159159

System and method for administering medicaments to a patient

Description

The invention relates to a system and a method for administering medicaments to a patient.

It is known that patients, in particular in intensive care, are supplied with medicaments and possibly artificial food by means of one or more supply devices, for example intravenously or by means of a feeding tube. For example, the supply device can be an insulin supply device or an infusion pump which keeps the insulin value present inside the bloodstream of the patient at a pre-determinable level in reaction to a previously measured blood glucose value in the bloodstream of the patient. In the same way, supply devices for at least one nutritional value of a food supplied to the bloodstream directly or indirectly by at least one food supply device can be administered to the patient.

Supply devices of this type have in common the fact that, even if they are integrated into a system for administering medicaments and/or nutritional values, they require the entering of values which are based upon supply by means of the supply device to be carried out by a doctor or a further clinical member of staff. For example, quantity values, time intervals in which the supply is to be carried out, intermittent supplies etc. can be entered here as a basis for the supply of insulin for example which is to be subsequently carried out.

Prior to this supply a blood sample is taken from the

G00002

patient, which is usually carried out by hand and which requires the intervention of clinical staff. In the same way, further clinical staff are required who have the necessary specialist knowledge for the entry functions of the supply device, such as the infusion pump, in order to carry out this supply subsequently.

In addition, supply devices of this type, such as infusion pumps, have a feed rate which is indicated in the form of volume per unit of time (ml/h). In contrast, the dosage unit is used in medicine for a supplied medicament solution. Consequently it is necessary for the dosage unit to be converted into a feed rate of the pump, which is the task of the attending doctor. A disadvantage of a conversion of this type can be frequent calculation errors, which lead to erroneous entries of the feed rate and thus to an incorrect administration of insulin to the patient.

It is also imaginable to make it possible to enter the dosage unit in an infusion pump. This, however, makes it necessary to take into consideration information on the concentration of the active material of the medicament to be administered and on the nature of the medicament. Until now, only the main active materials of the medicament have been taken into consideration both in the information on the concentration of the active material and in the entry of the dosage unit and the conversion thereof into the feed rate. This is frequently sufficient if only or primarily one specific medicament is to be administered.

Supply devices or feed apparatus for the supply of a medicament solution mixture into a body are known in a

multiplicity of forms. For example, apparatus / systems with a plurality of infusion and/or injection pumps are known, each of which supplies a solution with at least one specific active material of a medicament to a body and, as a result, a medicament solution mixture is formed.

Infusion pump systems of this type are frequently used in the case of patients who require an intensive medical treatment. In this case the infusion pumps have the property of continuous precise dosing of the medication in their supply. In order to achieve an optimum adjustment of these pumps in their dosing, the pumps are integrated in a common classification system which usually has a central control unit, an operating unit and an alarming unit. During the conveying of already prepared medicaments, which can be present inside a syringe for example, to the actual infusion pump there is frequently the risk that confusion may arise with respect to the medicament dosage and the patient. For example it is possible for syringes of this type with medicaments of a pre-determined dose contained in them to be allocated to the wrong infusion pump by the clinical staff and thus to be administered to the wrong patient. The result of this is that a patient receives the wrong medicament and/or the wrong dose or dosage. Problems of this type occur in particular when a large number of patients is supplied with medicaments for their infusion pumps by the attending person and so a large number of infusion pumps with medicament syringes have to be supplied from a central medicament preparation station. In particular, in conjunction with a blood analysis device which is frequently present as a common analysis device for a large number of patients whose blood is to be analysed, there is a risk of confusion of the medicaments resulting

from the performed blood analysis in the respective syringes during the transfer to the respective infusion pumps and the patient associated with them.

Consequently the object of the invention is to make available a system and a method for administering medicaments to a large number of patients which makes available a high degree of reliability in the allocation of the correct medicament to the respective patient and his or her supply device.

This object is attained with respect to the system by the features of claim 1 and with respect to the method by the features of claim 8.

The key concept of the invention is that in a system for administering medicaments to a large number of patients, in particular to a selected patient, the following features are present:

- at least one mobile medicament container with at least one liquid medicament;
- an identification element production device for producing at least one first identification element with first data relating to the person, medicament and/or treatment in order to attach them to the medicament container;
- at least one reading device for reading the first data from or out of the first identification element;
- a supply device for supplying the medicament from the medicament container inserted in the supply device to the patient;
- the reading device likewise being suitable for reading second data, which are attached to or in a second identification element which is allocated to the patient,

and being connected to the supply device, and
- a control unit inside the supply device transmitting a first control signal for activating the supply procedure to one of a plurality of supply units of the supply device if the first and the second data correspond at least in part.

A system of this type is advantageously characterized in that it provides a high degree of reliability in the transfer of a prepared medicament in a medicament container provided therefor to a respective supply device of a patient with respect to the correct allocation, since on account of using identification elements with the data attached to or in them a confusion of medicament containers of this type with the medicaments contained in them is no longer possible. On account of reading and comparing different data, confusion of the medicaments is in fact eliminated.

To this end, there is a first comparator unit inside the supply device for comparing the first and second data with respect to the correspondence of the data relating to the person. This means that the person or the patient according to the first data, who has already served in the preparation of the medicament as the allocated person for the medicament produced, can be compared with those data - relating to the person - of the second data which can be taken from an armband or the like which is attached to the person. This ensures that the correct medicament is allocated to the correct patient since otherwise the control unit would not emit a release signal for activating the supply procedure. This means that the supply device, which can be an insulin pump, is not capable of being activated. The insulin pump for

example is in fact capable of being activated only when it receives the correct medicament with the associated medicament container, such as for example a syringe, and establishes a correspondence of the data relating to the person which are present on the syringe and on the patient.

A second comparator unit inside the supply device is provided for comparing the data - relating to the medicament - of the first data with the second data relating to the medicament contained in a memory unit of the supply device. This makes it possible for medicament compositions already saved in advance inside the memory unit of the supply device to be compared with those compositions of the medicaments of the syringe used, so as to prevent incorrectly prepared medicaments with unrealistic medicament compositions from being administered to the patient. In fact, for example, the second comparator unit of the supply device permits a supply procedure only when the first data - relating to the medicament - of the first data which are attached to the identification element of the medicament container are within a parameter or data range which has been saved inside the memory unit as being permissible and suitable for the second data relating to the medicament. In this way, a patient is prevented from inadvertently receiving a medicament with a composition which could lead to a further illness of the patient or could even lead to death. In this case too, a higher degree of reliability in the allocation of the correct medicament to each patient is provided.

Advantageously each composition of the previously prepared medicament can be conveyed automatically through

the identification element production device to the identification element, so as to ensure that no constituents or portions of the composition are overlooked by the attending person.

In accordance with a preferred embodiment a selection unit of the supply device is provided for the selection at least in part of the first and/or the second data relating to the medicament. This selection unit is intended to be used so that the correct data relating to the medicament is selected. To this end it is possible to resort either to first data relating to the medicament which are arranged on the medicament container by means of the identification element, or to the second data relating to the medicament which are saved inside the memory unit of the supply device, in order optionally to select this more advantageous medicament composition. Alternatively, parameters of the selected second data relating to the medicament or of the selected first data relating to the medicament can be changed in order to be able to administer an altered medicament composition with other dosages on the basis of events which have occurred only recently.

In accordance with a preferred embodiment a blocking unit is provided for blocking the start of a supply procedure on receipt of a second control signal of the control unit, the control unit sending this second control signal when the first and second data do not correspond at least in part.

A blocking unit of this type has the aim that the continuation of the procedure which is intended to start a supply procedure of a medicament to the patient is not

possible from the supply device, if non-corresponding data are established. This means that a stoppage of the procedure by the appliance automatically occurs if non-corresponding data are established. As a result, a high degree of reliability should be provided for a correct allocation of the medicament to the respective patient. In particular, if a large number of medicament allocations are present as a result of allocations of the medicament containers to the different infusion pumps in different rooms of a hospital, the risk of a wrong allocation of a medicament to the wrong patient is eliminated by this, since the infusion pump or the supply device simply does not permit such an administration of a medicament. Conclusion of the procedure by means of the blocking unit is in fact achieved.

The identification element is advantageously a barcode label, a Data Matrix code label and/or a transponder. These labels can advantageously be secured by adhesion to the outer face of the medicament container, in which case the barcode label and the Data Matrix code label are printed out of the identification element production device and where a transponder is present the data are saved on the transponder by means of a writer. This transponder can then be read out on the supply device by means of a reader, whereas the barcode label and the Data Matrix code label can be read out by means of a barcode scanner or a Data Matrix code scanner.

It is advantageous for the supply device to be an insulin pump, the supply unit to be one of a plurality of insulin pump units and the medicament container to be a syringe.

A method of administering medicaments to patients advan-

tageously has the following steps:
- preparation of at least one liquid medicament in a mobile medicament container;
- production of at least one first identification element with first data relating to the person, medicament and/or treatment by means of an identification element production device;
- application of the identification element to the medicament container;
- reading of the first data from or out of the first identification element by means of at least one reading device;
- reading of second data, which are attached to or in a second identification element which is allocated to the patient;
- comparison of the first and second data for correspondence at least in part by means of a first comparator unit, and
- activation of a supply procedure for supplying the medicament to the patient with a supply device by means of a first control signal of a control unit to the supply device.

A method of this type allows the self-acting or automatic comparison of read data in order to ensure that only when there is a correspondence of the read data is the procedure continued and so a supply procedure of the medicament to the patient is possible. This results in a high degree of reliable allocation of the correct medicament to the correct patient in order to prevent the administration of wrong medicaments and thus further undesired symptoms of the patient.

In accordance with a preferred embodiment of the method

according to the invention it is provided in a step of reading third data which are attached to or in a third identification element which is allocated to a person treating the patient that only the authorized attending person, i.e. a person from the clinical staff, will perform the administration of the medicament with the correct allocation to the patient. Other persons thus have no access to the administration appliance which constitutes the supply device. As a result, a protection against unauthorized actuation of the supply device and the supply of medicaments can be achieved.

In the same way, it is advantageous for a step of comparing first data - relating to the medicament - of the first data with second data relating to the medicament saved in a memory unit of the supply device to be provided. In this step it is ensured that first data relating to the medicament which are saved on the identification element are compared with second data relating to the medicament saved in the memory unit, and in this way it can be established whether the medicament composition inside the medicament container corresponds to a permitted medicament composition range within which the medicaments to be administered are to lie.
Further advantageous embodiments are set out in the sub-claims. Advantages and expedient features may be seen in the following description in conjunction with the drawing.
In the drawing

Figure 1 is a diagrammatic illustration of the system according to the invention in accordance with an embodiment of the invention in its functional sequence, and

Figures 2a and 2b show the method according to the invention in accordance with an embodiment of the invention.

Figure 1 is a diagrammatic illustration of the system - according to the invention - of an embodiment of the invention. The medicament composition with the respective data relating to the person and the manner of treatment is entered in a computer device 1 by the medical staff by means of a keyboard 2.

After that, a barcode 5a which contains at least parts of the first data relating to the person, the medicament and/or the treatment is printed inside an identification element production device 3 which is present in the form of a barcode printer. This barcode is printed out in the form of a label and comprises for example a patient identification number as data relating to the person, the name of the medicament and the concentration thereof as data relating to the medicament, and different dosage parameters, such as for example the duration of the dosage, as data relating to the treatment.

For example, the barcode label can have the inscription "Hans Müller", "Adrenalin", "2 mg/50" in addition to the barcode or the Data Matrix code. This means that a dosage of 2 mg/50 for the medicament adrenalin, which is to be provided in a syringe 5, is present. At the same time the medicament is prepared in a composition in a medicament preparation station 4 and is supplied to the syringe 5. After that or beforehand, the barcode 5a is secured by adhesion to the syringe 5 by means of an adhesive surface.

After that, the barcode label 5a is read out in a reading device 6 by means of a barcode scanner 7, as a result of which the data relating to the person, the medicament and/or the treatment are read in inside a supply device 11.

At the same time a barcode, which is provided on an armband 10 of a patient 9 and likewise contains data relating to the person, is read out from this armband 10 by means of a further or the same barcode scanner 8.

The data provided are then passed on to a first comparator unit 15 which is preferably arranged inside the supply device 11. The comparator unit 15 compares the data relating to the person, as provided on the armband 10 by means of a barcode for example, with the data relating to the person on the barcode label 5a, as originally produced by the computer unit 1 with reference to the medicament produced by the medicament preparation station 4.

If correspondence of the data relating to the person, but also optionally of the data relating to the medicament, is established inside the first comparator unit 15, an appropriate signal is passed on from the first comparator unit 15 to a control unit 16 which causes a first control signal 13 to be sent by means of a control line to the infusion syringe 14 used, in order to actuate the supply unit 12b for compressing the syringe 14.

It should be noted in each case that different syringes, which contain different medicaments for administration to the patient, can be arranged in different supply units 12a, 12b, 12c, 12d and 12e. In this case the syringe 14

is that syringe 5 which contains the medicament as has been prepared beforehand.

If the first comparator unit establishes that there is no correspondence in the data relating to the person and optionally in the data relating to the medicament, the control unit 16 will send an appropriate signal to a blocking unit 20 in order to effect a termination of the procedure and a blocking of the entire supply device 11 by means of this blocking unit. This ensures that the person is not allocated the wrong medicament, since the medicament contains data relating to the person and the armband of the person 19 or of the patient 19 respectively contains data relating to the person which have to correspond thereto.

At the same time or in advance, third data which contain the person-related data of a nurse are read in by means of the barcode scanner 7 or the barcode scanner 8 from an armband of the nurse. These third data are used to compare the latter with permanently saved data which can be contained for example in a memory unit 19, in order to establish that the nurse has authorized access for operating the appliance or this supply device 11. If it is established that other person-related data are involved here, for example since this nurse is not authorized to administer insulin, then - in accordance with the signals of a control unit - the < blocking unit 20 > is in turn activated and causes a conclusion of the procedure of the supply device 11.

Data - relating to the medicament - of the first data are compared with second data relating to the medicament which are contained in the memory unit 19. This

comparison is carried out inside a second comparator unit 18. If it is established in a comparison of this type that there are deviations between the first data relating to the medicament read in by means of the barcode scanner 7 and the second data relating to the medicament from the memory unit 19, or the first data are outside a range provided for the second data, then the user or the nurse is asked by means of a display unit and input unit 17 whether he or she still wants to continue the treatment and which data he or she wants to implement. As a result, the nurse can select the first data relating to the medicament or the second data relating to the medicament in order to continue the treatment.

In addition or at the same time, the nurse can of course make a change to the parameters on the supply device 11 by means of the display and input unit 17, in order for example to change as a result the dosage of the medicament to be administered. This takes place in the constant data exchange with the control unit 16 which subsequently in turn actuates the supply unit 12b accordingly.

If the user or the nurse wishes to decide on one of the sets of data or the first or second set of data relating to the medicament respectively during a comparison by the second comparator unit 18, then an appropriate fault signal is sent by means of a selection unit 21 to the control unit 16 which in turn actuates the supply unit 12b with the syringe 14 inserted therein in accordance with the selected data in order to start the supply procedure or, where appropriate, to continue it.

After the administration of the medicament, which can be

insulin for example, has taken place, an automated documentation of the administration parameters and the entire supply procedure as well as the entire sequence is in turn produced automatically, this preferably being carried out in the computer unit 1. This can be carried out by means of wireless LAN for example as indicated by the arrow 22.

The method according to the invention is shown in accordance with an embodiment of the invention in figures 2a and 2b.

In a step 25 the preparation of a medicament in accordance with the parameters and data entered is carried out. After that, in a step 26 an automated formation of a barcode label for application to a medicament container is then carried out.

After that, in step 27 the attachment of the barcode label as an ID element is then carried out by means of an adhesive surface for example.

After the syringe arrives at the supply device in the form of an insulin pump, a reading 28 of the first data which are contained on the barcode label, preferably encrypted, takes place. At the same time, a reading of second data 29 which are present on an armband in the form of a barcode label, preferably encrypted, takes place.

A comparison is now carried out between the first and the second data for the correspondence thereof in accordance with step 30, in order to effect a conclusion of the entire procedure in the event of non-correspondence in

accordance with step 31. If corresponding data, in particular with respect to data relating to the person, are established, however, a reading 32 of third data takes place, which in a step 33 are in turn compared with data already saved in the insulin pump. These are data on the attending person in order to establish whether this person is authorized for access. If this is negative, in a step 34 no permission for treatment is allowed and termination takes place.

If, however, it is established that the nurse is authorized for access and is authorized for treatment as the attending person, in a step 35 first data relating to the medicament are compared for correspondence with second data relating to the medicament. This is intended to ensure that the data of the barcode relating to the medicament, as indicated on the syringe, do not differ in an undesired manner from data ranges relating to the medicament as provided which have already been saved inside the insulin pump. If a comparison of this type leads to a denial with respect to the correspondence, in a step 36 a conclusion of the procedure is carried out.

If an affirmative to this comparison is established in accordance with step 35, a release signal is sent in a step 37 to one of the supply units and an activation of the supply procedure takes place. After that, a display of supply parameters is carried out in a step 38.

With renewed preparation in the event of a change in measured blood glucose reference values in accordance with step 39 the cycle is started from the beginning as shown by arrow 40.

All the features disclosed in the application documents are claimed as being essential to the invention, insofar as they are novel either individually or in combination as compared with the prior art.

List of References

1	computer device
2	keyboard
3	identification element production device
4	medicament preparation station
5	syringe
5a	barcode
6	reading device
7	first barcode scanner
8	further barcode scanner
9	patient
10	armband
11	supply device
12a	supply unit
12b	supply unit
12c	supply unit
12d	supply unit
12e	supply unit
13	control signal
14	infusion syringe
15	comparator unit
16	control unit
17	input unit
18	comparator unit
19	memory unit
20	blocking unit
21	selection unit
22	arrow
25	preparation of the medicament
26	production of the barcode label
27	application of the barcode label
28	reading of the first data
29	reading of the second data

30 comparison between the first and the second data

31 conclusion of the entire procedure in the event of non-correspondence

32 reading of third data

33 comparison of the third data with data already saved

34 termination of the procedure on account of impermissibility of the treatment

35 comparison of the first data relating to the medicament with the second ones

36 conclusion of the procedure

37 sending a release signal to one of the supply units

38 display of the supply parameters

39 renewed preparation in the event of a change in the measured blood glucose values

40 arrow - start of the cycle from the beginning

Claims

1. A system for administering medicaments to a patient, comprising:
   - at least one mobile medicament container (5) with at least one liquid medicament;
   - an identification element production device (3) for producing at least one first identification element (5a) with first data relating to the person, medicament and/or treatment in order to attach it to the medicament container (5);
   - at least one reading device (6) for reading the first data from or out of the first identification element (5a);
   - at least one supply device for supplying the medicament from the medicament container (5, 14) inserted in the supply device (11) to the patient;
   wherein the reading device (6) is likewise suitable for reading second data, which are attached to or in a second identification element (10) which is allocated to the patient (9), and is connected to the supply device (11), and
   - a control unit (16) inside the supply device (11) transmits a first control signal (13) for activating the supply procedure to at least one of a plurality of supply units (12a - e) of the supply device (11) if the first and the second data correspond at least in part.

2. A system according to claim 1, characterized by a first comparator unit (15) inside the supply device

(11) for comparing the first and second data with respect to the correspondence of the data relating to the person.

3. A system according to claim 1 or 2, characterized by a second comparator unit (18) inside the supply device (11) for comparing the data - relating to the medicament - of the first data with second data relating to the medicament contained in a memory unit (19) of the supply device (11).

4. A system according to claim 3, characterized by a selection unit (21) of the supply device (11) for the selection at least in part of the first and/or the second data relating to the medicament.

5. A system according to any one of the preceding claims, characterized by a blocking unit (22) for blocking the start of a supply procedure on receipt of a second control signal of the control unit (16), which is sent when the first and second data do not correspond at least in part.

6. A system according to any one of the preceding claims, characterized in that the identification element (5a) is a barcode label, a Data Matrix code label and/or a transponder.

7. A system according to any one of the preceding claims, characterized in that the supply device is an insulin pump (11), the supply unit is one of a plurality of insulin pump units (12a to 12d) and the medicament container is a syringe (5).

8. A method for administering medicaments to patients, with the following steps:
- preparation (25) of at least one liquid medicament in a mobile medicament container (5);
- production (26) of at least one first identification element (5a) with first data relating to the person, medicament and/or treatment by means of an identification element production device (3);
- application (27) of the identification element (5a) to the medicament container (5);
- reading (28) of the first data from or out of the first identification element (5a) by means of at least one reading device (6);
- reading (29) of second data, which are attached to or in a second identification element (10) which is allocated to the patient (9);
- comparison (30) of the first and second data for correspondence at least in part by means of a first comparator unit (15), and
- activation (37) of a supply procedure for supplying the medicament to the patient (9) with a supply device (11) by means of a first control signal (13) of a control unit (16) to the supply device (11).

9. A method according to claim 8, characterized by a step (32) of reading third data which are attached to or in a third identification element which is allocated to a person treating the patient.

10. A method according to claim 8 or 9, characterized by a step (35) of comparing first data - relating to the medicament - of the first data with second data relating to the medicament saved in a memory unit (19) of the supply device (11).