



(51) International Patent Classification:
A61B 5/00 (2006.01)

(21) International Application Number:
PCT/IL2011/000488

(22) International Filing Date:
20 June 2011 (20.06.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/344,273 22 June 2010 (22.06.2010) US

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(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,

ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

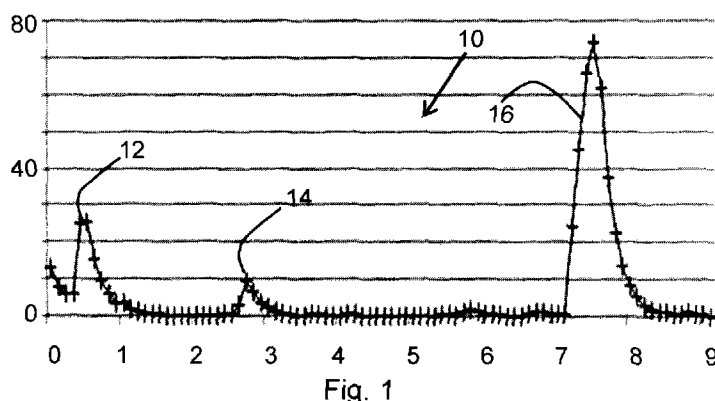
Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))
- of inventorship (Rule 4.17(iv))

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: IMPROVED SYSTEM AND METHOD FOR DETECTING SYMPTOMS OF HYPOGLYCEMIA



(57) Abstract: An improved system and method for detecting a hypoglycemic event of a diabetic individual is provided. The system of the invention includes at least three sensors for monitoring the respective physiological parameter selected from the following list: heart rate, motorial activity, respiring rate, vasoconstriction, temperature of the skin and galvanic resistance of the skin of the user. The system automatically alerts the user and/or a member of medical care personnel in a case that at least three different symptoms of a hypoglycemic event, each of which associated with a respective physiological parameter, simultaneously occur. According to the method of the present invention basal levels and basal rates of changes of the respective physiological parameters are generated and repeatedly updated. These basal levels and/or rates provides for detecting changes that go beyond predefined limits for determining a symptom of a hypoglycemic event which is associated with the respective physiological parameter.

IMPROVED SYSTEM AND METHOD FOR DETECTING SYMPTOMS OF HYPOGLYCEMIA

FIELD OF THE INVENTION

5 The present invention generally relates to the field of physiological measurement. More particularly, the present invention relates to a system and method for monitoring motorial activity and/or tremor, heart rate, respiration rate, peripheral vasoconstriction, surface temperature and electrical conductivity of the skin as means for detecting symptoms associated with hypoglycemic
10 event of a diabetic individual.

BACKGROUND OF THE INVENTION

 Hypoglycemic events are typically associated with a range of symptoms such as dizziness, impaired coordination, mental confusion, and
15 altered behavior, increased and irregular heart rate, enhanced perspiration, tremor and heavy respiration. An untreated hypoglycemic event may lead to extreme hypoglycemia that may result in spasms, coma, brain damage or even death. Therefore the development of noninvasive methods and systems for detecting symptoms of hypoglycemic events are ongoing.

20 A few exemplary systems and methods for detecting some of the above mentioned hypoglycemic symptoms that provide for alerting a user of an occurring hypoglycemic event are listed below. A system for detecting the level of perspiration is disclosed in US Patent US4365637. A system incorporating measurement of the skin temperature and the level of perspiration is disclosed
25 in US Patent US4509531. However, a study in which the last system was used along 1444 nights by insulin dependant diabetic subjects reveals a significantly high rate of false alarms. The main cause for the high false alarm rate is

interpreted by enhanced sleep sweatiness that is not caused by hypoglycemic event, as is reported in Diabetes Care, Vol.6, November 1983.

A system and method that is capable of screening out cases in which the skin temperature of a diabetes subject decreases and/or cases in which his or her perspiration level increases due to environmental situations other than hypoglycemic events is disclosed in US patent US7052472. The disclosed system automatically derives the rate of change of the skin temperature as well as the level of perspiration and compares them to respective basal rates that are continuously derived by the system. However, cases in which a hypoglycemic event is not associated with an increased sweatiness cannot be detected by such a system.

A system and method for monitoring heart rate especially including the length in time of the QT intervals by means of ECG signals and the mean or peak frequency of the alpha wave by means of EEG signals in addition to monitoring the impedance of the skin for monitoring perspiration level is disclosed in US patent US7450986. The disclosed method seems more robust and less susceptible to false alarms. However such system requires attaching electrodes to the skull of the user in addition to attaching electrodes to his or her chest. Such setup is somewhat cumbersome and less convenient compared to wristwatch like systems that can be attached to a limb of the user.

Another system that monitors the level of perspiration, detects tremor and looks for an increase in the heart rate is disclosed in Japanese patent application the publication number of which is JP20082535660A2.

A system and method for monitoring hemodynamic parameters, such as a radius of a peripheral blood vessel, by means of light scattering measurements is disclosed in US Patent US6280390.

Therefore a system capable for detecting hypoglycemic events which is characterized with high sensitivity and low false alarm rate is called for.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exemplary time profile of motorial activity of a type I diabetic subject;

Fig. 2 is an exemplary time profile of heart rate of the same individual
5 whose motorial activity is shown in Fig. 1;

Fig. 3 is an exemplary time profile of skin temperature of the same individual whose motorial activity is shown in Fig. 1;

Fig. 4 is an exemplary time profile of galvanic resistance of the skin of the same individual whose motorial activity is shown in Fig. 1;

10 Fig. 5 is an exemplary time profile of glucose suspended in the blood of the same individual whose motorial activity is shown in Fig. 1;

DETAILED DESCRIPTION OF THE PRESENT INVENTION

In accordance with the present invention an improved non-invasive
15 system and method for detecting a hypoglycemic event is provided. The method of the present invention provides for significantly reducing the rate of false alarms and yet retaining a high sensitivity of detecting hypoglycemic events at their early stages. A system of the invention is adapted and arranged for monitoring the following physiological parameters: i. heart rate; ii. motorial
20 level; iii. vasoconstriction and skin temperature, and iv. galvanic resistance of the skin. According to the method of the present invention changes in the level of each of these physiological parameters are recorded and compared to respective scales. A symptom of a hypoglycemic event is determined in any of the following cases: a. an increase in the heart rate which crosses and exceeds
25 a respective predefined threshold; b. an increase in the motorial level that crosses or exceeds a respective predefined threshold; c. a decrease in the galvanic resistance of the skin that down crosses a respective predefined galvanic resistance level, and d. vasoconstriction and/or a decrease in the temperature of the skin which exceeds a respective predefined rate of cooling.

A case in which any of the symptom of a hypoglycemic event is determined despite the fact that a hypoglycemic event has not occurred is considered as a false alarm. Reducing the rate of false alarms according to the method of the present invention is accomplished by diagnosing a hypoglycemic event when at least three different symptoms are simultaneously determined. However in this case the conditions for determining a symptom are somewhat less stringent. Namely, instead of independently comparing the magnitude of the change in the level of each physiological parameter to a respective threshold a combination of such deviations is first evaluated and its value is compared to a different predefined threshold, as further described infra.

Systems of the invention further monitor the ambient temperature of a user. In cases in which the ambient temperature changes, the level by which it is changed is considered for reducing biases that might be added to the measured temperature of the skin. A system of the invention further monitors the galvanic resistance of the skin for deriving the level of perspiration. Relatively high ambient temperature may impact the level of perspiration thereby add biases to, and/or obscure, the measured galvanic resistance of the skin. Therefore the measured levels of the galvanic resistance are such weighted according to the method of the present invention to reduce their impact in diagnosing hypoglycemic events in cases in which the ambient temperature exceeds a predefined temperature level. A three axes accelerometer incorporated in a system of the invention provides for monitoring the level of movements of the user and for detecting tremor.

An exemplary sensor for noninvasively monitoring vasoconstriction and evaluating the magnitude of the radii of the blood vessel considered has two light detectors that are spaced apart by a predefined distance such positioned that their active faces face the skin of a user. Each light detector comprises an illuminating LED that is operative in the range of near infra-red (NIR) and a photodiode of the same spectral range for receiving the light reflected off the skin. These light detectors are such placed onto the skin of a user that each light detector faces a segment of a peripheral blood vessel or a set of blood capillaries. Measuring the radius of a peripheral blood vessel is

accomplished, such as described in US Patent US6280390. However, detecting the phenomena of vasoconstriction can be accomplished by means of only one such light detector. Namely monitoring vasoconstriction is accomplished according to the method of the present invention by measuring
5 the intensity of infrared light reflected off the skin by means of one such light detector. A case in which the magnitude of the radius decreases such that the amplitude of the reflected light decreases below a given predefined level is considered according to the method of the present invention as a symptom of suspected hypoglycemic event. One such light detector can implement
10 according to the present invention as a multipurpose sensor for monitoring pulse or heart rates as known and for monitoring vasoconstriction as well as for implementing a non-contact temperature sensor for measuring the temperature of the skin. Obviously the amplitude of the intensity of light scattered off the skin and received by the photodiode considered is proportional to the quantity of
15 blood that passes through the peripheral blood vessels. The rate in which peaks of the time profile of this amplitude occur is equivalent to the pulse rate. Additionally, the intensity of the reflected light averaged along a time interval that include a few pulses, is proportional to the average quantity of blood that passes through the peripheral blood vessels along a time unit and therefore
20 functionally dependent (when a single valued function is considered) on the temperature of the skin. Therefore by employing a suitable calibrating curve the respective temperature of the skin is derived. Whenever the same system component is used as a multipurpose sensor it is regarded according to the present invention as a bunch including the respective number of different
25 sensors that are independently incorporated into the system of the invention.

An improved and non-invasive system for detecting hypoglycemic events according to a preferred embodiment of the present invention has two separate units. One of the units, which is the first unit, is structured such as a wristwatch having a chassis to which a strap attachable to a limb of a user is
30 connected. This unit is equipped with two non-contact temperature sensors. A light detector such as described above implements one of these non-contact temperature sensors. This light detector is such positioned at the inner surface of the chassis that it faces a peripheral blood vessel or a bunch of capillaries.

The same light detector is regarded as a second sensor that additionally provides for measuring the heart rate, as described above. The other temperature sensor is such connected to the external surface of the chassis that it cannot face the skin of the user. Alternatively according to another preferred embodiment of the present invention a cable connects the second temperature sensor to this unit such that it can be placed and directed aside of the user. A sensor for monitoring the level of perspiration is implemented by means of two spaced apart electrodes (by a predefined distance). Both electrode are attached to the inner surface of the strap such that a segment of each electrode touches the skin of the user. Both electrodes are electrically connected to a an electric circuitry for measuring the galvanic resistance a segment of the skin which electrically connects between them. This electric circuit is attached to the chassis. A three axes accelerometer connected to a dedicated electric circuitry implements the movement, or rather the motorial activity sensor which is also housed in the chassis of the first unit. All the above mentioned sensors are connected to respective sampling and digitizing units which are further connected to a programmable processor having a memory. This processor is operative inter alia in comparing the monitored levels of the physiological parameters considered to respective scales stored in its memory; carrying out numerical calculations such as for deriving the heart rate, or the spectrum of the motorial activity of the user. The processor is similarly installed in the chassis of the first unit. Electrical cable that includes wires respectively leading control signals and power connects between the first and second units of the system. The second unit is housed in a case that can be placed near by the user. The second unit includes electrical power supply and an alarm member implemented by a buzzer which is activated by the processor of the first unit. Additional electrical cable provides for connecting the power supply to an external power line. Alternatively, the power supply is substituted with rechargeable batteries. Optionally the second unit is further electrically connected by means of a wireless link, such as by employing Bluetooth protocol to a remote alarm unit for alerting a care providing personnel member, or a relative of the user, in cases of diagnosed hypoglycemic events.

Monitoring any of the aforementioned physiological parameters provides for deriving a respective instantaneous levels as well as deriving the respective basal levels the monitored parameters and/or rates of their respective changes. Deriving the instantaneous level and/or rate of change of a monitored parameter is accomplished as known by averaging a predefined number of samples. Averaging can be accomplished by means of a moving window technique which considers a relatively small number of elements; and/or averaging by means of a FIFO filter that considers samples received along a relatively small time intervals which are referred hereinafter as measuring time intervals. These measuring time intervals are respectively of a few seconds up to a number of minutes. The respective basal levels and/or rate of changes are derived according to the present invention by averaging measured instantaneous levels along a relatively long time interval, which is referred hereinafter as the basal time interval and ranges along a few dozens of lengths of measuring intervals, such as of a number of dozens of minutes. In accordance with the method of the present invention statistical analysis is continuously carried out by which characteristic statistics, and statistical moments such as mean value and standard deviation of each of the physiological parameters are repeatedly updated. Such updating goes on along each and every time in which the system of the invention is used. Therefore, at initial stages of each daily operation long term mean values can be used instead of respective basal levels as long as the respective basal level has not stabilized in time yet. The currently updated basal levels, and characteristic statistics, as well as the long term statistics are stored in the memory of the system processor to be used as respective scales against which the instantaneous levels are compared. Additionally, in accordance with another embodiment of the present invention, whenever an instantaneous level of any of the physiological parameters exceeds the basal level by more than a predefined portion of the magnitude of respective long term standard deviation, a hypoglycemic event is diagnosed regardless of the measured levels of the other physiological parameters.

The instantaneous level of the temperature of the skin and/or the ambient temperatures is repeatedly measured at a predefined repetition rate

(which equals the reciprocal of the length of the measuring time interval). In cases in which the currently measured instantaneous skin temperature decreases compared to the respective basal level at a rate faster than the rate by which the ambient temperature decreases and/or at a rate that exceeds a predefined threshold, such temperature decrease is considered according to an embodiment of the method of the present invention for determining a symptom of decreasing skin temperature that is indicative to a hypoglycemic event.

The instantaneous level of the galvanic resistance of the skin is compared to the respective scale such as typically recorded in handbooks. Alternatively such a scale is experimentally derived by carrying out suitable statistical analysis for determining typical galvanic resistance levels that respectively correspond to the resistance of a skin under different levels of sweatiness. When the currently measured resistance gets down compared to such scale and crosses a predefined threshold a symptom of hypoglycemic event associated with perspiring is determined. When the ambient temperature is lower than a predefined temperature it is unlikely that such perspiring is caused by the ambient temperature. Therefore such crossing of the threshold of galvanic resistance is considered as a sweatiness symptom of suspected hypoglycemic event.

Signals of the three axes accelerometer are repeatedly sampled along each axis at sampling frequencies which range a number of dozens of cycles per second (CPS) up to say ten dozens of CPSs. A spectrum of these signals is derived according to a preferred embodiment of the method of the present invention, as described following. First the number of crossing along any of the three axes of a predefined level of acceleration, which occur along one second is counted in each and every second. Then the system time tags and records those seconds that such crossing of this acceleration level has occurred at least a predefined number of times per second, say a dozen crossing per second. Such seconds are considered according to the present invention as motorial active seconds. Then the number of motorial active seconds that are included within a measuring time interval having a predefined length, say of a given number of minutes, is referred hereinafter as the measured number of active

seconds, its value is time tagged and recorded. Values of measured numbers of active seconds are averaged along a basal time interval for deriving the basal number of motorial active seconds that are included within a measuring time interval. The length of a basal time interval equals the length of the
5 aforementioned measuring time interval multiplied by, say, dozen times. A symptom of a hypoglycemic event associated to the increased motorial activity is determined when the number of active seconds included within the current measuring time interval exceeds the basal value by at least a given number. The various thresholds, namely the level of acceleration considered for
10 determining a crossing, the number of crossing above which a second is regarded as motorial active second, as well as the threshold for determining a symptom that whenever the number of active seconds that are included in a measuring time interval exceeds it, are experimentally derived by conducting statistical analysis of measurement during trials in which insulin dependent
15 diabetic subjects take part.

Alternatively a spectrum of the cyclic movements such as of heart rate and/or mechanical vibrations can be computed such as by carrying out DFT calculations. Abrupt movements of the user that are typical to tremor are characterized with predefined frequencies. Similarly respiration rates can be
20 derived from such computed spectra of the amplitude of the pulses measured with the light detector. By subtracting the magnitudes of the relevant frequency levels from the respective basal magnitudes and comparing the derived differences with respective threshold levels provides for detecting tremor as well as for detecting an increase in the respiration rate. Hence a system that has
25 three axes accelerometer and a light detector is capable for detecting symptoms of increased movement, tremor and increased respiring rate in addition to monitoring vasoconstriction and detecting events associated with cooling down of the skin. One light detector in combination with respective software programs installed in the system processor provides according to the
30 present invention instead for measuring levels of four different parameter such as accomplished by means of four independent sensors. Embodiment variants of the system for detecting hypoglycemic event in which such light detector is incorporated and used as multipurpose sensor are in accordance with the

present invention. Such multipurpose sensor is respectively regarded hereinafter as a bunch of two, three and/or four different sensors, each of which is independently linked to the system processor.

5 A basal respiration rate is derived by averaging instantaneous respiring rates. The instantaneous respiring rates are derived in consideration with the lower frequencies of the spectrum of the DFT analysis of the pulses of blood their amplitude is measured such as with a light detector, as known. The level by which an instantaneous level deviates from the respective basal rate is compared to calibrating scale. When this deviation exceeds a predefined
10 threshold a symptom of heavy respiring is determined.

In cases in which all the above mentioned symptoms simultaneously occur a hypoglycemic event is detected according to an embodiment of the method of the present invention. Alternatively scores associated with at least some of the above mentioned parameters are evaluated and their summation
15 exceeds a respective predefined threshold level a hypoglycemic event is diagnosed. Obviously in cases that smaller number of symptoms is simultaneously determined the rate of false alarm increases if one retains the same sensitivity of detection.

Following is a description of the process for diagnosing a
20 hypoglycemic event according to a preferred embodiment of the present invention. This process is applicative in cases in which at least three physiological parameter are monitored, wherein those three are selected out of the following physiological parameters (i) motorial activity, (ii) heart rate, (iii) respiring rate, (iv) temperature of the skin or preferably vasoconstriction without
25 evaluating the radii of the blood vessels, and (v) galvanic resistance of the skin.

First, levels of the differences between the instantaneous levels measured at each and every measuring cycle and the basal level of the respective monitored physiological parameters (except for the perspiration sensor) are scored. Scoring is accomplished by mapping the respective
30 maximal level of any of the differences according to the method of the present invention to one. (similarly any instantaneous level measured for the

physiological parameter considered, that is higher than such maximal level, is also mapped to one.) any level of such difference which equals zero or is negative is mapped to zero. The full range between the maximal level of difference is linearly mapped into the open interval (0,1). Scoring levels of galvanic resistance of the skin is accomplished by mapping the range of the respective levels of galvanic resistances into the closed interval [0,1] as follows: any resistance which equals or exceeds a predefined maximal level of resistance, such as 250 K Ω , is mapped to zero. Any resistance which equals or is lower compared to a predefined minimal resistance, say 100 K Ω , is mapped to one. All the levels between these two limits are linearly mapped into the open interval (0,1) in accordance with the equation $S=1-(R-100)/150$, where S is the score received for these predefined maximal and minimal levels of resistance; R is the level of the measured galvanic resistance given in K Ω . The minimal and maximal levels are derived by statistically averaging measurements results of experiments in which a large number of diabetic participants took part. The differences that are associated to the physiological parameters other than the levels of galvanic resistance of the skin are scored as follows: first a range of the differences between an instantaneous level and the basal level is selected then the upper end of this range is mapped to one. And differences that are negative or equals zero are mapped to zero. Any intermediate level is respectively scored by dividing its value by the magnitude of the upper limit. Therefore all the intermediate levels are mapped into the open interval (0,1).

Such derived scores for all the monitored parameters are summed together into a combined score. The combined score is further compared to a respective threshold level. When the combined score exceeds a predefined threshold level a hypoglycemic event is detected. In cases of ambient temperature that is too high that might cause the user to perspire, it is preferable to avoid using the perspiration sensor and the threshold for the combined score is lowered accordingly. Such approach provides for retaining the level of sensitivity however on the other hand, the rate of false alarms is somewhat increased. In cases in which the ambient temperature decreases at a rate higher than a predefined cooling rate, it is preferable according to the method of the present invention to avoid using the skin temperature sensor for

a while and wait until the ambient temperature stabilizes. A different predefined threshold level for the combined score that does not consider the score associated to skin temperature is used in such case. Such approach provides for retaining the sensitivity level of the system however the rate of false alarm is
5 somewhat increased.

EXAMPLE 1

An experiment in which a group of insulin dependent diabetic members, each using a system for detecting hypoglycemic events according to
10 an embodiment of the present invention, is hereby described with reference to **Figs 1 – 5**. Time profiles of the motorial activity, heart rate, temperature of the skin, galvanic resistance of the skin, and the level of glucose suspended in the blood, all of which were derived for an exemplary user, are respectively shown in **Figs 1 – 5**. The horizontal axis shown in each of this graphs indicate time
15 measured in hours starting at the beginning of a night sleep. Identical lengths of the measuring time interval are employed in any of the graphs shown, all of which equals five minutes. The systems employed are structured such as a wristwatch to be worn on an arm of the user. The systems include: a light detector for measuring heart rate; thermistor that implements temperature
20 sensor for measuring skin temperatures; a sensor for measuring galvanic resistance of the skin and three axes accelerometer operated in a mode for measuring motorial activity as described hereinabove. Commercial Glucometer of the type Dexcom Seven Plus continuously intrusively monitored the actual level of glucose suspended in the blood of the users. The scale of the vertical
25 axis of **Fig. 1** is dimensionless. Plot **10** is the time profile of the number of

motorial active seconds included in any measuring time interval. Peaks **12**, **14**, **16** can be interpreted as presenting determined symptoms. Namely cases in which a significant change of the number of active seconds currently occurred compared to the basal count. The value of basal level that provide for deriving

5 Peak **12**, might be questionable due to stabilization time that could be longer compared to the time elapsed from the moment in which measuring is started. Nevertheless point **14** indicates a symptom of a hypoglycemic event related to motorial activity which simultaneously occurs with symptom of the other three physiological parameters at the same point in time. (This point in time is fifteen

10 minutes prior to three.) Plot **20** presents the time profile of the pulse rate, the units of the vertical axis are beats per minute, measuring the pulse rate is repeatedly accomplished each and every measuring time interval. The peak located close to point **22** corresponds to a symptom of an increased heart rate, by indicating a change in the currently measured pulse rate compared to the

15 basal rate of about nine pulses per minute. Indeed point **22** indicates determining a symptom of a hypoglycemic event related to increased pulse rate, which occurs synchronously with the symptom indicated by point **14**. Successive points leading to point **24** of the following peak correspond to changes of three beats per minute at most. Plot **30** presents the time profile of

20 the temperature of the skin, measured in degrees Celsius. Point **32** indicates a state in which symptom of a hypoglycemic event related to falling temperature of the skin is determined. There are additional points along this plot that exhibit decreasing temperature however none of these additional points comply with respective symptoms of motorial activity nor of heart rate. Therefore according

25 to the method of the present invention any of these additional points cannot

provide for diagnosing a hypoglycemic event even in cases that there are respective points that belong to the time profile of the galvanic resistance of the skin which respectively present determined symptoms of enhanced perspiring. The scale of **Fig. 4** is measured by kilo-Ohms; plot **40** presents the time profile of the galvanic resistance of the skin. Point **42** indicates a point in time in which the combined scoring according to the preferred embodiment of the method of the present invention for diagnosing a hypoglycemic event described hereinabove. Plots **30** and **40** are significantly more oscillatory compared to plots **10**, **20** and **50**. Indeed the temperature of the skin normally varies along time during the night by a few degrees Celsius. Covering with a blanket and/or exposing the temperature sensor and the organ onto which this sensor is attached to the ambient air, may easily cause such variations. Therefore it is preferable according to the method of the present invention to monitor respiring rates rather than the temperature of the skin, thereby promoting the chances for retaining high sensitivity and a relatively lower false alarm rate.

Furthermore, perspiring can occur independently of a hypoglycemic event. However, most of the hypoglycemic events are associated with heavily perspiring. Therefore lack of perspiring may require more stringent conditions for diagnosing a hypoglycemic event and retaining a permissible rate of false alarms.

Plot **50** present the actual time profile of the level of glucose suspended in the blood of this very user. Point **52** is the very point of this plot that corresponds in time to points **14**, **22**, **32**, **42**. Indeed a level of 65 mg/ml of glucose corresponds to a situation of a user who experiences for quite a

significant time a hypoglycemic event. (However for the sake of full disclosure a statement should be made with regard to poor calibration of the continuous glucometer at relatively low levels of concentration of glucose, namely levels which correspond to hypoglycemic event can be erroneous by dozens of
5 percents or more since calibrating at such levels is practically impossible).

CLAIMS

1. A method for non-invasively detecting a hypoglycemic event comprising:

- 5 • comparing a level of each of at least three different physiological parameters to a respective scale for evaluating changes occurring in any of said levels;
 - 10 • determining a symptom of hypoglycemic event respectively related to each of said at least three physiological parameters, when a change in the level of each of said at least three physiological parameters crosses a predefined level, which is associated to the respective physiological parameter of said at least three physiological parameters, and
 - 15 • correlating in time said determined symptoms with each other, for detecting a hypoglycemic event when at least three of said determined symptoms simultaneously occur, and
- wherein each of said physiological parameters is selected from a group of physiological parameters consisting of: heart rate, respiring rate, motorial activity, vasoconstriction, skin temperature, galvanic resistance of the skin, and any combination thereof.
- 20

2. A method as in claim 1, further comprising respectively scoring the changes in the levels of at least two of said physiological parameters prior to said determining.

3. A method as in claim 2, wherein a combined score is derived in consideration with said scores which is further compared to a predefined threshold prior to said detecting a hypoglycemic event
- 5 4. An improved system for non-invasively detecting hypoglycemic event having an alarming member which can be activated by an integral programmable processor, said system comprising at least three different sensors for monitoring levels of respective physiological parameters, wherein each of said physiological parameters is selected
10 from a group of physiological parameters consisting of: motorial activity, heart rate, respiring rate, vasoconstriction, temperature of the skin, galvanic resistance of a skin and any combination thereof, and wherein said at least three sensors are linked to said programmable processor, and wherein said programmable processor is operative at
15 least in comparing a level of at least one of said physiological parameters, which is the first physiological parameter, with a respective scale stored in a memory of said programmable processor.
5. A system as in claim 4, wherein said programmable processor is
20 further operative in determining a symptom of a hypoglycemic event associated with said first physiological parameter when said level of said first parameter crosses a predefined level stored in said memory.
6. A system as in claim 5, wherein said symptom of hypoglycemic event
25 associated with said first physiological parameter is the first symptom, and wherein said programmable processor is further operative in

determining at least another symptom of hypoglycemic event, which is the second symptom that is associated with a physiological parameter which is different from said first physiological parameter, and wherein said programmable processor is further operative in time correlating said first symptom with said second symptom for detecting a hypoglycemic event.

7. A system as in claim 4, wherein said programmable processor is further operative in evaluating changes in the level of said first physiological parameter in consideration with said scale.
8. A system as in claim 7, wherein said programmable processor is further operative in scoring said evaluated changes and comparing the evaluated score, which is the first score, to a respective scale for determining a symptom of hypoglycemic event, which is the first symptom determined by scoring, and is associated with said first physiological parameter.
9. A system as in claim 8, wherein said programmable processor is further operative in evaluating changes in a level of at least one additional physiological parameter which is different from said first physiological parameter, and wherein said programmable processor is further operative in scoring said changes and determining a symptom of hypoglycemic event related to the additional physiological parameter, which is the second symptom determined by scoring, and wherein said programmable processor is further operative in deriving

a combined score in consideration with said first and second symptoms derived by scoring.

10. A system as in claim 4, wherein said system structured and arranged,
5 such as a wristwatch, to be worn on a limb of a user.
11. A system as in claim 11, wherein said alarming member is electrically connected to said programmable processor by means of a wireless link.

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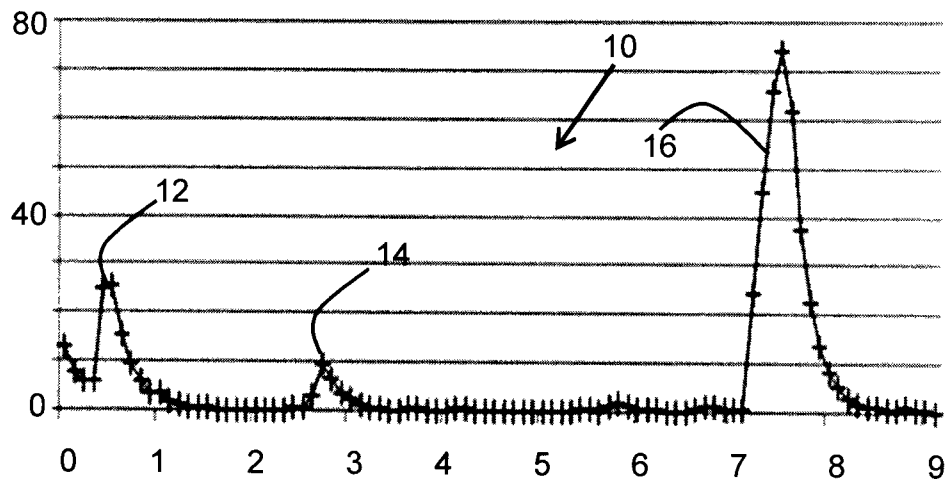


Fig. 1

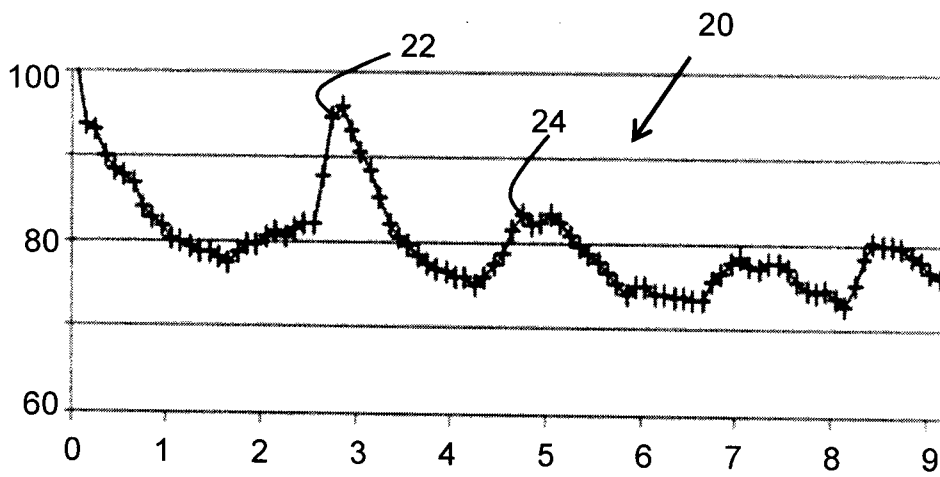


Fig. 2

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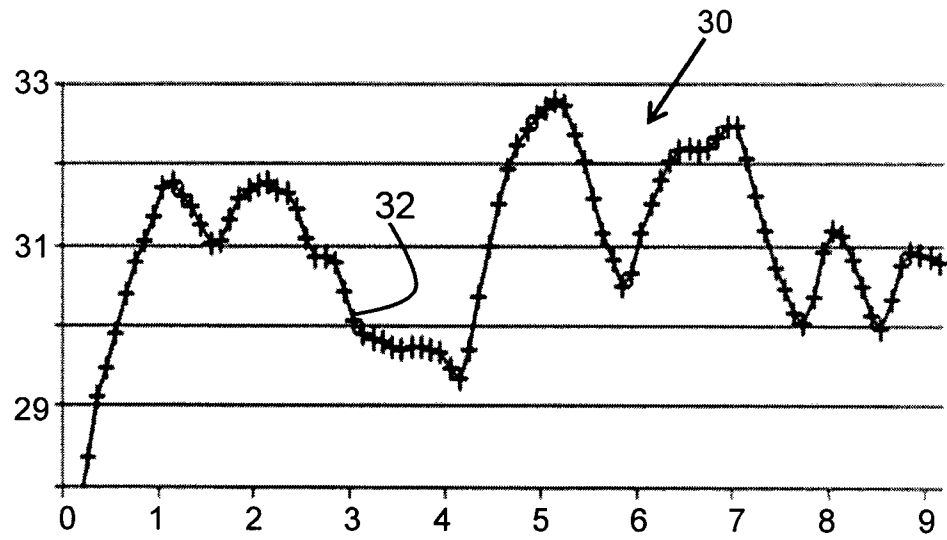


Fig. 3

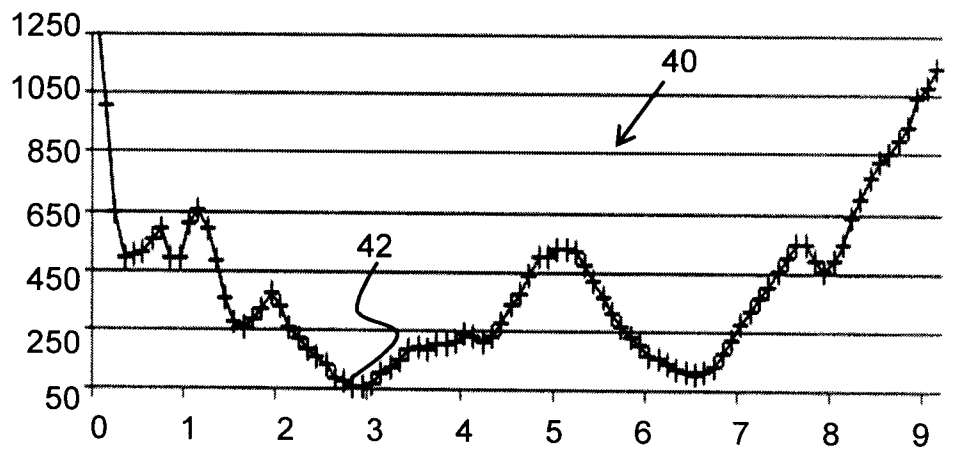


Fig. 4

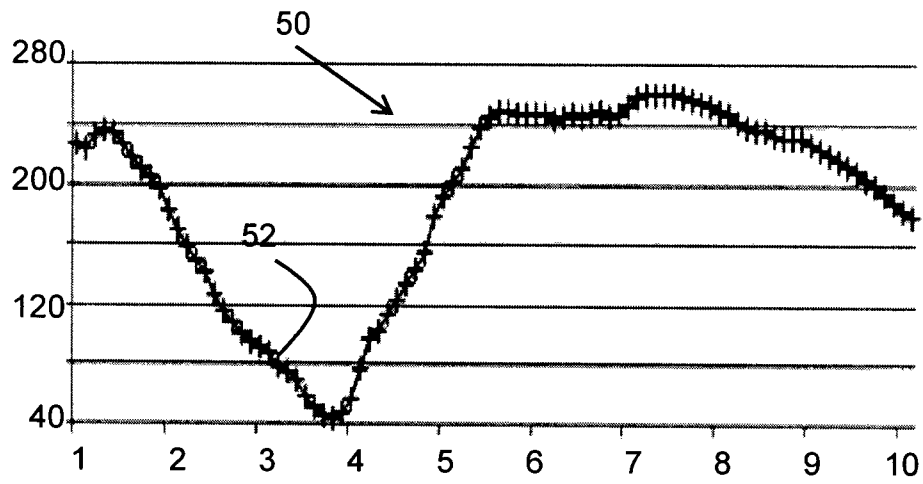


Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL 11/00488

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 5/00 (2011.01)

USPC - 600/365

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

USPC: 600/365

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

USPC: 600/365, 600/316; 600/346; 600/347; 600/365

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

DIALOG: (All Patents); Google Scholar

Search Terms: HYPOGLYCEM, DETECT, WARN, MEASURE, MONITOR, HEART RATE, SKIN TEMP, GALVANIC RESIST), alarm

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0030092 A1 (KRISTENSEN et al.) 4 February 2010 (04.02.2010): para. [0009]-[0016], [0017], [0020], [0028], [0030], [0032], [0034], [0036], [0049], [0050], [0061].	1-11

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

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

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

08 November 2011 (08.11.2011)

Date of mailing of the international search report

23 NOV 2011

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

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专利名称(译)	用于检测低血糖症状的改进系统和方法		
公开(公告)号	EP2584959A4	公开(公告)日	2014-03-12
申请号	EP2011797725	申请日	2011-06-20
[标]申请(专利权)人(译)	吉里医疗有限公司		
申请(专利权)人(译)	GILI MEDICAL LTD.		
当前申请(专利权)人(译)	GILI MEDICAL LTD.		
[标]发明人	SCHECHTER AMIR		
发明人	SCHECHTER, AMIR		
IPC分类号	A61B5/00 A61B5/02 A61B5/0205 A61B5/024 A61B5/053 A61B5/08 A61B5/11 A61B5/145		
CPC分类号	A61B5/0205 A61B5/00 A61B5/02007 A61B5/024 A61B5/0531 A61B5/0816 A61B5/11 A61B5/1118 A61B5/14532 A61B5/6802 A61B5/681 A61B5/7246 A61B5/7282 A61B5/746		
优先权	61/344273 2010-06-22 US		
其他公开文献	EP2584959A1		
外部链接	Espacenet		

摘要(译)

提供了一种用于检测糖尿病个体的低血糖事件的改进系统和方法。本发明的系统包括至少三个传感器，用于监测从以下列表中选择的相关生理参数：心率，运动活动，呼吸速率，血管收缩，皮肤温度和使用者的皮肤的电阻。在低血糖事件的至少三种不同症状同时发生的情况下，系统自动警告用户和/或医疗护理人员。根据本发明的方法，生成并重复更新各个生理参数的基础水平和基础变化率。这些基础水平和/或速率提供检测超出预定限制的变化，以确定与相应生理参数相关的低血糖事件的状况。