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(54) METHOD AND SYSTEM FOR FACILITATING PATIENT SELF-MEASURING AND RECORDING

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(57) **ABSTRACT**

Systems and methods for facilitating patient self-measuring and recording are provided. In some embodiments, an exhalation pressure of a patient may be measured via a pressure transducer during a time period associated with an examination. A graphical component (indicating the exhalation pressure measurement) may be presented on a display such that the graphical component is continuously updated in real-time, as the exhalation pressure is being measured, until at least the end of the time period associated with the examination. Another graphical component (indicating a remaining time of the time period) may be presented on the display such that the other graphical component is continuously updated in real-time, as the exhalation pressure is being measured, until at least the end of the time period associated with the examination. A heart rate of the patient may be measured via electrocardiogram (ECG) electrodes during the time period associated with the examination.

Diagnostic tests for cardiovascular autonomic neuropathy

Resting heart rate
100 beats/minute is abnormal

Beat-to-beat heart rate variation
The patient should abstain from drinking coffee overnight
Test should not be performed after overnight hypoglycemic episodes
When the patient lies supine and breathes 6 times per minute, a difference in heart rate of less than 10 beats/minute is abnormal
An expiration: inspiration R-R ratio > 1.17 is abnormal

Heart rate response to standing
The R-R interval is measured at beats 15 and 30 after the patient stands
A 30:15 ratio of less than 1.03 is abnormal

Heart rate response to Valsalva maneuver
The patient forcibly exhales into the mouthpiece of a manometer, exerting a pressure of 40 mm Hg for 15 seconds
A ratio of longest to shortest R-R interval of less than 1.2 is abnormal

Systolic blood pressure response to standing
Systolic blood pressure is measured when the patient is lying down and 2 minutes after the patient stands
A fall of more than 30 mm Hg is abnormal
A fall of 10 to 29 mm Hg is borderline

Diastolic blood pressure response to isometric exercise
The patient squeezes a handgrip dynamometer to establish his or her maximum
The patient then squeezes the grip at 30% maximum for 5 minutes
A rise of less than 16 mm Hg in the contralateral arm is abnormal

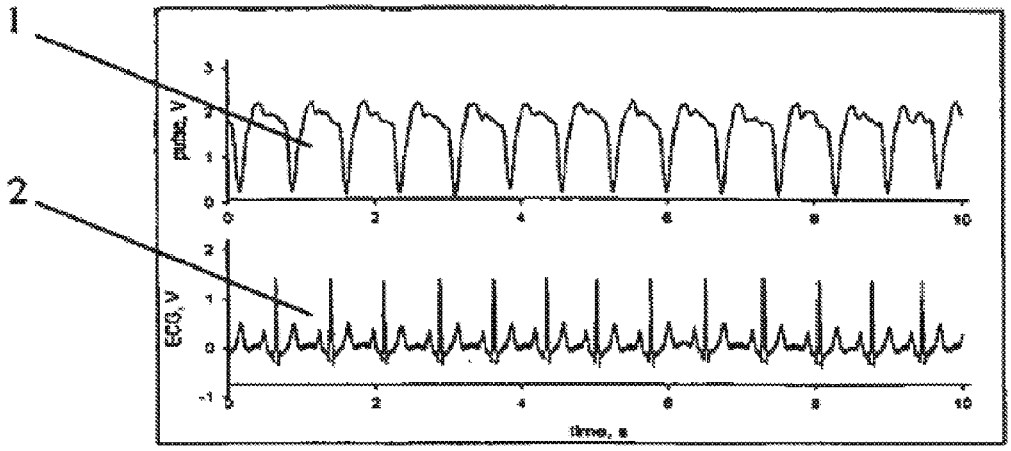
1
2
pulse, V
ECG, V
time, s

FIG. 1

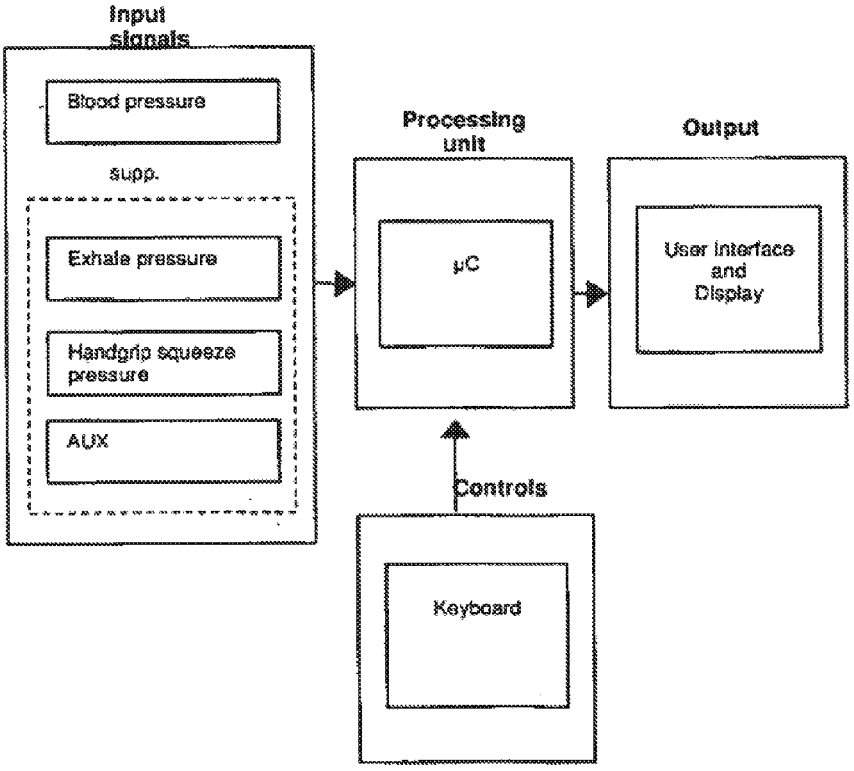
Input signals
Blood pressure
supp.
Exhale pressure
Handgrip squeeze pressure
AUX
Processing unit
µC
Output
User interface and Display
Controls
Keyboard

FIG. 2

Diagnostic tests for cardiovascular autonomic neuropathy

Resting heart rate
100 beats/minute is abnormal

Beat-to-beat heart rate variation
The patient should abstain from drinking coffee overnight
Test should not be performed after overnight hypoglycemic episodes
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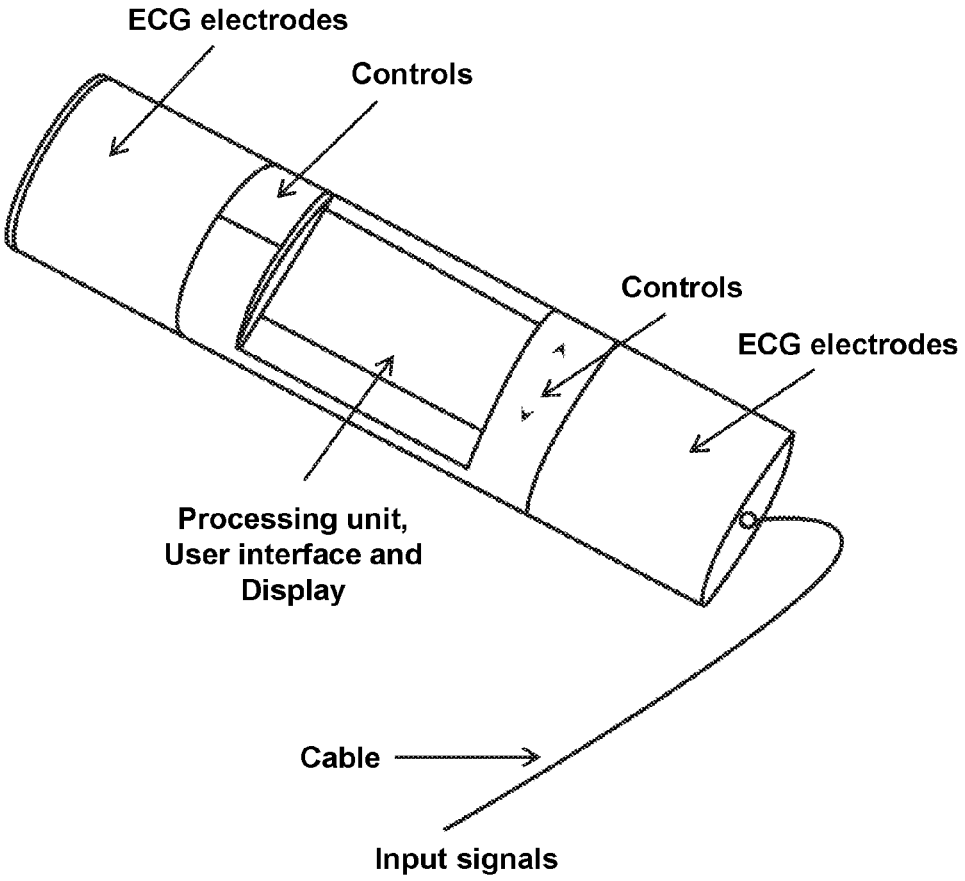
The patient squeezes a handgrip dynamometer to establish his or her maximum
The patient then squeezes the grip at 30% maximum for 5 minutes
A rise of less than 16 mm Hg in the contralateral arm is abnormal

FIG. 3


ECG electrodes
Controls
Controls
ECG electrodes
Processing unit,
User interface and
Display
Cable
Input signals

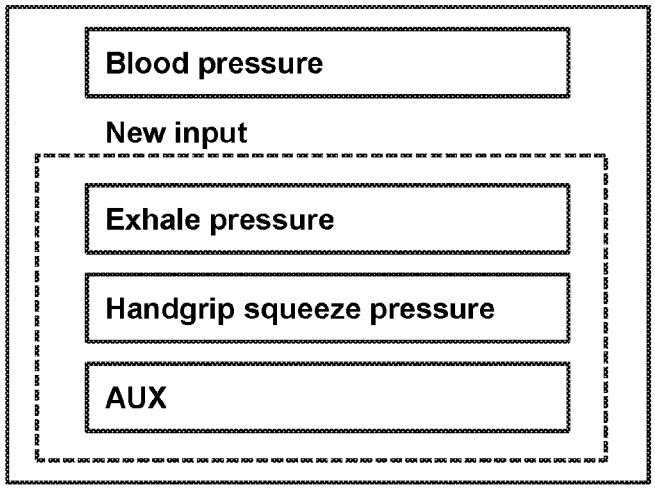

Blood pressure
New input
Exhale pressure
Handgrip squeeze pressure
AUX

FIG. 4

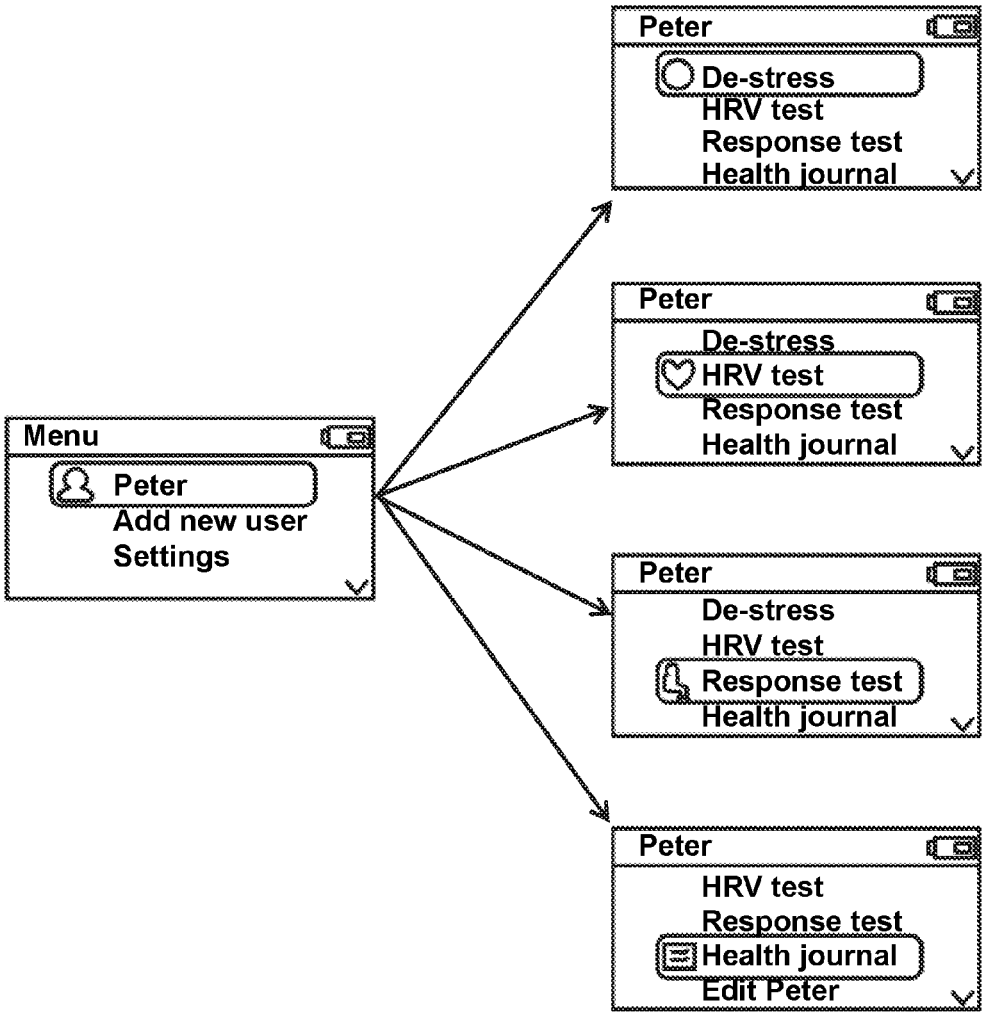

Menu
Peter
Add new user
Settings
Peter
De-stress
HRV test
Response test
Health journal
Peter
De-stress
HRV test
Response test
Health journal
Peter
De-stress
HRV test
Response test
Health journal
Peter
HRV test
Response test
Health journal
Edit Peter

FIG. 5

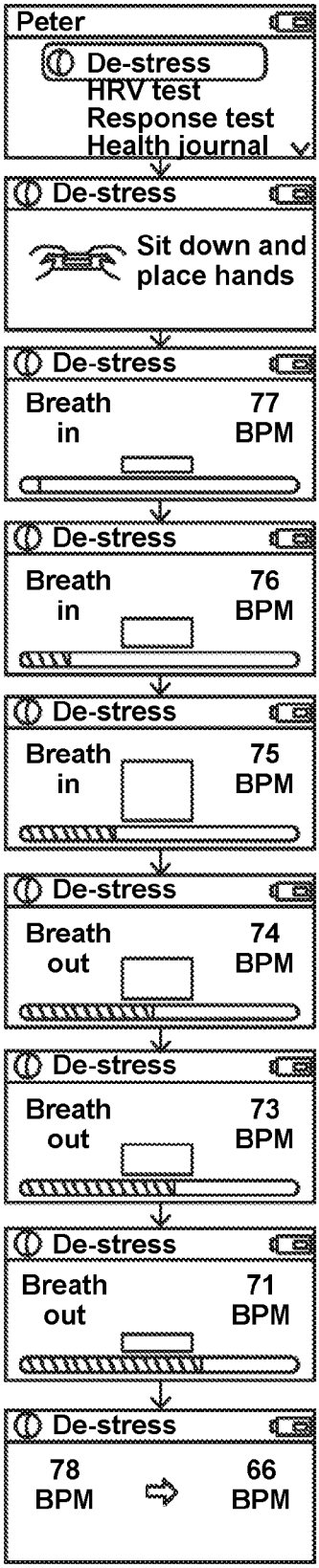

Peter
De-stress
HRV test
Response test
Health journal
De-stress
Sit down and place hands
De-stress
Breath in
77 BPM
De-stress
Breath in
76 BPM
De-stress
Breath in
75 BPM
De-stress
Breath out
74 BPM
De-stress
Breath out
73 BPM
De-stress
Breath out
71 BPM
De-stress
78 BPM
66 BPM

FIG. 6

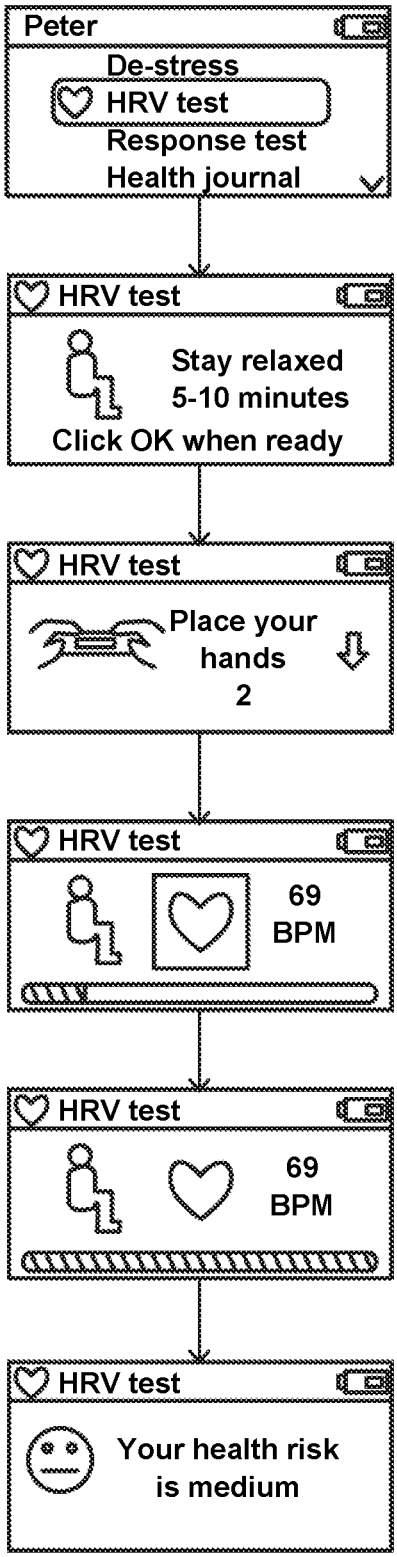

Peter
De-stress
HRV test
Response test
Health journal
HRV test
Stay relaxed
5-10 minutes
Click OK when ready
HRV test
Place your
hands
2
HRV test
69
BPM
HRV test
69
BPM
HRV test
Your health risk
is medium

FIG. 7

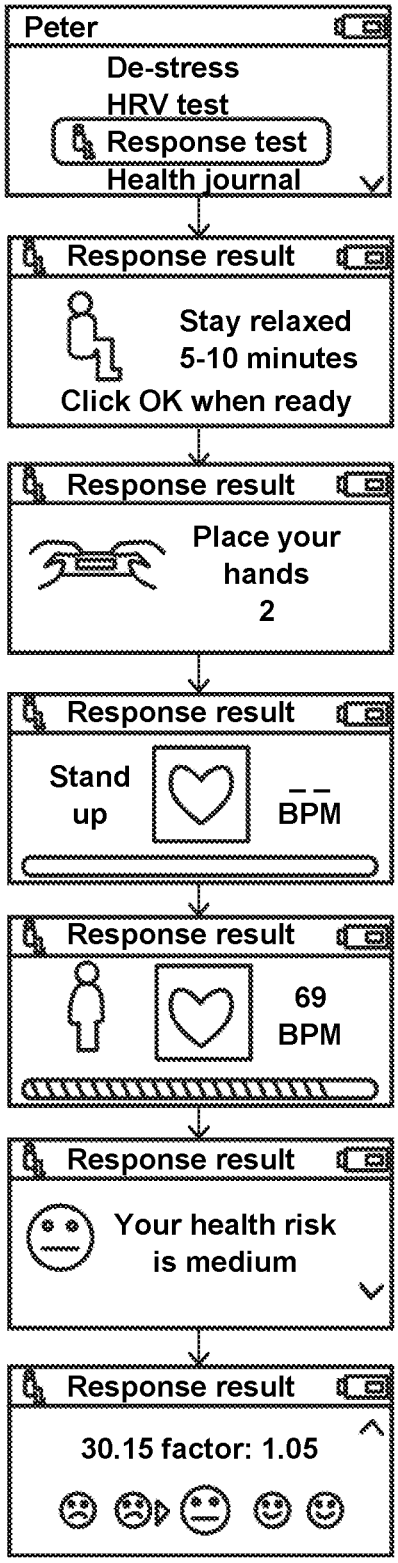

Peter
De-stress
HRV test
Response test
Health journal
Response result
Stay relaxed
5-10 minutes
Click OK when ready
Response result
Place your
hands
2
Response result
Stand
up
_ _
BPM
Response result
69
BPM
Response result
Your health risk
is medium
Response result
30.15 factor: 1.05

FIG. 8

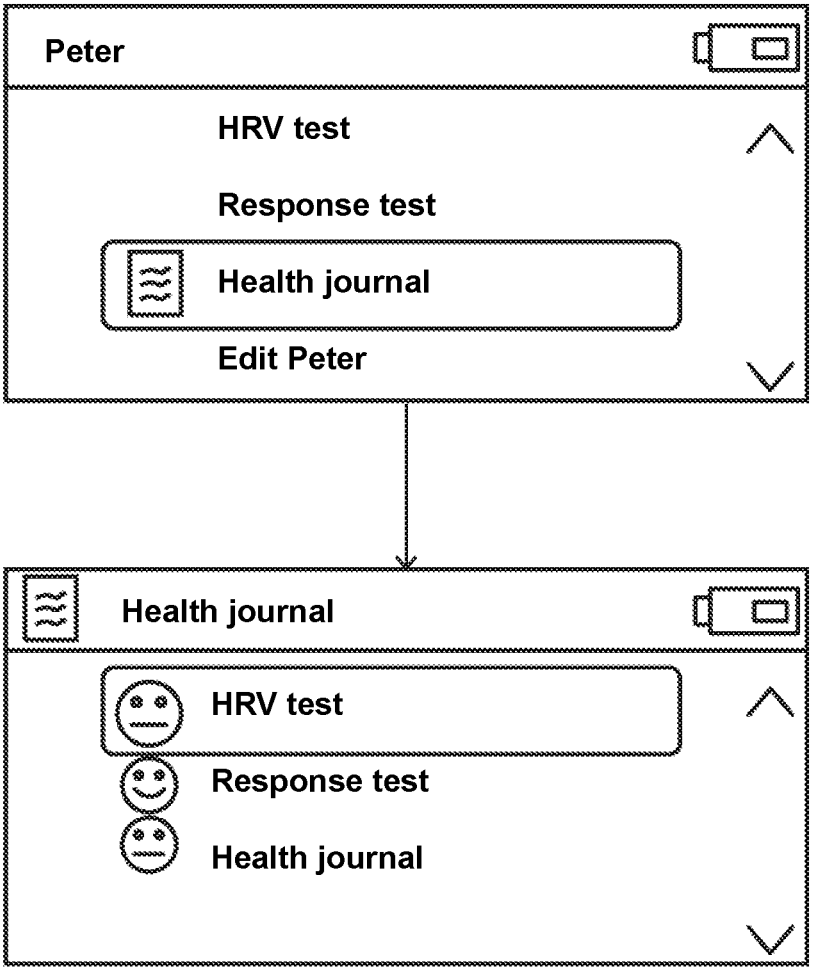

Peter
HRV test
Response test
Health journal
Edit Peter
Health journal
HRV test
Response test
Health journal

FIG. 9

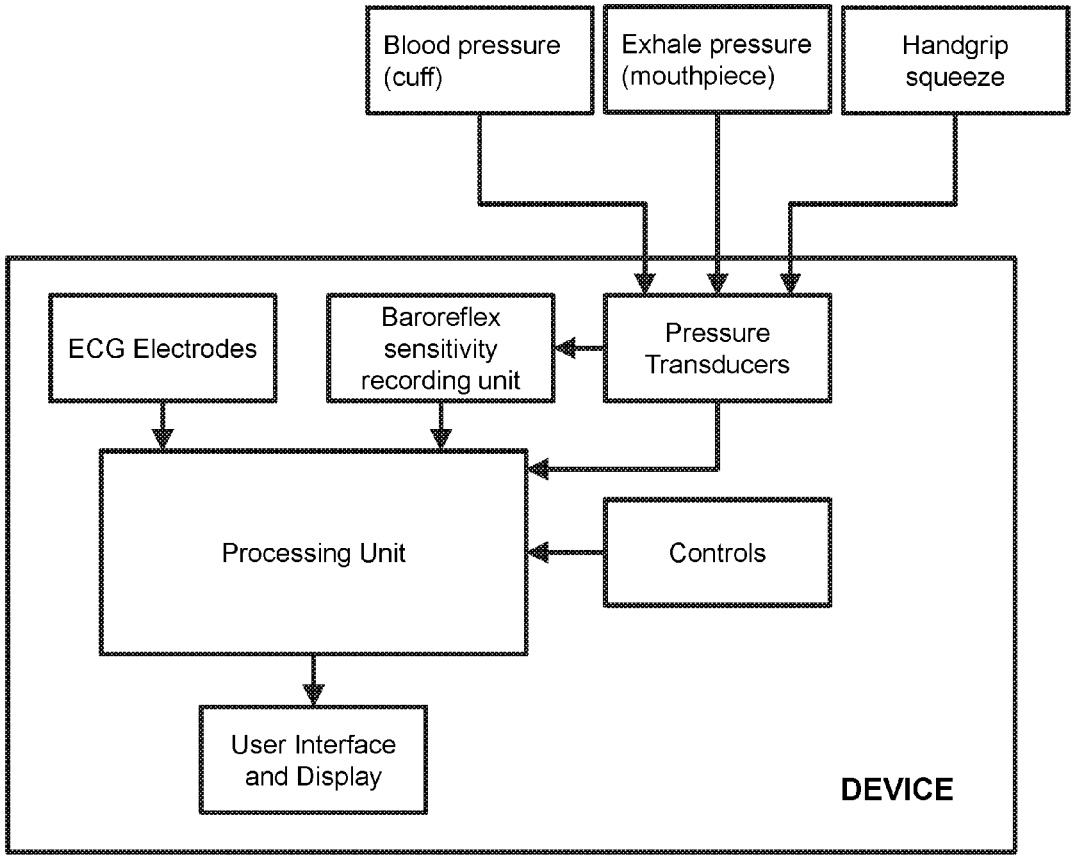

Blood pressure (cuff)
Exhale pressure (mouthpiece)
Handgrip squeeze
ECG Electrodes
Baroreflex sensitivity recording unit
Pressure Transducers
Processing Unit
Controls
User Interface and Display
DEVICE

FIG. 10

METHOD AND SYSTEM FOR FACILITATING PATIENT SELF-MEASURING AND RECORDING

FIELD OF THE INVENTION

[0001] The invention relates to methods and systems for facilitating patient self-measuring and recording.

BACKGROUND OF THE INVENTION

[0002] It is known to perform measurements on humans or animals in order to deduce information about the physiological state of the measuring objects. Blood pressure is among the physiological data, which in this connection, is often registered.

[0003] The blood pressure is routinely being measured both in healthy people, e.g., athletes as a part of optimizing training activities, as well as in ill people, where the information about the blood pressure is often a significant parameter in the clinical diagnosis.

[0004] The blood pressure is often measured as one of several physiological parameters, which combined can provide better and more clearly defined information about the physiological state of the measuring object.

[0005] One of the most important additional physiological data, which is often collected as an addition to the blood pressure determination, is information about the heart pulse, typically including recording of the so-called electrocardiographic signal (ECG).

[0006] Among the parameters, which are often desired to be derived in relation with assessment of the physiological state, is the so-called Heart Rate Variability (HRV), which is defined as the distance in milliseconds from heartbeat to heartbeat.

[0007] Another important parameter, which directly connects information about blood pressure and heart pulse, is the so-called baroreflex sensitivity (BRS), which is defined as the change in the distance in milliseconds from heartbeat to heartbeat as a result of change in the so-called systolic pressure and is thereby measured in the unit [msjmmHg].

[0008] As a result of the still more intense physiological and medical research, there is a still increasingly demand for linkage of different physiological data such as blood pressure and heart pulse.

[0009] With the hitherto known technique, these compound physiological data have been collected with a number of separate measuring instruments, which have separately measured the single physiological data such as blood pressure and heart pulse.

[0010] It has been found, however, that this known technique involves some drawbacks.

[0011] One of these drawbacks originates from the fact that the measuring procedures become complicated since there is often simultaneously being used several measuring devices.

[0012] Besides the difficult and time-consuming aspect of getting several independent measurement devices to work simultaneously, the possibilities of erroneous measurement will statistically increase along with the complexity of the measurements.

[0013] Moreover the analysis work is made inconvenient since data from different measurement devices must be integrated, including scaled and time-synchronized before the data processing can be completed.

[0014] Besides being time-consuming and thereby adding to costs as well as being subjected to an increased risk of errors, the compound measurements with use of several different measurement devices is also causing an increased discomfort for the people, who are going to be subjected to measurements.

[0015] The complexity of the measurements also means that the measurements must in practice be carried out in a laboratory environment, despite the measurements would typically have had a higher relevance in the assessment of the physiological state if they had been performed in the persons' daily environments.

SUMMARY OF THE INVENTION

[0016] In some embodiments, a method uses a measurement device, which can emit an electric signal proportional to the blood pressure of the measuring object, as well as being provided with technical means such as a digital signal processor for calculation of data such as Heart Rate Variability (HRV) and baroreflex sensitivity (BRS) values, as well as being provided with interface electronics for connection of additional signaling units such as pressure transducers and manometers, and being provided with algorithms for user control, calculation and data presentation of examination sequences, such as (1) resting heart rate, (2) beat-to-beat heart rate variation, (3) heart rate response to standing, (4) heart rate response to Valsalva maneuver, (5) systolic blood pressure response to standing, or (6) diastolic blood pressure response to isometric exercise. In this way, it thus becomes possible with only a single measurement device to measure inter-related physiological data, which includes both the blood pressure and the heart pulse.

[0017] As mentioned the invention also relates to an apparatus. In some embodiments, this apparatus is characterized in that the apparatus emits an electric signal, which is proportional to the blood pressure of the measuring object, as well as being provided with means such as a digital signal processor for recording and processing of the blood pressure signal, as well as algorithms for derivation of data such as Heart Rate Variability (HRV) and/or baroreflex sensitivity (BRS) values. Hereby, it thus becomes possible, solely on the basis of measuring the blood pressure, to derive information about the heart pulse and thereby calculate HRV as well as BRS values.

[0018] In some embodiments, it may be a characteristic feature of the invention is that the device is provided with means for data recording such as pressure transducers, including ones for recording of exhalation air pressure and hand grip squeeze pressure, as well as algorithms for user control and data processing for carrying out test and/or examination sequences, as well as means such as display and/ or sound device(s) such as, e.g., loudspeakers for guiding a user and data presentation. Hereby, the advantage is achieved that physiologically connected data can be measured solely by using a single measurement device, which can besides, via an appropriate data presentation medium such as a display, guide the user through possible test(s) and exercises, which are included in a specific type of examination.

[0019] Further embodiments of the invention are described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0020] The invention will now be explained more fully with reference to the drawings, in which:

[0021] FIG. **1** shows correlation between blood pressure signal and ECG signal from the heart of a measurement object.

[0022] FIG. **2** shows a block diagram for the structure of an apparatus for measurement of compound physiological data, which involves both blood pressure and heart pulse.

[0023] FIG. **3** shows a list of standardized physiological tests where both blood pressure and heart pulse are included.

[0024] FIG. **4** shows attachment of input signal mediums to a central calculation, interface, and display unit.

[0025] FIG. **5** shows an example of visual display-guiding of examination choice.

[0026] FIG. **6** shows an example of visual display-guiding of a selected so-called de-stress examination type.

[0027] FIG. **7** shows an example of visual display-guiding of a selected so-called HRV test examination type.

[0028] FIG. **8** shows an example of visual display-guiding of a selected so-called response test examination type.

[0029] FIG. **9** shows an example of visual display-guiding of a selection of a so-called health journal.

[0030] FIG. **10** shows an example block diagram with respect to the measurement device in FIG. **4**.

DETAILED DESCRIPTION OF THE INVENTION

[0031] FIG. **1** shows blood pressure signal **1**, as it can be measured from, e.g., a human by using a blood pressure gauge, characterized in that it contains a transducer, which can submit an electric signal proportional to the registered blood pressure. The vertical axis shows the amplitude of the blood pressure (e.g., scaled in volt (V)), while the horizontal axis shows the time sequence (e.g., scaled in seconds (s)).

[0032] Moreover, in addition to the blood pressure signal **1**, ECG signal **2** from the same measurement object is shown. The ECG signal **2** is shown with the same horizontal timescale, as the blood pressure signal **1**, and the vertical axis for the ECG signal likewise specifies the amplitude of this signal.

[0033] It is common clinical practice to express the heart pulse on the basis of the distance between the so-called R signal components (the dominating peak) in the ECG signal based on the formula: Pulse=**60**/(R-R distance measured in seconds).

[0034] As it is seen from the two curve sequences for respectively blood pressure and the ECG, these proceed simultaneously over time.

[0035] Experiments have shown that it is possible by using an appropriate signal processing of the blood pressure signal to derive the heart pulse information from the blood pressure signal with a precision, which is comparable with the calculation based on the RR interval from the ECG signal.

[0036] When the heart pulse is derived on the background of the blood pressure signal, the ECG measurement device or similar special measurement devices can be excluded for physiological examinations, which link blood pressure and heart pulse.

[0037] FIG. **2** shows a block diagram, which basically describes the hardware structure of an integrated measurement apparatus, which can be used for physiological examinations, which involves data for both blood pressure and heart pulse.

[0038] The measurement device consists of a central processing unit marked μC, which can in practice be a digital signal processor or another similar component device.

[0039] The processing unit μC is controlled by a control unit, which can e.g. be a keyboard or a number of pushbuttons.

[0040] To the central process unit μC is also connected an output medium, which can e.g. be a display or a monitor including one, which includes a sound device.

[0041] The central processor μC moreover receives data from some input signals, including data from a blood pressure measuring unit, from which both blood pressure and the heart pulse can be derived.

[0042] The central processor μC can moreover be provided with additional input signal units, which can give information about e.g. exhale pressure and handgrip squeeze pressure as well as one or more additional aux signal input units for other specific measurement data.

[0043] By application of the shown hardware configuration the same, in the principle simple, measurement device can be used for recording and presentation of many different important physiological examinations.

[0044] FIG. **3** shows an overview of a number of examinations with physiological relevance, which the apparatus presented in FIG. **2** can be used to carry out.

[0045] The specified examinations include (1) resting heart rate, (2) beat-to-beat heart rate variation, (3) heart rate response to standing, (4) heart rate response to Valsalva maneuver, (5) systolic blood pressure response to standing, or (6) diastolic blood pressure response to isometric exercise.

[0046] All the shown examinations can be carried out with the measurement device (e.g., shown in FIG. **2**), that is without parallel application of ECG or another specific device for measuring heart pulse.

[0047] As it will appear from FIG. **3**, there is connected a specific procedure to several of the stated examination methods, which must be followed during the data recording.

[0048] It is a part of the present invention that the apparatus/device as shown in FIG. **2** contains algorithms, which can guide the user, including both the measurement object and the user of the device, to run and complete a specific examination correctly.

[0049] As an example of this the so-called Heart rate response to Valsalva maneuver examination can be mentioned, which is based on that the examined person exhales air with a pressure of 40 mmHg in a period of 15 seconds.

[0050] Here, the measuring apparatus shown in FIG. **2** will be able to graphically represent both the pressure, with which the person exhales and thereby guide the person to the correct pressure, as well as show the lapse of time and show the remaining time in which the person must maintain the correct exhalation pressure.

[0051] FIGS. **5-9** show examples of how the user as well as the person being examined via a display can be guided through all the phases in a selected examination type.

[0052] After the data collection the measuring device can, controlled by implemented calculation algorithms, subsequently derive the desired results and show these on the display unit or via a wireless data communication unit

transmit these to an external unit such as a computer including an electronic patient record.

[0053] With integration of a wireless data communication unit it will also be possible to record data wirelessly from the object being measured, so that wires etc. connected to the measuring object can be reduced to a minimum.

[0054] With the simplified measuring apparatus in accordance to the invention, it will be possible to move even complex physiological examinations away from dedicated examination laboratories and out in the environments, where the examined are normally to be found, which will be able to improve the physiological information.

[0055] The invention is not limited to the methods and devices, which are directly described or illustrated in this present document, but also includes all methods and devices/apparatus, which can indirectly be inferred from the text or the figures or a combination of these.

1. A system for facilitating patient self-measuring and recording, the system:

a pressure transducer, a display, electrocardiogram (ECG) electrodes, and a processor, the processor being configured to:

measure, via the pressure transducer, an exhalation pressure of a patient during a time period associated with an examination;

cause a first graphical component indicating the exhalation pressure measurement to be presented on the display such that the first graphical component is continuously updated in real-time, as the exhalation pressure is being measured, until at least the end of the time period associated with the examination;

cause a second graphical component indicating a remaining time of the time period to be presented on the display such that the second graphical component is continuously updated in real-time, as the exhalation pressure is being measured, until at least the end of the time period associated with the examination;

measure, via the ECG electrodes, a heart rate of the patient during the time period associated with the examination; and

calculate heart rate variability of the time period associated with the examination based on the heart rate measurement and cause a graphical component indicating the heart rate variability to be presented on the display.

2. The system of claim **1**, wherein the processor is further configured to:

measure, via the pressure transducer, a blood pressure of the patient during the time period associated with the examination.

3. The system of claim **1**, wherein the processor is further configured to:

measure, via the pressure transducer, a hand grip squeeze pressure of the patient during the time period associated with the examination.

4. The system of claim **1**, further comprising a baroreflex sensitivity recording unit.

5. The system of claim **1**, further comprising a plurality of push buttons configured to provide control signals to the processor.

6. The system of claim **1**, wherein the system is adapted to simultaneously measure pressure and ECG signals.

7. The system of claim **1**, wherein the processor is further configured to:

cause step-by-step instructions for performing patient self-measuring to be presented on the display during the examination and prior to the time period associated with the examination.

8. The system of claim **1**, wherein the processor is further configured to:

cause step-by-step instructions for performing patient self-measuring to be presented on the display prior to and during the time period associated with the examination.

9. The system of claim **1**, wherein the processor is further configured to:

cause one or more results of the examination to be presented on the display subsequent to the time period associated with the examination.

10. A method for facilitating patient self-measuring and recording, the method being implemented by a computer system comprising one or more processors executing computer program instructions that, when executed, perform the method, the method comprising:

measuring, via a pressure transducer, an exhalation pressure of a patient during a time period associated with an examination;

causing a first graphical component indicating the exhalation pressure measurement to be presented on a display such that the first graphical component is continuously updated in real-time, as the exhalation pressure is being measured, until at least the end of the time period associated with the examination;

causing a second graphical component indicating a remaining time of the time period to be presented on the display such that the second graphical component is continuously updated in real-time, as the exhalation pressure is being measured, until at least the end of the time period associated with the examination;

measuring, via electrocardiogram (ECG) electrodes, a heart rate of the patient during the time period associated with the examination; and

calculating heart rate variability of the time period associated with the examination based on the heart rate measurement and cause a graphical component indicating the heart rate variability to be presented on the display.

11. The method of claim **10**, further comprising:

measuring, via the pressure transducer, a blood pressure of the patient during the time period associated with the examination.

12. The method of claim **10**, further comprising:

measuring, via the pressure transducer, a hand grip squeeze pressure of the patient during the time period associated with the examination.

13. The method of claim **10**, further comprising:

causing step-by-step instructions for performing patient self-measuring to be presented on the display during the examination and prior to the time period associated with the examination.

14. The method of claim **10**, further comprising:

causing step-by-step instructions for performing patient self-measuring to be presented on the display prior to and during the time period associated with the examination.

15. The method of claim **10**, further comprising:

causing one or more results of the examination to be presented on the display subsequent to the time period associated with the examination.

* * * * *