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Schurman et al.

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(54) **SYSTEM AND METHOD FOR CREATING A STABLE OPTICAL INTERFACE**

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(52) **U.S. Cl.** **600/344**; 600/310; 600/316
(58) **Field of Classification Search** 600/309–344, 600/473, 476
See application file for complete search history.

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Assistant Examiner — Marjan Fardanesh
(74) *Attorney, Agent, or Firm* — Knobbe Martens Olson & Bear LLP

(57) **ABSTRACT**

A system and a method for creating a stable and reproducible interface of an optical sensor system for measuring blood glucose levels in biological tissue include a dual wedge prism sensor attached to a disposable optic that comprises a focusing lens and an optical window. The disposable optic adheres to the skin to allow a patient to take multiple readings or scans at the same location. The disposable optic includes a Petzval surface placed flush against the skin to maintain the focal point of the optical beam on the surface of the skin. Additionally, the integrity of the sensor signal is maximized by varying the rotation rates of the dual wedge prisms over time in relation to the depth scan rate of the sensor. Optimally, a medium may be injected between the disposable and the skin to match the respective refractive indices and optimize the signal collection of the sensor.

23 Claims, 13 Drawing Sheets

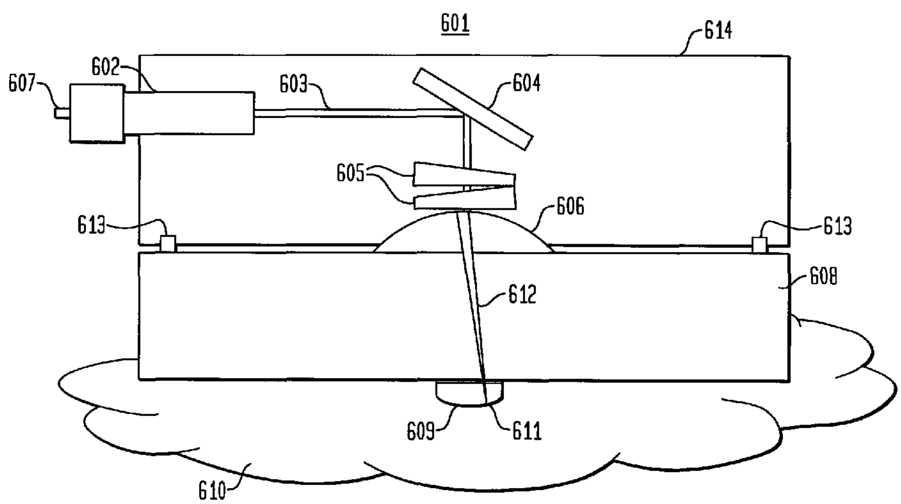

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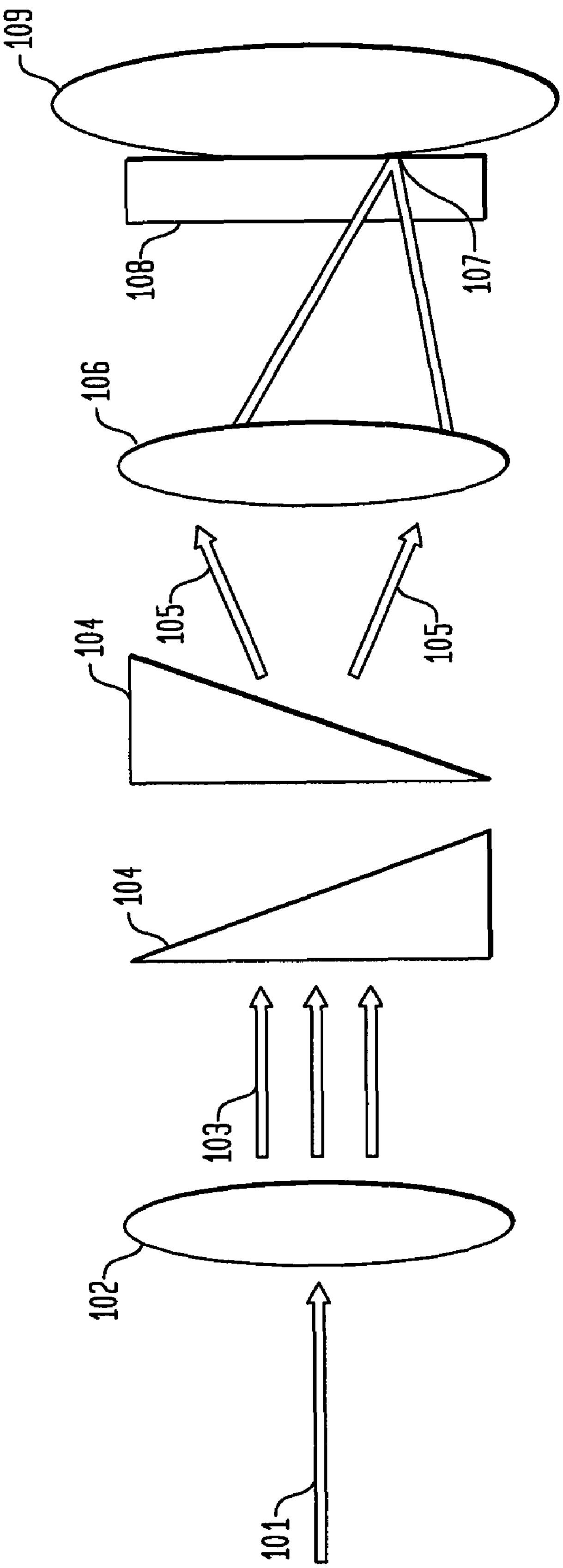
FIG. 1



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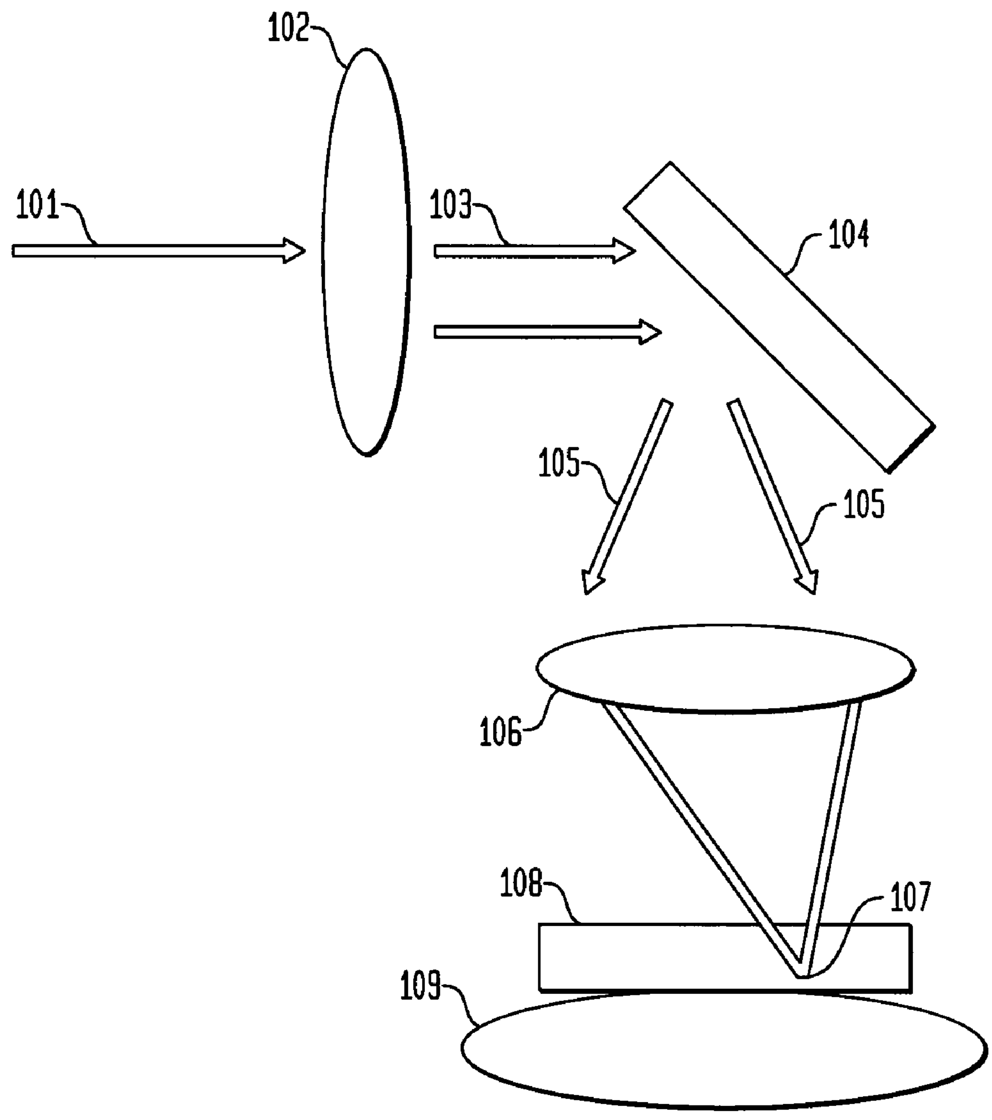

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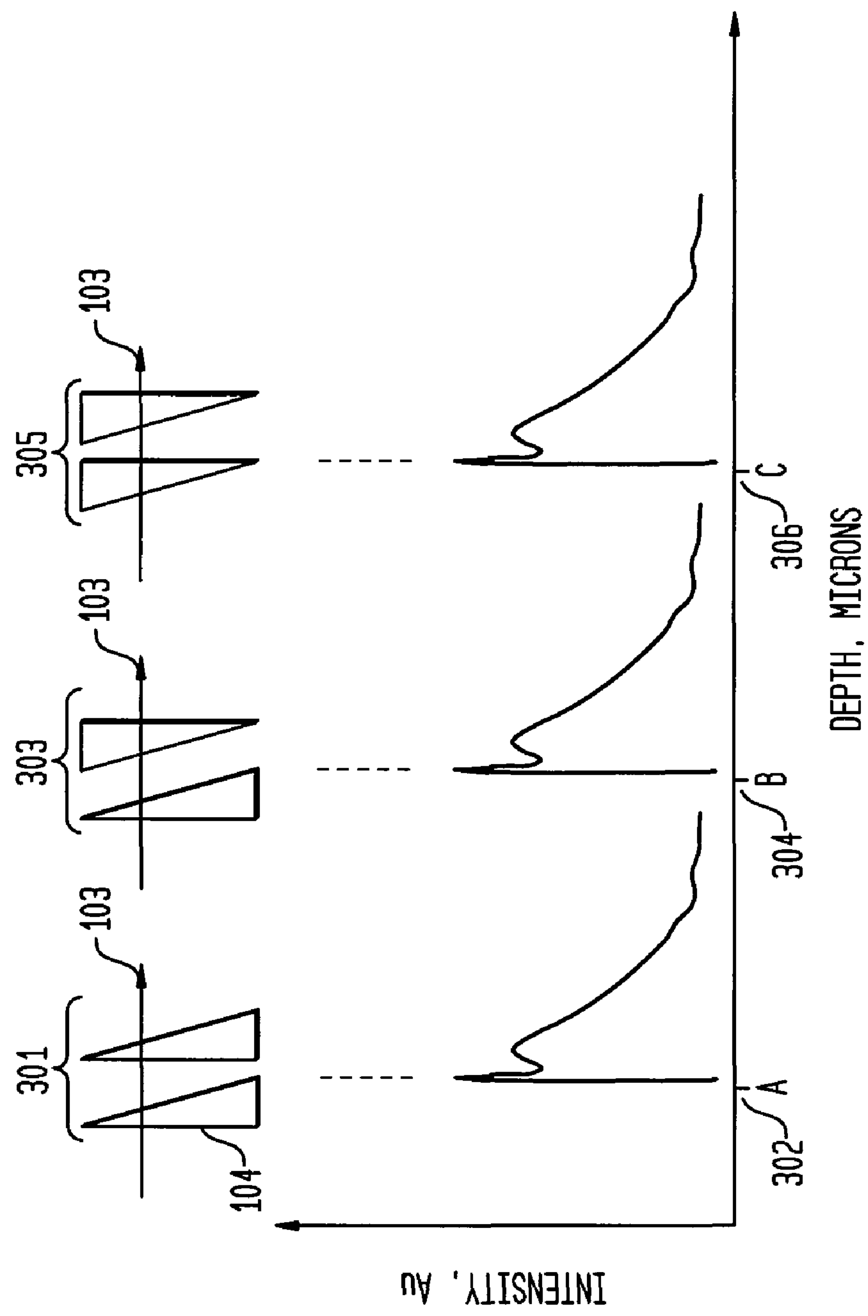
103
103
103
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303
301
104
302
A
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B
306
C
DEPTH, MICRONS
INTENSITY, Au

FIG. 4A

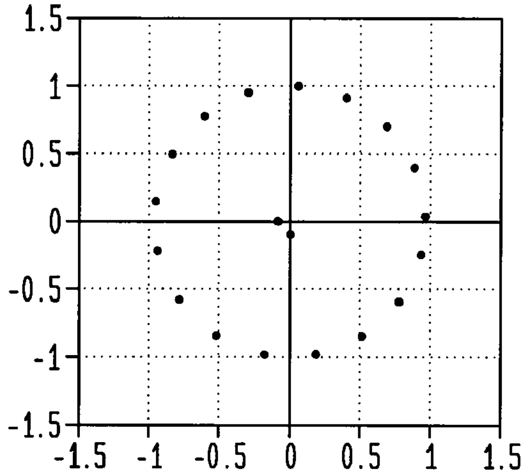


FIG. 4B

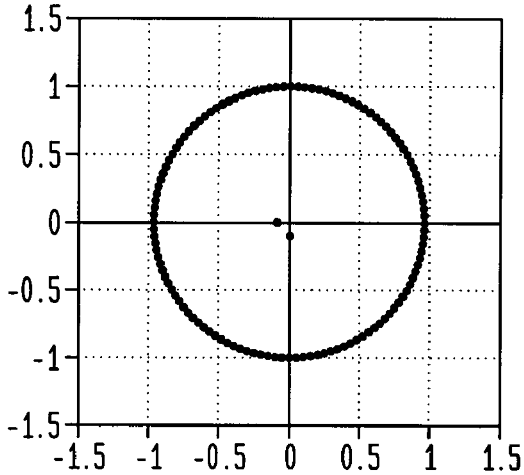


FIG. 4C

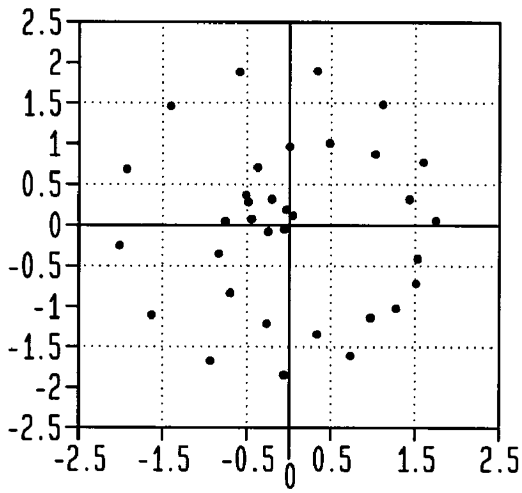


FIG. 5A

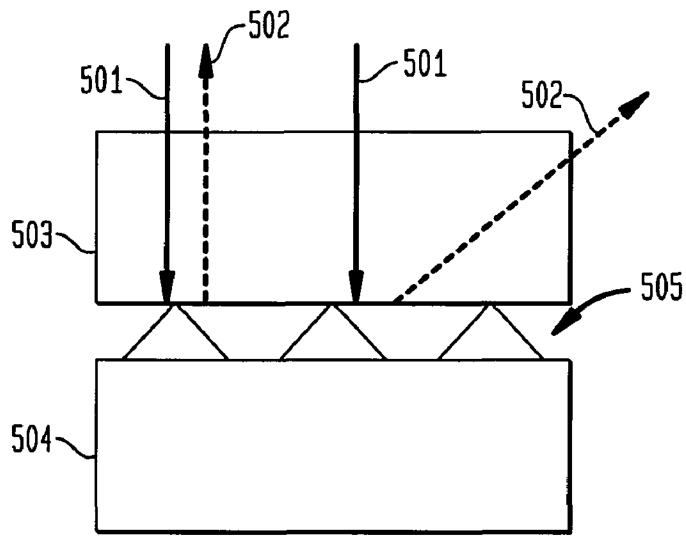

502
501
501
502
503
505
504

FIG. 5B

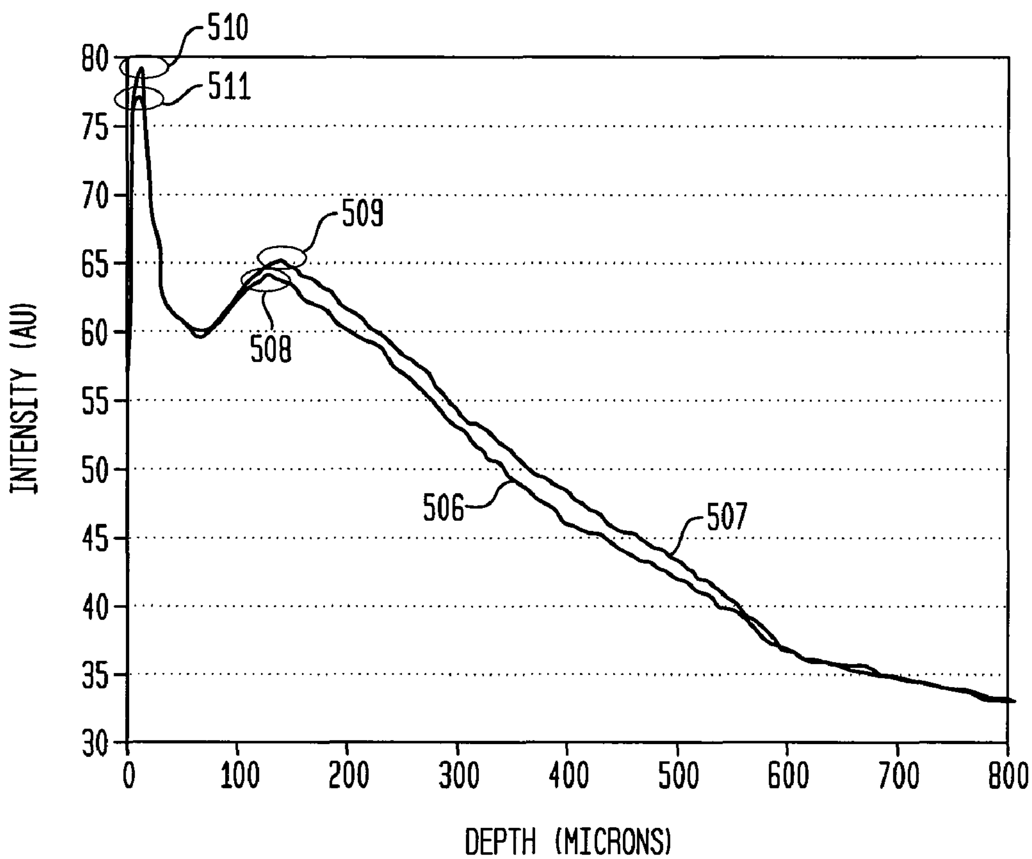

510
511
509
508
506
507
INTENSITY (AU)
DEPTH (MICRONS)
80
75
70
65
60
55
50
45
40
35
30
0
100
200
300
400
500
600
700
800

FIG. 5C

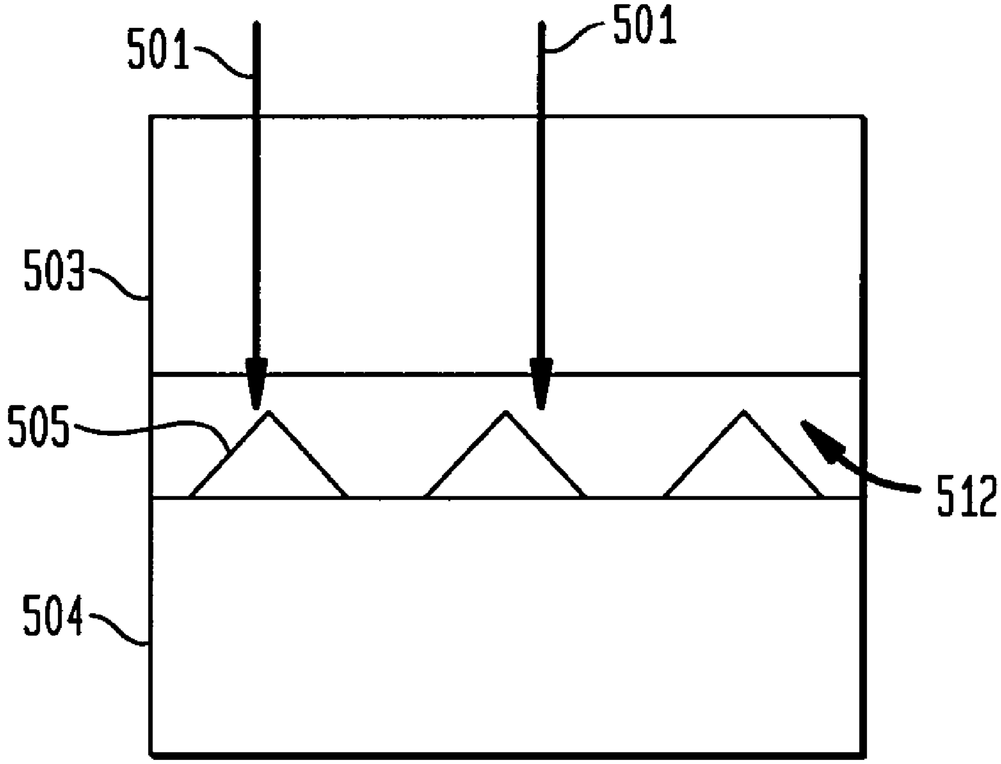


FIG. 6A

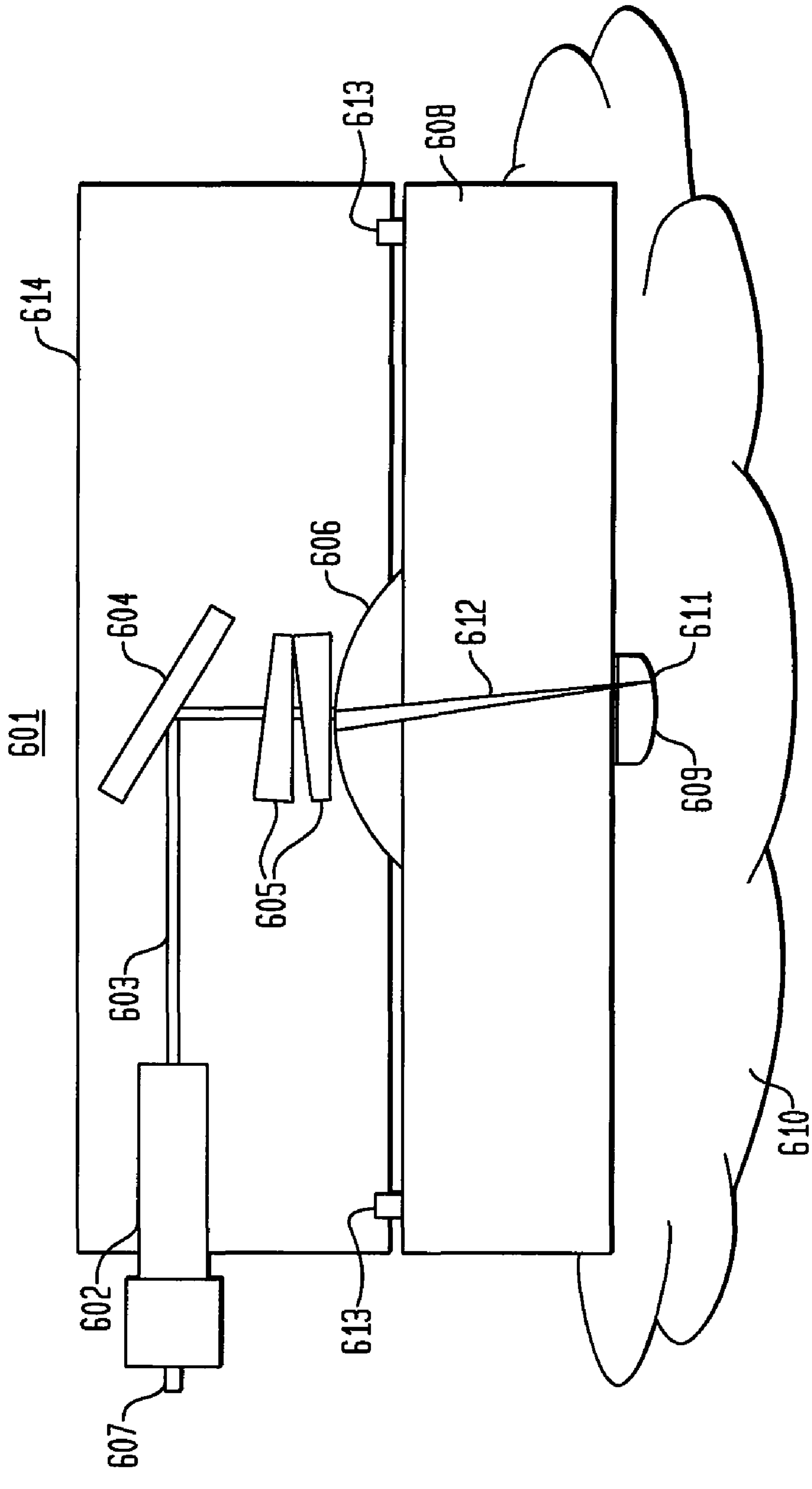


FIG. 6B

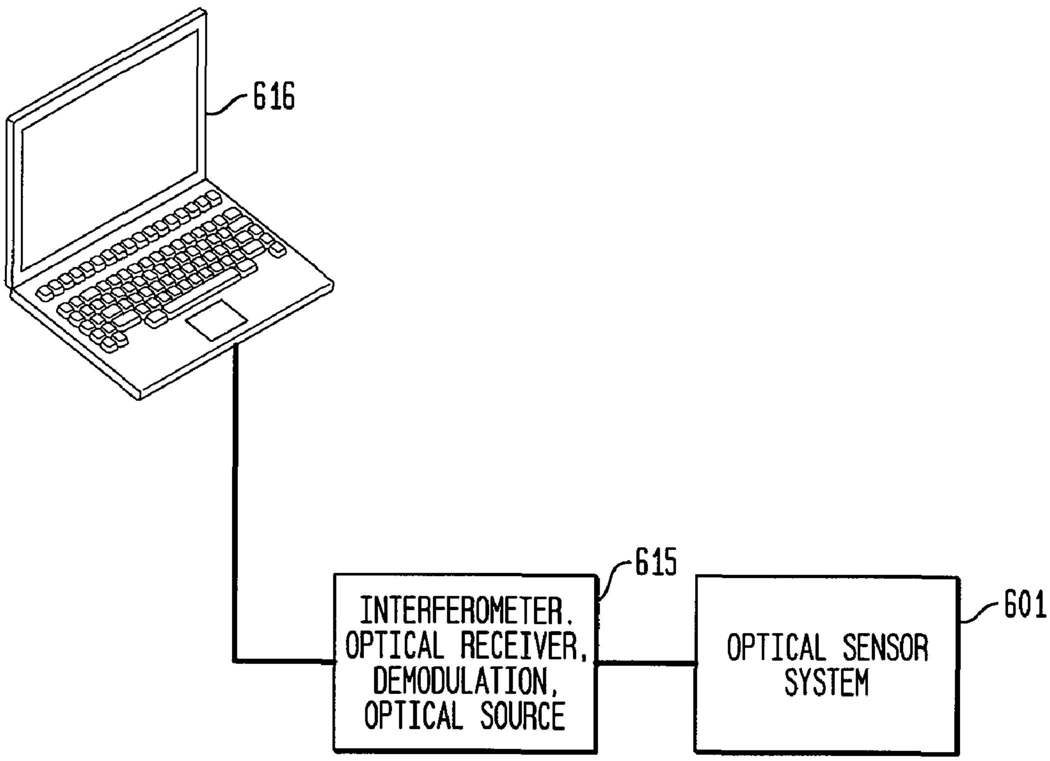

616
615
INTERFEROMETER,
OPTICAL RECEIVER,
DEMODULATION,
OPTICAL SOURCE
601
OPTICAL SENSOR
SYSTEM

FIG. 7A

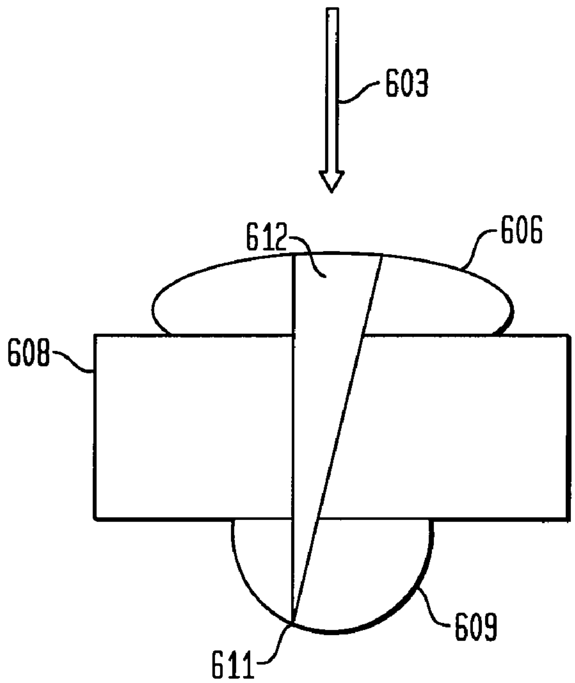


FIG. 7B

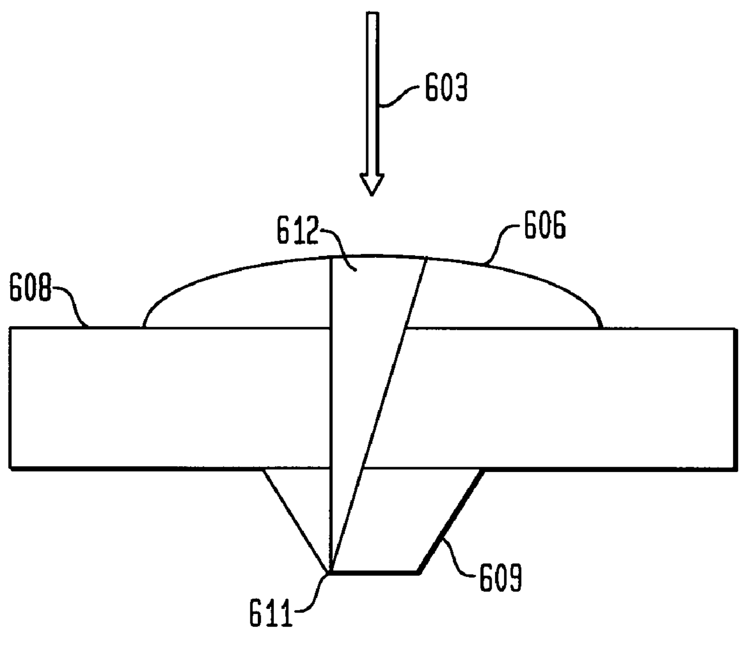
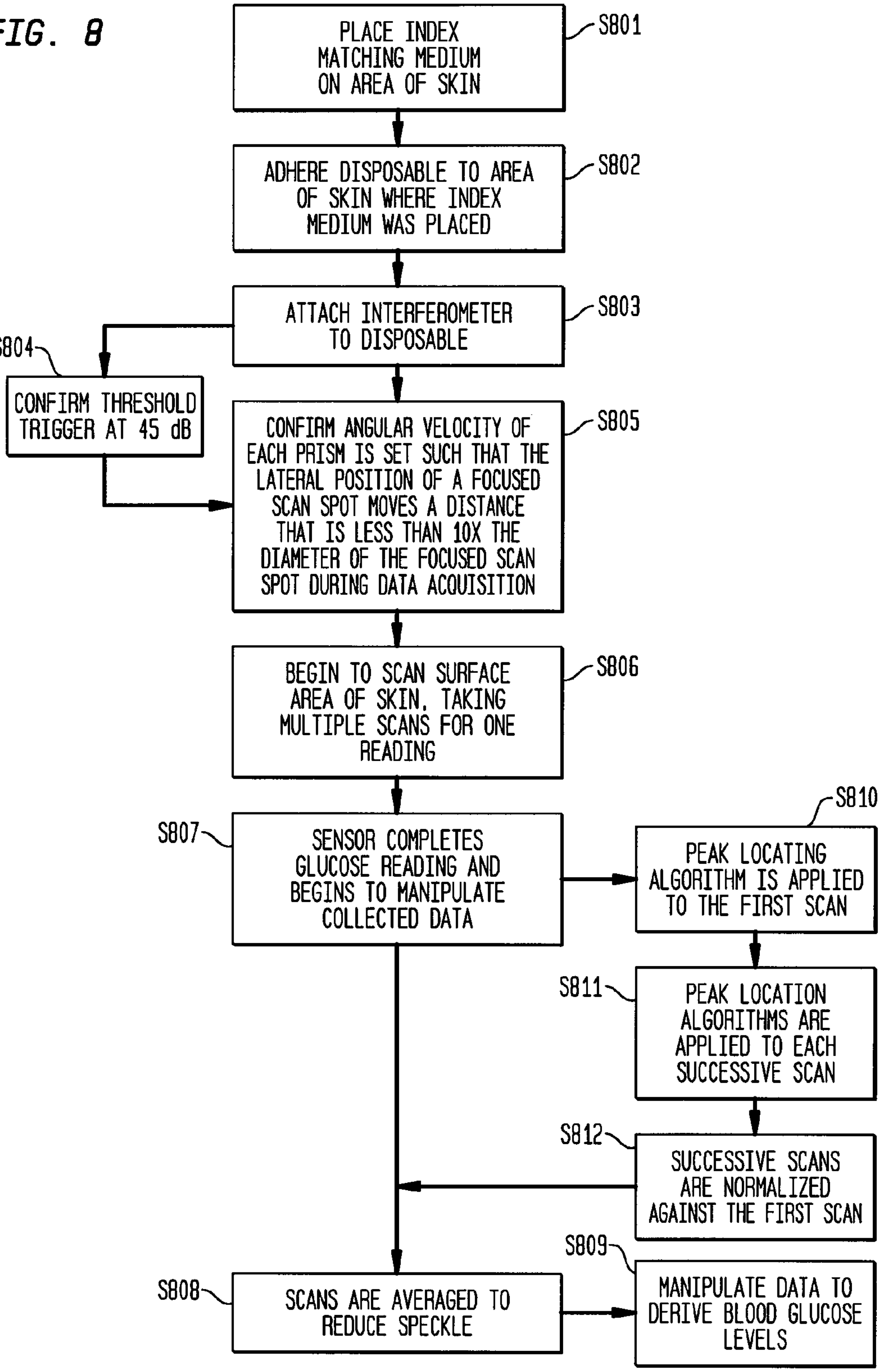
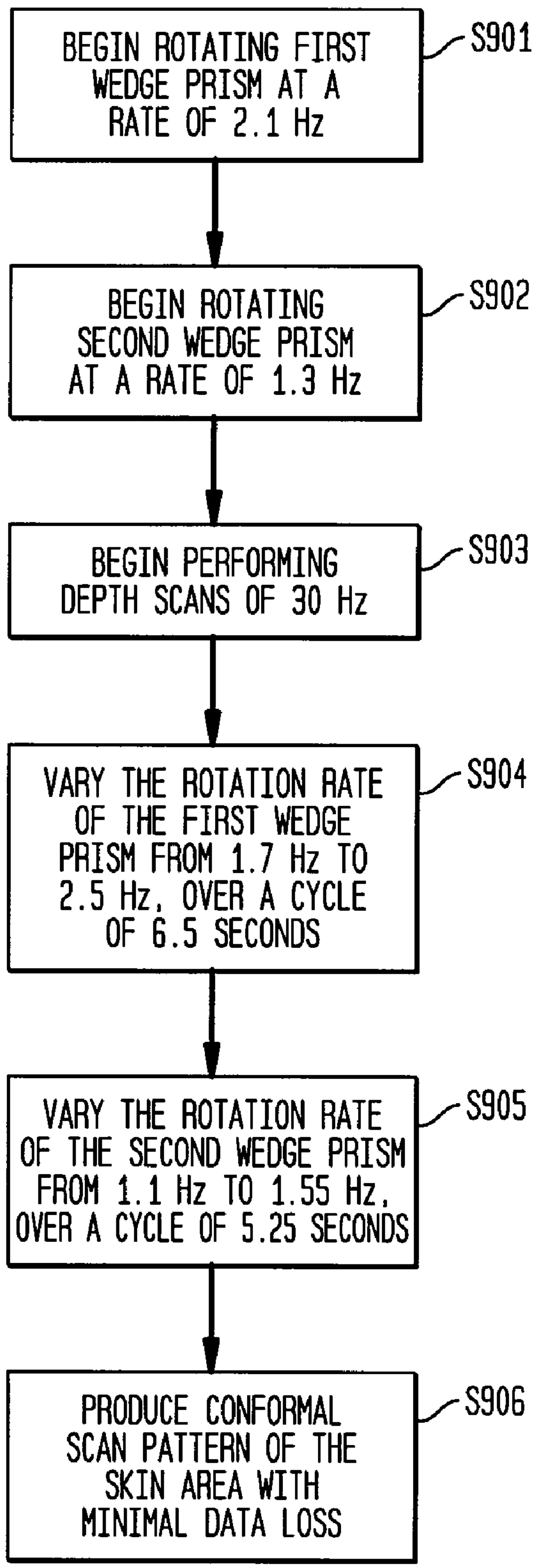


FIG. 8



PLACE INDEX MATCHING MEDIUM ON AREA OF SKIN
S801
ADHERE DISPOSABLE TO AREA OF SKIN WHERE INDEX MEDIUM WAS PLACED
S802
ATTACH INTERFEROMETER TO DISPOSABLE
S803
S804
CONFIRM THRESHOLD TRIGGER AT 45 dB
CONFIRM ANGULAR VELOCITY OF EACH PRISM IS SET SUCH THAT THE LATERAL POSITION OF A FOCUSED SCAN SPOT MOVES A DISTANCE THAT IS LESS THAN 10X THE DIAMETER OF THE FOCUSED SCAN SPOT DURING DATA ACQUISITION
S805
BEGIN TO SCAN SURFACE AREA OF SKIN, TAKING MULTIPLE SCANS FOR ONE READING
S806
S807
SENSOR COMPLETES GLUCOSE READING AND BEGINS TO MANIPULATE COLLECTED DATA
S810
PEAK LOCATING ALGORITHM IS APPLIED TO THE FIRST SCAN
S811
PEAK LOCATION ALGORITHMS ARE APPLIED TO EACH SUCCESSIVE SCAN
S812
SUCCESSIVE SCANS ARE NORMALIZED AGAINST THE FIRST SCAN
S809
MANIPULATE DATA TO DERIVE BLOOD GLUCOSE LEVELS
S808
SCANS ARE AVERAGED TO REDUCE SPECKLE

FIG. 9



BEGIN ROTATING FIRST WEDGE PRISM AT A RATE OF 2.1 Hz
S901
BEGIN ROTATING SECOND WEDGE PRISM AT A RATE OF 1.3 Hz
S902
BEGIN PERFORMING DEPTH SCANS OF 30 Hz
S903
VARY THE ROTATION RATE OF THE FIRST WEDGE PRISM FROM 1.7 Hz TO 2.5 Hz, OVER A CYCLE OF 6.5 SECONDS
S904
VARY THE ROTATION RATE OF THE SECOND WEDGE PRISM FROM 1.1 Hz TO 1.55 Hz, OVER A CYCLE OF 5.25 SECONDS
S905
PRODUCE CONFORMAL SCAN PATTERN OF THE SKIN AREA WITH MINIMAL DATA LOSS
S906

FIG. 10A

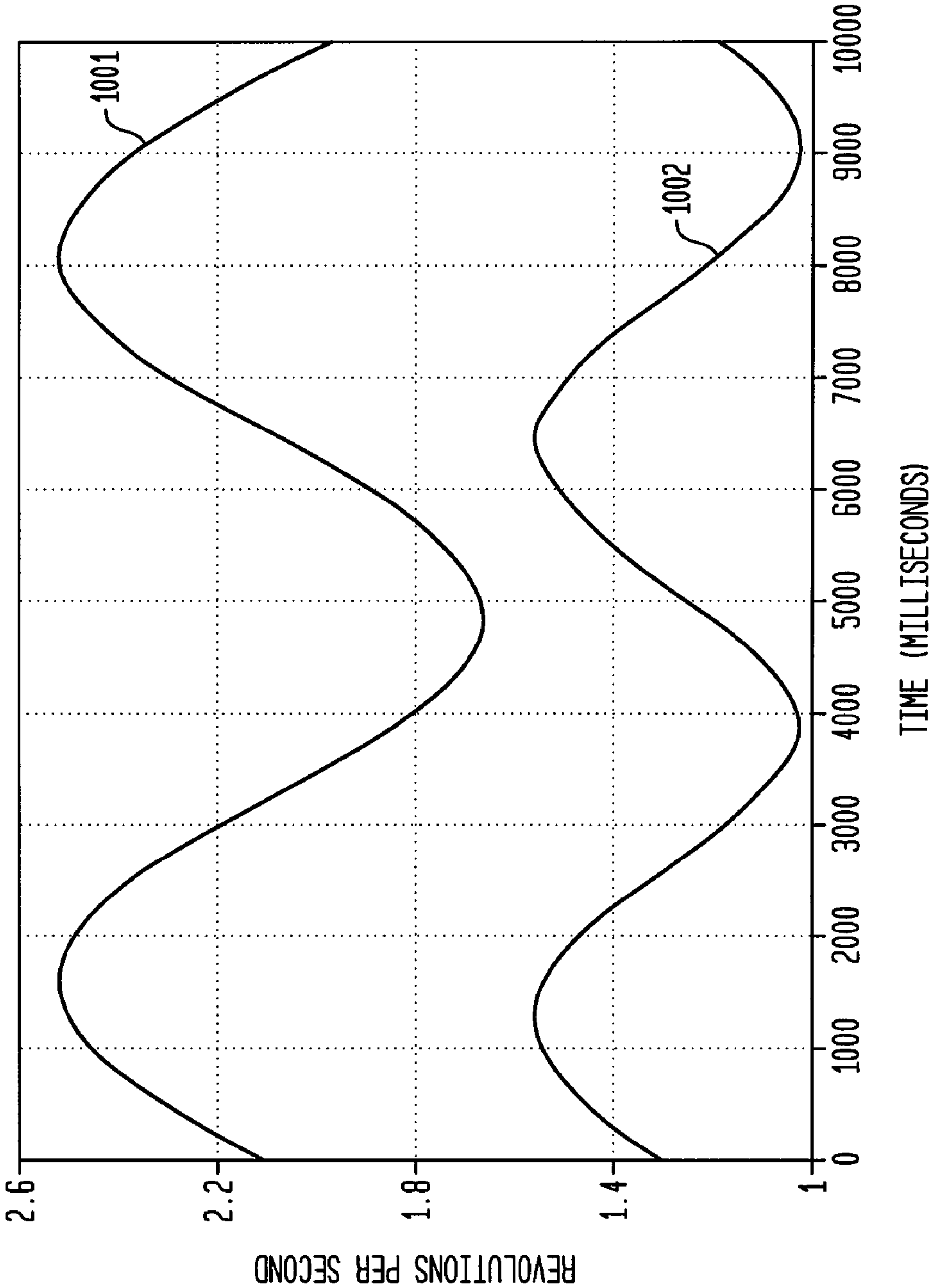
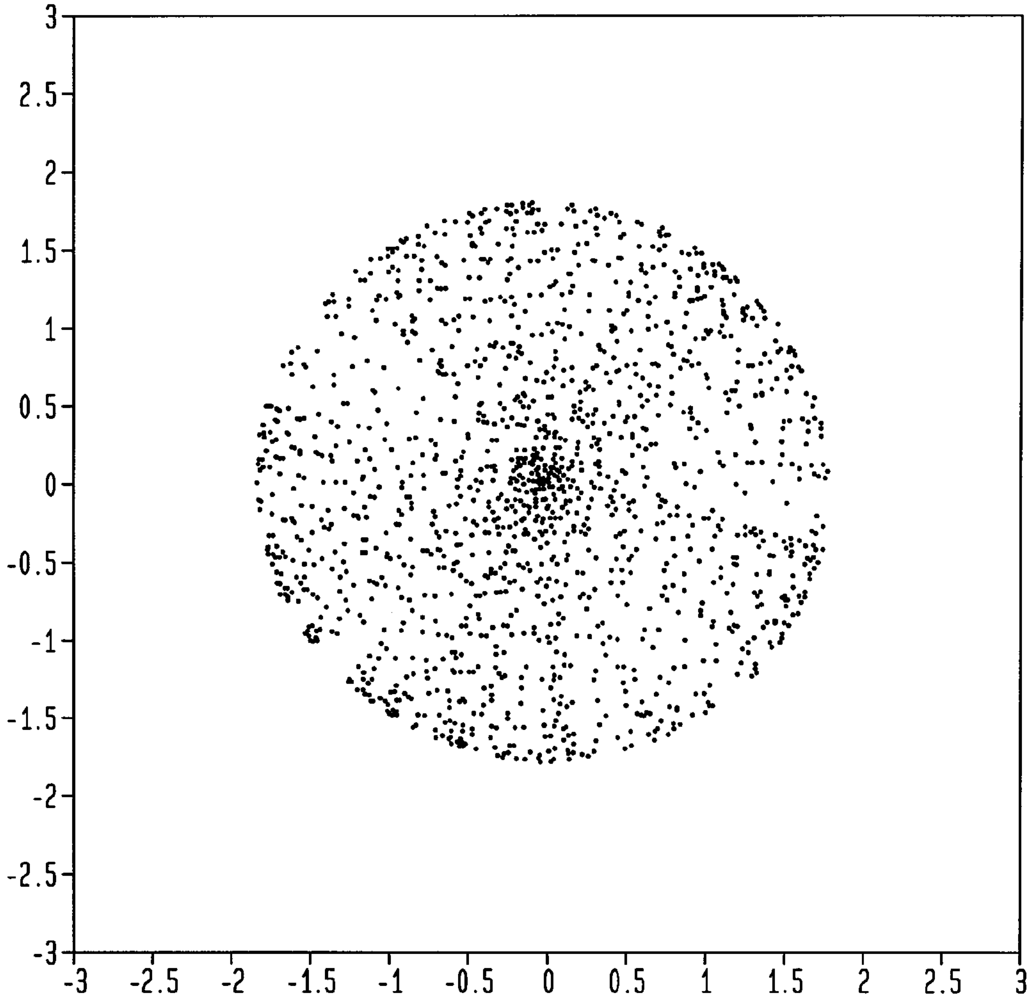

1001
1002
2.6
2.2
1.8
1.4
1
REVOLUTIONS PER SECOND
0
1000
2000
3000
4000
5000
6000
7000
8000
9000
10000
TIME (MILLISECONDS)

FIG. 10B



SYSTEM AND METHOD FOR CREATING A STABLE OPTICAL INTERFACE

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to stabilizing an optical interface and, more specifically, to creating a reproducible and stable optical interface between biological tissue and an optical blood glucose sensor.

2. Related Art

Monitoring of blood glucose concentration levels has long been critical to the treatment of diabetes in humans. Current blood glucose monitors involve a chemical reaction between blood serum and a test strip, requiring an invasive extraction of blood via a lancet or pinprick. Small handheld monitors have been developed to enable a patient to perform this procedure anywhere, at any time. But the inconvenience of this procedure—specifically the blood extraction and the use and disposition of test strips—has led to a low level of compliance. Such low compliance can lead to serious medical complications. Thus, a non-invasive method for monitoring blood glucose is needed.

Studies have shown that optical methods can detect small changes in biological tissue scattering related to changes in levels of blood sugar. Although highly complex, a first order approximation of monochromatic light scattered by biological tissue can be described by the following simplified Equation 1:

$$I_R = I_O \exp[-(\mu_a + \mu_s)L] \qquad \text{Eq. 1}$$

where I_R is the intensity of light reflected from the skin, I_O is the intensity of the light illuminating the skin, μ_a is the absorption coefficient of the skin at the specific wavelength of light, μ_s is the scatter coefficient of the skin at the specific wavelength of light, and L is the total path traversed by the light. From this relationship, it can be seen that the intensity of the light decays exponentially as either the absorption or the scattering of the tissue increases.

It is well established that there is a difference in the index of refraction between blood serum/interstitial fluid (blood/IF) and membranes of cells such as blood cells and skin cells. (See, R. C. Weast, ed., CRC Handbook of Chemistry and Physics, 70th ed., (CRC Cleveland, Ohio 1989)). This difference can produce characteristic scattering of transmitted light. Glucose, in its varying forms, is a major constituent of blood/IF. The variation of glucose levels in blood/IF changes its refractive index and thus, the characteristic scattering from blood-profused tissue. In the near infrared wavelength range (NIR), blood glucose changes the scattering coefficient more than it changes the absorption coefficient. Thus, the optical scattering of the blood/IF and cell mixture varies as the blood glucose level changes. Accordingly, an optical method presents a potential option for non-invasive measurement of blood glucose concentration.

Non-invasive optical techniques being explored for blood glucose application include polarimetry, Raman spectroscopy, near-infrared absorption, scattering spectroscopy, photoacoustics and optoacoustics. Despite significant efforts, these techniques have shortcomings such as low sensitivity, low accuracy (less than current invasive home monitors) and insufficient specificity of glucose concentration measurement within the relevant physiological range (4-30 mM or 72-540 mg/dL). Accordingly, there is a need for an improved method to non-invasively monitor glucose.

Optical coherence tomography, or OCT, is an optical imaging technique using light waves that produces high resolution imagery of biological tissue. OCT creates its images by focusing a beam of light into a medium and interferometrically scanning the depth of a linear succession of spots and measuring the absorption and/or the scattering of the light at different depths in each successive spot. The data is then processed to present an image of the linear cross section of the medium scanned. It has been proposed that OCT might be useful in measuring blood glucose.

One drawback associated with using OCT for monitoring blood glucose is the signal noise associated with optical interferometry, also known as speckle. As discussed in U.S. application Ser. No. 10/916,236 by M. Schurman, et al, entitled "Method and Apparatus for Monitoring Glucose Levels In A Biological Tissue," to reduce speckle, a glucose monitor incorporating OCT methodology may scan a beam of collimated light continuously and laterally across a two-dimensional surface area of a patient's tissue or skin, while interferometrically scanning the tissue in depth. Preferably, the scanning is accomplished with a small, lightweight, and robust mechanism that can be incorporated into a sensor to be used in a fiber-optics based product or, alternately, a non fiber-optics based product. One main objective of using this type of sensor is to generate a reproducible stable optical interface between the subject's skin and optical path of the sensor in order to take multiple readings from the same lateral location on the skin while maintaining the integrity of the optical interface. As discussed below, there are multiple problems associated with providing and maintaining a stable and reproducible optical interface between an OCT sensor and the skin of a patient.

Two Basic Optic Designs

Two well known sensor designs that use OCT are schematically shown in FIGS. **1** and **2**. FIG. **1** shows a design based on the use of two rotating wedge prisms to change the angle of collimated light incident on a focusing lens. In FIG. **1**, incoming light beam **101** hits a collimating lens **102**, which splits the beam **101** into multiple parallel beams of light, or collimated light **103**. The collimated light **103** then passes through one or more wedge prisms **104**, which are rotating at predefined rates. As shown in FIG. **1**, dual rotating wedge prisms **104** generate an angular deviation in the collimated light **103** from the optical axis of the sensor, which is the "centerline" axis passing through the elements of the sensor, perpendicular to the surface area of skin **109** to be tested. By deviating the angle of the collimated light **103**, the focal point of the light moves around on a focal plane of an optical window **108** that is flush against the skin **109**, thereby scanning different lateral locations on the skin **109**. As shown at **105**, once passing through wedge prisms **104**, the parallel rays of collimated light **103** may be angled away from the optical axis, depending on what portion of the wedge prisms **104** the collimated light **103** passes through. The angled beams **105** then pass through a focusing lens **106**, and begin to focus together to a focal point **107** at the bottom surface of an optical window **108**.

FIG. **2** shows a similar concept to FIG. **1**, however the dual wedge prisms **104** of FIG. **1** are replaced with an angled mirror **201**, for example, a 45 degree angled mirror, that oscillates along two axes, thereby deviating the angle of collimated light **103** from the optical axis in order to move the focal point **108** around on the surface area of skin **109**. Accordingly, this OCT sensor design is well known in the art. Both designs facilitate scanning an area of skin by deviating the angle of collimated beam **103** from the optical axis, thereby moving the focal point **107** a proportional distance laterally in the focal plane along the bottom of the optical lens **108**, and, accordingly, along the surface area of the patient's skin **109**.

While both sensor designs provide mechanisms for incorporating OCT into a noninvasive blood glucose sensor, there are several drawbacks associated with the above designs as described below.

Variations in Optical Path Length

One drawback associated with the dual wedge prism sensor design of FIG. **1** is illustrated in FIG. **3**. In an interferometer, the optical path length of a beam of light is determined by the physical or geometric path length of the beam and the index of refraction of the medium which the beam is passing through as shown in Equation 2:

$$L_{OPT}=n \cdot L_{GEO} \quad \text{Eq. 2}$$

where "L_{OPT}" is the optical path length, "n" is the index of refraction, and "L_{GEO}" is the geometric or physical path length

As shown in FIG. **3**, depending on the position of the wedge prisms **104** at the time the collimated beam **103** shines through, while the geometric path length of the collimated beam **103** stays the same, the index of refraction changes due to the changing thickness of the wedge prisms **104** as the prisms rotate, thereby altering the optical path length of the collimated beam **103**. This continuous change in the thickness of the wedge prisms **104** continuously alters the optical path length of the collimated beam **103** as it passes through. As shown in FIG. **3**, the placement of the wedges may extend the length of the optical path, making it seem as though the skin **109** is moving away from the sensor. Thus, three optical scans taken through the dual wedge prisms **104** when the prisms **104** are in different rotated positions produce three scans beginning at different positions in depth. Since the sensor data is an average of multiple scans, if each scan begins at a different position in depth, the resulting ensemble average will not be representative of a true averaging of multiple scans.

For example, in FIG. **3**, when the collimated beam **103** passes through the thinnest area of the wedge prisms **104**, as shown at **301**, the sensor begins to collect data at Depth A, interpreting the interface between the optical window **108** and the skin **109** to be at Depth A, as shown at **302**. However, when the collimated beam **103** passes though a thin portion of the first wedge prism and a thick portion of the second wedge prism, as shown at **302**, the sensor begins to collect data at Depth B, interpreting the interface between the optical window **108** and the skin **109** to be at Depth B, as shown at **304**. Further, when the collimated beam **103** passes through the thickest portion of both wedge prisms, as shown at **305**, the sensor begins to collect data at Depth C, interpreting the interface between the optical window **108** and the skin **109** to be at Depth C, as shown at **306**. Since typically multiple scans (e.g., greater than 100 scans) are taken and then averaged to reduce speckle, scans taken at different positions in depth cannot be averaged. Thus, a solution to this problem is desired.

Another drawback associated with the dual wedge prism sensor is the distortion of the scan along the depth axis or z-axis of the light beam entering and exiting the skin. If the rotation speed of the wedge prisms **104** is several orders of magnitude larger than the depth scan rate of the optical sensor, then the depth scale measured by the scan is either "stretched" or "shrunk" by the entire amount of the difference in optical path induced by the changing thickness of the wedge prisms **104**. However, if the rotation speed of the wedge prisms **104** is much slower than the depth scan rate, then the changing thickness of the wedge prisms **104** has a minimal effect on the depth scale. For example, if the depth scans occur at 60 Hz, which means that the sensor completes one depth scan within in $1/60^{th}$ of a second, and the prisms rotate at 3600 rpm, then each wedge prism makes a full rotation during the time it takes the sensor to complete one depth scan. Because the thickness of each wedge prisms varies as the prisms rotate, the optical path length changes during each depth scan, which distorts the depth data collected by the sensor by changing the depth scale during a single scan. Thus, there is an optimization that must occur between the depth scan rate and the prism rotation rate such that the entire surface area is thoroughly scanned while minimizing the z-axis scan distortion.

Scan Pattern Stability

Accordingly, it is desired is that each depth scan be taken at a different lateral position on the surface of the skin **109** such that the ensemble of all the depth scan positions are randomly and uniformly distributed throughout the scan region. The lateral locations of each depth scan must be spatially independent to 1) effectively encompass regions of blood glucose change during a sensor reading and 2) effectively reduce speckle. However, a problem associated with the dual wedge prism sensor in FIG. **1** and the oscillating mirror sensor in FIG. **2** is the inability to capture each depth scan position due to the angular velocity of the wedge prism(s) **104** or the oscillation rate of the angled mirror **201** being harmonic in phase with the depth scan rate of the optical sensor, i.e., the frequency of the angular velocity is a multiple or integral of the depth scan rate of the sensor. When either the angular velocity or oscillation rate is an integral of the depth scan rate, the two rates "beat" against each other, and produce a loss of conformal coverage of the surface area of the skin **109** being scanned.

As shown in FIG. **4**B, when using a single rotating wedge prism or oscillating angled mirror in a sensor as described above, the optimal result of multiple depth scans is a circle pattern on the surface area of the skin **109**, which each "dot" representing a depth scan. Each depth scan occurs along the path of this circle pattern, effectively breaking the circle up into a series of scanned points. However, if the angular velocity is an integral or harmonic of the depth scan rate, the depths scans begin to overlap in location, thereby producing an incomplete circle pattern and a loss of spatially independent depth scans, as shown in FIG. **4**A. With an overlap of depth scans, the same locations of tissue are scanned, causing less speckle reduction and poor imaging of structures within the scanned tissue. The problem becomes even more pronounced in the case of a sensor with two wedge prisms, as shown in FIG. **4**C.

Focal Plane Instability

Another challenge presented by both the wedge prism design in FIG. **1** and the oscillating mirror design in FIG. **2** is the inability to maintain the focal point **107** of the focused collimated beam on the focal plane, or the interface between the optical window **108** and the surface area of the skin **109** being scanned. Optical lenses do not project an image onto a flat plane, such as the flat bottom surface of the optical window **108**, but, instead, naturally project an image onto a curved surface, much like the curved interior of the eye. This curved surface is well known as a Petzval surface. Thus, as the collimated light **103** enters the focusing lens **106**, the focal point **107** of the collimated light **103** traces out a curved focal plane or Petzval surface based on the design of the focusing lens **106**, caused by the angular deviation from the optical axis due to the wedge prisms **104** in FIG. **1** or the angled mirror

201 in FIG. 2. Thus, the flat bottom of the optical window 108 does not allow the focal point 107 to remain on the focal plane.

When the focal point 107 moves off of the Petzval surface, the efficiency of the focused light being collected begins to drop, since focal plane is where the light capture is maximized. Additionally, the depth scale of the focused light is affected such that the displacement of the focal point 107 off of the focal plane results in an equivalent loss in the depth scale of the signal. This results in a blurring of the optical axis, causing measurable details within the skin to be blurred or washed out. Thus, a displacement of the focal point off the focal plane results in a reduction in the sensor signal intensity and a blurring of the optical axis.

Additionally, optical lenses are not perfect. Therefore, as the focal point 107 moves away from the optical axis due to the rotating wedge prisms 104 or the oscillating angled mirror 201, the focused beam drifts away from the skin 109 and back towards the focusing lens 106, and, thus, moves off the focal plane. As discussed above, when the focal point 107 is no longer on the focal plane, the collection efficiency of the light drops, resulting in the collected data incorrectly indicating a reduction in power. This, in turn, alters the depth of the focused beam, thereby unwittingly washing out details in the skin and lowering the resolution and integrity of the scan.

Skin/Sensor Optical Interface

The surface of the skin is "rough" relative to the light entering and exiting the skin during an optical scan. This is well known as optical roughness. Additionally, the refractive index of the skin being scanned typically is different from the refractive index of the material of an optical window of a sensor. As shown in FIG. 5A, the optical window 503 is not necessarily flush against the surface of the skin 504, due to optical roughness 505 of the skin. Accordingly, as incident light 501 is directed towards the skin, some of the light is reflected and/or diffracted, as shown at 502, because there is a mismatch between the index of refraction of the optical window 503 and the index of refraction of the skin 504. This mismatch of refractive indices and, in addition, the space between the skin 504 and the optical window 503 due to the optical roughness 505 reduces the reliability of data taken by the sensor.

FIG. 5B displays two scans taken at the same location on the skin but measured at different points in time with constant optical contact between the skin 109 and the optical window 108 of a sensor. Such scans may be produced by either the dual wedge prism sensor of FIG. 1 or the angled mirror sensor of FIG. 2. Data line 506 represents an averaged optical scan taken at Time 0 while data line 507 represents an averaged optical scan taken thirty minutes after Time 0. Typically, the focused beam hits the interface between the optical window 503 and the skin 504, a sharp rise or peak in the signal is produced, as shown at peaks 510 and 511. The signal then drops as the beam moves through the skin 504 and begins to rise again as the beam hits the interface between the epidermis and dermis layers, as shown at peaks 508 and 509. The signal again drops and continues to drop as the beam reaches the desired depth then returns back to the sensor.

As shown in FIG. 5B, while constant optical contact is maintained between the skin 504 and the optical window 503 of the sensor, over time the optical signal drifts, as illustrated by the peaks at the interface between the dermis and epidermis layers, which rises over time, from peak 508 at Time 0 to peak 509 at Time 0+30 minutes. However, the peak at the interface between the optical window 503 and the skin 504 drops over time, from peak 510 at Time 0 to peak 511 at Time 0+30 minutes. This change in signal intensity is due to a gradual change in the optical interface created by an accumulation of sweat and skin oils at the interface of the optical window 503 and the skin 504, as shown at 512 in FIG. 5C, which serves as an optical transition for the incident light 501 to efficiently travel from the optical window 503 to the skin 504. Additionally, the accumulation of sweat and skin oils smoothes out the optical roughness of the skin. Although the refractive index between the optical window 503 and the skin 504 will stabilize or reach an equilibrium value due to sweat, oil, and other fluids produced by the skin over time, this process could take upwards of 60-90 minutes. Unfortunately, these changes in signal intensity over this extended period of time may completely mask the changes that are occurring along the OCT signal, and thus prevent proper correlation of changes in the OCT signal to changing glucose levels, as discussed in U.S. Provisional Applications Nos. 60/671,007 and 60/671,285, both entitled "Method For Data Reduction and Calibration of an OCT-Based Blood Glucose Monitor." Thus, multiple scans taken over time cannot produce a reliable measurement from the same lateral location on the skin. In addition, a patient would be required to place the sensor onto his or her skin and wait 60-90 minutes before using it, in order to receive reliable and reproducible results, which creates an inefficient sensor.

Thus, a need exists for an optical sensor for measuring blood glucose levels and other physiological effects that overcomes the deficiencies discussed above.

SUMMARY OF INVENTION

According to one embodiment of the present invention, a system for generating a stable and reproducible optical interface includes an OCT-based interferometer connected to an optical sensor that utilizes a collimated beam of light and comprises dual wedge prisms to move the collimated beam to different lateral locations on the skin, and a disposable optical lens apparatus that attaches to the skin surface using an adhesive, where the disposable optical lens apparatus comprises a focusing lens and an optical window that interfaces directly with the skin. Alternately, the optical sensor may utilize an angled mirror that oscillates along two axes to move the beam of light to different lateral locations on the skin surface.

By using a disposable optical lens apparatus, a patient may place the sensor onto the optical lens apparatus, take a reading, then remove the sensor and leave the optical lens apparatus attached to his or her skin, for example, on an arm. When another reading is taken at a later time, the patient simply reattaches the sensor to the optical lens apparatus, guaranteeing that the lateral location of the sensor remains the same, in order to produce a comparable optical scan. At some point in time, the patient may remove the disposable optical lens apparatus and discard it, only to replace it with another. Thus, the disposable optical lens apparatus may be made from different materials, such as, for example, glass, plastic, or other polymer material, and may be customized for each patient's needs. A computer also may be connected to the optical sensor and/or interferometer, where the computer manipulates the sensor data and produces physiological data, such as blood glucose levels.

As mentioned above, multiple scans may be taken during a single sensor use and then averaged together to reduce or remove the speckle associated with an OCT-based system. To account for variations in the optical path length of the collimated beam produced by the varying thicknesses of the rotating dual wedge prisms, the resulting scan data is manipulated. According to an embodiment of the present invention, a method for resolving the variations in optical path length includes the steps of (i) locating the first peak, which represents the interface between the optical window and the patient's skin, of the first scan taken by the sensor, (ii) locating the first peak in each subsequent scan taken during the single use, and (iii) normalize each first peak in the subsequent scans against the peak of the first scan. The method further comprises the step of (iv) averaging the normalized scans to produce an averaged scan result. To locate the peaks, algorithms such as Gaussian peak fitting and second-derivative residual methods may be used and are well known within the field of the invention.

An alternate embodiment of the present invention presents a more time-efficient method for resolving the variations in the optical path length. The method includes the steps of (i) setting a peak threshold trigger in the signal intensity and (ii) holding off of true data acquisition until the signal hits the threshold trigger. Once signal reaches the threshold trigger, the system begins to collect the scan data. Different optical arrangements may require different threshold triggers, where optical arrangements may vary due to the angle of the wedge prisms in the optical sensor. However, to optimize the threshold trigger, at least a 10 db difference may exist between the threshold trigger and the first peak intensity value, where the signal intensity is measured in decibels. For example, if the first peak measures 60 db, then the threshold trigger is set to less than or equal to 50 db. Additionally, the threshold trigger may be set above the highest noise peak produced by the signal until the focused beam hits the optical window, where the signal begins to rise in intensity. For example, if the highest noise peak is 30 db and the first intensity peak reaches 60 db, then setting a threshold trigger between 30 db and 50 db is preferable. Since the most useful data is acquired beginning typically around 150 microns in depth (within the dermis layer of the skin), and the first peak in intensity typically occurs around 20 or 30 microns in depth, by setting a threshold trigger near the rise of the first signal peak, any mismatch in the optical path length will be less than half the coherence length of the optical sensor system, which is below the resolution of the interferometer.

The coherence length of the optical sensor system, which is a measure of the depth resolution of the system, is broadly inversely related to the bandwidth of the optical source of the system, such as, for example, a superluminescent diode. Thus, as the bandwidth of the optical source increases, the coherence length of the system decreases, and accordingly, the depth resolution of the system improves. The interface between the optical sensor and the skin has a specific peak intensity value, for example, 60 dB, and the width of the peak is the coherence length of the optical sensor system, for example, 30 microns. However, for each depth scan, the optical sensor/skin interface peak doesn't always occur at the exact location in depth, i.e., the peak location may be offset by a few microns in depth. If, for example, the threshold trigger is set to a value that is near the signal peak intensity value, then the offset of the location of each peak value for each depth scan cannot be more than a fraction of the coherence length, which is below the resolution of the optical system. Thus, the offset does not affect the data collected by the sensor and the depth scans may be averaged to reduce speckle and to produce an accurate sensor reading.

According to an aspect of the embodiment, the optical sensor system may be set to acquire data once the focused beam reaches a specific structural feature. For example, the threshold trigger may be set to correspond to an intensity value of light once the focused light reaches the interface between the skin and the optical window, which may occur, for example, at a depth of one-half of a millimeter ("mm"). Thus, if the optical window/skin interface occurs at an intensity value of 60 dB, then the trigger threshold may be set to a value of 50 dB. Therefore, the optical window/skin interface becomes a reference point for each depth scan to be lined up against, in order for the depth scans to be averaged.

According to another embodiment of the present invention, a method for minimizing the distortion in the depth scale due to change in thickness of the dual wedge prisms as they rotate includes the step of optimizing the depth scan rate versus the prism angular velocity in order to minimize any distortion of the scan in depth, or along the z-axis. If the depth scans occur at a rate at or near the angular velocity of the wedge prism, then each depth scan performed by the sensor occurs within a time period close to the time period of a single rotation of the wedge prisms. As discussed above, because the wedge prisms are not a uniform thickness and the thickness affects the refractive index and the optical path length, as the prisms rotate, the depth of each depth scan is distorted within a single scan because the optical path length is changing during a single scan when the time periods are close or exact. To prevent this problem, the method includes the step of setting the angular velocity of the wedge prisms to a value such that the lateral position of the scan spot on the skin surface moves a distance that is less than ten times ("10×") a diameter of the scan spot during the data acquisition of a single depth scan. This method allows the optical path length to remain stable during each depth scan taken.

In yet another embodiment of the present invention, a method for stabilizing the scan pattern of the optical sensor includes the step of (i) setting the angular velocity of the wedge prisms to a non-harmonic phase value in relation to the depth scan rate. By doing so, conformal coverage of the scanning area may be achieved. However, due to the drift of the angular velocities common in such a system, it is likely that the angular velocity will drift into a harmonic phase of the depth scan rate, and conformal coverage will be lost. Thus, the method further comprises the steps of (ii) varying the angular velocities of the dual wedge prisms during the total time of an entire sensor reading (i.e., 1500 scans), and (iii) varying the angular velocities of each wedge prism with respect to the other wedge prism over the total time of the sensor reading. By varying both the angular velocity of the wedge prisms over time in relation to the depth scan rate, and the angular velocity of each wedge prism over time in relation to the other wedge prism, conformal coverage of the scan surface area is maximized. According to an aspect of the present embodiment, the method may be modified to vary the oscillation rate of the angled mirror in the mirror sensor such that the oscillation rate in both axes of movement is not a harmonic of the depth scan rate of the sensor.

According to an alternate embodiment of the present invention, in an optical sensor with rotating dual wedge prisms, two harmonically related phase signals may be used to vary the angular velocities of each wedge prism so long as the time period of one phase signal associated with one of the wedge prisms is several times longer than the time period of one phase signal associated with the other wedge prism, and both phase signals are non-harmonic values of the depth scan rate. For example, if 2.0 Hz and 0.02 Hz are the angular velocities maintained over time of the wedge prisms, and the depth scan rate is 57 Hz, the problem is minimized and conformal coverage of the scan pattern is maximized. The embodiment encompasses numerous ways to vary the angular velocity of the wedge prisms, for example, a saw tooth wave, a sinusoidal wave, a triangle wave, etc.

In yet another embodiment of the present invention, a method for optimizing an amount of light entering and exiting an area of skin includes modifying the disposable optical lens as described above by incorporating a dome shape to the bottom surface of the optical window. The dome shape is designed to represent the Petzval surface of the focusing lens, and follows the variation in the focal point displacement that occurs as the focal point deviates from the optical axis through increasing incidence angles of the focused beam. Thus, the Petzval surface rests between the skin and the optical window of the disposable. Additionally, the Petzval surface also improves the interface between the disposable apparatus and the skin by stabilizing the local pressure on the skin in the vicinity of the depth scans. For a flat optical window, the pressure on the skin is distributed widely across the entire skin interface of the optical window, which is a relatively wide area. This wide distribution of pressure reduces the optical coupling efficiency of the sensor. Accordingly, the dome shape of the Petzval surface concentrates the pressure on the skin tissue towards the center of the dome where the scan is taking place, which optimizes the optical coupling efficiency of the sensor.

According to another aspect of the present embodiment, a pedestal shape may be incorporated onto the skin interface side of the optical window, to stabilize the local pressure on the skin in the vicinity of the depth scans by distributing the pressure along the plateau edge of the pedestal, thereby improving the optical contact.

The Petzval surface facilitates maintaining the focal point on the surface skin and reducing the blurring of the optical axis and maximizing the uniformity of light captured entering and exiting the skin at all points in the area scan. Using the Petzval surface, whenever the focused beam hits the surface of the skin, it is focused and maximized, providing the highest efficiency of the light as well as maintaining the same distance in depth that would be available along the optical axis due to the skin wrapping around the Petzval surface. The size of the Petzval surface is a function of the focusing lens design in the disposable apparatus. Both depth resolution and optical collection efficiency are optimized by maintaining the focal point on the Petzval surface.

According to another embodiment of the present invention, a method for improving the optical interface between a sensor and a surface of the skin includes the step of using an index matching medium at this optical interface, where the medium improves and stabilizes the optical interface and provides an optical transition for an optimal amount of incident light from the sensor to pass through to the skin. A wide variety of mediums that can be used, each with differing optical properties and viscosities, such as, for example, fluids such as glycerin, saline, and mineral oil, gels, such as medical gels or a gel moleskin, or adhesive-type materials, so long as the refractive index of the medium is less than the refractive index of the disposable apparatus. Preferably, the index matching medium provides a thin conformal coating on the skin and the associated disposable interface, and smoothes the optical roughness of the skin, reducing the loss of incident light entering the skin. By using an index matching medium, a patient need not wait the 60-90 minutes for the interface of the disposable and the skin to stabilize, but may use the OCT sensor at any given time by simply connecting it to the disposable optical lens apparatus adhered to the skin.

Additionally, the index matching medium smoothes out the relatively rough surface of the skin, which may cause a scattering of the focused beam at the skin surface. Accordingly, the index matching medium coats the skin and reduces the optical roughness of the skin surface, thereby optimizing the intensity of the light that goes into and comes out of the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be more readily understood from the detailed description of the preferred embodiment(s) presented below considered in conjunction with the attached drawings, of which:

FIG. **1** illustrates a rotating dual wedge prism optical scanning apparatus, according to an embodiment of the present invention;

FIG. **2** illustrates a mirror based optical scanning apparatus, according to an embodiment of the present invention;

FIG. **3** graphically shows how the relative position of an object being scanned by a rotating wedge prism optical scanning apparatus changes due to the orientation of the wedge prism;

FIGS. **4**A-**4**C illustrate the relationship between the angular velocity of one or more wedge prisms and the depth scan rate of a sensor in relation to the scan pattern of the sensor, according to an embodiment of the present invention;

FIG. **5**A presents a magnified view of the optical interface between an optical window and a surface of skin;

FIG. **5**B illustrates the effect of sweat and bodily fluids on the data produced by an optical signal;

FIG. **5**C presents a magnified view of the effect of sweat and bodily fluids on an optical interface between an optical window and a surface of skin;

FIG. **6**A presents an optical sensor system, according to an embodiment of the present invention;

FIG. **6**B presents an optical scanning system, according to an embodiment of the present invention;

FIG. **7**A presents a Petzval surface design for a disposable optical lens apparatus, according to an embodiment of the present invention;

FIG. **7**B presents a pedestal surface design for a disposable optical lens apparatus, according to an embodiment of the present invention;

FIG. **8** presents a method of using an optical scanning apparatus to measure blood glucose, according to an embodiment of the present invention;

FIG. **9** presents a method for stabilizing a scan pattern of an optical scanning apparatus, according to an embodiment of the present invention;

FIG. **10**A is a graphical illustration of varying the angular velocities of dual wedge prisms in an optical scanning apparatus over time; and

FIG. **10**B illustrates the effect of varying the angular velocities of dual wedge prisms in an optical scanning apparatus in comparison to the depth scan rate of the sensor apparatus, according to an embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. **6**A presents an optical scanning apparatus system or sensor system for taking blood glucose measurements, according to an embodiment of the present invention. Specifically, the sensor system in FIG. **6**A includes a dual wedge prism sensor housing **616** attached to a disposable optical lens apparatus **608** with a Petzval surface **609**. In FIG. **6**A, sensor system **601** comprises a sensor housing **614** that includes a collimator **602** connected to a light source at a connector **607**, wherein the light source produces a collimated light **603**. An example of a connector is a fiber-optic cable. The collimated light **603** hits a fixed mirror **604**, which bends the collimated light **603** to a ninety degree angle. The collimated light **603** passes through rotating dual wedge prisms **605** that deviate the angle of collimated light **603** off the optical axis of the sensor **601**. The amount of deviation is based on the thickness of each wedge prism **605** that the collimated light **603** passes through as the wedge prisms **605** rotate. The collimated light **603** then passes through a focusing lens **606**, which combines the collimated light **603** into converged light **612**, and facilitates focusing the converged light **612** to the focal plane and focal point **611**. The converged light **612** then passes through a disposable optical apparatus **608**. The disposable apparatus **608** provides an interface between the sensor and the surface of the skin **610** and facilitates setting a distance from focusing lens **606** to the focal plane that is fixed at the skin surface **610** by positioning the interface of the skin surface **610** with the optical window **608** to the focal plane. Because the focal point **611** traces out a curved path as it deviates from the optical axis, attached to the bottom surface of the disposable apparatus **608** is a Petzval dome **609** that acts as an optical window and focuses the focal point **611** onto the surface of the skin **610**. As shown in FIG. **6**A, the Petzval surface **609** is a separate component physically attached to the bottom surface of the disposable apparatus **608**. Alternately, the Petzval surface **609** may be integrally formed from the same material as the disposable apparatus **608**. A data collecting device, such as a computer may connect to the sensor housing **616** via the connector **602**.

In FIG. **6**B, an interferometer, an optical receiver, a demodulator, and an optical source may be miniaturized and coupled directly to the sensor housing via the connector **607**, as shown at **615**, making the sensor a "sample arm" of the interferometer. Additionally, the interferometer **615** may be connected to a computer **616** that downloads the sensor data and manipulates the data to produce a blood level glucose or other physiological reading.

In FIG. **6**A, the disposable optical lens apparatus **608**, including the focusing lens **606** and the Petzval surface **609**, may be attached and left on the skin **610** using a topical adhesive, such as, for example, cyanoacrylate or medical adhesive, such as 3M Medical Adhesive. The sensor housing **614** then attaches to the disposable apparatus **608** at connectors **613**. When a patient has completed taking a glucose reading, the patient may remove the sensor housing **614** and leave the disposable apparatus **608** attached to the skin. Thus, for the next glucose reading, which may be at some later point in time, perhaps after a meal, the patient need not worry about trying to place the sensor system **601** in the same location as the previous reading in order to produce comparable results. Instead, the patient may merely attach the sensor housing **614** to the disposable apparatus **608** using connectors **613** whenever a glucose reading is desired. The disposable apparatus **608** then may be removed and discarded at the end of a day, for example, and replaced with a new disposable apparatus **608** the following day. Alternately, the patient may leave the sensor housing **614** attached to the disposable apparatus **608** for an extended period of time to permit continuous blood glucose readings.

FIGS. **7**A and **7**B present disposable optical lens apparatuses, according to an embodiment of the present invention. As shown in FIG. **7**A, collimated light **603** pass through the focusing lens **606** and combine to become converged light **612** to pass through the disposable optical apparatus **608**. The converged light **612** focus into focal point **611** on the focal plane. The focal plane is captured by the dome-shaped Petzval surface **609** attached to the bottom surface of the disposable apparatus **608**. The Petzval surface **609** ensures that the focal point **611** remains at the skin interface to optimize the amount of light entering and exiting the skin **610**. FIG. **7**B presents a similar design of a disposable optical apparatus **608**, but with a pedestal-shaped optical window **609**, according to an embodiment of the present invention.

FIG. **8** presents an exemplary method of using the optical sensor system **601** for blood glucose measurements. The steps of the method need not be in the sequence illustrated, and some steps may occur essentially simultaneously. At step S**801**, a patient may place or rub an index matching medium, such as glycerine, onto an area of skin **610** where a blood glucose reading is to be taken. Use of an index matching medium facilitates matching the indices of refraction between the material of the Petzval surface **609** with the patient's skin **610** in order to optimize the amount of light that enters and exits the skin **610**, and expedites the time required for the Petzval surface **609** to reach equilibrium with the skin surface **610**. For example, if the material used in the Petzval surface **609** has an index of refraction of 1.5 and the patient's skin **610** has an index of refraction of 1.3, then without an index matching medium some of the focused converged light **612** entering the skin is lost due to the lower index of refraction of the skin **610**. Accordingly, not all of the light exits the skin **610** due to the lower index of refraction, which causes a loss of data. By using an index matching medium with, in this example, a refractive index of 1.4, the medium provides an optical transition for the converged light **612** between the Petzval surface **609** and the skin **610**, which increases the amount of light that enters and exits the skin **610**. Without the index matching medium, a patient would have to wait upwards of 60 to 90 minutes for the skin to produce sweat and other skin oils at the area where the disposable is placed, in order to optimize the data collection of the sensor.

With the medium in place, at step S**802**, the patient may adhere the disposable lens apparatus **608** to the area where the index matching medium was placed. Common adhesives such as cyanoacrylate or medical adhesive may be used to secure the disposable apparatus **608** to the skin **610**. Once the patient feels that the disposable apparatus **608** is secure, at step S**803**, the patient couples the sensor housing **614** to the disposable apparatus **608** using the connectors **613**.

At step S**804**, sensor diagnostics verify that a threshold trigger of 45 dB has been pre-set to normalize the scans and resolve for variations in the optical path lengths of the scans produced by the rotating wedge prisms **605** and, accordingly, the change in the thickness of each wedge prism **605** during the rotations. At step S**805**, sensor diagnostics verify that the angular velocity of each wedge prism **605** has been pre-set to a value such that the lateral position of each focused scan spot moves less than 10× the diameter of the focused scan spot during the data acquisition of the depth scan. For example, if focused scan spot size has a diameter of 20 microns, then the angular velocity is set to a value such that the focused beam **611** does not move laterally more than 200 microns during the depth scan. By setting the angular velocity of each wedge prism **605** to such a value, the distortion in the depth scale of each scan produced by the change in thickness of the wedge prism **605** as it rotates is minimized. The threshold trigger, depth scan rate and angular velocities are presets that may be optimized and built into the sensor system **601**.

At step S**806**, the patient sets the sensor system **601** to begin scanning the skin **610**. Since a threshold trigger was set at 45 dB in step S**804**, the sensor system **601** will not accumulate scan data until the intensity of the optical signal produced by the sensor system **601** reaches a value of 45 dB. Preferably, the threshold is above the highest noise peak produced by the signal but at least 10 dB lower than the intensity peak at the interface between the skin **610** and the disposable apparatus **614**.

Once the sensor system **601** has completed taking multiple scans, preferably around 1500 scans, at step S**807**, the sensor housing **614** may be removed from the disposable apparatus **608**, or, alternately, the sensor housing **614** may remain and begin to take another glucose reading. The disposable apparatus **608** remains adhered to the patient's skin **610**. The scan data then is manipulated by computer **616** connected to the interferometer **615**. Because the threshold trigger was used, all the scans taken begin at a signal intensity of 45 dB, which is equivalent to Time **0**, and accordingly, at step S**808**, the scans are averaged to reduce the speckle associated with the sensor **601**. At step S**809**, the averaged scan data is manipulated using algorithms, such as those described in U.S. Provisional Applications Nos. 60/671,007 and 60/671,285, to derive blood glucose levels. At any later time, such as after a meal, the patient may reattach the sensor housing **614** to the disposable apparatus **608** to take another glucose measurement.

Alternately, the sensor system **601** may be designed to not use a threshold trigger setting at S**804**, and may normalize the scans once the data has been acquired. For example, once the sensor completes a glucose reading at step S**807**, computer **616** of the sensor system **601** may apply a peak locating algorithm such as, for example, Gaussian peak fitting, to the first scan to locate the first peak, at step S**810**. Once step S**810** has been completed, the peak locating algorithm is applied to each successive scan, as shown at step S**811**. At step S**812**, the successive scans are normalized in depth against the first scan by essentially designating the location of each peak as at Time **0**, in order to average the scans together. Thus, any distortion in the optical path length due to the change in the thickness of the wedge prisms **605** as they rotate is removed.

FIG. **9** presents an exemplary method for stabilizing the scan pattern of sensor **601** and is discussed in conjunction with FIG. **10**A, which is a graphical illustration of varying the angular velocities of the dual wedge prisms **605** of sensor system **601**. When using the sensor system **601** to take a blood glucose measurement, the first wedge prism **605** begins rotating at a rate of 2.1 revolutions per second ("rps"), which is equivalent to 2.1 Hz, at step S**901**, as shown at **1001** in FIG. **10**A. Similarly, at step S**902**, the second wedge prism **605** begins rotating at a rate of 1.3 Hz, as shown at **1002**, where 2.1 Hz and 1.3 Hz are not integrals of each other. The sensor system **601** then begins to perform depth scans at a rate of 30 Hz, at step S**903**. An integral of 30 Hz is 2 Hz (i.e., 2 multiplied by 15 equals 30). Additionally, another integral of 30 Hz is 1.5 Hz (i.e., 1.5 multiplied by 20 equals 30 Hz). Thus, although the wedge prisms **605** begin to rotate at rates that are non-integrals of 30 Hz, if the angular velocities **1001**, **1002** of both wedge prisms **605** remain at 2.1 Hz and 1.3 Hz, the angular velocities may drift towards 2.0 Hz and 1.5 Hz, thereby becoming integrals of 30 Hz, and preventing conformal coverage of the scan pattern area of the skin **610**.

To prevent the angular velocities from becoming integrals of the depth scan rate and remaining at the integral rates, both angular velocities **1001** and **1002** of the wedge prisms **605** are varied over time, in relation to the depth scan rate and in relation to each wedge prism **605**, as shown in FIG. **10**A. At step S**904**, the angular velocity **1001** of the first wedge prism **605** is varied as the sensor system **601** continues to perform depth scans. In FIG. **10**A, the angular velocity **1001** of the first wedge prism **605** is sinusoidal, oscillating from 2.5 Hz to 1.7 Hz, over a period of 6500 milliseconds, or 6.5 seconds. At step S**905**, the angular velocity **1002** of the second wedge prism **605** is varied independent of the angular velocity **1001** of the first wedge prism **605**, as shown in FIG. **10**A. In FIG. **10**A, the angular velocity **1002** of the second wedge prism **605** is sinusoidal, oscillating from 1.55 Hz to 1.1 Hz, over a period of 5250 milliseconds, or 5.25 seconds. Thus, although the angular velocities of both wedge prisms **605** may hit a harmonic of 30 Hz during the variation, the angular velocities only remain an integral of 30 rpm for one or two depth scans before the velocities change, thereby minimizing the loss of depth scan data due to the angular velocities being integrals of the depth scan rate. The result is a random, conformal mapping of the scanned surface area of the skin **610** with minimal overlapping within the results, as shown at step S**906**.

FIG. **10**B illustrates the results of varying the angular velocities of the wedge prisms **605** over time with respect the depth scan rate of sensor system **601** and with respect to each wedge prism **605**. By minimizing the potential for a harmonic phase to be created between the depth scan rate and the angular velocities of the wedge prisms **605**, conformal coverage of the area of skin **610** scanned is optimized, with each dot representing a position of an individual depth scan on the skin **610**.

While the present invention has been described with respect to what is presently considered to be the preferred embodiments, it is to be understood that the invention is not limited to the disclosed embodiments. To the contrary, the invention is intended to cover various modifications and equivalent arrangements included within the spirit and scope of the appended claims. The scope of the following claims is to be accorded the broadest interpretation so as to encompass all such modifications and equivalent structures and functions.

What is claimed is:

1. A system for creating a stable and reproducible optical interface in an optical sensor system for performing an optical scan on biological tissue comprises:
- an optical interferometer sensor utilizing a beam of light;
- an interferometer connected to the optical sensor;
- a computer connected to an optical receiver associated with the interferometer; and
- a disposable optical apparatus attachable to the optical sensor, wherein the disposable optical apparatus comprises:
  - a focusing lens; and
  - an optical window connected to the focusing lens on a first side of the optical window, the optical window including a dome shaped surface on a second side of the optical window;
- wherein the disposable optical apparatus is attachable to a surface area of biological tissue, wherein the dome shaped surface is configured to interface with the surface area of the biological tissue.

2. The system of claim **1**, wherein the optical sensor utilizes at least one rotating wedge prism to deviate an angle of the beam of light from an optical axis of the system.

3. The system of claim **1**, wherein the optical sensor utilizes at least one oscillating angled mirror to deviate an angle of the beam of light from an optical axis of the system.

4. The system of claim **1**, wherein the dome shaped surface includes a Petzval surface.

5. The system of claim **1**, wherein the focusing lens and the dome shaped surface are configured to focus the beam of light onto the biological tissue.

6. The system of claim **5**, wherein the beam of light is received by the focusing lens and subsequently received by the dome shaped surface.

7. The system of claim **1**, wherein the first side of the optical window is opposite the second side.

8. The system of claim **1**, wherein the disposable optical apparatus is attachable to the surface area of the biological tissue using an adhesive.

9. A method of using an optical system with an optical interferometer sensor and a disposable optical apparatus for performing an optical scan on biological tissue comprises:

attaching the disposable apparatus to a surface area of biological tissue, the disposable apparatus including 1) a focusing lens for receiving light from the optical sensor and 2) a focusing surface for receiving the light from the focusing lens, the focusing surface distinct from the focusing lens, the focusing lens and the focusing surface configured to focus the light onto the biological tissue;

coupling the optical sensor to the disposable apparatus; and

performing an optical scan using the optical sensor.

10. The method of claim **9**, further comprising the steps of:

removing the optical sensor from the disposable apparatus; and

leaving the disposable apparatus on the surface area of biological tissue for later use.

11. The method of claim **9**, further comprising the step of placing an index matching medium between the disposable apparatus and the surface area of the biological tissue.

12. The method of claim **9**, wherein the focusing surface comprises a Petzval surface.

13. The method of claim **9**, wherein the focusing surface comprises a dome shape.

14. The method of claim **9**, wherein the focusing surface is configured to interface with the surface area of the biological tissue.

15. The method of claim **9**, wherein the focusing surface comprises a pedestal shape.

16. A disposable optical apparatus configured to attach to an optical sensor, the disposable optical apparatus comprising:

a releasable connector for temporarily attaching the optical sensor to the disposable optical apparatus;

a focusing lens configured to receive light from the optical sensor;

an optical window connected to the focusing lens on a first side of the optical window;

a dome shaped surface on a second side of the optical window, the dome shaped surface configured to receive light from the focusing lens; and

an attachment layer for attaching the disposable optical apparatus is to a patient's skin;

wherein the focusing lens and the dome shaped surface are configured to focus the light onto the patient's skin.

17. The apparatus of claim **16**, wherein the first side of the optical window is opposite the second side.

18. The apparatus of claim **16**, wherein the dome shaped surface includes a biasing area configured to concentrate pressure on the patient's skin towards the vicinity of the light focused on the biological tissue.

19. The apparatus of claim **16**, wherein the dome shaped surface includes a Petzval surface.

20. The apparatus of claim **16**, wherein the focusing lens and the dome shaped surface are configured to focus the light onto the biological tissue.

21. The apparatus of claim **16**, wherein the first side of the optical window is opposite the second side.

22. The apparatus of claim **16**, wherein the dome shaped surface is integrated with the optical window.

23. The apparatus of claim **16**, wherein the attachment layer includes an adhesive.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,219,172 B2
APPLICATION NO. : 11/378538
DATED : July 10, 2012
INVENTOR(S) : Schurman et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specifications:

At column 1, line 49, change “blood-profused” to --blood perfused--.

At column 3, line 19, change “length” to --length.--.

In the Claims:

At column 16, line 12 (approx.), in Claim 16, change “apparatus is” to --apparatus--.

Signed and Sealed this
Twenty-second Day of January, 2013

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office