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<p>(21) International Application Number: PCT/US00/02418 (22) International Filing Date: 28 January 2000 (28.01.00) (30) Priority Data: 60/117,966 29 January 1999 (29.01.99) US (71)(72) Applicants and Inventors: POUGATCHEV, Vadim I. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). BOGOMOLOV, Evgueni N. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). IAROSLAVSTEV, Igor V. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). ZHIRNOV, Eugene N. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). GRIBKOV, Eugene N. [RU/US]; 12422 Peacock Hill Ave. NW, Gig Harbor, WA 98332 (US). (74) Agent: JOHNSON, Larry, D.; Suite 130, 175 N. Redwood Drive, San Rafael, CA 94903 (US).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published Without international search report and to be republished upon receipt of that report.</p>
<p>(54) Title: PERSONAL PHYSIOLOGICAL MONITOR</p> <p>(57) Abstract</p> <p>A personal physiological monitor for evaluating autonomic nervous system functioning, said monitor including PPG, and/or GSR, and/or temperature sensors for acquiring raw physiological signals; a data processor for computing interbeat intervals from the raw PPG signal and re-sampling interbeat interval sequences with a linear interpolation procedure; transmission means for transmitting both raw signals and the interbeat intervals to a computer through a communication port; a visual display; and built-in flash memory.</p> <p style="text-align: right;">Apple Inc. APL1066 U.S. Patent No. 8,923,941</p>		

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PERSONAL PHYSIOLOGICAL MONITOR
DESCRIPTION

TECHNICAL FIELD

5 This invention is related to the subject of the
monitoring and assessment of the specific physiological
conditions reflecting the functions of the autonomic
nervous system (ANS) - heart rate variability, blood
volume pulse, galvanic skin reactions (GSR) and peripheral
10 skin temperature (TMP).

BACKGROUND ART

 It is known that the overall functioning of a living
organism is controlled by the autonomic nervous system.
15 The ANS has two antagonistic branches - the sympathetic
and parasympathetic nervous systems. Every organ is
activated by one branch and inhibited by the other.
Generally when the organism is in a calm state
(relaxation, sleep, etc.) several organs, including the
20 heart, lungs and blood vessels, are under the dominance of
parasympathetic control. When the organism is activated by
physical activity, psycho-emotional arousal or stress, the
organs are under dominant control of the sympathetic
nervous system. A healthy organism is capable of adjusting
25 to any outer influence by means of a quick and adequate
sympathetic response. Once that factor disappears the
parasympathetic activity increases balancing the
organism's overall autonomic regulation.

 It is important to have a means of measuring these
30 specific physiological parameters used for the evaluation
of the level of balance between the branches of autonomic
nervous system and their reactions. With such means,
specific provocative test factors are evaluated as well as
the condition of both branches. Such a tool can help a
35 human being learn how to cope with stress, thereby
achieving an autonomic balance as well as measuring
certain physiological effects of the autonomic nervous
systems regulations.

One of the most informative methods for the evaluation of the status of ANS sympathetic and parasympathetic branches is heart rate variability analysis. It is known that the time intervals between each two consecutive heartbeats vary and are under control of the autonomic nervous system. When the parasympathetic system is dominant the heart interbeat intervals (IBI) are oscillating with higher frequencies (0.15 - 0.4 Hz). When sympathetic arousal occurs, lower frequency oscillations take place.

There are two other physiological modalities that reflect the condition of autonomic regulation: skin conductance (galvanic skin response: GSR) and peripheral skin temperature. Skin conductance reflects changes in sweat gland activity driven by involuntary arousal of the sympathetic nervous system. These changes are rapid and varied as a reaction of the organism to outer events and slower changes reflecting variations of overall tonus of the sympathetic system. The skin temperature reflects a degree of vasoconstriction or dilation of the peripheral blood vessels, which also reflects a long-term process of the interaction of both branches of autonomic nervous systems. There is some disagreement regarding the efficacy of these latter two modalities for evaluating ANS balance, so they are noted here for reference purposes only.

Another physiological measure - blood volume pulse reflects the level of peripheral blood vessels constriction / dilation. Blood volume pulse is affected by the same autonomic function activity.

There is a standard mathematical procedure for short-term HRV evaluation, suggested by the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology (1996). It provides both time and frequency domain analysis of the IBI time series. There are three important parameters of frequency domain analysis of HRV that reflect the levels of sympathetic and parasympathetic activities and their balance. The high frequency range (0.15 Hz- 0.4 Hz) of the

IBI power spectrum (HF) reflects parasympathetic influence on heart rate. The low frequency range (0.04 Hz -0.15 Hz) of the IBI power spectrum (LF) has a considerable input of the both branches of the autonomic nervous system.

5 To perform the HRV analysis an electrocardiograph (ECG) signal is usually measured. The IBI are derived from the ECG as the intervals between consecutive R-peaks. This method is very accurate and reliable but has a serious disadvantage - it requires the use of complex ECG
10 equipment with the inconvenience of multiple site electrode placement. An alternative is to use a photoplethysmograph (PPG) measurement, which is a portable and convenient optical sensor that can be applied in many places to pick up peripheral blood flow changes (e.g.
15 fingers, ear lobe, etc.). The PPG emits an infrared (IR) light on the skin. The emitted light is partially consumed by the blood flow. The degree of light consumption / reflection is proportional to the changes in blood flow. The PPG signal has periodic peaks that represent flow
20 pulsation in blood vessels. It can be used to derive the IBI by measuring the time between two PPG peaks. Blood volume pulse information can be derived as well.

DISCLOSURE OF INVENTION

25 The personal physiological monitoring method of the present invention includes several possible hardware configurations of the physiological monitoring apparatus. Generally a physiological monitor continuously carries out any of the following functions depending on the particular
30 hardware configuration:

1. Acquires raw signals any of the following physiological modalities: PPG, GSR or temperature;
2. Computes interbeat intervals from the raw PPG signal;
- 35 3. Re-samples interbeat interval sequence with a linear interpolation procedure;
4. Transmits both raw signals and the interbeat intervals to a computer through a communication port;

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