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(54) **ADHERENT CARDIAC MONITOR WITH ADVANCED SENSING CAPABILITIES**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

834,261 A 10/1906 Chambers
2,087,124 A 7/1937 Smith et al.
(Continued)

FOREIGN PATENT DOCUMENTS

AU 2003-220574 A8 10/2003
EP 1487535 12/2004
(Continued)

OTHER PUBLICATIONS

Extended European Search Report for corresponding EP Application No. 08830769.9 mailed on Jun. 18, 2014.
(Continued)

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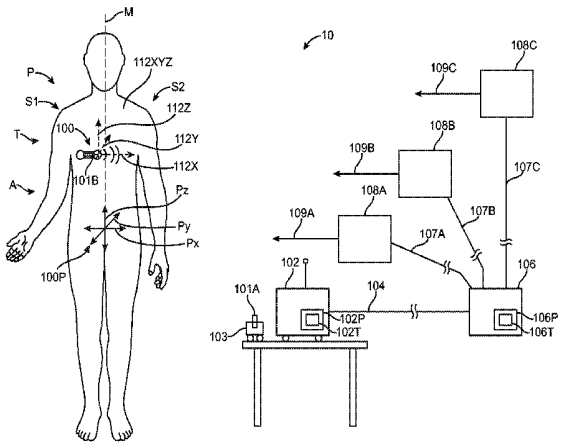
(57) **ABSTRACT**

An adherent device comprises an adhesive patch with at least two electrodes and an accelerometer. The accelerometer can be used to determine an orientation of the at least two measurement electrodes on a patient. By determining the orientation of the electrodes of the patch on the patient, physiologic measurements with the at least two electrodes can be adjusted and/or corrected in response to the orientation of the patch on the patient. The adherent patch and/or electrodes can be replaced with a second adherent patch and/or electrodes, and the orientation of the second adherent patch and/or electrodes can be determined with the accelerometer or a second accelerometer. The determined orientation of the second patch and/or electrodes on the patient can be used to correct measurements made with the second adherent patch and/or electrodes.

25 Claims, 14 Drawing Sheets



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(56) **References Cited**

U.S. PATENT DOCUMENTS

2,184,511	A	12/1939	Bagno et al.
3,170,459	A	2/1965	Phipps et al.
3,232,291	A	2/1966	Parker
3,370,459	A	2/1968	Cescati
3,517,999	A	6/1970	Weaver
3,620,216	A	11/1971	Szymanski
3,677,260	A	7/1972	Funfstuck et al.
3,805,769	A	4/1974	Sessions
3,845,757	A	11/1974	Weyer
3,874,368	A	4/1975	Asrican
3,882,853	A	5/1975	Gofman et al.
3,942,517	A	3/1976	Bowles et al.
3,972,329	A	8/1976	Kaufman
4,008,712	A	2/1977	Nyboer
4,024,312	A	5/1977	Korpman
4,077,406	A	3/1978	Sandhage et al.
4,121,573	A	10/1978	Crovella et al.
4,141,366	A	2/1979	Cross, Jr. et al.
RE30,101	E	9/1979	Kubicek et al.
4,185,621	A	1/1980	Morrow
4,216,462	A	8/1980	McGrath et al.
4,300,575	A	11/1981	Wilson
4,308,872	A	1/1982	Watson et al.
4,358,678	A	11/1982	Lawrence
4,409,983	A	10/1983	Albert
4,450,527	A	5/1984	Sramek
4,451,254	A	5/1984	Dinius et al.
4,478,223	A	10/1984	Allor
4,498,479	A	2/1985	Martio et al.
4,522,211	A	6/1985	Bare et al.
4,661,103	A	4/1987	Harman
4,664,129	A	5/1987	Helzel et al.
4,669,480	A	6/1987	Hoffman
4,673,387	A	6/1987	Phillips et al.
4,681,118	A	7/1987	Asai et al.
4,692,685	A	9/1987	Blaze
4,699,146	A	10/1987	Sieverding
4,721,110	A	1/1988	Lampadius
4,730,611	A	3/1988	Lamb
4,733,107	A	3/1988	O'Shaughnessy et al.
4,781,200	A	11/1988	Baker
4,793,362	A	12/1988	Tedner
4,838,273	A	6/1989	Cartmell
4,838,279	A	6/1989	Fore
4,850,370	A	7/1989	Dower
4,880,004	A	11/1989	Baker, Jr. et al.
4,895,163	A	1/1990	Libke et al.
4,911,175	A	3/1990	Shizgal
4,945,916	A	8/1990	Kretschmer et al.
4,955,381	A	9/1990	Way et al.
4,966,158	A	10/1990	Honma et al.
4,981,139	A	1/1991	Pfohl
4,988,335	A	1/1991	Prindle et al.
4,989,612	A	2/1991	Fore
5,001,632	A	3/1991	Hall-Tipping
5,012,810	A	5/1991	Strand et al.
5,025,791	A	6/1991	Niwa
5,027,824	A	7/1991	Dougherty et al.
5,050,612	A	9/1991	Matsumura
5,063,937	A	11/1991	Ezenwa et al.
5,080,099	A	1/1992	Way et al.
5,083,563	A	1/1992	Collins
5,086,781	A	2/1992	Bookspan
5,113,869	A	5/1992	Nappholz et al.
5,125,412	A	6/1992	Thornton
5,133,355	A	7/1992	Strand et al.
5,140,985	A	8/1992	Schroeder et al.
5,150,708	A	9/1992	Brooks
5,168,874	A	12/1992	Segalowitz
5,226,417	A	7/1993	Swedlow et al.
5,241,300	A	8/1993	Buschmann
5,257,627	A	11/1993	Rapoport
5,271,411	A	12/1993	Ripley et al.
5,273,532	A	12/1993	Niezink et al.
5,282,840	A	2/1994	Hudrlik
5,291,013	A	3/1994	Nafarrate et al.
5,297,556	A	3/1994	Shankar
5,301,677	A	4/1994	Hsung
5,319,363	A	6/1994	Welch et al.
5,331,966	A	7/1994	Bennett et al.
5,335,664	A	8/1994	Nagashima
5,343,869	A	9/1994	Pross et al.
5,353,793	A	10/1994	Bornn
5,362,069	A	11/1994	Hall-Tipping
5,375,604	A	12/1994	Kelly et al.
5,411,530	A	5/1995	Akhtar
5,437,285	A	8/1995	Verrier et al.
5,443,073	A	8/1995	Wang et al.
5,449,000	A	9/1995	Libke et al.
5,450,845	A	9/1995	Axelgaard
5,454,377	A	10/1995	Dzwonczyk et al.
5,464,012	A	11/1995	Falcone
5,469,859	A	11/1995	Tsoglin et al.
5,482,036	A	1/1996	Diab et al.
5,496,361	A	3/1996	Moberg et al.
5,503,157	A	4/1996	Sramek
5,511,548	A	4/1996	Riazzi et al.
5,511,553	A	4/1996	Segalowitz
5,518,001	A	5/1996	Snell
5,523,742	A	6/1996	Simkins et al.
5,529,072	A	6/1996	Sramek
5,544,661	A	8/1996	Davis et al.
5,558,638	A	9/1996	Evers et al.
5,560,368	A	10/1996	Berger
5,564,429	A	10/1996	Bornn et al.
5,564,434	A	10/1996	Halperin et al.
5,566,671	A	10/1996	Lyons
5,575,284	A	11/1996	Athan et al.
5,607,454	A	3/1997	Cameron et al.
5,632,272	A	5/1997	Diab et al.
5,634,468	A	6/1997	Platt et al.
5,642,734	A	7/1997	Ruben et al.
5,673,704	A	10/1997	Marchlinski et al.
5,678,562	A	10/1997	Sellers
5,687,717	A	11/1997	Halpern et al.
5,710,376	A	1/1998	Weber, Jr.
5,718,234	A	2/1998	Warden et al.
5,724,025	A	3/1998	Tavori
5,738,107	A	4/1998	Martinsen et al.
5,748,103	A	5/1998	Flach et al.
5,767,791	A	6/1998	Stoop et al.
5,769,793	A	6/1998	Pincus et al.
5,772,508	A	6/1998	Sugita et al.
5,772,586	A	6/1998	Heinonen et al.
5,778,882	A	7/1998	Raymond et al.
5,788,643	A	8/1998	Feldman

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,788,682 A 8/1998 Maget
5,803,915 A 9/1998 Kremenchugsky et al.
5,807,272 A 9/1998 Kun
5,814,079 A 9/1998 Kieval et al.
5,817,035 A 10/1998 Sullivan
5,833,603 A 11/1998 Kovacs et al.
5,836,990 A 11/1998 Li
5,855,614 A 1/1999 Stevens et al.
5,860,860 A 1/1999 Clayman
5,862,802 A 1/1999 Bird
5,862,803 A 1/1999 Besson et al.
5,865,733 A 2/1999 Malinouskas et al.
5,876,353 A 3/1999 Riff
5,904,708 A 5/1999 Goedeke
5,935,079 A 8/1999 Swanson et al.
5,941,831 A 8/1999 Turcott
5,944,659 A 8/1999 Flach et al.
5,949,636 A 9/1999 Johnson et al.
5,957,854 A 9/1999 Besson et al.
5,957,861 A 9/1999 Combs et al.
5,964,703 A 10/1999 Goodman et al.
5,970,986 A 10/1999 Bolz et al.
5,984,102 A 11/1999 Tay
5,987,352 A 11/1999 Klein et al.
6,007,532 A 12/1999 Netherly
6,027,523 A 2/2000 Schmieding
6,045,513 A 4/2000 Stone et al.
6,047,203 A 4/2000 Sackner et al.
6,047,259 A 4/2000 Campbell et al.
6,049,730 A 4/2000 Kristbjarnarson
6,050,267 A 4/2000 Nardella et al.
6,050,951 A 4/2000 Friedman et al.
6,052,615 A 4/2000 Feild et al.
6,067,467 A 5/2000 John
6,080,106 A 6/2000 Lloyd et al.
6,081,735 A 6/2000 Diab et al.
6,095,991 A 8/2000 Krausman et al.
6,102,856 A 8/2000 Groff et al.
6,104,949 A 8/2000 Pitts Crick et al.
6,112,224 A 8/2000 Peifer et al.
6,117,077 A 9/2000 Del Mar et al.
6,125,297 A 9/2000 Siconolfi
6,129,744 A 10/2000 Boute
6,141,575 A 10/2000 Price
6,144,878 A 11/2000 Schroeppel et al.
6,164,284 A 12/2000 Schulman et al.
6,181,963 B1 1/2001 Chin et al.
6,185,452 B1 2/2001 Schulman et al.
6,190,313 B1 2/2001 Hinkle
6,190,324 B1 2/2001 Kieval et al.
6,198,394 B1 3/2001 Jacobsen et al.
6,198,955 B1 3/2001 Axelgaard et al.
6,208,894 B1 3/2001 Schulman et al.
6,212,427 B1 4/2001 Hoover
6,213,942 B1 4/2001 Flach et al.
6,225,901 B1 5/2001 Kail, IV
6,245,021 B1 6/2001 Stampfer
6,259,939 B1 7/2001 Rogel
6,267,730 B1 7/2001 Pacunas
6,272,377 B1 8/2001 Sweeney et al.
6,277,078 B1 8/2001 Porat et al.
6,287,252 B1 9/2001 Lugo
6,289,238 B1 9/2001 Besson et al.
6,290,646 B1 9/2001 Cosentino et al.
6,295,466 B1 9/2001 Ishikawa et al.
6,305,943 B1 10/2001 Pougatchev et al.
6,306,088 B1 10/2001 Krausman et al.
6,308,094 B1 10/2001 Shusterman et al.
6,312,378 B1 11/2001 Bardy
6,315,721 B2 11/2001 Schulman et al.
6,327,487 B1 12/2001 Stratbucker
6,330,464 B1 12/2001 Colvin et al.
6,336,903 B1 1/2002 Bardy
6,339,722 B1 1/2002 Heethaar et al.
6,343,140 B1 1/2002 Brooks
6,347,245 B1 2/2002 Lee et al.
6,358,208 B1 3/2002 Lang et al.
6,385,473 B1 5/2002 Haines et al.
6,398,727 B1 6/2002 Bui et al.
6,400,982 B2 6/2002 Sweeney et al.
6,409,674 B1 6/2002 Brockway et al.
6,411,853 B1 6/2002 Millot et al.
6,416,471 B1 7/2002 Kumar et al.
6,440,069 B1 8/2002 Raymond et al.
6,442,422 B1 8/2002 Duckert
6,450,820 B1 9/2002 Palsson et al.
6,450,953 B1 9/2002 Place et al.
6,453,186 B1 9/2002 Lovejoy et al.
6,454,707 B1 9/2002 Casscells, III et al.
6,454,708 B1 9/2002 Ferguson et al.
6,459,930 B1 10/2002 Takehara et al.
6,463,328 B1 10/2002 John
6,473,640 B1 10/2002 Erlebacher
6,480,733 B1 11/2002 Turcott
6,480,734 B1 11/2002 Zhang et al.
6,485,461 B1 11/2002 Mason et al.
6,490,478 B1 12/2002 Zhang et al.
6,491,647 B1 12/2002 Bridger et al.
6,494,829 B1 12/2002 New, Jr. et al.
6,496,715 B1 12/2002 Lee et al.
6,512,949 B1 1/2003 Combs et al.
6,520,967 B1 2/2003 Cauthen
6,527,711 B1 3/2003 Stivoric et al.
6,527,729 B1 3/2003 Turcott
6,528,960 B1 3/2003 Roden et al.
6,544,173 B2 4/2003 West et al.
6,544,174 B2 4/2003 West et al.
6,551,251 B2 4/2003 Zuckerwar et al.
6,551,252 B2 4/2003 Sackner et al.
6,569,160 B1 5/2003 Goldin et al.
6,572,557 B2 6/2003 Tchou et al.
6,572,636 B1 6/2003 Hagen et al.
6,577,139 B2 6/2003 Cooper
6,577,893 B1 6/2003 Besson et al.
6,577,897 B1 6/2003 Shurubura et al.
6,579,231 B1 6/2003 Phipps
6,580,942 B1 6/2003 Willshire
6,584,343 B1 6/2003 Ransbury et al.
6,587,715 B2 7/2003 Singer
6,589,170 B1 7/2003 Flach et al.
6,595,927 B2 7/2003 Pitts-Crick et al.
6,595,929 B2 7/2003 Stivoric et al.
6,600,949 B1 7/2003 Turcott
6,602,201 B1 8/2003 Hepp et al.
6,605,038 B1 8/2003 Teller et al.
6,611,705 B2 8/2003 Hopman et al.
6,611,783 B2 * 8/2003 Kelly, Jr. A61B 5/0002 340/573.1
6,616,606 B1 9/2003 Petersen et al.
6,622,042 B1 9/2003 Thacker
6,636,754 B1 10/2003 Baura et al.
6,641,542 B2 11/2003 Cho et al.
6,645,153 B2 11/2003 Kroll et al.
6,649,829 B2 11/2003 Garber et al.
6,650,917 B2 11/2003 Diab et al.
6,658,300 B2 12/2003 Govari et al.
6,659,947 B1 12/2003 Carter et al.
6,659,949 B1 12/2003 Lang et al.
6,687,540 B2 2/2004 Marcovecchio
6,697,658 B2 2/2004 Al-Ali
RE38,476 E 3/2004 Diab et al.
6,699,200 B2 3/2004 Cao et al.
6,701,271 B2 3/2004 Willner et al.
6,714,813 B2 3/2004 Ishigooka et al.
RE38,492 E 4/2004 Diab et al.
6,721,594 B2 4/2004 Conley et al.
6,728,572 B2 4/2004 Hsu et al.
6,748,269 B2 6/2004 Thompson et al.
6,749,566 B2 6/2004 Russ
6,751,498 B1 6/2004 Greenberg et al.
6,760,617 B2 7/2004 Ward et al.
6,773,396 B2 8/2004 Flach et al.
6,775,566 B2 8/2004 Nissila
6,790,178 B1 9/2004 Mault et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,795,722 B2 9/2004 Sheraton et al.
6,814,706 B2 11/2004 Barton et al.
6,816,744 B2 11/2004 Garfield et al.
6,819,956 B2 11/2004 DiLorenzo
6,821,249 B2 11/2004 Casscells, III et al.
6,824,515 B2 11/2004 Suorsa et al.
6,827,690 B2 12/2004 Bardy
6,829,503 B2 12/2004 Alt
6,858,006 B2 2/2005 MacCarter et al.
6,871,211 B2 3/2005 Labounty et al.
6,878,121 B2 4/2005 Krausman et al.
6,879,850 B2 4/2005 Kimball
6,881,191 B2 * 4/2005 Oakley A61B 5/0006 600/391
6,887,201 B2 5/2005 Bardy
6,890,096 B2 5/2005 Tokita et al.
6,893,396 B2 5/2005 Schulze et al.
6,894,204 B2 5/2005 Dunshee
6,906,530 B2 6/2005 Geisel
6,912,414 B2 6/2005 Tong
6,936,006 B2 8/2005 Sabra
6,940,403 B2 9/2005 Kail, IV
6,942,622 B1 9/2005 Turcott
6,952,695 B1 10/2005 Trinks et al.
6,970,742 B2 11/2005 Mann et al.
6,972,683 B2 12/2005 Lestienne et al.
6,978,177 B1 12/2005 Chen et al.
6,980,851 B2 12/2005 Zhu et al.
6,980,852 B2 12/2005 Jersey-Willuhn et al.
6,985,078 B2 1/2006 Suzuki et al.
6,987,965 B2 1/2006 Ng et al.
6,988,989 B2 1/2006 Weiner et al.
6,993,378 B2 1/2006 Wiederhold et al.
6,997,879 B1 2/2006 Turcott
7,003,346 B2 2/2006 Singer
7,009,362 B2 3/2006 Tsukamoto et al.
7,010,340 B2 3/2006 Scarantino et al.
7,018,338 B2 3/2006 Vetter et al.
7,020,508 B2 3/2006 Stivoric et al.
7,027,862 B2 4/2006 Dahl et al.
7,041,062 B2 5/2006 Friedrichs et al.
7,044,911 B2 5/2006 Drinan et al.
7,047,067 B2 5/2006 Gray et al.
7,050,846 B2 5/2006 Sweeney et al.
7,054,679 B2 5/2006 Hirsh
7,059,767 B2 6/2006 Tokita et al.
7,088,242 B2 8/2006 Aupperle et al.
7,113,826 B2 9/2006 Henry et al.
7,118,531 B2 10/2006 Krill
7,127,370 B2 10/2006 Kelly, Jr. et al.
7,129,836 B2 10/2006 Lawson et al.
7,130,396 B2 10/2006 Rogers et al.
7,130,679 B2 10/2006 Parsonnet et al.
7,133,716 B2 11/2006 Kraemer et al.
7,136,697 B2 11/2006 Singer
7,136,703 B1 11/2006 Cappa et al.
7,142,907 B2 11/2006 Xue et al.
7,149,574 B2 12/2006 Yun et al.
7,149,773 B2 12/2006 Haller et al.
7,153,262 B2 12/2006 Stivoric et al.
7,156,807 B2 1/2007 Carter et al.
7,156,808 B2 1/2007 Quy
7,160,252 B2 1/2007 Cho et al.
7,160,253 B2 1/2007 Nissila
7,166,063 B2 1/2007 Rahman et al.
7,167,743 B2 1/2007 Heruth et al.
7,184,821 B2 2/2007 Belalcazar et al.
7,191,000 B2 3/2007 Zhu et al.
7,194,306 B1 3/2007 Turcott
7,206,630 B1 4/2007 Tarler
7,209,787 B2 4/2007 DiLorenzo
7,212,849 B2 5/2007 Zhang et al.
7,215,984 B2 5/2007 Diab et al.
7,215,991 B2 5/2007 Besson et al.
7,231,254 B2 6/2007 DiLorenzo
7,238,159 B2 7/2007 Banet et al.
7,248,916 B2 7/2007 Bardy
7,251,524 B1 7/2007 Hepp et al.
7,257,438 B2 8/2007 Kinast
7,261,690 B2 8/2007 Teller et al.
7,277,741 B2 10/2007 Debreczeny et al.
7,284,904 B2 10/2007 Tokita et al.
7,285,090 B2 10/2007 Stivoric et al.
7,294,105 B1 11/2007 Islam
7,295,879 B2 11/2007 Denker et al.
7,297,119 B2 11/2007 Westbrook et al.
7,318,808 B2 1/2008 Tarassenko et al.
7,319,386 B2 1/2008 Collins, Jr. et al.
7,324,851 B1 1/2008 DiLorenzo
7,336,187 B2 2/2008 Hubbard, Jr. et al.
7,346,380 B2 3/2008 Axelgaard et al.
7,382,247 B2 6/2008 Welch et al.
7,384,398 B2 6/2008 Gagnadre et al.
7,390,299 B2 6/2008 Weiner et al.
7,395,106 B2 7/2008 Ryu et al.
7,423,526 B2 9/2008 Despotis
7,423,537 B2 9/2008 Bonnet et al.
7,443,302 B2 10/2008 Reeder et al.
7,450,024 B2 11/2008 Wildman et al.
7,468,032 B2 12/2008 Stahmann et al.
7,510,699 B2 3/2009 Black et al.
7,660,632 B2 2/2010 Kirby et al.
7,701,227 B2 4/2010 Saulnier et al.
7,813,778 B2 10/2010 Benaron et al.
7,881,763 B2 2/2011 Brauker et al.
7,942,824 B1 5/2011 Kayyali et al.
8,249,686 B2 8/2012 Libbus et al.
8,285,356 B2 10/2012 Bly et al.
8,795,174 B2 * 8/2014 Manicka A61B 5/4875 600/301
9,101,285 B2 * 8/2015 Markowitz A61B 5/0422
9,113,807 B2 * 8/2015 Koyrakh A61B 5/053
9,345,414 B1 * 5/2016 Bardy A61B 5/04017
9,364,155 B2 * 6/2016 Bardy A61B 5/02055
2001/0047127 A1 11/2001 New, Jr. et al.
2002/0004640 A1 1/2002 Conn et al.
2002/0019586 A1 2/2002 Teller et al.
2002/0019588 A1 2/2002 Marro et al.
2002/0022786 A1 2/2002 Takehara et al.
2002/0028989 A1 3/2002 Pelletier et al.
2002/0032581 A1 3/2002 Reitberg
2002/0045836 A1 4/2002 Alkawwas
2002/0088465 A1 7/2002 Hill
2002/0099277 A1 7/2002 Harry et al.
2002/0116009 A1 8/2002 Fraser et al.
2002/0123672 A1 9/2002 Christophersom et al.
2002/0123674 A1 9/2002 Plicchi et al.
2002/0138017 A1 9/2002 Bui et al.
2002/0167389 A1 11/2002 Uchikoba et al.
2002/0182485 A1 12/2002 Anderson et al.
2003/0009092 A1 1/2003 Parker
2003/0023184 A1 1/2003 Pitts-Crick et al.
2003/0028221 A1 2/2003 Zhu et al.
2003/0028327 A1 2/2003 Brunner et al.
2003/0045922 A1 3/2003 Northrop
2003/0051144 A1 3/2003 Williams
2003/0055460 A1 3/2003 Owen et al.
2003/0083581 A1 5/2003 Taha et al.
2003/0085717 A1 5/2003 Cooper
2003/0087244 A1 5/2003 McCarthy
2003/0092975 A1 5/2003 Casscells, III et al.
2003/0093125 A1 5/2003 Zhu et al.
2003/0093298 A1 5/2003 Hernandez et al.
2003/0100367 A1 5/2003 Cooke
2003/0105411 A1 6/2003 Smallwood et al.
2003/0135127 A1 7/2003 Sackner et al.
2003/0143544 A1 7/2003 McCarthy
2003/0149349 A1 8/2003 Jensen
2003/0181815 A1 9/2003 Ebner et al.
2003/0187370 A1 10/2003 Kodama
2003/0191503 A1 10/2003 Zhu et al.
2003/0212319 A1 11/2003 Magill
2003/0221687 A1 12/2003 Kaigler
2003/0233129 A1 12/2003 Matos

(56) **References Cited**

U.S. PATENT DOCUMENTS

2004/0006279 A1 1/2004 Arad (Abboud)
2004/0010303 A1 1/2004 Bolea et al.
2004/0014422 A1 1/2004 Kallio
2004/0015058 A1 1/2004 Besson et al.
2004/0019292 A1 1/2004 Drinan et al.
2004/0044293 A1 3/2004 Burton
2004/0049132 A1 3/2004 Barron et al.
2004/0064133 A1 4/2004 Miller et al.
2004/0073094 A1 4/2004 Baker
2004/0073126 A1 4/2004 Rowlandson
2004/0077954 A1* 4/2004 Oakley A61B 5/0006 600/483
2004/0100376 A1 5/2004 Lye et al.
2004/0102683 A1 5/2004 Khanuja et al.
2004/0106951 A1 6/2004 Edman et al.
2004/0122489 A1 6/2004 Mazar et al.
2004/0127790 A1 7/2004 Lang et al.
2004/0133079 A1 7/2004 Mazar et al.
2004/0133081 A1 7/2004 Teller et al.
2004/0134496 A1 7/2004 Cho et al.
2004/0143170 A1 7/2004 DuRousseau
2004/0147969 A1 7/2004 Mann et al.
2004/0152956 A1 8/2004 Korman
2004/0158132 A1 8/2004 Zaleski
2004/0167389 A1 8/2004 Brabrand
2004/0172080 A1 9/2004 Stadler et al.
2004/0199056 A1 10/2004 Husemann et al.
2004/0215240 A1 10/2004 Lovett et al.
2004/0215247 A1 10/2004 Bolz
2004/0220639 A1 11/2004 Mulligan et al.
2004/0225199 A1 11/2004 Evanyk et al.
2004/0225203 A1 11/2004 Jemison et al.
2004/0243018 A1 12/2004 Organ et al.
2004/0267142 A1 12/2004 Paul
2005/0004506 A1 1/2005 Gyory
2005/0015094 A1 1/2005 Keller
2005/0015095 A1 1/2005 Keller
2005/0020935 A1 1/2005 Helzel et al.
2005/0027175 A1 2/2005 Yang
2005/0027204 A1 2/2005 Kligfield et al.
2005/0027207 A1 2/2005 Westbrook et al.
2005/0027918 A1 2/2005 Govindarajulu et al.
2005/0043675 A1 2/2005 Pastore et al.
2005/0054944 A1 3/2005 Nakada et al.
2005/0059867 A1 3/2005 Chung
2005/0065445 A1 3/2005 Arzbaecher et al.
2005/0065571 A1 3/2005 Imran
2005/0070768 A1 3/2005 Zhu et al.
2005/0070778 A1 3/2005 Lackey et al.
2005/0080346 A1 4/2005 Gianchandani et al.
2005/0080460 A1 4/2005 Wang et al.
2005/0080463 A1 4/2005 Stahmann et al.
2005/0085734 A1 4/2005 Tehrani
2005/0091338 A1 4/2005 de la Huerga
2005/0096513 A1 5/2005 Ozguz et al.
2005/0113703 A1 5/2005 Farringdon et al.
2005/0124878 A1 6/2005 Sharony
2005/0124901 A1 6/2005 Misczynski et al.
2005/0124908 A1 6/2005 Belalcazar et al.
2005/0131288 A1 6/2005 Turner et al.
2005/0137464 A1 6/2005 Bomba
2005/0137626 A1 6/2005 Pastore et al.
2005/0148895 A1 7/2005 Misczynski et al.
2005/0158539 A1 7/2005 Murphy et al.
2005/0177038 A1 8/2005 Kolpin et al.
2005/0187482 A1 8/2005 O'Brien et al.
2005/0187796 A1 8/2005 Rosenfeld et al.
2005/0192488 A1 9/2005 Bryenton et al.
2005/0197654 A1 9/2005 Edman et al.
2005/0203433 A1 9/2005 Singer
2005/0203435 A1 9/2005 Nakada
2005/0203436 A1 9/2005 Davies
2005/0203637 A1 9/2005 Edman et al.
2005/0206518 A1 9/2005 Welch et al.
2005/0215914 A1 9/2005 Bornzin et al.
2005/0215918 A1 9/2005 Frantz et al.
2005/0228234 A1 10/2005 Yang
2005/0228238 A1 10/2005 Monitzer
2005/0228244 A1 10/2005 Banet
2005/0239493 A1 10/2005 Batkin et al.
2005/0240087 A1 10/2005 Keenan et al.
2005/0251044 A1 11/2005 Hoctor et al.
2005/0256418 A1 11/2005 Mietus et al.
2005/0261598 A1 11/2005 Banet et al.
2005/0261743 A1 11/2005 Kroll
2005/0267376 A1 12/2005 Marossero et al.
2005/0267377 A1 12/2005 Marossero et al.
2005/0267381 A1 12/2005 Benditt et al.
2005/0273023 A1 12/2005 Bystrom et al.
2005/0277841 A1 12/2005 Shennib
2005/0277842 A1 12/2005 Silva
2005/0277992 A1 12/2005 Koh et al.
2005/0280531 A1 12/2005 Fadem et al.
2005/0283197 A1 12/2005 Daum et al.
2005/0288600 A1 12/2005 Zhang et al.
2005/0288601 A1 12/2005 Wood et al.
2006/0004300 A1 1/2006 Kennedy
2006/0004377 A1 1/2006 Keller
2006/0009697 A1 1/2006 Banet et al.
2006/0009701 A1 1/2006 Nissila et al.
2006/0010090 A1 1/2006 Brockway et al.
2006/0020218 A1 1/2006 Freeman et al.
2006/0025661 A1 2/2006 Sweeney et al.
2006/0030781 A1 2/2006 Shennib
2006/0030782 A1 2/2006 Shennib
2006/0031102 A1 2/2006 Teller et al.
2006/0041280 A1 2/2006 Stahmann et al.
2006/0047215 A1 3/2006 Newman et al.
2006/0052678 A1 3/2006 Drinan et al.
2006/0058543 A1 3/2006 Walter et al.
2006/0058593 A1 3/2006 Drinan et al.
2006/0064030 A1 3/2006 Cosentino et al.
2006/0064040 A1 3/2006 Berger et al.
2006/0064142 A1 3/2006 Chavan et al.
2006/0066449 A1 3/2006 Johnson
2006/0074283 A1 4/2006 Henderson et al.
2006/0074462 A1 4/2006 Verhoef
2006/0075257 A1 4/2006 Martis et al.
2006/0084881 A1 4/2006 Korzinov et al.
2006/0085049 A1 4/2006 Cory et al.
2006/0089679 A1 4/2006 Zhu et al.
2006/0094948 A1 5/2006 Gough et al.
2006/0102476 A1 5/2006 Niwa et al.
2006/0116592 A1 6/2006 Zhou et al.
2006/0122474 A1 6/2006 Teller et al.
2006/0135858 A1 6/2006 Nidd et al.
2006/0142654 A1 6/2006 Rytky
2006/0142820 A1 6/2006 Von Arx et al.
2006/0149168 A1 7/2006 Czarnek
2006/0155174 A1 7/2006 Glukhovsky et al.
2006/0155183 A1 7/2006 Kroecker et al.
2006/0155200 A1 7/2006 Ng
2006/0157893 A1 7/2006 Patel
2006/0161073 A1 7/2006 Singer
2006/0161205 A1 7/2006 Mitrani et al.
2006/0161459 A9 7/2006 Rosenfeld et al.
2006/0167374 A1 7/2006 Takehara et al.
2006/0173257 A1 8/2006 Nagai et al.
2006/0173269 A1 8/2006 Glossop
2006/0195020 A1 8/2006 Martin et al.
2006/0195039 A1 8/2006 Drew et al.
2006/0195097 A1 8/2006 Evans et al.
2006/0195144 A1 8/2006 Giftakis et al.
2006/0202816 A1 9/2006 Crump et al.
2006/0212097 A1 9/2006 Varadan et al.
2006/0224051 A1 10/2006 Teller et al.
2006/0224072 A1 10/2006 Shennib
2006/0224079 A1 10/2006 Washchuk
2006/0235281 A1 10/2006 Tuccillo
2006/0235316 A1* 10/2006 Ungless A61B 5/0006 600/509
2006/0235489 A1 10/2006 Drew et al.
2006/0238333 A1 10/2006 Welch et al.
2006/0241641 A1 10/2006 Albans et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2006/0241701 A1 10/2006 Markowitz et al.
2006/0241722 A1 10/2006 Thacker et al.
2006/0247545 A1 11/2006 St. Martin
2006/0252999 A1 11/2006 Devaul et al.
2006/0253005 A1 11/2006 Drinan et al.
2006/0253044 A1 11/2006 Zhang et al.
2006/0258952 A1 11/2006 Stahmann et al.
2006/0264730 A1 11/2006 Stivoric et al.
2006/0264767 A1 11/2006 Shennib
2006/0264776 A1 11/2006 Stahmann et al.
2006/0271116 A1 11/2006 Stahmann et al.
2006/0276714 A1 12/2006 Holt et al.
2006/0281981 A1 12/2006 Jang et al.
2006/0281996 A1 12/2006 Kuo et al.
2006/0293571 A1 12/2006 Bao et al.
2006/0293609 A1 12/2006 Stahmann et al.
2007/0010721 A1 1/2007 Chen et al.
2007/0010750 A1 1/2007 Ueno et al.
2007/0015973 A1 1/2007 Nanikashvili
2007/0015976 A1 1/2007 Miesel et al.
2007/0016089 A1 1/2007 Fischell et al.
2007/0021678 A1 1/2007 Beck et al.
2007/0021790 A1 1/2007 Kieval et al.
2007/0021792 A1 1/2007 Kieval et al.
2007/0021794 A1 1/2007 Kieval et al.
2007/0021796 A1 1/2007 Kieval et al.
2007/0021797 A1 1/2007 Kieval et al.
2007/0021798 A1 1/2007 Kieval et al.
2007/0021799 A1 1/2007 Kieval et al.
2007/0027388 A1 2/2007 Chou
2007/0027497 A1 2/2007 Parnis
2007/0032749 A1 2/2007 Overall et al.
2007/0038038 A1 2/2007 Stivoric et al.
2007/0038078 A1 2/2007 Osadchy
2007/0038255 A1 2/2007 Kieval et al.
2007/0038262 A1 2/2007 Kieval et al.
2007/0043301 A1 2/2007 Martinsen et al.
2007/0043303 A1 2/2007 Osypka et al.
2007/0048224 A1 3/2007 Howell et al.
2007/0060800 A1 3/2007 Drinan et al.
2007/0060802 A1 3/2007 Ghevondian et al.
2007/0069887 A1 3/2007 Welch et al.
2007/0073132 A1 3/2007 Vosch
2007/0073168 A1 3/2007 Zhang et al.
2007/0073181 A1 3/2007 Pu et al.
2007/0073361 A1 3/2007 Goren et al.
2007/0082189 A1 4/2007 Gillette
2007/0083092 A1 4/2007 Rippo et al.
2007/0092862 A1 4/2007 Gerber
2007/0100666 A1 5/2007 Stivoric et al.
2007/0104840 A1 5/2007 Singer
2007/0106132 A1 5/2007 Elhag et al.
2007/0106137 A1 5/2007 Baker, Jr. et al.
2007/0106167 A1 5/2007 Kinast
2007/0118039 A1 5/2007 Bodecker et al.
2007/0123756 A1 5/2007 Kitajima et al.
2007/0123903 A1 5/2007 Raymond et al.
2007/0123904 A1 5/2007 Stad et al.
2007/0129622 A1 6/2007 Bourget et al.
2007/0129643 A1 6/2007 Kwok et al.
2007/0129769 A1 6/2007 Bourget et al.
2007/0142715 A1 6/2007 Banet et al.
2007/0142732 A1 6/2007 Brockway et al.
2007/0149282 A1 6/2007 Lu et al.
2007/0150008 A1 6/2007 Jones et al.
2007/0150009 A1 6/2007 Kveen et al.
2007/0150029 A1 6/2007 Bourget et al.
2007/0162089 A1 7/2007 Mosesov
2007/0167753 A1 7/2007 Van Wyk et al.
2007/0167848 A1 7/2007 Kuo et al.
2007/0167849 A1 7/2007 Zhang et al.
2007/0167850 A1 7/2007 Russell et al.
2007/0172424 A1 7/2007 Roser
2007/0173705 A1 7/2007 Teller et al.
2007/0180047 A1 8/2007 Dong et al.
2007/0180140 A1 8/2007 Welch et al.
2007/0191723 A1 8/2007 Prystowsky et al.
2007/0207858 A1 9/2007 Breving
2007/0208233 A1 9/2007 Kovacs
2007/0208235 A1 9/2007 Besson et al.
2007/0208262 A1 9/2007 Kovacs
2007/0232867 A1 10/2007 Hansmann
2007/0244403 A1 10/2007 Natarajan et al.
2007/0249946 A1 10/2007 Kumar et al.
2007/0250121 A1 10/2007 Miesel et al.
2007/0255120 A1 11/2007 Rosnov
2007/0255153 A1 11/2007 Kumar et al.
2007/0255184 A1 11/2007 Shennib
2007/0255531 A1 11/2007 Drew
2007/0260133 A1 11/2007 Meyer
2007/0260155 A1 11/2007 Rapoport et al.
2007/0260289 A1 11/2007 Giftakis et al.
2007/0270678 A1 11/2007 Fadem et al.
2007/0273504 A1 11/2007 Tran
2007/0276273 A1 11/2007 Watson, Jr.
2007/0282173 A1 12/2007 Wang et al.
2007/0299325 A1 12/2007 Farrell et al.
2008/0004499 A1 1/2008 Davis
2008/0004547 A1 1/2008 Dinsmoor et al.
2008/0004904 A1 1/2008 Tran
2008/0021336 A1 1/2008 Dobak
2008/0024293 A1 1/2008 Stylos
2008/0024294 A1 1/2008 Mazar
2008/0033260 A1 2/2008 Sheppard et al.
2008/0039700 A1 2/2008 Drinan et al.
2008/0058614 A1 3/2008 Banet et al.
2008/0058656 A1 3/2008 Costello et al.
2008/0059239 A1 3/2008 Gerst et al.
2008/0091089 A1 4/2008 Guillory et al.
2008/0114220 A1 5/2008 Banet et al.
2008/0120784 A1 5/2008 Warner et al.
2008/0139934 A1 6/2008 McMorrow et al.
2008/0146892 A1 6/2008 LeBoeuf et al.
2008/0167538 A1 7/2008 Teller et al.
2008/0171918 A1 7/2008 Teller et al.
2008/0171922 A1 7/2008 Teller et al.
2008/0171929 A1 7/2008 Katims
2008/0183052 A1 7/2008 Teller et al.
2008/0200774 A1 8/2008 Luo
2008/0214903 A1 9/2008 Orbach
2008/0220865 A1 9/2008 Hsu
2008/0221399 A1 9/2008 Zhou et al.
2008/0221402 A1 9/2008 Despotis
2008/0224852 A1 9/2008 Dicks et al.
2008/0228084 A1 9/2008 Bedard et al.
2008/0275465 A1 11/2008 Paul et al.
2008/0287751 A1 11/2008 Stivoric et al.
2008/0287752 A1 11/2008 Stroetz et al.
2008/0293491 A1 11/2008 Wu et al.
2008/0294019 A1 11/2008 Tran
2008/0294020 A1 11/2008 Sapounas
2008/0318681 A1 12/2008 Rofougaran et al.
2008/0319279 A1 12/2008 Ramsay et al.
2008/0319282 A1 12/2008 Tran
2008/0319290 A1 12/2008 Mao et al.
2009/0005016 A1 1/2009 Eng et al.
2009/0018410 A1 1/2009 Coene et al.
2009/0018456 A1 1/2009 Hung
2009/0048526 A1 2/2009 Aarts
2009/0054737 A1 2/2009 Magar et al.
2009/0062670 A1 3/2009 Sterling et al.
2009/0073991 A1 3/2009 Landrum et al.
2009/0076336 A1 3/2009 Mazar et al.
2009/0076341 A1 3/2009 James et al.
2009/0076342 A1 3/2009 Amurthur et al.
2009/0076343 A1 3/2009 James et al.
2009/0076344 A1 3/2009 Libbus et al.
2009/0076345 A1 3/2009 Manicka et al.
2009/0076346 A1 3/2009 James et al.
2009/0076348 A1 3/2009 Manicka et al.
2009/0076349 A1 3/2009 Libbus et al.
2009/0076350 A1 3/2009 Bly et al.
2009/0076363 A1 3/2009 Bly et al.
2009/0076364 A1 3/2009 Libbus et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2009/0076397	A1	3/2009	Libbus et al.	
2009/0076401	A1	3/2009	Mazar et al.	
2009/0076405	A1	3/2009	Amurthur et al.	
2009/0076410	A1	3/2009	Libbus et al.	
2009/0076559	A1	3/2009	Libbus et al.	
2009/0177145	A1	7/2009	Ohlander et al.	
2009/0182204	A1	7/2009	Semler et al.	
2009/0234410	A1	9/2009	Libbus et al.	
2009/0264792	A1	10/2009	Mazar	
2009/0292194	A1	11/2009	Libbus et al.	
2010/0056881	A1	3/2010	Libbus et al.	
2010/0069735	A1*	3/2010	Berkner	A61B 5/04028 600/382
2010/0191310	A1	7/2010	Bly et al.	
2015/0087921	A1*	3/2015	Felix	A61B 5/04087 600/301
2015/0087922	A1*	3/2015	Bardy	A61B 5/02055 600/301
2015/0087923	A1*	3/2015	Bardy	A61B 5/04087 600/301
2015/0087949	A1*	3/2015	Felix	A61B 5/04087 600/382
2015/0087950	A1*	3/2015	Felix	A61B 5/04087 600/382
2015/0094557	A1*	4/2015	Hsu	A61B 5/6833 600/391
2016/0007872	A1*	1/2016	Bishay	A61B 5/0452 600/382
2016/0007875	A1*	1/2016	Felix	A61B 5/04087 600/382
2016/0007877	A1*	1/2016	Felix	A61B 5/04325 600/523
2016/0150989	A1*	6/2016	Felix	A61B 5/04017 600/523

FOREIGN PATENT DOCUMENTS

EP	1579801	A1	9/2005
GB	2 425 181	A	10/2006
JP	2005-521448		7/2005
WO	WO 95/07048		3/1995
WO	WO 00/79255		12/2000
WO	01/89362	A2	11/2001
WO	WO 02/092101		11/2002
WO	WO 03/082080		10/2003
WO	WO 2005/051164		6/2005
WO	WO 2005/104930		11/2005
WO	WO 2006/008745		1/2006
WO	WO 2006/102476		9/2006
WO	WO 2006/111878	A1	11/2006
WO	WO 2007/041783		4/2007
WO	WO 2007/038607	A2	5/2007
WO	WO 2007/094729	A1	8/2007
WO	2007/106455	A2	9/2007
WO	2009/116906	A1	9/2009

OTHER PUBLICATIONS

Pinna et al., "Home telemonitoring of respiratory activity and heart rate variability in chronic heart failure patients: the challenge of the home or hospital in heart failure project," Computers in Cardiology (2003) 30: 197-200.

"Acute Decompensated Heart Failure"—Wikipedia Entry, downloaded from: <http://en.wikipedia.org/wiki/Acute_decompensated_heart_failure>, submitted version downloaded Feb. 11, 2011, 6 pages total.

"Heart Failure"—Wikipedia Entry, downloaded from the Internet: <http://en.wikipedia.org/wiki/Heart_failure>, submitted version downloaded Feb. 11, 2011, 17 pages total.

3M Corporation, "3M Surgical Tapes—Choose the Correct Tape" quicksheet (2004).

Cooley, "The Parameters of Transthoracic Electical Conduction," Annals of the New York Academy of Sciences, 1970; 170(2):702-713.

EM Microelectronic—Marin SA, "Plastic Flexible LCD," [product brochure]; retrieved from the Internet: <<http://www.em-microelectronic.com/Line.asp?IdLine=48>>, copyright 2009, 2 pages total.

HRV Enterprises, LLC, "Heart Rate Variability Seminars," downloaded from the Internet: <<http://hrventerprise.com/>> on Apr. 24, 2008, 3 pages total.

HRV Enterprises, LLC, "LoggerPro HRV Biosignal Analysis," downloaded from the Internet: <<http://hrventerprise.com/products.html>> on Apr. 24, 2008, 3 pages total.

International Search Report and Written Opinion of PCT Application No. PCT/US08/76217, dated Nov. 10, 2008, 16 pages total.

AD5934: 250 kSPS 12-Bit Impedance Converter Network Analyzer, Analog Devices, retrieved from the Internet: <<http://www.analog.com/static/imported-files/data_sheets/AD5934.pdf>>, 40 pages.

Something in the way he moves, The Economist, 2007, retrieved from the Internet: <<http://www.economist.com/science/printerFriendly.cfm?story id=9861412>>.

Abraham, "New approaches to monitoring heart failure before symptoms appear," Rev Cardiovasc Med. 2006 ;7 Suppl 1 :33-41.

Adams, Jr. "Guiding heart failure care by invasive hemodynamic measurements: possible or useful?", Journal of Cardiac Failure 2002; 8(2):71-73.

Adamson et al., "Continuous autonomic assessment in patients with symptomatic heart failure: prognostic value of heart rate variability measured by an implanted cardiac resynchronization device ," Circulation. 2004;110:2389-2394.

Adamson et al., "Ongoing right ventricular hemodynamics in heart failure," J Am Coll Cardiol, 2003; 41:565-57.

Adamson, "Integrating device monitoring into the infrastructure and workflow of routine practice," Rev Cardiovasc Med. 2006 ;7 Suppl 1:42-6.

Adhere [presentation], "Insights from thedhere Registry: Data from over 100,000 patient cases," 70 pages total.

Advamed White Sheet, "Health Information Technology: Improving Patient Safety and Quality of Care," Jun. 2005, 23 pages.

Aghababian, "Acutely decompensated heart failure: opportunities to improve care and outcomes in the emergency department," Rev Cardiovasc Med. 2002;3 Suppl 4:S3-9.

Albert, "Bioimpedance to prevent heart failure hospitalization," Curr Heart Fail Rep. Sep. 2006;3(3):136-42.

American Heart Association, "Heart Disease and Stroke Statistics—2006 Update," 2006, 43 pages.

American Heart Association, "Heart Disease and Stroke Statistics—2007 Update. A Report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee," Circulation 2007; 115;e69-e171.

Belalcazar et al., "Monitoring lung edema using the pacemaker pulse and skin electrodes," Physiol. Meas. 2005; 26:S153-S163.

Bennet, "Development of implantable devices for continuous ambulatory monitoring of central hemodynamic values in heart failure patients," PACE Jun. 2005; 28:573-584.

Bourge, "Case studies in advanced monitoring with the chronicle device," Rev Cardiovasc Med. 2006 ;7 Suppl 1:S56-61.

Braunschweig, "Continous haemodynamic monitoring during withdrawal of diuretics in patients with congestive heart failure," European Heart Journal 2002 23(1):59-69.

Braunschweig, "Dynamic changes in right ventricular pressures during haemodialysis recorded with an implantable haemodynamic monitor ," Nephrol Dial Transplant 2006; 21:176-183.

Brennan, "Measuring a Grounded Impedance Profile Using the AD5933," Analog Devices, retrieved from the internet <<http://http://www.analog.com/static/imported-files/application_notes/4270952823815101 89AN847_0.pdf>>, 12 pages total.

Buono et al., "The effect of ambient air temperature on whole-body bioelectrical impedance," Physiol. Meas. 2004;25:119-123.

Burkhoff et al., "Heart failure with a normal ejection fraction: Is it really a disorder of diastolic function?" Circulation 2003; 107:656-658.

(56) **References Cited**

OTHER PUBLICATIONS

Burr et al., "Heart rate variability and 24-hour minimum heart rate," Biological Research for Nursing, 2006; 7(4):256-267.

Cardionet, "CardioNet Mobile Cardiac Outpatient Telemetry: Addendum to Patient Education Guide", CardioNet, Inc., 2007, 2 pages.

Cardionet, "Patient Education Guide", CardioNet, Inc., 2007, 7 pages. Undated.

Charach et al., "Transthoracic monitoring of the impedance of the right lung in patients with cardiogenic pulmonary edema," Crit Care Med Jun. 2001;29(6):1137-1144.

Charlson et al., "Can disease management target patients most likely to generate high costs? The Impact of Comorbidity," Journal of General Internal Medicine, Apr. 2007, 22(4):464-469.

Chaudhry et al., "Telemonitoring for patients with chronic heart failure: a systematic review," J Card Fail. Feb. 2007; 13(1): 56-62.

Chung et al., "White coat hypertension: Not so benign after all?," Journal of Human Hypertension (2003) 17, 807-809.

Cleland et al., "The EuroHeart Failure survey programme—a survey on the quality of care among patients with heart failure in Europe—Part 1: patient characteristics and diagnosis," European Heart Journal 2003 24(5):442-463.

Cowie et al., "Hospitalization of patients with heart failure. A population-based study," European Heart Journal 2002 23(11):877-885.

Dimri, Chapter 1: Fractals in geophysics and seimology: an introduction, *Fractal Behaviour of the Earth System,* Springer Berlin Heidelberg 2005, pp. 1-22. [Summary and 1st page Only].

El-Dawlatly et al., "Impedance cardiography: noninvasive assessment of hemodynamics and thoracic fluid content during bariatric surgery," Obesity Surgery, May 2005, 15(5):655-658.

Erdmann, "Editorials: The value of diuretics in chronic heart failure demonstrated by an implanted haemodynamic monitor," European Heart Journal 2002 23(1):7-9.

FDA—Medtronic Inc., Chronicle 9520B Implantable Hemodynamic Monitor Reference Manual, 2007, 112 pages.

FDA Executive Summary Memorandum, prepared for Mar. 1, 2007, meeting of the Circulatory Systems Devices Advisory Panel, P050032 Medtronic, Inc. Chronicle Implantable Hemodynamic Monitor (IHM) System, 23 pages. Retrieved from the Internet: <<http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4284b1_02.pdf>>.

FDA Executive Summary, Medtronic Chronicle Implantable Hemodynamic Monitoring System P050032: Panel Package Sponsor Executive Summary; vol. 1, section 4: Executive Summary. 12 pages total. Retrieved from the Internet: <<http://www.fda.gov/OHRMS/DOCKETS/AC/07/briefing/2007-4284b1_03.pdf>>.

FDA—Medtronic Chronicle Implantable Hemodynamic Monitoring System P050032: Panel Package Section 11: Chronicle IHM Summary of Safety and Effectiveness, 2007; retrieved from the Internet: <http://www.fda.gov/OHRMS/DOCKETS/AC/07/briefing/2007-4284b1_04.pdf>, 77 pages total.

FDA, Draft questions for Chronicle Advisory Panel Meeting, 3 pages. Retrieved from the Internet: <<http://www.fda/gov/ohrms/dockets/ac/07/questions/2007-4284q1_draft.pdf>>.

FDA, References for Mar. 1 Circulatory System Devices Panel, 1 page total. 2007. Retrieved from the Internet: <<http://www.fda.gov/OHRMS/DOCKETS/AC/07/briefing/2007-4284bib1_01.pdf>>.

FDA Panel Recommendation, "Chronicle Analysis," Mar. 1, 2007, 14 pages total.

Fonarow et al., "Risk stratification for in-hospital mortality in acutely decompensated heart failure: classification and regression tree analysis," JAMA. Feb. 2, 2005;293(5):572-580.

Fonarow, "How well are chronic heart failure patients being managed?", Rev Cardiovasc Med. 2006;7 Suppl 1:S3-11.

Fonarow, "Maximizing Heart Failure Care" [Powerpoint Presentation], downloaded from the Internet <<http://www.medreviews.com/media/MaxHFCore.ppt>>, 130 pages total.

Fonarow, "Proactive monitoring and management of the chronic heart failure patient," Rev Cardiovasc Med. 2006; 7 Suppl 1:S1-2.

Fonarow, "The Acute Decompensated Heart Failure National Registry (ADHERE): opportunities to improve care of patients hospitalized with acute decompensated heart failure," Rev Cardiovasc Med. 2003;4 Suppl 7:S21-S30.

Ganion et al., "Intrathoracic impedance to monitor heart failure status: a comparison of two methods in a chronic heart failure dog model," Congest Heart Fail. Jul.-Aug. 2005;11(4):177-81, 211.

Gass et al., "Critical pathways in the management of acute decompensated heart failure: A CME-Accredited monograph," Mount Sinai School of Medicine, 2004, 32 pages total.

Gheorghiade et al., "Congestion is an important diagnostic and therapeutic target in heart failure," Rev Cardiovasc Med. 2006 ;7 Suppl 1 :12-24.

Gilliam, III et al., "Changes in heart rate variability, quality of life, and activity in cardiac resynchronization therapy patients: results of the HF-HRV registry," Pacing and Clinical Electrophysiology, Jan. 18, 2007; 30(1): 56-64.

Gilliam, III et al., "Prognostic value of heart rate variability footprint and standard deviation of average 5-minute intrinsic R-R intervals for mortality in cardiac resynchronization therapy patients.," J Electrocardiol. Oct. 2007;40(4):336-42.

Gniadecka, "Localization of dermal edema in lipodermatosclerosis, lymphedema, and cardiac insufficiency high-frequency ultrasound examination of intradermal echogenicity," J Am Acad oDermatol, Jul. 1996; 35(1):37-41.

Goldberg et al., "Randomized trial of a daily electronic home monitoring system in patients with advanced heart failure: The Weight Monitoring in Heart Failure (WHARF) Trial," American Heart Journal, Oct. 2003; 416(4):705-712.

Grap et al., "Actigraphy in the Critically Ill: Correlation With Activity, Agitation, and Sedation," American Journal of Critical Care. 2005;14: 52-60.

Gudivaka et al., "Single- and multifrequency models for bioelectrical impedance analysis of body water compartments," J Appl Physiol, 1999;87(3):1087-1096.

Guyton et al., Unit V: The Body Fluids and Kidneys, Chapter 25: The Body Fluid Compartments: Extracellular and Intracellular Fluids; Interstitial Fluid and Edema, *Guyton & Hall Textbook of Medical Physiology* 11th Edition, Saunders 2005; pp. 291-306.

Hadase et al., "Very low frequency power of heart rate variability is a powerful predictor of clinical prognosis in patients with congestive heart Failure," Circ J 2004; 68(4):343-347.

Hallstrom et al., "Structural relationships between measures based on heart beat intervals: potential for improved risk assessment," IEEE Biomedical Engineering 2004, 51(8):1414-1420.

HFSA 2006 Comprehensive Heart Failure Practice Guideline—Executive Summary: HFSA 2006 Comprehensive Heart Failure Practice Guideline, Journal of Cardiac Failure 2006;12(1):10-e38.

HFSA 2006 Comprehensive Heart Failure Practice Guideline—Section 12: Evaluation and Management of Patients With Acute Decompensated Heart Failure, Journal of Cardiac Failure 2006;12(1):e86-e103.

HFSA 2006 Comprehensive Heart Failure Practive Guideline—Section 2: Conceptualization and Working Definition of Heart Failure, Journal of Cardiac Failure 2006;12(1):e10-e11.

HFSA 2006 Comprehensive Heart Failure Practice Guideline—Section 3: Prevention of Ventricular Remodeling Cardiac Dysfunction, and Heart Failure Overview, Journal of Cardiac Failure 2006;12(1):e12-e15.

HFSA 2006 Comprehensive Heart Failure Practice Guideline—Section 4: Evaluation of Patients for Ventricular Dysfunction and Heart Failure, Journal of Cardiac Failure 2006;12(1):e16-e25.

HFSA 2006 Comprehensive Heart Failure Practice Guideline—Section 8: Disease Management in Heart Failure Education and Counseling, Journal of Cardiac Failure 2006;12(1):e58-e68.

Hunt et al., "ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): Developed in Collaboration With the American College of

(56) **References Cited**

OTHER PUBLICATIONS

Chest Physicians and the International Society for Heart and Lung Transplantation: Endorsed by the Heart Rhythm Society," Circulation. 2005;112:e154-e235.

Hunt et al., ACC/AHA Guidelines for the Evaluation and Management of Chronic Heart Failure in the Adult: Executive Summary a Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1995 Guidelines for the Evaluation and Management of Heart Failure), Circulation. 2001;104:2996-3007.

Imhoff et al., "Noninvasive whole-body electrical bioimpedance cardiac output and invasive thermodilution cardiac output in high-risk surgical patients," Critical Care Medicine 2000; 28(8):2812-2818.

Jaeger et al., "Evidence for Increased Intrathoracic Fluid Volume in Man at High Altitude," J Appl Physiol 1979; 47(6): 670-676.

Jerant et al., "Reducing the cost of frequent hospital admissions for congestive heart failure: a randomized trial of a home telecare intervention," Medical Care 2001, 39(11):1234-1245.

Jaio et al., "Variance fractal dimension analysis of seismic refraction signals," WESCANEX 97: Communications, Power and Computing. IEEE Conference Proceedings., May 22-23, 1997, pp. 163-167 [Abstract Only].

Kasper et al., "A randomized trial of the efficacy of multidisciplinary care in heart failure: outpatients at high risk of hospital readmission," J Am Coll Cardiol, 2002; 39:471-480.

Kaukinen, "Cardiac output measurement after coronary artery bypass grafting using bolus thermodilution, continuous thermodilution, and whole-body impedance cardiography," Journal of Cardiothoracic and Vascular Anesthesia 2003; 17(2):199-203.

Kawaguchi et al., "Combined ventricular systolic and arterial stiffening in patients with heart failure and preserved ejection fraction: implications for systolic and diastolic reserve limitations," Circulation. 2003;107:714-720.

Kawasaki et al., "Heart rate turbulence and clinical prognosis in hypertrophic cardiomyopathy and myocardial infarction," Circ J. Jul. 2003;67(7):601-604.

Kearney et al., "Predicting death due to progressive heart failure in patients with mild-to-moderate chronic heart failure," J Am Coll Cardiol, 2002; 40(10):1801-1808.

Kitzman et al., "Pathophysiological characterization of isolated diastolic heart failure in comparison to systolic heart failure," JAMA Nov. 2002; 288(17):2144-2150.

Kööbi et al., "Non-invasive measurement of cardiac output : whole-body impedance cardiography in simultaneous comparison with thermodilution and direct oxygen Fick methods," Intensive Care Medicine 1997; 23(11):1132-1137.

Koyama et al., "Evaluation of heart-rate turbulence as a new prognostic marker in patients with chronic heart failure," Circ J 2002; 66(10):902-907.

Krumholz et al., "Predictors of readmission among elderly survivors of admission with heart failure," American Heart Journal 2000; 139 (1):72-77.

Kyle et al., "Bioelectrical Impedance Analysis—part I: review of principles and methods," Clin Nutr. Oct. 2004;23(5):1226-1243.

Kyle et al., "Bioelectrical Impedance Analysis—part II: utilization in clinical practice," Clin Nutr. Oct. 2004;23(5):1430-1453.

Lee et al., "Predicting mortality among patients hospitalized for heart failure: derivation and validation of a clinical model," JAMA 2003;290(19):2581-2587.

Leier "The Physical Examination in Heart Failure—Part I," Congest Heart Fail. Jan.-Feb. 2007;13(1):41-47.

LifeShirt® Model 200 Directions for Use, "Introduction", VivoMetrics, Inc. 9 page total.

Liu et al., "Fractal analysis with applications to seismological pattern recognition of underground nuclear explosions," Singal Processing, Sep. 2000, 80(9):1849-1861. [Abstract Only].

Lozano-Nieto, "Impedance ratio in bioelectrical impedance measurements for body fluid shift determination," Proceedings of the IEEE 24th Annual Northeast Bioengineering. Conference, Apr. 9-10, 1998, pp. 24-25.

Lucreziotti et al., "Five-minute recording of heart rate variability in severe chronic heart failure : Correlates with right ventricular function and prognostic implications," American Heart Journal 2000; 139(6):1088-1095.

Lüthje et al., "Detection of heart failure decompensation using intrathoracic impedance monitoring by a triple-chamber implantable defibrillator," Heart Rhythm Sep. 2005;2(9):997-999.

Magalski et al., "Continuous ambulatory right heart pressure measurements with an implantable hemodynamic monitor: a multicenter, 12-Month Follow-up Study of Patients With Chronic Heart Failure," J Card Fail 2002, 8(2):63-70.

Mahlberg et al., "Actigraphy in agitated patients with dementia: Monitoring treatment outcomes," Zeitschrift für Gerontologie und Geriatrie, Jun. 2007; 40(3)178-184. [Abstract Only].

Matthie et al., "Analytic assessment of the various bioimpedance methods used to estimate body water," Appl Physiol 1998; 84(5):1801-1816.

Matthie, "Second generation mixture theory equation for estimating intracellular water using bioimpedance spectroscopy," J Appl Physiol 2005; 99:780-781.

McMurray et al., "Heart Failure: Epidemiology, Aetiology, and Prognosis of Heart Failure," Heart 2000;83:596-602.

Miller, "Home monitoring for congestive heart failure patients," Caring Magazine, Aug. 1995: 53-54.

Moser et al., "Improving outcomes in heart failure: it's not unusual beyond usual Care," Circulation. 2002;105:2810-2812.

Nagels et al., "Actigraphic measurement of agitated behaviour in dementia," International journal of geriatric psychiatry , 2009; 21(4):388-393. [Abstract Only].

Nakamura et al., "Universal scaling law in human behavioral organization," Physical Review Letters, Sep. 28, 2007; 99(13):138103 (4 pages).

Nakaya, "Fractal properties of seismicity in regions affected by large, shallow earthquakes in western Japan: Implications for fault formation processes based on a binary fractal fracture network model," Journal of geophysical research, Jan. 2005; 11(B1):B01310.1-B01310.15. [Abstract Only].

Naylor et al., "Comprehensive discharge planning for the hospitalized elderly: a randomized clinical trial ," Amer. College Physicians 1994; 120(12):999-1006.

Nesiritide (Natrecor),, [Presentation] Acutely Decompensated Congestive Heart Failure: Burden of Disease, downloaded from the Internet: <<http://www.huntsvillehospital.org/foundation/events/cardiologyupdate/CHF.ppt.>>, 39 pages.

Nieminen et al., "EuroHeart Failure Survey II (EHFS II): a survey on hospitalized acute heart failure patients: description of population," European Heart Journal 2006; 27(22):2725-2736.

Nijsen et al., "The potential value of three-dimensional accelerometry for detection of motor seizures in severe epilepsy," Epilepsy Behav. Aug. 2005;7(1):74-84.

Noble et al., "Diuretic induced change in lung water assessed by electrical impedance tomography," Physiol. Meas. 2000; 21(1):155-163.

Noble et al., "Monitoring patients with left ventricular failure by electrical impedance tomography," Eur J Heart Fail. Dec. 1999;1(4):379-84.

O'Connell et al., "Economic impact of heart failure in the United States: time for a different approach," J Heart Lung Transplant., Jul.-Aug. 1994 ; 13(4):S107-S112.

Ohlsson et al., "Central hemodynamic responses during serial exercise tests in heart failure patients using implantable hemodynamic monitors," Eur J Heart Fail. Jun. 2003;5(3):253-259.

Ohlsson et al., "Continuous ambulatory monitoring of absolute right ventricular pressure and mixed venous oxygen saturation in patients with heart failure using an implantable haemodynamic monitor," European Heart Journal 2001 22(11):942-954.

(56) **References Cited**

OTHER PUBLICATIONS

Packer et al., "Utility of impedance cardiography for the identification of short-term risk of clinical decompensation in stable patients with chronic heart failure," J Am Coll Cardiol, 2006; 47(11):2245-2252.

Palatini et al., "Predictive value of clinic and ambulatory heart rate for mortality in elderly subjects with systolic hypertension" Arch Intern Med. 2002;162:2313-2321.

Piiria et al., "Crackles in patients with fibrosing alveolitis bronchiectasis, COPD, and Heart Failure," Chest May 1991; 99(5):1076-1083.

Pocock et al., "Predictors of mortality in patients with chronic heart failure," Eur Heart J 2006; (27): 65-75.

Poole-Wilson, "Importance of control of fluid volumes in heart failure," European Heart Journal 2000; 22(11):893-894.

Raj et al., 'Letter Regarding Article by Adamson et al, "Continuous Autonomic Assessment in Patients With Symptomatic Heart Failure: Prognostic Value of Heart Rate Variability Measured by an Implanted Cardiac Resynchronization Device"', Circulation 2005;112:e37-e38.

Ramirez et al., "Prognostic value of hemodynamic findings from impedance cardiography in hypertensive stroke," AJH 2005; 18(20):65-72.

Rich et al., "A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure," New Engl. J. Med. 1995;333:1190-1195.

Roglieri et al., "Disease management interventions to improve outcomes in congestive heart failure," Am J Manag Care. Dec. 1997;3(12):1831-1839.

Sahalos et al., "The Electrical impedance of the human thorax as a guide in evaluation of intrathoracic fluid volume," Phys. Med. Biol. 1986; 31:425-439.

Saxon et al., "Remote active monitoring in patients with heart failure (rapid-rf): design and rationale," Journal of Cardiac Failure 2007; 13(4):241-246.

Scharf et al., "Direct digital capture of pulse oximetry waveforms," Proceedings of the Twelfth Southern Biomedical Engineering Conference, 1993., pp. 230-232.

Shabetai, "Monitoring heart failure hemodynamics with an implanted device: its potential to improve outcome," J Am Coll Cardiol, 2003; 41:572-573.

Small, "Integrating monitoring into the Infrastructure and Workflow of Routine Practice: OptiVol," Rev Cardiovasc Med. 2006 ;7 Supp 1: S47-S55.

Smith et al., "Outcomes in heart failure patients with preserved ejection fraction: mortality, readmission, and functional decline ," J Am Coll Cardiol, 2003; 41:1510-1518.

Someren, "Actigraphic monitoring of movement and rest-activity rhythms inaging, Alzheimer's disease, and Parkinson's disease," IEEE Transactions on Rehabilitation Engineering, Dec. 1997; 5(4):394-398. [Abstract Only].

Starling, "Improving care of chronic heart failure: advances from drugs to devices," Cleveland Clinic Journal of Medicine Feb. 2003; 70(2):141-146.

Steijaert et al., "The use of multi-frequency impedance to determine total body water and extracellular water in obese and lean female individuals," International Journal of Obesity Oct. 1997; 21(10):930-934.

Stewart et al., "Effects of a home-based intervention among patients with congestive heart failure discharged from acute hospital care," Arch Intern Med. 1998;158:1067-1072.

Stewart et al., "Effects of a multidisciplinary, home-based intervention on planned readmissions and survival among patients with chronic congestive heart failure: a randomised controlled study," The Lancet Sep. 1999, 354(9184):1077-1083.

Stewart et al., "Home-based intervention in congestive heart failure: long-term implications on readmission and surival," Circulation. 2002;105:2861-2866.

Stewart et al., "Prolonged beneficial effects of a home-based intervention on unplanned readmissions and mortality among patients with congestive heart failure," Arch Intern Med. 1999;159:257-261.

Stewart et al., "Trends in Hospitalization for Heart Failure in Scotland, 1990-1996. An Epidemic that has Reached Its Peak?," European Heart Journal 2001 22(3):209-217.

Swedberg et al., "Guidelines for the diagnosis and treatment of chronic heart failure: executive summary (update 2005): The Task Force for the Diagnosis and Treatment of Chronic Heart Failure of the European Society of Cardiology," Eur Heart J. Jun. 2005; 26(11):1115-1140.

Tang, "Case studies in advanced monitoring: OptiVol," Rev Cardiovasc Med. 2006;7 Suppl 1:S62-S66.

The ESCAPE Investigators and ESCAPE Study Coordinators, "Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness," JAMA 2005;294:1625-1633.

Tosi et al., "Seismic signal detection by fractal dimension analysis," Bulletin of the Seismological Society of America; Aug. 1999; 89(4):970-977. [Abstract Only].

Van De Water et al., "Monitoring the chest with impedance," Chest. 1973;64:597-603.

Vasan et al., "Congestive heart failure in subjects with normal versus reduced left ventricular ejection fraction," J Am Coll Cardiol, 1999; 33:1948-1955.

Verdecchia et al., "Adverse prognostic value of a blunted circadian rhythm of heart rate in essential hypertension," Journal of Hypertension 1998; 16(9):1335-1343.

Verdecchia et al., "Ambulatory pulse pressure: a potent predictor of total cardiovascular risk in hypertension," Hypertension. 1998;32:983-988.

Vollmann et al., "Clinical utility of intrathoracic impedance monitoring to alert patients with an implanted device of deteriorating chronic heart failure," Euorpean Heart Journal Advance Access published on Feb. 19, 2007, downloaded from the Internet:<<http://eurheartj.oxfordjournals.org/cgi/content/full/ehl506v1>>, 6 pages total.

Vuksanovic et al., "Effect of posture on heart rate variability spectral measures in children and young adults with heart disease," International Journal of Cardiology 2005;101(2): 273-278.

Wang et al., "Feasibility of using an implantable system to measure thoracic congestion in an ambulatory chronic heart failure canine model," PACE 2005;28(5):404-411.

Wickemeyer et al., #197—"Association between atrial and ventricular tachyarrhythmias, intrathoracic impedance and heart failure decompensation in CRT-D Patients," Journal of Cardiac Failure 2007; 13 (6) Suppl.; S131-132.

Williams et al, "How do different indicators of cardiac pump function impact upon the long-term prognosis of patients with chronic heart failure," American Heart Journal, 150(5):983.e1-983.e6.

Wonisch et al., "Continuous haemodynamic monitoring during exercise in patients with pulmonary hypertension," Int J Cardiol. Jun. 8, 2005;101(3):415-420.

Wynne et al., "Impedance cardiography: a potential monitor for hemodialysis," Journal of Surgical Research 2006, 133(1):55-60.

Yancy "Current approaches to monitoring and management of heart failure," Rev Cardiovasc Med 2006; 7 Suppl 1:S25-32.

Ypenburg et al., "Intrathoracic Impedance Monitoring to Predict Decompensated Heart Failure," Am J Cardiol 2007, 99(4):554-557.

Yu et al., "Intrathoracic Impedance Monitoring in Patients With Heart Failure: Correlation With Fluid Status and Feasibility of Early Warning Preceding Hospitalization," Circulation. 2005;112:841-848.

Zannad et al., "Incidence, clinical and etiologic features, and outcomes of advanced chronic heart failure: The EPICAL Study," J Am Coll Cardiol, 1999; 33(3):734-742.

Zile, "Heart failure with preserved ejection fraction: is this diastolic heart failure?" J Am Coll Cardiol, 2003; 41(9):1519-1522.

U.S. Appl. No. 60/006,600, filed Nov. 13, 1995; inventor: Terry E. Flach.

U.S. Appl. No. 60/972,316, filed Sep. 12, 2008; inventor: Imad Libbus et al.

(56) **References Cited**

OTHER PUBLICATIONS

U.S. Appl. No. 60/972,329, filed Sep. 14, 2007; inventor: Yatheendhar Manicka et al.
U.S. Appl. No. 60/972,333, filed Sep. 14, 2007; inventor: Mark Bly et al.
U.S. Appl. No. 60/972,336, filed Sep. 14, 2007; inventor: James Kristofer et al.
U.S. Appl. No. 60/972,340, filed Sep. 14, 2007; inventor: James Kristofer et al.
U.S. Appl. No. 60/972,343, filed Sep. 14, 2007; inventor: James Kristofer et al.
U.S. Appl. No. 60/972,354, filed Sep. 14, 2007; inventor: Scott Thomas Mazar et al.
U.S. Appl. No. 60/972,359, filed Sep. 14, 2007; inventor: Badri Amurthur et al.
U.S. Appl. No. 60/972,363, filed Sep. 14, 2007; inventor: Badri Amurthur et al.
U.S. Appl. No. 60/972,512, filed Sep. 14, 2007; inventor: Imad Libbus et al.
U.S. Appl. No. 60/972,537, filed Sep. 14, 2007; inventor: Yatheendhar Manicka et al.
U.S. Appl. No. 60/972,581, filed Sep. 14, 2007; inventor: Imad Libbus et al.
U.S. Appl. No. 60/972,616, filed Sep. 14, 2007; inventor: Imad Libbus et al.
U.S. Appl. No. 60/972,629, filed Sep. 14, 2007; inventor: Mark Bly et al.
U.S. Appl. No. 61/035,970, filed Mar. 12, 2008; inventor: Imad Libbus et al.
U.S. Appl. No. 61/046,196, filed Apr. 18, 2008; inventor: Scott T. Mazar.
U.S. Appl. No. 61/047,875, filed Apr. 25, 2008; inventor: Imad Libbus et al.
U.S. Appl. No. 61/055,645, filed May 23, 2008; inventor: Mark Bly et al.
U.S. Appl. No. 61/055,656, filed May 23, 2008; inventor: Imad Libbus et al.
U.S. Appl. No. 61/055,662, filed May 23, 2008; inventor: Imad Libbus et al.
U.S. Appl. No. 61/055,666, filed May 23, 2008; inventor: Yatheendhar Manicka et al.
U.S. Appl. No. 61/079,746, filed Jul. 10, 2008; inventor: Brett Landrum.
U.S. Appl. No. 61/084,567, filed Jul. 29, 2008; inventor: Mark Bly.

* cited by examiner

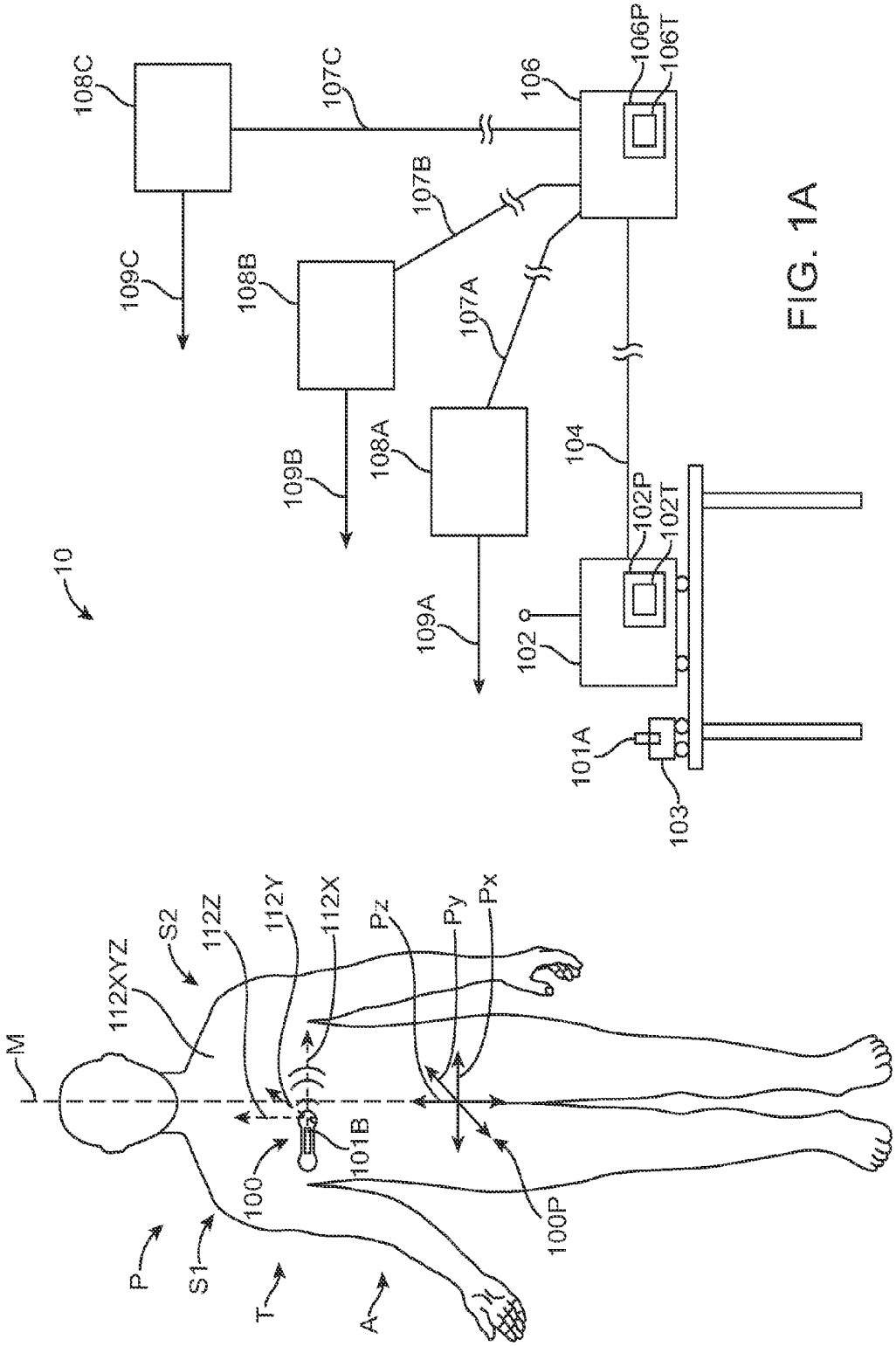
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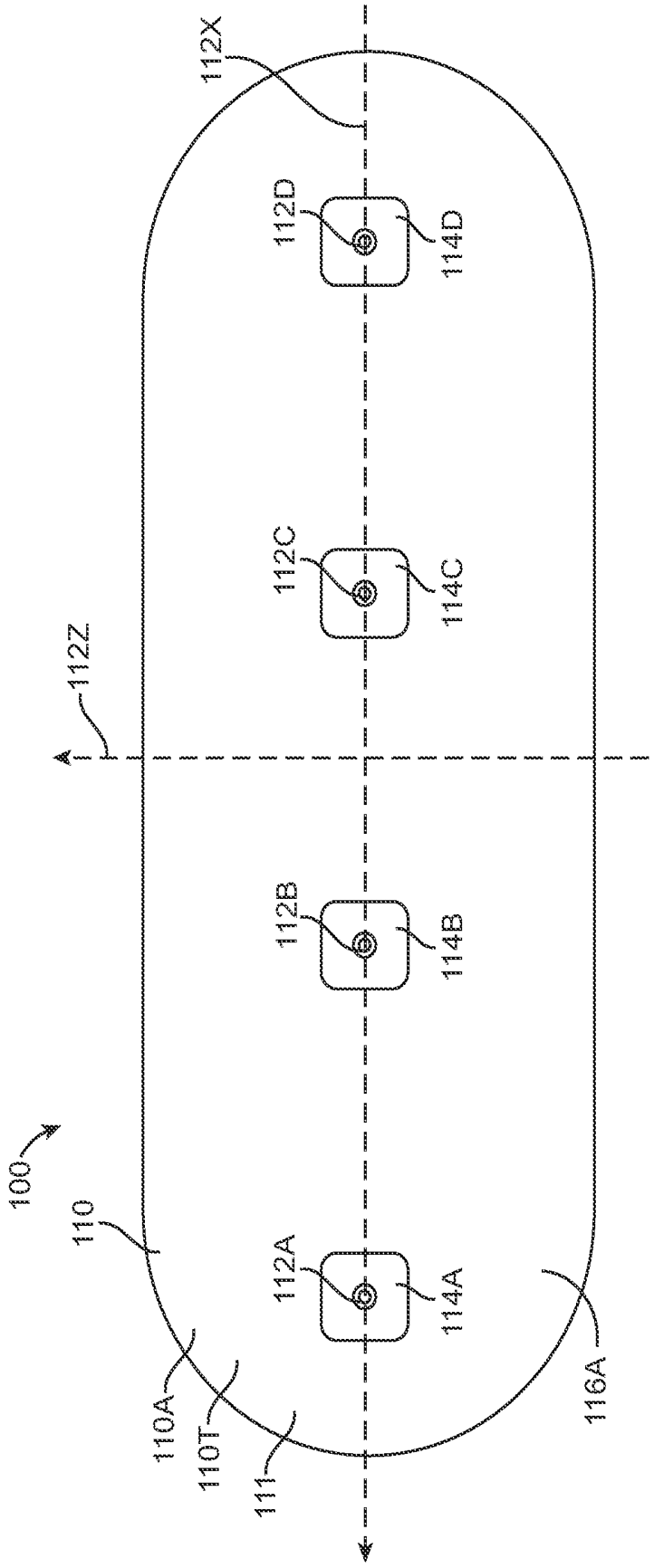
FIG. 1A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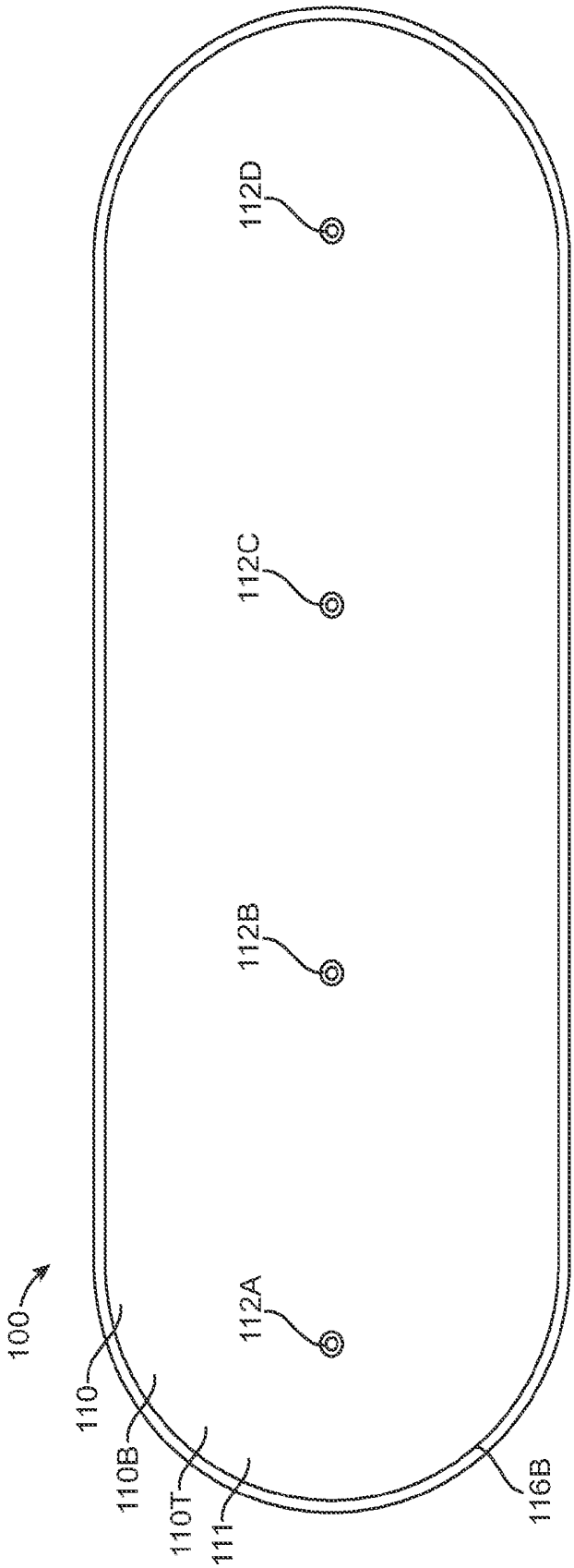

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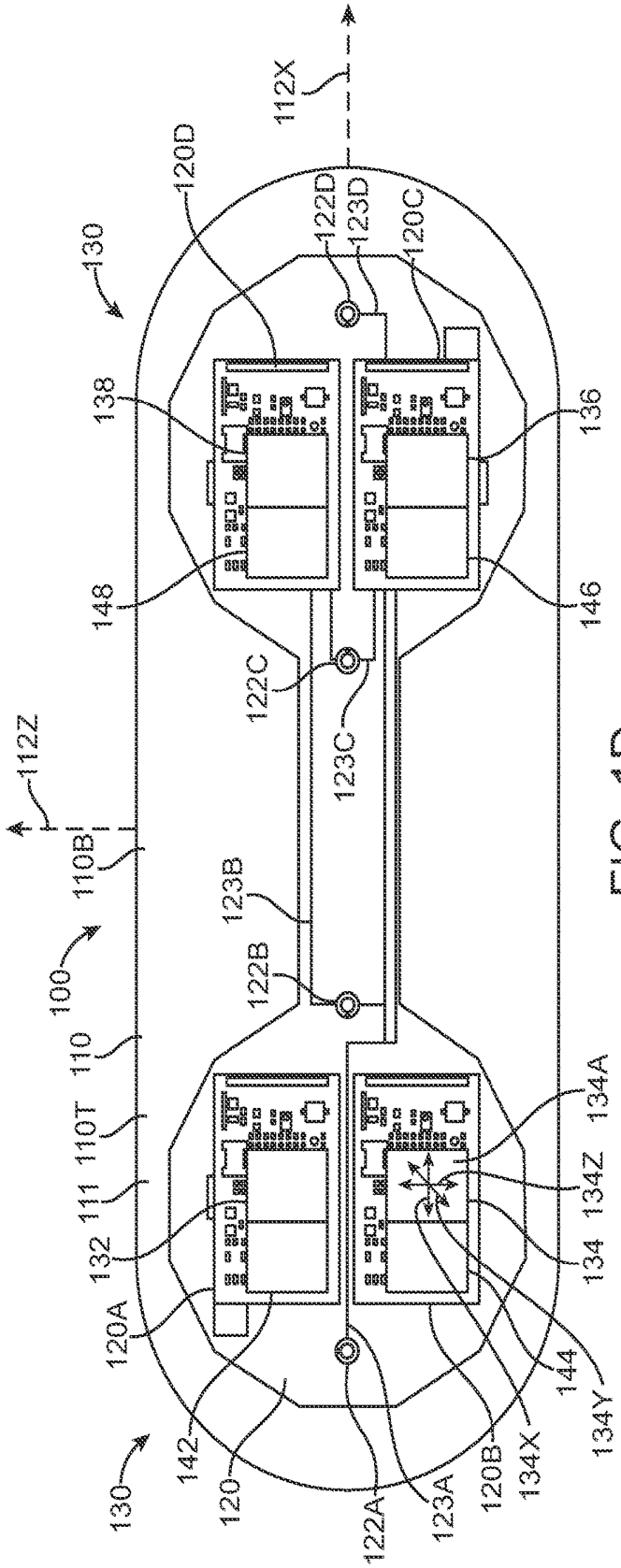

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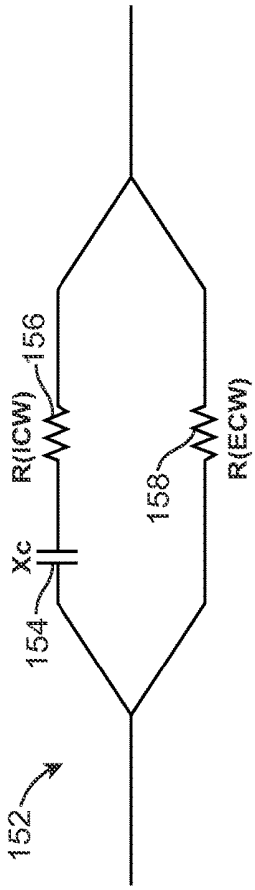


FIG. 1D1

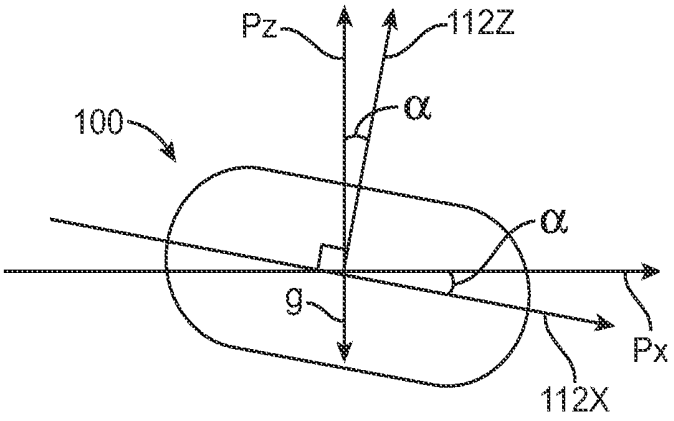
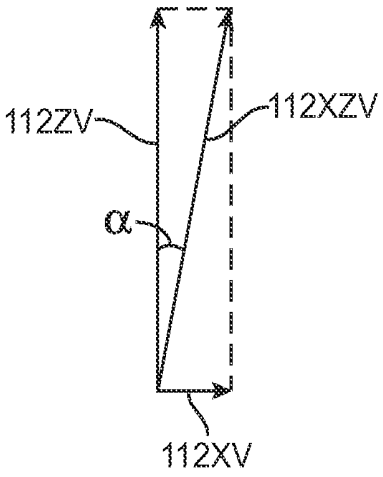


FIG. 1D2



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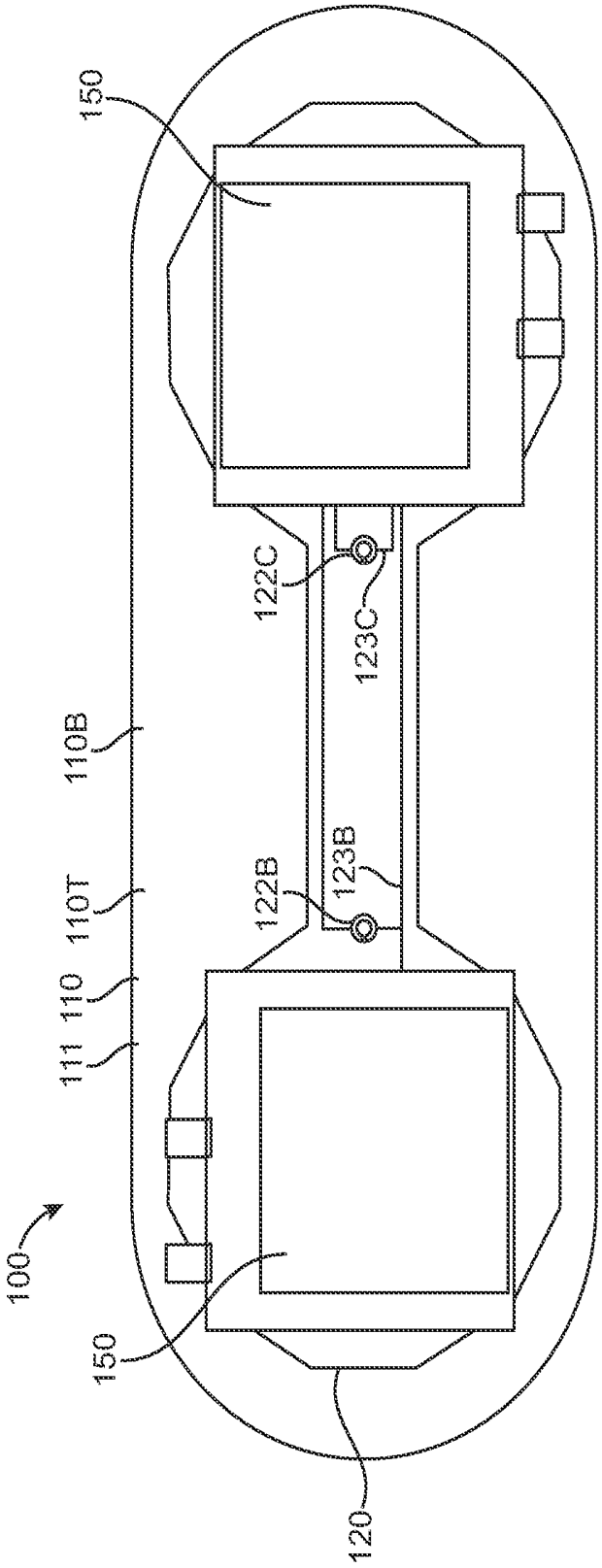

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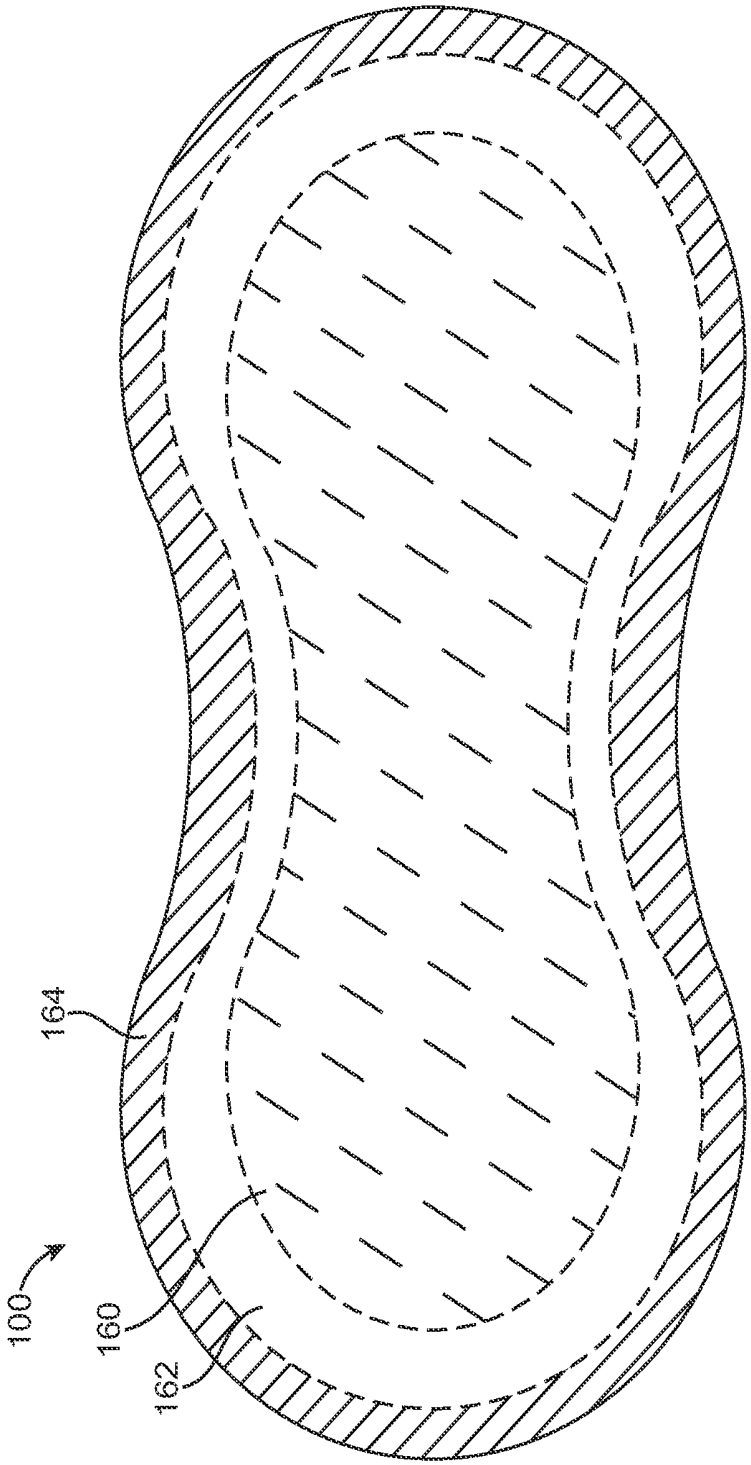

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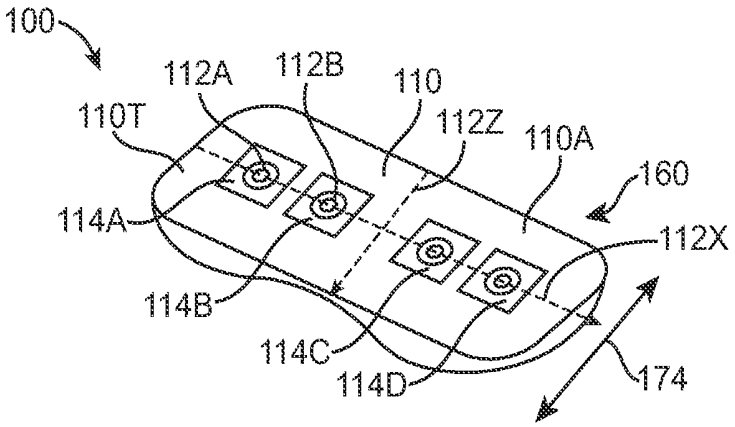
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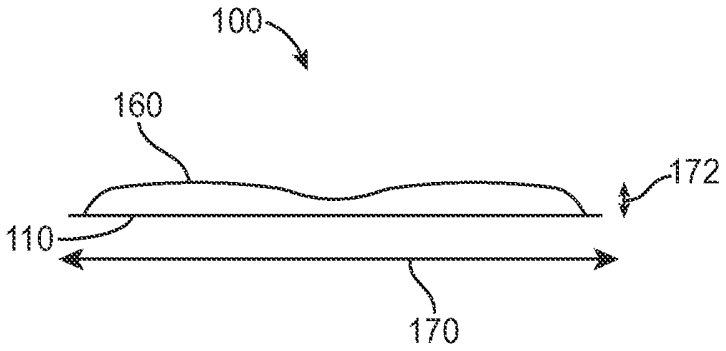
174

FIG. 1H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160
172
110
170

FIG. 1G

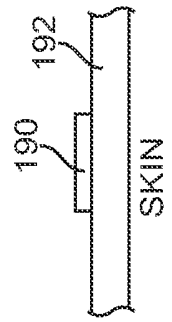
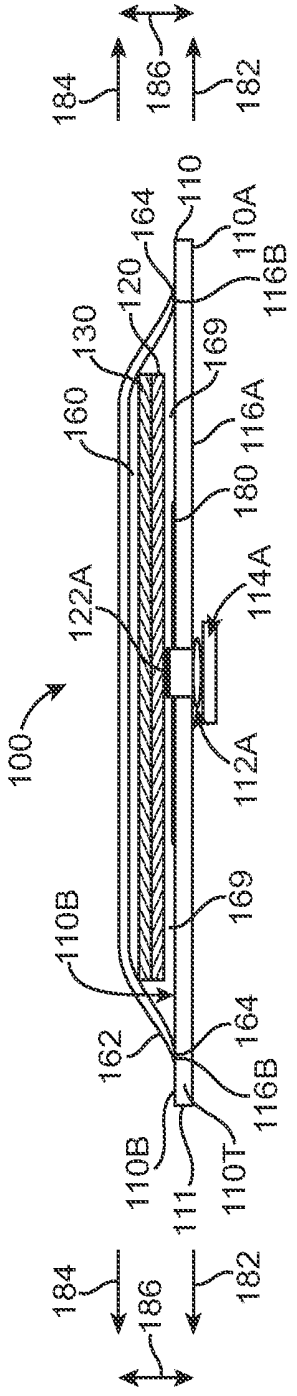

190
192
SKIN

FIG. 1K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116A
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114A
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110B
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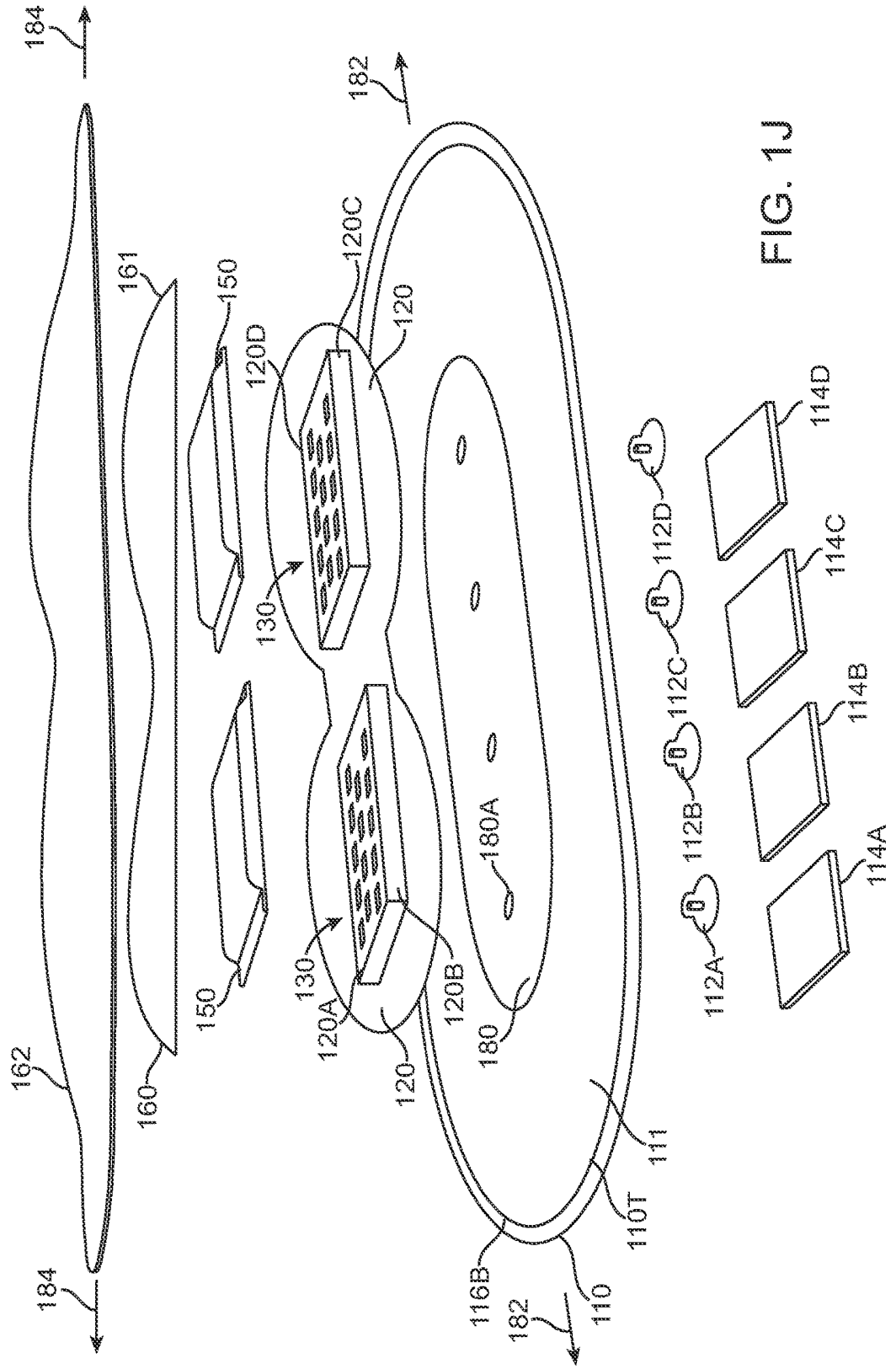
162
164
116B
110B
111
110T
184
186
182

FIG. 1T


184
182
161
150
120C
120D
120
130
112D
114D
114C
112C
114B
112B
112A
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120B
180
120
162
160
111
110T
116B
110
182
184

FIG. 1J

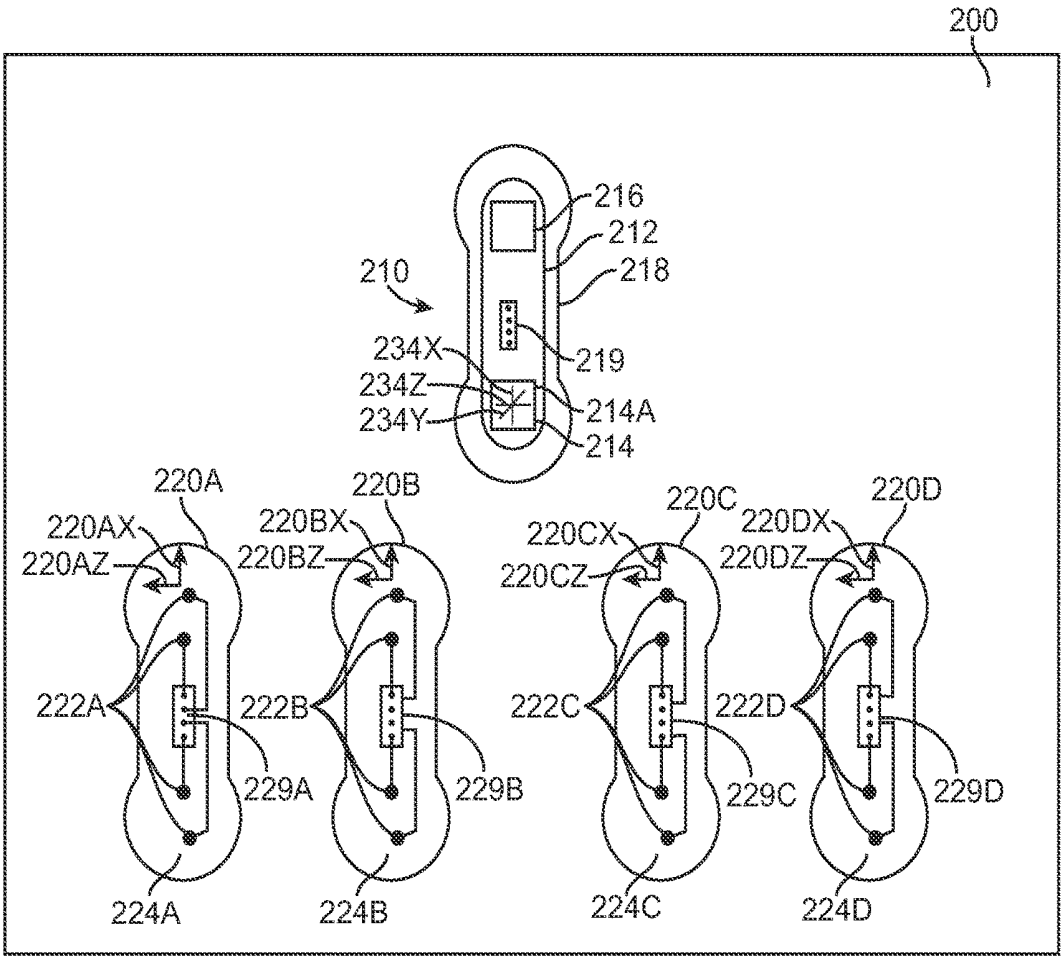


FIG. 2A

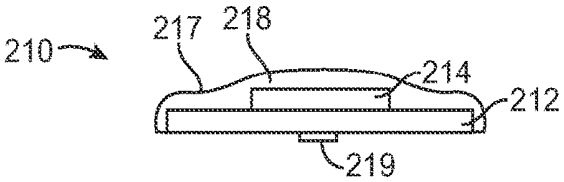


FIG. 2B

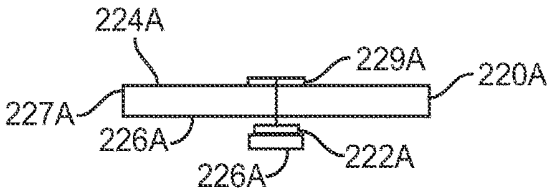
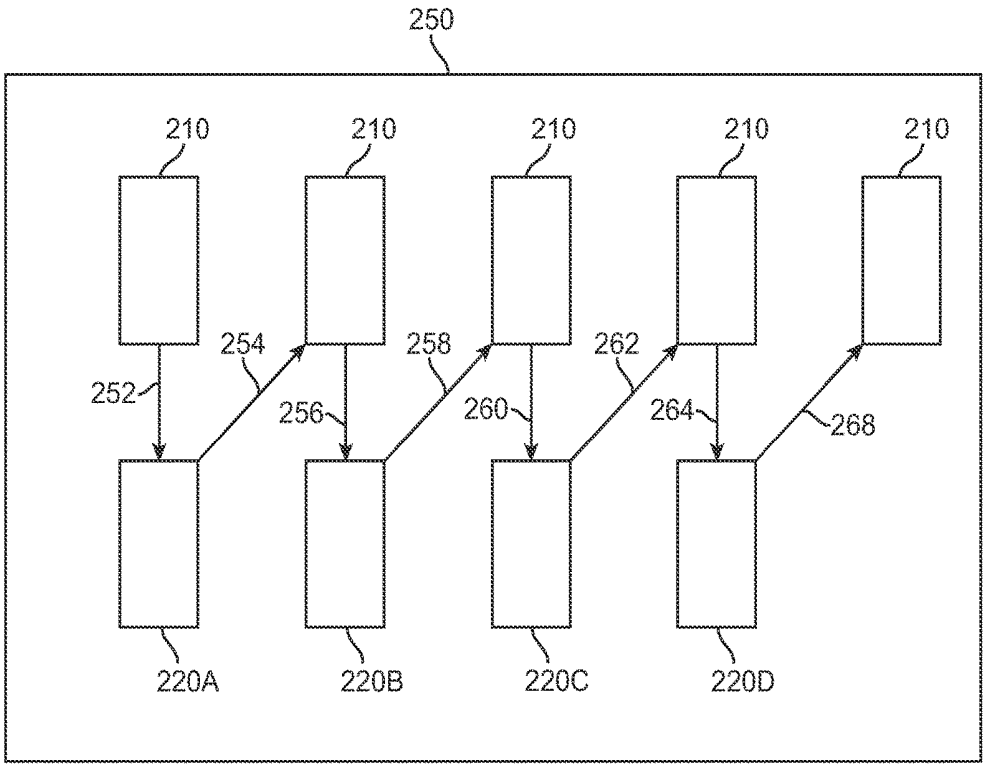


FIG. 2C


250
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260
262
264
268
220A
220B
220C
220D

FIG. 2D

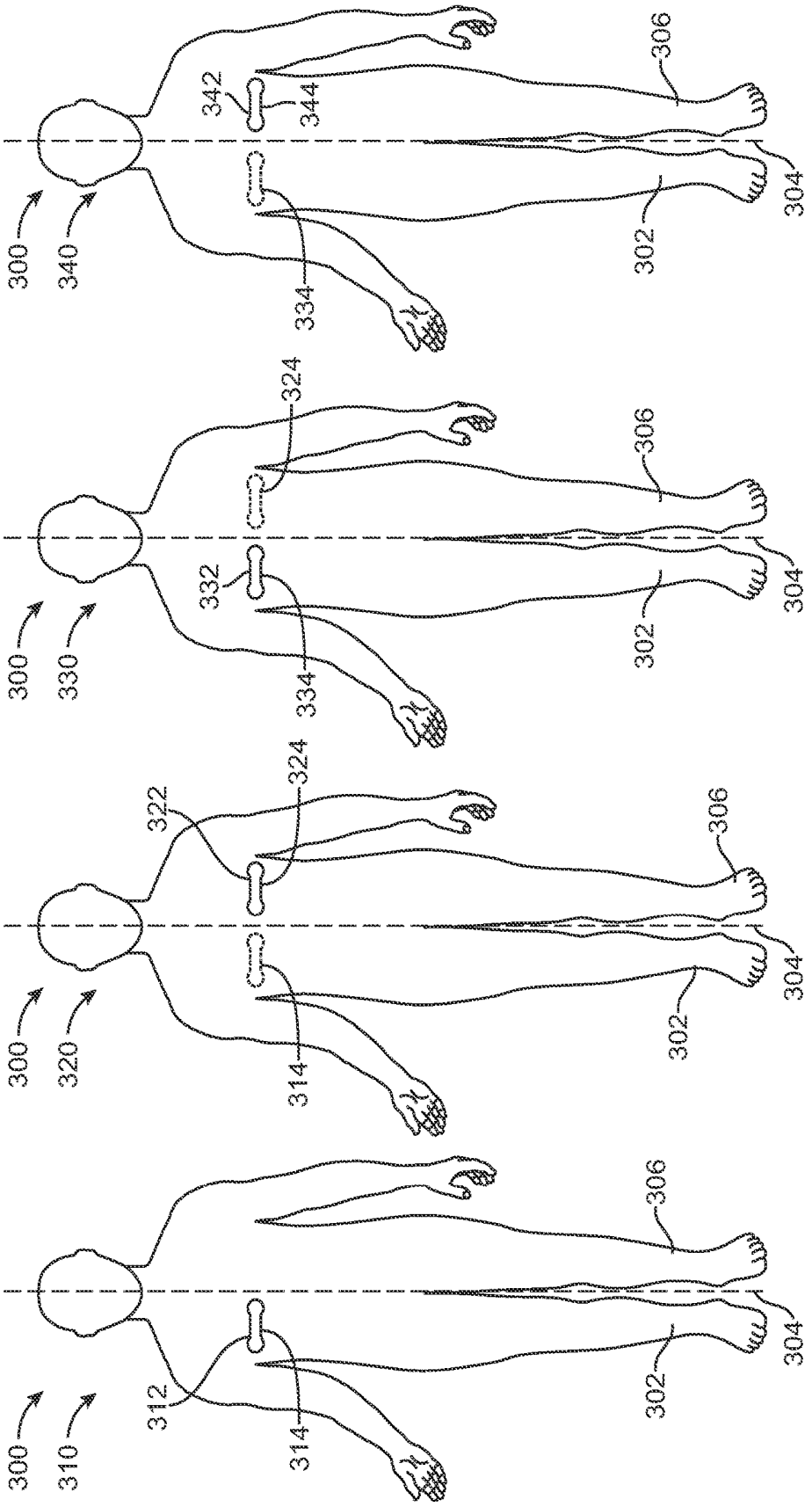

FIG. 3A

FIG. 3B

FIG. 3C

FIG. 3D

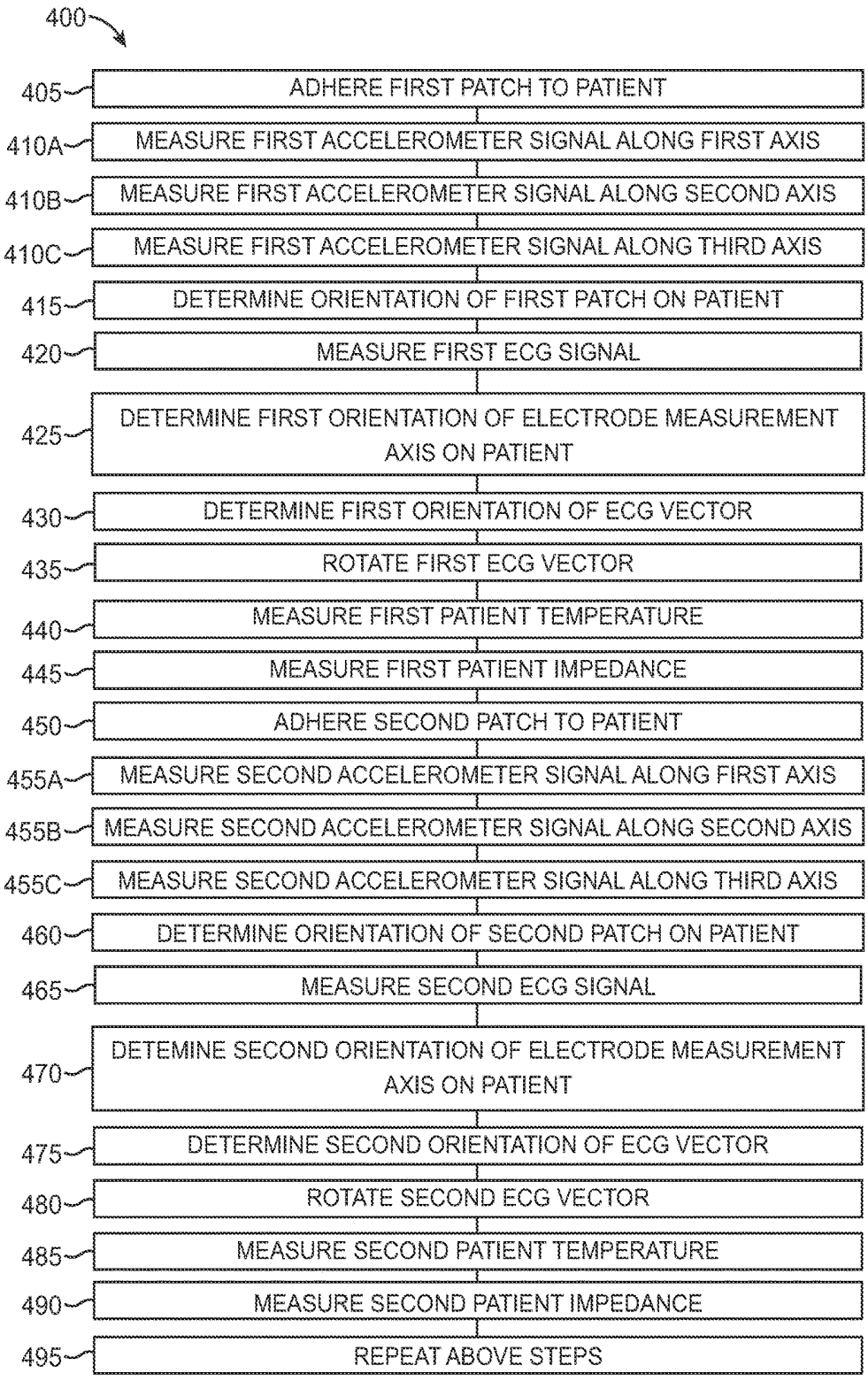
400
405
ADHERE FIRST PATCH TO PATIENT
410A
MEASURE FIRST ACCELEROMETER SIGNAL ALONG FIRST AXIS
410B
MEASURE FIRST ACCELEROMETER SIGNAL ALONG SECOND AXIS
410C
MEASURE FIRST ACCELEROMETER SIGNAL ALONG THIRD AXIS
415
DETERMINE ORIENTATION OF FIRST PATCH ON PATIENT
420
MEASURE FIRST ECG SIGNAL
425
DETERMINE FIRST ORIENTATION OF ELECTRODE MEASUREMENT AXIS ON PATIENT
430
DETERMINE FIRST ORIENTATION OF ECG VECTOR
435
ROTATE FIRST ECG VECTOR
440
MEASURE FIRST PATIENT TEMPERATURE
445
MEASURE FIRST PATIENT IMPEDANCE
450
ADHERE SECOND PATCH TO PATIENT
455A
MEASURE SECOND ACCELEROMETER SIGNAL ALONG FIRST AXIS
455B
MEASURE SECOND ACCELEROMETER SIGNAL ALONG SECOND AXIS
455C
MEASURE SECOND ACCELEROMETER SIGNAL ALONG THIRD AXIS
460
DETERMINE ORIENTATION OF SECOND PATCH ON PATIENT
465
MEASURE SECOND ECG SIGNAL
470
DETEMINE SECOND ORIENTATION OF ELECTRODE MEASUREMENT AXIS ON PATIENT
475
DETERMINE SECOND ORIENTATION OF ECG VECTOR
480
ROTATE SECOND ECG VECTOR
485
MEASURE SECOND PATIENT TEMPERATURE
490
MEASURE SECOND PATIENT IMPEDANCE
495
REPEAT ABOVE STEPS

FIG. 4A

ADHERENT CARDIAC MONITOR WITH ADVANCED SENSING CAPABILITIES

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a divisional of U.S. Non-Provisional application Ser. No. 12/209,265 filed on Sep. 12, 2008, which claims the benefit under 35 USC 119(e) of U.S. Provisional Application Nos. 60/972,537 filed Sep. 14, 2007, 61/055,666 and 61/055,662 both of which were filed May 23, 2008; the full disclosures of each of which are incorporated herein by reference in their entirety.

The subject matter of the present application is related to the following applications: 60/972,512; 60/972,329; 60/972,354; 60/972,616; 60/972,363; 60/972,343; 60/972,581; 60/972,629; 60/972,316; 60/972,333; 60/972,359; 60/972,336; 60/972,340 all of which were filed on Sep. 14, 2007; 61/046,196 filed Apr. 18, 2008; 61/047,875 filed Apr. 25, 2008; 61/055,645, 61/055,656 all filed May 23, 2008; and 61/079,746 filed Jul. 10, 2008.

The following applications are being filed concurrently with the present application, on Sep. 12, 2008: U.S. Application No. 12/209,279 entitled "Multi-Sensor Patient Monitor to Detect Impending Cardiac Decompensation Prediction"; 026843-000220US entitled "Adherent Device with Multiple Physiological Sensors"; 026843-000410US entitled "Injectable Device for Physiological Monitoring"; 026843-000510US entitled "Delivery System for Injectable Physiological Monitoring System"; 026843-000620US entitled "Adherent Device for Cardiac Rhythm Management"; 026843-000710US entitled "Adherent Device for Respiratory Monitoring"; 026843-000810US entitled "Adherent Athletic Monitor"; 026843-000910US entitled "Adherent Emergency Monitor"; 026843-001320US entitled "Adherent Device with Physiological Sensors"; 026843-001410US entitled "Medical Device Automatic Start-up upon Contact to Patient Tissue"; 026843-001900US entitled "System and Methods for Wireless Body Fluid Monitoring"; 026843-002410US entitled "Adherent Device for Sleep Disordered Breathing"; 026843-002710US entitled "Dynamic Pairing of Patients to Data Collection Gateways"; 026843-003010US entitled "Adherent Multi-Sensor Device with Implantable Device Communications Capabilities"; 026843-003110US entitled "Data Collection in a Multi-Sensor Patient Monitor"; 026843-003210US entitled "Adherent Multi-Sensor Device with Empathic Monitoring"; 026843-003310US entitled "Energy Management for Adherent Patient Monitor"; and 026843-003410US entitled "Tracking and Security for Adherent Patient Monitor."

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to patient monitoring. Although embodiments make specific reference to monitoring impedance and electrocardiogram signals with an adherent patch, the system methods and device described herein may be applicable to many applications in which physiological monitoring is used, for example wireless physiological monitoring for extended periods.

Patients are often treated for diseases and/or conditions associated with a compromised status of the patient, for example a compromised physiologic status. In some instances, a patient may report symptoms that require diagnosis to determine the underlying cause. For example, a patient may report fainting or dizziness that requires diagnosis, in which long term monitoring of the patient can provide useful information as to the physiologic status of the patient. In some instances a patient may have suffered a heart attack and require care and/or monitoring after release from the hospital. One example of a device to provide long term monitoring of a patient is the Holter monitor, or ambulatory electrocardiography device.

In addition to measuring heart signals with electrocardiograms, known physiologic measurements include impedance measurements. For example, transthoracic impedance measurements can be used to measure hydration and respiration.

Work in relation to embodiments of the present invention suggests that known methods and apparatus for long term monitoring of patients may be less than ideal. Although transthoracic measurements can be useful, such measurements may use electrodes that may be somewhat uncomfortable and/or cumbersome for the patient to wear. Also, it would be helpful to detect subtle changes in patient physiology, for example based on subtle changes in electrocardiogram signals and/or patient hydration signals. In at least some instances, electrodes that are held against the skin of the patient can become detached and/or dehydrated, such that the electrodes must be replaced. Replacement of electrodes can result in a change in the orientation of the electrodes that may affect the measured signal in at least some instances. Examples of physiological measurements that may be affected by electrode placement include electrocardiogram signals and tissue impedance signals to measure hydration and/or respiration of a patient. Therefore, a need exists to improve the quality of long term patient measurements with external devices, for example those worn by the patient.

Although implantable devices may be used in some instances, many of these devices can be invasive and/or costly, and may suffer at least some of the shortcomings of known wearable devices.

Therefore, a need exists for improved patient monitoring. Ideally, such improved patient monitoring would avoid at least some of the short-comings of the present methods and devices.

2. Description of the Background Art

The following US Patents and Publications may describe relevant background art: U.S. Pat. Nos. 4,121,573; 4,478,223; 4,850,370; 4,955,381; 4,981,139; 5,080,099; 5,125,412; 5,331,966; 5,353,793; 5,511,553; 5,544,661; 5,558,638; 5,724,025; 5,772,586; 5,862,802; 5,970,986; 5,987,352; 6,047,203; 6,052,615; 6,117,077; 6,129,744; 6,225,901; 6,385,473; 6,416,471; 6,454,707; 6,480,733; 6,496,715; 6,527,711; 6,527,729; 6,551,252; 6,595,927; 6,595,929; 6,605,038; 6,611,705; 6,645,153; 6,699,200; 6,821,249; 6,912,414; 6,881,191; 6,980,851; 7,020,508; 7,054,679; 7,153,262; 7,206,630; 2002/0045836; 2003/0092975; 2003/0149349; 2005/0065445; 2005/0113703; 2005/0131288; 2005/0267381; 2006/0010090; 2006/0031102; 2006/0089679; 2006/0116592; 2006/0122474; 2006/0155183; 2006/0253044; 2006/0224051; 2006/0264730; 2007/0016089; 2007/0021678; 2007/0038038; 2007/0073132; 2007/0142715; 2007/0167849; 2007/0167850; and 2007/0208233.

BRIEF SUMMARY OF THE INVENTION

The present invention relates to patient monitoring. Although embodiments make specific reference to monitoring impedance and electrocardiogram signals with an adher-

ent patch, the system methods and device described herein may be applicable to any application in which physiological monitoring is used, for example wireless physiological monitoring for extended periods.

In many embodiments, an adherent device comprises an adhesive patch with at least two electrodes and an accelerometer. The accelerometer can be used to determine an orientation of the at least two measurement electrodes on a patient, for example a measurement axis defined by the at least two electrodes. This use of the accelerometer and the at least two measurement electrodes can be particularly advantageous with patient monitoring for an extended period, for example when it is desirable to detect subtle changes in patient physiology and the adherent patch with electrodes is replaced. By determining the orientation of the electrodes of the patch on the patient, physiologic measurements with the at least two electrodes can be adjusted and/or corrected in response to the orientation of the patch on the patient. In many embodiments, the accelerometer may be oriented with respect to an electrode measurement axis in a predetermined configuration, which can facilitate determination of the electrode measurement axis in response to the accelerometer signal. In many embodiments, the adherent patch and/or electrodes are replaced with a second adherent patch and/or electrodes, and the orientation of the second adherent patch and/or electrodes determined with the accelerometer or a second accelerometer. The determined orientation of the second patch and/or electrodes on the patient can be used to correct measurements made with the second adherent patch and/or electrodes, such that errors associated with the alignment of the first and second patch on the patient can be minimized, even inhibited.

In a first aspect, embodiments of the present invention provide a method of monitoring a patient. An adherent device is adhered to a skin of the patient. The adherent device comprises an accelerometer and at least two measurement electrodes. The at least two measurement electrodes can be separated by a distance to define an electrode measurement axis. An accelerometer signal is measured when the device is adhered to the patient. An orientation of the electrode measurement axis on the patient is determined in response to the accelerometer signal.

In many embodiments, the accelerometer comprises at least one measurement axis sensitive to gravity aligned with the electrode measurement axis. The at least one accelerometer measurement axis can be configured to extend substantially horizontally on the patient when the device is adhered to the patient. The accelerometer signal may correspond to at least one accelerometer measurement vector in a direction along the at least one accelerometer measurement axis.

In many embodiments, the accelerometer comprises at least one accelerometer measurement axis sensitive to gravity, and the at least one accelerometer measurement axis is oriented with respect to the electrode measurement axis in a predetermined configuration.

The at least two electrodes may comprise a positive electrode and a negative electrode that define an orientation of an electrode measurement vector along the electrode measurement axis. The accelerometer signal may correspond to at least one accelerometer measurement vector that extends away from the electrode measurement axis. The at least one accelerometer measurement vector can be sensitive to gravity such that the accelerometer signal indicates when the patch adhered to the patient is upside down.

In many embodiments, the adherent device comprises an adherent surface to adhere to a skin of the patient, and electrode measurement axis extends along the adherent surface. The accelerometer may comprise three axes, and a first axis and a second axis of the three axes may extend along the measurement surface. A third axis of the three axes may extend away from the measurement surface.

In a specific embodiment, the accelerometer measurement signal may correspond to three orthogonal measurement vectors and each of the three orthogonal measurement vectors can extends along one of the accelerometer measurement axes.

In many embodiments, an electrocardiogram signal is measured with the at least two measurement electrodes, and the electrocardiogram signal is modified in response to the accelerometer signal. For example, the electrocardiogram vector can be rotated in response to the accelerometer signal to obtain a standard electrocardiogram vector. As a result of the rotation, the amplitude and direction of electrocardiogram features can be modified so as to approximate those of a standard electrocardiogram vector.

In another aspect, embodiments of the present invention provide a method of monitoring a patient. A first adherent patch is adhered to a skin of the patient, and the first patch comprises an adhesive and electrodes. A first accelerometer signal is measured when the first adherent patch is adhered to the patient. A second adherent patch is adhered to the skin of the patient, and the second patch comprises an adhesive and electrodes. A second accelerometer signal is measured when the second adherent patch is adhered to the patient. An orientation on the patient of at least one of the first patch or the second patch is determined in response to at least one of the first accelerometer signal or the second accelerometer signal.

In many embodiments, a first electrocardiogram signal is measured when the first adherent patch is adhered to the patient. A second electrocardiogram signal is measured when the second adherent patch is adhered to the patient. At least one of the first electrocardiogram signal or the second electrocardiogram signal is adjusted in response to at least one of the first accelerometer signal or the second accelerometer signal.

In another aspect, embodiments of the present invention provide a method of monitoring a patient. A first adherent measurement device is adhered to a skin of the patient. The first adherent measurement device comprises a first accelerometer and a first at least two measurement electrodes. A second adherent measurement device is adhered to a skin of the patient. The second adherent measurement device comprises a second accelerometer and a second at least two measurement electrodes. A first accelerometer signal is measured and a first electrocardiogram signal is measured with the first at least two measurement electrodes. The first accelerometer signal and the first electrocardiogram signal are measured when the first adherent measurement device is adhered to the skin of the patient. A second accelerometer signal is measured and a second electrocardiogram signal is measured with the second at least two measurement electrodes. The second accelerometer signal and the second electrocardiogram signal are measured when the second adherent measurement device is adhered to the skin of the patient. The first electrocardiogram signal is combined with the second electrocardiogram signal in response to the first accelerometer signal and the second accelerometer signal. The electrocardiogram signals can be combined by summing a scaled version of each signal.

In many embodiments, the first accelerometer comprises a first accelerometer measurement axis and the first at least two electrodes are separated by a first distance to define a

first electrode measurement axis. The first accelerometer measurement axis can be aligned with the first electrode measurement axis. The second accelerometer may comprise a second accelerometer measurement axis and the second at least two electrodes can be separated by a second distance to define a second electrode measurement axis. The second accelerometer measurement axis may be aligned with the second electrode measurement axis.

In many embodiments, an orientation of the first electrode measurement axis is determined in response to the first accelerometer signal. An orientation of the second electrode measurement axis is determined in response to the to the accelerometer signal.

In many embodiments, the first electrocardiogram signal is combined with the second electrocardiogram signal when the second adherent measurement device is adhered to the skin of the patient.

In another aspect, embodiments of the present invention provide a device for monitoring a patient. The device comprises a support with an adhesive to adhere to a skin of the patient, and an accelerometer to generate an accelerometer signal with the accelerometer supported with the support. At least two measurement electrodes are supported with the support, and the at least two measurement electrodes are separated by a distance to define an electrode measurement axis. The device comprises circuitry to measure the accelerometer signal when the device is adhered to the patient. A processor comprises a tangible medium configured to determine an orientation of the electrode measurement axis on the patient in response to the accelerometer signal.

In many embodiments, the support comprises an adhesive patch with an adhesive to adhere the support, to the patient. The adhesive patch may comprise a breathable tape with adhesive to adhere the support to the patient.

In many embodiments, the accelerometer comprises at least one measurement axis sensitive to gravity aligned with the electrode measurement axis. The accelerometer may comprise at least one accelerometer measurement axis sensitive to gravity, and the accelerometer may be positioned and supported with the support such that the measurement axis extends substantially horizontally on the patient when the support is adhered to the patient.

In many embodiments, the accelerometer signal corresponds to at least one accelerometer measurement vector along the at least one accelerometer measurement axis.

In many embodiments, the accelerometer comprises at least one accelerometer measurement axis sensitive to gravity, and the at least one accelerometer measurement axis is oriented with respect to the electrode measurement axis in a predetermined configuration. The at least two electrodes may comprise a positive electrode and a negative electrode that define an orientation of an electrode measurement vector along the electrode measurement axis.

In many embodiments, the accelerometer signal corresponds to at least one measurement vector that extends away from the electrode measurement axis such that the accelerometer signal indicates when the patch adhered to the patient is upside down.

In many embodiments, the adherent device comprises an adherent surface to adhere to a skin of the patient, and the electrode measurement axis extends along the adherent surface. The accelerometer may comprise three axes, and a first axis and a second axis of the three axes can extend along the adherent surface. A third axis of the three axes can extend away from the adherent surface.

In many embodiments, the accelerometer signal corresponds to three orthogonal measurement vectors, and each of the three orthogonal measurement vectors extends along one of the accelerometer measurement axes.

In many embodiments, measurement circuitry is coupled to the at least two measurement electrode to measure an electrocardiogram signal. A processor is coupled to the measurement circuitry and comprises a tangible medium configured to modify the electrocardiogram signal in response to the accelerometer signal.

In another aspect, embodiments of the present invention provide a system for monitoring a patient. The system comprises a first support, with a first adhesive to adhere to a skin of the patient. First electrodes are supported with the support to couple to the skin of the patient. The system comprises a second support with a second adhesive to adhere to the skin of the patient. Second electrodes are supported with the second support to couple to the skin of the patient. At least one accelerometer is coupled to at least one of the first support or the second support to determine an orientation of at least one of the first electrodes or the second electrodes when the at least one of the first electrodes or the second electrodes are coupled to the patient.

In many embodiments, the at least one accelerometer comprises a first accelerometer removably coupled to the first support in a first predetermined orientation and a second accelerometer removably coupled to the second support in a second predetermined orientation.

In many embodiments, the at least one accelerometer comprises an accelerometer removably coupled to the first support in a first predetermined orientation and wherein the accelerometer is removably coupled to the second support in a second predetermined orientation such that the accelerometer can be reused.

In many embodiments, the first support with the first adhesive comprises a first breathable tape and the second support with the second adhesive comprises a second breathable tape.

In another aspect, embodiments of the present invention provide a system for monitoring a patient. The system comprises a first adherent measurement device comprising a first support with a first adhesive to adhere the first support to a skin of the patient. The first adherent measurement device comprises a first accelerometer and a first at least two measurement electrodes. The first adherent device comprises first measurement circuitry to measure a first accelerometer signal with the accelerometer and a first electrocardiogram signal with the first at least two measurement electrodes. A second adherent measurement device comprises a second support with a second adhesive to adhere the second support to a skin of the patient. The second adherent measurement device comprises a second accelerometer and a second at least two measurement electrodes. The second accelerometer comprises second circuitry to measure a second accelerometer signal with the second accelerometer and a second electrocardiogram signal with the second at least two measurement electrodes. A processor system comprises a tangible medium configured to combine the first electrocardiogram signal with the second electrocardiogram signal in response to the first accelerometer signal and the second accelerometer signal.

In many embodiments, the first accelerometer comprises a first accelerometer measurement axis and the first at least two electrodes are separated by a first distance to define a first electrode measurement axis. The first accelerometer measurement axis is aligned with the first electrode measurement axis. The second accelerometer comprises a sec-

ond accelerometer measurement axis and the second at least two electrodes are separated by a second distance to define a second electrode measurement axis. The second accelerometer measurement axis may be aligned with the second electrode measurement axis. The processor system can be configured to determine an orientation of the first electrode measurement axis in response to the first accelerometer signal and determine an orientation of the second electrode measurement axis in response to the to the accelerometer signal.

The processor system may comprise at least one processor supported with at least one of the first support or the second support, and the at least one processor can be configured to combine the first electrocardiogram signal with the second electrocardiogram signal in response to the first accelerometer signal and the second accelerometer signal. Combining may include scaling each signal and summing the signals together.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**A shows a patient and a monitoring system comprising an adherent device, according to embodiments of the present invention;

FIG. **1**B shows a bottom view of the adherent device as in FIG. **1**A comprising an adherent patch;

FIG. **1**C shows a top view of the adherent patch, as in FIG. **1**B;

FIG. **1**D shows a printed circuit boards and electronic components over the adherent patch, as in FIG. **1**C;

FIG. **1**D**1** shows an equivalent circuit that can be used to determine optimal frequencies for determining patient hydration, according to embodiments of the present invention;

FIG. **1**D**2** shows an adherent devices as in FIGS. **1**A-**1**D positioned on a patient to determine orientation of the adherent patch on the patient, according to embodiments of the present invention;

FIG. **1**D**3** shows vectors from a 3D accelerometer to determine orientation of the measurement axis of the patch adhered on the patient, according to embodiments of the present invention;

FIG. **1**E shows batteries positioned over the printed circuit board and electronic components as in FIG. **1**D;

FIG. **1**F shows a top view of an electronics housing and a breathable cover over the batteries, electronic components and printed circuit board as in FIG. **1**E;

FIG. **1**G shows a side view of the adherent device as in FIGS. **1**A to **1**F;

FIG. **1**H shown a bottom isometric view of the adherent device as in FIGS. **1**A to **1**G;

FIGS. **1**I and **1**J show a side cross-sectional view and an exploded view, respectively, of the adherent device as in FIGS. **1**A to **1**H;

FIG. **1**K shows at least one electrode configured to electrically couple to a skin of the patient through a breathable tape, according to embodiments of the present invention;

FIGS. **2**A to **2**C show a system to monitor a patient for an extended period comprising a reusable electronic component and a plurality of disposable patch components, according to embodiments of the present invention;

FIG. **2**D shows a method of using the system as in FIGS. **2**A to **2**C;

FIGS. **3**A to **3**D show a method of monitoring a patient for an extended period with an adherent patch with adherent patches alternatively adhered to the right side or the left side of the patient; and

FIG. **4**A shows a method of monitoring a patient, according to embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

Embodiments of the present invention relate to patient monitoring. Although embodiments make specific reference to monitoring impedance and electrocardiogram signals with an adherent patch, the system methods and device described herein may be applicable to any application in which physiological monitoring is used, for example wireless physiological monitoring for extended periods.

In many embodiments, an adherent device comprises an adhesive patch with at least two electrodes and an accelerometer. The accelerometer can be used to determine an orientation of the at least two measurement electrodes on a patient, for example a measurement axis defined by the at least two electrodes. This use of the accelerometer and the at least two measurement electrodes can be particularly advantageous with patient monitoring for an extended period, for example when it is desirable to detect subtle changes in patient physiology and the adherent patch with electrodes is replaced. By determining the orientation of the electrodes of the patch on the patient, physiologic measurements with the at least two electrodes can be adjusted and/or corrected in response to the orientation of the patch on the patient. In many embodiments, the accelerometer may be oriented with respect to an electrode measurement axis in a predetermined configuration, which can facilitate determination of the electrode measurement axis in response to the accelerometer signal. In many embodiments, the adherent patch and/or electrodes are replaced with a second adherent patch and/or electrodes, and the orientation of the second adherent patch and/or electrodes determined with the accelerometer or a second accelerometer. The determined orientation of the second patch and/or electrodes on the patient can be used to correct measurements made with the second adherent patch and/or electrodes, such that errors associated with the alignment of the first and second patch on the patient can be minimized, even inhibited.

As used herein, an adhesive patch encompasses a piece of soft material with an adhesive that can cover a part of the body.

In many embodiments, the adherent devices described herein may be used for 90 day monitoring, or more, and may comprise completely disposable components and/or reusable components, and can provide reliable data acquisition and transfer. In many embodiments, the patch is configured for patient comfort, such that the patch can be worn and/or tolerated by the patient for extended periods, for example 90 days or more. In many embodiments, the adherent patch comprises a tape, which comprises a material, preferably breathable, with an adhesive, such that trauma to the patient skin can be minimized while the patch is worn for the extended period. In many embodiments, the printed circuit board comprises a flex printed circuit board that can flex with the patient to provide improved patient comfort.

FIG. **1**A shows a patient P and a monitoring system **10**. Patient P comprises a midline M, a first side S**1**, for example a right side, and a second side S**2**, for example a left side. Monitoring system **10** comprises an adherent device **100**. Adherent device **100** can be adhered to a patient P at many

locations, for example thorax T of patient P. In many embodiments, the adherent device may adhere to one side of the patient, from which side data can be collected. Work in relation with embodiments of the present invention suggests that location on a side of the patient can provide comfort for the patient while the device is adhered to the patient.

Adherent device **100** can be aligned and/or oriented with respect to axes of patient P. Orientation of adherent device **100** can comprise orientation of device **100** with a patient coordinate system **100**P aligned with axes of the patient. Patient P comprises a horizontal axis Px that extends laterally from one side of the patient to the other, for example from side S1 to side S1 across midline M. Patient P comprises an anterior posterior axis Py that extends from the front, or anterior, of the patient to the back, or posterior of the patient. Patient P comprises a vertical axis Pz that extends vertically along the patient, for example vertically along the midline of the patient from the feet of the patient toward the head of the patient. In many embodiments, horizontal axis Px, anterior posterior axis Py and vertical axis Pz may comprise a right handed triple of orthogonal coordinate references.

Adherent device **100** may comprise a 3D coordinate reference system **112**XYZ. Device **100** may comprise an X-axis **112**X for alignment with horizontal axis Px of the patient, a Y-axis for alignment with anterior posterior axis Py of the patient and a Z axis for alignment with vertical axis Pz of the patient. Coordinate reference system **112**XYZ may comprise X-axis **112**X, Y-axis **112**Y and Z-axis **112**Z. Coordinate reference system **112**XYZ may comprise a right handed triple, although other non-orthogonal and orthogonal reference systems may be used.

Adherent device **100** may comprise indicia for alignment with an axis of the patient. The indicia can be used to align at least one axis of device **100** with at least one axis of the patient. The indicia, can be positioned on at least one of the adherent patch, a cover, or an electronics module. The indicia can be visible to the patient and or a care provider to adhere device **100** to the patient in alignment with at least one axis of the patient. A vertical line along Z-axis **112**Z can indicate vertical axis **112**Z to the patient and/or care provider, and a horizontal line along X-axis **112**X can indicate horizontal X-axis **112**X to the patient and/or care provider. A name, logo and/or trademark can be visible the outside of device **100** to indicate that device **100** correctly oriented, and arrows can also be used, for example a vertical arrow pointing up and a horizontal arrow pointing to the right.

Monitoring system **10** includes components to transmit data, to a remote center **106**. Remote center **106** can be located in a different building from the patient, for example in the same town as the patient, and can be located as far from the patient as a separate continent from the patient, for example the patient located on a first continent and the remote center located on a second continent. Adherent device **100** can communicate wirelessly to an intermediate device **102**, for example with a single wireless hop from the adherent device on the patient to the intermediate device. Intermediate device **102** can communicate with remote center **106** in many ways, for example with an internet connection and/or with a cellular connection. In many embodiments, monitoring system **10** comprises a distributed processing system with at least one processor comprising a tangible medium of device **100**, at least one processor **102**P of intermediate device **102**, and at least one processor **106**P at remote center **106**, each of which processors can be in electronic communication with the other processors. At least one processor **102**P comprises a tangible medium **102**T, and at least one processor **106**P comprises a tangible medium **106**T. Remote processor **106**P may comprise a backend server located at the remote center. Remote center **106** can be in communication with a health care provider **108**A with a communication system **107**A, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Health care provider **108**A, for example a family member, can be in communication with patient P with a communication, for example with a two way communication system, as indicated by arrow **109**A, for example by cell phone, email, landline. Remote center **106** can be in communication with a health care professional, for example a physician **108**B, with a communication system **107**B, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Physician **108**B can be in communication with patient P with a communication, for example with a two way communication system, as indicated by arrow **109**B, for example by cell phone, email, landline. Remote center **106** can be in communication with an emergency responder **108**C, for example a 911 operator and/or paramedic, with a communication system **107**C, such as the Internet, an intranet, phone lines, wireless and/or satellite phone. Emergency responder **108**C can travel to the patient as indicated by arrow **109**C. Thus, in many embodiments, monitoring system **10** comprises a closed loop system in which patient care can be monitored and implemented from the remote center in response to signals from the adherent device.

In many embodiments, the adherent device may continuously monitor physiological parameters, communicate wirelessly with a remote center, and provide alerts when necessary. The system may comprise an adherent patch, which attaches to the patient's thorax and contains sensing electrodes, battery, memory, logic, and wireless communication capabilities. In some embodiments, the patch can communicate with the remote center, via the intermediate device in the patient's home. In some embodiments, remote center **106** receives the patient data and applies a patient evaluation algorithm, for example an algorithm to calculate the apnea hypopnea index. When a flag is raised, the center may communicate with the patient, hospital, nurse, and/or physician to allow for therapeutic intervention.

The adherent device may be affixed and/or adhered to the body in many ways. For example, with at least one of the following: an adhesive tape, a constant-force spring, suspenders around shoulders, a screw-in microneedle electrode, a pre-shaped electronics module to shape fabric to a thorax, a pinch onto roll of skin, or transcutaneous anchoring. Patch and/or device replacement may occur with a keyed patch (e.g. two-part patch), an outline or anatomical mark, a low-adhesive guide (place guide|remove old patch|place new patch|remove guide), or a keyed attachment for chatter reduction. The patch and/or device may comprise an adhesiveless embodiment (e.g. chest strap), and/or a low-irritation adhesive for sensitive skin. The adherent patch and/or device can comprise many shapes, for example at least one of a dogbone, an hourglass, an oblong, a circular or an oval shape.

In many embodiments, the adherent device may comprise a reusable electronics module with replaceable patches, and each of the replaceable patches may include a battery. The module may collect cumulative data for approximately 90 days and/or the entire adherent component (electronics+ patch) may be disposable. In a completely disposable embodiment, a "baton" mechanism may be used for data transfer and retention, for example baton transfer may include baseline information. In some embodiments, the device may have a rechargeable module, and may use dual

battery and/or electronics modules, wherein one module **101**A can be recharged using a charging station **103** while the other module **101**B is placed on the adherent patch with connectors. In some embodiments, the intermediate device **102** may comprise the charging module, data transfer, storage and/or transmission, such that one of the electronics modules can be placed in the intermediate device for charging and/or data transfer while the other electronics module is worn by the patient.

System **10** can perform the following functions: initiation, programming, measuring, storing, analyzing, communicating, predicting, and displaying. The adherent device may contain a subset of the following physiological sensors: bioimpedance, respiration, respiration rate variability, heart rate (ave, min, max), heart rhythm, hear rate variability (HRV), heart rate turbulence (HRT), heart sounds (e.g. S3), respiratory sounds, blood pressure, activity, posture, wake/sleep, orthopnea, temperature/heat flux, and weight. The activity sensor may comprise one or more of the following: ball switch, accelerometer, minute ventilation, HR, bioimpedance noise, skin temperature/heat flux, BP, muscle noise, posture.

The adherent device can wirelessly communicate with remote center **106**. The communication may occur directly (via a cellular or Wi-Fi network), or indirectly through intermediate device **102**. Intermediate device **102** may consist of multiple devices, which can communicate wired or wirelessly to relay data to remote center **106**.

In many embodiments, instructions are transmitted from remote site **106** to a processor supported with the adherent patch on the patient, and the processor supported with the patient can receive updated instructions for the patient treatment and/or monitoring, for example while worn by the patient.

FIG. **1**B shows a bottom view of adherent device **100** as in FIG. **1**A comprising an adherent patch **110**. Adherent patch **110** comprises a first side, or a lower side **110**A, that is oriented toward the skin of the patient when placed on the patient. In many embodiments, adherent patch **110** comprises a tape **110**T which is a material, preferably breathable, with an adhesive **116**A. Patient side **110**A comprises adhesive **116**A to adhere the patch **110** and adherent device **100** to patient P. Electrodes **112**A, **112**B, **112**C and **112**D are affixed to adherent patch **110**. In many embodiments, at least four electrodes are attached to the patch, for example six electrodes. In some embodiments the patch comprises two electrodes, for example two electrodes to measure the electrocardiogram (ECG) of the patient. Gel **114**A, gel **114**B, gel **114**C and gel **114**D can each be positioned over electrodes **112**A, **112**B, **112**C and **112**D, respectively, to provide electrical conductivity between the electrodes and the skin of the patient. In many embodiments, the electrodes can be affixed to the patch **110**, for example with known methods and structures such as rivets, adhesive, stitches, etc. In many embodiments, patch **110** comprises a breathable material to permit air and/or vapor to flow to and from the surface of the skin.

Electrodes **112**A, **112**B, **112**C and **112**D extend substantially along a horizontal measurement axis that corresponds to X axis-**112**X of the measurement device. Electrodes **112**, **112**B, **112**C and **112**D can be affixed to adherent patch **110**A, such that the positions of electrodes **112**A, **112**B, **112**C and **112**D comprise predetermined positions on adherent patch **110**A. Z-axis **112**Z can extend perpendicular to the electrode measurement axis, for example vertically and perpendicular to X-axis **112** when adhered on the patient. X-axis **112**X and Z-axis **112**Z can extend along an adhesive surface of adherent patch **110**A, and a Y-axis **112**Y can extend away from the adhesive surface of adherent device **110**A.

FIG. **1**C shows a top view of the adherent patch **100**, as in FIG. **1**B. Adherent patch **100** comprises a second side, or upper side **110**B. In many embodiments, electrodes **112**A, **112**B, **112**C and **112**D extend from lower side **110**A through adherent patch **110** to upper side **110**B. An adhesive **116**B can be applied to upper side **110**B to adhere structures, for example a breathable cover, to the patch such that the patch can support the electronics and other structures when the patch is adhered to the patient. The PCB may comprise completely flex PCB, rigid PCB, rigid PCB combined flex PCB and/or rigid PCB boards connected by cable.

FIG. **1**D shows a printed circuit boards and electronic components over adherent patch **110**, as in FIG. **1**A to **1**C. In some embodiments, a printed circuit board (PCB), for example flex printed circuit board **120**, may be connected to electrodes **112**A, **112**B, **112**C and **112**D with connectors **122**A, **122**B, **122**C and **122**D. Flex printed circuit board **120** can include traces **123**A, **123**B, **123**C and **123**D that extend to connectors **122**A, **122**B, **122**C and **122**D, respectively, on the flex PCB. Connectors **122**A, **122**B, **122**C and **122**D can be positioned on flex printed circuit board **120** in alignment with electrodes **112**A, **112**B, **112**C and **112**D so as to electrically couple the flex PCB with the electrodes. For example, connectors **122**A and **122**D may comprise a flexible polyester film coated with conductive silver ink. In some embodiments, connectors **122**A, **122**B, **122**C and **122**D may comprise insulated wires and/or a film with conductive ink that provide strain relief between the PCB and the electrodes. In some embodiments, additional PCB's, for example rigid PCB's **120**A, **120**B, **120**C and **120**D, can be connected to flex printed circuit board **120**. Electronic components **130** can be connected to flex printed circuit board **120** and/or mounted thereon. In some embodiments, electronic components **130** can be mounted on the additional PCB's.

Electronic components **130** comprise components to take physiologic measurements, transmit data to remote center **106** and receive commands from remote center **106**. In many embodiments, electronics components **130** may comprise known low power circuitry, for example complementary metal oxide semiconductor (CMOS) circuitry components. Electronics components **130** comprise an activity sensor and activity circuitry **134**, impedance circuitry **136** and electrocardiogram circuitry, for example ECG circuitry **136**. In some embodiments, electronics circuitry **130** may comprise a microphone and microphone circuitry **142** to detect an audio signal from within the patient, and the audio signal may comprise a heart sound and/or a respiratory sound, for example an S3 heart sound and a respiratory sound with rales and/or crackles.

Electronics circuitry **130** may comprise a temperature sensor, for example a thermistor in contact with the skin of the patient, and temperature sensor circuitry **144** to measure a temperature of the patient, for example a temperature of the skin of the patient. A temperature sensor may be used to determine the sleep and wake state of the patient. The temperature of the patient can decrease as the patient goes to sleep and increase when the patient wakes up.

Work in relation to embodiments of the present invention suggests that skin temperature may effect impedance and/or hydration measurements, and that skin temperature measurements may be used to correct impedance and/or hydration measurements. In some embodiments, increase in skin temperature or heat flux can be associated with increased vaso-dilation near the skin surface, such that measured

impedance measurement decreased, even through the hydration of the patient in deeper tissues under the skin remains substantially unchanged. Thus, use of the temperature sensor can allow for correction of the hydration signals to more accurately assess the hydration, for example extra cellular hydration, of deeper tissues of the patient, for example deeper tissues in the thorax.

Electronics circuitry **130** may comprise a processor **146**. Processor **146** comprises a tangible medium, for example read only memory (ROM), electrically erasable programmable read only memory (EEPROM) and/or random access memory (RAM). Processor **146** may comprise many known processors with real time clock and frequency generator circuitry, for example the PIC series of processors available from Microchip, of Chandler Ariz. In some embodiments, processor **136** may comprise the frequency generator and real time clock. The processor can be configured to control a collection and transmission of data from the impedance circuitry electrocardiogram circuitry and the accelerometer. In many embodiments, device **100** comprise a distributed processor system, for example with multiple processors on device **100**.

In many embodiments, electronics components **130** comprise wireless communications circuitry **132** to communicate with remote center **106**. The wireless communication circuitry can be coupled to the impedance circuitry, the electrocardiogram circuitry and the accelerometer to transmit to a remote center with a communication protocol at least one of the hydration signal, the electrocardiogram signal or the inclination signal. In specific embodiments, wireless communication circuitry is configured to transmit the hydration signal, the electrocardiogram signal and the inclination signal to the remote center with a single wireless hop, for example from wireless communication circuitry **132** to intermediate device **102**. The communication protocol comprises at least one of Bluetooth, Zigbee, WiFi, WiMax, IR, amplitude modulation or frequency modulation. In many embodiments, the communications protocol comprises a two way protocol such that the remote center is capable of issuing commands to control data collection.

Intermediate device **102** may comprise a data collection system to collect and store data from the wireless transmitter. The data collection system can be configured to communicate periodically with the remote center. The data collection system can transmit data in response to commands from remote center **106** and/or in response to commands from the adherent device.

Activity sensor and activity circuitry **134** can comprise many known activity sensors and circuitry. In many embodiments, the accelerometer comprises at least one of a piezoelectric accelerometer, capacitive accelerometer or electromechanical accelerometer. The accelerometer may comprise a 3-axis accelerometer to measure at least one of an inclination, a position, an orientation or acceleration of the patient in three dimensions. Work in relation to embodiments of the present invention suggests that three dimensional orientation of the patient and associated positions, for example sitting, standing, lying down, can be very useful when combined with data from other sensors, for example ECG data and/or bioimpedance data, for example a respiration rate of the patient.

Activity sensor **134** may comprise an accelerometer with at least one measurement axis, for example two or more measurement axes. In some embodiments, activity sensor **134** comprises three axis accelerometer **134**A. Three axis accelerometer **134**A may comprise an X-axis **134**X, a Y-axis **134**Y and a Z-axis **134**Z with each axis sensitive to gravity such that the orientation of the accelerometer can be determined in relation to gravity. Three axis accelerometer **134**A can be aligned with electrodes of adherent patch **110**A. X-axis **134**X can be aligned with X-axis **112**X of adherent patch **110**. Y-axis **134**Y can be aligned with Y-axis **112**Y of adherent patch **110**, Z-axis **134**Z can be aligned with Z-axis **112**Z of adherent patch **110**. Axes of accelerometer **134**A can be aligned with axes of patch **110**A, for example with connectors **122**A, **122**B, **122**C and **122**D, such that the axes of the accelerometer are aligned with adherent patch and/or the electrodes in a predetermined configuration. Although the axes of the patch and accelerometer are shown substantially parallel, the axes of the patch can be aligned with the axes of the accelerometer in a non-parallel configuration, for example an oblique configuration with oblique angles between axes of the accelerometer and axes of the adherent patch and/or electrodes.

Impedance circuitry **136** can generate both hydration data and respiration data. In many embodiments, impedance circuitry **136** is electrically connected to electrodes **112**A, **112**B, **112**C and **112**D in a four pole configuration, such that electrodes **112**A and **112**D comprise outer electrodes that are driven with a current and comprise force electrodes that force the current through the tissue. The current delivered between electrodes **112**A and **112**D generates a measurable voltage between electrodes **112**B and **112**C, such that electrodes **112**B and **112**C comprise inner, sense, electrodes that sense and/or measure the voltage in response to the current from the force electrodes. In some embodiments, electrodes **112**B and **112**C may comprise force electrodes and electrodes **112**A and **112**B may comprise sense electrodes. The voltage measured by the sense electrodes can be used to measure the impedance of the patient and determine the respiration rate and/or hydration of the patient.

FIG. **1D1** shows an equivalent circuit **152** that can be used to determine optimal frequencies for measuring patient hydration. Work in relation to embodiments of the present invention indicates that the frequency of the current and/or voltage at the force electrodes can be selected so as to provide impedance signals related to the extracellular and/or intracellular hydration of the patient tissue. Equivalent circuit **152** comprises an intracellular resistance **156**, or R(ICW) in series with a capacitor **154**, and an extracellular resistance **158**, or R(ECW). Extracellular resistance **158** is in parallel with intracellular resistance **156** and capacitor **154** related to capacitance of cell membranes. In many embodiments, impedances can be measured and provide useful information over a wide range of frequencies, for example from about 0.5 kHz to about 200 KHz. Work in relation to embodiments of the present invention suggests that extracellular resistance **158** can be significantly related extracellular fluid and to cardiac decompensation, and that extracellular resistance **158** and extracellular fluid can be effectively measured with frequencies in a range from about 0.5 kHz to about 20 kHz, for example from about 1 kHz to about 10 kHz. In some embodiments, a single frequency can be used to determine the extracellular resistance and/or fluid. As sample frequencies increase from about 10 kHz to about 20 kHz, capacitance related to cell membranes decrease the impedance, such that the intracellular fluid contributes to the impedance and/or hydration measurements. Thus, many embodiments of the present invention measure hydration with frequencies from about 0.5 kHz to about 20 kHz to determine patient hydration.

In many embodiments, impedance circuitry **136** can be configured to determine respiration of the patient. In specific embodiments, the impedance circuitry can measure the

hydration at 25 Hz intervals, for example at 25 Hz intervals using impedance measurements with a frequency from about 0.5 kHz to about 20 kHz.

ECG circuitry **138** can generate electrocardiogram signals and data from two or more of electrodes **112**A, **112**B, **112**C and **112**D in many ways. In some embodiments, ECG circuitry **138** is connected to inner electrodes **112**B and **122**C, which may comprise sense electrodes of the impedance circuitry as described above. In some embodiments, ECG circuitry **138** can be connected to electrodes **112**A and **112**D so as to increase spacing of the electrodes. The inner electrodes may be positioned near the outer electrodes to increase the voltage of the ECG signal measured by ECG circuitry **138**. In many embodiments, the ECG circuitry may measure the ECG signal from electrodes **112**A and **112**D when current is not passed through electrodes **112**A and **112**D.

ECG circuitry **138** can be coupled to the electrodes in many ways to define an electrocardiogram vector. For example electrode **112**A can be coupled to a positive amplifier terminal of ECG circuitry **138** and electrode **112**D can be coupled to a negative amplifier terminal of ECG circuitry **138** to define an orientation of an electrocardiogram vector along the electrode measurement axis. To define an electrocardiogram vector with an opposite orientation electrode **112**D can be couple to the positive amplifier terminal of ECG circuitry **138** and electrode **112**A can be coupled to the negative amplifier terminal of ECG circuitry **138**. The ECG circuitry may be coupled to the inner electrodes so as to define an ECG vector along a measurement axis of the inner electrodes.

FIG. **1D2** shows adherent device **100** positioned on patient P to determine orientation of the adherent patch. X-axis **112**X of device **100** is inclined at an angle α to horizontal axis Px of patient P. Z-axis **112**Z of device **100** is inclined at angle α to vertical axis Pz of patient P. Y-axis **112**Y may be inclined at a second angle, for example β, to anterior posterior axis Py and vertical axis Pz. As the accelerometer of adherent device **100** can be sensitive to gravity, inclination of the patch relative to axis of the patient can be measured, for example when the patient stands.

FIG. **1D3** shows vectors from a 3D accelerometer to determine orientation of the measurement axis of the patch adhered on the patient. A Z-axis vector **112**ZV can be measured along vertical axis **112**Z with an accelerometer signal from axis **134**Z of accelerometer **134**A. An X-axis vector **112**XV can be measured along horizontal axis **112**X with an accelerometer signal from axis **134**X of accelerometer **134**A. Inclination angle α can be determined in response to X-axis vector **112**XV and Z-axis vector **112**ZV, for example with vector addition of X-axis vector **112**XV and Z-axis vector **112**ZV. An inclination angle β for the patch along the Y and Z axes can be similarly obtained an accelerometer signal from axis **134**Y of accelerometer **134**A and vector **112**ZV.

FIG. **1E** shows batteries **150** positioned over the flex printed circuit board and electronic components as in FIG. **1D**. Batteries **150** may comprise rechargeable batteries that can be removed and/or recharged. In some embodiments, batteries **150** can be removed from the adherent patch and recharged and/or replaced.

FIG. **1F** shows a top view of a cover **162** over the batteries, electronic components and flex printed circuit board as in FIGS. **1A** to **1E**. In many embodiments, an electronics housing **160** may be disposed under cover **162** to protect the electronic components, and in some embodiments electronics housing **160** may comprise an encapsulant over the electronic components and PCB. In some embodiments, cover **162** can be adhered to adherent patch **110** with an adhesive **164** on an underside of cover **162**. In many embodiments, electronics housing **160** may comprise a water proof material, for example a sealant adhesive such as epoxy or silicone coated over the electronics components and/or PCB. In some embodiments, electronics housing **160** may comprise metal and/or plastic. Metal or plastic may be potted with a material such as epoxy or silicone.

Cover **162** may comprise many known biocompatible cover, casing and/or housing materials, such as elastomers, for example silicone. The elastomer may be fenestrated to improve breathability. In some embodiments, cover **162** may comprise many known breathable materials, for example polyester, polyamide, and/or elastane (Spandex). The breathable fabric may be coated to make it water resistant, waterproof, and/or to aid in wicking moisture away from the patch.

FIG. **1G** shows a side view of adherent device **100** as in FIGS. **1A** to **1F**. Adherent device **100** comprises a maximum dimension, for example a length **170** from about 2 to 10 inches (from about 50 mm to about 250 mm), for example from about 4 to 6 inches (from about 100 mm to about 150 mm). In some embodiments, length **170** may be no more than about 6 inches (no more than about 150 mm). Adherent device **100** comprises a thickness **172**. Thickness **172** may comprise a maximum thickness along a profile of the device. Thickness **172** can be from about 0.1 inches to about 0.4 inches (from about 5 mm to about 10 mm), for example about 0.3 inches (about 7.5 mm).

FIG. **1H** shown a bottom isometric view of adherent device **100** as in FIGS. **1A** to **1G**. Adherent device **100** comprises a width **174**, for example a maximum width along a width profile of adherent device **100**. Width **174** can be from about 1 to about 4 inches (from about 25 mm to 100 mm), for example about 2 inches (about 50 mm).

FIGS. **1I** and **1J** show a side cross-sectional view and an exploded view, respectively, of adherent device **100** as in FIGS. **1A** to **1H**. Device **100** comprises several layers. Gel **114**A, or gel layer, is positioned on electrode **112**A to provide electrical conductivity between the electrode and the skin. Electrode **112**A may comprise an electrode layer. Adhesive patch **110** may comprise a layer of breathable tape **110**T, for example a known breathable tape, such as tricot-knit polyester fabric. An adhesive **116**A, for example a layer of acrylate pressure sensitive adhesive, can be disposed on underside **110**A of adherent patch **110**. A gel cover **180**, or gel cover layer, for example a polyurethane non-woven tape, can be positioned over patch **110** comprising the breathable tape. A PCB layer, for example flex printed circuit board **120**, or flex PCB layer, can be positioned over gel cover **180** with electronic components **130** connected and/or mounted to flex printed circuit board **120**, for example mounted on flex PCB so as to comprise an electronics layer disposed on the flex PCB layer. In many embodiments, the adherent device may comprise a segmented inner component, for example the PCB may be segmented to provide at least some flexibility. In many embodiments, the electronics layer may be encapsulated in electronics housing **160** which may comprise a waterproof material, for example silicone or epoxy. In many embodiments, the electrodes are connected to the PCB with a flex connection, for example trace **123**A of flex printed circuit board **120**, so as to provide strain relive between the electrodes **112**A, **112**B, **112**C and **112**D and the PCB. Gel cover **180** can inhibit flow of gel **114**A and liquid. In many embodiments, gel cover **180** can inhibit gel **114**A from seeping through breathable tape **110**T to maintain gel

integrity over time. Gel cover **180** can also keep external moisture, for example liquid water, from penetrating though the gel cover into gel **114**A while allowing moisture vapor from the gel, for example moisture vapor from the skin, to transmit through the gel cover. In many embodiments, cover **162** can encase the flex PCB and/or electronics and can be adhered to at least one of the electronics, the flex PCB or adherent patch **110**, so as to protect at least the electronics components and the PCB. Cover **162** can attach to adhesive patch **110** with adhesive **116**B. Cover **162** can comprise many known biocompatible cover materials, for example silicone. Cover **162** can comprise an outer polymer cover to provide smooth contour without limiting flexibility. In many embodiments, cover **162** may comprise a breathable fabric. Cover **162** may comprise many known breathable fabrics, for example breathable fabrics as described above. In some embodiments, the breathable cover may comprise a breathable water resistant cover. In some embodiments, the breathable fabric may comprise polyester, nylon, polyamide, and/or elastane (Spandex) to allow the breathable fabric to stretch with body movement. In some embodiments, the breathable tape may contain and elute a pharmaceutical agent, such as an antibiotic, anti-inflammatory or antifungal agent, when the adherent device is placed on the patient.

The breathable cover **162** and adherent patch **110** comprises breathable tape can be configured to couple continuously for at least one week the at least one electrode to the skin so as to measure breathing of the patient. The breathable tape may comprise the stretchable breathable material with the adhesive and the breathable cover may comprises a stretchable water resistant material connected to the breathable tape, as described above, such that both the adherent patch and cover can stretch with the skin of the patient. Arrows **182** show stretching of adherent patch **110**, and the stretching of adherent patch can be at least two dimensional along the surface of the skin of the patient. As noted above, connectors **122**A, **122**B, **122**C and **122**D between PCS **130** and electrodes **112**A, **112**B, **112**C and **112**D may comprise insulated wires that provide strain relief between the PCB and the electrodes, such that the electrodes can move with the adherent patch as the adherent patch comprising breathable tape stretches. Arrows **184** show stretching of cover **162**, and the stretching of the cover can be at least two dimensional along the surface of the skin of the patient. Cover **162** can be attached to adherent patch **110** with adhesive **116**B such that cover **162** stretches and/or retracts when adherent patch **110** stretches and/or retracts with the skin of the patient. For example, cover **162** and adhesive patch **110** can stretch in two dimensions along length **170** and width **174** with the skin of the patient, and stretching along length **170** can increase spacing between electrodes. Stretching of the cover and adhesive patch **110**, for example in two dimensions, can extend the time the patch is adhered to the skin as the patch can move with the skin such that the patch remains adhered to the skin. Cover **162** can be attached to adherent patch **110** with adhesive **116**B such that cover **162** stretches and/or retracts when adherent patch **110** stretches and/or retracts with the skin of the patient, for example along two dimensions comprising length **170** and width **174**. Electronics housing **160** can be smooth and allow breathable cover **162** to slide over electronics housing **160**, such that motion and/or stretching of cover **162** is slidably coupled with housing **160**. The printed circuit board can be slidably coupled with adherent patch **110** that comprises breathable tape **110**T, such that the breathable tape can stretch with the skin of the patient when the breathable tape is adhered to the skin of the patient. Electronics components **130** can be affixed to printed circuit board **120**, for example with solder, and the electronics housing can be affixed over the PCB and electronics components, for example with dip coating, such that electronics components **130**, printed circuit board **120** and electronics housing **160** are coupled together. Electronics components **130**, printed circuit board **120**, and electronics housing **160** are disposed between the stretchable breathable material of adherent patch **110** and the stretchable water resistant material of cover **160** so as to allow the adherent patch **110** and cover **160** to stretch together while electronics components **130**, printed circuit board **120**, and electronics housing **160** do not stretch substantially, if at all. This decoupling of electronics housing **160**, printed circuit board **120** and electronic components **130** can allow the adherent patch **110** comprising breathable tape to move with the skin of the patient, such that the adherent patch can remain adhered to the skin for an extended time of at least one week, for example two or more weeks.

An air gap **169** may extend from adherent patch **110** to the electronics module and/or PCB, so as to provide patient comfort. Air gap **169** allows adherent patch **110** and breathable tape **110**T to remain supple and move, for example bend, with the skin of the patient with minimal flexing and/or bending of printed circuit board **120** and electronic components **130**, as indicated by arrows **186**. Printed circuit board **120** and electronics components **130** that are separated from the breathable tape **110**T with air gap **169** can allow the skin to release moisture as water vapor through the breathable tape, gel cover, and breathable cover. This release of moisture from the skin through the air gap can minimize, and even avoid, excess moisture, for example when the patient sweats and/or showers.

The breathable tape of adhesive patch **110** may comprise a first mesh with a first porosity and gel cover **180** may comprise a breathable tape with a second porosity, in which the second porosity is less than the first porosity to minimize, and even inhibit, flow of the gel through the breathable tape. The gel cover may comprise a polyurethane film with the second porosity.

In many embodiments, the adherent device comprises a patch component and at least one electronics module. The patch component may comprise adhesive patch **110** comprising the breathable tape with adhesive coating **116**A, at least one electrode, for example electrode **114**A and gel **114**. The at least one electronics module can be separable from the patch component. In many embodiments, the at least one electronics module comprises the flex printed circuit board **120**, electronic components **130**, electronics housing **160** and cover **162**, such that the flex printed circuit board, electronic components, electronics housing and cover are reusable and/or removable for recharging and data transfer, for example as described above. In many embodiments, adhesive **116**B is coated on upper side **110**A of adhesive patch **110**B, such that the electronics module can be adhered to and/or separated from the adhesive component. In specific embodiments, the electronic module can be adhered to the patch component with a releasable connection, for example with Velcro™, a known hook and loop connection, and/or snap directly to the electrodes. Two electronics modules can be provided, such that one electronics module can be worn by the patient while the other is charged, as described above. Monitoring with multiple adherent patches for an extended period is described in U.S. Pat. App. No. 60/972,537, the full disclosure of which is incorporated herein by reference and may be suitable for combination with some embodiments of the present invention. Many patch components can be pro-

vided for monitoring over the extended period. For example, about 12 patches can be used to monitor the patient for at least 90 days with at least one electronics module, for example with two reusable electronics modules.

At least one electrode **112**A can extend through at least one aperture **180**A in the breathable tape **110** and gel cover **180**.

In some embodiments, the adhesive patch may comprise a medicated patch that releases a medicament, such as antibiotic, beta-blocker, ACE inhibitor, diuretic, or steroid to reduce skin irritation. The adhesive patch may comprise a thin, flexible, breathable patch with a polymer grid for stiffening. This grid may be anisotropic, may use electronic components to act as a stiffener, may use electronics-enhanced adhesive elution, and may use an alternating elution of adhesive and steroid.

FIG. **1**K shows at least one electrode **190** configured to electrically couple to a skin of the patient through a breathable tape **192**. In many embodiments, at least one electrode **190** and breathable tape **192** comprise electrodes and materials similar to those described above. Electrode **190** and breathable tape **192** can be incorporated into adherent devices as described above, so as to provide electrical coupling between the skin and electrode through the breathable tape, for example with the gel.

FIGS. **2**A to **2**C show a schematic illustration of a system **200** to monitor a patient for an extended period.

FIG. **2**A shows a schematic illustration of system **200** comprising a reusable electronics module **210** and a plurality of disposable patch components. FIG. **2**B shows a schematic illustration of a side cross-sectional view of reusable electronics module **210**. System **200** may comprise a first disposable patch component **220**A, a second disposable patch component **220**B, a third disposable patch component **220**C and a fourth disposable patch component **220**D. Although four patch components a shown the plurality may comprise as few as two patch component and as many as three or more patch components, for example 25 patch components.

Reusable electronics module **210** may comprise a connector **219** adapted to connect to each of the disposable patch components, sequentially, for example one disposable patch component at a time. Connector **219** can be formed in many ways, and may comprise known connectors as described above, for example a snap. In some embodiments, the connectors on the electronics module and adhesive component can be disposed at several locations on the reusable electronics module and disposable patch component, for example near each electrode, such that each electrode can couple directly to a corresponding location on the flex PCB of the reusable electronics component.

Reusable electronics module **210** may comprise additional reusable electronics modules, for example two or more rechargeable electronics modules each with a 3D accelerometer, such that the first module comprising a first 3D accelerometer can be recharged while the second module comprising a second 3D accelerometer is worn by the patient. The second module can be recharged and connected to a third adhesive patch when the first adhesive patch is removed from the patient. The second module comprising the second accelerometer can be removably coupled to the adhesive patch such that the second accelerometer can be recharged and connected to a fourth adhesive patch when the second adhesive patch is removed from the patient.

Reusable electronics module **210** may comprises many of the structures described above that may comprise the electronics module. In many embodiments, reusable electronics module **210** comprises a PCB, for example a flex PCB **212**, electronics components **214**, batteries **216**, and a cover **217**, for example as described above. In some embodiments, reusable electronics module **210** may comprise an electronics housing over the electronics components and/or PCB as described above. The electronics components may comprise circuitry and/or sensors for measuring ECG signals, hydration impedance signals, respiration impedance signals and accelerometer signals, for example as described above.

Electronics components **214** may comprise an accelerometer **214**A. Accelerometer **214**A may comprise a three axis accelerometer, for example as described above. Accelerometer **214**A may comprise an X-axis **234**X, a Y-axis **234**Y and a Z-axis **234**Z with each axis sensitive to gravity such that the orientation of the accelerometer, for example 3D orientation, can be determined in relation to gravity, as described above. Alignment of the accelerometer, for example the axes of the accelerometer **214**A, can be aligned with the axes of the adherent patches using the connectors. For example connector **219** can connect with at least one of connector **229**A, connector **229**B, connector **229**C and connector **229**D to align the respective patch with accelerometer **214**A.

First disposable patch component **220**A comprises a connector **229**A to mate with connector **219** on reusable electronics module **210** such that the first disposable patch component **220**A is aligned with the reusable electronics module with a predetermined orientation. First disposable patch component **220**A comprises a first axis **220**AX substantially aligned with electrodes **222**A. A second axis **220**AZ corresponds to vertical on the patient when first disposable patch component **220**A is adhered to the patient. Connector **229**A is configured to mate with connector **219** such that axis **234**X is aligned with first axis **220**AX and axis **234**Z is aligned with axis **220**AZ.

Second disposable patch component **220**B comprises a connector **229**B to mate with connector **219** on reusable electronics module **210** such that the second disposable patch component **220**B is aligned with the reusable electronics module with the predetermined orientation similar to first disposable patch component **220**A. Second disposable patch component **220**B comprises a first axis **220**BX substantially aligned with electrodes **222**B. A second axis **220**BZ corresponds to vertical on the patient when second disposable patch component **220**B is adhered to the patient. Connector **229**B is configured to mate with connector **219** such that axis **234**X is aligned with first axis **220**BX and axis **234**Z is aligned with axis **220**BZ.

Third disposable patch component **220**C comprises a connector **229**C to mate with connector **219** on reusable electronics module **210** such that the third disposable patch component **220**C is aligned with the reusable electronics module with the predetermined orientation similar to second disposable patch component **220**B. Third disposable patch component **220**C comprises a first axis **220**CX substantially aligned with electrodes **222**C. A second axis **220**CZ corresponds to vertical on the patient when second disposable patch component **220**C is adhered to the patient. Connector **229**C is configured to mate with connector **219** such that axis **234**X is aligned with first axis **220**CX and axis **234**Z is aligned with axis **220**CZ.

Fourth disposable patch component **220**D comprises a connector **229**D to mate with connector **219** on reusable electronics module **210** such that the fourth disposable patch component **220**D is aligned with the reusable electronics module with the predetermined orientation similar to third disposable patch component **220**C. Fourth disposable patch component **220**D comprises a first axis **220**DX substantially

aligned with electrodes **222**D. A second axis **220**DZ corresponds to vertical on the patient when second disposable patch component **220**D is adhered to the patient Connector **229**D is configured to mate with connector **219** such that axis **234**X is aligned with first axis **220**DX and axis **234**Z is aligned with axis **220**DZ.

FIG. **2**C shows a schematic illustration first disposable patch component **220**A of the plurality of disposable patch components that is similar to the other disposable patch components, for example second disposable patch component **220**B, third disposable patch component **220**C and fourth disposable patch component **220**C. The disposable patch component comprises a breathable tape **227**A, an adhesive **226**A on an underside of breathable tape **227**A to adhere to the skin of the patient, and at least four electrodes **222**A. The at least four electrodes **224**A are configured to couple to the skin of a patient, for example with a gel **226**A, in some embodiments the electrodes may extend through the breathable tape to couple directly to the skin of the patient with aid form the gel. In some embodiments, the at least four electrodes may be indirectly coupled to the skin through a gel and/or the breathable tape, for example as described above. A connector **229**A on the upper side of the disposable adhesive component can be configured for attachment to connector **219** on reusable electronics module **210** so as to electrically couple the electrodes with the electronics module. The upper side of the disposable patch component may comprise an adhesive **224**A to adhere the disposable patch component to the reusable electronics module. The reusable electronics module can be adhered to the patch component with many additional known ways to adhere components, for example with Velcro™ comprising hooks and loops, snaps, a snap fit, a lock and key mechanisms, magnets, detents and the like.

FIG. **2**D shows a method **250** of using system **200**, as in FIGS. **2**A to **2**C. A step **252** adheres electronics module **210** to first disposable adherent patch component **220**A of the plurality of adherent patch components and adheres the first disposable patch component to the skin of the patient, for example with the first adherent patch component adhered to the reusable electronics module. The orientation on the patient of first disposable patch component **220**A is determined with the accelerometer, for example as described above, when the first disposable patch component is adhered to the patient. Patient measurements can be taken with the electronics module and/or adjusted in response to the orientation of the first patch on the patient. A step **254** removes the first disposable adherent patch from the patient and separates first disposable adherent patch component **220**A from reusable electronics module **210**.

A step **256** adheres electronics module **210** to second disposable adherent patch component **220**B and adheres the second disposable patch component to the skin of the patient, for example with the second adherent patch component adhered to the reusable electronics module. The orientation on the patient of second disposable patch component **220**B is determined with the accelerometer, for example as described above, when the second disposable patch component is adhered to the patient. Patient measurements can be taken with the electronics module and/or adjusted in response to the orientation of the second patch on the patient. A step **258** removes the second disposable adherent patch from the patient and separates second disposable adherent patch component **220**B from reusable electronics module **210**.

A step **260** adheres electronics module **210** to third disposable adherent patch component **220**C and adheres the third disposable patch component to the skin of the patient, for example with the third adherent patch component adhered to the reusable electronics module. The orientation on the patient of third disposable patch component **220**C is determined with the accelerometer, for example as described above, when the third disposable patch component is adhered to the patient. Patient measurements can be taken with the electronics module and/or adjusted in response to the orientation of the third patch on the patient. A step **262** removes the third disposable adherent patch from the patient and separates third disposable adherent patch component **220**C from reusable electronics module **210**.

A step **264** adheres electronics module **210** to fourth disposable adherent patch component **220**D and adheres the fourth disposable patch component to the skin of the patient, for example with the third adherent patch component adhered to the reusable electronics module. The orientation on the patient of fourth disposable patch component **220**D is determined with the accelerometer, for example as described above, when the fourth disposable patch component is adhered to the patient. Patient measurements can be taken with the electronics module and/or adjusted in response to the orientation of the fourth patch on the patient. A step **268** removes the fourth disposable adherent patch from the patient and separates fourth disposable adherent patch component **220**D from reusable electronics module **210**.

In many embodiments, physiologic signals, for example ECG, hydration impedance, respiration impedance and accelerometer impedance are measured when the adherent patch component is adhered to the patient, for example when any of the first, second, third or fourth disposable adherent patches is adhered to the patient.

FIGS. **3**A to **3**D show a method **300** of monitoring a patient for an extended period with adherent patches alternatively adhered to a right side **302** and a left side **304** of the patient. Work in relation to embodiments of the present invention suggests that repeated positioning of a patch at the same location can irritate the skin and may cause patient discomfort. This can be minimized, even avoided, by alternating the patch placement between left and right sides of the patient, often a front left and a front right side of the patient where the patient can reach easily to replace the patch. In some embodiments, the patch location can be alternated on the same side of the patient, for example higher and/or lower on the same side of the patient without substantial overlap to allow the skin to recover and/or heal. In many embodiments, the patch can be symmetrically positioned on an opposite side such that signals may be similar to a previous position of the patch symmetrically disposed on an opposite side of the patient. In many embodiments, the duration between removal of one patch and placement of the other patch can be short, such that any differences between the signals may be assumed to be related to placement of the patch, and these differences can be removed with signal processing.

In many embodiments each patch comprises at least four electrodes configured to measure an ECG signal and impedance, for example hydration and/or respiration impedance. In many embodiments, the patient comprises a midline **306**, with first side, for example right side **302**, and second side, for example left side **304**, symmetrically disposed about the midline. A step **310** adheres a first adherent patch **312** to at a first location **314** on a first side **302** of the patient for a first period of time, for example about 1 week. When the adherent patch **312** is position at first location **314** on the first side of the patient, the accelerometer signals are measured to determine the orientation of the patch and the electrodes of

the patch are coupled to the skin of the patient to measure the ECG signal and impedance signals.

A step **320** removes patch **312** and adheres a second adherent patch **322** at a second location **324** on a second side **206** of the patient for a second period of time, for example about 1 week. In many embodiments, second location **324** can be symmetrically disposed opposite first location **314** across midline **304**, for example so as to minimize changes in the sequential impedance signals measured from the second side and first side. When adherent patch **322** is position at second location **324** on the second side of the patient, the orientation of the patch can be measured with the accelerometer and the electrodes of the patch are coupled to the skin of the patient to measure the ECG signal and impedance signals. In many embodiments, while adherent patch **322** is positioned at second location **324**, skin at first location **314** can heal and recover from adherent coverage of the first patch. In many embodiments, second location **324** is symmetrically disposed opposite first location **314** across midline **304**, for example so as to minimize changes in the impedance signals measured between the first side and second side. In many embodiments, the duration between removal of one patch and placement of the other patch can be short, such that any differences between the signals may be determined to be related to orientation of the patch, and these differences can be corrected in response to the measured orientation of the patch on the patient.

A step **330** removes second patch **322** and adheres a third adherent patch **332** at a third location **334** on the first side, for example right side **302**, of the patient for a third period of time, for example about 1 week. In many embodiments, third location **334** can be symmetrically disposed opposite second location **324** across midline **304**, for example so as to minimize changes in the sequential impedance signals measured from the third side and second side. In many embodiments, third location **334** substantially overlaps with first location **314**, so as to minimize differences in measurements between the first adherent patch and third adherent patch that may be due to patch location. When adherent patch **332** is positioned at third location **334** on the first side of the patient, the orientation of the patch is measured with the accelerometer and the electrodes of the patch are coupled to the skin of the patient to measure the ECG signal and impedance signals. In many embodiments, while adherent patch **332** is positioned at third location **334**, skin at second location **324** can heal and recover from adherent coverage of the second patch. In many embodiments, the duration between removal of one patch and placement of the other patch can be short, such that differences between the signals may be determined to be related to orientation of the patch, and these differences can be corrected in response to the measured orientation of the patch on the patient.

A step **340** removes third patch **332** and adheres a fourth adherent patch **342** at a fourth location **344** on the second side, for example left side **306**, of the patient for a fourth period of time, for example about 1 week. In many embodiments, fourth location **344** can be symmetrically disposed opposite third location **334** across midline **304**, for example so as to minimize changes in the sequential impedance signal measured from the fourth side and third side. In many embodiments, fourth location **344** substantially overlaps with second location **324**, so as to minimize differences in measurements between the second adherent patch and fourth adherent patch that may be due to patch location. When adherent patch **342** is positioned at fourth location **344** on the second side of the patient, the orientation of patch is measured with the accelerometer and the electrodes of the patch are coupled to the skin of the patient to measure the ECG signal and impedance signals. In many embodiments, while adherent patch **342** is positioned at fourth location **324**, skin at third location **334** can heal and recover from adherent coverage of the third patch. In many embodiments, the duration between removal of one patch and placement of the other patch can be short, such that differences between the signals may be determined to be related to orientation of the patch, and these differences can be corrected in response to the measured orientation of the patch on the patient.

The accelerometer signal measured to determine the orientation on the patient for each of adherent patch **312**, adherent patch **322**, adherent patch **332** or adherent patch **342** can be measured with a reusable accelerometer of a reusable electronics module, for example as described above, or measured with a disposable accelerometer affixed to each patch and disposed of with the patch after the patch is removed from the patient.

It should be appreciated that the specific steps illustrated in FIGS. **3**A to **3**D provide a particular method of monitoring a patient for an extended period, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in FIGS. **3**A to **3**D may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

FIG. **4**A shows a method **400** of monitoring a patient. A step **405** adheres a first adherent patch to the patient, for example an adherent patch as described above. The first adherent patch may comprise a first patch that is separable from an electronics module, as described above. The first adherent patch may comprise a first patch of a first device with the electronics module fixed to the adherent patch, for example disposable electronics with a disposable patch.

A step **410**A measures a first accelerometer signal along a first axis, for example an X-axis of a 3D accelerometer responsive to gravity as described above. A step **410**B measures a first accelerometer signal along a second axis, for example a y-axis of a 3D accelerometer as described above. A step **410**C measures a first accelerometer signal along a third axis, for example a Z-axis of a 3D accelerometer as described above. Measurement of the accelerometer signal with step **410**A, step **410**B and step **41**C, which may comprise sub-steps, can be performed with the patient in a known and/or determined position. The patient may be asked to stand and/or sit upright in a chair and the first signal measured. In some embodiments, the 3D accelerometer signal can be analyzed to determine that the patient is standing, walking and the first signal determined from a plurality of measurements to indicate that the patient is upright for the measurement of the first signal.

A step **415** determines an orientation of the first patch on the patient. The accelerometer can be coupled to the patch with a pre-determined orientation, for example with connectors as described above, such that the orientation of the patch can be determined from the accelerometer signal and the orientation of the 3D accelerometer on the adherent patch and the orientation of the patient.

A step **420** measures a first ECG signal. The first ECG signal can be measured with the electrodes attached to the patient when the patch comprises the first orientation. The

ECG signal can be measured with electronics components and electrodes, as described above.

A step **425** determines a first orientation of an electrode measurement axis on the patient. The electrode measurement axis may correspond to one of the measurement axes of the 3D accelerometer, for example an X-axis of the accelerometer as described above. However, the orientation of the electrode measurement axis can be aligned in relation to the axes of the accelerometer in many ways, for example at oblique angles, such that the alignment of the accelerometer with the electrode measurement axis is known and the signal from the accelerometer can be used to determine the alignment of the electrode measurement axis.

A step **430** determines a first orientation of the ECG vector. The orientation of the ECG vector can be determined in response to the polarity of the measurement electrodes and orientation of the electrode measurement axis, as described above.

A step **435** rotates a first ECG vector. The first ECG vector orientation of the ECG vector can be used to rotate the ECG vector onto a desired axis, for example an X-axis of the patient in response to the first orientation of the ECG vector and the accelerometer signal. For example, if the first measurement axis of the first ECG vector is rotated five degrees based on the accelerometer signal, the first ECG vector can be rotated by five degrees so as to align the first ECG vector with the patient axis.

A step **440** measures a first patient temperature. The first temperature of the patient can be measured with electronics of the adherent device, as described above.

A step **445** measures a first patient impedance. The first patient impedance may comprise a four pole impedance measurement, as described above. The first patient impedance can be used to determine respiration of the patient and/or hydration of the patient.

A step **450** adheres a second patch to the patient. The second patch may comprise a second patch connected to a reusable electronics module, for example a reusable electronics module connected to the first patch for the first patient measurements above. The second patch may comprise a second patch of a second adherent device comprising a second electronics module in which the second patch and second electronics module comprise a disposable second adherent device and the first adherent patch and first electronics module comprise a first disposable adherent device.

A step **455**A measures a second accelerometer signal along a first axis, for example an x-axis of the accelerometer as described above. The first axis may comprise the first axis of the first accelerometer as described above, for example the X-axis of the accelerometer used to measure the X-axis signal with the first measurement. In some embodiments, the second accelerometer signal along the first axis may comprise an X-axis of a second accelerometer, for example a second disposable electronics module, aligned with an electrode measurement axis as described above.

A step **455**B measures a second accelerometer signal along a second axis. The second axis may comprise the second axis of the first accelerometer as described above, for example the Y-axis of the accelerometer used to measure the Y-axis signal with the first measurement. In some embodiments, the second accelerometer signal along the second axis may comprise a Y-axis of a second accelerometer, for example a second disposable electronics module, aligned with an electrode measurement axis as described above.

A step **455**C measures a second accelerometer signal along a third axis. The third axis may comprise the third axis of the first accelerometer as described above, for example the Z-axis of the accelerometer used to measure the Z-axis signal with the first measurement. In some embodiments, the second accelerometer signal along the third axis may comprise a Z-axis of a second accelerometer, for example a second disposable electronics module, aligned with an electrode measurement axis as described above.

A step **460** determines an orientation of the second patch on the patient. The accelerometer can be coupled to the second patch with a pre-determined orientation, for example with connectors as described above, such that the orientation of the second patch can be determined from the second accelerometer signal and the orientation of the 3D accelerometer on the adherent patch and the orientation of the patient.

A step **465** measures a second ECG signal. The second ECG signal can be measured with the electrodes attached to the patient when the second patch comprises the second orientation, for example after the first patch has been removed and the second patch has been positioned on the patient as described above. The ECG signal can be measured with electronics components and electrodes, as described above.

A step **470** determines a second orientation of the electrode measurement axis on the patient. The second orientation of the electrode measurement axis may comprise orientation of an axis of a second set of electrodes, for example a second set of electrodes disposed along an axis of the second patch. The second orientation of the electrode measurement axis may correspond to one of the measurement axes of the 3D accelerometer, for example an X-axis of the accelerometer as described above. However, the second orientation of the electrode measurement axis can be aligned in relation to the axes of the accelerometer in many ways, for example at oblique angles, such that the alignment of the accelerometer with the second electrode measurement axis is known and the signal from the accelerometer can be used to determine the alignment of the electrode measurement axis.

A step **475** determines a second orientation of the ECG vector. The second orientation of the ECG vector can be determined in response to the polarity of the second measurement electrodes and second orientation of the electrode measurement axis, for example second measurement electrodes on the second adherent patch that extend along the electrode measurement axis of the second adherent patch.

A step **480** rotates a second ECG vector. The second ECG vector orientation of the second ECG vector can be used to rotate the second ECG vector onto the desired axis, for example the X-axis of the patient in response to the first orientation of the ECG vector and the accelerometer signal. For example, if the first measurement axis of the first ECG vector is rotated five degrees from the X-axis based on the accelerometer signal, the first ECG vector can be rotated by five degrees so as to align the first ECG vector with the X-axis of the patient, for example the horizontal axis of the patient.

A step **485** measures a second patient temperature. The second temperature of the patient can be measured with electronics of the adherent device, as described above.

A step **490** measures a second patient impedance. The second patient impedance may comprise a four pole impedance measurement, as described above. The second patient impedance can be used to determine respiration of the patient and/or hydration of the patient.

A step **495** repeats the above steps. The above steps can be repeated to provide longitudinal monitoring of the patient with differential measurement of patient status. The moni-

toring of the patient may comprise a comparison of baseline patient data with subsequent patient date.

Many of the steps of method **400** can be performed with the processor system, as described above.

It should be appreciated that the specific steps illustrated in FIG. **4**A provides a particular method of monitoring a patient, according to an embodiment of the present invention. Other sequences of steps may also be performed according to alternative embodiments. For example, alternative embodiments of the present invention may perform the steps outlined above in a different order. Moreover, the individual steps illustrated in FIG. **4**A may include multiple sub-steps that may be performed in various sequences as appropriate to the individual step. Furthermore, additional steps may be added or removed depending on the particular applications. One of ordinary skill in the art would recognize many variations, modifications, and alternatives.

While the exemplary embodiments have been described in some detail, by way of example and for clarity of understanding, those of skill in the art will recognize that a variety of modifications, adaptations, and changes may be employed. Hence, the scope of the present invention should be limited solely by the appended claims.

What is claimed is:

1. A system for monitoring a patient, the system comprising:

a first adherent device adapted to be adhered to a skin of a patient, the first adherent device having a first support with a first adhesive configured to adhere the first support to the skin, the first adherent device including first electrodes supported with the first support to couple to the skin of the patient, the first adherent device adapted to measure physiological parameters of the patient with the first electrodes when coupled to the skin of the patient during a first monitoring period, the first electrodes defining a first electrode axis;

a second adherent device adapted to be adhered to the skin of the patient, the second adherent device having a second support with a second adhesive configured to adhere the second support to the skin, the second adherent device including second electrodes supported with the second support to couple to the skin of the patient, the second adherent device adapted to measure physiological parameters of the patient with the second electrodes when coupled to the skin of the patient during a second monitoring period subsequent the first monitoring period, the second electrodes define a second electrode axis;

at least one accelerometer couplable to at least one of the first adherent device or the second adherent device and having a measurement axis aligned with the respective electrode axis, wherein the at least one accelerometer is adapted to determine an orientation of the respective electrode axis of the first electrodes or the second electrodes relative a reference axis of the patient when coupled to the first or second adherent device during the respective monitoring periods; and

a processor system comprising a tangible medium configured to modify the measured physiological parameters based on the determined orientations of the first electrode axis or the second electrode axis such that errors in the physiological parameter measurements associated with changes in the orientation of the first and second adherent devices are reduced.

2. The system of claim **1**, wherein the at least one accelerometer comprises a first accelerometer coupled to the first adherent device in a first predetermined orientation and a second accelerometer coupled to the second adherent device in a second predetermined orientation.

3. The system of claim **1** wherein the reference axis of the patient corresponds to a vertical axis of the patient that extends vertically when the patient is standing or sitting.

4. The system of claim **1**, wherein one or both of the first and second monitoring period is 90 days or more.

5. The system of claim **1**, further comprising:

a remote server communicatively coupled with the intermediate device such that the remote server receives the physiological measurements from the intermediate device for physiological monitoring of the patient.

6. A system for monitoring a patient, the system comprising:

a first adherent measurement device adapted to be adhered to a skin of a patient, the first adherent measurement device comprising a first support with a first adhesive configured to adhere the first support to a skin of the patient, the first adherent measurement device comprising a first accelerometer and a first at least two measurement electrodes, the first adherent device comprising first measurement circuitry configured to measure a first accelerometer signal with the accelerometer and a first electrocardiogram signal with the first at least two measurement electrodes during a first monitoring period;

a second adherent measurement device adapted to be adhered to the skin of the patient, the second adherent measurement device comprising a second support with a second adhesive configured to adhere the second support to the skin, the second adherent measurement device comprising a second accelerometer and a second at least two measurement electrodes, the second accelerometer comprising second circuitry configured to measure a second accelerometer signal with the second accelerometer and a second electrocardiogram signal with the second at least two measurement electrodes during a second monitoring period subsequent the first monitoring period; and

a processor system comprising a tangible medium configured to combine the first electrocardiogram signal with the second electrocardiogram signal in response to the first accelerometer signal and the second accelerometer signal, wherein the processor system is configured to determine an orientation of the first electrode measurement axis relative a reference axis of the patient in response to the first accelerometer signal and determine an orientation of the second electrode measurement axis relative the reference axis of the patient in response to the to the accelerometer signal, wherein the reference axis corresponds to a vertical axis of the patient that extends vertically along the patient when the patient is standing or sitting.

7. The system of claim **6** wherein the first accelerometer comprises a first accelerometer measurement axis and the first at least two electrodes are separated by a first distance to define a first electrode measurement axis, the first accelerometer measurement axis aligned with the first electrode measurement axis, and wherein the second accelerometer comprises a second accelerometer measurement axis and the second at least two electrodes are separated by a second distance to define a second electrode measurement axis, the second accelerometer measurement axis aligned with the second electrode measurement axis.

8. The system of claim **6** wherein the processor system comprises at least one processor supported by at least one of the first support or the second support, the at least one

processor configured to combine the first electrocardiogram signal and the second electrocardiogram signal in response to the first accelerometer signal and the second accelerometer signal.

9. The system of claim **6** wherein the processor is configured to scale each electrocardiogram signal and sum the scaled electrocardiogram signals together to combine the electrocardiogram signals.

10. A method of monitoring a patient, the method comprising:

adhering a first adherent device to a skin of the patient, the adherent device comprising a first accelerometer and at least two physiological measurement electrodes, the at least two physiological measurement electrodes separated by a distance to define an electrode measurement axis;

a processor system receiving an accelerometer signal provided by the accelerometer of the first adherent device when the first adherent device is adhered to the patient;

the processor system determining a reference axis of the patient corresponding to a vertical axis that extends vertically along the patient when the patient is standing and determining an orientation of the electrode measurement axis of the first adherent device relative the reference axis in response to the accelerometer signal of the first adherent device;

the processor system receiving physiological parameters of the patient provided by with the at least two physiological measurement electrodes of the first adherent device when the first adherent device is coupled to the skin of the patient and the processor system modifying the physiological parameter measurements obtained from the first adherent device based on the determined orientation of the electrode measurement axis of the first adherent device;

adhering a second adherent device to a skin of the patient, the adherent device comprising the first accelerometer or a second accelerometer and at least two physiological measurement electrodes, the at least two physiological measurement electrodes separated by a distance to define an electrode measurement axis;

the processor system receiving an accelerometer signal provided by from the accelerometer of the second adherent device when the second adherent device is adhered to the patient;

the processor system determining an orientation of the electrode measurement axis of the second adherent device relative the reference axis of the patient in response to the accelerometer signal of the second adherent device;

removing the first adherent device from the patient; and

the processor system receiving physiological parameters of the patient provided by the at least two physiological measurement electrodes of the second adherent device and the processor system modifying the physiological parameter measurements obtained from the second adherent device based on the determined orientation of the electrode measurement axis of the second adherent device relative the reference axis of the patient such that differences in the measured physiological parameters associated with changes in the orientation of the first and second adherent devices are reduced.

11. The method of claim **10** wherein the first accelerometer or the first and second accelerometers each comprises at least one measurement axis sensitive to gravity aligned with the electrode measurement axis.

12. The method of claim **10** wherein the first accelerometer or the first and second accelerometers each comprises at least one accelerometer measurement axis sensitive to gravity, the at least one accelerometer measurement axis configured to extend substantially horizontally on the patient when the device is adhered to the patient.

13. The method of claim **10** wherein the accelerometer signal of the first accelerometer or of the first and second accelerometers corresponds to at least one accelerometer measurement vector in a direction along the at least one accelerometer measurement axis.

14. The method of claim **10** wherein the first accelerometer or the first and second accelerometers each comprises at least one accelerometer measurement axis sensitive to gravity and wherein the at least one accelerometer measurement axis is oriented with respect to the electrode measurement axis in a predetermined configuration.

15. The method of claim **10** wherein each of the first and second adherent devices comprises an adherent surface to adhere to a skin of the patient and wherein the electrode measurement axis extends along the adherent surface.

16. The method of claim **10** wherein the first accelerometer or the first and second accelerometers each comprises three axes, wherein a first axis and a second axis of the three axes extend along the measurement surface and a third axis of the three axes extends away from the measurement surface and the accelerometer measurement signal corresponds to three orthogonal measurement vectors, wherein each of the three orthogonal measurement vectors extends along one of the accelerometer measurement axes.

17. The method of claim **10** further comprising the processor system receiving an electrocardiogram signal sensed by the at least two measurement electrodes of each of the first and second adherent devices when coupled to the patient and modifying the electrocardiogram signal of the second adherent device in response to the accelerometer signal.

18. The method of claim **17** wherein modifying comprises rotating the electrocardiogram vector in response to the accelerometer signal to obtain a standard electrocardiogram vector.

19. The method of claim **18** wherein an amplitude and a direction of features of the electrocardiogram signal are modified to approximate a standard electrocardiogram vector.

20. The method of claim **10**, further comprising:

an intermediate device wirelessly coupled with each of the first adherent device and second adherent device when coupled to the skin of the patient, and receiving physiological measurement from the at least two physiological measurement electrodes of each of the first adherent device and second adherent device.

21. The method of claim **20**, further comprising:

a remote server communicatively coupled with the intermediate device such that the remote server receives the physiological measurements from the intermediate device for physiological monitoring of the patient.

22. The method of claim **21**, wherein the remote server comprises a processor for modifying the physiological measurement data.

23. The method of claim **10**, wherein the second adherent device is adhered before removal of the first adherent device.

24. The method of claim **10**, wherein the second adherent device is adhered after removal of the first adherent device.

25. The method of claim **10**, further comprising:

removing the accelerometer from the first adherent device and coupling the accelerometer to the second adherent device such that the first and second adherent devices utilize the same accelerometer.

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