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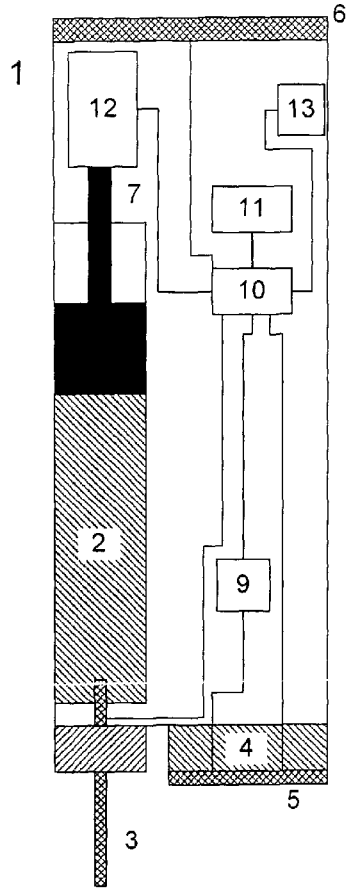
(54) Title: NEEDLE INSERTION SENSOR



(57) Abstract: This invention relates to a doser comprising a syringe (2) with a needle (3) which extends beyond the doser (1), which comprises an engagement face (4) in the vicinity of the needle so that the engagement face rests against the surface of the tissue into which the needle is inserted. Detector means (5) are provided on said engagement face to sample signals on the skin of the patient, said means being arranged for providing heart rate signals. The invention further provides means (13) for receiving information related to health monitoring of a patient. This provides a doser that may record heart rate, EKG, BGM and hypo-alarm administered medicine. The doser may further be arranged to calculate an appropriate dose of medication on the basis of a number of acquired inputs.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Needle insertion sensor

Field of the invention

The present invention relates to a doser comprising a syringe having a needle which extends outside the doser, which comprises an engagement face in the vicinity of the needle so that the engagement face rests against the tissue into which the injection is inserted.

Background of the invention

Injection devices for multiple use having an exchangeable insulin ampoule have been developed, which calculate an optimum dose of medicine for a given patient (WO 00/32088). This calculation can take the patient's health, food habits and recordings of previously administered doses into consideration. For this determination of dose it is necessary to know the patient's received dose precisely to avoid overdosing or underdosing, as this may have fatal consequences for the diabetic.

Object of the invention

The object of the invention is to utilize the known sophisticated electronics fo even better information of the user on the basis of the provision of additional input signals to the electronics, without the user having to do anything else than he/she normally does.

This object is obtained in that measurements of the heart rate are accomplished in that signal processing known per se is used in combination with one or more electrode means for this measurement being provided on said engagement face.

Thereby signals are obtained that are related to heart activity and by expanding the doser with additional electrode means provided on the handle, it is possible to obtain electrocardiograms. Preferably additional electrode means are provided that can be located elsewhere on the body and, either via wires or wireless communication links, they are connected to the doser.

Preferably electrical signals are used, but it is also an option to use optical signals, like eg in connection with BGM measurements (Blood Glucose Measurement).

Typically, the impedance is measured in the tissue touched by the engagement face of the doser or, alternatively, light is used. The signals may be modulated to avoid noise from the surroundings.

An important feature of the invention is the finding that merely by a very simple detection of heart signals, it is possible to considerably improve the applicability. This is due to the fact that the prior art calculating circuits are very sophisticated, ia with self-learning software routines that can either be executed within the doser as such or be executed in a large, external computer connected to the doser via a wire or a wireless communication link. In this manner the doser may have very large signal-processing capacity and therefore the doser can advantageously be provided with means for receiving external signals.

By the provision of extra electrode means at the end opposite that end of the doser which is in contact with the skin of the stomach of the user, it is accomplished that the patient's hand touches the additional electrode means, whereby the measurement will take place through the patient's heart region. It is therefore possible, by simple means, to considerably broaden the applicability. By supplementing with light detection it is also possible to perform a

blood glucose measurement (BGM) in connection with the doser that thus also lends itself for use as hypoglycemia alarm.

A further advantageous use of the invention relates to administering of the dosis which is injected. It is assumed in the calculations that all the medicine discharged from the ampoule is administered to the patient. When replacing the reservoir it is essential to drain the injection doser needle as well as the syringe for any possible air, as this might fill the patient's veins. Consequently, the operator usually performs a first time shot e.g. into a sponge after reservoir replacement to make sure that there is no air left in the needle or eventual in the syringe. This shot will inappropriately be recorded in the doser as an injection shot into the patient, and it will therefore be necessary to observe whether the needle is inserted into biological tissue, e.g. a human body. This drawback is avoided by the doser according to the invention that can very reliably detect whether dosis is administered to biological tissue, since the decision can be taken on the basis of the detection of heart rate.

Brief description of the drawings

The accompanying drawings illustrate the present invention by way of the embodiments in which:

Fig. 1 shows an embodiment of the doser according to the present invention where the engagement face rests against skin.

Fig. 2 illustrates an embodiment of the invention in detail and with sensor means on the injection button.

Fig. 3 shows an embodiment of a sensor with two electrodes according to the present invention.

Fig. 4 illustrates a QRS-pass as seen on a typical electrocardiogram.

Figure 1 shows detector means (5) on the engagement face (4) of a doser that naturally contacts the skin (8) in normal use.

The doser (1) comprises a syringe (2) having a needle (3) that generally extends outside the doser that comprises an engagement face (4) in the vicinity of the needle, so that the engagement face rests against the surface of the tissue (8) into which the needle has been inserted. The engagement face has one or more closely spaced electrodes connected to detector means for measuring electrical pulses.

Figure 3 shows an example of such a sensor (5) with two closely spaced electrodes (5a, 5b).

In an embodiment, the electrical impedance between such two electrodes is measured, and it can hereby be determined whether the doser is in engagement with human tissue. The doser may thus be adapted for specifically recording the amount of administered dose to a tissue type having human characteristics.

According to the invention, the heart rate of the patient can be determined by a continuous recording of the impedance of the skin, which gives a further indication of live tissue not obtained in prior art whereby a more safe decision can be made to determine whether the insulin discharge takes place in a patient.

More importantly, the detector means according to the invention can be used to determine the heart rate itself, even if a person skilled in the art would expect that heart rate signals obtained in a way according to the invention - at

least to a certain extent – would be of too low a quality to make a decision on something as important as the heart rate.

By combining the detector means according to the invention with modern signal shaping routines, e.g. comprising naural network analysis (see WO 02/069798) reliable results can be obtained on the basis of less reliable detector signals whereby the invention is operable even under difficult conditions.

If the patient's skin is wet, the impedance between the electrodes of the engagement face will be measured so low that it is determined by the doser that human-like skin is not involved. In this case it is therefore expedient that the needle can comprise a sensor, e.g. an electrode, thereby allowing a measurement between the sensor of the engagement face (5) and the sensor of the needle. This provides an extra possibility of reliable measurement results.

In a preferred embodiment a sensor is embedded also in the handle of the doser (6). This allows for measurement between it and the sensor of the engagement face (5) and/or the sensor of the needle (3). According to the invention, this makes the heart rate signals useable for obtaining electrocardiogram signals, as will be described below.

Since an injection is typically made in the patient's thigh or pit of the stomach, the current path between the sensors of the doser at the end of the engagement face and the handle of the doser will run through the patient's heart region and one arm, which enables mapping of the heart rate as well as diastole and systole of the patient's ventricles. This possibility allows diagnosis of the patient's circulatory state, that is, if the patient himself operates the doser.

In this embodiment, the doser may moreover be adapted for calculating correlation between a sensor signal originating from the engagement face (5) and the sensor signal of the handle (6) so as to determine whether these pulse rates are consistent. If these two signals do not resemble each other, it will mean that the patient does not operate the apparatus himself, but that the apparatus is operated by another person, e.g. a nurse. The doser can thus determine on the basis of this correlation that it is not possible to create a valid pseudo electrocardiogram (ECG).

The basics of the doser according to the present invention are shown in figure 2. Signal processing/calculation means (10) is connected with memory storage (11) containing e.g. user information, operating system, executable program, etc.

The processing means may include a microprocessor, an application-specific integrated circuit, or another integrated circuit, a smart card, a general purpose computer adapted by suitable software, or the like. The processing means may be designed to acquire information from the internal sensors/electrodes (3, 5 and 6) as well as from an external communication link (13). The communication link (13) may be any transmission line which may comprise wire and wire-less communication links.

Additionally, the processing means may comprise means to control the generation of control signals to a pump (12), e.g. a DC-driven motor, etc., which may enable an injection by way of moving a piston rod (7) in the syringe (2). Further, a signal device (9) may be present to generate measurement impulses, e.g. a light emitter generator etc.

Creation of a standard ECG signal requires measurement on three points on the patient's body. Even though the number of acceptable sensor points in this embodiment will be three (handle, needle, and engagement face), this

method will not always be sufficient to obtain a complete electrocardiogram. Since the needle and engagement face sensor points are spaced closely together, the measurement signal processing requires an unacceptable high signal/noise ratio. To overcome this, it is therefore desirable to ensure that at least one external sensor for this purpose can be connected to the doser. In this embodiment, it will thus be possible to generate a true balanced measuring signal. This connection may be carried out by a physical wire and/or radio communication. To screen noise from the surroundings, it is necessary strongly to filter the resulting signal of especially the 50/60 HZ power supply frequency. The signal may then be chased for a possible useful ECG signal where a QRS course is desired.

In this case, the doser is adapted to recognize the shape of the QRS course of a human heart. To achieve a better noise/signal ratio, the measuring signal may be modulated in frequency to a range, which is discordant relative to the frequency of the power supply, that is, at a frequency which is not a whole numbered multiple of the power supply frequency.

If freedom of movement is desired, this sensor may consist of a wireless electrode having a plurality of electrodes (US 6 073 046) adhered to the patient's chest. By implementation of ECG monitoring by means of the doser, this can completely replace a commonly used ECG apparatus.

It is also to be understood that the communication link 13 can be used to transmit information about the heart rate signals measured to a separate computer. Especially when a neural network is used to enhance the quality of the signal as disclosed in WO 02/069798, it may be expedient to use an external computer with large processing power instead of building in an internal computer having limited processing power.

It is moreover possible to replace the electrodes by an emitter/detector or receiver/transducer so as to enable emission and reception of optical signals and ultrasonic signals, respectively.

The use of optical signals provides a new possibility for the field of use of the doser for measuring physiological parameters. For an effective treatment of diabetes, it is necessary to know the patient's content of glucose in the blood (called BGM below), since this quantity influences the determination of the insulin dose amount. Currently, much research is focused on intravenous measuring methods which can determine the BGM by means of optics (US 6 043 492) or by means of electrochemical sensors (US 5 954 685). These sensors measure on the patient's skin and therefore eliminate the need for invasion.

The use of such sensors in the doser allows these methods to be employed for carrying out glucometry during injection, without the patient noticing this or performing any other actions. When commencing an injection, the doser may record the BGM with a view to determining the insulin amount and/or recommending an optimum diet for the patient, as described in WO 00/32088.

Some times, however, the patient wants to check the glucose state before he/she decides on insulin injection. If the patient exclusively wants to know the BGM and therefore does not want to insert the needle into the body, it will be desirable that the doser is adapted to accommodate the entire needle so that the needle may be pushed/pulled into the doser, whereby the needle will be hidden at times when it is not needed. As long as the needle does not extend outside the doser, a measurement may be performed simply by keeping the doser with the engagement face against the skin. This simple measuring method will motivate the patient to check the BGM to a greater extent, which can contribute to a better controlled treatment and therefore fewer sufferings because of diabetes over a span of years.

In summary, when detector means are provided on a doser for detecting of heart rate, a lot of new features can be obtained. Obtaining partly or full-scale EKG signals and the option of BGM measurements have been described. It will be understood that these features could also be made use of for making a hand-held hypo-alarm.

Patent Claims

1. A doser comprising a syringe with a needle, which extends beyond the doser, which comprises, in the vicinity of the needle, an engagement face for engaging a surface of a tissue into which the needle is to be inserted, characterized in that detector means capable of detecting heart rate are provided on said engagement face.

2. A doser according to claim 1, characterized in that the doser comprises additional electrode means capable of detecting heart rate.

3. A doser according to claim 2, characterized in that the additional electrode means are provided on the handle of the doser.

4. A doser according to claim 1-3, characterized in that the needle comprises electrode means.

5. A doser according to claims 1-4, characterized in that the electrode means are sensitive to electrical signals.

6. A doser according to claims 1-4, characterized in that the electrode means are sensitive to optical signals.

7. A doser according to claim 5, characterized in that the doser comprises electrical circuits for generating and for receiving electrical signals for measuring the impedance between electrodes.

8. A doser according to claim 6, characterized in that the doser comprises an emitter for generating and emitting light and detector means for detecting light.

9. A doser according to claims 7-8, characterized in that the signals are modulated.

10. A doser according to claims 7-8, characterized in that the doser contains a calculating circuit and a storage circuit adapted to process and store the value of said signals.

11. A doser according to claims 1-10, characterized in that the doser has means for receiving external signals, and that the circuit in the doser is adapted to combine the external signals with signals from said detector means.

12. A doser according to claims 1-11, characterized in that the doser contains means for wireless communication.

13. A doser according to claims 1-12, characterized in that the detector means comprise a neural network program for signal processing.

14. A doser according to claim 13, characterized in that the neural network program is executed on an external computer connected to the doser via a wireless communication link.

15. A doser according to claim 1 or 14, characterized in that said electrode means comprise a pair of mutually closely spaced electrodes.

16. A doser according to claims 9-13, characterized in that the doser is adapted to estimate electrocardiogram signals.

17. A doser according to claims 9-13, characterized in that the circuit is adapted to recognize specific signal shapes.

18. A doser according to claims 9-13, characterized in that the circuit is adapted to determine pulse rates.

19. A doser according to claim 5, characterized in that the circuit is adapted to calculate the blood glucose level.

20. A doser according to claim 19, characterized in that the circuit is adapted to calculate doses in dependence on the calculated blood glucose level.

21. A doser according to claim 20, characterized in that the circuit is adapted to control the generation of control signals to a pump in the doser.

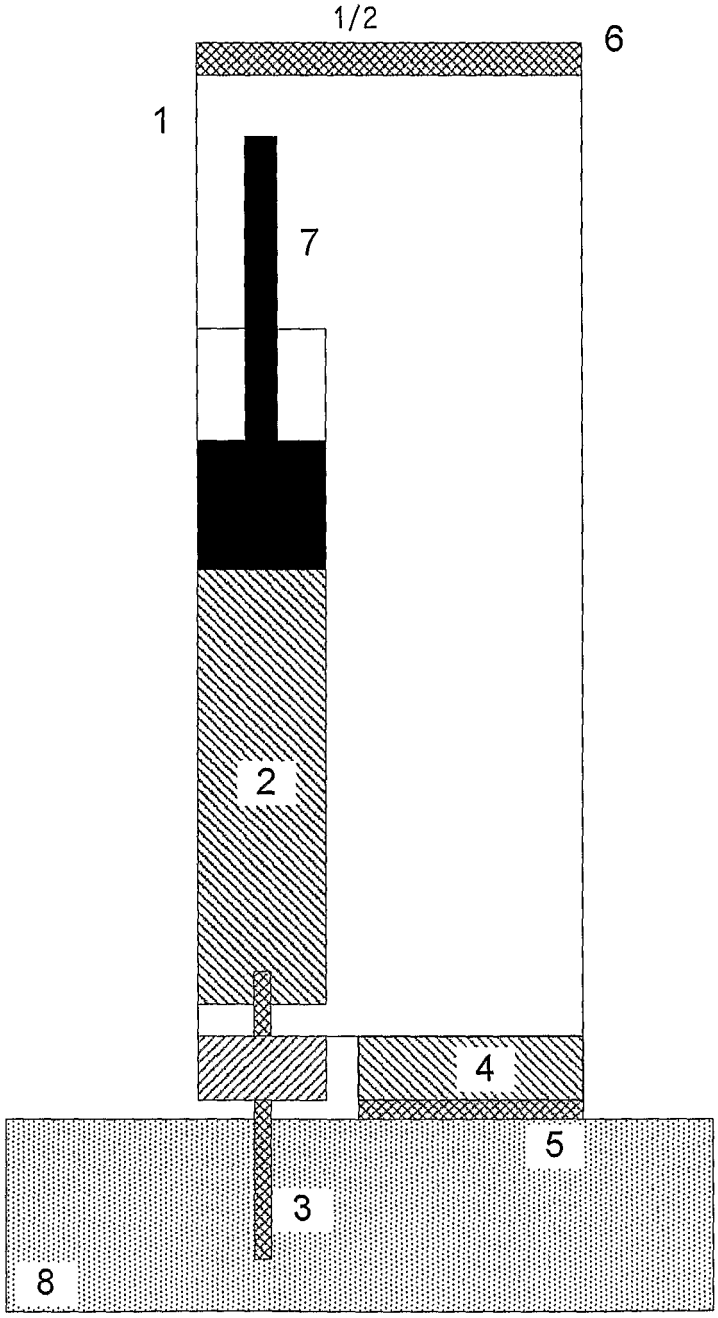

Fig. 1

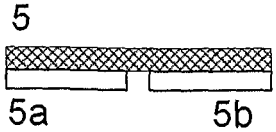

Fig. 3

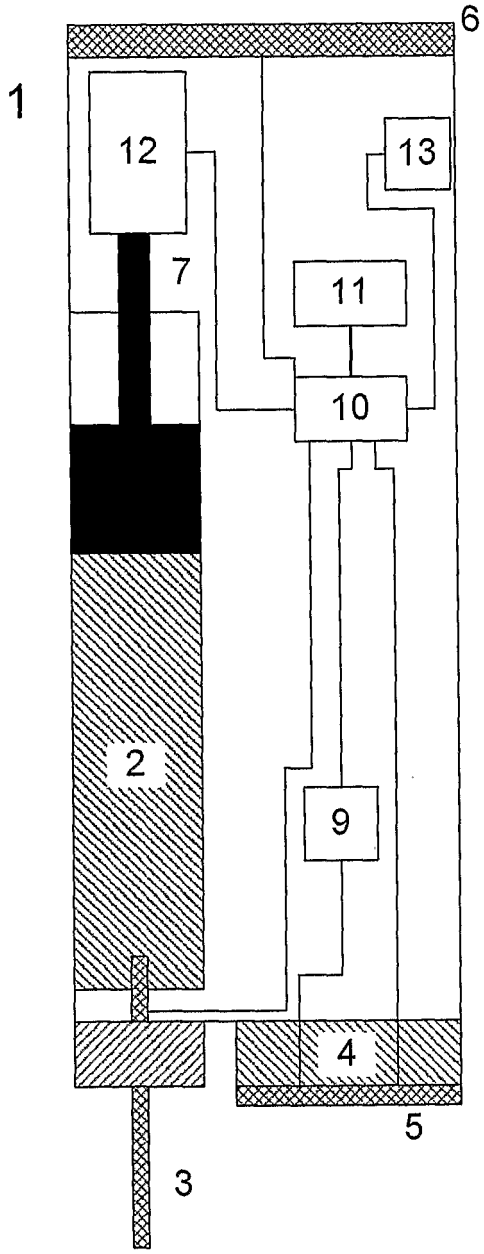

Fig. 2

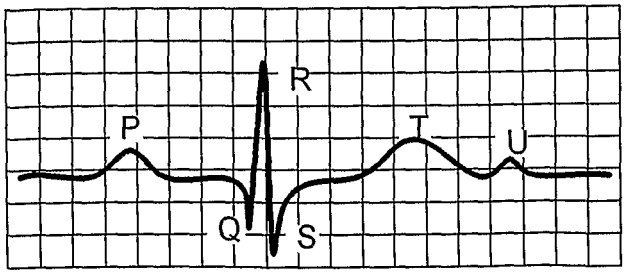

Fig. 4

INTERNATIONAL SEARCH REPORT

PCT/DK 03/00275

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, INSPEC, MEDLINE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2002/002326 A1 (HENKE JAMES L ET AL) 3 January 2002 (2002-01-03) paragraph [0121] abstract ---	1-21
A	GB 2 309 644 A (WAGNER WOLFGANG) 6 August 1997 (1997-08-06) page 32, line 24 - line 36 page 67, line 15 -page 68, line 11 abstract ---	1-21
A	US 5 971 963 A (CHOI SOO BONG) 26 October 1999 (1999-10-26) column 7, line 62 -column 8, line 23 abstract --- -/--	4-6, 19-21

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 July 2003	25 07 2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	SOFIE CARLSSON/JA A

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 741 211 A (VAN LEEUWEN FRANK ET AL) 21 April 1998 (1998-04-21) column 3, line 41 - line 49 abstract ---	1-21
A	US 4 871 351 A (FEINGOLD VLADIMIR) 3 October 1989 (1989-10-03) column 2, line 34 - line 43 abstract -----	1-21

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PCT/DK 03/00275

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专利名称(译)	针插入传感器		
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申请号	EP2003717172	申请日	2003-04-29
[标]申请(专利权)人(译)	诺沃挪第克公司		
申请(专利权)人(译)	诺和诺德公司A / S		
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IPC分类号	A61B5/0245 A61B5/00 A61B5/0402 A61B5/0428 A61B5/05 A61M1/36 A61M5/00 A61M5/145 A61M5/20		
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优先权	200200650 2002-04-30 DK		
其他公开文献	EP1501405B1		
外部链接	Espacenet		

摘要(译)

本发明涉及一种包括注射器（2）的注射器，该注射器具有延伸超过配量器（1）的针（3），该针（3）包括在针附近的接合面（4），使得接合面靠在表面上针插入的组织的一部分。检测器装置（5）设置在所述接合面上以对患者皮肤上的信号进行采样，所述装置被设置用于提供心率信号。本发明还提供了用于接收与患者的健康监测有关的信息的装置（13）。这提供了可记录心率，EKG，BGM和低报警药物的加料器。定量给料器还可以被布置成基于所获取的输入的数量来计算适当的药物剂量。