

difficulty in treating them, mark an extremely good opportunity to introduce a low cost, non-invasive system capable of early detection. While traditional laser Doppler systems are able to deliver relatively accurate and reliable information, they cannot be used for continuous monitoring of patients, since they require bulky and extremely expensive equipment. Such solutions that are too expensive or difficult to deploy significantly limit adoption.

[0013] Hence, there is a need to develop a monitoring and preventive solution to scan the tissue and measure tissue perfusion status as a measure for the level of oxygen distribution and penetration throughout the tissue as an indicator of tissue health. Accordingly, an object of the present invention is the use of photoplethysmographic in conjunction with pressure sensor signals to monitor perfusion levels of patients suffering from or at risk of venous ulcers.

BRIEF SUMMARY OF THE INVENTION

[0014] The systems and methods of the present invention include a compact perfusion scanner configured to scan and map tissue blood perfusion as a mean to detect and monitor the development of ulcers. The device incorporates a platform, a digital signal processing unit, a serial connection to a computer, pressure sensor, pressure metering system, an LED and photodiode sensor pair and a data explorer visual interface.

[0015] The systems and methods of the present invention provide effective preventive measures by enabling early detection of ulcer formation or inflammatory pressure that would otherwise have not been detected for an extended period, thus increasing risk of infection and higher stage ulcer development.

[0016] In a preferred embodiment, the compact perfusion scanner and method of characterizing tissue health status according to the present invention incorporates pressure sensing components in conjunction with the optical sensors to monitor the level of applied pressure on target tissue for precise skin/tissue blood perfusion measurements and oximetry. The systems and methods of the present invention enable new capabilities including but not limited to: measurement capabilities such as perfusion imaging and perfusion

mapping (geometric and temporal), signal processing and pattern recognition, automatic assurance of usage via usage tracking and pressure imaging, as well as data fusion.

5 **[0017]** One particular benefit of the sensor-enhanced system of the present invention is the ability to better manage each individual patient, resulting in a timelier and more efficient practice in hospitals and even nursing homes. This is applicable to patients with a history of chronic wounds, diabetic foot ulcers, pressure ulcers or post-operative wounds.

10 **[0018]** In addition, alterations in signal content may be integrated with the activity level of the patient, the position of patient's body and standardized assessments of symptoms. By maintaining the data collected in these patients in a signal database, pattern classification, search, and pattern matching algorithms may be used to better map symptoms with alterations in skin characteristics and ulcer development.

15 **[0019]** An aspect is an apparatus for monitoring perfusion oxygenation of a target tissue region of a patient, comprising: a scanner comprising: a planar sensor array; the sensor array configured to be positioned in contact with a surface of the target tissue region; the sensor array comprising one or more LED's configured to emit light into the target tissue region at a wavelength
20 keyed for hemoglobin; the sensor array comprising one or more photodiodes configured to detect light reflected from the LED's; and a data acquisition controller coupled to the one or more LED's and to the one or more photodiodes for controlling the emission and reception of light from the sensor array to obtain perfusion oxygenation data associated with the target tissue
25 region.

30 **[0020]** Another aspect is a system for monitoring perfusion oxygenation of a target tissue region of a patient, comprising: (a) a scanner comprising: a planar sensor array; the sensor array configured to be positioned in contact with a surface of the target tissue region; the sensor array comprising one or more light sources configured to emit light into the target tissue region at a wavelength keyed for hemoglobin; the sensor array comprising one or more

sensors configured to detect light reflected from the light sources; a pressure sensor coupled to the sensor array; the pressure sensor configured to obtain pressure readings of the sensor array's contact with a surface of the target tissue region; and (b) a data acquisition controller coupled to the one or more sensors and for controlling the emission and reception of light from the sensor array to obtain perfusion oxygenation data associated with the target tissue; and (c) a processing module coupled to the data acquisition controller; (d) the processing module configured to control sampling of the pressure sensor and sensor array for simultaneous acquisition of perfusion oxygenation data and pressure sensor data to ensure proper contact of the scanner with the surface of the target tissue region.

[0021] A further aspect is a method for performing real-time monitoring of perfusion oxygenation of a target tissue region of a patient, comprising: positioning a sensor array in contact with a surface of the target tissue region; emitting light from lights sources in the sensor array into the target tissue region at a wavelength keyed for hemoglobin; receiving light reflected from the light sources; obtaining pressure data associated with the sensor array's contact with a surface of the target tissue region; obtaining perfusion oxygenation data associated with the target tissue region; and sampling the perfusion oxygenation data and pressure data to ensure proper contact of the sensor array with the surface of the target tissue region.

[0022] It is appreciated that the systems and methods of the present invention are not limited to the specific condition of ulcer or wound, but may have broad application in all forms of wound management, such as skin diseases or treatments.

[0023] Further aspects of the invention will be brought out in the following portions of the specification, wherein the detailed description is for the purpose of fully disclosing preferred embodiments of the invention without placing limitations thereon.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS
OF THE DRAWING(S)

[0024] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

5 **[0025]** FIG. 1 shows a preferred embodiment of a perfusion oxygenation monitoring (POM) system for analyzing a region of tissue in accordance with the present invention

[0026] FIGS. 2A and 2B illustrate front and right perspective views of the perfusion hardware printed circuit board of the present invention.

10 **[0027]** FIG. 3 illustrates an exemplary LED emitter in accordance with the present invention.

[0028] FIG. 4 illustrates LED driver circuit in accordance with the present invention.

15 **[0029]** FIG. 5 illustrates an exemplary photodiode read circuit configured for reading the signal from photodiode sensor array.

[0030] FIG. 6 illustrates a calibration setup for calibration of the pressure sensor.

[0031] FIG. 7 shows a plot of results from the pressure verification trials of weights of 50g, 100g, 200g and 500g on a single sensor.

20 **[0032]** FIG. 8 is a plot showing measured pressure response curve, interpolated curve (exponential), and the point where the pressure sensor is specified to saturate.

[0033] FIG. 9 shows results from pressure verification trials on a second 1-pound sensor.

25 **[0034]** FIG. 10 is a plot showing raw pressure response curves, and various fits.

[0035] FIG. 11 illustrates a PC setup for running the perfusion oxygenation monitoring (POM) system of the present invention.

30 **[0036]** FIG. 12 shows a screenshot of the hardware configuration module interface in accordance with the present invention.

[0037] FIG. 13 shows a screenshot of the graphical user interface in

accordance with the present invention.

[0038] FIG. 14 shows an exemplary interpolation performed via a Kriging algorithm.

[0039] FIG. 15 shows a schematic diagram of a marker pattern used for testing the feature extraction module.

[0040] FIG. 16 illustrates the setup of FIG. 15 overlaid on an image.

[0041] FIG. 17 illustrates a block diagram of a method for outputting a mapped and interpolated perfusion image.

[0042] FIG. 18 shows an example of heterodyning used to help eliminate in-band noise in accordance with the present invention.

[0043] FIG. 19 is a plot of the theoretical response of the subtraction method of FIG. 18 in relation to noise and correction frequency.

[0044] FIG. 20 is a plot of the frequency response of the subtraction method shown on a dB scale.

[0045] FIG. 21 shows results from employing noise subtraction on a high frequency LED drive signal, and averaging several LED drive periods to obtain similar data rates as before.

[0046] FIG. 22 illustrates a zoomed view of FIG. 21.

[0047] FIG. 23 shows a sample of the time domain signals used for comparison of neck and thumb tissue measurements.

[0048] FIG. 24 shows the frequency domain representation of the measured signals.

[0049] FIG. 25 shows results from extracted plethysmograph signals of the forehead.

[0050] FIG. 26 shows a comparison of readings of extracted plethysmograph signals from under the knuckle on the thumb.

[0051] FIG. 27 shows results from varying pressure using the reflectance sensor on the neck.

[0052] FIG. 28 shows the results from both over and to the side of the black tape.

DETAILED DESCRIPTION OF THE INVENTION

[0053] FIG. 1 shows a preferred embodiment of a perfusion oxygenation monitoring (POM) system 10 for analyzing a region of tissue 52 of a patient 18 in accordance with the present invention. System 10 generally comprises six primary components: red/infrared LED array 44, photodiode array 46, pressure sensor 50, pressure metering system 48 (which includes amplification and filtering circuitry), data acquisition unit 40, digital signal processing module 12 and application module 14 having a user interface.

[0054] The system 10 comprises sensing hardware component 16 that includes arrays of emitters/sensors (44, 46, 50) and data acquisition unit 40, preferably in a handheld enclosure (not shown). The LED array 44 and photodiode arrays 46 coupled to the data acquisition unit 40 (e.g. through cabling or wireless connection) can be physically configured in a variety of arrays. The data acquisition unit 40 is preferably capable of interfacing with a large number of individual LEDs and photodiodes. Signal amplification and filtering unit 49 may be used to condition the photodiode signal/data prior to being received by the data acquisition unit 40. In a preferred embodiment, the photodiode signal amplification and filtering unit 49 may comprise a photodiode read circuit 120 shown in FIG. 5 and described in further detail below.

[0055] Sensing/scanning hardware component 16 may also include an intensity controller 42 for controlling the output of LED array 44. Intensity controller 42 preferably comprises LED driver circuit 100 shown in FIG. 4, and described in further detail below.

[0056] The data acquisition system 40 also interfaces with application module 14 on PC 154 (see FIG. 11), allowing a user to configure the LED array 44 signaling as well as sampling rate of the signal from photodiode array 46 via a hardware configuration module 34 that is viewed through the graphical user interface 36. Data acquired from DAC 40 is preferably stored in a database 32 for subsequent processing.

[0057] The pressure sensor 50 is configured to measure the pressure applied

perfusion hardware printed circuit board (PCB) 60. PCB 60 comprises LED array 44 of two LED pairs 64 spaced between two arrays 46 of photodiodes 62. The board 60 also comprises pressure sensor 50 to monitor the applied pressure on the target tissue 52.

5 **[0063]** As shown in FIG. 2A, the optical sensors (e.g. LED array 44 and photodiode array 46) are located on the front side 66 of the PCB 60 and are configured to face and press onto (either directly or adjacently with respect to transparent cover (not shown)) the target tissue 52.

10 **[0064]** Referring to FIG. 2B, driving circuitry, e.g. connector head 70, are located on the back side 68 of the PCB 60 safely out of contact with the test subject, and the front of the PCB (right) which houses the sensor portion of the array. The arrays 44, 46 are located such that connector head 70 and corresponding leads 72 and cables 74 (which couple to the data acquisition unit 40) do not interfere with using the device.

15 **[0065]** The arrays 44, 46 are shown in FIG. 2A as two LED's 64 positioned between four photodiodes 62. However, it is appreciated that the array may comprise any number of and planar configuration of at least one LED emitter 64 and one photodiode receiver.

20 **[0066]** FIG. 3 illustrates an exemplary LED emitter 64 (OSI Optoelectronics DLED-660/880 CSL-2) having 660nm red emitter 84 and 880nm Infrared emitter 82.

25 **[0067]** FIG. 4 illustrates LED driver circuit 100 in accordance with the present invention. LED driver circuit 100 is configured to allow the red LED 88 and infrared LED 82 in the LED package 64 to be driven independently, even though the LEDs are common anode, sharing a V_{DD} connection via leads 80.

30 **[0068]** Driver circuit 100 includes a low-noise amplifier 110 coupled to the LED 64. In a preferred embodiment, the amplifier 110 comprises a LT6200 chip from Linear Technologies. However, it is appreciated that other amplifiers available in the art may also be employed. LED driver circuit 100 further comprises a p-channel MOS field-effect transistor (FET) 112 (e.g. MTM76110 by Panasonic), which provides negative feedback. As voltage is increased at

current output of the photodiode and converts it to voltage, allowing the data acquisition unit to read the voltage via its voltage input module.

[0072] It is appreciated that the individual components of the LED driver circuit 100 and photodiode read circuit 120 are shown for exemplary purposes only, and that other models, or types of components may be used as desired.

[0073] In one embodiment of the present invention, the data acquisition controller 40 comprises National Instruments CompactRIO 9014 real-time controller coupled with an NI 9104 3M gate FPGA chassis. The data acquisition controller 40 interfaces with the LED arrays 44 and photodiodes 46 using three sets of modules for current output, current input, and voltage input.

[0074] In one embodiment, the controller 40 comprises a processor, real-time operating system, memory, and supports additional storage via USB (all not shown). The controller 40 may also include an Ethernet port (not shown) for connection to the user interface PC 154. The controller 40 comprises an FPGA backplane, current output module (e.g. NI 9263), current input module (e.g. NI 9203), and voltage input module (e.g. NI 9205) allowing multiple voltage inputs from photodiode/amplifier modules.

[0075] The POM system 10 preferably employs a pressure sensor 50 to measure pressure and ensure consistent results (e.g. 1lb. Flexiforce sensor). Due to the confounding effect varying pressure can have on plethysmograph measurements, readings from the pressure sensor 50 provide a metric from which the user can apply the sensor hardware 16 to the patient's skin 52.

[0076] The pressure sensor 50 is preferably attached behind the LED array 44, and measures the pressure used in applying it to a target location. The pressure sensor 50 is preferably configured to deliver accurate measurements of pressure in a specified range, e.g. a range from zero to approximately one pound, which encompasses the range of pressures that can reasonably be applied when using the POM sensing hardware 16.

[0077] The pressure sensor 50 is used to guide the user into operating the scanner 16 more consistently, so that the sensor/scanner 16 is positioned in a similar manner every measurement. The oximetry data that is taken is thus

An example of code for carrying out method 220 may be found in the Source Code Appendix attached hereto. It is appreciated that the provided code is merely one example of how to perform the methods of the present invention.

5 **[0092]** Acquired data from the data acquisition unit 40 (which may be stored on server 32) is first extracted at step 222 (via processing scripts 24). This extracted data is then used for simultaneously extracting location data, perfusion data and pressure data from each measurement point. The processing software 12 may simultaneously sample location, perfusion, and pressure readings (e.g. at 3Hz interval), in order to creating a matching set of
10 pressure, position, and blood oxygen measurements at each interval.

[0093] In order to generate useful information and metrics from the raw data recorded by the perfusion module 228, a number of algorithms are used.

[0094] At step 230, features are extracted from the data (e.g. via the feature extraction module 28). Position data corresponding to the hardware sensor 16
15 location is then mapped at step 232. After a scan has been completed, the oximetry data is mapped at step 234 to appropriate coordinates corresponding to the obtained sensor position data from step 232. At step 236, the mapped data is interpolated (e.g. using the Kriging algorithm shown in FIG. 14). The interpolated data may be compiled into a color coded image, and displayed to
20 the user, and/or the perfusion data may then overlayed on a background image (e.g. image 205) of the scan site as described in FIGS. 15 and 16.

[0095] On the perfusion side, RF noise filtering is then performed on the extracted data at step 224. Motion noise is then removed at step 226 to obtain the perfusion data at step 228. Steps 224 and 226 may be performed
25 via filtering module 22.

[0096] In a preferred method illustrated in FIG. 18, heterodyning is used to help eliminate in-band noise. The data recorded from when the LED arrays 44 are off is subtracted from adjacent data from when LED arrays 44 are on (subtraction method). This creates high frequency noise, but removes low
30 frequency in band noise, which is a larger issue. The additional high frequency noise that is introduced is then filtered out by a low pass filter. The algorithms

version of FIG. 21, showing the noise spike that is removed by differential noise subtraction. These plots show that the noise subtraction method of the present invention is effective in removing in band noise.

5 **[00102]** Frequency domain analysis/experiments were performed with the frequency domain signals of the plethysmograph measurements. The experiments revealed not only high magnitude elements at the heart rate frequency, but also its harmonics. This appears fairly consistent between locations.

10 **[00103]** In order to verify that the harmonics shown in the frequency domain were not the result of noise or jitter, but represented real components of the pulse waveform, a sinusoid wave was constructed. The sinusoid was created by summing sinusoids at the frequency for each separate pulse waveform peak. This superposition was intended to model the effects of frequency jitter in the waveform, while removing any frequency components due to the pulse waveform shape.

15 **[00104]** A comparison of signals is shown in FIGS. 23 and 24. FIG. 23 shows a sample of the time domain signals used for comparison. Neck measurements were compared to thumb measurements, taken at equal pressure. FIG. 24 shows the frequency domain representation of the measured signals. Note the
20 second harmonic at 128BPM (2.13Hz), the third harmonic at 207BPM (3.45Hz), etc. The results demonstrate that the harmonics shown below are indeed intrinsic to the pulse waveform, and are not the result of noise or frequency jitter.

25 **[00105]** Experiments were performed on number of body locations, including neck, thumb and forehead using the perfusion system 10 of the present invention. Samples of extracted plethysmograph signals are reported in FIGS. 25-27, which clearly show that perfusion system successfully removes the motion and ambient noises and extracts the plethysmograph signal from different body location.

30 **[00106]** FIG. 25 shows results from extracted plethysmograph signals of the forehead. Pressure values are given in terms of resistance measured using

CLAIMS

What is claimed is:

1. An apparatus for monitoring perfusion oxygenation of a target tissue
5 region of a patient, comprising:
a scanner comprising:
a planar sensor array;
the sensor array configured to be positioned in contact with a surface of
the target tissue region;
10 the sensor array comprising one or more LED's configured to emit light
into the target tissue region at a wavelength keyed for hemoglobin;
the sensor array comprising one or more photodiodes configured to
detect light reflected from the LED's; and
a data acquisition controller coupled to the one or more LED's and to
15 the one or more photodiodes for controlling the emission and reception of light
from the sensor array to obtain perfusion oxygenation data associated with the
target tissue region.
2. An apparatus as recited in claim 1, the scanner further comprising:
20 a pressure sensor coupled to the sensor array;
the pressure sensor configured to obtain pressure readings of the sensor
array's contact with a surface of the target tissue region;
wherein the scanner is configured to obtain pressure sensor readings while
obtaining perfusion oxygenation data to ensure proper contact of the scanner with the
25 surface of the target tissue region.
3. An apparatus as recited in claim 2:
wherein the pressure sensors and sensor array are connected to a first
side of a printed circuit board (PCB); and
30 wherein the data acquisition controller is connected to the PCB on a
second side opposite said first side.

4. An apparatus as recited in claim 1, wherein each LED comprises dual emitters configured for emitting red (660nm) and infrared (880nm) light.

5. An apparatus as recited in claim 4:
5 wherein the one or more of the LED's are coupled driver circuit; and
wherein the driver circuit is configured to allow the red LED emitter and
infrared LED emitter to be driven independently while sharing a common anode.

6. An apparatus as recited in claim 5, wherein the driver circuit comprises
10 an amplifier; and
a field-effect transistor configured for providing negative feedback.

7. An apparatus as recited in claim 2, further comprising:
a processing module coupled to the data acquisition controller;
15 the processing module configured to control sampling of the pressure sensor
and sensor array for simultaneous acquisition of pressure sensor data and perfusion
oxygenation data.

8. An apparatus as recited in claim 7, wherein the processing module is
20 configured to obtain readings from the sensor array to obtain position data of the
scanner.

9. An apparatus as recited in claim 8, wherein the processing module is
configured to generate a perfusion oxygenation map of the target tissue.

25 10. An apparatus as recited in claim 8, wherein the processing module is
configured to control sampling of the pressure sensor and sensor array for
simultaneous acquisition of two or more data parameters selected from the group
consisting of pressure sensor data, perfusion oxygenation data, and position data, to
30 simultaneously display said two or more data parameters.

11. A system for monitoring perfusion oxygenation of a target tissue region of a patient, comprising:

(a) a scanner comprising:

a planar sensor array;

5 the sensor array configured to be positioned in contact with a surface of the target tissue region;

the sensor array comprising one or more light sources configured to emit light into the target tissue region at a wavelength keyed for hemoglobin;

10 the sensor array comprising one or more sensors configured to detect light reflected from the light sources;

a pressure sensor coupled to the sensor array;

the pressure sensor configured to obtain pressure readings of the sensor array's contact with a surface of the target tissue region; and

15 (b) a data acquisition controller coupled to the one or more sensors and for controlling the emission and reception of light from the sensor array to obtain perfusion oxygenation data associated with the target tissue; and

(c) a processing module coupled to the data acquisition controller;

20 (d) the processing module configured to control sampling of the pressure sensor and sensor array for simultaneous acquisition of perfusion oxygenation data and pressure sensor data to ensure proper contact of the scanner with the surface of the target tissue region.

12. A system as recited in claim 11:

25 wherein the sensor array comprises one or more LED's configured to emit light into the target tissue region at a wavelength keyed for hemoglobin; and

wherein the sensor array comprises one or more photodiodes configured to detect light reflected from the LED's.

13. A system as recited in claim 12:

30 wherein each of the one or more LED's comprises dual emitters configured for emitting red (660nm) and infrared (880nm) light;

wherein the one or more LED's are coupled to the driver circuit; and
wherein the driver circuit is configured to allow the red LED emitter and the
infrared LED emitter to be driven independently while sharing a common anode

5 14. A system as recited in claim 11, further comprising:
 a graphical user interface;

 wherein the graphical user interface is configured to display the perfusion
oxygenation data and pressure sensor data.

10 15. A system as recited in claim 14, the processing module is further
configured to obtain readings from the sensor array to obtain position data of the
scanner.

 16. A system as recited in claim 15, wherein the processing module is
15 further configured to interpolate the position data to generate a perfusion oxygenation
map of the target tissue.

 17. A system as recited in claim 16, wherein the processing module is
configured to control sampling of the pressure sensor and sensor array for
20 simultaneous acquisition of two or more data parameters selected from the group
consisting of pressure sensor data, perfusion oxygenation data, and position data, to
simultaneously display the two or more data parameters.

 18. A system as recited in claim 16, wherein the processing module is
25 configured to receive an image of the target tissue, and overlay the perfusion
oxygenation map over the image.

 19. A system as recited in claim 14, wherein the graphical user interface is
30 configured to allow user input to manipulate settings of the sensor array and pressure
sensor.

20. A system as recited in claim 11, wherein the processing module further comprises:

a filtering module;

the filtering module configured to filter in-band noise by subtracting data
5 recorded when the one or more light sources are in an "off" state from data recorded
when the one or more light sources are in an "on" state.

21. A method for performing real-time monitoring of perfusion oxygenation
of a target tissue region of a patient, comprising:

10 positioning a sensor array in contact with a surface of the target tissue region;
emitting light from light sources in the sensor array into the target tissue
region at a wavelength keyed for hemoglobin;

receiving light reflected from the light sources;

obtaining pressure data associated with the sensor array's contact with a
15 surface of the target tissue region;

obtaining perfusion oxygenation data associated with the target tissue region;

and

sampling the perfusion oxygenation data and pressure data to ensure proper
contact of the sensor array with the surface of the target tissue region.

20

22. A method as recited in claim 21:

wherein the sensor array comprises one or more LED's configured to emit light
into the target tissue region at a wavelength keyed for hemoglobin; and

wherein the sensor array comprises one or more photodiodes configured to
25 detect light reflected from the LED's.

23. A method as recited in claim 22:

wherein each of the one or more LED's comprises dual emitters configured for
emitting red (660nm) and infrared (880nm) light;

30 the method further comprising independently driving the red LED emitter and
infrared LED emitter while the red LED emitter and infrared LED emitter share a

common anode

24. A method as recited in claim 21, further comprising:
simultaneously displaying the perfusion oxygenation data and pressure sensor
5 data.

25. A method as recited in claim 21, further comprising:
acquiring readings from the sensor array to obtain position data of the
10 scanner.

26. A method as recited in claim 25, further comprising:
interpolating the position data to generate a perfusion oxygenation map of the
target tissue.

27. A method as recited in claim 26, wherein interpolating the position data
15 comprises applying a Kriging algorithm to the acquired position data.

28. A method as recited in claim 26, further comprising:
sampling of the pressure sensor and sensor array for simultaneous acquisition
20 of pressure sensor data, perfusion oxygenation data, and position data; and
simultaneously displaying the pressure sensor data, perfusion oxygenation
data, and position data.

29. A method as recited in claim 26, further comprising:
25 receiving an image of the target tissue; and
overlaying the perfusion oxygenation map over the image.

30. A method as recited in claim 21, further comprising:
providing a graphical user interface to allow user input; and
30 manipulating sampling settings of the sensor array and pressure sensor
according to said user input.

31. A method as recited in claim 21, further comprising:
- cycling the one or more light sources between a period when the one or more light sources are on, and a period when the one or more light sources are off; and
- 5 filtering in-band noise by subtracting data recorded from when the one or more light sources are in an "off" state from data from when the one or more light sources are in an "on" state.

difficulty in treating them, mark an extremely good opportunity to introduce a low cost, non-invasive system capable of early detection. While traditional laser Doppler systems are able to deliver relatively accurate and reliable information, they cannot be used for continuous monitoring of patients, since they require bulky and extremely expensive equipment. Such solutions that are too expensive or difficult to deploy significantly limit adoption.

[0013] Hence, there is a need to develop a monitoring and preventive solution to scan the tissue and measure tissue perfusion status as a measure for the level of oxygen distribution and penetration throughout the tissue as an indicator of tissue health. Accordingly, disclosed herein is the use of photoplethysmographic in conjunction with pressure sensor signals to monitor perfusion levels of patients suffering from or at risk of venous ulcers.

BRIEF SUMMARY OF THE INVENTION

[0013a] The invention is defined in the independent claims. Some optional features of the invention are defined in the dependent claims.

[0014] The systems and methods as disclosed herein include a compact perfusion scanner configured to scan and map tissue blood perfusion as a mean to detect and monitor the development of ulcers. The device incorporates a platform, a digital signal processing unit, a serial connection to a computer, pressure sensor, pressure metering system, an LED and photodiode sensor pair and a data explorer visual interface.

[0015] The systems and methods as disclosed herein may provide effective preventive measures by enabling early detection of ulcer formation or inflammatory pressure that would otherwise have not been detected for an extended period, thus increasing risk of infection and higher stage ulcer development.

[0016] In a preferred embodiment, the compact perfusion scanner and method of characterizing tissue health status incorporates pressure sensing components in conjunction with the optical sensors to monitor the level of applied pressure on target tissue for precise skin/tissue blood perfusion measurements and oximetry. The systems and methods disclosed herein may enable new capabilities including but not limited to: measurement capabilities such as perfusion imaging and perfusion

mapping (geometric and temporal), signal processing and pattern recognition, automatic assurance of usage via usage tracking and pressure imaging, as well as data fusion.

[0017] One particular benefit of the described sensor-enhanced system is the ability to better manage each individual patient, resulting in a timelier and more efficient practice in hospitals and even nursing homes. This is applicable to patients with a history of chronic wounds, diabetic foot ulcers, pressure ulcers or post-operative wounds.

[0018] In addition, alterations in signal content may be integrated with the activity level of the patient, the position of patient's body and standardized assessments of symptoms. By maintaining the data collected in these patients in a signal database, pattern classification, search, and pattern matching algorithms may be used to better map symptoms with alterations in skin characteristics and ulcer development.

[0019] An aspect is an apparatus for monitoring perfusion oxygenation of a target tissue region of a patient, comprising: a scanner comprising: a planar sensor array; the sensor array configured to be positioned in contact with a surface of the target tissue region; the sensor array comprising one or more LED's configured to emit light into the target tissue region at a wavelength keyed for hemoglobin; the sensor array comprising one or more photodiodes configured to detect light reflected from the LED's; and a data acquisition controller coupled to the one or more LED's and to the one or more photodiodes for controlling the emission and reception of light from the sensor array to obtain perfusion oxygenation data associated with the target tissue region.

[0020] Another aspect is a system for monitoring perfusion oxygenation of a target tissue region of a patient, comprising: (a) a scanner comprising: a planar sensor array; the sensor array configured to be positioned in contact with a surface of the target tissue region; the sensor array comprising one or more light sources configured to emit light into the target tissue region at a wavelength keyed for hemoglobin; the sensor array comprising one or more

sensors configured to detect light reflected from the light sources; a pressure sensor coupled to the sensor array; the pressure sensor configured to obtain pressure readings of the sensor array's contact with a surface of the target tissue region; and (b) a data acquisition controller coupled to the one or more sensors and for controlling the emission and reception of light from the sensor array to obtain perfusion oxygenation data associated with the target tissue; and (c) a processing module coupled to the data acquisition controller; (d) the processing module configured to control sampling of the pressure sensor and sensor array for simultaneous acquisition of perfusion oxygenation data and pressure sensor data to ensure proper contact of the scanner with the surface of the target tissue region.

[0021] A further aspect is a method for performing real-time monitoring of perfusion oxygenation of a target tissue region of a patient, comprising: positioning a sensor array in contact with a surface of the target tissue region; emitting light from lights sources in the sensor array into the target tissue region at a wavelength keyed for hemoglobin; receiving light reflected from the light sources; obtaining pressure data associated with the sensor array's contact with a surface of the target tissue region; obtaining perfusion oxygenation data associated with the target tissue region; and sampling the perfusion oxygenation data and pressure data to ensure proper contact of the sensor array with the surface of the target tissue region.

[0022] It is appreciated that the systems and methods disclosed herein are not limited to the specific condition of ulcer or wound, but may have broad application in all forms of wound management, such as skin diseases or treatments.

[0023] Further aspects of the invention will be brought out in the following portions of the specification, wherein the detailed description is for the purpose of fully disclosing preferred embodiments of the invention without placing limitations thereon.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS
OF THE DRAWING(S)

- [0024] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:
- [0025] FIG. 1 shows a preferred embodiment of a perfusion oxygenation monitoring (POM) system for analyzing a region of tissue.
- [0026] FIGS. 2A and 2B illustrate front and right perspective views of the perfusion hardware printed circuit board.
- [0027] FIG. 3 illustrates an exemplary LED emitter.
- [0028] FIG. 4 illustrates LED driver circuit.
- [0029] FIG. 5 illustrates an exemplary photodiode read circuit configured for reading the signal from photodiode sensor array.
- [0030] FIG. 6 illustrates a calibration setup for calibration of the pressure sensor.
- [0031] FIG. 7 shows a plot of results from the pressure verification trials of weights of 50g, 100g, 200g and 500g on a single sensor.
- [0032] FIG. 8 is a plot showing measured pressure response curve, interpolated curve (exponential), and the point where the pressure sensor is specified to saturate.
- [0033] FIG. 9 shows results from pressure verification trials on a second 1- pound sensor.
- [0034] FIG. 10 is a plot showing raw pressure response curves, and various fits.
- [0035] FIG. 11 illustrates a PC setup for running the perfusion oxygenation monitoring (POM) system.
- [0036] FIG. 12 shows a screenshot of the hardware configuration module interface.
- [0037] FIG. 13 shows a screenshot of the graphical user interface

[0038] FIG. 14 shows an exemplary interpolation performed via a Kriging algorithm.

[0039] FIG. 15 shows a schematic diagram of a marker pattern used for testing the feature extraction module.

[0040] FIG. 16 illustrates the setup of FIG. 15 overlaid on an image.

[0041] FIG. 17 illustrates a block diagram of a method for outputting a mapped and interpolated perfusion image.

[0042] FIG. 18 shows an example of heterodyning used to help eliminate in- band noise.

[0043] FIG. 19 is a plot of the theoretical response of the subtraction method of FIG. 18 in relation to noise and correction frequency.

[0044] FIG. 20 is a plot of the frequency response of the subtraction method shown on a dB scale.

[0045] FIG. 21 shows results from employing noise subtraction on a high frequency LED drive signal, and averaging several LED drive periods to obtain similar data rates as before.

[0046] FIG. 22 illustrates a zoomed view of FIG. 21.

[0047] FIG. 23 shows a sample of the time domain signals used for comparison of neck and thumb tissue measurements.

[0048] FIG. 24 shows the frequency domain representation of the measured signals.

[0049] FIG. 25 shows results from extracted plethysmograph signals of the forehead.

[0050] FIG. 26 shows a comparison of readings of extracted plethysmograph signals from under the knuckle on the thumb.

[0051] FIG. 27 shows results from varying pressure using the reflectance sensor on the neck.

[0052] FIG. 28 shows the results from both over and to the side of the black tape.

DETAILED DESCRIPTION OF THE INVENTION

[0053] FIG. 1 shows a preferred embodiment of a perfusion oxygenation monitoring (POM) system 10 for analyzing a region of tissue 52 of a patient 18. System 10 generally comprises six primary components: red/infrared LED array 44, photodiode array 46, pressure sensor 50, pressure metering system 48 (which includes amplification and filtering circuitry), data acquisition unit 40, digital signal processing module 12 and application module 14 having a user interface.

[0054] The system 10 comprises sensing hardware component 16 that includes arrays of emitters/sensors (44, 46, 50) and data acquisition unit 40, preferably in a handheld enclosure (not shown). The LED array 44 and photodiode arrays 46 coupled to the data acquisition unit 40 (e.g. through cabling or wireless connection) can be physically configured in a variety of arrays. The data acquisition unit 40 is preferably capable of interfacing with a large number of individual LEDs and photodiodes. Signal amplification and filtering unit 49 may be used to condition the photodiode signal/data prior to being received by the data acquisition unit 40. In a preferred embodiment, the photodiode signal amplification and filtering unit 49 may comprise a photodiode read circuit 120 shown in FIG. 5 and described in further detail below.

[0055] Sensing/scanning hardware component 16 may also include an intensity controller 42 for controlling the output of LED array 44. Intensity controller 42 preferably comprises LED driver circuit 100 shown in FIG. 4, and described in further detail below.

[0056] The data acquisition system 40 also interfaces with application module 14 on PC 154 (see FIG. 11), allowing a user to configure the LED array 44 signaling as well as sampling rate of the signal from photodiode array 46 via a hardware configuration module 34 that is viewed through the graphical user interface 36. Data acquired from DAC 40 is preferably stored in a database 32 for subsequent processing.

[0057] The pressure sensor 50 is configured to measure the pressure applied

perfusion hardware printed circuit board (PCB) 60. PCB 60 comprises LED array 44 of two LED pairs 64 spaced between two arrays 46 of photodiodes 62. The board 60 also comprises pressure sensor 50 to monitor the applied pressure on the target tissue 52.

[0063] As shown in FIG. 2A, the optical sensors (e.g. LED array 44 and photodiode array 46) are located on the front side 66 of the PCB 60 and are configured to face and press onto (either directly or adjacently with respect to transparent cover (not shown)) the target tissue 52.

[0064] Referring to FIG. 2B, driving circuitry, e.g. connector head 70, are located on the back side 68 of the PCB 60 safely out of contact with the test subject, and the front of the PCB (right) which houses the sensor portion of the array. The arrays 44, 46 are located such that connector head 70 and corresponding leads 72 and cables 74 (which couple to the data acquisition unit 40) do not interfere with using the device.

[0065] The arrays 44, 46 are shown in FIG. 2A as two LED's 64 positioned between four photodiodes 62. However, it is appreciated that the array may comprise any number of and planar configuration of at least one LED emitter 64 and one photodiode receiver.

[0066] FIG. 3 illustrates an exemplary LED emitter 64 (OSI Optoelectronics DLED-660/880 CSL-2) having 660nm red emitter 84 and 880nm Infrared emitter 82.

[0067] FIG. 4 illustrates LED driver circuit 100. LED driver circuit 100 is configured to allow the red LED 88 and infrared LED 82 in the LED package 64 to be driven independently, even though the LEDs are common anode, sharing a VDD connection via leads 80.

[0068] Driver circuit 100 includes a low-noise amplifier 110 coupled to the LED 64. In a preferred embodiment, the amplifier 110 comprises a LT6200 chip from Linear Technologies. However, it is appreciated that other amplifiers available in the art may also be employed. LED driver circuit 100 further comprises a p-channel MOS field-effect transistor (FET) 112 (e.g. MTM76110 by Panasonic), which provides negative feedback. As voltage is increased at

current output of the photodiode and converts it to voltage, allowing the data acquisition unit to read the voltage via its voltage input module.

[0072] It is appreciated that the individual components of the LED driver circuit 100 and photodiode read circuit 120 are shown for exemplary purposes only, and that other models, or types of components may be used as desired.

[0073] In one example, the data acquisition controller 40 comprises National Instruments CompactRIO 9014 real-time controller coupled with an NI 9104 3M gate FPGA chassis. The data acquisition controller 40 interfaces with the LED arrays 44 and photodiodes 46 using three sets of modules for current output, current input, and voltage input.

[0074] In one embodiment, the controller 40 comprises a processor, real-time operating system, memory, and supports additional storage via USB (all not shown). The controller 40 may also include an Ethernet port (not shown) for connection to the user interface PC 154. The controller 40 comprises an FPGA backplane, current output module (e.g. NI 9263), current input module (e.g. NI 9203), and voltage input module (e.g. NI 9205) allowing multiple voltage inputs from photodiode/amplifier modules.

[0075] The POM system 10 preferably employs a pressure sensor 50 to measure pressure and ensure consistent results (e.g. 11b. Flexiforce sensor). Due to the confounding effect varying pressure can have on plethysmograph measurements, readings from the pressure sensor 50 provide a metric from which the user can apply the sensor hardware 16 to the patient's skin 52.

[0076] The pressure sensor 50 is preferably attached behind the LED array 44, and measures the pressure used in applying it to a target location. The pressure sensor 50 is preferably configured to deliver accurate measurements of pressure in a specified range, e.g. a range from zero to approximately one pound, which encompasses the range of pressures that can reasonably be applied when using the POM sensing hardware 16.

[0077] The pressure sensor 50 is used to guide the user into operating the scanner 16 more consistently, so that the sensor/scanner 16 is positioned in a similar manner every measurement. The oximetry data that is taken is thus

An example of code for carrying out method 220 may be found in the Source Code Appendix attached hereto. It is appreciated that the provided code is merely one example of how to perform the disclosed methods.

[0092] Acquired data from the data acquisition unit 40 (which may be stored on server 32) is first extracted at step 222 (via processing scripts 24). This extracted data is then used for simultaneously extracting location data, perfusion data and pressure data from each measurement point. The processing software 12 may simultaneously sample location, perfusion, and pressure readings (e.g. at 3Hz interval), in order to creating a matching set of pressure, position, and blood oxygen measurements at each interval.

[0093] In order to generate useful information and metrics from the raw data recorded by the perfusion module 228, a number of algorithms are used.

[0094] At step 230, features are extracted from the data (e.g. via the feature extraction module 28). Position data corresponding to the hardware sensor 16 location is then mapped at step 232. After a scan has been completed, the oximetry data is mapped at step 234 to appropriate coordinates corresponding to the obtained sensor position data from step 232. At step 236, the mapped data is interpolated (e.g. using the Kriging algorithm shown in FIG. 14). The interpolated data may be compiled into a color coded image, and displayed to the user, and/or the perfusion data may then overlaid on a background image (e.g. image 205) of the scan site as described in FIGS. 15 and 16.

[0095] On the perfusion side, RF noise filtering is then performed on the extracted data at step 224. Motion noise is then removed at step 226 to obtain the perfusion data at step 228. Steps 224 and 226 may be performed via filtering module 22.

[0096] In a preferred method illustrated in FIG. 18, heterodyning is used to help eliminate in-band noise. The data recorded from when the LED arrays 44 are off is subtracted from adjacent data from when LED arrays 44 are on (subtraction method). This creates high frequency noise, but removes low frequency in band noise, which is a larger issue. The additional high frequency noise that is introduced is then filtered out by a low pass filter. The algorithms

version of FIG. 21, showing the noise spike that is removed by differential noise subtraction. These plots show that the noise subtraction method is effective in removing in band noise.

[00102] Frequency domain analysis/experiments were performed with the frequency domain signals of the plethysmograph measurements. The experiments revealed not only high magnitude elements at the heart rate frequency, but also its harmonics. This appears fairly consistent between locations.

[00103] In order to verify that the harmonics shown in the frequency domain were not the result of noise or jitter, but represented real components of the pulse waveform, a sinusoid wave was constructed. The sinusoid was created by summing sinusoids at the frequency for each separate pulse waveform peak. This superposition was intended to model the effects of frequency jitter in the waveform, while removing any frequency components due to the pulse waveform shape.

[00104] A comparison of signals is shown in FIGS. 23 and 24. FIG. 23 shows a sample of the time domain signals used for comparison. Neck measurements were compared to thumb measurements, taken at equal pressure. FIG. 24 shows the frequency domain representation of the measured signals. Note the second harmonic at 128BPM (2.13Hz), the third harmonic at 207BPM (3.45Hz), etc. The results demonstrate that the harmonics shown below are indeed intrinsic to the pulse waveform, and are not the result of noise or frequency jitter.

[00105] Experiments were performed on number of body locations, including neck, thumb and forehead using the perfusion system 10 Samples of extracted plethysmograph signals are reported in FIGS. 25-27, which clearly show that perfusion system successfully removes the motion and ambient noises and extracts the plethysmograph signal from different body location.

[00106] FIG. 25 shows results from extracted plethysmograph signals of the forehead. Pressure values are given in terms of resistance measured using

CLAIMS

1. An apparatus for monitoring perfusion oxygenation of a target tissue region of a patient, comprising:
 - a scanner comprising:
 - a planar sensor array configured to be positioned in contact with a surface of the target tissue region,
 - wherein the planar sensor array comprising
 - one or more light emitting diodes (LED's) configured to emit light into the target tissue region at a wavelength keyed for hemoglobin;
 - and
 - one or more photodiodes configured to detect light reflected from the LED's;
 - a data acquisition controller arranged for coupling to the one or more LED's and arranged for coupling to the one or more photodiodes for controlling the emission and reception of light from the planar sensor array to obtain perfusion oxygenation data associated with the target tissue region;
 - an intensity controller comprising a light emitting source driver circuit arranged for electrical connection to said data acquisition controller, wherein said intensity controller is configured to control the output of said light emitting sources to penetrate light throughout the target tissue; and
 - a processing module arranged for coupling to the data acquisition controller and configured to obtain readings from the sensor array to obtain position data of the scanner, wherein the processing module is configured to generate a perfusion oxygenation map of the target tissue as a function of the acquired position data and perfusion oxygenation data, wherein said perfusion oxygenation map represent levels of oxygen spatial distribution and depth penetration throughout the target tissue.

2. An apparatus as recited in claim 1 , the scanner further comprising:
 - a pressure sensor arranged for coupling to the planar sensor array;
 - the pressure sensor configured to obtain pressure readings of the planar sensor array's contact with a surface of the target tissue region;
 - wherein the scanner is configured to obtain pressure sensor readings, and obtaining perfusion oxygenation data upon proper contact of the scanner with the surface of the target tissue region at a specified pressure range.
3. An apparatus as recited in claim 2:
 - wherein the pressure sensor and planar sensor array are arranged for connection to a first side of a printed circuit board (PCB); and
 - wherein the data acquisition controller is arranged for connection to the PCB on a second side opposite said first side.
4. An apparatus as recited in claim 1 , wherein each LED comprises dual emitters configured for emitting red (660nm) and infrared (880nm) light.
5. An apparatus as recited in claim 4:
 - wherein the driver circuit is further configured to allow the red LED emitter and infrared LED emitter to be driven independently while sharing a common anode.
6. An apparatus as recited in claim 5, wherein the driver circuit comprises
 - an amplifier; and
 - a field-effect transistor configured for providing negative feedback.
7. An apparatus as recited in claim 2,

wherein said LED's are spaced apart over a surface area of the target tissue region, and
the pressure sensor comprising a first pressure sensor among an array of spaced-apart pressure sensors over the surface area of the target tissues region; and
wherein the processing module configured to control sampling of the pressure sensor and planar sensor array for simultaneous acquisition of pressure sensor data and perfusion oxygenation data.

8. An apparatus as recited in claim 7, wherein the processing module is configured to control sampling of the pressure sensor and planar sensor array for simultaneous acquisition of two or more data parameters selected from the group consisting of pressure sensor data, perfusion oxygenation data, and position data, to simultaneously display said two or more data parameters.
9. A system for monitoring perfusion oxygenation of a target tissue region of a patient, comprising:
 - (a) a scanner comprising:
 - a planar sensor array configured to be positioned in contact with a surface of the target tissue region;
 - the sensor array comprising
 - one or more light sources configured to emit light into the target tissue region at a wavelength keyed for hemoglobin; and
 - one or more sensors configured to detect light reflected from the light sources;
 - a pressure sensor arranged for coupling to the planar sensor array, the pressure sensor configured to obtain pressure readings of the planar sensor array's contact with a surface of the target tissue region; and

(b) a data acquisition controller arranged for coupling to the one or more sensors and for controlling the emission and reception of light from the planar sensor array to obtain perfusion oxygenation data associated with the target tissue;

(c) an intensity controller comprising a light source driver circuit and arranged for electrical connection to said data acquisition controller, wherein said intensity controller is configured to control the output of said one or more light sources to penetrate light throughout the target skin; and

(d) a processing module arranged for coupling to the data acquisition controller; wherein the processing module is configured to obtain readings from the planar sensor array to obtain position data of the scanner, configured to control sampling of the pressure sensor and sensor array for simultaneous acquisition of perfusion oxygenation data and pressure sensor data to ensure proper contact of the scanner with the surface of the target tissue region, and configured to generate a perfusion oxygenation map of the target tissue as a function of the acquired position data and perfusion oxygenation data, wherein said perfusion oxygenation map represent levels of oxygen spatial distribution and depth penetration throughout the target tissue.

10. A system as recited in claim 9:

wherein the one or more light sources comprises one or more light emitting diodes (LED's) configured to emit light into the target tissue region at a wavelength keyed for hemoglobin; and

wherein the one or more sensors comprises one or more photodiodes configured to detect light reflected from the LED's.

11. A system as recited in claim 10:

wherein each of the one or more LED's comprises dual emitters configured for emitting red (660nm) and infrared (880nm) light;

wherein the one or more LED's are arranged for coupling to the driver circuit; and

wherein the driver circuit is further configured to allow the red LED emitter and the infrared LED emitter to be driven independently while sharing a common anode

12. A system as recited in claim 9, further comprising:
a graphical user interface;
wherein the graphical user interface is configured to display the perfusion oxygenation data and pressure sensor data.
13. A system as recited in claim 9, wherein the processing module is further configured to interpolate the position data to generate a perfusion oxygenation map of the target tissue.
14. A system as recited in claim 13, wherein the processing module is configured to control sampling of the pressure sensor and planar sensor array for simultaneous acquisition of two or more data parameters selected from the group consisting of pressure sensor data, perfusion oxygenation data, and position data, to simultaneously display the two or more data parameters.
15. A system as recited in claim 13, wherein the processing module is configured to receive an image of the target tissue, and overlay the perfusion oxygenation map over the image.
16. A system as recited in claim 12, wherein the graphical user interface is configured to allow user input to manipulate settings of the planar sensor array and pressure sensor.
17. A system as recited in claim 9, wherein the processing module further comprises:
a filtering module;

the filtering module configure to filter in-band noise by subtracting data recorded when the one or more light sources are in an “off” state from data recorded when the one or more light sources are in an “on” state.

18. A method for performing real-time monitoring of perfusion oxygenation of a target tissue region of a patient, comprising:

positioning a sensor array in contact with a surface of the target tissue region;
emitting light from lights sources in the sensor array into the target tissue region at a wavelength keyed for hemoglobin;
receiving light reflected from the light sources;
obtaining pressure data associated with the sensor array's contact with a surface of the target tissue region;
obtaining perfusion oxygenation data associated with the target tissue region; and
sampling the perfusion oxygenation data and pressure data to ensure proper contact of the sensor array with the surface of the target tissue region,
obtaining readings from the sensor array to obtain position data of the sensor array; and
generating a perfusion oxygenation map of the target tissue as a function of the acquired position data and perfusion oxygenation data, wherein said perfusion oxygenation map represent levels of oxygen spatial distribution and depth penetration throughout the target tissue.

19. A method as recited in claim 18:

wherein the sensor array comprises one or more LED's configured to emit light into the target tissue region at a wavelength keyed for hemoglobin; and
wherein the sensor array comprises one or more photodiodes configured to detect light reflected from the LED's.

20. A method as recited in claim 19:

wherein each of the one or more LED's comprises dual emitters configured for emitting red (660nm) and infrared (880nm) light;
the method further comprising independently driving the red LED emitter and infrared LED emitter while the red LED emitter and infrared LED emitter share a common anode

21. A method as recited in claim 18 , further comprising:
simultaneously displaying the perfusion oxygenation data and pressure sensor data.
22. A method as recited in claim 18, further comprising:
interpolating the position data to generate a perfusion oxygenation map of the target tissue.
23. A method as recited in claim 22, wherein interpolating the position data comprises applying a Kriging algorithm to the acquired position data.
24. A method as recited in claim 22, further comprising:
sampling of the pressure sensor and sensor array for simultaneous acquisition of pressure sensor data, perfusion oxygenation data, and position data; and
simultaneously displaying the pressure sensor data, perfusion oxygenation data, and position data.
25. A method as recited in claim 22, further comprising:
receiving an image of the target tissue; and
overlaying the perfusion oxygenation map over the image.
26. A method as recited in claim 18 , further comprising:

providing a graphical user interface to allow user input; and
manipulating sampling settings of the sensor array and pressure sensor according
to said user input.

27. A method as recited in claim 18 , further comprising:
cycling the one or more light sources between a period when the one or more light
sources are on, and a period when the one or more light sources are off;
and filtering in-band noise by subtracting data recorded from when the one
or more light sources are in an “off” state from data from when the one or
more light sources are in an “on” state.
28. The apparatus as recited in claim 1, wherein said planar sensor array further comprises a
laser configured to obtain location readings.