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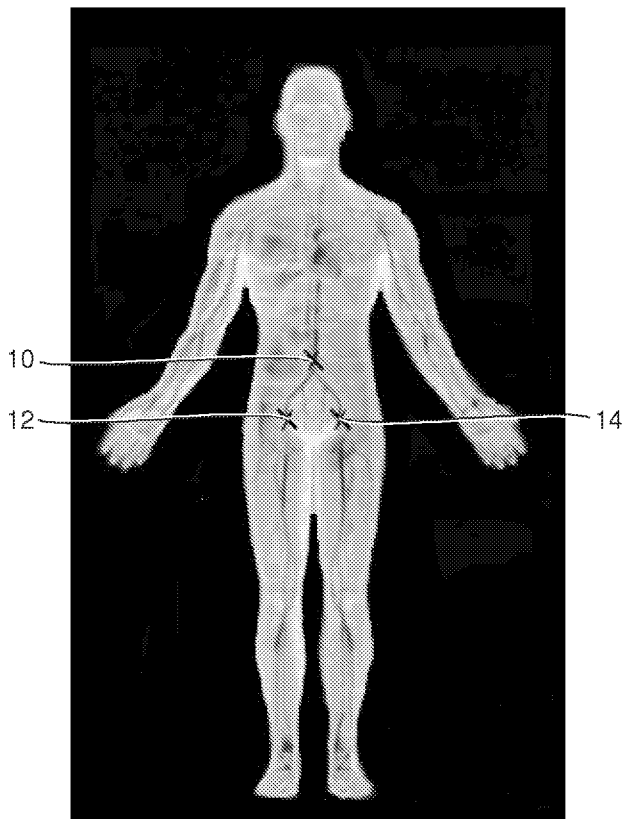
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(54) Title: **WEARABLE MONITORING SYSTEM**

(57) Abstract: A system for measuring/monitoring the vital signs of a patient especially blood pressure, comprising a plurality of electrodes arranged at least in the waistband of an undergarment, and means for deriving measurements from the electrodes using pulse- transit times.



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## Wearable Monitoring System

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This invention relates to monitoring systems adapted for continuously or at least regularly monitoring the vital signs of a subject, and particularly to a system for measuring blood pressure.

10 In all developed countries, cardio-vascular diseases like myocardial infarction, congestive heart failure or hypertension have an increasing impact on mortality and morbidity. There is an increasing demand for long term continuous monitoring of a patient's vital signs, which offers the opportunity to evaluate the performance of the cardio-vascular system. Various different blood pressure measurement systems have commonly been used in the past, which require a pressurised  
15 cuff or similar device which must be specially attached to the patient when a measurement is to be taken, and also require a suitably skilled clinician to operate them. Consequently such devices are usually confined to uses in a doctor's premises or in hospital, for example, and are not adapted for continuous or regular monitoring purposes.

20 Accordingly the present invention seeks to provide a blood pressure measuring system, which utilises Pulse Transit Time methodology for deriving measurements from detected signals such as the ECG, and can also be used for monitoring other vital signs. It is particularly suitable for implementation in a continuously wearable undergarment with integrated measuring sensors or electrodes, so  
25 as to be directly in contact with the subject's skin. Preferably the garment includes at least four electrodes in order to allow PTT measurements to be made without additional connections to the patient's body.

Preferably the sensors are of a type which do not require special attachment systems, gels or pastes to make proper electrical contact, for example they

may be dry electrodes of a type recently developed, made from conductive rubber, which rely only on naturally-produced sweat to make a conductive bridge between the skin and the electrode. Preferably, the undergarment comprises underpants having electrodes arranged internally, at least in the waistband area.

5                    Preferably, electrodes are so arranged as to measure the passing of pulses of the central artery, and the left and right femoralis, as well as the ECG. The system may also be arranged to monitor the temperature, the posture and the level of activity of the subject.

                    Preferably, pulse detection is achieved using bio-impedance methodology,  
10 by injecting a small AC current using a first pair of electrodes, and detecting voltage changes caused by the injected current, with a second pair of electrodes so as to produce an impedance plethysmogram. The preferred arrangement of the electrodes is such that it is possible to measure the plethysmogram of the central aorta, as well as the left and right femoralis. At the same time, it is also possible to measure the ECG, using the dry  
15 electrodes in the waistband.

                    Some embodiments of the invention will now be described by way of example, with reference to the accompanying drawings, in which:

20                    Figure 1 is a diagrammatic view showing the main arteries in a human body;

                    Figure 2 illustrates a typical electrode arrangement for impedance plethysmography;

                    Figure 3 shows a dry electrode of conductive rubber;

25                    Figure 4 illustrates an undergarment with integrated dry electrodes;

                    Figure 5 illustrates an ECG signal measured at the waist;

                    Figure 6 illustrates diagrammatically, the relative position of integrated dry electrodes in an undergarment, and the relevant measurement regions;

30                    Figure 7 is a schematic diagram of a signal processing unit;

Figure 8 illustrates ECG, IPG1, and IPG2 signals measured with the system of the invention; and

Figure 9 is a close-up of the signals of Figure 8.

5

The present invention proposes to use pulse wave velocity methodology, as a means of measuring vital parameters.

Pulse wave velocity (PWV) methodology is a suitable approach for monitoring mechanical parameters, but requires a set of at least two sensors distributed  
 10 around the body. For instance recent research has confirmed a good correlation between the blood pressure BP and the velocity of pulse wave (PWV). After calibration e.g. via a blood pressure reference measurement with a cuff this technique allows a beat-to-beat determination of BP. Typically a relation of blood pressure and PWV in arteries is expressed by the Moens-Korteweg-relation, which can be derived from hydrodynamic  
 15 theory:

$$c = \sqrt{\frac{hE_t}{2\rho R}}$$

Equation 1: Moens-Korteweg-equation often used to describe the relation of pulse-wave-velocity and blood pressure

where: c = pulse wave velocity,  $E_t$  = tangential elasticity module,  $\rho$  =  
 20 density,

R = radius of artery, h = artery wall thickness.

The experimentally verified relation:

$$E = E_0 e^{\alpha P}, \alpha \approx 0.017 \text{ mmHg}^{-1}$$

Provides the link between the PWV and blood pressure (P) variations.

25 The calibration step is necessary to scale the PWV to BP conversion, the other parameters ( $\alpha$ ,  $E_0$ , h, r) being clearly subject-dependent and quite difficult to measure directly.

The PWV can be determined by measuring the time of a pressure wave travelling a certain distance in the arterial system in various ways (this time will be called pulse transit time PTT) e.g.:

1. The time-difference of a pulse passing two points at a distance  $d$ .
- 5 2. The time-difference between the R-peak in ECG-signal and a passing pulse in an artery at a certain body position.

Typical set-ups in the literature are:

1. ECG – and Photoplethysmography PPG; PTT is given by time-difference between R-peak and characteristic points in PPG. The PPG can be measured  
10 at various positions on the body e.g. ear or finger.
2. ECG and bio-impedance measurement at arm (impedance plethysmography IPG); PTT is given by the time-difference between R-peak and characteristic points in the IPG.
3. Impedance Cardiography (ICG) of the thorax and bio-impedance  
15 measurement at arm (IPG); PTT is given by the time-difference between characteristic points in the ICG and characteristic points in the IPG.
4. Impedance plethysmogram (IPG1) at a first position on an arm and bio-impedance measurement at a second position on an arm (IPG2); PTT is given by the time-difference between characteristic points in the IPG1 and characteristic points in  
20 the IPG2.

If clinical standard sensors or methodologies are used, all these methods have several disadvantages especially for Personal Healthcare applications. State of the art sensors such as finger or ear sensors measuring a photoplethysmogram or bio-impedance methodologies are rather an inconvenience in normal life requiring finger and  
25 ear PPG sensors or special medical electrodes, which must be glued to the skin. Therefore such state-of-the-art sensors are not suitable for long term continuous monitoring in Personal Healthcare applications.

The general principle of bio-impedance measurements is illustrated by the diagram of Figure 2, which shows the technique applied to the leg 2 of a patient, in  
30 which a small AC current is passed through it via a first pair of electrodes 4. The

exciting current is a constant high frequency AC current with a very low amplitude (about 1 milliamp), which is therefore imperceptible to the patient, and does not have any significant physiological effects.

A further pair of electrodes 6 are then used to detect voltage changes  
5 caused by the exciting current, which are a measure of the variation in impedance caused by changes in blood volume and velocity. This enables the arterial volume pulsation to be measured, via a control/measuring circuit 8.

It will be appreciated that the same principle can be applied to  
10 measurements made in other regions of the body, and the present invention therefore proposes to make measurements in the region of the subject's waist, as indicated at 10 in the schematic of Figure 1, and also at 12 and 14 at the right and left femoralis, since these positions represent the major branching point of the subject's arterial system. The waistband position also has the significant advantage that a reasonably close fit of the electrodes in this region, will more naturally be accepted by the subject, since it  
15 corresponds to the normal position of the waistband of a garment. It is also significantly closer to the patient's heart, for making ECG measurements, and less subject to hydrostatic effects and motion artefacts than other possible monitoring sites for example in the limbs.

Figure 3 illustrates a dry electrode made of conductive rubber, which has  
20 a flexible body and is therefore ideal for integrating into an item of clothing. In the preferred arrangement of the invention, electrodes of this kind are integrated into an undergarment, such as the underpants 16 illustrated in Figure 4, where a number of such electrode are fixed into the waistband, as indicated at positions 18. These electrodes are adapted to make good electrical contact to the wearer's skin, without requiring any  
25 special paste or glue, but simply by utilising the conductivity of naturally secreted sweat. As is also shown in this Figure, a signal-processing circuit 20, corresponding to circuit 8 illustrated in Figure 2, can also be integrated into the waistband of the garment, behind a zip pocket as illustrated at 20.

Figure 5 illustrates a typical ECG of a subject at rest, measured with the  
30 electrode arrangement of Figure 4, in which the electrode positions are adjacent to the

patient's hips, so that they are relatively well spaced apart and thus enclose a reasonably significant volume of the subject's body. It can be seen that all of the significant regions, i.e. the P-wave, the QRS complex, and the T-wave are clearly delineated in the signal.

Figure 6 illustrates in a diagrammatic form, the different regions where a suitable undergarment may have integrated electrodes, so as to enable measurements to be made at the positions of the right and left femoralis, as well in the waistband area as indicated in Figure 4. As can be seen in this Figure, a first pair of electrodes 22 in the waistband are arranged at the hip positions, where a current  $I_1$  is injected, i.e. corresponding generally to the electrodes 4 illustrated in Figure 2, whilst a further pair of electrodes 24 also in the waistband are used for making a corresponding measurement of voltage changes  $V_1$ , i.e. corresponding generally to the electrodes 6 of Figure 2.

Further electrodes 26 and 28 are arranged respectively at the right and left leg positions, and in this way, for example, a current  $I_2$  can be injected between the corresponding waistband electrode 22 and the right leg electrode 26, to enable a voltage  $V_2$  to be measured, relative to the waistband position, at an electrode 30. Similarly, by injecting a current  $I_3$  between a left leg electrode 28 and the corresponding waistband electrode 22, a voltage  $V_3$  can be measured, relative to the waistband, at an electrode 32.

Figure 7 illustrates a signal processing circuit, suitable for integration into a garment as indicated at 20 in Figure 4, which combines a number of functions in the same unit. A front-end circuit 34 for impedance and a front-end circuit 36 for ECG measurements are connected to a central processing unit 38, and in order to allow compensation to be made for patient movements as well as the detection of the patient's posture and activity, a 3 axis accelerometer 40 may also be incorporated, as well as a temperature sensing device 42.

A power supply 44, which preferably incorporates long-life or rechargeable batteries, is provided for powering the unit, and a RF transceiver 46 enables the device to communicate data with external systems, such as a user interface. Storage means 48, for example a flash memory, is also incorporated to allow data to be stored or buffered whenever necessary. In this way the device can also be employed as a "Holter

monitor" (ambulatory electrocardiography device) so as to record cardiac activity over an extended period of time.

Figure 8 illustrates examples of signal measurements made with the system, in which figure 8(a) shows an ECG measurement taken at the waistband.

5 Similarly, figure 8(b) illustrates an IPG1 (impedance plethysmogram) as measured at the waistband, and figure 8(c) indicates a corresponding plethysmogram IPG2 taken at the right femoralis.

Figure 9 is an enlarged close-up view of the signals of figure 8, which shows how features can be extracted from the signals. By comparison of figures 9(a) and 9(b), a pulse transit time 1, i.e. ECG to IPG1, can be derived, and by comparison of  
10 and 9(b), a pulse transit time 1, i.e. ECG to IPG1, can be derived, and by comparison of figures 9(a) and 9(c), a pulse transit time PTT2, i.e. ECG to IPG2 can be also be derived.

Accordingly, it will be appreciated that the system of the invention allows the following different measurements to be taken:

15 Measured Signals:

- The ECG of a subject, the electrical activity of the heart (no standard lead)
- The blood volume pulse going into the left and right leg during a heartbeat (measured by an Impedance plethysmogram (IPG) of right and  
20 left leg), which indicates the mechanical performance of the heart activity
- 3 axis acceleration (static and dynamic)
- Temperature
- Time

Consequently the system is able to provide information on a broad  
25 portfolio of cardio-vascular parameters derived from the measured signals such as:

- Heart rate
- Detection of Arythmias
- 4 several Pulse transit Times (ECG->IPG1, ECG->IPG2, ECG->IPG3,  
30 IPG1->IPG2)

- Arterial stiffness/Augmentation index
- Relative blood pressure changes
- Absolute blood pressure
- Blood perfusion to left and right leg
- 5 • Stroke volume
- Activity measures (at rest, posture, movements)
- Context information derived from these signals (time, temperature, acceleration)

Various different useful applications are therefore possible, such as:

- 10 - Continuous Blood Pressure monitoring
- Sleep quality detection
- Hypertension Management
- Blood Pressure Halter Monitoring
- Elderly Care
- 15 - Continuous monitoring e.g. during cardiac-rehabilitation

## CLAIMS:

1. A system for measuring/monitoring the vital signs of a patient especially blood pressure, comprising a plurality of electrodes arranged at least in the waistband of an undergarment, and means for deriving measurements from the electrodes using pulse-transit times.
- 5 2. A system according to claim 1 in which the electrodes comprise dry electrodes of conductive rubber.
3. A system according to claim 1 or claim 2 in which there are four electrodes in the waistband, comprising a first pair of electrodes for injecting a current, and a second pair of electrodes for measuring a resulting voltage change, whereby measurements can be  
10 made using bio-impedance technology.
4. A measuring system according to any one of the preceding claims in which the electrodes are so arranged as to measure passing pulses in the central aorta of the patient.
5. A measuring system according to any preceding claim in which the undergarment  
15 comprises underpants.
6. A measuring system according to claim 5 in which additional electrodes are provided in the leg portions of the underpants, so as to measure passing pulses in the left and right femoralis.
7. A measuring system according to any preceding claim in which pulse-wave  
20 velocity measurements are made by detecting pulse transit times between spaced-apart sensors.
8. A measuring system according to any one of claims 1 to 6 in which pulse-wave velocity measurements are made by detecting the time difference between the R-peak of an ECG, and a passing pulse in an artery at a given sensor position on the body.

9. A measuring system according to any preceding claim further comprising a 3-axis accelerometer whereby the system can detect the patient's posture or activity level and compensate for signal artefacts caused by movements.
10. A measuring system according to any preceding claim including a signal-  
5 processing unit having a front-end circuit for receiving sensor signals means for storing data, and rf-transceiver means for communication with external data-processing and/or control means.
11. A measuring system according to claim 10 in which the unit is also adapted to  
10 receive manual input from the patient and to transmit information relating to the condition of the system and of the patient, to the external means.
12. A measuring system according to claim 10 or claim 11 further comprising an alarm for alerting the patient to a critical condition.
13. A measuring system according to any one of claims 10 to 12 further comprising means for sending an alert to a source of external professional assistance.
- 15 14. A measuring system according to any one of claims 10 to 13 in which the system is arranged to operate as a Holter monitor or ambulatory electrocardiography device, so as to record cardiac activity over an extended period of time.

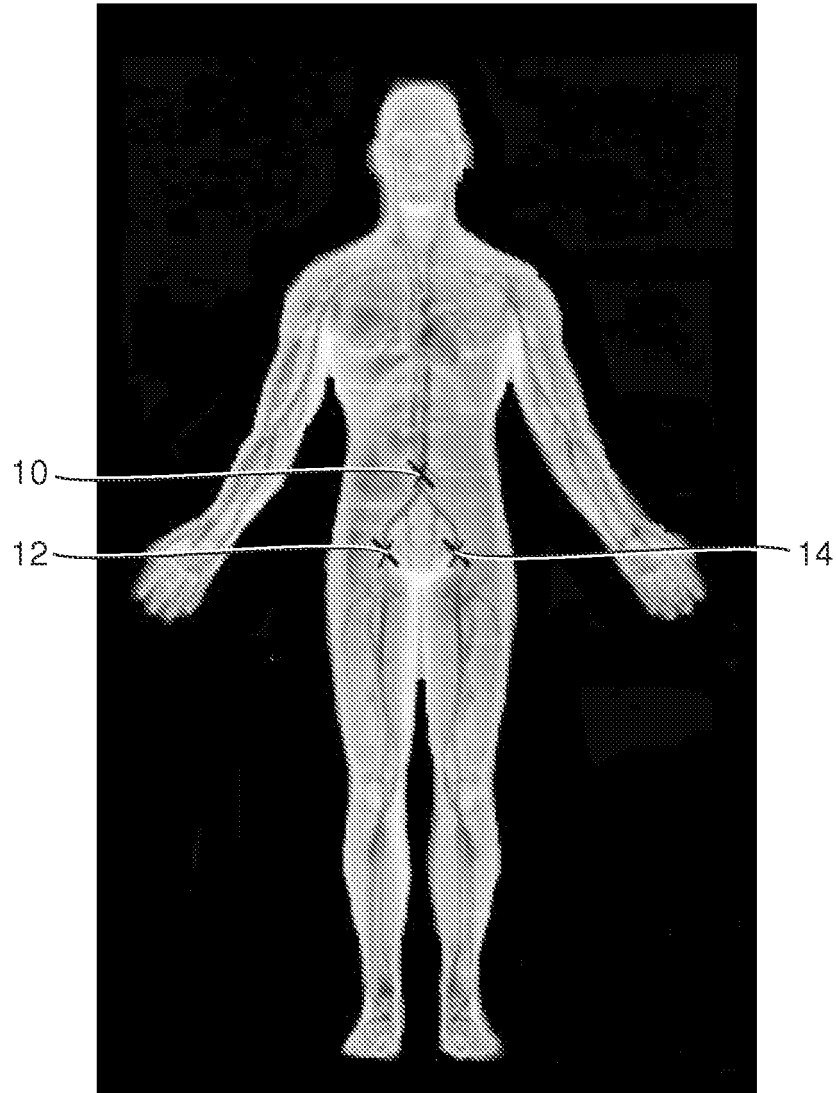


FIG. 1

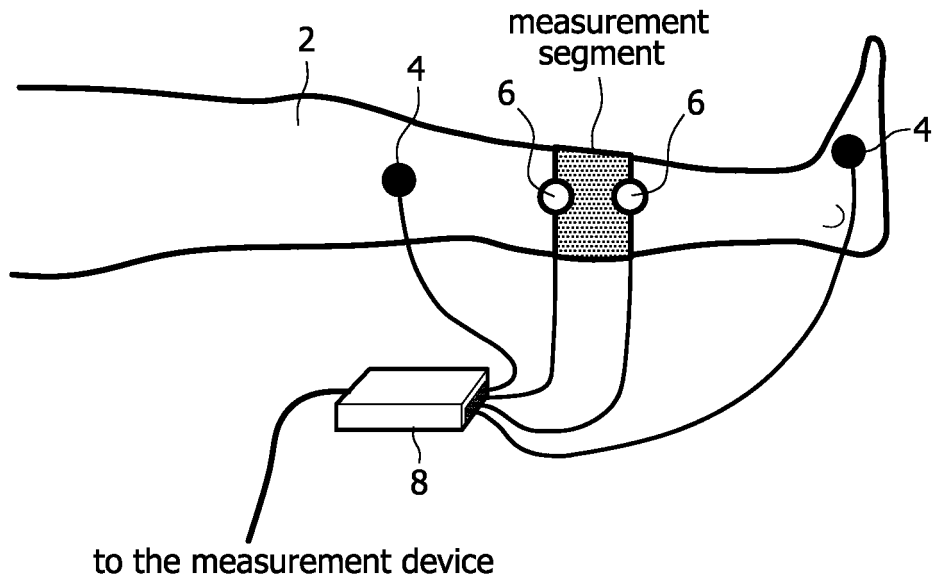


FIG. 2

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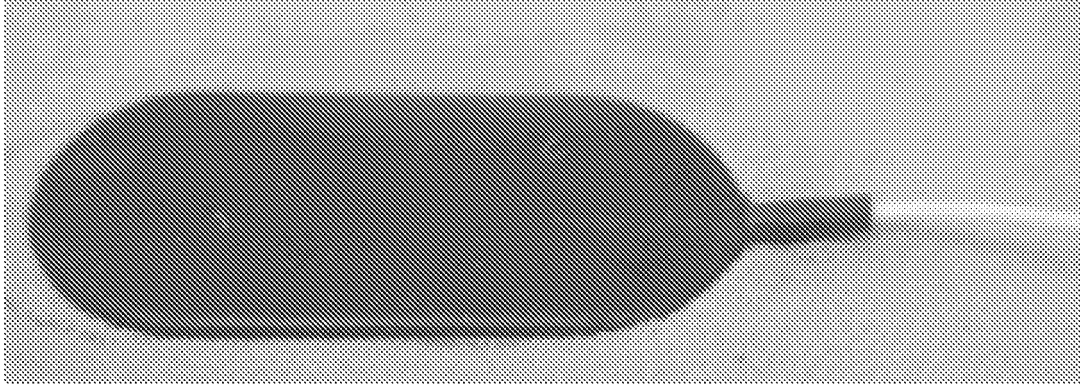


FIG. 3

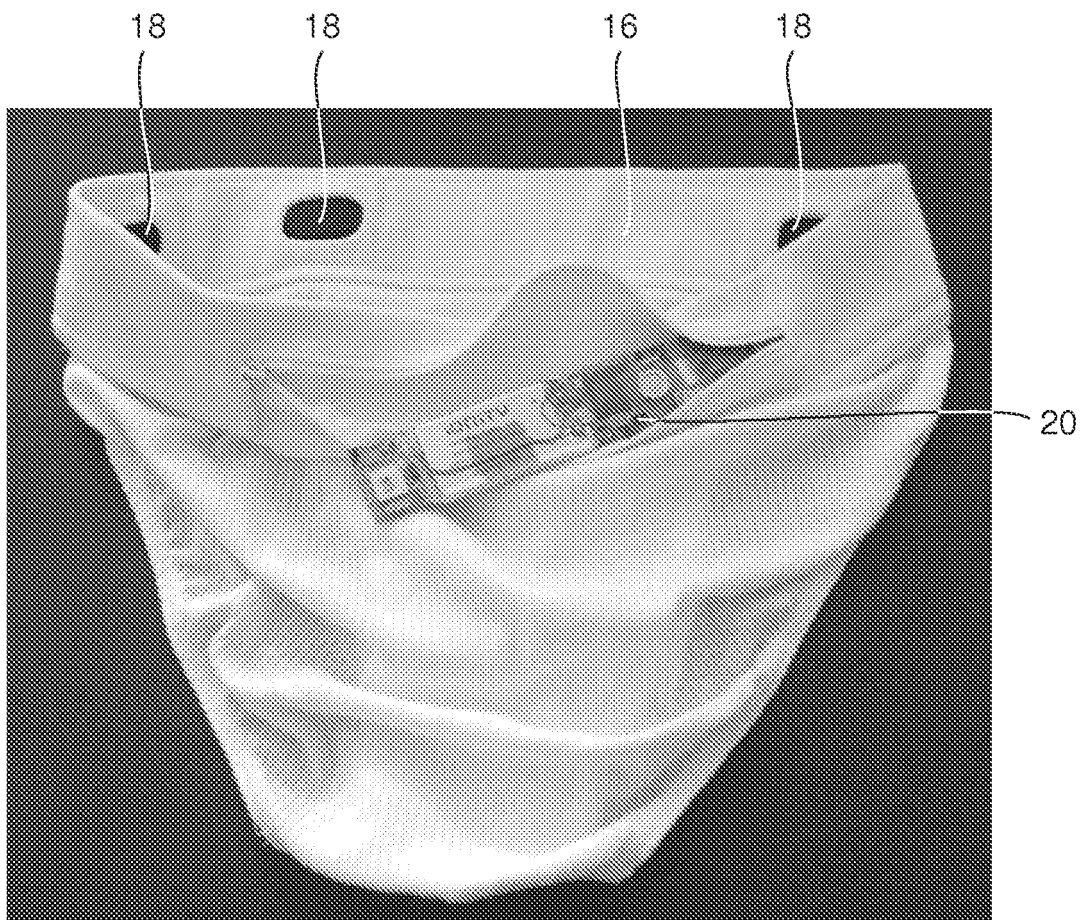


FIG. 4

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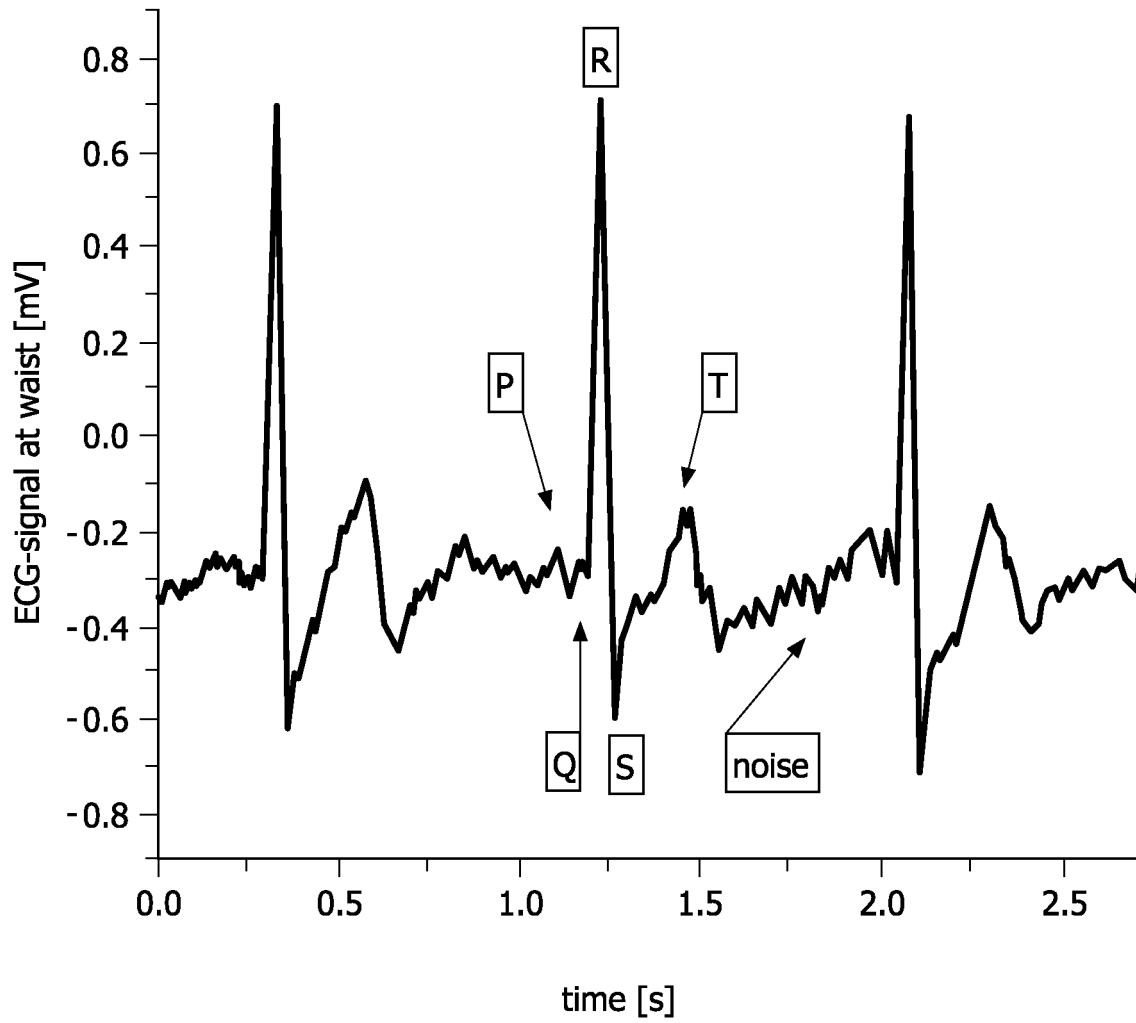


FIG. 5

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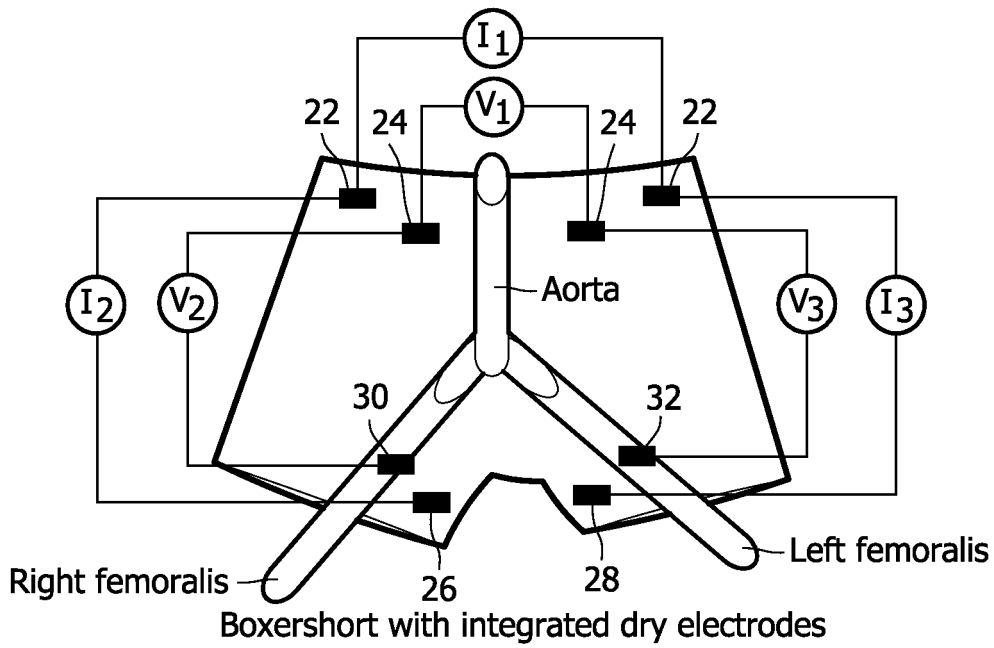


FIG. 6

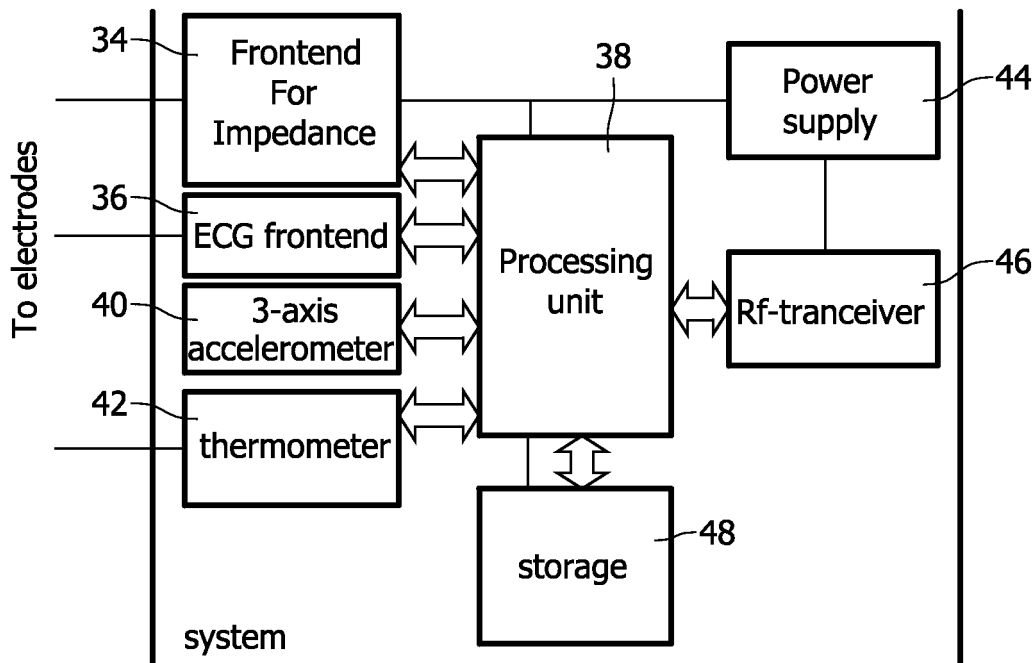


FIG. 7

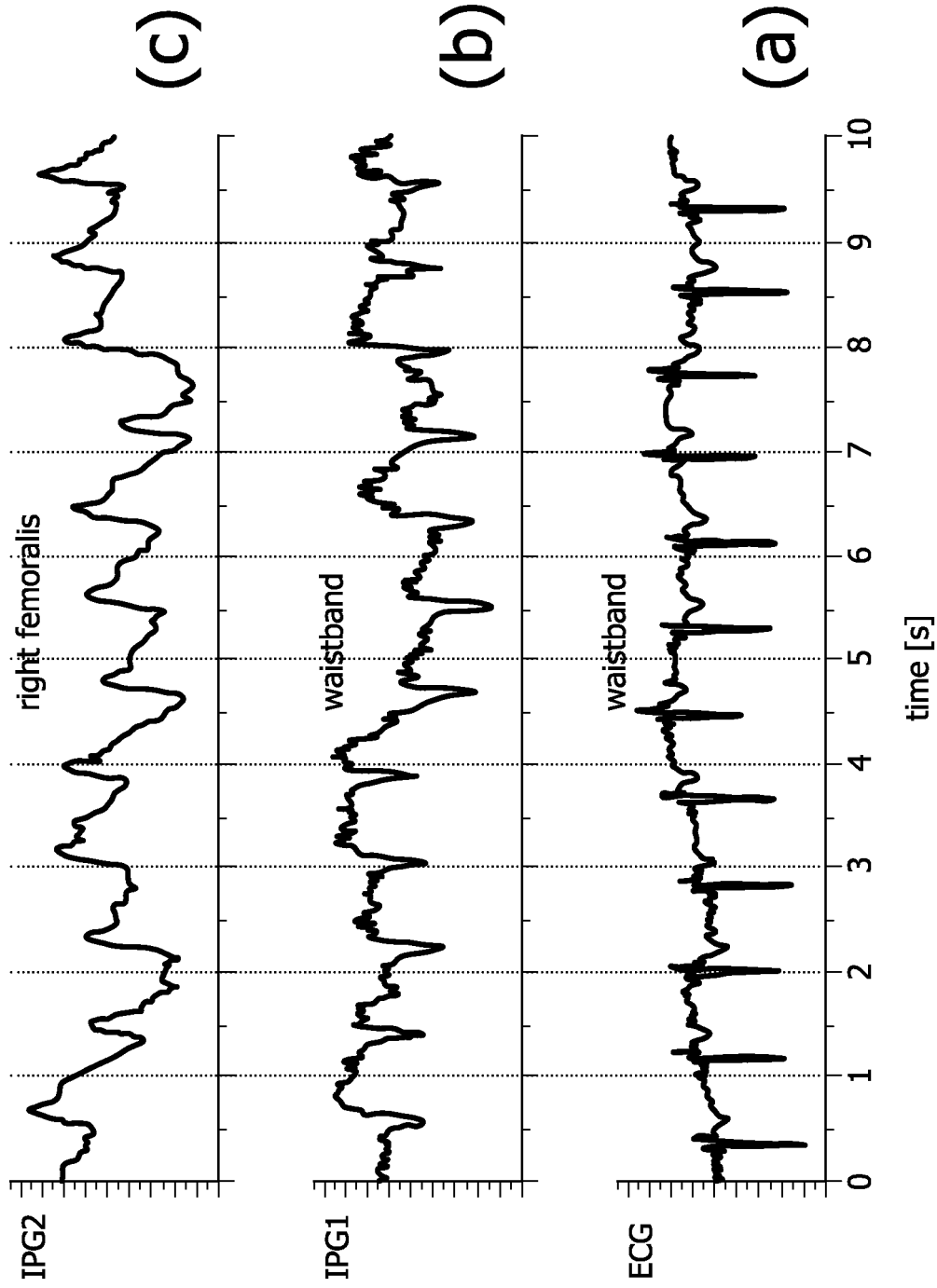


FIG. 8

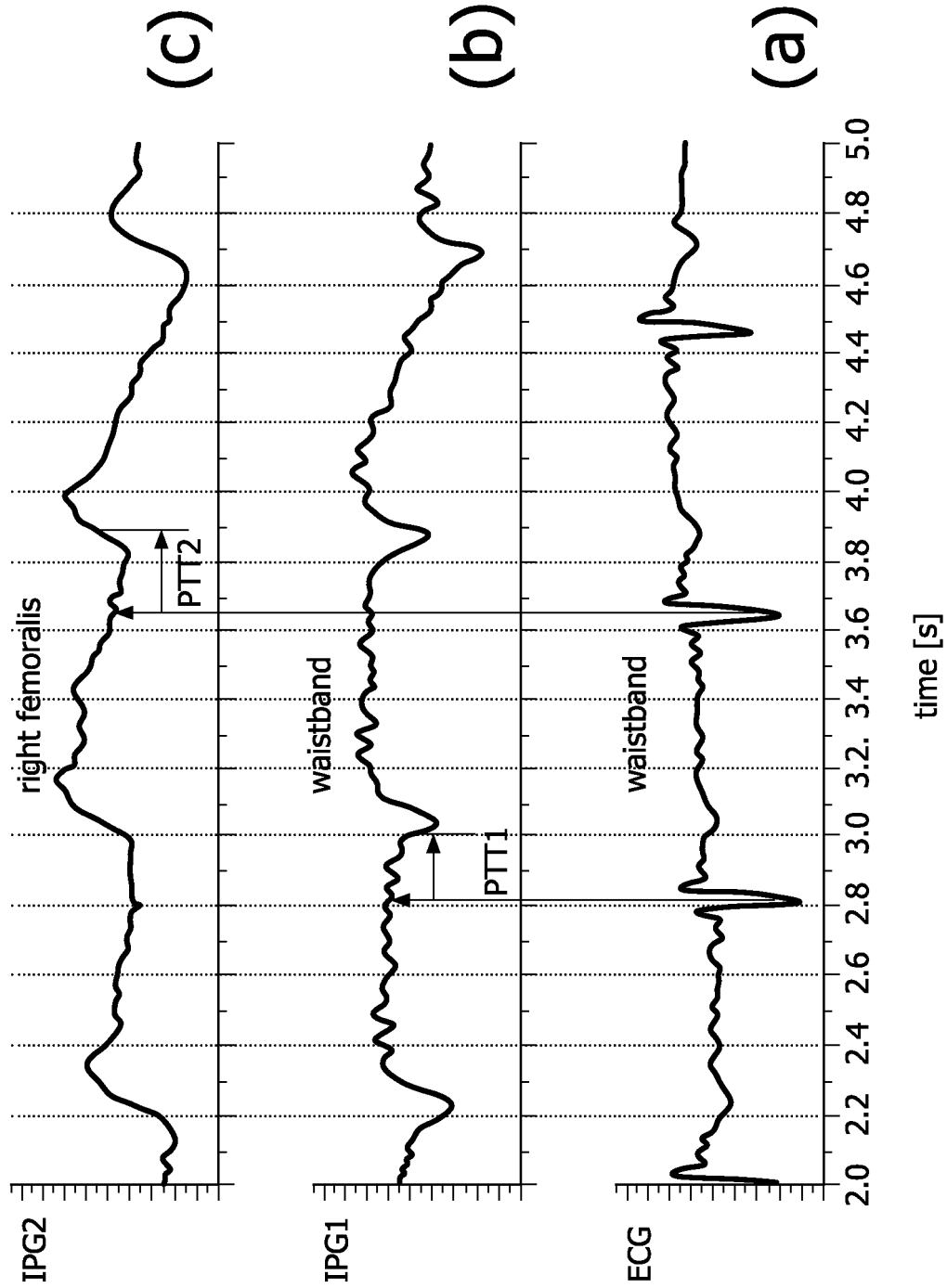


FIG. 9