

### (12) United States Patent Chin et al.

(10) Patent No.: US 7,720,516 B2

(45) Date of Patent:

\*May 18, 2010

### (54) MOTION COMPATIBLE SENSOR FOR NON-INVASIVE OPTICAL BLOOD ANALYSIS

(75) Inventors: Rodney Chin, Oakland, CA (US); Paul

Mannheimer, Danville, CA (US); Ross

Flewelling, Oakland, CA (US)

Assignee: Nellcor Puritan Bennett LLC, Boulder,

CO (US)

(\*) Notice: Subject to any disclaimer, the term of this

patent is extended or adjusted under 35

U.S.C. 154(b) by 1583 days.

This patent is subject to a terminal dis-

claimer.

(21) Appl. No.: 10/990,686

(22)Filed: Nov. 16, 2004

(65)**Prior Publication Data** 

> US 2005/0070773 A1 Mar. 31, 2005

### Related U.S. Application Data

(60) Continuation of application No. 10/080,433, filed on Feb. 21, 2002, now Pat. No. 6,845,256, which is a division of application No. 09/348,437, filed on Jul. 7, 1999, now Pat. No. 6,374,129, which is a division of application No. 08/722,443, filed on Oct. 10, 1996, now Pat. No. 6,018,673.

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

(52) U.S. Cl. ...... 600/322; 600/323

(58) Field of Classification Search ...... 600/310, 600/322, 323, 336; 702/189, 190 See application file for complete search history.

#### (56)**References Cited**

### U.S. PATENT DOCUMENTS

5/1963 Salisbury et al. 3,090,377 A 3,095,872 A 7/1963 Tolles

3,638,640 A 2/1972 Shaw 12/1987 Hamaguri et al. 4,714,341 A 2/1989 Goodman et al. 4,802,486 A 4,805,623 A 2/1989 Jöbsis

### (Continued)

### FOREIGN PATENT DOCUMENTS

DE 19640807 9/1997

### (Continued)

### OTHER PUBLICATIONS

Odell, Richard M. et al., "Use of pulse oximetry to monitor venous saturation during extracorporeal life support", Critical Care Medicine, vol. 22, No. 4, 1994.

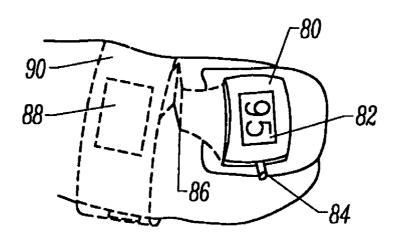
### (Continued)

Primary Examiner—Eric F Winakur Assistant Examiner—Etsub D Berhanu (74) Attorney, Agent, or Firm—Fletcher Yoder

#### ABSTRACT (57)

A non-invasive optical sensor which uses the motion signal to calculate the physiological characteristic being measured. For pulse oximetry, a least squares or a ratio-of-ratios technique can be applied to the motion signal itself. This is made possible by selecting a site on the patient where variations in motion produce signals of two wavelengths which are sufficiently correlated. In particular, it has been determined that a sensor placed on a nail, in particular a thumbnail, exhibits the characteristics of having the red and infrared signals correlated when used for pulse oximetry, and the resulting signals correlate to arterial oxygen saturation.

### 9 Claims, 10 Drawing Sheets



# US 7,720,516 B2 Page 2

				_,
U.S. PATENT	DOCUMENTS	5,588,427 A	12/1996	
4,807,631 A 2/1989	Hersh et al.	5,590,649 A		Caro et al.
	Aoyagi et al.	5,590,652 A	1/1997	
, ,	Stone et al.	5,595,176 A		Yamaura
	Peñáz	5,611,337 A	3/1997	
	Merrick	5,617,852 A		Macgregor
	Hausman et al.	5,630,413 A		Thomas et al.
		5,632,272 A		Diab et al.
, ,	Suzuki et al.	5,638,816 A		Kiani-Azarbayjany et al.
	Corenman et al.	5,645,059 A		Fein et al.
	Cheung et al.	5,645,060 A		Yorkey
	Shiga et al.	5,662,106 A		Swedlow et al.
	Corenman et al.	5,676,141 A	10/1997	
	Mersch	5,680,857 A		Pelikan et al.
, , , , , , , , , , , , , , , , , , ,	Goodman et al.	5,685,299 A	11/1997	Diab et al.
4,955,379 A 9/1990		5,687,719 A	11/1997	Sato et al.
, ,	Conlon et al 600/336	5,687,722 A	11/1997	Tien et al.
′ ′	Hasebe et al.	5,692,503 A	12/1997	Keunstner
, ,	Chance	5,692,505 A	12/1997	Fouts
, , , , , , , , , , , , , , , , , , ,	Awazu et al.	5,713,355 A	2/1998	Richardson
5,025,791 A 6/1991		5,730,124 A	3/1998	Yamauchi
	Rosenthal et al.	5,731,582 A	3/1998	West
5,055,671 A 10/1991		5,743,263 A	4/1998	Baker, Jr.
The state of the s	Hasebe et al.	5,746,206 A	5/1998	Mannheimer
, ,	Stone et al.	5,758,644 A	6/1998	Diab et al.
	Stengel	5,769,785 A	6/1998	Diab et al.
5,099,842 A 3/1992	Mannheimer et al.	5,776,059 A		Kaestle et al.
5,111,817 A 5/1992	Clark et al.	5,779,631 A		Chance
5,119,815 A 6/1992	Chance	5,782,757 A		Diab et al.
5,122,974 A 6/1992	Chance	5,786,592 A	7/1998	
5,167,230 A 12/1992	Chance	5,792,050 A		Alam et al.
5,190,038 A 3/1993	Polson et al.	5,803,908 A		Steuer et al.
5,218,962 A 6/1993	Mannheimer et al.	5,817,009 A		Rosenheimer
5,226,417 A 7/1993	Swedlow et al.	5,830,136 A		DeLonzor et al.
	DeLonzor	5,830,139 A	11/1998	
	Norwood	5,831,598 A		Kauffert et al.
' '	Centa et al.	5,842,981 A		Larsen et al.
	Swedlow et al.	5,846,190 A		Woehrle
5,267,565 A 12/1993		5,853,364 A		Baker et al.
	Kronberg et al.	5,860,919 A		Kiani-Azarbayjany et al.
	Griebel	5,871,442 A	2/1999	• • •
	Martens et al.			Chance et al.
	Secker	5,873,821 A 5,879,373 A		Roper et al.
	Pologe			-
	Shankar	5,885,213 A		Richardson et al.
	Potratz	5,920,263 A 5,934,277 A		Huttenhoff et al.
	Thomas et al.		8/1999	
	Ukawa et al.	5,995,855 A		Kiani et al.
	Swedlow et al.	5,995,856 A		Mannheimer et al.
	Steuer et al.	5,995,859 A		Takahashi Diab et al
, ,	Aoyagi	6,011,986 A		Diab et al.
	Centa et al.	6,018,673 A		Chin et al.
· · · · · · · · · · · · · · · · · · ·	Swedlow et al.	6,022,321 A		Amano et al.
	Polson et al.	6,036,642 A		Diab et al.
	Schmidt et al.	6,064,898 A		Aldrich
	Casciani et al.	6,081,735 A		Diab et al.
, ,	Mathews	6,081,742 A		Amano et al.
	Branigan et al.	6,083,172 A		Baker et al.
	DeLonzor et al.	6,088,607 A		Diab et al.
		6,104,938 A		Huiku et al.
	Corenman	6,120,460 A	9/2000	
	Diab et al.	6,134,460 A	10/2000	
	Uchikoga	6,150,951 A		Olejniczak
	Baker, Jr 600/323	6,154,667 A		Miura et al.
5,490,505 A 2/1996		6,157,850 A		Diab et al.
	Steuer	6,163,715 A		Larsen et al.
	Pologue et al.	6,181,958 B1		Steuer et al.
	Gerhard	6,181,959 B1		Schöllermann et al.
	Mannheimer	6,206,830 B1		Diab et al.
	Chance	6,217,523 B1	4/2001	Amano et al.
	Richardson	6,222,189 B1		Misner et al.
· · · · · · · · · · · · · · · · · · ·	Chance	6,230,035 B1	5/2001	Aoyagi et al.
5,575,285 A 11/1996				
, ,	Takanashi et al.	6,236,872 B1	5/2001	Diab et al.
	Takanashi et al. Sackner et al.	6,236,872 B1 6,263,222 B1		Diab et al. Diab et al.

# US 7,720,516 B2 Page 3

6,266,546 E	31 7/2001	Steuer et al.	7,024,235	B2 4/2006	Melker et al.
6,285,895 E		Ristolainen et al.	7,027,849		Al-Ali
6,312,393 E		Abreu	7,030,749		Al-Ali
6,353,750 E		Kimura et al.	7,035,697		Brown
			7,041,060		Flaherty et al.
6,385,471 E					
6,397,091 E		Diab et al.	7,047,056		Hannula et al.
6,411,832 E		Guthermann	7,127,278		Melker et al.
6,411,833 E		Baker et al.	7,162,306		Caby et al.
6,415,236 E		Kobayashi et al.	7,209,775		Bae et al.
6,419,671 E	31 7/2002	Lemberg	7,215,984	B2 5/2007	Diab et al.
6,438,399 E	8/2002	Kurth	7,215,986	B2 5/2007	Diab et al.
6,461,305 E	31 10/2002	Schnall	7,236,811	B2 6/2007	Schmitt
6,466,809 E	31 10/2002	Riley	7,239,905	B2 7/2007	Kiani-Azarbayjany et al.
6,487,439 E		Skladnev et al.	7,263,395		Chan et al.
6,501,974 E			7,272,426		Schmid
6,501,975 E		Diab et al.	7,315,753		Baker et al.
6,526,301 E		Larsen et al.	7,328,053		Diab et al.
					Baker et al.
6,544,193 E			7,336,983		
6,546,267 E		Sugiura et al.	7,373,193		Al-Ali et al.
6,549,795 E		Chance	7,376,453		Diab et al.
6,580,086 E		Schulz et al.	7,383,070		Diab et al.
6,591,122 E		Schmitt	2001/0005773		Larsen et al.
6,594,513 E		Jobsis et al.	2001/0020122	A1 9/2001	Steuer et al.
6,606,509 E	32 8/2003	Schmitt	2001/0039376	A1 11/2001	Steuer et al.
6,606,511 E	8/2003	Ali et al.	2001/0044700	A1 11/2001	Kobayashi et al.
6,615,064 E	9/2003	Aldrich	2002/0026106	A1 2/2002	Khalil et al.
6,618,042 E	9/2003	Powell	2002/0035318	A1 3/2002	Mannheimer et al.
6,622,095 E		Kobayashi et al.	2002/0038079		Steuer et al.
6,650,917 E		Diab et al.	2002/0042558		Mendelson
6,654,621 E		Palatnik et al.	2002/0049389		Abreu
6,654,624 E		Diab et al.	2002/0049389		Diab et al.
6,658,276 E		Kianl et al.	2002/0111748		Kobayashi et al.
6,658,277 E		Wasserman	2002/0128544		Diab et al.
6,662,030 E		Khalil et al.	2002/0133068		Huiku -
6,668,183 E		Hicks et al.	2002/0156354		Larson
6,671,526 E	31 12/2003	Aoyagi et al.	2002/0161287	A1 10/2002	Schmitt
6,671,528 E	32 12/2003	Steuer et al.	2002/0161290		Chance
6,678,543 E	32 1/2004	Diab et al.	2002/0165439	A1 11/2002	Schmitt
6,681,128 E	32 1/2004	Steuer et al.	2002/0198443	A1 12/2002	Ting
6,684,090 E	32 1/2004	Ali et al.	2003/0023140	A1 1/2003	Chance
6,690,958 E	31 2/2004	Walker et al.	2003/0055324	A1 3/2003	Wasserman
6,697,658 E	32 2/2004	Al-Ali	2003/0060693	A1 3/2003	Monfre et al.
RE38,476 E		Diab et al.	2003/0139687		Abreu
6,708,048 E		Chance	2003/0144584		Mendelson
6,711,424 E		Fine et al.	2003/0220548		
6,711,425 E			2003/0220576		
6,714,245 E RE38,492 E			2004/0010188		Wasserman
		Diab et al.	2004/0054270		Pewzner et al.
6,721,584 E		Baker, Jr. et al.	2004/0064020		Diab et al.
6,731,274 E		Powell	2004/0068164		Diab et al.
6,745,060 E		Diab et al.	2004/0087846		Wasserman
6,785,568 E		Chance	2004/0107065		Al-Ali
6,793,654 E		Lemberg	2004/0127779		Steuer et al.
6,801,797 E		Mannheimer et al.	2004/0158135		Baker et al.
6,801,798 E	32 10/2004	Geddes et al.	2004/0171920	A1 9/2004	Mannheimer et al.
6,801,799 E	32 10/2004	Mendelson	2004/0176670	A1 9/2004	Takamura et al.
6,826,419 E	32 11/2004	Diab et al.	2004/0176671	A1 9/2004	Fine et al.
6,829,496 E		Nagai et al.	2004/0181134		Baker et al.
6,836,679 E		Baker et al.	2004/0204636		Diab et al.
6,850,053 E		Daalmans et al.	2004/0204638		Diab et al.
6,863,652 E		Huang et al.	2004/0210146		Diab et al.
6,873,865 E		Steuer et al.	2004/0230106		Schmitt et al.
6,889,153 E		Dietiker	2004/0236196		Diab et al.
6,898,451 E			2005/0080323		
6,931,268 E		Kiani-Azarbayjany et al.	2005/0085735		Baker, Jr. et al.
6,939,305 E		Flaherty et al.	2005/0101850		Parker
6,939,307 E		Dunlop	2005/0113651		Wood et al.
6,947,780 E			2005/0113656		Chance
6,949,081 E		Chance	2005/0143634		Baker, Jr. et al.
6,961,598 E			2005/0168722		Forstner et al.
6,983,178 E		Fine et al.	2005/0177034		Beaumont
6,993,371 E		Kiani et al.	2005/0192488		Bryenton et al.
6,996,427 E	32 2/2006	Ali et al.	2005/0203357	A1 9/2005	Debreczeny et al.

2005/0209517	' A1 9/2005	Diab et al.	WO WO2005009221 2/2005	
2005/0228248		Dietiker	OTHER PUBLICATIONS	
2005/0267346 2005/0283059		Faber et al. lyer et al.	OTHER PUBLICATIONS	
2006/0009688		Lamego et al.	, ,	of
2006/0015021		Cheng	microvasculature of human finger skin", <i>The Hand</i> , vol. 10, No. 2	2,
2006/0020181		Schmitt	1978.	+
2006/0030763		Mannheimer et al.	Atlas of Human Anatomy, "Systemic anatomy", Frick, Kummer, Puted., Karger, Basel, Switzerland, 1990.	ιz
2006/0052680			"Sensor für durchführung medizinischer messungen, insbesonder	re
2006/0058683 2006/0064024		Chance Schnall	pulsoximetrischer messungen, am menschlichen finger", Researc	
2006/0195028		Hannula et al.	Disclosure, Dec. 1995, pp. 831-832.	
2006/0217609	A1 9/2006	Diab et al.	S. Takatani et al., "A non-invasive reflectance pulse oximeter sensor	
2006/0224058		Mannheimer	Annual International Conference of the IEEE Engineering in Med cine and Biology Society, vol. 13, No. 4, 1991.	.1-
2006/0247501			Aoyagi T. et al.; "Analysis of Motion Artifacts in Pulse Oximetry	<b>,</b> ,
2006/0258921 2007/0225581		Addison et al.  Diab et al.	Japanese Society ME vol. 42 p. 20 (1993) (Article i	
2007/0249918		Diab et al.	Japanese—contains English summary of article).	
2007/0291832		Diab et al.	Barreto A.B. et al.; "Adaptive Cancelation of Motion artifact is	
2008/0004514	A1 1/2008	Diab et al.	Photoplethysmographic Blood Volume Pulse Measurements for Exercise Evaluation" <i>IEEE-EMBC and CMBEC—Theme 4: Signature</i>	
2008/0033266		Diab et al.	Processing pp. 983-984 (1995).	u
2008/0045823	A1 2/2008	Diab et al.		of
FC	OREIGN PATE	NT DOCUMENTS	Photoplethysmographic Blood Volume Pulse Measurements" pp 114-117 (1996).	p.
EP	0615723	9/1994	Barreto Armando B. et al.; "Adaptive LMS Delay Measurement i	in
EP	0630203	12/1994	dual Blood Volume Pulse Signals for Non-Invasive Monitoring	
EP	734223	5/1998	<i>IEEE</i> pp. 117-120 (1997).	
EP	1491135	12/2004	Barnum P.T. et al.; "Novel Pulse Oximetry Technology Capable of	
JP JP	63275325 3170866	11/1988 7/1991	Reliable Bradycardia Monitoring in the Neonate" <i>Respiratory Car</i> vol. 42 No. 1 p. 1072 (Nov. 1997).	re
JP	4191642	7/1992	Leahy Martin J. et al.; "Sensor Validation in Biomedical Applica	a-
JP	4332536	11/1992	tions" IFAC Modelling and Control in Biomedical Systems Warwic	
JP	6285048	10/1994	UK; pp. 221-226 (1997).	
JР	7124138	5/1995	Masin Donald 1. et al.; "Fetal Transmission Pulse Oximetry" Pro	9- 2
JP JP	7136150 7171139	5/1995 7/1995	ceedings 19 <sup>th</sup> International Conference IEEE/EMBS Oct. 30-Nov. 2 1997; pp. 2326-2329.	2,
JP	10216115	8/1998	Pickett John et al.; "Pulse Oximetry and PPG Measurements i	in
JP	3238813	10/2001	Plastic Surgery' Proceedings—19 <sup>th</sup> International	
	003194714	7/2003	Conference—IEEE/EMBS Chicago Illinois Oct. 30-Nov. 2, 1997 pp	p.
	003210438	7/2003	2330-2332.	
	003275192 003339678	9/2003 12/2003	Plummer John L. et al.; "Identification of Movement Artifact by the Nellcor N-200 and N-3000 Pulse Oximeters" <i>Journal of clinica</i>	
	004008572	1/2004	Monitoring vol. 13 pp. 109-113 (1997).	u
	004113353	4/2004	Poets C. F. et al.; "Detection of movement artifact in recorded puls	se
	004135854	5/2004	oximeter saturation" Eur. J. Pediatr.; vol. 156 pp. 808-811 (1997).	
	004194908	7/2004	East Christine E. et al.; "Fetal Oxygen Saturation and Uterine Con	
	2004202190 2004248819	7/2004 9/2004	tractions During Labor" American Journal of Perinatology vol. 1	.5
	004290545	10/2004	No. 6 pp. 345-349 (Jun. 1998). Edrich Thomas et al.; "Can the Blood Content of the Tissues b	30
	005034472	2/2005	Determined Optically During Pulse Oximetry Without Knowledge	
	VO9101678	2/1991	the Oxygen Saturation?—An In-Vitro Investigation" Proceedings	
	VO9111137 A1	8/1991	the 20 <sup>th</sup> Annual International conference of the IEEE Engie in Med	i-
	O92/16142 O92/21281	10/1992 12/1992	cine and Biology Society vol. 20 No. 6 p. 3072-3075 1998.	
	VO92/21281	12/1992	Hayes Matthew J. et al.; "Quantitative evaluation of photoplethysmographic artifact reduction for pulse oximetry" SPI	
	VO9309711	5/1993	vol. 3570 pp. 138-147 (Sep. 1998).	L
WO V	VO9403102	2/1994		in
	VO9423643 A1	10/1994	photoplethysmography" Applied Optics vol. 37 No. 31 pp. 7433	
	VO9512349 VO9516388	5/1995 6/1995	7446 (Nov. 1998).	
	O96/39926	12/1996	Such Hans Olaf; "Optoelectronic Non-invasive Vascular Diagnostic	
	VO9639927	12/1996	Using multiple Wavelength and Imaging Approach" <i>Dissertatio</i> (1998).	m
WO V	VO9749330	12/1997	Kaestle S.; "An Algorithm for Reliable Processing of Pulse Oximetr	۲V
	VO9842249	10/1998	Signals Under strong Noise Conditions" Dissertation Book Lubec	
	VO9842251	10/1998	University Germany (1999).	
	VO9843071	10/1998	Rhee Sokwoo et al.; "Design of a Artifact-Free Wearable	
	VO9932030 VO0021438	7/1999 4/2000	Plethysmographic Sensor" Proceedings of the First joint BME.	S/
	VO0021438 VO0140776	6/2001	EMBS Conference Oct. 13-16, 1999 Altanta Georgia p. 786. Rheineck-Leyssius Aart t. et al., "Advanced Pulse Oximeter Signa	a1
	VO0176461	10/2001	Processing Technology Compared to Simple Averaging: 1. Effect of	
	VO0176471	10/2001	Frequency of Alarms in the Operating Room" <i>Journal of clinica</i>	
WO W	O03039326	5/2003	Anestesia vol. 11 pp. 192-195 (1999).	

Seelbach-Göbel Birgit et al.; "The prediction of fetal acidosis by means of intrapartum fetal pulse oximetry" *Am J. Obstet. Gynecol.* vol. 180 No. 1 Part 1 pp. 73-81 (1999).

Todd Bryan et al.; "The Identification of Peaks in Physiological Signals" *Computers and Biomedical Research* vol. 32 pp. 322-335 (1999).

Coetzee Frans M.; "Noise-Resistant Pulse Oximetry Using a Synthetic Reference Signal" *IEEE Transactions on Biomedical Engineering* vol. 47 No. 8 Aug. 2000 pp. 1018-1026.

Goldman Julian M.; "Masimo Signal Extraction Pulse Oximetry" *Journal of Clinical Monitoring and Computing* vol. 16 pp. 475-483 (2000).

Kaestle S.; "Determining Artefact Sensitivity of New Pulse Oximeters in Laboratory Using Signals Obtained from Patient" *Biomedizinische Technik* vol. 45 (2000).

Nilsson Lena et al.; "Monitoring of Respiratory Rate in Postoperative Care Using a New Photoplethysmographic Technique" *Journal of Clinical Monitoring and Computing* vol. 16 pp. 309-315 (2000).

Tremper K.K.; "A Second Generation Technique for Evaluating Accuracy and Reliability of Second Generation Pulse Oximeters" *Journal of Clinical Monitoring and Computing* vol. 16 pp. 473-474 (2000).

Belal Suliman Yousef et al.; "A fuzzy system for detecting distorted plethysmogram pulses in neonates and paediatric patients" *Physiol. Meas.* vol. 22 pp. 397-412 (2001).

Cysewska-Sobusaik Anna; "Metrological Problems With noninvasive Transillumination of Living Tissues" *Proceedings of SPIE* vol. 4515 pp. 15-24 (2001).

Earthrowl-Gould T. et al.; "Chest and abdominal surface motion measurement for continuous monitoring of respiratory function" *Proc. Instn Mech Engrs* V215 Part H; pp. 515-520 (2001).

Hayes Matthew J. et al.; "A New Method for Pulse Oximetry Possessing Inherent Insensitivity to Artifact" *IEEE Transactions on Biomedical Engineering* vol. 48 No. 4 pp. 452-461 (Apr. 2001).

Maletras Francois-Xavier et al.; "Construction and calibration of a new design of Fiber Optic Respiratory Plethysmograph (FORP)" *Optomechanical Design and Engineering Proceedings of SPIE* vol. 4444 pp. 285-293 (2001).

Chan K.W. et al.; "17.3: Adaptive Reduction of Motion Artifact from Photoplethysmographic Recordings using a Variable Step-Size LMS Filter" *IEEE* pp. 1343-1346 (2002).

Gehring Harmut et al.; "The Effects of Motion Artifact and Low Perfusion on the Performance of a New Generation of Pulse Oximeters in Volunteers Undergoing Hypoxemia" *Respiratory Care* Vo. 47 No. 1 pp. 48-60 (Jan. 2002).

Gostt R. et al.; "Pulse Oximetry Artifact Recognition Algorithm for Computerized Anaesthetic Records" *Journal of Clinical Monitoring and Computing Abstracts* p. 471 (2002).

Jopling Michae W. et al.; "Issues in the Laboratory Evaluation of Pulse Oximeter Performance" *Anesth Analg* vol. 94 pp. S62-S68 (2002).

Relente A.R. et al.; "Characterization and Adaptive Filtering of Motion Artifacts in Pulse Oximetry using Accelerometers" *Proceedings of the Second joint EMBS/BMES Conference* Houston Texas Oct. 23-26, 2002; pp. 1769-1770.

Yamaya Yoshiki et al.; "Validity of pulse oximetry during maximal exercise in normoxia hypoxia and hyperoxia" *J. Appl. Physiol.* vol. 92 pp. 162-168 (2002).

Yao Jianchu et al.; "Design of a Plug-and-Play Pulse Oximeter" *Proceedings of the Second Joint EMBS/BMES Conference* Houston Texas Oct. 23-26, 2002; pp. 1752-1753.

Yoon Gilwon et al.; Multiple diagnosis based on Photoplethysmography: hematocrit SpO2 pulse and respiration *Optics in*  Health Care and Biomedical optics: Diagnostics and Treatment; Proceedings of the SPIE vol. 4916; pp. 185-188 (2002).

Aoyagi Takuo; "Pulse oximetry: its invention theory and future" *Journal of Anesthesia* vol. 17 pp. 259-266 (2003).

Cyrill D. et al.; "Adaptive Comb Filter for Quasi-Periodic Physiologic Signals" *Proceedings of the 25<sup>th</sup> Annual International Conference of the IEEE EMBS* Cancun Mexico Sep. 17-21, 2003; pp. 2439-2442.

A. Johansson; "Neural network for photoplethysmographic respiratory rate monitoring" *Medical & Biological Engineering & Computing* vol. 41 pp. 242-248 (2003).

Lee C.M. et al.; "Reduction of motion artifacts from photoplethysmographic recordings using wavelet denoising approach" *IEEE EMBS Asian-Pacific Conference on Biomedical Engineering* Oct. 20-22, 2003; pp. 194-195.

Matthews Nora S. et al.; "An evaluation of pulse oximeters in dogs cats and horses" *Veterinary Anaesthesia and Analgesia* vol. 30 pp. 3-14 (2003).

Stetson Paul F.; "Determining Heart Rate from Noisey Pulse Oximeter Signals Using Fuzzy Logic" *The IEEE International Conference on Fuzzy Systems* St. Louis Missouri May 25-28, 2003; pp. 1053-1058.

Addison Paul S. et al.; "A novel time-frequency-based 3D Lissajous figure method and its application to the determination of oxygen saturation from the photoplethysmogram" *Institute of Physic Publishing Meas. Sci. Technol.* vol. 15 pp. L15-L18 (2004).

Johnston W.S. et al.; "Extracting Breathing Rate Infromation from a Wearable Reflectance Pulse Oximeter Sensor" *Proceedings of the 26<sup>th</sup> Annual International conference of the IEEE EMBS* San Francisco California; Sep. 1-5, 2004; pp. 5388-5391. Spigulis Janis et al.; "Optical multi-channel sensing of skin blood

Spigulis Janis et al.; "Optical multi-channel sensing of skin blood pulsations" *Optical Sensing Proceedings of SPIE* vol. 5459 pp. 46-53 (2004).

Matsuzawa Y. et al.; "Pulse Oximeter" *Home Care Medicine* pp. 42-45 (Jul. 2004); (Article in Japanese—contains English summary of article).

Yao Jianchu et al.; "A Novel Algorithm to Separate Motion Artifacts from Photoplethysmographic Signals Obtained With a Reflectance Pulse Oximeter" *Proceedings of the 26<sup>th</sup> Annual International conference of the IEEE EMBS* San Francisco California Sep. 2004 pp. 2153-2156.

Yan Yong-sheng et al.; "Reduction of motion artifact in pulse oximetry by smoothed pseudo Wigner-Ville distribution" *Journal of NeuroEngineering and Rehabilitation* vol. 2 No. 3 (9 pages) (Mar. 2005)

Hamilton Patrick S. et al.; "Effect of Adaptive Motion-Artifact Reduction on QRS Detection" *Biomedical Instrumentation & Technology* pp. 197-202 (undated).

Kim J.M. et al.; "Signal Processing Using Fourier & Wavelet Transform" pp. 11-310-11-311 (undated).

J. Huang et al.; "Low Power Motion Tolerant Pulse Oximetry" Abstracts A7 p. S103. (undated).

P. Lang et al.; "Signal Identification and Quality Indicator™ for Motion Resistant Pulse Oximetry" *Abstracts* A10 p. S105. (undated). R. Neumann et al.; "Fourier Artifact suppression Technology Provides Reliable SpO<sub>2</sub>" *Abstracts* A11 p. S105. (undated).

Odagiri Y.; "Pulse Wave Measuring Device" *Micromechatronics* vol. 42 No. 3 pp. 6-11 (undated) (Article in Japanese—contains English summary of article).

Yamazaki Nakaji et al.; "Motion Artifact Resistant Pulse Oximeter (Durapulse PA 2100)" *Journal of Oral Cavity Medicine* vol. 69 No. 4 pp. 53 (date unknown) (Article in Japanese—contains English summary of article).

\* cited by examiner

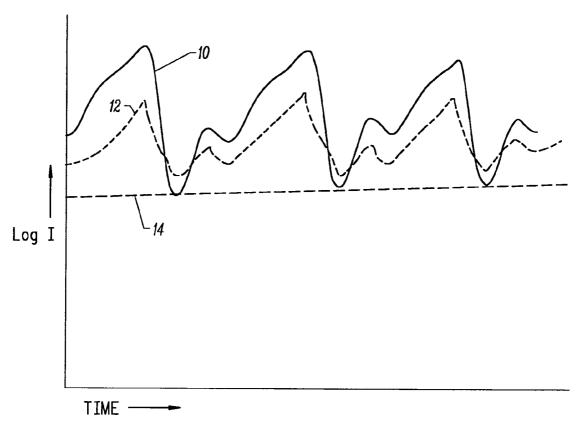


FIG. 1

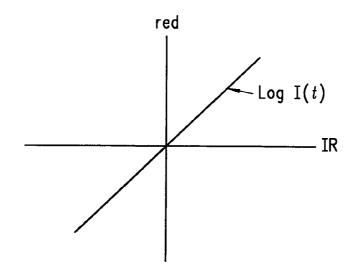
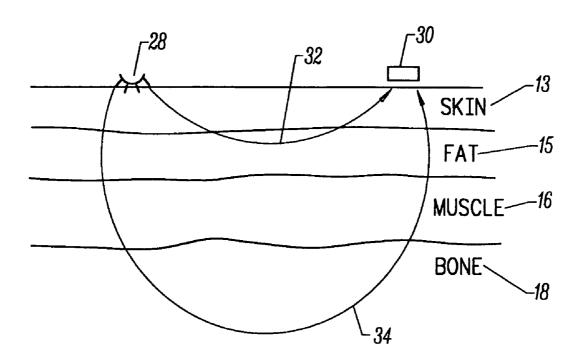


FIG. 2



*FIG.* 3

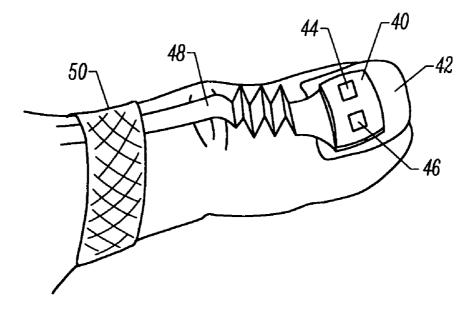
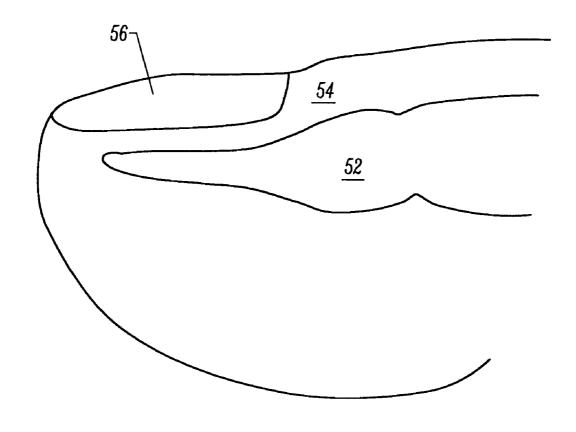


FIG. 4



*FIG.* 5

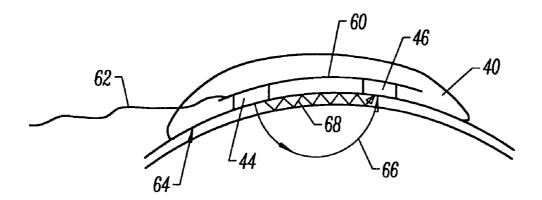


FIG. 6

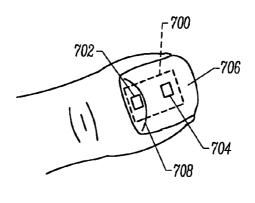
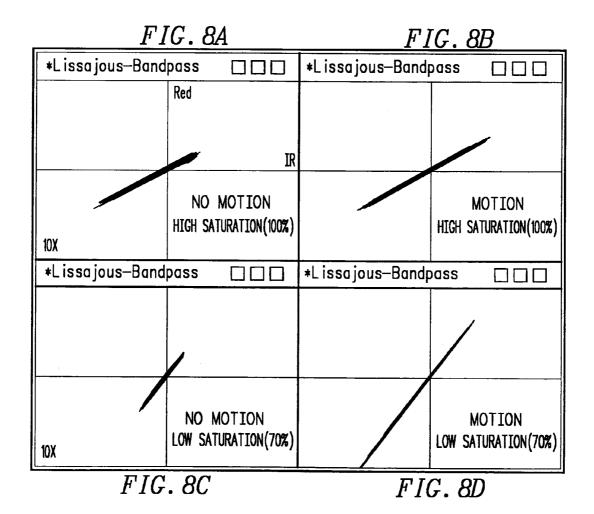
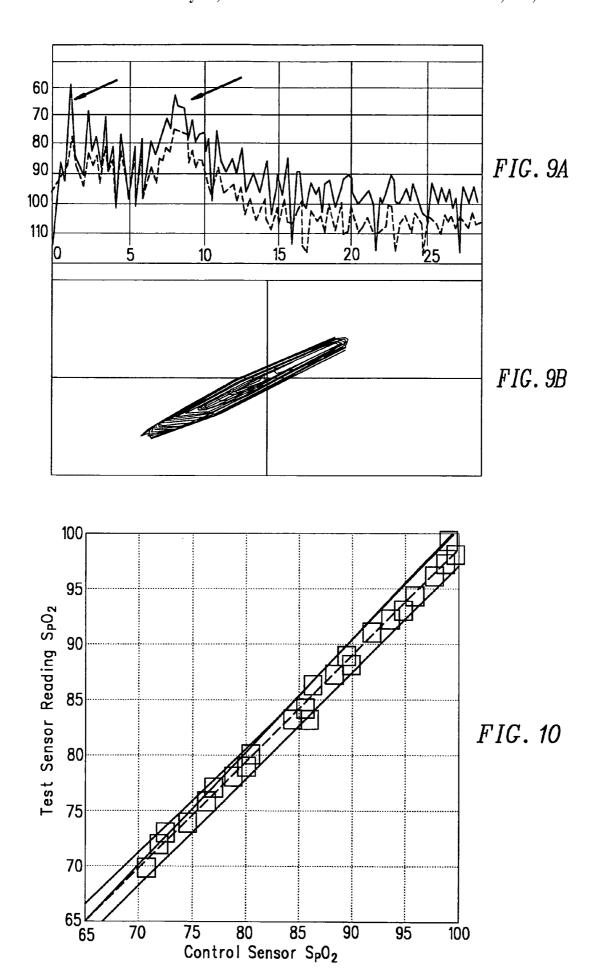


FIG. 7





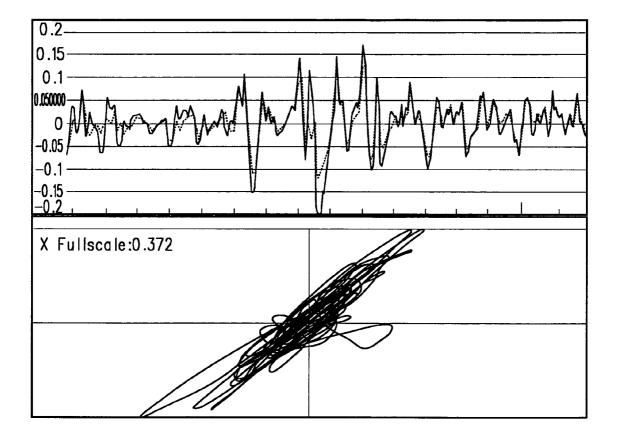


FIG. 11A (PRIOR ART)

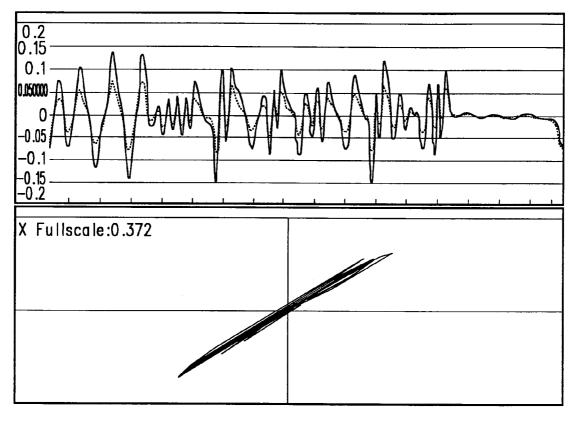
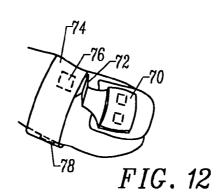
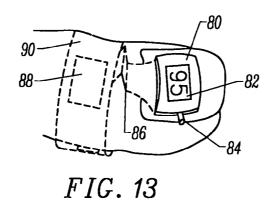


FIG. 11B

May 18, 2010





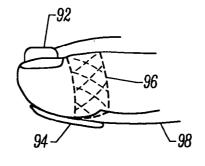


FIG. 14

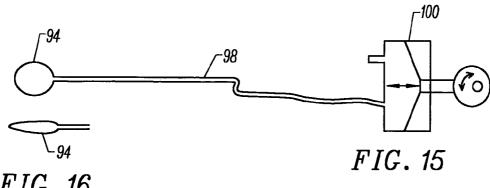
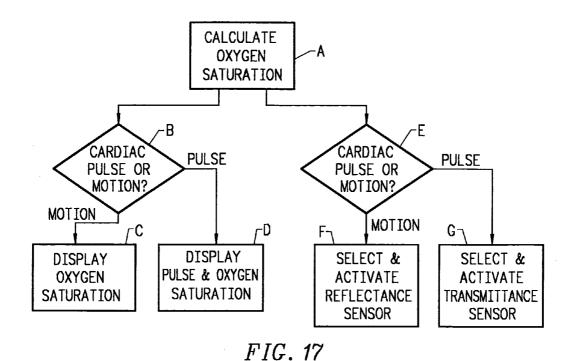


FIG. 16



SENSOR R CAL MONITOR -122 -120 -114 **SENSOR** A/D DRIVE CONTROLLER **DETECTOR** CIRCUIT 110--116 FREQ. **BANDPASS** GEN. **FILTER** 112-**OXYGEN** -118 **PUMP** SAT. CONTROL CALC. FIG. 18 **PROCESSOR** 

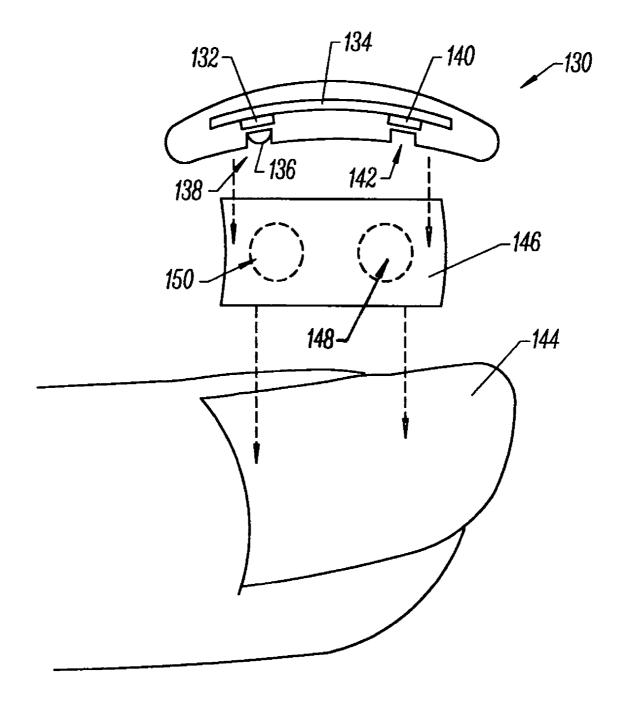


FIG. 19

1

## MOTION COMPATIBLE SENSOR FOR NON-INVASIVE OPTICAL BLOOD ANALYSIS

## CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 10/080,433, filed Feb. 21, 2002, now U.S. Pat. No. 6,845, 256, which is a division of U.S. application Ser. No. 09/348, 437, filed Jul. 7, 1999, now U.S. Pat. No. 6,374,129, which is a division of U.S. application Ser. No. 08/722,443, filed Oct. 10, 1996, now U.S. Pat. No. 6,018,673, which disclosures are incorporated by reference for all purposes.

### STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK

NOT APPLICABLE

### BACKGROUND OF THE INVENTION

The present invention relates to optical sensors for non-invasive determination of physiological characteristics, and  $_{30}$  in particular to sensors for making such determinations in the presence of motion.

Many types of optical sensors are used to measure physiological characteristics of a patient. Typically, an optical sensor provides emitted light which is then scattered through 35 tissue and detected. Various characteristics of a patient can be determined from analyzing such light, such as oxygen saturation, pulse rate, pH, etc.

Pulse oximetry is typically used to measure various blood characteristics including, but not limited to, the blood-oxygen 40 saturation of hemoglobin in arterial blood, the volume of individual blood pulsations supplying the tissue, and the rate of blood pulsations corresponding to each heartbeat of a patient. Measurement of these characteristics has been accomplished by use of a non-invasive sensor which scatters 45 light through a portion of the patient's tissue where blood perfuses the tissue, and photoelectrically senses the absorption of light in such tissue. The amount of light absorbed is then used to calculate the amount of blood constituent being measured.

The light scattered through the tissue is selected to be of one or more wavelengths that are absorbed by the blood in an amount representative of the amount of the blood constituent present in the blood. The amount of transmitted light scattered through the tissue will vary in accordance with the 55 changing amount of blood constituent in the tissue and the related light absorption. For measuring blood oxygen level, such sensors have typically been provided with a light source that is adapted to generate light of at least two different wavelengths, and with photodetectors sensitive to both of 60 those wavelengths, in accordance with known techniques for measuring blood oxygen saturation.

Known non-invasive sensors include devices that are secured to a portion of the body, such as a finger, an ear or the scalp. In animals and humans, the tissue of these body portions is perfused with blood and the tissue surface is readily accessible to the sensor. A photoelectric pulse transducer

2

from World Precision Instruments is described as even recording signals through the fingernail.

Optical sensors are typically either reflective or transmissive. Transmissive sensors have the emitter and detector on opposite sides of a finger, toe, nose or other tissue. They measure light transmitted through the tissue from one side to the other. Reflectance sensors, on the other hand, have the emitter and detector side-by-side, such as placement on the forehead, or on a fetus where it is difficult to position a sensor over a finger, etc. Reflectance sensors detect light which is scattered back to the same surface.

In pulse oximetry, the goal is to determine the amount of oxygen in arterial blood, as distinguished from venous blood or the tissue itself. The light emitted can be absorbed by all three, however, and they need to be distinguished among. FIG. 1 illustrates a plot of the logarithm of the detected intensity signal versus time. Solid line 10 is the detected infrared signal in a pulse oximeter, shown varying with time. Dotted line 12 is the detected red wavelength signal. As can be seen, the value moves up and down with the heartbeat frequency, due to the pulsing of the blood through the arteries. The portion of the signal below line 14 is representative of light absorbed by the tissue, venous blood, and a baseline component of the arterial blood.

Using appropriate signal analysis, the DC portion can be eliminated, leaving an extracted AC portion which is due to absorption by arterial blood. As can be seen in FIG. 1, and more clearly in FIG. 2, the red and infrared signals, although varying by different amounts, are in phase. FIG. 2 illustrates a plot over an epoch of time of the red logarithmic signal versus the infrared logarithmic signal, and is commonly referred to as a Lissajous plot. As can be seen, a line is formed, indicating they are in phase.

This characteristic of the red and infrared signals allows the determination of oxygen saturation through two methods. In a first method, the "ratio of ratios" is calculated, which is the ratio, between red and infrared, of the logarithms of the quotients obtained by dividing the maximum signal intensity and the subsequent minimum signal intensity. This ratio-of-ratios is then used in a predetermined formula to calculate arterial oxygen saturation. This is described more fully in U.S. Pat. No. 4,653,498.

In a second method, referred to here as "least squares," a least squares regression analysis is performed on the abovementioned Lissajous plot to determine the slope of the ensemble of data points taken during an epoch of time. This slope is then used in a predetermined formula to determine arterial oxygen saturation. Other techniques are set forth in a co-pending application entitled "Method and Apparatus for Estimating Physiological Parameters Using Model-Based Adaptive filtering," filed Jun. 7, 1996, Ser. No. 08/660,510, the disclosure of which is hereby incorporated by reference.

In some cases, it is desirable to measure the oxygen saturation of the venous blood in order to get an indication of how much oxygen is being used by the body. The arterial blood, on the other hand, gives an indication of how much oxygen is being delivered to the body. In Shiga U.S. Pat. No. 4,927,264, the oxygen saturation in venous blood is determined by inducing a venous pressure with a pressure cuff. This effectively varies line 14 of FIG. 1 at a frequency different from the heart rate, so that it can be separately filtered and isolated and compared to the arterial pulse. The non-varying portion is then assumed to be the tissue absorption and can be distinguished from the slowly varying pressure induced venous blood absorption. An alternate approach can be used in extracorporeal monitoring where the blood is actually pumped out of the body and then back in. Such a technique is set forth in

an article by Odell et al., entitled "Use of Pulse Oximetry to Monitor Venous Saturation During Extracorporeal Life Support" Critical Care Medicine, vol. 22, no. 4 (Apr. 4, 1994). In Odell, the venous blood being pumped out of the body passes the sensor, and the pumping mechanism provides an artificial 5 pulse allowing the use of pulse oximetry techniques.

Motion artifact can degrade a pulse oximetry signal relied upon by a physician, without the physician's awareness. This is especially true if the monitoring of the patient is remote, the motion is too small to be observed, or the doctor is watching the instrument or other parts of the patient, and not the sensor site. Thus, typically techniques are employed to reduce the effects of motion or compensate for motion.

In one oximeter system described in U.S. Pat. No. 5,025, 791, an accelerometer is used to detect motion. When motion 15 is detected, readings influenced by motion are either eliminated or indicated as being corrupted. In a typical oximeter, measurements taken at the peaks and valleys of the blood pulse signal are used to calculate the desired characteristic. Motion can cause a false signal peak and valley, resulting in a 20 measurement having an inaccurate value and one which is recorded at the wrong time. In U.S. Pat. No. 4,802,486, assigned to Nellcor Puritan Bennett, the assignee of the present invention, an EKG signal is monitored and correlated to the oximeter reading to provide synchronization to limit the 25 effect of noise and motion artifact pulses on the oximeter readings. This reduces the chances of the oximeter locking onto a periodic motion signal. Still other systems, such as the one described in U.S. Pat. No. 5,078,136, assigned to Nellcor Puritan Bennett, use signal processing in an attempt to limit 30 the effect of noise and motion artifact. The '136 patent, for instance, uses linear interpolation and rate of change techniques to analyze the oximeter signal. U.S. Pat. No. 5,337,744 sets forth sensor modifications used to improve the immunity of the signal from motion artifacts.

The motion signal impedes the measurement because it obscures the cardiac signal. The motion signal can have many components, such as, for example, the emitter or detector physically moving away from the body, or a volume of venous and arterial blood sloshing around in response to the motion, 40 or the signal path being shortened or lengthened by expansion or compression of the tissue due to motion.

Contrary to conventional practice, signal analysis might be able to directly use the time-varying motion signal to calculate oxygen saturation. Under some conditions, the ratio-of- 45 ratios (or least squares) resulting from a motion-induced signal has the same value as the ratio-of-ratios (or least squares) for the cardiac induced signal. The red and infrared intensity signals are often not in phase, and can limit the use of the motion signal for calculating oxygen saturation. One of the 50 ing its components. factors that may cause this is illustrated in FIG. 3. As FIG. 3 illustrates, light from emitter 28 can pass through skin 13, fat 15, muscle 16, and bone 18, on its way to a detector 30. Light of one wavelength may, on average, take path 32, while light of another wavelength may penetrate deeper and take path 34. 55 Motion will cause disproportionate variances in the path lengths of the two wavelengths of light, resulting in out-ofphase signals of the detector.

### BRIEF SUMMARY OF THE INVENTION

The present invention provides a non-invasive optical sensor which uses the motion signal to calculate the physiological characteristic being measured. For pulse oximetry, a least squares or a ratio-of-ratios technique can be applied to the 65 slope of the motion signal itself. This is made possible by selecting a site on the patient where motion produces signals

4

at two wavelengths which are adequately correlated with each other. Adequately correlated signals have a "closed" or "nearly closed" Lissajous. In particular, it has been determined that a sensor placed on a nail, in particular a thumbnail, exhibits the characteristics of having the red and infrared signals in phase when used for pulse oximetry.

The present invention also provides an optical sensor which fits entirely on a nail. No adhesive or other securing mechanism around the rest of the finger is necessary, resulting in the entire sensor moving with the nail. The use of the nail site reduces the likelihood of out-of-phase motion signals for red and infrared wavelengths, and takes advantage of the predominantly arterial blood saturation characteristic of the blood present beneath the nail. In addition, the nail is an advantageous surface for adhering the sensor to, and at this location the method of attachment allows a low profile, low mass sensor to be used which further limits differential phase errors due to motion.

Preferably, the sensor on a nail of the present invention is a reflectance-type sensor. In one embodiment, a closer spacing is used than in typical prior art sensors, preferably less than 5 mm, more preferably approximately 4 mm. It has been empirically determined that the physiological characteristics at a nail site produce an improved signal with closer spacing. In addition, the sensor preferably has a curvature which conforms to the shape of the nail, and is attached with an adhesive

In alternate embodiments of the invention, artificial motion may be induced with an air bag or otherwise to produce a motion signal which can be used with the sensor of the invention. In particular, this could be used for patients with low perfusion, a weak heartbeat or no heartbeat such as is the case during heart bypass surgery.

For a further understanding of the nature and advantages of the invention, reference should be made to the following description taken in conjunction with the accompanying drawings.

### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a graph of the log of the infrared and red intensity signals for pulse oximeters.

FIG. 2 is a graph of the red and IR signals showing correlation.

FIG. 3 is a diagram of the different average paths of different wavelength light through a patient.

FIG. 4 is a perspective view of a nail sensor according to the present invention on a thumb.

FIG. 5 is a cross-sectional, cutaway view of a thumb showing its components.

FIG. **6** is a end, cutaway view of one embodiment of a conformable nail sensor according to the present invention.

FIG. 7 is a diagram of a sensor according to the present invention placed longitudinally to span the lunula of the nail.

FIGS. 8A-8D are Lissajous plots of the output of a sensor according to the invention with and without motion, and at low and high saturation.

FIG. **9**A is a plot of the red and infrared frequency distribution (FFT of time signals) showing experimental results from a thumbnail sensor according to the invention.

FIG. 9B is a plot of the Lissajous for the results of FIG. 9A. FIG. 10 is a graph showing a plot of oxygen saturation readings of a sensor according to the present invention compared to a standard prior art sensor.

FIGS. 11A and 11B compare the prior art sensor and the present invention. The output waveforms and Lissajous plot are shown for each.

5

FIG. 12 is a diagram of an alternate embodiment of the invention showing a combination reflective and transmissive sensor

FIG. 13 is a diagram of an alternate embodiment of the invention showing a self-contained nail sensor with its own 5 display.

FIG. 14 is a diagram of a nail sensor with a motion inducing mechanism according to the present invention.

FIGS. 15 and 16 are top and side views of the motion stimulating mechanism of FIG. 14.

FIG. 17 is a flowchart of one embodiment of a program for responding to whether motion or a cardiac pulse is used for calculating saturation.

FIG. 18 is a block diagram of one embodiment of portions of an oximeter using controlled generation of motion.

FIG. 19 is a diagram of an embodiment of the sensor using a cylindrical lens and a tinted adhesive.

### DETAILED DESCRIPTION OF THE INVENTION

FIG. 4 illustrates a sensor 40 according to the present invention preferably mounted on a nail 42 (a thumbnail or any other digit may be used). The sensor is held on with adhesive, and has an emitter 44 and a detector 46. A flexible circuit 48 provides the electrical connections to the emitter and detector, and may be accordion-shaped between the sensor and a securing band 50 to provide additional strain relief. This isolates the sensor from tugging or pulling on the electrical connection cord from either the sensor side or the other direction. Band 50 may be, for instance, an elastic band, cloth wrap secured with Velcro™, or another device. Flexible circuit 48 could be electrical wires or fiber optic cables. The different wavelength light could be premixed using the fiber optic cable.

The placement on the top of the nail allows the cable to extend along the top of the finger or other digit, without the sensor or the cable being on the palmar side of the digit where it would interfere with grasping or other functionality of the band

As can be seen, the emitter **44** and detector **46** are arranged laterally across the width of the nail. However, a longitudinal arrangement (discussed more fully below) or any other arrangement on a nail is possible. The spacing of the emitter and detector may be varied, but an optimum spacing was experimentally found to be less than 10 mm, preferably less than 5 mm, more preferably approximately 4 mm.

The nailbed makes a good site for the sensor because it has been observed that motion generates artifact signals for the red and infrared wavelengths that are largely correlated to one 50 another. The inventors have observed that this results in a ratio-of-ratios (or least squares) which correlates well with the arterial oxygen saturation.

Referring to FIG. 5, a cross-sectional view of the thumb is shown. As can be seen, the thumb includes a bone 52 with a 55 thin layer of connective tissue 54 between the bone and thumbnail 56. A number of characteristics may contribute to the improved signal and the motion induced artifact being in phase. The different wavelength paths illustrated in FIG. 3 may be limited by the presence of bone 52, preventing one of 60 the wavelengths from going deeper into tissue and having a different distance to travel. This effect is provided by the selection of the thumbnail as a site, and the use of reflectance oximeter sensor as opposed to a transmissive sensor. In a transmissive sensor, light would have to travel around the 65 bone deep through the tissue, and the red and infrared may travel different lengths and be affected differently by motion.

6

Connective tissue layer **54** is thin and apparently strongly connective. Thus, the expansion and compression of tissues, particularly fatty tissues, which may cause out of phase motion artifacts for other sites and types of sensors, is apparently greatly reduced here. Because the thumbnail **56** itself provides a strong mounting platform, the sensor can be securely attached to it with adhesive, avoiding the emitter and detector from separating from the patient and causing gaps that may cause corrupt ratio-of-ratio values.

The region beneath nail **56** also provides a region which appears to be concentrated with oxygen saturated blood similar to the saturation of arterial blood. Oxygen consumption beneath the nail appears to be small relative to the circulation there, or the relative volume of venous blood may be negligibly small.

The presence of many small capillaries, rather than large vessels, makes the region more homogeneous, and thus lessens the likelihood that two different light wavelengths would be affected differently by passing through differing regions.

20 In the absence of motion, the high perfusion allows a normal pulse oximetry reading to be made. During the occurrence of motion, the large amount of blood present allows a strong motion signal to be obtained, since a lot of blood is moved around by the motion. In experiments conducted by the inventors, motion artifact signals greater than 50 times that of a normal pulsatile plethysmogram signal have been observed. The nail site also appears to have a nailbed-tissue boundary that is optically phase-matched for the wavelengths of the sensor.

In addition to measuring oxygen saturation, the nailbed is a good site for other optical sensors. For example, glucose detection which requires the use of a near infrared wavelength could be used. Among the blood properties or constituents that can be measured are blood gases (CO<sub>2</sub>, O<sub>2</sub>), pH, glucose,
 drug concentrations, or other analytes (THb, Hct, lactate, K<sup>+</sup>, Na<sup>+</sup>, Ca<sub>2</sub><sup>+</sup>, etc.).

FIG. 6 is an end, cutaway view of one embodiment of a sensor 40 according to the present invention. Emitter 44 and detector 46 are shown mounted on a flexible circuit board 60. An electrical cord 62 provides the connection to the electrical components of circuit board 60. The body of the sensor is preferably a semi-rigid piece of black poron foam. A metal strip could be imbedded to give extra rigidity. An adhesive is attached to underside 64 of the sensor to attach it securely to the nail. The underside is also curved to conform to the shape of the nail, but is slightly flexible to allow adaptation to differing nail shapes. Different curvature sensors could be provided for different sizes and shapes of nails to provide optimum fit, or the bottom surface could be fabricated from a softer, more conforming material.

One characteristic of the nail as a site is that the nail itself could act as a light pipe, shunting light between the emitter and the detector. Preferably, the light travels through the tissue beneath the nail along a path 66. However, some light could bounce back and forth through the nail itself on a path 68 between the emitter and detector in a manner not unlike a waveguide. To limit this shunting, the sensor body is made to absorb light, or at least the region between the emitter and detector is made at least partially absorbing to the wavelengths of interest. In this way, each time light strikes the side of the nail adjacent the absorbing layer, it will be absorbed, rather than propagating along the nail.

Shunting can also be limited by recessing the emitter and detector and providing a narrow numerical aperture. Because of the rigidity of the sensor body, recessing will not produce variations in distance during motion. By limiting the numerical aperture of the emitter and detector to values less than 0.9,

7

preferably to values less than 0.5, the emitter will not directly launch light into the nail "waveguide," and light which does potentially travel path 68 will be outside the acceptance angle of the detector.

The nail also provides advantages for adhering the sensor 5 to the patient since the nail does not have the quantity of oils or sweat as present on the skin.

FIG. 7 is a diagram of a sensor 700 arranged longitudinally along a nail 706. The sensor has an emitter 702 and a detector 704 which are not both on the lunula of the nail. The lunula is 10 the light colored area of the nail below line 708 in FIG. 7. It is believed that if both the emitter and detector are located on the lunula, more undesirable shunting of light will occur.

FIG. 8 has FIGS. 8A-8D which show the Lissajous plots and calculated saturations for a sensor according to the 15 present invention during four conditions: motion and no motion at high and low saturation. As can be seen in FIGS. 8A and 8B at high saturation, the calculated saturation 100% is equivalent with or without motion. In FIG. 8B, the motion signal is seen to be more than 10 times larger than the cardiac 20 signal of FIG. 8A (FIGS. 8A and 8C are magnified by 10). Similar results occur at low saturation as seen in FIGS. 8C and 8D where the saturation values are calculated to be 70% under both conditions.

FIG. 9A is a graph of the frequency distribution of the 25 detected red and infrared signals for a sensor of the present invention in an experiment with an 8 Hz artificial motion pulse applied. The cardiac signature can be seen at the lower frequencies below 5 Hz, while the 8 Hz driven motion signal is also visible. FIG. 9B is a graph of the red versus infrared 30 intensity signals for the experiment illustrating that both signals are correlated and representative of the same saturation.

FIG. 10 illustrates the oxygen saturation readings of a sensor according to the present invention in experimental tests without motion comparing it with a standard prior art 35 transmissive sensor at another site. A close agreement was noted, indicating the calibration of this sensor on the nailbed site is similar to a conventional transmission sensor.

FIGS. 11A and 11B show a comparison of the output waveform and Lissajous, in the presence of motion, of a sensor according to the present invention (FIG. 11B) with a standard prior art transmissive sensor at another site (FIG. 11A).

deflates it, causing a pressure wave through the thumb, giving artificially induced motion. This pressure induced motion provides the variation needed for sensor 92 to measure the oxygen saturation using either the ratio-of-ratios or a least squares technique. If the motion is in the frequency range of

FIG. 12 illustrates an alternate embodiment of the present invention in which a nail sensor 70 according to the present 45 invention is attached via a flexible circuit 72 to a transmissive sensor 74 which wraps around the finger and has an emitter 76 and detector 78 positioned on top and on the bottom of the finger. Such a combination sensor could allow the oximeter monitor with its program to choose between the sensors 50 flat. depending upon motion conditions. When motion is present, nail sensor 70 could be used, and when motion is not present, sensor 74, which may be more sensitive to the cardiac pulse signal, could be used. Alternately, a single pair of red and infrared emitters could be used, with a reflectance detector on 55 the nail, and a transmissive detector off the nail. Depending on the mode, a switch in the sensor, or in an intermediate amplifier module, or in the oximeter monitor could select between the detectors. In another embodiment, a single detector is used, with one pair of emitters on the nail, and another 60 pair of emitters off the nail. Alternately, a completely separate transmissive sensor could be used.

In some patients, in particular those with low blood perfusion, it may be difficult to lock onto a pulse waveform. The additional transmissive sensor could be used to enable locking on for such patients. In addition, a transmissive sensor could be used to calibrate the nail sensor "on-the-fly."

8

Because of shunting and other unique aspects of the nail site, a predetermined calibration may be off. A measurement of saturation using the transmissive and the nail reflectance sensors could be done in the absence of motion, with a correction factor applied to the reflectance sensor. The correction could be a constant which is added or a multiplicative factor, or both. If measurements are done at different saturations, a calibration line or curve could be determined by the oximeter to allow adjustments anywhere along the calculated curve. Subsequently, in the presence of motion, the nail sensor will be more accurately calibrated.

FIG. 13 illustrates an alternate embodiment of the invention in which a self-contained sensor 80 according to the present invention includes the processing circuitry on one or more semiconductor chips inside, and has its own display 82, which may be a liquid crystal display, for instance. In one embodiment, a button 84 allows switching between modes, such as between displaying a pulse and oxygen saturation. In an alternate embodiment, a flex connection 86 to a module 88 attached on a band 90 may be used. Module 88 might contain the battery, or alternately the processing circuitry, or the display. Additionally, either embodiment could be used for a wireless transmission to an oximeter, with the transmitting circuit either being in module 88 or sensor body 80.

FIG. 14 illustrates another embodiment of the present invention in which a stimulator is used to generate an artificial pulse. A stimulator could electrically stimulate the nerves to cause motion of an appendage, or could use a pneumatic pressure cuff to stimulate an artificial pulse, or use electromechanical stimulation or any other mechanism which generates a pulse characteristically different (e.g., amplitude, frequency, shape, etc.) than the cardiac pulse so that the cardiac pulse need not be used. Such an apparatus would be particularly advantageous for patients with low blood perfusion or a weak heartbeat. FIG. 14 is one embodiment showing a sensor 92 mounted on a thumbnail, with an airbag 94 mounted to the bottom of the thumb and held in place with a band 96. A hose 98 to the airbag periodically inflates and deflates it, causing a pressure wave through the thumb, giving provides the variation needed for sensor 92 to measure the oxygen saturation using either the ratio-of-ratios or a least squares technique. If the motion is in the frequency range of a heartbeat, the sensor can be backward compatible with existing oximeter monitors, even those that look for a cardiac signal.

FIG. 15 illustrates airbag 94 in a top view, showing hose 98 connected to a diaphragm pump 100. FIG. 16 shows a side view of the airbag 94 of FIG. 15, showing that it is wide but flat

FIG. 17 is a flowchart of one embodiment of a portion of a program for operating an oximeter so that either cardiac pulses or motion pulses can be used to calculate oxygen saturation. The oxygen saturation is calculated in a known manner (step A). In a first alternative, the signal is analyzed to determine if it is a cardiac pulse or a motion pulse (step B). This can be done using any of the pulse qualification or motion detection techniques known to those of skill in the art. If a motion signal is present and used for the oxygen saturation calculation, then in step C only the oxygen saturation signal is displayed, and not a pulse rate (which would be a motion pulse rate, and not the patient's heart rate). If a cardiac pulse is used, the pulse rate is also displayed (step D).

Alternately, a pulse determination step E could be used where the sensor includes both a reflectance sensor and a transmittance sensor. If motion is present above a predetermined threshold (such as at least twice the arterial pulse

signal), the reflectance sensor is used, which uses the motion signal, and alters any motion filtering or motion reduction techniques (step F). If the motion signal is below the threshold, the transmittance sensor is used (step G), with standard motion reduction techniques being employed (either hard- 5 ware or software or both).

Both sensors could be energized in an ongoing manner, and the saturation and rate could be chosen to come from the sensor considered most reliable, depending on the instrument's assessment of motion. Simultaneous computation may further allow improved processed signal estimates of cardiac rate in the presence of motion given knowledge of estimated saturation.

FIG. 18 is a block diagram of a portion of a pulse oximeter monitor used in conjunction with an artificial pulse generator, such as shown in FIGS. 14-16. A frequency generator 110 produces a desired frequency for the motion pulse. This could be varied to give a frequency which is not interfered with by other noise, or frequency hopping could be used to isolate the signal from other sources of motion or noise. A pump con-  $^{20}$ troller 112 activates a pump or motor 100 (FIG. 12) at the generated frequency. Since the driven frequency is known, optionally other frequencies could be filtered out to reduce noise. After a signal is captured and converted to digital form by a circuit 114, a bandpass filter 116 is used to reduce other 25 frequency signals. A control signal from frequency generator 110 could vary the bandpass frequency. A circuit or processor 118 then calculates the oxygen saturation. A central controller 120 controls the rest of the circuitry, including a sensor driver circuit 122, which could selectively activate different reflec- 30 tance and transmittance emitters in one embodiment. Controller 120 could also analyze the signals for the presence of motion to alternate between motion and cardiac pulse modes in one embodiment. Alternately, a separate motion sensor could provide an input to controller 120. Note that other  $^{35}$ physical implementations are possible, such as using a single processor to do the filtering, the frequency generation and the oxygen saturation calculation.

A calibration resistor (or other active or passive element) provides it to a calibration reader circuit or CPU 120. The wavelength indicated is used to select coefficients stored in the monitor. Such a calibration technique is described in more detail in U.S. Pat. No. 4,621,643, the disclosure of which is incorporated herein by reference.

FIG. 19 is a cut-away view of an embodiment of a sensor 130 according to the invention. An emitter 132 is mounted on a circuit 134 inside the sensor housing. A cylindrical lens 136 is mounted in an aperture 138. The lens directs the light down through the nail, minimizing the light which hits the nail at an angle and can be shunted to the detector. An aperture itself can perform the same function, but the lens insures that more of the light is used, maintaining a higher intensity at a given power, or allowing less power to be used. Detector 140 is recessed in an aperture 142 to avoid shunted light on the receiving end.

The sensor is secured to a nail 144 using an adhesive layer 146. The adhesive layer can act as a shunt path itself. Accordingly, the adhesive layer may be tinted to be opaque to the wavelengths used, with preferably transparent windows 148 and 150 for the detector and emitter apertures.

10

As will be understood by those of skill in the art, the present invention could be embodied in other specific forms without departing from the spirit or essential characteristics thereof. For example, a sensor could be placed on a fingernail other than the thumb nail, and could be placed on toenails. Alternately, a sensor could be placed on the cuticle or the live nail fold skin extending over the beginning of the nail. The sensor could be attached with a clip-type sensor, or an elastic wrap, bandage or adhesive which encircles the appendage could be used. The sensor could be placed at locations other than the nailbed where signals at the multiple wavelengths in the presence of motion are still adequately correlated. The emitter in the sensor could be fabricated using an optical fiber to carry the light from a source remotely located, and equivalently the detector could be an optical light guide to pipe the light to a remote detector. Accordingly, reference should be made to the following claims which set forth the scope of the inven-

What is claimed is:

- 1. A photometric processing device for processing detector signals from a radiation detector in a patient sensor also having a radiation emitter, comprising:
  - a first processing unit configured to determine a blood parameter from a cardiac signal derived plethysmogram from the detector;
  - a second processing unit configured to determine the blood parameter from a motion artifact waveform from the detector; and
  - a control unit configured to utilize the first and second processing units responsive to a motion artifact content of the detector signals.
- 2. The photometric processing device of claim 1 further comprising a processor and a memory, wherein the first and second processing units and the control unit are first, second and third programs stored in the memory.
- 3. The photometric processing device of claim 1 further comprising a selector configured to select between a reflectance mode and a transmittance mode of the sensor.
- 4. The photometric processing device of claim 3 wherein 115 encodes the mean wavelength of at least one LED, and 40 the control unit is further configured to switch between the first and second processing units in accordance with a selection of the selector.
  - 5. The photometric processing device of claim 4 wherein the selector is responsive to the motion artifact content of the detector signals.
  - 6. The photometric processing device of claim 1 wherein the radiation emitter emits and the radiation detector detects radiation at two or more wavelengths, wherein the detector signals at the two or more wavelengths are correlated in the presence of motion.
  - 7. The photometric processing device of claim 6 wherein the detector signals produce a closed Lissajous.
  - 8. The photometric processing device of claim 1 wherein the detector signals are generated in response to at least two wavelengths and are correlated in the presence of non-cardiac pulses.
  - 9. The photometric processing device of claim 8 wherein the detector signals include predominately motion-induced variations and the sensor is configured to be placed on a nail on a digit.



专利名称(译)	运动兼容传感器,用于非侵入式光学血液分析			
公开(公告)号	<u>US7720516</u>	公开(公告)日	2010-05-18	
申请号	US10/990686	申请日	2004-11-16	
[标]申请(专利权)人(译)	内尔科尔普里坦贝内特公司			
申请(专利权)人(译)	NELLCOR PURITAN BENNETT INCORPORATED			
当前申请(专利权)人(译)	NELLCOR PURITAN BENNETT LLC			
[标]发明人	CHIN RODNEY MANNHEIMER PAUL FLEWELLING ROSS			
发明人	CHIN, RODNEY MANNHEIMER, PAUL FLEWELLING, ROSS			
IPC分类号	A61B5/1455 A61B5/145 A61B5/00 A61B5/1464 A61B5/1495			
CPC分类号	A61B5/14552 A61B5/6826 A61B5/6833 A61B5/7207 A61B5/6838			
其他公开文献	US20050070773A1			
外部链接	Espacenet USPTO			

### 摘要(译)

一种非侵入式光学传感器,其使用运动信号来计算被测量的生理特征。 对于脉搏血氧测定法,可以将最小二乘法或比率比技术应用于运动信号 本身。这可以通过选择患者的位置来实现,其中运动的变化产生两个充 分相关的波长的信号。特别地,已经确定放置在指甲上的传感器,特别 是缩略图,表现出当用于脉搏血氧测定时具有相关的红色和红外信号的 特性,并且所得到的信号与动脉血氧饱和度相关。

