



US009936875B2

(12) **United States Patent**
Bardy et al.

(10) **Patent No.:** **US 9,936,875 B2**
(45) **Date of Patent:** ***Apr. 10, 2018**

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

(71) Applicant: **Bardy Diagnostics, Inc.**, Charlotte, NC (US)

(72) Inventors: **Gust H. Bardy**, Carnation, WA (US); **Jon Mikalson Bishay**, Lexington, KY (US)

(73) Assignee: **Bardy Diagnostics, Inc.**, Seattle, WA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.
This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/785,317**

(22) Filed: **Oct. 16, 2017**

(65) **Prior Publication Data**
US 2018/0049640 A1 Feb. 22, 2018

Related U.S. Application Data
(60) Continuation of application No. 15/362,743, filed on Nov. 28, 2016, now Pat. No. 9,788,722, which is a (Continued)

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/145 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC **A61B 5/0006** (2013.01); **A61B 5/0022** (2013.01); **A61B 5/01** (2013.01);
(Continued)

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

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,215,136 A 11/1965 Holter et al.
3,699,948 A 10/1972 Ota et al.
(Continued)

FOREIGN PATENT DOCUMENTS

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

OTHER PUBLICATIONS

15 of the Hottest Wearable Gadgets, URL <http://thehottestgadgets.com/2008/09/the-15-hottest-wearable-gadgets-001253>.

(Continued)

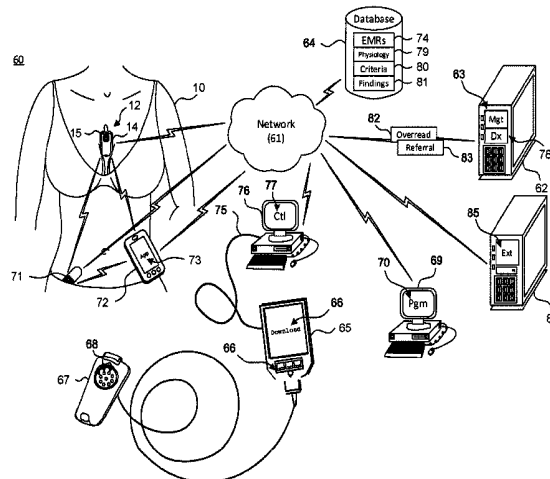
Primary Examiner — Neal Sereboff

(74) *Attorney, Agent, or Firm* — Patrick J. S. Inouye; Leonid Kisseley

(57) **ABSTRACT**

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

20 Claims, 5 Drawing Sheets



Related U.S. Application Data

division of application No. 14/875,622, filed on Oct. 5, 2015, now Pat. No. 9,504,423.

(51) Int. Cl.

A61B 5/01 (2006.01)
A61B 5/08 (2006.01)
A61B 5/0245 (2006.01)
A61B 5/0464 (2006.01)
A61B 5/0468 (2006.01)
A61B 5/046 (2006.01)
A61B 5/1477 (2006.01)
A61B 5/021 (2006.01)
A61B 5/0402 (2006.01)
A61B 5/0404 (2006.01)

(52) U.S. Cl.

CPC *A61B 5/021* (2013.01); *A61B 5/0245* (2013.01); *A61B 5/0402* (2013.01); *A61B 5/0404* (2013.01); *A61B 5/046* (2013.01); *A61B 5/0464* (2013.01); *A61B 5/0468* (2013.01); *A61B 5/0816* (2013.01); *A61B 5/1477* (2013.01); *A61B 5/14532* (2013.01); *A61B 5/14542* (2013.01); *A61B 5/7246* (2013.01); *A61B 5/7282* (2013.01); *A61B 5/746* (2013.01); *A61B 2560/0475* (2013.01); *A61B 2562/04* (2013.01)

(56)

References Cited

U.S. PATENT DOCUMENTS

3,893,453 A	7/1975	Goldberg	5,749,902 A	5/1998	Olsen et al.
4,123,785 A	10/1978	Cherry et al.	5,788,633 A	8/1998	Mahoney
4,328,814 A	5/1982	Arkans	5,817,151 A	10/1998	Olsen et al.
4,441,500 A	4/1984	Sessions et al.	5,819,741 A	10/1998	Karlsson et al.
4,532,934 A	8/1985	Kelen	5,850,920 A	12/1998	Gilman et al.
4,546,342 A	10/1985	Weaver et al.	D407,159 S	3/1999	Roberg
4,550,502 A	11/1985	Grayzel	5,876,351 A	3/1999	Rohde
4,580,572 A	4/1986	Granek et al.	5,906,583 A	5/1999	Rogel
4,716,903 A	1/1988	Hansen	5,951,598 A	9/1999	Bishay et al.
4,809,705 A	3/1989	Ascher	5,957,857 A	9/1999	Hartley
4,915,656 A	4/1990	Alferness	5,984,102 A	11/1999	Tay
5,025,794 A	6/1991	Albert et al.	6,032,064 A	2/2000	Devlin et al.
5,107,480 A	4/1992	Naus	6,038,469 A	3/2000	Karlsson et al.
5,168,876 A	12/1992	Quedens et al.	6,101,413 A	8/2000	Olsen et al.
5,215,098 A	6/1993	Steinhaus	6,115,638 A	9/2000	Groenke
D341,423 S	11/1993	Bible	6,117,077 A	9/2000	Del Mar et al.
5,265,579 A	11/1993	Ferrari	6,134,479 A	10/2000	Brewer et al.
5,333,615 A	8/1994	Craelius et al.	6,148,233 A	11/2000	Owen et al.
5,341,806 A	8/1994	Gadsby et al.	6,149,602 A	11/2000	Arcelus
5,355,891 A	10/1994	Wateridge et al.	6,149,781 A	11/2000	Forand
5,365,934 A	11/1994	Leon et al.	6,188,407 B1	2/2001	Smith et al.
5,392,784 A	2/1995	Gudaitis	D443,063 S	5/2001	Pisani et al.
D357,069 S	4/1995	Plahn et al.	6,245,025 B1	6/2001	Torok et al.
5,402,780 A	4/1995	Faasse, Jr.	6,246,330 B1	6/2001	Nielsen
5,402,884 A	4/1995	Gilman et al.	D445,507 S	7/2001	Pisani et al.
5,450,845 A	9/1995	Axelgaard	6,269,267 B1	7/2001	Bardy et al.
5,458,141 A	10/1995	Neil	6,272,385 B1	8/2001	Bishay et al.
5,473,537 A	12/1995	Glazer et al.	6,298,255 B1	10/2001	Cordero et al.
5,483,969 A	1/1996	Testerman et al.	6,301,502 B1	10/2001	Owen et al.
5,511,553 A	4/1996	Segalowitz	6,304,773 B1	10/2001	Taylor et al.
5,540,733 A	7/1996	Testerman et al.	6,304,780 B1	10/2001	Owen et al.
5,546,952 A	8/1996	Erickson	6,304,783 B1	10/2001	Lyster et al.
5,549,655 A	8/1996	Erickson	6,374,138 B1	4/2002	Owen et al.
5,579,919 A	12/1996	Gilman et al.	6,416,471 B1	7/2002	Kumar et al.
5,582,181 A	12/1996	Ruess	6,418,342 B1	7/2002	Owen et al.
D377,983 S	2/1997	Sabrie et al.	6,424,860 B1	7/2002	Karlsson et al.
5,601,089 A	2/1997	Bledsoe et al.	6,427,083 B1	7/2002	Owen et al.
5,623,935 A	4/1997	Faisandier	6,456,872 B1	9/2002	Faisandier
5,682,901 A	11/1997	Kamen	6,463,320 B1	10/2002	Xue et al.
5,697,955 A	12/1997	Stolte	6,546,285 B1	4/2003	Owen et al.
			6,605,046 B1	8/2003	Del Mar
			6,607,485 B2	8/2003	Bardy
			6,611,705 B2	8/2003	Hopman et al.
			6,671,545 B2	12/2003	Fincke
			6,671,547 B2	12/2003	Lyster et al.
			6,694,186 B2	2/2004	Bardy
			6,704,595 B2	3/2004	Bardy
			6,705,991 B2	3/2004	Bardy
			6,719,701 B2	4/2004	Lade
			6,754,523 B2	6/2004	Toole
			6,782,293 B2	8/2004	Dupelle et al.
			6,856,832 B1	2/2005	Matsumura
			6,860,897 B2	3/2005	Bardy
			6,866,629 B2	3/2005	Bardy
			6,887,201 B2	5/2005	Bardy
			6,893,397 B2	5/2005	Bardy
			6,904,312 B2	6/2005	Bardy
			6,908,431 B2	6/2005	Bardy
			6,913,577 B2	7/2005	Bardy
			6,944,498 B2	9/2005	Owen et al.
			6,960,167 B2	11/2005	Bardy
			6,970,731 B1	11/2005	Jayaraman et al.
			6,978,169 B1	12/2005	Guerra
			6,993,377 B2	1/2006	Flick et al.
			7,020,508 B2	3/2006	Stivoric et al.
			7,027,864 B2	4/2006	Snyder et al.
			7,065,401 B2	6/2006	Worden
			7,085,601 B1	8/2006	Bardy et al.
			7,104,955 B2	9/2006	Bardy
			7,134,996 B2	11/2006	Bardy
			7,137,389 B2	11/2006	Berthon-Jones
			7,147,600 B2	12/2006	Bardy
			7,215,991 B2	5/2007	Besson et al.
			7,248,916 B2	7/2007	Bardy
			7,257,438 B2	8/2007	Kinast
			7,277,752 B2	10/2007	Matos
			D558,882 S	1/2008	Brady
			7,328,061 B2	2/2008	Rowlandson et al.
			7,412,395 B2	8/2008	Rowlandson et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

7,429,938	B1	9/2008	Corndorf	2003/0211797	A1	11/2003	Hill et al.
7,552,031	B2	6/2009	Vock et al.	2004/0008123	A1	1/2004	Carrender
D606,656	S	12/2009	Kobayashi et al.	2004/0019288	A1	1/2004	Kinast
7,706,870	B2	4/2010	Shieh et al.	2004/0034284	A1	2/2004	Aversano et al.
7,756,721	B1	7/2010	Falchuk et al.	2004/0049132	A1	3/2004	Barron et al.
7,787,943	B2	8/2010	McDonough	2004/0073127	A1	4/2004	Istvan et al.
7,874,993	B2	1/2011	Bardy	2004/0087836	A1	5/2004	Green et al.
7,881,785	B2	2/2011	Nassif et al.	2004/0088019	A1	5/2004	Rueter et al.
D639,437	S	6/2011	Bishay et al.	2004/0093192	A1	5/2004	Hasson et al.
7,959,574	B2	6/2011	Bardy	2004/0148194	A1	7/2004	Wellons et al.
8,116,841	B2	2/2012	Bly et al.	2004/0207530	A1	10/2004	Nielsen
8,150,502	B2	4/2012	Kumar et al.	2004/0236202	A1	11/2004	Burton
8,160,682	B2	4/2012	Kumar et al.	2004/0243435	A1	12/2004	Williams
8,172,761	B1	5/2012	Rulkov et al.	2004/0256453	A1	12/2004	Lammle
8,180,425	B2	5/2012	Selvitelli et al.	2004/0260188	A1	12/2004	Syed et al.
8,200,320	B2	6/2012	Kovacs	2004/0260192	A1	12/2004	Yamamoto
8,231,539	B2	7/2012	Bardy	2005/0096717	A1	5/2005	Bishay et al.
8,231,540	B2	7/2012	Bardy	2005/0108055	A1	5/2005	Ott et al.
8,239,012	B2	8/2012	Felix et al.	2005/0154267	A1	7/2005	Bardy
8,249,686	B2	8/2012	Libbus et al.	2005/0182308	A1	8/2005	Bardy
8,260,414	B2	9/2012	Nassif et al.	2005/0182309	A1	8/2005	Bardy
8,266,008	B1	9/2012	Siegal et al.	2005/0215918	A1	9/2005	Frantz et al.
8,277,378	B2	10/2012	Bardy	2005/0222513	A1	10/2005	Hadley et al.
8,285,356	B2	10/2012	Bly et al.	2005/0228243	A1	10/2005	Bardy
8,285,370	B2	10/2012	Felix et al.	2005/0245839	A1	11/2005	Stivoric et al.
8,308,650	B2	11/2012	Bardy	2006/0025696	A1	2/2006	Kurzweil et al.
8,366,629	B2	2/2013	Bardy	2006/0025824	A1	2/2006	Freeman et al.
8,374,688	B2	2/2013	Libbus et al.	2006/0030767	A1	2/2006	Lang et al.
8,412,317	B2	4/2013	Mazar	2006/0041201	A1	2/2006	Behbehani et al.
8,460,189	B2	6/2013	Libbus et al.	2006/0122469	A1	6/2006	Martel
8,473,047	B2	6/2013	Chakravarthy et al.	2006/0124193	A1	6/2006	Orr et al.
8,478,418	B2	7/2013	Fahey	2006/0224072	A1*	10/2006	Shennib A61B 5/0408 600/509
8,554,311	B2	10/2013	Warner et al.	2006/0235320	A1	10/2006	Tan et al.
8,591,430	B2	11/2013	Amurthur et al.	2006/0253006	A1	11/2006	Bardy
8,594,763	B1	11/2013	Bibian et al.	2006/0264730	A1	11/2006	Stivoric et al.
8,600,486	B2	12/2013	Kaib et al.	2006/0264767	A1	11/2006	Shennib
8,613,708	B2	12/2013	Bishay et al.	2007/0003115	A1	1/2007	Patton et al.
8,613,709	B2	12/2013	Bishay et al.	2007/0038057	A1	2/2007	Nam et al.
8,620,418	B1	12/2013	Kuppuraj et al.	2007/0050209	A1	3/2007	Yered
8,626,277	B2	1/2014	Felix et al.	2007/0078324	A1	4/2007	Wijisiriwardana
8,668,653	B2	3/2014	Nagata et al.	2007/0093719	A1	4/2007	Nichols, Jr. et al.
8,684,925	B2	4/2014	Manicka et al.	2007/0100248	A1	5/2007	Van Dam et al.
8,688,190	B2	4/2014	Libbus et al.	2007/0100667	A1	5/2007	Bardy
8,718,752	B2	5/2014	Libbus et al.	2007/0123801	A1	5/2007	Goldberger et al.
8,744,561	B2	6/2014	Fahey	2007/0136091	A1	6/2007	McTaggart
8,774,932	B2	7/2014	Fahey	2007/0179357	A1	8/2007	Bardy
8,790,257	B2	7/2014	Libbus et al.	2007/0185390	A1	8/2007	Perkins et al.
8,790,259	B2	7/2014	Katra et al.	2007/0203415	A1	8/2007	Bardy
8,795,174	B2	8/2014	Manicka et al.	2007/0203423	A1	8/2007	Bardy
8,798,729	B2	8/2014	Kaib et al.	2007/0208232	A1	9/2007	Kovacs
8,798,734	B2	8/2014	Kuppuraj et al.	2007/0208233	A1	9/2007	Kovacs
8,818,478	B2	8/2014	Scheffler et al.	2007/0208266	A1	9/2007	Hadley
8,818,481	B2	8/2014	Bly et al.	2007/0225611	A1	9/2007	Kumar et al.
8,823,490	B2	9/2014	Libbus et al.	2007/0244405	A1	10/2007	Xue et al.
8,903,484	B2	12/2014	Mazar	2007/0265510	A1	11/2007	Bardy
8,938,287	B2	1/2015	Felix et al.	2007/0276270	A1	11/2007	Tran
8,965,492	B2	2/2015	Baker et al.	2007/0276275	A1	11/2007	Proctor et al.
9,066,664	B2	6/2015	Karjalainen	2007/0293738	A1	12/2007	Bardy
9,155,484	B2	10/2015	Baker et al.	2007/0293739	A1	12/2007	Bardy
9,204,813	B2	12/2015	Kaib et al.	2007/0293740	A1	12/2007	Bardy
9,277,864	B2	3/2016	Yang et al.	2007/0293741	A1	12/2007	Bardy
9,339,202	B2	5/2016	Brockway et al.	2007/0293772	A1	12/2007	Bardy
9,439,566	B2	9/2016	Arne et al.	2007/0299325	A1	12/2007	Farrell et al.
2002/0013538	A1	1/2002	Teller	2007/0299617	A1	12/2007	Willis
2002/0013717	A1	1/2002	Ando et al.	2008/0051668	A1	2/2008	Bardy
2002/0103422	A1	8/2002	Harder et al.	2008/0058661	A1	3/2008	Bardy
2002/0120310	A1	8/2002	Linden et al.	2008/0091097	A1	4/2008	Linti et al.
2002/0184055	A1	12/2002	Naghavi et al.	2008/0108890	A1	5/2008	Teng et al.
2002/0193668	A1	12/2002	Munneke	2008/0114232	A1	5/2008	Gazit
2003/0004547	A1	1/2003	Owen et al.	2008/0139953	A1	6/2008	Baker et al.
2003/0073916	A1	4/2003	Yonce	2008/0143080	A1	6/2008	Burr
2003/0083559	A1	5/2003	Thompson	2008/0177168	A1	7/2008	Callahan et al.
2003/0097078	A1	5/2003	Maeda	2008/0194927	A1	8/2008	KenKnight et al.
2003/0139785	A1	7/2003	Riff et al.	2008/0208009	A1	8/2008	Shklarski
2003/0176802	A1	9/2003	Galen et al.	2008/0208014	A1	8/2008	KenKnight et al.
				2008/0284599	A1	11/2008	Zdeblick et al.
				2008/0288026	A1	11/2008	Cross et al.
				2008/0306359	A1	12/2008	Zdeblick et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2008/0312522 A1 12/2008 Rowlandson
 2009/0054952 A1 2/2009 Glukhovskiy et al.
 2009/0062897 A1 3/2009 Axelgaard
 2009/0069867 A1 3/2009 KenKnight et al.
 2009/0073991 A1 3/2009 Landrum et al.
 2009/0076336 A1 3/2009 Mazar et al.
 2009/0076341 A1 3/2009 James et al.
 2009/0076342 A1 3/2009 Amurthur et al.
 2009/0076343 A1 3/2009 James et al.
 2009/0076346 A1 3/2009 James et al.
 2009/0076349 A1 3/2009 Libbus et al.
 2009/0076397 A1 3/2009 Libbus et al.
 2009/0076401 A1 3/2009 Mazar et al.
 2009/0076559 A1 3/2009 Libbus et al.
 2009/0088652 A1 4/2009 Tremblay
 2009/0112116 A1 4/2009 Lee et al.
 2009/0131759 A1 5/2009 Sims et al.
 2009/0156908 A1 6/2009 Belalcazar et al.
 2009/0216132 A1 8/2009 Orbach
 2009/0270708 A1 10/2009 Shen et al.
 2009/0270747 A1 10/2009 Van Dam et al.
 2009/0292194 A1 11/2009 Libbus et al.
 2010/0007413 A1 1/2010 Herleikson et al.
 2010/0022897 A1 1/2010 Parker et al.
 2010/0056881 A1 3/2010 Libbus et al.
 2010/0081913 A1 4/2010 Cross et al.
 2010/0185063 A1 7/2010 Bardy
 2010/0185076 A1 7/2010 Jeong et al.
 2010/0191154 A1 7/2010 Berger et al.
 2010/0191310 A1 7/2010 Bly
 2010/0234715 A1 9/2010 Shin et al.
 2010/0234716 A1 9/2010 Engel
 2010/0280366 A1 11/2010 Arne et al.
 2010/0324384 A1 12/2010 Moon et al.
 2011/0021937 A1 1/2011 Hugh et al.
 2011/0054286 A1 3/2011 Crosby et al.
 2011/0066041 A1 3/2011 Pandia et al.
 2011/0077497 A1 3/2011 Oster et al.
 2011/0144470 A1 6/2011 Mazar et al.
 2011/0160548 A1 6/2011 Forster
 2011/0224564 A1 9/2011 Moon et al.
 2011/0237924 A1 9/2011 McGusty et al.
 2011/0245699 A1 10/2011 Snell et al.
 2011/0245711 A1 10/2011 Katra et al.
 2012/0003933 A1 1/2012 Baker et al.
 2012/0029306 A1 2/2012 Paquet et al.
 2012/0029315 A1 2/2012 Raptis et al.
 2012/0029316 A1 2/2012 Raptis et al.
 2012/0035432 A1 2/2012 Katra et al.
 2012/0088998 A1 4/2012 Bardy et al.
 2012/0088999 A1 4/2012 Bishay et al.
 2012/0089000 A1 4/2012 Bishay et al.
 2012/0089001 A1 4/2012 Bishay et al.
 2012/0089037 A1 4/2012 Bishay et al.
 2012/0089412 A1 4/2012 Bardy et al.
 2012/0089417 A1 4/2012 Bardy et al.
 2012/0095352 A1 4/2012 Tran
 2012/0101358 A1 4/2012 Boettcher et al.
 2012/0101396 A1 4/2012 Solosko et al.
 2012/0165645 A1 6/2012 Russel et al.
 2012/0172695 A1 7/2012 Ko et al.
 2012/0302906 A1 11/2012 Felix et al.
 2012/0330126 A1 12/2012 Hoppe et al.
 2013/0041272 A1 2/2013 Javier et al.
 2013/0077263 A1 3/2013 Oleson et al.
 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.
 2013/0123651 A1 5/2013 Bardy
 2013/0158361 A1 6/2013 Bardy
 2013/0225963 A1 8/2013 Kodandaramaiah et al.
 2013/0225966 A1 8/2013 Macia Barber et al.
 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.
 2013/0325359 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.
 2014/0140359 A1 5/2014 Kalevo et al.
 2014/0189928 A1 7/2014 Oleson et al.
 2014/0206977 A1 7/2014 Bahney et al.
 2014/0215246 A1 7/2014 Lee et al.
 2014/0358193 A1 12/2014 Lyons et al.
 2015/0048836 A1 2/2015 Guthrie et al.
 2015/0065842 A1 3/2015 Lee et al.
 2015/0177175 A1 6/2015 Elder et al.
 2015/0257670 A1 9/2015 Ortega et al.
 2015/0305676 A1 11/2015 Shoshani
 2015/0359489 A1 12/2015 Baudenbacher et al.
 2016/0217691 A1 7/2016 Kadobayashi et al.

FOREIGN PATENT DOCUMENTS

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

OTHER PUBLICATIONS

Alivecor, URL <<http://www.businesswire.com/news/home/20121203005545/en/AliveCor%E2%80%99s-Heart-Monitor-Phone-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> (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; e1-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 Gravitz, "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,

(56)

References Cited

OTHER PUBLICATIONS

vol. 13, No. 3, Mar. 1, 2008 (Mar. 1, 2008), pp. 123-126, XP009155082, ISSN: 1462-4753.

McManus et al., "A Novel Application for the Detection of an Irregular Pulse using an iPhone 4S in Patients with Atrial Fibrillation," vol. 10(3), pp. 315-319 (Mar. 2013.).

Nike+ Fuel Band, URL <http://www.nike.com/us/en_us/c/nikeplus-fuelband> (Web page cached on Jan. 11, 2013.).

P. Libby et al., "Braunwald's Heart Disease—A Textbook of Cardiovascular Medicine," Chs. 11, pp. 125-148 and 12, pp. 149-193 (8th ed. 2008), American Heart Association.

Polar Loop, URL <<http://www.dcrainmaker.com/2013/09/polar-loop-firstlook.html>>.

Sittig et al., "A Computer-Based Outpatient Clinical Referral System," International Journal of Medical Informatics, Shannon, IR, vol. 55, No. 2, Aug. 1, 1999, pp. 149-158, XO004262434, ISSN: 1386-5056(99)00027-1.

Sleepview, URL <<http://www.cleveland.com/sleepview/overview.shtml>> (Web page cached on Sep. 4, 2013.).

Actigraphy/ Circadian Rhythm SOMNOwatch, URL <<http://www.somnomedics.eu/news-events/publications/somnowatchtm.html>> (Web page cached on Jan. 23, 2010).

Zio Event Card, URL <<http://www.irhythmtech.com/zio-solution/zio-event/>> (Web page cached on Mar. 11, 2013.).

Zio Patch System, URL <<http://www.irhythmtech.com/zio-solution/zio-system/index.html>> (Web page cached on Sep. 8, 2013.).

Saadi et al. "Heart Rhythm Analysis Using ECG Recorded With a Novel Sternum Based Patch Technology—A Pilot Study." Cardio technix 2013—Proceedings of the International Congress on Cardiovascular Technologies, Sep. 20, 2013.

Anonymous. Omegawave Launches Consumer App 2.0 in U.S. "Endurance Sportswire—Endurance Sportswire." Jul. 11, 2013. URL: <http://endurancesportswire.com/omegawave-launches-consumer-app-2-0-in-u-s/>.

Chan et al. "Wireless Patch Sensor for Remote Monitoring of Heart Rate, Respiration, Activity, and Falls." pp. 6115-6118. 2013 35th Annual International Conference of the IEEE Engineering in Medical and Biology Society. Jul. 1, 2013.

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," NORISIG, Jan. 1, 1999.

A Voss et al., "Linear and Nonlinear Methods for Analyses of Cardiovascular Variability in Bipolar Disorders." Bipolar Disorders, vol. 8, No. 5p1, Oct. 1, 2006, pp. 441-452, XP55273826, DK ISSN: 1398-5647, DOI: 10.1111/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].

<https://web.archive.org/web/20130831204020/http://www.biopac.com/research.asp?CatID=37&Main=Software> (Aug. 2013).

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

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

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).

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.

http://www.originlab.com/origin/Data_Exploration 2015. <http://www.gtec.at/Products/Software/g.BSanalyze-Specs-Features> (2014).

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/>.

* cited by examiner

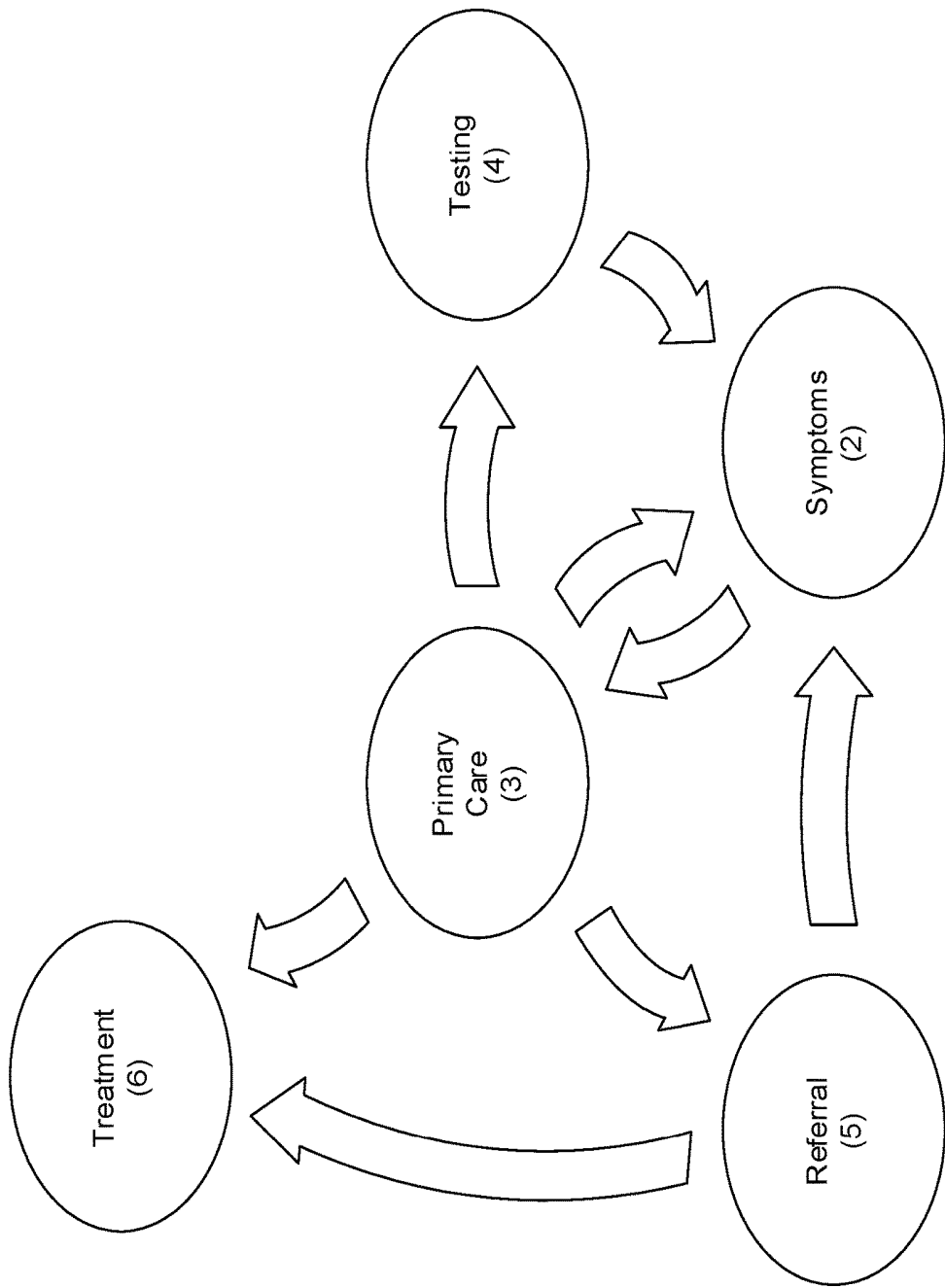


Fig. 1
(prior art).
1

Fig. 2.

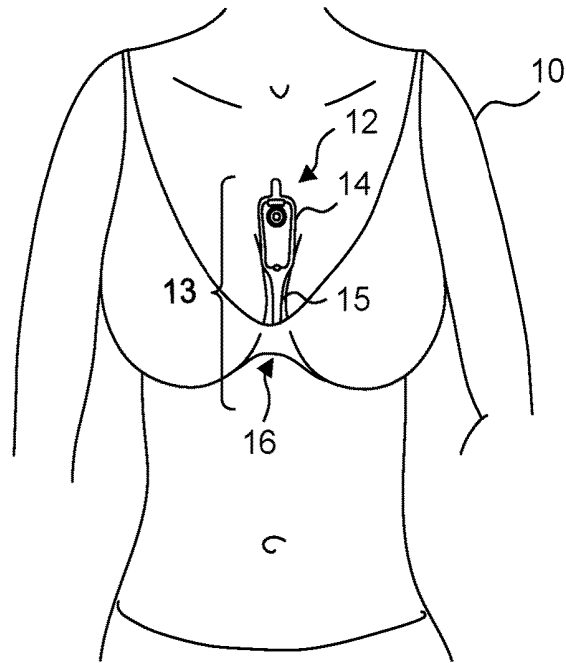


Fig. 3.

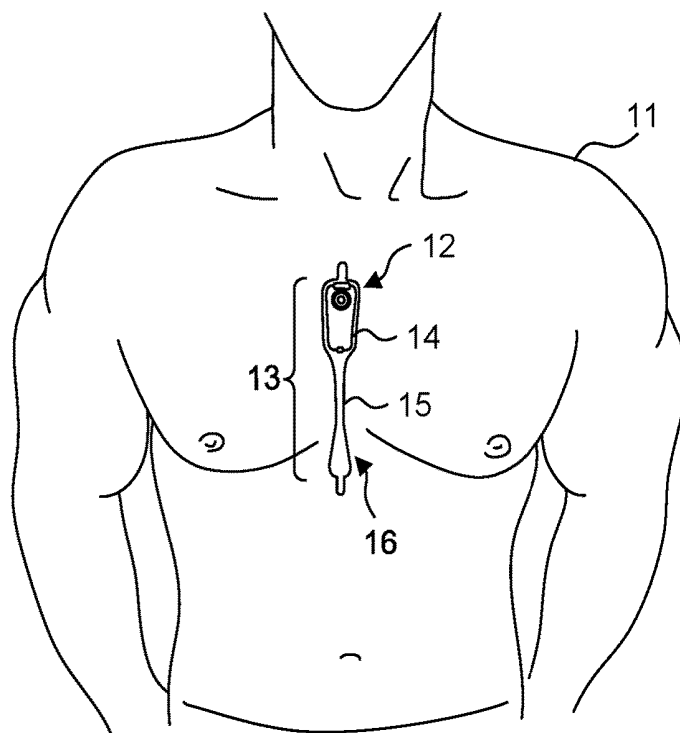


Fig. 4.

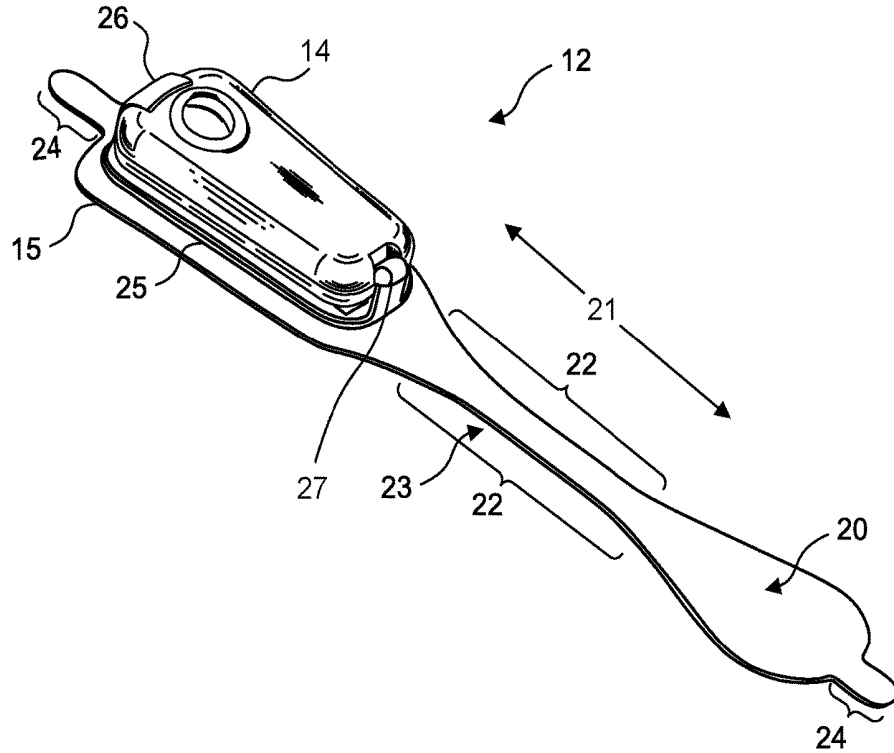
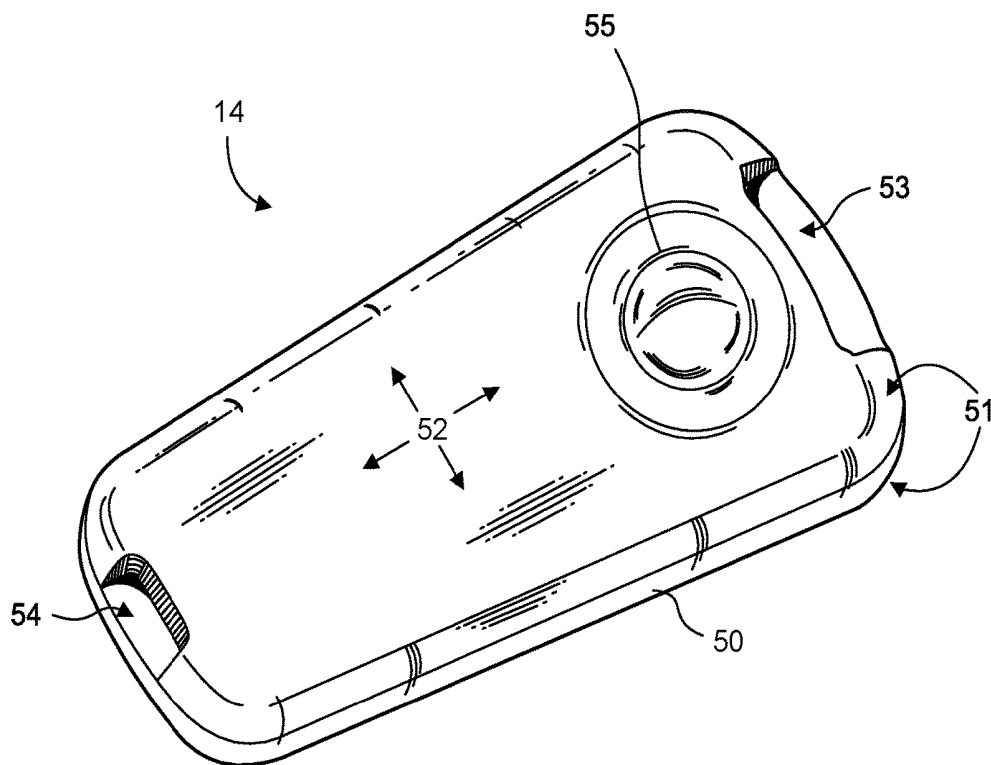


Fig. 5.



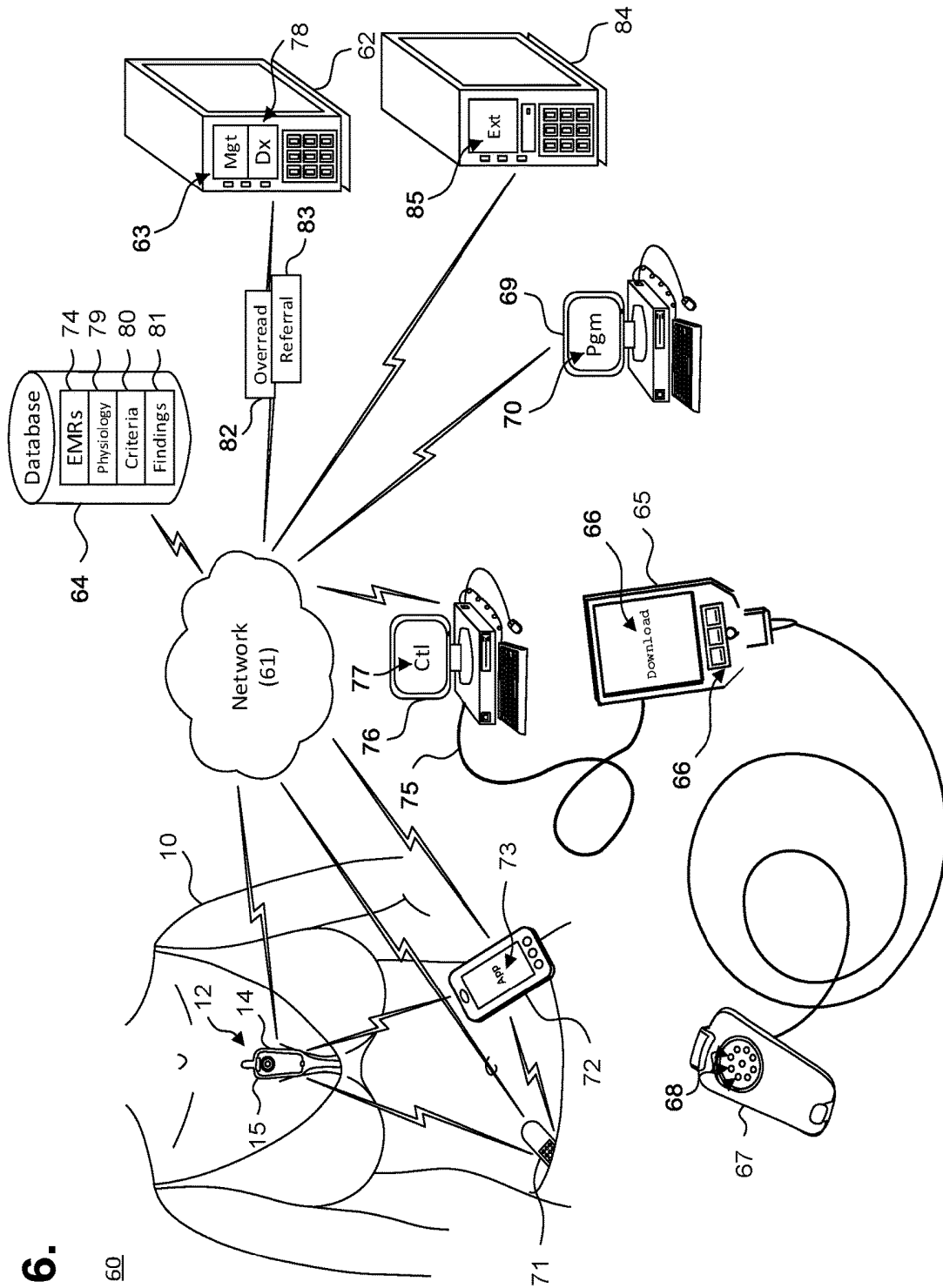


Fig. 6.

60

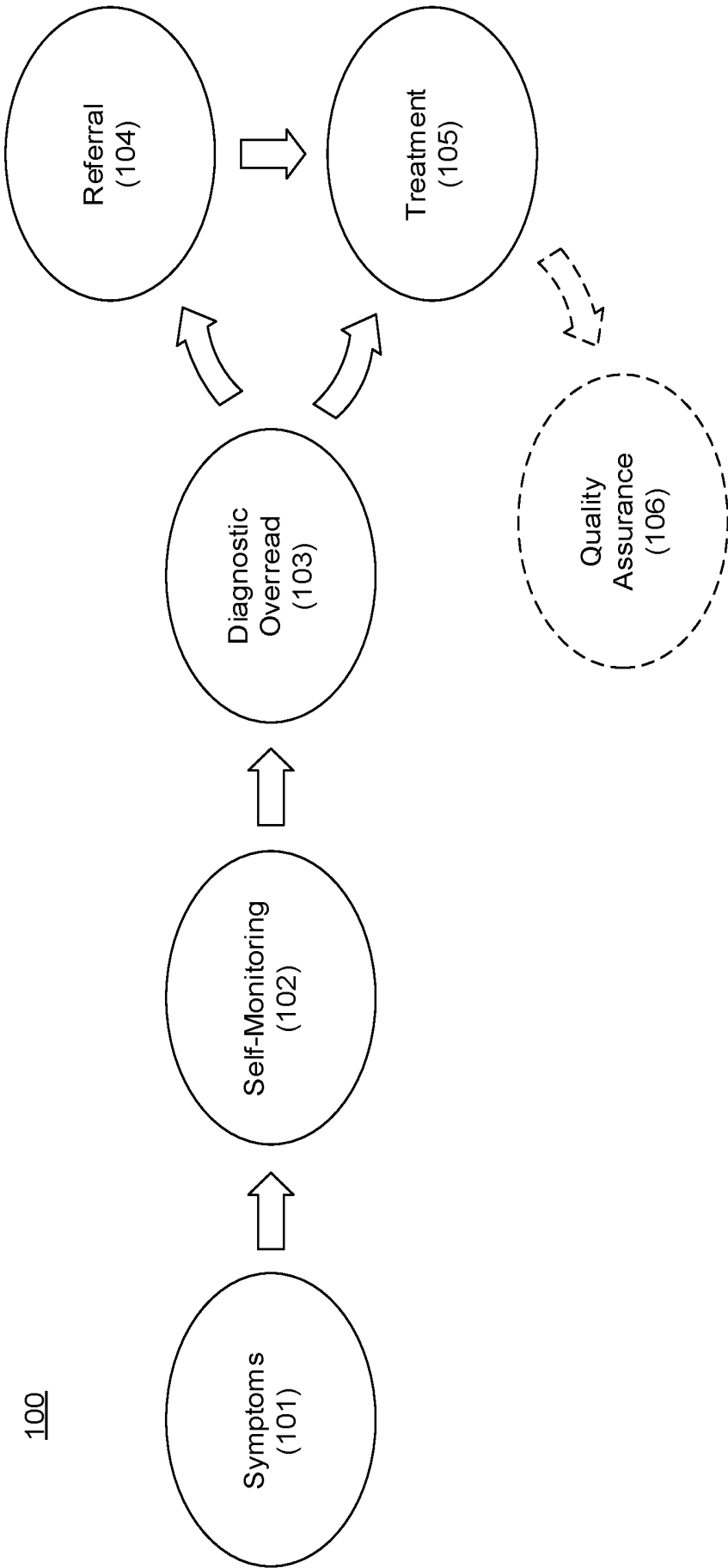


Fig. 7.

100

HEALTH MONITORING APPARATUS FOR INITIATING A TREATMENT OF A PATIENT 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. 15/362,743, filed Nov. 28, 2016, 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 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 information 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 preauthorization, 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 with the aid of a digital computer is provided. The apparatus includes a wearable health monitor, which includes a disposable extended wear electrode patch and a monitor recorder capable of recording physiology throughout the monitoring period into an onboard memory. The disposable extended wear electrode patch includes: a flexible backing; a plurality of electrocar-

diographic electrodes comprised on the flexible backing and provided to sense a patient's physiology over a monitoring period; a non-conductive receptacle affixed to a non-contacting surface of the flexible backing; and a pair of flexible circuit traces affixed at each end of the flexible backing with each circuit trace connecting one of the electrocardiographic electrodes to an electro-mechanical docking interface. The monitor recorder includes a sealed housing adapted to be removably secured into the non-conductive receptacle; and electronic circuitry comprised within the sealed housing and comprising the onboard memory and an external interface configured to be removably connected to the electrocardiographic electrodes via the docking interface. The health monitoring apparatus further includes a download station comprising an interface over which the physiology can be downloaded from the onboard memory of the wearable health monitor upon completion of the monitoring period. The health monitoring apparatus further includes a computer adapted to be interfaced to the download station, which includes: a database includes the physiology as retrieved from the download station and a medical diagnostic criteria; a processor and a memory configured to store code executable by the processor and including: a comparison module configured to compare the physiology to the medical diagnostic criteria and to generate a diagnostic overread that comprises one or more diagnostic findings; 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 over-read.

In a further embodiment, a health monitoring apparatus for patient referral with the aid of a digital computer is provided. The apparatus includes a wearable health monitor, which includes a disposable extended wear electrode patch and a monitor recorder capable of recording physiology throughout the monitoring period into an onboard memory. The disposable extended wear electrode patch includes: 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; a non-conductive receptacle affixed to a non-contacting surface of the flexible backing; and a pair of flexible circuit traces affixed at each end of the flexible backing with each circuit trace connecting one of the electrocardiographic electrodes to an electro-mechanical docking interface. The monitor recorder includes a sealed housing adapted to be removably secured into the non-conductive receptacle; and electronic circuitry comprised within the sealed housing and comprising the onboard memory and an external interface configured to be removably connected to the electrocardiographic electrodes via the docking interface. The health monitoring apparatus further includes a download station comprising an interface over which the physiology can be downloaded from the onboard memory of the wearable health monitor upon completion of the monitoring period. The health monitoring apparatus further includes a computer adapted to be interfaced to the download station, which includes: a database includes the physiology as retrieved from the download station and a medical diagnostic criteria; a processor and a memory configured to store code executable by the processor and including: a comparison module configured to compare the physiology to the medical diagnostic criteria and to generate a diagnostic overread that comprises one or more diagnostic findings; and a referral module configured to refer the patient to one or more pre-identified care providers for facilitated diagnosis based on the diagnostic 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 maldagnosis 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 torquing 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 reusably snaps into an electrically non-conductive receptacle **25** during use. The monitor recorder **14** contains electronic circuitry for recording and storing the patient's electrocardiography as sensed via a pair of ECG electrodes provided on the 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 com-

munications 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 collabora-

tively 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 program (“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 with the aid of a digital computer, comprising:
 - a wearable health monitor comprising:
 - a disposable extended wear electrode patch 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;
 - a non-conductive receptacle affixed to a non-contacting surface of the flexible backing; and
 - a pair of flexible circuit traces affixed at each end of the flexible backing with each circuit trace connecting one of the electrocardiographic electrodes to an electro-mechanical docking interface; and
 - a monitor recorder capable of recording the physiology throughout the monitoring period into an onboard memory, comprising:
 - a sealed housing adapted to be removably secured into the non-conductive receptacle; and
 - an electronic circuitry comprised within the sealed housing and comprising the onboard memory and an external interface configured to be removably connected to the electrocardiographic electrodes via the docking interface;
 - a download station comprising an interface over which the physiology can be downloaded from the onboard memory of the wearable health monitor upon completion of the monitoring period; and
 - a computer adapted to be interfaced to the download station, comprising:
 - a database, comprising:
 - the physiology as retrieved from the download station; and
 - a medical diagnostic criteria;
 - a processor and a memory configured to store code executable by the processor and comprising:
 - a comparison module configured to compare the physiology to the medical diagnostic criteria and to generate a diagnostic overread that comprises one or more diagnostic findings; 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 over-read.
2. A health monitoring apparatus according to claim 1, the monitor recorder further comprising:
 - a microcontroller operable to store the recorded physiology into the onboard memory.
3. A health monitoring apparatus according to claim 2, further comprising:
 - a wireless transceiver electrically interfaced with the microcontroller and operable to wirelessly interface with one or more external wireless-enabled devices.
4. A health monitoring apparatus according to claim 1, further comprising:
 - a mobile device configured to create a confirmation of the patient's receipt of the wearable health monitor and to transmit the confirmation.
5. A health monitoring apparatus according to claim 4, wherein the confirmation comprises a recording of the wearable health monitor on the patient's chest and one or more identifying marks of at least one of the patient and the wearable health monitor.

6. A health monitoring apparatus according to claim 4, wherein the confirmation is transmitted to at least one of a physician of the patient and the wearable health monitor.
7. A health monitoring apparatus according to claim 4, wherein the confirmation comprises a biometric identifier scanned from the patient.
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.
11. A health monitoring apparatus for patient referral with the aid of a digital computer, comprising:
 - a wearable health monitor comprising:
 - a disposable extended wear electrode patch 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;
 - a non-conductive receptacle affixed to a non-contacting surface of the flexible backing; and
 - a pair of flexible circuit traces affixed at each end of the flexible backing with each circuit trace connecting one of the electrocardiographic electrodes to an electro-mechanical docking interface; and
 - a monitor recorder capable of recording the physiology throughout the monitoring period into an onboard memory, comprising:
 - a sealed housing adapted to be removably secured into the non-conductive receptacle; and
 - an electronic circuitry comprised within the sealed housing and comprising the onboard memory and an external interface configured to be removably connected to the electrocardiographic electrodes via the docking interface;
 - a download station comprising an interface over which the physiology can be downloaded from the onboard

memory of the wearable health monitor upon completion of the monitoring period; and
 a computer adapted to be interfaced to the download station, comprising:
 a database, comprising:
 the physiology as retrieved from the download station; and
 a medical diagnostic criteria;
 a processor and a memory configured to store code executable by the processor and comprising:
 a comparison module configured to compare the physiology to the medical diagnostic criteria and to generate a diagnostic overread that comprises one or more diagnostic findings; and
 a referral module configured to refer the patient to one or more pre-identified care providers for facilitated diagnosis based on the diagnostic overread.

12. A health monitoring apparatus according to claim **11**, the monitor recorder further comprising:
 a microcontroller operable to store the recorded physiology into the onboard memory.

13. A health monitoring apparatus according to claim **12**, further comprising:
 a wireless transceiver electrically interfaced with the microcontroller and operable to wirelessly interface with one or more external wireless-enabled devices.

14. A health monitoring apparatus according to claim **11**, further comprising:
 a mobile device configured to create a confirmation of the patient's receipt of the wearable health monitor and to transmit the confirmation.

15. A health monitoring apparatus according to claim **14**, wherein the confirmation comprises a recording of the wearable health monitor on the patient's chest and one or more identifying marks of at least one of the patient and the wearable health monitor.

16. A health monitoring apparatus according to claim **14**, wherein the confirmation is transmitted to at least one of a physician of the patient and the wearable health monitor.

17. A health monitoring apparatus according to claim **14**, wherein the confirmation comprises a biometric identifier scanned from the patient.

18. A health monitoring apparatus according to claim **11**, 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.

19. A health monitoring apparatus according to claim **18**, 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.

20. A health monitoring apparatus according to claim **11**, 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)	用于借助数字计算机启动患者治疗的健康监测装置		
公开(公告)号	US9936875	公开(公告)日	2018-04-10
申请号	US15/785317	申请日	2017-10-16
[标]申请(专利权)人(译)	BARDY诊断		
申请(专利权)人(译)	BARDY诊断, INC.		
当前申请(专利权)人(译)	BARDY诊断, INC.		
[标]发明人	BARDY GUST H BISHAY JON MIKALSON		
发明人	BARDY, GUST H. BISHAY, JON MIKALSON		
IPC分类号	A61B5/00 A61B5/0245 A61B5/0464 A61B5/0468 A61B5/046 A61B5/1477 A61B5/021 A61B5/0402 A61B5/0404 A61B5/08 A61B5/145 A61B5/01		
CPC分类号	A61B5/0006 A61B5/01 A61B5/021 A61B5/0245 A61B5/0402 A61B5/0404 A61B5/046 A61B5/0464 A61B5/0468 A61B5/0816 A61B5/1477 A61B5/14532 A61B5/14542 A61B5/6823 A61B5/7246 A61B5 /7282 A61B5/0022 A61B2562/04 A61B5/746 A61B2560/0475 G16H40/67 G06F19/00		
优先权	14/875622 2016-11-29 US		
其他公开文献	US20180049640A1		
外部链接	Espacenet USPTO		

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，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。

