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System and method for monitoring at least one blood parameter

The invention concerns a system and a method for monitoring at least one blood parameter of the blood of a prespecified patient, with an access device to create an access to the patient's blood, an extraction device to extract a quantity of blood to obtain a blood sample, a blood analysis device to analyse the blood sample, a calculation device to calculate medicament parameters of a medicament to be administered to the patient, and a supply device to supply the medicament with the calculated medicament parameters, according to the preamble of claim 1 and the preamble of claim 9.

Systems for extracting blood and monitoring at least one blood parameter of the blood of a prespecified patient are well known in various forms. For example there are systems which monitor the glucose value of the blood as a relevant blood parameter in order, after calculation of an insulin value, to supply to the patient as a medicament a corresponding quantity of insulin in response to the glucose value determined.

Conventionally patients, in particular in intensive treatment units, are supplied with medicaments and where applicable synthetic nutrition by means of one or more supply devices, for example intravenously or by means of a gastric probe. For example the supply device can be an insulin supply device or an infusion pump which maintains the insulin value present in the patient's blood circulation at a prespecifiable level in response to a previously measured blood glucose value in the patient's blood circulation. Also supply devices for at least one nutrient of nutrition supplied to the blood circulation directly or indirectly via at least one nutrition supply device can be administered to the patient.

All such supply devices, also when integrated into a system for administering medicaments and/or nutrients, have previously required the input of values by a doctor or further clinical personnel to form the basis for the supply by means of the supply device. Here, for example, quantity values, time intervals at which the supply should be made, intermittent supply etc. are entered as the basis for subsequent supply of for example insulin.

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This supply is preceded by the manual taking of a blood sample from the patient, which requires the intervention of clinical personnel. Also further clinical personnel is required with the necessary professional knowledge of the input function of the supply device, such as the infusion pump, in order to subsequently perform the supply. Such an extraction of blood by the clinical personnel has the disadvantage that blood samples taken can be confused. This means that wrong blood samples can be allocated to the patient, wherein it must be taken into account that blood analysis devices are frequently used in common for a large number of blood samples from widely varying patients.

Consequently the invention is based on the object of providing a system and a method for monitoring at least one blood parameter of the blood of a prespecified patient, which has a high degree of automation and avoids the errors caused by clinical personnel.

This object is achieved by the system with the features of claim 1 and by the method with the features of claim 9.

The core concept of the invention is that in a system for monitoring at least one blood parameter of the blood of a prespecified patient with the following devices:

- an access device to create an access to the patient's blood through the skin;
- an extraction device for extracting a blood quantity to obtain a blood sample;
- a blood analysis device that can be used for a multiplicity of blood samples from various patients to analyse the blood sample with regard to prespecifiable blood parameters;
- a first calculation device for calculating medicament parameters of a medicament to be administered to the patient on the basis of the parameters determined from the blood analysed; and
- a supply device to supply the medicament with the calculated medicament parameters;

an allocation is made directly after extraction of the blood quantity and before its supply to the blood analysis device, namely between the blood sample and at least one identification element with personal and treatment-related data in order to

perform an automatic identification. For this an identification element generating device is used which has the function of generating the identification element, which can for example be a barcode or data matrix code in two-dimensional or three-dimensional form, or is a transponder, in order to then allocate this to the extraction device.

As blood analysis devices are frequently used centrally for a multiplicity of widely varying blood samples from different patients, in principle there is a risk of confusing blood samples on delivery from the point of extraction of the blood quantity from the human body or the patient to the input or supply of the blood sample to the blood analysis device. This can be avoided by the system and method according to the invention. Also with the system and method according to the invention it is possible that patient-specific or personal and treatment-related data can be supplied to the blood analysis device together with the extraction device which may be a syringe. In parallel for comparison purposes, data which are also patient-related or personal and also treatment-related data can be entered in the blood analysis device by means of a determination or calculation device such as for example a PC with an input keyboard or a PC with connected read device for a barcode scanner, and compared with the data from the identification element which is for example a barcode and is read by means of the blood analysis device.

Such comparison allows the avoidance of errors in allocation of the blood to be analysed to the respective patient, since subsequent blood analysis takes place only when the comparison unit and the allocation unit give a release signal to the analysis unit. This occurs only when the comparison unit establishes correlating data.

Advantageously such a determination or reading of personal and treatment-related data can take place by means of a barcode scanner which scans the armband of a patient bearing such a barcode, and reads the barcode. The barcode read is then printed out by means of a printer or the identification element generating device and applied to the syringe or other container.

This is applied preferably to the blood-receiving container of the syringe on the outside by means of an adhesive surface or to a connected blood-receiving container.

Also the barcode read is converted by means of a second calculation device into personal and treatment-related data and correspondingly determined, in order then for this data to be passed on to the blood analysis device for comparison purposes. As already stated, the data entered in the second calculation device are the scanned data of a further identification element or the data entered via a keyboard on the person and treatment of the patient.

Advantageously the personal and treatment-related data on the identification element are encrypted. The data can be information on a prespecifiable time of the blood extraction to be performed, the name of the patient and the medicament, the medicament dose to be administered, and similar data.

The blood parameters to be determined of the blood to be analysed however can contain glucose values, pH values, coagulation factors of the blood and further blood gas data such as for example CO_2 values, PO_2 values, potassium values, bicarbonate values, basic deviation values and similar.

Also because of the encryption of the data contained on or in the identification element, transport of blood samples secure against unauthorised reading and also secure carrying of the identification element applied to the patient is possible.

Further data which can be contained on or in the identification feature which is applied to the blood sample or applied to the syringe can be information on the time of blood extraction, the date of blood extraction, the summer or winter time, or similar. Also data on the type of blood can be included in the identification element of the blood sample. As a result comprehensively all data can be passed on to the blood analysis device, wherein data such as information on the time, date and summer or winter time can also be generated by means of the second calculation device on input of the personal and treatment-related data and passed on to the blood analysis device.

The blood analysis device is connected with the first calculation device and this is connected with the supply device for the supply of medicament such that a data transfer can take place. This can be both hard-wired and wireless. Thus the various devices can be arranged at different places and a high degree of automation is achieved in the automated administration of medicaments, even to patients in the intensive treatment unit, on the basis of measurement values and patient-induced parameters.

It is advantageous in a method for monitoring at least one blood parameter of the blood of a prespecified patient and for administration of a medicament to the patient, to provide the following sequence of steps according to the invention, wherein the blood parameter to be determined can be glucose and the medicament to be administered can be insulin and the supply device can be an insulin pump:

- creation of an access by means of the access device to the patient's blood through the skin;
- extraction of a blood quantity by means of the extraction device to obtain a blood sample;
- analysis of the blood sample with regard to the prespecifiable blood parameters by means of a blood analysis device which can be used for a multiplicity of blood samples from different patients;
- calculation by means of a first calculation device of medicament parameters of a medicament to be administered to the patient on the basis of the parameters determined from the blood analysed; and
- supply by means of the supply device of the medicament with the calculated medicament value parameters.

Directly after extraction of the blood quantity and before its supply to the blood analysis device, the blood sample is allocated by means of an identification element generating device to at least one identification element with personal and treatment-related data in order to obtain automatic identification.

The method also comprises the reading of personal and treatment-related data of the identification element by means of a read unit which is preferably connected with

the blood analysis device or arranged within this, and the allocation by means of an allocation unit of the data read to the blood to be analysed within the blood analysis device.

Further advantages and suitabilities arise from the description below in conjunction with the drawing. This shows:

- Fig. 1 in a diagrammatic depiction, the system and its function in one embodiment of the invention;

- Figs. 2a and 2b a flow diagram which illustrates the method according to one embodiment of the invention.

Fig. 1 in a diagrammatic depiction shows the system according to the invention according to one embodiment of the invention. This depiction shows that a needle 2 penetrates through the skin of a patient 1, of whom a hand and arm are shown, as an access device in order to extract blood.

The blood extraction takes place in the normal known manner, for example by means of a syringe 3 as an extraction device.

By means of a barcode scanner 5 connected with a read device 6, an armband 4 is scanned on which a barcode is shown. This barcode contains personal and treatment-related data of the patient wearing this armband. For example these can be the patient's name, the name of the medicament to be administered, the age and further personal data.

After scanning of the barcode on the armband 4, the read device 6 sends a corresponding barcode signal to a calculation device 7 whose task is to determine, from the read barcode, the relevant personal and treatment-specific data - which includes the time of blood extraction - and pass on these data to an identification element generating device 9 which can be a barcode printer. This printer 9 prints a barcode with the personal and treatment-specific data and the barcode is affixed, for

example in the form of a barcode label 10, onto the blood sample receiving container of the syringe 3.

At the same time the calculation device 7 sends the personal and treatment-specific data determined to a comparison unit 15 within a blood analysis device 12. Alternatively or additionally by means of a keyboard 8 personal and treatment-specific data can be entered in the calculation device 7 in order to be included in the barcode to be printed or taken into account in the comparison unit 15.

After the syringe 3 with the applied barcode 10 has been inserted in one of the blood receiving devices 11, 11a present of the blood analysis device 12, the blood present in the syringe 3 is collected by the blood analysis device 12 for analysis purposes. At the same time the barcode 10 is scanned by a further barcode scanner 13 which is connected with a read unit 14 within the blood analysis device 12. The barcode data read are again converted into personal and treatment-specific electronic data and passed on to the comparison unit 15.

Within the comparison unit 15, the data which have been read by the barcode scanner 13 from the barcode 10 are now compared with the data provided by the calculation device 7. As soon as correlations in the data are found on such a comparison, these personal and treatment-related data are allocated to the blood sample 3. This is carried out by an allocation unit 16.

After allocation by the allocation unit 16, within an analysis unit 17 the actual analysis of the blood to be analysed takes place and then one or more desired blood parameter values are established. Here, for example, the glucose value within the blood taken can be found, in order to subsequently administer as a medicament insulin at the desired level corresponding to the medicament parameters.

After analysis within the analysis unit 17, the data which reflect the analysis measurement values and for example contain the amount of a glucose value, are passed on to a calculation device 18 whose purpose is to determine, by means of an internal database and corresponding memory unit, the associated medicament with

a dose corresponding to the glucose value. In this case the amount of insulin to be administered is determined by means of the calculation device 18.

Then data which reflect the amount of the insulin value and the quantity of the insulin value are transferred to a supply device 19 which in this case is formed as an insulin pump. This insulin pump 19 delivers insulin via a catheter 20 to the patient 1 in the desired quantity and at the desired time.

Figs. 2a and 2b illustrate the method according to the invention according to one embodiment of the invention. It is clear from this depiction that in a step 21 a barcode is scanned on the armband of the patient by means of a barcode scanner and data are determined by means of the second calculation device 7.

In a step 22, a barcode label is printed by means of the printer 9. The barcode label is then applied to the blood sample vessel in a step 23.

The blood sample is then introduced in a blood analysis device in a step 24, whereupon the barcode label is read by a barcode scanner of the blood analysis device in a step 25.

After the data of the barcode label and the data determined are compared in the comparison unit 15 according to step 26, it is established in a query 27 whether these are identical. If this is not the case, according to step 28 no analysis is possible and the process is terminated.

If this is the case, in a step 29 and a step 30, the data are allocated to the blood sample to be analysed and the blood sample is analysed.

After the determined blood parameters of the blood sample to be analysed have been sent to the first calculation device according to a step 31, in a step 32 this calculation device calculates the medicament parameters. These are for example the amount and duration of administration of the medicament insulin.

In a step 33 then on the basis of the medicament parameters determined a signal is sent to the pump 19, which in a step 34 administers the medicament to the patient in the desired quantity and at the desired time interval.

All features disclosed in the application documents are claimed as essential to the invention where novel individually or in combination in relation to the prior art.

List of reference numerals

1	System for monitoring at least one blood parameter / patient
2	Access device
3	Syringe / extraction device / blood sample
4	Armband
5	Barcode scanner
6	Read device
7	Second calculation device
8	Keyboard
9	Identification element generating device
10	Barcode label
11	Blood receiving device
11a	Blood receiving device
12	Blood analysis device
13	Barcode scanner
14	Read unit
15	Comparison unit
16	Allocation unit
17	Analysis unit
18	First calculation device
19	Insulin pump
20	Catheter
21	Scanning of a barcode
22	Printing of a barcode label
23	Application of the barcode label

24 Introduction of the blood sample in a blood analysis device

25 Reading of the barcode label

26 Comparison of data

27 Query

28 End of the process

29 Allocation of data analysis

31 Determination of blood parameters

32 Calculation of medicament parameters

33 Sending of a signal to the pump

34 Administration of the medicament

Claims

1. System for monitoring at least one blood parameter of the blood of a prespecified patient (1) comprising:
   - an access device (2) to create an access to the blood of the patient (1) through the skin;
   - an extraction device (3) for extracting a blood quantity to obtain a blood sample (3);
   - a blood analysis device (12) that can be used for a multiplicity of blood samples (3) from various patients to analyse the blood sample (3) with regard to prespecifiable blood parameters;
   - a first calculation device (18) for calculating medicament parameters of a medicament to be administered to the patient (1) on the basis of the parameters determined from the blood analysed; and
   - a supply device (19, 20) to supply the medicament with the calculated medicament parameters;

   characterised in that directly after extraction of the blood quantity and before its supply to the blood analysis device (12), the blood sample (3) can be allocated by means of an identification element generating device (9) to at least one identification element (10) with personal and treatment-related data in order to perform an automatic identification.

2. System according to claim 1, characterised in that the allocated identification element (10) is a least one barcode and/or data matrix code applied to the extraction device (3).

3. System according to claim 1, characterised in that the allocated identification element (10) is at least one transponder.

4. System according to any of the preceding claims, characterised in that the blood analysis device (12) comprises a read unit (14) for reading the personal and treatment-related data of the identification element (10) and an allocation unit (16) to allocate the read data to the blood to be analysed.

5. System according to claim 4, characterised in that the blood analysis device (12) is connected with the first calculation device (18) which is connected with the supply device (19 - 21) for a data transfer.

6. System according to any of the preceding claims, characterised in that the identification element generating device (9) is connected with a second calculation device (7) which determines the personal and treatment-related data from data previously entered in the second calculation device (7) and sends this to the identification element generating device (9), wherein the entered data are scanned data of a further identification element (4) or data entered by means of the keyboard (8) on the person and treatment of the patient (1).

7. System according to any of the preceding claims, characterised in that the personal and treatment-related data are encrypted and contain information on the time of the blood extraction to be performed, the name of the patient and the medicament of the medicament dose to be administered, and similar data.

8. System according to any of the preceding claims, characterised in that the extraction device (1b, 2b, 3b) is a syringe or a blood extraction needle, the blood-receiving container of which or a connected blood-receiving container is connected on the outside with a barcode/data matrix code label and/or a transponder.

9. Method for monitoring at least one blood parameter of the blood of a prespecified patient (1) with the following steps:
   - creation of an access by means of an access device (2) to the blood of the patient (1) through the skin;
   - extraction of a blood quantity by means of the extraction device (3) to obtain a blood sample;
   - analysis (30) of the blood sample (3) with regard to the prespecifiable blood parameters by means of a blood analysis device (12) which can be used for a multiplicity of blood samples (3);

- calculation (32) by means of a first calculation device (18) of medicament parameters of a medicament to be administered to the patient (1) on the basis of the parameters determined from the blood analysed;
- supply (34) by means of a supply device (19, 20) of the medicament with the calculated medicament parameters,

characterised in that directly after extraction of the blood quantity and before its supply (24) to the blood analysis device (12), the blood sample (3) is allocated by means of an identification element generating device (9) to at least one identification element (10) with personal and treatment-related data in order to perform an automatic identification.

10. Method according to claim 9, characterised in that as an identification element at least one barcode and/or data matrix code applied to the extraction device (3) or a transponder is used.

11. Method according to claim 9 or 10, characterised in that the personal and treatment-related data of the identification element (10) are read (25) by means of a read unit (14) and the read data are allocated (29) to the blood to be analysed by means of an allocation unit (16).

12. Method according to claims 9 to 11, characterised in that as parameters determined of the blood to be analysed, parameters are determined such as glucose values, pH values, coagulation factors of the blood, blood gas data such as CO_2 values, PO_2 values, potassium values, bicarbonate values and/or basic deviation values.