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(54) **Apparatus for noninvasively measuring a concentration of a blood component**

Gerät zur nichtinvasiven Konzentrationsmessung einer Blutkomponente

Appareil pour la mesure non-invasive de la concentration d'un composant sanguin

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**Description**

5 [0001] The present invention relates to a noninvasive measurement of a concentration of a blood component. More particularly, the present invention relates to a method and apparatus for noninvasively measuring a concentration of a blood component using a differential absorption spectrum corresponding to a variation of amounts of blood and interstitial fluid in a blood vessel, the variation being generated by varying a thickness of a particular soft tissue of a subject.

10 [0002] With overall improvements in quality of life and living conditions, interest in personal health has increased. As a result, a wide array of home medical equipment that allows people to easily monitor their personal health has been researched and developed. In a normal human body, bodily fluid is organically circulated and adjusted so that an amount of bodily fluid is maintained within a predetermined range. Bodily fluids include blood, urine, interstitial fluid, sweat, and saliva. In particular, concentrations of blood and urine (glucose and protein) are essential parameters in determining a person's state of health. In addition, concentrations of blood components, such as glucose, hemoglobin, bilirubin, cholesterol, albumin, creatinine, protein, and urea, play an important role in assessing a person's state of health.

15 [0003] When a human body is infected with a disease, a composition or amount of a component of a bodily fluid changes, which may result in death. For example, a normal person's blood glucose concentration is about 80 mg/dl before meal and about 120 mg/dl after meal. In order to maintain such a normal glucose concentration, a human pancreas secretes an appropriate amount of insulin before or after the meal so that glucose can be absorbed into the liver and skeletal muscle cells. However, when the pancreas does not secrete an appropriate amount of insulin to maintain a normal blood glucose concentration due to a disease or other causes, an excessive amount of glucose exists in the blood, which causes a disease of the heart or the liver, arteriosclerosis, hypertension, cataract, retinal bleeding, nerve damage, hearing loss, or visual disturbance, all of which may cause serious problems including death. Accordingly, a technique of measuring a change in a bodily fluid of a human body is considered very important.

20 [0004] Methods of measuring a concentration of a component of a bodily fluid include invasive methods of directly collecting a sample of a target matter and performing measurement on the collected sample of the target matter and noninvasive methods of performing measurement without directly collecting a target matter. Since invasive methods have many problems, techniques of easily analyzing components of a bodily fluid using a noninvasive method have been continuously researched and developed. Conventionally, when measuring a component of a bodily fluid, for example, blood glucose, blood is extracted, reacted with a reagent, and then analyzed by using a clinical analysis system or quantifying a change in color of a test strip. When such a blood glucose test is performed every day, a patient suffers pain resulting from the direct blood collection and is susceptible to infection. Moreover, since it is difficult to continuously monitor the blood glucose level, it is difficult to properly treat a patient in an emergency situation. In addition, use of disposable strips and reagents may be a financial burden on the patient. Furthermore, these disposable strips and reagents cause environmental contamination, and as such, require special treatment. Accordingly, development of a technique of measuring a blood glucose concentration without extracting blood is desired for monitoring and adjusting a blood glucose level of a diabetic or diagnosing a person's state of health. Many methods of noninvasively measuring blood glucose have been researched, but instruments using these methods have not been commercialized.

30 [0005] In most conventional, spectroscopic methods for measuring a concentration of a blood component in a human body, light within a visible ray and near infrared ray (NIR) wavelength range is radiated onto a part of the body. Then, light reflected from or transmitted through the body is detected. In such spectroscopic methods, a spectrum is usually measured to measure the concentration of a blood component. Here, a reference light source having a wavelength that best responds to a blood component to be measured and a bandwidth that effectively counterbalances an influence of an interference substance is required. In addition, since a concentration of a component to be measured may be very low in blood and a light diffusion effect is greater than a light absorption effect in living tissue and blood, a detected signal is very weak. Thus, a method of amplifying the signal is required. Moreover, since organic substances in the body flow continuously, a component concentration can be accurately measured only when the measurement is quickly performed. In addition, it must be noted that an average energy radiated onto a human body should not go beyond a limit that may damage the human body. In particular, in an NIR wavelength range of about 700 through 2500 nm, a glucose absorption band is widely distributed, and glucose absorption is small as compared to a large aqueous background spectrum. Resultantly, a signal to noise ratio (SNR) is small, which makes accurate measurement very difficult.

35 [0006] US 5127406 discloses a method for noninvasively measuring the concentration of substances in blood. Light of first and second wavelengths is emitted through a pulsating living tissue. The amounts of light of the first and second wavelengths transmitted through the tissue are measured for first and second different thicknesses of the tissue. A calculation is then carried out to determine the concentration of the predetermined substance based on the detected amounts of light of the first and second wavelengths when the tissue has the first thickness, the amounts of light of the first and second wavelengths detected when the tissue has the second thickness, and absorption coefficients of the substance and absorption coefficients of water at the first and second wavelengths.

40 [0007] According to the present invention, there is provided an apparatus for noninvasively measuring a concentration of a blood component, comprising: a light source arranged to emit light; a spectroscope arranged to separate the light

emitted from the light source into components of different wavelengths; a body-machine interface unit, for mounting on a body part of a subject, arranged to radiate the light from the spectroscope onto the body part, collect light transmitted through the body part, vary a thickness of the body part according to a pressure applied to the body part, and secure the body part; a detection unit arranged to detect a first through a fourth absorption spectrum from the light collected by the body-machine interface unit; and a signal processor arranged to generate a signal for the body-machine interface unit to apply pressure to change the thickness of the body part, and estimate the concentration of a blood component from a second differential absorption spectrum obtained at the body part based on a statistical model of the blood component, the statistical model being established using a first differential absorption spectrum between the first and second absorption spectrums measured by the detection unit at different thicknesses of the body part and an actually measured concentration of the blood component.

**[0008]** In one embodiment of the apparatus, the signal processor generates signals for increasingly varying the thickness of the body part from an initial thickness to a first thickness and then a second thickness in correspondence with the actually measured concentration, obtains one of  $K$  first differential absorption spectrums between the first and second absorption spectrums measured from the body part at the first and second thicknesses, respectively, and performs multivariate statistical analysis on the  $K$  first differential absorption spectrums and  $K$  actually measured concentrations, thereby establishing the statistical model of the blood component. Further, the signal processor generates signals for increasingly varying the thickness of the body part from the initial thickness to the first thickness and then the second thickness, obtains the second differential absorption spectrum between the third absorption spectrum and the fourth absorption spectrum measured from the body part at the first and second thicknesses, respectively, and estimates the concentration of the blood component based on the statistical model. Preferably, a variation between the initial thickness and the first thickness is less than about 0.2 mm and a variation between the first thickness and the second thickness ranges from about 0.1 to 0.3 mm.

**[0009]** In another embodiment of the apparatus, the signal processor generates signals for increasingly varying the thickness of the body part from an initial thickness to a first thickness in correspondence with the actually measured concentration, holds the state in standby for a predetermined period of time, increasingly varies the thickness of the body part from the first thickness to a second thickness and then a third thickness, obtains one of  $K$  first differential absorption spectrums between the first and second absorption spectrums measured from the body part at the second and third thicknesses, respectively, and performs multivariate statistical analysis on the  $K$  first differential absorption spectrums and  $K$  actually measured concentrations, thereby establishing the statistical model of the blood component. Further, the signal processor generates signals for increasingly varying the thickness of the body part from the first thickness to the second thickness and then the third thickness, obtains the second differential absorption spectrum between the third absorption spectrum and the fourth absorption spectrum measured from the body part at the second and third thicknesses, respectively, and estimates the concentration of the blood component based on the statistical model. Preferably, a variation between the first thickness and the second thickness ranges from about 0.05 to 0.2 mm and a variation between the second thickness and the third thickness ranges from about 0.1 to 0.3 mm.

**[0010]** In the apparatus, the body-machine interface unit may include a beam guide portion transmitting parallel light from the spectroscope, a light receiver collecting light from the body part, a pressure sensor attached to the light receiver, and a securing/compressing member that secures the body part between the beam guide portion and the light receiver and varies the thickness of the body part by adjusting the pressure applied to the body part.

**[0011]** The present invention thus provides an apparatus for noninvasively measuring a concentration of a blood component using a differential absorption spectrum corresponding to a variation of amounts of blood and interstitial fluid, the variation being generated by varying a thickness of a particular soft tissue of a subject.

**[0012]** Also disclosed is a method, associated with the above apparatus, for noninvasively measuring a concentration of a blood component. The method includes (a) varying a thickness of a body part of a subject, measuring absorption spectrums at different thicknesses of the body part, obtaining a first differential absorption spectrum between the absorption spectrums measured at different thicknesses, actually measuring concentrations of the blood component, and establishing a statistical model using the first differential absorption spectrum and the actually measured concentrations; and (b) estimating the concentration of the blood component using a second differential absorption spectrum obtained with respect to the body part based on the statistical model.

**[0013]** In the method, (a) may include (a1) determining an initial thickness of the body part of the subject, (a2) increasing the thickness of the body part from the initial thickness to a first thickness and measuring a first absorption spectrum with respect to the body part, (a3) increasing the thickness of the body part from the first thickness to a second thickness and measuring a second absorption spectrum with respect to the body part, (a4) generating one of  $K$  first differential absorption spectrums between the first and second absorption spectrums, (a5) obtaining the  $K$  first differential absorption spectrums by repeating operations (a2) through (a4)  $K$  times in correspondence with  $K$  concentrations of the blood component actually measured from the subject, and (a6) establishing the statistical model of the blood component by performing multivariate statistical analysis on the  $K$  first differential absorption spectrums and the  $K$  concentrations actually measured. Further, operation (b) may include (b1) increasing the thickness of the body part from the initial

thickness to the first thickness and measuring a third absorption spectrum with respect to the body part, (b2) increasing the thickness of the body part from the first thickness to the second thickness and measuring a fourth absorption spectrum with respect to the body part, (b3) generating the second differential absorption spectrum between the third and fourth absorption spectra, and (b4) estimating the concentration of the blood component using the second differential absorption spectrum generated in operation (b3) and the statistical model. Preferably, a variation between the initial thickness and the first thickness is less than about 0.2 mm and a variation between the first thickness and the second thickness ranges from about 0.1 to 0.3 mm.

**[0014]** In an alternative method, (a) may include (a1) determining an initial thickness of the body part of the subject, (a2) increasing the thickness of the body part from the initial thickness to a first thickness and holding the state in standby for a predetermined period of time, (a3) increasing the thickness of the body part from the first thickness to a second thickness and measuring a first absorption spectrum with respect to the body part, (a4) increasing the thickness of the body part from the second thickness to a third thickness and measuring a second absorption spectrum with respect to the body part, (a5) generating one of  $K$  first differential absorption spectra between the first and second absorption spectra, (a6) obtaining the  $K$  first differential absorption spectra by repeating operations (a2) through (a5)  $K$  times in correspondence with  $K$  concentrations of the blood component actually measured from the subject, and (a7) establishing the statistical model of the blood component by performing multivariate statistical analysis on the  $K$  first differential absorption spectra and the  $K$  concentrations actually measured. Further, operation (b) may include (b1) increasing the thickness of the body part from the initial thickness to the first thickness and holding the state in standby for the predetermined period of time, (b2) increasing the thickness of the body part from the first thickness to the second thickness and measuring a third absorption spectrum with respect to the body part, (b3) increasing the thickness of the body part from the second thickness to the third thickness and measuring a fourth absorption spectrum with respect to the body part, (b4) generating the second differential absorption spectrum between the third and fourth absorption spectra, and (b5) estimating the concentration of the blood component using the second differential absorption spectrum generated in operation (b4) and the statistical model. Preferably, the predetermined period of time ranges from about 30 to 180 seconds. Preferably, a variation between the first thickness and the second thickness ranges from about 0.05 to 0.2 mm and a variation between the second thickness and the third thickness ranges from about 0.1 to 0.3 mm.

**[0015]** The above and other features and advantages of the present invention will become more apparent to those of ordinary skill in the art by describing in detail preferred embodiments thereof with reference to the attached drawings in which:

FIG. 1 is a block diagram of an apparatus for noninvasively measuring a concentration of a blood component according to an embodiment of the present invention;

FIGS. 2A to 2C illustrate a shape and a detailed structure of a body-machine interface unit of FIG. 1;

FIG. 3 is a flowchart of a method of noninvasively measuring a concentration of a blood component;

FIGS. 4A and 4B, collectively, are a flowchart of a method of noninvasively measuring a concentration of a blood component;

FIG. 5 is a detailed flowchart of operations 311 and 411, as shown in FIGS. 3 and 4, respectively;

FIG. 6 is a graph showing variations of reaction forces at different thicknesses of a web of a hand over time;

FIG. 7 is a graph showing changes in reaction force and absorptance of a web versus changes in thickness of the web of a hand;

FIG. 8 is a graph showing examples of an absorption spectrum and a differential absorption spectrum when a thickness of a web of a hand is adjusted to about 1.7 mm and 1.9 mm;

FIGS. 9A and 9B are graphs showing distributions of estimations of glucose values with respect to a reference value when calibration and cross-validation are performed when the first and second thicknesses are about 1.5 mm and 1.7 mm; and

FIGS. 10A and 10B are graphs showing distributions of estimations of glucose values with respect to a reference value when calibration and cross-validation are performed when the first and second thicknesses are about 1.7 mm and 1.9 mm.

**[0016]** The present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the invention are shown. The invention may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. Like reference numerals refer to like elements throughout.

**[0017]** Seventy-three percent (73%) of a human body is composed of water, of which 1/3 is extracellular water and 2/3 is intracellular water. Three-quarters (3/4) of the extracellular water is an interstitial fluid and 1/4 is an intravascular fluid. A blood glucose concentration of a human body indicates a concentration of glucose in blood, but a concentration of blood glucose in a capillary vessel is almost the same as a concentration of glucose in the interstitial fluid. The present

invention is based on this feature of the blood glucose included in the interstitial fluid and the intravascular fluid.

**[0018]** FIG. 1 is a block diagram of an apparatus for noninvasively measuring a concentration of a blood component according to an embodiment of the present invention. The apparatus includes a light source 110, a spectroscope 120, a body-machine interface unit 130, a detection unit 140, a signal processor 150, a storage unit 160, and a display unit 170. The body-machine interface unit 130, the detection unit 140, the signal processor 150, the storage unit 160, and the display unit 170 or some of these components may be embodied in an integrated form.

**[0019]** Referring to FIG. 1, the light source 110 is implemented by, for example, a halogen lamp, and emits light having a predetermined wavelength band. The spectroscope 120 separates the light emitted from the light source 110. The body-machine interface unit 130 radiates the separated light onto a particular part of a subject, i.e., a human body, collects light transmitted through the human body, and provides the collected light to the detection unit 140. The body-machine interface unit 130 is mounted on a particular body part to be measured and is designed to vary a thickness of the particular body part according to a pressure applied to the particular body part and secure the particular body part.

**[0020]** The detection unit 140 detects a first through a fourth absorption spectrum from the light collected from the secured particular body part and radiated by the body-machine interface unit 130. The detection unit 140 provides the first and second absorption spectrums and the third and fourth absorption spectrums to the signal processor 150. The signal processor 150 is provided with a program for executing a method of noninvasively measuring a concentration of a blood component according to an embodiment of the present invention and includes a statistical model, which is established by the program to calculate the concentration of a particular blood component. The signal processor 150 measures absorption spectrums detected by the detection unit 140 from the soft tissue of the particular body part having different thicknesses, generates a first and a second differential absorption spectrum corresponding to a variation in thicknesses, and estimates a concentration of a particular blood component, which corresponds to the first differential absorption spectrum, using the statistical model.

**[0021]** The storage unit 160 stores the result of the processing performed by the signal processor 150. The display unit 170 displays the estimated concentration to inform a tester and/or a testee of the result of the measurement.

**[0022]** FIGS. 2A to 2C illustrate a shape and a detailed structure of the body-machine interface unit 130 of FIG. 1. The body-machine interface unit 130 has a clamp structure operable to compress a soft tissue. Preferably, the body-machine interface unit 130 has a shape that includes a pair of opposite, facing surfaces, as shown in FIG. 2A. As shown in FIG. 2B, the body-machine interface unit 130 includes a securing/compressing member 250, which secures an area of soft tissue and varies a thickness of the soft tissue.

**[0023]** Referring to FIG. 2B, the body-machine interface unit 130 includes a beam guide portion 210 transmitting light from the spectroscope 120, a light receiver 230 collecting light from a body part 220, a holder 240 attached to the light receiver 230, and the securing/compressing member 250. The securing/compressing member 250 secures the body part 220 between the beam guide portion 210 and the light receiver 230 and varies a thickness of the body part 220 by adjusting a pressure applied to the body part 220.

**[0024]** Referring to FIGS. 2B and 2C, the securing/compressing member 250 includes a first member 250a installed parallel to the beam guide portion 210, a second member 250b connected to the light receiver 230 through the holder 240, a fixing plate 250c\_1 of a third member 250c is screw-coupled to the first member 250a, and a moving plate 250c\_2 of a third member 250c is coupled to screw-type handle 240d and screw-coupled to the second member 250b. By manipulating the screw-type handle 240d, the second member 250b coupled to moving plate 250c\_2 moves up and down, thereby adjusting the pressure applied to the body part 220 and adjusting the thickness of the body part 220. This principle is the same as that of common linear motors or lead-screw motor.

**[0025]** FIG. 3 is a flowchart of a method of noninvasively measuring a concentration of a blood component according to a first embodiment of the present invention. The method includes an initial operation 310 for establishing a statistical model and a subsequent operation 320 for measuring a concentration of a blood component.

**[0026]** Referring to FIG. 3, operation 310 includes, in operation 311, determining an initial thickness corresponding to a predetermined excessive pressure applied to a subject's body part from which a concentration of a blood component is to be measured. The excessive pressure is a maximum pressure applied to the body part to determine an initial thickness of the body part. The initial thickness may vary depending on an individual person and a particular body part being compressed. Operation 311 will be described in greater detail with reference to FIG. 5.

**[0027]** In operation 312, the thickness of the body part is increased by a predetermined value from the initial thickness by controlling the body-machine interface unit 130. The increased thickness is set as a first thickness. Light having a particular wavelength band especially responding to a particular blood component is then radiated onto the body part, and a first absorption spectrum is measured from light transmitted through the body part. The body part may be a web of a hand between a thumb and an index finger, as shown in FIG. 2A, an earflap, an earlobe, a nose, or a lip, all of which have soft tissue. The wavelength band of light radiated onto the body part varies depending on a blood component to be measured. It is preferable that the wavelength band is about 1100 through 2500 nm when a blood component to be measured is glucose. It is preferable that a variation between the initial thickness and the first thickness does not exceed about 0.2 mm.

[0028] In operation 313, the thickness of the body part is again increased and set as a second thickness. Light having the particular wavelength band is then radiated onto the body part, and a second absorption spectrum is measured from light transmitted through the body part. It is preferable that a variation between the first thickness and the second thickness is about 0.1 through 0.3 mm.

[0029] In operation 314, a first differential absorption spectrum between the first absorption spectrum and the second absorption spectrum is obtained. The first differential absorption spectrum does not include a spectrum of an element, such as water or fat of the tissue, which disturbs or interferes with measurement of the concentration of the blood component. More specifically, the first and second absorption spectra include errors caused by factors that are not related to the particular blood component to be measured. For example, factors such as the subject's body temperature, or a presence of hydrates, bones, cartilages, and collagen influence an optical measurement of vital components, but they are not directly related to the vital components. Thus, these errors can be removed by performing a subtraction between the first and second absorption spectra.

[0030] FIG. 8 is a graph showing examples of the first and second absorption spectra and the first differential absorption spectrum when the first and second thicknesses of a body part are set to about 1.7 (represented by line nd171, nd172 and nd173, which represent a location near to thumb, web center, a location near to an index finger) and 1.9 mm (represented by line nd191, nd192 and nd193, which represent a location near to thumb, web center, a location near to an index finger) at different portions of a web of a hand. It is preferable that the first differential absorption spectrum is processed using mean centering (MC), multiple scattering correction (MSC), or partial smoothing (PS). When PS is used, smoothing is performed only on a particular wavelength range, for example, a wavelength range having a high absorbance, among all of the data of the first differential absorption spectrum, and all of the original data except the particular wavelength range is used without modification.

[0031] Referring back to FIG. 3, in operation 315, a statistical model is established by performing multivariate statistical analysis on  $K$  concentrations of the particular blood component, which are actually measured from blood directly collected from the subject, and  $K$  first differential absorption spectra obtained by repeating operations 312 through 314. This operation will be described in detail below.

[0001] The  $K$  first differential absorption spectra can be expressed as Formula (1).

$$A_i = (A_{\lambda i1}, A_{\lambda i2}, \dots, A_{\lambda in}), \quad i = 1, \dots, K \quad \dots(1)$$

[0032] Here, a single first differential absorption spectrum  $A_i$  can be expressed as a matrix of absorptances  $A_{\lambda in}$  at  $n$  wavelengths  $\lambda_{in}$  in the measurement wavelength band.

[0033] Next, a statistical model for calculating a concentration  $C$  of the particular blood component of the subject is established by Formula (2) using multivariate statistical analysis, for example, principal component regression or partial least square regression, of the  $K$  first differential absorption spectra and the  $K$  actually measured concentrations.

$$C = \beta_1 A_{\lambda i1} + \beta_2 A_{\lambda i2} + \dots + \beta_n A_{\lambda in} \quad \dots(2)$$

[0034] More specifically, coefficients  $\beta_1$  through  $\beta_n$  of the absorptances  $A_{\lambda in}$  at different wavelengths are obtained through the multivariate statistical analysis using Formula (2). The statistical model of the subject is stored in the signal processor 150.

[0035] When the concentration of the blood component is measured in operation 320, in operation 321, a third absorption spectrum is measured from the body part set to the first thickness, in operation 322, a fourth absorption spectrum is measured from the body part set to the second thickness, and, in operation 323, a second differential absorption spectrum between the third and fourth absorption spectra is obtained. Operations 321 through 323 are performed in a manner substantially similar to operations 312 through 314.

[0036] In operation 324, a concentration of the particular blood component is estimated using the second differential absorption spectrum obtained in operation 323 and the statistical model established in operation 315. More specifically, the concentration  $C$  can be obtained by applying the values of  $A_{\lambda i1}$  through  $A_{\lambda in}$  obtained from the second differential absorption spectrum to Formula (2).

[0037] The first and second thicknesses are obtained when pressures lower than the excessive pressure are applied.

[0038] FIGS. 4A and 4B, collectively, are a flowchart of a method of noninvasively measuring a concentration of a blood component according to a second embodiment of the present invention. The method includes an initial operation 410 for establishing a statistical model and a subsequent operation 420 for measuring a concentration of a blood

component.

**[0039]** Referring to FIG. 4A, operation 410 includes, in operation 411, determining an initial thickness corresponding to a predetermined excessive pressure applied to a subject's body part.

**[0040]** In operation 412, the thickness of the body part is increased by a predetermined value from the initial thickness by controlling the body-machine interface unit 130. The increased thickness is set as a first thickness, and this state is held in standby for a predetermined period of time. It is preferable that a variation of thicknesses is about 0.2 mm and the standby duration for stabilization is about 30 through 180 seconds.

**[0041]** In operation 413, the first thickness of the body part is increased to a second thickness. Light having a particular wavelength band is then radiated onto the body part, and a first absorption spectrum is measured. It is preferable that a variation of the first and second thicknesses is about 0.05 through 0.2 mm.

**[0042]** In operation 414, the second thickness of the body part is increased to a third thickness. Light having the particular wavelength band is then radiated onto the body part, and a second absorption spectrum is measured. It is preferable that a variation of the second and third thicknesses is about 0.1 through 0.3 mm.

In operation 415, a first differential absorption spectrum between the first absorption spectrum and the second absorption spectrum is obtained.

**[0043]** In operation 416, in the same manner as in the first embodiment, a statistical model is established by performing multivariate statistical analysis on  $K$  concentrations of the particular blood component, which are actually measured from blood directly collected from the subject, and  $K$  first differential absorption spectrums obtained by repeating operations 412 through 415.

**[0044]** Referring to FIG. 4B, operation 420 includes, in operation 421, setting the thickness of the body part to the first thickness and holding the state in standby for a predetermined duration, in operation 422, increasing the thickness of the body part to the second thickness and obtaining a third absorption spectrum from the body part set to the second thickness, in operation 423, increasing the thickness of the body part to the third thickness and obtaining a fourth absorption spectrum from the body part set to the third thickness, and, in operation 424, obtaining a second differential absorption spectrum between the third and fourth absorption spectrums.

**[0045]** In operation 425, a concentration of the particular blood component is obtained using the second differential absorption spectrum obtained in operation 424 and the statistical model established in operation 416. More specifically, the concentration  $C$  can be obtained by applying the values of  $A_{\lambda_{i1}}$ , through  $A_{\lambda_{in}}$  obtained from the second differential absorption spectrum to Formula (2).

**[0046]** The first through third thicknesses are thicknesses that are obtained when pressures lower than the excessive pressure are applied.

**[0047]** When a wavelength range of a light source is changed in the methods shown in FIGS. 3 and 4, components other than glucose, such as hemoglobin, cholesterol, and medicines, may be measured.

**[0048]** FIG. 5 is a detailed flowchart of operations 311 and 411 shown in FIGS. 3 and 4, respectively. For clarity of the description, it is assumed that a body part having soft tissue is a web of the hand.

**[0049]** Referring to FIG. 5, in operation 511, under the control of the body-machine interface unit 130, the thickness of the web is changed by a predetermined value, for example, about 0.1 mm, from a first thickness, for example, about 1.5 mm, to a second thickness, for example, about 2.2 mm. Since the body part is elastic, a reaction force thereof rapidly changes over time in an initial compressing stage. However, as the compressing continues, the elasticity of the body part becomes almost nonexistent, and thereafter, the reaction force barely changes. Accordingly, it is preferable that a pressure is applied onto the body part for about 120 seconds. The thickness of the body part sensed by the pressure sensor 240 at this time is provided to the signal processor 150.

**[0050]** In operation 512, variations of reaction forces of the web of the hand are measured at different thicknesses of the web, which are adjusted by increasing or decreasing a pressure applied to the web for about 120 seconds. When the thickness of the web is changed from about 1.5 mm (represented by line th151, th152, th153) to about 2.2 mm (represented by line th221, th222, th223), variations of reaction forces are shown in a graph of FIG. 6.

**[0051]** In operation 513, a thickness corresponding to the excessive pressure is determined based on the graph shown in FIG. 6. Referring to FIG. 6, when the thickness of the web is about 1.5 through 1.6 mm, that is, when a pressure exceeds the excessive pressure, the web has constant reaction force even as time lapses. However, when the thickness of the web increases above about 1.6 mm, that is, when an applied pressure decreases, the reaction force of the web decreases or becomes almost zero as time lapses. A pressure or a reaction force of a human body at a boundary thickness between a thickness maintaining the reaction force constant and a thickness decreasing the reaction force, about 1.6 mm in FIG. 6, is determined as the excessive pressure, and the thickness at the excessive pressure is determined as the initial thickness.

**[0052]** FIG. 7 is a graph showing changes in reaction force and absorptance of the web versus changes in thickness of the web. The changes in reaction force were compared when the initial thickness of the web was set to 2.0 mm (represented by line th20), was then decreased to 1.6 mm (represented by line th16), and was then changed to 1.7 mm, 1.8 mm, 1.9 mm, and 2.0 mm (represented by lines th17, th18, th19, and th202, respectively). The changes in absorptance

were compared with the changes in absorptance when the initial thickness of the web was set to 2.0 mm (represented by line pre1 s20), was then decreased to 1.6 mm (represented by line pre1s16), and was then changed to 1.7 mm, 1.8 mm, 1.9 mm, and 2.0 mm (represented by lines pre1s17, pre1s18, pre1s19, and pre1s20r, respectively).

**[0053]** Here, each thickness was maintained for 120 seconds, before being changed. Referring to FIG. 7, when the thickness was changed to 1.7 mm, 1.8 mm, 1.9 mm, and 2.0 mm above a thickness of 1.6 mm corresponding to the excessive pressure, the absorptance almost linearly changed while the reaction force was very slowly restored. More specifically, it can be inferred that a body part having soft tissue is released from pressure, an extracellular fluid moves very swiftly, but the compressed tissue is slowly restored. Based on such a difference between the two conditions, only a spectrum of the extracellular fluid can be separated. Accordingly, it is preferable that a thickness is changed within a range that can induce only such changes in the fluid. These preferable changes in thickness can be achieved by applying lower pressures than the excessive pressure.

**[0054]** FIGS. 9A and 9B are graphs showing distributions of estimations of glucose values with respect to a reference value when calibration and cross-validation were performed when the first and second thicknesses were about 1.5 mm and 1.7 mm. A thickness of about 1.5 mm was obtained when a pressure greater than the excessive pressure was applied to the web. It may be seen that when glucose is measured using a statistical model established when the first and second thicknesses are about 1.5 mm and 1.7 mm, an error in the statistical model is great and linearity is bad. More specifically, as a result of calibration, standard error of calibration (SEC)=38.83 mg/dl (ten factors) and R=0.672. As a result of cross-validation, standard error of cross-validation (SECV)=45.764 mg/dl (three factors) and R=0.429.

**[0055]** FIGS. 10A and 10B are graphs showing distributions of estimations of glucose values with respect to a reference value when calibration and cross-validation were performed when the first and second thicknesses were about 1.7 mm and 1.9 mm. Thicknesses of about 1.7 mm and 1.9 mm were obtained when pressures lower than the excessive pressure were applied to the web. It may be seen that when glucose is measured using a statistical model established when the first and second thicknesses are about 1.7 mm and 1.9 mm, an error in the statistical model is small and linearity is improved. More specifically, as a result of calibration, SEC=23.876 mg/dl (ten factors) and R=0.826. As a result of cross-validation, SECV=27.957 mg/dl (seven factors) and R=0.739. Thus, the standard error is decreased significantly.

**[0056]** The present invention can be realized as a code that is recorded on a computer readable recording medium and can be read by a computer. The computer readable recording medium may be any type of medium on which data that can be read by a computer system can be recorded, for example, a ROM, a RAM, a CD-ROM, a magnetic tape, a floppy disc, or an optical data storage device. The present invention can also be realized as carrier waves (for example, transmitted through Internet). Alternatively, computer readable recording media may be distributed among computer systems connected through a network so that the present invention may be realized as a code that is stored in the recording media and can be read and executed in the computers. Functional programs, codes, and code segments for implementing the present invention can be easily inferred by programmers in the art of the present invention.

**[0057]** As described above, in the present invention, a statistical model is established using a first differential absorption spectrum corresponding to a variation of the amounts of extracellular fluid at different thicknesses of a body part having soft tissue, which are adjusted by applying lower pressures than an excessive pressure to the body part, and a concentration of a particular blood component can be estimated using a second differential absorption spectrum and the statistical model. Accordingly, an influence of the extracellular fluid can be increased, and factors disturbing or interfering with the measurement of the concentration of the particular blood component can be removed. Therefore, the concentration of the particular blood component can be more accurately estimated.

**[0058]** In addition, since a thickness corresponding to an excessive pressure is determined for each person, and a statistical model is established on the basis of the thickness, measurement conditions for each person can be numerically expressed. Moreover, since only an effect of a fluid can be separated, a concentration can be accurately estimated. Since the fluid, rather than tissue, is moved by decreasing a pressure applied to soft tissue, reproducibility of the measurement of spectrum is satisfactory.

**[0059]** Preferred embodiments of the present invention have been disclosed herein and, although specific terms are employed, they are used and are to be interpreted in a generic and descriptive sense only and not for purpose of limitation. Accordingly, it will be understood by those of ordinary skill in the art that various changes in form and details may be made without departing from the scope of the present invention as set forth in the following claims.

## Claims

1. An apparatus for noninvasively measuring a concentration of a blood component, comprising:

- a light source (110) arranged to emit light;
- a spectroscope (120) arranged to separate the light emitted from the light source (110) into components of different wavelengths;

a body-machine interface unit (130), for mounting on a body part of a subject, arranged to radiate the light from the spectroscope (120) onto the body part, collect light transmitted through the body part, vary a thickness of the body part according to a pressure applied to the body part, and secure the body part;  
 a detection unit (140) arranged to detect a first through a fourth absorption spectrum from the light collected by the body-machine interface unit (130); and  
 a signal processor (150) arranged to generate a signal for the body-machine interface unit to apply pressure to change the thickness of the body part, and estimate the concentration of a blood component from a second differential absorption spectrum between the third and fourth absorption spectrum obtained at the body part based on a statistical model of the blood component, the statistical model being established using a first differential absorption spectrum between the first and second absorption spectrums measured by the detection unit (140) at different thicknesses of the body part and an actually measured concentration of the blood component.

2. The apparatus as claimed in claim 1, wherein the signal processor (150) is arranged to generate signals for increasingly varying the thickness of the body part from an initial thickness to a first thickness and then a second thickness in correspondence with the actually measured concentration, obtain one of  $K$  first differential absorption spectrums between the first and second absorption spectrums measured from the body part at the first and second thicknesses, respectively, where  $K$  is a positive integer, and perform multivariate statistical analysis on the  $K$  first differential absorption spectrums and  $K$  actually measured concentrations, thereby establishing the statistical model of the blood component.
3. The apparatus as claimed in claim 2, wherein the signal processor (150) is arranged to generate signals for increasingly varying the thickness of the body part from the initial thickness to the first thickness and then the second thickness, obtain the second differential absorption spectrum between the third absorption spectrum and the fourth absorption spectrum measured from the body part at the first and second thicknesses, respectively, and estimate the concentration of the blood component based on the statistical model.
4. The apparatus as claimed in claim 2 or 3, wherein a variation between the initial thickness and the first thickness is less than 0.2 mm.
5. The apparatus as claimed in any one of claims 2 to 4, wherein a variation between the first thickness and the second thickness ranges from 0.1 to 0.3 mm.
6. The apparatus as claimed in claim 1, wherein the signal processor (150) is arranged to generate signals for increasingly varying the thickness of the body part from an initial thickness to a first thickness in correspondence with the actually measured concentration, hold the state in standby for a predetermined period of time, increasingly vary the thickness of the body part from the first thickness to a second thickness and then a third thickness, obtain one of  $K$  first differential absorption spectrums between the first and second absorption spectrums measured from the body part at the second and third thicknesses, respectively, where  $K$  is a positive integer, and perform multivariate statistical analysis on the  $K$  first differential absorption spectrums and  $K$  actually measured concentrations, thereby establishing the statistical model of the blood component.
7. The apparatus as claimed in claim 6, wherein the signal processor (150) is arranged to generate signals for increasingly varying the thickness of the body part from the first thickness to the second thickness and then the third thickness, obtain the second differential absorption spectrum between the third absorption spectrum and the fourth absorption spectrum measured from the body part at the second and third thicknesses, respectively, and estimate the concentration of the blood component based on the statistical model.
8. The apparatus as claimed in claim 6 or 7, wherein a variation between the first thickness and the second thickness ranges from 0.05 to 0.2 mm.
9. The apparatus as claimed in any one of claims 6 to 8, wherein a variation between the second thickness and the third thickness ranges from 0.1 to 0.3 mm.
10. The apparatus as claimed in any one of claims 1 to 9, wherein the body-machine interface unit (130) comprises:

a beam guide portion (210) arranged to transmit parallel light from the spectroscope (120);  
 a light receiver (230) arranged to collect light from the body part;  
 a holder (240) attached to the light receiver (230); and

a securing and compressing member (250) arranged to secure the body part between the beam guide portion (210) and the light receiver (230) and vary the thickness of the body part by adjusting the pressure applied to the body part.

5

## Patentansprüche

### 1. Gerät zur nichtinvasiven Messung einer Konzentration einer Blutkomponente umfassend:

10 eine Lichtquelle (110), so angeordnet, dass sie Licht emittiert;  
ein Spektroskop (120), so angeordnet, dass es das von der Lichtquelle (110) emittierte Licht in Komponenten unterschiedlicher Wellenlängen trennt;  
eine Körper-Maschine-Schnittstelleneinheit (130) zum Anbringen an einem Körperteil eines Probanden, so angeordnet, dass es das Licht vom Spektroskop (120) auf den Körperteil ausstrahlt, durch den Körperteil geleitetes Licht einfängt, eine Dicke des Körperteils gemäß eines auf den Körperteil aufgetragenen Drucks verändert und den Körperteil sichert;  
15 eine Erfassungseinheit (140), so angeordnet, dass sie ein erstes bis viertes Absorptionsspektrum von dem von der Körper-Maschine-Schnittstelleneinheit (130) eingefangenen Licht erfasst; und  
einen Signalprozessor (150), so angeordnet, dass er ein Signal für die Körper-Maschine-Schnittstelleneinheit erzeugt, um Druck zum Verändern der Dicke des Körperteils aufzubringen und die Konzentration einer Blutkomponente von einem zweiten Differentialabsorptionsspektrum zwischen dem dritten und vierten Absorptionsspektrum, erhalten am Körperteil ausgehend von einem statistischen Modell der Blutkomponente abzuschätzen, wobei das statistische Modell erstellt ist unter Verwendung eines ersten Differentialabsorptionsspektrums zwischen dem ersten und zweiten Absorptionsspektrum gemessen von der Erfassungseinheit (140) bei  
20 verschiedenen Dicken des Körperteils und einer tatsächlich gemessenen Konzentration der Blutkomponente.

25  
2. Gerät wie in Anspruch 1 beansprucht, worin der Signalprozessor (150) so angeordnet ist, dass er Signale erzeugt für zunehmend veränderte Dicke des Körperteils von einer Anfangsdicke zu einer ersten Dicke und dann einer zweiten Dicke entsprechend der tatsächlich gemessenen Konzentration, eines von K ersten Differentialabsorptionsspektren zwischen dem ersten und zweiten Absorptionsspektrum erhält, die entsprechend am Körperteil bei der  
30 ersten und zweiten Dicke gemessen sind, wo K eine positive ganze Zahl ist und multivariante statistische Analyse an den K ersten Differentialabsorptionsspektren und K tatsächlich gemessenen Konzentrationen durchführt, wodurch das statistische Modell für die Blutkomponente erstellt wird.

35 3. Gerät wie in Anspruch 2 beansprucht, worin der Signalprozessor (150) so angeordnet ist, dass er Signale erzeugt für zunehmend veränderte Dicke des Körperteils von einer Anfangsdicke zur ersten Dicke und dann der zweiten Dicke, das zweite Differentialabsorptionsspektrum zwischen dem dritten Absorptionsspektrum und dem vierten Absorptionsspektrum erhält; die entsprechend am Körperteil bei der ersten und zweiten Dicke gemessen sind, und die Konzentration der Blutkomponente ausgehend vom statistischen Modell abschätzt.

40 4. Gerät wie in Anspruch 2 oder 3 beansprucht, worin eine Variation zwischen der Anfangsdicke und der ersten Dicke weniger als 0,2 mm beträgt.

45 5. Gerät wie in einem der Ansprüche 2 bis 4 beansprucht, worin eine Variation zwischen der ersten Dicke und der zweiten Dicke im Bereich von 0,1 bis 0,3 mm liegt.

50 6. Gerät wie in Anspruch 1 beansprucht, worin der Signalprozessor (150) so angeordnet ist, dass er Signale erzeugt für zunehmend veränderte Dicke des Körperteils von einer Anfangsdicke zu einer ersten Dicke entsprechend der tatsächlich gemessenen Konzentration, den Zustand für eine bestimmte Zeitspanne im Standby hält, die Dicke des Körperteils von der ersten Dicke zu einer zweiten Dicke und dann einer dritten Dicke zunehmend verändert, eines von K ersten Differentialabsorptionsspektren zwischen dem ersten und zweiten Absorptionsspektrum erhält, die entsprechend am Körperteil bei der zweiten und dritten Dicke gemessen sind, wo K eine positive ganze Zahl ist, und multivariante statistische Analyse an den K ersten Differentialabsorptionsspektren und K tatsächlich gemessenen Konzentrationen durchführt, wodurch das statistische Modell für die Blutkomponente erstellt wird.

55 7. Gerät wie in Anspruch 6 beansprucht, worin der Signalprozessor (150) so angeordnet ist, dass er Signale erzeugt für zunehmend veränderte Dicke des Körperteils von der ersten Dicke zur zweiten Dicke und dann der dritten Dicke, das zweite Differentialabsorptionsspektrum zwischen dem dritten Absorptionsspektrum und dem vierten Absorpti-

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onsspektrum erhält, die am Körperteil bei der zweiten bzw. dritten Dicke gemessen sind, und die Konzentration der Blutkomponente ausgehend vom statistischen Modell abschätzt.

- 5 8. Gerät wie in Anspruch 6 oder 7 beansprucht, worin eine Variation zwischen der ersten Dicke und der zweiten Dicke im Bereich von 0,05 bis 0,2 mm liegt.
9. Gerät wie in einem der Ansprüche 6 bis 8 beansprucht, worin eine Variation zwischen der zweiten Dicke und der dritten Dicke im Bereich von 0,1 bis 0,3 mm liegt.
- 10 10. Gerät wie in einem der Ansprüche 1 bis 9 beansprucht, worin die Körper-Maschine-Schnittstelleneinheit (130) umfasst:

15 einen Strahlführungsteil (210), so angeordnet, dass er paralleles Licht vom Spektroskop (120) führt; einen Lichtempfänger (230), so angeordnet, dass er Licht vom Körperteil einfängt; einen Halter (240), der am Lichtempfänger (230) angebracht ist; und ein Sicherungs- und Kompressionsglied (250), so angeordnet, dass es den Körperteil zwischen dem Strahlführungsteil (210) und dem Lichtempfänger (230) sichert und die Dicke des Körperteils durch Einstellen des auf den Körperteil aufgebrachten Drucks verändert.

20

### Revendications

1. Appareil pour mesurer sans effraction tissulaire une concentration d'un composant sanguin, comprenant :
- 25 une source de lumière (110) agencée pour émettre de la lumière ; un spectroscope (120) agencé pour séparer la lumière émise par la source de lumière (110) en composantes de différentes longueurs d'onde ; une unité d'interface corps-machine (130), destinée à être installée sur une partie du corps d'un sujet, agencée pour rayonner la lumière du spectroscope (120) sur la partie du corps, pour recueillir la lumière transmise à travers la partie du corps, pour faire varier une épaisseur de la partie du corps en fonction d'une pression appliquée à la partie du corps, et pour fixer la partie du corps ;
- 30 une unité de détection (140) agencée pour détecter des premier à quatrième spectres d'absorption à partir de la lumière recueillie par l'unité d'interface corps-machine (130) ; et un processeur de signal (150) agencé pour générer un signal pour que l'unité d'interface corps-machine applique une pression pour modifier l'épaisseur de la partie du corps et pour estimer la concentration d'un composant sanguin à partir d'un deuxième spectre d'absorption différentiel entre les troisième et quatrième spectres d'absorption obtenus au niveau de la partie du corps sur la base d'un modèle statistique du composant sanguin, le modèle statistique étant établi en utilisant un premier spectre d'absorption différentiel entre les premier et deuxième spectres d'absorption mesurés par l'unité de détection (140) à différentes épaisseurs de la partie du corps et une concentration réellement mesurée du composant sanguin.
- 40
2. Appareil selon la revendication 1, dans lequel le processeur de signal (150) est agencé pour générer des signaux pour modifier de manière croissante l'épaisseur de la partie du corps d'une épaisseur initiale à une première épaisseur et ensuite à une deuxième épaisseur en correspondance avec la concentration réellement mesurée, pour obtenir l'un de K premiers spectres d'absorption différentiels entre les premier et deuxième spectres d'absorption mesurés à partir de la partie du corps aux première et deuxième épaisseurs, respectivement, où K est un entier positif, et pour effectuer une analyse statistique à plusieurs variables sur les K premiers spectres d'absorption différentiels et K concentrations réellement mesurées, établissant de ce fait le modèle statistique du composant sanguin.
- 45
3. Appareil selon la revendication 2, dans lequel le processeur de signal (150) est agencé pour générer des signaux pour faire varier de manière croissante l'épaisseur de la partie du corps de l'épaisseur initiale à la première épaisseur et ensuite à la deuxième épaisseur, pour obtenir le deuxième spectre d'absorption différentiel entre le troisième spectre d'absorption et le quatrième spectre d'absorption mesurés à partir de la partie du corps aux première et deuxième épaisseurs, respectivement, et pour estimer la concentration du composant sanguin sur la base du modèle statistique.
- 50
- 55 4. Appareil selon la revendication 2 ou 3, dans lequel une variation entre l'épaisseur initiale et la première épaisseur est inférieure à 0,2 mm.

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5. Appareil selon l'une quelconque des revendications 2 à 4, dans lequel une variation entre la première épaisseur et la deuxième épaisseur va de 0,1 à 0,3 mm.
- 5 6. Appareil selon la revendication 1, dans lequel le processeur de signal (150) est agencé pour générer des signaux pour faire varier de manière croissante l'épaisseur de la partie du corps d'une épaisseur initiale à une première épaisseur en correspondance avec la concentration réellement mesurée, pour maintenir l'état en attente pendant une période de temps prédéterminée, pour faire varier l'épaisseur de la partie du corps de la première épaisseur à une deuxième épaisseur et ensuite à une troisième épaisseur, pour obtenir l'un de K premiers spectres d'absorption différentiels entre les premier et deuxième spectres d'absorption mesurés à partir de la partie du corps aux deuxième et troisième épaisseurs, respectivement, où K est un entier positif, et pour effectuer une analyse statistique à plusieurs variables sur les K premiers spectres d'absorption différentiels et K concentrations réellement mesurées, établissant de ce fait le modèle statistique du composant sanguin.
- 10 7. Appareil selon la revendication 6, dans lequel le processeur de signal (150) est agencé pour générer des signaux pour faire varier de manière croissante l'épaisseur de la partie du corps de la première épaisseur à la deuxième épaisseur et ensuite à la troisième épaisseur, pour obtenir le deuxième spectre d'absorption différentiel entre le troisième spectre d'absorption et le quatrième spectre d'absorption mesurés à partir de la partie du corps aux deuxième et troisième épaisseurs, respectivement, et pour estimer la concentration du composant sanguin sur la base du modèle statistique.
- 15 8. Appareil selon la revendication 6 ou 7, dans lequel une variation entre la première épaisseur et la deuxième épaisseur va de 0,05 à 0,2 mm.
- 20 9. Appareil selon l'une quelconque des revendications 6 à 8, dans lequel une variation entre la deuxième épaisseur et la troisième épaisseur va de 0,1 à 0,3 mm.
- 25 10. Appareil selon l'une quelconque des revendications 1 à 9, dans lequel l'unité d'interface corps-machine (130) comprend :
- 30 une partie de guidage de faisceau (210) agencée pour transmettre une lumière parallèle provenant du spectroscope (120) ;  
un récepteur de lumière (230) agencé pour recueillir la lumière provenant de la partie du corps ;  
un support (240) fixé au récepteur de lumière (230) ; et  
un élément de fixation et de compression (250) agencé pour fixer la partie du corps entre la partie de guidage  
35 de faisceau (210) et le récepteur de lumière (230) et pour modifier l'épaisseur de la partie du corps en ajustant la pression appliquée à la partie du corps.
- 40
- 45
- 50
- 55

FIG. 1

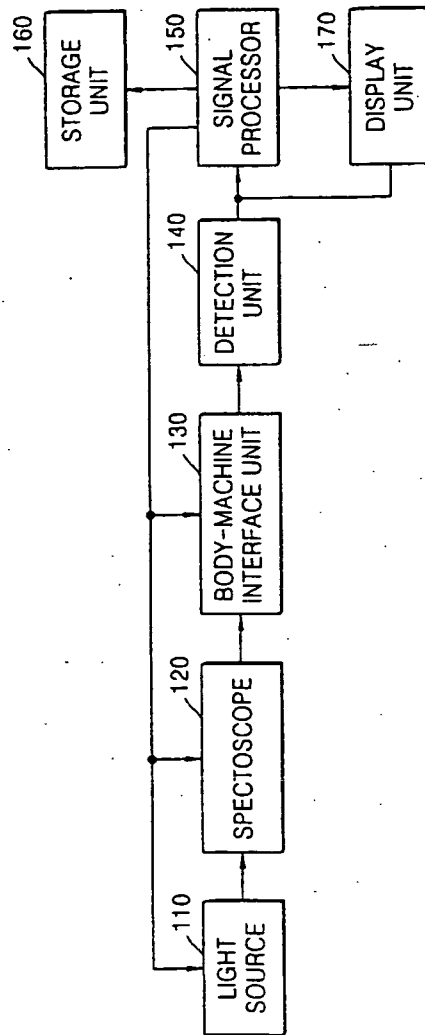


FIG. 2A

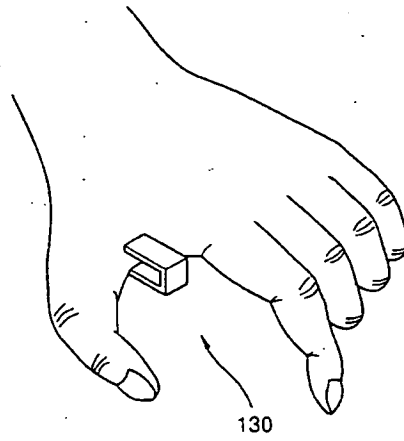


FIG. 2B

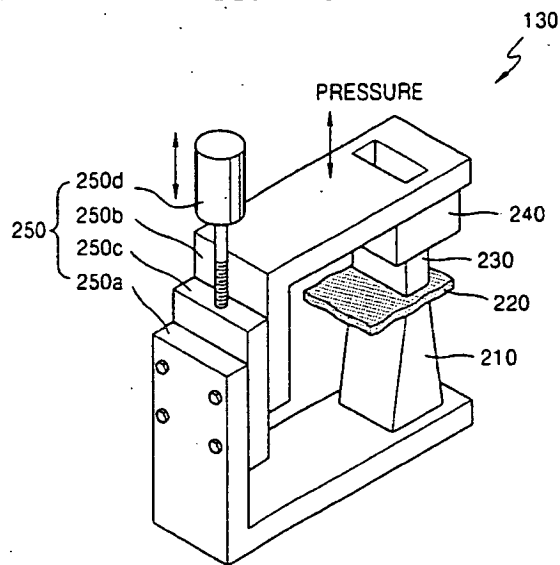


FIG. 2C

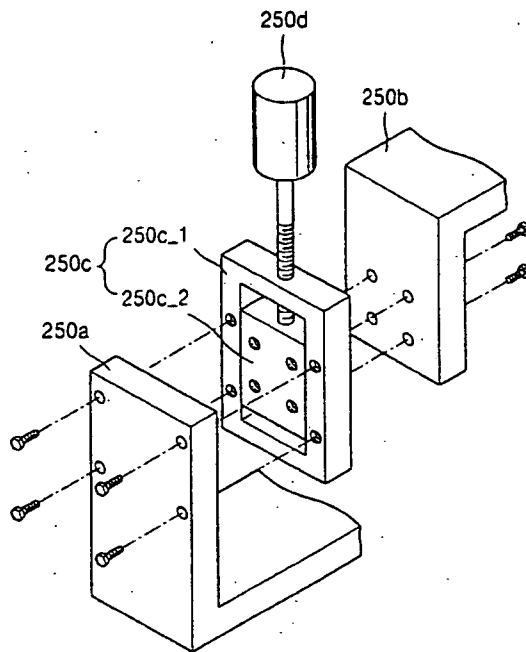


FIG. 3

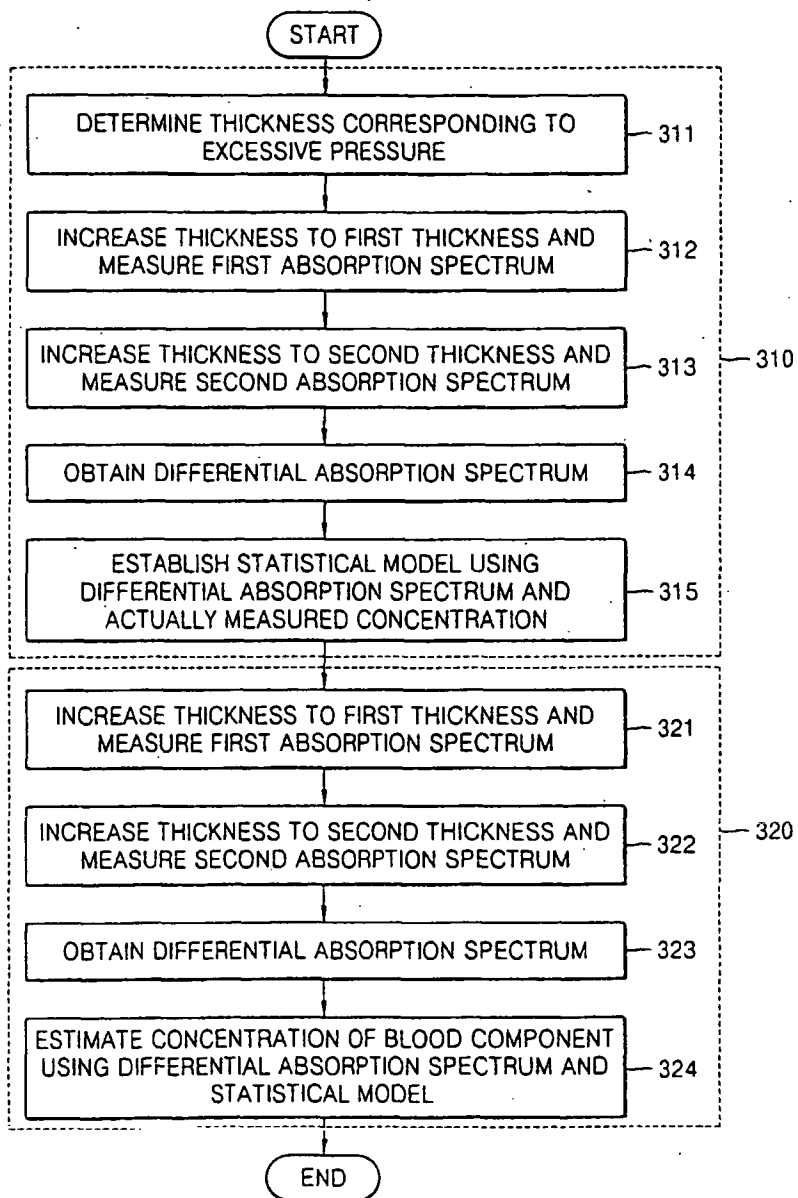


FIG. 4A

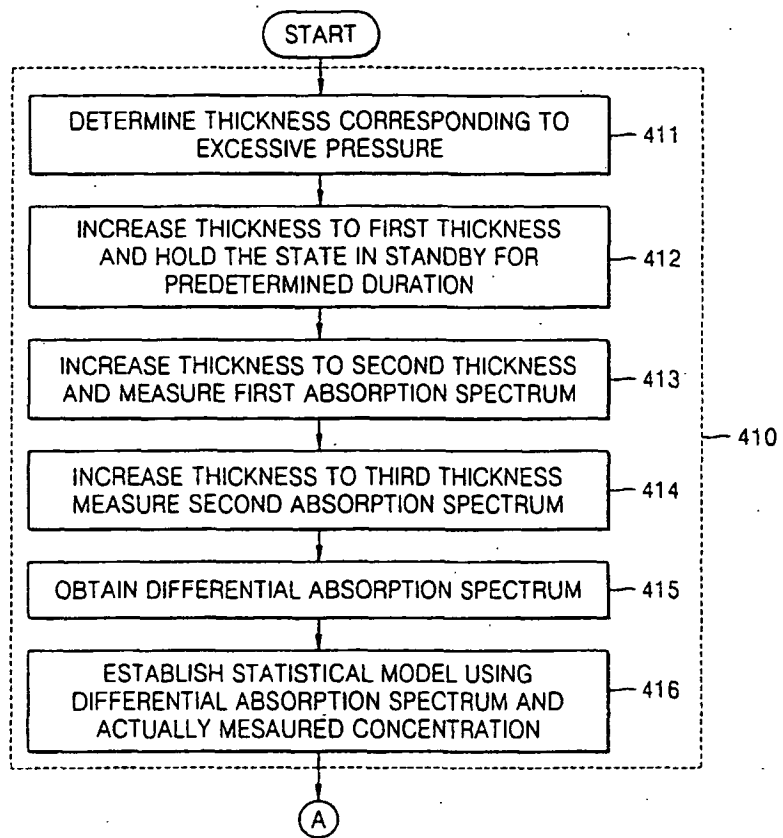


FIG. 4B

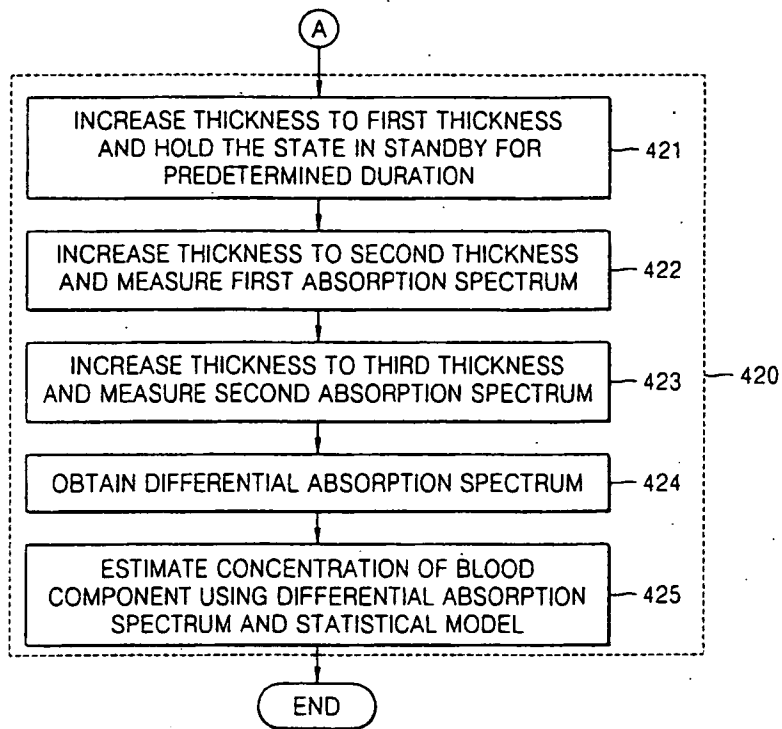


FIG. 5

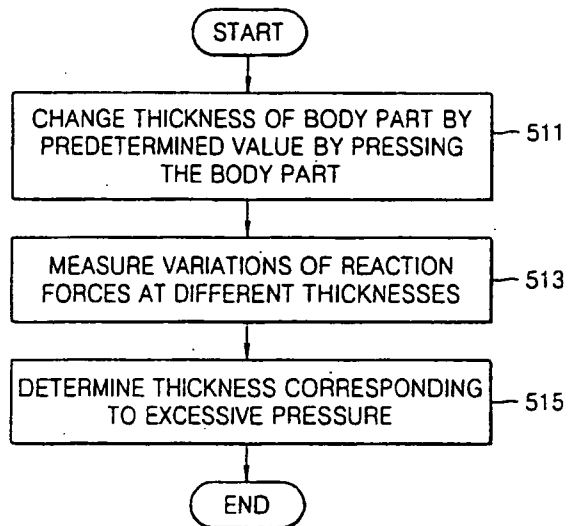


FIG. 6

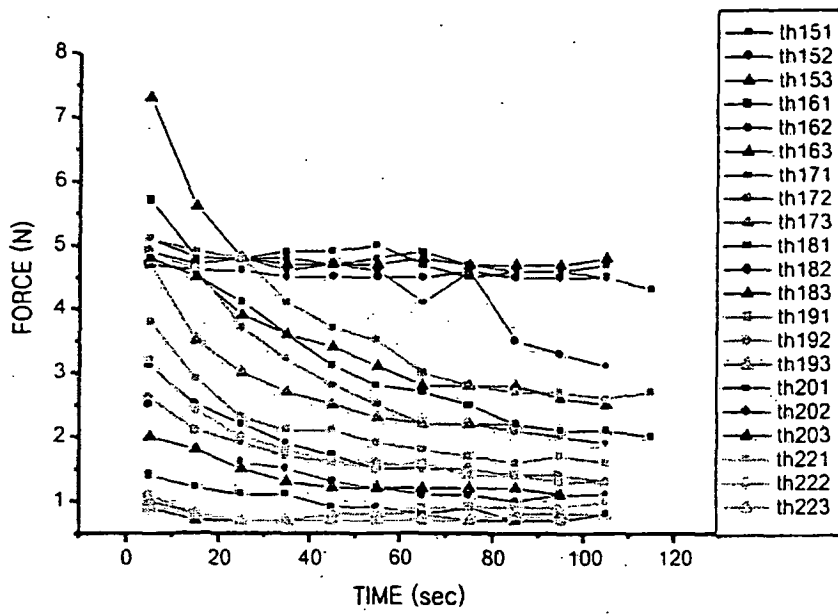


FIG. 7

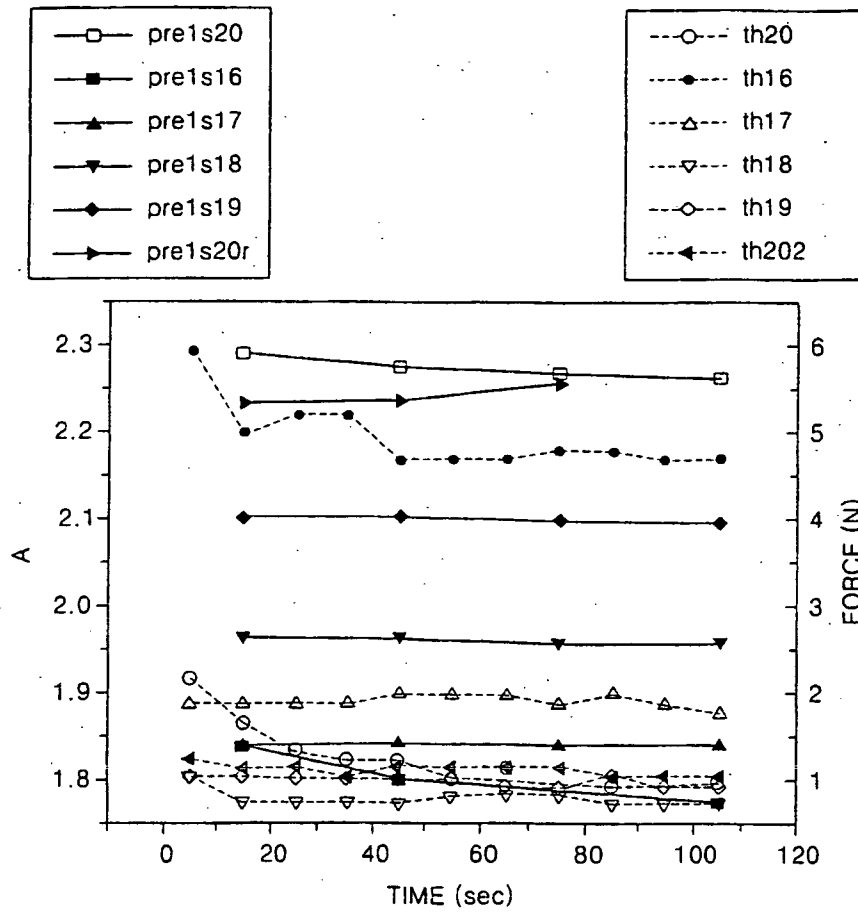


FIG. 8

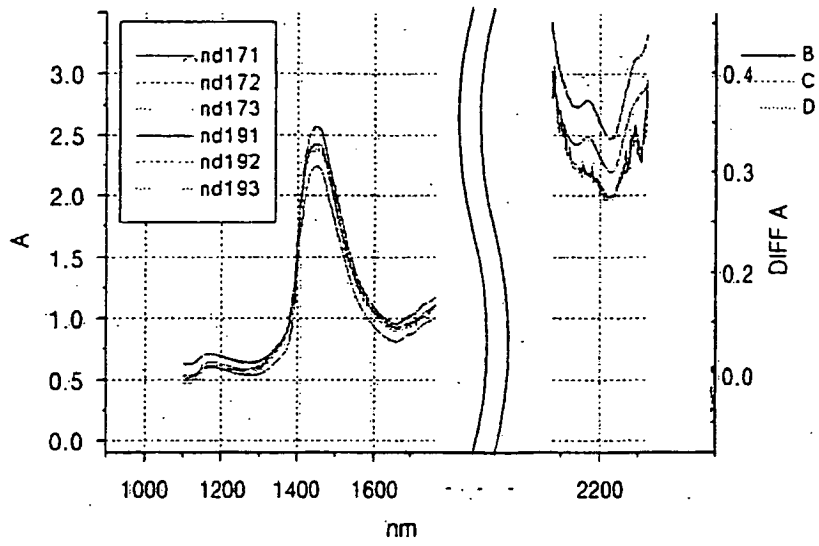


FIG. 9A

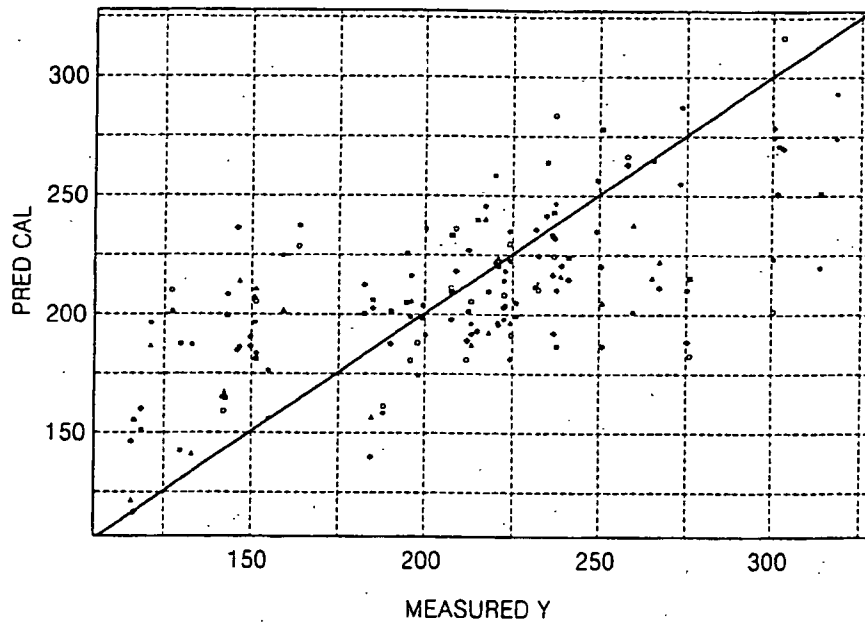


FIG. 9B

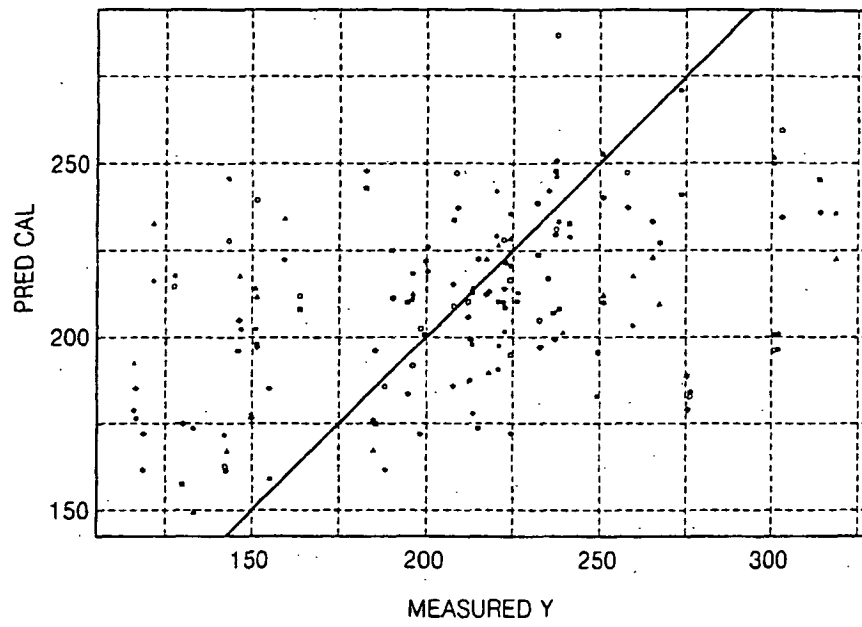


FIG. 10A

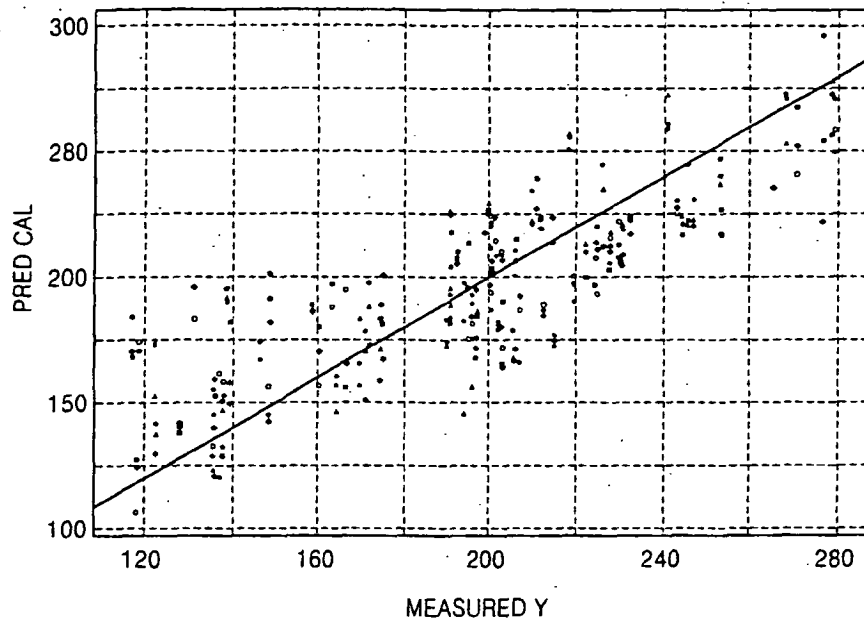
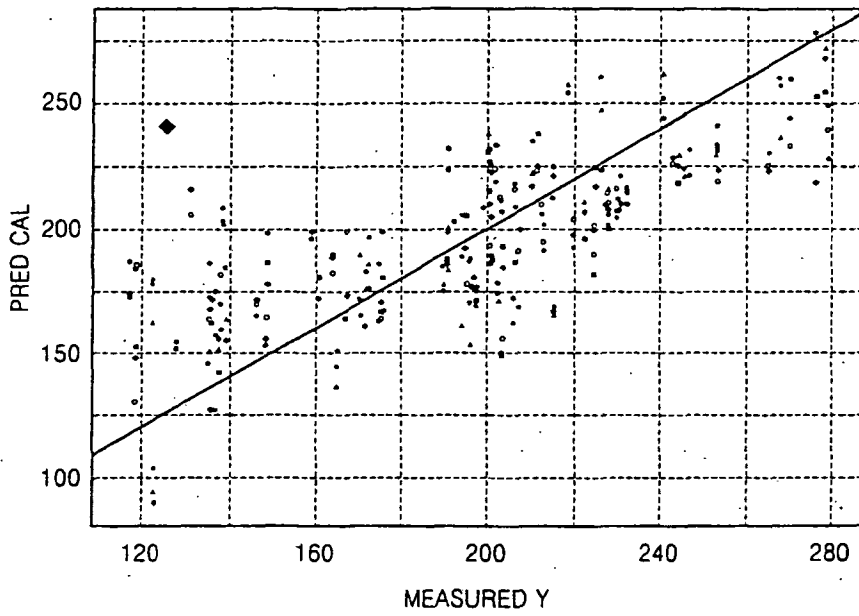


FIG. 10B



专利名称(译)	用于非侵入性地测量血液成分浓度的装置		
公开(公告)号	<a href="#">EP1459679B1</a>	公开(公告)日	2006-06-07
申请号	EP2004251608	申请日	2004-03-19
[标]申请(专利权)人(译)	三星电子株式会社		
申请(专利权)人(译)	SAMSUNG ELECTRONICS CO. , LTD.		
当前申请(专利权)人(译)	SAMSUNG ELECTRONICS CO. , LTD.		
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外部链接	<a href="#">Espacenet</a>		

摘要(译)

在非侵入性地测量血液成分浓度的装置和方法中，该方法包括 ( a ) 改变受试者身体部位的厚度，测量身体部位的不同厚度的吸收光谱，获得第一差分吸收光谱。在不同厚度下测量吸收光谱，实际测量血液成分的浓度，并使用第一差分吸收光谱和实际测量的浓度建立统计模型; ( b ) 基于统计模型，使用相对于身体部位获得的第二差分吸收光谱估计血液成分的浓度。

