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Khair et al.

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(45) **Date of Patent: Mar. 18, 2003**

(54) **OPTICAL NONINVASIVE BLOOD PRESSURE SENSOR AND METHOD**

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(73) Assignee: **Motorola Inc.**, Schaumburg, IL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

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(22) Filed: **May 10, 2000**

(51) **Int. Cl.**[7] **A61B 5/02**

(52) **U.S. Cl.** **600/503**; 600/480; 600/500; 600/503

(58) **Field of Search** 600/485, 480, 600/500, 503

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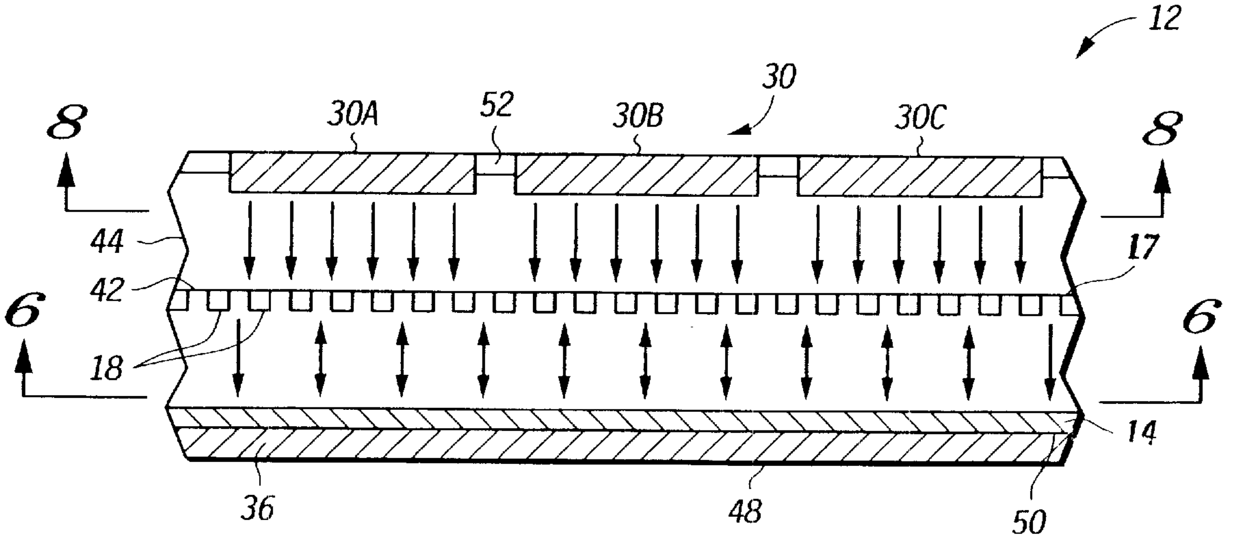
(57) **ABSTRACT**

A blood pressure sensor includes a source of photo-radiation, such as an array of laser diodes. The sensor also includes a two-dimensional, flexible reflective surface. The reflective surface is nominally positioned relative to the radiation source such that the radiation travels in a direction normal to the reflective surface. The reflective surface is placed adjacent to the location on the patient where the blood pressure data is to be acquired. Radiation from the source is reflected off of the reflective surface onto a two-dimensional array of photo-detectors. Systolic and diastolic blood pressure fluctuations in the patient are translated into deflections of the patient's skin. These deflections cause corresponding deflections in the two dimensional reflective surface. The associated movement of said flexible reflective surface due to blood pulsation causes scattering patterns from said reflective surface to be detected by the two dimensional array of photo-detectors. The output from the array of photo-detectors is calibrated to blood pressure in mmHg during a calibration procedure to obtain a set of calibration relationships for one or more of the individual detectors. The calibration relationship are then used during acquisition of blood pressure data to arrive at blood pressure data.

30 Claims, 15 Drawing Sheets



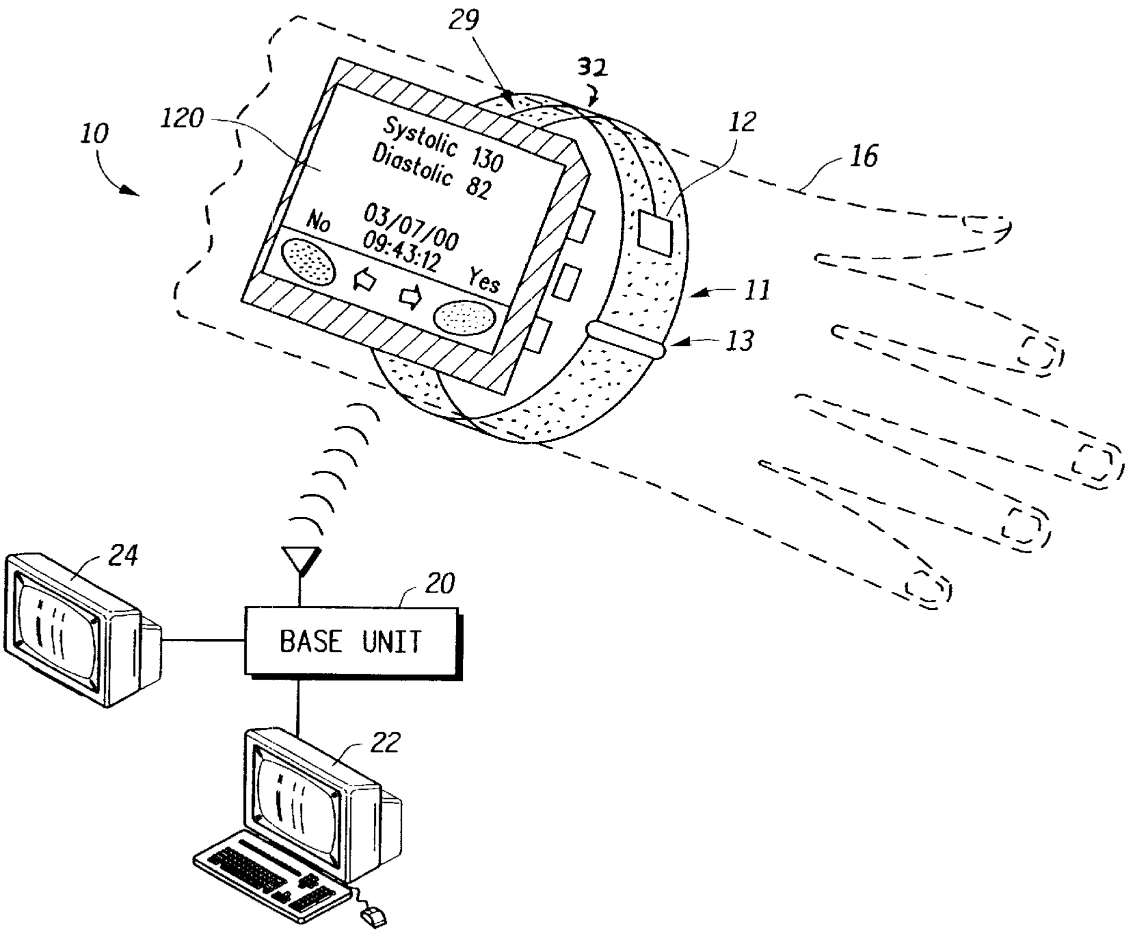

29
32
10
120
Systolic 130
Diastolic 82
No
03/07/00
09:43:12
Yes
12
16
11
13
24
20
BASE UNIT
22

FIG.1

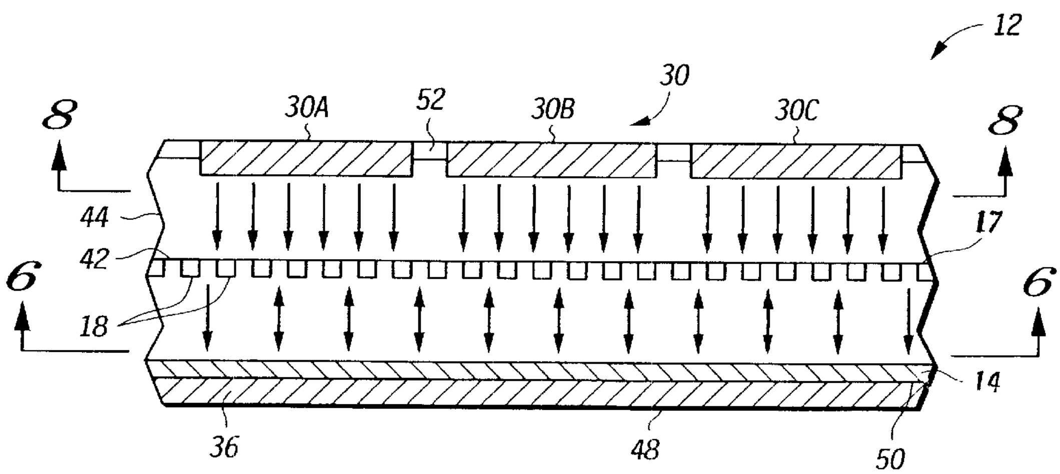

12
30
30A
52
30B
30C
8
8
44
42
17
6
6
18
14
36
48
50

FIG.2

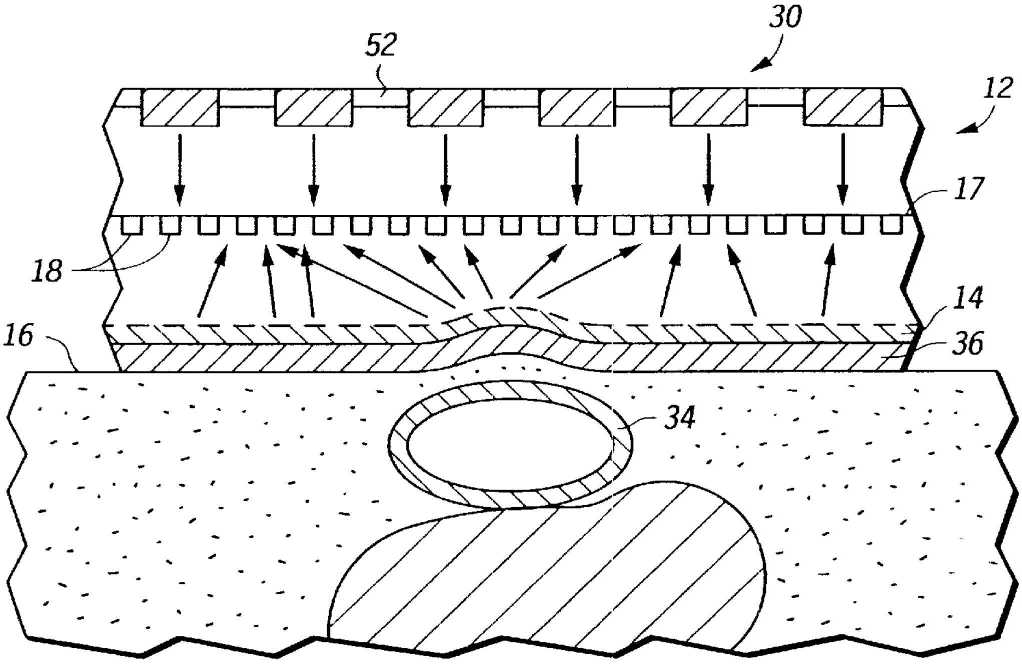


FIG. 3

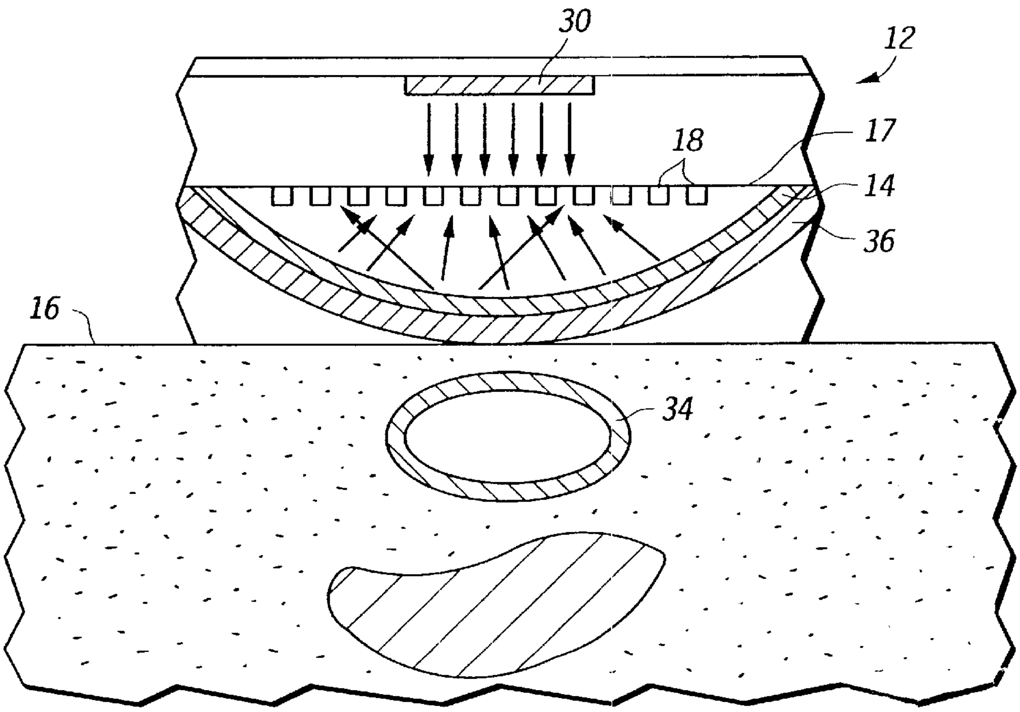


FIG. 4

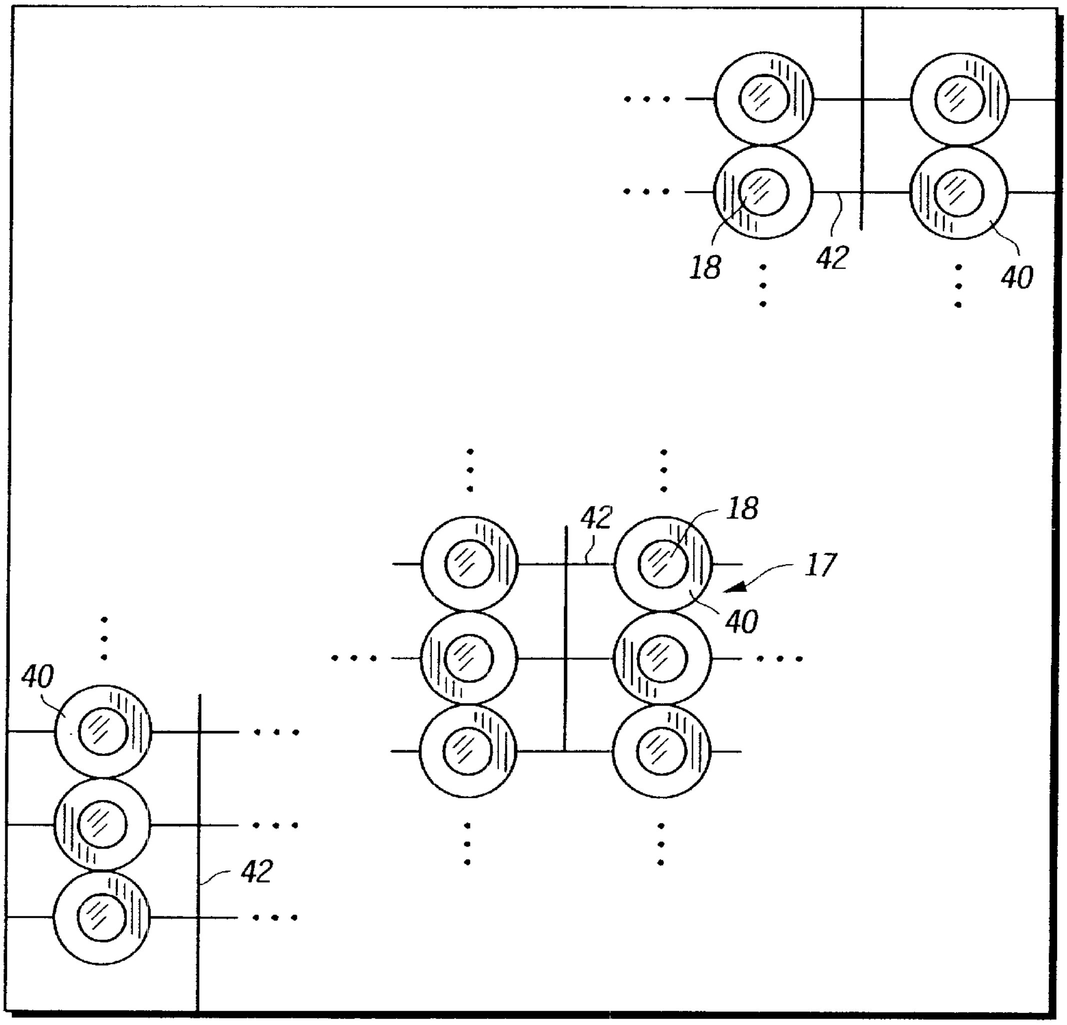
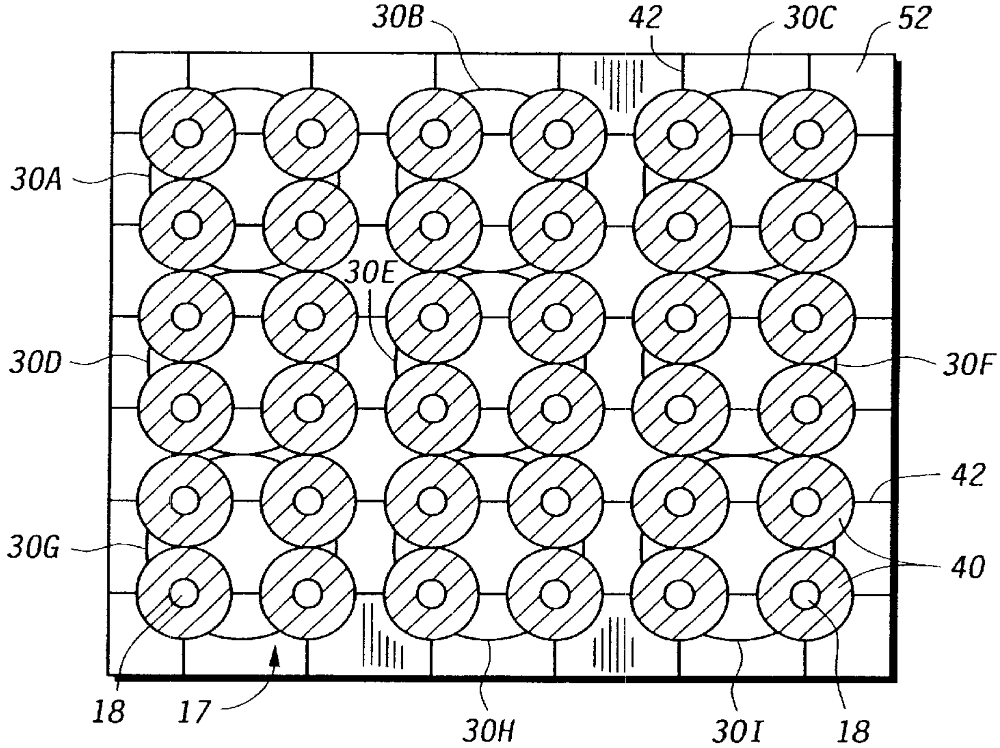
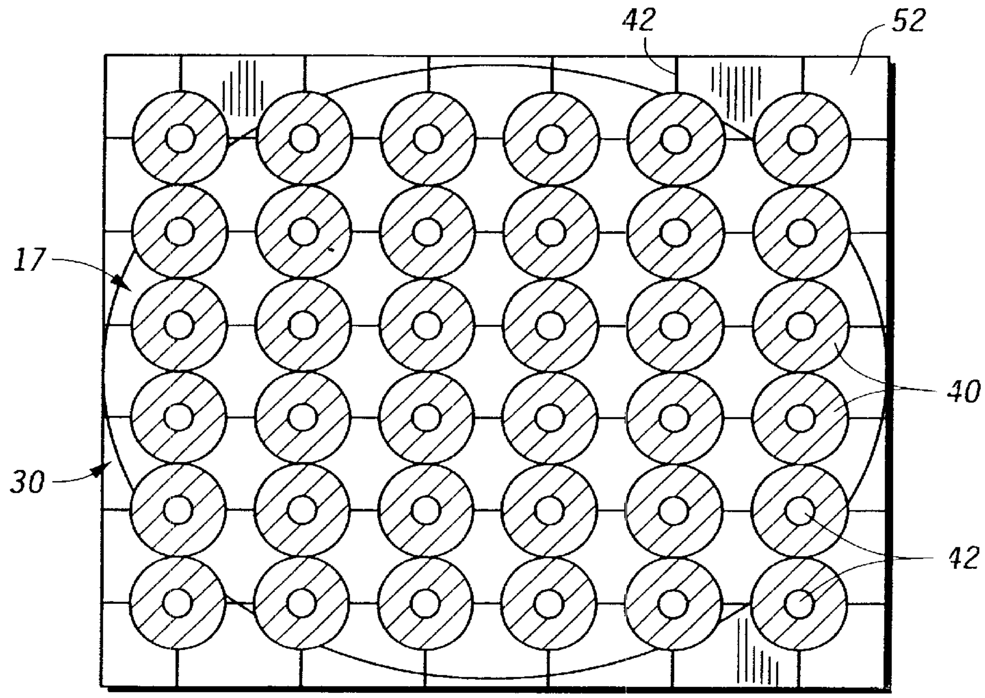


FIG. 5



30B
42
30C
52
30A
30E
30D
30F
42
30G
40
18
17
30H
30I
18

FIG. 6



42
52
17
40
30
42

FIG. 7

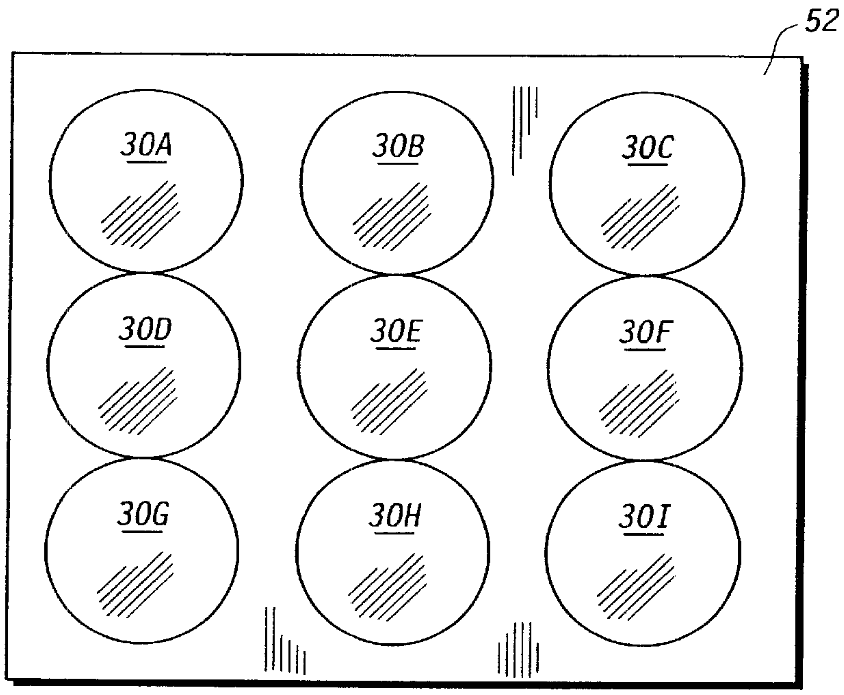


FIG. 8

FIG. 9

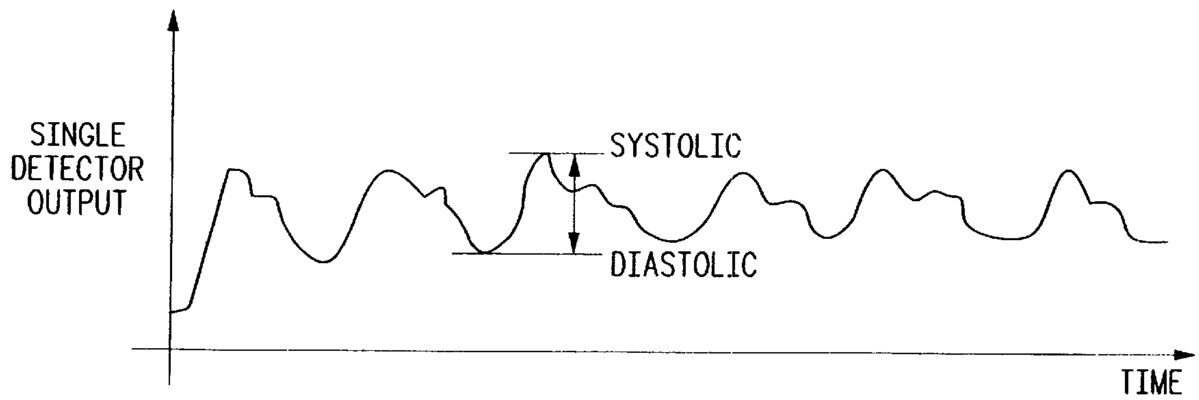

SINGLE
DETECTOR
OUTPUT
SYSTOLIC
DIASTOLIC
TIME

FIG. 10

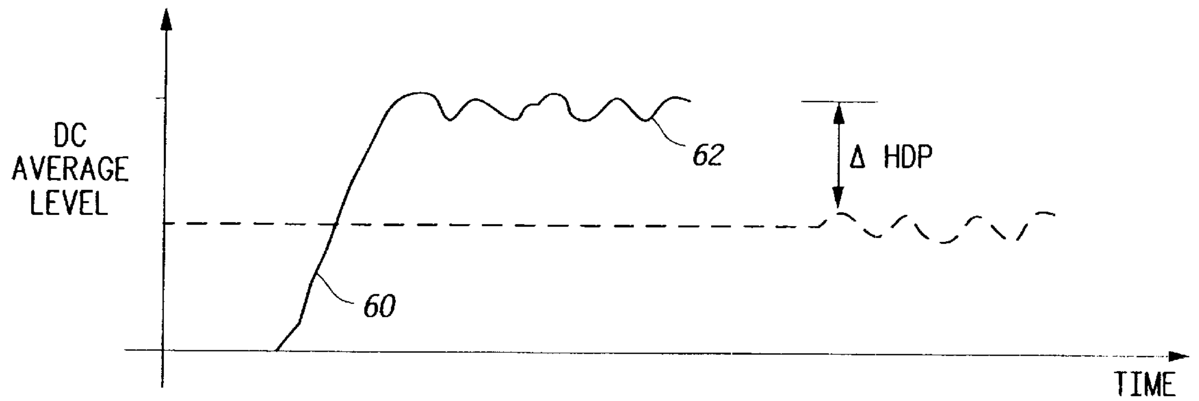

DC
AVERAGE
LEVEL
62
Δ HDP
60
TIME

FIG. 11

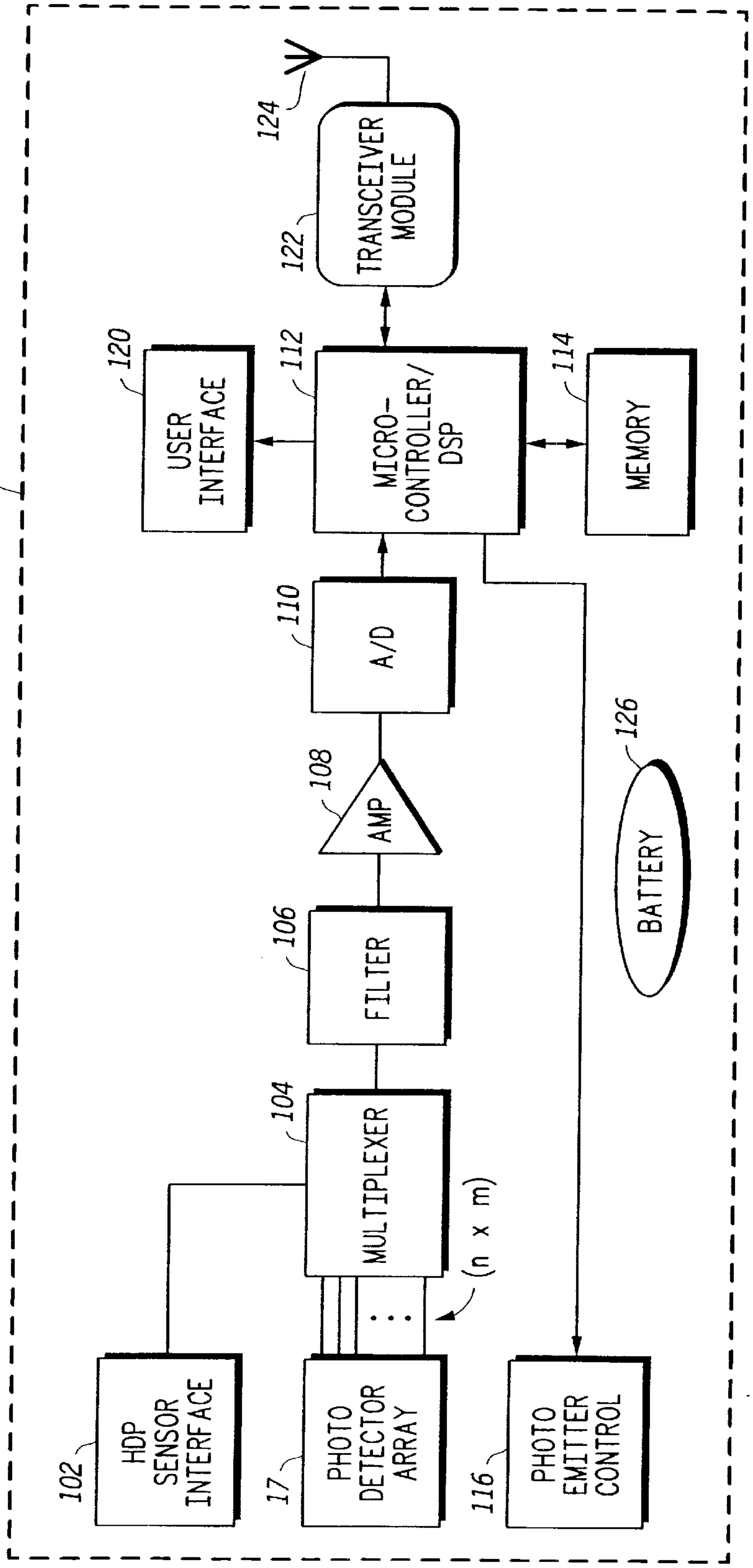

100
124
TRANSCEIVER MODULE
122
USER INTERFACE
120
MICRO-CONTROLLER/ DSP
112
MEMORY
114
A/D
110
AMP
108
BATTERY
126
FILTER
106
MULTIPLEXER
104
(n x m)
HDP SENSOR INTERFACE
102
PHOTO DETECTOR ARRAY
17
PHOTO EMITTER CONTROL
116

FIG.12

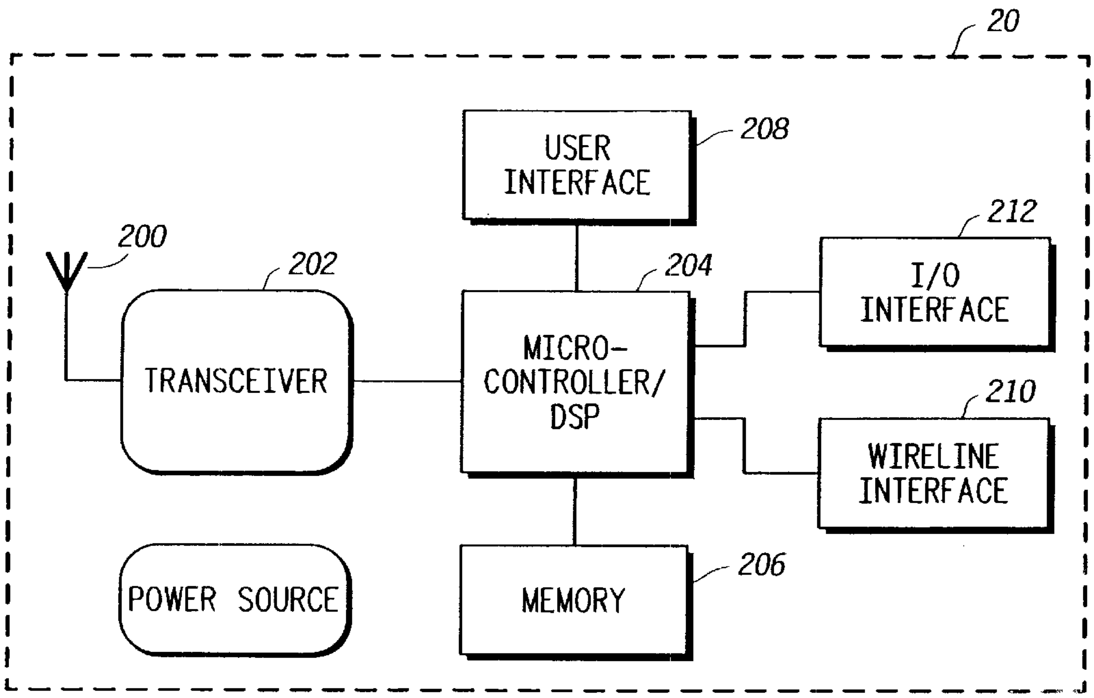

20
USER INTERFACE
208
212
200
202
204
I/O INTERFACE
TRANSCEIVER
MICRO-CONTROLLER/ DSP
210
WIRELINE INTERFACE
POWER SOURCE
MEMORY
206

FIG. 13

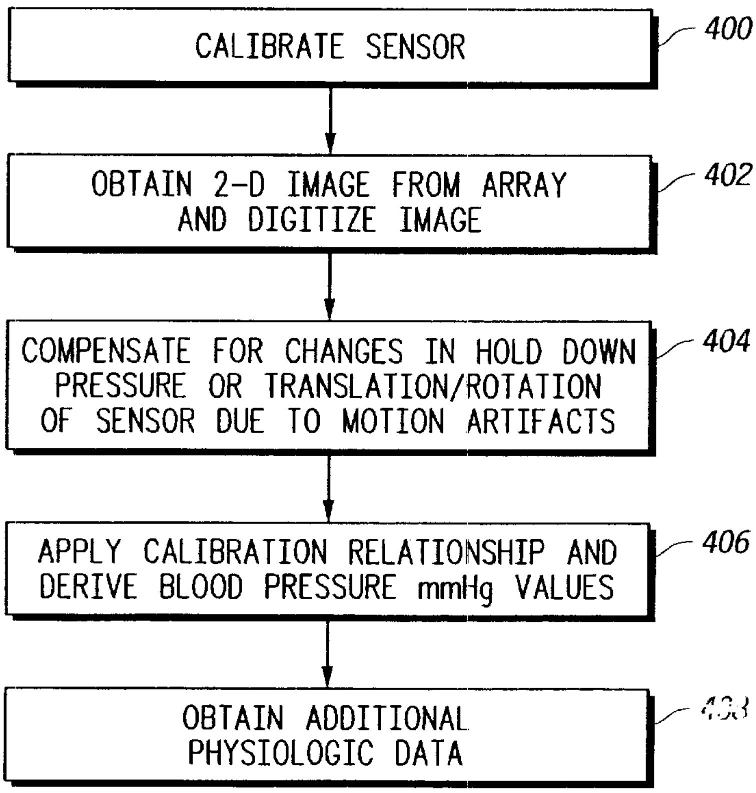

CALIBRATE SENSOR
400
OBTAIN 2-D IMAGE FROM ARRAY AND DIGITIZE IMAGE
402
COMPENSATE FOR CHANGES IN HOLD DOWN PRESSURE OR TRANSLATION/ROTATION OF SENSOR DUE TO MOTION ARTIFACTS
404
APPLY CALIBRATION RELATIONSHIP AND DERIVE BLOOD PRESSURE mmHg VALUES
406
OBTAIN ADDITIONAL PHYSIOLOGIC DATA

FIG. 14

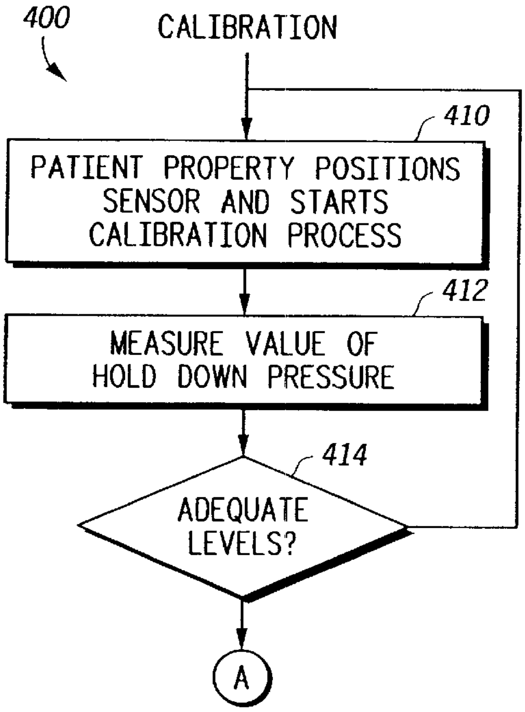


FIG.15A

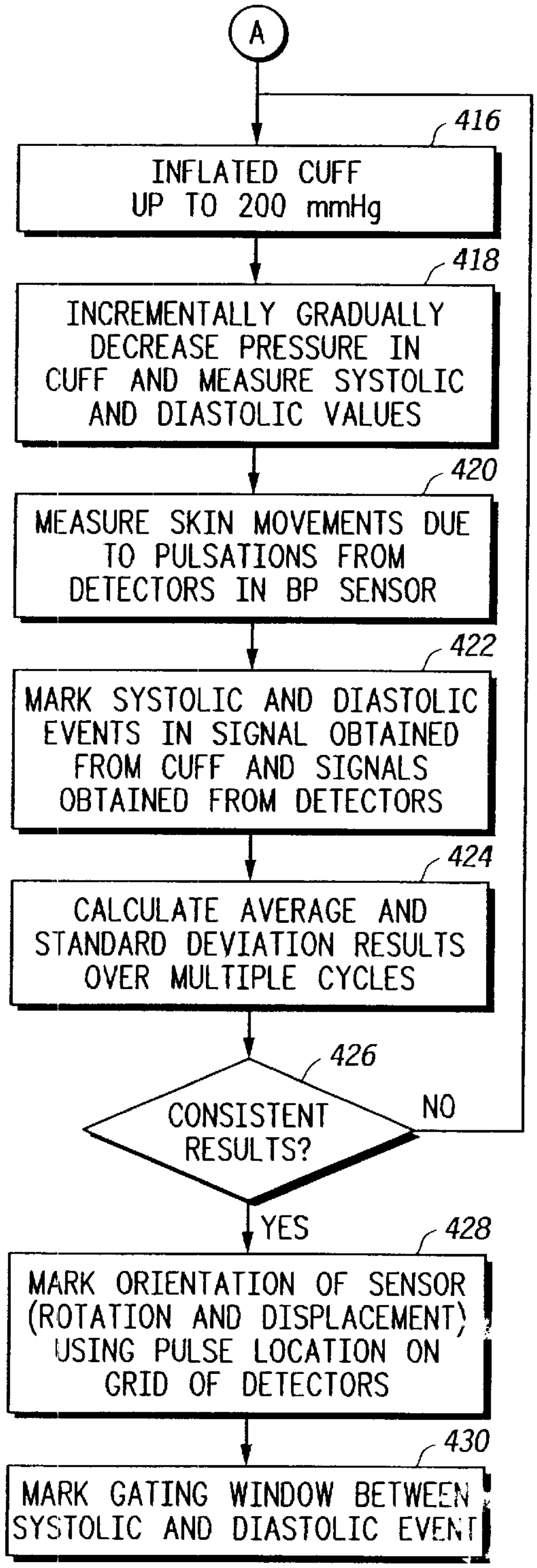


FIG.15B

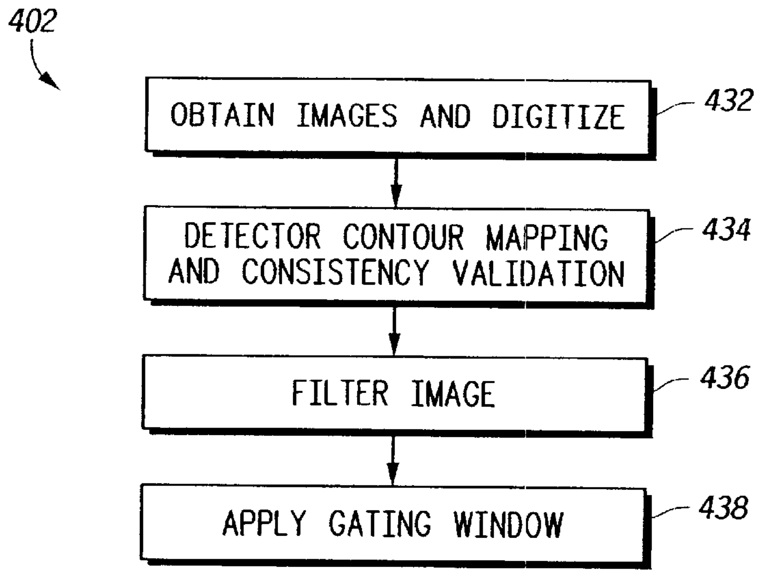

402
OBTAIN IMAGES AND DIGITIZE
432
DETECTOR CONTOUR MAPPING AND CONSISTENCY VALIDATION
434
FILTER IMAGE
436
APPLY GATING WINDOW
438

FIG. 16

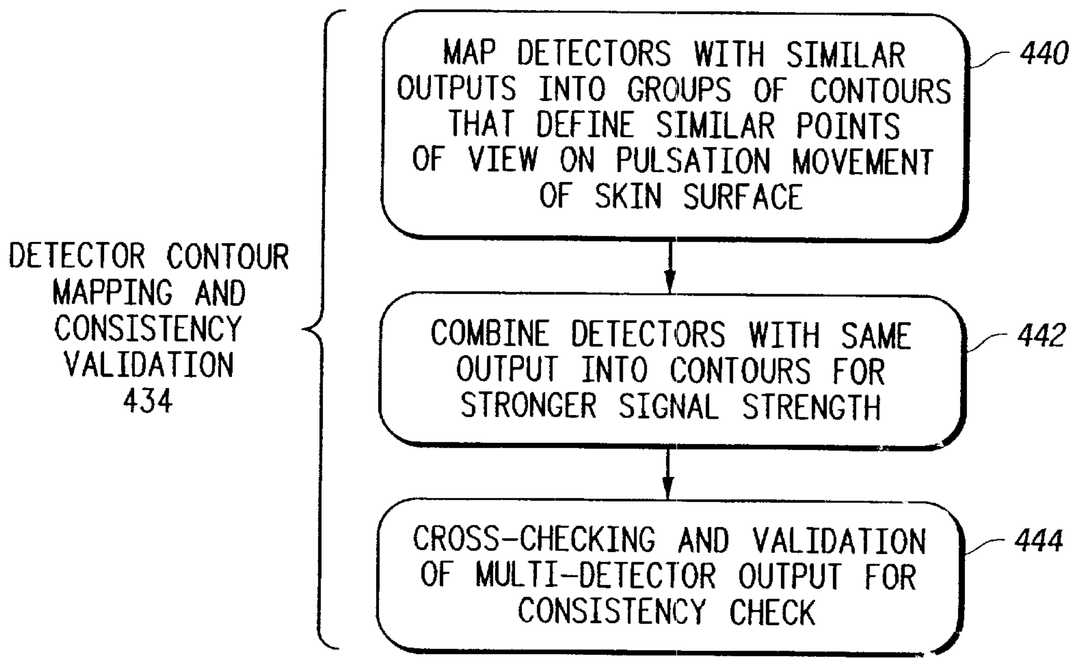

DETECTOR CONTOUR MAPPING AND CONSISTENCY VALIDATION 434
MAP DETECTORS WITH SIMILAR OUTPUTS INTO GROUPS OF CONTOURS THAT DEFINE SIMILAR POINTS OF VIEW ON PULSATION MOVEMENT OF SKIN SURFACE
440
COMBINE DETECTORS WITH SAME OUTPUT INTO CONTOURS FOR STRONGER SIGNAL STRENGTH
442
CROSS-CHECKING AND VALIDATION OF MULTI-DETECTOR OUTPUT FOR CONSISTENCY CHECK
444

FIG. 17

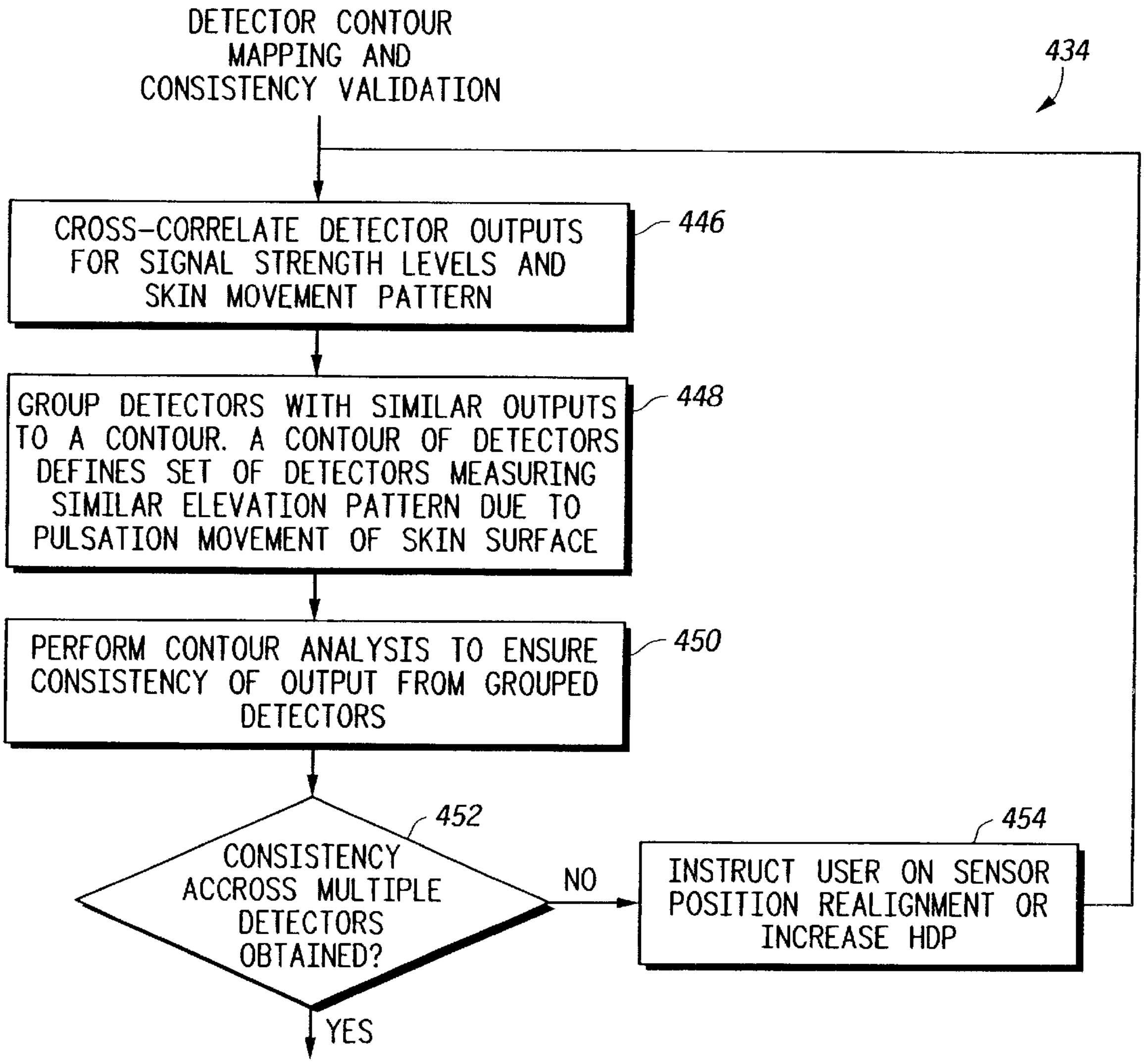

DETECTOR CONTOUR MAPPING AND CONSISTENCY VALIDATION
434
CROSS-CORRELATE DETECTOR OUTPUTS FOR SIGNAL STRENGTH LEVELS AND SKIN MOVEMENT PATTERN
446
GROUP DETECTORS WITH SIMILAR OUTPUTS TO A CONTOUR. A CONTOUR OF DETECTORS DEFINES SET OF DETECTORS MEASURING SIMILAR ELEVATION PATTERN DUE TO PULSATION MOVEMENT OF SKIN SURFACE
448
PERFORM CONTOUR ANALYSIS TO ENSURE CONSISTENCY OF OUTPUT FROM GROUPED DETECTORS
450
CONSISTENCY ACCROSS MULTIPLE DETECTORS OBTAINED?
452
NO
INSTRUCT USER ON SENSOR POSITION REALIGNMENT OR INCREASE HDP
454
YES

FIG. 18

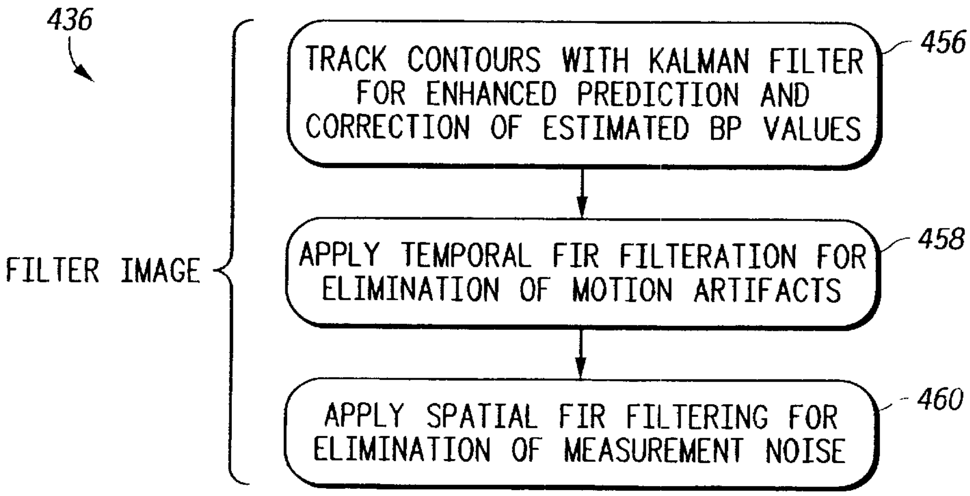

436
FILTER IMAGE
TRACK CONTOURS WITH KALMAN FILTER FOR ENHANCED PREDICTION AND CORRECTION OF ESTIMATED BP VALUES
456
APPLY TEMPORAL FIR FILTERATION FOR ELIMINATION OF MOTION ARTIFACTS
458
APPLY SPATIAL FIR FILTERING FOR ELIMINATION OF MEASUREMENT NOISE
460

FIG. 19

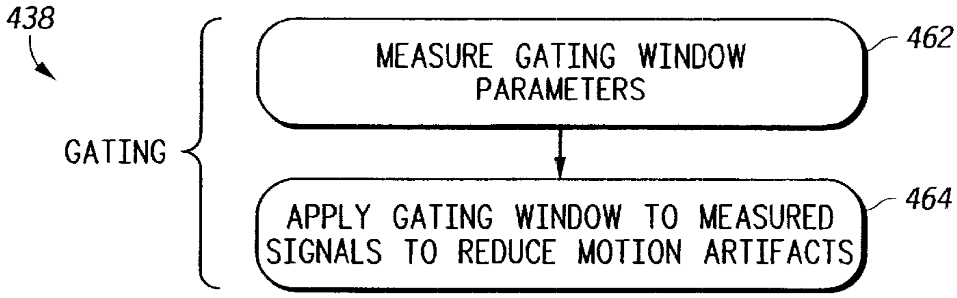

438
GATING
MEASURE GATING WINDOW PARAMETERS
462
APPLY GATING WINDOW TO MEASURED SIGNALS TO REDUCE MOTION ARTIFACTS
464

FIG.20

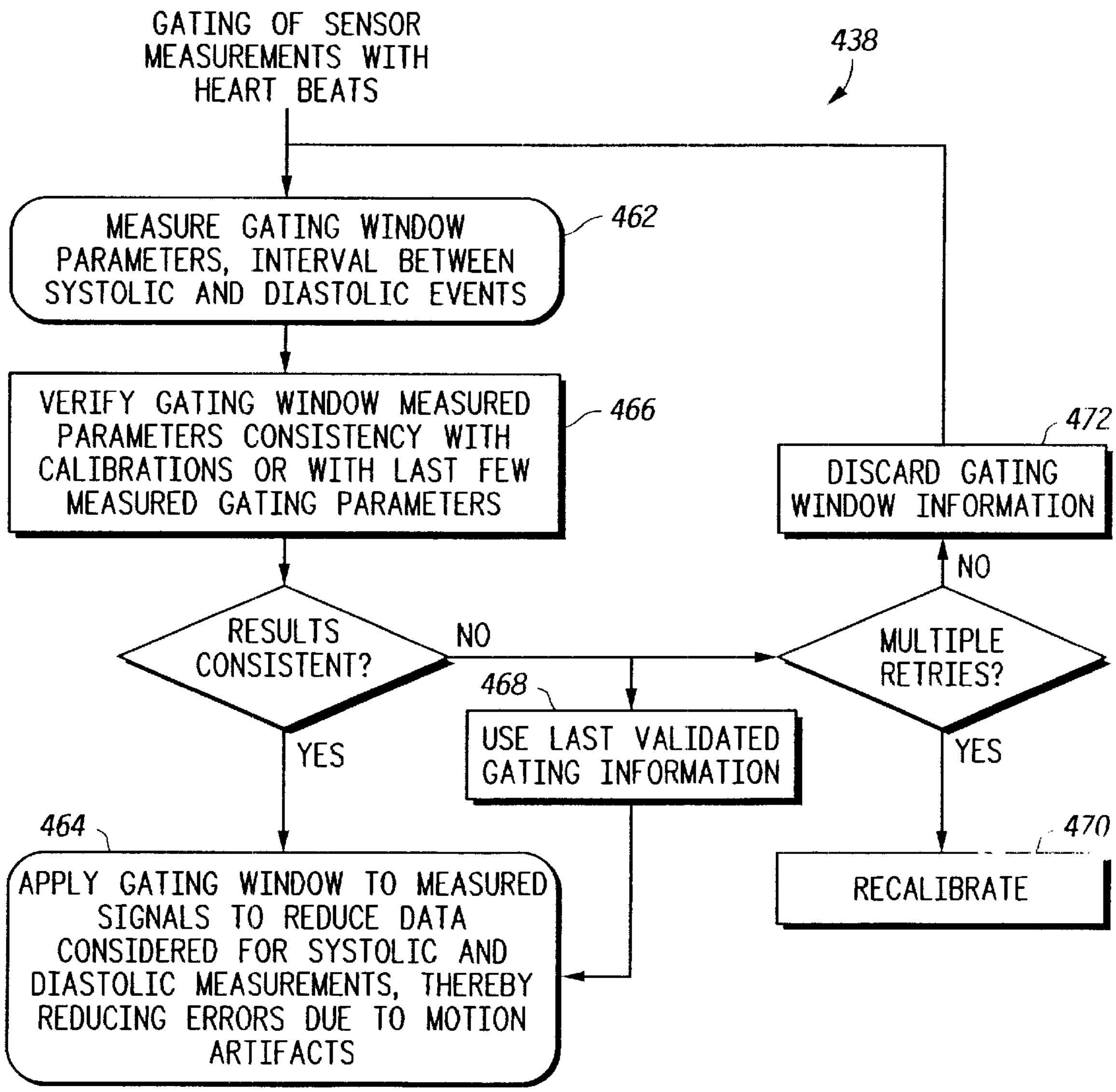

GATING OF SENSOR MEASUREMENTS WITH HEART BEATS
438
MEASURE GATING WINDOW PARAMETERS, INTERVAL BETWEEN SYSTOLIC AND DIASTOLIC EVENTS
462
VERIFY GATING WINDOW MEASURED PARAMETERS CONSISTENCY WITH CALIBRATIONS OR WITH LAST FEW MEASURED GATING PARAMETERS
466
RESULTS CONSISTENT?
NO
YES
468
USE LAST VALIDATED GATING INFORMATION
MULTIPLE RETRIES?
NO
YES
472
DISCARD GATING WINDOW INFORMATION
470
RECALIBRATE
464
APPLY GATING WINDOW TO MEASURED SIGNALS TO REDUCE DATA CONSIDERED FOR SYSTOLIC AND DIASTOLIC MEASUREMENTS, THEREBY REDUCING ERRORS DUE TO MOTION ARTIFACTS

FIG.21

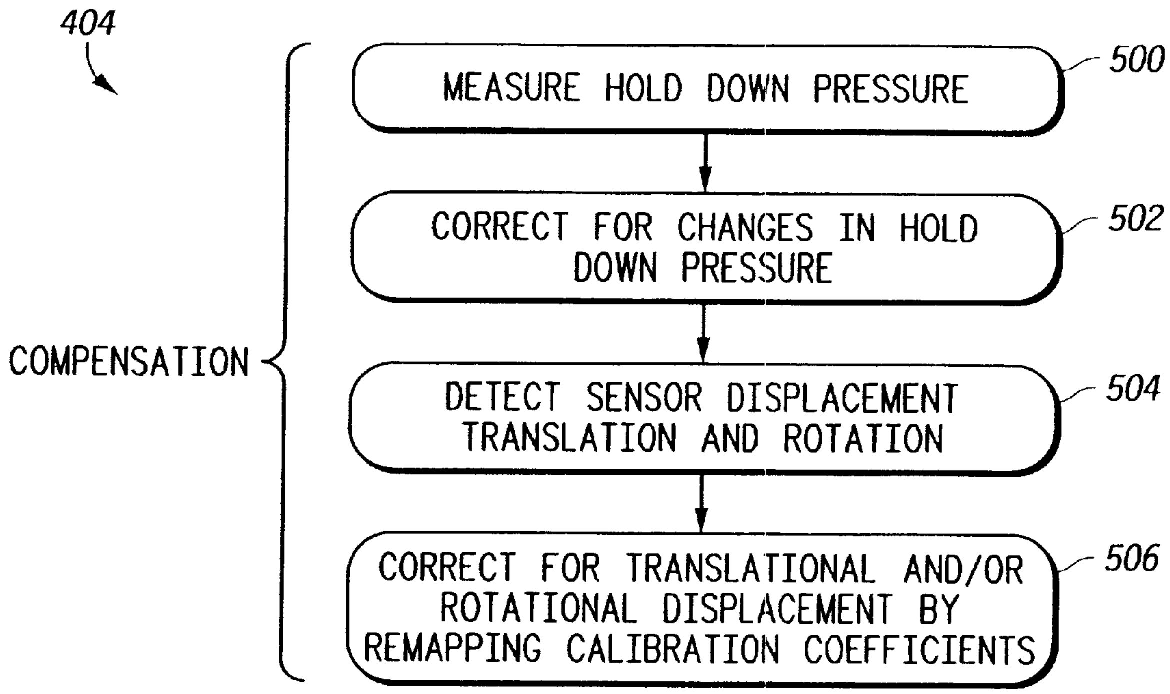
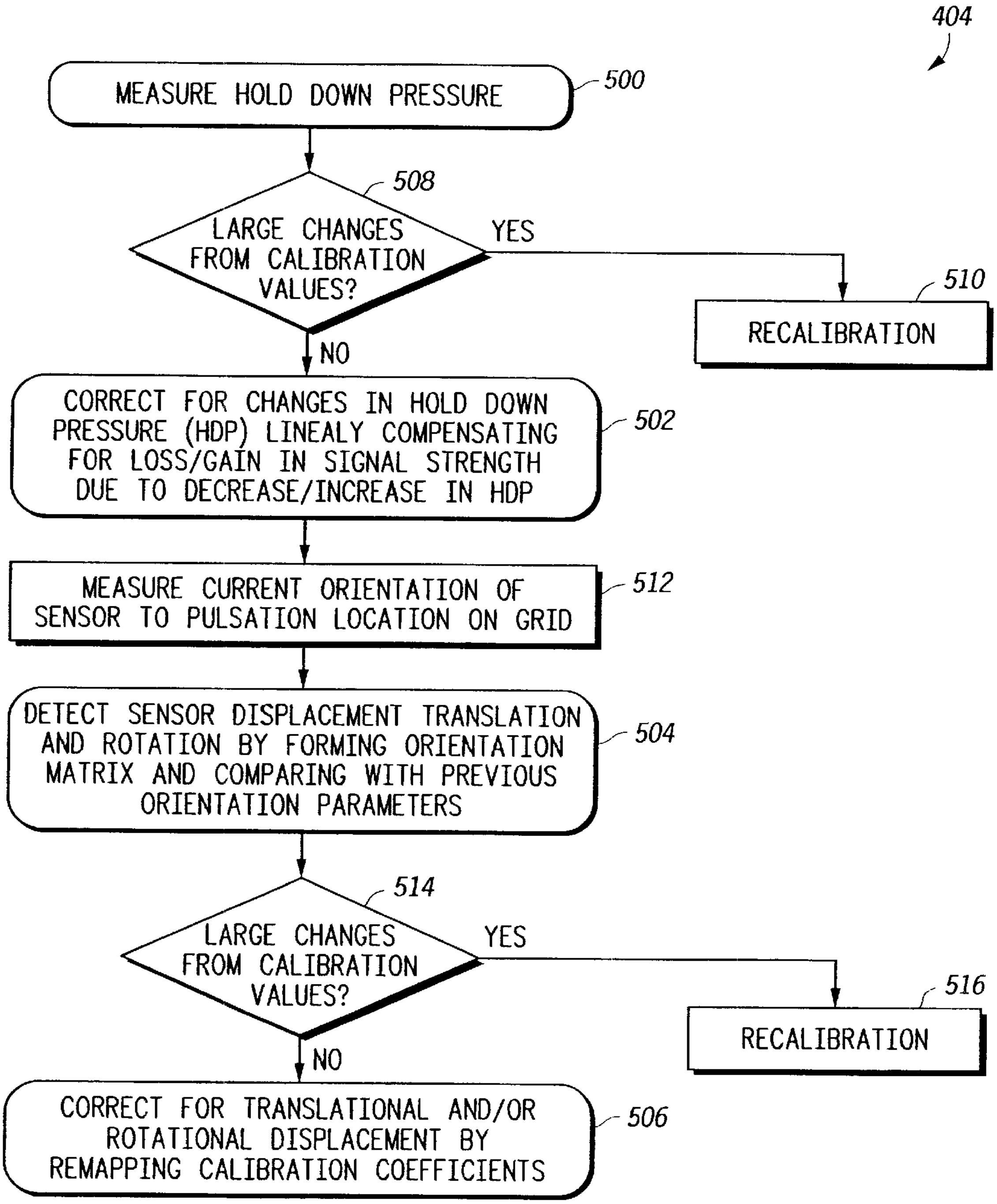

404
COMPENSATION
MEASURE HOLD DOWN PRESSURE
500
CORRECT FOR CHANGES IN HOLD DOWN PRESSURE
502
DETECT SENSOR DISPLACEMENT TRANSLATION AND ROTATION
504
CORRECT FOR TRANSLATIONAL AND/OR ROTATIONAL DISPLACEMENT BY REMAPPING CALIBRATION COEFFICIENTS
506

FIG.22



COMPENSATION

FIG. 23

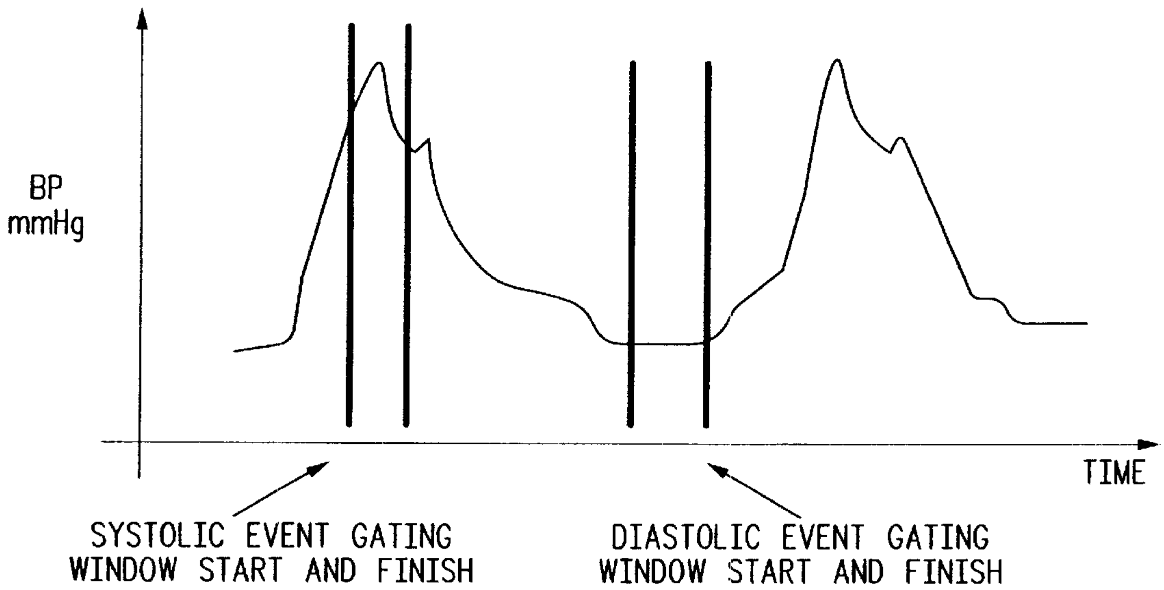

BP
mmHg
TIME
SYSTOLIC EVENT GATING
WINDOW START AND FINISH
DIASTOLIC EVENT GATING
WINDOW START AND FINISH

FIG.24

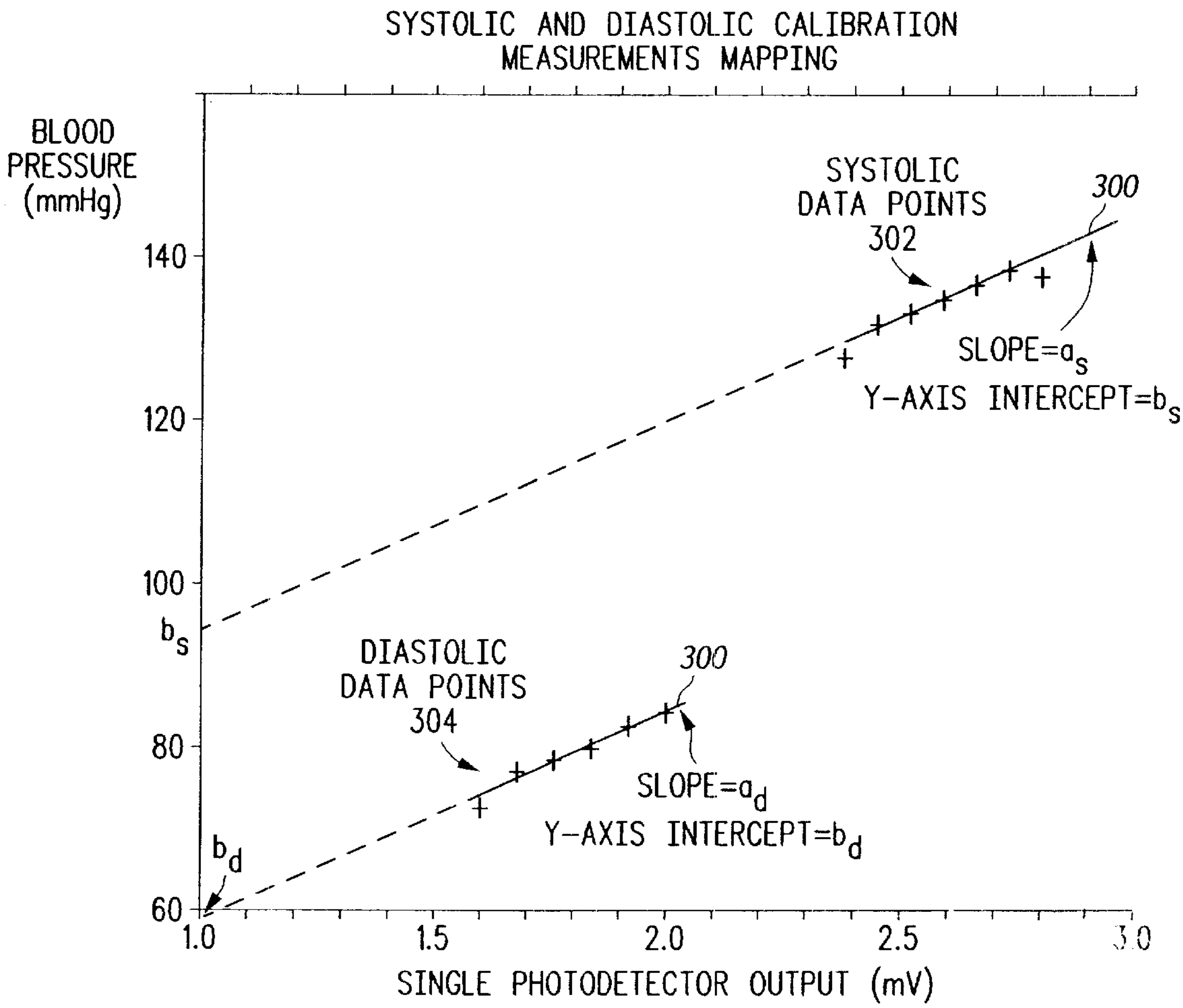

SYSTOLIC AND DIASTOLIC CALIBRATION
MEASUREMENTS MAPPING
BLOOD
PRESSURE
(mmHg)
140
120
100
80
60
b_s
b_d
SYSTOLIC
DATA POINTS
302
300
SLOPE=a_s
Y-AXIS INTERCEPT=b_s
DIASTOLIC
DATA POINTS
304
300
SLOPE=a_d
Y-AXIS INTERCEPT=b_d
1.0
1.5
2.0
2.5
3.0
SINGLE PHOTODETECTOR OUTPUT (mV)

FIG.25

OPTICAL NONINVASIVE BLOOD PRESSURE SENSOR AND METHOD

CROSS-REFERENCE TO RELATED APPLICATION

This application is related to the patent application filed by the same inventors concurrently herewith, Ser. No. 09/568,781, entitled "METHOD FOR OBTAINING BLOOD PRESSURE DATA FROM OPTICAL SENSOR," the contents of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

A. Field of the Invention

This invention relates generally to the field of devices used to measure blood pressure. More particularly, the invention relates to a wearable, non-invasive device for accurate and continuous blood pressure data acquisition. The device uses optical techniques for generating blood pressure data. The device either generates and displays the blood pressure data locally, or transmits the data via wireless techniques to a base unit for display or transmission to appropriate monitoring equipment.

B. Statement of Related Art

Non-invasive systems for continuous monitoring of blood pressure, for example during anesthesia, have been proposed in the prior art. Representative patents include the patents to Shinoda et al., U.S. Pat. No. 5,165,416; the patents to Erkele et al., U.S. Pat. Nos. 4,802,488 and 4,799,491; Jones et al., U.S. Pat. No. 5,140,990, Jackson et al., U.S. Pat. No. 5,485,848 and Pytel et al., U.S. Pat. No. 5,195,522. It is also known to use optical sensors as the means to acquire blood pressure data. See the patents to Butterfield, et al., U.S. Pat. Nos. 5,908,027; 5,158,091; 5,261,412 and 5,273,046; Cerwin, U.S. Pat. No. 5,984,874 and Tenerz et al., U.S. Pat. No. 5,018,529. The above-referenced patents are incorporated by reference herein.

Prior art mechanical sensors commonly measure blood pressure by detecting transducer changes that are proportional to the detected changes in external force measured at the skin surface during pulsation. These sensors depend on mechanical parts and are therefore more prone to breakdown due to moving parts, and are larger in size thus requiring more space for fitting it on the patient skin. These sensors employ the use of a single sensor, or an array of sensors from which only one (the one with the highest signal strength) is selected for measurement. Such sensors only cover a small surface area on the skin and are therefore very sensitive to initial exact placement of the sensor on top of the artery. They are also sensitive to movement or minor accidental repositioning. This typically invalidates all calibrations, requiring a need for re-calibrating the system with an air cuff pressure reference. Providing a corrective feedback mechanism for compensating for minor positional changes in sensor placement is not possible due to dependency on a single-point or single-sensor measurement. Furthermore, the resolution of these sensors to blood pressure changes at low level signal strength is not sufficient to obtain accurate results. Other sensors typically require higher hold down pressure (HDP) values in order to obtain a stronger signal strength due to their low sensitivity. They also offer no corrective feedback mechanism for compensating for minor variations in the hold down pressure, often requiring a need for re-calibration of the sensor at the new hold down pressure value.

Portable oscillometric wrist mounted blood pressure devices also exist, such as the Omron model HEM-609, but

these are not intended for continuous blood pressure monitoring. The oscillometric method requires the patient to be at a rested state, and a cuff pressure to be applied by the device that is above the systolic blood pressure of the patient (thus temporarily cutting off circulation in the artery and causing discomfort).

Spacelabs' Modular Digital Telemetry system offers an ambulatory blood pressure (ABP) option for wireless transmission of noninvasive blood pressure data to a central computer, however it is not a tonometric optical blood pressure monitor and it is transmit only.

The above-referenced '027 Butterfield et al. patent describes a device and technique for measuring tonometric blood pressure non-invasively using a one-dimensional optical sensor array. The sensor used in the '027 patent is also described in U.S. Pat. No. 5,158,091 to Butterfield et al. The array detects photo-radiation (i.e., light) that is reflected off of a semiconductor, thermally sensitive diaphragm, with the diaphragm deflected in response to arterial pulsation. The diaphragm's thermal properties affect how its surface is deflected. Such thermal properties are associated with calibration coefficients which are used for mapping measured deflections into mmHg blood pressure values. The calibration procedure requires taking such thermal properties into consideration, including thermal heating of the diaphragm. Additional calibration considerations are optimum vs. non-optimum applanation state of the underlying artery, compensation for deformable and a nondeformable portions of the diaphragm, so that calibration coefficients can be obtained to map measured sensor output signal into blood pressure.

The present invention is believed to be a substantial improvement over the type of sensors proposed in the prior art. The sensor itself does not depend on thermal considerations. The diaphragm or reflective surface in the present sensor is responsive to any input stress on its surface. Furthermore, a priori knowledge of the exact applanation state is not needed for proper calibration.

Additionally, the sensor is calibrated against a standard conventional air cuff for measuring blood pressure. The calibration procedure automatically compensates for variability that is inherent in patient anatomy and physiological parameters, such as body weight, size, skin thickness, arterial depth, arterial wall rigidity and compliance, body fat, etc. When the sensor is calibrated against known blood pressure (such as using an air-cuff system) all such detailed variables are individually and collectively integrated and linearized in the process of calibrating the sensor. In other words our calibration process is customized to the individual patient anatomy. Accordingly, the sensor and method of the invention produces more accurate results.

The '027 patent describes a set of detectors which are arranged in a single dimensional row. Image processing techniques are not particularly applicable in the format of arrangement of the detectors. In contrast, the sensor and method of the present invention uses a two-dimensional array of photo-sensitve elements which is cabable of producing a digitized two-dimensional image of the underlying skin surface variations due to pulsation. The number and density of elements are significantly higher. Accordingly, the array produces an image that can be processed using image processing techniques, including image transformation algorithms to detect translation or rotation of the sensor. Image processing methods can also be used for filtering, calibrating, tracking, and error-correcting the output of the sensor.

The '027 patent requires a mechanical assembly to provide a means for mechanically pushing the sensor onto the surface of skin tissue, and adjusting the force used for obtaining optimal artery applanation. The present invention does not require the need for such stress-sensing mechanical assembly for proper positioning and adjustment to achieve optimum applanation of the artery. The sensor does require a measurable hold down pressure to be applied on the sensor to produce measurable results for calibration purposes. The hold down pressure can be produced by mounting the sensor to a wrist watch band for example. Furthermore, the sensor and inventive method provide for compensating for changes in the hold down pressure between initial or calibration values of hold down pressure and values of hold down pressure later on when blood pressure data is obtained.

The present invention thus provides a convenient, non-obtrusive, wearable device for accurate and reliable continuous noninvasive blood pressure (NIBP) monitoring of an individual either as a standalone unit, or in conjunction with an in-home or hospital wireless base unit and associated monitor. The blood pressure data can be visually displayed to the user on the device itself or can be wirelessly transmitted to the base unit. The base unit can be coupled to a computer for collecting, displaying, and analyzing data, or coupled to a wireline interface to an external monitoring station. The sensor can also be used to monitor other physiologic parameters in addition to blood pressure, such as blood flow, pulse rate, pulse pressure, and arterial compliance.

SUMMARY OF THE INVENTION

In a first aspect of the invention, a sensor assembly for acquiring blood pressure data from a patient is provided. The sensor includes a housing adapted to be placed adjacent to the patient's body, such as at the wrist, and a strap or similar means for applying a hold down force for the sensor in a location where the blood pressure data is to be acquired during use of the sensor assembly. The sensor also includes a source of photo-radiation, which in preferred embodiment takes the form of one or more coherent light sources, such as laser diodes. The laser diodes may be arranged in a two dimensional array in one possible embodiment. The sensor also includes a two-dimensional, flexible reflective surface. The reflective surface may take the form of a reflective coating applied to a polymeric membrane. The reflective surface is nominally positioned relative to the radiation source such that the radiation travels in a direction normal to the reflective surface. The reflective surface is placed adjacent to the location on the patient where the blood pressure data is to be acquired. A hold down pressure sensor, preferably in the form of a strain gauge arranged as a flexible membrane or diaphragm, is also incorporated into the sensor.

Radiation from the source is reflected off of the reflective surface onto a two-dimensional array of photo-detectors. The array of photo-detectors is nominally placed in the optical path of the radiation source, but they do not block all the radiation; rather they are spaced from one another to allow incident radiation from the source to pass in between the detectors and impinge upon the reflective surface at an angle that is normal to the reflective surface. Systolic and diastolic blood pressure fluctuations in the patient are translated into deflections of the patient's skin. These deflections cause corresponding deflections in the two dimensional reflective surface. The associated movement of the flexible reflective surface due to blood pulsation causes scattering patterns to be detected by the array of photo-detectors. These scattering patterns are processed either in the sensor assembly or in a remote processing unit into useful blood pressure data for the patient.

In a preferred embodiment, the blood pressure sensor is calibrated against known blood pressure data and scattering patterns obtained while the known blood pressure is obtained at a known hold down pressure. During data acquisition, scattering patterns (i.e., output signals from the photo-detectors) are linearly scaled to the calibrated values of signal output and hold down pressure. Thus, the calibration is patient-specific and thereby more accurate than prior art calibration techniques for optical sensors.

The blood pressure sensor may also include a wireless transceiver for sending blood pressure data to a base unit and for receiving configuration or data acquisition commands from the base unit. The sensor may also include a micro-controller and Digital Signal Processor (DSP) or other type of computing platform and a memory storing a set of instructions. The computing platform in the sensor is responsive to commands from the base unit, such as start and stop data acquisition. Together, the blood pressure sensor and the base unit comprise an optical, noninvasive wireless blood pressure data acquisition system.

In another aspect, a method is provided for obtaining blood pressure data from a patient using an optical blood pressure sensor. The optical blood pressure sensor has a two-dimensional array of photo-detectors detecting scattering patterns from a reflective surface placed against the surface of the patient. The method comprises the steps of placing the optical blood pressure sensor against the patient's body at a location where blood pressure data is to be obtained, and simultaneously measuring the patient's blood pressure with a second blood pressure device (which can be a conventional sphygmomanometer) and measuring the hold down force of the blood pressure sensor against the patient's body. Output signals from the array of photo-detectors are obtained. The output signals are calibrated against the measured blood pressure and hold down force, and calibration data is stored in a memory. Then, when blood pressure data is obtained, the sensor obtains output signals from the array of photo-detectors during a blood pressure data acquisition period. The hold down force is also obtained. The output signals from the detectors are scaled to the previous calibration data and hold down force data to thereby obtain blood pressure data.

A method of calibrating a noninvasive optical blood pressure sensor is also provided. The method comprises the steps of placing the optical blood pressure sensor against the patient's body at a location where blood pressure data is to be obtained, and simultaneously measuring the patient's blood pressure with a second blood pressure device and measuring the hold down force of the blood pressure sensor against the patient's body. Output signals from the array of photo-detectors are obtained. The output signals are calibrated against the measured blood pressure and hold down force, and calibration data is stored in a memory.

Further details on these and other features of the invention will be described in the following detailed description of a presently preferred embodiment of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

A presently preferred embodiment of the invention is described below in conjunction with the appended drawing figures, wherein like reference numerals refer to like elements in the various views, and wherein:

FIG. 1 is a perspective view of an optical sensor for obtaining blood pressure data from a patient in the region of the radial artery at the wrist;

FIG. **2** is a cross-sectional view of the optical sensor of FIG. **1**, showing radiation from the light sources in the sensor being directed normal to the reflective surface of the sensor;

FIG. **3** is a cross-sectional view of the sensor of FIG. **1** shown during use, with skin deflections due to blood pulsation causing the reflective surface in the sensor to scatter light from the radiation sources, with the scattering patterns being detected by the array of photo-sensitive elements in the sensor;

FIG. **4** is a cross-sectional view of an alternative embodiment of the sensor;

FIG. **5** is a plan view of the array of photo-sensitive elements of FIG. **1** in a presently preferred photo-detector embodiment;

FIG. **6** a plan view of the sensor of FIG. **2** taken along the lines **6—6**, with the detector array comprising a 6×6 array of photo-detectors, and the light source comprising a 3×3 array of laser diodes;

FIG. **7** is a plan view of an alternative arrangement of the sensor, in which a single light source is used in conjunction with a n array of photo-detectors;

FIG. **8** is a plan view of the array of laser diodes in the embodiment of FIGS. **2** and **6**;

FIG. **9** is a simulation of an image of the surface of the skin that would be obtained by a high resolution photo-detector array;

FIG. **10** is a graph of the output of a single detector as function of time, showing the relationship between sensor output and blood pressure value;

FIG. **11** is a graph of the hold down pressure for the sensor as a function of time;

FIG. **12** is a block diagram of the electronics for the sensor of FIG. **2**, in an embodiment in which the sensor communicates with a remotely-located base unit using wireless transmission methods;

FIG. **13** is a block diagram of a base unit processing sensor data to obtain blood pressure data;

FIG. **14** is a flow chart showing a method by which the optical sensor acquires blood pressure data in accordance with the invention;

FIGS. **15**A and **15**B are a flow chart showing the calibration step of FIG. **14** in further detail;

FIG. **16** is a flow chart showing the procedure of obtaining images of FIG. **14** in further detail;

FIG. **17** is a flow chart showing a procedure for detector contour mapping and consistency validation of FIG. **16** in further detail;

FIG. **18** is another flow chart illustrating the procedure for detector contour mapping and consistency validation of FIG. **16** in further detail;

FIG. **19** is a flow chart of the filter image procedure of FIG. **16**;

FIG. **20** is a flow chart of the gating procedure of FIG. **16**;

FIG. **21** is a more detailed flow chart of the gating procedure of FIG. **20**;

FIG. **22** is a flow chart of the compensation procedure of FIG. **14**;

FIG. **23** is a more detailed flow chart of the compensation procedure of FIG. **22**;

FIG. **24** is a graph of blood pressure in mmHg as a function of time, showing the application of gating windows to measurements of systolic and diastolic pressure; and

FIG. **25** is a graph of measurements of blood pressure and a single photo-detector output during the systolic and diastolic measurement events, taken during a calibration step. A linear polynomial best fit algorithm is applied to the data points in order to obtain the calibration coefficients of equation (1) set forth below.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Overview

With reference to FIGS. **1–3**, the present invention provides a non-invasive blood pressure sensor apparatus **10** suitable for application to a patient's wrist area to acquire blood pressure data. The blood pressure data is acquired via optical techniques described at length herein. In a preferred embodiment, the sensor is capable of wireless bi-directional data communication with a base unit **20**, but it can alternatively be constructed as a stand-alone device with a user interface for displaying blood pressure data. In the wireless embodiment, the base unit **20** can be coupled to a computer **22** for display and analysis of blood pressure data or a wireline interface to transmit the data to a remote monitoring station **24**.

The sensor apparatus **10**, which is mounted to an adjustible, flexible band **11**, contains a novel optical sensor arrangement **12** for measuring tonometric blood pressure non-invasively. The sensor's concept of operation is using a light source **30** and light scattering from a reflective surface **14** that is layered against the skin surface **16** to measure blood pressure. The scattering patterns impinge upon a two dimensional array **17** of photo-sensitive elements **18**, such as an array of photo-detectors. The array **17** forms a two-dimensional image which is digitized and processed according to techniques described herein to obtain blood pressure data.

The sensor **12** is initially calibrated against known blood pressure measurements for the patient, and the calibration relationships between sensor output signals and known blood pressure measurements are used to linearly scale or map output values from the optical sensor to blood pressure data. See FIGS. **10** and **25**. Components for the sensor assembly are preferably selected such a linear calibration relationship exists between sensor output signals and blood pressure in mmHg, at least to a satisfactory level of approximation. This calibration relationship preferably takes the form of the equation:

$$Y^{s,d}(n,m)=a_{n,m}{}^{s,d}X(n,m)+b_{n,m}{}^{s,d} \tag{1}$$

where $Y^{s,d}$ is blood pressure for systolic and diastolic events, (n,m) are one or more individual photo-sensitive elements in an n by m array of such elements, X (n,m) is output signal value (for example, in millivolts for the photo-sensitive element), and $a_{n,m}{}^{s,d}$ and $b_{n,m}{}^{s,d}$ are calibration coefficients during systolic and diastolic events for each photo-sensitive element, determined during calibration of the sensor arrangement **10**. An example of the calibration data points for systolic and diastolic events for a single photo-sensitive element is shown in FIG. **25** and described subsequently.

The reflective surface **14** is made of a polymeric material coated with a reflective surface that exhibits good localized deformation properties and moisture and thermal insulation against body and environmental moisture and temperature variations so as not to affect its mechanical deformation properties. Suitable materials for the reflective surface are polyimide, polyester, or filled teflon membranes that are coated with a reflective surface. Force from arterial pulsation causes deflections of the skin surface which are measured optically through the reflective scattering of incident rays on the reflective surface **14**.

As shown in FIGS. **1–3**, the pressure sensor apparatus **10** is attached to the wrist on top of the radial artery. The band **11** includes an adjustment device **13**. The sensor includes a light source **30**, such as one or more miniature laser diode sources **30** A–F shown in FIG. **2**, which emits coherent light that impinges upon the reflective surface **14**. The source **30** is oriented relative to the reflective surface **14** such that the direction of propagation of the light is nominally normal to the reflective surface, i.e., when the reflective surface is in a planar attitude with no deflections. If the reflective surface is positioned perfectly perpendicular to direction of propagation, the light beams are reflected vertically and are not scattered into the photo-detectors, as indicated in FIG. **2**. The source of radiation could be remotely located and the beam originating from the source conveyed by a light pipe or waveguide **29** (FIG. **1**) to the vicinity of the reflective surface **14**.

During use, the reflector surface **14** is layered against the skin over the radial artery area in the wrist area with a certain hold down pressure (HDP). Due to the blood pulsations in the radial artery **34** and corresponding skin deflections due to such pulsations, the reflective surface will assume a deflected shape, as shown in FIG. **3**, adapting to the local anatomy due to the hold down pressure applied by the sensor's wrist strap **32**, as shown in FIG. **1**. Scattered reflected light is collected on a ceiling grid of photo-sensitive elements arranged in a two-dimensional array **17**, such as an array of 32×32 miniature photo-detectors **18**. The light is reflected with a certain pattern that is adapted to the local radial area anatomical surface. Variations in the local surface anatomy due to pulsation are immediately detected as variations in the scattering pattern of the reflected light beams. These variations are detected as fluctuations in the measured power received at the photo-detectors, which provide a direct correlation to the variations of actual blood pressure in the artery in accordance with the calibration relationship of equation (1).

Initial calibration blood pressure values for the sensor are obtained from a conventional air-cuff sphygmomanometer on the arm where the sensor is placed. The systolic and diastolic blood pressure readings can be either measured and entered manually at the base unit or measured electronically by known means and then transmitted digitally to the receiving base unit. A calibration relationship is obtained between the recorded air- cuff systolic and diastolic events and the digitized output signals from the photo-detectors, expressed as equation (1). The output signals from the photo-detectors can therefore be mapped or scaled linearly during subsequent use of the sensor so that photo-detector output represents blood pressure measurements in mmHg. Each photo-detector **18** output represents the average power of the amount of light received at that detector. The higher the density of light received the higher the output signal amplitude produced by the photo-detector. The more scattered or spread the reflected light is, the less dense the light beam and therefore the lower the amplitude of the receiving photo-detector output. Since laser light is incident on the reflective surface in a coherent beam, the reflected beam will have maximum density if the reflective surface is planar. If the reflective surface is deformed, then the incident beam will scatter according to the deformations in the surface. The deformations in the reflective surface will vary dynamically as the skin surface layered against the reflective surface moves due to pulsation of the artery **34** underneath.

In general, more spreading or fanning out of the beam is expected during systolic blood pressure phase than the diastolic phase. This is due to higher vertical deflection or deformation in the skin surface at the systolic event. The difference between the minimum and maximum (delta change) in average power received at each photo-detector at both the systolic and diastolic phases is recorded. The minimum and maximum values of each of these photo-detectors outputs are mapped (by linear scaling) into the corresponding diastolic or systolic blood pressure values (in mmHg) measured during calibration.

The overall collective output of the two dimensional array of photo-detectors can be visualized as a two-dimensional image of the activity on the skin surface underneath the sensor, as in the simulated image of FIG. **9**. The produced image will contain a pattern produced by the reflected light at the diastolic blood pressure phase that is different from the pattern obtained during the systolic blood pressure phase. This pattern will change dynamically with the pulsation movements of the skin surface. In the illustrated embodiment, the two-dimensional images are generated on a continuous basis, enabling continuous monitoring of the patient's blood pressure.

The sensor also includes a hold down pressure sensor **36** in the form of a strain gauge arranged as a membrane placed below the reflective surface **14**. The sensor **36** is used to measure the value of the hold down pressure in terms of resistive change due to strain on that surface. A strain gauge is a resistive elastic sensor whose resistance is a function of applied strain (force). A wire strain gauge is composed of a resistor bonded with an elastic carrier (backing). The backing is applied to the wrist where stress or force could be measured. Many metals can be used to fabricate strain gauges. Typical resistances vary from 100 to several thousand ohms. There are also semiconductive strain gauges, but they are usually quite sensitive to temperature variations. Therefore, interface circuits to these gauges must contain temperature compensation networks. In a preferred embodiment, a hold down pressure interface circuit that connects to the strain gauge could consist of a resistor bias network (such as a Wheatstone bridge circuit) that would translate a hold down pressure to an analog voltage level.

The array **17** of photo-detectors can provide a two dimensional image of skin surface topology, such as shown in FIG. **9**. Each single photo-detector sensor represents a single pixel in that image. A higher density grid or array of photo-detectors increases the sensitivity of measurements. A preferred embodiment is a 32×32 photo-detector grid density within a 1 cm^2 area. This would correspond to a reflective surface having an area of also approximtely 1 cm^2 area. The main idea is the reflective surface should be sized sufficiently that it covers sufficient surface area where skin deflections due to arterial pulsations can be detected with sufficient resolution.

As shown in FIGS. **5–7** and explained in further detail subsequently, each photo-detector **18** is positioned in the middle of a black background that blocks light from the emitting source **30**. This allows only reflected light to be measured by each photo-detector. Light from the emitting source travels in a direction perpendicular to the reflector surface, as well as cover the whole area of the reflector surface. The diameter of each photo-detector **18** is determined proportionally to selected grid density and desired sensor surface area. There are companies that manufacture custom photo-detector arrays. One such company, Cal Sensor, Inc., of 5460 Skylane Blvd., Santa Rosa Calif. offers custom high density sensor arrays that may be suitable for the instant application.

As shown in FIG. 4, the reflective surface **14** and HDP sensor **36** could be constructed and arranged in a curved form, such as a parabola, and the calibration and use of the device would proceed as just described.

The present invention also provides a method for obtaining blood pressure data using a blood pressure sensor placed against a patient's body. The sensor includes the two-dimensional array **17** of photo-sensitive elements **18** that obtain image data of the surface of the patient's body. Specifically, the array generates information as to the deflection of the patient's body due to arterial blood flow, such as images, by detecting radiation reflecting off a flexible reflective surface **14** placed against the patient's body. The scattering patterns are recorded electronically as two-dimensional images (or equivalently, as a two dimensional matrix of output values from the individual photo-sensitive elements). The images are in turn digitized and processed in accordance with the method of the invention to arrive at blood pressure readings, as indicated generally in FIG. **10**.

The method includes a first step of calibrating the optical sensor **12**. The step of calibrating comprises the steps of obtaining a first digitized two-dimensional matrix of output values (e.g., an image) of a portion of the patient's body using the optical sensor, such as the patient's wrist area in the vicinity of the radial artery. Preferably a series of images is obtained during calibration during systolic and diastolic events, and a first order (linear polynomial) best fit routine is applied to the resulting output signals from one or more photosensitive elements to find a first order calibration curve for each photo-detector, and thus the calibration coefficients $a_{n,m}^{s,d}$ and $b_{n,m}^{s,d}$ from equation (1). While the images are being obtained, blood pressure measurements are made of the patient, such as using a conventional air-cuff sphygmomanometer. The blood pressure measurement is compared to at least one portion of the first image, namely one or more photo-sensitive elements **18** in the n×m array **17** of elements, to thereby obtain a calibration relationship between the selected portion of the calibration images (i.e., the digitized output signal for photo-sensitive elements corresponding to the selected portion of the image) and the blood pressure measurement. The calibration relationship may take the form of equation (1) above.

With the sensor thus calibrated, it is now ready to be used to obtain blood pressure data from the patient. A second digitized two-dimension image (or, equivalently, set of output values from the array) is obtained during a period in which the blood pressure data is sought from the patient. FIG. **9** is a simulation of an image that would be generated with a high resolution embodiment of the array. The calibration relationship that was derived for the selected portion of the first calibration image(s) (set of photo-detectors) is then applied to a corresponding portion of the second image. Blood pressure data is then derived from the application of the calibration relationship to the corresponding portion of the second image. If the blood pressure is the same, the digitized output signal for the selected portion of the calibration images and the data acquisition images would be expected to be the same, and the sensor would therefore report blood pressure data as being the same. If the output signal is different for the second image, a linear scaling of the calibration relationship is performed using equation (1) and the blood pressure data is derived from the calibration relationship as applied to the output of the selected photo-detectors for the data acquisition image.

The selected portion of the calibration images, in the preferred embodiment, comprises a contour, i.e., a subset of the n×m photosensitive elements, having substantially the same image intensity values, and the calibration relationship is obtained for the contour. Alternatively, the selected portion of the calibration images could be a single location, i.e., a single photo-detector. The calibration relationship is obtained for the single photo-detector. The calibration relationship obtained for the single photo-detector is then applied to the same photo-detector's output in the data acquisition image. Alternatively, the selected portion of the calibration images could consist of a set of locations, i.e., a subset of photo-detectors, having substantially different image intensity values. The calibration relationship is obtained for this set of locations and applied to output signals from the set of photo-detectors from the second image, with the resulting blood pressure data averaged to arrive at a reported blood pressure.

The optical sensor **12** offers, by nature of its design components, a high sensitivity to variations in blood pressure detected as deformation of the skin surface during pulsation. Each photo-detector acts as a contributing sensor that is providing measurements from a different point of view on the same physical phenomena. The more photodetectors in the grid, or the denser the grid is, the higher the sensitivity of the sensor. A 32×32 array of photo-detectors covering a 1 square centimeter area is considered a representative embodiment, but higher denisities (and thus higher resolution) can be obtained with different array formats, or by using a charge-coupled device. The processing algorithm combines low level signals from all photodetectors to provide collectively a stronger sensitivity and higher resolution for low level measurements.

The mapping of photo-detector outputs into actual blood pressure measurements can be done per individual photo-detector sensor signal basis, or by mathematically combining the signals from multiple photo-detectors. A multi-dimensional signal provides a multi-point sensing mechanism which enables cross-checking and verification of the results from multiple "points-of-view" as seen by a group of photo-detectors. This ultimately provides improved consistency in the reported results, and reduces the probability of error. The availability of a dynamic image that reflects the skin surface topology due to pulsation enables image processing techniques to be used to detect minor sensor position displacements, and respectively adjusting photo-detector calibrations due to such displacements.

As explained above, the processing algorithm maps linearly the measured variations in output from the photo-detectors into blood pressure values. Initial calibration of the sensor with an air-cuff sphygmomanometer generating a known blood pressure measurment provides a linear scaling factor(s) for the peak-to-peak delta difference between systolic to diastolic output of the photo-detector(s). Preferrably, for each photodetector, multiple scaling factors are obtained to describe the linear mapping over many cycles of systolic and diastolic readings during calibration. The multiple scaling factors data is then fitted with a linear polynomial best line fit. When such calibration polynomial scaling factor(s) are applied to each individually corresponding photo-detector output, it will provide a high degree of precision for mapping photodetector readings into actual calibrated blood pressure values. Each photodetector can actually act as an independent blood pressure sensor device, however the combination of multiple detector outputs will provide for a more reliable blood pressure reading. Such multi-point sensor may be useful for validating results for consistency from multiple "points-of-view". The output from each detector can be compared with its nearest neighbor's output to ensure consistency of results, and results that are not reasonable are simply either neglected or averaged out in the process of calculation of mean output diastolic and systolic blood pressure values.

The availability of a multi-point grid of detectors also enables operations to be performed on their combined output, that can yield even more reliable and consistent estimates for actual blood pressure values. A spatial Finite Impulse Response (FIR) filter, for example, can be defined with appropriate coefficients to enhance detection and elimination of motion artifacts or noise. A contour map of grouped photo-detectors with similar output levels during a pulse dynamic event can be generated. Photo-detectors associated with a single contour are connected in a closed loop, and their output can be averaged. Such contours can be further tracked dynamically in time to trace pulsation movements. The output of a full contour of photodetectors, instead of a single detector output, could be used to produce the linear mapping into a blood pressure values.

Since the degree of skin deformation due to pulsation is measured during calibration, exact reproduction of such deformation is expected assuming that all environmental and physiological conditions remain the same. A change in physiological conditions may lower or higher the blood pressure or the pulse pressure (systolic-diastolic) values. This can be tracked as increase or decrease in end-systolic and end-diastolic pressure values. If a major change occurs in a single detector or a contour of detectors' output, that may indicate a displacement such as translation or rotation of the sensor **12** relative to the radial artery site, and thus requires application of sensor position correction. To correct for such displacement, the method optionally provides for computing the values for translation and/or rotation of each image frame to the corresponding image frame acquired during calibration. This can be performed using known image transformation and image processing algorithms. The result is an average estimate of the rotation and translation displacement. The transformation is applied to the calibration scaling factors, resulting in correction for translation or rotational errors.

The sensor **12** design enables changes in hold down pressure (HDP) to be compensated for and therefore more accurate blood pressure values to be obtained. For example, if a reduced end-systolic or end-diastolic pressure value was obtained, it could be due to either a physiological event or a change in the average HDP of the sensor applied to the patient. In the illustrated embodiment, the average sensor HDP on the patients is measured by means of the HDP sensor **36** of FIGS. **2** and **3**. Such measurement can be part of the calibration procedure. Minor variations from the calibraton HDP value can be compensated for by means of a linear scaling of the blood pressure calibration relationship to obtain a more accurate blood pressure reading.

FIG. **11** is a graph of hold down pressure expressed in terms of DC voltage from the hold down pressure sensor **36** as a function of time. The ramp up **60** indicates the tightening of the wrist strap for the sensor. The oscillation **62** about the average level is due to blood pressure events in the patient during calibration. Deviation from the average hold down pressure during data acquisition phase (as indicated by the dashed lines) will affect sensor output, but this difference ($\Delta HDP_{average}$) can be linearly scaled to the outputs of the photo-detectors to arrive at accurate blood pressure readings. The procedure is explained in further detail below. As shown in FIG. **11**, the measured HDP will have a DC component representing overall average HDP, and an AC component representing small variations in HDP due to effect in pulsation. The DC average value of the HDP is used to indicate changes in overall sensor placement force to the skin, thus indicating any motion artifacts or sensor loose attachment or complete detachment from the skin surface.

The optical sensor can provide very high resolution to even faint pulsation movement of the skin due to the nature of the multiplicity of the photo-detectors in the array, and due to the deflection of incident photons in proportion with the reflective surface deformation. No hysteresis effect is experienced by such sensor surface deformation. Also, the higher the density of the photo-detectors in the grid, the higher the sensitivity of the sensor to movement of skin under pulsation.

Sensor Design

Turning now again to the Figures, and in particular to FIGS. **2**, **3** and **5**–**7**, the array **17** of photo-detectors **17** of FIGS. **2** and **3** is shown in a plan view in FIG. **5**. The array **17** of FIG. **5** consists of a 32×32 array of detectors **18**, but a higher or lower density of detectors is of course possible. The two-dimensional array **17** of photo-detectors preferably comprises an array of at least **18** photo-detectors and is spatially arranged to cover at least one square centimeter in area. An array of 32×32 detectors is a more preferred embodiment with high numbers of detectors increasing cost but resulting in higher resolution and increased sensitivity.

The individual detectors **18** are centered in a black radiation-absorbing background substrate or material **40**. Individual columns of detectors are separated from one another by means of a grid or lattice **42**, which connects the substrate or material **40** together in both the column and row directions and thereby provide a means for supporting the photo-detectors below the light source **30** of FIGS. **2** and **3**. The radiation-absorbing material **40** blocks light from the source **30**, thereby only allowing radiation reflected from the reflective surface to impinge upon the photo-detectors. The light source for the photo-detectors is placed behind the lattice **42** and photo-detectors as indicated in FIGS. **2** and **3**, with the coherent laser light from the light source passing in between the columns of photo-detectors in the region of the lattice **42**, where it travels to reflect off the reflective surface **14**.

The assembly of the detectors **18**, light source **30**, reflective surface **14** and hold down pressure sensor **36** are incorporated into a housing **44** adapted to be placed adjacent to the wrist of the patient. A strap **11** (FIG. **1**) provides a hold down force to the sensor assembly. The strain gauge **36** measures the hold down force. The strain gauge **36** is preferably configured as a flexible two-dimensional sheet having a lower surface **48** placed adjacent to the surface of the patient and an upper surface **50** adhered to the lower surface of the reflective surface **14**.

FIG. **6** a plan view of the sensor of FIG. **2** taken along the lines **6**–**6**, in which the detector array **17** comprises a 6×6 array of photo-detectors **18**. The light source **30** comprises a 3×3 array of laser diodes **30**A, **30**B, **30**C, . . . **30**I. Radiation from the light sources **30**A–**30**I passes through the lattice **42** around the periphery of the black radiation absorbing material **40** down onto the reflective surface **14** of FIG. **2** and **3**. The light sources are embedded in a suitable substrate **52**. As indicated in FIG. **7**, the light source could consist of a single large laser diode **30**. Alternatively, the light could be remotely located and directed past the lattice **42** by means of a waveguide and suitable lenses or other optical system to broaden the beam to the desired width. FIG. **8** is a plan view of the laser diode light sources **30**A–I of FIG. **6**. Preferably the substrate or mounting material **52** is sufficiently rigid such that the laser diodes remain in a plane such that the light from all the sources **30** travels in a direction that is nominally normal to the reflecting surface. The laser diodes are formed in an array configuration as shown in FIG. **8** and placed in optical alignment with the two dimensional array of photo-detectors, as shown in FIGS. **2**, **3** and **6**.

The scattering patterns acquired by the array **17** could be processed either in the sensor assembly itself and reported by a user interface incorporated in the sensor, or they could be sent to a remote processing unit such as the base unit of FIG. **1** and there processed into useful blood pressure data. FIG. **12** is a block diagram of the electronics for the sensor assembly **12** in an embodiment in which the processing of the data from the sensor is performed either locally or remotely in the base unit. The sensor assembly **12** includes a miniaturized electronics module **100** consisting of a HDP sensor interface **102**, and a multiplexer **104** receiving the output signals from the photo-detector array **17**. The n×m photo-detector analog signals and the HDP sensor signals are multiplexed in multiplexer **104**, filtered by an anti-aliasing low pass filter **106**, amplified by amp **108**, and sampled and converted into digital signals in an analog to digital converter **110**.

The digital signals are supplied to a computing platform in the form of a microcontroller and digital signal processor unit **112**. The microcontroller performs signal processing of the digital signal supplied by the A/D converter. The signal processing functions include noise filtering and gain control of the digital signal. The microcontroller executes operating system and image processing and calibration routines which are stored in machine-readable form in a memory **114**. The memory **114** also stores acquired image data and hold down pressure data from both the calibration phase and the data acquisition phase, and also is used in the HDP and sensor translation and rotation compensation procedures. The microcontroller also issues commands to a photo-emitter control module **116**, which controls the illumination of the light source **30** (FIG. **2**). The microcontroller presents blood pressure and other physiologic data to the user via a user interface **120**, such as a LCD display. Alternatively, the acquired blood pressure data could be transmitted to the base unit using a wireless transceiver module **122** and a low power, miniature RF antenna **124**.

The wireless transceiver module **122** may include a buffer, encoder, modulator/demodulator, transmitter, power amp, receiver, filters and an antenna switch, all of which are conventional in the art of wireless communication and omitted for the sake of brevity. A frequency generator is also included in the module **122** which generates a carrier frequency for the RF transmission. The frequency is adjustable by the microcontroller. The microcontroller/DSP controls the frequency generator so as to select a frequency for wireless transmission of data and control messages to the base unit.

A battery **126** with a negative terminal connected to a local ground reference provides DC power to the components.

An embodiment in which the sensor assembly works in conjunction with a wireless base unit can allow the sensor assembly to be remotely managed and configured by the base unit. The wireless arrangement makes possible communications protocols, including command and message procedures, to be employed between the base unit and the wireless sensor. These commands can include start data acquisition commands, data transmission commands, error recovery and retransmission commands, and many others. The patent application of Mohammad Khair, et al., Ser. No. 09/551,719, filed Apr. 18, 2000, which is incorporated by reference herein, sets forth a wireless communication protocol that is particularly well suited for a wireless implementation of the invention.

Base Unit

The wireless embodiment of the invention includes the base unit **20** of FIG. **1**, which is shown in block-diagram form in FIG. **13**. The base unit **20** includes a wireless antenna **200** and transceiver module **202** for two way RF communication with the sensor apparatus **10**. The transceiver module includes a buffer, encoder, modulator/demodulator, transmitter, power amp, receiver, filters and an antenna switch, all of which are conventional in the art of wireless communication and omitted for the sake of brevity. The base unit also includes a microcontroller and DSP computing platform **204** that performs error correction and error diagnosis of the incoming digital communications from the sensor. The microcontroller executes operating system, configuration, transmission management, calibration and data processing routines stored in the memory **206**. The microcontroller outputs useful blood pressure and other physiologic data to the user via a user interface **208**, or sends it out a wireline interface **210** (such as an RS 232 port) for transmission to a remote location. The base unit also includes an input/output interface **212** for allowing access to the base unit for programming and software downloads by a test or diagnostic machine or an attached computer.

Together, the blood pressure sensor of FIG. **1** and the base unit comprise a noninvasive wireless blood pressure data acquisition system. The sensor has a wireless transceiver for transmitting blood pressure data to the base unit, and receives data acquisition or configuration commands from the base unit. In a preferred embodiment the image processing for calibration and blood pressure data from sensor output signals is performed in the base unit to minimize the cost, size and complexity of the design of the sensor electronics.

Calibration

The calibration of the optical sensor **10** proceds as follows. First, the blood pressure sensor **12** is placed against the patient's body at a location where blood pressure data is to be obtained. Measurements of the patient's blood pressure are made with a second blood pressure device, such as an air cuff. The hold down force of the optical blood pressure sensor against the patient's body is made by the strain gauge **36**. Output signals (i.e., images) are obtained from the array of photo-detectors during systolic and diastolic events, and preferably a multitude of images are obtained as the blood pressure is gradually released. The output signals are calibrated against the measured blood pressure and hold down force data as described herein, to thereby obtain a set of calibration relationships as described in equation (1) for one or more of the photo-detectors. The calibration relationships are stored in a memory, such as in the memory of the sensor or in the memory of the base unit in a wireless embodiment.

Equation (1) is used to linearly map the measured variations in output from the photo-detectors into blood pressure values. Initial calibration with an air-cuff sphygmomanometer provides the linear scaling correlation relationships, namely correlation coefficients $a_{n,m}^{s,d}$ and $b_{n,m}^{s,d}$. For one or more photodetectors, multiple data points are obtained over many cycles of systolic and diastolic readings during calibration. The multiple data points **302** and **304**, such as shown in FIG. **25**, is then fitted with a first order least-squares polynomial best line fit, represented by the lines **300**. Other known methods for best-line fit techniques such as singular value decomposition or weighted least squares fit may be applied. Assume the systolic cuff reading was represented by $Y^s(t)$ and systolic photo-detector readings for a photo-detector were represented by $X^s(t)$ where t is measurement number taken at a discrete instance in time t=0,1, 2,3, . . . , N. N is the maximum number of measurements taken during calibration. Similarly we represent the diastolic cuff reading by $Y^d(t)$ and the diastolic photo-detector reading to be $X^d(t)$. Then $Y^s(t)=a_sX^s(t)+b_s$ and $Y^d(t)=a_dX^d(t)+b_d$ where a_s and a_d are respectively the systolic and diastolic scaling multiplication coefficients of a first order least squares polynomial line fit through the multiple calibration measurements, and the b_s and b_d are respectively the systolic and diastolic offset coefficients of the straight line fit equations. The process is repeated for all the n×m detectors, or, alternatively, from some smaller subset of the detectors. The graph of FIG. **25** shows an example for mapping between systolic and diastolic readings between the cuff and a photo-detector output. The scaling and offset coefficients are applied through the above equation (1) whenever a conversion from a specific photodetector electrical output in mV into a mmHg is needed.

Method of Operation

The method of operation of the sensor is illustrated in flow chart form in FIG. **14**. The method involves the initial calibration of the sensor, step **400**, which is described above. Then the sensor is placed on the patient and two-dimensional images in the form of scattering patterns are obtained and digitized, as indicated by step **402**. This process preferably is a continuous process. The method continues with an optional step **404** of compensating for changes in hold down pressure or rotation or translation of the sensor relative to the patient's body between calibration and data acquisition. Step **404** may or may not be required depending on the readings from the HDP sensor or drift in sensor output values that indicate that translation or rotation has occurred. At step **406**, the calibration relationships from equation (1) is applied to the sensor output to derive blood pressure. At step **408**, additional physiologic data such as arterial compliance, pulse rate, etc. is obtained from the sensor. Step **408** is also optional.

FIGS. **15**A and **15**B is a flow-chart illustrating the calibration step **400**. At step **410**, the patient properly positions the sensor on their wrist and starts the calibration process. At step **412**, a measurement of the hold down pressure is made with the strain gauge. At **414**, a check is made to determine whether the hold down pressure level is adequate. At step **416**, the nurse or technician places an air cuff over the patient's arm and inflates the air cuff to **200** mmHg. At step **418**, the technician gradually decreases the pressure in the cuff and measures systolic and diastolic values. The values are entered into the base unit via the user interface, or alternatively electronically using wireless transmission. At step **420**, the blood pressure sensor measures skin movements in the form of scattering patterns due to blood pulsations simultaneously with the measurements of blood pressure, i.e., generates a series of images with the photo-detector array. The images are digitized and stored in memory in the sensor or transmitted to the base unit. At step **422**, systolic and diastolic events are marked in the acquired sensor signal and in the air-cuff signal. At step **424**, the computing platform in the base unit performs an average and standard deviation of the blood pressure measurements and output signals over multiple cycles. At step **426**, the processing routine in the base unit looks to see if the results are consistent, and if not the process goes back to step **416** and repeats.

If the results are consistent, the orientation of the sensor is obtained by processing the output signals from the detectors during calibration to identify the pulse location. The position is marked, such as by storing a coordinate of the n×m array. Then, a gating window (i.e., temporal duration) for systolic and diastolic events is marked. The gating window is illustrated in FIG. **24**. The gating window is a procedure to obtain systolic and diastolic data during a window of time when the events are expected to occur based on the patient's current heart rate.

FIG. **16** is a flow-chart illustrating a preferred embodiment of the procedure **402** of obtaining images from FIG. **14** in further detail. In a preferred embodiment the array of photo-detectors generates images at a readout rate of say 10 or 100 per second at step **432**. The images are digitized in the sensors. Then, contour mapping is performed at step **434**. Basically, the image processing routine in the sensor (or base unit) looks for individual sensor outputs that are substantially the same for any given image, and the set of sensors forms a contour. Several different contours can be thus derived. A consistency validation can then be performed both among and between contour sets to insure that the blood pressure readings are accurate. At step **436**, the image is filtered using one or more of a variety of filters, such as Kalman predictor-corrector filter for improved tracking of blood pressure measured estimates with actual pressure, and later optionally applying temporal and/or spatial low pass finite impulse response filters, to produce filtered, smoothed images. Then gating windows are applied at step **438** to the set of collected images to process those images obtained during the gating window.

The detector contour mapping and consistency validation in step **438** is shown in further detail in FIG. **17**. In a first step **440**, detectors with similar outputs are mapped or associated into groups of contours, which define similar "points of view" on pulsation movements on the surface of the skin. At step **442**, detectors with the same output level are combined into contours to increase the signal strength. At step **444**, a cross-checking between contours and validation of multiple photo-detector output is performed for a consistency check or validation.

Another embodiment of the procedure **438** is shown in FIG. **18**. In a first step **446**, a cross-correlation between detector outputs for signal strength level and skin movement pattern is performed. At step **448**, detectors that have similar outputs are grouped into a contour. At step **450**, contour analysis is performed to ensure consistency of output from grouped detectors. At step **452**, a check is performed of the consistency of the outputs across multiple detectors. If consistency is not obtained, the user is instructed to realign the sensor or adjust the hold down pressure, as indicated at **454**. If consistency is obtained, the process proceeds to the filter process **436** of FIG. **16**.

A preferred embodiment of the filter process **436** includes the steps shown in FIG. **19**. At step **456**, contours are tracked with a Kalman filter for enhanced prediction and correction of estimated blood pressure values. At step **458**, a temporal FIR filter is applied to the images to eliminate motion artifacts. At step **460**, a spatial FIR filter is applied for elimination of measurement noise. Coefficients for the FIR and Kalman filters can be obtained using known methods.

Reduction of motion artifacts and noise in sensor output can be obtained in two ways: First, by means of application of a filter such as a one dimensional temporal low pass filter applied on the time varying output of each individual detector, or a two-dimensional spatial FIR filter kernel that is applied on a group of detectors output, or a combined spatial and temporal filter applied on multiple detectors output. A two dimensional spatial FIR filter can be applied by defining a filter kernel that is convolved with the image matrix, to produce a new filtered image matrix as a result of the convolution. The direct convolution can be expressed as:

$$Y(n,m)=\Sigma_{k1}\Sigma_{k2}h(k_1,k_2)X(n-k_1,m-k_2)$$

where h defines the filter kernel that has support over the region $\{(n,m): 0<=n<N_1, 0<=m<N_2\}$ and $k_1=0$ to N_1-1, $k_2=0$ to N_2-1.

The gating window procedure **438** of FIG. **16** is shown in FIG. **20**. Basically, gating window parameters, such as frequency and duration of the systolic and diastolic events, are measured at step **462**. At step **464**, the gating window is applied to the stream of images generated by the array to select images generated during the gating window and thereby reduce motion artifacts that may be occurring outside of the window.

FIG. **21** is a flow chart of an alternative embodiment of the gating window procedure **438**. After the measuring gating window parameters (step **462**, same as FIG. **20**), the gating window parameters are verified for consistency with calibration gating windows, or else with the last few measured gating window parameters, at step **466**. If the results are consistent, the process proceeds to the application step **464**. If not, the method can either use the last validated gating information at step **468**. If there have been multiple retries of the gating window verification and it still has not been verified, the sensor is re-calibrated at step **470**. If there have been no previous attempts of window verification, the gating window information is discarded and the process goes back to step **462** as indicated at step **472**.

FIG. **22** is a illustration of one form of the compensation step **404** of FIG. **14**. First, at step **500** the hold down pressure is obtained while the data is acquired from the sensor. At step **502**, changes in the hold down pressure are corrected for by linear scaling of the output of the detectors. At step **506**, translation and/or rotational displacement are compensated or by re-mapping calibration coefficients.

This can be tracked as increase or decrease in end-systolic and end-diastolic pressure values. If a major change occurs in a single detector or a contour of detectors' output, that may indicate a displacement of the sensor, and thus requires application of sensor position correction. To correct for such displacement, we can compute the values for translation and/or rotation of each image frame to the corresponding image frame acquired during calibration. The result is an average estimate of the rotation and translation displacement. The transformation is applied to the calibration scaling factors, resulting in correction for error in previously mis-calibrated blood pressure values under displacement. The affine transformation between coordinates x,y in one image and u,v in a transformed image can be described as

$$[x, y, 1] = [u, v, 1]\begin{bmatrix} a_{11} & a_{12} & 0 \\ a_{21} & a_{22} & 0 \\ a_{31} & a_{32} & 1 \end{bmatrix},\ \text{so } x = a_{11}u + a_{21}v + a_{31} \text{ and } y = a_{12}u + a_{22}v + a_{32}.$$

$$\text{where } a_{11} = \cos\theta,\ a_{12} = \sin\theta,\ a_{21} = -\sin\theta,\ a_{22} = \cos\theta,\ a_{31} = T_u,\ a_{32} = T_v.$$

The parameters express both a translation transformation with T_u, T_v, and a rotation transformation of angle θ expressed as

$$[x, y, 1] = [u, v, 1]\begin{bmatrix} 1 & 0 & 0 \\ 0 & 1 & 0 \\ T_u & T_v & 1 \end{bmatrix} \quad [x, y, 1] = [u, v, 1]\begin{bmatrix} \cos\theta & \sin\theta & 0 \\ -\sin\theta & \cos\theta & 0 \\ 0 & 0 & 1 \end{bmatrix}$$

The separation between measured skin deformation, the variable that is mapped into blood pressure values, and the average hold down pressure as an independent variable, enables us to measure and use the average HDP in calculating more accurate blood pressure values. For example, obtaining a reduced end-systolic or end-diastolic pressure values could be due to either a physiological event or a change in the average HDP of the sensor on top of the skin. We can measure the average sensor HDP on the skin by means of the strain gauge located below the reflective surface. Such measurement can be part of the calibration values, and minor variation from calibrated values can be compensated for to obtain more accurate reporting of the estimated blood pressure. The relationship between the average HDP and the photodetector output is again expressed as a linear equation. Such linear equation can be obtained via known method of least squares polynomial line fit of the first order between multiple measured average hold down pressure values vs. corresponding photodetector output values for a specified deformation of the reflective surface. Such relationship can be expressed as $Z(t)=c\,HDP(t)+d$, where $Z(t)$ represents the output of the photodetector in mV at time t due to HDP(t), with the HDP value taken at measurement time t. The coefficients c and d represent the scaling and offset factors respectively. For the calibration mapping into mmHg, Y(t) are affected by measured variation in HDP as follows:

$$Y^s(t)=a_s(X^s(t)+\Delta Z(t))+b_s,$$

where

$$\Delta Z(t)=c(HDP(t)_{current}-HDP_{calibration}).$$

A modification of the compensation procedure **404** of FIG. **22** is shown in FIG. **23**. After hold down pressure is measured, the process looks to see if there are large changes from the calibration values at step **508**. If large changes are present, it indicates that the hold down pressure is sufficiently changed that an accurate scaling of output signals to blood pressure data cannot be performed and the user is instructed to re-calibrate the sensor. Assuming the changes are below a threshold level, the HDP compensation is performed at steps **502**. At step **512**, the current orientation of the sensor to the location or coordinate of the pulse location during calibration is measured. This can be done using known correlation or image processing methods. From the measurements, the sensor translation and rotation is then determined. If there are large changes from the calibrated orientation, the calibration is repeated as indicated at **516**. Otherwise, the translation or rotation of the sensor relative to the patient is compensated by re-mapping the calibration coefficients.

A windowed-time average can also be applied over multiple pulses to compute average systolic and diastolic blood pressure values. In other words, the average over the last three readings of systolic and diastolic BP values is reported instead of the instantaneous value. That will produce to more consistent results and reduces discontinuities and abnormal variation in reported trends of blood pressure.

Providing good tracking between our measured estimate of blood pressure and the actual blood pressure can be achieved by once more applying a Kalman filter predictor-corrector type. The predicted values from the Kalman filter can be used to correct for potential errors in measurements. This will help prevent accumulation of residual errors (differences between actual and estimated BP values) in reported blood pressure values. Close tracking is particularly important in continuous monitoring of blood pressure values as such monitoring is performed over extended periods of time.

Use of Sensor to Obtain Additional Physiologic Data

In addition to reporting blood pressure and pulse pressure, arterial compliance can be further evaluated by means of computing the rate of change in skin displacement due to pulsation. Measured detector signals represent displacement of skin in time, or skin movement velocity. The first derivative will yield a skin movement acceleration value, that basically represents the speed of response of artery to input pressure during pulsation. This is directly correlated to the degree of elasticity in the artery being represented.

Because of the fact that the sensor detection field spans a full plane of skin area and because we have a grid of photo-detectors and not just a single sensor, we can construct a dynamic image of flow of pulse pressure wave in the artery. From such a pulse wave, we can extract information such as blood flow rate which can be measured as the pulse moves across the field of view of the sensor crossing a known distance in a specific interval of time. Such known distance can be deduced by the known separation between photo-detector centers in a photo-detector grid of known photo-detector density and size. The pulse could travel in any direction in the field of view, and the speed of which can be measured independent of its direction. Blood flow rate is then represented as the speed at which systolic and diastolic events are marked at different distant points in the sensor.

Furthermore, the pulse rate can be measured as the rate at which systolic and diastolic events occur per selected interval of time.

Presently preferred embodiments have been described with particularity. Persons skilled in the art will appreciate that modifications and alternative configurations to the optical, electrical and mechanical design of the illustrated embodiments can be made. The true scope of the invention is to be determined by reference to the claims.

We claim:

1. A sensor assembly for acquiring blood pressure data from a patient, comprising:

a housing adapted to be placed adjacent to said patient with a hold down force in a location where said blood pressure data is to be acquired during use of said sensor assembly;

a source of photo-radiation,

a two-dimensional, flexible reflective surface, said reflective surface positioned relative to said radiation source such that said radiation travels in a direction normal to said reflective surface, and wherein said blood pressure data is to be acquired during use of said sensor assembly;

a two-dimensional array of photo-sensitive elements adjacent the source of photo-radiation and the two-dimensional, flexible reflective surface, said array collecting radiation emitted from said source and reflected off said reflective surface, said two-dimensional array comprising an N×M array of the photo-sensitive elements where both N and M are greater than 1 for at least a portion of the two-dimensional array; and

a hold down pressure sensor adapted for measuring said hold down force;

wherein movement of said flexible reflective surface due to blood pulsations in said patient causes scattering patterns of said radiation from said reflective surface to be detected by said two dimensional array of photo-sensitive elements, said scattering patterns acquired by said array of photo-detectors processed either in said sensor assembly or in a remote processing unit into useful blood pressure data for said patient.

2. The sensor assembly of claim **1**, wherein said source of photo-radiation comprises a source of coherent radiation.

3. The sensor assembly of claim **2**, wherein said source of coherent radiation comprises at least one laser diode.

4. The sensor assembly of claim **2**, wherein said source of coherent radiation comprises an array of laser diodes, said array of laser diodes placed in alignment with said two dimensional array of photo-sensitive elements.

5. The sensor assembly of claim **1**, wherein said reflective surface comprises a polymeric material coated with a reflective surface.

6. The sensor assembly of claim **1**, wherein said photo-sensitive elements comprise photo-detectors, each of said photo-detectors positioned within a radiation-absorbing material blocking light from said radiation source, thereby only allowing radiation reflected from said reflective surface to impinge upon said photo-detector.

7. The sensor assembly of claim **6**, wherein said two dimensional array of photo-detectors comprise an array of at least 18 photo-detectors.

8. The sensor assembly of claim **6**, wherein said two dimensional array of photo-detectors is spatially arranged to cover at least one square centimeter in area.

9. The sensor assembly of claim **1**, wherein said source of radiation comprises a single laser light source and an optical system spreading radiation from said light source into a sufficient spatial area so as to direct light past said two-dimensional array of photo-detectors onto said reflective surface.

10. The sensor assembly of claim **1**, wherein said sensor further comprises a wireless transceiver transmitting blood pressure data from said patient to a base unit.

11. The sensor assembly of claim **10**, wherein said sensor assembly further comprises a computing platform and a memory storing a set of instructions, said computing platform responsive to commands from said base unit.

12. The sensor assembly of claim **11**, wherein said commands comprise a start data acquisition command and a stop data acquisition command.

13. The sensor assembly of claim **1**, wherein said sensor further comprises a computing platform processing said scattering patterns and a user interface displaying blood pressure data.

14. The sensor assembly of claim **1**, wherein said sensor is assembled in a housing having an adjustable band for encircling the wrist of said patient.

15. The sensor assembly of claim **1**, wherein said housing comprises a source of coherent photo-radiation, and a light pipe transmitting said coherent photo-radiation to the vicinity of said flexible reflective surface.

16. A sensor assembly for acquiring blood pressure data from a patient, comprising:

a housing adapted to be placed adjacent to the wrist of said patient with a hold down force in a location where said blood pressure data is to be acquired during use of said sensor assembly;

a sensor for measuring said hold down force, said sensor configured as a flexible two-dimensional sheet having a lower surface for being placed adjacent to the surface of said patient at said location and an upper surface;

a source of photo-radiation;

a two-dimensional, flexible reflective surface coupled to said upper surface of said flexible sheet, said reflective surface positioned relative to said radiation source such that said radiation travels in a direction normal to said reflective surface, and wherein said blood pressure data is to be acquired during use of said sensor assembly;

a two-dimensional array of photo-detectors placed in the optical path between said source of photo-radiation and said two-dimensional flexible reflective surface, said array of photo-detectors collecting radiation emitted from said source and reflected off said reflective surface;

wherein movement of said flexible reflective surface due to blood pulsations in said patient at said location causes scattering patterns of said radiation from said reflective surface to be detected by said two dimensional array of photo-detectors, said scattering patterns acquired by said array of photo-detectors processed either in said sensor assembly or in a remote processing unit into useful blood pressure for said patient.

17. The sensor assembly of claim **16**, wherein said source of photo-radiation comprises a source of coherent light.

18. The sensor assembly of claim **17**, wherein said source of coherent light comprises at least one laser diode.

19. The sensor assembly of claim **17**, wherein said source of coherent light comprises an array of laser diodes, said array of laser diodes placed in optical alignment with said two dimensional array of photo-detectors.

20. A optical, noninvasive wireless blood pressure data acquisition system, comprising:

a blood pressure sensor adapted for optical detection of skin deflection of a patient due to blood flow, said blood pressure sensor further comprising a wireless transceiver for transmitting blood pressure data and receiving data acquisition or configuration commands; and

a base unit comprising a computing platform, memory and wireless transceiver for receiving said blood pressure data from said sensor and transmitting said data acquisition or configuration commands to said sensor.

21. The system of claim **20**, wherein said sensor comprises a two-dimensional array of photo-sensitive elements.

22. The system of claim **20**, wherein said sensor comprises a two-dimensional, flexible reflective surface.

23. A method of obtaining blood pressure data from a patient using an optical blood pressure sensor, said optical blood pressure sensor comprising a two-dimensional array of photo-detectors detecting scattering patterns from a reflective surface placed against the surface of said patient, comprising the steps of:

placing said optical blood pressure sensor against the patient's body at a location where blood pressure data is to be obtained;

simultaneously measuring the patient's blood pressure with a second blood pressure device;

measuring the hold down force of said blood pressure sensor against the patient's body;

generating output signals from said array of photo-detectors;

calibrating said output signals of said photo-detectors against said measured blood pressure and hold down force and storing calibration data in a memory;

subsequently obtaining output signals from said array of photo-detectors during a blood pressure data acquisition period;

obtaining hold down force data during said obtaining of output signals; and

scaling said output signals to said calibration data and to said hold down force data to thereby obtain blood pressure data.

24. The method of claim **23**, further comprising the step of transmitting digital data representing said output signals from said sensor to a base unit.

25. The method of claim **24**, wherein said step of transmitting is performed using wireless transmission techniques.

26. The method of claim **24**, wherein said base unit performs said step of scaling.

27. A method of calibrating a noninvasive optical blood pressure sensor, said optical blood pressure sensor comprising a two-dimensional array of photo-detectors detecting scattering patterns from a reflective surface placed against the surface of said patient, comprising the steps of:

placing said optical blood pressure sensor against the patient's body at a location where blood pressure data is to be obtained;

simultaneously measuring the patient's blood pressure with a second blood pressure device;

measuring the hold down force of said blood pressure sensor against the patient's body; and

generating output signals from said array of photo-detectors;

calibrating said output signals of said photo-detectors against said measured blood pressure and hold down force and storing calibration data in a memory.

28. The method of claim **27**, wherein said measurements of blood pressure are supplied to a base unit having a wireless transceiver for communicating with said blood pressure sensor, and wherein said blood pressure sensor further comprises a wireless transceiver for communicating with said base unit.

29. The method of claim **28**, wherein said step of calibrating is performed by said base unit.

30. The method of claim **28**, wherein said step of calibrating is performed by said blood pressure sensor from a calibration program stored in a memory in said blood pressure sensor.

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摘要(译)

血压传感器包括光辐射源，例如激光二极管阵列。传感器还包括二维柔性反射表面。反射表面名义上相对于辐射源定位，使得辐射在垂直于反射表面的方向上行进。将反射表面放置在患者上将要获取血压数据的位置附近。来自光源的辐射从反射表面反射到二维光电探测器阵列上。患者的收缩压和舒张压波动被转化为患者皮肤的偏转。这些偏转导致二维反射表面中的相应偏转。由于血液脉动引起的所述柔性反射表面的相关运动导致来自所述反射表面的散射图案被二维光电探测器阵列检测到。在校准过程期间，将光电检测器阵列的输出校准为mmHg的血压，以获得一个或多个单独检测器的一组校准关系。然后在获取血压数据期间使用校准关系以得到血压数据。