



US011217342B2

(12) **United States Patent**
O'Reilly et al.

(10) **Patent No.:** **US 11,217,342 B2**
(45) **Date of Patent:** **Jan. 4, 2022**

(54) **INGESTIBLE EVENT MARKER DATA FRAMEWORK**

(71) Applicant: **Otsuka Pharmaceutical, Co., Ltd.**, Tokyo (JP)

(72) Inventors: **David O'Reilly**, Palo Alto, CA (US); **Erika Karplus**, Silverthorne, CO (US); **Andrew Thompson**, Portola Valley, CA (US); **George Savage**, Portola Valley, CA (US); **Mark Zdeblick**, Portola Valley, CA (US); **Timothy Robertson**, Belmont, CA (US); **Lawrence Arne**, Redwood City, CA (US); **Yashar Behzadi**, Redwood City, CA (US); **Gregory Moon**, Orinda, CA (US); **Patrick Beaulieu**, San Jose, CA (US)

(73) Assignee: **OTSUKA PHARMACEUTICAL CO., LTD.**, Tokyo (JP)

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

(21) Appl. No.: **15/498,396**

(22) Filed: **Apr. 26, 2017**

(65) **Prior Publication Data**
US 2017/0290513 A1 Oct. 12, 2017

Related U.S. Application Data
(63) Continuation of application No. 12/522,249, filed as application No. PCT/US2009/049618 on Jul. 2, 2009, now abandoned.

(51) **Int. Cl.**
A61B 5/07 (2006.01)
G16H 20/30 (2018.01)
(Continued)

(52) **U.S. Cl.**
CPC **G16H 20/30** (2018.01); **A61B 5/0022** (2013.01); **A61B 5/07** (2013.01); **G16H 20/10** (2018.01);
(Continued)

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

(56) **References Cited**
U.S. PATENT DOCUMENTS

3,218,638 A 11/1965 Honig
3,345,989 A 10/1967 Reynolds
(Continued)

FOREIGN PATENT DOCUMENTS

CA 2953847 11/2006
CN 1588649 3/2005
(Continued)

OTHER PUBLICATIONS

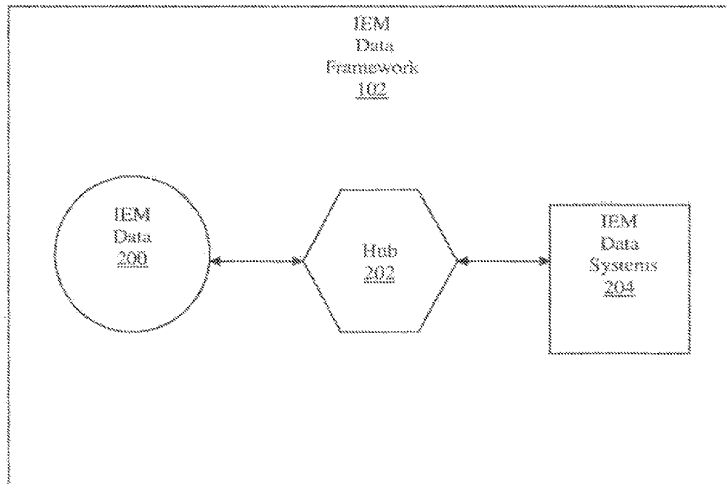
Van der Biest, O., et al., "Electrophoretic deposition of materials," *Annu. Rev. Mater. Sci.* 1999, 29: pp. 327-352.

(Continued)

Primary Examiner — Michael R Bloch
(74) *Attorney, Agent, or Firm* — Pillsbury Winthrop Shaw Pittman LLP

(57) **ABSTRACT**
The ingestible event marker data framework provides a uniform, comprehensive framework to enable various functions and utilities related to ingestible event marker data (IEM data). The functions and utilities include data and/or information having an aspect of data derived from, collected by, aggregated by, or otherwise associated with, an ingestion event.

10 Claims, 32 Drawing Sheets



Related U.S. Application Data

		4,767,627 A	8/1988	Caldwell et al.
		4,784,162 A	11/1988	Ricks
		4,793,825 A	12/1988	Benjamin et al.
(60)	Provisional application No. 61/079,082, filed on Jul. 8, 2008.	4,809,705 A	3/1989	Ascher
		4,835,373 A	5/1989	Adams et al.
		4,844,076 A	7/1989	Lesho
(51)	Int. Cl.	4,871,974 A	10/1989	Davis et al.
	<i>G16H 20/10</i> (2018.01)	4,876,093 A	10/1989	Theeuwes et al.
	<i>G16H 20/60</i> (2018.01)	4,896,261 A	1/1990	Nolan
	<i>A61B 5/00</i> (2006.01)	4,975,230 A	12/1990	Pinkhasov
	<i>A61B 5/021</i> (2006.01)	4,987,897 A	1/1991	Funke
	<i>G16H 40/67</i> (2018.01)	5,000,957 A	3/1991	Eckenhoff et al.
(52)	U.S. Cl.	5,016,634 A	5/1991	Vock et al.
	CPC <i>G16H 20/60</i> (2018.01); <i>A61B 5/021</i> (2013.01); <i>G16H 40/67</i> (2018.01)	5,079,006 A	1/1992	Urguhart
		5,167,626 A	12/1992	Casper
		5,176,626 A	1/1993	Soehendra
		5,179,578 A	1/1993	Ishizu
		5,245,332 A	9/1993	Katzenstein et al.
		5,261,402 A	11/1993	DiSabito
		5,263,481 A	11/1993	Axelgaard et al.
		5,276,710 A	1/1994	Iwasaki
		5,279,607 A	1/1994	Schentag et al.
		5,281,287 A	1/1994	Lloyd
		5,283,136 A	2/1994	Peled et al.
		5,288,564 A	2/1994	Klein
		5,305,745 A	4/1994	Zacouto
		5,318,557 A	6/1994	Gross
		5,394,882 A	3/1995	Mawhinney
		5,395,366 A	3/1995	D'Andrea et al.
		5,411,535 A	5/1995	Fujii et al.
		5,412,372 A	5/1995	Parkhurst et al.
		5,428,961 A	7/1995	Sakakibara
		5,436,091 A	7/1995	Shackle et al.
		5,443,461 A	8/1995	Atkinson et al.
		5,443,843 A	8/1995	Curatolo et al.
		5,458,141 A	10/1995	Neil et al.
		5,468,222 A	11/1995	Altchuler
		5,485,841 A	1/1996	Watkin et al.
		5,511,548 A	4/1996	Riazzi et al.
		5,538,007 A	7/1996	Gorman
		5,551,953 A	9/1996	Lattin et al.
		5,567,210 A	10/1996	Bates et al.
		5,596,302 A	1/1997	Mastrocola et al.
		D377,983 S	2/1997	Sabri et al.
		5,600,548 A	2/1997	Nguyen et al.
		5,634,466 A	6/1997	Gruner
		5,634,468 A	6/1997	Platt
		5,638,406 A	6/1997	Sogabe
		5,645,063 A	7/1997	Straka et al.
		5,705,189 A	1/1998	Lehmann et al.
		5,720,771 A	2/1998	Snell
		5,738,708 A	4/1998	Peachey et al.
		5,740,811 A	4/1998	Hedberg
		5,757,326 A	5/1998	Koyama et al.
		5,792,048 A	8/1998	Schaefer
		5,802,467 A	9/1998	Salazar
		5,833,716 A	11/1998	Bar-Or
		5,836,474 A	11/1998	Wessberg
		5,845,265 A	12/1998	Woolston
		5,862,803 A	1/1999	Besson
		5,862,808 A	1/1999	Albarelo
		5,868,136 A	2/1999	Fox
		5,914,701 A	6/1999	Gershened et al.
		5,917,346 A	6/1999	Gord
		5,921,925 A	7/1999	Cartmell et al.
		5,925,030 A	7/1999	Gross et al.
		5,925,066 A	7/1999	Kroll et al.
		5,946,550 A	8/1999	Papadimitrakopoulos
		5,957,854 A	9/1999	Besson et al.
		5,963,132 A	10/1999	Yoakum et al.
		5,965,629 A	10/1999	Jung et al.
		5,974,124 A	10/1999	Schlueter, Jr. et al.
		5,981,166 A	11/1999	Mandecki
		5,999,846 A	12/1999	Pardey et al.
		6,009,350 A	12/1999	Renken
		6,023,631 A	2/2000	Cartmell et al.
		6,038,464 A	3/2000	Axelgaard et al.
		6,042,710 A	3/2000	Dubrow
		6,047,203 A	4/2000	Sackner

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,353,539 A	11/1967	Preston
3,409,721 A	11/1968	Applezweig
3,419,736 A	12/1968	Walsh
3,589,943 A	6/1971	Grubb et al.
3,607,788 A	9/1971	Adolph
3,628,669 A	12/1971	McKinnis et al.
3,642,008 A	2/1972	Bolduc
3,679,480 A	7/1972	Brown et al.
3,682,160 A	8/1972	Murata
3,719,183 A	3/1973	Schwartz
3,727,616 A	4/1973	Lenzkes
3,799,802 A	3/1974	Schneble, Jr. et al.
3,825,016 A	7/1974	Laie et al.
3,828,766 A	8/1974	Krasnow
3,837,339 A	9/1974	Aisenberg et al.
3,893,111 A	7/1975	Cotter
3,944,064 A	3/1976	Bashaw et al.
3,967,202 A	6/1976	Batz
3,989,050 A	11/1976	Buchalter
4,017,856 A	4/1977	Wiegand
4,055,178 A	10/1977	Harrigan
4,062,750 A	12/1977	Butler
4,077,397 A	3/1978	Ellis
4,077,398 A	3/1978	Ellis
4,082,087 A	4/1978	Howson
4,090,752 A	5/1978	Long
4,105,023 A	8/1978	Merchese et al.
4,106,348 A	8/1978	Auphan
4,129,125 A	12/1978	Lester
4,133,730 A	1/1979	DuBois et al.
4,141,349 A	2/1979	Ory et al.
4,166,453 A	9/1979	McClelland
4,239,046 A	12/1980	Ong
4,251,795 A	2/1981	Shibasaki et al.
4,269,189 A	5/1981	Abraham
4,281,664 A	8/1981	Duggan
4,331,654 A	5/1982	Morris
4,345,588 A	8/1982	Widder et al.
4,418,697 A	12/1983	Tama
4,425,117 A	1/1984	Hugemann
4,439,196 A	3/1984	Higuchi
4,494,950 A	1/1985	Fischell
4,526,474 A	7/1985	Simon
4,547,391 A	10/1985	Jenkins
4,559,950 A	12/1985	Vaughan
4,564,363 A	1/1986	Bagnall et al.
4,578,061 A	3/1986	Lemelson
4,618,533 A	10/1986	Steuck
4,635,641 A	1/1987	Hoffman
4,654,165 A	3/1987	Eisenber
4,663,250 A	5/1987	Ong et al.
4,669,479 A	6/1987	Dunseath
4,681,111 A	7/1987	Silvian
4,687,660 A	8/1987	Baker et al.
4,725,997 A	2/1988	Urquhart et al.
4,749,575 A	6/1988	Rotman et al.
4,763,659 A	8/1988	Dunseath

(56)

References Cited

U.S. PATENT DOCUMENTS

6,076,016 A	6/2000	Feierbach et al.	6,680,923 B1	1/2004	Leon
6,081,734 A	6/2000	Batz	6,683,493 B1	1/2004	Fujimora et al.
6,083,248 A	7/2000	Thompson	6,689,117 B2	2/2004	Sweeney et al.
6,090,489 A	7/2000	Hayakawa et al.	6,694,161 B2	2/2004	Mehrotra
6,091,975 A	7/2000	Daddona et al.	6,704,602 B2	3/2004	Berg et al.
6,095,985 A	8/2000	Raymond et al.	6,720,923 B1	4/2004	Hayward et al.
6,099,482 A	8/2000	Brune et al.	6,738,671 B2	5/2004	Christophersom et al.
6,115,636 A	9/2000	Ryan	6,740,033 B1	5/2004	Olejniczak et al.
6,117,077 A	9/2000	Del Mar et al.	6,745,082 B2	6/2004	Axelgaard et al.
6,122,351 A	9/2000	Schlueter, Jr. et al.	6,755,783 B2	6/2004	Cosentino
6,141,592 A	10/2000	Pauly	6,757,523 B2	6/2004	Fry
6,149,940 A	11/2000	Maggi et al.	6,759,968 B2	7/2004	Zierolf
6,200,265 B1	3/2001	Walsh et al.	6,771,174 B2	8/2004	Broas
6,204,764 B1	3/2001	Maloney	6,773,429 B2	8/2004	Sheppard et al.
6,206,702 B1	3/2001	Hayden et al.	6,800,060 B2	10/2004	Marshall
6,217,744 B1	4/2001	Crosby	6,801,137 B2	10/2004	Eggers et al.
6,231,593 B1	5/2001	Meserol	6,804,558 B2	10/2004	Haller et al.
6,245,057 B1	6/2001	Sieben et al.	6,814,706 B2	11/2004	Barton et al.
6,269,058 B1	7/2001	Yamanoi et al.	6,822,554 B2	11/2004	Vrijens et al.
6,275,476 B1	8/2001	Wood	6,836,862 B1	12/2004	Erekson et al.
6,285,897 B1	9/2001	Kilcoyne et al.	6,839,659 B2	1/2005	Tarassenko et al.
6,287,252 B1	9/2001	Lugo	6,840,904 B2	1/2005	Goldberg
6,288,629 B1	9/2001	Cofino et al.	6,842,636 B2	1/2005	Perrault
6,289,238 B1	9/2001	Besson et al.	6,845,272 B1	1/2005	Thomsen
6,315,719 B1	11/2001	Rode et al.	6,864,780 B2	3/2005	Doi
6,342,774 B1	1/2002	Kreisinger et al.	6,879,810 B2	4/2005	Bouet
6,344,824 B1	2/2002	Takasugi et al.	6,882,881 B1	4/2005	Lesser et al.
6,358,202 B1	3/2002	Arent	6,897,788 B2	5/2005	Khair et al.
6,364,834 B1	4/2002	Reuss	6,909,878 B2	6/2005	Haller
6,366,206 B1	4/2002	Ishikawa et al.	6,922,592 B2	7/2005	Thompson et al.
6,368,190 B1	4/2002	Easter et al.	6,928,370 B2	8/2005	Anuzis et al.
6,371,927 B1	4/2002	Brune	6,929,636 B1	8/2005	Von Alten
6,374,670 B1	4/2002	Spelman	6,937,150 B2	8/2005	Medema
6,380,858 B1	4/2002	Yarin et al.	6,939,292 B2	9/2005	Mizuno
6,390,088 B1	5/2002	Noehl et al.	6,942,616 B2	9/2005	Kerr
6,394,953 B1	5/2002	Devlin et al.	6,946,156 B2	9/2005	Bunick
6,394,997 B1	5/2002	Lemelson	6,951,536 B2	10/2005	Yokoi
6,409,674 B1	6/2002	Brockway et al.	6,957,107 B2	10/2005	Rogers et al.
6,411,567 B1	6/2002	Niemiec et al.	6,959,929 B2	11/2005	Pugnet et al.
6,426,863 B1	7/2002	Munshi	6,968,153 B1	11/2005	Heinonen
6,432,292 B1	8/2002	Pinto et al.	6,987,965 B2	1/2006	Ng et al.
6,440,069 B1	8/2002	Raymond et al.	6,990,082 B1	1/2006	Zehavi et al.
6,441,747 B1	8/2002	Khair	7,002,476 B2	2/2006	Rapchak
6,453,199 B1	9/2002	Kobozev	7,004,395 B2	2/2006	Koenck
6,477,424 B1	11/2002	Thompson et al.	7,009,634 B2	3/2006	Iddan et al.
6,482,156 B2	11/2002	Lliff	7,009,946 B1	3/2006	Kardach
6,494,829 B1	12/2002	New et al.	7,013,162 B2	3/2006	Gorsuch
6,496,705 B1	12/2002	Ng et al.	7,016,648 B2	3/2006	Haller
6,505,077 B1	1/2003	Kast et al.	7,020,508 B2	3/2006	Stivoric
6,525,996 B1	2/2003	Miyazawa	7,023,940 B2	4/2006	Nakamura et al.
6,526,315 B1	2/2003	Inagawa	7,024,248 B2	4/2006	Penner et al.
6,531,026 B1	3/2003	Takeichi et al.	7,031,745 B2	4/2006	Shen
6,540,699 B1	4/2003	Smith	7,031,857 B2	4/2006	Tarassenko et al.
6,544,174 B2	4/2003	West	7,039,453 B2	5/2006	Mullick
6,564,079 B1	5/2003	Cory	7,044,911 B2	5/2006	Drinan et al.
6,572,636 B1	6/2003	Hagen et al.	7,046,649 B2	5/2006	Awater et al.
6,574,425 B1	6/2003	Weiss et al.	7,050,419 B2	5/2006	Azenkot et al.
6,577,893 B1	6/2003	Besson et al.	7,062,308 B1	6/2006	Jackson
6,579,231 B1	6/2003	Phipps	7,069,062 B2	6/2006	Minotani et al.
6,595,929 B2	7/2003	Stivoric	7,076,437 B1	7/2006	Levy
6,599,284 B2	7/2003	Faour et al.	7,081,693 B2	7/2006	Hamel et al.
6,605,038 B1	8/2003	Teller	7,091,726 B2	8/2006	Sano et al.
6,605,046 B1	8/2003	Del Mar	7,118,531 B2 *	10/2006	Krill A61B 1/041 600/309
6,609,018 B2	8/2003	Cory	7,125,382 B2	10/2006	Zhou et al.
6,612,984 B1	9/2003	Kerr	7,127,300 B2	10/2006	Mazar et al.
6,632,175 B1	10/2003	Marshall	7,146,228 B2	12/2006	Nielsen
6,632,216 B2	10/2003	Houzege et al.	7,146,449 B2	12/2006	Do et al.
6,635,279 B2	10/2003	Kolter et al.	7,149,581 B2	12/2006	Goedeke
6,638,231 B2	10/2003	Govari et al.	7,154,071 B2	12/2006	Sattler et al.
6,643,541 B2	11/2003	Mok et al.	7,155,232 B2	12/2006	Godfrey et al.
6,650,718 B1	11/2003	Fujimura et al.	7,160,258 B2	1/2007	Imran
6,654,638 B1	11/2003	Sweeney	7,161,484 B2	1/2007	Tsoukalis
6,663,846 B1	12/2003	McCombs	7,162,307 B2	1/2007	Patrias
6,673,474 B2	1/2004	Yamamoto	7,164,942 B2	1/2007	Avrahami
6,679,830 B2	1/2004	Kolarovic et al.	7,171,166 B2	1/2007	Ng et al.
			7,171,177 B2	1/2007	Park et al.
			7,171,259 B2	1/2007	Rytky
			7,176,784 B2	2/2007	Gilbert et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

7,187,960 B2	3/2007	Abreu	7,519,416 B2	4/2009	Sula et al.
7,188,767 B2	3/2007	Penuela	7,523,756 B2	4/2009	Minai
7,194,038 B1	3/2007	Inkinen	7,525,426 B2	4/2009	Edelstein
7,206,630 B1	4/2007	Tarler	7,539,533 B2	5/2009	Tran
7,209,790 B2	4/2007	Thompson et al.	7,542,878 B2	6/2009	Nanikashvili
7,215,660 B2	5/2007	Perlman	7,547,278 B2	6/2009	Miyazaki et al.
7,215,991 B2	5/2007	Besson	7,551,590 B2	6/2009	Haller
7,218,967 B2	5/2007	Bergelson	7,554,452 B2	6/2009	Cole
7,231,451 B2	6/2007	Law	7,558,620 B2	7/2009	Ishibashi
7,243,118 B2	7/2007	Lou	7,558,622 B2	7/2009	Tran
7,246,521 B2	7/2007	Kim	7,558,965 B2	7/2009	Wheeler et al.
7,249,212 B2	7/2007	Do	7,575,005 B2	8/2009	Mumford
7,252,792 B2	8/2007	Perrault	7,614,743 B2	11/2009	Geiger
7,253,716 B2	8/2007	Lovoi et al.	7,616,111 B2	11/2009	Covannon
7,261,690 B2	8/2007	Teller	7,616,710 B2	11/2009	Kim et al.
7,270,633 B1	9/2007	Goscha	7,617,001 B2	11/2009	Penner et al.
7,273,454 B2	9/2007	Raymond et al.	7,639,473 B2	12/2009	Hsu et al.
7,285,090 B2	10/2007	Stivoric et al.	7,640,802 B2	1/2010	King et al.
7,289,855 B2	10/2007	Nghiem	7,647,112 B2	1/2010	Tracey
7,291,014 B2	11/2007	Chung et al.	7,647,185 B2	1/2010	Tarassenko et al.
7,291,497 B2	11/2007	Holmes	7,653,031 B2	1/2010	Godfrey et al.
7,292,139 B2	11/2007	Mazar et al.	7,668,437 B1	2/2010	Yamada et al.
7,294,105 B1	11/2007	Islam	7,683,761 B2	2/2010	Burghard et al.
7,295,877 B2	11/2007	Govari	7,672,703 B2	3/2010	Yeo et al.
7,311,665 B2	12/2007	Hawthorne	7,672,714 B2	3/2010	Kuo
7,313,163 B2	12/2007	Liu	7,673,679 B2	3/2010	Harrison et al.
7,317,378 B2	1/2008	Jarvis et al.	7,678,043 B2	3/2010	Gilad
7,318,808 B2	1/2008	Tarassenko et al.	7,689,437 B1	3/2010	Teller et al.
7,336,732 B1	2/2008	Wiss	7,689,833 B2	3/2010	Lange
7,336,929 B2	2/2008	Yasuda	7,697,994 B2	4/2010	VanDanacker et al.
7,342,895 B2	3/2008	Serpa	7,712,288 B2	5/2010	Ramasubramanian et al.
7,346,380 B2	3/2008	Axelgaard et al.	7,720,036 B2	5/2010	Sadri
7,349,722 B2	3/2008	Witkowski et al.	7,729,776 B2	6/2010	Von Arx et al.
7,352,998 B2	4/2008	Palin	7,733,224 B2	6/2010	Tran
7,353,258 B2	4/2008	Washburn	7,736,318 B2	6/2010	Costentino
7,357,891 B2	4/2008	Yang et al.	7,747,454 B2	6/2010	Bartfeld et al.
7,359,674 B2	4/2008	Markki	7,756,587 B2	7/2010	Penner et al.
7,366,558 B2	4/2008	Virtanen et al.	7,764,996 B2	7/2010	Zhang et al.
7,366,675 B1	4/2008	Walker et al.	7,779,614 B1	8/2010	McGonagle et al.
7,368,190 B2	5/2008	Heller et al.	7,796,043 B2	9/2010	Euliano et al.
7,368,191 B2	5/2008	Andelman et al.	7,797,033 B2	9/2010	D'Andrea et al.
7,373,196 B2	5/2008	Ryu et al.	7,806,852 B1	10/2010	Jursen
7,375,739 B2	5/2008	Robbins	7,809,399 B2	10/2010	Lu
7,376,435 B2	5/2008	McGowan	7,811,231 B2	10/2010	Jin et al.
7,382,247 B2	6/2008	Welch et al.	7,844,341 B2	11/2010	Von Arx et al.
7,382,263 B2	6/2008	Danowski et al.	7,857,766 B2	12/2010	Lasater et al.
7,387,607 B2	6/2008	Holt	7,860,731 B2	12/2010	Jackson et al.
7,388,903 B2	6/2008	Godfrey et al.	7,871,734 B2	1/2011	Hertz et al.
7,389,088 B2	6/2008	Kim	7,899,526 B2	3/2011	Benditt et al.
7,392,015 B1	6/2008	Farlow	7,904,133 B2	3/2011	Gehman et al.
7,395,106 B2	7/2008	Ryu et al.	D639,437 S	6/2011	Bishay et al.
7,396,330 B2	7/2008	Banet	7,978,064 B2	7/2011	Zdeblick et al.
7,404,968 B2	7/2008	Abrams et al.	8,025,149 B2	9/2011	Sterry et al.
7,413,544 B2	8/2008	Kerr	8,036,731 B2	10/2011	Kimchy et al.
7,414,534 B1	8/2008	Kroll et al.	8,036,748 B2	10/2011	Zdeblick et al.
7,414,543 B2	8/2008	Rye et al.	8,055,334 B2	11/2011	Savage et al.
7,415,242 B1	8/2008	Ngan	8,060,249 B2	11/2011	Bear et al.
7,419,468 B2	9/2008	Shimizu et al.	8,073,707 B2	12/2011	Teller et al.
7,424,268 B2	9/2008	Diener	8,083,128 B2	12/2011	Dembo et al.
7,424,319 B2	9/2008	Muehlsteff	8,108,083 B2	1/2012	Kameyama
7,427,266 B2	9/2008	Ayer et al.	8,123,576 B2	2/2012	Kim
7,433,731 B2	10/2008	Matsumura et al.	8,135,596 B2	3/2012	Jung et al.
7,449,262 B2	11/2008	Christie et al.	8,142,513 B2	3/2012	Shalon et al.
7,462,150 B1	12/2008	Bharmi	8,177,611 B2	5/2012	Kang
7,471,665 B2	12/2008	Perlman	8,180,425 B2	5/2012	Selvitelli et al.
7,485,093 B2	2/2009	Glukhovskiy	8,185,191 B1	5/2012	Shapiro et al.
7,485,095 B2	2/2009	Shusterman	8,185,646 B2	5/2012	Headley
7,499,674 B2	3/2009	Salokannel	8,200,320 B2	6/2012	Kovacs
7,502,643 B2	3/2009	Farrington et al.	8,209,018 B2	6/2012	Osorio et al.
7,505,795 B1	3/2009	Lim et al.	8,214,007 B2	7/2012	Baker et al.
7,508,248 B2	3/2009	Yoshida	8,224,667 B1	7/2012	Miller et al.
7,510,121 B2	3/2009	Koenck	8,238,998 B2	8/2012	Park
7,512,448 B2	3/2009	Malick	8,249,686 B2	8/2012	Libbus et al.
7,512,860 B2	3/2009	Miyazaki et al.	8,253,586 B1	8/2012	Matak
7,515,043 B2	4/2009	Welch	8,254,853 B2	8/2012	Rofougaran
			8,258,962 B2	9/2012	Robertson et al.
			8,262,394 B2	9/2012	Walker et al.
			8,271,106 B2	9/2012	Wehba et al.
			8,285,356 B2	10/2012	Bly et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

8,290,574 B2	10/2012	Felid et al.	2001/0006368 A1	7/2001	Maloney	
8,301,232 B2	10/2012	Albert et al.	2001/0027331 A1	10/2001	Thompson	
8,308,640 B2	11/2012	Baldus et al.	2001/0031071 A1	10/2001	Nichols et al.	
8,314,619 B2	11/2012	Takiguchi	2001/0039503 A1	11/2001	Chan et al.	
8,315,687 B2	11/2012	Cross et al.	2001/0044588 A1	11/2001	Mault	
8,343,068 B2	1/2013	Najafi et al.	2001/0051766 A1	12/2001	Gazdinski	
8,369,936 B2	2/2013	Farringdon et al.	2001/0056262 A1	12/2001	Cabiri et al.	
8,386,009 B2	2/2013	Lindberg et al.	2002/0002326 A1	1/2002	Causey et al.	
8,389,003 B2	3/2013	Mintchev et al.	2002/0019586 A1	2/2002	Teller et al.	
8,404,275 B2	3/2013	Habboushe	2002/0026111 A1	2/2002	Ackerman	
8,440,274 B2	5/2013	Wang	2002/0032384 A1	3/2002	Raymond et al.	
8,454,528 B2	6/2013	Yuen et al.	2002/0032385 A1	3/2002	Raymond et al.	
8,454,561 B2	6/2013	Uber, III et al.	2002/0040278 A1	4/2002	Anuzis et al.	
8,514,086 B2	8/2013	Harper et al.	2002/0067270 A1	6/2002	Yarin et al.	
8,542,123 B2	9/2013	Robertson	2002/0077620 A1	6/2002	Sweeney et al.	
8,564,432 B2	10/2013	Covannon et al.	2002/0128934 A1	9/2002	Shaer	
8,564,627 B2	10/2013	Suzuki et al.	2002/0132226 A1	9/2002	Nair	
8,583,227 B2	11/2013	Savage et al.	2002/0138009 A1	9/2002	Brockway et al.	
8,597,186 B2	12/2013	Hafezi et al.	2002/0184415 A1	12/2002	Naghavi et al.	
8,634,838 B2	1/2014	Hellwig et al.	2002/0192159 A1	12/2002	Reitberg	
8,660,645 B2	2/2014	Stevenson et al.	2002/0193669 A1	12/2002	Glukhovskiy	
8,668,280 B2	3/2014	Heller et al.	2002/0193846 A1	12/2002	Pool et al.	
8,668,643 B2	3/2014	Kinast	2002/0198470 A1	12/2002	Imran et al.	
8,709,635 B1	4/2014	Benson et al.	2003/0017826 A1	1/2003	Fishman	
8,718,193 B2	5/2014	Arne et al.	2003/0023150 A1	1/2003	Yokoi et al.	
8,722,085 B2	5/2014	McKinney et al.	2003/0028226 A1	2/2003	Thompson	
8,762,733 B2	6/2014	Derchak et al.	2003/0037063 A1	2/2003	Schwartz	
8,771,183 B2	7/2014	Sloan	2003/0040662 A1	2/2003	Keys	
8,785,569 B2	7/2014	Wang et al.	2003/0063522 A1	4/2003	Sagar	
8,801,636 B2	8/2014	Lewicke et al.	2003/0065536 A1	4/2003	Hansen	
8,810,260 B1	8/2014	Zhou	2003/0076179 A1	4/2003	Branch et al.	
8,810,409 B2	8/2014	Robertson et al.	2003/0083559 A1	5/2003	Thompson	
8,823,510 B2	9/2014	Downey et al.	2003/0126593 A1	7/2003	Mault	
8,836,513 B2	9/2014	Hafezi et al.	2003/0130714 A1	7/2003	Nielsen et al.	
8,838,217 B2	9/2014	Myr	2003/0135128 A1	7/2003	Suffin et al.	
8,858,432 B2	10/2014	Robertson	2003/0135392 A1	7/2003	Vrijens et al.	
8,868,453 B2	10/2014	Zdeblick	2003/0152622 A1	8/2003	Louie-Helm et al.	
8,908,943 B2	12/2014	Berry et al.	2003/0158466 A1	8/2003	Lynn et al.	
8,926,509 B2	1/2015	Magar et al.	2003/0158756 A1	8/2003	Abramson	
8,932,221 B2	1/2015	Colliou et al.	2003/0162556 A1	8/2003	Libes	
8,945,005 B2	2/2015	Hafezi et al.	2003/0164401 A1	9/2003	Andreasson et al.	
8,956,287 B2	2/2015	Zdeblick et al.	2003/0167000 A1	9/2003	Mullick et al.	
8,956,288 B2	2/2015	Hafezi et al.	2003/0171791 A1	9/2003	KenKnight	
8,966,973 B1	3/2015	Milone	2003/0171898 A1	9/2003	Tarassenko et al.	
8,989,837 B2	3/2015	Weinstein et al.	2003/0181788 A1	9/2003	Yokoi et al.	
9,031,658 B2	5/2015	Chiao et al.	2003/0181815 A1	9/2003	Ebner et al.	
9,047,746 B1	6/2015	Euliano et al.	2003/0185286 A1	10/2003	Yuen	
9,060,708 B2	6/2015	Robertson et al.	2003/0187337 A1	10/2003	Tarassenko et al.	
9,083,589 B2	7/2015	Arne et al.	2003/0187338 A1	10/2003	Say et al.	
9,088,168 B2	7/2015	Mach et al.	2003/0195403 A1	10/2003	Berner et al.	
9,125,868 B2	9/2015	McKinney et al.	2003/0198619 A1	10/2003	Dong et al.	
9,189,941 B2	11/2015	Eschelman et al.	2003/0213495 A1	11/2003	Fujita et al.	
9,198,608 B2	12/2015	Hafezi et al.	2003/0214579 A1	11/2003	Iddan	
9,226,663 B2	1/2016	Fei	2003/0216622 A1	11/2003	Meron et al.	
9,226,679 B2	1/2016	Balda	2003/0216625 A1	11/2003	Phipps	
9,235,683 B2	1/2016	Robertson et al.	2003/0216666 A1	11/2003	Ericson et al.	
9,258,035 B2	2/2016	Robertson et al.	2003/0216729 A1	11/2003	Marchitto	
9,270,025 B2	2/2016	Robertson et al.	2003/0216793 A1	11/2003	Karlsson et al.	
9,277,864 B2	3/2016	Yang et al.	2003/0229382 A1	12/2003	Sun et al.	
9,278,177 B2	3/2016	Edwards et al.	2003/0232895 A1	12/2003	Omidian et al.	
9,320,455 B2	4/2016	Hafezi et al.	2004/0005051 A1 *	1/2004	Wheeler	H04L 9/3231 380/28
9,433,371 B2	9/2016	Hafezi et al.	2004/0008123 A1	1/2004	Carrender et al.	
9,439,582 B2	9/2016	Berkman et al.	2004/0018476 A1	1/2004	LaDue	
9,439,599 B2	9/2016	Thompson et al.	2004/0019172 A1	1/2004	Yang et al.	
9,444,503 B2	9/2016	Arne et al.	2004/0034295 A1	2/2004	Salganicoff	
9,517,012 B2	12/2016	Lane et al.	2004/0049245 A1	3/2004	Gass	
9,597,010 B2	3/2017	Thompson et al.	2004/0073095 A1	4/2004	Causey et al.	
9,603,550 B2	3/2017	Behzadi	2004/0073454 A1	4/2004	Urquhart et al.	
9,659,423 B2	5/2017	Robertson et al.	2004/0077995 A1	4/2004	Ferek-Petric	
9,756,874 B2	9/2017	Arne et al.	2004/0082982 A1	4/2004	Gord et al.	
9,883,819 B2	2/2018	Jensen et al.	2004/0087839 A1	5/2004	Raymond et al.	
10,542,909 B2	1/2020	Zdeblick et al.	2004/0092801 A1	5/2004	Drakulic	
10,720,044 B2	7/2020	Zdeblick et al.	2004/0106859 A1	6/2004	Say et al.	
10,772,522 B2	9/2020	Zadig	2004/0111011 A1	6/2004	Uchiyama et al.	
10,797,758 B2	10/2020	Shirvani et al.	2004/0115507 A1	6/2004	Potter et al.	
			2004/0115517 A1	6/2004	Fukada et al.	
			2004/0121015 A1	6/2004	Chidlaw et al.	
			2004/0122296 A1	6/2004	Hatlestad	

(56)

References Cited

U.S. PATENT DOCUMENTS

2004/0122297 A1	6/2004	Stahmann et al.	2005/0267556 A1	12/2005	Shuros et al.	
2004/0138558 A1	7/2004	Dunki-Jacobs et al.	2005/0267756 A1	12/2005	Schultz et al.	
2004/0147326 A1	7/2004	Stiles	2005/0277912 A1	12/2005	John	
2004/0148140 A1	7/2004	Tarassenko et al.	2005/0277999 A1	12/2005	Strother et al.	
2004/0153007 A1	8/2004	Harris	2005/0280539 A1	12/2005	Pettus	
2004/0167226 A1	8/2004	Serafini	2005/0281439 A1*	12/2005	Lange	A61B 5/04525 382/115
2004/0167801 A1	8/2004	Say et al.	2005/0285732 A1	12/2005	Sengupta et al.	
2004/0171914 A1	9/2004	Avni	2005/0285746 A1	12/2005	Sengupta	
2004/0193020 A1	9/2004	Chiba	2005/0288594 A1	12/2005	Lewkowicz et al.	
2004/0193029 A1	9/2004	Gluhovsky	2006/0001496 A1	1/2006	Abrosimov et al.	
2004/0193446 A1	9/2004	Mayer et al.	2006/0028727 A1	2/2006	Moon et al.	
2004/0199222 A1	10/2004	Sun et al.	2006/0036134 A1	2/2006	Tarassenko et al.	
2004/0215084 A1	10/2004	Shimizu et al.	2006/0058602 A1	3/2006	Kwiatkowski et al.	
2004/0218683 A1	11/2004	Batra	2006/0061472 A1	3/2006	Lovoi et al.	
2004/0220643 A1	11/2004	Schmidt	2006/0065713 A1	3/2006	Kingery	
2004/0224644 A1	11/2004	Wu	2006/0068006 A1	3/2006	Begleiter	
2004/0225199 A1	11/2004	Evanyk	2006/0074283 A1	4/2006	Henderson	
2004/0253304 A1	12/2004	Gross et al.	2006/0074319 A1	4/2006	Barnes et al.	
2004/0258571 A1	12/2004	Lee et al.	2006/0078765 A1	4/2006	Yang et al.	
2004/0259899 A1	12/2004	Sanghvi et al.	2006/0089858 A1	4/2006	Ling	
2004/0260154 A1	12/2004	Sidelnik	2006/0095091 A1	5/2006	Drew	
2004/0267240 A1	12/2004	Gross et al.	2006/0095093 A1	5/2006	Bettesh et al.	
2005/0017841 A1	1/2005	Doi	2006/0100533 A1	5/2006	Han	
2005/0020887 A1	1/2005	Goldberg	2006/0107997 A1	5/2006	Matsui et al.	
2005/0021103 A1	1/2005	DiLorenzo	2006/0109058 A1	5/2006	Keating	
2005/0021370 A1	1/2005	Riff	2006/0109130 A1	5/2006	Hattick et al.	
2005/0021372 A1	1/2005	Mikkelsen	2006/0110962 A1	5/2006	Powell	
2005/0024198 A1	2/2005	Ward	2006/0122474 A1	6/2006	Teller et al.	
2005/0027175 A1	2/2005	Yang	2006/0122667 A1	6/2006	Chavan et al.	
2005/0027205 A1	2/2005	Tarassenko et al.	2006/0129060 A1	6/2006	Lee et al.	
2005/0038321 A1	2/2005	Fujita et al.	2006/0136266 A1	6/2006	Tarassenko et al.	
2005/0038680 A1	2/2005	McMahon	2006/0142648 A1	6/2006	Banet	
2005/0043583 A1	2/2005	Killman et al.	2006/0145876 A1	7/2006	Kimura	
2005/0043634 A1	2/2005	Yokoi et al.	2006/0148254 A1	7/2006	McLean	
2005/0043894 A1	2/2005	Fernandez	2006/0149339 A1	7/2006	Burnes	
2005/0054897 A1	3/2005	Hashimoto et al.	2006/0155174 A1	7/2006	Glukhovsky et al.	
2005/0055014 A1	3/2005	Coppeta et al.	2006/0155183 A1	7/2006	Kroecker	
2005/0062644 A1	3/2005	Leci	2006/0158820 A1	7/2006	Tagiguchi	
2005/0065407 A1	3/2005	Nakamura et al.	2006/0161225 A1	7/2006	Sormann et al.	
2005/0070778 A1	3/2005	Lackey	2006/0164213 A1	7/2006	Burghard	
2005/0075145 A1	4/2005	Dvorak et al.	2006/0179949 A1	8/2006	Kim	
2005/0090753 A1	4/2005	Goor et al.	2006/0183992 A1	8/2006	Kawashima	
2005/0092108 A1	5/2005	Andermo	2006/0183993 A1	8/2006	Horn	
2005/0096514 A1	5/2005	Starkebaum	2006/0184092 A1	8/2006	Atanasoska et al.	
2005/0096562 A1	5/2005	Delalic et al.	2006/0204738 A1	9/2006	Dubrow et al.	
2005/0101843 A1	5/2005	Quinn	2006/0204764 A1	9/2006	Hirao et al.	
2005/0101872 A1	5/2005	Sattler	2006/0210626 A1	9/2006	Spaeder	
2005/0115561 A1	6/2005	Stahmann et al.	2006/0216603 A1	9/2006	Choi	
2005/0116820 A1	6/2005	Goldreich	2006/0218011 A1	9/2006	Walker	
2005/0117389 A1	6/2005	Worledge	2006/0229053 A1	10/2006	Sivard	
2005/0121322 A1	6/2005	Say et al.	2006/0235489 A1	10/2006	Drew	
2005/0131281 A1	6/2005	Ayer et al.	2006/0243288 A1*	11/2006	Kim	A61B 1/041 128/899
2005/0137480 A1	6/2005	Alt et al.	2006/0247505 A1	11/2006	Siddiqui	
2005/0143623 A1	6/2005	Kojima	2006/0253004 A1	11/2006	Frisch et al.	
2005/0146594 A1	7/2005	Nakatani et al.	2006/0253005 A1	11/2006	Drinan	
2005/0148883 A1	7/2005	Boesen	2006/0255064 A1	11/2006	Donaldson	
2005/0151625 A1	7/2005	Lai	2006/0265246 A1	11/2006	Hoag	
2005/0154277 A1	7/2005	Tang et al.	2006/0267774 A1	11/2006	Feinberg et al.	
2005/0154428 A1	7/2005	Bruinsma	2006/0270346 A1	11/2006	Ibrahim	
2005/0156709 A1	7/2005	Gilbert et al.	2006/0273882 A1	12/2006	Posamentier	
2005/0159789 A1	7/2005	Brockway	2006/0276702 A1	12/2006	McGinnis	
2005/0165323 A1	7/2005	Montgomery	2006/0280227 A1	12/2006	Pinkney	
2005/0177069 A1	8/2005	Takizawa	2006/0282001 A1	12/2006	Noel	
2005/0182389 A1	8/2005	LaPorte	2006/0285607 A1	12/2006	Strodtbeck et al.	
2005/0187789 A1	8/2005	Hatlestad et al.	2006/0287693 A1	12/2006	Kraft et al.	
2005/0192489 A1	9/2005	Marshall	2006/0289640 A1	12/2006	Mercure	
2005/0197680 A1	9/2005	DelMain et al.	2006/0293607 A1	12/2006	Alt	
2005/0228268 A1	10/2005	Cole	2007/0000776 A1	1/2007	Karube et al.	
2005/0234307 A1	10/2005	Heinonen	2007/0002038 A1	1/2007	Suzuki	
2005/0240305 A1	10/2005	Bogash et al.	2007/0006636 A1	1/2007	King et al.	
2005/0245794 A1	11/2005	Dinsmoor	2007/0008113 A1	1/2007	Spoonhower et al.	
2005/0245839 A1	11/2005	Stivoric et al.	2007/0016089 A1	1/2007	Fischell et al.	
2005/0259768 A1	11/2005	Yang et al.	2007/0016443 A1	1/2007	Wachman et al.	
2005/0261559 A1	11/2005	Mumford	2007/0025739 A1	2/2007	Moore et al.	
2005/0267550 A1	12/2005	Hess et al.	2007/0027386 A1	2/2007	Such	
			2007/0027388 A1	2/2007	Chou	
			2007/0038054 A1	2/2007	Zhou	

(56)

References Cited

U.S. PATENT DOCUMENTS

2007/0049339 A1	3/2007	Barak et al.	2008/0097549 A1	4/2008	Colbaugh	
2007/0055098 A1	3/2007	Shimizu et al.	2008/0097917 A1	4/2008	Dicks	
2007/0060797 A1	3/2007	Ball	2008/0099366 A1	5/2008	Niemic et al.	
2007/0060800 A1	3/2007	Drinan et al.	2008/0103440 A1	5/2008	Ferren et al.	
2007/0066929 A1	3/2007	Ferren et al.	2008/0112885 A1*	5/2008	Okunev	A61B 5/0022 424/9.1
2007/0072156 A1	3/2007	Kaufman et al.	2008/0114224 A1	5/2008	Bandy et al.	
2007/0073353 A1	3/2007	Rooney et al.	2008/0119705 A1	5/2008	Patel	
2007/0088194 A1	4/2007	Tahar	2008/0119716 A1	5/2008	Boric-Lubecke	
2007/0096765 A1	5/2007	Kagan	2008/0121825 A1	5/2008	Trovato et al.	
2007/0106346 A1	5/2007	Bergelson	2008/0137566 A1	6/2008	Marholev	
2007/0123772 A1	5/2007	Euliano	2008/0139907 A1	6/2008	Rao et al.	
2007/0129622 A1	6/2007	Bourget	2008/0140403 A1	6/2008	Hughes et al.	
2007/0130287 A1	6/2007	Kumar	2008/0146871 A1	6/2008	Arneson et al.	
2007/0135691 A1	6/2007	Zingelewicz et al.	2008/0146889 A1	6/2008	Young	
2007/0135803 A1	6/2007	Belson	2008/0146892 A1	6/2008	LeBeouf	
2007/0142721 A1	6/2007	Berner et al.	2008/0154104 A1	6/2008	Lamego	
2007/0156016 A1	7/2007	Betesh	2008/0166992 A1	7/2008	Ricordi	
2007/0160789 A1	7/2007	Mercial	2008/0175898 A1	7/2008	Jones et al.	
2007/0162089 A1	7/2007	Mosesov	2008/0183245 A1	7/2008	Van Oort	
2007/0162090 A1	7/2007	Penner	2008/0188763 A1	8/2008	John et al.	
2007/0167495 A1	7/2007	Brown et al.	2008/0188837 A1	8/2008	Belsky et al.	
2007/0167848 A1	7/2007	Kuo et al.	2008/0194912 A1	8/2008	Trovato et al.	
2007/0172424 A1	7/2007	Roser	2008/0208009 A1	8/2008	Shklarski	
2007/0173701 A1	7/2007	Al-Ali	2008/0214901 A1	9/2008	Gehman	
2007/0179347 A1	8/2007	Tarassenko et al.	2008/0214903 A1	9/2008	Orbach	
2007/0179371 A1	8/2007	Peyser et al.	2008/0214985 A1	9/2008	Yanaki	
2007/0180047 A1	8/2007	Dong et al.	2008/0223936 A1	9/2008	Mickle et al.	
2007/0185393 A1	8/2007	Zhou	2008/0243020 A1	10/2008	Chou	
2007/0191002 A1	8/2007	Ge	2008/0249360 A1	10/2008	Li	
2007/0196456 A1	8/2007	Stevens	2008/0249808 A1*	10/2008	Jung	G06Q 10/10 705/3
2007/0207793 A1	9/2007	Myer	2008/0262320 A1	10/2008	Schaefer et al.	
2007/0207858 A1	9/2007	Breving	2008/0262336 A1	10/2008	Ryu	
2007/0208233 A1	9/2007	Kovacs	2008/0269664 A1	10/2008	Trovato et al.	
2007/0213659 A1	9/2007	Trovato et al.	2008/0275312 A1	11/2008	Mosesov	
2007/0237719 A1	10/2007	Jones	2008/0281636 A1	11/2008	Jung et al.	
2007/0244370 A1	10/2007	Kuo et al.	2008/0284599 A1	11/2008	Zdeblick et al.	
2007/0244810 A1	10/2007	Rudolph	2008/0288026 A1	11/2008	Cross et al.	
2007/0249946 A1	10/2007	Kumar et al.	2008/0288027 A1	11/2008	Kroll	
2007/0255198 A1	11/2007	Leong et al.	2008/0294020 A1	11/2008	Sapounas	
2007/0255330 A1	11/2007	Lee	2008/0299197 A1	12/2008	Toneguzzo et al.	
2007/0270672 A1	11/2007	Hayter	2008/0300572 A1	12/2008	Rankers	
2007/0279217 A1	12/2007	Venkatraman	2008/0303638 A1	12/2008	Nguyen	
2007/0282174 A1	12/2007	Sabatino	2008/0303665 A1	12/2008	Naik et al.	
2007/0282177 A1	12/2007	Pilz	2008/0306357 A1	12/2008	Korman	
2007/0291715 A1	12/2007	Laroia et al.	2008/0306359 A1	12/2008	Zdeblick et al.	
2007/0299480 A1	12/2007	Hill	2008/0306360 A1	12/2008	Robertson et al.	
2008/0004503 A1	1/2008	Nisani et al.	2008/0306362 A1	12/2008	Davis	
2008/0014866 A1	1/2008	Lipowshi	2008/0311852 A1	12/2008	Hansen	
2008/0015421 A1	1/2008	Penner	2008/0312522 A1	12/2008	Rowlandson	
2008/0015494 A1	1/2008	Santini et al.	2008/0316020 A1	12/2008	Robertson	
2008/0015893 A1	1/2008	Miller et al.	2009/0006133 A1	1/2009	Weinert	
2008/0020037 A1	1/2008	Robertson et al.	2009/0009330 A1	1/2009	Sakama et al.	
2008/0021519 A1	1/2008	DeGeest	2009/0009332 A1	1/2009	Nunez et al.	
2008/0021521 A1	1/2008	Shah	2009/0010321 A1	1/2009	Chalopin et al.	
2008/0027679 A1	1/2008	Shklarski	2009/0024045 A1	1/2009	Prakash	
2008/0033273 A1	2/2008	Zhou	2009/0024112 A1	1/2009	Edwards et al.	
2008/0033301 A1	2/2008	Dellavecchia et al.	2009/0030293 A1	1/2009	Cooper et al.	
2008/0038588 A1	2/2008	Lee	2009/0030297 A1	1/2009	Miller	
2008/0039700 A1	2/2008	Drinan et al.	2009/0034209 A1	2/2009	Joo	
2008/0045843 A1	2/2008	Tsuji et al.	2009/0043171 A1	2/2009	Rule	
2008/0046038 A1	2/2008	Hill	2009/0048498 A1	2/2009	Riskey	
2008/0051647 A1	2/2008	Wu et al.	2009/0062634 A1	3/2009	Say et al.	
2008/0051667 A1	2/2008	Goldreich	2009/0062670 A1	3/2009	Sterling	
2008/0051767 A1	2/2008	Rossing et al.	2009/0062730 A1	3/2009	Woo	
2008/0058614 A1	3/2008	Banet	2009/0069642 A1	3/2009	Gao	
2008/0061945 A1	3/2008	Hoshina	2009/0069655 A1	3/2009	Say et al.	
2008/0062856 A1	3/2008	Feher	2009/0069656 A1	3/2009	Say et al.	
2008/0065168 A1	3/2008	Bitton et al.	2009/0069657 A1	3/2009	Say et al.	
2008/0074307 A1	3/2008	Boric-Lubecke	2009/0069658 A1	3/2009	Say et al.	
2008/0077015 A1	3/2008	Botic-Lubecke	2009/0076340 A1	3/2009	Libbus et al.	
2008/0077028 A1	3/2008	Schaldach et al.	2009/0076343 A1	3/2009	James	
2008/0077188 A1	3/2008	Denker et al.	2009/0076350 A1	3/2009	Bly et al.	
2008/0077430 A1	3/2008	Singer et al.	2009/0076397 A1	3/2009	Libbus et al.	
2008/0091089 A1	4/2008	Guillory et al.	2009/0082645 A1	3/2009	Hafezi et al.	
2008/0091114 A1	4/2008	Min	2009/0087483 A1	4/2009	Sison	
			2009/0088618 A1	4/2009	Arneson	
			2009/0099435 A1	4/2009	Say et al.	

(56)

References Cited

U.S. PATENT DOCUMENTS

2009/0105561 A1	4/2009	Boydon et al.	2009/0228214 A1	9/2009	Say et al.
2009/0110148 A1	4/2009	Zhang	2009/0231125 A1	9/2009	Baldus
2009/0112626 A1	4/2009	Talbot	2009/0234200 A1	9/2009	Husheer
2009/0124871 A1	5/2009	Arshak	2009/0234203 A1	9/2009	Arita
2009/0131774 A1	5/2009	Sweitzer	2009/0243833 A1	10/2009	Huang
2009/0134181 A1	5/2009	Wachman et al.	2009/0247836 A1	10/2009	Cole et al.
2009/0135886 A1	5/2009	Robertson et al.	2009/0253960 A1	10/2009	Takenaka et al.
2009/0142853 A1	6/2009	Warrington et al.	2009/0264714 A1	10/2009	Chou
2009/0149708 A1	6/2009	Hyde et al.	2009/0264964 A1	10/2009	Abrahamson
2009/0149839 A1	6/2009	Hyde et al.	2009/0265186 A1	10/2009	Tarassenko et al.
2009/0157113 A1	6/2009	Marcotte	2009/0273467 A1	11/2009	Elixmann
2009/0157358 A1	6/2009	Kim	2009/0277815 A1	11/2009	Kohl et al.
2009/0161602 A1	6/2009	Matsumoto	2009/0281539 A1	11/2009	Selig
2009/0163789 A1	6/2009	Say et al.	2009/0287109 A1	11/2009	Ferren et al.
2009/0171180 A1	7/2009	Pering	2009/0292194 A1	11/2009	Libbus et al.
2009/0173628 A1	7/2009	Say et al.	2009/0295548 A1	12/2009	Ronkka
2009/0177055 A1	7/2009	Say et al.	2009/0296677 A1	12/2009	Mahany
2009/0177056 A1	7/2009	Say et al.	2009/0301925 A1	12/2009	Alloro et al.
2009/0177057 A1	7/2009	Say et al.	2009/0303920 A1	12/2009	Mahany
2009/0177058 A1	7/2009	Say et al.	2009/0306633 A1	12/2009	Trovato et al.
2009/0177059 A1	7/2009	Say et al.	2009/0312619 A1	12/2009	Say et al.
2009/0177060 A1	7/2009	Say et al.	2009/0318303 A1	12/2009	Delamarche et al.
2009/0177061 A1	7/2009	Say et al.	2009/0318761 A1	12/2009	Rabinovitz
2009/0177062 A1	7/2009	Say et al.	2009/0318779 A1	12/2009	Tran
2009/0177063 A1	7/2009	Say et al.	2009/0318783 A1	12/2009	Rohde
2009/0177064 A1	7/2009	Say et al.	2009/0318793 A1	12/2009	Datta
2009/0177065 A1	7/2009	Say et al.	2010/0001841 A1	1/2010	Cardullo
2009/0177066 A1	7/2009	Say et al.	2010/0006585 A1	1/2010	Flowers et al.
2009/0182206 A1	7/2009	Najafi	2010/0010330 A1	1/2010	Rankers
2009/0182207 A1	7/2009	Riskey et al.	2010/0015584 A1	1/2010	Singer et al.
2009/0182212 A1	7/2009	Say et al.	2010/0019848 A1	1/2010	Rossi
2009/0182213 A1	7/2009	Say et al.	2010/0033324 A1	2/2010	Shimizu et al.
2009/0182214 A1	7/2009	Say et al.	2010/0036269 A1	2/2010	Ferren et al.
2009/0182215 A1	7/2009	Say et al.	2010/0049004 A1	2/2010	Edman et al.
2009/0182388 A1	7/2009	Von Arx	2010/0049006 A1	2/2010	Magar
2009/0184842 A1*	7/2009	Baldus G06F 19/3418 340/870.07	2010/0049012 A1	2/2010	Dijkman et al.
2009/0187088 A1	7/2009	Say et al.	2010/0049069 A1	2/2010	Tarassenko et al.
2009/0187089 A1	7/2009	Say et al.	2010/0056878 A1	3/2010	Partin
2009/0187090 A1	7/2009	Say et al.	2010/0056891 A1	3/2010	Say et al.
2009/0187091 A1	7/2009	Say et al.	2010/0056939 A1	3/2010	Tarassenko et al.
2009/0187092 A1	7/2009	Say et al.	2010/0057041 A1	3/2010	Hayter
2009/0187093 A1	7/2009	Say et al.	2010/0062709 A1	3/2010	Kato
2009/0187094 A1	7/2009	Say et al.	2010/0063438 A1	3/2010	Bengtsson
2009/0187095 A1	7/2009	Say et al.	2010/0063841 A1	3/2010	D'Ambrosia et al.
2009/0187381 A1	7/2009	King et al.	2010/0069002 A1	3/2010	Rong
2009/0192351 A1	7/2009	Nishino	2010/0069717 A1	3/2010	Hafezi et al.
2009/0192368 A1	7/2009	Say et al.	2010/0082367 A1	4/2010	Hains et al.
2009/0192369 A1	7/2009	Say et al.	2010/0099967 A1	4/2010	Say et al.
2009/0192370 A1	7/2009	Say et al.	2010/0099968 A1	4/2010	Say et al.
2009/0192371 A1	7/2009	Say et al.	2010/0099969 A1	4/2010	Say et al.
2009/0192372 A1	7/2009	Say et al.	2010/0100077 A1	4/2010	Rush
2009/0192373 A1	7/2009	Say et al.	2010/0100078 A1	4/2010	Say et al.
2009/0192374 A1	7/2009	Say et al.	2010/0100237 A1	4/2010	Ratnakar
2009/0192375 A1	7/2009	Say et al.	2010/0106001 A1	4/2010	Say et al.
2009/0192376 A1	7/2009	Say et al.	2010/0118853 A1	5/2010	Godfrey
2009/0192377 A1	7/2009	Say et al.	2010/0131434 A1	5/2010	Magent et al.
2009/0192378 A1	7/2009	Say et al.	2010/0139672 A1	6/2010	Kroll et al.
2009/0192379 A1	7/2009	Say et al.	2010/0160742 A1	6/2010	Seidl et al.
2009/0198115 A1	8/2009	Say et al.	2010/0168659 A1	7/2010	Say et al.
2009/0198116 A1	8/2009	Say et al.	2010/0179398 A1	7/2010	Say et al.
2009/0198175 A1	8/2009	Say et al.	2010/0183199 A1	7/2010	Smith et al.
2009/0203964 A1	8/2009	Shimizu et al.	2010/0191073 A1	7/2010	Tarassenko et al.
2009/0203971 A1	8/2009	Sciarappa	2010/0203394 A1	8/2010	Bae et al.
2009/0203972 A1	8/2009	Heneghan	2010/0210299 A1	8/2010	Gorbachov
2009/0203978 A1	8/2009	Say et al.	2010/0217100 A1	8/2010	LeBocuf et al.
2009/0204265 A1	8/2009	Hackett	2010/0222652 A1	9/2010	Cho
2009/0210164 A1	8/2009	Say et al.	2010/0228113 A1	9/2010	Solosko
2009/0216101 A1	8/2009	Say et al.	2010/0233026 A1	9/2010	Ismagliov et al.
2009/0216102 A1	8/2009	Say et al.	2010/0234706 A1	9/2010	Gilland
2009/0227204 A1	9/2009	Robertson et al.	2010/0234715 A1	9/2010	Shin
2009/0227876 A1	9/2009	Tran	2010/0234914 A1	9/2010	Shen
2009/0227940 A1	9/2009	Say et al.	2010/0245091 A1	9/2010	Singh
2009/0227941 A1	9/2009	Say et al.	2010/0249541 A1	9/2010	Geva et al.
2009/0227988 A1	9/2009	Wood et al.	2010/0249881 A1	9/2010	Corndorf
			2010/0256461 A1	10/2010	Mohamedali
			2010/0259543 A1	10/2010	Tarassenko et al.
			2010/0268048 A1	10/2010	Say et al.
			2010/0268049 A1	10/2010	Say et al.
			2010/0268050 A1	10/2010	Say et al.

(56)

References Cited

U.S. PATENT DOCUMENTS

2010/0268288 A1 10/2010 Hunter et al.
 2010/0274111 A1 10/2010 Say et al.
 2010/0280345 A1 11/2010 Say et al.
 2010/0280346 A1 11/2010 Say et al.
 2010/0295694 A1 11/2010 Kauffman et al.
 2010/0298668 A1 11/2010 Hafezi et al.
 2010/0298730 A1 11/2010 Tarassenko et al.
 2010/0299155 A1 11/2010 Findlay et al.
 2010/0312188 A1 12/2010 Robertson et al.
 2010/0312577 A1 12/2010 Goodnow et al.
 2010/0312580 A1 12/2010 Tarassenko et al.
 2010/0332443 A1 12/2010 Gartenberg
 2011/0004079 A1 1/2011 Al Ali et al.
 2011/0009715 A1 1/2011 O'Reilly et al.
 2011/0021983 A1 1/2011 Jurson
 2011/0029622 A1 2/2011 Walker et al.
 2011/0050431 A1 3/2011 Hood et al.
 2011/0054265 A1 3/2011 Hafezi et al.
 2011/0065983 A1 3/2011 Hafezi et al.
 2011/0077660 A1 3/2011 Janik et al.
 2011/0081860 A1 4/2011 Brown et al.
 2011/0105864 A1 5/2011 Robertson et al.
 2011/0112686 A1 5/2011 Nolan et al.
 2011/0124983 A1 5/2011 Kröll et al.
 2011/0144470 A1 6/2011 Mazar et al.
 2011/0160549 A1 6/2011 Saroka et al.
 2011/0204483 A1 8/2011 McNally et al.
 2011/0212782 A1 9/2011 Thompson et al.
 2011/0224912 A1 9/2011 Bhavaraju et al.
 2011/0230732 A1 9/2011 Edman et al.
 2011/0231202 A1 9/2011 Hanina et al.
 2011/0237924 A1 9/2011 McGusty et al.
 2011/0270112 A1 11/2011 Manera et al.
 2011/0270135 A1 11/2011 Dooley et al.
 2011/0279963 A1 11/2011 Kumar et al.
 2012/0024889 A1 2/2012 Robertson et al.
 2012/0029309 A1 2/2012 Paquet et al.
 2012/0032816 A1 2/2012 Cho et al.
 2012/0062371 A1 3/2012 Radivojevic et al.
 2012/0071743 A1 3/2012 Todorov et al.
 2012/0083715 A1 4/2012 Yuen et al.
 2012/0089000 A1 4/2012 Bishay et al.
 2012/0101396 A1 4/2012 Solosko et al.
 2012/0116184 A1 5/2012 Shieh
 2012/0179004 A1 7/2012 Roesicke et al.
 2012/0197144 A1 8/2012 Christ et al.
 2012/0214140 A1 8/2012 Brynson et al.
 2012/0265544 A1 10/2012 Hwang et al.
 2012/0310070 A1 12/2012 Kumar et al.
 2012/0316413 A1 12/2012 Liu et al.
 2013/0002423 A1 1/2013 Robertson et al.
 2013/0030259 A1 1/2013 Thomsen et al.
 2013/0057385 A1 3/2013 Murakami et al.
 2013/0060115 A1 3/2013 Gehman et al.
 2013/0073312 A1 3/2013 Thompson et al.
 2013/0171596 A1 7/2013 French
 2013/0185228 A1 7/2013 Dresner
 2013/0196012 A1 8/2013 Dill
 2013/0275296 A1 10/2013 Tietzen et al.
 2013/0328416 A1 12/2013 Whitworth et al.
 2013/0338452 A1 12/2013 Robertson et al.
 2014/0004492 A1 1/2014 O'Reilly et al.
 2014/0039445 A1 2/2014 Austin et al.
 2014/0051965 A1 2/2014 Zdeblick et al.
 2014/0203950 A1 7/2014 Zdeblick et al.
 2014/0280125 A1 9/2014 Bhardwaj et al.
 2014/0308930 A1 10/2014 Tran
 2014/0315170 A1 10/2014 Ionescu et al.
 2014/0349256 A1 11/2014 Connor
 2014/0374276 A1 12/2014 Guthrie et al.
 2015/0051465 A1 2/2015 Robertson et al.
 2015/0080678 A1 3/2015 Frank et al.
 2015/0080679 A1 3/2015 Frank et al.
 2015/0080680 A1 3/2015 Zdeblick et al.
 2015/0080681 A1 3/2015 Hafezi et al.

2015/0127737 A1 5/2015 Thompson et al.
 2015/0127738 A1 5/2015 Thompson et al.
 2015/0149375 A1 5/2015 Thompson et al.
 2015/0165313 A1 6/2015 Thompson et al.
 2015/0171924 A1 6/2015 Zdeblick
 2015/0182463 A1 7/2015 Hafezi et al.
 2015/0193593 A1 7/2015 Zdeblick et al.
 2015/0230728 A1 8/2015 Hafezi et al.
 2016/0106339 A1 4/2016 Behzadi et al.
 2016/0155316 A1 6/2016 Hafezi et al.
 2017/0000179 A1 1/2017 Cheng et al.
 2017/0215761 A1 8/2017 Zdeblick
 2017/0270779 A1 9/2017 Zdeblick et al.
 2017/0303818 A1 10/2017 Behzadi et al.
 2018/0026680 A1 1/2018 Shirvani et al.
 2018/0184698 A1 7/2018 Arne et al.
 2018/0279910 A1 10/2018 Jensen et al.
 2019/0133958 A1 5/2019 Hafezi et al.
 2019/0158151 A1 5/2019 Shirvani et al.
 2019/0191006 A1 9/2019 Thompson
 2020/0229758 A1 7/2020 Savage

FOREIGN PATENT DOCUMENTS

CN 2748032 12/2005
 CN 1991868 7/2007
 CN 101005470 7/2007
 CN 201076456 6/2008
 CN 101524267 9/2009
 DE 10313005 10/2004
 EP 0344939 12/1989
 EP 0526166 2/1993
 EP 1199670 4/2002
 EP 1246356 10/2002
 EP 1342447 9/2003
 EP 1534054 5/2005
 EP 1702553 9/2006
 EP 1098591 1/2007
 EP 1789128 5/2007
 EP 2143369 1/2010
 GB 775071 5/1957
 GB 2432862 6/2007
 IL 172917 6/2010
 JP 2000506410 5/1912
 JP S6117949 1/1986
 JP S63280393 11/1988
 JP H01285247 11/1989
 JP 05228128 9/1993
 JP H0884779 4/1996
 JP 09330159 12/1997
 JP 1014898 1/1998
 JP H11195415 7/1999
 JP 2001078974 3/2001
 JP 2002224053 8/2002
 JP 2002263185 9/2002
 JP 2002282218 10/2002
 JP 2002282219 10/2002
 JP 2002291684 10/2002
 JP 2003210395 7/2003
 JP 3454525 10/2003
 JP 2003325440 11/2003
 JP 2004007187 1/2004
 JP 2004507188 3/2004
 JP 2004134384 4/2004
 JP 2004274452 9/2004
 JP 2004313242 11/2004
 JP 2004313242 A * 11/2004
 JP 2004318534 11/2004
 JP 2004364016 12/2004
 JP 2005031840 2/2005
 JP 2005073886 3/2005
 JP 2005124708 5/2005
 JP 2005148021 6/2005
 JP 2005152037 6/2005
 JP 2005287691 10/2005
 JP 2005304880 11/2005
 JP 2005532841 11/2005
 JP 2005532849 11/2005
 JP 2005343515 12/2005

(56)

References Cited

FOREIGN PATENT DOCUMENTS

JP	2006006377	1/2006	WO	WO2005020023	3/2005
JP	2006509574	3/2006	WO	WO2005024687	3/2005
JP	2006177699	7/2006	WO	WO2005041767	5/2005
JP	2006187611	7/2006	WO	WO2005047837	5/2005
JP	2006278091	10/2006	WO	WO2005051166	6/2005
JP	2006346000	12/2006	WO	WO2005053517	6/2005
JP	3876573	1/2007	WO	WO2005069887	8/2005
JP	2007151809	6/2007	WO	WO2005082436	9/2005
JP	2007159631	6/2007	WO	WO2005083621	9/2005
JP	2007200739	8/2007	WO	WO2005110238	11/2005
JP	2007313340	12/2007	WO	WO2005117697	12/2005
JP	2007330677	12/2007	WO	WO2006009404	1/2006
JP	2008011865	1/2008	WO	WO2006016370	2/2006
JP	2008501415	1/2008	WO	WO2006021932	3/2006
JP	2008176434	7/2008	WO	WO2006027586	3/2006
JP	2008191955	8/2008	WO	WO2006028347	3/2006
JP	2008289724	12/2008	WO	WO2006035351	4/2006
JP	2009034345	2/2009	WO	WO2006037802	4/2006
JP	2009050541	3/2009	WO	WO2006046648	5/2006
JP	2009061236	3/2009	WO	WO2006055892	5/2006
JP	2009065726 A	3/2009	WO	WO2006055956	5/2006
JP	2011015817 A	1/2011	WO	WO2006059338	6/2006
JP	2011091680 A	5/2011	WO	WO2006075016	7/2006
JP	2011519583	7/2011	WO	WO2006100620	9/2006
KR	20020015907	3/2002	WO	WO2006104843	10/2006
KR	20020061744	7/2002	WO	WO2006109072	10/2006
KR	200600977523	7/2006	WO	WO2006116718	11/2006
KR	100927471	11/2009	WO	WO2006119345	11/2006
KR	20110137001	12/2011	WO	WO2006123346	11/2006
KR	10-2012-099995	9/2012	WO	WO2006127355	11/2006
TW	200301864	7/2003	WO	WO2007001724	1/2007
TW	553735	9/2003	WO	WO2007001742	1/2007
TW	200724094	7/2007	WO	WO2007013952	2/2007
TW	200812556	3/2008	WO	WO2007014084	2/2007
TW	201120673	6/2011	WO	WO2007014527	2/2007
WO	WO1988002237	4/1988	WO	WO2007021496	2/2007
WO	WO1992021307	12/1992	WO	WO2007027660	3/2007
WO	WO1993008734	5/1993	WO	WO2007028035	3/2007
WO	WO1993019667	10/1993	WO	WO2007036687	4/2007
WO	WO1994001165	1/1994	WO	WO2007036741	4/2007
WO	WO9516393	6/1995	WO	WO2007036746	4/2007
WO	WO1997014112	4/1997	WO	WO2007040878	4/2007
WO	WO1997039963	10/1997	WO	WO2007067054	6/2007
WO	WO1998043537	10/1998	WO	WO2007071180	6/2007
WO	WO1999037290	7/1999	WO	WO2007096810	8/2007
WO	WO1999059465	11/1999	WO	WO2007101141	9/2007
WO	200016236 A1	3/2000	WO	WO2007115087	10/2007
WO	WO2000033246	6/2000	WO	WO2007120946	10/2007
WO	WO2001000085	1/2001	WO	WO2007123923	11/2007
WO	WO2001047466	7/2001	WO	WO2007127316	11/2007
WO	WO2001049364	7/2001	WO	WO2007127879	11/2007
WO	WO2001074011	10/2001	WO	WO2007127945	11/2007
WO	WO2001080731	11/2001	WO	WO2007128165	11/2007
WO	WO200235997	5/2002	WO	WO2007130491	11/2007
WO	WO2002045489	6/2002	WO	WO2007133526	11/2007
WO	WO2002058330	7/2002	WO	WO2007143535	12/2007
WO	WO2002062276	8/2002	WO	WO2007149546	12/2007
WO	WO2002087681	11/2002	WO	WO2008008281	1/2008
WO	WO2002095351	11/2002	WO	WO2008012700	1/2008
WO	WO2003005877	1/2003	WO	WO2008030482	3/2008
WO	WO2003050643	6/2003	WO	WO2008039030	4/2008
WO	WO2003068061	8/2003	WO	WO2008052136	5/2008
WO	WO2004014225	2/2004	WO	WO2008061138	5/2008
WO	WO2004019172	3/2004	WO	WO2008063626	5/2008
WO	WO2004039256	5/2004	WO	WO2008066617	6/2008
WO	WO2004059551	7/2004	WO	WO2008076464	6/2008
WO	WO2004066833	8/2004	WO	WO2008085131	7/2008
WO	WO2004066834	8/2004	WO	WO2008089232	7/2008
WO	WO2004066903	8/2004	WO	WO2008091683	7/2008
WO	WO2004068748	8/2004	WO	WO2008095183	8/2008
WO	WO2004068881	8/2004	WO	WO2008097652	8/2008
WO	WO2004075751	9/2004	WO	WO2008101107	8/2008
WO	WO2004109316	12/2004	WO	WO2008112577	9/2008
WO	WO2004110555	12/2004	WO	WO2008112578	9/2008
WO	WO2005011237	2/2005	WO	WO2008120156	10/2008
			WO	WO2008133394	11/2008
			WO	WO2008134185	11/2008
			WO	WO2008150633	12/2008
			WO	WO2009001108	12/2008

(56)

References Cited

FOREIGN PATENT DOCUMENTS

WO	WO2009005759	1/2009
WO	WO2009006615	1/2009
WO	WO2009022343	2/2009
WO	WO2009029453	3/2009
WO	WO2009032381	3/2009
WO	WO2009036334	3/2009
WO	WO2009051829	4/2009
WO	WO2009051830	4/2009
WO	WO2009063377	5/2009
WO	WO2009081348	7/2009
WO	WO2009111664	9/2009
WO	WO2009146082	12/2009
WO	WO2010009100	1/2010
WO	WO2010011833	1/2010
WO	WO2010019778	2/2010
WO	WO2010057049	5/2010
WO	WO2010075115	7/2010
WO	WO2010080765	7/2010
WO	WO2010080843	7/2010
WO	WO2010107563	9/2010
WO	WO2010107980	9/2010
WO	WO2010115194	10/2010
WO	WO2010132331	11/2010
WO	WO2010135516	11/2010
WO	WO2011024560	3/2011
WO	WO2011068963	6/2011
WO	WO2011133799	10/2011
WO	WO2011159336	12/2011
WO	WO2011159337	12/2011
WO	WO2011159338	12/2011
WO	WO2011159339	12/2011
WO	WO2012104657	8/2012
WO	WO2012158190	11/2012
WO	WO2013012869	1/2013
WO	WO2015112603	7/2015

OTHER PUBLICATIONS

AADE, "AADE 37th Annual Meeting San Antonio Aug. 4-7, 2010" American Association of Diabetes Educators August (2010); <http://www.diabeteseducator.org/annualmeeting/2010/index.html>; 2 pp.

Aronson, J., "Meyer's Side Effects of Cardiovascular Drugs," Elsevier, Mar. 2, 2009, Medical, 840 pages. (Not Attached).

Arshak et al., "A Review and Adaptation of Methods of Object Tracking to Telemetry Capsules IC-Med; Jan. 2007 vol. 1, No. 1, Issue 1, 12pp.

"ASGE Technology Status Evaluation Report: wireless capsule endoscopy" American Soc. for Gastrointestinal Endoscopy; Apr. 2006 vol. 63, No. 4; 7 pp.

Au-Yeung, K., et al., "A Networked System for Self-Management of Drug Therapy and Wellness", Wireless Health '10, Oct. 5-7, 2010, San Diego, 9 pages.

Aydin et al., "Design and implementation considerations for an advanced wireless interface in miniaturized integrated sensor Microsystems" Sch. of Eng. & Electron., Edinburgh Univ., UK; Sep. 2003; Abstract Only.

Barrie, Heidelberg pH capsule gastric analysis. Textbook of Natural Medicine, (1992), Pizzorno, Murray & Barrie.

Baskiyar, S. "A Real-time Fault Tolerant Intra-body Network" Dept. of Comp. Sci & Soft Eng; Auburn University; Proceedings of the 27th Annual IEEE Conference; 0742-1303/02 (2002) IEEE; 6 pp.

Bohidar et al., "Dielectric Behavior of Gelatin Solutions and Gels" Colloid Polym Sci (1998) 276:81-86.

Brock, "Smart Medicine: The Application of Auto-ID Technology to Healthcare" Auto-ID Labs (2002) <http://www.autoidlabs.org/uploads/media/MIT-AUTOID-WH-010.pdf>.

Carlson et al., "Evaluation of a non-invasive respiratory monitoring system for sleeping subjects" Physiological Measurement (1999) 20(1): 53.

Chan, Adrian D.C., et al.; "Wavelet Distance Measure for Person Identification Using Electrocardiograms," IEEE Transactions on

Instrumentation and Measurement, IEEE Service Center, Piscataway, NJ, US, vol. 57, No. 2, Feb. 1, 2008, pp. 248-253.

Consolvo, Sunny et al., "Design Requirement for Technologies that Encourage Physical Activity," CHI 2006 Proceedings, Designing for Tangible Interactions, Apr. 22, 2006, Montreal, Quebec, Canada, pp. 457-466.

Coury, L. "Conductance Measurement Part 1: Theory"; Current Separations, 18:3 (1999) p. 91-96.

Delvaux et al., "Capsule endoscopy: Technique and indications" Clinical Gastroenterology; Oct. 2008 vol. 22, Issue 5, 1pp. (Abstract Only).

Description of ePatch Technology Platform for ECG and EMG, located at http://www.madebydelta.com/imported/images/DELTA_Web/documents/ME/ePatch_ECG_EMG.pdf, Dated Sep. 2, 2010.

Dhar et al., "Electroless nickel plated contacts on porous silicon" Appl. Phys. Lett. 68 (10) pp. 1392-1393 (1996).

Eldek A., "Design of double dipole antenna with enhanced usable bandwidth for wideband phased array applications" Progress in Electromagnetics Research PIER 59, 1-15 (2006).

Evanczuk, S., "PIC MCU software library uses human body for secure communications link"; EDN Network; <http://www.edn.com/electronics-products/other/4407842/PIC-MCU-software-library-uses-human-body-for-secure-communications-link>; Feb. 26, 2013; 5 pp.

Fawaz et al., "Enhanced Telemetry System using CP-QPSK Band-Pass Modulation Technique Suitable for Smart Pill Medical Application" IFIP IEEE Dubai Conference Apr. 2008; http://www.asic.fh-offenburg.de/downloads/ePille/IFIP_IEEE_Dubai_Conference.pdf.

Ferguson et al., "Dielectric Constant Studies III Aqueous Gelatin Solutions" J. Chem. Phys. 2, 94(1934) p. 94-98.

Ferguson et al., "Wireless communication with implanted medical devices using the conductive properties of the body," Expert Rev Med Devices, Jul. 2011, 8(4): 427-433.

Furse C. M., "Dipole Antennas" J. Webster (ed). Wiley Encyclopedia of Electrical and Electronics Engineering (1999) p. 575-581.

Gaglani S. "Put Your Phone, or Skin, on Vibrate" MedGadget; Mar. 2012 <http://medgadget.com/2012/03/put-your-phone-or-skin-on-vibrate.html> 8pp.

Gilson, D.R. "Molecular dynamics simulation of dipole interactions", Department of Physics, Hull University, Dec. 2002, p. 1-43.

Given Imaging, "Agile Patency Brochure" (2006) http://www.inclino.no/documents/AgilePatencyBrochure_Global_GMB-0118-01.pdf; 4pp.

Gonzalez-Guillaumin et al., "Ingestible capsule for impedance and pH monitoring in the esophagus" IEEE Trans Biomed Eng; Dec. 2007 54(12) 1pp. (Abstract Only).

Greene, "Edible RFID microchip monitor can tell if you take your medicine" Bloomberg Businessweek; Mar. 2010 2 pp.; <http://www.businessweek.com/idg/2010-03-31/edible-rfid-microchip-monitor-can-tell-if-you-take-your-medicine.html>.

Greene, "Medicaid Efforts to Incentivize Healthy Behaviours", Center for Health Care Strategies, Inc., Resource Paper, Jul. 2007.

Halhion Medical Technologies "Providing Ambulatory Medical Devices Which Monitor, Measure and Record" webpage. Online website: <http://www.halhion.com/>; downloaded May 30, 2012; 2 pp.

Herbig, S.M., "Asymmetric-membrane tablet coatings for osmotic drug delivery", Journal of Controlled Release 35 (1995) 127-136.

Heydari et al., "Analysis of the PLL jitter due to power/ground and substrate noise"; IEEE Transactions on Circuits and Systems (2004) 51(12): 2404-16.

Hoeksma, J. "New 'smart pill' to track adherence" E-Health-Insider; http://www.e-health-insider.com/news/5910/new_'smart_pill'_monitors_medicines; May 17, 2010 (2010); 1pp.

Hoover et al., "Rx for health: Engineers design pill that signals it has been swallowed" University of Florida News; Mar. 2010 2pp.; <http://news.ufl.edu/2010/03/31/antenna-pill-2/>.

Hotz "The Really Smart Phone" The Wall Street Journal, What They Know (2011); 6 pp.; http://online.wsj.com/article/SB10001424052748704547604576263261679848814.html?mod=djemTECH_t.

(56)

References Cited

OTHER PUBLICATIONS

- Intromedic, MicroCam Innovative Capsule Endoscope Pamphlet. (2006) 8 pp (<http://www.intromedic.com/en/product/productinfo.asp>).
- ISFET—Ion Sensitive Field-Effect Transistor; Microsens S.A. pdf document. Office Action dated Jun. 13, 2011 for U.S. Appl. No. 12/238,345; 4pp.
- Jimbo et al., "Gastric-fluid-utilized micro battery for micro medical devices" The Sixth International Workshop on Micro and Nanotechnology for Power Generation and Energy Conservation Applications, (2006) pp. 97-100.
- Jung, S. "Dissolvable 'Transient Electronics' Will Be Good for Your Body and the Environment" MedGadget; Oct. 1, 2012; Online website: <http://medgadget.com/2012/10/dissolvable-transient-electronics-will-be-good-for-your-body-and-the-environment.html>; downloaded Oct. 24, 2012; 4 pp.
- Juvenile Diabetes Research Foundation International (JDRF), "Artificial Pancreas Project" Jun. 2010; <http://www.artificialpancreasproject.com/>; 3 pp.
- Kamada K., "Electrophoretic deposition assisted by soluble anode" Materials Letters 57 (2003) 2348-2351.
- Kendle, Earl R. and Morris, Larry A., "Preliminary Studies in the Development of a Gastric Battery for Fish" (1964). Nebraska Game and Parks Commission White Papers, Conference Presentations, & Manuscripts. Paper 22. p. 1-6.
- Kim et al., "A Semi-Interpenetrating Network System for a Polymer Membrane"; Eur. Polym. J. vol. 33 No. 7; pp. 1009-1014 (1997).
- Lee, K. B.; "Two-step activation of paper batteries for high power generation: design and fabrication of biofluid- and wateractivated paper batteries"; J. Micromech. Microeng. 16 (2006) 2312-2317.
- Lee, K. B.; "Urine-activated paper batteries for Biosystems"; J. Micromech. Microeng. 15 (2005) S21 O-S214.
- Li, P-Y, et al. "An electrochemical intraocular drug delivery device", Sensors and Actuators A 143; p. 41-48.; Jul. 2007.
- Lifescan, "OneTouch UltraLink™" <http://www.lifescan.com/products/meters/ultralink>; Jul. 2010 2 pp.
- Lin et al., "Do Physiological Data Relate to Traditional Usability Indexes?" Proceedings of OZCHI 2005, Canberra, Australia (2005) 10 pp.
- Mackay et al., "Radio Telemetry from within the Body" Inside Information is Revealed by Tiny Transmitters that can be Swallowed or Implanted in Man or Animal Science (1991) 1196-1202; 134; American Association for the Advancement of Science, Washington D.C.
- Mackay et al., "Endoradiosonde" Nature, (1957) 1239-1240, 179 Nature Publishing Group.
- Mandryk et al., "A physiological approach for continuously modeling user emotion in interactive play environments" Proceedings of Measuring Behavior (2008) (Maastricht The Netherlands Aug. 26-29) 2 pp.
- Mandryk et al., "Objectively Evaluating Entertainment Technology" Simon Fraser University; CHI (2004) ACM 1-58113-703-6/04/0004; 2 pp.
- McDermott-Wells, P., "What is Bluetooth?"; IEEE Potentials, IEEE, New York, NY, vol. 23, No. 5, Dec. 1, 2004, pp. 33-35.
- McKenzie et al., "Validation of a new telemetric core temperature monitor" J. Therm. Biol. (2004) 29(7-8):605-11.
- Medtronic, "CareLink Therapy Management Software for Diabetes" Jul. 2010; <https://carelink.minimed.com/patient/entry.jsp?bhcp=1>; 1 pp.
- Medtronic, "Carelink™ USB" (2008) http://www.medtronicdiabetes.com/pdf/carelink_usb_factsheet.pdf 2pp.
- Medtronic "The New MiniMed Paradigm® REAL-Time Revel™ System" Aug. 2010 <http://www.medtronicdiabetes.com/products/index.html>; 2 pp.
- Medtronic, "Mini Med Paradigm® Revel™ Insulin Pump" Jul. 2010 <http://www.medtronicdiabetes.com/products/insulinpumps/index.html>; 2 pp.
- Medtronic, Mini Med Paradigm™ Veo™ System: Factsheet (2010). <http://www.medtronic-diabetes.com.au/downloads/Paradigm%20Veo%20Factsheet.pdf>; 4 pp.
- Melanson, "Walkers swallow RFID pills for science" Engadget; Jul. 2008; <http://www.engadget.com/2008/07/29/walkers-swallow-rfid-pills-for-science/>.
- Minimitter Co. Inc. "Actiheart" Traditional 510(k) Summary. Sep. 27, 2005.
- Minimitter Co. Inc. Noninvasive technology to help your studies succeed. Mini Mitter.com Mar. 31, 2009.
- Mini Mitter Co, Inc. 510(k) Premarket Notification Mini-Logger for Diagnostic Spirometer. 9-21 (1999).
- Mini Mitter Co, Inc. 510(k) Premarket Notification for VitalSense. Apr. 22, 2004.
- Minimitter Co. Inc. VitalSense Integrated Physiological Monitoring System. Product Description. Jul. 2005.
- Minimitter Co. Inc. VitalSense Wireless Vital Signs Monitoring. Temperatures.com Mar. 31, 2009.
- Mojaverian et al., "Estimation of gastric residence time of the Heidelberg capsule in humans: effect of varying food composition" Gastroenterology (1985) 89:(2): 392-7.
- O'Brien et al., "The Production and Characterization of Chemically Reactive Porous Coatings of Zirconium Via Unbalanced Magneton Sputtering" Surface and Coatings Technology (1996) 86-87; 200-206.
- Owano, N., "Study proposes smart sutures with sensors for wounds" PHYS.ORG. Aug. 2012. <http://phys.org/news/2012-08-smart-sutures-sensors-wounds.html>; 2pp.
- "PALO Bluetooth Baseband" PALO Bluetooth Resource Center; Retrieved from internet Dec. 12, 2012 at URL:<http://palowireless.com/bluearticles/baseband.asp>; first cited in Office Action dated Jan. 17, 2013 for EP08853901.0 (2013); 6pp.
- Park, "Medtronic to Buy MiniMed for \$3.7 Billion" (2001) HomeCare; http://homecaremag.com/mag/medical_medtronic_buy_minimed/; 2 pp.
- Platt, D., "Modulation and Deviation" AE6EO, Foothills Amateur Radio Society; Oct. 26, 2007; 61 pp.
- Radio Antennae, <http://www.erikdeman.de/html/sail018h.htm>; (2008) 5 pages.
- "RFID "pill" monitors marchers" RFID News; Jul. 2008 <http://www.rfidnews.org/2008/07/23/rfid-pill-monitors-marchers/>.
- Rolison et al., "Electrically conductive oxide aerogels: new materials in electrochemistry" J. Mater. Chem. (2001) 1, 963-980.
- Roulstone, et al., "Studies on Polymer Latex Films: I. A study of latex film morphology" Polymer International 24 (1991) pp. 87-94.
- Sammoura, F. et al., "Water-activated disposable and long shelf life microbatteries", Sensors and Actuators A 111 (2004) 79-86.
- Sanduleanu et al., "Octave tunable, highly linear, RC-ring oscillator with differential fine-coarse tuning, quadrature outputs and amplitude control for fiber optic transceivers" (2002) IEEE MTT-S International Microwave Symposium Digest 545-8.
- Santini, J.T. et al., "Microchips as controlled drug delivery-devices", Agnew. Chem. Int. Ed. (2000), vol. 39, p. 2396-2407.
- "SensiVida minimally invasive clinical systems" Investor Presentation Oct. 2009 28pp; <http://www.sensividamedtech.com/SensiVidaGeneralOctober09.pdf>.
- Sharma, et al., "The Future is Wireless: Advances in Wireless Diagnostic and Therapeutic Technologies in Gastroenterology," Gastroenterology, Elsevier, Philadelphia, PA, vol. 137, No. 2, Aug. 1, 2009, pp. 434-439.
- Shawgo, R.S. et al. "BioMEMS from drug delivery", Current Opinion in Solid State and Material Science 6; May 2002, p. 329-334.
- Shin et al., "A Simple Route to Metal Nanodots and Nanoporous Metal Films"; Nano Letters, vol. 2, No. 9 (2002) pp. 933-936.
- Shrivastava et al., "A New Platform for Bioelectronics-Electronic Pill", Cummins College, (2010); http://www.cumminscollege.org/downloads/electronics_and_telecommunication/Newsletters/Current%20Newsletters.pdf; First cited in third party client search conducted by Patent Eagle Search May 18, 2010 (2010).
- "Smartlife awarded patent for knitted transducer" Innovation in Textiles News: <http://www.innovationintextiles.com/articles/208.php>; 2pp. Aug. 2009.

(56)

References Cited

OTHER PUBLICATIONS

- "The SmartPill Wireless Motility Capsule" SMARTPILL, The Measure of GI Health; May 2010 http://www.smartpillcorp.com/index.cfm?pagepath=Products/The_SmartPill_Capsule&id=17814.
- Solanas et al., "RFID Technology for the Health Care Sector" Recent Patents on Electrical Engineering (2008) 1, 22-31.
- Soper, S.A. et al. "Bio-Mems Technologies and Applications", Chapter 12, "MEMS for Drug Delivery", p. 325-346 (2007).
- Swedberg, "University Team Sees Ingestible RFID Tag as a Boon to Clinical Trials" RFID Journal (2010) Apr. 27; <http://www.rfidjournal.com/article/view/7560/1>, 3pp.
- Tajalli et al., "Improving the power-delay performance in subthreshold source-coupled logic circuits" Integrated Circuit and System Design. Power and Timing Modeling, Optimization and Simulation, Springer Berlin Heidelberg (2008) 21-30.
- Tatbul et al., "Confidence-based data management for personal area sensor networks" ACM International Conference Proceeding Series (2004) 72.
- Tierney, M.J. et al "Electroreleasing Composite Membranes for Delivery of Insulin and other Biomacromolecules", J. Electrochem. Soc., vol. 137, No. 6, Jun. 1990, p. 2005-2006.
- Trutag, Technologies, Inc., Spectral Microtags for Authentication and Anti-Counterfeiting; "Product Authentication and Brand Protection Solutions"; <http://www.trutags.com/>; downloaded Feb. 12, 2013 (2013); 1 pp.
- Vonstetten, F. et al., "Biofuel cells as power generation for implantable devices", Pore. Eurosensors XX, (2006), pp. 22-225.
- Walkey, "Mosfet Structure and Processing"; 97.398* Physical Electronics Lecture 20.
- Watson, et al., "Determination of the relationship between the pH and conductivity of gastric juice" Physiol Meas. 17 (1996) pp. 21-27.
- Winter, J. et al. "The material properties of gelatin gels"; USA Ballistic Research Laboratories, Mar. 1975, p. 1-157.
- Wongmanerod et al., "Determination of pore size distribution and surface area of thin porous silicon layers by spectroscopic ellipsometry" Applied Surface Science 172 (2001) 117-125.
- Xiaoming et al., "A telemedicine system for wireless home health-care based on bluetooth and the internet" Telemedicine Journal and e-health (2004) 10(S2): S110-6.
- Yang et al., "Fast-switching frequency synthesizer with a discriminator-aided phase detector" IEEE Journal of Solid-State Circuits (2000) 35(10): 1445-52.
- Yao et al., "Low Power Digital Communication in Implantable Devices Using Volume Conduction of Biological Tissues" Proceedings of the 28th IEEE, EMBS Annual International Conference, Aug. 30-Sep. 3, 2006.
- Zhang, Y-T. et al., "Wireless Biomedical Sensing," Wiley Encyclopedia of Biomedical Engineering, 2006, pp. 1-9.
- Zimmerman, "Personal Area Networks: Near-field intrabody communication" IBM Systems Journal (1996) 35 (3-4):609-17.
- Zworkin, "A Radio Pill" Nature, (1957) 898, 179 Nature Publishing Group.
- Browne, et al., Let visuals tell the story: Medication adherence in patients with type II diabetes captured by a novel ingestion sensor platform, JMIR Mhealth Uhealth (Dec. 31, 2015), 3(4)e108:1-27.
- Frias, et al., Effectiveness of Digital Medicines to Improve Clinical Outcomes in Patients with Uncontrolled Hypertension and Type 2 Diabetes: Prospective, Open-Label, Cluster-Randomized Pilot Clinical Trial, J Med Internet Res (2017), 19(7):e246, pp. 1-16.
- Guimard et al., Design of a Novel Electrically Conducting Biocompatible Polymer with Degradable Linkages for Biomedical Applications, MRS Proceedings, 950, 0950-D09-08. (Year: 2006).
- Kang, et al., Tungsten/copper composite deposits produced by a cold sputter, Scripta Materialia (2003), 49:1169-1174.
- Martins, et al., Polypyrrole coatings as a treatment for zinc-coated steel surfaces against corrosion, Corrosion Science (Apr. 22, 2004), 46:2361-2381.
- Noble et al., Medication adherence and activity patterns underlying uncontrolled hypertension: Assessment and recommendations by practicing pharmacists using digital health care, Journal of the American Pharmacists Association (2016), 56:310-315.
- Rivers et al., Synthesis of a Novel, Biodegradable Electrically Conducting Polymer for Biomedical Applications, Adv. Funct. Mater. (Jan. 2002), 12(1):33-37.
- Savage, Predictive Analytics: Advancing Precision and Population Medicine, Harvard Health Policy Review (2015), 14(2):1-4.

* cited by examiner

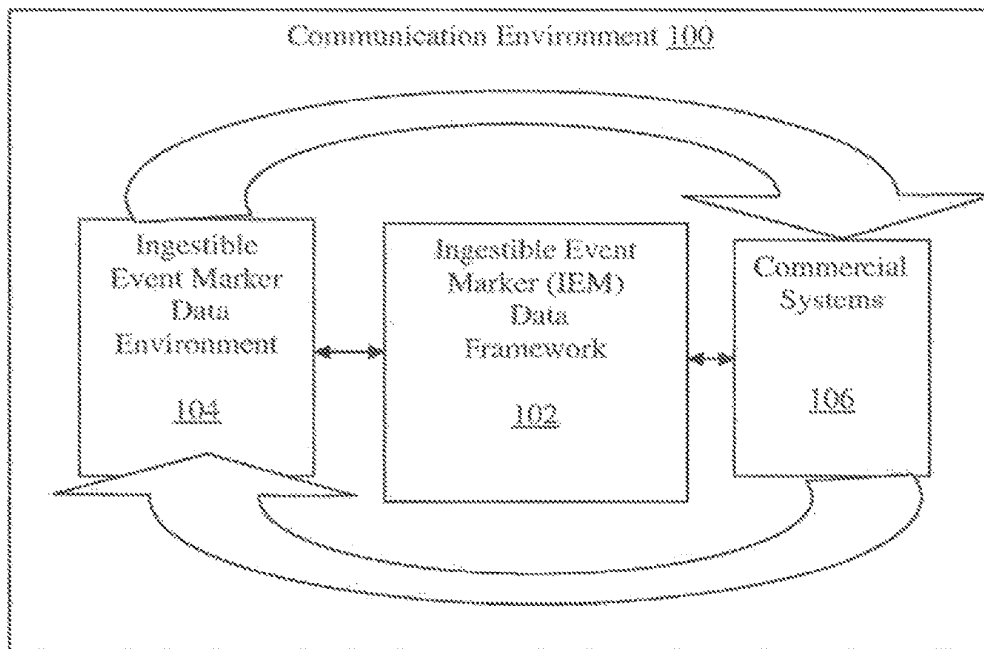


FIG. 1

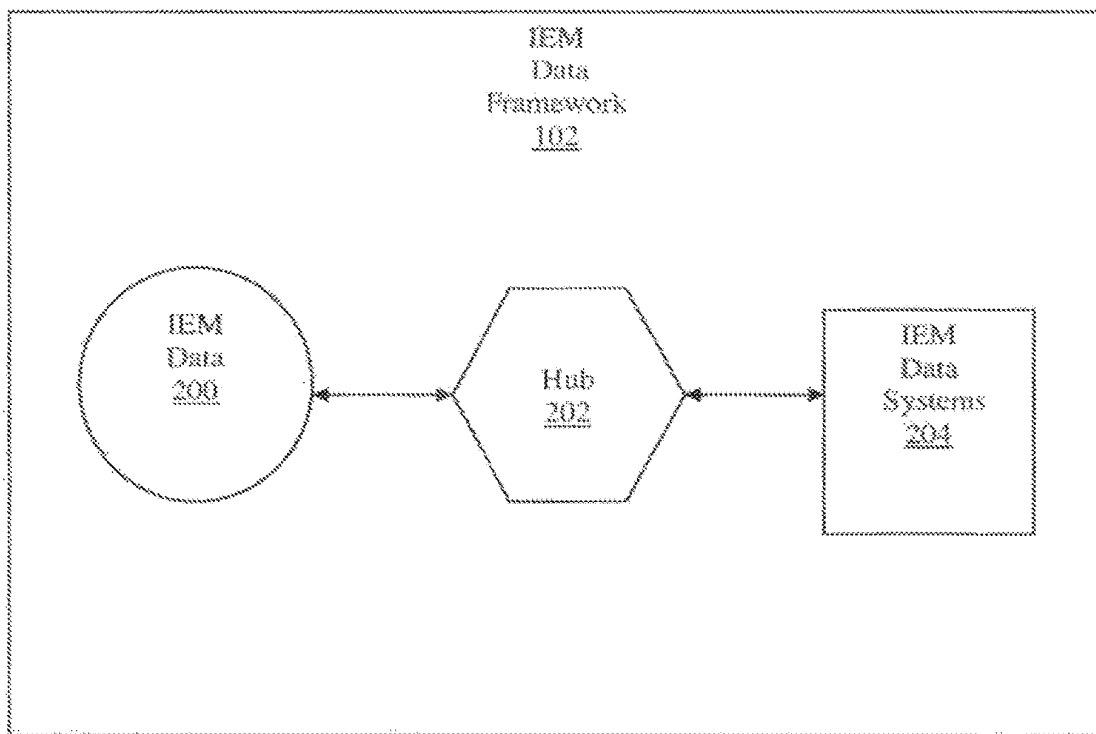


FIG. 2

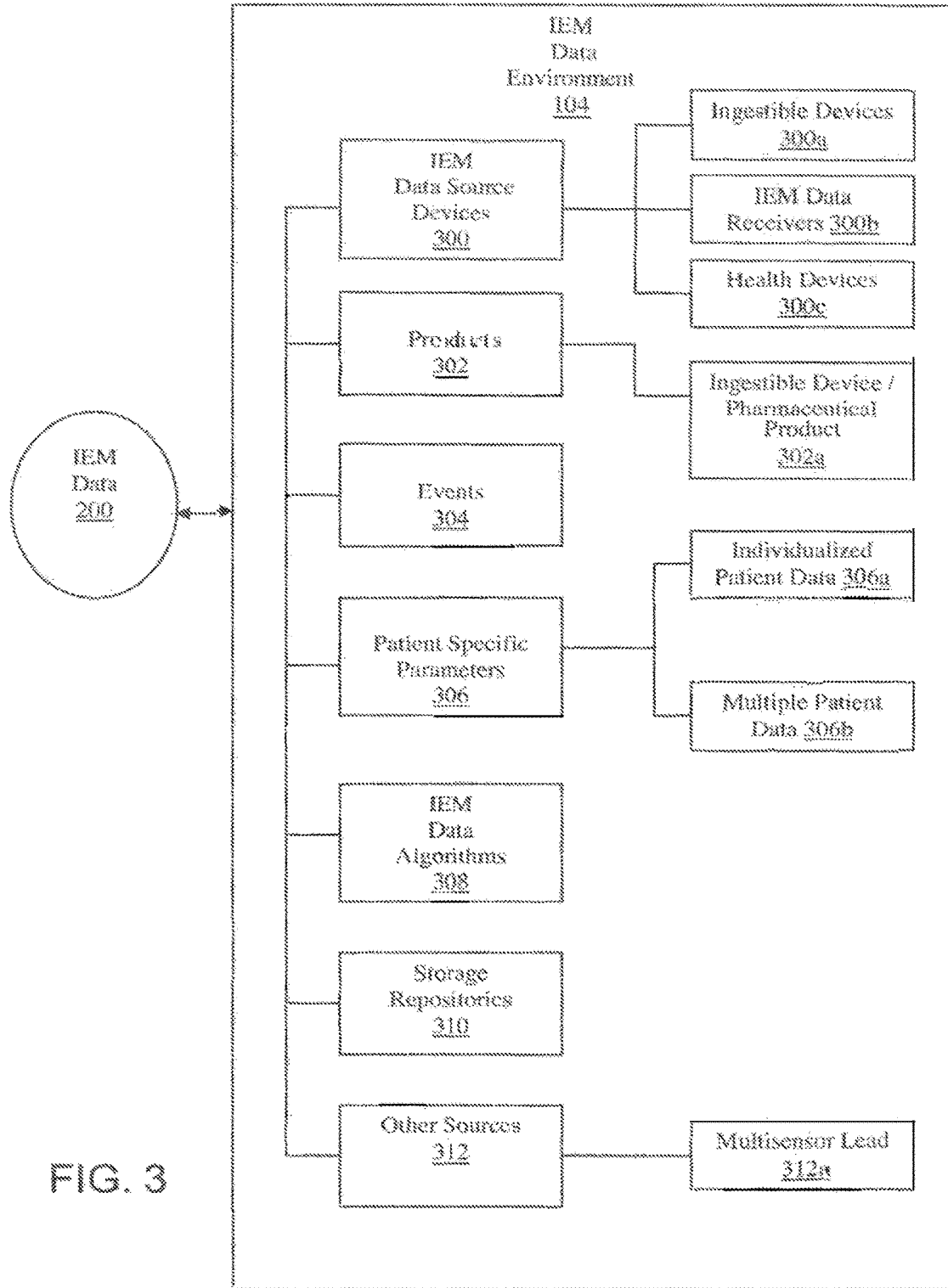


FIG. 3

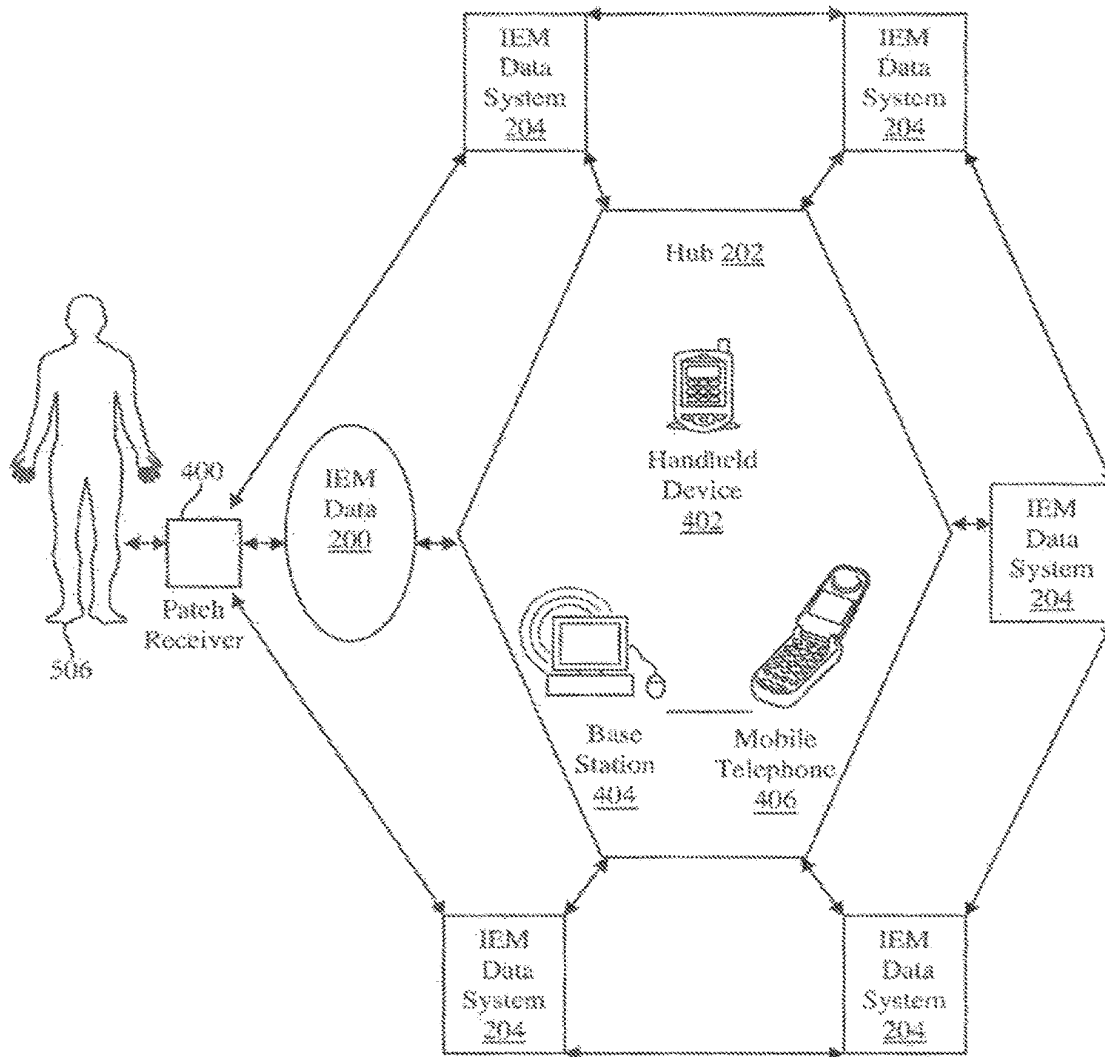


FIG. 4

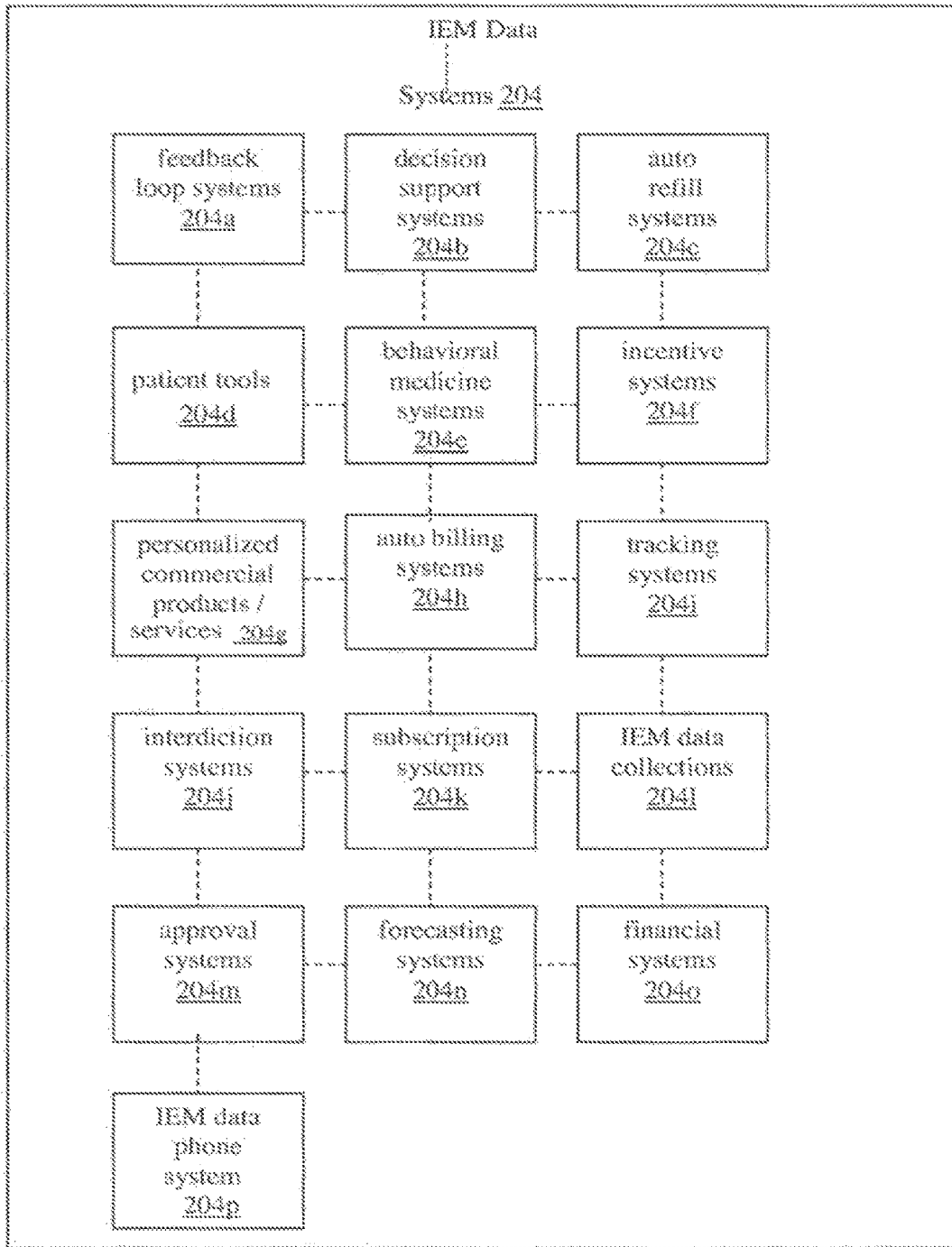


FIG. 5

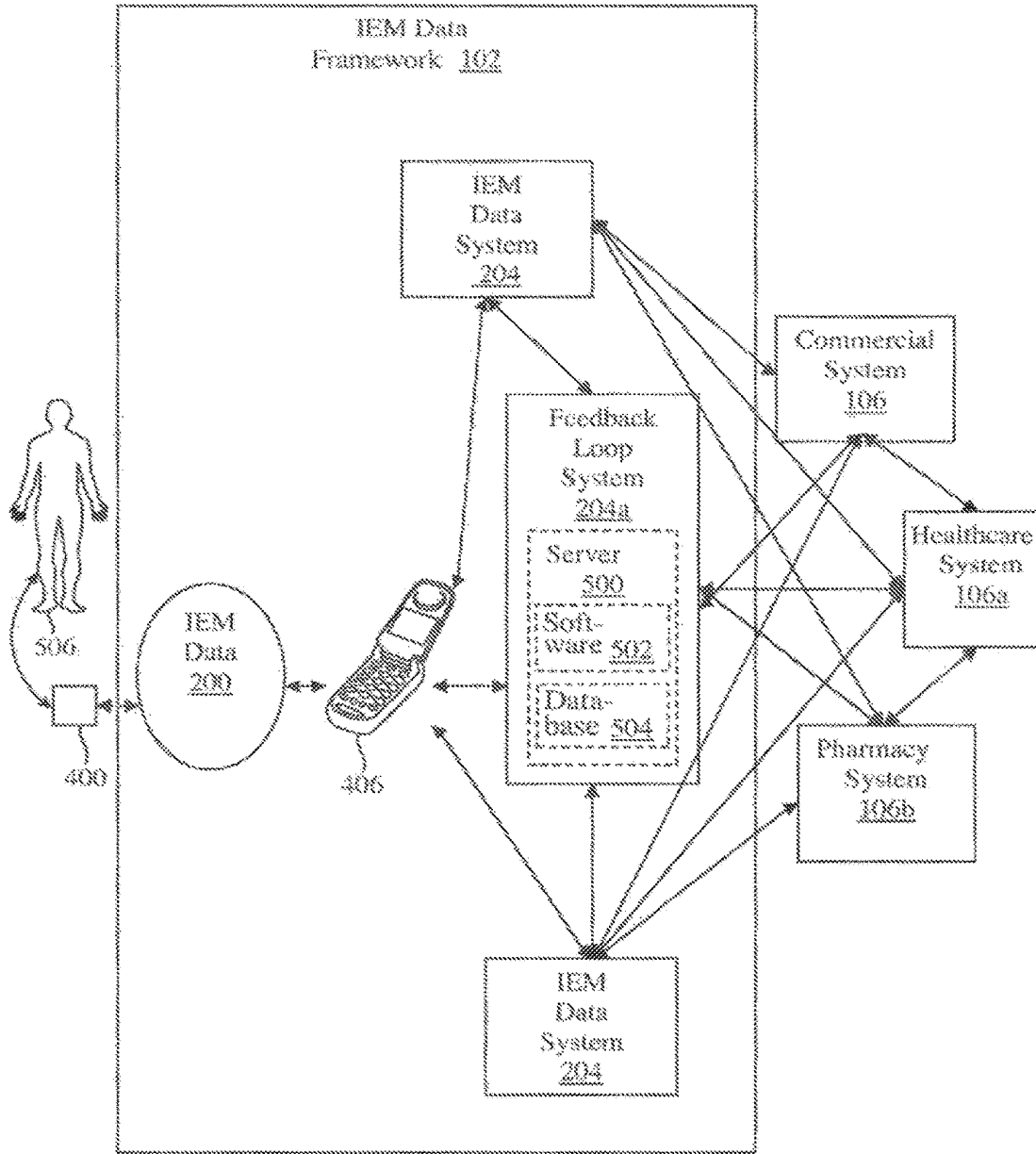


FIG. 6

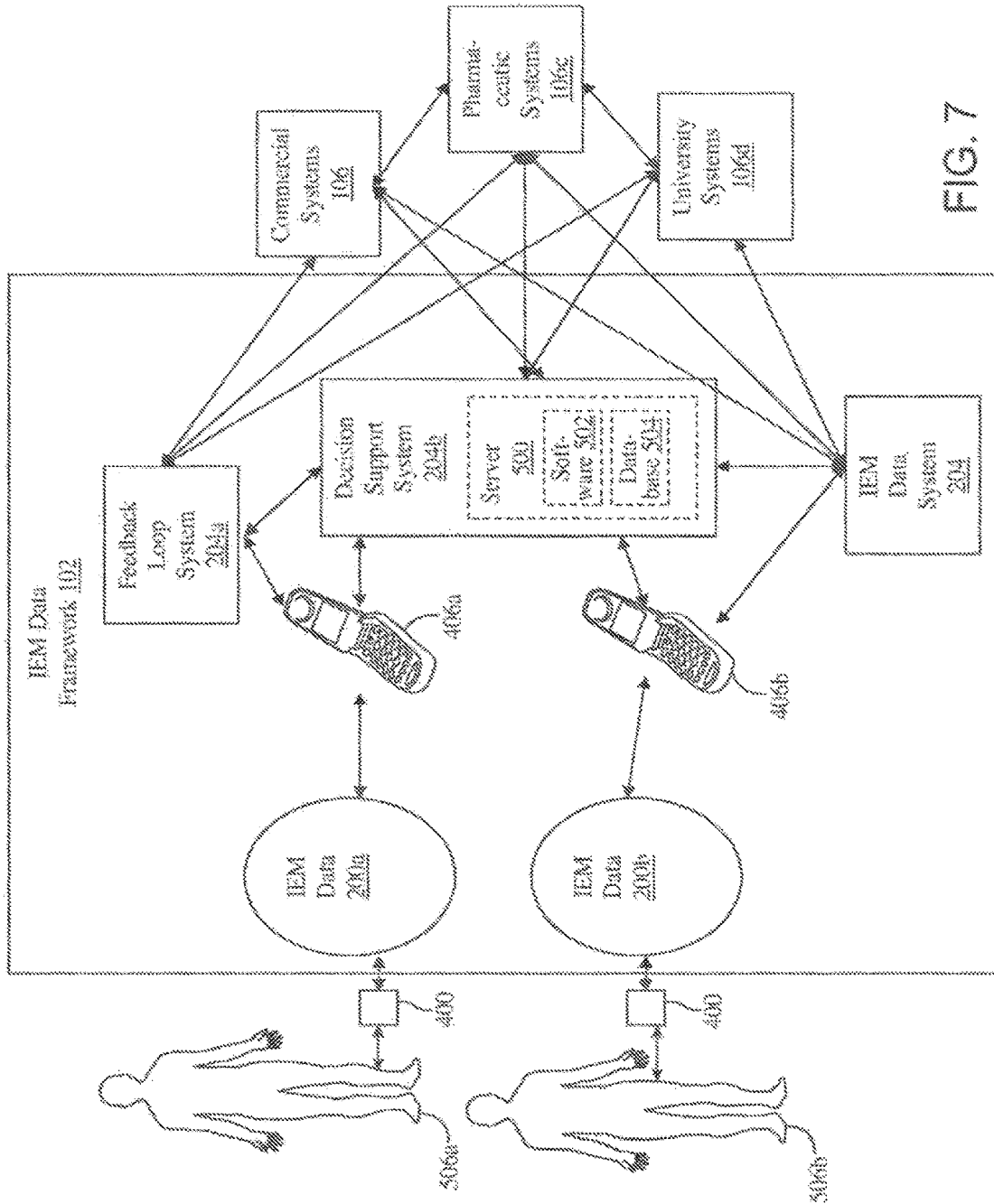


FIG. 7

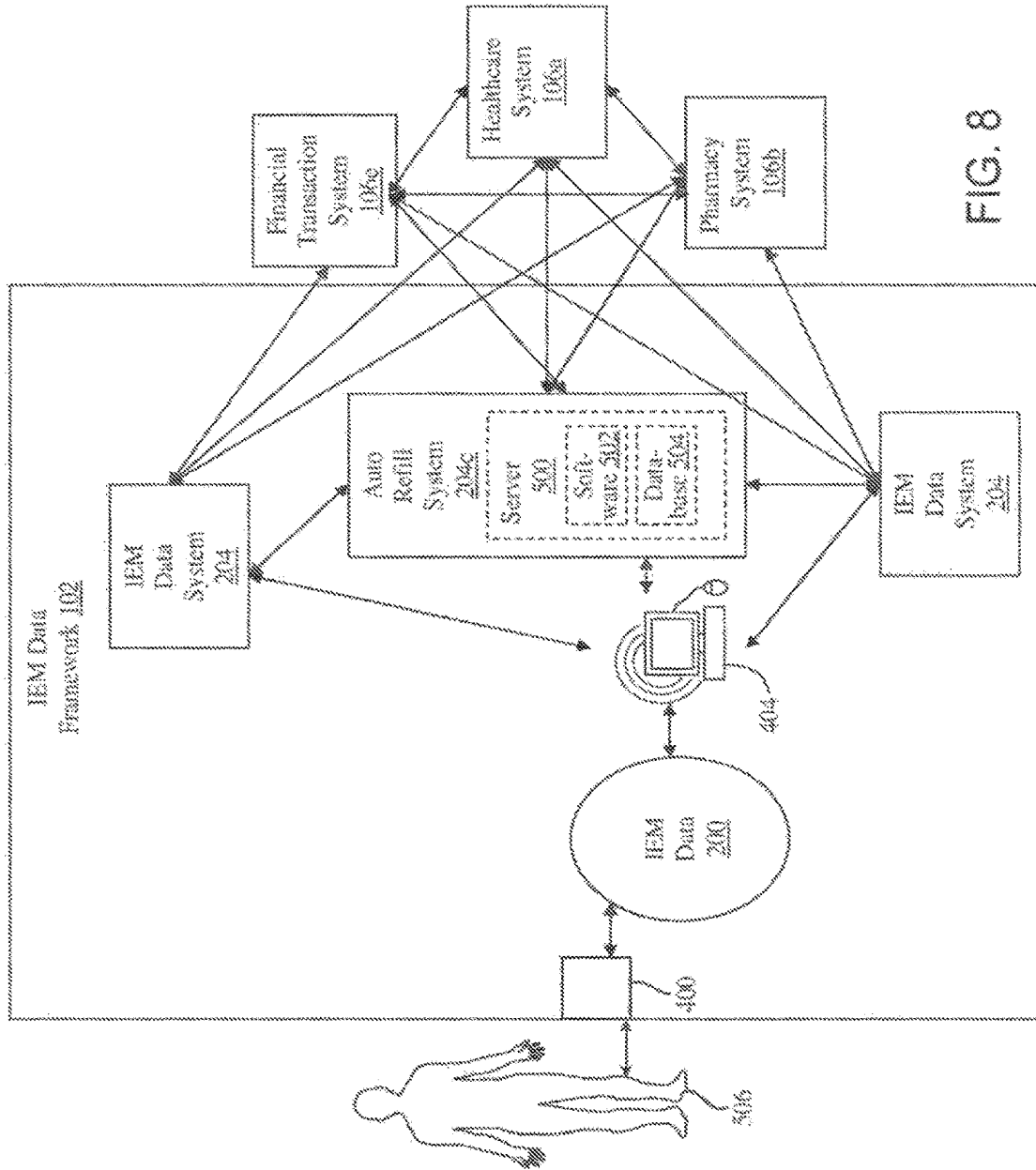


FIG. 8

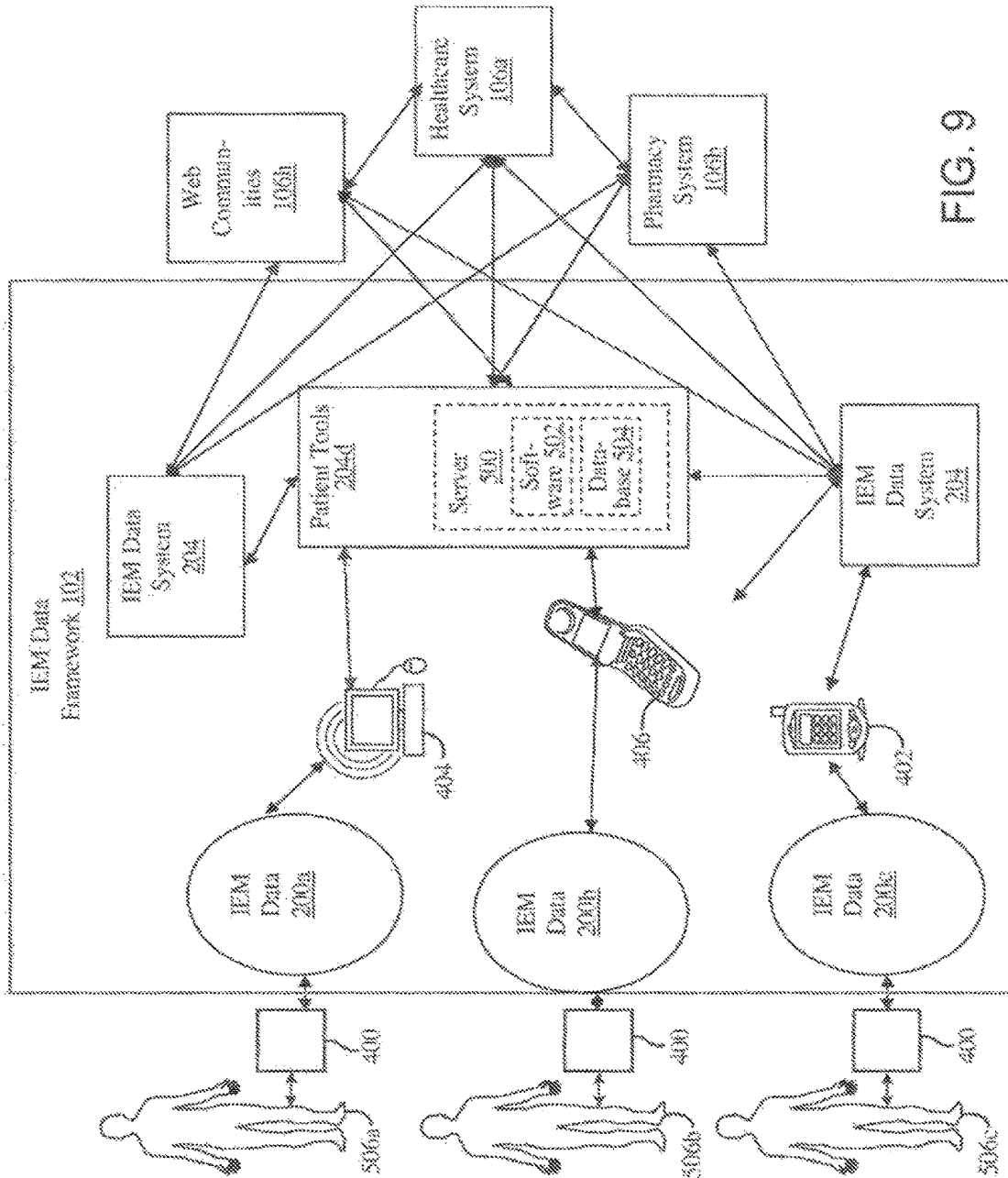


FIG. 9

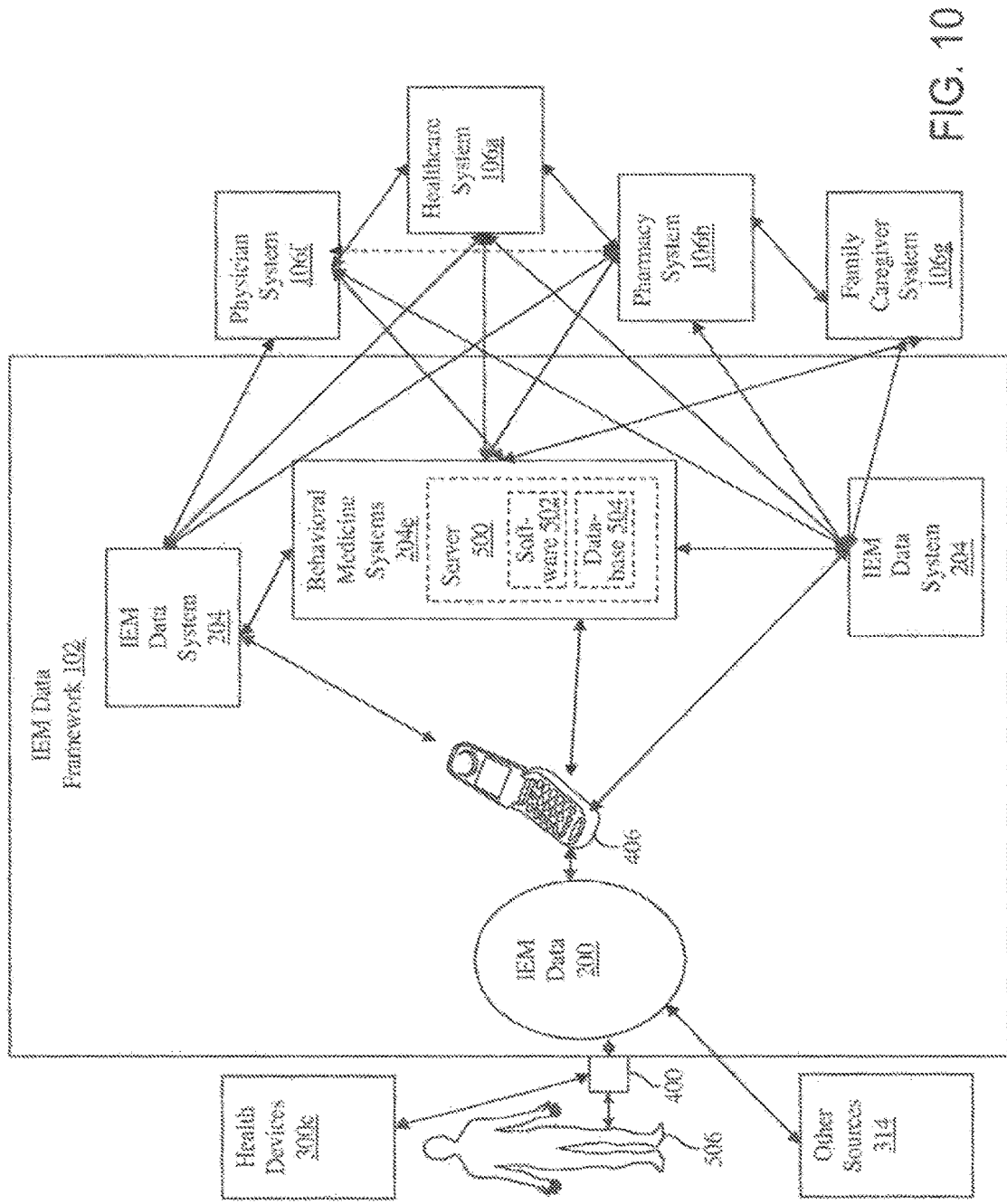


FIG. 10

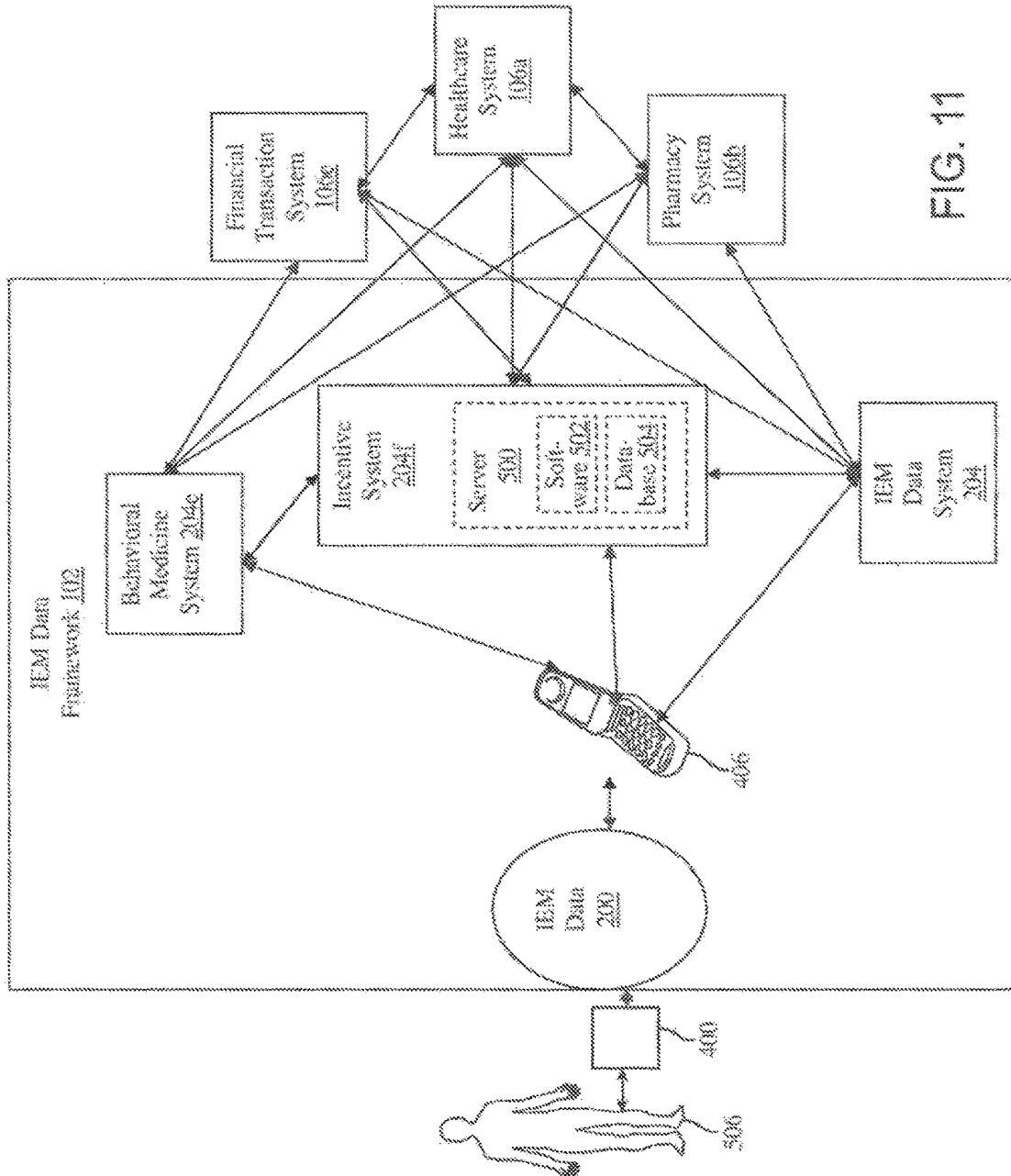


FIG. 11

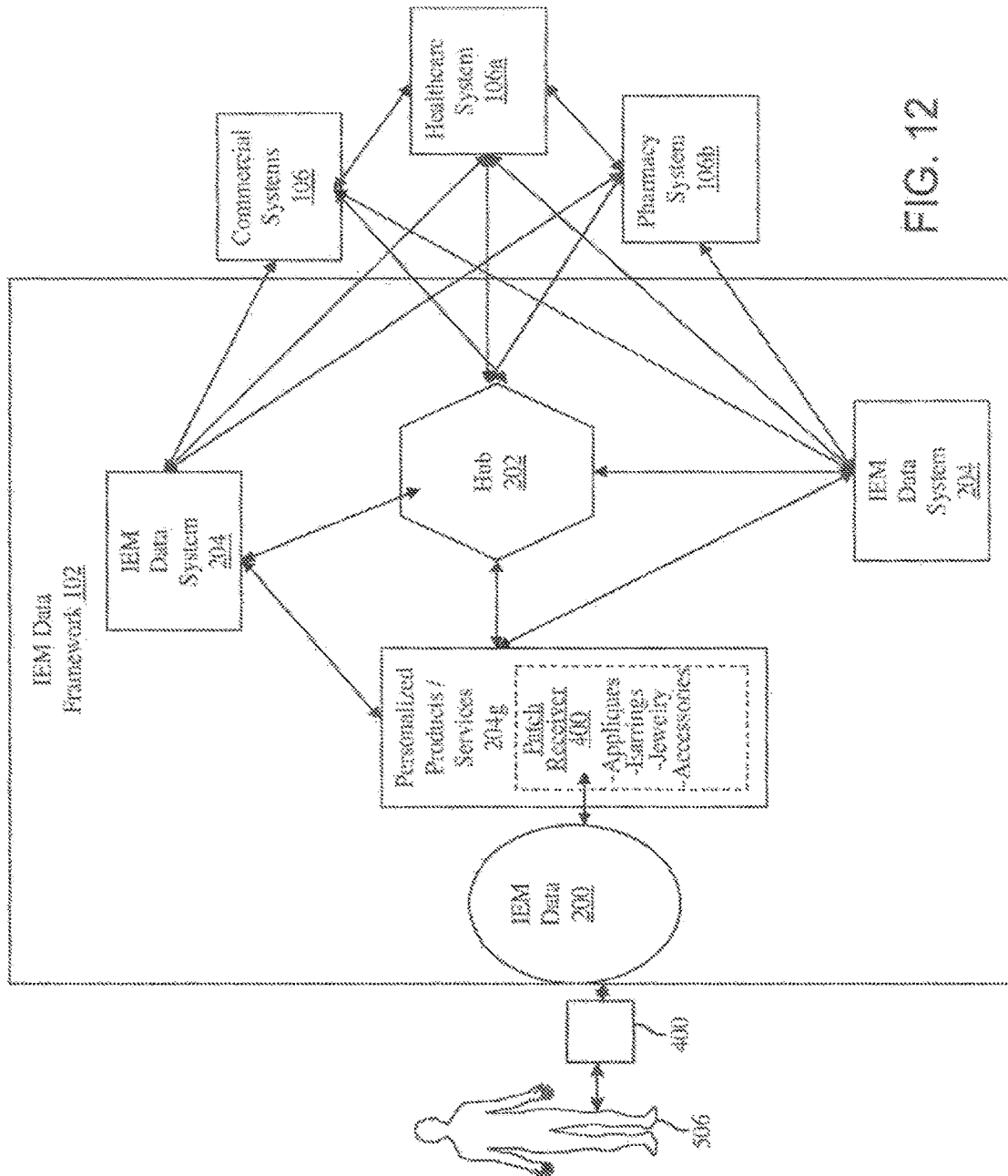


FIG. 12

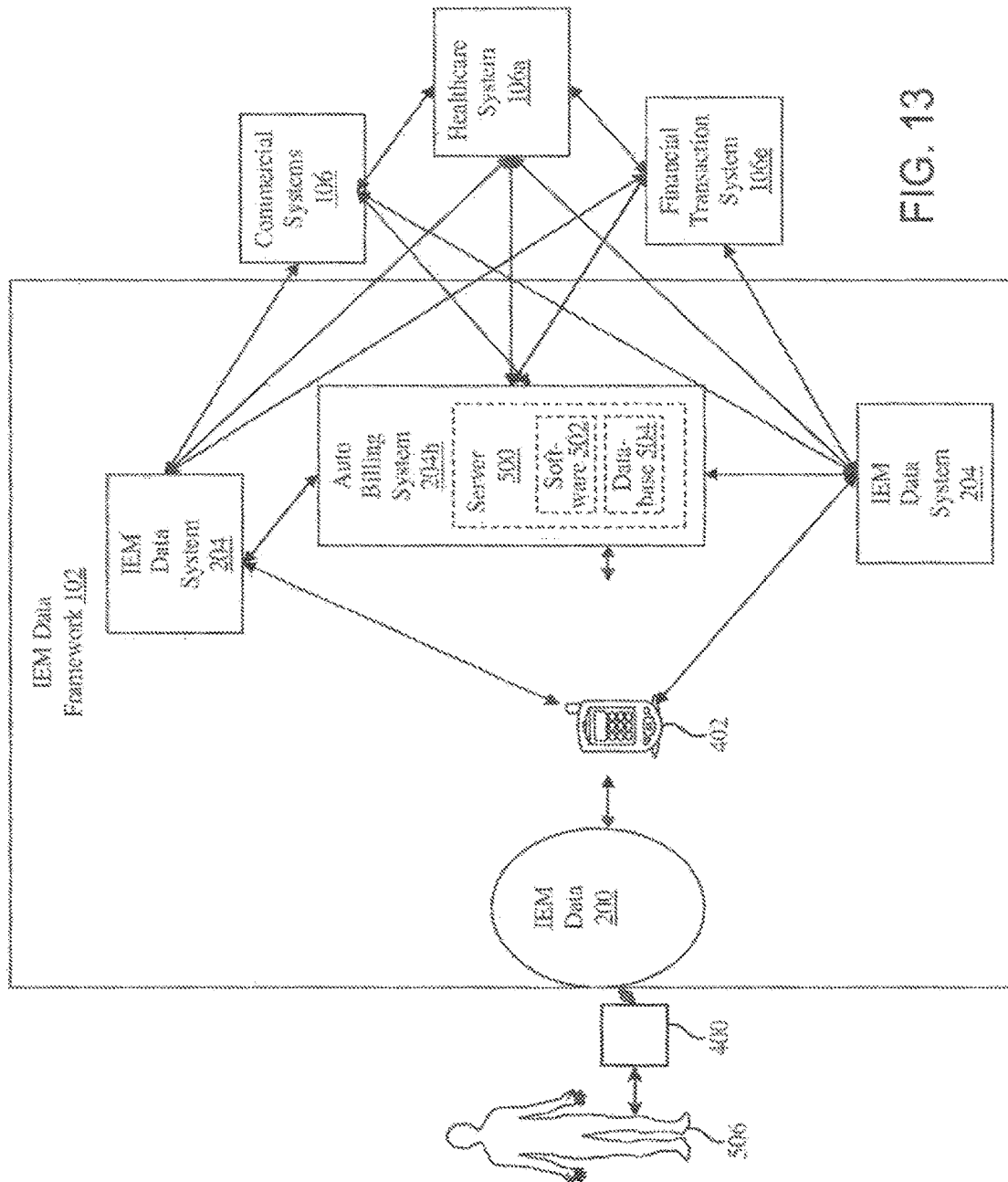


FIG. 13

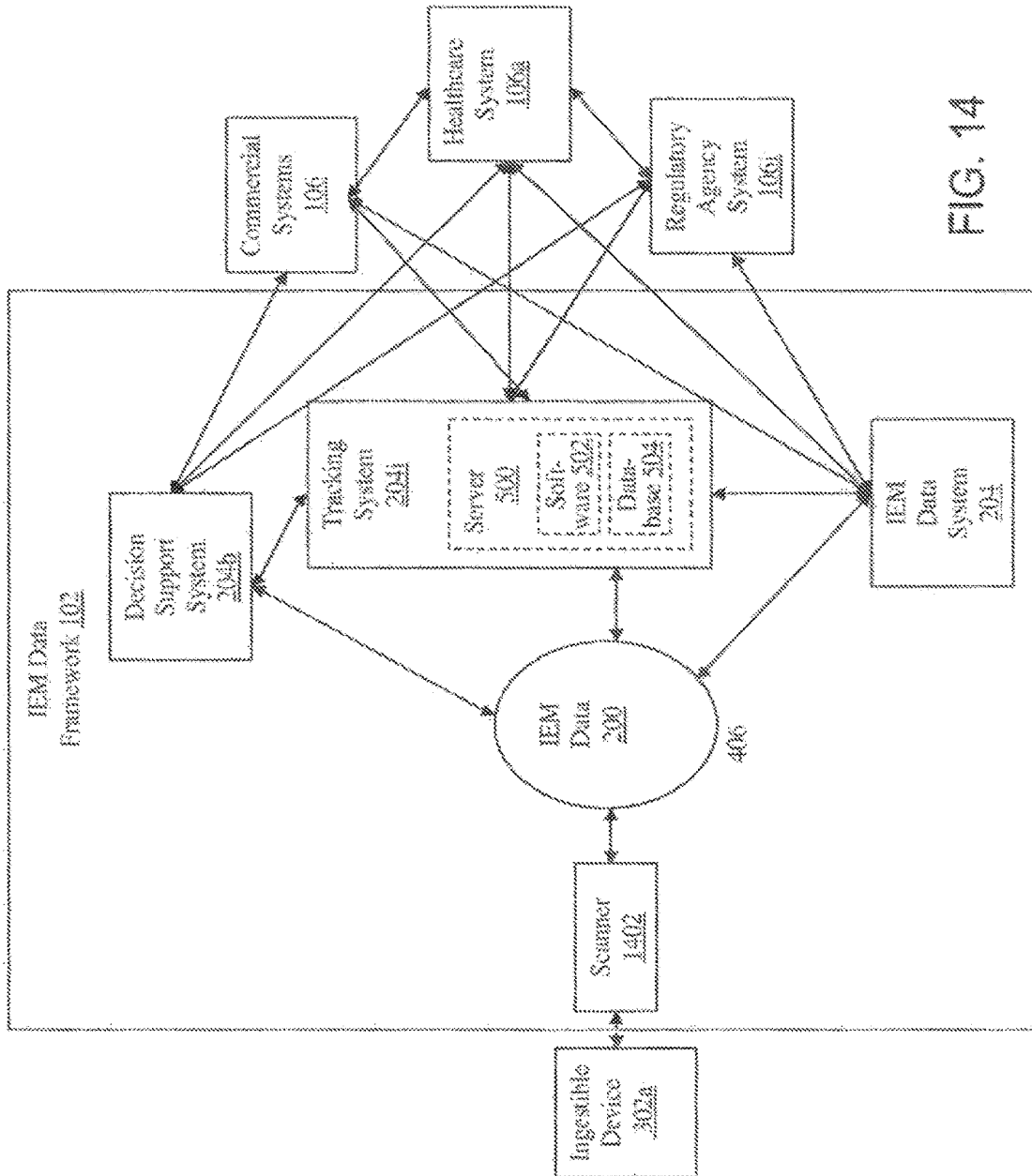


FIG. 14

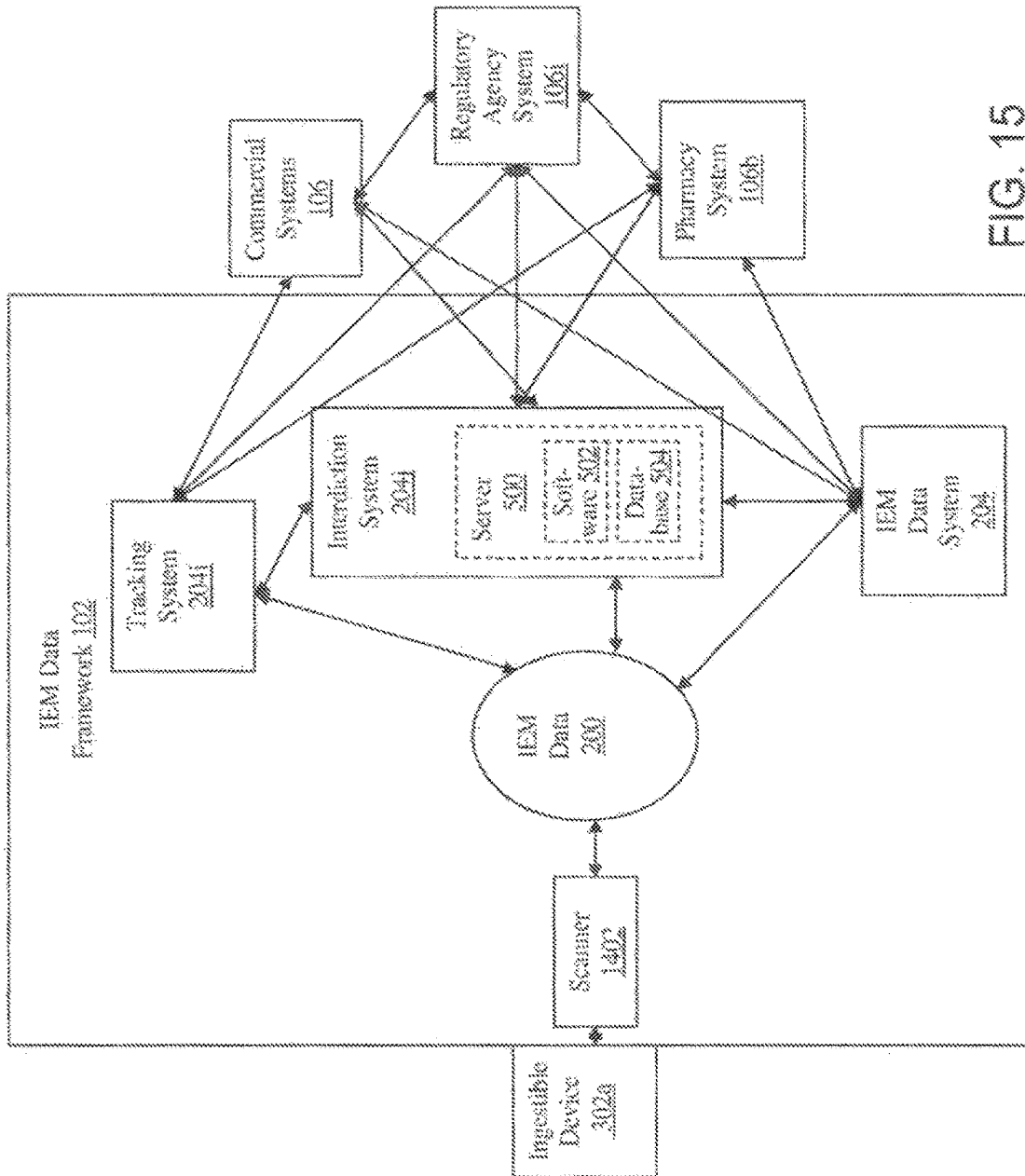


FIG. 15

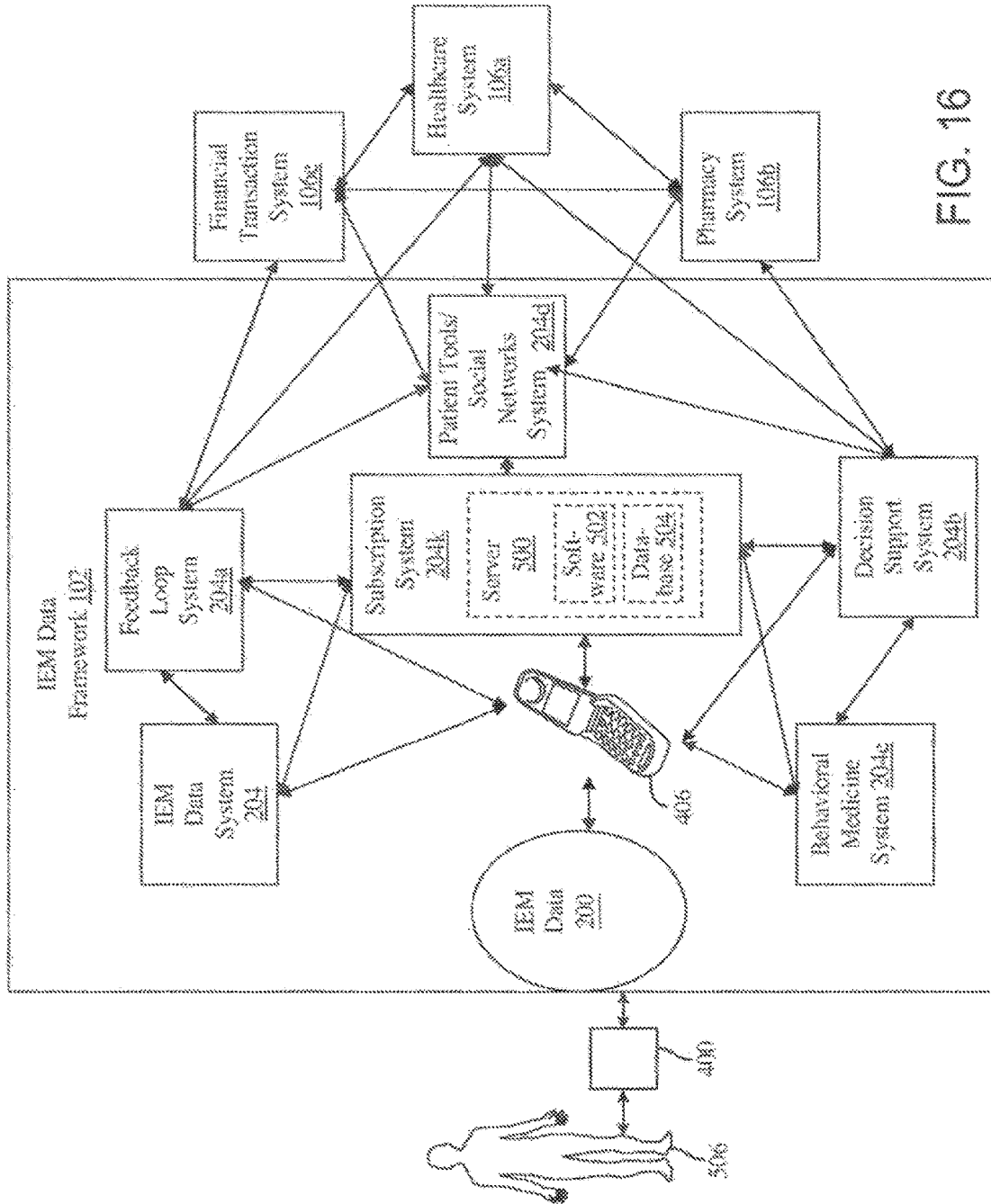


FIG. 16

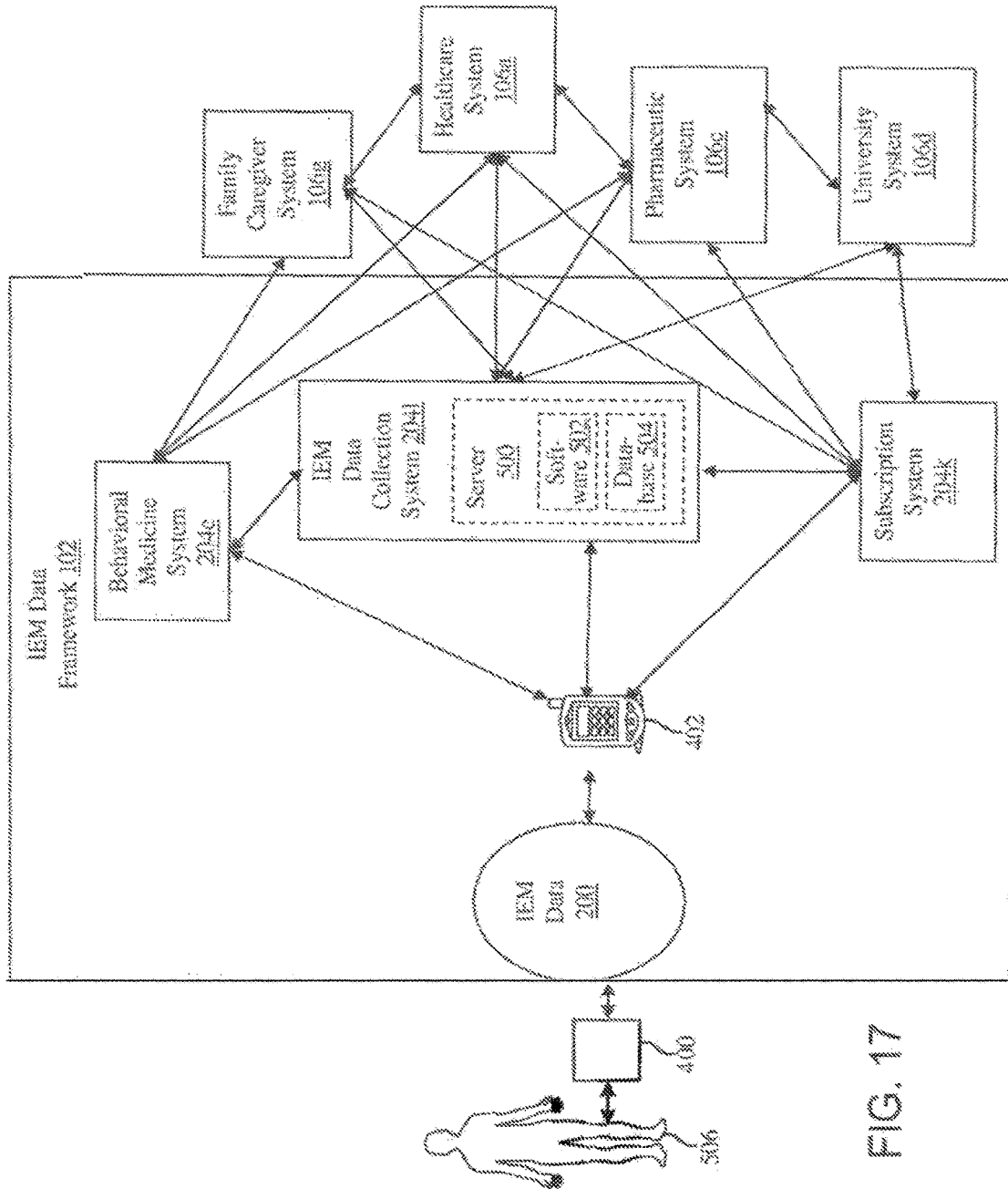


FIG. 17

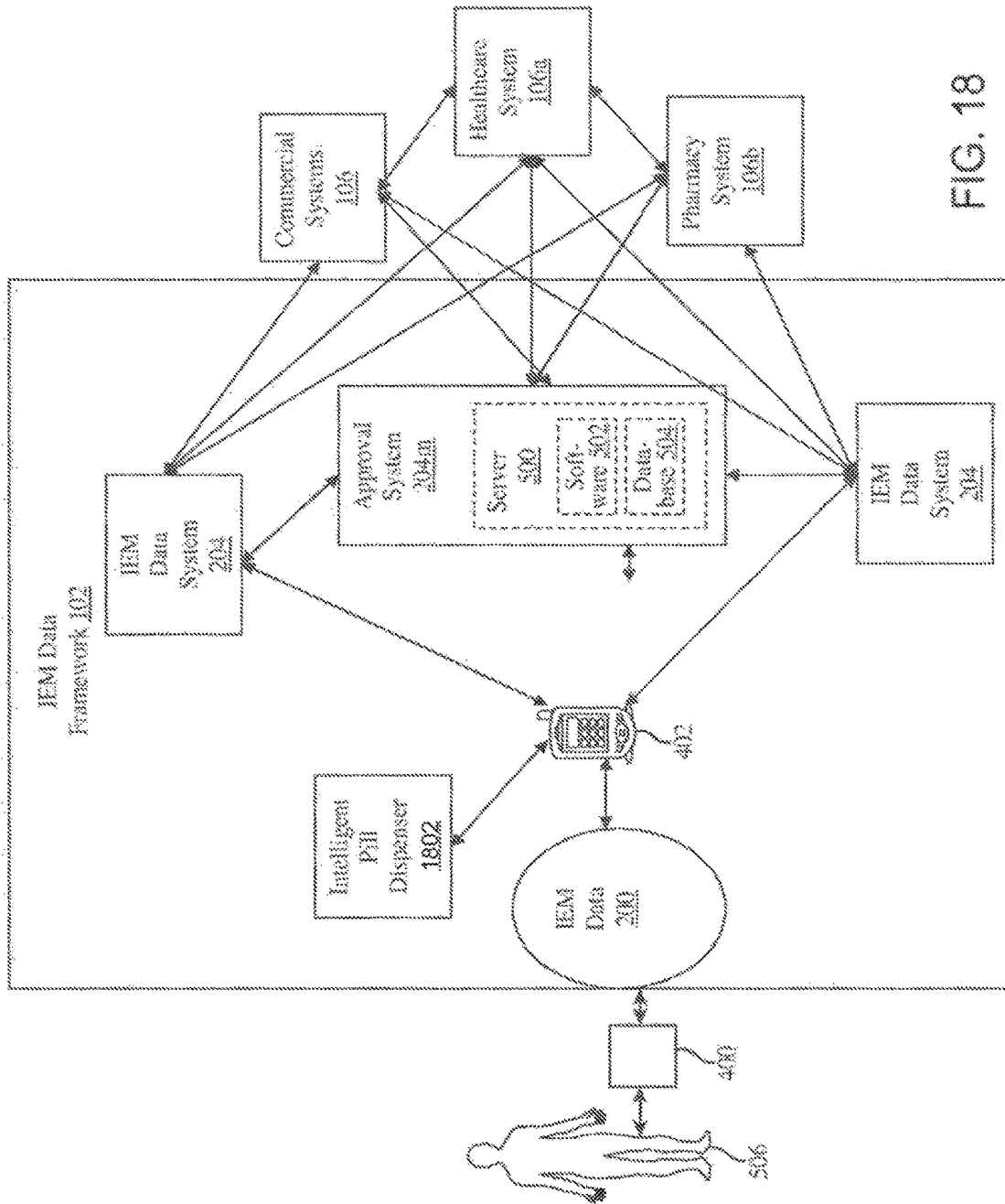


FIG. 18

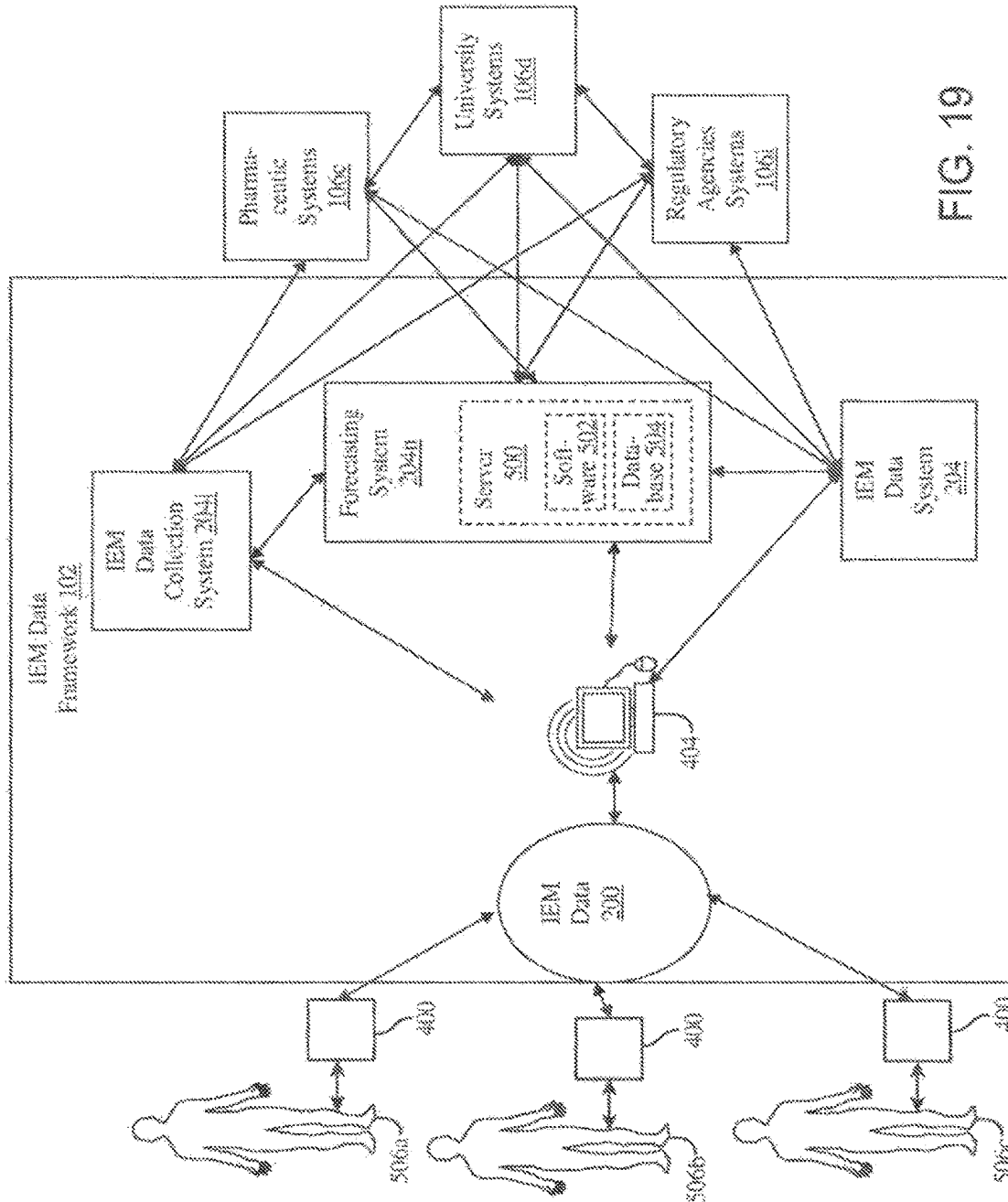


FIG. 19

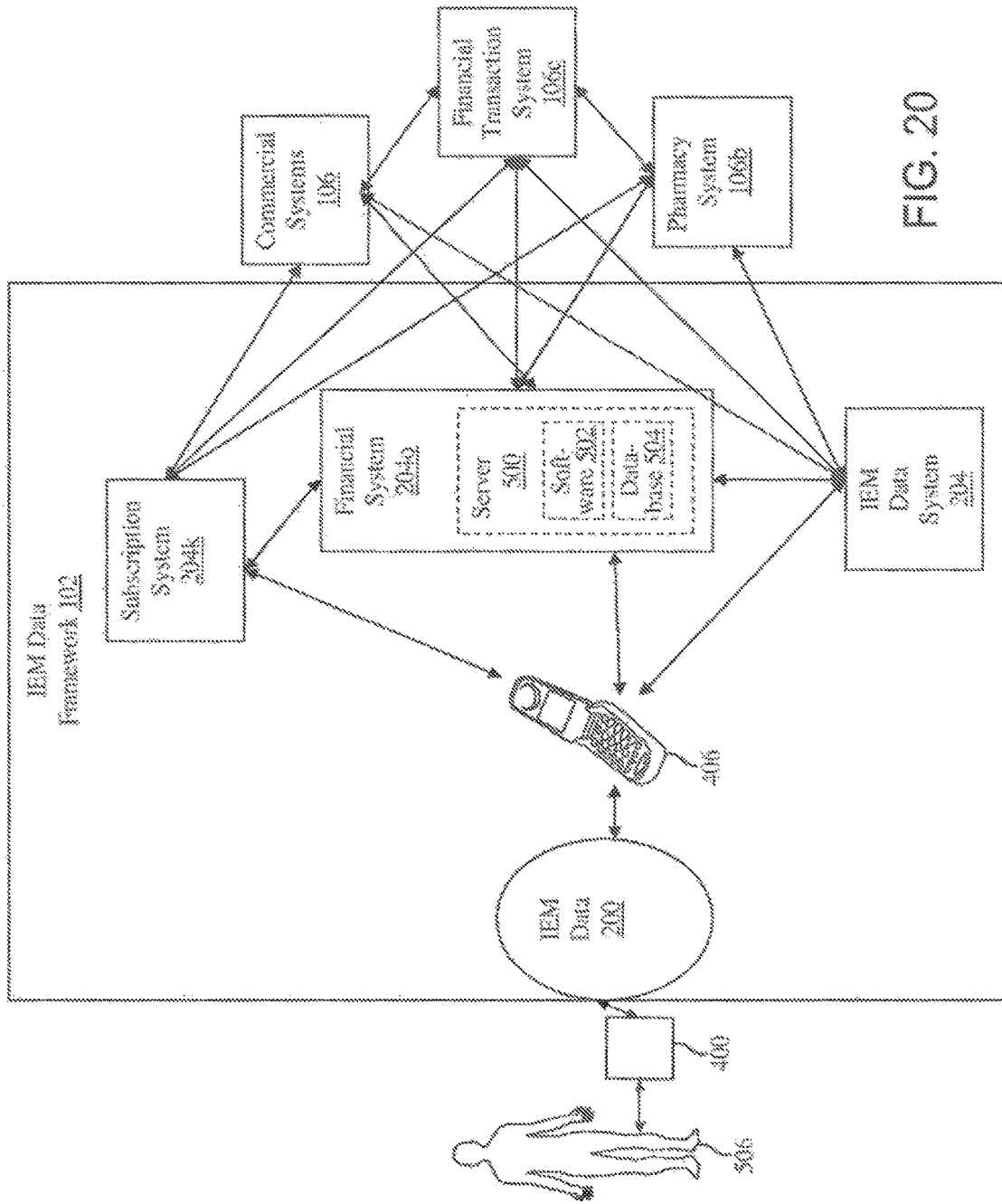


FIG. 20

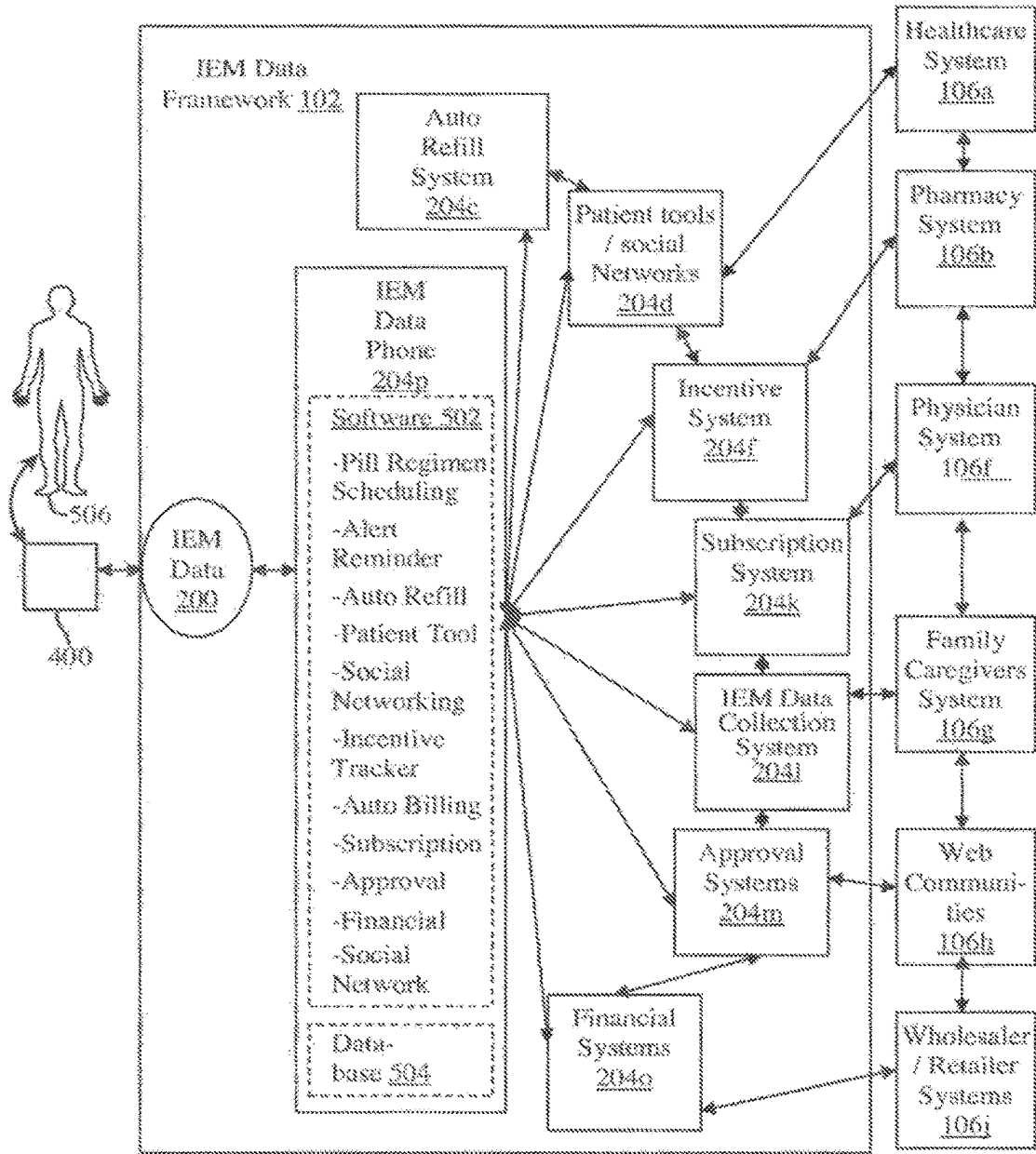


FIG. 21

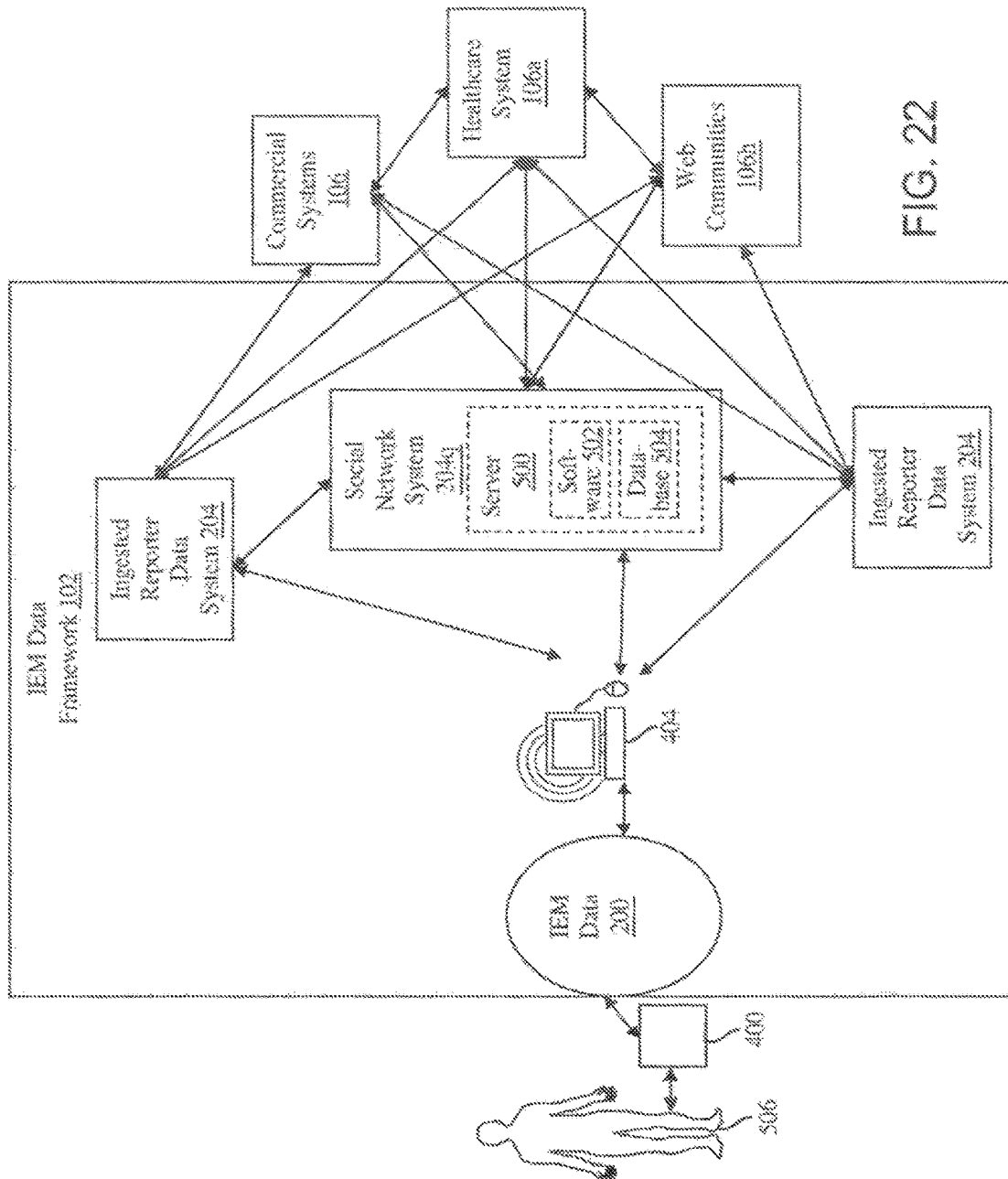


FIG. 22

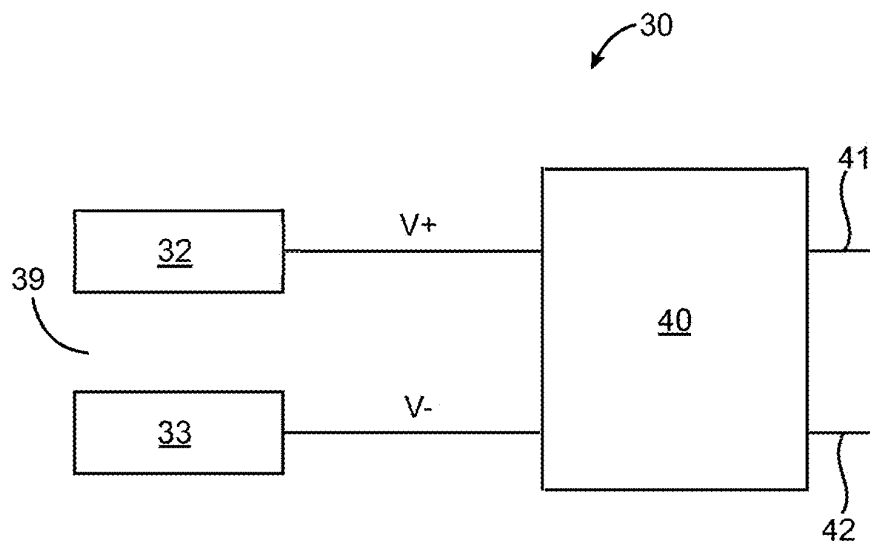


FIG. 23

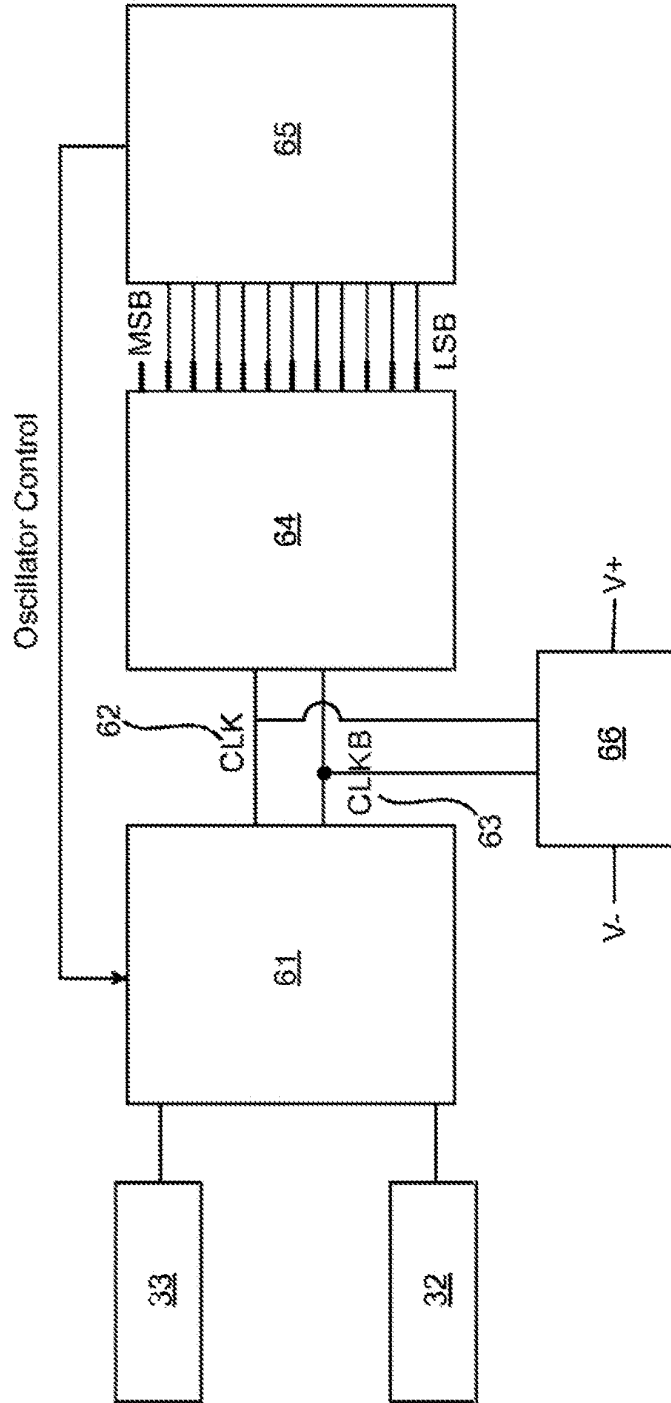


FIG. 24

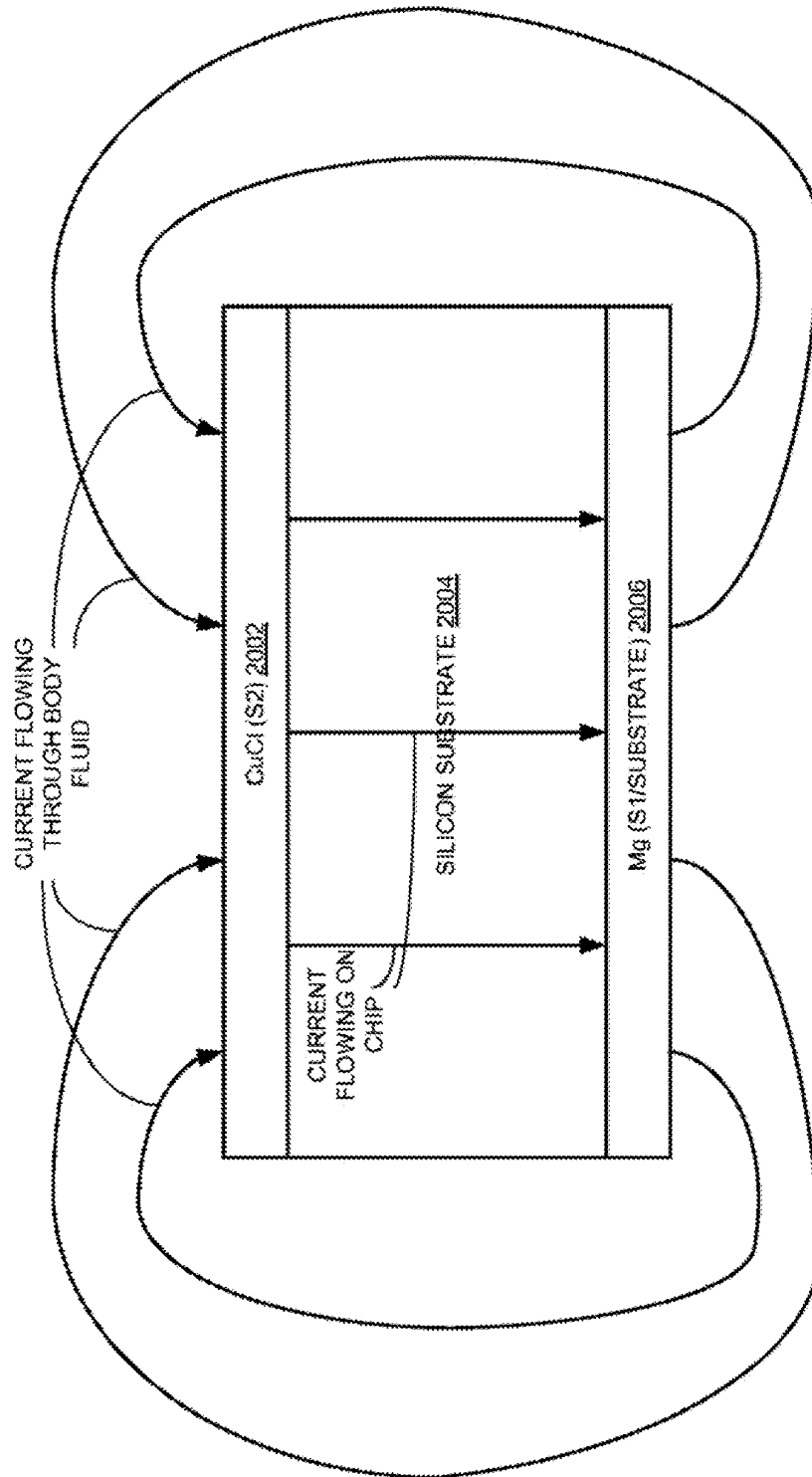


FIG. 25

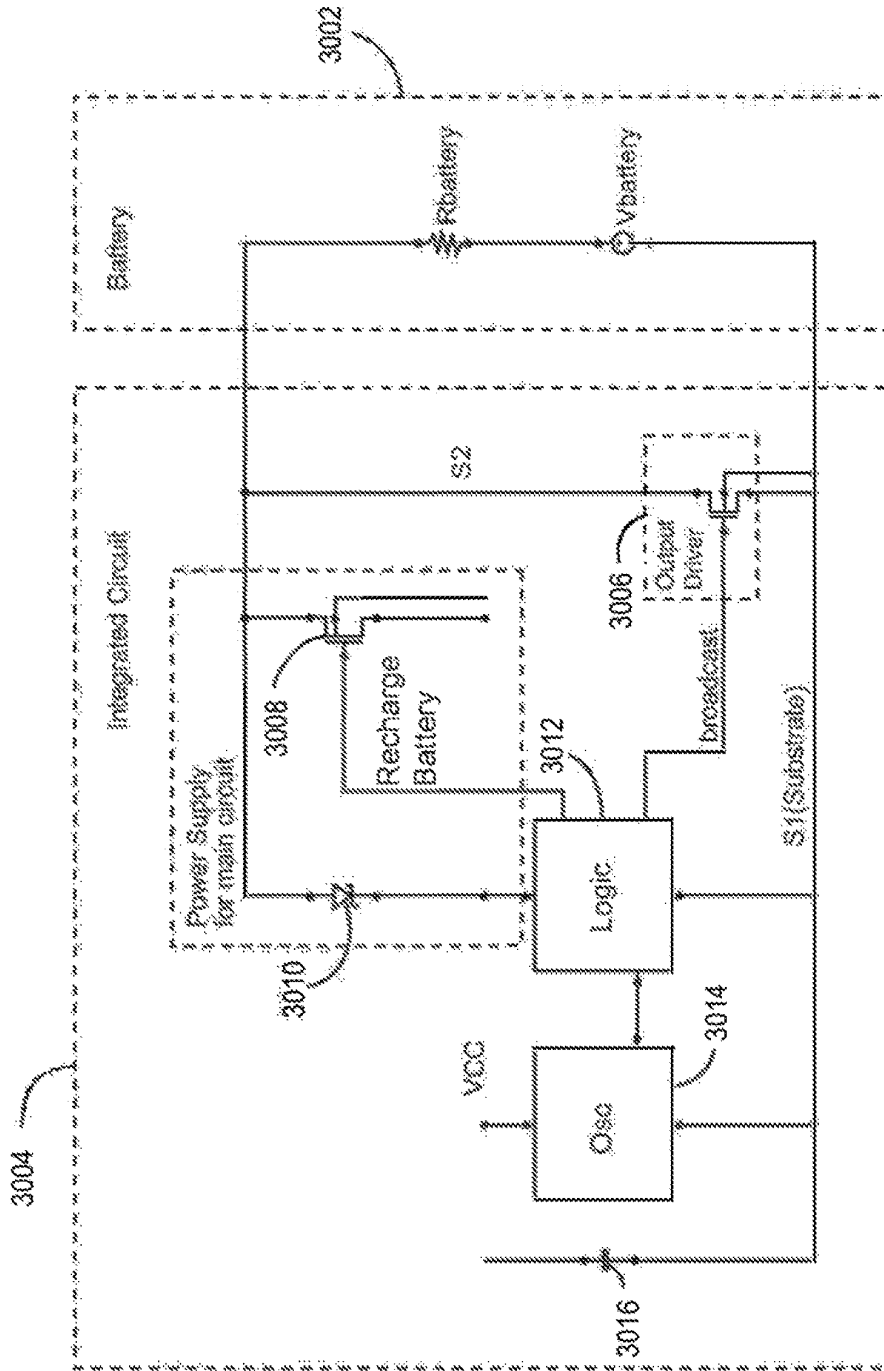


FIG. 26

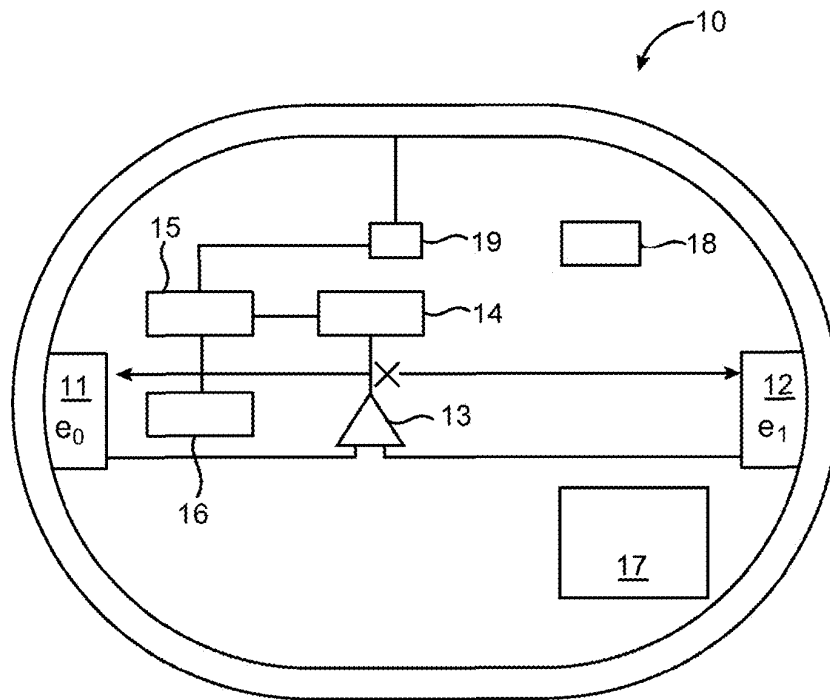


FIG. 27

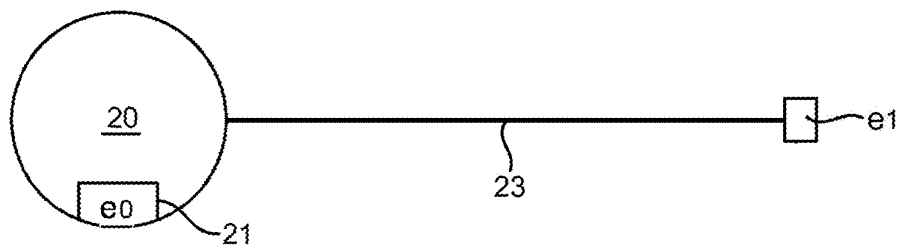


FIG. 28

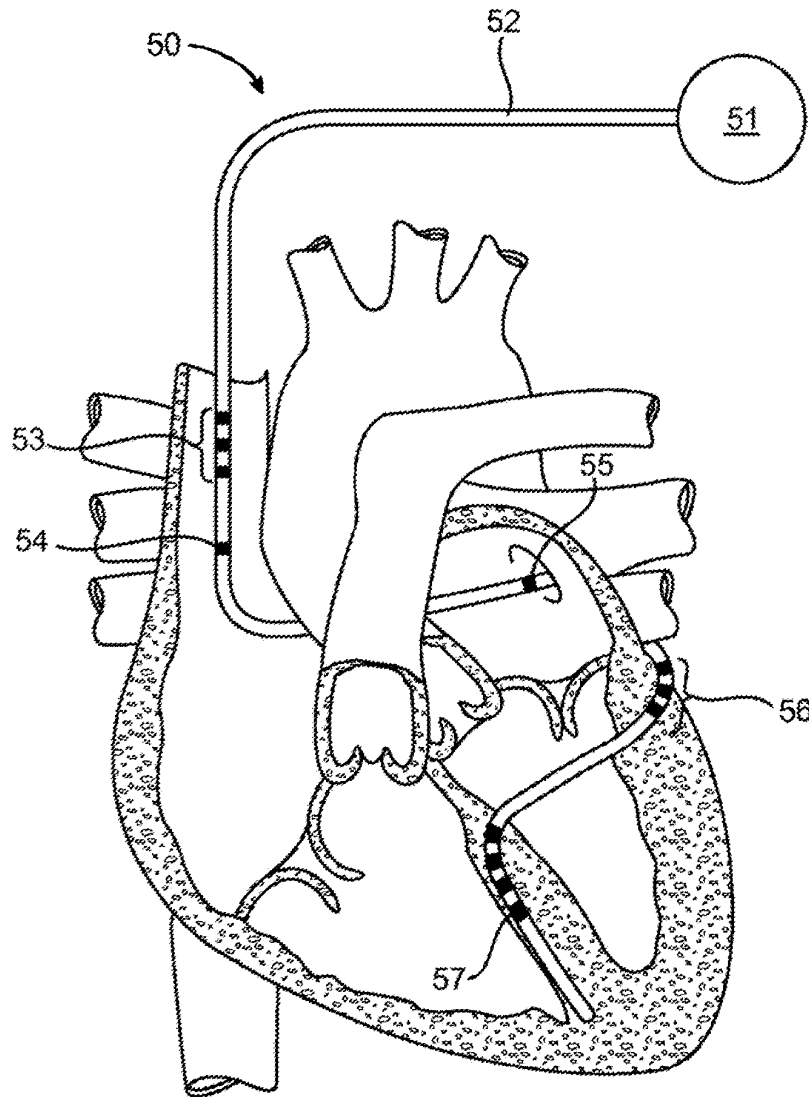


FIG. 29

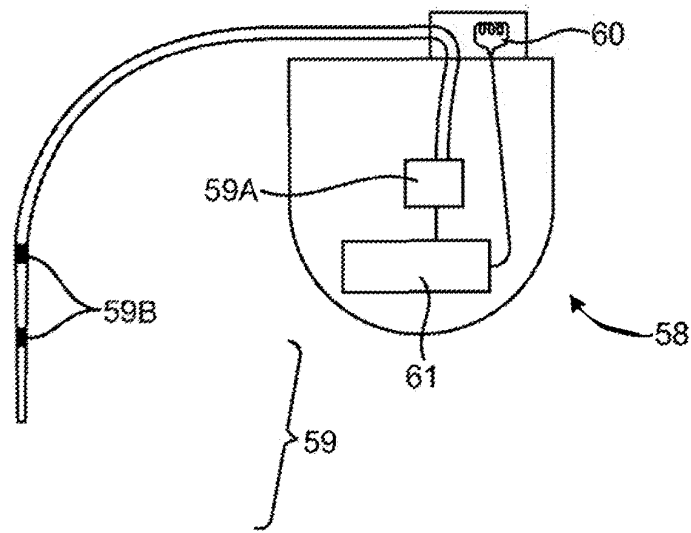


FIG. 30

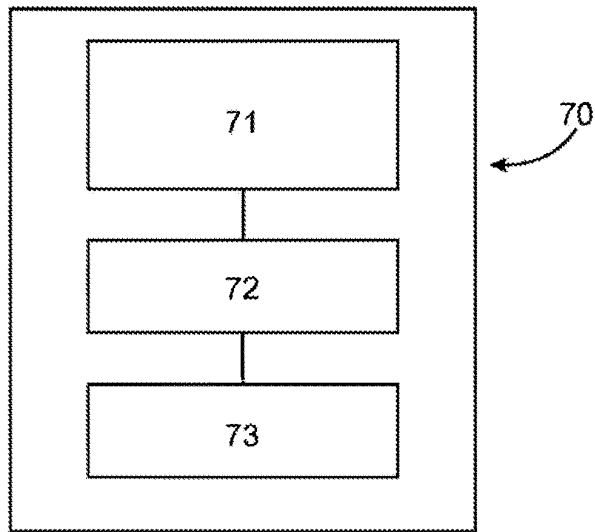


FIG. 31A

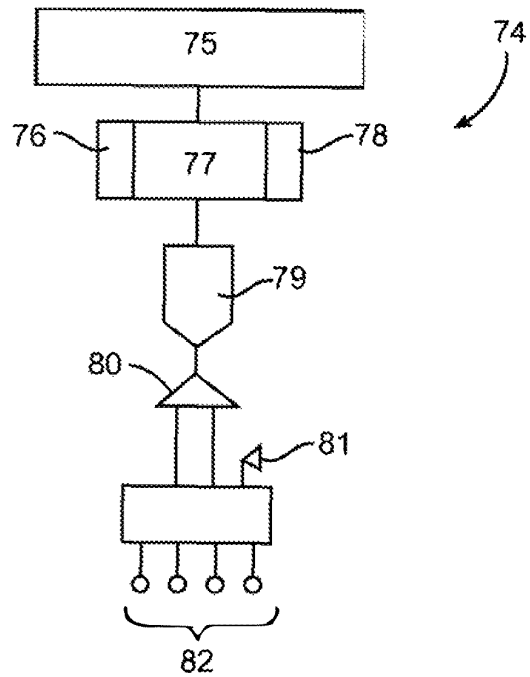


FIG. 31B

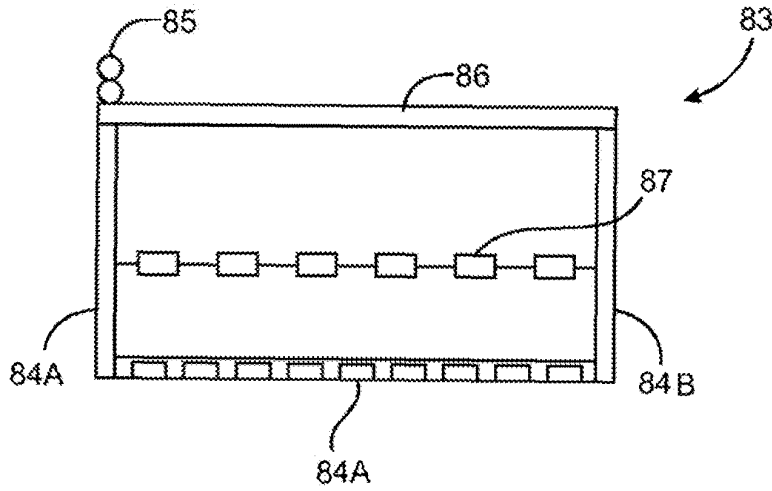


FIG. 32

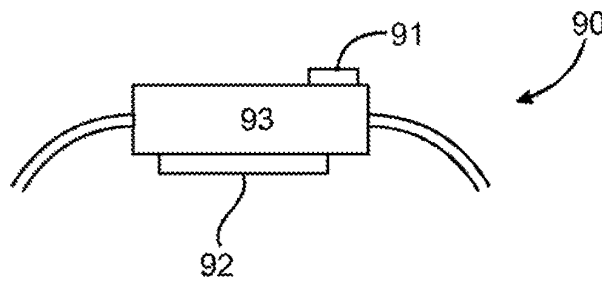


FIG. 33

1

INGESTIBLE EVENT MARKER DATA FRAMEWORK

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation application claiming priority under 35 U.S.C. § 120 to U.S. patent application Ser. No. 12/522,249, entitled INGESTIBLE EVENT MARKER DATA FRAMEWORK, filed Jul. 6, 2009, now U.S. Patent Application Publication No. 2011/0009715, which is a U.S. National Stage Entry under 35 U.S.C. § 371 of International Patent Application No. PCT/USO9/49618, entitled INGESTIBLE EVENT MARKER DATA FRAMEWORK, filed Jul. 2, 2009, which claims the benefit under 35 U.S.C. § 119 (e) of U.S. Provisional Patent Application Ser. No. 61/079,082, entitled INGESTIBLE EVENT MARKER DATA FRAMEWORK, filed on Jul. 8, 2008, the entire disclosures of which are hereby incorporated by reference herein.

FIELD OF THE INVENTION

The present invention relates generally to the technical fields of ingestible devices and communications. More specifically, and in various example embodiments, the present invention relates to a method, article, and system of generating, collecting, managing, distributing, and otherwise utilizing information associated with ingestible events and responses to the ingestible events.

BACKGROUND

Information related to personal events is widely needed in various pursuits. A personal event is an event that is specific to an individual. Examples of personal events include onset of a physiologic parameter of interest, ingestion of a therapeutic agent, etc.

There are many instances where one may want to note a personal event. Examples of such instances include onset of one or more physiologic parameters of interest including appearance of disease symptoms, administration of medication, ingestion of certain types of foods, commencement of an exercise regimen, ingestion of certain substance, etc.

A variety of different methods and technologies have been developed to note a personal event. For example, techniques have been developed in which individuals can manually record data in a log or physically enter data via a computer device.

The accuracy of such notations may be dependent on the accuracy of data input, the accuracy of proxies used as actual data substitutions, etc. As a result, inaccuracies may occur.

In one example, an individual may suffer from one or multiple health conditions that require therapy with multiple medications. The multiple medications may be prescribed according to an intricate dosing schedule. The complexities associated with multiple health conditions, multiple medication therapies, and intricate dosing schedules may confuse the patient, resulting in inaccurate data capture.

In one example, the individual may have physical or cognitive deficits which may result in difficulties inputting and capturing data. The individual may forget to enter the data, or may enter the data incorrectly.

In one example, the individual may not wish to be inconvenienced and thus may intentionally refuse to enter the data. Conversely, the individual may unintentionally or intentionally enter/record data which is completely inaccurate.

2

rate. For example, the individual may receive periodic, prescheduled reminders to take some medication. The reminders are unable to take into account actual ingestion of the medication. If the individual has already taken the medication, the reminder is both moot and likely to inconvenience the individual. If the medication has not been taken, an inconvenient or unneeded reminder or alert may prompt the user to enter data or send a message advising that the medication has been taken just to quell the alarm while not actually taking the medication. The individual may intentionally leave out portions of the data. In one example, proxies for data and information may also be inaccurate. For example, “intelligent” medication containers may contain microchips that sense opening of the medication container. From the sensed act of opening the container, an inference may be drawn that medication associated with the medication container has been ingested. The inference may be inaccurate, however, as medication is not necessarily ingested by virtue of opening a medication container.

The above-instances may ripen into further issues if particular parties besides the individual wish to use the individual’s personal event data.

EXAMPLES

of users and potential users (sometimes collectively referred to herein as “party” or “parties”) of personal event data include family and professional caregivers; communication companies; government agencies, e.g., agencies associated with government provided healthcare coverage; private insurance providers; Food and Drug Administration (FDA); Drug Enforcement Administration (DEA); US Bureau of Alcohol, Tobacco, and Firearms (ATF); care providers; medical device manufacturers; patients; clinicians; pharmaceutical manufacturers; pharmacies; web communities; software providers; marketing and financial analysts; and insurance companies.

Competing interests may exist between an individual’s privacy interests in personal event data and the acquisition and appropriation of the personal event data by third parties.

Further, various parties may have a compelling interest in receipt of accurate and comprehensive data, e.g., useful data, either in isolated form (data germane to a particular individual) or empirical form (aggregated data from various sources, various individuals, various personal events of an individual, etc.)

In many circumstances, however, accurate personal event data are not available. The party may have access to faulty data or a crude approximation of the information sought, as discussed above. Thus, the party must rely on such crude proxies to formulate a conclusion. It follows, then, that such conclusions may themselves be skewed or inaccurate. Actions taken in reliance on such conclusions may prove misguided, error-prone, and/or harmful.

To illustrate, a healthcare provider or family member may receive a message from a patient indicating that the patient has taken the medication when, in fact, the patient is merely providing the message without having actually ingested the medication. If the healthcare provider notices changes in the patient’s symptoms in close temporal proximity to receipt of the flawed information suggesting medication ingestion, the healthcare provider may mistakenly conclude that the patient’s symptoms are a result of the medication ingestion. Based on the mistaken conclusion, the healthcare provider may adjust the medication dosage in an attempt to alleviate the symptoms, perhaps to the patient’s detriment.

Of note, the more widely propagated and aggregated the inaccurate data, the more prolific the spread of and reliance on error-associated data and conclusions drawn therefrom.

In addition, recipients of the personal event data may wish to timely receive and utilize such information via a user-friendly, reliable and sophisticated means. The recipients may wish to receive and/or utilize information in discrete areas, integrate the personal event information with other data, and use the personal event information for various purposes.

Examples of various purposes include refining and optimizing data such as patient population data; incentivizing individuals or groups based on personal event data, e.g., ingestible event marker data (“IEM data”); corroborating and advancing decisions; supporting stakeholders’ decisions; using IEM data in personalized products and services, e.g., user applications on a mobile telephone; auto refilling prescription medications; managing pharmaceutical life cycle systems and controlled substances; compiling and delivering IP news and information feeds; accessing open sources of anonymized patient population data; determining eligibility and approval for refills, insurance coverage, etc.; using patient tools; participating in social network systems; analyzing aggregated data to derive and/or generate predictive information; supporting and enabling financial transactions; identifying direct and indirect causal failure points in treatment and predict corrective action; and providing dynamic, accurate calendaring/scheduling functions.

Finally, parties may also wish to access personal event data in conjunction with existing systems, e.g., commercial systems such as automated pharmacy systems, banking and financial systems, etc.

As can be seen, methods and systems are needed to seamlessly collect, manage, and distribute personal event data to various parties and systems.

Therefore, there is a need for controlled collection, management, and delivery of accurate personal event data to multi-profile parties for various purposes.

BRIEF SUMMARY OF THE INVENTION

The ingestible event marker data framework provides a uniform, comprehensive framework to enable various functions and utilities related to ingestible event marker data (IEM data). The functions and utilities include data and/or information having an aspect of data derived from, collected by, aggregated by, or otherwise associated with, an ingestion event. In one example, the IEM data are generated via an ingested device. The term “ingested device” includes any device, mechanism, structure, combined structure, or object capable of ingestion by a human subject or a non-human subject.

The IEM data framework is highly scalable and integratable with various existing systems, e.g., systems having computer-related component(s). Specific examples of such systems include pharmacy systems, communication systems, financial and banking systems, school systems, medical systems, government agencies, web communities, and personal computer systems. Such existing systems are herein collectively referred to as “commercial systems”.

The IEM data framework enables multiple and various types of implementations. The implementations include various configurations of hardware, software, communication components, and/or data. For example, in one aspect, the IEM data framework is implemented with a basic complement of core components; namely, ingestible event marker data; a hub to receive the ingestible event marker

data; and at least one ingestible event marker data system to receive, directly or indirectly, the ingestible event marker data from the hub.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 provides a diagrammatic representation of a communication environment including an IEM data framework, according to one embodiment.

FIG. 2 provides a diagrammatic representation of the IEM data framework of FIG. 1, according to one embodiment.

FIG. 3 illustrates IEM data and an IEM data environment associated with the IEM data framework of FIG. 2, according to one embodiment.

FIG. 4 illustrates a hub associated with the IEM data framework of FIG. 2, according to one embodiment.

FIG. 5 illustrates exemplary IEM data systems associated with the IEM data framework of FIG. 2, according to one embodiment.

FIG. 6 illustrates an exemplary IEM data framework having a feedback loop system, according to one embodiment.

FIG. 7 illustrates an exemplary IEM data framework having a decision support system, according to one embodiment.

FIG. 8 illustrates an exemplary IEM data framework having auto refill system, according to one embodiment.

FIG. 9 illustrates an exemplary IEM data framework having patient tools, according to one embodiment.

FIG. 10 illustrates an exemplary IEM data framework having a behavioral medicine system, according to one embodiment.

FIG. 11 illustrates an exemplary IEM data framework having an incentive system, according to one embodiment.

FIG. 12 illustrates an exemplary IEM data framework having a personalized commercial products/services system, according to one embodiment.

FIG. 13 illustrates an exemplary IEM data framework having an auto billing system, according to one embodiment.

FIG. 14 illustrates an exemplary IEM data framework having a tracking system, according to one embodiment.

FIG. 15 illustrates an exemplary IEM data framework having an interdiction system, according to one embodiment.

FIG. 16 illustrates an exemplary IEM data framework having a subscription system, according to one embodiment.

FIG. 17 illustrates an exemplary IEM data framework having an ingestible event marker data collection system, according to one embodiment.

FIG. 18 illustrates an exemplary IEM data framework having an approval system, according to one embodiment.

FIG. 19 illustrates an exemplary IEM data framework having a forecasting system, according to one embodiment.

FIG. 20 illustrates an exemplary IEM data framework having a financial system, according to one embodiment.

FIG. 21 illustrates an exemplary IEM data framework having an ingestible event marker data phone system, according to one embodiment.

FIG. 22 illustrates an exemplary IEM data framework having a social network system, according to one embodiment.

FIG. 23 provides a diagrammatic representation of an identifier according to an embodiment of the invention.

FIG. 24 provides detail of certain implementations of an electronic circuit of various embodiments of the invention.

FIG. 25 illustrates an exemplary device configuration of an IEM IC in accordance with one embodiment of the present invention.

FIG. 26 presents an exemplary schematic diagram illustrating the design of an IEM IC in accordance with one embodiment of the present invention.

FIG. 27 shows diagrammatically a signal receiver according to an embodiment of the invention.

FIG. 28 shows diagrammatically a signal receiver according to a second embodiment of the invention.

FIG. 29 shows diagrammatically a signal receiver having a multi-sensor lead (MSL) according to another embodiment of the invention.

FIG. 30 provides a view of an implantable pulse generator that includes a receiver component according to an embodiment of the invention.

FIGS. 31A and 31B provide additional information about various aspects of embodiments of external receivers according to embodiments of the invention.

FIG. 32 provides a view of receiver/pill dispenser device according to an embodiment of the invention.

FIG. 33 provides a view of a wrist band receiver embodiment of the invention.

DETAILED DESCRIPTION

1.0 Overview

2.0 Ingestible Event Marker (IEM) Data Framework

2.1 IEM Data

2.1.1 IEM Data Environment

2.1.1.1 IEM Data Source Devices

2.1.1.2 Products

2.1.1.3 Events

2.1.1.4 Patient Specific Parameters

2.1.1.5 IEM Data Algorithms

2.1.1.6 Storage Repositories

2.1.1.7 Other IEM Data Sources

2.2 Hub

2.3 IEM Data Systems

2.3.1 Feedback Loops

2.3.2 Decision Support Systems

2.3.3 Auto Refill Systems

2.3.4 Patient Tools

2.3.5 Behavioral Medicine Systems

2.3.6 Incentive Systems

2.3.7 Personalized Commercial Products/Services

2.3.8 Auto Billing Systems

2.3.9 Tracking Systems

2.3.10 Interdiction Systems

2.3.11 Subscription Systems

2.3.12 IEM Data Collection Systems

2.3.13 Approval Systems

2.3.14 Forecasting Systems

2.3.15 Financial Systems

2.3.16 IEM Data Phone

2.3.17 Social Network System

3.0 IEM Data Framework Method

4.0 IEM Data Framework Article

5.0 IEM Data Framework System

6.0 IEM System Structural Framework

1.0 Overview

The ingestible event marker (IEM) data framework provides an integrated, seamless solution to enable the collection, management, distribution, and utilization of IEM data. The versatile IEM data framework facilitates integration and

implementation of the IEM data with existing data and utilization of the IEM data with existing systems, i.e., commercial systems. The information and communication systems include discrete systems, cross-configured systems, and hybrid systems.

Broadly, various aspects of the IEM data framework include a basic complement of core components, e.g., IEM data; a hub; and at least one IEM data system. Any one or a combination of these core components is capable of interoperability, communication, and/or integration with various components of other information/communication systems. The terms “data” and “information” are used interchangeably herein.

The IEM data include information about an ingestion event, information about a response to the ingestion event, or both. The information about an ingestion event may include, for example, information about the ingestion event of a medication or set of medications. The information about a response to the ingestion event may include, for example, physiologic parameter(s) such as a physiologic status or physiologic change event based on the ingestion event. A physiologic status may be, for example, a heart rate, blood pressure measure, etc., ascertained in close temporal proximity to the time of ingestion of medication (and, therefore, likely to be influenced by or a result of ingestion of the medication).

Examples of IEM data include data ingestion time(s) of medication, identification of the type(s) of medication ingested at a particular time, the dosage amounts of medication ingested at a particular time, etc.

Typically, the IEM data may be generated and/or communicated via an ingestible device such as an ingestible event marker (IEM), which generates and communicates data associated with the ingestion event. The IEM may be associated, for example, with a receiver, i.e., a device capable of receiving the IEM data on ingestion and further capable of measuring additional IEM data on response to the ingestion event(s). The IEM and the receiver are discussed in detail hereinafter. In various aspects, the ingestible event data may originate from multiple ingested event markers. In various aspects, the IEM data may be communicated directly from the IEM to a device other than the receiver, e.g., an IEM business system adapted to receive the IEM data directly from the IEM via a communication channel.

In various aspects, the IEM data may be associated with other data, e.g., combined with data related to events other than an ingestion event or response(s) to an ingestion event. Some examples of other data are data associated with various medical devices and data associated with consumer and personal devices such as intelligent devices/appliances. All are discussed in greater detail hereinafter.

In various aspects, the IEM data may be associated with an IEM data environment and/or commercial systems.

In various aspects, the IEM data may be associated with a unique identifier, e.g., sample data reflective of physiologic patterns associated with a particular individual such as heart rate variability, breathing rate, and/or heart rate (ECG) patterns. For example, a portion or all of the IEM data may be compared with a unique identifier generated by or stored on the receiver.

The hub includes any hardware device, software, and/or communications component(s), as well as systems, subsystems, and combinations of the same which generally function to communicate the IEM data. Communication of the IEM data includes receiving, storing, manipulating, displaying, processing, and/or transmitting the IEM data.

In various aspects, the hub also functions to communicate, e.g., receive and transmit, non-IEM data. Non-IEM data includes non-IEM physiologic data. One example is cardiac data generated by a separate cardiac-related device such as an implanted pacemaker and communicated to the hub directly or indirectly, e.g., via the receiver.

Broad categories of hubs include, for example, base stations, personal communication devices, and mobile telephones.

For example, the hub includes a software application associated with a mobile telephone of a patient. The application and mobile telephone function to receive IEM data from a receiver, which, in turn, receives the IEM data from an ingestible device ingested by the patient. The hub stores, manipulates, and/or forwards the IEM data, alone or in combination with other data, to an IEM data system.

The IEM data systems include any hardware device, software, and/or communications component, as well as systems and subsystems of the same, which generally function to provide a service or activity related to the IEM data. The IEM data systems, for example, collect, manipulate, calculate, transmit, receive, store, and/or communicate at least a portion of the IEM data.

Each IEM data system may be built around predefined function(s) or service(s) and may be enabled via the IEM data framework.

One or more IEM data systems may be integrated, interoperate, intercommunicate or otherwise share or further the collection, management, distribution/dissemination, billing or other activities related to IEM data. One example of an IEM data system is a feedback loop system to refine and optimize IEM data and other data, e.g., medical database data.

Various aspects of the IEM data framework provide on-demand, accurate and efficient services with respect to provision and utilization of IEM data, while reducing redundancies, errors, and inaccuracies associated with personal event data that are sometimes found in the prior art. Various aspects of the IEM data framework further ensure generation and communication of accurate IEM data in a timely manner.

Further, the IEM data framework is applicable to any communication environment. Communication environments include any environment having therein, or associated with, data or communication of data.

Various aspects of the IEM data framework utilize the IEM data, the hub, and one or more IEM data systems to enable useful, secure, and efficient use of the IEM data among multi-profile parties in one or various communication environments.

FIG. 1 provides a diagrammatic representation of communication environment **100** including an IEM data framework **102**, according to one embodiment. The communication environment **100** may further include, for example, an IEM data environment **104** and one or more commercial systems **106**.

Communication environment **100** includes any environment having therein, or associated with, data or communication of data. Communication includes any method, act, or vehicle of communication, and/or combinations thereof. For example, communication methods include manual, wired, and wireless, etc. Wireless technologies include radio signals, such as x-rays, ultraviolet light, the visible spectrum, infrared, microwaves, and radio waves, etc. Wireless services include voice and messaging, handheld and other Internet-enabled devices, data networking, etc.

Vehicles of communication include the Internet, wired channels, wireless channels, communication devices including telephones, computers, wire, radio, optical or other electromagnetic channels, and combinations thereof, including other devices and/or components capable of/associated with communicating data. For example, the communication environments include in-body communications; various devices; various modes of communications such as wireless communications, wired communications, and combinations of the same, etc.

In-body communications include any communication of data or information via the body, i.e., communication via or associated with inter-body aspects, intra-body aspects, and a combination of the same. For example, inter-body aspects include communications associated with devices designed to attach to a body surface. Intra-body aspects include communications associated with data generated from within the body, e.g., by the body itself or by a device implanted, ingested, or otherwise locatable in, or partially in, the body.

Communications include and/or may be associated with software, hardware, circuitry, various devices, and combinations thereof.

The devices include devices associated with IEM data generation, transmission, reception, communication, etc. The devices further include various implantable, ingestible, insertable, and/or attachable devices associated with the human body or other living organisms. The devices further include multimedia devices such as telephones, stereos, audio players, PDA's, handheld devices, and multimedia players.

Wireless communication modes include any mode of communication between points that utilizes, at least in part, wireless technology including various protocols and combinations of protocols associated with wireless transmission, data, and devices. The points include, for example, wireless devices such as wireless headsets; audio and multimedia devices and equipment, such as audio players and multimedia players; telephones, including mobile telephones and cordless telephones; and computers and computer-related devices and components, such as printers.

Wired communication modes include any mode of communication between points that utilizes wired technology including various protocols and combinations of protocols associated with wired transmission, data, and devices. The points include, for example, devices such as audio and multimedia devices and equipment, such as audio players and multimedia players; telephones, including mobile telephones and cordless telephones; and computers and computer-related devices and components, such as printers.

The IEM data framework **102** enables exchange, transmission, receipt, manipulation, management, storage, and other activities and events related to IEM data. Such activities and events may be contained within the IEM data framework **102**, partially integrated with the IEM data framework **102**, or associated with externalities, e.g., activities, systems, components, and the like which are external to the IEM data framework **102**. Externalities include, for example, the IEM data environment **104** and commercial systems **106**, either or both of which may also be integral to, or partially integrated with, the IEM data framework **102**.

The IEM data environment **104** includes any source of information or data, including remote computer systems, local computer devices, etc. The information or data may comprise IEM data in whole or in part. The information or data may also be independent of the IEM data, e.g., may be capable of aggregation and/or integration with the IEM data.

The commercial systems **106** include various existing systems that utilize one or various types of data to accomplish a particular purpose. One example of a commercial system is a computerized pharmacy system utilized in a pharmacy. The computerized pharmacy system may function to automatically, e.g., electronically, receive prescriptions, verify patient and prescription information, verify insurance coverage, process the prescription order, and generate an invoice.

The IEM data framework **102**, the IEM data environment **104**, and the commercial systems **106** are discussed in greater detail hereinafter.

2.0 IEM Data Framework

FIG. 2 provides a diagrammatic representation of the IEM data framework **102** of FIG. 1, according to one embodiment. The IEM data framework **102** includes IEM data **200**, hub **202**, and one or more IEM data systems **204**.

The IEM data **200** include data associated with an ingestion event, i.e., an act of ingestion. Additionally, the IEM data **200** may include, be included in, or be combined with data from other systems or sources, e.g., medical devices, local or remote computer devices and systems, etc. An example of the IEM data **200** is data having an identification of the type of an ingested medication and the time at which the medication was ingested.

The hub **202** includes any hardware, software, and/or communications component(s) in any combination/configuration, which generally function to communicate the IEM data **200**. One example includes communicating the IEM data **200** to the IEM data systems **204**. For example, the hub **202** receives the IEM data **200** from an ingested device and forwards the IEM data **200**, alone or in combination with other data from other sources, to an IEM data system **204**.

The IEM data systems **204** provide discrete services and/or activities related to the IEM data **200**. The discrete services and/or activities include, for example, propagation of information, data, etc., to a particular user, or group of users, via various system component configurations, etc.

In one example, an auto refill system receives IEM data **200** from the hub **202**. The IEM data **200** include an indication that the last remaining pill of a prescription has been ingested. The auto refill system uses this information to contact a local or remote data resource having refill information, verify the refill information, and automatically transmit a request to a pharmacy system (commercial system) for refill of the prescription.

2.1 IEM Data

The ingestible event marker (IEM) data **200** are associated with at least one of an ingestion event and a response to the ingestion event. The ingestion event may be associated with, for example, data related to and/or gathered during transit through the alimentary system, e.g., oral cavity, pharynx, esophagus, stomach, small intestine, large intestine, anus, etc. Examples of IEM data include an ingestion time, identification of ingested substance, expiration date of an associated medication, dosage of an ingested substance, etc. The information about an ingestion event may include, for example, information about the ingestion event of a medication or set of medications. The information about a response to the ingestion event may include, for example, physiologic parameter(s) such as a physiologic status or physiologic change event based on the ingestion event. A physiologic status may be, for example, a heartrate, blood pressure measure, etc., ascertained in close temporal proximity to the time of ingestion.

In various aspects, the IEM data **200** typically may be generated via one or more ingestible event markers (IEMs), discussed hereinafter in detail. The generation of IEM data via multiple IEMs ensures comprehensive data reporting, e.g., data generated from multiple ingestion events of multiple IEMs over a time interval, data generated from multiple IEMs ingested at approximately the same time, etc. In this manner, comprehensive IEM data may be provided.

In various aspects, the IEM data may be communicated to, i.e., received by, a receiver. The receiver may be embodied in various ways, including an implantable device, a semi-implantable device such as a subcutaneous device, and an externally-applied device such as a personal signal receiver. One example of a personal signal receiver is a "patch" receiver which may be removably affixed to the individual's person, apparel, etc.

In various aspects, the IEM data **200** can be associated with other data, e.g., a personal event not associated with an ingestion event or a response to an ingestion event. A personal event includes any parameter or circumstance associated with a person, e.g., any event associated with ingestion, inhalation, injection, implantation, insertion, and/or imbibing of a device, substance, liquid, etc. A personal event further includes any event associated with personal data, e.g., a physiologic parameter such weight.

In various aspects, the IEM data may be associated with a unique identifier, e.g., heart rate variability, breathing rate, and/or heart rate (ECG) patterns associated with a particular individual. The unique identifier may be variously embodied. One example is a personal identifier assigned to an individual, e.g., an alphanumeric code, etc. Another example is a unique identifier reflective of an individual trait, such as a physiologic pattern.

To illustrate, a patient may ingest an IEM (discussed hereinafter) integrated with medication. The IEM may communicate IEM data to a receiver such as a patch receiver (discussed hereinafter). The data may include, for example, a unique identifier which may be compared to data associated with the receiver for validation purposes.

In one scenario, the IEMs associated with medication prescribed for a particular patient may each be encoded and deployed with corresponding unique identifiers. The unique identifier may be, for example, a predetermined physiologic data sample associated the particular patient. Various physiologic data samples include a data sample reflective of the particular patient's heart rate variability, a data sample reflective of the particular patient's breathing rate, a data sample reflective of the particular patient's heart rate (ECG) patterns, etc.

When the receiver is affixed or otherwise associated with an individual, programming logic associated with the receiver may receive actual data samples of the individual, e.g., from data sources such as heart devices, etc. The receiver may communicate the actual data samples received from the data sources and the unique identifier(s) received from the IEM(s) to a computer-related device, e.g., a server, which may compare the actual data samples of the individual with the unique identifier to verify that the medication was actually ingested by the particular patient for whom it was prescribed. In various aspects, predetermined actions based on the verification outcome may be taken, e.g., alerts may be sent to a device associated with the prescribing physician, etc.

2.1.1 IEM Data Environment

In various embodiments, IEM data **200** are generated, received, gathered, etc., from one or a variety of sources and comprise various structures, content, types, etc. The IEM

data environment includes at least one of an IEM data source device, products, events, patient specific parameters, IEM data algorithms, and storage repositories. The sources include, for example, various devices, storage repositories, and systems capable of generating, identifying, gathering or otherwise producing data related to ingestion, the ingestion environment, e.g., the alimentary system of a human subject or non-human subject and/or other personal events. The types include, for example, raw data, processed data, aggregated data, combined data, data from various sources, etc. The processed data include, for example, data processed according to a variety of methods, e.g., algorithms such as IEM data algorithms discussed below.

FIG. 3 illustrates IEM data environment 104 associated with the IEM data framework 102 of FIG. 2, according to one embodiment. The IEM data environment 104 includes, for example, IEM data source devices 300, products 302, events 304, patient specific parameters 306, IEM data algorithms 308, storage repositories 310, and other sources 312 such as a multisensory lead 312a.

2.1.1.1 IEM Data Source Devices

The ingestible event marker (IEM) data source devices 300 include, for example, devices capable of gathering, collecting, generating, receiving, storing and/or transmitting, etc., IEM data. One example of such a device is a microchip capable of or otherwise enabling or facilitating the collection, generation, receipt, transmission, etc., of data. Such a microchip may be integrated or associated with the IEM data source devices 300. The IEM data source devices 300 may be embodied, for example, as ingestible devices 300a, receivers 300b, and/or health devices 300c.

In various aspects, IEM data may be related to various devices. For example, a device may be an ingestible device, an inhalable device, an injectable device, an implantable device, an insertable device, and an imbibable device. The foregoing may be embodied, for example, as a microchip alone or in combination with other structural components, each capable of at least one of ingestion, inhalation, injection, implantation, insertion, and imbibement by a human body or a non-human body.

The ingestible device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a medication, e.g., a pill (refer to IEM system, *infra*).

The inhalable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a device. The inhalable device is capable of ascertaining parameter(s) associated with inhalation, e.g., measuring or tallying doses of an inhalant. The inhalable device may also comprise, for example, an inhalable microchip used to ascertain parameter(s), e.g., inhalation time, identify an inhaled substance, etc.

The injectable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a device. The injectable device is capable of ascertaining parameter(s) associated with injection, e.g., time of injection, identification of an injected substance, etc. In various aspects, the injectable device is capable of injection into a human body or a non-human body, e.g., injection into the circulatory system of a human body.

The implantable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or

otherwise integrated with a device. The implantable device is capable of ascertaining parameter(s) associated with implantation, e.g., time of implantation, physiologic parameters such as heart rate, EKG data, activity management data, temperature, galvanic skin response data, respiratory data, fluid status data, heart rate variability, etc.

In one aspect, the implantable device is embodied as an implantable receiver, *supra*, for receiving various data. The implantable receiver may also process, store, transmit, etc. the data. Various other implantable devices include, for example, heart monitors and the like having a microchip to ascertain parameter(s), e.g., heart rate, heart pressure, etc.

The insertable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a device. The insertable device is capable of ascertaining parameter(s) associated with insertion, e.g., time of insertion, physiologic parameters such as environmental content/fluid identification, etc. In one aspect, the insertable device is embodied as a microchip mechanically associated with a suppository for rectal insertion, vaginal insertion, etc.

The imbibable device may comprise, for example, a microchip. The microchip may be independently deployed. The microchip may also be attached to, embedded in, or otherwise integrated with a substance, e.g., a potable solution or fluid such as a beverage, etc. The imbibable device is capable of ascertaining parameter(s) associated with imbibing, e.g., time of drinking, physiologic parameters such as environmental content/fluid identification, etc. In one aspect, the imbibable device is embodied as a microchip and imbibed together with a beverage. The beverage may aid in swallowing, may be used as a medication, etc.

Further, the IEM data may be associated with administration of a therapeutic agent, etc. For example, administration includes, but is not limited to, parenteral administration, i.e., administration in a manner other than through the alimentary system, such as by intravenous or intramuscular injection or inhalation.

In some aspects, the devices are capable of ingestion, i.e., entry into the alimentary system of a human body or a non-human; inhalation (either the device or a substance associated with the device, e.g., a nasal inhalant). In various aspects the devices are capable of injection, insertion, implantation and/or imbibing, etc., into/by a human body or a non-human body.

The ingestible devices 300a gather/collect/generate IEM data via various methods, e.g., ingestion timing, contact with alimentary system substances, sampling, etc. Further, various ingestible event marker data source devices 300 communicate the IEM data via various methods, e.g., wireless methods, conductive methods via body tissue, etc. The following are examples of the ingestible devices 300a.

A pharma-informatics system described in PCT/US2006/016370, filed Apr. 28, 2006, includes compositions, systems and methods that allow for the detection of the actual physical delivery of a pharmaceutical agent to a body are provided. Embodiments of the compositions include an identifier and an active agent.

An IEM system described in PCT/US2008/52845, filed Feb. 1, 2008, the entirety of which is hereby incorporated by reference, includes an ingestible event marker (IEM) and a personal signal receiver. Aspects of the IEM include an identifier, which may or may not be present in a physiologically acceptable carrier. The identifier is characterized by being activated upon contact with a target internal physiological site of a body, such as digestive tract internal target

site. The personal signal receiver is configured to be associated with a physiological location, e.g., inside of or on the body, and to receive a signal of the IEM. During use, the IEM broadcasts a signal which is received by the personal signal receiver.

The IEM data associated with the IEM system include personal data, e.g., physiologic data generated by the IEM. Examples are derived metrics, e.g., processed physical data to derive various metrics such as time of ingestion data; combined metrics, e.g., derived metrics combined with other derived metric data such as time of ingestion data combined with data identifying the ingested substance; and IEM data, e.g., derived metrics and/or combined metrics aggregated with various physiologic data such as time of ingestion data combined with data identifying the ingested substance and physiologic data such as ECG data, temperature, etc.

A controlled activation ingestible identifier described in PCT/USO7/82563, filed Oct. 17, 2007, includes ingestible compositions such as pharma-informatics enabled compositions. The controlled activation ingestible identifiers include a controlled activation element that provides for activation of the identifier in response to the presence of a predetermined stimulus at a target site of interest.

A life cycle pharma informatics system described in U.S. Patent Applications Ser. No. 61/034,085, filed Mar. 5, 2008 includes RFID and conductive communications technology combined with medication and/or medication packaging such that the medication can be tracked for the duration of its existence. The system further allows in-body data transmissions while addressing the potential privacy and signal degradation concerns associated with RFID technology.

The IEM data receivers **300b** include devices capable of receipt of IEM data **200**. Receipt may be, for example, via wireless or wired channels, etc. The IEM data receiver **300b** may also transmit or otherwise forward data. In various aspects, the IEM data receiver **300b** may perform, facilitate, or enable various other functionalities related to the IEM data **200** and/or other data. In various aspects, the IEM data receiver **300b** may be attachable, implantable, semi-implantable or otherwise associated with a human body or a non-human body.

The IEM data receiver **300b** include personal signal receivers such as patch receivers, e.g., removably attachable externally to a human body or a non-human body; subcutaneous devices; implantable devices; external devices, i.e., devices which are not designed for attachment or other permanent or semi-permanent contact with the body, e.g., a mobile telephone. The following are examples of the IEM data receiver **300b**.

The IEM system, PCT/US2008/52845, includes an ingestible event marker (IEM) and/or a personal signal receiver.

An active signal processing personal health signal receiver described in PCT/USO7/24225, filed Nov. 19, 2007, includes a receiver associated with a body, e.g., located inside or within close proximity to a body, configured to receive and decode a signal from an in vivo transmitter which is located inside the body.

The health devices **300c** include multiple devices (and methods associated with the devices) associated with the IEM data **200**. The health devices **300c**, for example, may gather, collect, aggregate, store, transmit, receive, or otherwise communicate data, including the IEM data **200**.

Communication may be, for example, via wireless or wired channels, etc. The IEM data receiver may also transmit or otherwise forward data. In various aspects, the IEM data receiver **300b** may perform, facilitate, or enable various

other functions related to the IEM data and/or other data. Examples include functions to store data, process data, etc.

In various aspects, the health device **300c** may be attachable, implantable, semi-implantable or otherwise associated with a human body or a non-human body.

For example, "intelligent" devices such as intelligent scales, intelligent blood pressure cuffs, intelligent refrigerators, etc., may be integrated in various configurations. As used herein, the term "intelligent devices" refers to one or more devices capable of generating and/or communicating data, e.g., wirelessly transmitted data, via a communication channel to a destination.

2.1.1.2 Products

IEM data **200** also includes IEM data related to products **302**. The products **302** include, for example, an ingestible device/pharmaceutical product **302a**. One example of an ingestible device/pharmaceutical product **302a** is an IEM mechanically associated with medication. The IEM may be mechanically associated with the medication in various ways, including externally affixed to the medication, partially integrated with the medication, and wholly integrated with the medication.

The IEM may be affixed via various means, e.g., with various adhesive or formulated substances. The IEM may be associated with the medication at various phases, e.g., during a medication manufacturing process, at various points in time after a medication manufacturing process, etc.

2.1.1.3 Events

IEM data **200** further includes data related to events **304**, e.g., personal events, event parameters, etc. Further examples include time of ingestion of a medication, dosage and identity of medication taken at time of ingestion, etc. Events may include physiologic events, e.g., respiration rate; environmental events, e.g., time of day; usage events, e.g., ingestion of a medication, use of a cardiac resuscitation device, etc.

2.1.1.4 Patient Specific Parameters

IEM data **200** still further includes data related to patient specific parameters **306**, e.g., individualized patient data **306a** pertaining to an individual patient and multiple patient data **306b** pertaining to multiple patients. Examples of patient specific parameters include physiologic data, etc. Multiple patient data include aggregated patient data, patient population data, e.g., combined patient data which includes various predetermined aspects of data regarding at least one patient and excludes data tending to identify a particular patient or an aspect in which the patient has a privacy interest, e.g., name, age, diagnosis and/or other data which the patient wishes to retain as confidential and/or undisclosed to the public.

2.1.1.5 IEM Data Algorithms

IEM data **200** also includes data related to IEM data algorithms **308**, e.g., raw data, processed data, or a combination of the same, which undergo processing. In one example, the IEM data **200** have one or more algorithms applied thereto, with processed data as an output. The data, for example, includes individualized patient data **306a** and multiple patient data **306b**, e.g., patient population data.

The IEM data algorithms may be related to aspects such as data processing associated with the IEM data **200** generated by one or more ingestible devices, e.g., an IEM system.

With respect to IEM data processing associated with an ingestible device, aspects include, for example, transmission of the IEM data **200**, IEM data processing associated with a receiver, and IEM data post-processing aspects.

Transmission aspects of IEM data and algorithms may include, for example, modulation schemes, coding, and error code aspects.

The transmission aspects include, for example, analog, digital, spread spectrum, combinatorial, and contention avoidance.

The analog transmission aspects include, for example, amplitude modulation, single sideband modulation, frequency modulation, phase modulation, quadrature amplitude modulation, and space modulation methods, etc.

The digital transmission aspects include on/off keying, frequency-shift keying, amplitude-shift keying, phase-shift keying, e.g., binary phase-shift keying, quadrature phase-shift keying, higher order and differential encoded, quadrature amplitude modulation, minimum shift keying, continuous phase modulation, pulse-position modulation, trellis coded modulation, and orthogonal frequency-division multiplexing.

The spread spectrum transmission aspects include, for example, frequency hopping spread-spectrum and direct-sequence spread spectrum.

The combinatorial transmission aspects include, for example, binary phase shift-keying with carrier frequency modulation.

The contention avoidance transmission aspects include, for example, duty-cycle modulation and carrier frequency modulation.

The coding aspects include, for example, wake-up schemes, preamble schemes, data packet schemes, and error code schemes.

The wake-up schemes include, for example, multi-tone schemes and chirp schemes.

The preamble schemes include, for example, unique identifier for packet start schemes.

The data packet schemes include, for example, data related to pill type, pill expiration, manufacturer, lot number, amount, prescribing physician, pharmacy, etc.

The error code schemes include, for example, repetition schemes, parity schemes, checksums, cyclic redundancy checks, hamming distance schemes, and forward error correction schemes, e.g., Reed-Solomon codes, binary Golay codes, convolutional codes, turbo codes, etc.

With respect to IEM data processing and the receiver, considerations may be given to, for example, position, energy conservation schemes, carrier identification, decoding and error correcting.

The position of the receiver includes, for example, the stomach, the side and the xiphoid.

The energy conservation schemes include schemes for a periodic wake-up, e.g., to sense IEM wake-up such that energy, e.g., battery resources, is conserved during non-awake periods.

The carrier identification aspects include, for example, Fourier transform analysis, e.g., fast Fourier transform and discrete Fourier transform, phase locked loop, filter bank, match filter, and combinatorial such as use of previous knowledge about frequency to tune-in.

The decoding aspects and error correcting aspects include, for example, the above-iterated aspects.

With respect to IEM data post-processing, aspects include, for example, pill detection, e.g., multiplicity of identification and count in time aspects, adherence metrics, etc.

With respect to IEM data processing associated with physiologic parameter metrics, aspects include, for example, electrocardiogram (EKG or ECG), impedance, acceleration, optical, pressure, temperature, sound, biochemical/biologi-

cal, weight, position, derived electromyography (EMG), and electroencephalography (EEG).

IEM data processing related to EKGs includes, for example, compression data, e.g., wavelet and ICA/PCA, R-wave detection such as Hamilton-Tompkins, etc., heart-rate variability, e.g., SDNN, standard deviation in a 24 hour period, standard deviation of consecutive five minute periods, foot print heart rate versus standard heart rate, distribution-based histogram, etc., arrhythmia, and respiration, e.g., principal axis modulation.

IEM data processing related to impedance includes, for example, respiration, fluid status, Galvanic skin response, blood flow, etc.

IEM data processing related to acceleration, includes, for example, direct acceleration, which includes total activity and derived acceleration, which further includes activity type.

IEM data processing related to optical includes, for example, hematocrit, O₂ saturation, pulse oximetry, etc.

IEM data processing related to temperature includes, for example, body temperature, heat flux, etc.

IEM data processing related to sound includes, for example, heart sounds, valvular events, etc.

IEM data processing related to biochemical/biological includes, for example, lactose, glucose, antibody, biomarker, bacterial, osmolarity, etc.

IEM data processing related to derived data include, for example, sleep, total energy, etc.

2.1.1.6 Storage Repositories

Ingestible event marker data also includes data related to storage repositories **310**, i.e., databases and/or other storage implementations that temporarily and/or permanently retain, store, etc., data related to IEM data, including data to be combined or aggregated with ingestible event marker data.

Storage may be in any form or format, as is known or will be known in the future. In various aspects, the storage repositories **310** may be independently embodied and/or may be partially or wholly integrated with computer-related system(s). The storage repositories **310**, for example, may interoperate or otherwise be associated with various computer systems, software, hardware, communication components, etc. For example, the storage repositories **310**, may be part of a medical office computer system and may contain IEM data **200** related to a particular's patient's medication regimen. At various times, e.g., scheduled or ad hoc, various IEM data **200** embodied as medical data may be communicated to/from the storage repositories **310** and/or from/to various points/components.

In another illustration, methods, systems and compositions that allow for treating a patient according to a patient customized therapeutic regimen are described in PCT/US2007/1068, filed May 2, 2007, which include obtaining dosage administration information from a patient and using the same to tailor a therapeutic regimen for the patient, as well as preparing and forwarding to the patient physical pharmaceutical dosages based on the customized therapeutic regimen. The dosage administration information from the patient may be stored, for example, on the database **306**. The IEM data **200** containing information about the ingestion time of a particular medication can be combined with the dosage administration information to customize the therapeutic regimen.

2.1.1.7 Other IEM Data Sources

In various aspects, various other IEM data sources **312**, such as a multisensory lead **312a**, are/can be included. Further, it is noted that data and/or IEM data **200** from multiple sources can be aggregated, integrated, refined, etc.

via a variety of methods. To illustrate, IEM data **200** such as ingestion data related to ingestion of a medication are generated from an IEM data source device **300** such as the IEM system. The ingestion data are wirelessly transmitted to an IEM receiver.

Concurrently or in an alternative time period, physiologic data such as cardiac parameters are generated by a health device **300c** such as the system for monitoring and treating hemodynamic parameters, supra, is generated and wirelessly transmitted to the IEM data receiver **300b**. The IEM data **200** and the cardiac physiologic data are aggregated for onward communication to an IEM data system such as an auto refill system.

To illustrate, cardiac data is derived via various methods and systems. One example is continuous field tomography, e.g., electrical tomography (ET). One continuous field tomography method is described in the U.S. Patent Application Ser. No. 60/797,403, filed May 2, 2006. The cardiac data includes cardiac-related parameters, as well as clinical data for clinical applications. Using ET, various cardiac parameters are measured, such as stroke volume, ejection fraction, $dP/dt(max)$, strain rate(max), peak systolic mitral annular velocity, end systolic volume, end diastolic volume, and ORS length, etc. The cardiac measurements may be used to derive or infer various performance and wellness diagnostics/inferences. For example, an ejection fraction parameter may be used as a basis to predict ventricular synchrony performance.

The metrics generated from the continuous field tomography include, for example, velocity, acceleration, and displacement.

The clinical data derived from the metrics include, for example, left ventricle stiffness as well as ET proxies for other physiologic parameters such as ejection fraction (EF) and dP/dt .

In various aspects, the clinical data may be combined with the IEM data to provide additional information. The information may be useful, for example, in various diagnostic and analytical pursuits. Comprehensive patient-related data displays having clinical data and IEM data are described in the U.S. Patent Application Ser. No. 61/076,577, filed Jun. 27, 2008, wherein various ET physiologic parameters and derivations such as EF and ventricle stiffness are displayed together with IEM data such as medication ingestion time. From such a display, the efficacy of the medication therapy may be gauged.

2.2 Hub

The hub **202** includes any hardware device, software, and/or communications component(s), as well as systems, subsystems, and combinations of the same which generally function to communicate the IEM data **200**, including receiving, storing, manipulating, displaying, processing, and/or transmitting the IEM data **200**.

In various aspects, the hub **202** receives, generates, communicates, and/or transmits, the IEM data **200**, alone or in combination with other data, i.e., non-IEM data from various sources. Non-IEM data includes non-IEM physiologic data. Examples of non-IEM data include heart rate, heart rate variability, respiration, physical activity level, wake patterns, temperature, etc.

Communication of the IEM data **200** to and from the hub **202** includes any transmission means or carriers, and combinations thereof, including wireless, wired, RF, conductive, etc. as is known in the art or as may become available in the future.

FIG. 4 illustrates the hub **202** associated with the IEM data framework **102** of FIG. 2, according to one embodi-

ment. The hub **202** comprises various categories of devices, e.g., personal communication devices, base stations, and mobile telephones.

Personal communication devices include, for example, devices having communication and computer functionality and typically intended for individual use, e.g., mobile computers, sometimes referred to as “handheld devices”.

Base stations comprise any device or appliance capable of receiving data such as IEM data. Examples include computers, such as desktop computers and laptop computers, and intelligent devices/appliances.

Intelligent devices/appliances include consumer and home devices and appliances that are capable of receipt of data such as IEM data. Intelligent devices/appliances may also perform other data-related functions, e.g., transmit, display, store, and/or process data. Examples of intelligent devices/appliances include devices and appliances having refrigerators, weight scales, toilets, televisions, door frame activity monitors, bedside monitors, bed scales. Such devices and appliances may include additional functionality such as sensing or monitoring various physiologic parameters, e.g., weight, heart rate, etc.

Mobile telephones include telephonic communication devices associated with various mobile technologies, e.g., cellular networks.

In one aspect, the hub **202** includes an IEM data receiver embodied, for example, as a receiver such as a patch receiver **400**; a personal communication devices such as a handheld device **402**; a base station **404**; and a mobile telephone **406**.

The patch receiver **400** includes, for example, devices capable of at least receiving data, signals, etc. Patch receivers **400** may be attachable, e.g., permanently or removably attachable externally to a human body or a non-human body. For example, the patch receiver **400** may include a receiver and an adhesive layer to provide for attachment to and removal from a region of skin. Alternatively, the patch receiver **400** may be implantable or semi-implantable, e.g., subcutaneous implantation. One such removably attachable patch receiver **400** is the personal signal receiver of the IEM system described in PCT/US2008/52845.

The handheld device **402**, also referred to as a “mobile computer”, includes, for example, computing devices having computer-related functionality, e.g., typically having a display screen with touch input functionality, a miniature keyboard, etc. Types of handheld devices include, for example, a personal digital assistant (PDA) having the input and output combined into a touch-screen interface; and enterprise digital assistants offering integrated data capture devices like bar code, radio frequency identification (RFID), and smart card readers, etc.

In various aspects, the handheld device **402** includes software, e.g., a software agent/application, associated with the IEM data **200**. In various embodiments of the handheld device **402**, the software is preconfigured, i.e., configurable by the manufacturer/retailer; configurable by the consumer, i.e., downloadable from a website; or a combination of the same.

One example of software is an auto refill application related to or integrated with an auto refill system to facilitate automated prescription refill functions.

The base station **404** includes systems, subsystems, devices, and/or components that receive, transmit, and/or relay the IEM data **200**. In various aspects, the base station communicably interoperates with a receiver such as the patch receiver **400** and a communications network such as the Internet. Examples of base stations **404** are computers,

e.g., servers, personal computers, desktop computers, laptop computers, intelligent devices/appliances, etc., as heretofore discussed.

In various aspects, the base station **404** may be embodied as an integrated unit or as distributed components, e.g., a desktop computer and a mobile telephone in communication with one another and in communication with a patch receiver and the Internet.

In some aspects, the base station **404** includes the functionality to wirelessly receive and/or wirelessly transmit data, e.g., IEM data **200** received from and transmitted to the patch receiver **400** and the Internet.

Further, in various aspects, the base station **404** may incorporate and/or be associated with, e.g., communicate with, various devices. Such devices may generate, receive, and/or communicate data, e.g., IEM data **200**. The devices include, for example, clock radios, intelligent pill dispensers, pill managers, e.g., devices capable of receiving various substances and producing a combined substance, dose(s) of substances, etc., pharmaceutical compounding devices, "intelligent" devices such as scales, blood pressure measurement devices, exercise equipment, e.g., tread mills. Further examples include body weight sensors, motion sensors, position sensors, e.g., bed sensors, chair sensors, portals in doorways, refrigerator and food devices, bathroom facilities devices, etc.

The mobile telephone **406** includes, for example, devices such as a short-range, portable electronic device used for mobile voice or data communication over a network of specialized cell site base stations. The mobile telephone **406** is sometimes known as or referred to as "mobile", "wireless", "cellular phone", "cell phone", or "hand phone (HP)".

In addition to the standard voice function of a telephone, various embodiments of mobile telephones may support many additional services and accessories such as short message service (SMS) for text messaging, email, packet switching for access to the Internet, java gaming, Bluetooth (short range data/voice communications), infrared, camera with video recorder, and MMS for sending and receiving photos and video. Some embodiments of mobile telephones connect to a cellular network of base stations (cell sites), which is, in turn, interconnected to the public switched telephone network (PSTN) or satellite communications in the case of satellite phones. Various embodiments of mobile telephones can connect to the Internet, at least a portion of which can be navigated using the mobile telephones.

In various aspects, the mobile telephone **406** includes software, e.g., a software agent/application, associated with the IEM data **200**. One example is an auto refill application related to or integrated with an auto refill system to facilitate automated prescription refill functions. In various embodiments of the mobile telephone **406**, the software is preconfigured, i.e., configurable by the manufacturer/retailer; configurable by the consumer, i.e., downloadable from a website; or a combination of the same.

Further, various embodiments of the hub ensure privacy requirements via predetermined methods, e.g., an IEM data source device **300** ingested by an individual transmits sensitive IEM data **200** via body tissues to an IEM data receiver **302** embodied in a patch receiver **400** removably attached to the individual's body. Signals associated with the sensitive IEM data **200** remain undetectable beyond the individual's body. Once received by the patch receiver **400**, various computing components of the patch receiver **400** cleanse and/or encrypt the IEM data **200** for onward secure trans-

mission. In this manner, breaches of sensitive data transmissions and/or unauthorized access to the sensitive data are avoided.

Further, various aspects of the hub include combinations of devices. One such combination is an IEM data receiver **300b** such as the patch receiver **400** in communication with the handheld device **402** or the mobile telephone **406**. Thus, for example, the patch receiver **400** wirelessly transmits IEM data **200** to the mobile telephone **406** having a receiver and a software agent available thereon. The receiver of the mobile telephone **406** receives the IEM data **200**. A software agent, e.g., an application, processes the ingested reported data **200** and displays various information related to the IEM data **200** via, for example, a customized graphical user interface (GUI). In some aspects, the software agent generates displays with a predetermined "look and feel", i.e., recognizable to a user as belonging to a predetermined group of software programs, GUIs, source devices, communities, etc.

To illustrate the foregoing, the IEM data **200** may include data about an ingested medication. Once received by the mobile telephone **406**, the software agent may compare the data about the medication to a predetermined medication regimen. Upon verification that the proper medication has been ingested at the proper time, the software disables an audible alarm scheduled to alert the individual to take the (already ingested) medication, thus averting an unnecessary reminder and removing the annoyance associated therewith. The software agent, via the GUI, displays a standard message to the individual notifying of the medication ingested and the time of the next dosage.

Additionally, the software agent may include functionality to generate or facilitate a financial transaction. In one example, upon occurrence of a certain event, such as verification that the proper medication has been ingested at the proper time, the software agent generates a predetermined charge for the ingested medication, the verification service, or both. The charge is transmitted to a financial system, e.g., the patient's cell phone transmits the charge via an IEM data system to a computer system associated with the patient's financial institution where the charge is automatically applied against a financial account of the patient.

In various other aspects, the transaction model may be based on various parameters. In one example, a transaction is associated with a time based model wherein use of a product or service is charged according to the length of time the product or service is used. In another example, a transaction is associated with a measured value delivery, wherein the value of the product or service is metered, measured, or otherwise valued and charged according to the ascertained value at predetermined time intervals. In still another example, a transaction is associated with therapy delivery, i.e., delivery of a therapeutic substance, event, service, etc. Examples of therapeutic substances include medication. Examples of therapeutic events include cardiac defibrillation acts and cardiac resynchronization acts. Examples of therapeutic services include administration of therapeutics, therapeutic consultations, etc.

2.3 IEM Data Systems

The IEM data systems **204** include any hardware component, software component, and/or communications component, as well as networks, systems, and subsystems of the same, which generally function to provide a service, function, activity, etc. related to the IEM data **200**. The IEM data systems, for example, collect, manipulate, calculate, transmit, receive, store, and/or otherwise communicate at least a portion of the IEM data.

Each IEM data system is built around a predefined business function or service and is enabled via the IEM data framework. One or more IEM data systems may be integrated, interoperate, intercommunicate or otherwise share or further the collection, management, distribution/dissemination, billing and/or other activities related to IEM data.

Further, one or more IEM data systems may be associated with one or more commercial systems. For example, one or more IEM data systems may be integrated with, interoperate with, and/or intercommunicate with one or more commercial systems. One or more IEM data systems may otherwise share or further the IEM data related activities with one or more commercial systems.

The IEM data systems **204** include at least one component, e.g., hardware device, software, and/or communications component, which generally function to provide a service or activity related to the IEM data **200**, e.g., a computer to receive IEM data **200** from the hub **202** and display the IEM data **200** in conjunction with other information.

Examples of components include a computer, a receiver, a transmitter, an application, a software module, a data storage medium, a processor, a memory component, a personal communication device, software, a communication link, and a handheld device. It is noted that two or more IEM data systems **204** can cooperatively or independently use one or more of the same components. For example, an auto refill system and an approval system can each access a data storage medium having IEM data related to patients and prescriptions and can each utilize the IEM data for predetermined purpose(s).

FIG. 5 illustrates exemplary IEM data systems **204** associated with the IEM data framework of FIG. 2, according to one embodiment. The exemplary IEM data systems **204** include, for example, feedback loop systems **204a**, decision support systems **204b**, auto refill systems **204c**, patient tools **204d**, behavioral medicine systems **204e**, incentive systems **204f**, personalized commercial products/services **204g**, auto billing systems **204h**, tracking systems **204i**, interdiction systems **204j**, subscription systems **204k**, IEM data collections **204l**, approval systems **204m**, forecasting systems **204n**, financial systems **204o**, an IEM data phone system **204p**, and social networks **204q**.

2.3.1 Feedback Loop Systems

Feedback loop systems aggregate various sources of data, e.g., IEM data, analyze the aggregated data, and/or provide feedback information to multiple profile recipients based on the aggregation/analysis.

FIG. 6 illustrates an exemplary IEM data framework **102** including a feedback loop system **204a**, according to one embodiment. The feedback loop system **204a** includes, for example, server **500** having application **502** and database **504**. The IEM data framework **102** further includes IEM data **200** and the hub, embodied here as the mobile telephone **406**. In various aspects, the feedback loop system **204a** may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

In one scenario, a patient **506** ingests medication having an ingestible device integrated therein. The ingestible device generates IEM data **200** in the form of medication identification and time of ingestion information. The ingestible device transmits the information to a receiver. The receiver, in turn, communicates the information to the hub **202** embodied as a mobile telephone **406** associated with the patient **506**.

A software agent resident on the mobile telephone **406** aggregates the received medication identification and time of ingestion information with the blood pressure measurement information and forwards the aggregated data to the feedback loop system **204a**. The feedback loop system **204a**, having server **500**, software **502**, and database **504**, receives the aggregated data from the mobile telephone **406** and, via the software **502**, compares the aggregated data to patient information in the database **504** to determine if the patient **506** took the most recent dose of medication in a timely manner, if the patient **506** has consistently taken the medication in a timely manner, and if the blood pressure measurement coincides with an acceptable range of blood pressure measurements.

Based on an analysis of the data, the feedback loop system **204a** generates additional IEM data **200** in the form of a decision on patient adherence and a decision on treatment efficacy. The IEM data **200** decisions are stored in database **504** for future reference and forwarded to a commercial system such as a healthcare system **106a** associated with a medical center computer system and having patient data such as physician's medication instructions, etc.

The healthcare system **106a** facilitates automatic processing and feedback, enables accessibility to the IEM data **200**, e.g., by a healthcare provider, enables data input, e.g., healthcare instructions by the healthcare provider, etc.

For example, the healthcare system **106a** compares the decision data received from the feedback loop system **106a** with stored healthcare providers instructions, e.g., medication regimen adherence is satisfactory and no action is needed at this time; medication regimen adherence is not satisfactory and action is needed at this time; medication regimen is satisfactory but action is needed at this time, e.g., titration is needed, etc., and generates the comparison result data for review by the healthcare provider.

The healthcare provider utilizes the information to advantageously adjust patient treatment parameters, e.g., prescription and dosage requirements. The healthcare provider inputs data based on the comparison results, e.g., the adjusted treatment parameters. The input data are processed by the healthcare system **106a** and forwarded to the feedback loop system **204a**. The feedback loop system **204a** receives the feedback loop data, reconciles the feedback loop data with the patient information resident in the database **504**, and forwards the notification to the mobile telephone **406** of the patient **506**.

In various aspects, the feedback loop system **204a** and/or the healthcare system **106a** interoperate, e.g., communicate with at least one other IEM data system **204** and/or commercial system **106**.

To continue the foregoing illustration, in addition to forwarding the adjusted medication regimen instructions to the patient's mobile telephone **406**, either the feedback loop system **204a** or the healthcare system **106a** forwards the adjusted medication regimen in the form of a prescription to a commercial system such as a pharmacy system **106b** for refill. The pharmacy system **106b** fills the prescription and communicates a message to the feedback loop system **204a** notifying of the same. The feedback loop system **204a** updates the patient's data in database **504** to reflect the new prescription and fulfillment of the prescription, and communicates the notification to the patient's mobile telephone **406**.

2.3.2 Decision Support Systems

Decision support systems, e.g., personal wellness systems, may generate, store, provide data, e.g., IEM data, which may be used to inform and support decisions, e.g.,

stakeholders' decisions. In one example, multiple 25 instances of individualized ingestible event marker data and physiologic data are gathered and combined into anonymized patient population data. Pharmaceutical research and development groups, universities, etc., utilize the data for various purposes, e.g., information to formulate new product lines, adjust existing therapies, etc. The data may be accessed, for example, by subscription to population data feeds, access to the database, etc.

FIG. 7 illustrates an exemplary IEM data framework 102 10 having a decision support system 204b, according to one embodiment. The IEM data framework 102 further includes IEM data 200 and the hub 202, shown here embodied as the mobile telephone 406. In various aspects, the feedback loop system 204a may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, IEM data, e.g., IEM data 200a and IEM data 200b, an IEM data 200c, related to multiple individuals, e.g., patient 506a and patient 506b, and patient 506c, respectively, are communicated via the hubs, e.g., mobile telephone 406a and mobile telephone 406b, respectively, to the decision support system 204b comprising, for example, server 500, software 502, and database 504. The IEM data 200a and 200b may be encrypted. The decision support system 204b processes and stores the received data. For example, software 502 anonymizes the patient data, i.e., removes all aspects of the data tending to identify an individual and removes, according to a predetermined scheme, all aspects of the data designated as private, sensitive, confidential in nature, etc. The software 502 may provide various other functions such as integrating the anonymized patient data with existing patient population data in the database 504.

The integrated data in database 504 may be accessed by, delivered to, or otherwise utilized by multiple systems and parties. Such systems include for example, commercial systems 104 such as pharmaceutical systems 106c and university systems 106d. Parties associated with the pharmaceutical systems 106c may utilize the patient population data, for example, for statistical analysis and projective capabilities such as determining the efficacy, cost efficiency, profit, etc. of a particular medication and projecting from the determination new product line concepts/therapies, etc. Parties associated with universities may utilize the patient population data to research symptomatology, analyze medication risks, etc.

In various aspects, the decision support system 204b, IEM data system(s), and/or commercial system(s) interoperate, e.g., communicate, therebetween. To continue the foregoing illustration, in addition to the provision of decision support data such as patient population data, the decision support system 204b communicates patient population data to the feedback loop system 204a. The feedback loop system 204a communicates the patient population data to mobile telephone 406a of patient 506a.

In one scenario, the decision data derived from a patient population such as medication efficacy may be correlated with an individual's medication therapy, and communicated via marketing system specifically targeted for that individual.

2.3.3 Auto Refill Systems

Auto refill systems automatically fill or refill prescriptions. In one example, IEM data identifying an ingested medication are gathered and reconciled with current prescription information to identify depleted prescription supplies. If the supply is depleted, a refill order is automatically

triggered to the appropriate pharmacy. The pharmacy automatically refills the order, generates a bill, and charges the appropriate account, e.g., via a real time, online financial transaction.

FIG. 8 illustrates an exemplary IEM data framework 102 5 having an auto refill system 204c, according to one embodiment. The IEM data framework 102 further includes IEM data 200 and the hub 202, shown here embodied as the base station 404. In various aspects, the auto refill system 204c may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, the patient 506 ingests prescription medication in conjunction with an ingestible device. The ingestible device identifies the medication type and dosage, and transmits the IEM data 200 via, for example, conductive transmission to the patch receiver 400, which may be removably attached to the patient 506. The patch receiver 400 transmits the IEM data 200 to base station 404. The base station 400 forwards the IEM data 200 to the auto refill system 204c. The software 502 of the auto refill system 204c compares the medication type and dosage of the IEM data 200 against prescription information stored in the database 504. The prescription information, for example, may include the number of tablets in the prescription at time of fill, the dosage instructions, and a running total of the ingested tablets as per previously received information. If the comparison indicates depletion of the prescription medication, database 504 is checked for the number of remaining refills. If refills are remaining, any sensitive data of the IEM data 200 are cleansed, i.e., removed, and a prescription refill request with pertinent information is compiled and transmitted according to predetermined security protocol and via predetermined channel(s) to a commercial system 106 such as the pharmacy system 106b. Upon receipt by the pharmacy system 106b, the refill request is parsed and verified, and the prescription is refilled.

Payment for refill can be effected, for example, via a real-time, online transaction between the pharmacy system 106b and an IEM data system 204 and/or commercial system, e.g., financial transaction system 106e. The financial transaction system 106e, for example, may receive the financial transaction, e.g., prescription refill charge, via a predetermined communication channel. The financial transaction system 106e verifies the patient account information and completes the transaction, notifying the pharmacy system 106b.

Notification of status of refill and payment for refill can be provided via predetermined communication channel(s) to the base station 300, e.g., an email for display on the laptop computer, a text message to the patient's mobile telephone, etc.

2.3.4 Patient Tools

Patient tools include any data, information, software, websites, etc. that provide information or assist a particular patient focus, e.g., tracking tools to assist a patient in cardiac health management, patient personalization of their own data, etc. Various users may be associated with the patient tools. Examples include various users within a patient community, e.g., patients, family caregivers, and professional caregivers such as physicians.

FIG. 9 illustrates an exemplary IEM data framework 102 65 having a patient tools 204d, according to one embodiment. The IEM data framework 102 further includes IEM data 200a-c and the hubs, shown here embodied as the base station 404, the mobile telephone 406, and the handheld device 402. In various aspects, the patient tools 204d may

interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

In one scenario, multiple parties such as patients **506a-c** access the patient tools **204d**, which may be embodied as the server **500** having the software **502** and the database **504** having IEM data **200** in the form of at least patient tools. Patients **506a-c** may access the patient tools **204d**, for example, via the base station **404**, the mobile telephone **406**, and the handheld device **402**, respectively.

Patient **506b** may search the database **504** for patient tools related to mental illness management. The patient tools, for example, may be provided in the form of downloadable data/applications to assist in tracking, monitoring, diagnosing, and notifying a patient of a relevant health issue, e.g., medication dosage schedule, etc. Patient **506b** may download the application onto, for example, the mobile telephone **406**. Patient **506b** may further communicate via, for example, the mobile telephone **406** with at least one commercial system such as the healthcare system **106a**, which may provide further medical data, instruction, etc., relevant to the patient **506b**'s mental illness management pursuit.

In various aspects the patient tools **204d** may be configured for and utilized by for various parties besides the patient, e.g., a patient community, family caregivers, and professional caregivers.

2.3.5 Behavioral Medicine Systems

Behavioral medicine systems may collect, track, and analyze behavior-related data to identify causal failure points in treatment and to predict corrective action by prescribing specific behavior modifications. In various aspects, the behavioral medicine systems may assist patients via questionnaires and patient profile assessment on symptomatologic or therapeutic subjects, e.g., in various decision processes by display a menu-guided series of questions and receiving answer(s) from the patient.

FIG. 10 illustrates an exemplary IEM data framework **102** having a behavioral medicine system **204e**, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as the base station **404** and the mobile telephone **406**. In various aspects, the behavioral medicine system **204e** may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

In one scenario, the behavioral medicine system **204e**, e.g., a software agent, may be located in whole or in part on a patient-related device such as the mobile telephone **406**. The software agent may assist the patient in various endeavors, e.g., diet choices, smoking cessation, etc. The assistance may be provided, by example, by generating for display on the mobile telephone **406** question sets related to diet and smoking cessation. The patient may answer the questions, e.g., select from various answer options. Based on the patient's answers to the questions, the software agent may categorize the patient according to predetermined categories. The software agent may provide language and menu choices based on the patient categorization.

In another scenario, patient behavior is tracked with respect to various IEM data, e.g., patient parameters, sometimes referred to herein as "sentinels for wellness". Examples of sentinels for wellness include medication therapy adherence, weight, blood pressure, etc. The sentinels for wellness may be derived, for example, from various health devices **300c** such as intelligent scales, cardiac-related devices, etc.

To illustrate, patient **506** ingests medication according to physician instructions. The IEM data **200** in the form of

ingestion information identifying the ingested medication and the time of ingestion are captured via an ingestion device and communicated to the patient's mobile telephone **406**. Also captured via health device(s) **300c** at the time of medication ingestion are the patient's blood pressure and weight. The timing of the foregoing data captures may be synchronized via, for example, software utilizing a reminder system to alert the patient to take the medication at a particular time. Upon receiving the ingestion information, e.g., confirmation of ingestion, the software associated with the mobile telephone **406** communicably triggers health device(s) **300c** to determine blood pressure and weight, and forwards such data to the mobile telephone **406** for aggregation with the IEM data **200** in the form of the ingestion information.

The aggregated data may be forwarded to behavioral medicine system **204e**, which may be configured, for example, as the mobile telephone and software **406**, the server **500** including the software **502** and the database **504**, and/or other configurations. Upon receipt of the aggregated data, various processing may take place.

One example of processing is analysis of the IEM data **200** to determine degree of patient adherence to medication regimen, i.e., determine if the patient ingested the prescribed medication in the right dosage at the prescribed time interval (s).

Another example of processing is analysis of the IEM data **200** to determine if the blood pressure measurement is in line with physician expectations. Thus, the notification of patient adherence to the medication regimen and the blood pressure measurement may be communicated to a physician system **106f** for review by the patient's physician. The physician, in turn, may update the IEM data **200**, e.g., determine an adjustment in the medication regimen is needed and communicate, via the behavioral medicine system, the updated medication regimen to the patient's mobile telephone **406** and to the pharmacy system **106b** for filling the updated prescription.

In cases of a nonadherence determination, the physician may alert the patient, via the behavioral medicine system **204e**, to make an appointment for a physical review. In various aspects, the behavioral medicine system **204e** may generate and/or forward a reminder to the hub, e.g., mobile telephone **406** of the patient **506**. The reminder, for example, may include the dosing schedule, a reminder for the upcoming dose, instructions to follow in case of a missed dose, etc.

In cases of underdosage/overdosage, the behavioral medicine system **204e** may interoperate with an alert system, e.g., the IEM data phone system, infra, and compare current dosage information to predetermined thresholds to determine if a critical status dosing event exists, e.g., the patient is critically underdosed or critically overdosed. If such a determination is made, the appropriate system may generate an alert to appropriate parties, e.g., generate a 911 emergency call for medical assistance, generate an emergency alert to the physician system **106f**, and generate an alert to a family caregiver system **106g**, e.g., a family member's mobile telephone.

In still another scenario, analysis of the patient's communication patterns/habits is performed to determine patient parameters, indicated actions, etc. To illustrate, an application such as software **502** resident on the mobile telephone **406** tracks the patient's phone usage to determine communication patterns. For example, the family caregivers, physician, etc., may selectively configure tracking parameters of the application to determine various patient communication thresholds, patterns, etc. The software monitors communi-

cation from/to the selected device, e.g., the patient's mobile telephone **406**. In various aspects, the application mines mobile telephone records of the associated carrier to determine calling and called parties, heavy volume call time, no call times, etc. and builds a profile against the same. The application monitors use of the mobile telephone **406** and identifies significant, e.g., user selected, deviations from the profile. Upon identification of a deviation, the application initiates predetermined actions, e.g., communicates an alert to the physician and/or family caregiver via the healthcare system **106a**, the physician system **106f**, and/or the family caregiver system **106g**.

Another example of processing is analysis of the IEM data **200** together with data from another source **314**, e.g., aggregated data. The aggregated data may be collected from various sources, aggregated at various and/or multiple points, and/or communicated via various channels to/from various devices.

To illustrate, cardiac data is derived via electrical tomography, as heretofore discussed. The cardiac data is communicated directly or indirectly, e.g., by the patch receiver **400**, to a software application on the hub, e.g., the mobile telephone **406**. The software application on the mobile telephone **406** aggregates the cardiac data with the IEM data, e.g., pill ingestion-related data, and displays the various data via a graphical user interface (GUI).

Subsequent to enrollment, the behavioral medicine system ascertains that the patient has neglected to take the medication at the appropriate times. Reminder alerts for upcoming medication dosing time(s) are sent to the patient via the mobile telephone. Upon receiving the alerts, the patient timely ingests the medication, resulting in a change in the sentinels for wellness.

2.3.6 Incentive Systems

Incentive systems provide incentives and rebates through various programs. The incentives and rebates are based on, or otherwise associated with, the IEM data. The IEM data may be analyzed via, for example, an IEM data system **204** to determine if certain criteria/thresholds/goals are evident. Based on the determination, incentives tied to or associated with the criteria/threshold/goals may be generated.

FIG. 11 illustrates an exemplary IEM data framework **102** having an incentive system **204f**; according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as the mobile telephone **406**. In various aspects, the incentive system **204f** may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

In one scenario, patient adherence is tracked with respect to various patient parameters, e.g., medication therapy and adherence. Incentives may be awarded accordingly. For example, patient **506** ingests medication according to physician instructions. The IEM data **200** in the form of ingestion information identifying the ingested medication and the time of ingestion are captured via an ingestion device and communicated to the patient's mobile telephone **406**, and to the behavioral medicine system **204e**. The behavioral medicine system **204e** verifies patient **506** adherence to the prescribed medication regimen, and sends verification to the incentive system **204f**. The incentive system **204f**, via the software **502** and the database **504**, determines the price paid for the medication, and issues a rebate or credit against the cost. For example, the rebate may be issued and a financial transaction in the amount of the rebate posted to the patient's financial account via the financial transaction system **106e**.

In another example, the rebate may be communicated and applied to an account associated with the patient via the pharmacy system **106b** with, for example, a credit against the next refill for the patient's prescription medication.

In another example, the patient's blood pressure and weight may be captured via health device(s) **300c** at time of medication ingestion. The timing of the foregoing data captures may be synchronized via software utilizing a reminder system to alert the patient to take the medication at a particular time. Upon receiving the ingestion information, e.g., confirmation of ingestion, the software associated with the mobile telephone **406** may communicably trigger health device(s) **300c** to determine blood pressure and weight, and forward such data to the mobile telephone **406** for aggregation with the IEM data **200** in the form of the ingestion information. The aggregated data may be communicated to the incentive system **204f** where the software **502** and/or database **504** may be utilized to determine if the patient's weight and blood pressure meet acceptable predetermined thresholds. If, for example, the weight exceeds an acceptable threshold, the incentive system **204f** may generate an incentive in the form of a discount membership offering at a local health club, etc. The offering may be constructed using various data parameters and demographics, e.g., geographical location of the patient, amount of weight to be lost, health assessment scoring based on individualized patient health parameters, lists of participating health clubs, etc.

The incentive may be communicated to the patient **506** via, for example, the patient's mobile telephone **506**.

2.3.7 Personalized Commercial Products/Services

Personalized commercial products/services provide individualized products and services predicated on or related to IEM data.

FIG. 12 illustrates an exemplary IEM data framework **102** having a personalized commercial products/services system **204g**, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and the hub **202**. In various aspects, the commercial products/services system **204g** may be embodied as, for example, an IEM data device, e.g., a patch receiver. In various aspects, the commercial products/services system **204g** may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

In one scenario, commercial products/services system **204g** include consumer-friendly receivers, such as patch receivers. The receivers comprise various accessories and incorporate various designs. For example, children's patch receivers may comprise cartoon character appliques. Youths' patch receivers may comprise tattoo-like design aspects. Further examples include IEM data receivers embodied as I integrated into accessories, e.g., earrings, naval rings, and other means of adornment, etc.

Commercial products/services system **204g** further comprise branded or "community" associated products and services.

2.3.8 Auto Billing Systems

Auto billing systems receive, process, and/or facilitate payment via a financial account. Auto billing applications associated with the auto billing system and/or with financial institution systems seamlessly interoperate to generate a bill, verify account holder information, charge an account, etc. Statements are updated to reflect payment information. Similar applications may be applied for prescriptions, consumer products, information provision via personal devices, etc.

FIG. 13 illustrates an exemplary IEM data framework **102** having an auto billing system **204h**, according to one

embodiment. The IEM data framework **102** further includes IEM data **200** and the hub, shown here embodied as the handheld device **402**. In various aspects, the auto billing system **204h** may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

In one scenario, various parties such as patient **506**, physicians, pharmaceutical companies, etc., subscribe to information feeds/patient population data of IEM data **200** to further business goals, manage health care, etc. The parties may receive the information feeds/access population data, etc. via a variety of devices. For example, patient **506** may receive an information feed via hub **202** embodied as the handheld device **402**, which, via a software agent, may generate a financial transaction in the form of an invoice for the information feed displayed for the patient **506**. Payment may be effected via automated methods.

In a patient selection method, for example, the patient selects various payment options via the software agent resident on the handheld device **402**. A payment transaction is generated and communicated to the financial transaction system **106e**. The financial transaction system **106e** automatically charges an account associated with the patient **506**. Confirmation of the payment together with digital, e.g., electronic, copies of the invoice are provided to the software agent resident on the handheld device **402** for the patient **506** to view, etc.

In an automated method, for example, a bill and/or financial transaction are automatically generated upon predetermined criteria. The predetermined criteria include, for example, delivery of information associated with an information feed or other source, access to a data collection, e.g., patient population data stored in a database, etc. The patient selects various payment options via the software agent resident on the handheld device **402**, and a payment transaction is generated and communicated to the financial transaction system **106e**. The financial transaction system **106e** automatically charges an account associated with the patient **506**. Confirmation of the payment together with digital copies of the invoice are provided to the software agent resident on the handheld device **402** for the patient **506** to view, etc. For example, a healthcare provider may access patient population data stored in decision support system **204b** via the healthcare system **106a**. Software of the decision support system **204b** may cooperate with the software **502** and the database **504** of the auto billing system **204h** to identify the party to be billed for the access. Upon identification, the auto billing system **204h** may automatically generate a bill and/or financial transaction for the access via one or more of the aforescribed channels.

2.3.9 Tracking Systems

Tracking systems track and integrate product movement data. In one example, the life cycle of an ingestible device may be tracked from manufacture to shipment, pharmacy inventory, delivery to patient, ingestion and expulsion.

FIG. **14** illustrates an exemplary IEM data framework **102** having a tracking system **204i**, according to one embodiment. The IEM data framework **102** further includes the IEM data **200** and the hub, shown here embodied as a scanner **1402**. In various aspects, the tracking system **204i**, may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

In one scenario, a pharmaceutical manufacturer produces an ingestible device **302a** such as a particular medication having an IEM system device therein. The IEM system device contains various IEM data **200** such as medication

identification, batch number, lot number, and manufacturer identification. The scanner **1402** may be utilized at various times/locations to scan the ingestible device **302a** and capture the IEM data **200** associated therewith. The IEM data **200** may then be stored, processed, etc., via, for example, the software **502** and the database **504** of the tracking system **204i**. For example, the IEM data **200** may be read by the scanner at a shipping point and when received by a pharmacy to ensure inventory control, distribution integrity, and chain of custody for restricted pharmaceuticals, etc.

The tracking information may be used, for example, by regulatory agencies systems **106i** to determine regulatory adherence, etc.

2.3.10 Interdiction Systems

Interdiction systems track, reconcile, and support interdiction programs. The interdiction programs include, for example, programs related to drug identification and use detection by sworn personnel, search and seizure activities, etc.

FIG. **15** illustrates an exemplary IEM data framework **102** having an interdiction system **204j**, according to one embodiment. The IEM data framework **102** further includes IEM data **200** and hub, shown here embodied as a scanner **1402**. In various aspects, the interdiction system **204j** may interoperate, or be otherwise associated with, one or more IEM data systems **204** and/or one or more commercial systems **106**.

In one scenario, a pharmaceutical manufacturer produces an ingestible device **302a** such as a particular medication having an IEM system device therein. The IEM system device contains various IEM data **200** such as medication identification, batch number, lot number, and manufacturer identification. The scanner **1402** may be utilized at various times/locations to scan the ingestible device **302a** and capture the IEM data **200** associated therewith. The IEM data **200** may then be communicated to, for example, the software **502** and the database **504** of the interdiction system **204j**, where the IEM data **200** may be accessed by and communicated to regulatory agency systems **106i** to facilitate various regulatory and enforcement functions, to locate missing controlled substances, to intercept contraband, to identify unknown substances, and to otherwise support agency and regulatory activities.

In various aspects, the IEM data **200** may be communicated to/from, for example the interdiction system **204j** from/to the tracking system **204i**, for processing, storage, etc. For example, the IEM data **200** may be read by the scanner at a shipping point and read by a pharmacy to ensure inventory control, distribution integrity, and chain of custody for restricted pharmaceuticals, etc. The scanned (read) IEM data **200** may be reconciled between the interdiction system **204j** and the tracking system **204i** to ensure complete shipment, to track shipments through various jurisdictions, etc. In one example, the IEM data **200** such as the identifier data, shipment data, patient information, recipient information, and commercial activities are tracked and reconciled to intercept contraband and otherwise support agency and regulatory activities.

2.3.11 Subscription Systems

Subscription systems enable subscription to various IR information feeds and data/knowledge collections, e.g., IEM data collection system. For example, patients subscribe to IEM data information feeds and/or IEM data collections, which aggregate various sources of data and fuse the data into integrated, individualized information based on the subscriber's requirements. The information fusion may include, for example, personalized medication regimens and

alert applications, individual social community information, music, etc. The information may be automatically billed, for example, under a single point of charge model on a recurring basis. The agent may be provided as part of an embedded device, e.g., standard application on a mobile telephone, etc.

FIG. 16 illustrates an exemplary IEM data framework 102 having a subscription system 204k, according to one embodiment. The IEM data framework 102 further includes IEM data 200 and the hub, shown here embodied as a mobile telephone 406. In various aspects, the subscription system 204k may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, the patient 506 subscribes to various information feed(s) and/or IEM data collections, discussed hereinafter in detail. The information feed(s) include, for example, structured and non-structured information on a variety of topics generated or delivered from various sources, e.g., websites, blogs, etc. The IEM data collections include storage repositories having IEM data. The storage repositories may be associated, e.g., integral to or remote from, the subscription system 204k. For example, an IEM data collection may be resident in part or wholly in database 504 of the subscription system 204k.

In one scenario, IEM data 200 are communicated from a subscription source to a subscriber, e.g., a subscriber's device. The subscription source includes, for example, IEM data systems 204, e.g., the database 504 of the subscription system 204k, feedback loop system 204a, patient tools 204d, and decision support system 204b; commercial systems 106b, e.g., online medical and business information/newsfeed sources, healthcare system 106a; and other sources, e.g., devices associated with the patient 506, the hub, etc. The subscriber includes, for example, a person, group, or resource, e.g., a database, a computer system, server, network, etc.

In various aspects, subscription services may be initiated via, for example, a software agent resident on the hub or communication with a local or remote system such as the healthcare system 106a.

In various aspects, the subscriptions services may be billed and paid via, for example, the subscription system 204k and the financial transaction system 106e.

In various aspects, the subscription newsfeeds/data may be combined or integrated into a single or multiple newsfeeds, e.g., the software 502 and/or the database 504 of the subscription system 204k may enable data aggregation, etc.

To illustrate, the patient 506 subscribes to a healthcare newsfeed and a pharmacy newsfeed, one or more having IEM data 200, via the subscription system 204k. The patient subscribes by selecting an application, e.g., software agent resident on the hub, illustratively embodied here as the mobile telephone 406. Once the patient has selected the subscription options, the order is communicated to the subscription system 204k, which, via the software 502 and the database 504, confirms, processes, stores, and bills the order. The subscriber's financial account may be automatically charged, for example, by communicating invoice information to a financial transaction system 106e associated with the subscriber's account. Confirmation of the charge may be communicated from the financial transaction system 106e to the subscriber via the subscription system 204k and/or the mobile telephone 406.

Based on the subscription parameters, the subscription system 204k receives the healthcare newsfeed information and the pharmacy newsfeed information. The software 502 of the subscription system compares subscriber data of the

patient 506 in the database 504 against subscriber data found in the pharmacy newsfeed, e.g., patients who are prescribed medications for cardiac therapy. Based on the comparison, software 502 separates the data of the pharmacy newsfeeds relevant to the subscriber, combines the relevant data with the healthcare newsfeed information and communicates the combined newsfeed information to the mobile telephone 406 for access and display.

2.3.12 IEM Data Collection System

The IEM data collection system provides/facilitates access to/storage of the IEM data. Examples of the IEM data include patient population data and electronic medical records. In various aspects, IEM data collections may include functionality related to the collection, management, manipulation, storage, dissemination, and billing of IEM data.

FIG. 17 illustrates an exemplary IEM data framework 102 having an IEM data collection system 2041, according to one embodiment. The IEM data framework 102 further includes IEM data 200 and the hub, shown here embodied as a handheld device 402. In various aspects, the IEM data collection system 2041, may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, patient population data, e.g., anonymized, empirical patient data, is stored in one or more repositories, e.g., the database 504 of the IEM data collection system 2041. The patient population data may be received from various sources, e.g., the IEM data 200 associated with one or more patient 506, IEM data systems 204 such as behavioral medicine systems 204e, subscription systems 204k, patient tools 204d, etc., and commercial systems such as healthcare systems 106a, pharmaceutical systems 106c, university systems 106d, etc.

In various aspects, the IEM data collection system 2041 may be consolidated in a single physical and/or logical location, e.g., the database 504 of the server 500 of the IEM data collection system 2041, or distributed across two or more systems or locations, e.g., remotely distributed on multiple IEM data systems 204, associated with commercial systems 106, and/or distributed between the IEM data collection system 2041 and other systems/locations.

Multiprofile users may access, utilize, and/or contribute to the IEM data collection system 2041. Multiprofile users include, for example, individuals or groups using various methods/devices for access, utilization, and/or contribution. Examples of multiprofile users include patient 506, family members and family caregivers, professionals, academics, corporates, etc. The methods/devices include the hub devices such as a mobile telephone, base station, handheld device, etc., as well as system components associated with IEM data systems and commercial systems, e.g., laptop computer associated with a university network, a desktop computer associated with the family caregiver system 106g, etc.

To continue the foregoing illustration, a researcher, using the university system 106d, accesses the IEM data collection system 2041 via the Internet, etc. and submits queries against the patient population data, extracts various data, etc.

In various aspects, the IEM data collection system 2041 includes privacy assurance, authentication, and validation mechanisms with respect to financial, medical, and other privacy information. For example, the software 502 may authenticate users. The software 502 may cleanse/verify data to ensure predetermined privacy thresholds are met.

2.3.13 Approval Systems

Approval systems aggregate and/or analyze various data to enable an informed approval decision.

FIG. 18 illustrates an exemplary IEM data framework 102 having an approval system 204m, according to one embodiment. The IEM data framework 102 further includes IEM data 200, the hub, shown here embodied as a handheld device 402, and an associated intelligent pill dispenser 1802. In various aspects, the approval system 204m, may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, the patient 506 opens an intelligent pill dispenser 1802, e.g., a pill dispenser having a microchip and communication abilities. The patient 506 removes a pill having an IEM system from the intelligent pill dispenser 1802. The intelligent pill dispenser 1802, via its microchip, senses the removal of the pill, receives a signal from an IEM system that the patient 506 has ingested the pill, and determines the remaining quantity. If the remaining quantity is fewer than a predetermined threshold quantity, the intelligent pill dispenser 1802 communicates a refill request to the approval system 204m. The approval system 204m via, for example, the software 502 and the database 504, verify information associated with the patient 506, e.g., patient name, prescription identification, medication ingestion verification, refill timing, etc. The approval system 204m may interoperate with, e.g., communicate with, various IEM data systems 204 and/or commercial systems 106 to obtain/validate information. For example, data provided to/resident in the approval system 204m may be reconciled with medical records of healthcare system 106, the refill request approved by approval system 204m, and a refill communicated to the pharmacy system 106b.

2.3.14 Forecasting Systems

Forecasting systems aggregate data and/or facilitate analysis of the aggregated data/data collections to derive/generate predictive information.

FIG. 19 illustrates an exemplary IEM data framework 102 having a forecasting system 204n, according to one embodiment. The IEM data framework 102 further includes IEM data 200 and the hub, shown here embodied as a base station 404. In various aspects, the forecasting system 204n, may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, for example, IEM data 200 are received by the base station 404 from ingestible devices associated with patients 506a-c. The base station 404 communicates the IEM data 200 to the IEM data collection system 2041, which anonymizes the IEM data 200 and aggregates the anonymized IEM data 200 with patient population data.

The IEM data collection system 2041 communicates all or a portion of the patient population data to the forecasting system 204n, where the software 502, e.g., one or more applications, processes the patient population data to derive various statistics, conclusions, forecasts, etc., according to predetermined requirements, objectives, etc. For example, the software 502 processes the patient population data and correlates various data such as blood pressure readings over a predetermined period of time versus medication taken versus adherence to medication regimen to determine overall efficacy of medication regimen and to forecast titrated patient dosing based on the overall efficacy findings.

Multiple profile parties, e.g., analysts using the pharmaceutical systems 106e, agents using the regulatory agency systems 106i, and researchers using the university systems 106d, access the forecasting system 204n. The multiple

profile parties utilize various tools, e.g., the software 502, to run analytical and forecasting applications against the patient population data and to access various forecasting data available in connection with the forecasting system 204n.

2.3.15 Financial Systems

Financial systems support and enable financial transactions associated with IEM data. In various aspects, the financial systems are communicably interoperable with existing automated banking systems and networks, etc.

FIG. 20 illustrates an exemplary IEM data framework 102 having a financial system 2040, according to one embodiment. The IEM data framework 102 further includes IEM data 200 and the hub, shown here embodied as a mobile telephone 406. In various aspects, the financial system 2040, may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, the patient 506, via the mobile telephone 406, places an order for a product/service, e.g., a newsfeed service from the subscription system 204k. The subscription system 204k, via its software, interoperates with the financial system 2040. The subscription system 204k, for example, securely communicates encrypted patient financial information such as account number and subscription information. The financial system 2040 authenticates the patient information and securely interoperates with the patient's financial institution, e.g., via a commercial system 106 such as the financial transaction system 106e to charge the patient's account and provide charge information/confirmation to the patient 506 via, for example, the mobile telephone 406.

2.3.16 IEM Data Phone

The IEM data phone enables IEM data—related applications. For example, application(s) include pill regimen scheduling applications, alert reminder applications, auto refill for medication applications, patient tool applications, social networking applications, incentive tracker applications, auto billing applications, subscription applications, approval applications, and financial transaction applications. The applications may be integrated with, associated with, or independent of one another. The applications may further be manufacturer-installable on the IEM data phone, downloadable or otherwise installable by a wholesaler, retailer, user, etc. Installation may be independent or bundled with other software, products, etc. In various aspects, the applications are user-configurable, downloadable, upgradeable, etc.

In various aspects, the IEM data phone and/or its applications may share common features, e.g., a common graphical user interface (GUI); branding, i.e., a collection of images and ideas representing an economic producer such as concrete symbols embodied as a name, logo, slogan, design scheme, etc. The IEM data phone may also include various connectivity schemes, e.g., Internet and cellular; may provide multimedia capabilities; and may embody various hardware and software configurations. The IEM data phone may be embodied in a variety of devices, e.g., the mobile telephone 406, the handheld device 402, etc.

FIG. 21 illustrates an exemplary IEM data framework 102 having an IEM dataphone 204p, according to one embodiment. The IEM data phone 204p may serve as the hub, for example. IEM data framework 102 further includes IEM data 200. In various aspects, the IEM data phone 204p, may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, the IEM data phone 204p includes the software 502, e.g., a portfolio of branded applications such

as pill regimen scheduling, alert reminders, auto refills, patient tools, social networking, incentive trackers, auto billing, subscriptions, approvals, and financial applications.

The pill regimen scheduling application may accept, reconcile, calendar, and manage contraindications and interactions of medication regimen(s). For example, the patient **506** may input information related to one or more prescriptions, including the pharmaceutical name and dosage. The pill regimen scheduling application may check the input information against existing information stored on the IEM data phone **204p**, e.g., in the database **504**, or elsewhere, e.g., the pharmacy **106b**. The pill regimen scheduling application may provide information regarding contraindicated medications, side effects, precautionary instructions. The pill regimen scheduling application may calendar the dosing information and generate alerts, e.g., reminders generated at appropriate times alerting the patient to ingest the medication. The alerts may be audible, visual, email, text message, etc. and may be integrated with, or independent of, alert reminder application(s).

The alert reminder application may accept or access various data associated with scheduling, including IEM data **200**, and generate alerts at appropriate times. The alerts may be audible, visual, email, text message, etc. and may be integrated with or independent of alert reminder application(s). The alert application may be user-configurable, e.g., type of alert, repetition of alert, interval of repetition, receivers of alert. The alerts may be associated with various devices of the patient, family caregivers, friends, etc. In one example, the patient **506** may schedule reminders to be sent to the user's device, e.g., the IEM data phone **204p**, the handheld device **402**, the base station **404**, the mobile telephone **406**, etc.

The alert reminder application may be integrated with other applications/systems. To illustrate an IEM system associated with the patient **506** that may, for example, detect medication ingestion event(s) and communicate the IEM data **200** associated with the medication ingestion event(s) to the alert reminder application via the IEM data phone **204p**. The alert reminder application may interoperate with the pill regimen scheduling application and perform various checks, e.g., the ingested medication was actually prescribed for the person that ingested it; the ingested medication was ingested in the correct dosage; the ingested medication was ingested at the prescribed time interval; etc.

Predetermined criteria may be used to determine if/when the alert reminders application generates an alert, reminder, etc. To continue with the foregoing illustration, upon a determination that the ingested medication was not prescribed for the person ingesting it or the wrong dosage was ingested, the alert reminder system generates alert(s) to a predetermined destination, e.g., alerts in the form of text messages to mobile telephones associated with the family caregiver system **106g**, alerts in the form of email/text messages to the healthcare system **106a** and the physician system **106f**. If the event is deemed critical, e.g., ingestion of non-prescribed medication, overdosage, etc., the alert reminder application may generate a call from the IEM data phone **204p** to the emergency assistance system, e.g., place a 911 call. The call (prerecorded audio, text message, etc.) may contain information such as the patient's name, the nature of the emergency, the ingestion details, physician and family caregiver information, and the physical location of the person ingesting the medication.

The auto refill application may facilitate automatic refill of a prescription medication via interoperation with, for example, the pharmacy system **106b**, etc.

The patient tool application may be provided on or accessible from the IEM data phone **204p**. For example, software tools for tracking dietary and physiologic symptoms may facilitate user entry of dietary intake and symptoms, collection of device-associated physiologic parameters such as blood pressure, heart rate, etc., correlation/analysis of the data, and feedback based on the correlation/analysis. The patient tool application may provide data, e.g., the feedback, for display on the IEM data phone **204p**, the IEM data system(s) **204**, and/or the commercial system(s) **106**.

The social networking application may facilitate social networking functionality. For example, the social networking application may retain various links to selected profiles of various social networks, receive data related to the selected profiles, e.g., updates to the profiles, facilitate messaging and other communication, update the user's profile, etc., communicate with the IEM data systems(s) **204**, and/or the commercial system(s) **106**, such as the patient tools/social network **204d** and the web communities **106h**.

The incentive tracker application may collect, manage, track, update, etc. incentive information. For example, the incentive tracker application may reconcile data associated with IEM data collection systems **204i** and wholesaler/retailer systems **106j** to determine incentive eligibility, e.g., a patient rebate. The incentive tracker application may further tally points under various reward systems, notify the patient **506** of milestones, goals, award of incentive, etc.

The auto billing application may facilitate billing for various transactions. The auto billing application may interoperate with various applications/systems, including the IEM data system(s) **204** and/or the commercial system(s) **106**, such as the billing for an auto refill via the pharmacy system, etc.

The subscription application facilitates ordering, receipt, management, etc. of various subscriptions, e.g., newsfeeds, access to various data collections on a subscription basis, etc. The subscriptions application may interoperate with various applications/systems, including the IEM data system(s) **204** and/or the commercial system(s) **106**, such as the subscription system **204k**, the IEM data collection system **204i**, etc.

The approval application aggregates and/or analyzes various sources of data to enable an informed approval decision. The approvals application may interoperate with various applications/systems, including the IEM data system(s) **204** and/or the commercial system(s) **106**, such as the auto refill system **204c**, the subscription system **204f**, the financial systems **2040**, the pharmacy systems **106b**, the wholesaler/retailer systems **106j**, etc.

The financial application supports and enables financial transactions associated with IEM data **200**. The financial application may interoperate with various applications/systems, including the IEM data system(s) **204** and/or the commercial system(s) **106**, such as the auto refill system **204c**, the incentive system **204f**, the subscription system **204k**, the approval system **204m**, the financial systems **2040**, the pharmacy system **106b**, the wholesaler/retailer systems **106j**.

2.3.17 Social Network System

Social networks are a social structure made of one or more nodes, e.g., components such as websites, accessed by individuals or organizations. The social network is typically tied by one or more specific types of interdependency, such as epidemiology, therapeutic regimen, healthcare management, etc., and thus may attract the interest of otherwise unrelated individuals and groups having in common an

interest in the interdependencies. Social networks may be built around various communities, e.g., family caregivers, patients, medical conditions, etc.

One example of a social network is a patient information community that provides information related to a particular medical condition, treatments, medications, regimens, and side effects based on both provider and anecdotal data. The availability of such data may provide benchmark-type services, e.g., facilitate self-assessment of personal progress and adjustment in therapies and behaviors by comparing and contrasting an individual's progress with the particulars of others having the same condition, similar therapies, etc.

FIG. 22 illustrates an exemplary IEM data framework 102 having a social network system 204g, according to one embodiment. The IEM data framework 102 further includes IEM data 200, and the hub, shown here embodied as the base station 404. In various aspects, the social network system 204g may interoperate, or be otherwise associated with, one or more IEM data systems 204 and/or one or more commercial systems 106.

In one scenario, patient 506 suffers from a cardiac condition. The patient 506 accesses the social network system 204g, which may be embodied as the server 500 having the software 502 and the database 504 having IEM data 200. Patient 506 may access the social network system 204g, for example, via the base station 404. The patient 506a searches the database 504 for patient profiles also having cardiac conditions similar to that of patient 506. The social network system 204g provides multiple profiles of patients having similar conditions. The profiles include various data pertinent to each patient such as medication therapies, personal behavior histories, etc. The patient 506 requests a comparison of his medication therapy, medication therapy adherence, and behavior to that listed in the profiled. The social network system 204g provides the requested comparative data in the form of a graphical display. From the display, the patient 506 is able to determine the profiles having the most favorable treatment outcomes. From such profiles, the patient 506 and/or social network system 204g analyze the differences between his medication, medication therapy adherence, behavior, etc. and the corresponding interdependencies of the profiles having the most favorable treatment outcomes.

The analysis may contrast the differences found in various areas, as well as generate prescriptive advice, e.g., in which areas the patient 506 may want to adjust and specific adjustments based on the analysis. The patient 506 may adopt the prescriptive advice, i.e., adjust accordingly, to improve his own personal outcome. Further, the patient 506 may update the social network system 204g with the adjustment data, which may be used in the future for tracking personal improvement as well as benchmarking purposes by other individuals. In various aspects, the social network system 204g may be communicably associated with other web communities 106h, e.g., youth communities, business communities, etc.

3.0 IEM Data Framework Method

One aspect comprises, for example, receiving, via a hub, ingestible event 5 data that originates from multiple ingested event markers; and communicating, via the hub, at least a portion of the ingestible event marker data to at least one ingestible event marker data system.

4.0 IEM Data Framework Article

One aspect comprises, for example, a storage medium having instructions, that when executed by a computing

platform, result in execution of a method of utilizing ingestible event marker data, comprising: receiving, via a hub, the ingestible event data that originates from multiple ingested event markers; and communicating, via the hub, at least a portion of the ingestible event marker data to at least one ingestible event marker data system.

5.0 IEM Data Framework System

One aspect comprises, for example, a receive module to receive, via a hub, ingestible event data that originates from multiple ingested event markers; and a communicate module to communicate, via the hub, at least a portion of the ingestible event marker data to at least one ingestible event marker data system.

Further, any of the embodiments disclosed herein may be performed in a data processing system. To illustrate, a diagrammatic system comprises, for example, a processor, a main memory, a static memory, a bus, a video display, an alpha-numeric input device, a cursor control device, a drive unit, a signal generation device, a network interface device, a machine readable medium, instructions and a network, according to one embodiment.

The diagrammatic system may indicate a personal computer and/or a data processing system in which one or more operations disclosed herein may be performed. The processor may be a microprocessor, a state machine, an application-specific integrated circuit, a field programmable gate array, etc. The main memory may be a dynamic random access memory and/or a primary memory of a computer system. The static memory may be a hard drive, a flash drive, and/or other memory information associated with the data processing system.

The bus may be an interconnection between various circuits and/or structures of the data processing system. The video display may provide graphical representation of information on the data processing system. The alpha-numeric input device may be a keypad, a keyboard and/or any other input device of text, e.g., a special device to aid the physically challenged. The cursor control device may be a pointing device such as a mouse. The drive unit may be a hard drive, a storage system, and/or other longer term storage subsystem. The signal generation device may be a bias and/or a functional operating system of the data processing system. The network interface device may be a device that may perform interface functions such as code conversion, protocol conversion and/or buffering required for communication to and from the network. The machine readable medium may provide instructions on which any of the methods disclosed herein may be performed. The instructions may provide source code and/or data code to the processor to enable any one/or more operations disclosed herein.

Although the present embodiments have been described with reference to specific example embodiments, it will be evident that various modifications and changes may be made to these embodiments without departing from the broader spirit and scope of the various embodiments. For example, the various devices, modules, etc. described herein may be enabled and operated using hardware circuitry, e.g., CMOS based logic circuitry, firmware, software and/or any combination of hardware, firmware, and/or software, e.g., embodied in a machine readable medium.

For example, the various electrical structure and methods may be embodied using transistors, logic gates, and electrical circuits, e.g., Application Specific Integrated circuitry (ASIC) and/or in Digital Signal Processor (DSP) circuitry.

For example, the receive module and the communicate module and other modules may be enabled using one or more of the technologies described herein.

In addition, it will be appreciated that the various operations, processes, and methods disclosed herein may be embodied in a machine-readable medium and/or a machine accessible medium compatible with a data processing system, e.g., a computer system, and may be performed in any order. Accordingly, the specification and drawings are to be regarded in an illustrative rather than a restrictive sense.

Any or all data associated with the aforementioned devices and methods, for example, may be used alone or in combination with other data to constitute IEM data, i.e., data having an IEM data aspect.

In certain embodiments, the system and/or method steps further includes/utilizes an element for storing data, i.e., a data storage element, where this element is present on an external device, such as a bedside monitor, PDA, smart phone, computer server, etc. Typically, the data storage element is a computer readable medium. The term “computer readable medium” as used herein refers to any storage or transmission medium that participates in providing instructions and/or data to a computer for execution and/or processing. Examples of storage media include floppy disks, magnetic tape, CD-ROM, a hard disk drive, a ROM or integrated circuit, a magneto-optical disk, or a computer readable card such as a PCMCIA card and the like, whether or not such devices are internal or external to the computer. A file containing information may be “stored” on a computer readable medium, where “storing” means recording information such that it is accessible and retrievable at a later date by a computer and/or computer-related component. With respect to computer readable media, “permanent memory” refers to memory that is permanent. Permanent memory is not erased by termination of the electrical supply to a computer of processor. Computer hard-drive ROM, i.e., not used as virtual memory, CD-ROM, floppy disk and DVD are all examples of permanent memory. Random Access Memory (RAM) is an example of non-permanent memory. A file in permanent memory may be editable and re-writable.

Also provided are computer executable instructions, i.e., programming, for performing the above methods, e.g., for programming the IEM, receiver, and other components of the system. The computer executable instructions are present on a computer readable medium. Accordingly, various aspects provide a computer readable medium containing programming for use in providing ingestible event marker data.

As such, in certain embodiments the systems include one or more of: a data storage element, a data processing element, a data display element, a data transmission element, a notification mechanism, and a user interface. These elements may be present or otherwise associated with at least one of the ingestible event marker data, the hub, and the IEM data systems.

One of the above-described systems is reviewed in terms of a receive module and a communicate module. The aspects, however, are not so limited. In a broader sense, the systems are composed of two or more different modules that communicate with each other, e.g., using the hub functionalities as reviewed above, e.g., using the IEM data in the communication, e.g., using the IEM data systems’ functionalities.

6.0 IEM System Structural Framework

FIG. 23 provides a diagrammatic representation of an identifier according to an embodiment of the invention. First

and second electrode materials (32 and 33) are in an ionic solution 39 (e.g., stomach fluid). This configuration creates a low voltage (V-) and a high voltage (V+) as applied to an electronic circuit 40. The two outputs of that electronic circuit 40 are E0 41 and E1 42, which are the signal-transmission electrodes. In an alternate embodiment, the signal generation element 30 includes a single electrode. In an alternative embodiment, a coil for communication may be provided. In certain embodiments, a structure, e.g., membrane, larger than the chip which defines a path for the current to travel is provided.

Electrodes 32 and 33 can be made of any two materials appropriate to the environment in which the identifier 30 will be operating. The active materials are any pair of materials with different electrochemical potentials. For instance, in some embodiments where ionic solution 39 comprises stomach acids, electrodes 32 and 33 may be made of a noble metal (e.g., gold, silver, platinum, palladium or the like) so that they do not corrode prematurely. Alternatively, the electrodes can be fabricated of aluminum or any other conductive material whose survival time in the applicable ionic solution is long enough to allow identifier 30 to perform its intended function. Suitable materials are not restricted to metals, and in certain embodiments the paired materials are chosen from metals and non-metals, e.g., a pair made up of a metal (such as Mg) and a salt (such as CuI). With respect to the active electrode materials, any pairing of substances—metals, salts, or intercalation compounds—with suitably different electrochemical potentials (voltage) and low interfacial resistance are suitable.

The signal generation component of the identifier element is a structure that, upon activation by the activation component, emits a detectable signal, e.g., that can be received by a receiver, e.g., as described in greater detail below. The signal generation component of certain embodiments can be any convenient component or element that is capable of producing a detectable signal and/or modulating transduced broadcast power, upon activation by the activation component. Detectable signals of interest include, but are not limited to: conductive signals, acoustic signals, etc. As reviewed above, the signals emitted by the signal generator may be generic or unique signals, where representative types of signals of interest include, but are not limited to: frequency shift coded signals; amplitude modulation signals; frequency modulation signals; etc.

In certain embodiments, the signal generation element includes circuitry, as developed in more detail below, which produces or generates the signal. The type of circuitry chosen may depend, at least in part, on the driving power that is supplied by the power source of the identifier. For example, where the driving power is 1.2 volts or above, standard CMOS circuitry may be employed. In other embodiments where the driving power ranges from about 0.7 to about 1.2 V, sub-threshold circuit designs may be employed. For driving powers of about 0.7 V or less, zero-threshold transistor designs may be employed.

In certain embodiments, the signal generation component includes a voltage-controlled oscillator (VCO) that can generate a digital clock signal in response to activation by the activation component. The VCO can be controlled by a digital circuit, which is assigned an address and which can control the VCO with a control voltage. This digital control circuit can be embedded onto a chip that includes the activation component and oscillator. Using amplitude modulation or phase shift keying to encode the address, an identifying signal is transmitted.

The signal generation component may include a distinct transmitter component that serves to transmit the generated signal to a remote receiver, which may be internal or external to the patient, as reviewed in greater detail below. The transmitter component, when present, may take a number of different configurations, e.g., depending on the type of signal that is generated and is to be emitted. In certain embodiments, the transmitter component is made up of one or more electrodes. In certain embodiments, the transmitter component is made up of one or more wires, e.g., in the form of antenna(e). In certain embodiments, the transmitter component is made up of one or more coils. As such, the signal transmitter may include a variety of different transmitters, e.g., electrodes, antennas (e.g., in the form of wires) coils, etc. In certain embodiments, the signal is transmitted either by one or two electrodes or by one or two wires (a two-electrode transmitter is a dipole; a one electrode transmitter forms a monopole). In certain embodiments, the transmitter only requires one diode drop of power. In some embodiments, the transmitter unit uses an electric dipole or electric monopole antenna to transmit signals. In certain embodiments, the identifier employs a conductive near-field mode of communication in which the body itself is employed as a conductive medium. In such embodiments, the signal is not a magnetic signal or high frequency (RF) signal.

FIG. 24 shows the detail of one implementation of an electronic circuit that can be employed in an identifier according to the present invention. On the left side are the two battery electrodes, metal 1 and metal 2 (32 and 33). These metals, when in contact with an electrolyte, form a battery that provides power to an oscillator 61, in this case shown as a schematic. The metal 1 32 provides a low voltage, (ground) to the oscillator 61. Metal 2 33 provides a high voltage (V-high) to the oscillator 61. As the oscillator 61 becomes operative, it generates a clock signal 62 and an inverted clock signal 63, which are opposites of each other. These two clock signals go into the counter 64 which simply counts the number of clock cycles and stores the count in a number of registers. In the example shown here, an 8 bit counter is employed. Thus, the output of counter 64 begins with a value of "0000000," changes to "0000001" at the first clock cycle, and continues up to "1111111." The 8-bit output of counter 64 is coupled to the input of an address multiplexer (mux) 65. In one embodiment, mux 65 contains an address interpreter, which can be hard-wired in the circuit, and generates a control voltage to control the oscillator 61. Mux 65 uses the output of counter 64 to reproduce the address in a serial bit stream, which is further fed to the signal-transmission driving circuit. Mux 65 can also be used to control the duty-cycle of the signal transmission. In one embodiment, mux 65 turns on signal transmission only one sixteenth of the time, using the clock counts generated by counter 64. Such a low duty cycle conserves power and also allows other devices to transmit without jamming their signals. The address of a given chip can be 8 bits, 16 bits or 32 bits.

According to one embodiment, mux 65 produces a control voltage, which encodes the address serially and is used to vary the output frequency of oscillator 61. By example, when the control voltage is low, that is, when the serial address bit is at a 0, a 1 megahertz signal is generated by the oscillator. When the control voltage is high, that is, when the address bit is a 1, a 2 megahertz signal is generated the oscillator. Alternately, this can be 10 megahertz and 20 megahertz, or a phase shift keying approach where the device is limited to modulating the phase. The purpose of

mux 65 is to control the frequency of the oscillator or an AC alternative embodiment of the amplified signal of oscillation.

The outputs of mux 65 are coupled to electrode drive 66 which can drive the electrodes to impose a differential potential to the solution, drive an oscillating current through a coil to generate a magnetic signal, or drive a single electrode to push or pull charge to or from the solution.

In this manner, the device broadcasts the sequence of 0's and 1's which constitute the address stored in mux 65. That address would be broadcast repeatedly, and would continue broadcasting until metal 1 or metal 2 (32 and 33) is consumed and dissolved in the solution, when the battery no longer operates.

Other configurations for the signal generation component are of course possible. Other configurations of interest include, but are not limited to: those described in copending PCT application serial no. PCT/US2006/016370.

In certain embodiments, the activation component includes a power storage element. For example, a duty cycle configuration may be employed, e.g., where slow energy production from a battery is stored in a power storage element, e.g., in a capacitor, which then provides a burst of power that is deployed to the signal generation component. In certain embodiments, the activation component includes a timing element which modulates, e.g., delays, delivery of power to the signal generation element, e.g., so signals from different compositions, e.g., different IEMs, that are administered at substantially the same time are produced at different times and are therefore distinguishable.

In certain embodiments, the components or functional blocks of the identifiers of the ingestible event markers are present on integrated circuits, where the integrated circuits include a number of distinct functional blocks, i.e., modules. Within a given identifier, at least some of, e.g., two or more, up to an including all of, the functional blocks, e.g., power source, transmitter, etc., may be present in a single integrated circuit in the receiver. By single integrated circuit is meant a single circuit structure that includes all of the different functional blocks. As such, the integrated circuit is a monolithic integrated circuit (also known as IC, microcircuit, microchip, silicon chip, computer chip or chip) that is a miniaturized electronic circuit (which may include semiconductor devices, as well as passive components) that has been manufactured in the surface of a thin substrate of semiconductor material. The integrated circuits of certain embodiments of the present invention may be hybrid integrated circuits, which are miniaturized electronic circuits constructed of individual semiconductor devices, as well as passive components, bonded to a substrate or circuit board.

Embodiments of the present invention provide a low-power, miniature, ingestible marker that includes an integrated circuit (IC) which automatically activates itself after the contacts a patient's body fluid, transmits a predetermined signal based on locally generated power, and de-activates itself after a certain period of time. In these embodiments, as described above, the IEM uses the patient's body fluid, such as the stomach acid, to form a voltaic cell. Furthermore, the IEM uses a special circuit that changes the impedance of a closed circuit which forms the voltaic cell, thereby creating an external signal by modulating the amplitude and waveform of the current that flows through the patient's tissue and body fluid. As described in more detail below, such a circuit configuration allows the circuitry to operate at a low voltage while generating a signal that is sufficiently strong to be detected by a receiver in contact with the patient's body.

An IEM's IC can be packaged with an integrated voltaic cell which can be manufactured on the same substrate as the IC circuit. This wafer level integration significantly reduces the chip and simplifies the manufacturing process. As a result, each IEM's cost can be considerably lowered. In one embodiment, the anode and cathode electrode materials are fabricated on each side of the substrate, whereby the IC logic is situated between the two electrodes. In one embodiment, the logic circuit is situated in a location chosen to minimize the area overlapping vertically with the anode or cathode electrode.

FIG. 25 illustrates an exemplary device configuration of the IEM IC in accordance with one embodiment of the present invention. In one embodiment, the IC chip's substrate **2004** is coupled to the anode (S1) of the voltaic cell, which can be a layer of Magnesium (Mg) **2006** coated on the backside of substrate **2004**. On the opposite side of substrate **2004** is a layer of cathode (S2) material **2002**, which in this example is Copper Chloride (CuCl). The electrodes **2002** and **2006**, and the body fluid which serves as an electrolyte fluid, form the voltaic cell. The IEM IC circuitry, which is fabricated on substrate **2004**, is the "external" circuit that forms a return circuit for the voltaic cell. Essentially, the IEM IC changes the impedance of this "external" circuit, thereby changing the total amount of current flowing through the body fluid. A receiving circuit, e.g., on a personal health receiver as described in greater detail below, in contact with the body fluid can detect this current change and receive the encoded messages.

Note that the two electrodes S1 and S2 of the voltaic cell also serve as the transmission electrodes for the IC. This configuration significantly reduces the complexity of the IC chip. Furthermore, since a fluid-metal interface often exhibits high impedances, using a separate pair of electrodes which are different from the voltaic-cell electrodes can introduce additional high impedance to the circuit, thereby reducing the transmission efficiency and increasing power consumption. Therefore, using the voltaic-cell electrodes for transmission also improves the power-efficiency of the IC circuitry.

The IC of the IEM functions as an ingestible transmitter that transmits a unique identification code once powered on. This IC can be packaged within a pharmaceutically acceptable vehicle, e.g., as described above. When the IEM is swallowed and inside the stomach, the integrated voltaic cell, or battery, uses the stomach acid as the battery electrolyte to power up the main chip and commences broadcasting thereafter. Furthermore, several pills can be ingested and transmit at the same time. During operation, a unique identification code, e.g., using BPSK modulation, is broadcasted. This broadcast can be received and demodulated by a receiver, e.g., as described below, which is either implanted under the skin or in contact with the patient's body tissue. The receiver can decode and store the identification code with a time stamp.

In one embodiment, a IEM IC includes an impedance-detection circuitry. This circuitry is configured to detect the impedance between the anode and cathode electrodes. When the electrodes are not submerged in an electrolyte fluid, e.g., stomach acid, the impedance between the electrodes is high and the IC is not activated. When the electrodes are in contact with the electrolyte fluid and the impedance-detection circuit detects the drop in impedance, the IC is then activated.

Embodiments of the present invention allow the smart pill to operate at unconventionally low voltages. In general, the IC can operate with a power supply at 0.8-2 V. In one

embodiment, the IC is configured to operate with a power supply at approximately 1.0-1.6 V. In addition, the voltaic cell exhibits an internal impedance of 200-10K Ohm. In one embodiment, the voltaic cell exhibits in internal impedance of approximately 500-5K Ohm. The IC also provides an ultra stable carrier clock frequency, thereby facilitating error-resistant communications.

In one embodiment, an IC includes three parts of circuitry. The first part is an impedance-detection circuitry that uses the battery as the power supply. The second part is the main circuit that broadcasts the messages. The impedance detection circuit can hold the main circuit at substantially zero power consumption before the battery detects an impedance lower than 10K Ohms. When the impedance drops to approximately 10K Ohms, the main circuit is activated and the impedance detection circuit can decouple itself from the battery. The third part is a watchdog circuitry designed to protect the patient's safety when hazardous situation occurs.

FIG. 26 presents an exemplary schematic diagram illustrating the design of a IEM IC in accordance with one embodiment of the present invention. In general, the IEM chip has a battery section **3002** and an IC circuitry **3004**. Battery section **3002** includes the voltaic-cell electrodes, which when coupled with electrolyte fluid form a voltaic cell. The two battery electrodes are coupled to the high-voltage rail (VCC) and ground for the IC circuitry, respectively. IC circuitry **3004** includes a transmission switch transistor **3006**, a recharge transistor **3008**, a recharge-protection diode **3010**, a recharge capacitor **3016**, a local oscillator **3014**, and control logic **3012**. Local oscillator **3014** produces one or more carrier frequencies which is used by control logic **3012** to issue a transmission command (labeled as "broadcast") to turn on and off transmission switch transistor **3006**. For example, oscillator **3016** can produce a 20 KHz signal, based on which control logic **3012** can generate a binary-phase shift keying (BPSK)-encoded message. Control logic **3012** then switches on and off transistor **3006** to transmit these messages.

When transistor **3012** is turned on, a low-impedance external return circuit is provided between the two voltaic-cell electrodes. Consequently, the current flowing through the patient's body is also increased. When transistor **3012** is turned off, the external return circuit between the two voltaic-cell electrodes exhibits a high impedance. Correspondingly, the current flowing through the patient's body is significantly lower. Note that the current draw of the rest of the circuitry, e.g., the oscillator **3014** and control logic **3012**, is sufficiently low so that there is a significant difference in the body current between the broadcast period and the silence period.

When transistor **3006** is turned on, the two voltaic-cell electrodes are effectively shorted. As a result, the voltage provided by the electrodes is significantly lower than when transistor **3006** is turned off. To ensure that control logic **3012** continues to operate properly, recharge capacitor **3016** provides the necessary voltage (VCC) to control logic **3012**. Note that recharge capacitor **3016** is recharged when the IC chip is in a silence period, i.e., when transistor **3006** remains off. When transistor **3006** turns on which causes the voltage between the battery electrodes to drop, diode **3010** prevents the charges stored in capacitor **3016** from flowing back to the battery electrodes. In one embodiment, diode **3010** is a Schottky diode to ensure a fast switching time.

It is possible that, during the transmission period, oscillator **3014** and/or control logic **3012** have depleted the charges stored in capacitor **3016**, causing VCC to drop below a certain threshold. For example, the voltage provided

by recharge capacitor **3016** may drop below the voltage provided by the voltaic cell. The difference between these two voltages may not be large enough to turn on Schottky diode **3010**. In this case, control logic **3012** can issue a recharge signal to turn on recharge switching transistor **3008**, which couples the battery voltage to capacitor **3016** and recharges capacitor **3016**.

In one embodiment, the communication between the IEM IC and the receiver is simplex. That is, the IEM IC only transmits signals without receiving any signals. The communication is performed via direct coupling between the IC electrodes and the receiver circuitry through the patient's body tissue and fluids. The transmission is performed at two frequencies, for example, one at 10 kHz and the other at 20 kHz. Other numbers of frequencies and frequency values are also possible. In general, different data-packet formats can be used with the present inventive system. In one embodiment, the transmitted data packet is 40-bit long, of which 16 bits are used as a synchronization/preamble pattern. The rest 24 bits carry a payload that encodes the IEM's identifier. In one embodiment, the payload can also include a forward error correction (FEC) code so that the transmission is more robust. In one embodiment, a data bit occupies 16 cycles of the carrier clock. The bits are BPSK encoded. Other encoding schemes are also possible. In a further embodiment, the 16-bit synchronization/preamble pattern include 12 bits for synchronization and 4 bits as a preamble.

FIG. 27 provides a schematic representation of a functional block diagram according to an embodiment of the invention. In FIG. 27, receiver **10** includes first and second electrodes, e_0 and e_1 (**11** & **12** respectively), which are separated by distance X and serve as an antenna to receive a signal generated by an identifier of a pharmaceutical enabled pharmaceutical composition. The distance X may vary, and in certain embodiments ranges from about 0.5 to about 5 cm, such as from about 0.5 to about 1.5 cm, e.g., about 1 cm. Amplifier **13** detects the differential signal across the electrodes. The detected signal then goes into the demodulator **14**. Also shown is memory **15** to store the demodulated data. Clock **16** which writes to that memory which time-stamps the events. Transmit circuit (Tx) **19** transfers data from the memory out to the external receiver (not shown). There is also a power source **17** which powers all the microelectronics. In the embodiment depicted, also present is a microprocessor **18**, which coordinates the function between all these blocks.

Finally, a coil **19** wound around the perimeter provides for RF transmission out. As summarized above, all of the different functional blocks shown in the embodiment of FIG. 27 could be on the same integrated circuit.

An alternative embodiment is depicted in FIG. 28. In FIG. 28, the main portion of the receiver **20** includes all of the functionalities listed above (not shown) and e_0 (**21**). Also shown is e_1 , which is at the end of wire **23**. This configuration provides for sufficient distance between e_0 and e_1 to serve as an effective receiver and yet minimizes the overall size of the receiver **20**.

As reviewed above, in certain embodiments the signal receiver is physically coupled to a medical carrier, e.g., a lead, which has on it one or more distinct physiological sensors. In such embodiments, the lead may have one or more, e.g., two or more, three or more, four or more, 5 or more, about 10 or more, about 15 or more, etc., distinct physiological sensors, where the sensors may be any sensor of interest, including those referred to above. FIG. 29 provides a representation of a signal receiver that is configured specifically for use in monitoring and treating cardiac

condition. In FIG. 29, receiver **50** includes main receiver component **51** and cardiovascular lead **52**, where lead **52** includes a number of different sensors and therefore may be referred to as a multi-sensor lead or MSL. Also shown on lead **52** are conductive blood flow sensors **53**, temperature sensor **54** positioned to measure the temperature of blood entering the heart, temperature sensor **55** positioned to measure the coronary sinus temperature, sense electrodes **56**, positioned to measure movement of relevant cardiac tissue and stimulating electrodes **57**. The sense and stimulating electrodes may be ring electrodes or segmented electrodes. By segmented electrode structure is meant an electrode structure that includes two or more, e.g., three or more, including four or more, disparate electrode elements.

In the embodiment shown in FIG. 29, the MSL goes from the receiver down into the heart, and can be employed to measure cardiac parameters of interest, e.g., blood temperature, heart rate, blood pressure, movement data, including synchrony data, IEGM data, as well as pharmaceutical therapy compliance. The obtained data is stored in the receiver. Embodiments of this configuration may be employed as an early heart failure diagnostic tool. This configuration may be put into a subject before they got very sick from heart failure, with the goal of monitoring them closely and keep them from getting sicker. Ultimately, when stimulation therapy is required, the receiver may be replaced with an implantable pulse generator, which may then employ the stimulating electrodes to provide appropriate pacing therapy to the patient.

The signal receiver can be a component of an implantable device that includes other functionality. For example, the signal receiver can be a component of an implantable pulse generator **58**, such as a pacemaker, etc. FIG. 30 provides a view of an implantable pulse generator **58** that includes a receiver component **59** according to an embodiment of the invention, where the receiver component includes receive circuitry **59A** and receive electrodes **59B**. Also shown is external interface antenna **60** and pacing electronics **61**.

Where the signal receivers are external, they may be configured in any convenient manner. External configuration may include any of the elements described above with respect to implantable embodiments, as desired. As such, external receivers may include circuits as depicted in FIG. 27, and described above. Accordingly, elements as described above, such as signal receivers, transmitters, memory, processors, demodulators, etc., may be present in external receivers of the invention, as desired. For example, functional diagrams of circuitry that may be present in external receivers of the invention are provided in FIGS. 31A and 31B. FIG. 31A provides a functional block diagram of a receiver **70** according to the invention, where the receiver includes an external interface block **71**, where the external interface block may include a wireless communication element (e.g., antenna), serial port, conductive interface, etc. Also present is signal receive circuitry block **72**. Also present is receive electrodes functional block **73**. FIG. 31B provides a view of a circuit **74** found in a receiver according to an embodiment of the invention. Circuit **74** includes external interface **75**, memory **76**, digital signal processor (DSP) **77** and real time clock (RTC) **78**. Also shown is analog to digital converter (ADC) **79**, pre-amplifier **80**, optional reference (common mode cancellation circuit) **81** and electrodes **82**.

In certain embodiments, the signal receivers are configured to be associated with a desirable skin location. As such, in certain embodiments the external signal receivers are configured to be contacted with a topical skin location of a

subject. Configurations of interest include, but are not limited to: patches, wrist bands, belts, harnesses, devices configured to associates with articles of clothing, e.g., shoes, necklaces, etc., or other body associated devices, e.g., hearing aids, eye glasses, and the like. For instance, a watch or belt worn externally and equipped with suitable receiving element, e.g., electrode or pair of electrodes as described in greater detail below, can be used as a signal receiver in accordance with one embodiment of the present invention.

In certain external embodiments, the receiver may be configured to be in contact with or associated with a patient only temporarily, i.e., transiently, for example while the ingestible event marker is actually being ingested. For example, the receiver may be configured as an external device having two finger electrodes or handgrips. Upon ingestion of the IEM, the patient touches the electrodes or grabs the handgrips completely to produce a conductive circuit with the receiver. Upon emission of the signal from the IEM, e.g., when the IEM contacts the stomach, the signal emitted by the identifier of the IEM is picked up by the receiver. At this point, the receiver may provide an indication to the patient, e.g., in the form of an audible or visual signal, that the signal from the IEM has been received. As indicated above, in certain external embodiments, the receiver is configured to be in contact with or associated with a patient only temporarily, i.e., transiently, for example while the pill, ingestible marker, etc., is actually being ingested. For example, the receiver may be configured as an external device, such as the medication dispenser box **83** shown in FIG. **32**. Dispense box **83** includes two finger electrodes **84A** and **84B**. In certain embodiments these electrodes are in the form of handgrips or other convenient patient contact format. During use, the patient initially activates the device and receiver by opening the lid **86**. To alert the patient that it is time to take medication, the box may be configured to provide a signal or alarm. Upon removal of a dosage from the box (where the dosage is present in a compartment **87**, a first signal may be provided, e.g., a red light, for example at indicator light **85**. The patient then ingests the pill which includes the IEM, and touches a right finger to the right finger electrode **84B** and a left finger to the left finger electrode **84A** to complete a conductive circuit with the receiver. Upon emission of the signal from the IEM which is associated with the pill, e.g., when the pill dissolves in the stomach, the signal emitted by the identifier of the pill is picked up by the receiver. At this point, the receiver may provide an indication to the patient, e.g., the form of an audible or visual signal (such as a green light) that the signal from the pill has been received. The patient can then release the receiver until the next time that the patient is scheduled to take pill. The box **83** includes detection circuitry, memory and transmit functionality **88**, e.g., as described above. Such embodiments have applications in a wide variety of different settings, e.g., for Tuberculosis patients on long term therapeutic regimens.

FIG. **33** provides a view of a wrist band receiver embodiment of the invention. As shown, the receiver is in the form of a wrist band **90** which includes a top **91** and bottom **92** contact, where the bottom contact is for contacting the wrist of the patient. The top contact is for the patient to touch with a right finger during use. During use of this device, upon ingestion of an IEM, the patient then touches the right finger to the contact **91** on the receiver **93** which is also in contact with the left wrist via contact **92**, thereby completing the circuit. Upon detection of the IEM generated signal, the patient can remove the finger from the receiver.

Such a system is useful in monitoring patient compliance with a therapeutic regimen, e.g., where ingestion of the IEM is associated with administration of therapeutic active agent (as described in greater detail below). The patient can then release the receiver until the next time that the patient is scheduled to take the active agent. Such embodiments have applications in a wide variety of different settings, e.g., for tuberculosis patients on long term therapeutic regimens, where embodiments of such systems are further described in greater detail below.

In certain embodiments, the external signal receiver includes miniaturized electronics which are integrated with the electrodes to form a band-aid style patch. The patch includes electrodes that when applied, contact the skin. The bandaid style patch may be configured to be positioned on a desirable target skin site of the subject, e.g., on the chest, back, side of the torso, etc. In these embodiments, the receiver circuitry may be configured to receive signals from devices inside of the subject, e.g., from an identifier IEM. Bandaid style receivers may be readily adapted for use in the present systems.

For the external signal receivers, embodiments include structures that have electrodes opposed to the skin, the demodulator, storage, and power. The communication may be wireless or performed over one or more conductive media, e.g., wires, optical fibers, etc. In certain embodiments, the same electrodes are used for receiving and transmitting signals. One example is a wristwatch format which is conductively in contact with the body, where to move the data from the implant to the wristwatch one would send currents out the pads and those would be received by the wristwatch. There are a number of RF techniques for getting the transmission out of the body that may be employed, such as inductive protocols that employ coils. Alternatively, one could employ electric fields, where one would use insulated electrodes, not conductively contacted electrodes.

Where the signal receiver includes an external component, that component may have output devices for providing, e.g., audio and/or visual feedback; examples include audible alarms, LEDs, display screens, or the like. The external component may also include an interface port via which the component can be connected to a computer for reading out data stored therein.

The signal receivers reviewed above are described primarily in terms of being configured to receive a signal from an ingestible event marker (IEM). However, the signal receivers of the invention may be ones configured to receive a signal from a pharma-informatics enabled pharmaceutical composition (e.g., as described in PCT application Ser. No. US2006/016370); an ingestible event marker; or a smart parenteral device; the disclosures of which are herein incorporated by reference, or analogous device.

It is to be understood that this invention is not limited to particular embodiments described, and as such may vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting, since the scope of the present invention will be limited only by the appended claims.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range, is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller

ranges and are also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either or both of those included limits are also included in the invention.

Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. Although any methods and materials similar or equivalent to those described herein can also be used in the practice or testing of the present invention, representative illustrative methods and materials are now described.

All publications and patents cited in this specification are herein incorporated by reference as if each individual publication or patent were specifically and individually indicated to be incorporated by reference and are incorporated herein by reference to disclose and describe the methods and/or materials in connection with which the publications are cited. The citation of any publication is for its disclosure prior to the filing date and should not be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed.

It is noted that, as used herein and in the appended claims, the singular forms “a”, “an”, and “the” include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as “solely,” “only” and the like in connection with the recitation of claim elements, or use of a “negative” limitation.

As will be apparent to those of skill in the art upon reading this disclosure, each of the individual embodiments described and illustrated herein has discrete components and features which may be readily separated from or combined with the features of any of the other several embodiments without departing from the scope or spirit of the present invention. Any recited method can be carried out in the order of events recited or in any other order which is logically possible.

Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it is readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit or scope of the appended claims.

Accordingly, the preceding merely illustrates the principles of the invention. It will be appreciated that those skilled in the art will be able to devise various arrangements which, although not explicitly described or shown herein, embody the principles of the invention and are included within its spirit and scope.

Furthermore, all examples and conditional language recited herein are principally intended to aid the reader in understanding the principles of the invention and the concepts contributed by the inventors to furthering the art, and are to be construed as being without limitation to such specifically recited examples and conditions. Moreover, all statements herein reciting principles, aspects, and embodiments of the invention as well as specific examples thereof, are intended to encompass both structural and functional equivalents thereof. Additionally, it is intended that such equivalents include both currently known equivalents and

equivalents developed in the future, i.e., any elements developed that perform the same function, regardless of structure. The scope of the present invention, therefore, is not intended to be limited to the exemplary embodiments shown and described herein. Rather, the scope and spirit of present invention is embodied by the appended claims.

What is claimed is:

1. A compliance system, comprising:
 - an ingestible event marker (IEM) device encoded with a physiologic pattern for a physiologic parameter identifying a patient, the IEM device configured to:
 - generate a signal comprising the physiologic pattern;
 - transmit the signal comprising the physiologic pattern through a body of an individual after ingestion by the individual;
 - a receiver associated with the individual and configured to receive the signal from the IEM device; and
 - a computer-related device, wherein the computer-related device comprises a processor configured to execute programming logic that causes the computer-related device to:
 - receive data associated with the signal from the receiver;
 - measure the physiologic parameter of the individual;
 - compare the physiologic parameter as measured to the physiologic pattern to confirm that the individual is the patient; and
 - verify that the individual associated with the physiological pattern has ingested the IEM device.
2. The compliance system of claim 1, wherein the physiologic parameter comprises at least one of a heart rate variability, a breathing rate, or a heart rate pattern associated with the individual.
3. The compliance system of claim 2, wherein the heart rate pattern comprises an electrocardiogram (ECG) pattern.
4. The compliance system of claim 1, wherein the IEM device is integrated with a medication.
5. The compliance system of claim 1, wherein the receiver comprises a personal signal receiver external to the body of the individual.
6. The compliance system of claim 1, wherein the computer-related device is further configured to transmit an alert to a mobile device based on the comparison between the measured physiologic parameter and the physiologic pattern.
7. The compliance system of claim 1, further comprising:
 - a data source device associated with the body of the individual, wherein the data source device is configured to generate at least one actual data sample of the physiologic parameter from the individual;
 wherein the computer-related device is configured to
 - measure the physiologic parameter of the individual based at least in part on the at least one actual data sample.
8. The compliance system of claim 7, wherein the data source device comprises an ingestible device, an inhalable device, an injectable device, an implantable device, an insertable device, or an imbibable device.
9. A compliance system, comprising:
 - an ingestible event marker (IEM) device encoded with a physiologic pattern for a physiologic parameter identifying a patient, the IEM device configured to:
 - generate a signal comprising the physiologic pattern;
 - transmit the signal comprising the physiologic pattern through a body of an individual after ingestion by the individual;

a data source device associated with the body of the individual, wherein the data source device is configured to generate at least one actual data sample of the physiologic parameter from the individual; and
 a receiver associated with the individual and configured to receive the signal from the IEM device; and
 a computer-related device, wherein the computer-related device comprises a processor configured to execute programming logic that causes the computer-related device to:
 receive the signal from the receiver;
 measure the physiologic parameter of the individual based at least in part on the at least one actual data sample;
 compare the physiologic parameter as measured to the physiologic pattern to confirm that the individual is the patient;
 and
 verify that the individual is the patient and that the IEM device was actually ingested by the patient based, at least in part, on the comparison.

10. The compliance system of claim 9, wherein the data source device comprises at least one of an inhalable device, an injectable device, an implantable device, an insertable device, and an imbibable device, or combinations thereof.

* * * * *