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(54) **MULTIPLE SENSOR WEARABLE AND PORTABLE NON-INVASIVE RESPIRATION MONITORING INSTRUMENTATION**

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(52) **U.S. Cl.**

CPC ***A61B 5/6844*** (2013.01); ***A61B 5/053*** (2013.01); *A61B 5/0816* (2013.01); ***A61B 5/0205*** (2013.01); ***A61B 5/0402*** (2013.01)

(57) **ABSTRACT**

A system, apparatus, and method using multiple complementary sensors for the monitoring and wireless communication of several respiration characteristics—that is badge-size, wearable on the outside of clothing, and non-invasive.

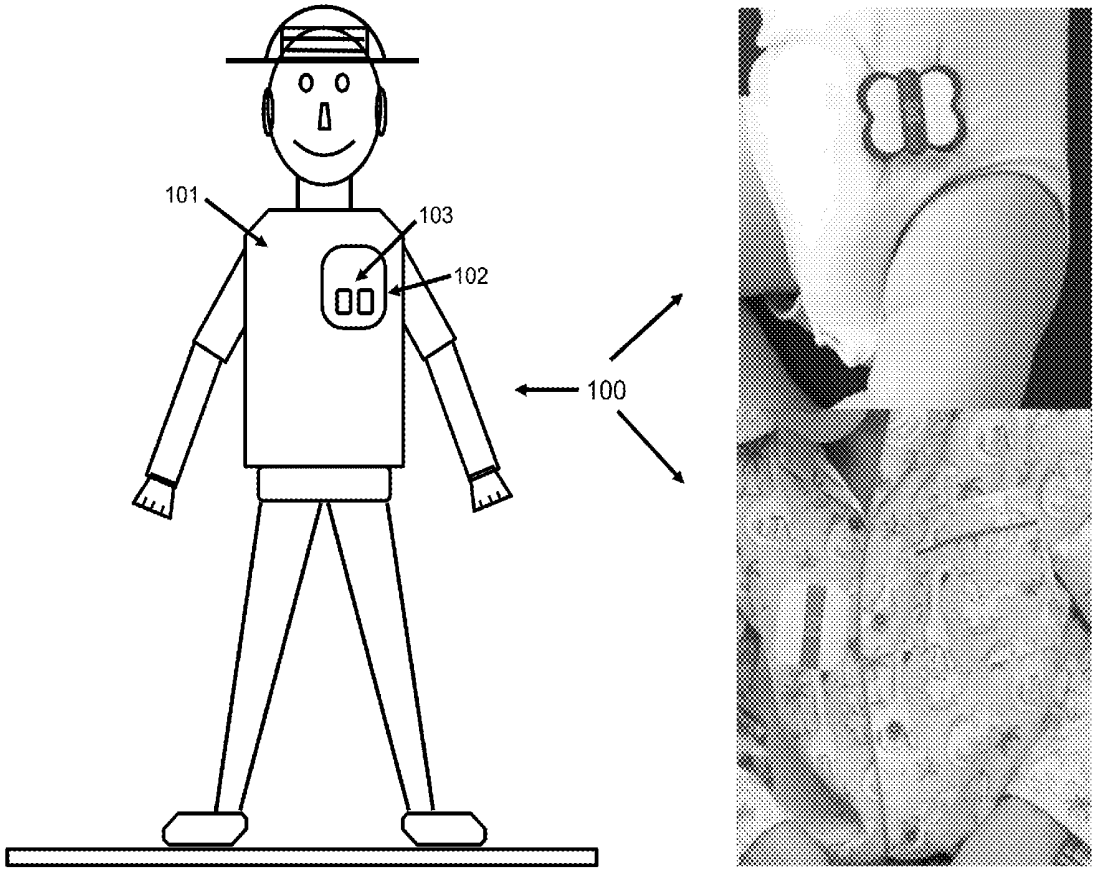
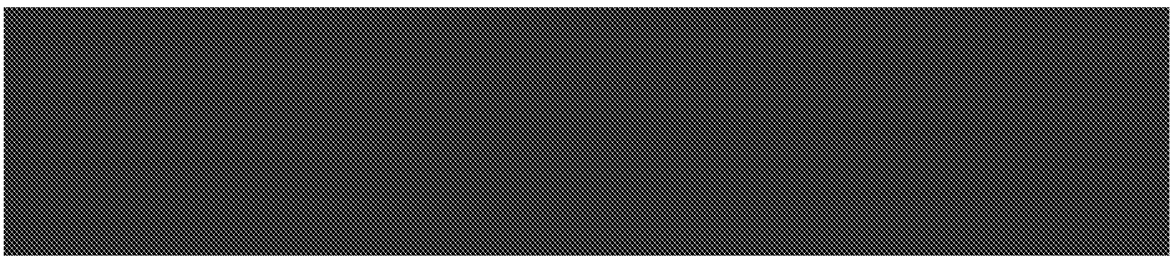
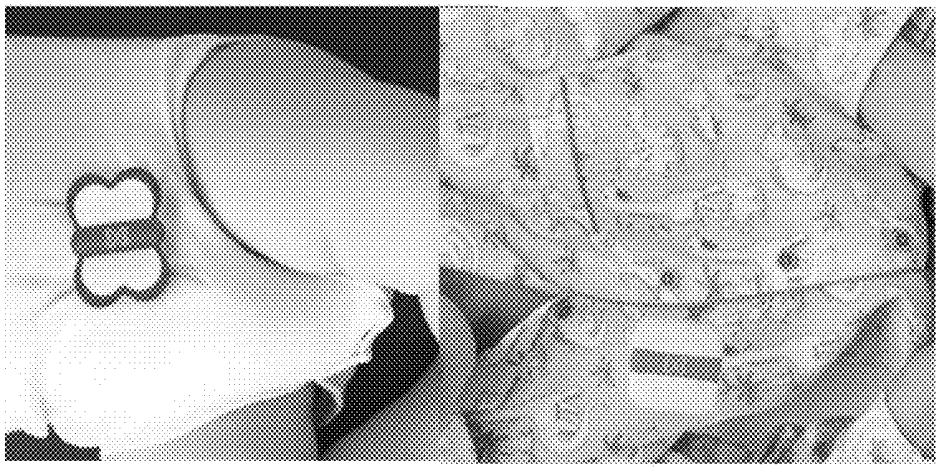


FIGURE 1





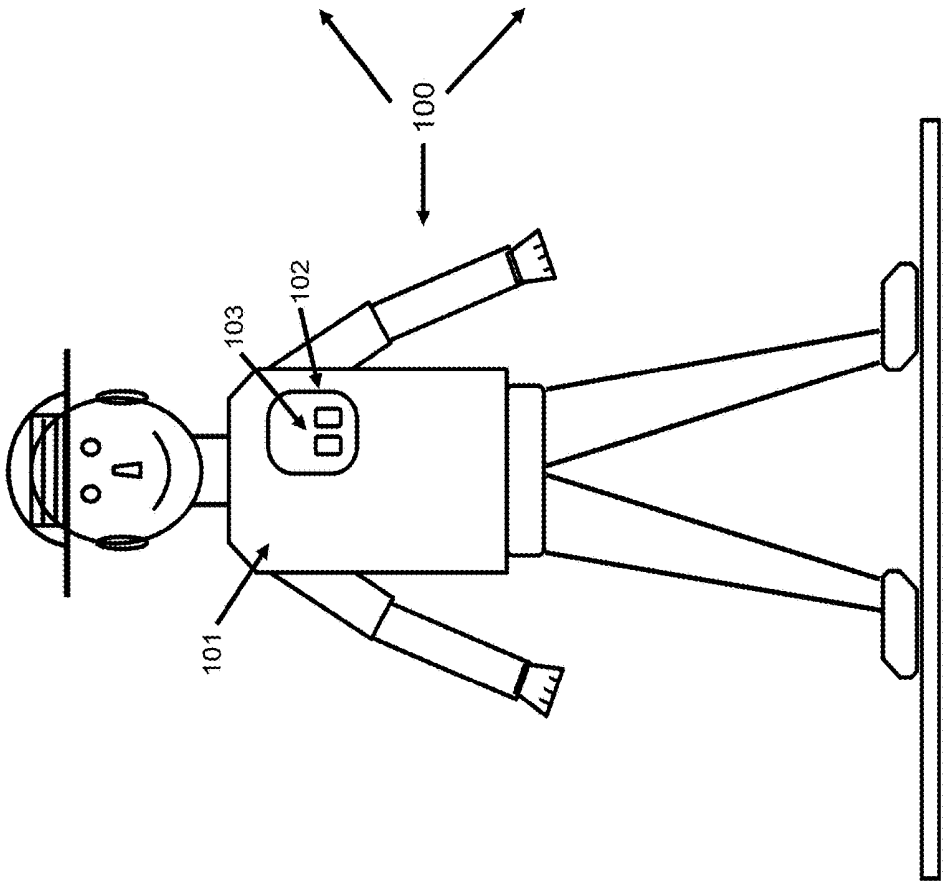


FIGURE 1

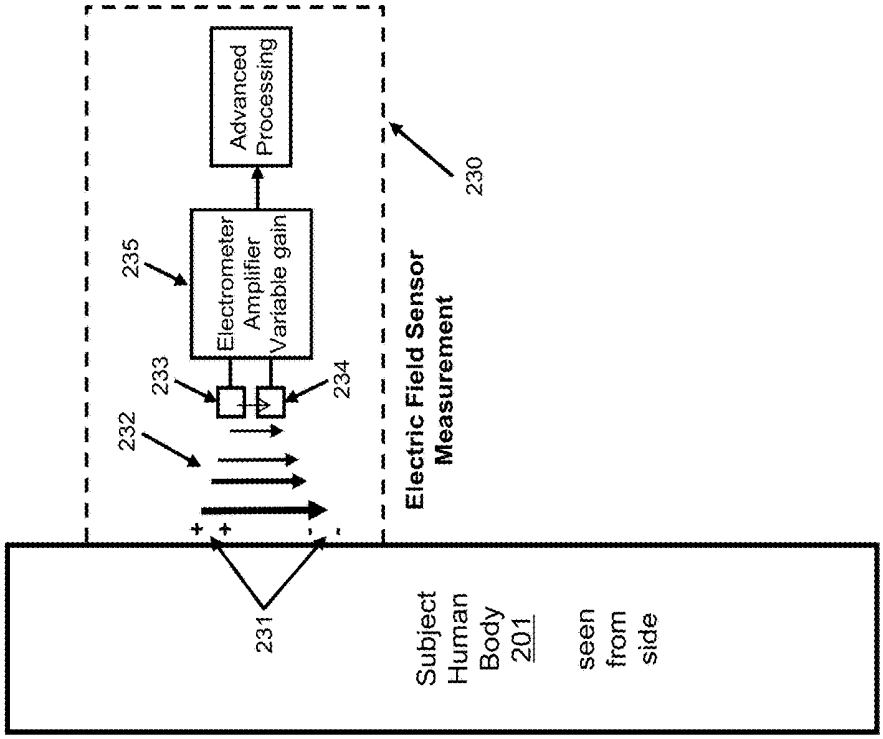


FIGURE 2B

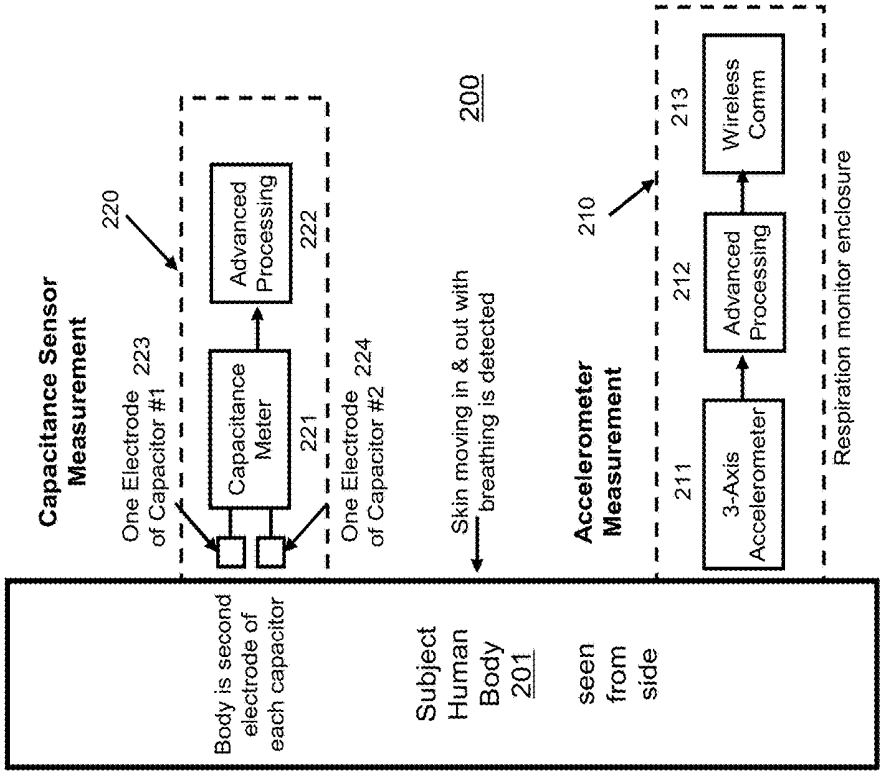


FIGURE 2A

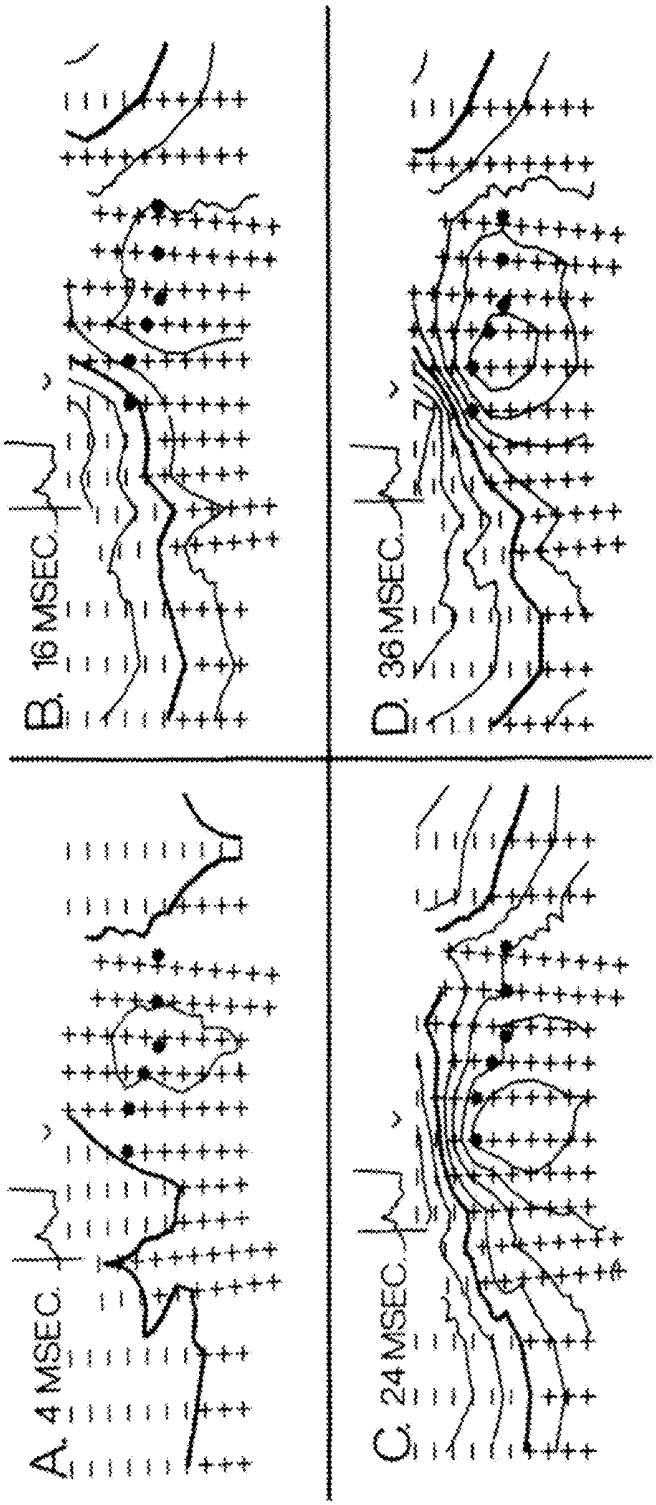


FIGURE 2. *Isopotential body surface maps corresponding to instants 4 msec (A), 16 msec (B), 24 msec (C) and 36 msec (D) after the onset of the P wave. Positive and negative signs correspond to the 150 electrode locations, with the sign indicating the polarity of the recorded potential. The V indicates the location of the sternal notch. The electrode column at the left edge of the map is along the vertebral column and that at the right edge is on the left paravertebral zone. Vertical displacement of the columns to the right and to the left of the midsternal line locate the axillary zones. Contour lines are at 10-μV intervals. The line of zero potential is overdrawn. The timing of each map is indicated on the root-mean-square potential plot included within each panel.*

FIGURE 3A (Prior Work)

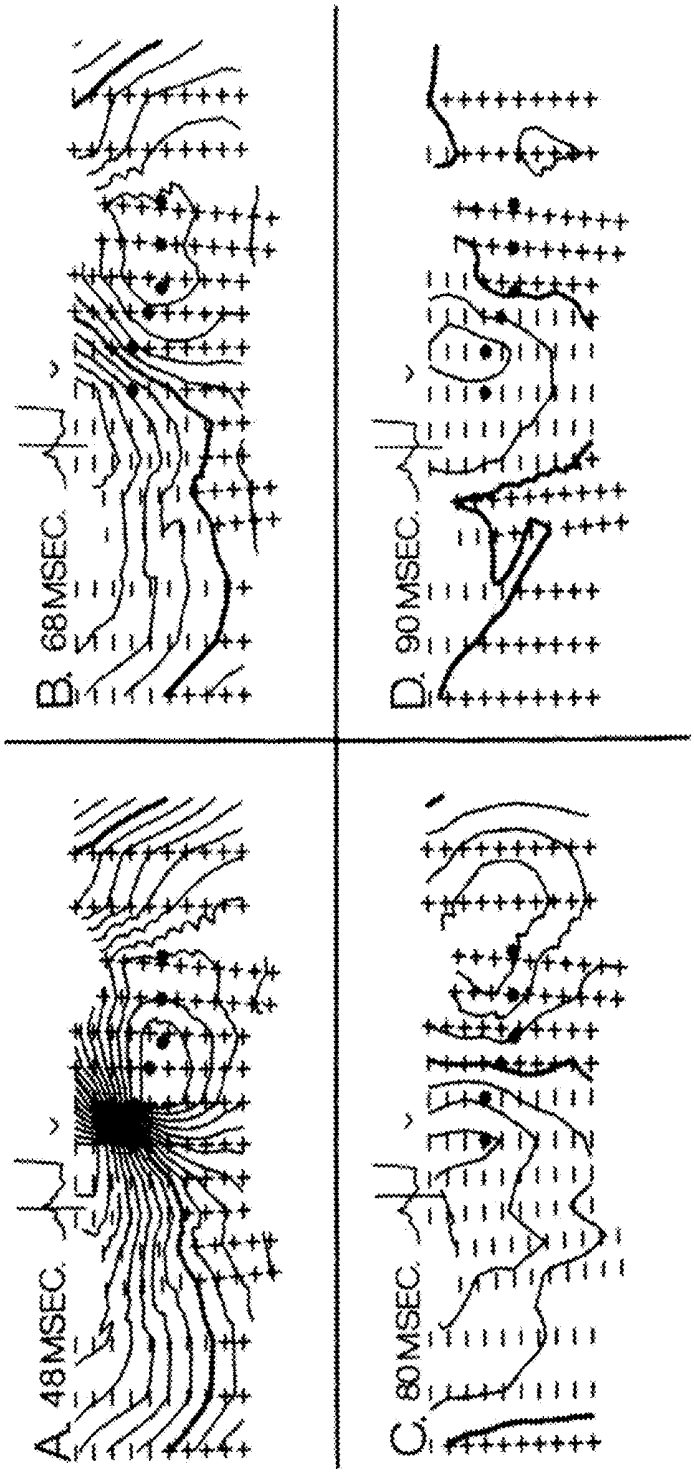
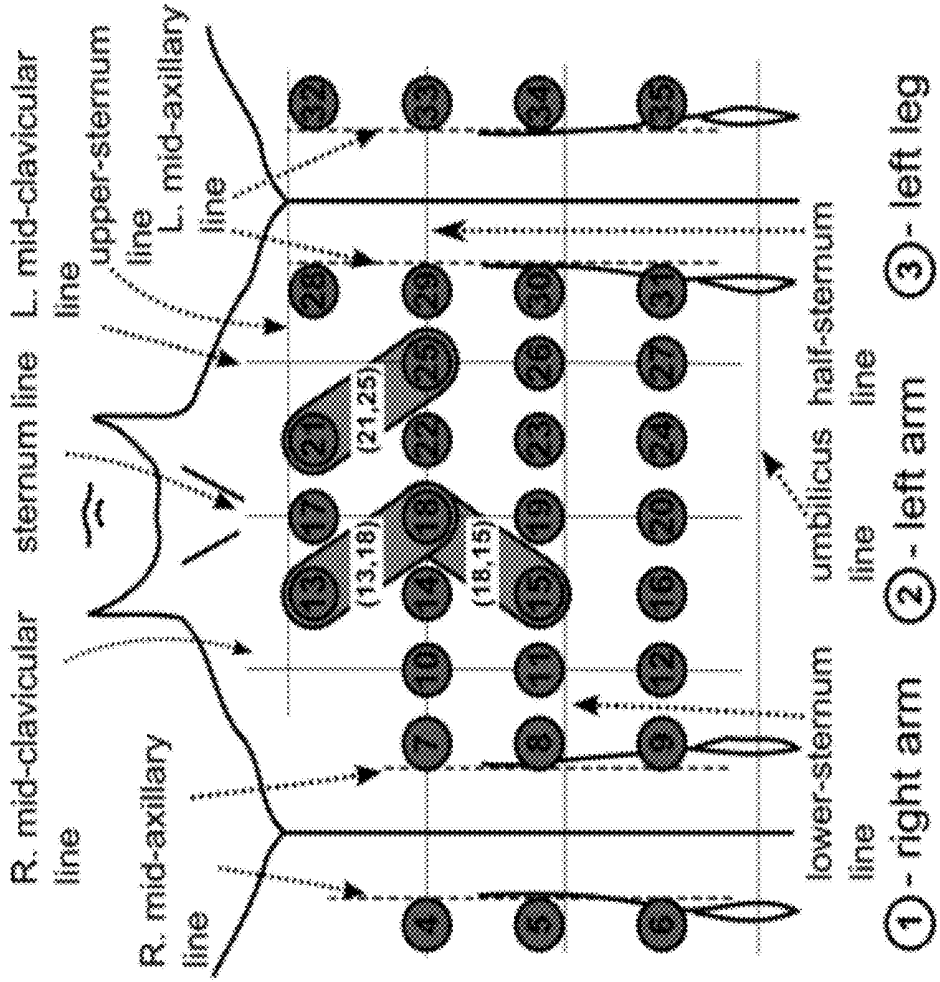


FIGURE 3. *Isopotential body surface maps drawn at instants 48 msec (A), 68 msec (B), 80 msec (C) and 90 msec (D) after the onset of the P wave. All conventions and contour intervals are as in figure 2.*

From: "Body Surface Distribution of Electrical Potential during Atrial Depolarization and Repolarization" D. M. Mirvis, MD Univ. of Tennessee, "Circulation" 62, No. 1, 1980 (circ.ahajournals.org/content/circulationaha/62/1/167)

FIGURE 3B (Prior Work)



From: "Two Proximal Skin Electrodes—A Respiration Rate Body Sensor"; Trobec, Rashkovska, Avbelj Jozef Stefan Institute, Slovenia; "Sensors" 2012, 12, 13813-13828

FIGURE 4

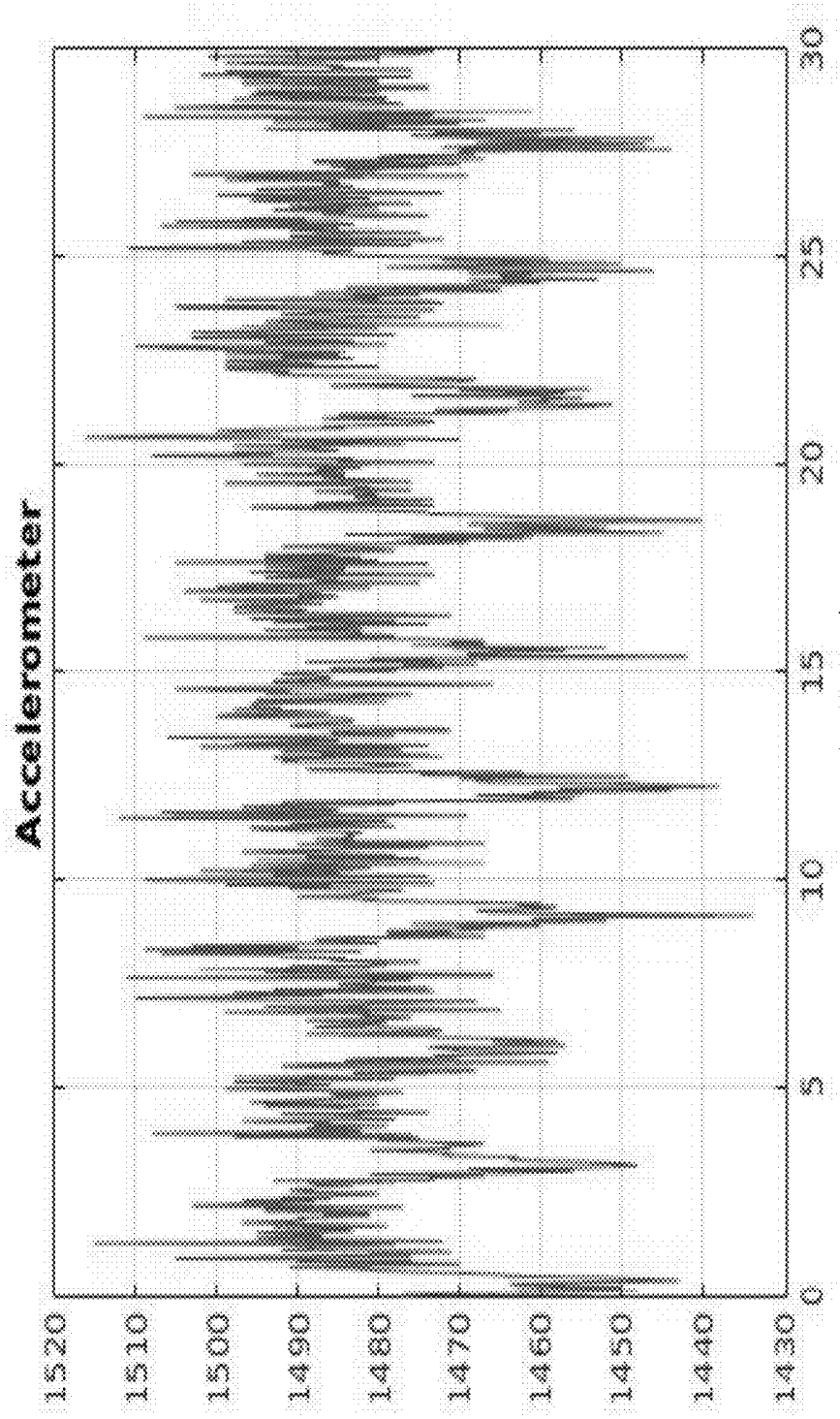

Accelerometer
1520
1510
1500
1490
1480
1470
1460
1450
1440
1430
0
5
10
15
20
25
30
Seconds

FIGURE 5

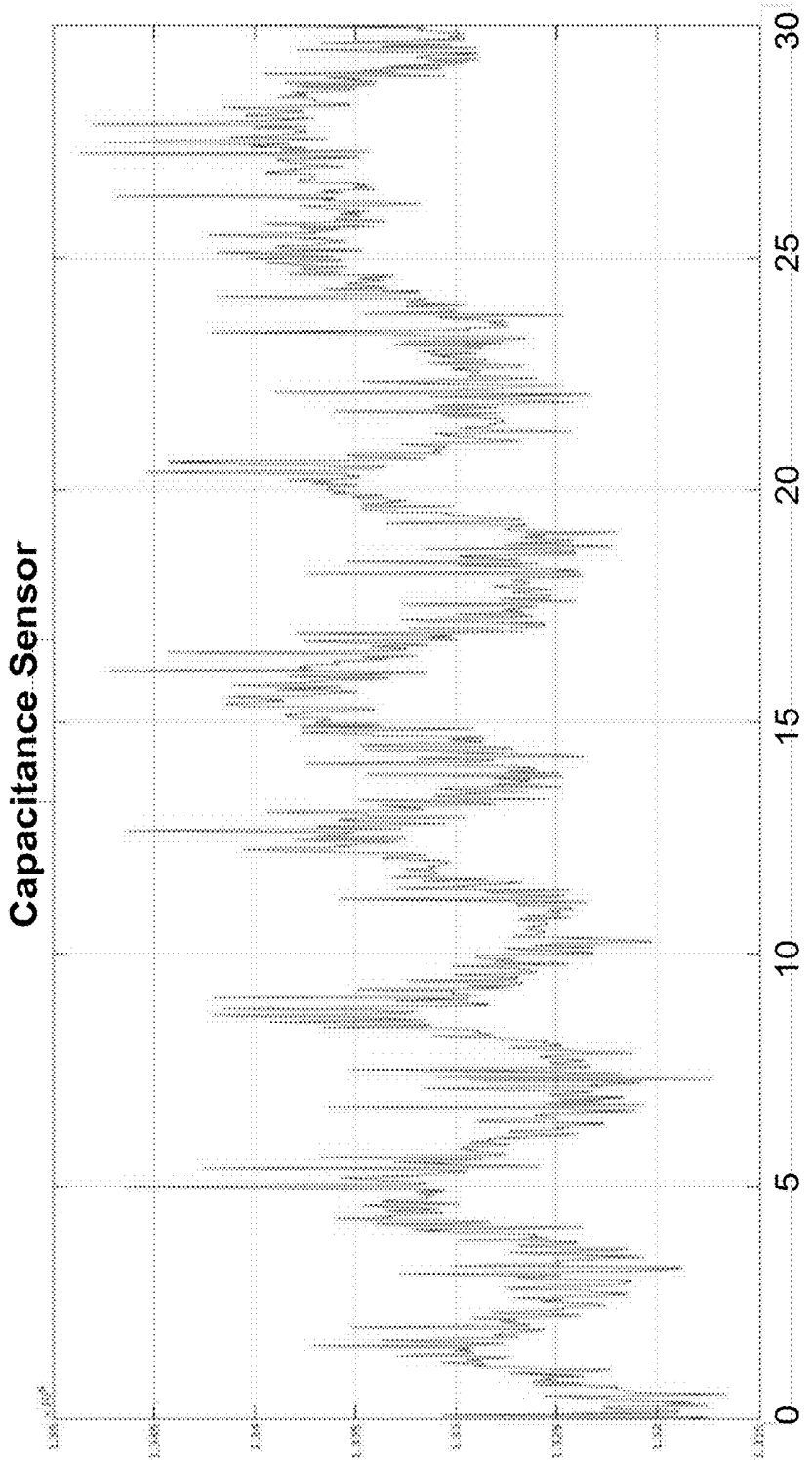


FIGURE 6

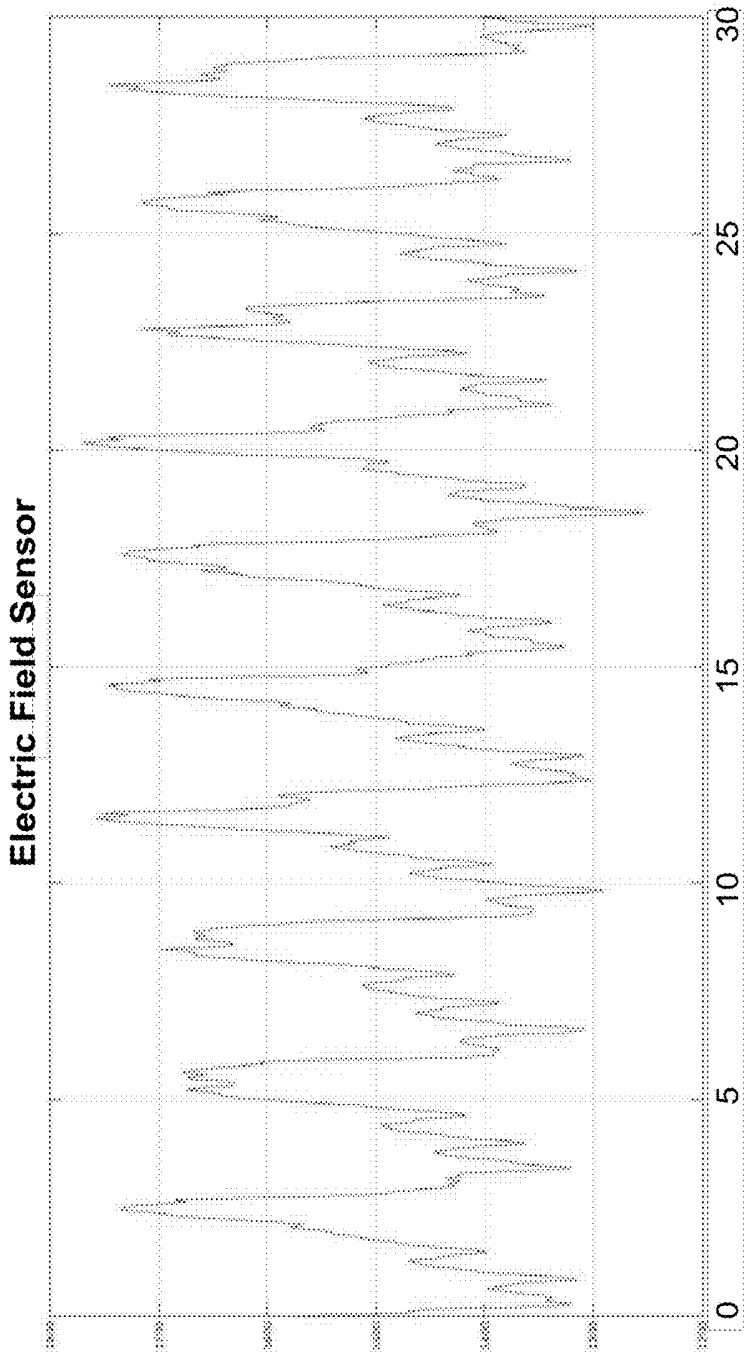


FIGURE 7

MULTIPLE SENSOR WEARABLE AND PORTABLE NON-INVASIVE RESPIRATION MONITORING INSTRUMENTATION

CROSS-REFERENCE TO RELATED APPLICATION

[0001] Priority is claimed under 37 CFR 1.78 and 35 USC 119(e) to U.S. Provisional Application 62/632,907 (XT1802201), filed 20 Feb. 2018, which is incorporated by reference.

TECHNICAL FIELD

[0002] This disclosure relates generally to the non-invasive measurement of bodily functions. More specifically, this disclosure relates to the simultaneous use of multiple sensors and circuitry located within a non-intrusive wearable and portable instrument for the reliable detection, characterization, and real time wireless communication of the respiration function. The instrument is safe, convenient to use and maintain, and reliable, regardless of activity level and orientation of the wearer.

BACKGROUND

[0003] Apparatus to monitor the breathing of subjects has existed for many years. "Breathing is one of the most obvious signs of human vitality and activity; however, it can also reflect the status of a patient and the progression of an illness. The entire process, from inhalation to the exhalation, is referred to as the breathing or respiration cycle (RC). Respiratory rate indicates the frequency of breathing or the time between two consecutive RCs. Any alterations in the respiratory rate can help predict potentially serious clinical events, such as a cardiac arrest, or it may suggest that a patient be admitted to an intensive-care unit." (Cretikos, M.A.; Bellomo, R.; Hillman, K.; Chen, J.; Finfer, S.; Flabouris, A. Respiratory rate: The neglected vital sign. Med. J. Aust. 2008, 188, 657-659)

[0004] It is considered important to monitor the time pattern, volume, and depth of respiration of a variety of subjects, such as infants, athletes, truck drivers, soldiers in the field, as well as those already known to suffer from dangerous medical conditions. It has also been demonstrated that detailed knowledge of breathing characteristics supports the ability to diagnose disease conditions. Such knowledge can be used to recommend therapeutic procedures to prevent or forestall further permanent medical damage and/or death. Moreover, as respiration monitoring products become more convenient and economical, it will be used routinely, including by those who are ill but are unaware of it.

[0005] Historically, respiratory measurements have not only lacked the cost requirements and convenience to encourage every-day and every-night out-of-clinic use, but they have been unavailable to infants and children, who do not tolerate invasive or intrusive equipment. People in general do not choose intrusive and/or inconvenient monitoring systems for themselves or loved ones, unless there is already a strong indication of adverse medical conditions.

[0006] Examples of intrusive and/or invasive respiration measurement systems include belts with strain sensors, nasal air flow rate and/or temperature sensing during the breathing cycle, and processed electrocardiogram data. Examples of non-intrusive respiration measurement systems include photographic methods and ultra-wideband pulse radar. These latter systems are neither portable nor wearable. Clearly there is a need for a respiration measurement instrument system that is wearable, non-invasive, non-intrusive, and portable.

BRIEF SUMMARY

[0007] This Brief Summary is provided as a general introduction to the Disclosure provided by the Detailed Description and Figures, summarizing some aspects of the disclosed invention. It is not a detailed overview of the Disclosure and should not be interpreted as identifying key elements of the invention, or otherwise characterizing the scope of the invention disclosed in this Patent Document.

[0008] The portable, wearable, and non-intrusive/non-invasive respiration monitoring system described in the instant disclosure is contained in a badge-sized, light, and safe enclosure that easily attaches to the outside of inner clothing, i.e. makes no contact with the skin. All sensors, measurement circuitry, power source and management, signal processing, data storage, and wireless communication circuitry are contained within the enclosure.

[0009] The present example embodiment includes three sensors, having complementary uses to detect and characterize breathing, depending upon the position and activity of the wearer, as well as the relative motion of the wearer and clothing. The detected and processed signals are of sufficient quality to monitor several critical aspects of respiration: breathing rate, depth, volume, and pattern. These sensors draw extremely low power and are intrinsically safe. They induce no electric currents within the body and make use of naturally occurring physical effects within the skin. In addition to said principal function, these sensors could be used to detect and communicate, whether or not said monitoring system is or is not attached to a subject.

[0010] One sensor is a three-axis accelerometer that operates successfully during periods when the clothing to which the monitoring system enclosure is attached is very thin and tight against the wearer/subject's body. A second sensor measures the capacitance between its electrodes and the body. It is useful when the monitor is up to several centimeters from the body, such as when attached to the outside of a diaper. The third sensor operates efficiently when the clothing is separated from the skin within the range of 1 to 10 centimeters, such as on the outside of loose, hanging clothing. Its set of electrodes develops electric potential differences that are caused by naturally occurring potential differences on the skin, through the intermediary of the electric field created by the latter.

[0011] Other aspects, features and advantages of the invention will be apparent to those skilled in the art from the following Disclosure.

BRIEF DESCRIPTION OF DRAWINGS

[0012] For a more complete understanding of this disclosure and its features, reference is now made to the following description, taken in conjunction with the accompanying drawings, in which:

[0013] FIG. **1** illustrates a basic wearable multiple sensor respiration Monitor on three subjects.

[0014] FIG. **2** shows a block diagram of the Respiration Monitor attached to a Human Body.

[0015] FIG. **3**A, **3**B displays prior work that established, by application of ECG probes, potential gradients on the skin surface.

[0016] FIG. **4** displays prior work showing that body surface potential variations can be used to derive rate and other features of respiration.

[0017] FIG. **5** shows measured respiration data from an accelerometer contained in a wearable monitor designed by the inventor.

[0018] FIG. **6** shows measured respiration data from a capacitance sensor contained in a wearable monitor designed by the inventor.

[0019] FIG. **7** shows measured respiration data from an electric field sensor contained in a wearable monitor designed by the inventor.

DETAILED DESCRIPTION

[0020] The various figures, discussed below, and the various embodiments used to describe the principles of the present invention in this patent document are by way of illustration only and should not be construed in any way to limit the scope of the invention. Those skilled in the art will understand that the principles of the invention may be implemented in any type of suitably arranged device or system.

[0021] In general, this disclosure provides the description of a novel, multiple complementary sensor contained in a non-intrusive, non-invasive portable and wearable system to monitor respiration and its detailed characteristics.

[0022] Depending on the implementation, this technique can provide significant benefits in a range of fields, such as detection and monitoring of unfavorable health conditions indicated by specific respiration rates, patterns, volume, and depth.

[0023] FIG. **1** illustrates a basic wearable multiple sensor respiration Monitor on three subjects **100**. The subject on the left is wearing an undergarment **101**, with a Monitor assembly **102** that contains a multiplicity of sensors used for breathing and other bodily functions. One said sensor, **103**, is designed to register the existence of an electric field having some component in the horizontal direction by creating an electric potential difference between the illustrated electrodes. Sensor **103** and the remaining sensors (not shown) are connected to measurement and processing circuitry as well as wireless communications circuitry. Monitor **102** is smaller, relative to the size of the subject, than the one shown in the figure. Not shown in the figure are any over-garments that cover the undergarment **101** and Monitor **102**, allowing the latter to be comfortable and unobtrusive. Monitor Assembly **102** could be attached to clothing on many parts of the body, including, as examples, to the outside of a diaper or sleepwear, as shown for the remaining two subjects in the figure.

[0024] FIG. **2** shows a block diagram of the Respiration Monitor **200** attached to Human Body **201**. FIG. **2**A illustrates functioning of said accelerometer measurement block **210** and capacitance measurement block **220**, and FIG. **2**B illustrates functioning of said electric field sensor block **230**. Not shown is that all three sensors and processing circuitry are contained within the Respiration Monitor **200** Enclosure, and that the Wireless Communication module **213** services everything in the Monitor.

[0025] The 3-axis accelerometer sensor **211** detects breathing when the Respiration Monitor Enclosure is in close contact with the body surface, including on the outside of thin clothing. The raw data from the accelerometer sensor **211** is refined by advanced processing block **212**, which includes filtering and other processing, such as artificial intelligence circuitry.

[0026] If the Respiration Monitor is **200** separated from the body surface but by not more than about 5 centimeters, the capacitance measurement block **220** detects breathing. Capacitor #**1** **223** electrodes include the one shown in the Figure and the body surface. Correspondingly, Capacitor #**2** **224** electrodes include the one shown in the Figure and the body surface. The capacitance meter **221** sees the two capacitors **223**, **224** as a series circuit. The relative positions of the body surface and Monitor **200** modulate the capacitance seen by the meter **221**. The advanced processing circuitry **222** distinguishes the breathing curve from any miscellaneous motion of loose clothing. This capacitive measurement block **220** operates in both low and high humidity environments.

[0027] When the Subject is active and wearing loose clothing, separation of the body surface and Respiration Monitor may exceed several centimeters. In this case, the Electric Field measurement block **230**—depicted in FIG. **2**B—which operates with a separation of up to about 10 centimeters, is utilized. It has been shown that electrical potential gradients **231** exist on the skin, which are correlated with aspects of the breathing cycle, such as depth. Potential gradients **231** on the skin surface cause electric fields **232** that extend beyond the skin surface. If the there is a finite component of the electric field **232** vector in the direction along the axis of the electrode assembly **233**, **234**, a potential (voltage) exists between these electrodes. Said voltage is detected with an extremely high impedance (electrometer) amplifier **235** that includes an automatic gain control feature to handle a large range of signal levels.

[0028] FIG. **3**A, **3**B displays prior work that established by application of ECG probes the existence, magnitudes, and spatial and time patterns of said potential gradients on the skin surface. The captions therein adequately describe the measurement results and are not repeated in the instant Specification text.

[0029] FIG. **4** displays prior work showing that body surface potential variations, measured by a pair of ECG-type electrodes, can be used to derive rate and other features of respiration. A 37-lead ECG system was used to identify the most favorable proximal location pairs to probe.

[0030] FIGS. **5**, **6**, and **7** show measured respiration data from the accelerometer measurement module **210**, capacitance measurement module **220**, and electric field measurement module **230** respectively. Said data was acquired from said measurement modules as part of the complete portable, wearable and non-intrusive/non-invasive respiration monitoring system **200** as described in the instant disclosure. The data is raw, prior to the extensive cleanup processing contained with said monitoring system. The linear vertical scales shown are arbitrary. Hidden in the data may be pulse rate and/or ECG information, which may be recoverable using various additional processing methods.

[0031] The details provided in the instant specification describe particular implementations of systems for portable, wearable and non-intrusive/non-invasive respiration monitoring. Other embodiments could be implemented in any other suitable manner.

[0032] It may be advantageous to set forth definitions of certain words and phrases used throughout this patent document. The term "couple" and its derivatives refer to any direct or indirect communication between two or more elements, whether or not those elements are in physical contact with one another. The terms "transmit," "receive," and "communicate," as well as derivatives thereof, encompass both direct and indirect communication. The terms "include" and "comprise," as well as derivatives thereof, mean inclusion without limitation. The term "or" is inclusive, meaning and/or. The phrases "associated with" and "associated therewith," as well as derivatives thereof, may mean to include, be included within, interconnect with, contain, be contained within, connect to or with, couple to or with, be communicable with, cooperate with, interleave, juxtapose, be proximate to, be bound to or with, have, have a property of, have a relationship to or with, or the like.

[0033] While this disclosure has described certain embodiments and generally associated methods, alterations and permutations of these embodiments and methods will be apparent to those skilled in the art. Accordingly, the above description of example embodiments does not define or constrain this disclosure. Other changes, substitutions, and alterations are also possible without departing from the spirit and scope of this disclosure, as defined by the following claims.

What is claimed is:

1. A method to monitor respiration using an unobtrusive badge-size apparatus that could be mounted over or between layers of tight or loose clothing, that makes use of a multiplicity of complementary sensors, such as:

an accelerometer for when said apparatus is either in contact with the skin or on the outside of thin, tight clothing;

a capacitance sensor for when said apparatus is in short range of the body surface;

an electric field sensor for when said apparatus is greater than about 3 centimeters from the body surface.

2. The method of claim **1**, but also used to monitor pulse rate and/or Electrocardiogram features.

3. The method of claim **1**, but also includes the ability to detect and report whether or not the apparatus is located on a wearer/subject.

* * * * *

专利名称(译)	多传感器可穿戴和便携式无创呼吸监测仪器		
公开(公告)号	US20190254606A1	公开(公告)日	2019-08-22
申请号	US16/257034	申请日	2019-01-24
[标]申请(专利权)人(译)	SARHAN萨迈赫		
申请(专利权)人(译)	SARHAN，萨迈赫		
当前申请(专利权)人(译)	SARHAN，萨迈赫		
[标]发明人	SARHAN SAMEH		
发明人	SARHAN, SAMEH		
IPC分类号	A61B5/00 A61B5/053 A61B5/0402 A61B5/0205		
CPC分类号	A61B5/6844 A61B5/053 A61B5/0402 A61B5/0205 A61B5/0816 A61B2562/0219 A61B5/02438		
优先权	62/632907 2018-02-20 US		
外部链接	Espacenet USPTO		

摘要(译)

一种系统，装置和方法，其使用多个互补传感器来监测和无线通信若干呼吸特征 - 徽章大小，可穿戴在衣服外部，并且是非侵入性的。

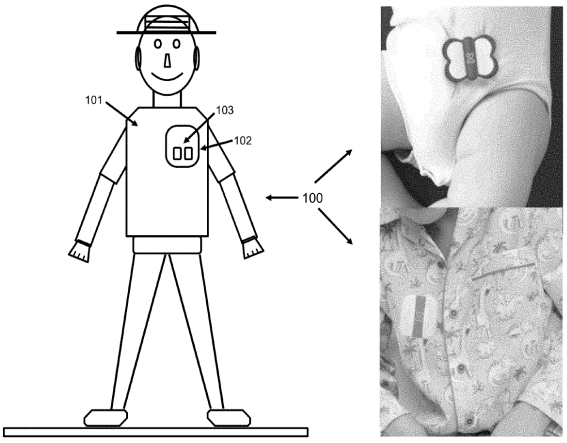


FIGURE 1