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(54) **Assessment method to process a glucose concentration signal**

Beurteilungsverfahren zum Verarbeiten eines Glukosekonzentrationssignals

Procédé d'évaluation pour le traitement d'un signal de concentration en glucose

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Description

Technical Field

[0001] The invention relates to an assessment method to process a signal corresponding to a glucose concentration, in particular obtained from continuous glucose monitoring, performing a retrospective analysis. The invention further relates to a device to process a signal corresponding to a glucose concentration, which is designed and programmed to perform such an assessment method.

Background Art

[0002] Diabetes is a disease in which the body does not produce an adequate amount of insulin or does not properly respond to the insulin produced. This results in an unbalanced blood glucose concentration (hyper- or hypoglycemia) leading to severe consequences such as ketoacidosis (diabetic coma), vascular complications as well as loss of consciousness or seizures. In order to maintain a healthy blood glucose concentration, patients usually keep a strict diet in combination with selective boluses of insulin. A bolus of insulin needs to be adjusted to the individual human body to provide an appropriate amount and distribution of insulin. Whether or not the amount and distribution of insulin are appropriate strongly depends on several factors such as the quantity and type of food and physical activity, e. g. exercise, stress or illness. Hence, the necessary amount of insulin varies depending on the patient's physical condition. To respectively serve the appropriate amount of insulin, the patient's response to certain factors like a meal needs to be considered. In addition to the amount and distribution of an insulin bolus, the timing of the bolus is of particular importance.

[0003] Existing methods to deal with monitoring the glucose concentration usually comprise the use of spot monitoring of blood glucose with a strip meter or tape cassette or the use of a continuous blood glucose monitoring device. Further, it is known to display the measured data in the form of a glucose concentration excursion curve. This provides rather exact and complete but more or less raw data, which are complicated to be interpreted by a patient or his or her health care provider (HCP).

[0004] When conventional methods are applied, the patient or his or her HCP respectively gets information about the glucose concentration excursion of a predefined period of time, e. g. of the last 12 or 24 hours. Moreover, the measurements usually do not consider the individual timing of relevant events such as physical activities or eating habits of a patient but measure over a fixed and predetermined period of time.

[0005] Glucose concentration is a value which is influenced by parameters such as the amount, distribution and timing of a bolus of insulin as well as by meals or physical activities of the patient. Said conventional measuring methods can only show absolute values of the respective blood glucose concentration at a specific time or within a specific period of time without taking other parameters such as timing of a meal or physical activity into account.

[0006] Any predetermined and fixed timing of a continuous measuring cycle or spot measurement, which is not synchronised with all influences to the blood glucose concentration excursion, is unable to react to the patient's individual habits. An intuitive analysis of measured values therefore is not possible if only the previously described conventional measuring methods are used. Even though the fact that e. g. a meal has been ingested can be seen from the blood glucose concentration excursion, its precise timing does not come out of the measured data. Therefore, in order to consider this timing, a parallel log of events with their respective time becomes necessary.

[0007] Thus, applying conventional monitoring and analysing methods, an efficient determination of the right choice of the amount, distribution and timing of a bolus with respect to a specific meal or a specific activity and the like is only possible if the patient shows a strict discipline in matters of nutrition, sports and other physical activities or if he or she adhers to a strict logging of any possibly influencing event.

[0008] For a useful therapy and regimen respectively, a wide knowledge of a specific human body's response to a bolus of insulin as well as to nutrition and physical activities is crucial. Therefore therapies which are based on averaged data or a fixed measurement programme are not satisfyingly matching the needs and requirements of an individual patient.

[0009] EP 1 338 295 relates to user-interactive remote control of continuous-delivery medication infusion pump and a percutaneous physiological fluid monitoring device. A hand-held "fob" is provided for the remote control of the infusion pump and/or monitoring device. The monitoring of the physiological fluid may be done on a substantially continuous basis. The fob has a test strip for episodic measurement of the blood glucose concentration. The user's actual blood glucose level, the amount of carbohydrates to be consumed, and the bolus dosage correction factors are to be entered on a real-time basis by the user. Upon selecting blood glucose calculator mode, the fob prompts the user to enter the most recent blood glucose concentration or a value measured by the monitoring device may be transmitted to the fob. The fob determines the standard bolus dosage to be delivered. The fob prompts the user to enter a blood glucose correction factor to fine-tune the bolus volume, for example, when the user anticipates exercising soon after a meal. A delivery command is then sent to the pump.

Summary of the invention

[0010] It is the object of the invention to create a method as well as a device pertaining to the technical field initially mentioned, which allow an easy determination of the appropriate amounts, distributions and timings of insulin boluses in different situations with respect to each individual patient. A further object of the invention is to simplify the analysis of measured data, to allow a more flexible analysis and thus to enhance the individual usefulness of an assessment of a glucose concentration measurement.

[0011] The solution of the invention is specified by the features of claims 1 and 12, respectively. According to the invention the assessment method to process a signal corresponding to a glucose concentration consists in performing a retrospective analysis of the measured data and comprises the steps of starting the assessment initiated by a first trigger, collecting the data to be analysed, analysing the collected data initiated by a second trigger and displaying the results of the analysis. This assessment method may be performed using a device which comprises a measuring device for collecting the data to be analysed, a computing device for analysing the collected data, a storage device for recording the collected data and the results of the analysis, a display for visualising the analysed data and a communication link for transmitting data between the measuring device and the computing/storage device and display, respectively.

[0012] By performing a user-triggered and retrospective analysis of data which have been collected in particular during or after a relevant event such as a meal or physical activity, the user has the opportunity of choosing the time period the analysis is performed for. This ensures that the analysis relates to a certain event-specific context and therefore enhances the usefulness of the assessment of a glucose concentration.

[0013] The assessment process can be initiated by a first trigger which should correspond to a situation that needs examination with respect to glucose concentration. Then the data collection is performed by using glucose concentration measuring methods that are known as such, in particular by using a continuous monitoring of glucose concentration, whereas the first trigger defines the beginning of a segment of the continuous measurement. Alternatively, data can be collected using spot monitoring of glucose concentration using a strip meter or a tape cassette, whereas the first trigger defines e. g. the first of a series of spot measurements. Then a second trigger initiates the analysis of the collected data. It defines the end of the collected data to be analysed. Eventually, the results of the analysis can be displayed. It is also possible to simply store the analysis and display it later in time or in combination with other analyses.

[0014] The first and the second trigger of the assessment method can correspond to a user input, such as e. g. pressing a button, contacting a touch screen, activating a voice sensitive device or similar interactions.

[0015] The first as well as the second trigger can also correspond to a predetermined time. Such a trigger can preferably be used as the second one, meaning that the data collection is performed during a predefined time. This time can be deduced from medical aspects such as an average reaction time of the blood glucose level to a meal or, e. g. during an insulin therapy, the period of time that a bolus of insulin works. Using a predetermined time as a first trigger can be particularly useful if a regular event is monitored (e. g. regular meals).

[0016] Further, a certain value and/or a progression of a glucose concentration can be employed as a trigger. If it is of interest whether the glucose concentration exceeds or falls below a certain (maybe critical) value, e. g. in order to monitor the development of the glucose concentration, the collection process and analysis can meet this demand by starting to collect data and stopping to collect data, respectively, when such a value is reached. Also a certain progression of the glucose concentration, e. g. a particularly flat or steep slope or a local minimum or maximum of the glucose concentration, can be used as a first and/or second trigger.

[0017] A signal of an external device such as e. g. an insulin pump, a blood glucose meter for spot measurements, a thermometer or a pulse monitor can be used as a trigger as well, providing a plurality of possible trigger events, e. g. corresponding to events that have a direct connection with insulin therapy or that relate to physiological parameters such as a certain and possibly predefined body temperature or heart rate.

[0018] Preferably also combinations of these possible triggers can be used such as e. g. a user input as a first trigger combined with a predetermined time of e. g. four hours after initiation of data collection as a second trigger. It is even possible to combine different conditions (e. g. a certain glucose concentration determined by CGM during a certain predetermined time interval) in such a way that the starting or stopping of data collection is triggered only when all conditions are fulfilled.

[0019] The assessment method can be applied to glucose concentration excursion data corresponding to a reaction to a relevant event such as e. g. a meal or physical activity. This is of particular interest during insulin therapy, providing an online feedback, a therapy support and/or an assessment for therapy optimisation. By monitoring the glucose concentration excursion, the effect of the therapy can be determined and optimised. E. g. the assessment of previous events can show whether the amount of insulin or the timing of the respective bolus sufficiently matches with the individual human body. Therefore, by monitoring and analysing such relevant events, future therapy can be improved. In order that a measured glucose concentration excursion curve can be compared with an estimated excursion curve, a grading measure can be determined from the collected data.

[0020] One criterion for a grading of a measured glucose concentration excursion comprises a discrete number of

target gates. A target gate comprises an interval of values enclosing a centre value, which is preferably defined by an estimated glucose concentration, corresponding to an optimum reaction of the human body to a certain challenge (meal, bolus, physical activity etc.). The width of a target gate can be defined by an absolute value or by a relative width i. e. relative to the centre value. In particular, to achieve a more accurate grading in the sense of smaller steps between the respective grades, each target gate can be substituted by a set of target gates. A set of target gates comprises at least a first target gate of a first width and a second target gate of a second width. Preferably there are more than two target gates in each set. Again the width of each target gate of the set of target gates can be given by an absolute value or by a relative width. The centres of the target gates of each set of target gates preferably lie on the very spot. It might also be advantageous to displace the centres of the target gates so the interval values of the glucose excursion of the corresponding grade are displaced. In particular this might be the case if a value of the estimated glucose concentration excursion e. g. is close to a critical value so a deviation in one direction is not as significant as a deviation in the opposite one.

[0021] In the case of single target gates, the grading criterion of the glucose concentration excursion further comprises the number of target gates which enclose the measured glucose concentration excursion curve. As each target gate stands for a certain (absolute or relative) deviation of a measured value from its corresponding estimated value, the grade of the measured glucose concentration excursion curve is the better, the more target gates enclose it. In case of sets of target gates, the criterion of a grading of the glucose concentration excursion comprises the number of the first gates, the second gates and optionally additional gates of other widths that enclose the glucose concentration excursion curve. The best grading is achieved if the smallest target gate of each set of target gates encloses the glucose concentration excursion curve.

[0022] A further criterion for a grading of a glucose concentration excursion comprises a band of relative target ranges, whereas the width of the relative target ranges is determined as being a percentage of the appropriate value of the estimated glucose concentration excursion. In particular, in order to gain a more accurate grading, in the sense of smaller steps between the respective grades, the band of relative target ranges can be substituted by a set of bands of relative target ranges, which comprises at least one first band of a first relative target range and one second band of a second relative target range and preferably further bands of relative target ranges of different widths. Each of the relative target ranges is preferably centred on the estimated glucose concentration excursion curve. However, the centres of the bands of relative target ranges can also be displaced out of the estimated glucose concentration excursion curve where that might be advantageous.

[0023] In case of one band of relative target ranges this criterion further comprises the relative time during which the measured glucose concentration excursion curve is enclosed by the band of relative target ranges. In case of a set of bands of relative target ranges this criterion further comprises the relative time in which the measured glucose concentration excursion curve is enclosed by each band of relative target ranges. Similarly to the above mentioned criterion of discrete target gates the best grade is achieved when the measured glucose concentration curve is completely enclosed by the narrowest band of relative target ranges. More generally speaking, the longer the measured glucose concentration excursion curve is enclosed by a narrow band of relative target ranges, the better is its grading.

[0024] A further criterion for a grading of a glucose concentration excursion comprises the use of j-indices, whereas a j-index is calculated using the mean value as well as the standard deviation of a number of measured glucose concentrations. The resulting j-index indicates how the measured glucose concentration excursion is to be graded relative to the estimated glucose concentration excursion. I. e. one or several ranges of numbers of j-indices categorise the deviations of the measured glucose concentration excursion with respect to the estimated glucose concentration excursion.

[0025] The previously described grading of a measured glucose concentration excursion allows for an online feedback of a glucose concentration control. The quality/grading of the glucose concentration control can be determined by one of the previously described grading processes and displayed. Thus, due to the ability of determining the quality/grading of the glucose concentration control, the effect of parameters of the glucose concentration control such as the amount or distribution of insulin or the timing of a bolus can be monitored and corrected. This is in order to match the treatment with the reaction of the organism of an individual person and helps to optimise future treatments of that person.

[0026] The determination of the quality/grading of the glucose concentration control can be based on the number of glucose values which lie within a target gate relative to the total number of target gates. That means that the percentage of target gates which enclose the glucose concentration excursion relates to the grading of the glucose concentration control as the deviation of the measured glucose concentration excursion is compared with and graded with respect to an estimated ideal glucose concentration excursion curve. In particular, providing a more accurate determination of the quality/grading of the glucose concentration control, it can be based on the respective numbers of glucose values which lie within the target gates of the first width, second width and optionally other widths, respectively, relative to the total number of sets of target gates. Here only the smallest target gate per set of target gates, which encloses the glucose concentration excursion curve, is considered because if a narrow target gate encloses the glucose concentration excursion curve, a wider target gate of the same set of target gates necessarily encloses the glucose concentration excursion

curve as well. The overall determination of the quality/grading of the glucose concentration control is subsequently deduced from the respective percentage of first, second and optionally other target gates, which enclose the measured glucose concentration excursion curve.

[0027] Further, the determination of the quality/grading of the glucose concentration control can be based on the relative time where the glucose concentration excursion curve lies within the band of relative target range. This relative time stands for the percentage where the band of relative target range encloses the measured glucose concentration excursion curve, similar to the previously described percentage of target gates that enclose the glucose concentration excursion curve but with a much larger total number of target gates and therefore a quasi-continuous band of relative target range. In particular, to achieve a more accurate determination of the quality/grading of the glucose concentration control, it can be based on the relative time where the glucose concentration excursion curve lies within the first, second and optionally other bands of relative target ranges, respectively.

[0028] A device or arrangement which is designed and programmed to perform an assessment method on a signal corresponding to a glucose concentration as previously described comprises a measuring device for collecting the data to be analysed. Such a measuring device can be e. g. a continuous glucose measuring device or a strip meter or tape cassette. A computing device can analyse the collected data in the previously described way and control the assessment process, respectively. Further, a storage device can be used for recording the collected data in particular during the collection process. Analyses performed by the computing unit can also be stored in the storage device for future reviews or further processing of the analyses. The analysed and - if applicable - the stored data then can be visualised on a display providing an online feedback to the user. For transmission of data between the measuring device on the one hand and the computing device, storage device and display on the other hand, a communication link is comprised by the inventive glucose concentration processing device.

[0029] Preferably, the communication link for data transmission between the measuring device on the one hand and the computing device, storage device and display on the other hand is working automatically without user interaction. Thus, the components can communicate with each another independently, and each trigger e. g. by user input or other previously described incidents can be internally processed without the need of further user interaction.

[0030] The previously described assessment processing device preferably is capable of applying at least two criteria and/or methods for determining the grading of a glucose concentration excursion and the criterion and/or method can be chosen online by the user. This feature of the device helps to improve the assessment as the previously described criteria and/or methods show individual advantages and disadvantages for certain applications and patients, respectively. Furthermore, combining more than one criteria or methods, respectively, may lead to an even clearer picture. Thus, a device that offers a choice of different assessment methods or grading criteria is much more flexible than a device with a fixed and predefined assessment method.

[0031] Other advantageous embodiments and combinations of features come out from the detailed description below and the totality of the claims.

Brief description of the drawings

[0032] The drawings used to explain the embodiments show:

Fig. 1 A diagram representing a blood glucose concentration excursion and a scheme of target gates;

Fig. 2 a diagram showing a distribution of grades determined by the target gates scheme;

Fig. 3 a diagram representing a blood glucose concentration excursion and a scheme of relative target ranges;

Fig.4 a diagram showing a distribution of grades determined by the relative target ranges scheme;

Fig. 5 a diagram representing a blood glucose concentration excursion and a prandial/fasting grading scheme; and

Fig. 6 a schematic representation of a device for insulin therapy assessment.

[0033] In the figures, the same components are given the same reference symbols.

Preferred embodiments

[0034] Figure 1 shows a diagram with its horizontal axis 3 annotated by time after a meal start 9 (in minutes) and its vertical axis 7 annotated by blood glucose concentration BG (in mmol/l). A measurement of a blood glucose concentration excursion 2 as well as thresholds of the critical blood glucose concentrations of hypoglycemia (threshold 1) and hyper-

glycemia (threshold 8) are plotted in the diagram. Several sets of target gates 4, 5, 6 indicate ranges of blood glucose concentrations around an ideal excursion. Target gates of a first width 4 define the smallest deviation of the measured glucose concentration excursion with respect to the ideal one. The target gates of second and third widths 5, 6 define further deviations of the measurement with respect to the ideal values. In the target gate method the measured data is downsampled to a few data points - in this example down to six points in time - to look at, which highly reduces the analysis effort.

[0035] Target gates of different widths 4, 5, 6 are defined at the same timed points along the glucose trace. They are further defined by their centre point, which corresponds to an ideal glucose concentration at the respective timed point and a width towards higher and lower concentrations. A smaller width of a gate results in a better grading. In order to determine a grading for the blood glucose concentration excursion control, the grading of all sets of gates is taken into account.

[0036] A set of target gates comprises all equally timed target gates of different widths. In figure 1, the set corresponding to two hours (120 minutes) after meal start is given by the three gates 4, 5 and 6. Further sets of target gates are positioned at two hours before meal start (fasting), at meal start (pre-prandial), at one and three hours after meal start (post prandial) and at four hours after meal start (fasting). The distribution of the sets of target gates is chosen with respect to the ideal glucose concentration excursion but may be subject to change depending on the scope of the assessment of the blood glucose concentration excursion. Application of the target gate method does only consider discretely timed and meaningful points along the excursion curve.

[0037] The target gate method is triggered by the user, which is why this assessment method can be adapted to any individual patient's eating habits. Even without cyclic eating habits, a retrospective analysis of the blood glucose concentration control by a particular amount, timing and distribution of insulin can be performed as the analysing process is triggered individually. At the end of the excursion, which typically occurs about four hours after the meal start, or at the user's next input, an online feedback can be given to the user. The feedback concerns the effect of the amount, timing and distribution of the insulin bolus, which has been applied with respect to the previous meal. This retrospective analysing method does clearly determine how good the matching of the applied bolus of insulin to the specific meal was and thus gives advice for the further treatment.

[0038] In figure 2, the summarising assessment of the blood glucose concentration control is shown. At the timed position of the target gates, the measured glucose concentration values are compared to the minimum and maximum values of the respective target gates. The best applicable grade, which is attributed to the narrowest gate that encloses the glucose concentration value, is assigned to the value of that timing. Subsequent application of this step results in a number of respective grades. The percentage of each grade with respect to the total number of grades, i. e. the total number of target gates, is shown in figure 2.

[0039] In figure 2 the summarised grading is shown as a column diagram 11, whereas the best grade I is plotted at the lowest position with the next best grade positioned on top of the first one and so on. A legend 12 shows the different grades, whereas I means the best grade (corresponding to the narrowest target gate), II and III the second and third best grade. V means that the measured glucose concentration value is not enclosed by a target gate and therefore indicates a lack of blood glucose concentration control. On the left hand side of the diagram there is a scale 10 showing percentages of 0% up to 100% for determining the accumulated percentage of a certain grade and better grades. E. g. 17% of the measurement were categorised grade II and III, respectively, as opposed to 67% of the measurement being categorised grade I. On the scale 10 an accumulated percentage of 84% of the measurement being categorised in grade II or better can be read.

[0040] Figure 3 shows a diagram with its horizontal axis 3 annotated by time after a meal start 9 (in minutes) and its vertical axis 7 annotated by blood glucose concentration BG (in mmol/l). A measurement of blood glucose concentration excursion 23 is plotted as well as a plurality of relative target ranges 16, 22; 17, 21; 18, 20 spaced from an ideal glucose concentration excursion depicted as crosses 19 to both sides. Each relative target range is defined by a width, which is relative to the centre value given by the ideal glucose concentration 19. A first width of 25% relative to the ideal glucose concentration is represented by continuous lines 18, 20, a second width of 66%, by dashed lines 17,21 and a third width of 100% is plotted as dashed-dotted lines 16, 22, whereas the recited widths are total widths meaning that a width of 25% corresponds to 12.5%, 66% to 33% and 100% to 50%, respectively, towards higher as well as lower values.

[0041] The relative target range method is similar to the target gate method but with a far greater number of target gates. Being a continuous or quasi-continuous assessment method, a more accurate determination of the quality of the glucose concentration excursion control is possible. This method therefore is particularly useful for continuous glucose concentration monitoring. As in the previously described target gate method, the assessment of the insulin regimen is performed either over a tunable period of time or between two triggering events resulting from user input. A first trigger can start the assessment and data collection. The time of triggering can set the assumed time of meal start or another time preferably before the time of meal start. The relative target ranges are subsequently arranged around the ideal glucose concentration excursion curve and the categorising step is taking place during the measurement process. On a second trigger the result of the analysing process is immediately shown to the user.

[0042] If the measured blood glucose concentration value lies within the first width of 25% it is categorised as a, within the second width of 66% as b, within the third width of 100% as c and if the values do not lie within a relative target range, they are categorised as *d* These categories can directly be compared to those of the target gate method, whereas a is comparable to I, bto II, cto III and dto V.

[0043] The metric for the relative target range method for performing the summarised assessment of the blood glucose concentration excursion control is also similar to that of the target gate method. As the number of gates goes to infinity, an enumeration is not preferred, instead, the respective period of time in which the curve is enclosed by each relative target range is preferably chosen for being the basis for determining the percentage of the grading, i. e. the period of time spent by the measured curve within a relative target range is assigned to the corresponding grade. After finishing the measurement, the relative time in which the curve was enclosed by each relative target range denotes the fraction of the corresponding grade with respect to the total measurement. Assuming a measurement of 240 minutes, a summarised grading of 62% of grade a is achieved if the curve is enclosed by the narrowest relative target range for 149 minutes.

[0044] Figure 4 corresponds to the result of the relative target range method as depicted in figure 3, whereas the relative target ranges 15 a to c correspond to the relative widths of 25%, 66% and 100% respectively. Target range *d* stands for a measured glucose concentration excursion which is separated from the ideal excursion by more than 100%, which is assumed as lack of glucose concentration excursion control. The column diagram 14 is similar to the column diagram 11 in figure 2. It shows the percentage of the respective relative target ranges. The scale 13 on the left hand side of the figure measures the accumulated percentage of a grade and all better grades. E. g. an accumulated percentage of 76% for grade b or better can be read from the scale 13 in connection with the column diagram 14.

[0045] Figure 5 shows a diagram with its horizontal axis 3 annotated by time after a meal start 9 (in minutes) and its vertical axis 7 annotated by blood glucose concentration BG (in mmol/l). A measurement of blood glucose concentration excursion 27 is plotted. This figure illustrates the prandial/fasting scheme as described in *L. J. Chassin et al., "Grading System to Assess Clinical Performance of Closed-Loop Glucose Control; Diabetes Technology and Therapeutics7* (2005) 72 - 82. The prandial/fasting scheme distinguishes the outside-meal condition (fasting) 30, 32 from the postprandial condition (prandial) 31, which is defined as a period of time of from 15 minutes to 180 minutes after meal ingestion. Each of the conditions represents a physiological status and defines threshold values for determination of the grade of a blood glucose concentration value.

[0046] The scheme comprises grades A to F, whereas A and B characterise excellent and good glucose control, respectively, without the need for a corrective action. Grade C represents suboptimal control with a recommendation for a corrective action. Grade D represents poor control requiring a corrective action. Grades E and F represent very poor and life-threatening control, respectively, with a need for an immediate corrective action or requiring an external assistance. Again, these grades can be looked at as corresponding directly to the previously described grades I to V and *a* to *d*, respectively. In contrast to the previously described assessment methods, the prandial/fasting scheme provides a simpler categorisation with respect to time after meal start.

[0047] In figure 5 the grades are plotted as areas between lines of different shapes 24 - 29, 33 - 44. The following table may give an overview of said categories.

Blood glucose concentration (BG)	Fasting condition	Prandial condition
≤ 2.8	F	F
≤ 3.3	E	E
≤ 4.4	C	D
≤ 6.1	A	B
≤ 7.2	B	A
≤ 7.8	C	A
≤ 10.0	D	B
≤ 13.9	D	C
≤ 25	E	D
>25	F	F

[0048] In the fasting condition there is no grade B or D in the hypoglycemic regime, whereas the prandial condition does not show a grade C in this regime as opposed to no grade E in case of hyperglycemia.

[0049] The metric for the summarised assessment of the blood glucose concentration excursion control is essentially the same as for the relative target range method, considering the respective period of time the curve is enclosed by each area as chosen for being the basis for determining the percentage of the grading. I. e. the period of time spent by the measured curve within an area is assigned to the corresponding grade. After finishing the measurement, the relative time in which the curve was enclosed by each area gives the fraction of the corresponding grade with respect to the total measurement.

[0050] Figure 6 shows a device for performing the previously described assessment methods. It comprises a central unit 52, which coordinates the measurement and calculates the summarised assessment of the blood glucose concentration excursion control. It can be triggered by a user via a user interface 46 e. g. a button which defines the start of the measurement and/or the meal start. Triggered by the user input the central unit 52 starts assessment of the measurements, which are performed by a blood glucose concentration monitoring device 45 e. g. by spot monitoring of blood glucose concentration by a strip meter or cassette or by continuous monitoring of blood (or interstitial) glucose concentration. The measured data are processed by the central unit 52 using one of the previously described assessment methods. Either on a second trigger by the user or after a tunable period of time, which might be set by the user e. g. using a countdown 48, the results of the summarised assessment of the blood glucose concentration excursion control are displayed on a display device 47, these results can also be printed on a printer 49 that can be connected to the central unit 52.

[0051] In summary, it is to be noted that the previously described assessment schemes are a selection of a plurality of different methods to deal with grading of a glucose concentration excursion control. Other examples are the j-index (also j-value) method which leads to a grading by calculating a j-value using the definition

$$j = 0.324 \cdot (mean(BG) + SD(BG))^2,$$

with mean(BG) being the mean of the measured blood glucose concentration (in mmol/l) and SD(BG) being the standard deviation of the blood glucose concentration (also in mmol/l). The actual grading subsequently is defined by ranges of j-values i. e. $10 < j < 20$ for ideal blood glucose concentration control up to $j > 40$ for lack of blood glucose concentration control. Other known assessment schemes such as pi-index method or determination of the area under the curve or incremental area under the curve, respectively, as well as those being further described in Diabetes Techn. Therp. 7 (2005) 72-82 by Chassin *et al.* can also be incorporated to the assessment device.

[0052] The assessment device as depicted in figure 6 can be modified e. g. in such a way that the user interface to trigger the assessment method as well as the display device can be combined in the central unit making the assessment device a single apparatus. The assessment device can also be combined with the measuring device e. g. in a closed-loop control of blood glucose concentration.

[0053] The number and meaning of the grading can be adapted to the scope of the assessment or therapy support. During optimisation of the therapy the grading can be varied in such a way that the different grades get closer to one another as the optimisation goes on. E. g. in the case of the target gate method all the gates can be made narrower and with less difference in width to each other in order to provide a finer grading of the therapy.

[0054] Triggering the assessment method can preferably be done by a simple user input such as pressing a button. Other instruments for user input e. g. a touch screen on the display or a trigger using an external device can be employed. As for the second trigger, besides the same user input as that being used for the first one, a countdown may set the end of the assessment. In addition to these triggers by user input a triggering event can also be formed by a specific shape of the glucose concentration curve such as a steep slope or by a specific absolute value of the blood glucose concentration.

[0055] In order to observe and control proceedings in a diabetes therapy, the results of a plurality of assessments can be recorded and graphically displayed. This can also have a positive psychological effect on the patient as advances in the glucose concentration control and therefore in the efficiency of the therapy become apparent. The simple way of using the device enables any patient to perform an assessment of his/her actual glucose concentration excursion control. This in turn leads to a more reliable monitoring of the therapy and allows conclusion about the quality of the blood glucose concentration control. In particular a well-founded binary judgement in the sense of deciding on the therapy as being good or bad lies in the scope of the described assessment method.

Claims

1. Assessment method to process a signal corresponding to a glucose concentration, performing a retrospective analysis, whereas the assessment is comprising the steps of

a) starting the assessment initiated by a first trigger, wherein the first trigger defines the beginning of a segment of a continuous measurement of glucose concentration or defines the first of a series of spot measurements of glucose concentration,'
b) collecting data of the continuous measurement or the series of spot measurements of glucose concentration to be analysed, wherein the collected data relate to a glucose concentration excursion corresponding to a reaction to a relevant event such as a meal or physical activity,'
c) analysing the collected data initiated by a second rigger, wherein the second trigger defines the end of the collected data to be analysed,[3] wherein a measure for a grading of the excursion is determined from the collected data,[4] and
d) displaying the results of the analysis.

2. Method as recited in claim 1, **characterised in that** the first and/or the second trigger corresponds to

a) user input,
b) a predetermined time,
c) a value and/or progression of glucose concentration,
d) a signal of an external device
or a combination thereof.

3. Method as recited in one of claims 1 or 2, **characterised in that** criteria for the determination of the grading of the glucose concentration excursion are given by

a) a discrete number of target gates (4, 5, 6) as well as
b) the number of these target gates (4, 5, 6) that enclose a curve (2) corresponding to the glucose concentration excursion,
in particular that the criteria are given by
c) a discrete number of sets of target gates (4, 5, 6), whereas each set of target gates comprises at least one first target gate (4) of a first width and one second target gate (5) of a second width, whereas the centres of the at least two target gates (4, 5) of the set show the same position in time, as well as
d) the numbers of the first gates (4), the second gates (5) and optionally additional gates (6) of other widths that enclose the curve (2) corresponding to the glucose concentration excursion.

4. Method as recited in one of claims 1 or 2, **characterised in that** criteria for the determination of the grading of the glucose concentration excursion are given by

a) a band of a relative target range (18, 20; 17, 21; 16, 22) as well as
b) the relative time the band encloses the glucose concentration excursion curve (23),
in particular that the criteria are given by
c) a set of bands of relative target ranges, comprising at least one first band (18, 20) of a first relative target range and one second band (17, 21) of a second relative target range, as well as
d) the relative time each band of relative target range (18, 20; 17, 21) respectively encloses the glucose concentration excursion curve (23).

5. Method as recited in one of claims 1 or 2, **characterised in that** criteria for the determination of the grading of the glucose concentration excursion are given by a range of j-indices, whereas a j-index is calculated using the mean value as well as the standard deviation of glucose concentrations, in particular criteria for the determination of the grading of the glucose concentration excursion are given by a set of different ranges of j-indices indicating the grading of the glucose concentration excursion.

6. Method as recited in one of claims 1 to 5, **characterised in that** conclusions about the quality of a glucose concentration control resulting from the measured glucose concentration excursion are determined and displayed.

7. Method as recited in claims 3 and 6, **characterised in that** the quality of the glucose concentration control is determined based on the number of glucose values, which lie within a target gate (4, 5, 6) relative to the total number of target gates, in particular based on the respective numbers of glucose values, which lie within the target gates of the first width (4), second width (5) and optionally other widths (6), respectively, whereas only the smallest gate, which encloses the respective glucose value, is considered for each set of gates, relative to the total number of sets of target gates.

8. Method as recited in claims 4 and 6, **characterised in that** the quality of the glucose concentration control is determined based on the relative time where the glucose concentration excursion curve lies within the band of relative target range (18, 20; 17, 21; 16, 22), in particular the relative time, where the glucose concentration excursion lies within the first (18, 20), second (17, 21) and optionally other bands (16, 22) of relative target ranges, respectively.

9. Device to process a signal corresponding to a glucose concentration, **characterised in that** it is designed and programmed to perform an assessment method as recited in one of claims 1 to 8 comprising

a) a measuring device (45) for collecting the data to be analysed,
b) a computing device (52) for analysing the collected data,
c) a storage device (50) for recording the collected data and the analysis,
d) a display (47) for visualising the analysed data, and
e) a communication link (51) for transmitting data between the measuring device and the computing/storage device and display, respectively.

10. Device as recited in claim 9, **characterised in that** the measuring device (45) on the one hand and the computing device (52), storage device (50) and display (47) on the other hand communicate automatically, without user interaction.

11. Device as recited in one of claims 9 or 10, **characterised in that** it is capable of applying at least two criteria and/or methods for determining the grading of a glucose concentration excursion and that the criterion and/or method to be used can be chosen online by the user.

Patentansprüche

1. Bewertungsverfahren zum Verarbeiten eines einer Glukosekonzentration entsprechenden Signals mit Durchführung einer Retrospektivanalyse, wobei die Bewertung die folgenden Schritte umfasst:

a) durch einen ersten Auslöser initiiertes Starten der Bewertung, wobei der erste Auslöser den Beginn eines Abschnitts einer kontinuierlichen Glukosekonzentrationsmessung oder die erste einer Reihe von Glukosekonzentrationspunktmessungen definiert;
b) Sammeln von zu analysierenden Daten der kontinuierlichen Messung oder der Reihe von Glukosekonzentrationspunktmessungen, wobei die gesammelten Daten in Beziehung zu einem Glukosekonzentrationsausschlag stehen, der einer Reaktion auf ein relevantes Ereignis, wie etwa eine Mahlzeit oder physische Betätigung, entspricht;
c) durch einen zweiten Auslöser initiiertes Analysieren der gesammelten Daten, wobei der zweite Auslöser das Ende der zu analysierenden Daten definiert, wobei ein Maß für ein Einstufen des Ausschlags aus den gesammelten Daten bestimmt wird; und
d) Darstellen der Ergebnisse der Analyse.

2. Verfahren nach Anspruch 1, **dadurch gekennzeichnet, dass** der erste und/oder der zweite Auslöser

a) einer Eingabe durch den Anwender,
b) einer vorbestimmten Zeit,
c) einem Wert und/oder einer Steigerung der Glukosekonzentration,
d) einem Signal einer externen Vorrichtung
oder einer Kombination davon entspricht.

3. Verfahren nach einem der Ansprüche 1 oder 2, **dadurch gekennzeichnet, dass** Kriterien für die Bestimmung der Einstufung des Glukosekonzentrationsausschlags durch

a) eine diskrete Anzahl von Zielfenstern (4, 5, 6) ebenso wie
b) die Anzahl dieser Zielfenster (4, 5, 6), die eine dem Glukosekonzentrationsausschlag entsprechende Kurve (2) einschließen, gegeben sind,
insbesondere, dass die Kriterien durch
c) eine diskrete Anzahl von Sätzen von Zielfenstern (4, 5, 6), während jeder Satz von Zielfenstern wenigstens ein erstes Zielfenster (4) einer ersten Breite und ein zweites Zielfenster (5) einer zweiten Breite umfasst, während

die Zentren der wenigstens zwei Zielfenster (4, 5) des Satzes zeitlich die gleiche Position zeigen, ebenso wie
d) die Anzahl der ersten Fenster (4), der zweiten Fenster (5) und gegebenenfalls zusätzlicher Fenster (6) mit anderen Breiten, die die dem Glukosekonzentrationsausschlag entsprechende Kurve (2) einschließen, gegeben sind.

4. Verfahren nach einem der Ansprüche 1 oder 2, **dadurch gekennzeichnet, dass** Kriterien für die Bestimmung der Einstufung des Glukosekonzentrationsausschlags durch

a) eine Bandbreite eines relativen Zielbereichs (18, 20; 17, 21; 16, 22) ebenso wie
b) die relative Zeit, die die Bandbreite die Glukosekonzentrationsausschlagskurve (23) einschließt, gegeben sind,
insbesondere, dass die Kriterien durch
c) einen Satz von Bandbreiten relativer Zielbereiche, umfassend wenigstens eine erste Bandbreite (18, 20) eines ersten relativen Zielbereichs und eine zweite Bandbreite (17, 21) eines zweiten relativen Zielbereichs, ebenso wie
d) die relative Zeit, die jede Bandbreite des relativen Zielbereichs (18, 20; 17, 21) jeweils die Glukosekonzentrationsausschlagskurve (23) einschließt, gegeben sind.

5. Verfahren nach einem der Ansprüche 1 oder 2, **dadurch gekennzeichnet, dass** Kriterien für die Bestimmung der Einstufung des Glukosekonzentrationsausschlags durch einen Bereich von j-Indizes gegeben sind, während ein j-Index unter Verwendung des Mittelwerts ebenso wie der Standardabweichung von Glukosekonzentrationen berechnet wird, insbesondere Kriterien für die Bestimmung der Einstufung des Glukosekonzentrationsausschlags durch einen Satz unterschiedlicher Bereiche von j-Indizes, die die Einstufung des Glukosekonzentrationsausschlags anzeigen, gegeben sind.

6. Verfahren nach einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet, dass** Schlussfolgerungen über die Qualität einer Glukosekonzentrationskontrolle als Ergebnis des gemessenen Glukosekonzentrationsausschlags bestimmt und dargestellt werden.

7. Verfahren nach Anspruch 3 und 6, **dadurch gekennzeichnet, dass** die Qualität der Glukosekonzentrationskontrolle bezogen auf die Anzahl von Glukosewerten, die innerhalb eines Zielfensters (4, 5, 6) relativ zu der Gesamtzahl an Zielfenstern liegen, insbesondere bezogen auf die jeweilige Anzahl von Glukosewerten, die innerhalb der Zielfenster der ersten Breite (4), zweiten Breite (5) bzw. gegebenenfalls anderer Breiten (6) liegen, bestimmt wird, während für jeden Satz von Fenstern, relativ zur Gesamtzahl an Sätzen von Zielfenstern, jeweils nur das kleinste Fenster, das den jeweiligen Glukosewert einschließt, betrachtet wird.

8. Verfahren nach Anspruch 4 und 6, **dadurch gekennzeichnet, dass** die Qualität der Glukosekonzentrationskontrolle bezogen auf die relative Zeit, in der die Glukosekonzentrationsausschlagskurve innerhalb der Bandbreite relativer Zielbereiche (18, 20; 17, 21; 16, 22) liegt, insbesondere die relative Zeit, in der der Glukosekonzentrationsausschlag innerhalb der ersten (18, 20), zweiten (17, 21) bzw. gegebenenfalls anderer Bandbreiten (16, 22) relativer Zielbereiche liegt, bestimmt wird.

9. Vorrichtung zum Verarbeiten eines einer Glukosekonzentration entsprechenden Signals, **dadurch gekennzeichnet, dass** sie zur Durchführung eines Bewertungsverfahrens nach einem der Ansprüche 1 bis 8 konstruiert und programmiert ist, umfassend

a) eine Messvorrichtung (45) zum Sammeln der zu analysierenden Daten,
b) eine Rechnervorrichtung (52) zum Analysieren der gesammelten Daten,
c) eine Speichervorrichtung (50) zum Aufzeichnen der gesammelten Daten und der Analyse,
d) ein Display (47) zur optischen Darstellung der analysierten Daten und
e) eine Kommunikationsverbindung (51) zur Übertragung von Daten zwischen der Messvorrichtung und der Rechner-/Speichervorrichtung bzw. dem Display.

10. Vorrichtung nach Anspruch 9, **dadurch gekennzeichnet, dass** zwischen der Messvorrichtung (45) einerseits sowie der Rechnervorrichtung (52), der Speichervorrichtung (50) und dem Display (47) andererseits eine automatische Kommunikation, ohne Interaktion des Anwenders, erfolgt.

11. Vorrichtung nach einem der Ansprüche 9 oder 10, **dadurch gekennzeichnet, dass** sie in der Lage ist, wenigstens

zwei Kriterien und/oder Verfahren zur Bestimmung der Einstufung eines Glukosekonzentrationsausschlags anzuwenden, und dass das anzuwendende Kriterium und/oder Verfahren vom Anwender online gewählt werden kann.

Revendications

1. Procédé d'évaluation pour traiter un signal correspondant à une concentration de glucose, en effectuant une analyse rétrospective, l'évaluation comprenant les étapes consistant à

   a) lancer l'évaluation à l'initiative d'un premier déclencheur, le premier déclencheur définissant le début d'un segment d'une mesure continue de concentration de glucose ou définissant la première d'une série de mesures ponctuelles de concentration de glucose,
   b) collecter des données de la mesure continue ou de la série de mesures ponctuelles de concentration de glucose à analyser, les données collectées étant liées à un écart de concentration de glucose correspondant à une réaction à un évènement significatif tel qu'un repas ou une activité physique,
   c) analyser les données collectées à l'initiative d'un second déclencheur, le second déclencheur définissant la fin des données collectées à analyser, une mesure pour une classification de l'écart étant déterminée à partir des données collectées, et
   d) afficher les résultats de l'analyse.

2. Procédé selon la revendication 1, **caractérisé en ce que** le premier et/ou le second déclencheur correspondent à

   a) une entrée d'utilisateur,
   b) un temps prédéterminé,
   c) une valeur et/ou une progression de la concentration de glucose,
   d) un signal d'un dispositif externe

   ou une combinaison de ceux-ci.

3. Procédé selon l'une des revendications 1 et 2, **caractérisé en ce que** des critères pour la détermination de la classification de l'écart de concentration de glucose sont donnés par

   a) un nombre discret de fenêtres cibles (4, 5, 6) ainsi que
   b) le nombre de ces fenêtres cibles (4, 5, 6) qui délimitent une courbe (2) correspondant à l'écart de concentration de glucose,
   en particulier **en ce que** les critères sont donnés par
   c) un nombre discret d'ensembles de fenêtres cibles (4, 5, 6), chaque ensemble de fenêtres cibles comprenant au moins une première fenêtre cible (4) d'une première largeur et une seconde fenêtre cible (5) d'une seconde largeur, les centres des au moins deux fenêtres cibles (4, 5) de l'ensemble indiquant la même position dans le temps, ainsi que
   d) les nombres des premières fenêtres (4), des secondes fenêtres (5) et éventuellement de fenêtres supplémentaires (6) d'autres largeurs qui délimitent la courbe (2) correspondant à l'écart de concentration de glucose.

4. Procédé selon l'une des revendications 1 et 2, **caractérisé en ce que** des critères pour la détermination de la classification de l'écart de concentration de glucose sont donnés par

   a) une bande d'une plage relative cible (18, 20 ; 17, 21 ; 16, 22) ainsi que
   b) le temps relatif pendant lequel la bande délimite la courbe d'écart de concentration de glucose (23),
   en particulier **en ce que** les critères sont donnés par
   c) un ensemble de bandes de plages relatives cibles, comprenant au moins une première bande (18, 20) d'une première plage relative cible et une seconde bande (17, 21) d'une seconde plage relative cible, ainsi que
   d) le temps relatif pendant lequel chaque bande de plage relative cible (18, 20 ; 17, 21) délimite respectivement la courbe d'écart de concentration de glucose (23).

5. Procédé selon l'une des revendications 1 et 2, **caractérisé en ce que** des critères pour la détermination de la classification de l'écart de concentration de glucose sont donnés par une gamme d'indices j, un indice j étant calculé en utilisant la valeur moyenne ainsi que l'écart type de concentrations de glucose, en particulier **en ce que** des critères pour la détermination de la classification de l'écart de concentration de glucose sont donnés par un ensemble

de gammes différentes d'indices j indiquant la classification de l'écart de concentration de glucose.

6. Procédé selon l'une des revendications 1 à 5,
caractérisé en ce que des conclusions sur la qualité d'un contrôle de concentration de glucose résultant de l'écart mesuré de concentration de glucose sont déterminées et affichées.

7. Procédé selon les revendications 3 et 6,
caractérisé en ce que la qualité du contrôle de concentration de glucose est déterminée en fonction du nombre de valeurs de glucose qui se situent à l'intérieur d'une fenêtre cible (4, 5, 6) par rapport au nombre total de fenêtres cibles, en particulier en fonction des nombres respectifs de valeurs de glucose qui se situent à l'intérieur des fenêtres cibles respectivement de la première largeur (4), de la seconde largeur (5) et éventuellement d'autres largeurs (6), seule la plus petite fenêtre qui délimite la valeur respective de glucose étant prise en compte pour chaque ensemble de fenêtres, par rapport au nombre total d'ensembles de fenêtres cibles.

8. Procédé selon les revendications 4 et 6,
caractérisé en ce que la qualité du contrôle de concentration de glucose est déterminée en fonction du temps relatif pendant lequel la courbe d'écart de concentration de glucose se situe à l'intérieur de la bande de plage relative cible (18, 20 ; 17, 21 ; 16, 22), en particulier le temps relatif pendant lequel l'écart de concentration de glucose se situe respectivement à l'intérieur de la première (18, 20), de la seconde (17, 21) et éventuellement d'autres bandes (16, 22) de plages relatives cibles.

9. Dispositif pour traiter un signal correspondant à une concentration de glucose, **caractérisé en ce qu'**il est conçu et programmé pour mettre en oeuvre un procédé d'évaluation selon l'une des revendications 1 à 8, comprenant

a) un dispositif de mesure (45) pour collecter les données à analyser,
b) un dispositif de calcul (52) pour analyser les données collectées,
c) un dispositif de stockage (50) pour enregistrer les données collectées et l'analyse,
d) un écran (47) pour visualiser les données analysées, et
e) un lien de communication (51) pour transmettre des données entre le dispositif de mesure et le dispositif de calcul/stockage et l'écran, respectivement.

10. Dispositif selon la revendication 9, **caractérisé en ce que** le dispositif de mesure (45) d'une part et le dispositif de calcul (52), le dispositif de stockage (50) et l'écran (47) d'autre part communiquent automatiquement, sans interaction avec un utilisateur.

11. Dispositif selon l'une des revendications 9 et 10, **caractérisé en ce qu'**il est capable d'appliquer au moins deux critères et/ou procédés pour déterminer la classification d'un écart de concentration de glucose et **en ce que** le critère et/ou le procédé à utiliser peuvent être choisis en ligne par l'utilisateur.

Fig. 1

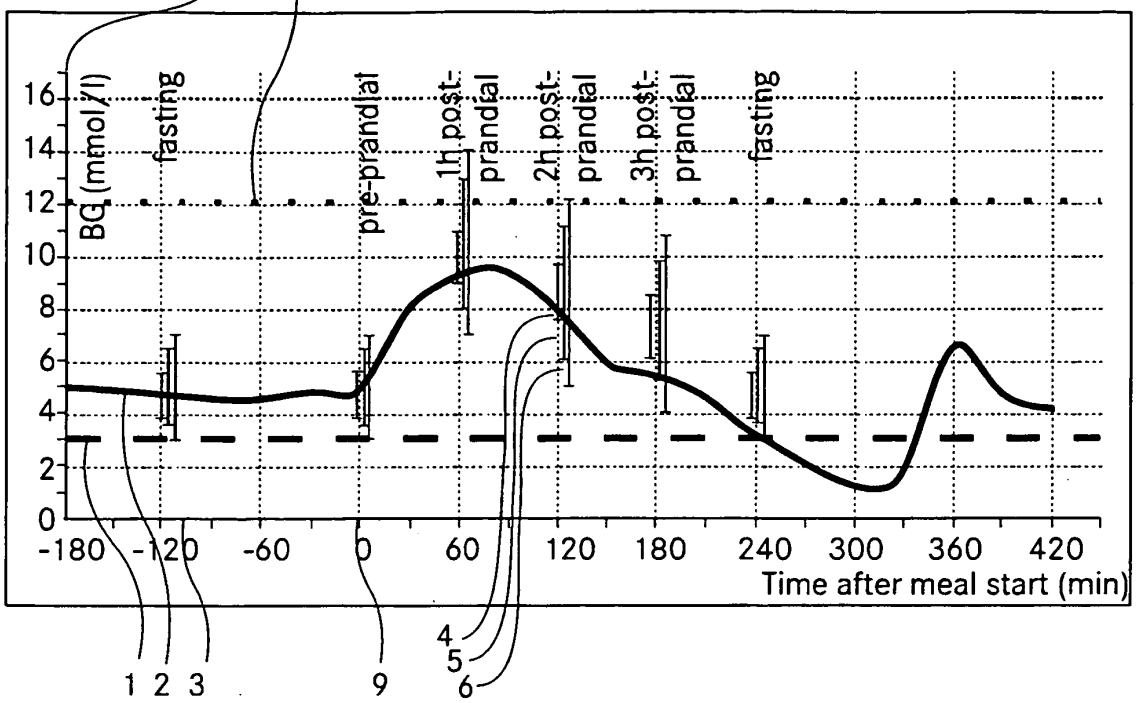


Fig. 2

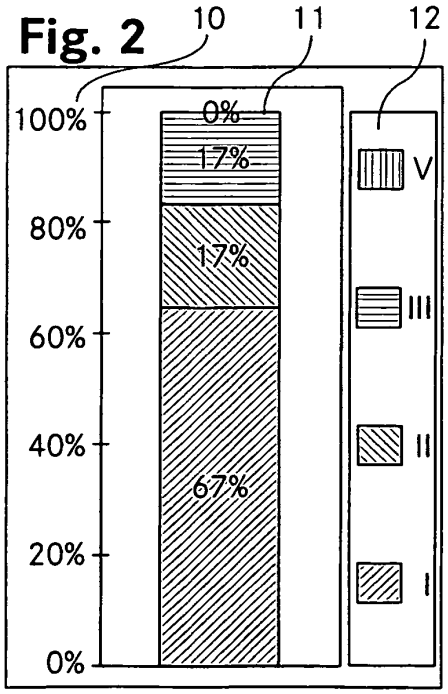


Fig. 4

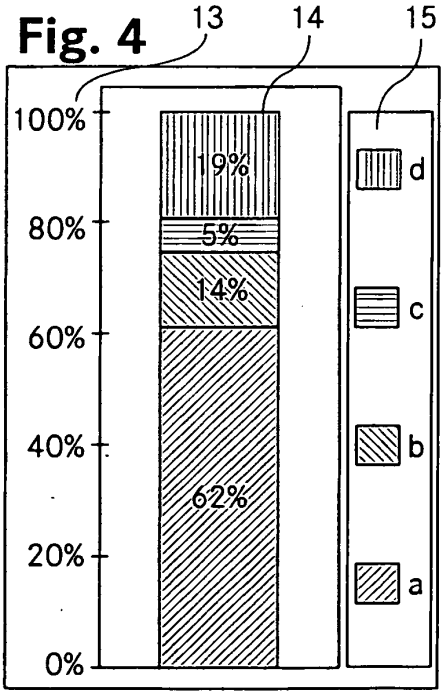


Fig. 3

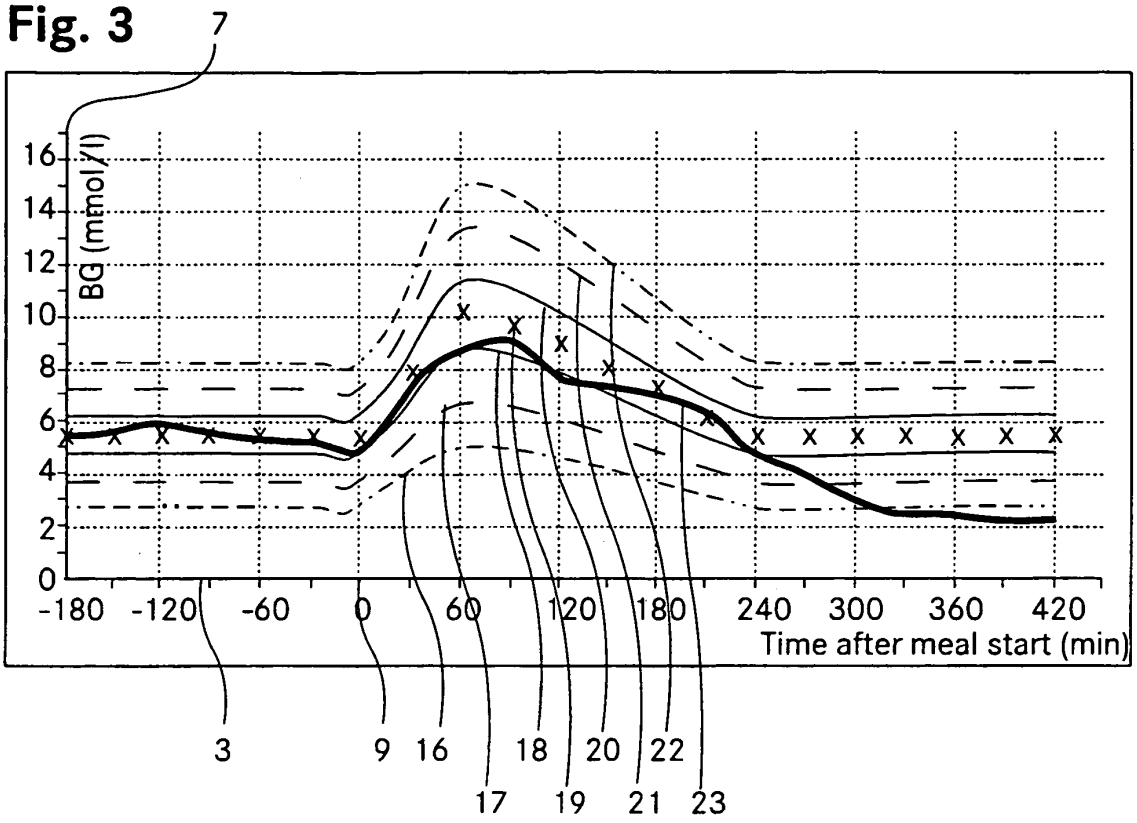

7
BG (mmol/l)
16
14
12
10
8
6
4
2
0
-180
-120
-60
0
60
120
180
240
300
360
420
Time after meal start (min)
3
9
16
17
18
19
20
21
22
23

Fig. 5

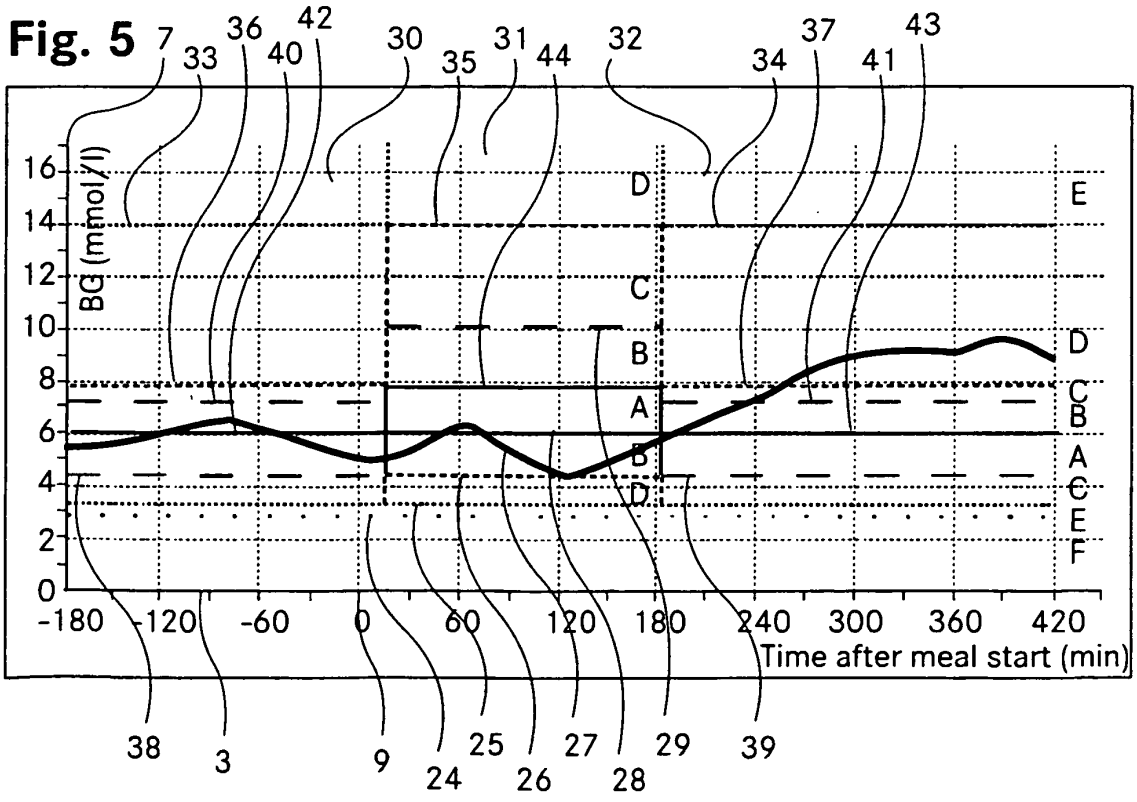
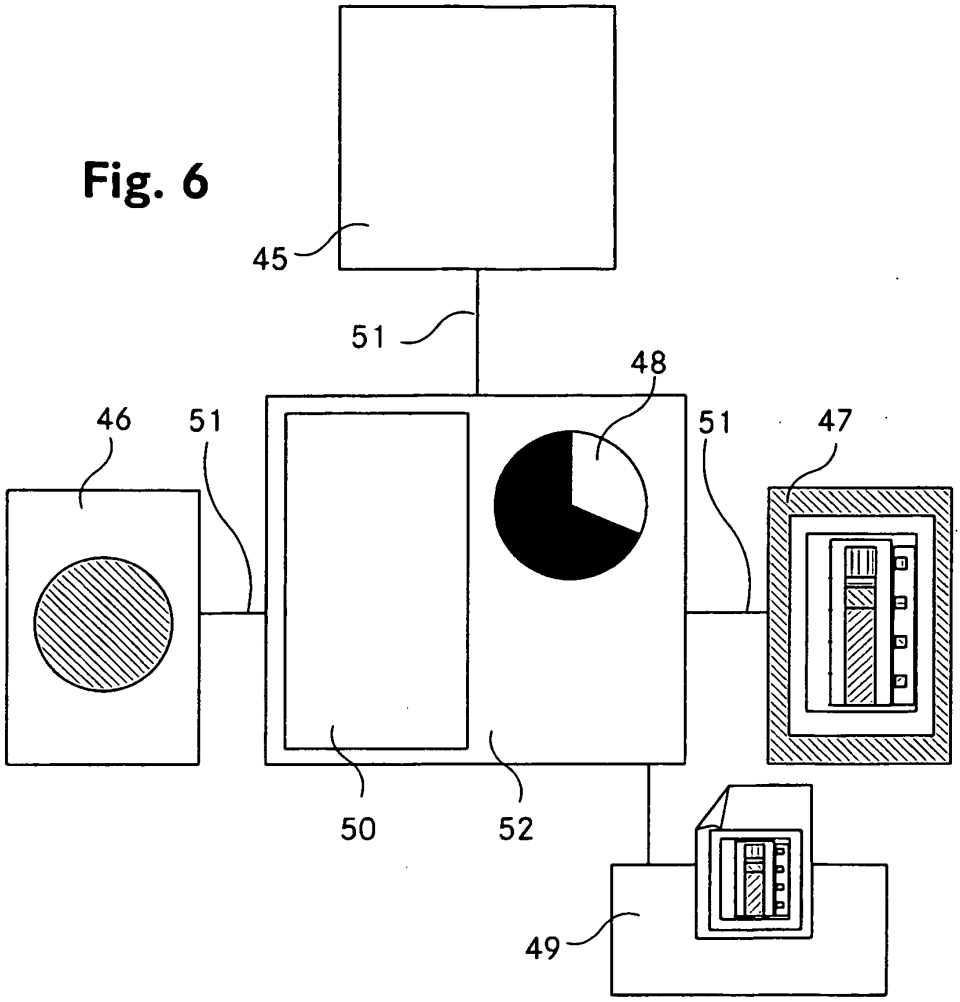

7
33
36
40
42
30
35
31
44
32
34
37
41
43
BG (mmol/l)
16
14
12
10
8
6
4
2
0
A
B
C
D
E
F
-180
-120
-60
0
60
120
180
240
300
360
420
Time after meal start (min)
38
3
9
24
25
26
27
28
29
39

Fig. 6



REFERENCES CITED IN THE DESCRIPTION

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- EP 1338295 A **[0009]**

Non-patent literature cited in the description

- **CHASSIN.** *Diabetes Techn. Therp,* 2005, vol. 7, 72-82 **[0051]**

专利名称(译)	处理葡萄糖浓度信号的评估方法		
公开(公告)号	EP1949849B1	公开(公告)日	2009-09-09
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IPC分类号	A61B5/00 G01N35/10 G06F19/00 G16B45/00		
CPC分类号	A61B5/14532 A61B5/7275 A61B5/7285 G06F19/00 G06F19/324 G06F19/3456 G16H20/10 G16H50/20 G16H70/00		
其他公开文献	EP1949849A1		
外部链接	Espacenet		

摘要(译)

本发明涉及一种通过执行回顾性分析来处理对应于葡萄糖浓度的信号的评估方法，而评估包括开始由第一触发器启动的评估，收集待分析的数据，分析由第二个触发器，显示分析结果。本发明还涉及一种设备，其被设计和编程以执行所述评估方法，至少包括用于收集待分析数据的测量设备（45），用于分析所收集数据的计算设备（52），存储装置（50），用于记录收集的数据和分析，显示器（47），用于可视化分析的数据;以及通信链路（51），用于分别在测量装置和计算/存储装置和显示器之间传输数据。用户有机会选择执行分析的时间段。通过采用用户触发的和回顾性的数据分析，特别是在诸如进餐的相关事件期间或之后收集的数据，确保分析涉及特定事件特定的背景，因此增强了葡萄糖评估的有用性。浓度。

$$j = 0.324 \cdot (mean(BG) + SD(BG))^2,$$