(57) Abrégé/Abstract:
The invention relates to a system and a method for monitoring in each case at least one blood parameter of the blood of various patients by means of a plurality of access devices for in each case setting up at least one access to the blood of each patient.
(57) **Abrégé(suite)/Abstract(continued):**
through his skin, a plurality of extraction devices, in each case for extraction of an amount of blood from each patient in order to obtain at least one blood sample in each case, blood analysis devices (7, 9), which are used jointly for a plurality of blood samples, for analysis of predeterminable parameters of the blood from the blood sample, a common calculation device for calculation of medicament parameters for the medicaments to be prescribed to the respective patient on the basis of data records of the determined parameters of the analyzed blood, and a plurality of feed devices for feeding in the respective medicament with the calculated medicament parameters.
(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
Internationales Büro

(43) Internationales Veröffentlichungsdatum

(10) Internationale Veröffentlichungsnummer
WO 2011/107570 A1

(51) Internationale Patentklassifikation:
D06F 19/00 (2011.01) G01N 35/00 (2006.01)

(54) Titel: SYSTEM AND METHOD FOR MONITORING THE TIME PERIOD FOR BLOOD PARAMETER MONITORING PROCESSES

(54) Bezeichnung: SYSTEM UND VERFAHREN FÜR DIE ÜBERWACHUNG DES ZEITABSCNITTS BEI BLUTPARAMETERÜBERWACHUNGEN

(57) Abstract: The invention relates to a system and a method for monitoring in each case at least one blood parameter of the blood of various patients by means of a plurality of access devices for in each case setting up at least one access to the blood of each patient through his skin, a plurality of extraction devices, in each case for extraction of an amount of blood from each patient in order to obtain at least one blood sample in each case, blood analysis devices (7, 9), which are used jointly for a plurality of blood samples, for analysis of predeterminable parameters of the blood from the blood sample, a common calculation device for calculation of medicament parameters for the medicaments to be prescribed to the respective patient on the basis of data records of the determined parameters of the analyzed blood, and a plurality of feed devices for feeding in the respective medicament with the calculated medicament parameters.

(57) Zusammenfassung:

[Fortsetzung auf der nächsten Seite]
System and method for monitoring the time period for blood parameter monitoring processes

Description

The invention relates to a system and a method for monitoring respectively at least one blood parameter of the blood of various patients using a plurality of access devices for establishing respectively at least one access to the blood of each patient through his or her skin, a plurality of sampling devices each for taking an amount of blood from each patient for obtaining respectively at least one blood sample, a blood analysis device (7, 9) to be commonly used for a plurality of blood samples, for analysing the blood sample with regard to specifiable parameters of the blood, a common calculation device for calculating medicament parameters of the medicaments to be administered to the respective patients on the basis of data records of the determined parameters of the analysed blood, as well as a plurality of feeding devices for feeding the respective medicaments having the calculated medicament parameters according to the preamble of patent claim 1 and the preamble of patent claim 11.

Such a system and such a method are used for an automated administration of the medicaments and nutrients.

Conventionally patients, in particular those in intensive care units, are supplied with medication and, if needed, artificial nutrition by means of one or more feeding devices, for example intravenously or via a feeding tube. The feeding device may for example be an insulin feeding device or an infusion pump, which maintains the insulin level present in
the blood circulation of the patient on a specifiable level as a response to a previously measured blood glucose level in the blood circulation of the patient. Similarly, feeding devices for at least one nutrition value of a nutriment directly or indirectly fed to the blood circulation using at least one feeding device may be administered to the patient.

So far, all of these feeding devices, even if they are integrated in a system for administering medicaments and/or nutrients, have required a physician or other clinical personnel to input values that are the basis for a feeding process by means of the feeding device. For example, amounts, time periods over which the feeding is to be carried out, intermittent feeding etc., have to be input as the basis for the feeding to be subsequently carried out, for example with insulin.

This feeding follows the taking of a blood sample from the patient, which is mostly carried out by hand, which requires the involvement of clinical personnel. In particular, so far the individual blood samples taken had to be associated with the respective patients by hand, for example by writing the name of the patient by hand onto the respective blood sample, subsequently introducing the blood sample into a blood analysis device, and the obtained result of the analysed blood levels in turn had to be associated with the specific patient by hand by way of inputting the medicament parameters resulting from the determined analysed blood levels in terms of the desired amounts and levels by hand into the infusion pump of this patient. Similarly, further clinical personnel having the necessary expert knowledge for these input functions into the feeding device,
such as the infusion pump, is required so as to subsequently carry out this feeding process.

Furthermore, such feeding devices, such as infusion pumps, have a delivery rate that is expressed in terms of volume per time unit (ml/h). In the medical field, in contrast, the dose unit is used for a supplied medicament solution. Consequently, the dose unit has to be converted into a delivery rate of the pump, which is a task for the treating physician. What can be disadvantageous in such conversions are frequently calculation mistakes, which lead to incorrect entries of delivery rates, so that for example an incorrect amount of insulin is administered to the patient.

It is also conceivable that an infusion pump would allow dose units to be input. However, this requires that inputs as concerns the concentration of the active ingredient of the medicament to be administered and the type of medicament are taken into account. So far, both when indicating the concentration of the active ingredient and when inputting the dose unit and converting it into a delivery rate, only the main active ingredients of the medicament have been taken into account. This is often sufficient, provided that only or preferentially one specific medicament is to be administered.

A number of feeding devices and/or delivery devices for feeding a medicament solution mixture to a body are known. For example, devices/systems having a plurality of infusion and/or syringe pumps are known, each of which feeds a solution including at least one specific active medicament ingredient to a body, so that a medicament solution mixture is obtained.
Such infusion pumps/systems are often used for patients who are in need of intensive medical care. In this connection, the infusion pumps have the characteristics of a continuously accurate dosing of the medication that is being fed. In order to achieve an optimal adjustment of the dosing in these pumps, they are integrated in a common arrangement system that usually comprises a central control unit, an operating unit and an alarm unit.

The data interconnection between several pumps and/or control units may also be combined within the framework of a server. This allows if needed, in an additional calculation unit/a medical computer, to match, and feed accurately dosed even a double-digit number of different medicaments to one body. The data is distributed to the various infusion pumps either on a wired base or as a WLAN.

Similarly, the common server can be used to drive a plurality of pumps or delivery devices that are located with different patients and are used for feeding these different patients.

Pump systems of such a design, if necessary in connection with a server, in turn require the input of the respective data into the dose unit and the like by the medical personnel, whilst care has to be taken to ensure that the correct data that is associated with this patient is input into the infusion pumps associated with the respective patient. Consequently, the correct selection of the pumps associated with the desired patient has to be made by the medical personnel, which carries the risk of an incorrect input.
Consequently, it is an object of the invention to provide a system and a method for monitoring with a degree of automation as high as possible respectively at least one blood parameter for a plurality of patients, which allow the error rate of an incorrect data input to be reduced.

With respect to the system, this object is achieved by means of the features of patent claim 1, and with respect to the method, by means of the features of patent claim 11.

An essential point of the invention is that a system for monitoring respectively at least one blood parameter of the blood of various patients comprises the following:

- a plurality of access devices for establishing respectively at least one access to the blood of each patient through his or her skin;

- a plurality of sampling devices for respectively taking an amount of blood from each patient so as to obtain respectively at least one blood sample;

- a blood analysis device that can be commonly used for a plurality of blood samples of different patients for analysing the blood sample in respect of specifiable parameters of the blood;

- a common calculation device for calculating medicament parameters of the medicaments to be administered to the respective patients, on the basis of data records of the determined parameters of the analysed blood;

- a plurality of feeding devices for feeding the respective medicament having the calculated medicament parameters; and

- an association device that is common to all blood samples, for associating respectively one identification
label for identifying a patient and/or a time period label for indicating a period of time during which the blood sampling was carried out, with each data record of the parameters of the analysed blood of a patient that was determined by the blood analysis device.

Such a system allows in an advantageous manner, by means of the association device, the association of the identification label specific to the respective patient and the associated time period label of the associated blood sample, as a result of which it is established in an advantageously automated manner - without the involvement of any clinical personnel - which parameters of a blood are associated with which blood and with which patient, and the common data records resulting therefrom can be transferred separately or concurrently to the calculation device and subsequently in a distributed and automated manner to the respective associated feeding devices. Therefore it is not necessary for the levels obtained as a result of the blood analysis to be read out by clinical personnel on the blood analysis device, to be manually associated with the respective patient to which the analysed blood sample belongs, and subsequently to input them by hand after the calculation of the medicament parameters in the associated infusion pumps associated with these patients. Therefore, an incorrect input is prevented by such an automated association of identification labels and time period labels with the respective blood samples.

Due to the additional use of a time period label it is also possible to associate several blood samples taken in different periods of time from the same patient and analysed
by the blood analysis device in correspondence with the time periods in a reliable and correct manner, so that any risk of confusion in respect of any previous blood analyses from the same patients will be avoided.

Advantageously, such a common association device is disposed within the blood analysis device, so that the blood samples introduced into it can immediately be provided with the required identification label and the time period label as well as further labels, if needed, once the determined blood parameters have been obtained.

According to a preferred embodiment, each data record of the determined parameters of the analysed blood can be respectively transmitted as a common data record in a line-based or wired manner or in a cordless or wireless manner from the blood analysis device to one or several feeding devices, and it is possible to calculate a priori, by means of a commonly used centralised calculation device, the required medicament parameters from the determined parameters of the analysed blood, and can subsequently be transmitted in an automated manner to the associated feeding devices to be selected by the blood analysis device and/or the calculation device.

Preferably, at least one identification element generating device is provided, by means of which each blood sample may have associated therewith, immediately after the amount of blood has been taken and prior to it having been fed to the blood analysis device, the identification label and/or the time period label in the form of a barcode, a data matrix code and/or a transponder, on the sampling device containing the blood sample. The sampling device may here be
a syringe, the blood collection container of which, or a blood collection container coupled therewith, is linked on the outside thereof with the barcode, the data matrix code and/or the transponder. This allows a prior association of the identification label and time period label with the respective blood sample by means of the barcode, the data matrix code and/or the transponder during the sampling step, and to this end any necessary labels may be represented for example on the patient's wristband also in the form of a barcode, a data matrix code and/or a transponder, and can thus be read by means of a barcode scanner or a scanner for data matrix codes or a reader for transponders. Such a barcode, data matrix code and/or transponder would then be simultaneously read by means of a barcode, data matrix code and/or transponder reader whilst the blood sample is introduced from the syringe into the blood analysis device, and could subsequently be electronically associated by means of the association device of the respective analysed blood sample, in order to forward the common data record resulting therefrom to the calculation device.

Consequently, the blood analysis device preferably has a reading unit for reading the barcode, the data matrix code and/or the transponder.

The blood analysis device is connected to the calculation device.

According to a preferred embodiment, the identification labels and the time period labels are present in the form of data encrypted to protect from unauthorised reading both in the barcode, the data matrix code, the transponder and in the common data record that is subsequently sent to the
calculation unit and then to the individual feeding devices, which may for example be insulin pumps, which are operated as a response to the patient's determined blood glucose level.

According to a preferred embodiment, the data record of the determined blood parameters is frequency and/or amplitude modulated with the data of the identification label and the time period label within the common data records.

Alternatively or in addition, the common data records may be present in a binary-coded form.

Advantageously, a method for monitoring respectively at least one blood parameter of the blood of various patients comprises the following steps:

A method for monitoring respectively at least one blood parameter of the blood of different patients (1, 2, 3), comprising the following steps:

- establishing respectively at least one access to the blood of each patient (1, 2, 3) by means of a plurality of access units (1a, 2a, 3a);

- taking (30) an amount of blood from each patient (1-3) for obtaining respectively at least one blood sample by means of a plurality of sampling units (1b, 2b, 3b);

- analysing (32) the blood sample with regard to specifiable parameters of the blood by means of a blood analysis device (7, 9) that can be commonly used for a plurality of blood samples from different patients (1-3);

- calculating (35) medicament parameters of the medicaments to be administered to the respective patient on the basis of data records of the determined parameters of the analysed blood by means of a common calculation device (15); and
- feeding (37) the respective medicament with the calculated medicament parameters by means of a plurality of feeding devices (19, 20, 21),

wherein an association device (11) is used to associate respectively one identification label for identifying a patient and/or a time period label for indicating a time period during which the blood was taken, to each data record of the parameters of the analysed blood, which were determined by the blood analysis device (7, 9), of a patient (1-3).

In such a method, each data record of the determined parameters of the analysed blood is transferred, together with the identification label and a time period label, respectively as a common data record in a wired or wireless manner from the blood analysis device (7, 9) to one or more of the feeding devices (19, 20, 21).

Further advantageous embodiments will become evident from the dependent claims and the description following below in connection with the drawing, wherein:

Figure 1 shows a schematic view of a system according to the invention for monitoring respectively at least one blood parameter of the blood of various patients according to an embodiment of the invention; and

Figure 2 shows a flow diagram of the method according to the invention for monitoring respectively at least one blood parameter of the blood of various patients according to one embodiment of the invention.

Figure 1 shows a schematic view of the basic function and the devices or units of a system for monitoring respectively at least one blood parameter of the blood of
various patients according to one embodiment of the invention.

As can be seen from the illustration shown in Figure 1, blood is taken from a total of three hospital patients 1, 2 and 3 by means of a blood sampling system (e.g. a syringe 1b, 2b and 3b, each comprising a needle 1a, 2a and 3a).

Each patient is wearing a wristband 1c, 2c and 3c on his or her arm, which carries patient-specific data, such as for example by means of a barcode, a data matrix code or a transponder. These may for example be the identification labels of the patient.

As soon as a blood sample has been taken by means of the blood sampling system 1b, 2b and 3b, these syringes are taken along the transport paths 4, 5 and 6 shown to a blood analysis device 7.

At the same time or prior to this, the labels on the wristbands 1c, 2c and 3c of patients 1, 2, 3 are read by means of a barcode or data matrix code reader 26 or a reading unit for transponders, and a corresponding barcode or data matrix code is printed out or a transponder is written upon by means of a barcode or data matrix code generating device 25 or by means of a writing unit for transponders. This barcode or data matrix code respectively or this transponder is affixed to the outside of the respective sample container (e.g. a syringe).

Upon arrival at the blood analysis device 7, these barcodes, data matrix codes and/or transponders are read by means of a reading unit 7a and at the same time the blood samples are introduced into the blood analysis device.
A subsequent data transfer from the reading unit 7 to an analysis unit 9 within the blood analysis device 7, as indicated by reference numeral 8, leads to the identification label and time period label being forwarded to the analysis unit and, according to reference numeral 10, to an association device 11, whilst at the same time the blood sample is analysed within the analysis unit 9 in order to determine specifiable blood parameters.

Within the association device 11, the identification labels and time period labels are now associated with the determined blood parameter levels or determined parameters. Here, any additional data in respect of the blood sample and/or the patient can be input by means of a keypad or a similar input device into a memory 11a, in which also the identification labels and time period labels read at the beginning are stored, and are subsequently associated with the determined parameters within the association device 11.

Advantageously, such an association of the identification label and of further data with the respective analysed blood sample will be reliably carried out in the correct manner, so that as a result a common data record is obtained from the determined blood parameters and the correctly associated labels.

Subsequently, such data records as indicated by reference numerals 12, 13 and 14 are forwarded to a common calculation device 15 which has the task of calculating the corresponding medicament parameters for the medicament or medicaments to be administered from the transmitted parameters. These medicament parameters, too, have the associated identification label and time period label, so
that there is no risk of confusion between the blood parameters or the blood parameter levels of the different patients. This process is carried out in an automated manner just as the process within the association device 11.

Subsequently, a data record with the medicament parameters, such as for example a dose unit and the like, is transmitted to the respectively correct infusion pump 19, 20 and 21, as is indicated by the reference numerals 16, 17 and 18. The infusion pumps 19, 20 and 21 will now administer a corresponding amount of for example insulin to the correct patient, in accordance with the transferred medicament parameters, as indicated by reference numerals 22, 23 and 24. This process, too, is carried out in an automated manner.

Figure 2 shows a flow diagram of an embodiment of the method according to the invention.

In step 30, blood samples are initially taken from several patients. Subsequently, a concurrent or consecutive reading of several sets of blood sample data into the blood analysis device is carried out in step 31.

After that, the various blood samples are analysed in step 32, and in step 33, the identification labels and time period labels read are associated with the respective blood samples in order to generate common data records.

Once a transfer of the generated data records for the common calculation device has been carried out according to step 34, it is calculated in step 35 which medicament parameters belong to the respective data records, in order to subsequently carry out, in step 36, a transfer of the respectively associated medicament parameter data to the associated infusion pumps.
Subsequently, the medicament is administered to the respectively associated patient by means of the infusion pumps.

Reference numeral 38 identifies the circulation of this process, in which subsequently another blood sample is taken after a specifiable period of time, and again a corresponding insulin dose is calculated, for example on the basis of the determined glucose level, and is administered to the patient.

All of the features disclosed in the application documents are claimed as being essential to the invention in as far as they are novel over the prior art either individually or in combination.
List of reference numerals

1  Patient 1
la Needle patient 1
lb Syringe patient 1
5  lc Wristband patient 1
2  Patient 2
2a Needle patient 2
2b Syringe patient 2
2c Wristband patient 2
10 3  Patient 3
3a Needle patient 3
3b Syringe patient 3
3c Wristband patient 3
4  Transport route
15 5  Transport route
6  Transport route
7  Reading unit
8  Data transfer
9  Analysis unit
20 10 Forwarding of the identification label and the time period label
11  Association device
11a Memory
12 Forwarding of the data records
25 13 Forwarding of the data records
14 Forwarding of the data records
15 Calculation device
16 Transmission of the medicament parameters to the infusion pump
17 Transmission of the medicament parameters to the infusion pump
18 Transmission of the medicament parameters to the infusion pump
5  19 Feeding device
  20 Feeding device
  21 Feeding device
22 Administration of the correct dose of insulin
23 Administration of the correct dose of insulin
10  24 Administration of the correct dose of insulin
  25 Barcode or data matrix code generating unit
  26 Data matrix code reader
30  31 Taking an amount of blood
  32 Analysing the blood sample
15  33 Associating the blood
34 Transferring the generated data records to the calculation device
35 Calculating the medicament parameters
36 Transferring the medicament parameters to the infusion pumps
20  37 Feeding the medicament
  38 Circulation of the process
17

System and method for monitoring the time period for blood parameter monitoring processes

**Patent Claims**

1. A system for monitoring respectively at least one blood parameter of the blood of various patients (1, 2, 3), comprising:
   - a plurality of access devices (1a, 2a, 3a) for establishing respectively at least one access to the blood of each patient (1, 2, 3) through his or her skin;
   - a plurality of sampling devices (1b, 2b, 3b) for respectively taking an amount of blood from each patient (1-3), in order to obtain respectively at least one blood sample;
   - a blood analysis device (7, 9) that can be commonly used for a plurality of blood samples from different patients (1-3), for analysing the blood sample with respect to specifiable parameters of the blood;
   - a common calculation device (15) for calculating medicament parameters of the medicaments to be administered to the respective patients (1-3), on the basis of data records of the determined parameters of the analysed blood; and
   - a plurality of feeding devices (19-21) for feeding the respective medicament with the calculated medicament parameters,

characterised in that an association device (11) for associating respectively one identification label for identifying a patient and/or a time period label for
indicating a time period during which the blood was taken, to each data record of the parameters of the analysed blood of a patient (1-3), which were determined by the blood analysis device (7, 9).

2. The system as claimed in claim 1, characterised in that the association device (11) is provided within the blood analysis device (7).

3. The system as claimed in claim 1 or 2, characterised in that each data record of the determined parameters of the analysed blood can be transferred in a wired or wireless manner respectively as a common data record from the blood analysis device (7, 9) to one or more feeding devices (19, 20, 21) together with the patient-specific identification label and the time period label.

4. The system as claimed in any one of the preceding claims, characterised by at least one identification element generation device (25), by means of which the identification label and/or the time unit label can be associated with each blood sample on the sampling device (25) containing the blood sample immediately after the amount of blood has been taken and prior to it having been fed to the blood analysis device (7, 9), in the form of a barcode, a data matrix code and/or a transponder.

5. The system as claimed in any one of the preceding claims, characterised in that the blood analysis device (7,
9) includes a reading unit (7a) for reading the barcode, the data matrix code and/or the transponder.

6. The system as claimed in claim 5, characterised in that the blood analysis device (7, 9) is connected to the calculation device (15) and the latter is connected with all of the feeding devices (19-21) for a data transfer.

7. The system as claimed in any one of the preceding claims, characterised in that the identification label and the time period label and/or the determined parameter data are encrypted.

8. The system as claimed in any one of the preceding claims, characterised in that the sampling device (1b, 2b, 3b) is a syringe or a blood sampling tube, the blood collection container of which or a blood collection container coupled therewith is linked on the outside thereof with the barcode, the data matrix code and/or a transponder.

9. The system as claimed in any one of claims 2-7, characterised in that within the common data record, the data record of the determined parameters is frequency and/or amplitude modulated with the data of the identification label and the time period label.

10. The system as claimed in any one of claims 2-7, characterised in that the common data record is present in a binary-coded form.
11. A method for monitoring respectively at least one blood parameter for blood of various patients (1, 2, 3), comprising the following steps:

- establishing respectively at least one access to the blood of each patient (1, 2, 3) by means of a plurality of access devices (1a, 2a, 3a);
- taking (30) an amount of blood from each patient (1-3), in order to obtain respectively at least one blood sample, by means of a plurality of sampling devices (1b, 2b, 3b);
- analysing (32) the blood sample with regard to the specifiable parameters of the blood by means of blood analysis devices (7, 9) that can be commonly used for a plurality of blood samples from different patients (1-3);
- calculating (35) medicament parameters of the medicaments to be administered to the respective patients on the basis of data records of the determined parameters of the analysed blood by means of a common calculation device (15); and
- feeding (37) the respective medicament with the calculated medicament parameters by means of a plurality of feeding devices (19, 20, 21);

characterised in that by means of an association device (11), respectively one identification label for identifying a patient and/or a time period label for indicating a time period during which the blood was taken, are associated (33) with each data record of the parameters of the analysed blood, which were determined by the blood analysis device (7, 9), of a patient (1-3).
12. The method as claimed in claim 11, characterised in that each data record of the determined parameters of the analysed blood is transferred in a wired or wireless manner respectively as a common data record from the blood analysis device (7, 9) to one or more of the feeding devices (19, 20, 21) together with the identification label and the time period label.
2/2

Take blood sample from several patients

Simultaneously or consecutively reading several blood samples

Analysing the blood samples

Associate read identification labels and time period labels with respect to the respective blood samples for generating common data records

Transfer the data records to the calculation device

Calculate the medicament parameters to obtain the respective data records

Transfer the respectively associated medicament parameter data to the associated infusion pump

Administer the medicament

Fig. 2