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(54) **APPARATUS FOR REGULATING THE CONCENTRATION OF GLUCOSE IN THE BLOOD OF A PERSON**

(57) The invention relates to an apparatus for regulating the concentration of glucose in the blood of a person, said apparatus comprising:

- at least one glucose sensor that is arranged to measure the glucose concentration of the person, for example in the interstitial fluid or blood;
- a pump means for selectively introducing at least one substance influencing the blood glucose levels into the body of the person, for instance by means of at least one cannula or catheter to be inserted into the body of said person, and

- a control means for controlling said at least one substance influencing the blood glucose levels to be introduced to the person based on data received from said glucose sensor, wherein said apparatus comprises at least one further sensor that is arranged to monitor a further characteristic of the person.

The at least one further sensor may comprise an accelerometer, a heart rate sensor, a temperature sensor, a pH sensor, a ketone sensor, a GPS receiver and/or a skin resistance sensor.

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Description

[0001] The invention relates to an apparatus for regulating the concentration of glucose in the blood of a person. In particular the invention relates to such an apparatus, comprising:

- at least one glucose sensor that is arranged to measure the glucose concentration of the person, for example in the interstitial fluid or blood;
- a pump means for selectively introducing at least one substance influencing the blood glucose levels into the body of the person, for instance by means of at least one cannula or catheter to be inserted into the body of said person, and
- a control means for controlling said at least one substance influencing the blood glucose levels to be introduced to the person based on data received from said glucose sensor.

[0002] Such an apparatus is known per se. For example, such an apparatus is known from the international patent application WO2007/049961.

[0003] It is an object of the invention to improve apparatus disclosed in WO2007/049961.

[0004] This object is achieved by providing an apparatus of the type described in the preamble that is characterized by at least one further sensor that is arranged to monitor a further characteristic of the person.

[0005] Monitoring said further characteristic of the person can be used for more accurately determining a type and/or an amount of the substance that influences blood glucose levels to be provided to the person. Additionally or alternatively, the further characteristic can be used to adapt the behaviour and/or settings of the apparatus.

[0006] Said substance that may influence the blood glucose level may be any suitable substance. Said substance may influence the blood glucose level either directly or indirectly. Said substance may for example be insulin, glucagon or another hormone, or glucose.

[0007] Said further sensor may be any type of sensor. In particular said further sensor may be any sensor providing data that is indicative for the responsiveness of the person to said at least one substance influencing the blood glucose levels and may therefore require an adaption of the amount of substance influencing blood glucose levels to be provided to that person. The amount of substance influencing blood glucose levels to be provided to that person may be calculated using an algorithm taking into account both the glucose concentration of the person as measured by the glucose sensor and the data that is indicative for the responsiveness of the person to said at least one substance influencing blood glucose levels as measured by said at least one further sensor.

[0008] For example, the physical or mental activity of the person may influence the responsiveness of the person to said at least one substance influencing blood glucose levels and may therefore require an adaption of the

amount of this substance to be provided to that person. The amount of blood glucose level influencing substance to be provided to that person may be calculated using an algorithm taking into account both the glucose concentration of the person as measured by the glucose sensor and the physical and/or mental activity as measured directly or indirectly by said further sensor.

[0009] Said further sensor may therefore in particular be a sensor for measuring data indicative for the physical and/or mental activity of the person.

[0010] In an embodiment of the apparatus according to the invention said control means for controlling said at least one substance influencing the blood glucose levels to be introduced to the person may also be based on data received from said at least one further sensor.

[0011] In another embodiment of the apparatus according to the invention said at least one further sensor is an accelerometer.

[0012] With use of such an accelerometer various data about the person may be provided. The accelerometer may for example provide data on the type of physical activity of the person and/or the intensity thereof and/or the position and/or orientation of the body.

[0013] In another embodiment of the apparatus according to the invention said at least one further sensor is a heart rate sensor arranged to measure the heart rate of the person.

[0014] If a person is physically or mentally active the heart rate of the person may be relatively high, and vice versa. As such, the heart rate of the person may be indicative for the mental and/or physical activity of the person, such that the behaviour of the apparatus for regulating the glucose concentration in the body of a person may be adapted thereto.

[0015] In another embodiment of the apparatus according to the invention said at least one further sensor is a temperature sensor arranged to measure the body temperature of the person.

[0016] If a person is physically or mentally active and starts sweating, the body temperature of the person may decrease, or vice versa. As such, the body temperature may be indicative for the mental and/or physical activity of the person, such that the behaviour of the apparatus for regulating the glucose concentration in the body of a person may be adapted thereto.

[0017] In yet another embodiment, the at least one further sensor may comprise a pH sensor arranged to measure the acidity of the blood of the person. A lack of insulin may lead to acidification of the body, which may be detected by measuring the pH of the blood.

[0018] In another embodiment of the apparatus the at least one further sensor may comprise a ketone sensor which is arranged to detect ketone bodies in the body of the person. Such ketone bodies are formed when there is a lack of insulin, so that the amount of ketone bodies may serve as an indication e.g. that the person is not responding to an insulin injection.

[0019] It is also conceivable that the at least one further

sensor comprises a GPS receiver arranged to detect the location of the person. Although such a GPS receiver can obviously not monitor any bodily characteristic, it does provide information about movement of the person. GPS data allow a determination to be made if the person is exercising, e.g. walking, running or cycling, or if the person is driving around in a car. This information may be useful e.g. in determining a dosage regimen for insulin, glucagon or glucose.

[0020] If the at least one further sensor comprises a skin resistance sensor arranged to measure galvanic resistance of the skin of the person, an indication is provided of the amount of perspiration, since perspiration leads to a change in the galvanic resistance. Perspiration may either be an indication of physical exercise, or an indication of a decrease in the blood glucose level. When the skin resistance sensor is combined with an accelerometer or a GPS receiver, the system can distinguish between perspiration due to physical exercise, which will involve continuous movement or acceleration, and perspiration due to falling blood glucose levels, which may occur even when the person is at rest.

[0021] As indicated above, the output of said at least one further sensor may be used to adapt the behaviour and/or settings of the apparatus for regulating the glucose concentration in the blood of a person. For instance, if the output of the further sensor indicates that the person is asleep, then the volume of an alarm function of the apparatus may be temporarily reduced and/or an alarm may temporarily not be provided and/or a display of the apparatus may be dimmed and/or messages of low priority may not be shown and/or said apparatus may check and if necessary adapt its settings. It is noted that said apparatus may in particular be arranged such that it does not provide the alarm or reduces the volume of the alarm function only when the situation is not critical. Said apparatus may return to its normal settings when said person wakes up.

[0022] For example said accelerometer may be used to determine if said person is asleep, because the orientation of said person may be determined thereby, by means of which lying down may be distinguished from standing still.

[0023] In another embodiment of the apparatus according to the invention said apparatus comprises a second glucose sensor that is arranged to measure the concentration of glucose in the body of the person.

[0024] An advantage of providing two glucose sensors is that the measurements may continue if one fails, i.e. for redundancy. Additionally or alternatively, the measurements of the two glucose sensors may be compared to verify the quality of the measurements, or they may be combined to generate an average value. In any event the second glucose sensor is important for the quality and continuity of the monitoring.

[0025] In another embodiment of the apparatus according to the invention said apparatus comprises at least two further sensors.

[0026] Said at least two further sensors may be any type of sensor, for example any type of sensor as described above and/or in the claims. In particular any of said further sensors may be chosen from the group comprising an accelerometer, a heart rate sensor, a temperature sensor, a pH sensor, a ketone sensor, a skin resistance sensor and a GPS receiver

[0027] Said at least two further sensors may be the same or different sensors.

[0028] Said at least two further sensors may be provided for redundancy or for improving the quality of the measurements of the physical and/or mental activity.

[0029] For example, when two accelerometers are provided, the type of physical activity performed by the person may be more accurately determined. The two further sensors may for example be applied to different parts of the body of the person.

[0030] It is noted that for example cycling is a difficult activity to distinguish from other activities. With use of two accelerometers which measure an acceleration of the body of the person at two different positions thereof, it is possible to determine whether the person is cycling or performing another activity.

[0031] Any of said glucose sensor(s) and/or said further sensor(s) may be arranged such that it may be attached to the body of the person.

[0032] Such a glucose sensor and/or further sensor that is attached to the body of the person may provide more accurate information compared to a sensor that is not attached to said person.

[0033] For example, any of said glucose sensor(s) and/or further sensor(s) may be attached to the skin of the person by using an adhesive such that the glucose and/or further sensor sticks to the skin of the person, for example as a plaster.

[0034] Alternatively, any of said glucose sensor(s) and/or further sensor(s) may be an invasive sensor. In such an embodiment that glucose and/or further sensor may be in contact with the bodily fluid or the blood of a patient.

[0035] Said measurement may be performed either through the skin, subcutaneously, or directly in the blood of the patient.

[0036] Said apparatus may be any type of apparatus for regulating the concentration of glucose in the blood of a person such as, but not limited thereto, an artificial pancreas, a bionic pancreas, a closed loop glucose control system, a low glucose suspend system or a hybrid closed loop control system,

[0037] An advantage of such apparatuses is that they may automatically calculate the required amount of blood glucose influencing substances to be injected to achieve stable blood glucose levels. These substances may be introduced in the body with or without intervention of the user.

[0038] Such apparatuses may make use of an algorithm which incorporates an adjustable curve corresponding to the amount of blood glucose influencing sub-

stances introduced into the body of the person and the nominal concentration of the glucose in the body of the person as a reaction thereto. The data provided by said (second) further sensor may be used in this algorithm or adjustable curve.

[0039] In particular the apparatus may be the apparatus described WO2007/049961 which is incorporated herein in its entirety by reference.

[0040] In another embodiment of the apparatus according to the invention the pump means comprise two pumps, one for introducing substances to increase the blood glucose levels of the person and one for introducing substances to decrease the blood glucose levels of the person, and an individual cannula or catheter is added to each pump.

[0041] In another embodiment of the apparatus according to the invention the pump means comprise two pumps, one for introducing substances to increase the blood glucose levels of the person and one for introducing substances to decrease the blood glucose levels of the person, and one shared cannula or catheter with two passages is added to the two pumps, wherein one serves for transport of substances to increase the blood glucose levels of the person and one for transport of substances to decrease the blood glucose levels of the person.

[0042] In an embodiment of the apparatus according to the invention any of the (shared) cannula(s) or catheter(s) comprise(s) said glucose sensor(s) and/or said at least one further sensor(s). For example, said glucose sensor(s) and/or said further sensor(s) may be carried by, or may be part of any of said (shared) cannula(s) or catheter(s).

[0043] The invention will be further elucidated with reference to a figure shown in a drawing in which:

Figure 1 schematically shows a person carrying an apparatus according to the invention;

Figure 2 is a cross section through a sensor device of the system of figure 1;

Fig. 3 is a schematic representation of the glucose concentration regulating apparatus of the invention; and

Fig. 4 is a flow chart showing how sensor outputs are used to control a supply of a blood glucose influencing substance to a person.

[0044] Figure 1 schematically shows a person 1 carrying an apparatus 2 for regulating the concentration of glucose in the blood of the person. In the illustrated embodiment the apparatus 2 comprises a system 9 of multiple sensor devices 3A, 3B, although the apparatus 2 could also comprise only a single sensor device 3. Each sensor device 3A, 3B is connected to a controller 10, which in turn is connected to a pump means 4, which serves to introduce substances influencing the blood glucose levels into the body of the person under control of the controller 10. The pump means 4 includes at least one pump 11 and at least one cannula or catheter 5 con-

nected to the pump 11. In the illustrated embodiment the apparatus 2 comprises two pumps 11A, 11B, each connected to a respective cannula or catheter 5A, 5B.

[0045] Each of said sensor devices 3 comprises a glucose sensor 6 that is arranged to measure the concentration of glucose in the body of the person 1 and at least one further sensor 7 that is arranged to monitor a further characteristic of the person.

[0046] The further characteristic may be a bodily characteristic, for example the person's heart rate or the person's body temperature. Further bodily characteristics include the acidity of the person's blood, the presence of ketone bodies or the galvanic resistance of the person's skin. Accordingly, the further sensor 7 may be a heart rate sensor, a temperature sensor, a pH sensor, a ketone sensor or a skin resistance sensor, respectively.

[0047] Other characteristics, which are not related to the person's body, include the person's position, the speed with which the person moves or the person's acceleration. For monitoring or measuring these characteristics the further sensor 7 may be a GPS receiver or an accelerometer, respectively. The acceleration that is measured may be the acceleration of the person 1, which may be derived from the person's speed, which in turn may be derived from the person's position. However, the acceleration may also be an acceleration of a body part, which may be indicative of a particular type of physical activity, e.g. running or cycling. In that case typically an accelerometer is attached to the relevant body part.

[0048] In case of a sensor system 9 including multiple sensor devices 3A, 3B, the further sensors 7A, 7B may be different sensors, so that a greater number of characteristics can be monitored simultaneously.

[0049] As is shown in figure 2, part of the apparatus 2 may be invasive and extend through the skin of the person 1. The invasive part of the apparatus may be the cannula or catheter 5 which serves for introducing blood glucose influencing substances into the body of the person 1. The cannula or catheter 5 may also serve for measuring the glucose concentration and/or for monitoring said further characteristic, if the further characteristic is a bodily characteristic. The two pumps 11A, 11B of the pump means 4 may serve for introducing different glucose influencing substances. Each cannula or catheter 5 may be one shared cannula or catheter with two passages, wherein both passages serve for different glucose influencing substance transport.

[0050] Instead of being integrated with the cannula or catheter 5 for introducing blood glucose influencing substances into the body of the person 1, the glucose sensors 6 and/or the further sensors 7 may also be separate therefrom. In particular when the further sensor 7 is arranged for monitoring a non-bodily characteristic, its location on the person's body may be spaced apart from the glucose sensor 6 and from the cannula or catheter 5. The glucose sensors 6 and the further sensors 7 are arranged to send output signals to the controller 10 by means of connections 8. These connections 8 may be

wired or wireless communications channels.

[0051] One way in which the apparatus 2 may be used to regulate the blood glucose level of the person is illustrated in Fig. 4. A sample is taken from a measurement by the first glucose sensor 6A (step 100). Then a determination is made if the sample is valid (step 101). This determination involves checking the measurement for noise and plausibility. If the sample cannot be validated, then the program returns to step 100 and a new sample taken by sensor 6A is selected.

[0052] If the measurement is validated, then a sample is taken from a measurement of a second sensor (step 102). In this embodiment the sample is a glucose measurement by the second glucose sensor 6B. Again, a determination is made whether or not the sample is valid.

[0053] If the sample is not validated, then the amount of blood glucose level influencing substance to be administered is calculated only on the basis of the measurement performed by the first glucose sensor (step 108). The calculated amount is then administered (step 115).

[0054] If the sample taken from the second glucose sensor 6B is found to be valid, then a sample is taken from a measurement by a third sensor 7A (step 104). In this embodiment the third sample is taken from a measurement of skin resistance by means of a galvanic resistance sensor 7A.

[0055] Again, a determination is made whether or not the third sample is valid (step 105).

[0056] If the sample is found not to be valid, then the samples from the first and second sensors 6A, 6B are compared (step 109). In case the values of these samples are found to be incompatible, the program returns to step 100 and a new sample from the glucose measurement sensor 6A is taken.

[0057] If, on the other hand, the samples are found to be compatible, then the amount of blood glucose level influencing substance to be administered is calculated on the basis of the measurements performed by the first and second glucose sensors 6A, 6B (step 110). In this embodiment an average value of the two glucose measurements is determined. Subsequently, the calculated amount of blood glucose level influencing substance is administered (step 115).

[0058] If the sample taken from the third sensor 7A is validated, then a sample is taken from a measurement by a fourth sensor 7B (step 106). In this embodiment, the fourth sample is taken from an acceleration measurement by means of an accelerometer 7B.

[0059] Once again, a determination is made whether or not the sample from the fourth sensor 7B is valid (step 107).

[0060] If the fourth sample is found not to be valid, then the samples from the first, second and third sensors 6A, 6B, 7A are compared (step 111). In case the values of these samples are found to be incompatible, the program returns to step 100 and a new sample from the glucose measurement sensor 6A is taken.

[0061] If the samples are found to be compatible, then

the amount of blood glucose level influencing substance to be administered is calculated on the basis of the measurements performed by the first and second glucose sensors 6A, 6B and the skin resistance sensor 7A (step 112).

In this embodiment the values of the two glucose measurements are compared to the galvanic skin resistance. If an increased level of perspiration is measured by the skin resistance sensor 7A while the blood glucose levels measured by the first and second glucose sensors 6A, 6B are low, this may be an indication of a hypoglycemia. This may lead to a higher or lower dose of the blood glucose level influencing substance being administered than would be done at normal level levels of perspiration. Then the calculated amount of blood glucose level influencing substance is administered (step 115).

[0062] In case the fourth sample is validated, then the samples from the first, second, third and fourth sensors 6A, 6B, 7A, 7B are compared (step 113). In case the values of these samples are found to be incompatible, the program returns to step 100 and a new sample from the glucose measurement sensor 6A is taken.

[0063] If the samples are found to be compatible, then the amount of blood glucose level influencing substance to be administered is calculated on the basis of the measurements performed by the first and second glucose sensors 6A, 6B, the skin resistance sensor 7A and the accelerometer 7B (step 114). In this embodiment the values of the two glucose measurements are compared to the galvanic skin resistance and the acceleration. If an increased level of perspiration is measured at low blood glucose levels while the person is physically active, as indicated by the accelerometer 7B, this may lead to a higher or lower dose of the blood glucose level influencing substance being administered than would be done if the person were sweating at low glucose levels and no physical activity. Then the calculated amount of blood glucose level influencing substance is administered (step 115).

[0064] It is noted that the invention is not limited to the shown embodiments but also extends to variants within the scope of the appended claims

Claims

1. Apparatus for regulating the concentration of glucose in the blood of a person, said apparatus comprising:

- at least one glucose sensor that is arranged to measure the glucose concentration of the person, for example in the interstitial fluid or blood;
- a pump means for selectively introducing at least one substance influencing the blood glucose levels into the body of the person, for instance by means of at least one cannula or catheter to be inserted into the body of said person, and
- a control means for controlling said at least one

substance influencing the blood glucose levels to be introduced to the person based on data received from said glucose sensor,

characterized in that said apparatus comprises at least one further sensor that is arranged to monitor a further characteristic of the person. 5

2. Apparatus according to claim 1, wherein said at least one further sensor comprises an accelerometer. 10

3. Apparatus according to claim 1 or 2, wherein said at least one further sensor comprises a heart rate sensor arranged to measure the heart rate of the person. 15

4. Apparatus according to any of the preceding claims, wherein said at least one further sensor comprises a temperature sensor arranged to measure the body temperature of the person. 20

5. Apparatus according to any of the preceding claims, wherein said at least one further sensor comprises a pH sensor arranged to measure the acidity of the blood of the person. 25

6. Apparatus according to any of the preceding claims, wherein said at least one further sensor comprises a ketone sensor arranged to detect ketone bodies in the body of the person. 30

7. Apparatus according to any of the preceding claims, wherein said at least one further sensor comprises a GPS receiver arranged to detect the location of the person. 35

8. Apparatus according to any of the preceding claims, wherein said at least one further sensor comprises a skin resistance sensor arranged to measure galvanic resistance of the skin of the person. 40

9. Apparatus according to any of the preceding claims, wherein any of said at least one glucose sensor(s) and/or said at least one further sensor(s) is/are arranged such that it may be attached to the body of the person, for example as an invasive sensor. 45

10. Apparatus according to claim 9, wherein the or a cannula or catheter comprises any of said at least one glucose sensor(s) and/or said at least one further sensor(s). 50

11. Apparatus according to any of the preceding claims, wherein said apparatus is arranged to determine if said person is asleep or awake. 55

12. Apparatus according to claim 11, wherein, if said apparatus determines that said person is asleep, said apparatus is arranged to:

- temporarily reduce a volume of an alarm function of the apparatus; and/or
- temporarily not provide an alarm;
- temporarily dim a display of the apparatus; and/or
- temporarily not show messages of low priority; and/or
- check and if necessary adapts its settings.

FIG. 1

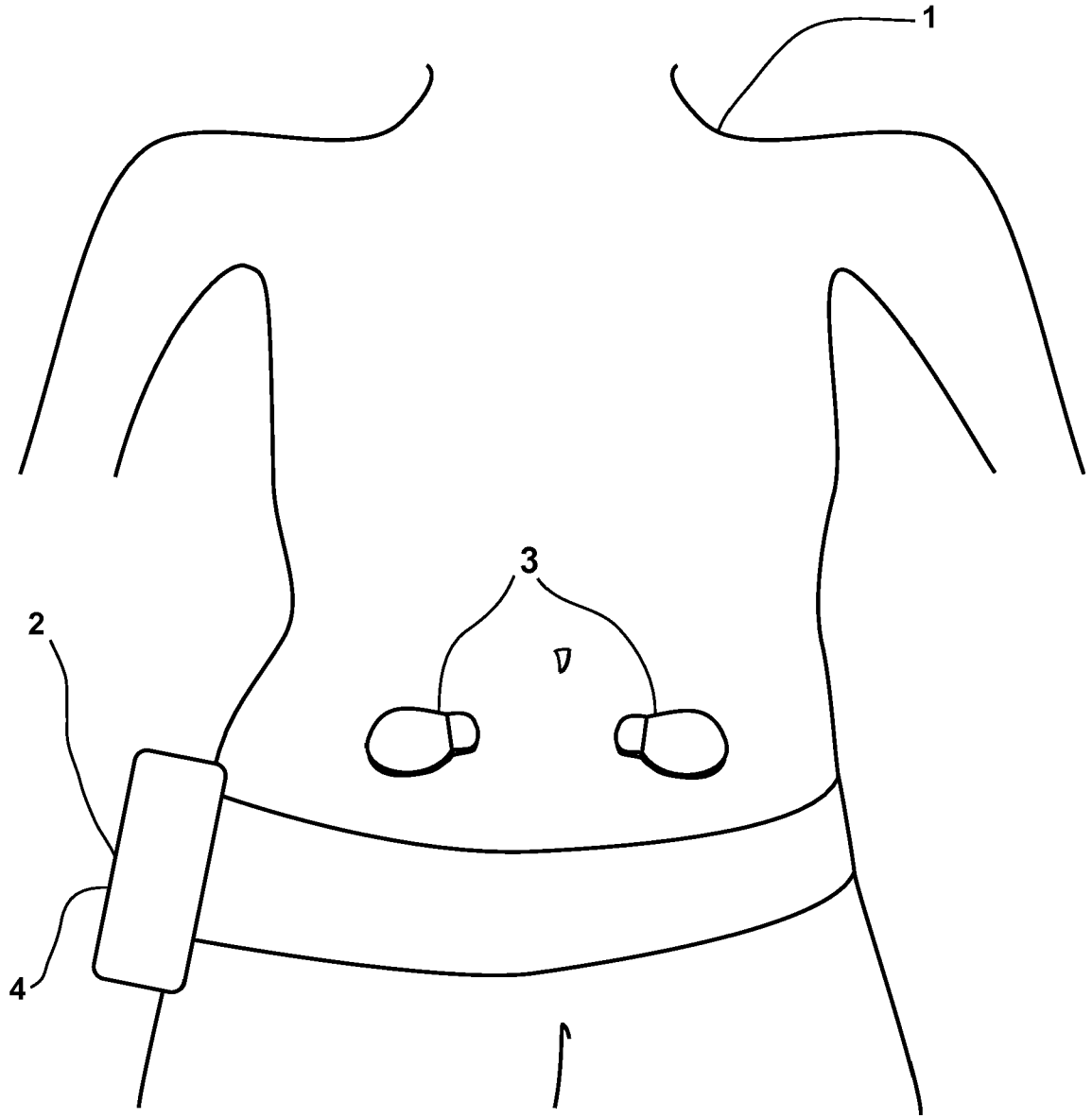


FIG. 2

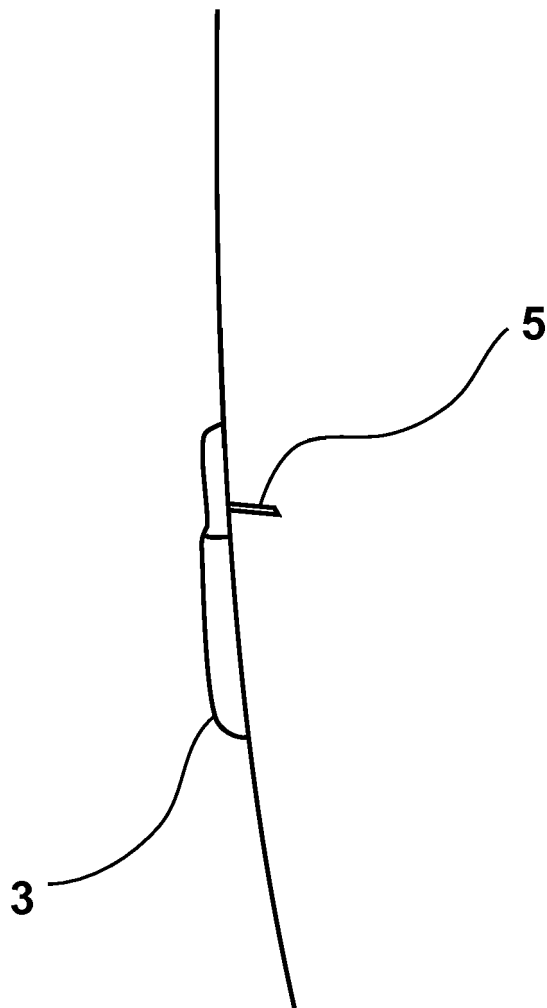


FIG. 3

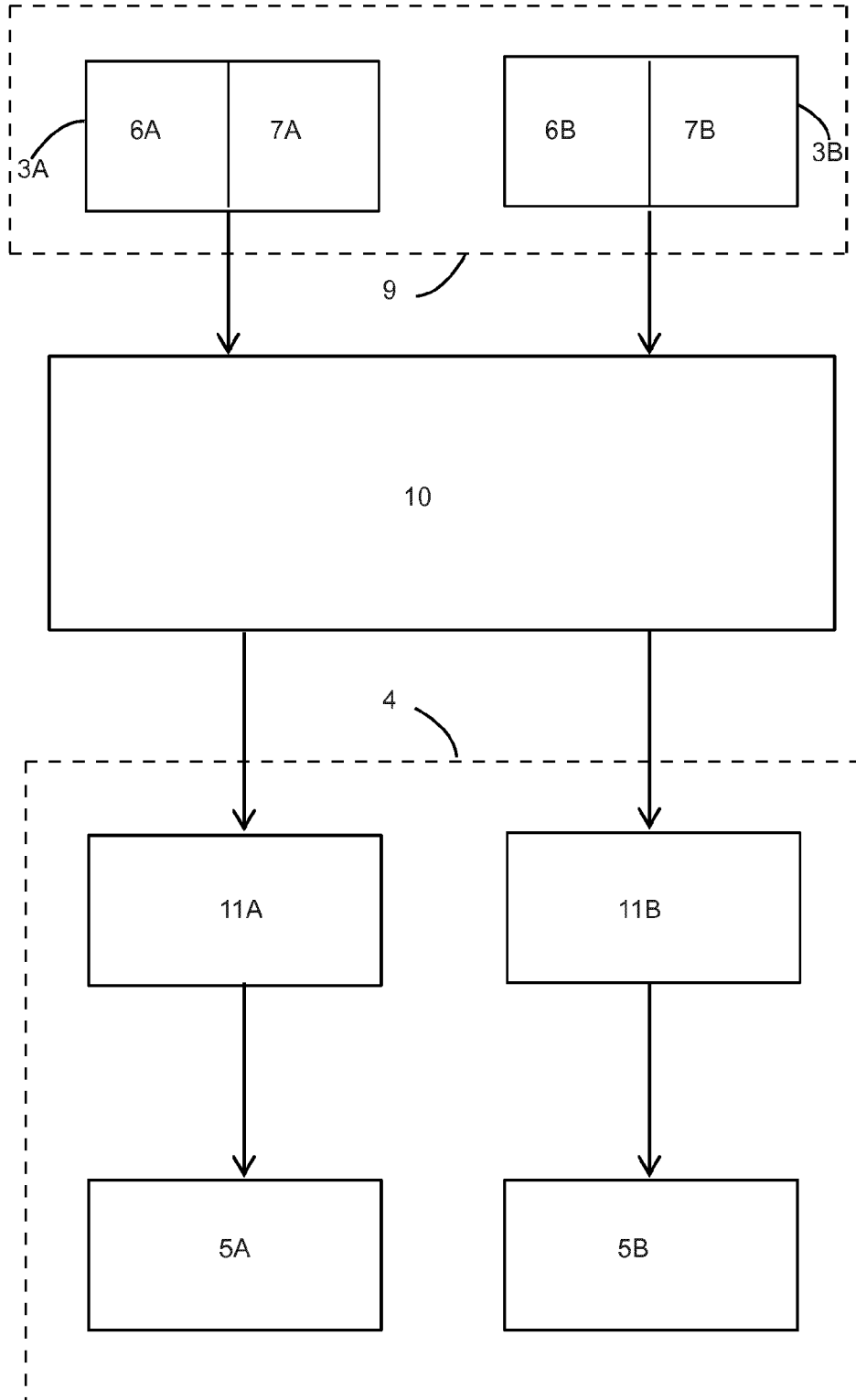
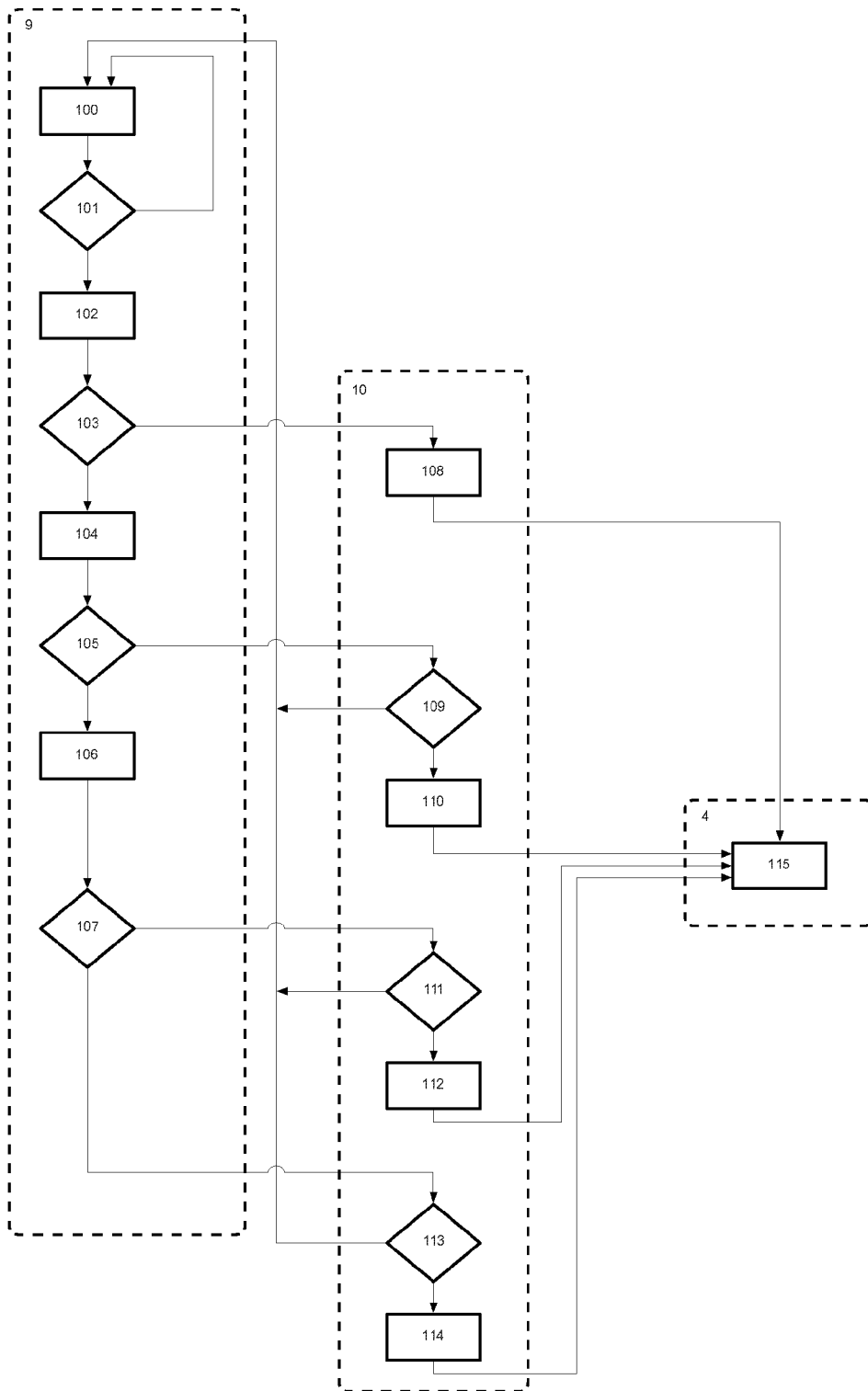


FIG. 4





EUROPEAN SEARCH REPORT

Application Number
EP 16 20 1413

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DOCUMENTS CONSIDERED TO BE RELEVANT			
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X	US 4 403 984 A (ASH STEPHEN R [US] ET AL) 13 September 1983 (1983-09-13) * column 2, line 19 - line 66 * * column 4, line 7 - column 5, line 65 * * column 6, lines 7-20 * * column 9, lines 37-45 *	1,4-6	ADD. A61B5/01 A61B5/02 A61B5/11 A61B5/00
X	WO 2009/081262 A1 (INSULINE MEDICAL LTD [IL]; PESACH BENNY [IL]; BITTON GABRIEL [IL]; NAG) 2 July 2009 (2009-07-02) * paragraphs [0040] - [0045], [0060] - [0064] *	1,2,4, 11,12	
			TECHNICAL FIELDS SEARCHED (IPC)
			A61B A61M
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 30 May 2017	Examiner Kowalczyk, Szczepan
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

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5 This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

30-05-2017

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专利名称(译)	用于调节人体血液中葡萄糖浓度的装置		
公开(公告)号	EP3329847A1	公开(公告)日	2018-06-06
申请号	EP2016201413	申请日	2016-11-30
[标]申请(专利权)人(译)	INREDA糖尿病		
申请(专利权)人(译)	INREDA糖尿病B.V.		
当前申请(专利权)人(译)	INREDA糖尿病B.V.		
[标]发明人	KOOPS ROBIN WESTEN GIJS BENNO		
发明人	KOOPS, ROBIN WESTEN, GIJS BENNO		
IPC分类号	A61B5/145 A61M5/172 A61B5/01 A61B5/02 A61B5/11 A61B5/00		
CPC分类号	A61B5/01 A61B5/02 A61B5/1112 A61B5/14532 A61B5/4809 A61B5/486 A61B2562/0219 A61M5/16836 A61M5/1723 A61M39/0247 A61M2205/3303 A61M2205/3324 A61M2205/3368		
外部链接	Espacenet		

摘要(译)

本发明涉及一种用于调节人体血液中葡萄糖浓度的装置，所述装置包括：- 至少一个葡萄糖传感器，用于测量人体的葡萄糖浓度，例如在间质液或血液中；- 泵装置，用于选择性地至少一种影响血糖水平的物质引入人体内，例如通过插入所述人体内的至少一个套管或导管，和 - 用于基于从所述葡萄糖传感器接收的数据控制所述至少一种影响要引入人体的血糖水平的物质，其中所述设备包括至少一个另外的传感器，其被设置为监测人的另一特征。所述至少一个另外的传感器可包括加速计，心率传感器，温度传感器，pH传感器，酮传感器，GPS接收器和/或皮肤电阻传感器。

