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Description

[0001] This invention relates to a patient monitor, which is used in such a manner to monitor certain physiological conditions of a patient, and transmit the signals relating to these physiological conditions to a receiver unit, where the signals are processed to analyse and inform the patient/carer the severity status of the physiological condition.

[0002] More specifically the invention relates to a non-invasive method and apparatus for determining the onset of physiological conditions, such as, hypoglycaemia, hyperglycaemia, irregular blood glucose levels (BGL) and onset of fatigue.

[0003] Earlier filed patent application WO 02/069798, relates to a non-invasive method and apparatus for determining onset of physiological conditions such as hypoglycaemia, irregular BGL, SIDS and the onset of fatigue.

[0004] As disclosed in the above PCT application:

- It is desirable with some physiological conditions to be able to monitor a patient in a non-invasive manner so that when a physiological condition presents itself, an alarm signal is triggered. The alarm activation will enable the patient to take remedial action or medication to prevent that physiological condition causing harm to the patient.
- Certain physiological conditions, such as hypoglycaemia can be extremely dangerous and in many cases the symptoms can occur without the patient becoming aware of his/hers low BGL. The drop in BGL can occur reasonably fast, hence, a fast and accurate monitoring of low BGL (hypoglycaemia) is essential, particularly, when the BGL is being monitored indirectly. The indirect BGL measurement methodology occurs by the monitoring of certain physiological parameters, including, skin impedance, heart rate, certain components of the electrocardiogram (such as QT interval) and their subsequent rate of change over the time.
- It is also desirable that monitoring these physiological parameters cause minimal discomfort to the patient. Since many patients will require to monitor the physiological conditions for long periods of time (e. g. throughout the night), it is important that the monitoring system can be set up and used with minimum inconvenience and discomfort to the patient.

[0005] Prior art patent specifications have described various forms of belt or chest straps for monitoring certain physiological functions of the patient or user. For example one such belt is described and shown in U. S. Pat. No. 5,036, 869, which uses chest belt with wireless telemetry system to transmit body signals from human body to a receiver. The body signals measured include electrode discharge detecting circuit, pacemaker signal detector, ECG and non-invasive sphygmomanometer (blood pressure measurement). These signals are then decoded and data processed by the receiver unit and interfaced to a generic measurement apparatus. The disclosed patent's claims are focused towards the telemetry platform of the system, and enhanced capability for measuring multiple body signals. Another patent described in U. S. Pat. No. 4, 889, 131 discloses a portable belt-type monitor which measures breathing and heart rate and produces an alarm signal when dysfunctions are detected. The alarm signals are then transmitted via wireless telemetry platform to a remote receiver unit. The core claims within this patent specification discuss the improved method of measuring ECG (or EKG) and respiration parameters. The claims also disclose a portable microcomputer system, with display, which can be attached to the described utility chest belt.

[0006] There are other chest-belt monitoring systems, including patents such as US 5,464, 021, US 4,966, 155, GB 2,291, 505 and GB 2,368, 645. In general, the devices and systems disclosed within these prior art specifications do not exhibit methodology and functionalities for detecting the early onset of certain physiological conditions. These prior art systems do not have the real- time analytical capabilities for detecting the onset of the physiological conditions.

[0007] US 2002/019586 discloses a device in accordance with the preamble of claim 1.

[0008] According to the invention there is provided a monitoring device for monitoring the physiological condition of a patient on a continuous basis, the monitoring device comprising: a transmitter unit adapted to attach to a patient so as to be in contact with the skin of a patient, the transmitter unit including: attachment means comprising a chest belt adapted to attach to or around the chest of a patient;at least three sensors mounted to the attachment means adapted to monitor a plurality of patient parameters, the sensors adapted to produce signals related to the parameters being monitored; a microcontroller to which the sensors are connected, the microcontroller being adapted to process the signals; and a wireless transmitter to which the microcontroller is connected, the wireless transmitter being adapted to transmit a processed signal related to the patient parameters monitored by the sensors; a portable receiver unit adapted to receive and process the signal received from said wireless transmitter, the portable receiver unit comprising: a wireless receiver adapted to receive the signal from the wireless transmitter; a processor adapted to process the signal; and display means for displaying data relating to the patient characterised in that: the sensors are adapted to monitor at least the skin impedance, heart rate and ECG of the patient, a switching circuit is provide for switching the sensors from measuring one parameter to measuring another parameter in accordance with a pre-programmed switching sequence, and the physiological condition which the device is adapted to monitor is a hypoglycaemic condition.

[0009] The portable receiver unit will preferably include communication means for communicating with a network. The

receiver unit will preferably also include an input keyboard for inputting data and communicating with the receiver unit.

[0010] The transmitter unit preferably includes analogue electronics circuitry to pre-filter, process and prepare the signals related to the physiological conditions monitored by the sensors and interface to the microcontroller.

[0011] The microcontroller may be adapted to perform all required control mechanism for the transmitter unit, provide digital signal processing of the information by the pre-processed analogue circuitry and prepare these signals for wireless transmission.

[0012] The wireless transmitter to which the microcontroller is connected may be adapted to transmit the digitally processed signals related to the physiological conditions monitored by the sensors.

[0013] These and other features and advantages of the invention will be made apparent from the description of an embodiment thereof given below by way of example. In the description reference is made to the accompanying drawings, but the specific features shown in the drawings should not be construed as limiting on the invention.

Figure 1 shows a patient with a chest-belt transmitter together with a handheld processing unit formed in accordance with the present invention.

Figure 2 shows a greater detail view of the chest-belt transmitter unit, including the sensors for use therewith.

Figure 3 shows in diagrammatic form the chest-belt transmitter and the handheld receiver unit according to the present invention.

Figure 4 shows the detailed functional block diagram of the chest-belt transmitter unit.

Figures 5a, 5b and 5c show the format of the packet stream transmitted by the chest-belt transmitter.

Figure 6a and 6b show the data acquisition process embedded within the central processing unit of the handheld receiver.

Figure 7 shows the contents sample to be displayed in the display unit within the hand held receiver unit.

[0014] Referring to figure 1, a patient 1 as shown wearing a chest-belt unit 2 which is located around the patient in the upper thoracic region of the patient. The chest-belt unit 2 includes an adjustable elasticated strap 3 which is adapted to engage tightly around the patient's chest using a suitable and secure fastening system 6 which is relatively easy to engage and disengage to enable the belt unit 2 to be put on and taken off without difficulty. The strap unit 3 can also be adapted to fit around a child's chest in the same manner as the adult patient. The belt unit 2 incorporates an electronic housing 4 located in the centre of the belt unit 2, in front of the patient. The housing 4 includes, within its enclosure, a wireless transmitter, analogue electronic circuitry and a microcontroller, which will be described in more detail below.

[0015] Associated with the belt unit 2, is a hand-held receiver unit 5 which is adapted to process signals monitored by the unit 2 and transmitted to unit 5 by the transmitter unit located within the housing 4. The units 2 and 5 will be encoded to communicate only with each other.

[0016] As shown in figure 2, the belt unit 2 embeds four sensors which have been marked as E1, E2, E3 and E4 located on the underside thereof. These sensor units, E1 to E4, are in the form of skin surface electrodes and each of these sensors E1 to E4 is adapted to monitor a different patient physiological parameter. The sensors E1 to E4 will measure physiological parameters such as skin impedance, ECG and segments thereof, including QT-interval and ST-segment, heart rate and the mean peak frequency of the heart rate. These aspects are further discussed in detail in WO 02/069798.

[0017] The sensors E1 to E4 are composed of a conductive polymer based material such as polypyrrole, having low impedance and low noise characteristics. These characteristics enable the sensors to measure ECG quality signals of the patient. These electrodes will also preferably be flexible so that the belt unit 2 will fit uniformly across the chest of the patient, and the electrodes will conform to contours of the chest, thereby ensuring quality contact at all times. The elasticity of the strap 3 will be such as to ensure proper contact of the electrodes with the user's skin.

[0018] As shown in the block diagram of figure 3, the electrodes E1-E4 provide the signals which interface to the front-end analogue electronics circuitry 7 in which they are processed, amplified, filtered and interface to the microcontroller (μC) unit 8. The μC unit 8 digitises the signals using an A/D (analogue-to-digital) converter and transmits the digitised signals via a wireless communication platform modulator 9 to the central receiver unit 5. In the unit 5, the received will be demodulated by a wireless receiver unit 10 and stored into the random access memory (RAM) of a central processing unit (CPU) 11. A blood glucose monitoring, hypoglycaemia and other physiological conditions detection algorithm 12 will then be used to calculate and estimate the onset of these conditions. The manner in which this is done is described in detail in the prior patent application WO 02/069798. The resulting data will then de displayed in a display unit 14. The data can also be used to trigger an alarm system 15 to inform the patient or his or her carer as to the status relating to his or her physiological condition. In addition, the central receiver unit 5 includes a network communication port 16 with which the patient can communicate information relating to his or her physiological condition to a medical practitioner such as an endocrinologist or cardiologist.

[0019] Figure 4 shows the detailed function operation of the belt unit 2. The electrodes E1-E4 are multiplexed and shared to measure the physiological parameters such as the ECG and skin impedance. Hence, these electrodes are

interfaced and controlled by an electrode switching circuit 17. This circuit unit 17 determines which physiological parameter is to be measured and directs the signal to the appropriate monitoring circuit, i.e. either the ECG monitoring circuit 18 or skin impedance monitoring circuit 19. The actual switching timetable will be pre-programmed and stored within the μC unit 8.

[0020] The ECG signal output from the monitoring circuit 18 is amplified, filtered within the ECG signal bandwidth of 150 Hz and interfaced to the A/D component of the μC unit 8. The skin impedance circuit 19 uses a variable frequency constant-current sinusoidal signal that is directed to one of the electrodes and the resulting voltage measured represents the skin impedance of the patient. The constant-current signal by the unit 19 uses a frequency range between 1 kHz and 1 MHz with a current amplitude between 10 μA and 1 mA. The resulting voltage measured by the electrodes are amplified, filtered and rectified by the monitoring unit 19, and interfaced to the A/D component of the μC unit 8, represent a DC signal representing the skin impedance of the patient. The monitoring circuit 19 also incorporates a gain switching circuitry which provides the amplification of skin impedance using three gain settings, i.e. gain of 1, 3 and 10. The A/D circuit within the μC unit 8 digitises the physiological signals into a 12-bit digital signal and stores these signals appropriately with the memory unit of 8.

[0021] The belt unit 2 consists of a body contact detection circuit 21 which is used to monitor and detect the detachment of the belt unit 2 from the patient. A digital output signal from this detection unit 21 is interfaced to the μC unit 8, representing the status of contact of the belt unit 2. That is, a digital signal high ("1") indicates belt unit 2 in contact with patient, a digital signal low ("0") indicates lift-off from patient. The belt unit 2 also consists of a calibration circuit 20 used to calibrate the measured signals by the skin impedance circuitry 19. Prior to the measurement of each skin impedance parameter, the circuit 20 switches a known impedance source (test circuit with known resistance value) at the input to the sensors E1-E4, and measures the resulting calibration signals, via the monitoring circuit 19, and stores the signal values in the μC unit 8. During the measurement of actual skin impedance signals, the circuit 19 disables the known impedance and resumes normal operations. The calibration signals are then used to calculate the accuracy of the constant-current source and the measured actual skin impedance values by the following:

Skin impedance (test circuit) measured from output of circuit 19 (in volts) = SI_t

Skin impedance (actual) measured from output of circuit 19 (in volts) = SI_a

Known resistance value in test circuit (in ohms) = R_t

Constant-current source (calculated) $I_{const} = SI_t / R_t$

Therefore, SI_a (in ohms) = SI_a / I_{const}

[0022] As shown in figure 5a, the stored digitised signals obtained by μC unit 8 from the circuit unit 18 (EGG signals), circuit unit 19 (skin impedance) and battery monitoring circuit 22 are compiled and tagged to form a 16-bit data packet 24. The format of this 16-bit packet is 24 comprises of 12-bit signal data 25 together with a 3-bit identification header 26. Figure 5b provides the description for each of the 3-bit ID header 26. ID bit 000 represents a zero packet, bit 001 represents the skin impedance using the calibration unit 20 to obtain the SI_t value, bit 010 represents skin impedance with zero impedance using unit 20, bit 011 represents measured skin impedance using gain of 1, bit 100 represents measured skin impedance using gain of 3, bit 101 represents measured skin impedance using gain of 10, bit 110 represents the amount of charge left in the battery of unit 2 and bit 111 represents an ECG value.

[0023] As shown in figure 5c, the μC unit 8 further formats the 16-bit packet 24 into a long data stream sequence 27, which will be transmitted by the transmitter unit 9 and consequently received by the receiver unit 10. The data stream 27 consists of five skin impedance values (SI_t, SI_S, SI_{G1}, SI_{G3}, SI_{G10}), single battery voltage level (VBAT) followed by 'n' number of ECG values. The value 'n' can be programmable by the μC unit 8, to read plurality of ECG values from 1 up to 4096 times. Following the completion of the ECG stream six further skin impedance and battery voltage measurements (SI_t, SI_S, SI_{G1}, SI_{G3}, SI_{G10} and VBAT) are made and formatted to the data stream 27. The resulting data stream 27 is encoded into a bi-phase (Manchester code) format and transferred to the transmitter unit 9, where the encoded stream 27 is transmitted via the embedded antenna 23 within the belt unit 2. The sequence of transmitting the data stream 27 via the μC unit 2 and the transmitter unit 9 is repeated up to 'N' times, where the value 'N' is programmable by the μC unit 8, to process the stream 27 up to 4096 times. The resulting 'N' number of encoded data stream 27 is received by the hand-held unit 5, via the receiver antenna 28 and transferred to the wireless receiver unit 10. The receiver unit 10 demodulates the bi-phase data back to the original data stream 27 and transfers and stores the resulting data to the RAM of the CPU unit 11.

[0024] Figure 6 outlines the data acquisition and processing implemented within the CPU unit 11, in order to carry out all functional operations of the device and provide information relating to the onset of physiological condition of a patient.

The identifying data packet unit 30 breaks down the data stream 27 into the 12-bit parameter data values 25 according to the 3-bit identification header 26. The ECG data packets (bit 111 of packet) is applied to an ECG digital filter processor unit 31, to detect sub-components of ECG including the QT-interval, ST-segment, heart rate and the average heart rate intervals.

[0025] The ECG filter unit 31 is a six part process consisting of a low-pass filter (LPF) unit 32, high-pass filter (HPF) unit 33, derivative unit 34, squaring function unit 35, moving averaging unit 36 and the QRS detection unit 37. The raw ECG data is applied to the LPF unit 32, which produces a band-limited signal, filtered for signals above the cut-off frequency of 11 Hz with a processing delay of 6 samples. The output data stream from unit 32 is then applied to the HPF unit 33, which filters for signals below 5 Hz cut-off frequency, with a processing delay of 16 samples. The filtered data is differentiated by the derivative unit 34 (using summation of first and second derivative approach) to provide the QRS peak slope value against its entire frequency bandwidth. Following the differentiation, the ECG data is applied to a squaring function unit 35 to produce all positive valued data stream and amplifies the QRS complex of the data enabling enhanced detection of the QRS peak. The data stream is further filtered by the stream to a moving average window unit 36 to remove unwanted side-band signals of the stream and produce a uniform waveform feature. The moving average window uses a window size of 32 data samples to produce the filtered output. The final stage of the ECG filtering process is the QRS complex detection unit 37 which performs a QRS peak detection algorithm and stores the resulting values. These results, in the form of R-R interval (interval between two consecutive QRS complex peaks) are used by the heart rate processing unit 39 to calculate the real-time hear rate value. The detection unit 37 uses three continuously changing threshold levels, including *PrimThresh, EcgThresh* and *NoiseThresh.* If the filtered ECG data stream is greater than the *PrimThresh* then a QRS peak has been detected. The PrimThresh is updated by the combination of the *EcgThresh* and *NoiseThresh* values. If a QRS complex is detected then *EcgThresh* is updated, otherwise *NoiseThresh* is updated.

[0026] The data acquisition process decides whether a QRS complex has been detected using unit 38, if so then the process continues to perform heart rate, QT-interval, ST-segment and skin impedance averaging calculations. The process also stores the data into the ROM of CPU unit 11 and writes results to various text files. However, if no QRS complex was detected then the process continues back to the start of data acquisition unit 29 and the process restarts.

[0027] The QRS detection intervals (R-R intervals) obtained by the detection unit 37 is applied to heart rate calculating unit 39 to obtain the real-time and the average heart rate values. The calculating unit 39 decides whether the current R-R interval ($R\text{-}R_c$) falls between a lower and upper limit of the average for the 8 most recent R-R intervals ($R\text{-}R_{avg1}$). The $R\text{-}R_c$ must be within 0.8 $R\text{-}R_{avg1}$ and 1.2 $R\text{-}R_{avg1}$ to be accepted into the new $R\text{-}R_{avg1}$ stream, otherwise $R\text{-}R_c$ is stored into a backup R-R interval average stream ($R\text{-}R_{avg2}$) in case no QRS complex is found in 8 consecutive ECG streams. The resulting QRS intervals ($R\text{-}R_c$, $R\text{-}R_{avg1}$ and $R\text{-}R_{avg2}$) are converted to the equivalent heart rate values (HR_c, HR_{avg1} and HR_{avg2}) according to formula: (1/R-R interval) x 60. The heart rate values HR_c, HR_{avg1} and HR_{avg2}, along with the rate-of-change of heart rate, dHR (difference between current heart rate HR_c and previous heart rate HR_{c_prev}) are stored in the RAM module of the CPU unit 11.

[0028] The data acquisition sequence following QRS detection is the calculations of the QT-interval and ST-segments of the ECG using processing units 40 and 41 respectively. The QT-interval is calculated using the vector length between the start point of the QRS complex and the end of the T wave. The intersection point between the final slope of the T wave and a variable threshold value marks the end of the T wave. The threshold value is 0.15 of the previous T wave value. The calculating unit 40 analyses the current QT-interval (QT_c) for acceptance, between the range of 0.85 and 1.15 of the average for the 8 most recent QT values, QT_{avg}. The QT-interval values, QT_c, QT_{avg} and dQT (difference between current QT_c and previous QT-interval $QT_{c\text{-}prev}$) are stored in the RAM module and ROM module (as text files) of the CPU unit 11.

[0029] The ST-segment is calculated using the vector length between the end of the QRS complex and the start of the T wave. The intersection point between the first positive of the derivative of the ECG and a variable threshold level marks the beginning of the T wave. Similarly to the QT-interval, the calculating unit 41 observes the current ST-interval (ST_c) for acceptance between the range of 0.85 and 1.15 of the average for the 8 most recent ST-segment values, ST_{avg}. The ST-segment values, ST_c, ST_{avg} and dST (difference between current ST_c and previous ST-interval ST_{c_prev}) are stored in the RAM and ROM module (as text files) of the CPU unit 11.

[0030] The skin impedance averaging process 42 provides a single absolute skin impedance value (SI_{avg}) based upon the average of all three gain settings, i.e. with gain setting of 1 (SI_{G1}), gain setting of 3 (SI_{G3}) and gain setting of 10 (SI_{G10}). The flow of the process 42 algorithm is as follows:

1. Obtain SI_{G1} reference value.

2. Check the range of SI_{G3}. If SI_{G3} falls between 0.8 and 1.2 of SI_{G1}, then divide SI_{G3} by 3 and average the results with SI_{G1}.

3. Similarly, check the range of SI_{G10}. If SI_{G10} falls between 0.8 and 1.2 of SI_{G1}, then divide SI_{G10} by 10 and average

the results with SI_{G1} and SI_{G3} to obtain SI_{avg}.

4. Convert the single SI_{avg} measured in volts to absolute skin impedance in ohms by dividing by I_{const}.

5. Also store SI_{avg} into a data stream containing the average for the 8 most recent SI_{avg} values, denoted as SI_{avg_hist}.

[0031] The skin impedance values SI_{avg}, SI_{avg_hist} and dSI (difference between the current SI_{avg} and the previous skin impedance value SI_{avg_prev}) are stored in the RAM and ROM module (as text files) of the CPU unit 11.

[0032] The completed parameter data sequence, comprising of heart rate adapt set [HR_c, HR_{avg1}, HR_{avg2}, dHR], QT-interval data set [QT_c, QT_{avg}, dQT], ST-segment data set [ST_c, ST_{avg} and dST] and skin impedance data set [SI_{avg}, $SI_{avg-hist}$ and dSI] is applied to the first stage of the detection algorithm unit 12 for updating and learning phase (methodology is described in detail in the prior patent application WO 02/069798. The data acquisition process is repeated through the loop, starting from processing unit 29 to the detection algorithm unit 12, until the entire data stream 27 has bee processed by the first stage algorithm unit 12 and stored within the RAM and ROM memory of the CPU unit 11. At the completion of the acquisition processing loop the accumulated parameter data sets are applied to the second-stage of the detection algorithm 12 for the real-time detection for the onset of a physiological condition. The detection algorithm 12 will output the results, via the CPU unit 12, to a display unit 14, the status and severity of the physiological condition.

[0033] Figure 7 shows a sample contents of information that may be displayed during an onset of a physiological condition (example data based on hypoglycaemia) on the display unit 14. The main physiological condition level is displayed as unit 44, informing the user in the form of absolute units. Display information 44 will also aid in administrating counter-regulatory action (by user or carer) against the onset of physiological condition. In the case for the onset of hypoglycaemia or hyperglycaemia, administration of glucose or insulin may be undertaken to counteract the onset and recover the patient to euglycaemia. In addition, information 44 may also be used in a control loop in conjunction to an automated control apparatus, such as an insulin-pump or an artificial pancreas, to automatically counter-regulate the physiological condition. The display information 45 is used to inform the user/patient the status category of the physiological condition. Depending on the physiological condition, e.g. hypoglycaemia, the categories may include: *normal, mild hypoglycaemia, mild-severe hypoglycaemia* and *severe hypoglycaemia.* The display information 46 shows the status of the alarm activation, based on the severity of the physiological condition. There will be two states for the alarm information 46, i.e. *active* and *inactive.* When in *active* mode, a variable audio tone (a 'beep' usually 0.5 seconds in duration) is sent by the CPU unit 11 to the audio alarm unit 15 indicating the severity of the physiological condition. The following describes the rate of tone generated in case of hypoglycaemia:

Euglycaemia:	Alarm *inactive* and no tone is generated
Mild hypoglycaemia,:	Alarm *active,* 'beep' every second is generated
Mild-severe hypoglycaemia:	Alarm *active,* 2 'beep' every second is generated
Severe hypoglycaemia:	Alarm *active,* 3 'beep' every second is generated

[0034] It will be understood that the present invention disclosed and defined herein extends to all alternative combinations of two or more of the individual features mentioned or evident from the text or drawings. All of these different combinations constitute various alternative aspects of the invention.

[0035] The foregoing describes embodiments of the present invention and modifications, obvious to those skilled in the art can be made thereto, without departing from the scope of the invention, as defined by the claims.

Claims

1. A monitoring device for monitoring the physiological condition of a patient on a continuous basis, the monitoring device comprising:

a transmitter unit adapted to attach to a patient so as to be in contact with the skin of a patient, the transmitter unit including:

attachment means comprising a chest belt (2) adapted to attach to or around the chest of a patient;
at least three sensors (E1, E2, E3, E4) mounted to the attachment means adapted to monitor a plurality of patient parameters, the sensors adapted to produce signals related to the parameters being monitored;
a microcontroller (8) to which the sensors are connected, the microcontroller being adapted to process the signals; and
a wireless transmitter (9) to which the microcontroller is connected; the wireless transmitter being adapted

to transmit a processed signal related to the patient parameters monitored by the sensors;
a portable receiver unit (5) adapted to receive and process the signal received from said wireless transmitter, the portable receiver unit comprising:

a wireless receiver (10) adapted to receive the signal from the wireless transmitter;
a processor (11) adapted to process the signal; and
display means (14) for displaying data relating to the patient

characterised in that:

the sensors comprise electrodes (E_1, E_2, E_3, E_4) and are adapted to monitor at least the skin impedance, heart rate and ECG of the patient, a switching circuit is provided for switching the electrodes (E_1, E_2, E_3, E_4) from measuring one parameter to measuring another parameter in accordance with a pre-programmed switching sequence, and the physiological condition which the device is adapted to monitor is a hypoglycaemic condition.

2. A monitoring device according to claim 1 **characterised in that** the portable receiver unit includes communication means (16) for communicating with a network.

3. A monitoring device according to either preceding claim **characterised in that** the portable receiver unit includes an input keyboard for inputting data and communicating with the receiver unit.

4. A monitoring device according to any preceding claim **characterised in that** the transmitter unit includes analogue electronics circuitry to pre-filter, process and prepare the signals related to the patient parameters being monitored by the sensors and interface to the microcontroller.

5. A monitoring device according to any preceding claim **characterised in that** the microcontroller is adapted to control the transmitter unit, provide digital signal processing of the information by the pre-processed analogue circuitry and prepare these signals for wireless transmission.

6. A monitoring device according to any preceding claim **characterised in that** the microcontroller is adapted to output digitally processed signals related to the patient parameters monitored by the sensors.

7. A monitoring device according to any preceding claim **characterised in that** the sensors comprise skin-surface electrode sensors comprised of flexible conductive polymer.

8. A monitoring device according to any preceding claim **characterised in that** the transmitter unit is adapted to detect contact and lift-off of the sensors.

9. A monitoring device according to any preceding claim **characterised in that** the processed signal transmitted by the transmitter unit comprises encoded packets of data including data relating to parameter identification.

10. A monitoring device according to claim 9 **characterised in that** the central processor is adapted apply a digital signal processing algorithm to the packets of data.

11. A monitoring device according to any preceding claim **characterised in that** the central processor comprises a learning neural network processor programmed with a fast learning algorithm.

12. A monitoring device according to any preceding claim **characterised in that** the hypoglycaemic condition is monitored by estimating the blood glucose level of the patient.

13. A monitoring device according claim 12 **characterised in that** the receiver unit is adapted to display the estimated blood glucose level of the patient.

14. A monitoring device according to any preceding claim **characterised in that** the transmitter unit and receiver unit communicate across a plurality of radio frequency bandwidths.

15. A monitoring device according to any preceding claim **characterised in that** the patient parameters are repeatedly monitored in sequence and the processed signal which is transmitted includes different components for the different

parameters being monitored.

Patentansprüche

1. Überwachungsvorrichtung zur Überwachung des physiologischen Zustandes eines Patienten auf kontinuierlicher Basis, wobei die Überwachungsvorrichtung aufweist:

   eine Übertragungseinheit, die dafür eingerichtet ist, an einem Patienten angebracht zu werden bzw. diesen zu kontaktieren, um mit der Haut eines Patienten in Kontakt zu stehen, wobei die Übertragungseinheit beinhaltet:

   Anbringungsmittel mit einem Brustgurt (2), die dafür eingerichtet sind, an oder um die Brust eines Patienten angebracht zu werden;
   wenigstens drei an die Anbringungsmittel angebrachte Sensoren (E1, E2, E3, E4), die dafür eingerichtet sind, eine Anzahl Patientenparameter zu überwachen, wobei die Sensoren dafür eingerichtet sind, Signale, die mit den überwachten Parametern in Beziehung stehen, zu erzeugen;
   einen Mikrocontroller (8), mit welchem die Sensoren verbunden sind, wobei der Mikrocontroller dafür eingerichtet ist, die Signale zu verarbeiten;
   eine Drahtlos-Übertragungseinrichtung (9) mit welcher der Mikrocontroller verbunden ist, wobei die Drahtlos-Übertragungseinrichtung dafür eingerichtet ist, ein verarbeitetes, mit den durch die Sensoren überwachten Patientenparametern in Beziehung stehendes Signal zu übertragen;
   eine tragbare Empfangseinheit (5), die dafür eingerichtet ist, die von der Drahtlos-Übertragungseinrichtung empfangenen Signale zu empfangen und zu verarbeiten, wobei die tragbare Empfangseinheit aufweist:

   einen Drahtlos-Empfänger (10), der dafür eingerichtet ist, die Signale vom der Drahtlos-Übertragungseinrichtung zu empfangen;
   einen Prozessor (11), der dafür eingerichtet ist, das Signal zu verarbeiten; und Anzeigemittel (14) zum Anzeigen mit dem Patienten in Beziehung stehender Daten, **dadurch gekennzeichnet, dass**:

   die Sensoren Elektroden (E1, E2, E3, E4) aufweisen und dafür eingerichtet sind, wenigstens die Hautimpedanz, die Herzfrequenz und/oder das EKG des Patienten zu überwachen, eine umschalteschaltung zum Umschalten der Elektroden (E1, E2, E3, E4) vom Messen eines Parameters zum Messen eines anderen Parameters in Übereinstimmung mit einer vorprogrammierten Umschaltsequenz vorgesehen ist, und der physiologische Zustand, welchen die Vorrichtung zu überwachen eingerichtet ist, ein hypoglykämischer Zustand ist.

2. Überwachungsvorrichtung nach Anspruch 1, **dadurch gekennzeichnet, dass** die tragbare Empfangseinheit Kommunikationsmittel (16) zum Kommunizieren mit einem Netzwerk beinhaltet.

3. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** die tragbare Empfangseinheit eine Eingabetastatur zum Eingeben von Daten und zum Kommunizieren mit der Empfangseinheit aufweist.

4. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** die Übertragungseinheit eine analoge Elektronikschaltung zum vorfiltern, verarbeiten und vorbereiten der mit den durch die Sensoren überwachten Patientenparametern in Beziehung stehenden Daten und zum Koppeln an den Mikrocontroller aufweist.

5. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** der Mikrocontroller dafür eingerichtet ist, die Übertragungseinrichtung zu steuern, eine digitale Signalverarbeitung durch die vorverarbeitete analoge Schaltung bereitzustellen, und diese Signale zur Drahtlosübertragung vorzubereiten.

6. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** der Mikrocontroller dafür eingerichtet ist, digital verarbeitete Signale, die mit den durch die Sensoren überwachten Patientenparametern in Beziehung stehen, auszugeben.

7. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** die Sensoren Hautoberflächen-Elektrodensensoren, die aus flexiblem, leitendem Polymer bestehen, beinhalten.

8. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** die Übertragungseinheit dafür eingerichtet ist, einen Kontakt und ein Abheben der Sensoren festzustellen

9. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** das durch die Übertragungseinheit übertragene verarbeitete Signal kodierte Datenpakete mit Daten, die mit einer Parameteridentifikation in Beziehung stehen, aufweist.

10. Überwachungsvorrichtung nach Anspruch 9, **dadurch gekennzeichnet, dass** der zentrale Prozessor dafür eingerichtet ist, einen digitalen Signalverarbeitungsalgorithmus auf die Datenpakete anzuwenden.

11. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** der zentrale Prozessor einen lernenden Neuralnetzwerkprozessor, der mit einem schnellen Lernalgorithmus programmiert ist, aufweist.

12. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** der hypoglykämische Zustand durch Beurteilen bzw. Schätzen des Blutglucosespiegels des Patienten überwacht wird.

13. Überwachungsvorrichtung nach Anspruch 12, **dadurch gekennzeichnet, dass** die Empfangseinheit dafür eingerichtet ist, den geschätzten Blutglucosespiegel des Patienten anzuzeigen.

14. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** die Übertragungseinheit und die Empfangseinheit über eine Anzahl Hochfrequenzbandbreiten kommunizieren.

15. Überwachungsvorrichtung nach einem der vorstehenden Ansprüche, **dadurch gekennzeichnet, dass** die Patientenparameter wiederholt sequentiell überwacht werden und das übertragene verarbeitete Signal unterschiedliche Komponenten für die unterschiedlichen überwachten Parameter beinhaltet.

Revendications

1. Appareil de monitorage surveillant de façon continue l'état physiologique d'un patient, l'appareil de monitorage comprenant :

une unité émettrice accommodée pour être raccordée à un patient afin d'être en contact avec la peau d'un patient, l'unité émettrice comprenant :

des moyens de fixation comprenant un bracelet (2) pour région précordiale apte à être fixé sur la poitrine d'un patient, ou autour de celle-ci ;
au moins trois capteurs (E1, E2, E3, E4) montés sur les moyens de fixation, aptes à surveiller une pluralité de paramètres d'un patient, les capteurs étant agencés pour produire des signaux en rapport avec les paramètres surveillés ;
un microcontrôleur (8) auquel les capteurs sont connectés, le microcontrôleur étant agencé pour traiter les signaux ; et
un émetteur sans fil (9) auquel le microcontrôleur est connecté, l'émetteur sans fil étant apte à émettre un signal traité en rapport avec les paramètres du patient surveillés par les capteurs ;
une unité réceptrice portable (5) agencée pour recevoir et pour traiter le signal reçu en provenance dudit émetteur sans fil, l'unité réceptrice portable comprenant :

un récepteur sans fil (10) agencé pour recevoir le signal en provenance de l'émetteur sans fil ;
un processeur (11) agencé pour traiter le signal ; et
des moyens d'affichage (14) affichant des données ayant un rapport avec le patient,

caractérisé en ce que :

les capteurs comprennent des électrodes (E1, E2, E3, E4) et sont agencés de façon à contrôler au moins l'impédance de la peau, la fréquence cardiaque et l'ECG du patient, un circuit de commutation étant prévu pour commuter les électrodes (E1, E2, E3, E4) afin de mesurer un paramètre puis un autre selon une séquence de commutation préprogrammée, et **en ce que** l'état physiologique que l'appareil est agencé pour surveiller est

un état hypoglycémique.

2. Appareil de monitorage selon la revendication 1, **caractérisé en ce que** l'unité réceptrice portable comporte des moyens de communication (16) communiquant avec un réseau.

3. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'unité réceptrice portable comporte un clavier d'entrée entrant des données et communiquant avec l'unité réceptrice.

4. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'unité émettrice comporte des circuits électroniques analogiques destinés à effectuer un filtrage préalable, à traiter et à préparer les signaux en rapport avec les paramètres du patient surveillé par les capteurs, et à s'interfacer avec le microcontrôleur.

5. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le microcontrôleur est agencé pour commander l'unité émettrice, pour fournir un traitement numérique du signal des informations à l'aide des circuits analogiques de pré-traitement et pour préparer ces signaux pour une émission sans fil.

6. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le microcontrôleur est agencé pour délivrer en sortie des signaux traités de manière numérique en rapport avec les paramètres d'un patient surveillé par les capteurs.

7. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les capteurs comprennent des capteurs à électrodes placés à la surface de la peau qui sont réalisés dans un polymère conducteur souple.

8. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'unité émettrice est agencée pour détecter un contact et un décollement des capteurs.

9. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le signal traité émis par l'unité émettrice comprend des paquets de données codés, y compris des données qui se rapportent à l'identification d'un paramètre.

10. Appareil de monitorage selon la revendication 9, **caractérisé en ce que** le processeur central est agencé pour appliquer un algorithme de traitement numérique du signal aux paquets de données.

11. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le processeur central comprend un processeur de réseau neuronal d'apprentissage programmé avec un algorithme d'apprentissage rapide.

12. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'état hypoglycémique est surveillé en estimant le taux de glucose dans le sang du patient.

13. Appareil de monitorage selon la revendication 12, **caractérisé en ce que** l'unité réceptrice est agencée pour afficher le taux estimé de glucose dans le sang du patient.

14. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'unité émettrice et l'unité réceptrice communiquent sur une pluralité de largeurs de bandes de fréquences radioélectriques.

15. Appareil de monitorage selon l'une quelconque des revendications précédentes, **caractérisé en ce que** les paramètres du patient sont surveillés séquentiellement à plusieurs reprises, et **en ce que** le signal traité qui est émis comprend différentes composantes pour les différents paramètres surveillés.

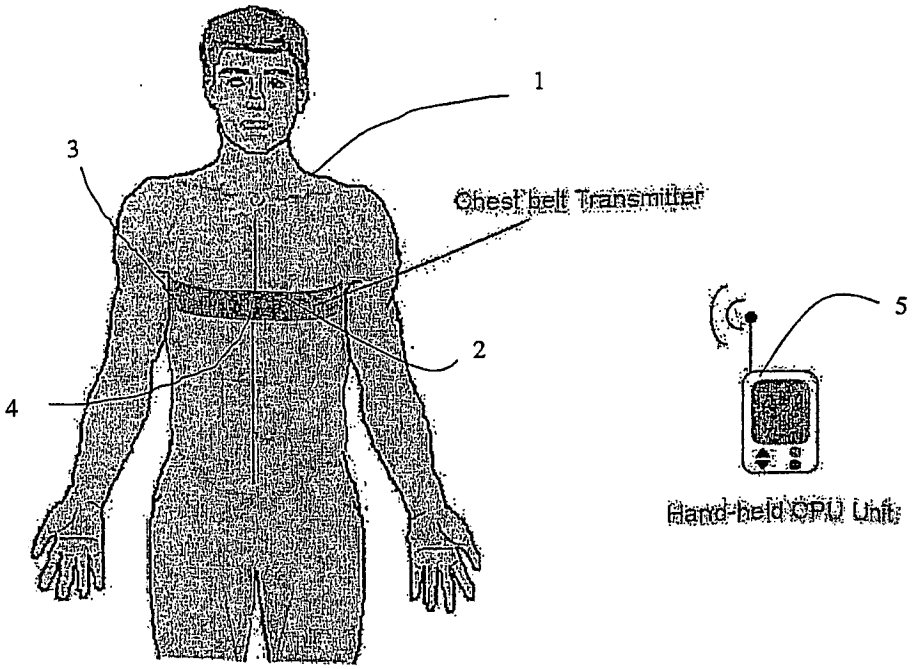
1
3
Chest belt Transmitter
2
4
5
Hand-held CPU Unit

FIG. 1

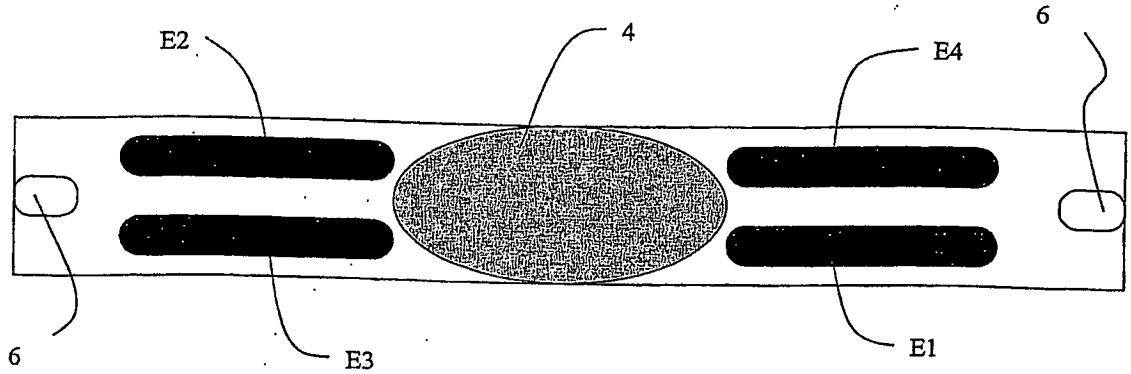
E2
4
6
E4
6
E3
E1

FIG. 2

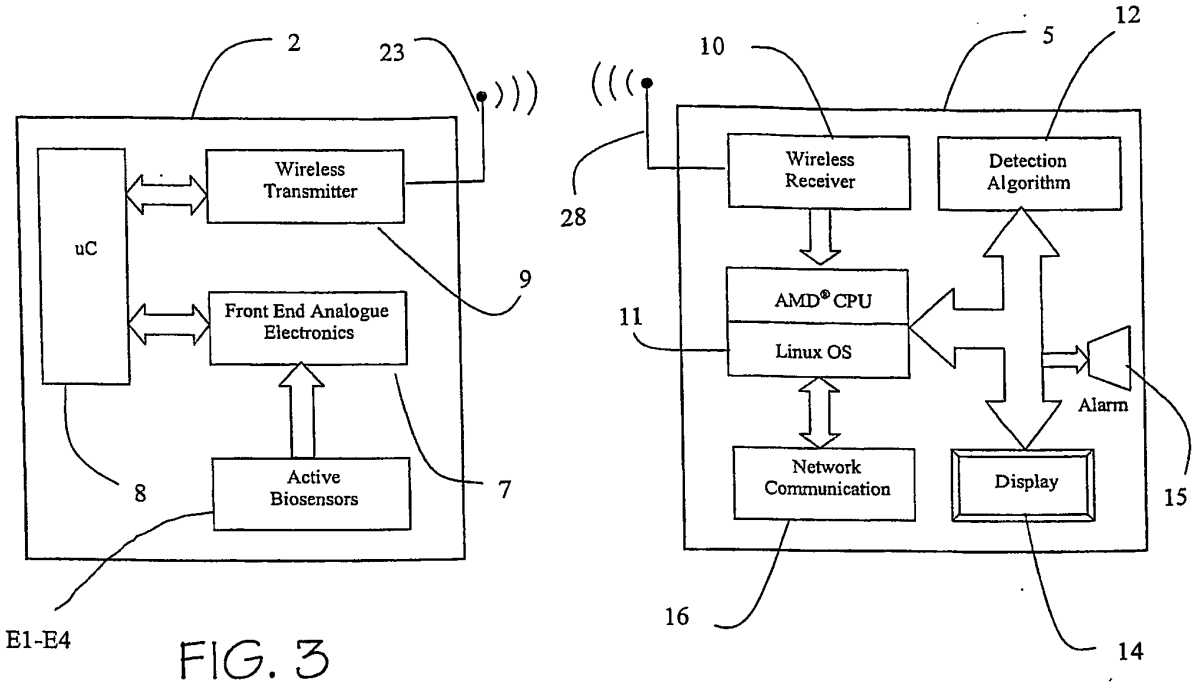
2
23
uC
Wireless Transmitter
Front End Analogue Electronics
Active Biosensors
8
9
7
E1-E4
10
5
12
28
Wireless Receiver
Detection Algorithm
AMD® CPU
Linux OS
11
Alarm
Network Communication
Display
15
16
14

FIG. 3

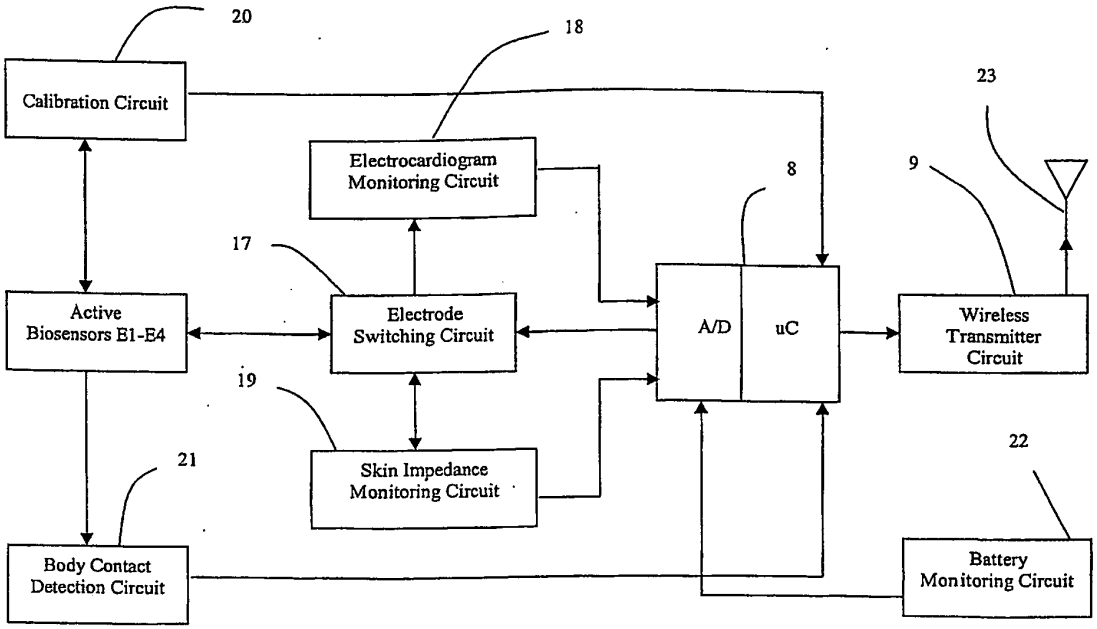
20
Calibration Circuit
18
Electrocardiogram Monitoring Circuit
23
9
8
17
Active Biosensors E1-E4
Electrode Switching Circuit
A/D
uC
Wireless Transmitter Circuit
19
Skin Impedance Monitoring Circuit
22
21
Body Contact Detection Circuit
Battery Monitoring Circuit

FIG. 4

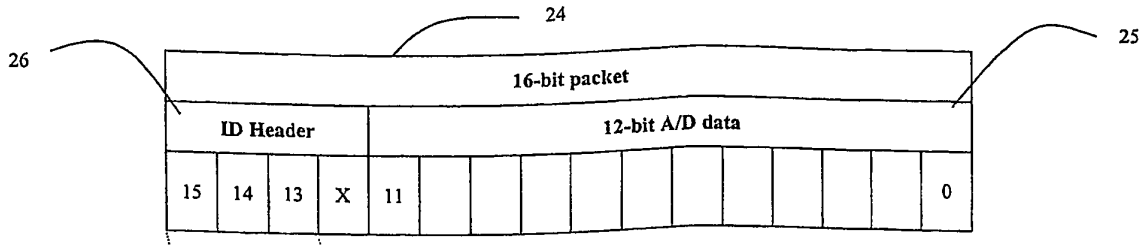

Figure 5a: Transmission Data Format

15	14	13	ID bits Description	ID
0	0	0	Zero	Z
0	0	1	Skin imp. test circuit	SIt
0	1	0	Skin imp. short circuit	SIs
0	1	1	Skin impedance (gain = 1)	SI_{G1}
1	0	0	Skin impedance (gain = 3)	SI_{G3}
1	0	1	Skin impedance (gain = 10)	SI_{G10}
1	1	0	Battery voltage	VBAT
1	1	1	ECG	ECG

Figure 5b: Transmission Data ID Description

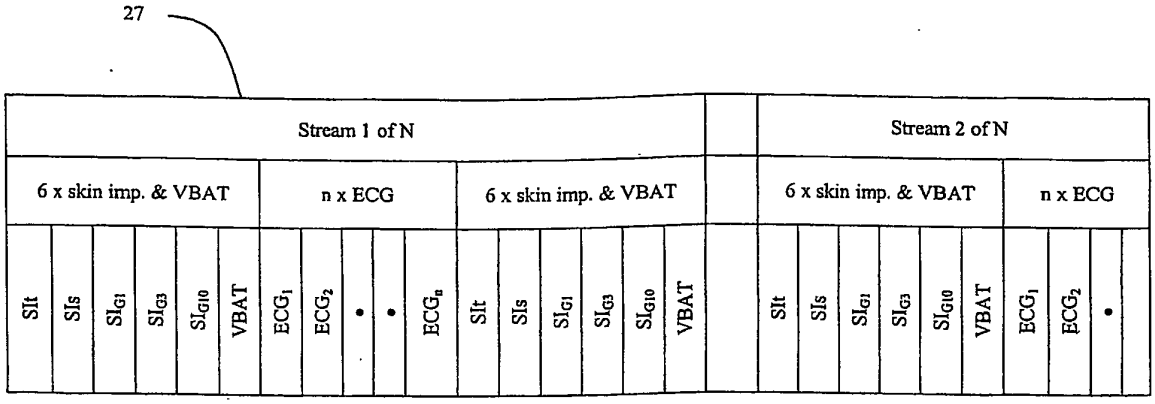

Figure 5c: Transmitter data sequence stream

FIG. 5

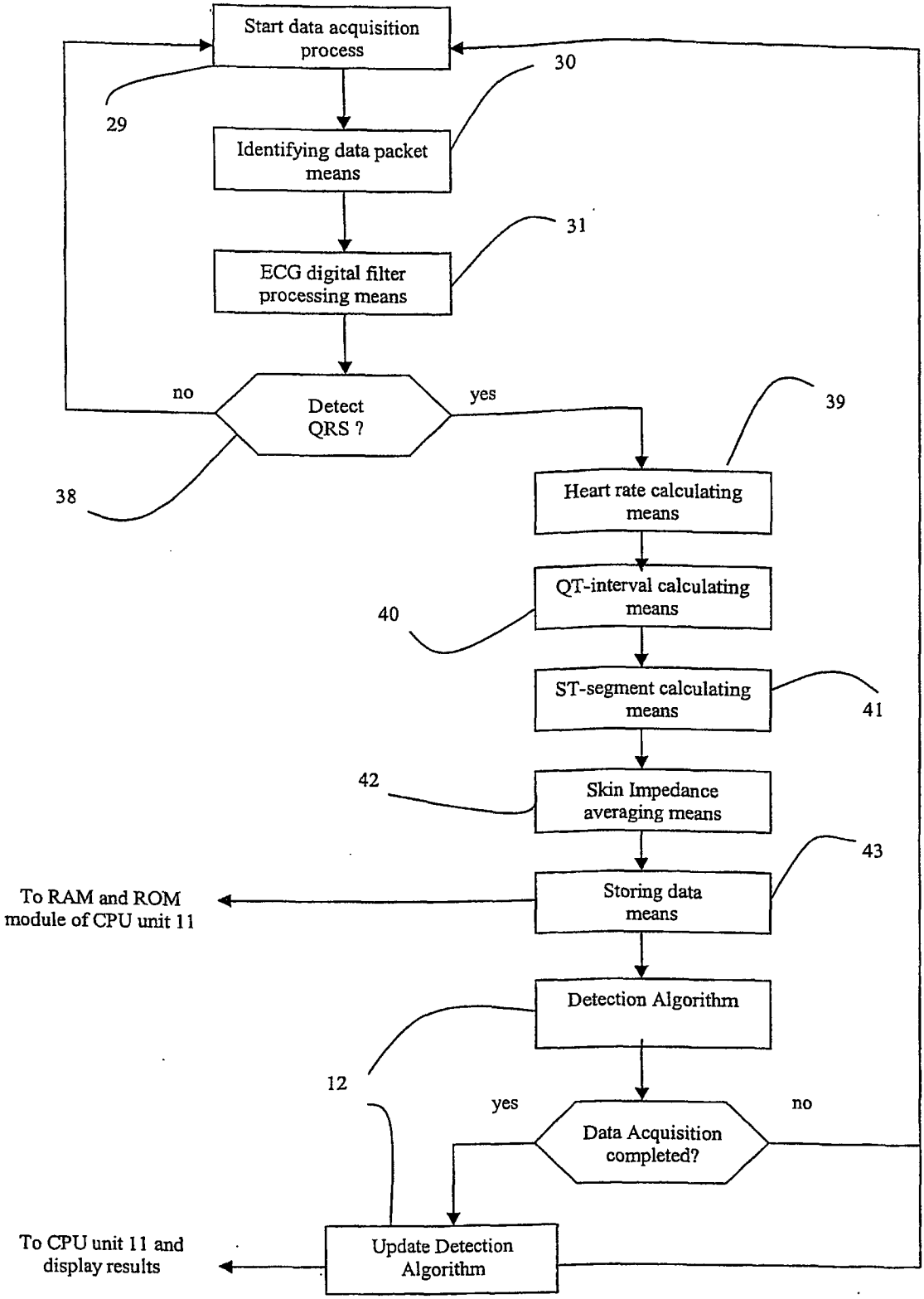

Figure 6a: Data acquisition process

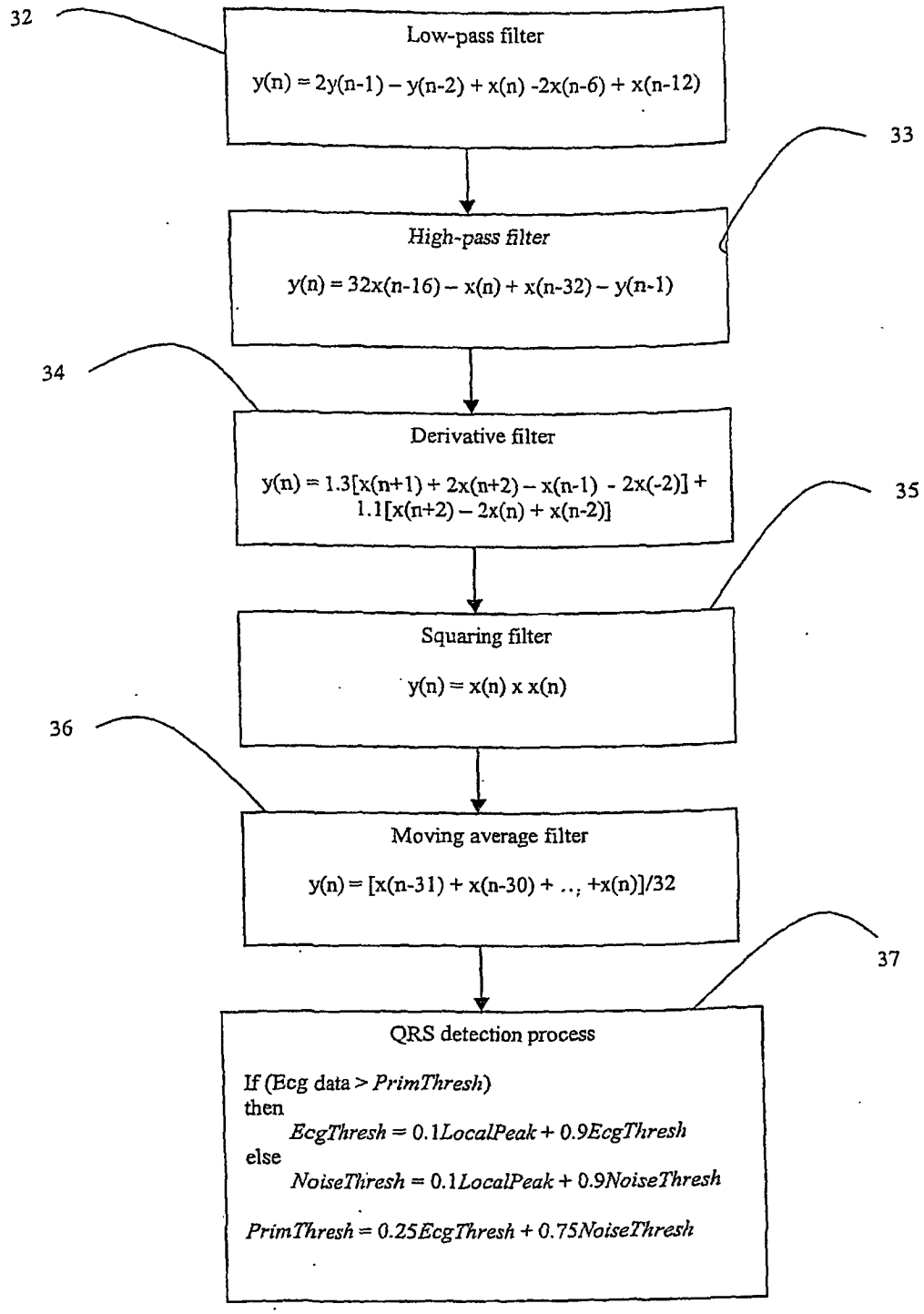

Figure 6b: ECG digital filtering process

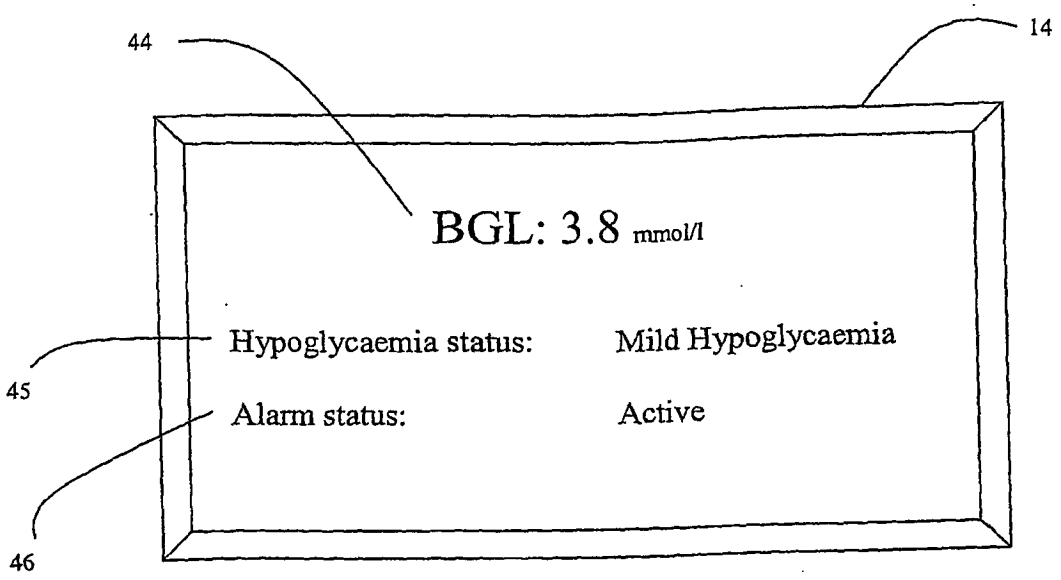
44
14
BGL: 3.8 mmol/l
Hypoglycaemia status:
Mild Hypoglycaemia
45
Alarm status:
Active
46

FIG. 7

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	病人监护仪		
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申请(专利权)人(译)	AIMEDICS PTY LTD		
当前申请(专利权)人(译)	AIMEDICS PTY LTD		
[标]发明人	GHEVONDIAN NEJHDEH C O SUITE 15 NAT INN CENT WILLSHIRE RICHARD JOHN C O SUITE 15 NAT INN CTR		
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IPC分类号	A61B5/0205 A61B5/00 A61B5/0402 A61B5/053		
CPC分类号	A61B5/6831 A61B5/0002 A61B5/0205 A61B5/0402 A61B5/0531 A61B5/4806 G06F19/34		
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优先权	2003902187 2003-05-08 AU		
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外部链接	Espacenet		

摘要(译)

一种用于连续监测患者（1）的生理状况的监测装置，其包括适于附接到患者以使其与患者皮肤接触的发射器单元（2），相应的接收器单元。（5）。 发射器单元包括适于附接到患者的身体部位或围绕患者的身体部位的皮带或皮带（3）。 多个传感器（E）安装在皮带上，用于监视多个患者生理参数，至少包括患者的皮肤阻抗，心率和心跳方面。 传感器连接到微控制器（8），微控制器（8）处理信号并链接到无线发射器（9）。 便携式接收器单元适于接收和处理来自发射器的信号。 接收器单元包括用于与患者有关的数据的显示器（14），并且优选地包括警报器（15）。

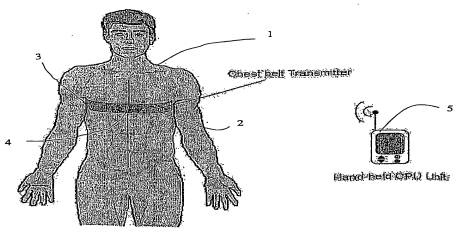

FIG. 1

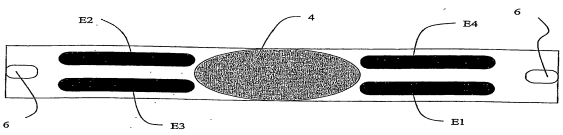

FIG. 2