

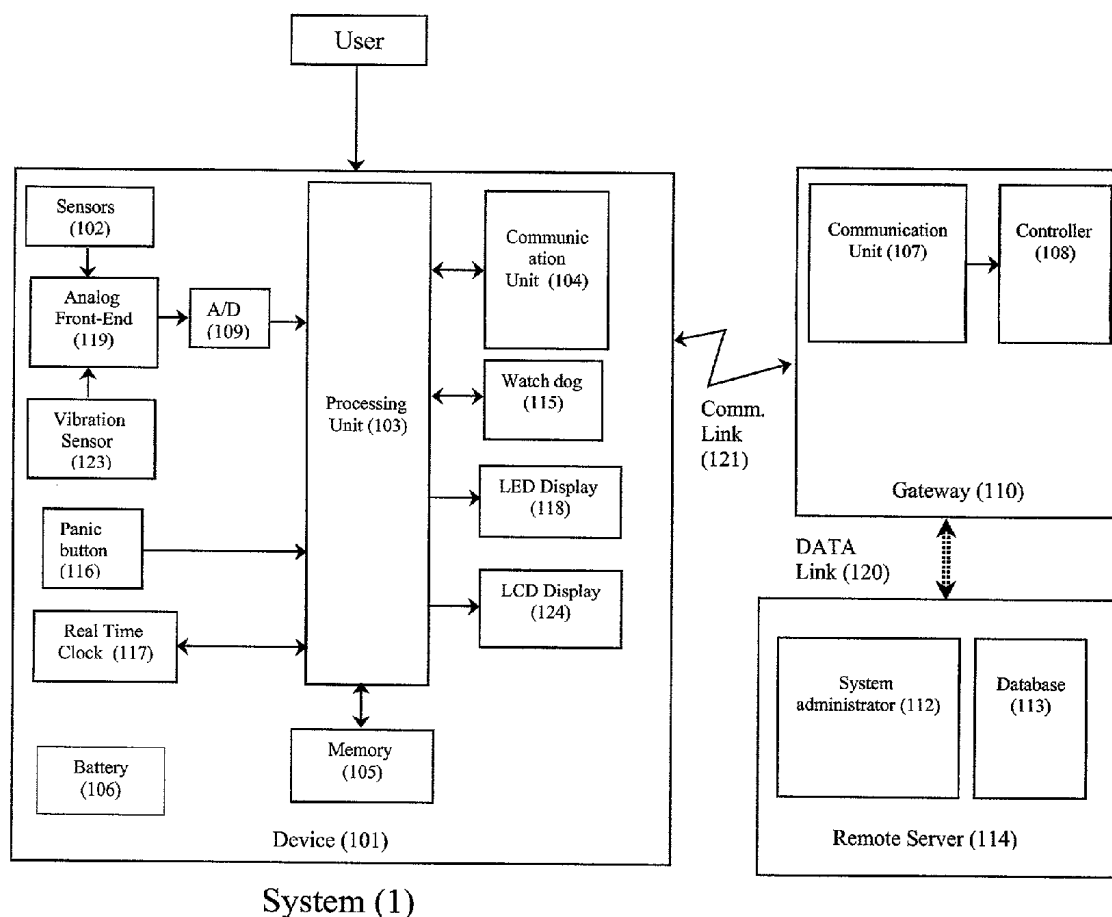


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**Korman et al.**(10) **Pub. No.: US 2003/0107487 A1**(43) **Pub. Date: Jun. 12, 2003**(54) **METHOD AND DEVICE FOR MEASURING  
PHYSIOLOGICAL PARAMETERS AT THE  
WRIST**(22) Filed: **Dec. 10, 2001****Publication Classification**(76) Inventors: **Ronen Korman**, Petach-Tikva (IL);  
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Ha'ayin (IL)(51) **Int. Cl.<sup>7</sup>** ..... **G08B 23/00**(52) **U.S. Cl.** ..... **340/573.1; 340/539.12; 600/301**(57) **ABSTRACT**

A wrist-mounted device for measuring at least one physiological parameter of the user. The present invention enables such a measurement to preferably be transformed into clinically useful information about the user. Such information may then optionally be sent to medical personnel, for example at a contact and/or monitoring center, through a gateway device. The gateway device preferably communicates with the wrist-mounted device of the present invention through a wireless communication channel.

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A schematic block diagram of a system according to the present invention.

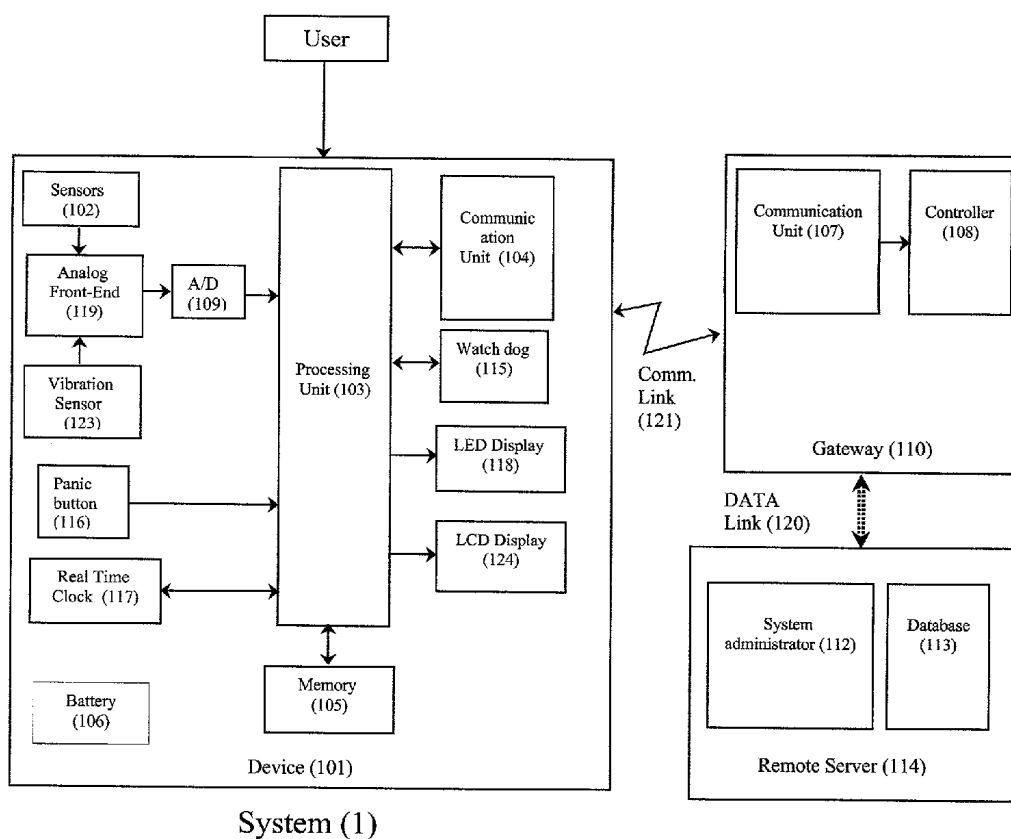


FIGURE 1: A schematic block diagram of a system according to the present invention.

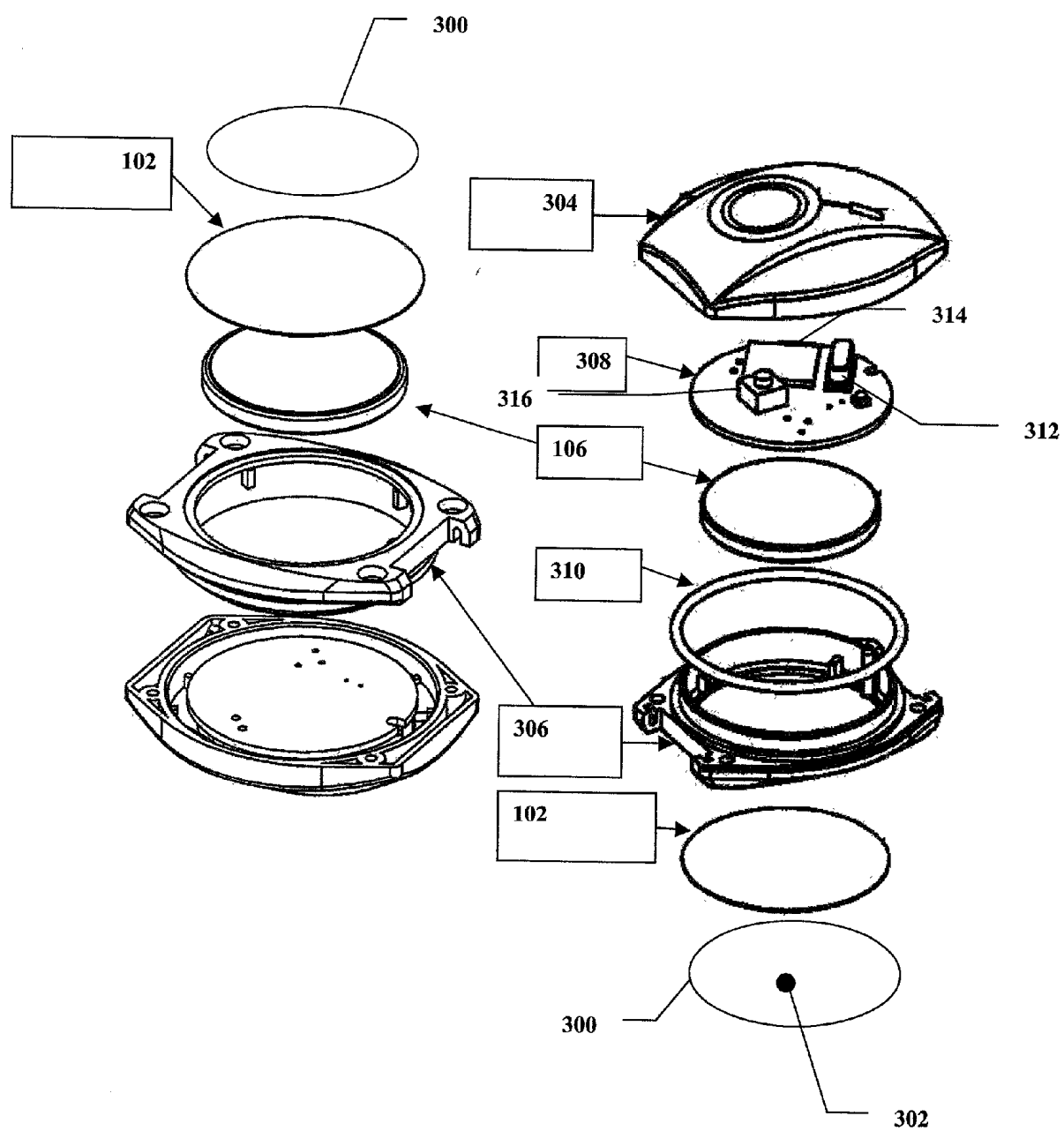


Figure 2: exploded view of the device 101

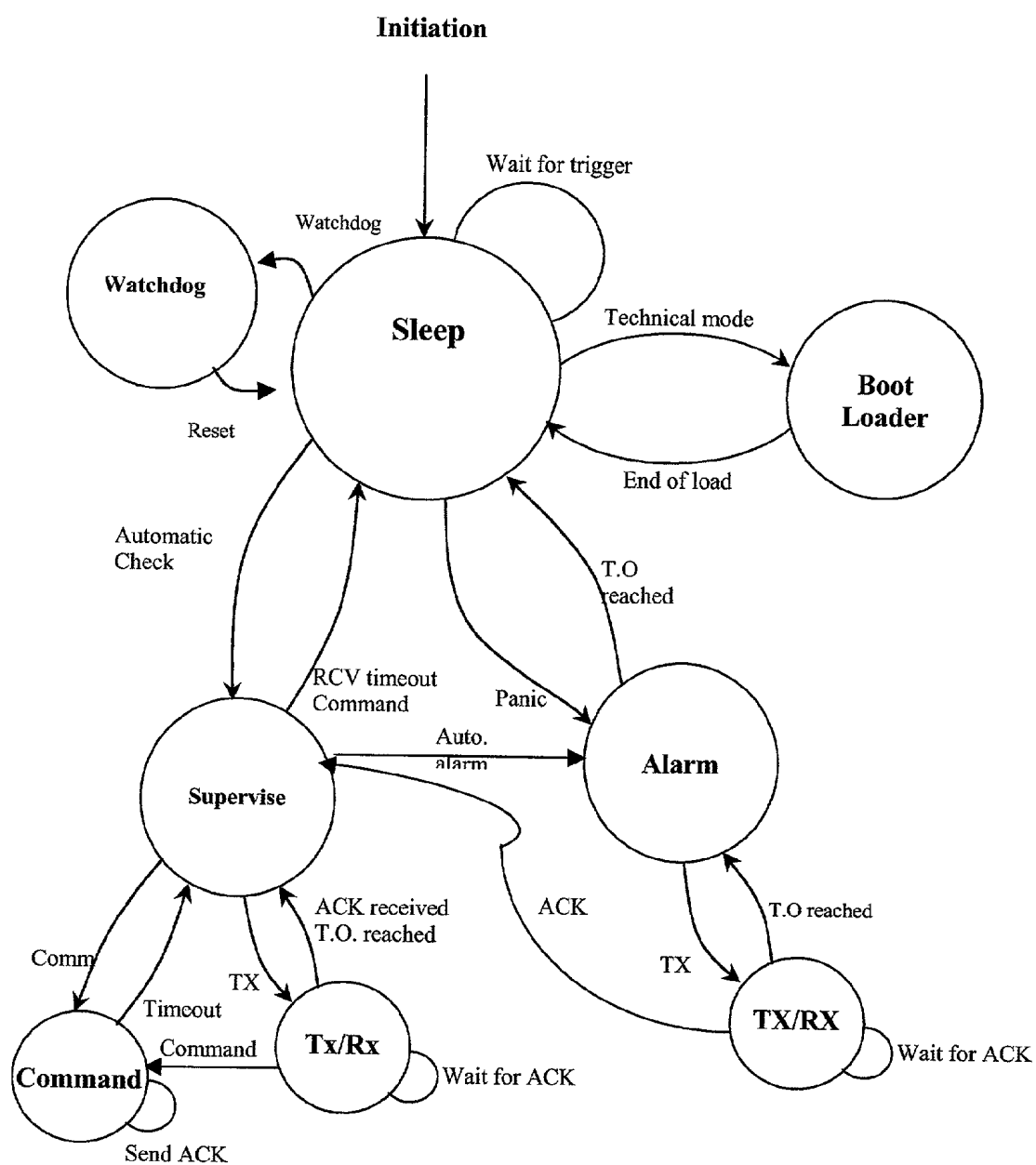


Figure 3: general state flow diagram

## METHOD AND DEVICE FOR MEASURING PHYSIOLOGICAL PARAMETERS AT THE WRIST

### FIELD OF THE INVENTION

[0001] The present invention is of a method and device for measuring at least one physiological parameter of a subject at the wrist, preferably for extracting clinically useful information thereof. More specifically, the present invention is of a device which may be worn at the wrist of the subject with a strap or other fastening article, and which may then be used to monitor the subject through measurement of the physiological parameter.

### BACKGROUND OF THE INVENTION

[0002] Currently, a number of different types of devices are available for monitoring human subjects in a non-invasive manner. For example, heart function can be monitored in a patient through the use of electrodes which must be attached to the skin of the patient. Although non-invasive, such equipment is nevertheless uncomfortable for the patient, who is attached to a network of cables and wired sensors. In addition, such equipment is very expensive, limiting its use to hospitals and other medical settings in which both the cost and the discomfort of the patient can be justified. Furthermore, patients may become anxious when examined by medical personnel, thereby significantly altering the normal readings for these patients.

[0003] However, there are many different situations in which non-invasive monitoring of a human subject is desired. For example, such monitoring could be very useful as part of the overall health maintenance of the human subject, and could be used in order to detect a deterioration in the physiological condition of the subject before a concomitant deterioration in the health of the subject becomes noticeable. Examples of adverse physiological conditions which could be detected with regular non-invasive monitoring include but are not limited to excessive weight gain or loss; arrhythmia and other heart conditions; incipient diabetes in the form of improper glucose metabolism; and loss of lung capacity or other problems with respiration.

[0004] Heart rate and blood pressure are important factors in determining the state of a person's health and the physical condition of a person's body in response to physical or emotional stress. Periodic monitoring of these physical parameters is particularly important for individuals having cardiac disease and/or lowered cardiac functioning, or high blood pressure. However, physically healthy individuals may also wish to periodically monitor their heart rate and blood pressure in stressful situations, for example when engaging in strenuous exercise.

[0005] In order to support regular monitoring of human subjects in their normal environment, such as in the home and at the office for example, the equipment must be non-invasive and easy to use. The equipment would then be able to monitor at least one physiological parameter of the user, without requiring the user to perform any complicated actions and/or to operate complex devices. Indeed, it would be highly preferred for the equipment to be incorporated as part of the regular daily living routine of the subject, since the requirement for any additional or special actions on the part of human subject is likely to result in decreased compliance. In addition, the equipment should be robust yet inexpensive.

[0006] One example of such a device incorporates a wristband to attach a physiological sensor to the wrist of the subject. Currently, a number of different types of such wristband devices are available, most of which are intended to be used as stand-alone devices to provide information about the subject's own physical condition, mainly for heart rate and blood pressure. Most of these devices obtain such measurements by using an inflating cuff, which is bulky and awkward for the subject.

[0007] Wrist-mounted heart rate monitors are known to the art and have been disclosed, for example, in the patent to Orr et al, U.S. Pat. No. 3,807,388, wherein the duration of a heart beat is measured by counting electrical pulses recurring at a known frequency. The duration of the heart-beat is then related to a particular average heart beat rate. However, the disclosed measurement system does not directly measure the heart rate and, therefore, is subject to inaccuracies of measurement due to the instability of heart beat duration over brief intervals of time.

[0008] A blood pressure measuring device is disclosed in the patent to Petzke et al, U.S. Pat. No. 3,926,179, in which a probe is applied adjacent to the radial artery of a wrist. A pressure-sensitive transducer on the probe generates electrical signals corresponding to the blood pressure pulses of the radial artery. The electrical pulses are applied to analog circuitry that generates a systolic signal corresponding to the integrated voltage at the peak of the electrical pulse signal and a diastolic signal corresponding to the voltage at the low point of the pulse signal. The analog device of Petzke et al requires a substantial amount of power to operate and, therefore, is not suitable for use in a small, compact stand-alone device for being worn on the wrist.

[0009] A blood pressure and a heart rate measuring wrist watch is also disclosed in the patent to Broadwater, U.S. Pat. No. 4,331,154, in which a digital watch is employed to measure systolic and diastolic blood pressure as well as heart rate. The band of the watch supports a piezoelectric transducer that is held in contact with the wrist adjacent to the radial artery when a switch on the band is activated. The absolute values required for this method to evaluate blood pressure cause the device to be subject to inaccurate readings, since the tissues of the hand and wrist may be expected to expand and contract according to such factors as the time of day, and the condition of the external environment such as the atmospheric pressure. Such expansion or contraction may cause different degrees of tension on the wrist-mounted device, which is therefore not suitable for use without daily calibrations.

[0010] Other wrist-mounted devices are for wireless panic alarm systems, mainly for elderly people who live alone. These devices are usually shaped as a wristband or a pendant. Whenever the user becomes distressed, the user presses a panic button located on the device. The device then sends a digitally coded wireless message to a gateway device located nearby, usually in the same room, by using a unidirectional wireless data communication link. The gateway device then contacts a manually operated contact center, for example with a land based or cellular telephone connection. A particular identifier for the user is usually sent first, after which the human operator is allowed to talk to the user through a speaker and to listen through a sensitive microphone located within the gateway. However, none of

the above systems contains any physiological measurement device within, in order to learn about the current physiological status of the user.

[0011] In such a situation as described above, the operator at the call center learns about the user's condition only by speaking with the user. However, this is only possible if the user is actually able to speak. High levels of background noise may also prevent the user from being heard by the microphone of the gateway device.

#### SUMMARY OF THE INVENTION

[0012] The background art does not teach or suggest a device which can conveniently, non-intrusively and autonomously measure one or more physiological parameters, in order to extract medical information such as heart rate, breathing rate and blood pressure, and which may be worn on the wrist of the user. The background art also does not teach or suggest such a wrist-mounted device which can measure such parameters and then send the information to a contact center or other location containing medical personnel. The background art also does not teach or suggest such a wrist-mounted device which is compact, non-invasive, and light.

[0013] The present invention overcomes these deficiencies of the background art by providing a wrist-mounted device for measuring at least one physiological parameter of the user. The present invention enables such a measurement to preferably be transformed into medical information about the user, and/or displays the results on a LCD display. As used herein, the term "physiological parameter" refers to the signal which is received from the sensor, while the term "medical information" refers to the information which may be extracted or otherwise obtained by analyzing this signal and/or a combination of signals. Such information may then optionally be sent to medical personnel (for example at a contact monitoring center) and/or to a remote server, through a gateway device. The gateway device preferably communicates with the wrist-mounted device of the present invention through a wireless communication channel.

[0014] The present invention has the option to display the medical information to the user on a local LCD display, such that the user is optionally and preferably able to read the result locally.

[0015] Examples of medical information which may be extracted from the measured physiological parameter or parameters include, but are not limited to: heart rate; variability in heart rate; breathing rate; arrhythmia of the heart (if any), as well as the general rhythm and functioning of the heart; blood pressure; presence of abnormal body movements such as convulsions for example; body position; general body movements; body temperature; presence and level of sweat; oxygen pressure in the blood; and glucose levels in the blood.

[0016] Optionally and more preferably, the present invention also features an alarm signal for being transmitted through the gateway device in order to indicate an emergency or otherwise dangerous situation for the user. The alarm signal may optionally be transmitted according to a manual action of the user, such as pressing a "panic button" for example.

[0017] Upon receipt of the manually activated alarm signal, the gateway would preferably initiate immediately a call

to a human operated call center. Then the device would preferably automatically collect one or more current measurements of physiological parameters of the user. These measurements may be sent directly to the gateway, or alternatively may be analyzed in order to compute the medical information of the user before sending the results to the gateway. The human operator would then preferably be able to assess the user's medical condition from the received information.

[0018] Most preferably, the alarm signal is transmitted automatically upon measurement of one or more physiological parameters of the user, preferably even if the user is unable to press the panic button. Optionally, the alarm signal may be given to the user, additionally or alternatively, for example by sounding an audible alarm, more preferably from the wrist-mounted device itself.

[0019] The device of the present invention also monitors, at least periodically but more preferably continuously, one or more physiological parameters of the user. Continuous monitoring would more easily enable the device to transmit the alarm signal if one or more physiological parameters are determined to be above predefined criteria, which may represent such medical information as unstable or excessive heart rate, or very high or low blood pressure.

[0020] According to preferred embodiments of the present invention, the wrist-mounted device features one or more sensors attached to a wristband or other fastening article. The sensor(s) are preferably connected to a microprocessor, optionally by a wire but alternatively through a wireless connection. The microprocessor may optionally also be located within the wristband, or otherwise attached to the wristband. The sensor(s) preferably support automatic collection of the measurement of the at least one physiological parameter; more preferably, the microprocessor is able to execute one or more instructions for extracting medical information about the user from such measurement(s).

[0021] The microprocessor more preferably operates a software program to process and analyze the data which is collected, in order to compute medical information. The extracted information, optionally also with the raw data, is then preferably transferred to the previously described gateway device. The gateway device then preferably relays such information to a remote server, which more preferably is able to provide such information to medical personnel, for example as part of a contact center. Therefore, continuous monitoring of the medical information and/or physiological parameters of the user may optionally and more preferably be made, enabling better medical care for the user. According to the present invention there is provided a device for measuring at least one physiological parameter of a subject, comprising: (a) a fastening article for being fastened to a wrist of the user; (b) a sensor for measuring at least one physiological function of the user, the sensor being in contact with at least a portion of the wrist and the sensor being attached to the fastening article; and (c) a processor for receiving a signal from the sensor and for converting at least one measurement to form the at least one physiological parameter. Optionally and preferably, the data may be stored on a non-volatile memory for being downloaded later by the user or by an operator.

[0022] According to another embodiment of the present invention, there is provided a system for measuring at least

one physiological parameter of a subject, comprising: (a) a device for measuring the at least one physiological parameter, comprising: (i) a fastening article for being fastened to a wrist of the user; (ii) a sensor for measuring at least one physiological parameter of the user, the sensor being in contact with at least a portion of the wrist and the sensor being attached to the fastening article; (iii) a communication unit for at least transmitting data; and (b) a gateway device for receiving the transmitted data for being monitored.

[0023] According to another embodiment of the present invention, there is provided a method for monitoring a physiological parameter of a user, comprising: providing a device for monitoring the physiological parameter, the device being attached to at least a portion of the user at a pulse point of the user; monitoring the physiological parameter through the pulse point; and if a level of the physiological parameter of the user is outside of an expected range, transmitting an alarm.

[0024] According to still another embodiment of the present invention, there is provided a device for measuring at least one physiological parameter of a subject, comprising: (a) a fastening article for being fastened to a wrist of the user; (b) a piezoceramic sensor for measuring at least one physiological parameter of the user at a pulse point of the wrist and the sensor being attached to the fastening article; and (c) a processor for receiving a signal from the sensor and for converting the at least one measurement to form medical information.

[0025] Hereinafter, the term "microprocessor" includes, but is not limited to, general-purpose microprocessor, a DSP, a micro-controller or a special ASIC designed for that purpose.

[0026] The method of the present invention could be described as a process for being performed by a data processor, and as such could optionally be implemented as software, hardware or firmware, or a combination thereof. For the present invention, a software application could be written in substantially any suitable programming language, which could easily be selected by one of ordinary skill in the art. The programming language chosen should be compatible with the computational device (computer hardware and operating system) according to which the software application is executed. Examples of suitable programming languages include, but are not limited to, Visual Basic, Assembler, Visual C, standard C, C++ and Java.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0027] The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

[0028] FIG. 1 is a schematic block diagram of a system according to the present invention;

[0029] FIG. 2 shows an exploded view of the device;

[0030] FIG. 3 describes a general state flow diagram; and

[0031] FIG. 4 describes a bi-directional message format between the device and the gateway.

#### DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0032] The present invention is of a wrist-mounted device for measuring at least one physiological parameter of the

user. The present invention enables such a measurement to preferably be transformed into medical information about the user. Such information may then optionally be sent to medical personnel (for example at a contact monitoring center) and/or to a remote server, through a gateway device. The gateway device preferably communicates with the wrist-mounted device of the present invention through a wireless communication channel.

[0033] Examples of medical information which may be extracted from the measured physiological parameter or parameters include, but are not limited to: heart rate; variability in heart rate; breathing rate; arrhythmia of the heart (if any), as well as the general rhythm and functioning of the heart; blood pressure; presence of abnormal body movements such as convulsions for example; body position; general body movements; body temperature; presence and level of sweat; oxygen pressure in the blood; and glucose levels in the blood.

[0034] Optionally and more preferably, the present invention also features an alarm signal for being transmitted through the gateway device in order to indicate an emergency or otherwise dangerous situation for the user. The alarm signal may optionally be transmitted according to a manual action of the user, such as pressing a "panic button" for example.

[0035] Most preferably, the alarm signal is transmitted automatically upon measurement of the one or more physiological parameters of the user, preferably even if the user is unable to press the panic button. Optionally, the alarm signal may be given to the user, additionally or alternatively, for example by sounding an audible alarm, more preferably from the wrist-mounted device itself. Upon receipt of the manually/automatically activated alarm signal, the gateway would preferably initiate immediately a call to a human operated call center. Then the device would preferably automatically collect one or more current physiological measurements of the user. These measurements may be sent directly to the gateway, or alternatively may be analyzed in order to compute the medical parameters of the user before sending the results to the gateway. The human operator would then preferably be able to assess the user's medical condition from the received information.

[0036] The device of the present invention may also monitor, at least periodically but more preferably continuously, the value or condition of one or more physiological parameters of the user. Continuous monitoring would more easily enable the device to transmit the alarm signal if measurements of one or more physiological parameters are collected and analyzed by the microprocessor to form medical information, which then could be determined to be above predefined criteria, such as unstable heart rate, or very high or low blood pressure, for example.

[0037] According to preferred embodiments of the present invention, the wrist-mounted device features one or more sensors attached to a wristband or other fastening article. The sensor(s) are preferably connected to a microprocessor, optionally by a wire but alternatively through a wireless connection. The microprocessor may optionally also be located within the wristband, or otherwise attached to the wristband. The sensor(s) preferably support automatic collection of at least one physiological measurement; more preferably, the microprocessor is able to execute one or more

instructions for extracting clinically useful information about the user from such measurement(s).

[0038] The microprocessor more preferably operates a software program to process and analyze the data which is collected, in order to compute medical information. The extracted medical information, optionally also with the raw data, is then preferably transferred to the previously described gateway device. The gateway device then preferably relays such information to a remote server, which more preferably is able to provide such information to medical personnel, for example as part of a contact center. Therefore, continuous monitoring of the physiological parameters of the user may optionally and more preferably be made, enabling better medical care for the user.

[0039] A general, non-limiting example of suitable formulae for measuring the heart rate and/or other heart-related physiological parameters of a subject who is wearing the device according to the present invention may be found in the article "Cuff-less Continuous Monitoring of Beat-To-Beat Blood Pressure Using Sensor Fusion", by Boo-Ho Yang, Yi Zhang and H. Harry Asada—IEEE (also available through <http://web.mit.edu/zyi/www/pdf/IEEETrans2000.pdt> as of Dec. 9, 2001), hereby incorporated by reference as if fully set forth herein, where systolic and diastolic blood pressure are calculated using the pulse pressure shape per heartbeat. The disclosure does not describe a device which has the functionality according to the present invention, but the disclosed method is generally useful for determining blood pressure from an external measurement of pressure from the pulse through the skin of the subject.

[0040] The principles and operation of a device and method according to the present invention may be better understood with reference to the drawings and the accompanying description.

[0041] Referring now to the drawings, FIG. 1 is a schematic block diagram of a system according to the present invention. As shown, a system 1 features a wearable device 101 to be worn by a user, preferably as a wrist-mounted device, for example by being attached with a wristband or other fastening article to the wrist of the user. Device 101 features at least one physiological sensor 102 for measuring at least one physiological parameter of the user. The function of an exemplary sensor 102 is described in greater detail below.

[0042] The device 101 also preferably features a vibration sensor 123, preferably a piezoceramic sensor, which is not in direct contact with the skin of the user. Sensor 123 measures the movement of the wrist. The output of sensor 123 can be used by a processing unit 103 to capture the movement of the wrist and to recover some noise received by sensor 102 which is caused by such movement.

[0043] In order to support processing of the measured physiological parameter or parameters, processing unit 103 more preferably includes internal RAM and non-volatile program memory (not shown). Also more preferably, processing unit 103 includes an extended data memory 105 located externally to processing unit 103. Processing unit 103 preferably executes at least one instruction for processing the data obtained by sensor 102.

[0044] Examples of such processing units 103 include but are not limited to PIC18LC452 by Microchip Technology

Inc., which contains 10 channels of 10 bit A/D converters, a 1.5K bytes of internal RAM and 32K Bytes of non-volatile program memory.

[0045] Extended memory component 105 is preferably an electrically erasable non-volatile external memory component. Examples of such a memory component include but are not limited to FM24CL64-S (Ramtron, USA), with 64 Kbit of fast access read/write serial memory for storing temporary data related to the sampled physiological parameter.

[0046] Device 101 optionally and preferably features a real time clock 117 in order to provide an accurate time and date for each measurement, as device 101 can optionally store a few measurements before transmitting such data and/or information to a gateway device 110, as described in greater detail below. Stored data and/or information may also optionally be used for such applications as reminding the subject to take medication, perform a medical diagnostic measurement, and so forth. An A/D converter 109 with multiple inputs is also optionally and preferably present if sensor 102 is an analog sensor, in order to convert the analog signal to a digital signal.

[0047] Device 101 preferably features an internal communication unit 104, for at least unidirectional, but more preferably bi-directional, communication with gateway device 110. Gateway device 110 also preferably features a communication unit 107. Communication unit 104 may optionally communicate with communication unit 107 through a wire or alternatively through a wireless communication link 121. According to preferred embodiments of the present invention, gateway device 110 is located relatively close to the user and hence to device 101, for example by being located in the same building. As a non-limiting example, gateway device 110 could optionally be installed in the home of the user.

[0048] Gateway device 110 also optionally and preferably features a controller 108 for controlling functions of gateway device 110, such as communication with device 101 for example.

[0049] Gateway device 110 preferably communicates with a remote server 114 through a data link 120, which could optionally be a direct dial-up modem connection with DTMF coding or TCP/IP using regular LAN or dial-up modem connection to an ISP, for example. In any case, data link 120 may optionally be a wired or wireless link, for example through a cellular telephone and/or land-based telephone system, or a combination thereof.

[0050] Remote server 114 optionally and more preferably features a system administrator 112, which may be a person (for manual operation) or a software program (for automatic operation), or a combination thereof. Remote server 114 also preferably features a database 113 for storing data received from gateway device 110.

[0051] Device 101 may also feature a manually operated panic alarm button 116 to be manually activated by the user, for example if the user is in distress. Device 101 may also optionally feature a LED display 118, for example in order to indicate of alert activation or a low battery level.

[0052] Physiological sensor 102 is preferably part of a sensor assembly. Without wishing to be limited in any way,



the following discussion centers around such a physiological sensor **102** which contains a piezoceramic transducer for generating an electrical signal, having an amplitude corresponding to the magnitude of applied pressure. Therefore, if at least a portion of the transducer is located adjacent to, and in physical contact with, an area of the wrist where blood pressure pulses may be detected, the transducer generates electrical pressure pulses corresponding to the detected blood pressure pulses. Each of the electrical pressure pulses preferably defines a maximum voltage over a systolic interval and a minimum voltage over a diastolic interval.

[0053] Although a piezoceramic sensor is used as a pressure transducer according to a preferred embodiment of the invention, it should be appreciated that other transducers known to the art may be employed without departing from the spirit of the invention. Examples of such sensors include but are not limited to piezoelectric transducers, resistive strain gauges and pressure sensor made of fiber-optic techniques.

[0054] The piezoceramic transducer is desirable for the present invention since the transducer measures the direct effect of the pressure exerted within the radial artery, while other transducers, for example resistive strain gauges, measure secondary effects such as the strain forces that are applied at the surface of the skin due to the expansion of the radial artery. Piezoceramic transducers are also cheaper than piezoelectric transducers but still produce a high-quality signal.

[0055] As shown with regard to **FIG. 1**, the analog output of sensor **102** is first preferably treated by an analog front-end **119** which more preferably contains an analog filter (not shown). As a non-limiting example, this analog filter preferably has a cutoff of about 20Hz, a linear phase response, a flat amplitude response up to 10 Hz and an amplification of about 3 for acquiring the full spectrum of a typical blood pressure pulse. The filtered signal then enters A/D converter **109**.

[0056] Processing unit **103** preferably controls the operation of A/D converter **109**. When a physiological measurement is initiated, A/D converter **109** starts sampling the filtered analog signal of sensor **102** from analog front-end **119**, preferably at a rate controlled by processing unit **103**. This rate is optionally and more preferably 80 samples per second as to over sample the data by a factor of 4 to maintain a good quality sampled signal. A/D converter **109** preferably transfers the analog data into a digital coded word, preferably at resolution of 10 bits per sample.

[0057] Preferably about 30 seconds of data is gathered for each measurement. Processing unit **103** preferably operates a software program for examining the validity of the sampled data, in order to determine whether the data contains some indications of legitimate physiological data (such as of a blood pressure pulse of an artery) or alternatively whether the data contains only noise or poor readings. In the second case, A/D converter **109** preferably starts sampling the signal again in order to obtain data for measurement. This process preferably continues until the software determines that sufficient valid data has been collected or after a few successive rejections (usually after 3 times).

[0058] Then, the software program preferably performs an algorithm for calculating some medical parameters from the

sampled data, such as the calculation of systolic and diastolic blood pressure using a method as disclosed in the previously described U.S. Pat. No. 4,418,700, which is hereby incorporated by reference as if fully set forth herein.

[0059] The calculated parameters are then preferably stored in memory **105**. The data stored in memory **105** is preferably transmitted to gateway device **110** periodically, or alternatively or additionally after manual operation of panic button **116**.

[0060] The calculated parameters are also optionally and preferably displayed on a local LCD display (**124**), so the user can view the last medical results locally.

[0061] More preferably, data for all medical parameters that are sent to remote server (**114**) are sent according to a security protocol for maintaining the privacy of the user.

[0062] Furthermore, the software program preferably performs another algorithm for generating an alert if the medical parameters have values beyond or otherwise outside of the normal expected values.

[0063] Although a one-way link from device **101** to gateway device **110** may be used, device **101** preferably features a two-way communication link as shown for link **121**, for establishing more reliable communication with gateway device **110**. Examples of communication units **104**, **107** include but are not limited to a nRF401 UHF transceiver (Nordic), which operates in the universal ISM band (433.92 Mhz), an infrared transceiver, and a "Bluetooth" protocol enabled-transceiver operating bi-directionally in the 2.4 GHz band.

[0064] Device **101** preferably has its own unique identifier, stored in non-volatile data storage, more preferably in memory **105**. Each time device **101** sends a wireless message to gateway device **110**, device **101** also preferably sends the unique identifier to gateway device **110**, although optionally the identifier may be sent only periodically, for example once per day. Gateway device **110** also preferably sends a message to a particular device **101** by including the device identifier in the message, thereby specifying which such device should receive the message.

[0065] As previously described, device **101** preferably has its own real time clock **117**. For periodic monitoring of the user, real time clock **117** is preferably used to provide a time tag for each set of results. This time tag is very important for continuous monitoring of the user for long periods of time. By examining the data recorded over of the user for long period of time, a change or alteration in the health condition of the user may be detected. Real time clock **117** may optionally be implemented by separate hardware such as RTC8564 (EPSON, US) for example, or alternatively by a software program for operation by processing unit **103**.

[0066] Device **101** also preferably features a power source such as a battery **106**, which powers device **101**. Examples of suitable batteries include but are not limited to the silver oxide coin battery model 386 (Panasonic, Japan) having 150 mAh in capacity with a pulse burst of 75 mA for a short period of time (about 5 sec for each pulse). Battery **106** optionally and preferably contains enough energy to power the device for more than one year of operation without being replaced.

[0067] FIG. 2 shows an exploded view of the exemplary device according to FIG. 1. As shown, the device features sensor 102, shown with the preferred but exemplary implementation of a piezoceramic sensor as previously described. The device also optionally and preferably features battery 106, and a push button 316 (for optional implementation of the alarm button of the device of FIG. 1). Battery 106 may optionally be replaced with a plurality of smaller batteries (not shown). The device preferably features a processor 314 (which may optionally be similar or identical to the processing unit of the device of FIG. 1).

[0068] For this exemplary implementation, sensor 102 is in physical contact with an anvil 300. Anvil 300 preferably features a protrusion 302 which presses against the skin of the wrist of the subject (not shown), more preferably at a pulse point. Protrusion 302 therefore receives pressure with each pulse of the blood of the subject. This pressure is transduced through anvil 300 to sensor 102, which then emits voltage to form a signal, preferably according to a linear output.

[0069] This signal is then received by processor 314, which preferably extracts medical information from the measurement of the physiological parameter. Processor 314 optionally and preferably features a crystal oscillator 314, for stabilizing the internal clock of processor 314. Processor 314 is also preferably in contact with the real time clock of the device (not shown). Also not shown are the extended memory, transceiver (communication unit), A/D converter and analog front end of the device.

[0070] Processor 314, oscillator 312 and push button 316 are all preferably mounted on a PCB board 308. PCB board 308 is then preferably sandwiched between battery 106 and a device cover 304. Device cover 304 preferably features a soft cover, which may be rubber for example, for enabling the user to locate and depress the alarm button through push button 316.

[0071] An o-ring 310 is preferably used for waterproof sealing between the upper and the bottom parts of the device. Anvil 300 then is held between sensor 102 and the skin of the user (not shown), for example by being affixed to sensor 102 with an adhesive substance.

[0072] According to an alternative implementation of the device of FIGS. 1 and 2, sensor 102 and anvil 300 could optionally be located in the wristband for affixing the device to the wrist of the user (not shown).

[0073] FIG. 3 is a flow chart of the operation of the device. As the device software begins operation for the first time, the software preferably makes some initializations using default values. Once the device has been initialized, the software preferably triggers a watchdog function shown as a "Watchdog" process, and then enters a sleeping mode for saving battery life, shown as a "Sleep" process.

[0074] If the end of a watchdog time period is reached, the device is assumed to have a fault in its operation, and a master reset is preferably initiated automatically.

[0075] The device is preferably "woken up" according to one of three triggers. First, the device is preferably woken up when the user presses a panic button manually. This process is shown by the "Alarm" state. The device then preferably immediately starts a transmission to the gateway device,

containing a distress indication and the device identifier. Then the device enters a receiving mode for a few seconds, waiting for acknowledge (ACK) from the gateway device. This process is shown as a "TX/RX" state.

[0076] If the acknowledge message is not received within this period of time a repeated message is initiated. Additional transmissions are initiated, if necessary. However, if after a predefined number of repeated times an acknowledge message is not received, an error message is stored within a log and no more tries are made. More preferably an indication LED starts blinking for a few seconds, optionally with an audible alarm. Then, the process returns to the "Sleep" state.

[0077] After receiving acknowledge, the process turns to "Supervise" state, where the device collects data from its sensors, preferably calculates some medical information concerning the current physiological status of the user. Then, it turns into "Tx/Rx" state, where the device transmits a message containing the identifier, and the calculated medical parameters. And if the received ACK contains no commands it returns to the "Sleep" state, otherwise it does the command and sends an ACK to the gateway. The gateway returns an ACK with another command to continue or without a command to terminate this process. After doing the last command the device returns to the "Sleep" state.

[0078] In the next case where the device exits its "Sleep" state, an external real time clock signals the device to execute an automatic check. Then, the process enters "Supervise" state as discussed in the above paragraph, only that this time for saving battery life, the device initiate the "Tx/Rx" process only once for a few successive times sending all the accumulated data in one transmission. Then, the device preferably enters a "Sleep" state unless the measured parameters exceed a predefined threshold at least once, but preferably for a few successive measurements. In this case, the device initiates an automatic alarm entering the "Alarm" state, if the device has permission to do so, as previously described.

[0079] When a timer for a supervise process has been running or after an alarm, the device preferably exercises an automatic check as described above, and after that initiates a transmission to the gateway device including all the data collected after the last transmission. Then the device preferably waits for acknowledge, preferably repeating the transmission again if not receiving such an acknowledge message. In the acknowledge message, a command for the device can be stored. In such a case the device performs this command and then it sends an acknowledge message to the gateway device. This process may optionally continue until an acknowledge message without a command is received, after which the device preferably returns to sleep mode.

[0080] In the third case, the device exit "Sleep" mode if of technical reasons a technician wants to change the operation software, the device enters "Boot Loader" state where a new software is loaded "on the fly" without a need to disconnect the batteries.

[0081] FIG. 4 describes an exemplary message format for exchanging messages between the device and the gateway device. Every message preferably starts with a preamble STX byte (hex 7E), followed by a byte which contains the number of bytes in the current message, and three bytes of

address, followed by a command byte and its corresponding data bytes. This is followed by two bytes of CRC and an ETX byte (hex 7B).

[0082] As such, the message is a variable length message with strong error detection and correction method for enhanced communication reliability. Each message optionally and preferably contains a low battery indication, if necessary.

[0083] In case of a unidirectional communication link between the device and the gateway, a repeated message is preferably transmitted for a predefined number of times, such as 20 times for example, after which the device preferably enters a sleeping mode if no answer is received.

[0084] In case of a bi-directional link, for each message sent to the gateway device, an acknowledge message is preferably returned by the gateway device and vice versa. This message may also contain a command for the device encoded in the CMD byte within the message. Commands could optionally include, but are not limited to, one or more of the following:

[0085] 1) Get/Set service type

[0086] 2) Get/Set device ID

[0087] 3) Set interval between successive medical checking

[0088] 4) Set interval between successive supervision transmissions

[0089] 5) Set Time and date

[0090] 6) Set threshold for automatic alerts

[0091] 7) Set device calibration

[0092] Each time the device sends a message to the gateway, it may optionally contain a Battery OK/Battery Low indication for the battery situation. This signal preferably appears three months before the battery finishes, enough time to ask the user to replace the battery.

[0093] Each time the device sends a supervise-type message to the gateway, it preferably sends also all the medical data stored in its memory with that message.

[0094] Each time the gateway device sends a command back to the device, the device preferably returns an acknowledge message with a 3 bit message serial number to the gateway device, in order to fulfill a full handshake between the two. If the gateway device does not receive acknowledge from the device within a few seconds, the gateway device preferably sends its transmission message again with the same serial number. The message may even be repeated a few times, each time waiting for acknowledge. If acknowledge is not received, a logbook is updated with an error message, and more preferably an indication LED is turned on for error indication.

[0095] It will be appreciated that the above descriptions are intended only to serve as examples, and that many other embodiments are possible within the spirit and the scope of the present invention.

What is claimed is:

1. A device for measuring at least one physiological parameter of a subject, comprising:

- (a) a fastening article for being fastened to a wrist of the user;
- (b) a sensor for measuring at least one physiological parameter of the user, said sensor being in contact with at least a portion of said wrist and said sensor being attached to said fastening article; and
- (c) a processor for receiving a signal from said sensor and for converting said at least one measurement to form medical information.

2. The device of claim 1, wherein said sensor is an analog sensor, the device further comprising an A/D (analog to digital) converter for receiving an analog signal from said sensor and for converting said analog signal to a digital signal, said digital signal being sent to said processor.

3. The device of claim 2, wherein a rate of sampling by said A/D converter is determined by said processor.

4. The device of claim 3, wherein said rate of sampling is at least partially determined according to a type of physiological parameter being measured.

5. The device of claim 1, wherein said physiological parameter is heart-related.

6. The device of claim 5, wherein said physiological parameter includes at least one of heart rate and blood pressure.

7. The device of claim 6, wherein said sensor is selected from the group consisting of a piezoceramic transducer, a piezoelectric transducer, a resistive strain gauge and a pressure sensor with fiber-optic components.

8. The device of claim 5, wherein said physiological parameter includes variability in heart rate.

9. The device of claim 5, wherein said physiological parameter includes breathing rate.

10. The device of claim 5, wherein said physiological parameter includes at least one of arrhythmia and overall cardiac rhythm.

11. The device of claim 5, wherein said physiological parameter includes body movements.

12. The device of claim 11, wherein said body movements include presence of abnormal body movements.

13. The device of claim 5, wherein said physiological parameter includes body temperature.

14. The device of claim 1, further comprising:

- (d) a non-volatile memory for storing at least one instruction for execution by said processor.

15. The device of claim 1, further comprising:

- (e) a communication unit for at least transmitting data.

16. The device of claim 15, wherein said communication unit also transmits a device identifier for uniquely identifying the device.

17. The device of claim 15, wherein said communication unit also receives data.

18. The device of claim 1, wherein said fastening article is a wristband.

19. A system for measuring at least one physiological parameter of a subject, comprising:

- (a) a device for measuring the at least one physiological parameter, comprising:

- (i) a fastening article for being fastened to a wrist of the user;
  - (ii) a sensor for measuring at least one physiological parameter of the user, said sensor being in contact with at least a portion of said wrist and said sensor being attached to said fastening article;
  - (iii) a communication unit for at least transmitting data; and
- (b) a gateway device for receiving said transmitted data for being monitored.
- 20.** The system of claim 19, wherein said transmitted data is monitored manually.
- 21.** The system of claim 20, further comprising:
- (c) a remote server in communication with said gateway device, said remote server providing said transmitted data to a human operator for manual monitoring.
- 22.** The system of claim 21, wherein at least one of a communication link between said gateway device and said remote server includes a telephonic connection.
- 23.** The system of claim 19, wherein said transmitted data is monitored at least partially automatically by said gateway device.
- 24.** The system of claim 19, wherein said device and said gateway device communicate bi-directionally, such that a message transmitted from said device is acknowledged by said gateway device, and such that if said gateway device does not acknowledge correct reception of said message, said device transmits said message again.
- 25.** The system of claim 19, wherein said device for measuring the at least one physiological parameter further comprises:
- (iv) a processor for receiving a signal from said sensor and for converting at least one measurement to form medical information.
- 26.** The system of claim 19, wherein at least one of a communication link between said device and said gateway device is a wireless link.
- 27.** The system of claim 19, wherein at least one of a communication link between said device and said gateway device is a wired link.
- 28.** The system of claim 19, wherein said communication unit of said device also receives data, such that communication between said device and said gateway device includes an acknowledge procedure.

**29.** The system of claim 19, wherein said device automatically performs a measurement of the physiological parameter upon manual activation of an alarm function by the subject.

**30.** The system of claim 29, wherein said data is automatically transmitted to said gateway device upon said manual activation.

**31.** The system of claim 19, wherein said device automatically and periodically performs a measurement of the physiological parameter.

**32.** The system of claim 31, wherein said data is automatically transmitted to said gateway device if said measurement is outside of an acceptable range.

**33.** The system of claim 32, wherein said measurement is combined with another measurement of at least one other parameter to determine if said measurements are outside of said acceptable range.

**34.** A method for monitoring a physiological parameter of a user, comprising:

providing a device for monitoring the physiological parameter, said device being attached to at least a portion of the user at a pulse point of the user;

monitoring the physiological parameter through said pulse point; and

if a level of the physiological parameter of the user is outside of an expected range, transmitting an alarm.

**35.** A device for measuring at least one physiological parameter of a subject, comprising:

(a) a fastening article for being fastened to a wrist of the user;

(b) a piezoceramic sensor for measuring at least one physiological parameter of the user at a pulse point of said wrist and said sensor being attached to said fastening article; and

(c) a processor for receiving a signal from said sensor and for converting said at least one measurement to form medical information.

\* \* \* \* \*

专利名称(译)	用于测量手腕处的生理参数的方法和设备		
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# 摘要(译)

一种用于测量用户的至少一个生理参数的腕戴式设备。本发明使得这种测量优选地能够转换成关于用户的临床有用信息。然后可以可选地通过网关设备将这样的信息发送给医务人员，例如在联系人和/或监控中心。网关设备优选地通过无线通信信道与本发明的腕戴式设备通信。

