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(54) **SYSTEMS AND METHODS FOR ACQUIRING CALIBRATION DATA USABLE IN A PULSE OXIMETER**

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See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,109,643	A	8/1978	Bond et al.
4,331,962	A	5/1982	Neumann

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0 553 372 A1	8/1993
EP	0 601 589 A2	6/1994

(Continued)

OTHER PUBLICATIONS

A.L. Ronald et al., "Continuous Collection of Pulse Oximetry Data: New, Inexpensive, Portable computerized Method", British Journal of Anaesthesia 1992,69:105-107.
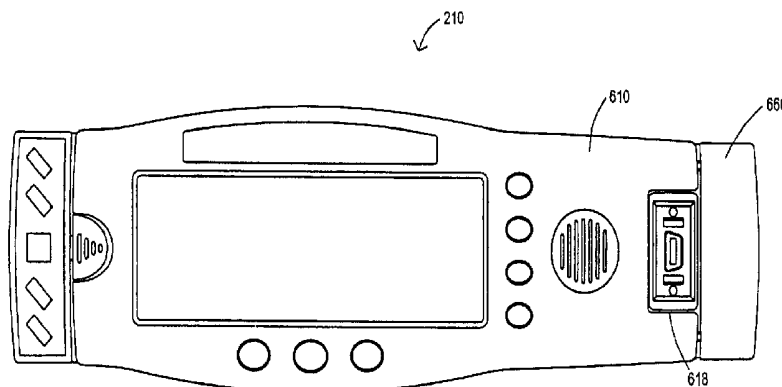
(Continued)

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(57) **ABSTRACT**

The present disclosure includes a portable physiological monitor including a first local display and configured to communicate with a second physiological monitor including a second display.

10 Claims, 16 Drawing Sheets

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(56)   **References Cited**

U.S. PATENT DOCUMENTS

4,704,007 A	11/1987	Landre et al.
4,715,385 A	12/1987	Cudahy et al.
4,825,879 A	5/1989	Tan et al.
4,865,038 A	9/1989	Rich et al.
4,895,161 A	1/1990	Cudahy et al.
4,942,877 A	7/1990	Sakai et al.
4,960,128 A	10/1990	Gordon et al.
4,964,408 A	10/1990	Hink et al.
5,041,187 A	8/1991	Hink et al.
5,069,213 A	12/1991	Polczynski
5,111,817 A	5/1992	Clark et al.
5,159,936 A	11/1992	Yelderman et al.
5,163,438 A	11/1992	Gordon et al.
5,209,343 A	5/1993	Romano et al.
5,231,981 A	8/1993	Schreiber et al.
5,332,876 A	7/1994	Romano et al.
5,337,744 A	8/1994	Branigan
5,341,805 A	8/1994	Stavridi et al.
5,343,869 A	9/1994	Pross et al.
D353,195 S	12/1994	Savage et al.
D353,196 S	12/1994	Savage et al.
5,375,604 A	12/1994	Kelly et al.
5,377,676 A	1/1995	Vari et al.
5,417,222 A	5/1995	Dempsey et al.
D359,546 S	6/1995	Savage et al.
5,431,170 A	7/1995	Mathews
5,434,964 A	7/1995	Moss et al.
D361,840 S	8/1995	Savage et al.
D362,063 S	9/1995	Savage et al.
5,448,991 A	9/1995	Polson et al.
5,452,717 A	9/1995	Branigan et al.
D363,120 S	10/1995	Savage et al.
5,456,252 A	10/1995	Vari et al.
5,473,536 A	12/1995	Wimmer
5,482,036 A	1/1996	Diab et al.
5,490,505 A	2/1996	Diab et al.
5,494,043 A	2/1996	O'Sullivan et al.
5,533,511 A	7/1996	Kaspari et al.
5,561,275 A	10/1996	Savage et al.
5,562,002 A	10/1996	Lalin
5,566,098 A	10/1996	Lucente et al.
5,579,001 A	11/1996	Dempsey et al.
5,590,649 A	1/1997	Caro et al.
5,602,924 A	2/1997	Ourand et al.
5,627,531 A	5/1997	Posso et al.
5,632,272 A	5/1997	Diab
5,638,816 A	6/1997	Kiani-Azarbayjany et al.
5,638,818 A	6/1997	Diab et al.
5,640,627 A	6/1997	Nakano et al.
5,640,953 A	6/1997	Bishop et al.
5,645,440 A	7/1997	Tobler et al.
5,657,210 A *	8/1997	Yamanaka
5,661,632 A	8/1997	Register
5,661,658 A	8/1997	Putt et al.
5,685,299 A	11/1997	Diab et al.
5,685,314 A	11/1997	Geheb et al.
5,687,717 A	11/1997	Halpern et al.
D393,830 S	4/1998	Tobler et al.
5,743,262 A	4/1998	Lepper, Jr. et al.
5,758,644 A	6/1998	Diab et al.
5,760,910 A	6/1998	Lepper, Jr. et al.
5,769,785 A	6/1998	Diab et al.
5,779,630 A	7/1998	Fein et al.
5,782,757 A	7/1998	Diab et al.
5,782,805 A	7/1998	Meinzer et al.
5,785,659 A	7/1998	Caro et al.
5,791,347 A	8/1998	Flaherty et al.
5,807,247 A	9/1998	Merchant et al.
5,810,734 A	9/1998	Caro et al.
5,823,950 A	10/1998	Diab et al.
5,830,131 A	11/1998	Caro et al.
5,830,137 A	11/1998	Scharf
5,833,618 A	11/1998	Caro et al.
5,860,918 A	1/1999	Schradi et al.
5,860,919 A	1/1999	Kiani-Azarbayjany et al.
5,868,710 A	2/1999	Battiato et al.
5,890,929 A	4/1999	Mills et al.
5,904,654 A	5/1999	Wohltmann et al.
5,910,797 A	6/1999	Beuk
5,910,882 A *	6/1999	Burrell 361/679.56
5,913,823 A	6/1999	Hedberg et al.
5,919,134 A	7/1999	Diab
5,931,791 A	8/1999	Saltzstein et al.
5,934,925 A	8/1999	Tobler et al.
5,940,182 A	8/1999	Lepper, Jr. et al.
5,944,659 A	8/1999	Flach et al.
5,947,907 A	9/1999	Duich
5,987,343 A	11/1999	Kinast
5,995,855 A	11/1999	Kiani et al.
5,997,343 A	12/1999	Mills et al.
6,002,952 A	12/1999	Diab
6,011,986 A	1/2000	Diab et al.
6,027,452 A	2/2000	Flaherty et al.
6,036,642 A	3/2000	Diab et al.
6,045,509 A	4/2000	Caro et al.
6,067,462 A	5/2000	Diab et al.
6,081,735 A	6/2000	Diab et al.
6,088,607 A	7/2000	Diab et al.
6,110,522 A	8/2000	Lepper, Jr. et al.
6,124,597 A	9/2000	Shehada
6,134,504 A	10/2000	Douglas et al.
6,137,468 A	10/2000	Martinez et al.
6,144,868 A	11/2000	Parker
6,151,516 A	11/2000	Kiani-Azarbayjany et al.
6,152,754 A	11/2000	Gerhardt et al.
6,157,850 A	12/2000	Diab
6,165,005 A	12/2000	Mills et al.
6,184,521 B1	2/2001	Coffin, IV et al.
6,185,095 B1 *	2/2001	Helot et al.
6,201,554 B1	3/2001	Lands
6,206,830 B1	3/2001	Diab et al.
6,221,012 B1 *	4/2001	Maschke et al.
6,229,856 B1	5/2001	Diab et al.
6,232,609 B1	5/2001	Snyder et al.
6,236,872 B1	5/2001	Diab et al.
6,241,683 B1	6/2001	Macklem et al.
6,253,097 B1	6/2001	Aronow et al.
6,256,523 B1	7/2001	Diab et al.
6,263,222 B1	7/2001	Diab
6,278,522 B1	8/2001	Lepper, Jr. et al.
6,280,213 B1	8/2001	Tobler et al.
6,285,896 B1	9/2001	Tobler et al.
6,321,100 B1	11/2001	Parker
6,322,502 B1	11/2001	Schoenberg et al.
6,334,065 B1	12/2001	Al-Ali
6,343,224 B1	1/2002	Parker
6,349,228 B1	2/2002	Kiani et al.
6,352,504 B1	3/2002	Ise et al.
6,360,114 B1	3/2002	Diab et al.
6,368,283 B1	4/2002	Xu et al.
6,371,921 B1	4/2002	Caro et al.
6,377,829 B1	4/2002	Al-Ali
6,388,240 B2	5/2002	Schulz et al.
6,397,091 B2	5/2002	Diab et al.
6,400,376 B1	6/2002	Singh et al.
6,415,166 B1	7/2002	Van Hoy et al.
6,430,525 B1	8/2002	Weber et al.
6,441,828 B1	8/2002	Oba et al.
6,453,173 B1	9/2002	Reber et al.
6,463,311 B1	10/2002	Diab
6,470,199 B1	10/2002	Kopotic et al.
6,501,975 B2	12/2002	Diab et al.
6,505,059 B1	1/2003	Kollias et al.
6,515,273 B2	2/2003	Al-Ali
6,519,487 B1	2/2003	Parker
6,525,386 B1	2/2003	Mills et al.
6,526,300 B1	2/2003	Kiani et al.
6,541,756 B2	4/2003	Schulz et al.
6,542,764 B1	4/2003	Al-Ali et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,570,758 B1 *	5/2003	Maeda 361/679.4
6,580,086 B1	6/2003	Schulz et al.
6,584,336 B1	6/2003	Ali et al.
6,595,316 B2	7/2003	Cybulski et al.
6,597,932 B2	7/2003	Tian et al.
6,597,933 B2	7/2003	Kiani et al.
6,606,511 B1	8/2003	Ali et al.
6,632,181 B2	10/2003	Flaherty et al.
6,639,668 B1	10/2003	Trepagnier
6,640,116 B2	10/2003	Diab
6,643,530 B2	11/2003	Diab et al.
6,650,917 B2	11/2003	Diab
6,654,624 B2	11/2003	Diab et al.
6,658,276 B2	12/2003	Kianl et al.
6,661,161 B1	12/2003	Lanzo et al.
6,671,531 B2	12/2003	Al-Ali et al.
6,678,543 B2	1/2004	Diab et al.
6,684,090 B2	1/2004	Ali et al.
6,684,091 B2	1/2004	Parker
6,697,656 B1	2/2004	Al-Ali
6,697,657 B1	2/2004	Shehada et al.
6,697,658 B2	2/2004	Al-Ali
RE38,476 E	3/2004	Diab et al.
6,699,194 B1	3/2004	Diab
6,714,804 B2	3/2004	Al-Ali et al.
RE38,492 E	4/2004	Diab et al.
6,721,582 B2	4/2004	Trepagnier et al.
6,721,585 B1	4/2004	Parker
6,725,075 B2	4/2004	Al-Ali
6,728,560 B2	4/2004	Kollias et al.
6,735,459 B2	5/2004	Parker
6,745,060 B2	6/2004	Diab et al.
6,760,607 B2	7/2004	Al-Ali
6,770,028 B1	8/2004	Al-Ali
6,771,994 B2	8/2004	Kiani et al.
6,792,300 B1	9/2004	Diab et al.
6,813,511 B2	11/2004	Diab et al.
6,816,741 B2	11/2004	Diab
6,822,564 B2	11/2004	Al-Ali
6,826,419 B2	11/2004	Diab et al.
6,830,711 B2	12/2004	Mills et al.
6,850,787 B2	2/2005	Weber et al.
6,850,788 B2	2/2005	Al-Ali
6,852,083 B2	2/2005	Caro et al.
6,861,639 B2	3/2005	Al-Ali
6,898,452 B2	5/2005	Al-Ali et al.
6,920,345 B2	7/2005	Al-Ali et al.
6,931,268 B1	8/2005	Kiani-Azarbayjany et al.
6,934,570 B2	8/2005	Kiani et al.
6,939,305 B2	9/2005	Flaherty et al.
6,943,348 B1	9/2005	Coffin, IV
6,950,687 B2	9/2005	Al-Ali
6,961,598 B2	11/2005	Diab
6,970,792 B1	11/2005	Diab
6,979,812 B2	12/2005	Al-Ali
6,985,764 B2	1/2006	Mason et al.
6,993,371 B2	1/2006	Kiani et al.
6,996,427 B2	2/2006	Ali et al.
6,999,904 B2	2/2006	Weber et al.
7,003,338 B2	2/2006	Weber et al.
7,003,339 B2	2/2006	Diab et al.
7,015,451 B2	3/2006	Dalke et al.
7,024,233 B2	4/2006	Ali et al.
7,027,849 B2	4/2006	Al-Ali
7,030,749 B2	4/2006	Al-Ali
7,039,449 B2	5/2006	Al-Ali
7,041,060 B2	5/2006	Flaherty et al.
7,044,918 B2	5/2006	Diab
7,067,893 B2	6/2006	Mills et al.
7,096,052 B2	8/2006	Mason et al.
7,096,054 B2	8/2006	Abdul-Hafiz et al.
7,132,641 B2	11/2006	Schulz et al.
7,142,901 B2	11/2006	Kiani et al.
7,149,561 B2	12/2006	Diab
7,186,966 B2	3/2007	Al-Ali
7,190,261 B2	3/2007	Al-Ali
7,215,984 B2	5/2007	Diab
7,215,986 B2	5/2007	Diab
7,221,971 B2	5/2007	Diab
7,225,006 B2	5/2007	Al-Ali et al.
7,225,007 B2	5/2007	Al-Ali
RE39,672 E	6/2007	Shehada et al.
7,239,905 B2	7/2007	Kiani-Azarbayjany et al.
7,245,953 B1	7/2007	Parker
7,254,429 B2	8/2007	Schurman et al.
7,254,431 B2	8/2007	Al-Ali
7,254,433 B2	8/2007	Diab et al.
7,254,434 B2	8/2007	Schulz et al.
7,254,953 B2	8/2007	Parker
7,272,425 B2	9/2007	Al-Ali
7,274,955 B2	9/2007	Kiani et al.
D554,263 S	10/2007	Al-Ali
7,280,858 B2	10/2007	Al-Ali et al.
7,289,835 B2	10/2007	Mansfield et al.
7,292,883 B2	11/2007	De Delice et al.
7,295,866 B2	11/2007	Al-Ali
7,328,053 B1	2/2008	Diab et al.
7,332,784 B2	2/2008	Mills et al.
7,340,287 B2	3/2008	Mason et al.
7,341,559 B2	3/2008	Schulz et al.
7,343,186 B2	3/2008	Lamego et al.
D566,282 S	4/2008	Al-Ali et al.
7,355,512 B1	4/2008	Al-Ali
7,356,365 B2	4/2008	Schurman
7,371,981 B2	5/2008	Abdul-Hafiz
7,373,193 B2	5/2008	Al-Ali et al.
7,373,194 B2	5/2008	Weber et al.
7,376,453 B1	5/2008	Diab et al.
7,377,794 B2	5/2008	Al Ali et al.
7,377,899 B2	5/2008	Weber et al.
7,383,070 B2	6/2008	Diab et al.
7,415,297 B2	8/2008	Al-Ali et al.
7,428,432 B2	9/2008	Ali et al.
7,438,683 B2	10/2008	Al-Ali et al.
7,440,787 B2	10/2008	Diab
7,454,240 B2	11/2008	Diab et al.
7,467,002 B2	12/2008	Weber et al.
7,469,157 B2	12/2008	Diab et al.
7,471,969 B2	12/2008	Diab et al.
7,471,971 B2	12/2008	Diab et al.
7,483,729 B2	1/2009	Al-Ali et al.
7,483,730 B2	1/2009	Diab et al.
7,489,958 B2	2/2009	Diab
7,496,391 B2	2/2009	Diab et al.
7,496,393 B2	2/2009	Diab et al.
D587,657 S	3/2009	Al-Ali et al.
7,499,741 B2	3/2009	Diab
7,499,835 B2	3/2009	Weber et al.
7,500,950 B2	3/2009	Al-Ali et al.
7,509,154 B2	3/2009	Diab
7,509,494 B2	3/2009	Al-Ali
7,510,849 B2	3/2009	Schurman et al.
7,526,328 B2	4/2009	Diab et al.
7,530,942 B1	5/2009	Diab
7,530,949 B2	5/2009	Al-Ali
7,530,955 B2	5/2009	Diab et al.
7,563,110 B2	7/2009	Al-Ali et al.
7,596,398 B2	9/2009	Al-Ali et al.
7,618,375 B2	11/2009	Flaherty
D606,659 S	12/2009	Kiani et al.
7,647,083 B2	1/2010	Al-Ali et al.
D609,193 S	2/2010	Al-Ali et al.
D614,305 S	4/2010	Al-Ali et al.
RE41,317 E	5/2010	Parker
7,729,733 B2	6/2010	Al-Ali et al.
7,734,320 B2	6/2010	Al-Ali
7,761,127 B2	7/2010	Al-Ali et al.
7,761,128 B2	7/2010	Al-Ali et al.
7,764,982 B2	7/2010	Dalke et al.
7,991,446 B2	8/2011	Ali et al.
2002/0140675 A1	10/2002	Ali et al.
2003/0197679 A1	10/2003	Ali et al.
2005/0065417 A1	3/2005	Ali et al.
2006/0258926 A1	11/2006	Ali et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2008/0030468 A1	2/2008	Ali et al.
2008/0039701 A1	2/2008	Ali et al.
2009/0076400 A1	3/2009	Diab et al.
2009/0099430 A1	4/2009	Diab et al.
2009/0182211 A1	7/2009	Diab et al.
2011/0288384 A1	11/2011	Ali et al.

FOREIGN PATENT DOCUMENTS

EP	0 707 824 A2	4/1996
EP	0 707 825 A2	4/1996
EP	0 707 867 A2	4/1996
EP	0821911	2/1998
EP	1 460 516 A2	9/2004
JP	60-163633	8/1985
JP	62-8738	1/1987
JP	62-197032	8/1987
JP	2-55033	2/1990
JP	4-12736	1/1992
JP	4-176445	6/1992
JP	7-152553	6/1995
WO	WO 87/00027	1/1987
WO	WO 89/00061	1/1989
WO	WO 94/24929	11/1994
WO	WO 96/16591	6/1996
WO	WO 97/08605	3/1997
WO	WO 97/22293	6/1997
WO	WO 98/11820	3/1998
WO	WO 00/42911	7/2000
WO	WO 00/64346	11/2000
WO	WO 01/26232 A2	4/2001
WO	WO 02/15781 A1	2/2002

OTHER PUBLICATIONS

Advertisement for MediSense Precision PCx Glucose Monitor, Sep. 1999.

Chih-Lung Lin et al., "A Portable Monitor for Fetal Heart Rate and Uterine Contraction", IEEE Engineering in Medicine & Biology, Nov./Dec. 1997,80-84.

Correll G. et al., "Evaluation of several blood glucose monitoring systems for whole blood glucose measurements at the point of care", 52nd Annual MCC Meeting, Jul. 23-27, 2000, Abstract 20.

David J. Farrar et al., "Portable Pneumatic Biventricular Driver for the Thoratec Ventricular Assist Device", ASAIO Journal 1997, 43: M631-M634.

Extended European Search Report and European Search Opinion for App. No. 07021807.8-2310, dated Oct. 21, 2009 in 10 pages.

Extended European Search Report, App. No. 08012674.1-2310, dated Oct. 21, 2009 in 7 pages.

J.D.E. Van Suijlen et al., "New Trends in bedside blood glucose monitoring", Ned Tijdschr Klin Chem 2000, Apr. 6, 2000, vol. 25, No. 2.

James H. Nichols, "Management of Point-of-Care Testing", Blood Gas News, Dec. 9, 1999, vol. 8, No. 2.

Jing Bai et al., "Home Telemonitoring Framework Based on Integrated Functional Modules", IEEE 2000, Proceedings of the 22nd Annual EMBS Int'l Conference, Jul. 23-28, 2000,778-781.

M.1. Fikhman, "Problems in Cardiomonitoring System Design, Biomedical Engineering", vol. 29, No. 4, 199, 180-182.

M.Nakagawara and K. Yamakoshi, "A portable instrument for non-invasive monitoring of beat-by-beat cardiovascular haemodynamic parameters based on the volume-compensation and electrical-admittance method", Med. Biol. Eno. Cornput., 2000, vol. 38, 17-25.

Complaint for Patent Infringement, *Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH*, (District of Delaware, Case No. 09-000080(JJF)), dated Feb. 3, 2009.

First Amended Complaint for Patent Infringement, *Masimo Corporation v. Philips Electronics North America Corporation and Philips*

Medizin Systeme Böblingen GMBH, (District of Delaware, Case No. 09-00080(JJF)) dated May 12, 2009.

Defendants' Answer and Philips Electronics North America Corporation's Counterclaims to Masimo's First Amended Complaint, *Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH*, (District of Delaware, Case No. 09-00080(JJF)) dated Jun. 15, 2009.

Masimo's Answer to Philips' Counterclaims, *Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH*, (District of Delaware, Case No. 09-00080(JJF)) dated Jul. 9, 2009.

Defendant/Counterclaim-Plaintiff Philips Electronics North America Corporation Answer to Masimo's Counterclaims, *Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH*, (District of Delaware, Case No. 09-00080(JJF)) dated Aug. 3, 2009, pp. 1-23.

Defendants' Answer and Philips Electronics North America Corporation's Amended Counterclaims to Masimo's First Amended Complaint, *Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH*, (District of Delaware, Case No. 09-00080(JJF)) dated Apr. 21, 2010.

Masimo's Answer to Philips' Amended Counterclaims, *Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH*, (District of Delaware, Case No. 09-00080(JJF)) dated May 10, 2010.

Philips Electronics North America Corporation's Answer to Masimo's Amended Counterclaims, *Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH*, (District of Delaware, Case No. 09-00080(JJF)) dated May 27, 2010.

Philips North America Corporation and Philips Medizin Systeme Böblingen GMBH's Seventh Supplemental Objections and Responses to Masimo Corporation's First Set of Interrogatories (Nos. 1-8), *Masimo Corporation v. Philips Electronics North America Corporation and Philips Medizin Systeme Böblingen GMBH*, (District of Delaware, Case No. 09-00080(JJF)) dated Jun. 30, 2010 (Redacted).

Michael A.E. Schneider, et al., "Use of a Relational Database for Patient- and Data-Management in the Electrophysiologic Catheter Laboratory", Computers in Cardiology 1994, 513-515.

N.D. Harris, et al., "Can Changes in QT Interval be used to Predict the Onset of Hypoglycemia in Type 1 Diabetes?", Computers in Cardiology 2000; 27:375-278.

P. Draycon, "Advanced technology in patient monitoring is expected to reduce costs", Min Invas Ther & Allied Technol1997: 6: 308-309.

S. Weber, "Remote network (Ethernet) connectivity for glucose testing at the point-of-care", 51st Annual MCC Conference, Jul. 25-29, 1999, Abstract 111.

Thoratec VADIVAD System Clinical Operation & Patient Management, 2004.

Toshiyo Tamura et al., "A system for monitoring temperature distribution in bed and its application to the assessment of body movement", Physiol. Meas. 14 (1993) 33-41.

HP Component Monitoring System, System Information, Edition 7—vol. 1, printed in Jul. 1994, in 252 pages.

HP Component Monitoring System, Parameter Information, Edition 7—vol. 2, printed in Jul. 1994, in 252 pages.

Service Manual, NELLCOR Interface/Display Module, Model N-50, 1992, in 21 pages.

NELLCOR PB N-200 Pulse Oximeter (NPN-200), in 4 pages.

British Journal of Anaesthesia, 1991, "The World's Most Advanced Pulse Oximetry System Just Became Even More Versatile," in 2 pages.

HP VueLink and Baxter's Explorer and Vigilance Monitors, in 2 pages.

Mallinckrodt, Inc. v. Masimo Corp., 147 Fed. Appx. 158, 2005 WL 2139867 (Fed. Cir. 2005).

Mallinckrodt Inc. v. Masimo Corp., 2004 U.S. Dist. Lexis 28518 (C.D. Cal. Jul. 12, 2004).

Comus International, 3 pages alleged to be downloaded and printed from the World Wide Web on Mar. 15, 2002.

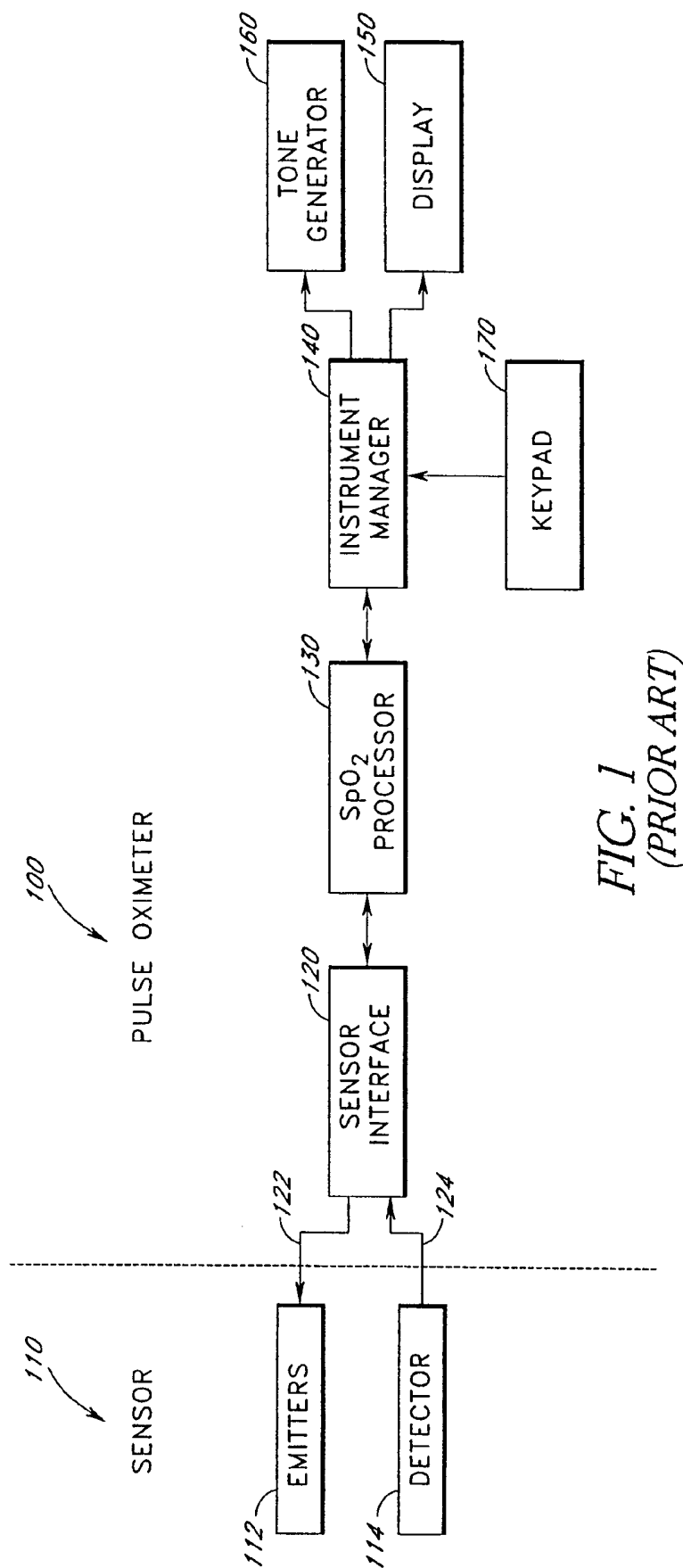Copending U.S. Appl. No. 09/641,542, filed Aug. 18, 2000, and pending claims.

(56)   **References Cited**

OTHER PUBLICATIONS

Copending U.S. Appl. No. 10/153,263, filed May 21, 2002, and pending claims.
Copending U.S. Appl. No. 10/911,391, filed Aug. 3, 2004.
Copending U.S. Appl. No. 11/431,151, filed May 8, 2006.
Copending U.S. Appl. No. 11/894,722, filed Aug. 20, 2007.
Copending U.S. Appl. No. 12/039,704, filed Feb. 28, 2008.
European Patent Office Official Communication pursuant to Article 96(2) EPC, Application No. 01 962 370.1-2305, Mailing date: Jun. 28, 2007, in 4 pages.
European Search Report, App. No. 07021807.8-2310, dated Jul. 31, 2009 in 4 pages.
PCT International Search Report, App. No. PCT/US 01/41705, App. Date: Jan. 17, 2002.
U.S. Appl. No. 09/491,175, filed Jan. 25, 2000, now abandoned.
U.S. Appl. No. 10/153,263, filed May 21, 2002 in 48 pages.
U.S. Appl. No. 10/420,994, filed Apr. 22, 2003 in 48 pages.
U.S. Appl. No. 10/911,391, filed May 8, 2006 in 63 pages.
U.S. Appl. No. 11/431,151, filed May 8, 2006 in 49 pages.
U.S. Patent and Trademark Office Notice of Allowance, U.S. Appl. No. 09/516,110, Mailing date: Feb. 5, 2003, in 6 pages.
U.S. Patent and Trademark Office Notice of Allowance, U.S. Appl. No. 09/516,110, Mailing date: Sep. 11, 2002, in 9 pages.
U.S. Patent and Trademark Office Notice of Allowance, U.S. Appl. No. 09/641,542, Mailing date: Mar. 24, 2004, in 4 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 09/641,542, Mailing date: May 14, 2003, in 9 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 09/641,542, Mailing date: Oct. 10, 2002, in 9 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 09/641,542, Mailing date: Oct. 16, 2003, in 7 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 10/153,263, Mailing date: Apr. 30, 2007, in 12 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 10/153,263, Mailing date: Nov. 1, 2005, in 8 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 10/153,263, Mailing date: Sep. 22, 2004, in 11 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 10/153,263, Mailing date: Oct. 5, 2006, in 12 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 10/420,994, Mailing date: Feb. 24, 2006, in 6 pages.
U.S. Patent and Trademark Office Office Action, U.S. Appl. No. 10/420,994, Mailing date: Oct. 18, 2006, in 7 pages.
European Search Report, App. No. 09002646.9-2319, dated Nov. 17, 2010.
Mallinckrodt, Inc. v. *Masimo Corp.*, 254 F. Supp.2d 1140 (C.D. Cal. 2003).
Revised Joint Claim Construction Chart, *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 Oct. 19, 2010.
Philips' Opening Markman Brief, *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 Oct. 19, 2010.
Masimo Corporation's Opening Claim Construction Brief, *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 Oct. 19, 2010.
Declaration of Perry D. Oldham in Support of Masimo Corporation's Opening Claim Construction Brief, *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 Oct. 19, 2010.
Declaration of Robert T. Stone in Support of Philips' Responsive Markman Brief, *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 Nov. 15, 2010.
Masimo Corporation's Responsive Claim Construction Brief, *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 Nov. 19, 2010 (Redacted).
Confidential Declaration of Michelle Armond in Support of Masimo Corporation's Responsive Claim Construction Brief, *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 Nov. 19, 2010 (Redacted).
Philips' Responsive Markman Brief, *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 Nov. 22, 2010.
Masimo's Technical Tutorial, *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 Dec. 1, 2010.
Phlips' Claim Construction Hearing, Presentation Materials, *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 Dec. 1, 2010.
Transcript of Markman Hearing, *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 Dec. 1, 2010.
Report and Recommendation re Claim Construction, *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 Feb. 18, 2011.
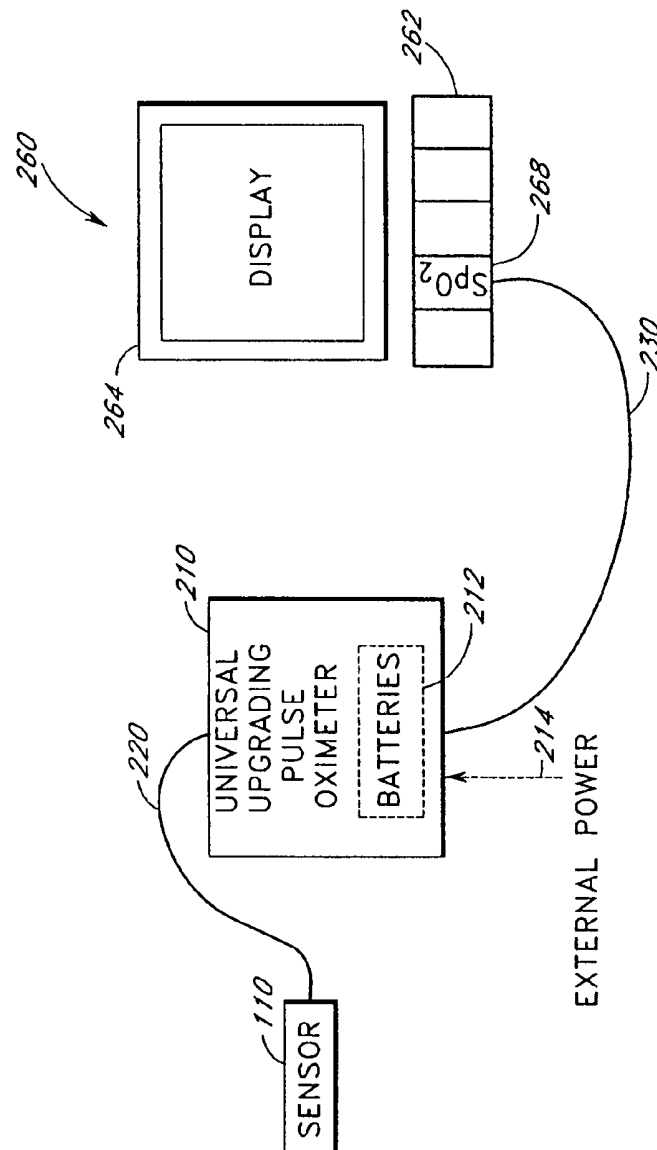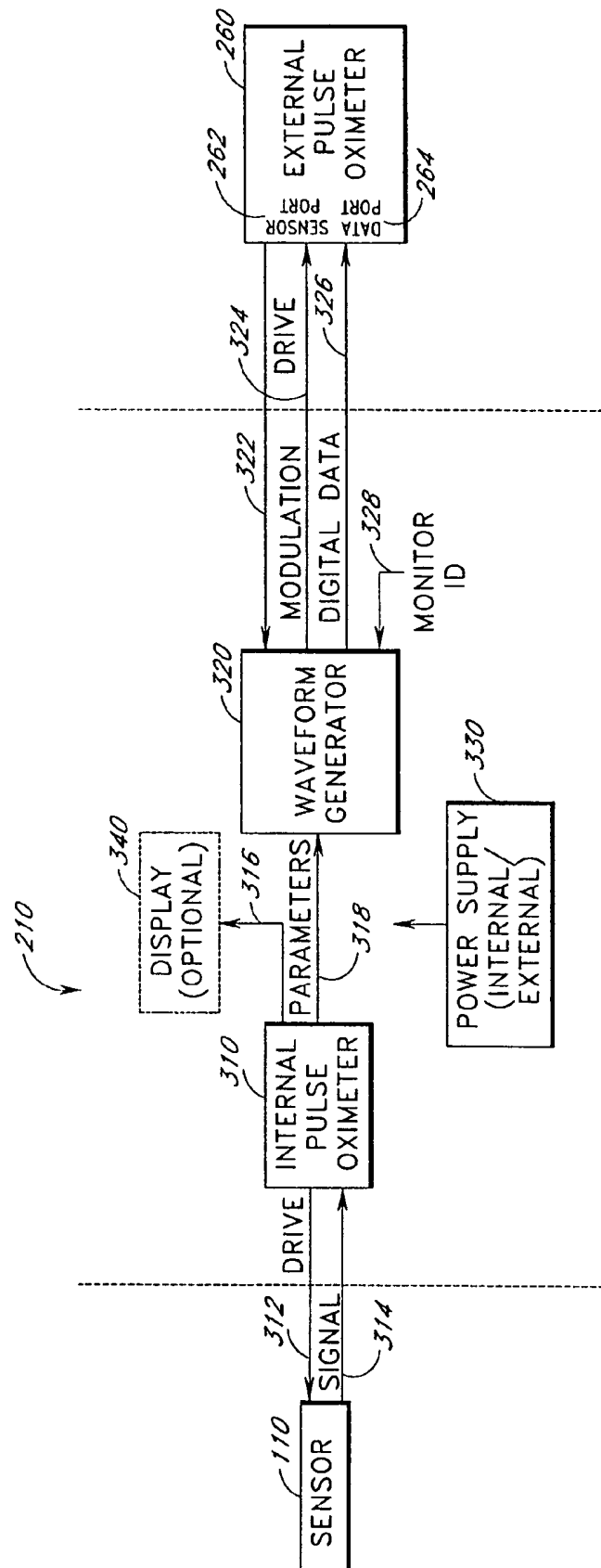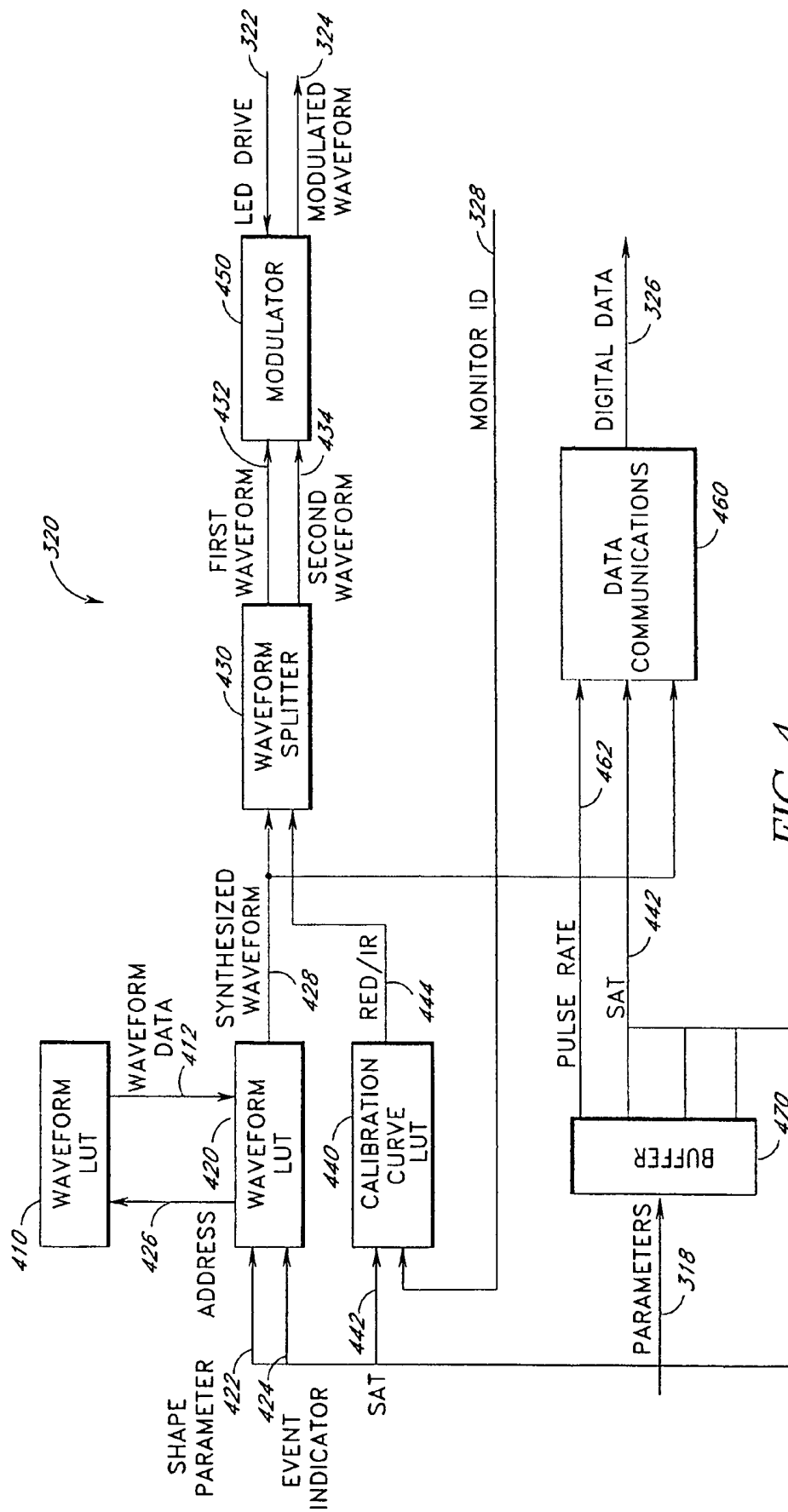
* cited by examiner

FIG. 1
(PRIOR ART)
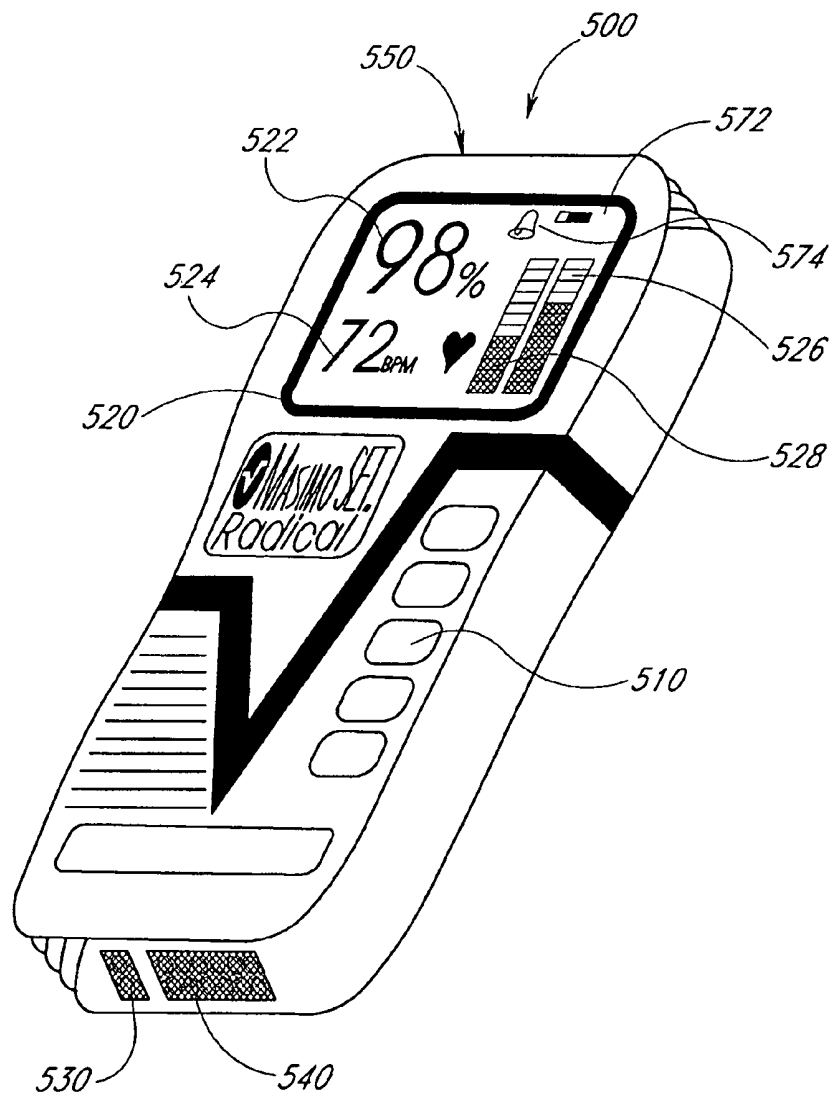
DISPLAY

SpO₂

UNIVERSAL
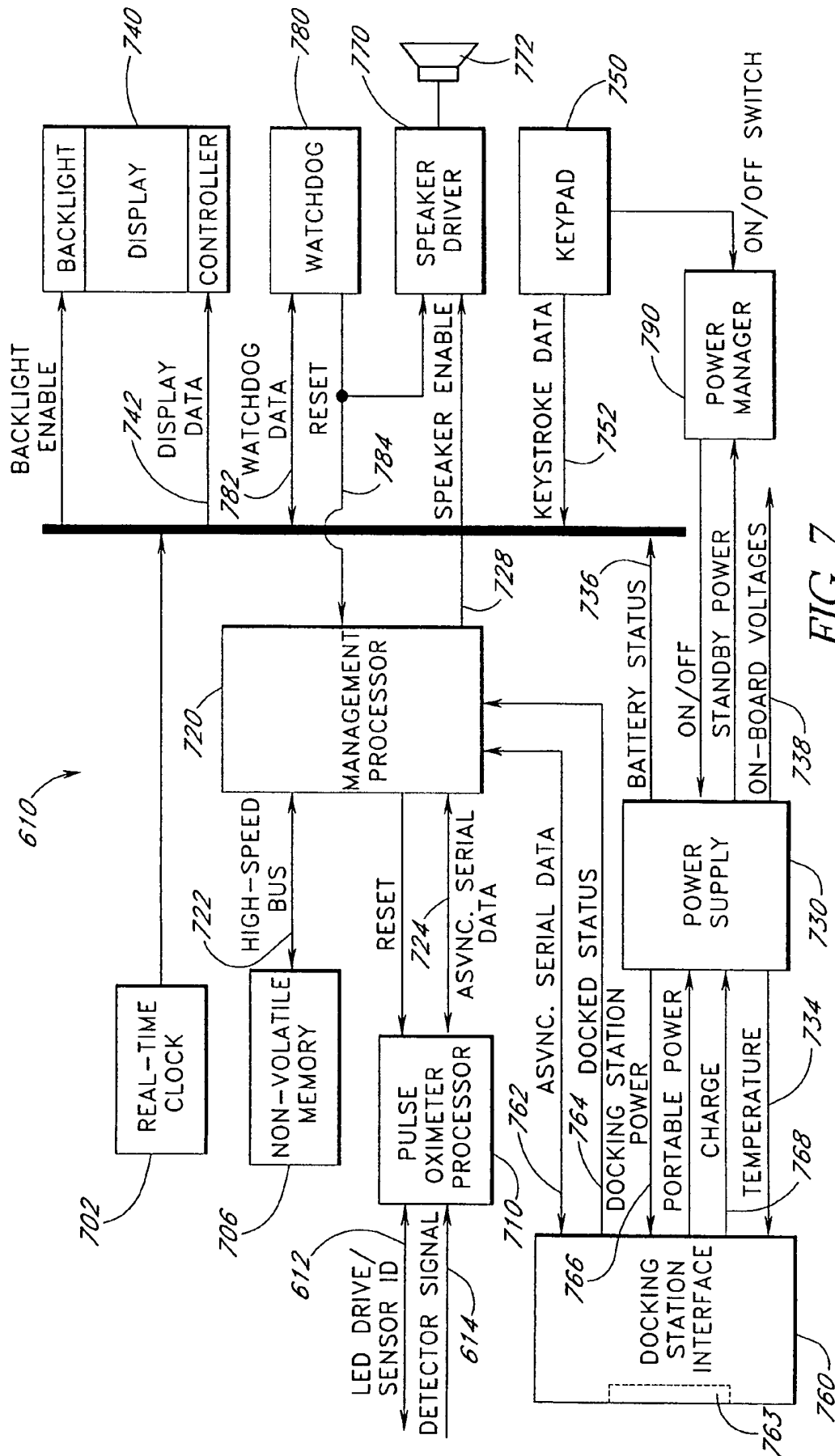UPGRADING
PULSE
OXIMETER

BATTERIES

SENSOR

EXTERNAL POWER

FIG. 2

FIG. 3

FIG. 4

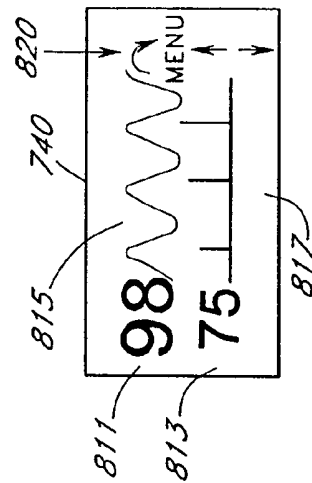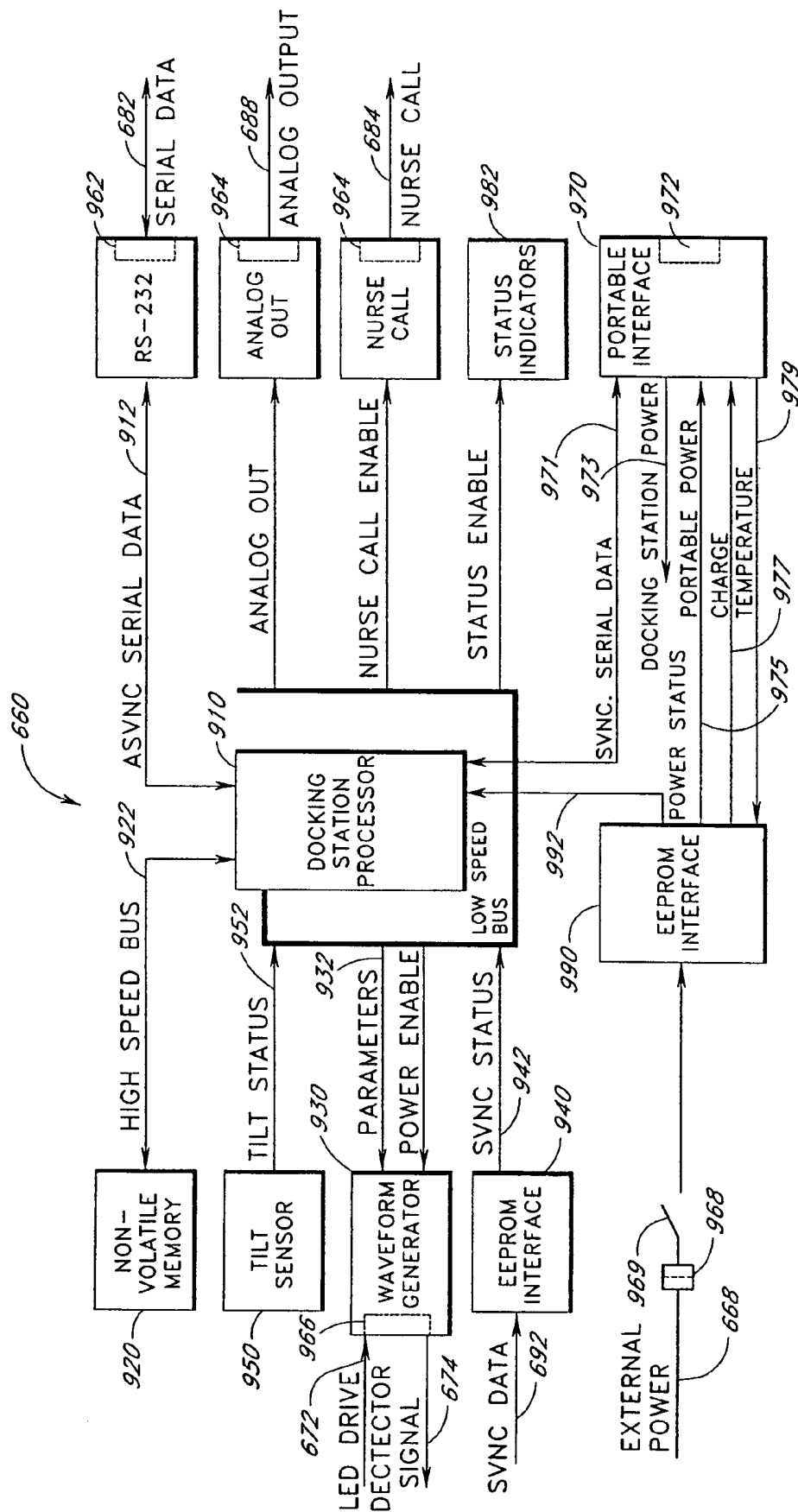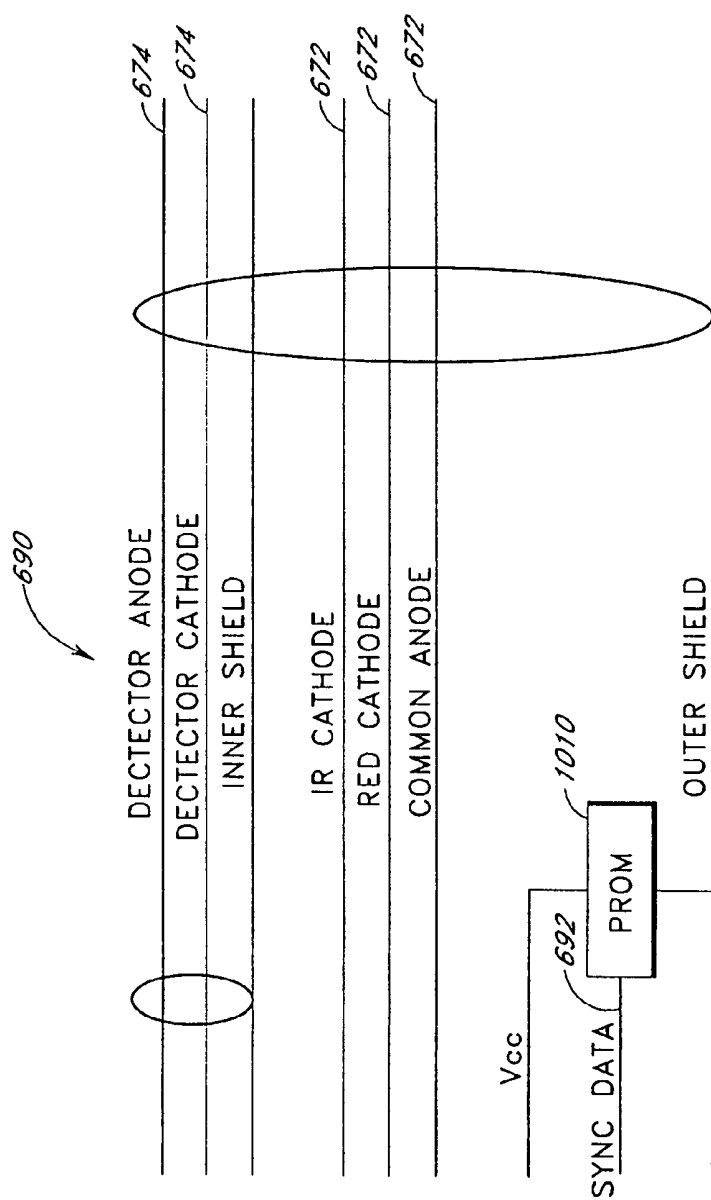*FIG. 5*
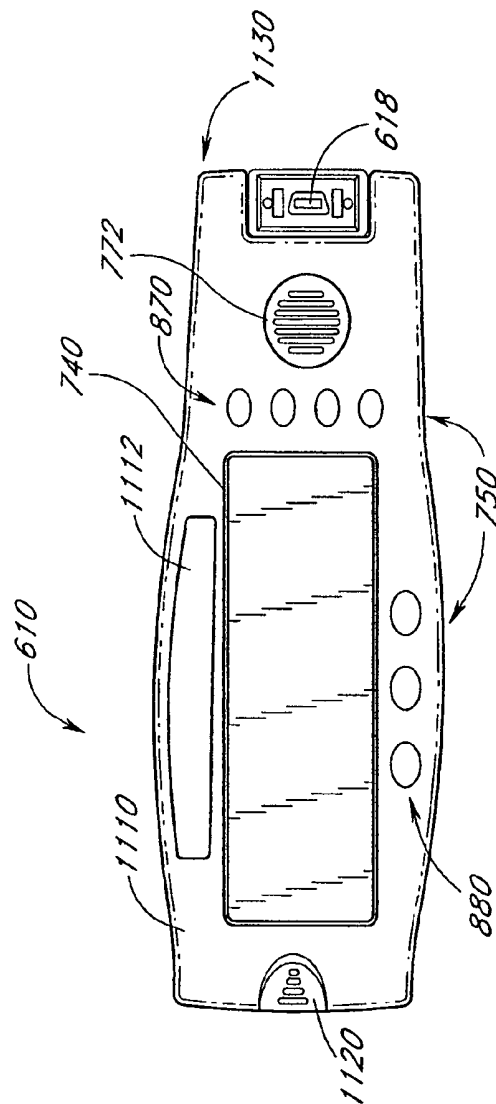
FIG. 6

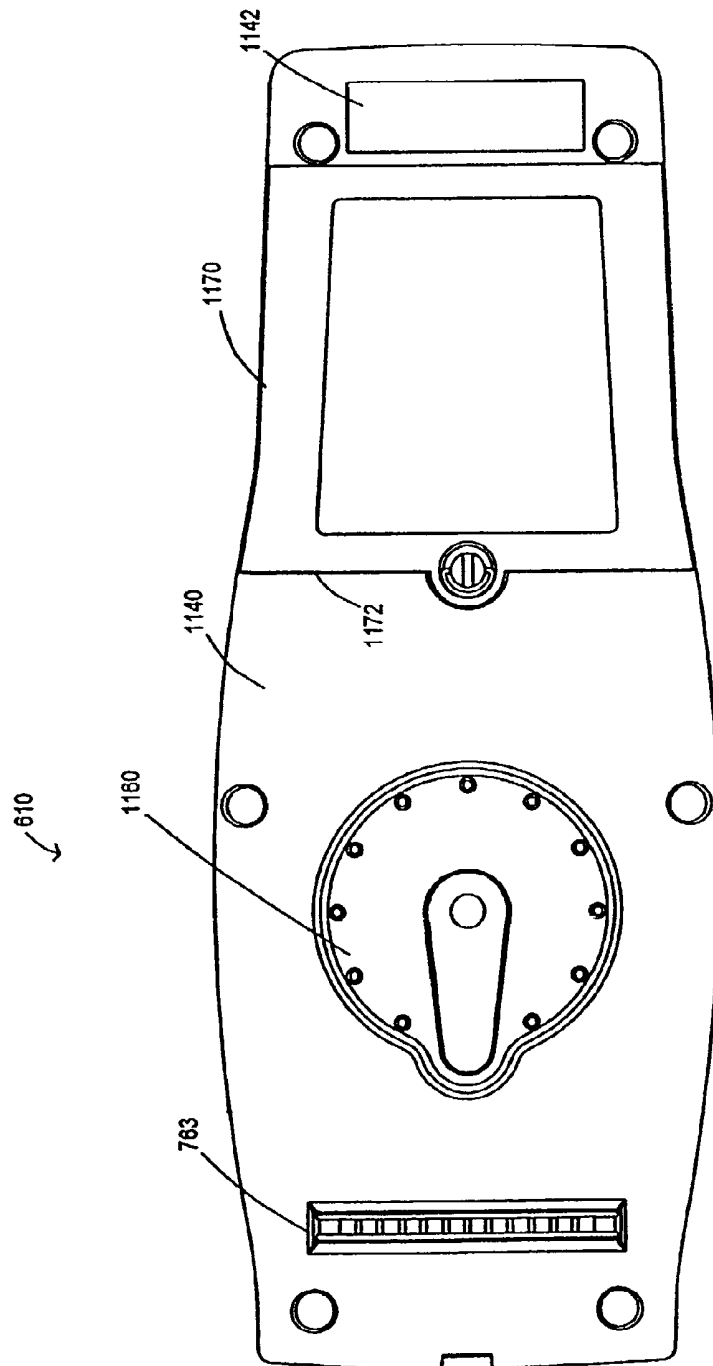*FIG. 7*

FIG. 8C

FIG. 8B

DOT MATRIX DISPLAY (160x480)
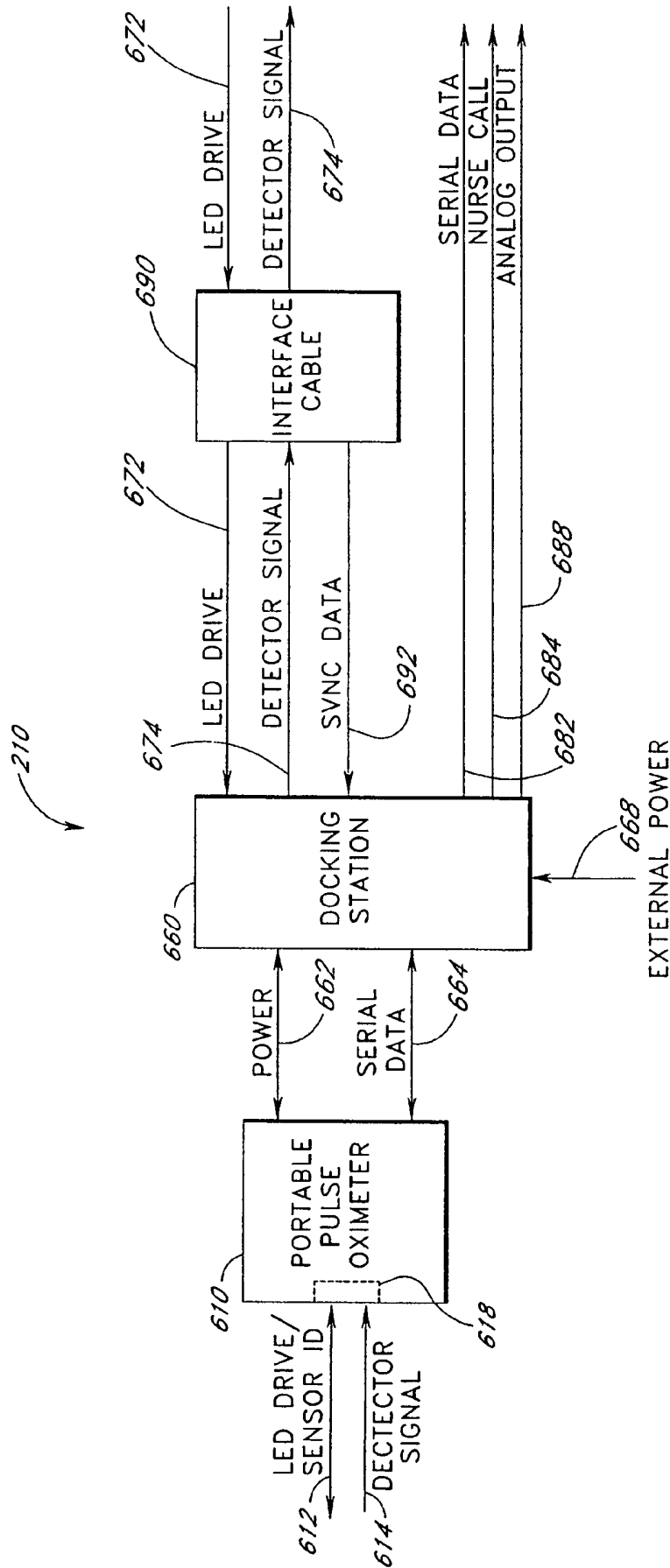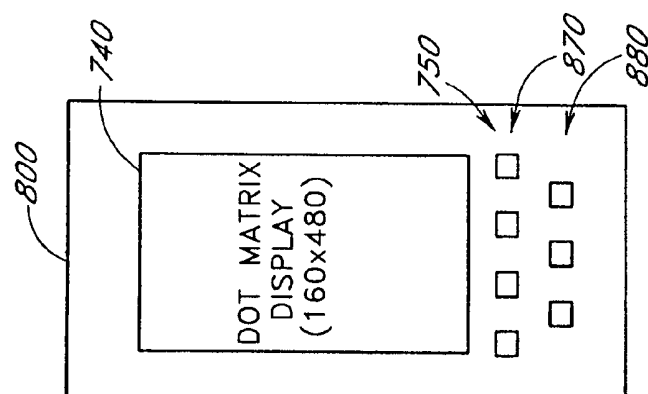
FIG. 8A
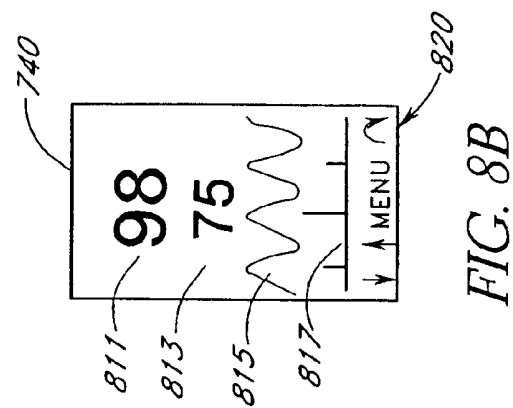
FIG. 9

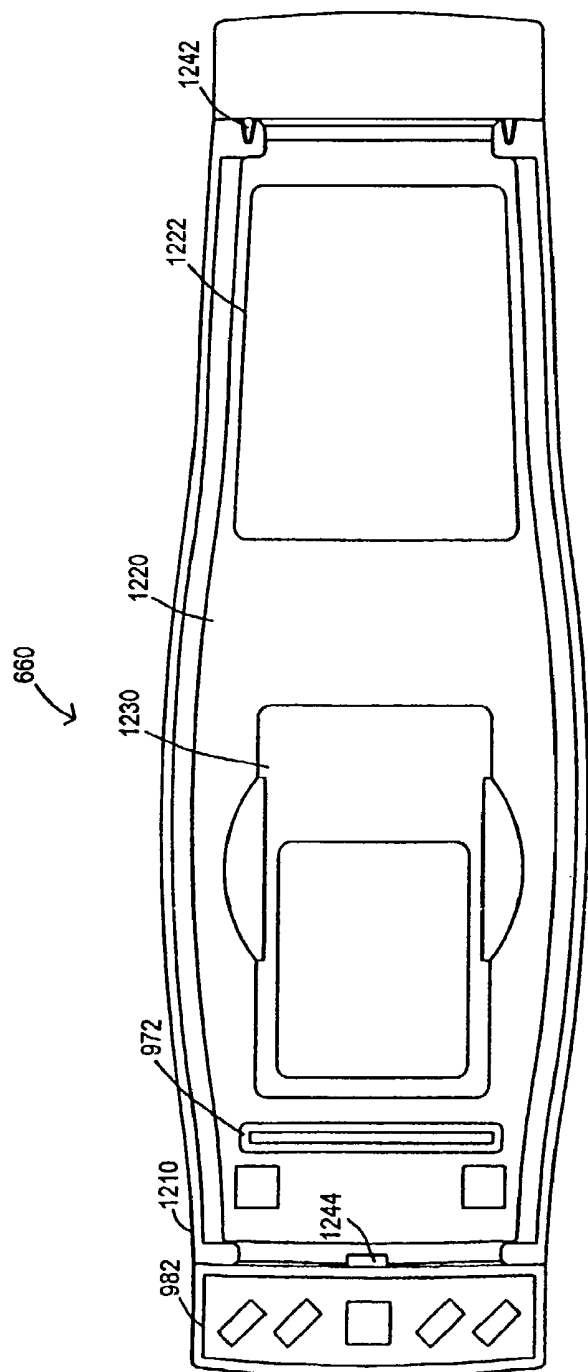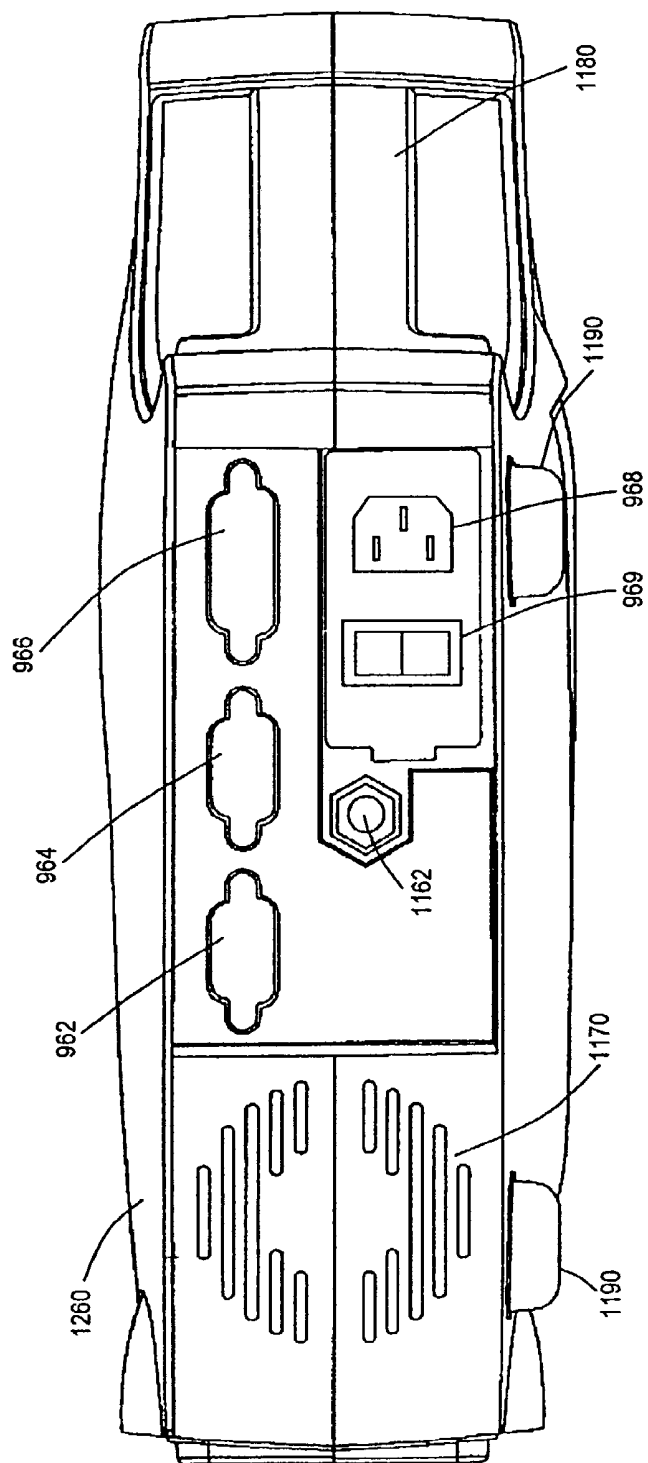FIG. 10

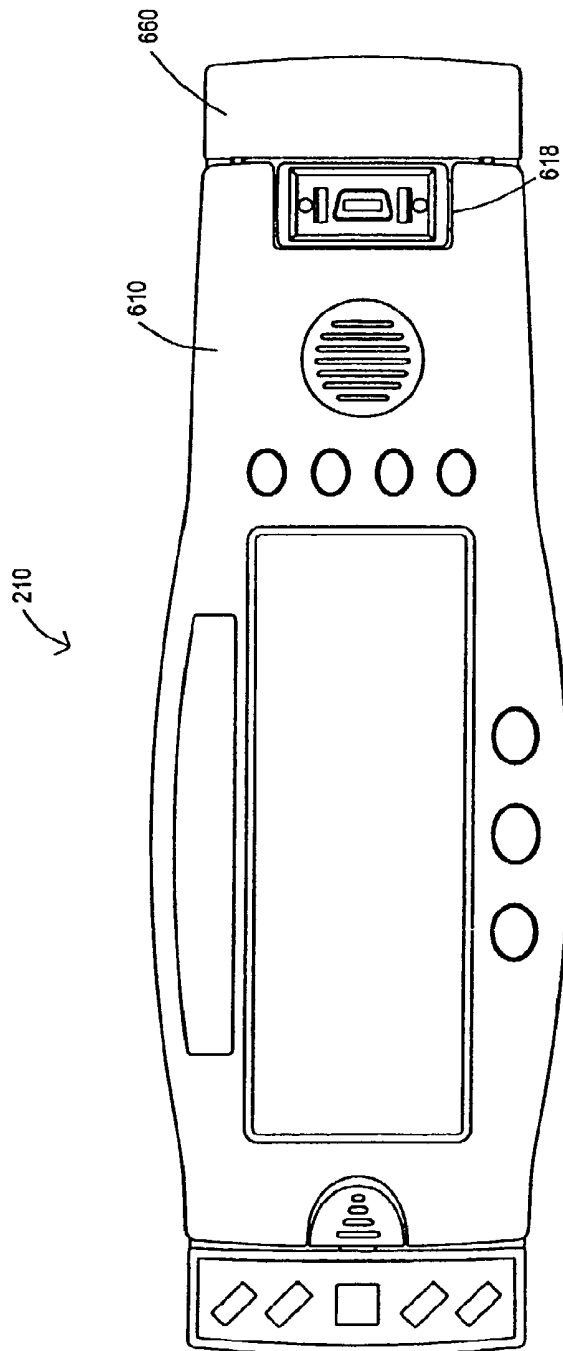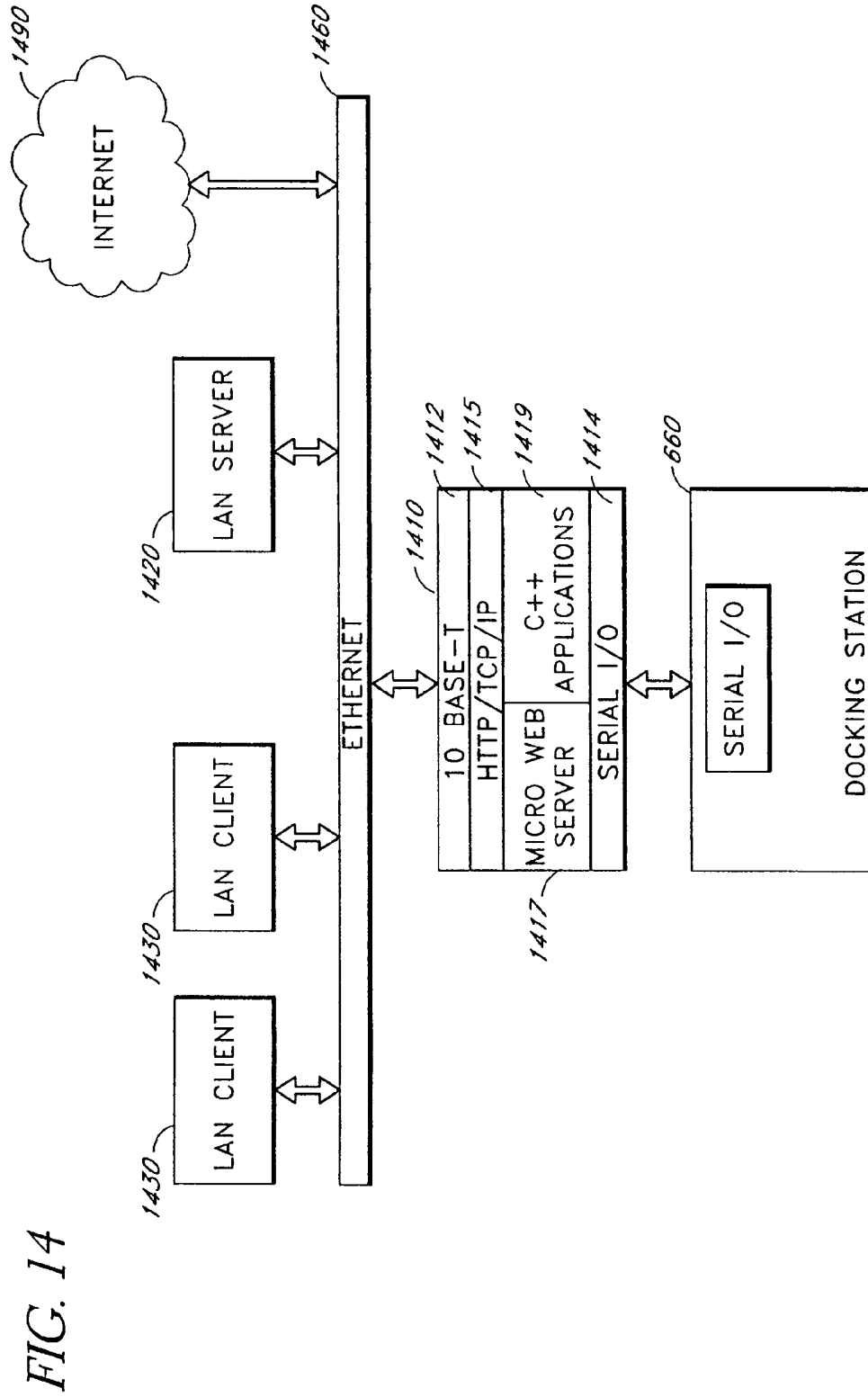FIG. 11A

FIG. 11B

FIG. 12A

FIG. 12B

FIG. 13

FIG. 14

SYSTEMS AND METHODS FOR ACQUIRING CALIBRATION DATA USABLE IN A PULSE OXIMETER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 10/153,263, filed May 21, 2002, entitled "System And Method For Altering A Display Mode Based On A Gravity-Responsive Sensor," which is a continuation of U.S. patent application Ser. No. 09/516,110, filed Mar. 1, 2000, entitled "Universal/Upgrading Pulse Oximeter," now U.S. Pat. No. 6,584,336, which is a continuation of U.S. patent application Ser. No. 09/491,175, filed Jan. 25, 2000, entitled "Universal/Upgrading Pulse Oximeter," now abandoned, and application Ser. No. 09/491,175 claims the benefit of U.S. Provisional Application No. 60/161,565, filed Oct. 26, 1999, entitled "Improved Universal/Upgrading Pulse Oximeter, and Application No. 60/117,097, filed Jan. 25, 1999, entitled "Universal/Upgrading Pulse Oximeter." Each of the foregoing applications is incorporated by reference herein.

BACKGROUND OF THE INVENTION

Oximetry is the measurement of the oxygen level status of blood. Early detection of low blood oxygen level is critical in the medical field, for example in critical care and surgical applications, because an insufficient supply of oxygen can result in brain damage and death in a matter of minutes. Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of oxygen supply. A pulse oximetry system consists of a sensor applied to a patient, a pulse oximeter, and a patient cable connecting the sensor and the pulse oximeter.

The pulse oximeter may be a standalone device or may be incorporated as a module or built-in portion of a multiparameter patient monitoring system, which also provides measurements such as blood pressure, respiratory rate and EKG. A pulse oximeter typically provides a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each pulse. In addition, the pulse oximeter may display the patient's plethysmograph, which provides a visual display of the patient's pulse contour and pulse rate.

SUMMARY OF THE INVENTION

FIG. 1 illustrates a prior art pulse oximeter 100 and associated sensor 110. Conventionally, a pulse oximetry sensor 110 has LED emitters 112, typically one at a red wavelength and one at an infrared wavelength, and a photodiode detector 114. The sensor 110 is typically attached to an adult patient's finger or an infant patient's foot. For a finger, the sensor 110 is configured so that the emitters 112 project light through the fingernail and through the blood vessels and capillaries underneath. The LED emitters 112 are activated by drive signals 122 from the pulse oximeter 100. The detector 114 is positioned at the fingertip opposite the fingernail so as to detect the LED emitted light as it emerges from the finger tissues. The photodiode generated signal 124 is relayed by a cable to the pulse oximeter 100.

The pulse oximeter 100 determines oxygen saturation (SpO_2) by computing the differential absorption by arterial blood of the two wavelengths emitted by the sensor 110. The pulse oximeter 100 contains a sensor interface 120, an SpO_2 processor 130, an instrument manager 140, a display 150, an

audible indicator (tone generator) 160 and a keypad 170. The sensor interface 120 provides LED drive current 122 that alternately activates the sensor red and IR LED emitters 112. The sensor interface 120 also has input circuitry for amplification and filtering of the signal 124 generated by the photodiode detector 114, which corresponds to the red and infrared light energy attenuated from transmission through the patient tissue site. The SpO_2 processor 130 calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The instrument manager 140 provides hardware and software interfaces for managing the display 150, audible indicator 160 and keypad 170. The display 150 shows the computed oxygen status, as described above. The audible indicator 160 provides the pulse beep as well as alarms indicating desaturation events. The keypad 170 provides a user interface for such things as alarm thresholds, alarm enablement, and display options.

Computation of SpO_2 relies on the differential light absorption of oxygenated hemoglobin, HbO_2, and deoxygenated hemoglobin, Hb, to determine their respective concentrations in the arterial blood. Specifically, pulse oximetry measurements are made at red and IR wavelengths chosen such that deoxygenated hemoglobin absorbs more red light than oxygenated hemoglobin, and, conversely, oxygenated hemoglobin absorbs more infrared light than deoxygenated hemoglobin, for example 660 nm (red) and 905 nm (IR).

To distinguish between tissue absorption at the two wavelengths, the red and IR emitters 112 are provided drive current 122 so that only one is emitting light at a given time. For example, the emitters 112 may be cycled on and off alternately, in sequence, with each only active for a quarter cycle and with a quarter cycle separating the active times. This allows for separation of red and infrared signals and removal of ambient light levels by downstream signal processing. Because only a single detector 114 is used, it responds to both the red and infrared emitted light and generates a time-division-multiplexed ("modulated") output signal 124. This modulated signal 124 is coupled to the input of the sensor interface 120.

In addition to the differential absorption of hemoglobin derivatives, pulse oximetry relies on the pulsatile nature of arterial blood to differentiate hemoglobin absorption from absorption of other constituents in the surrounding tissues. Light absorption between systole and diastole varies due to the blood volume change from the inflow and outflow of arterial blood at a peripheral tissue site. This tissue site might also comprise skin, muscle, bone, venous blood, fat, pigment, etc., each of which absorbs light. It is assumed that the background absorption due to these surrounding tissues is invariant and can be ignored. Thus, blood oxygen saturation measurements are based upon a ratio of the time-varying or AC portion of the detected red and infrared signals with respect to the time-invariant or DC portion:

$$RD/IR = (Red_{AC}/Red_{DC})/(IR_{AC}/IR_{DC}).$$

The desired SpO_2 measurement is then computed from this ratio. The relationship between RD/IR and SpO_2 is most accurately determined by statistical regression of experimental measurements obtained from human volunteers and calibrated measurements of oxygen saturation. In a pulse oximeter device, this empirical relationship can be stored as a "calibration curve" in a read-only memory (ROM) look-up table so that SpO_2 can be directly read-out of the memory in response to input RD/IR measurements.

Pulse oximetry is the standard-of-care in various hospital and emergency treatment environments. Demand has lead to

pulse oximeters and sensors produced by a variety of manufacturers. Unfortunately, there is no standard for either performance by, or compatibility between, pulse oximeters or sensors. As a result, sensors made by one manufacturer are unlikely to work with pulse oximeters made by another manufacturer. Further, while conventional pulse oximeters and sensors are incapable of taking measurements on patients with poor peripheral circulation and are partially or fully disabled by motion artifact, advanced pulse oximeters and sensors manufactured by the assignee of the present invention are functional under these conditions. This presents a dilemma to hospitals and other caregivers wishing to upgrade their patient oxygenation monitoring capabilities. They are faced with either replacing all of their conventional pulse oximeters, including multiparameter patient monitoring systems, or working with potentially incompatible sensors and inferior pulse oximeters manufactured by various vendors for the pulse oximetry equipment in use oat the installation.

Hospitals and other caregivers are also plagued by the difficulty of monitoring patients as they are transported from one setting to another. For example, a patient transported by ambulance to a hospital emergency room will likely be unmonitored during the transition from ambulance to the ER and require the removal and replacement of incompatible sensors in the ER. A similar problem is faced within a hospital as a patient is moved between surgery, ICU and recovery settings. Incompatibility and transport problems are exacerbated by the prevalence of expensive and non-portable multiparameter patient monitoring systems having pulse oximetry modules as one measurement parameter.

The Universal/Upgrading Pulse Oximeter (UPO) according to the present invention is focused on solving these performance, incompatibility and transport problems. The UPO provides a transportable pulse oximeter that can stay with and continuously monitor the patient as they are transported from setting to setting. Further, the UPO provides a synthesized output that drives the sensor input of other pulse oximeters. This allows the UPO to function as a universal interface that matches incompatible sensors with other pulse oximeter instruments. Further, the UPO acts as an upgrade to existing pulse oximeters that are adversely affected by low tissue perfusion and motion artifact. Likewise, the UPO can drive a SpO_2 sensor input of multiparameter patient monitoring systems, allowing the UPO to integrate into the associated multiparameter displays, patient record keeping systems and alarm management functions.

One aspect of the present invention is a measurement apparatus comprising a sensor, a first pulse oximeter and a waveform generator. The sensor has at least one emitter and an associated detector configured to attach to a tissue site. The detector provides an intensity signal responsive to the oxygen content of arterial blood at the tissue site. The first pulse oximeter is in communication with the detector and computes an oxygen saturation measurement based on the intensity signal. The waveform generator is in communication with the first pulse oximeter and provides a waveform based on the oxygen saturation measurement. A second pulse oximeter is in communication with the waveform generator and displays an oxygen saturation value based on the waveform. The waveform is synthesized so that the oxygen saturation value is generally equivalent to the oxygen saturation measurement.

In another aspect of the present invention, a measurement apparatus comprises a first sensor port connectable to a sensor, an upgrade port, a signal processor and a waveform generator. The upgrade port is connectable to a second sensor port of a physiological monitoring apparatus. The signal processor is configured to compute a physiological measurement based on a signal input to the first sensor port. The waveform generator produces a waveform based on the physiological measurement, and the waveform is available at the upgrade port. The waveform is adjustable so that the physiological monitoring apparatus displays a value generally equivalent to the physiological measurement when the upgrade port is attached to the second sensor port.

Yet another aspect of the present invention is a measurement method comprising the steps of sensing an intensity signal responsive to the oxygen content of arterial blood at a tissue site and computing an oxygen saturation measurement based on the intensity signal. Other steps are generating a waveform based on the oxygen saturation measurement and providing the waveform to the sensor inputs of a pulse oximeter so that the pulse oximeter displays an oxygen saturation value generally equivalent to the oxygen saturation measurement.

An additional aspect of the present invention is a measurement method comprising the steps of sensing a physiological signal, computing a physiological measurement based upon the signal, and synthesizing a waveform as a function of the physiological measurement. A further step is outputting the waveform to a sensor input of a physiological monitoring apparatus. The synthesizing step is performed so that the measurement apparatus displays a value corresponding to the physiological measurement.

A further aspect of the present invention is a measurement apparatus comprising a first pulse oximeter for making an oxygen saturation measurement and a pulse rate measurement based upon an intensity signal derived from a tissue site. Also included is a waveform generation means for creating a signal based upon the oxygen saturation measurement and the pulse rate measurement. In addition, there is a communication means for transmitting the signal to a second pulse oximeter.

Another aspect of the present invention is a measurement apparatus comprising a portable portion having a sensor port, a processor, a display, and a docking connector. The sensor port is configured to receive an intensity signal responsive to the oxygen content of arterial blood at a tissue site. The processor is programmed to compute an oxygen saturation value based upon the intensity signal and to output the value to the display. A docking station has a portable connector and is configured to accommodate the portable so that the docking connector mates with the portable connector. This provides electrical connectivity between the docking station and the portable. The portable has an undocked position separate from the docking station in which the portable functions as a handheld pulse oximeter. The portable also has a docked position at least partially retained within the docking station in which the combination of the portable and the docking station has at least one additional function compared with the portable in the undocked position.

A further aspect of the present invention is a measurement apparatus configured to function in both a first spatial orientation and a second spatial orientation. The apparatus comprises a sensor port configured to receive a signal responsive to a physiological state. The apparatus also has a tilt sensor providing an output responsive to gravity. In addition, there is a processor in communication with the sensor port and the tilt sensor output. The processor is programmed to compute a physiological measurement value based upon the signal and to determine whether the measurement apparatus is in the first orientation or the second orientation based upon the tilt sensor output. A display has a first mode and a second mode and is driven by the processor. The display shows the measurement value in the first mode when the apparatus is in the first

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orientation and shows the measurement value in the second mode when the apparatus is in the second orientation.

Another aspect of the present invention is a measurement method comprising the steps of sensing a signal responsive to a physiological state and computing physiological measurement based on the signal. Additional steps are determining the spatial orientation of a tilt sensor and displaying the physiological measurement in a mode that is based upon the determining step.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of a prior art pulse oximeter;

FIG. 2 is a diagram illustrating a patient monitoring system incorporating a universal/upgrading pulse oximeter (UPO) according to the present invention;

FIG. 3 is top level block diagram of a UPO embodiment;

FIG. 4 is a detailed block diagram of the waveform generator portion of the UPO embodiment shown in FIG. 3;

FIG. 5 is an illustration of a handheld embodiment of the UPO;

FIG. 6 is a top level block diagram of another UPO embodiment incorporating a portable pulse oximeter and a docking station;

FIG. 7 is a detailed block diagram of the portable pulse oximeter portion of FIG. 6;

FIG. 8A is an illustration of the portable pulse oximeter user interface, including a keyboard and display;

FIGS. 8B-C are illustrations of the portable pulse oximeter display showing portrait and landscape modes, respectively;

FIG. 9 is a detailed block diagram of the docking station portion of FIG. 6;

FIG. 10 is a schematic of the interface cable portion of FIG. 6;

FIG. 11A is a front view of an embodiment of a portable pulse oximeter;

FIG. 11B is a back view of a portable pulse oximeter;

FIG. 12A is a front view of an embodiment of a docking station;

FIG. 12B is a back view of a docking station;

FIG. 13 is a front view of a portable docked to a docking station; and

FIG. 14 is a block diagram of one embodiment of a local area network interface for a docking station.

DETAILED DESCRIPTION

FIG. 2 depicts the use of a Universal/Upgrading Pulse Oximeter ("UPO") 210 to perform patient monitoring. A pulse oximetry sensor 110 is attached to a patient (not illustrated) and provides the UPO 210 with a modulated red and IR photo-plethysmograph signal through a patient cable 220. The UPO 210 computes the patient's oxygen saturation and pulse rate from the sensor signal and, optionally, displays the patient's oxygen status. The UPO 210 may incorporate an internal power source 212, such as common alkaline batteries or a rechargeable power source. The UPO 210 may also utilize an external power source 214, such as standard 110V AC coupled with an external step-down transformer and an internal or external AC-to-DC converter.

In addition to providing pulse oximetry measurements, the UPO 210 also separately generates a signal, which is received by a pulse oximeter 268 external to the UPO 210. This signal is synthesized from the saturation calculated by the UPO 210 such that the external pulse oximeter 268 calculates the equivalent saturation and pulse rate as computed by the UPO 210. The external pulse oximeter 268 receiving the UPO

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signal may be a multiparameter patient monitoring system (MPMS) 260 incorporating a pulse oximeter module 268, a standalone pulse oximeter instrument, or any other host instrument capable of measuring SpO_2. The MPMS 260 depicted in FIG. 2 has a rack 262 containing a number of modules for monitoring such patient parameters as blood pressure, EKG, respiratory gas, and SpO_2. The measurements made by these various modules are shown on a multiparameter display 264, which is typically a video (CRT) device. The UPO 210 is connected to an existing MPMS 260 with a cable 230, advantageously integrating the UPO oxygen status measurements with other MPMS measurements. This allows the UPO calculations to be shown on a unified display of important patient parameters, networked with other patient data, archived within electronic patient records and incorporated into alarm management, which are all MPMS functions convenient to the caregiver.

FIG. 3 depicts the major functions of the UPO 210, including an internal pulse oximeter 310, a waveform generator 320, a power supply 330 and an optional display 340. Attached to the UPO 210 are a sensor 110 and an external pulse oximeter 260. The internal pulse oximeter 310 provides the sensor 110 with a drive signal 312 that alternately activates the sensor's red and IR LEDs, as is well-known in the art. A corresponding detector signal 314 is received by the internal pulse oximeter 310. The internal pulse oximeter 310 computes oxygen saturation, pulse rate, and, in some embodiments, other physiological parameters such as pulse occurrence, plethysmograph features and measurement confidence. These parameters 318 are output to the waveform generator 320. A portion of these parameters may also be used to generate display drive signals 316 so that patient status may be read from, for example, an LED or LCD display module 340 on the UPO.

The internal pulse oximeter 310 may be a conventional pulse oximeter or, for upgrading an external pulse oximeter 260, it may be an advanced pulse oximeter capable of low perfusion and motion artifact performance not found in conventional pulse oximeters. An advanced pulse oximeter for use as an internal pulse oximeter 310 is described in U.S. Pat. No. 5,632,272 assigned to the assignee of the present invention and incorporated herein by reference. An advanced pulse oximetry sensor for use as the sensor 110 attached to the internal pulse oximeter 310 is described in U.S. Pat. No. 5,638,818 assigned to the assignee of the present invention and incorporated herein by reference. Further, a line of advanced Masimo SET® pulse oximeter OEM boards and sensors are available from the assignee of the present invention.

The waveform generator 320 synthesizes a waveform, such as a triangular waveform having a sawtooth or symmetric triangle shape, that is output as a modulated signal 324 in response to an input drive signal 322. The drive input 322 and modulation output 324 of the waveform generator 320 are connected to the sensor port 262 of the external pulse oximeter 260. The synthesized waveform is generated in a manner such that the external pulse oximeter 260 computes and displays a saturation and a pulse rate value that is equivalent to that measured by the internal pulse oximeter 310 and sensor 110. In the present embodiment, the waveforms for pulse oximetry are chosen to indicate to the external pulse oximeter 260 a perfusion level of 5%. The external pulse oximeter 260, therefore, always receives a strong signal. In an alternative embodiment, the perfusion level of the waveforms synthesized for the external pulse oximeter can be set to indicate a perfusion level at or close to the perfusion level of the patient being monitored by the internal pulse oximeter 310. As an

alternative to the generated waveform, a digital data output **326**, is connected to the data port **264** of the external pulse oximeter **260**. In this manner, saturation and pulse rate measurements and also samples of the unmodulated, synthesized waveform can be communicated directly to the external pulse oximeter **260** for display, bypassing the external pulse oximeter's signal processing functions. The measured plethysmograph waveform samples output from the internal pulse oximeter **310** also may be communicated through the digital data output **326** to the external pulse oximeter **260**.

It will be understood from the above discussion that the synthesized waveform is not physiological data from the patient being monitored by the internal pulse oximeter **310**, but is a waveform synthesized from predetermined stored waveform data to cause the external pulse oximeter **260** to calculate oxygen saturation and pulse rate equivalent to or generally equivalent (within clinical significance) to that calculated by the internal pulse oximeter **310**. The actual physiological waveform from the patient received by the detector is not provided to the external pulse oximeter **260** in the present embodiment. Indeed, the waveform provided to the external pulse oximeter will usually not resemble the plethysmographic waveform of physiological data from the patient being monitored by the internal pulse oximeter **260**.

The cable **230** (FIG. 2) attached between the waveform generator **320** and external pulse oximeter **260** provides a monitor ID **328** to the UPO, allowing identification of predetermined external pulse oximeter calibration curves. For example, this cable may incorporate an encoding device, such as a resistor, or a memory device, such as a PROM **1010** (FIG. 10) that is read by the waveform generator **320**. The encoding device provides a value that uniquely identifies a particular type of external pulse oximeter **260** having known calibration curve, LED drive and modulation signal characteristics. Although the calibration curves of the external pulse oximeter **260** are taken into account, the wavelengths of the actual sensor **110**, advantageously, are not required to correspond to the particular calibration curve indicated by the monitor ID **328** or otherwise assumed for the external pulse oximeter **260**. That is, the wavelength of the sensor **110** attached to the internal pulse oximeter **310** is not relevant or known to the external pulse oximeter **260**.

FIG. **4** illustrates one embodiment of the waveform generator portion **320** of the UPO **210** (FIG. 3). Although this embodiment is illustrated and described as hardware, one of ordinary skill will recognize that the functions of the waveform generator may be implemented in software or firmware or a combination of hardware, software and firmware. The waveform generator **320** performs waveform synthesis with a waveform look-up table ("LUT") **410**, a waveform shaper **420** and a waveform splitter **430**. The waveform LUT **410** is advantageously a memory device, such as a ROM (read only memory) that contains samples of one or more waveform portions or segments containing a single waveform. These stored waveform segments may be as simple as a single period of a triangular waveform, having a sawtooth or symmetric triangle shape, or more complicated, such as a simulated plethysmographic pulse having various physiological features, for example rise time, fall time and dicrotic notch.

The waveform shaper **420** creates a continuous pulsed waveform from the waveform segments provided by the waveform LUT **410**. The waveform shaper **420** has a shape parameter input **422** and an event indicator input **424** that are buffered **470** from the parameters **318** output from the internal pulse oximeter **310** (FIG. 3). The shape parameter input **422** determines a particular waveform segment in the waveform LUT **410**. The chosen waveform segment is specified by

the first address transmitted to the waveform LUT **410** on the address lines **426**. The selected waveform segment is sent to the waveform shaper **420** as a series of samples on the waveform data lines **412**.

The event indicator input **424** specifies the occurrence of pulses in the plethysmograph waveform processed by the internal pulse oximeter **310** (FIG. 3). For example, the event indicator may be a delta time from the occurrence of a previously detected falling pulse edge or this indicator could be a real time or near real time indicator of the pulse occurrence. The waveform shaper **420** accesses the waveform LUT **410** in a manner to create a corresponding delta time between pulses in the synthesized waveform output **428**. In one embodiment, the waveform shaper is clocked at a predetermined sample rate. From a known number of samples per stored waveform segment and the input delta time from the event indicator, the waveform shaper **420** determines the number of sequential addresses to skip between samples and accesses the waveform LUT **410** accordingly. This effectively "stretches" or "shrinks" the retrieved waveform segment so as to fit in the time between two consecutive pulses detected by the UPO.

The waveform splitter **430** creates a first waveform **432** corresponding to a first waveform (such a red wavelength) expected by the external pulse oximeter **260** (FIG. 3) and a second waveform (such as infrared) **434** expected by the external pulse oximeter **260**. The relative amplitudes of the first waveform **432** and second waveform **434** are adjusted to correspond to the ratio output **444** from a calibration curve LUT **440**. Thus, for every value of measured oxygen saturation at the sat input **442**, the calibration curve LUT **440** provides a corresponding ratio output **444** that results in the first waveform **432** and the second waveform **434** having an amplitude ratio that will be computed by the external pulse oximeter **260** (FIG. 3) as equivalent to the oxygen saturation measured by the internal pulse oximeter **310** (FIG. 3).

As described above, one particularly advantageous aspect of the UPO is that the operating wavelengths of the sensor **110** (FIG. 3) are not relevant to the operating wavelengths required by the external pulse oximeter **260** (FIG. 3), i.e. the operating wavelengths that correspond to the calibration curve or curves utilized by the external pulse oximeter. The calibration curve LUT **440** simply permits generation of a synthesized waveform as expected by the external oximeter **260** (FIG. 3) based on the calibration curve used by the external pulse oximeter **260** (FIG. 3). The calibration curve LUT **440** contains data about the known calibration curve of the external pulse oximeter **260** (FIG. 3), as specified by the monitor ID input **328**. In other words, the waveform actually synthesized is not a patient plethysmographic waveform. It is merely a stored waveform that will cause the external pulse oximeter to calculate the proper oxygen saturation valve and pulse rate values. Although this does not provide a patient plethysmograph on the external pulse oximeter for the clinician, the calculated values, which is what is actually sought, will be accurate.

A modulator **450** responds to an LED drive input **322** to generate a modulated waveform output **324** derived from the first waveform **432** and second waveform **434**. Also, a data communication interface **460** transmits as a digital data output **326** the data obtained from the sat **442**, pulse rate **462** and synthesized waveform **428** inputs.

FIG. **5** depicts a handheld UPO **500** embodiment. The handheld UPO **500** has keypad inputs **510**, an LCD display **520**, an external power supply input **530**, an output port **540** for connection to an external pulse oximeter and a sensor input **550** at the top edge (not visible). The display **520** shows the measured oxygen saturation **522**, the measured pulse rate

524, a pulsating bar **526** synchronized with pulse rate or pulse events, and a confidence bar **528** indicating confidence in the measured values of saturation and pulse rate. Also shown are low battery **572** and alarm enabled **574** status indicators.

The handheld embodiment described in connection with FIG. **5** may also advantageously function in conjunction with a docking station that mechanically accepts, and electrically connects to, the handheld unit. The docking station may be co-located with a patient monitoring system and connected to a corresponding SpO₂ module sensor port, external power supply, printer and telemetry device, to name a few options. In this configuration, the handheld UPO may be removed from a first docking station at one location to accompany and continuously monitor a patient during transport to a second location. The handheld UPO can then be conveniently placed into a second docking station upon arrival at the second location, where the UPO measurements are displayed on the patient monitoring system at that location.

FIG. **6** shows a block diagram of a UPO embodiment, where the functions of the UPO **210** are split between a portable pulse oximeter **610** and a docking station **660**. The portable pulse oximeter **610** ("portable") is a battery operated, fully functional, stand-alone pulse oximeter instrument. The portable **610** connects to a sensor **110** (FIG. **2**) through a UPO patient cable **220** (FIG. **2**) attached to a patient cable connector **618**. The portable **610** provides the sensor **110** with a drive signal **612** that alternately activates the sensor's red and IR LEDs, as is well-known in the art. The portable also receives a corresponding detector signal **614** from the sensor. The portable can also input a sensor ID on the drive signal line **612**, as described in U.S. Pat. No. 5,758,644 entitled Manual and Automatic Probe Calibration, assigned to the assignee of the present invention and incorporated herein by reference.

The portable **610** can be installed into the docking station **660** to expand its functionality. When installed, the portable **610** can receive power **662** from the docking station **660** if the docking station **660** is connected to external power **668**. Alternately, with no external power **668** to the docking station **660**, the portable **610** can supply power **662** to the docking station **660**. The portable **610** communicates to the docking station with a bidirectional serial data line **664**. In particular, the portable **610** provides the docking station with SpO₂, pulse rate and related parameters computed from the sensor detector signal **614**. When the portable **610** is installed, the docking station **660** may drive a host instrument **260** (FIG. **2**) external to the portable **610**. Alternatively, the portable **610** and docking station **660** combination may function as a standalone pulse oximeter instrument, as described below with respect to FIG. **13**.

In one embodiment, the docking station **660** does not perform any action when the portable **610** is not docked. The user interface for the docking station **660**, i.e. keypad and display, is on the portable **610**. An indicator LED on the docking station **660** is lit when the portable is docked. The docking station **660** generates a detector signal output **674** to the host instrument **260** (FIG. **2**) in response to LED drive signals **672** from the host instrument and SpO₂ values and related parameters received from the portable **610**. The docking station **660** also provides a serial data output **682**, a nurse call **684** and an analog output **688**.

An interface cable **690** connects the docking station **660** to the host instrument patient cable **230** (FIG. **2**). The LED drive signals **672** and detector signal output **674** are communicated between the docking station **660** and the host instrument **260** (FIG. **2**) via the interface cable **690**. The interface cable **690** provides a sync data output **692** to the docking station **660**, communicating sensor, host instrument (e.g. monitor ID **328**,

FIG. **3**) and calibration curve data. Advantageously, this data allows the docking station **660** to appear to a particular host instrument as a particular sensor providing patient measurements.

FIG. **7** provides further detail of the portable **610**. The portable components include a pulse oximeter processor **710**, a management processor **720**, a power supply **730**, a display **740** and a keypad **750**. The pulse oximeter processor **710** functions as an internal pulse oximeter, interfacing the portable to a sensor **110** (FIG. **2**) and deriving SpO₂, pulse rate, a plethysmograph and a pulse indicator. An advanced pulse oximeter for use as the pulse oximeter processor **710** is described in U.S. Pat. No. 5,632,272, referenced above. An advanced pulse oximetry sensor for use as the sensor **110** (FIG. **2**) attached to the pulse oximeter processor **710** is described in U.S. Pat. No. 5,638,818, also referenced above. Further, a line of advanced Masimo SET® pulse oximeter OEM boards and sensors are available from the assignee of the present invention. In one embodiment, the pulse oximeter processor **710** is the Masimo SET® MS-3L board or a low power MS-5 board.

The management processor **720** controls the various functions of the portable **610**, including asynchronous serial data communications **724** with the pulse oximeter processor **710** and synchronous serial communications **762** with the docking station **660** (FIG. **6**). The physical and electrical connection to the docking station **660** (FIG. **6**) is via a docking station connector **763** and the docking station interface **760**, respectively. The processor **720** utilizes a real-time clock **702** to keep the current date and time, which includes time and date information that is stored along with SpO₂ parameters to create trend data. The processor of the portable **610** and the docking station **660** (FIG. **6**) can be from the same family to share common routines and minimize code development time.

The processor **720** also controls the user interface **800** (FIG. **8**A) by transferring data **742** to the display **740**, including display updates and visual alarms, and by interpreting keystroke data **752** from the keypad **750**. The processor **720** generates various alarm signals, when required, via an enable signal **728**, which controls a speaker driver **770**. The speaker driver **770** actuates a speaker **772**, which provides audible indications such as, for example, alarms and pulse beeps. The processor **720** also monitors system status, which includes battery status **736**, indicating battery levels, and docked status **764**, indicating whether the portable **610** is connected to the docking station **660** (FIG. **6**). When the portable **610** is docked and is on, the processor **720** also decides when to turn on or off docking station power **732**.

Advantageously, the caregiver can set (i.e. configure or program) the behavior of the portable display **740** and alarms when the docked portable **610** senses that an interface cable **690** has connected the docking station **660** to an external pulse oximeter, such as a multiparameter patient monitoring system. In one user setting, for example, the portable display **740** stops showing the SpO₂ **811** (FIG. **8**) and pulse rate **813** (FIG. **8**) values when connected to an external pulse oximeter to avoid confusing the caregiver, who can read equivalent values on the patient monitoring system. The display **740**, however, continues to show the plethysmograph **815** (FIG. **8**) and visual pulse indicator **817** (FIG. **8**) waveforms. For one such user setting, the portable alarms remain active.

Another task of the processor **720** includes maintenance of a watchdog function. The watchdog **780** monitors processor status on the watchdog data input **782** and asserts the μP reset

output **784** if a fault is detected. This resets the management processor **720**, and the fault is indicated with audible and visual alarms.

The portable **610** gets its power from batteries in the power supply **730** or from power **766** supplied from the docking station **660** (FIG. **6**) via the docking station interface **760**. A power manager **790** monitors the on/off switch on the keypad **750** and turns-on the portable power accordingly. The power manager **790** turns off the portable on command by the processor **720**. DC/DC converters within the power supply **730** generate the required voltages **738** for operation of the portable **610** and docking station power **732**. The portable batteries can be either alkaline rechargeable batteries or another renewable power source. The batteries of the power supply **730** supply docking station power **732** when the docking station **660** (FIG. **6**) is without external power. A battery charger within the docking station power supply provides charging current **768** to rechargeable batteries within the power supply **730**. The docking station power supply **990** (FIG. **9**) monitors temperature **734** from a thermistor in the rechargeable battery pack, providing an indication of battery charge status.

A non-volatile memory **706** is connected to the management processor **720** via a high-speed bus **722**. In the present embodiment, the memory **706** is an erasable and field reprogrammable device used to store boot data, manufacturing serial numbers, diagnostic failure history, adult SpO_2 and pulse rate alarm limits, neonate SpO_2 and pulse rate alarm limits, SpO_2 and pulse rate trend data, and program data. Other types of non-volatile memory are well known. The SPO_2 and pulse rate alarm limits, as well as SpO_2 related algorithm parameters, may be automatically selected based on the type of sensor **110** (FIG. **2**), adult or neonate, connected to the portable **610**.

The LCD display **740** employs LEDs for a backlight to increase its contrast ratio and viewing distance when in a dark environment. The intensity of the backlight is determined by the power source for the portable **610**. When the portable **610** is powered by either a battery pack within its power supply **730** or a battery pack in the docking station power supply **990** (FIG. **9**), the backlight intensity is at a minimum level. When the portable **610** is powered by external power **668** (FIG. **6**), the backlight is at a higher intensity to increase viewing distance and angle. In one embodiment, button on the portable permits overriding these intensity settings, and provides adjustment of the intensity. The backlight is controlled in two ways. Whenever any key is pressed, the backlight is illuminated for a fixed number of seconds and then turns off, except when the portable is docked and derives power from an external source. In that case, the backlight is normally on unless deactivated with a key on the portable **610**.

FIG. **8A** illustrates the portable user interface **800**, which includes a display **740** and a keypad **750**. In one embodiment, the display **740** is a dot matrix LCD device having 160 pixels by 480 pixels. The display **740** can be shown in portrait mode, illustrated in FIG. **8B**, or in landscape mode, illustrated in FIG. **8C**. A tilt sensor **950** (FIG. **9**) in the docking station **660** (FIG. **6**) or a display mode key on the portable **610** (FIG. **6**) determines portrait or landscape mode. The tilt sensor **950** (FIG. **9**) can be a gravity-activated switch or other device responsive to orientation and can be alternatively located in the portable **610** (FIG. **6**). In a particular embodiment, the tilt sensor **950** (FIG. **9**) is a non-mercury tilt switch, part number CW 1300-1, available from Comus International, Nutley, N.J. (www.comus-intl.com). The tilt sensor **950** (FIG. **9**) could also be a mercury tilt switch.

Examples of how the display area can be used to display SpO_2 **811**, pulse rate **813**, a plethysmographic waveform **815**, a visual pulse indicator **817** and soft key icons **820** in portrait and landscape mode are shown in FIGS. **8B** and **8C**, respectively. The software program of the management processor **720** (FIG. **7**) can be easily changed to modify the category, layout and size of the display information shown in FIGS. **8B-C**. Other advantageous information for display is SpO_2 limits, alarm, alarm disabled, exception messages and battery status.

The keypad **750** includes soft keys **870** and fixed keys **880**. The fixed keys **880** each have a fixed function. The soft keys **870** each have a function that is programmable and indicated by one of the soft key icons **820** located next to the soft keys **870**. That is, a particular one of the soft key icons **820** is in proximity to a particular one of the soft keys **870** and has a text or a shape that suggests the function of that particular one of the soft keys **870**. In one embodiment, the button portion of each key of the keypad **750** is constructed of florescent material so that the keys **870**, **880** are readily visible in the dark.

In one embodiment, the keypad **750** has one row of four soft keys **870** and one row of three fixed keys **880**. Other configurations are, of course, available, and specific arrangement is not significant. The functions of the three fixed keys **880** are power, alarm silence and light/contrast. The power function is an on/off toggle button. The alarm silence function and the light/contrast function have dual purposes depending on the duration of the key press. A momentary press of the key corresponding to the alarm silence function will disable the audible alarm for a fixed period of time. To disable the audible alarm indefinitely, the key corresponding to the alarm silence function is held down for a specified length of time. If the key corresponding to the alarm silence function is pressed while the audible alarm has been silenced, the audible alarm is reactivated. If the key corresponding to the light/contrast function is pressed momentarily, it is an on/off toggle button for the backlight. If the key corresponding to the light/contrast function is held down, the display contrast cycles through its possible values.

In this embodiment, the default functions of the four soft keys **870** are pulse beep up volume, pulse beep down volume, menu select, and display mode. These functions are indicated on the display by the up arrow, down arrow, "menu" and curved arrow soft key icons **820**, respectively. The up volume and down volume functions increase or decrease the audible sound or "beep" associated with each detected pulse. The display mode function rotates the display **740** through all four orthogonal orientations, including portrait mode (FIG. **8B**) and landscape mode (FIG. **8C**), with each press of the corresponding key. The menu select function allows the functionality of the soft keys **870** to change from the default functions described above. Examples of additional soft key functions that can be selected using this menu feature are set SpO_2 high/low limit, set pulse rate high/low limit, set alarm volume levels, set display to show trend data, print trend data, erase trend data, set averaging time, set sensitivity mode, perform synchronization, perform rechargeable battery maintenance (deep discharge/recharge to remove battery memory), and display product version number.

FIG. **9** provides further details of the docking station **660**, which includes a docking station processor **910**, a non-volatile memory **920**, a waveform generator **930**, a PROM interface **940**, a tilt sensor **950**, a portable interface **970** and associated connector **972**, status indicators **982**, a serial data port **682**, a nurse call output **684**, an analog output **688** and a power supply **990**. In one embodiment, the docking station **660** is intended to be associated with a fixed (non-transportable)

host instrument, such as a multiparameter patient monitoring instrument in a hospital emergency room. In a transportable embodiment, the docking station **660** is movable, and includes a battery pack within the power supply **990**.

The docking station processor **910** orchestrates the activity on the docking station **660**. The processor **910** provides the waveform generator **930** with parameters **932** as discussed above for FIGS. **3** and **4**. The processor **910** also provides asynchronous serial data **912** for communications with external devices and synchronous serial data **971** for communications with the portable **610** (FIG. **6**). In addition, the processor **910** determines system status including sync status **942**, tilt status **952** and power status **992**. The portable management processor **720** (FIG. **7**) performs the watchdog function for the docking station processor **910**. The docking station processor **910** sends watchdog messages to the portable processor **720** (FIG. **7**) as part of the synchronous serial data **972** to ensure the correct operation of the docking station processor **910**.

The docking station processor **910** accesses non-volatile memory **920** over a high-speed bus **922**. The non-volatile memory **920** is re-programmable and contains program data for the processor **910** including instrument communication protocols, synchronization information, a boot image, manufacturing history and diagnostic failure history.

The waveform generator **930** generates a synthesized waveform that a conventional pulse oximeter can process to calculate SpO_2 and pulse rate values or exception messages, as described above with respect to FIG. **4**. However, in the present embodiment, as explained above, the waveform generator output does not reflect a physiological waveform. It is merely a waveform constructed to cause the external pulse oximeter to calculate the correct saturation and pulse rate. In an alternative embodiment, physiological data could be provided to the external pulse oximeter, but the external pulse oximeter would generally not be able to calculate the proper saturation values, and the upgrading feature would be lost. The waveform generator **930** is enabled if an interface cable **690** (FIG. **6**), described below with respect to FIG. **10**, with valid synchronization information is connected. Otherwise, the power to the waveform generator **930** is disabled.

The status indicators **982** are a set of LEDs on the front of the docking station **660** used to indicate various conditions including external power (AC), portable docked, portable battery charging, docking station battery charging and alarm. The serial data port **682** is used to interface with either a computer, a serial port of conventional pulse oximeters or serial printers via a standard RS-232 DB-9 connector **962**. This port **682** can output trend memory, SpO_2 and pulse rate and support the system protocols of various manufacturers. The analog output **688** is used to interface with analog input chart recorders via a connector **964** and can output "real-time" or trend SpO_2 and pulse rate data. The nurse call output **684** from a connector **964** is activated when alarm limits are exceeded for a predetermined number of consecutive seconds. In another embodiment, data, including alarms, could be routed to any number of communications ports, and even over the Internet, to permit remote use of the upgrading pulse oximeter.

The PROM interface **940** accesses synchronization data **692** from the PROM **1010** (FIG. **10**) in the interface cable **690** (FIGS. **6, 10**) and provides synchronization status **942** to the docking station processor **910**. The portable interface **970** provides the interconnection to the portable **610** (FIG. **6**) through the docking station interface **760** (FIG. **7**).

As shown in FIG. **9**, external power **668** is provided to the docking station **660** through a standard AC connector **968** and

on/off switch **969**. When the docking station **660** has external power **668**, the power supply **990** charges the battery in the portable power supply **730** (FIG. **7**) and the battery, if any, in the docking station power supply **990**. When the portable **610** (FIG. **6**) is either removed or turned off, the docking station power **973** is removed and the docking station **660** is turned off, except for the battery charger portion of the power supply **990**. The docking station power **973** and, hence, the docking station **660** turn on whenever a docked portable **610** (FIG. **6**) is turned on. The portable **610** (FIG. **6**) supplies power for an embodiment of the docking station **660** without a battery when external power **668** is removed or fails.

FIG. **10** provides further detail regarding the interface cable **690** used to connect between the docking station **660** (FIG. **6**) and the patient cable **230** (FIG. **2**) of a host instrument **260** (FIG. **2**). The interface cable **690** is configured to interface to a specific host instrument and to appear to the host instrument as a specific sensor. A PROM **1010** built into the interface cable **690** contains information identifying a sensor type, a specific host instrument, and the calibration curve of the specific host instrument. The PROM information can be read by the docking station **660** (FIG. **6**) as synchronization data **692**. Advantageously, the synchronization data **692** allows the docking station **660** (FIG. **6**) to generate a waveform to the host instrument that causes the host instrument to display SpO_2 values equivalent to those calculated by the portable **610** (FIG. **6**). The interface cable **690** includes an LED drive path **672**. In the embodiment shown in FIG. **10**, the LED drive path **672** is configured for common anode LEDs and includes IR cathode, red cathode and common anode signals. The interface cable **690** also includes a detector drive path **674**, including detector anode and detector cathode signals.

A menu option on the portable **610** (FIG. **6**) also allows synchronization information to be calculated in the field. With manual synchronization, the docking station **660** (FIG. **6**) generates a waveform to the host instrument **260** (FIG. **2**) and displays an expected SpO_2 value. The user enters the SPO_2 value displayed on the host instrument using the portable keypad **750** (FIG. **7**). These steps are repeated until a predetermined number of data points are entered and the SpO_2 values displayed by the portable and the host instrument are consistent.

FIGS. **11**A-B depict an embodiment of the portable **610**, as described above with respect to FIG. **6**. FIGS. **12**A-B depict an embodiment of the docking station **660**, as described above with respect to FIG. **6**. FIG. **13** depicts an embodiment of the UPO **210** where the portable **610** is docked with the docking station **660**, also as described above with respect to FIG. **6**.

FIG. **11**A depicts the portable front panel **1110**. The portable **610** has a patient cable connector **618**, as described above with respect to FIG. **6**. Advantageously, the connector **618** is rotatably mounted so as to minimize stress on an attached patient cable (not shown). In one embodiment, the connector **618** can freely swivel between a plane parallel to the front panel **1110** and a plane parallel to the side panel **1130**. In another embodiment, the connector **618** can swivel between, and be releasably retained in, three locked positions. A first locked position is as shown, where the connector is in a plane parallel to the front panel **1110**. A second locked position is where the connector **618** is in a plane parallel to the side panel **1130**. The connector **618** also has an intermediate locked position 45° between the first and the second locked positions. The connector **618** is placed in the first locked position for attachment to the docking station **660**.

Shown in FIG. 11A, the portable front panel **1110** also has a speaker **772**, as described with respect to FIG. **7**. Further, the front panel **1110** has a row of soft keys **870** and fixed keys **880**, as described above with respect to FIG. **8**. In addition, the front panel **1110** has a finger actuated latch **1120** that locks onto a corresponding catch **1244** (FIG. **12A**) in the docking station **660**, allowing the portable **610** to be releasably retained by the docking station **660**. An OEM label can be affixed to a recessed area **1112** on the front panel **1110**.

FIG. **11B** depicts the portable back panel **1140**. The back panel **1140** has a socket **763**, a pole clamp mating surface **1160**, and a battery pack compartment **1170**. The socket **763** is configured to mate with a corresponding docking station plug **972** (FIG. **12A**). The socket **763** and plug **972** (FIG. **12A**) provide the electrical connection interface between the portable **610** and the docking station **660** (FIG. **12A**). The socket **763** houses multiple spring contacts that compress against plated edge-connector portions of the docking station plug **972** (FIG. **12A**). A conventional pole clamp (not shown) may be removably attached to the mating surface **1160**. This conveniently allows the portable **610** to be held to various patient-side or bedside mounts for hands-free pulse oximetry monitoring. The portable power supply **730** (FIG. **7**) is contained within the battery pack compartment **1170**. The compartment **1170** has a removable cover **1172** for protection, insertion and removal of the portable battery pack. Product labels, such as a serial number identifying a particular portable, can be affixed with the back panel indent **1142**.

FIG. **12A** depicts the front side **1210** of the docking station **660**. The front side **1210** has a docking compartment **1220**, a pole clamp recess **1230**, pivots **1242**, a catch **1244**, a plug connector **972** and LED status indicators **982**. The docking compartment **1220** accepts and retains the portable **610** (FIGS. **11A-B**), as shown in FIG. **13**. When the portable **610** (FIGS. **11A-B**) is docked in the compartment **1220**, the pole clamp recess **1230** accommodates a pole clamp (not shown) attached to the portable's pole clamp mating surface **1160** (FIG. **11B**), assuming the pole clamp is in its closed position. The portable **610** (FIGS. **11A-B**) is retained in the compartment **1220** by pivots **1242** that fit into corresponding holes in the portable's side face **1130** and a catch **1244** that engages the portable's latch **1120** (FIG. **11A**). Thus, the portable **610** (FIGS. **11A-B**) is docked by first attaching it at one end to the pivots **1242**, then rotating it about the pivots **1242** into the compartment **1220**, where it is latched in place on the catch **1244**. The portable **610** (FIGS. **11A-B**) is undocked in reverse order, by first pressing the latch **1120** (FIG. **11A**), which releases the portable from the catch **1244**, rotating the portable **610** (FIGS. **11A-B**) about the pivots **1242** out of the compartment **1220** and then removing it from the pivots **1242**. As the portable is rotated into the compartment, the docking station plug **972** inserts into the portable socket **763** (FIG. **11B**), providing the electrical interface between the portable **610** and the docking station **660**. The status indicators **982** are as described above with respect to FIG. **9**.

FIG. **12B** depicts the back side **1260** of the docking station **660**. The back side **1260** has a serial (RS-232 or USB) connector **962**, an analog output and nurse call connector **964**, an upgrade port connector **966**, an AC power plug **968**, an on/off switch **969** and a ground lug **1162**. A handle **1180** is provided at one end and fan vents **1170** are provided at the opposite end. A pair of feet **1190** are visible near the back side **1260**. A corresponding pair of feet (not visible) are located near the front side **1210** (FIG. **12A**). The feet near the front side **1210** extend so as to tilt the front side **1210** (FIG. **12A**) upward, making the display **740** (FIG. **13**) of a docked portable **610** (FIG. **13**) easier to read.

FIG. **13** illustrates both the portable **610** and the docking station **660**. The portable **610** and docking station **660** constitute three distinct pulse oximetry instruments. First, the portable **610** by itself, as depicted in FIGS. **11A-B**, is a handheld pulse oximeter applicable to various patient monitoring tasks requiring battery power or significant mobility, such as ambulance and ER situations. Second, the portable **610** docked in the docking station **660**, as depicted in FIG. **13**, is a standalone pulse oximeter applicable to a wide-range of typical patient monitoring situations from hospital room to the operating room. Third, the portable **610** docked and the upgrade port **966** (FIG. **12B**) connected with an interface cable to the sensor port of a conventional pulse oximeter module **268** (FIG. **2**) within a multiparameter patient monitoring instrument **260** (FIG. **2**) or other conventional pulse oximeter, is a universal/upgrading pulse oximeter (UPO) instrument **210**, as described herein. Thus, the portable **610** and docking station **660** configuration of the UPO **210** advantageously provides a three-in-one pulse oximetry instrument functionality.

Another embodiment of the docking station **660** incorporates an input port that connects to a blood pressure sensor and an output port that connects to the blood pressure sensor port of a multiparameter patient monitoring system (MPMS). The docking station **660** incorporates a signal processor that computes a blood pressure measurement based upon an input from the blood pressure sensor. The docking station **660** also incorporates a waveform generator connected to the output port that produces a synthesized waveform based upon the computed measurement. The waveform generator output is adjustable so that the blood pressure value displayed on the MPMS is equivalent to the computed blood pressure measurement. Further, when the portable **610** is docked in the docking station **660** and the blood pressure sensor is connected to the input port, the portable displays a blood pressure value according to the computed blood pressure measurement. Thus, in this embodiment, the docking station **660** provides universal/upgrading capability for both blood pressure and SpO$_2$.

Likewise, the docking station **660** can function as an universal/upgrading instrument for other vital sign measurements, such as respiratory rate, EKG or EEG. For this embodiment, the docking station **660** incorporates related sensor connectors and associated sensor signal processors and upgrade connectors to an MPMS or standalone instrument. In this manner, a variety of vital sign measurements can be incorporated into the docking station **660**, either individually or in combination, with or without SpO$_2$ as a measurement parameter, and with or without the portable **610**. In yet another embodiment, the docking station **660** can be configured as a simple SpO$_2$ upgrade box, incorporating a SpO$_2$ processor and patient cable connector for a SpO$_2$ sensor that functions with or without the portable **610**.

Unlike a conventional standalone pulse oximeter, the standalone configuration shown in FIG. **13** has a rotatable display **740** that allows the instrument to be operated in either a vertical or horizontal orientation. A tilt sensor **950** (FIG. **9**) indicates when the bottom face **1310** is placed along a horizontal surface or is otherwise horizontally-oriented. In this horizontal orientation, the display **740** appears in landscape mode (FIG. **8C**). The tilt sensor **950** (FIG. **9**) also indicates when the side face **1320** is placed along a horizontal surface or is otherwise horizontally oriented. In this vertical orientation, the display **740** appears in portrait mode (FIG. **8B**). A soft key **870** on the portable **610** can override the tilt sensor, allowing the display to be presented at any **900** orientation, i.e. portrait, landscape, "upside-down" portrait or "upside-

down" landscape orientations. The handheld configuration (FIG. 11A), can also present the display 740 at any 900 orientation using a soft key 870. In the particular embodiment described above, however, the portable 610 does not have a tilt sensor and, hence, relies on a soft key 870 to change the orientation of the display when not docked.

FIG. 14 illustrates the docking station 660 incorporated within a local area network (LAN). The LAN shown is Ethernet-based 1460, using a central LAN server 1420 to interconnect various LAN clients 1430 and other system resources such as printers and storage (not shown). An Ethernet controller module 1410 is incorporated with the docking station 660. The controller module 1410 can be incorporated within the docking station 660 housing or constructed as an external unit. In this manner, the UPO, according to the present invention, can communicate with other devices on the LAN or over the Internet 1490.

The Ethernet controller module 1410 can be embedded with web server firmware, such as the Hewlett-Packard (HP) BFOOT-10501. The module 1410 has both a 10 Base-T Ethernet interface for connection to the Ethernet 1460 and a serial interface, such as RS-232 or USB, for connection to the docking station 660. The module firmware incorporates HTTP and TCP/IP protocols for standard communications over the World Wide Web. The firmware also incorporates a micro web server that allows custom web pages to be served to remote clients over the Internet, for example. Custom C++ programming allows expanded capabilities such as data reduction, event detection and dynamic web page configuration.

As shown in FIG. 14, there are many applications for the docking station 660 to Ethernet interface. Multiple UPOs can be connected to a hospital's LAN, and a computer on the LAN could be utilized to upload pulse rate and saturation data from the various UPOs, displaying the results. Thus, this Ethernet interface could be used to implement a central pulse oximetry monitoring station within a hospital. Further, multiple UPOs from anywhere in the world can be monitored from a central location via the Internet. Each UPO is addressable as an individual web site and downloads web pages viewable on a standard browser, the web pages displaying oxygen saturation, pulse rate and related physiological measurements from the UPO. This feature allows a caregiver to monitor a patient regardless of where the patient or caregiver is located. For example a caregiver located at home in one city or at a particular hospital could download measurements from a patient located at home in a different city or at the same or a different hospital. Other applications include troubleshooting newly installed UPOs or uploading software patches or upgrades to UPOs via the Internet. In addition alarms could be forwarded to the URL of the clinician monitoring the patient.

The UPO may have other configurations besides the handheld unit described in connection with FIG. 5 or the portable 610 and docking station 660 combination described in connection with FIGS. 11-13. The UPO may be a module, with or without a display, that can be removably fastened to a patient via an arm strap, necklace or similar means. In a smaller embodiment, this UPO module may be integrated into a cable or connector used for attaching a sensor to a pulse oximeter. The UPO may also be a circuit card or module that can externally or internally plug into or mate with a standalone pulse oximeter or multiparameter patient monitoring system. Alternatively, the UPO may be configured as a simple standalone upgrade instrument.

Further, although a universal/upgrading apparatus and method have been mainly described in terms of a pulse oximetry measurement embodiment, the present invention is

equally applicable to other physiological measurement parameters such as blood pressure, respiration rate, EEG and ECG, to name a few. In addition, a universal/upgrading instrument having a single physiological measurement parameter or a multiple measurement parameter capability and configured as a handheld, standalone, portable, docking station, module, plug-in, circuit card, to name a few, is also within the scope of the present invention.

The UPO has been disclosed in detail in connection with various embodiments of the present invention. These embodiments are disclosed by way of examples only and are not to limit the scope of the present invention, which is defined by the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications within the scope of this invention.

What is claimed is:

1. A portable physiological measurement device configured to communicate with a docking station, the portable physiological measurement device comprising:

a first local display;

a handheld housing configured to physically and electrically mate with a docking station in communication with a second local display, the housing including a releasable coupling means configured to allow the handheld housing to be released and removed from said docking station using a single hand, wherein the coupling means is configured to be released using a single finger of the single hand while removing the handheld housing;

a patient cable connection port on the handheld housing, the port connected with a cable in communication with a sensor in contact with a patient when the handheld housing is in use;

a processor included in said housing capable of operating in a portable mode, said portable mode providing portable monitoring as a standalone patient monitor of one or more physiological parameters of a patient through communication with one or more noninvasive sensors, and capable of operating in a docked mode, said docked mode providing monitoring of one or more physiological parameters of a patient; and

an output configured to communicate with the docking station.

2. The patient monitoring system of claim 1, wherein the output is configured to communicate with a management processor of the docking station.

3. The patient monitoring system of claim 1, wherein the one or more physiological parameters comprises one or more of blood oxygen content, respiratory gas, blood pressure, ECG, and pulse rate.

4. A portable physiological measurement device configured to communicate with a docking station, the portable physiological measurement device comprising:

a first local display;

a handheld portable housing configured to physically and electrically mate with a docking station in communication with a second local display, the housing including a releasable coupling configured to allow the handheld portable housing to be released and removed from said docking station using a single hand, the releasable coupling configured to be released using a single finger of the single hand while removing the handheld housing;

a patient cable connection port on the handheld housing, the port connected with a cable in communication with a sensor in contact with a patient when the handheld housing is in use;

a processor included in said housing capable of operating in a portable mode, said portable mode providing por-

table monitoring as a fully functioning standalone patient monitor of one or more physiological parameters of a patient through communication with one or more noninvasive sensors, and capable of operating in a docked mode, said docked mode providing monitoring of one or more physiological parameters of a patient; and

an output configured to communicate with the docking station.

5. The patient monitoring system of claim **4**, wherein the output is configured to communicate with a management processor of the docking station.

6. The patient monitoring system of claim **4**, wherein the one or more physiological parameters comprises one or more of blood oxygen content, respiratory gas, blood pressure, ECG, and pulse rate.

7. The patient monitoring system of claim **4**, wherein the handheld portable housing is configured to be released by pressing a latch configured to secure at least one side of the handheld portable housing.

8. The patient monitoring system of claim **7**, wherein a second side of the handheld portable housing is secured to the docking station using pivots.

9. The patient monitoring system of claim **1**, wherein the handheld portable housing is configured to be released by pressing a latch configured to secure at least one side of the handheld portable housing.

10. The patient monitoring system of claim **9**, wherein a second side of the handheld portable housing is secured to the docking station using pivots.

*　*　*　*　*

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO.   : 9,375,185 B2
APPLICATION NO.   : 11/894721
DATED   : June 28, 2016
INVENTOR(S)   : Ammar Al-Ali

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

On the Title Page

Page 1 (item (75), Inventors) at Line 5, Change "Irvine, CA" for Julian M. Goldman to
--Newton, MA--.

In Column 1 (page 4, item (56)) at Lines 57-58 (approx.), Under Other Publication, Below "778-781."
delete "M.1. Fikhman, "Problems in Cardiomonitoring System Design, Biomedical Engineering", vol.
29, No. 4, 199, 180-182.".

In Column 2 (page 4, item (56)) at Lines 60-61 (approx.), Under Other Publications, Below "21
pages." delete "NELLCOR PB N-200 Pulse Oximeter (NPN-200), in 4 pages.".

In the Drawings

Sheet 6 of 16 (Referral Numeral 614, FIG. 6) at Line 1, Change "DECTECTOR" to --DETECTOR--.

Sheet 6 of 16 (Referral Numeral 692, FIG. 6) at Line 1, Change "SVNC" to --SYNC--.

Sheet 7 of 16 (Referral Numeral 724, FIG. 7) at Line 1, Change "ASVNC." to --ASYNC.--.

Sheet 7 of 16 (Referral Numeral 762, FIG. 7) at Line 1, Change "ASVNC." to --ASYNC.--.
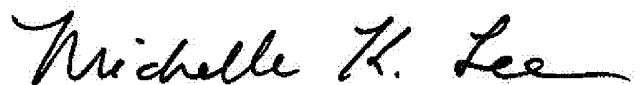
Sheet 9 of 16 (Referral Numeral 912, FIG. 9) at Line 1, Change "ASVNC" to --ASYNC--.

Sheet 9 of 16 (Referral Numeral 672, FIG. 9) at Line 2, Change "DECTECTOR" to --DETECTOR--.

Sheet 9 of 16 (Referral Numeral 942, FIG. 9) at Line 1, Change "SVNC" to --SYNC--.

Sheet 9 of 16 (Referral Numeral 692, FIG. 9) at Line 1, Change "SVNC" to --SYNC--.

Signed and Sealed this
Twenty-eighth Day of March, 2017

Michelle K. Lee
Director of the United States Patent and Trademark Office

Sheet 9 of 16 (Referral Numeral 971, FIG. 9) at Line 1, Change "SVNC." to --SYNC.--.

Sheet 10 of 16 (FIG. 10) at Line 1, Change "DECTECTOR" to --DETECTOR--.

Sheet 10 of 16 (FIG. 10) at Line 2, Change "DECTECTOR" to --DETECTOR--.

In the Specification

In Column 16 at Line 66, Change "900" to --90°--.

In Column 17 at Line 2, Change "900" to --90°--.

专利名称(译)	用于获取可在脉搏血氧计中使用的校准数据的系统和方法		
公开(公告)号	US9375185	公开(公告)日	2016-06-28
申请号	US11/894721	申请日	2007-08-20
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CPC分类号	A61B5/7278 A61B5/0002 A61B5/0205 A61B5/0402 A61B5/1495 A61B5/14551 A61B5/742 A61B5/743 A61B2560/0271 A61B2560/0456 A61B2562/085		
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外部链接	

摘要(译)

本公开包括便携式生理监测器，其包括第一本地显示器并且被配置为与
包括第二显示器的第二生理监测器通信。