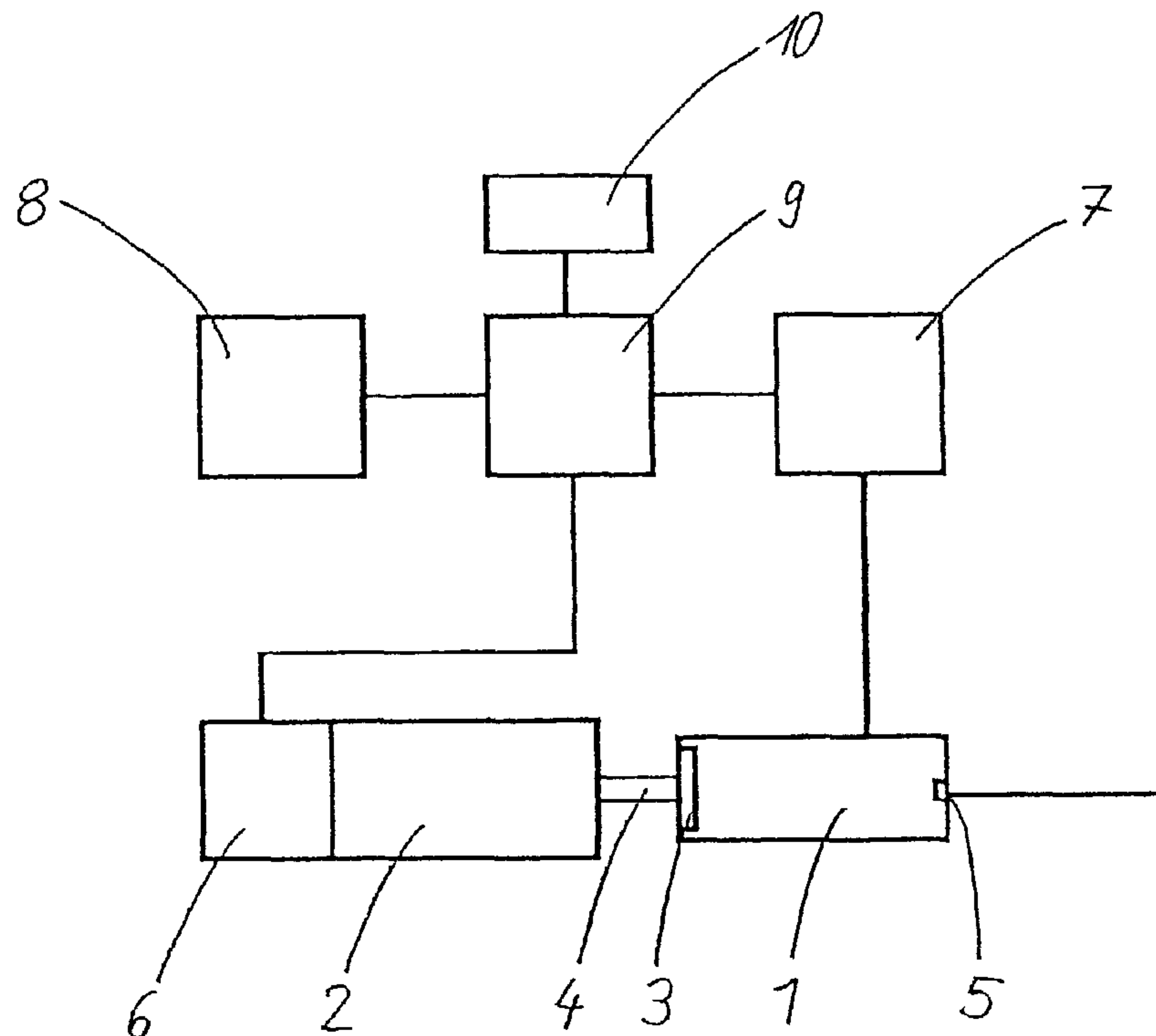




(86) Date de dépôt PCT/PCT Filing Date: 2003/08/27
(87) Date publication PCT/PCT Publication Date: 2004/03/25
(85) Entrée phase nationale/National Entry: 2005/02/22
(86) N° demande PCT/PCT Application No.: EP 2003/009476
(87) N° publication PCT/PCT Publication No.: 2004/024217
(30) Priorités/Priorities: 2002/08/31 (1488/02) CH;
2002/09/03 (60/407,812) US

(51) Cl.Int.⁷/Int.Cl.⁷ A61M 5/00
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(54) Titre : DISPOSITIF D'ADMINISTRATION POURVU D'UN CAPTEUR DE TEMPERATURE
(54) Title: ADMINISTERING DEVICE COMPRISING A TEMPERATURE SENSOR



(57) Abrégé/Abstract:

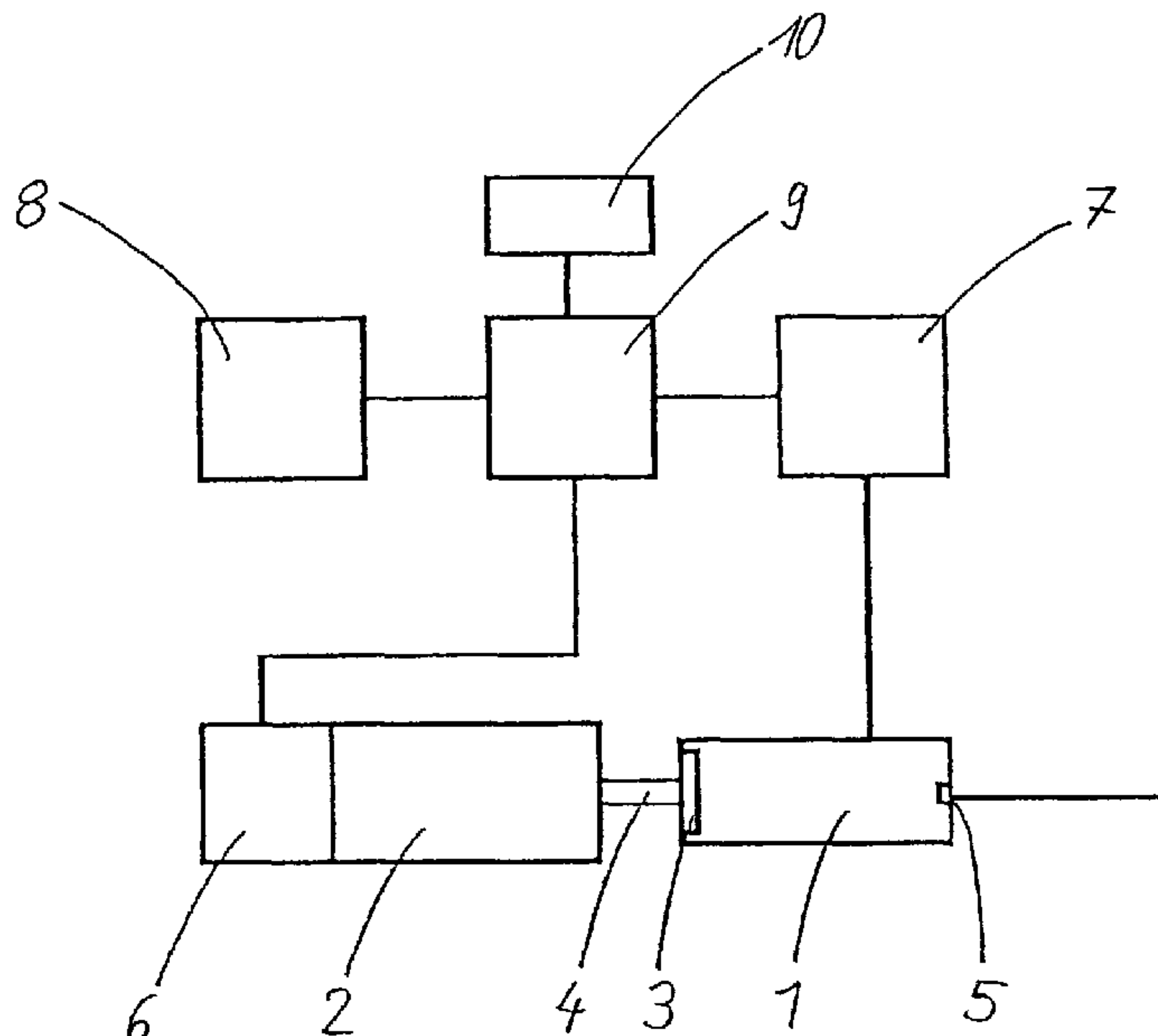
Disclosed is a device for administering a fluid product, comprising a container (1) for the fluid product, an apparatus (2) for dispensing the fluid product from the container (1), and a metering apparatus (6) for adjusting a product dose. At least one temperature sensor (7) measuring the temperature is disposed inside the container (1) and/or near the fluid product. Also disclosed is a method for controlling administration of a fluid product. According to said method, a metered quantity of a product dose, which is to be administered, is adjusted in accordance with the temperature of the fluid product and/or the temperature of the surroundings of the container (1).



(10) Internationale Veröffentlichungsnummer
WO 2004/024217 A1

- [Fortsetzung auf der nächsten Seite]

(54) Bezeichnung: VERABREICHUNGSVORRICHTUNG MIT TEMPERATURSENSOR



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TM), europäisches Patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI-Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Zur Erklärung der Zweibuchstaben-Codes und der anderen Abkürzungen wird auf die Erklärungen ("Guidance Notes on Codes and Abbreviations") am Anfang jeder regulären Ausgabe der PCT-Gazette verwiesen.

Veröffentlicht:

— mit internationalem Recherchenbericht

(57) Zusammenfassung: Eine Vorrichtung zur Verabreichung eines fluiden Produkts umfasst einen Behälter (1) für das fluide Produkt, eine Abgabeeinrichtung (2) zur Verabreichung des fluiden Produkts aus dem Behälter (1) und eine Dosiereinrichtung (6) zur Einstellung einer Produktdosis. In dem Behälter (1) und/oder in der Nähe des fluiden Produkts ist wenigstens ein Temperatursensor (7) zur Messung der Temperatur vorgesehen. Bei einem Verfahren zur Steuerung einer Verabreichung eines fluiden Produkts wird eine zu verabreichende Dosismenge einer Produktdosis in Abhängigkeit von der Temperatur des fluiden Produkts und/oder in Abhängigkeit von der Temperatur der Umgebung nahe des Behälters (1) eingestellt.

Administering Device with Temperature Sensor

The invention relates to a device for administering a fluid product and to a method for controlling the administering of a fluid product. In particular, the invention relates to an infusion apparatus for administering insulin.

Such devices are for example used in medical or therapeutic applications, for repeatedly or continuously administering a product dosage comprising a particular dosage amount of a fluid product. The fluid product can for example be a liquid active solution such as for instance insulin or growth hormones. The administering devices can be formed as stationary apparatus or as portable apparatus which the user carries around, for example on the body.

An infusion pump which serves to infuse an active solution is for example known from EP-B-0 143 895. The infusion pump comprises a casing in which a container for the active solution, an administering means for administering the active solution from the container and a dosing means for setting a particular product dosage to be administered are accommodated. A stopper is provided in the container and is accommodated such that it can shift in an advancing direction towards an outlet in order to delivery the active solution within the container. The administering means comprises a driven member and a drive means. The driven member is connected to the stopper in the container and is driven by the drive means in order to advance the stopper within the container. The dosing means sets a dosage comprising a desired dosage amount of the active substance. The dosage is for example set by limiting the advancing path of the stopper within the container in accordance with the dosage amount. The drive means can be activated by hand or an electric motor can be provided which serves as the drive for the driven member. The driven member and/or stopper within the container can also be advanced by a rotational mechanism in which a rotation is converted into a translational movement for driving the stopper. The active solution and/or fluid product is administered such that when the administering means is activated, the stopper is shifted by a set path length towards a container outlet and the active

substance can thus be dispensed for example into a flexible infusion tube and introduced into a patient via an access, for example in the form of a cannula.

Such administering devices are generally partially pre-programmed, i.e. administering the fluid product is controlled via a memory and control unit, using which for example the size of a dosage amount and the administering frequency can be determined. Furthermore, conventional administering devices can have various control and display means in order to enable the administering of the product to be monitored. For this purpose, measuring systems are for example used for recording various body parameters of a patient, such as for instance measuring the pulse rate, blood pressure, blood sugar level or the body temperature. These parameters can then be relayed to the memory and control unit, in order to control the administering. This can for example improve the delivery accuracy of the fluid product or detect occlusions or leaks within a conduit system for the fluid product.

Up until now, however, variable parameters of the fluid product have not been considered when controlling such administering devices. The delivery accuracy is for example affected by temperature fluctuations to which the administering device and therefore the fluid product are subjected. The fluid product can exhibit different forms of state depending on temperature. A solvent in which an active substance is dissolved can for example exhibit a greater volume at higher temperatures, such that the concentration of the active substance in the solution changes. Furthermore, the active substance itself can change its properties in accordance with a particular temperature. A change in the fluid product with temperature also changes the amount of the active substance which is dispensed when a set product dosage is administered. In this way, a patient can be given too much or too little active substance.

Measurements have for example shown that for insulin in a container of for example 300 units, temperature fluctuations with temperature differences of 15°C can result in an inaccuracy of ± 1 unit. Such a temperature fluctuation can for example occur when going to bed or spending a short time in the sun. Many diabetics have an average insulin delivery rate of for example 0.5 units per hour. A temperature-dependent inaccuracy in the administered dosage amount can therefore easily result in the insulin being incorrectly dosed and the patient therefore being incorrectly treated.

It is therefore an object of the present invention to provide a device for administering a fluid product and a method for controlling the administering of the fluid product, wherein the dosage setting and dispensing accuracy of a product dosage are improved, wherein temperature fluctuations are taken into account and it is ensured that the administering device functions reliably.

The object is solved by a device for administering a fluid product as set forth in claim 1 and by a method for controlling the administering of a fluid product as set forth in claim 7. Advantageous embodiments of the device and the method follow from the sub-claims.

Accordingly, a device for administering a fluid product, for instance a liquid active solution, comprises a container for the fluid product, a dispensing means for administering the fluid product from the container and a dosing means for setting a product dosage. The product container can for example be provided by a conventional ampoule, or the fluid product can be poured into a chamber of the administering device which serves as the container. As described above, the container comprises an outlet for dispensing the product from the container and a stopper which can be moved in the advancing direction by the dispensing means. The dosing means preferably comprises a rotational mechanism in which, in order to set a product dosage by setting a particular rotational position of a rotational member, the advancing path of the stopper within the container is limited. A drainage conduit for dispensing the fluid product is connected to the container outlet. For this purpose, a flexible tube can for example be provided and a cannula which is arranged on a surface of a body tissue of the patient and leads into said tissue.

In accordance with the invention, the administering device comprises at least one temperature sensor which measures the temperature of the fluid product in the container and/or the temperature in the vicinity of the fluid product and/or the container. For this purpose, the at least one temperature sensor is preferably arranged on or in the container. A number of temperature sensors can also be provided, which are provided at different locations on or in the container and/or the administering device, in order for example to enable the temperature to be measured accurately by comparing temperatures.

In order to control the administering of the fluid product from the administering device described above, the administering device comprises for example a control unit comprising a memory and a battery and using which a dosage amount of a product which is to be dispensed during administering can be set with the aid of a dosing means. In accordance with the invention, the dosage amount is set in accordance with the temperature of the fluid product and/or in accordance with the temperature of the environment near the container or near the administering device. For an administering control method in accordance with the invention, a temperature value measured by a temperature sensor can for example be outputted to the control unit, whereupon the control unit determines the setting of the dosage amount by means of the dosing means and correspondingly controls the dosing means and/or corrects the setting.

Determining the temperature of the fluid product or the temperature in the vicinity of the fluid product and taking into account this temperature when setting the dosage can significantly improve the dispensing accuracy of an active substance to a patient. Under- or overdosing can be prevented. This enables the success of a therapy or the wellbeing of a patient to be significantly increased.

One preferred embodiment of the present invention is formed by an administering device in the form of a portable insulin pump in which at least one temperature sensor is arranged within a chamber in the insulin pump into which an ampoule can be inserted which is filled with the fluid product. Advantageously, the temperature sensor is directly adjacent to the ampoule. It would also be possible to form the chamber such that the fluid product can be poured directly into the chamber; in this case, the temperature sensor comes into direct contact with the fluid product. Another temperature sensor can be arranged on the outside of the administering device, e.g. on a device casing. Conventional sensors, which are available cost-effectively as mass-produced products, can be used as temperature sensors.

The administering device in accordance with the invention preferably comprises an alarm means which outputs an alarm signal when a predetermined temperature and/or predetermined temperature difference with respect to a settable reference temperature is exceeded. The alarm signal can for example be provided by an acoustic, visual and/or vibration signal. If a temperature signal is transmitted from the temperature sensor to the control unit which exceeds a

predetermined temperature and/or predetermined temperature difference, the dosing means can be automatically controlled to adjust a product dosage, or the user can decide on the basis of the alarm signal whether he wishes to change the dosage or not.

In a particularly preferred embodiment, the administering device comprises a monitoring means for monitoring an occlusion or a leak within the device, which comprises sensors within the administering device, for monitoring. Such occlusions and/or leak sensors are based on measuring a force or pressure acting on the fluid product or the dispensing means, and/or measuring the force necessary from the dispensing means for administering. The readings from the sensors are transmitted to the control unit which, when a limit value of the readings is exceeded, interrupts or prevents the fluid product from being administered by the administering device, and/or outputs an alarm signal. The readings from such sensors are, however, dependent on the temperature of the fluid product, i.e. the force to be expended for administering or the pressure prevalent in the container fluctuate with temperature. In accordance with the invention, the limit values used by the monitoring means for monitoring an occlusion or a leak are set or corrected in accordance with the temperature of the fluid product and/or in accordance with the temperature of the environment near the product container.

In the administering control method in accordance with the invention, the dosage amount of a product dosage is preferably set in accordance with a temperature difference with respect to a reference temperature. Room temperature or the temperature which is prevalent on a patient's body at the location at which an administering apparatus is worn can for example be used as the reference temperature. In the event of a particular deviation from this reference value, i.e. when a particular temperature difference is exceeded, a product dosage setting which is correct for the reference temperature can then be adjusted and/or corrected in accordance with the level of the temperature difference, in order while administering to dispense the product amount required for a successful treatment of the patient. Accordingly, the predetermined dosage amount is changed such that the desired amount is also actually dispensed. When a temperature difference is exceeded, an alarm signal can be outputted by the alarm means, such that the user can independently perform or trigger a correction. However, the dosage is advantageously corrected automatically by the control unit. The dosage setting and the correction can then be indicated on

a display. The correction, however, need not necessarily be displayed, since due to the correction, the desired dosage amount indicated on the display is maintained.

Particularly preferably, the dosage amount is corrected when the temperature difference is exceeded within a predetermined period of time. In the case of merely brief fluctuations in temperature, when the pre-set temperature difference and/or reference temperature is therefore only briefly exceeded, it may be that a correction is not necessary. For example, the state of the fluid product within the container only changes once an increased or reduced temperature acts on the product over a certain period of time. It is therefore useful to take into account the change in temperature over time when controlling the administering of product.

The idea of the invention has been illustrated by way of an administering device having an open system, i.e. a fluid is dispensed from the device. In principle, however, it is also conceivable to employ the features of the present invention in a closed system, for example in a measuring method having a closed fluid cycle, in which a measuring liquid is used as the fluid.

The invention is explained by way of an example embodiment by the drawing comprising a schematic representation of an administering device.

A device for administering a fluid product, such as is shown in the drawing, comprises a container 1 for the fluid product and a dispensing means 2 for administering the fluid product from the container 1. The container 1 is formed such that it can accommodate an ampoule containing the fluid product. For this purpose, a stopper 3 is arranged in the container 1 and is advanced towards an outlet 5 of the container 1 by a driven member 4 of the dispensing means 2. The administering device further comprises a dosing means 6 for setting a dosage amount of a product dosage of the fluid product. A temperature sensor 7 is arranged on an inner wall of the container 1 and comes to rest next to the ampoule when the ampoule is introduced. The administering device further comprises a monitoring means 8 comprising an occlusion and leak sensor for monitoring an occlusion and/or leak within the administering device.

The temperature sensor 7, the occlusion and leak sensor, the dosing means 6 and the dispensing means 2 are connected to a control unit 9. The control unit 9 comprises at least one memory, for

example for storing particular administering or patient parameters. The temperature value measured by the temperature sensor 7 in the container 1, i.e. near the fluid product, is outputted to the control unit 9. In accordance with the temperature measured by the sensor 7, the control unit 9 corrects a dosage setting on the dosing means 6 and/or the administering of the fluid product by the dispensing means 2. That is to say, the advancing path travelled by the stopper 3 for administering is changed in accordance with the measured temperature. Furthermore, the limit values of the monitoring means 8, used to monitor an occlusion or leak, are adjusted in accordance with the temperature measured by the temperature sensor 7.

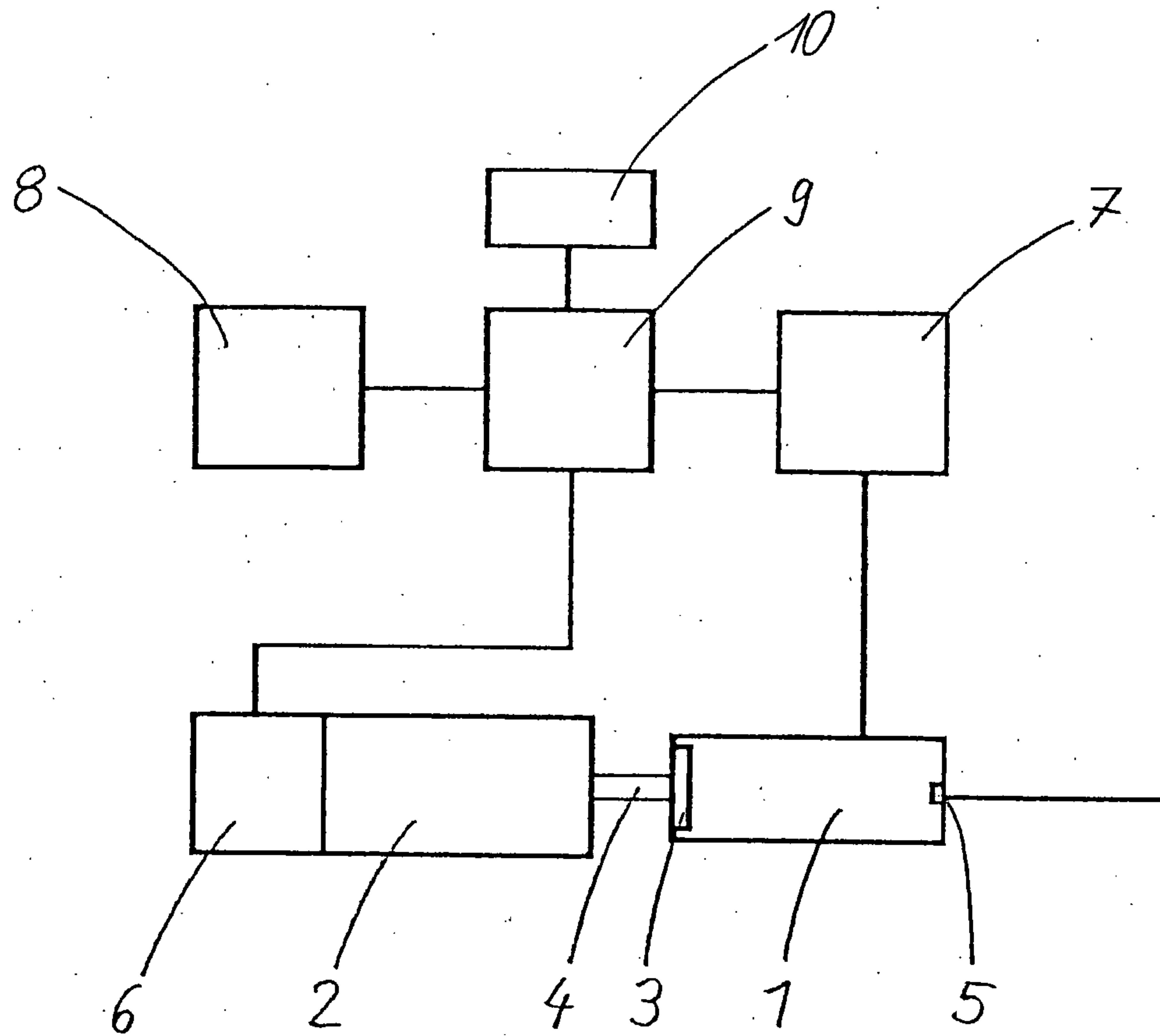
A display 10 serves to display various parameters of the administering device, such as a dosage setting, and can indicate a visual warning signal when a temperature difference measured by the temperature sensor 7 is exceeded. When a warning is indicated, the user can correct a dosage via operating buttons.

Administering Device with Temperature Sensor

Patent claims

1. A device for administering a fluid product, comprising:
 - a) a container (1) for the fluid product;
 - b) a dispensing means (2) for administering the fluid product from the container 1; and
 - c) a dosing means (6) for setting a product dosage;characterised by
 - d) at least one temperature sensor (7) for measuring the temperature of the fluid product and/or the temperature in the vicinity of the fluid product.
2. The administering device as set forth in claim 1, wherein the at least one temperature sensor (7) is arranged on or in the container (1).
3. The administering device as set forth in claim 1 or 2, wherein an alarm means is provided which outputs an alarm signal when a temperature difference with respect to a reference temperature is exceeded.
4. The administering device as set forth in the preceding claim, wherein the alarm signal is an acoustic, visual and/or vibration alarm signal.
5. The administering device as set forth in any one of the preceding claims, wherein the dosing means (6) sets the product dosage in accordance with the temperature measured by the temperature sensor (7).

6. The administering device as set forth in any one of the preceding claims, wherein a monitoring means (8) for monitoring an occlusion and/or leak in the administering device can be set in accordance with the temperature measured by the temperature sensor (7).
7. A method for controlling the administering of a fluid product from a container (1) for the fluid product, wherein a dosage amount of a product dosage to be administered is set by a dosing means (6), wherein the dosage amount is set in accordance with the temperature of the fluid product and/or in accordance with the temperature of the environment near the container (1).
8. The method as set forth in claim 7, wherein the dosage amount is set in accordance with a temperature difference with respect to a reference temperature.
9. The method as set forth in claim 7 or 8, wherein a predetermined dosage amount is changed when the temperature difference is exceeded.
10. The method as set forth in any one of claims 7 to 9, wherein the predetermined dosage amount is changed when the temperature difference is exceeded within a predetermined period of time.
11. The method as set forth in any one of claims 7 to 10, wherein the dosage amount is changed automatically.
12. The method as set forth in any one of claims 7 to 11, wherein an alarm is outputted when the temperature difference is exceeded.
13. The method as set forth in any one of claims 7 to 12, wherein a limit value of a monitoring means for monitoring an occlusion and/or leak in an administering device is set in accordance with the temperature of the fluid product and/or in accordance with the temperature of the environment near the container (1).

*Fig. 1*

