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(54) **DEVICE AND PROGRAM FOR DIABETES CARE**

VORRICHTUNG UND PROGRAMM FÜR DIE DIABETES-VERSORGUNG

DISPOSITIF ET PROGRAMME POUR SOINS DU DIABETE

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EP 1 921 978 B1

Description

BACKGROUND OF THE INVENTION

[0001] The invention relates to a medical device for diabetes care being a blood glucose meter or an insulin pump or a continuous glucose monitoring device. The invention further relates to a program for determining postprandial glucose concentration and to a data carrier including such a program.

PRIOR ART

[0002] Considerable progress has been made in the development of diagnostic, therapeutic and educational tools for diabetes self-management. However, it is less recognized that in the daily life of people with diabetes mellitus all such tools are characterized by rather large and varying margins of error. There exists insufficient knowledge about the effects of such errors on postprandial blood glucose and thus about their contribution to the increases risk of hypoglycemia and hyperglycemia.

[0003] Presently known systems, and in particular systems for continuous glucose monitoring, do not display actual results to avoid a possibly false therapy decision based on an uncertain measuring value (a value with a measuring error that could be too large). With such systems only a retrospective analysis of the measured values is possible. [Mastrototaro J. The MiniMed Continuous Glucose Monitoring System. Journal of Pediatric Endocronology & Metabolism, 12, 751-758 (1999)].

[0004] Other systems for continuously monitoring glucose do display actual measurement values but are not approved for therapy decisions. For such decisions it is in both cases necessary to measure the blood glucose value with strip measurement devices. [FDA Approval order GlucoWatch Automatic Glucose Biographer-P990026, http://www.fda.gov/cdrh/pdf/p990026.html].

[0005] According to the manufacturer's information a system for continuous glucose monitoring shall be able to allow therapy decision without confirmaton by a conventional measuring system. [Feldman B, Brazg R, Schwartz S, Weinstein R. A Continuous Glucose Sensor Based on Wired Enzyme Technology. Diabetes Technology & Therapeutics, 5, 5, 769-779, 2003].

[0006] WO 03/030731 A1 relates to the measurement of an actual blood glucose value with an error and to the application of a transfer function to this erroneous value, so that an adjusted value is displayed that always leads to a treatment that is not dangerous to the patient. EP 1 281 351 A1 relates to a system that predicts a glucose value at a predetermined time in the future. No measurement errors or other errors are taken into account. CHASSIN L J ET AL: "Evaluation of glucose controllers in virtual environment: methodology and sample application", ARTIFICIAL INTELLIGENCE IN MEDICINE, ELSEVIER, NL, vol.32, no.3, 1. November 2004, pages 171 - 181 deals with a methodology to test glucose controllers of an artificial pancreas in a simulated (virtual) environment. An error is considered in form of a particular measurement error of the glucose sensor or an error of the insulin delivery.

BRIEF SUMMARY OF THE INVENTION

[0007] It is a general objective of the invention to provide a device being a blood glucose meter or an insulin pump or a continuous glucose monitor that allows a person with diabetes or a practioner to predict a postprandial blood glucose value. It is a further object of the invention to provide a computer program for determining postprandial glucose concentration. Now, in order to implement these and still further objects of the invention, which will become more readily apparent as the description proceeds, the invention is manifested by a device being a blood glucose meter or an insulin pump or a continuous glucose monitor being adapted for determining postprandial blood glucose with the features of claim 1.

[0008] Included as parameters are:

a) preprandial measurement, b) effect of carbohydrate portions (CARB-P) on maximum glucose increase, c) patient estimate of carbohydrate amounts in food, d) effect of insulin on maximum glucose decrease, e) insulin dosage. The invention analyzes (for example in 1mg/dl steps) the maximum effect of the above parameters (including the margins of error of at least the parameter of preprandial measurement) on postprandial glucose. Covering preferably the clinically relevant range of preprandial blood glucose values (30-330 mg/dl) the device simulates the postprandial blood glucose values as outcome according to a treatment algorithm in adult persons with diabetes. If the postprandial "outcome" is not normoglycemia but turns into hyperglycemia or hypoglycemia, a "critical point (CP)" can be evaluated. All of the above parameters can induce a critical point of postprandial blood glucose if they reach a specific margin of error. The invention in all its forms relates to the measurement of blood glucose.

[0009] The device is a blood glucose meter or a continuous glucose monitor or an insulin pump, with the features of

claim 1. Covering preferably the clinically relevant range of preprandial blood glucose values (30-330 mg/dl) the device simulates the postprandial blood glucose values as outcome according to a treatment algorithm.

[0010] The device can then give a suggestion of treatment based on the postprandial glucose. It can avoid reaching a critical point by giving advice or perform functions that avoid reaching the critical point.

[0011] The invention is further manifested by a software program or a data carrier including such a program that is provided with the features of claim 8. Covering preferably the clinically relevant range of preprandial blood glucose values (30-330 mg/dl) the program simulates the postprandial blood glucose values as outcome according to a treatment algorithm.

[0012] In the invention an error is as well taken into account for one or several of

- effect of carbohydrate-portion on maximum glucose incrase, preferably blood glucose increase,
- estimate of carbohydrate amount in meal
- the effect of prandial insulin on maximum glucose decrease, preferably blood glucose decrease,
- insulin dosage.

[0013] In a preferred embodiment of the invention postprandial glucose is determined for different ranges of preprandial blood glucose values, according to the therapeutic scheme and the result is displayed as postprandial blood glucose over preprandial glucose. In a further preferred embodiment it is determined whether a critical point is reached by exceeding a lower limit for glucose or by exceeding an upper limit for glucose, preferably again for blood glucose.

[0014] It is further preferred that the therapeutic scheme includes a preprandial insulin dose self-adjustment according to the relation:

BG (mg/dl): <61 61-80 81-120 121-160 161-200 201-240 241-300 301-360 Ins.-Dose (U) : 0 -1Y Y +1Y +2Y +3Y +4Y +5Y wherein Y equals e.g. 1 unit insulin per 1 CARB-P for the blood glucose range of 81-120 mg/dl.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The invention will be better understood and objects other than those set forth above will become apparent when consideration is given to the following detailed description thereof. Such description makes reference to the annexed drawings, wherein

Figure 1 shows parts of a screenshot of a first embodiment of the invention;
Figure 2 shows a list of the parameters of the device or program according to this embodiment of the invention;
Figure 3 shows a table of the margins of error for the parameters of Figure 2;
Figure 4 shows a diagram generated by the device or program according to the invention with zero error of all parameters;
Figure 5 shows a diagram as in Figure 4 but with a +20% error of preprandial self-monitored blood glucose;
Figure 6 shows another diagram as in Figure 5 with an error of 12% for the self-monitored blood glucose;
Figure 7 shows a diagram as in Figure 5 but with an error of +25%;
Figure 8 shows a diagram as in Figure 5 but with an error of +40%;
Figure 9 shows a table of parameter errors leading to critical point in postprandial blood glucose;
Figure 10 shows a known error grid model for judging acceptance of measurement errors;
Figure 11 shows a new error grid model;
Figure 12 shows the new error grid model used to measure the quality of blood glucose measurements;
Figure 13 shows the new error grid model in comparison with the known EGA model

DETAILED DESCRIPTION OF THE INVENTION

[0016] **Figure 1** shows a screenshot of a preferred embodiment of the invention. As explained above, the invention can be embodied as a devicebeing a glucose meter or an insulin pump or a continuous glucose monitor or as a program. All these embodiments are encompassed when the invention is explained in the following and sometimes called as Diabetes Error Test Model (DETM).

[0017] The preferred DETM "calculates" the postprandial blood glucose value. Preferably it does not show a blood glucose (BG) curve over time but focuses mainly on the maximum effect resulting from insulin and carbohydrates consumed. However, these are not the only factors contributing to the BG result. There are numerous factors that affect the postprandial BG. The following are taken into account in the DETM and are shown in **Figure 2** as parameters that can be set. **Figure 3** shows the margins of error that are used in the present embodiment of the invention. The parameters can be set in the shown example by entering values in the fields and by moving the shown slide input means (Figure

1). Of course in other embodiments of the invention, for example in a device being a blood glucose meter or a continuous glucose monitor, parameters will be either measured directly, such as preprandial blood glucose or be entered via input means on the device or being stored beforehand. The parameters shown in Figures 1 and 2 are: a) The preprandial blood glucose (BG) being in the range of 30mg/dl to 330mg/dl which has actually been measured preprandial by a device for self-monitoring of blood glucose, for example with a strip blood glucose meter; b) the variability or effect of a carbohydrate portion, giving the blood glucose increase in mg/dl of one carbohydrate portion and being settable between 20mg/dl and 80mg/dl; c) the amount of carbohydrate portions the patients aims or estimates to eat (C-P) with a value of 1 to 5; d) the variability or effect of the insulin, giving the blood glucose decrease in mg/dl for a unit of insulin and being settable between 30mg/dl and 50mg/dl; and e) the insulin dosage.

[0018] **Figure 3** shows the margin of error for the parameters: a) the error in % with which the pre-prandial glucose concentration has been measured, with a range of -50% to +50% error (0% meaning no error); b) the error or variability of the effect of the carbohydrate effect with 45mg/dl as normal value and an error of up to 80mg/dl and down to 20mg/dl; c) the error in estimating the desired amount of carbohydrate portions in % between 40% and 200% and wherein 100% means no error in estimating by the person with diabetes; d) the error or variability of the glucose concentration decrease by the insulin with a value of 40mg/dl as errorless value and highest and lowest error values of 50mg/dl and 30mg/dl; and e) the error in dosing the correct amount of insulin in % and being settable between -25% and +50% wherein 0% means no error in dosing.

[0019] The treatment algorithm used in the DETM is based on the clinical experience of the German Diabetes Research Institute/German Diabetes Centre at the Heinrich-Heine-University of Duesseldorf and can be shown in table 1 and table 2:

Table 1

Carbohydrate Self-adjustment in relation to pre-prandial BG:
(Base: X number of CARB-P (X = 1, 2, 3, 4 or 5) for BG-range 61-120 mg/dl)

BG (mg/dl)	<40	40-60	61-120	121-160	161-200	201-240	241-300	301-360
CARB-P (n)	X+2	X+1	X	X-1	X-2	X-3	X-4	X-5

Table 2

Pre-prandial Analog-Insulin Dose Self-adjustment
(Base: Y; e.g. I U/ I CARB-P for BG range 81-120 mg/dl)

BG (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Ins.-Dose (U)	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

[0020] So, as an example of table 1 if in the blood glucose range of 61 to 120 mg/dl a carbohydrate portion X of 1 to 5 is considered, this portion value will be adjusted to X-2 when the self-monitored blood glucose value is in the range of 161 to 200 mg/dl.

[0021] As an example of table 2, one unit of insulin (Y) is considered per carbohydrate portion if the self-monitored pre-prandial blood glucose value is in the range of 81 to 120mg/dl but is made higher by +2 units if the blood glucose value is in the range of 161 to 200mg/dl. Other treatment algorithms could be used as well but the preferred algorithm is simple to implement since it is based on addition and subtraction of carbohydrate portions and insulin units for the shown ranges of preprandial self-monitored blood glucose. The ranges can be shifted to vary the algorithm and fractions of insulin units or carbohydrate portion could be used.

[0022] The aim of the treatment algorithm is to lead the patient's BG to normoglycemia (60-160 mg/dl), whole blood. This range from 60-160 mg/dl is called target range. Of course it can be chosen to either adjust using insulin or carbohydrates for BG>120 mg/dl. As an example a calculation based on the preferred treatment algorithm can be shown as follows wherein the error of the self-monitored blood glucose is taken into account by 10% and for example additionally the errors of carbohydrate and insulin effects could be considered but are set to zero % in this calculation, so the blood glucose increase of one portion carbohydrates is 45mg/dl and the decrease caused by the insulin is 40mg/dl:

True BG: 120
Measurement error: 10%
Effect CARP-P: 45

Effect insulin: 40
Error: 0%
Number of carb. portions: 5 Carp-P
True BG with error (measured blood glucose): 120mg/dl x 1,1 = 132mg/dl

[0023] According to the treatment algorithm above 132mg/dl leads to:

either 1 CARP-P less than intended is eaten (X-1) since the blood glucose is now in the range of 121 to 160 and thus 120mg/dl + (4*45mg/dl) - (5*40mg/dl) = 100mg/dl and thus normoglycemia;
or 1 additional unit insulin is administered (+1Y) if the intended carbohydrate portion is eaten since the blood glucose is now in the range of 121 to 160, and thus 120mg/dl +(5*45)-(6*40) = 105mg/dl and thus normoglycemia.

[0024] The device and program according to the invention allows to calculate the postprandial blood glucose as the outcome of the pre-prandial blood glucose if the therapeutic action is taken according to the algorithm (or if the case may be, not according to the invention, according to another algorithm). Preferably the values of postprandial glucose concentration is then displayed over pre-prandial measured glucose concentration. At first, the effects of BG measurement errors are evaluated while all other parameters are kept at 0% error. **Figure 4** shows postprandial glucose concentration kept within the target range (shown by the horizontal lines at 60mg/dl and 160mg/dl posprandial glucose concentration). As an indicator for the error of the self-monitored glucose concentration the 0% error line is additionally shown which is usually not the case, so that the preferred display shows only measured pre-prandial blood glucose values on the horizontal x-axis and calculated postprandial blood glucose values on the lefthand vertical y-axis.

[0025] The DETM-program can display all variables relevant in the calculation of the glucose concentration outcome in an additional window not shown in Figure 1. Among those are the final carbohydrate portions the patients will eat after considering his current situation (C-P), the insulin he needs to apply (Y IU) and of course the glucose concentration result (BG_R). The "interesting" values can be checked to be displayed in a graph as for example shown in **Figure 4.** This graph can display the postprandial glucose concentration in relation to one changing variable. The other variables are kept constant to the set value. The preferred graph used most often is the shown relation between the pre-prandial (reference) glucose concentration (with values between 30 and 330 mg/dl) and the postprandial outcome.

[0026] In the graph of **Figure 4** it can be seen that with all parameters kept at 0% error all preprandial values from 30-330 mg/dl will result in postprandial values between 60 and 160 mg/dl target range). The characteristic saw tooth nature of this graph and the following graphs is a result of the stepwise nature from the treatment algorithm.

[0027] **Figure 5** shows that a glucose concentration error of +20% (classified by e.g. the Error Grid Analysis as related to zone A and thus so far as allowable, see further below) results as postprandial "outcome" in normoglycemia if pre-prandial glucose concentration values are in the ranges of 30-130mg/dl and 260-330 mg/dl. However, the postprandial glucose concentration results unexpectedly in hypoglycemia if preprandial erroneous BG values are between 131 and 259 mg/dl. In this range the critical point where the target range is left for hypoglycemia is already reached at a BG measurement error of +12% as can be shown in **Figure 6**. Thus a device such as a blood glucose meter or an insulin pump will be able to display useful values or therapeutic advice if the preprandial values are in the range of 30-130mg/dl and will act accordingly while on the other hand such a device will inhibit the display of results in the range of 131-259mg/dl or will inhibit displaying therapeutical advice or will give a warning. **Figures 7 and 8** show postprandial glucose values for other error percentages of the self-monitored glucose. **Figure 7** shows the postprandial blood glucose to decrease into hypoglycemia due to a preprandial self-monitored glucose measurement with an error of +25% (with all other errors of the system kept to 0%). **Figure 8** shows a decrease into hypoglycemia due to a preprandial error of 40%.

[0028] In conclusion, the DETM device and program allow to characterize the relevance of errors of parameters affecting BG on postprandial BG outcome. It describes in detail the effects of potential errors of parameters affecting glucose concentration on postprandial glucose values within the clinically relevant glucose range. It evaluates the clinical relevance of these errors and presents a detailed risk assessment with the focus on postprandial outcome. It is therefore preferably used in educational tools for explaining the relations to people with diabetes. It is further used in devices for the diabetes care. When used in a blood glucose meter, the program will know the measurement error of this device and can therefore calculate the postprandial blood glucose and can give a warning if a critical point is reached. The device can further give a corrected treatment advice if it detects that based on the self-monitored blood glucose value, the error and the other parameters a critical point would be reached for the postprandial blood glucose value.

[0029] The Critical Point: A Critical Point is reached if (preprandial) normoglycemia turns into (postprandial) hypo- or hyperglycemia or (preprandial) hyperglycemia turns into (postprandial) hypoglycemia or (preprandial) hypoglycemia turns into (postprandial) hyperglycemia. For example if the glucose measurement error is 11% this leads for the pre-prandial glucose value of 219 mg/dl to a postprandial value of 59 mg/dl (outside the target range). As 11% is the lowest value for the glucose measurement error to result in at least one value outside the target range this is called the Critical Point. **Figure 9** shows a table of critical points reached by parameter errors.

[0030] The treatment algorithm can be extended to Continuous Glucose Monitoring (CGM). The following assumptions are made for possible glucose changes:

Very Fast glucose increase	>+ 2 mg/dl/min	UU
Fast	+ (1 - 2) mg/dl/min	U
Slow changes	<± 1 mg/dl/min	=
Fast decrease	-(1 -2)mg/dl/min	D
Very Fast decrease	>- 2 mg/dl/mim	DD

	glucose-Trend (mg/dl/min)		glucose-Change(mg/dl) in 30 minutes	
	mean	range	mean	range
UU	+3.0	+(2.1→3.9) →	+45	+(31 →59)
U	+1.5	+(1.0→2.0) →	+23	+(15→30)
=	±0	-0.9→+0.9 →	±0	-14→+14
D	-1.5	-(1.0→2.0) →	-23	-(15→30)
DD	-3.0	-(2.1→3.9) →	-45	-(31→59)

This leads to the following treatment algorithms for adapting the insulin units:

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Trend								
UU	**0**	**Y**	**+1Y**	**+2Y**	**+3Y**	**+4Y**	**+5Y**	**+6Y**
U	**0**	**-1Y**	**Y**	**+1Y**	**+2Y**	**+3Y**	**+4Y**	**+5Y**
=	**0**	**-1Y**	**Y**	**+1Y**	**+2Y**	**+3Y**	**+4Y**	**+5Y**
D	**0**	**-2Y**	**-1Y**	**Y**	**+1Y**	**+2Y**	**+3Y**	**+4Y**
DD	**0**	**-3Y**	**-2Y**	**-1Y**	**Y**	**+1Y**	**+2Y**	**+3Y**

In the DETM-program or device the CGM-algorithms can be used for any calculation made. In particular the device in this case of algorithm is a continuously measuring glucose monitor.

[0031] By using the DETM algorithms, an error grid model similar to the EGA can be calculated, called hereinafter the EAA. **Figure 10** shows the EGA as known. [Joan L.Parkes, Scott Pardo, Stephen 1. Slatin, Barry H. Ginsberg, "A new consensus Error Grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose", Diabetes Care, Vol 23, No. 8, pages 1143-1148, August 2000].

[0032] By using the DETM program with the preferred algorithms, an error grid model similar to the EGA can be calculated:

The target range is amended with an acceptance range (50-200 mg/dl); the target range is the equivalent to EGA zone A; the acceptance range is the equivalent to EGA zone B; for the EAA it is calculated which measurement error at which pre-prandial glucose value leads to a post-prandial BG value outside the target/acceptance range

[0033] The result is a relation between preprandial reference glucose and preprandial self-monitored glucose as shown in **Figure 11.** The full lines represent the target range, the dotted lines the acceptance range. The EAA can now be used to measure the quality of glucose measurements by projecting the reference value and self-measurement value into the grid as shown in **Figure 12.** Points outside the full/dotted lines mean, that if a patient measured this value (with the corresponding reference value), his/her glucose concentration would result in hypo/hyperglycemia after applying his treatment algorithm. In this figure most of the points lie between the lines, but several points are outside (above). This means that using this glucose meter, the patient is in danger of ending up in hypoglycemia.

[0034] In order to evaluate the exact risk, the program offers the option of calculating both EAA and EGA as shown in **Figure 13:** In this calculation it can be seen that 9% of the points are outside the acceptance range. Interestingly; no point is outside zone A of the EGA. This means, that according to the EGA, this measurement device is perfect, according to the EAA it is unusable. The EGA can be painted into the EAA as shown to provide an optical visualization.

[0035] Notes and considerations: the DETM and treatment algorithms are calibrated to whole blood. Nevertheless the system, tools, devices and the program may offer the option of switching to plasma. The DETM focuses on the BG-

outcome after food intake and insulin administration (with several side effects).

[0036] The EAA focuses on evaluating the quality of a measurement device. This quality depends on the treatment algorithm used (which can be adapted in the DETM-program).

Continuous glucose monitoring is implemented using slight modifications to the standard treatment algorithm without breaking the scheme.

All parameters/features can be combined. This means, that e.g. all EAA calculations can be performed for higher insulin impact then usual.

The DETM-program has preferably a database attached so that results from tests of measurement devices can be stored and selected easily

[0037] The measurement error of an analytical system such as a blood glucose meter or a continuous glucose monitor influences the usefulness and significance of the analytical result. If the measured glucose value is outside of a physiologically preferable concentration a therapeutic action is initiated with the aim of restoring the physiologically preferred state. In case of diabetes mellitus therapeutical interventions such as administering.insulin or carbohydrates are taken to bring the concentration of glucose back to normoglycemia. The analytical result can be displayed or otherwise presented as numerical value or as a therapeutic advice based on the measurement which can be a single measurement or a measurement and a consideration of earlier measurements as in continuous glucose monitoring.

[0038] While there are shown and described presently preferred embodiments of the invention, it is to be distinctly understood that the invention is not limited thereto but may be otherwise variously embodied and practiced within the scope of the following claims.

Claims

1. A device being a blood glucose meter or an insulin pump or a continuous glucose monitor, being adapted for determining postprandial glucose concentration by analyzing the maximum effect of the following parameters on postprandial glucose

- preprandial glucose measurement by self-monitoring of glucose
- effect of carbohydrate-portion on maximum glucose concentration increase
- estimate of carbohydrate amount in meal
- the effect of prandial insulin on maximum glucose concentration decrease
- insulin dosage

that are either measurable directly by the device or enterable via input means of the device or being storable beforehand in the device, wherein the device is adapted to calculate postprandial glucose values based on a therapeutic action scheme, simulating the postprandial blood glucose values as outcome according to a treatment algorithm in adult persons with diabetes, **characterised in that**: the device is adapted to include a margin of error for self-monitored preprandial glucose in the analysis and wherein
the device is further adapted in include
a margin of error during analysis for one or several of the parameters

- effect of carbohydrate-portion on maximum glucose concentration increase
- estimate of carbohydrate amount in meal
- the effect of prandial insulin on maximum glucose concentration decrease
- insulin dosage,

and
wherein the therapeutic action scheme includes a carbohydrate self-adjustment in relation to preprandial glucose concentration according to the relation:

Glucose (mg/dl)	<40	40-60	61-120	121-160	161-200	201-240	241-300	301-360
CARB-P (n)	X+2	X+1	X	X-1	X-2	X-3	X-4	X-5

wherein X equals the number of carbohydrate portions (X = 1, 2, 3, 4 or 5) for the glucose-range of 61-120 mg/dl.

2. A device according to claim 1 wherein the device is adapted to determine postprandial glucose concentration for different ranges of preprandial glucose values according to the therapeutic action scheme.

3. A device according to one of claims 1 or 2 wherein the device is adapted to display the result as postprandial glucose concentration over preprandial glucose concentration.

4. A device according to one of claims 1 to 3 wherein the device is adapted to determine whether a critical point is reached by exceeding a lower limit for glucose concentration or by exceeding an upper limit for glucose concentration.

5. A device according to one of claims 1 to 4 wherein the therapeutic action scheme includes a preprandial insulin dose self-adjustment according to the relation:

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Ins.-Dose (U)	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

wherein Y equals e.g. 1 unit insulin per 1 CARB-P for the glucose range of 81-120 mg/dl.

6. A device according to one of claims 1 to 4 wherein a trend of a continuous glucose monitoring is considered as follows

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Trend								
UU	0	Y	+1Y	+2Y	+3Y	+4Y	+5Y	+6Y
U	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
=	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
D	0	-2Y	-1Y	Y	+1Y	+2Y	+3Y	+4Y
DD	0	-3Y	-2Y	-1Y	Y	+1Y	+2Y	+3Y

and wherein trends are defined as follows

Very Fast Glucose increase	>+ 2 mg/dl/min	UU
Fast	+(1 - 2) mg/dl/min	U
Slow changes	<± 1 mg/dl/min	=
Fast decrease	-(1 - 2) mg/dl/min	D
Very Fast decrease	>- 2 mg/dl/mim	DD

7. A computer program for determining postprandial glucose concentration by analyzing the maximum effect of the following parameters on postprandial glucose

- preprandial glucose measurement by self-monitoring of glucose
- effect of carbohydrate-portion on maximum glucose increase
- estimate of carbohydrate amount in meal
- the effect of prandial insulin on maximum glucose decrease
- insulin dosage

wherein, when run on a computer, postprandial glucose values are calculated by the program based on a therapeutic action scheme simulating the postprandial blood glucose values as outcome according to a treatment algorithm in adult persons with diabetes, wherein a margin of error for self monitored preprandial glucose is included in the analysis by the program and wherein a margin of error is as well included by the program during analysis for one or several of the parameters

- effect of carbohydrate-portion on maximum glucose increase
- estimate of carbohydrate amount in meal
- the effect of of prandial insulin on maximum blood glucose decrease
- insulin dosage,

and

wherein the therapeutic action scheme includes a carbohydrate self-adjustment in relation to preprandial glucose concentration according to the relation:

Glucose (mg/dl)	<40	40-60	61-120	121-160	161-200	201-240	241-300	301-360
CARB-P (n)	X+2	X+1	X	X-1	X-2	X-3	X-4	X-5

wherein X equals the number of carbohydrate portions (X = 1, 2, 3, 4 or 5) for the glucose-range of 61-120 mg/dl.

8. A computer program according to claim 7 wherein, when run on a computer, postprandial glucose concentration is determined for different ranges of preprandial blood glucose values according to the therapeutic action scheme.

9. A computer program according to one of claims 7 or 8 wherein , when run on a computer including a display, the result is displayed as postprandial glucose concentration over preprandial glucose concentration.

10. A computer program according to one of claims 7 to 9 wherein, when run on a computer, it is determined by the program whether a critical point is reached by exceeding a lower limit for glucose or by exceeding an upper limit for glucose concentration.

11. A computer program according to one of claims 7 to 10 wherein the therapeutic action scheme includes a preprandial insulin dose self-adjustment according to the relation:

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Ins.-Dose (U)	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

wherein Y equals e.g. 1 unit insulin per 1 CARB-P for the glucose concentration range of 81-120 mg/dl.

12. A computer pogram according to one of claims 7 to 10 wherein a trend of a continuous blood glucose monitoring is considered as follows

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Trend								
UU	0	Y	+1Y	+2Y	+3Y	+4Y	+5Y	+6Y
U	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
=	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
D	0	-2Y	- 1Y	Y	+1Y	+2Y	+3Y	+4Y
DD	0	- 3Y	- 2Y	- 1Y	Y	+1Y	+2Y	+3Y

and wherein trends are defined as follows

Very fast glucose BG increase	>+ 2 mg/dl/min	UU
Fast	+ (1- 2) mg/dl/min	U
Slow changes	<± 1 mg/dl/min	=
Fast decrease	- (1 - 2) mg/dl/min	D
Very fast decrease	>- 2 mg/dl/mim	DD

13. A data carrier containing a computer program according to one of claims 7 to 12.

Patentansprüche

1. Vorrichtung als Blutzuckermessgerät oder als Insulinpumpe oder als kontinuierliches Blutzuckerüberwachungsgerät, welche zur Feststellung der postprandialen Blutzuckerkonzentration durch Analyse des maximalen Effekts der folgenden Parameter auf den postprandialen Blutzucker ausgestaltet ist:

- Prepandiale Blutzuckermessung durch SelbstÜberwachung von Blutzucker
- Effekt einer Kohlenhydratportion auf die maximale Erhöhung der Blutzuckerkonzentration
- Schätzung des Kohlenhydratgehalts in einer Mahlzeit
- Effekt des prandialen Insulins auf die maximale Abnahme der Blutzuckerkonzentration
- Insulindosierung

die entweder direkt von der Vorrichtung messbar oder mittels Eingabemittel der Vorrichtung eingebbar sind oder die im Vorfeld in der Vorrichtung speicherbar sind, wobei die Vorrichtung zur Berechnung der postprandialen Blutzuckerwerte basierend auf therapeutische Massnahmen, welche die postprandialen Blutzuckerwerte als Resultat gemäss einem Behandlungsalgorithmus bei erwachsenen Personen mit Diabetes simuliert, ausgestaltet ist, **dadurch gekennzeichnet, dass** die Vorrichtung zur Einbeziehung eines Fehlerbereichs für selbst-überwachtes preprandiales Insulin in die Analyse ausgestaltet ist und wobei die Vorrichtung weiter zur Einbeziehung eines Fehlerbereichs während der Analyse eines oder mehrerer der Parameter ausgestaltet ist:

- Effekt der Kohlenhydratportion auf die maximale Erhöhung der Blutzuckerkonzentration
- Schätzung des Kohlenhydratgehalts in einer Mahlzeit
- Effekt des prandialen Insulins auf die maximale Abnahme der Blutzuckerkonzentration
- Insulindosierung,

und
wobei die therapeutische Massnahme eine Selbstregulierung der Kohlenhydrate abhängig von der preprandialen Blutzuckerkonzentration gemäss der Relation:

Blutzucker (mg/dl)	<40	40-60	61-120	121-160	161-200	201-240	241-300	301-360
CARB-P (n)	X+2	X+1	X	X-1	X-2	X-3	X-4	X-5

umfasst, wobei X gleich der Anzahl der Kohlenhydratportionen (X = 1, 2, 3, 4 oder 5) für den Blutzuckerbereich von 61-120 mg/dl ist.

2. Vorrichtung nach Anspruch 1, wobei die Vorrichtung zur Feststellung der postprandialen Blutzuckerkonzentration für unterschiedliche Bereiche der preprandialen Blutzuckerwerte gemäss den therapeutischen Massnahmen ausgestaltet ist.

3. Vorrichtung nach einem der Ansprüche 1 oder 2, wobei die Vorrichtung zur Anzeige des Ergebnisses als postprandiale Blutzuckerkonzentration über preprandiale Blutzuckerkonzentration ausgestaltet ist.

4. Vorrichtung nach einem der Ansprüche 1 bis 3, wobei die Vorrichtung derart ausgestaltet ist, dass sie feststellt, ob ein kritischer Punkt durch die Unterschreitung einer Untergrenze der Blutzuckerkonzentration oder durch die Überschreitung einer Obergrenze der Blutzuckerkonzentration erreicht ist.

5. Vorrichtung nach einem der Ansprüche 1 bis 4, wobei die therapeutischen Massnahmen eine preprandiale Selbstregulierung der Insulindosierung gemäss der Relation:

Blutzucker (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Insulindosierung (U)	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

umfasst, wobei Y gleich z.B. einer Insulineinheit pro 1 CARB-P für den Blutzuckerbereich von 81-120 mg/dl ist.

6. Vorrichtung nach einem der Ansprüche 1 bis 4, wobei ein Trend einer kontinuierlichen Blutzuckerüberwachung wie folgt berücksichtigt wird

Blutzucker (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Trend								
UU	0	Y	+1Y	+2Y	+3Y	+4Y	+5Y	+6Y
U	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

(fortgesetzt)

Blutzucker (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Trend								
=	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
D	0	-2Y	-1Y	Y	+1Y	+2Y	+3Y	+4Y
DD	0	-3Y	-2Y	-1Y	Y	+1Y	+2Y	+3Y

und wobei Trends wie folgt definiert sind

Sehr schnelle Blutzuckererhöhung	>+2	mg/dl/min	UU
Schnell	+(1-2)	mg/dl/min	U
Langsame Änderungen	<+/- 1	mg/dl/min	=
Schnelle Abnahme	-(1-2)	mg/dl/min	D
Sehr schnelle Abnahme	>-2	mg/dl/min	DD

7. Computerprogramm zur Feststellung der preprandialen Blutzuckerkonzentration durch Analyse des maximalen Effekts der folgenden Parameter auf den postprandialen Blutzucker

- prepandiale Blutzuckermessung durch SelbstÜberwachung von Blutzucker
- Effekt einer Kohlenhydratportion auf die maximale Erhöhung der Blutzuckerkonzentration
- Schätzung des Kohlenhydratgehalts in einer Mahlzeit
- Effekt des prandialen Insulins auf die maximale Abnahme der Blutzuckerkonzentration
- Insulindosierung

wobei die postprandialen Blutzuckerwerte vom Programm, wenn dieses auf einem Computer ausgeführt wird, basierend auf therapeutische Massnahmen, welche die postprandialen Blutzuckerwerte als Resultat gemäss einem Behandlungsalgorithmus bei erwachsenen Personen mit Diabetes simuliert, berechnet wird, wobei ein Fehlerbereich für selbst-überwachtes preprandiales Insulin vom Programm in die Analyse einbezogen wird und wobei ein Fehlerbereich während der Analyse eines oder mehrerer Parameter auch vom Programm einbezogen wird:

- Effekt der Kohlenhydratportion auf die maximale Erhöhung der Blutzuckerkonzentration
- Schätzung des Kohlenhydratgehalts in einer Mahlzeit
- Effekt des prandialen Insulins auf die maximale Abnahme der Blutzuckerkonzentration
- Insulindosierung,

und
wobei die therapeutischen Massnahmen eine Selbstregulierung der Kohlenhydrate abhängig von der preprandialen Blutzuckerkonzentration gemäss der Relation:

Blutzucker (mg/dl)	<40	40-60	61-120	121-160	161-200	201-240	241-300	301-360
CARB-P (n)	x+2	X+1	X	X-1	X-2	X-3	X-4	X-5

umfasst, wobei X gleich der Anzahl der Kohlenhydratportionen (X = 1, 2, 3, 4 oder 5) für den Blutzuckerbereich von 61-120 mg/dl ist.

8. Computerprogramm nach Anspruch 7, wobei die postprandiale Blutzuckerkonzentration für unterschiedliche Bereiche der preprandialen Blutzuckerwerte gemäss den therapeutischen Massnahmen festgestellt wird, wenn das Computerprogramm auf einem Computer ausgeführt wird.

9. Computerprogramm nach einem der Ansprüche 7 oder 8, wobei das Ergebnis als postprandiale Blutzuckerkonzentration über preprandiale Blutzuckerkonzentration angezeigt wird, wenn das Computerprogramm auf einem Computer mit einem Display ausgeführt wird.

10. Computerprogramm nach einem der Ansprüche 7 bis 9, wobei vom Computerprogramm festgestellt wird, wenn ein

kritischer Punkt durch die Unterschreitung einer Untergrenze der Blutzuckerkonzentration oder durch die Überschreitung einer Obergrenze der Blutzuckerkonzentration erreicht ist, wenn das Computerprogramm auf einem Computer ausgeführt wird.

11. Computerprogramm nach einem der Ansprüche 7 bis 10, wobei die therapeutischen Massnahmen eine preprandiale Selbstregulierung der Insulindosierung gemäss der Relation:

Blutzucker (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Insulindosierung (U)	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

umfasst, wobei Y gleich einer Insulineinheit pro 1 CARB-P für den Blutzuckerbereich von 81-120 mg/dl ist.

12. Computerprogramm nach einem der Ansprüche 7 bis 10, wobei ein Trend einer kontinuierlichen Blutzuckerüberwachung wie folgt berücksichtigt wird

Blutzucker (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Trend								
UU	0	Y	+1Y	+2Y	+3Y	+4Y	+5Y	+6Y
U	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
=	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
D	0	-2Y	-1Y	Y	+1Y	+2Y	+3Y	+4Y
DD	0	-3Y	-2Y	-1Y	Y	+1Y	+2Y	+3Y

und wobei Trends wie folgt definiert sind

Sehr schnelle Blutzuckererhöhung	>+2	mg/dl/min	UU
Schnell	+(1-2)	mg/dl/min	U
Langsame Änderungen	<+/- 1	mg/dl/min	=
Schnelle Abnahme	-(1-2)	mg/dl/min	D
Sehr schnelle Abnahme	>-2	mg/dl/min	DD

13. Datenträger mit einem Computerprogramm nach einem der Ansprüche 7 bis 12.

Revendications

1. Dispositif étant un appareil de mesure de glycémie ou une pompe à insuline ou un appareil de surveillance continue de la glucose, étant adapté à déterminer la concentration de glucose post-prandiale en analysant l'effet maximale de paramètres suivants sur la glucose post-prandiale

- mesure de glucose pre-prandiale par une autosurveillance de glucose
- effet d'une portion glucidique sur l'augmentation maximale de la concentration de glucose
- estimation du contenu de glucide dans un repas
- l'effet d'insuline prandiale sur la réduction maximale de la concentration de glucose
- dosage d'insuline

qui sont ou mesurable directement par le dispositif ou qui peuvent être entrés par des moyen d'entrée du dispositif ou qui peuvent être enregistrés au préalable dans le dispositif, le dispositif étant adapté à calculer des valeurs de glucose post-prandiale basé sur des mesures thérapeutiques simulant les valeurs de glycémie post-prandiale comme un résultat selon un algorithme de traitement pour des personnes adultes atteintes du diabète, **caractérisé en ce que** le dispositif est adapté à inclure une plage d'erreurs pour une glucose pre-prandiale auto-surveillée dans l'analyse et **en ce que** le dispositif est en outre adapté à inclure une plage d'erreurs pendant l'analyse pour un ou plusieurs des paramètres

- effet d'une portion glucidique sur l'augmentation maximale de la concentration de glucose
- estimation du contenu de glucide dans un repas
- l'effet d'insuline prandiale sur la réduction maximale de la concentration de glucose
- dosage d'insuline,

et
les mesures thérapeutiques incluant un auto-ajustement de glucide dépendant de la concentration de glucose pre-prandiale selon la relation:

Glucose (mg/dl)	<40	40-60	61-120	121-160	161-200	201-240	241-300	301-360
CARB-P (n)	X+2	X+1	X	X-1	X-2	X-3	X-4	X-5

X étant égale au numéro des portions glucidiques (X = 1, 2, 3, 4, 5) pour la gamme de glucose de 61-120 mg/dl.

2. Dispositif selon la revendication 1, le dispositif étant adapté à déterminer la concentration de glucose post-prandiale pour des différentes gammes de valeurs de glucose pre-prandiale selon les mesures thérapeutiques.

3. Dispositif selon l'une des revendications 1 ou 2, le dispositif étant adapté à afficher le résultat sous forme de concentration de glucose post-prandiale en dépendance de la concentration de glucose pre-prandiale.

4. Dispositif selon l'une des revendications 1 à 3, le dispositif étant adapté à déterminer si un point critique est atteint par dépasser une limite inférieure de concentration de glucose ou par dépasser une limite supérieure de concentration de glucose.

5. Dispositif selon l'une des revendications 1 à 4, les mesures thérapeutiques incluant un auto-ajustement de la dose d'insuline pre-prandiale selon la relation:

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Dosage d'insuline (U)	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

Y étant égale à par exemple 1 unité d'insuline par 1 CARB-P pour la gamme de glucose de 81-120 mg/dl.

6. Dispositif selon l'une des revendications 1 à 4, une tendance d'une surveillance de glucose continue étant considérée comme suit

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Tendance								
UU	0	Y	+1Y	+2Y	+3Y	+4Y	+5Y	+6Y
U	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
=	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
D	0	-2Y	-1Y	Y	+1Y	+2Y	+3Y	+4Y
DD	0	-3Y	-2Y	-1Y	Y	+1Y	+2Y	+3Y

les tendances étant définies comme suit

Très rapide augmentation de glucose	>+2	mg/dl/min	UU
Rapide	+(1-2)	mg/dl/min	U
Changements lents	<+/- 1	mg/dl/min	=
Diminution rapide	-(1-2)	mg/dl/min	D
Diminution très rapide	>-2	mg/dl/min	DD

7. Programme d'ordinateur pour déterminer la concentration de glucose post-prandiale en analysant l'effet maximale des paramètres suivants sur la glucose post-prandiale

- mesure de glucose pre-prandiale par une autosurveillance de glucose
- effet d'une portion glucidique sur l'augmentation maximale de la concentration de glucose
- estimation du contenu de glucide dans un repas
- l'effet d'insuline prandiale sur la réduction maximale de la concentration de glucose
- dosage d'insuline

des valeurs de glucose post-prandiale étant calculées par le programme, lorsqu'il est exécuté sur un ordinateur, basé sur des mesures thérapeutiques simulant les valeurs de glycémie post-prandiale comme un résultat selon un algorithme de traitement pour des personnes adultes atteintes du diabète, **caractérisé en ce qu'**une plage d'erreurs pour une glucose pre-prandiale auto-surveillée est incluse dans l'analyse par le programme et **en ce qu'**une plage d'erreurs est aussi incluse par le programme pendant l'analyse pour un ou plusieurs des paramètres

- effet d'une portion glucidique sur l'augmentation maximale de la concentration de glucose
- estimation du contenu de glucide dans un repas
- l'effet d'insuline prandiale sur la réduction maximale de la concentration de glucose
- dosage d'insuline,

et
les mesures thérapeutiques incluant un auto-ajustement de glucide dépendant de la concentration de glucose pre-prandiale selon la relation:

Glucose (mg/dl)	<40	40-60	61-120	121-160	161-200	201-240	241-300	301-360
CARB-P (n)	X+2	X+1	X	X-1	X-2	X-3	X-4	X-5

X étant égale au numéro des portions glucidiques (X = 1, 2, 3, 4, 5) pour la gamme de glucose de 61-120 mg/dl.

8. Programme d'ordinateur selon la revendication 7, lorsqu'il est exécuté sur un ordinateur la concentration de glucose post-prandiale étant déterminée pour des différentes gammes de valeurs de glucose pre-prandiale selon les mesures thérapeutiques.

9. Programme d'ordinateur selon l'une des revendications 7 ou 8, lorsqu'il est exécuté sur un ordinateur avec un écran le résultat étant affiché sous forme de concentration de glucose post-prandiale en dépendance de la concentration de glucose pre-prandiale.

10. Programme d'ordinateur selon l'une des revendications 7 à 9, lorsqu'il est exécuté sur un ordinateur il est déterminé si un point critique est atteint par dépasser une limite inférieure de concentration de glucose ou par dépasser une limite supérieure de concentration de glucose.

11. Programme d'ordinateur selon l'une des revendications 7 à 10, les mesures thérapeutiques incluant un auto-ajustement de la dose d'insuline preprandiale selon la relation:

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Dosage d'insuline (U)	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

Y étant égale à par exemple 1 unité d'insuline par 1 CARB-P pour la gamme de glucose de 81-120 mg/dl.

12. Programme d'ordinateur selon l'une des revendications 7 à 10, la tendance d'une surveillance de glucose continue étant considérée comme suit

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Tendance								
UU	0	Y	+1Y	+2Y	+3Y	+4Y	+5Y	+6Y
U	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
=	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
D	0	-2Y	-1Y	Y	+1Y	+2Y	+3Y	+4Y

(suite)

Glucose (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
Tendance								
DD	0	-3Y	-2Y	-1Y	Y	+1Y	+2Y	+3Y

les tendances étant définies comme suit

Très rapide augmentation de glucose	>+2	mg/dl/min	UU
Rapide	+(1-2)	mg/dl/min	U
Changements lents	<+/- 1	mg/dl/min	=
Diminution rapide	-(1-2)	mg/dl/min	D
Diminution très rapide	>-2	mg/dl/min	DD

13. Support des données contenant un programme d'ordinateur selon l'une des revendications 7 à 12.

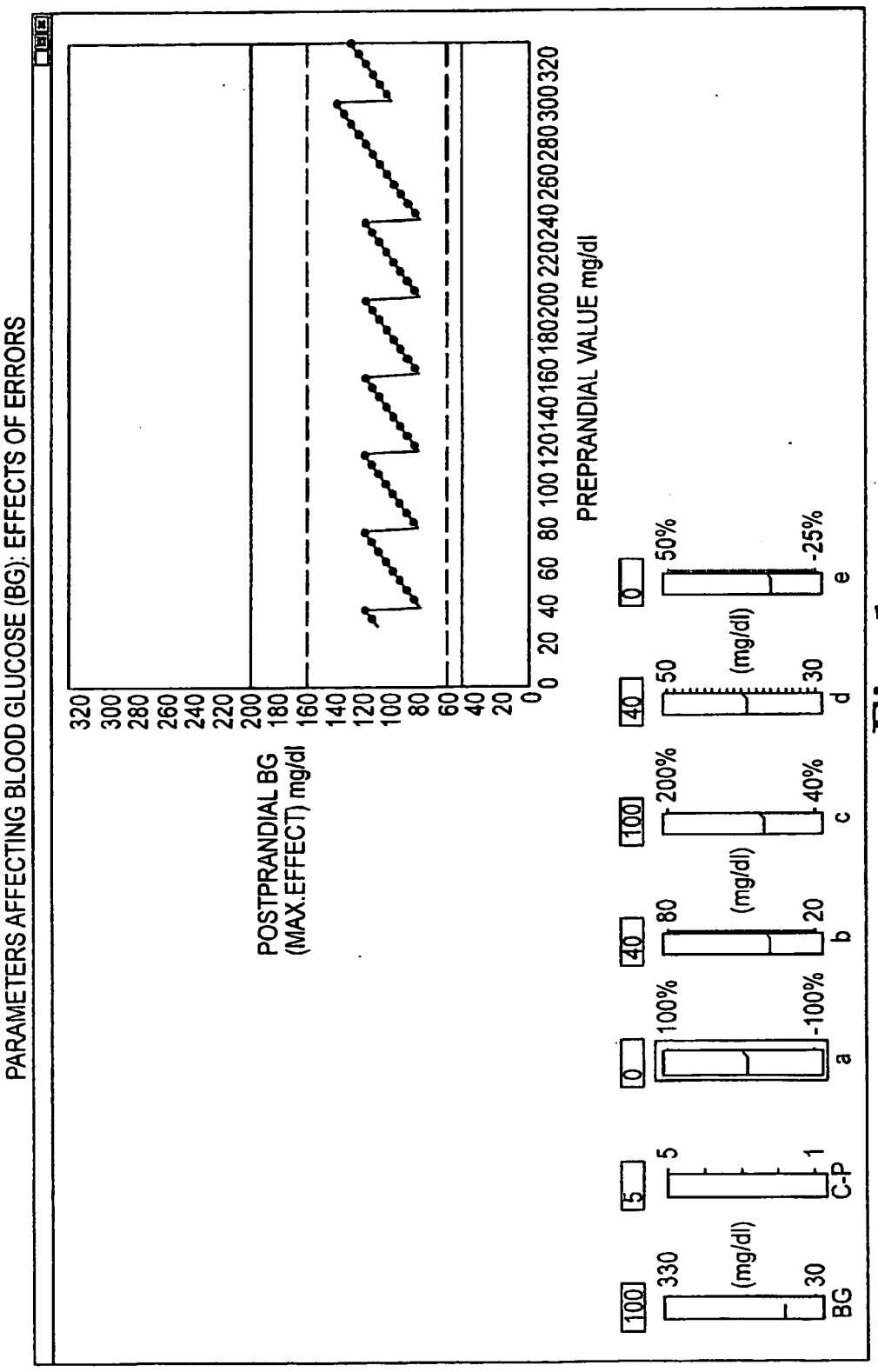
PARAMETERS AFFECTING BLOOD GLUCOSE (BG): EFFECTS OF ERRORS
POSTPRANDIAL BG (MAX.EFFECT) mg/dl
320 300 280 260 240 220 200 180 160 140 120 100 80 60 40 20 0
0 20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320
PREPRANDIAL VALUE mg/dl
100
330
(mg/dl)
30
BG
5
5
1
C-P
0
100%
-100%
a
40
80
(mg/dl)
20
b
100
200%
40%
c
40
50
(mg/dl)
30
d
0
50%
-25%
e

Fig. 1

FIG. 2

Model Parameters

a) Blood Glucose (BG) measurement (preprandial) by SMBG
b) Effect of Carbohydrate-Portion (CARB-P) on maximum BG increase
c) Patient estimate of carbohydrate amount in meals
d) Effect of s.c. prandial insulin on max. BG decrease
e) Insulin dosage

FIG. 3

	a	b	c	d	e
ME	BG Measurement %	CARB-P BG increase mg/dl	CARB Estimate %	Insulin BG decrease mg/dl	1 IU Insulin %
Highest	+50%	80	200%	50	+50%
No error	0%	40	100%	40	0%
Lowest	-50%	20	40%	30	-25%

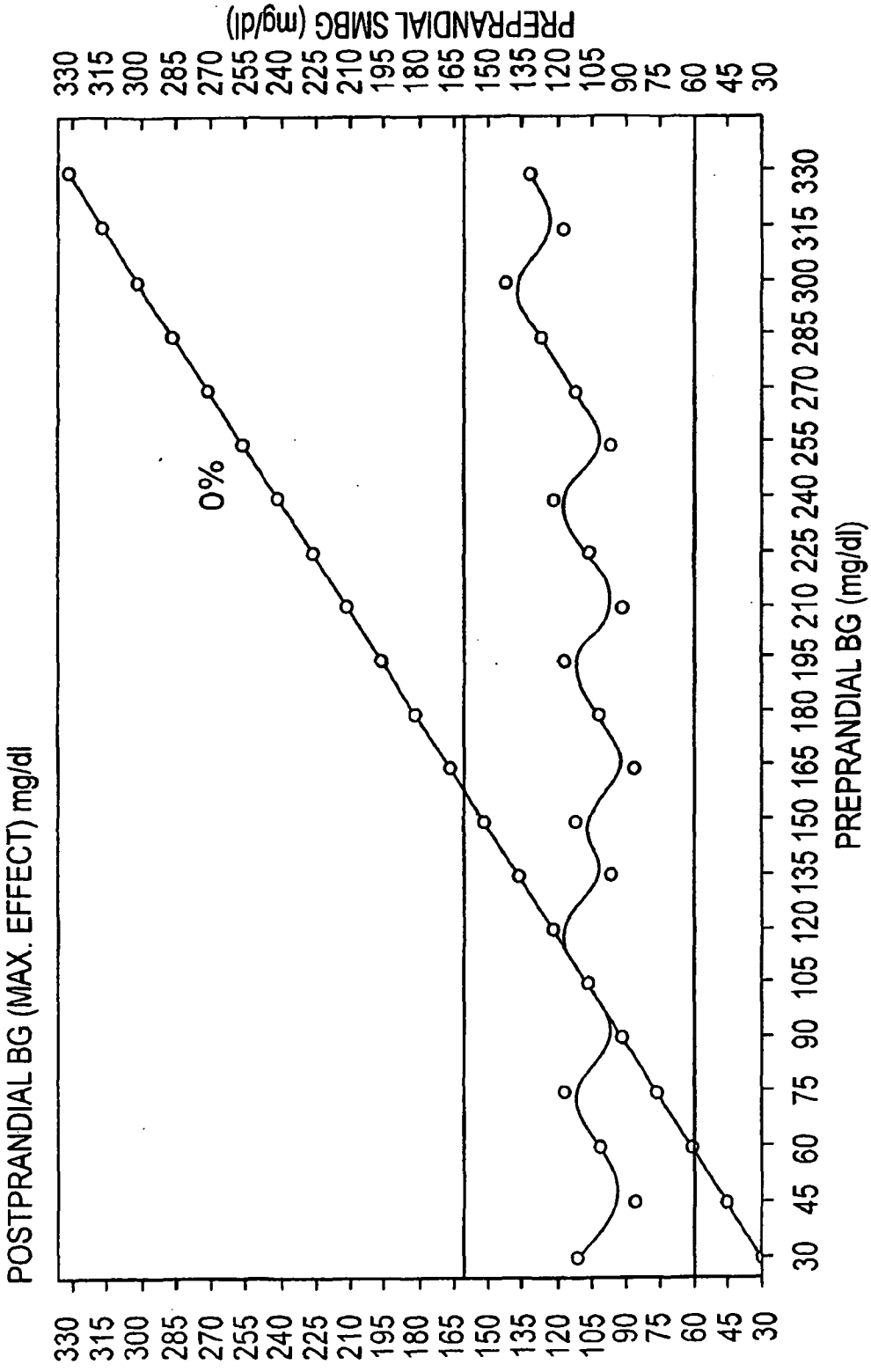
POSTPRANDIAL BG (MAX. EFFECT) mg/dl
PREPRANDIAL SMBG (mg/dl)
PREPRANDIAL BG (mg/dl)
0%
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330

Fig. 4

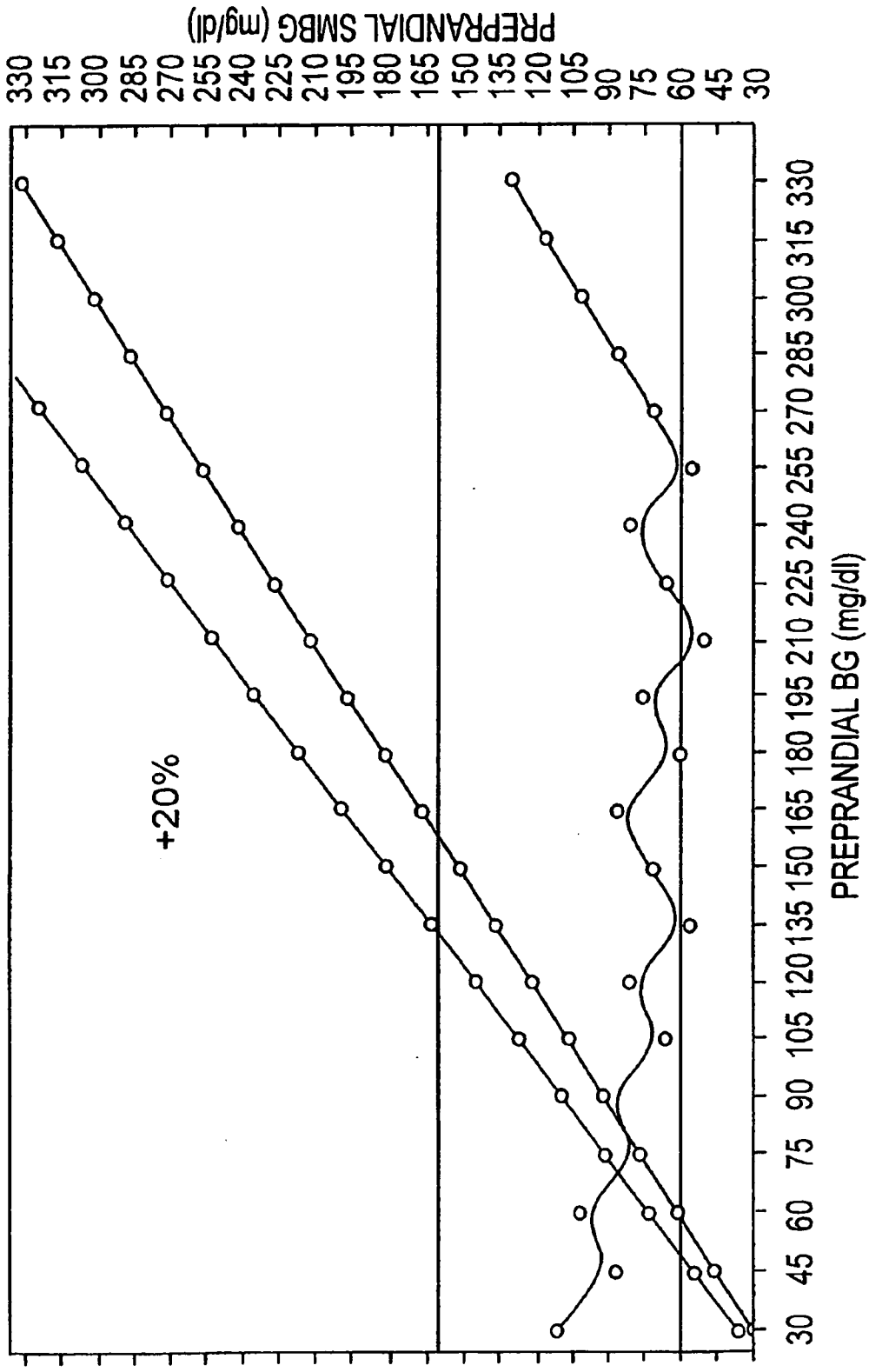
PREPRANDIAL SMBG (mg/dl)
330 315 300 285 270 255 240 225 210 195 180 165 150 135 120 105 90 75 60 45 30
+20%
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
PREPRANDIAL BG (mg/dl)

Fig. 5

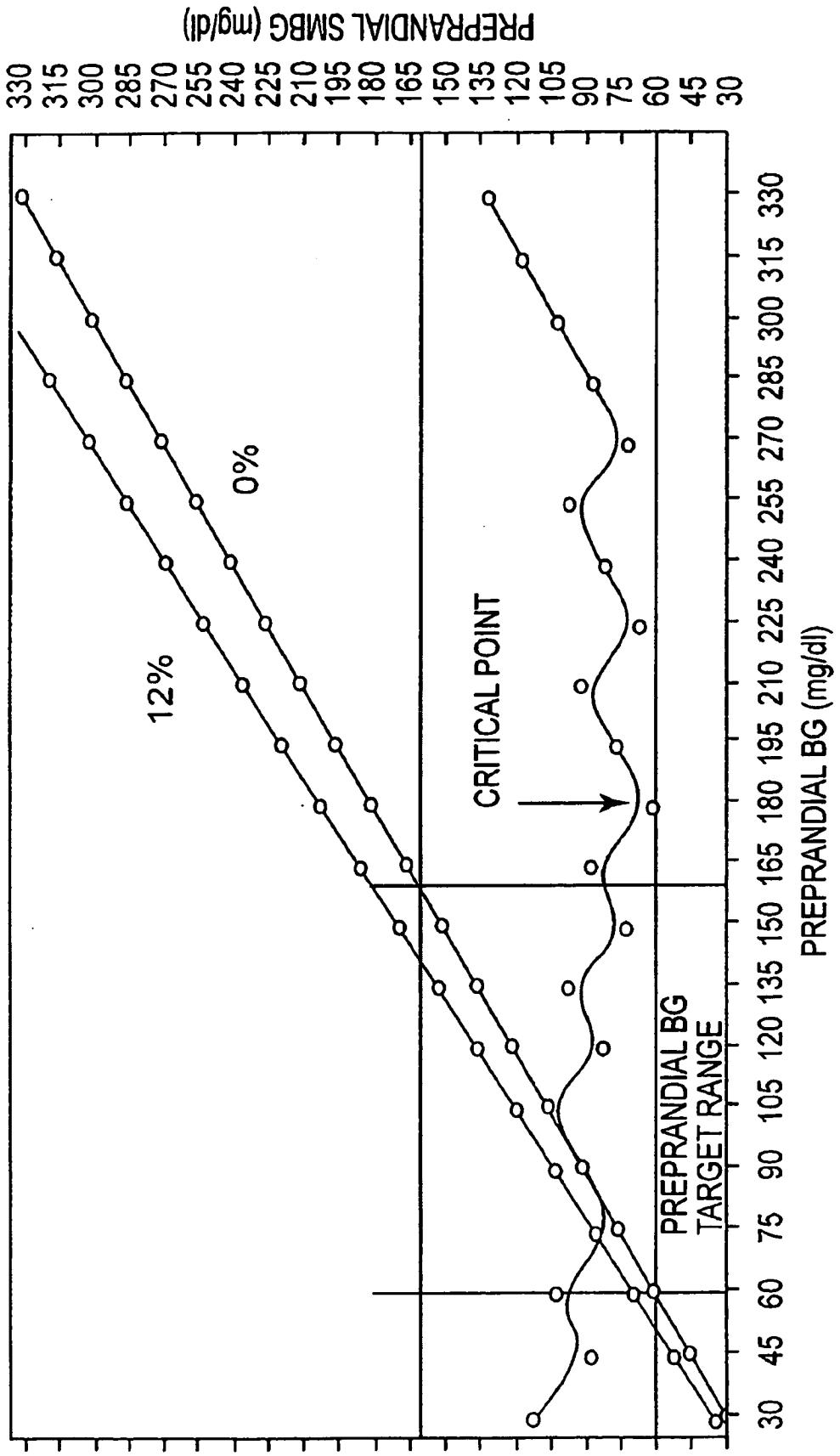
PREPRANDIAL SMBG (mg/dl)
330 315 300 285 270 255 240 225 210 195 180 165 150 135 120 105 90 75 60 45 30
12%
0%
CRITICAL POINT
PREPRANDIAL BG TARGET RANGE
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
PREPRANDIAL BG (mg/dl)

Fig. 6

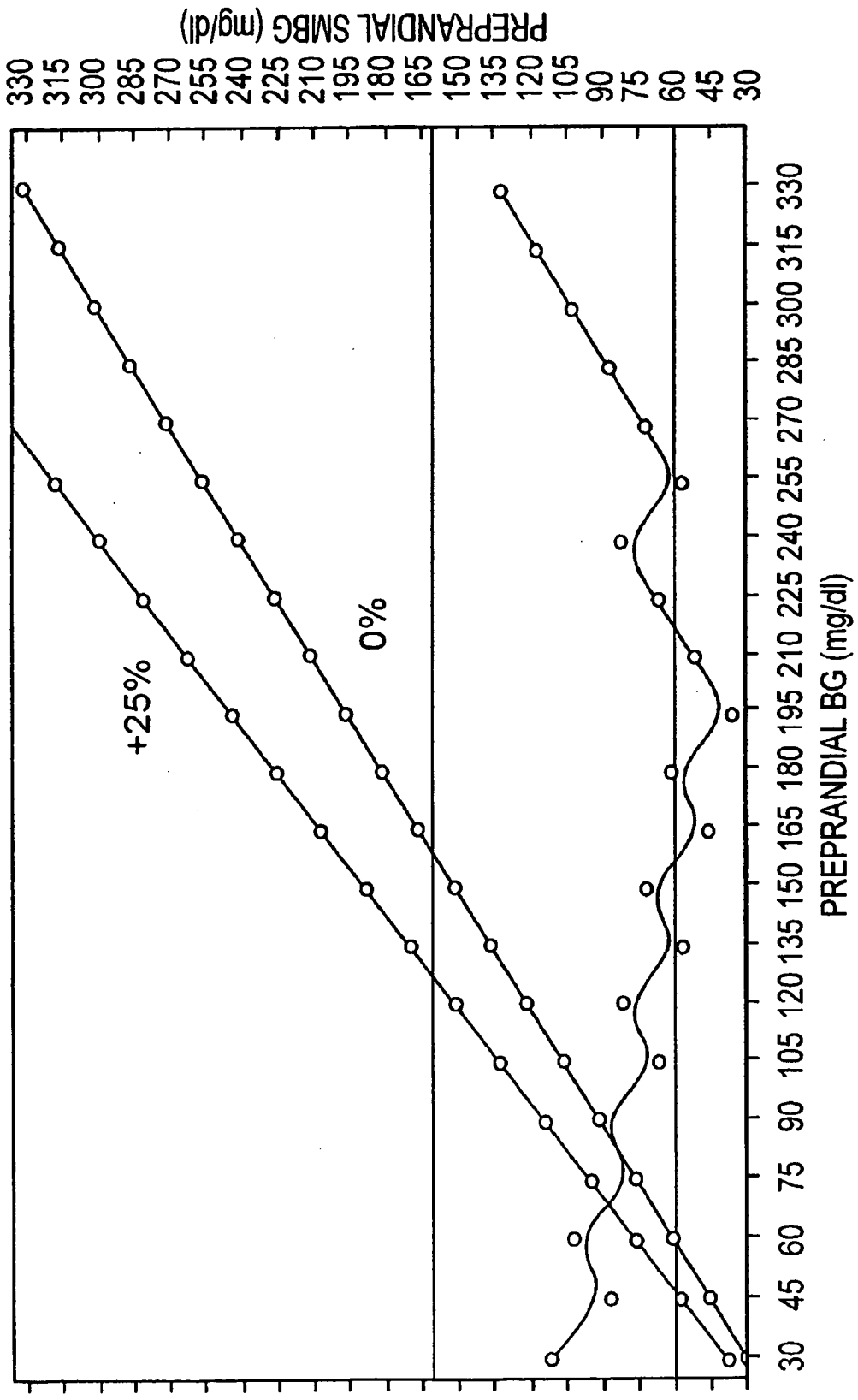
PREPRANDIAL SMBG (mg/dl)
330 315 300 285 270 255 240 225 210 195 180 165 150 135 120 105 90 75 60 45 30
+25%
0%
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
PREPRANDIAL BG (mg/dl)

Fig. 7

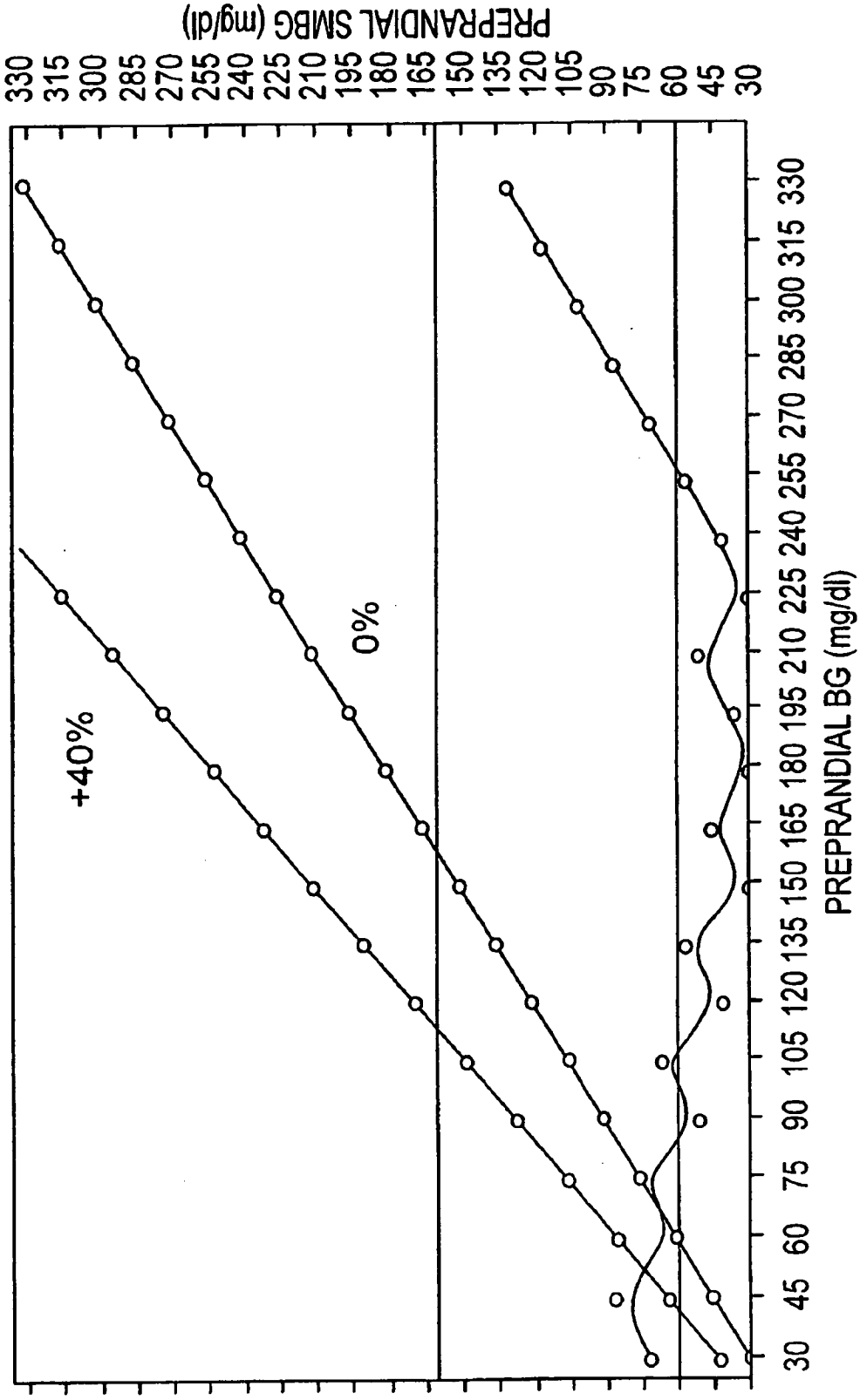
PREPRANDIAL SMBG (mg/dl)
330 315 300 285 270 255 240 225 210 195 180 165 150 135 120 105 90 75 60 45 30
+40%
0%
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
PREPRANDIAL BG (mg/dl)

Fig. 8

FIG. 9

Critical Points (CP) of Parameter Errors

Parameters affecting BG	CP Hypoglycemia Δ from mean (ideal)	CP Hyperglycemia Δ from mean (ideal)
a) SMBG Test	+12%	– 41%
b) BG↑ effect/CARB-P	– 10%	+20%
c) Estimate/CARB-P	+12%	– 20%
d) BG↓effect/ IU insulin	+10%	– 20%

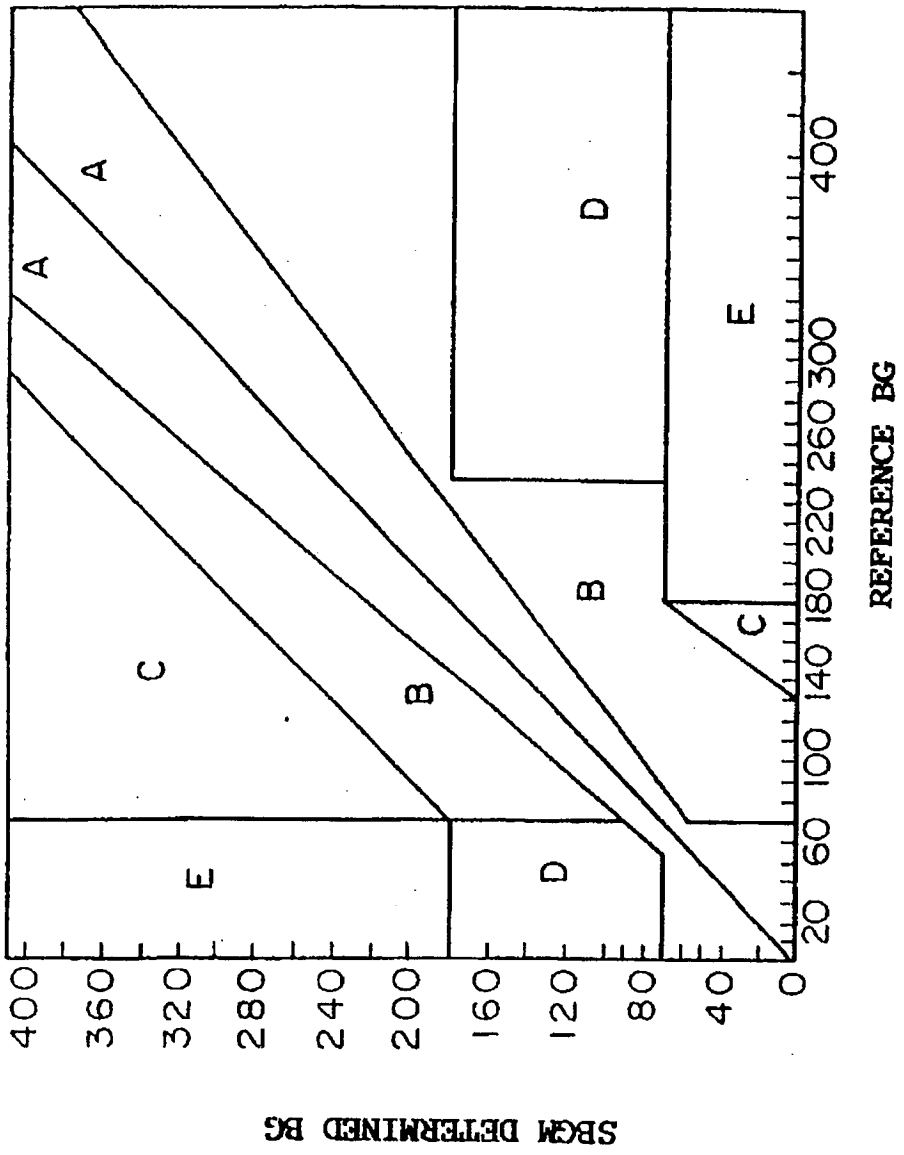
A
A
A
B
B
C
C
D
D
E
E
0
20
40
60
80
100
120
140
160
180
200
220
240
260
280
300
320
340
360
380
400
REFERENCE BG
SBGM DETERMINED BG

FIG.10

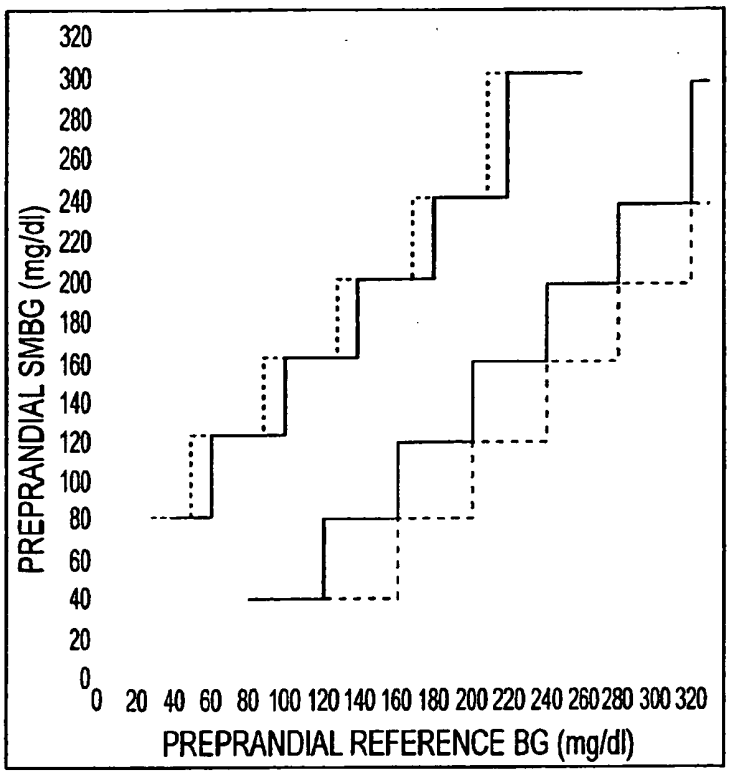
PREPRANDIAL SMBG (mg/dl)
320
300
280
260
240
220
200
180
160
140
120
100
80
60
40
20
0
0 20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320
PREPRANDIAL REFERENCE BG (mg/dl)

Fig. 11

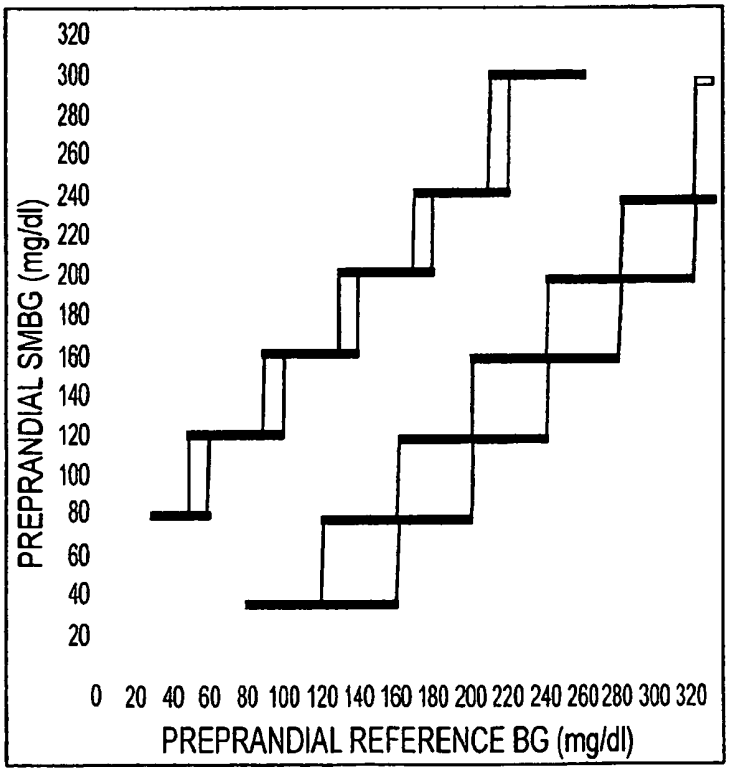
PREPRANDIAL SMBG (mg/dl)
320
300
280
260
240
220
200
180
160
140
120
100
80
60
40
20
0 20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320
PREPRANDIAL REFERENCE BG (mg/dl)

Fig. 12

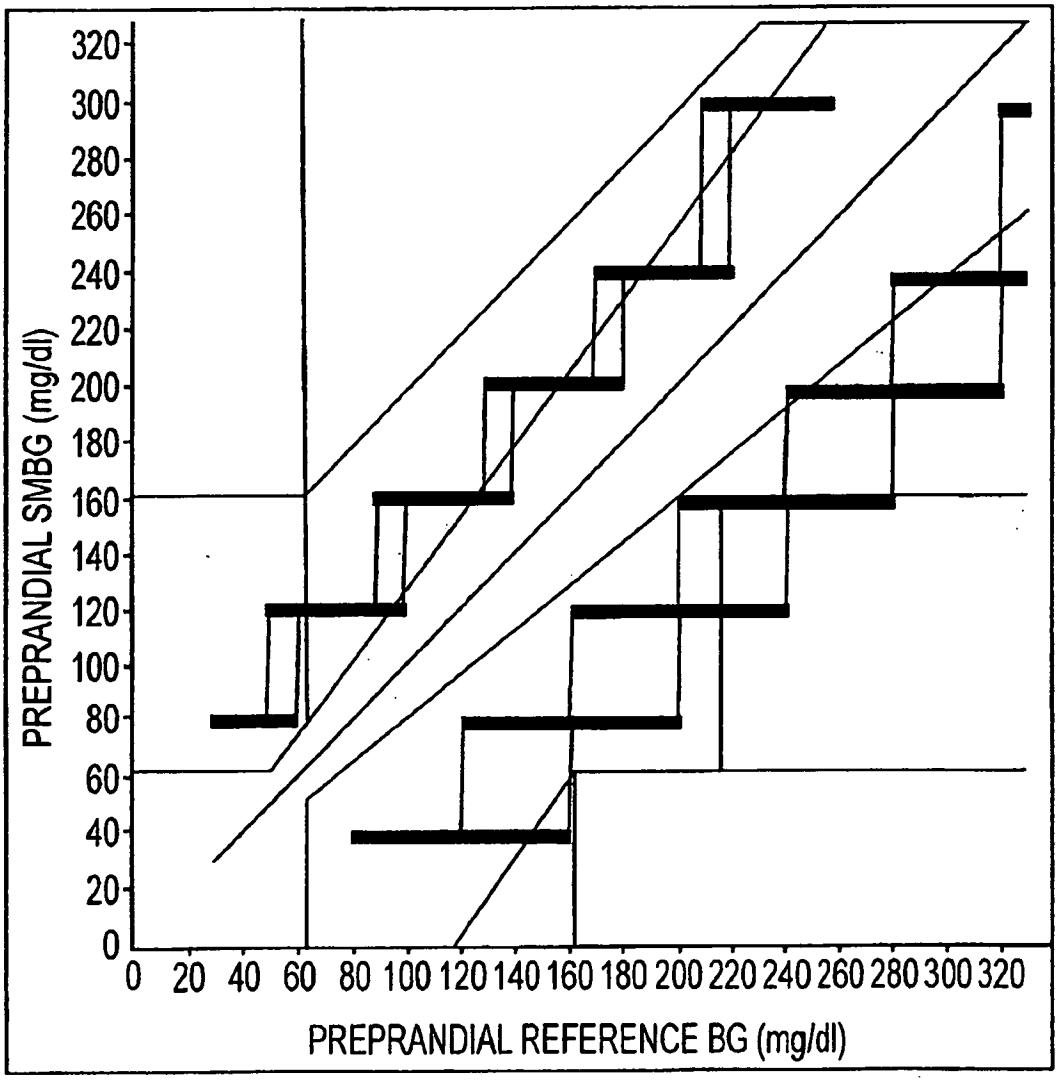
PREPRANDIAL SMBG (mg/dl)
320
300
280
260
240
220
200
180
160
140
120
100
80
60
40
20
0
0 20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320
PREPRANDIAL REFERENCE BG (mg/dl)

Fig. 13

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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Non-patent literature cited in the description

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专利名称(译)	用于糖尿病护理的装置和程序		
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摘要(译)

系统，工具，装置方法和程序允许表征影响葡萄糖浓度的参数的误差与患有糖尿病的人的餐后葡萄糖浓度结果的相关性。它详细描述了影响葡萄糖浓度的参数的潜在误差对临床相关葡萄糖范围内的餐后葡萄糖浓度值的影响。