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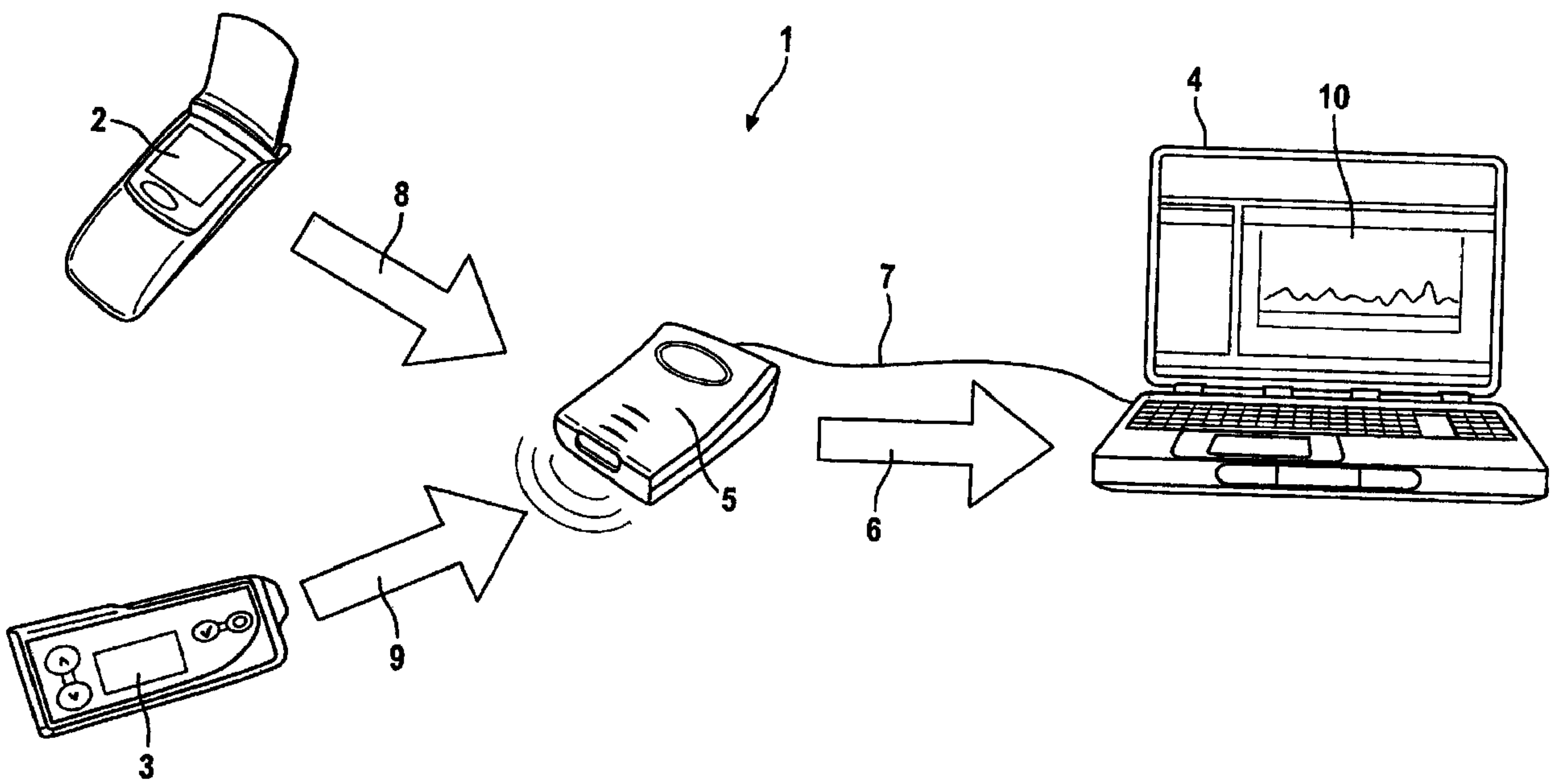
(54) **Titre :** SYSTEME POUR LE GLUCOSE SANGUIN A SYNCHRONISATION TEMPORELLE
(54) **Title:** BLOOD GLUCOSE SYSTEM HAVING TIME SYNCHRONIZATION



(57) **Abrégé/Abstract:**
The invention relates to a blood glucose system (1) for treating a glucose metabolic disorder, comprising a dosing device (3) having an integrated time counter for generating relative time values and a memory unit, a blood glucose measuring device (2) having an integrated time standard and a memory unit, and a data processing apparatus (4) for processing data sets of the dosing device (3) and the blood glucose measuring device (2). According to the invention, the data processing apparatus (4) is implemented to synchronize the data sets of the dosing device (3) and the data sets of the blood glucose measuring device (2) with one another using the time value of a time standard by an assigned linkage.

Abstract of the Disclosure

The invention relates to a blood glucose system (1) for treating a glucose metabolic disorder, comprising a dosing device (3) having an integrated time counter for generating relative time values and a memory unit, a blood glucose measuring device (2) having an integrated time standard and a memory unit, and a data processing apparatus (4) for processing data sets of the dosing device (3) and the blood glucose measuring device (2). According to the invention, the data processing apparatus (4) is implemented to synchronize the data sets of the dosing device (3) and the data sets of the blood glucose measuring device (2) with one another using the time value of a time standard by an assigned linkage.

(Figure 1)

Applicant : F. Hoffmann-La Roche AG

Blood glucose system having time synchronization

The invention relates to a blood glucose system for treating a glucose metabolic disorder having a dosing device for delivering a medicinal agent for treating the glucose metabolic disorder to a body, a blood glucose measuring device for determining the blood glucose content of the body, and a data processing apparatus for processing stored data sets of the dosing device and the blood glucose measuring device. The invention is thus directed to devices for the diagnosis or treatment of a glucose metabolic disorder, such as diabetes.

The dosing device for delivering a medicinal agent for treating the glucose metabolic disorder to a body is preferably an injection device or an inhalation device, preferably a device for delivering or injecting insulin. Such devices are known, for example, as an insulin pen (for example, from Novonordisc and J&J), as an insulin pump (for example, from Roche), or as insulin inhalers. Insulin pens are thick sticks having a needle and an insulin cartridge for delivering multiple individual doses of insulin, a new piercing occurring each time. The number of units of insulin to be delivered upon a piercing is set by a setting wheel. Insulin pen injection devices having an integrated time standard are known from US 5,925,021 and DE 695 34 225 T2.

An insulin pump is a medical device for continuous or interval-type subcutaneous insulin infusion. It is a small infusion device which is worn on the body and supplies insulin to the body continuously or at intervals via a catheter and a needle lying below the skin. The dosing may also be adapted to a specific daily rhythm or specific events, such as the taking of meals.

A blood glucose measuring device in the context of the invention is an analytical measuring device for determining or recording (so-called "electronic diary") a blood glucose value. Such devices are also referred to as blood glucose meters, blood sugar measuring devices, or blood glucose recorders. Blood glucose recorders are devices which record blood glucose concentrations over a predefined period of time, for example, to be able to establish a suitable insulin dosing scheme for a diabetes patient.

A blood glucose measuring device is a device, with the aid of which the blood sugar content may be determined. For this purpose, a piercing wound is typically generated in a body, a blood droplet is taken, and the blood glucose content in the droplet is determined with the aid of the blood sugar measuring device. However, it is also conceivable to measure the blood glucose by a permanent measurement, for example, using sensors inserted into the body or by measuring through the skin.

Dosing devices and blood glucose measuring devices which are capable of functioning and are operable independently, i.e., independently of other connected components or devices, are especially preferred in the context of the invention. For example, this means that a measuring device delivers measured values or an insulin pump operates without being connected to another device. It also has a separate internal power supply in this case and is operable line-independent.

A data processing apparatus in the context of the invention may, for example, be a PDA, a data manager, a communication adapter (see EP 1 762 955 A1), or a PC, which is used to read out, store, or display stored data of the dosing device and the blood glucose measuring device.

The dosing device according to the invention comprises an integrated time counter for generating relative time values, a memory unit, in which data sets of dosing quantities and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus. The blood glucose measuring device for determining the blood glucose content of the body comprises an integrated time standard and a memory unit, in which data sets of blood glucose measurements and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus. The device for transmitting the data sets may be integrated in the blood glucose measuring device, be connected as a separate module thereto, or be integrated in the data processing apparatus.

Dosing data of the dosing device and analysis results of the blood glucose measuring device are transmitted together with associated time values of the time counter of the dosing device and associated time values of the time counter of the blood glucose measuring device to the data processing apparatus and processed therein, the time values being converted into corrected time values by comparison with the time standard. The term "associated time values" means that the particular time values at which the corresponding, i.e., associated dosing or analysis occurred are transmitted.

A plurality of usually portable devices for measuring the blood sugar level is known in the prior art, in which a blood sample is dispensed onto a test element, which is subsequently analyzed using the blood glucose measuring device. Blood glucose measuring devices of this type typically have a memory, in which analysis results and the instants at which the analyses were performed are stored. Furthermore, there are systems in the prior art in which the analysis results of a blood glucose measuring device are relayed to an analysis unit. Devices of this type are receiving increasing significance in particular in the care and education of diabetics. The diabetic may solely decide whether insulin must be injected on the basis of individual measurements. In contrast, through the acquisition of blood sugar measurements over the day and during multiple days or weeks, the diabetic may obtain information about how his blood sugar level is influenced by ingestion of food, physical activities, and other factors. In addition, the diabetic receives the important information of how his special organism responds individually to the delivery of insulin by a history monitoring of the blood sugar level.

A diabetes data management system is commercially available from Roche Diagnostics GmbH. The data obtained using a handy blood sugar measuring device are transmitted in this system to a PC, which displays the history of the blood sugar level over time and also allows analyses which provide the patient with indications of the strength of the above-mentioned influencing factors. Systems for the history monitoring of the blood sugar level are designed in such a manner that the user first performs a plurality of measurements and transmits the measurement results to an analysis unit at a later point in time. It is therefore necessary to also store in the blood glucose measuring device the instants at which the analyses were performed together with the analysis results.

Because both dosing devices and also blood glucose measuring devices must operate reliably over a period of time of months or years, it is necessary to either install a clock having very high running precision in the device or to provide the possibility that the clock may be set. On the one hand, clocks having high running precision in the event of changing ambient temperatures are still relatively expensive. On the other hand, it is uncomfortable for the user to have to perform setting of the clock. In addition, setting the clock requires additional operating elements which must be integrated in the device and make it more costly. Moreover, it is also undesirable in many cases that the diabetic can adjust the clock. Specifically, history monitoring is frequently performed to check whether the diabetic maintains the behavior rules ordered by the physician. A further aspect are time changes, for example, between summer and winter time and upon the change between time zones. Adjusting the clock to the current time may have the result that the later assignment of measured values to absolute times is no longer uniquely possible.

For such cases it may therefore be advantageous to block possibilities for adjusting the clock of the device or the time counter.

For more precise and informative history monitoring of a diabetes treatment and optimization of the treatment on the basis of a precise diagnosis, it is necessary to consider not only the history data of the blood glucose measuring device, but rather also to register the insulin doses administered by the dosing device precisely and compare them to the measured values, to be able to optimize the therapy on the basis of an analysis based thereon. For this reason, the dosing devices used in the corresponding systems also have a memory apparatus for storing the history data.

Therefore, the requirement results on one hand for the analysis of the data of the dosing device and the blood glucose measuring device to allow a time registration of both the history data both in the dosing device and also the blood glucose measuring device and also to assign the data registered by the dosing device and the blood glucose measuring device to one another in regard to time, i.e., to synchronize them in regard to time, in order to compensate for errors and deviations in the time registration in this manner and to analyze the data using the same correct timescale. The effort is to be kept as small as possible.

A system having a dosing device, a blood glucose measuring device, and a computer for displaying history data, as well as a communication adapter connecting the dosing device and the blood glucose measuring device to the computer, is known from EP 1 762 955 A1. Both the dosing device and also the blood glucose measuring device have a time standard, i.e., a clock, and the storage of a data set in the devices comprises the particular associated clock time. On one hand, this requires a high effort, and in addition the problem of the time synchronization and assignment of the history data is not solved for the case of unavoidably occurring deviations of the clocks in the two devices. The history data are received in the computer and/or the communication adapter unchanged and without time alignment.

An infusion pump is known from EP 1 115 435 B1, which may be connected to a computer to read out history data. The absolute clock times in the infusion pump and the computer are compared and if a deviation occurs, the user is requested to set the clock time again (see [0039]). The clock in the infusion pump is implemented by a counter which starts at the instant of the device production and is set to an absolute time (see [0110]). The current clock time of the insulin pump then results from the start time and the number of count pulses passed since then. A corresponding implementation of an integrated time standard in a portable electrocardiogram recorder is described in US 4,653,022.

A portable, independent ambulantly operable blood glucose measuring device for determining the blood glucose content of a sample of a body is known from DE 197 33 445 A1 and equivalent US 6,216,096 B1, which comprises an integrated time counter for generating relative time values, a memory unit, in which data sets of blood glucose measurements and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus.

WO 2005/043306 A2 describes a time synchronization system in an apparatus for emergency monitoring, in which all system components comprise an integrated time standard, i.e., a clock. This reference teaches the synchronization of different medical devices used in emergency medicine, such as physiological monitors and defibrillators, which each comprise a separate integrated time standard. These devices used in emergency medicine are typically so large and costly that an integration of a precise clock or a comfortable, clearly arranged operating unit is not a significant cost aspect. In contrast, in a blood glucose system for treating a glucose metabolic disorder, both the costs and also the size play a significant role. In addition, the devices of a blood glucose system to which the invention is directed are not operated by trained qualified personnel, in contrast to emergency-medicine devices, but rather by laypersons, who cannot be expected to perform complex operation of the devices, in particular because diabetes patients are frequently restricted in their manual capabilities.

The present invention is directed to a concept of time management in a blood glucose system having a combination of a dosing device, in particular an insulin pen, and a blood glucose measuring device working together with the dosing device, in which registration and integration of dispensing instants, such as injection instants, of the dosing device with instants of blood sugar measurements of the blood glucose measuring device is implemented.

The object of the present invention was to suggest such a blood glucose system, using which the obtained blood glucose measurement results may be assigned as exactly as possible to the analysis instants and the instants of the associated dosing deliveries, and in which both costly precision clocks and also operating elements for setting clocks may be largely avoided, so that the devices may be both cost-effective and also small, and in addition may be operated easily.

According to the invention, the object is achieved by a blood glucose system for treating a glucose metabolic disorder, which comprises the following features:

- a portable, independent ambulantly operable dosing device for delivering a medicinal agent for the treatment of the glucose metabolic disorder to a body, which comprises an integrated time counter for generating relative time values, a memory unit, in which data sets of dosing quantities and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus,
- a portable, independent ambulantly operable blood glucose measuring device for determining the blood glucose content of the body, which comprises an integrated time standard and a memory unit, in which data sets of blood glucose measurements and associated time values are stored, and a device for transmitting stored data sets to a data processing unit, and

- a data processing unit for processing data sets of the dosing device and the blood glucose measuring device, having a receiving device for receiving the data sets from the dosing device and the blood glucose measuring device and an arithmetic unit for converting the time values of the data sets of the dosing device into absolute time values on the basis of a comparison of the time value of the time counter of the dosing device to the time value of a time standard,

the data processing apparatus being implemented to synchronize the data sets of the dosing device and the data sets of the blood glucose measuring device with one another using the time value of the time standard by an assigned linkage.

A main advantage of the invention is that the portable, independent ambulantly operable dosing device, such as an insulin pump or insulin pen, does not require a precise time standard, i.e., a costly clock having very high running precision, but rather only an integrated time counter for generating relative time values, because it is sufficient if another system component, such as the blood glucose measuring device or the data processing apparatus, contains an integrated time standard, i.e., a precisely-running clock. Furthermore, no operating elements must be provided on the dosing device for setting such a time standard. The system according to the invention is thus cost-effective, has a compact construction, and simplifies the operation by the user.

Relative time values are time data which are registered in relation to a reference instant, the reference instant in turn being able to be a relative instant or an absolute instant. A time standard, in contrast, is a clock which does not provide a relative time, but rather an absolute time. An integrated time standard is a clock which is installed as a component in the particular device.

In the present invention, a dosing device is used which contains a time counter, on which only low requirements must be placed in regard to its running precision. Furthermore, the dosing device is equipped for the storage of data sets of dosing deliveries and time values. The blood glucose system also contains a data processing apparatus and a time standard, which may be located in the data processing apparatus or the blood glucose measuring device. By comparing the relative time value of the time counter of the dosing device to the time of the time standard, the time value of the time counter may be converted into an absolute time and thus the stored dosing history data may be assigned absolute time values. In this manner, cost-effective time counters may be used in the dosing device, and an assignment of the stored history data of the dosing device to comparatively exact times is still possible. Furthermore, errors due to a misaligned time counter are avoided, and operating elements are saved on the dosing device.

For example, typical quartz pulse generators or electronic shift registers may be used as the time counter in the dosing device. For the present invention, it is unimportant whether the time counter provides a clock time or simply the count of a shift register. However, it is important that the time counter must not have excessively large running inaccuracies. The pulse rate of the time counter should be as constant as possible and known in advance, however, so that the differences of various counts may be converted into time differences or absolute times. This may be performed according to the following formula: $tA = tD - (nD - nA)/v$. tA is the absolute time, at which a dosing A was performed. The following are necessary for its calculation according to the above formula:

- tD: time of the data transmission, i.e., a time at which the time value of the time counter and clock time of the time standard may be compared.
- nD: count of the time counter upon comparison to the time standard (typically upon data transmission).
- nA: count of the time counter which was stored at the instant of the dose delivery.
- v: pulse rate of the time counter, for example, in counting units (clock pulses, counting pulses, counting steps) per minute.

The pulse rate (counts per time unit) is preferably known and the data processing apparatus is programmed in such a manner that it takes this pulse rate into consideration or the pulse rate is transmitted from the dosing device to the data processing apparatus.

However, the pulse rate may also be ascertained by the data processing apparatus. For this purpose two or more data transmissions at different times from one another are used: v = (n2 - n1)/(t2 - t1).

A difference (n2 - n1), which is calculated from two counts, is divided by the associated difference of the times of the time standard. Associated means that t1 and n1 and t2 and n2 were each ascertained at the same real instant. The more the times t1 and t2 differ from one another, the more precisely may the pulse rate v be ascertained. The pulse rate ascertainment may be performed without additional effort, if t,n value pairs of one or more preceding data transmissions are stored and the pulse rate calculation is performed upon a further data transmission in consideration of stored values and the current t, n value pair. The present invention provides independence in the ascertainment of absolute time values for dosing deliveries from an offset (i.e., an adjustment) of the time counter. The time counter preferably begins to run with the application or contacting of an operating voltage. The user of the dosing device may also set the time counter. However, the user preferably does not have any influence on the time value of the time counter.

In a preferred embodiment, a time counter may be used which begins to run when connected to the battery. The status of the time counter is relayed to a conversion unit, which ascertains a clock time from this value, which is displayed on the display. The user may be given the capability via operating buttons of performing reprogramming of the conversion unit or, in other words, setting the clock. However, the value of the time counter remains unaffected by the intervention of the user, so that no error is induced in the calculation of the absolute instants of the dosing deliveries by setting the clock. For example, if the user performs measurements for winter time and then changes the clock over to

summer time, this has no influence on the time counter and a unique assignment of the history data to absolute times is still possible.
The dosing device may advantageously have a conversion unit, which converts time values of the time counter into a clock time, and the conversion unit may be reprogrammed by the user and/or by the data processing apparatus to correct the clock time.

For the history monitoring of blood glucose data, it is advantageous to record a plurality of data sets, which contain the dosing deliveries and/or blood glucose values and associated time values. A dosing device and accordingly the blood glucose measuring device according to the present invention thus require a memory unit for storing one or more data sets. Commercially available devices are typically already equipped with a memory of this type. Furthermore, the devices also have a device for transmitting stored data sets to the data processing apparatus. In commercially available systems, a data transmission is implemented via plug connections and cables. Furthermore, it is also possible to implement a wireless data transmission, e.g., via an optocoupler (IR) or by radio (Bluetooth, RF).

A very simple data transmission which is comfortable for the user is possible if the device contains a transmitter which transmits the data to the data processing apparatus without a mechanical coupling having to be performed. An electrical separation of measuring device and data processing apparatus is thus also achieved. This may be implemented, for example, by an infrared diode in the device and a corresponding infrared detector in the data processing apparatus, as is known from remote controls for televisions. The data transmission occurs via modulated light in such an embodiment. It is advantageous if the data transmission is not performed only unidirectionally from the device to the data processing apparatus, but rather if the data processing apparatus in turn also contains a unit for transmitting data to the device, so that bidirectional communication between the units is possible. This may favorably be used so that the data processing apparatus first reacts to the device and requests data. After completed data transmission, the data processing apparatus may confirm receipt, so that it is ensured that the data exchange has occurred completely.

A data processing apparatus for processing history data may be implemented, for example, by a personal computer having corresponding software. The data processing apparatus may also be a handy unit, however, which corresponds to a notebook, notepad, palmtop, or the like. The data processing apparatus contains a processing unit (CPU), a memory unit, and preferably a display for displaying analysis results.

The processing of the history data by the data processing apparatus may include calculations, using which the dosing deliveries or analysis results are converted into other units, for example. An important aspect of the processing of the history data may also be in its graphic display, the ascertainment of trends, and the correlation of influencing variables to changes of the analysis results. The processing of the analysis results may therefore be performed, for example, in a form which gives a diabetic information about how he must behave and which insulin doses he must inject to obtain the most uniform possible blood sugar level, which lies in the standard range. The data processing apparatus has a device for receiving data sets of the dosing device and the blood glucose measuring device. As already described together with the dosing device, a device of this type may be implemented via electrical supply lines or also via radio receiver or optical receiver.

In the assignment of the data from the dosing device and the blood glucose measuring device, the data processing apparatus considers a time standard which is used as a reference to convert the time values of the dosing device into absolute time values. The time standard may be implemented in the blood glucose measuring device or in the data processing apparatus or by a combination of both. Accordingly, in a first advantageous embodiment, the time values of the time standard of the blood glucose measuring device may be used as time values for linking the data sets of the dosing device and the blood glucose measuring device. According to an advantageous second embodiment, the data processing apparatus comprises an integrated time standard, and the time values of the time standard of the blood glucose measuring device or the time values of the time standard of the data processing apparatus are used as time values for linking the data sets of the dosing device and the blood glucose measuring device, or a combination of time values of both time standards is used.

Absolute time values in the meaning of the invention do not have to be absolutely correct; rather, this term is to be understood in contrast to the time value of the time counter, which may be a number or a completely incorrect clock time, that a conversion to a clock time (and a date) was performed, which was corrected by offsets and possibly running inaccuracies. For example, quartz clocks having high running precision and radio clocks are suitable as the time standard. The quartz clocks normally contained in computers do not have especially high running precision, but may be set easily by the user. The time standard may also be obtained from a time server via radio or via a data connection (e.g., via the Internet).

Setting the time standard is less disadvantageous for several reasons than setting the time registration contained in the dosing device. Firstly, the setting of the time standard may be performed simply and comfortably via a keyboard. If necessary, the data processing apparatus may typically be placed under the control of an attending physician or adviser, so that manipulations are avoided. Moreover, in practice not every user of an analysis device typically has an own data processing apparatus, but rather the users of an analysis device go to their attending physician or adviser, who has the data processing apparatus. One data processing apparatus may therefore be used to process the data of many different blood glucose systems. Therefore, only one single time standard which must be monitored is necessary for this plurality of blood glucose systems.

It is provided a blood glucose system for treating a glucose metabolic disorder, comprising:

a portable, independent ambulantly operable dosing device for delivering a medicinal agent for the treatment of the glucose metabolic disorder to a body, the dosing device being free from having an integrated time standard and including an integrated time counter for generating relative time values, the integrated time counter tracking only a time count in relation to a reference instant without tracking an actual time, a memory unit in which data sets of dosing quantities and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus;

a portable, independent ambulantly operable blood glucose measuring device for determining the blood glucose content of the body, the blood glucose measuring device including an integrated time standard, a memory unit in which data sets of blood glucose measurements and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus; and

a data processing apparatus for processing data sets of the dosing device and the blood glucose measuring device, the data processing apparatus having a receiving device for receiving the data sets from the dosing device and the blood glucose measuring device and an arithmetic unit for converting the time values of the data sets of the dosing device into absolute time values based on the comparison of the time value of the time counter of the dosing device to the time value of a time standard;

wherein, the data processing apparatus synchronizes the data sets of the dosing device and the data sets of the blood glucose measuring device with one another using the time value of the time standard by an assigned linkage.

It is provided a method for processing analysis results using a blood glucose system for treating a glucose anabolic disorder, the blood glucose system comprising a dosing device for delivering a medicinal agent for the treatment of the glucose metabolic disorder to a body, the dosing device being free from having an integrated time standard and including an integrated time counter for generating relative time values, the integrated time counter tracking only a time count in relation to a reference instant without tracking an actual time, a memory unit in which data sets of dosing quantities and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus, a blood glucose measuring device for determining the blood glucose content of the body and which comprises an integrated time standard, a memory unit in which data sets of blood glucose measurements and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus, and a data processing apparatus for processing data sets of the dosing device and the blood glucose measuring device and having a receiving device for receiving the data sets from the dosing device and the blood glucose measuring device and an arithmetic unit for converting the time values of the data sets of the dosing device into absolute time values on the basis of a comparison of the time value of the time counter of the dosing device to the time value of a time standard, wherein the data processing apparatus is implemented to synchronize the data sets of the dosing device and the data sets of the blood glucose measuring device with one another using the time value of the time standard by an assigned linkage, the method comprises:

storing one or more data sets of deliveries of a medicinal agent for the treatment of the glucose metabolic disorder in the dosing device, the data sets comprising dosing quantities and time values which were obtained using the integrated time counter at the instant of the particular delivery;

storing one or more data sets of blood glucose measurements in the blood glucose measurement device, the data sets containing analysis results and time values obtained from using the integrated time standard at the instant of each measurement,

transmitting one or more data sets of the blood glucose measuring device and the dosing device to the data processing apparatus and transferring the current time value of the time counter of the dosing device to the data processing apparatus;

calculating the absolute time values at which the agent was delivered by the dosing device using the data processing apparatus from the time values of the data set of the dosing device by comparing the current time value of the time counter of the dosing device to the time value of a time standard, the data sets of the dosing device and the blood glucose measuring device being synchronized with one another using the time value of the time standard by an assigned linkage; and

processing the dosing quantities and analysis results based on the calculated absolute time values.

The present invention also relates to a method for processing analysis results using a blood glucose system for treating a glucose metabolic disorder, the blood glucose system comprising

- a portable, independent ambulantly operable dosing device for delivering a medicinal agent for the treatment of the glucose metabolic disorder to a body, which comprises an integrated time counter for generating relative time values, a memory unit, in which data sets of dosing quantities and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus,
- a portable, independent ambulantly operable blood glucose measuring device for determining the blood glucose content of the body, which comprises an integrated time standard and a memory unit, in which data sets of blood glucose measurements and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus, and
- a data processing apparatus for processing data sets of the dosing device and the blood glucose measuring device, having a receiving device for receiving the data sets from the dosing device and the blood glucose measuring device and an arithmetic unit for converting the time values of the data sets of the dosing device into absolute values on the basis of a comparison of the time value of the time counter of the dosing device to the time value of a time standard,

the data processing apparatus being implemented to synchronize the data sets of the dosing device and the data sets of the blood glucose measuring device to one another using the time value of the time standard by an assigned linkage,

the method comprising the following steps:

- storing one or more data sets in the dosing device of deliveries of a medicinal agent for the treatment of the glucose metabolic disorder performed using the dosing device, containing dosing quantities and time values, which were obtained using the integrated time counter at the instant of the particular delivery,

- storing one or more data sets in the blood glucose measuring device of blood glucose measurements performed using the blood glucose measuring device, containing analysis results and time values which were obtained using the integrated time standard at the instant of the particular measurement,
- transmitting one or more data sets of the blood glucose measuring device and the dosing device to the data processing apparatus and transferring the current time value of the time counter of the dosing device to the data processing apparatus,
- calculating the absolute time values at which the agent was delivered by the dosing device, using the data processing apparatus, from the time values of the data set of the dosing device by comparing the current time value of the time counter of the dosing device to the exact time value of a time standard, the data sets of the dosing device and the data sets of the blood glucose measuring device being synchronized with one another using the time value of the time standard by an assigned linkage, and
- processing the dosing quantities and analysis results on the basis of the calculated instants.

The step of processing of dosing quantities and analysis results may be understood in the broadest meaning as the storage, transmission to a data processing apparatus, or display of the synchronized data sets of the dosing device and the blood glucose measuring device. The manner of operation of the method according to the invention is explained on the basis of the following example.

When the time counter is contacted by an operating voltage, it begins to run at a constant and in advance known pulse rate. A first dosing is performed by the user using the dosing device at instant T1 and a corresponding data set is stored, which comprises the delivered dose and the associated time count. Some time later, the user goes to his physician, where a transmission of the data set to the data processing apparatus is performed at instant T2. Together with the dose value and the associated time value, the current time value of the time counter is also transmitted to the data processing apparatus by the dosing device. In addition, data sets of the blood glucose measuring device are also read out by the data processing apparatus.

The data processing apparatus calculates the difference between the current time value of the time counter of the dosing device and the associated relative time value of the time standard. Upon a subsequent analysis of the history data of the dosing device, the relative time values of the data sets are converted by subtraction of the time difference into absolute time values. It is clear that the time values of time counter and time standard which are used for calculating the difference must represent the same real instant. Therefore, the current time value of the time counter is preferably transmitted for calculating the difference and the time value of the time standard provided at the instant of the transmission is used. A time difference is ascertained from the time value of the time standard at a specific instant and the time value of the time counter at the same instant and the time values of the data sets are converted into absolute time values by addition of the time difference.

A further advantageous aspect of the present invention is that, using a data transmission, a synchronization may be performed with the data sets downloaded from the blood glucose measuring device, i.e., this data may also be converted with the data of the dosing device to a uniform, common precise absolute time and assigned to one another. Furthermore, the time counter in the dosing device may be set or the status of the time counter and the associated time of the time standard is stored, so that this data pair may be used as a new calculation basis for a conversion of time values into absolute times. In this manner, offsets of the time counter and running inaccuracies which have occurred before the synchronization no longer have influence on time calculations which occur after the synchronization.

The advantages of a system according to the invention may be recognized especially clearly on the basis of the following table:

Table 1

	Time counter	Time standard	Line
Factory setting	June 15, 2002 9:30:00	June 15, 2002 9:30:00	1
Dose delivery I	July 15, 2002 8:40:00	July 15, 2002 8:45:00	2
Transmission	July 17, 2002 10:25:00	July 17, 2002 10:30:20	3
Transmission	January 15, 2007 9:30:00	January 15, 2007 15:00:00	4
Dose delivery II	January 16, 2007 9:30:00	January 16, 2007 15:00:10	5
Transmission	January 22, 2007 10:00:00	January 22, 2007 15:31:10	6

A time counter of a dosing device which loses approximately 10 seconds/day was used for the above table. Line 2 of the table shows that upon a dose delivery two months after setting the time counter, a running difference to the time standard (in the blood glucose measuring device or the data processing apparatus) specifying the correct absolute time of 5 minutes already occurs. If the patient goes two days later to his physician and has a transmission of the data sets performed in connection with the data sets of the blood glucose measuring device, the system according to the invention recognizes a time difference of time counter to time standard of 5 minutes and 20 seconds. A simple addition of this difference to the time value for the dose delivery I already reduces the running difference from 5 minutes to one of 20 seconds. However, if the system is used for the history monitoring of blood sugar levels, a running difference of 5 minutes is of subordinate significance for most evaluations. Therefore, a corresponding observation for a measurement 5 years after setting the time counter is performed in table 1. Line 4 of table 1 shows that upon a dose delivery on January 15, 2007, a running difference of four hours already exists between the time values of the data sets of the dosing device and the time values of the data sets of the blood glucose measuring device. If dosing values and analysis results in the year 2007 were analyzed without a correction, a history monitoring of the blood sugar level would fail completely, because a blood sugar level from midday would be interpreted as a blood sugar level from the morning.

A dose delivery according to line 5 of table 1 may be corrected easily in regard to the time values if, during the transmission of the data sets, i.e., the next transmission of stored data sets from the dosing device to the data processing apparatus, the time difference between the time counter of the dosing device and the time standard is ascertained and the ascertained time difference is used immediately or at a later instant for correcting the time values of the data sets of the dosing device. For example, upon a first data transmission, a first time difference between time standard and time counter may be ascertained, and upon a following second data transmission, a corresponding second time difference and time values lying between the data transmissions may be ascertained by interpolation between first and second time differences and addition of the interpolated time difference to the time value of the dose delivery. For example, if a transmission is performed on January 22, 2007, the time difference is calculated at 5 hours, 31 minutes, and 10 seconds. Upon addition of this difference to the time value of the time counter on January 16, 2007 (see column 5), the inaccuracy may be reduced to 1 minute, which is well acceptable for normal history monitoring.

For evaluations at a specific instant, a correction of the time value ascertained by the time counter may advantageously be ascertained by interpolation of running inaccuracies, which were found upon transmission before the measurement and after the measurement. For example, it may be ascertained from the data shown in lines 4 and 6 that a running inaccuracy of 70 seconds has occurred within 7 days. It may correspondingly be concluded that the running inaccuracy ascertained on January 15, 2007 has had a further 10 seconds running inaccuracy added at the date of the analysis (line 5). However, because in practice running inaccuracies are not material constants, but are caused to different extents by temperature differences and other influencing factors, the precision achievable by interpolation is limited.

The dosing device has a relative time and the blood glucose measuring device has an absolute time. The data processing apparatus either has no time connection or may also have a time standard. If the data processing apparatus has no time connection, it reads out the time from the blood glucose measuring device, converts the data from the dosing device therewith, and thus generates a common data set from the data of the dosing device and the blood sugar measuring device for the display. If the data processing apparatus has a time connection or a time standard, the time standard of the data processing apparatus may additionally or alternatively be used.

The insulin delivery using the dosing device may be triggered by the user at an arbitrary instant or may also occur at a fixed frequency, for example, once per minute. The dosing quantities are stored in this fixed sequence in the memory of the dosing device and the memory pointer is increased by one. Upon readout of the data by the data processing apparatus, only the current memory pointer, the associated measured value, and the measured values lying before it are transmitted, but without their pointers. To reconstruct the history, the data processing apparatus assigns the absolute instant to the current measured value, namely the instant of the data transmission, based on the time standard of the blood glucose measuring device, the data processing apparatus, or a combination of both, and stores the dosing value with the absolute time in the memory of the data processing apparatus. The preceding dosing values are stored without times in the dosing device. The time reference at the instant of the data transmission to the data processing apparatus is in turn provided via a time rule and the memory pointer in the dosing device. Memory space is saved in this manner. The condition so that an absolute time may be assigned to a specific data set is that the data processing apparatus accesses the dosing device at least once in the corresponding time interval and the data are transmitted.

The dosing device has an automatic data collection and data storage having a time marking on a relative time basis. This may be performed on one hand in a permanently predefined time interval of the individual dosing or measuring points or may be triggered by the user on the basis of his subjective sensitivity.

For example, a quartz may generate a time signal, from which a microcontroller derives a precise time interval. With a time counter implemented in this manner, for example, a data set is generated each minute and stored consecutively in the memory. A convention in the system then makes the time assignment occurring in the data processing apparatus possible via the knowledge of the memory address. A difference from a blood glucose recorder, i.e., a blood glucose measuring device having history measurement, which also has a time controller, is that in such a blood glucose recorder, which measures at predefined time intervals, the instants of the blood glucose measurement are triggered using the time counter, i.e., the time counter is the trigger triggering the measurement, and the chronological assignment of the measurement is made possible via the memory space address. In a dosing device according to the invention, in contrast, the user performs an delivery of insulin at any instant and a count is then assigned to this dosing delivery. The triggering is thus performed by the user and the time counter allows the chronological assignment of the dosing delivery to a time.

Thus, in a blood glucose recorder, measurement is performed using a fixed measuring frequency of 1 Hz, for example, and the measured values are stored in a fixed sequence in the memory. Upon readout, only the memory space index and the measured value have to be transmitted to be able to reconstruct the history. A time counter in the meaning of the invention is thus not necessary in a blood glucose measuring device. In a dosing device according to the invention, in contrast, instant and frequency of the dosing deliveries are unknown. Therefore, at least one relative chronological assignment of the dosing deliveries must also be stored in the data sets, to allow a chronological history assignment of the history later. A time standard or, to simplify the apparatus outlay, a time counter according to the invention may be used for this purpose.

The time counter is used for the chronological assignment of the data (boli) stored in the dosing device to the blood glucose measured values of the blood glucose measuring device if the data of the dosing device and the blood glucose measuring device are displayed jointly in the data processing apparatus or a device connected to the data processing apparatus in a graph or adjacent to one another in multiple graphs, the relative chronological assignment of the data from the dosing device to the data from the blood glucose measuring device having to be ascertained and considered. According to the invention, a time standard is not integrated in the dosing device, but rather a time counter. The time counter is used for the relative time registration. For this purpose, a time generator or a counter is integrated in the dosing device which counts up or down in a fixed cycle. For each delivered bolus, the associated count of the time counter is stored. Upon read in of the history data stored by the dosing device and the blood glucose measuring device, the current time of the time standard used, i.e., of the blood glucose measuring device, the data processing apparatus, or a combination of both is taken as the starting time and assigned to the current count. Starting from this current count, boli stored earlier in time are then assigned to absolute times.

The advantages of this procedure are that no time synchronization is necessary between the dosing device and the data processing apparatus and no time has to be set on the dosing device.

The history data of the dosing device may also be displayed in graphic form by the data processing apparatus using only a relative time axis; otherwise, the time reference point is predefined by the user or the time standard, i.e., the blood glucose measuring device or the data processing apparatus.

The period of time which has passed since the last bolus or the last boli may be indicated on the dosing device. Such a relative time specification will suffice for most users or even be more desirable than an absolute specification of the time of the last bolus, because in this case the user must first calculate the period of time which has passed using the current clock time.

A further advantage is that even if the time of the dosing device is incorrect, the relative assignment of the data of the dosing device to those of the blood glucose measuring device remains correct and no misinterpretation of the combined data occurs, at least as long as no time adjustments are performed in the blood glucose measuring device, which remain unknown if they are not marked.

The limiting of the runtime to two years prescribed for insulin pens may also be monitored and registered by the time counter, without an absolute clock being required for this purpose.

Furthermore, the time counter in the dosing device may also be used for generating and displaying a current clock time on the dosing device. For this purpose, during the production of the dosing device, at a specific count of the time counter, for example, at the count zero, the current absolute time is stored; the absolute time may then be calculated from the count for other later instants. This may be expedient for various applications, for example, for the following: 1) For displaying the current clock time in the display of the dosing device. 2) Upon transmission of the data sets from the dosing device to the data processing apparatus, without a time standard (from the blood sugar measuring device or the data processing apparatus) being available, an at least orienting correct time axis may be defined. 3) The data of the dosing device and the blood glucose measuring device may be synchronized and it may be checked whether the current time corresponds on both devices. 4) Upon each communication with a data processing apparatus, for example, upon transmission of the data to the data processing apparatus, the dosing device may request the absolute time of the data processing apparatus (such as the PC time) and thus further calibrate the chronological assignment to the count of the time counter in the dosing device. 5) Worldwide time synchronization, the time counter being calibrated to a worldwide synchronized standard time upon its installation in the dosing device and, upon readout of the time value, being converted back into the worldwide synchronized standard time and from there into the local absolute time.

The fundamental advantages of a time registration integrated in the dosing device are as follows:

- The duration of an injection may be registered. This registration in the data set of the dosing device is performed, for example, in such a manner that the beginning and the end of a dosing delivery are marked in the data set for associated time values. Upon readout of the data set in the dosing device for display using the dosing device or upon readout of the dosing device using a data processing apparatus, not only are the particular injection instants available for analysis, but rather also the associated injection durations. Depending on the design of the dosing device, the injection duration may contain information about the injection speed and/or the dosing quantity. Furthermore, it may be displayed on the display of the dosing device how slowly the dosing is to be performed, or an injection which is too rapid, in which the insulin sprays past the piercing point or comes back out, may be recognized as a possible error source upon a data analysis.

- The injection speed, the so-called flow, may be determined from the insulin quantity and the injection time. A recommended quantity-dependent injection time may be displayed on the display using this information, for example, by a countdown, or upon a data analysis, an injection which is performed too rapidly may be recognized as a possible error source.

- If an additional needle sensor is installed, which registers whether the needle used is located in the body during the delivery of agent, e.g., a mechanical feeler or an electrical conductivity measurement of the needle, it may be indicated on the display of the dosing device how long the needle is to remain in the body after the injection. A time period of approximately 10 seconds is recommended for this purpose. It may be registered and/or stored in the data set stored by the dosing device how long the needle actually remained in the body to recognize deviations as a possible error source in the data analysis. Such a needle sensor may also be used as a priming sensor; when a bolus is delivered without the needle being injected in the body, the bolus is evaluated as priming and is not indicated as the last bolus on the display of the dosing device or in the graphic representation using the data processing apparatus. The stored data set is marked accordingly.

Priming refers to the checking of the insulin flow to prepare the insulin pen before the injection. In the event of storage of an open insulin cartridge having attached needle tip and before the first use of a new insulin cartridge, there may be air bubbles in the cartridge and/or the needle tip, because of which the insulin dose set on the insulin pen is possibly not delivered completely. During the priming, the insulin pen is held with the injection needle upward. The insulin cartridge is tapped carefully several times using the finger, so that possibly present air bubbles rise upward. The dose indication is set to four units for a new cartridge, for example, and to one unit for an open cartridge. The set dose is delivered vertically into the air. An insulin droplet must exit from the needle tip, i.e., the air is completely removed. If this is not the case, the dose delivery is repeated until an insulin drop exits from the needle tip.

- Furthermore, the cartridge change may be interpreted and thus the cartridge usage duration, such as the mean duration, the deviations therefrom, etc., may be displayed, stored, and analyzed.

Methods according to the invention for analyzing analysis results may be improved in that one or more checksums are transmitted to the data processing apparatus together with the transmitted data sets, which permit a check of whether the data transmission has occurred error-free. Furthermore, it is advantageous if a device-specific identifier of the dosing device and the blood glucose measuring device is also transmitted, so that the data processing apparatus may differentiate between various analysis devices. It was already described above that it is frequently the case in practice that a plurality of users go to a physician or adviser with their own dosing devices and blood glucose measuring devices to have an analysis performed there using a data processing apparatus. If an identifier of the particular devices is used, mix-ups may be avoided.

The invention is explained in greater detail hereafter on the basis of an exemplary embodiment shown in the figure. The special features described therein may be used individually or in combination with one another to provide preferred embodiments of the invention.

Figure 1 shows components of a blood glucose system 1 according to the invention, comprising a dosing device 2 in the form of an insulin pump (or alternatively, for example, an insulin pen or an insulin inhaler), a blood glucose measuring device or blood glucose meter 3, and a data processing apparatus 4. A communication adapter 5, to which the dosing device 2 and the blood glucose measuring device 3 are connected, is provided as an additional device. The manner of operation of the optional communication adapter 5 is described in EP 1 762 955 A1. The dosing device 2 and the blood glucose measuring device 3 are portable, line-independent ambulantly operable medical devices, which are used by a user in combination with one another. Both devices have an interface for transmitting and/or receiving data, which is implemented as an infrared interface, for example.

The blood glucose measuring device 2 operates using test elements which are inserted into a chamber of the device. The blood glucose measuring device 2 also has operating elements and a display for displaying analysis results. A memory unit, which is integrated in the blood glucose measuring device 2 and is used for storing data sets which contain the analysis results and associated time values, is of special significance for the present invention. In addition, the blood glucose measuring device 2 has a time standard which relays time values belonging to analysis instants to the memory unit. Furthermore, the blood glucose measuring device 2 has a wired or wireless interface for communication with the data processing apparatus 4.

The dosing device 3 may deliver insulin doses to a body. It also has operating elements and a display for displaying functional parameters. A memory unit which is integrated in the dosing device 3 and is used for storing data sets, which contain dosing deliveries and associated time values, is of special significance for the present invention. In addition, the blood glucose measuring device 2 has a time counter which relays time values belonging to dosing instants to the memory unit. Furthermore, the dosing device 3 has a wired or wireless interface for communication with the data processing apparatus 4.

The communication adapter 5 is connected using a transmission cable 7 to the data processing apparatus 4 for the wired data transmission 6. The data processing apparatus 4 is a computer and may be, for example, a personal computer, a laptop, a handheld computer, or the computer in an Internet café, in a doctor's office, at home, or in a pharmacy, wherein the user of the system 1 must only go with his devices 2, 3 or with his devices 2, 3 and a communication adapter 5. The data processing apparatus 4 optionally contains a time standard in addition to a computer unit.

To read out the data of the devices 2, 3 using the data transmissions 8, 9 and display them on the monitor 10 of the computer 4, firstly the communication adapter 5 is connected to the computer 4 using the cable 7. The communication adapter 5 may also be integrated in the computer, however, and the data transmission may occur directly from the devices 2, 3 to the computer 4.

The dosing device 3 does not have a clock, i.e., no absolute time, but rather only a time counter. The time counter is a pulse generator, i.e., a time difference standard, having a memory in the form of a table. The data sets stored in the table each comprise the number of ticks (pulses) of the time counter which have passed since the last insulin delivery, and the delivered insulin quantity, but not the instant at which the insulin delivery occurred.

These data are downloaded from the dosing device 3 into the data processing device 4. This data processing device 4 has a time standard (a clock) available, either an integrated time standard or a time standard of the blood glucose measuring device 2 and thus has the absolute time available. Upon download of the data from the dosing device 2, the download instant, which is known to the data manager as the absolute time, is used to back-calculate the absolute instants at which the insulin deliveries occurred from the stored number of ticks (pulses). However, it may also suffice if the download instant is stored, for example, in the communication adapter 7, and the back calculation to the dosing instants first occurs in the data processing device 4.

If it turns out in the data processing that the clock in the data manager deviates from the actual time, for example, by a comparison to the time of the PC 4, which is synchronized with the time via the Internet in many cases, this systematic deviation of the clock of the data manager may be taken into consideration easily by a corresponding correction shift.

An advantage of the time counter according to the invention in the dosing device 3 is that, in contrast to the prior art, no synchronization has to be performed between a clock of the dosing device 3 and a clock of the data manager, it remaining open which of the two clocks has priority in case of deviation or how the deviation is handled. Furthermore, an absolute calibration may also be performed easily by the later optional alignment with a world time, for example, via the PC 4.

List of reference numerals

1 blood glucose system
2 blood glucose meter
3 insulin pump
4 data processing apparatus
5 communication adapter
6 data transmission
7 transmission cable
8 data transmission
9 data transmission
10 monitor

CLAIMS:

1. A blood glucose system for treating a glucose metabolic disorder, comprising:

a portable, independent ambulantly operable dosing device for delivering a medicinal agent for the treatment of the glucose metabolic disorder to a body, the dosing device being free from having an integrated time standard and including an integrated time counter for generating relative time values, the integrated time counter tracking only a time count in relation to a reference instant without tracking an actual time, a memory unit in which data sets of dosing quantities and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus;

a portable, independent ambulantly operable blood glucose measuring device for determining the blood glucose content of the body, the blood glucose measuring device including an integrated time standard, a memory unit in which data sets of blood glucose measurements and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus; and

a data processing apparatus for processing data sets of the dosing device and the blood glucose measuring device, the data processing apparatus having a receiving device for receiving the data sets from the dosing device and the blood glucose measuring device and an arithmetic unit for converting the time values of the data sets of the dosing device into absolute time values based on the comparison of the time value of the time counter of the dosing device to the time value of a time standard;

wherein, the data processing apparatus synchronizes the data sets of the dosing device and the data sets of the blood glucose measuring device with one another using the time value of the time standard by an assigned linkage.

2. The system of claim 1, wherein the time values of the time standard of the blood glucose measuring device are used as time values for linking the data sets of the dosing device and the blood glucose measuring device.

3. The system of claim 1, wherein the data processing apparatus further comprises an integrated time standard, the time values of the time standard of the blood glucose measuring device or the time values of the time standard of the data processing apparatus are used as time values for linking the data sets of the dosing device and the blood glucose measuring device.

4. The system of claim 1, wherein the dosing device comprises an injection device or inhalation device.

5. The system of claim 1, wherein transmission of the data sets from the blood glucose measuring device or the dosing device to the data processing apparatus is performed using a cable connection or wirelessly.

6. The system of claim 1, wherein the data processing apparatus comprises a conversion unit which converts time values of the time counter of the dosing device into clock times.

7. A method for processing analysis results using a blood glucose system for treating a glucose anabolic disorder, the blood glucose system comprising a dosing device for delivering a medicinal agent for the treatment of the glucose metabolic disorder to a body, the dosing device being free from having an integrated time standard and including an integrated time counter for generating relative time values, the integrated time counter tracking only a time count in relation to a reference instant without tracking an actual time, a memory unit in which data sets of dosing quantities and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus, a blood glucose measuring device for determining the blood glucose content of the body and which comprises an integrated time standard, a memory unit in which data sets of blood glucose measurements and associated time values are stored, and a device for transmitting stored data sets to a data processing apparatus, and a data processing apparatus for processing data sets of the dosing device and the blood glucose measuring device and having a receiving device for receiving the data sets from the dosing device and the blood glucose measuring device and an arithmetic unit for converting the time values of the data sets of the dosing device into absolute time values on the basis of a comparison of the time value of the time counter of the dosing device to the time value of a time standard, wherein the data processing apparatus is implemented to synchronize the data sets of the dosing device and the data sets of the blood glucose measuring device with one another using the time value of the time standard by an assigned linkage, the method comprises:

storing one or more data sets of deliveries of a medicinal agent for the treatment of the glucose metabolic disorder in the dosing device, the data sets comprising dosing quantities and time values which were obtained using the integrated time counter at the instant of the particular delivery;

storing one or more data sets of blood glucose measurements in the blood glucose measurement device, the data sets containing analysis results and time values obtained from using the integrated time standard at the instant of each measurement,

transmitting one or more data sets of the blood glucose measuring device and the dosing device to the data processing apparatus and transferring the current time value of the time counter of the dosing device to the data processing apparatus;

calculating the absolute time values at which the agent was delivered by the dosing device using the data processing apparatus from the time values of the data set of the dosing device by comparing the current time value of the time counter of the dosing device to the time value of a time standard, the data sets of the dosing device and the blood glucose measuring device being synchronized with one another using the time value of the time standard by an assigned linkage; and

processing the dosing quantities and analysis results based on the calculated absolute time values.

8. The method of claim 7, wherein the time values of the time standard of the blood glucose measuring device are used as the time values for linking the data sets of the dosing device and the blood glucose measuring device.

9. The method of claim 7, wherein the data processing apparatus further comprises an integrated time standard, the time values of the time standard of the blood glucose measuring device or the data processing apparatus being used as the time standard for synchronizing and linking the data sets of the dosing device and the blood glucose measuring device with calculation of the time instants at which the agent was delivered by the dosing device.

10. The method of claim 7, wherein a time difference is ascertained from the time value of the time standard at a specific instant and the time value of the time counter at the same instant, whereby the time values of the data sets are converted into absolute time values by adding the time difference.

11. The method of claim 10, wherein, when stored data sets are transmitted from the dosing device to the data processing apparatus, the time difference between the time counter of the dosing device and the time standard is ascertained and the ascertained time difference is used immediately or at a later instant for correcting the time values of the data sets of the dosing device.

12. The method of claim 7, wherein, upon a first data transmission, a first time difference between the time standard and time counter is ascertained, and upon a subsequent second data transmission a corresponding second time difference is ascertained, such that time values lying between the first and second data transmissions are ascertained by interpolating between the first and second time differences and adding the interpolated time difference to the time value of the dose delivery.

13. The method of claim 7, wherein the step of processing dosing quantities and analysis results further comprises storing the data sets, transmitting the data sets to the data processing apparatus, or displaying the synchronized data sets of the dosing device and the blood glucose measuring device.

14. The method of claim 7, wherein the time counter counts using a predefined pulse rate and the calculation of the dosing time instants is calculated from the formula $tA = tD - (nD - nA)/v$.

15. The method of claim 7, wherein the duration of the dosing delivery is registered in the data set stored by the dosing device, such that the beginning and the end of a dosing delivery is marked in the data set of the dosing device at associated time values.

16. The method of claim 7, further comprising detecting whether a needle is located in a body during delivery of agent.

17. The method of claim 16, wherein the detecting step is performed by a needle sensor of the dosing device.

18. The method of claim 17, wherein the needle sensor comprises a priming sensor when a bolus is delivered without the needle being injected into the body, the bolus being used for priming the needle and the stored data set being marked.

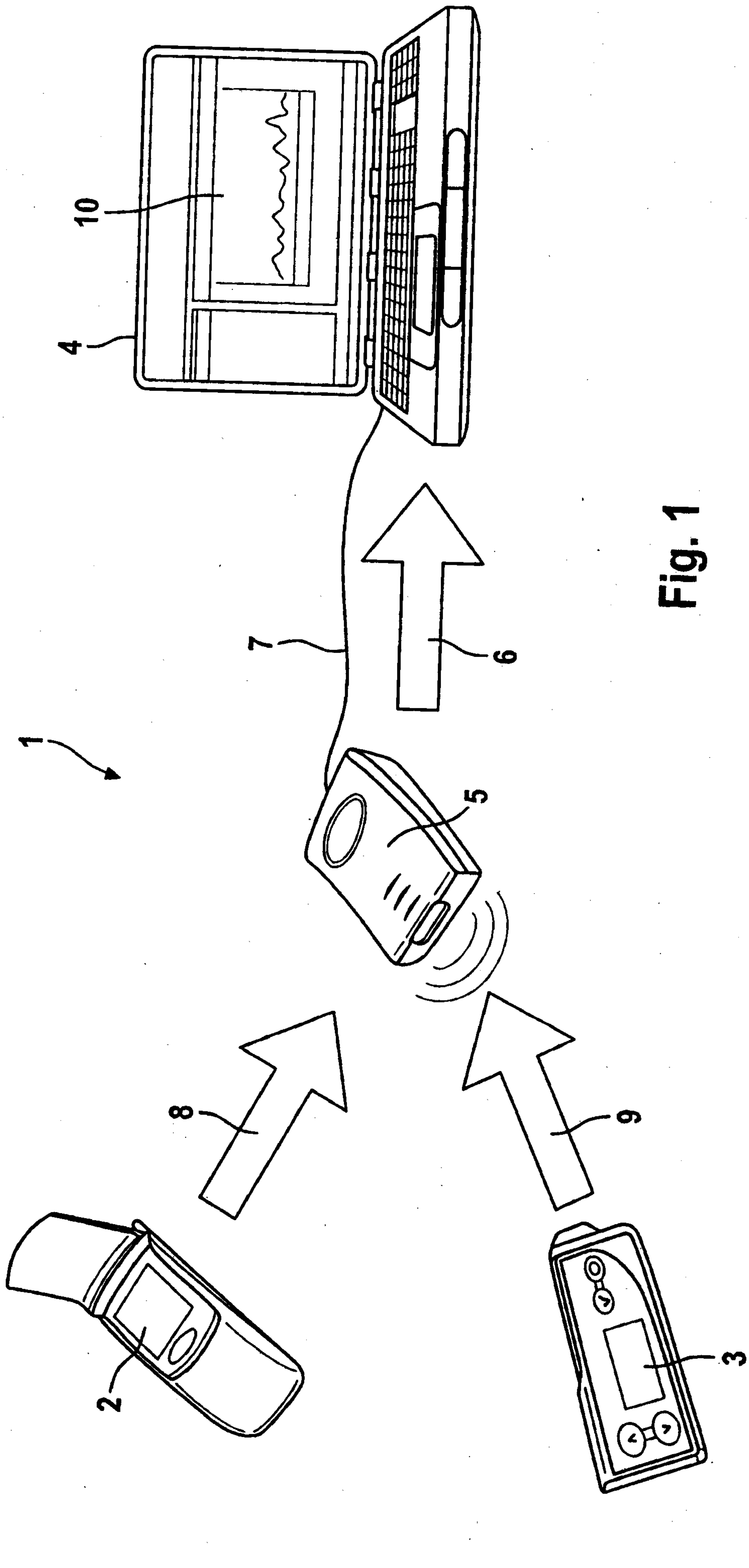


Fig. 1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