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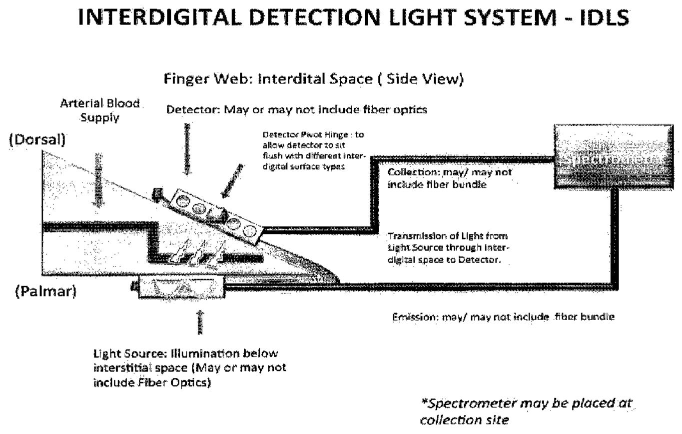
FIG 1A



(57) Abstract: A system for detection of blood analytes comprising a detector, a light source, and a resilient connector extending between the detector and the light source and positioning the detector and light source relative to one another such that one is positioned on the dorsal surface of a user's interdigital space and the other is positioned on the palmar surface of a user's interdigital space. A further system for detection of blood trace analytes is also disclosed. The system comprises an illumination disc supporting a plurality of sources of electromagnetic radiation and rotatable relative to an interdigital location of a subject, and a spectrometer disc supporting a plurality of spectrometers able to process the electromagnetic radiation from the illumination disc and rotatable relative to the interdigital location of a subject at a position opposite that of the illumination disc.

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INTERDIGITAL DETECTION SYSTEM AND MEMS SPECTROMETER 2 DISK SYSTEMS

CROSS-REFERENCE TO RELATED APPLICATION(S)

[0001] This application claims the benefit and the priority of U.S. Patent Application No. 15/043,494, filed February 12, 2016 and U.S. Patent Application No. 15/069,933, filed March 14, 2016.

BACKGROUND OF THE INVENTION

[0002] This invention relates to the field of medical devices for non-invasive blood trace analyte detection, measurement, and medical analysis thereof. More specifically, the invention comprises a non-invasive measurement system using a detection mechanism positioned between the interdigital space targeting arterial blood supply.

SUMMARY

[0003] The detection mechanism used in a device or system may be any of a wide variety of detection mechanisms, such as spectroscopy, fluoroscopy, pulse-oximetry, or microscopy. For example, the detection mechanism may be spectroscopy. Spectroscopy covers analysis of any blood trace analyte whereby the light source located on bottom (palmar aspect) side, emits electromagnetic radiation to pass through the arterial blood supply (palmar artery), and the detector (dorsal aspect) side receives the light information that has passed through the interdigital spacing between probe and detector. The form of spectroscopy or other detection mechanism method will be integrated into the system.

[0004] The form of spectroscopy may also cover the opposite direction of transmission whereby the light source located on the top (dorsal aspect) side, emits electromagnetic radiation to pass through the arterial blood supply (palmar artery), and the detector (palmar) side receives the light information that has passed through the interdigital spacing between probe and detector. With either form of spectroscopy, the method will be integrated into the system.

[0005] The method for non-invasively evaluating blood trace analytes of a subject may include providing a source of electromagnetic radiation to a device, positioning the device at an interdigital location between fingers or toes of a subject, and receiving the electromagnetic radiation that has passed through or reflected from the subject between the interdigital space between the proximal phalanx and between the adjacent metacarpophalangeal joints.

[0006] In an embodiment of the present invention, the method includes applying the device to a surface of the subject at a substantially constant pressure, and the device can be applied such that it is it to be substantially flush with the surface of the subject's skin. The device may also include a touch and/or other type of sensor to activate the device and/or a pressure sensor to ensure the device is operated at a particular pressure. The device may or may not include a pulse LED or electromagnetic transmission device to ensure proper placement, for accurate detection and measurement of arterial blood.

[0007] In an embodiment of the present invention, the system includes a probe light source base (positioned at the palmar aspect between the metacarpophalangeal joint) and a probe detector head (positioned at the dorsal aspect between the metacarpophalangeal joint). The system may include foam-like padding (e.g. neoprene for optimal ergonomic fit) which also serves to block any unnecessary light at the interface.

[0008] In an aspect of an embodiment of the present invention, the electromagnetic radiation can be near infrared radiation, fluoroscopy, pulse oximetry, and/or transmission spectroscopy methods. A wide variety of light sources may be used in the device as appropriate to the form of detection being implemented.

[0009] In another embodiment to the present invention, an apparatus for non-invasively evaluating blood trace analytes of a subject includes a means for providing a source of electromagnetic radiation to a device, a means for positioning the device at an interdigital location between fingers or toes of the subject, and a means for receiving the electromagnetic radiation absorbed or reflected from the subject. Receiving the electromagnetic radiation may or may not occur on the dorsal aspect of the interdigital space, whereby the light source may or may not be positioned on the palmar side, and emits electromagnetic radiation.

[0010] Another embodiment of the present invention is directed toward an interdigital detection light system for non-invasively evaluating body fluids of a subject. The system includes a source of electromagnetic radiation, a probe light source which may or may not include fiber optics conveying electromagnetic radiation from the source to the probe detector, which may or may not include fiber optics, adapted to receive the emitted electromagnetic radiation at an interdigital location between fingers or toes of the subject. The light source transmits light from the palmar aspect between two metacarpophalangeal joint, and the detector receives information from the dorsal aspect between two metacarpophalangeal joints.

[0011] A wide variety of detectors or detection mechanisms may be used in the device as may be appropriate to the analyte to be detected. Various infrared detectors may be used to detect blood alcohol or blood glucose levels for example. Various imaging mechanisms, whether two dimensional or three dimensional, may also be used.

[0012] In another embodiment of the present invention, the detection light system includes a source of electromagnetic radiation that detects near infrared radiation, X-ray (fluoroscopy), pulse-oximetry, or any wavelength capable of transmission spectroscopy.

[0013] This invention relates to the field of medical devices for non-invasive blood trace analyte detection, measurement, and medical analysis thereof. More specifically, one or more embodiments of the invention comprise non-invasive measurement system with a MEMS spectrometer disc, and an illumination disc (2disc system) that rotate, controlled by a micro positioning control panel, to measure all blood constituents with absorption between 100nm-5000nm. The light source assigned to a specific wavelength region coupled with the MEMS spectrometer chip specific to that same wavelength region will use a transmission spectroscopy method.

[0014] One or more embodiments of the system will work by using a microprocessor to position MEMS spectrometers (rotational position on the y-axis), in position with a light source from an illumination disk (rotational position on the x-axis) to ensure alignment based on wavelength. The coordinated positioning coordinates the electromagnetic radiation emission and the MEMS spectrometers that correspond to processing a specified electromagnetic radiation wavelength region. This coordinated system will allow for non-invasive detection and quantification of multiple analytes detectable from wavelengths from 100nm-5000nm wavelengths.

[0015] The form of spectroscopy covers analysis of any blood trace analyte whereby the illumination disc, consisting of several different light sources, located on bottom (palmar aspect) side, emits electromagnetic radiation to pass through the arterial blood supply (palmar artery), and the MEMS spectrometer disc (dorsal aspect), consisting of several MEMS spectrometers, receives the light information that has passed through the interdigital spacing between illumination disk and the MEMS spectrometer disk. This may use several MEMS chip spectrometers that cover certain wavelength regions, and several light sources from the illumination disc that correspond to the wavelength regions of interest. See Fig. 11.

[0016] The method for non-invasively evaluating blood trace analytes of a subject may include providing a source of electromagnetic radiation to a device, positioning the MEMS chip spectrometer disc at an interdigital location between fingers or toes of a subject, and receiving the electromagnetic radiation that has passed through or reflected from the subject between the interdigital space between the proximal phalanx and between the adjacent metacarpophalangeal joints. See Fig. 16.

[0017] In an aspect of an embodiment of the present invention, the method includes applying the device to a surface of the subject at a substantially constant pressure, and the device can be applied such that it is it to be substantially flush with the surface of the subject's skin. The device may also include a touch and/or other type of sensor to activate the device and/or a pressure sensor to ensure the device is operated at a particular pressure. However, it should be understood that the device may also be applied so as to be spaced from the surface of the subject's skin.

[0018] In an aspect of embodiment of the present invention, the system includes a MEMS spectrometer disc (positioned at the dorsal aspect between the metacarpophalangeal joint) that rotates along the y-axis plane, allowing for non-invasive measurement of blood analytes detectable from 100nm - 5000nm through a series of MEMS spectrometers, and the illumination disc (positioned at the palmar aspect between the metacarpophalangeal joint) with several lights sources that rotate along the x-axis palmar plane to provide electromagnetic radiation from 100nm-5000nm.

[0019] In an aspect of an embodiment of the present invention, the electromagnetic radiation can be near infrared radiation, fluoroscopy, pulse oximetry, and include diffuse reflectance or transmission spectroscopy methods.

[0020] In another aspect of an embodiment to the present invention, an apparatus is provided for non-invasively evaluating blood trace analytes of a subject including a means for providing a multiple sources of electromagnetic radiation to a device, a means for positioning the device at an interdigital location between fingers or toes of the subject, and a means for receiving multiple electromagnetic radiation signals absorbed and or reflected from the subject. Receiving the electromagnetic radiation may occur on the dorsal aspect of the interdigital space, whereby the illumination occurs from the palmar aspect. See Fig.11.

[0021] Another aspect of an embodiment of the present invention is directed toward a multiple spectrometer plus multiple light source detection system for non-invasive evaluation of body fluids of a subject. The system includes multiple sources of electromagnetic radiation and may or may not use probe light source(s), light pipe(s) or fiber optic(s). Conveyance of the electromagnetic radiation from the illumination disk to the MEMS Spectrometer Disk may or may not include fiber optics. The integration of choosing light source to MEMS chip corresponds to the wavelength region of interest whereby the emitted electromagnetic radiation at specific wavelength regions is in parity with the illumination lights source from disk. The system can operate at any interdigital location between fingers or toes of the subject. The illumination disk may consist of multiple light sources that transmit light from the palmar aspect between two metacarpophalangeal joints, and the MEMS spectrometer detectors will receive information from the dorsal aspect between two metacarpophalangeal joints. See Fig. 16 Target Measurement Zone and Fig. 12.

[0022] In another aspect of an embodiment of the present invention, the MEMS spectrometer disk and illumination disk detection light system includes a source of electromagnetic radiation covering wavelength regions from 100nm – 5000nm capable of transmission spectroscopy.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Fig. 1a is a schematic diagram of an embodiment of the present invention.

[0024] Fig. 1b is a schematic diagram of another embodiment of the present invention.

[0025] Fig. 2 is a schematic rendering of one embodiment of a system of the present invention.

[0026] Fig. 3 is a schematic rendering of another embodiment of a system of the present invention.

[0027] Fig. 4 is a schematic rendering of another view of the embodiment shown in Fig. 3.

[0028] Fig. 5 is a diagram showing blood pathways in areas of potential interest for the present invention.

[0029] Fig. 11 is a schematic side view of a system according to the present invention.

[0030] Fig. 12 is a schematic side view of another system according to the present invention.

[0031] Fig. 13 is a schematic top view of a component that could be used in a system according to the present invention.

[0032] Fig. 14 is a schematic top view of a user interfacing with a component that could be used in a system according to the present invention.

[0033] Fig. 15 is a schematic bottom view of the component of Fig. 4.

[0034] Fig. 16 is a diagram of a circulatory system in a patient's hand showing potential target zones for use of the present invention.

DETAILED DESCRIPTION

[0035] An apparatus for evaluation of a subject's body fluids may be used at the interdigital region adjacent to or in between a subject's extremities. The evaluation positioning consists of a light source (probe) on the palmar aspect, which may or may not include fiber optics, and a detector (probe) on the dorsal aspect, which may or may not include fiber optics. The measurement device may be positioned flush with skin at both palmar/dorsal aspects of hand between the second and third proximal phalanx and between the (MCP) metacarpophalangeal joint. The spectroscopy, fluoroscopy, pulse-oximetry and/or microscopy targets the palmar digital arterial blood supply at the interdigital spacing between any hand or foot digit, see Fig 5., and can detect and quantify multiple blood analytes using various methods. The system can be used measure blood trace analytes such as: blood alcohol, blood glucose, cancer biomarkers, biomarkers, chemotherapy, pharmaceuticals drugs, blood oxygenation levels, and or pulse/ heart rate for any medical screening or diagnostic purposes.

[0036] The device may possess one or more of the movements such as rotational, translational, and/or vertical freedom necessary for the probes to contact the subjects tissue at a consistent angle and pressure while accommodating the different size of the subjects extremities, and may be of any memory yielding material optimized for attaining reproducible blood flow to the region of the subject that is measured, and for minimizing the effects of pulling, stretching, pressing, compressing the subject's skin. A smooth fit that does not clamp or clip to the user is preferred.

[0037] To allow the detector to rest flush with the user's skin surface, a pivot hinge 24 may be provided at the sides of the detector facing the adjacent user digits. The pivot hinge on each side is received into openings in a connector or carrier means 14 so that the detector can rotate as needed to rest flush.

[0038] In addition, the measurement device may be coupled with a temperature measurement means that detects the subject's body temperature in or near the region being measured, or the subject's core or mean body temperature, or the ambient temperature proximate to the probes, detectors, or sensors.

[0039] In addition, the spectroscopic measurement may be coupled with a biometric scanner that detects the subject's identity. the biometric scanner can be positioned to measure the fingerprint of any digit on the hand or foot. The system may couple blood trace analyte measurements with GPS, accelerometer, or gyroscopic measurements: speed, velocity, global positioning, altitude, longitude position, latitude position, or relative location. The system may couple heart rate (pulse), and blood oxygenation measurement levels, with GPS or gyroscopic measurement. The system may also include one or more methods to communicate information of a subject to a mobile device, computer, cell phone, subject database, or computer software.

[0040] An apparatus for non-invasive spectroscopic measurement according to the one embodiment of the present invention is suitable for many applications, particularly for non-invasively evaluating blood trace analytes such as: synthetic markers or nano-particles that have been coupled to certain components or analytes in a bodily fluid of a subject, such as the subject's blood, where the markers or nano particles are designed to have a particular spectroscopic or visual signature. In addition, the apparatus could be used to detect toxins or hazardous chemicals in the blood. The apparatus can measure cancer biomarkers, pulse (heart rate), blood oxygenation, and pharmaceutical drugs.

[0041] Such an apparatus could be useful in biomedical applications. For example the apparatus could be used to monitor cancer biomarkers, or biomarkers in the blood for preventative screening. In such applications, the apparatus could be configured to be attachable to a patient for continuous monitoring whereby the system is integrated into a glove. See Figure 2. When coupled with a biometric identification device, the apparatus could also link to insurance and/ or medical records of a patient. This link could be used to update patient information or to make comparisons of past fluoroscopic readings, by way of example, as an aid in diagnosis and treatment of patients with cancer.

[0042] Such an apparatus could be useful in the biomedical application of heart rate and blood oxygenation monitoring and serve as a pulse oximetry sports glove. When coupled with GPS, and accelerometer, or gyroscopic device, the apparatus can give real-time information on heart rate and blood oxygenation level with body position. This technology can transmit via Bluetooth, or direct sync to a mobile device, cell phone, or computer.

[0043] Multiple embodiments include many different light sources to provide a source of electromagnetic radiation. In one embodiment, fluoroscopy-imaging technique using x-rays can be used to measure cancer biomarkers or blood trace analytes in two dimensional or three dimensional capacity. In another, embodiment, a quartz halogen lamp is used to provide a source of electromagnetic radiation in the near infrared region; suitable for non-invasive measurement of concentrations of blood components or blood analytes, such as alcohol or glucose. Other light producing devices such as flash lamps, tungsten-halogen lights, light emitting diodes, quartz halogen, or laser sources can be used in conjunction with filtering mechanisms to produce a certain spectral range that corresponds to the spectral range absorption of other targeted tissue components or analytes to be measured. The transmission of this electromagnetic radiation from the palmar aspect at the interdigital space between the metacarpophalangeal (MCP) joint and received on the dorsal aspect of the interdigital space between the metacarpophalangeal (MCP) joint are part of what makes this invention unique. Additionally, the system may or may not integrate into a glove to ensure proper fit, placement, and ergonomic comfort at the target measurement zone. The detector pivot hinge is an additional design component that ensures optimal flush positioning of the detector and light source with the interdigital space. The system may or may not be connected to a spectrometer with or without fiber optics. The spectrometer may or may not include light source and detector at some aspect of the hand; either dorsal or palmar. The system may or may not be connected to LCD screens, which will display/ process measurement metrics/information, which can transmit data via Bluetooth or direct connection to a computer, wireless device, or processing software system.

[0044] As noted, the detector or detector mechanism may be in the form of microscopy, or other form of imaging, whether two dimensional or three dimensional. For example, the detector may be a microscope on a chip. Such chips are available from the Swiss company Nanolive, and are described in U.S. Patent No. 8,937,722, the entire disclosure of which is incorporated by reference herein.

[0045] Figures 1a and 1b illustrate a schematic side view of the system interface having a probe head (detector) 10, which may or may not include fiber optics, a probe base (light source) 12 that may or may not include fiber optics, and a mechanism 14 connecting the probe head to the probe base. The connection may include any material that allows the light source and detector to sit flush with the interdigital space. The light source will emit from the palmar aspect with detection on the dorsal aspect positioned between any interdigital space of the hand, and or the interdigital space of the feet at the palmar digital crease. The light source may also emit from the dorsal aspect with detection on the palmar aspect positioned between any interdigital space of the hand, and or the interdigital space of the feet at the palmar digital crease. The detector and light source must be flush with skin and are ergonomically positioned using the interface. The method of spectroscopy, fluoroscopy, pulse-oximetry, or microscopy covers any form of electromagnetic radiation at any wavelength and any type of detector whereby the light source is positioned on the palmar or dorsal aspect, and the detector is correspondingly positioned on the dorsal or palmar aspect of the subject.

[0046] The light source and/or the detector and/or any collector mechanism used in the system may be incorporated into or on a chip. As noted, various different light sources, detectors and collectors may be used with the system depending upon the analyte being monitored. In an embodiment of the system, the system may be configured to accept and retain interchangeable chips. In this way, a system may be customized for a particular patient, situation or analyte by interchanging the chips used in the system. The light source chip 12 may be changed to incorporate a different light source. Similarly, the detector or collector chip 10 can be changed as is appropriate to the circumstances. The light source and detector chips may also be interchanged between dorsal and palmar aspects if desired. Removeable chips also allow for removal and replacement of light sources and/or detectors that have stopped operating.

[0047] Figure 2 illustrates a method of spectroscopy (sensor) integrated into a glove 16 where the system is stitched into a glove, which serves as the mechanism that connects the light source probe and detector. The system may also include neoprene padding to ensure no peripheral light into a measurement zone. Light source can emit from either palmar /dorsal aspect, and detection can occur at either dorsal / palmar aspect. Measurement site occurs at the interdigital space between the first (index) finger and the second (middle) finger, but is not limited to this region and can include any interdigital space whereby arterial blood supply is targeted for detection, measurement, and or analysis of measureable blood trace analytes. See Fig. 5. The system also illustrates the ability to communicate subject information to a mobile device 18, cell phone, computer 20, patient database, or computer software. Communication of information can occur via direct connectivity (e.g. USB) or via Bluetooth. Biometric identification capabilities are also possible to exclusively identify patient, and ensure HIPAA compliance. Spectroscopy measurements and data gathered can couple with GPS or gyroscopic measurements.

[0048] Figure 3 illustrates the top view of hand (dorsal) system location: Between the knuckles of any interdigital spacing whereby the system targets arterial blood supply for detection, measurement, and medical analysis of blood analytes measured at this site. This view illustrates the location and method of spectroscopy whereby the detector probe 10 collects from the dorsal aspect. The illustration is an artistic rendering of a system without the glove to demonstrate target measurement zone and ergonomics. The collection (detector) may or may not include a fiber bundle.

[0049] Figure 4 illustrates the bottom view of the hand (palmar) system location: Between the palmar beds of any interdigital spacing whereby the system emits electromagnetic radiation directly through arterial blood supply for detection, measurement, and medical analysis of blood analytes at this site. This view illustrates the location and method of spectroscopy whereby the light source probe emits from the palmar aspect. The illustration is an artistic rendering of what the system will look like from the palmar aspect. The light source probe may or may not include a fiber bundle.

[0050] Figure 5 illustrates the target measurement zones "TMZs" (arterial blood supply). The TMZ is the arterial blood supply from the digital palmar artery. The TMZ is at the interdigital space between the metacarpophalangeal joint.

[0051] The system will typically consist of a light source and detector made of any resilient material that allows for flush skin contact of both the detector and light source. This may include, but is not limited to: a specially designed tissue interface with an integrated detector and light source, spectrometer with/without fiber optics, fluoroscopy, X-ray, pulse oximetry, or microscopy.

[0052] The detector may or may not include fiber bundle. The detector / sensor can be a probe, collection fiber bundle, or chip sensor. The detector may be connected to a spectrometer via fiber bundle.

[0053] The light may or may not include fiber bundle. The light source can be any electromagnetic radiation: a quartz halogen, laser, light emitting diode, or a probe at the tip of light source fiber optics.

[0054] The interdigital tissue interface may consist of any malleable material that allows consistent pressure of the detector and light source to position flush with the interdigital space between the hand or feet digits. The interdigital tissue interface can be integrated into a glove, hand cradle, adjustable attachment means, etc.

[0055] The system interface components can be made of any resilient material with memory, and may include but not limited to: plastic, aluminum, carbon, rubber, latex, fabric, neoprene, etc.

[0056] The system may include a spring hinge 22 to facilitate constant pressure at the interdigital space.

[0057] The system can couple with biometric identification capabilities to share information with handheld devices, mobile phones, computers, patient databases or any software integrated into the aforementioned devices capable of receiving such.

[0058] The system can couple with global positioning system to sync information gathered from non-invasive blood analysis to location coordinates and subject positioning (e.g. heart rate at a specific location).

[0059] The system can couple with an accelerometer to facilitate battery preservation when sensor is not in motion for a specific amount of time (e.g. heart rate monitoring turned off when stationary for more than an hour or heart rate at a certain speed).

[0060] The system can couple with gyroscopic technology to pair orientation with non-invasive blood analysis (e.g. heart rate measured laying down).

[0061] The system can couple with an altimeter to pair altitude with non-invasive blood analysis (e.g. heart rate at a certain altitude).

[0062] Fig. 11 illustrates a side view of a system interface having a MEMS spectrometer disk with multiple spectrometers and detector, which may or may not be directly attached to the MEMS spectrometer. The system may or may not include fiber optics. The illumination disk (light source) may or may not include fiber optics, and a mechanism connecting the MEMS spectrometer disk to the illumination disk. The connection may include any material or bracket that allows the illumination disk and MEMS spectrometer disks to ensure flush positioning with the interdigital space. The light source(s) will emit from the palmar aspect with detection/spectrometer(s) on the dorsal aspect positioned between any interdigital space of the hand, and or the interdigital space of the feet at the palmar digital crease. The MEMS spectrometer disk and illumination disk may be flush with skin and are ergonomically positioned using the system interface. The method of spectroscopy covers any form of electromagnetic radiation at any wavelength and any type of detector whereby the light source is positioned with respect to the appropriate detecting spectrometer.

[0063] Fig. 12 illustrates a method of spectroscopy integrated into a handheld unit where the system is integrated into the handheld unit. A processor that ensures proper alignment of illumination disk and spectrometer disk will control the system compact XY axis interface. The system handheld unit may also include several ergonomic enhancements such as palmar padding. Light source(s) emits from the palmar aspect, and detection occurs at the dorsal aspect. Measurement site occurs at the interdigital space between the first (index) finger and the second (middle) finger, but is not limited to this region and can include any interdigital space whereby arterial blood supply is targeted for detection, measurement, and or analysis of measureable blood trace analytes. See Fig. 15. The system also illustrates the ability to communicate subject information to a mobile device, cell phone, computer, patient database, or computer software. Biometric identification capabilities are also possible to exclusively identify patient, and ensure HIPAA compliance.

[0064] Fig. 13 illustrates the top view of a system handheld unit. System location: Between the knuckles of any interdigital spacing whereby the system targets arterial blood supply for detection, measurement, and medical analysis of blood analytes measured at this site. It also illustrates the location and method of spectroscopy whereby the MEMS spectrometers collect from the dorsal aspect. The illustration is an artistic rendering of a system handheld unit to illustrate top view and where a subject inserts a hand for measurement.

[0065] Fig. 14 illustrates the top view of the hand (dorsal) integrated into the system handheld unit. System measurement location: Between the metacarpophylangial joints of any interdigital spacing whereby the system collects electromagnetic radiation directly through arterial blood supply for detection, measurement, and medical analysis of blood analytes at this site. It also illustrates the location of spectroscopy whereby the detection source is located on the dorsal aspect. The illustration is an artistic rendering of what the system will look like from the dorsal aspect. The MEMs spectrometer source(s) disc may or may not include a fiber bundle(s) or light pipe(s).

[0066] Fig. 15 illustrates the bottom view of the hand (Palmar) integrated into the system handheld unit. The system measurement location: between the palmar beds on the palmar aspect of the metacarpophalangeal joint.

[0067] Fig. 16 illustrates the target measurement zones “TMZs” (Arterial Blood Supply). The TMZ is the arterial blood supply from the digital palmar artery. The TMZ is at the interdigital space between the metacarpophalangeal joints.

[0068] An apparatus for non-invasive spectroscopic measurement according to the one embodiment of the present invention is suitable for many applications, particularly for non-invasively evaluating blood trace analytes such as: minerals, organic, and inorganic compounds, pharmaceutical drugs, synthetic markers or nano-particles. In addition, the apparatus could be used to detect toxins or hazardous chemicals in the blood.

[0069] Such an apparatus could be useful in biomedical applications. For example the apparatus could be used as a screening device to quickly analyze blood. In such applications, the apparatus could be configured to be attachable to a patient for continuous monitoring whereby the system is integrated into a hand held unit. Continuous monitoring would allow for real time monitoring of blood samples to track fluctuations of blood analytes. When coupled with a biometric identification device, the apparatus could also link to insurance and/or medical records of a patient. This link could be used to update patient blood panel information or to make comparisons of past blood panel readings; serving as a valuable instrument in monitoring and tracking continuous changes patient blood over time.

[0070] Such an apparatus could be useful in the biomedical application of complete blood analysis device. The system may be capable of measuring and detecting all blood constituents with absorption between 100nm-5000nm. This technology can transmit via Bluetooth, or direct sync to mobile device, cell phone, or computer. The valuable data can then be stored in a database whereby international blood profiles can be compared, analyzed, or referenced.

[0071] Multiple embodiments include many different light sources within the illumination disk to provide multiple sources of electromagnetic radiation within the 100nm-5000nm windows. In such an embodiment, for example, a quartz halogen lamp is used to provide a source of electromagnetic radiation in the near infrared region; suitable for non-invasive measurement of concentrations of certain blood components or blood analytes, such as alcohol or glucose. Other light producing devices such as flash lamps, tungsten-halogen, lights, light emitting diodes, quartz halogen, or laser sources can be used in conjunction with filtering mechanisms to produce a certain spectral range that corresponds to the spectral range absorption of other targeted tissue components or analytes to be measured. The capability of transmission of multiple forms of electromagnetic radiation from the palmar aspect at the interdigital space between the metacarpophalangeal (MCP) joint and multiple receiving MEMS spectrometer & detectors on the dorsal aspect of the interdigital space between the metacarpophalangeal (MCP) joint is part of what makes this invention unique. Additionally, the system will integrate into a handheld device that is easily transportable, and ergonomically designed to ensure proper fit, placement, and ergonomic comfort of subject hand will in the system handheld unit. The XY multi-axis multi axis illumination disk and MEMS spectrometer disc system is an additional design component that ensures multiple measurement capabilities across a 5000nm region. The system may/may not use fiber optics or light pipes. The system may/may not be connected to LCD screens, which will display/process measurement metrics/information, which can transmit signal via blue tooth or direct connection to a computer, wireless device, or processing software system.

[0072] MEMS spectrometer disk plus illumination disc will consist of a light source disk, " illumination disk," and a MEMS spectrometer/detector disk. Both disks will operate in perpendicular form along an X and Y axis system. The XY rotational sync system will ensure proper alignment of the light source with MEMs detector; ensuring proper wavelengths of electromagnetic radiation corresponding to the proper spectrometer. The illumination disk rotates on the X-axis, and the MEMS spectrometer disk rotates on the Y-axis.

[0073] Spectrometer/detector: May or may not include fiber bundle(s) or light pipe(s). Detector/sensor may or may not be a probe, collection fiber bundle, or chip sensor. Detector may or may not be directly attached to the spectrometer.

[0074] Light: May or may not include fiber bundle. Light source can be any electromagnetic radiation: a quartz halogen, laser, light emitting diode, or a probe at the tip of light source fiber optics. Light source may integrate several light source types in a disk orientation that will rotate for optimal emission corresponding to targeted blood analyte.

[0075] Interdigital tissue interface: The interface may consist of any malleable material that allows consistent pressure of the detector and light source to position flush with the interdigital space between the hand or feet digits. The interdigital tissue interface can be integrated into a handheld device, hand cradle, adjustable clip, ergonomic bracket, etc.

[0076] Two disk connection system: The system may consist of a bracket that allows for proper alignment of the illumination disk and MEMS spectrometer disk, and allow for adjustment to properly adjust to difference hand shaped and sized. The illumination disk may be stationary, as it may be placed on the bottom of the handheld unit, whereby the movement of the MEMS spectrometer disk will move up/down along the Y-axis.

[0077] Material: Can be any resilient material with memory, and may include but not limited to: plastic, aluminum, carbon, rubber, latex, fabric, neoprene, etc.

[0078] The system can couple with biometric identification capabilities to share information with handheld devices, mobile phones, computers, patient databases or any software integrated into the aforementioned devices capable of receiving such.

[0079] An apparatus for spectroscopic evaluation of a subject's body fluids may be used at the interdigital region adjacent to or in between a subject's extremities using spectroscopy. The spectroscopy positioning consists of multiple MEMS spectrometers/detectors on a disc at the dorsal aspect, and multiple light sources on a disc on the palmar aspect. The spectroscopic measurement system may be positioned flush with or spaced from skin at both palmar/dorsal aspects of hand measuring between the second and third proximal phalanx and between the (MCP) metacarpophalangeal joint. The imaging system which may include spectroscopy or fluoroscopy, targets the palmar digital arterial blood supply at the interdigital spacing between any hand or foot digit *(see Fig. 16)* and can detect and quantify multiple blood analytes using spectroscopy methods. The spectroscopy system can be used to measure multiple blood trace analytes such as: blood alcohol, blood glucose, pharmaceuticals, drugs, blood oxygenation levels, sodium, magnesium, urea, calcium, chloride, carbon dioxide, creatinine, potassium, lactic acid and or pulse/heart rate for any medical screening or diagnostic purposes to analyze a blood panel. The spectroscopic device may possess one or more of the movements such as rotational, translational, and/or vertical freedom necessary for the disks or interface to contact the subject's tissue at a consistent angle and pressure while accommodating the different size of the subjects extremities, and may be of any memory yielding material optimized for attaining reproducible blood flow to the region of the subject that is measured, and for minimizing the effects of pulling, stretching, pressing, compressing the subject's skin. In addition, the spectroscopic measurement device may be coupled with a temperature measurement means that detects the subject's body temperature in or near the region being measured, or the subject's core or mean body temperature, or the ambient temperature proximate to the probes, detectors, or sensors. In addition, the spectroscopic measurement may be coupled with a biometric scanner that detects the subject's identity. The biometric scanner can be positioned to measure the fingerprint of any digit on the hand or foot. The system may also include one or more methods to communicate information of a subject to a mobile device, computer, cell phone, subject database, or computer software.

WHAT IS CLAIMED IS:

1. A system for detection of blood analytes comprising:

a detector;

a light source;

a resilient connector extending between the detector and the light source and positioning the detector and light source relative to one another such that one is positioned on the dorsal surface of a user's interdigital space and the other is positioned on the palmar surface of a user's interdigital space.

2. A system for detection of blood trace analytes comprising:

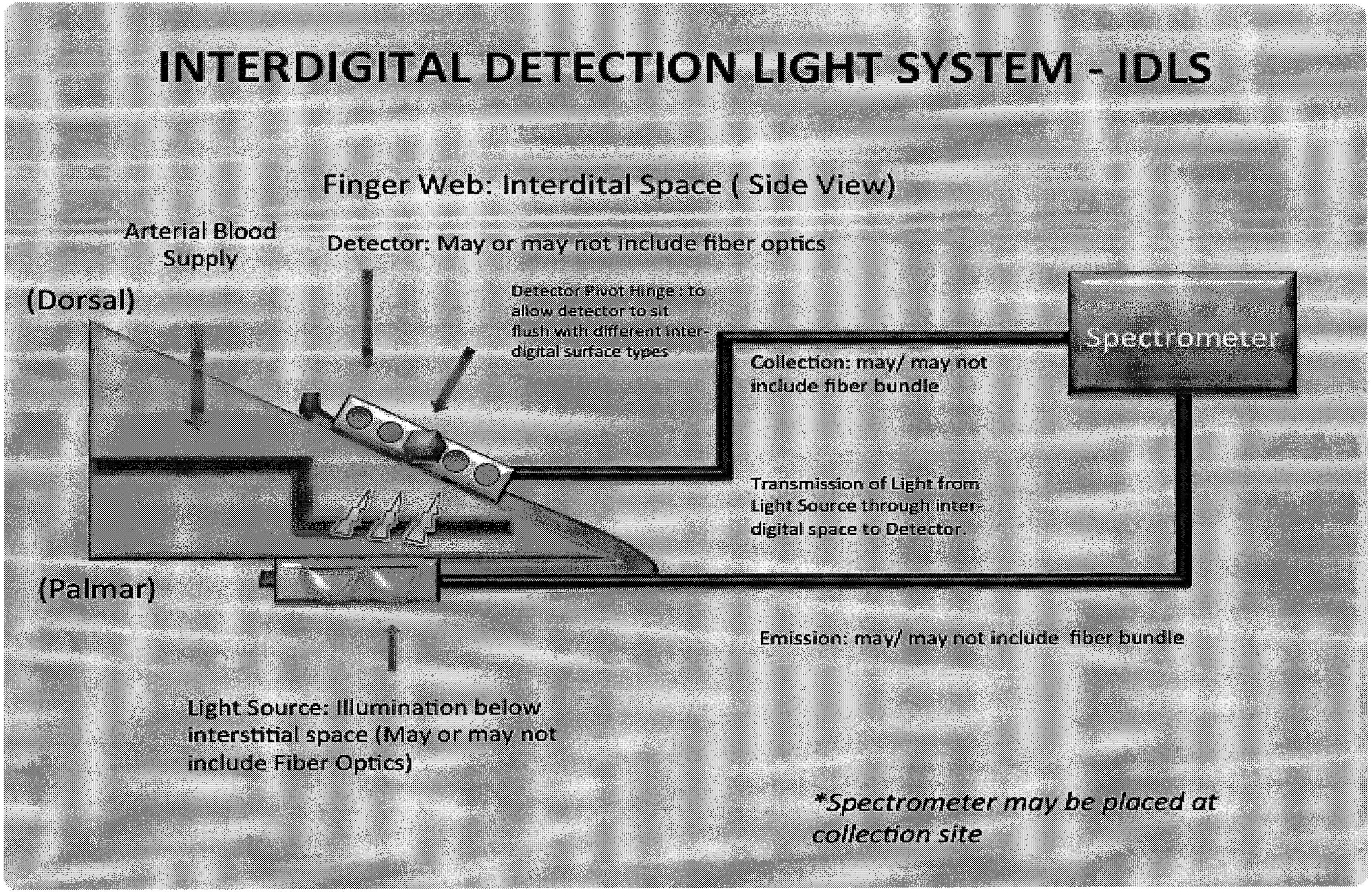
an illumination disc supporting a plurality of sources of electromagnetic radiation and rotatable relative to an interdigital location of a subject;

a spectrometer disc supporting a plurality of spectrometers able to process the electromagnetic radiation from the illumination disc and rotatable relative to the interdigital location of a subject at a position opposite that of the illumination disc.

3. A system according to claim 2 wherein the sources of electromagnetic radiation cover wavelength regions from 100nm to 5000nm.

4. A system according to claim 2 wherein the illumination disc and the spectrometer disc are positioned relative to the subject to allow for transmission spectroscopy.

FIG 1A


INTERDIGITAL DETECTION LIGHT SYSTEM - IDLS
Finger Web: Interdital Space (Side View)
Arterial Blood Supply
Detector: May or may not include fiber optics
(Dorsal)
Detector Pivot Hinge : to allow detector to sit flush with different inter-digital surface types
Spectrometer
Collection: may/ may not include fiber bundle
Transmission of Light from Light Source through inter-digital space to Detector.
(Palmar)
Emission: may/ may not include fiber bundle
Light Source: Illumination below interstitial space (May or may not include Fiber Optics)
*Spectrometer may be placed at collection site

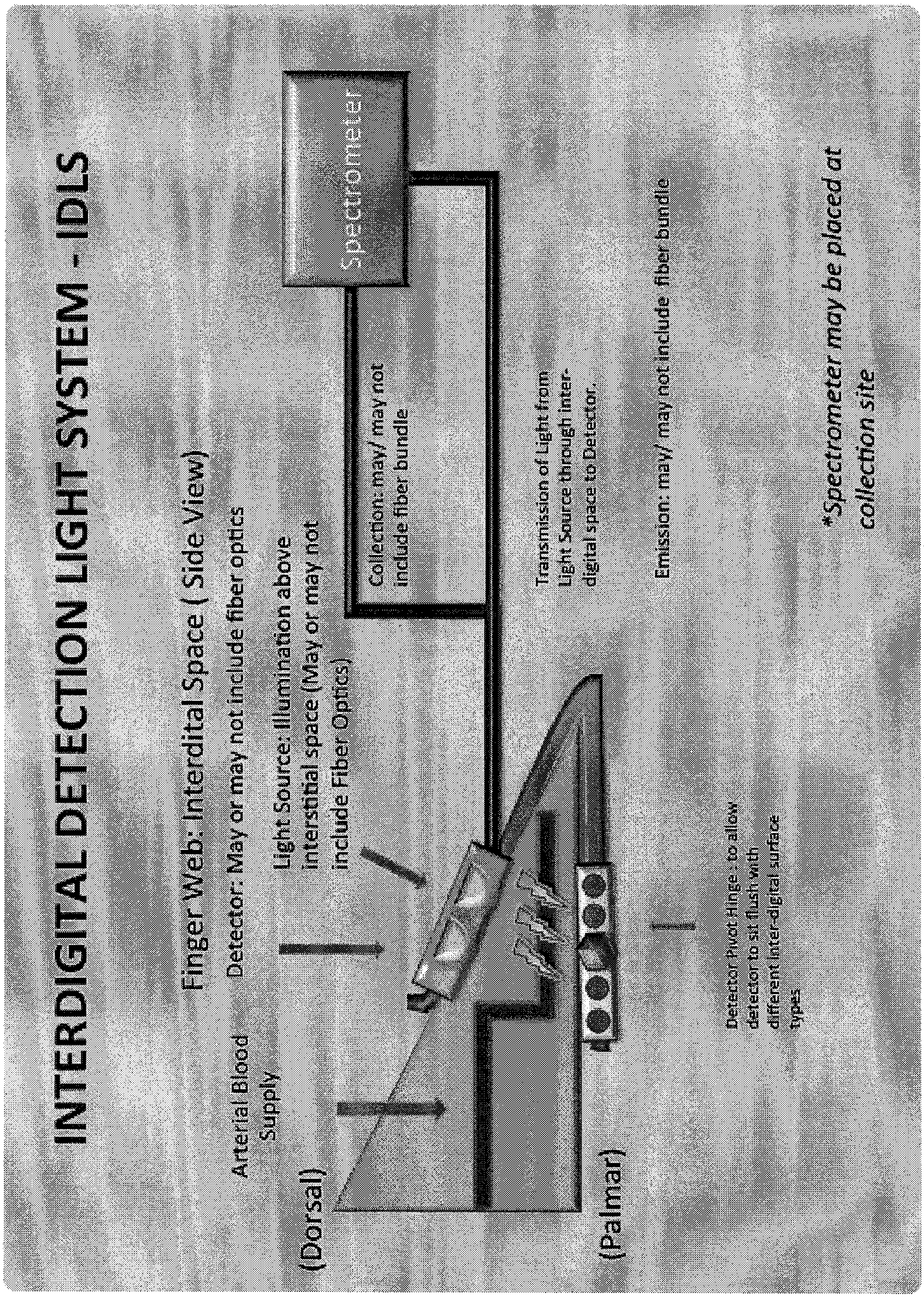

INTERDIGITAL DETECTION LIGHT SYSTEM - IDLS
Finger Web: Interdital Space (Side View)
Detector: May or may not include fiber optics
Light Source: Illumination above interstitial space (May or may not include Fiber Optics)
Arterial Blood Supply
(Dorsal)
(Palmar)
Spectrometer
Collection: may/ may not include fiber bundle
Transmission of Light from Light Source through inter-digital space to Detector.
Emission: may/ may not include fiber bundle
Detector Pivot Hinge : to allow detector to sit flush with different inter-digital surface types
*Spectrometer may be placed at collection site

FIG. 1B

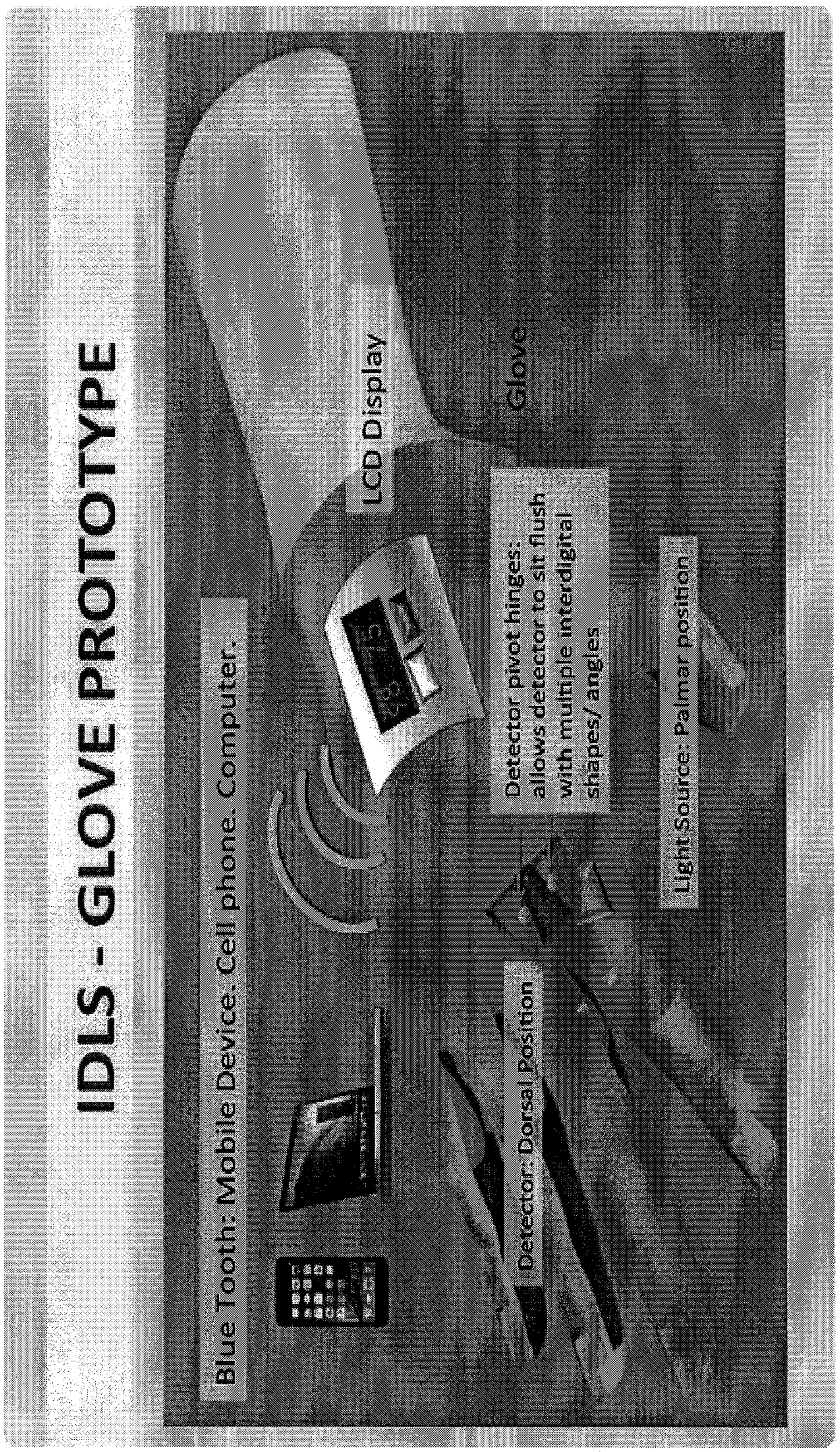

IDLS - GLOVE PROTOTYPE
Blue Tooth: Mobile Device. Cell phone. Computer.
LCD Display
Glove
Detector pivot hinges: allows detector to sit flush with multiple interdigital shapes/ angles
Detector: Dorsal Position
Light Source: Palmar position

FIG. 2

FIG. 3

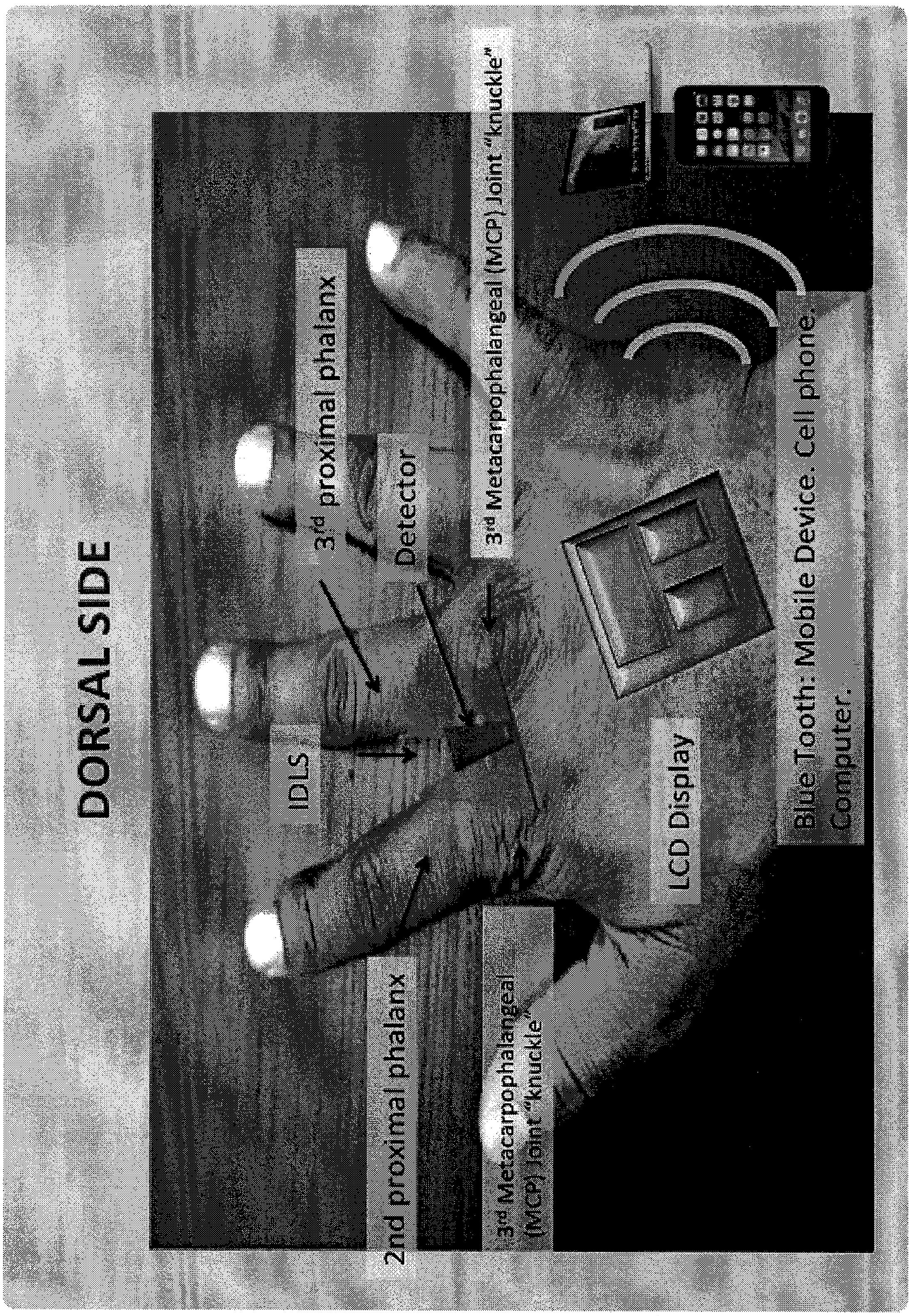

DORSAL SIDE
3rd proximal phalanx
Detector
3rd Metacarpophalangeal (MCP) Joint "knuckle"
IDLS
LCD Display
Blue Tooth: Mobile Device. Cell phone. Computer.
2nd proximal phalanx
3rd Metacarpophalangeal (MCP) Joint "knuckle"

FIG. 4

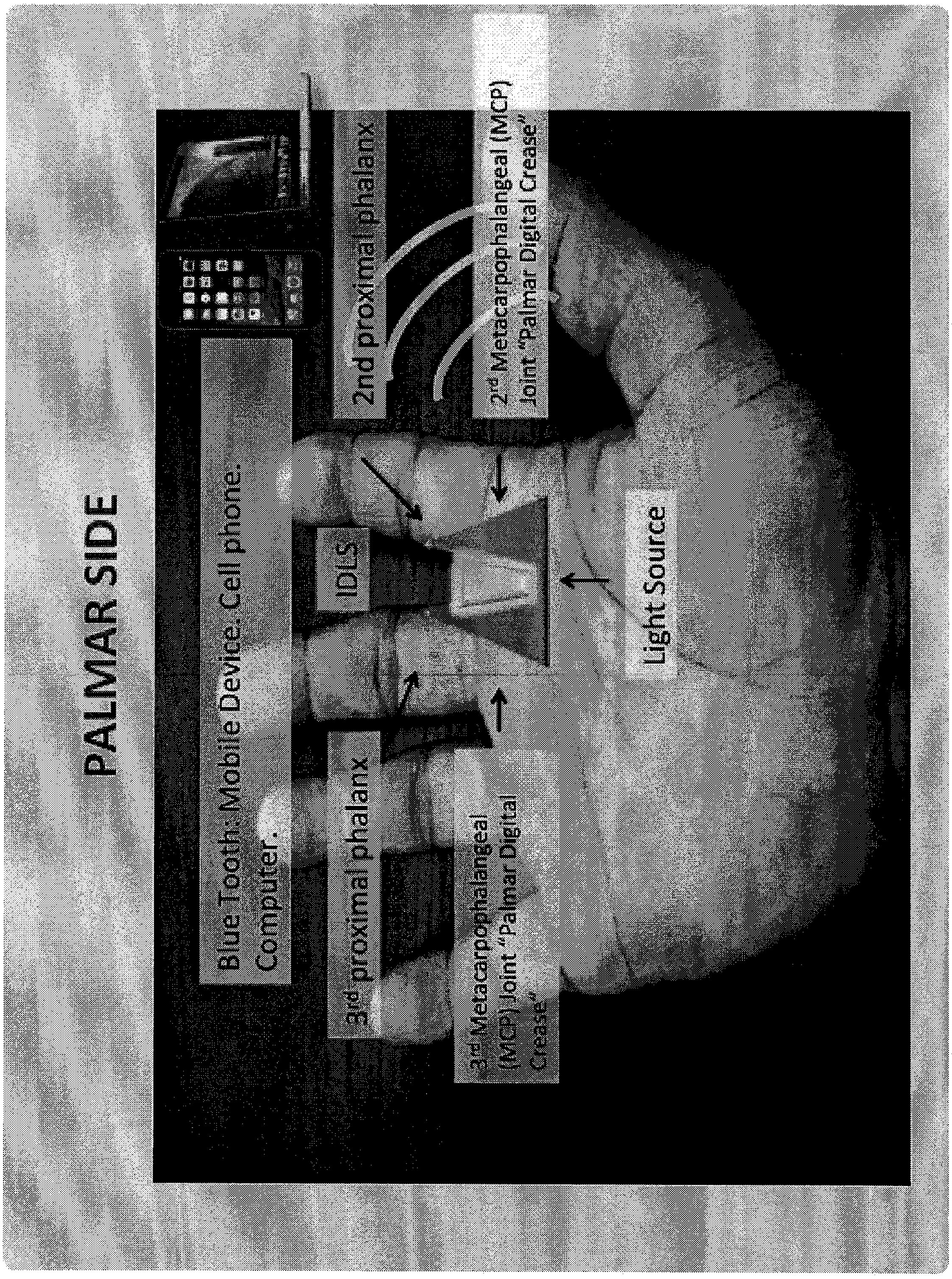

PALMAR SIDE
Blue Tooth: Mobile Device. Cell phone. Computer.
IDLS
Light Source
2nd proximal phalanx
2nd Metacarpophalangeal (MCP) Joint "Palmar Digital Crease"
3rd proximal phalanx
3rd Metacarpophalangeal (MCP) Joint "Palmar Digital Crease"

FIG. 5

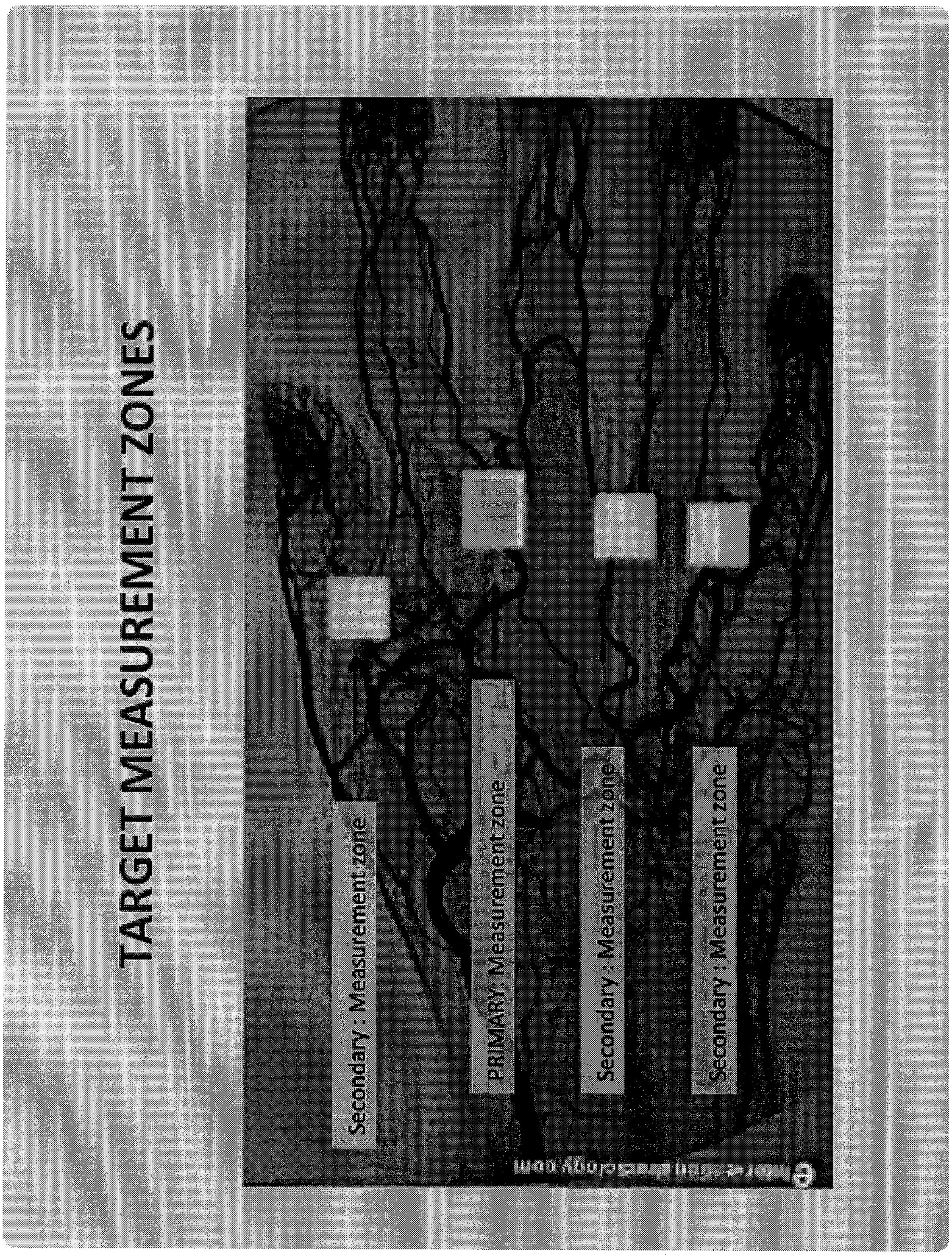

TARGET MEASUREMENT ZONES
Secondary : Measurement zone
PRIMARY: Measurement zone
Secondary : Measurement zone
Secondary : Measurement zone

FIG. 11

MEMS Spectrometer 2 Disc System [M.S.II.D.S]

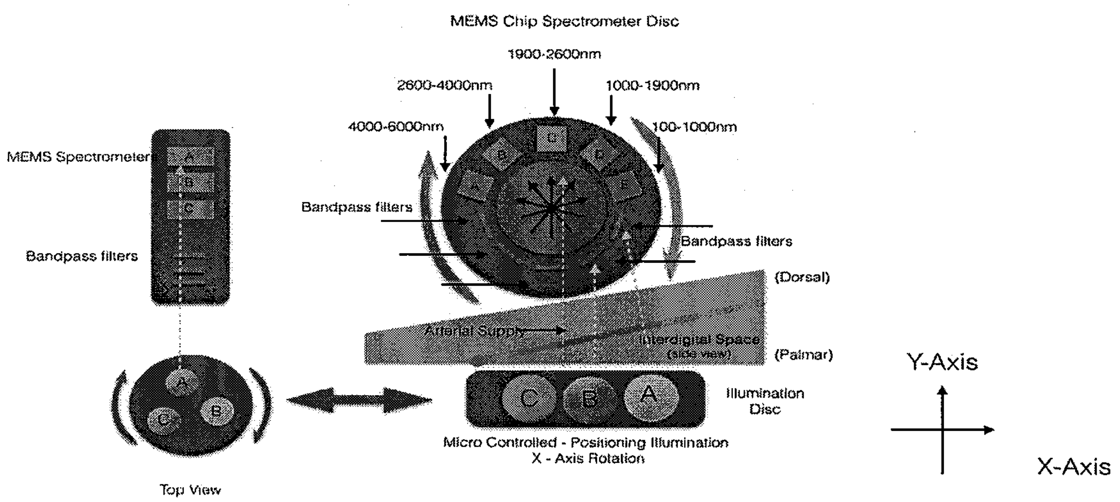
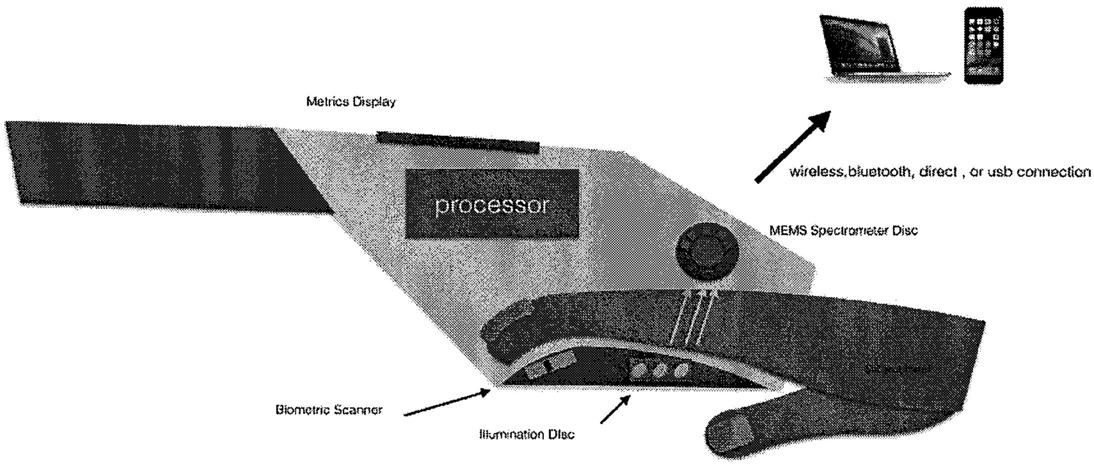


FIG. 12

[M.S.II.D.S] Handheld Unit



Side View

FIG. 13

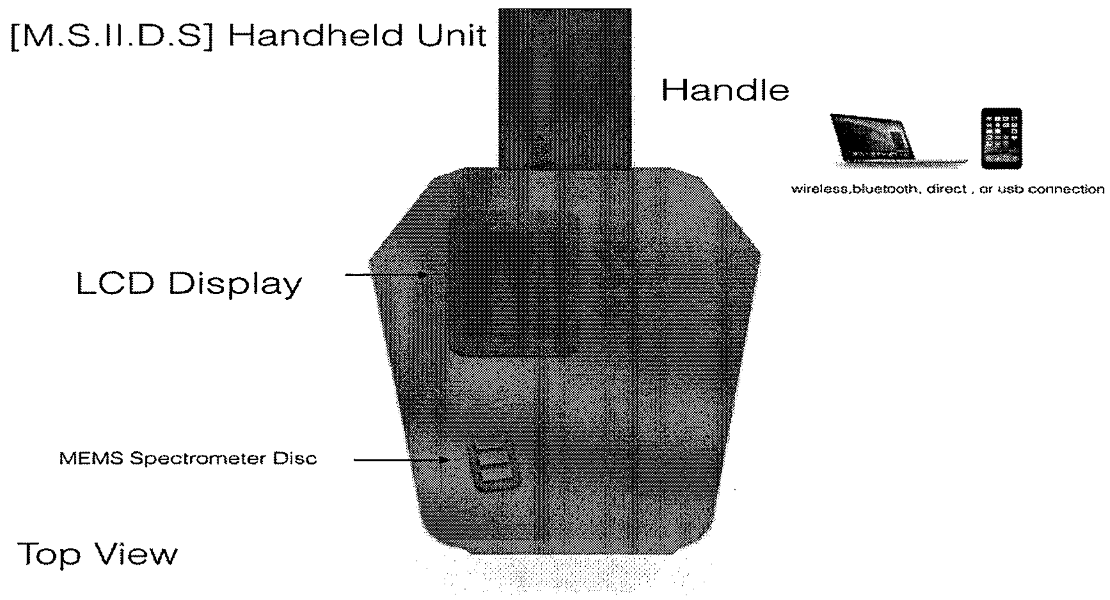

[M.S.II.D.S] Handheld Unit
Handle
wireless,bluetooth, direct , or usb connection
LCD Display
MEMS Spectrometer Disc
Top View

FIG. 14

FIG. 15

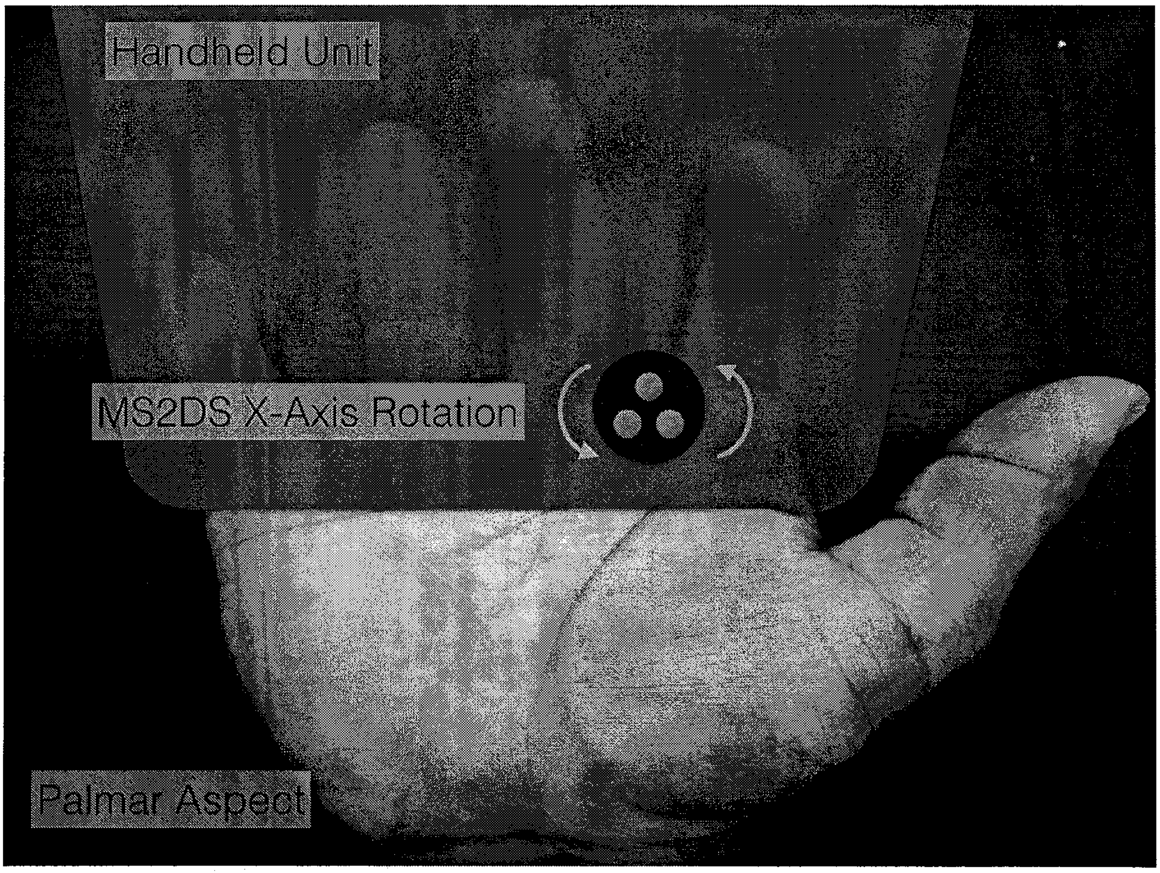
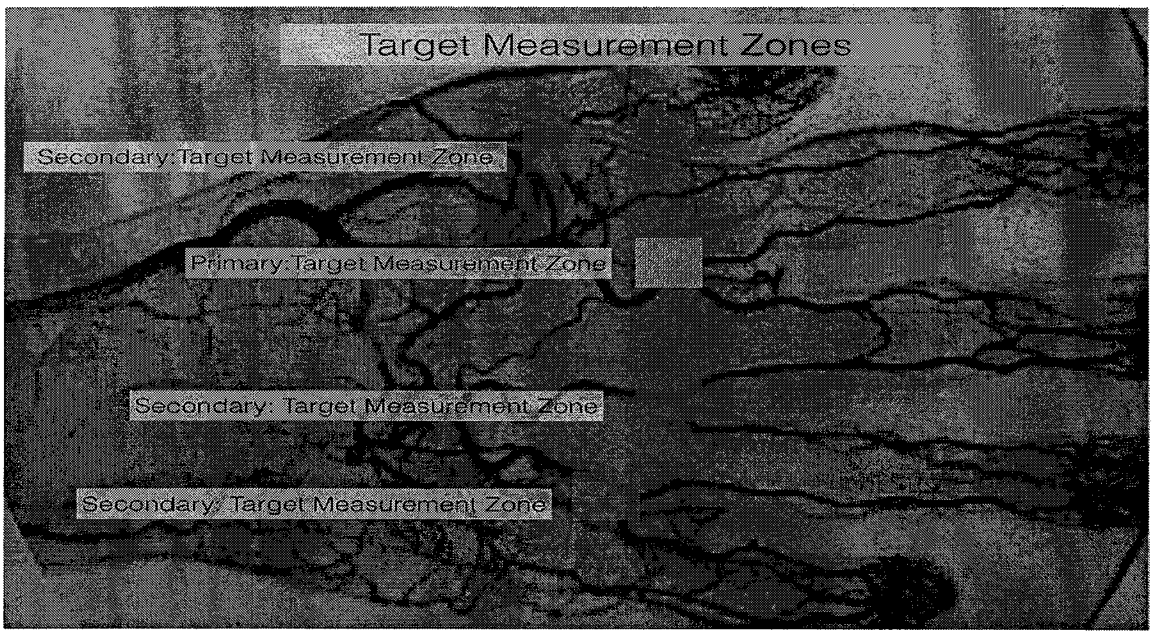


FIG. 16


Target Measurement Zones
Secondary:Target Measurement Zone
Primary:Target Measurement Zone
Secondary: Target Measurement Zone
Secondary: Target Measurement Zone

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2017/013985

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/00; A61B 5/0245; A61B 5/145; G01N 21/35 (2017.01)
CPC - A61B 5/14532; A61B 5/14546; A61B 5/14551; A61B 5/14552; A61B 5/6806; A61B 5/6825; A61B 5/6826 (2017.02)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 600/310; 600/322; 600/344 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2005/0234312 A1 (SUZUKI et al) 20 October 2005 (20.10.2005) entire document	1
X	US 2010/0160750 A1 (WHITE et al) 24 June 2010 (24.06.2010) entire document	2-4
A	US 2006/0258928 A1 (ORTNER et al) 16 November 2006 (16.11.2006) entire document	1-4

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 March 2017	21 MAR 2017

Name and mailing address of the ISA/US	Authorized officer
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774