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**Bardy et al.**

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(54) **HEALTH MONITORING APPARATUS FOR INITIATING A TREATMENT OF A PATIENT BASED ON PHYSIOLOGICAL DATA WITH THE AID OF A DIGITAL COMPUTER**

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

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(56) **References Cited**

U.S. PATENT DOCUMENTS

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3,215,136 A 11/1965 Holter et al.  
3,569,852 A 3/1971 Berkovits  
(Continued)

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FOREIGN PATENT DOCUMENTS

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

This patent is subject to a terminal disclaimer.

OTHER PUBLICATIONS

15 of the Hottest Wearable Gadgets, URL <<http://thehottestgadgets.com/2008/09/the-15-hottest-wearable-gadgets-001253>> (Web page cached on Sep. 27, 2008).

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(60) Continuation of application No. 15/948,915, filed on Apr. 9, 2018, now Pat. No. 10,123,703, which is a (Continued)

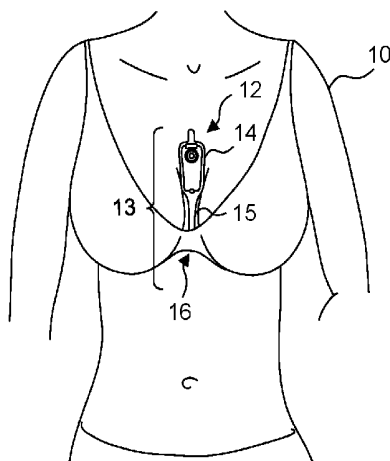
(57) **ABSTRACT**

(51) **Int. Cl.**  
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Individuals who suffer from certain kinds of medical conditions, particularly conditions that only sporadically exhibit measurable symptoms, can feel helpless in their attempts to secure access to medical care because, at least in part, they are left to the mercy of their condition to present symptoms at the right time to allow diagnosis and treatment. Providing these individuals with ambulatory extended-wear health monitors that record ECG and physiology, preferably available over-the-counter and without health insurance preauthorization, is a first step towards addressing their needs. In addition, these individuals need a way to gain entry into the health care system once a medically-actionable medical condition has been identified. Here, the ECG and physiology is downloaded and evaluated post-monitoring against medical diagnostic criteria. Medical specialists are pre-identified

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and paired up with key diagnostic findings, such that an individual whose monitoring data indicates a medical concern will be automatically referred and treated.

**10 Claims, 5 Drawing Sheets**

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continuation of application No. 15/785,317, filed on Oct. 16, 2017, now Pat. No. 9,936,875, which is a continuation of application No. 15/362,743, filed on Nov. 28, 2016, now Pat. No. 9,788,722, which is a division of application No. 14/875,622, filed on Oct. 5, 2015, now Pat. No. 9,504,423.

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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,699,948 A 10/1972 Ota et al.  
 3,718,772 A 2/1973 Sanctuary  
 3,893,453 A 7/1975 Goldberg  
 4,123,785 A 10/1978 Cherry et al.  
 4,151,513 A 4/1979 Menken 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  
 5,168,876 A 12/1992 Quedens et al.  
 5,215,098 A 6/1993 Steinhaus  
 5,231,990 A 8/1993 Gauglitz

D341,423 S 11/1993 Bible  
 5,263,481 A 11/1993 Axelgaard  
 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.  
 5,348,008 A 9/1994 Bornn 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  
 5,451,876 A 9/1995 Sendford et al.  
 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  
 5,724,967 A 3/1998 Venkatachalam  
 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 Xue 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.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

6,694,186	B2	2/2004	Bardy	8,620,418	B1	12/2013	Kuppuraj et al.
6,704,595	B2	3/2004	Bardy	8,626,277	B2	1/2014	Felix et al.
6,705,991	B2	3/2004	Bardy	8,628,020	B2	1/2014	Beck
6,719,701	B2	4/2004	Lade	8,668,653	B2	3/2014	Nagata et al.
6,754,523	B2	6/2004	Toole	8,684,925	B2	4/2014	Manicka et al.
6,782,293	B2	8/2004	Dupelle et al.	8,688,190	B2	4/2014	Libbus et al.
6,856,832	B1	2/2005	Matsumura	8,718,752	B2	5/2014	Libbus et al.
6,860,897	B2	3/2005	Bardy	8,744,561	B2	6/2014	Fahey
6,866,629	B2	3/2005	Bardy	8,774,932	B2	7/2014	Fahey
6,887,201	B2	5/2005	Bardy	8,790,257	B2	7/2014	Libbus et al.
6,893,397	B2	5/2005	Bardy	8,790,259	B2	7/2014	Katra et al.
6,904,312	B2	6/2005	Bardy	8,795,174	B2	8/2014	Manicka et al.
6,908,431	B2	6/2005	Bardy	8,798,729	B2	8/2014	Kaib et al.
6,913,577	B2	7/2005	Bardy	8,798,734	B2	8/2014	Kuppuraj et al.
6,944,498	B2	9/2005	Owen et al.	8,818,478	B2	8/2014	Scheffler et al.
6,960,167	B2	11/2005	Bardy	8,818,481	B2	8/2014	Bly et al.
6,970,731	B1	11/2005	Jayaraman et al.	8,823,490	B2	9/2014	Libbus et al.
6,978,169	B1	12/2005	Guerra	8,938,287	B2	1/2015	Felix et al.
6,993,377	B2	1/2006	Flick et al.	8,965,492	B2	2/2015	Baker et al.
7,020,508	B2	3/2006	Stivoric et al.	9,066,664	B2	6/2015	Karjalainen
7,027,864	B2	4/2006	Snyder et al.	9,155,484	B2	10/2015	Baker et al.
7,065,401	B2	6/2006	Worden	9,204,813	B2	12/2015	Kaib et al.
7,085,601	B1	8/2006	Bardy et al.	9,241,649	B2	1/2016	Kumar et al.
7,104,955	B2	9/2006	Bardy	9,259,154	B2	2/2016	Miller et al.
7,134,996	B2	11/2006	Bardy	9,277,864	B2	3/2016	Yang et al.
7,137,389	B2	11/2006	Berthon-Jones	9,339,202	B2	5/2016	Brockway et al.
7,147,600	B2	12/2006	Bardy	9,375,179	B2	6/2016	Schultz et al.
7,215,991	B2	5/2007	Besson et al.	9,414,786	B1	8/2016	Brockway et al.
7,248,916	B2	7/2007	Bardy	9,439,566	B2	9/2016	Arne et al.
7,257,438	B2	8/2007	Kinast	9,597,004	B2	3/2017	Hughes et al.
7,277,752	B2	10/2007	Matos	9,603,542	B2	3/2017	Veen et al.
7,294,108	B1	11/2007	Bomzin et al.	9,700,222	B2	7/2017	Quinlan et al.
D558,882	S	1/2008	Brady	9,770,182	B2	9/2017	Bly et al.
7,328,061	B2	2/2008	Rowlandson et al.	10,034,614	B2	7/2018	Edic et al.
7,412,395	B2	8/2008	Rowlandson et al.	10,045,708	B2	8/2018	Dusan
7,429,938	B1	9/2008	Corndorf	10,049,182	B2	8/2018	Cheffles et al.
7,552,031	B2	6/2009	Vock et al.	2002/0013538	A1	1/2002	Teller
D606,656	S	12/2009	Kobayashi et al.	2002/0013717	A1	1/2002	Ando et al.
7,706,870	B2	4/2010	Shieh et al.	2002/0016798	A1	2/2002	Sakai
7,756,721	B1	7/2010	Falchuk et al.	2002/0103422	A1	8/2002	Harder et al.
7,787,943	B2	8/2010	McDonough	2002/0109621	A1	8/2002	Khair et al.
7,874,993	B2	1/2011	Bardy	2002/0120310	A1	8/2002	Linden et al.
7,881,785	B2	2/2011	Nassif et al.	2002/0128686	A1	9/2002	Minogue et al.
D639,437	S	6/2011	Bishay et al.	2002/0184055	A1	12/2002	Naghavi et al.
7,959,574	B2	6/2011	Bardy	2002/0193668	A1	12/2002	Munneke
8,108,035	B1	1/2012	Bharmi	2003/0004547	A1	1/2003	Owen et al.
8,116,841	B2	2/2012	Bly et al.	2003/0073916	A1	4/2003	Yonce
8,135,459	B2	3/2012	Bardy et al.	2003/0083559	A1	5/2003	Thompson
8,172,761	B1	5/2012	Rulkov et al.	2003/0097078	A1	5/2003	Maeda
8,180,425	B2	5/2012	Selvitelli et al.	2003/0139785	A1	7/2003	Riff et al.
8,200,320	B2	6/2012	Kovacs	2003/0176802	A1	9/2003	Galen et al.
8,231,539	B2	7/2012	Bardy	2003/0211797	A1	11/2003	Hill et al.
8,231,540	B2	7/2012	Bardy	2004/0008123	A1	1/2004	Carrender
8,239,012	B2	8/2012	Felix et al.	2004/0019288	A1	1/2004	Kinast
8,249,686	B2	8/2012	Libbus et al.	2004/0034284	A1	2/2004	Aversano et al.
8,260,414	B2	9/2012	Nassif et al.	2004/0049132	A1	3/2004	Barron et al.
8,266,008	B1	9/2012	Siegal et al.	2004/0073127	A1	4/2004	Istvan et al.
8,277,378	B2	10/2012	Bardy	2004/0087836	A1	5/2004	Green et al.
8,285,356	B2	10/2012	Bly et al.	2004/0088019	A1	5/2004	Rueter et al.
8,285,370	B2	10/2012	Felix et al.	2004/0093192	A1	5/2004	Hasson et al.
8,308,650	B2	11/2012	Bardy	2004/0148194	A1	7/2004	Wellons et al.
8,366,629	B2	2/2013	Bardy	2004/0163034	A1	8/2004	Colbath et al.
8,374,688	B2	2/2013	Libbus et al.	2004/0167416	A1	8/2004	Lee
8,412,317	B2	4/2013	Mazar	2004/0207530	A1	10/2004	Nielsen
8,460,189	B2	6/2013	Libbus et al.	2004/0210165	A1	10/2004	Marmaropoulos et al.
8,473,047	B2	6/2013	Chakravarthy et al.	2004/0236202	A1	11/2004	Burton
8,478,418	B2	7/2013	Fahey	2004/0243435	A1	12/2004	Williams
8,538,503	B2	9/2013	Kumar et al.	2004/0256453	A1	12/2004	Lammle
8,554,311	B2	10/2013	Warner et al.	2004/0260188	A1	12/2004	Syed et al.
8,560,046	B2	10/2013	Kumar et al.	2004/0260192	A1	12/2004	Yamamoto
8,591,430	B2	11/2013	Amurthur et al.	2005/0010139	A1	1/2005	Aminian et al.
8,594,763	B1	11/2013	Bibian et al.	2005/0096717	A1	5/2005	Bishay et al.
8,600,486	B2	12/2013	Kaib et al.	2005/0108055	A1	5/2005	Ott et al.
8,613,708	B2	12/2013	Bishay et al.	2005/0151640	A1	7/2005	Hastings
8,613,709	B2	12/2013	Bishay et al.	2005/0154267	A1	7/2005	Bardy
				2005/0182308	A1	8/2005	Bardy
				2005/0182309	A1	8/2005	Bardy
				2005/0215918	A1	9/2005	Frantz et al.
				2005/0222513	A1	10/2005	Hadley et al.

(56)

## References Cited

## U.S. PATENT DOCUMENTS

2005/0228243	A1	10/2005	Bardy	2009/0069867	A1	3/2009	KenKnight et al.
2005/0245839	A1	11/2005	Stivoric et al.	2009/0073991	A1	3/2009	Landrum et al.
2005/0275416	A1	12/2005	Hervieux et al.	2009/0076336	A1	3/2009	Mazar et al.
2006/0025696	A1	2/2006	Kurzweil et al.	2009/0076341	A1	3/2009	James et al.
2006/0025824	A1	2/2006	Freeman et al.	2009/0076342	A1	3/2009	Amurthur et al.
2006/0030767	A1	2/2006	Lang et al.	2009/0076343	A1	3/2009	James et al.
2006/0030904	A1	2/2006	Quiles	2009/0076346	A1	3/2009	James et al.
2006/0041201	A1	2/2006	Behbehani et al.	2009/0076349	A1	3/2009	Libbus et al.
2006/0084883	A1	4/2006	Linker	2009/0076397	A1	3/2009	Libbus et al.
2006/0111642	A1	5/2006	Baura et al.	2009/0076401	A1	3/2009	Mazar et al.
2006/0122469	A1	6/2006	Martel	2009/0076559	A1	3/2009	Libbus et al.
2006/0124193	A1	6/2006	Orr et al.	2009/0088652	A1	4/2009	Tremblay
2006/0224072	A1	10/2006	Shennib	2009/0112116	A1	4/2009	Lee et al.
2006/0229522	A1	10/2006	Barr	2009/0131759	A1	5/2009	Sims et al.
2006/0235320	A1	10/2006	Tan et al.	2009/0156908	A1	6/2009	Belalcazar et al.
2006/0253006	A1	11/2006	Bardy	2009/0216132	A1	8/2009	Orbach
2006/0264730	A1	11/2006	Stivoric et al.	2009/0270708	A1	10/2009	Shen et al.
2006/0264767	A1	11/2006	Shennib	2009/0270747	A1	10/2009	Van Dam et al.
2007/0003115	A1	1/2007	Patton et al.	2009/0292194	A1	11/2009	Libbus et al.
2007/0038057	A1	2/2007	Nam et al.	2010/0007413	A1	1/2010	Herleikson et al.
2007/0050209	A1	3/2007	Yered	2010/0022897	A1	1/2010	Parker et al.
2007/0078324	A1	4/2007	Wijisiriwardana	2010/0056881	A1	3/2010	Libbus et al.
2007/0078354	A1	4/2007	Holland	2010/0081913	A1	4/2010	Cross et al.
2007/0088406	A1	4/2007	Bennett et al.	2010/0174229	A1	7/2010	Hsu et al.
2007/0089800	A1	4/2007	Sharma	2010/0177100	A1	7/2010	Carnes et al.
2007/0093719	A1	4/2007	Nichols, Jr. et al.	2010/0185063	A1	7/2010	Bardy
2007/0100248	A1	5/2007	Van Dam et al.	2010/0185076	A1	7/2010	Jeong et al.
2007/0100667	A1	5/2007	Bardy	2010/0191154	A1	7/2010	Berger et al.
2007/0123801	A1	5/2007	Goldberger et al.	2010/0191310	A1	7/2010	Bly
2007/0131595	A1	6/2007	Jansson et al.	2010/0223020	A1	9/2010	Goetz
2007/0136091	A1	6/2007	McTaggart	2010/0234715	A1	9/2010	Shin et al.
2007/0179357	A1	8/2007	Bardy	2010/0234716	A1	9/2010	Engel
2007/0185390	A1	8/2007	Perkins et al.	2010/0280366	A1	11/2010	Arne et al.
2007/0203415	A1	8/2007	Bardy	2010/0312188	A1	12/2010	Robertson et al.
2007/0203423	A1	8/2007	Bardy	2010/0324384	A1	12/2010	Moon et al.
2007/0208232	A1	9/2007	Kovacs	2011/0021937	A1	1/2011	Hugh et al.
2007/0208233	A1	9/2007	Kovacs	2011/0054286	A1	3/2011	Crosby et al.
2007/0208266	A1	9/2007	Hadley	2011/0060215	A1	3/2011	Tupin et al.
2007/0225611	A1	9/2007	Kumar et al.	2011/0066041	A1	3/2011	Pandia et al.
2007/0244405	A1	10/2007	Xue et al.	2011/0077497	A1	3/2011	Oster et al.
2007/0249946	A1	10/2007	Kumar et al.	2011/0105861	A1	5/2011	Derchak et al.
2007/0255153	A1	11/2007	Kumar et al.	2011/0144470	A1	6/2011	Mazar et al.
2007/0265510	A1	11/2007	Bardy	2011/0160548	A1	6/2011	Forster
2007/0276270	A1	11/2007	Tran	2011/0224564	A1	9/2011	Moon et al.
2007/0276275	A1	11/2007	Proctor et al.	2011/0237922	A1	9/2011	Parker, III et al.
2007/0293738	A1	12/2007	Bardy	2011/0237924	A1	9/2011	McGusty et al.
2007/0293739	A1	12/2007	Bardy	2011/0245699	A1	10/2011	Snell et al.
2007/0293740	A1	12/2007	Bardy	2011/0245711	A1	10/2011	Katra et al.
2007/0293741	A1	12/2007	Bardy	2011/0288605	A1	11/2011	Kaib et al.
2007/0293772	A1	12/2007	Bardy	2012/0003933	A1	1/2012	Baker et al.
2007/0299325	A1	12/2007	Farrell et al.	2012/0029306	A1	2/2012	Paquet et al.
2007/0299617	A1	12/2007	Willis	2012/0029315	A1	2/2012	Raptis et al.
2008/0027339	A1	1/2008	Nagai et al.	2012/0029316	A1	2/2012	Raptis et al.
2008/0051668	A1	2/2008	Bardy	2012/0035432	A1	2/2012	Katra et al.
2008/0058661	A1	3/2008	Bardy	2012/0078127	A1	3/2012	McDonald et al.
2008/0143080	A1	3/2008	Burr	2012/0088998	A1	4/2012	Bardy et al.
2008/0088467	A1	4/2008	Al-Ali et al.	2012/0088999	A1	4/2012	Bishay et al.
2008/0091089	A1	4/2008	Guillory 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	2012/0089037	A1	4/2012	Bishay et al.
2008/0114232	A1	5/2008	Gazit	2012/0089412	A1	4/2012	Bishay et al.
2008/0139953	A1	6/2008	Baker et al.	2012/0089417	A1	4/2012	Bardy et al.
2008/0177168	A1	7/2008	Callahan et al.	2012/0095352	A1	4/2012	Tran
2008/0194927	A1	8/2008	KenKnight et al.	2012/0101358	A1	4/2012	Boettcher et al.
2008/0208009	A1	8/2008	Shklarski	2012/0101396	A1	4/2012	Solosko et al.
2008/0208014	A1	8/2008	KenKnight et al.	2012/0165645	A1	6/2012	Russel et al.
2008/0284599	A1	11/2008	Zdeblick et al.	2012/0306662	A1	6/2012	Vosch et al.
2008/0288026	A1	11/2008	Cross et al.	2012/0172695	A1	7/2012	Ko et al.
2008/0294024	A1	11/2008	Cosentino et al.	2012/0238910	A1	9/2012	Nordstrom
2008/0306359	A1	12/2008	Zdeblick et al.	2012/0253847	A1	10/2012	Dell'Anno et al.
2008/0312522	A1	12/2008	Rowlandson et al.	2012/0302906	A1	11/2012	Felix et al.
2009/0012412	A1	1/2009	Wesel	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	Glukhovsky et al.	2013/0077263	A1	3/2013	Oleson et al.
2009/0062897	A1	3/2009	Axelgaard	2013/0079611	A1	3/2013	Besko
				2013/0085347	A1	4/2013	Manicka et al.
				2013/0085403	A1	4/2013	Gunderson et al.
				2013/0096395	A1	4/2013	Katra et al.
				2013/0116533	A1	5/2013	Lian et al.

## (56) References Cited

## U.S. PATENT DOCUMENTS

2013/0123651 A1 5/2013 Bardy  
 2013/0158361 A1 6/2013 Bardy  
 2013/0197380 A1 8/2013 Oral et al.  
 2013/0225963 A1 8/2013 Kodandaramaiah et al.  
 2013/0225966 A1 8/2013 Macia Barber et al.  
 2013/0231947 A1 9/2013 Shusterman  
 2013/0243105 A1 9/2013 Lei et al.  
 2013/0274584 A1 10/2013 Finlay et al.  
 2013/0275158 A1 10/2013 Fahey  
 2013/0324809 A1 12/2013 Lisogurski et al.  
 2013/0324855 A1 12/2013 Lisogurski et al.  
 2013/0324856 A1 12/2013 Lisogurski et al.  
 2013/0325081 A1 12/2013 Karst et al.  
 2013/0325359 A1 12/2013 Jarverud et al.  
 2013/0331665 A1 12/2013 Libbus et al.  
 2013/0338448 A1 12/2013 Libbus et al.  
 2013/0338472 A1 12/2013 Macia Barber et al.  
 2014/0012154 A1 1/2014 Mazar et al.  
 2014/0056452 A1 2/2014 Moss et al.  
 2014/0088399 A1 3/2014 Lian et al.  
 2014/0140359 A1 5/2014 Kalevo et al.  
 2014/0180027 A1 6/2014 Buller  
 2014/0189928 A1 7/2014 Oleson et al.  
 2014/0206977 A1 7/2014 Bahney et al.  
 2014/0215246 A1 7/2014 Lee et al.  
 2014/0249852 A1 9/2014 Proud  
 2014/0296651 A1 10/2014 Stone  
 2014/0343390 A1 11/2014 Berzowska et al.  
 2014/0358193 A1 12/2014 Lyons et al.  
 2014/0364756 A1 12/2014 Brockway et al.  
 2015/0048836 A1 2/2015 Guthrie et al.  
 2015/0065842 A1 3/2015 Lee et al.  
 2015/0164349 A1 6/2015 Gopalakrishnan et al.  
 2015/0165211 A1 6/2015 Naqvi et al.  
 2015/0177175 A1 6/2015 Elder 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.  
 2016/0135746 A1 5/2016 Kumar et al.  
 2016/0144190 A1 5/2016 Cao et al.  
 2016/0144192 A1 5/2016 Sanghera et al.  
 2016/0217691 A1 7/2016 Kadobayashi et al.  
 2016/0235318 A1 8/2016 Sarkar  
 2019/0021671 A1 1/2019 Kumar 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 199852463 11/1998  
 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 2008092098 7/2008  
 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 6/2010  
 WO 2011047207 4/2011  
 WO 2012140559 10/2012  
 WO 2012146957 11/2012

## OTHER PUBLICATIONS

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.asp?doc\\_id=1278571](http://www.eetimes.com/document.asp?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, 1210.  
 Epstein, Andrew E. et al.; ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. J. Am. Coll. Cardiol. 2008; 51; el-e62, 66 Pgs.  
 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.  
 Lauren Gravit, "When Your Diet Needs a Band-Aid," Technology Review, MIT. (May 1, 2009).  
 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](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.  
 Initial hands-on with Polar Loop activity tracker, URL <<http://www.dcrainmaker.com/2013/09/polar-loop-firstlook.html>> (Sep. 17, 2013).  
 Seifert, Dan, Samsung dives into fitness wearable with the Gear Fit/ The Verge, URL <<http://www.theverge.com/2014/2/24/5440310/samsung-dives-into-fitness-wearables-with-the-gear-fit>> (Feb. 24, 2014).  
 Soper, Taylor, Samsung's new Galaxy S5 flagship phone has fingerprint reader, heart rate monitor, URL <<http://www.geekwire.com/2014/samsung-galaxy-s5-fingerprint/>> (Feb. 24, 2014).  
 Dolcourt, See the Samsung Galaxy S5's Heart rate monitor in action, URL <<http://www.cnet.com/news/see-the-samsung-galaxy-s5s-heart-rate-monitor-in-action/>> (Feb. 25, 2014).  
 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, 2011).  
 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/>.

(56)

**References Cited**

## OTHER PUBLICATIONS

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.

Wei et al. "A Stretchable and Flexible System for Skin-Mounted Measurement of Motion Tracking and Physiological Signals." pp. 5772-5775. 2014 36th Annual International Conference of the IEEE Engineering in Medicine and Biology Society. Aug. 26, 2014.

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 (INDICON), 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,

votl. 8, No. 5p1, Oct. 1, 2006, pp. 441-452, XP55273826, DK ISSN: 1398-5647, DOI: 10.1111/i.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].

Vedapulse UK, Jan. 1, 2014 (Jan. 1, 2014), XP002757887, Retrieved from the Internet: URL:<http://www.vedapulseuk.com/diagnostic/> [retrieved on May 19, 2016].

[http://www.originlab.com/origin#Data\\_Exploration](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).

<http://www.gtec.at/Products/Software/g.BSanalyze-Specs-Features> (2014).

Adinstruments:ECG Analysis Module for LabChart & PowerLab, 2008.

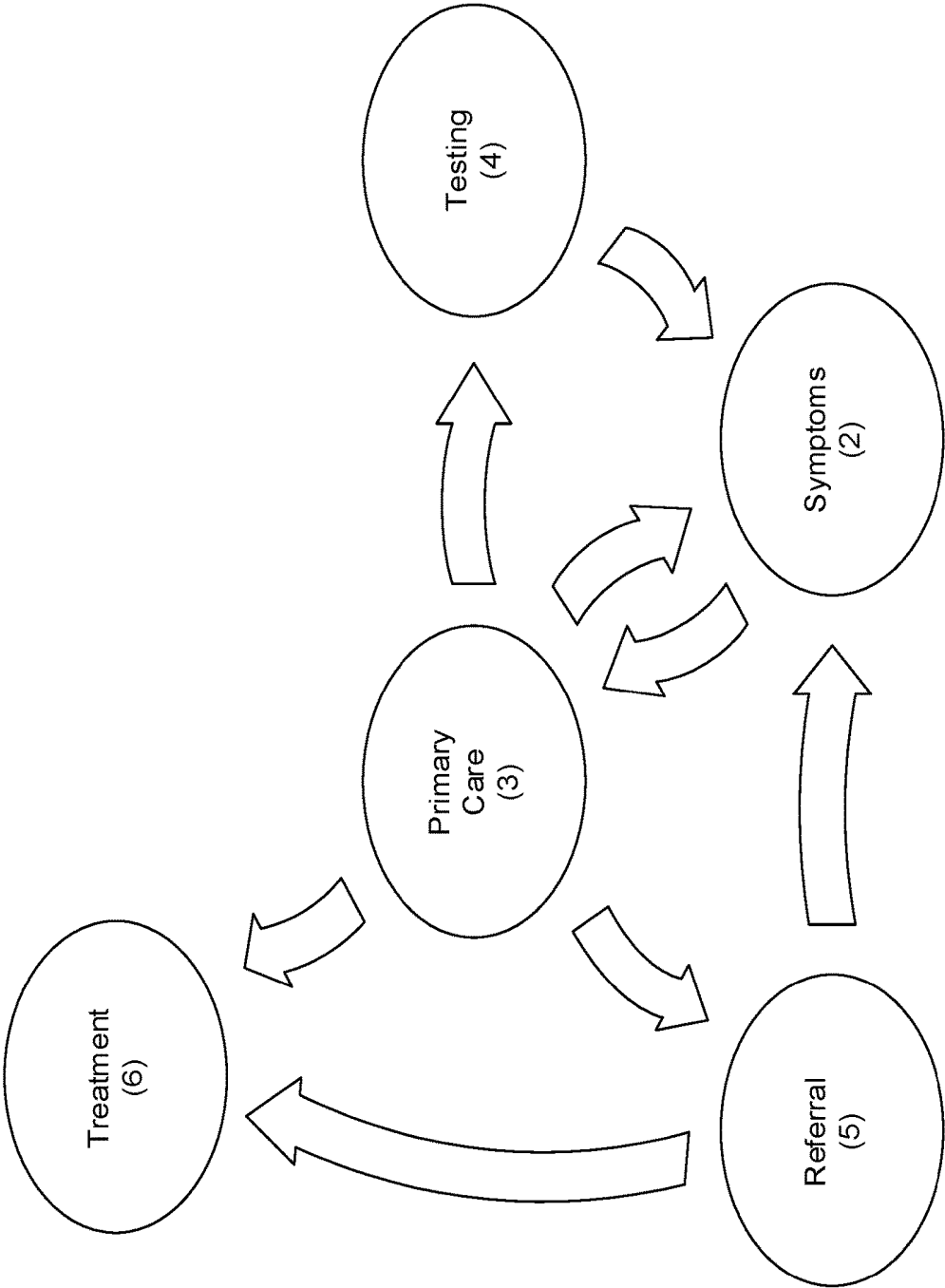
BIOPAC Systems, Inc. #AS148-Automated ECG Analysis , Mar. 24, 2006.

Health Research—Hexoskin Biometric Shirt | Hexoskin URL:<http://www.hexoskin.com/pages/health-research> (Web page cached on Dec. 2, 2014).

Jacob Kastrenakes, "Apple Watch uses four sensors to detect your pulse," Sep. 9, 2014. URL: <http://www.theverge.com/2014/9/9/6126991/apple-watch-four-back-sensors-detect-activity>.

Nicole Lee, "Samsung Gear S review: an ambitious and painfully flawed smartwatch," Dec. 1, 2014. URL: <http://www.engadget.com/2014/12/01/samsung-gear-s-review/>.

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].



**Fig. 1**  
**(prior art).**  
1

Fig. 2.

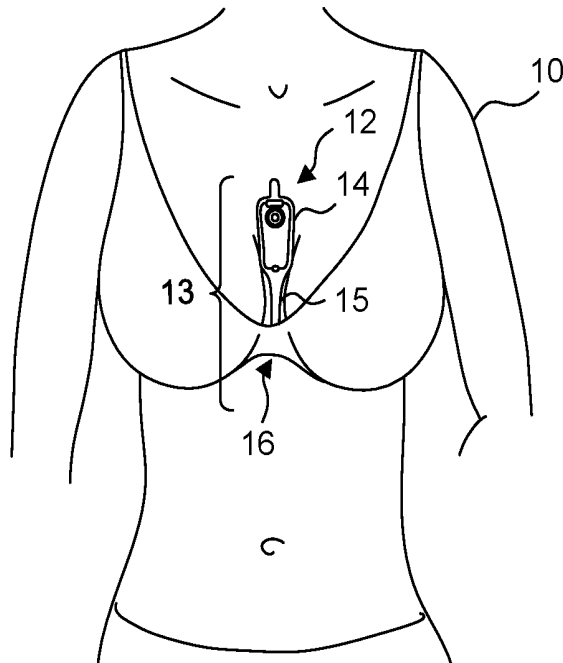


Fig. 3.

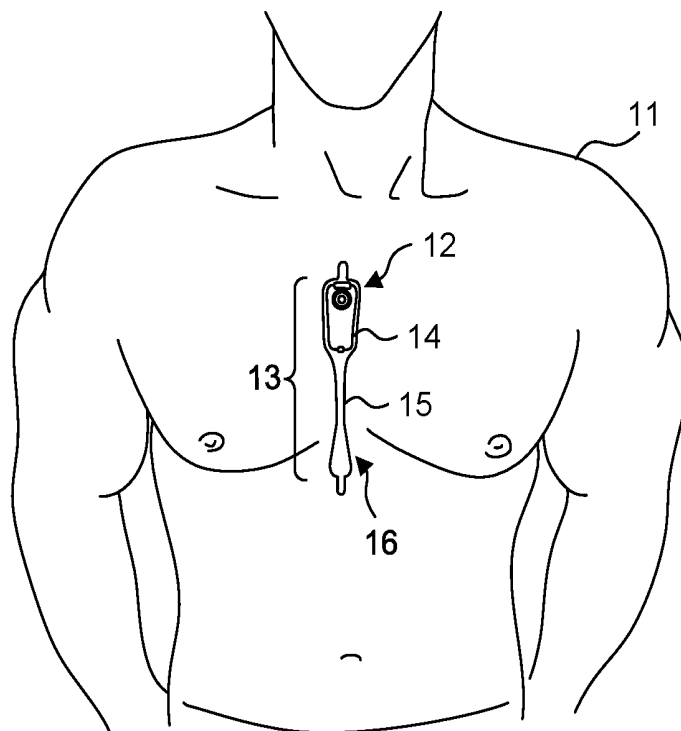


Fig. 4.

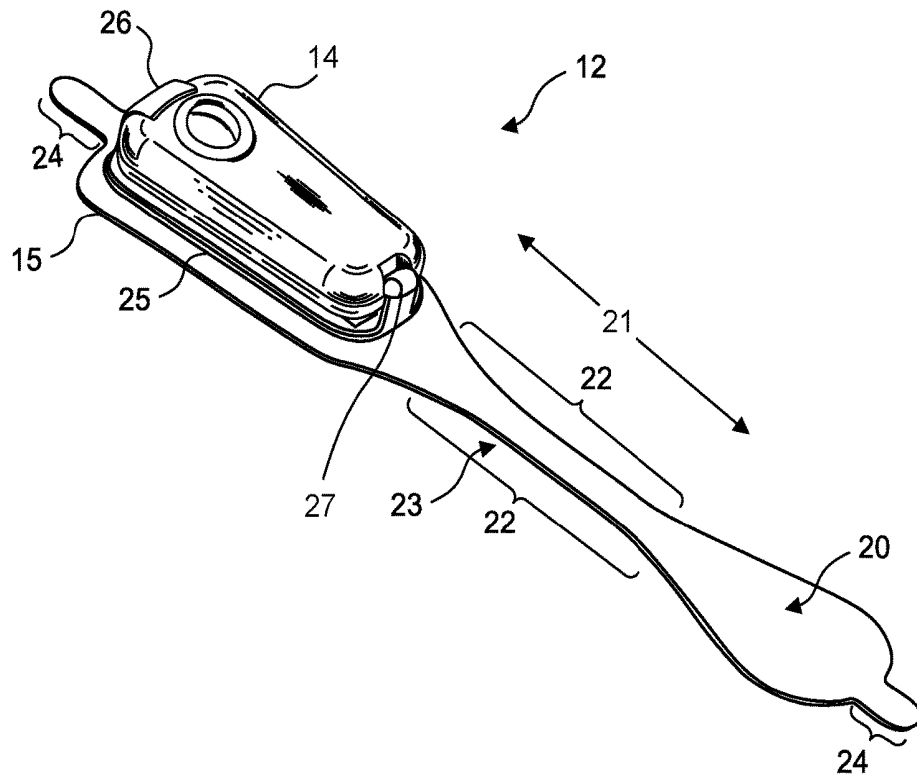
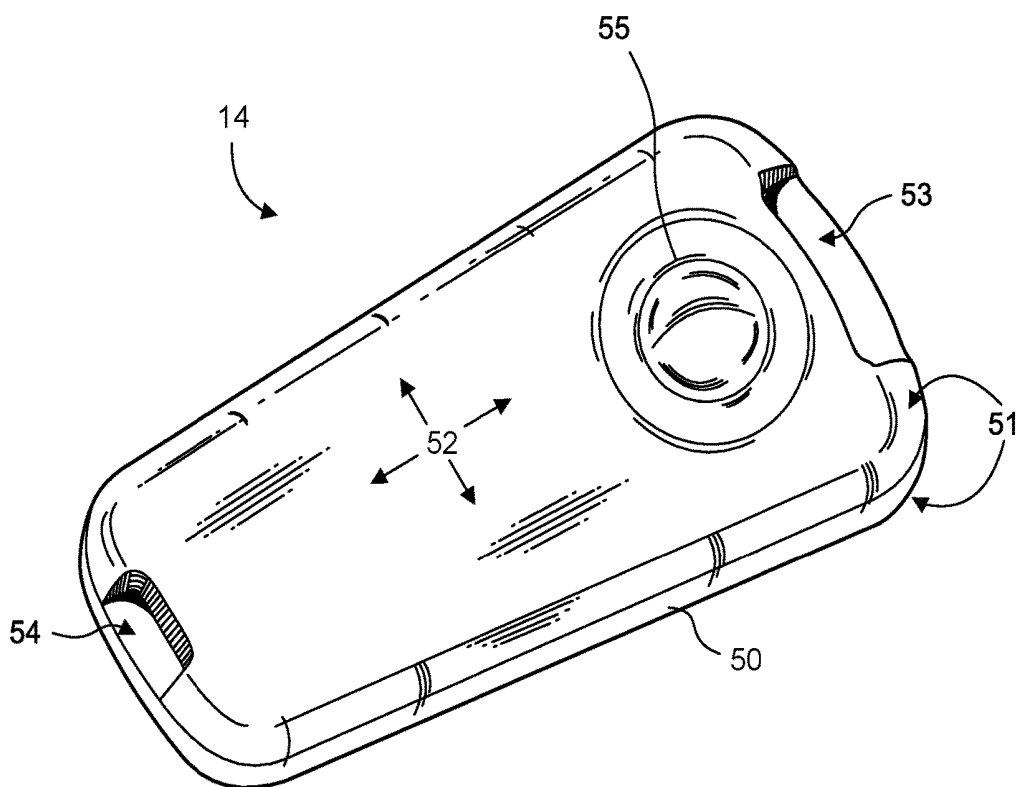


Fig. 5.



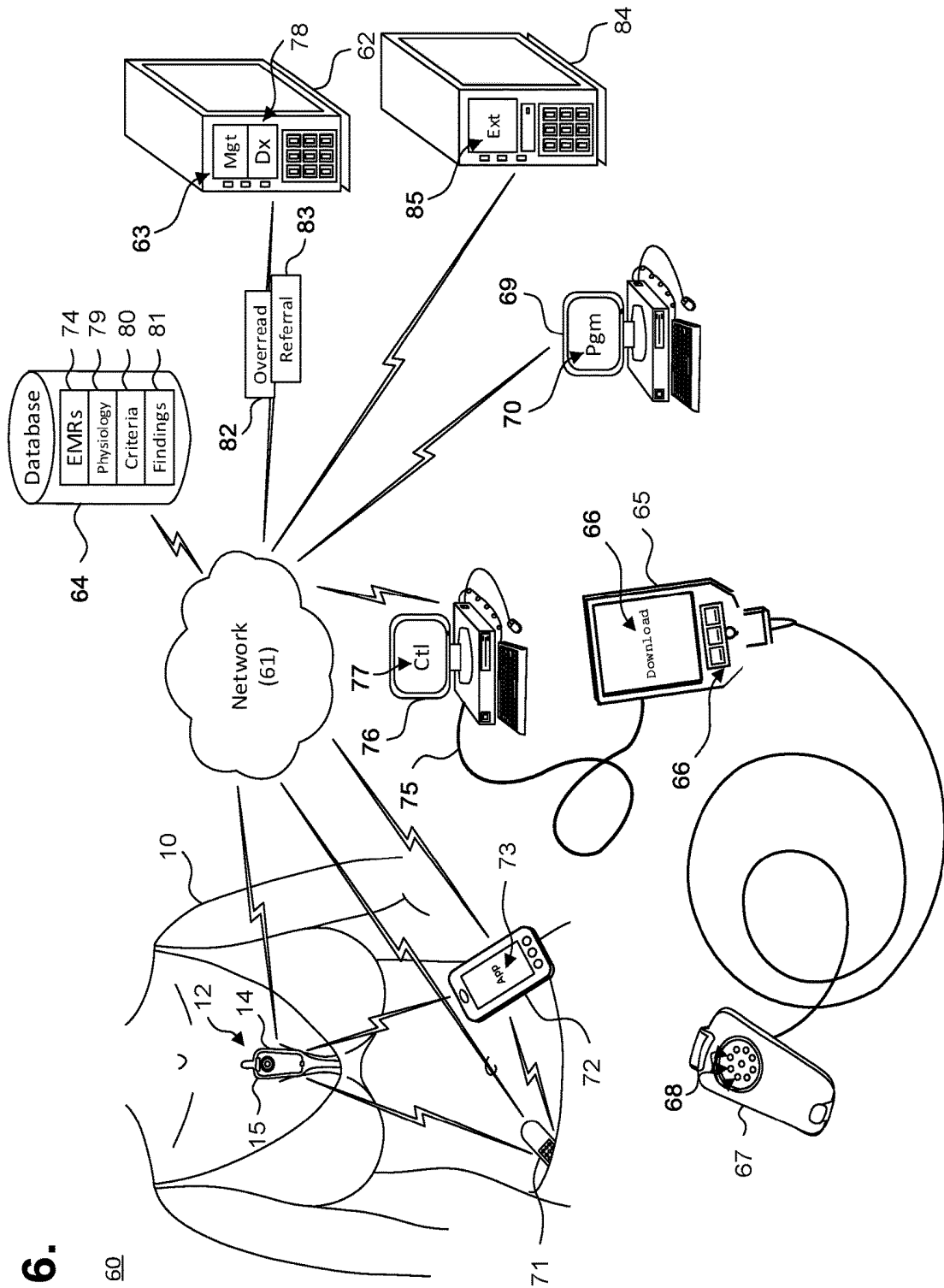


Fig. 6.

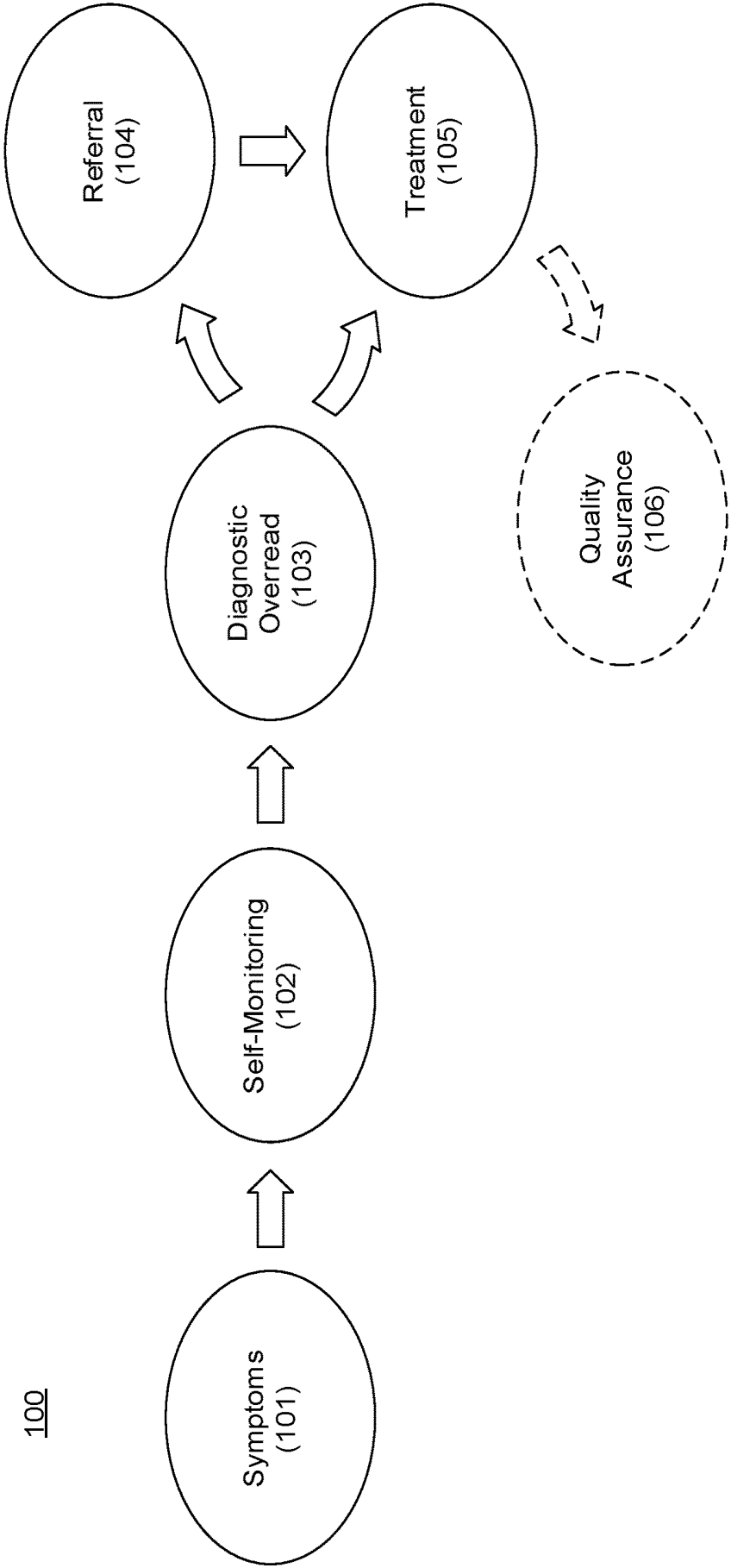


Fig. 7.

100

# HEALTH MONITORING APPARATUS FOR INITIATING A TREATMENT OF A PATIENT BASED ON PHYSIOLOGICAL DATA WITH THE AID OF A DIGITAL COMPUTER

## CROSS-REFERENCE TO RELATED APPLICATION

This non-provisional patent application is a continuation of U.S. patent application Ser. No. 15/948,915, filed Apr. 9, 2018, which is a continuation of U.S. Pat. No. 9,936,875, issued Apr. 10, 2018, which is a continuation of U.S. Pat. No. 9,788,722, issued Oct. 17, 2017, which is a divisional of U.S. Pat. No. 9,504,423, issued Nov. 29, 2016, the disclosures of which are incorporated by reference.

## FIELD

This application relates in general to wearable health monitors and, in particular, to a health monitoring apparatus with wireless capabilities for initiating a patient treatment with the aid of a digital computer.

## BACKGROUND

Ensuring ready access to health care remains a pressing concern in our increasingly fast-paced society, but the ever climbing costs of health care makes having health insurance or similar financial arrangements all but essential for practically everyone except the wealthy or destitute. For the insured, the average health insurance carrier effectively serves as the gatekeeper that controls entry into the health care system and who manages the provisioning or denial of health care by stipulating the terms under which benefits will be paid. Thusly, health insurance subscribers (or enrollees) are at times caught in the middle between the dictates of their insurer and their ability to readily address their health concerns. On the one hand, a subscriber who bypasses his primary care provider, as typically required by an insurer as a first contact, and instead seeks out a medical specialist on his own may be taking a financial risk, as a health insurer could deny coverage. On the other hand, the primary care provider may not always offer a satisfactory or practicable solution, particularly in situations where a condition has symptoms that are transient or infrequent, or which underlies a disorder with a long incubatory or onset period, as can happen with certain chronic conditions.

For instance, cardiac rhythm disorders may present with lightheadedness, fainting, chest pain, hypoxia, syncope, palpitations, and congestive heart failure (CHF), yet cardiac rhythm disorders are often sporadic in occurrence and may not show up in-clinic during a conventional 12-second electrocardiogram (ECG). Moreover, some types of cardiac rhythm disorders may warrant immediate subspecialist care, such as heart blockage, tachycardia and bradycardia, which require the attention of an electrophysiologist. Continuous ambulatory ECG monitoring over an extended period is more apt to capture sporadic cardiac events, yet health insurers often require a primary care referral to a monitoring laboratory before underwriting long-term ECG monitoring and access to a specialist may be delayed or denied, depending upon the ECG monitoring results.

Notwithstanding, if a subscriber's ECG could be recorded in an ambulatory setting over a prolonged time period, particularly for as long as seven days or more, thereby allowing the subscriber to engage in activities of daily living, the chances of acquiring meaningful medical infor-

mation and capturing an abnormal event while the subscriber is engaged in normal activities are vastly improved. Unfortunately, few, if any, options for long-term ambulatory ECG monitoring that a subscriber could undertake on his own are available, and existing ECG monitoring solutions require physician involvement with tacit insurer approval. For instance, Holter monitors are widely used for extended ECG monitoring, typically for 24-48 hour time periods. A typical Holter monitor is a wearable and portable version of an ECG and, as such, is cumbersome, expensive and typically available for use only through a prescription, which limits their usability, and the discretion to refer the subscriber still remains with the attending physician.

Similarly, the ZIO XT Patch and ZIO Event Card devices, manufactured by iRhythm Tech., Inc., San Francisco, Calif., are wearable 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. The ZIO XT Patch device is limited to a 14-day period, while just the electrodes of the ZIO Event Card device can be worn for up to 30 days. Both devices represent compromises between length of wear and quality of ECG monitoring. Moreover, both of these devices are also prescription-only, which limits their usability and, the same as a Holter monitor, the discretion to refer the subscriber remains with the attending physician.

Therefore, a need remains for a low cost monitor for recording an ECG and other physiology that can be used by an individual on their own, without health insurance pre-authorization, yet which can identify and generate an actionable, health condition-specific (and ideally health insurance-payable) referral to a medical specialist when medically appropriate.

## SUMMARY

Certain kinds of medical conditions, particularly conditions that only sporadically exhibit measurable symptoms, defy conventional forms of medical diagnosis centered on in-clinic testing. Individuals who suffer from such conditions can feel helpless in their attempts to secure access to medical care because, at least in part, they are left to the mercy of their condition to present symptoms at the right time to allow diagnosis and treatment. Moreover, such individuals may present to a physician or other health care provider unable to provide state-of-the-art care for cardiac conditions, especially cardiac rhythm disorders. Providing these individuals with ambulatory extended-wear health monitors that record ECG and physiology, preferably available over-the-counter and without health insurance pre-authorization, is a first step towards addressing their needs expeditiously. In addition, these individuals need a way to gain entry into the health care system once a medically-actionable medical condition has been identified. Here, the ECG and physiology is downloaded and evaluated post-monitoring against medical diagnostic criteria. Medical specialists are pre-identified and paired up with key diagnostic findings, such that an individual whose monitoring data indicates a medical concern will be automatically referred and scheduled for a consultation, thereby removing delays and bypassing intermediaries who will not provide definitive interventions for the patient.

In one embodiment, a health monitoring apparatus for initiating a patient treatment based on physiological data with the aid of a digital computer is provided. The apparatus includes a wearable health monitor, a download station configured to receive the physiology sensed by the wearable

health monitor, and an at least one computer interfaced to the download station. The wearable health monitor includes a flexible backing; a plurality of electrocardiographic electrodes included on the flexible backing and provided to sense a patient's physiology over a monitoring period; and a plurality of flexible circuit traces affixed at each end of the flexible backing with each circuit trace connecting one of the electrocardiographic electrodes and via which the sensed physiology is recorded by the wearable health monitor. The at least one computer includes a database configured to store the physiology and medical diagnostic criteria; and a processor and a memory configured to store code executable by the processor and including: a comparison module configured to generate a diagnostic overread of the physiology using the medical diagnostic criteria; and an initiation module configured to initiating medical care of the patient with one or more pre-identified care providers via the computer based on the overread.

In a further embodiment, a health monitoring apparatus for initiating a patient treatment based on physiological data with the aid of a digital computer is provided. The apparatus includes a wearable health monitor, a download station configured to receive the physiology sensed by the wearable health monitor, and an at least one computer interfaced to the download station. The wearable health monitor includes a sealed housing; and an electronic circuitry included within the sealed housing and including an external interface configured to be connected to a pair of electrocardiographic electrodes configured to sense physiology of a patient throughout an extended period and an onboard memory configured to store the recorded physiology. The at least one computer includes a database configured to store the physiology and medical diagnostic criteria; and a processor and a memory configured to store code executable by the processor and including: a comparison module configured to generate a diagnostic overread of the physiology using the medical diagnostic criteria; and an initiation module configured to initiating medical care of the patient with one or more pre-identified care providers via the computer based on the overread.

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

FIG. 1 is a process flow diagram showing, by way of example, one prior art approach to addressing medical conditions in a managed care model of health insurance.

FIGS. 2 and 3 are diagrams showing, by way of examples, an extended wear electrocardiography and physiological wearable monitor respectively fitted to the sternal region of a female patient and a male patient.

FIG. 4 is a perspective view showing a contact-activated 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 functional block diagram showing a system for addressing medical conditions with the aid of a digital computer through the monitor recorder of FIG. 4, in accordance with one embodiment.

FIG. 7 is a process flow diagram showing a method addressing medical conditions through a wearable health monitor with the aid of a digital computer in accordance with one embodiment.

#### DETAILED DESCRIPTION

For certain types of medical conditions, gaining access to health care can be a time-consuming and often frustrating experience. In the case of cardiac rhythm disorders, such delays can cause death. One possible reason stems from the restrictions often imposed on subscribers of both private and government mandated health insurance, especially when provided in the form of managed care, which employs a network of contracted health care providers and medical facilities that are structured to control costs and help to improve overall quality of care. FIG. 1 is a process flow diagram showing, by way of example, one prior art approach to addressing medical conditions in a managed care model 1 of health insurance. In this model, the average health insurance carrier, such as those provided by the Affordable Care Act, effectively serves as the gatekeeper that controls entry into the health care system and who manages the provisioning or denial of health care by stipulating the terms under which benefits will be paid. At times, the goals of the health insurer as the arbiter of benefits can be at odds with the medical concerns of their subscribers, who are generally expected to comply with their insurer's guidelines to receive care for non-urgent health conditions, or to seek an exception, preferably beforehand.

The managed care model 1 of health insurance can work well in providing access to care for those subscribers who are able to be served by the network of health care providers and facilities that has been set up by the health insurer to address the majority of expected health concerns. For example, for non-urgent, undiagnosed physical ailments and health conditions, a health insurer will generally require a subscriber suffering symptoms (step 2) to see their primary care provider first (step 3). The subscriber may undergo testing (step 4) and follow up with the primary care provider (step 3) with the expectation that most health conditions can be resolved without departing from the primary care level. When circumstances dictate, the subscriber may be referred to a medical specialist (step 5); ordinarily, a showing of medical necessity will be required before the health insurer will be contractually obligated to pay benefits. The type of medical specialist to whom the subscriber is referred is based upon the primary care provider's understanding of the health condition, experience, and referral network, which may be biased towards the health care provider network already set in place. At its best, such a system may still cause considerable delays in diagnosis and management of a cardiac rhythm disorder or other serious physiological condition.

The managed care model 1 can begin to fail when health insurance subscribers encounter medical conditions that depart from the expected norm, particularly medical conditions whose symptoms are transient or infrequent, or which underlie a disorder with a long incubatory or onset period, such as heart disease, diabetes mellitus, epilepsy, Parkinson's disease, and Alzheimer's disease. The cycle of having symptoms (step 2), seeing a primary care provider (step 3), undergoing testing (step 4), and perhaps receiving a medical

specialist referral (step 5) may be repeated several times until the health condition either resolves on its own (step 2), is diagnosed and treated at the primary care level (step 3), or possibly worsens, perhaps significantly, such that intervention by a medical specialist is necessary (step 6), albeit at the cost of potentially complicating treatment, endangering cure or effective management, increasing medical costs, and negatively affecting quality or duration of life.

In these situations, access to care is hindered, at least in part, by the difficulty of or inability to narrow down the cause of the symptoms through in-clinic testing. Repetitions of the primary care cycle may not always be efficacious; for example, in-clinic testing of a subscriber is only effective if administered coincident to the timely occurrence of a sporadically-occurring medical condition, yet such conditions, such as an abnormal heart rhythm or syncope, rarely occur on demand or when needed for present diagnosis. In addition, some health conditions may require a level of care or medical specialization with which the primary care provider is unversed, and a referral may not provide the relief ultimately sought. In some situations, the cycle of testing and follow up may be repeatedly revisited; the subscriber may be forced to undergo more testing and delay until and if an appropriate medical specialist becomes involved. Misdiagnosis or maldiagnosis remain potential risks.

As an example, consider the potentially life-threatening problem of syncope, or loss of consciousness. Syncope affects millions of Americans annually. Syncope also can be extremely difficult to diagnose because the condition is intermittent and gives no warning. Causes can range from the relatively trivial, such as fainting from emotional excitement, to a life-threatening cardiac rhythm disorder, like transient heart block, that if the condition were to persist, would result in death, and not just transient loss of consciousness. Atrial fibrillation, another potential cause of syncope, is extremely common and is an occult and leading cause of stroke. Most patients with syncope never see a physician because they either dismiss the condition as a one-time event, rationalizing its import away, or struggle to see a physician of some sort, almost always a generalist, for help. Many such physicians either inappropriately dismiss the patient as anxious or begin the long-process to getting at the root cause. At minimum, this process requires referral to a cardiologist, who then prescribes an ECG monitor, usually the traditional 24-hour Holter monitor, which in turn must be interpreted. The patient must then return for evaluation and possible therapy. The delay for each of these steps can take weeks. Often, the patient (or sometimes the doctor) gives up and returns to his "normal" life only to experience a second episode of syncope or something worse, like a stroke or death. The better way to deal with syncope is for the patient to self-apply an over-the-counter ECG monitor at modest personal expense, yielding valuable data in a fraction of the time and cost of the traditional approach, potential preventing a stroke or even saving the patient's life.

The shortcomings of the managed care model 1, as well as other types of health care provisioning arrangements that mandate who an individual must see first for non-urgent, undiagnosed medical conditions, can be significantly overcome by empowering the patient with basic self-help tools that improve access to health care. These tools include the ability to perform self-monitoring of personal physiology, including ECG monitoring, as described in the previous paragraph, and to be able to tap into an automated referral network that, when medically appropriate, will connect the individual with the right specialist for the medical conditions observed and diagnosed. Such physiological monitoring can

be provided through a wearable monitor that can be interfaced with a diagnostics computer system that can download physiology recorded by the wearable monitor and generate a medically-actionable diagnostic overread, all without requiring the constant oversight or active involvement of a health insurer or managed care system.

By way of example, using the heretofore referenced problem of syncope resulting from a cardiac rhythm disorder, the wearable monitor includes two components, a flexible extended wear electrode patch and a removable reusable monitor recorder. FIGS. 2 and 3 are diagrams showing, by way of example, an extended wear electrocardiography and physiological wearable 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. Both the monitor recorder 14 and the electrode patch 15 are optimized to capture electrical signals from the propagation of low amplitude, relatively low frequency content cardiac action potentials, particularly the P-waves generated during atrial activation. The wearable monitor 12 could include additional sensors to monitor and record other types of physiology, including blood pressure, respiratory rate, temperature, and blood glucose, either in addition to or in lieu of heart rate.

The wearable monitor 12 sits centrally (in the midline) on the patient's chest over the mid-sternum 13 oriented top-to-bottom with the monitor recorder 14 preferably situated towards the patient's head. The electrode patch 15 is shaped to fit comfortably, conforming 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.

During ECG monitoring, the amplitude and strength of action potentials sensed on the body's surface are affected to varying degrees by cardiac, cellular, and extracellular structure and activity, vector of current flow, and physical factors, like obesity, dermatitis, large breasts, and high impedance skin, as can occur in dark-skinned individuals. Sensing along 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 by countering some of the effects of these factors, such as described in commonly-assigned U.S. Patent application Publication No. 2016/0007872, published Jan. 14, 2016, pending, the disclosure of which is incorporated by reference, 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 16 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 excellent recordation of the QRS interval as the xiphoid process overlies the apical region of the ventricles.

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, with the monitoring being initiated upon the recorder **14** detecting contact with the patient. (Note that the monitor can also be snapped into place on a table prior to removing adhesive liner and application of the electrode patch to the skin.) FIG. **4** is a perspective view showing a contact-activated extended wear electrode patch **15** with a monitor recorder **14** 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 “hourglass”-like shape, when viewed from above. The upper part of the “hourglass” is sized to allow an electrically non-conductive receptacle **25**, sits on top of the outward-facing surface of the electrode patch **15**, to be affixed to the electrode patch **15** with an ECG electrode placed underneath on the patient-facing underside, or contact, surface of the electrode patch **15**; the upper part of the “hourglass” has a longer and wider profile (but still rounded and tapered to fit comfortably between the breasts) than the lower part of the “hourglass,” which is sized primarily to allow just the placement of an ECG electrode of appropriate shape and surface area to record the P-wave and the QRS signals sufficiently given the inter-electrode spacing.

The electrode patch **15** incorporates features that significantly improve wearability, performance, and patient comfort throughout an extended monitoring period for men or women. During wear, the electrode patch **15** is susceptible to pushing, pulling, and torqueing movements, including compressional and torsional forces when the patient bends forward, and tensile and torsional forces when the patient leans backwards or twists their thorax. To counter these stress forces, the electrode patch **15** incorporates strain and crimp reliefs, such as described in commonly-assigned U.S. Patent application Publication No. 2015/0087948, published Mar. 26, 2015, pending, and U.S. Pat. No. 9,433,380, the disclosures of which are 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 reusable 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 electrode patch **15**, such as described in commonly-assigned U.S. Patent Application Publication No. 2015/0087949, published Mar. 26, 2015, pending, 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** has a rounded isosceles trapezoidal-like shape **52**, for comfort with women, when viewed from above, such as described in commonly-assigned U.S. Design Pat. No. D717,955, entitled “Electrocardiography Monitor,” issued Nov. 18, 2014, the disclosure of which is incorporated by reference. In addition, a label, barcode, QR code, or other visible or electronic indicia can be printed on the outside of, applied to the outside of, or integrated into the sealed housing **50** to uniquely identify the monitor recorder **14** and can include a serial number, manufacturing lot number, date of manufacture, and so forth. 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.

When operated standalone, the monitor recorder **14** senses and records the patient’s ECG and physiology data into an onboard memory, which can be downloaded and evaluated to identify and generate an actionable, health condition-specific (and ideally health insurance-payable) referral to a medical specialist when medically appropriate. In addition, the wearable monitor **12** can interoperate with other devices, which further improves upon a patient’s ability to address medical conditions on his own. FIG. **6** is a functional block diagram showing a system **60** for addressing medical conditions with the aid of a digital computer **62** through the monitor recorder **14** of FIG. **4**, in accordance with one embodiment. In one form, 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, 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 65, which could be a dedicated programmer or other device, including a digital computer, such as personal computer 76, that permits the retrieval of stored ECG monitoring data, execution of diagnostics on or programming of the monitor recorder 14, or performance of other functions.

To facilitate physical connection with a download station 65, 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 68 on a paired receptacle 67 of the download station 65. In turn, the download station 65 executes a communications or offload program 66 (“Offload”) or similar program that interacts with the monitor recorder 14 via the physical interface to retrieve the stored ECG and physiology monitoring data. The download station 65 could be a server, personal computer, such as personal computer 76, tablet or handheld computer, smart mobile device, or purpose-built device designed specific to the task of interfacing with a monitor recorder 14. Still other forms of download station 65 are possible. In a further embodiment, the data from the monitor 12 can be offloaded wirelessly and the monitor 12 can interface with the download station 65 wirelessly.

The ECG and physiology data retrieved from the monitor recorder 14 by the download station 65 can, in turn, be retrieved from the download station 65 over a hard link 75 using a control program 77 (“Ctl”) or analogous application executing on a personal computer 76 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 76 or other connectable device may also execute middleware that converts ECG and physiology data and other information into a format suitable for use by a third-party post-monitoring analysis program. Formatted data stored on the personal computer 76 is maintained and safeguarded in the same manner as electronic medical records (EMRs) 74 are protected in the secure database 64, as further discussed infra. In a further embodiment, the download station 65 is able to directly interface with other devices over a computer communications network 61, which could be some combination of a local area network and a wide area network, including the Internet or another telecommunications network, over a wired or wireless connection.

A client-server model could be used for ECG and physiology data download and analysis. In this model, a server 62 remotely interfaces with the download station 65, by way of the personal computer 76, over the network 61 and retrieves the formatted data or other information. The server 62 executes a patient management program 63 (“Mgt”) or similar application that stores the retrieved formatted data and other information in a secure database 64 cataloged in that patient’s EMRs 74. Patients’ EMRs can be supplemented with other information, such as medical history, testing results, and so forth, which can be factored into automated diagnosis and referral. In addition, the patient management program 63 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 63, or other trusted application, also maintains and safeguards the secure database 64 to limit access to patient EMRs 74 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 64. The physician would execute an application program 70 (“Pgm”), such as a post-monitoring ECG analysis program, on a personal computer 69 or other connectable computing device, and, through the application program 70, coordinate access to his patient’s EMRs 74 with the patient management program 63. Other schemes and safeguards to protect and maintain the integrity of patient EMRs 74 are possible.

In a further embodiment, the wearable monitor 12 can interoperate wirelessly with other wearable physiology monitors and activity sensors 71, such as activity trackers worn on the wrist or body, and with mobile devices 72, including smart watches and smartphones. Wearable physiology monitors and activity sensors 71 encompass a wide range of wirelessly interconnectable devices that measure or monitor a patient’s physiological data, such as heart rate, temperature, blood pressure, respiratory rate, blood pressure, blood sugar (with appropriate subcutaneous probe), oxygen saturation, minute ventilation, and so on; physical states, such as movement, sleep, footsteps, and the like; and performance, including calories burned or estimated blood glucose level. The physiology sensors in non-wearable mobile devices, particularly smartphones, are generally not meant for continuous tracking and do not provide medically precise and actionable data sufficient for a physician to prescribe a surgical or serious drug intervention; such data can be considered screening information that something may be wrong, but not data that provides the highly precise information that may allow for a surgery, such as implantation of a pacemaker for heart block or a defibrillator for ventricular tachycardia, or the application of serious medications, like blood thinners for atrial fibrillation or a cardiac ablation procedure. Such devices, like smartphones, are better suited to pre- and post-exercise monitoring or as devices that can provide a signal that something is wrong, but not in the sufficient detail and medico-legal validation to allow for medical action. Conversely, medically actionable wearable sensors and devices sometimes provide continuous recording for relatively short time periods, but must be paired with a smartphone or computer to offload and evaluate the recorded data, especially if the data is of urgent concern, such as mobile cardiac outpatient telemetry devices.

Wearable physiology monitors and activity sensors 71, also known as “activity monitors,” and to a lesser extent, “fitness” sensor-equipped mobile devices 72, can trace their life-tracking origins to ambulatory devices used 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. Data is typically tracked by the wearable physiology monitors or activity sensors 71 and mobile device 72 for only the personal use of the wearer. The physiological monitoring is usually considered informational only, even where a device originated within the medical or health care community, in part, because the data has not been (and is not intended to be) time-correlated to physician-supervised monitoring. Importantly, medically-significant events, such as cardiac rhythm disorders, including tachyarrhythmias, like ventricular tachycardia or atrial fibrillation, and bradyarrhythmias, like

heart block, while potentially detectable with the appropriate diagnostic heuristics, are neither identified nor acted upon by the wearable physiology monitors and activity sensors **71** and the mobile device **72**. Nevertheless, wearable physiology monitors or activity sensors **71** and mobile device **72** may play a role in helping a patient start to address a medical concern at a lay level.

Frequently, wearable physiology monitors and activity sensors **71** are capable of wirelessly interfacing with mobile devices **72**, particularly smart mobile devices, including so-called “smartphones” and “smart watches,” as well as with personal computers and tablet or handheld computers, to download monitoring data either in real-time or in batches. The wireless interfacing of such activity monitors is generally achieved using transceivers that provide low-power, short-range wireless communications, such as Bluetooth, although some wearable physiology monitors and activity sensors **71**, like their mobile device cohorts, have transceivers that provide true wireless communications services, including 4G or better mobile telecommunications, over a telecommunications network. Other types of wireless and wired interfacing are possible.

Where the wearable physiology monitors and activity sensors **71** are paired with a mobile device **72**, the mobile device **72** executes an application (“App”) that can retrieve the data collected by the wearable physiology monitor and activity sensor **71** 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. Where the wearable physiology monitors and activity sensors **71** has sufficient onboard computational resources, the activity monitor itself executes an app without the need to relay data to a mobile device **72**. Generally, such more computationally-capable wearable physiology monitors and activity sensors are also equipped with wireless communications services transceivers, such as found in some smart watches that combine the features of activity monitors with mobile devices. Still other activity monitor and mobile device functions on the collected data are possible.

In a further embodiment, a wearable physiology monitor, activity sensor **71**, or mobile device **72** worn or held by the patient **10**, or otherwise be used proximal to the patient’s body, can be used to first obtain and then work collaboratively with a more definitive (medical grade) monitor recorder **14** to enable the collection of physiology by the monitor recorder **14** before, during, and after potentially medically-significant events. The wearable physiology monitor, activity sensor **71**, or mobile device **72** must be capable of sensing cardiac activity, particularly heart rate or rhythm, or other types of physiology or measures, either directly or upon review of relayed data. Where the wearable physiology monitor or activity sensor **71** is paired with a mobile device **72**, the mobile device **72** serves as a relay device and executes an application that will trigger the dispatch of a monitor recorder **14** to the patient **10** upon detecting potentially medically-significant events in the data provided by the paired activity monitor, such as cardiac rhythm disorders, including tachyarrhythmias and bradyarrhythmias, which are readily identifiable respectively based on abnormally rapid or slow heart rate. If the mobile device **72** is itself performing the monitoring of the patient’s physiology, the mobile device **72** executes an application that will trigger the dispatch of a monitor recorder **14** to the patient **10** in near-real time upon detecting potentially medically-significant events, thereby avoiding the delay incurred by data relay from an activity monitor. Finally, if the wearable physiology monitor or activity sensor **71** has

sufficient onboard computational resources and also is equipped with a wireless communications services transceiver, the wearable physiology monitor or activity sensor **71** effectively becomes the mobile device **72** and executes an application that will trigger the dispatch of a monitor recorder **14** to the patient **10** in near-real time upon detecting potentially medically-significant events without the need to first interface with a mobile device **72**. Still other configurations of the detection application are possible.

The act of triggering the dispatch of a monitor recorder **14** represents the first step in a cascade of possible medical interventions of potentially increasing seriousness and urgency. Sensors **71** and devices **73** are generally considered not to be capable of detecting and recording medically precise and actionable data, whereas, as a device designed and approved for extended wear, the monitor recorder **14** continually monitors the patient’s physiology over a long time period and will capture any medically-actionable data leading up to, throughout the occurrence of, and following an event of potential medical concern.

The monitoring data recorded by the monitor recorder **14** can be uploaded directly into the patient’s EMRs **74**, either by using a mobile device **72** as a conduit for communications with a server **62** coupled to a secure database **64** within which the patient’s EMRs **74** are stored, or directly to the server **62**, if the monitor recorder **14** is appropriately equipped with a wireless transceiver or similar external data communications interface, as further described infra. Thus, the data recorded by the monitor recorder **14** would directly feed into the patient’s EMRs **74**, thereby allowing the data to be made certifiable for immediate use by a physician or healthcare provider. No intermediate steps would be necessary when going from cutaneously sensing cardiac electric signals and collecting the patient’s physiology using a monitor recorder **14** to presenting that recorded data to a physician or healthcare provider for medical diagnosis and care. The direct feeding of data from the monitor recorder **14** to the EMRs **74** clearly establishes the relationship of the data, as recorded by the monitor recorder **14**, to the patient **10** that the physician is seeing and appropriately identifies any potentially medically-significant event recorded in the data as originating in the patient **10** and nobody else.

Based on the monitoring ECG and physiology data, physicians and healthcare providers can rely on the data as certifiable and can directly proceed with determining the appropriate course of treatment for the patient **10**, including undertaking further medical interventions as appropriate. The server **62** executes a patient diagnosis program **78** (“Dx”) or similar application that can evaluate the recorded physiology **79**, as fed into the patient’s EMRs **74**. The patient diagnosis program **78** compares the recorded physiology **79** of each patient to a set of medical diagnostic criteria **80**, from which a diagnostic overread **82** is generated. Each diagnostic overread **82** includes one or more diagnostic findings **81** that are rated by degree of severity. If at least one of the diagnostic findings **81** for a patient exceed a threshold level of tolerance, which may be tailored to a specific client, disease or medical condition group, or applied to a general patient population, a referral **83**, which can include orders to seek immediate treatment, is generated on behalf of the patient to a pre-identified care provider for medical care and the patient is notified.

The referral **83** is an actionable, health condition-specific form of communication that is electronically dispatched directly to a care provider. The care provider is reached through a care provider network server **84**, or other patient referral system, that executes an external patient care pro-

gram (“Ext”) and which interfaces over the network **61** to the patient diagnosis program **78** executing on the server **62**. In a further embodiment, the care provider and patient could also be reached using social media, provided the necessary patient privacy permissions are in place. The referral **83** represents a request on behalf of the patient to an appropriate type of care provider, which could be a general practice physician if the patient’s physiology **79** represents normal tracings or a medical specialist, for instance, a cardiac electrophysiologist referral when the physiology **79** includes a diagnostic finding **81** of an event of sufficient potential severity to warrant the possible implantation of a pacemaker for heart block or a defibrillator for ventricular tachycardia. A further example would be the direct referral to a cardiologist for the finding of atrial fibrillation for the initiation of blood thinners and possibly an ablation procedure.

Other uses of the data recorded by the monitor recorder **14** and other devices are possible. For instance, a patient **10** who has previously suffered heart failure is particularly susceptible to ventricular tachycardia following a period of exercise or strenuous physical activity. A wearable sensor **71** or device **73** that includes a heart rate monitor would be able to timely detect an irregularity in heart rhythm. The application executed by the sensor **71** or device **73** allows those devices to take action by triggering the dispatch of a monitor recorder **14** to the patient **10**, even though the data recorded by the sensor **71** or device **73** is itself generally medically-insufficient for purposes of diagnosis and care. Thus, rather than passively recording patient data, the sensor **71** or device **73** takes on an active role in initiating the provisioning of medical care to the patient **10** and starts a cascade of appropriate medical interventions under the tutelage of and followed by physicians and trained healthcare professionals.

In a still further embodiment, the monitor recorder **14** could upload an event detection application to the sensor **71** or device **73** to enable those devices to detect those types of potentially medically-significant events, which would trigger the dispatch of a monitor recorder **14** to the patient **10**. Alternatively, the event detection application could be downloaded to the sensor **71** or device **73** from an online application store or similar online application repository. Finally, the monitor recorder **14** could use the sensor **71** or device **73** to generate an appropriate alert, including contacting the patient’s physician or healthcare services, via wireless (or wired) communications, upon detecting a potentially medically-significant event or in response to a patient prompting.

The patient **10** could be notified by the sensor **71** or device **73**, through the sensor’s or device’s user interface, that an event of potential medical concern has been detected coupled with an offer to have a monitor recorder **14** sent out to the patient **10**, assuming that the patient **10** is not already wearing a monitor recorder **14**. Alternatively, the sensor **71** or device **73** could unilaterally send out a request for a monitor recorder **14**. The request for a monitor recorder **14** could be sent via wireless (or wired) communications to the patient’s physician, a medical service provider organization, a pharmacy, an emergency medical service, or other appropriate healthcare entity that would, in turn, physically provide the patient with a monitor recorder **14**. The patient **10** could also be told to pick up a monitor recorder **14** directly from one of the above-identified sources.

Conventional Holter monitors, as well as the ZIO XT Patch and ZIO Event Card devices, described supra, are currently available only by a physician’s prescription for a specific patient **10**. As a result, the physiological data recorded by these monitors and devices are assumed by

healthcare professional to belong to the patient **10**. In this prescriptive medicine context, grave questions as to the authenticity of the patient’s identity and the data recorded do not generally arise, although current medical practice still favors requesting affirmative patient and caregiver identification at every step of healthcare provisioning. As a device intended for adoption and usage broader than prescriptive medicine, the monitor recorder **14** carries the potential to be used by more than one individual, which can raise concerns as to the veracity of the data recorded.

In a still further embodiment, the mobile device **72**, or, if properly equipped, the activity monitor, can be used to help authenticate the patient **10** at the outset of and throughout the monitoring period. The mobile device **72** (or activity monitor) must be appropriately equipped with a digital camera or other feature capable of recording physical indicia located within the proximity of the mobile device **72**. For instance, the Samsung Galaxy S5 smartphone has both a biometric fingerprint reader and autofocus digital camera built in. Upon receipt of a monitor recorder **14**, the patient **10** can use the photographic or other recording features of the mobile device **72** (or activity monitor) to physically record the placement and use of the monitor recorder **14**. For instance, the patient **10** could take a picture or make a video of the monitor recorder **14** using as applied to the chest using the built-in digital camera. The patient **10** could also swipe a finger over the biometric fingerprint reader. Preferably, the patient **10** would include both his or her face or similar uniquely-identifying marks or indicia, such as a scar, tattoo, body piercing, or RFID chip, plus any visible or electronic indicia on the outside of the monitor recorder’s housing, as further described infra with reference to FIG. 5, in the physical recording. The physical recording would then be sent by the mobile device **72** (or activity monitor) via wireless (or wired) communications to the patient’s physician’s office or other appropriate caregiver, thereby facilitating the authentication of the data recorded by the monitor recorder **14**. Alternatively, the physical recording could be securely stored by the monitor recorder **14** as part of the monitoring ECG and physiology data set.

The mobile device **72** could also serve as a conduit for providing the data collected by the wearable physiology monitor or activity sensor **71** to the server **62**, or, similarly, the wearable physiology monitor or activity sensor **71** could itself directly provide the collected data to the server **62**. The server **62** could then merge the collected data into the wearer’s EMRs **74** in the secure database **64**, if appropriate (and permissible), or the server **62** could perform an analysis of the collected data, perhaps based by comparison to a population of like wearers of the wearable physiology monitor or activity sensor **71**. Still other server **62** functions on the collected data are possible.

Finally, the monitor recorder **14** can also be equipped with a wireless transceiver. Thus, when wireless-enabled, both wearable physiology monitors, activity sensors **71**, and mobile devices **72** can 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 **62**, analysis, or other purpose. In addition, the monitor recorder **14** could wirelessly interface directly with the server **62**, personal computer **69**, or other computing device connectable over the network **61**, when the monitor recorder **14** is appropriately equipped for interfacing with such devices. In one embodiment, network **61** can be a telecommunications network, such as the Internet or a cellular network, and the wireless transceiver can have at least some

cellular phone capabilities, such as by being able to connect to the telecommunications networks. For example, if implemented using the standard such as Bluetooth® 4.2 standard or a Wi-Fi standard, the transceiver can connect to the Internet. Similarly, if implemented using a cellular standard and including a cellular chipset, the transceiver can connect to a cellular network as further described below. Once connected, the monitor recorder **14** can interface with the above-described devices via connecting to the telecommunications network. Still other types of remote interfacing of the monitor recorder **14** are possible.

The wearable monitor **12** records a patient's cardiac activity, with an emphasis on sensing atrial activity and, to a lesser extent, ventricular activity, over an extended period of monitoring. The wearable monitor **12** could include additional sensors to monitor and record other types of physiology, including blood pressure, respiratory rate, temperature, and blood glucose, either in addition to or in lieu of heart rate. FIG. 7 is a process flow diagram showing a method **100** addressing medical conditions through a wearable health monitor **12** with the aid of a digital computer **62** in accordance with one embodiment. The method **100** can be implemented with the aid of software, firmware or hardware and execution of the method **100** can be performed in salient part on a download station **65**, which could be a programmer or other device, or a digital computer, including a server **62** or personal computer **76**, as a series of process or method modules or steps. For convenience, the method **100** will be described in the context of being performed by a digital computer. Execution of the method **100** by other types of computing devices would be analogous mutatis mutandis.

At the outset, a patient suffering symptoms indicative of a non-urgent physical ailment or health condition (step 101) will obtain a wearable monitor **12**, or similar device, and initiate self-monitoring (step 102). The wearable monitor **12** will record the patient's ECG and physiology data over a monitoring period and the data will be recorded into an onboard memory. Upon completion of the monitoring period, the ECG and physiology data will be downloaded into a digital computer with, for instance, the assistance of a download station **65** or similar device, or via wireless connection, if the wearable monitor **12** is so equipped.

The ECG and physiology data **79** retrieved from the wearable monitor **12** is evaluated to identify situations in which the patient requires specific actionable health care. The digital computer generates a diagnostic overread (step 103) of the ECG and physiology data **79** by comparing the data to a set of diagnostic criteria **80**. The ECG and physiology data **79** may be structured along a temporal spectrum that reflects changes in physiology over time, or could be structured on a per event basis where a change in physiology alone suffices to raise a concern. A diagnostic criteria **80** can be defined generally for classes of health conditions, such as cardiac disorder, respiratory distress, hypoglycemia, and hypoxia, or for specific medical conditions, for instance, light headedness that consists of near syncope, atrial fibrillation that consists of episodes longer than 1 minute, ectopy that consists, on average, of over 3 PVCs per minute, palpitations that consist of rapid fluttering over the left side of the chest, supraventricular tachycardia that consists of rates greater than 180 bpm, ventricular tachycardia that consists of more than 3 ventricular beats in a row, bradycardia that consists of pauses greater than 3 seconds, or heart blockage that consists of uncondacted normal sinus impulses. Other diagnostic criteria are possible.

Diagnostic findings **81** are made for each of the diagnostic criteria **80**. The diagnostic findings **81** are rated by the digital

computer by degree of severity and compared to a threshold level of tolerance for each finding. The diagnostic findings **81** may be tailored to a specific client, disease or medical condition group, or applied to a general patient population. If any of the diagnostic findings **81** rate severely enough to warrant medical attention, a referral **83** is automatically generated on behalf of the patient to a pre-identified care provider (step 104) primarily when the patient's medical condition is novel and has not previously been noted in the patient's medical history, although a referral may still be appropriate in some situations where the medical condition has already presented. When the patient's medical condition is pre-existing, the patient may be told to seek immediate medical treatment with a pre-identified medical facility (step 105), thereby bypassing the sequential and laggard referral route, although a referral and immediate medical treatment could both be triggered regardless of medical condition, should the patient so desire, regardless of monitoring outcome. In this instance, where the monitor shows only normal activity or unactionable activity, the patient will likely be referred to a general practitioner.

The foregoing solution to addressing a patient's medical conditions can happen without having to preemptively involve health insurance. Moreover, the wearable monitor **12** works particularly well with medical conditions that defy in-clinic testing. In addition, a database of pre-identified care providers ordered by medical specialty or other selection criteria can be paired with the diagnostic criteria to ensure that a patient gains access to the appropriate type of medical care required based on the diagnostic findings made for his medical condition. In a further embodiment, quality assurance can be performed (step 106) following the dispatch of a referral to rate the health care received by the patient using metrics such as quality, efficiency, and expediency. Other quality assurance metrics are possible. 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 health monitoring apparatus for initiating a patient treatment based on physiological data with the aid of a digital computer, comprising:

a wearable health monitor comprising:

a flexible backing;

a plurality of electrocardiographic electrodes comprised on the flexible backing and provided to sense a patient's physiology over a monitoring period; and a plurality of flexible circuit traces affixed at each end of the flexible backing with each circuit trace connecting one of the electrocardiographic electrodes and via which the sensed physiology is recorded by the wearable health monitor;

a download station configured to receive the physiology sensed by the wearable health monitor;

at least one computer interfaced to the download station, comprising:

a database configured to store the physiology and medical diagnostic criteria; and

a processor and a memory configured to store code executable by the processor and comprising:

a comparison module configured to generate a diagnostic overread of the physiology using the medical diagnostic criteria; and

an initiation module configured to initiating medical care of the patient with one or more pre-identified care providers via the computer based on the overread.

2. A health monitoring apparatus according to claim 1, further comprising:

the database further comprising the patient's electronic medical records, wherein the diagnostic overread is generated further based on the electronic medical records.

3. A health monitoring apparatus according to claim 1, wherein the electronic medical records comprise the patient's medical history and testing results.

4. A health monitoring apparatus according to claim 1, the wearable health monitor further comprising:

a wireless transceiver operable to wirelessly interface with one or more external wireless-enabled devices.

5. A health monitoring apparatus according to claim 4, wherein one of the wireless-enabled devices comprises a mobile device configured to receive the physiology recorded by the wearable physiology monitor and to transmit the physiology to the download station.

6. A health monitoring apparatus according to claim 1, the wearable health monitor comprising an additional physiological sensor configured to collect additional physiological data, wherein the diagnostic overread is further based on the additional physiological data.

7. A health monitoring apparatus according to claim 6, wherein the additional physiological data comprises blood pressure, respiratory rate, temperature, and blood glucose.

8. A health monitoring apparatus according to claim 1, the referral module further comprising at least one of:

a notification module configured to notify a general practice physician upon a diagnostic finding comprising normal physiological data despite patient complaints of light headedness or syncope;

a notification module configured to notify a cardiologist upon a diagnostic finding comprising atrial fibrillation of over 1 minute duration, ectopy comprising more than 3 PVCs per minute, palpitations comprising fluttering of the chest, and supraventricular tachycardia comprising heart rates over 180 bpm; and

a notification module configured to notify an electrophysiologist upon a diagnostic finding comprising ventricular tachycardia comprising 3 or more consecutive abnormal ventricular beats, bradycardia comprising pauses greater than 3 seconds, and heart blockage comprising the non-conduction of any normal sinus beat.

9. A health monitoring apparatus according to claim 8, the referral module further comprising:

a notification module configured to generate a referral to one such care provider if the diagnostic findings comprises a medical condition not found in the patient's medical history; and

a notification module configured to engage proactive health care management if the diagnostic findings comprises a medical condition found in the patient's medical history.

10. A health monitoring apparatus according to claim 1, the database further comprising the pre-identified care providers ordered by medical specialty and paired with one or more of the diagnostic criteria.

\* \* \* \* \*

专利名称(译)	健康监测装置，用于借助数字计算机基于生理数据启动患者的治疗		
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[标]申请(专利权)人(译)	BARDY诊断		
申请(专利权)人(译)	BARDY诊断，INC.		
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IPC分类号	A61B5/00 A61B5/0404 A61B5/021 A61B5/0402 A61B5/1477 G16H40/67 A61B5/08 A61B5/01 A61B5/145 A61B5/0245 A61B5/0464 A61B5/0468 A61B5/046		
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优先权	15/785317 2018-04-10 US 15/362743 2017-10-17 US		
其他公开文献	US20190076023A1		
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摘要(译)

患有某些类型的医疗条件的个人，特别是偶尔会出现可测量症状的病症，在尝试获得医疗护理时会感到无助，因为至少在某种程度上，他们会受到病情的摆布而出现症状在合适的时间允许诊断和治疗。为这些人提供记录心电图和生理学的门诊延长服用健康监测器，最好是非处方药和没有健康保险预授权，这是满足他们需求的第一步。此外，一旦确定了医学上可行的医学病症，这些人就需要一种进入医疗保健系统的方法。在此，根据医学诊断标准下载并评估ECG和生理学。医学专家已预先确定并与关键诊断结果配对，以便监测数据表明医疗问题的个人将被自动转介和治疗。

