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(54) **SMART MESSAGES AND ALERTS FOR AN INFUSION DELIVERY AND MANAGEMENT SYSTEM**

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CPC ***A61B 5/0031*** (2013.01); ***A61B 5/14532*** (2013.01); ***A61B 5/4839*** (2013.01); ***G06F 19/3468*** (2013.01)

(58) **Field of Classification Search**

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(56) **References Cited**

U.S. PATENT DOCUMENTS

3,923,060	A	12/1975	Ellinwood, Jr.
4,003,379	A	1/1977	Ellinwood, Jr.
4,055,175	A	10/1977	Clemens et al.
4,076,182	A	2/1978	Stites
4,151,845	A	5/1979	Clemens
4,360,019	A	11/1982	Portner et al.
4,387,863	A	6/1983	Edmonston
4,441,968	A	4/1984	Emmer et al.
4,464,170	A	8/1984	Clemens et al.
4,601,707	A	7/1986	Albisser et al.
4,629,145	A	12/1986	Graham
4,667,896	A	5/1987	Frey et al.
4,685,903	A	8/1987	Cable et al.
4,725,010	A	2/1988	Lothamer
4,802,638	A	2/1989	Burger et al.
4,847,785	A	7/1989	Stephens
4,886,505	A	12/1989	Haynes et al.
5,019,096	A	5/1991	Fox, Jr. et al.
5,051,688	A	9/1991	Murase et al.

(Continued)

FOREIGN PATENT DOCUMENTS

WO	WO-01/52935	7/2001
WO	WO-01/54753	8/2001

(Continued)

OTHER PUBLICATIONS

PCT Application No. PCT/US2007/062999, International Preliminary Report on Patentability and Written Opinion of the International Searching Authority mailed Sep. 12, 2008.

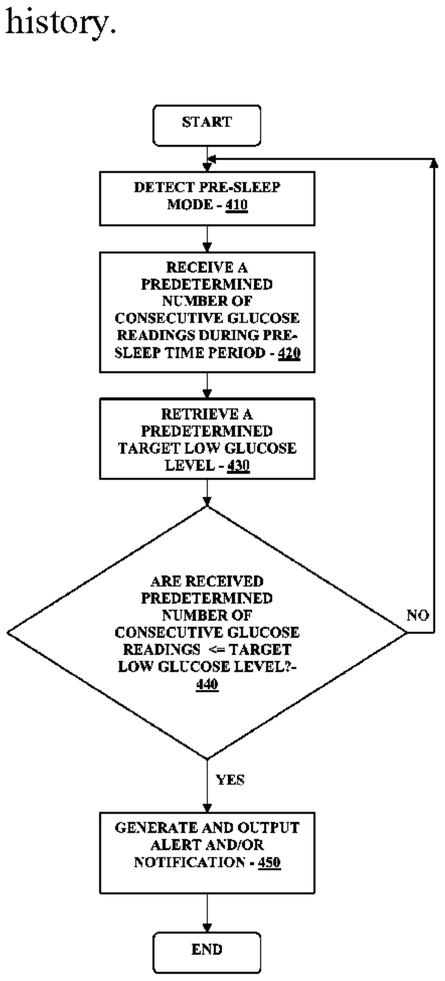
(Continued)

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(57) **ABSTRACT**

Method and system for providing diabetes management is provided.

13 Claims, 6 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

5,067,665	A		11/1991	LoStracco et al.
5,097,834	A		3/1992	Skrabal
5,109,577	A		5/1992	Young
5,135,004	A		8/1992	Adams et al.
5,202,261	A		4/1993	Musho et al.
5,209,414	A		5/1993	Clemens et al.
5,210,778	A		5/1993	Massart
5,228,449	A		7/1993	Christ et al.
5,231,988	A		8/1993	Wernicke et al.
5,236,143	A		8/1993	Dragon
5,237,993	A		8/1993	Skrabal
5,250,023	A		10/1993	Lee
5,251,126	A		10/1993	Kahn et al.
5,266,359	A		11/1993	Spielvogel
5,344,411	A		9/1994	Domb et al.
5,349,852	A		9/1994	Kamen et al.
5,384,547	A		1/1995	Lynk et al.
5,390,671	A		2/1995	Lord et al.
5,394,877	A		3/1995	Orr et al.
5,402,780	A		4/1995	Faasse, Jr.
5,410,326	A		4/1995	Goldstein
5,437,656	A		8/1995	Shikani et al.
5,451,424	A		9/1995	Solomon et al.
5,526,844	A		6/1996	Kamen et al.
5,533,389	A		7/1996	Kamen et al.
5,552,997	A		9/1996	Massart
5,558,640	A		9/1996	Pfeiler
5,569,186	A		10/1996	Lord et al.
5,593,852	A		1/1997	Heller et al.
5,599,321	A		2/1997	Conway et al.
5,601,435	A		2/1997	Quy
5,609,575	A		3/1997	Larson et al.
5,662,904	A		9/1997	Ferguson et al.
5,673,691	A		10/1997	Abrams et al.
5,726,646	A		3/1998	Bane et al.
5,748,103	A		5/1998	Flach et al.
5,807,375	A		9/1998	Gross et al.
5,822,715	A		10/1998	Worthington et al.
5,833,603	A		11/1998	Kovacs et al.
5,899,855	A		5/1999	Brown
5,918,603	A		7/1999	Brown
5,925,021	A		7/1999	Castellano et al.
5,951,521	A		9/1999	Mastrototaro et al.
5,954,643	A		9/1999	VanAntwerp et al.
5,956,501	A		9/1999	Brown
5,975,120	A		11/1999	Novosel
5,987,353	A		11/1999	Khatchatrian et al.
5,988,545	A		11/1999	King
6,028,413	A		2/2000	Brockmann
6,052,565	A		4/2000	Ishikura et al.
6,066,243	A		5/2000	Anderson et al.
6,083,248	A		7/2000	Thompson
6,091,975	A		7/2000	Daddona et al.
6,093,146	A	*	7/2000	Filangeri G06F 19/3406 128/904
6,096,364	A		8/2000	Bok et al.
6,129,823	A		10/2000	Hughes et al.
6,134,461	A		10/2000	Say et al.
6,141,573	A		10/2000	Kurnik et al.
6,143,164	A		11/2000	Heller et al.
6,175,752	B1		1/2001	Say et al.
6,233,539	B1		5/2001	Brown
6,247,664	B1		6/2001	Petersen et al.
6,248,067	B1		6/2001	Causey et al.
6,254,586	B1		7/2001	Mann et al.
6,270,455	B1		8/2001	Brown
6,284,478	B1		9/2001	Heller et al.
6,314,317	B1		11/2001	Willis
6,359,270	B1		3/2002	Bridson
6,379,301	B1		4/2002	Worthington et al.
6,387,048	B1		5/2002	Schulman et al.
6,418,332	B1		7/2002	Mastrototaro et al.
6,427,088	B1		7/2002	Bowman, IV et al.
6,471,689	B1		10/2002	Joseph et al.
6,482,156	B2		11/2002	Iliff
6,484,045	B1		11/2002	Holker et al.
6,485,461	B1		11/2002	Mason et al.
6,493,069	B1		12/2002	Nagashimada et al.
6,544,212	B2		4/2003	Galley et al.
6,546,268	B1		4/2003	Ishikawa et al.
6,554,798	B1		4/2003	Mann et al.
6,558,320	B1		5/2003	Causey, III et al.
6,558,321	B1		5/2003	Burd et al.
6,558,351	B1		5/2003	Steil et al.
6,562,001	B2		5/2003	Lebel et al.
6,564,105	B2		5/2003	Starkweather et al.
6,571,128	B2		5/2003	Lebel et al.
6,572,542	B1		6/2003	Houben et al.
6,577,899	B2		6/2003	Lebel et al.
6,585,644	B2		7/2003	Lebel et al.
6,598,824	B2		7/2003	Schmidt
6,635,014	B2		10/2003	Starkweather et al.
6,641,533	B2		11/2003	Causey, III et al.
6,641,562	B1		11/2003	Peterson
6,648,821	B2		11/2003	Lebel et al.
6,656,114	B1		12/2003	Poulsen et al.
6,656,158	B2		12/2003	Mahoney et al.
6,656,159	B2		12/2003	Flaherty
6,658,396	B1		12/2003	Tang et al.
6,659,948	B2		12/2003	Lebel et al.
6,668,196	B1		12/2003	Villegas et al.
6,669,669	B2		12/2003	Flaherty et al.
6,676,816	B2		1/2004	Mao et al.
6,687,546	B2		2/2004	Lebel et al.
6,692,457	B2		2/2004	Flaherty
6,694,191	B2		2/2004	Starkweather et al.
6,699,218	B2		3/2004	Flaherty et al.
6,702,857	B2		3/2004	Brauker et al.
6,723,072	B2		4/2004	Mahoney et al.
6,733,446	B2		5/2004	Lebel et al.
6,736,797	B1		5/2004	Larsen et al.
6,740,059	B2		5/2004	Flaherty
6,740,075	B2		5/2004	Lebel et al.
6,741,877	B1		5/2004	Shults et al.
6,744,350	B2		6/2004	Blomquist
6,749,587	B2		6/2004	Flaherty
6,758,810	B2		7/2004	Lebel et al.
6,768,425	B2		7/2004	Flaherty et al.
6,810,290	B2		10/2004	Lebel et al.
6,811,533	B2		11/2004	Lebel et al.
6,811,534	B2		11/2004	Bowman, IV et al.
6,813,519	B2		11/2004	Lebel et al.
6,830,558	B2		12/2004	Flaherty et al.
6,837,858	B2		1/2005	Cunningham et al.
6,850,790	B2		2/2005	Berner et al.
6,852,104	B2		2/2005	Blomquist
6,862,465	B2		3/2005	Shults et al.
6,873,268	B2		3/2005	Lebel et al.
6,882,940	B2		4/2005	Potts et al.
6,887,270	B2		5/2005	Miller et al.
6,896,666	B2		5/2005	Kochamaba et al.
6,902,207	B2		6/2005	Lickliter
6,916,159	B2		7/2005	Rush et al.
6,923,763	B1		8/2005	Kovatchev et al.
6,931,327	B2		8/2005	Goode, Jr. et al.
6,936,006	B2		8/2005	Sabra
6,946,446	B2		9/2005	Ma et al.
6,950,708	B2		9/2005	Bowman IV et al.
6,958,705	B2		10/2005	Lebel et al.
6,960,192	B1		11/2005	Flaherty et al.
6,974,437	B2		12/2005	Lebel et al.
6,999,854	B2		2/2006	Roth
7,003,336	B2		2/2006	Holker et al.
7,015,817	B2		3/2006	Copley et al.
7,016,713	B2		3/2006	Gardner et al.
7,018,360	B2		3/2006	Flaherty et al.
7,024,245	B2		4/2006	Lebel et al.
7,027,848	B2		4/2006	Robinson et al.
7,027,931	B1		4/2006	Jones et al.
7,029,455	B2		4/2006	Flaherty
7,034,677	B2		4/2006	Steinthal et al.
7,041,468	B2		5/2006	Drucker et al.
7,046,153	B2		5/2006	Oja et al.
7,052,251	B2		5/2006	Nason et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

7,052,472	B1	5/2006	Miller et al.	
7,066,922	B2	6/2006	Angel et al.	
7,074,307	B2	7/2006	Simpson et al.	
7,077,328	B2	7/2006	Krishnaswamy et al.	
7,079,977	B2	7/2006	Osorio et al.	
7,081,195	B2	7/2006	Simpson et al.	
7,092,891	B2	8/2006	Maus et al.	
7,108,778	B2	9/2006	Simpson et al.	
7,110,803	B2	9/2006	Shults et al.	
7,113,821	B1	9/2006	Sun et al.	
7,133,717	B2	11/2006	Coston et al.	
7,134,999	B2	11/2006	Brauker et al.	
7,136,689	B2	11/2006	Shults et al.	
7,137,964	B2	11/2006	Flaherty	
7,144,384	B2	12/2006	Gorman et al.	
7,153,265	B2	12/2006	Vachon	
7,155,112	B2	12/2006	Uno et al.	
7,155,290	B2	12/2006	Von Arx et al.	
7,167,818	B2	1/2007	Brown	
7,171,274	B2	1/2007	Starkweather et al.	
7,171,312	B2	1/2007	Steinthal et al.	
7,179,226	B2	2/2007	Crothall et al.	
7,192,450	B2	3/2007	Brauker et al.	
7,207,974	B2	4/2007	Safabash et al.	
7,216,665	B1	5/2007	Sims, Jr.	
7,226,278	B2	6/2007	Nason et al.	
7,226,442	B2	6/2007	Sheppard et al.	
7,226,978	B2	6/2007	Tapsak et al.	
7,229,042	B2	6/2007	Thebault et al.	
7,267,665	B2	9/2007	Steil et al.	
7,276,029	B2	10/2007	Goode, Jr. et al.	
7,286,894	B1	10/2007	Grant et al.	
7,303,549	B2	12/2007	Flaherty et al.	
7,310,544	B2	12/2007	Brister et al.	
7,318,816	B2	1/2008	Bobroff et al.	
7,324,012	B2	1/2008	Mann et al.	
7,329,239	B2	2/2008	Safabash et al.	
7,335,294	B2	2/2008	Heller et al.	
7,354,420	B2	4/2008	Steil et al.	
7,364,568	B2	4/2008	Angel et al.	
7,364,592	B2	4/2008	Carr-Brendel et al.	
7,366,556	B2	4/2008	Brister et al.	
7,379,765	B2	5/2008	Petisce et al.	
7,381,184	B2	6/2008	Funderburk et al.	
7,402,153	B2	7/2008	Steil et al.	
7,424,318	B2	9/2008	Brister et al.	
7,429,258	B2	9/2008	Angel et al.	
7,455,663	B2	11/2008	Bikovsky	
7,460,898	B2	12/2008	Brister et al.	
7,462,264	B2	12/2008	Heller et al.	
7,467,003	B2	12/2008	Brister et al.	
7,471,972	B2	12/2008	Rhodes et al.	
7,483,736	B2	1/2009	Marchitto et al.	
7,494,465	B2	2/2009	Brister et al.	
7,497,827	B2	3/2009	Brister et al.	
7,499,002	B2	3/2009	Blasko et al.	
7,519,408	B2	4/2009	Rasdal et al.	
7,547,281	B2	6/2009	Hayes et al.	
7,583,990	B2	9/2009	Goode, Jr. et al.	
7,591,801	B2	9/2009	Brauker et al.	
7,599,726	B2	10/2009	Goode, Jr. et al.	
7,613,491	B2	11/2009	Boock et al.	
7,615,007	B2	11/2009	Shults et al.	
7,630,748	B2	12/2009	Budiman	
7,632,228	B2	12/2009	Brauker et al.	
7,637,868	B2	12/2009	Saint et al.	
7,640,048	B2	12/2009	Dobbles et al.	
7,645,263	B2	1/2010	Angel et al.	
7,651,596	B2	1/2010	Petisce et al.	
7,651,845	B2	1/2010	Doyle, III et al.	
7,654,956	B2	2/2010	Brister et al.	
7,657,297	B2	2/2010	Simpson et al.	
7,697,967	B2	4/2010	Stafford	
7,699,775	B2	4/2010	Desai et al.	
7,711,402	B2	5/2010	Shults et al.	
7,713,574	B2	5/2010	Brister et al.	
7,715,893	B2	5/2010	Kamath et al.	
7,727,147	B1	6/2010	Osorio et al.	
7,731,657	B2	6/2010	Stafford	
7,736,344	B2	6/2010	Moberg et al.	
7,763,042	B2	7/2010	Iio et al.	
7,766,829	B2	8/2010	Sloan et al.	
7,783,333	B2	8/2010	Brister et al.	
7,792,562	B2	9/2010	Shults et al.	
7,811,231	B2	10/2010	Jin et al.	
7,813,809	B2	10/2010	Strother et al.	
7,822,454	B1	10/2010	Alden et al.	
7,826,981	B2	11/2010	Goode, Jr. et al.	
7,889,069	B2	2/2011	Fifolt et al.	
7,899,511	B2	3/2011	Shults et al.	
7,899,545	B2	3/2011	John	
7,905,833	B2	3/2011	Brister et al.	
7,914,450	B2	3/2011	Goode, Jr. et al.	
7,938,797	B2	5/2011	Estes	
7,941,200	B2	5/2011	Weinert et al.	
7,946,985	B2	5/2011	Mastrototaro et al.	
7,970,448	B2	6/2011	Shults et al.	
7,972,296	B2	7/2011	Braig et al.	
7,974,672	B2	7/2011	Shults et al.	
7,976,466	B2	7/2011	Ward et al.	
7,978,063	B2	7/2011	Baldus et al.	
8,010,174	B2	8/2011	Goode et al.	
8,010,256	B2	8/2011	Oowada	
RE43,316	E	4/2012	Brown et al.	
8,192,394	B2	6/2012	Estes et al.	
8,282,549	B2	10/2012	Brauker et al.	
8,597,570	B2	12/2013	Terashima et al.	
2001/0020124	A1	9/2001	Tamada	
2001/0037366	A1	11/2001	Webb et al.	
2001/0047604	A1	12/2001	Valiulis	
2002/0016719	A1	2/2002	Nemeth et al.	
2002/0054320	A1	5/2002	Ogino	
2002/0095076	A1	7/2002	Krausman et al.	
2002/0106709	A1	8/2002	Potts et al.	
2002/0107476	A1	8/2002	Mann et al.	
2002/0133107	A1	9/2002	Darcey	
2002/0147135	A1	10/2002	Schnell	
2002/0169635	A1	11/2002	Shillingburg	
2002/0193679	A1	12/2002	Malave et al.	
2003/0021729	A1	1/2003	Moller et al.	
2003/0023317	A1	1/2003	Brauker et al.	
2003/0028089	A1	2/2003	Galley et al.	
2003/0032874	A1	2/2003	Rhodes et al.	
2003/0040661	A1*	2/2003	Abraham-Fuchs et al.	G06F 19/324 600/300
2003/0060692	A1	3/2003	Ruchti et al.	
2003/0060753	A1	3/2003	Starkweather et al.	
2003/0065308	A1	4/2003	Lebel et al.	
2003/0069541	A1	4/2003	Gillis et al.	
2003/0073414	A1	4/2003	Capps	
2003/0100040	A1	5/2003	Bonnecaze et al.	
2003/0114836	A1	6/2003	Estes et al.	
2003/0114897	A1	6/2003	Von Arx et al.	
2003/0122021	A1	7/2003	McConnell et al.	
2003/0130616	A1	7/2003	Steil et al.	
2003/0144362	A1	7/2003	Utterberg et al.	
2003/0147515	A1	8/2003	Kai et al.	
2003/0175323	A1	9/2003	Utterberg et al.	
2003/0176933	A1	9/2003	Lebel et al.	
2003/0212379	A1	11/2003	Bylund et al.	
2003/0212579	A1*	11/2003	Brown et al.	A61B 5/411 705/2
2003/0217966	A1	11/2003	Tapsak et al.	
2004/0011671	A1	1/2004	Shults et al.	
2004/0045879	A1	3/2004	Shults et al.	
2004/0063435	A1	4/2004	Sakamoto et al.	
2004/0099529	A1	5/2004	Mao et al.	
2004/0122530	A1	6/2004	Hansen et al.	
2004/0135684	A1	7/2004	Steinthal et al.	
2004/0147872	A1	7/2004	Thompson	
2004/0152622	A1	8/2004	Keith et al.	
2004/0155770	A1	8/2004	Nelson et al.	
2004/0162521	A1	8/2004	Bengtsson	

(56) **References Cited**

U.S. PATENT DOCUMENTS

2004/0167464	A1	8/2004	Ireland et al.	
2004/0172307	A1	9/2004	Gruber	
2004/0186362	A1	9/2004	Brauker et al.	
2004/0193025	A1	9/2004	Steil et al.	
2004/0193090	A1	9/2004	Lebel et al.	
2004/0199059	A1	10/2004	Brauker et al.	
2004/0204868	A1	10/2004	Maynard et al.	
2004/0210180	A1	10/2004	Altman	
2004/0210208	A1	10/2004	Paul et al.	
2004/0225338	A1	11/2004	Lebel et al.	
2004/0254433	A1	12/2004	Bandis et al.	
2004/0260478	A1	12/2004	Schwamm	
2005/0001024	A1	1/2005	Kusaka et al.	
2005/0004439	A1	1/2005	Shin et al.	
2005/0010269	A1	1/2005	Lebel et al.	
2005/0027180	A1	2/2005	Goode, Jr. et al.	
2005/0031689	A1	2/2005	Shults et al.	
2005/0038332	A1	2/2005	Saidara et al.	
2005/0038674	A1	2/2005	Braig et al.	
2005/0043598	A1	2/2005	Goode, Jr. et al.	
2005/0049179	A1	3/2005	Davidson et al.	
2005/0060199	A1*	3/2005	Siegel	G06F 19/322 705/2
2005/0065464	A1	3/2005	Talbot et al.	
2005/0070774	A1	3/2005	Addison et al.	
2005/0090607	A1	4/2005	Tapsak et al.	
2005/0096511	A1	5/2005	Fox et al.	
2005/0096516	A1	5/2005	Soykan et al.	
2005/0112169	A1	5/2005	Brauker et al.	
2005/0113653	A1	5/2005	Fox et al.	
2005/0113886	A1	5/2005	Fischell et al.	
2005/0116683	A1	6/2005	Cheng et al.	
2005/0119540	A1	6/2005	Potts et al.	
2005/0137530	A1	6/2005	Campbell et al.	
2005/0143635	A1	6/2005	Kamath et al.	
2005/0171512	A1	8/2005	Flaherty	
2005/0176136	A1	8/2005	Burd et al.	
2005/0181010	A1	8/2005	Hunter et al.	
2005/0182306	A1	8/2005	Sloan	
2005/0182358	A1	8/2005	Veit et al.	
2005/0182366	A1	8/2005	Vogt et al.	
2005/0187442	A1	8/2005	Cho et al.	
2005/0187720	A1	8/2005	Goode, Jr. et al.	
2005/0192557	A1	9/2005	Brauker et al.	
2005/0195930	A1	9/2005	Spital et al.	
2005/0203360	A1	9/2005	Brauker et al.	
2005/0203461	A1	9/2005	Flaherty et al.	
2005/0204134	A1	9/2005	Von Arx et al.	
2005/0214892	A1	9/2005	Kovatchev et al.	
2005/0238507	A1	10/2005	DiIanni et al.	
2005/0245795	A1	11/2005	Goode, Jr. et al.	
2005/0245799	A1	11/2005	Brauker et al.	
2005/0251033	A1	11/2005	Scarantino et al.	
2005/0261667	A1	11/2005	Crank et al.	
2005/0277872	A1	12/2005	Colby et al.	
2005/0277912	A1	12/2005	John	
2006/0001551	A1	1/2006	Kraft et al.	
2006/0004603	A1	1/2006	Peterka et al.	
2006/0010098	A1	1/2006	Goodnow et al.	
2006/0015020	A1	1/2006	Neale et al.	
2006/0016700	A1	1/2006	Brister et al.	
2006/0017923	A1	1/2006	Ruchti et al.	
2006/0019327	A1	1/2006	Brister et al.	
2006/0020186	A1	1/2006	Brister et al.	
2006/0020187	A1	1/2006	Brister et al.	
2006/0020188	A1	1/2006	Kamath et al.	
2006/0020189	A1	1/2006	Brister et al.	
2006/0020190	A1	1/2006	Kamath et al.	
2006/0020191	A1	1/2006	Brister et al.	
2006/0020192	A1	1/2006	Brister et al.	
2006/0020300	A1	1/2006	Nghiem et al.	
2006/0036139	A1	2/2006	Brister et al.	
2006/0036140	A1	2/2006	Brister et al.	
2006/0036141	A1	2/2006	Kamath et al.	
2006/0036142	A1	2/2006	Brister et al.	
2006/0036143	A1	2/2006	Brister et al.	
2006/0036144	A1	2/2006	Brister et al.	
2006/0036145	A1	2/2006	Brister et al.	
2006/0041229	A1	2/2006	Garibotto et al.	
2006/0065772	A1	3/2006	Grant et al.	
2006/0079740	A1	4/2006	Silver et al.	
2006/0091006	A1	5/2006	Wang et al.	
2006/0095020	A1	5/2006	Casas et al.	
2006/0142651	A1	6/2006	Brister et al.	
2006/0154642	A1	7/2006	Scannell	
2006/0166629	A1	7/2006	Reggiardo	
2006/0173406	A1	8/2006	Hayes et al.	
2006/0173444	A1	8/2006	Choy et al.	
2006/0173712	A1	8/2006	Joubert	
2006/0178633	A1	8/2006	Garibotto et al.	
2006/0189863	A1	8/2006	Peyser et al.	
2006/0193375	A1	8/2006	Lee et al.	
2006/0202805	A1	9/2006	Schulman et al.	
2006/0222566	A1	10/2006	Brauker et al.	
2006/0224141	A1	10/2006	Rush et al.	
2006/0226985	A1	10/2006	Goodnow et al.	
2006/0247508	A1	11/2006	Fennell	
2006/0258929	A1	11/2006	Goode et al.	
2006/0272652	A1	12/2006	Stocker et al.	
2006/0282290	A1	12/2006	Flaherty et al.	
2006/0290496	A1	12/2006	Peeters et al.	
2006/0293577	A1	12/2006	Morrison et al.	
2006/0293607	A1	12/2006	Alt et al.	
2007/0016381	A1	1/2007	Kamath et al.	
2007/0016449	A1*	1/2007	Cohen et al.	705/3
2007/0017983	A1	1/2007	Frank et al.	
2007/0027381	A1	2/2007	Stafford	
2007/0032717	A1	2/2007	Brister et al.	
2007/0033074	A1	2/2007	Nitzan et al.	
2007/0060869	A1	3/2007	Tolle et al.	
2007/0060870	A1	3/2007	Tolle et al.	
2007/0060871	A1	3/2007	Istoc et al.	
2007/0060979	A1	3/2007	Strother et al.	
2007/0066956	A1	3/2007	Finkel	
2007/0073129	A1	3/2007	Shah et al.	
2007/0078320	A1	4/2007	Stafford	
2007/0078321	A1	4/2007	Mazza et al.	
2007/0078322	A1	4/2007	Stafford	
2007/0078818	A1	4/2007	Zvitz et al.	
2007/0093786	A1	4/2007	Goldsmith et al.	
2007/0100222	A1	5/2007	Mastrototaro et al.	
2007/0106135	A1	5/2007	Sloan et al.	
2007/0118405	A1	5/2007	Campbell et al.	
2007/0128682	A1	6/2007	Rosman et al.	
2007/0129621	A1*	6/2007	Kellogg et al.	600/365
2007/0149875	A1	6/2007	Ouyang et al.	
2007/0163880	A1	7/2007	Woo et al.	
2007/0191702	A1	8/2007	Yodfat et al.	
2007/0203407	A1	8/2007	Hoss et al.	
2007/0203966	A1	8/2007	Brauker et al.	
2007/0208246	A1	9/2007	Brauker et al.	
2007/0213657	A1	9/2007	Jennewine et al.	
2007/0219480	A1	9/2007	Kamen et al.	
2007/0219597	A1	9/2007	Kamen et al.	
2007/0228071	A1	10/2007	Kamen et al.	
2007/0235331	A1	10/2007	Simpson et al.	
2007/0249922	A1	10/2007	Peyser et al.	
2007/0255114	A1	11/2007	Ackermann et al.	
2007/0255321	A1	11/2007	Gerber et al.	
2007/0255348	A1	11/2007	Holtzclaw	
2007/0299409	A1	12/2007	Whitbourne et al.	
2008/0004515	A1	1/2008	Jennewine et al.	
2008/0004601	A1	1/2008	Jennewine et al.	
2008/0009692	A1	1/2008	Stafford	
2008/0018480	A1	1/2008	Sham	
2008/0021436	A1	1/2008	Wolpert et al.	
2008/0021666	A1	1/2008	Goode, Jr. et al.	
2008/0033254	A1	2/2008	Kamath et al.	
2008/0033268	A1	2/2008	Stafford	
2008/0039702	A1	2/2008	Hayter et al.	
2008/0045824	A1	2/2008	Tapsak et al.	
2008/0058773	A1	3/2008	John	
2008/0060955	A1	3/2008	Goodnow	
2008/0061961	A1	3/2008	John	

(56) **References Cited**

U.S. PATENT DOCUMENTS

2008/0064937 A1 3/2008 McGarraugh et al.
2008/0071156 A1 3/2008 Brister et al.
2008/0083617 A1 4/2008 Simpson et al.
2008/0086042 A1 4/2008 Brister et al.
2008/0086044 A1 4/2008 Brister et al.
2008/0086273 A1 4/2008 Shults et al.
2008/0092638 A1 4/2008 Brenneman et al.
2008/0093447 A1 4/2008 Johnson et al.
2008/0097246 A1 4/2008 Stafford
2008/0108942 A1 5/2008 Brister et al.
2008/0114228 A1 5/2008 McCluskey et al.
2008/0139910 A1 6/2008 Mastrototaro et al.
2008/0177149 A1 7/2008 Weinert et al.
2008/0183061 A1 7/2008 Goode, Jr. et al.
2008/0183399 A1 7/2008 Goode, Jr. et al.
2008/0188731 A1 8/2008 Brister et al.
2008/0189051 A1 8/2008 Goode, Jr. et al.
2008/0194934 A1 8/2008 Ray et al.
2008/0194935 A1 8/2008 Brister et al.
2008/0194936 A1 8/2008 Goode, Jr. et al.
2008/0194937 A1 8/2008 Goode, Jr. et al.
2008/0194938 A1 8/2008 Brister et al.
2008/0195232 A1 8/2008 Carr-Brendel et al.
2008/0195967 A1 8/2008 Goode, Jr. et al.
2008/0197024 A1 8/2008 Simpson et al.
2008/0200788 A1 8/2008 Brister et al.
2008/0200789 A1 8/2008 Brister et al.
2008/0200791 A1 8/2008 Simpson et al.
2008/0208025 A1 8/2008 Shults et al.
2008/0214915 A1 9/2008 Brister et al.
2008/0214918 A1 9/2008 Brister et al.
2008/0228051 A1 9/2008 Shults et al.
2008/0228054 A1 9/2008 Shults et al.
2008/0228055 A1 9/2008 Sher
2008/0234663 A1 9/2008 Yodfat et al.
2008/0234943 A1 9/2008 Ray et al.
2008/0242961 A1 10/2008 Brister et al.
2008/0242963 A1 10/2008 Essenpreis et al.
2008/0254544 A1 10/2008 Modzelewski et al.
2008/0262469 A1 10/2008 Brister et al.
2008/0269687 A1 10/2008 Chong et al.
2008/0269714 A1 10/2008 Mastrototaro et al.
2008/0269723 A1 10/2008 Mastrototaro et al.
2008/0275313 A1 11/2008 Brister et al.
2008/0287764 A1 11/2008 Rasdal et al.
2008/0287765 A1 11/2008 Rasdal et al.
2008/0287766 A1 11/2008 Rasdal et al.
2008/0296155 A1 12/2008 Shults et al.
2008/0300572 A1 12/2008 Rankers et al.
2008/0306368 A1 12/2008 Goode, Jr. et al.
2008/0306434 A1 12/2008 Dobbles et al.
2008/0306435 A1 12/2008 Kamath et al.
2008/0306444 A1 12/2008 Brister et al.
2008/0319085 A1 12/2008 Wright et al.
2009/0005666 A1 1/2009 Shin et al.
2009/0012379 A1 1/2009 Goode, Jr. et al.
2009/0018424 A1 1/2009 Kamath et al.
2009/0030294 A1 1/2009 Petisce et al.
2009/0036758 A1 2/2009 Brauker et al.
2009/0036763 A1 2/2009 Brauker et al.
2009/0040022 A1 2/2009 Finkenzeller
2009/0043181 A1 2/2009 Brauker et al.
2009/0043182 A1 2/2009 Brauker et al.
2009/0043525 A1 2/2009 Brauker et al.
2009/0043541 A1 2/2009 Brauker et al.
2009/0043542 A1 2/2009 Brauker et al.
2009/0045055 A1 2/2009 Rhodes et al.
2009/0048503 A1 2/2009 Dalal et al.
2009/0054745 A1 2/2009 Jennewine et al.
2009/0054747 A1 2/2009 Fennell
2009/0054748 A1 2/2009 Feldman
2009/0062633 A1 3/2009 Brauker et al.
2009/0062635 A1 3/2009 Brauker et al.
2009/0069650 A1 3/2009 Jennewine et al.
2009/0076356 A1 3/2009 Simpson et al.
2009/0076359 A1 3/2009 Peyser
2009/0076360 A1 3/2009 Brister et al.
2009/0076361 A1 3/2009 Kamath et al.
2009/0082693 A1 3/2009 Stafford
2009/0085873 A1 4/2009 Betts et al.
2009/0088614 A1 4/2009 Taub
2009/0093687 A1 4/2009 Telfort et al.
2009/0099436 A1 4/2009 Brister et al.
2009/0102678 A1 4/2009 Mazza et al.
2009/0105569 A1 4/2009 Stafford
2009/0105570 A1 4/2009 Sloan et al.
2009/0105571 A1 4/2009 Fennell et al.
2009/0124877 A1 5/2009 Goode, Jr. et al.
2009/0124878 A1 5/2009 Goode, Jr. et al.
2009/0124879 A1 5/2009 Brister et al.
2009/0124964 A1 5/2009 Leach et al.
2009/0131768 A1 5/2009 Simpson et al.
2009/0131769 A1 5/2009 Leach et al.
2009/0131776 A1 5/2009 Simpson et al.
2009/0131777 A1 5/2009 Simpson et al.
2009/0137886 A1 5/2009 Shariati et al.
2009/0137887 A1 5/2009 Shariati et al.
2009/0143659 A1 6/2009 Li et al.
2009/0143660 A1 6/2009 Brister et al.
2009/0156919 A1 6/2009 Brister et al.
2009/0156924 A1 6/2009 Shariati et al.
2009/0163790 A1 6/2009 Brister et al.
2009/0163791 A1 6/2009 Brister et al.
2009/0178459 A1 7/2009 Li et al.
2009/0182217 A1 7/2009 Li et al.
2009/0192366 A1 7/2009 Mensinger et al.
2009/0192380 A1 7/2009 Shariati et al.
2009/0192722 A1 7/2009 Shariati et al.
2009/0192724 A1 7/2009 Brauker et al.
2009/0192745 A1 7/2009 Kamath et al.
2009/0192751 A1 7/2009 Kamath et al.
2009/0203981 A1 8/2009 Brauker et al.
2009/0204340 A1 8/2009 Feldman et al.
2009/0204341 A1 8/2009 Brauker et al.
2009/0216100 A1 8/2009 Ebner et al.
2009/0216103 A1 8/2009 Brister et al.
2009/0240120 A1 9/2009 Mensinger et al.
2009/0240128 A1 9/2009 Mensinger et al.
2009/0240193 A1 9/2009 Mensinger et al.
2009/0242399 A1 10/2009 Kamath et al.
2009/0242425 A1 10/2009 Kamath et al.
2009/0247855 A1 10/2009 Boock et al.
2009/0247856 A1 10/2009 Boock et al.
2009/0247931 A1 10/2009 Damgaard-Sorensen
2009/0287073 A1 11/2009 Boock et al.
2009/0287074 A1 11/2009 Shults et al.
2009/0292188 A1 11/2009 Hoss et al.
2009/0298182 A1 12/2009 Schulat et al.
2009/0299155 A1 12/2009 Yang et al.
2009/0299156 A1 12/2009 Simpson et al.
2009/0299162 A1 12/2009 Brauker et al.
2009/0299276 A1 12/2009 Brauker et al.
2010/0010324 A1 1/2010 Brauker et al.
2010/0010329 A1 1/2010 Taub et al.
2010/0010331 A1 1/2010 Brauker et al.
2010/0010332 A1 1/2010 Brauker et al.
2010/0016687 A1 1/2010 Brauker et al.
2010/0016698 A1 1/2010 Rasdal et al.
2010/0022855 A1 1/2010 Brauker et al.
2010/0030038 A1 2/2010 Brauker et al.
2010/0030053 A1 2/2010 Goode, Jr. et al.
2010/0030484 A1 2/2010 Brauker et al.
2010/0030485 A1 2/2010 Brauker et al.
2010/0036215 A1 2/2010 Goode, Jr. et al.
2010/0036216 A1 2/2010 Goode, Jr. et al.
2010/0036222 A1 2/2010 Goode, Jr. et al.
2010/0036223 A1 2/2010 Goode, Jr. et al.
2010/0036225 A1 2/2010 Goode, Jr. et al.
2010/0041971 A1 2/2010 Goode, Jr. et al.
2010/0045465 A1 2/2010 Brauker et al.
2010/0049024 A1 2/2010 Saint et al.
2010/0063373 A1 3/2010 Kamath et al.
2010/0076283 A1 3/2010 Simpson et al.
2010/0081908 A1 4/2010 Dobbles et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2010/0081910	A1	4/2010	Brister et al.
2010/0087724	A1	4/2010	Brauker et al.
2010/0096259	A1	4/2010	Zhang et al.
2010/0099970	A1	4/2010	Shults et al.
2010/0099971	A1	4/2010	Shults et al.
2010/0105999	A1	4/2010	Dixon et al.
2010/0119693	A1	5/2010	Tapsak et al.
2010/0121169	A1	5/2010	Petisce et al.
2010/0141656	A1	6/2010	Krieftewirth
2010/0152554	A1	6/2010	Steine et al.
2010/0160759	A1	6/2010	Celentano et al.
2010/0168538	A1	7/2010	Keenan et al.
2010/0174266	A1	7/2010	Estes
2010/0185175	A1	7/2010	Kamen et al.
2010/0191082	A1	7/2010	Brister et al.
2010/0198142	A1	8/2010	Sloan et al.
2010/0213080	A1	8/2010	Celentano et al.
2010/0240975	A1	9/2010	Goode et al.
2010/0274111	A1	10/2010	Say et al.
2010/0292634	A1	11/2010	Kircher et al.
2010/0313105	A1	12/2010	Nekoomaram et al.
2011/0031986	A1	2/2011	Bhat et al.
2011/0077490	A1	3/2011	Simpson et al.
2011/0148905	A1	6/2011	Simmons et al.
2011/0208027	A1	8/2011	Wagner et al.
2011/0257895	A1	10/2011	Brauker et al.
2011/0287528	A1	11/2011	Fern et al.
2012/0165640	A1	6/2012	Galley et al.
2013/0235166	A1	9/2013	Jones et al.

FOREIGN PATENT DOCUMENTS

WO	WO-2006/037109	4/2006
WO	WO-2007/101260	9/2007
WO	WO-2008/003003	1/2008
WO	WO-2008/005780	1/2008

OTHER PUBLICATIONS

PCT Application No. PCT/US2007/062999, International Search Report and Written Opinion of the International Searching Authority mailed May 22, 2008.

U.S. Appl. No. 11/365,168, Notice of Allowance mailed Mar. 25, 2011.

U.S. Appl. No. 11/365,168, Office Action mailed Aug. 5, 2010.

U.S. Appl. No. 11/365,168, Office Action mailed Jan. 18, 2011.

Bremer, T. M., et al., "Benchmark Data from the Literature for Evaluation of New Glucose Sensing Technologies", *Diabetes Technology & Therapeutics*, vol. 3, No. 3, 2001, pp. 409-418.

Cheyne, E. H., et al., "Performance of a Continuous Glucose Monitoring System During Controlled Hypoglycaemia in Healthy Volunteers", *Diabetes Technology & Therapeutics*, vol. 4, No. 5, 2002, pp. 607-613.

Diem, P., et al., "Clinical Performance of a Continuous Viscometric Affinity Sensor for Glucose", *Diabetes Technology & Therapeutics*, vol. 6, 2004, pp. 790-799.

Garg, S., et al., "Improvement in Glycemic Excursions with a Transcutaneous, Real-Time Continuous Glucose Sensor", *Diabetes Care*, vol. 29, No. 1, 2006, pp. 44-50.

Kondepati, V., et al., "Recent Progress in Analytical Instrumentation for Glycemic Control in Diabetic and Critically Ill Patients", *Analytical Bioanalytical Chemistry*, vol. 388, 2007, pp. 545-563.

Kuure-Kinsey, M., et al., "A Dual-Rate Kalman Filter for Continuous Glucose Monitoring", *Proceedings of the 28th IEEE, EMBS Annual International Conference*, New York City, 2006, pp. 63-66.

Li, Y., et al., "In Vivo Release From a Drug Delivery MEMS Device", *Journal of Controlled Release*, vol. 100, 2004, 99. 211-219.

Lodwig, V., et al., "Continuous Glucose Monitoring with Glucose Sensors: Calibration and Assessment Criteria", *Diabetes Technology & Therapeutics*, vol. 5, No. 4, 2003, pp. 573-587.

Morbiducci, U, et al., "Improved Usability of the Minimal Model of Insulin Sensitivity Based on an Automated Approach and Genetic Algorithms for Parameter Estimation", *Clinical Science*, vol. 112, 2007, pp. 257-263.

Mougiakakou, et al., "A Real Time Simulation Model of Glucose-Insulin Metabolism for Type 1 Diabetes Patients", *Proceedings of the 2005 IEEE*, 2005, pp. 298-301.

Panteleon, A. E., et al., "The Role of the Independent Variable to Glucose Sensor Calibration", *Diabetes Technology & Therapeutics*, vol. 5, No. 3, 2003, pp. 401-410.

Parker, R., et al., "Robust H∞ Glucose Control in Diabetes Using a Physiological Model", *AIChE Journal*, vol. 46, No. 12, 2000, pp. 2537-2549.

* cited by examiner

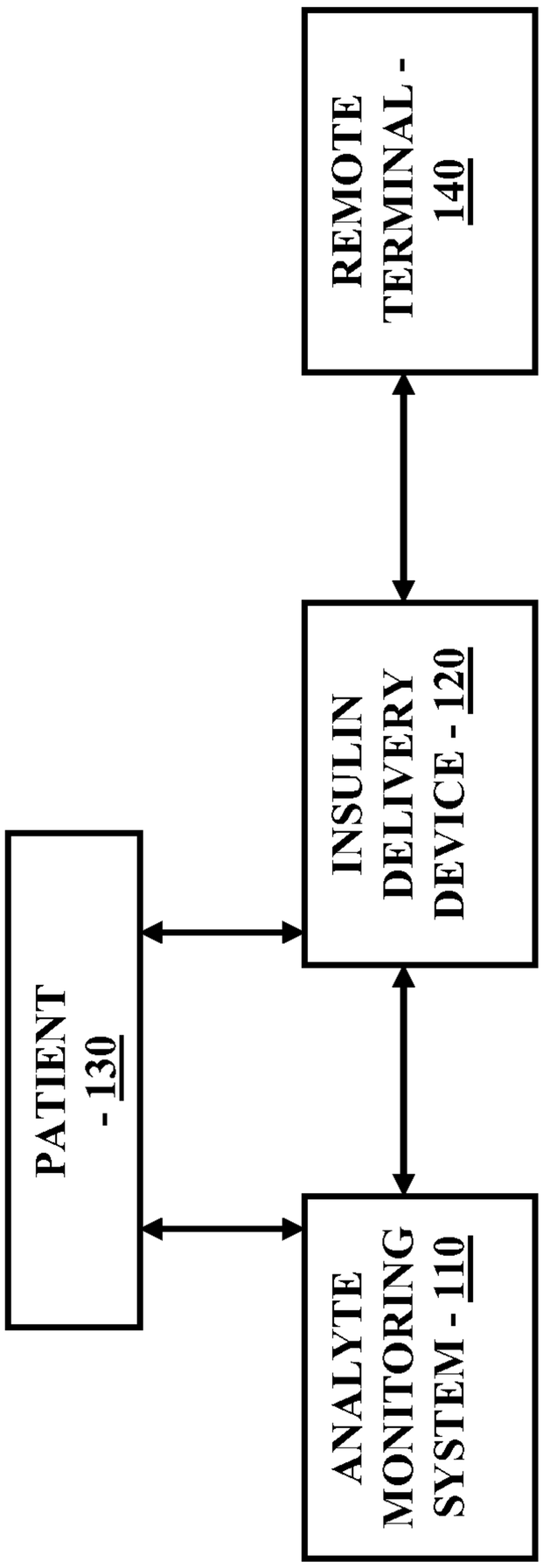
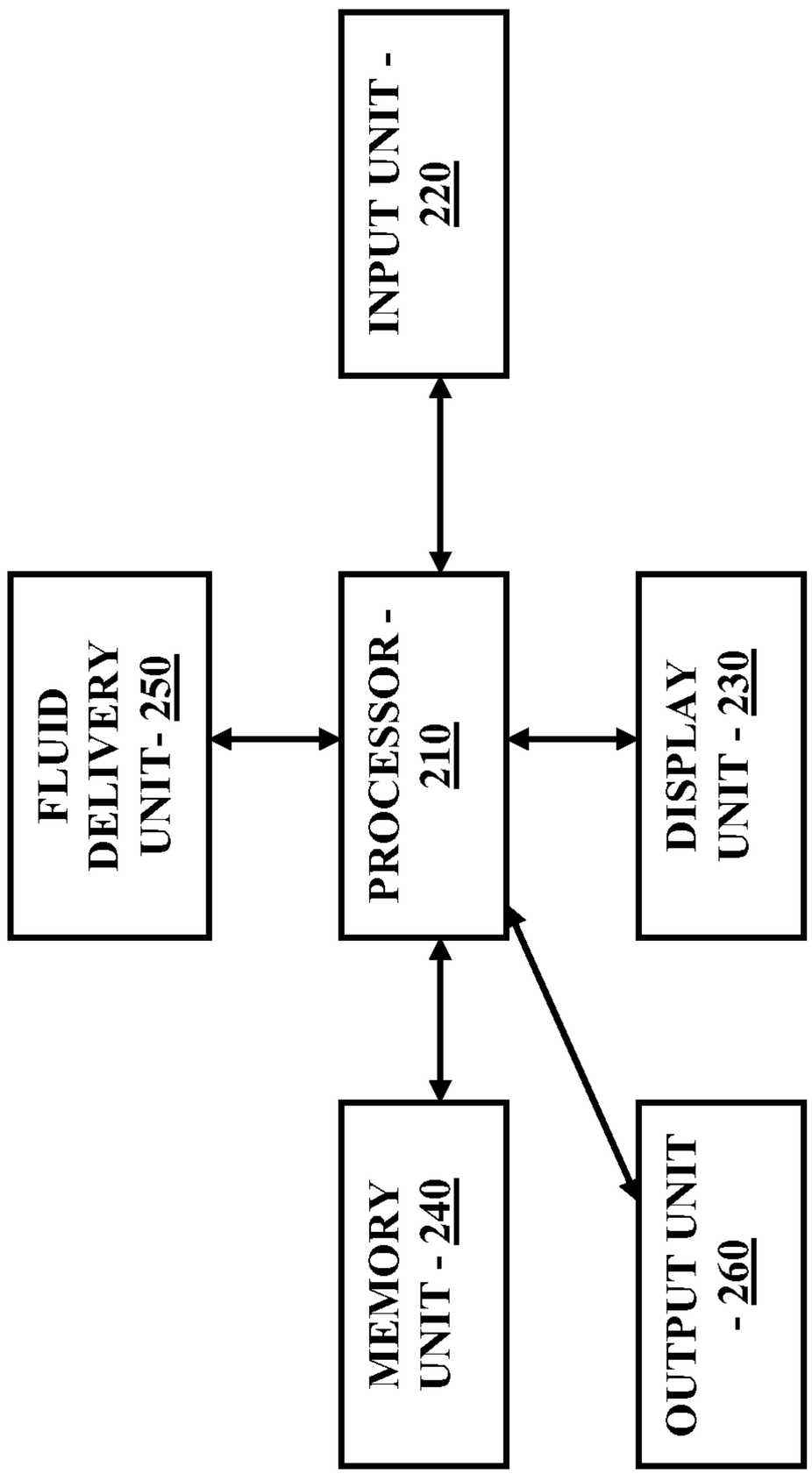

REMOTE TERMINAL - 140
INSULIN DELIVERY DEVICE - 120
PATIENT - 130
ANALYTE MONITORING SYSTEM - 110
100

FIGURE 1


INPUT UNIT - 220
FLUID DELIVERY UNIT- 250
PROCESSOR - 210
DISPLAY UNIT - 230
MEMORY UNIT - 240
OUTPUT UNIT - 260

120

FIGURE 2

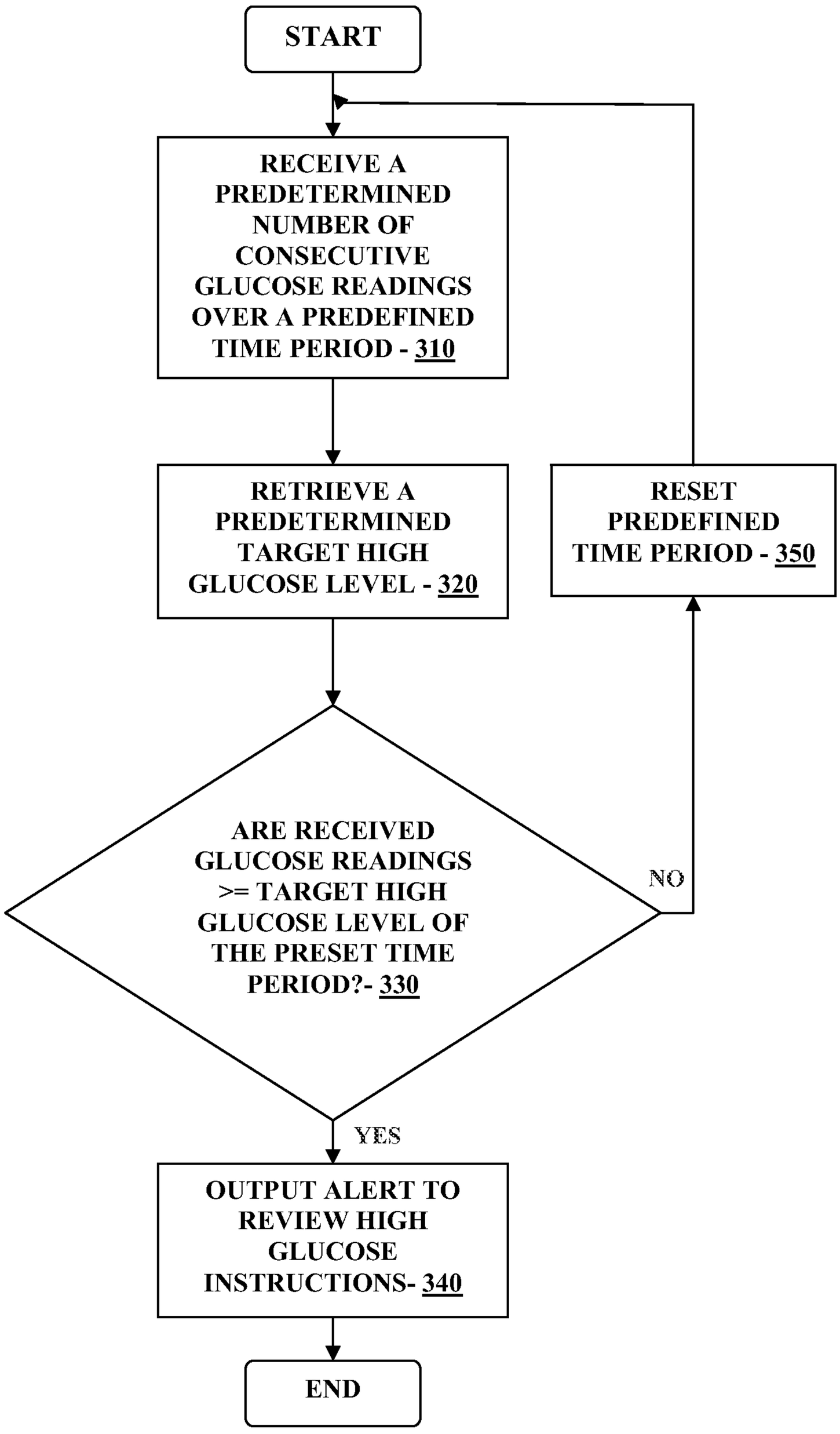

START
RECEIVE A PREDETERMINED NUMBER OF CONSECUTIVE GLUCOSE READINGS OVER A PREDEFINED TIME PERIOD - 310
RETRIEVE A PREDETERMINED TARGET HIGH GLUCOSE LEVEL - 320
ARE RECEIVED GLUCOSE READINGS >= TARGET HIGH GLUCOSE LEVEL OF THE PRESET TIME PERIOD?- 330
NO
YES
RESET PREDEFINED TIME PERIOD - 350
OUTPUT ALERT TO REVIEW HIGH GLUCOSE INSTRUCTIONS- 340
END

FIGURE 3

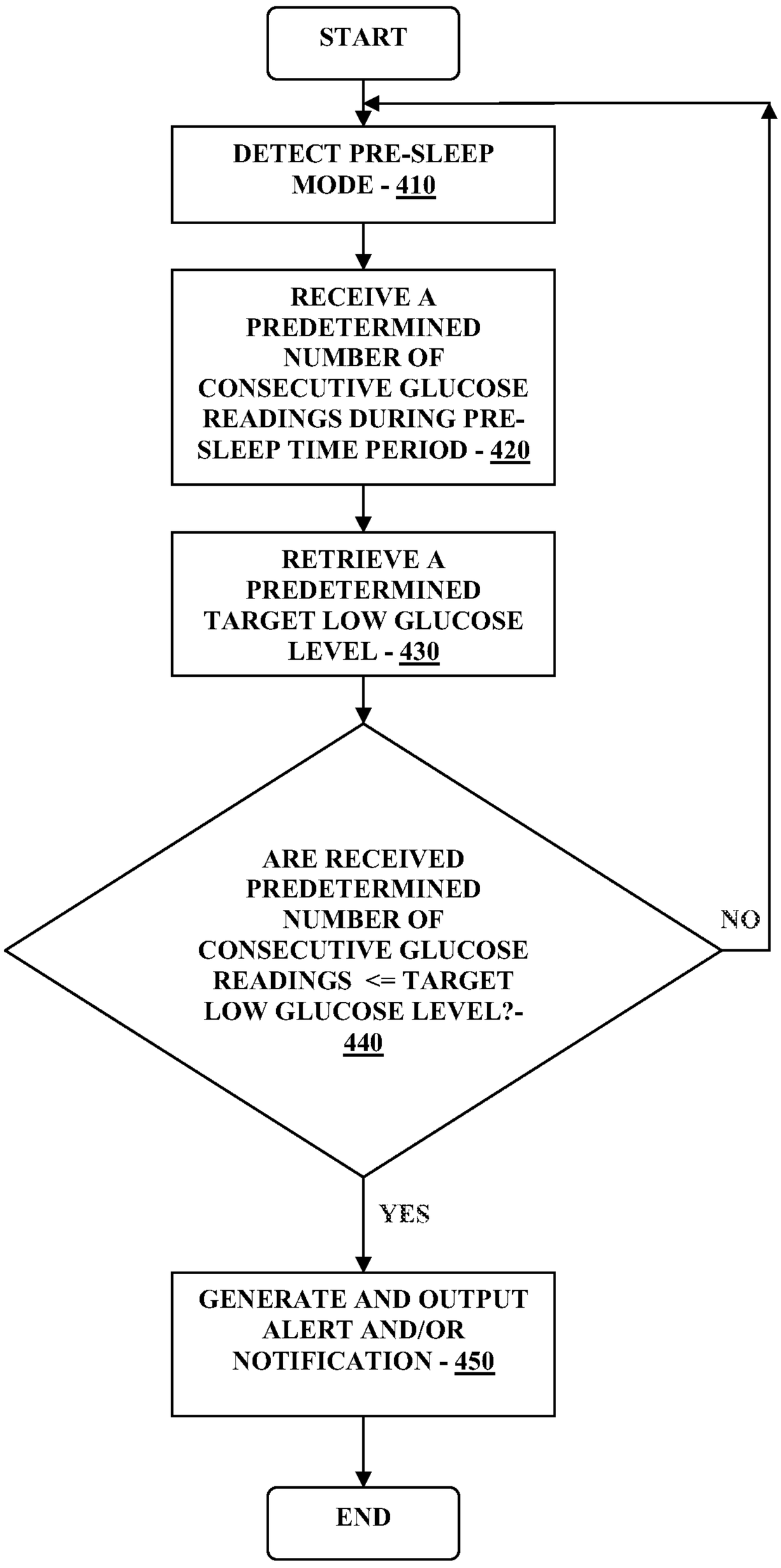

START
DETECT PRE-SLEEP MODE - 410
RECEIVE A PREDETERMINED NUMBER OF CONSECUTIVE GLUCOSE READINGS DURING PRE-SLEEP TIME PERIOD - 420
RETRIEVE A PREDETERMINED TARGET LOW GLUCOSE LEVEL - 430
ARE RECEIVED PREDETERMINED NUMBER OF CONSECUTIVE GLUCOSE READINGS <= TARGET LOW GLUCOSE LEVEL?- 440
NO
YES
GENERATE AND OUTPUT ALERT AND/OR NOTIFICATION - 450
END

FIGURE 4

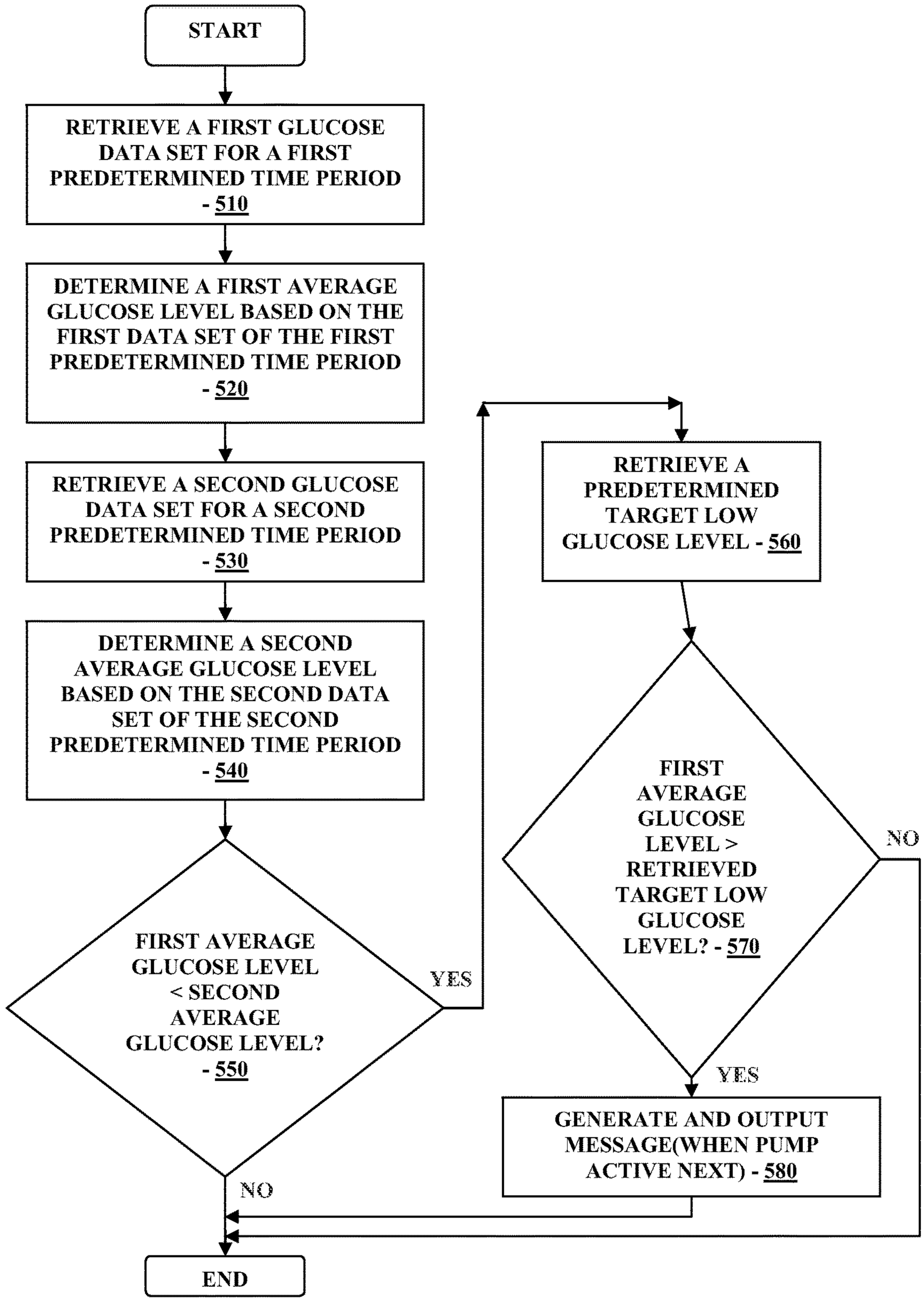

START
RETRIEVE A FIRST GLUCOSE DATA SET FOR A FIRST PREDETERMINED TIME PERIOD - 510
DETERMINE A FIRST AVERAGE GLUCOSE LEVEL BASED ON THE FIRST DATA SET OF THE FIRST PREDETERMINED TIME PERIOD - 520
RETRIEVE A SECOND GLUCOSE DATA SET FOR A SECOND PREDETERMINED TIME PERIOD - 530
DETERMINE A SECOND AVERAGE GLUCOSE LEVEL BASED ON THE SECOND DATA SET OF THE SECOND PREDETERMINED TIME PERIOD - 540
FIRST AVERAGE GLUCOSE LEVEL < SECOND AVERAGE GLUCOSE LEVEL? - 550
YES
NO
RETRIEVE A PREDETERMINED TARGET LOW GLUCOSE LEVEL - 560
FIRST AVERAGE GLUCOSE LEVEL > RETRIEVED TARGET LOW GLUCOSE LEVEL? - 570
NO
YES
GENERATE AND OUTPUT MESSAGE(WHEN PUMP ACTIVE NEXT) - 580
END

FIGURE 5

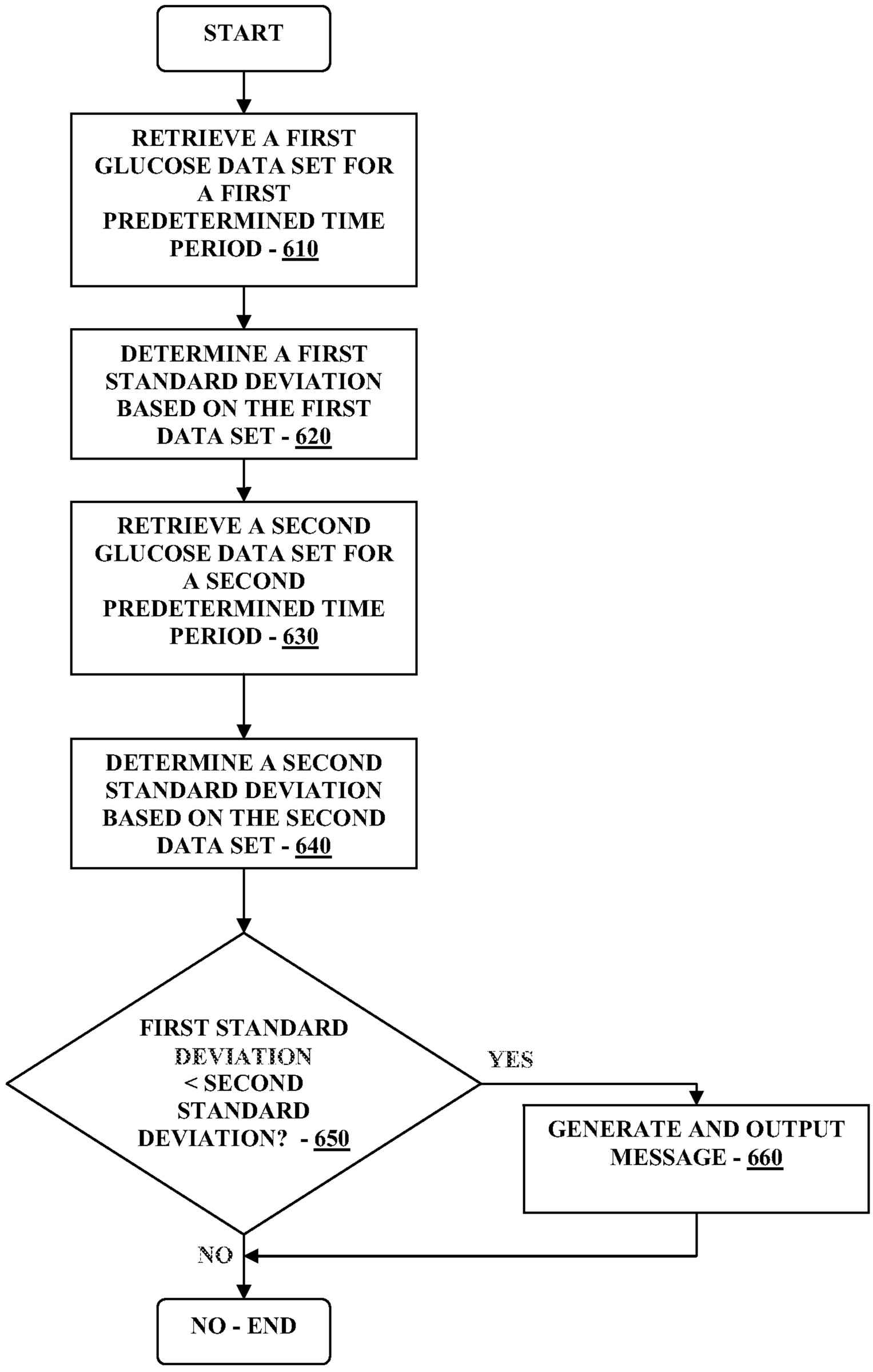

START
RETRIEVE A FIRST GLUCOSE DATA SET FOR A FIRST PREDETERMINED TIME PERIOD - 610
DETERMINE A FIRST STANDARD DEVIATION BASED ON THE FIRST DATA SET - 620
RETRIEVE A SECOND GLUCOSE DATA SET FOR A SECOND PREDETERMINED TIME PERIOD - 630
DETERMINE A SECOND STANDARD DEVIATION BASED ON THE SECOND DATA SET - 640
FIRST STANDARD DEVIATION < SECOND STANDARD DEVIATION? - 650
YES
GENERATE AND OUTPUT MESSAGE - 660
NO
NO - END

FIGURE 6

SMART MESSAGES AND ALERTS FOR AN INFUSION DELIVERY AND MANAGEMENT SYSTEM

RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 11/365,168 filed Feb. 28, 2006, now U.S. Pat. No. 7,981,034, the disclosure of which is incorporated herein by reference for all purposes.

BACKGROUND

With increasing use of pump therapy for Type 1 diabetic patients, young and old alike, the importance of controlling the infusion device, such as external infusion pumps, is evident. Indeed, presently available external infusion devices typically include an input mechanism such as buttons through which the patient may program and control the infusion device. Such infusion devices also typically include a user interface such as a display which is configured to display information relevant to the patient's infusion progress, status of the various components of the infusion device, as well as other programmable information such as patient specific basal profiles.

The external infusion devices are typically connected to an infusion set which includes a cannula that is placed transcutaneously through the skin of the patient to infuse a select dosage of insulin based on the infusion device's programmed basal rates or any other infusion rates as prescribed by the patient's doctor. Generally, the patient is able to control the pump to administer additional doses of insulin during the course of wearing and operating the infusion device, such as for administering a carbohydrate bolus prior to a meal. Certain infusion devices include a food database that has associated therewith, an amount of carbohydrate, so that the patient may better estimate the level of insulin dosage needed for, for example, calculating a bolus amount.

However, in general, most estimation or calculation of a bolus amount for administration, or a determination of a suitable basal profile, for that matter, are educated estimates based on the patient's physiology as determined by the patient's doctor, or an estimate performed by the patient. Moreover, the infusion devices do not generally include enhancement features that would better assist the diabetic patients to control and/or manage the glucose levels.

In view of the foregoing, it would be desirable to have an approach to provide methods and system for providing proactive notifications to the patients using infusion devices that may assist in better controlling and treating diabetes, such as, for example, by programming the pump and/or determining frequency of event occurrences that are relevant to different types of diabetes-associated episodes such as hyperglycemic state, hypoglycemic state, monitoring of glucose levels and the like.

SUMMARY OF THE INVENTION

In accordance with the various embodiments of the present invention, there are provided methods and system for notification of patient parameters and physiological states to prompt the user to take proactive measures such as additional capillary blood glucose testing, consumption of snacks, and/or other diabetes management related alerts to the patient prior to the onset of the relevant condition such that the patients may better control the glucose levels during

the course of the day when using an insulin infusion pump. In addition, system and methods in accordance with the present inventions include data analysis of the patient's glucose levels over extended periods of time to generate notification to the patients to inform them of the analysis results so as to provide additional motivation or incentive to improve upon the existing glucose management.

These and other objects, features and advantages of the present invention will become more fully apparent from the following detailed description of the embodiments, the appended claims and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a block diagram illustrating an insulin therapy management system for practicing one embodiment of the present invention;

FIG. **2** is a block diagram of the insulin delivery device of FIG. **1** in one embodiment of the present invention;

FIG. **3** is a flow chart illustrating a notification procedure to prevent DKA from persistent high blood glucose level in accordance with one embodiment of the present invention;

FIG. **4** is a flow chart illustrating a notification procedure for minimizing nocturnal hypoglycemia in accordance with one embodiment of the present invention;

FIG. **5** is a flow chart illustrating a notification procedure for improving blood glucose level control in a patient in accordance with one embodiment of the present invention; and

FIG. **6** is a flow chart illustrating a notification procedure for improving blood glucose level control in a patient in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION

FIG. **1** is a block diagram illustrating an insulin therapy management system for practicing one embodiment of the present invention. Referring to FIG. **1**, the insulin therapy management system **100** includes an analyte monitoring system **110** operatively coupled to an insulin delivery device **120**, which may be, in turn, operatively coupled to a remote terminal **140**. As shown the Figure, the analyte monitoring system **110** is, in one embodiment, coupled to the patient **130** so as to monitor or measure the analyte levels of the patient. Moreover, the insulin delivery device **120** is coupled to the patient using, for example, an infusion set and tubing connected to a cannula (not shown) that is placed transcutaneously through the skin of the patient so as to infuse medication such as, for example, insulin, to the patient.

Referring to FIG. **1**, in one embodiment the analyte monitoring system **110** in one embodiment may include one or more analyte sensors subcutaneously positioned such that at least a portion of the analyte sensors are maintained in fluid contact with the patient's analytes. The analyte sensors may include, but are not limited to, short term subcutaneous analyte sensors or transdermal analyte sensors, for example, which are configured to detect analyte levels of a patient over a predetermined time period, and after which, a replacement of the sensors is necessary.

The one or more analyte sensors of the analyte monitoring system **110** is coupled to a respective one or more of a data transmitter unit which is configured to receive one or more signals from the respective analyte sensors corresponding to the detected analyte levels of the patient, and to transmit the information corresponding to the detected analyte levels to a receiver device, and/or insulin delivery device **120**. That is,

over a communication link, the transmitter units may be configured to transmit data associated with the detected analyte levels periodically, and/or intermittently and repeatedly to one or more other devices such as the insulin delivery device and/or the remote terminal **140** for further data processing and analysis.

The transmitter units of the analyte monitoring system **110** may in one embodiment be configured to transmit the analyte related data substantially in real time to the insulin delivery device **120** and/or the remote terminal **140** after receiving it from the corresponding analyte sensors such that the analyte level, such as glucose level, of the patient **130** may be monitored in real time. In one aspect, the analyte levels of the patient may be obtained using one or more of a discrete blood glucose testing device, such as blood glucose meters, or a continuous analyte monitoring system, such as continuous glucose monitoring systems.

Additional analytes that may be monitored, determined or detected the analyte monitoring system **110** include, for example, acetyl choline, amylase, bilirubin, cholesterol, chorionic gonadotropin, creatine kinase (e.g., CK-MB), creatine, DNA, fructosamine, glucose, glutamine, growth hormones, hormones, ketones, lactate, peroxide, prostate-specific antigen, prothrombin, RNA, thyroid stimulating hormone, and troponin. The concentration of drugs, such as, for example, antibiotics (e.g., gentamicin, vancomycin, and the like), digitoxin, digoxin, drugs of abuse, theophylline, and warfarin, may also be determined.

Moreover, within the scope of the present invention, the transmitter units of the analyte monitoring system **110** may be configured to directly communicate with one or more of the remote terminal **140** or the insulin delivery device **120**. Furthermore, within the scope of the present invention, additional devices may be provided for communication in the analyte monitoring system **100** including additional receiver/data processing unit, remote terminals (such as a physician's terminal and/or a bedside terminal in a hospital environment, for example). In addition, within the scope of the present invention, one or more of the analyte monitoring system **110**, the insulin delivery device **120** and the remote terminal **140** may be configured to communicate over a wireless data communication link such as, but not limited to, RF communication link, Bluetooth® communication link, infrared communication link, or any other type of suitable wireless communication connection between two or more electronic devices, which may further be uni-directional or bi-directional communication between the two or more devices. Alternatively, the data communication link may include wired cable connection such as, for example, but not limited to, RS232 connection, USB connection, or serial cable connection.

The insulin delivery device **120** may include in one embodiment, but is not limited to, an external infusion device such as an external insulin infusion pump, an implantable pump, a pen-type insulin injector device, a patch pump, an inhalable infusion device for nasal insulin delivery, or any other type of suitable delivery system. In addition, the remote terminal **140** in one embodiment may include for example, a desktop computer terminal, a data communication enabled kiosk, a laptop computer, a hand-held computing device such as a personal digital assistant (PDA), or a data communication enabled mobile telephone.

Referring back to FIG. **1**, in one embodiment, the analyte monitoring system **100** includes a strip port configured to receive a test strip for capillary blood glucose testing. In one aspect, the glucose level measured using the test strip may in addition, be configured to provide periodic calibration of the analyte sensors of the analyte monitoring system **100** to assure and improve the accuracy of the analyte levels detected by the analyte sensors.

FIG. **2** is a block diagram of an insulin delivery device of FIG. **1** in one embodiment of the present invention. Referring to FIG. **2**, the insulin delivery device **120**, in one embodiment, includes a processor **210** operatively coupled to a memory unit **240**, an input unit **220**, a display unit **230**, an output unit **260**, and a fluid delivery unit **250**. In one embodiment, the processor **210** includes a microprocessor that is configured to and capable of controlling the functions of the insulin delivery device **120** by controlling and/or accessing each of the various components of the insulin delivery device **120**. In one embodiment, multiple processors may be provided as a safety measure and to provide redundancy in case of a single processor failure. Moreover, processing capabilities may be shared between multiple processor units within the insulin delivery device **120** such that pump functions and/or control may be performed faster and more accurately.

Referring back to FIG. **2**, the input unit **220** operatively coupled to the processor **210** may include a jog dial, key pad buttons, a touch pad screen, or any other suitable input mechanism for providing input commands to the insulin delivery device **120**. More specifically, in case of a jog dial input device, or a touch pad screen, for example, the patient or user of the insulin delivery device **120** will manipulate the respective jog dial or touch pad in conjunction with the display unit **230** which performs as both data input and output units. The display unit **230** may include a touch sensitive screen, an LCD screen, or any other types of suitable display units for the insulin delivery device **120** that are configured to display alphanumeric data as well as pictorial information such as icons associated with one or more predefined states of the insulin delivery device **120**, or graphical representation of data such as trend charts and graphs associated with the insulin infusion rates, trend data of monitored glucose levels over a period of time, or textual notification to the patients.

Referring to FIG. **2**, the output unit **260** operatively coupled to the processor **210** may include an audible alarm including one or more tones and/Nor preprogrammed or programmable tunes or audio clips, or vibratory alert features having one or more pre-programmed or programmable vibratory alert levels. In one embodiment, the vibratory alert may also assist in priming the infusion tubing to minimize the potential for air or other undesirable material in the infusion tubing. Also shown in FIG. **2** is the fluid delivery unit **250** which is operatively coupled to the processor **210** and configured to deliver the insulin doses or amounts to the patient from the insulin reservoir or any other types of suitable containment for insulin to be delivered (not shown) in the insulin delivery device **120** via an infusion set coupled to a subcutaneously positioned cannula under the skin of the patient.

Referring yet again to FIG. **2**, the memory unit **240** may include one or more of a random access memory (RAM), read only memory (ROM), or any other types of data storage units that is configured to store data as well as program instructions for access by the processor **210** and execution to control the insulin delivery device **120** and/or to perform data processing based on data received from the analyte monitoring system **110**, the remote terminal **140**, the patient **130** or any other data input source.

FIG. **3** is a flow chart illustrating a notification procedure to prevent diabetic ketoacidosis (DKA) from persistent high blood glucose level in accordance with one embodiment of

the present invention. Referring to FIG. **3**, in one embodiment of the present invention, the insulin delivery device **120** may be programmed such that at step **310**, a predetermined number of consecutive glucose readings is received over a predefined period of time. The glucose readings may be received from the analyte monitoring system **110** and stored, for example, in the memory unit **240** of the insulin delivery device **120**. For example, in one embodiment, the patient may be prompted to provide a predetermined number, such as three, of consecutive readings of blood glucose measurements over the predefined time period such as within a thirty minute window to a four hour window.

Within the scope of the present invention, the insulin delivery device **120** may be configured to ascertain these consecutive glucose readings from the data stream received from the analyte monitoring system **110**. Moreover, the predefined time period may additionally include any other suitable time period where the monitored analyte levels may provide information associated with the patient's physiological condition as pertains to the insulin therapy and diabetes management. For example, the predefined time period may include a 4-7 day period (or longer or shorter as may be appropriate), where the insulin delivery device **120** may be configured to receive the glucose readings at a specific time of the day (for example, at 7 am in the morning). In this case, the consecutive glucose readings may include each measured glucose level at 7 am in the morning for the 4-7 day period.

Referring to FIG. **3**, at step **320**, a predetermined target high glucose level which is pre-programmed and pre-stored in the memory unit **240** of the insulin delivery device **120**, for example, may be retrieved by the processor **210** of the insulin delivery device **120**. Alternatively, the patient may be prompted to provide a suitable target high glucose level at step **320** by the insulin delivery device **120**. Thereafter, at step **330**, the consecutive glucose readings over the predefined time period received at step **310** are compared with the target high glucose level from step **320**. If it is determined at step **330** that the predetermined number of consecutive glucose readings over the predefined time period are not equal to or greater than the target high glucose level retrieved from step **320**, then at step **350**, the predefined time period may be optionally reset, and the routine returns to step **310**. For example, the system may be configured to wait for the subsequent predefined time period, for example, between a time period of 30 minutes to one or two hour windows depending upon the time of the day and also, depending upon the time of the day in close proximity to a meal or physical activity, as may be programmed by the patient or the patient's physician or care provider, before executing the routine as described in FIG. **3** again.

Referring back to FIG. **3**, if, at step **330**, it is determined that the predetermined number of consecutive glucose readings over the predefined time period is greater or equal to the predetermined target high glucose level retrieved from memory unit **240** (FIG. **2**), or received from the patient via the input unit **220** (FIG. **2**) at step **320**, then at step **340**, an alert or notification is generated and output to the patient, either visually, audibly, tactily, or any combination of the output mechanism such as a visual alert displayed on the display unit **230** in combination with a vibratory alert providing tactile notification to the patient, and/or an audible alert. In one embodiment, the output alert notification provided to the patient may include a warning notification that the patient's consecutive blood glucose readings are persistently above the predetermined or programmed target high glucose level, and also provide a recommendation to take possible corrective or confirmatory actions such as intake of insulin, and/or additional glucose testing such as, for example, using fingerstick capillary blood glucose measurements. By way of an example, the insulin delivery device **120** may be configured to display a notification such as, but not limited to:

"3 High BGs in a Row—Consider Insulin Injection and Site Change",
"Test Ketones",
"If vomiting Go to Emergency Room",
"Take Insulin Bolus",
"Change Infusion Site",
"Retest Glucose Level in 30 Minutes",
"Call Doctor if Glucose Remains Elevated",

or any other suitable notification that may assist the patient in preventing diabetic ketoacidosis (DKA) which is associated with disruption of insulin delivery. As it is important for patients using insulin delivery device **120** to prevent going into DKA on the delivery device **120**, the notification may be accompanied by one or more associated audible or tactile alerts such that the patients are readily and quickly able to ascertain the condition for which the insulin delivery device **120** is prompting the patients, and to take corrective actions immediately or as soon as possible.

Referring to FIG. **3**, in one embodiment, the predetermined target high glucose level stored in the memory unit **240** of the insulin delivery device **120** may be 250 mg/dL, and which may be adjustable by the patient or the patient's care provider. For example, a diabetic patient experiencing thirst and irritation which are generally symptoms of elevated glucose readings, at 2 pm, determines, based on measured glucose readings (for example, received from the analyte monitoring system **110**), that the glucose level is at 263 mg/dL. The patient has programmed the insulin delivery device **120** to a target high glucose level of 250 mg/dL, with a predetermined number of consecutive glucose readings at two readings, and the predefined time period to be a 2 hour window.

With the initial glucose reading of 263 mg/dL, the patient may initially be prompted to trouble shoot certain settings of the delivery device **120**, for example, to confirm that the lunch bolus was delivered, no additional carbohydrate was ingested, verify the infusion tubing (fluid delivery unit **250**) for possible air bubbles. If all settings are in their accurate modes, then a correction bolus may be administered using the insulin delivery device **120**. Thereafter, the glucose level after 2 hours is retrieved, for example, from the memory unit **240** as received from the analyte monitoring system **110** (including, a separate real time capillary blood fingerstick testing, for example), and compared with the target high glucose level of 250 mg/dL. If it is determined that the second glucose measurement is still above the 250 mg/dL level, then the patient is provided with one or more of the alerts or notifications as described above to troubleshoot the persistent high glucose level condition, and thus take corrective measures to avoid the onset of DKA condition.

Referring yet again to FIG. **3**, while the above description of processes and routines related to preventing DKA is provided in the context of the insulin delivery device **120**, within the scope of the present invention, the calculation, determination or any programming and data processing to achieve the functions as set forth in FIG. **3** may be performed either alternately or in conjunction with the insulin delivery device **120**, by the analyte monitoring system **110**, or the remote terminal **140**, as may be convenient or practical to the patient **130**.

FIG. **4** is a flow chart illustrating a notification procedure for minimizing nocturnal hypoglycemia in accordance with one embodiment of the present invention. Referring to FIG. **4**, at step **410** a pre-sleep mode is detected. That is, the insulin delivery device **120** may be configured to automatically enter the pre-sleep mode based on a clock mechanism in the insulin delivery device **120** which provides real time timing data, and further, in conjunction with the patient specified meal and sleep schedule as they may be individual and different from patient to patient. For example, the patient using the insulin delivery device **120** may program a pre-sleep mode to be defined as a time period post dinner or the last meal of the day, and prior to the patient sleeping. One example may be the time period of 9 pm to midnight, with the assumption that the patient has consumed dinner or the last substantial carbohydrate intake two to three hours prior to the onset of the pre-sleep mode time period of 9 pm.

Referring to FIG. **4**, upon initiation or detection of the pre-sleep mode at step **410**, the insulin delivery device **120** in one embodiment is configured to retrieve consecutive glucose readings during the pre-sleep mode time period for example, from the analyte monitoring system **110** (FIG. **1**). In one embodiment, the number of predetermined consecutive glucose readings received at step **420** may include three consecutive readings, two consecutive readings, or any other suitable number of consecutive readings that may be appropriate to detecting the potential onset of hypoglycemic condition.

After receiving the predetermined consecutive glucose readings during the pre-sleep time period at step **420**, a predetermined and/or pre-programmed target low glucose level is retrieved from, for example, the memory unit **240** of the insulin delivery device **120** (FIG. **2**) at step **430**. Thereafter, at step **440**, the predetermined number of consecutive glucose readings are each compared with the predetermined target low glucose level (for example, 80 mg/dL). If it is determined that one or more of the predetermined number of consecutive glucose readings during the pre-sleep time period is higher than the predetermined target low glucose level at step **440**, then the routine returns to step **410** and awaits to enter the subsequent pre-sleep mode initiation.

On the other hand, referring back to FIG. **4**, if at step **440** it is determined that each of the predetermined number of consecutive glucose readings during the pre-sleep time period is lower or equal to the predetermined target low glucose level, then at step **450**, an alert and/or notification is generated and output to the patient to take certain predefined and appropriate corrective actions and device status verifications. Examples of such alerts and/or notifications may include one or more of a visual, audible, or tactile notification of the measured consecutive low glucose levels, and a suggestion or recommendation to ingest a snack and or modify the existing basal rate of the insulin delivery device **120** prior to going to sleep.

In this manner, in one embodiment of the present invention, early onset of nocturnal hypoglycemic state may be detected and the patient may be notified prior to going to sleep to take one or more certain appropriate corrective actions to prevent entering into hypoglycemic state while sleeping. Suitable alerts or notifications include, for example, but are not limited to, the following:

"Three Pre-sleep Low BGs in a Row—Check Bedtime Basal",

"Consider Basal Adjustment",

"Eat a Bedtime Snack"

In the manner described above, in accordance with one embodiment of the present invention, there is provided an approach to prevent or minimize the potential for nocturnal hypoglycemia for the Type-1 diabetic patient. Moreover, while the above description of processes and routines related to minimizing nocturnal hypoglycemia is provided in the context of the insulin delivery device **120**, within the scope of the present invention, the calculation, determination or any programming and data processing to achieve the functions as set forth in FIG. **3** may be performed either alternately or in conjunction with the insulin delivery device **120**, by the analyte monitoring system **110**, or the remote terminal **140**, as may be convenient or practical to the patient **130**.

FIG. **5** is a flow chart illustrating a notification procedure for improving blood glucose level control in a patient in accordance with one embodiment of the present invention. Referring to FIG. **5**, at step **510** insulin delivery device **120** may be configured to retrieve a first glucose data set based on measured glucose levels of the patient **130** for a first predetermined time period (which may be a 7 day period, for example). Thereafter at step **520**, a first running average glucose level is determined based on the first date set for the first predetermined time period. The calculated first running average glucose level may be optionally stored in the memory unit **240** of the insulin delivery device **120**.

Referring back to FIG. **5**, after determining the first running average glucose level for the first predetermined time period at step **520**, a second glucose data set is retrieved at step **530**, which corresponds to the measured glucose levels of the patient **130** for a second predetermined time period (for example, a 30 day period). Thereafter, at step **540**, a second average glucose level based on the second glucose data set is determined for the second predetermined time period. Again, optionally, the calculated second average glucose level may be stored in the memory unit **240** of the insulin delivery device **120**.

Thereafter, referring again to FIG. **5**, at step **550**, the first average glucose level is compared with the second average glucose level. If it is determined at step **550** that the first average glucose levels is not less than the second average glucose level, then the routine terminates. On the other hand, if at step **550**, it is determined that the first average glucose level calculated based on the first predetermined time period is less than the second average glucose level calculated over the second predetermined time period, then at step **560**, a predetermined target low glucose level is retrieved (for example, from memory unit **240**), and at step **570** the retrieved predetermined target low glucose level is compared with the first average glucose level calculated at step **520**. In one embodiment, the predetermined target low glucose level may be set by the patient or the patient's care provider at a suitable level, such as, for example, but not limited to, 80 mg/dL.

If at step **570** it is determined that the first average glucose level calculated for the first predetermined time period is greater than the retrieved predetermined target low glucose level, then at step **580**, an appropriate notification is generated and output to the patient on one or more of the output unit **260** or the display unit **230** of the insulin delivery device **120**. An example of such notification may include "Congratulations!—better BG control than Last Week," or "Good BG Control is Worth the Effort!".

In this manner, one or more of notifications providing encouragements to the patients may be provided based on monitored glucose levels so that the patients continue to make efforts in controlling and improving their blood glucose levels. Moreover, while 7 days and 30 days are described as the predetermined first and second time period,

respectively, within the scope of the present invention, these time periods may be altered as suited to each patient and as appropriate so as to accurately and effectively evaluate monitored glucose levels of the patients over extended periods of time and to provide notifications to the patients. Moreover, within the scope of the present invention, the calculation, determination or any programming and data processing to achieve the functions as set forth in FIG. **5** may be performed either alternately or in conjunction with the insulin delivery device **120**, by the analyte monitoring system **110**, or the remote terminal **140**, as may be convenient or practical to the patient **130**.

FIG. **6** is a flow chart illustrating a notification procedure for improving blood glucose level control in a patient in accordance with another embodiment of the present invention. Referring to FIG. **6**, at step **610**, a first glucose data set corresponding to the measured glucose levels of the patient **130** is retrieved, for example, from the memory unit **240** of the insulin delivery device **120** as received from, for example, the analyte monitoring system **110** (FIG. **1**) for a predetermined time period (such as 7 days, for example). Thereafter, a first standard deviation is determined at step **620** based on the first glucose data set. Thereafter, a second glucose data set for a second predetermined time period (such as 30 days, for example) is retrieved at step **630**, and a second standard deviation based on the second glucose data set is determined at step **640**.

Referring to FIG. **6**, after determining the first and second standard deviations based on the first glucose data set and the second glucose data set, respectively, at step **650**, the first standard deviation is compared with the second standard deviation. If at step **650** the first standard deviation is not less than the second standard deviation, then the routine terminates. On the other hand, if at step **650** it is determined that the first standard deviation is less than the second standard deviation, then at step **660**, an output notification is generated and output to the patient on one or more of the output unit **260** or the display unit **230**. Examples of the output notification may include, for example, a notification including "Congratulations!—Fewer Highs and Lows Than Last Week!" or "Good BG Control is Important!", or any other suitable notification which corresponds to the glucose level standard deviations determined and compared based on the patient's monitored glucose levels.

Optionally, within the scope of the present invention, the step outputting the generated notification may be performed upon the first reactivation of the insulin delivery device **120** after the routine in FIG. **6** is performed. In this manner, the insulin delivery device **120** may be configured to provide one or more notifications based on the patient's monitored glucose levels, and to assist the patient **130** in continuing to improve monitoring and management of the glucose levels.

In a further embodiment, the patient's analyte levels may be monitored over an extended time period such as over a 4-7 day period (for example), at a specific time of the day (for example, at 7 am every morning), and the system may be configured to analyze the obtained or monitored analyte levels each day at the specified time of day to determine or generate one or more appropriate patient notifications or alerts to be provided to the patient. In this manner, the patient may be able to improve insulin therapy and diabetes management.

Moreover, within the scope of the present invention, the calculation, determination or any programming and data processing to achieve the functions as set forth in FIG. **6** may be performed either alternately or in conjunction with the insulin delivery device **120**, by the analyte monitoring system **110**, or the remote terminal **140**, as may be convenient or practical to the patient **130**. In addition, in the manner described above, any other types of glucose related data may be monitored or analyzed over a period of time in conjunction with the basal profile of the patient **130** to provide a comprehensive insulin therapy management and diabetes care system.

The various processes described above including the processes performed by the processor **210** in the software application execution environment in the insulin delivery device **120** as well as any other suitable or similar processing units embodied in the analyte monitoring system **110** and the remote terminal **140**, including the processes and routines described in conjunction with FIGS. **3-6**, may be embodied as computer programs developed using an object oriented language that allows the modeling of complex systems with modular objects to create abstractions that are representative of real world, physical objects and their interrelationships. The software required to carry out the inventive process, which may be stored in the memory unit **240** (or similar storage devices in the analyte monitoring system **110** and the remote terminal **140**) of the processor **210**, may be developed by a person of ordinary skill in the art and may include one or more computer program products.

Accordingly, a method of diabetes management in one embodiment of the present invention includes comparing each of a predetermined number of consecutive analyte related levels for a predefined time period to a predetermined target level, and generating an alert when each of the predetermined number of consecutive analyte related levels deviates from the predetermined target level.

The method may further include the step of measuring an analyte level of a patient to determine the one or more of the predetermined number of consecutive analyte related levels, where the measuring step may, in one embodiment, include the step of using one or more of a discrete blood glucose meter or a continuous analyte monitoring system.

The method may further include the step of outputting the alert on an infusion device.

Moreover, in one embodiment, the predefined time period may include one of a time period between 30 minutes and four hours.

The predetermined number of consecutive analyte related levels in another aspect may include one of two, three, four or five analyte related levels.

Additionally, the predetermined target level may include a target high analyte level.

The analyte levels may include glucose levels, and the predetermined target level may include a target high glucose level.

The alert may, in one embodiment, include one or more of an audible alert, a visual alert, or a tactile alert, where the visual alert may include one or more of an alphanumeric output display, a graphical output display, an icon display, a video output display, a color display and an illumination display.

The color display may include a change in color of an output image, animation, or background of the display unit **230**, for example, and the illumination display may include, for example, but is not limited to, a persistent or sequential flashing of the backlight feature on the display unit **230**.

The method may further include the step of outputting the generated alert.

The predefined time period, in one embodiment, may include a pre-sleep time period, which, in one embodiment, may be configured to begin at approximately a predetermined number of hours past the last meal of the day, and to terminate at the beginning of entering sleep cycle.

Alternatively, the pre-sleep time period may be configured to begin at approximately 9 pm and to terminate at approximately 12 am in a 24 hour daily time period.

Alternatively, the pre-sleep time period maybe configured to begin at approximately 9 pm and to terminate at approximately at 12 am in a 24 hour daily time period.

In a further aspect, the predetermined target level may include a target low analyte level, where the alert may be generated when each of the predetermined number of analyte related levels falls below the target low analyte level.

A system for providing diabetes management in accordance with another embodiment of the present invention includes an interface unit configured to receive one or more analyte related data, a processor unit operatively coupled to the interface unit, the processor unit configured to perform data processing based on the one or more received analyte related data, the processing unit further configured to generate one or more of an alert or a notification for output via the interface unit, where the processor unit is configured to compare the one or more analyte related data to one or more of a predetermined target analyte level, and, in accordance therewith, generate the one or more of the alert or the notification for one or more of an audible output, visual output or a tactile output.

The interface unit may include an input unit and an output unit, the input unit configured to receive the one or more analyte related data, and the output unit configured to output the one or more of the alert of the notification.

The processor unit may be configured to receive substantially, in real time, a plurality of analyte levels of a patient.

The interface unit and the processor unit may be operatively coupled to a housing of an infusion device.

The infusion device may include an external insulin pump.

A system for providing diabetes management in accordance with yet another embodiment includes an analyte monitoring system configured to monitor an analyte level of a patient substantially in real time, a medication delivery unit operatively for wirelessly receiving data associated with the monitored analyte level of the patient substantially in real time from the analyte monitoring system, and a data processing unit operatively coupled to the one or more of the analyte monitoring system or the medication delivery unit, the data processing unit configured to perform data processing based on the monitored analyte level of the patient, and to generate and output one or more of an alert or notification corresponding to the monitored analyte levels.

The analyte monitoring system may be configured to wirelessly communicate with the medication delivery unit over a radio frequency (RF) communication link, a Bluetooth® communication link, an Infrared communication link, or a local area network (LAN).

Various other modifications and alterations in the structure and method of operation of this invention will be apparent to those skilled in the art without departing from the scope and spirit of the invention. Although the invention has been described in connection with specific preferred embodiments, it should be understood that the invention as claimed should not be unduly limited to such specific embodiments. It is intended that the following claims define the scope of the present invention and that structures and methods within the scope of these claims and their equivalents be covered thereby.

What is claimed is:

1. A method of managing hypoglycemia in real time performed by an electronic therapy device, comprising:

detecting a pre-sleep time period comprising a time period prior to when a user enters a sleep cycle and entering a pre-sleep mode in response thereto;

receiving, automatically without user input and during the pre-sleep time period, a predetermined number of consecutive analyte related level readings for the pre-sleep time period, wherein the predetermined number of consecutive analyte related level readings includes two or more consecutive analyte related level readings;

retrieving, automatically without user input and during the pre-sleep time period, a predetermined target analyte level for the pre-sleep time period from a memory;

comparing, automatically without user input and during the pre-sleep time period, each of the predetermined number of consecutive analyte related level readings for the pre-sleep time period to the predetermined target analyte level;

in response to one or more of the predetermined number of consecutive analyte related level readings being greater than the predetermined target analyte level, exiting the pre-sleep mode and waiting for a subsequent pre-sleep time period; and

in response to all of the predetermined number of consecutive analyte related level readings being equal to or lower than the predetermined target analyte level, generating and outputting an alert.

2. The method of claim **1**, further including measuring an analyte related level of the user during the pre-sleep time period to determine the predetermined number of consecutive analyte related level readings.

3. The method of claim **2**, wherein measuring the analyte related level includes using one or more of a discrete blood glucose meter or a continuous analyte monitoring system.

4. The method of claim **1**, further including outputting the alert on a medication delivery unit.

5. The method of claim **1**, wherein the alert includes one or more of an audible alert, a visual alert, or a tactile alert.

6. The method of claim **5**, wherein the visual alert includes one or more of an alphanumeric output display, a graphical output display, an icon display, a video output display, a color display or an illumination display.

7. The method of claim **1**, wherein the pre-sleep time period begins at approximately a predetermined number of hours after the last meal of the day, and terminates at the beginning of entering the sleep cycle.

8. The method of claim **1**, wherein generating the alert includes generating a treatment recommendation.

9. A system for managing hypoglycemia in real time, comprising:

a processor unit coupled to a non-transitory memory, the non-transitory memory comprising a plurality of instructions that, when executed, cause the processor unit to:

detect a pre-sleep time period comprising a time period prior to when a user enters a sleep cycle and enter a pre-sleep mode in response thereto;

automatically receive, without user input and during the pre-sleep time period, a predetermined number of consecutive analyte related level readings, wherein the predetermined number of consecutive analyte related level readings includes two or more consecutive analyte related level readings;

automatically retrieve from the non-transitory memory, without user input and during the pre-sleep time period, a predetermined target analyte level for the pre-sleep time period,

automatically compare, without user input and during the pre-sleep time period, each of the predetermined

number of consecutive analyte related level readings for the pre-sleep time period to the predetermined target analyte level,

in response to one or more of the predetermined number of consecutive analyte related level readings being greater than the predetermined target analyte level, exit the pre-sleep mode and wait for a subsequent pre-sleep time period; and

in response to all of the predetermined number of consecutive analyte related level readings being equal to or lower than the predetermined target level, automatically generate and output one or more of an alert and a notification for one or more of an audible output, a visual output and a tactile output.

10. The system of claim **9**, wherein the processor unit is operatively coupled to a housing of an infusion device.

11. The system of claim **10**, wherein the infusion device includes an insulin pump.

12. A system for managing hypoglycemia in real time, comprising:

an analyte monitoring system configured to monitor an analyte level of a user substantially in real time;

a medication delivery unit operatively coupled to the analyte monitoring system for wirelessly receiving data associated with the monitored analyte level of the user substantially in real time from the analyte monitoring system automatically without user input; and

a data processing unit operatively coupled to one or more of the analyte monitoring system and the medication delivery unit and operatively coupled to a non-transitory memory, the non-transitory memory comprising a plurality of instructions that, when executed, cause the data processing unit to:

detect a pre-sleep time period comprising a time period prior to when a user enters a sleep cycle and, upon detection of the pre-sleep time period, enter a pre-sleep mode;

automatically receive, without user input and during the pre-sleep time period, a predetermined number of consecutive monitored analyte level readings, wherein the predetermined number of consecutive analyte related level readings includes two or more consecutive analyte related level readings,

automatically retrieve from the non-transitory memory, without user input and during the pre-sleep time period, a predetermined target analyte level for the pre-sleep time period,

compare automatically, without user input and during the pre-sleep time period, each of the predetermined number of consecutive monitored analyte level readings during the pre-sleep time period to the predetermined target level,

in response to one or more of the predetermined number of consecutive analyte related level readings is greater than the predetermined target analyte level, exit the pre-sleep mode and wait for a subsequent pre-sleep time period, and

in response to all of the predetermined number of consecutive monitored analyte related level readings being equal to or lower than the predetermined target level, automatically generate and output, without user input and during the pre-sleep time period, one or more of an alert and a notification to the user.

13. The system of claim **12**, wherein the analyte monitoring system is configured to wirelessly communicate with the medication delivery unit over a radio frequency (RF) communication link, a Bluetooth communication link, an Infrared communication link, or a local area network (LAN).

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