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(54) DEVICE FOR VERIFYING THE ACCURACY OF A SPECTRAL ANALYZER

VORRICHTUNG ZUR ÜBERPRÜFUNG DER GENAUIGKEIT EINES SPEKTRALANALYSATORS

DISPOSITIF DE VERIFICATION DE HAUTE PRECISION D'UN ANALYSEUR SPECTRAL

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Description

FIELD OF INVENTION

[0001] This invention is in the field of non-invasive spectral analysis of analytes in tissues and relates more particularly to a device which may be used with a non-invasive monitoring system used for determining concentrations of various blood components.

BACKGROUND OF INVENTION

[0002] Non-invasive devices exist which are used externally to measure either the concentration of the constituents in gases admitted by the body or the concentrations contained in a patient's body part, typically a finger. United States 5,429,128 describes a finger receptor which receives a finger of a user and is for use with a non-invasive monitoring device. United States 5,361,758 describes such a monitoring device.

[0003] During the course of using a monitoring device which is operatively coupled to a finger receptor, many uses of the receptor and the monitoring device will with time result in variations in readings due to internal drift and other variable aspects of such monitoring devices. Accordingly, it is desirable to have a means to rapidly and easily check the precision and accuracy of such a monitoring device.

[0004] U.S. Patent No. 5,166,517 discloses a device according to the preamble of claim 1, for testing the accuracy of a pulse oximeter. The device includes i) a rigid, transparent thermoplastic tube, ii) a transparent, resiliently flexible thermoplastic tube having a displaceable wall and containing a first fluid, and iii) a resiliently flexible member containing the first fluid. The flexible thermoplastic tube is disposed within the rigid tube to define an annular intervening space, which contains a second liquid comprising an aqueous solution of an infrared radiation absorbing compound and a visible red radiation absorbing compound.

[0005] U.S. Patent No. 5,166,517 also discloses a manually operable device for checking the accuracy of a pulse oximeter, which comprises a pair of thin, rectangular shaped plates formed of a material transparent to infrared radiation. A resiliently flexible material separates the rectangular shaped plates from each other. The plates and the resiliently flexible material define a volume occupied by an aqueous solution of an infrared radiation-absorbing compound and a visible red radiation-absorbing compound.

SUMMARY OF THE INVENTION

[0006] The present inventors have developed a device shaped to fit a receptor which is operatively connected to a non-invasive monitoring device, which device is useful in monitoring the precision and accuracy of the non-invasive monitoring device and which permits photometric correction of the instrument.

[0007] In its broad aspect the invention provides a method as defined in claim 8 and a device according to claim 1. The device is made of materials which reproduce absorption spectra associated with various body parts when such parts are subjected to spectral determination. A device according to the present invention is made of a material that exhibits the same light scattering and absorbance characteristics as a body part, preferably of an earlobe, lip, fold of skin or finger, most preferably, a finger.

[0008] According to one embodiment of the present invention there is provided an artificial member defining one or more than one chamber, the artificial member made of a light-scattering and light-reflecting material and configured in the shape of a body part, the light-scattering and light-reflecting material approximating the light-scattering and light-absorbing characteristics of the body part, the artificial member comprising means for sealing the one, or more than one chamber.

[0009] In another embodiment the present invention provides an artificial member defining one, or more than one chamber, the artificial member made of a light-scattering and light-reflecting material selected from the group consisting of Teflon® (polytetrafluoroethylene), Teflon® (polytetrafluoroethylene) with 25% glass fibers, and Fluorosint™, the artificial member configured in the shape of a body part.

[0010] Preferably each chamber is filled with an O-Cel-O™ material, which mimics the light scattering properties of tissue. Preferably each chamber is filled with a gel material containing Amaranth and sodium benzoate and holding light scattering and reflective particles which mimic the light scattering properties of tissue. In yet another embodiment the reflective particles comprise Teflon-PTFE, Titanium Dioxide (TiO2) or are Polystyrene nanospheres.

[0011] In yet another embodiment the member further comprises a stabilizing member extending from the outer portion to reversibly urge the artificial member into contact with the measuring receptor. Preferably the stabilizing member is as depicted in. Figure 9.

[0012] In another aspect according to the present invention there is provided a method for verifying the precision and accuracy of a non-invasive monitoring device comprising:

a) inserting the artificial member of the invention into a measuring receptor, the measuring receptor operatively connected to the non-invasive monitoring device;
b) measuring the absorbance spectrum of the artificial member; and
c) comparing the absorbance spectrum of the artificial member with an absorbance spectrum obtained from the body part, thereby verifying the precision and accuracy of the non-invasive monitoring device.

[0013] Other features and advantages of the present

invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples while indicating preferred embodiments of the invention are given by way of illustration only, since various changes and modifications within the scope of the invention as defined in the appended claims will become apparent to those skilled in the art from this detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The invention will now be described in relation to the drawings in which.

Figure 1: shows absorbance spectra from 500-1380 nm for globulins, glucose, urea, creatinine, cholesterol and human serum albumin with water displacement compensation.

Figure 2 shows 2013 absorbance spectra from 585-1100 nm for the finger from 32 subjects.

Figure 3 shows absorbance spectra (580-1100 nm) for water in a subject's finger and an artificial member of the present invention.

Figure 4 shows absorbance spectra from 580-1100 nm for a subject's finger and an artificial member as shown in Figure 3 as well as the curve representing difference of the first two spectra.

Figure 5 is absorbance spectra from 580-1100 nm for water in a finger and in an artificial member of the invention where the member contains pink sponge (SCOTCH BRIGHT™) and water.

Figure 6 is absorbance spectra from 580-1100 nm for water in a finger and in an artificial member of the invention where the member contains Polystyrene nanospheres in water and gelatin plus Amaranth and sodium benzoate as a preservative.

Figure 7 is an isometric exploded view of an artificial member according to the present invention in a configuration for use with a finger receptor.

Figure 8 is a side view of the member of Figure 7.

Figure 9 is an isometric exploded view of a further embodiment of an artificial member according to the present invention in a configuration for use with a finger receptor.

Figure 10 is a side view of the member of Figure 9.

Figure 11 is a side view of an assembled member of Figures 9 and 10.

DETAILED DESCRIPTION OF THE INVENTION

[0015] As used herein "concentration" or "concentration level" means the amount or quantity of a constituent in a solution whether the solution is in vitro or in vivo.

[0016] As used herein, "constituent" means a substance, or analyte found in a tissue and includes carbohydrates such as for example glucose, bilirubin, a protein, for examples albumin or , hemoglobin.

[0017] As used herein, "fluid free" means having no appreciable amount of liquid present,

[0018] As used herein, "tissue" means any tissue of the body of a subject including for example, blood, extracellular spaces, and can mean the entire composition of a body part such as a finger or ear lobe.

[0019] As used herein "subject" means any member of the animal kingdom including, preferably, humans.

[0020] As stated above, the present inventors have prepared a device which is capable of insertion in a receptor which is used with a non-invasive monitoring device. The use of such a device or artificial member is to enable the user of such a non-invasive monitoring device to quickly and easily check the precision and accuracy of the non-invasive monitoring device.

[0021] Spectral data, obtained using a standard spectrophotometer and compensated for water displacement, were collected from in vitro measurement of a cuvette containing samples of various blood constituents and are illustrated in Figure 1. As may be seen, the spectra associated with the various constituents are complex. In contrast, the spectra for a living finger is relatively simple, particularly in the 500-1100 nm region. This may be seen in Figure 2. Measurements taken in this region are relatively consistent regardless of individual measurements or the individual being scanned. In this respect, the data presented in Figure 2 represent the combined spectra of 33 people for whom a total of 2,013 measurements were taken and are collectively presented. Accordingly, an artificial member must be able to provide a spectrum which is comparable to those presented in Figure 2 or the absorbance spectra of another body part. It will be appreciated that in order to develop a comparable artificial member, such member must mimic the situation of which light is directed to a body part. Light entering the body is scattered and that light which emerges and radiates in virtually every direction. Absorption begins at the point of which the light enters the tissue. In the case of transmission, as the light passes through the tissue, more and more light is absorbed as the path length increases. Clearly, if path length is too great, very little light is left for measurement and the absorbance calculations will be subject to considerable error due to noise. The considerations are also true in respect of the artificial mem-

ber. Consequently, according to one embodiment of the present invention, it is the artificial member that will exhibit the same properties of light scattering, reflectivity and absorption as exhibited by a living human finger. Accordingly, an artificial member of the present invention is made of a highly reflective material such as, for example, teflon, in particular teflon-PTFE virgin material (where PTFE means polytetrafluoroethylene). In addition, to concurrently mimic scatter, which is derived from the interior of a living body part, the artificial member must show sufficient internal reflectance to achieve a comparable result. In this respect, a chamber, or container space exists in the member, although, depending on the body part being mimiced, reflective material may comprise part of the internal structure of the chamber of the member.

[0022] An artificial member must be capable of being easily inserted into and removed from a receptor which is used to measure spectral characteristics of constituents in a body part. In this respect, the shape of the artificial member will be determined by the shape of the receptor. In the case of a finger receptor, the artificial member must have corresponding shapes to ensure that there is a constant path length from the point at which light is delivered to the finger or artificial finger and the point at which light exists the finger or artificial body part.

[0023] It will be appreciated by those skilled in the art that an artificial member of the present invention is for use in association with any measuring receptor which is combined with any non-invasive monitoring device which is based on the principle of measuring the absorbance (or reflectance) of radiation passing through (or reflecting from) a body part. In this respect, such devices operate according to the Beer-Lambert law, namely that the concentration of constituents is proportional to a constant of proportionality (the extinction coefficient), the path length, and the absorbance (LOG_{10} [1 /T], where T is the transmittance, i.e., the proportion of light of a given wavelength that is transmitted through the matrix).

[0024] By measuring the absorbance at a number of predetermined wavelengths, some of which will control for path length, it is possible to calculate the concentration of a given constituent. The same principles of measurement which are applied to determining concentration of constituents in body parts with a non-invasive device are equally applicable to an artificial member of the present invention. Consequently, while water is a preferred constituent for measurement and accuracy testing with an artificial member, any other constituent, or constituents may be used. In this respect, it will be appreciated that the constituents will be preferably held in the member, preferably in the chamber or chambers of the member. In some applications it may be necessary to introduce other absorbing or reflecting material in the chamber or intermixed with the composition of the reflective material.

[0025] It should be noted that there are several ways in which absorbance measurements may be taken, and without limiting the scope of the applicability of the present invention, the two methods are: (1) use light from a scanning monochromator and pass it through a selected part of the body and collect the light transmitted through onto a silicon detector. A second measurement involves a measurement of the light transmitted in the absence of the body part. From these two measurements the transmittance, and hence the absorbance, may be calculated; (2) use a polychromatic light source, pass it through the body part to be measured, collect the light, collimate it onto a diffraction grating and focus the different wavelengths of light on a linear array detector. Each element of the array will then measure the intensity of light for a narrow band of wavelengths. A similar measurement in the absence of the body part (reference scan) will then allow computation of the transmittance for each element. Because the various elements of the array have slightly difference dark leakage currents, it is necessary to record a dark current and subtract it from both the sample scan and the reference scan before calculation of transmittance and absorbance.

[0026] There are several typical parts of the body from which measurements are made and these include the finger, the lip, the earlobe, a pinch of skin at the waist, the web between the thumb and forefinger, the web between toes. Accordingly, the present invention includes artificial members replicating each of these.

[0027] One of the problems encountered in measuring absorbance in tissue is the spectral variability from one instrument to another due to physical differences in light transmission and collection. Because the phantom finger is designed to minimize variability of spectral response and physical placement in the finger receptor, it can be used to quantify the spectral differences between instruments. With careful wavelength calibration, the difference in spectral response of the phantom finger between one instrument and another may be used to correct the spectrum of the second instrument to that of the first by adding the spectral difference to the second instrument. This is termed photometric correction and coupled with suitable wavelength accuracy, is the basis on which algorithms can be transferred from one instrument to another.

DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0028] We will now describe two non-limiting exemplary embodiments of the present invention. Firstly, referring to Figures 7 and 8, an artificial member according to the present invention is illustrated. In particular, the artificial member is intended to represent an artificial finger for use in association with a finger receptor which is operatively connected to a non-invasive monitoring device such as a spectrophotometer.

[0029] The artificial finger is comprised of a handle which may be prepared from aluminum or any other material which is rigid and has strength characteristics. The handle at 20 has a tip 30 which is used to connect the handle with a holding collar 40. The holding collar is used

to provide a large grasping, means as well as sealing cover for the highly reflective and light scattering portion of the artificial finger 80. The holding collar 40 is made of black plastic (DELRIN); however, any other minimally reflective or nonreflective plastic material is acceptable. The holding collar fits by means of an interference fit over the artificial member 80. The artificial member 80 is comprised of a material which provides a scattering effect similar to tissue such as the skin or a digit, namely Teflon-PTFE; however, any other material such as Fluorosint™ (DSM Engineering Plastic Products, Inc.) or Teflon-PTFE with 25% glass fibers which is capable of providing such a scattering effect is suitable. This member has a hollow or chamber-like portion which determines the amount of internal scattering based on the material filling the cavity. The exact dimensions of this chamber are selected to achieve a spectrum of absorption similar to that observed of a natural finger. More than one chamber may be used. According to a preferred embodiment the chamber as shown in Figure 7 is divided into two portions, 90 and 100, although similar results may be achieved with more chambers. The chambers 90 and 100 act as containers to hold water or any other solutions which are being used as part of the artificial member. Also placed in the artificial member for the purposes of replicating absorbance of a finger are O-cello materials commonly available as sponge (SCOTCH BRIGHT™) and which are shaped to fit into the containers 90 or 100. The chamber may also be filled with gel materials which hold light scattering materials such as Titanium Dioxide (TiO2) or Polystyrene nanospheres.

[0030] A stopper made of rubber or other suitable material is fashioned to fit in to seal the top open end of containers 90 and 100 over which holder collar 40 is placed. These parts and their interrelationship is better seen in Figure 8 which provides a side view of the artificial finger and illustrates the components in place. The shaping of the artificial finger in order to provide an interface between the artificial member and the receptor thereby achieving a minimum of variability and maximum of repeatability whilst allowing for the passage of light through the artificial member thereby optimizing pathlength and its variability between measurements with the artificial member is seen in the isometric exploded view in Figure 6 as item 110. This shaping will vary from one artificial member to the other depending upon the receptor for which the artificial members created and depending upon the device in which the artificial member is being used to verify the accuracy of the spectral analyzer.

[0031] Referring now to Figures 9 10, and 11, another embodiment of an artificial member according to the present invention is illustrated. In particular, this artificial member is also intended to represent an artificial finger for use in association with a finger receptor which is operatively connected to a non-invasive monitoring device such as a spectrophotometer.

[0032] The artificial finger (200) of Figures 9, 10, and 11 is comprised of a handle, which may be prepared from aluminum or any other material, which is rigid and has strength characteristics. The handle at 290 has a tip 300, which is used to connect the handle to the artificial member 210 at 230. The artificial member is comprised of a material which provides a scattering effect similar to tissue such as the skin or a digit, namely Teflon-PTFE; however, any other material such as Fluorosint™ or Teflon-PTFE with 25% glass fibers which is capable of providing such a scattering effect is suitable. This member has a hollow or chamber-like portion 220, which determines the amount of internal scattering based on the material filling the cavity. The exact dimensions of this chamber are selected to achieve a spectrum of absorption similar to that observed of a natural finger. More than one chamber may be used. The chamber 220 acts as container to hold water or any other solutions which are being used as part of the artificial member 210. Also placed in the artificial member for the purposes of replicating absorbance of a finger are O-cell-o materials commonly available as sponge 260 (SCOTCH BRIGHT™) and which is shaped to fit into the container 220. The chamber 220 may also be filled with gel materials, which hold light scattering materials such as Titanium Dioxide (TiO2) or Polystyrene nanospheres. A stopper 270 made of rubber or other suitable material is fashioned to fit in to seal the top open end of the chamber 220. The stopper 270 maybe inserted or removed by gripping the stub 280 provided or this purpose. A plunger, or "stabilizing member" 240 made of 303 Stainless Steel or other material which is rigid and has strength characteristics is press fit into the top of the artificial member into mating cavity 250 and is held in place by an interference fit between the two parts. The purpose of the interlocking plunger 240 is to provide exact placement and holding of the artificial member when inserted into a finger receptor which is operatively connected to a non-invasive monitoring device. The stabilizing member 240 when the artificial member is inserted into the finger receptor mates with a corresponding hole precisely placed in the finger receptor for this purpose, resulting in accurate placement of the artificial member 210 each time it is inserted into the finger receptor. These parts and their interrelationship is better seen in Figure 11 which provides a side view of the artificial finger and illustrates the components in place.

[0033] The following non-limiting examples are illustrative of the present invention.

EXAMPLES

Example 1

[0034] An artificial finger made of Teflon-PTFE was prepared, although as just stated any other highly reflective and light scattering material can be used. The artificial finger has a hollow portion containing within a further reflective surface, also made of Teflon-PTFE. When filled with water, the artificial finger provides a spectrum somewhat similar to that observed in a normal finger (see Fig-

ure 3). However, the peak of high absorbance found in the 580 nm region for a normal finger is noticeably missing. Indeed, the different aspects of the artificial finger and a normal finger are illustrated in Figure 4. As may be seen the only significant difference resides in the portion of the spectrum peak in the 580 nm region. To overcome the deficiency of the absorption spectra, various materials were tried; however, the inventors have determined that sponge pads (e.g. SCOTCH BRIGHT™) or other similar material is capable of providing an absorption spectrum like that of Amaranth which is comparable to absorption in a normal human finger. This may be seen most clearly in Figure 5. This artificial finger can be used to check the performance of any non-invasive monitoring device which is used to monitor the concentrations of various components of a subject's body parts.

Example 2

[0035] An artificial finger made of Teflon-PTFE was prepared, although as just stated any other highly reflective and light scattering material can be used. The artificial finger has a hollow portion containing within a further reflective surface, also made of Teflon-PTFE. When filled with water, the artificial finger provides a spectrum somewhat similar to that observed in a normal finger (see Figure 3). However, the peak of high absorbance found in the 580 nm region for a normal finger is noticeably missing. Indeed, the different aspects of the artificial finger and a normal finger are illustrated in Figure 4. As may be seen the only significant difference resides in the portion of the spectrum peak in the 580 nm region. To overcome the deficiency of the absorption spectra, various materials were tried; however, the inventors have determined that sponge pads (e.g. SCOTCH BRIGHT™) or other similar material is capable of providing an absorption spectrum like that of Amaranth which is comparable to absorption in a normal human finger. This may be seen most clearly in Figure 5.

[0036] An artificial finger made of Teflon-PTFE was prepared, and as just stated any other highly reflective and light scattering material can be used. The artificial finger has a hollow portion containing within a further reflective surface, also made of Teflon-PTFE. As just described, when filled with water, the artificial finger provides a spectrum somewhat similar to that observed in a normal finger, and the only significant difference resides in the portion of the spectrum peak in the 580 nm region. To overcome the deficiency of the absorption spectra nanospheres of polystyrene in water and gelatin plus Amaranth and sodium benzoate as a preservative were used. The results are illustrated in Figure 6 .

[0037] As is readily apparent from the foregoing, this artificial finger can be used to check the performance of any non-invasive monitoring device which is used to monitor the concentrations of various components of a subject's body parts.

[0038] While the present invention has been described with reference to what are presently considered to be preferred examples, it is to be understood that the invention is not limited to the disclosed examples. To the contrary, the invention is intended to cover various modifications scope of the appended claims.

Claims

1. An artificial member (80,200,210), which mimics the absorbance spectrum of a body part and includes spectral components of blood analytes, said artificial member defining at least one chamber (90,100), said member being configured to be reproducibly received in a measuring receptor and said artificial member being configured in the shape of a body part, **characterised in that** said member is made of light scattering and light reflecting material selected from the group consisting of Teflon® (PTFE), Teflon® with 25% glass fibers, and Fluorosint™.

2. The artificial member (80, 200, 210) of claim 1, wherein the body part is selected from the group consisting of a finger, a lip, an earlobe, a pinch of skin at the waist, a web between the thumb and forefinger, a web between toes.

3. The artificial member (80, 200, 210) of claim 1 or 2, wherein the at least one chamber, (90, 100, 220) is filled with water, O-Cel-O™, or a gel material containing Amaranth, sodium benzoate and light-scattering and reflective particles.

4. The artificial member (80, 200, 210) according to claim 3, wherein the light-scattering and reflective particles comprise Teflon® (polytetrafluoroethylene), Titanium Dioxide (TiO_2) or polystyrene nanospheres.

5. The artificial member (80, 200, 210) of any one of claims 1 to 4, wherein the artificial member defines two or more than two chambers (90, 100, 220).

6. The artificial member (80, 200, 210) of any one of claims 1 to 4, further comprising a removable seal for sealing the at least one chamber (90, 100, 220).

7. The artificial member (80, 200, 210) of claim 5, further comprising a removable seal for sealing the two or more than two chambers (90, 100, 220).

8. A method for verifying the precision and accuracy of a non-invasive monitoring device comprising:

   inserting the artificial member (80, 200, 210) according to any one of claims 1 to 7 into a measuring receptor, the measuring receptor operatively connected to the non-invasive monitoring

device;
measuring the absorbance spectrum of the artificial member (80, 200, 210); and
comparing the absorbance spectrum of the artificial member (80, 200, 210) with an absorbance spectrum obtained from the body part, thereby verifying the precision and accuracy of the non-invasive monitoring device.

Patentansprüche

1. Künstliches Teil (80, 200, 210), das das Absorptionsspektrum eines Körperteils nachahmt und Spektralkomponenten von Blutbestandteilen aufweist, wobei das künstliche Teil wenigstens eine Kammer (90, 100, 220) definiert, wobei das Teil eingerichtet ist, um reproduzierbar von einem Meßrezeptor aufgenommen zu werden, und wobei das künstliche Teil in der Form eines Körperteils ausgebildet ist, **dadurch gekennzeichnet, daß** das Teil aus einem lichtstreuenden und lichtreflektierenden Material besteht, welches ausgewählt ist aus der Gruppe bestehend aus Teflon® (PTFE), Teflon® (PTFE) mit 25% Glasfasern, und Fluorosint™.

2. Künstliches Teil (80, 200, 210) nach Anspruch 1, bei dem das Körperteil ausgewählt ist aus der Gruppe bestehend aus einem Finger, einer Lippe, einem Ohrläppchen, einer Hautfalte am Bauch, Gewebe zwischen dem Daumen und dem Zeigefinger, und Gewebe zwischen Zehen.

3. Künstliches Teil (80, 200, 210) nach Anspruch 1 oder 2, bei dem die wenigstens eine Kammer (90, 100, 220) gefüllt ist mit Wasser, O-Cel-O™, oder einem Gelmaterial, das Amarant, Natriumbenzoat und lichtstreuende und reflektierende Teilchen enthält.

4. Künstliches Teil (80, 200, 210) nach Anspruch 3, bei dem die lichtstreuenden und reflektierenden Teilchen Teflon® (Polytetrafluoroethylen), Titandioxid (TiO_2) oder Polystyrol Nanokügelchen umfassen.

5. Künstliches Teil (80, 200, 210) nach einem der Ansprüche 1 bis 4, bei dem das künstliche Teil zwei oder mehr als zwei Kammern (90, 100, 220) definiert.

6. Künstliches Teil (80, 200, 210) nach einem der Ansprüche 1 bis 4, das ferner eine entfernbare Dichtung umfaßt, um die wenigstens eine Kammer (90, 100, 220) abzudichten.

7. Künstliches Teil (80, 200, 210) nach Anspruch 5, das ferner eine entfernbare Dichtung umfaßt, um die zwei oder mehr als zwei Kammern (90, 100, 220) abzudichten.

8. Verfahren zur Überprüfung der Präzision und Genauigkeit einer eingriffsfreien Kontrollvorrichtung, umfassend:

a) Einführen des künstlichen Teils (80, 200, 210) gemäß einem der Ansprüche 1 bis 7 in einen Meßrezeptor, wobei der Meßrezeptor mit der eingriffsfreien Kontrollvorrichtung zusammenwirkt;
b) Messen des Absorptionsspektrums des künstlichen Teils (80, 200, 210); und
c) Vergleichen des Absorptionsspektrums des künstlichen Teils (80, 200, 210) mit einem Absorptionsspektrum, das von dem Körperteil erhalten wurde, wodurch die Präzision und Genauigkeit der eingriffsfreien Kontrollvorrichtung überprüft wird.

Revendications

1. Un membre artificiel (80, 200, 210) qui imite le spectre d'absorbance d'une partie de corps et comprend des composantes spectrales d'analytes sanguins, ledit membre artificiel définissant au moins une chambre (90, 100, 220), ledit membre étant configuré pour être reçu de façon reproductible dans un récepteur de mesure et ledit membre artificiel étant configuré sous la forme d'une partie de corps, **caractérisé en ce que** ledit membre est réalisé en un matériau qui diffuse la lumière et qui réfléchit la lumière sélectionné dans le groupe consistant en Teflon® (PTFE), Teflon® (PTFE) possédant 25 % de fibres de verre, et Fluorosint™.

2. Le membre artificiel (80, 200, 210) de la revendication 1, dans lequel la partie de corps est sélectionnée dans le groupe consistant en un doigt, une lèvre, un lobe d'oreille, un pli de peau au niveau de la taille, une commissure interdigitale entre le pouce et l'index, et une commissure interdigitale entres les orteils.

3. Le membre artificiel (80, 200, 210) de la revendication 1 ou 2, dans lequel cette au moins une chambre (90,100, 220) est remplie d'eau, d'O-Cel-O™ ou d'un matériau gélifié contenant de l'amarante, du benzoate de sodium et des particules réfléchissantes et qui diffusent la lumière.

4. Le membre artificiel (80, 200, 210) selon la revendication 3, dans lequel les particules réfléchissantes et qui diffusent la lumière comportent du Teflon® (polytétrafluoroéthylène), du dioxyde de titane (TiO_2) ou des nanosphères de polystyrène.

5. Le membre artificiel (80, 200, 210) de n'importe laquelle des revendications 1 à 4, dans lequel le mem-

bre artificiel définit deux ou plus de deux chambres (90, 100, 220).

6. Le membre artificiel (80, 200, 210) de n'importe laquelle des revendications 1 à 4, comportant en outre un joint pouvant être retiré destiné à fermer hermétiquement cette au moins une chambre (90, 100, 220).

7. Le membre artificiel (80, 200, 210) de la revendication 5, comportant en outre un joint pouvant être retiré destiné à fermer hermétiquement les deux ou plus de deux chambres (90, 100, 220).

8. Une méthode destinée à vérifier la précision et l'exactitude d'un dispositif de surveillance non invasif, comportant :

a) insérer le membre artificiel (80, 200, 210) selon n'importe laquelle des revendications 1 à 7 jusque dans un récepteur de mesure, le récepteur de mesure étant raccordé de façon opérationnelle au dispositif de surveillance non invasif ;
b) mesurer le spectre d'absorbance du membre artificiel (80, 200, 210) ; et
c) comparer le spectre d'absorbance du membre artificiel (80, 200, 210) et un spectre d'absorbance obtenu à partir de la partie de corps, vérifiant de ce fait la précision et l'exactitude du dispositif de surveillance non invasif.

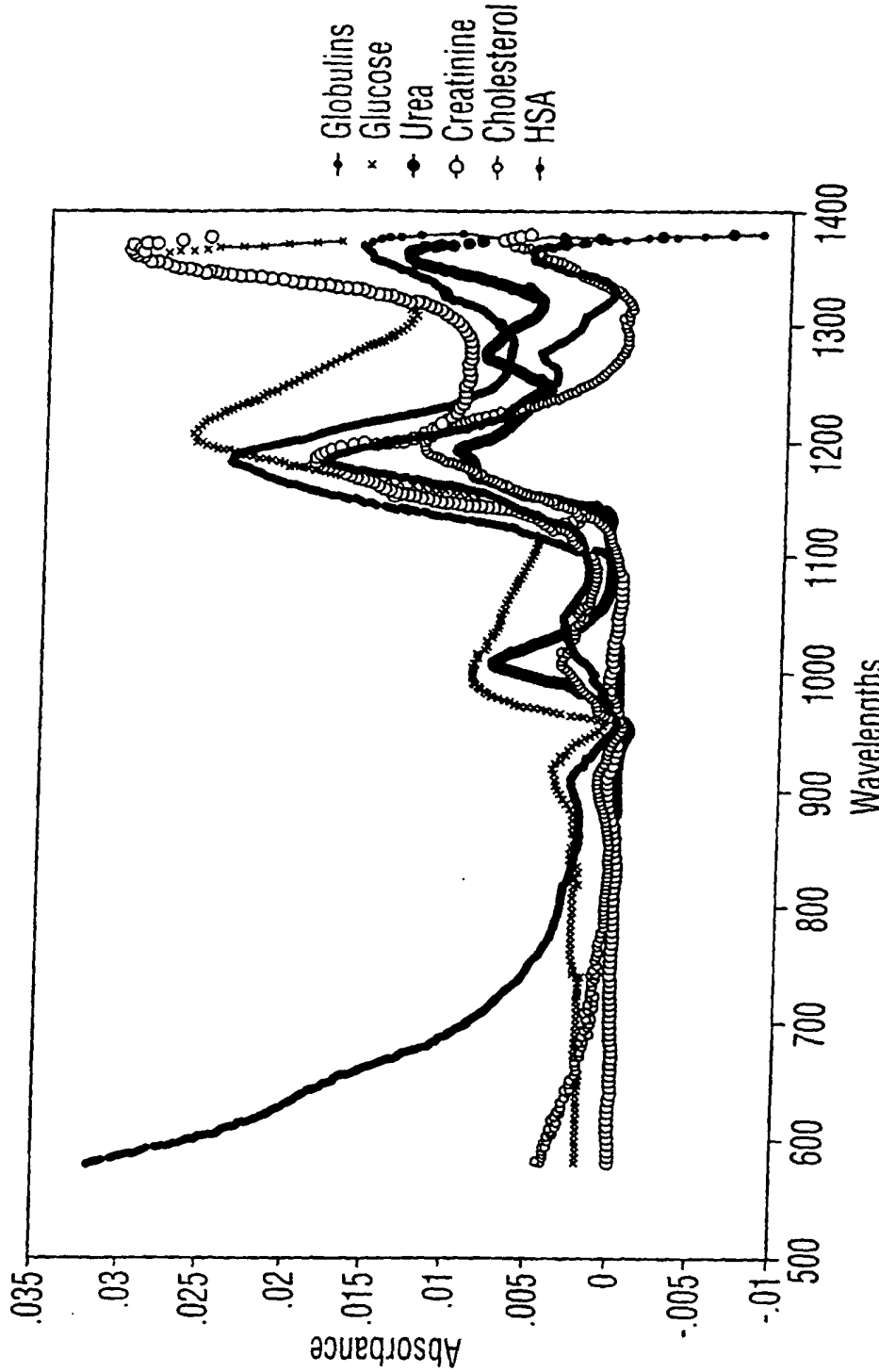
Globulins
Glucose
Urea
Creatinine
Cholesterol
HSA
Absorbance
.035
.03
.025
.02
.015
.01
.005
0
-.005
-.01
500
600
700
800
900
1000
1100
1200
1300
1400
Wavelengths

FIGURE 1

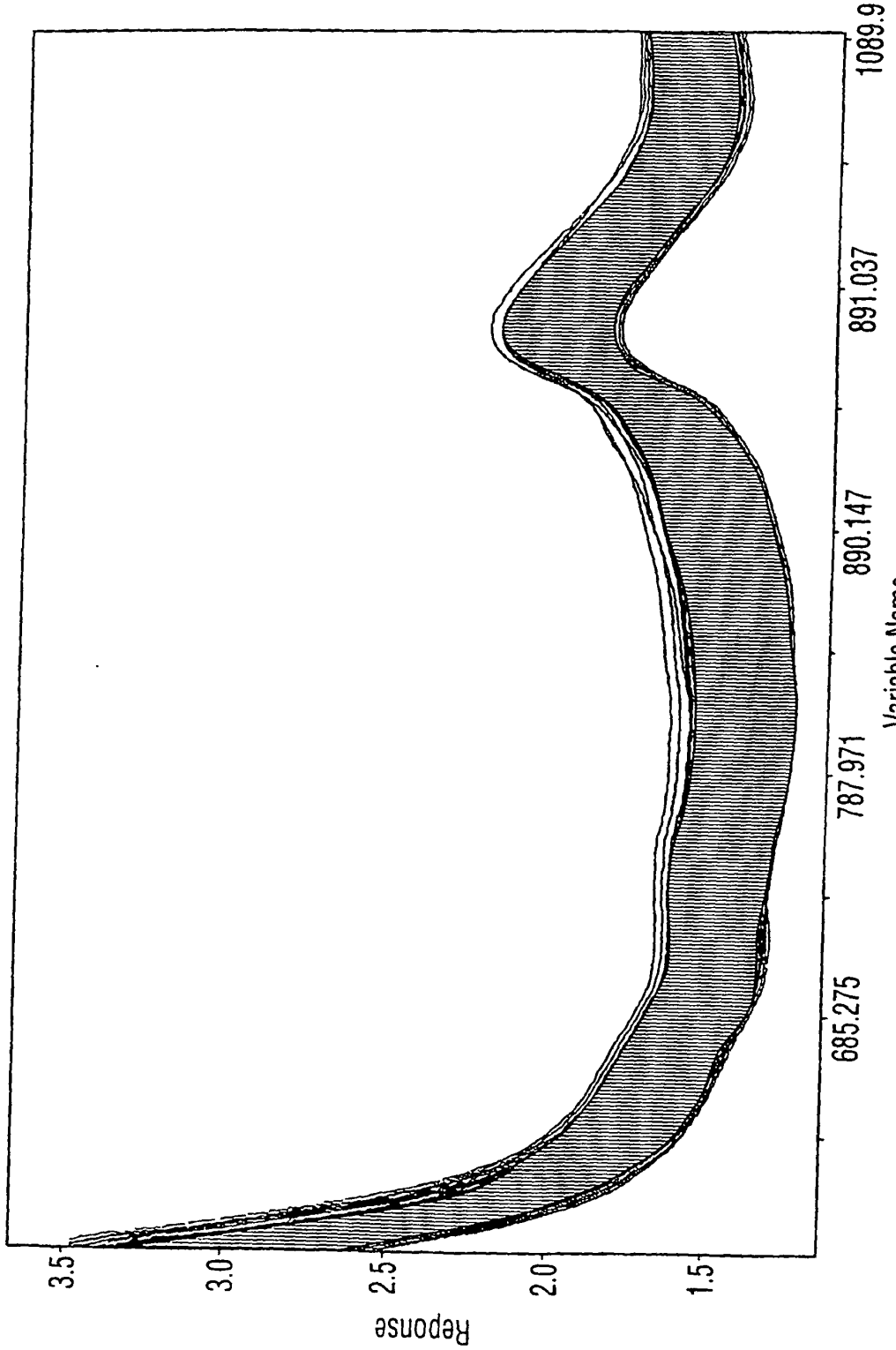
Response
3.5
3.0
2.5
2.0
1.5
685.275
787.971
890.147
891.037
1089.9
Variable Name

FIGURE 2

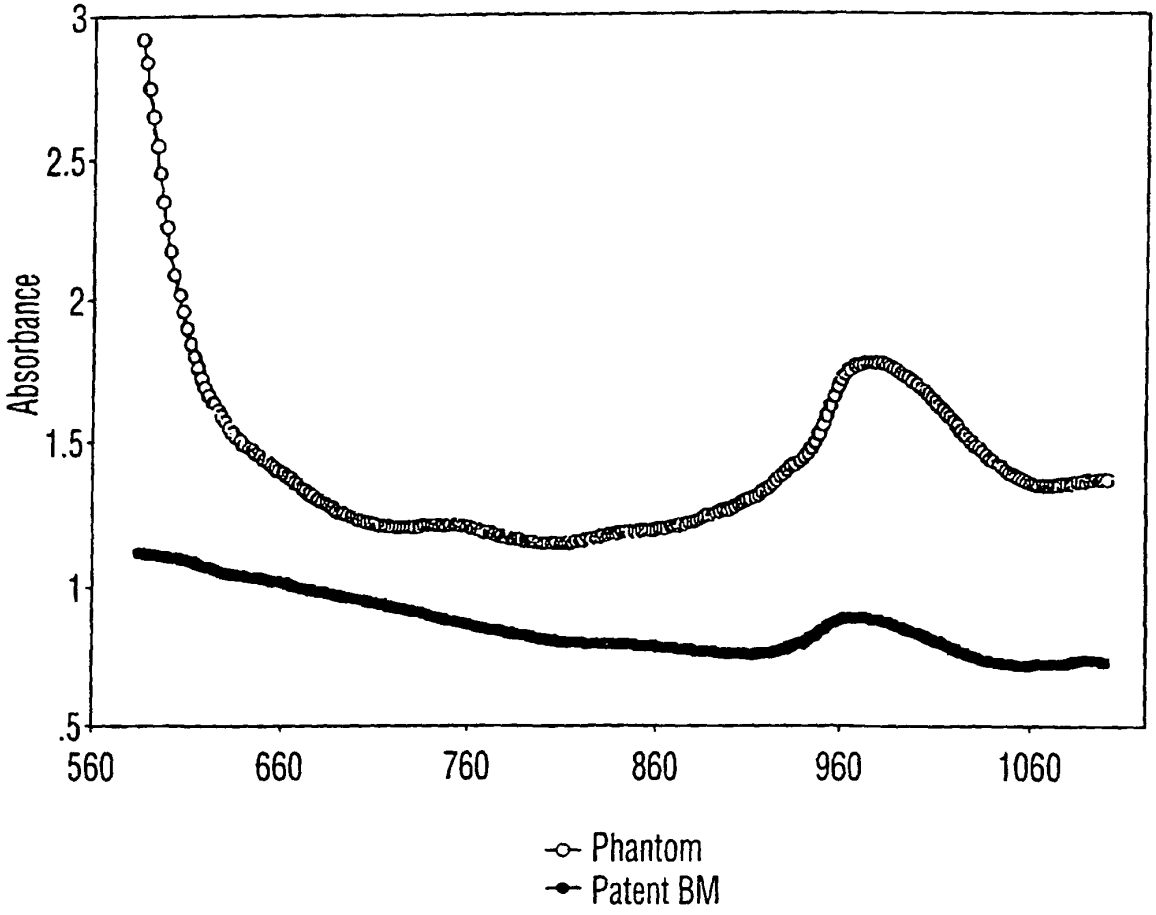
3
2.5
2
1.5
1
.5
Absorbance
560
660
760
860
960
1060
Phantom
Patent BM

FIGURE 3

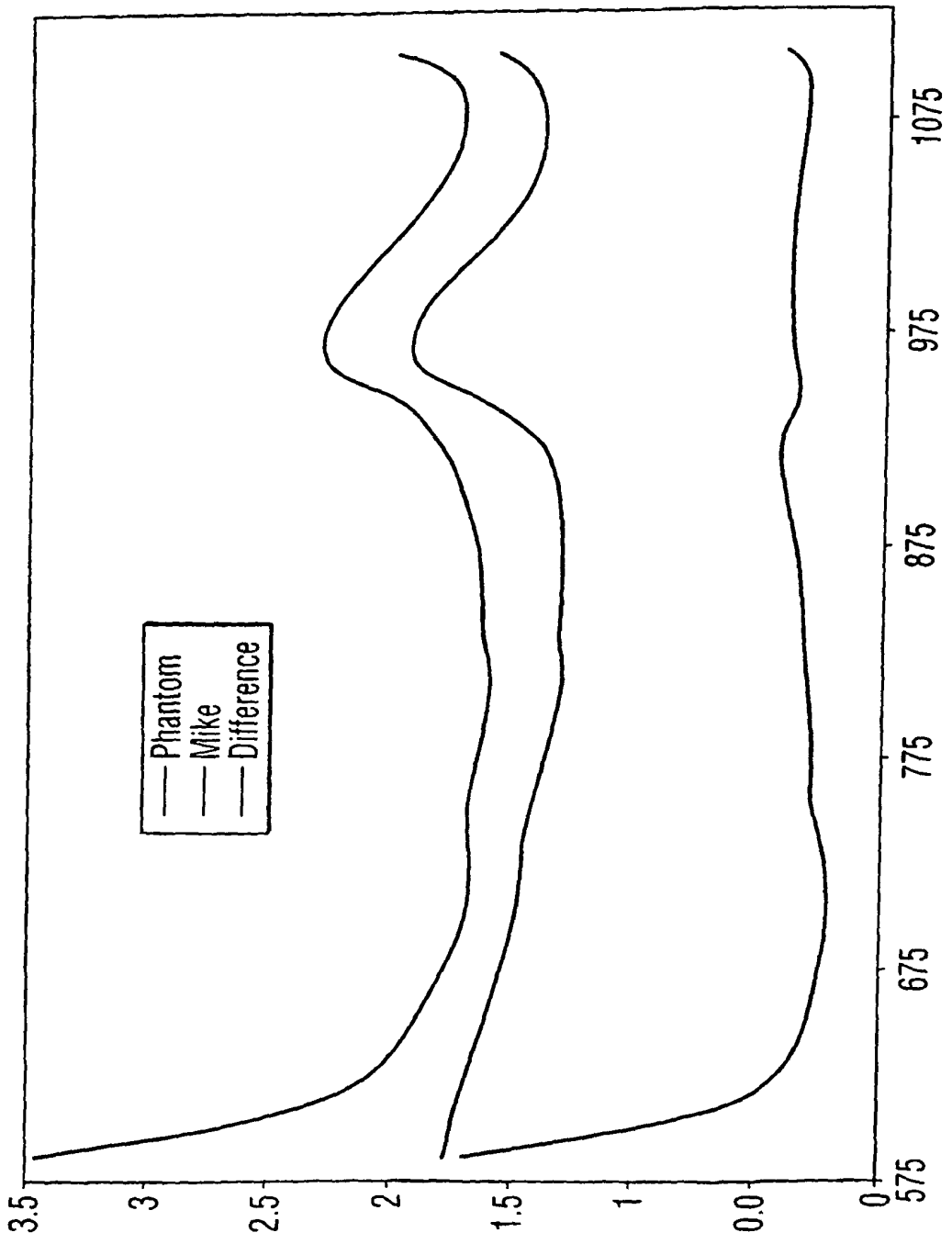
Phantom
Mike
Difference
3.5
3
2.5
2
1.5
1
0.0
0
575
675
775
875
975
1075

FIGURE 4

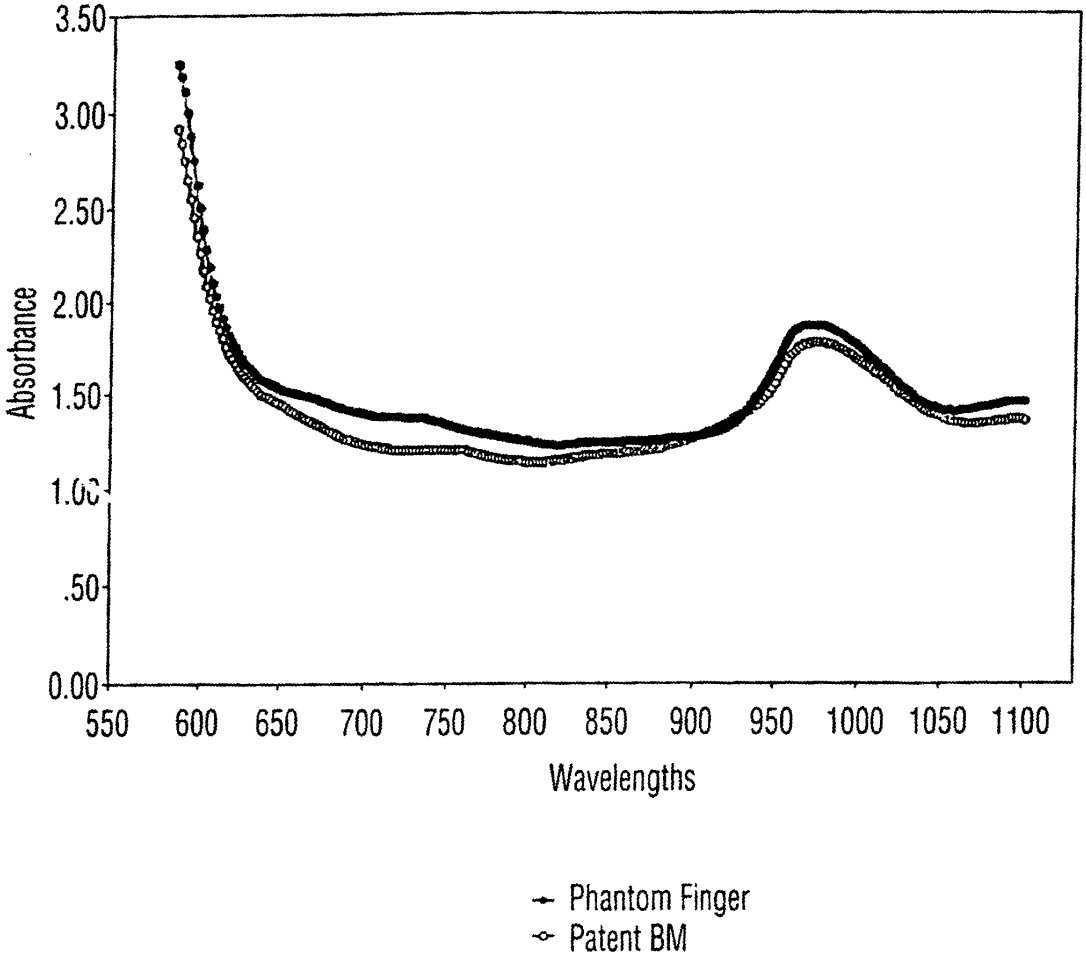
3.50
3.00
2.50
2.00
1.50
1.00
.50
0.00
Absorbance
550
600
650
700
750
800
850
900
950
1000
1050
1100
Wavelengths
Phantom Finger
Patent BM

FIGURE 5

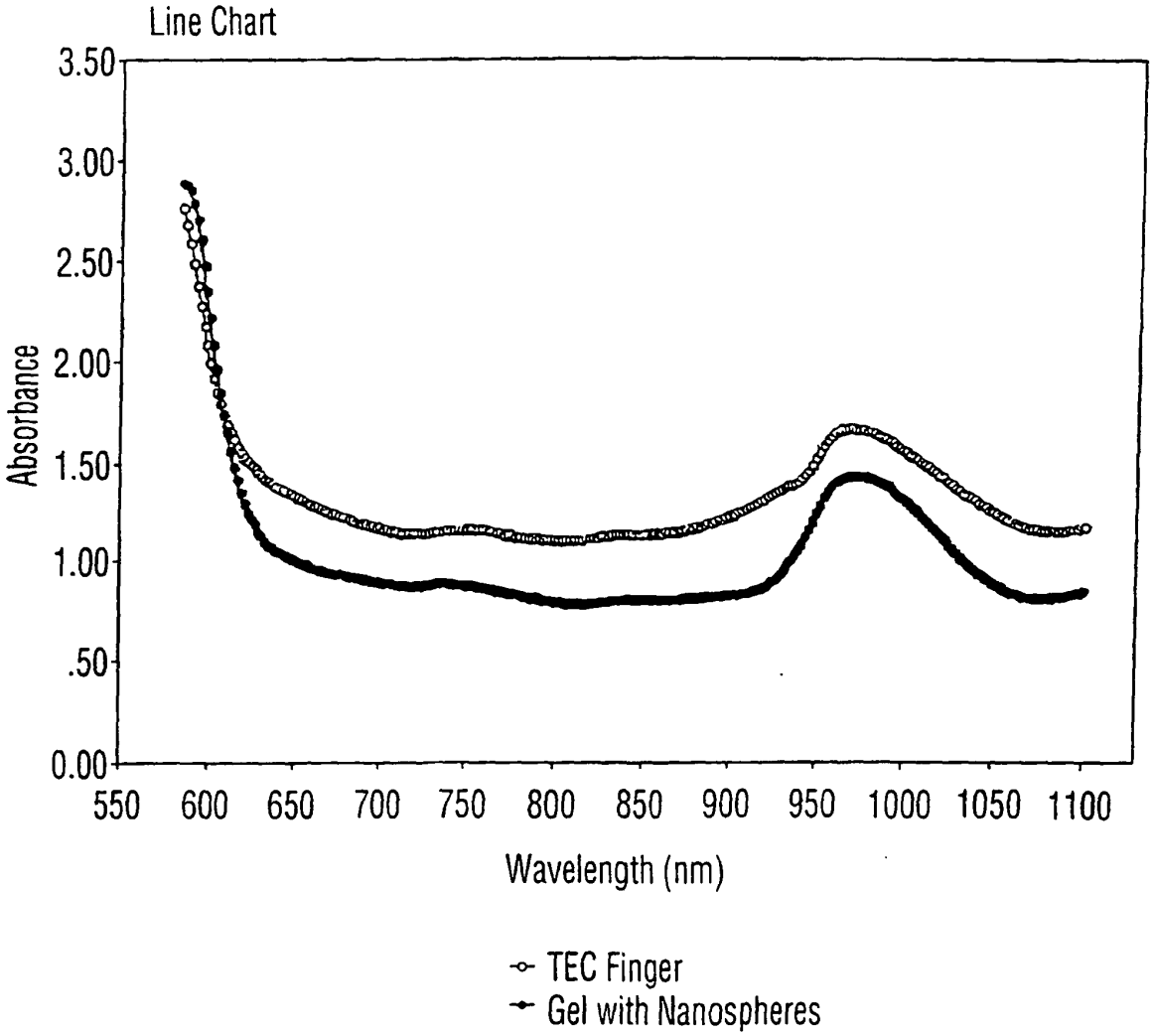
Line Chart
3.50
3.00
2.50
2.00
1.50
1.00
.50
0.00
Absorbance
550
600
650
700
750
800
850
900
950
1000
1050
1100
Wavelength (nm)
TEC Finger
Gel with Nanospheres

FIGURE 6

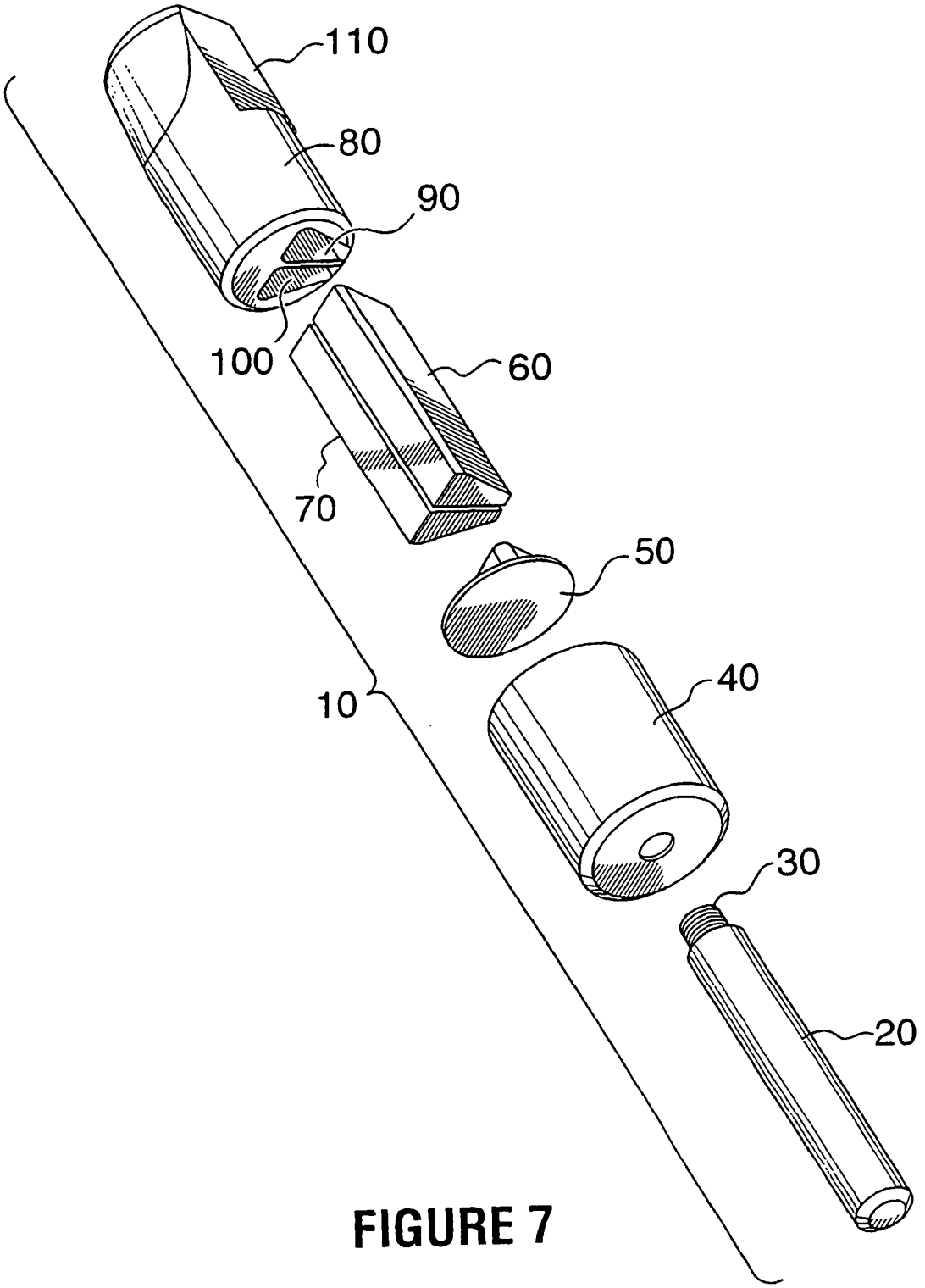

FIGURE 7

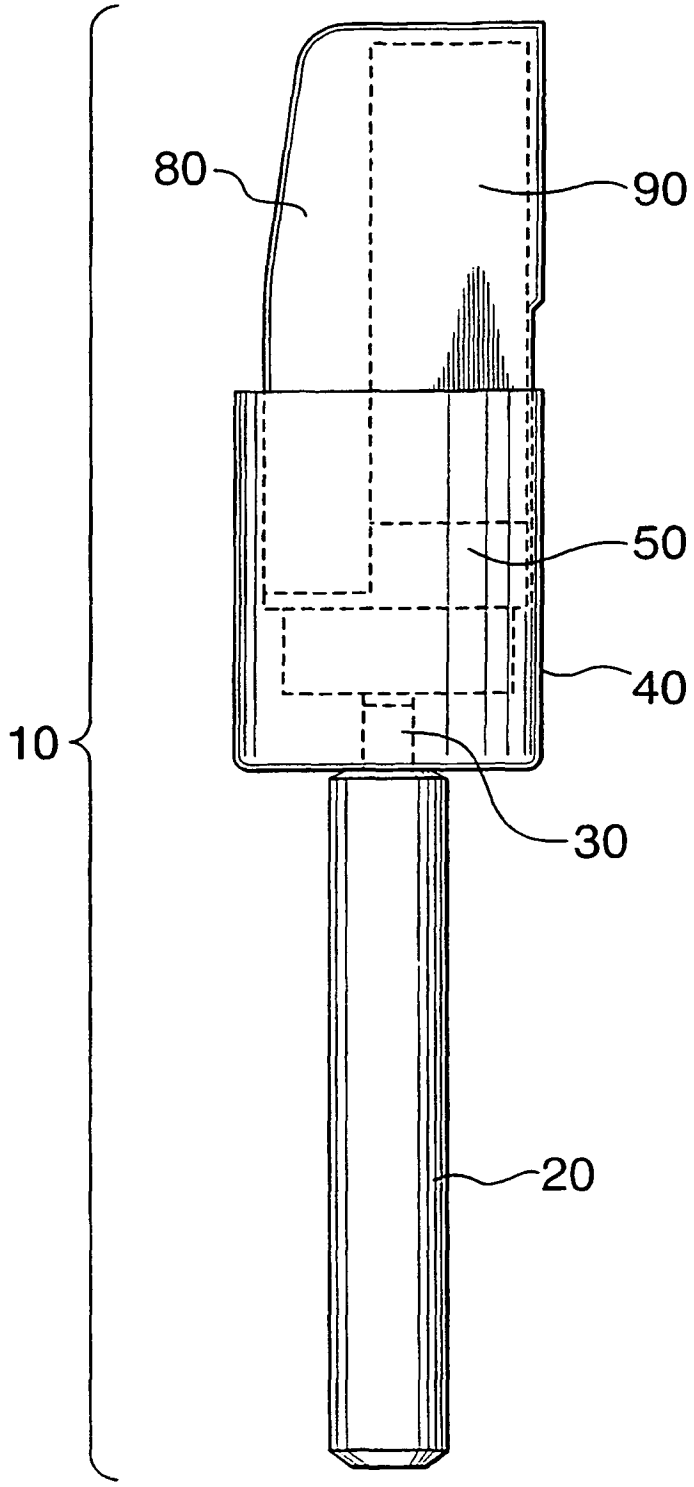

FIGURE 8

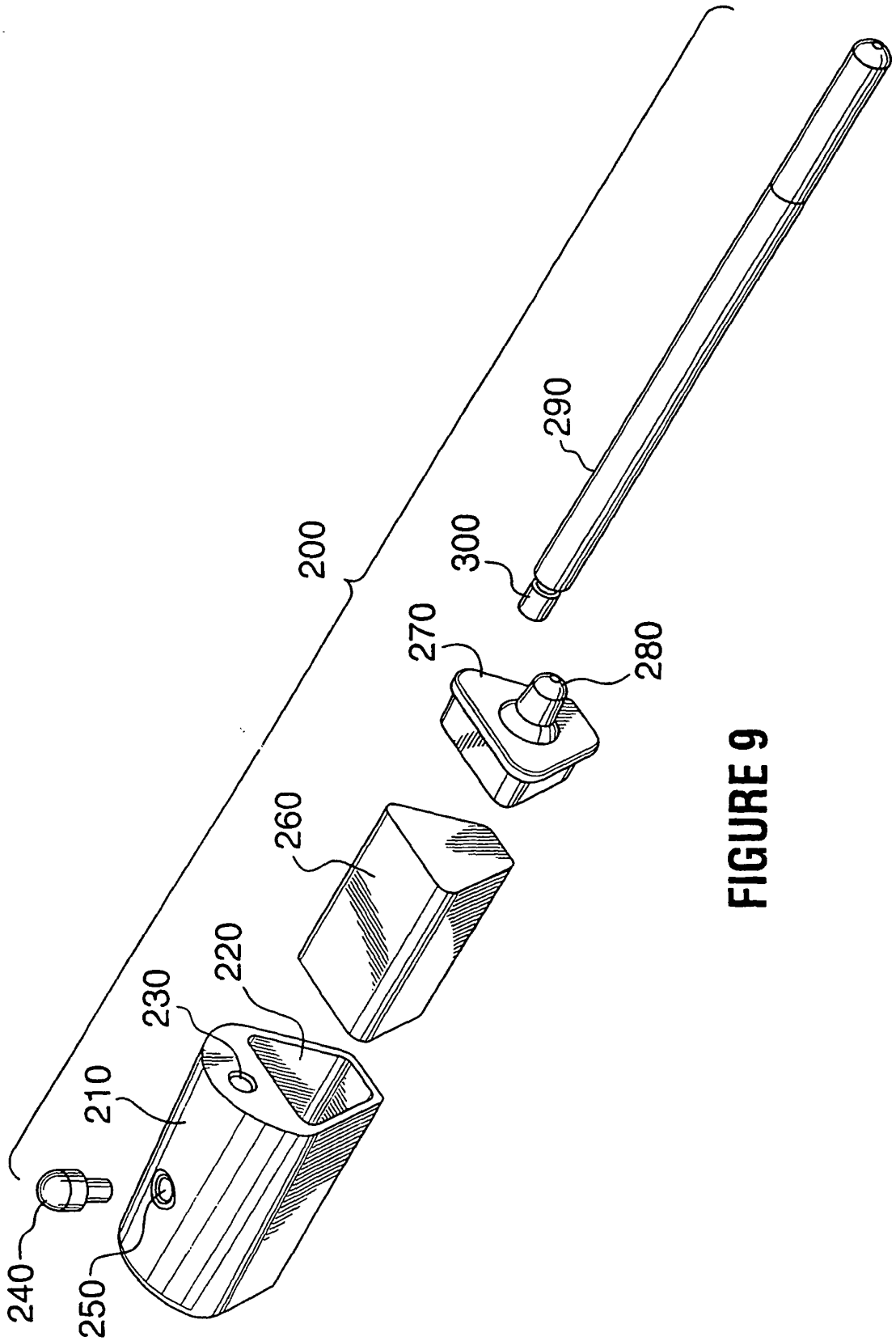

FIGURE 9

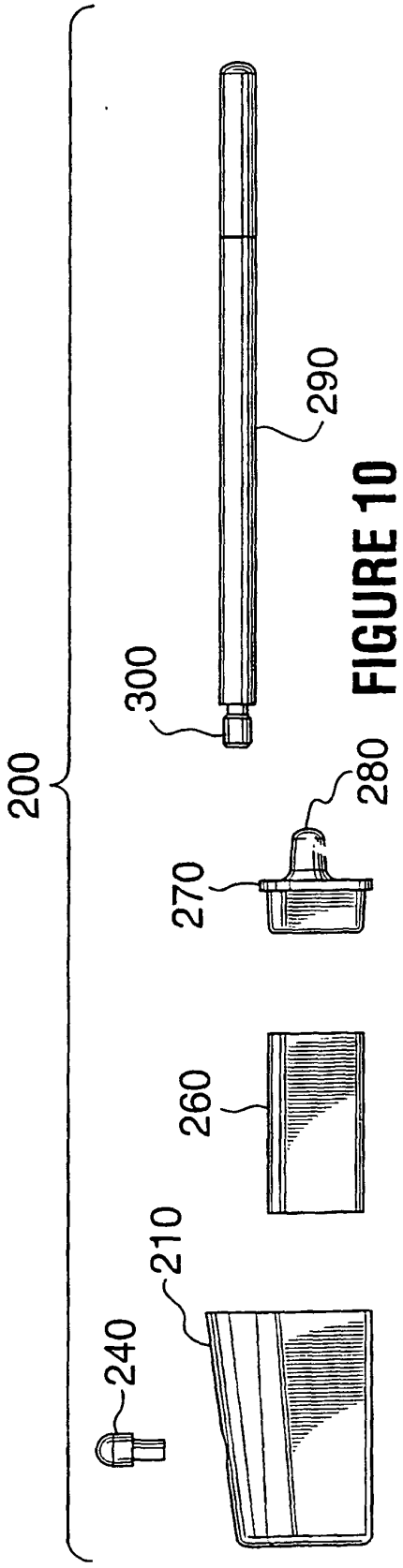

FIGURE 10

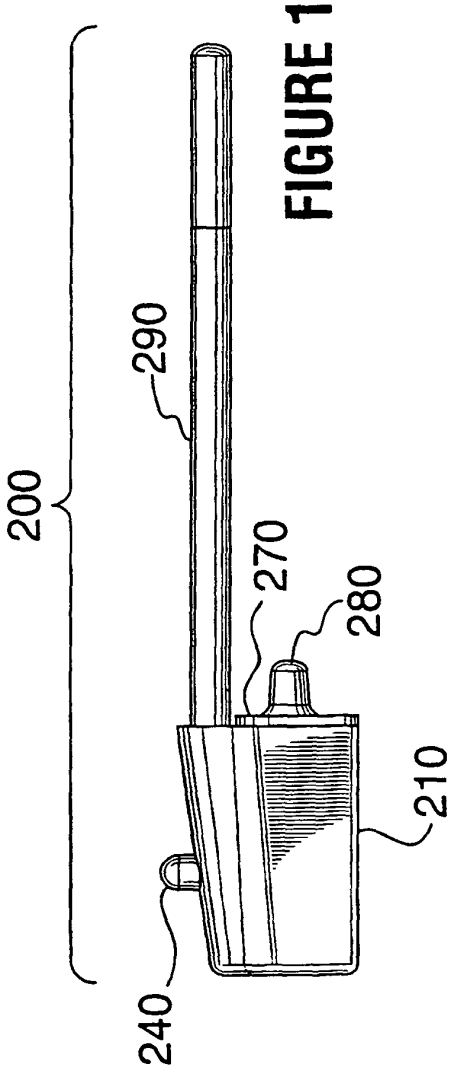

FIGURE 11

专利名称(译)	用于验证光谱分析仪精度的装置		
公开(公告)号	EP1207780B1	公开(公告)日	2006-10-25
申请号	EP2000955998	申请日	2000-08-31
[标]申请(专利权)人(译)	CME TELEMETRIX		
申请(专利权)人(译)	CME TELEMETRIX INC.		
当前申请(专利权)人(译)	近红外诊断INC.		
[标]发明人	CADELL THEODORE E DRENNAN PAUL SAMSOONDAR JAMES PAWLUCZYK ROMUALD KAUSHAL ASHWANI BEDNARZ BRONISLAW KUTA JOHN		
发明人	CADELL, THEODORE, E. DRENNAN, PAUL SAMSOONDAR, JAMES PAWLUCZYK, ROMUALD KAUSHAL, ASHWANI BEDNARZ, BRONISLAW KUTA, JOHN		
IPC分类号	A61B5/00 G01N21/27 A61B5/145 A61B5/1455 G01N21/35 G01N21/47		
CPC分类号	B82Y15/00 A61B5/14532 A61B5/1455 A61B5/1495 A61B2560/0233 G01N21/4785 Y10S977/904 Y10S977/926 Y10S977/954 Y10S977/958		
优先权	60/151681 1999-08-31 US		
其他公开文献	EP1207780A1		
外部链接	Espacenet		

摘要(译)

本发明提供一种人造构件（80,210），其模仿身体部位的吸收光谱并包括血液分析物的光谱成分。人造构件包括光散射和反射材料，并且具有包括一个或多个腔室（90,100,220）的腔室部分。人造构件被配置成可再现地接收在测量接收器中，该接收器可操作地连接到非侵入式监测装置。

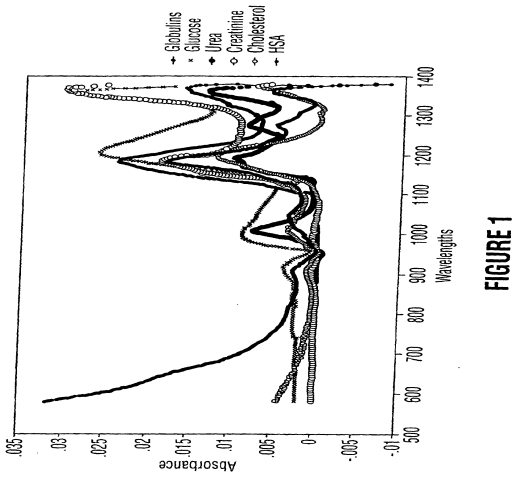

FIGURE 1