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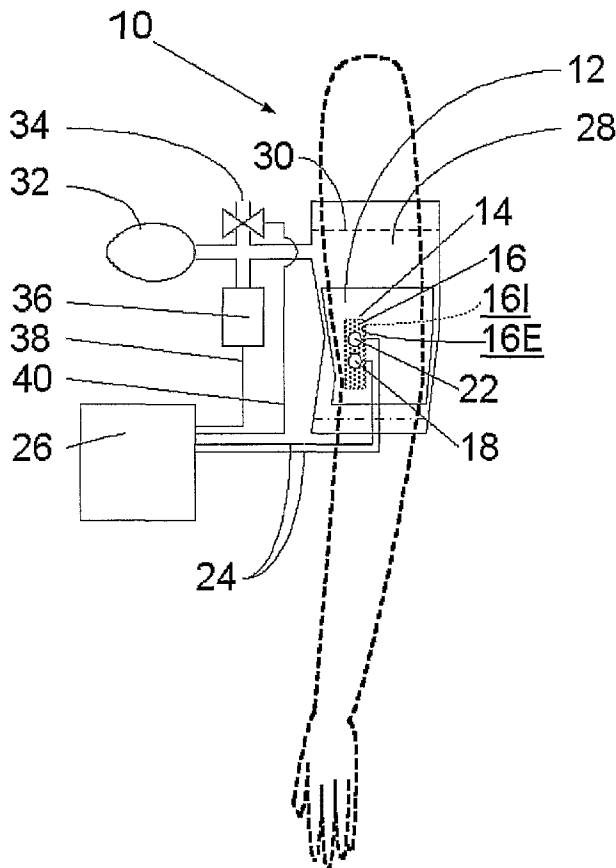
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(54) Title: BLOOD PRESSURE MONITORING SYSTEM AND METHOD



(57) Abstract: A system and method for monitoring blood pressure of a wearer has an inflatable arm cuff that is selectably inflatable to differing air pressures that incorporates a fabric having both a light transmission property and a light reflection property when the fabric is illuminated with light having wavelength(s) in the range from about 400 to about 2200 nanometers. A radiation source and a detector are attached to the fabric in relative positions such that the reception of incident radiation by the detector is directly affected by a change in the amount of light transmitted through the fabric relative to the amount of light reflected by the fabric as the fabric stretches in response to motion in the wearer's body due to changes in the flow of blood through an artery disposed beneath the fabric occurring in consonance with variations in the air pressure within the inflatable cuff.

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BLOOD PRESSURE MONITORING SYSTEM AND METHOD HAVING  
AN EXTENDED OPTICAL RANGE

Cross-Reference to Related Applications Subject matter disclosed herein is disclosed in the following co-pending applications:

System for Monitoring Motion of a Member, **US Application No. 60/502,760**; (LP-5345USPRV), filed September 11, 2003 in the name of Chia Kuo and George W. Coulston.

Blood Pressure Monitoring System and Method, **US Application No. 60/502,751**; (LP-5347USPRV), filed September 11, 2003 in the names of George W. Coulston and Thomas A. Micka.

Reflective System for Monitoring Motion of a Member, **US Application No. 60/502,750**; (LP-5346US PRV), filed September 11, 2003 in the name of George W. Coulston;

Blood Pressure Monitoring System and Method Having Extended Optical Range, **US Application No. 60/526,187**; (LP-5622USPRV), filed December 2, 2003 in the names of George W. Coulston and Thomas A. Micka.

Extended Optical Range Reflective System for Monitoring Motion of a Member, **US Application No. 60/526,429**; (LP-5621USPRV), filed December 2, 2003 in the name of George W. Coulston.

Extended Optical Range System for Monitoring Motion of a Member, **US Application No. 60/526,188**; (LP-5620USPRV), filed December 2, 2003 in the name of Chia Kuo and George W. Coulston.

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to a system and a method for monitoring blood pressure using a fabric having predetermined optical properties that respond to the motion(s) generated by geometric changes in a body due to the conduction of blood through an artery located beneath the fabric.

Description of the Prior Art

The "pulse" of the heart is associated with pressure pulses known to exist in the arteries carrying blood throughout the body. The periodic pumping of the heart produces these pressure pulses, which in turn flex the artery walls in rhythm with the pumping of the heart. The maximum, or peak, pressure exerted against the arterial wall occurs during the

systole phase of the beat and is termed "systolic pressure". The lowest, or baseline, pressure (known as the "diastolic pressure") occurs during the diastole phase of the beat.

As the heart beats the pressure in the arteries fluctuates (higher during the systole phase and lower during the diastole phase of each beat), and is best described by the values for the systolic and diastolic pressures. Typical practice is to express blood pressure as a ratio of the maximum and minimum values.

The generally known method to determine these two blood pressure extremes is the auscultatory method. In this method a pressure cuff is applied to a person's upper arm. This cuff includes a bladder capable of holding air at a predetermined known pressure. The cuff bladder is inflated to a pressure above the highest expected pressure to be measured, *i.e.*, above the systolic pressure. When inflated at this highest pressure, the cuff prevents the flow of blood in the brachial artery of the arm underlying the pressure cuff. The bladder is equipped with a valve, which allows the pressure to be reduced in a controlled way.

As air is released from the bladder, blood flow in the brachial artery is re-established. The inflow of blood through the artery is accompanied by pulsing sounds known as the Korotkoff sounds. These sounds are detected using a stethoscope at a point on the brachial artery just below the pressure cuff. The falling pressure in the cuff bladder is observed while air is released.

The Korotkoff sounds are divided in five phases based on loudness and certain qualitative features. The five phases of the Korotkoff sounds are also identified with certain pressure regimes, as normal arterial blood flow is being re-established. The first phase of the Korotkoff sounds (Phase 1) is heard at about 120 millimeters of mercury (mm Hg) characterized by a sharp "thud"; this is the systolic (maximum) blood pressure. Phase 2 is identified with a pressure of about 110 mm Hg and is heard as a swishing or blowing sound. Phase 3 is identified with a pressure of about 100 mm Hg and is described as a thud that is softer than that of Phase 1. At a pressure of about 90 mm Hg the first diastolic pressure is detected, called the Phase 4 Korotkoff sound, and heard as a softer blowing sound which disappears. Phase 5 is identified with about 80 mm Hg, and is called the second diastolic pressure. This last phase is silent, meaning that a laminar blood flow has been again established. Phase 5 may be absent in some human subjects. For this reason, the first diastolic pressure of Phase 4 is recorded as the lowest pressure in the artery.

An automated auscultatory apparatus relies on detecting sound levels and complex processing of these sounds into electronic signals, which are correlated with the phases of the Korotkoff sounds. Representative of an automated arrangement that uses an

auscultatory method is the measurement system disclosed in U.S. Patent 6,511,435 (Bluth et al.)

The re-establishment of blood flow in an occluded artery is also accompanied by a relatively significant flexure of the arterial wall. The flexure diminishes as the artery widens with the decrease in cuff pressure. In an alternative form of blood pressure measuring apparatus, known as an oscillatory measurement system, the mechanical vibrations accompanying arterial wall flexure are transformed into sound as they enter the inflated bladder of the cuff. This sound is detectable using a microphone located in the bladder. U.S. Patent 6,458,085 (Vu et al.) discloses an oscillatory blood pressure measurement arrangement. An oscillatory blood pressure measurement arrangement is also disclosed in the above-mentioned U.S. Patent 6,511,435 (Bluth et al.).

One drawback of oscillatory measuring apparatus is the reliance upon a cuff bladder modified to contain a microphone and associated connections to an external signal processor. Using a microphone to detect changes in sound pressure level and recognizing a pattern from the waveform so generated is difficult.

#### SUMMARY OF THE INVENTION

The present invention is directed to a system and method for monitoring blood pressure by detecting motion due to geometric changes in the wearer's body.

The present invention is usable with an inflatable arm cuff that is selectively inflatable to differing air pressures and incorporates a fabric which has both a light transmission property and a light reflection property when the fabric is illuminated with light having wavelength(s) in the range of from about 400 nanometers to about 2200 nanometers, and particularly in the ranges from about 400 to about 800 nanometers and from about 700 to about 2200 nanometers. The amount of light transmitted through the fabric relative to the amount of light reflected by the fabric is able to change when the fabric stretches in response to motion in the wearer's body due to changes in the flow of blood through an artery disposed beneath the fabric.

A radiation source that emits radiation with wavelength(s) in the range from about 400 nanometers to about 2200 nanometers, and particularly in the ranges from about 400 to about 800 nanometers and from about 700 to about 2200 nanometers, and a radiation detector are attached to the fabric in relative positions such that the reception of incident radiation by the detector is directly affected by a change in the amount of light transmitted through the fabric relative to the amount of light reflected by the fabric as the fabric

stretches in response to motion in the body of a wearer due to changes in the flow of blood through an artery disposed beneath the patch occurring in consonance with variations in the air pressure within the inflatable cuff. A pressure recorder responsive to the signal output from the detector records the pressure of the cuff when the output of the detector is at a minimum value and the pressure in the cuff following the minimum when the signal from the detector again lies within a predetermined range of a baseline signal value. In one embodiment, the fabric forms a patch that is disposed on or over the inflatable arm cuff.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description, taken in connection with the accompanying drawings, which form a part of this application, and in which:

Figure 1 is a schematic diagram of a system useful for the monitoring blood pressure of a subject by sensing geometric changes in the body of the subject due to the motion of blood passing through blood vessels underlying a patch of monitoring fabric;

Figures 2A and 2B are diagrammatic views illustrating possible light transmission and reflection response of the fabric used in the monitoring system of the present invention during normal systole and diastole phases of heart action;

Figures 2C and 2D are respective diagrammatic views illustrating possible light transmission and reflection response of the fabric when a blood vessel underlying a patch formed of such fabric is totally occluded and when blood flow is re-established;

Figure 2E is a graphical representation of the change in the amount of light transmitted through the fabric relative to the amount of light reflected by the fabric as the fabric stretches and recovers during normal systole and diastole phases of heart action (Figures 2A and 2B), and when a blood vessel underlying the fabric is totally occluded and when blood flow is thereafter re-established (Figures 2C and 2D);

Figure 2F is a graphical representation of a signal, periodic in time, representing the changes in the amount of light transmitted through the monitoring fabric relative to the amount of light reflected by the monitoring fabric as represented in Figure 2E; and

Figure 3 is a diagram illustrating the temporal relationship between pressure measured in an inflatable cuff disposed over an artery of a wearer and the voltage appearing of the detector when the method and system of the present invention is used to monitor blood pressure of the wearer.

DETAILED DESCRIPTION OF THE INVENTION

Throughout the following detailed description similar reference characters refer to similar elements in all figures of the drawings.

Figure 1 is a stylized pictorial representation of a system **10** useful with the method of the present invention for directly monitoring blood pressure of a subject by sensing motion due to geometric changes in the body of the subject associated with the flexing of arterial walls produced by blood pressure pulses.

As seen in Figure 1, the system **10** includes a sleeve **12** having any convenient fabric construction (e.g., knitting, weaving) and made from any suitable textile filament apparel denier yarn. The sleeve **12** includes at least a portion, or patch, **14** formed from a monitoring fabric **16**. The monitoring fabric **16** has an inner surface **16I** and exterior or outer surface **16E**. Although the patch **14** is represented as rectangular in shape in Figure 1, it should be understood that the patch **14** may take any convenient or desired shape. If desired, a portion or even the entirety of the sleeve **12** may be made from the monitoring fabric **16**.

The monitoring fabric **16** in accordance with the present invention exhibits both a light transmission property and a light reflection property when the fabric is illuminated with light having a wavelength in the extended range from about 400 to about 2200 nanometers. This range is extended in the sense that it encompasses both near infrared light and visible broad spectrum white light.

As used herein the term "broad spectrum white light" means light having a wavelength in the range from about four hundred (400) nanometers to about eight hundred (800) nanometers.

As used herein the term "near infrared light" means light having a wavelength in the range from about seven hundred (700) nanometers to about twenty two hundred (2200) nanometers. The wavelength of 805 nanometers or the wavelength of 880 nanometers may be used in systems operating in the near infrared spectrum. The wavelength of 805 nanometers is preferred.

In accordance with the present invention, the amount of light transmitted through the fabric **16** relative to the amount of light reflected by the fabric **16** is able to change as the fabric stretches. The fabric stretches in response to geometric changes of the body of the subject due to the flexing of the arteries in response to blood pressure pulses. The term

“light balance” may be used herein to refer to the amount of light transmitted through the fabric **16** relative to the amount of light reflected by the fabric **16**.

Light reflected by the fabric toward an aperture of acceptance defined with respect to an axis extending from the surface of the fabric is useful in producing a signal output from a detector located in the aperture. Alternatively, light transmitted through the fabric is “lost” to a detector placed at the aperture of acceptance.

The monitoring fabric **16** used in the patch **14** can be made from a reflective yarns, stretchable yarns any combination of reflective and stretchable yarn or any like material. In one exemplary construction a first plurality of reflective yarns is combined with a second plurality of stretchable yarns. The yarns can be combined in any conventional manner including woven or non-woven construction.

For woven constructions, yarns can be combined in plain weave, satin weave, twill weave or any other well known constructions. Woven fabrics may also include weft elastic, warp elastic or bielastic woven fabrics for varying fabric elasticity.

For non-woven constructions such as knit constructions, yarns can be combined by circular knit, warp knit or any other suitable knit construction. In circular knits, typical constructions are single jersey (i.e. different structure in front and back, e.g. 1x1 knit) and double jersey (i.e. same structure in front and back, e.g. 2x1 knit). The stitch size and distance determine the openness of the knit fabric. Warp knits may include tricot and raschel constructions where the tightness is determined by the number of needles/inch or the stitch size.

Any suitable apparel denier and any suitable needle combination or warp/weft intensity may be used in making the monitoring fabric. Each reflective yarn may comprise a coating of a specularly reflective material thereon. The coating may also be electrically conductive. Furthermore, the reflective yarn may be elastic. Each stretchable yarn is formed as a combination of an elastic yarn component and a hard yarn component.

In the preferred instance, the reflective yarn is that yarn sold by Laird Sauquoit Technologies, Inc. (300 Palm Street, Scranton, Pennsylvania, 18505) under the trademark X-static® yarn. X-static® yarn is based upon a 70 denier (77 dtex), 34 filament textured nylon available from INVISTA North America S. à r. l., Wilmington, Delaware 19805, as product ID 70-XS-34X2 TEX 5Z electroplated with electrically conductive silver.

Alternatively, another method of forming the monitoring fabric **16** is to screen-print a pattern using an electrically conductive ink after constructing the yarns in any conventional woven or non-woven manner. Suitable electrically conductive inks include, but are not

limited to, those sold by DuPont Microcircuit Materials, Research Triangle Park, NC 27709, as silver ink 5021 or silver ink 5096, and the like.

A screen-printed pattern of conductive inks must also allow the fabric to move. Preferably, the conductive ink does not affect the ability of the fabric to stretch and recover. One way to prevent affecting the stretch and recovery properties of fabric is to screen-print a pattern of conductive ink(s) in the form of a matrix of dots. Such a dot matrix pattern provides full freedom of movement for the yarns in the fabric, while still exhibiting desired light reflection and transmission properties.

The patch 14 of monitoring fabric 16 can alternatively be formed from elastic and electrically conductive composite yarn comprising a core yarn made of, for instance, LYCRA® spandex yarn wrapped with insulated silver-copper metal wire obtained from ELEKTRO-FEINDRAHT AG, Escholzmatt, Switzerland, using a standard spandex covering process. The core yarn may further be covered with any nylon hard yarn or polyester hard yarn.

Stretchable yarn can be formed in any conventional manner. For example, the stretchable yarn can be formed as a combination of a covered elastic yarn and a hard yarn.

In one preferred embodiment, the covered elastic yarn can be comprised of a twenty (20) denier (22 dtex) LYCRA® spandex yarn single-covered with a ten (10) denier (11 dtex) seven filament nylon yarn. LYCRA® spandex yarn is available from INVISTA North America S. à r. l., Wilmington, Delaware 19805. Alternatively, the elastic yarn component of the present invention may comprise elastane yarn or polyester bicomponent yarns, such as those known as ELASTERELL-P™ from INVISTA North America S. à r. l., Wilmington, Delaware 19805. The terms spandex and elastane are used interchangeably in the art. An example of a branded spandex yarn suitable for use with the present invention is LYCRA®.

Synthetic bicomponent multifilament textile yarns may also be used to form the elastic yarn component. One preferred synthetic bicomponent filament component polymer can be thermoplastic. The synthetic bicomponent filaments can be melt spun or formed in any other manner common in the art of filament formation. In the most preferred embodiment, the component polymers can be polyamides or polyesters.

A preferred class of polyamide bicomponent multifilament textile yarns comprises those nylon bicomponent yarns which are self-crimping, also called "self-texturing". These bicomponent yarns comprise a component of nylon 66 polymer or copolyamide having a first relative viscosity and a component of nylon 66 polymer or copolyamide having a second relative viscosity, wherein both components of polymer or copolyamide are in side-

by-side relationship as viewed in the cross section of the individual filament. Self-crimping nylon yarn such as that yarn sold by INVISTA North America S. à r. l., Wilmington, Delaware 19805 under the trademark TACTEL® T-800™ is an especially useful bicomponent elastic yarn.

Some examples of polyester component polymers include polyethylene terephthalate (PET), polytrimethylene terephthalate (PTT) and polytetrabutylene terephthalate. In one preferred embodiment, polyester bicomponent filaments comprise a component of PET polymer and a component of PTT polymer in a side-by-side relationship as viewed in the cross section of the individual filament. One exemplary yarn having this structure is sold by INVISTA North America S. à r. l., Wilmington, Delaware 19805 under the trademark T-400™ *Next Generation Fiber*.

The hard component could be made from any inelastic synthetic polymer fiber(s) or from natural textile fibers, such as wool, cotton, ramie, linen, rayon, silk, and the like. The synthetic polymer fibers may be continuous filament or staple yarns selected from the multifilament flat yarns, partially oriented yarns, textured yarns, bicomponent yarns selected from nylon, polyester or filament yarn blends. The hard component is preferably 260 denier (286 dtex) 68 filament nylon yarn.

Nylon yarns may comprise synthetic polyamide component polymers, such as nylon 6, nylon 66, nylon 46, nylon 7, nylon 9, nylon 10, nylon 11, nylon 610, nylon 612, nylon 12 and mixtures and copolyamides thereof. In the case of copolyamides, especially preferred are those including nylon 66 with up to 40 mole percent of a polyadipamide wherein the aliphatic diamine component is selected from the group of diamines available from E.I. Du Pont de Nemours and Company of Wilmington, Delaware under the respective trademarks DYTEK A® and DYTEK EP®.

Further in accordance with the present invention, the hard yarn portion may comprise polyesters such as, for example, polyethylene terephthalate (PET), polytrimethylene terephthalate (PTT), polybutylene terephthalate and copolyesters thereof.

The monitoring fabric **16** may also be formed from composite yarns in which the reflective and stretchable components are combined in the same yarn. Such a composite yarn would include a covering yarn having a spectrally reflective outer surface that is wrapped about an elastic yarn component in one or more layers.

The remainder of the structure of the sleeve **12**, if not also formed of the monitoring fabric, may exhibit any convenient textile construction (e.g. knitting or weaving as described above), and may be made from any suitable textile filament apparel denier yarn.

In one embodiment, the monitoring fabric **16** used in the patch **14** is attached to the sleeve **12**. The patch **14** could be sewn, glued, taped, buttoned, interwoven or attached to the sleeve by any conventional means. In another embodiment, the sleeve **12** is completely constructed of the monitoring fabric **16**.

The present invention is directed to monitoring the light balance of a monitoring fabric **16** as it stretches and recovers. For this purpose, the system **10** includes a suitable source **18** of radiation operable in the wavelength range from about 400 nanometers to about 2200 nanometers, and particularly in the ranges from about 400 to about 800 nanometers and from about 700 to about 2200 nanometers. An associated detector **22** is responsive to incident radiation in the given wavelength range and subranges for producing signals in response thereto.

In the case of operation with near infrared light, the radiation source **18** can be a compound semiconductor-based (e.g., gallium arsenide or gallium aluminum arsenide) photo-emitting diode operating in the infrared range (at a wavelength of, for example, 805 nanometers or 880 nanometers). The detector **22** can be any device that can detect radiation, for instance, a photodiode coupled to appropriately configured output amplification stages. Any well known semiconductors can be used for forming the photodiode including silicon or germanium. A commercially available radiation source and detector package suitable for use in the system of the present invention is that available from Fourier Systems Ltd. (9635 Huntcliff Trace, Atlanta, Georgia, 30350) as model DT155 (0-5 volt output).

For broad spectrum white light (400 to 800 nanometers) operation, the source **18** can be a compound semiconductor-based "white LED" (e.g., a light emitting diode employing an indium gallium nitride based device with suitable phosphors to provide broad spectrum white light emission). An LED source of broad spectrum white light is available from Lumitex® Inc., 8443 Dow Circle, Strongsville, Ohio 44136, USA; Part No. 003387. Such an LED provides radiation in the wavelength range of 430 to 700 nanometers. The detector **22** is preferably a silicon phototransistor coupled to appropriately configured output amplification stages.

The radiation source **18** and the detector **22** are attached to monitoring fabric **16** in predetermined relative positions. The positions were determined such that the reception of incident radiation by the detector **22** is directly affected by a change in the amount of light transmitted through the monitoring fabric **16** relative to the amount of light reflected by the monitoring fabric **16** when the fabric stretches and recovers. In the preferred case, the

radiation source **18** and detector **22** are embedded, or fixed firmly, into the textile structure of the monitoring fabric **16**. The radiation source **18** and detector **22** can be fixed using any well known attachment method, including, but not limited to, clamping, gluing, sewing, taping, or hook and loop fasteners (Velcro). Optionally, it may be desirable in some operational configurations of the invention to dispose both the source and the detector remotely from and not in direct contact with the fabric **16**. In such a remote arrangement, the radiation source **18** and detector **22** could be located in any arrangement that permits the detector **22** to detect changes in the transmission and reflection of radiation during stretching and recovery.

The source **18** may be arranged in such a way as to maintain its relative position to the detector **22**. For instance, the source **18** and the detector **22** may be rigidly connected together on one side of the fabric **16** to maintain a spatial relationship. Alternatively, the position of the source **18** relative to the detector **22** can be maintained on opposite sides of the monitoring fabric **16** for monitoring light transmission. In such an embodiment, the radiation source is connected to the radiation detector using a "clothes-pin" or alligator style clamp. Other well known means of maintaining spatial relationship between the source and the detector are contemplated.

The apparatus **10** represented in Figure 1 further includes an inflatable cuff **28** substantially similar to a standard cuff known in the blood pressure measurement art. The cuff **28** is typically a woven nylon sleeve with a seamless inner bladder **30** of latex rubber. The inner bladder **30** communicates with an external air pump **32**, valve **34** and a pressure measurement device **36** for measuring the internal pressure of the bladder **30**. The pressure measurement device **36** communicates electrically with the processor **26** over an electrical connection **38**. The valve **34** may be configured for automatic operation by the signal processor **26** over a control line **40**.

The pump **32** may take the form of any conventional pump including a manually operated device, an automated piston or diaphragm air pump. The pressure measurement device **36** may be implemented using a manometer of known design. Such a manometer is constructed using known barometric measurement techniques that include a column of mercury, a Bourdon gauge movement, and a measurement device having a high reproducibility of measurement in the expected range of operation, for example, from about ten (10) millimeters of mercury to about five hundred (500) millimeters of mercury (mm Hg). A suitable pressure measurement device **36** could be a direct capacitance measurement device provided with a fully electronic output suitable for use with traditional digital signal

processors. A pressure transducer operable to measure the pressure within the cuff at predetermined sampling time intervals is also suitable for use as the pressure measurement device. The miniature silicon pressure sensor package available from Advanced Custom Sensors, Inc. Irvine, California, 92618 as Model 7277 (zero to five volt output; zero to seven pounds per square inch gage rating) is such a device, though any similar means for measuring pressure is contemplated.

The principles of operation by which the motion of a subject's body due to geometric changes generated by blood pressure pulses may be monitored in accordance with the system of the present invention may be more clearly understood with reference to Figures 2A through 2F. In the discussion that follows both the source **18** and the detector **22** are mounted adjacent to the same surface **16E** of the monitoring fabric **16** so as to operate in a "reflection mode". Alternatively, it is contemplated within the scope of the invention to operate in a "transmission mode". In the alternative transmission mode of operation, the source **18** and the detector **22** are mounted to opposite sides of the monitoring fabric **16**.

The reaction of the fabric **16** during normal diastole and systole phases of heart action are depicted in Figures 2A and 2B.

As represented in Figure 2A in a normal diastole phase the yarns **16Y** forming the monitoring fabric **16** lie within a relatively close distance of each other to define a pattern of relatively narrow gaps **16G**. A generally circular spot indicated by the reference character **17** represents the area of the monitoring fabric **16** illuminated by the source **18**. Of the photons emitted from the radiation source **18** toward the surface **16E** of the fabric **16** some photons are absorbed (e.g., represented by a ray **18C**) by the yarns **16Y** of the fabric while other photons (e.g., the rays **18A** and **18B**) pass through gaps **16G** therein. These photons are lost to the detector **22**. The major portion of the light (e.g., represented by the rays **18D** through **18G**) is reflected from the surface **16E** of the monitoring fabric **16** toward the detector **22**. This major portion of the light is detected by detector **22**, which in turn produces a corresponding output signal.

During a normal systole phase of a heart beat, the size of the gaps **16G** formed in the monitoring fabric **16** increases in response to motion induced by the flexure of the underlying blood vessels. This increase in size of the gaps **16G** (Figure 2B) increases the likelihood that a photon will pass through the fabric **16**, and decreases the likelihood that a photon will reflect toward the detector **22**. The total number of photons lost to the detector **22** by transmission through or absorption by the fabric (e.g., represented by the rays **18A**, **18B** and **18C**) increases. The signal output from the detector **22** concomitantly decreases.

Although the number of photons lost to the detector **22** by absorption (e.g., represented by the ray **18C**) does not necessarily change, the likelihood that a photon will strike a yarn **16F** and be reflected or absorbed decreases since the spot size **17** remains constant in the area while the gap **16G** size increases.

As the systolic phase of the pulse beat gives way to the diastolic phase, the fabric **16** undergoes the elastic recovery. The gaps **16G** return to their original size (Figure 2A). The major portion of the light is again reflected toward the detector **22**, increasing the output signal therefrom.

The left hand portion of Figure 2E illustrates the waveform of the signal generated at the detector **22** as the fabric undergoes its stretch cycle from the initial diastolic phase (represented by the reference character "I") through a systolic phase (represented by the reference character "II") and back to the diastolic phase ("I"). This portion of Figure 2E graphically illustrates that during the course of a stretch cycle the light balance (reference character "LB" in Figure 2E) of the fabric changes.

As shown in Figure 2E, at diastolic phase ("I") of Figure 2A, the reflected light represented by the bottom portion below the "LB" is greater than the transmitted light represented by the upper portion above the "LB". In contrast, Figure 2E shows that at systolic phase ("II") of Figure 2B, the reflected light represented by the bottom portion below the "LB" is less than the transmitted light represented by the upper portion above the "LB".

Comparison between the diastolic and systolic phases indicates that the amount of light transmitted through the monitoring fabric **16** relative to the amount of light reflected by the monitoring fabric **16** changes in a periodic fashion over time as the fabric stretches. Light lost to the detector **22** by absorption may be considered as contributing to the "transmitted light" section of the graph of Figure 2E. This periodic variation in light balance is represented in the left-hand portion of Figure 2F as a time-varying signal synchronized with the elongation and recovery stages of fabric stretch (e.g., diastolic phase represented by character "I" and systolic phase represented by character "II").

The situation that arises when a cuff is fully pressurized is depicted in Figure 2C. In this case the flow of blood is completely interrupted and no flexure of the underlying artery occurs. The fabric **16** reverts to a fully unstretched condition with the gap spacing **16G** between yarns **16Y** being at its minimum. Substantially all of the photons falling on the illuminated spot **17** are reflected toward the detector **22** resulting in the light balance depicted at reference character "III" in the right hand portion of Figure 2E. At reference "III",

the reflected light represented by the bottom portion below the "LB" is significantly greater than the transmitted light represented by the upper portion above the "LB".

Figure 2D depicts the situation when blood flow through the previously occluded artery is re-established. The sudden rush of blood through the artery elongates the fabric **16** and extends the gaps **16G** to a wider extent than in the systolic phase (shown in Figure 2B). The amount of light transmitted through the fabric **16** increases commensurately while the amount of light reflected significantly decreases. This result is illustrated in the change in light balance depicted at reference character "IV" in the right hand portion of Figure 2E. In Figure 2E, at reference character "IV", the reflected light represented by the bottom portion below the "LB" is less than the transmitted light represented by the upper portion above the "LB". The right hand portion of Figure 2F illustrates the rapid decrease in signal output from the detector **22** caused by the sudden rush of blood through the previously occluded artery (e.g., the change in detector output voltage from phase "III" to phase "IV" shown in Figure 2F)

As the rush of blood diminishes the light balance and the signal output from the detector **22** would revert toward the ranges exhibited during normal diastolic and systolic operation.

#### OPERATION

In an exemplary mode of operation the apparatus of the present invention would be applied to the arm of a person generally in the position indicated by the dotted outline in Figure 1, with the fabric patch **14** of sleeve **12** over the brachial artery. The inflatable cuff **28** is applied over the sleeve **12**.

Figure 3 illustrates the temporal relationship between pressure measured in the cuff **28** and a voltage resulting from the radiation detected by the detector **22** in reflection mode. In a reflection mode of operation, the source **18** and the detector **22** are arranged adjacent to side **16E** of the fabric **16**. As discussed in connection with Figures 2A through 2F, any fabric **16** elongation is accompanied by a decreasing signal (voltage) from the detector **22**, corresponding to increased light transmission through the fabric **16**.

Considering again Figure 3, the pressure in the cuff **28** is at atmospheric pressure  $P_0$  during the time interval between  $t_0$  and  $t_1$ . Also, during this same time interval the signal at detector **22** is a mean value  $V_N$  varying between the limits of  $(V_N + \Delta)$  and  $(V_N - \Delta)$

This mean voltage  $V_N$  results from the subtle flexing of the arterial walls and subsequent subtle movement of tissue underlying the fabric **16**. This subtle movement is due to the arterial pressure fluctuations from the systolic to the diastolic pressure extremes.

Because blood flow is laminar and silent during this interval, the net average force on the arterial walls is constant. During the arbitrary time interval  $t_0$  to  $t_1$ , the voltage reading from detector **22** is sampled; and a voltage  $V_N (+/-\Delta)$  is stored in memory of the processor **26**.

Next, at time  $t_1$ , under control of the processor **26**, the valve **34** is closed and the pump **32** activated. Accordingly, during the time interval from  $t_1$  to  $t_2$ , the pressure in the cuff **28** rises to a pressure  $P_H$ , a pressure value chosen to be above the highest expected systolic pressure (e.g. 300 to 330 mm Hg). This pressure value is also stored in memory of the processor **26**. During this time interval, the brachial arterial blood flow becomes totally interrupted. Effectively, there is no arterial wall flexing or underlying body tissue movement because blood flow is occluded. As explained in connection with Figure 2C, the voltage output from the detector **22** rises to  $V_H$ .

During the time interval from  $t_1$  to  $t_2$ , the cuff pressure and detector voltage are sampled and stored at a fixed sampling frequency (chosen in a frequency range from ten (10) Hertz to ten thousand (10,000) Hertz). The voltage reading from detector **22** when the pressure in cuff **28** reaches its maximum value  $P_H$  (at time  $t_2$  in Figure 3) is stored in processor **26**.

At  $t_2$  the pressure in the cuff **28** is released by opening valve **34** under control of the processor **26**. During the time interval  $t_2$  to  $t_3$  the voltage output from detector **22** and the pressure in the cuff **28** are sampled and stored at the sampling frequency. During the interval  $t_2$  to  $t_3$  the rate of pressure change within the cuff **28** is about two (2) mm Hg to about six (6) mm Hg per second.

As the cuff pressure is reduced, at some time within the interval  $t_2$  to  $t_3$ , the pressure in the cuff **28** is equal to the systolic (highest) arterial blood pressure and the artery snaps open with a sudden flow of blood. In turn, as explained in connection with Figure 2D, the voltage at the detector **22** experiences a maximum in rate of change and falls to a maximum deviation from  $V_N$ , to a voltage value  $V_L$ . As shown in Figure 3, this voltage  $V_L$ , detected at  $t_3$ , corresponds to the sudden rush of arterial blood filling the formerly occluded artery with a sharp flexing of the artery walls. This sharp flexing of the walls in turn stimulates movement of the tissue overlying the artery and underlying the fabric **16**. This movement corresponds to a maximum amplitude for the motion of the tissue underlying the fabric **16**. At  $t_3$ , corresponding to voltage  $V_L$ , this maximum amplitude in tissue movement forces maximum fabric **16** flexing, sudden elongation, signaling that a peak or systolic pressure  $P_S$  is present in the brachial artery.

During the interval of time  $t_3$  to  $t_4$  the pressure in the cuff **28** is further decreasing. The voltage and pressure values are sampled at the predetermined frequency. The voltage output at the detector **22** continues to rise during this time interval  $t_3$  to  $t_4$ .

Following the occurrence of the minimum voltage  $V_L$ , the output voltage of the detector again returns to within the predetermined range about the baseline value (within the limits  $(V_N + \Delta)$  and  $(V_N - \Delta)$ ) and the pressure in the cuff **20** passes through a point of equivalence with the diastolic (lowest) pressure in the brachial artery, uniquely defining  $t_4$ . Any further drop in pressure in the cuff **28**, to atmospheric pressure, produces no further rise in voltage at detector **22** during the time interval  $t_4$  to  $t_t$ .

The system and method of the present invention may alternatively be operated in a transmission mode where the source **18** is disposed on side **16E** of the fabric **16** while the detector **22** is disposed on the opposite side **16I**. The dot-dashed outline of detector **22**, shown in Figures 2A through 2D represents the location of detector **22** in transmission mode. The light balance between reflection and transmission will be the same as the situation discussed in connection with the reflection mode. However, the detector output voltage shown in Figure 2F is reversed since more fabric stretch results in higher light transmission providing a commensurately higher detector voltage. The detector voltage waveform shown in Figure 3 is therefore reversed or inverted as well. In contrast to the reflection mode shown in Figure 3, the transmission mode measures a decrease in voltage between the interval of time  $t_1$  to  $t_2$  and an increase between the interval of time  $t_2$  to  $t_3$ . Finally, in contrast to Figure 3 the detector voltage decreases between  $t_3$  and  $t_4$  to return to voltage  $V_N$ .

The measurement of pressures  $P_S$  and  $P_D$  is, in principle, determined by means of signal processing techniques known in the art. For example, one commercially available pressure transducer **36**, Model 7277 from Advanced Custom Sensors, Inc. Irvine, California, 92618, is a miniature silicon pressure sensor package, with 0 to 5 volt output, and 0 to 7 pound per square inch gage rating. This pressure transducer **36** will communicate directly with signal processor **26** such as a Z8<sup>®</sup> microcontroller, Model Z86C08 from ZILOG, Inc., Campbell, California, 95008-6600 with electronically programmable memory and associated circuitry.

Those skilled in the art, having the benefit of the teachings of the present invention as hereinabove set forth, may effect modifications thereto. Such modifications are to be construed as lying within the scope of the present invention, as defined by the appended claims.

## WHAT IS CLAIMED IS:

1. A system for monitoring blood pressure, comprising:  
an inflatable arm cuff that is selectably inflatable to differing air pressures;  
a fabric that has both a light transmission property and a light reflection property that change when the fabric stretches;  
a radiation source; and  
a radiation detector.
2. The system of claim 1, wherein:  
the radiation source emits radiation with a wavelength in the range of from about 400 to about 2200 nanometers; and  
the detector responds to incident radiation with a wavelength in the range of from about 400 to about 2200 nanometers.
3. The system of claim 1, wherein the fabric is attached to a surface of the cuff.
4. The system of claim 1, wherein the fabric is integral with the cuff.
5. The system of claim 1, wherein the fabric comprises reflective yarns and stretchable yarns.
6. The system of claim 1, wherein  
the fabric has a first side and a second side; and wherein  
the source and the detector are mounted on a same side of the fabric.
7. The system of claim 1 wherein:  
the fabric has a first side and a second side; and wherein  
the source and the detector are mounted on opposing sides of the fabric.
8. A method for monitoring blood pressure, comprising the steps of:  
inflating an inflatable cuff disposed over a portion of a wearer's body over which the cuff is disposed;

disposing within or over the inflatable cuff a fabric which has both a light transmission property and a light reflection property and in which the amount of light transmitted through the fabric relative to the light reflected by the fabric changes when the fabric stretches; using a radiation source, illuminating the fabric with radiation having wavelength(s) in the range of from about 400 to about 2200 nanometers;

detecting the amount of light reflected or transmitted by the fabric with a radiation detector responsive to incident radiation having wavelength(s) in the range of from about 400 to about 2200 nanometers; and

recording the pressure in the cuff in response to the signal output from the detector.

9. The method of claim 8, wherein recording the pressure comprises measuring the pressure in the cuff when the output of the detector is at a minimum value, and measuring the pressure in the cuff when the signal from the detector lies within a predetermined range of a baseline signal value.

10. The method of claim 8, wherein the source and the detector are attached to the fabric in relative positions such that the reception of incident radiation by the detector is directly affected by a change in the amount of light transmitted through the fabric relative to the amount of light reflected by the fabric as the fabric stretches in response to motion in the wearer's body due to changes in the flow of blood through an artery disposed beneath the fabric occurring in consonance with variations in the air pressure within the inflatable cuff.

11. A sleeve, comprising:  
fabric which has a light transmission property and a light reflection property that undergo measurable change when the fabric stretches;  
a radiation source; and  
a radiation detector.

12. The sleeve of claim 11, wherein the fabric comprises reflective yarns and stretchable yarns.

13. The sleeve of claim 11, wherein the fabric is attached to a surface of the sleeve.

14. The sleeve of claim 11, wherein each reflective yarn has a coating of a specularly reflective material thereon.

15. The sleeve of claim 11, wherein the fabric has a first side and a second side; and wherein the source and the detector are mounted on opposing sides of the fabric.

16. The sleeve of claim 11, wherein the fabric has a first side and a second side; and wherein the source and the detector are mounted on a same side of the fabric.

17. A system for monitoring blood pressure that includes an inflatable arm cuff which is sized for receipt over a portion of a wearer's body and wherein the cuff is selectively inflatable to differing air pressures to modify the flow of blood through an artery located in the portion of the wearer's body over which the cuff is disposed, comprising:

- a patch disposed on or over the cuff, wherein at least a portion of the patch is formed from a fabric that has both a light transmission property and a light reflection property when the fabric is illuminated with light having wavelength(s) in the range of from about 400 to about 2200 nanometers, and wherein the amount of light transmitted through the fabric relative to the amount of light reflected by the fabric changes when the fabric stretches in response to changes in blood flow through an artery disposed beneath the patch;
- a source of radiation with wavelength(s) in the range of from about 400 to about 2200 nanometers;
- a detector that produces a signal in response to incident radiation with wavelength(s) in the range of from about 400 to about 2200 nanometers;
- wherein the source and the detector are attached to the fabric in relative positions such that the reception of incident radiation by the detector is directly affected by a change in the amount of light transmitted through the fabric relative to the amount of light reflected by the fabric as the fabric stretches in response to motion in the wearer's body due to changes in the flow of blood through an artery disposed beneath the patch occurring in consonance with variations in the air pressure within the inflatable cuff; and

a pressure recorder responsive to the signal output from the detector for recording the pressure of the cuff when the output of the detector is at a minimum value, and for recording the pressure in the cuff following the minimum value when the signal from the detector again lies within a predetermined range of a baseline signal value.

18. The monitoring system of claim 17, wherein the fabric has a first side and a second side, and wherein the source and the detector are mounted on opposing sides of the fabric.

19. The monitoring system of claim 17, wherein the fabric has a first side and a second side, and wherein the source and the detector are mounted on a same side of the fabric.

20. A method for monitoring blood pressure of a wearer, comprising the steps of:  
inflating an inflatable cuff disposed over a portion of a wearer's body to differing air pressures thereby to modify the flow of blood through an artery located in the portion of the wearer's body over which the cuff is disposed;

disposing on or over the inflatable cuff a patch at least a portion of which is formed from a fabric which has both a light transmission property and a light reflection property when the fabric is illuminated with light having wavelength(s) in the range of from about 400 to about 2200 nanometers, wherein the amount of light transmitted through the fabric relative to the light reflected by the fabric is able to change when the fabric stretches in response to motion in the wearer's body due to changes in the flow of blood through an artery disposed beneath the patch;

using a radiation source, illuminating the patch with radiation having wavelength(s) in the range of from about 400 to about 2200 nanometers;

using a radiation detector responsive to incident radiation with wavelength(s) in the range of about 400 to about 2200 nanometers to detect radiation and produce a signal, wherein the source and the detector are attached to the fabric in relative positions such that the detection of incident radiation by the detector is directly affected by a change in the amount of light transmitted through the fabric relative to the light reflected by the fabric as the fabric stretches in response to motion in the wearer's body due to changes in the flow of blood through an artery disposed beneath the patch occurring in consonance with variations in the air pressure within the inflatable cuff; and

recording the pressure in the cuff in response to the signal output from the detector when the output of the detector is at a minimum value and recording the pressure in the cuff following the minimum when the signal from the detector again lies within a predetermined range of a baseline signal value.

Figure 1.

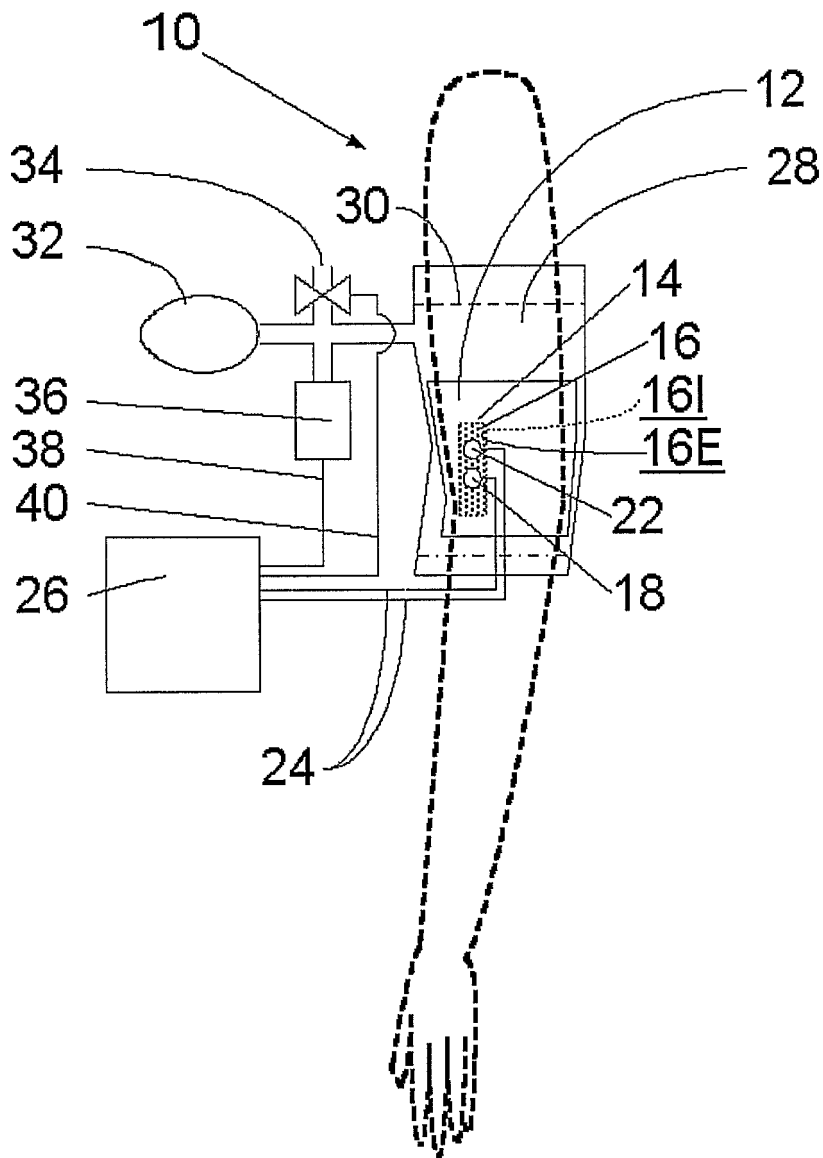


Figure 2A

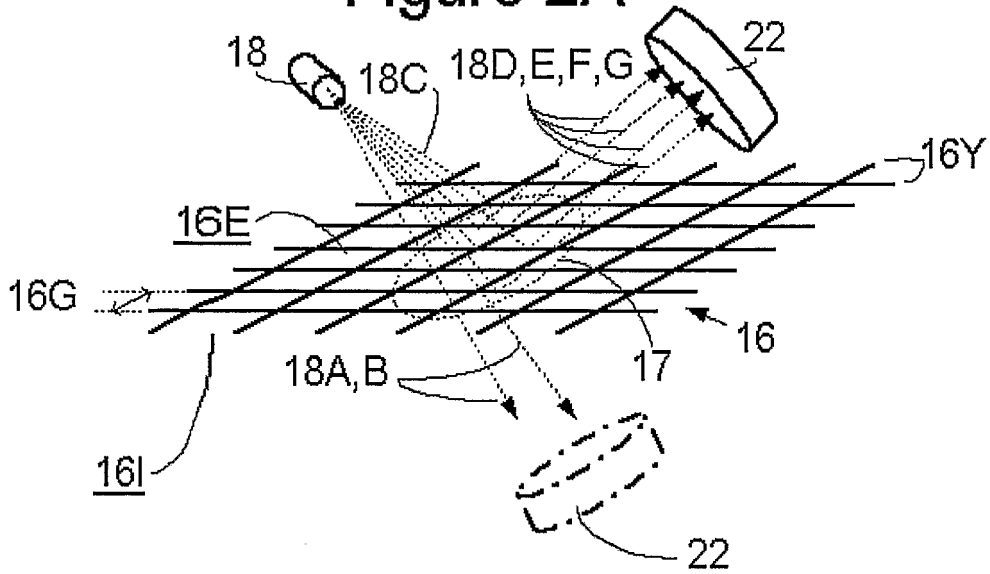


Figure 2B

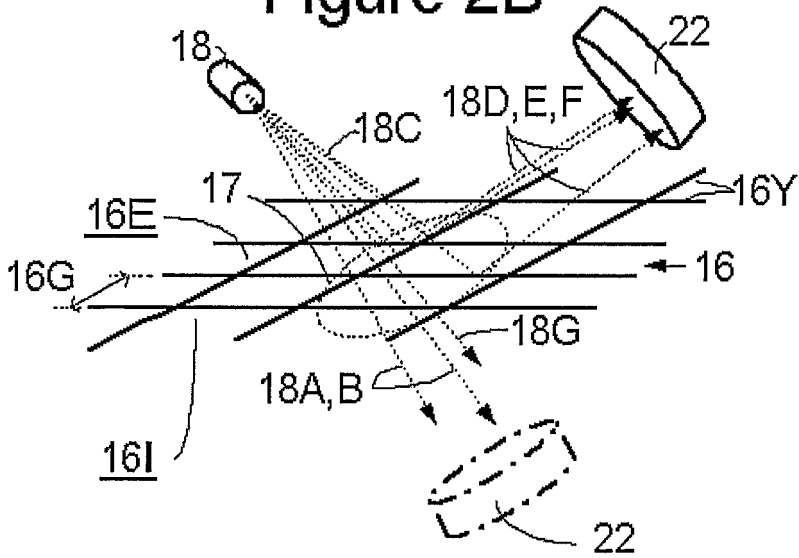


Figure 2C

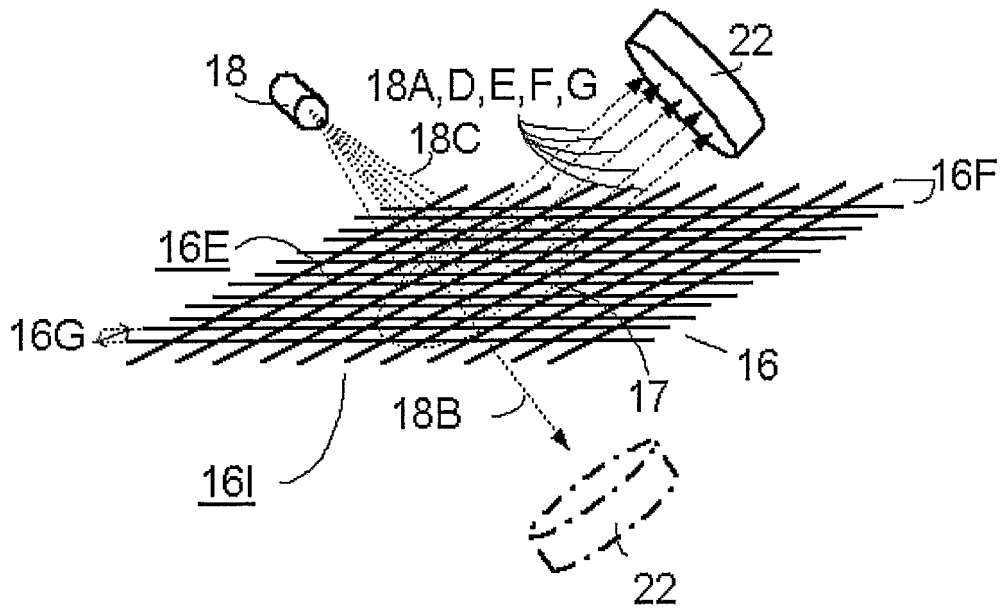
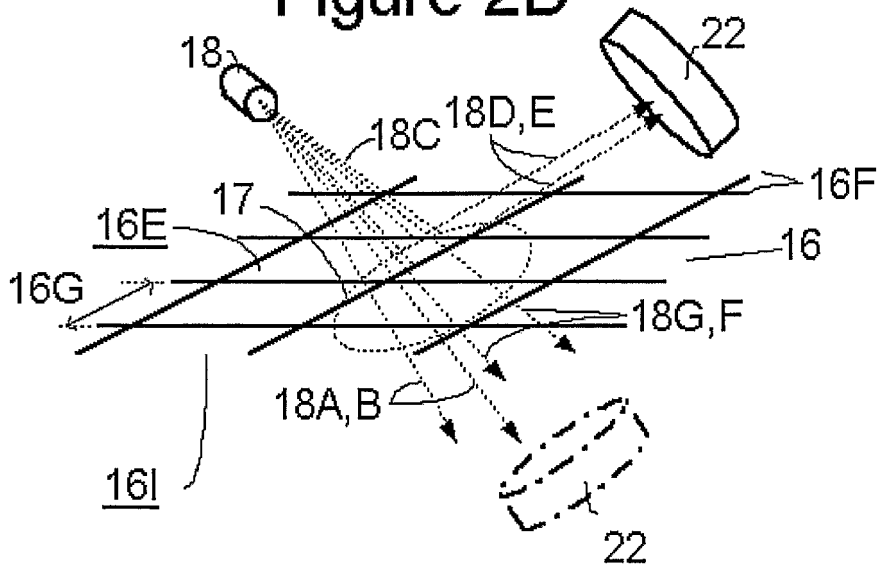
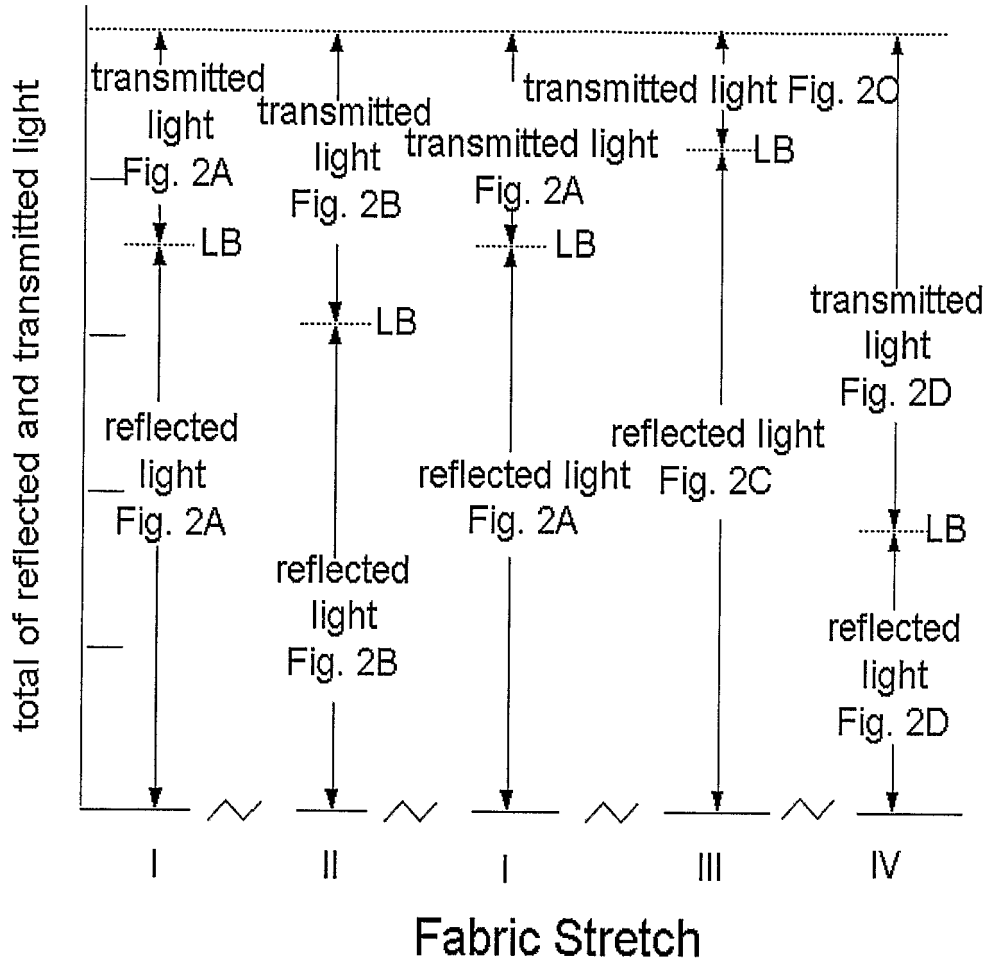


Figure 2D



# Figure 2E.



# Figure 2F

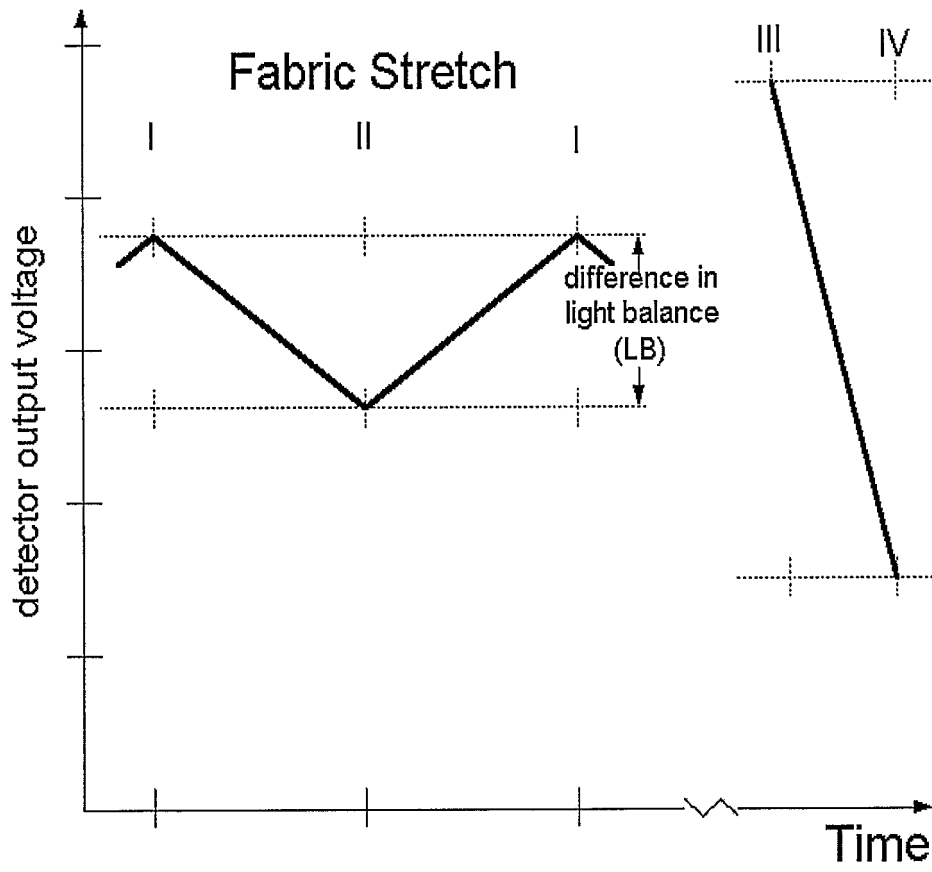
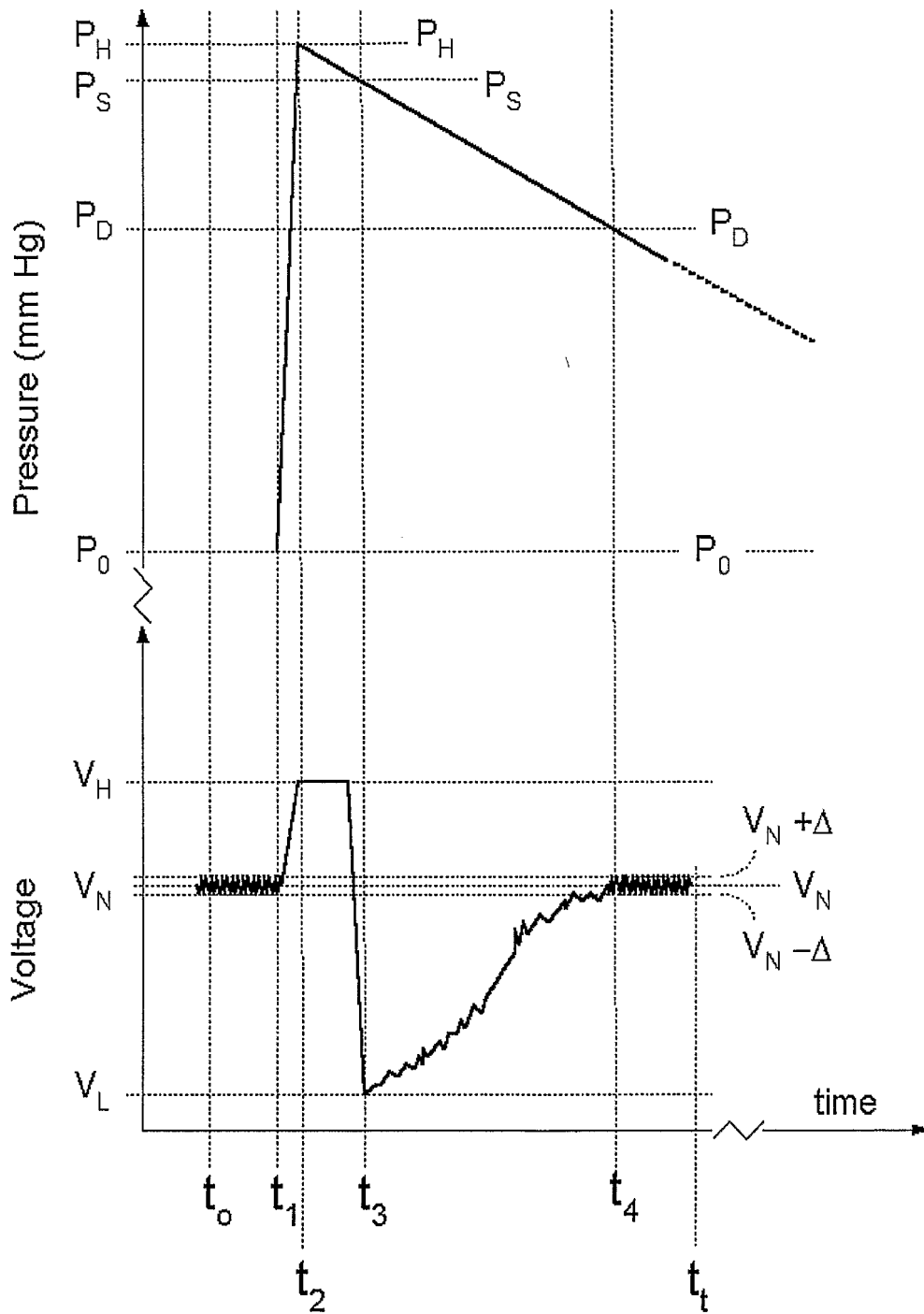


Figure 3.



## INTERNATIONAL SEARCH REPORT

 International Application No  
 PCT/US2004/029791

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> IPC 7 A61B5/00 A61B5/024		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 847 724 A (A & D CO LTD ; TOCHIKUBO OSAMU (JP)) 17 June 1998 (1998-06-17) column 4, line 21 - column 6, line 41; claim 1; figures 1-3	1-4,8, 10,11,13
Y	US 3 517 999 A (WEAVER DAVID P) 30 June 1970 (1970-06-30) the whole document	1-4,8, 10,11,13
A	EP 0 724 860 A (SPACELABS MEDICAL INC) 7 August 1996 (1996-08-07) column 5, line 12 - column 6, line 19; claim 1	1-20
A	US 5 222 020 A (TAKEDA FUMIHIDE) 22 June 1993 (1993-06-22) claim 1	1-20
	----- -/-- -----	
<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
° Special categories of cited documents :		
*A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document but published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed		*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family
Date of the actual completion of the international search  13 December 2004		Date of mailing of the international search report  21/12/2004
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer  Chopinaud, M

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US2004/029791

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 511 435 B1 (BLUTH CHARLES ET AL) 28 January 2003 (2003-01-28) cited in the application the whole document -----	1-20

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No  
PCT/US2004/029791

Patent document cited in search report	A	Publication date	Patent family member(s)	Publication date
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专利名称(译)	血压监测系统和方法		
公开(公告)号	<a href="#">EP1662985A1</a>	公开(公告)日	2006-06-07
申请号	EP2004788709	申请日	2004-09-10
[标]申请(专利权)人(译)	因温斯特技术公司		
申请(专利权)人(译)	英威达科技S.A.R.L.		
当前申请(专利权)人(译)	TEXTRONICS INC.		
[标]发明人	COULSTON GEORGE W MICKA THOMAS A		
发明人	COULSTON, GEORGE, W. MICKA, THOMAS, A.		
IPC分类号	A61B5/00 A61B5/024 A41D13/12 A61B5/02 A61B5/022 A61B5/11 A61B5/113 D04B1/14 G01L1/24		
CPC分类号	A41D13/1281 A61B5/022 A61B5/02233 A61B5/02416 A61B5/02438 A61B5/02444 A61B5/1126 A61B5/1128 A61B5/1135 A61B5/6804 A61B5/6805 D04B1/14 D10B2403/02431 Y10T442/30 Y10T442/3008 Y10T442/3024 Y10T442/3382 Y10T442/3976 Y10T442/40 Y10T442/413		
优先权	60/526188 2003-12-02 US 60/526187 2003-12-02 US 60/526429 2003-12-02 US 60/502751 2003-09-12 US 60/502750 2003-09-12 US 60/502760 2003-09-12 US		
其他公开文献	EP1662985B1		
外部链接	<a href="#">Espacenet</a>		

#### 摘要(译)

一种用于监测穿着者的血压的系统和方法具有可充气的袖带，该袖带可选择地对不同的气压进行充气，当使用具有波长的光照射织物时，所述气囊包括具有透光性和光反射性的织物。 ) 在约400至约2200纳米的范围内。辐射源和检测器在相对位置附着到织物上，使得检测器对入射辐射的接收直接受到透过织物的光量相对于织物反射的光量的变化的影响。由于血液流过布置在织物下方的动脉的变化，织物随着可充气袖带内的气压变化而发生，以响应穿着者身体的运动而伸展。