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(54) **REMOTE INTERFACING
ELECTROCARDIOGRAPHY PATCH**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,215,136 A 11/1965 Holter et al.
3,554,311 A 1/1971 Thompson et al.
(Continued)

FOREIGN PATENT DOCUMENTS

DE 19955211 5/2001
EP 1859833 11/2007
(Continued)

OTHER PUBLICATIONS

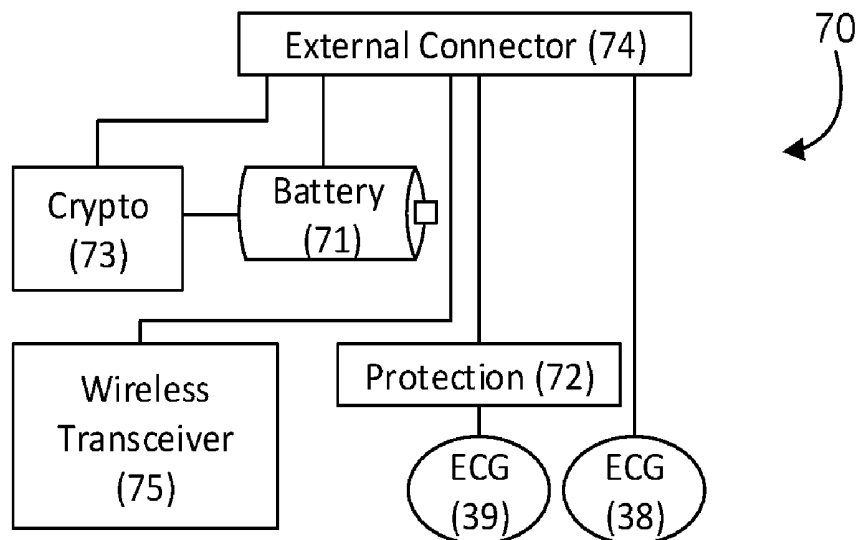
Epstein, Andrew E et al.; ACC/AHA/HRS 2008 Guidelines for
Device-Based Therapy of Cardiac Rhythm Abnormalities. *J. Am.*
Coll. Cardiol. 2008; 51; e1-e62, 66 Pgs.
(Continued)

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(57) **ABSTRACT**

A remotely-interfaceable electrocardiography patch is provided. A flexible backing is formed from an elongated strip of material. A pair of electrocardiographic electrodes are exposed on a contact surface of the flexible backing for capturing electrocardiographic signals. A non-conductive receptacle is adhered to an outward-facing surface of the flexible backing and includes a plurality of electrical pads. A flexible circuit has a pair of circuit traces electrically coupled to the pair of electrocardiographic electrodes and a pair of the electrical pads. A wireless transceiver communicates samples of the electrocardiographic signals.

20 Claims, 8 Drawing Sheets



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		5,215,098 A	6/1993	Steinhaus
		D341,423 S	11/1993	Bible
		5,265,579 A	11/1993	Ferrari
		5,333,615 A	8/1994	Craelius et al.
		5,341,806 A	8/1994	Gadsby et al.
		5,355,891 A	10/1994	Wateridge et al.
		5,365,934 A	11/1994	Leon et al.
		5,365,935 A	11/1994	Righter et al.
		5,392,784 A	2/1995	Gudaitis
		D357,069 S	4/1995	Plahn et al.
		5,402,780 A	4/1995	Faasse, Jr.
		5,402,884 A	4/1995	Gilman et al.
		5,450,845 A	9/1995	Axelgaard
		5,458,141 A	10/1995	Neil
		5,473,537 A	12/1995	Glazer et al.
		5,483,969 A	1/1996	Testerman et al.
		5,511,553 A	4/1996	Segalowitz
		5,540,733 A	7/1996	Testerman et al.
		5,546,952 A	8/1996	Erickson
		5,549,655 A	8/1996	Erickson
		5,579,919 A	12/1996	Gilman et al.
		5,582,181 A	12/1996	Ruess
		D377,983 S	2/1997	Sabri et al.
		5,601,089 A	2/1997	Bledsoe et al.
		5,623,935 A	4/1997	Faisandier
		5,682,901 A	11/1997	Kamen
		5,697,955 A	12/1997	Stolte
		5,749,902 A	5/1998	Olsen et al.
		5,788,633 A	8/1998	Mahoney
		5,817,151 A	10/1998	Olsen et al.
		5,819,741 A	10/1998	Karlsson et al.
		5,850,920 A	12/1998	Gilman et al.
		D407,159 S	3/1999	Roberg
		5,876,351 A	3/1999	Rohde
		5,906,583 A	5/1999	Rogel
		5,951,598 A	9/1999	Bishay et al.
		5,957,857 A	9/1999	Hartley
		5,984,102 A	11/1999	Tay
		6,032,064 A	2/2000	Devlin et al.
		6,038,469 A	3/2000	Karlsson et al.
		6,101,413 A	8/2000	Olsen et al.
		6,115,638 A	9/2000	Groenke
		6,117,077 A	9/2000	Del Mar et al.
		6,134,479 A	10/2000	Brewer et al.
		6,148,233 A	11/2000	Owen et al.
		6,149,602 A	11/2000	Arcelus
		6,149,781 A	11/2000	Forand
		6,188,407 B1	2/2001	Smith et al.
		D443,063 S	5/2001	Pisani et al.
		6,245,025 B1	6/2001	Torok et al.
		6,246,330 B1	6/2001	Nielsen
		6,249,696 B1	6/2001	Olson et al.
		D445,507 S	7/2001	Pisani et al.
		6,269,267 B1	7/2001	Bardy et al.
		6,272,385 B1	8/2001	Bishay et al.
		6,298,255 B1	10/2001	Cordero et al.
		6,301,502 B1	10/2001	Owen et al.
		6,304,773 B1	10/2001	Taylor et al.
		6,304,780 B1	10/2001	Owen et al.
		6,304,783 B1	10/2001	Lyster et al.
		6,374,138 B1	4/2002	Owen et al.
		6,381,482 B1	4/2002	Jayaraman et al.
		6,416,471 B1	7/2002	Kumar et al.
		6,418,342 B1	7/2002	Owen et al.
		6,424,860 B1	7/2002	Karlsson et al.
		6,427,083 B1	7/2002	Owen et al.
		6,427,085 B1	7/2002	Boon et al.
		6,454,708 B1	9/2002	Ferguson et al.
		6,456,872 B1	9/2002	Faisandier
		6,463,320 B1	10/2002	Kue et al.
		6,546,285 B1	4/2003	Owen et al.
		6,605,046 B1	8/2003	Del Mar
		6,607,485 B2	8/2003	Bardy
		6,611,705 B2	8/2003	Hopman et al.
		6,671,545 B2	12/2003	Fincke
		6,671,547 B2	12/2003	Lyster et al.
		6,694,186 B2	2/2004	Bardy
		6,704,595 B2	3/2004	Bardy
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	See application file for complete search history.			
(56)	References Cited			
	U.S. PATENT DOCUMENTS			
	3,569,852 A	3/1971	Berkovits	
	3,699,948 A	10/1972	Ota et al.	
	3,893,453 A	7/1975	Goldberg	
	4,123,785 A	10/1978	Cherry et al.	
	4,328,814 A	5/1982	Arkans	
	4,441,500 A	4/1984	Sessions et al.	
	4,532,934 A	8/1985	Kelen	
	4,546,342 A	10/1985	Weaver et al.	
	4,550,502 A	11/1985	Grayzel	
	4,580,572 A	4/1986	Granek et al.	
	4,635,646 A	1/1987	Gilles et al.	
	4,653,022 A	3/1987	Koro	
	4,716,903 A	1/1988	Hansen	
	4,809,705 A	3/1989	Ascher	
	4,915,656 A	4/1990	Alferness	
	5,007,429 A	4/1991	Treatch et al.	
	5,025,794 A	6/1991	Albert et al.	
	5,107,480 A	4/1992	Naus	

(56)

References Cited

U.S. PATENT DOCUMENTS

6,705,991 B2	3/2004	Bardy	8,744,561 B2	6/2014	Fahey
6,719,701 B2	4/2004	Lade	8,774,932 B2	7/2014	Fahey
6,754,523 B2	6/2004	Toole	8,790,257 B2	7/2014	Libbus et al.
6,782,293 B2	8/2004	Dupelle et al.	8,790,259 B2	7/2014	Katra et al.
6,856,832 B1	2/2005	Matsumura	8,795,174 B2	8/2014	Manicka et al.
6,860,897 B2	3/2005	Bardy	8,798,729 B2	8/2014	Kaib et al.
6,866,629 B2	3/2005	Bardy	8,798,734 B2	8/2014	Kuppuraj et al.
6,887,201 B2	5/2005	Bardy	8,818,478 B2	8/2014	Scheffler et al.
6,893,397 B2	5/2005	Bardy	8,818,481 B2	8/2014	Bly et al.
6,904,312 B2	6/2005	Bardy	8,823,490 B2	9/2014	Libbus et al.
6,908,431 B2	6/2005	Bardy	8,938,287 B2	1/2015	Felix et al.
6,913,577 B2	7/2005	Bardy	8,965,492 B2	2/2015	Baker et al.
6,944,498 B2	9/2005	Owen et al.	9,066,664 B2	6/2015	Karjalainen
6,960,167 B2	11/2005	Bardy	9,155,484 B2	10/2015	Baker et al.
6,970,731 B1	11/2005	Jayaraman et al.	9,204,813 B2	12/2015	Kaib et al.
6,978,169 B1	12/2005	Guerra	9,277,864 B2	3/2016	Yang et al.
6,993,377 B2	1/2006	Flick et al.	9,339,202 B2	5/2016	Brockway et al.
7,020,508 B2	3/2006	Stivoric et al.	9,439,566 B2	9/2016	Arne et al.
7,027,864 B2	4/2006	Snyder et al.	2002/0013538 A1	1/2002	Teller
7,065,401 B2	6/2006	Worden	2002/0013717 A1	1/2002	Ando et al.
7,085,601 B1	8/2006	Bardy et al.	2002/0016798 A1	2/2002	Sakai et al.
7,104,955 B2	9/2006	Bardy	2002/0103422 A1	8/2002	Harder et al.
7,134,996 B2	11/2006	Bardy	2002/0109621 A1	8/2002	Khair et al.
7,137,389 B2	11/2006	Berthon-Jones	2002/0120310 A1	8/2002	Linden et al.
7,147,600 B2	12/2006	Bardy	2002/0128686 A1	9/2002	Minogue et al.
7,215,991 B2	5/2007	Besson et al.	2002/0184055 A1	12/2002	Naghavi et al.
7,248,916 B2	7/2007	Bardy	2002/0193668 A1	12/2002	Munneke
7,257,438 B2	8/2007	Kinast	2003/0004547 A1	1/2003	Owen et al.
7,277,752 B2	10/2007	Matos	2003/0073916 A1	4/2003	Yonce
D558,882 S	1/2008	Brady	2003/0083559 A1	5/2003	Thompson
7,328,061 B2	2/2008	Rowlandson et al.	2003/0097078 A1	5/2003	Maeda
7,412,395 B2	8/2008	Rowlandson et al.	2003/0139785 A1	7/2003	Riff et al.
7,429,938 B1	9/2008	Corndorf	2003/0176802 A1	9/2003	Galen et al.
7,552,031 B2	6/2009	Vock et al.	2003/0211797 A1	11/2003	Hill et al.
D606,656 S	12/2009	Kobayashi et al.	2004/0008123 A1	1/2004	Carrender
7,706,870 B2	4/2010	Shieh et al.	2004/0019288 A1	1/2004	Kinast
7,756,721 B1	7/2010	Falchuk et al.	2004/0034284 A1	2/2004	Aversano et al.
7,787,943 B2	8/2010	McDonough	2004/0049132 A1	3/2004	Barron et al.
7,874,993 B2	1/2011	Bardy	2004/0073127 A1	4/2004	Istvan et al.
7,881,785 B2	2/2011	Nassif et al.	2004/0087836 A1	5/2004	Green et al.
D639,437 S	6/2011	Bishay et al.	2004/0088019 A1	5/2004	Rueter et al.
7,959,574 B2	6/2011	Bardy	2004/0093192 A1	5/2004	Hasson et al.
8,116,841 B2	2/2012	Bly et al.	2004/0148194 A1	7/2004	Wellons et al.
8,135,459 B2	3/2012	Bardy et al.	2004/0163034 A1	8/2004	Colbath et al.
8,172,761 B1	5/2012	Rulkov et al.	2004/0207530 A1	10/2004	Nielsen
8,180,425 B2	5/2012	Selvitelli et al.	2004/0236202 A1	11/2004	Burton
8,200,320 B2	6/2012	Kovacs	2004/0243435 A1	12/2004	Williams
8,231,539 B2	7/2012	Bardy	2004/0256453 A1	12/2004	Lammle
8,231,540 B2	7/2012	Bardy	2004/0260188 A1	12/2004	Syed
8,239,012 B2	8/2012	Felix et al.	2004/0260192 A1	12/2004	Yamamoto
8,249,686 B2	8/2012	Libbus et al.	2005/0096717 A1	5/2005	Bishay et al.
8,260,414 B2	9/2012	Nassif et al.	2005/0108055 A1	5/2005	Ott et al.
8,266,008 B1	9/2012	Siegal et al.	2005/0154267 A1	7/2005	Bardy
8,277,378 B2	10/2012	Bardy	2005/0182308 A1	8/2005	Bardy
8,285,356 B2	10/2012	Bly et al.	2005/0182309 A1	8/2005	Bardy
8,285,370 B2	10/2012	Felix et al.	2005/0215918 A1	9/2005	Frantz et al.
8,308,650 B2	11/2012	Bardy	2005/0222513 A1	10/2005	Hadley et al.
8,366,629 B2	2/2013	Bardy	2005/0228243 A1	10/2005	Bardy
8,374,688 B2	2/2013	Libbus et al.	2005/0245839 A1	11/2005	Stivoric et al.
8,412,317 B2	4/2013	Mazar	2006/0025696 A1	2/2006	Kurzweil et al.
8,460,189 B2	6/2013	Libbus et al.	2006/0025824 A1	2/2006	Freeman et al.
8,473,047 B2	6/2013	Chakravarthy et al.	2006/0030767 A1	2/2006	Lang et al.
8,478,418 B2	7/2013	Fahey	2006/0030904 A1	2/2006	Quiles
8,591,430 B2	11/2013	Amurthur et al.	2006/0041201 A1	2/2006	Behbehani et al.
8,594,763 B1	11/2013	Bibian et al.	2006/0122469 A1	6/2006	Martel
8,600,486 B2	12/2013	Kaib et al.	2006/0124193 A1	6/2006	Orr et al.
8,613,708 B2	12/2013	Bishay et al.	2006/0124193 A1	6/2006	Orr et al.
8,613,709 B2	12/2013	Bishay et al.	2006/0224072 A1	10/2006	Shennib
8,620,418 B1	12/2013	Kuppuraj et al.	2006/0235320 A1	10/2006	Tan et al.
8,626,277 B2	1/2014	Felix et al.	2006/0253006 A1	11/2006	Bardy
8,628,020 B2	1/2014	Beck	2006/0264730 A1	11/2006	Stivoric et al.
8,668,653 B2	3/2014	Nagata et al.	2006/0264767 A1	11/2006	Shennib
8,684,925 B2	4/2014	Manicka et al.	2007/0003115 A1	1/2007	Patton et al.
8,688,190 B2	4/2014	Libbus et al.	2007/0038057 A1	2/2007	Nam et al.
8,718,752 B2	5/2014	Libbus et al.	2007/0050209 A1	3/2007	Yered
			2007/0078324 A1	4/2007	Wijisiriwardana
			2007/0078354 A1	4/2007	Holland
			2007/0088406 A1	4/2007	Bennett et al.
			2007/0089800 A1	4/2007	Sharma
			2007/0093719 A1	4/2007	Nichols, Jr. et al.

(56)		References Cited						
		U.S. PATENT DOCUMENTS						
2007/0100248	A1	5/2007	Van Dam et al.	2010/0191310	A1	7/2010	Bly	
2007/0100667	A1	5/2007	Bardy	2010/0223020	A1	9/2010	Goetz	
2007/0123801	A1	5/2007	Goldberger et al.	2010/0234715	A1	9/2010	Shin et al.	
2007/0131595	A1	6/2007	Jansson et al.	2010/0234716	A1	9/2010	Engel	
2007/0136091	A1	6/2007	McTaggart	2010/0280366	A1	11/2010	Arne et al.	
2007/0179357	A1	8/2007	Bardy	2010/0312188	A1*	12/2010	Robertson	A61B 5/0006 604/156
2007/0185390	A1	8/2007	Perkins et al.	2010/0324384	A1	12/2010	Moon et al.	
2007/0203415	A1	8/2007	Bardy	2011/0021937	A1	1/2011	Hugh et al.	
2007/0203423	A1	8/2007	Bardy	2011/0054286	A1	3/2011	Crosby et al.	
2007/0208232	A1	9/2007	Kovacs	2011/0060215	A1	3/2011	Tupin et al.	
2007/0208233	A1	9/2007	Kovacs	2011/0066041	A1	3/2011	Pandia et al.	
2007/0208266	A1	9/2007	Hadley	2011/0077497	A1	3/2011	Oster et al.	
2007/0225611	A1	9/2007	Kumar et al.	2011/0105861	A1	5/2011	Derchak et al.	
2007/0244405	A1	10/2007	Xue et al.	2011/0144470	A1	6/2011	Mazar et al.	
2007/0249946	A1	10/2007	Kumar et al.	2011/0160548	A1	6/2011	Forster	
2007/0255153	A1	11/2007	Kumar et al.	2011/0224564	A1	9/2011	Moon et al.	
2007/0265510	A1	11/2007	Bardy	2011/0237922	A1	9/2011	Parker, III et al.	
2007/0276270	A1	11/2007	Tran	2011/0237924	A1	9/2011	McGusty et al.	
2007/0276275	A1	11/2007	Proctor et al.	2011/0245699	A1	10/2011	Snell et al.	
2007/0293738	A1	12/2007	Bardy	2011/0245711	A1	10/2011	Katra et al.	
2007/0293739	A1	12/2007	Bardy	2011/0288605	A1	11/2011	Kalb et al.	
2007/0293740	A1	12/2007	Bardy	2012/0003933	A1	1/2012	Baker et al.	
2007/0293741	A1	12/2007	Bardy	2012/0029306	A1	2/2012	Paquet et al.	
2007/0293772	A1	12/2007	Bardy	2012/0029315	A1	2/2012	Raptis et al.	
2007/0299325	A1	12/2007	Farrell et al.	2012/0029316	A1	2/2012	Raptis et al.	
2007/0299617	A1	12/2007	Willis	2012/0035432	A1	2/2012	Katra et al.	
2008/0027339	A1	1/2008	Nagai et al.	2012/0078127	A1	3/2012	McDonald et al.	
2008/0051668	A1	2/2008	Bardy	2012/0088998	A1	4/2012	Bardy et al.	
2008/0058661	A1	3/2008	Bardy	2012/0088999	A1	4/2012	Bishay et al.	
2008/0088467	A1	4/2008	Al-Ali et al.	2012/0089000	A1	4/2012	Bishay et al.	
2008/0091097	A1	4/2008	Linti et al.	2012/0089001	A1	4/2012	Bishay et al.	
2008/0108890	A1	5/2008	Teng et al.	2012/0089037	A1	4/2012	Bishay et al.	
2008/0114232	A1	5/2008	Gazit	2012/0089412	A1	4/2012	Bardy et al.	
2008/0139953	A1	6/2008	Baker et al.	2012/0095352	A1	4/2012	Tran	
2008/0143080	A1	6/2008	Burr	2012/0101358	A1	4/2012	Boettcher et al.	
2008/0177168	A1	7/2008	Callahan et al.	2012/0101396	A1	4/2012	Solosko et al.	
2008/0194927	A1	8/2008	KenKnight et al.	2012/0165645	A1	6/2012	Russel et al.	
2008/0208009	A1	8/2008	Shklarski	2012/0306662	A1	6/2012	Vosch et al.	
2008/0208014	A1	8/2008	KenKnight et al.	2012/0172695	A1	7/2012	Ko et al.	
2008/0284599	A1	11/2008	Zdeblick et al.	2012/0089417	A1	8/2012	Bardy et al.	
2008/0288026	A1	11/2008	Cross et al.	2012/0238910	A1	9/2012	Nordstrom	
2008/0294024	A1	11/2008	Cosentino et al.	2012/0253847	A1	10/2012	Dell'Anno et al.	
2008/0306359	A1	12/2008	Zdeblick et al.	2012/0302906	A1	11/2012	Felix et al.	
2008/0312522	A1	12/2008	Rowlandson et al.	2012/0330126	A1	12/2012	Hoppe et al.	
2009/0012979	A1	1/2009	Bateni et al.	2013/0041272	A1	2/2013	Javier et al.	
2009/0054952	A1	2/2009	Glukhovskiy et al.	2013/0077263	A1	3/2013	Oleson et al.	
2009/0062897	A1	3/2009	Axelgaard	2013/0079611	A1	3/2013	Besko	
2009/0069867	A1	3/2009	KenKnight et al.	2013/0085347	A1	4/2013	Manicka et al.	
2009/0073991	A1	3/2009	Landrum et al.	2013/0085403	A1	4/2013	Gunderson et al.	
2009/0076336	A1	3/2009	Mazar et al.	2013/0096395	A1	4/2013	Katra et al.	
2009/0076341	A1	3/2009	James et al.	2013/0116533	A1	5/2013	Lian et al.	
2009/0076342	A1	3/2009	Amurthur et al.	2013/0123651	A1	5/2013	Bardy	
2009/0076343	A1	3/2009	James et al.	2013/0158361	A1	6/2013	Bardy	
2009/0076346	A1	3/2009	James et al.	2013/0197380	A1	8/2013	Oral et al.	
2009/0076349	A1	3/2009	Libbus et al.	2013/0225963	A1	8/2013	Kodandaramaiah et al.	
2009/0076397	A1	3/2009	Libbus et al.	2013/0225966	A1	8/2013	Macia Barber et al.	
2009/0076401	A1	3/2009	Mazar et al.	2013/0243105	A1	9/2013	Lei et al.	
2009/0076559	A1	3/2009	Libbus et al.	2013/0274584	A1	10/2013	Finlay et al.	
2009/0088652	A1	4/2009	Tremblay	2013/0275158	A1	10/2013	Fahey	
2009/0112116	A1	4/2009	Lee et al.	2013/0324809	A1	12/2013	Lisogurski et al.	
2009/0131759	A1	5/2009	Sims et al.	2013/0324855	A1	12/2013	Lisogurski et al.	
2009/0156908	A1	6/2009	Belalcazar et al.	2013/0324856	A1	12/2013	Lisogurski et al.	
2009/0216132	A1	8/2009	Orbach	2013/0325359	A1	12/2013	Jarverud et al.	
2009/0270708	A1	10/2009	Shen et al.	2013/0331665	A1	12/2013	Libbus et al.	
2009/0270747	A1	10/2009	Van Dam et al.	2013/0338448	A1	12/2013	Libbus et al.	
2009/0292194	A1	11/2009	Libbus et al.	2013/0338472	A1	12/2013	Macia Barber et al.	
2010/0007413	A1	1/2010	Herleikson et al.	2014/0012154	A1	1/2014	Mazar et al.	
2010/0022897	A1	1/2010	Parker et al.	2014/0056452	A1	2/2014	Moss et al.	
2010/0056881	A1	3/2010	Libbus et al.	2014/0140359	A1	5/2014	Kalevo et al.	
2010/0081913	A1	4/2010	Cross et al.	2014/0180027	A1	6/2014	Buller	
2010/0174229	A1	7/2010	Hsu et al.	2014/0189928	A1	7/2014	Oleson et al.	
2010/0177100	A1	7/2010	Carnes et al.	2014/0206977	A1	7/2014	Bahney et al.	
2010/0185063	A1	7/2010	Bardy	2014/0215246	A1	7/2014	Lee et al.	
2010/0185076	A1	7/2010	Jeong et al.	2014/0249852	A1	9/2014	Proud	
2010/0191154	A1	7/2010	Berger et al.	2014/0296651	A1	10/2014	Stone	
				2014/0358193	A1	12/2014	Lyons et al.	
				2014/0364756	A1	12/2014	Brockway et al.	
				2015/0048836	A1	2/2015	Guthrie et al.	

(56) **References Cited**

U.S. PATENT DOCUMENTS

2015/0065842	A1	3/2015	Lee et al.
2015/0250422	A1	9/2015	Bay
2015/0257670	A1	9/2015	Ortega et al.
2015/0305676	A1	11/2015	Shoshani
2015/0359489	A1	12/2015	Baudenbacher et al.
2016/0217691	A1	7/2016	Kadobayashi et al.

FOREIGN PATENT DOCUMENTS

EP	2438851	4/2012
EP	2438852	4/2012
EP	2465415	6/2012
EP	2589333	5/2013
JP	H06319711	11/1994
JP	H11188015	7/1999
JP	2004129788	4/2004
JP	2007082938	4/2007
JP	2009219554	10/2009
WO	00/78213	12/2000
WO	2003032192	4/2003
WO	2006009767	1/2006
WO	2006014806	2/2006
WO	2007066270	6/2007
WO	2007092543	8/2007
WO	2008010216	1/2008
WO	2008057884	5/2008
WO	2009036306	3/2009
WO	2009036313	3/2009
WO	2009036327	3/2009
WO	2009112976	9/2009
WO	2009112978	9/2009
WO	2009112979	9/2009
WO	2009142975	11/2009
WO	2010066507	6/2010
WO	2010105045	9/2010
WO	2011047207	4/2011
WO	2012140559	10/2012
WO	2012146957	11/2012

OTHER PUBLICATIONS

- Fitbit Tracker, URL <<http://www.fitbit.com/>> (Web page cached on Sep. 10, 2008.).
- Smith, Jawbone Up, URL <<http://www.businessinsider.com/fitbit-flex-vs-jawbone-up-2013-5?op=1>> (Jun. 1, 2013).
- Kligfield, Paul et al., Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part I. *J. Am. Coll. Cardiol.* 2007; 49: 1109-27, 75 Pgs.
- Lieberman, Jonathan, "How Telemedicine Is Aiding Prompt ECG Diagnosis in Primary Care," *British Journal of Community Nursing*, vol. 13, No. 3, Mar. 1, 2008 (Mar. 1, 2008), pp. 123-126, XP009155082, ISSN: 1462-4753.
- McManus et al., "A Novel Application for the Detection of an Irregular Pulse using an iPhone 4S in Patients with Atrial Fibrillation," vol. 10(3), pp. 315-319 (Mar. 2013.).
- Nike+Fuel Band, URL <http://www.nike.com/us/en_us/c/nikeplus-fuelband> (Web page cached on Jan. 11, 2013.).
- P. Libby et al., "Braunwald's Heart Disease—A Textbook of Cardiovascular Medicine," Chs. 11, pp. 125-148 and 12, pp. 149-193 (8th ed. 2008), American Heart Association.
- Polar Loop, URL <<http://www.drainmaker.com/2013/09/polar-loop-firstlook.html>>.
- Sittig et al., "A Computer-Based Outpatient Clinical Referral System," *International Journal of Medical Informatics*, Shannon, IR, vol. 55, No. 2, Aug. 1, 1999, pp. 149-158, XO004262434, ISSN: 1386-5056(99)00027-1.
- Sleepview, URL <<http://www.clevemed.com/sleepview/overview.shtml>> (Web page cached on Sep. 4, 2013.).
- Actigraphy/ Circadian Rhythm SOMNOWatch, URL <<http://www.somnomedics.eu/news-events/publications/somnowatchtm.html>> (Web page cached on Jan. 23, 2010).
- Zio Event Card, URL <<http://www.irhythmtech.com/zio-solution/zio-event/>> (Web page cached on Mar. 11, 2013.).
- Zio Patch System, URL <<http://www.irhythmtech.com/zio-solution/zio-system/index.html>> (Web page cached on Sep. 8, 2013).
- Saadi et al. "Heart Rhythm Analysis Using ECG Recorded With a Novel Sternum Based Patch Technology—A Pilot Study." *Cardio technix 2013—Proceedings of the International Congress on Cardiovascular Technologies*, Sep. 20, 2013.
- Anonymous. "Omegawave Launches Consumer App 2.0 in U.S. Endurance Sportswire—Endurance Sportswire." Jul. 11, 2013. URL: <http://endurancesportswire.com/omegawave-launches-consumer-app-2-0-in-u-s/>.
- Chan et al. "Wireless Patch Sensor for Remote Monitoring of Heart Rate, Respiration, Activity, and Falls." pp. 6115-6118. 2013 35th Annual International Conference of the IEEE Engineering in Medical and Biology Society. Jul. 1, 2013.
- Lauren Gravitz, "When Your Diet Needs a Band-Aid," *Technology Review*, MIT. (May 1, 2009).
- Daoud et al. "Fall Detection Using Shimmer Technology and Multiresolution Analysis." Aug. 2, 2013. URL: <https://decibel.ni.com/content/docs/DOC-26652>.
- Libbus. "Adherent Cardiac Monitor With Wireless Fall Detection for Patients With Unexplained Syncope." Abstracts of the First AMA-IEEE Medical Technology Conference on Individualized Healthcare. May 22, 2010.
- Duttweiler et al., "Probability Estimation in Arithmetic and Adaptive-Huffman Entropy Coders," *IEEE Transactions on Image Processing*, vol. 4, No. 3, Mar. 1, 1995, pp. 237-246.
- Gupta et al., "An ECG Compression Technique for Telecardiology Application," *India Conference (IDICON), 2011 Annual IEEE*, Dec. 16, 2011, pp. 1-4.
- Nave et al., "ECG Compression Using Long-Term Prediction," *IEEE Transactions on Biomedical Engineering*, IEEE Service Center, NY, USA, vol. 40, No. 9, Sep. 1, 1993, pp. 877-885.
- Skretting et al., "Improved Huffman Coding Using Recursive Splitting," *NORSIG*, Jan. 1, 1999.
- A Voss et al., "Linear and Nonlinear Methods for Analyses of Cardiovascular Variability in Bipolar Disorders," *Bipolar Disorders*, vol. 8, No. 5p1, Oct. 1, 2006, pp. 441-452, XP55273826, DK ISSN: 1398-5647, DOI: 10.1111/1399-5618.2006.00364.x.
- Varicrad-Kardi Software User's Manual Rev. 1.1, Jul. 8, 2009 (Jul. 8, 2009), XP002757888, retrieved from the Internet: URL: <http://www.ehrlich.tv/KARDiVAR-Software.pdf> [retrieved on May 20, 2016].
- http://www.originlab.com/origin#Data_Exploration 2015.
- <https://web.archive.org/web/20130831204020/http://www.biopac.com/research.asp?CatID=37&Main=Software> (Aug. 2013).
- Adinstruments: ECG Analysis Module for LabChart & PowerLab, 2008.
- BIOPAC Systems, Inc. #AS148—Automated ECG Analysis, Mar. 24, 2006.
- 15 of the Hottest Wearable Gadgets, URL <http://thehottestgadgets.com/2008/09/the-15-hottest-wearable-gadgets-001253>.
- Alivecor, URL <<http://www.businesswire.com/news/home/20121203005545/en/AliveCor%E2%80%99s-Heart-Monitor-iPhone-Receives-FDA-Clearance#U7rtq7FVtYf>> (Dec. 3, 2012).
- Bharadwaj et al., Techniques for Accurate ECG signal processing, *EE Times*, URL <www.eetimes.com/document.as?doc_id=1278571> (Feb. 14, 2011).
- Chen et al. "Monitoring Body Temperature of Newborn Infants at Neonatal Intensive Care Units Using Wearable Sensors," *BodyNets 2010*, Corfu Island, Greece. Sep. 10-12, 2010.
- G. G. Ivanov, "HRV Analysis Under the Usage of Different Electrocardiography Systems," Apr. 15, 2008 (Apr. 15, 2008), XP55511209, Retrieved from the Internet: URL: [http://www.drkucera.eu/upload_doc/hrv_analysis_\(methodical_recommendations\).pdf](http://www.drkucera.eu/upload_doc/hrv_analysis_(methodical_recommendations).pdf) [retrieved on Oct. 1, 2018].

* cited by examiner

Fig. 1.

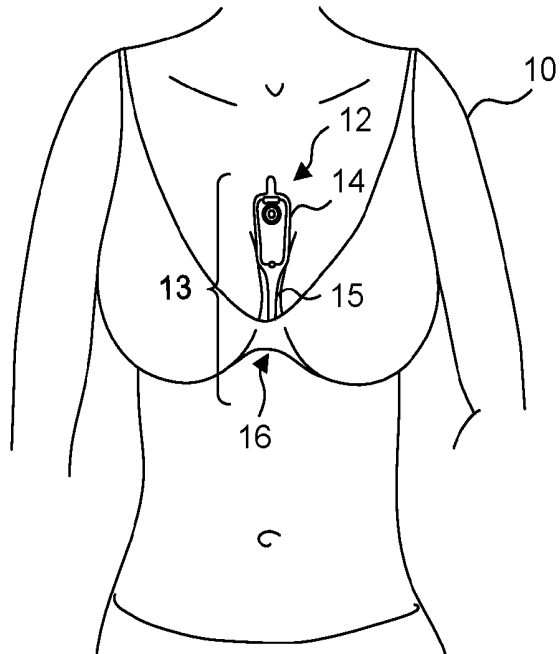


Fig. 2.

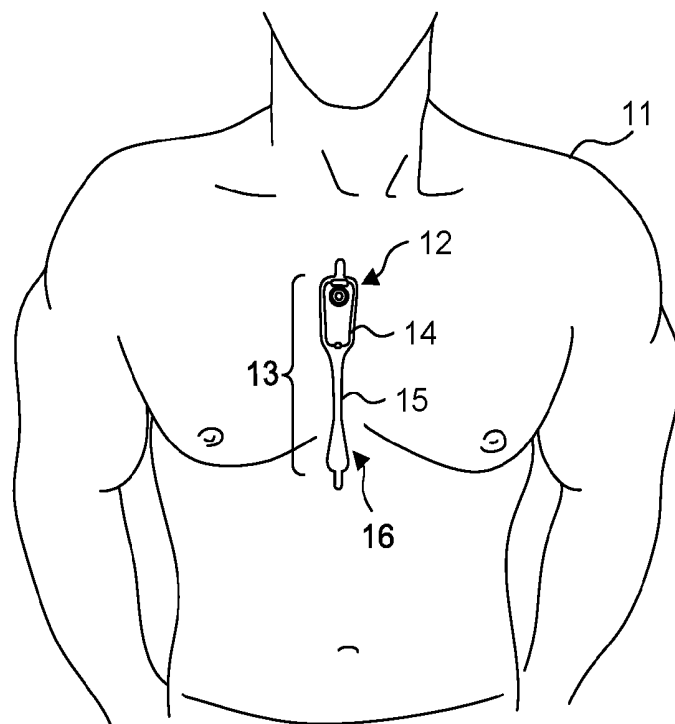


Fig. 3.

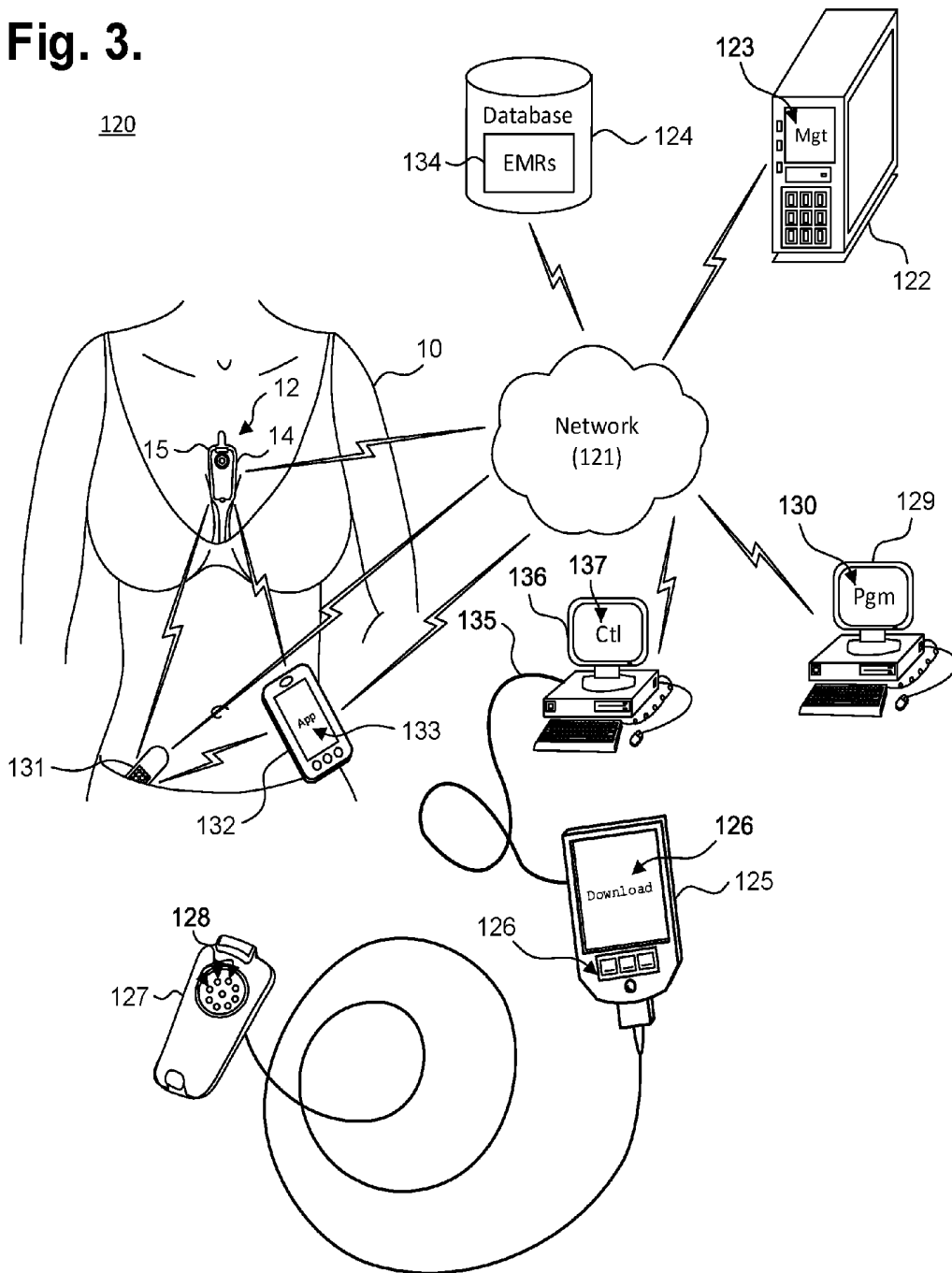


Fig. 4.

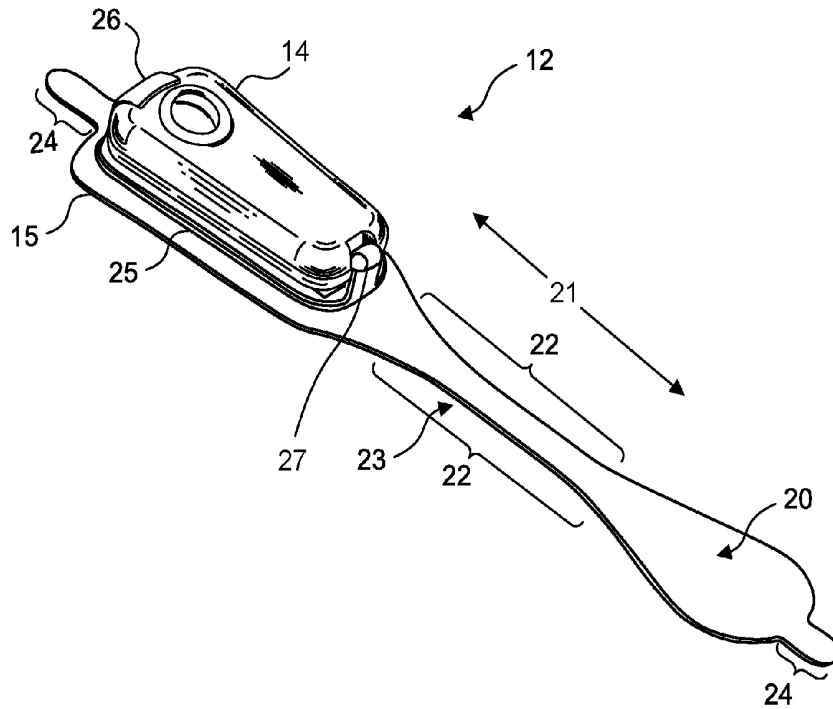


Fig. 5.

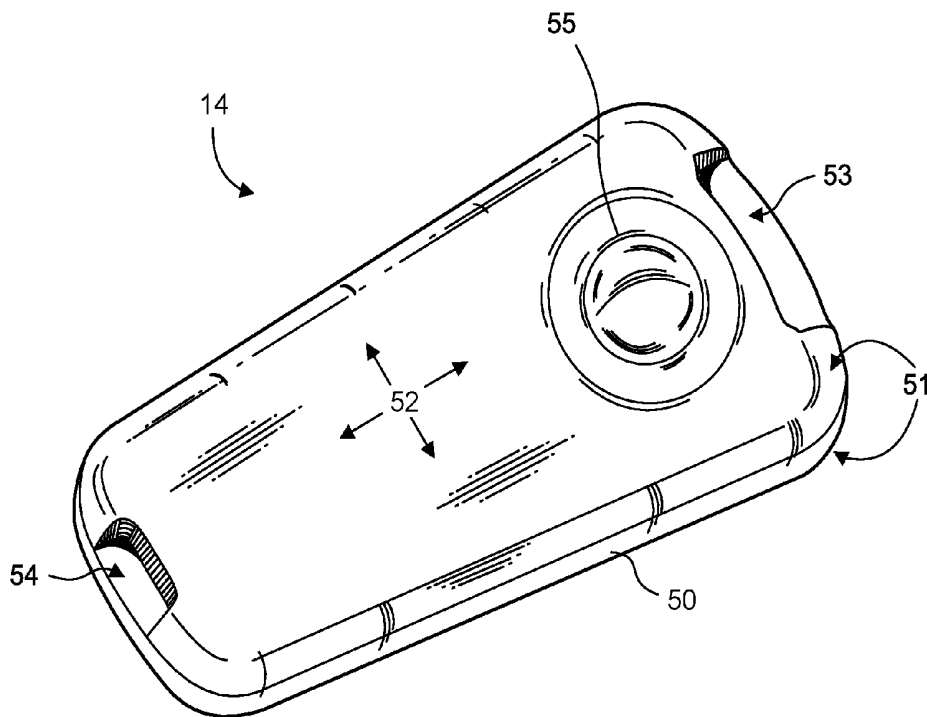


Fig. 6.

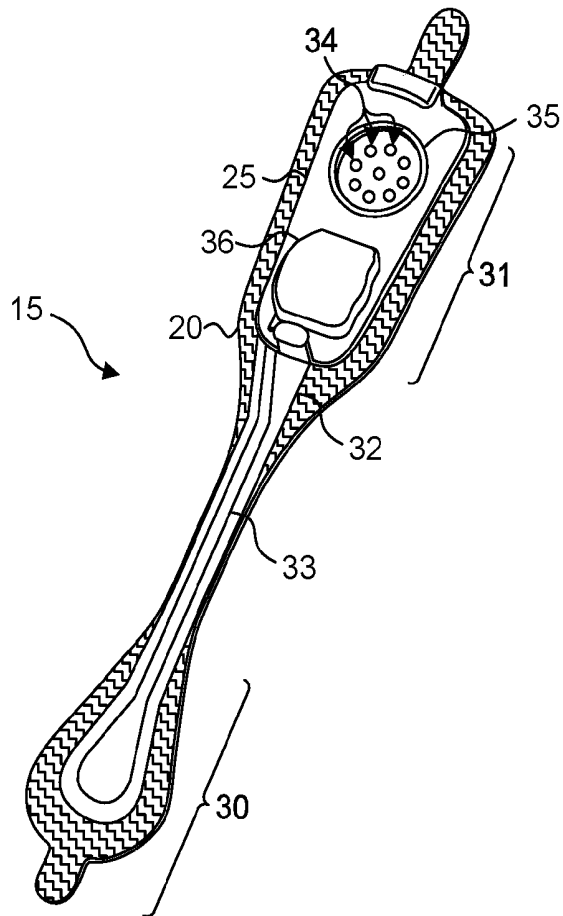


Fig. 7.

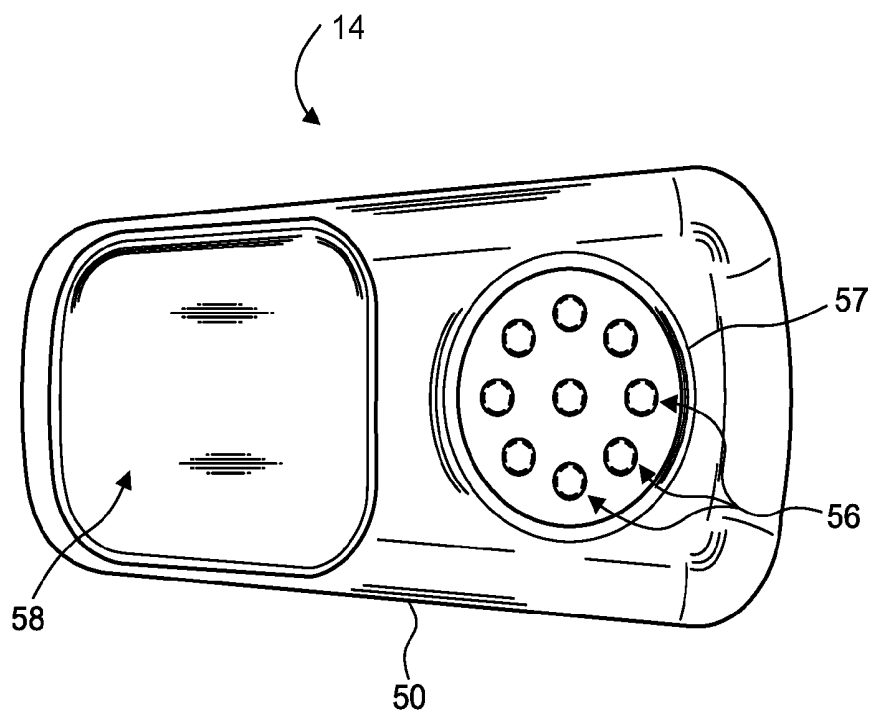


Fig. 8.

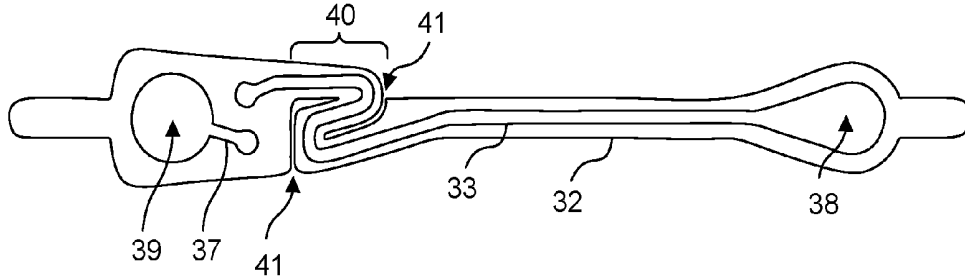


Fig. 9.

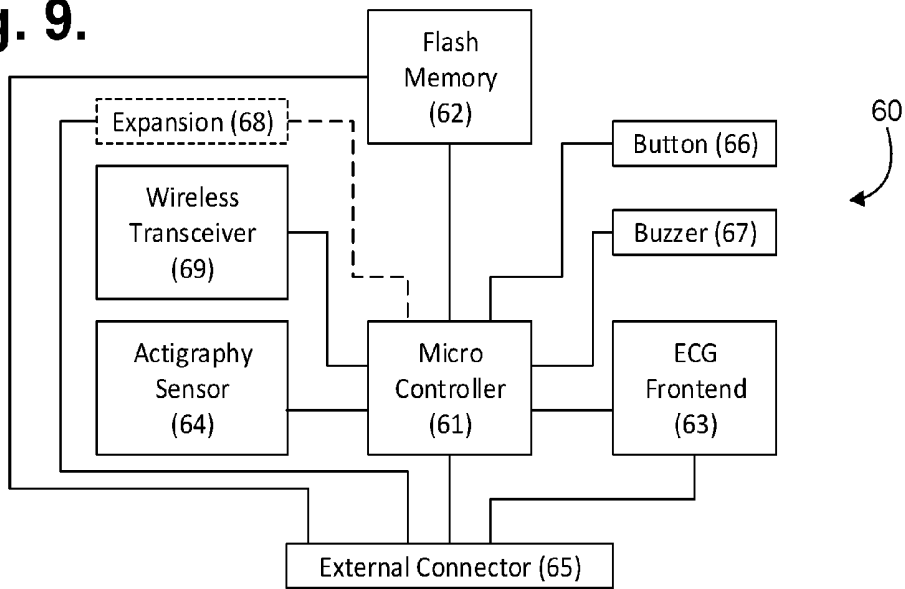


Fig. 10.

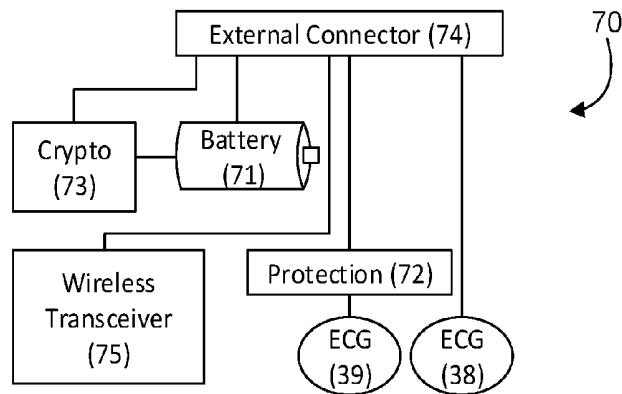


Fig. 11.

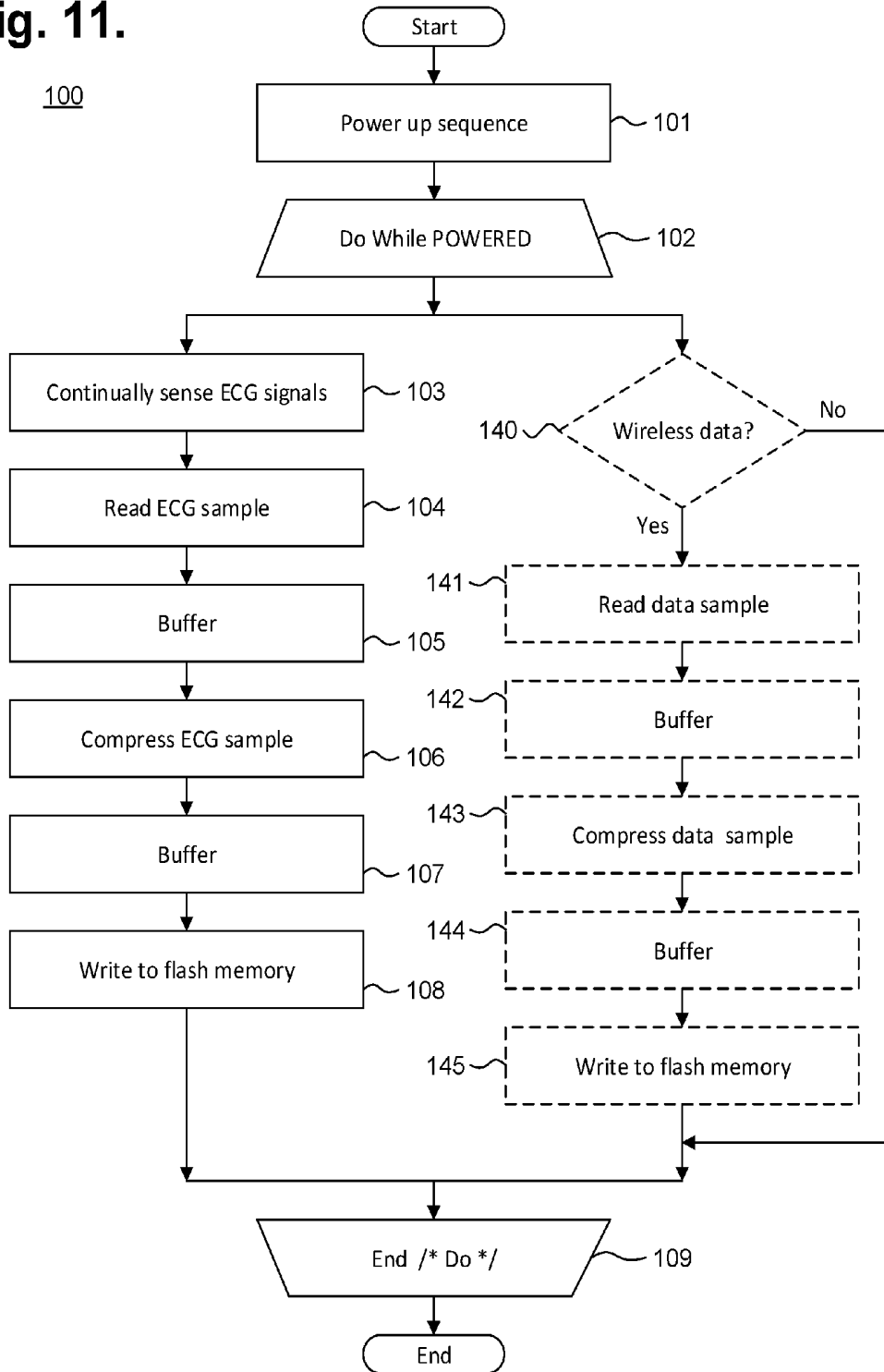


Fig. 12.

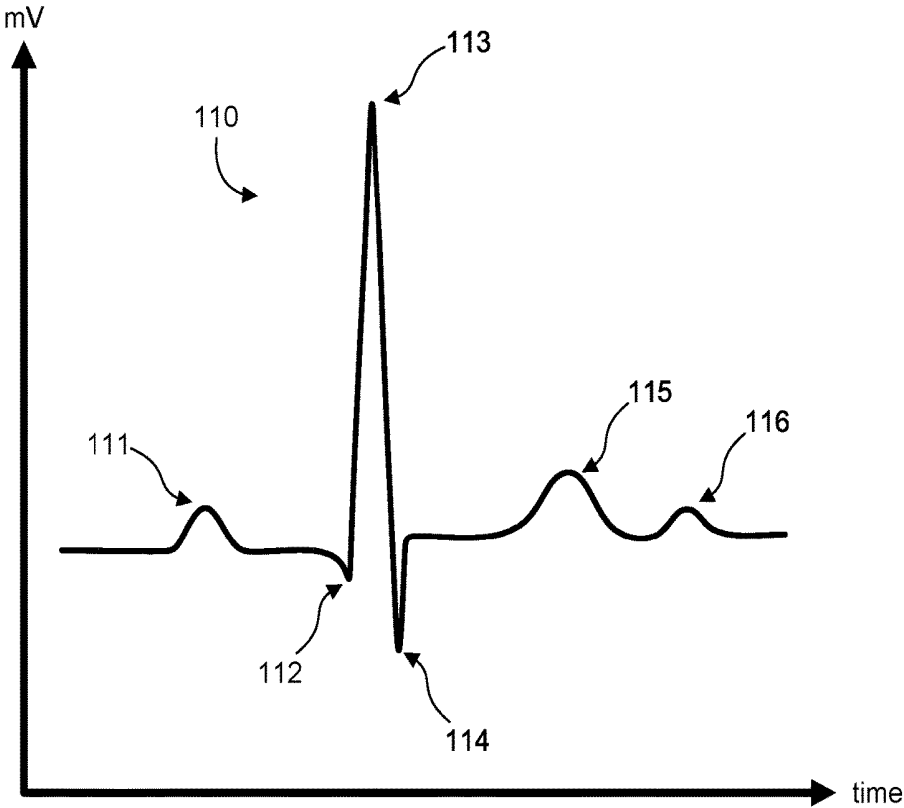
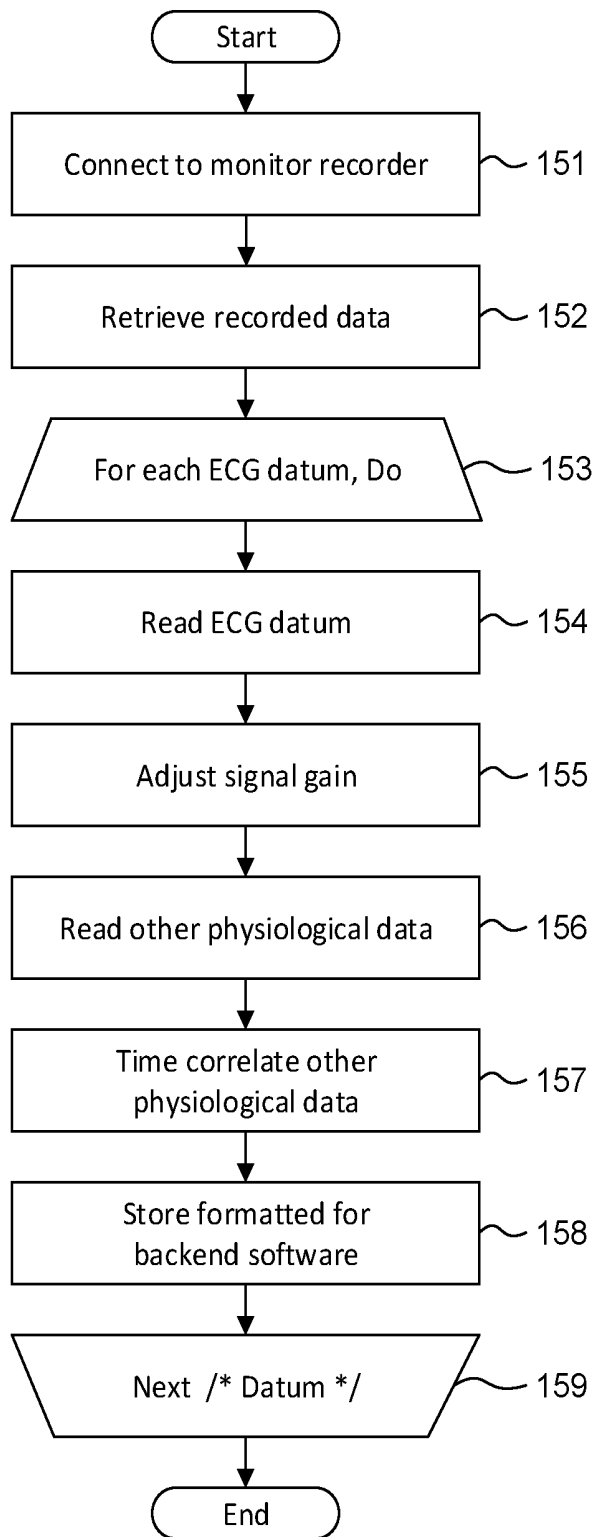


Fig. 13.

150



REMOTE INTERFACING ELECTROCARDIOGRAPHY PATCH

CROSS-REFERENCE TO RELATED APPLICATION

This non-provisional patent application is a continuation of, U.S. Pat. No. 9,820,665, issued Nov. 21, 2017, which is a continuation of U.S. Pat. No. 9,433,367, issued Sep. 6, 2016, which is a continuation-in-part of U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, and a continuation-in-part of U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, and further claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent application, Ser. No. 61/882,403, filed Sep. 25, 2013, the disclosures of which are incorporated by reference.

FIELD

This application relates in general to electrocardiographic monitoring and, in particular, to remote interfacing electrocardiography patch.

BACKGROUND

The heart emits electrical signals as a by-product of the propagation of the action potentials that trigger depolarization of heart fibers. An electrocardiogram (ECG) measures and records such electrical potentials to visually depict the electrical activity of the heart over time. Conventionally, a standardized set format 12-lead configuration is used by an ECG machine to record cardiac electrical signals from well-established traditional chest locations. Electrodes at the end of each lead are placed on the skin over the anterior thoracic region of the patient's body to the lower right and to the lower left of the sternum, on the left anterior chest, and on the limbs. Sensed cardiac electrical activity is represented by PQRSTU waveforms that can be interpreted post-ECG recordation to derive heart rate and physiology. The P-wave represents atrial electrical activity. The QRSTU components represent ventricular electrical activity.

An ECG is a tool used by physicians to diagnose heart problems and other potential health concerns. An ECG is a snapshot of heart function, typically recorded over 12 seconds, that can help diagnose rate and regularity of heartbeats, effect of drugs or cardiac devices, including pacemakers and implantable cardioverter-defibrillators (ICDs), and whether a patient has heart disease. ECGs are used in-clinic during appointments, and, as a result, are limited to recording only those heart-related aspects present at the time of recording. Sporadic conditions that may not show up during a spot ECG recording require other means to diagnose them. These disorders include fainting or syncope; rhythm disorders, such as tachyarrhythmias and bradyarrhythmias; apneic episodes; and other cardiac and related disorders. Thus, an ECG only provides a partial picture and can be insufficient for complete patient diagnosis of many cardiac disorders.

Diagnostic efficacy can be improved, when appropriate, through the use of long-term extended ECG monitoring. Recording sufficient ECG and related physiology over an extended period is challenging, and often essential to enabling a physician to identify events of potential concern. A 30-day observation period is considered the "gold standard" of ECG monitoring, yet achieving a 30-day observation day period has proven unworkable because such ECG monitoring systems are arduous to employ, cumbersome to the patient, and excessively costly. Ambulatory monitoring

in-clinic is implausible and impracticable. Nevertheless, if a patient's ECG could be recorded in an ambulatory setting, thereby allowing the patient to engage in activities of daily living, the chances of acquiring meaningful information and capturing an abnormal event while the patient is engaged in normal activities becomes more likely to be achieved.

For instance, the long-term wear of ECG electrodes is complicated by skin irritation and the inability ECG electrodes to maintain continual skin contact after a day or two. Moreover, time, dirt, moisture, and other environmental contaminants, as well as perspiration, skin oil, and dead skin cells from the patient's body, can get between an ECG electrode, the non-conductive adhesive used to adhere the ECG electrode, and the skin's surface. All of these factors adversely affect electrode adhesion and the quality of cardiac signal recordings. Furthermore, the physical movements of the patient and their clothing impart various compressional, tensile, and torsional forces on the contact point of an ECG electrode, especially over long recording times, and an inflexibly fastened ECG electrode will be prone to becoming dislodged. Moreover, dislodgment may occur unbeknownst to the patient, making the ECG recordings worthless. Further, some patients may have skin that is susceptible to itching or irritation, and the wearing of ECG electrodes can aggravate such skin conditions. Thus, a patient may want or need to periodically remove or replace ECG electrodes during a long-term ECG monitoring period, whether to replace a dislodged electrode, reestablish better adhesion, alleviate itching or irritation, allow for cleansing of the skin, allow for showering and exercise, or for other purpose. Such replacement or slight alteration in electrode location actually facilitates the goal of recording the ECG signal for long periods of time.

Conventionally, Holter monitors are widely used for long-term extended ECG monitoring. Typically, they are used for only 24-48 hours. A typical Holter monitor is a wearable and portable version of an ECG that include cables for each electrode placed on the skin and a separate battery-powered ECG recorder. The cable and electrode combination (or leads) are placed in the anterior thoracic region in a manner similar to what is done with an in-clinic standard ECG machine. The duration of a Holter monitoring recording depends on the sensing and storage capabilities of the monitor, as well as battery life. A "looping" Holter monitor (or event) can operate for a longer period of time by overwriting older ECG tracings, thence "recycling" storage in favor of extended operation, yet at the risk of losing event data. Although capable of extended ECG monitoring, Holter monitors are cumbersome, expensive and typically only available by medical prescription, which limits their usability. Further, the skill required to properly place the electrodes on the patient's chest hinders or precludes a patient from replacing or removing the precordial leads and usually involves moving the patient from the physician office to a specialized center within the hospital or clinic.

The ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, Calif., are wearable stick-on monitoring devices that are typically worn on the upper left pectoral region to respectively provide continuous and looping ECG recording. The location is used to simulate surgically implanted monitors. Both of these devices are prescription-only and for single patient use. The ZIO XT Patch device is limited to a 14-day monitoring period, while the electrodes only of the ZIO Event Card device can be worn for up to 30 days. The ZIO XT Patch device combines both electronic recordation components, including battery, and physical electrodes into a unitary

assembly that adheres to the patient's skin. The ZIO XT Patch device uses adhesive sufficiently strong to support the weight of both the monitor and the electrodes over an extended period of time and to resist disadherence from the patient's body, albeit at the cost of disallowing removal or relocation during the monitoring period. Moreover, throughout monitoring, the battery is continually depleted and battery capacity can potentially limit overall monitoring duration. The ZIO Event Card device is a form of downsized Holter monitor with a recorder component that must be removed temporarily during baths or other activities that could damage the non-waterproof electronics. Both devices represent compromises between length of wear and quality of ECG monitoring, especially with respect to ease of long term use, female-friendly fit, and quality of atrial (P-wave) signals.

In addition, with the advent of wireless communications and wearable computing, other types of personal ambulatory monitors, of varying degrees of sophistication, have become increasingly available. For example, adherents to the so-called "Quantified Self" movement combine wearable sensors and wearable computing to self-track activities of their daily lives, including inputs, states, and performance. The Nike+ FuelBand, manufactured by Nike Inc., Beaverton, Oreg., for instance, provides an activity tracker that is worn on the wrist and allows the wearer to temporally track the number of foot steps taken each day and an estimation of the calories burned. The activity tracker can interface with a smart phone device to allow a wearer to monitor their progress towards a fitness goal. Such quantified physiology, however, is typically tracked for only the personal use of the wearer and is not time-correlated to physician-supervised monitoring.

Therefore, a need remains for an extended wear continuously recording ECG monitor practicably capable of being worn for a long period of time in both men and women and capable of recording atrial signals reliably.

A further need remains for facilities to integrate wider-ranging physiological and "life tracking"-type data into long-term ECG and physiological data monitoring.

SUMMARY

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. The wearable monitor sits centrally (in the midline) on the patient's chest along the sternum oriented top-to-bottom. The placement of the wearable monitor in a location at the sternal midline (or immediately to either side of the sternum), with its unique narrow "hourglass"-like shape, benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch anywhere within the general region of the sternum, the area most likely to record high quality atrial signals or P-waves. The wearable monitor can also interoperate wirelessly with other wearable physiology and activity sensors and with wearable or mobile communications devices, including so-called "smart phones," to download monitoring data either in real-time or in batches. The monitor recorder can also be equipped with a wireless transceiver to either provide data or other information to, or receive data or other information from, an interfacing wearable physiology and activity sen-

sor, or wearable or mobile communications devices for relay to a further device, such as a server, analysis, or other purpose.

One embodiment provides a remotely-interfaceable electrocardiography patch. A flexible backing is formed from an elongated strip of material. A pair of electrocardiographic electrodes are exposed on a contact surface of the flexible backing for capturing electrocardiographic signals. A non-conductive receptacle is adhered to an outward-facing surface of the flexible backing and includes a plurality of electrical pads. A flexible circuit has a pair of circuit traces electrically coupled to the pair of electrocardiographic electrodes and a pair of the electrical pads. A wireless transceiver communicates samples of the electrocardiographic signals.

A further embodiment provides a remotely-interfaceable electrocardiography and physiological sensor monitor. An electrocardiography patch includes a flexible backing formed of an elongated strip of material, a pair of electrocardiographic electrodes exposed on a contact surface of the flexible backing, and a non-conductive receptacle adhered to an outward-facing surface of the flexible backing and having a plurality of electrical pads. The electrocardiography patch also includes a flexible circuit having a pair of circuit traces electrically coupled to the pair of electrocardiographic electrodes and a pair of the electrical pads, and a wireless transceiver to communicate samples of the electrocardiographic signals. An electrocardiography monitor has a sealed housing and includes a set of electrical contacts that protrude from the bottom surface and that are arranged in alignment with the electrical pads provided on the non-conductive receptacle. The electrocardiography monitor also has electronic circuitry that includes a micro-controller operable to execute under micro programmable control and electrically interfaced to an electrocardiographic front end circuit that is operable to sense electrocardiographic signals through the electrocardiographic electrodes via the pair of the electrical pads, and a flash memory electrically interfaced with the micro-controller and operable to store the samples of the electrocardiographic signals.

The monitoring patch is especially suited to the female anatomy. The narrow longitudinal midsection can fit nicely within the intermammary cleft of the breasts without inducing discomfort, whereas conventional patch electrodes are wide and, if adhered between the breasts, would cause chafing, irritation, frustration, and annoyance, leading to low patient compliance.

The foregoing aspects enhance ECG monitoring performance and quality, facilitating long-term ECG recording, critical to accurate arrhythmia diagnosis.

In addition, the foregoing aspects enhance comfort in women (and certain men), but not irritation of the breasts, by placing the monitoring patch in the best location possible for optimizing the recording of cardiac signals from the atrium, another feature critical to proper arrhythmia diagnosis.

Finally, the foregoing aspects as relevant to monitoring are equally applicable to recording other physiological measures, such as temperature, respiratory rate, blood sugar, oxygen saturation, and blood pressure, and as well as other measures of body chemistry and physiology.

Still other embodiments will become readily apparent to those skilled in the art from the following detailed description, wherein are described embodiments by way of illustrating the best mode contemplated. As will be realized, other and different embodiments are possible and the embodiments' several details are capable of modifications in various obvious respects, all without departing from their

spirit and the scope. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not as restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 and 2 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor respectively fitted to the sternal region of a female patient and a male patient.

FIG. 3 is a functional block diagram showing a system for remote interfacing of an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

FIG. 4 is a perspective view showing an extended wear electrode patch with a monitor recorder inserted.

FIG. 5 is a perspective view showing the monitor recorder of FIG. 4.

FIG. 6 is a perspective view showing the extended wear electrode patch of FIG. 4 without a monitor recorder inserted.

FIG. 7 is a bottom plan view of the monitor recorder of FIG. 4.

FIG. 8 is a top view showing the flexible circuit of the extended wear electrode patch of FIG. 4 when mounted above the flexible backing.

FIG. 9 is a functional block diagram showing the component architecture of the circuitry of the monitor recorder of FIG. 4.

FIG. 10 is a functional block diagram showing the circuitry of the extended wear electrode patch of FIG. 4.

FIG. 11 is a flow diagram showing a monitor recorder-implemented method for monitoring ECG data for use in the monitor recorder of FIG. 4.

FIG. 12 is a graph showing, by way of example, a typical ECG waveform.

FIG. 13 is a flow diagram showing a method for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor in accordance with one embodiment.

DETAILED DESCRIPTION

Physiological monitoring can be provided through a wearable monitor that includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. 1 and 2 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological sensor monitor 12, including a monitor recorder 14 in accordance with one embodiment, respectively fitted to the sternal region of a female patient 10 and a male patient 11. The wearable monitor 12 sits centrally (in the midline) on the patient's chest along the sternum 13 oriented top-to-bottom with the monitor recorder 14 preferably situated towards the patient's head. In a further embodiment, the orientation of the wearable monitor 12 can be corrected post-monitoring, as further described infra. The electrode patch 15 is shaped to fit comfortably and conformal to the contours of the patient's chest approximately centered on the sternal midline 16 (or immediately to either side of the sternum 13). The distal end of the electrode patch 15 extends towards the Xiphoid process and, depending upon the patient's build, may straddle the region over the Xiphoid process. The proximal end of the electrode patch 15, located under the monitor recorder 14, is below the manubrium and, depending upon patient's build, may straddle the region over the manubrium.

The placement of the wearable monitor 12 in a location at the sternal midline 16 (or immediately to either side of the sternum 13) significantly improves the ability of the wearable monitor 12 to cutaneously sense cardiac electric signals, particularly the P-wave (or atrial activity) and, to a lesser extent, the QRS interval signals in the ECG waveforms that indicate ventricular activity, while simultaneously facilitating comfortable long-term wear for many weeks. The sternum 13 overlies the right atrium of the heart and the placement of the wearable monitor 12 in the region of the sternal midline 13 puts the ECG electrodes of the electrode patch 15 in a location better adapted to sensing and recording P-wave signals than other placement locations, say, the upper left pectoral region or lateral thoracic region or the limb leads. In addition, placing the lower or inferior pole (ECG electrode) of the electrode patch 15 over (or near) the Xiphoid process facilitates sensing of ventricular activity and provides superior recording of the QRS interval.

When operated standalone, the monitor recorder 14 of the extended wear electrocardiography and physiological sensor monitor 12 senses and records the patient's ECG data into an onboard memory. In addition, the wearable monitor 12 can interoperate with other devices. FIG. 3 is a functional block diagram showing a system 120 for remote interfacing of an extended wear electrocardiography and physiological sensor monitor 12 in accordance with one embodiment. The monitor recorder 14 is a reusable component that can be fitted during patient monitoring into a non-conductive receptacle provided on the electrode patch 15, as further described infra with reference to FIG. 4, and later removed for offloading of stored ECG data or to receive revised programming. The monitor recorder 14 can then be connected to a download station 125, which could be a programmer or other device that permits the retrieval of stored ECG monitoring data, execution of diagnostics or programming of the monitor recorder 14, or performance of other functions. The monitor recorder 14 has a set of electrical contacts (not shown) that enable the monitor recorder 14 to physically interface to a set of terminals 128 on a paired receptacle 127 of the download station 125. In turn, the download station 125 executes a communications or offload program 126 ("Offload") or similar program that interacts with the monitor recorder 14 via the physical interface to retrieve the stored ECG monitoring data. The download station 125 could be a server, personal computer, tablet or handheld computer, smart mobile device, or purpose-built programmer designed specific to the task of interfacing with a monitor recorder 14. Still other forms of download station 125 are possible.

Upon retrieving stored ECG monitoring data from a monitor recorder 14, middleware first operates on the retrieved data to adjust the ECG capture quality, as necessary, and to convert the retrieved data into a format suitable for use by third party post-monitoring analysis software, as further described infra with reference to FIG. 13. The formatted data can then be retrieved from the download station 125 over a hard link 135 using a control program 137 ("Ctl") or analogous application executing on a personal computer 136 or other connectable computing device, via a communications link (not shown), whether wired or wireless, or by physical transfer of storage media (not shown). The personal computer 136 or other connectable device may also execute middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program, as further described infra with reference to FIG. 13. Note that formatted data stored on the personal computer 136 would have to be maintained and safeguarded in the same manner as electronic medical

records (EMRs) 134 in the secure database 124, as further discussed infra. In a further embodiment, the download station 125 is able to directly interface with other devices over a computer communications network 121, which could be some combination of a local area network and a wide area network, including the Internet, over a wired or wireless connection.

A client-server model could be used to employ a server 122 to remotely interface with the download station 125 over the network 121 and retrieve the formatted data or other information. The server 122 executes a patient management program 123 (“Mgt”) or similar application that stores the retrieved formatted data and other information in a secure database 124 cataloged in that patient’s EMRs 134. In addition, the patient management program 123 could manage a subscription service that authorizes a monitor recorder 14 to operate for a set period of time or under pre-defined operational parameters.

The patient management program 123, or other trusted application, also maintains and safeguards the secure database 124 to limit access to patient EMRs 134 to only authorized parties for appropriate medical or other uses, such as mandated by state or federal law, such as under the Health Insurance Portability and Accountability Act (HIPAA) or per the European Union’s Data Protection Directive. For example, a physician may seek to review and evaluate his patient’s ECG monitoring data, as securely stored in the secure database 124. The physician would execute an application program 130 (“Pgm”), such as a post-monitoring ECG analysis program, on a personal computer 129 or other connectable computing device, and, through the application 130, coordinate access to his patient’s EMRs 134 with the patient management program 123. Other schemes and safeguards to protect and maintain the integrity of patient EMRs 134 are possible.

The wearable monitor 12 can interoperate wirelessly with other wearable physiology and activity sensors 131 and with wearable or mobile communications devices 133. Wearable physiology and activity sensors 131 encompass a wide range of wirelessly interconnectable devices that measure or monitor data physical to the patient’s body, such as heart rate, temperature, blood pressure, and so forth; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level. These devices originate both within the medical community to sense and record traditional medical physiology that could be useful to a physician in arriving at a patient diagnosis or clinical trajectory, as well as from outside the medical community, from, for instance, sports or lifestyle product companies who seek to educate and assist individuals with self-quantifying interests.

Frequently, wearable physiology and activity sensors 131 are capable of wireless interfacing with wearable or mobile communications devices 133, particularly smart mobile devices, including so-called “smart phones,” to download monitoring data either in real-time or in batches. The wearable or mobile communications device 133 executes an application (“App”) that can retrieve the data collected by the wearable physiology and activity sensor 131 and evaluate the data to generate information of interest to the wearer, such as an estimation of the effectiveness of the wearer’s exercise efforts. Still other wearable or mobile communications device 133 functions on the collected data are possible.

The wearable or mobile communications devices 133 could also serve as a conduit for providing the data collected by the wearable physiology and activity sensor 131 to a server 122, or, similarly, the wearable physiology and activ-

ity sensor 131 could itself directly provide the collected data to the server 122. The server 122 could then merge the collected data into the wearer’s EMRs 134 in the secure database 124, if appropriate (and permissible), or the server 122 could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology and activity sensor 131. Still other server 122 functions on the collected data are possible.

Finally, the monitor recorder 14 can also be equipped with a wireless transceiver, as further described infra with reference to FIGS. 9 and 10. Thus, when wireless-enabled, both wearable physiology and activity sensors 131 and wearable or mobile communications devices 133 could wirelessly interface with the monitor recorder 14, which could either provide data or other information to, or receive data or other information from an interfacing device for relay to a further device, such as the server 122, analysis, or other purpose. In addition, the monitor recorder 14 could wirelessly interface directly with the server 122, personal computer 129, or other computing device connectable over the network 121, when the monitor recorder 14 is appropriately equipped for interfacing with such devices. Still other types of remote interfacing of the monitor recorder 14 are possible.

During use, the electrode patch 15 is first adhered to the skin along the sternal midline 16 (or immediately to either side of the sternum 13). A monitor recorder 14 is then snapped into place on the electrode patch 15 to initiate ECG monitoring. FIG. 4 is a perspective view showing an extended wear electrode patch 15 with a monitor recorder 14 in accordance with one embodiment inserted. The body of the electrode patch 15 is preferably constructed using a flexible backing 20 formed as an elongated strip 21 of wrap knit or similar stretchable material with a narrow longitudinal mid-section 23 evenly tapering inward from both sides. A pair of cut-outs 22 between the distal and proximal ends of the electrode patch 15 create a narrow longitudinal midsection 23 or “isthmus” and defines an elongated “hour-glass”-like shape, when viewed from above.

The electrode patch 15 incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period. During wear, the electrode patch 15 is susceptible to pushing, pulling, and torquing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards. To counter these stress forces, the electrode patch 15 incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. patent, entitled “Extended Wear Electrocardiography Patch,” U.S. Pat. No. 9,545,204, issued Jan. 17, 2017, the disclosure of which is incorporated by reference. In addition, the cut-outs 22 and longitudinal midsection 23 help minimize interference with and discomfort to breast tissue, particularly in women (and gynecomastic men). The cut-outs 22 and longitudinal midsection 23 further allow better conformity of the electrode patch 15 to sternal bowing and to the narrow isthmus of flat skin that can occur along the bottom of the intermammary cleft between the breasts, especially in buxom women. The cut-outs 22 and longitudinal midsection 23 help the electrode patch 15 fit nicely between a pair of female breasts in the intermammary cleft. Still other shapes, cut-outs and conformities to the electrode patch 15 are possible.

The monitor recorder 14 removably and reusably snaps into an electrically non-conductive receptacle 25 during use. The monitor recorder 14 contains electronic circuitry for recording and storing the patient’s electrocardiography as sensed via a pair of ECG electrodes provided on the elec-

trode patch **15**, such as described in commonly-assigned U.S. patent, entitled “Extended Wear Ambulatory Electrocardiography and Physiological Sensor Monitor,” U.S. Pat. No. 9,730,593, issued Aug. 15, 2017, the disclosure which is incorporated by reference. The non-conductive receptacle **25** is provided on the top surface of the flexible backing **20** with a retention catch **26** and tension clip **27** molded into the non-conductive receptacle **25** to conformably receive and securely hold the monitor recorder **14** in place.

The monitor recorder **14** includes a sealed housing that snaps into place in the non-conductive receptacle **25**. FIG. 5 is a perspective view showing the monitor recorder **14** of FIG. 4. The sealed housing **50** of the monitor recorder **14** intentionally has a rounded isosceles trapezoidal-like shape **52**, when viewed from above, such as described in commonly-assigned U.S. Design patent, entitled “Electrocardiography Monitor,” No. D717,955, issued Nov. 18, 2014, the disclosure of which is incorporated by reference. The edges **51** along the top and bottom surfaces are rounded for patient comfort. The sealed housing **50** is approximately 47 mm long, 23 mm wide at the widest point, and 7 mm high, excluding a patient-operable tactile-feedback button **55**. The sealed housing **50** can be molded out of polycarbonate, ABS, or an alloy of those two materials. The button **55** is waterproof and the button’s top outer surface is molded silicon rubber or similar soft pliable material. A retention detent **53** and tension detent **54** are molded along the edges of the top surface of the housing **50** to respectively engage the retention catch **26** and the tension clip **27** molded into non-conductive receptacle **25**. Other shapes, features, and conformities of the sealed housing **50** are possible.

The electrode patch **15** is intended to be disposable. The monitor recorder **14**, however, is reusable and can be transferred to successive electrode patches **15** to ensure continuity of monitoring. The placement of the wearable monitor **12** in a location at the sternal midline **16** (or immediately to either side of the sternum **13**) benefits long-term extended wear by removing the requirement that ECG electrodes be continually placed in the same spots on the skin throughout the monitoring period. Instead, the patient is free to place an electrode patch **15** anywhere within the general region of the sternum **13**.

As a result, at any point during ECG monitoring, the patient’s skin is able to recover from the wearing of an electrode patch **15**, which increases patient comfort and satisfaction, while the monitor recorder **14** ensures ECG monitoring continuity with minimal effort. A monitor recorder **14** is merely unsnapped from a worn out electrode patch **15**, the worn out electrode patch **15** is removed from the skin, a new electrode patch **15** is adhered to the skin, possibly in a new spot immediately adjacent to the earlier location, and the same monitor recorder **14** is snapped into the new electrode patch **15** to reinitiate and continue the ECG monitoring.

During use, the electrode patch **15** is first adhered to the skin in the sternal region. FIG. 6 is a perspective view showing the extended wear electrode patch **15** of FIG. 4 without a monitor recorder **14** inserted. A flexible circuit **32** is adhered to each end of the flexible backing **20**. A distal circuit trace **33** and a proximal circuit trace (not shown) electrically couple ECG electrodes (not shown) to a pair of electrical pads **34**. The electrical pads **34** are provided within a moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**. When the monitor recorder **14** is securely received into the non-conductive receptacle **25**, that is, snapped into place, the electrical pads **34** interface to electrical contacts (not shown) protruding

from the bottom surface of the monitor recorder **14**, and the moisture-resistant seal **35** enables the monitor recorder **14** to be worn at all times, even during bathing or other activities that could expose the monitor recorder **14** to moisture.

In addition, a battery compartment **36** is formed on the bottom surface of the non-conductive receptacle **25**, and a pair of battery leads (not shown) electrically interface the battery to another pair of the electrical pads **34**. The battery contained within the battery compartment **35** can be replaceable, rechargeable or disposable.

The monitor recorder **14** draws power externally from the battery provided in the non-conductive receptacle **25**, thereby uniquely obviating the need for the monitor recorder **14** to carry a dedicated power source. FIG. 7 is a bottom plan view of the monitor recorder **14** of FIG. 4. A cavity **58** is formed on the bottom surface of the sealed housing **50** to accommodate the upward projection of the battery compartment **36** from the bottom surface of the non-conductive receptacle **25**, when the monitor recorder **14** is secured in place on the non-conductive receptacle **25**. A set of electrical contacts **56** protrude from the bottom surface of the sealed housing **50** and are arranged in alignment with the electrical pads **34** provided on the bottom surface of the non-conductive receptacle **25** to establish electrical connections between the electrode patch **15** and the monitor recorder **14**. In addition, a seal coupling **57** circumferentially surrounds the set of electrical contacts **56** and securely mates with the moisture-resistant seal **35** formed on the bottom surface of the non-conductive receptacle **25**.

The placement of the flexible backing **20** on the sternal midline **16** (or immediately to either side of the sternum **13**) also helps to minimize the side-to-side movement of the wearable monitor **12** in the left- and right-handed directions during wear. To counter the dislodgment of the flexible backing **20** due to compressional and torsional forces, a layer of non-irritating adhesive, such as hydrocolloid, is provided at least partially on the underside, or contact surface of the flexible backing **20**, but only on the distal end **30** and the proximal end **31**. As a result, the underside, or contact surface of the longitudinal midsection **23** does not have an adhesive layer and remains free to move relative to the skin. Thus, the longitudinal midsection **23** forms a crimp relief that respectively facilitates compression and twisting of the flexible backing **20** in response to compressional and torsional forces. Other forms of flexible backing crimp reliefs are possible.

Unlike the flexible backing **20**, the flexible circuit **32** is only able to bend and cannot stretch in a planar direction. The flexible circuit **32** can be provided either above or below the flexible backing **20**. FIG. 8 is a top view showing the flexible circuit **32** of the extended wear electrode patch **15** of FIG. 4 when mounted above the flexible backing **20**. A distal ECG electrode **38** and proximal ECG electrode **39** are respectively coupled to the distal and proximal ends of the flexible circuit **32**. A strain relief **40** is defined in the flexible circuit **32** at a location that is partially underneath the battery compartment **36** when the flexible circuit **32** is affixed to the flexible backing **20**. The strain relief **40** is laterally extendable to counter dislodgment of the ECG electrodes **38**, **39** due to tensile and torsional forces. A pair of strain relief cutouts **41** partially extend transversely from each opposite side of the flexible circuit **32** and continue longitudinally towards each other to define in ‘S’-shaped pattern, when viewed from above. The strain relief respectively facilitates longitudinal extension and twisting of the flexible circuit **32** in response to tensile and torsional forces. Other forms of circuit board strain relief are possible.

ECG monitoring and other functions performed by the monitor recorder 14 are provided through a micro controlled architecture. FIG. 9 is a functional block diagram showing the component architecture of the circuitry 60 of the monitor recorder 14 of FIG. 4. The circuitry 60 is externally powered through a battery provided in the non-conductive receptacle 25 (shown in FIG. 6). Both power and raw ECG signals, which originate in the pair of ECG electrodes 38, 39 (shown in FIG. 8) on the distal and proximal ends of the electrode patch 15, are received through an external connector 65 that mates with a corresponding physical connector on the electrode patch 15. The external connector 65 includes the set of electrical contacts 56 that protrude from the bottom surface of the sealed housing 50 and which physically and electrically interface with the set of pads 34 provided on the bottom surface of the non-conductive receptacle 25. The external connector includes electrical contacts 56 for data download, microcontroller communications, power, analog inputs, and a peripheral expansion port. The arrangement of the pins on the electrical connector 65 of the monitor recorder 14 and the device into which the monitor recorder 14 is attached, whether an electrode patch 15 or download station (not shown), follow the same electrical pin assignment convention to facilitate interoperability. The external connector 65 also serves as a physical interface to a download station that permits the retrieval of stored ECG monitoring data, communication with the monitor recorder 14, and performance of other functions.

Operation of the circuitry 60 of the monitor recorder 14 is managed by a microcontroller 61. The micro-controller 61 includes a program memory unit containing internal flash memory that is readable and writeable. The internal flash memory can also be programmed externally. The microcontroller 61 draws power externally from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. The microcontroller 61 connects to the ECG front end circuit 63 that measures raw cutaneous electrical signals and generates an analog ECG signal representative of the electrical activity of the patient's heart over time.

The circuitry 60 of the monitor recorder 14 also includes a flash memory 62, which the micro-controller 61 uses for storing ECG monitoring data and other physiology and information. The flash memory 62 also draws power externally from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. Data is stored in a serial flash memory circuit, which supports read, erase and program operations over a communications bus. The flash memory 62 enables the microcontroller 61 to store digitized ECG data. The communications bus further enables the flash memory 62 to be directly accessed externally over the external connector 65 when the monitor recorder 14 is interfaced to a download station.

The circuitry 60 of the monitor recorder 14 further includes an actigraphy sensor 64 implemented as a 3-axis accelerometer. The accelerometer may be configured to generate interrupt signals to the microcontroller 61 by independent initial wake up and free fall events, as well as by device position. In addition, the actigraphy provided by the accelerometer can be used during post-monitoring analysis to correct the orientation of the monitor recorder 14 if, for instance, the monitor recorder 14 has been inadvertently installed upside down, that is, with the monitor recorder 14 oriented on the electrode patch 15 towards the patient's feet, as well as for other event occurrence analyses, such as described in commonly-assigned U.S. Pat. No. 9,737,224, issued Aug. 22, 2017, the disclosure of which is incorporated by reference.

The circuitry 60 of the monitor recorder 14 includes a wireless transceiver 69 that can provides wireless interfacing capabilities. The wireless transceiver 69 also draws power externally from the battery provided on the electrode patch 15 via a pair of the electrical contacts 56. The wireless transceiver 69 can be implemented using one or more forms of wireless communications, including the IEEE 802.11 computer communications standard, that is Wi-Fi; the 4G mobile phone mobile communications standard; the Bluetooth data exchange standard; or other wireless communications or data exchange standards and protocols. The type of wireless interfacing capability could limit the range of interoperability of the monitor recorder 14; for instance, Bluetooth-based implementations are designed for low power consumption with a short communications range.

The microcontroller 61 includes an expansion port that also utilizes the communications bus. External devices, separately drawing power externally from the battery provided on the electrode patch 15 or other source, can interface to the microcontroller 61 over the expansion port in half duplex mode. For instance, an external physiology sensor can be provided as part of the circuitry 60 of the monitor recorder 14, or can be provided on the electrode patch 15 with communication with the micro-controller 61 provided over one of the electrical contacts 56. The physiology sensor can include an SpO2 sensor, blood pressure sensor, temperature sensor, respiratory rate sensor, glucose sensor, airflow sensor, volumetric pressure sensing, or other types of sensor or telemetric input sources. For instance, the integration of an airflow sensor is described in commonly-assigned U.S. Pat. No. 9,364,155, issued Jun. 14, 2016, the disclosure which is incorporated by reference.

Finally, the circuitry 60 of the monitor recorder 14 includes patient-interfaceable components, including a tactile feedback button 66, which a patient can press to mark events or to perform other functions, and a buzzer 67, such as a speaker, magnetic resonator or piezoelectric buzzer. The buzzer 67 can be used by the microcontroller 61 to output feedback to a patient such as to confirm power up and initiation of ECG monitoring. Still other components as part of the circuitry 60 of the monitor recorder 14 are possible.

While the monitor recorder 14 operates under micro control, most of the electrical components of the electrode patch 15 operate passively. FIG. 10 is a functional block diagram showing the circuitry 70 of the extended wear electrode patch 15 of FIG. 4. The circuitry 70 of the electrode patch 15 is electrically coupled with the circuitry 60 of the monitor recorder 14 through an external connector 74. The external connector 74 is terminated through the set of pads 34 provided on the bottom of the non-conductive receptacle 25, which electrically mate to corresponding electrical contacts 56 protruding from the bottom surface of the sealed housing 50 to electrically interface the monitor recorder 14 to the electrode patch 15.

The circuitry 70 of the electrode patch 15 performs three primary functions. First, a battery 71 is provided in a battery compartment formed on the bottom surface of the non-conductive receptacle 25. The battery 71 is electrically interfaced to the circuitry 60 of the monitor recorder 14 as a source of external power. The unique provisioning of the battery 71 on the electrode patch 15 provides several advantages. First, the locating of the battery 71 physically on the electrode patch 15 lowers the center of gravity of the overall wearable monitor 12 and thereby helps to minimize shear forces and the effects of movements of the patient and clothing. Moreover, the housing 50 of the monitor recorder 14 is sealed against moisture and providing power externally

avoids having to either periodically open the housing **50** for the battery replacement, which also creates the potential for moisture intrusion and human error, or to recharge the battery, which can potentially take the monitor recorder **14** off line for hours at a time. In addition, the electrode patch **15** is intended to be disposable, while the monitor recorder **14** is a reusable component. Each time that the electrode patch **15** is replaced, a fresh battery is provided for the use of the monitor recorder **14**, which enhances ECG monitoring performance quality and duration of use. Finally, the architecture of the monitor recorder **14** is open, in that other physiology sensors or components can be added by virtue of the expansion port of the microcontroller **61**. Requiring those additional sensors or components to draw power from a source external to the monitor recorder **14** keeps power considerations independent of the monitor recorder **14**. Thus, a battery of higher capacity could be introduced when needed to support the additional sensors or components without effecting the monitor recorders circuitry **60**.

Second, the pair of ECG electrodes **38, 39** respectively provided on the distal and proximal ends of the flexible circuit **32** are electrically coupled to the set of pads **34** provided on the bottom of the non-conductive receptacle **25** by way of their respective circuit traces **33, 37**. The signal ECG electrode **39** includes a protection circuit **72**, which is an inline resistor that protects the patient from excessive leakage current.

Last, in a further embodiment, the circuitry **70** of the electrode patch **15** includes a cryptographic circuit **73** to authenticate an electrode patch **15** for use with a monitor recorder **14**. The cryptographic circuit **73** includes a device capable of secure authentication and validation. The cryptographic device **73** ensures that only genuine, non-expired, safe, and authenticated electrode patches **15** are permitted to provide monitoring data to a monitor recorder **14**, such as described in commonly-assigned U.S. Pat. No. 9,655,538, issued May 23, 2017, the disclosure which is incorporated by reference.

In a further embodiment, the circuitry **70** of the electrode patch **15** includes a wireless transceiver **75**, in lieu the including of the wireless transceiver **69** in the circuitry **60** of the monitor recorder **14**, which interfaces with the microcontroller **61** over the microcontroller's expansion port via the external connector **74**.

The monitor recorder **14** continuously monitors the patient's heart rate and physiology. FIG. **11** is a flow diagram showing a monitor recorder-implemented method **100** for monitoring ECG data for use in the monitor recorder **14** of FIG. **4**. Initially, upon being connected to the set of pads **34** provided with the non-conductive receptacle **25** when the monitor recorder **14** is snapped into place, the microcontroller **61** executes a power up sequence (step **101**). During the power up sequence, the voltage of the battery **71** is checked, the state of the flash memory **62** is confirmed, both in terms of operability check and available capacity, and microcontroller operation is diagnostically confirmed. In a further embodiment, an authentication procedure between the microcontroller **61** and the electrode patch **15** are also performed.

Following satisfactory completion of the power up sequence, an iterative processing loop (steps **102-109**) is continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, the ECG front end **63** (shown in FIG. **9**) continually senses the cutaneous ECG electrical signals (step **103**) via the ECG electrodes **38, 29** and is optimized to maintain the integrity of the P-wave. A sample of the ECG signal is read (step **104**) by the micro-

controller **61** by sampling the analog ECG signal output front end **63**. FIG. **12** is a graph showing, by way of example, a typical ECG waveform **110**. The x-axis represents time in approximate units of tenths of a second. The y-axis represents cutaneous electrical signal strength in approximate units of millivolts. The P-wave **111** has a smooth, normally upward, that is, positive, waveform that indicates atrial depolarization. The QRS complex usually begins with the downward deflection of a Q wave **112**, followed by a larger upward deflection of an R-wave **113**, and terminated with a downward waveform of the S wave **114**, collectively representative of ventricular depolarization. The T wave **115** is normally a modest upward waveform, representative of ventricular depolarization, while the U wave **116**, often not directly observable, indicates the recovery period of the Purkinje conduction fibers.

Sampling of the R-to-R interval enables heart rate information derivation. For instance, the R-to-R interval represents the ventricular rate and rhythm, while the P-to-P interval represents the atrial rate and rhythm. Importantly, the PR interval is indicative of atrioventricular (AV) conduction time and abnormalities in the PR interval can reveal underlying heart disorders, thus representing another reason why the P-wave quality achievable by the extended wear ambulatory electrocardiography and physiological sensor monitor described herein is medically unique and important. The long-term observation of these ECG indicia, as provided through extended wear of the wearable monitor **12**, provides valuable insights to the patient's cardiac function and overall well-being.

Each sampled ECG signal, in quantized and digitized form, is temporarily staged in buffer (step **105**), pending compression preparatory to storage in the flash memory **62** (step **106**). Following compression, the compressed ECG digitized sample is again buffered (step **107**), then written to the flash memory **62** (step **108**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

In a further embodiment, the monitor recorder **14** also continuously receives data from wearable physiology and activity sensors **131** and wearable or mobile communications devices **133** (shown in FIG. **3**). the data is received in a conceptually-separate execution thread as part of the iterative processing loop (steps **102-109**) continually executed by the microcontroller **61**. During each iteration (step **102**) of the processing loop, if wireless data is available (step **140**), a sample of the wireless is read (step **141**) by the microcontroller **61** and, if necessary, converted into a digital signal by the onboard ADC of the microcontroller **61**. Each wireless data sample, in quantized and digitized form, is temporarily staged in buffer (step **142**), pending compression preparatory to storage in the flash memory **62** (step **143**). Following compression, the compressed wireless data sample is again buffered (step **144**), then written to the flash memory **62** (step **145**) using the communications bus. Processing continues (step **109**), so long as the monitoring recorder **14** remains connected to the electrode patch **15** (and storage space remains available in the flash memory **62**), after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

The monitor recorder **14** stores ECG data and other information in the flash memory **62** (shown in FIG. **9**) using a proprietary format that includes data compression. As a result, data retrieved from a monitor recorder **14** must first

be converted into a format suitable for use by third party post-monitoring analysis software. FIG. 13 is a flow diagram showing a method 150 for offloading and converting ECG and other physiological data from an extended wear electrocardiography and physiological sensor monitor 12 in accordance with one embodiment. The method 150 can be implemented in software and execution of the software can be performed on a download station 125, which could be a programmer or other device, or a computer system, including a server 122 or personal computer 129, such as further described supra with reference to FIG. 3, as a series of process or method modules or steps. For convenience, the method 150 will be described in the context of being performed by a personal computer 136 or other connectable computing device (shown in FIG. 3) as middleware that converts ECG data and other information into a format suitable for use by a third-party post-monitoring analysis program. Execution of the method 150 by a computer system would be analogous mutatis mutandis.

Initially, the download station 125 is connected to the monitor recorder 14 (step 151), such as by physically interfacing to a set of terminals 128 on a paired receptacle 127 or by wireless connection, if available. The data stored on the monitor recorder 14, including ECG and physiological monitoring data, other recorded data, and other information are retrieved (step 152) over a hard link 135 using a control program 137 ("Ctl") or analogous application executing on a personal computer 136 or other connectable computing device.

The data retrieved from the monitor recorder 14 is in a proprietary storage format and each datum of recorded ECG monitoring data, as well as any other physiological data or other information, must be converted, so that the data can be used by a third-party post-monitoring analysis program. Each datum of ECG monitoring data is converted by the middleware (steps 153-159) in an iterative processing loop. During each iteration (step 153), the ECG datum is read (step 154) and, if necessary, the gain of the ECG signal is adjusted (step 155) to compensate, for instance, for relocation or replacement of the electrode patch 15 during the monitoring period.

In addition, depending upon the configuration of the wearable monitor 12, other physiological data (or other information), including patient events, such as a fall, peak activity level, sleep detection, Detection of patient activity levels and states, and so on, may be recorded along with the ECG monitoring data. For instance, actigraphy data may have been sampled by the actigraphy sensor 64 based on a sensed event occurrence, such as a sudden change in orientation due to the patient taking a fall. In response, the monitor recorder 14 will embed the actigraphy data samples into the stream of data, including ECG monitoring data, that is recorded to the flash memory 62 by the micro-controller 61. Post-monitoring, the actigraphy data is temporally matched to the ECG data to provide the proper physiological context to the sensed event occurrence. As a result, the three-axis actigraphy signal is turned into an actionable event occurrence that is provided, through conversion by the middleware, to third party post-monitoring analysis programs, along with the ECG recordings contemporaneous to the event occurrence. Other types of processing of the other physiological data (or other information) are possible.

Thus, during execution of the middleware, any other physiological data (or other information) that has been embedded into the recorded ECG monitoring data is read (step 156) and time-correlated to the time frame of the ECG signals that occurred at the time that the other physiological

data (or other information) was noted (step 157). Finally, the ECG datum, signal gain adjusted, if appropriate, and other physiological data, if applicable and as time-correlated, are stored in a format suitable to the backend software (step 158) used in post-monitoring analysis.

In a further embodiment, the other physiological data, if apropos, is embedded within an unused ECG track. For example, the SCP-ENG standard allows multiple ECG channels to be recorded into a single ECG record. The monitor recorder 14, though, only senses one ECG channel. The other physiological data can be stored into an additional ECG channel, which would otherwise be zero-padded or altogether omitted. The backend software would then be able to read the other physiological data in context with the single channel of ECG monitoring data recorded by the monitor recorder 14, provided the backend software implemented changes necessary to interpret the other physiological data. Still other forms of embedding of the other physiological data with formatted ECG monitoring data, or of providing the other physiological data in a separate manner, are possible.

Processing continues (step 159) for each remaining ECG datum, after which the processing loop is exited and execution terminates. Still other operations and steps are possible.

While the invention has been particularly shown and described as referenced to the embodiments thereof, those skilled in the art will understand that the foregoing and other changes in form and detail may be made therein without departing from the spirit and scope.

What is claimed is:

1. A remotely-interfaceable electrocardiography patch, comprising:

a flexible backing formed of an elongated strip of material;

a pair of electrocardiographic electrodes exposed on a contact surface of the flexible backing for capturing electrocardiographic signals with one of the electrocardiographic electrodes on each end of the flexible backing;

a non-conductive receptacle adhered to an outward-facing surface of the flexible backing on one of the ends and comprising a plurality of electrical pads;

a flexible circuit comprising a pair of circuit traces electrically coupled to the pair of electrocardiographic electrodes and a pair of the electrical pads; and

a wireless transceiver to communicate samples of the electrocardiographic signals.

2. A remotely-interfaceable electrocardiography patch according to claim 1, further comprising:

one of the electrocardiographic electrodes being disposed for being adhered to a region overlying the Xiphoid process on a patient's chest; and

an other of the electrocardiographic electrodes being disposed for being adhered to the region near the manubrium on the patient's chest oriented centrally (in the midline) along the sternum upwards from the one electrocardiographic electrode.

3. A remotely-interfaceable electrocardiography patch according to claim 2, further comprising:

an upper part of the elongated strip defined on one end of the flexible backing and sized to be affixed to a bottom surface of the non-conductive receptacle, the other of the electrocardiographic electrodes being affixed to and conductively exposed on the contact surface of the upper part; and

a lower part of the elongated strip defined on another end of the flexible backing; the one of the electrocardio-

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graphic electrodes being affixed to and conductively exposed on the contact surface of the lower part, wherein the lower part of the elongated strip is provided for being adhere to the region overlying the Xiphoid process on the patient's chest with a midsection oriented centrally (in the midline) along the sternum and the upper part of the elongated strip oriented upwards towards the manubrium.

4. A remotely-interfaceable electrocardiography patch according to claim 1, further comprising:

a moisture-resistant seal formed on a bottom surface of the non-conductive receptacle.

5. A remotely-interfaceable electrocardiography patch according to claim 1, further comprising:

an electrocardiography monitor having a sealed housing and comprising a set of electrical contacts that protrude from the bottom surface and are arranged in alignment with the electrical pads provided on the non-conductive receptacle.

6. A remotely-interfaceable electrocardiography patch according to claim 5, further comprising:

a plurality of fasteners comprised on the non-conductive receptacle and oriented to securely receive and to hold captive the electrocardiography monitor into the non-conductive receptacle.

7. A remotely-interfaceable electrocardiography patch according to claim 5, further comprising:

at least one of an SpO2 sensor, a blood pressure sensor, a temperature sensor, respiratory rate sensor, a glucose sensor, an air flow sensor, and a volumetric pressure sensor provided to supplement the electrocardiography monitor by one of direct incorporation into the electrocardiography monitor and direct receipt on the non-conductive receptacle.

8. A remotely-interfaceable electrocardiography patch according to claim 1, further comprising:

a non-irritating adhesive dressing at least partially coated on each end of the elongated strip on the contact surface.

9. A remotely-interfaceable electrocardiography patch according to claim 1, further comprising:

a battery compartment provided in the non-conductive receptacle and comprising a pair of battery leads electrically coupleable to a battery; and the non-conductive receptacle further comprising power terminals aligned to electrically interface the pair of battery leads to an electrocardiography monitor.

10. A remotely-interfaceable electrocardiography patch according to claim 1, further comprising:

rounded edges defined about a bottom surface of the non-conductive receptacle;

a gel well circumferentially defined about at least one of the electrocardiographic electrodes on the contact surface of the end of the flexible backing on which the at least one electrocardiographic electrode is affixed; and placement and removal tabs comprised as part of the flexible backing and extending longitudinally beyond at least one end of the flexible backing.

11. A remotely-interfaceable electrocardiography and physiological sensor monitor, comprising:

an electrocardiography patch, comprising:

a flexible backing formed of an elongated strip of material;

a pair of electrocardiographic electrodes exposed on a contact surface of the flexible backing with one of the electrocardiographic electrodes on each end of the flexible backing;

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a non-conductive receptacle adhered to an outward-facing surface of the flexible backing on one of the ends and comprising a plurality of electrical pads;

a flexible circuit comprising a pair of circuit traces electrically coupled to the pair of electrocardiographic electrodes and a pair of the electrical pads; and

a wireless transceiver to communicate samples of the electrocardiographic signals; and

an electrocardiography monitor having a sealed housing shaped to fit within the non-conductive receptacle of the electrocardiography patch and comprising a set of electrical contacts that protrude from a bottom surface and are arranged in alignment with the electrical pads provided on the non-conductive receptacle, wherein the electrocardiography monitor comprises electronic circuitry, comprising:

a micro-controller operable to execute under micro programmable control and electrically interfaced to an electrocardiographic front end circuit that is operable to sense electrocardiographic signals through the electrocardiographic electrodes via the pair of the electrical pads; and

a flash memory electrically interfaced with the micro-controller and operable to store the samples of the electrocardiographic signals.

12. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 11, wherein the electrocardiography monitor comprises a patient-operable tactile-feedback button provided on a top surface of the sealed housing.

13. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 11, further comprising:

one of the electrocardiographic electrodes being disposed for being adhered to a region overlying the Xiphoid process on a patient's chest; and

an other of the electrocardiographic electrodes being disposed for being adhered to the region near the manubrium on the patient's chest oriented centrally (in the midline) along the sternum upwards from the one electrocardiographic electrode.

14. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 13, further comprising:

an upper part of the elongated strip defined on one end of the flexible backing and sized to be affixed to a bottom surface of the non-conductive receptacle, the other of the electrocardiographic electrodes being affixed to and conductively exposed on the contact surface of the upper part; and

a lower part of the elongated strip defined on another end of the flexible backing; the one of the electrocardiographic electrodes being affixed to and conductively exposed on the contact surface of the lower part,

wherein the lower part of the elongated strip is provided for being adhered to the region overlying the Xiphoid process on the patient's chest with a midsection oriented centrally (in the midline) along the sternum and the upper part of the elongated strip oriented upwards towards the manubrium.

15. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 11, further comprising:

a moisture-resistant seal formed on a bottom surface of the non-conductive receptacle.

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16. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 11, further comprising:

a plurality of fasteners comprised on the non-conductive receptacle and oriented to securely receive and to hold captive the electrocardiography monitor into the non-conductive receptacle.

17. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 11, further comprising:

at least one of an SpO2 sensor, a blood pressure sensor, a temperature sensor, respiratory rate sensor, a glucose sensor, an air flow sensor, and a volumetric pressure sensor provided to supplement the electrocardiography monitor by one of direct incorporation into the electrocardiography monitor and direct receipt on the non-conductive receptacle.

18. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 11, further comprising:

a non-irritating adhesive dressing at least partially coated on each end of the elongated strip on the contact surface.

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19. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 11, further comprising:

a battery compartment provided in the non-conductive receptacle and comprising a pair of battery leads electrically coupleable to a battery; and

the non-conductive receptacle further comprising power terminals aligned to electrically interface the pair of battery leads to the electrocardiography monitor.

20. A remotely-interfaceable electrocardiography and physiological sensor monitor according to claim 11, further comprising:

rounded edges defined about a bottom surface of the non-conductive receptacle;

a gel well circumferentially defined about at least one of the electrocardiographic electrodes on the contact surface of the end of the flexible backing on which the at least one electrocardiographic electrode is affixed; and placement and removal tabs comprised as part of the flexible backing and extending longitudinally beyond at least one end of the flexible backing.

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摘要(译)

提供可远程连接的心电图贴片。柔性背衬由细长的材料条带形成。一对心电电极暴露在柔性背衬的接触表面上，用于捕获心电图信号。非导电插座粘附到柔性背衬的向外表面并包括多个电垫。柔性电路具有电耦合到一对心电电极和一对电焊盘的一对电路迹线。无线收发器传送心电图信号的样本。

