means.

According to a twelfth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the tenth aspect, further including: waveform storing means for storing an output waveform provided by the filtering means; and display means for displaying the content stored in the waveform storing means.

According to a thirteenth aspect of the present invention, there is provided a motion intensity measuring apparatus based on any one of the second through seventh aspects, further including: motion intensity storing means for storing a measurement result provided by the measuring means; and display means for displaying the measurement result stored in the motion intensity storing means.

According to a fourteenth aspect of the present invention, there is provided a motion intensity measuring apparatus based on any one of the second through fourth aspects, wherein the light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by the respective plurality of light emitting means, the plurality of light emitting means and the plurality of light receiving means being arranged in the lateral direction of a finger.

According to a fifteenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the first, eighth, ninth, or tenth aspect, wherein the light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by the respective plurality of light emitting means, the plurality of light emitting means and the plurality of light receiving means being arranged in the lateral direction of a finger.

According to a sixteenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the first, eighth, ninth or tenth aspect, wherein at least one of means including the light detecting means and the discrimination means is adapted to be supplied with electric power only when measurement is carried out.

According to a seventh aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the first, eighth, ninth, or tenth aspect, wherein at least one of means including the light detecting means and the discrimination means is adapted to be supplied with electric power only when measurement is carried out at measurement timing which has been set in an intermittent fashion.

According to an eighteenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the sixteenth or seventeenth aspect, wherein the electric power is supplied in a pulse current form.

According to a nineteenth aspect of the present invention, there is provided a blood pulse wave detecting apparatus based on the first, eighth, ninth, or tenth aspect, wherein the light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by the respective plurality of light emitting means, the plurality of light emitting means and the plurality of light receiving means being arranged in the lateral direction of a finger.

The apparatus according to the present invention operates as follows: When a living organism is illuminated with light having different wavelengths, the amount of light transmitted through or reflected from the living organism depends on absorbance of oxygen haemoglobin included in arterial blood and also depends on reduced haemoglobin included in venous blood. Furthermore, the absorbances of both oxygen haemoglobin and reduced haemoglobin depend on the wavelength of light in different conditions. When a living body is in motion, the body motion is superimposed on both arterial blood and venous blood. Therefore, the amount of light detected by the light detecting means is influenced by the absorbance, which is dependent on the wavelength, as well as the body motion. Thus, if the amplitudes of frequency components included in a signal detected by the light detecting means are compared to one another for each wavelength, the blood pulse wave can be discriminated from the body motion wave according to the relationships between the ratios of amplitudes (the first aspect).

The absorbance of reduced haemoglobin varies depending on its oxygen content, that is, on the motion intensity. Therefore, if the body motion wave is discriminated from the blood pulse wave, and furthermore the amplitudes of body motion waves are compared between different wavelengths, then the motion intensity of a living body can be measured according to the change in the ratio of the amplitudes (the second aspect). The motion intensity can also be measured according to the change in the ratio of the amplitude of the body motion wave to the amplitude of the blood pulse wave (the third aspect).

If light having a wavelength at which the absorbance of oxygen haemoglobin is equal to that of reduced haemoglobin is employed as one of measuring light rays, then the amount of received light associated with this light can be used as a reference value (the fourth aspect).

The blood pulse wave can also be identified by performing frequency analysis on a signal detected by the light detecting means and determining which one of predefined modes the analysis result belongs to (the fifth aspect).

The blood pulse frequency can be determined by performing Fourier transformation, which is one of ways to perform frequency analysis, and comparing the resultant spectra (the sixth aspect).

The blood pulse wave can be detected by using filter means which passes only a specific frequency component and its harmonics (the seventh aspect).

Embodiments of the present invention will now be described with reference to the accompanying drawings, of which:

Figure 1 is a block diagram illustrating the configuration of an embodiment of the present invention;

Figure 2 is a schematic diagram illustrating sensors for use in the embodiment, wherein the sensors are attached to a finger;

Figure 3 is a schematic representation of the "Lambert's" law;

Figure 4 is a schematic representation of an absorbance distribution of a human blood vessel illuminated with light;

Figure 5 is a graph illustrating the change in blood pulses as a function of distance from a heart from the left ventricle to the large vein;
Figure 6 is a graph illustrating absorbance characteristics of oxygen haemoglobin and reduced haemoglobin;
Figure 7 is a schematic diagram illustrating amplitudes of detected signal components corresponding to blood pulses and body motion, respectively, for both cases where the detection is carried out with light having wavelengths 660 nm and 940 nm;
Figure 8 is a schematic diagram illustrating the relationships of absorbance between arterial blood and venous blood for both cases where the detection is carried out with light having wavelengths 660 nm and 940 nm;
Figure 9 is a schematic diagram illustrating the method of determining the correspondence between two frequency components detected with two light rays having wavelengths of 660 nm, 940 nm and their origins to determine blood pulses and body motion;
Figure 10 is a graph illustrating frequency spectra of signals detected with light having wavelengths of 660 nm and 940 nm; and
Figure 11 is a schematic diagram illustrating an example of an actual measurement result regarding the change in the ratio of the amplitude associated with frequency 0_s to the amplitude associated with frequency 0_M wherein the measurement was carried out using light with a wavelength of 660 nm.

Detection Principle of the Invention

In the present invention, a pulse wave and motion intensity is detected according to the following principle:

(a) The Principle of Detecting Pulses via Light

First, the principle of detection of blood pulses via light will be described. When a thin film is illuminated with light, the ratio of the intensity of transmitted light to that of incident light will decreases depending on the density of matter and on the optical length. This fact is known well as the "Lambert's" law.

According to this law, the density of matter can be determined as follows: As shown in Figure 3(a), if the density of matter M is represented by C, a small optical length by 0L, the amount of incident light by I_{in}, the absorption factor of the matter M by k, then the following equation holds.

$$I_{out}/I_{in} = 1 - kC\Delta L \quad (1)$$

If the optical path is increased by a factor of 5 as shown in Figure (b), equation 1 becomes:

$$I_{out}/I_{in} = (1 - kC\Delta L)^5 \quad (2)$$

In Figure 3(a), for example, when the amount of incident light I_{in} is 10 and the amount of transmitted light is 9, then in the case of Figure 3(b), when the amount of incident light I_{in} is 10, the amount of transmitted light will be 10×0.9^5, or $I_{out}/I_{in} = 0.9^5$. i.e. $I_{out} = 5.9$.

The relationship between the amount of incident light and the amount of transmitted light for an arbitrary distance L can be obtained by integrating equation 1, thus:

$$\log(I_{out}/I_{in}) = (-kCL) \quad (3)$$

Equation 3 can be rewritten as:

$$I_{out} = I_{in} \times \exp(-kCL) \quad (4)$$

As can be seen from the above equation, if the amount of incident light I_{in}, the absorption factor k, and the optical length L are all maintained constant, then it is possible to measure the change in density of matter M by detecting the amount of transmitted light I_{out}.

Instead of detecting the amount of transmitted light, it is also possible to measure the change in density by detecting the amount of the light reflected from the matter M according to the same principle.

When a human blood vessel is illuminated with external light, the distribution of the absorption factor will be such as that shown in Figure 4. In the figure, I_2 represents the absorption caused by tissue, I_3 represents the absorption caused by venous blood, and I_4 represents the absorption caused by arterial blood.

Because the density of tissue does not change, the absorption I_2 caused by tissue is constant. The absorption I_3 by venous blood is also constant. This is because there is no pulsation in venous blood and therefore there is no change in its density. This can be seen apparently from Figure 5, which shows the decay of pulsation of blood sent from a heart compared to the distance from the heart. When blood reaches a vein, pulsation no longer occurs.

On the other hand, the absorption I_4 by arterial blood shows a change corresponding to the change in density induced by pulses. This means that pulses can be detected by illuminating a blood vessel with light and detecting the change in the amount of reflected or transmitted light. The above-described detection principle is also disclosed in Japanese Patent Laid-Open No. 2-44534.

If a human body is in motion, the body movement influences the flow of blood through the vessels including veins. As a result, the flow of venous blood becomes dynamic. This produces a change in light absorption of venous blood. Similarly, when arms or legs are in a swinging motion, vibrations of tissue also produce a change in its light absorption. Therefore, when a human body is in motion, simple detection of the amount of light reflected from or transmitted through a vessel cannot detect pulses.

(b) The Principle of Detecting Pulse Waves of a Living Body in Motion

The principle of detecting the pulse rate of a living body in motion will be described below.

Curves C1 and C2 in Figure 6 represent the absorption spectrum of haemoglobin. Haemoglobin combined with a sufficient amount of oxygen will be referred to as oxygen haemoglobin hereafter and which is provided by a heart. Reduced haemoglobin is that returning to the heart through a vein: the oxygen of which has been consumed by a body. As shown in Figure 6, the absorbance depends on the wavelength of light. The oxygen haemoglobin shows strong absorption of light in an infrared range (with a peak at 940 nm), and the reduced haemoglobin shows strong absorption of light in a red range (with a peak at 660 nm). Both types of haemoglobin have similar absorbance for light near 805 nm.

The difference in absorption characteristics between the two types of haemoglobin results from the difference in the amount of oxygen. The absorption spectrum changes from curve C1 to C2 with the consumption of oxygen.

When a human body is in motion, it consumes a greater amount of oxygen than when it is at rest. Therefore, the absorption characteristic of reduced haemoglobin varies depending on the amount of consumed oxygen. In contrast, it is known that the oxygen content combined with haemoglobin in arterial blood (or oxygen saturation ratio of arterial blood) is maintained constant regardless of the motion intensity. Therefore, if absorption is measured for different wavelengths, the motion intensity of a living body can be determined by comparing the results obtained at different wavelengths. In this technique, if the measurement is carried out for example at 940 nm and 660 nm, it is possible to achieve emphasized detection of motion intensity.

When a living body is in motion, because the body movement influences the flow of blood, the light transmitted through or reflected from a vessel includes pulses produced by the body movement superimposed on normal pulses. These body movement components should be distinguished. Otherwise, it would be impossible to detect either normal pulses or motion intensity. This point will be further discussed below.

The detection of pulse waves of a living body at rest by means of light can be represented by the following equation:

The amount of received light =
The amount of emitted light
- The amount of light absorbed by tissue
- K_{artery}•(Artery DC component + Pulse amplitude•$F(\theta_M)$)
- K_{vein}•Vein level (5)

where K_{artery} is the absorbance of arterial blood, K_{vein} is the absorbance of venous blood, Artery DC component is the DC component (constant component) of arterial blood, Vein level is the flow rate of venous blood (which has no pulse component as described above). Furthermore, $F(\theta_M)$ is the AC component of arterial blood, or a periodic function representing an amplitude (pulse amplitude) of the amount of haemoglobin which varies in an AC fashion at frequency θ_M.

When the living body is in motion, pulse components induced by the body movement are superimposed on both artery and vein blood flow. The amount of light which is received when the living body is in motion can be represented by adding these components to equation 5. For example, when an arm is in swing motion, the following equation holds:

The amount of received light =
The amount of emitted light
- The amount of light absorbed by tissue
- K_{artery}•(Artery DC component + Pulse amplitude•$F(0_M)$ + Arm amplitude•$F'(\theta_s)$)
- K_{vein}•(Vein level + Arm amplitude•$F'(\theta_s)$ (6)

In this equation, arm amplitude•$F'(\theta_s)$ is a periodic function having an amplitude (arm amplitude) of an AC component corresponding to the variation in the amount of haemoglobin induced by strokes of an arm and having a frequency of θ_s.

The amount of received light represented by equation 6 can be further modified, as shown in the following equations, for the case where the detection is done at two different wavelengths (660 nm and 940 nm in this example).

The amount of received light (660) =
The amount of emitted light (660)
- The amount of light absorbed by tissue (660)
- $K_{artery660}$•(Artery DC component + Pulse amplitude•$F(\theta_M)$ + Arm amplitude•$F'(\theta_s)$)
- $K_{vein660}$•(Vein level + Arm amplitude•$F'(\theta_s)$ - (7)

The amount of received light (940) =
The amount of emitted light (940)
- The amount of light absorbed by tissue (940)
- $K_{artery940}$•(Artery DC component + Pulse amplitude•$F(\theta_M)$ + Arm amplitude•$F'(\theta_S)$)
- $K_{vein940}$•(Vein level + Arm amplitude•$F'(\theta_S)$ - (8)

In the above equations 7 and 8, subscripts 660 and 940 represent wavelengths at which the detection is done, and the terms or coefficients having the subscripts represent the values at the corresponding wavelengths.

The amount of light given by equation 7 or 8, which will be referred to as a "received signal" hereafter, is a periodic function represented in the time domain. If each received signal is subjected to Fourier transformation, amplitudes of frequency components included in each received signal can be detected. In Figure 7(a), for example, the amplitude corresponding to $K_{artery660}$•Pulse amplitude, or the amplitude of the frequency component associated with pulses of arterial blood, is detected at frequency 0_M for the wavelength of 660 nm, and the amplitude corresponding to ($K_{artery660}$ + $K_{vein660}$)Arm amplitude or the amplitude of the frequency component associated with strokes of an arm superimposed on both vein and artery is detected at frequency 0_s. As shown in Figure 7(b), similar amplitudes are also detected at the same frequencies in the case of the wavelength of 940 nm.

If the absorbance characteristics shown in Figure 6 are taken into accounts, the relationships in absorbance between arterial blood and venous blood for respective wavelengths are such as those shown in Figure 8, or represented by the following inequalities:

$$K_{artery660} < K_{vein660},\ K_{artery940} > K_{vein940} \quad (9)$$

For example, as shown in Figure 9, when amplitudes of components at frequencies f_1 and f_2 are a and b, respectively, for the wavelength of 660 nm, and c and d, respectively, for the wavelength of 940 nm, if (a/b) < (c/d) or (c/a) > (d/b), then it is concluded that f_1 is the frequency corresponding to arterial blood pulses, and f_2 is the frequency corresponding to arm swinging.

Once the frequency which corresponds to arterial blood pulses has been detected, the pulse rate can be determined by converting the frequency to a number of pulses per minute. In this way, the pulse rate of a living body in motion can be detected.

Figure 10 illustrates one example of experimental results, wherein Figures 10(a) and 10(b) frequency spectra of signals detected for wavelengths of 660 nm and 940 nm, respectively. In this experiment, a man under examination swung his arms at a constant rate in synchronism with a metronome as in running, and the pulses were measured by an electrocardiograph for verification. In Figures 10(a) and 10(b), S1 denotes a fundamental frequency of arm strokes (body motion), S2 denotes the second-order harmonic of the arm strokes, and M1 denotes the fundamental frequency of blood pulses (that is, the pulse rate).

If the ratio of M1 to S1 is compared between the ratio shown in Figure 10(a) and the ratio shown in Figure 10(b), it is concluded from the above relationships that M1 represents pulses. The pulse ratio obtained in this way shows good agreement with that obtained by the electrocardiograph.

(c) The Principle of Detecting Motion Intensity

If the arterial blood pulse frequency and the body motion frequency are discriminated, the motion intensity of a living body can be detected by comparing amplitudes of these frequency components. In Figures 9(a) and 9(b), the amplitude of the frequency component 0_s representing the body motion (strokes) depends on the light absorbance of arterial and venous blood. The absorbance of arterial blood is constant regardless of the change in motion intensity, while the absorbance of venous blood varies depending on the motion intensity (the amount of oxygen consumption). As a result, the motion intensity can be determined as follows:

(1) The amplitude at frequency 0_s associated with the wavelength of 660 nm or 940 nm is sampled in a proper manner. The change in motion intensity of a living body in motion can be detected from the change in the sampled value which reflects the motion intensity.

(2) If the comparison of the ratio of the amplitude at frequency 0_s to the amplitude at frequency 0_M is made between wavelengths of 660 nm and 940 nm, the ratio reflects the motion intensity because the amplitude at frequency 0_M is independent of the motion intensity. From the change in this ratio, therefore, it is possible to detect the change in motion intensity of a living body. If the relationship between the above ratio and the motion intensity has been examined and stored in memory, the motion intensity can be determined by referring to the information stored in the memory.

Figure 11 illustrates actually-measured data with respect to the ratio of the amplitude at frequency 0_s to the amplitude at frequency 0_M - (corresponding to the ratio a/b in Figure 9) for the wavelength of 660 nm. In this measurement, a man under examination was forced to do

continuous motion, and the amplitudes at various frequencies were measured. The ratios of amplitudes are plotted as a function of the pulse rate. As represented by the alternate long and short dash line in Figure 11, the plotted points show a tendency to increase with the pulse rate. An increase in pulse rate can be regarded as an increase in motion intensity. An increase in motion intensity results in an increase in oxygen consumption of blood, and thus results in an increase in light absorbance. As a result, the amplitude at frequency 0_s (which corresponds to "b" in Figure 9) decreases with increasing motion intensity, and thus the ratio a/b increases. Therefore, the motion intensity can be detected from the change in ratio a/b.

(3) Light having a wavelength of about 805 nm is used to give a reference value of an amount received light. At this wavelength, both oxygen haemoglobin and reduced haemoglobin have constant absorbance, as shown in Figure 6. Therefore, the received signal associated with light having such a wavelength can be used to give a reference value which is compared to the amplitude of a component having a frequency of 0_s included in a received signal associated with light having another wavelength. From the change of this ratio, the motion intensity can be detected.

(d) The Principle of Detecting the Pulse Waveform of a Living Body in Motion

If the frequency reflecting artery blood pulses can be distinguished in the above-described manner, it is possible to detect a pulse waveform by using a filter which can pass this frequency and its harmonics.

A pulse wave consists of a fundamental wave and various orders of harmonics. If these components are extracted using a filter which can pass these components but which cannot pass the other frequency components, the pulse wave associated with a living body in motion is detected.

B: The Construction of Embodiments

Figure 1 is a block diagram illustrating the construction of one embodiment of this invention. In this figure, reference numerals 1 and 2 denote photosensors of the photo-coupler type for wavelengths 660 nm and 940 nm, respectively. As shown in Figure 2(a), these sensors 1 and 2 are disposed in a proper cap. The cap is adapted to be attached to the end portion of a finger in such a manner that sensors 1 and 2 are arranged in the longitudinal direction of the finger. Otherwise, the cap may also be adapted such that the sensors 1 and 2 are arranged in the lateral direction of a finger when the cap is attached to the finger.

The light beams emitted by the sensors 1 and 2 are reflected from blood vessels or tissue, and detected by photo-sensing elements of the sensors 1 and 2. As shown in Figure 1, the detected signals are applied as signals Sa and Sb, respectively, to a fast Fourier transformation circuit 3. The fast Fourier transformation circuit 3 performs Fourier transformation on signals Sa and Sb, and provides frequency spectra associated with these signals. The frequency spectra provided by the fast Fourier transformation circuit 3 are applied to a comparator 4. The comparator 4 stores the frequency spectra temporarily, and compares the magnitudes of major lines included in the spectra with one another. For example, the magnitudes of S1 and M1 shown in Figure 10(a) are compared. Similarly, the magnitudes of S1 and M1 shown in Figure 10(b) are compared. The comparison results are supplied to a decision circuit 5. Referring to comparison result patterns stored in advance, the decision circuit 5 determines which frequency corresponds to pulses and which one corresponds to body motion.

As described above, if the amplitudes a, b, c, and d of frequency components f_1 and f_2 shown in Figure 9 satisfy the relationship (a/b) < (c/d) or (c/a) > (d/b), then it is decided that frequency f_1 corresponds to arterial blood pulses, and that frequency f_2 corresponds to arm strokes. According to the decision made by the decision circuit 5, a display unit 6 including a liquid crystal display element or the like converts the frequency fc, which has been considered to correspond to the pulse rate, into a frequency per minute, and displays it on the display element.

According to the comparison results provided by the comparator 4, the decision circuit 5 detects the change in motion intensity from the ratio of the amplitude at frequency S1 to the amplitude at frequency at M1 associated with the wavelength of 660 nm or 940 nm, and outputs a signal representing the detection result to the display unit 6. The display unit 6 displays the change of motion intensity in a numerical or graphic fashion.

An active filter 10 extracts the frequency fc considered to correspond to blood pulses and its harmonics (for example, up to fifth- or sixth-order harmonics) from the output signal Sa or Sb outputted by the sensor 1 or 2. Therefore, the output signal of the active filter 10 consists of a pure pulse wave signal containing no stroke components (body motion components).

A measuring circuit 11 performs various kinds of measurement on the basis of the pulse wave signal provided by the active filter 10. For example, experiments have revealed that the ratio of the amplitude of the second-order harmonic to the am-

plitude of the third-order harmonic reflects the stress. It is also known that the mental and physical status can be measured from characteristic features of pulse waves. Thus, the measuring circuit 11 analyzes the pulse waves according to predetermined analytic methods, and outputs a signal representing the result to the display unit 6. The display unit 6 displays the measured result according to the output signal of the measuring circuit 11.

C: The Operation of the Embodiment

First, a person to be examined attaches the cap shown in Figure 2 to one of his or her fingers, and then exercises (runs, for example). Signals Sa and Sb including a blood pulse wave and body motion components superposed on it are obtained. These signals Sa and Sb are subjected to Fourier transformation in the fast Fourier transformation circuit 3. Then, amplitudes of major frequency components are compared to one another by the comparator 4. According to the comparison result, the decision circuit 5 discriminates the pulse wave and the body motion. The display unit 6 displays a pulse rate corresponding to the fundamental frequency of the pulse wave. The display unit 6 stores the pulse rate, and continues displaying this stored value until the pulse rate has been updated. The display unit 6 also displays the change of motion intensity detected by the decision circuit 5. Thus, during the exercise, it is possible to observe the change in motion intensity of the person under examination.

The active filter 10 extracts only pulse wave components and outputs them to the measuring circuit 11, which in turn performs measurement. In this way, the pulse wave of the person in motion is detected, and his (her) mental and physical status is detected from the pulse wave form. The detected results are displayed on the display unit 6 so that the mental and physical status (stress, for example) can be observed during his (her) exercising.

In the above example, the comparator 4 makes comparison of amplitudes between the fundamental wave of a pulse wave and the fundamental wave of body motion. However, the invention is not limited only to such comparison. The comparator 4 may also compare for example the fundamental wave of a pulse wave to the second-order harmonic of body motion, or compare the second-order harmonic of the pulse wave to the fundamental wave of body motion. Basically, any waves which can be discriminated clearly can be designated to be used in comparison. In some cases, body motion of a person under examination does not have periodicity. In this case, since major frequency components obtained by the Fourier transformation all result from blood pulses, it is much easier to discriminate the pulse wave. In the comparator 4 of this embodiment, when the output signal of the fast Fourier transformation circuit 3 contains only one fundamental wave and its harmonics, it is concluded that only blood pulse wave are detected, and its fundamental wave is regarded as blood pulses.

D: Modifications

The aforegoing description has been given by way of example only and it will be appreciated by a person skilled in the art that modifications can be made without departing from the scope of the present invention.

The above-described embodiment can be modified as follows:

(1) In the above embodiment, sensors are attached to the end portion of a finger to detect pulse waves at the end of the finger. Alternatively, the sensors may also be attached in such a manner that pulse waves at the root portion of a finger can be detected. Furthermore, the sensors may also be attached to detect blood pulses at a radius of a limb or at an ear. In addition to those described above, the sensors may be attached to an arbitrary portion as long as an artery and vein passing through that portion can be illuminated with light.

(2) In the above embodiment, sensors are attached with a cap (refer to Figure 2). However, the sensors may also be attached in a different manner. For example, a glove, band, tape, or the like may be used to attach the sensors to a portion to be detected.

(3) In the above embodiment, the Fourier transformation is utilized to perform frequency analysis on a sensed signal. Alternatively, discrete Fourier transformation or maximum entropy scheme may be employed. Basically, any method, which can extract frequency components included in a sensed signal and can compare amplitudes of these components to one another, can be employed.

(4) In the above embodiment, light beams having wavelengths of 660 nm and 940 nm are used for measurement. However, the wavelength is not limited only to those. Arbitrary wavelengths which lead to a difference in absorbance between oxygen haemoglobin and reduced haemoglobin may be employed.

(5) Furthermore, a light ray having a wavelength of 805 nm can be used as a reference light ray for measurement. At this wavelength, as shown in Figure 6, there is no difference in absorbance between oxygen haemoglobin and reduced haemoglobin. Therefore, the received signal associated with the light having this wavelength

can be used to give a reference value which is compared to the amplitude of a component having a frequency of θ_s included in a received signal associated with light having another wavelength. From the change of this ratio, the absolute value of the motion intensity can be detected.

(6)According to the above embodiment, it is possible to detect the frequency of body motion. Therefore, arm strokes during walking or running can be detected. Because the arm strokes correspond to the pitch of walking or running, the detection of body motion frequency allows the detection of the sum of step number. That is, the embodiment of this invention can also be used as a pedometer.

(7) The measuring circuit 11 may be adapted to include a pulse wave memory to store pulse waves outputted by the active filter 10, and pulse waves stored in the pulse wave memory may be displayed on the display unit 6. This arrangement allows visual recognition of the pulse wave form. This facilitates a grasp of the mental and physical status of a person under examination.

(8) There may be provided a motion intensity memory for temporarily storing the motion intensity detected by the decision circuit 5, and the motion intensity (or the change in motion intensity) stored in the motion intensity memory may be displayed on the display unit 6. This arrangement allows visual recognition of the motion intensity (or the change in motion intensity). This facilitates a grasp of more detailed mental and physical status of a person under examination.

(9) There may be provided a switch for performing on-off control of electric power thereby supplying the power to the entire circuit shown in Figure 1 or a specific part of the circuit only when measurement is carried out.

Furthermore, the above embodiment can be modified such that measurement is carried out at predetermined times. That is to say, electric power is intermittently supplied to the entire circuit or a specific part of the circuit only at the predetermined times for the measurement. In this case, the measurement timing can be set using a timer implemented in a hardware circuit or can be programmed in a microcomputer.

Furthermore, in either case where the electric power is supplied in on-off switching fashion or intermittent fashion, the power may be supplied in the form of a pulse current, thereby achieving a great reduction in power consumption.

According to the present invention, as described above, it is possible to perform accurate and reliable detection of the pulse ratio or the pulse wave of a living body which is even in continuous motion. Furthermore, it is also possible to detect the motion intensity during the motion of a living body.

Claims

1. A blood pulse wave detecting apparatus characterised by comprising:

   light detecting means (1,2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths; and

   discrimination means (3, 4, 5, 10, 11) for making comparison of amplitudes of frequency components associated with each said wavelength wherein said frequency components are included in a detected signal provided by said light detecting means, thereby discriminating a blood pulse wave of said living organism from its body motion wave according to the relationships between the ratios of said amplitudes of frequency components.

2. A motion intensity measuring apparatus characterised by comprising:

   light detecting means (1, 2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

   discrimination means (3, 6, 10, 11) for making comparison of amplitudes of frequency components associated with each said wavelength wherein said frequency components are included in a detected signal provided by said light detecting means, thereby discriminating a blood pulse wave of said living organism from its body motion wave according to the relationships between the ratios of said amplitudes of frequency components; and

   measuring means (4) for making comparison of amplitudes of body motion associated with said different wavelengths wherein said amplitudes have been discriminated by said discrimination means,thereby measuring the motion intensity of said living organism according to the change in the ratio of said amplitudes of body motion.

3. A motion intensity measuring apparatus characterised by comprising:

   light detecting means (1,2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

   discrimination means (3, 5, 10, 11) for making comparison of amplitudes of frequency components associated with each said

wavelength wherein said frequency components are included in a detected signal provided by said light detecting means, thereby discriminating a blood pulse wave of said living organism from its body motion wave according to the relationships between the ratios of said amplitudes of frequency components; and

measuring means (14) for making comparison of the amplitude of the body motion to the amplitude of the blood pulse wave wherein the amplitudes of the body motion and blood pulse wave have been discriminated by said discrimination means, thereby measuring the motion intensity of said living organism according to the change in the ratio between the amplitudes.

4. A motion intensity measuring apparatus according to Claim 2 or 3, wherein light having such a wavelength at which the absorbance of oxygen haemoglobin is equal to that of reduced haemoglobin is used as one of said light having different wavelengths, and wherein said measuring means employs the amplitude of a blood pulse wave included in a detected signal associated with this light as a reference value, and compares the amplitude of a blood pulse wave included in a detected signal associated with another light to said reference value, thereby measuring said motion intensity of a living organism.

5. A motion intensity measuring apparatus according to Claim 2, 3, or 4 wherein at least one of means including said light detecting means, said discrimination means and said measuring means is adapted to be supplied with electric power only when measurement is carried out.

6. A motion intensity measuring apparatus according to Claim 2, 3, or 4 wherein at least one of means including said light detecting means, said discrimination means and said measuring means is adapted to be supplied with electric power only when measurement is carried out at measurement timing which has been set in an intermittent fashion.

7. A motion intensity measuring apparatus according to Claim 5 or 6 wherein said electric power is supplied in a pulse current form.

8. A blood pulse wave detecting apparatus characterised by comprising:

light detecting means (1,2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

frequency analyzing (3) means for performing frequency analysis on a detected signal provided by said light detecting means, for each of light having said different wavelengths; and

blood pulse frequency identifying means (5) for identifying the blood pulse frequency of said living organism by determining which one of predefined modes the analysis result provided by said frequency analyzing means belongs to.

9. A blood pulse wave detecting apparatus characterised by comprising:

light detecting means (1, 2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

Fourier transformation means (3) for performing Fourier transformation on a detected signal provided by said light detecting means for each of said light having different wavelengths; and

blood pulse frequency identifying means (5) for identifying the blood pulse frequency of said living organism by comparing spectra provided by said Fourier transformation means for said respective different wavelengths thereby determining which one of predefined modes the comparison result belongs to.

10. A blood pulse wave detecting apparatus characterised by comprising:

light detecting means (1, 2) for detecting the amount of light transmitted through or reflected from a living organism illuminated with light having different wavelengths;

Fourier transformation means (3) for performing Fourier transformation on a detected signal provided by said light detecting means for each of said light having different wavelengths;

blood pulse frequency identifying means (5) for identifying the blood pulse frequency of said living organism by comparing spectra provided by said Fourier transformation means for respective said different wavelengths thereby determining which one of predefined modes the comparison result belongs to; and

filtering means (10) for passing only the frequency component identified by said blood pulse frequency identifying means and its harmonics included in the detected signal provided by said light detecting means.

11. A blood pulse wave detecting apparatus according to any one of Claims 8 through 10, further including:

storage means for storing the identification result provided by said blood pulse frequency identifying means; and

display means for displaying the content stored in said storage means.

12. A blood pulse wave detecting apparatus according to Claim 10, further including:

waveform storing means for storing an output waveform provided by said filtering means; and

display means for displaying the content stored in said waveform storing means.

13. A motion intensity measuring apparatus according to any one of Claims 2 through 7, further including:

motion intensity storing means for storing a measurement result provided by said measuring means; and

display means for displaying the measurement result stored in said motion intensity storing means.

14. A motion intensity measuring apparatus according to any one of Claims 2 through 4, wherein said light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by respective said plurality of light emitting means, said plurality of light emitting means and said plurality of light receiving means being arranged in the lateral direction of a finger.

15. A blood pulse wave detecting apparatus according to Claim 1, 8, 9, or 10, wherein said light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by respective said plurality of light emitting means, said plurality of light emitting means and said plurality of light receiving means being arranged in the lateral direction of a finger.

16. A blood pulse wave detecting apparatus according to Claim 1, 8, 9 or 10 wherein at least one of means including said light detecting means and said discrimination means is adapted to be supplied with electric power only when measurement is carried out.

17. A blood pulse wave detecting apparatus according to Claim 1, 8, 9 or 10 wherein at least one of means including said light detecting means and said discrimination means is adapted to be supplied with electric power only when measurement is carried out at measurement timing which has been set in an intermittent fashion.

18. A blood pulse wave detecting apparatus according to Claim 16 or 17 wherein said electric power is supplied in a pulse current form.

19. A blood pulse wave detecting apparatus according to Claim 1, 8, 9 or 10, wherein said light detecting means includes a plurality of light emitting means for emitting light rays having different wavelengths, and further includes a plurality of light receiving means for receiving reflected light associated with the light rays emitted by respective said plurality of light emitting means, said plurality of light emitting means and said plurality of light receiving means being arranged in the lateral direction of a finger.

FIG.1.

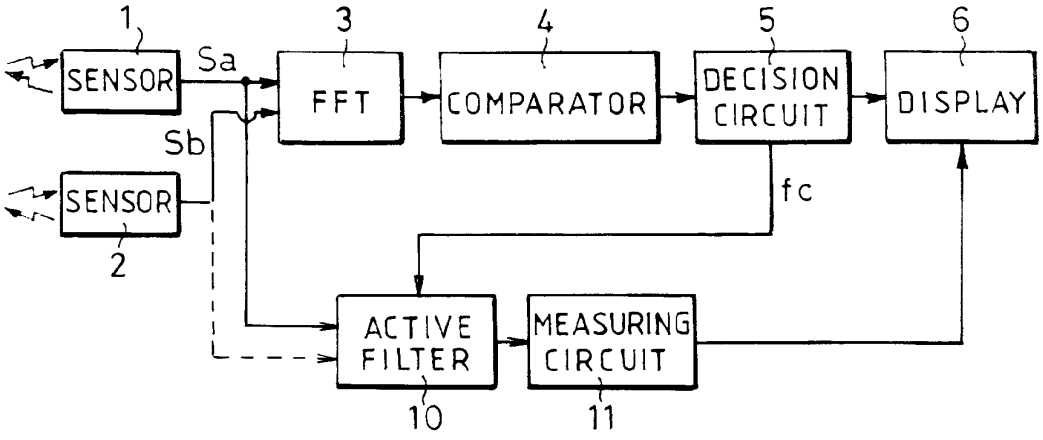
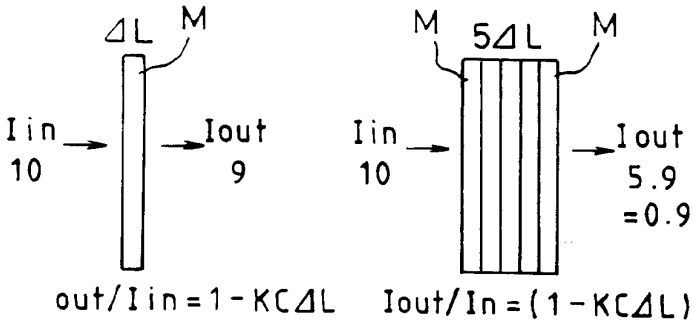

1
3
4
5
6
SENSOR
Sa
FFT
COMPARATOR
DECISION CIRCUIT
DISPLAY
Sb
SENSOR
2
fc
ACTIVE FILTER
MEASURING CIRCUIT
10
11

FIG.2


(a)
(b)
CAP
CAP
1
2
1
2



K:ABSORPTION FACTOR
L:OPTICAL LENGTH

SCHEMATIC REPRESENTATION OF THE LAMBERT'S LAW

FIG. 3

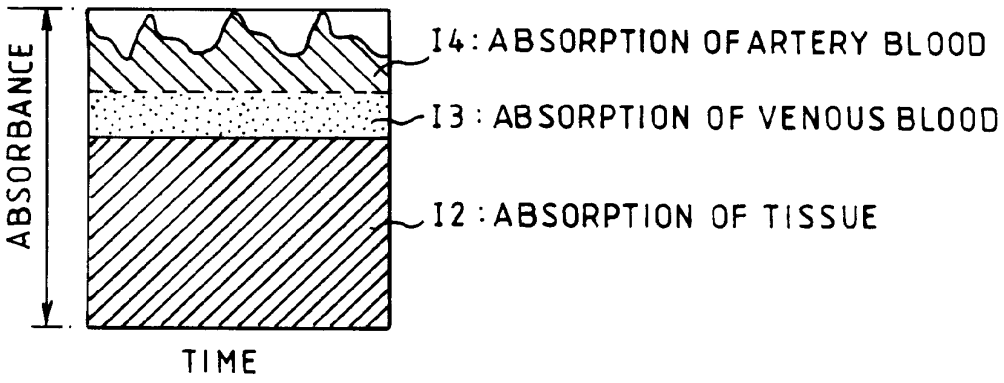


FIG.4

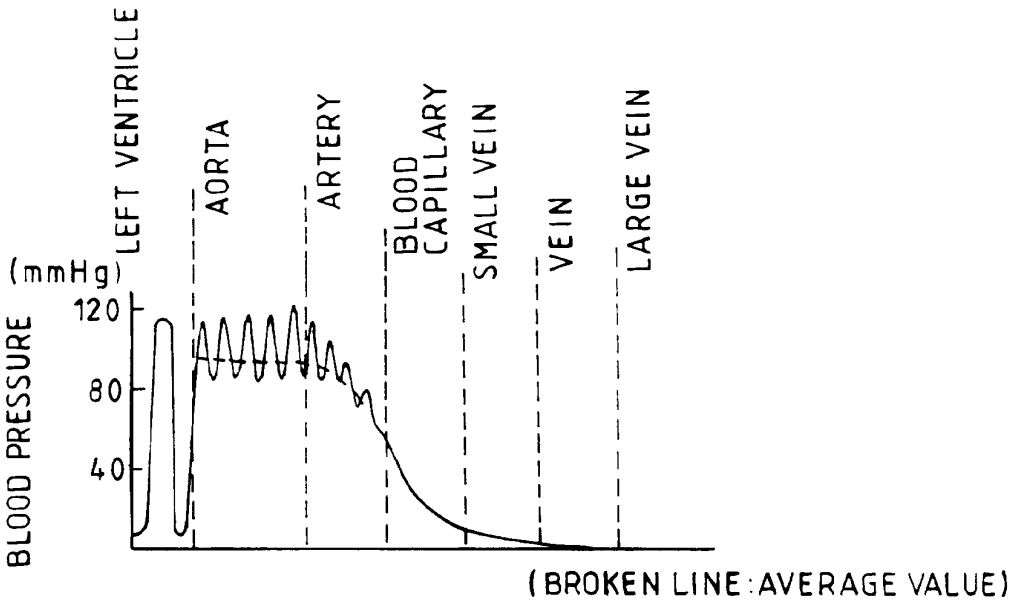
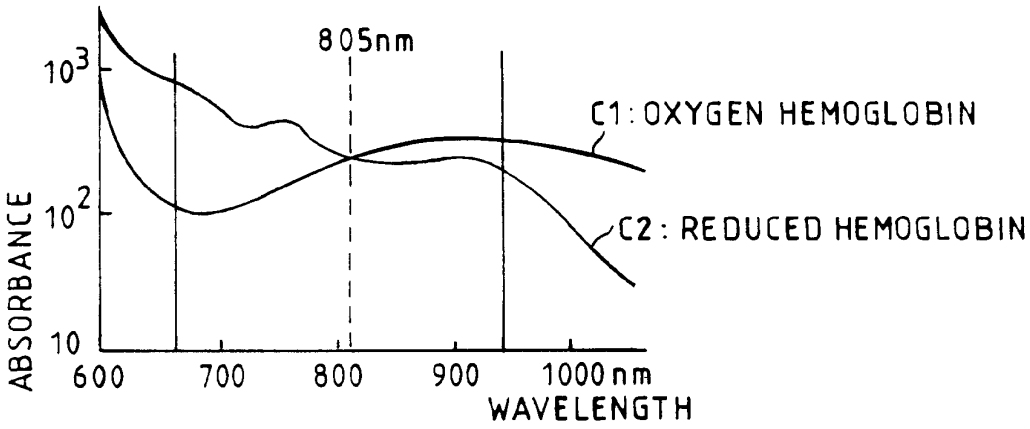


FIG.5



ABSORPTION SPECTRA OF REDUCED HEMOGLOBIN AND OXYGEN HEMOGLOBIN

FIG.6

FIG.7

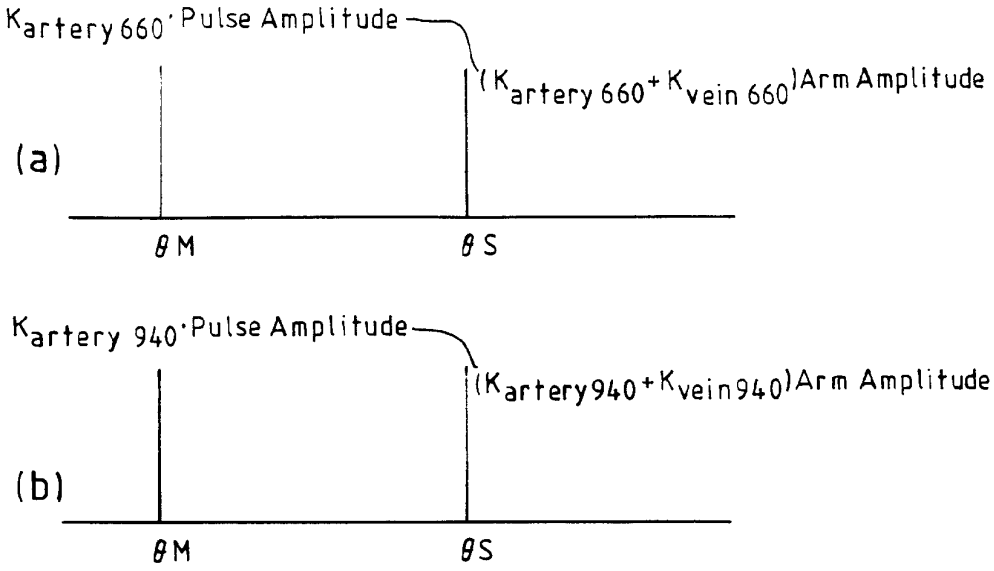

$K_{artery\,660}$·Pulse Amplitude
$(K_{artery\,660}+K_{vein\,660})$Arm Amplitude
(a)
θM
θS
$K_{artery\,940}$·Pulse Amplitude
$(K_{artery\,940}+K_{vein\,940})$Arm Amplitude
(b)
θM
θS

FIG.8

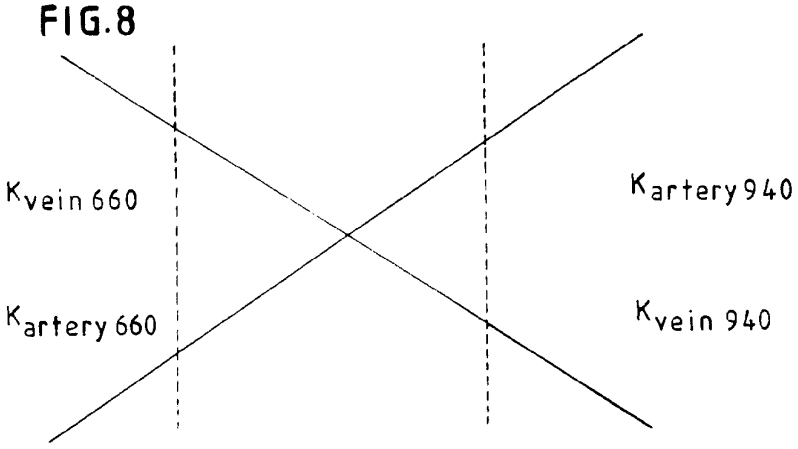
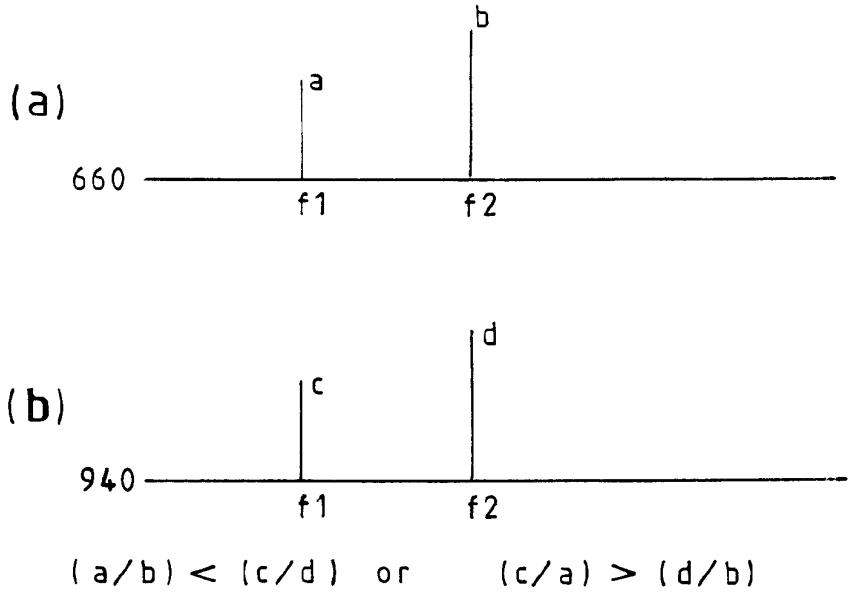

$K_{vein\,660}$
$K_{artery\,660}$
$K_{artery\,940}$
$K_{vein\,940}$

FIG.9



$(a/b) < (c/d)$ or $(c/a) > (d/b)$

Then f1 corresponds to pulses and f2 corresponds to strokes

FIG.10

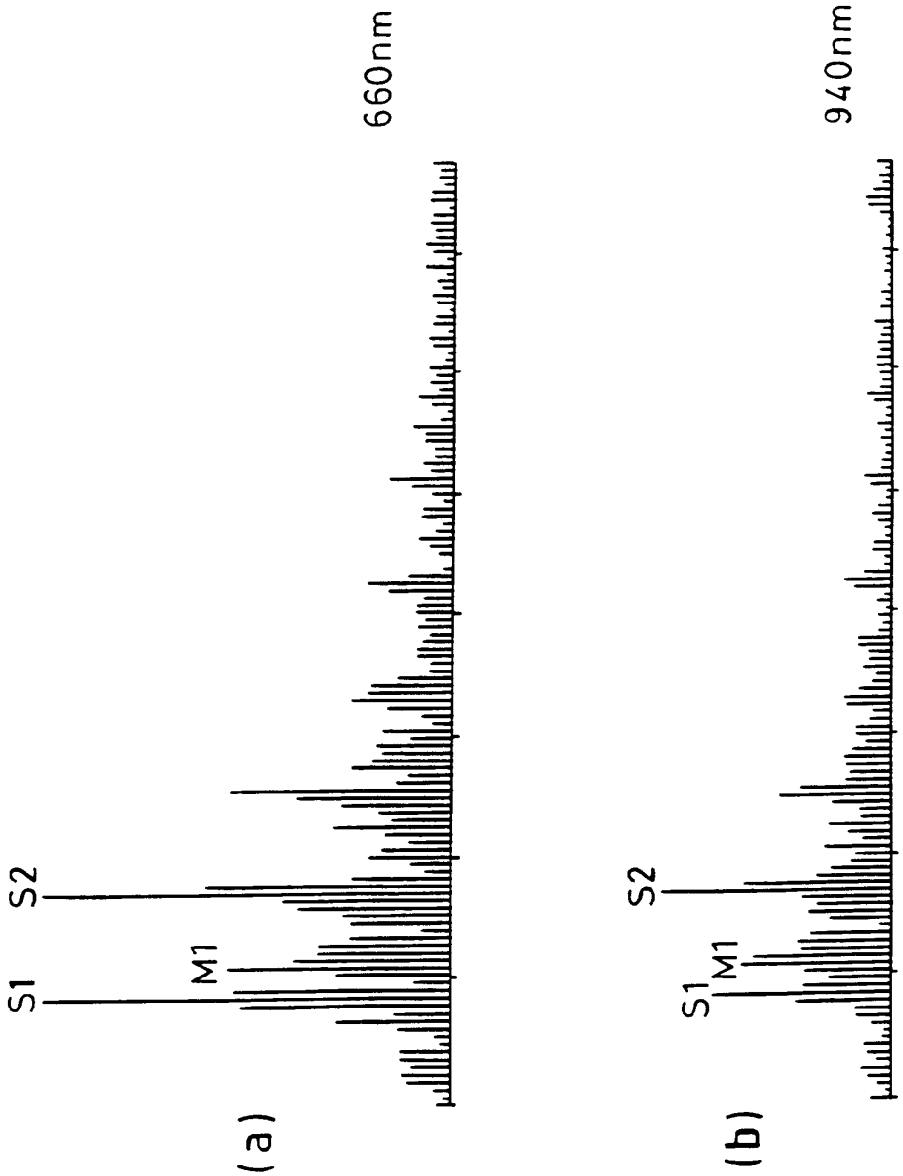
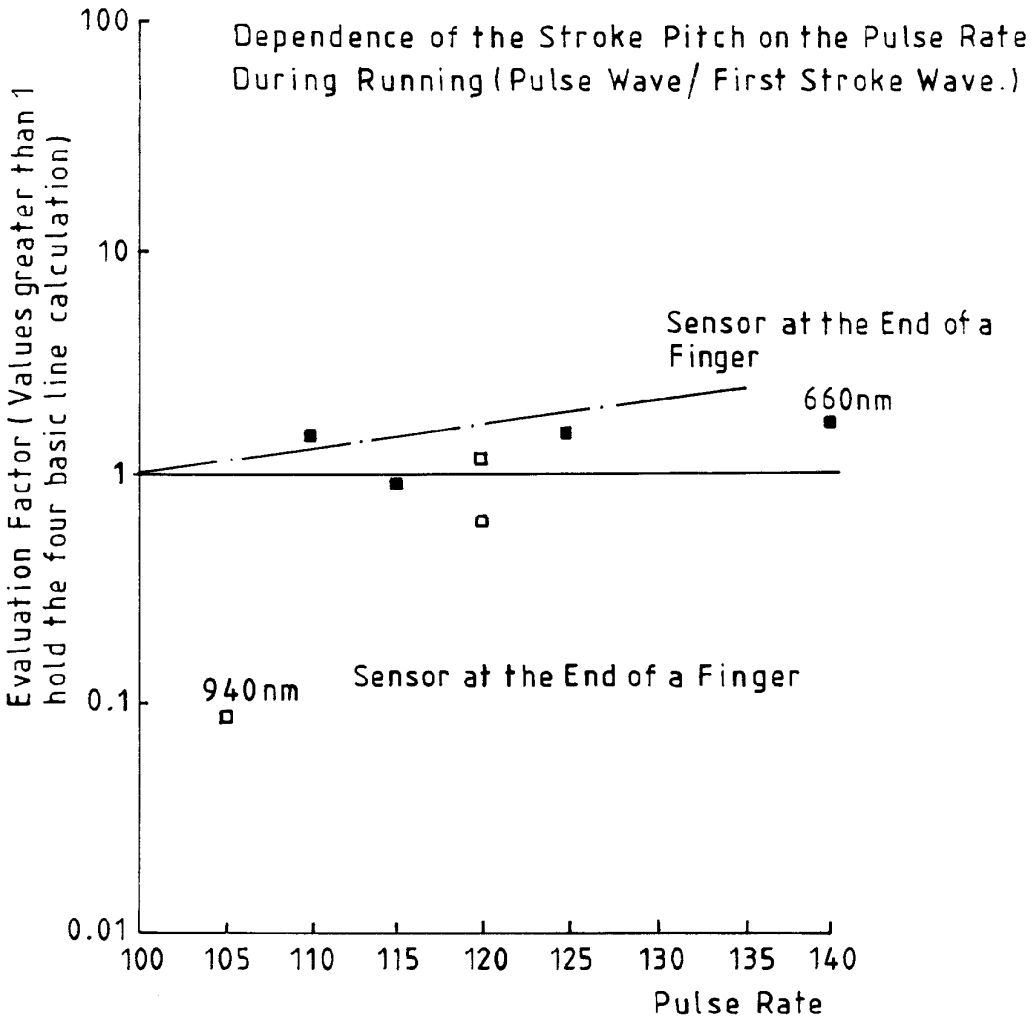


FIG.11


Dependence of the Stroke Pitch on the Pulse Rate
During Running (Pulse Wave/ First Stroke Wave.)
Evaluation Factor (Values greater than 1 hold the four basic line calculation)
100
10
1
0.1
0.01
Sensor at the End of a Finger
660nm
940nm
Sensor at the End of a Finger
100
105
110
115
120
125
130
135
140
Pulse Rate

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT

EP 94307001.1

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
Y	EP - A - 0 379 140 (SUMITOMO) * Totality * --	1-8	A 61 B 5/0245 A 61 B 5/026 A 61 B 5/0285 A 61 B 5/11
Y	DE - A - 3 150 925 (HONEYWELL) * Totality * --	9-19 1-8	
Y	DE - A - 4 001 574 (WALZ) * Claims; figs. * --	9-19	
A	US - A - 4 911 427 (MATSUMOTO) * Claims; figs. * --	1-3, 8-10	TECHNICAL FIELDS SEARCHED (Int. Cl. 6)
A	EP - A - 0 410 658 (SEIKO) * Claims; figs. * ----	1-3, 8-10	A 61 B 5/00

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
VIENNA	28-02-1995	NARDAI

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
O : non-written disclosure
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D : document cited in the application
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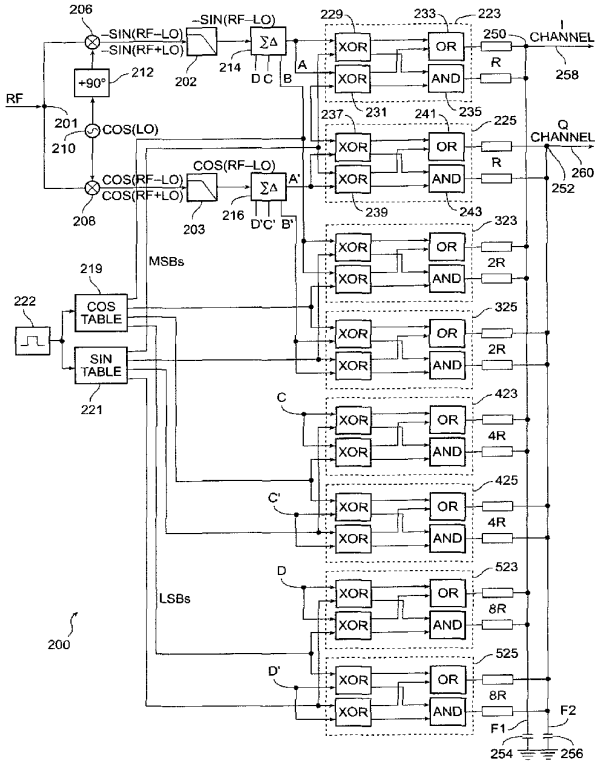
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(54) Title: IMAGE REJECT CIRCUIT USING SIGMA-DELTA CONVERSION



(57) Abstract: In a digital IF downconversion circuit, in-phase and quadrature signal components are processed in the form of a single serial digital bit stream through a set of simple logic in combination with a reconstruction filter. A source digital oscillator supplying digital signal mixers employs an oversampled digital word of four bits in length, all of which are binary weighted, to achieve at least sixteen levels of accuracy for a sine wave mixing signal without significant phase or amplitude error. The mixer mixes the digitized serial bit stream according to the clock with output of a four-bit wide table representing the source oscillator and the in-phase and quadrature signals are recombined digitally, followed by binary weighting using weighted resistors coupled into a filter. Thus, image rejection is a digital function which is unaffected by resistor tolerance.

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IMAGE REJECT CIRCUIT USING SIGMA-DELTA CONVERSION

CROSS-REFERENCES TO RELATED APPLICATIONS

[01] NOT APPLICABLE

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[02] NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

[03] NOT APPLICABLE

BACKGROUND OF THE INVENTION

[04] This invention relates to digital IF downconversion and particularly to digital IF downconversion of relatively wide bandwidth signals at microwave frequencies.

[05] Digital IF downconversion has the advantage of flexibility for multi-mode operation, such as is useful for multiple modes of cellular communication and controllable accuracy and thus good performance with wide bandwidth signals wherever the sampling rate and coefficient accuracy is adequate for the frequencies of interest. In typical operation, the full bandwidth range is captured in an analog-to-digital converter employing a bandpass sigma-delta converter, followed by a final digital filtering channel.

[06] The challenge of processing a wideband digital IF converted signal is rejection of unwanted image and spurious signals which when they occur on the frequency of interest block the desired signal (and hence are called blockers). For this purpose, a DSP filter that is programmed for the appropriate mode of operation is commonly used following wideband downconversion.

[07] Figure 1 illustrates one typical configuration of a downconverter circuit 100 with an image reject stage. Radio Frequency (RF) signals are processed through an in-phase (I) channel 102 and a quadrature phase channel 104 implemented by downconverting mixers 106 and 108 referenced to an analog reference signal of an analog source 110, wherein the reference signals are precisely 90 degrees out of phase (as represented by a 90 degree or p/2

delay element 112). The reference signal has a typical operating frequency of 100 kHz below the nominal RF frequency. The analog signals are processed through conventional sigma-delta analog to digital converters 114, 116 to produce respective one-bit wide serial bit streams. Each channel of the circuit 100 includes a decimator 118, 120 to convert the high-speed serial bit streams to parallel bit streams. There are typically four or eight parallel streams in each path. The parallel bit streams are each supplied to respective fractional filters to make the sampling integer in nature. There is a corresponding compensation filter function for extracting the desired signal of the defined bandwidth. These two functions may be combined in a digital finite impulse response (FIR) filter 122, 124 whose characteristics are defined by a set of filter coefficients.

[08] It is known that out-of-bandwidth attenuation degrades as fewer bits are used to represent filter coefficients. Thus, overall performance depends on the number of bits employed to represent the filter characteristic. The outputs of the FIR filters 122, 124 are mixed and summed digitally in a mixing/summing stage 126 to cancel the unwanted components and to generate as output I and Q multi-bit digital bit streams representing the pure I component and the pure Q component of the wanted signal with maximum image rejection. The digital I and Q components are then processed through digital-to-analog converters 128, 130 (operating at the Nyquist rate) to recover the signal as I and Q analog components 132, 134 at baseband.

[09] This conventional image cancellation scheme has a number of practical drawbacks. According to the conventional approach, in order to achieve targeted performance levels, it has been a practice to use relatively power-consumptive parallel processing techniques operative on the in-phase and quadrature signal components in the form of digital word streams. Not only do these techniques consume more power than is desirable, they also require deployment of relatively large integrated circuits. In a typical configuration, the decimators 118, 120, FIR filter 122, 124, the summing stage 126 and the DACs 128, 130 require on the order of 25,000 gates to implement, which translates to almost 3 square millimeters of valuable circuit area and relatively high power consumption. Both power and circuit size are premium in a portable battery operated digital device such as a cellular telephone.

[10] A representative description of one published prior art implementation is Rudell et al., "A 1.9 GHz Wide-Band IF Double Conversion CMOS Receiver for Cordless Telephone Applications," *IEEE Journal of Solid-State Circuits*, Vol. 32, No. 12, December 1997.

[11] Another representative reference is Canadian patent application 2,284,948 published April 4, 2001 of Birkett et al.

[12] What is needed is a more efficient image reject circuit in a digital IF downconversion circuit for a portable digital device such as a cellular telephone.

SUMMARY OF THE INVENTION

[13] According to the invention, in a digital IF downconversion circuit, in-phase and quadrature signal components are processed in the form of a parallel channels of single serial digital bit stream through a set of simple logic elements, such as a novel grouping of Exclusive OR gates, AND gates and OR gates, operating as adders and multipliers in combination with a "reconstruction filter" to recover the analog in-phase and quadrature phase baseband components substantially free of images. In a preferred embodiment, the two bit streams output from I and Q sigma-delta A/D converter are split and then each exclusive-ORed with both a high accuracy sine function and a cosine function bit stream, then the outputs of the XOR gates are each both ORed together and ANDed together. This Boolean product and this Boolean sum are then each binary weighted and combined in a reconstruction filter formed of weighting resistors that are combined with other weighted outputs to form respective analog I and Q channel signals at baseband.

[14] Further specifically according to the invention, a source digital oscillator supplying digital signal mixers employs an oversampled digital word of four bits in length, all of which are binary weighted relative to one another, to achieve at least sixteen levels of accuracy for a sine wave mixing signal without significant phase or amplitude error. The mixer mixes the digitized serial bit stream according to the clock with output of a four-bit wide digital cosine/sine table representing the source oscillator by means of a simple exclusive OR, and the in-phase and quadrature signals are recombined digitally using a simple AND and OR summer, followed by binary weighting using weighted resistors coupled into a filter. Thus, image rejection is a digital function which is unaffected by resistor tolerance.

The invention will be better understood by reference to the following detailed description in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[15] Figure 1 is a block diagram of a prior art digital RF downconverter.

[16] Figure 2 is a block diagram of a digital RF down converter according to the invention.

[17] Figure 3 is a block diagram of a cosine/sine generator suitable for use according to the invention.

DETAILED DESCRIPTION OF THE INVENTION

[18] Referring to Figure 2, a sigma delta low IF image reject circuit 200 according to the invention is shown. Not shown is the front end of the receiver, which typically comprises a surface acoustic wave (SAW) filter and low noise amplifier (LNA) which feed RF signals to an input splitter 201. The outputs from the splitter 201 provide the source for first and second quadrature low side injection mixers 206, 208, which are driven by a first local oscillator 210 at a frequency of LO = RF-100kHz. The 100kHz signal is selected to conform with the channel spacing requirements. A linear 90 degree phase shifter 212 assures a constant quadrature relation between the signals. As a consequence, where the local oscillator 210 is referenced to an analog cosine signal, the output of the first mixer 206 is of the frequencies:

[19] -sin(RF-LO); and

[20] -sin(RF+LO).

[21] The output of the second mixer 208 is of the frequencies:

[22] cos(RF-LO); and

[23] cos(RF+LO).

[24] This means that both the wanted signal and the image mix down to 100kHz. The outputs of the mixers 206, 208 each then feed into first and second low-pass filters 202, 203 to reject the respective signals -sin(RF+LO) and cos(RF+LO).

[25] After the filter 202, 203, the signals -sin(RF-LO) and cos(RF-LO) are fed to respective sigma-delta analog to digital converters 214, 216 to produce a single serial bit stream output. For the purposes of illustration only, the output is shown as two pairs of four parallel channels as hereinafter explained so they can interact with corresponding bits of sine and cosine tables 219, 221 over-clocked by a 39MHz clock/counter 222. The clocked tables together define an effective second local oscillator to mix down the 100kHz signal to baseband while rejecting the image. For purposes of explanation, the outputs of the sigma-delta converters 214, 216 are shown as four parallel lines each A, B, C, D and A', B', C' and D' corresponding to the Most Significant Bit to Least Significant Bit associated with the converter outputs. The bits are actually fed serially on a common line. These bits are synchronized to the bits supplied from the cosine table 219 and the sine table 221 by appropriate timing. The complete sine table and cosine for sixteen levels over one-quarter cycle is reproduced below in connection with the circuit of Figure 3. These values are stored in memory locations or elements, as hereinafter explained.

[26] Table Loc. SineTable Cosine Table

[27] _____

	[28]	1	1	0	0	0	1	1	1	1
	[29]	2	1	0	0	0	1	1	1	1
	[30]	3	1	0	0	0	1	1	1	1
	[31]	4	1	0	0	0	1	1	1	1
5	**[32]**	5	1	0	0	0	1	1	1	1
	[33]	6	1	0	0	0	1	1	1	1
	[34]	7	1	0	0	1	1	1	1	1
	[35]	8	1	0	0	0	1	1	1	1
	[36]	9	1	0	0	1	1	1	1	1
10	**[37]**	10	1	0	0	0	1	1	1	1
	[38]	11	1	0	0	1	1	1	1	1
	[39]	12	1	0	0	1	1	1	1	1
	[40]	13	1	0	0	1	1	1	1	1
	[41]	14	1	0	1	0	1	1	1	1
15	**[42]**	15	1	0	0	1	1	1	1	1
	[43]	16	1	0	0	1	1	1	1	1
	[44]	17	1	0	1	0	1	1	1	1
	[45]	18	1	0	1	0	1	1	1	1
	[46]	19	1	0	1	0	1	1	1	1
20	**[47]**	20	1	0	0	1	1	1	1	1
	[48]	21	1	0	1	1	1	1	1	1
	[49]	22	1	0	1	0	1	1	1	1
	[50]	23	1	0	1	0	1	1	1	1
	[51]	24	1	0	1	0	1	1	1	0
25	**[52]**	25	1	0	1	1	1	1	1	1
	[53]	26	1	0	1	0	1	1	1	0
	[54]	27	1	0	1	1	1	1	1	1
	[55]	28	1	0	1	1	1	1	1	0
	[56]	29	1	0	1	1	1	1	1	1
30	**[57]**	30	1	0	1	1	1	1	1	0
	[58]	31	1	0	1	1	1	1	1	0
	[59]	32	1	0	1	1	1	1	1	0
	[60]	33	1	1	0	0	1	1	1	0
	[61]	34	1	0	1	1	1	1	1	0

	[62]	35	1	1	0	0	1	1	1	0
	[63]	36	1	0	1	1	1	1	1	0
	[64]	37	1	1	0	0	1	1	1	0
	[65]	38	1	1	0	0	1	1	1	0
	[66]	39	1	1	0	0	1	1	0	1
	[67]	40	1	1	0	0	1	1	1	0
	[68]	41	1	1	0	0	1	1	0	1
	[69]	42	1	1	0	0	1	1	1	0
	[70]	43	1	1	0	1	1	1	0	1
	[71]	44	1	1	0	0	1	1	0	1
	[72]	45	1	1	0	1	1	1	0	1
	[73]	46	1	1	0	0	1	1	1	0
	[74]	47	1	1	0	1	1	1	0	1
	[75]	48	1	1	0	1	1	1	0	1
	[76]	49	1	1	0	0	1	1	0	0
	[77]	50	1	1	0	1	1	1	0	1
	[78]	51	1	1	0	1	1	1	0	1
	[79]	52	1	1	1	0	1	1	0	0
	[80]	53	1	1	0	1	1	1	0	1
	[81]	54	1	1	0	1	1	1	0	0
	[82]	55	1	1	0	1	1	1	0	1
	[83]	56	1	1	1	0	1	1	0	0
	[84]	57	1	1	0	1	1	1	0	0
	[85]	58	1	1	1	0	1	1	0	0
	[86]	59	1	1	0	1	1	1	0	0
	[87]	60	1	1	1	0	1	1	0	0
	[88]	61	1	1	1	0	1	1	0	0
	[89]	62	1	1	1	0	1	0	1	1
	[90]	63	1	1	1	0	1	1	0	0
	[91]	64	1	1	1	0	1	0	1	1
	[92]	65	1	1	1	0	1	1	0	0
	[93]	66	1	1	1	0	1	0	1	1
	[94]	67	1	1	1	0	1	0	1	1
	[95]	68	1	1	1	0	1	0	1	1

	[96]	69	1	1	1	1	1	0	1	1
	[97]	70	1	1	1	0	1	0	1	1
	[98]	71	1	1	1	1	1	0	1	1
	[99]	72	1	1	1	0	1	0	1	0
5	[100]	73	1	1	1	1	1	0	1	1
	[101]	74	1	1	1	0	1	0	1	0
	[102]	75	1	1	1	1	1	0	1	0
	[103]	76	1	1	1	1	1	0	1	0
	[104]	77	1	1	1	1	1	0	1	1
10	[105]	78	1	1	1	1	1	0	0	1
	[106]	79	1	1	1	1	1	0	1	0
	[107]	80	1	1	1	1	1	0	1	0
	[108]	81	1	1	1	1	1	0	1	0
	[109]	82	1	1	1	1	1	0	0	1
15	[110]	83	1	1	1	1	1	0	0	1
	[111]	84	1	1	1	1	1	0	1	0
	[112]	85	1	1	1	1	1	0	0	1
	[113]	86	1	1	1	1	1	0	0	1
	[114]	87	1	1	1	1	1	0	0	1
20	[115]	88	1	1	1	1	1	0	0	0
	[116]	89	1	1	1	1	1	0	0	1
	[117]	90	1	1	1	1	1	0	0	0
	[118]	91	1	1	1	1	1	0	0	1
	[119]	92	1	1	1	1	1	0	0	0
25	[120]	93	1	1	1	1	1	0	0	0
	[121]	94	1	1	1	1	1	0	0	0
	[122]	95	1	1	1	1	1	0	0	0
	[123]	96	1	1	1	1	1	0	0	0
	[124]	97	1	1	1	1	1	0	0	0
30	[125]	98	1	1	1	1	0	1	1	1

[126] _____

[127] The clock/counter 222 comprises a 39 MHz clock 612, an up/down binary counter 614 which outputs a seven-bit address word, and an up vs. down logic selector 616 which

reads the counter 614 output and reverses the count direction at peaks and at zero address positions.

[128] The sine table 221 comprises an addressable memory such as a ROM 602 containing the values of the sine table above and inversion logic 604 for converting the values according to the appropriate quadrants of the cycle. The cosine table comprises an addressable memory such as a ROM 606 containing the values of the cosine table above and inversion logic for converting the values according to the same quadrants. Inversion detector 610 is shared with the inversion logic elements 604, 608 and reads the output of counter 614 to sense zero crossing positions and add the appropriate sign bit.

[129] The two bit streams output from I and Q sigma-delta A/D converters 214, 216 are split and then each exclusive-ORed with both the corresponding sine function bits from sine table 221 and the cosine function bits from cosine table 219. Then the outputs of the XOR gates are each both ORed together and ANDed together. This Boolean product and this Boolean sum are then each binary weighted and combined in an reconstruction filter formed of weighting resistors that are combined with other weighted outputs to form respective analog I and Q channel signals at baseband.

[130] In a specific embodiment according to the invention, a bank of pairs of digital signal mixers 223, 225; 323, 325; 423, 425; 523, 525 are provided using for example XOR gates 229, 231 with an AND gate 235 and an OR gate 233 in one of the pair, and further using XOR gates 237, 239 with an AND gate 243 and an OR gate 241 in the other of the pair.

[131] The source digital oscillator supplying the digital signal mixers employs an oversampled digital word of four bits in length, all of which are binary weighted relative to one another, to achieve at least sixteen levels of accuracy for a sine wave mixing signal without significant phase or amplitude error. The mixer 223, 225 mixes the digitized serial bit stream from converters 214 and 216 according to the clock, at 39 MHz for example, with the output of the four-bit wide digital cosine/sine tables 219/221 representing the source oscillator by means of a simple exclusive OR at gates 229, 231, and the in-phase and quadrature signals are recombined digitally using a simple AND and OR summer 233, 235. For the Most Significant Bit (MSB) of the In-phase channel, one bit output of the converter 214 is XORed with the corresponding sin bit in the first XOR gate 229 and is simultaneously XORed with the corresponding cos bit in the second XOR gate 231. The output of the first XOR gate 229 is ORed in the first OR gate 233 with the output of the second XOR gate 231, while the output of the first XOR gate 229 is simultaneously ANDed in the second AND gate

235 with the output of the second XOR gate 231. The result is the desired I channel signal ready for analog scaling according to the weighting of the bit.

[132] For the Most Significant Bit (MSB) of the Quadrature-phase channel, one bit output of the converter 216 is XORed with the corresponding cos bit in the third XOR gate 237 and is simultaneously XORed with the corresponding sin bit in the fourth XOR gate 239. The output of the third XOR gate 237 is ORed in the second OR gate 241 with the output of the fourth XOR gate 239, while the output of the third XOR gate 237 is simultaneously ANDed in the second AND gate 243 with the output of the fourth XOR gate 239. The result is the desired Q channel signal ready for analog scaling according to the weighting of the bit.

[133] This configuration and operation is performed for each significant bit output from the converters 214, 216, effectively operating in parallel.

[134] The output of the final gates are followed by binary weighting using weighting resistors of value R, 2R, 4R and 8R, corresponding to their respective binary values. Each channel is summed at a summing node 250, 252 coupled at respective capacitors 254, 256 serving as lowpass filters F1, F2. The resultant output is the analog I channel 258 with signal $-\cos(\text{RF-LO-LO2})$ and Q channel 260 with signal $-\sin(\text{RF-LO-LO2})$, both with desired image rejection.

[135] The image rejection is typcially limited by the tolerance of the weighting resistors. While initial image rejection is as high as –35dBc, once the first mixers have contributed their error, the image rejection is much less. It is thus better to do the summation digitally and then reconstruct the outputs into the filter afterwards. This method means that the image rejection is not affected by the resistor tolerance but only by the harmonic rejection of the sine and cosine table.

[136] In the GSM band plan, the channel spacing is 200kHz, which requires a quadrature second Local Oscillator frequency to be 100kHz. A square wave at 100kHz would mix down not only the wanted to baseband but all odd harmonics of the 100kHz passband. The third harmonic (300kHz) is the adjacent channel and the fifth harmonic (500kHz) is the bi-adjacent channel. Thus, all channels are mixed to some degree into the wanted passband. The use of highly-accurate (16 level) oversampled sine/cosine table overcomes much of this problem.

[137] The bandwidth of the reconstruction filters 254, 256 (Figure 2) are not critical because they merely need to provide rejection of the high frequency switching noise in the MHz region. The pole should be set so that it does not attenuate the maximum 67kHz deviation from the design bandwidth for GMSK but will provide maximum attenuation of all higher

frequencies. This type of filter can be implemented either as an R-C circuit as illustrated or as a charge pump circuit feeding an external capacitor (not shown).

[138] It has been found that even with blockers larger than allowed by the GSM 05:05 Specification they will not be mixed down to baseband to a degree where they will degrade performance. It has also been found that with −104dBm input to the low IF receiver board the LO2 level is −8dBc from the wanted. This is obtained without trying to correct for the sigma delta comparator DC bias level and offset voltage level. The image rejection has been measured at −17dBc with no correction for the front end amplitude/phase errors and while using RC components in the sigma delta whose bandwidth tolerance is unknown. In any event, the number of gates required to implement the circuit is reduced by an order of magnitude.

[139] The invention has been explained with reference to specific drawings and embodiments. Other embodiments will be evident to those of ordinary skill in the art. It is therefore intended that the invention not be limited except as indicated by the appended claims.

WHAT IS CLAIMED IS:

1. In a digital intermediate frequency downconversion circuit for downconverting in-phase and quadrature signal components of a digitized communication signal, a method for processing the in-phase and quadrature signal components of the digital signal comprising:

processing a single serial digital bit stream formed of the in-phase and quadrature signal components through a set of simple logic to produce a digital representation of downconverted in-phase and quadrature components; and

recombining the digital representation of the downconverted in-phase and quadrature components with a reconstruction filter in a manner to obtain a digital representation of a baseband signal substantially free of image artifacts.

2. The method according to claim 1 further including the steps of:

employing an oversampled digital word of four bits in length from a source digital oscillator as a reference signal;

supplying digital signal mixers with said reference signal to achieve at least sixteen levels of accuracy as a sine wave mixing signal without significant phase or amplitude error;

mixing the digitized serial bit stream according to a clock with output of a four-bit wide table representing the reference signal;

recombining digitally the in-phase and quadrature signals to obtain a digitally combined signal; and

binary weighting the combined signal into a digital reconstruction filter to produce a downconverted signal is unaffected by resistor tolerance.

3. In a digital IF downconversion circuit for downconverting in-phase and quadrature signal components of a digitized communication signal, a processor for in-phase and quadrature signal components of the digital signal comprising:

logic for processing a single serial digital bit stream formed of the in-phase and quadrature signal components to produce a digital representation of downconverted in-phase and quadrature components; and

a digital reconstruction filter for recombining the digital representation of the downconverted in-phase and quadrature components in a manner to obtain a digital representation of a baseband signal substantially free of image artifacts.

4. The circuit according to claim 3 further including:

a source digital oscillator supplying digital signal mixers with an oversampled digital word of four bits in length to achieve at least sixteen levels of accuracy for a sine wave mixing signal without significant phase or amplitude error.

5. The circuit according to claim 1 further including resistor means coupled to input of the digital reconstruction filter for binary weighting the digital recombined signal produce a downconverted signal is unaffected by resistor tolerance.

6. A method of image rejection processing of a received RF signal, comprising:

performing downconversion of the received RF signal to produce analog I and Q signals; and

for each of the analog I signal and the analog Q signal:

oversampling the analog signal to obtain an oversampled digital signal;

producing a periodic oversampled digital reference signal; and

logically combining the digital signal with the digital reference signal to produce an image-canceled digital baseband signal.

7. The method of claim 6, comprising:

converting the digital baseband signal to an analog baseband signal.

8. An image reject circuit apparatus comprising:

a first frequency downconversion circuit employing a first local oscillator for downconverting in-phase and quadrature signal components of a digitized communication signal to a first intermediate frequency;

sigma delta converters for generating an in phase digital bit stream and a quadrature phase digital bit stream;

a digital in-phase and quadrature phase second local oscillator;

mixing circuitry for mixing respective single serial digital bit stream in-phase signal and single serial digital bit stream quadrature phase signal through a set of logic gates to produce a digital representation of downconverted in-phase and quadrature components; and

weighting resistances in series with the outputs of the logic gates for combining the digital representation of the downconverted in-phase and quadrature components according to value in an in-phase signal and in a quadrature phase signal; and

reconstruction filters to recover in-phase and quadrature phase baseband signals from said downconverted in-phase and quadrature components substantially free of image artifacts.

9. The image reject circuit apparatus according to claim 8 wherein said mixing circuitry comprises, for each significant bit:

first and second exclusive-OR gates coupled to receive as first input an in phase digital bit stream and as second inputs a high accuracy sine function bit stream and a high accuracy cosine function bit stream;

third and fourth exclusive-OR gates coupled to receive as first input a quadrature phase digital bit stream and as second inputs a high accuracy sine function bit stream;

first OR gate for logically adding the outputs of the first and second XOR gates for the in-phase channel;

first AND gate for logically multiplying the outputs of the first and second XOR gates for the in-phase channel;

second OR gate for logically adding the outputs of the third and fourth XOR gates for the quadrature phase channel; and

second AND gate for logically multiplying the outputs of the third and fourth XOR gates for the quadrature phase channel.

10. The circuit apparatus according to claim 9 wherein the reconstruction filter comprises:

weighting resistors for each output of each of the first and second AND gates and first and second OR gates, said weighting resistors defining a binary weight for its corresponding bit;

a first lowpass filter means at a first combining node of the first AND gate and first OR gate;

a second lowpass filter means at a second combining node of the second AND gate and second OR gate;

wherein each said weighting resistor of the in-phase channel is connected to said first lowpass filter; and

wherein each said weighting resistor of the quadrature phase channel is connected to said second filter

to yield respective analog I and Q channel signals at baseband.

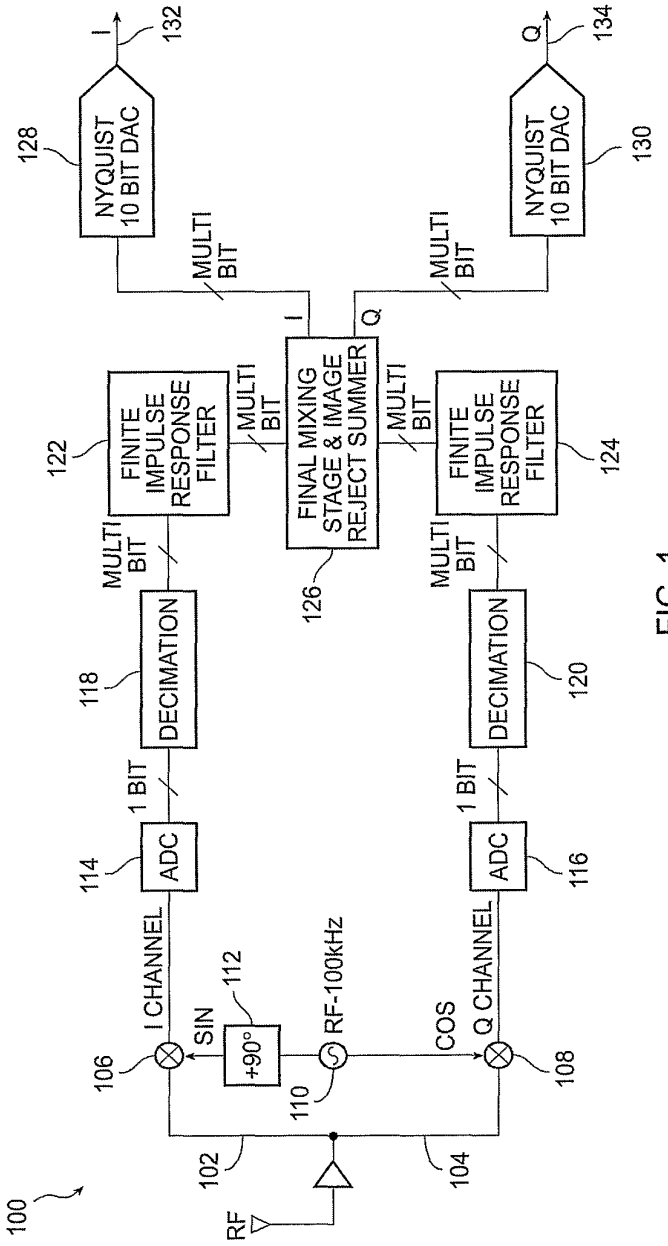


FIG. 1
(PRIOR ART)

2/3

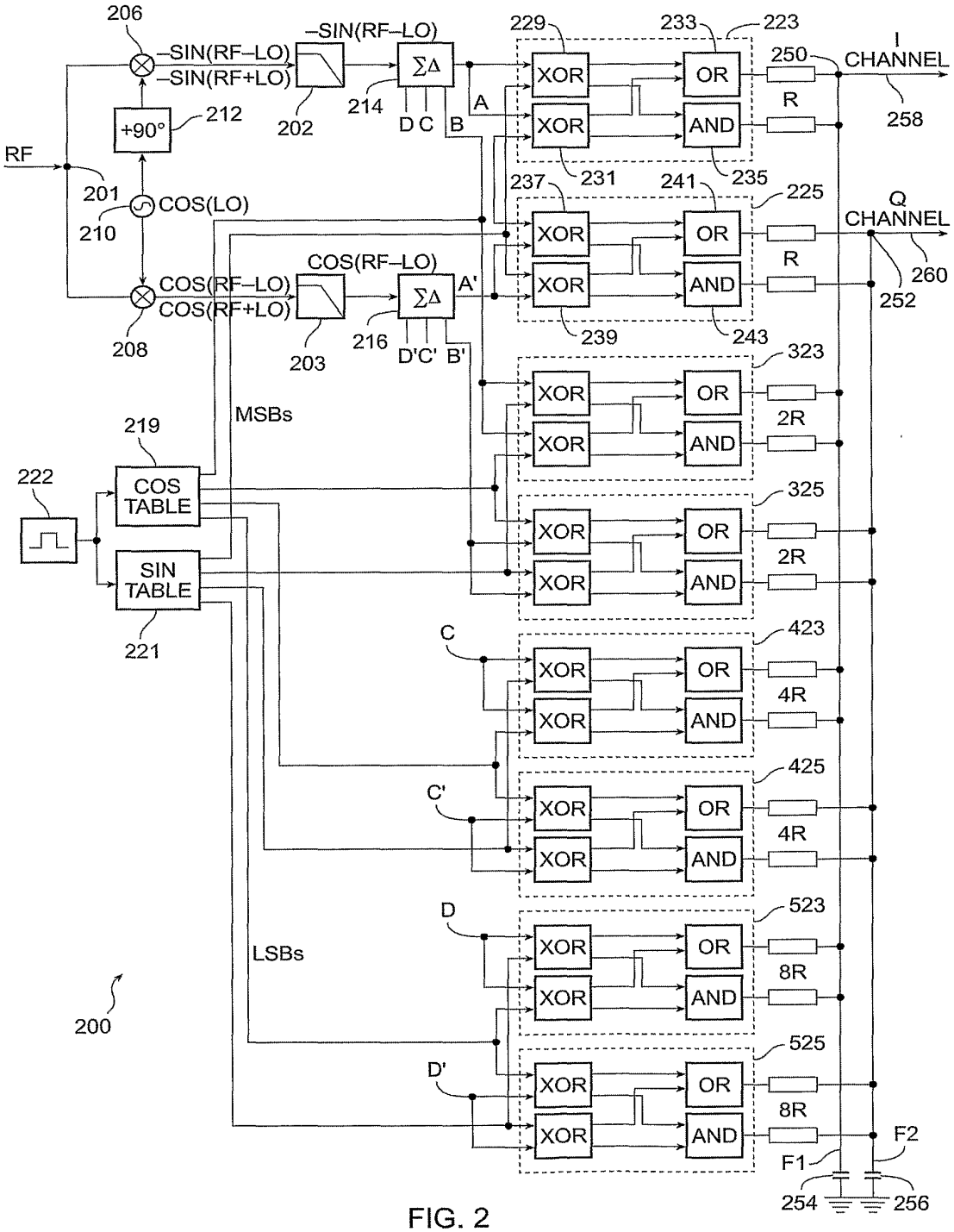

206
−SIN(RF−LO)
−SIN(RF+LO)
+90°
212
RF
201
210
COS(LO)
208
COS(RF−LO)
COS(RF+LO)
−SIN(RF−LO)
202
214
ΣΔ
D C B
A
203
216
D'C' B'
A'
COS(RF−LO)
MSBs
219
COS TABLE
222
SIN TABLE
221
LSBs
200
229
233
223
XOR
OR
AND
250
R
I CHANNEL
258
231
235
237
241
225
Q CHANNEL
260
252
239
243
323
2R
325
423
4R
425
C
C'
D
D'
523
8R
525
F1
F2
254
256

FIG. 2

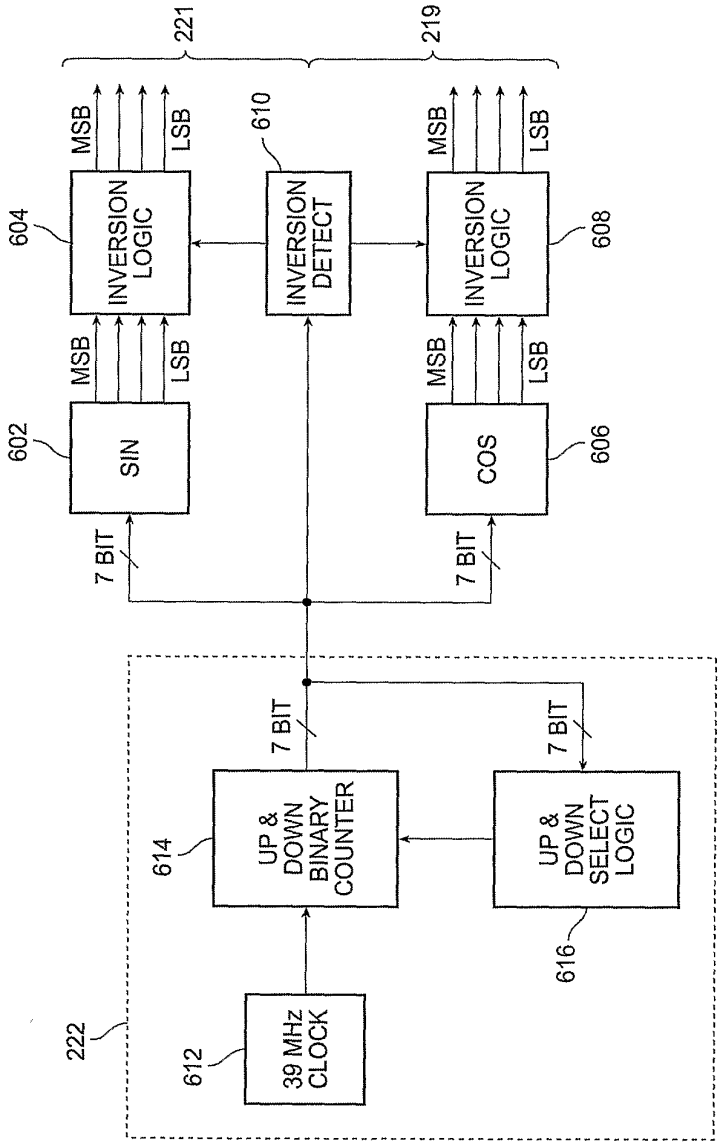

221
219
MSB
LSB
610
604
INVERSION LOGIC
INVERSION DETECT
INVERSION LOGIC
608
602
SIN
COS
606
7 BIT
7 BIT
7 BIT
7 BIT
614
UP & DOWN BINARY COUNTER
UP & DOWN SELECT LOGIC
616
222
612
39 MHz CLOCK

FIG. 3

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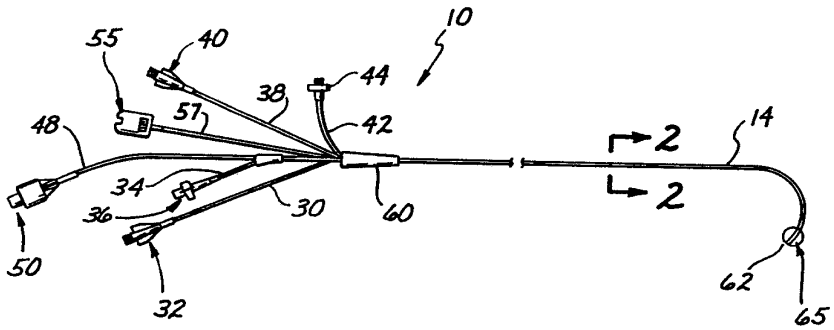
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(54) Title: CARDIOPULMONARY MONITORING SYSTEM WITH INTEGRATED BLOOD OXYGENATION SIGNAL QUALITY INDICATOR



(57) Abstract

A cardiopulmonary monitoring system (100) transmits and receives optical signals to and from the interior of a blood vessel via a fiberoptic catheter (10). The signals may be processed to obtain a measurement of the blood oxygenation saturation level of the blood within the blood vessel. The cardiopulmonary monitoring system includes a detector which detects optical signals. A detector (402) provides an electrical output signal which has an amplitude that is proportional to the intensity of the detected optical signal transmitted from the blood vessel. The monitoring system (100) further comprises a signal processing device (420), which includes means for comparing the amplitude of the output signal with a threshold amplitude value, monitoring the frequency with which the output signal exceeds the threshold value during a selected interval of time, and generating a first signal quality indicator value based upon the monitored frequency. The monitoring device (100) also monitors the magnitude variations in the output signal due to pulsatile blood flow through the blood vessel and generates a second quality indicator value in response thereto. The monitoring device (100) also monitors the amplitude of the output signal and generates a third signal quality indicator value in response thereto. The three indicator values are then compared, and the highest one is selected to be output as a quality display value. The output quality display value is indicative of the reliability of the blood oxygenation saturation level reading output by the monitoring system.

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CARDIOPULMONARY MONITORING SYSTEM WITH INTEGRATED BLOOD OXYGENATION SIGNAL QUALITY INDICATOR

Field of the Invention

The present invention is related to fiberoptic cardiac catheters.

Background of the Invention

Fiberoptic cardiac catheters are well known in devices which measure the oxygenation of the blood between the heart and the lungs. Typically, light in two or three distinct wavelengths is introduced into the bloodstream by means of transmitting fiberoptic lines. The light signals, (generally in the red and infrared color bands), are reflected and refracted by the blood so that a portion of the light signals are received by sensing fiberoptic lines which are also within the cardiac catheter. The oxygenation of the blood may then be determined from the information obtained from the received signals.

In simplified terms, the oxygenation of the blood is measured by determining the color of the blood using the fiberoptic catheter. As described in U.S. Patent Nos. 4,641,658 and 4,651,741, the oxygenation of the blood may be determined using the information obtained from the backscattering of red (R) and infrared (IR) signals. Because the amplitude of both the R signal and the IR signal is affected by, among other things, artifacts such as clots and flow patterns, the oxygenation of the blood has traditionally been measured by generating an R/IR signal in which the artifacts cancel out. The oxygenation percentage is a known function of the R/IR ratio, and the oxygenation percentage can thus be measured. U.S. Patent Nos. 4,641,658 and 4,651,741 are herein incorporated by reference.

As the blood under test flows about the catheter tip, the amplitude of the backscattered radiation (most notably

the IR radiation) fluctuates as an AC signal in synchronization with the patient's heartbeat. It is believed that this is due, in part, to the turbulence created by eddy currents about the catheter tip as blood flows past the catheter. Generally, turbulent blood scatters more light than stationary blood, so that, as the blood alternately flows and rests with the heart's pumping action, the amplitude of the received IR signal varies accordingly. The pulsatile fluctuations of the IR signal typically exhibit sinusoidal characteristics and are generally smooth with gradual changes in amplitude. In many instances, however, the amplitude of the received IR signal exhibits spiking characteristics wherein a sharp increase in amplitude occurs at each heartbeat. This is often the case when the catheter tip is positioned near the wall of a blood vessel. When the tip of the catheter impacts or closely approaches the wall of a blood vessel, the increased reflectivity of the vessel wall in comparison with the blood itself causes a greater amount of light to be reflected into the receiving fiberoptic line, thereby causing the amplitude of the received signal to sharply increase. Since the vessel wall exhibits reflective characteristics which are not necessarily related to blood oxygen saturation, these substantial fluctuations resulting in greatest part from the reflectance of the vessel wall can introduce inaccuracies into the measurement of blood oxygen.

Various techniques have been used for reducing or eliminating these substantial fluctuations. In one system, the catheter tip is enclosed in a cage-type structure to prevent the tip of the catheter from impacting the vessel wall. While the cage structure may effectively separate the catheter tip from the vessel wall, the structure also greatly increases the tendency for deposits to form on the catheter tip, an undesirable result. In another system, a signal filter removes data above a predetermined threshold

amplitude in an attempt to eliminate any erroneous data. This approach may be effective as long as the artifact is not too severe, or does not last too long. However, if a large portion of the signal readings have to be filtered, there may not be enough good readings to maintain tracking of oxygenation saturation levels.

Some techniques include displaying the IR signal intensity, which requires the user to interpret the display as to whether or not it is normal, and separate on/off alerts for each condition detected. The user, however, has no direct interest in the particular characteristics of the signals that are detected. Instead, the user is concerned with whether or not the blood oxygenation reading is reliable.

Summary of the Invention

The present invention is a cardiopulmonary monitoring system which is connected to a fiberoptic cardiac catheter. The system transmits and receives optical signals to and from the interior of a blood vessel via the fiberoptic catheter. The cardiopulmonary monitoring system comprises a detector for detecting an optical signal transmitted from the blood vessel and for generating an output signal in response thereto. The monitoring system further comprises a signal processing device. The signal processing device includes a first signal processing means for comparing the amplitude of the output signal with a threshold amplitude value, monitoring the frequency with which the output signal exceeds the threshold value during a selected interval of time, and generating a first indicator based upon the monitored frequency.

In a preferred embodiment, the system includes second and third processing means for generating second and third indicators respectively. The system further includes means for sensing the first, second and third indicators and generating a quality display signal in response thereto. In a particularly preferred embodiment, the second

processing means monitors the magnitude variations in the output signal due to pulsatile blood flow through the blood vessel, and the third processing means monitors the amplitude of the output signal.

Another aspect of the present invention encompasses a cardiopulmonary monitoring system which comprises a detector for detecting an optical signal transmitted from the blood vessel and generating an output signal having a waveform in response to the optical signal. The monitoring system comprises a means for recursively generating a variable indicative a waveform characteristic, such as spikes in the waveform, and a means for generating an indicator based upon the variable.

The present invention further encompasses a method for monitoring an optical signal from a cardiopulmonary catheter comprising the steps of: 1) detecting the optical signal and generating a waveform in response thereto, 2) monitoring the spikes in the waveform during a second interval, and 3) utilizing the results of steps 1) and 2) to generate an indicator.

Brief Description of the Drawings

Figure 1 is a plan view of a fiberoptic cardiac catheter used in accordance with the present invention.

Figure 2 is a cross-sectional view of a section of tube of the catheter shown in figure 1.

Figure 3 is a front view of the cardiopulmonary monitoring apparatus of the present invention which shows the details of the display panel.

Figure 4 is a simplified block diagram which shows the processing circuitry used within the cardiopulmonary monitoring system shown in Figure 3.

Figure 5 is a flowchart which shows the overall method of processing cardiopulmonary data in accordance with the present invention.

Figure 6 is a flowchart which details the method used in accordance with the data acquisition and filtering

subroutine block of Figure 5.

Figure 7 is a flowchart which details the method used in accordance with the update quality display signal subroutine block of Figure 5.

Detailed description of the Preferred Embodiment

Figures 1 and 2 show a side view and a cross-sectional view respectively of a fiberoptic cardiac catheter 10 which may be used in accordance with the present invention. The catheter 10 includes an elongated catheter tube 14 having an inflation lumen 16, a distal lumen 18, a thermistor wires lumen 20, an injectate lumen 22, an RV port infusion lumen 24, and a fiberoptic lumen 26. A distal lumen tube 30, having a distal lumen hub 32 attached thereto, is fused to the tube 14 within the distal lumen 18. In a like manner, an inflation lumen tube 34 with an inflation valve 36, an injectate lumen tube 38 with an injectate hub 40, and an RV port infusion tube 42 with an RV port infusion connector 44, are all fused to the tube 14 within the inflation lumen 16, the injectate lumen 22, and the RV port infusion lumen 24 respectively. Thermistor wires (not shown) within a thermistor tube 48 having a thermistor connector 50 attached thereto, extend through the tube 14 within the thermistor wires lumen 20. Fiberoptic lines extend from a fiberoptic oximetry connector 55 within a tube 57. The tube 57 is also fused to the catheter tube 14 so that the fiberoptic lines extend along the length of the catheter tube 14 within the fiberoptic lumen 26.

The catheter tube 14 may be extruded from a suitable biocompatible plastic material. The tube 14 is advantageously flexible and sized to be received within a blood vessel. The tube 14 has a proximal end situated within a flexible jacket 60, and a distal end 62 to which a balloon 65 is connected. The inflation lumen 16 terminates within the balloon 65 so that the balloon 65 may be inflated using the inflation lumen 16. In one preferred embodiment, the catheter 10 is a Swan-Ganz ® oximetry

catheter, model 93A-780H-7.5F.

The fiberoptic lines within the lumen 26 may be single or multi-mode fiberoptic cables and are advantageously constructed to transmit light in the red and infrared frequency spectrum. At the distal end of the tube 14, the fiberoptic lines are exposed so that light may be radiated into, and received from, the bloodstream when the catheter 10 is inserted into a blood vessel. At the opposite end, the fiberoptic lines are optically connected to the fiberoptic oximetry connector 55. The connector 55 may be hooked up to a monitoring device 100 (Fig. 3).

The monitoring device 100 is capable of generating optical signals in the appropriate wavelengths (e.g., 660nm and 810nm) for transmitting along the fiberoptic lines. The monitoring device 100 is also capable of receiving and processing optical signals, so that the backscattered optical signals sensed by the receiving fiberoptic lines may be monitored and measured by the device 100. The monitoring device 100 advantageously includes an output display for presenting significant information to a user. Such information may include a blood oxygenation saturation reading in numerical 105 and graphical form 107, an alarm signal 110 to indicate conditions which may be dangerous for a patient, and a quality display signal 120, which indicates the reliability of the current blood oxygenation reading.

Figure 4 is a simplified block diagram which shows the general circuitry 400 used within the device 100 to process the incoming optical signals, and to output information to the display of the monitoring device 100. The circuitry 400 includes an electro-optical coupler 402 for receiving optical R and IR signals, and outputting corresponding analog electrical signals which have an amplitude that is proportional to the amplitude of the optical signals. The analog electrical signals are then transmitted to a gate array 410, which provides all required timing and control

signals to the analog circuitry, and serves to convert the analog signals to digital signals at a rate of one sample per millisecond. The gate array 410 may pass the data in either a data mode or an offset mode. The gate array 410 is set in the offset mode when it is desired to calculate offset values, used to correct for system offsets, at each gain level. During normal operation of the monitoring system 100, the gate array 410 is set to the data mode, and basically acts as an A/D convertor which averages 50 input data samples at a rate of one sample per millisecond and outputs a two-byte digital value every 50 ms. These digital signals are then transmitted to a microprocessor 420. The microprocessor 420 performs most of the signal processing and calculates output values which are sent to a display driver 430, which in turn drives a display output 435. The microprocessor 420 also has access to a read only memory (ROM) 450 and a random access memory 455.

Figure 5 is a flowchart which shows the overall method of processing the data obtained from the light backscattered from blood within a blood vessel. The method begins in a block 500 and control is transferred to an activity block 510, wherein the monitoring system 100 is initialized and self tests are performed. Such tests include power-up, offset determination of the R and IR signals at each gain level, initiation of a watchdog-timer, and initiation of run-time diagnostics. Once the monitoring system has been initialized and the watchdog-timer and run-time diagnostics are running, control passes to a subroutine block 520, wherein the data from the receiving fiberoptic line is acquired and filtered.

Basically, within the subroutine block 520, the optical data is converted into electrical signals by the optical coupler 402. These signals are then converted into digital signals via the gate array 410. The gate array 410 then outputs these signals to the microprocessor 420 wherein the digitized signals are filtered and averaged.

Initially, a baseline value and a threshold value are calculated, and those digital signals which are in excess of the calculated threshold value are clipped, so that they are equal to the threshold value. That is, the values which exceed the threshold value are assigned the value of the threshold, while those values which are not in excess of the threshold value remain unchanged. These values are then transmitted to a series of filters and averagers to provide values appropriate for calculating the blood oxygenation saturation level, as well as the blood flow rate. The subroutine block 520 will be described in greater detail in reference to Figure 6 below.

Once the data has been acquired and filtered in the subroutine block 520, control passes to an activity block 530, wherein the cardiopulmonary monitoring system 100 is calibrated and updated. The monitoring system 100 may be calibrated in two ways: in vitro, or in vivo. This calibration and update technique is described in detail in U.S. Patent No.4,651,741. Once calibration has occurred in the activity block 530, control passes to an activity block 540.

In the activity block 540, the value of the blood oxygenation saturation level is calculated and displayed. The blood oxygenation saturation level, S, may be calculated as:

$$S = AX^2 - BX + C - D/X \qquad (1)$$

where A, B, C, and D are constants determined by the design of the catheter 10, and X is calculated as:

$$X = (IROUT/REDOUT)*M - Z \qquad (2)$$

where M and Z are constants determined at calibration, and R and IR are the amplitudes of the filtered red and infrared digital signals respectively. The value of the

blood oxygenation saturation level, S, is then output to the numerical display 105 and the graphical display 107 (Fig. 3).

Once the value of the blood oxygenation saturation level has been out put to the displays 105, 107, control passes to an activity block 550, wherein any alarm conditions are checked. Such alarm conditions include a high/low saturation alarm, a saturation "out-of-range" alert, and a light "out-of-range" alert. The high/low saturation alarm indicates that the blood oxygenation saturation level of the patient has exceeded or dipped below certain operator determined safety levels. The saturation "out-of-range" alert is activated when the value of X is above or below certain predetermined values (e.g., 0.54 and 2.57 in one embodiment). Finally, the light "out-of-range" alert is activated when the R or IR signal is either overscale, or too small to depend upon an adequate signal-to-noise ratio. For example, overscale may occur when the amplitude of one of the received light signals needs to be brought down to a lower gain, but the gain scale is already on the lowest level. The low-light alert is activated when the mean digital value of either the R or IR signals over a period of two seconds is below a certain digital value, and the gain scale is set to the highest level. If any of the alarm conditions has been activated, a flag is set to indicate which alarm has been activated. Control then passes to a decision block 555 wherein a test is performed to determine if any of the alarms Have been activated. If so, then control passes to an activity block 560, wherein the appropriate alarm display is activated, and control is then passed to a subroutine block 570.

If no alarms have been activated, then control passes directly from the decision block 555 to the subroutine block 570, wherein a quality display signal is updated. The quality display signal indicates the reliability of the

blood oxygenation saturation level readings output by the monitoring system 100. In a preferred embodiment, the quality display signal assumes values from one to four, wherein each value is indicative of the quality of the saturation reading. A quality display signal value of "1" indicates that the blood oxygenation saturation level readings are normal, and have an accuracy of +/- 2%. A value of "2" indicates that the saturation readings are moderately degraded, and that the user may wish to adjust the catheter 10 or monitoring system 100 to obtain more accurate readings. A value of "3" indicates that the saturation readings are significantly degraded and the probability of significant errors is increasing. At a value of "3" corrective action is suggested. A value of "4" indicates that the saturation readings are very significantly degraded, and should not be relied upon. When the quality display signal is at level "4," corrective action is strongly recommended. The quality display signal is produced by selecting the highest of three indicator values, wherein each indicator value assumes a value of one to four. In one embodiment, these three indicators are functions of 1) the frequency of clipping exhibited by the R and IR signals, 2) the calculated rate of blood flow in the host vessel, and 3) the shift in intensity of the IR signal over successive half second intervals. The method of updating the quality display signal is described in detail with reference to Figure 7 below. Once the quality display signal is updated in the subroutine block 570, control returns to the activity block 540, wherein the blood oxygenation saturation level is again calculated. This process is repeated continuously to provide suitable monitoring of the blood oxygenation saturation level while the catheter 10 is in place within a patient.

Figure 6 is a flowchart which details the method of acquiring and filtering data within the subroutine block 520. Due to the size of the flowchart, a first portion of

the flowchart is shown on a drawing sheet labeled 6A, and a second portion of the flowchart is shown on a drawing sheet labeled 6B. The method begins in a begin block 600 and control passes to a decision block 602 wherein a test is performed to determine if the gate array 410 is in the offset mode. If the gate array is in the offset mode, control passes to an activity block 604 wherein the offset values of the R and IR signals are calculated at each gain range. This is advantageously done by reading in 500 successive input bits and calculating the offset value as:

$$OFFSET = INT(51200*(N1-1)/(499-N0)) \quad (3)$$

where N1 is the number of digital 1's within the 500 bit sample, and N0 is the number of leading and trailing zero's (the number of zero's before the first 1 and after the last 1). The calculated offset value for the R signal is designated as OSRED, while the calculated offset value for the IR signal is designated as OSIR. In a preferred embodiment, an automatic gain control AGC having gain level values of 1, 4, 16, and 64 is employed which adjusts the system gain as a function of the light intensities of the R and IR signals. Thus, an offset value is calculated as described above for each gain level. Control then passes to an activity block 606 wherein the offset values for each gain level are stored in the RAM 450. Control then returns to the decision block 602. Once the gate array is no longer in the offset mode, control passes to an activity block 610 thereby indicating that the gate array 410 is in the data mode.

In the block 610, two-byte integer values (representative of the R and IR signal intensities) obtained from the gate array 410 at each 50 ms interval are multiplied by a gain value of 64. The full scale value (that is the maximum allowable value) of the integer values is 800 so that, after multiplication, the new full scale

value is 51200. These new upscaled integer values are assigned to the variables RED and IRED. Once the new integer values representing the R and IR signal intensities are determined, control passes to an activity block 612.

In the activity block 612, initial maximum threshold values are set for both the R and IR signal values. These threshold values are used within a clipping subroutine, generally designated as a clipper 611, and are updated periodically. In the clipper 611, the digital values representing the intensities of the R and IR signals are filtered so that those values which fall above the maximum threshold value are assigned the same value as the threshold while those values that are not in excess of the threshold value remain unchanged. At the same time, the values of the thresholds are periodically adjusted in response to the average amplitude of the R and IR signals. Once the initial values are set within the activity block 612, control passes to an activity block 614, wherein the most recent limit values for the R and IR signals are calculated respectively as:

$$LIMRNEW = AVE2R + INT(REDOUT*3/8) \quad (4)$$

$$LIMINEW = AVE2IR + INT(IROUT*3/8) \quad (5)$$

where the values of AVE2R and AVE2IR, and REDOUT and IROUT are feedback values from the output of the processing routine. Control then passes to an activity block 616, wherein a limiting value LIMMIN is calculated for each of the R and IR signals as a value, LORLOW, times 11/16. The value LOWROW is the light out-of-range value (the value which indicates that the R or IR signal intensity is too low for a given gain level) which may be determined in accordance with system requirements. However, if the gain scale (i.e., 1, 4, 16, or 64) is at 64, then the value of LIMMIN is calculated as LORLOW*11/8. Once the limiting

value LIMMIN has been calculated, control passes to a decision block 618, wherein a test is performed to determine if the value of LIMRNEW is less than the limit value LIMMIN. If so, control passes to an activity block 620, wherein the value of LIMRNEW is set to the value of LIMMIN and control then passes to a decision block 622. If the value of LIMRNEW is not less than the value of LIMMIN, then control passes directly to the decision block 622, wherein a test is performed to determine if the value of LIMINEW is less than the value of LIMMIN. If so, control passes to an activity block 624, wherein the value of LIMINEW is set to the value of LIMMIN, and control then passes to a decision block 626. If the value of LIMINEW is not less than the value of LIMMIN, then control passes directly to the decision block 626, wherein a test is performed to determine if the number of clipped values (NC) over the last 500 ms update period (the time necessary to average ten signal values each of the R and IR signals) is equal to 0 or 20 (the minimum or maximum values which NC may assume).

If the value of NC is not equal to 0 or 20, then control passes to an activity block 628, wherein the new threshold values for the R and IR signals are calculated as:

$$LIMRED = INT[(3*LIMRED + LIMRNEW)/4] \quad (6)$$

$$LIMIR = INT[(3*LIMIR + LIMINEW)/4] \quad (7)$$

so that, in essence, a weighted average is calculated to determine the new threshold as a function of the old threshold value and the most recent limit value. If the value of NC is equal to zero or 20, this indicates that the old threshold values should be radically altered, and control passes instead to an activity block 630, wherein the new R and IR threshold values are directly assigned the

values of LIMRNEW and LIMINEW respectively. This initialization of the values of LIMRNEW and LIMINEW serves to decrease settling time so that the calculated limits do not take a long time to reach their appropriate values when the monitoring system is first turned on.

Once the new threshold values have been determined, a fresh sample of 20 signal values (10 R and 10 IR) are filtered. To accomplish this, control passes to a decision block 634 wherein a test is performed to determine if the digital value corresponding to the signal intensity of the R signal, RED, is greater than the newly determined threshold LIMRED. If so, then the output of the R clipper, which shall be designated as the variable E2RED, is assigned the value of the threshold, LIMRED, and NC is incremented by one in the activity block 636. If the value of RED is not greater than the threshold LIMRED, then the output E2RED of the R clipper retains the value of the input, (i.e., E2RED = RED). In a similar manner, the digital value representing the input IR signal is clipped. Control passes to a decision block 642, wherein a test is performed to determine if the value of IRED is greater than the value of the threshold LIMIR. If so, then control passes to an activity block 646, wherein the output of the IR clipper, E2IR is assigned the value of the threshold LIMIR, and the value of NC is incremented by one. If the value of IRED is not greater than the value of LIMIR, then control passes instead to an activity block 644, where E2IR is assigned the value of the input, IRED. Thus, each of the digital values input to the clipper 611 retains its original value or is assigned a new value that is equal to the threshold value.

Once the values have been clipped, control passes from either block 644 or 646 to an activity block 650, wherein the digital values output from the clipper are filtered and averaged. The general procedure followed within the filtering and averaging activity blocks may be

described in program form as follows:

```
DO;
    SUM = 0;
    DO  I = 1 TO N;
        G = G -F + E;
        F = INT(G/K);
        SUM = SUM + F;
        END;
    AVE = INT(SUM/N);
    END;
```

where N represents the number of values being averaged, E is the input variable, G is an intermediate filtering variable, K is a filtering constant, F is the filter output value, and AVE is the average value output. In the filtering and averaging activity block 650, the number of samples being averaged is 10 (N = 10) and the value of the filtering constant K is 32. Thus, assuming an input value every 50 ms, an F value is output every 50 ms, an AVE value is output every 500 ms (10 * 50 ms), and the filter time constant is 1.6 seconds (32 * 50 ms). Note that during in vitro calibration, the time constant is usually smaller (e.g., 400 ms corresponding to K = 8). Therefore, within the activity block 650, an F2 value is output every 50 ms, and an AVE2 value is output every 500 ms for both the R and IR signals.

Once the signals are averaged and filtered in the block 650, control passes to an activity block 654, wherein final output values of the R and IR signals are calculated by subtracting previously determined offset values, OSRED and OSIR, as follows:

$$REDOUT = AVE2R - OSRED \quad (8)$$

$$IROUT = AVE2IR - OSIR \quad (9)$$

Note that the values AVE2R, AVE2IR, REDOUT, and IROUT are fed back to the clipper so that they may be used to calculate the new limit values, LIMRNEW and LIMINEW, which are used to adjust the threshold levels. The values of REDOUT and IROUT are also used to calculate the blood oxygenation saturation level within the activity block 540 of Figure 5. Once REDOUT and IROUT are calculated within the activity block 654, control then passes to an activity block 658, wherein the values of REDOUT and IROUT are stored within the RAM memory 450.

Control then passes to an activity block 662, wherein a difference signal, E3IR, is generated by subtracting the filtered IR value, F2IR, from the value, E2IR, output from the IR clipper, and taking the absolute value (i.e., E3IR = ABS(E2IR - F2IR)). This difference signal may be used to calculate a cardiac flow monitor value, CFM, that is indicative of the rate of blood flow past the catheter 10 within a blood vessel. Note that only the IR signal is used to indicate the rate of blood flow past the catheter. Once the difference signal E3IR is calculated, control passes to an activity block 668, wherein the signal E3IR, which is produced every 50 ms, is filtered and averaged according to a similar method described in accordance with the activity block 650 (i.e., K=32, and N=10). Thus, an F3 value is generated every 50 ms, and an AVE3 value is generated every 500 ms. Control then passes to an activity block 672, wherein an index value E4 is calculated as AVE3/IROUT every 500 ms. The signal E4 is then filtered and averaged within an activity block 676.

The filtering done in the activity block 676 is slightly different than the filtering described in accordance with the activity block 650. In particular, the values of N and K are 4 and 16 respectively. Also, since the incoming data (i.e., E4) is fractional, the program steps:

$$G = G - F + E; \quad (10)$$

$$F = INT(G/K); \quad (11)$$

in the filtering program described above are replaced with a single step:

$$F4 = F4 + (E4 - F4)/K \quad (12)$$

to allow for fractional values at the output. The value of AVE4 which is calculated every 2 seconds is then assigned as the CFM value within an activity block 680. Control then passes out of the subroutine block 520 and proceeds to the calibration and update block 530 as shown in Figure 5.

Figure 7 is a flowchart which details the method used in accordance with the update quality display signal subroutine 570 of Figure 5. The method initiates in a begin block 700 and proceeds to an activity block 710, wherein the intensity shift (IS) signal quality indicator value is determined. This value is determined as a function of a baseline level as will be discussed below. Once the IS quality indicator is determined in the activity block 710, control passes to an activity block 720, wherein the cardiac flow monitor (CFM) indicator value is determined. This value is a function of the CFM index value, AVE4. Control then passes to an activity block 730, wherein a clipping frequency indicator (CFI) value is determined as a function of the last indicator value as well as the number of clips NC within the last 500 ms update cycle. Control then passes to an activity block 740, wherein the highest indicator value of the three indicators (i.e., IS, CFM, and CFI) is selected as the quality display signal. This signal 120 is displayed as a bar graph on the display panel of the monitoring apparatus 100 shown in Figure 3. Recall that each of the three indicators assumes a value of 1 to 4, so that the range of

values of the quality display signal is also 1 to 4. Control then returns to the activity block 710, and the cycle repeats. Note that each indicator value is determined at 2 second update cycles so that the quality display signal is also updated every 2 seconds. A detailed account of the procedure for determining the indicator values for the IS, CFM, and CFI signals follows.

Intensity Shift:

The IS value is based upon the IROUT signal relative to a baseline value. The baseline value is obtained or updated at each calibration or hematocrit update. To obtain the baseline value, a period of approximately 12 seconds is allowed to pass after the monitoring system initiates operation. Following this delay period, the next 16 values (corresponding to 8 seconds) of AVE2IR are averaged. This eight second average is then normalized by multiplying by 64, and dividing by the present gain level to determine the baseline value. Note that the monitoring system includes an automatic gain control (AGC) system to retain accuracy over an extended range of light intensities transmitted by the fiber optic cardiac catheter 10. In a preferred embodiment the four gain levels are 1, 4, 16, and 64. Thus, if the eight second average is determined to be a digital value of 12608, and the monitoring system is presently operating at a gain level of 16, the baseline value would be calculated as (64*12608/16) or 50432.

Large variations from this calculated baseline are indicative of large intensity shifts in the IR signal which may be due to kinks in the fiberoptic lines within the catheter 10, so that the level of the SI indicator increases as the IROUT signal increases in variation relative to the calculated baseline value. In particular, the IS level is determined from the percent change from the baseline and the following limits:

LEVEL 1: 0.67 < IROUT/BASE < 1.50
LEVEL 2: 0.5< IROUT/BASE <0.67, OR 1.5< IROUT/BASE <2.0
LEVEL 3: 0.4< IROUT/BASE <0.50, OR 2.0< IROUT/BASE <2.5
LEVEL 4: IROUT/BASE < 0.40, OR 2.50 < IROUT/BASE

Thus, if the value of the ratio IROUT/BASE is 0.45, then an IS indicator value of 3 will be generated.

Cardiac Flow Monitor:

The calculation of the CFM index, AVE4, is described in detail with reference to the flowchart of Figure 6. Within each 2 second display cycle, the CFM indicator level is determined by converting the value of AVE4 to percent and comparing it to the following limits:

LEVEL 1: 4.5% TO 15%
LEVEL 2: 4.0% TO 4.5% OR 15% TO 18%
LEVEL 3: 3.5% TO 4.0% OR 18% TO 22%
LEVEL 4: LESS THAN 3.5% OR GREATER THAN 22%

Thus if the value of AVE4*100 = 12, then the CFM indicator will be set to a value of 1.

Clipping Frequency Indicator:

The CFI value is determined as a function of the number of clipped values (NC) in the last 500 ms update cycle as well as the last CFI value. At each CFM level, local variables Z, UP, and DN are assigned set values. Another local variable W is then calculated as a function of the last W value, NC and Z. The CFI level is then adjusted as a function of the value of W. In a preferred embodiment, the CFI level is determined according to the following procedure:

Initially, the local variables Z, UP, and DN are set, as a function of the last CFI level.

IF CFI = 1, THEN Z=6, UP=49, and DN=0;
IF CFI = 2, THEN Z=10, UP=104, and DN=11;
IF CFI = 3, THEN Z=14, UP=164, and DN=51;
IF CFI = 4, THEN Z=18, UP=175, and DN=101;

The value of the variable W is then calculated as:

$$W = W_p + 4*NC - Z \quad (13)$$

Where W_p is the value of W for the preceding 500 ms time period. Thus, the calculation of the value W is recursive in that the prior value of W is used as an input value for calculating the current value of W. If the calculated value of W is less than zero, then W is assigned a value of zero. If the calculated value of W exceeds 175, then W is assigned a value of 175. This is done to insure that W does not fall outside of the acceptable range. If the value of W is greater than the current value of UP, then this indicates that the blood oxygenation saturation level reading has become less reliable, and the CFI value is incremented by one. However, if the value of W is less than the current value of DN, this indicates that the blood oxygenation saturation level reading has become more reliable, and the CFI level is decremented by one. If the value of W falls between the current values of UP and DN, then the CFI value remains the same. In this manner the CFI level may be determined.

Once the indicator levels have been determined for the IS, CFM and CFI conditions, the final quality display signal is determined as the highest of the three, and output as a bar graph display 120 on the display panel of the monitoring system 100. Thus, a method and apparatus are provided for the monitoring of the reliability of the blood oxygenation saturation level reading.

The invention may be embodied in other specific forms

without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

WHAT IS CLAIMED IS:

1. A cardiopulmonary monitoring apparatus for connection to a catheter having fiber optics which transmit optical signals to and from the interior of a blood vessel, said monitoring apparatus comprising:

a detector for detecting an optical signal transmitted from said blood vessel and generating an output signal in response thereto; and

a signal processing device comprising first signal processing means for (i) comparing the amplitude of said output signal with a threshold amplitude value, (ii) monitoring the frequency with which said output signal exceeds the threshold value during a selected interval of time and (iii) generating a first indicator based on said frequency.

2. The apparatus of Claim 1, wherein the value of said first indicator for said selected interval of time is based on the value of the first indicator during a preceding interval of time.

3. The apparatus of Claim 1, wherein the first indicator for said selected time interval is dependent on a variable W, said variable W being a function of (i) the variable W for a preceding interval of time, (ii) the frequency with which the output signal exceeds the threshold value during the selected time interval, and (iii) a variable Z which is function of the value of the first indicator during the preceding interval of time.

4. The apparatus of Claim 3, wherein the value of the first indicator for the selected time interval remains equal to the value of the first indicator for the preceding time interval unless the variable W is outside of a predetermined range, said predetermined range being a function of the value of the first indicator S for the preceding time interval.

5. The apparatus of Claim 1, wherein said signal processing device additionally comprises second signal processing means for generating a second indicator signal.

6. The apparatus of Claim 5, wherein said signal processing device additionally comprises third signal processing means for generating a third indicator.

7. The apparatus of Claim 6, additionally comprising means for sensing said first, second, and third indicators and responsively generating a display signal.

8. The apparatus of Claim 7, wherein said display signal has a value corresponding to the highest of said first, second, or third indicators.

9. The apparatus of Claim 5, wherein said second signal processing means monitors the magnitude of variations in said output signal caused by pulsatile blood flow through said blood vessel.

10. The apparatus of Claim 6, wherein said third signal processing means monitors the amplitude of said output signal.

11. A cardiopulmonary monitoring apparatus for connection to a catheter having fiber optics which transmit optical signals to and from the interior of a blood vessel, said monitoring apparatus comprising:

a detector for detecting an optical signal transmitted from said blood vessel and generating an output signal in response thereto, said output signal having a waveform;

means for recursively generating a variable indicative of a characteristic of said waveform; and

means for generating an indicator based on said variable.

12. The apparatus of claim 11, wherein said waveform characteristic comprises spikes in said waveform.

13. A method of monitoring an optical signal from a cardiopulmonary catheter, comprising:

detecting said optical signal and generating a

waveform in response thereto;

monitoring spikes in said waveform during a first time interval;

monitoring spikes in said waveform during a second interval; and

utilizing the results of steps (b) and (c) to generate an indicator.

14. The method of Claim 13, additionally comprising the step of comparing the indicator with another indicator and generating a display signal based on the results of the comparison.

15. The method of Claim 14, wherein the display signal has a value corresponding to the value of the highest of said indicators.

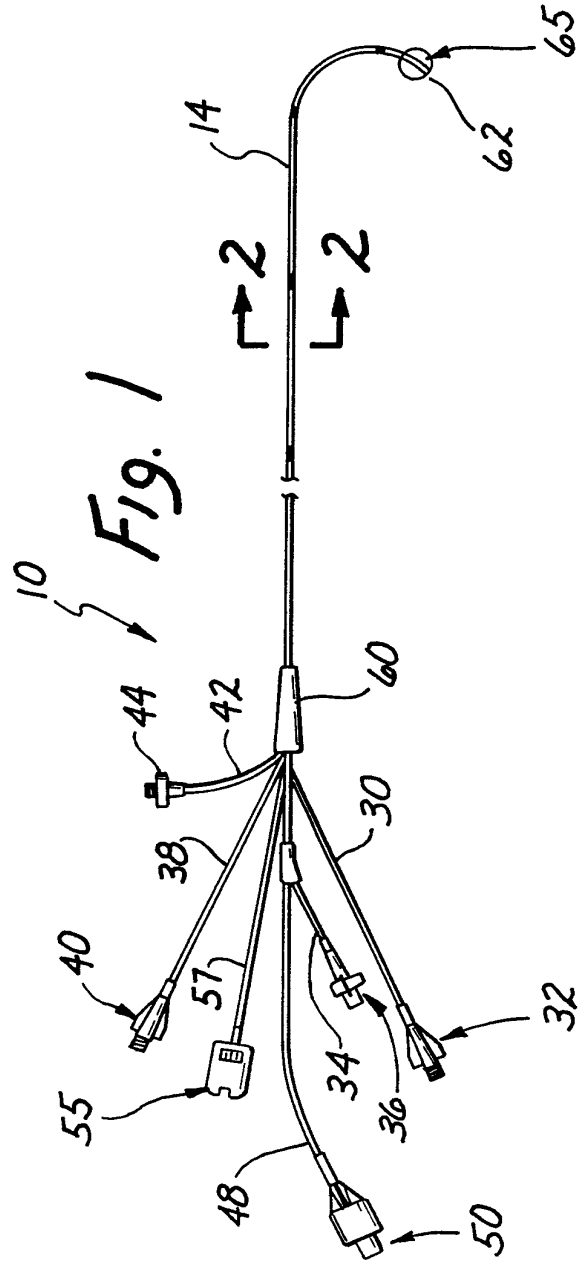


FIG. 1

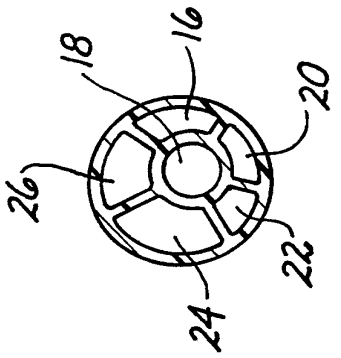


FIG. 2

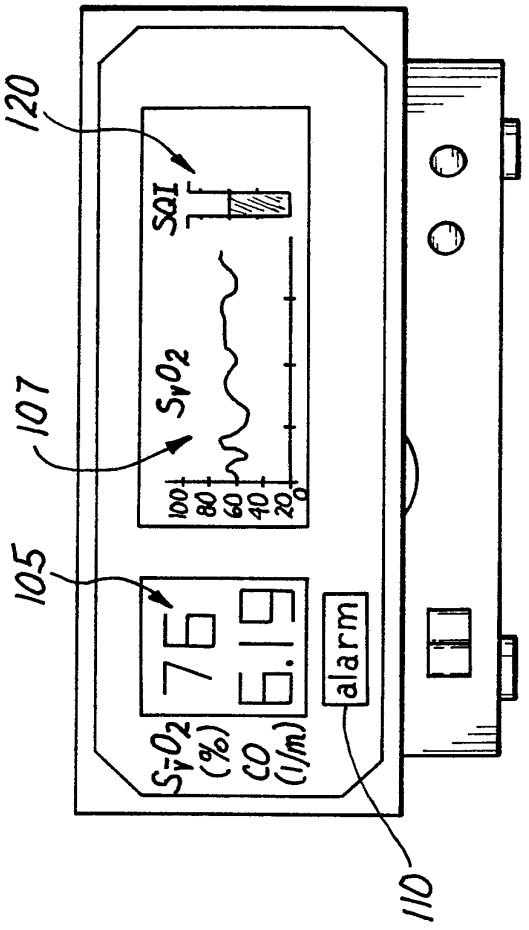


Fig. 3

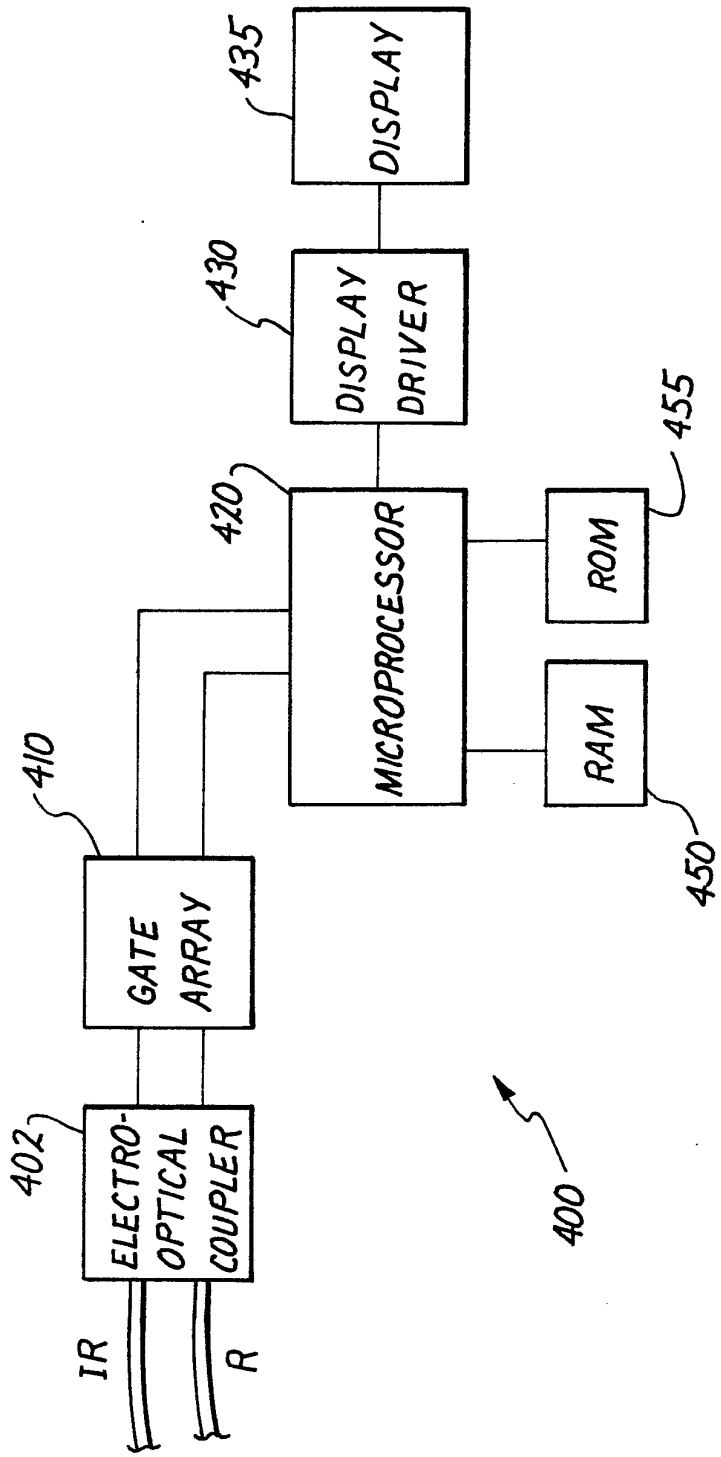

435
DISPLAY
430
DISPLAY DRIVER
420
MICROPROCESSOR
455
ROM
450
RAM
410
GATE ARRAY
402
ELECTRO-OPTICAL COUPLER
IR
R
400

Fig. 4

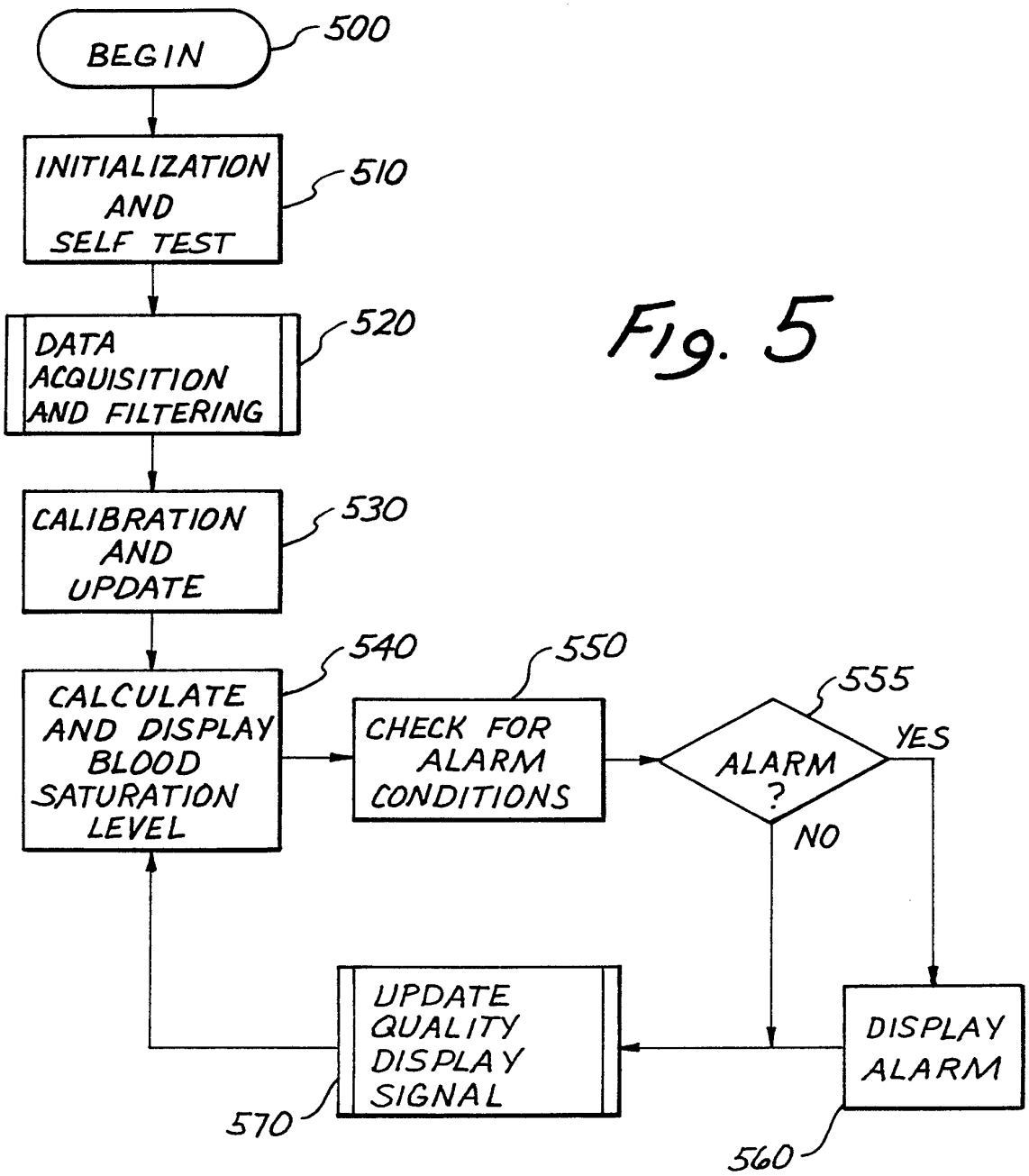
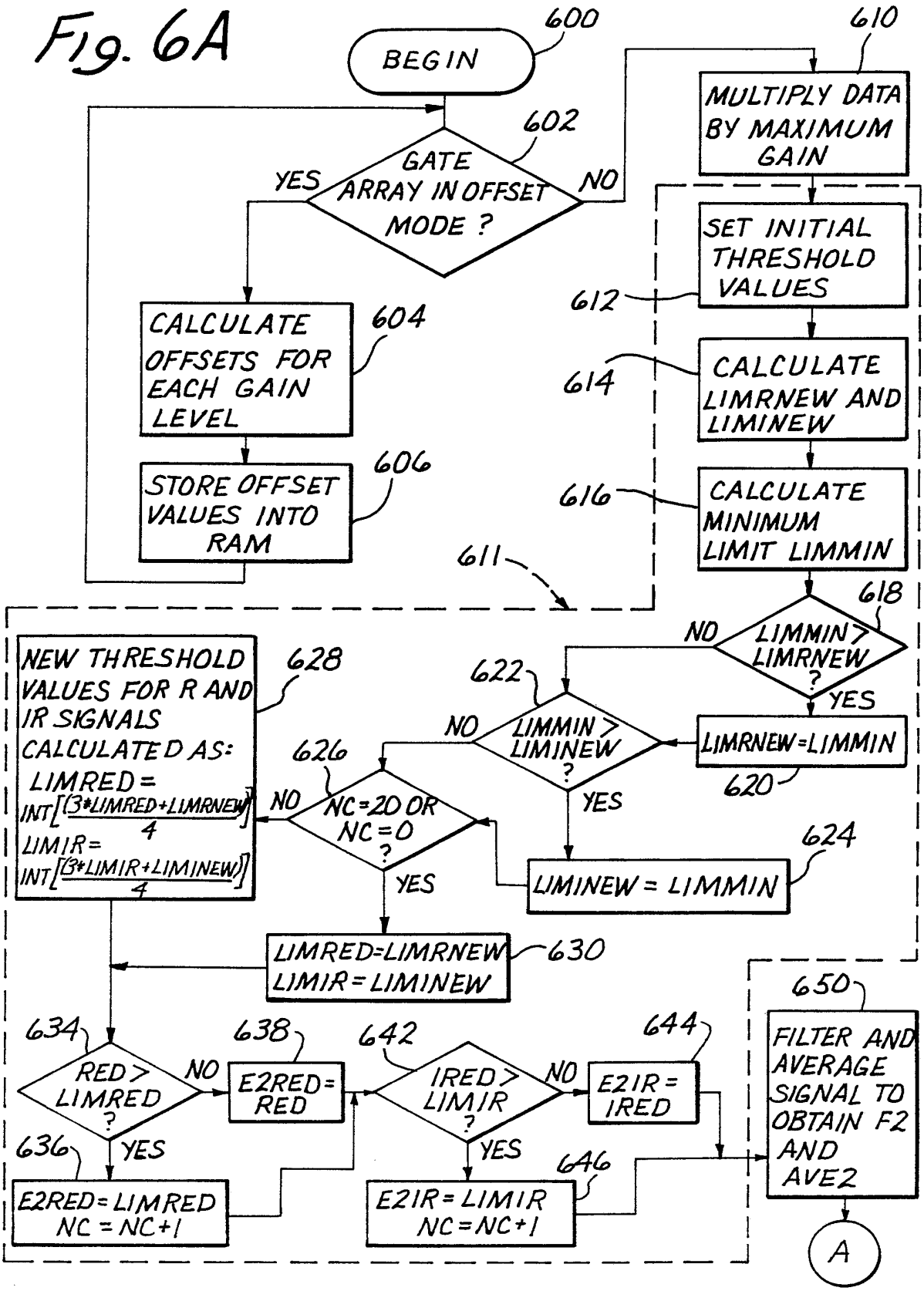

BEGIN
500
INITIALIZATION AND SELF TEST
510
DATA ACQUISITION AND FILTERING
520
CALIBRATION AND UPDATE
530
CALCULATE AND DISPLAY BLOOD SATURATION LEVEL
540
CHECK FOR ALARM CONDITIONS
550
ALARM ?
555
YES
NO
DISPLAY ALARM
560
UPDATE QUALITY DISPLAY SIGNAL
570

Fig. 5

Fig. 6A


600
BEGIN
602
GATE ARRAY IN OFFSET MODE ?
YES
NO
604
CALCULATE OFFSETS FOR EACH GAIN LEVEL
606
STORE OFFSET VALUES INTO RAM
610
MULTIPLY DATA BY MAXIMUM GAIN
612
SET INITIAL THRESHOLD VALUES
614
CALCULATE LIMRNEW AND LIMINEW
616
CALCULATE MINIMUM LIMIT LIMMIN
611
618
LIMMIN > LIMRNEW ?
NO
YES
622
LIMMIN > LIMINEW ?
NO
YES
620
LIMRNEW=LIMMIN
626
NC=20 OR NC=0 ?
NO
YES
624
LIMINEW = LIMMIN
628
NEW THRESHOLD VALUES FOR R AND IR SIGNALS CALCULATED AS:
LIMRED = INT[(3*LIMRED+LIMRNEW)/4]
LIMIR = INT[(3*LIMIR+LIMINEW)/4]
630
LIMRED=LIMRNEW
LIMIR=LIMINEW
634
RED > LIMRED ?
NO
YES
638
E2RED=RED
636
E2RED=LIMRED
NC=NC+1
642
IRED > LIMIR ?
NO
YES
644
E2IR=IRED
646
E2IR=LIMIR
NC=NC+1
650
FILTER AND AVERAGE SIGNAL TO OBTAIN F2 AND AVE2
A

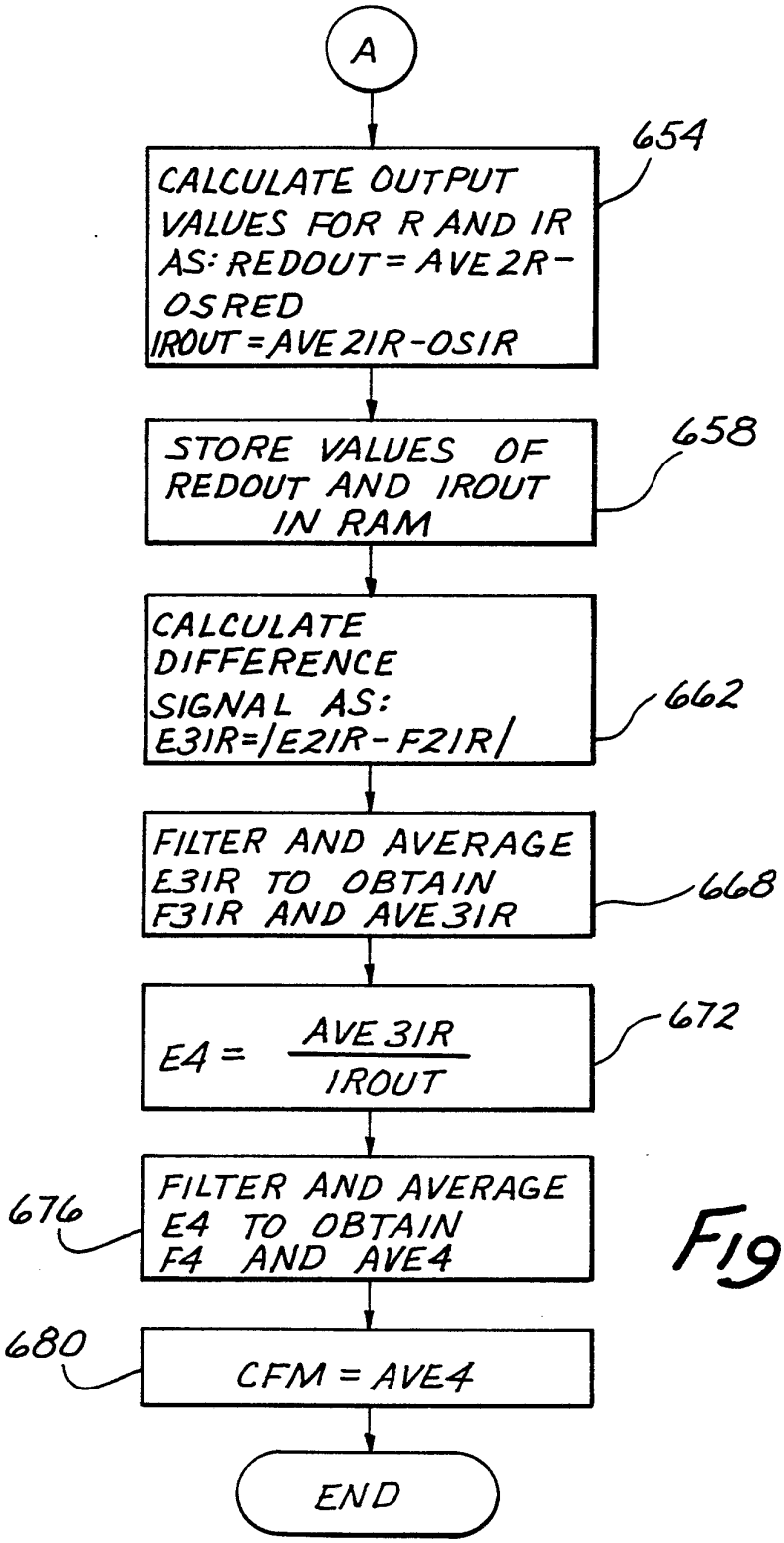

A
654
CALCULATE OUTPUT VALUES FOR R AND IR AS: REDOUT = AVE2R - OSRED
IROUT = AVE2IR - OSIR
658
STORE VALUES OF REDOUT AND IROUT IN RAM
662
CALCULATE DIFFERENCE SIGNAL AS: E3IR = |E2IR - F2IR|
668
FILTER AND AVERAGE E3IR TO OBTAIN F3IR AND AVE3IR
672
E4 = AVE3IR / IROUT
676
FILTER AND AVERAGE E4 TO OBTAIN F4 AND AVE4
680
CFM = AVE4
END

Fig. 6B

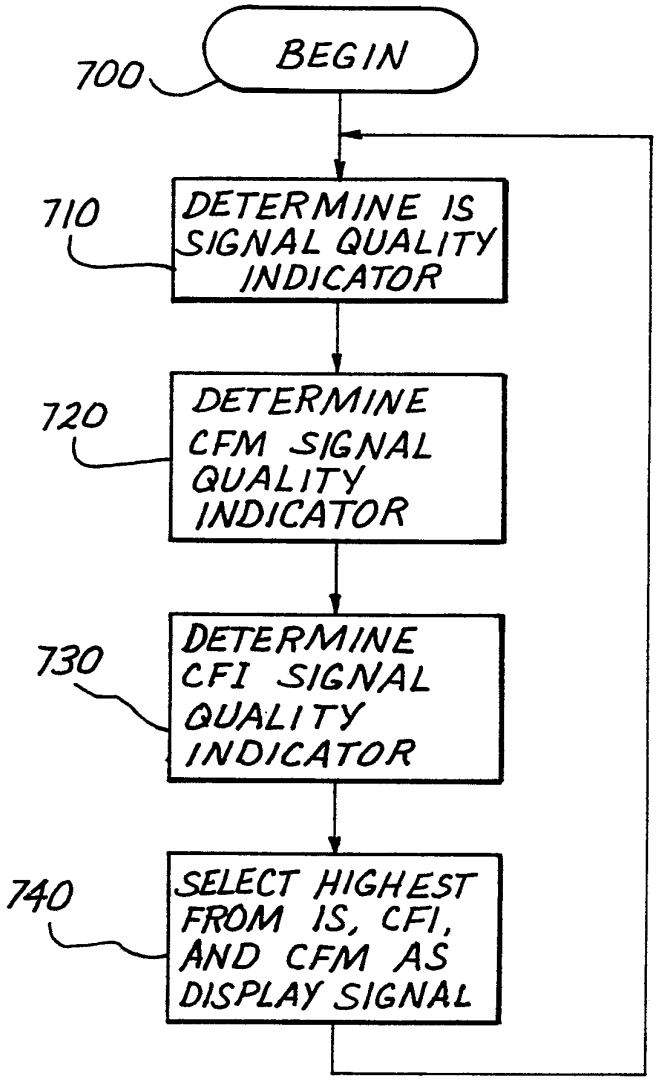

BEGIN
700
DETERMINE IS SIGNAL QUALITY INDICATOR
710
DETERMINE CFM SIGNAL QUALITY INDICATOR
720
DETERMINE CFI SIGNAL QUALITY INDICATOR
730
SELECT HIGHEST FROM IS, CFI, AND CFM AS DISPLAY SIGNAL
740

Fig. 7

INTERNATIONAL SEARCH REPORT

PCT/US 92/00298

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B5/00; G06F15/20

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B ; G06F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
Y	WO,A,8 201 948 (OXIMETRIC INC.) 10 June 1982	1,2,11, 12,13
A	see abstract see page 1, line 27 - page 3, line 29 see page 5, line 12 - line 29 see page 8, line 18 - page 12, line 17; figures 1-3	3,4

Y	WO,A,9 009 144 (PRECOR INCORPORATED) 23 August 1990	1,2,11, 12,13
A	see page 12, line 35 - page 13, line 38 see page 15, line 15 - page 16, line 8 see page 24, line 3 - page 26, line 11; figures 1-3,5,6	9,10

A	EP,A,0 245 039 (WESTINGHOUSE ELECTRIC CORPORATION) 11 November 1987 see page 8, line 11 - line 24	5-8,14, 15

° Special categories of cited documents :[10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
24 APRIL 1992	15. 05. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	FONTENAY P.H.

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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9200298 SA 56476

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 24/04/92
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A-8201948	10-06-82	US-A- 4453218	05-06-84
		AU-B- 550477	20-03-86
		AU-A- 7932282	17-06-82
		CA-A- 1169681	26-06-84
		EP-A,B 0065007	24-11-82
		GB-A,B 2102647	02-02-83
		NL-T- 8120475	01-10-82
		US-A- 4523279	11-06-85
WO-A-9009144	23-08-90	US-A- 4938228	03-07-90
		AU-A- 5197990	05-09-90
		EP-A- 0458896	04-12-91
		GB-A- 2228331	22-08-90
EP-A-0245039	11-11-87	JP-A- 63059606	15-03-88
		US-A- 4902469	20-02-90
		US-A- 5032978	16-07-91

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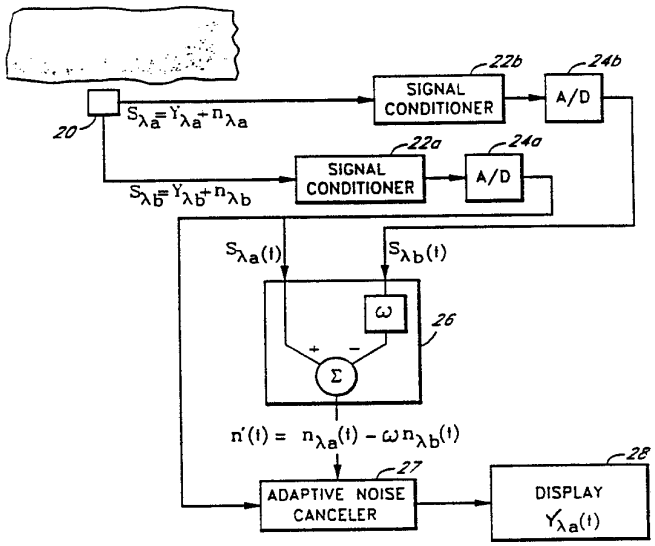
(72) Inventors: DIAB, Mohamed, K. ; 29773 Niguel Road, #C, Laguna Niguel, CA 92677 (US). KIANI-AZARBAYJANY, Esmaiel ; 35 Brindisi, Laguna Niguel, CA 92677 (US).

(74) Agent: FISCHER, Morland, C.; Hawes & Fischer, 660 Newport Center Drive, #460, Newport Beach, CA 92660 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), BF (OAPI patent), BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH (European patent), CI (OAPI patent), CM (OAPI patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GA (OAPI patent), GB (European patent), GN (OAPI patent), GR (European patent), IT (European patent), JP, KR, LU (European patent), MC (European patent), ML (OAPI patent), MR (OAPI patent), NL (European patent), RU, SE (European patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent).

Published
With international search report.

(54) Title: SIGNAL PROCESSING APPARATUS AND METHOD



(57) Abstract

A signal processor which acquires a first signal (Sλa), including a first desired signal portion (Yλa) and a first undesired signal portion (nλa), and a second signal (Sλb), including a second desired signal portion (Yλb) and a second undesired signal portion (nλb), wherein the first and second desired signal portions are correlated. The processor (26) of the present invention generates a noise reference signal (n'(t)) which is a combination of only the undesired signal portions and is correlated to both the first and second undesired signal portions. The noise reference signal (n'(t)) is then used to remove the undesired portion of each of the first and second measured signals via an adaptive noise canceler (27), preferably of the joint process estimator type. The processor (26) may be employed in conjunction with an adaptive noise canceler (27) in physiological monitors (20) wherein the known properties of energy attenuation through a medium are used to determine physiological characteristics of the medium.

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SIGNAL PROCESSING APPARATUS AND METHOD

TECHNICAL FIELD

The present invention relates to the field of signal processing. More specifically, the present invention relates to the processing of measured signals to remove undesired portions when little is known about the undesired signal portion.

BACKGROUND ART

Signal processors are typically employed to remove undesired portions from a composite measured signal including a desired signal portion and an undesired signal portion. If the undesired signal portion occupies a different frequency spectrum than the desired signal, then conventional filtering techniques such as low pass, band pass, and high pass filtering could be used to separate the desired portion from the total signal. Fixed single or multiple notch filters could also be employed if the undesired signal portions(s) exist at a fixed frequency(s).

However, it is often the case that an overlap in frequency spectrum between the desired and undesired signal portions does exist and the statistical properties of both signal portions change with time. In such cases, conventional filtering techniques are totally ineffective in extracting the desired signal. If, however, a description of the undesired portion can be made available, adaptive noise canceling can be employed to remove the undesired portion of the signal leaving the desired portion available for measurement. Adaptive noise cancelers dynamically change their transfer function to adapt to and remove the undesired signal portions of a composite signal. Adaptive noise cancelers require a noise reference signal which is correlated to the undesired signal portion. The noise reference signal is

not necessarily a representation of the undesired signal portion, but has a frequency spectrum which is similar to that of the undesired signal. In many cases, it requires considerable ingenuity to determine a noise reference signal since nothing is a priori known about the undesired signal portion.

One area where composite measured signals comprise a desired signal portion and an undesired signal portion about which no information can easily be determined is physiological monitoring. Physiological monitoring apparatuses generally measure signals derived from a physiological system, such as the human body. Measurements which are typically taken with physiological monitoring systems include electron cardiographs, blood pressure, blood gas saturation (such as oxygen saturation), capnographs, heart rate, respiration rate, and depth of anesthesia, for example. Other types of measurements include those which measure the pressure and quantity of a substance within the body such as breathalizer testing, drug testing, cholesterol testing, glucose testing, arterial carbon dioxide testing, protein testing, and carbon monoxide testing, for example. The source of the undesired signal portion in these measurements is often due to motion of the patient, both external and internal (muscle movement, for example), during the measurement process.

Knowledge of physiological systems, such as the amount of oxygen in a patient's blood, can be critical,

for example during surgery. Data can be determined by a lengthy invasive procedure of extracting and testing matter, such as blood, from a patient, or by more expedient, non-invasive measures. Many types of non-invasive measurements can be made by using the known properties of energy attenuation as a selected form of energy passes through a medium.

Energy is caused to be incident on a medium either derived from or contained within a patient and the amplitude of transmitted or reflected energy is then measured. The amount of attenuation of the incident energy caused by the medium is strongly dependent on the thickness and composition of the medium through which the energy must pass as well as the specific form of energy selected. Information about a physiological system can be derived from data taken from the attenuated signal of the incident energy transmitted through the medium if the noise can be removed. However, non-invasive measurements often do not afford the opportunity to selectively observe the interference causing the undesired signal portion, making it difficult to remove.

These undesired signal portions often originate from both AC and DC sources. The first undesired portion is an easily removed DC component caused by transmission of the energy through differing media which are of relatively constant thickness within the body, such as bone, tissue, skin, blood, etc. Second, is an erratic AC component caused when differing media being measured are perturbed

and thus, change in thickness while the measurement is being made. Since most materials in and derived from the body are easily compressed, the thickness of such matter changes if the patient moves during a non-invasive physiological measurement. Patient movement can cause the properties of energy attenuation to vary erratically. Traditional signal filtering techniques are frequently totally ineffective and grossly deficient in removing these motion induced effects from a signal. The erratic or unpredictable nature of motion induced undesired signal components is the major obstacle in removing them. Thus, presently available physiological monitors generally become totally inoperative during time periods when the patient moves.

A blood gas monitor is one example of a physiological monitoring system which is based upon the measurement of energy attenuated by biological tissues or substances. Blood gas monitors transmit light into the tissue and measure the attenuation of the light as a function of time. The output signal of a blood gas monitor which is sensitive to the arterial blood flow contains a component which is a waveform representative of the patient's arterial pulse. This type of signal, which contains a component related to the patient's pulse, is called a plethysmographic wave, and is shown in Figure 1 as curve Y. Plethysmographic waveforms are used in blood pressure or blood gas saturation measurements, for example. As the heart beats the amount of blood in the arteries increases

and decreases, causing increases and decreases in energy attenuation, illustrated by the cyclic wave Y in Figure 1.

Typically, a digit such as a finger, an ear lobe, or other portion of the body where blood flows close to the skin, is employed as the medium through which light energy is transmitted for blood gas attenuation measurements. The finger comprises skin, fat, bone, muscle, etc., shown schematically in Figure 2, each of which attenuates energy incident on the finger in a generally predictable and constant manner. However, when fleshy portions of the finger are compressed erratically, for example by motion of the finger, energy attenuation becomes erratic.

An example of a more realistic measured waveform S is shown in Figure 3, illustrating the effect of motion. The desired portion of the signal Y is the waveform representative of the pulse, corresponding to the sawtooth-like pattern wave in Figure 1. The large, motion-induced excursions in signal amplitude hide the desired signal Y. It is easy to see how even small variations in amplitude make it difficult to distinguish the desired signal Y in the presence of a noise component n.

A specific example of a blood gas monitoring apparatus is a pulse oximeter which measures the saturation of oxygen in the blood. The pumping of the heart forces freshly oxygenated blood into the arteries causing greater energy attenuation. The saturation of oxygenated blood may be determined from the depth of the

valleys relative to the peaks of two plethysmographic waveforms measured at separate wavelengths. However, motion induced undesired signal portions, or motion artifacts, must be removed from the measured signal for the oximeter to continue the measurement during periods when the patient moves.

SUMMARY OF THE INVENTION

The present invention is a signal processor which acquires a first signal and a second signal that is correlated to the first signal. The first signal comprises a first desired signal portion and a first undesired signal portion. The second signal comprises a second desired signal portion and a second undesired signal portion. The signals may be acquired by propagating energy through a medium and measuring an attenuated signal after transmission or reflection. Alternatively, the signal may be acquired by measuring energy generated by the medium.

The first and second measured signals are processed to generate a noise reference signal which does not contain the desired signal portions from either of the first or second measured signals. The remaining undesired signal portions from the first and second measured signals are combined to form a noise reference signal. This noise reference signal is correlated to the undesired signal portion of each of the first and second measured signals.

The noise reference signal is then used to remove the undesired portion of each of the first and second measured signals via an adaptive noise canceler. An adaptive noise canceler can be described by analogy to a dynamic multiple notch filter which dynamically changes its transfer function in response to the noise reference signal and the

measured signals to remove frequencies from the measured signals that are also present in the noise reference signal. Thus, a typical adaptive noise canceler receives the signal from which it is desired to remove noise and a noise reference signal. The output of the adaptive noise canceler is a good approximation to the desired signal with the noise removed.

Physiological monitors can often advantageously employ signal processors of the present invention. Often in physiological measurements a first signal comprising a first desired portion and a first undesired portion and a second signal comprising a second desired portion and a second undesired portion are acquired. The signals may be acquired by propagating energy through a patient's body (or a material which is derived from the body, such as breath, blood, or tissue, for example) and measuring an attenuated signal after transmission or reflection. Alternatively, the signal may be acquired by measuring energy generated by a patient's body, such as in electrocardiography. The signals are processed via the signal processor of the present invention to acquire a noise reference signal which is input to an adaptive noise canceler.

One physiological monitoring apparatus which can advantageously incorporate the features of the present invention is a monitoring system which determines a signal which is representative of the arterial pulse, called a plethysmographic wave. This signal can be used in blood

pressure calculations, blood gas saturation measurements, etc. A specific example of such a use is in pulse oximetry which determines the saturation of oxygen in the blood. In this configuration, the desired portion of the signal is the arterial blood contribution to attenuation of energy as it passes through a portion of the body where blood flows close to the skin. The pumping of the heart causes blood flow to increase and decrease in the arteries in a periodic fashion, causing periodic attenuation wherein the periodic waveform is the plethysmographic waveform representative of the pulse.

A physiological monitor particularly adapted to pulse oximetry oxygen saturation measurement comprises two light emitting diodes (LED's) which emit light at different wavelengths to produce first and second signals. A detector registers the attenuation of the two different energy signals after each passes through an absorptive media, for example a digit such as a finger, or an earlobe. The attenuated signals generally comprise both desired and undesired signal portions. A static filtering system, such as a band pass filter, removes a portion of the undesired signal which is static, or constant, or outside of a known bandwidth of interest, leaving an erratic or random undesired signal portion, often caused by motion and often difficult to remove, along with the desired signal portion.

Next, a processor of the present invention removes the desired signal portions from the measured signals

yielding a noise reference signal which is a combination of the remaining undesired signal portions. The noise reference signal is correlated to both of the undesired signal portions. The noise reference signal and at least one of the measured signals are input to an adaptive noise canceler which removes the random or erratic portion of the undesired signal. This yields a good approximation to the desired plethysmographic signal as measured at one of the measured signal wavelengths. As is known in the art, quantitative measurements of the amount of oxygenated blood in the body can be determined from the plethysmographic signal in a variety of ways.

One aspect of the present invention is a signal processor comprising a detector for receiving a first signal which travels along a first propagation path and a second signal which travels along a second propagation path wherein a portion of the first and second propagation paths are located in a propagation medium. The first signal has a first desired signal portion and a first undesired signal portion and the second signal has a second desired signal portion and a second undesired signal portion. The first and second undesired signal portions are a result of a perturbation of the propagation medium. This aspect of the invention additionally comprises a reference processor having an input for receiving the first and second signals. The processor is adapted to combine the first and second signals to generate a reference signal having a primary component

which is a function of the first and said second undesired signal portions.

The above described aspect of the present invention may further comprise an adaptive signal processor for receiving the reference signal and the first signal and for deriving therefrom an output signal having a primary component which is a function of the first desired signal portion of the first signal. Alternatively, the above described aspect of the present invention my further comprise an adaptive signal processor for receiving the reference signal and the second signal and for deriving therefrom an output signal having a primary component which is a function of the second desired signal portion of the second signal. The adaptive signal processor may comprise an adaptive noise canceler. The adaptive noise canceler may be comprise a joint process estimator having a least-squares-lattice predictor and a regression filter.

The detector in the aspect of the signal processor of the present invention described above may further comprise a sensor for sensing a physiological function. The sensor may comprise a light sensitive device. Additionally, the present invention may further comprising a pulse oximeter for measuring oxygen saturation in a living organism.

Another aspect of the present invention is a physiological monitoring apparatus comprising a detector for receiving a first physiological measurement signal which travels along a first propagation path and a second physiological measurement signal which travels along a

second propagation path. A portion of the first and second propagation paths is located in a propagation medium. The first signal has a first desired signal portion and a first undesired signal portion and the second signal has a second desired signal portion and a second undesired signal portion. The physiological monitoring apparatus further comprises a reference processor having an input for receiving the first and second signals. The processor is adapted to combine the first and second signals to generate a reference signal having a primary component which is a function of the first and the second undesired signal portions.

The physiological monitoring apparatus may further comprise an adaptive signal processor for receiving the reference signal and the first signal and for deriving therefrom an output signal having a primary component which is a function of the first desired signal portion of the first signal. Alternatively, the physiological monitoring apparatus may further comprise an adaptive signal processor for receiving the reference signal and the second signal and for deriving therefrom an output signal having a primary component which is a function of the second desired signal portion of the second signal. The physiological monitoring apparatus may further comprise a pulse oximeter.

A further aspect of the present invention is an apparatus for measuring a blood constituent comprising an energy source for directing a plurality of predetermined

wavelengths of electromagnetic energy upon a specimen and a detector for receiving the plurality of predetermined wavelengths of electromagnetic energy from the specimen. The detector produces electrical signals corresponding to the predetermined wavelengths in response to the electromagnetic energy. At least two of the electrical signals each has a desired signal portion and an undesired signal portion. Additionally, the apparatus comprises a reference processor having an input for receiving the electrical signals. The processor is configured to combine said electrical signals to generate a reference signal having a primary component which is derived from the undesired signal portions.

This aspect of the present invention may further comprise an adaptive signal processor for receiving the reference signal and one of the two electrical signals and for deriving therefrom an output signal having a primary component which is a function of the desired signal portion of the electrical signal. This may be accomplished by use of an adaptive noise canceler in the adaptive signal processor which may employ a joint process estimator having a least-squares-lattice predictor and a regression filter.

Yet another aspect of the present invention is a blood gas monitor for non-invasively measuring a blood constituent in a body comprising a light source for directing at least two predetermined wavelengths of light upon a body and a detector for receiving the light from

the body. The detector, in response to the light from the body, produces at least two electrical signals corresponding to the at least two predetermined wavelengths of light. The at least two electrical signals each has a desired signal portion and an undesired signal portion. The blood oximeter further comprises a reference processor having an input for receiving the at least two electrical signals. The processor is adapted to combine the at least two electrical signals to generate a reference signal with a primary component which is derived from the undesired signal portions. The blood oximeter may further comprise an adaptive signal processor for receiving the reference signal and the two electrical signals and for deriving therefrom at least two output signals which are substantially equal, respectively, to the desired signal portions of the electrical signals.

The present invention also includes a method of determining a noise reference signal from a first signal comprising a first desired signal portion and a first noise portion and a second signal comprising a second desired signal portion and a second noise portion. The method comprises the steps of selecting a signal coefficient which is proportional to a ratio of predetermined attributes of the first desired signal portion and predetermined attributes of the second desired signal portion. The first signal and the second signal coefficient are input into a signal multiplier wherein the first signal is multiplied by the signal coefficient

thereby generating a first intermediate signal. The second signal and the first intermediate signal are input into a signal subtractor wherein the first intermediate signal is subtracted from the second signal. This generates a noise reference signal having a primary component which is derived from the first and second noise signal portions. The first and second signals in this method may be derived from light energy transmitted through an absorbing medium.

The present invention further embodies a physiological monitoring apparatus comprising means for acquiring a first signal comprising a first desired signal portion and a first undesired signal portion and a second signal comprising a second desired signal portion and a second undesired signal portion. The physiological monitoring apparatus of the present invention also comprises means for determining from the first and second signals a noise reference signal. Additionally, the monitoring apparatus comprises an adaptive noise canceler having a noise reference input for receiving the noise reference signal and a signal input for receiving the first signal wherein the adaptive noise canceler, in real or near real time, generates an output signal which approximates the first desired signal portion. The adaptive noise canceler may further comprise a joint process estimator.

A further aspect of the present invention is an apparatus for processing an amplitude modulated signal

having a signal amplitude complicating feature, the apparatus comprising an energy source for directing electromagnetic energy upon a specimen. Additionally, the apparatus comprises a detector for acquiring a first amplitude modulated signal and a second amplitude modulated signal. Each of the first and second signals has a component containing information about the attenuation of electromagnetic energy by the specimen and a signal amplitude complicating feature. The apparatus includes a reference processor for receiving the first and second amplitude modulated signals and deriving therefrom a noise reference signal which is correlated with the signal amplitude complicating feature. Further, the apparatus incorporates an adaptive noise canceler having a signal input for receiving the first amplitude modulated signal, a noise reference input for receiving the noise reference signal, wherein the adaptive noise canceler produces an output signal having a primary component which is derived from the component containing information about the attenuation of electromagnetic energy by the specimen.

Still another aspect of the present invention is an apparatus for extracting a plethysmographic waveform from an amplitude modulated signal having a signal amplitude complicating feature, the apparatus comprising a light source for transmitting light into an organism and a detector for monitoring light from the organism. The detector produces a first light attenuation signal and a second light attenuation signal, wherein each of the first

and second light attenuation signals has a component which is representative of a plethysmographic waveform and a component which is representative of the signal amplitude complicating feature. The apparatus also includes a reference processor for receiving the first and second light attenuation signals and deriving therefrom a noise reference signal. The noise reference signal and the signal amplitude complicating feature each has a frequency spectrum. The frequency spectrum of the noise reference signal is correlated with the frequency spectrum of the signal amplitude complicating feature. Additionally incorporated into this embodiment of the present invention is an adaptive noise canceler having a signal input for receiving the first attenuation signal and a noise reference input for receiving the noise reference signal. The adaptive noise canceler produces an output signal having a primary component which is derived from the component which is representative of a plethysmographic waveform.

The present invention also comprises a method of removing a motion artifact signal from a signal derived from a physiological measurement wherein a first signal having a physiological measurement component and a motion artifact component and a second signal having a physiological measurement component and a motion artifact component are acquired. From the first and second signals a motion artifact noise reference signal which is a primary function of the first and second signals motion

artifact components is derived. This method of removing a motion artifact signal from a signal derived from a physiological measurement may also comprise the step of inputting the motion artifact noise reference signal into an adaptive noise canceler to produce an output signal which is a primary function of the first signal physiological measurement component.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates an ideal plethysmographic waveform.

FIG. 2 schematically illustrates the cross-sectional structure of a typical finger.

FIG. 3 illustrates a plethysmographic waveform which includes a motion-induced undesired erratic signal portion.

FIG. 4 illustrates a schematic diagram of a physiological monitor incorporating a processor of the present invention and an adaptive noise canceler.

FIG. 4a illustrates the transfer function of a multiple notch filter.

FIG. 5 illustrates an example of an adaptive noise canceler which could be employed in a physiological monitor which also incorporates the processor of the present invention.

FIG. 6a illustrates a schematic absorbing material comprising N constituents within an absorbing material.

FIG. 6b illustrates another schematic absorbing material comprising N constituents within an absorbing material.

FIG. 7 is a schematic model of a joint process estimator comprising a least-squares lattice predictor and a regression filter.

FIG. 8 is a flowchart representing a subroutine capable of implementing a joint process estimator as modeled in FIG. 7.

FIG. 9 is a schematic model of a joint process estimator with a least-squares lattice predictor and two regression filters.

FIG. 10 is an example of a physiological monitor incorporating a processor of the present invention and an adaptive noise canceler within a microprocessor. This physiological monitor is specifically designed to measure a plethysmographic waveform and perform pulse oximetry measurements.

FIG. 11 is a graph of oxygenated and deoxygenated absorption coefficients vs. wavelength.

FIG. 12 is a graph of the ratio of the absorption coefficients of deoxygenated hemoglobin divided by oxygenated hemoglobin vs. wavelength.

FIG. 13 is an expanded view of a portion of FIG. 11 marked by a circle labelled 13.

FIG. 14 illustrates a signal measured at a first red wavelength $\lambda a=\lambda red1=650nm$ for use in a processor of the present invention employing the ratiometric method for determining the noise reference signal n'(t) and for use in a joint process estimator. The measured signal comprises a desired portion $Y_{\lambda a}(t)$ and an undesired portion $n_{\lambda a}(t)$.

FIG. 15 illustrates a signal measured at a second red wavelength $\lambda b=\lambda red2=685nm$ for use in a processor of the present invention employing the ratiometric method for determining the noise reference signal n'(t). The measured signal comprises a desired portion $Y_{\lambda b}(t)$ and an undesired portion $n_{\lambda b}(t)$.

FIG. 16 illustrates a signal measured at an infrared wavelength $\lambda c=\lambda IR=940nm$ for use in a joint process estimator. The measured signal comprises a desired portion $Y_{\lambda c}(t)$ and an undesired portion $n_{\lambda c}(t)$.

FIG. 17 illustrates the noise reference signal n'(t) determined by a processor of the present invention using the ratiometric method.

FIG. 18 illustrates a good approximation $Y'_{\lambda a}(t)$ to the desired portion $Y_{\lambda a}(t)$ of the signal $S_{\lambda a}(t)$ measured at $\lambda a=\lambda red1=650nm$ estimated with a noise reference signal n'(t) determined by the ratiometric method.

FIG. 19 illustrates a good approximation $Y'_{\lambda c}(t)$ to the desired portion $Y_{\lambda c}(t)$ of the signal $S_{\lambda c}(t)$ measured at $\lambda c=\lambda IR=940nm$ estimated with a noise reference signal n'(t) determined by the ratiometric method.

FIG. 20 illustrates a signal measured at a red wavelength $\lambda a=\lambda red=660nm$ for use in a processor of the present invention employing the constant saturation method for determining the noise reference signal n'(t) and for use in a joint process estimator. The measured signal comprises a desired portion $Y_{\lambda a}(t)$ and an undesired portion $n_{\lambda a}(t)$.

FIG. 21 illustrates a signal measured at an infrared wavelength $\lambda b=\lambda IR=940nm$ for use in a processor of the present invention employing the constant saturation method for determining the noise reference signal n'(t) and for use in a joint process estimator. The measured signal

comprises a desired portion $Y_{\lambda b}(t)$ and an undesired portion $n_{\lambda b}(t)$.

FIG. 22 illustrates the noise reference signal n'(t) determined by a processor of the present invention using the constant saturation method.

FIG. 23 illustrates a good approximation $Y'_{\lambda a}(t)$ to the desired portion $Y_{\lambda a}(t)$ of the signal $S_{\lambda a}(t)$ measured at $\lambda a=\lambda red=660nm$ estimated with a noise reference signal n'(t) determined by the constant saturation method.

FIG. 24 illustrates a good approximation $Y'_{\lambda b}(t)$ to the desired portion $Y_{\lambda b}(t)$ of the signal $S_{\lambda b}(t)$ measured at $\lambda b=\lambda IR=940nm$ estimated with a noise reference signal n'(t) determined by the constant saturation method.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is a processor which determines a noise reference signal n'(t) for use in an adaptive noise canceler. An adaptive noise canceler estimates a good approximation Y'(t) to a desired signal Y(t) from a composite signal S(t) = Y(t) + n(t) which, in addition to the desired portion Y(t) comprises an undesired portion n(t). The undesired portion n(t) may contain one or more of a constant portion, a predictable portion, an erratic portion, a random portion, etc. The approximation to the desired signal Y'(t) is derived by removing as many of the undesired portions n(t) from the composite signal S(t) as possible. The constant portion and predictable portion are easily removed with traditional filtering techniques, such as simple subtraction, low pass, band pass, and high pass filtering. The erratic portion is more difficult to remove due to its unpredictable nature. If something is known about the erratic signal, even statistically, it could be removed from the measured signal via traditional filtering techniques. However, it is often the case that no information is known about the erratic portion of the noise. In this case, traditional filtering techniques are usually insufficient. Often no information about the erratic portion of the measured signal is known. Thus, an adaptive noise canceler is utilized in the present invention to remove the erratic portion.

Generally, an adaptive noise canceler has two signal inputs and one output. One of the inputs is the noise reference signal n'(t) which is correlated to the erratic undesired signal portions n(t) present in the composite signal S(t). The other input is for the composite signal S(t). Ideally, the output of the adaptive noise canceler Y'(t) corresponds to the desired signal portion Y(t) only. Often, the most difficult task in the application of adaptive noise cancelers is determining the noise reference signal n'(t) which is correlated to the erratic undesired portion n(t) of the measured signal S(t) since, as discussed above, unpredictable signal portions are usually quite difficult to isolate from the measured signal S(t). In the signal processor of the present invention, a noise reference signal n'(t) is determined from two composite signals measured simultaneously, or nearly simultaneously, at two different wavelengths, λa and λb. The signal processor of the present invention can be advantageously used in a monitoring device, such a monitor being well suited for physiological monitoring.

A block diagram of a generic monitor incorporating a signal processor, or reference processor, according to the present invention and an adaptive noise canceler is shown in Figure 4. Two measured signals, $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$, are acquired by a detector 20. One skilled in the art will realize that for some physiological measurements, more than one detector may be advantageous. Each signal is conditioned by a signal conditioner 22a and 22b.

Conditioning includes, but is not limited to, such procedures as filtering the signals to remove constant portions and amplifying the signals for ease of manipulation. The signals are then converted to digital data by an analog-to-digital converter 24a and 24b. The first measured signal $S_{\lambda a}(t)$ comprises a first desired signal portion, labelled herein $Y_{\lambda a}(t)$, and a first undesired signal portion, labelled herein $n_{\lambda a}(t)$. The second measured signal $S_{\lambda b}(t)$ is at least partially correlated to the first measured signal $S_{\lambda a}(t)$ and comprises a second desired signal portion, labelled herein $Y_{\lambda b}(t)$, and a second undesired signal portion, labelled herein $n_{\lambda b}(t)$. Typically the first and second undesired signal portions, $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$, are uncorrelated and/or erratic with respect to the desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$. The undesired signal portions $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$ are often caused by motion of a patient. The signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ are input to a reference processor 26. The reference processor 26 multiplies the second measured signal $S_{\lambda b}(t)$ by a factor $\hat{\omega}$ and then subtracts the second measured signal $S_{\lambda b}(t)$ from the first measured signal $S_{\lambda a}(t)$. The factor $\hat{\omega}$ is determined to cause the desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ to cancel when the two signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ are subtracted. Thus, the output of the reference processor 26 is a noise reference signal $n'(t) = n_{\lambda a}(t) - \hat{\omega} n_{\lambda b}(t)$ which is correlated to both of the erratic undesired signal portions $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$. The noise reference signal $n'(t)$ is input, along with one of

the measured signals $S_{\lambda a}(t)$, to an adaptive noise canceler 27 which uses the noise reference signal n'(t) to remove the undesired signal portion $n_{\lambda a}(t)$ or $n_{\lambda b}(t)$ from the measured signal $S_{\lambda a}(t)$. It will be understood that $S_{\lambda b}(t)$ could have been input to the adaptive noise canceler 27 along with the noise reference signal n'(t) instead of $S_{\lambda a}(t)$. The output of the adaptive noise canceler 27 is a good approximation $Y'_{\lambda a}(t)$ to the desired signal $Y_{\lambda a}(t)$. The approximation $Y'_{\lambda a}(t)$ is displayed on the display 28.

An adaptive noise canceler 30, an example of which is shown in block diagram in Figure 5, is employed to remove the erratic, undesired signal portions $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$ from the measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$. The adaptive noise canceler 30 in Figure 5 has as one input a sample of the noise reference signal n'(t) which is correlated to the undesired signal portions $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$. The noise reference signal n'(t) is determined from the two measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ by the processor 26 of the present invention as described herein. A second input to the adaptive noise canceler is a sample of either the first or second measured signal $S_{\lambda a}(t) = Y_{\lambda a}(t) + n_{\lambda a}(t)$ or $S_{\lambda b}(t) = Y_{\lambda b}(t) + n_{\lambda b}(t)$.

The adaptive noise canceler 30 functions to remove frequencies common to both the noise reference signal n'(t) and the measured signal $S_{\lambda a}(t)$ or $S_{\lambda b}(t)$. Since the noise reference signal n'(t) is correlated to the erratic undesired signal portions $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$, the noise reference signal n'(t) is also erratic. The adaptive

noise canceler acts in a manner which may be analogized to a dynamic multiple notch filter based on the spectral distribution of the noise reference signal n'(t).

Referring to Figure 4a, the transfer function of a multiple notch filter is shown. The notches, or dips in the amplitude of the transfer function, indicate frequencies which are attenuated or removed when a composite measured signal passes through the notch filter. The output of the notch filter is the composite signal having frequencies at which a notch was present removed. In the analogy to an adaptive noise canceler, the frequencies at which notches are present change continuously based upon the inputs to the adaptive noise canceler.

The adaptive noise canceler 30 shown in Figure 5 produces an output signal, labelled herein $Y'_{\lambda a}(t)$ or $Y'_{\lambda b}(t)$, which is fed back to an internal processor 32 within the adaptive noise canceler 30. The internal processor 32 automatically adjusts its own transfer function according to a predetermined algorithm such that the output of the internal processor 32, labelled b(t), closely resembles the undesired signal portion $n_{\lambda a}(t)$ or $n_{\lambda b}(t)$. The output b(t) of the internal processor 32 is subtracted from the measured signal, $S_{\lambda a}(t)$ or $S_{\lambda b}(t)$, yielding a signal $Y'_{\lambda a}(t) \approx S_{\lambda a}(t) + n_{\lambda a}(t) - b_{\lambda a}(t)$ or $Y'_{\lambda b}(t) \approx S_{\lambda b}(t) + n_{\lambda b}(t) - b_{\lambda b}(t)$. The internal processor optimizes $Y'_{\lambda a}(t)$ or $Y'_{\lambda b}(t)$ such that $Y'_{\lambda a}(t)$ or $Y'_{\lambda b}(t)$ is

approximately equal to the desired signal $Y_{\lambda a}(t)$ or $Y_{\lambda b}(t)$, respectively.

One algorithm which may be used for the adjustment of the transfer function of the internal processor 32 is a least-squares algorithm, as described in Chapter 6 and Chapter 12 of the book Adaptive Signal Processing by Bernard Widrow and Samuel Stearns, published by Prentice Hall, copyright 1985. This entire book, including Chapters 6 and 12, is hereby incorporated herein by reference.

Adaptive processors 30 have been successfully applied to a number of problems including antenna sidelobe canceling, pattern recognition, the elimination of periodic interference in general, and the elimination of echoes on long distance telephone transmission lines. However, considerable ingenuity is often required to find a suitable noise reference signal n'(t) for a given application since the random or erratic portions $n_{\lambda a}(t)$ or $n_{\lambda b}(t)$ cannot easily be separated from the measured signal $S_{\lambda a}(t)$ or $S_{\lambda b}(t)$. If the actual undesired signal portion $n_{\lambda a}(t)$ or $n_{\lambda b}(t)$ were a priori available, techniques such as adaptive noise canceling would not be necessary. The unique determination of a suitable noise reference signal n'(t) from measurements taken by a monitor incorporating a reference processor of the present invention is one aspect of the present invention.

GENERALIZED DETERMINATION OF NOISE REFERENCE SIGNAL

An explanation which describes how the noise reference signal n'(t) may be determined as follows. A first signal is measured at, for example, a wavelength λa, by a detector yielding a signal $S_{\lambda a}(t)$:

$$S_{\lambda a}(t) = Y_{\lambda a}(t) + n_{\lambda a}(t); \quad (1)$$

where $Y_{\lambda a}(t)$ is the desired signal and $n_{\lambda a}(t)$ is the noise component.

A similar measurement is taken simultaneously, or nearly simultaneously, at a different wavelength, λb, yielding:

$$S_{\lambda b}(t) = Y_{\lambda b}(t) + n_{\lambda b}. \quad (2)$$

Note that as long as the measurements, $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$, are taken substantially simultaneously, the undesired signal components, $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$, will be correlated because any random or erratic functions will affect each measurement in nearly the same fashion.

To obtain the noise reference signal n'(t), the measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ are transformed to eliminate the desired signal components. One way of doing this is to find a proportionality constant, ω_1, between the desired signals $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ such that:

$$Y_{\lambda a}(t) = \omega_1 Y_{\lambda b}(t). \quad (3)$$

This proportionality relationship can be satisfied in many measurements, including but not limited to absorption measurements and physiological measurements. Additionally, in most measurements, the proportionality

constant ω_1 can be determined such that:

$$n_{\lambda a}(t) \neq \omega_1 n_{\lambda b}(t). \quad (4)$$

Multiplying equation (2) by ω_1 and then subtracting equation (2) from equation (1) results in a single equation wherein the desired signal terms $Y_{\lambda a}(t)$ and $S_{\lambda b}(t)$ cancel, leaving:

$$n'(t) = S_{\lambda a}(t) - \omega_1 S_{\lambda b}(t) = n_{\lambda a}(t) - \omega_1 n_{\lambda b}(t); \quad (5)$$

a non-zero signal which is correlated to each undesired signal portion $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$ and can be used as the noise reference signal $n'(t)$ in an adaptive noise canceler.

EXAMPLE OF DETERMINATION OF NOISE REFERENCE SIGNAL IN AN ABSORPTIVE SYSTEM

Adaptive noise canceling is particularly useful in a large number of measurements generally described as absorption measurements. An example of an absorption type monitor which can advantageously employ adaptive noise canceling based upon a noise reference signal $n'(t)$ determined by a processor of the present invention is one which determines the concentration of an energy absorbing constituent within an absorbing material when the material is subject to perturbation. Such perturbations can be caused by forces about which information is desired, or alternatively, by random or erratic forces such as a mechanical force on the material. Random or erratic interference, such as motion, generates undesired noise

components in the measured signal. These undesired components can be removed by the adaptive noise canceler if a suitable noise reference signal n'(t) is known.

A schematic N constituent absorbing material comprising a container 42 having N different absorbing constituents, labelled A_1, A_2, A_3, ... A_N, is shown schematically in Figure 6a. The constituents A_1 through A_N in Figure 6a are arranged in a generally orderly, layered fashion within the container 42. An example of a particular type of absorptive system is one in which light energy passes through the container 42 and is absorbed according to the generalized Beer-Lambert Law of light absorption. For light of wavelength λa, this attenuation may be approximated by:

$$I=I_0 e^{-\Sigma_{i=0}^{N} \varepsilon_{i,\lambda a} c_i x_i} \tag{6}$$

Initially transforming the signal by taking the natural log of both sides and manipulating terms, the signal is transformed such that the signal components are combined by addition rather than multiplication, i.e.:

$$S_{\lambda a}=\ln(I_0/I) = \Sigma_{i=0}^{N} \varepsilon_{i,\lambda a} c_i x_i \tag{7}$$

where I_0 is the incident light energy intensity; I is the transmitted light energy intensity; $\varepsilon_{i,\lambda a}$ is the absorption coefficient of the ith constituent at the wavelength λa; $x_i(t)$ is the optical path length of ith layer, i.e., the thickness of material of the ith layer through which

optical energy passes; and $c_i(t)$ is the concentration of the ith constituent in the volume associated with the thickness $x_i(t)$. The absorption coefficients ε_1 through ε_N are known values which are constant at each wavelength. Most concentrations $c_1(t)$ through $c_N(t)$ are typically unknown, as are most of the optical path lengths $x_i(t)$ of each layer. The total optical path length is the sum of each of the individual optical path lengths $x_i(t)$ of each layer.

When the material is not subject to any forces which cause perturbation in the thicknesses of the layers, the optical path length of each layer, $x_i(t)$, is generally constant. This results in generally constant attenuation of the optical energy and thus, a generally constant offset in the measured signal. Typically, this portion of the signal is of little interest since knowledge about a force which perturbs the material is usually desired. Any signal portion outside of a known bandwidth of interest, including the constant undesired signal portion resulting from the generally constant absorption of the constituents when not subject to perturbation, should be removed. This is easily accomplished by traditional band pass filtering techniques. However, when the material is subject to forces, each layer of constituents may be affected by the perturbation differently than each other layer. Some perturbations of the optical path lengths of each layer $x_i(t)$ may result in excursions in the measured signal which represent desired information. Other perturbations of the

optical path length of each layer $x_i(t)$ cause undesired excursions which mask desired information in the measured signal. Undesired signal components associated with undesired excursions must also be removed to obtain desired information from the measured signal.

The adaptive noise canceler removes from the composite signal, measured after being transmitted through or reflected from the absorbing material, the undesired signal components caused by forces which perturb the material differently from the forces which perturbed the material to cause the desired signal component. For the purposes of illustration, it will be assumed that the portion of the measured signal which is deemed the desired signal $Y_{\lambda a}(t)$ is the attenuation term $\varepsilon_5 c_5 x_5(t)$ associated with a constituent of interest, namely A_5, and that the layer of constituent A_5 is affected by perturbations differently than each of the layers of other constituents A_1 through A_4 and A_6 through A_N. An example of such a situation is when layer A_5 is subject to forces about which information is desired and, additionally, the entire material is subject to forces which affect each of the layers. In this case, since the total force affecting the layer of constituents A_5 is different than the total forces affecting each of the other layers and information is desired about the forces and resultant perturbation of the layer of constituents A_5, attenuation terms due to constituents A_1 through A_4 and A_6 through A_N make up the undesired signal $n_{\lambda a}(t)$. Even if the additional forces

which affect the entire material cause the same perturbation in each layer, including the layer of A_5, the total forces on the layer of constituent A_5 cause it to have different total perturbation than each of the other layers of constituents A_1 through A_4 and A_6 through A_N.

It is often the case that the total perturbation affecting the layers associated with the undesired signal components is caused by random or erratic forces. This causes the thickness of layers to change erratically and the optical path length of each layer, $x_i(t)$, to change erratically, thereby producing a random or erratic undesired signal component $n_{\lambda a}(t)$. However, regardless of whether or not the undesired signal portion $n_{\lambda a}(t)$ is erratic, the undesired signal component $n_{\lambda a}(t)$ can be removed via an adaptive noise canceler having as one input a noise reference signal $n'(t)$ determined by a processor of the present invention as long as the perturbation on layers other than the layer of constituent A_5 is different than the perturbation on the layer of constituent A_5. The adaptive noise canceler yields a good approximation to the desired signal $Y'_{\lambda a}(t)$. From this approximation, the concentration of the constituent of interest, $c_5(t)$, can often be determined since in some physiological measurements, the thickness of the desired signal component, $x_5(t)$ in this example, is known or can be determined.

The adaptive noise canceler utilizes a sample of a noise reference signal $n'(t)$ determined from two

substantially simultaneously measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$. $S_{\lambda a}(t)$ is determined as above in equation (7). $S_{\lambda b}(t)$ is determined similarly at a different wavelength λb. To find the noise reference signal n'(t), attenuated transmitted energy is measured at the two different wavelengths λa and λb and transformed via logarithmic conversion. The signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ can then be written (logarithm converted) as:

$$S_{\lambda a}(t) = \epsilon_{5,\lambda a} C_5 X_5(t) + [\Sigma_{i=1}^{4} \epsilon_{i,\lambda a} C_i X_i(t) + \Sigma_{k=6}^{N} \epsilon_{k,\lambda a} C_k X_k(t)] \quad (8)$$

$$= \epsilon_{5,\lambda a} C_5 X_5(t) + n_{\lambda a}(t) \quad (9)$$

$$S_{\lambda b}(t) = \epsilon_{5,\lambda b} C_5 X_5(t) + [\Sigma_{i=1}^{4} \epsilon_{i,\lambda b} C_i X_i(t) + \Sigma_{k=6}^{N} \epsilon_{k,\lambda b} C_k X_k(t)] \quad (10)$$

$$= \epsilon_{5,\lambda b} C_5 X_5(t) + n_{\lambda b}(t) \quad (11)$$

A further transformation of the signals is the proportionality relationship defining ω_2, similarly to equation (3), which allows determination of a noise reference signal n'(t), is:

$$\epsilon_{5,\lambda a} = \omega_2 \epsilon_{5,\lambda b}; \text{ where} \quad (12)$$

$$n_{\lambda a} \approx \omega_2 n_{\lambda b}. \quad (13)$$

It is often the case that both equations (12) and (13) can be simultaneously satisfied. Multiplying equation (11) by ω_2 and subtracting the result from equation (9) yields a non-zero noise reference signal which is a linear sum of

undesired signal components:

$$n'(t) = S_{\lambda a}(t) - \omega_2 S_{\lambda b}(t) = n_{\lambda a}(t) - \omega_2 n_{\lambda b}(t). \quad (14)$$

$$= \Sigma_{i=1}^{4} \epsilon_{i,\lambda a} c_i x_i(t) + \Sigma_{k=6}^{N} \epsilon_{k,\lambda a} c_k x_k(t) - \Sigma_{i=1}^{4} \omega_2 \epsilon_{i,\lambda b} c_i x_i(t) - \Sigma_{k=6}^{N} \omega_2 \epsilon_{k,\lambda b} c_k x_k(t)$$

(15)

$$= \Sigma_{i=1}^{4} c_i x_i(t) [\epsilon_{i,\lambda a} - \omega_2 \epsilon_{i,\lambda b}] + \Sigma_{k=6}^{N} c_k x_k(t) [\epsilon_{k,\lambda a} - \omega_2 \epsilon_{k,\lambda b}]$$

(16)

A sample of this noise reference signal $n'(t)$, and a sample of either measured signal $S_{\lambda a}(t)$ or $S_{\lambda b}(t)$, are input to an adaptive noise canceler, one model of which is shown in Figure 5 and a preferred model of which is discussed herein under the heading PREFERRED ADAPTIVE NOISE CANCELER USING A JOINT PROCESS ESTIMATOR IMPLEMENTATION. The adaptive noise canceler removes the undesired portion of the measured signal $n_{\lambda a}(t)$ or $n_{\lambda b}(t)$, yielding a good approximation to the desired portion of signal $Y'_{\lambda a}(t) \approx \varepsilon_{5,\lambda a} c_5 x_5(t)$ or $Y'_{\lambda b}(t) \approx \varepsilon_{5,\lambda b} c_5 x_5(t)$. The concentration $c_5(t)$ may then be determined from the approximation to the desired signal $Y'_{\lambda a}(t)$ or $Y'_{\lambda b}(t)$ according to:

$$c_5(t) \approx Y'_{\lambda a}(t)/\varepsilon_{5,\lambda a} x_5(t) \approx Y'_{\lambda b}(t)/\varepsilon_{5,\lambda b} x_5(t). \quad (17)$$

As discussed previously, the absorption coefficients are constant at each wavelength λa and λb and the thickness of the desired signal component, $x_5(t)$ in this example, is often known or can be determined as a function of time, thereby allowing calculation of the concentration $c_5(t)$ of constituent A_5.

DETERMINATION OF CONCENTRATION OR SATURATION
IN A VOLUME CONTAINING MORE THAN ONE CONSTITUENT

Referring to Figure 6b, another material having N different constituents arranged in layers is shown. In this material, two constituents A_5 and A_6 are found within one layer having thickness $x_{5,6}(t) = x_5(t) + x_6(t)$, located generally randomly within the layer. This is analogous to combining the layers of constituents A_5 and A_6 in Figure 6a. A combination of layers, such as the combination of layers of constituents A_5 and A_6, is feasible when the two layers are under the same total forces which result in the same perturbation of the optical path lengths $x_5(t)$ and $x_6(t)$ of the layers.

Often it is desirable to find the concentration or the saturation, i.e., a percent concentration, of one constituent within a given thickness which contains more than one constituent and is subject to unique forces. A determination of the concentration or the saturation of a constituent within a given volume may be made with any number of constituents in the volume subject to the same total forces and therefore under the same perturbation. To determine the saturation of one constituent in a volume comprising many constituents, as many measured signals as there are constituents which absorb incident light energy are necessary. It will be understood that constituents which do not absorb light energy are not consequential in

the determination of saturation. To determine the concentration, as many signals as there are constituents which absorb incident light energy are necessary as well as information about the sum of concentrations.

It is often the case that a thickness under unique motion contains only two constituents. For example, it may be desirable to know the concentration or saturation of A_5 within a given volume which contains A_5 and A_6. In this case, the desired signals $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ comprise terms related to both A_5 and A_6 so that a determination of the concentration or saturation of A_5 or A_6 in the volume may be made. A determination of saturation is discussed herein. It will be understood that the concentration of A_5 in volume containing both A_5 and A_6 could also be determined if it is known that $A_5+A_6=1$, i.e., that there are no constituents in the volume which do not absorb incident light energy at the particular measurement wavelengths chosen. The measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ can be written (logarithm converted) as:

$$S_{\lambda a}(t) = \varepsilon_{5,\lambda a}c_5x_{5,6}(t) + \varepsilon_{6,\lambda a}c_6x_{5,6}(t) + n_{\lambda a}(t) \quad (18)$$

$$= Y_{\lambda a}(t) + n_{\lambda a}(t); \quad (19)$$

$$S_{\lambda b}(t) = \varepsilon_{5,\lambda b}c_5x_{5,6}(t) + \varepsilon_{6,\lambda b}c_6x_{5,6}(t) + n_{\lambda b}(t) \quad (20)$$

$$= Y_{\lambda b}(t) + n_{\lambda b}(t). \quad (21)$$

Any signal portions outside of a known bandwidth of interest, including the constant undesired signal portion resulting from the generally constant absorption of the constituents when not under perturbation, should be removed to determine an approximation to the desired

signal. This is easily accomplished by traditional band pass filtering techniques. As in the previous example, it is often the case that the total perturbation affecting the layers associated with the undesired signal components is caused by random or erratic forces, causing the thickness of each layer, or the optical path length of each layer, $x_i(t)$, to change erratically, producing a random or erratic undesired signal component $n_{\lambda a}(t)$. Regardless of whether or not the undesired signal portion $n_{\lambda a}(t)$ is erratic, the undesired signal component $n_{\lambda a}(t)$ can be removed via an adaptive noise canceler having as one input a noise reference signal n'(t) determined by a processor of the present invention as long as the perturbation in layers other than the layer of constituents A_5 and A_6 is different than the perturbation in the layer of constituents A_5 and A_6. The erratic undesired signal components $n_{\lambda a}(t)$ and $n_{\lambda b}(t)$ may advantageously be removed from equations (18) and (20), or alternatively equations (19) and (21), by an adaptive noise canceler. The adaptive noise canceler, again, requires a sample of a noise reference signal n'(t).

DETERMINATION OF NOISE REFERENCE SIGNAL FOR SATURATION MEASUREMENT

Two methods which may be used by a processor of the present invention to determine the noise reference signal n'(t) are a ratiometric method and a constant saturation

method. The preferred embodiment of a physiological monitor incorporating a processor of the present invention utilizes the ratiometric method wherein the two wavelengths λa and λb, at which the signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ are measured, are specifically chosen such that a relationship between the absorption coefficients $\varepsilon_{5,\lambda a}$, $\varepsilon_{5,\lambda b}$, $\varepsilon_{6,\lambda a}$ and $\varepsilon_{6,\lambda b}$ exists, i.e.:

$$\varepsilon_{5,\lambda a}/\varepsilon_{6,\lambda a} = \varepsilon_{5,\lambda b}/\varepsilon_{6,\lambda b} \quad (22)$$

The measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ can be factored and written as:

$$S_{\lambda a}(t) = \varepsilon_{6,\lambda a}[(\varepsilon_{5,\lambda a}/\varepsilon_{6,\lambda a})c_5x(t) + c_6x(t)] + n_{\lambda a}(t) \quad (23)$$

$$S_{\lambda b}(t) = \varepsilon_{6,\lambda b}[(\varepsilon_{5,\lambda b}/\varepsilon_{6,\lambda b})c_5x(t) + c_6x(t)] + n_{\lambda b}(t). \quad (24)$$

The wavelengths λa and λb, chosen to satisfy equation (22), cause the terms within the square brackets to be equal, thereby causing the desired signal portions $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$ to be linearly dependent. Then, a proportionality constant $\hat{\omega}_{r3}$ which causes the desired signal portions $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$ to be equal and allows determination of a non-zero noise reference signal n'(t) is:

$$\varepsilon_{6,\lambda a} = \hat{\omega}_{r3}\varepsilon_{6,\lambda b}; \text{ where} \quad (25)$$

$$n_{\lambda a} \neq \hat{\omega}_{r3}n_{\lambda b}. \quad (26)$$

It is often the case that both equations (25) and (26) can be simultaneously satisfied. Additionally, since absorption coefficients of each constituent are constant with respect to wavelength, the proportionality constant $\hat{\omega}_{r3}$ can be easily determined. Furthermore, absorption coefficients of other constituents A_1 through A_4 and A_7

through A_N are generally unequal to the absorption coefficients of A_5 and A_6. Thus, the undesired noise components $n_{\lambda a}$ and $n_{\lambda b}$ are generally not made linearly dependent by the relationships of equations (22) and (25).

Multiplying equation (24) by $\hat{w}_{r3}$ and subtracting the resulting equation from equation (23), a non-zero noise reference signal is determined by:

$$n'(t) = S_{\lambda a}(t) - \hat{w}_{r3}S_{\lambda b}(t) = n_{\lambda a}(t) - \hat{w}_{r3}n_{\lambda b}(t). \quad (27)$$

An alternative method for determining the noise reference signal from the measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ using a processor of the present invention is the constant saturation approach. In this approach, it is assumed that the saturation of A_5 in the volume containing A_5 and A_6 remains relatively constant, i.e.:

$$\text{Saturation}(A_5(t)) = c_5(t)/[c_5(t) + c_6(t)] \quad (28)$$

$$= \{1 + [c_6(t)/c_5(t)]\}^{-1} \quad (29)$$

is substantially constant over many samples of the measured signals $S_{\lambda a}$ and $S_{\lambda b}$. This assumption is accurate over many samples since saturation generally changes relatively slowly in physiological systems.

The constant saturation assumption is equivalent to assuming that:

$$c_5(t)/c_6(t) = \text{constant} \quad (30)$$

since the only other term in equation (29) is a constant, namely the numeral 1.

Using this assumption, the proportionality constant $\hat{w}_{s3}(t)$ which allows determination of the noise reference