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(54) **A system, tools, devices and a program for diabetes care**

Ein System, Tools, Vorrichtung und ein Programm für die Diabetisbehandlung

Système, outils, dispositif et programme pour le traitment du diabète

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Description

BACKGROUND OF THE INVENTION

[0001] The invention relates to a medical device for diabetes care and in particular a blood glucose meter or an insulin pump or a continuous glucose monitoring device. The invention further relates to a method of operation of a blood glucose meter or a continuous glucose monitor or an insulin pump.

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. US 2002/19707 A1 describes a glucose meter that is able to connect to a remote processing centre. It is contemplated that errors of a measurement can be detected there by a statistic of earlier measurements so that the patient can be warned about a measurement that results in an abnormal value. US 2005/114062 A1 relates to a reduction of the effect of interferences by other substances when measuring glucose. A corrected value is generated or an error message may be displayed instead of a glucose value. US 5 791 344 A relates to a patient monitoring system which also monitors glucose with more than one sensor. An error signal is generated if the sensor signals deviate too much from each other.

BRIEF SUMMARY OF THE INVENTION

[0007] It is an object of the invention to provide an improved medical device for diabetes care, in particular a blood glucose meter or a continuous blood glucose monitor or an insulin pump and an improved method of operation of a blood glucose meter or a continuous blood glucose monitor or an insulin pump.

[0008] This object is met with a device according to claim 1 and a method according to claim 12.

[0009] Accordingly, the invention comprises a device, and in particular a blood glucose meter or a continuous blood glucose monitor or an insulin pump and a method of its operation wherein on the basis of at least one result of the analysis of blood glucose at least one result or an advice is given and wherein the result or advice is given depending on the measurement error.

[0010] The device or method is adapted to display results or advice in a first measurement range or several first measurement ranges despite the measurement error and adapted to inhibit the display of results or advice or display results or advice in a different mode in a second measurement range or in several measurement ranges depending on the measurement error.

The display may be on the device or separate therefrom and being in wire or wireless connection with the device. The device may comprise at least one movement sensor and the display may be activated or inhibited dependent on a signal from the movement sensor. The device has preferably incorporated therein a system for determining postprandial blood glucose taking into account

- preprandial blood glucose measurement by self-monitoring of glucose,
- the effect of carbohydrate-portion on maximum glucose incrase
- an estimate of carbohydrate amount in meal
- the effect of preprandial insulin on maximum glucose decrease
- insulin dosage

wherein a margin of error for self-monitored preprandial glucose is taken into account and postprandial glucose values are calculated based on a therapeutic action scheme.

[0011] The system has been developed to evaluate the effects and the clinical relevance of the margins of error of parameters affecting glucose. It is based on a diabetes treatment concept aimed at normoglycemia after meals by preprandial injections of insulin. The system includes as parameters:

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 system 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.

[0012] In preferred embodiments of 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 further preferred embodiment of the invention postprandial glucose is determined for different ranges of preprandial glucose values, preferably blood glucose values, according to the therapeutic scheme and the result is displayed as postprandial glucose (preferably 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 blood glucose.

Preferaby the therapeutic scheme includes a carbohydrate self-adjustment in relation to preprandial blood glucose (BG) according to the relation:

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-3w-4	X-4x	X-5

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

[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;

Figure 2 shows a list of the parameters of the system according to a preferred 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 system according to a preferred embodiment of 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] The measurement error of an analytical medical diabetes care device 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.

[0017] The therapeutic intervention depends on the concentration or concentration range of the glucose value and the target range for normoglycemia. In the present invention the display or presentation of a therapeutic advice is made dependent on the outcome of the glucose value (e.g. the postprandial value) which on the other hand depends on the error of the measurement as explained below.

[0018] The advantage of the present invention is therefore that in those ranges of glucose where a correct therapy advice can be given despite a large measurement error such advice will be given. On the other hand in those ranges where it is necessary to have a low error for giving a correct therapy advice such an advice can be inhibited or modified or replaced by a warning.

[0019] Accordingly, since the display of a measured value or an advice, in particular a therapeutic advice is given under consideration of the measurement error and its relevance for the later reached blood glucose value, it is possible to have a therapeutic advice or measurement display that is always informative and correct for the user. It can be taken into account by the device that a measurement is within a range that allows an advice despite the measurement error or is within a range that leads to a critical point so that no advice or a modified advice has to be given.

[0020] The display is arranged either directly on the device or is arranged in wireless (infrared, radiofrequencies) or wirebound data connection with the device.

[0021] In particular if the device is a continuously monitoring glucose device that reacts on movements of the wearer in such a way that movements may increase the measurement error it is preferred to have a movement sensor included in the device so that the error by movement can be included in the above explained calculation by adding a further error parameter.

[0022] In particular an advice is only given if the below explained system within the device detects that postprandial glucose is within the target range for the actual measurement range.

[0023] **Figure 1** shows a screenshot. As explained above, a preferred mode of the invention can be embodied as a system explained in the following and sometimes called as Diabetes Error Test Model (DETM).

[0024] 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 pre-prandial 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 carbo-

hydrate 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.

[0025] **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.

[0026] The preferred 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. 1 U/1 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**

[0027] 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.

[0028] 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.

[0029] 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

[0030] 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.

[0031] The system 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 preferred algorithm (or if the case may be 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.

[0032] 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.

[0033] 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.

[0034] 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%.

[0035] In conclusion, the DETM system allows 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, according to a preferred embodiment, the system 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.

[0036] 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.

[0037] 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(mgdl) in 30 minutes	
	mean	range	mean	range
UU	+3.0	+(2.1→3.9) →	+4.5	-(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	+1X	+2Y	+3Y	+4Y	+5Y	+6Y
U	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5X
=	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y
D	0	-2Y	-1Y	Y	+1Y	+2Y	+3Y	+4Y
DD	0	-3Y	-2Y	-1Y	Y	+1X	+2Y	+3Y

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

[0038] Another aspect is that by using the DETM model and 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 l. 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].

[0039] By using the DETM system 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

[0040] 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.

[0041] In order to evaluate the exact risk, the system, tool and 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.

[0042] Notes and considerations: the DETM and treatment algorithms are calibrated to whole blood. Nevertheless the system, tools, devices and the program may offers the option of switching to plasma. The DETM focuses on the BG-

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

[0043] 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

[0044] 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 medical device for diabetes care, in particular a blood glucose meter or a continuous glucose monitor or an insulin pump, wherein said device is adapted to give on the basis of at least one result of an analysis of a glucose measurement, the measurement having a percentage measurement error, at least one result or an advice and wherein the result or advice is given depending on the percentage measurement error, wherein, for a measurement in a first measurement range or in several first measurement ranges, said device is adapted to display results or advice despite the measurement having a percentage measurement error and **characterized in that**, for a measurement in a second measurement range or in several second measurement ranges, the measurement having the same percentage measurement error, said device is adapted to inhibit the display of results or advice.

2. The device according to claim 1 including a display on the device or separate therefrom and being in wired or wireless connection with the device.

3. The device according to one of claims 1 or 2 comprising at least one movement sensor wherein the display may be activated or inhibited dependent on a signal from the movement sensor.

4. The device according to one of claims 1 to 3 having incorporated therein a system for determining postprandial glucose concentration taking into account

   - preprandial glucose concentration 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 a margin of error for self-monitored preprandial glucose is taken into account and postprandial glucose values are calculated based on a therapeutic action scheme.

5. The device according to claim 4 wherein an error is as well taken into account by said system for one or several of

   - 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.

6. The device according to claim 4 or claim 5 wherein postprandial glucose concentration is determined for different ranges of preprandial glucose concentration values according to the therapeutic scheme.

7. The device according to one of claims 4 to 6 wherein the result is displayed as postprandial blood glucose over preprandial blood glucose.

8. The device according to one of claims 5 to 7 wherein it is determined whether a critical point is reached by exceeding

a lower limit for glucose concentration or by exceeding an upper limit for glucose concentration.

9. The device according to one of claims 5 to 8 wherein the therapeutic scheme includes a carbohydrate self-adjustment in relation to preprandial glucose concentration according to the relation:

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-3w-4	X-4x	X-5

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

10. The device according to one of claims 1 to 6 wherein the therapeutic scheme includes a pre-prandial 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.

11. The device according to one of claims 5 to 9 wherein the 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 the 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

12. A method of operation of a device being one of a blood glucose meter or a continuous glucose monitor or an insulin pump, wherein on the basis of at least one result of an analysis of a glucose measurement, the measurement having a percentage measurement error, at least one result or an advice is given and wherein the result or advice is given depending on the percentage measurement error, wherein for a measurement in a first measurement range or in several first measurement ranges, said device will display results or advice despite the measurement having a percentage measurement error and **characterized in that**, for a measurement in a second measurement range or several second measurement ranges, the measurement having the same percentage measurement error, said device will inhibit the display of results or advice.

Patentansprüche

1. Eine medizinische Vorrichtung für die Diabetes Behandlung, insbesondere ein Blutglukosemessgerät oder ein Gerät zur kontinuierlichen Glukoseüberwachung oder eine Insulinpumpe, wobei die Vorrichtung derart ausgestaltet ist, dass sie auf der Basis mindestens eines Ergebnisses einer Analyse einer Glukosemessung, wobei die Glukosemessung einen Messfehleranteil hat, mindestens ein Ergebnis oder einen Rat ausgibt und wobei das Ergebnis oder

der Rat in Abhängigkeit vom Messfehleranteil gegeben wird, wobei die Vorrichtung derart ausgestaltet ist, dass sie für eine Messung in einem ersten Messbereich oder in mehreren ersten Messbereichen Ergebnisse oder einen Rat trotzdem dass die Messung einen Messfehleranteil hat, ausgibt und **dadurch gekennzeichnet, dass** die Vorrichtung derart ausgestaltet ist, dass sie in einem zweiten Messbereich oder in mehreren zweiten Messbereichen, wobei die Messung den gleichen Messfehleranteil hat, die Anzeige von Ergebnissen oder eines Rats unterdrückt.

2. Die Vorrichtung nach Anspruch 1, einschliessend eine Anzeige auf der Vorrichtung oder getrennt davon, die in kabelgebundene oder kabellose Verbindung mit der Vorrichtung ist.

3. Die Vorrichtung nach Anspruch 1 oder 2, umfassend mindestens einen Bewegungssensor, wobei die Anzeige in Abhängigkeit von einem Signal vom Bewegungssensor aktiviert oder unterdrückt wird.

4. Die Vorrichtung nach einem der Ansprüche 1 bis 3, umfassend ein System zur Bestimmung einer postprandialen Glukosekonzentration, unter Berücksichtigung

- einer Messung der preprandialen Glukosekonzentration mittels Selbstüberwachung der Glukose
- einer Wirkung der Kohlenhydratportion auf die maximale Erhöhung der Glukose
- eine Schätzung der Kohlenhydratmenge in der Speise
- die Wirkung des prandialen Insulins auf die maximale Abnahme der Glukose
- eine Insulindosierung

wobei eine Fehlergrenze für die selbst überwachte preprandiale Glukose berücksichtigt wird und postprandiale Glukosewerte auf der Basis eines therapeutischen Aktionsplans berechnet werden.

5. Die Vorrichtung nach Anspruch 4, wobei ein Fehler vom System auch für ein oder mehreren von

- einer Wirkung der Kohlenhydratportion auf die maximale Erhöhung der Glukose
- eine Schätzung der Kohlenhydratmenge in der Speise
- die Wirkung des prandialen Insulins auf die maximale Abnahme der Glukose
- eine Insulindosierung

berücksichtigt wird.

6. Die Vorrichtung nach Anspruch 4 oder 5, wobei die postprandiale Glukosekonzentration für unterschiedliche Bereiche von preprandialen Glukosekonzentrationswerten gemäss dem therapeutischen Aktionsplan bestimmt wird.

7. Die Vorrichtung nach einem der Ansprüche 4 bis 6, wobei das Ergebnis als postprandiale Blutglukose in Abhängigkeit der preprandialen Blutglukose angezeigt wird.

8. Die Vorrichtung nach einem der Ansprüche 5 bis 7, wobei bestimmt wird, ob ein kritischer Punkt durch Unterschreiten einer unteren Grenze der Glukosekonzentration oder durch Überschreiten einer oberen Grenze der Glukosekonzentration erreicht wird.

9. Die Vorrichtung nach einem der Ansprüche 5 bis 8, wobei der therapeutische Plan eine Kohlenhydrat-Selbstanpassung in Abhängigkeit von der preprandialen Glukosekonzentration nach der Relation:

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-3w-4	X-4x	X-5

einschliesst,
wobei X die Anzahl von Kohlenhydratportionen (X = 1, 2, 3, 4 oder 5) für den Blutglukose-Bereich von 61-120 mg/dl bedeutet.

10. Die Vorrichtung nach einem der Ansprüche 1 bis 6, wobei der therapeutische Plan eine Selbstanpassung der preprandialen Insulindosis gemäss der Relation:

BG (mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360

(fortgesetzt)

insulindosis (U)	0	-1Y	Y	+1Y	+2Y	+3Y	+4Y	+5Y

einschliesst,
wobei Y z.B. Eine Einheit Insulin pro 1 CARB-P für den Blutglukose-Bereich von 81-120 mg/dl bedeutet.

11. Die Sensorvorrichtung nach einem der Ansprüche 5 bis 9, wobei der Trend einer kontinuierlichen Blutglukose-Überwachung wie folgt berücksichtigt wird:

Glukose(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

wobei die Trends wie folgt definiert sind:

Sehr schnelles Ansteigen der Glukose	>+2 mg/dl/min	UU
Schnell	+(1-2) mg/dl/min	U
Langsame Änderungen	<±1 mg/dl/min	=
Schnelles Abnehmen	-(1-2) mg/dl/min	D
Sehr schnelles Abnehmen	>-2 mg/dl/min	DD

12. Ein Betriebsverfahren für eine Vorrichtung, die ein Blutglukosemessgerät oder ein Gerät zur kontinuierlichen Glukoseüberwachung oder eine Insulinpumpe sein kann, wobei auf der Basis mindestens eines Ergebnisses einer Analyse einer Glukosemessung, wobei die Glukosemessung einen Messfehleranteil hat, mindestens ein Ergebnis oder ein Rat ausgegeben wird und wobei das Ergebnis oder der Rat in Abhängigkeit vom Messfehleranteilgegeben wird, wobei die Vorrichtung für eine Messung in einem ersten Messbereich oder in mehreren ersten Messbereichen Ergebnisse oder einen Rat ausgibt, trotzdem dass die Messung einen Messfehleranteil hat, und **dadurch gekennzeichnet, dass** die Vorrichtung in einem zweiten Messbereich oder in mehreren zweiten Messbereichen die Anzeige von Ergebnissen oder eines Rats unterdrückt.

Revendications

1. Un dispositif médical pour le traitement du diabète, particulièrement un dispositif de mesure du glucose sanguin ou un moniteur de glucose ou une pompe à insuline, ledit dispositif étant adapté à donner au moins un résultat ou un conseil basé sur au moins un résultat d'une analyse d'une mesure de glucose, la mesure ayant un pourcentage d'erreur de mesure, et le résultat ou le conseil étant donné dépendant du pourcentage d'erreur de mesure, ledit dispositif étant adapté à afficher des résultats ou des conseils malgré la mesure avec un pourcentage d'erreur de mesure, pour une mesure comprise dans une première gamme de mesures ou dans plusieurs premières gammes de mesures, et **caractérisé en ce que** ledit dispositif est adapté à inhiber l'affichage des résultats ou des conseils pour une mesure dans une deuxième gamme de mesures ou dans plusieurs deuxièmes gammes de mesures, la mesure ayant le même pourcentage d'erreurs de mesure.

2. Le dispositif selon la revendication 1, incluant un affichage sur le dispositif ou séparé du même et étant en connexion avec fil ou sans fil avec le dispositif.

3. Le dispositif selon l'une des revendications 1 ou 2, comprenant au moins un capteur de mouvement, l'affichage pouvant être activé ou inhibé dépendant d'un signal du capteur de mouvement.

4. Le dispositif selon l'une des revendications 1 à 3, ayant incorporé dedans un système pour déterminer une concentration de glucose postprandiale prenant en compte

- une mesure de concentration de glucose préprandiale par auto surveillance du glucose
- un effet d'une portion des hydrates de carbone sur une augmentation maximale de glucose
- une estimation d'une quantité d'hydrate de carbone dans un repas
- l'effet d'insuline prandiale sur la décroissance maximale de glucose
- un dosage d'insuline

une marge d'erreur pour la glucose préprandiale auto-surveillée étant prise en compte et des valeurs postprandiales de glucose étant calculées à la base d'un programme d'action thérapeutique.

5. Le dispositif selon la revendication 4, une erreur étant aussi prise en compte par ledit système pour un ou plusieurs

- d'un effet d'une portion d'hydrates de carbone sur une augmentation maximale de la concentration de glucose
- d'une estimation d'une quantité d'hydrate de carbone dans un repas
- l'effet d'insuline prandiale sur la décroissance maximale de glucose
- un dosage d'insuline

6. Le dispositif selon la revendication 4 ou 5, la concentration postprandiale de glucose étant déterminée pour des gammes différentes des valeurs de concentration préprandiale de glucose selon le programme thérapeutique.

7. Le dispositif selon l'une des revendications 4 à 6, le résultat étant affiché comme glucose sanguine postprandiale en dépendance du glucose sanguin préprandial.

8. Le dispositif selon l'une des revendications 5 à 7, une détermination étant effectuée
si un point critique est atteint en dépassant une limite basse de la concentration de glucose ou en dépassant une limite haute de la concentration de glucose.

9. Le dispositif selon l'une des revendications 5 à 8, le programme thérapeutique incluant une auto-adaptation des hydrates de carbone en relation avec la concentration préprandiale de glucose selon la relation:

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-3w-4	X-4x	X-5

X représentant le numéro des portion d'hydrates de carbone (X = 1, 2, 3, 4 ou 5) pour la gamme de glucose sanguine comprise entre 61 et 120 mg/dl.

10. Le dispositif selon l'une des revendications 1 à 6, le programme thérapeutique incluant une auto-adaptation de la dose d'insuline préprandiale selon la relation:

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

Y étant par exemple une unité d'insuline par 1 CARB-P pour la gamme de glucose sanguine comprise entre 81-120 mg/dl.

11. Le dispositif selon l'une des revendications 5 à 9, la tendance d'une surveillance continue du glucose sanguin 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

(suite)

Glucose(mg/dl)	<61	61-80	81-120	121-160	161-200	201-240	241-300	301-360
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
Lents changements	<±1 mg/dl/min =
Rapide décroissance	-(1-2) mg/dl/min D
Très rapide décroissance	>-2 mg/dl/min DD

12. Procédé d'opération d'un dispositif de mesure du glucose sanguine ou un dispositif de surveillance continue de glucose ou une pompe d'insuline, au moins un résultat ou un conseil basé sur au moins un résultat d'une analyse d'une mesure de glucose, la mesure ayant un pourcentage d'erreur de mesure, étant donné, et le résultat ou le conseil étant donné dépendant du pourcentage d'erreur de mesure, ledit dispositif affichant des résultats ou des conseils malgré la mesure ayant un pourcentage d'erreur de mesure, pour une mesure comprise dans une première gamme de mesures ou dans plusieurs premières gammes de mesures, et **caractérisé en ce que** ledit dispositif est adapté à inhiber l'affichage des résultats ou des conseils pour une mesure dans une deuxième gamme de mesures ou dans plusieurs deuxièmes gammes de mesures, la mesure ayant le même pourcentage d'erreurs de mesure.

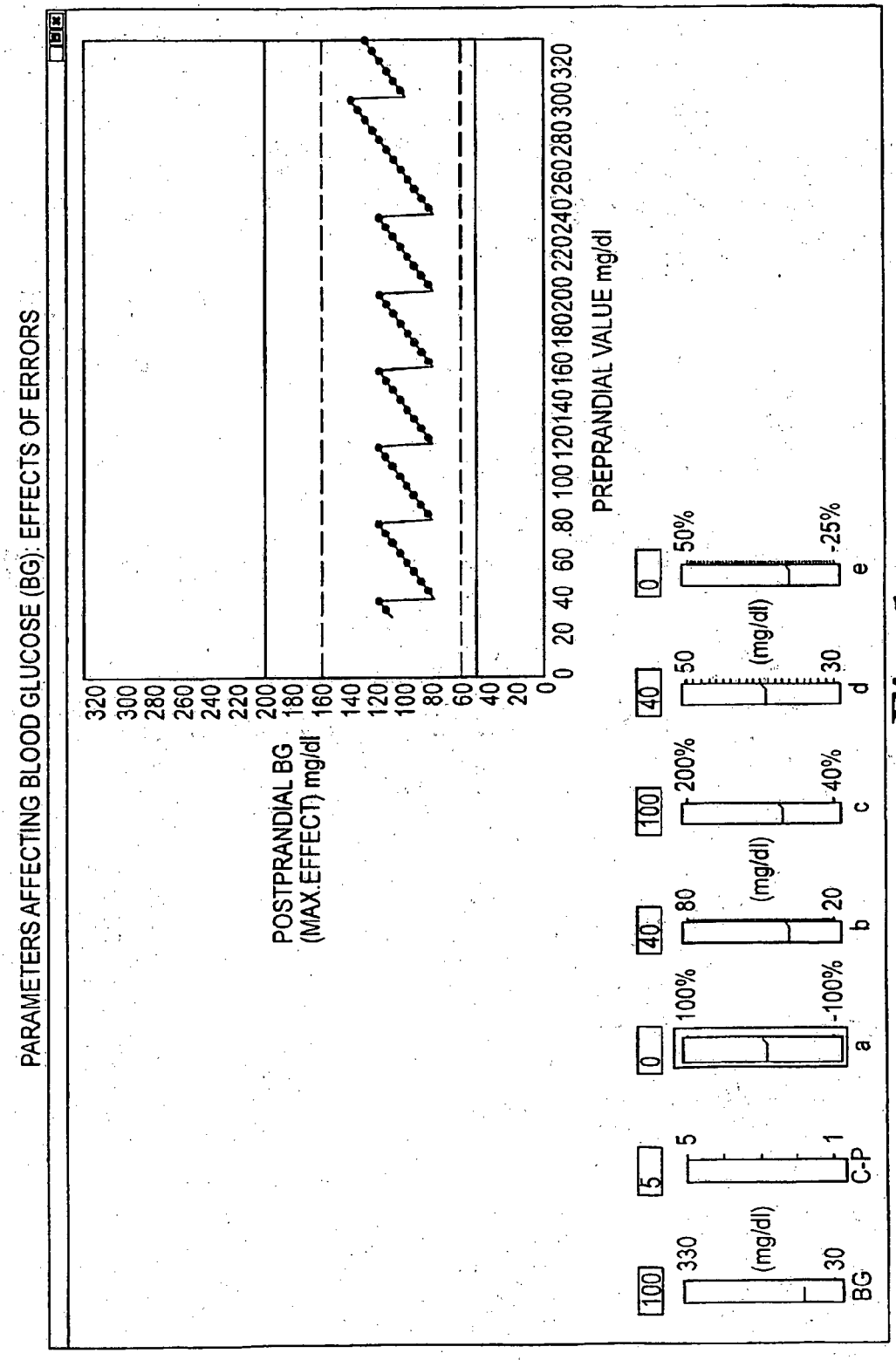
PARAMETERS AFFECTING BLOOD GLUCOSE (BG): EFFECTS OF ERRORS
POSTPRANDIAL BG (MAX.EFFECT) mg/dl
320 300 280 260 240 220 200 180 160 140 120 100 80 60 40 20 0
0 20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320
PREPRANDIAL VALUE mg/dl
100
330
(mg/dl)
30
BG
5
1
C-P
0
100%
-100%
a
40
80
(mg/dl)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

Fig. 1

FIG. 2

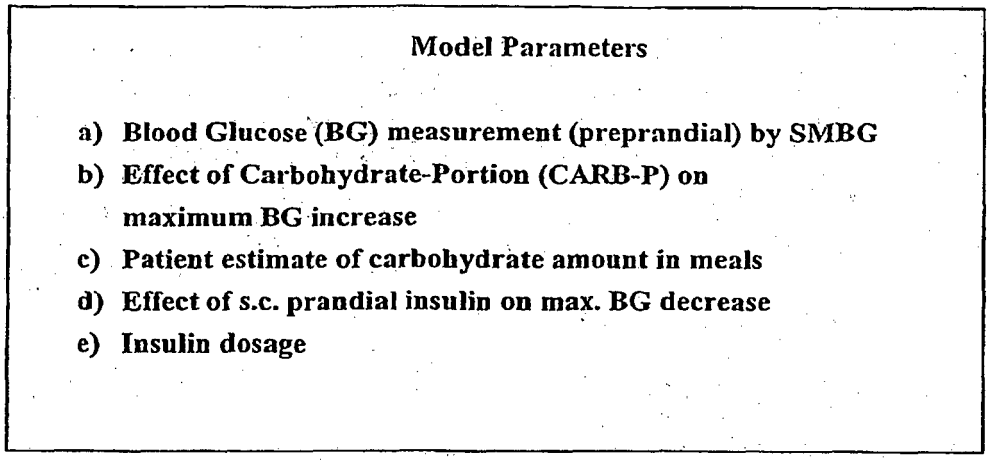

FIG. 3

	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%

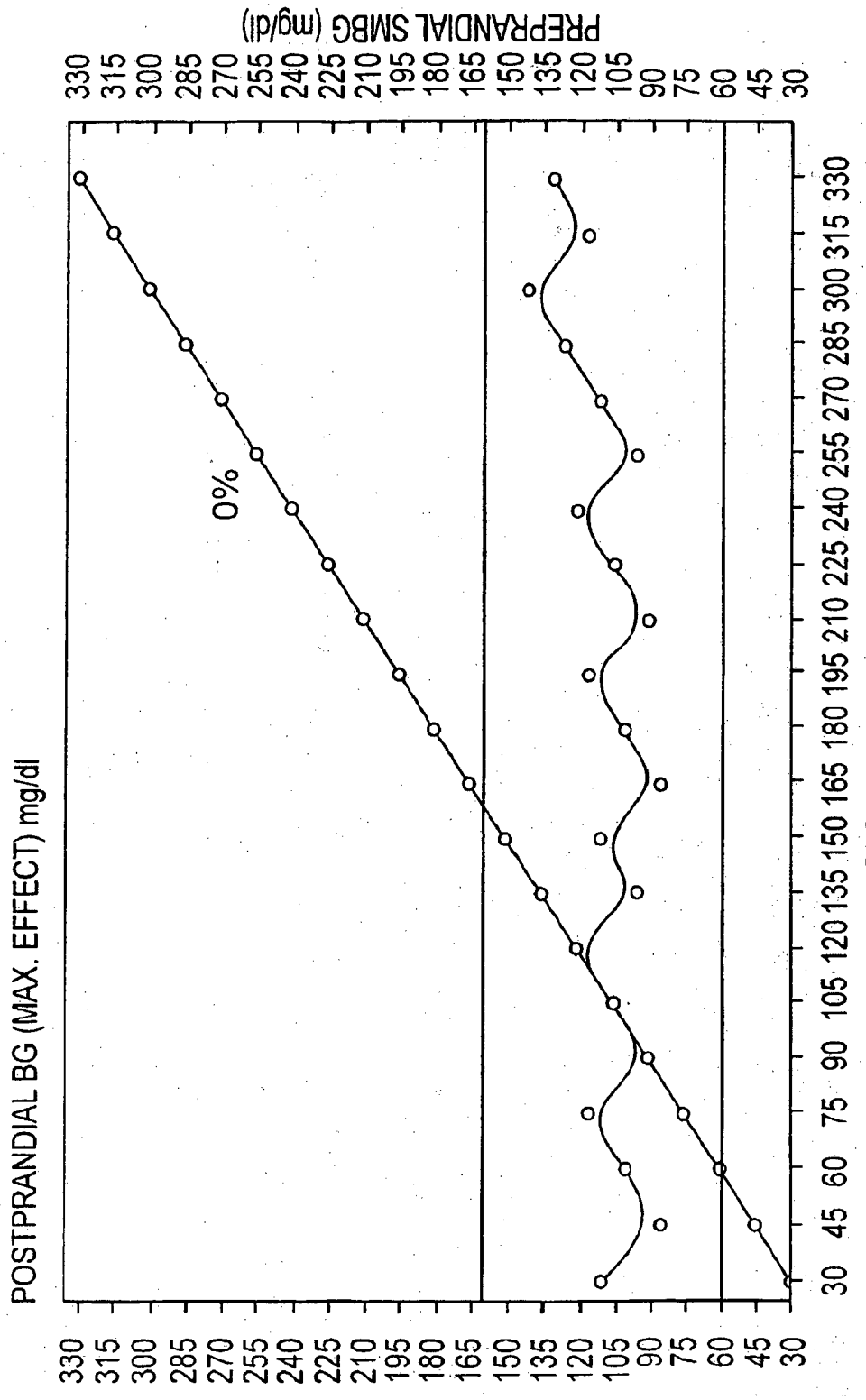
POSTPRANDIAL BG (MAX. EFFECT) mg/dl
PREPRANDIAL BG (mg/dl)
PREPRANDIAL SMBG (mg/dl)
0%
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330

Fig. 4

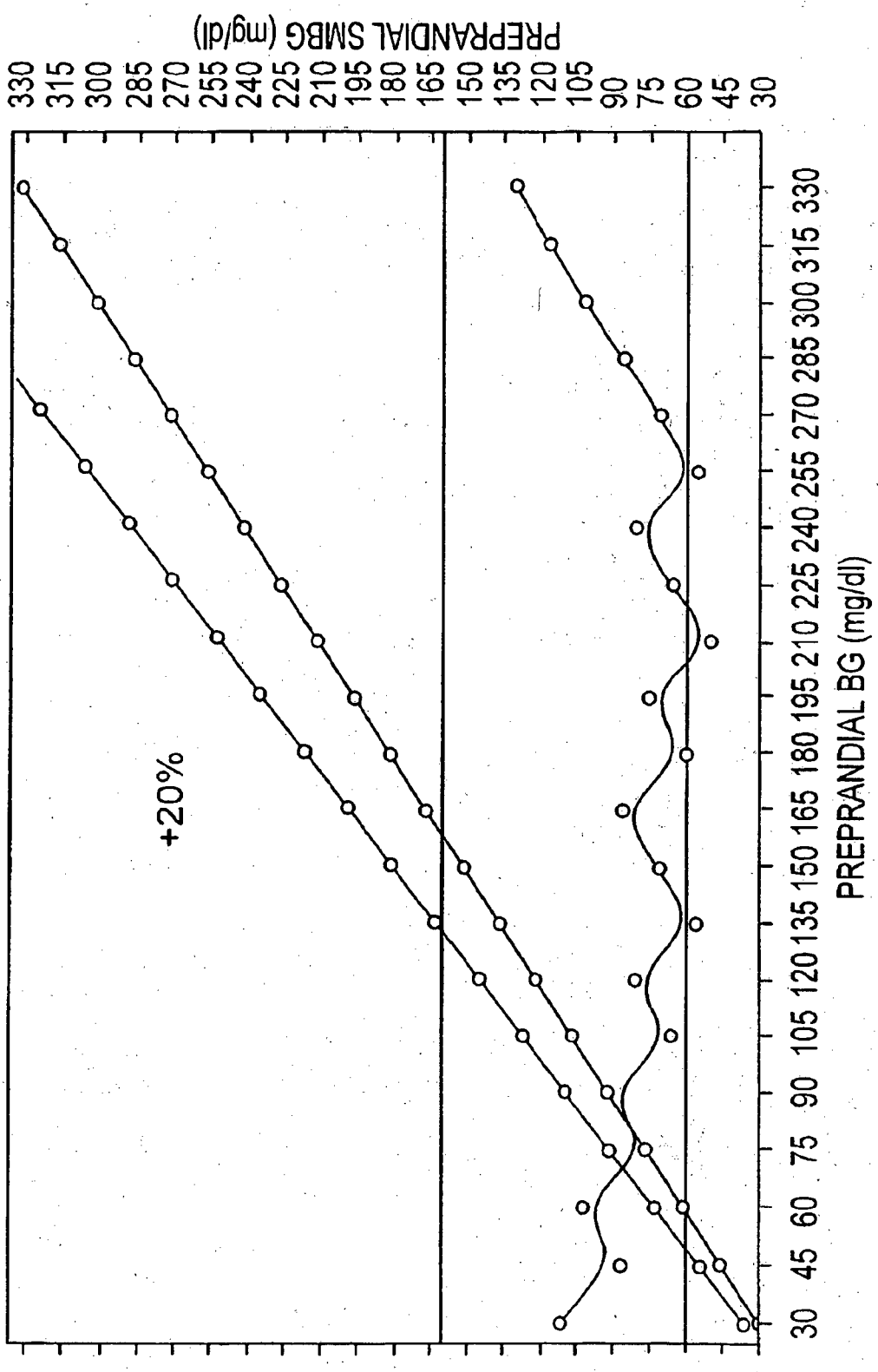
PREPRANDIAL SMBG (mg/dl)
330 315 300 285 270 255 240 225 210 195 180 165 150 135 120 105 90 75 60 45 30
+20%
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
PREPRANDIAL BG (mg/dl)

Fig. 5

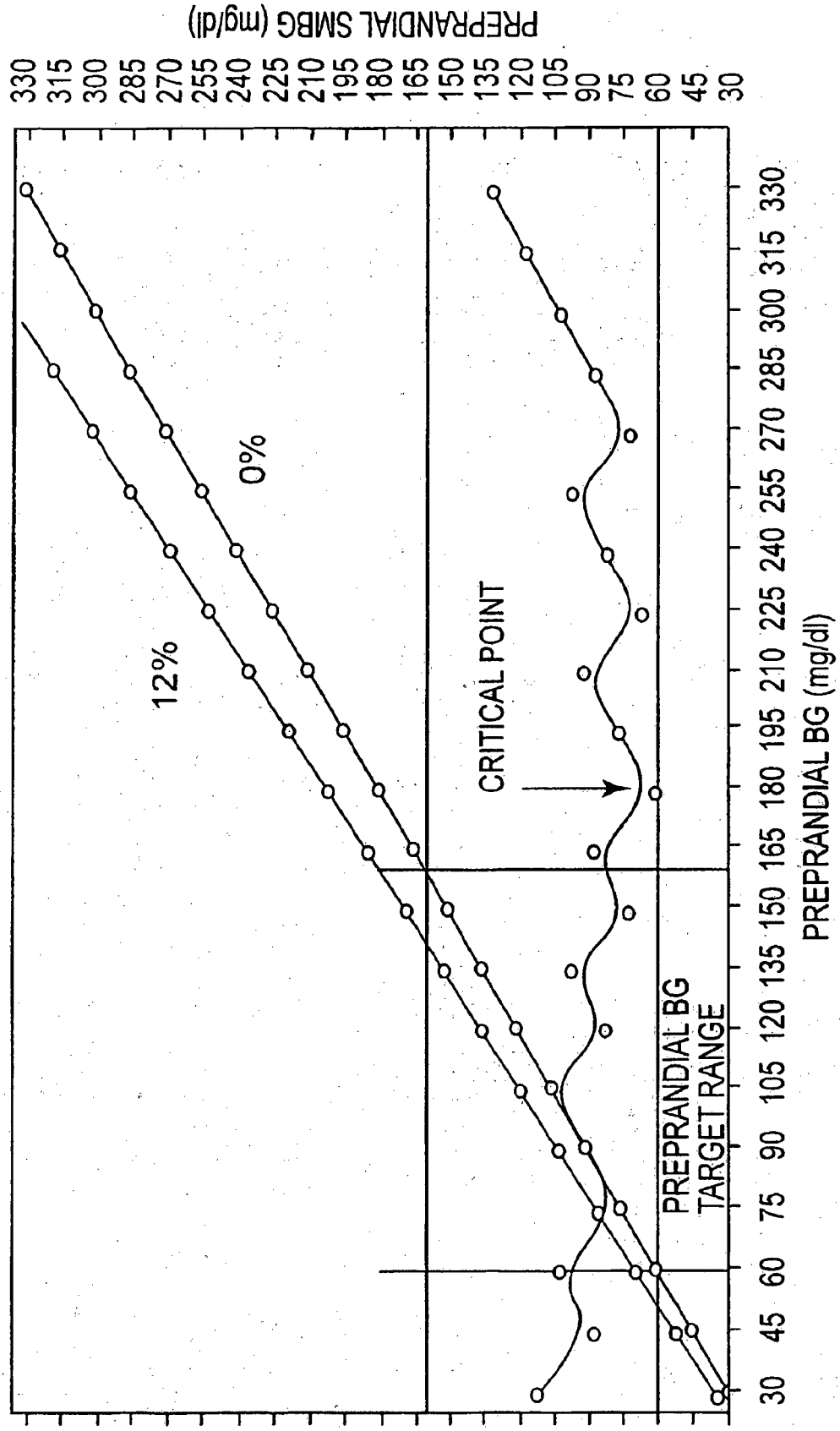
PREPRANDIAL SMBG (mg/dl)
330 315 300 285 270 255 240 225 210 195 180 165 150 135 120 105 90 75 60 45 30
12%
0%
CRITICAL POINT
PREPRANDIAL BG TARGET RANGE
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
PREPRANDIAL BG (mg/dl)

Fig. 6

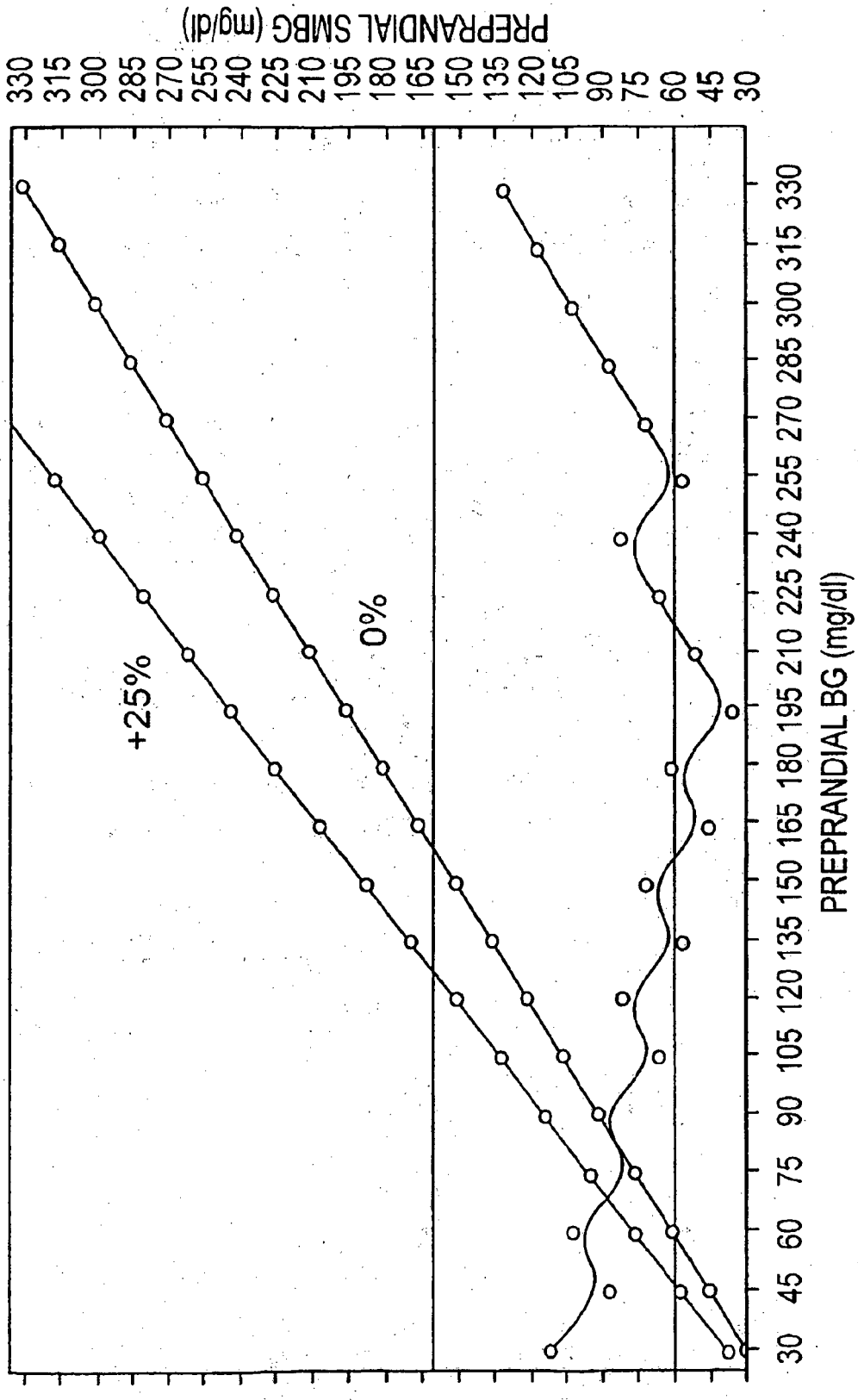
PREPRANDIAL SMBG (mg/dl)
330 315 300 285 270 255 240 225 210 195 180 165 150 135 120 105 90 75 60 45 30
+25%
0%
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
PREPRANDIAL BG (mg/dl)

Fig. 7

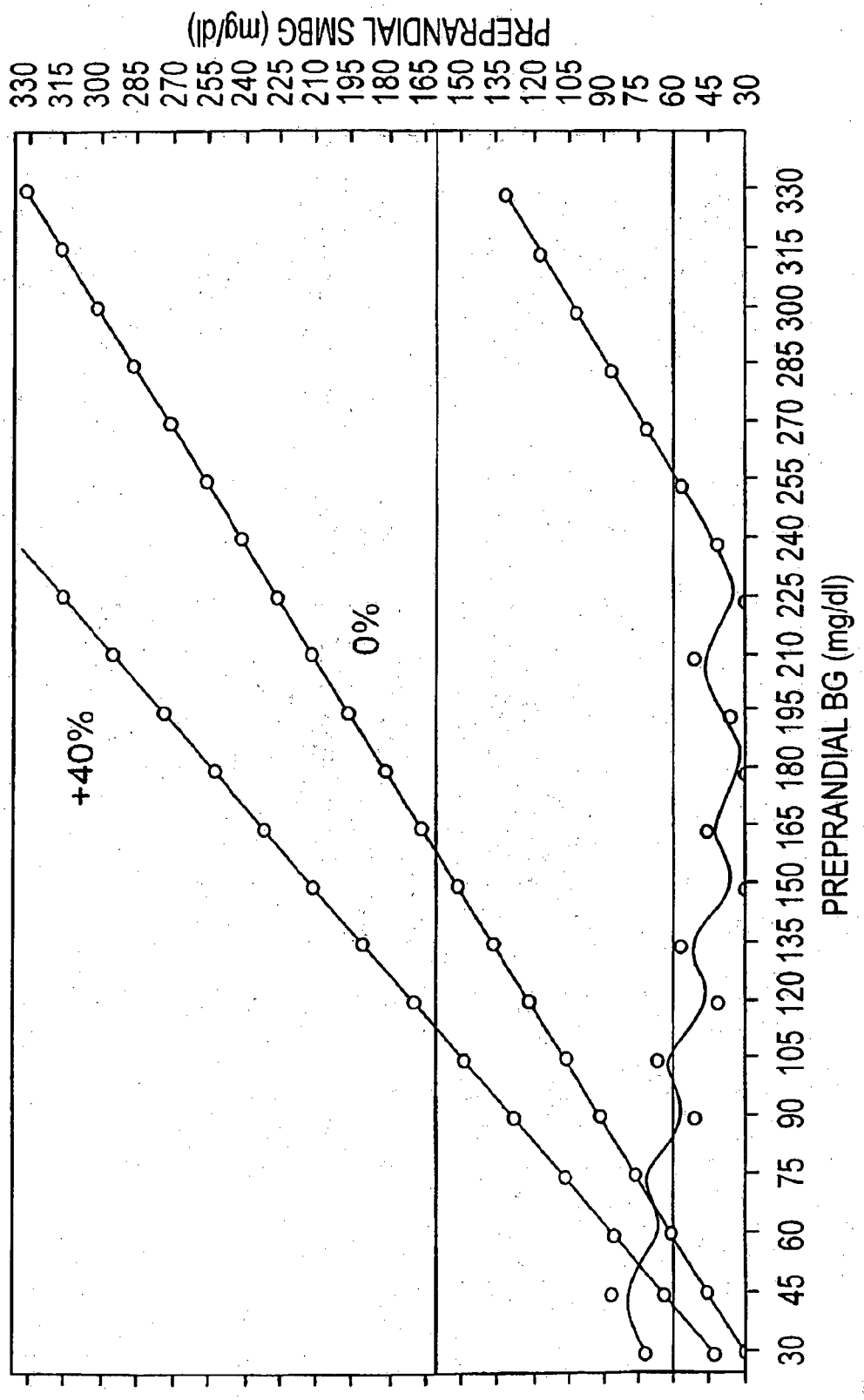
PREPRANDIAL SMBG (mg/dl)
330 315 300 285 270 255 240 225 210 195 180 165 150 135 120 105 90 75 60 45 30
+40%
0%
30 45 60 75 90 105 120 135 150 165 180 195 210 225 240 255 270 285 300 315 330
PREPRANDIAL BG (mg/dl)

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%

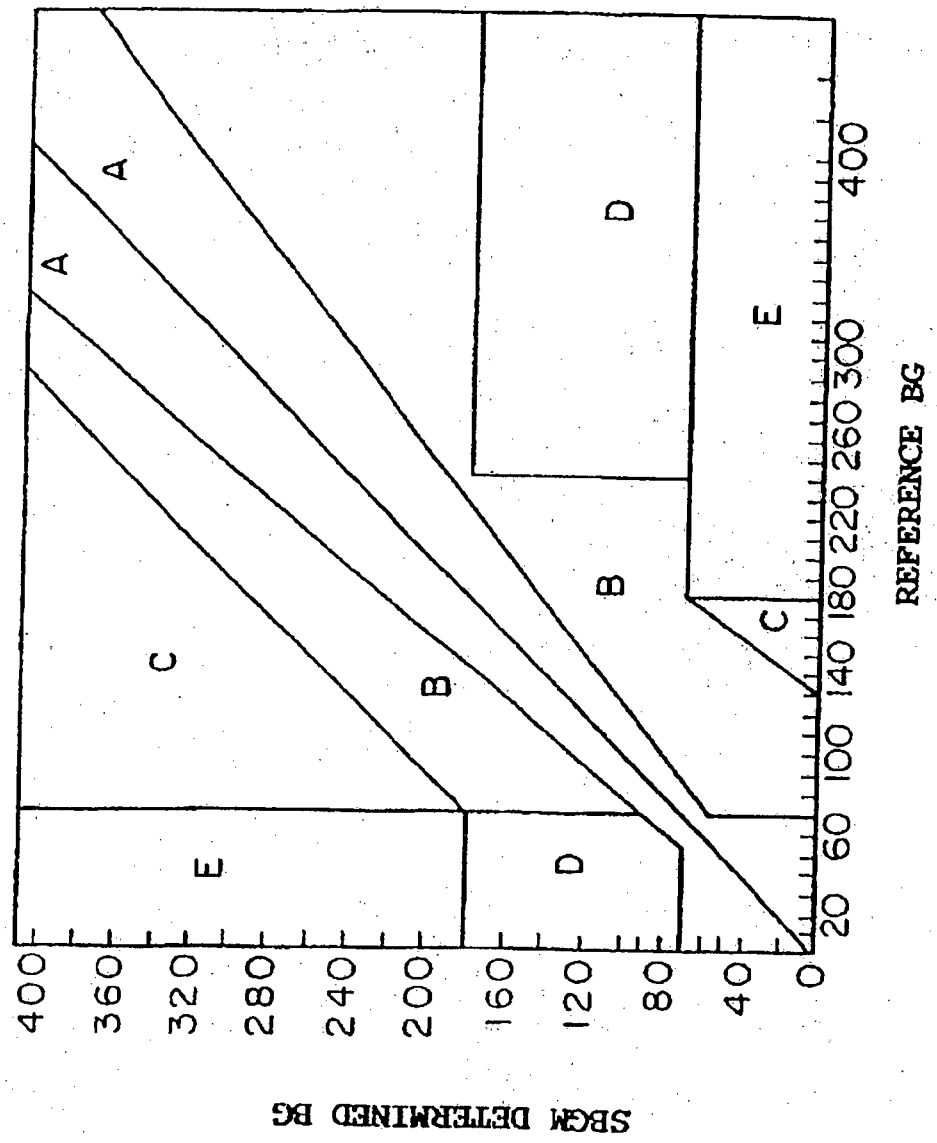
SBGM DETERMINED BG
REFERENCE BG
0
40
80
120
160
200
240
280
320
360
400
20
60
100
140
180
220
260
300
400
A
A
A
B
B
C
C
D
D
E
E

FIG.10

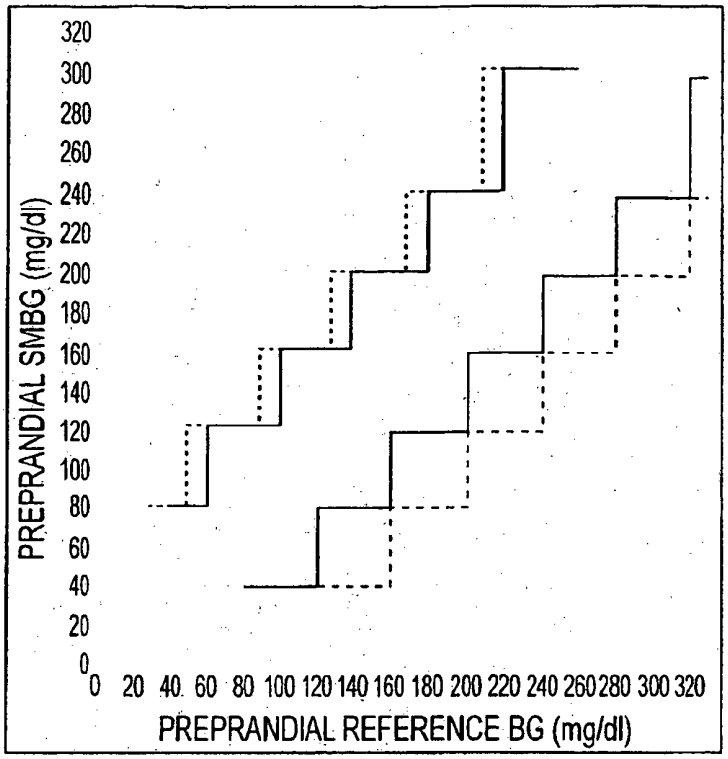
PREPRANDIAL SMBG (mg/dl)
320
300
280
260
240
220
200
180
160
140
120
100
80
60
40
20
0
0 20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320
PREPRANDIAL REFERENCE BG (mg/dl)

Fig. 11

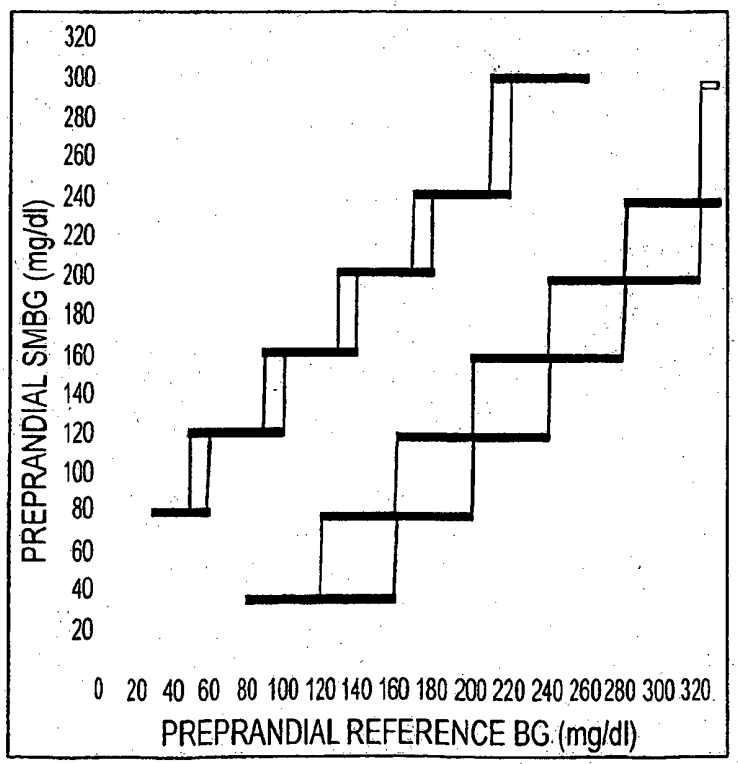
PREPRANDIAL SMBG (mg/dl)
320
300
280
260
240
220
200
180
160
140
120
100
80
60
40
20
0 20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320
PREPRANDIAL REFERENCE BG (mg/dl)

Fig. 12

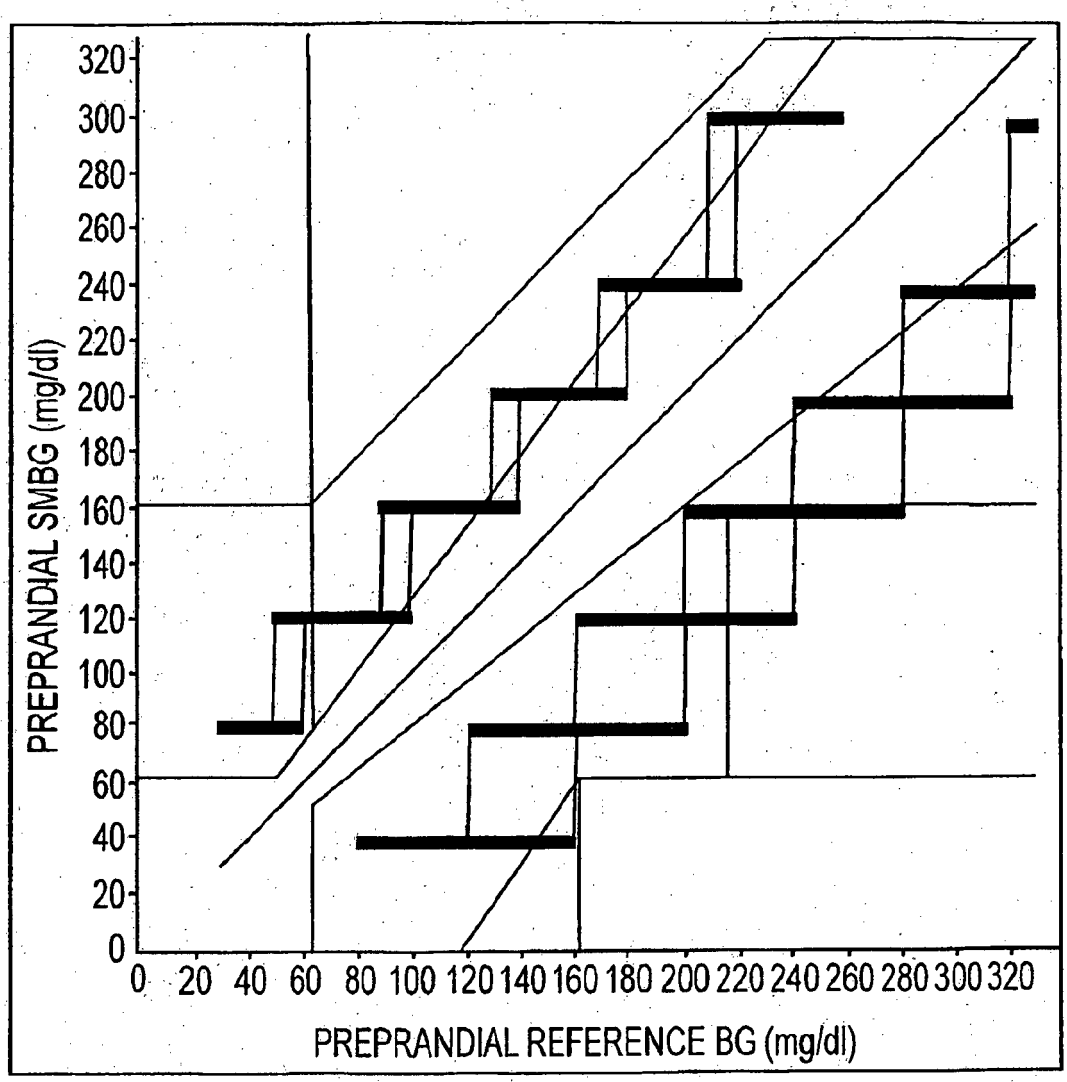
PREPRANDIAL SMBG (mg/dl)
320
300
280
260
240
220
200
180
160
140
120
100
80
60
40
20
0
0 20 40 60 80 100 120 140 160 180 200 220 240 260 280 300 320
PREPRANDIAL REFERENCE BG (mg/dl)

Fig. 13

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于糖尿病护理的系统，工具，设备和程序		
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[标]申请(专利权)人(译)	罗氏诊断公司		
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IPC分类号	A61B5/00		
CPC分类号	A61B5/743 A61B5/14532 A61B5/7275 A61B5/7445 G16H20/17 G16H50/20		
代理机构(译)	沙尔赫，RAINER		
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其他公开文献	EP2260757A1		
外部链接	Espacenet		

摘要(译)

本发明涉及一种装置和方法，其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，并允许根据误差给出建议。

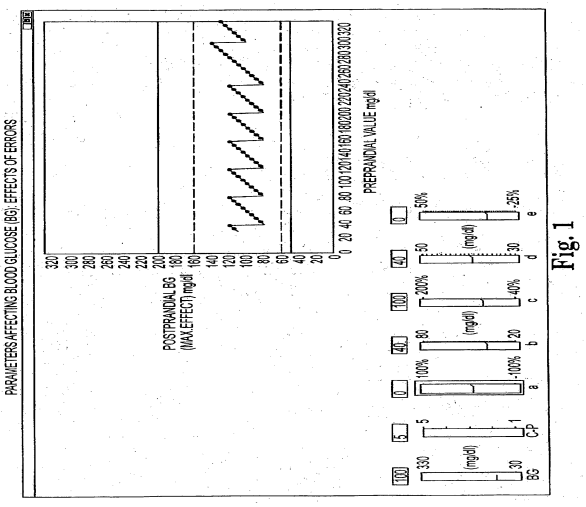

Fig. 1