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US
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 06-098045- -00003-0000

Fecha: 2008-04-02 16:28:54 Dep. 2020 NUECREACION
1ra. 2 PALENTES Eve: 1 REGDEPOSITO
Act. 533 PETICION Folios: 2

Clarke, Modet & Cº

COLOMBIA

SEÑORES
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES
E.S.D.

REF: EXPEDIENTE No. 06098045
FECHA DE LA SOLICITUD: septiembre 28, 2006
SOLICITANTE: FRANCISCO JAVIER MARTINEZ TABARES Y
JOHON JAMES OSORIO GRANADOS
TITULO: CHALECO Y SISTEMA BIOTELEMÉTRICO PORTÁTIL PARA
MONITOREO MÉDICO INALAMBRICO Y PREDIAGNÓSTICO EN TIEMPO
REAL

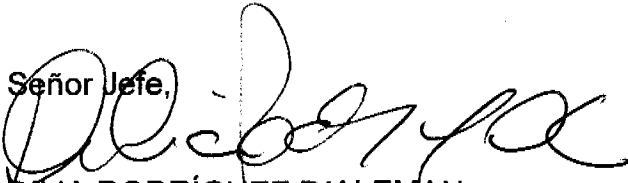
ASUNTO: SOLICITUD ESTUDIO DE FONDO

DILIA RODRÍGUEZ D'ALEMAN, en mi condición de apoderada de la Sociedad solicitante, por el presente escrito atentamente solicito a Usted que habiéndose surtido la publicación de la presente solicitud, en la Gaceta de la Propiedad Industrial No.581 de fecha 30 de octubre de 2007 se proceda con el estudio de Fondo.

Para tal fin me permito anexar la tasa correspondiente.

Agradezco continuar con el presente trámite.

Señor Jefe,

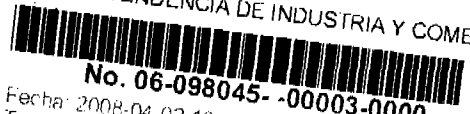

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NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 08 - 22,409
FECHA : MARZO 13 DE 2008

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 06-098045-00003-0000

Fecha: 2008-04-02 16:28:54
Tra 2 PATENTES
Act 5.30 PLICACION
LIT 1 RECIBO DEPOSITO

***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vt. PAGO
CLARKE MODET Y CO. COLOMBIA	CONSIGNACION	BANCO DE BOGOTA	062754387	2881311	13/03/2008	24,030,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01	SOLICITUDES	
		112 PTO CAP-I EXAMEN DE PATENTIBILIDA	420,000.00
		TOTAL :	\$ 420,000.00

SUN: CUATROCIENTOS VEINTE MIL PESOS

RESPONSABLE :

RECIBO DE CASH APLICADO AL EXPEDIENTE No.



US006687523B1

(12) **United States Patent**
Jayaramen et al.

(10) Patent No.: **US 6,687,523 B1**
 (45) Date of Patent: ***Feb. 3, 2004**

(54) **FABRIC OR GARMENT WITH INTEGRATED FLEXIBLE INFORMATION INFRASTRUCTURE FOR MONITORING VITAL SIGNS OF INFANTS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 133 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/610,929**

(22) Filed: **Jul. 6, 2000**

Related U.S. Application Data

- (63) Continuation-in-part of application No. 09/273,175, filed on Mar. 19, 1999, now Pat. No. 6,381,482, and a continuation-in-part of application No. 09/157,607, filed on Sep. 21, 1998, now Pat. No. 6,145,551.
 (60) Provisional application No. 60/142,360, filed on Jul. 6, 1999, provisional application No. 60/085,266, filed on May 13, 1998, and provisional application No. 60/059,444, filed on Sep. 22, 1997.

- (51) Int. Cl.⁷ **A61B 5/04**
 (52) U.S. Cl. **600/388; 600/390; 600/534**
 (58) Field of Search **600/372, 373, 600/382-384, 391-393, 534, 538, 388-390; 607/152**

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,282,908 A 10/1918 Miller
 2,579,383 A 12/1951 Goudsmit
 2,935,096 A 5/1960 Cole

3,020,935 A 2/1962 Balis
 3,409,007 A 11/1968 Fuller
 3,483,861 A 12/1969 Tiep
 3,534,727 A 10/1970 Roman
 3,610,250 A 10/1971 Sarbacher
 3,970,116 A 7/1976 Takada
 4,016,868 A 4/1977 Allison
 4,055,166 A 10/1977 Simpson et al.

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

DE 826183 7/1949
 DE 29813614 U1 10/1998
 DE 298 13 614 U 10/1998
 FR 2225560 11/1974
 FR 2737651 2/1997
 FR 2 737 651 A 2/1997
 WO WO99/64657 12/1999
 WO WO 99 64657 A 12/1999

OTHER PUBLICATIONS

Slide Presentation Titled High Velocity Penetration Analysis from the DLA/ARPA/NRaD Sensate Liner Workshop held Apr. 11, 1996; Author: Dr. Robert Eisler, MRC., Inc.
 Slide Presentation Titled Introducing Clarity Fit Technologies from the DLA/ARPA/NRaD Sensate Liner Workshop held Apr. 11, 1996; Author: Edith Gazzuolo, Clarity Inc.

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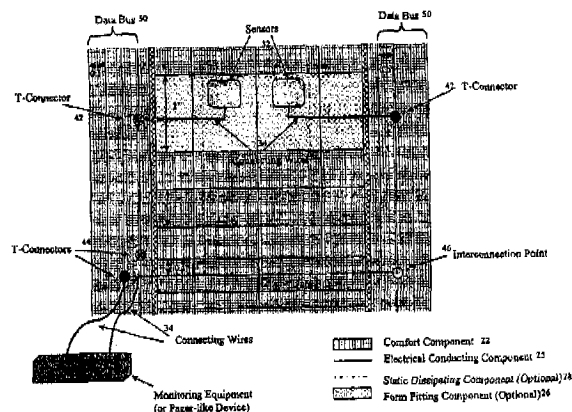
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(57) **ABSTRACT**

A garment for infants comprises a comfort component serving as a base, a plurality of signal transmission paths integrated within the comfort component; and at least one interface that provides a transmission path between the information infrastructure component and an external device. In addition, the garment has the means to ensure a snug fit for the baby so that the sensors stay in place to minimize the risk of false alarms while the baby is safe and comfortable. This feature also helps to extend the usable life of the garment as the baby grows.

23 Claims, 18 Drawing Sheets



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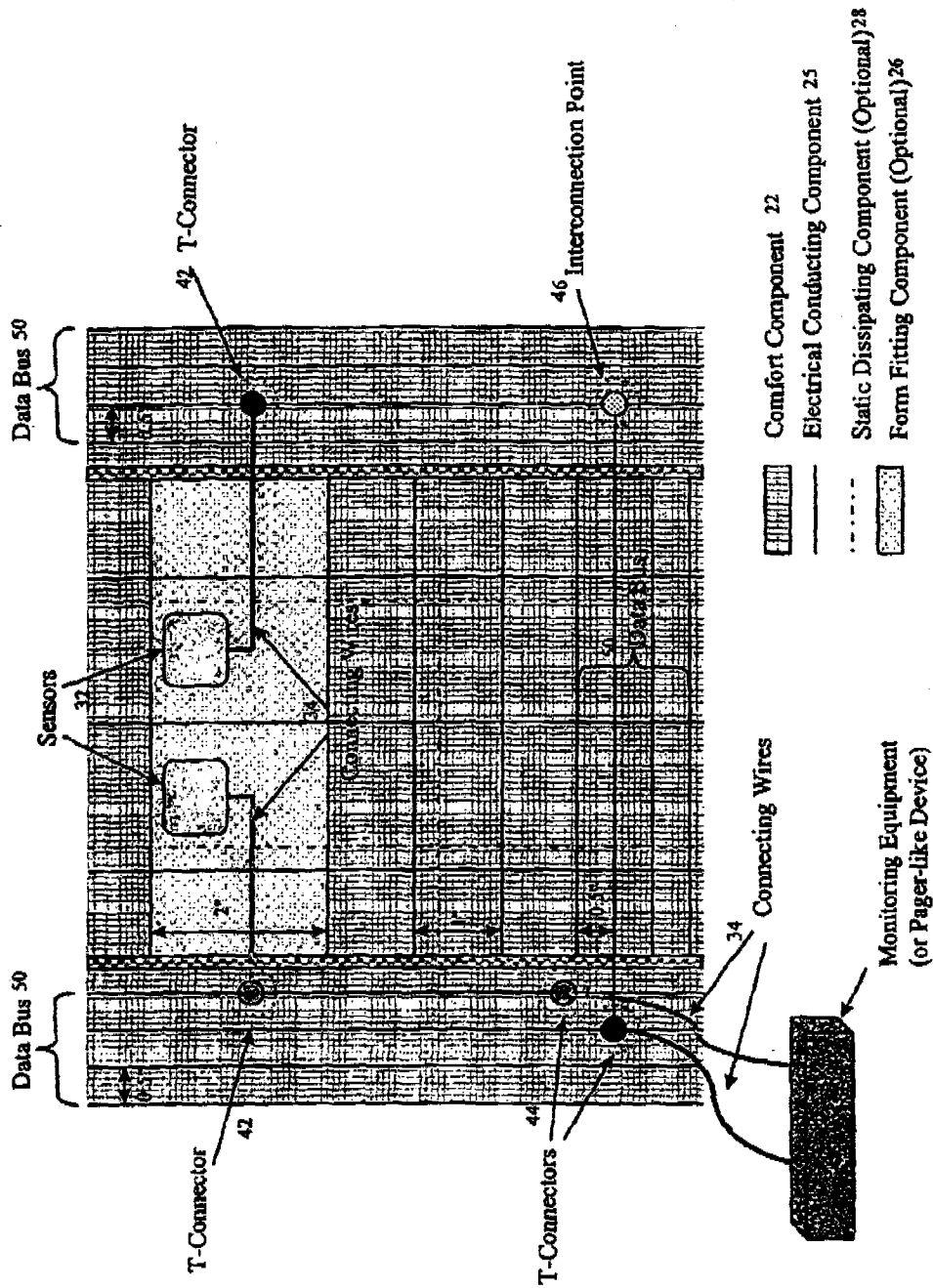


Figure 6

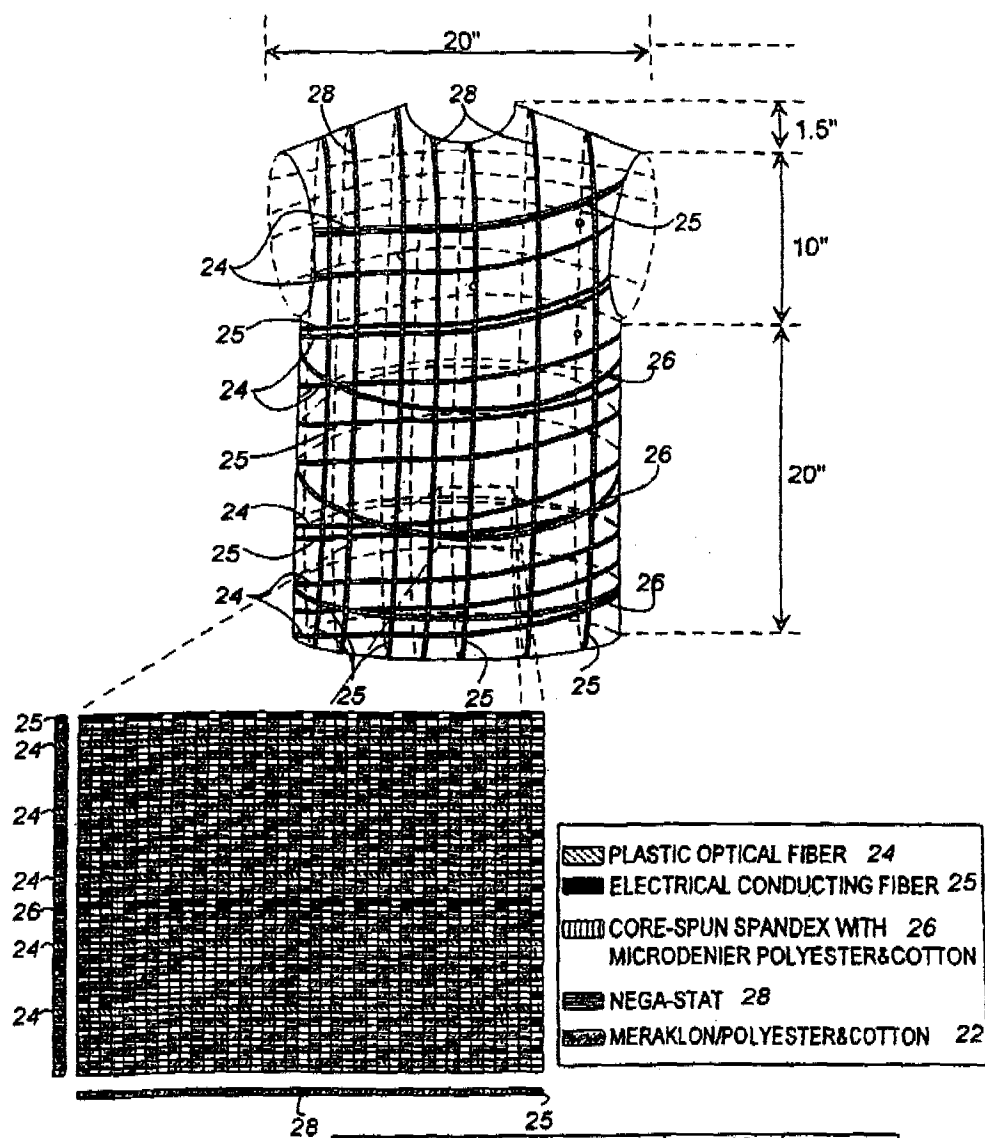
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FIG. 20

MATERIAL	ENDS PER INCH	PICKS PER INCH
PLASTIC OPTICAL FIBER 24	0	5.5
ELECTRICAL CONDUCTING FIBER 25	0.5	0.5
CORE-SPUN SPANDEX WITH MICRODENIER POLYESTER & COTTON 26	0	1
NEGA-STAT 28	0.5	0
MERAKLON/POLYESTER & COTTON 22	39	47

**FABRIC OR GARMENT WITH INTEGRATED
FLEXIBLE INFORMATION
INFRASTRUCTURE FOR MONITORING
VITAL SIGNS OF INFANTS**

This application claims priority to U.S. provisional application No. 60/142,360, filed on Jul. 6, 1999, now abandoned, and is a continuation-in-part of U.S. Ser. No. 09/157,607, filed on Sep. 21, 1998, now U.S. Pat. No. 6,145,551, which claims priority to U.S. provisional application No. 60/059,444, filed on Sep. 22, 1997, now abandoned. This application is also a continuation-in-part of U.S. Ser. No. 09/273,175, filed on Mar. 19, 1999, now U.S. Pat. No. 6,381,482, which claims priority to U.S. provisional application No. 60/085,266, filed on May 13, 1998, now abandoned.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a fabric or garment, and which includes an integrated infrastructure for monitoring the vital signs of infants.

2. Background of the Art

Efforts have been made previously to create fabrics and garments which incorporate electrodes for monitoring the condition of the wearer, such as EKG, or conductive fibers for electromagnetic screening. For example, U.S. Pat. No. 4,668,545 to Lowe and U.S. Pat. No. 5,103,504 to Dordevic disclose fabrics including conductive fibers for electromagnetic screening and for protecting a wearer from magnetic radiation.

U.S. Pat. No. 4,580,572 to Granek et al. discloses a garment for delivering and receiving electric impulses which can include a conductive medium knitted or woven into the cloth, wires sewn onto the cloth or conducting cloth sewn onto nonconducting cloth.

However, these patents fail to disclose either a woven or knitted fabric which incorporates information infrastructure component in the form of a textile fiber which can include an electrical conductive component of the fabric for collecting or monitoring physical or vital signs of a wearer of the fabric and which may be worn and washed in the same manner as conventional clothing.

A need, therefore, exists for a fabric having an integrated information infrastructure which can be incorporated or fashioned into a wearable garment and which includes a flexible infrastructure for collecting, processing, transmitting and receiving information concerning a wearer of the garment. It is to the provision of such a fabric or garment with an integrated information infrastructure to which the present invention is one aspect directed.

A problem affecting infants is known as Sudden Infant Death Syndrome (SIDS). SIDS is generally the death of an infant, usually under one year old, that is unexplained by any prior medical diagnosis, postmortem examination or other factors. SIDS is the leading cause of post-neonatal mortality in the United States, accounting for almost 40% of deaths in infants from 1 month to 1 year of age. Approximately 7 of every 10,000 live born infants in the United States succumb to SIDS. Infants that are classified to have a higher risk of the likelihood of SIDS include premature infants, siblings of SIDS victims and infants who have experienced apparent life-threatening episodes, e.g., turning blue and/or stoppage of respiration.

To detect problems that can lead to SIDS, special home cardiorespiratory monitors can be used to receive data about

the infant. The data is obtained at the infant's home by a home cardiorespiratory monitor that is attached to the infant and records the infant's heart rate and chest wall movement. The heart rate and breathing rate can be monitored by simple cardiorespiratory sensors (e.g., EKG) attached to the infant. The monitor continuously records data about the infant's heart rate and breathing. If certain preset parameters for apnea and/or bradycardia are violated, the monitor sets out an alarm to warn the caregiver of the problem and the monitor will record the EKG, trend event of the heart rate and the respiratory waveform. The recorded data can be downloaded by telephone modem to a specialized apnea center at a hospital in order to verify the event. The data can then be utilized by specialist physicians who receive the data from the monitors to diagnose the cause of the episode that caused the breathing or heart to stop or slow to abnormal levels. The potential problems include heart blocks, arrhythmias, and seizures which are difficult for a primary care physician to detect.

A problem with home cardiorespiratory monitors is that even when available they are not used. There are three major causes for the non-use of the cardiorespiratory monitors. First, is that most of the electrodes used to record the vital signs are rubberized electrode patches that are placed on the infant's chest and are held in place by VELCRO belts applied over the patches. These VELCRO belts are difficult to apply. If not applied properly, the belt and/or electrodes irritate the infant's skin (sometimes to the point of blistering and even bleeding). Second, they can also trigger false alarms. For these reasons, the parents may stop using the equipment. Lastly, caregivers and parents are reluctant to use the monitor because they believe that the protruding wires that go from the sensors on the body to the monitoring equipment can wrap around the neck of the infant if the infant rolls over.

Therefore, there exists a need for a device that overcomes the problems with using VELCRO belts to hold the sensors in place on the infants for monitoring them using cardiorespiratory monitors to prevent SIDS.

It is to the provision of such a fabric or garment to meet the two needs to which the present invention is one aspect directed.

SUMMARY OF THE INVENTION

In one embodiment, the present invention comprises a garment for infants comprising a comfort component serving as a base, a plurality of signal transmission paths integrated within the comfort component, and at least one interface that provides a transmission path between the information infrastructure component that is part of the garment and the external device.

In another embodiment, the present invention comprises a garment for infants comprising a comfort component serving as a base, a form-fitting component to provide a 'form fit' to the wearer, a plurality of signal transmission paths integrated within the comfort component and at least one interface that provides a transmission path between the information infrastructure component that is part of the garment and the external device. In additional embodiments, this garment may be made up of an additional static dissipating component and with or without the form-fitting component (the comfort component and plurality of signal paths will be required).

In another embodiment, the present invention comprises a fabric comprising a comfort component, an information infrastructure component integrated within the comfort

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component, and at least one interface that provides a transmission path between the information infrastructure component and an external device.

In any of the above embodiments, the garments can further comprise means for adjusting the size of the garment, means for easily attaching and detaching sensors and means for easily putting on and taking off the garment.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front elevational view of a garment into which the wearable fabric with integrated information infrastructure of the present invention has been incorporated;

FIG. 2 is the outside view of the front panel (piece) of the garment of the invention in which the means for adjusting the size of the garment are shown along with the signal transmission paths;

FIG. 3 is the inside view of the front panel of the garment of the invention in which the means for attaching the sensors are shown along with the signal transmission paths;

FIG. 4 is the inside view of the back panel (piece) of the garment of the present invention with the signal transmission paths, the T-Connectors for the connecting wires (sensor leads) and the means for adjusting the garment size and binding to the front panel of the garment;

FIG. 5 shows the opened out view with the two panels (front and back) of the garment of the present invention overlaid on top of each other;

FIG. 6 shows the schematic layout or overall architecture of one embodiment of the garment of the present invention in FIG. 1;

FIG. 7 is the view with the sensors attached to the inside of the front piece (FIG. 3) of the garment of the present invention;

FIG. 8 is the view with the sensor leads or connecting wires plugged into the top set of T-Connectors in FIG. 4;

FIG. 9 is the view with the connecting wires carrying the vital signs data to the monitoring equipment plugged into the bottom set of T-Connectors in FIG. 4;

FIG. 10 illustrates another aspect of the present invention, namely, the interconnection of intersecting electrically conductive fibers in the fabric or garment of a preferred embodiment of the present invention;

FIG. 11 illustrates another embodiment of the present invention.

FIG. 12 illustrates the opened out view of FIG. 11 in which the T-connectors have been connected to electrically conductive fibers using the interconnection technology of FIG. 10;

FIG. 13 is the rear view of the embodiment in FIG. 11 showing the VELCRO attachments on the back side of the garment and the flaps on the front side of the garment.

FIG. 14 illustrates the sensors and the connecting wires plugged into the embodiment in FIG. 11.

FIG. 15 shows the sensors and the sensor leads (connecting wires) that are used to plug into the T-Connectors integrated into the garments of the present invention.

FIG. 16 illustrates a woven portion of a garment including the integrated information infrastructure according to one embodiment of the present invention;

FIG. 17 illustrates a woven portion of a garment including the integrated information infrastructure according to another embodiment of the present invention;

FIG. 18 illustrates a woven portion of a garment including the integrated information infrastructure according to a further embodiment of the present invention;

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FIG. 19 illustrates a woven portion of a garment including the integrated information infrastructure according to another embodiment of the present invention;

FIG. 20 illustrates a further embodiment of the present invention including the information infrastructure fashioned into a wearable garment.

DETAILED DESCRIPTION OF THE ILLUSTRATIVE EMBODIMENTS

Referring now to the above figures, wherein like reference numerals represent like parts throughout the several views, the fabric of the present invention having a multi-functional information infrastructure integrated within the fabric for information collection, processing, reception and transmission capability, along with capability to easily wear and adjust the size of the garment will be described in detail.

The fabric of our present invention is wearable and, thus, provides a wearable information infrastructure integrated within the fabric that has hitherto been typically resident in a computer. When fitted with, or connected to, a data collector(s) such as, but not limited to, a sensor for monitoring body physical signs and connected to a data transmitter or processing unit, as described in detail below, our wearable fabric provides information pathways that allow the sensor to provide information to the transmitter or processor, and vice versa. In this context, the information infrastructure of our fabric invention can manage the transfer of data between the sensor and the transmitter or processing unit. Since the sensor can be considered a "hardware peripheral", our wearable fabric, which can be fashioned into a garment, having an integrated information infrastructure can be conceived of as a "wearable motherboard." When we use the term "wearable motherboard", we are using the term in the context described immediately above.

A. A Fabric Having An Integrated Flexible Information Infrastructure in Accordance With the Present Invention

As illustrated generally in FIG. 1, the fabric of our present invention can be integrated or fashioned into a garment, for example an undershirt, by any appropriate joining technique, such as by sewing, gluing, attachment through a hook and loop-type fastener, such as VELCRO, buttons, zipper, and the like. The fabric provides an infrastructure for a garment for collecting, monitoring, and/or tracking data regarding physical conditions of a wearer of the garment, such as body vital signs or voice, and transmitting such data to a remote location. The fabric can be provided with means in the form of sensors, or connectors for sensors to be worn on the body, for monitoring body physical signs, such as heart rate or EKG, pulse, voice and temperature, and blood oxygen levels, and atmospheric exposure, such as chemical and biological exposure, atmospheric smoke and oxygen levels, radiation exposure, as well as penetration. The fabric with integrated information infrastructure consists of the following components: a base fabric or "comfort component," and an information infrastructure component. The base fabric can be either a two-dimensional woven or knitted fabric into which the information infrastructure component is incorporated. Additionally, either or both a form-fitting component and a static dissipating component may be included, if desired. Finally, it can be a tubular, woven or knitted fabric or a full-fashioned garment with the integrated information infrastructure component.

The information infrastructure component can include any or all of the following, individually or in any

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combination, electrically conductive components, sensors, processors, or wireless transmission devices and, if desired, penetration detection components.

1. Knitted Fabric

FIG. 1 illustrates one embodiment of the fabric (garment) of the present invention consisting of a knitted comfort component of cotton yarn. A data bus for carrying the sensor data or other information is integrated into the fabric in two ways: (i) by inlaying the conducting yarn 25 in the structure (FIG. 2); and (ii) by knitting the conducting fibers as a "bus" 50 separately and attaching it to the sides of the fabric as flaps 52 (FIG. 4). The garment is made up of two parts or panels: the front part shown in FIG. 2 and the back part shown in FIG. 4. The two parts or panels are bound together by means of VELCRO 60, 64 to provide the right degree of form and fit so that the garment is comfortable for the baby while providing the required functionality. Although VELCRO is preferred, other joining means such as sewing, gluing, hooks, zippers and buttons or any combination thereof can be used to integrate the two parts.

FIG. 2 shows the VELCRO strip 60 in the center of the outside of the front panel (piece) of the garment into which the VELCRO strips 64 on the flaps 52 of the back panel (piece) will join to provide the correct fit to the infant. Thus, the garment of the present invention can be adjusted in size (using the adjustable VELCRO strips) to accommodate the baby's growth. The VELCRO strips 62 in the front piece and 66 in the back piece provide the capability to adjust the shoulder size to better fit the baby. The front and back pieces can be joined at the bottom using the closures 90 and 92 in FIGS. 2 and 4, respectively, thus creating the complete well-fitting garment shown in FIG. 1.

Parameter	Details
Knitting Machine	Flat Bed
Description	1x1 Rib
Gauge (Needles Per Inch)	5
Width	10 Inches
Wales per Inch	10
Courses per Inch	20
Comfort Component: Cotton	16s Ne Yarn
Electrical Conductive Components	X-Static Conducting Nylon fiber with insulated PVC Sheath from Sauquoit Industries, Pennsylvania

The above table shows the parameters used for producing the knitted fabric embodiment of our present invention having an information infrastructure integrated within the fabric as shown in FIG. 5. These parameters can be adjusted, as desired, to affect the characteristics of the resulting knitted fabric. The comfort component, Cotton 22 forms the 1x1 rib structure and serves as the base of the fabric. The Electrical Conductive Yarn 25 is inlaid in the structure as shown in FIGS. 2-4. The electrical bus 50 in the structure is also shown in FIGS. 4 and 5. In this embodiment, the electrical bus 50 has been knitted separately and attached to the structure. The schematic layout of the garment of one embodiment of the present invention is shown in FIG. 6.

The comfort component 22 is the base of the fabric and can in one embodiment be a standard fabric used as component of clothing. The comfort component will ordinarily be in immediate contact with the wearer's skin and will provide the necessary comfort properties for the fabric/garment. Therefore, the chosen material should preferably provide at least the same level of comfort and fit as compared to a typical fabric used for clothing, e.g., good fabric hand, air permeability, moisture absorption and stretchability.

The comfort component can consist of any yarn applicable to conventional apparel fabrics. The choice of material for the yarn will ordinarily be determined by the end use of the fabric and will be based on a review of the comfort, fit, fabric hand, air permeability, moisture absorption and structural characteristics of the yarn. Suitable yarns include, but are not limited to, cotton, polyester/cotton blends and microdenier polyester/cotton blends.

The fibers preferably suitable for use in the comfort component are cotton, polyester, and microdenier polyester/cotton blend. Cotton is a natural fiber and possesses excellent moisture absorption properties and is very soft on the skin. It has the required mechanical and abrasion properties and is typically used for undergarments; it is especially desirable for baby clothes. Microdenier polyester/cotton blends are extremely versatile fibers and are characterized by: (a) good feel, i.e., handle; (b) good moisture absorption; (c) good mechanical properties and abrasion resistance; and (d) ease of processing. It should be recognized that other fibers meeting such performance requirements are also suitable. Microdenier polyester/cotton blended fibers are available from Hamby Textile Research of North Carolina. Microdenier fibers for use in the blend are available from DuPont.

The information infrastructure component of the fabric 20 can include materials 25 for sensing one or more body vital signs. These materials are inlaid during the knitting of the comfort component of the fabric. They can also be knitted separately, as a bus 50 and attached to the fabric as shown in FIG. 4. After fashioning of the fabric into a garment is completed, these materials can be connected to a monitor (referred to as a "personal status monitor" or "PSM") which will take readings from the sensing materials, monitor the readings and issue an alert depending upon the readings and desired settings for the monitor, as described in more detail below. The PSM can also be used for geolocations (GPS, and a spread spectrum ratio) of its wearer. One example of the PSM is the cardiorespiratory monitoring unit from Respirationics, Inc. which is commonly used for monitoring infants prone to SIDS. Alternatively, the PSM can be a 'pager-like' device that can transmit the information through wireless technology and eliminate the "physical" hook-up (using connecting wires 34) of the monitoring equipment to the garment of the present invention.

The information infrastructure component may consist of either a high or a low conductivity electrical conducting material component (ECC) 25 or both high and low conductivity fibers. The electrical conductive fiber preferably has a resistivity of from about 0.07×10^{-3} to 10 kohms/cm. The ECC 25 can be used to monitor one or more body vital signs including heart rate, pulse rate, temperature, and oxygen saturation (pulse ox), through sensors on the body and for linking to a personal status monitor (PSM). It can also be used to monitor levels of selected parameters in the body's environment, such as chemical, biological, and radiation (nuclear) levels, as well as smoke levels and oxygen content in the atmosphere. Suitable materials include the three classes of intrinsically conducting polymers, doped fibers and metallic fibers, respectively.

Polymers that conduct electric currents without the addition of conductive (inorganic) substances are known as "intrinsically conductive polymers" (ICP). Electrically conducting polymers have a conjugated structure, i.e., alternating single and double bonds between the carbon atoms of the main chain. In the late 1970s, it was discovered that polyacetylene could be prepared in a form with a high electrical conductivity, and that the conductivity could be further

increased by chemical oxidation. Thereafter, many other polymers with a conjugated (alternating single and double bonds) carbon main chain have shown the same behavior, e.g., polythiophene and polypyrrole. Initially, it was believed that the processability of traditional polymers and the discovered electrical conductivity could be combined. However, it has been found that the conductive polymers are rather unstable in air, have poor mechanical properties and cannot be easily processed. Also, all intrinsically conductive polymers are insoluble in solvents and they possess a very high melting point and exhibit little other softening behavior. Consequently, they cannot be processed in the same way as normal thermoplastic polymers and are usually processed using a variety of dispersion methods. Because of these shortcomings, fibers made up of fully conducting polymers with good mechanical properties are not yet commercially available and hence are not presently preferred for use in the fabric.

Yet another class of conducting fibers consists of those that are doped within organic or metallic particles. The conductivity of these fibers is quite high if they are sufficiently doped with metal particles, but this would make the fibers less flexible. Such fibers can be used to carry information from the sensors to the monitoring unit if they are properly insulated.

Metallic fibers, such as copper and stainless steel insulated with polyethylene or polyvinyl chloride, can also be used as the conducting fibers in the fabric. With their exceptional current carrying capacity, copper and stainless steel are more efficient than any doped polymeric fibers. Also, metallic fibers are strong and they resist stretching, neck-down, creep, nicks and breaks very well. Therefore, metallic fibers of very small diameter (of the order of 0.1 mm) will be sufficient to carry information from the sensors to the monitoring unit. Even with insulation, the fiber diameter will be less than 0.3 mm and hence these fibers will be very flexible and can be easily incorporated into the fabric. Also, the installation and connection of metallic fibers to the PSM unit will be simple and there will be no need for special connectors, tools, compounds and procedures. One example of a high conductive yarn suitable for this purpose is Bekinox available from Bekaert Corporation, Marietta, Ga., a subsidiary of Bekintex NV, Wetteren, Belgium, which is made up of stainless steel fibers and has a resistivity of 60 ohm-meter. The bending rigidity of this yarn is comparable to that of the polyamide high-resistance yarns and can be easily incorporated into the information infrastructure in our present invention.

Thus, the preferred electrical conducting materials for the information infrastructure component for the fabric are: (i) doped nylon fibers with conductive inorganic particles and insulated with PVC sheath; (ii) insulated stainless steel fibers; and (iii) thin gauge copper wires with polyethylene sheath. All of these fibers can readily be incorporated into the fabric and can serve as elements of a wearable motherboard, described below. An example of an available conducting fiber is X-Static coated nylon with PVC insulation (T66) from Sauquoit Industries, Scranton, Pa. An example of an available thin copper wire is 24-gauge insulated copper wire from Ack Electronics, Atlanta, Ga.

The electrical conducting component fibers 25 can be incorporated into the knitted fabric in two ways: (a) regularly spaced inlaid yarns acting as sensing elements; and (b) precisely positioned (inlaid) yarns for carrying signals from the sensors to the PSM. Additionally, the yarns can be knitted separately into a comfort component and the data bus 50 can be attached to the fabric as shown in FIGS. 4 and 6.

The form-fitting component (FFC) 26 provides form-fit to the wearer, if desired. More importantly, it keeps the sensors in place on the wearer's body during movement. Therefore, the material chosen should have a high degree of stretch to provide the required form-fit and at the same time, be compatible with the material chosen for the other components of the fabric. Any fiber meeting these requirements is suitable. The preferred form-fitting component is SPANDEX fiber, a block polymer with urethane groups. Its elongation at break ranges from 500 to 600% and, thus, can provide the necessary form-fit to the garment. Its elastic recovery is also extremely high (99% recovery from 25% stretch) and its strength is in the 0.6–0.9 grams/denier range. It is resistant to chemicals and withstands repeated machine washings and the action of perspiration. It is available in a range of linear densities.

The SPANDEX band 26 shown in FIG. 6 is the FFC providing the desired form-fit. These bands behave like "straps", but are unobtrusive and are well integrated into the fabric. There is no need for the wearer to tie something to ensure a good fit for the garment. Moreover, the SPANDEX band will expand and contract as the wearer's chest expands and contracts during normal breathing. The FFC may not be always be necessary especially for the knitted versions of the fabric/garment.

The purpose of the static dissipating component (SDC) 28 is to quickly dissipate any built-up static charge during the usage of the fabric. Such a component may not always be necessary. However, under certain conditions, several thousand volts may be generated which could damage the sensitive electronic components in the PSM Unit. Therefore, the material chosen must provide adequate electrostatic discharge protection (ESD) in the fabric.

NEGA-STAT, a bicomponent fiber produced by DuPont is the preferred material for the static dissipating component (SDC). It has a trilobal shaped conductive core that is sheathed by either polyester or nylon. This unique trilobal conductive core neutralizes the surface charge on the base material by induction and dissipates the charge by air ionization and conduction. The nonconductive polyester or nylon surface of NEGA-STAT fiber controls the release of surface charges from the thread to provide effective static control of material in the grounded or ungrounded applications according to specific end-use requirements. The outer shell of polyester or nylon ensures effective wear-life performance with high wash and wear durability and protection against acid and radiation. Other materials which can effectively dissipate the static charge and yet function as a component of a wearable, washable garment may also be used.

With reference to FIG. 3, the VELCRO strips 68 can be used to connect the body sensors 32 to the inside of the front piece of the garment of the present invention. This is illustrated in FIG. 7 which shows the sensors 32 attached to the front piece. The connecting wires from the sensors can be plugged into the top set of T-Connectors (similar to the "button clips" used in clothing), of the back panel of the garment shown in FIG. 5. This is illustrated in FIG. 8 where the connecting wires 34 are plugged into the top set of T-Connectors 42. The vital signs gathered by the sensors pass through the connecting wires or sensor leads 34 into the T-Connectors (42) at the top and are transmitted through the electrical conducting component 25 and the data bus 50 integrated into the garment (FIG. 5). This information is tapped out to the monitoring equipment or PSM through another set of connecting wires 34 plugged into the bottom set of T-Connectors 44. This is illustrated in FIG. 9. The

[54] **PORTABLE DEVICE FOR SENSING
CARDIAC FUNCTION AND
AUTOMATICALLY DELIVERING
ELECTRICAL THERAPY**

[75] Inventors: Marlin S. Heilman, Sarver; Arlan J. Brandt, Gibsonia; Larry D. Bowling; Joseph F. Russial, both of Pittsburgh, all of Pa.

[73] Assignee: Lifecor, Inc., Pittsburgh, Pa.

[21] Appl. No.: 185,781

[22] Filed: Apr. 25, 1988

[51] Int. Cl.⁵ A61N 1/00

[52] U.S. Cl. 128/421; 128/702;
128/419 D; 128/696

[58] Field of Search 128/419 D, 419 P, 419 PG,
128/421, 696, 702

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,241,556	3/1966	Zacouto	128/421
3,460,542	8/1969	Gemmer	128/421
3,702,613	11/1972	Panico et al.	128/417
3,826,245	7/1974	Funfstuck	128/206
3,942,533	3/1976	Cannon, III	128/417
3,961,623	6/1976	Milani et al.	128/206
4,002,239	1/1977	Buchalter	206/484

4,058,127	11/1977	Buchalter	128/417
4,088,138	5/1978	Diack et al.	128/419 D
4,576,170	3/1986	Bradley et al.	128/419 D
4,729,377	3/1988	Granek et al.	128/639

Primary Examiner—Francis Jaworski

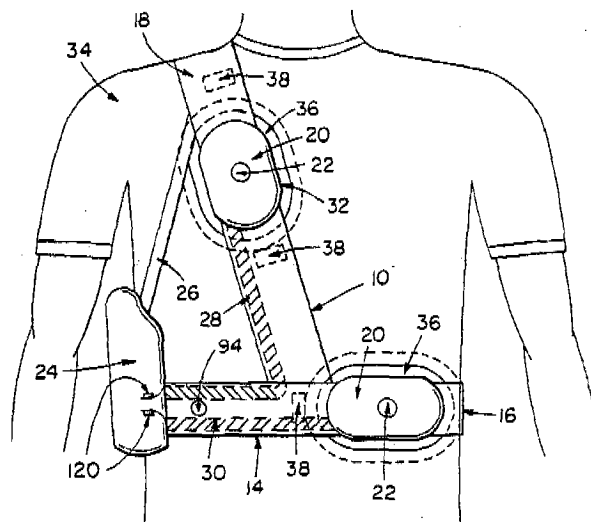
Assistant Examiner—George Manuel

Attorney, Agent, or Firm—Fleit, Jacobson, Cohn, Price, Holman & Stern

[57] **ABSTRACT**

A patient-worn harness or vest protects at-risk patients from the possibly fatal results of heart arrhythmias. The harness or vest incorporates sensing electrodes for monitoring heart condition, a microprocessor and memory for processing signals received from the sensing electrodes and comparing same with patient's data, and skin-contacting pulsing electrodes for applying electrical pulses to the patient's chest wall responsive to signals received from the microprocessor. The electrodes include automatic tightening and electrolyte gel release mechanisms for reducing impedance at the electrode-skin interface. A servicing subsystem is provided for the harness or vest and may be used to interface with the harness or vest and also to communicate with remote health care personnel through a suitable telephone link.

51 Claims, 15 Drawing Sheets



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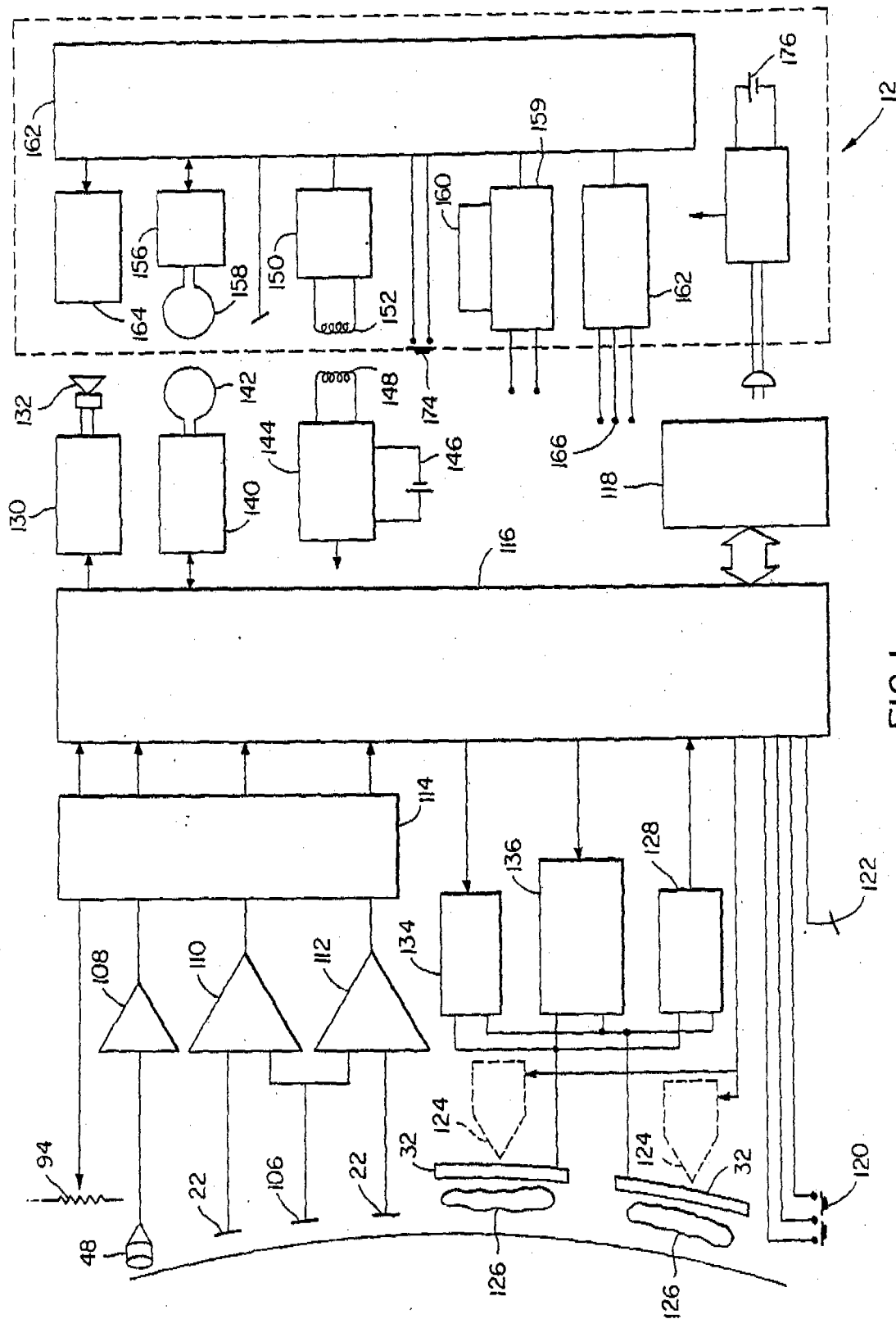


FIG. 1

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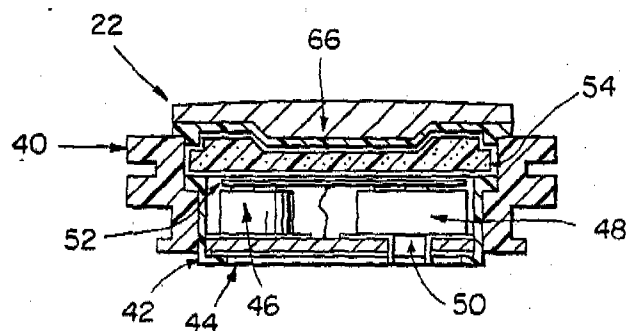


FIG. 2a

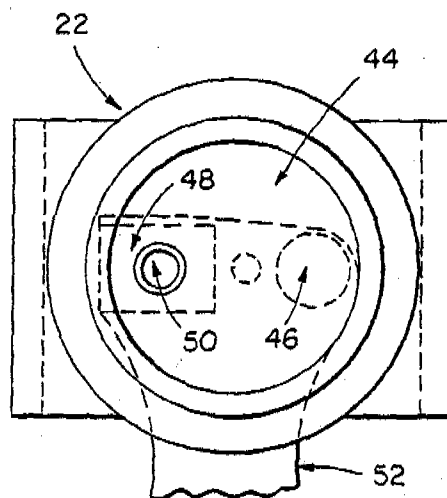


FIG. 2b

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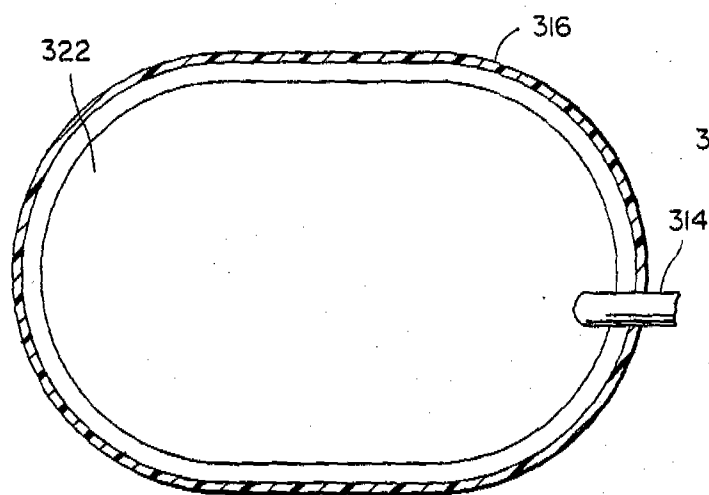


FIG. 15a

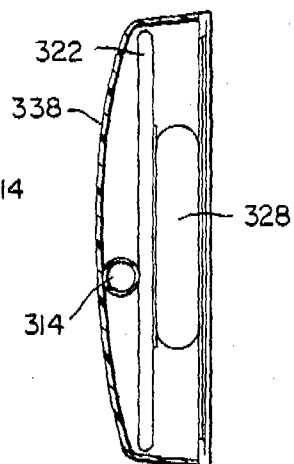


FIG. 15b

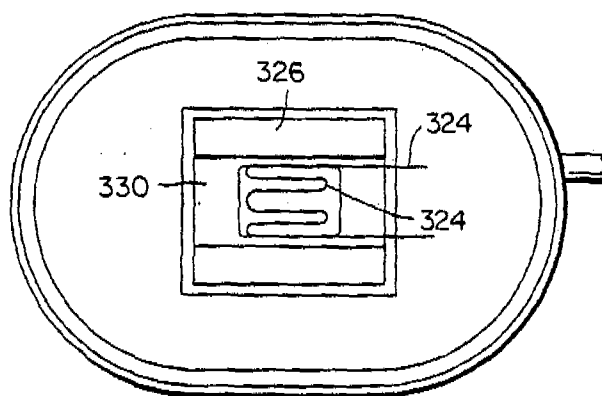


FIG. 15c

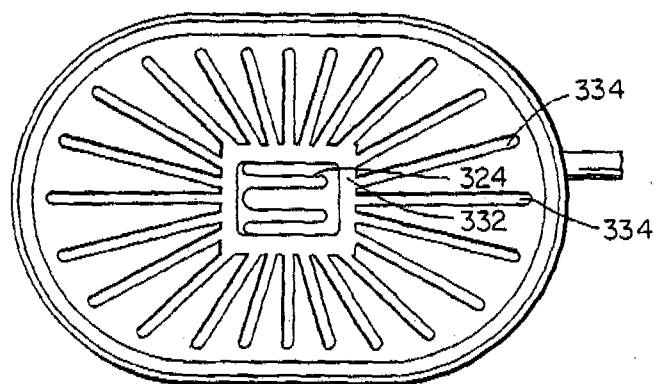


FIG. 15d



US006551252B2

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(12) **United States Patent**
Sackner et al.

(10) **Patent No.:** **US 6,551,252 B2**
(45) **Date of Patent:** ***Apr. 22, 2003**

(54) **SYSTEMS AND METHODS FOR
AMBULATORY MONITORING OF
PHYSIOLOGICAL SIGNS**

(75) **Inventors:** **Marvin A. Sackner**, Miami Beach, FL
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FL (US)

(73) **Assignee:** **VivoMetrics, Inc.**, Ventura, CA (US)

(*) **Notice:** Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.

This patent is subject to a terminal dis-
claimer.

(21) **Appl. No.:** **09/836,384**

(22) **Filed:** **Apr. 17, 2001**

(65) **Prior Publication Data**

US 2002/0032386 A1 Mar. 14, 2002

Related U.S. Application Data

(60) **Provisional application No.** 60/197,589, filed on Apr. 17,
2000.

(51) **Int. Cl.⁷** **A61B 5/08; A61B 5/02;**
A61B 5/04

(52) **U.S. Cl.** **600/536; 600/388; 600/389;**
600/301; 600/508; 600/509; 600/481

(58) **Field of Search** 600/536, 547,
600/529, 534, 509, 508, 483, 481, 390,
389, 388, 386, 301, 300, 587, 595

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,016,868 A * 4/1977 Allison 600/388
4,308,872 A * 1/1982 Watson et al. 600/534

4,373,534 A * 2/1983 Watson 600/534
4,572,197 A * 2/1986 Moore et al. 374/121
4,817,625 A * 4/1989 Miles 33/561.2
5,178,151 A * 1/1993 Sackner 600/485
5,331,968 A * 7/1994 Williams et al. 600/534
5,353,793 A * 10/1994 Borun 600/386
5,913,830 A * 6/1999 Miles 324/207.16
6,047,203 A * 4/2000 Sackner et al. 600/301

* cited by examiner

Primary Examiner—Max F. Hindenburg

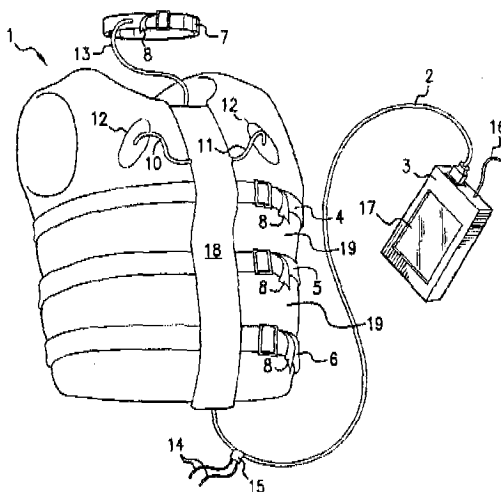
Assistant Examiner—Navin Natnithadha

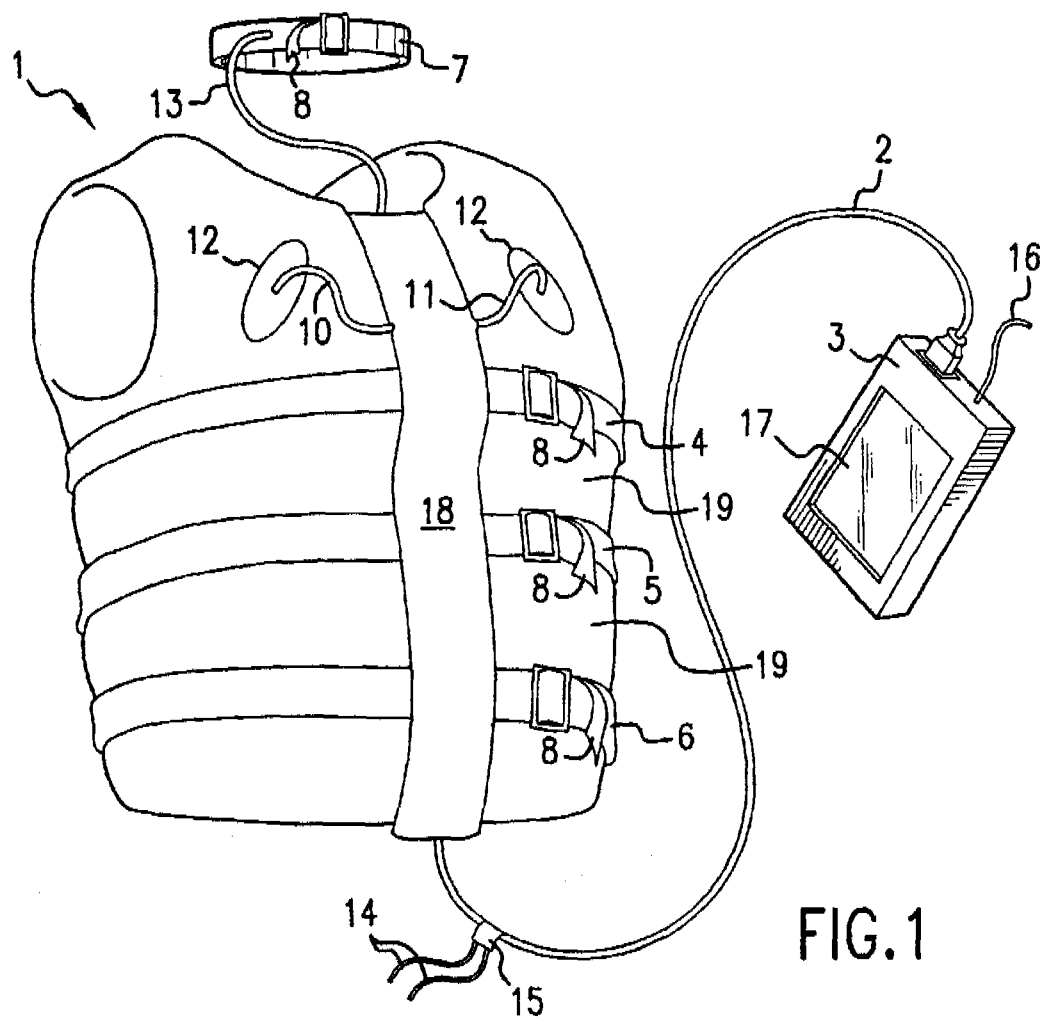
(74) **Attorney, Agent, or Firm**—Pennie & Edmonds LLP

(57) **ABSTRACT**

The present invention relates to the field of ambulatory and non-invasive monitoring of a plurality of physiological parameters of a monitored individual. The invention includes a physiological monitoring apparatus with an improved monitoring apparel worn by a monitored individual, the apparel having attached sensors for monitoring parameters reflecting pulmonary function, or parameters reflecting cardiac function, or parameters reflecting the function of other organ systems, and the apparel being designed and tailored to be comfortable during the individual's normal daily activities. The apparel is preferably also suitable for athletic activities. The sensors preferably include one or more ECG leads and one or more inductive plethysmographic sensor with conductive loops positioned closely to the individual to preferably monitor at least basic cardiac parameters, basic pulmonary parameters, or both. The monitoring apparatus also includes a unit for receiving data from the sensors, and for storing the data in a computer-readable medium. The invention also includes systems comprising a central data repository for receiving, storing, and processing data generated by a plurality of physiological monitored apparatus, and for making stored data available to the individual and to health care providers.

66 Claims, 10 Drawing Sheets





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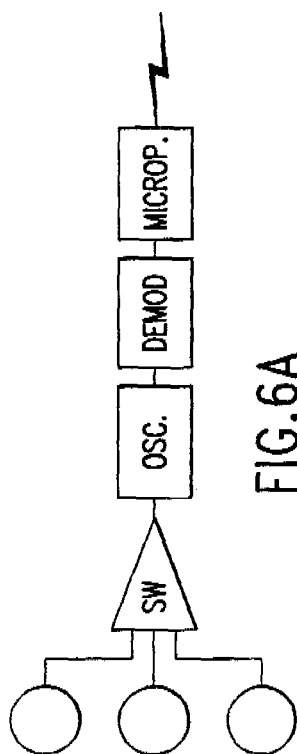


FIG. 6A

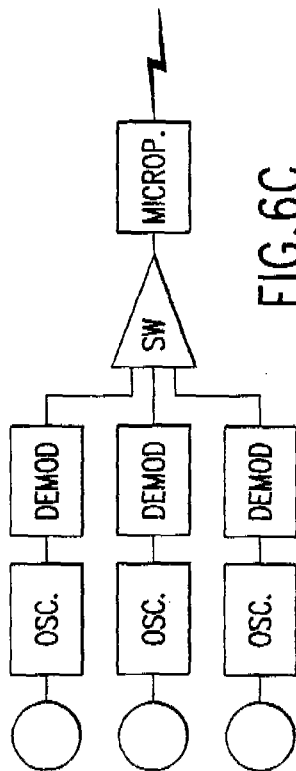


FIG. 6C

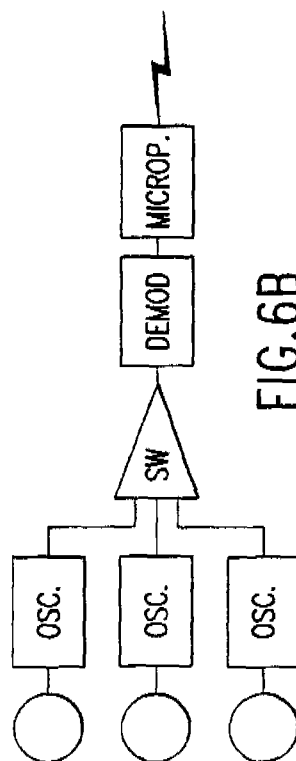
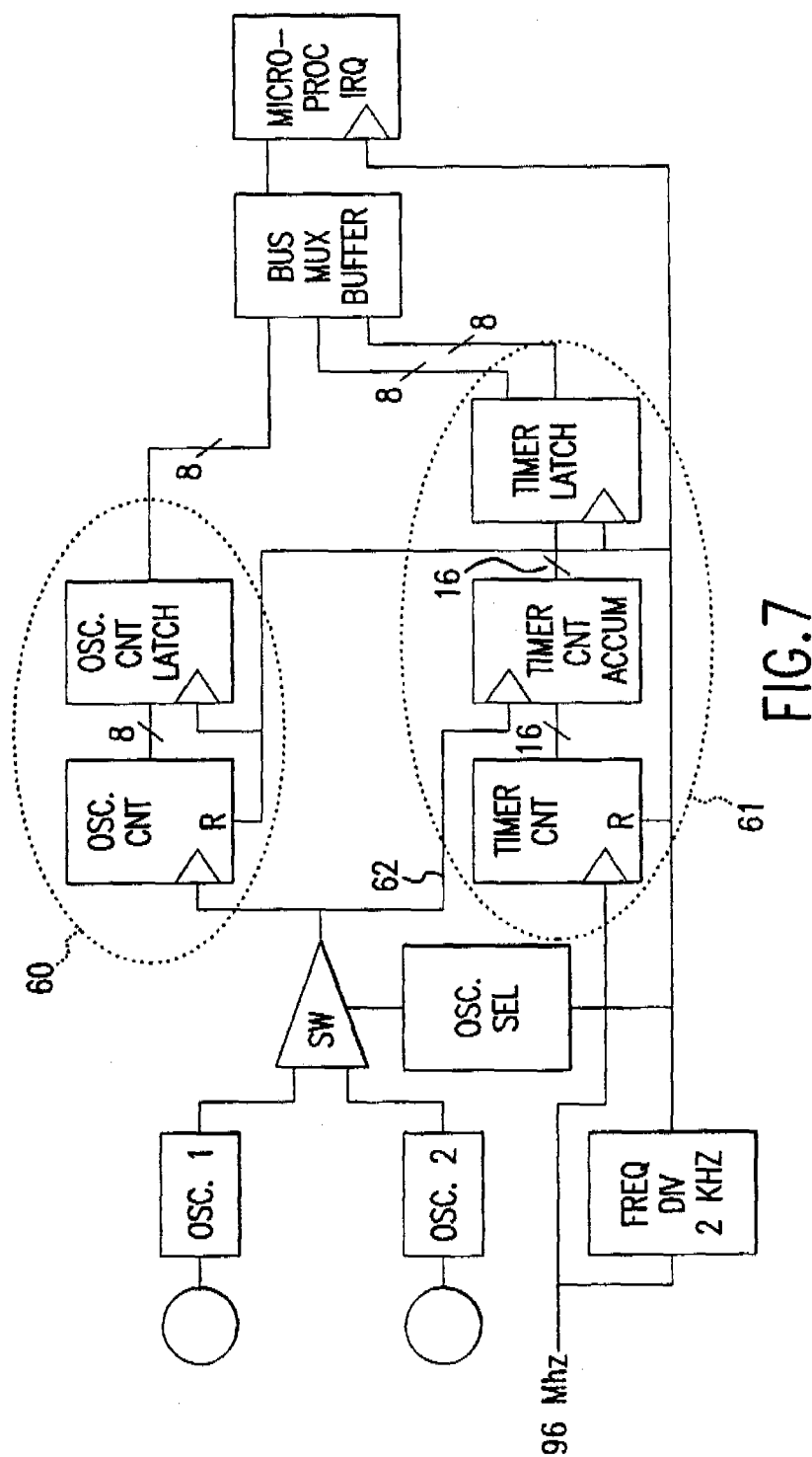


FIG. 6B



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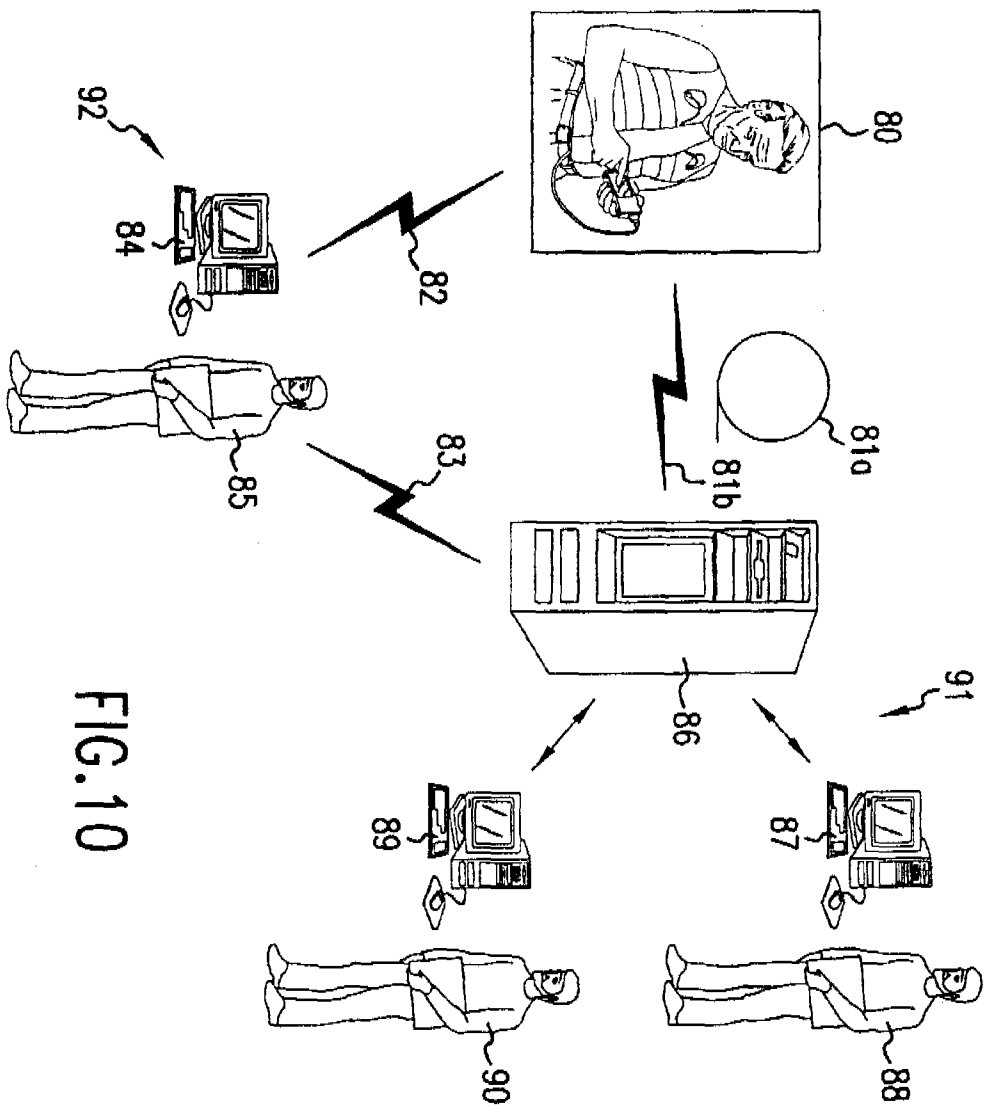


FIG. 10

SYSTEMS AND METHODS FOR AMBULATORY MONITORING OF PHYSIOLOGICAL SIGNS

This application claims the benefit of Provisional application Ser. No. 60/197,589, filed Apr. 17, 2000.

1. FIELD OF THE INVENTION

The present invention relates to the field of ambulatory and non-invasive monitoring of an individual's physiological parameters. In particular, the invention relates to a monitoring apparatus with an improved apparel worn by a monitored individual, the apparel having attached sensors for monitoring parameters reflecting pulmonary function, or parameters reflecting cardiac function, or parameters reflecting the function of other organ systems. The invention also includes systems for receiving, storing, and processing physiological-parameter data, and for making it available to the individual and to health care providers.

2. BACKGROUND OF THE INVENTION

In the following, the term "plethysmography" (and its derivative words) means measurement of a cross-sectional area of the body, such as a cross-sectional area of the chest or of the abdomen, or a body part, such as a cross-sectional area of the neck or of an arm. (This meaning is somewhat more limited than is standard in the medical arts.) Further, the phrase "inductive plethysmography" means herein plethysmographic measurements which depend on inductance determinations.

Measurement of pulmonary and cardiac physiological parameters by means of inductive plethysmography is known. For example, many measurement methods and apparatus are disclosed in the following U.S. patents, the entire disclosures of which are incorporated herein, in their entireties, by reference, for all purposes.

(1) The '872 patent: U.S. Pat. No. 4,308,872, issued Jan. 5, 1982 and titled "Method and Apparatus for Monitoring Respiration," discloses a method and apparatus for monitoring respiration volumes by measuring variations in the patient's chest cross sectional area, or variations in both chest and abdomen cross sectional areas, each area being measured by determining the inductance of an extensible electrical conductor closely looped around the body, and the measurements being calibrated by measuring the area variations for a few breaths while directly measuring corresponding volumes of breath, preferably while the patient assumes at least two body positions, for example sitting and supine.

(2) The '534 patent: U.S. Pat. No. 4,373,534, issued Feb. 15, 1983 and titled "Method and Apparatus for Calibrating Respiration Monitoring System," discloses methods and systems in which respiration volume is determined by weighting signals representing abdominal and chest cross-sectional areas, where the weighting factors are determined by a procedure involving measuring respiration volume by an alternate measuring apparatus along with unweighted chest and abdomen signals, the measurements occurring for a first series of breaths based with a first relative chest and abdominal contribution and for a second series of breaths based on a second relative chest and abdominal contribution.

(3) The '252 patent: U.S. Pat. No. 4,452,252, issued Jun. 5, 1984 and titled "Non-invasive Method for Monitoring Cardiopulmonary Parameters," discloses a method for monitoring cardiopulmonary events by inductive plethysmographic measurement of a cross-sectional area of the neck, and further discloses a method for monitoring mouth volume

by inductive plethysmographic measurement of a cross-sectional area of the head in a plane which extends through the mouth.

(4) The '015 patent: U.S. Pat. No. 4,456,015, issued Jun. 26, 1984 and titled "Non-invasive Method for Semiquantitative Measurement of Neck Volume Changes," discloses a method of plethysmographic measurement of a subject's neck volume by providing an extensible conductor closely circling the neck and, first, calibrated against cross-sectional area so that neck volume may be determined from the conductor's inductance, and also, second, calibrated against invasively-measured intrapleural pressure so that the intrapleural pressure may also be determined from the conductor's inductance, and also so that intrapleural pressure may also be obtained from measured neck volume.

(5) The '407 patent: U.S. Pat. No. 4,648,407, issued Mar. 10, 1987 and titled "Method for Detecting and Differentiating Central and Obstructive Apneas in Newborns," disclosing methods for detecting the presence and origin of apnea in newborns by concurrently monitoring relative movement of the cranial bones (which have been found to move with respiration as a function of intrapleural pressure), preferably by a surface inductive plethysmographic transducer, and nasal ventilation, preferably by a nasal cannula, thermistor, thermocouple or CO₂ sensor, wherein absence of changes in both cranial bone movement and respiratory air flow at the nose indicates of the presence of central apnea, while absence of nasal air flow accompanied by continuing cranial bone movements indicates of obstructive apnea.

(6) The '962 patent: U.S. Pat. No. 4,777,962, issued Oct. 18, 1988 and titled "Method and Apparatus for Distinguishing Central Obstructive and Mixed Apneas by External Monitoring Devices Which Measure Rib Cage and Abdominal Compartmental Excursions During Respiration," discloses an apparatus and method for distinguishing between different types of apneic episodes. The method includes measuring a new index, Total Compartmental Displacement/Tidal Volume (TCD/VT), and measuring the phase relation between the abdominal and rib cage contributions to total respiration volume, wherein an episode is classified as central, obstructive or mixed based on the value of TCD/VT and the phase relation.

(7) The '640 patent: U.S. Pat. No. 4,807,640, issued Feb. 28, 1989 and titled "Stretchable Band-type Transducer Particularly Suited for Respiration Monitoring Apparatus," discloses an improved, low-cost stretchable band incorporating a conductor for disposition about the human torso or other three dimensional object, and particularly intended for use with respiration monitoring by means of inductive plethysmography, a method for making the band, which method is suitable to mass production techniques, and an improved enclosure housing circuitry releasably connected to the conductor in the band when the band is incorporated in respiration monitoring apparatus.

(8) The '473 patent: U.S. Pat. No. 4,815,473, issued Mar. 28, 1989 and titled "Method and Apparatus for Monitoring Respiration," discloses a method and apparatus for monitoring respiration volumes by inductive plethysmographic measurement of variations in a patient's chest cross sectional area, or preferably, variations in both chest and abdomen areas during breathing, and a method for calibrating such an apparatus by measuring cross-sectional area variations for a few breaths while directly measuring corresponding volumes of breath, preferably while the patient assumes at least two body positions, for example sitting and supine.

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multate information reflecting a broad array of transdermally measurable physiological parameters in a scandalized ???manner and in a standardized format.

5.2.2. Microprocessor Unit and Cable

As described previously, the monitoring apparatus of this invention may be provided with primary and secondary signal cables. FIG. 1 illustrates primary signal cable 2 which carries signals from the primary sensor bands 4, 5, and 6, and secondary sensor band 7. This cable also has provision for carrying ECG signals, provided, for example, over leads 10 and 11, and provision for signals from other sensors received at connector 15. Further, secondary signal cable 16 may optionally carry signals from a number of other sensors arranged on the body.

Signals gathered by the monitoring apparatus are received by microprocessor unit 3. Unit 3 performs at least basic data entry and storage functions, and optionally performs alarm functions, communication functions, and power management functions. The unit may be built as an add-on to existing personal digital assistants (PDAs), cell phones, cell phone/PDA combinations, bidirectional pagers, especially those used for e-mail exchange, and other similar handheld devices. Also the unit may be a custom design including at least a microprocessor and associated components, and optionally signal processor circuits. Preferably, unit 3 has display screen 17 which is touch sensitive for data input by the monitored individual. Other user interface features may be provided, such as voice command recognition, voice or audible alarm output, attachable keyboard, and so forth. This unit may also optionally include wireless communication circuits. Also, although FIG. 1 illustrated unit 3 as possibly hand-held, it may also be carried on an individual normal clothing, for example, on a belt, or may be placed in a pocket provided on garment 1.

A first data entry function is to receive and store information input by a monitored individual. For example, a monitored individual may enter major activities during the day along with any symptoms that might be observed.

A second data entry and storage function, to receive and store digitized signals generated by the sensors of a monitoring apparatus of this invention, is closely linked with possible communication functions. Preferably, the present invention conforms to well known standards for "standard event recording" by advantageously and preferably storing all raw signal data, whether or not it is used only in summary form for health care personnel. Storing raw data in a central repository is encouraged by regulatory authorities, and is important in quality control of monitoring by the present invention. Further, health care personnel may from time-to-time wish to examine the raw data indicative of the physiological events occurring in the monitored individual, which is possible by accessing the central repository.

However, this raw data may be voluminous, even for a basic monitoring garment. Table I presents the data rates generated by the apparatus of FIG. 1 wherein operation is with preferred sample precision and data rate for each sensor.

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TABLE I

Exemplary Data Rates			
Sensor	Bits per sample	Samples per second	Data rate (MB/hr)
Chest sensor band	16	50	0.36
Abdominal sensor band	16	50	0.36
Thoracic cardiac sensor band	16	200	1.44
Neck sensor band	16	100	0.72
Accelerometer	8	10	0.04
ECG	12	200	1.08
Pulse oximeter	8	50	0.18
Throat microphone	8	10	0.04
TOTAL			4.22 (= 1.2 kbits/sec)

Therefore, the present invention includes various tradeoffs for the storage or raw data, which depend primarily on available battery power and accessible wireless facilities. For example, if high bandwidth wireless data transfer, for example 64 kbits/sec or greater, is available throughout an individual's daily activities, currently (as of this application's filing date) an unusual possibility, then wireless transmission of all raw data would require an apparatus transmitter duty cycle of 2% or less, which may be acceptable in view of available device battery power and the cost of wireless access. On the other hand, wireless access currently available supports data transmission rates at best of 14.4 kbits/sec. At these rates the apparatus transmitter would have a virtually 100% duty cycle, which is likely to be an unacceptable power and wireless access cost.

Alternatively, data may be stored locally in microprocessor unit 3 and transmitted periodically only in bulk. For example, a commonly available 64 MB flash memory module may easily store raw data for 12 or more hours. A 128 MB module could hold 24 hours of data. A full flash memory module may be replaced and sent by overnight mail services to the central repository. Alternatively, the data may be sent by high-speed wired digital connection (e.g., DSL or cable modem to internet) directly to the central repository. Other removable memory technologies, for example, micro-hard-drives or micro ZIP drives, may also be used. In this embodiment, unit 3 may communicate wirelessly only important or significant physiological events, such as alarms recognized. This would be a much smaller amount of data easily transmitted currently in most locations.

Therefore, depending on available wireless data rates and access cost, on available apparatus battery power, and available removable memory capacities, the present invention includes microprocessor unit designs from wireless transmission of all raw data to a central repository to local storage of all raw data with periodic transmission. The latter embodiment is currently preferred for most locations.

A further data storage embodiment includes local, private wireless transmission of data from a microprocessor unit of a monitoring garment to a local receiver within a short distance, perhaps 10 to 1000 feet, of the individual being monitored. From the local receiver, the data may be stored at a local computer system, for example a PC-type computer, for periodic transmission to a central repository for access by health care providers. The periodic transmission may be via removable media a few times daily, as described above, or may be via standard or high speed access (DSL or cable modem) perhaps hourly. Alternatively, the central repository may be replaced by a local server PC-type computer accessed by health care providers. Although not changing

Next, FIG. 6B illustrates an embodiment in which single demod and microp blocks are shared between three inductive plethysmographic loops, each loop having a dedicated oscillator. Preferably, the oscillators have digitized variable frequency output (e.g., a variable frequency square wave), and switch SW may be a standard controllable digital switch. Here, local modules include the osc blocks. FIG. 6B is a preferred embodiment.

Finally, FIG. 6C illustrates a third embodiment in which only the microp block is shared and in which the local modules include both the osc and the demod blocks. This is the currently less preferred embodiment, but may be more advantageous where the osc and demod blocks can be implemented on a single mixed-type integrated circuit (IC).

The operation of the demod block is not described in more detail with reference to FIG. 7, in which portions of the embodiment of FIG. 6B is illustrated in more detail. In general, the demod block is a frequency counter which samples a digitized variable frequency input of from 200 to 400 kHz, and produces a digital frequency output accurate to at least 10 ppm (more preferably to 5 ppm, and even more preferably to 1 ppm). The output is preferably 24 bits or more. While any such frequency counter may be used in the present invention, FIG. 7 illustrates a particular such counter that can be economically implemented as a single programmed logic array IC.

FIG. 7 illustrates only two inductive plethysmographic loops, each with a dedicated osc block, OSC 1 and OSC 2, respectively. The digitized oscillator output is sampled by controllable switch SW and directed to the demod block components. Also input to the demod block is a 96 MHz clock signal. Other, preferably higher clock frequencies may be used, 96 MHz being merely a convenient frequency less than the about 120 MHz which the 80 ns logic in the current implementation is capable. The clock signal is divided to a 2 kHz clock by FREQ DIV block, which is first applied through an oscillator select block (OSC SEL) to control switch SW to sequentially sample the switched osc blocks for 0.5 ms ($=\frac{1}{2}$ kHz). The 2 kHz clock provides for a convenient sampling period, other sampling clock rates could be used. The microprocessor (MICRO-PROC) is also interrupted (IRQ lead) at the 2 kHz clock rate to accept the output digital data through a bus buffer and multiplexer (BUS MUX BUFFER), calculate the frequency from the accepted data, and optionally average two or more successive frequency measurements to determine frequencies in sample periods that are multiples of 0.5 ms, such as 2.5 ms. Finally, the 2 kHz clock is applied to counter, accumulator, and latch components (at the latch and reset, R, inputs) of the demod block to reset this circuitry for the next period of frequency measurement.

Generally, the circuit of FIG. 7 operates by counting the number of 96 MHz clock pulses that occur in the number of oscillator periods that occur in a particular 0.5 ms sampling interval (or sampling interval of other length). The components in oval 60 count the oscillator periods in a sampling interval. The OSC CNT block is an 8 bit digital counter that counts the 200-400 kHz oscillator periods in the sampling interval, this count being latched into the OSC CNT LATCH and the counter reset every 0.5 ms. This eight bit count is supplied to the microprocessor through the BUS MUX BUFFER. Next, the components in oval 61 count the number of 96 MHz clock periods that occur in the counted number of oscillator periods. The TIMER CNT block is a 16 bit digital counter that counts clock periods. Since this count is latched into the TIMER CNT ACCUM block only on the occurrence of oscillator pulses applied to this block by lead

62, this accumulator block only contains counts of clock pulses within completed oscillator periods. At the end of a sampling period, the 16 bit count is latched into the TIMER LATCH, the counters are reset, and the 16 bit count is made available to the microprocessor through the BUS MUX BUFFER.

One of skill in the art will appreciate other equivalent circuit arrangements that are capable of obtaining these counts. In particular, FIG. 7 is hold circuitry, which prevents any activity for the first few (2-4) oscillator periods. This permits both accurate starting of the clock count as well as provides for circuit stabilization.

Finally, the MICRO-PROC divides the 8 bit oscillator period count by the 16 bit clock period count to obtain a 24 bit measured oscillator frequency. Note that it is oscillator period (the inverse of frequency) which varies directly with changes in cross sectional area as measured by the inductive loop.

Thus the demod block of FIG. 7 has a random error of one-half of a 96 MHz clock period, or 5.2 ns, during every 0.5 ms sampling interval. This is a less than 10 ppm error that may be reduced by averaging; for example, averaging for 2.5 ms results in a less than approximately 2 ppm error. Thus the demod block of FIG. 7 achieves the accuracy required for inductive plethysmography. On the other hand, if the demod merely counted the number of oscillator cycles within a 0.5 ms sampling interval, then the random error would be one-half of an approximately 300 kHz period, or 1.67 μ s every 0.5 ms, of about 3300 ppm. Such inaccuracies would totally hide both respiratory and cardiac inductive plethysmographic signals, which at most have an amplitude to 1000 ppm.

5.3. Systems and Methods

FIG. 10 illustrates overall methods of operation of a system according to the present invention incorporating a monitoring apparatus according to the present invention. Here, monitored individual 80 is illustrated as wearing a monitoring garment and holding (for data entry) a microprocessor unit (collectively, monitoring apparatus) according to preferred embodiments of the present invention.

The microprocessor unit may generate information and alarms directly to the monitored individual. Preferably, all data collected by the monitoring apparatus, including all raw data, is stored at a repository. Central repository 91, which is usually remote from the monitored individual, may store the data from many monitored individuals in server-type computer systems 86 equipped with database facilities. Monitored individuals may transmit data either by means of removable storage media 81a (such as a flash memory module) or by wireless transmission 81b, or by both means for different quantities and types of data.

Alternatively or additionally, data may be stored at local repository 92 after transmission by local wireless transmission 82. Removable media may also be used locally. In this case, the monitored individual's activities are usually restricted so that a substantial fraction of days are spent within a few hundred to a few thousand feet of the local repository. The local repository may be a PC-type computer with adequate storage, preferably hard disks of at least 10 GB capacity. Further the local repository may transmit 83 stored data periodically to central repository 91 (if present).

Users of this system include monitored individual 80, who enters data on, e.g., activities and symptoms into the microprocessor unit, and may receive medical reminders or alarms warning of conditions needing attention. Another

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogada
DILIA MARIA RODRIGUEZ D'ALEMAN

ASUNTO	Radicación	06-98045
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	Nº 1 3 7 2 2
	Folios	032 - -

Patente de Invención	☒	Patente de Modelo de Utilidad	☐
Vía Nacional	☒		
Vía PCT (fase nacional)	☐	Cap. I	☐
		Cap. II	☐

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

- 1.1. Descripción: Folios: 4 a 19 como se radicó inicialmente
- 1.2. Reivindicaciones: Folios: 20 a 25 como se radicó inicialmente
- 1.3. Dibujos: Folios 26 a 33 como se radicó inicialmente

2. Objeto de la invención

La presente solicitud se titula "CHALECO Y SISTEMA BIOTELEMETRICO PORTATIL PARA MONITOREO MEDICO INALAMBRICO Y PREDIAGNOSTICO EN TIEMPO REAL", Folio Nº 1.

El objeto de la presente solicitud de patente consiste en un sistema biotelemétrico portátil para el monitoreo de variables corporales en tiempo real, el cual utiliza un chaleco u otros medios portadores de transductores, con múltiple medidores de funciones corporales cuyos datos son enviados a un teléfono móvil o a una computadora en forma inalámbrica.

De otra parte, el pliego reclama: un chaleco o prenda biotelemétrica para el monitoreo de variables corporales de una persona o animal en tiempo real, relacionado en las reivindicaciones 1 a 6 y 14 a 16, un sensor para la obtención de medición de variables corporales, relacionado en las reivindicaciones 7 a 13 y un sistema biotelemétrico portátil relacionado en las reivindicaciones 17 a 25.

El objeto de la solicitud definido anteriormente se clasificó en la IPC A61 B 5/00.

3. Claridad de la solicitud

3.1. Descripción (artículo 28 D 486)

La numeración de las figuras no corresponde a la numeración referenciada en la descripción. Se debe replantear el capítulo descriptivo de manera que la materia allí relacionada corresponda a las figuras.

3.2. Reivindicaciones (artículo 30 D 486)

El pliego calificado no define de manera suficiente la materia a proteger. A continuación se relacionan los principales problemas encontrados al pliego reivindicatorio:

La reivindicación 1 especifica que una capa externa se encuentra dispuesta sobre la totalidad de la capa segunda, sin embargo no se especifica cual es esta segunda capa. Adicionalmente, esta reivindicación menciona una red eléctrica, sin especificar que elementos conforman esta red ni que circuitos comprende, por lo cual la reivindicación es demasiado general.

La reivindicación 2 no es clara porque esta caracterizando un producto (el chaleco) por medio de características de procedimiento ("un recubrimiento desarrollado con un proceso nanotecnológico"). Adicionalmente la antiaderencia y la súper hidrofobia son ventajas del recubrimiento NO características técnicas. La reivindicación debe definir las características técnicas que permiten que el producto obtenga determinadas propiedades, pero no definir el producto por sus propiedades.

La reivindicación 8 se refiere a la utilización del sensor (toma de ECG) lo cual NO es una característica técnica. Igual situación ocurre con las reivindicaciones 10 y 12.

La reivindicación 16 especifica que la prenda biométrica se puede adaptar para medir las variables corporales de un animal, esto es un posible uso que se le puede dar a la prenda, lo cual no constituye una característica técnica de la invención.

La reivindicación 17 se limita a enumerar una serie de componentes de un sistema biotelemétrico portátil, sin establecer la relación estructural entre estos elementos. Una reivindicación que se refiera a un producto (especialmente un producto del tipo eléctrico o electrónico) debe no solo mencionar los componentes que comprende el aparato o sistema, también debe establecer como son los circuitos, como es la conexión entre componentes, el cableado, la forma de comunicación entre componentes, etc., que son las características estructurales que permiten establecer el alcance de la invención.

Por otra parte, una solicitud de patente generalmente comprende una sola reivindicación independiente por categoría (producto o procedimiento). Varias reivindicaciones por categoría son admisibles cuando la materia no puede ser cubierta fácilmente por una sola reivindicación independiente (por ejemplo en el caso de una cerradura y una llave o en el caso de un sistema transmisor-receptor). La materia de la presente solicitud se puede cubrir fácilmente con una sola reivindicación independiente, más aún cuando la reivindicación 17 comprende al chaleco reclamado en las reivindicaciones anteriores. Por los motivos anteriores, y en vista del número de reivindicaciones independiente (tres), la oficina considera que el pliego NO es conciso.

Las reivindicaciones 21 a 25 se refieren al software que comprende el sistema

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biotelemétrico portátil. Dado que el software NO tiene carácter técnico, estas reivindicaciones no son admisibles dentro del pliego reivindicatorio. Igualmente la reivindicación 17 se está caracterizando por componentes de software, lo cual debe eliminarse del pliego.

Por los motivos anteriores, las reivindicaciones mencionadas no cumplen los requisitos de claridad y concisión exigidos en el Art. 30 de la Decisión.

4. Unidad de invención (artículo 25 D 486)

El pliego reivindicatorio presentado contiene los siguientes grupos de invenciones:

- Un sistema biotelemétrico portátil (reivindicaciones 17 a 25) que comprende un chaleco para el monitoreo de variables corporales (reivindicaciones 1 a 6 y 14 a 16).
- Un sensor para la obtención de medición de variables corporales. Reivindicaciones 7 a 13.

Claramente se ve que estos grupos de invenciones no están relacionados por un único concepto inventivo, debido a: 2) un sensor y un sistema telemétrico son invenciones de diferentes sectores tecnológicos, y no puede decirse que tienen un único concepto inventivo por el hecho de que el sistema utiliza sensores, puesto que esta es una sola de las múltiples utilidades que se le puede dar a un sensor. De esta manera, al estudiar la solicitud como un todo, no es posible establecer el aporte de la materia reivindicada al estado del arte

Por las razones anteriores, el pliego calificado NO tiene unidad de invención.

5. Determinación del Estado de la Técnica

Considerando que la fecha de presentación de la solicitud es del 26 de septiembre del 2006, se buscaron documentos del estado de la técnica relacionados, con fecha de publicación anterior a esta. Se realizó búsqueda de documentos relevantes dentro del estado de la técnica, entendiendo como estado de la técnica la definición provista en el Art. 16 D 486, y las excepciones fijadas en el Art. 17 de la misma.

No obstante, la solicitud presenta problemas de claridad y concisión, se realizó una búsqueda parcial la cual se complementará una vez se realicen los ajustes a la solicitud.

Se encontró como anterioridades los documentos relacionados a continuación que pueden afectar la patentabilidad del objeto de la presente solicitud

Nº	Documento*	Título	Fecha de publicación
D1	US6687523	FABRIC OR GARMENT WITH INTEGRATED FLEXIBLE INFORMATION INFRASTRUCTURE FOR MONITORING VITAL SIGNS OF INFANTS	2004-02-03
D2	US4928690	PORTABLE DEVICE FOR SENSING CARDIAC FUNCTION AND AUTOMATICALLY DELIVERING ELECTRICAL THERAPY	1990-05-29
D3	US6551252	SYSTEMS AND METHODS FOR	2003-04-22

		AMBULATORY MONITORING OF PHYSIOLOGICAL SIGNS	75/76
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*Los documentos mencionados se anexan al expediente

6. Análisis de patentabilidad (artículo 14 D486)

En cumplimiento del Art. 14 D486 se procedió a evaluar los requisitos de novedad, nivel inventivo y aplicabilidad industrial, con el fin de establecer la patentabilidad de la invención reivindicada de la solicitud en estudio.

6.1. Novedad (artículo 16 D486)

El requisito de novedad se evaluó por comparación entre lo solicitado y los documentos citados en el numeral 4.

La reivindicación 1 se refiere a un chaleco para el monitoreo de variables corporales que comprende:

- Una capa externa
- Una capa elástica
- Una capa interna donde se encuentra la red eléctrica
- Una cremallera para el ajuste al cuerpo.

La anterioridad **D1** se refiere a una prenda para niños que incluye una estructura integrada para monitorear los signos vitales de los niños. El tejido de esta prenda consiste en los siguientes componentes: un tejido base que puede estar dividido en dos dentro del cual se incorpora la estructura de información (col. 4 líneas 58 a 60). Este tejido se escoge de un material que ofrezca al menos el mismo confort y ajuste de un tejido usual en la fabricación de vestuario, ya que este componente estará en contacto directo con la piel del usuario (col. 5 líneas 58 a 67).

Los componentes que conforman la infraestructura de información consisten en materiales de alta o baja conductividad, preferiblemente fibras conductoras (col. 6 líneas 45 a 50).

El tejido también comprende un componente para el ajuste de forma que proporciona ajuste de la prenda al usuario (col. 8 líneas 1 y 2). Este componente mantiene los sensores en su lugar durante el movimiento del usuario, por lo cual el material debe tener un alto nivel de elasticidad para proporcionar el requerido ajuste. El material seleccionado es una fibra SPANDEX el cual proporciona el adecuado ajuste para la prenda (col. 8 líneas 2 a 16).

Finalmente, se encuentra que el objeto del documento **D1** puede ser implementado en prendas de vestir tal como camisetas, mediante apropiadas técnicas de unión, tal como costuras, pegamento, o uniones mediante VELCRO, botones o cremalleras (col. 4 líneas 40 a 45). De tal manera que esta anterioridad comprende todas las características reclamadas en la reivindicación 1.

La reivindicación 3 especifica que la red interior esta constituida por:

- Polímeros conductores.
- Sensores y demás circuitos
- Una microtarjeta de adquisición y transmisión de datos

La anterioridad **D1** comprende una infraestructura de información que incluye:

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componentes eléctricamente conductores, sensores, procesadores o dispositivos de transmisión inalámbrica (col. 4 línea 66 a col. 5 línea 3).

La reivindicaciones 4 a 6 especifican que los sensores son:

- Sensores para medir voltaje superficial de la piel
- Sensor de sonidos cardiacos
- Un sensor de temperatura corporal.
- Opcionalmente electrodos en las derivaciones unipolares del plano horizontal.
- Opcionalmente sensores para la medición de otras variables.

El documento **D1** especifica que el tejido proporciona sensores para monitorear signos físicos del cuerpo, tal como los sonidos del corazón, ECG, pulso, voz y temperatura, niveles de oxígeno en la sangre, exposición atmosférica así como exposición química y biológica, exposición a la radiación (col. 4 líneas 49 a 55)

La reivindicación 7 se refiere a un sensor para la obtención de medición de variables corporales que comprende:

- Un gas
- Un material elástico que contiene el gas
- Un compuesto conductor que recubre el material elástico que se extiende para formar un cable.

El documento **D2**, se refiere a un sistema para proteger pacientes susceptibles o en riesgo de sufrir muerte repentina debida a arritmias cardiacas. El sistema comprende un arreglo de electrodos **20**, el cual contiene los respectivos electrodos sensores **22** y **32**, estos electrodos comprenden:

- Un gas (col. 10 líneas 30 a 68)
- Una célula inflable en cada electrodo (col. 10 líneas 47 a 50)
- La célula inflable esta encerrada por los electrodos **336** y **338** (Fig. 16c). Los electrodos pueden ser capacitivos, de carbón conductivo o cualquier otro diseño que permita el uso sin producir irritación en la piel (col. 5 líneas 25 a 28).

La reivindicación 8 especifica que el sensor es para la toma de ECG.

La anterioridad **D2**, especifica que los electrodos sensores **22** contienen un electrodo para la toma de ECG **44** (col. 5 líneas 19 a 25)

La reivindicación 10 especifica que el sensor es un sensor para registrar sonidos cardiacos.

El documento **D2** especifica que los electrodos sensores **22** comprenden un amplificador **46** y un transductor de audio o micrófono **48**. (col. 5 líneas 24 y 25)

El objeto reclamado no presenta ninguna ventaja o efecto novedoso con respecto al estado del arte, por consiguiente se considera que las reivindicaciones mencionadas no tienen Novedad y no cumplen con los requisitos del artículo 14 de la decisión.

6.2. Nivel Inventivo (artículo 18 D486)

Las reivindicaciones 17 a 25, se ven afectadas por las anterioridades **D1** y **D3**, de la siguiente manera:

La reivindicación 17 reclama un sistema biotelemétrico portátil que comprende:

- Un chaleco para el monitoreo de variables corporales
- Receptores de información
- Un servidor para distribuir información

Como se dijo en el aparte anterior, el Documento **D1** se refiere a una prenda **20** que incluye una estructura eléctrica para monitorear los signos vitales de niños. Esta prenda incluye un monitor PSM capaz de transmitir información por medio de tecnología inalámbrica (col. 6 líneas 40 a 44).

De acuerdo a lo anterior, el documento **D1** contiene todos los elementos del sistema biotelemétrico reclamado a excepción del servidor para distribuir información. La anterioridad **D3**, se refiere a una prenda de vestir que contiene un aparato de monitoreo con sensores para medir funciones pulmonares, cardíacas o de cualquier otro órgano. La anterioridad presenta un sistema de monitoreo (Fig. 10) el cual consta de una prenda de monitoreo **1** (Fig. 1), una unidad de procesamiento **3** (Fig. 1) y un servidor **86** que distribuye la información aportada por el usuario **80** a profesionales locales **85**, al centro de profesionales **90** ó a otros **88** asociados con el repositorio central **91** (Fig. 10. Descripción, col. 28 línea 43 a col. 29 línea 35).

La reivindicación 18 a 20 especifica que los receptores de información son asistentes digitales personales PDA, teléfonos celulares y computadores. Que cuentan con un intercomunicador de radio.

El documento **D3** especifica que la unidad de procesamiento **3** puede ser construido mediante componentes existentes tal como PDAs, teléfonos celulares combinaciones de teléfonos celulares con PDAs, buscapersonas y elementos similares (col. 17 líneas 24 a 29). Esta unidad cuenta con circuitos para la comunicación inalámbrica (col. 17 líneas 35 a 38)

Las reivindicaciones 21 a 25 se refieren al software que comprende el sistema biotelemétrico, el cual no posee carácter técnico por lo cual estas reivindicaciones tampoco tienen nivel inventivo.

Así las cosas, una persona del oficio normalmente versada en la materia podría derivar de manera obvia el objeto la solicitud del estado de la técnica, por lo cual el objeto de la presente solicitud carece de nivel inventivo.

7. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

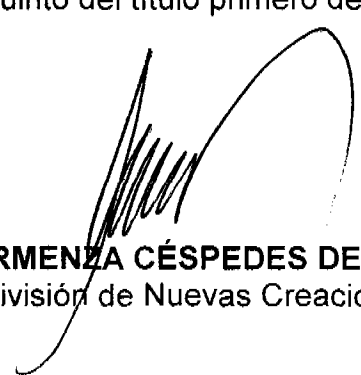
Nº	Documento Nº	Reivindicaciones Afectadas	Requisito que Afecta
D1	US6687523	1 a 6	Novedad
D1	US6687523	17 a 25	Nivel Inventivo
D2	US4928690	7, 8 y 10	Novedad
D3	US6551252	17 a 25	Nivel Inventivo

Si el interesado desea continuar la tramitación, deberá presentar un pliego reivindicatorio que defina claramente la materia, que se desea proteger, acorde a lo explicado anteriormente.

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Se recomienda, que tenga en cuenta que el replanteamiento de esos apartes NO podrá implicar una ampliación de la protección que correspondería a la divulgación contenida en la solicitud inicial, de acuerdo a lo que establece el artículo 34 de la Decisión 486.

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2 Literal e) del capítulo quinto del título primero de la Circular Única No. 10 de 2001.



ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha
30 OCT. 2008

CONCEPTO TECNICO No. 2912	EXAMINADOR TÉCNICO Código No. 202082
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