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Claims 16 - 27 are deemed to be abandoned due to non-payment of the claims fees (Rule 45(3) EPC).

(54) PERSONAL HEALTH MONITORING SYSTEM, MULTIPLE USER HEALTH MONITORING SYSTEM, AND METHOD

(57) The present invention relates to a personal health monitoring system comprising an implantable sensor and a monitoring device. The present invention further relates to a multiple user health monitoring system comprising a plurality of such personal health monitoring systems. The present invention further relates to a method of monitoring the biological parameters of at least one user.

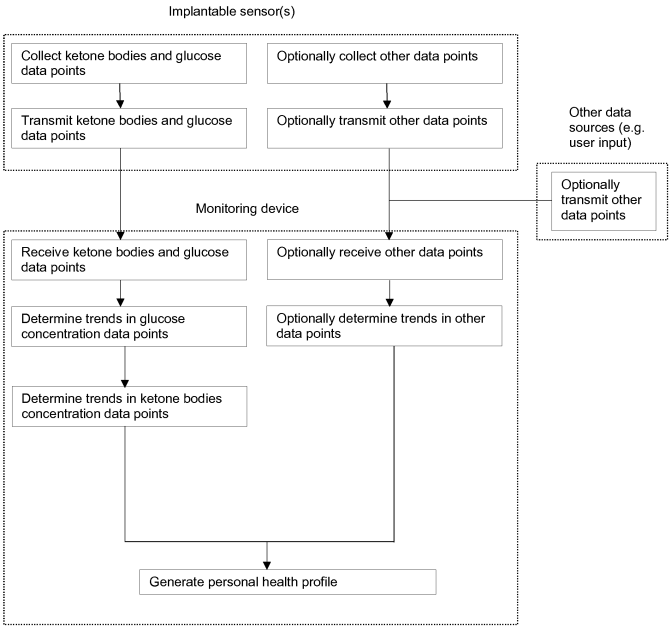

FIGURE 11

EP 3 443 902 A1

Description

Field of the invention

[0001] The present invention relates to a personal health monitoring system comprising an implantable sensor and a monitoring device. The present invention further relates to a multiple user health monitoring system comprising a plurality of such personal health monitoring systems. The present invention further relates to a method of monitoring the biological parameters of at least one user.

Background art

[0002] A personal health monitoring system is for example known from US 8,718,943, which describes a health-monitoring device which assesses the health of a user based on levels of two analytes in a biological fluid. A first analyte that is utilized to assess a user's health is a fat metabolism analyte, such as ketones, free fatty acids and glycerol, which is indicative of fat metabolism. A second analyte that is utilized is a glucose metabolism analyte, such as glucose. The levels of the two analytes are used to assess insulin sensitivity, to detect both recent hypoglycemia and the cause of high glucose levels, and/or to guide therapeutic intervention. The dual analyte model calculates a discrepancy between an actual insulin activity level and a theoretical insulin activity level.

[0003] US 2017/0095216 A1 describes a wrist-worn biowatch providing various health monitoring functions such as blood glucose level monitoring, blood pressure detection, pulse monitoring, heart stop detection, oxygen saturation saturation monitoring, and Ketoacidosis detection. The biowatch is actively monitoring the wellness data of its wearer, and adapted to alert the user and medical professionals if such wellness data veers outside normal ranges or acceptable trends.

Summary of the invention

[0004] It is a first aim of the present invention to provide a personal health monitoring system, comprising an implantable sensor and a monitoring device, and capable of generating an improved personal health profile from the collected sensor data.

[0005] It is a second aim of the present invention to provide a multiple user health monitoring system with improved capabilities of monitoring health conditions of user groups.

[0006] It is a third aim of the present invention to provide an efficient method for monitoring biological parameters of at least one user.

[0007] It is a fourth aim of the present invention to provide to the user personalized behavioural, life-style and therapeutic advice and/or interventions, based on the monitoring of those biological parameters.

[0008] These and other aims may be achieved by the subject-matter of the independent claims.

[0009] The invention provides, according to a first aspect, a personal health monitoring system, comprising an implantable sensor and a monitoring device. The implantable sensor comprises sensing means for sensing biological parameters in bodily fluids of a user and a first wireless transceiver for transmitting sensor data containing data points which are provided by said sensing means upon sensing said biological parameters. The sensed biological parameters comprise at least a glucose concentration and a ketone bodies concentration in said bodily fluids, such that said sensor data comprises at least glucose concentration data points and ketone bodies concentration data points. The monitoring device comprises a second wireless transceiver for communicating with said first wireless transceiver to receive said sensor data and processing means for processing said sensor data, wherein said processing means is equipped with an algorithm which is executable on said processing means and which, when executed, is provided for performing the following steps: determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points; and generating a personal health profile of the user.

[0010] The personal health monitoring system according to the invention senses and processes at least glucose and ketone bodies concentrations in bodily fluids.

[0011] The personal health monitoring system according to the invention uses the algorithm to analyse the sensor data. In preferred embodiments according to the invention, the algorithm is provided for detecting trends in sets of data points, and correlating trends of different sets of data points with each other. In this way, trends are detectable which are personal, i.e. specific to the user carrying the implanted sensor. Likewise, correlations between the trends in different biological parameters can be determined in a personal way, such as for example a normal evolution of glucose and ketones concentration for that user during the night or a normal evolution of glucose and ketones concentration for that user after a certain meal or a certain activity, etc. In this way, the personal health monitoring system according to the invention may be capable of "learning" for example which are normal evolutions of the biological parameters of the user and which are not normal and include this information in the personal health profile which it generates for the user. This information can then be further used by the system to for example make predictions, issue warnings, etc. In preferred embodiments according to the invention the algorithm of the monitoring device is provided for performing the following steps: determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points; detecting first user dependent correlations between said first trends and said second trends, and generating a personal health profile of the user based on said first user dependent correlations.

[0012] In embodiments according to the invention, the

personal health monitoring system may be provided for sensing and/or processing at least one of the following additional parameters: heart rate, body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level. It has been found that by taking one or more of these parameters into account, detecting trends and possibly correlations with the trends in other biological parameters, a further improved personal health profile may be achieved.

[0013] In embodiments according to the invention, the monitoring device may comprise a display for displaying the personal health profile. In embodiments, the monitoring device may be a mobile terminal such as a smart phone, tablet, smart watch or other wearable device. In embodiments, the monitoring device may be a dedicated monitoring device which is specifically designed for the purpose of communicating with the implantable sensor and generating the personal health profile. In embodiments the monitoring device may be provided for generating and/or communicating to the user personalized behavioural, life-style and therapeutic suggestions and actions, based on the monitoring of biological parameters. In embodiments, the monitoring device may be provided for generating instructions for a controller of an insulin pump or may form part of an insulin pumping device. In embodiments, the monitoring device may be an ensemble of one or more devices.

[0014] In embodiments according to the invention, the algorithm of the monitoring device may be provided for combining the sensor data with metadata (such as location data, calories intake data, activity data, agenda information and/or user habit information) upon generating the personal health profile. In case a mobile terminal is used as monitoring device, any metadata generated by means of applications running on the mobile terminal itself may be used for this purpose.

[0015] The implantable sensor is capable of continuous monitoring of biological parameters. The term 'continuous' or 'continuously' in relation to the invention should be construed as meaning 'regularly without requiring regular user intervention', the sampling rate can be a fixed number of measurements per time frame or varied by an integrated controller. In embodiments according to the invention, the implantable sensor may comprise an integrated controller which is provided for controlling the sensing means at a variable sampling rate. In embodiments, the integrated controller may be provided for detecting a variability level in said sensor data and adapting said variable sampling rate according to said detected variability level, for example by reducing the sample rate if a low variability level (beneath a certain threshold) is detected. In other embodiments, the sampling rate may also be controlled by the monitoring device. By reducing the sampling rate, for example when it is expected that the sensor data will not vary much over a longer period of time, energy consumption of the sensing means of the implanted sensor can be reduced and battery life can possibly be extended.

[0016] In embodiments according to the invention, the implantable sensor may comprise a rechargeable battery and/or components for wireless energy transfer, such that recharging can occur without having to remove the (implanted) sensor.

[0017] The invention provides, according to a second aspect, which may be combined with the other aspects and embodiments described herein, a multiple user health monitoring system which comprises a plurality of the personal health monitoring systems as described above. The multiple user health monitoring system comprises a remote server system which is provided for collecting the personal health profiles generated by the plurality of personal health monitoring systems. As a result of the self-learning capabilities of the individual personal health monitoring systems, the collected information can efficiently be used to generate e.g. reports, statistics, etc. of user groups.

[0018] The invention provides, according to a third aspect, which may be combined with the other aspects and embodiments described herein, a method for monitoring the biological parameters of at least one user. The method, and embodiments thereof, comprise substantially the steps as have already been described above in relation to the personal health monitoring system according to the invention.

Brief description of the drawings

[0019] The present invention will be discussed in more detail below, with reference to the attached drawings.

Fig. 1 shows an embodiment of the implantable sensor comprising sensor housing 1, sensing means 2, sensor housing adapted to sensing means 3 and a wireless transceiver 4.

Fig. 2 shows an embodiment of the implantable sensor with optical sensing means 5 and optical processor 6.

Fig. 3 shows an embodiment of the implantable sensor with components for wireless energy transfer 7.

Fig. 4 shows an embodiment of the implantable sensor with components for wireless energy transfer 7 and optical sensing means 5 and optical processor 6.

Fig. 5 shows an embodiment of the implantable sensor with processing means 9.

Fig. 6 shows an embodiment of the monitoring device comprising a wireless transceiver 4, monitoring device housing 8, processing means 9 and a memory 10.

Fig. 7 shows an embodiment of the monitoring device with display 11.

Fig. 8 shows an embodiment of the monitoring device with heart rate sensor 12.

Fig. 9 shows an embodiment of the monitoring device as an ensemble of devices.

Fig. 10 shows another embodiment of the monitoring device as an ensemble of devices.

Fig. 11 shows an embodiment of the algorithm of the health monitoring system.
Fig. 12 shows another embodiment of the algorithm of the health monitoring system.
Fig. 13 shows an embodiment of the algorithm of the health monitoring system with a heart rate monitor in the monitoring device.
Fig. 14 shows another embodiment of the algorithm of the health monitoring system with a heart rate monitor in the monitoring device.
Fig. 15 shows an embodiment of the health monitoring system comprising a remote server.
Fig. 16 shows an embodiment of the interaction of monitoring devices with a remote server.
Fig. 17 shows another embodiment of the interaction of monitoring devices with a remote server.
Fig. 18 shows an embodiment of the interaction of the monitoring device with an insulin pump controller.

Description of embodiments

[0020] The present invention will be described with respect to particular embodiments and with reference to certain drawings but the invention is not limited thereto but only by the claims. The drawings described are only schematic and are non-limiting. In the drawings, the size of some of the elements may be exaggerated and not drawn on scale for illustrative purposes. The dimensions and the relative dimensions do not necessarily correspond to actual reductions to practice of the invention.

[0021] Furthermore, the terms first, second, third and the like in the description and in the claims, are used for distinguishing between similar elements and not necessarily for describing a sequential or chronological order. The terms are interchangeable under appropriate circumstances and the embodiments of the invention can operate in other sequences than described or illustrated herein.

[0022] Moreover, the terms top, bottom, over, under and the like in the description and the claims are used for descriptive purposes and not necessarily for describing relative positions. The terms so used are interchangeable under appropriate circumstances and the embodiments of the invention described herein can operate in other orientations than described or illustrated herein.

[0023] Furthermore, the various embodiments, although referred to as "preferred" are to be construed as exemplary manners in which the invention may be implemented rather than as limiting the scope of the invention.

[0024] The term "comprising", used in the claims, should not be interpreted as being restricted to the elements or steps listed thereafter; it does not exclude other elements or steps. It needs to be interpreted as specifying the presence of the stated features, integers, steps or components as referred to, but does not preclude the presence or addition of one or more other features, integers, steps or components, or groups thereof. Thus, the scope of the expression "a device comprising A and B" should not be limited to devices consisting only of components A and B, rather with respect to the present invention, the only enumerated components of the device are A and B, and further the claim should be interpreted as including equivalents of those components.

[0025] Whenever in this document reference is made to an 'implantable' sensor, this should be construed to mean any sensor capable of in vivo measurements of one or more biological parameters in an animal or human. The implantable sensor may be located subcutaneous, intramuscular, intravascular, ocular such as in or attached to the cornea, in or attached to an organ, in or attached to the digestive tract or in or attached to a body cavity such as mouth, eye or ear. In a preferred embodiment the implantable sensor is a subcutaneous sensor.

[0026] The fatty acid metabolism and the glucose metabolism are two groups of biochemical processes which are responsible for most of the energy generation and consumption in mammals. They are also responsible for the formation, breakdown and interconversion of biologically important molecules.

[0027] The measurement of a fat metabolism analyte, such as ketone bodies, is indicative of fat metabolism.

[0028] Ketosis in humans is a nutritional process characterised by serum concentrations of ketone bodies over 0.5 mM, with low and stable levels of insulin and blood glucose. Long-term ketosis may result from fasting or staying on a low-carbohydrate diet (ketogenic diet), and deliberately induced ketosis can be a lifestyle choice or be used as a medical intervention for various conditions, such as intractable epilepsy, and the various types of diabetes. Ketosis can also occur in animals, for example in dairy cattle during the first weeks after giving birth to a calf or to sheep in pregnancy toxemia.

[0029] Ketoacidosis is a pathological metabolic state marked by extreme and uncontrolled ketosis caused by, for example, alcohol, starvation or diabetes. In ketoacidosis, the body fails to adequately regulate ketone production causing such a severe accumulation of keto acids that the pH of the blood is substantially decreased, eventually leading to coma and death.

[0030] Monitoring ketone bodies in a mammal is thus expected to provide essential information for subjects at risk of ketosis because of medical, dietary or lifestyle conditions.

[0031] The measurement of a glucose metabolism analyte, such as glucose, is indicative of glucose metabolism.

[0032] Hypoglycaemia, also known as low blood sugar, is a condition characterized by blood sugar levels below normal levels. This may result in a variety of symptoms including clumsiness, trouble talking, confusion, loss of consciousness, seizures, or death. A feeling of hunger, sweating, shakiness, and weakness may also be present. Hypoglycaemia may be present as a consequence of medical conditions (such as diabetes), a side-effect of a medical treatment, dietary or lifestyle condi-

tions.

[0033] Hyperglycaemia, also known as high blood sugar, is a condition characterized by blood sugar levels above normal levels. Acute hyperglycaemia can result in polyuria, polydipsia, weight loss, sometimes with polyphagia, and blurred vision and chronic hyperglycaemia may result in a range of medical conditions such as kidney damage, neurological damage, cardiovascular damage, damage to the retina, feet and legs. Hyperglycaemia may be present as a consequence of medical conditions (such as diabetes), a side-effect of a medical treatment, dietary or lifestyle conditions.

[0034] 2 hour plasma glucose (2hPG), fasting plasma glucose (FPG), random plasma glucose (PG) are widely used markers of glycemic control. Continuous glucose monitoring is the prerequisite to enable strict glycemic control, keeping blood glucose levels within a desired range, such as a range that prevents medical complications. The desired range is highly personal and may be governed by factors such as medical conditions, dietary of lifestyle choices. Even within the commonly accepted "healthy" range of 80-110 mg/dl blood glucose, the ideal blood glucose level for every individual is different.

[0035] Embodiments of the invention provide a personal health monitoring system, comprising an implantable sensor and a monitoring device, and capable of generating an improved personal health profile from the collected sensor data.

[0036] The health monitoring system may provide insight in the metabolic state of a user, by providing user dependent correlations between ketone bodies and glucose levels. The analysis of trends in glucose and ketone bodies levels while taking into account personal correlations may provide improved means for subjects to manage their metabolic state. For example, for patients suffering from diabetes, the change from modest hyperglycaemia to ketoacidosis can occur slowly or very rapidly, depending on the type of diabetes and the individual patient (e.g. infants vs. adults). Improved analysis of trends and prediction, taking into account individual correlations between ketone bodies and glucose levels, may be of vital importance for these patients. Patients following a ketogenic diet as (complementary) treatment of brain tumor may also benefit from the user dependent correlations between ketone bodies and glucose levels which are the object of some preferred embodiments of the personal health monitoring system of the present invention.

[0037] The ability to maintain blood glucose and ketone bodies within a desired range requires frequent measurements of glucose and ketone bodies. Each ketone bodies and glucose measurement provides information about the fatty acid and glucose metabolism that can be used to determine the personal health profile of a subject. This subject may be a patient (e.g. suffering from diabetes) or any person seeking to monitor and improve their personal health profile.

[0038] The implantable sensor of the health monitoring system of the present invention is shown in Fig. 1 and comprises sensor housing 1, means for sensing biological parameters in bodily fluids 2, an area of sensor housing which is adapted to the sensing means 3 and a wireless transceiver 4. The implantable sensor may be capable of sensing biological parameters based on surface chemical reactions and/or by using optical means. The implantable sensor may be capable of performing a reagent-free optical analysis method. The implantable sensor may comprise biocompatible packaging in order to reduce or minimize the risk of bio-fouling.

[0039] A preferred embodiment of an implantable sensor is shown in Fig. 2 and is equipped with optical sensing means 5 and an optical processor 6 (e.g. a single-chip optical sensor) for continuous analyte monitoring. The implantable sensor comprises an advanced optical processor in the sensor, allowing advanced and optionally complex radiation processing, e.g. allowing spectral and depth-resolved processing of radiation received or guided to a measurement region.

[0040] The implantable sensor comprises means for sensing biological parameters in bodily fluids and comprises a wireless transceiver for transmitting sensor data containing data points which are provided by said sensing means upon sensing biological parameters. The implantable sensor is provided for measuring at least glucose and ketone bodies in bodily fluids. The sensing means may be as described in US 9,532,738 B2, in particular column 11 line 15-67, which are hereby incorporated by reference.

[0041] In embodiments of the invention, the implantable sensor may be adapted for sensing biological parameters in bodily fluids wherein the bodily fluid may be interstitial fluid, ocular fluid, intermuscular fluid or peritoneal fluid. It has been found that measurements of biological parameters in the interstitial fluid present a reliable relationship with blood values, are minimally invasive and safe and present other advantages such as the elimination of the need for anticoagulants. Thus, in a preferred embodiment of the invention, the implantable sensor is a subcutaneous implantable sensor.

[0042] In embodiments of the invention, the implantable sensor may comprise a rechargeable battery and/or components for wireless energy transfer. A preferred embodiment of an implantable sensor is shown in Fig. 3 and is equipped with components for wireless energy transfer 7. A more preferred embodiment of an implantable sensor is shown in Fig. 4 and is equipped with optical sensing means 5 and an optical processor 6 and components for wireless energy transfer 7. In a preferred embodiment, the rechargeable battery is a solid state battery.

[0043] In embodiments of the invention, the implantable sensor may further be equipped with means for processing sensor data, wherein said processing means is equipped with an algorithm which is executable on said processing means and which is provided for converting sensor data before transmitting to the monitoring device. A preferred embodiment of an implantable sensor is shown in Fig. 5 and is equipped with a processing means

9.

[0044] The implantable sensor may further be capable of sensing heart rate, body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level.

[0045] A preferred embodiment of a monitoring device is shown in Fig. 6 and comprises a housing 8, a wireless transceiver 4 for communicating with the wireless transceiver of the implantable sensor or other devices of the monitoring device to receive sensor data. The monitoring device further comprises processing means 9 for processing said sensor data and a memory 10 for storing data. The processing means is equipped with an algorithm, an embodiment of which is shown in Fig. 11, which is loadable into the memory 10 for execution by said processing means. The algorithm is at least provided for: determining trends in glucose concentration data points and in ketone bodies concentration data points and generating a personal health profile of the user. In embodiments according to the invention, shown in Fig. 12, the algorithm of the monitoring device may be provided for performing the following steps: determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points; detecting first user dependent correlations between said first trends and said second trends, and generating a personal health profile of the user based on said first user dependent correlations. In a preferred embodiment of the invention the monitoring device is a smartphone. In another preferred embodiment of the invention the monitoring device is a smart watch.

[0046] Another embodiment of the monitoring device is shown in Figure 7 wherein the monitoring device is equipped with a user interface, comprising a display 11 for displaying the personal health profile and interacting with the user. The monitoring device may further be provided for receiving heart rate data points from a heart rate sensor, said heart rate data points being received from the implantable sensor or any other device which is capable of providing heart rate data points. For example, in case the monitoring device is a smart watch, a heart rate sensor may be provided on board the smart watch. Figure 8 shows a preferred embodiment of the monitoring device wherein the monitoring device is equipped with a heart rate sensor 12. The algorithm may be provided for determining trends in the heart rate data points and detecting user dependent correlations between trends in heart rate data points and trends in glucose concentration data points and/or ketone bodies concentration data points, and evaluating said user dependent correlations upon generating a personal health profile. Thus, a further improved personal health profile may be achieved. Figures 11 and 12 show embodiments of the algorithm wherein the heart rate data points could be received as other data points, while figures 13 and 14 show embodiments of the algorithm wherein the heart rate data points are being collected by the monitoring device.

[0047] In another embodiment of the present invention the monitoring device may further be provided for receiving and processing data points of one or more of the following parameters: body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level. These parameters may be provided by the implantable sensor or any one or more additional implantable sensors and/or other device which is capable of providing data points of one or more of said parameters. The algorithm executable on the processing means may then be provided for determining trends in the data points of the one or more additional parameters (body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level) and generating a personal health profile. In a preferred embodiment the algorithm executable on the processing means may then be provided for determining trends in the data points of the one or more additional parameters (body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level), detecting user dependent correlations between said trends and trends in heart rate data points, trends in glucose concentration data points and/or ketone bodies concentration data points, and evaluating said user dependent correlations upon generating a personal health profile. Thus, a further improved personal health profile may be achieved. Figures 11 and 12 show embodiments of the algorithm wherein the body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level data points could be received as other data points.

[0048] In another embodiment of the present invention the monitoring device may further be provided for receiving and processing data points of one or more of the following parameters: nutritional intake such as carbohydrate intake data points, activity such as accelerometer data points and/or blood pressure data points and location such as GPS data points, agenda item data points. These parameters may be provided by the implantable sensor or any one or more additional implantable sensors and/or other device which is capable of providing data points of one or more of said parameters and/or manual user input. The algorithm executable on the processing means may then be provided for determining trends in the data points of the one or more additional parameters (nutritional intake, activity, location) and generating a personal health profile. In a preferred embodiment the algorithm executable on the processing means may then be provided for determining trends in the data points of the one or more additional parameters (nutritional intake, activity), detecting user dependent correlations between said trends and trends in heart rate data points, trends in glucose concentration data points and/or ketone bodies concentration data points, and evaluating said user dependent correlations upon generating a personal health profile. Thus, a further improved personal health profile may be achieved. Figures 11 and 12 show embodiments of the algorithm wherein the nutritional intake, activity, location could be received as other data points.

[0049] The glucose ketone index is a biomarker that refers to the molar ratio of circulating glucose over β-

OHB, which is the major circulating ketone body. The glucose ketone index is a single value that can assess the relationship of the glucose to ketone bodies. The glucose ketone index is described in Meidenbauer et al. Nutrition & Metabolism 2015, 12:12, which is incorporated herein by reference. In another embodiment of the present invention, the monitoring device may comprise an algorithm executable on the processing means provided for determining the glucose ketone index (GKI). In a preferred embodiment the algorithm executable on the processing means may then be provided for determining trends in the glucose ketone index, detecting user dependent correlations between said trends and trends in heart rate data points, trends in glucose concentration data points and/or ketone bodies concentration data points, and evaluating said user dependent correlations upon generating a personal health profile. Thus, a further improved personal health profile may be achieved.

[0050] In another embodiment of the invention, different features of the monitoring device may be present on different devices. The monitoring device may thus be an ensemble of two or more devices, each device comprising a transceiver for receiving and transmitting data. Figures 9 and 10 show an embodiment of the invention wherein the monitoring device is an ensemble of devices. In a preferred embodiment the monitoring device comprises one or more of the following devices: a device equipped with a transceiver and a processor, a smartphone and a cloud server. In a more preferred embodiment the device equipped with a transceiver and a processor is capable of transmitting and receiving at least two different communication protocols. In embodiments, the at least two different communication protocols may be wired and/or wireless signals. In embodiments, the wireless signals may comprise signals according to different wireless bands and/or protocols such as IEEE802.11, bluetooth, cellular etc.

[0051] In another embodiment of the invention, the monitoring device may be an ensemble of two or more devices, each device comprising a transceiver for receiving and transmitting data, wherein two or more devices are each equipped with a processing means and an algorithm executable on the processing means. In a preferred embodiment of the invention, the algorithm of each device is provided performing one or more steps necessary for generating a personal health profile according to the invention.

[0052] In embodiments the monitoring device may be provided for generating and/or communicating to the user personalized behavioural, life-style and therapeutic suggestions and actions, based on the monitoring of biological parameters. In embodiments, the monitoring device may be provided for generating instructions for a controller of an insulin pump or may form part of an insulin pumping device.

[0053] In embodiments the monitoring device may be an ensemble of two or more devices wherein each device comprising a transceiver for receiving and transmitting data, wherein two or more devices are each equipped with a processing means and an algorithm executable on the processing means wherein the algorithm of each device is provided for performing one or more steps necessary for generating and/or communicating to the user personalized behavioural, life-style and therapeutic suggestions and actions, based on the monitoring of biological parameters. In a preferred embodiment of the invention the monitoring device is an ensemble of devices which includes an insulin pumping device and/or controller of an insulin pump. In a more preferred embodiment of the invention the monitoring device is an ensemble of devices which includes an insulin pumping device and/or controller of an insulin pump and a smartphone.

[0054] In a preferred embodiment of the invention, the monitoring device is an ensemble of devices which includes a remote server. In a more preferred embodiment of the invention, the monitoring device is an ensemble of devices which includes a remote server wherein the remote server is equipped with algorithm which is executable on said remote server and provided for performing one or more steps necessary for generating and/or communicating to the user a personal health profile and/or personalized behavioural, life-style and therapeutic suggestions and actions, based on the monitoring of biological parameters. In another preferred embodiment of the invention, the monitoring device is an ensemble of devices which does not include a remote server.

[0055] A preferred embodiment of the present invention, shown in Fig. 11 provides a multiple user health monitoring system comprising a plurality of personal health monitoring systems and further comprising a remote server system which is provided for collecting the personal health profiles generated by the plurality of personal health monitoring systems. In another embodiment, the remote server system is equipped with a further algorithm which is executable on said remote server system and provided for generating reports based on said collected personal health profiles. The reports may include personal recommendations optionally sent back to the monitoring device and displayed to the user, anonymous statistical data from a group of users or instructions for other devices such as an insulin pump. The reports may also include instructions for the monitoring device to be relayed to the implantable sensor.

[0056] The invention also provides a method to generate a personal health profile comprising measuring glucose concentration data points and ketone bodies concentration data points using an implantable sensor, transmitting glucose concentration data points and ketone bodies concentration data points to a monitoring device, determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points, detecting first user dependent correlations between said first trends and said second trends, and generating a personal health profile of the user based on said first user dependent correlations.

[0057] In embodiments the monitoring device may be

provided for generating and/or communicating to the user personalized behavioural, life-style and therapeutic advice and/or interventions, based on the monitoring of biological parameters. In a preferred embodiment of the present invention the behavioural, life-style and therapeutic suggestions and actions may be one or more of the following: nutritional advice, emergency care advice, therapeutic advice and/or interventions, insulin pump controller instructions.

Examples

[0058] Embodiments of the invention may for example be provided for detecting and correlating trends as follows.

[0059] Useful glucose and ketone concentration trends to be detected are for example:

- Moderate ketones and hypoglycaemia resulting in the generation of a personal health profile and recommendations and/or instructions comprising: increase carb intake and/or decrease basal insulin administration.
- High ketones and hyperglycaemia resulting in the generation of a personal health profile and recommendations and/or instructions comprising: possible insulin pump defect, danger for ketoacidosis, drink water and consult emergency medical care.
- low ketones and hypoglycaemia resulting in the generation of a personal health profile and recommendations and/or instructions comprising: possible insulin overadministration or insulin pump defect, increase carb intake.
- Linking glucose and ketone trends with glucose variability (GV) and HbAlc levels to generate a personal risk and health profile for complications of diabetes. This will enable the patient to improve his/her risk profile.
- Group analysis of glucose and ketones trend correlations enabling better prediction and treatment models based on patient type (age, gender, BMI, physical activity level).

[0060] Useful heart rate trends to be detected are for example:

- Loss in heart rate variability in combination with progressive hypoglycaemia resulting in the generation of a personal health profile and recommendations and/or instructions comprising: prevention of possible severe hypoglycaemia, consult emergency care.

[0061] Useful user dependent correlations are for example:

- Known high response rate of ketones and glucose to insulin administration resulting in the generation of a personal health profile and recommendations and/or instructions comprising: adapting the amount of insulin to be administered accordingly.

Claims

1. A personal health monitoring system, comprising:

an implantable sensor, comprising sensing means for continuously sensing biological parameters in bodily fluids of a user and a first wireless transceiver for transmitting sensor data containing data points which are provided by said sensing means upon sensing said biological parameters, wherein said biological parameters comprise at least a glucose concentration and a ketone bodies concentration in said bodily fluids such that said sensor data comprises at least glucose concentration data points and ketone bodies concentration data points; and
a monitoring device, comprising a second wireless transceiver for communicating with said first wireless transceiver to receive said sensor data and processing means for processing said sensor data, wherein said processing means is equipped with an algorithm which is executable on said processing means and which is provided for:

- determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points,
- generating a personal health profile of the user.

2. A personal health monitoring system according to claim 1 wherein the algorithm which is executable on said processing means and is provided for:

- determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points,
- detecting first user dependent correlations between said first trends and said second trends, and
- generating a personal health profile of the user based on said first user dependent correlations.

3. A personal health monitoring system, comprising:

an implantable sensor, comprising sensing means for continuously sensing biological parameters in bodily fluids of a user, a first processing means and a first wireless transceiver for transmitting sensor data containing data points which are provided by said sensing means upon sensing said biological parameters, wherein

said biological parameters comprise at least a glucose concentration and a ketone bodies concentration in said bodily fluids such that said sensor data comprises at least glucose concentration data points and ketone bodies concentration data points, wherein said first processing means is equipped with an algorithm which is executable on said first processing means and which is provided for converting sensor data before transmitting to the monitoring device; and a monitoring device, comprising a second wireless transceiver for communicating with said first wireless transceiver to receive said sensor data and second processing means for processing said sensor data, wherein said second processing means is equipped with an algorithm which is executable on said processing means and which is provided for:

- determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points,
- generating a personal health profile of the user.

4. A personal health monitoring system according to claim 3 wherein the algorithm which is executable on said processing means and is provided for:

- determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points,
- detecting first user dependent correlations between said first trends and said second trends, and
- generating a personal health profile of the user based on said first user dependent correlations.

5. The personal health monitoring system according to any one of claims 1 to 4, wherein the implantable sensor is a subcutaneous implantable sensor and the bodily fluid is interstitial fluid.

6. The personal health monitoring system according to any one of claims 1 to 5, comprising 2 or more implantable sensors.

7. The personal health monitoring system according to any one of claims 1 to 6, wherein the monitoring device is provided for receiving heart rate data points from a heart rate sensor, and wherein said algorithm is further provided for:

- determining third trends in said heart rate data points.

8. The personal health monitoring system according to claim 7, wherein said algorithm is further provided for:

- determining third trends in said heart rate data points
- detecting second user dependent correlations between said third trends and said first and/or second trends, and
- evaluating said second user dependent correlations upon generating said personal health profile.

9. The personal health monitoring system according to claim 7 or 8, wherein the implantable sensor comprises the heart rate sensor.

10. The personal health monitoring system according to any one of claims 1 to 5, wherein the biological parameters sensed by the sensing means of the implantable sensor further comprise at least one of the following: body temperature, urea, lactate, pH, fructosamine, oxaloacetate, oxaloacetate and/or hydration level; such that said sensor data comprises further data points relating to body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level; and wherein said algorithm is further provided for:

- determining fourth trends in said further data points,

11. The personal health monitoring system according to claim 10, wherein said algorithm is further provided for:

- determining fourth trends in said further data points,
- detecting third user dependent correlations between said fourth trends and said first, second and/or third trends, and
- evaluating said third user dependent correlations upon generating said personal health profile.

12. The personal health monitoring system according to claim 6, wherein the biological parameters sensed by the sensing means of the two or more implantable sensors further comprise at least one of the following: body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level; such that said sensor data comprises further data points relating to body temperature, urea, lactate, pH, fructosamine, oxaloacetate and/or hydration level; and wherein said algorithm is further provided for:

- determining fourth trends in said further data points,

13. The personal health monitoring system according to claim 12, wherein the algorithm is further provided for:

    - determining fourth trends in said further data points,
    - detecting third user dependent correlations between said fourth trends and said first, second and/or third trends, and
    - evaluating said third user dependent correlations upon generating said personal health profile.

14. The personal health monitoring system according to any one of the preceding claims, wherein the monitoring device comprises a display for displaying said personal health profile.

15. The personal health monitoring system according to any one of the preceding claims, wherein the personal health profile comprises recommendations or suggestions aimed at improving the user's health.

16. The personal health monitoring system according to any one of the preceding claims, further comprising an insulin pump, wherein the personal health profile comprises instructions for a controller of said insulin pump.

17. The personal health monitoring system according to any one of the preceding claims wherein the implantable sensor is capable of sensing biological parameters by using optical means.

18. The personal health monitoring system according to any one of the preceding claims, wherein the monitoring device is a mobile terminal and the algorithm is included in an app stored on said mobile terminal.

19. The personal health monitoring system according to claim 18, wherein the mobile terminal is provided for collecting metadata (such as location data, calories intake data, activity data, agenda information and/or user habit information) and wherein the algorithm is provided for evaluating said metadata upon generating said personal health profile.

20. The personal health monitoring system according to any one of the preceding claims, wherein the implantable sensor comprises an integrated controller which is provided for controlling the sensing means at a variable sampling rate.

21. The personal health monitoring system according to claim 20, wherein the integrated controller is provided for detecting a variability level in said sensor data and adapting said variable sampling rate according to said detected variability level.

22. The personal health monitoring system according to any one of the preceding claims, wherein the implantable sensor comprises an integrated memory for accumulating sensor data.

23. The personal health monitoring system according to any one of the preceding claims, wherein the implantable sensor comprises components for wireless energy transfer.

24. The personal health monitoring system according to any one of the preceding claims, wherein the monitoring device is an ensemble of devices.

25. A multiple user health monitoring system comprising a plurality of personal health monitoring systems according to any one of the preceding claims and further comprising a remote server system which is provided for collecting the personal health profiles generated by the plurality of personal health monitoring systems.

26. The multiple user health monitoring system according to claim 25, wherein the remote server system is equipped with a further algorithm which is executable on said remote server system and provided for generating reports based on said collected personal health profiles.

27. Method to generate a personal health profile comprising

    a) measuring glucose concentration data points and ketone bodies concentration data points using an implantable sensor,
    b) transmitting said glucose concentration data points and ketone bodies concentration data points to a monitoring device,
    c) determining first trends in said glucose concentration data points and second trends in said ketone bodies concentration data points,
    d) detecting first user dependent correlations between said first trends and said second trends, and generating a personal health profile of the user based on said first user dependent correlations.

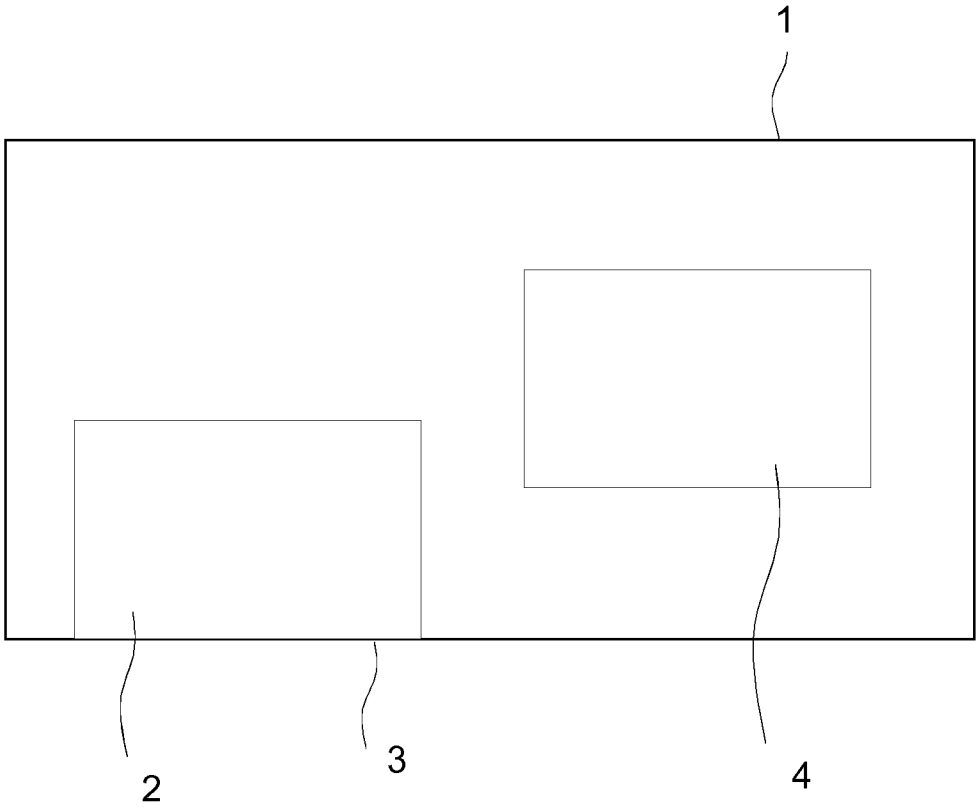

FIGURE 1

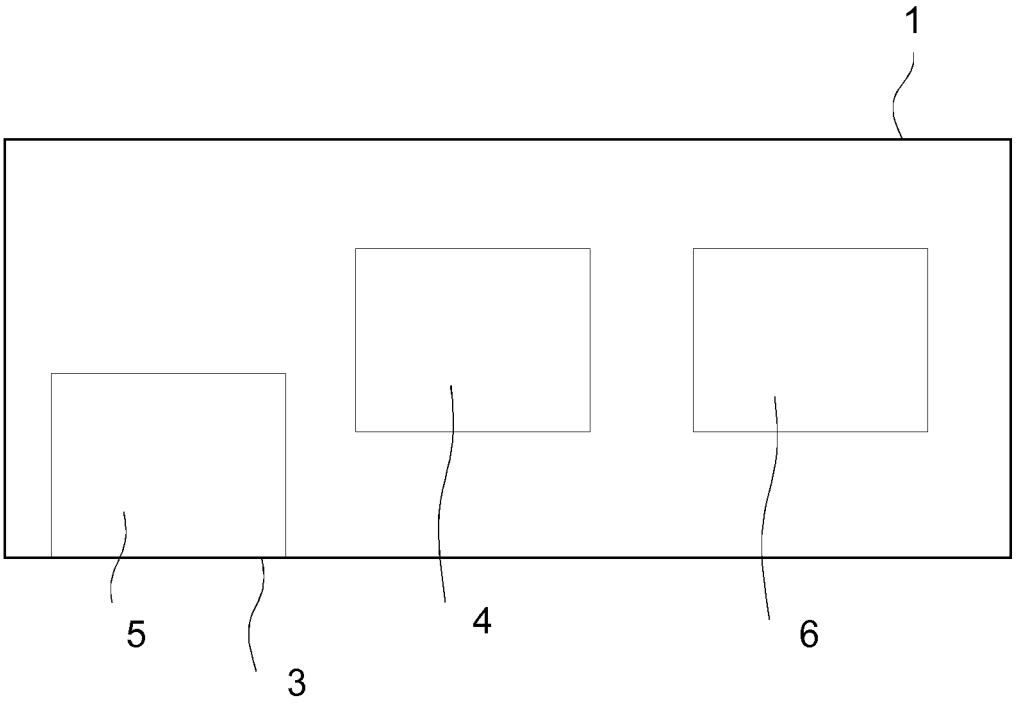

FIGURE 2

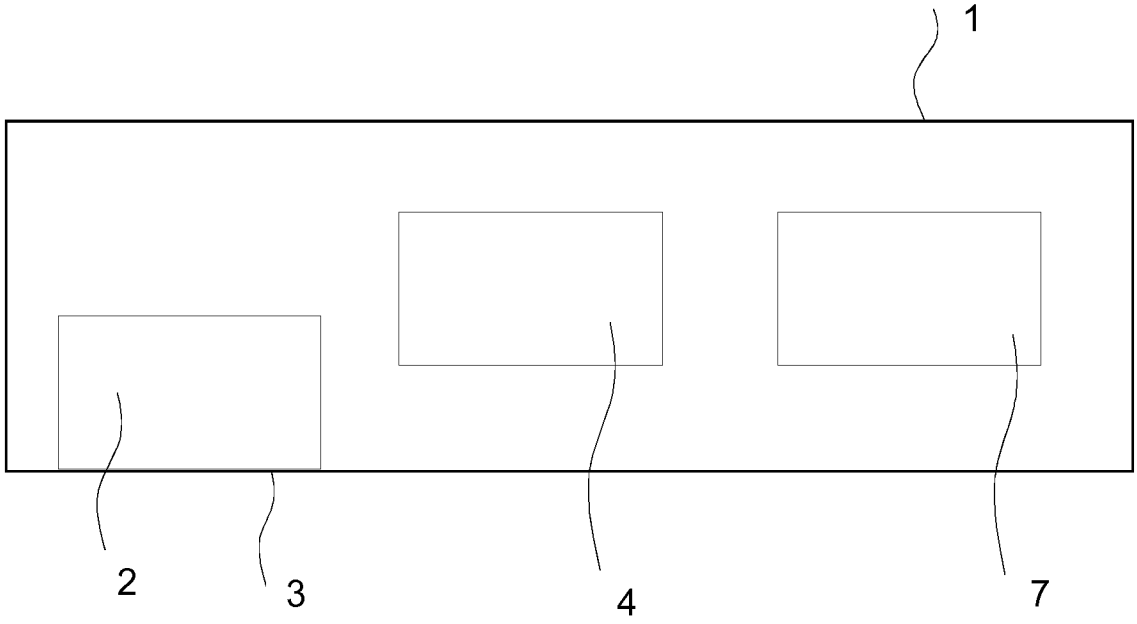

FIGURE 3

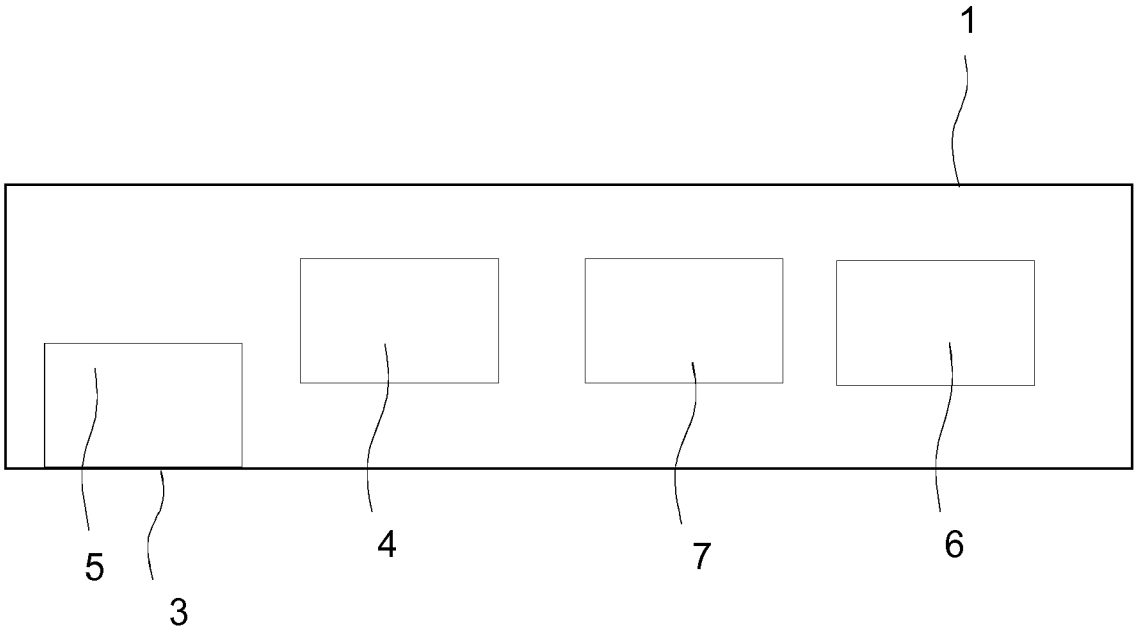

FIGURE 4

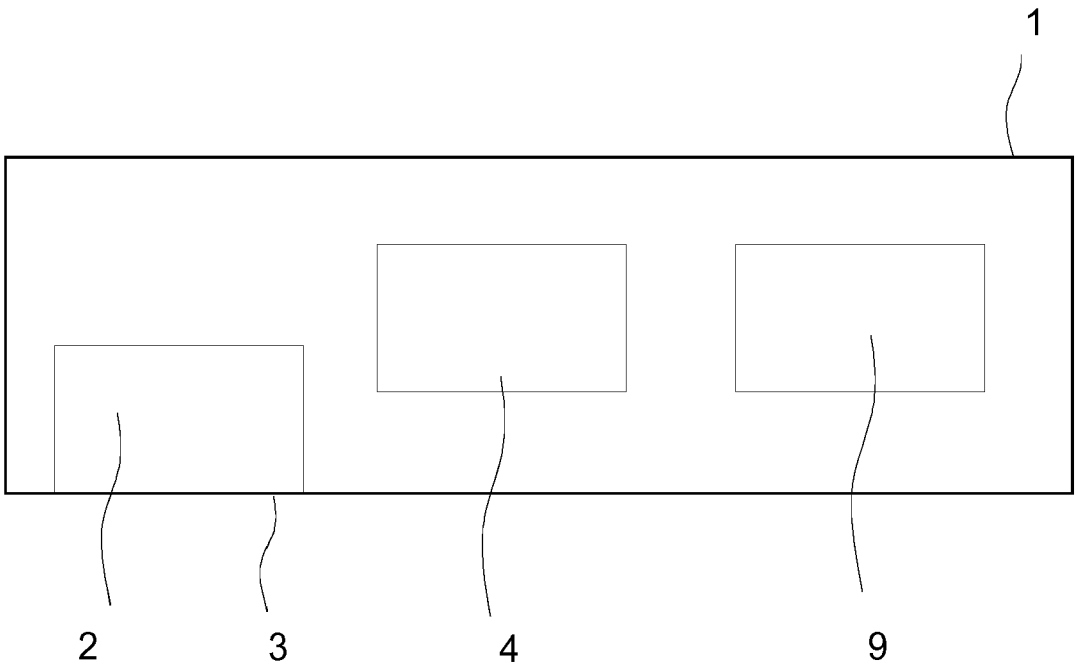

FIGURE 5

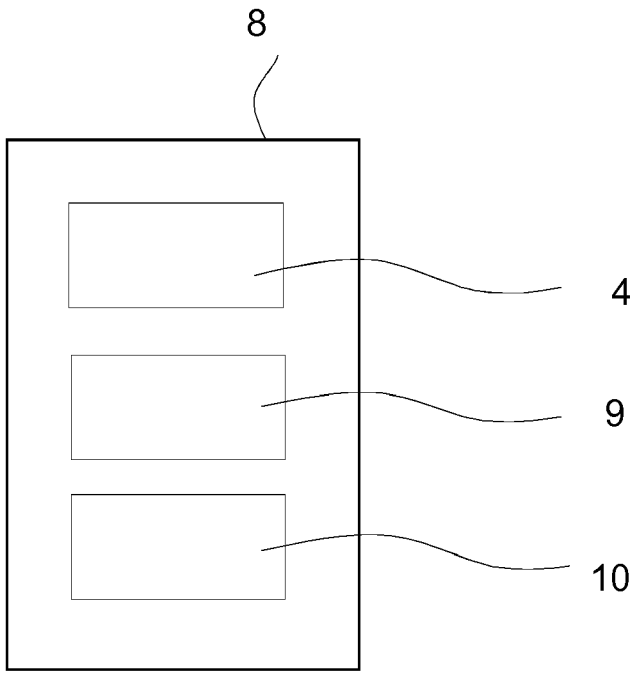

FIGURE 6

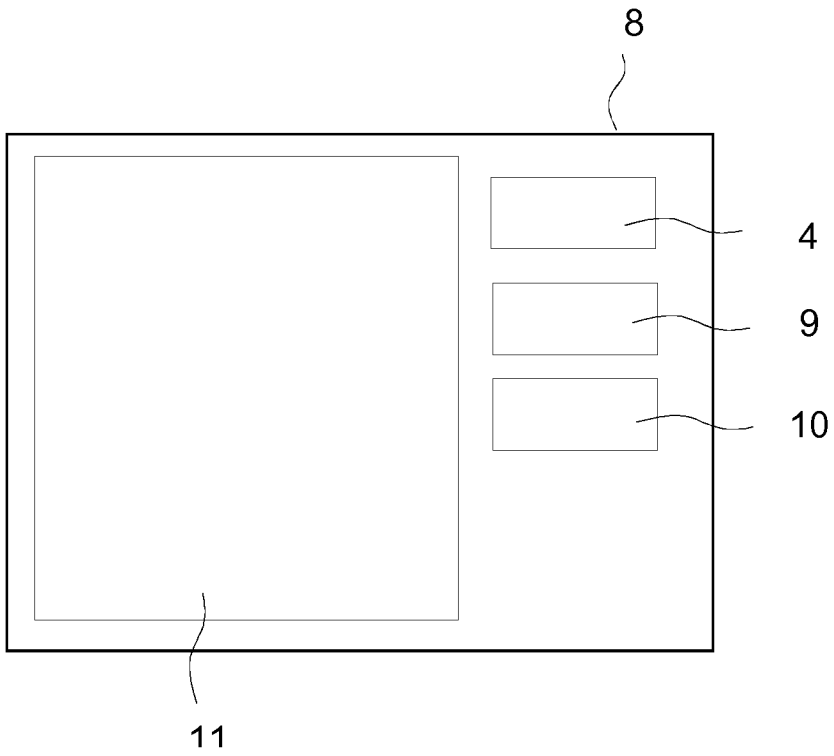

FIGURE 7

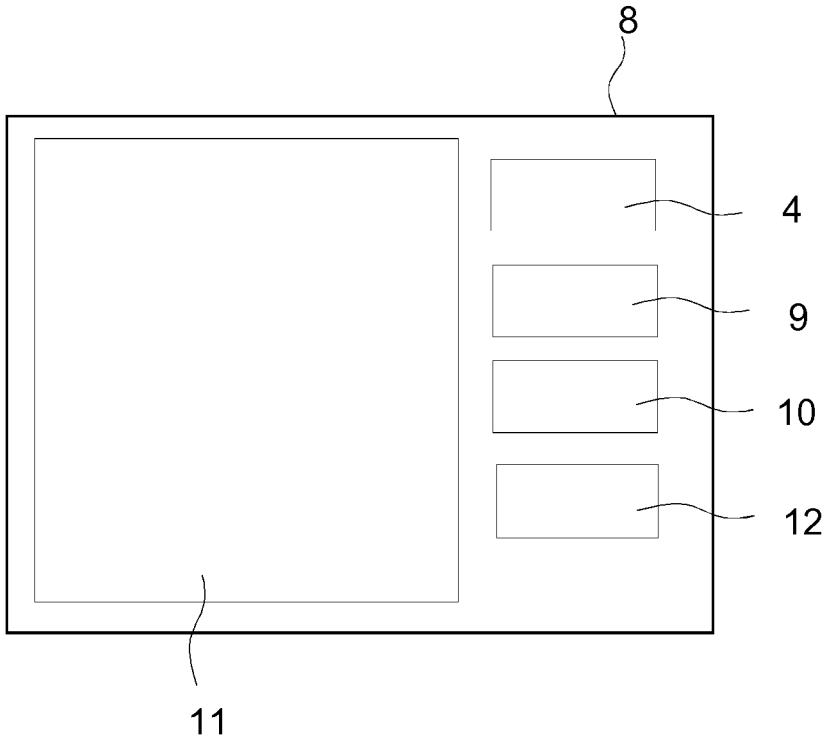

FIGURE 8

Monitoring device

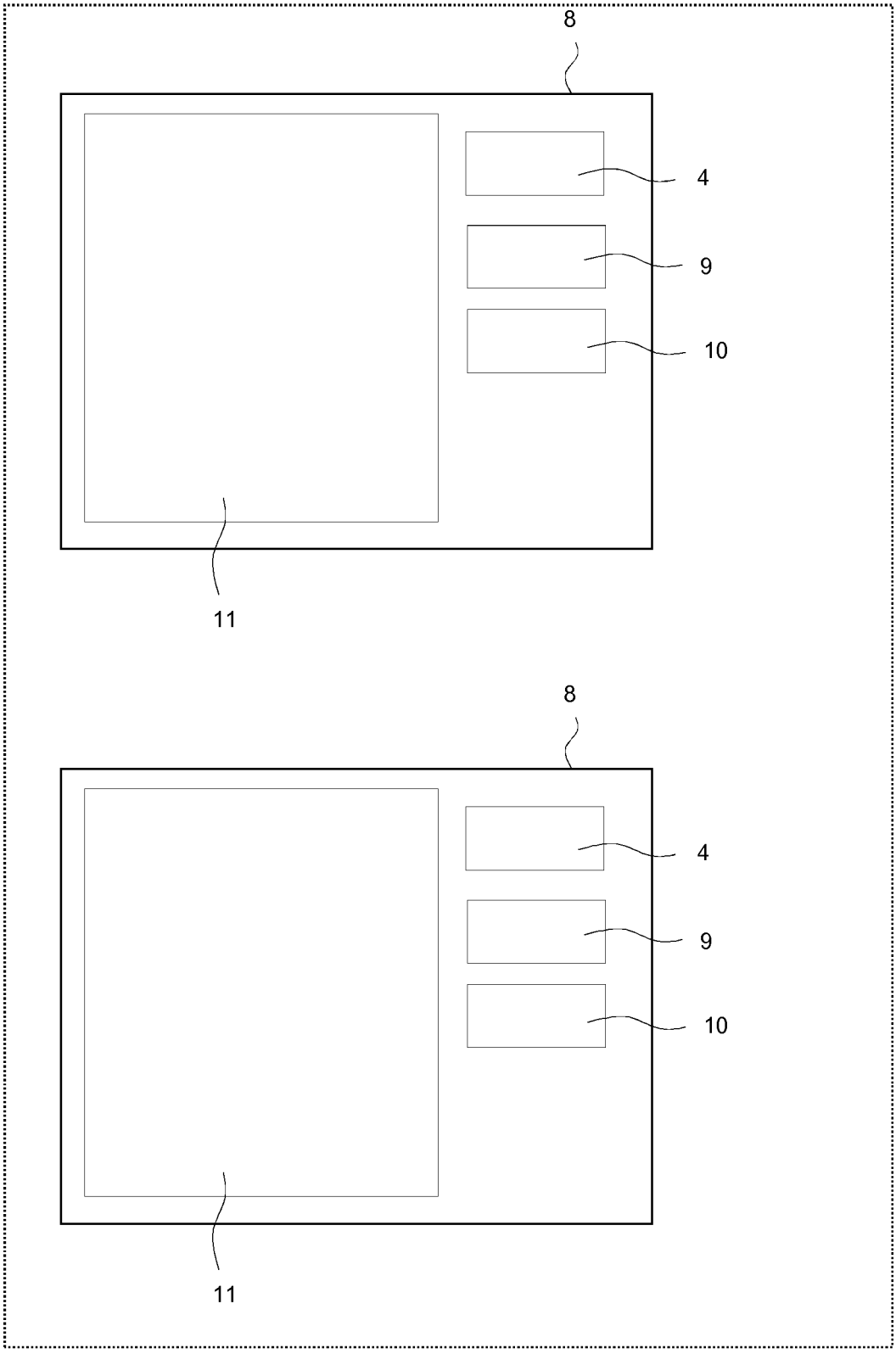

FIGURE 9

Monitoring device

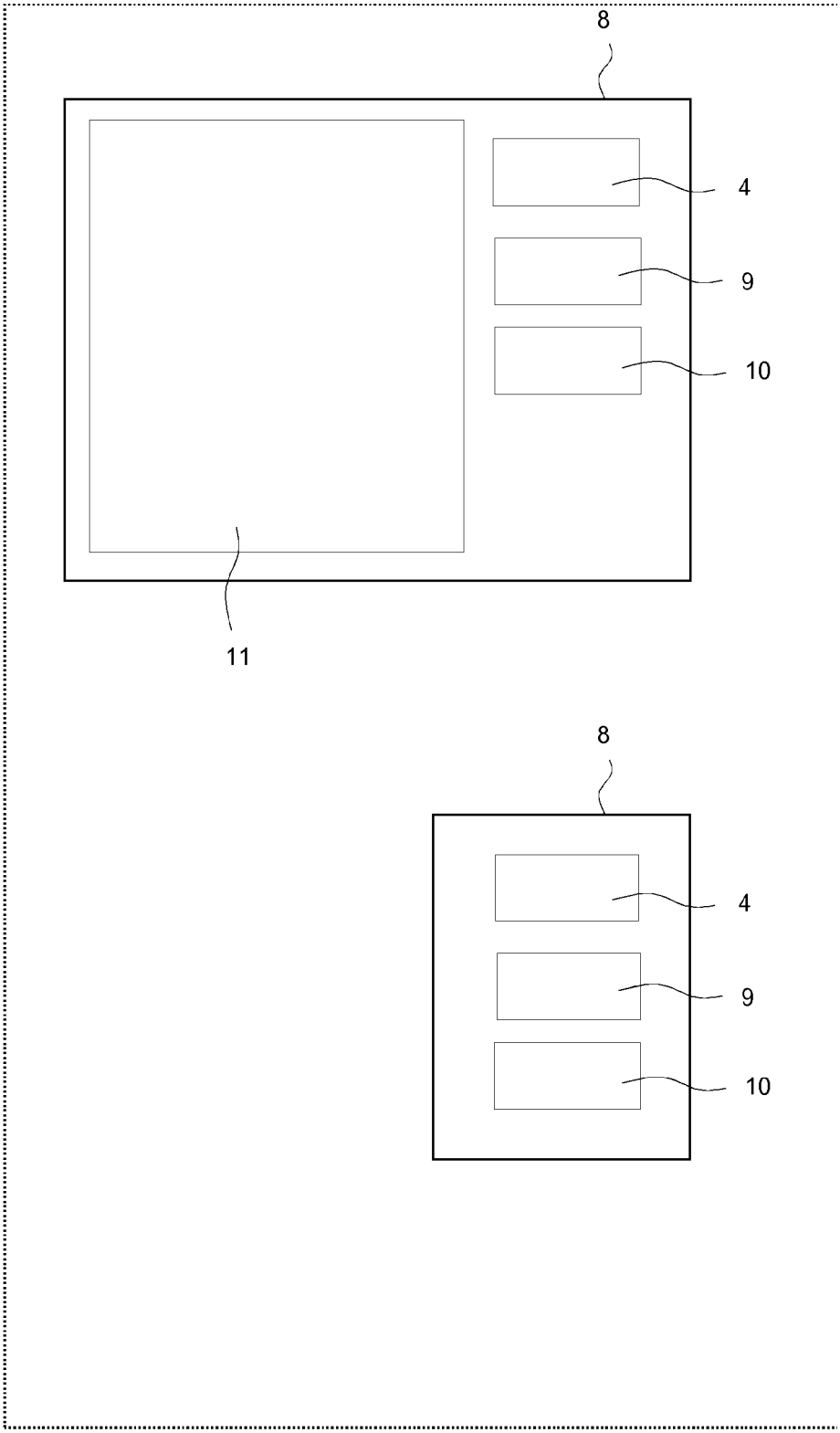

FIGURE 9

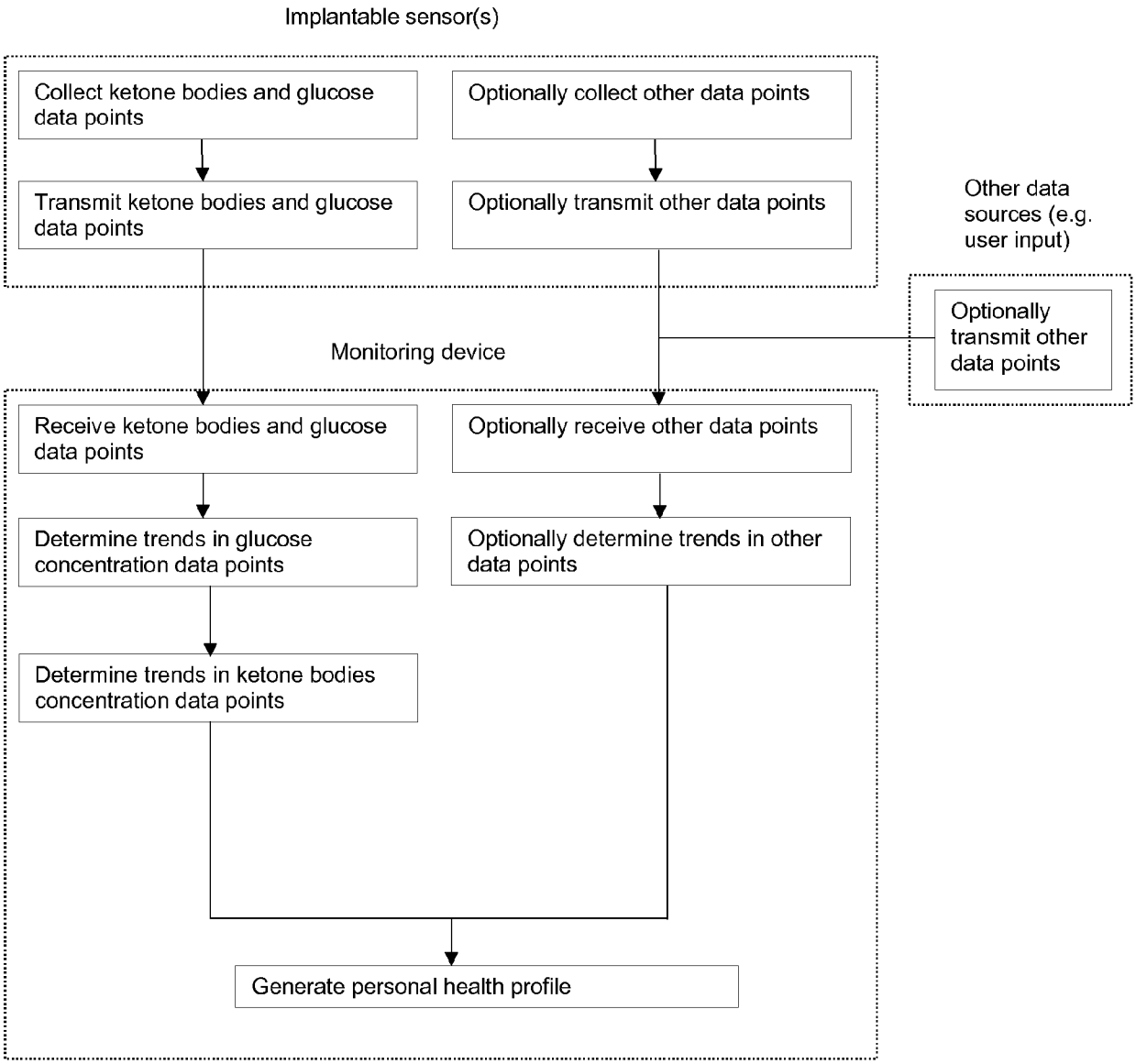
Implantable sensor(s)
Collect ketone bodies and glucose data points
Optionally collect other data points
Transmit ketone bodies and glucose data points
Optionally transmit other data points
Other data sources (e.g. user input)
Optionally transmit other data points
Monitoring device
Receive ketone bodies and glucose data points
Optionally receive other data points
Determine trends in glucose concentration data points
Optionally determine trends in other data points
Determine trends in ketone bodies concentration data points
Generate personal health profile

FIGURE 11

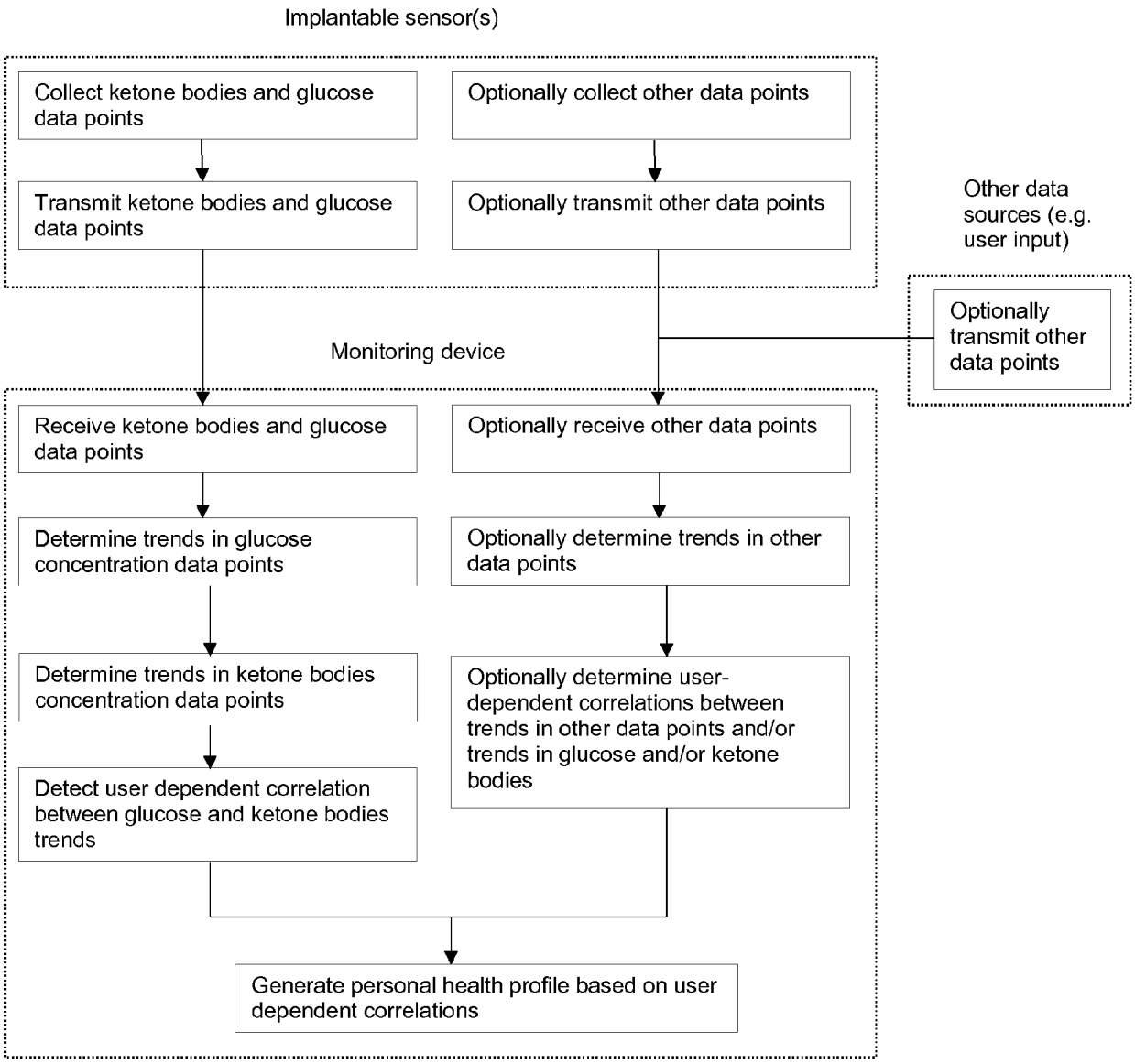
Implantable sensor(s)
Collect ketone bodies and glucose data points
Optionally collect other data points
Transmit ketone bodies and glucose data points
Optionally transmit other data points
Other data sources (e.g. user input)
Optionally transmit other data points
Monitoring device
Receive ketone bodies and glucose data points
Optionally receive other data points
Determine trends in glucose concentration data points
Optionally determine trends in other data points
Determine trends in ketone bodies concentration data points
Optionally determine user-dependent correlations between trends in other data points and/or trends in glucose and/or ketone bodies
Detect user dependent correlation between glucose and ketone bodies trends
Generate personal health profile based on user dependent correlations

FIGURE 12

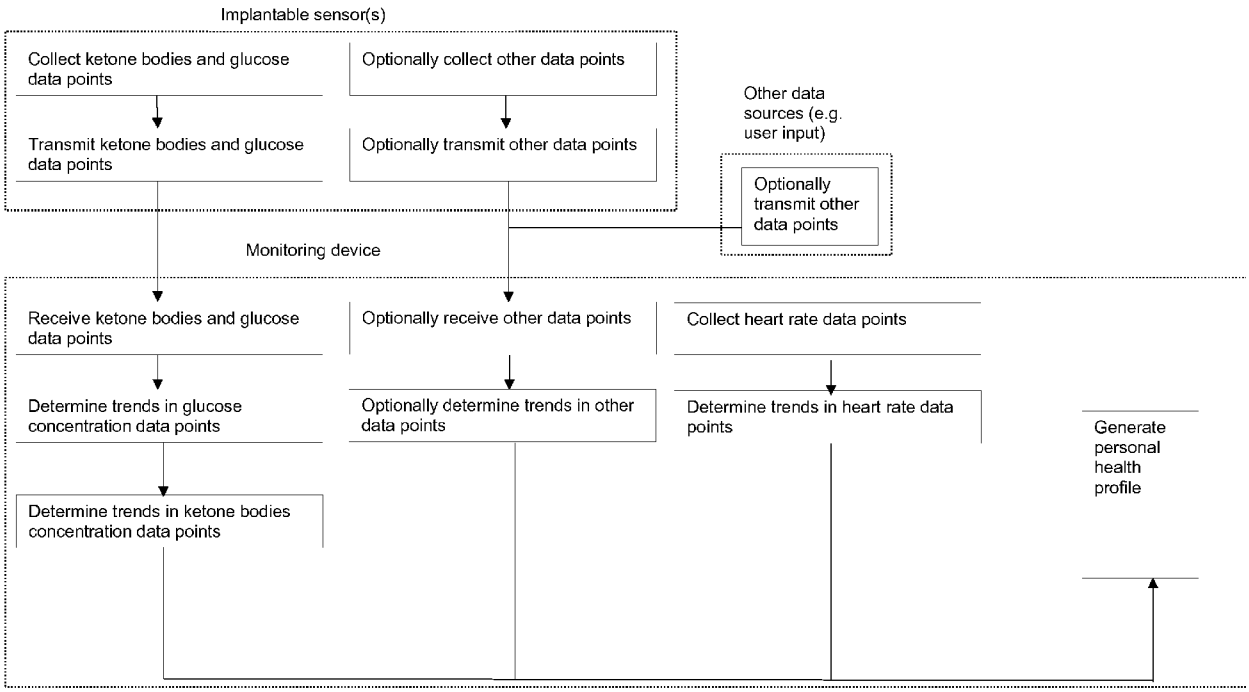
Implantable sensor(s)
Collect ketone bodies and glucose data points
Optionally collect other data points
Transmit ketone bodies and glucose data points
Optionally transmit other data points
Other data sources (e.g. user input)
Optionally transmit other data points
Monitoring device
Receive ketone bodies and glucose data points
Optionally receive other data points
Collect heart rate data points
Determine trends in glucose concentration data points
Optionally determine trends in other data points
Determine trends in heart rate data points
Determine trends in ketone bodies concentration data points
Generate personal health profile

FIGURE 13

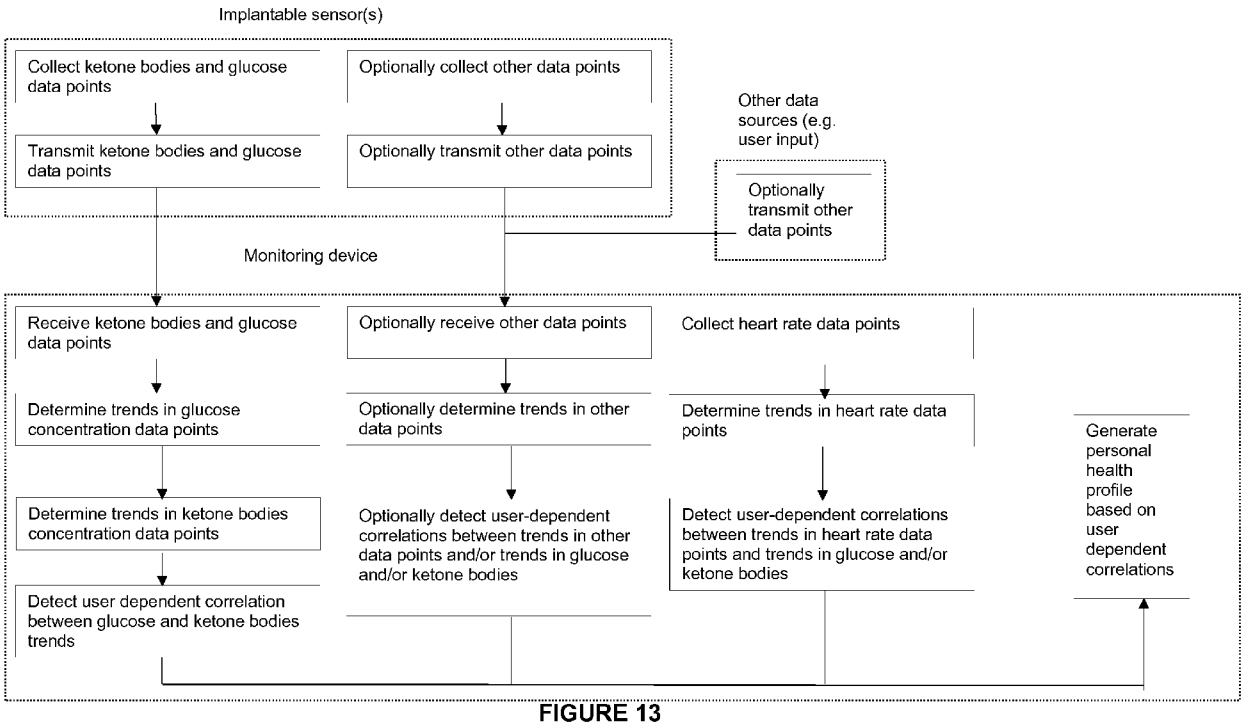
Implantable sensor(s)
Collect ketone bodies and glucose data points
Optionally collect other data points
Transmit ketone bodies and glucose data points
Optionally transmit other data points
Other data sources (e.g. user input)
Optionally transmit other data points
Monitoring device
Receive ketone bodies and glucose data points
Optionally receive other data points
Collect heart rate data points
Determine trends in glucose concentration data points
Optionally determine trends in other data points
Determine trends in heart rate data points
Determine trends in ketone bodies concentration data points
Optionally detect user-dependent correlations between trends in other data points and/or trends in glucose and/or ketone bodies
Detect user-dependent correlations between trends in heart rate data points and trends in glucose and/or ketone bodies
Detect user dependent correlation between glucose and ketone bodies trends
Generate personal health profile based on user dependent correlations

FIGURE 13

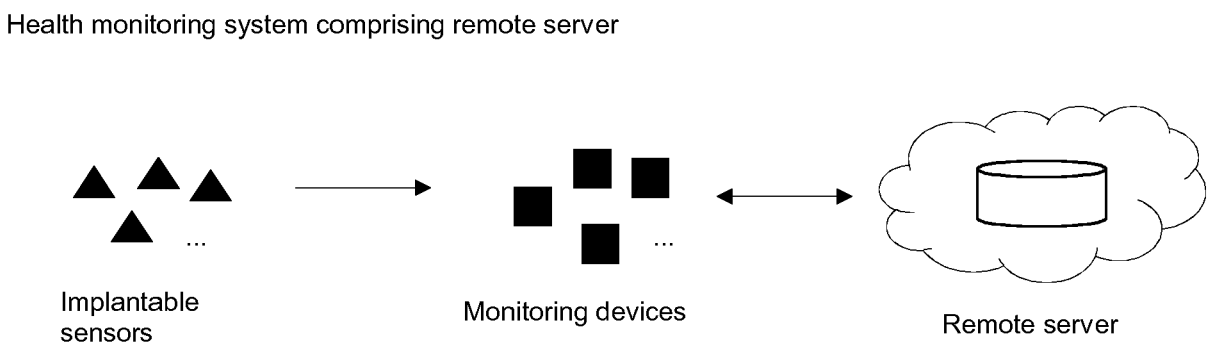

FIGURE 15

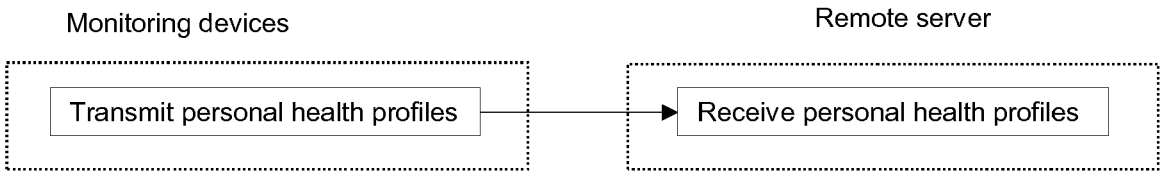

FIGURE 16

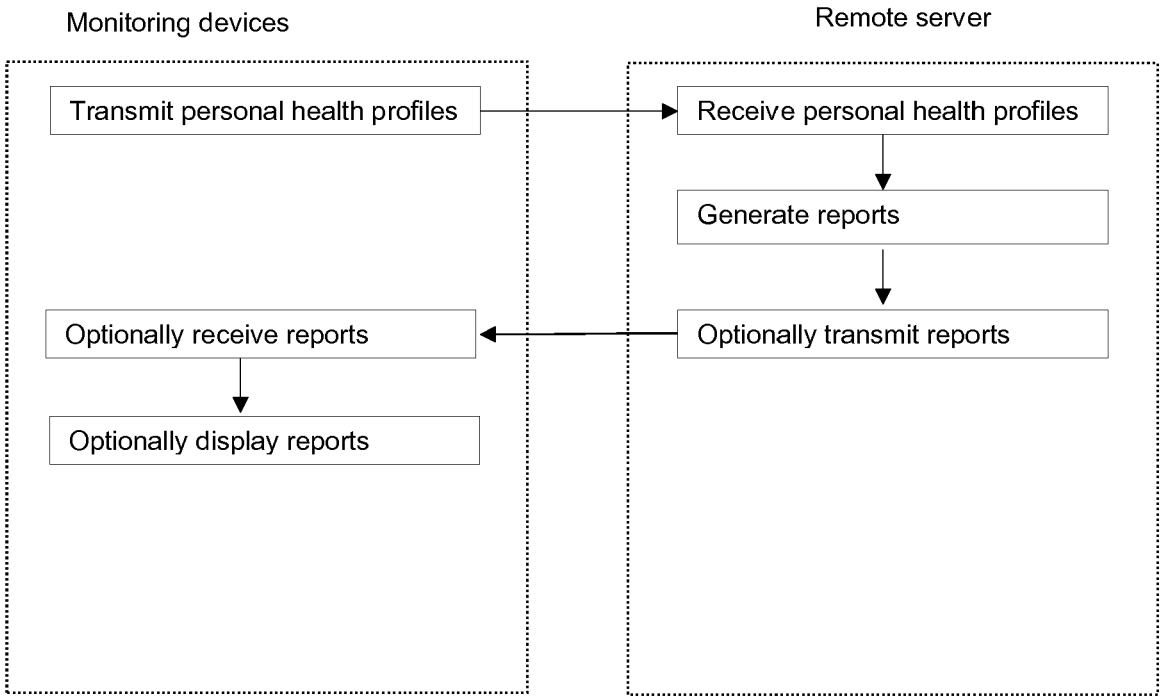

FIGURE 17

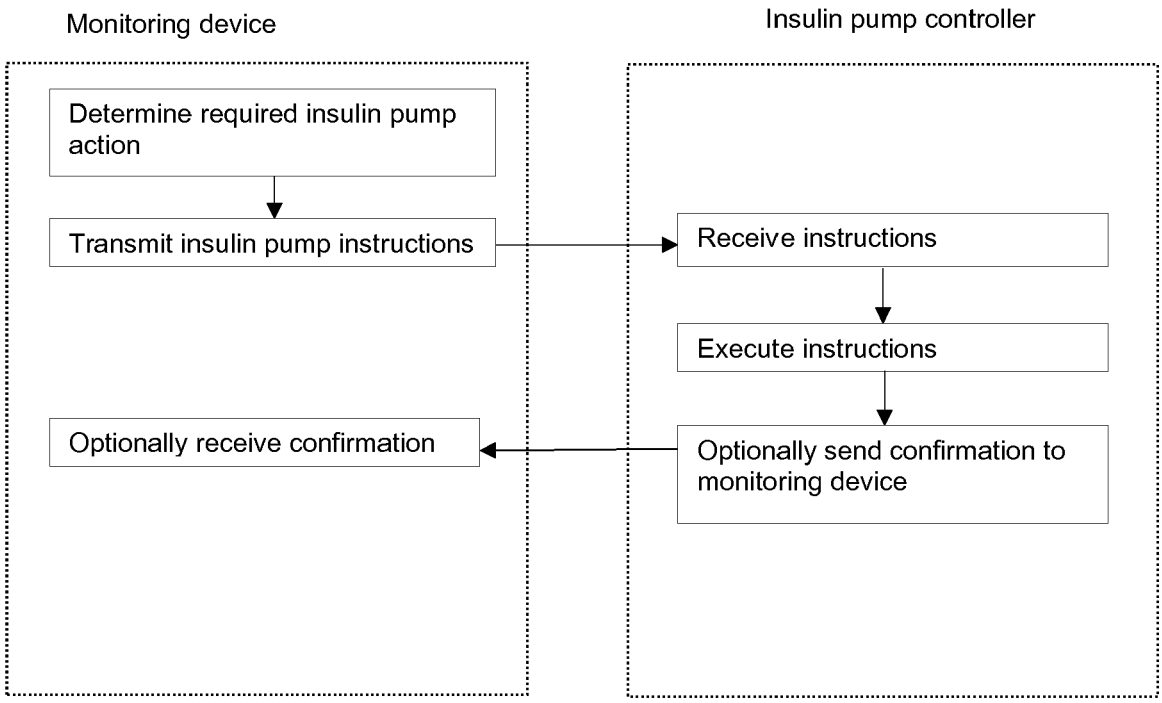

FIGURE 18

Europäisches Patentamt
European Patent Office
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EUROPEAN SEARCH REPORT

Application Number
EP 17 18 6763

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2015/289821 A1 (RACK-GOMER ANNA LEIGH [US] ET AL) 15 October 2015 (2015-10-15) * paragraphs [0056], [0068], [0073], [0074], [0104], [0110], [0115] - [0117], [0119], [0127], [0139], [0140], [0142] * * paragraphs [0171], [0183], [0187], [0280] * * figures 3, 7, 23 * -----	1-15	INV. A61B5/145 A61B5/1459 A61B5/00
X	US 2016/066843 A1 (MENSINGER MICHAEL ROBERT [US] ET AL) 10 March 2016 (2016-03-10) * paragraphs [0056], [0060] - [0062], [0078], [0079], [0081], [0083], [0084], [0176] * * figures 1,15 * -----	1-15	
A,D	JOSHUA J MEIDENBAUER ET AL: "The glucose ketone index calculator: a simple tool to monitor therapeutic efficacy for metabolic management of brain cancer", NUTRITION & METABOLISM, BIOMED CENTRAL. LONDON, GB, vol. 12, no. 1, 11 March 2015 (2015-03-11), page 12, XP021218198, ISSN: 1743-7075, DOI: 10.1186/S12986-015-0009-2 * page 2 * * figures 1, 2 * -----	1-15	TECHNICAL FIELDS SEARCHED (IPC) A61B
A	WO 2005/006969 A1 (KONINKL PHILIPS ELECTRONICS NV [NL]; PHILIPS INTELLECTUAL PROPERTY [DE) 27 January 2005 (2005-01-27) * page 7, lines 4-27 * * page 11, lines 4-31 * -----	1-15	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	7 June 2018	Worms, Georg

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

EPO FORM 1503 03.82 (P04C01)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Application Number
EP 17 18 6763

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):

☒ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

☐ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 17 18 6763

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
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07-06-2018

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		WO 2014011488 A2	16-01-2014
WO 2005006969 A1	27-01-2005	NONE	

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 8718943 B **[0002]**
- US 20170095216 A1 **[0003]**
- US 9532738 B2 **[0040]**

Non-patent literature cited in the description

- **MEIDENBAUER et al.** *Nutrition & Metabolism,* 2015, vol. 12, 12 **[0049]**

专利名称(译)	个人健康监测系统，多用户健康监测系统和方法		
公开(公告)号	EP3443902A1	公开(公告)日	2019-02-20
申请号	EP2017186763	申请日	2017-08-18
[标]发明人	THE DESIGNATION OF THE INVENTOR HAS NOT YET BEEN FILED		
发明人	THE DESIGNATION OF THE INVENTOR HAS NOT YET BEEN FILED		
IPC分类号	A61B5/145 A61B5/1459 A61B5/00		
CPC分类号	A61B5/0004 A61B5/0031 A61B5/14532 A61B5/14546 A61B5/1459 A61B5/1473 A61B5/7275 G16H50/30 A61B5/1451		
代理机构(译)	NEDERLANDSCH OCTROOIBUREAU		
外部链接	Espacenet		

摘要(译)

本发明涉及一种个人健康监测系统，包括可植入传感器和监测装置。本发明还涉及一种包括多个这种个人健康监测系统的多用户健康监测系统。本发明还涉及监测至少一个用户的生物学参数的方法。