



159159

System for determining treatment-related data for the administration of drugs to patients to be treated taking into account important individual factors

Description

5

The invention relates to a system for determining treatment-related data for the administration of at least one drug to a patient to be treated with at least one sampling device for continuous and successive removal of quantities of blood from the patient in order to obtain a plurality of blood samples, at least one, preferably several blood value measuring devices for measuring
10 blood values of the blood samples taken and in order to obtain blood value measurement data sets, and at least one calculating device for calculating treatment-related data from the blood value measurement data sets and optionally further data sets according to the preamble to Claims 1 and 8.

15 Patients, in particular those who are in the intensive care ward, are conventionally supplied with drugs and, if appropriate, artificial nutrition by means of one or more delivery devices, for example intravenously or by means of a gastric tube. The delivery device may for example be an insulin delivery device or respectively an infusion pump by which the insulin values within the patient's bloodstream are kept at a predeterminable level in reaction to a
20 previously measured blood glucose value in the patient's bloodstream. Likewise delivery units for at least one nutritional value of nutrition delivered directly or indirectly by at least one nutrition delivery device to the bloodstream can be given to the patient.

All delivery devices of this type, even if they are integrated in a system for administration of
25 drugs and/or nutritional values, have hitherto required the input by a doctor or other clinical staff of values on which the delivery by means of the delivery device is based and for example in this case quantities, time intervals in which the deliveries are to take place, intermittent delivery, etc., may be input as a basis for the delivery of for example insulin which is then to take place.

30



G00002

Such inputs of insulin values and thus of related drug parameters are frequently based on the experience of the clinical staff, taking account of previously ascertained blood values in this case.

5 This delivery is preceded by taking of a blood sample, generally by hand, from the patient, necessitating the involvement of clinical staff. Likewise there is a need for further clinical staff who have the necessary specialist knowledge of the input functions of the delivery device, such as the infusion pump, in order then perform this delivery.

10 It is possible that in an infusion pump the input of a dosage unit is possible. However, this necessitates the consideration of details about the concentration of the active substance of the drug to be administered and about the type of medicament. Both in the indication of the concentration of the active substance and in the input of the dosage unit and the conversion of these values into the delivery rate, hitherto exclusively the main active substances in the drug
15 have been taken into account. This is frequently sufficient if solely or primarily one specific drug is to be administered. Also in this case empirical values and data lists of the clinical staff, in particular a doctor, are consulted.

The infusion pump systems used in this connection are frequently used in patients who need
20 intensive medical treatment. In this case the infusion pumps have the characteristic of continuous precise dosage of the medication in their delivery. In order to achieve optimised calibration of these pumps in terms of dosage the pumps are integrated in a common organising system which usually includes a central control unit, operating unit and an alarm unit.

25

During treatment or therapy of a patient respectively the blood values determined from the preceding blood value measurements tabulated are archived as tables manually or in electronic form, but an assessment of the drug parameters for the current administration of the drug only takes place in consideration of the blood values from the past if the doctor or
30 the clinical personnel respectively have reason to consult these lists or tables.

Thus in the systems and the methods used hitherto for calculation of drug parameters and therapeutic data for the treatment of a patient, measured values from the past are not routinely included.

5 Consequently the object of the invention is to provide a system and a method for determination of treatment-related data for the administration of at least one drug to a patient to be treated, which enables improved treatment of the patient because of an improved calculation of the treatment-related data including values from the past, in particular in patients on the intensive care ward.

10

This object is achieved in terms of the system by the characterising features of Claim 1 and in terms of the method by the features of Claim 8.

An essential aspect of the invention is that a system for determining treatment-related data for the administration of at least one drug to a patient to be treated includes the following features:

15

- at least one sampling device for continuously and successively taking quantities of blood from the patient in order to obtain a plurality of blood samples;
- at least one, preferably several blood value measuring device(s), in order to measure blood values of the blood samples taken and to obtain blood value measurement data sets;
- a calculating device for calculating treatment-related data from the blood value measurement data sets and optionally further data sets.

20

25 At least one patient-related first identifier and one time-related second identifier concerning the time of taking the blood sample is assigned to each blood sample and each blood value measurement data set associated therewith. By means of a first evaluation unit the calculating device for calculation of the treatment-related data assigns at least one individual weighting factor, preferably a numerical factor, to each blood value measurement data set with the same first identifier and a different second identifier in order to characterise a weighting of the blood value measurement data in the calculation operation.

30

Such a system may advantageously take account of not only the blood values measured for the current calculation of therapeutic data but also takes account of the blood values from the past. For this reason during the treatment period or the observation period respectively blood is repeatedly taken from the patient in order to obtain successive blood samples. The number of blood samples taken is determined by the particular clinical symptoms. Each blood sample is labelled by means of a labelling device with patient-related first identifiers and time-related second identifiers. This may be done for example in that a barcode label or a data matrix code label and/or a transponder marked with at least the patient identification and a time stamp showing the time of blood sampling is adhered to the outside of a syringe which serves for take-up of the blood sample.

However, the assignment of each first and second identifier is also maintained if in the respective measuring device a blood value measurement data set is produced from the measured blood values of the blood sample and this is forwarded in the form of a data set to the calculating device. This may be achieved for example in that the barcode label and/or the data matrix code label are read by means of a barcode scanner and the first and second identifiers determined thereby are assigned as electronic data to the respectively produced blood value measurement data set after measurement of the blood values.

Such assignment of the first and second identifiers ensures that in the case where a plurality of measuring devices is used the particular blood sample is appropriately labelled and thus can be distinguished from the other blood samples.

In addition, a third identifier related to the measuring equipment and assigned to the particular measuring device and a fourth identifier related to the measurement accuracy can be assigned by means of an assigning device which is connected to each measuring device to each blood value measurement data set as it passes from a measuring device to the calculating device. The consequence of this is that the blood value measurement data set which results from the particular blood sample includes, in addition to the first and second identifier, the third identifier giving an identification number of the respective measuring instrument and the fourth identifier giving the degree of accuracy of measurement of the measuring device used. Such measuring devices can be associated, for example as electronic

data, with the calculating device. It is conceivable for the measuring devices to be disposed within a central laboratory or on a ward within a hospital. Naturally, as an alternative only one single measuring device may be used for a patient in order to measure all the blood samples over an entire treatment period with this device.

5

In addition to the point of time of blood sampling, the point of time of measurement may also be determined and can likewise be assigned as identifier to the blood value measurement data set. Likewise an identifier concerning the type of measuring device, which may reflect the quality of the measuring device, and concerning further quality features of the measurement *per se*, for example with regard to the accuracy, may be used.

10

Thus a data protocol from one or more measuring devices to the calculating device comprises at least the attributes of patient identification, time of measurement, time of sampling, identification of the measuring device, type of measuring device as well as a quality feature of the measurement and the measured value itself. According to a preferred embodiment a comparison unit is disposed within the calculating device in order to compare the blood values of different blood value measurement data in a patient, and a differentiation unit is disposed within the calculating device in order to calculate the difference between the compared blood values. This makes it possible that not only absolute values of the measured blood values are used for calculation of the therapeutic data, but also differential values relative to blood values of the preceding measured blood samples or also interrelations between them in order thus to use long-term analyses of the blood value levels as a basis for the treatment to take place as the next stage on the basis of the determined therapeutic data.

15

20

25

An assigning unit can also be disposed within the calculating device for assignment of each blood value measurement data set to patient-specific data sets which are stored in a storage unit of the calculating device and which also include blood value measurement data sets from preceding measurements. Thus, after checking of a patient identification (first identifier) upon input of the blood value measurement data set into the calculating device and after checking of the second identifier in relation to the time of blood sampling with regard to plausibility, this assigning unit makes it possible to assign the incoming measurement data or the blood value measurement data set respectively to a patient-specific data set which is

30

already stored. This may include the measurement results from the preceding blood value measurement data sets of this patient. Further data, such as for example special details about the patient with regard to his susceptibility to certain drugs may optionally be included. The progression of the blood values hitherto is primarily reflected in this data set.

5

The blood values may for example be a glucose value which serves as reference for the dosage of the insulin to be administered as drug.

10

As already mentioned, the calculating device evaluates the relevant blood values or the blood value measurement data set respectively with regard to the time of taking the blood samples and the accuracy of measurement of the measuring device with a certain weighting factor including the chronological blood value progression hitherto. Proposals for changing the treatment are then calculated and likewise proposals for the administration of the drug and therefore specific and previously defined relevant drug parameters are given.

15

20

According to a preferred embodiment, by means of a second evaluation unit at least one individual weighting factor, preferably a numerical factor, to characterise a weighting of the blood value measurement data in the calculation operation is assigned to each blood value measurement data set with the same first identifier and a different fourth identifier. This makes it possible for the accuracy of measurement of the reduced measuring device to be taken into account with a special numerical factor in the calculation of the treatment data, so that during the entire course of treatment from blood sample to blood sample a choice can be made between individual measuring devices even if these have different levels of accuracy of measurement. This is then taken into account accordingly in the subsequent calculation operation.

25

30

A measurement time determining unit is preferably provided for fixing the time of the next measurement taking into account of the previous metering data. Thus, after the calculation of the treatment data and as a function of these treatment data this measurement time determining device can at the same time fix the time of the next measurement or the next blood sampling from the body of the patient respectively, wherein this blood sampling measurement can also be automated.

Advantageously the calculating device may be additionally provided with information and data which are sent by medical devices connected to the patient. The information and data may for example be the drugs administered by an infusion pump and the drug parameters, so that the drug parameters and also the drugs of the current treatment or the preceding treatment are taken into account in the calculation operation.

After determination of the treatment data and the production of treatment proposals and the measurement times, these are transmitted together with the patient identification, that is to say the first identifier, and with the second identifier in digital form to one or more medical devices, in particular infusion pumps. A delivery device, preferably an insulin pump, is provided for this in order to deliver at least one drug to the patient with drug parameters which are determined from the treatment-based data by the calculating device.

The delivery device or the insulin pump respectively checks the patient-related identifier and the time-related identifier and, after successful checking, enables the administration of drugs with the drug parameters determined from the treatment data according to the newly calculated treatment and the next recommended measurement time. In addition or alternatively the treatment data in the form of the drug parameters can also be displayed on the delivery device.

A method for determining treatment-related data for the administration of at least one drug to patients to be treated comprises the following steps:

- continuously and successively taking quantities of blood from the patient in order to obtain a plurality of blood samples by means of at least one sampling device
- measuring blood values of the blood samples taken by means of at least one, preferably several blood value measuring device(s) and obtaining blood value measurement data sets; and
- calculating treatment-related data from the blood value measurement data sets and if appropriate further data by means of at least one calculating device,

wherein

at least one patient-related first identifier and one time-related second identifier concerning the time of taking the blood sample is assigned to each blood sample and each blood value measurement data set associated therewith, and by means of a first evaluation unit the calculating device for calculation of the treatment-related data assigns at least one individual weighting factor, preferably a numerical factor, to each blood value measurement data set with the same first identifier and a different second identifier in order to characterise a weighting of the blood value measurement data in the calculation operation.

By means of an assigning unit disposed within the calculating device, patient-specific data sets which are stored in a storage unit of the calculating device and which also include blood value measurement data sets from preceding measurements are assigned to each blood value measurement data set.

By means of a comparison unit disposed within the calculating device the blood values of different blood value measurement data of a patient are compared, and by means of a differentiation unit disposed within the calculating device the difference between the compared blood values is calculated.

In addition, a third identifier related to the measuring equipment being assigned to the particular measuring device and a fourth identifier related to the measurement accuracy are assigned by means of an assigning device, which is connected to each measuring device, to each blood value measurement data set. Further advantageous embodiments are apparent from the subordinate claims.

Advantages and expedient features can be seen in the following description in conjunction with the drawings. In the drawings:

Figure 1 shows a schematic overview of the entire system according to the invention;

Figure 2 shows a schematic representation of the system according to the invention with details.

The system according to the invention is shown in Figure 1 in a schematic overview of one embodiment of the invention. A patient 1 is for example in an intensive care ward of a hospital. Any number of blood samples N are taken from the patient in the course of the treatment period. This is shown by the two references 2 and 3. After these blood samples are taken they are given a time stamp and a patient identification which corresponds to the first and second identifier.

The blood samples taken are transferred to N measuring devices 4, 5 in order to measure blood value measurement data. In this case two measuring devices 4, 5 with a pre-defined accuracy of measurement and a measuring device identification number are shown.

After the measuring devices have measured the blood values and have produced a respective blood value measurement data set, this blood value measurement data set is provided with the time stamp of the patient identifier originating from the respective blood sample and with an identifier relating to the accuracy of measurement of the measuring device and, if appropriate, an identifier relating to the individual measuring device. As shown by the references 6 and 7, this is then forwarded to a common calculating device 9 for calculation of treatment data as proposed values.

This calculating device 9 is disposed within a common data transmission network 8, wherein the transmission of the measured values is preferably carried out by wireless means, for example by wireless LAN, or also by wired means.

A type of locating device 11 is also provided within the data transmission network and which serves to locate the particular infusion pump for administration of drugs to the specific patient 1 from whom the blood sample has been taken. For this purpose the locating device 11 can use the co-transmitted patient identification number of the determined treatment data, which also include the patient identification number and a time stamp, as shown by the reference 10.

The treatment data are then transmitted as proposed values according to reference 12 together with the patient identification number and the time stamp to the infusion pump which may for example be an insulin pump.

The infusion pump 13 may also be any other type of medical device for administration of drugs.

5 Within this infusion pump an evaluation of the time stamp and the patient identification number takes place again in order to establish that the transmitted treatment data are also securely assigned as medication 14 to this patient 1. Likewise the conversion of the treatment values into a special medication, that is to say for example drug parameters, takes place.

10 Figure 2 shows the system according to the invention in greater detail in a schematic representation. Parts which are the same or equivalent are at least partially provided with the same references.

15 A patient 1 undergoes blood sampling successively or simultaneously by means of blood sampling devices 17, 18, 19 and 20.

These blood sampling devices produce a blood sample which is provided in each case with the patient identification number and a time stamp which shows when the blood sampling took place.

20 The blood samples are then sent to measuring device 4, 5, 15 and 16 with to some extent different accuracy values in the measuring and with different quality values. These measuring instruments 4, 5, 15 and 16 can be used for determination of the same or different blood values.

25 In the determination of blood values which are the same, the use of a plurality of measuring devices may serve to compare the measured value with one another and thus monitoring of the correctness of the measured blood values takes place. In the case of successive measurement of the blood values, the different measuring devices may be used so that the
30 patient's blood values can be measured at different locations.

The particular measured values 21a, 21b, 21c and 21d together with the patient identification number and the time stamp with an identifier relating to the accuracy of measurement of the measuring device and/or the quality of the measuring device as well as the identification number of the measuring device are assigned within an assigning device 21. The plurality of blood value measurement data which have been determined and measured in each case by the measuring devices 4, 5, 15, 16 are then received in a calculating device 22 by means of a receiving unit 23.

The receiving unit 23 sends all the blood measurement data sets to a central control unit 33, which by means of a first evaluation unit 26 carries out the weighting of the time stamp, that is to say of the sampling time, relating to the particular blood value measurement data set.

The first evaluation unit 26 then sends a corresponding evaluation factor back to the control unit 33. The weighting with regard to accuracy of the measuring device which has supplied the blood value measurement data set is established by means of a second evaluation unit 27. As soon such a weighting factor or numerical factor respectively has been fixed by the evaluation unit 27 this is communicated to the control unit 33.

After checking of the patient identification and the time stamp for plausibility, an assigning unit 24 assigns the incoming blood value measurement data sets to a patient-specific data set which reflects the course of treatment hitherto and is stored within a storage unit 25. This patient-related data set is likewise used in order to establish the evaluation factors by means of the first evaluation unit.

In a comparison unit the values of the preceding blood value measurement data sets are compared with the blood values of the current blood value measurement data sets in order, if appropriate, to establish differences between these blood values by means of a differentiation unit 29. Differences which are established are sent back to the control unit 33 to take account of such differences and for calculation of relations in order to perform the calculation not only with absolute blood values but also with relations and differences with respect to the measured preceding blood values.

After calculation of the treatment data is completed, the time of the next measurement is determined and recommended in the form of a display in a measuring and determining unit 30.

- 5 All the data which are then available as treatment data after calculation is completed are transferred to a common transmission unit 31 from the control unit 33 in order that these treatment data can then be sent to a medical device 32, which may be an insulin pump. The insulin pump determines from the treatment data *inter alia* drug parameters for the administration of the insulin, in order then to administer the insulin in the form of the
- 10 recommended medication to the patient 1.

All the features disclosed in the application documents are claimed as essential to the invention in so far as they are individually or in combination novel over the prior art.

List of references

	1	patient
5	2	blood sample
	3	blood sample
	4	blood value measuring device
	5	blood value measuring device
	6	blood value measurement data sets
10	7	blood value measurement data sets
	8	data transmission network
	9	calculating device
	10	proposed value
	11	locating device
15	12	proposed value
	13	delivery unit
	14	drug
	15	blood value measuring device
	16	blood value measuring device
20	17	sampling device
	18	sampling device
	19	sampling device
	20	sampling device
	21	assigning device
25	21a-d	blood value measurement data sets
	22	calculating device
	23	receiving unit
	24	assigning unit
	25	storage unit
30	26	evaluation unit
	27	evaluation unit
	28	comparison unit

- 29 differentiation determining unit
- 30 measurement time determining unit
- 31 transmission unit
- 32 delivery unit
- 5 33 control unit

Claims

1. System for determining treatment-related data for the administration of at least one drug to a patient (1) to be treated, comprising:

- 5 - at least one sampling device (17-20) for continuously and successively taking quantities of blood from the patient (1) in order to obtain a plurality of blood samples (2, 3; 17-20);
- at least one, preferably several blood value measuring device(s) (4,5, 15,16), in order to measure blood values of the blood samples (2, 3; 17-20) taken and to obtain blood value measurement data sets (6, 7; 21a-d);
- 10 - at least one calculating device (22; 9) for calculating treatment-related data from the blood value measurement data sets (6, 7; 21a-d) and optionally further data,

characterised in that at least one patient-related first identifier and one time-related second identifier concerning the point of time of taking the blood sample (2, 3; 17-20) is assigned to each blood sample (2, 3; 17-20) and each blood value measurement data set (6, 7; 21a-d) associated therewith, and by means of a first evaluation unit (26) the calculating device (22; 9) for calculation of the treatment-related data assigns at least one individual weighting factor, preferably a numerical factor, to each blood value measurement data set (6, 7; 21a-d) with the same first identifier and a different second identifier in order to characterise a weighting of the blood value measurement data (6, 7; 21a-d) in the calculation operation.

2. System as claimed in Claim 1, characterised by a comparison unit (28) disposed within the calculating device (22) in order to compare the blood values of different blood value measurement data sets (6, 7; 21a-d) of a patient (1), and a differentiation unit (29) disposed within the calculating device (22) in order to calculate the difference between the compared blood values.

3. System as claimed in Claim 1 or 2, characterised by an assigning unit (24) disposed within the calculating device (22) for assignment of each blood value measurement data set (6, 7; 21a-d) to patient-specific data sets which are stored in a storage unit (25) of the calculating device (22) and which also include blood value measurement data sets from preceding measurements.

4. System as claimed in one of the preceding claims, characterised by an assigning device (21) which is connected to each measuring device (4, 5, 15, 16) in order to assign a third identifier related to the measuring equipment, being assigned to the particular measuring devices (4, 5, 15, 16) and a fourth identifier related to the measurement accuracy to each blood value measurement data set (21a-d).

5. System as claimed in Claim 4, characterised by a second evaluation unit (27) in order to assign at least one individual weighting factor, preferably a numerical factor, for characterising a weighting of the blood value measurement data in the calculation operation to each blood value measurement data set (21a-d) with the same first identifier and a different fourth identifier.

6. System as claimed in any one of the preceding claims, characterised by a measurement time determining unit (30) for fixing the point of time of the next measurement taking into account of the previous blood value measurement data sets (6, 7; 21a-d).

7. System as claimed in any one of the preceding claims, characterised by a delivery device (13; 32), preferably an insulin pump, to deliver at least one drug (14) to the patient (1) with drug parameters which are determined from the treatment-related data by the calculating device (22).

8. Method for determining treatment-related data for the administration of at least one drug to a patient (1) to be treated, comprising the following steps:

- continuously and successively taking quantities of blood from the patient (1) in order to obtain a plurality of blood samples (2, 3; 17-20) by means of at least one sampling device (17-20);
- measuring blood values of the blood samples (2, 3; 17-20) taken by means of at least one, preferably several blood value measuring device(s) (4, 5, 15, 16) and obtaining blood value measurement data sets (6, 7; 21a-d);

- calculating treatment-related data from the blood value measurement data sets (6, 7; 21a-d) and if appropriate further data by means of at least one calculating device (22; 9),

characterised in that at least one patient-related first identifier and one time-related second identifier concerning the point of time of taking the blood sample (2, 3; 17-20) is assigned to each blood sample (2, 3; 17-20) and each blood value measurement data set (6, 7; 21a-d) associated therewith, and by means of a first evaluation unit (26) the calculating device (22; 9) for calculation of the treatment-related data assigns at least one individual weighting factor, preferably a numerical factor, to each blood value measurement data set (6, 7; 21a-d) with the same first identifier and a different second identifier in order to characterise a weighting of the blood value measurement data (6, 7; 21a-d) in the calculation operation.

9. Method as claimed in Claim 8, characterised in that by means of an assigning unit (24) disposed within the calculating device (22) patient-specific data sets which are stored in a storage unit (25) of the calculating device (22) and which also include blood value measurement data sets from preceding measurements are assigned to each blood value measurement data set (6, 7; 21a-d).

10. Method as claimed in Claim 8 or 9, characterised in that by means of a comparison unit (28) disposed within the calculating device (22) the blood values of different blood value measurement data sets (6, 7; 21a-d) of a patient (1) are compared, and by means of a differentiation unit (29) disposed within the calculating device (22) the difference between the compared blood values is calculated.

11. Method as claimed in any one of Claims 8-10, characterised in that by means of an assigning device (21) which is connected to each measuring device (4, 5, 15, 16) and by which a third identifier related to the measuring equipment and assigned to the particular measuring devices (4, 5, 15, 16) and a fourth identifier related to the measurement accuracy is assigned to each blood value measurement data set (21a-d), and that by means of a second evaluation unit (27) at least one individual weighting factor, preferably a numerical factor, is assigned to each blood value measurement data set (21a-d) with the same first identifier and a

- different fourth identifier in order to characterise a weighting of the blood value measurement data in the calculation operation.

· Key to drawings:

Figure 1

- 1 patient
- 2 sample N (time stamp PatID)
- 5 3 sample 1 (time stamp, PatID)
- 4 measuring device N with defined accuracy
- 5 measuring device 1 with defined accuracy
- 6 measured value N (time stamp, PatID), accuracy)
- 7 measured value 1 (time stamp, PatID), accuracy)
- 10 8 data transmission network
- 9 calculation of proposed values
- 10 proposed value (time stamp, PatID)
- 11 location of the medical equipment assigned to the patient by means of PatID
- 12 proposed value (time stamp, PatID)
- 15 13 medical instrument, evaluation of time stamp and PatID, conversion of proposed value into change to medication

Figure 2

- 1 patient
- 17 sample 1, time stamp
- 20 18 sample 2, time stamp
- 19 sample 3, time stamp
- 20 sample n, time stamp
- 4 measuring instrument 1
- 5 measuring instrument 2
- 25 15 measuring instrument 3
- 16 measuring instrument n
- 21a measured value 1, accuracy, quality, time stamp
- 21b measured value 2, accuracy, quality, time stamp
- 21c measured value 3, accuracy, quality, time stamp
- 30 21d measured value n, accuracy, quality, time stamp
- 32 medical instrument
- 1 patient