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## (12) United States Patent

#### Carr et al.

#### (54) PHYSIOLOGIC INSULIN-SENSITIVITY IMPROVEMENT

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

This patent is subject to a terminal disclaimer.

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- (51) **Int. Cl.**

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G06F 19/00	(2018.01)
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G01N 33/60	(2006.01)
G16H 30/40	(2018.01)
G16H 50/50	(2018.01)

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

(56) **References Cited** 

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#### (57) **ABSTRACT**

An individualized intravenous exogenous insulin-based therapy for infusing insulin intravenously to a subject or a patient to improve impaired hepatic glucose processing. The therapy includes treatment sessions involving the assessment of metabolic factors, forming a subject profile, and matching the subject profile to a diabetic treatment model. Using the diabetic treatment model, a quantity and frequency of intravenous insulin bolus, dosage amounts of magnesium, and dosage amounts of potassium can be calculated. The methods that improve impaired hepatic glucose processing in subjects and patients can simultaneously introduce separated insulin bolus from an insulin reservoir, dosage amounts of magnesium, and dosage amounts of potassium. The subject profile can create a weight management protocol that uses a metabolic enhancement, wherein the individualized intravenous exogenous insulin-based therapy produces a subject or a patient with improved cellular ATP functioning.

#### 20 Claims, 13 Drawing Sheets

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<b>LL</b>

	QUANTITY OF BOLUS PER BOLUS PER (#)	4 - 16	4 - 16	4 - 16	4 - 16	4 - 16	4 - 16	4 - 15	4-16	4-15	4 - 16	4 - 16	4 - 16	4 - 16	4 - 16	4-16	4-16	4-15	4-15	4 - 16	4 - 16	4 - 16	4 - 15	4 - 16	4 - 16
UNTS	UNEQUAL TAK PERIODS BETWEEN BOLUS INTRODUCTION (MIN-SEC)	240 sec - 480 sec	240 sec- 480 sec	240 sec - 480 sec	240 sec-480 sec	240 sec - 480 sec	240 sec - 480 sec	240 sec - 480 sec																	
AGE AMC	INSULIN SOLUS Dosage Volume Max (ml)	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
ME DOS/	INSULIN BOLLUS Dosage Volume Min (mi)	0.04	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
US VOLUI	INSULIN BOLUS DOSAGE MAX (mU)	450	500	550	600	650	200	750	800	850	300	950	1000	1050	1100	1150	1200	1250	1300	1350	1400	1450	1500	1550	1600
ITH BOL	INSULUN BOLUS DOSAGE MIN (mU)	400	460	510	560	610	660	710	160	810	860	910	960	1010	1060	1110	1160	1210	1260	1310	1360	1410	1460	1510	1560
AODEL W	INSULIN RESEVOIR VOLUME (ml)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10
EATMENT	SALINE DOSAGE (UNITS/mi)	6	10	11	12	13	14	15	16	17	18	5T	20	21	22	23	24	25	26	27	28	29	30	31	32
ABETIC TRI	MAGNESIUM TO SALINE DOSAGE (mg/ml)	1	**1	<b>1-1</b>	4-1		v-4	1	1	F	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2
Δ	POTASSIUM TO SALINE DOSAGE (meq/ml)	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02
	WEIGHT (Kg)	40 - 45	46-50	51-55	26-60	61-65	66 - 70	71 - 75	76 - 80	81-85	86-90	61-92	<u> </u>	101 - 105	106-110	111-115	116-120	121 - 125	126-130	131 - 135	136-140	141-145	146 - 150	151 - 155	155 - 160

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220
0.
100000
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	QUANTITY OF BOLUS PER TREATMENT CYCLE (#)	4 - 16	4 - 16	4 - 16	4 - 16	4 - 16	4 - 16	4-16	4-16	4 - 16	4 - 16	4 - 16	4 - 16	4 - 16	4 - 16	4-16	4-16	4-16	4-16	4-16	4-16	4-16	4 - 15	4 - 15
UNTS	UNEQUAL TIME PERIODS BETWEEN BOLUS INTRODUCTION (MIN/SEC)	240 sec - 480 sec	240 sec - 430 sec	240 sec - 480 sec	240 sec - 480 sec	240 sec - 480 sec	240 sec - 460 sec	240 sec - 480 sec	240 sec - 480 sec	240 sec - 430 sec	240 sec - 480 sec	Z40 sec - 430 sec	240 sec - 480 sec	Z40 sec - 480 sec	240 sec - 480 sec	240 sec - 480 sec								
AGE ANIC	INSULIN BOLUS DOSAGE VOLUME MAX (ml)	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05
ME DOS/	INSULIN BOLUS Dosage Volume Min (mi)	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0.05	0,05
US VOLU	INSULIN BOLUS DOSAGE MAX (mU)	1650	1700	1750	1800	1850	1900	1950	2000	2050	2100	2150	2200	2250	2300	2350	2400	2450	2500	2550	2600	2650	2700	2750
	INSULIN BOLUS DOSAGE MIN (mU)	1610	1660	1710	1760	1810	1860	1910	1360	2010	2060	2110	2160	2210	2260	2310	2360	2410	2460	2510	2560	2610	2660	2710
MODEL W	INSULIN RESEVOIR VOLUME (ml)	10	10	10	10	10	10	10	10	10	10	10	10	10	10	0I	10	10	10	10	10	30	10	01
EATMENT	INSULIN TO Saline dosage (UNITS/m)	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	6¢	20	51	52	53	54	53
ABETIC TR	MAGNESIUM TO SALINE DOSAGE (mg/ml)	2	2	2	2	2	2	2	2	3	m	3	e	3	£	ŝ	3	3	÷	e,	ŝ	÷	3	m
ā	POTASSIUM TO SALINE DOSAGE (meq/mi)	0.02	0.02	0.02	0.02	0,02	0.02	0.02	0.02	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03	0.03
****************	WEIGHT (kg)	161 - 165	166 - 170 🚦	171-175	176 - 180	181 - 185	186 - 190	191 - 195	196-200	201 - 205	206 - 210	211-215	216 - 220 §	221 - 225 {	226 - 230	231 - 235	236 - 240	241 - 245	246 - 250	251 - 255	256 - 260	261 - 265	266 - 270	271-275

BOLUS VOLUME DI	DSAGE A	DIUSTIME		6 8 0	Š	Z	88			5	0	Š	ě	Ä	S	لىلىيا ئا لىلى						
	<u>kuku</u>	RICOD GUCOSE LEVEL (mg/dl)	8	R	R	8	52	8		8	8	8	9	8	8	R.	ß	<u></u>	R	8	8	Πŝ
DURING HOURS 1 & 2 OF EACH TREATMENT SESS	NO						-				,			-		~~~~						T
IF BLOOD GLUCOSE INCREASES OF DECREASES BETWEEN THE Initial Blood Glucose Level check and the 30min and G vin Checks of Each Hour, then the Inflision Dosage Seculd be Adjusted Accordingly.		ADUST NOVGE (mU/kg)	0	÷	ø	c		***	4.7	- T-				9-1	-6	- 9-	-9-		9-1	-9-1	5.4	
DURING THE FIRST 30 MIN OF HOUR 3 OF EACH TI	REATMENT	SESSION														an a						T
F BLOOD GLICOSE INCREASES OR DECREASES BETWEEN THE MITIAL BLOOD GLUCOSE LEVEL CHECK AND THE 30 MIN CHECK 35 THEN THE INFUSION DOSAGE SHOULD BE ADJUSTED VCCORDINGLY.	LIKK C	ADUST DOSAGE (mU/kg)	-	÷	0	0	0	5-2	53	4	27 825 	- 5 /	- 20		- 6	9-1	-9-1	9-1	9	- <del>2</del>	4.5	- - - -
DURING THE LAST 30 MIN OF HOUR 3 OF EACH TH	EATMENT .	SESSION													***							
F BLOOD GLUCOSE LEVEL INVERANSS BETWEEK THE 30 MIN /A 30 MIN CHECK THEN THE INFLIGON DOSAGE SHOULD BE ADULS 40 CORONAET.	ND LHEN	INCREASE DOSAGE	0	0	0	0	0	-7	17 17	4-7	87. 1	9-1	-9-1	-9-		17 19 -	- Q-	9-1	9-1	9.4	9-5	-0 
F BLOOD GLUCOSE LEVEL DE CREASES BETWEEN THE 30 MIN A 20 Min Check then the influsion dosage should be aduls 47.commary	ND HEN	DECREASE DOSAGE	0	e	0		1-7	2-4	2.4 1	9-1	- 9 -	9-1	-9-1	-6	20	125		40	1423	4		8
EXEMPLARY TREATMENT SESSIONS DURING HOUL	18																					r T
	1000 GUCOSE	NULN CENCITVITV				SCHE	M	FOR B	OLUS		000	00		HAN	ME	B	M	8	8			T
	(ms/di)	HACOR .	89 87	\$~`,	ŝ	8 8	ģ.								a Sm			S.	Sa		ge Se	<b>1</b> 9.~
Nator AL	(W)	ESEMIT REALMENT	240 560	20.8%	20.000	260360	Ne ha	(1980) (1980)			1	2) X8(2)	0,880	0 sec	122	12850	0sec	0550	1 X83 (2)		()245 ()	T à
SURFECT AC	210	\$C50346	30.8%	210 %	30 ar	305 ser	100.025	20.00	8	80	25se [2]	1986	1	+			1		1		1	T
9.8.EC #3:	125	AB/AD	1	200 cor	0 52	200 cor	20% 00	100 can 10	A cartil		the second					1	t	Ť	1			T

) DSAGE PROTOCOL	GLUCOSE (gm)	50 - 60	44 - 55	25 - 25	30 - 40	25 - 35	20 - 30	15 - 25	10 - 20	5 - 15	.01 - 10	.01 - 5	.01 - 5	.01 - 5	.01 - 5	.01 - 5	.01 - 5	.01 - 5	.01 - 5
GLUCOSE D ADJUSTMENT	BLOOD GLUCOSE LEVEL (mg/dl)	> 100 - 100	101 - 125	151 - 175	176 - 200	201 - 225	226 - 250	251 - 275	276 - 300	301 - 325	326 - 350	351 - 375	376 - 400	401 - 425	426 - 450	451 - 475	476 - 500	501 - 525	526 - 550

FIO(RF 3

METABOLIC ENHAI	NCEMENT PR	otocol
Respiratory Quotient (CO <sub>2</sub> /O <sub>2</sub> )	Dos	0 50 6
1.20 <	C: 3	DAILY
1.19 - 1.00	A: 1	DAILY
0.99 - 0.90	A: 1	DAILY
0.89 - 0.80	8:2	ϽΑΙΓΥ
0.79 - 0.70	B: 21	ΟΑΙLΥ
> 69 <	B: 2	JAILY
* METABOLIC ENH	ANCEMENT CONTENTS	
Ingredient	Min Amount Per Dosage	Max Amount Per Dosage
VITAMIN D (AS CHOLECALCIFEROL)	009	2,0001U
VITAMIN B6 (AS PYRIDOXAL-5-PHOSPHATE)	10 mg	100 mg
FOLATE (FOLICACID)	200 mcg	2000 mcg
VITAMIN B12 (AS CYANOCOBALAMIN)	1,000 mcg	5,000 mcg
N-ACETYL L-CYSTEINE (NAC)	200 mg	600 mg
COENZYME Q10 (CoQ10)	60 mg	400 mg
ALPHA LIPOIC ACID (ALA)	50 mg	400 mg
NICOTINAMIDE ADENINE DINUCLEOTIDE (NADH)	ട് നു	5 mg
CHROMIUM PICOLINATE	200 mcg	300 mcg

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## FIGURE 5A

CREATING A SUBJECT PROFILE FOR A SUBJECT	]_500
ETABOLIC FACTORS OF THE SUBJECT AND STORING THE METABOLIC FACTORS IN THE SUBJECT PROFILE	502
CARE PLAN WITH A PLURALITY OF TREATMENT SESSIONS FOR THE SUBJECT WITH A PLAN GOAL	504
G GLUCOSE TO THE SUBJECT TO STIMULATE GASTROINTESTINAL HORMONE I, RESULTING IN THE RELEASE OF ENZYMES FROM THE SUBJECT'S LIVER AND E BLOOD GLUCOSE LEVELS OF THE SUBJECT TO BE IN A THERAPEUTIC RANGE	506
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NG THE IDENTIFIED WEIGHT MANAGEMENT PROTOCOL AND THE CARE PLAN IRST TREATMENT SESSION TO MANAGE WEIGHT OF THE SUBJECT WITH A ENHANCEMENT CAUSING IMPROVED CELLULAR ATP FUNCTIONING FOR THE E INFUSING INSULIN AND MODIFYING A QUANTITY AND DURATION OF UNEQUAL BETWEEN BOLUS INTRODUCTION IN THE SCHEDULE OF BOLUS INTRODUCTION AST ONE UNEQUAL TIME PERIOD BETWEEN AT LEAST ONE PAIR OF BOLUS TO IMPROVE IMPAIRED HEPATIC GLUCOSE PROCESSING	].:516
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## FIGURE 5B

FIGURE 5B @	
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554	MODIFYING A QUANTITY OF BOLUS FOR THE SUBJECT IDENTIFIED IN THE CARE PLAN FOR WOUND TREATMENT USING THE IDENTIFIED SKIN INTEGRITY AND CHANGES IN CLINICAL WOUND CHARACTERISTICS
556	MODIFYING THE SCHEDULE OF BOLUS INTRODUCTION HAVING AT LEAST ONE UNEQUAL TIME PERIOD BETWEEN BOLUS TO IMPROVE WOUND HEALING BY MODIFYING A QUANTITY AND DURATION OF UNEQUAL TIME PERIODS BETWEEN BOLUS INTRODUCTION TO REDUCE WOUND SIZE AND WOUND CHARACTERISTICS
],560	COMPARING C-PEPTIDES OF THE SUBJECT TO A PRESET NORM OF C-PEPTIDES TO IDENTIFY AN INSULIN SENSITIVITY FACTOR
]/562	MODIFYING A QUANTITY OF BOLUS FOR THE SUBJECT FOR THE INSULIN SENSITIVITY FACTOR
] 564	MODIFYING THE SCHEDULE OF BOLUS INTRODUCTION HAVING AT LEAST ONE UNEQUAL TIME PERIOD BETWEEN BOLUS TO IMPROVE AN INSULIN SENSITIVITY FACTOR USING ANALYSIS OF C-PEPTIDES BY MODIFYING A QUANTITY AND DURATION OF UNEQUAL TIME PERIODS BETWEEN BOLUS INTRODUCTION
].5 <b>70</b>	DETERMINING A QUANTITY AND FREQUENCY OF DOSAGE AMOUNTS OF MAGNESIUM AND INTRODUCING THE DOSAGE AMOUNTS OF MAGNESIUM SIMULTANEOUSLY TO THE SUBJECT WITH THE PLURALITY OF BOLUS USING THE SCHEDULE OF BOLUS INTRODUCTION HAVING AT LEAST ONE UNEQUAL TIME PERIOD
572	DETERMINING A QUANTITY AND FREQUENCY OF DOSAGE AMOUNTS OF POTASSIUM AND INTRODUCING THE DOSAGE AMOUNTS OF POTASSIUM SIMULTANEOUSLY TO THE SUBJECT WITH THE PLURALITY OF BOLUS USING THE SCHEDULE OF BOLUS INTRODUCTION HAVING AT LEAST ONE UNEQUAL TIME PERIOD
574	DETERMINING A QUANTITY AND FREQUENCY OF DOSAGE AMOUNTS OF SOMATOSTATIN AND INTRODUCING THE DOSAGE AMOUNTS OF SOMATOSTATIN SIMULTANEOUSLY TO THE SUBJECT WITH THE PLURALITY OF BOLUS USING THE SCHEDULE OF BOLUS INTRODUCTION HAVING AT LEAST ONE UNEQUAL TIME PERIOD
]-576	DETERMINING A QUANTITY AND FREQUENCY OF DOSAGE AMOUNTS OF GLUCAGON AND INTRODUCING THE DOSAGE AMOUNTS OF GLUCAGON SIMULTANEOUSLY TO THE SUBJECT WITH THE PLURALITY OF BOLUS USING THE SCHEDULE OF BOLUS INTRODUCTION HAVING AT LEAST ONE UNEQUAL TIME PERIOD
578	SCHEDULING DIAGNOSTIC TESTS AFTER A FIRST TREATMENT SESSION TO MODIFY THE CARE PLAN FOR IMPROVED CELLULAR ATP FUNCTIONING FOR THE SUBJECT AND IMPROVED HEPATIC GLUCOSE PROCESSING

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FIGURE 5C



## FIGURE 7A

ADMINISTRATIVE DATA STORAGE	-604
SUBJECT PROFILE	610
METABOLIC FACTORS	1000
BLOOD GLUCOSE LEVEL	1012
RESPIRATORY OUOTIENT	)614
INSULIN SENSITIVITY FACTOR	616
INDIVIDUAL TARGET BLOOD GLUCOSE LEVEL	618
PLURALITY OF CARE PLAN TEMPLATES	620
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PLURALITY OF THERAPEUTIC RANGES FOR BLOOD GLUCOSE LEVELS	/203

# FIGURE 7B

	ໆ <i>⊥60</i> 4
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U.S. Patent









#### PHYSIOLOGIC INSULIN-SENSITIVITY IMPROVEMENT

#### CROSS REFERENCE TO RELATED APPLICATION

The current application is a Continuation In Part of co-pending U.S. patent application Ser. No. 15/042,087 filed Feb. 11, 2016 and claims priority to and the benefit of expired U.S. Provisional Patent Application Ser. No. 62/117, <sup>10</sup> 393 filed on Feb. 17, 2015, entitled "METHODS THAT IMPROVE IMPAIRED HEPATIC GLUCOSE PROCESS-ING IN SUBJECTS". This reference is incorporated herein in its entirety.

#### FIELD

The present embodiments generally relate to improved methods and systems that improve impaired hepatic glucose processing in subjects. 20

#### BACKGROUND

Diabetes Mellitus is a disease or disorder of the body's metabolic functions, characterized by abnormally high lev- 25 els of blood glucose and inadequate levels of insulin. In 2012, 29.1 million Americans, or 9.3 percent of the population had diabetes, up from 25.8 million, or 8.3 percent, in 2010. New cases diagnosed in 2012 were 1.7 million, and in 2010 it was 1.9 million. Diabetes Mellitus Type 1, formerly 30 known as juvenile diabetes, is usually diagnosed in children and young adults, and only 5 percent of people with diabetes have this form of the disease.

In Type 1 diabetes, the body does not produce insulin, a hormone necessary to convert sugar, starches, and other food 35 into energy needed for daily life. Diabetes Mellitus Type 2 is far more common, and affects 90-95 percent of all diabetics in the United States of America. In Type 2 diabetes, the body does not use insulin properly, which is called insulin resistance. At first, the pancreas makes extra insulin 40 to make up for it, but, over time the pancreas is not able to keep up and can't make enough insulin to keep blood glucose at normal levels. The long-term adverse effects include blindness, loss of kidney function, nerve damage, loss of sensation, and poor circulation in the periphery, and 45 amputation of the extremities. As of Mar. 6, 2013, the total cost of diagnosed diabetes in the United States in 2012 was \$245 billion dollars.

In the treatment of Diabetes Mellitus, many varieties of insulin formulations have been suggested and used, such as 50 regular insulin, isophane insulin (designated NPH®), insulin zinc suspensions (such as SEMILENTE®, LENTE®, and ULTRALENTE®), and biphasic isophane insulin. As diabetic patients are treated with insulin for several decades, there is a major need for safe and life quality improving 55 insulin formulations. Some of the commercially available insulin formulations are characterized by a fast onset of action and other formulations have a relatively slow onset but show a more or less prolonged action. Fast-acting insulin formulations are usually solutions of insulin, while retarded 60 acting insulin formulations can have suspensions containing insulin in crystalline and/or amorphous form precipitated by addition of zinc salts alone, by addition of protamine, or by a combination of both.

In addition, some patients are using formulations having 65 both a fast onset of action and a more prolonged action. Such a formulation can be an insulin solution, wherein protamine

insulin crystals are suspended. Some patients do prepare the final formulation themselves by mixing a fast acting insulin solution with a protracted acting insulin suspension formulation in the ratio desired by the patient in question.

Glucose control is typically measured by a blood test, which determines the level of hemoglobin A1c, which has been the desired result of insulin therapy in diabetic patients for many years. However, it is clear that tight circulating glucose control was insufficient in 25 percent or more of the study participants to protect them from the onset or progression of diabetic retinopathy, nephropathy, or neuropathy. One method of glucose control is Pulsed Insulin Therapy.

The core concept of Pulsed Insulin Therapy has been <sup>15</sup> known for at least 20 years, by various names including Pulsatile Intravenous Insulin Therapy (PIVIT), Chronic Intermittent Intravenous Insulin Therapy (CIIIT), Metabolic Activation Therapy (MAT), and Hepatic Activation. In such therapies a patient's blood glucose is raised and lowered by <sup>20</sup> about 50 mg/dL to 75 mg/dL over a period of several hours by alternating between doses of insulin and sugars or high carbohydrates foods. Although the mechanisms of action have not been clearly explained, it is apparent from the clinical results that the technique has usefulness in treating <sup>25</sup> diabetic implications, including blindness and other ocular manifestations, nerve disease, cardiovascular disease, diabetic nephropathy, and poor wound healing.

Given the long history of these procedures, one would have expected that the treatment parameters would have been optimized long ago to produce the most favorable results. It turns out, however, that the known treatment parameters are insufficient in that regard.

A need exists for methods and systems that improve impaired hepatic glucose processing in subjects and produce superior results to those previously obtainable.

The present embodiments meet these needs.

#### BRIEF DESCRIPTION OF THE FIGURES

The detailed description will be better understood in conjunction with the accompanying drawings as follows:

FIG. 1A shows a diabetic treatment model with bolus volume dosage amounts for a subject with a weight from 40 kilograms to 160 kilograms.

FIG. 1B shows a diabetic treatment model with bolus volume dosage amounts for a subject with a weight from 161 kilograms to 275 kilograms.

FIG. **2** shows a bolus volume dosage adjustment protocol based on tested blood glucose levels as produced by a diabetic treatment model.

FIG. **3** depicts glucose dosage adjustment protocol as produced by a diabetic treatment model.

FIG. **4** depicts a metabolic enhancement protocol as produced by a diabetic treatment model and an exemplary metabolic enhancement by component.

FIGS. **5**A-**5**C depict steps of a method of the invention according to one or more embodiments.

FIG. 6 depicts a system of the invention according to one or more embodiments.

FIGS. **7**A and **7**B depict an administrative data storage usable in the system according to one or more embodiments.

FIGS. **8**A-**8**C provide exemplary subject profiles with an automatically generated care plan template and an automatically generated report according to one or more embodiments.

The present embodiments are detailed below with reference to the listed Figures.

#### DETAILED DESCRIPTION OF THE EMBODIMENTS

Before explaining the present methods and systems in detail, it is to be understood that the methods and the systems are not limited to the particular embodiments and that it can be practiced or carried out in various ways.

The present embodiments relate to improved methods and systems that improve impaired hepatic glucose processing in subjects.

The present embodiments further relate to an individualized intravenous exogenous insulin-based therapy for infusing insulin intravenously to a subject to improve impaired hepatic glucose processing.

When three treatment session are performed using the method as described herein patients report energy resorted, 20 medications reduced, wounds healed, amputations prevented, weight controlled, blood sugar controlled, blood pressure reduced, neuropathy diminished, retinopathy diminished, mood improved, sleep improved and erectile function restored.

The individualized intravenous exogenous insulin-based therapy uses a plurality of treatment sessions, generally 3 but up to 12 may be needed, each treatment session lasting from 1 hour to 3 hours.

The goal of the individualized intravenous exogenous 30 insulin-based therapy is to repair, recondition, and maintain a subject's impaired metabolism so that it functions and is maintained to provide a quality of life similar to that of a non-diabetic person.

To initiate the therapy a subject profile can be created.

Each treatment session can involve assessing for a subject's metabolic factors and storing the metabolic factors in the subject's profile. The subject profile can be stored in an administrative data storage connected to an administrative processor accessible via a network from a client device.

Each treatment session can involve matching the subject profile to a diabetic treatment model to create a schedule of bolus introduction with at least one unequal time period between bolus introductions.

The schedule can provide a quantity and frequency of 45 intravenous insulin bolus, a quantity and frequency of dosage amounts of magnesium, and a quantity and frequency of dosage amounts of potassium for the subject.

Each treatment session can involve introducing to the subject insulin bolus sequentially, at frequencies determined 50 from the diabetic treatment model, wherein each insulin bolus can be separated by irregular time periods.

Simultaneously with the sequential insulin bolus introduction, dosage amounts of magnesium and dosage amounts of potassium can be introduced to the subject. The magne- 55 sium and potassium can be introduced orally, transdermally, or by inhaling simultaneous with the insulin bolus introduction.

A weight management protocol can be identified from a library of weight management protocols given a subject's 60 profile. The subject can be required to follow the weight management protocol and use a specific metabolic enhancement that can be in pill form, powder form, a transdermal patch, or another form known in the industry.

After 3 to 6 treatments using a care plan connected to the 65 diabetic treatment model with a schedule for bolus instruction and at least one unequal period of time, the subject can

have at least 10 percent and up to 50 percent improved cellular ATP functioning that can last up to 90 days from the last treatment.

The present embodiments also relate to methods for infusing insulin intravenously to a subject to improve impaired hepatic glucose processing.

The term "5-MTHF" as used herein can refer to Levomefolic Acid, which is a primary form of folic acid used for DNA reproduction.

The term "A1C" as used herein refers to a blood test that shows how well individual diabetes is being controlled relative to a non-diabetic patient.

The term "Adenosine triphosphate (ATP)" as used herein refers a substance that transports chemical energy within cells for metabolism.

The term "Alpha Lipoic Acid" as used herein refers to an antioxidant that helps with the extraction of energy from food.

The term "biomarkers specific to diabetes" can refer to the three classifications of up to 89 different biomarkers that relate to metabolic rates of individuals. Some of the enzymes include glucokinase, 6-phosphofructo-1 kinase, 6-phosphofructo-2 kinase; citrate cleavage enzyme; pyruvate kinase,

HMG-CoA reductase, glycophosphoralase, fructose 2,6,biphosphatase, glycogen phosphoralase, pyruvate dehydrogenase complex, and others known in the art.

The term "blood glucose level therapeutic range" as used herein refers to a subject's designated target blood glucose level of 160 to 240 mg/dl during a treatment session.

The term "bolus" as used herein refers to a single dose of a medical substance and/or drug given all at once.

The term "catheter" as used herein refers to a thin tube that can be inserted into the body to remove bodily fluids or 35 add fluids to a patient during a treatment session.

The term "CoEnzy me Q10" as used herein refers to a chemical that extracts energy from food in the human digestive process.

The term "Complete Blood Count" (CBC) as used herein 40 refers to a blood test to evaluate cellular aspects of the blood and provide concentrations of components in the blood.

The term "C-peptide" as used herein refers to a chemical produced in the pancreas that appears in a 1:1 molecular ratio to insulin and that can be detected when a blood lab panel is performed on a blood sample.

The term "data storage" as used herein refers to a nontransitory computer readable medium, such as a hard disk drive, solid state drive, flash drive, tape drive, and the like. The term "non-transitory computer readable medium" excludes any transitory signals but includes any non-transitory data storage circuitry, e.g., buffers, cache, and queues, within transceivers of transitory signals.

The term "diabetic retinopathy" as used herein refers to a complication of diabetes that affects the eyes.

The term "diabetic treatment model" as used herein refers to a plurality of look up tables reflecting initial blend dosing adjustment protocols that reflect weight of the subject, types of insulin (long term and short term), a volume of bolus of insulin per treatment session, a quantity of bolus, a frequency of bolus for a treatment session and bolus intervals, dosage amounts of magnesium (including quantity and frequency) and dosage amounts of potassium (including quantity and frequency). The diabetic treatment model includes glucose dosage amounts which are milligrams/ deciliter (mg/dl) based on blood glucose of the subject. The diabetic treatment model generates a schedule of bolus introduction with at least one unequal time period between

at least one pair of bolus. In embodiments, the diabetic treatment model can be located in the administrative data storage.

For example, the diabetic treatment model receives from a doctor, nurse or technician the weight of a subject, such as 5 102 kilograms, and a blood glucose of the subject, such as 120 mg/dl. The diabetic treatment model then generates (i) a type of insulin to be introduced to the subject, such as short term insulin, (ii) a volume of bolus of insulin per treatment session for the subject, such as 0.5 milliliters, (iii) a quantity 10 of bolus per treatment session, such as 12, and (iv) a frequency of bolus introduction, which in embodiments, can be random for a treatment session of 3 hours. The time intervals between sequential bolus introductions can range from 2 minutes to 10 minutes between bolus. In embodi- 15 ment, the time intervals can be a random sequence.

The diabetic treatment model generates dosage amounts of magnesium, such as 2 milligrams per milliliter of saline (for intravenous introduction to the subject) during the treatment session.

The diabetic treatment model generates dosage amounts of potassium, such as 0.02 meq/millimeter of saline (for an intravenous introduction) during the treatment session.

The diabetic treatment model calculates glucose dosage amounts for a subject, which can range from 44 grams to 55 25 grams during the first 30 minutes of a treatment session and then different or the same glucose dosage amounts using real time blood glucose level tests of the subject, which can be performed providing new test results and recalculations of dosage amount of bolus every 30 minutes.

The diabetic treatment model evaluates for Type 2 Diabetes, pre-Diabetes, Metabolic Syndrome, Metabolic Disorder, Impaired Glucose Tolerance, and Impaired Fasting Glycemia.

The term "dosage amounts of magnesium" as used herein 35 refers to dosage amounts of magnesium in a saline carrier or in a pill form, for example, one that dissolves under the tongue of the subject.

The term "dosage amounts of potassium" as used herein refers to dosage amounts of magnesium in a saline carrier, 40 blend of methylcobalamin, (such as 5 mg), pyridoxal-5in a pill form, or as a banana. If a pill form is used, it can be in the form of a pill that dissolves under the tongue of the subject.

The term "Echocardiograph" as used herein refers to a multi-dimensional sonography of the heart that measures the 45 heart's mechanical functionality.

The term "exogenous" as used herein refers to materials or reactions that occur outside of the body.

The term "glucagon" as used herein refers to a counter regulatory hormone essential for glucose metabolism in 50 humans in particular.

The term "glucose" as used herein refers to the simple carbohydrate commonly referred to as "sugar"

The term "hyperglycemia" as used herein refers to high blood glucose level present in a subject's blood test. 55

The term "improved cellular ATP functioning" as used herein refers to "Adenosinie Triphosphatase" ("ATPase") functioning, which are one or more enzymes that catalyze the formation of adenosine triphosphate ("ATP") from adenosine diphosphate ("ADP") and the functioning is 60 indicative of the energy generated by a cell when it consumes glucose during metabolic processing.

The term "individual target blood glucose level" as used herein refers to a medical beneficial range that the patient or subject can achieve at least during treatments session created 65 by the diabetic treatment model, during the entire infusion therapy, such as a range from 125 mg/dl to 225 mg/dl, which

can be adjusted to a more narrow range, such from 180 mg/dl to 225 mg/dl for a specific subject.

The term "insulin" as used herein refers to a chemical that is a counter regulatory hormone essential for glucose metabolism.

The term "insulin bolus" as used herein refers to a dosage quantity of insulin given intravenously to a patient.

The term "insulin reservoir" as used herein can be a flexible pouch of insulin having multiple insulin bolus.

The term "insulin sensitivity factor" as used herein refers to how a subject responds after receiving one unit of insulin as a measure of decrease in blood glucose.

The term "Lipid Panel" as used herein refers to a blood test that measures a concentration of lipids, fats, and fatty substances used as a source of energy by a human body.

The term "metabolic factors" as used herein refers to a weight, such as 125 pounds, blood tests, such as a Comprehensive Metabolic Panel, a CBC panel, a C-peptide test, an 20 A1c test (known as a "lipid panel"), a urinalysis, a nerve conduction velocity test, an individual target blood glucose level, such as 110 mg/dl, a respiratory quotient, such as a ratio of the amount of carbon dioxide released based on oxygen consumed during a preset period of time, and an insulin sensitivity factor, such as a value indicating how a subject responds after receiving one unit of insulin as a measure of decrease in blood glucose.

The term "metabolic enhancement" as used herein refers to a blend of components that bond to enzymes in the patient and increases the enzyme activity for a patient or subject. The metabolic enhancement can be (1) a pill containing the components of the metabolic enhancement, (2) a drink containing the components of the metabolic enhancement, (3) a shake containing the components of the metabolic enhancement, (4) a food item, such an energy bar, fortified with the metabolic enhancement, (5) a transdermal patch or similar application delivering the components of the metabolic enhancement, and combinations thereof.

In one example, the metabolic enhancement can be a phosphate (such as 35 mg), 5-MTHF (known as an activated form of folic acid) (such as 1 mg), Alpha Lipoic Acid (such as 50 mg), NADH (such as 5 mg), CoEnzyme Q0 (such as 75 mg), N-Acetyl L-Cysteine (NAC) (such as 250 mg), Vitamin D (such as Cholecalciferol) (such as 2000 International Units (IU)) and Chromium Picolinate (such as 300 mcg).

The term "methylcobalamin" as used herein refers to one of two coenzyme forms of vitamin  $B_{12}$ .

The term "N-Acetyl Cysteine" as used herein refers to an amino acid that helps build proteins in the body.

The term "NADH" as used herein refers to Nicotinamide Adenine Dinucleotide which binds as a coenzyme to proteins and serves in respiratory metabolism.

The term "Nerve Conduction Velocity (NCV)" as use herein refers to a test to determine how fast electrical signals move throughout a nerve.

The term "non-transitory computer readable medium" as used herein excludes any transitory signals but includes any non-transitory data storage circuitry, e.g., buffers, cache, and queues, within transceivers of transitory signals.

The term "Peripheral Autonomic Neuropathy" as use herein refers to the symptoms that occur when there is damage to the nerves, such as weakness and numbness of a limb.

The term "plan goal" as used herein can refer to a purpose for the insulin therapy as identified by the subject and/or a

medical professional associated with the therapy and inserted into the care plan generated by the diabetic treatment model.

The term "processor" as used herein can refer to a computer, a laptop, a plurality of connected processors, a 5 tablet computer, a cellular telephone or smart phone, a portable processing device, or any similar device known in the industry.

The term "respiratory quotient" as used herein refers to the ratio of: carbon dioxide given off by a human and oxygen 10 consumed by a human, particularly under known resting conditions.

The term "saline" as used herein refers to a sterile solution of 900 grams of sodium chloride in 100 ml of water.

The term "schedule for bolus introduction" as used herein 15 refers to the plurality of specific time intervals between bolus introductions in a treatment session. For the invention, the "schedule for bolus introduction" requires at least one "unequal time period" between at least one pair of bolus per treatment session.

As an example of the schedule for bolus introduction for a treatment session: three bolus can be delivered to the subject sequentially, each bolus separated by a 4 minute time interval. Then, using the schedule for bolus introduction, a fourth bolus is delivered to the subject after a 6.5 minute 25 time interval. The 6.5 minute time interval is referred to herein as "an unequal time period" because it is different from the 4 minute time intervals on the schedule for bolus introduction.

In embodiments, all the time intervals between pairs of 30 bolus can be different for a subject. In embodiments, just one time interval between one pair of bolus can be different according to the schedule for bolus introduction.

In embodiments, many variations in time intervals on the schedule for bolus introduction can be computed by the 35 diabetic treatment model using the weight of the subject, insulin sensitivity factor of the subject and tested blood glucose levels of the subject.

Another example of the schedule of bolus introduction having an unequal time period can be 3 pairs of bolus that 40 management protocol initially can use a complete metabolic are sequentially introduced require 5 minute intervals of time between introductions then a seventh bolus requires a 6 minute interval of time prior to introduction to the subject. The 6 minute interval of time is an "unequal time period". The diabetic treatment model can indicate that the schedule 45 for bolus introduction can require all remaining time periods for the treatment session between pairs of bolus to be equal (the opposite of unequal periods of time). The plurality of time periods of the schedule for bolus introduction (the time between each pair of bolus) is generated by the diabetic 50 treatment model.

The term "subject profile" as used herein can refer to the name of an individual and the associated measured metabolic factors. The subject profile can include a subject history and a subject physical report of the subject, a subject 55 name and contact information, as well as a subject's blood test results. In embodiments, the subject profile can include a date, a name, an address, an email address, a telephone number, an ethnicity, a gender/sex, a type of diabetes, a date of birth, a weight, a height, a blood pressure, a temperature, 60 a heart rate, a blood type, a blood glucose level, insurance information, a responsible party name and contact information, a driver's license number or copy of the driver's license, employer information, insurance information, medical history including surgery and ancestor information and 65 allergies, current medications, other test results, including but not limited to urinalysis, emergency contact information,

and a primary care physician name and contact information. In embodiments, the subject profile can be inputted into a data storage associated with a processor.

The term "treatment session" as used herein refers to a plurality of treatment cycles during which a plurality of bolus are infused to a patient. Each treatment cycle can range from 40 minutes to 180 minutes. Each treatment session can range from 1 treatment cycle and up to 6 treatment cycles.

The term "unequal time period" as used herein refers to a unit of time between a pair of bolus in a treatment session that is different in length from a time period between another pair of bolus in a treatment session.

The term "weight management protocol" as used herein refers to a system of eating certain foods with a preset calorie content to ensure the patient or subject loses an amount of weight per week that aligns with the subject's metabolic factors.

The invention improves impaired hepatic glucose processing in subjects, which can be a human or a non-human, such as an animal.

In embodiments, the method can include creating a subject profile with assessed metabolic factors.

The method can include inserting the subject profile into a diabetic treatment model to determine: a quantity and frequency of sequential intravenous insulin bolus to a subject using a schedule of bolus introduction having at least one unequal time period between a pair of bolus, as well as determining a quantity and frequency of dosage amounts of magnesium and a quantity and frequency of dosage amounts of potassium.

The method can include selecting a weight management protocol using the subject profile and specific metabolic functions of the subject. For example, the metabolic function of respiratory quotient can be used to create a specific customized weight management protocol.

The subject can then follow the weight management protocol while taking a metabolic enhancement. The weight measurement system for cardio-pulmonary exercise stress and resting energy expenditure testing which can give a patient a resting metabolism score. The resting metabolic scores can range from 0.75 to 0.85 for fats, from 0.78 to 0.82 for protein, and from 0.88 to 0.92 for carbohydrates. Based on these resting metabolic scores, a subject's diet can be customized based on what the subject's body can actually metabolize.

A resting metabolic carbohydrate score in excess of 1.20 can indicate the subject's body is undergoing ketogenesis (metabolic production of ketones or ketone bodies or formation of acid ketone [substances that are made when the body breaks down fat for energy, any organic compound in which two carbon atoms are linked by the carbon of a carbonyl group (C-O), the simplest ketone and the most important in medicine is dimethyl ketone (acetone)] bodies, as in uncontrolled diabetes, starvation, or as a result of a diet with a very high fat content), and a different customized diet can be created for the subject or the patient.

The invention improves impaired hepatic glucose processing in subjects, by providing individualized intravenous exogenous insulin-based therapy that not only produces body tissue with improve cellular ATP functioning in the short term, by improves the ATP function by at least 10 percent and up to 40 percent, for a period of time that ranges from 7 days to 90 days from the last treatment session of the individualized intravenous exogenous insulin-based therapy.

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It should be noted that in embodiments, the dosage amounts of magnesium and potassium can be introduced to the subject intravenously from a second reservoir simultaneously as the insulin bolus are introduced.

Glucose is introduced to the subject as part of the therapy. The glucose is taken by the subject prior to receiving the insulin bolus. When glucose is used the dosage amounts of potassium and dosage amounts of magnesium can be adjusted based on the subject profile. The bolus introduction can be monitored and blood glucose levels tested allowing a therapist to change the quality and time intervals between bolus based on the diabetic treatment model until the blood glucose level of the subject reaches an individual target blood glucose level.

In embodiments, the unequal time periods between bolus introductions according to the schedule can range from 4 minutes to 8 minutes periods but can be as low as 1 minute and as high as 10 minutes. The unequal time periods can include minutes and seconds.

In embodiments, from 60 grams of glucose to 100 grams of glucose can be introduced to the subject to establish a blood glucose level of at least 125 mg/dl prior to introducing the bolus of insulin and dosage amounts of potassium and magnesium.

In embodiments, the methods that improve impaired hepatic glucose processing in subjects can measure success of the individualized intravenous exogenous insulin-based therapy method for infusing insulin intravenously to a subject by comparing a respiratory quotient of the subject 30 from a metabolism score with the subject in a resting state and applying the results into the diabetic treatment model to (i) modify the concentration of the potassium, the magnesium, or both or (ii) modify the number and frequency of the bolus infusions of insulin.

In embodiments, the methods that improve impaired hepatic glucose processing in subjects can measure the success of individualized intravenous exogenous insulinbased therapy for infusing insulin intravenously to a subject by comparing a cardiac function measured by echocardio- 40 graph with the subject in a resting state and applying the results into the diabetic treatment model to (i) modify the dosage amounts of the potassium, the magnesium, or both or (ii) modify the number and frequency of the bolus infusions of insulin.

In embodiments, the methods that improve impaired hepatic glucose processing in subjects can measure success of individualized intravenous exogenous insulin-based therapy for infusing insulin intravenously to a subject by comparing a peripheral autonomic neuropathy and micro- 50 circulation with the subject in a resting state prior to bolus injection and simultaneously as bolus are injected and after bolus have been injected and applying the results into the diabetic treatment model to (i) modify the dosage amounts of the potassium, the magnesium, or both or (ii) modify the 55 number and frequency of the bolus infusions of insulin.

In embodiments, the methods that improve impaired hepatic glucose processing in subjects can measure success of the individualized intravenous exogenous insulin-based therapy for infusing insulin intravenously to a subject by 60 comparing a retinal image captured by a non-mydriatic camera with the subject in a resting state to identify diabetic retinopathy after a series of bolus treatments are performed and applying the results into the diabetic treatment model to (i) modify the dosage amounts of the potassium, the mag- 65 mapped to the weight of the subject and to the potassium to nesium, or both or (ii) modify the number and frequency of the bolus infusions of insulin.

In embodiments, the methods that improve impaired hepatic glucose processing in subjects can measure success of the individualized intravenous exogenous insulin-based therapy for infusing insulin intravenously to a subject by comparing wounds to wound characteristics by dimensionally measuring wounds by length, width, and depth and related clinical characteristics with the subject in a resting state after a series of bolus treatments are performed and applying the results into the diabetic treatment model to (i) modify the dosage amounts of the potassium, the magnesium, or both or (ii) modify the number and frequency of the bolus infusions of insulin.

In embodiments, the methods that improve impaired hepatic glucose processing in subjects can measure success of the individualized intravenous exogenous insulin-based therapy for infusing insulin intravenously to a subject by comparing C-peptides, such as with the University of Oxford's HOMA2 Calculator, which act as a marker for 20 insulin production and insulin sensitivity factor and applying the results into the diabetic treatment model to (i) modify the dosage amounts of the potassium, the magnesium, or both, or (ii) modify the number and frequency of the bolus infusions of insulin.

In embodiments, the metabolic enhancement can have a nerve function improver to decrease homocysteine (a naturally occurring amino acid in all humans that is found in blood plasma) levels and improve cardio vascular health.

In embodiments, the weight management protocol can include additional nutritional supplements.

In embodiments, the insulin bolus can be intravenously infused using a needle or a catheter located in the subject's body, hand, or forearm.

Now turning to the Figures, FIG. 1A shows a diabetic treatment model with bolus volume dosage amounts for a subject with a weight from 40 kilograms to 160 kilograms.

A dosing protocol for insulin bolus, dosage amounts of potassium and dosage amounts of magnesium as generated by the diabetic treatment model using weight of a subject from 40 kilograms to 160 kilograms is shown. This chart can be used for one person or for a plurality of subjects.

Weight appears in the first column then a dosage amount of a ratio of potassium to saline, a dosage amount of a ratio 45 of magnesium to saline, a dosage amount of a ratio of insulin to create the amount of insulin to saline to be used for a treatment session and an insulin reservoir volume is depicted mapped to the weight of the subject and to the potassium to saline dosage, and magnesium to saline dosage and insulin to saline dosage.

The insulin reservoir volume is a liquid volume containing (i) the insulin and saline, (ii) the insulin, saline and potassium, (iii) the insulin, saline and magnesium, or (iv) the insulin, saline, potassium and magnesium, used in the bolus for the subject.

An insulin bolus dosage minimum is shown mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

An insulin bolus dosage maximum is shown mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

An insulin bolus dosage volume minimum is shown saline dosage, magnesium to saline dosage and insulin to saline dosage.

An insulin bolus dosage volume maximum is shown mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

A schedule of bolus introduction with a plurality of unequal time periods (in seconds) between bolus introduction is shown mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

A quantity of bolus per treatment cycle is shown mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

FIG. 1B shows a diabetic treatment model with bolus  $_{15}$  volume dosage mounts for a subject with a weight from 161 kilograms to 275 kilograms.

A dosing protocol for insulin bolus, dosage amounts of potassium and dosage amounts of magnesium as generated by the diabetic treatment model using weight of a subject <sub>20</sub> from 161 kilograms to 275 kilograms is shown. This chart can be used for one person or for a plurality of subjects.

Weight appears in the first column then a dosage amount of a ratio of potassium to saline, a dosage amount of a ratio of magnesium to saline, a dosage amount of a ratio of insulin<sup>25</sup> to create the amount of insulin to saline to be used for a treatment session, and an insulin reservoir volume is depicted mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.<sup>30</sup>

The insulin reservoir volume is a liquid volume containing (i) the insulin and saline, (ii) the insulin, saline and potassium, (iii) the insulin, saline and magnesium, or (iv) the insulin, saline, potassium and magnesium, used in the bolus for the subject.

An insulin bolus dosage minimum is shown mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

An insulin bolus dosage maximum is shown mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

An insulin bolus dosage volume minimum is shown 45 mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

An insulin bolus dosage volume maximum is shown mapped to the weight of the subject and to the potassium to 50 saline dosage, magnesium to saline dosage and insulin to saline dosage.

A schedule of bolus introduction with a plurality of unequal time periods (in seconds) between bolus introductions is shown mapped to the weight of the subject and to the 55 potassium to saline dosage, magnesium to saline dosage and insulin to saline dosage.

A quantity of bolus per treatment cycle is shown mapped to the weight of the subject and to the potassium to saline dosage, magnesium to saline dosage and insulin to saline 60 dosage.

FIG. **2** shows a bolus volume dosage adjustment protocol based on tested blood glucose levels as produced by the diabetic treatment model.

A dosage adjustment protocol of insulin is shown for three 65 time intervals: (i) a first time interval for hours 1 and 2 of each treatment session, (ii) a second time interval for a first

30 minutes of hour 3 of each treatment session, and (iii) a third time interval for a last 30 minutes of hour 3 of each treatment session.

A table of tested blood glucose level in view of dosage amounts of insulin are shown, which is generated by the diabetic treatment model.

This portion of the diabetic treatment model indicates that the amount of insulin or quantity of bolus can be increased or decreased based on real time test results of a subject's blood glucose level.

FIG. **3** depicts a glucose dosage adjustment protocol as produced by the diabetic treatment model.

A patient's tested blood glucose level ranging from 100 to 550 mg/dl is shown.

In the glucose dosage adjustment protocol, an amount of glucose to be administered using the method and system is depicted as mapped to a tested blood glucose level. The amount of glucose ranges from slightly above no glucose shown as 0.01 grams to 60 grams of glucose.

FIG. **4** depicts a metabolic enhancement protocol as produced by the diabetic treatment model and an exemplary metabolic enhancement by component.

The metabolic enhancement protocol shows dosage amounts of metabolic enhancement and respiratory quotients for a patient. The metabolic enhancement can be provided to a subject in dosage amounts as pills, in powder form, as a drink, a transdermal patch, or a delivery system known in the art.

The respiratory quotients range from 0.69 to 1.20. The dosage amounts of metabolic enhancement can range from 1 dose to 3 dosages daily, as shown corresponding to the tests of the subject showing the respiratory quotients.

Ingredients for an exemplary metabolic enhancement usable according to the diabetic treatment model are shown with minimum amounts per dosage and maximum amounts per dosage for the metabolic enhancement.

In embodiments, the ingredients for a usable metabolic 40 enhancement can be formed from a synergistic combination of nine ingredients, namely:

Vitamin D—as Cholecalciferol ranging in amounts from 600 IU to 2000 IU.

Vitamin  $B_6$ —as Pyridoxal-5-Phosphate ranging in amounts from 10 mg to 100 mg.

Folic Acid—as Folate ranging in amounts from 200 mcg to 2000 mcg.

Vitamin  $B_{12}$ —as Cyanocobalamin ranging in amounts from 1000 mcg to 5000 mcg.

An amino acid that builds proteins in a subject—as N-Acetyl L-Cysteine (NAC) ranging in amounts from 200 mg to 600 mg.

A coenzyme that extracts energy from food for a subject—as Coenzyme Q10 (CoQ10) ranging in amounts from 60 mg to 400 mg.

An antioxidant that extracts energy from food for a subject—as Alpha lipoic acid ranging in amounts from 50 mg to 400 mg.

A protein binding component that binds to proteins and serves as a respiratory metabolic enhancement for a subject—as Nicotinamide Adenine Dinucleotide (NADH) ranging in amounts from 0.5 mg to 5 mg.

A glucose utilization component to prevent or treat chromium deficiency in a subject and which additionally improves glucose utilization by insulin—as Chromium Picolinate ranging in amounts from 200 mg to 300 mg.

The following are non-limiting examples.

#### EXAMPLE 1

A comparative analysis was generated for Fred Smith, <sup>5</sup> Fred S. a 69-year-old man with Type 2 diabetes of 25 years' duration. Fred Smith arrived in a wheelchair, because walking was too painful for him. Fred Smith's left foot had all the toes amputated, and a non-healing wound on his other foot had caused his doctor to recommend amputation of a toe on <sup>10</sup> his right foot.

Conventional wound care treatment, including aggressive wound care, wound debridement, and hyperbaric treatment had failed. Fred Smith also developed a debilitating peripheral neuropathy.

At this point Fred Smith weighed 107.95 kilograms and began an intensive treatment protocol of three treatment sessions per week, the first week includes two treatment sessions the second and third weeks include one treatment session per week thereafter for weeks 4 through 12. During <sup>20</sup> each treatment session, Fred Smith received insulin and saline intravenously, alternating with glucose. Fred Smith received 36 bolus using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10<sup>25</sup> milli-units per kilogram, at a first set of unequal time periods of 5.3 minutes, 4 minutes, and 5.1 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

Fred Smith received a total of 16 treatments during the <sup>30</sup> three-month period, after the 6th treatment, he began to regain feeling in his feet.

Fred Smith due to the treatment was no longer in a wheelchair at the end of three months and was able to simply use a cane to get around.

Fred was able to decrease his hospital costs by \$255,000 from the prior year without treatment.

Additionally, Fred was able to decrease one of his blood pressure medications.

Post treatment, Fred's A1c test result was down 2.7 40 points. Fred no longer experienced hypoglycemic events and he had reduced his long-acting insulin by 20 percent and his short-acting insulin by 50 percent.

The primary care physician noted that Fred's wound had healed and no amputation was needed.

#### EXAMPLE 2

A comparative analysis was generated for Marianne Rutledge, a 60-year-old woman with Type 2 diabetes of 12 years 50 duration, who suffered from severe kidney disease and was fearful of becoming a dialysis patient.

Upon arrival Marianne Rutledge's blood test results showed an A1C of 10.2, blood glucose of 240 mg/dl, her blood pressure measured 150/92, and she weighed 212 55 pounds, or 96.3 kilograms.

Marianne Rutledge began an intensive treatment protocol of two treatment sessions per week the first two weeks, and one treatment session per week thereafter for weeks 3 through 12. During each treatment session, Marianne Rutledge received insulin and saline intravenously, alternating with glucose. Marianne Rutledge received 36 bolus per treatment session using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 65 milli-units per kilogram, at a first set of unequal time periods of 5.1 minutes, 4.6 minutes, and 5.6 minutes, with each set

of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

Marianne Rutledge received a total of 13 treatments during the three-month period, after the 2nd treatment, she noticed an extreme increase in her energy and stamina, and as she continued the treatment sessions, she reported that she looked forward to the next treatment session because it made her feel better than she had felt since she was diagnosed with diabetes and kidney disease.

Marianne Rutledge continued the therapy with regular treatment sessions each week, 3 to 4 hours each session, with the protocol of insulin and saline intravenously, alternating with glucose and using the schedule of bolus introduction having at least one unequal time period. After six months of treatment, her kidney function improved to the point that her doctor no longer considered dialysis probable.

#### EXAMPLE 3

Victoria Lord, a Type 2 diabetic on dialysis had vision problems including retinopathy and she also suffered from neuropathy and had trouble sleeping. A comparative analysis was generated for Victoria Lord, whose initial vital signs were blood glucose level 250, blood pressure 120/80, heart rate of 72, and HgbA1c of 9.2.

Victoria Lord began an intensive therapy of two treatment sessions on intravenous insulin alternating with oral glucose on consecutive days for the first two weeks then weekly treatment sessions thereafter for the next 10 weeks, then to be reevaluated.

Each treatment session consisted of 36 bolus. During each treatment session, Victoria Lord received insulin and saline intravenously, alternating with glucose. Victoria received the 36 bolus using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 5.0 minutes, 6.9 minutes, and 5.3 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

After her first four treatments over two weeks, she reported that her neuropathy decreased, which was confirmed by autonomic tests. Her blood glucose was decreased to 110, and she reported such extremely increased energy that she no longer required an afternoon nap. She also reported that she was sleeping better. Her lab tests after 14 treatments over 12 weeks showed Hgb A1c of 6.5, down from 9.2, or a decrease of about 30 percent.

#### EXAMPLE 4

Jim Pierce had severe foot neuropathy and had experienced no feeling in his feet for several years. He had been diagnosed with Type 2 Diabetes about 15 years ago and was insulin dependent. A friend knew of his debilitating neuropathy and recommended that he begin the therapy.

Jim Pierce reported that when his neuropathy began, it was so painful; he could not even stand for a sheet to touch his toes when he went to bed at night. As his neuropathy progressed, he lost all feeling in his feet and began to suffer injuries from falling. His doctor continued to treat him with insulin and prescription drugs, such as Gabapentin.

Jim Pierce's test results were reviewed, and he was put on a therapy of two treatment sessions on consecutive days for three weeks, two treatment sessions on consecutive days for two weeks after that, and then one treatment session per week for the balance of the first 12-week period.

Jim Pierce received 36 bolus during each treatment session using the schedule of bolus introduction having at least one unequal time period. During each treatment session Jim Pierce received insulin and saline intravenously, alternating with glucose.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 5.5 minutes, 5.1 minutes, and 5.6 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

After the first two treatments, Jim Pierce reported that the feeling began to return to his feet.

After he completed 8 treatments sessions, his doctor reduced his Gabapentin, and after 12 weeks, he no longer 15 took Gabapentin for his neuropathy. He reduced his insulin from 50 units every night to 30 units every night. His lab reports showed Hgb A1c 7.2, down from 10.5. After six months of the continued therapy he was able to do a three-mile hike on his vacation. 20

#### EXAMPLE 5

Sarah Hardin is a pre-diabetic with a genetic disposition to metabolic disorder and disease, including diabetes. Sar- 25 ah's pre-treatment metabolic rate or respiratory quotient (RQ), was 0.84. After her initial test results were reviewed, she began one treatment session per week for 12 weeks.

Each of Sarah's treatment sessions consisted of 36 bolus and during each treatment session, Sarah received insulin <sup>30</sup> and saline intravenously, alternating with glucose. Sarah received 36 bolus using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods <sup>35</sup> of 5.2 minutes, 4.7 minutes, and 6.3 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

Soon after starting the treatment therapy, Sarah Hardin noticed improvement in hair and nail growth, and she <sup>40</sup> documented it with photographs.

Sarah reported that her energy increased to the point that she no longer needed help taking care of her children. After 5 treatment sessions, a comparative analysis was performed and her RQ increased to 0.93, which demonstrated that she <sup>45</sup> was burning carbohydrates for energy.

#### EXAMPLE 6

Tatum Norris, age 18, a Type 1 diabetic diagnosed at age 50 10, had severe neuropathy and was housebound because of his pain. He began two treatment sessions on consecutive days, then 1 treatment session a week thereafter.

Each treatment session consisted of 36 bolus. During each treatment session, Tatum received insulin and saline intravenously, alternating with glucose. Tatum received 36 bolus using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods 60 of 5.4 minutes, 5.3 minutes, and 5.2 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

A Nerve Conduction Velocity (NCV) with Electromyopathy (EMG) was conducted pre-treatment on Tatum and 65 repeated 90 days after his initial treatment, which showed a marked decrease in his diabetic neuropathy.

After 8 or 10 treatments, Tatum began driving a car again and he was able to sit in movie theaters because the pain was now manageable. Tatum reported that he could now go visit his mom in Dallas and even hang out with friends.

#### EXAMPLE 7

Carmen Valdez, a 70-year-old Type 2 diabetic who had been diagnosed four years earlier, was on three types of blood pressure medication (Amlodipine, Lisinopril, and Lopressor) and three medications to control her blood sugar (Lantus, Metformin, and Onglyza). After her initial test results were reviewed, she began treatment sessions of two treatment sessions on consecutive days for the first two weeks and one treatment session per week thereafter for 12 weeks. Her pre-treatment RQ test result was 0.79.

During each treatment session, Carmen received insulin and saline intravenously, alternating with glucose. Carmen 20 received 36 bolus using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 6.4 minutes, 7.2 minutes, and 7.6 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

Carmen reported that she was surprised that she immediately experienced greatly increased energy and stamina, as well as a lowering of her daily blood pressure according to her self-tests, after only the first two treatments.

After three months, Carmen Valdez was able to discontinue taking Amlodipine, Lantus and Onglyzaone. At that point her RQ measured 0.95.

#### EXAMPLE 8

Harold Carson, a 65-year-old insulin-dependent Type 2 diabetic of 25 years, became insulin resistant and his medications were no longer working well. Mr. Carson was taking three 750-mg Glucophage tablets daily, 150 units of Humalog (short-acting) insulin daily, and a nighttime injection of 40 units of Humulin N (long-acting) insulin. He also took statin drugs for cholesterol and blood pressure medication.

After initial tests, his C-peptide was remarkable at 2.0. He began treatment sessions of two on consecutive days for two weeks, and then continued with weekly treatments for a total of 12 weeks.

During each treatment session, Mr. Carson received insulin and saline intravenously, alternating with glucose. He received 36 bolus per treatment session using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 5.7 minutes, 6.1 minutes, and 5.9 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

After he began the treatment sessions, he reported that he immediately noticed a better night's sleep, that his mental clarity was sharper, and even his golf score improved.

After two months of treatment he decreased his insulin usage by 70 percent (from 150 units daily to 45 units daily) and his C-peptide test resulted in a significant improvement of 2.8.

Harold Carson's RQ was 0.75 pre-treatment and a perfect 1.00 after two months of treatment. Harold reported that his dry skin improved, the neuropathy in his legs vanished, and

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his wife reported that his hair had grown "unbelievably" after he began the treatment therapy.

#### EXAMPLE 9

Stephen Henderson, a pre-diabetic with metabolic disorder and hyperlipidemia, had initial test results of Triglycerides 1290, LDL 183, and Cholesterol 271; his RQ was 0.74. He began treatment sessions once a week for 12 weeks. During each treatment session, Mr. Henderson received insulin and saline intravenously, alternating with glucose. Mr. Henderson received 36 bolus each treatment session using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 4.8 minutes, 4.8 minutes, and 5.3 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

Stephen reported that after only two treatments, his energy level increased and prior hair loss abruptly stopped. 20 After five treatments, he noticed significant hair growth. His test results after 12 treatment sessions were Triglycerides 123, LDL 86, Cholesterol 144, and RQ 0.98.

Stephen also reported that he noticed significant improvement in quantitative and qualitative analysis capability.

#### EXAMPLE 10

Alan Henderson traveled from Denver to Houston for his treatments. At age 71 he had a history of 13 heart stints, he had been a Type 2 diabetic for 20 years, and he was insulin dependent.

After initial testing and a review of his results, Alan Henderson began treatment sessions of two per week on consecutive days for two weeks, then one treatment session weekly for 10 more weeks.

During each treatment session, Alan received insulin, saline, potassium, and magnesium intravenously, alternating with glucose. Alan received 36 bolus each treatment session using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 6.4 minutes, 6.8 minutes, and 7.1 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

Alan's initial RQ was measured at 0.78, and his Hgb A1c was 13.4.

Over the course of three months, after his 12-week, 14-treatment therapy, he decreased his fast-acting insulin (Novalog) by 55 percent, down from 15-18 units to 10-12 units with meals and his long-acting insulin (Lantus) decreased by 65 percent, down from 75 units twice daily to 40 units daily.

After the first three months of treatment, Alan's Hgb A1c was down to 7.3 (more than 6-point decrease), and his RQ was 0.90.

Alan Henderson also suffered from diabetic neuropathy, for which he had been prescribed Gabapentin (six capsules per day) and a Lidocaine patch. After two months he reduced the amount of Gabapentin he was taking, and then completely eliminated it. He discontinued use of the Lidocaine <sup>60</sup> patch. He reports that he now has no pain or neuropathy in his hands or feet, and his energy level is "way up."

#### EXAMPLE 11

George Gilbert had a wound on his foot for three months that would not heal. He was also a Type 2 diabetic on Metformin orally. After review of his test results, he began treatment sessions of two sessions on consecutive days for the first week and weekly treatment sessions thereafter.

During each treatment session, George received insulin, saline, glucagon, and somatostatin intravenously, alternating with oral glucose. George received 36 bolus each treatment session using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 5.7 minutes, 5.4 minutes, and 5.0 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

After only three weeks of the treatment, he reduced the amount of Metformin he was taking, his wound healed, and his doctor made photographs of the wound before and after for the hospital record. George calls the treatment a "miracle."

#### EXAMPLE 12

Toby Rasmussen, a pre-diabetic of 8 years duration, began treatment sessions because of vision problems and a family history of diabetes. His initial RQ was 0.85. His Hgb Ale measured 7.0. He began treatment sessions once a week for 12 weeks.

During each treatment session, Toby received insulin and saline intravenously, alternating with glucose. Toby received 36 bolus each treatment session using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 5.3 minutes, 5.2 minutes, and 6.4 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

Toby reports that after the 12 treatments, he has more energy and his eyesight has improved so much that he now uses only bifocals instead of trifocals. After treatments, his RQ measured 0.98 and his A1c measured 6.1.

#### EXAMPLE 13

Hank Anderson, a Type 2 diabetic of 27 years, had an Hgb
A1c reading of 9.0, and was using Lantus insulin at 170 units
during the day and another 70 units at night. He also reported severe leg cramps.

A comparative analysis was performed on Hank Anderson, and he began treatment sessions weekly. During each treatment session, Hank received insulin and saline intravenously, alternating with glucose. He also received potassium 40 meq orally with each treatment session and daily on non-treatment days. Mr. Anderson received 36 bolus per treatment session using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods of 5.6 minutes, 5.1 minutes, and 5.4 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

After 12 weeks of weekly treatment sessions, Hank reported that since starting the treatment, his blood sugar is now controlled and his eyesight has improved so much that he went from legally blind without glasses to being able to read captions on a television with no glasses.

Hank was able to discontinue his nightly Lantus and his insulin went down from 6 vials of insulin per month to only 3, a significant costs saving.

Hank Anderson's A1c after 12 weeks of treatment sessions measured 8.3.

#### EXAMPLE 14

John Grayson, a Type 1 insulin-dependent diabetic, initially reported problems with his kidneys, eyes, low energy, mood swings, and erectile dysfunction. His RQ was 0.88 and his magnesium level was 1.5

After his test results were reviewed, John started treat-10 ment sessions of two sessions on consecutive days with weekly treatment sessions thereafter for a period of three months. During each treatment session, Hank received insulin and saline intravenously, alternating with oral glucose and somatostatin. Hank received 36 bolus per treatment session using the schedule of bolus introduction having at least one unequal time period.

Each bolus of insulin had an insulin concentration of 10 milli-units per kilogram at a first set of unequal time periods 20 a plurality of weight management protocols to identify a of 5.0 minutes, 5.2 minutes, and 5.3 minutes, with each set of unequal time periods between bolus introductions repeating for the entire treatment session, of about 3 to 4 hours.

Mr. Grayson also received magnesium chloride tablets of 40 mg orally with each treatment session and daily on 25 non-treatment days.

After the first two treatments, Mr. Grayson decreased his insulin use by 5-10 units per sliding scale and was extremely happy to report that he experienced increased blood flow.

After the third treatment, Mrs. Grayson was deliriously 30 excited about his improvement, especially with the blood flow.

FIGS. 5A-5C depict steps of a method of the invention according to one or more embodiments.

The method for providing an individualized intravenous 35 exogenous insulin-based therapy can include creating a subject profile for a subject, as shown in box 500. The subject profile can include: a subject history, such as having type II diabetes for the past three years and cataract surgery 4 years ago, a subject's physical reports including weight of 40 the subject and optionally objective physician reports, CT scans and other diagnostic reports, a subject's name, such as Carol Wilson, a subject's contact information such as a name, an address and a telephone number, and a subject's blood test results.

The method can include assessing metabolic factors of the subject and storing the metabolic factors in the subject profile, as shown in box 502. The metabolic factors needed in the subject file can include: a glucose level, such as an initial glucose level, a respiratory quotient, such as an initial 50 respiratory quotient, an insulin sensitivity factor, such as an initial or pre-treatment insulin senility factor, and an individual target blood glucose level which the subject desires to achieve with the treatments using the diabetic treatment model

The method can include creating a care plan with a plurality of treatment sessions for the subject and a plan goal, as shown in box 504. The care plan can indicate a schedule of bolus introduction with at least one unequal time period and the care plan can include a quantity and fre- 60 quency of a plurality of bolus containing saline and insulin for sequential intravenous introduction to a subject.

The method can include introducing glucose to the subject to stimulate gastrointestinal hormone production, resulting in the release of enzymes from the subject's liver and 65 causing blood glucose levels of the subject to be in a therapeutic range, as shown in box 506.

The method can include testing the subject for blood glucose levels to compare tested blood glucose levels to the plurality of therapeutic ranges and verify the subject is in the therapeutic range, as shown in box 508.

The method can include comparing tested blood glucose levels to a diabetic treatment model, as shown in box 510.

The method can include mapping tested blood glucose levels and insulin sensitive factors of the subject to the subject weight using the diabetic treatment model to determine a schedule for bolus introduction, wherein the schedule for bolus introduction has at least one unequal time period between at least one pair of bolus, as shown in box 512.

The method can include introducing to the subject a plurality of bolus of insulin and saline sequentially using the schedule for bolus introduction having at least one unequal time period between at least one pair of bolus, as shown in box 513.

The method can include comparing the subject profile to weight management protocol for the subject based upon assessed metabolic functions of the subject and saving the weight management protocol in the care plan, as shown in box 514.

The method can include implementing the identified weight management protocol and the care plan after a first treatment session to manage weight of the subject with a metabolic enhancement causing improved cellular ATP functioning for the subject while infusing insulin and modifying a quantity and duration of unequal time periods between bolus introduction in the schedule of bolus introduction having at least one unequal time period between at least one pair of bolus to improve impaired hepatic glucose processing, as shown in box 516.

The method can include using in the schedule of bolus introduction having at least one unequal time period, time periods varying from 2 minutes to 10 minutes. The unequal time periods can be time intervals from 1 percent to 30 percent different in length of time from each other.

The method can include introducing from 60 grams of glucose to 100 grams of glucose to the subject prior to initial bolus introduction to establish a blood glucose level of at least 125 mg/dl prior to introducing the plurality of bolus in a first treatment session.

The method can include comparing a respiratory quotient of the subject in a resting state to a plurality of metabolism scores, as shown in box 518.

The method can include modifying a quantity of bolus for the subject for each treatment session as identified in the care plan with schedule of bolus introduction having at least one unequal time period between bolus to improve a subject's respiratory quotient, as shown in box 520.

The method can include modifying the schedule of bolus 55 introduction having at least one unequal time period between bolus introduction by modifying a quantity and duration of unequal time periods between bolus introductions to improve the respiratory quotient, as shown in box 522.

The method can include comparing a measured cardiac function of the subject in a resting state to a preset norm of cardiac function, as shown in box 524.

The method can include modifying a quantity of bolus for the subject identified in the care plan using the preset norm of cardiac function, as shown in box 526.

The method can include modifying the schedule of bolus introduction having at least one unequal time period by

modifying a quantity and duration of unequal time periods between bolus introductions to improve cardiac function, as shown in box 528.

The method can include measuring a peripheral autonomic neuropathy and microcirculation of the subject in a resting state prior to bolus introduction comparing the measured peripheral autonomic neuropathy and microcirculation to a plurality of preset norms of peripheral autonomic neuropathies and microcirculations, as shown in box 530.

The method can include comparing a peripheral autonomic neuropathy and microcirculation of the subject in a resting state as bolus are sequentially introduced to the measured peripheral autonomic neuropathy and microcirculation, as shown in box 532.

The method can include comparing a peripheral autonomic neuropathy and microcirculation of the subject in a resting state after all bolus have been introduced in a first treatment session to the measured peripheral autonomic neuropathy and microcirculation, as shown in box 534.

The method can include modifying a quantity of bolus for the subject identified in the care plan to treat peripheral autonomic neuropathy and microcirculation, as shown in box 536.

The method can include modifying the schedule of bolus 25 introduction having at least one unequal time period by modifying a quantity and duration of unequal time periods between bolus introduction to improve the measured peripheral autonomic neuropathy and microcirculation, as shown in box 538.

The method can include viewing an initial retinal image of the subject captured by a non-mydriatic camera with the subject in a resting state to identify a diabetic retinopathy, as shown inbox 540.

The method can include viewing a post treatment retinal 35 image of the subject in a resting state after a first treatment session, as shown in box 541.

The method can include comparing the initial retinal image to the post treatment retinal image, as shown in box 542.

The method can include modifying a quantity of bolus for the subject if no change in the diabetic retinopathy has occurred, as shown in box 544.

The method can include modifying the schedule of bolus introduction having at least one unequal time period 45 between bolus to reduce the effects of diabetic retinopathy by modifying a quantity and duration of unequal time periods between bolus introductions to reduce the effects of diabetic retinopathy, as shown in box 546.

wounds by length, width, depth and identifying wound characteristics with the subject in a resting state, as shown in box 550.

The method can include dimensionally measuring wounds after at least one treatment session to identify skin 55 integrity and changes in clinical wound characteristics, as shown in box 552.

The method can include modifying a quantity of bolus for the subject identified in the care plan for wound treatment using the identified skin integrity and changes in clinical 60 wound characteristics, as shown in box 554.

The method can include modifying the schedule of bolus introduction having at least one unequal time period between bolus to improve wound healing by modifying a quantity and duration of unequal time periods between bolus 65 introduction to reduce wound size and wound characteristics, as shown in box 556.

The method can include comparing C-peptides of the subject to a preset norm of C-peptides to identify an insulin sensitivity factor, as shown in box 560.

The method can include modifying a quantity of bolus for the subject for the insulin sensitivity factor, as shown in box 562

The method can include modifying the schedule of bolus introduction having at least one unequal time period between bolus to improve an insulin sensitivity factor using analysis of C-peptides by modifying a quantity and duration of unequal time periods between bolus introductions, as shown in box 564.

In embodiments, the method can use at least one of: methylcobalamin, pyridoxal-5-phosphate, 5-MTHF, alpha lipoic acid, NADH, coenzyme Q10, chromium picolinate, and N-Acetyl cysteine, and vitamin D<sub>3</sub> as the metabolic enhancement.

In embodiments, a needle or a catheter can be used to introduce the bolus into the subject's hand or forearm to 20 deliver the insulin bolus.

The method can include determining a quantity and frequency of dosage amounts of magnesium and introducing the dosage amounts of magnesium simultaneously to the subject with the plurality of bolus using the schedule of bolus introduction having at least one unequal time period, as shown in box 570.

The method can include determining a quantity and frequency of dosage amounts of potassium and introducing the dosage amounts of potassium simultaneously to the subject with the plurality of bolus using the schedule of bolus introduction having at least one unequal time period, as shown in box 572.

The method can include determining a quantity and frequency of dosage amounts of somatostatin and introducing the dosage amounts of somatostatin simultaneously to the subject with the plurality of bolus using the schedule of bolus introduction having at least one unequal time period, as shown in box 574.

In embodiments, the somatostatin can be administered 40 orally or intravenously.

The method can include determining a quantity and frequency of dosage amounts of glucagon and introducing the dosage amounts of glucagon simultaneously to the subject with the plurality of bolus using the schedule of bolus introduction having at least one unequal time period, as shown in box 576.

In embodiments, the glucagon can be administered orally or intravenously

The method can include scheduling diagnostic tests after The method can include dimensionally measuring 50 a first treatment session to modify the care plan for improved cellular ATP functioning for the subject and improved hepatic glucose processing, as shown in box 578.

> FIG. 6 depicts a system of the invention according to one or more embodiments.

> The system for individualized intravenous exogenous insulin-based therapy can have an administrative processor 602 connected to an administrative data storage 604.

> The administrative processor, which can be a computer, can be connected to a network 606. In embodiments, the connection can be a wired or wireless connection. The network can be a cellular network, a satellite network, a global communication network, a local area network, a wide area network, a similar network known in the industry, or combinations thereof.

> The system can connect to a plurality of client devices 608a, 608b, and 608c. The client devices can be computers, laptops, tablet computers, cellular phones or smart phones,

or another digital input device that is cable of bidirectional communication and can be used to input subject information into a subject profile, which can be disposed in the administrative data storage **604**.

In embodiments, the system can connect to a hospital processor **607** and/or an insurance processor **609**. The hospital processor, the insurance processor or both can be in communication with the network **606** and can provide accelerated payment to the diabetic treatment center and provide improved data visibility for improved overall patient care by hospital doctors and medical staff treating the subject.

In embodiments, the system can connect to a doctor processor **611**, which can be a computer. In embodiments, <sup>15</sup> the doctor processor can be a group of processors, wherein each processor in the group can be connected to a different doctor specialist. In other embodiments, the doctor processor can be a processor accessible by a group of physicians.

In embodiments, the administrative processor can be a 20 cloud based computing system.

FIGS. **7**A and **7**B depict an administrative data storage usable in the system according to one or more embodiments.

The administrative data storage **604** can contain at least one subject profile **610**.

Each subject profile can contain a plurality of metabolic factors **605** of the subject, which can include, but is not limited to, a blood glucose level **612**, a respiratory quotient **614**, an insulin sensitivity factor **616**, and an individual target blood glucose level **618**.

The administrative data storage **604** can contain a plurality of care plan templates **620**.

In embodiments, the administrative data storage can contain various computer instructions, which can be used to instruct the administrative processor to perform various tasks.

The administrative data storage **604** can contain computer instructions **200** configured to instruct the administrative processor to create a customized care plan from one of the  $_{40}$ plurality of care plan templates, wherein the customized care plan indicates a plurality of treatment sessions for the subject with the subject profile and a plan goal, each customized care plan indicating a schedule of bolus introduction having at least one unequal time period between 45 bolus introduction, each bolus containing saline and insulin and each bolus introduced intravenously and sequentially to a subject

The administrative data storage **604** can contain computer instructions **202** configured to instruct the administrative <sup>50</sup> processor to compare tested blood glucose levels to a diabetic treatment model after introducing glucose to a subject to stimulate gastrointestinal hormone production, release of enzymes from the subject's liver and cause blood glucose levels of the subject to be in a therapeutic range. <sup>55</sup>

The administrative data storage **604** can contain a plurality of therapeutic ranges for blood glucose levels **203**.

The administrative data storage **604** can contain computer instructions **204** configured to instruct the administrative processor to compare tested blood glucose levels to the <sup>60</sup> plurality of therapeutic ranges for blood glucose levels and verify the subject is in the therapeutic range.

The administrative data storage **604** can contain a plurality of weight management protocols **205**.

The administrative data storage **604** can contain computer 65 instructions **206** configured to instruct the administrative processor to compare a subject profile to the plurality of

weight management protocols to identify a weight management protocol based upon metabolic functions of the subject.

The administrative data storage **604** can contain computer instructions **207** configured to instruct the administrative processor to save the identified weight management protocol in the generated customized care plan after saline with insulin in a plurality of bolus using the schedule of bolus introduction having at least one unequal time period have been administered to a subject.

It should be noted that the unequal time periods are determined by the diabetic treatment model and the care plan.

The administrative data storage **604** can contain computer instructions **208** configured to instruct the administrative processor to track weight management of the subject after a first treatment session and use of an identified weight management protocol and the care plan along with a metabolic enhancement to identify improved cellular ATP functioning for the subject and improve impaired hepatic glucose processing.

The administrative data storage **604** can contain a plurality of metabolism scores **209**, a plurality of preset norms of <sup>25</sup> cardiac function **210**, a plurality of preset norms of peripheral autonomic neuropathies and microcirculations **211**, a retinal image of the subject **212**, wound characteristics **214** and a plurality of preset norms of C-peptides **215**.

In embodiments, at least one the metabolic enhancements can be a synergistic combination of: Vitamin D ranging in amounts from 600 IU to 2000 IU, Vitamin B<sub>6</sub> ranging in amounts from 10 mg to 100 mg, Folic Acid ranging in amounts from 200 mcg to 2000 mcg, Vitamin  $\rm B_{12}$  ranging in amounts from 1000 mcg to 5000 mcg, an amino acid that builds proteins in a subject ranging in amounts from 200 mg to 600 mg, a coenzyme that extracts energy from food for a subject ranging in amounts from 60 mg to 400 mg, an antioxidant that extracts energy from food for a subject ranging in amounts from 50 mg to 400 mg, a protein binding component that binds to proteins and serves as a respiratory metabolic enhancement for a subject ranging in amounts from 0.5 mg to 5 mg, and a glucose utilization component to prevent or treat chromium deficiency in a subject which improves glucose utilization by insulin ranging in amounts from 200 mg to 300 mg.

A metabolic enhancement can consist of Cholecalciferol, Pyridoxal-5-Phosphate, Folate, Cyanocobalamin, N-Acetyl L-Cysteine (NAC), Coenzyme Q10 (CoQ10), an Alpha lipoic acid, Nicotinamide Adenine Dinucleotide (NADH), and Chromium Picolinate.

FIGS. 8A-8C provide exemplary subject profiles with an automatically generated care plan template and an automatically generated report according to one or more embodiments.

The care plan can be viewed in real time 24 hours a day, 7 days a week as each test is updated and the metabolic assessments are completed.

FIG. 8A shows a subject profile 610 with fields for a name 802, a patient ID number 804, a date of birth 806, a gender 808, an ethnicity 810, a blood type 812, allergies 814, a diagnosis 816, insurance 818, a primary care physician (PCP) 820, a primary care physician phone number 822, a primary care physician fax number 824, a patient address 826, a patient phone number 828, a patient email address 830, and a patient emergency contact 832. The subject profile **610** can include a narrative **834**, which can be written by a medical professional, documenting the condition of the patient and the medical history of the patient with the subject profile.

The subject profile **610** can include assessed metabolic <sup>5</sup> factors of the patient **605**, which can include fasting blood sugar **836**, A1c level in the blood **838**, C-peptide level in the blood **840**, a magnesium level in the blood **842**, a potassium level in the blood **844**, and urinalysis test results **846**.

The subject profile **610** can include an insulin sensitivity factor **848** for the subject and diagnostic tests results **850**.

The diagnostic test results **850** can include blood glucose level **612**, respiratory quotient **614**, blood pressure **852**, weight **854**, nerve conduction velocity **856**, retinal image of the subject **212**, autonomic test results for neuropathy **858**, cognitive test results **860**, and cardiac test results **862** indicating cardiac function. The cardiac tests can be EKG or 2D Echo tests.

The subject profile **610** can include current medications <sub>20</sub> **864** of the subject, such as aspirin or prescription medications the subject is currently using.

The subject profile **610** can have a home button **950**, a save button **952**, a previous page button **954**, a next page button **956**, and an exit button **958**. The buttons can be <sup>25</sup> interchangeable with icons depending on software used on an industry standard computer screen.

FIG. 8B shows the subject profile with a care plan template.

In embodiments, the can plan template can be filled in partially or completely and can be editable.

The care plan template **620** can have an infusion schedule **866**, which can indicate infusions by week, showing a quality of treatments and on which days the treatments must occur.

The care plan template **620** can include an infusion formulation **868**, which can be a combination of insulin, saline, potassium, magnesium, glucagon, and somatostatin.

The care plan template **620** can include treatment cycles <sub>40</sub> **870**, a quantity of bolus per treatment cycle **872**, and unequal time periods between bolus introductions in seconds **874**.

The care plan template **620** can include a blood glucose level therapeutic range **876**.

In embodiments, additional therapies can be tracked in the 45 care plan, including but not limited to, a quantity and frequency of dosage amounts of potassium **878**, a quantity and frequency of dosage amounts of magnesium **880**, a quantity and frequency of dosage amounts of glucagon **882**, and a quantity and frequency of dosage amounts of soma- 50 tostatin **884**.

The care plan template **620** can include diagnostic tests **886**, which can be scheduled after a first treatment session.

The care plan template **620** can include metabolic enhancements **888**, which can be a particular supplement 55 and instructions on dosage amounts and frequency for the subject in view of the diagnostic tests or other data in the care plan.

The care plan template **620** can include a weight management protocol **205**, which can be selected from the 60 plurality of weight management protocols in the administrative data storage.

The care plan template **620** can include an education schedule **889**, which can consist of a curriculum of education modules to be viewed or read by a subject by a certain 65 date, which can be automatically transmitted to a client device of the subject on a predetermined schedule.

The care plan template **620** can include at least one plan goal **890**, such as an increased metabolism for a subject, such as by 10 percent.

FIG. 8C shows the subject profile with a report.

The report **892** can show improved cellular ATP functioning for the subject identifying improve impaired hepatic glucose processing.

The report **892** can include a post treatment narrative **894**, which can be completed by a health care professional, indicating subjective and analytical assessments of metabolic factors of the subject.

The report **892** can include post treatment assessed metabolic factors **896** of the patient, a post treatment insulin sensitivity factor **898**, a post treatment patient testimonial **900**, post treatment diagnostic tests results **902** and post treatment medications **904**.

The report **892** can include an insulin sensitivity factor **848** for the subject and diagnostic tests results **850**.

The diagnostic test results **850** can include blood glucose level **612**, respiratory quotient **614**, blood pressure **852**, weight **854**, nerve conduction velocity **856**, retinal image of the subject **212**, autonomic test results for neuropathy **858**, cognitive test results **860**, and cardiac test results **862** indicating cardiac function. The cardiac tests can be EKG or 2D Echo tests.

The report can include assessed metabolic factors of the patient **605**, which can include fasting blood sugar **836**, Alec level in the blood **838**, C-peptide level in the blood **840**, a magnesium level in the blood **842**, a potassium level in the blood **844**, and urinalysis test results **846**.

While these embodiments have been described with emphasis on the embodiments, it should be understood that within the scope of the appended claims, the embodiments might be practiced other than as specifically described herein.

What is claimed is:

**1**. A method for individualized intravenous exogenous insulin-based treatment, comprising the steps of:

creating a subject profile for a subject, the subject profile comprising:

(i) a subject history;

(ii) subject physical reports including a subject weight;

(iii) subject name;

(iv) subject contact information; and

(v) subject blood test results;

- assessing metabolic factors of the subject and storing the metabolic factors in the subject profile, wherein the metabolic factors include: a glucose level, an insulinsensitivity factor, and an individual target blood glucose level;
- creating a care plan with a plurality of treatment sessions for the subject and a plan goal, wherein the care plan uses the assessed metabolic factors and indicates a schedule of bolus introductions with at least one unequal time period and a quantity and frequency of a plurality of boluses containing saline and insulin for sequential intravenous introduction to the subject;
- introducing glucose to the subject to stimulate gastrointestinal hormone production that results in a release of enzymes from the subject's liver and causing blood glucose levels of the subject to be in a therapeutic range;
- testing the subject for blood glucose levels, comparing tested blood glucose levels to a plurality of therapeutic ranges, and verifying that the subject is in at least one of the plurality of therapeutic ranges;

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comparing the tested blood glucose levels to a diabetic treatment model:

- mapping the tested blood glucose levels and the assessed metabolic factors of the subject by using the diabetic treatment model to determine the schedule for bolus <sup>5</sup> introductions:
- introducing, sequentially, to the subject a plurality of boluses by using the determined schedule for bolus introductions based on the mapping;
- comparing the subject profile to a plurality of weight management protocols to identify a weight management protocol for the subject based upon the assessed metabolic functions of the subject and saving the weight management protocol in the care plan; and
- <sup>15</sup> implementing the weight management protocol and the determined schedule of bolus introductions for the subject to improve insulin sensitivity, cellular ATP functioning, or both, of the subject.

**2**. The method for individualized intravenous exogenous  $_{20}$  insulin-based treatment of claim **1**, further comprising assessing at least one biomarker specific to diabetes of the subject and optionally storing the at least one biomarker in the subject profile.

**3**. The method for individualized intravenous exogenous  $^{25}$  insulin-based treatment of claim **1**, wherein the schedule of bolus introductions having the at least one unequal time period uses time periods varying from 2 minutes to 10 minutes, and wherein the unequal time periods are time intervals from 1 percent to 30 percent different in length of  $^{30}$  time from each other.

**4**. The method for individualized intravenous exogenous insulin-based treatment of claim **1**, further comprising introducing from 60 grams of glucose to 100 grams of glucose to the subject to establish a blood glucose level of at least 125 mg/dl prior to introducing the plurality of boluses in the first treatment session.

**5**. The method for individualized intravenous exogenous insulin-based treatment of claim **1**, further comprising:

- comparing a measured cardiac function of the subject in a resting state to a plurality of preset norms of cardiac function;
- modifying a quantity of bolus for the subject identified in the care plan using the plurality of preset norms of 45 cardiac function; and
- modifying the schedule of bolus introductions by modifying the quantity and duration of unequal time periods between the bolus introductions to improve cardiac function.

**6**. The method for individualized intravenous exogenous insulin-based treatment of claim **1**, further comprising:

- measuring a peripheral autonomic neuropathy and microcirculation of the subject in a resting state prior to a bolus introduction and comparing the measured periph-55 eral autonomic neuropathy and microcirculation to a plurality of preset norms of peripheral autonomic neuropathies and microcirculations;
- comparing a peripheral autonomic neuropathy and microcirculation of the subject in a resting state as boluses are 60 sequentially introduced to the measured peripheral autonomic neuropathy;
- comparing a peripheral autonomic neuropathy and microcirculation of the subject in a resting state after all boluses have been introduced in the first treatment 65 session to the measured peripheral autonomic neuropathy and microcirculation;

- modifying a quantity of boluses for the subject identified in the care plan to treat peripheral autonomic neuropathy and microcirculation; and
- modifying the schedule of bolus introductions by modifying the quantity and duration of unequal time periods between the bolus introductions to improve the measured peripheral autonomic neuropathy and microcirculation.

7. The method for individualized intravenous exogenous insulin-based treatment of claim 1, further comprising:

- viewing an initial retinal image of the subject captured by a non-mydriatic camera with the subject in a resting state to identify a diabetic retinopathy;
- viewing a post treatment retinal image of the subject in a resting state after the first treatment session;
- comparing the initial retinal image to the post treatment retinal image;
- modifying a quantity of bolus for the subject if no change m the diabetic retinopathy has occurred; and
- modifying the schedule of bolus introductions by modifying the quantity and duration of unequal time periods between the bolus introductions to reduce the effects of diabetic retinopathy.

**8**. The method for individualized intravenous exogenous insulin-based treatment of claim **1**, further comprising:

- dimensionally measuring wounds by length, width, and depth and identifying wound characteristics of the subject in a resting state;
- dimensionally measuring wounds after at least one treatment session to identify skin integrity and changes in clinical wound characteristics;
- modifying a quantity of bolus for the subject identified in the care plan for wound treatment using the identified skin integrity and changes in clinical wound characteristics; and
- modifying the schedule of bolus introductions by modifying the quantity and duration of unequal time periods between the bolus introductions to reduce wound size and wound characteristics.

**9**. The method for individualized intravenous exogenous insulin-based treatment of claim **1**, comprising:

- comparing C-peptides of the subject to a plurality of preset norms of C-peptides to identify an insulin sensitivity factor;
- modifying a quantity of bolus for the subject for the insulin sensitivity factor; and
- modifying the schedule of bolus introductions to improve the insulin sensitivity factor using analysis of the C-peptides by modifying the quantity and duration of unequal time periods between the bolus introductions.

10. The method for individualized intravenous exogenous insulin-based treatment of claim 1, wherein the implementing the weight management protocol comprises implementing use of a metabolic enhancement comprising methylcobalamin, pyridoxal-5-phosphate, 5-MTHF, alpha lipoic acid, NADH, coenzyme Q10, chromium picolinate, N-Acetyl cysteine, vitamin  $D_3$ , or combinations thereof.

11. The method for individualized intravenous exogenous insulin-based treatment of claim 1, further comprising determining a quantity and frequency of dosage amounts of magnesium and introducing the dosage amounts of magnesium simultaneously to the subject with the plurality of boluses using the schedule of bolus introductions.

12. The method for individualized intravenous exogenous insulin-based treatment of claim 1, determining a quantity and frequency of dosage amounts of potassium and intro-

ducing the dosage amounts of potassium simultaneously to the subject with the plurality of boluses using the schedule of bolus introductions.

13. The method for individualized intravenous exogenous insulin-based treatment of claim 1, determining a quantity and frequency of dosage amounts of somatostatin and introducing the dosage amounts of somatostatin simultaneously to the subject with the plurality of boluses using the schedule of bolus introductions.

**14**. The method for individualized intravenous exogenous <sup>10</sup> insulin-based treatment of claim **1**, determining a quantity and frequency of dosage amounts of glucagon and introducing the dosage amounts of glucagon simultaneously to the subject with the plurality of boluses using the schedule of <sup>15</sup> bolus introductions.

15. The method for individualized intravenous exogenous insulin-based treatment of claim 1, comprising scheduling diagnostic tests after the first treatment session to modify the care plan to improved the insulin sensitivity, cellular ATP  $_{20}$  functioning, or both, of the subject.

**16**. The method for individualized intravenous exogenous insulin-based treatment of claim **1**, further comprising modifying the determined schedule of bolus introductions.

**17**. The method for individualized intravenous exogenous <sup>25</sup> insulin-based treatment of claim **1**, further comprising measuring at least one of the metabolic factors, at least one biomarker, or both.

**18**. The method for individualized intravenous exogenous insulin-based treatment of claim **1**, further comprising comparing the determined schedule of bolus introductions to the diabetic treatment model.

**19**. A system for individualized intravenous exogenous insulin-based therapy comprising:

- an administrative processor connected to an administrative data storage, the administrative processor connected to a network;
- a plurality of client devices, wherein the plurality of client devices is configured for inputting subject information into at least one subject profile in the administrative <sup>40</sup> data storage, and wherein the at least one subject profile has a glucose level, an insulin sensitivity factor, and an individual target blood glucose level;
- a plurality of care plan templates in the administrative data storage;
  - computer instructions in the administrative data storage, wherein the computer instructions are configured to instruct the administrative processor to create

a care plan for a subject from one of the plurality of care plan templates, and wherein the care plan indicates:

- (i) a plurality of treatment sessions for the subject with the at least one subject profile with a plan goal; and
- (ii) a schedule of bolus introductions having at least one unequal time period between bolus introductions, wherein each bolus contains saline and insulin and each bolus is introduced intravenously and sequentially to the subject;
- computer instructions in the administrative data storage configured to instruct the administrative processor to compare tested blood glucose levels to a diabetic treatment model after introducing glucose to the subject to stimulate gastrointestinal hormone production that result in a release of enzymes from the subject's liver;
- a plurality of therapeutic ranges for blood glucose levels in the administrative data storage;
- computer instructions in the administrative data storage configured to instruct the administrative processor to compare the tested blood glucose levels to the plurality of therapeutic ranges and verify that the subject is in at least one of the plurality of therapeutic ranges;
- a plurality of weight management protocols in the administrative data storage;
- computer instructions in the administrative data storage configured to instruct the administrative processor to compare the at least one subject profile for the subject to the plurality of weight management protocols to identify a weight management protocol based upon metabolic functions of the subject and to save the weight management protocol to the care plan;
- computer instructions in the administrative data storage configured to map the tested blood glucose levels and the assessed metabolic factors of the subject by using the diabetic treatment model to determine the schedule for bolus introductions; and
- computer instructions in the administrative data storage configured to instruct the administrative processor to track implementation of the weight management protocol and the determined schedule of bolus introductions of the subject after a first treatment session.

**20**. The system for individualized intravenous exogenous insulin-based therapy of claim **19**, further comprising computer instructions in the administrative data storage configured to assess at least one biomarker specific to diabetes of the subject and optionally to store the at least one biomarker in the at least one subject profile for the subject.

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