signal n'(t) is:

$$\omega_{s3}(t) = \frac{\epsilon_{5,\lambda a}C_5X_{5,6}(t) + \epsilon_{6,\lambda a}C_6X_{5,6}(t)}{\epsilon_{5,\lambda b}C_5X_{5,6}(t) + \epsilon_{6,\lambda b}C_6X_{5,6}(t)} \tag{31}$$

$$= Y_{\lambda a}(t)/Y_{\lambda b}(t) \tag{32}$$

$$= \frac{\epsilon_{5,\lambda a}C_5 + \epsilon_{6,\lambda a}C_6}{\epsilon_{5,\lambda b}C_5 + \epsilon_{6,\lambda b}C_6} \tag{33}$$

$$= \frac{\epsilon_{5,\lambda a}(\frac{C_5(t)}{C_6(t)}) + \epsilon_{6,\lambda a}}{\epsilon_{5,\lambda b}(\frac{C_5(t)}{C_6(t)}) + \epsilon_{6,\lambda b}} \tag{34}$$

$$\approx Y'_{\lambda a}(t)/Y'_{\lambda b}(t) = \text{constant; where} \tag{35}$$

$$n_{\lambda a}(t) \approx \omega_{s3}(t)n_{\lambda b}(t). \tag{36}$$

It is often the case that both equations (35) and (36) can be simultaneously satisfied to determine the proportionality constant $\omega_{s3}(t)$. Additionally, the absorption coefficients at each wavelength $\epsilon_{5,\lambda a}$, $\epsilon_{6,\lambda a}$, $\epsilon_{5,\lambda b}$, and $\epsilon_{6,\lambda b}$ are constant and the central assumption of the constant saturation method is that $c_5(t)/c_6(t)$ is constant over many sample periods. Thus, a new proportionality constant $\omega_{s3}(t)$ may be determined every few samples from new approximations to the desired signal as output from the adaptive noise canceler. Thus, the approximations to the desired signals $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$, found by the adaptive noise canceler for a substantially immediately preceding set of samples of the measured signals $S_{\lambda a}(t)$ and

$S_{\lambda b}(t)$ are used in a processor of the present invention for calculating the proportionality constant, $\omega_{s3}(t)$, for the next set of samples of the measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$.

Multiplying equation (20) by $\omega_{s3}(t)$ and subtracting the resulting equation from equation (18) yields a non-zero noise reference signal:

$$n'(t) = S_{\lambda a}(t) - \omega_{s3}(t)S_{\lambda b}(t) = n_{\lambda a}(t) - \omega_{s3}(t)n_{\lambda b}(t). \quad (37)$$

It will be understood that equation (21) could be multiplied by $\omega_{s3}(t)$ and the resulting equation could be subtracted from equation (19) to yield the same noise reference signal n'(t) as given in equation (37).

When using the constant saturation method, it is necessary for the patient to remain motionless for a short period of time such that an accurate initial saturation value can be determined by known methods other than adaptive noise canceling on which all other calculations will be based. With no erratic, motion-induced undesired signal portions, a physiological monitor can very quickly produce an initial value of the saturation of A_5 in the volume containing A_5 and A_6. An example of a saturation calculation is given in the article "SPECTROPHOTOMETRIC DETERMINATION OF OXYGEN SATURATION OF BLOOD INDEPENDENT OF THE PRESENT OF INDOCYANINE GREEN" by G.A. Mook, et al., wherein determination of oxygen saturation in arterial blood is discussed. Another article discussing the calculation of oxygen saturation is "PULSE OXIMETRY: PHYSICAL PRINCIPLES, TECHNICAL REALIZATION AND PRESENT

LIMITATIONS" by Michael R. Neuman. Then, with values for $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$ determined, an adaptive noise canceler may be utilized with a noise reference signal n'(t) determined by the constant saturation method.

PREFERRED ADAPTIVE NOISE CANCELER USING A JOINT PROCESS ESTIMATOR IMPLEMENTATION

Once the noise reference signal n'(t) is determined by the processor of the present invention using either the above described ratiometric or constant saturation methods, the adaptive noise canceler can be implemented in either hardware or software.

The least mean squares (LMS) implementation of the internal processor 32 described above in conjunction with the adaptive noise canceler of Figure 5 is relatively easy to implement, but lacks the speed of adaptation desirable for most physiological monitoring applications of the present invention. Thus, a faster approach for adaptive noise canceling, called a least-squares lattice joint process estimator model, is preferably used. A joint process estimator 60 is shown diagrammatically in Figure 7 and is described in detail in Chapter 9 of Adaptive Filter Theory by Simon Haykin, published by Prentice-Hall, copyright 1986. This entire book, including Chapter 9, is hereby incorporated herein by reference. The function of the joint process estimator is to remove the undesired signal portions $n_{\lambda a}(t)$ or $n_{\lambda b}(t)$ from the measured signals

$S_{\lambda a}(t)$ or $S_{\lambda b}(t)$, yielding a signal $Y'_{\lambda a}(t)$ or $Y'_{\lambda b}(t)$ which is a good approximation to the desired signal $Y_{\lambda a}(t)$ or $Y_{\lambda b}(t)$. Thus, the joint process estimator estimates the value of the desired signal $Y_{\lambda a}(t)$ or $Y_{\lambda b}(t)$. The inputs to the joint process estimator 60 are the noise reference signal n'(t) and the composite measured signal $S_{\lambda a}(t)$ or $S_{\lambda b}(t)$. The output is a good approximation to the signal $S_{\lambda a}(t)$ or $S_{\lambda b}(t)$ with the noise removed, i.e. a good approximation to $Y_{\lambda a}(t)$ or $Y_{\lambda b}(t)$.

The joint process estimator 60 utilizes, in conjunction, a least square lattice predictor 70 and a regression filter 80. The noise reference signal n'(t) is input to the least square lattice predictor 70 while the measured signal $S_{\lambda a}(t)$ or $S_{\lambda b}(t)$ is input to the regression filter 80. For simplicity in the following description, $S_{\lambda a}(t)$ will be the measured signal from which the desired portion $Y_{\lambda a}(t)$ will be estimated by the joint process estimator 60. However, it will be noted that $S_{\lambda b}(t)$ could equally well be input to the regression filter 80 and the desired portion $Y_{\lambda b}(t)$ of this signal could equally well be estimated.

The joint process estimator 60 removes all frequencies that are present in both the noise reference signal n'(t) and the measured signal $S_{\lambda a}(t)$. The undesired signal portion $n_{\lambda a}(t)$ usually comprises frequencies unrelated to those of the desired signal portion $Y_{\lambda a}(t)$. It is highly improbable that the undesired signal portion $n_{\lambda a}(t)$ would be of exactly the same spectral content as the

desired signal portion $Y_{\lambda a}(t)$. However, in the unlikely event that the spectral content of $S_{\lambda a}(t)$ and n'(t) are similar, this approach will not yield accurate results. Functionally, the joint process estimator 60 compares input signal n'(t), which is correlated to the undesired signal portion $n_{\lambda a}(t)$, and input signal $S_{\lambda a}(t)$ and removes all frequencies which are identical. Thus, the joint process estimator 60 acts as a dynamic multiple notch filter to remove those frequencies in the undesired signal component $n_{\lambda a}(t)$ as they change erratically with the motion of the patient. This yields a signal having substantially the same spectral content as the desired signal $Y_{\lambda a}(t)$. The output of the joint process estimator 60 has substantially the same spectral content and amplitude as the desired signal $Y_{\lambda a}(t)$. Thus, the output $Y'_{\lambda a}(t)$ of the joint process estimator 60 is a very good approximation to the desired signal $Y_{\lambda a}(t)$.

The joint process estimator 60 can be divided into stages, beginning with a zero-stage and terminating in an mth-stage, as shown in Figure 7. Each stage, except for the zero-stage, is identical to every other stage. The zero-stage is an input stage for the joint process estimator 60. The first stage through the mth-stage work on the signal produced in the immediately previous stage, i.e., the $(m-1)^{th}$-stage, such that a good approximation to the desired signal $Y'_{\lambda a}(t)$ is produced as output from the mth-stage.

The least-squares lattice predictor 70 comprises registers 90 and 92, summing elements 100 and 102, and delay elements 110. The registers 90 and 92 contain multiplicative values of a forward reflection coefficient $\Gamma_{f,m}(t)$ and a backward reflection coefficient $\Gamma_{b,m}(t)$ which multiply the noise reference signal n'(t) and signals derived from the noise reference signal n'(t). Each stage of the least-squares lattice predictor outputs a forward prediction error $f_m(t)$ and a backward prediction error $b_m(t)$. The subscript m is indicative of the stage.

For each set of samples, i.e. one sample of the noise reference signal n'(t) derived substantially simultaneously with one sample of the measured signal $S_{ia}(t)$, the sample of the noise reference signal n'(t) is input to the least-squares lattice predictor 70. The zero-stage forward prediction error $f_0(t)$ and the zero-stage backward prediction error $b_0(t)$ are set equal to the noise reference signal n'(t). The backward prediction error $b_0(t)$ is delayed by one sample period by the delay element 110 in the first stage of the least-squares lattice predictor 70. Thus, the immediately previous value of the noise reference signal n'(t) is used in calculations involving the first-stage delay element 110. The zero-stage forward prediction error is added to the negative of the delayed zero-stage backward prediction error $b_0(t-1)$ multiplied by the forward reflection coefficient value $\Gamma_{f,1}(t)$ register 90 value, to produce a first-stage forward prediction error $f_1(t)$. Additionally,

the zero-stage forward prediction error $f_0(t)$ is multiplied by the backward reflection coefficient value $\Gamma_{b,1(t)}$ register 92 value and added to the delayed zero-stage backward prediction error $b_0(t-1)$ to produce a first-stage backward prediction error $b_1(t)$. In each subsequent stage, m, of the least square lattice predictor 70, the previous forward and backward prediction error values, $f_{m-1}(t)$ and $b_{m-1}(t-1)$, the backward prediction error being delayed by one sample period, are used to produce values of the forward and backward prediction errors for the present stage, $f_m(t)$ and $b_m(t)$.

The backward prediction error $b_m(t)$ is fed to the concurrent stage, m, of the regression filter 80. There it is input to a register 96, which contains a multiplicative regression coefficient value $\kappa_{m,\lambda a}(t)$. For example, in the zero-stage of the regression filter 80, the zero-stage backward prediction error $b_0(t)$ is multiplied by the zero-stage regression coefficient $\kappa_{0,\lambda a}(t)$ register 96 value and subtracted from the measured value of the signal $S_{\lambda a}(t)$ at a summing element 106 to produce a first stage estimation error signal $e_{1,\lambda a}(t)$. The first-stage estimation error signal $e_{1,\lambda a}(t)$ is a first approximation to the desired signal. This first-stage estimation error signal $e_{1,\lambda a}(t)$ is input to the first-stage of the regression filter 80. The first-stage backward prediction error $b_1(t)$, multiplied by the first-stage regression coefficient $\kappa_{1,\lambda a}(t)$ register 96 value is subtracted from the first-stage estimation error signal

$e_{1,\lambda a}(t)$ to produce the second-stage estimation error $e_{2,\lambda a}(t)$. The second-stage estimation error signal $e_{2,\lambda a}(t)$ is a second, somewhat better approximation to the desired signal $Y_{\lambda a}(t)$.

The same processes are repeated in the least-squares lattice predictor 70 and the regression filter 80 for each stage until a good approximation to the desired signal $Y'_{\lambda a}(t) = e_{m,\lambda a}(t)$ is determined. Each of the signals discussed above, including the forward prediction error $f_m(t)$, the backward prediction error $b_m(t)$, the estimation error signal $e_{m,\lambda a}(t)$, is necessary to calculate the forward reflection coefficient $\Gamma_{f,m}(t)$, the backward reflection coefficient $\Gamma_{b,m}(t)$, and the regression coefficient $\kappa_{m,\lambda a}(t)$ register 90, 92, and 96 values in each stage, m. In addition to the forward prediction error $f_m(t)$, the backward prediction error $b_m(t)$, and the estimation error $e_{m,\lambda a}(t)$ signals, a number of intermediate variables, not shown in Figure 7 but based on the values labelled in Figure 7, are required to calculate the forward reflection coefficient $\Gamma_{f,m}(t)$, the backward reflection coefficient $\Gamma_{b,m}(t)$, and the regression coefficient $\kappa_{m,\lambda a}(t)$ register 90,92, and 96 values.

Intermediate variables include a weighted sum of the forward prediction error squares $\mathcal{J}_m(t)$, a weighted sum of the backward prediction error squares $\beta_m(t)$, a scaler parameter $\Delta_m(t)$, a conversion factor $\gamma_m(t)$, and another scaler parameter $\rho_{m,\lambda a}(t)$. The weighted sum of the forward

prediction errors $\mathcal{J}_m(t)$ is defined as:

$$\mathcal{J}_m(t) = \sum_{i=1}^{t} \lambda^{t-i} |f_m(i)|^2; \quad (38)$$

where λ without a wavelength identifier, a or b, is a constant multiplicative value unrelated to wavelength and is typically less than or equal to one, i.e., $\lambda \leq 1$. The weighted sum of the backward prediction errors $\beta_m(t)$ is defined as:

$$\beta_m(t) = \sum_{i=1}^{t} \lambda^{t-i} |b_m(i)|^2 \quad (39)$$

where, again, λ without a wavelength identifier, a or b, is a constant multiplicative value unrelated to wavelength and is typically less than or equal to one, i.e., $\lambda \leq 1$. These weighted sum intermediate error signals can be manipulated such that they are more easily solved for, as described in Chapter 9, § 9.3. and defined hereinafter in equations (53) and (54).

DESCRIPTION OF THE JOINT PROCESS ESTIMATOR

The operation of the joint process estimator 60 is as follows. When the joint process estimator 60 is turned on, the initial values of intermediate variable and signal including the parameter $\Delta_{m-1}(t)$, the weighted sum of the forward prediction error signals $\mathcal{J}_{m-1}(t)$, the weighted sum of the backward prediction error signals $\beta_{m-1}(t)$, the parameter $\rho_{m,\lambda a}(t)$, and the zero-stage estimation error $e_{0,\lambda a}(t)$ are initialized, some to zero and some to a small positive number δ:

$$\Delta_{m-1}(0) = 0; \quad (40)$$

$$\mathcal{F}_{m-1}(0) = \delta; \quad (41)$$

$$\beta_{m-1}(0) = \delta; \quad (42)$$

$$\rho_{m,\lambda a}(0) = 0; \quad (43)$$

$$e_{0,\lambda a}(t) = S_{\lambda a}(t) \text{ for } t \geq 0. \quad (44)$$

After initialization, a simultaneous sample of the measured signal $S_{\lambda a}(t)$ and the noise reference signal $n'(t)$ are input to the joint process estimator 60, as shown in Figure 7. The forward and backward prediction error signals $f_0(t)$ and $b_0(t)$, and intermediate variables including the weighted sums of the forward and backward error signals $\mathcal{F}_0(t)$ and $\beta_0(t)$, and the conversion factor $\gamma_0(t)$ are calculated for the zero-stage according to:

$$f_0(t) = b_0(t) = n'(t) \quad (45)$$

$$\mathcal{F}_0(t) = \beta_0(t) = \lambda\mathcal{F}_0(t-1) + |n'(t)|^2 \quad (46)$$

$$\gamma_0(t-1) = 1 \quad (47)$$

where, again, λ without a wavelength identifier, a or b, is a constant multiplicative value unrelated to wavelength.

Forward reflection coefficient $\Gamma_{f,m}(t)$, backward reflection coefficient $\Gamma_{b,m}(t)$, and regression coefficient $\kappa_{m,\lambda a}(t)$ register 90, 92 and 96 values in each stage thereafter are set according to the output of the previous stage. The forward reflection coefficient $\Gamma_{f,1}(t)$, backward reflection coefficient $\Gamma_{b,1}(t)$, and regression coefficient $\kappa_{1,\lambda a}(t)$ register 90, 92 and 96 values in the first stage are thus set according to algorithm using values in the zero-stage of the joint process estimator 60. In each stage, m≥1, intermediate values and register values

including the parameter $\Delta_{m-1}(t)$; the forward reflection coefficient $\Gamma_{f,m}(t)$ register 90 value; the backward reflection coefficient $\Gamma_{b,m}(t)$ register 92 value; the forward and backward error signals $f_m(t)$ and $b_m(t)$; the weighted sum of squared forward prediction errors $\mathcal{J}_{f,m}(t)$, as manipulated in § 9.3 of the Haykin book; the weighted sum of squared backward prediction errors $\beta_{b,m}(t)$, as manipulated in § 9.3 of the Haykin book; the conversion factor $\gamma_m(t)$; the parameter $\rho_{m,\lambda a}(t)$; the regression coefficient $\kappa_{m,\lambda a}(t)$ register 96 value; and the estimation error $e_{m+1,\lambda a}(t)$ value are set according to:

$$\Delta_{m-1}(t) = \lambda\Delta_{m-1}(t-1) + \{b_{m-1}(t-1)f^*_{m-1}(t)/\gamma_{m-1}(t-1)\} \quad (48)$$

$$\Gamma_{f,m}(t) = -\{\Delta_{m-1}(t)/\beta_{m-1}(t-1)\} \quad (49)$$

$$\Gamma_{b,m}(t) = -\{\Delta^*_{m-1}(t)/\mathcal{J}_{m-1}(t)\} \quad (50)$$

$$f_m(t) = f_{m-1}(t) + \Gamma^*_{f,m}(t)b_{m-1}(t-1) \quad (51)$$

$$b_m(t) = b_{m-1}(t-1) + \Gamma^*_{b,m}(t)f_{m-1}(t) \quad (52)$$

$$\mathcal{J}_m(t) = \mathcal{J}_{m-1}(t) - \{|\Delta_{m-1}(t)|^2/\beta_{m-1}(t-1)\} \quad (53)$$

$$\beta_m(t) = \beta_{m-1}(t-1) - \{|\Delta_{m-1}(t)|^2/\mathcal{J}_{m-1}(t)\} \quad (54)$$

$$\gamma_m(t-1) = \gamma_{m-1}(t-1) - \{|b_{m-1}(t-1)|^2/\beta_{m-1}(t-1)\} \quad (55)$$

$$\rho_{m,\lambda a}(t) = \lambda\rho_{m,\lambda a}(t-1) + \{b_m(t)e^*_{m,\lambda a}(t)/\gamma_m(t)\} \quad (56)$$

$$\kappa_{m,\lambda a}(t) = \{\rho_{m,\lambda a}(t)/\beta_m(t)\} \quad (57)$$

$$e_{m+1,\lambda a}(t) = e_{m,\lambda a}(t) - \kappa^*_m(t)b_m(t) \quad (58)$$

where a (*) denotes a complex conjugate.

These equations cause the error signals $f_m(t)$, $b_m(t)$, $e_{m,\lambda a}(t)$ to be squared or to be multiplied by one another, in effect squaring the errors, and creating new intermediate error values, such as $\Delta_{m-1}(t)$. The error signals and the intermediate error values are recursively

tied together, as shown in the above equations (48) through (58). They interact to minimize the error signals in the next stage.

After a good approximation to the desired signal $Y'_{\lambda a}(t)$ has been determined by the joint process estimator 60, a next set of samples, including a sample of the measured signal $S_{\lambda a}(t)$ and a sample of the noise reference signal n'(t), are input to the joint process estimator 60. The re-initialization process does not re-occur, such that the forward and backward reflection coefficient $\Gamma_{f,m}(t)$ and $\Gamma_{b,m}(t)$ register 90, 92 values and the regression coefficient $\kappa_{m,\lambda a}(t)$ register 96 value reflect the multiplicative values required to estimate the desired portion $Y_{\lambda a}(t)$ of the sample of $S_{\lambda a}(t)$ input previously. Thus, information from previous samples is used to estimate the desired signal portion of a present set of samples in each stage.

FLOWCHART OF JOINT PROCESS ESTIMATOR

In a signal processor, such as a physiological monitor, incorporating a reference processor of the present invention to determine a noise reference signal n'(t) for input to an adaptive noise canceler, a joint process estimator 60 type adaptive noise canceler is generally implemented via a software program having an iterative loop. One iteration of the loop is analogous to a single stage of the joint process estimator as shown in

Figure 7. Thus, if a loop is iterated m times, it is equivalent to an m stage joint process estimator 60.

A flow chart of a subroutine to estimate the desired signal portion $Y_{\lambda a}(t)$ of a sample of a measured signal, $S_{\lambda a}(t)$ is shown in Figure 8. The flow chart describes how the action of a reference processor for determining the noise reference signal and the joint process estimator 60 would be implemented in software.

A one-time only initialization is performed when the physiological monitor is turned on, as indicated by an "INITIALIZE NOISE CANCELER" box 120. The initialization sets all registers 90, 92, and 96 and delay element variables 110 to the values described above in equations (40) through (44).

Next, a set of simultaneous samples of the measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ is input to the subroutine represented by the flowchart in Figure 8. Then a time update of each of the delay element program variables occurs, as indicated in a "TIME UPDATE OF $[Z^{-1}]$ ELEMENTS" box 130, wherein the value stored in each of the delay element variables 110 is set to the value at the input of the delay element variable 110. Thus, the zero-stage backward prediction error $b_0(t)$ is stored in the first-stage delay element variable, the first-stage backward prediction error $b_1(t)$ is stored in the second-stage delay element variable, and so on.

Then, using the set of measured signal samples $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$, the noise reference signal is calculated

according to the ratiometric or the constant saturation method described above. This is indicated by a "CALCULATE NOISE REFERENCE (n'(t)) FOR TWO MEASURED SIGNAL SAMPLES" box 140. The ratiometric method is generally preferred since no assumptions about constant saturation values need be made.

A zero-stage order update is performed next as indicated in a "ZERO-STAGE UPDATE" box 150. The zero-stage backward prediction error $b_0(t)$, and the zero-stage forward prediction error $f_0(t)$ are set equal to the value of the noise reference signal n'(t). Additionally, the weighted sum of the forward prediction errors $\mathcal{F}_m(t)$ and the weighted sum of backward prediction errors $\beta_m(t)$ are set equal to the value defined in equation (46).

Next, a loop counter, m, is initialized as indicated in a "m=0" box 160. A maximum value of m, defining the total number of stages to be used by the subroutine corresponding to the flowchart in Figure 8, is also defined. Typically, the loop is constructed such that it stops iterating once a criterion for convergence upon a best approximation to the desired signal has been met by the joint process estimator 60. Additionally, a maximum number of loop iterations may be chosen at which the loop stops iteration. In a preferred embodiment of a physiological monitor of the present invention, a maximum number of iterations, m=60 to m=80, is advantageously chosen.

Within the loop, the forward and backward reflection coefficient $\Gamma_{f,m}(t)$ and $\Gamma_{b,m}(t)$ register 90 and 92 values in the least-squares lattice filter are calculated first, as indicated by the "ORDER UPDATE MTH CELL OF LSL-LATTICE" box 170 in Figure 8. This requires calculation of intermediate variable and signal values used in determining register 90, 92, and 96 values in the present stage, the next stage, and in the regression filter 80

The calculation of regression filter register 96 value $\kappa_{m,\lambda a}(t)$ is performed next, indicated by the "ORDER UPDATE MTH STAGE OF REGRESSION FILTER(S)" box 180. The two order update boxes 170 and 180 are performed in sequence m times, until m has reached its predetermined maximum (in the preferred embodiment, m=60 to m=80) or a solution has been converged upon, as indicated by a YES path from a "DONE" decision box 190. In a computer subroutine, convergence is determined by checking if the weighted sums of the forward and backward prediction errors $\mathcal{F}_m(t)$ and $\beta_m(t)$ are less than a small positive number. An output is calculated next, as indicated by a "CALCULATE OUTPUT" box 200. The output is a good approximation to the desired signal, as determined by the reference processor and joint process estimator 60 subroutine corresponding to the flow chart of Figure 8. This is displayed (or used in a calculation in another subroutine), as indicated by a "TO DISPLAY" box 210.

A new set of samples of the two measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ is input to the processor and joint

process estimator 60 adaptive noise canceler subroutine corresponding to the flowchart of Figure 8 and the process reiterates for these samples. Note, however, that the initialization process does not re-occur. New sets of measured signal samples $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ are continuously input to the reference processor and joint process estimator 60 adaptive noise canceler subroutine. The output forms a chain of samples which is representative of a continuous wave. This waveform is a good approximation to the desired signal waveform $Y'_{\lambda a}(t)$ at wavelength λa.

CALCULATION OF SATURATION FROM ADAPTIVE NOISE CANCELER OUTPUT

Physiological monitors typically use the approximation of the desired signal $Y'_{\lambda a}(t)$ to calculate another quantity, such as the saturation of one constituent in a volume containing that constituent plus one or more other constituents. Generally, such calculations require information about a desired signal at two wavelengths. In some measurements, this wavelength is λb, the wavelength used in the calculation of the noise reference signal $n'(t)$. For example, the constant saturation method of determining the noise reference signal requires a good approximation of the desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ of both measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$. Then, the saturation is determined from the approximations to both signals, i.e. $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$.

In other physiological measurements, information about a signal at a third wavelength is necessary. For example, to find the saturation using the ratiometric method, signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ are used to find the noise reference signal $n'(t)$. But as discussed previously, λa and λb were chosen to satisfy a proportionality relationship like that of equation (22). This proportionality relationship forces the two desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ to be linearly dependant. Generally, linearly dependant mathematical equations cannot be solved for the unknowns. Analogously, some desirable information cannot be derived from two linearly dependent signals. Thus, to determine the saturation using the ratiometric method, a third signal is simultaneously measured at wavelength λc. The wavelength λc is chosen such that the desired portion $Y_{\lambda c}(t)$ of the measured signal $S_{\lambda c}(t)$ is <u>not</u> linearly dependent with the desired portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ of the measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$. Since all measurements are taken substantially simultaneously, the noise reference signal $n'(t)$ is correlated to the undesired signal portions $n_{\lambda a}$, $n_{\lambda b}$, and $n_{\lambda c}$ of each of the measured signals $S_{\lambda a}(t)$, $S_{\lambda b}(t)$, and $S_{\lambda c}(t)$ and can be used to estimate approximations to the desired signal portions $Y_{\lambda a}(t)$, $Y_{\lambda b}(t)$, and $Y_{\lambda c}(t)$ for all three measured signals $S_{\lambda a}(t)$, $S_{\lambda b}(t)$, and $S_{\lambda c}(t)$. Using the ratiometric method, estimation of the desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda c}(t)$ of two measured signals $S_{\lambda a}(t)$ and

$S_{\lambda c}(t)$, chosen correctly, is usually satisfactory to determine most physiological data.

A joint process estimator 60 having two regression filters 80a and 80b is shown in Figure 9. A first regression filter 80a accepts a measured signal $S_{\lambda a}(t)$. A second regression filter 80b accepts a measured signal $S_{\lambda b}(t)$ or $S_{\lambda c}(t)$, depending whether the constant saturation method or the ratiometric method is used to determine the noise reference signal n'(t). The first and second regression filters 80a and 80b are independent. The backward prediction error $b_m(t)$ is input to each regression filter 80a and 80b, the input for the second regression filter 80b bypassing the first regression filter 80a.

The second regression filter 80b comprises registers 98, and summing elements 108 arranged similarly to those in the first regression filter 80a. The second regression filter 80b operates via an additional intermediate variable in conjunction with those defined by equations (48) through (58), i.e.:

$$\rho_{m,\lambda b}(t) = \lambda\rho_{m,\lambda b}(t-1) + \{b_m(t)e^*_{m,\lambda b}(t)/\gamma_m(t)\}; \text{ or} \quad (59)$$

$$\rho_{m,\lambda c}(t) = \lambda\rho_{m,\lambda c}(t-1) + \{b_m(t)e^*_{m,\lambda c}(t)/\gamma_m(t)\}; \text{ and} \quad (60)$$

$$\rho_{0,\lambda b}(0) = 0; \text{ or} \quad (61)$$

$$\rho_{0,\lambda c}(0) = 0. \quad (62)$$

The second regression filter 80b has an error signal value defined similar to the first regression filter error signal values, $e_{m+1,\lambda a}(t)$, i.e.:

$$e_{m+1,\lambda b}(t) = e_{m,\lambda b}(t) - \kappa^*_{m,\lambda b}(t)b_m(t); \text{ or} \quad (63)$$

$$e_{m+1,\lambda c}(t) = e_{m,\lambda c}(t) - \kappa^*_{m,\lambda b}(t)b_m(t); \text{ and} \quad (64)$$

$$e_{0,\lambda b}(t) = S_{\lambda b}(t) \text{ for } t \geq 0; \text{ or} \quad (65)$$

$$e_{0,\lambda c}(t) = S_{\lambda c}(t) \text{ for } t \geq 0. \quad (66)$$

The second regression filter has a regression coefficient $\kappa_{m,\lambda b}(t)$ register 98 value defined similarly to the first regression filter error signal values, i.e.:

$$\kappa_{m,\lambda b}(t) = \{\rho_{m,\lambda b}(t)/\beta_m(t)\}; \text{ or} \quad (67)$$

$$\kappa_{m,\lambda c}(t) = \{\rho_{m,\lambda c}(t)/\beta_m(t)\}; \quad (68)$$

These values are used in conjunction with those intermediate variable values, signal values, register and register values defined in equations (40) through (58). These signals are calculated in an order defined by placing the additional signals immediately adjacent a similar signal for the wavelength λa.

For the ratiometric method, $S_{\lambda c}(t)$ is input to the second regression filter 80b. The output of the second regression filter 80b is then a good approximation to the desired signal $Y'_{\lambda c}(t)$. For the constant saturation method, $S_{\lambda b}(t)$ is input to the second regression filter 80b. The output is then a good approximation to the desired signal $Y'_{\lambda b}(t)$.

The addition of the second regression filter 80b does not substantially change the computer program subroutine represented by the flowchart of Figure 8. Instead of an order update of the mth stage of only one regression filter, an order update of the mth stage of both regression filters 80a and 80b is performed. This is characterized by the plural designation in the "ORDER UPDATE OF mth STAGE OF REGRESSION FILTER(S)" box 180 in Figure 8. Since the

regression filters 80a and 80b operate independently, independent calculations can be performed in the reference processor and joint process estimator 60 adaptive noise canceler subroutine modeled by the flowchart of Figure 8.

CALCULATION OF SATURATION

Once good approximations to the desired signals, $Y'_{\lambda a}(t)$ and $Y'_{\lambda c}(t)$ for the ratiometric method and $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$ for the constant saturation method, have been determined by the joint process estimator 60, the saturation of A_5 in a volume containing A_5 and A_6, for example, may be calculated according to various known methods. Mathematically, the approximations to the desired signals can be written:

$$Y'_{\lambda a}(t) \approx \varepsilon_{5,\lambda a} c_5 x_{5,6}(t) + \varepsilon_{6,\lambda a} c_6 x_{5,6}(t); \text{ and} \quad (69)$$

$$Y'_{\lambda c}(t) \approx \varepsilon_{5,\lambda c} c_5 x_{5,6}(t) + \varepsilon_{6,\lambda c} c_6 x_{5,6}(t). \quad (70)$$

for the ratiometric method using wavelengths λa and λc. For the constant saturation method, the approximations to the desired signals can be written in terms of λa and λb as:

$$Y'_{\lambda a}(t) \approx \varepsilon_{5,\lambda a} c_5 x_{5,6}(t) + \varepsilon_{6,\lambda a} c_6 x_{5,6}(t); \text{ and} \quad (71)$$

$$Y'_{\lambda b}(t) \approx \varepsilon_{5,\lambda b} c_5 x_{5,6}(t) + \varepsilon_{6,\lambda b} c_6 x_{5,6}(t). \quad (72)$$

This is equivalent to two equations having three unknowns, namely $c_5(t)$, $c_6(t)$ and $x_{5,6}(t)$. In both the ratiometric and the constant saturation cases, the saturation can be determined by acquiring approximations to the desired signal portions at two different, yet proximate times t_1

and t_2 over which the saturation of A_5 in the volume containing A_5 and A_6 does not change substantially. For example, for the desired signals estimated by the ratiometric method, at times t_1 and t_2:

$$Y'_{\lambda a}(t_1) \approx \varepsilon_{5,\lambda a}c_5x_{5,6}(t_1) + \varepsilon_{6,\lambda a}c_6x_{5,6}(t_1) \quad (73)$$

$$Y'_{\lambda c}(t_1) \approx \varepsilon_{5,\lambda c}c_5x_{5,6}(t_1) + \varepsilon_{6,\lambda c}c_6x_{5,6}(t_1) \quad (74)$$

$$Y'_{\lambda a}(t_2) \approx \varepsilon_{5,\lambda a}c_5x_{5,6}(t_2) + \varepsilon_{6,\lambda a}c_6x_{5,6}(t_2) \quad (75)$$

$$Y'_{\lambda c}(t_2) \approx \varepsilon_{5,\lambda c}c_5x_{5,6}(t_2) + \varepsilon_{6,\lambda c}c_6x_{5,6}(t_2) \quad (76)$$

Then, difference signals may be determined which relate the signals of equation (73) through (76), i.e.:

$$\Delta Y_{\lambda a} = Y'_{\lambda a}(t_1)-Y'_{\lambda a}(t_2) \approx \varepsilon_{5,\lambda a}c_5\Delta x + \varepsilon_{6,\lambda a}c_6\Delta x; \text{ and} \quad (77)$$

$$\Delta Y_{\lambda c} = Y'_{\lambda c}(t_1)-Y'_{\lambda c}(t_2) \approx \varepsilon_{5,\lambda c}c_5\Delta x + \varepsilon_{6,\lambda c}c_6\Delta x; \quad (78)$$

where $\Delta x = x_{5,6}(t_1) - x_{5,6}(t_2)$. The average saturation at time $t=(t_1+t_2)/2$ is:

$$\text{Saturation}(t) = c_5(t)/[c_5(t) + c_6(t)] \quad (79)$$

$$= \frac{\varepsilon_{6,\lambda a}-\varepsilon_{6,\lambda b}\left(\frac{\Delta Y_{\lambda a}}{\Delta Y_{\lambda b}}\right)}{\varepsilon_{6,\lambda a}-\varepsilon_{5,\lambda a}-(\varepsilon_{6,\lambda b}-\varepsilon_{5,\lambda b})\left(\frac{\Delta Y_{\lambda a}}{\Delta Y_{\lambda b}}\right)} \quad (80)$$

It will be understood that the Δx term drops out from the saturation calculation because of the division. Thus, knowledge of the thickness of the desired constituents is not required to calculate saturation.

PULSE OXIMETRY MEASUREMENTS

A specific example of a physiological monitor utilizing a processor of the present invention to

determine a noise reference signal n'(t) for input to an adaptive noise canceler that removes erratic motion-induced undesired signal portions is a pulse oximeter. A pulse oximeter typically causes energy to propagate through a medium where blood flows close to the surface for example, an ear lobe, or a digit such as a finger, or a forehead. An attenuated signal is measured after propagation through or reflection from the medium. The pulse oximeter estimates the saturation of oxygenated blood available to the body for use.

Freshly oxygenated blood is pumped at high pressure from the heart into the arteries for use by the body. The volume of blood in the arteries varies with the heartbeat, giving rise to a variation in absorption of energy at the rate of the heartbeat, or the pulse.

Oxygen depleted, or deoxygenated, blood is returned to the heart by the veins along with unused oxygenated blood. The volume of blood in the veins varies with the rate of breathing, which is typically much slower than the heartbeat. Thus, when there is no motion induced variation in the thickness of the veins, venous blood causes a low frequency variation in absorption of energy. When there is motion induced variation in the thickness of the veins, the low frequency variation in absorption is coupled with the erratic variation in absorption due to motion artifact.

In absorption measurements using the transmission of energy through a medium, two light emitting diodes (LED's)

are positioned on one side of a portion of the body where blood flows close to the surface, such as a finger, and a photodetector is positioned on the opposite side of the finger. Typically, in pulse oximetry measurements, one LED emits a visible wavelength, preferably red, and the other LED emits an infrared wavelength. However, one skilled in the art will realize that other wavelength combinations could be used.

The finger comprises skin, tissue, muscle, both arterial blood and venous blood, fat, etc., each of which absorbs light energy differently due to different absorption coefficients, different concentrations, and different thicknesses. When the patient is not moving, absorption is substantially constant except for the flow of blood. This constant attenuation can be determined and subtracted from the signal via traditional filtering techniques. When the patient moves, the absorption becomes erratic. Erratic motion induced noise typically cannot be predetermined and subtracted from the measured signal via traditional filtering techniques. Thus, determining the saturation of oxygenated arterial blood becomes more difficult.

A schematic of a physiological monitor for pulse oximetry is shown in Figure 10. Two LED's 300 and 302, one LED 300 emitting red wavelengths and another LED 302 emitting infrared wavelengths, are placed adjacent a finger 310. A photodetector 320, which produces an electrical signal corresponding to the attenuated visible

and infrared light energy signals is located opposite the LED's 300 and 302. The photodetector 320 is connected to a single channel of common processing circuitry including an amplifier 330 which is in turn connected to a band pass filter 340. The band pass filter 340 passes signal into a synchronized demodulator 350 which has a plurality of output channels. One output channel is for signals corresponding to visible wavelengths and another output channel is for signals corresponding to infrared wavelengths.

The output channels of the synchronized demodulator for signals corresponding to both the visible and infrared wavelengths are each connected to separate paths, each path comprising further processing circuitry. Each path includes a DC offset removal element 360 and 362, such as a differential amplifier, a programmable gain amplifier 370 and 372 and a low pass filter 380 and 382. The output of each low pass filter 380 and 382 is amplified in a second programmable gain amplifier 390 and 392 and then input to a multiplexer 400.

The multiplexer 400 is connected to an analog-to-digital converter 410 which is in turn connected to a microprocessor 420. Control lines between the microprocessor 420 and the multiplexer 400, the microprocessor 420 and the analog-to-digital converter 410, and the microprocessor 420 and each programmable gain amplifier 370, 372, 390, and 392 are formed. The microprocessor 420 has additional control lines, one of

which leads to a display 430 and the other of which leads to an LED driver 440 situated in a feedback loop with the two LED's 300 and 302.

The LED's 300 and 302 each emits energy which is absorbed by the finger 310 and received by the photodetector 320. The photodetector 320 produces an electrical signal which corresponds to the intensity of the light energy striking the photodetector 320 surface. The amplifier 330 amplifies this electrical signal for ease of processing. The band pass filter 340 then removes unwanted high and low frequencies. The synchronized demodulator 350 separates the electrical signal into electrical signals corresponding to the red and infrared light energy components. A predetermined reference voltage, V_{ref}, is subtracted by the DC offset removal element 360 and 362 from each of the separate signals to remove substantially constant absorption which corresponds to absorption when there is no motion induced undesired signal component. Then the first programmable gain amplifiers 370 and 372 amplify each signal for ease of manipulation. The low pass filters 380 and 382 integrate each signal to remove unwanted high frequency components and the second programmable gain amplifiers 390 and 392 amplify each signal for further ease of processing.

The multiplexer 400 acts as an analog switch between the electrical signals corresponding to the red and the infrared light energy, allowing first a signal corresponding to the red light to enter the analog-to-

digital convertor 410 and then a signal corresponding to the infrared light to enter the analog-to-digital convertor 410. This eliminates the need for multiple analog-to-digital convertors 410. The analog-to-digital convertor 410 inputs the data into the microprocessor 420 for calculation of a noise reference signal via the processing technique of the present invention and removal of undesired signal portions via an adaptive noise canceler. The microprocessor 420 centrally controls the multiplexer 400, the analog-to-digital convertor 410, and the first and second programmable gain amplifiers 370 and 390 for both the red and the infrared channels. Additionally, the microprocessor 420 controls the intensity of the LED's 302 and 304 through the LED driver 440 in a servo loop to keep the average intensity received at the photodetector 320 within an appropriate range. Within the microprocessor 420 a noise reference signal n'(t) is calculated via either the constant saturation method or the ratiometric method, as described above, the ratiometric method being generally preferred. This signal is used in an adaptive noise canceler of the joint process estimator type 60, described above.

The multiplexer 400 time multiplexes, or sequentially switches between, the electrical signals corresponding to the red and the infrared light energy. This allows a single channel to be used to detect and begin processing the electrical signals. For example, the red LED 300 is energized first and the attenuated signal is measured at

the photodetector 320. An electrical signal corresponding to the intensity of the attenuated red light energy is passed to the common processing circuitry. The infrared LED 302 is energized next and the attenuated signal is measured at the photodetector 320. An electrical signal corresponding to the intensity of the attenuated infrared light energy is passed to the common processing circuitry. Then, the red LED 300 is energized again and the corresponding electrical signal is passed to the common processing circuitry. The sequential energization of LED's 300 and 302 occurs continuously while the pulse oximeter is operating.

The processing circuitry is divided into distinct paths after the synchronized demodulator 350 to ease time constraints generated by time multiplexing. In the preferred embodiment of the pulse oximeter shown in Figure 10, a sample rate, or LED energization rate, of 1000 Hz is advantageously employed. Thus, electrical signals reach the synchronized demodulator 350 at a rate of 1000 Hz. Time multiplexing is not used in place of the separate paths due to settling time constraints of the low pass filters 380, 382, and 384.

In Figure 10, a third LED 304 is shown adjacent the finger, located near the LED's 300 and 302. The third LED 304 is used to measure a third signal $S_{\lambda c}(t)$ to be used to determine saturation using the ratiometric method. The third LED 304 is time multiplexed with the red and infrared LED's 300 and 302. Thus, a third signal is input

to the common processing circuitry in sequence with the signals from the red and infrared LED's 300 and 302. After passing through and being processed by the operational amplifier 330, the band pass filter 340, and the synchronized demodulator 350, the third electrical signal corresponding to light energy at wavelength λc is input to a separate path including a DC offset removal element 364, a first programmable gain amplifier 374, a low pass filter 384, and a second programmable gain amplifier 394. The third signal is then input to the multiplexer 400.

The dashed line connection for the third LED 304 indicates that this third LED 304 is incorporated into the pulse oximeter when the ratiometric method is used; it is unnecessary for the constant saturation method. When the third LED 304 is used, the multiplexer 400 acts as an analog switch between all three LED 300, 302, and 304 signals. If the third LED 304 is utilized, feedback loops between the microprocessor 420 and the first and second programmable gain amplifier 374 and 394 in the λc wavelength path are also formed.

For pulse oximetry measurements using the ratiometric method, the signals (logarithm converted) transmitted through the finger 310 at each wavelength λa, λb, and λc are:

$$S_{\lambda a}(t) = S_{\lambda red1}(t) = \epsilon_{HbO2,\lambda a} C^{A}_{HbO2} X^{A}(t) + \epsilon_{Hb,\lambda a} C^{A}_{Hb} X^{A}(t) + \epsilon_{HbO2,\lambda a} C^{V}_{HbO2} X^{V}(t) + \epsilon_{Hb,\lambda a} C^{V}_{Hb} X^{V}(t) + n_{\lambda a}(t) . \quad (81)$$

$$S_{\lambda b}(t) = S_{\lambda red2}(t) = \epsilon_{HbO2,\lambda b} C^{A}_{HbO2} X^{A}(t) + \epsilon_{Hb,\lambda b} C^{A}_{Hb} X^{A}(t) + \epsilon_{HbO2,\lambda b} C^{V}_{HbO2} X^{V}(t) + \epsilon_{Hb,\lambda b} C^{V}_{Hb} X^{V}(t) + n_{\lambda b}(t) . \quad (82)$$

$$S_{\lambda c}(t) = S_{\lambda IR}(t) = \epsilon_{HbO2,\lambda c} C^{A}_{HbO2} X^{A}(t) + \epsilon_{Hb,\lambda c} C^{A}_{Hb} X^{A}(t) + \epsilon_{HbO2,\lambda c} C^{V}_{HbO2} X^{V}(t) + \epsilon_{Hb,\lambda c} C^{V}_{Hb} X^{V} + n_{\lambda c}(t) . \quad (83)$$

In equations (81) through (83), $x^A(t)$ is the lump-sum thickness of the arterial blood in the finger; $x^V(t)$ is the lump-sum thickness of venous blood in the finger; $\varepsilon_{HbO2,\lambda a}$ $\varepsilon_{HbO2,\lambda b}$, $\varepsilon_{HbO2,\lambda c}$, $\varepsilon_{Hb,\lambda a}$, $\varepsilon_{Hb,\lambda b}$, and $\varepsilon_{Hb,\lambda c}$ are the absorption coefficients of the oxygenated and non-oxygenated hemoglobin, at each wavelength measured; and $c_{HbO2}(t)$ and $c_{Hb}(t)$ with the superscript designations A and V are the concentrations of the oxygenated and non-oxygenated arterial blood and venous blood, respectively.

For the ratiometric method, the wavelengths chosen are typically two in the visible red range, i.e., λa and λb, and one in the infrared range, i.e., λc. As described above, the measurement wavelengths λa and λb are advantageously chosen to satisfy a proportionality relationship which removes the desired signal portion

$Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$, yielding a noise reference signal n'(t). In the preferred embodiment, the ratiometric method is used to determine the noise reference signal n'(t) by picking two wavelengths that cause the desired portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ of the measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ to become linearly dependent similarly to equation (22); i.e. wavelengths λa and λb which satisfy:

$$\varepsilon_{HbO2,\lambda a}/\varepsilon_{Hb,\lambda a} = \varepsilon_{HbO2,\lambda b}/\varepsilon_{Hb,\lambda b} \quad (84)$$

Typical wavelength values chosen are λa = 650nm and λb = 685nm. Additionally a typical wavelength value for λc is λc = 940nm. By picking wavelengths λa and λb to satisfy equation (84) the venous portion of the measured signal is also caused to become linearly dependent even though it is not a portion of the desired signal. Thus, the venous portion of the signal is removed with the desired portion. The proportionality relationship between equations (81) and (82) which allows determination of a non-zero noise reference signal n'(t), similarly to equation (25) is:

$$\omega_{r4} = \varepsilon_{Hb,\lambda a}/\varepsilon_{Hb,\lambda b}; \text{ where} \quad (85)$$

$$n_{\lambda a}(t) \neq \omega_{r4} n_{\lambda b}(t). \quad (86)$$

In pulse oximetry, both equations (85) and (86) can typically be satisfied simultaneously.

Figure 11 is a graph of the absorption coefficients of oxygenated and deoxygenated hemoglobin (ε_{HbO2} and ε_{Hb}) vs. wavelength (λ). Figure 12 is a graph of the ratio of absorption coefficients vs. wavelength, i.e., $\varepsilon_{Hb}/\varepsilon_{HbO2}$ vs. λ over the range of wavelength within circle 13 in Figure 11. Anywhere a horizontal line touches the curve of

Figure 12 twice, as does line 400, the condition of equation (84) is satisfied. Figure 13 shows an exploded view of the area of Figure 11 within the circle 13. Values of ε_{HbO2} and ε_{Hb} at the wavelengths where a horizontal line touches the curve of Figure 12 twice can then be determined from the data in Figure 13 to solve for the proportionality relationship of equation (85).

A special case of the ratiometric method is when the absorption coefficients ε_{HbO2} and ε_{Hb} are equal at a wavelength. Arrow 410 in Figure 11 indicates one such location, called an isobestic point. Figure 13 shows an exploded view of the isobestic point. To use isobestic points with the ratiometric method, two wavelengths at isobestic points are determined to satisfy equation (84).

Multiplying equation (82) by $\hat{\omega}_{r4}$ and then subtracting equation (82) from equation (81), a non-zero noise reference signal n'(t) is determined by:

$$n'(t) = S_{\lambda a}(t) - \hat{\omega}_{r4}S_{\lambda b}(t) = n_{\lambda a}(t) - \hat{\omega}_{r4}n_{\lambda b}. \quad (87)$$

This noise reference signal n'(t) has spectral content corresponding to the erratic, motion-induced noise. When it is input to an adaptive noise canceler, with either the signals $S_{\lambda a}(t)$ and $S_{\lambda c}(t)$ or $S_{\lambda b}(t)$ and $S_{\lambda c}(t)$ input to two regression filters 80a and 80b, the adaptive noise canceler will function much like an adaptive multiple notch filter and remove frequency components present in both the noise reference signal n'(t) and the measured signals from the measured signals $S_{\lambda a}(t)$ and $S_{\lambda c}(t)$ or $S_{\lambda b}(t)$ and $S_{\lambda c}(t)$. Thus, the adaptive noise canceler is

able to remove erratic noise caused in the venous portion of the measured signals $S_{\lambda a}(t)$, $S_{\lambda b}(t)$, and $S_{\lambda c}(t)$ even though the venous portion of the measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ was not incorporated in the noise reference signal n'(t). However, the low frequency absorption caused by venous blood moving through the veins is generally not one of the frequencies incorporated into the noise reference signal n'(t). Thus, the adaptive noise canceler generally will not remove this portion of the undesired signal. However, a band pass filter applied to the approximations to the desired signals $Y'_{\lambda a}(t)$ and $Y'_{\lambda c}(t)$ or $Y'_{\lambda b}(t)$ and $Y'_{\lambda c}(t)$ can remove this portion of the undesired signal corresponding to the low frequency venous absorption.

For pulse oximetry measurements using the constant saturation method, the signals (logarithm converted) transmitted through the finger 310 at each wavelength λa and λb are:

$$S_{\lambda a}(t) = S_{\lambda red1}(t) = \epsilon_{HbO2,\lambda a} C^{A}_{HbO2} X^{A}(t) + \epsilon_{Hb,\lambda a} C^{A}_{Hb} X^{A}(t) + \epsilon_{HbO2,\lambda a} C^{V}_{HbO2} X^{V}(t) + \epsilon_{Hb,\lambda a} C^{V}_{Hb} X^{V}(t) + n_{\lambda a}(t) . \quad (88)$$

$$S_{\lambda b}(t) = S_{\lambda IR}(t) = \epsilon_{HbO2,\lambda b} C^{A}_{HbO2} X^{A}(t) + \epsilon_{Hb,\lambda b} C^{A}_{Hb} X^{A}(t) + \epsilon_{HbO2,\lambda b} C^{V}_{HbO2} X^{V}(t) + \epsilon_{Hb,\lambda b} C^{V}_{Hb} X^{V}(t) + n_{\lambda b}(t) . \quad (89)$$

For the constant saturation method, the wavelengths chosen are typically one in the visible red range, i.e., λa, and

one in the infrared range, i.e., λb. Typical wavelength values chosen are λa = 660nm and λb = 940nm. Using the constant saturation method, it is assumed that $C_{HbO2}(t)/C_{Hb}(t)$ = constant. The saturation of oxygenated arterial blood changes slowly, if at all, with respect to the sample rate, making this a valid assumption. The proportionality factor between equation (88) and (89) can then be written as:

$$\hat{\omega}_{s4}(t) = \frac{\varepsilon_{HbO2,\lambda a}C_{HbO2}x(t) + \varepsilon_{Hb,\lambda a}C_{Hb}x(t)}{\varepsilon_{HbO2,\lambda b}C_{HbO2}x(t) + \varepsilon_{Hb,\lambda b}C_{Hb}x(t)} \quad (90)$$

$$\approx Y'_{\lambda a}(t)/Y'_{\lambda b}(t); \text{ where} \quad (91)$$

$$n_{\lambda a}(t) \approx \hat{\omega}_{s4}(t)n_{\lambda b}(t). \quad (92)$$

In pulse oximetry, it is typically the case that both equations (91) and (92) can be satisfied simultaneously.

Multiplying equation (89) by $\hat{\omega}_{s4}(t)$ and then subtracting equation (89) from equation (88), a non-zero noise reference signal n'(t) is determined by:

$$n'(t) = S_{\lambda a}(t) - \hat{\omega}_{s4}(t)S_{\lambda b}(t) \quad (93)$$

$$= \epsilon_{HbO2,\lambda a}C^{V}_{HbO2}x^{V}(t) + \epsilon_{Hb,\lambda a}C^{V}_{Hb}x^{V}(t) + n_{\lambda a}(t)$$

$$- \omega_{s4}[\epsilon_{HbO2,\lambda b}C^{V}_{HbO2}x^{V}(t) + \epsilon_{Hb,\lambda b}C^{V}_{Hb}x^{V}(t) + n_{\lambda b}(t)]. \quad (94)$$

The constant saturation assumption does not cause the venous contribution to the absorption to be canceled along with the desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$, as did the relationship of equation (84) used in the ratiometric method. Thus, frequencies associated with both the low frequency modulated absorption due to venous absorption when the patient is still and the erratically modulated

absorption due to venous absorption when the patient is moving are represented in the noise reference signal n'(t). Thus, the adaptive canceler can remove both erratically modulated absorption due to venous blood in the finger under motion and the constant low frequency cyclic absorption of venous blood.

Using either method, a noise reference signal n'(t) is determined by the processor of the present invention for use in an adaptive noise canceler which is defined by software in the microprocessor. The preferred adaptive noise canceler is the joint process estimator 60 described above.

Illustrating the operation of the ratiometric method of the present invention, Figures 14, 15 and 16 show signals measured for use in determining the saturation of oxygenated arterial blood using a reference processor of the present invention which employs the ratiometric method, i.e., the signals $S_{\lambda a}(t) = S_{\lambda red1}(t)$, $S_{\lambda b}(t) = S_{\lambda red2}(t)$, and $S_{\lambda c}(t) = S_{\lambda IR}(t)$. A first segment 14a, 15a, and 16a of each of the signals is relatively undisturbed by motion artifact, i.e., the patient did not move substantially during the time period in which these segments were measured. These segments 14a, 15a, and 16a are thus generally representative of the desired plethysmographic waveform at each of the measured wavelengths. A second segment 14b, 15b, and 16b of each of the signals is affected by motion artifact, i.e., the patient did move during the time period in which these

segments were measured. Each of these segments 14b, 15b, and 16b shows large motion induced excursions in the measured signal. A third segment 14c, 15c, and 16c of each of the signals is again relatively unaffected by motion artifact and is thus generally representative of the desired plethysmographic waveform at each of the measured wavelengths.

Figure 17 shows the noise reference signal $n'(t) = n_{\lambda a} - \hat{\omega}_{r4} n_{\lambda b}(t)$, as determined by a reference processor of the present invention utilizing the ratiometric method. As discussed previously, the noise reference signal n'(t) is correlated to the undesired signal portions $n_{\lambda a}$, $n_{\lambda b}$, and $n_{\lambda c}$. Thus, a first segment 17a of the noise reference signal n'(t) is generally flat, corresponding to the fact that there is very little motion induced noise in the first segments 14a, 15a, and 16a of each signal. A second segment 17b of the noise reference signal n'(t) exhibits large excursions, corresponding to the large motion induced excursions in each of the measured signals. A third segment 17c of the noise reference signal n'(t) is generally flat, again corresponding to the lack of motion artifact in the third segments 14a, 14b, and 14c of each measured signal.

Figures 18 and 19 show the approximations $Y'_{\lambda a}(t)$ and $Y'_{\lambda c}(t)$ to the desired signals $Y_{\lambda a}(t)$ and $Y_{\lambda c}(t)$ as estimated by the joint process estimator 60 using a noise reference signal n'(t) determined by the ratiometric method. Note that the scale of Figures 14 through 19 is not the same

for each figure to better illustrate changes in each signal. Figures 18 and 19 illustrate the effect of the joint process estimator adaptive noise canceler using the noise reference signal n'(t) as determined by the reference processor of the present invention using the ratiometric method. Segments 18b and 19b are not dominated by motion induced noise as were segments 14b, 15b, and 16b of the measured signals. Additionally, segments 18a, 19a, 18c, and 19c have not been substantially changed from the measured signal segments 14a, 15a, 16a, 14c, 15c, and 16c where there was no motion induced noise.

Illustrating the operation of the constant saturation method of the present invention, Figures 20 and 21 show signals measured for input to a reference processor of the present invention which employs the constant saturation method, i.e., the signals $S_{\lambda a}(t) = S_{\lambda red}(t)$ and $S_{\lambda b}(t) = S_{\lambda IR}(t)$. A first segment 20a and 21a of each of the signals is relatively undisturbed by motion artifact, i.e., the patient did not move substantially during the time period in which these segments were measured. These segments 20a and 21a are thus generally representative of the desired plethysmographic waveform at each of the measured wavelengths. A second segment 20b and 21b of each of the signals is affected by motion artifact, i.e., the patient did move during the time period in which these segments were measured. Each of these segments 20b and 21b shows large motion induced excursions in the measured signal.

A third segment 20c and 21c of each of the signals is again relatively unaffected by motion artifact and is thus generally representative of the desired plethysmographic waveform at each of the measured wavelengths.

Figure 22 shows the noise reference signal $n'(t) = n_{\lambda a}(t) - \hat{\omega}_{s4} n_{\lambda b}(t)$, as determined by a reference processor of the present invention utilizing the constant saturation method. Again, the noise reference signal $n'(t)$ is correlated to the undesired signal portions $n_{\lambda a}$ and $n_{\lambda b}$. Thus, a first segment 22a of the noise reference signal $n'(t)$ is generally flat, corresponding to the fact that there is very little motion induced noise in the first segments 20a and 21a of each signal. A second segment 22b of the noise reference signal $n'(t)$ exhibits large excursions, corresponding to the large motion induced excursions in each of the measured signals. A third segment 22c of the noise reference signal $n'(t)$ is generally flat, again corresponding to the lack of motion artifact in the third segments 20b and 21c of each measured signal.

Figures 23 and 24 show the approximations $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$ to the desired signals $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ as estimated by the joint process estimator 60 using a noise reference signal $n'(t)$ determined by the constant saturation method. Note that the scale of Figures 20 through 24 is not the same for each figure to better illustrate changes in each signal. Figures 23 and 24 illustrate the effect of the joint process estimator adaptive noise canceler using the

noise reference signal n'(t) as determined by a reference processor of the present invention utilizing the constant saturation method. Segments 23b and 24b are not dominated by motion induced noise as were segments 20b and 21b of the measured signals. Additionally, segments 23a, 24a, 23c, and 24c have not been substantially changed from the measured signal segments 20a, 21a, 20c, and 21c where there was no motion induced noise.

METHOD FOR ESTIMATING DESIRED PORTIONS OF MEASURED SIGNALS IN A PULSE OXIMETER

A copy of a computer program subroutine, written in the C programming language, calculates a noise reference signal n'(t) using the ratiometric method and, using a joint process estimator 60, estimates the desired signal portions of two measured signals, each having an undesired portion which is correlated to the noise reference signal n'(t) and one of which was not used to calculate the noise reference signal n'(t), is appended in Appendix A. For example, $S_{\lambda a}(t) = S_{\lambda red1}(t) = S_{\lambda 650nm}(t)$ and $S_{\lambda c}(t) = S_{\lambda IR}(t) = S_{\lambda 940nm}(t)$ can be input to the computer subroutine. One skilled in the art will realize that $S_{\lambda a}(t) = S_{\lambda red2}(t) = S_{\lambda 685nm}(t)$ and $S_{\lambda c}(t) = S_{\lambda IR}(t) = S_{\lambda 940nm}(t)$ will also work. This subroutine is one way to implement the steps illustrated in the flowchart of Figure 8 for a monitor particularly adapted for pulse oximetry.

The program estimates the desired signal portions of two light energy signals, one preferably corresponding to light in the visible red range and the other preferably corresponding to light in the infrared range such that a determination of the amount of oxygen available to the body, or the saturation of oxygen in the arterial blood, may be made. The calculation of the saturation is performed in a separate subroutine. Various methods for calculation of the oxygen saturation are known to those skilled in the art. One such calculation is described in the articles by G.A. Mook, et al, and Michael R. Neuman cited above. Once the concentration of oxygenated hemoglobin and deoxygenated hemoglobin are determined, the value of the saturation is determined similarly to equations (73) through (80) wherein measurements at times t_1 and t_2 are made at different, yet proximate times over which the saturation is relatively constant. For pulse oximetry, the average saturation at time $t = (t_1+t_2)/2$ is then determined by:

$$\text{Saturation}(t) = C_{HbO2}(t)/[C_{HbO2}(t) + C_{Hb}(t)]. \quad (95)$$

$$= \frac{\epsilon_{Hb,\lambda a} - \epsilon_{Hb,\lambda b}\left(\frac{\Delta Y_{\lambda a}}{\Delta Y_{\lambda b}}\right)}{\epsilon_{Hb,\lambda a} - \epsilon_{HbO2,\lambda a} - (\epsilon_{Hb,\lambda b} - \epsilon_{HbO2,\lambda b})\left(\frac{\Delta Y_{\lambda a}}{\Delta Y_{\lambda b}}\right)} \quad (96)$$

Using the ratiometric method, three signals $S_{\lambda a}(t)$, $S_{\lambda b}(t)$, and $S_{\lambda c}(t)$ are input to the subroutine. $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ are used to calculate the noise reference signal $n'(t)$. As described above, the wavelengths of light at

which $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ are measured are chosen to satisfy the relationship of equation (84). Once the noise reference signal n'(t) is determined, the desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda c}(t)$ of the measured signals $S_{\lambda a}(t)$ and $S_{\lambda c}(t)$ are estimated for use in calculation of the oxygen saturation.

The correspondence of the program variables to the variables defined in the discussion of the joint process estimator is as follows:

$\Delta_m(t)$ = nc[].Delta
$\Gamma_{f,m(t)}$ = nc[].fref
$\Gamma_{b,m}(t)$ = nc[].bref
$f_m(t)$ = nc[].ferr
$b_m(t)$ = nc[].berr
$\mathcal{F}_m(t)$ = nc[].Fswsqr
$\beta_m(t)$ = nc[].Bswsqr
$\gamma_m(t)$ = nc[].Gamma
$\rho_{m,\lambda a}(t)$ = nc[].Roh_a
$\rho_{m\lambda c}(t)$ = nc[].Roh_c
$e_{m,\lambda a}(t)$ = nc[].err_a
$e_{m,\lambda c}(t)$ = nc[].err_c
$\kappa_{m,\lambda a}(t)$ = nc[].K_a
$\kappa_{m,\lambda c}(t)$ = nc[].K_c

A first portion of the program performs the initialization of the registers 90, 92, 96, and 98 and intermediate variable values as in the "INITIALIZE NOISE CANCELER" box 120 and equations (40) through (44) and equations (61), (62), (65), and (66). A second portion of the program performs the time updates of the delay element variables 110 where the value at the input of each delay element variable 110 is stored in the delay element variable 110 as in the "TIME UPDATE OF [Z^{-1}] ELEMENTS" box 130.

A third portion of the program calculates the noise reference signal, as in the "CALCULATE NOISE REFERENCE

(n'(t)) FOR TWO MEASURED SIGNAL SAMPLES" box 140 using the proportionality constant ω_{r4} determined by the ratiometric method as in equation (85).

A fourth portion of the program performs the zero-stage update as in the "ZERO-STAGE UPDATE" box 150 where the zero-stage forward prediction error $f_0(t)$ and the zero-stage backward prediction error $b_0(t)$ are set equal to the value of the noise reference signal n'(t) just calculated. Additionally, zero-stage values of intermediate variables $\mathcal{F}_0(t)$ and $\beta_0(t)$ (nc[].Fswsqr and nc[].Bswsqr in the program) are calculated for use in setting register 90, 92, 96, and 98 values in the least-squares lattice predictor 70 and the regression filters 80a and 80b.

A fifth portion of the program is an iterative loop wherein the loop counter, m, is reset to zero with a maximum of m = NC_CELLS, as in the "m=0" box 160 in Figure 8. NC_CELLS is a predetermined maximum value of iterations for the loop. A typical value of NC_CELLS is between 60 and 80, for example. The conditions of the loop are set such that the loop iterates a minimum of five times and continues to iterate until a test for conversion is met or m = NC_CELLS. The test for conversion is whether or not the sum of the weighted sum of forward prediction errors plus the weighted sum of backward prediction errors is less than a small number, typically 0.00001 (i.e, $\mathcal{F}_m(t)+\beta_m(t) \leq 0.00001$).

A sixth portion of the program calculates the forward and backward reflection coefficient $\Gamma_{m,f}(t)$ and $\Gamma_{m,b}(t)$

register 90 and 92 values (nc[].fref and nc[].bref in the program) as in the "ORDER UPDATE m^{th}-STAGE OF LSL-PREDICTOR" box 170 and equations (49) and (50). Then forward and backward prediction errors $f_m(t)$ and $b_m(t)$ (nc[].ferr and nc[].berr in the program) are calculated as in equations (51) and (52). Additionally, intermediate variables $\mathcal{J}_m(t)$, $\beta_m(t)$ and $\gamma_m(t)$ (nc[].Fswsqr, nc[].Bswsqr, nc[].Gamma in the program) are calculated, as in equations (53), (54), and (55). The first cycle of the loop uses the values for nc[0].Fswsqr and nc[0].Bswsqr calculated in the ZERO-STAGE UPDATE portion of the program.

A seventh portion of the program, still within the loop, calculates the regression coefficient $\kappa_{m,\lambda a}(t)$ and $\kappa_{m,\lambda c}(t)$ register 96 and 98 values (nc[].K_a and nc[].K_c in the program) in both regression filters, as in the "ORDER UPDATE m^{th} STAGE OF REGRESSION FILTER(S)" box 180 and equations (57) through (68). Intermediate error signals and variables $e_{m,\lambda a}(t)$, $e_{m,\lambda c}(t)$, $\rho_{m,\lambda a}(t)$, and $\rho_{m,\lambda c}(t)$ (nc[].err_a and nc[].err_c, nc[].roh_a, and nc[].roh_c in the subroutine) are also calculated as in equations (58), (64), (56), and (60), respectively.

The test for convergence of the joint process estimator is performed each time the loop iterates, analogously to the "DONE" box 190. If the sum of the weighted sums of the forward and backward prediction errors $\mathcal{J}_m(t)+\beta_m(t)$ is less than or equal to 0.00001, the loop terminates. Otherwise, the sixth and seventh portions of the program repeat.

When either the convergence test is passed or m = NC_CELLS, an eighth portion of the program calculates the output of the joint process estimator 60 adaptive noise canceler as in the "CALCULATE OUTPUT" box 200. This output is a good approximation to both of the desired signals $Y'_{\lambda a}(t)$ and $Y'_{\lambda c}(t)$ for the set of samples $S_{\lambda a}(t)$, $S_{\lambda b}(t)$, and $S_{\lambda c}(t)$ input to the program. After many sets of samples are processed by the joint process estimator, a compilation of the outputs provides output waves which are good approximations to the plethysmographic wave at each wavelength, λa and λc.

Another copy of a computer program subroutine, written in the C programming language, which calculates a noise reference signal n'(t) using the constant saturation method and, using a joint process estimator 60, estimates a good approximation to the desired signal portions of two measured signals, each having an undesired portion which is correlated to the noise reference signal n'(t) and each having been used to calculate the noise reference signal n'(t), is appended in Appendix B. This subroutine is another way to implement the steps illustrated in the flowchart of Figure 8 for a monitor particularly adapted for pulse oximetry. The two signals are measured at two different wavelengths λa and λb, where λa is typically in the visible region and λb is typically in the infrared region. For example, in one embodiment of the present invention, tailored specifically to perform pulse oximetry

using the constant saturation method, λa = 660nm and λb = 940nm.

The correspondence of the program variables to the variables defined in the discussion of the joint process estimator is as follows:

$\Delta_m(t)$ = nc[].Delta
$\Gamma_{f,m}(t)$ = nc[].fref
$\Gamma_{b,m}(t)$ = nc[].bref
$f_m(t)$ = nc[].ferr
$b_m(t)$ = nc[].berr
$\mathcal{F}_m(t)$ = nc[].Fswsqr
$\beta_m(t)$ = nc[].Bswsqr
$\gamma(t)$ = nc[].Gamma
$\rho_{m,\lambda a}(t)$ = nc[].Roh_a
$\rho_{m\lambda b}(t)$ = nc[].Roh_b
$e_{m,\lambda a}(t)$ = nc[].err_a
$e_{m,\lambda b}(t)$ = nc[].err_b
$\kappa_{m,\lambda a}(t)$ = nc[].K_a
$\kappa_{m,\lambda b}(t)$ = nc[].K_b

First and second portions of the subroutine are the same as the first and second portions of the above described subroutine tailored for the ratiometric method of determining the noise reference signal n'(t).

A third portion of the subroutine calculates the noise reference signal, as in the "CALCULATE NOISE REFERENCE (n'(t)) FOR TWO MEASURED SIGNAL SAMPLES" box 140 for the signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ using the a proportionality constant $\hat{\omega}_{s4}(t)$ determined by the constant saturation method as in equations (90) and (91). The saturation is calculated in a separate subroutine and a value of $\hat{\omega}_{s4}(t)$ is imported to the present subroutine for estimating the desired portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ of the composite measured signals $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$.

Fourth, fifth, and sixth portions of the subroutine are similar to the fourth, fifth, and sixth portions of

the above described program tailored for the ratiometric method. However, the signals being used to estimate the desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ in the present subroutine tailored for the constant saturation method, are $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$, the same signals that were used to calculate the noise reference signal n'(t).

A seventh portion of the program, still within the loop begun in the fifth portion of the program, calculates the regression coefficient register 96 and 98 values $\kappa_{m,\lambda a}(t)$ and $\kappa_{m,\lambda b}(t)$ (nc[].K_a and nc[].K_b in the program) in both regression filters, as in the "ORDER UPDATE m^{th} STAGE OF REGRESSION FILTER(S)" box 180 and equations (57) through (67). Intermediate error signals and variables $e_{m,\lambda a}(t)$, $e_{m,\lambda b}(t)$, $\rho_{m,\lambda a}(t)$, and $\rho_{m,\lambda b}(t)$ (nc[].err_a and nc[].err_b, nc[].roh_a, and nc[].roh_b in the subroutine) are also calculated as in equations (58), (63), (56), and (59), respectively.

The loop iterates until the test for convergence is passed, the test being the same as described above for the subroutine tailored for the ratiometric method. The output of the present subroutine is a good approximation to the desired signals $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$ for the set of samples $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ input to the program. After approximations to the desired signal portions of many sets of measured signal samples are estimated by the joint process estimator, a compilation of the outputs provides waves which are good approximations to the plethysmographic wave at each wavelength, λa and λb. The

estimating process of the iterative loop is the same in either subroutine, only the sample values $S_{\lambda a}(t)$ and $S_{\lambda c}(t)$ or $S_{\lambda a}(t)$ and $S_{\lambda b}(t)$ input to the subroutine for use in estimation of the desired signal portions $Y_{\lambda a}(t)$ and $Y_{\lambda c}(t)$ or $Y_{\lambda a}(t)$ and $Y_{\lambda b}(t)$ and how the noise reference signal $n'(t)$ is calculated are different for the ratiometric method and the constant saturation methods.

Independent of the method used, ratiometric or constant saturation, the approximations to the desired signal values $Y'_{\lambda a}(t)$ and $Y'_{\lambda c}(t)$ or $Y'_{\lambda a}(t)$ and $Y'_{\lambda b}(t)$ are input to a separate subroutine in which the saturation of oxygen in the arterial blood is calculated. If the constant saturation method is used, the saturation calculation subroutine also determines a value for the proportionality constant $\omega_{s4}(t)$ as defined in equations (90) and (91) and discussed above. The concentration of oxygenated arterial blood can be found from the approximations to the desired signal values since the desired signals are made up of terms comprising $x(t)$, the thickness of arterial blood in the finger; absorption coefficients of oxygenated and de-oxygenated hemoglobin, at each measured wavelength; and $C_{HbO2}(t)$ and $C_{Hb}(t)$, the concentrations of oxygenated and de-oxygenated hemoglobin, respectively. The saturation is a ratio of the concentration of one constituent, A_5, with respect to the total concentration of constituents in the volume containing A_5 and A_6. Thus, the thickness, $x(t)$, is divided out of the saturation calculation and need not be

predetermined. Additionally, the absorption coefficients are constant at each wavelength. The saturation of oxygenated arterial blood is then determined as in equations (95) and (96).

While one embodiment of a physiological monitor incorporating a processor of the present invention for determining a noise reference signal for use in an adaptive noise canceler to remove erratic noise components from a physiological measurement has been described in the form of a pulse oximeter, it will be obvious to one skilled in the art that other types of physiological monitors may also employ the above described techniques for noise reduction on a composite measured signal in the presence of noise.

Furthermore, it will be understood that transformations of measured signals other than logarithmic conversion and determination of a proportionality factor which allows removal of the desired signal portions for determination of a noise reference signal are possible. Additionally, although the proportionality factor $\hat{\omega}$ has been described herein as a ratio of a portion of a first signal to a portion of a second signal, a similar proportionality constant determined as a ratio of a portion of a second signal to a portion of a first signal could equally well be utilized in the processor of the present invention. In the latter case, a noise reference signal would generally resemble $n'(t) = n_{\lambda b}(t) - \hat{\omega} n_{\lambda a}(t)$.

It will also be obvious to one skilled in the art that for most physiological measurements, two wavelengths may be determined which will enable a signal to be measured which is indicative of a quantity of a component about which information is desired. Information about a constituent of any energy absorbing physiological material may be determined by a physiological monitor incorporating a signal processor of the present invention and an adaptive noise canceler by determining wavelengths which are absorbed primarily by the constituent of interest. For most physiological measurements, this is a simple determination.

Moreover, one skilled in the art will realize that any portion of a patient or a material derived from a patient may be used to take measurements for a physiological monitor incorporating a processor of the present invention and an adaptive noise canceler. Such areas include a digit such as a finger, but are not limited to a finger.

One skilled in the art will realize that many different types of physiological monitors may employ a signal processor of the present invention in conjunction with an adaptive noise canceler. Other types of physiological monitors include, but are in not limited to, electron cardiographs, blood pressure monitors, blood gas saturation (other than oxygen saturation) monitors, capnographs, heart rate monitors, respiration monitors, or depth of anesthesia monitors. Additionally, monitors

which measure the pressure and quantity of a substance within the body such as a breathalizer, a drug monitor, a cholesterol monitor, a glucose monitor, a carbon dioxide monitor, a glucose monitor, or a carbon monoxide monitor may also employ the above described techniques for removal of undesired signal portions.

Furthermore, one skilled in the art will realize that the above described techniques of noise removal from a composite signal including noise components can also be performed on signals made up of reflected energy, rather than transmitted energy. One skilled in the art will also realize that a desired portion of a measured signal of any type of energy, including but not limited to sound energy, X-ray energy, gamma ray energy, or light energy can be estimated by the noise removal techniques described above. Thus, one skilled in the art will realize that the processor of the present invention and an adaptive noise canceler can be applied in such monitors as those using ultrasound where a signal is transmitted through a portion of the body and reflected back from within the body back through this portion of the body. Additionally, monitors such as echo cardiographs may also utilize the techniques of the present invention since they too rely on transmission and reflection.

While the present invention has been described in terms of a physiological monitor, one skilled in the art will realize that the signal processing techniques of the present invention can be applied in many areas, including

but not limited to the processing of a physiological signal. The present invention may be applied in any situation where a signal processor comprising a detector receives a first signal which includes a first desired signal portion and a first undesired signal portion and a second signal which includes a second desired signal portion and a second undesired signal portion. The first and second signals propagate through a common medium and the first and second desired signal portions are correlated with one another. Additionally, at least a portion of the first and second undesired signal portions are correlated with one another due to a perturbation of the medium while the first and second signals are propagating through the medium. The processor receives the first and second signals and combines the first and second signals to generate a noise reference signal in which the primary component is derived from the first and second undesired signal portions. Thus, the signal processor of the present invention is readily applicable to numerous signal processing areas. What is claimed is:

CLAIMS

1. A signal processor comprising:

a detector for receiving a first signal which travels along a first propagation path and a second signal which travels along a second propagation path, a portion of said first and second propagation paths being located in a propagation medium, wherein said first signal has a first desired signal portion and a first undesired signal portion and said second signal has a second desired signal portion and a second undesired signal portion, wherein said first and second undesired signal portions are a result of a perturbation of said propagation medium; and

a reference processor having an input for receiving said first and second signals wherein said processor is adapted to combine said first and second signals to generate a reference signal having a primary component which is a function of said first and said second undesired signal portions.

2. The signal processor of Claim 1 further comprising an adaptive signal processor for receiving said reference signal and said first signal and for deriving therefrom an output signal having a primary component which is a function of said first desired signal portion of said first signal.

3. The signal processor of Claim 1 further comprising an adaptive signal processor for receiving said reference signal and said second signal and for deriving therefrom an output signal having a primary component which is a function of said second desired signal portion of said second signal.

4. The signal processor of Claim 2 wherein said adaptive signal processor comprises an adaptive noise canceler.

5. The signal processor of Claim 4 wherein said adaptive noise canceler comprises a joint process estimator.

6. The signal processor of Claim 5 wherein said joint process estimator comprises a least-squares-lattice predictor and a regression filter.

7. The signal processor of Claim 1 wherein said detector further comprises a sensor for sensing a physiological function.

8. The signal processor of Claim 7 wherein said sensor comprises a light sensitive device.

9. The signal processor of Claim 7 further comprising a pulse oximeter for measuring oxygen saturation in a living organism.

10. A physiological monitoring apparatus comprising:

a detector for receiving a first physiological measurement signal which travels along a first propagation path and a second physiological measurement signal which travels along a second propagation path, a portion of said first and second propagation paths being located in a propagation medium, wherein said first signal has a first desired signal portion and a first undesired signal portion and said second signal has a second desired signal portion and a second undesired signal portion; and

a reference processor having an input for receiving said first and second signals wherein said processor is adapted to combine said first and second signals to generate a reference signal having a primary component which is a function of said first and said second undesired signal portions.

11. The apparatus of Claim 10 further comprising an adaptive signal processor for receiving said reference signal and said first signal and for deriving therefrom an output signal having a primary component which is a function of said first desired signal portion of said first signal.

12. The apparatus of Claim 10 further comprising an adaptive signal processor for receiving said reference signal and said second signal and for deriving therefrom an output signal having a primary component which is a function of said second desired signal portion of said second signal.

13. The apparatus of Claim 11 wherein said adaptive signal processor comprises an adaptive noise canceler.

14. The apparatus of Claim 13 wherein said adaptive noise canceler comprises a joint process estimator.

15. The apparatus of Claim 14 wherein said joint process estimator comprises a least-squares-lattice predictor and a regression filter.

16. The apparatus of Claim 10 wherein said detector further comprises a light sensitive device.

17. The apparatus of Claim 10 further comprising a pulse oximeter.

18. An apparatus for measuring a blood constituent comprising:

an energy source for directing a plurality of predetermined wavelengths of electromagnetic energy upon a specimen;

a detector for receiving said plurality of

predetermined wavelengths of electromagnetic energy from said specimen and producing electrical signals corresponding to said predetermined wavelengths in response thereto, wherein at least two of said electrical signals each has a desired signal portion and an undesired signal portion; and

a reference processor having an input for receiving said electrical signals wherein said processor is configured to combine said electrical signals to generate a reference signal having a primary component which is derived from said undesired signal portions.

19. The apparatus of Claim 18 further comprising an adaptive signal processor for receiving said reference signal and one of said at least two said electrical signals and for deriving therefrom an output signal having a primary component which is a function of said desired signal portion of said electrical signal.

20. The apparatus of Claim 19, wherein said adaptive signal processor comprises an adaptive noise canceler.

21. The apparatus of Claim 20, wherein said adaptive noise canceler comprises a joint process estimator.

22. The apparatus of Claim 21 wherein said joint process estimator comprises a least-squares-lattice predictor and a regression filter.

23. A blood gas monitor for non-invasively measuring a blood constituent in a body comprising:

a light source for directing at least two predetermined wavelengths of light upon a body;

a detector for receiving said light from said body and, in response thereto, producing at least two electrical signals corresponding to said at least two predetermined wavelengths of light, wherein said at least two electrical signals each has a desired signal portion and an undesired signal portion; and

a reference processor having an input for receiving said at least two electrical signals wherein said processor is adapted to combine said at least two electrical signals to generate a reference signal with a primary component which is derived from said undesired signal portions.

24. The blood gas monitor of Claim 23 further comprising an adaptive signal processor for receiving said reference signal and said two electrical signals and for deriving therefrom at least two output signals which are substantially equal, respectively, to said desired signal portions of said electrical signals.

25. The blood gas monitor of Claim 24 wherein said adaptive signal processor comprises an adaptive noise canceler.

26. The blood gas monitor of Claim 25, wherein said adaptive noise canceler comprises a joint process estimator.

27. The blood gas monitor of Claim 26, wherein said joint process estimator comprises a least-squares-lattice predictor and a regression filter.

28. A method of determining a noise reference signal from a first signal comprising a first desired signal portion and a first noise portion and a second signal comprising a second desired signal portion and a second noise portion comprising the steps of:

selecting a signal coefficient which is proportional to a ratio of predetermined attributes of said first desired signal portion and predetermined attributes of said second desired signal portion;

inputting said first signal and said signal coefficient into a signal multiplier wherein said first signal is multiplied by said signal coefficient thereby generating a first intermediate signal; and

inputting said second signal and said first intermediate signal into a signal subtractor wherein said first intermediate signal is subtracted from said second signal thereby generating a noise reference signal having a primary component which is derived from said first and second noise signal portions.

29. The method of Claim 28 wherein said first and second signals are derived from light energy transmitted through an absorbing medium.

30. A physiological monitoring apparatus comprising:

means for acquiring a first signal comprising a first desired signal portion and a first undesired signal portion and a second signal comprising a second desired signal portion and a second undesired signal portion;

means for determining from said first and second signals a noise reference signal; and

an adaptive noise canceler having a noise reference input for receiving said noise reference signal and a signal input for receiving said first signal wherein said adaptive noise canceler, in real or near real time, generates an output signal which approximates said first desired signal portion.

31. The physiological monitoring apparatus as defined in Claim 30 wherein said adaptive noise canceler further comprises a joint process estimator.

32. The physiological monitoring apparatus as defined in Claim 31 wherein said joint process estimator further comprises a least-squares lattice predictor in conjunction with a regression filter.

33. An apparatus for processing an amplitude modulated signal having a signal amplitude complicating

feature comprising:

an energy source for directing electromagnetic energy upon a specimen;

a detector for acquiring a first amplitude modulated signal and a second amplitude modulated signal, wherein each of said first and second signals has a component containing information about the attenuation of electromagnetic energy by the specimen and a signal amplitude complicating feature;

a reference processor for receiving said first and second amplitude modulated signals and deriving therefrom a noise reference signal which is correlated with the signal amplitude complicating feature; and

an adaptive noise canceler having a signal input for receiving said first amplitude modulated signal, a noise reference input for receiving said noise reference signal, wherein said adaptive noise canceler produces an output signal having a primary component which is derived from said component containing information about the attenuation of electromagnetic energy by the specimen.

34. The apparatus as defined in Claim 33 wherein said adaptive noise canceler further comprises a joint process estimator.

35. The apparatus as defined in Claim 34 wherein said joint process estimator further comprises a least-squares lattice predictor in conjunction with a regression filter.

36. An apparatus for extracting a plethysmographic waveform from an amplitude modulated signal having a signal amplitude complicating feature comprising:

a light source for transmitting light into an organism;

a detector for monitoring light from said organism to produce a first light attenuation signal and a second light attenuation signal, wherein each of said first and second light attenuation signals has a component which is representative of a plethysmographic waveform and a component which is representative of the signal amplitude complicating feature;

a reference processor for receiving said first and second light attenuation signals and deriving therefrom a noise reference signal, wherein said noise reference signal and said signal amplitude complicating feature each has a frequency spectrum, said frequency spectrum of said noise reference signal being correlated with the frequency spectrum of said signal amplitude complicating feature; and

an adaptive noise canceler having a signal input for receiving said first attenuation signal, a noise reference input for receiving said noise reference signal, wherein said adaptive noise canceler produces an output signal having a primary component which is derived from said component which is representative of a plethysmographic waveform.

37. The apparatus as defined in Claim 36 wherein said adaptive noise canceler further comprises a joint process estimator.

38. The apparatus as defined in Claim 37 wherein said joint process estimator further comprises a least-squares lattice predictor in conjunction with a regression filter.

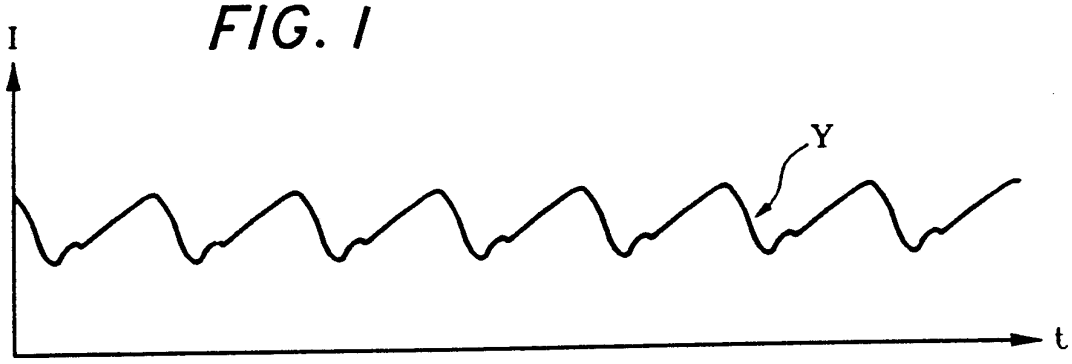
39. A method of removing a motion artifact signal from a signal derived from a physiological measurement comprising the steps of:

acquiring a first signal having a physiological measurement component and a motion artifact component and a second signal having a physiological measurement component and a motion artifact component; and

deriving from said first and second signals a motion artifact noise reference signal which is a primary function of said first and second signals motion artifact components.

40. A method as defined in Claim 39 further comprising the step of inputting said motion artifact noise reference signal into an adaptive noise canceler to produce an output signal which is a primary function of said first signal physiological measurement component.

FIG. 1



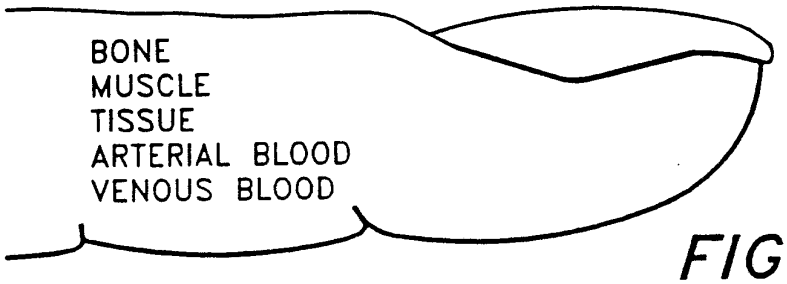
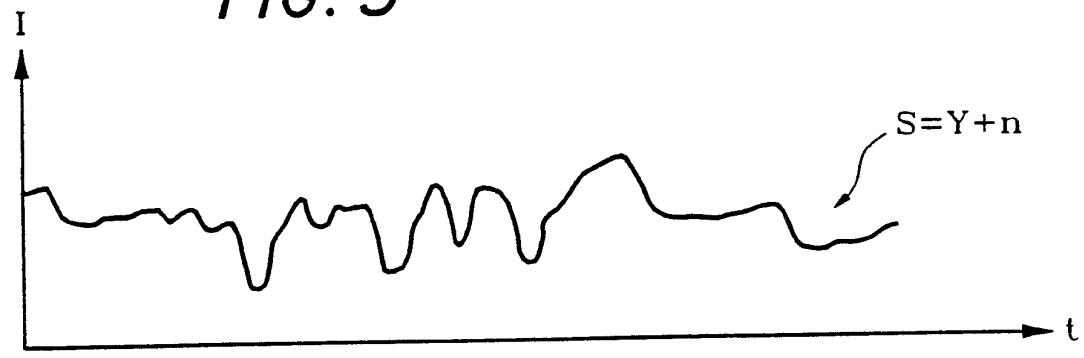


FIG. 2

FIG. 3



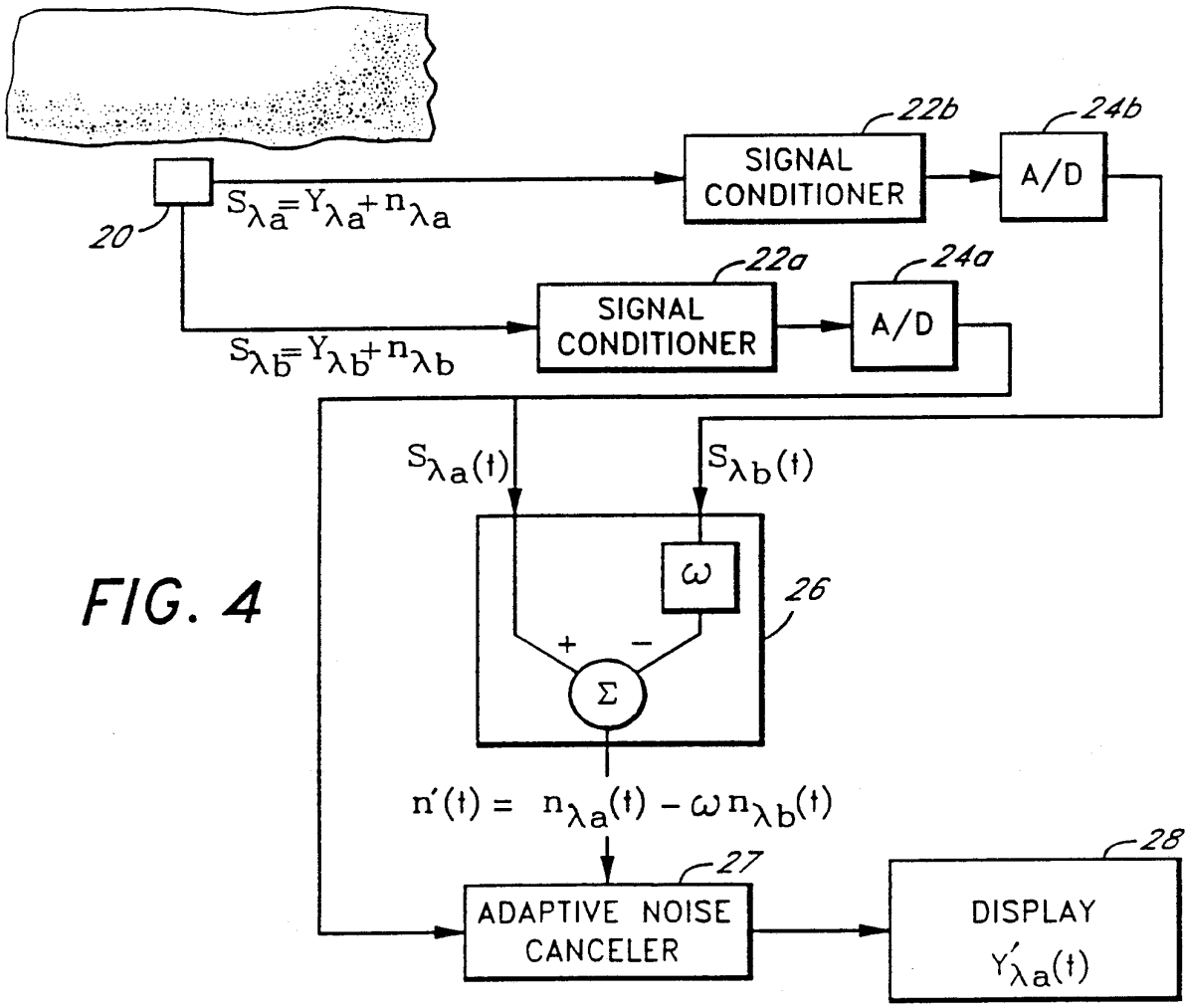

22b
24b
SIGNAL CONDITIONER
A/D
20
$S_{\lambda a} = Y_{\lambda a} + n_{\lambda a}$
22a
24a
SIGNAL CONDITIONER
A/D
$S_{\lambda b} = Y_{\lambda b} + n_{\lambda b}$
$S_{\lambda a}(t)$
$S_{\lambda b}(t)$
ω
26
+
−
Σ
$n'(t) = n_{\lambda a}(t) - \omega n_{\lambda b}(t)$
27
ADAPTIVE NOISE CANCELER
28
DISPLAY
$Y'_{\lambda a}(t)$

FIG. 4

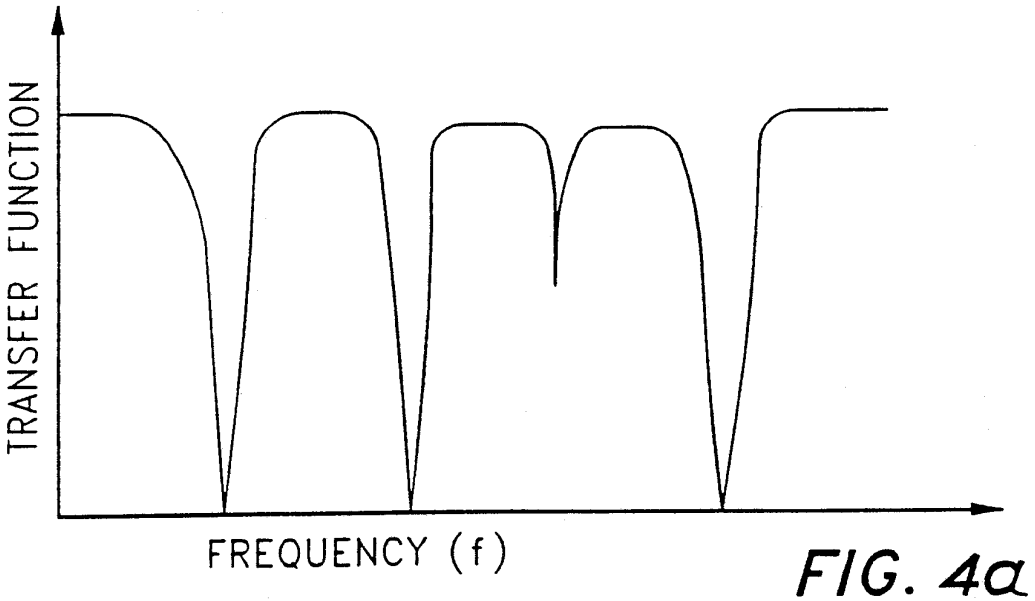

TRANSFER FUNCTION
FREQUENCY (f)

FIG. 4a

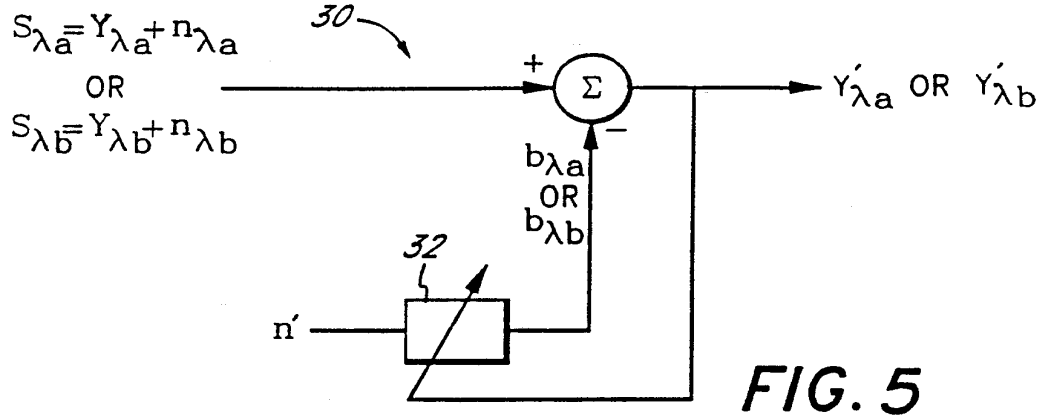


FIG. 5

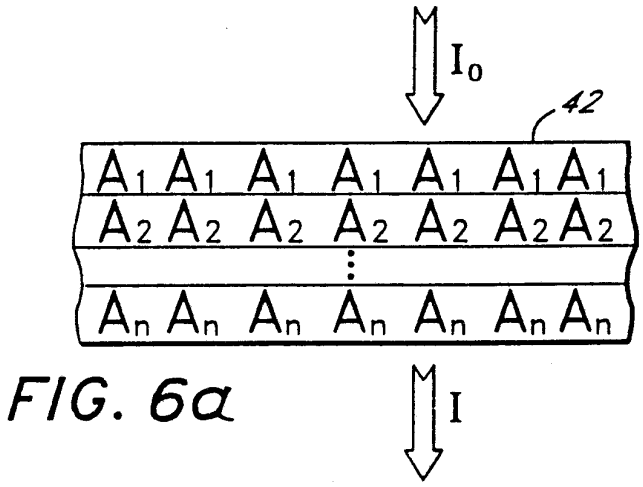


FIG. 6a

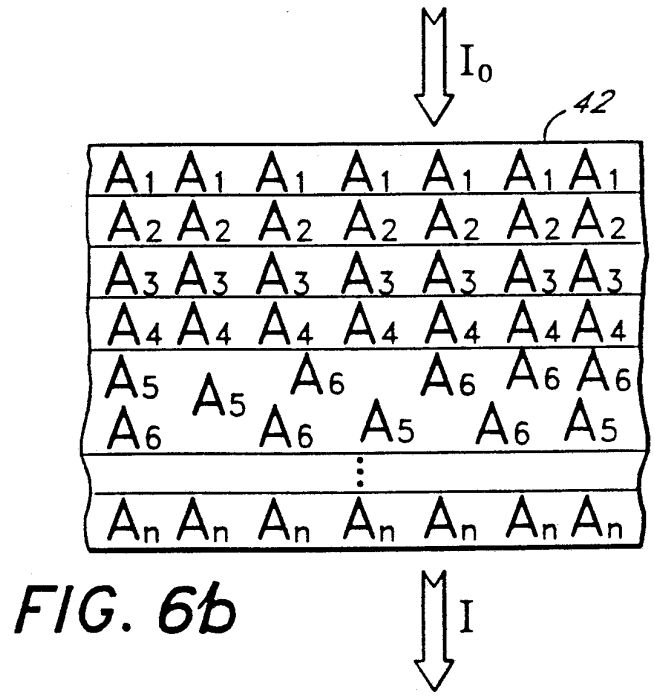


FIG. 6b

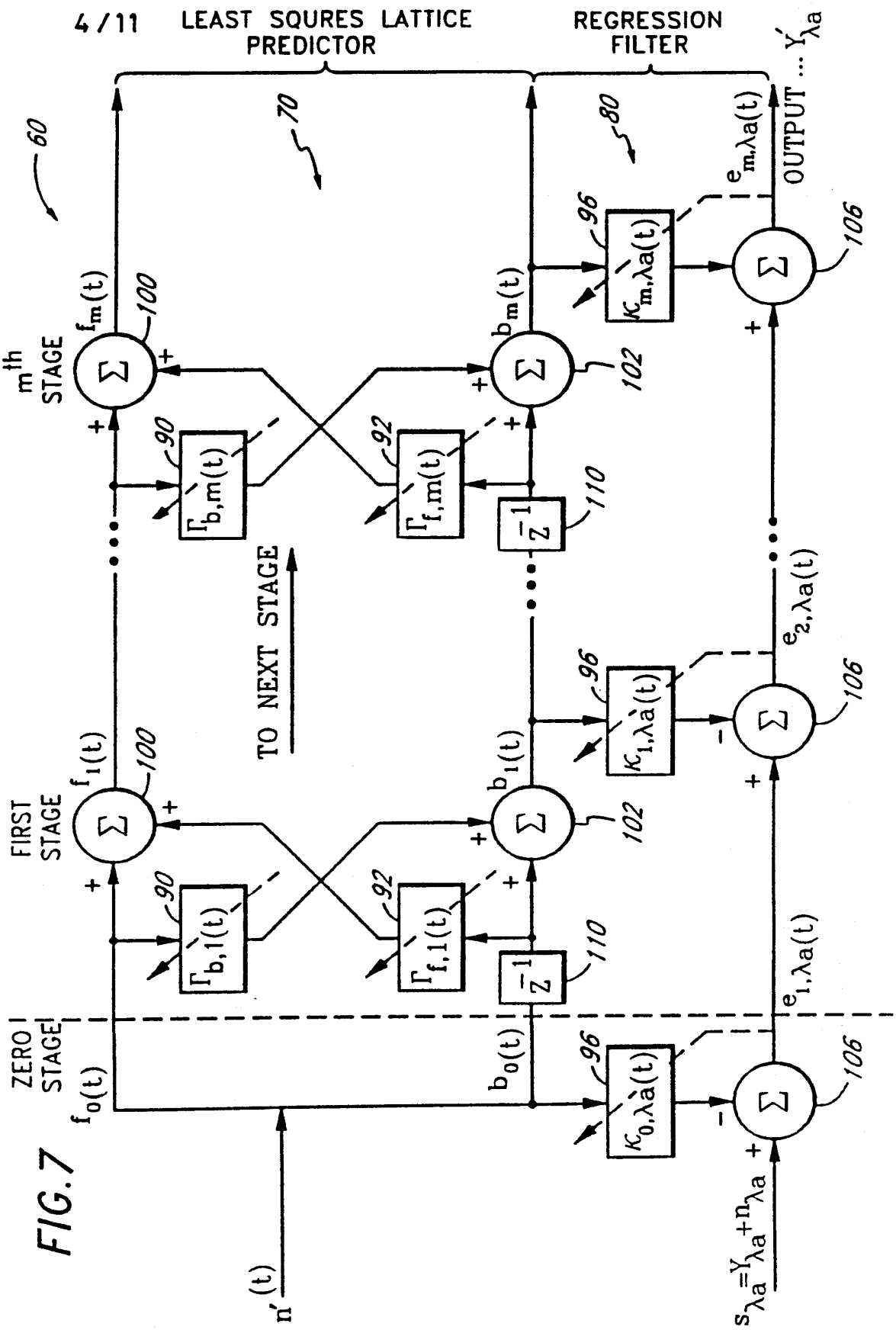

LEAST SQURES LATTICE PREDICTOR
REGRESSION FILTER
OUTPUT ... $Y'_{\lambda a}$
60
70
80
m^{th} STAGE
FIRST STAGE
ZERO STAGE
$f_m(t)$
$f_1(t)$
$f_0(t)$
$b_m(t)$
$b_1(t)$
$b_0(t)$
$e_{m,\lambda a}(t)$
$e_{2,\lambda a}(t)$
$e_{1,\lambda a}(t)$
$\kappa_{m,\lambda a}(t)$
$\kappa_{1,\lambda a}(t)$
$\kappa_{0,\lambda a}(t)$
$\Gamma_{b,m}(t)$
$\Gamma_{f,m}(t)$
$\Gamma_{b,1}(t)$
$\Gamma_{f,1}(t)$
Z^{-1}
TO NEXT STAGE
$n'(t)$
$s_{\lambda a}=Y_{\lambda a}+n_{\lambda a}$
90
92
96
100
102
106
110

FIG. 7

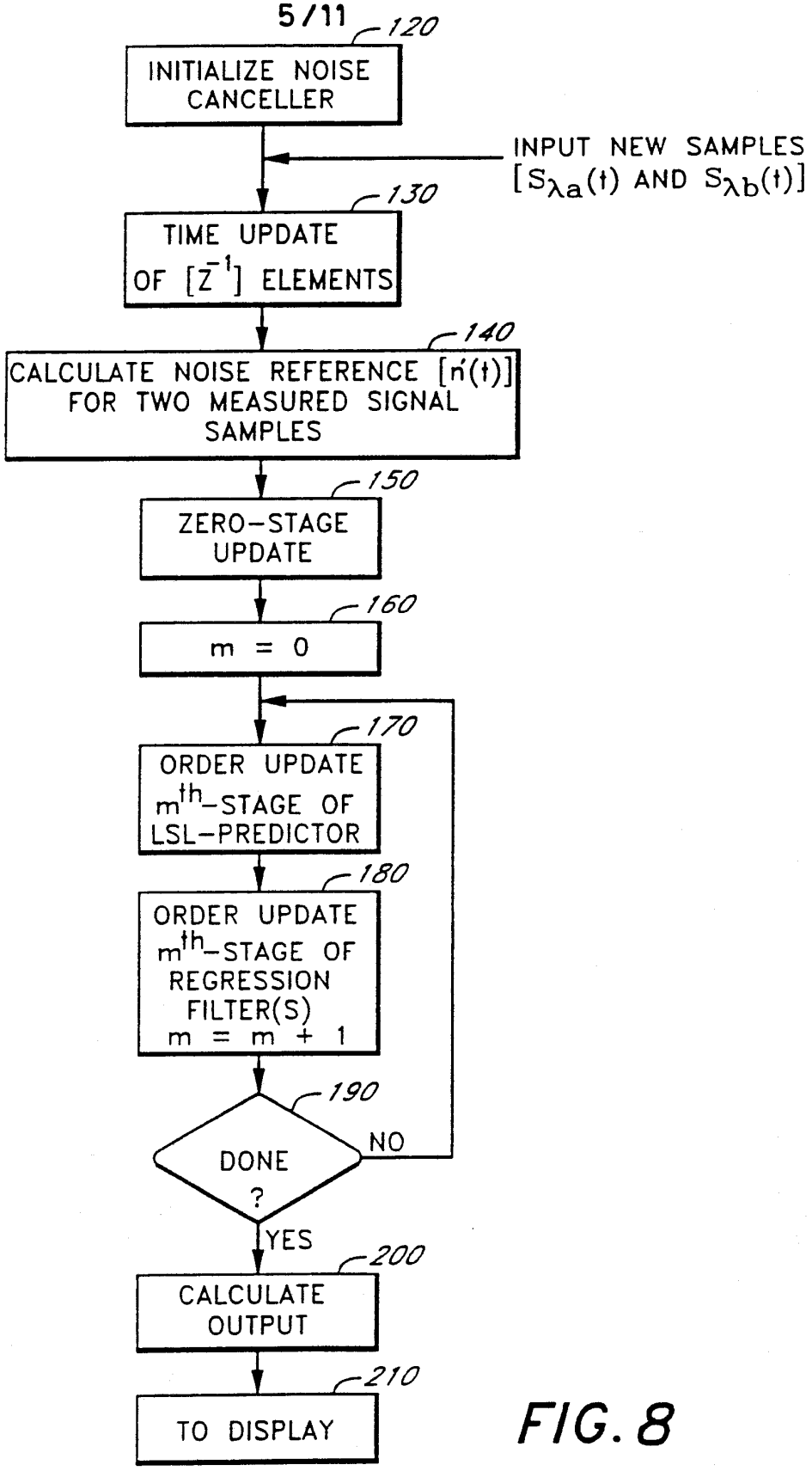

120
INITIALIZE NOISE CANCELLER
INPUT NEW SAMPLES [$S_{\lambda a}(t)$ AND $S_{\lambda b}(t)$]
130
TIME UPDATE OF [Z^{-1}] ELEMENTS
140
CALCULATE NOISE REFERENCE [$\hat{n}(t)$] FOR TWO MEASURED SIGNAL SAMPLES
150
ZERO-STAGE UPDATE
160
m = 0
170
ORDER UPDATE m^{th}-STAGE OF LSL-PREDICTOR
180
ORDER UPDATE m^{th}-STAGE OF REGRESSION FILTER(S) m = m + 1
190
DONE ?
NO
YES
200
CALCULATE OUTPUT
210
TO DISPLAY

FIG. 8

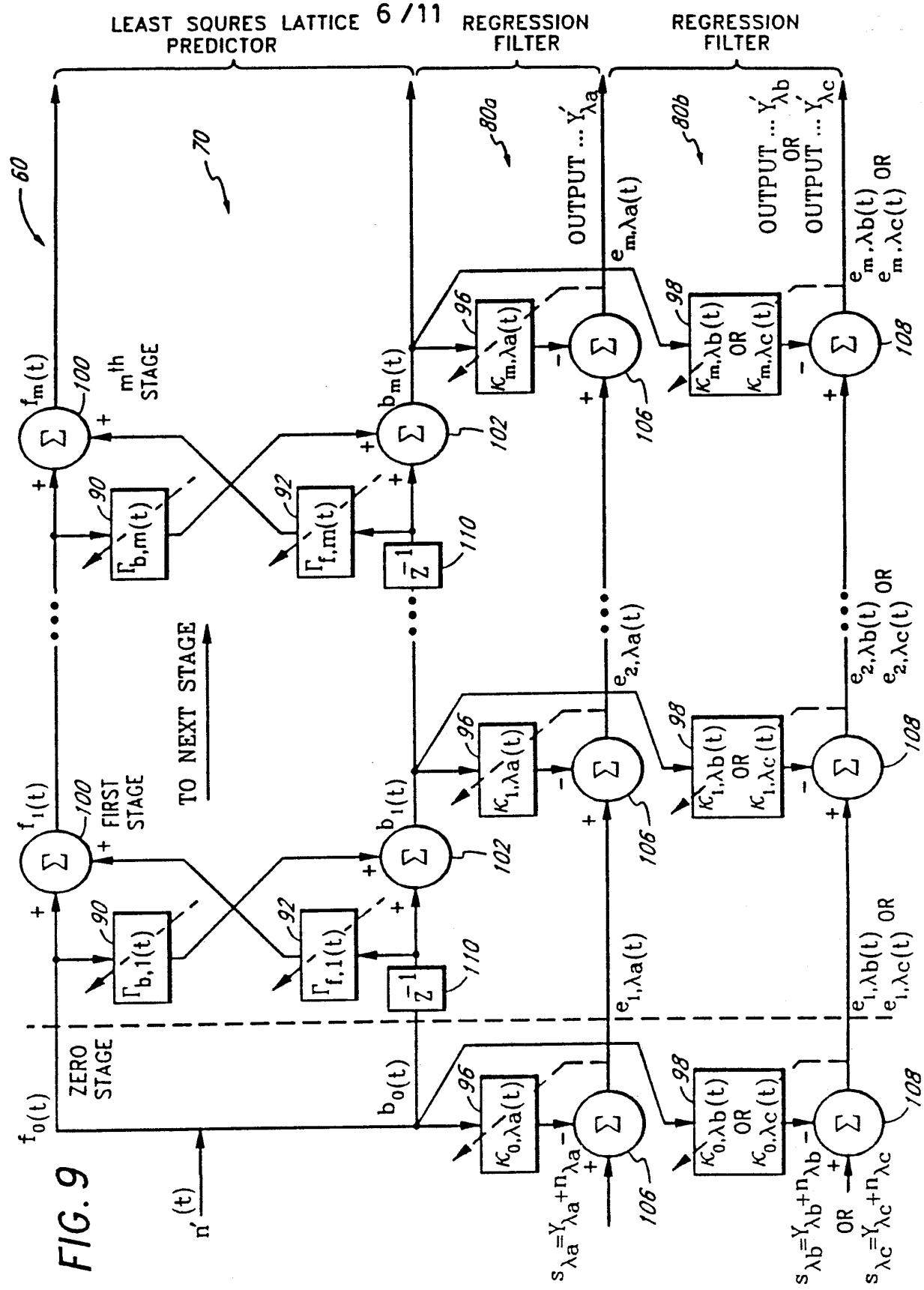

LEAST SQURES LATTICE PREDICTOR
REGRESSION FILTER
REGRESSION FILTER
60
70
80a
80b
OUTPUT ... $Y'_{\lambda a}$
OUTPUT ... $Y'_{\lambda b}$ OR OUTPUT ... $Y'_{\lambda c}$
$f_m(t)$
m^{th} STAGE
$b_m(t)$
$f_1(t)$
FIRST STAGE
$b_1(t)$
$f_0(t)$
ZERO STAGE
$b_0(t)$
TO NEXT STAGE
$e_{m,\lambda a}(t)$
$e_{m,\lambda b}(t)$ OR $e_{m,\lambda c}(t)$
$e_{2,\lambda a}(t)$
$e_{2,\lambda b}(t)$ OR $e_{2,\lambda c}(t)$
$e_{1,\lambda a}(t)$
$e_{1,\lambda b}(t)$ OR $e_{1,\lambda c}(t)$
$\Gamma_{b,m}(t)$
$\Gamma_{f,m}(t)$
$\Gamma_{b,1}(t)$
$\Gamma_{f,1}(t)$
$\kappa_{m,\lambda a}(t)$
$\kappa_{m,\lambda b}(t)$ OR $\kappa_{m,\lambda c}(t)$
$\kappa_{1,\lambda a}(t)$
$\kappa_{1,\lambda b}(t)$ OR $\kappa_{1,\lambda c}(t)$
$\kappa_{0,\lambda a}(t)$
$\kappa_{0,\lambda b}(t)$ OR $\kappa_{0,\lambda c}(t)$
Z^{-1}
90
92
96
98
100
102
106
108
110
$n'(t)$
$s_{\lambda a}=Y_{\lambda a}+n_{\lambda a}$
$s_{\lambda b}=Y_{\lambda b}+n_{\lambda b}$ OR $s_{\lambda c}=Y_{\lambda c}+n_{\lambda c}$

FIG. 9

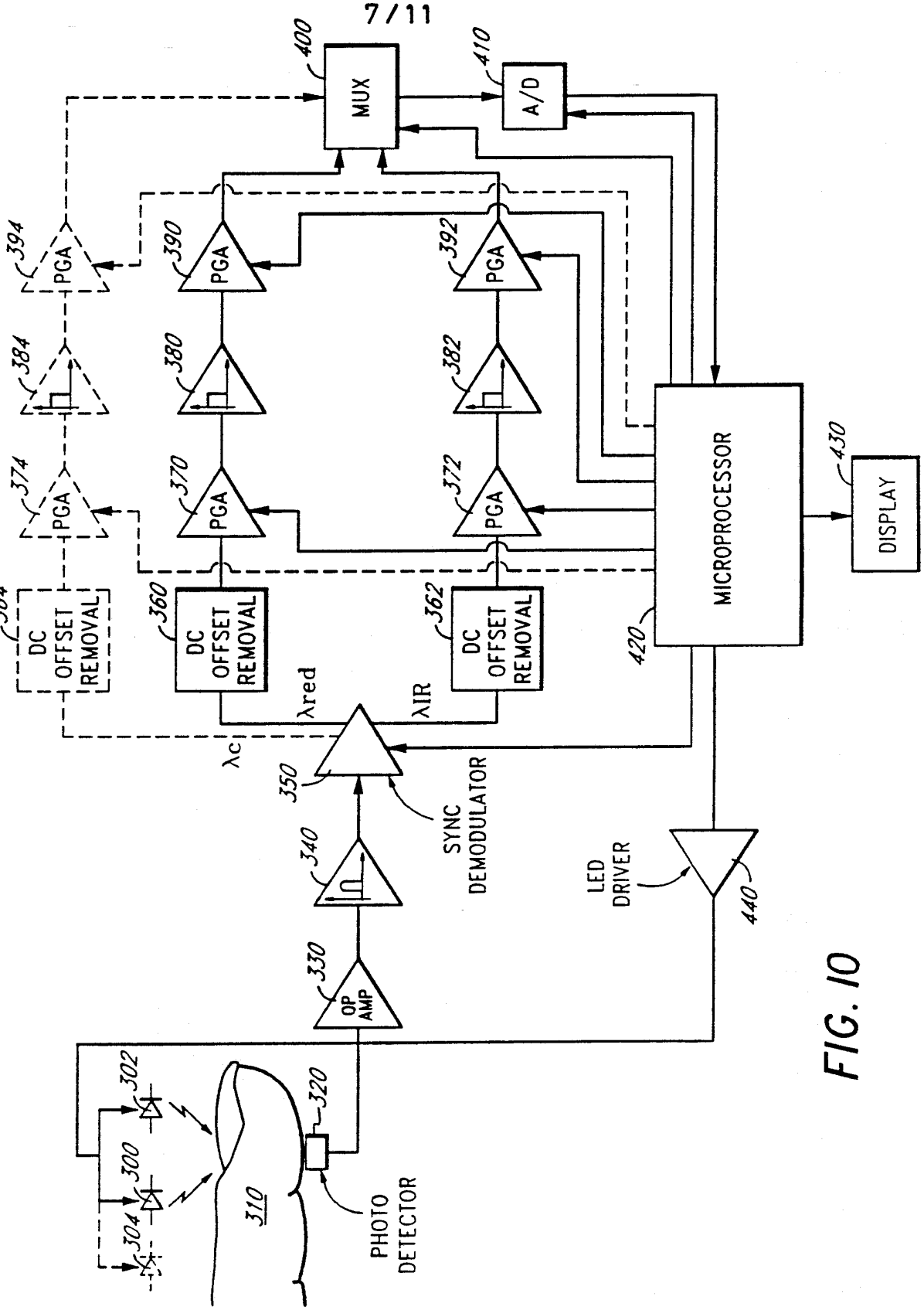
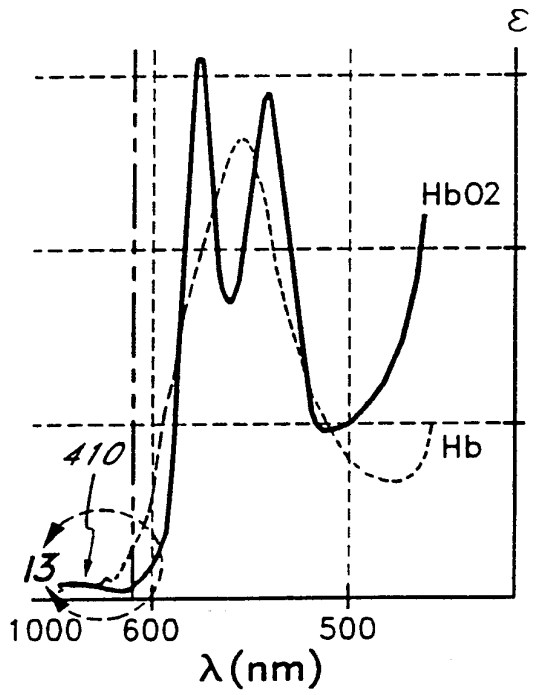

400
MUX
410
A/D
394
PGA
390
PGA
392
PGA
384
380
382
374
PGA
370
PGA
372
PGA
364
DC OFFSET REMOVAL
360
DC OFFSET REMOVAL
362
DC OFFSET REMOVAL
λred
λIR
λc
350
SYNC DEMODULATOR
340
330
OP AMP
MICROPROCESSOR
420
430
DISPLAY
LED DRIVER
440
302
300
304
310
320
PHOTO DETECTOR

FIG. 10

FIG. 11


ε
HbO2
Hb
410
13
1000
600
500
λ(nm)

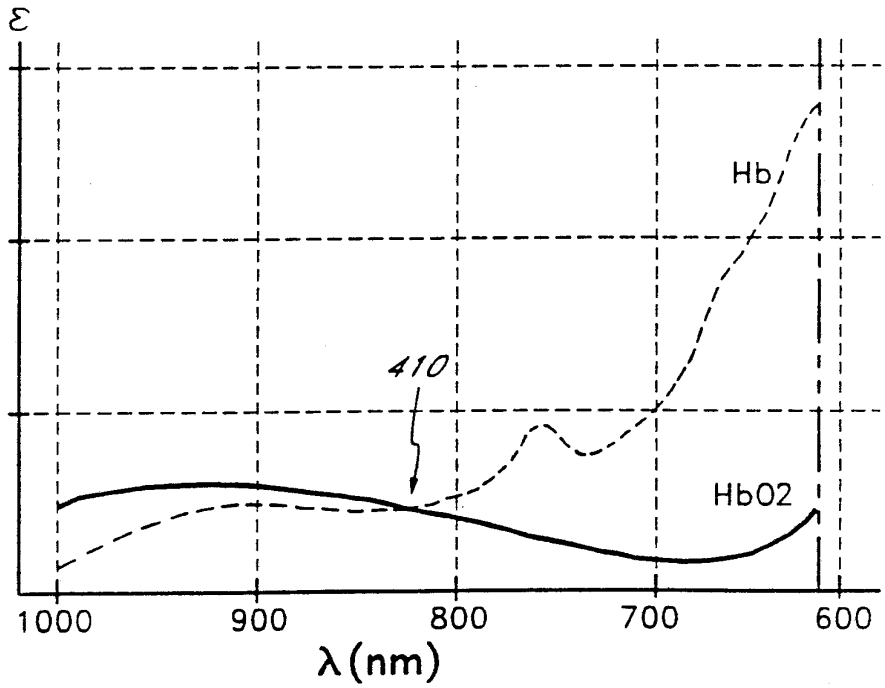

ε
Hb
410
HbO2
1000
900
800
700
600
λ(nm)

FIG. 13

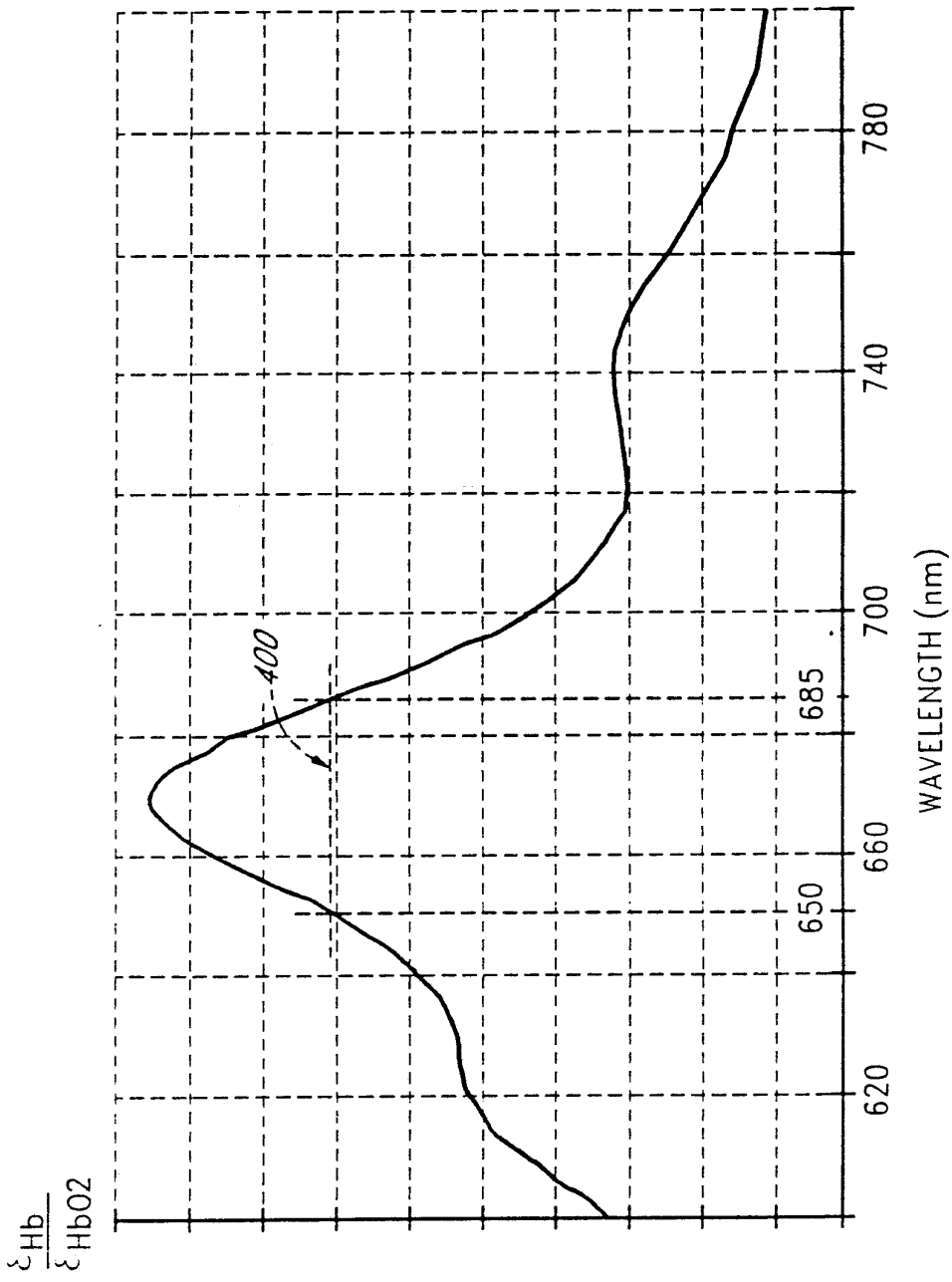

$\frac{\varepsilon Hb}{\varepsilon HbO2}$
400
620
650
660
685
700
740
780
WAVELENGTH (nm)

FIG. 12

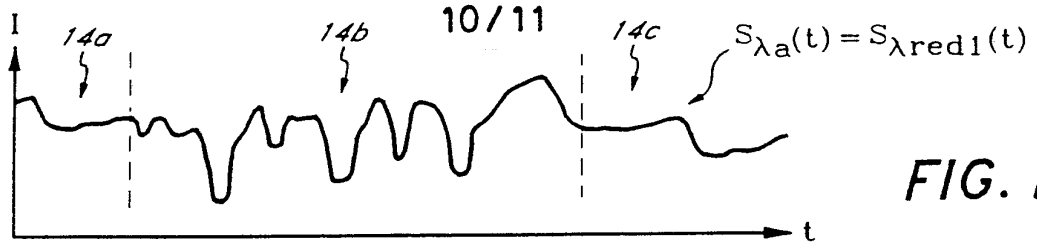


FIG. 14

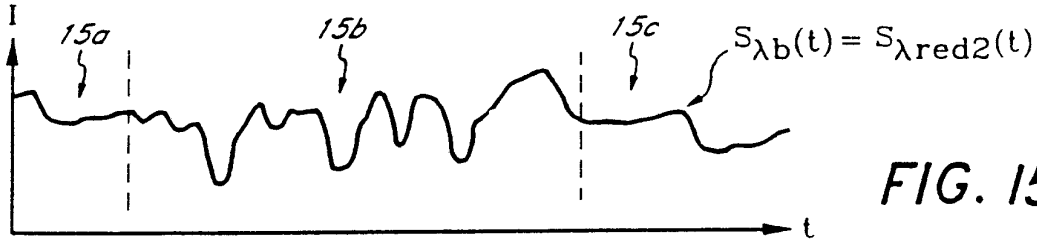


FIG. 15

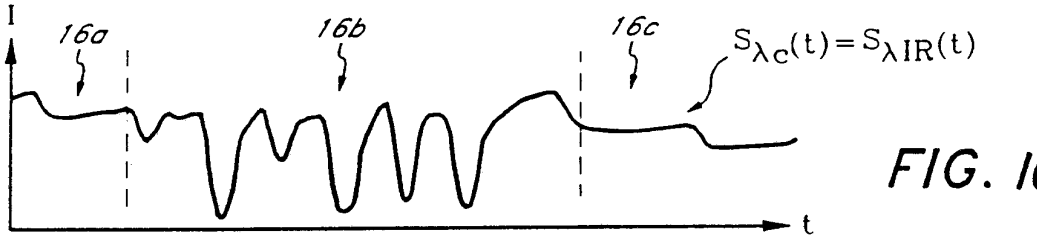


FIG. 16

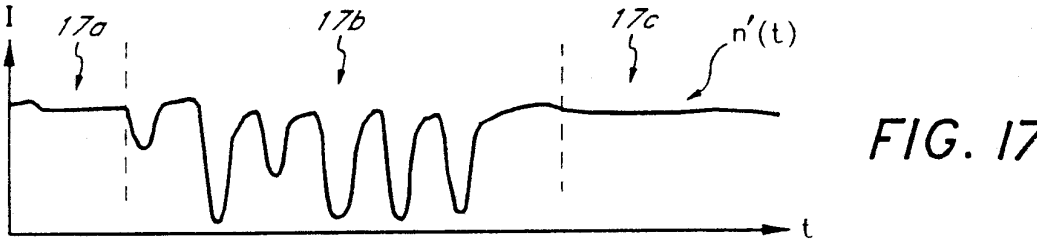


FIG. 17

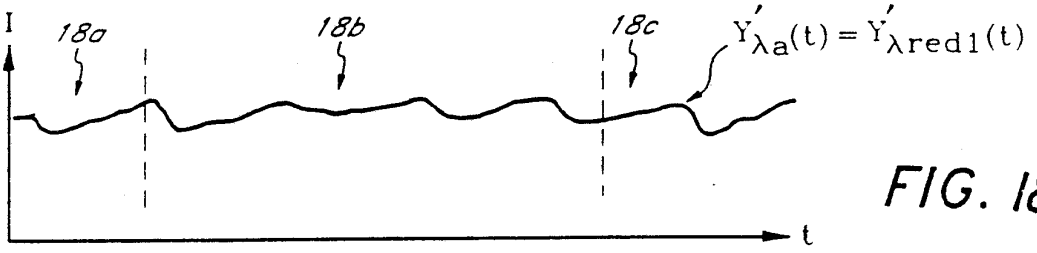


FIG. 18

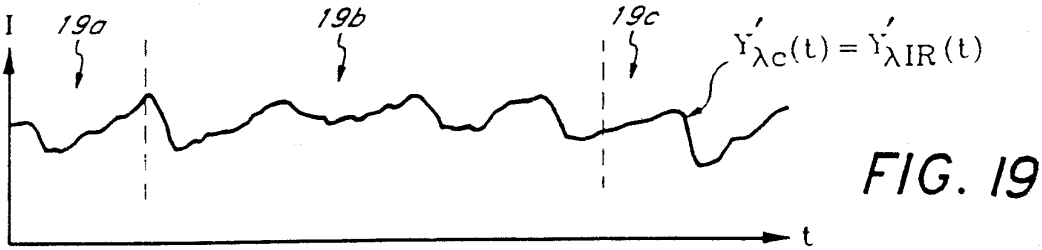


FIG. 19

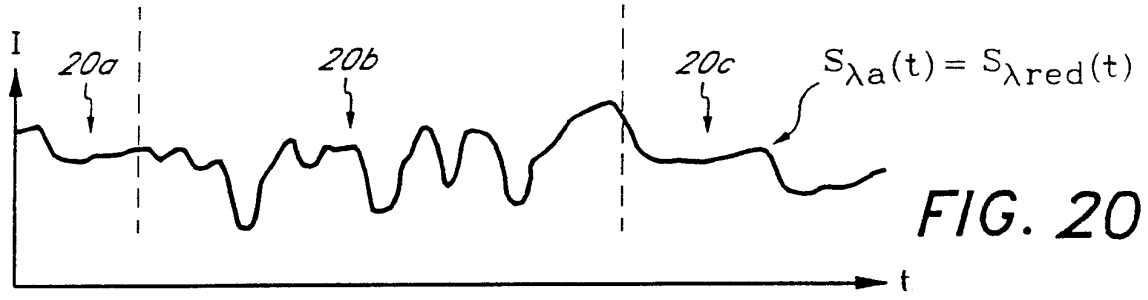


FIG. 20

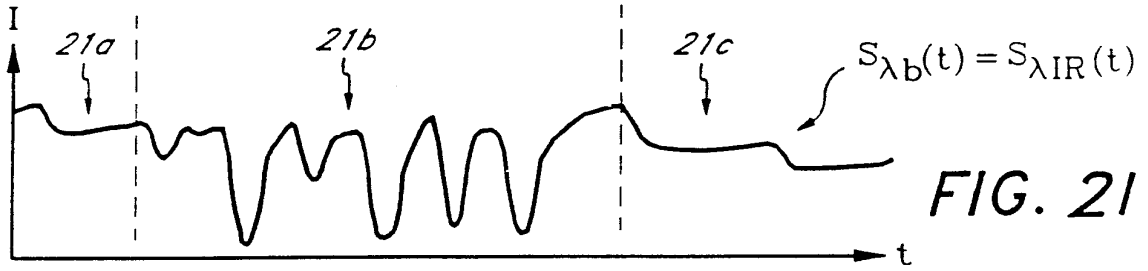


FIG. 21

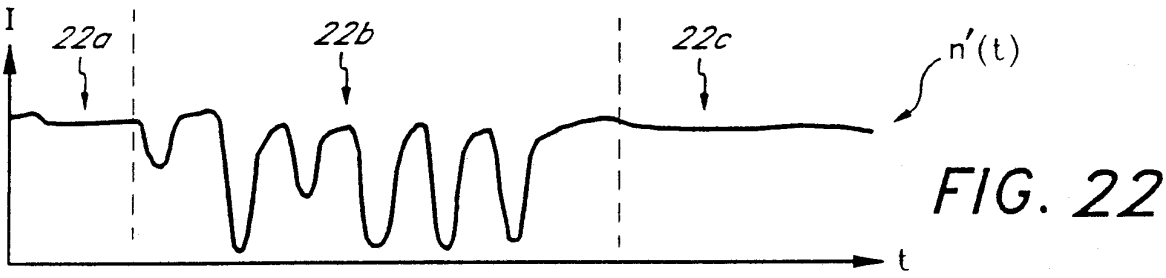


FIG. 22

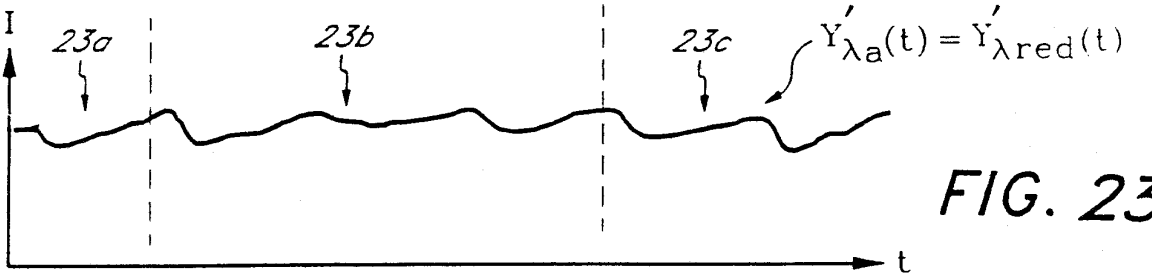


FIG. 23

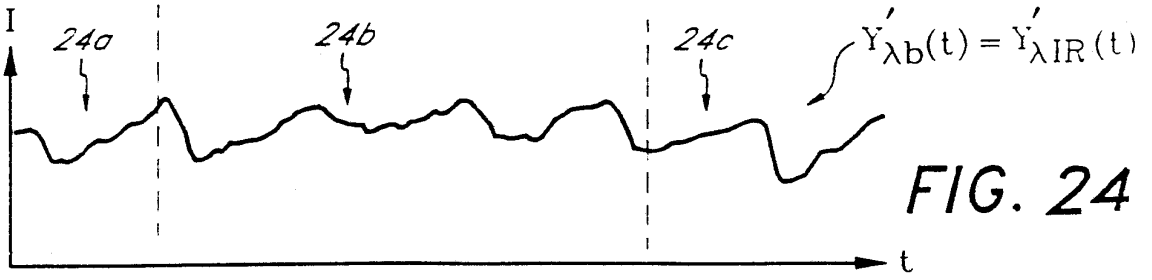


FIG. 24

INTERNATIONAL SEARCH REPORT

International Application No. PCT/US92/01895

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5) G06F 15/42; U.S. CL. 364/413.07

II. FIELDS SEARCHED

Minimum Documentation Searched [7]

Classification System	Classification Symbols
US	128/633 364/572, 574, 413.03, 413.07, 413.09 356/41

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
A	US, A, 4,649,505 (Zinser, Jr et al.), 10 March 1987, Fig. 2, 2a & 4.	1-22
A	US, A, 4,956,867 (Zurek et al.), 11 September 1990, Fig. 2, 3, 4 and col. 3.	1
Y	US, A, 4,537,200 (Widrow), 27 August 1985, Cols. 3-6.	1-17
A	US, A, 4,799,493 (DuFault), 24 January 1989, Figs. 4 and 5.	1-22
Y	US, A, 4,793,361 (DuFault), 27 December 1988, Entire reference.	1-22
Y	ADAPTIVE SIGNAL PROCESSING, (Bernard Widrow et al.), 1985, "Adaptive Interface Cancelling," Chapter 12.	1-40
Y	US, A, 4,867,571 (Frick et al.) 19 September 1989, Entire reference.	1-40

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

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"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
14 May 1992	25 JUN 1992
International Searching Authority	**Signature of Authorized Officer**
ISA/US	for Andrew Bodendorf NGUYEN NGOC-HO INTERNATIONAL DIVISION

Form PCT/ISA/210 (second sheet) (Rev.11-87)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y	US, A, 4,863,265 (Flower et al.), 05 September 1989, Col. 4 and Fig. 1.	1-40
Y	US, A, 4,824,242 (Frick et al.), 25 April 1989, Entire reference.	1-40
A	US, A, 4,063,551 (Sweeny), 20 December 1977, Fig. 3.	1-33

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ..... , because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

3. ☐ Claim numbers_____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [2]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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		(43) International Publication Date: 26 November 1992 (26.11.92)

(21) International Application Number: PCT/US92/04153

(22) International Filing Date: 18 May 1992 (18.05.92)

(30) Priority data:
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(60) Parent Application or Grant
(63) Related by Continuation
US 701,127 (CIP)
Filed on 16 May 1991 (16.05.91)

(71) Applicant *(for all designated States except US)*: NIM INCORPORATED [US/US]; 3624 Market Street, Suite 508, Philadelphia, PA 19104 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)* : CHANCE, Britton [US/US]; 4014 Pine Street, Philadelphia, PA 19104 (US).

(74) Agent: WILLIAMS, John, W.; Fish & Richardson, 225 Franklin Street, Boston, MA 02110-2804 (US).

(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent), US.

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: HEMOGLOBINOMETERS AND THE LIKE FOR MEASURING THE METABOLIC CONDITION OF A SUBJECT

(57) Abstract

An oximeter for determining the oxygenation state of localized body tissue per se, constructed to be worn over a period of activity by a user and comprising a flexible, body-conformable support member which supports, adjacent the skin of a user, over the localized tissue of interest, at least a pair of spaced apart light sources, and intermediate thereof, at least a pair of wavelength-specific photo detectors, each light source exposed to transmit wavelengths of both of said specific wavelengths toward the localized tissue of interest lying below the skin and below the associated subcutaneous fat layer of the user, and each detector exposed to receive photons of the respective specific wavelength that have originated from each light source, and scattered from the localized tissue and passed back to the detectors through the subcutaneous fat layer and skin of the user, the support member including conformable barrier means disposed between each light source and the detectors, said barrier means being of substance capable of conforming to the contour of the wearer and preventing light energy proceeding laterally in the region of the barrier means from reaching the detectors.

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HEMOGLOBINOMETERS AND THE LIKE FOR MEASURING THE METABOLIC CONDITION OF A SUBJECT

Background of the Invention

In one aspect, the present invention relates to wearable apparatus for noninvasive determinations of the concentration of oxygen in a specific target region of tissue. More specifically, the present invention discloses a user-wearable system for monitoring the oxygen concentration, or oxygenation trend, in the tissue of a subject undergoing aerobic stress, such as an exercising person.

The increasing popularity of all forms of exercise over the last several decades has also lead to an increased interest in the measurement of individual athletic performance. However, at the present time, athletes are limited to obtaining heartbeat and blood pressure data while they are exercising. Although of some use, these data do not reflect peripheral circulatory capacity or the oxygenation state of specific muscle tissue.

In order to measure oxygen delivery to the capillary bed of the muscles, an athlete must be tethered to electrocardiogram apparatus and have blood samples drawn while running on a treadmill. These are essentially operating room apparatus and procedures, which do not simulate the actual conditions of exercise. The measurement of aerobic efficiency by analyzing the oxygenation state of a particular muscle while exercising is important due to a variety of reasons. For example, as a casual jogger strives to become a marathon runner, the efficiency at which he/she uses oxygen can severely impact performance; data reflecting the utilization of oxygen can provide information which allows an athlete to

change pacing strategies or otherwise adjust their activity to produce better results. Other athletes, such as swimmers, cyclists and rowers would also find this information useful for evaluating performance. However, the use of blood oxygenation data is not limited to competitive athletes; even geriatrics who undergo mild aerobic exercise to maintain and improve their health can benefit from data concerning the changes in blood oxygenation brought about by exercise or other activity. Other animals, such as racehorses, can also benefit from this type of performance data. By measuring the oxygen delivery to the muscles, both the quality of training and the natural ability to exercise may be evaluated.

In addition to monitoring and maximizing athletic performance, information pertaining to the delivery of oxygen to the limbs and the brain is important in military and space applications where changes in gravity and other stresses may result in fatigue, and ultimately, blackouts.

Although apparatuses which measure the oxygenation content of blood using data collected from a fingertip or ear lobe are available, these devices do not actually measure the oxygenation state of nearby muscle groups or the brain. To monitor athletic performance, or the condition of exerted muscles, data collection must be performed at the site of interest. For example, runners will wish to be provided with this information during a race, not in a laboratory. Therefore, for an apparatus measuring the metabolic condition of an athlete to be truly useful, a rugged, lightweight, user-wearable system must be provided.

One method by which the oxygen level in a muscle may be measured is tissue spectrometry. For example, red and near-red light, having wavelengths between about 600-800 nanometers (nm), will harmlessly penetrate body

tissues. As the light penetrates the tissue, it migrates and is absorbed by deoxygenated hemoglobin in small blood vessels. Normally, tissue receives oxygen from hemoglobin contained in red blood cells, which circulate in the major blood vessels and eventually into the capillary bed, supplying muscle tissue with oxygen. Aerobic activity can cause the level of oxygen use to rise, causing a commensurate rise in the level of deoxyhemoglobin which is compensated for by increased blood flow in trained individuals. Near-red light is absorbed by tissue that is not receiving as much oxygen as the surrounding tissue due to increased levels of deoxyhemoglobin in less trained individuals. Thus, by determining the amount of incident radiation absorbed, the oxygenation state of a specific area of tissue, and the training level of an individual, can be determined.

The present invention also relates to a study of the linkage between cerebral activity and oxygen delivery and oxidative metabolism in the brain tissue. During a brain activity, blood flow can be studied using PET or NMR. Faster electrical and magnetic responses can be measured using EEG and MEG. While these techniques eventually might be able to provide examination and screening for neuronal deterioration and/or deterioration of brain function, they are relatively expensive and not suitable for emergency treatment situations wherein the diagnostic equipment should be taken to a patient. Optical techniques, on the other hand, might provide a suitable, cost effective alternative for examination and screening of a tissue of an organ.

SUMMARY OF THE INVENTION

The present invention provides a novel, wearable system for determining the metabolic condition of an aerobically stressed portion of the muscle tissue of an exercising person. The system comprises a lightweight

rugged detector, worn against the skin surface of the subject, adjacent to the muscle being monitored. The system of the present invention thus minimizes any performance impairment. The preferred system further comprises a wearable power pack and a wearable display means for displaying information indicative of the aerobic metabolic condition of the region being monitored. In a preferred embodiment intended for use while running or engaged in similar athletic activities, the display is worn on the wrist and displays information from a leg-mounted detector. In another embodiment, intended to provide information to coaches, a telemetry system is employed to transmit a signal carrying the data from the detector to a remote location, for processing and display.

The detector of the present invention preferably employs a continuous wave spectrophotometer having one or more sources of electromagnetic radiation with wavelengths between about 760 nanometers and about 800 nanometers directed into the tissue of the subject. The detector is efficiently coupled to the body tissue and utilizes the principle of photon migration to detect the portion of the transmitted radiation arriving at an adjacent skin region.

The present invention also discloses methods for displaying the aerobic metabolic condition of a subject. The percentage of deoxyhemoglobin in the blood of the subject is determined, and a signal representative of this percentage is converted into a graphic representation. The display may preferably be a digital display, a bar graph or a series of deoxyhemoglobin levels, placed on a time scale.

OBJECTS AND FEATURES OF THE INVENTION

It is an object of the present invention to provide methods and apparatus which allow a rapid

determination of the oxygenation state of tissue, such as muscle tissue, located beneath the surface of the skin of a subject, such as an athlete, without requiring the subject to be tethered or physically connected to laboratory or operating room monitoring equipment.

It is also an object of the present invention to provide apparatus which may be attached to a user which would determine the oxygenation state of a portion of the user's body and provide that information in a readily understandable form.

It is a further object of certain embodiments of the present invention to provide information pertaining to the oxygenation state of tissue directly to a user wearing the apparatus of the present invention.

It is another object of certain embodiments of the present invention to transmit information pertaining to the oxygenation state of tissue to a remote observer.

According to one aspect of the invention, an oximeter is provided for determining the oxygenation state of localized body tissue per se, constructed to be worn over a period of activity by a user and comprising a flexible, body-conformable support member which supports, adjacent the skin of a user, over the localized tissue of interest, at least a pair of spaced apart light sources, and intermediate thereof, at least a pair of wavelength-specific photo detectors, each light source exposed to transmit wavelengths of both of the specific wavelengths toward the localized tissue of interest lying below the skin and below the associated subcutaneous fat layer of the user, and each detector exposed to receive photons of the respective specific wavelength that have originated from each light source, and scattered from the localized tissue and passed back to the detectors through the subcutaneous fat layer and skin of the user, the support member including conformable barrier means disposed

between each light source and the detectors, the barrier means being of substance capable of conforming to the contour of the wearer and preventing light energy proceeding laterally in the region of the barrier means from reaching the detectors.

Somewhat more generally, according to another aspect of the invention, an oximeter is provided for determining the oxygenation state of localized body tissue per se, constructed to be worn over a period of activity by a user and comprising a flexible support member which supports, over the localized tissue of interest, at least a pair of spaced apart light sources, and intermediate thereof, at least a pair of wave length-specific light detectors (e.g., photo detectors), each light source exposed to transmit wavelengths of both of the specific wavelengths toward the localized tissue of interest, and each detector exposed to receive photons of the respective specific wavelength that have originated from each light source, and scattered from the localized tissue and passed back to the detectors.

Preferred embodiments of these aspects of the invention have one or more of the following features.

The light sources comprise broad spectrum CW light sources.

The light sources comprise tungsten filament lamps.

The oximeter includes control means for simultaneously flashing the light sources to enable each detector to pick up light energy at its specific wavelength simultaneously from each light source.

Means are provided to flash the light sources at selected intervals unrelated to the interval of heart beats of the user.

According to another aspect of the invention, an oximeter is provided comprising a flexible support member

comprised of a molded-elastomeric backing member, the backing member mounting at least one light source means capable of producing one or more (e.g., two) selected wavelengths and oriented to direct the light to tissue of a user and the backing member also mounting detector means capable of separately detecting energy at each of the wavelengths scattered by tissue of the user, integral elastomeric portions of the backing member defining a barrier exposed for conformable contact with an exposed surface of the user, in position to prevent lateral movement of light in subcutaneous layers from the source means to the detector means.

According to another aspect of the invention, an oximeter is provided comprising a flexible support member, the support member mounting at least one light source means capable of producing two selected wavelengths and oriented to direct the light to tissue of a user and the support member mounting detector means capable of separately detecting energy at each of the wavelengths scattered by tissue of the user, the support member supporting a barrier member exposed for conformable contact with an exposed surface of the user in position to prevent lateral movement of light from the source means to the detector means, the barrier comprising a member having an edge sized and positioned to indent skin and the flesh of the user thereby to intercept light migrating laterally in the subcutaneous fat layer and prevent such light from reaching said detector means.

Preferred embodiments of these aspects of the invention have one or more of the following features.

The barrier member is elastomeric, adapted to conform to the contour of the skin of the wearer.

The flexible support member comprises a molded-elastomeric backing member and the barrier member is integral with the backing member.

The member defining the flesh-indenting edge is about 0.5 cm thick in the region that engages the skin.

The barrier member comprises a rib-form member.

There are in series at least one (e.g., two) barrier members, one closely adjacent to the light source means and one closely adjacent to the detector means.

The support member mounts at least one (e.g., two) spaced-apart light sources and at least one (e.g., a pair) of detectors are disposed parallel to each other, disposed laterally relative to the line between the light sources and equal distance from each of the light sources.

The light sources comprise broad spectrum CW light sources.

Electronic control circuitry for the light source and the detector means are provided in which the circuitry is disposed upon a miniature semiconductor chip carried by the support member.

Electronic control circuitry is provided comprised of entirely non-magnetic components enabling use of the device in conjunction with nuclear magnetic resonance imaging.

The oximeter is combined with a real-time readout device constructed to be worn by the user and having a display responsive to the oximeter disposed for viewing by the user.

The oximeter is associated with means securing it to an appendage of the user and the readout device is constructed to be worn by a user.

The oximeter is combined with radio frequency telemetry means for transmitting oximeter data on a real time basis to a station remote from the user or to a

receiver in a readout device constructed to be worn by a user.

The oximeter includes electronic control circuitry for the light source and the detector means, the circuitry disposed upon a miniature semiconductor chip carried by the support member in combination with radio frequency telemetry means controlled by the circuitry for transmitting oximeter data on a real time basis to a station remote from the user.

Means are provided for battery-operation of the oximeter and to record oximetry data in internal digital memory for subsequent display or data analysis on a computer.

The oximeter includes electronic control circuitry for the light source and the detector means, the circuitry disposed upon a miniature semiconductor chip carried by the support member, and means for battery-operation of the oximeter and means to record oximetry data in internal digital memory for subsequent display or data analysis on a computer.

According to still another device aspect of the invention, an oximeter is provided comprising a support mounting a light source and detector means at fixed spacing, and electronic control circuitry for the light source and the detector means, the circuitry disposed upon a miniature semiconductor chip carried by the support member, the oximeter encapsulated in biocompatible, water impermeable material, the oximeter constructed and arranged for implantation under the skin of a user for monitoring internal tissue oxygen trends.

The invention also features a number of methods. The method is provided of monitoring the derivative or rate of change of the time based curve representing detected change of tissue oxygen levels and blood volume

and employing these rates as a quantitative standard of measurement of tissue oximetry.

The method is provided of assisting an aviator or other person engaged in activity that can subject the person to high G-forces including providing to the person a comfortable oximeter sensor suitable to be worn about the head (e.g., either integrally in a helmet or helmet lining) and capable of responding to tissue oxygen level and blood volume of brain tissue on a real time basis, employing the oximeter sensor to monitor oxygen level of brain tissue of the wearer as the wearer engages in the activity, comparing the monitored value to a standard and generating a signal, such as a warning or control signal, in the event the monitored level(s) violate(s) a pre-established standard.

Preferably, the oximeter is constructed to monitor the trend of oxygen level in the brain, and means are provided to evaluate the rate of change being detected and using the rate of change as the control value and alarm reference.

The method is provided of monitoring a person suspect of sleep apnea or sudden infant death syndrome including providing to the person a comfortable oximeter sensor capable of automatically responding to oxygen level of the person while permitting the person to sleep, automatically monitoring the output of the oximeter by comparing it to a standard and generating a signal, such as a warning or control signal, in the event the monitored level violates a pre-established standard. Preferably the oximeter sensor is taped comfortably to the head for monitoring. Also, preferably the method is used in conjunction with impedance pneumography (breathing rate measurement using chest-wall impedance) and/or EKG to provide an effective in-home apnea monitor to alarm the patient or other individuals in the area so

as to wake the patient and prevent hypoxic tissue damage during sleep.

The method is provided of monitoring the cerebral tissue oxygen rate of change as a means of triggering alarm to awaken a subject in danger of infarct due to hypoxia.

The method is provided of monitoring both tissue oxygen level and blood volume in skin flaps such as are produced either by wound or surgery, as the flaps heal, the separation between the source and the detector being established in relation to the thickness of the skin flap to ensure tissue of the flap per se is being monitored.

The method is provided of emergency monitoring of cerebral tissue oxygen level and blood volume in an emergency care situation with the implantable device, in this case, preferably a stand-alone oximeter carried on a backing member with micro-circuitry to monitor the brain or other tissues in peril of damage due to hypoxia.

The method is provided of employing the device of any of the configurations described above wherein the oxygen levels, blood volume and/or rate of charge are measured in cancerous tissue to indicate the activity and viability of the tissue. Also preferably the method includes monitoring of the viability of a tumor following treatment intended to wipe out the cancerous tissue.

Another aspect of the invention is a helmet into which is molded a tissue oximeter in position to engage the head of the wearer when the helmet is put on, the oximeter being of the NIR type, comprising light source means for transmitting near infrared light into the head, detector means held in spaced position relative to the light source means for receiving light scattered by brain tissue and a barrier disposed to engage the head between the light source means and the detector means to prevent light traveling laterally from the light source means

from reaching the detector means. Preferably the oximeter has other features described above. In particular, preferably, the oximeter in the helmet includes control circuitry on a miniature chip and preferably means are provided for determining the rate of change of oximetry readings and for comparing the rate of change to a standard and, e.g. producing an appropriate alarm and/or control signal.

Another feature of the invention is a tissue oximeter comprising a support, a detector fixed to the support and a light source mounted in an adjustable manner to the support to enable selection of the spacing between light source and detector for adjusting the mean depth of tissue to which the oximeter responds.

Still another feature of the invention is a tissue oximeter in combination with means connected to receive tissue oxygen readings from the oximeter, and to determine the rate of change of the readings, the rate of change serving as a quantified indication of the state of the charging metabolic process of the tissue.

Another feature of the invention is an oximeter as described, disposed on an endoscope, catheter or guidewire or the like for insertion via a body passage to internal tissue, and including means such as an inflatable balloon to press the oximeter sensor against the localized tissue of interest. Another feature includes providing a water impermeable coating over the device for use in the presence of water.

Somewhat more generally, according to another aspect of the invention, a cognition spectrophotometer system for transcranial examination of brain activity by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in the brain is provided. The cognition system comprises a light source adapted to introduce electromagnetic radiation of a

selected wavelength into the brain at an input port placed at a selected location on the exterior of the head; a detector adapted to detect, at a detection port placed at a selected location on the exterior of the head, radiation of the selected wavelength that has migrated in the brain; stimulation means adapted to cause stimulation of a brain activity while introducing the selected wavelength and while detecting radiation at the detection port; processing means adapted to process signals of the detected radiation that has migrated in the brain to create processed data, and evaluation means adapted to determine a characteristic of the brain activity by correlating the processed data with the caused stimulation of the brain activity.

Preferred embodiments of this aspect of the invention have one or more of the following features. Processing means adapted to process detected radiation that has migrated in the brain in the migration path between the input port and the output port being separated by a predetermined distance and being located at different locations on the exterior of the head.

The input port and the output port are located on the frontal bone, parietal bone, temporal bone or occipital bone, wherein the input port and the output port being separated by a predetermined distance in order to localize the migration of the radiation to a selected region of the brain. The predetermined distance can be 4 centimeters.

The system can also have a second light source adapted to introduce electromagnetic radiation of the selected wavelength into the brain at a second input port placed at a second selected location on the exterior of the head; a second detector adapted to detect, at a second detection port placed at a selected location on the exterior of the head, radiation of the selected

wavelength that has migrated along the migration path in the brain from the second input port to the second detection port, and processing means adapted to process signals of the detected radiation that has migrated in the brain from the second input port to the second detection port to create second processed data, wherein the evaluation means determine the characteristic of the brain activity by correlating both first mentioned and the second processed data with the caused stimulation of the brain.

This system is adapted to introduce the radiation simultaneously at the two input ports or sequentially at the first input port and detected at the first detection port, and subsequently introduce the radiation at the second input port and detected at the second detection port.

According to another aspect of the invention a cognition spectrophotometer system for transcranial examination of brain activity by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in the brain is provided. The cognition system comprises a first light source and a second light source adapted to introduce electromagnetic radiation of a selected wavelength into the brain simultaneously at a first input port and at a second input port; the first input port and the second input port being placed at a first selected location and a second selected location on the exterior of the head, respectively; a first detector and a second detector adapted to detect simultaneously, at a first detection port placed at a selected location on the exterior of the head, radiation that has migrated in the brain from the first input port to the first detection port and, at a second detection port placed at second selected location on the exterior of the head, radiation that has migrated in the brain from the second

input port to the second detection port; stimulation means adapted to cause stimulation of a brain activity while introducing the radiation at the first and second input ports and while detecting radiation at the first and second detection ports; processing means adapted to process signals of the detected radiation that has migrated in the brain to create processed data; and evaluation means adapted to determine a characteristic of the brain activity by correlating the processed data to the caused stimulation of the brain activity.

Preferred embodiments of this aspect of the invention have one or more of the following features. The system has the first input port and the first output port located on one parietal bone (or temporal bone), separated by a predetermined distance, in order to localize migration of the radiation in a selected region of the respective hemisphere of the brain, and the second input port and the second output port located on the other parietal bone (or temporal bone), separated by a predetermined distance, in order to localize migration of the radiation in a selected region of the other hemisphere of the brain.

The system's processing means are further adapted to compare electromagnetic radiation detected at the first and second detection ports to create processed data representing a differential signal.

The processing of the detected radiation can comprise Fourier transformation.

The stimulation means are adapted to cause visual stimulation, acoustic stimulation, or sensorimotor stimulation.

The evaluation means can be adapted to examine pathophysiological properties of the brain tissue or cognitive function of a selected region of the brain

based on correlation between the processed data and the caused stimulation of the brain activity.

The system's first and second light sources are tungsten lamps or light emitting diodes. The first or second detectors are silicon diodes or light-to-frequency convertors each with an interference filter adapted to detect the radiation of the selected wavelength.

The processing means comprise differential counter adapted to register differential signals received from the light-to-frequency convertors, clocking means adapted to route signals of the detected radiation from the light-to-frequency convertors to the differential counter, a frequency-to-voltage converter adapted to convert signals from the differential counter and/or a fast Fourier transformer adapted to process differential signal from the frequency-to-voltage converter.

The evaluation means comprise a storage oscilloscope adapted to analyze the Fourier transformed differential signal of the fast Fourier transformer, and/or computational means adapted to analyze the differential signal.

According to another aspect of the invention a cognition spectrophotometer system for transcranial examination of brain activity by measuring changes in light scattered and absorbed in a migration path in the brain is provided. The system comprises the above-described oximeter, stimulation means adapted to cause stimulation of a brain activity while introducing the light using the light source and while detecting the light that migrated in the localized tissue of interest of the brain, processing means adapted to process signals of the detected light that has migrated in the brain to create processed data, and evaluation means adapted to determine a characteristic of the brain activity by

correlating the processed data to the caused stimulation of the brain activity.

According to another aspect, the invented system enables examination of a tissue of an organ by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in the organ. The examination is performed by the steps of (a) introducing electromagnetic radiation of a selected wavelength into the organ simultaneously at a first input port and at a second input port; the first input port being placed at a first selected location, and a second selected location, respectively; (b) detecting simultaneously, at a first detection port placed at a selected location on the exterior of the head, radiation that has migrated in the organ from the first input port to the first detection port and, at a second detection port placed at second selected location on the exterior of the organ, radiation that has migrated in the brain from the second input port to the second detection port; (c) processing signals corresponding to radiation detected at the first and second detection port that have migrated in the brain to create first and second processed data, respectively; and (d) determining a selected property of the organ tissues by correlating the processed first and second data.

The organ can be the brain, breast, limb, etc. If the organ is the brain, then the first input port and the first output port are located on one parietal bone (or temporal bone), separated by a predetermined distance, in order to localize migration of the radiation in a selected region of the respective hemisphere of the brain, and the second input port and second output port are located on the other parietal bone (or temporal bone), separated by a predetermined distance, in order to localize migration of the radiation in a selected region of the other hemisphere of the brain.

Brief Description of the Drawings

Figure 1 is a depiction of a preferred configuration of an embodiment of the present invention.

Figure 2 is a partially diagrammatic, partially schematic representation of a preferred embodiment detector.

Figure 3 illustrates another preferred configuration of an embodiment of the present invention.

Figure 4 is a partially diagrammatic, partially schematic representation of an alternate preferred embodiment detector.

Figure 5 is a plan view of another preferred embodiment.

Figure 6a is a plan view of the oximeter sensor of Figure 5.

Figure 6b is a longitudinal sideview of the oximeter sensor of Figure 6a.

Figure 6c is a longitudinal cross-sectional view taken on line 6c of Figure 6a;

Figure 7 is a transverse cross-sectional view of a oximeter sensor according to the invention in place upon the flesh of a wearer;

Figures 8a, 8b and 8c are plan views of other preferred embodiments of the oximeter sensor;

Figure 9a is a plan view of an implantable oximeter sensor according to the invention;

Figure 9b is a longitudinal sideview of the oximeter of Figure 9a;

Figure 9c is a cross-sectional view taken on line 9c of Figure 9a;

Figure 10 is a block diagram of an analog version of the control system for the oximeter of the previous figures;

Figure 10a is a schematic representation of the oximeter control system shown in figure 10;

Figure 10b is a section of the schematic representation shown in figure 10a;

Figure 11 is a block diagram of a digital version of the control circuit of the oximeter of the previous figures;

Figure 12 is a software flow diagram of the software used with the circuitry of Figure 11;

Figure 13 is a front of a helmet according to the invention;

Figure 14 shows an endoscopic oximeter according to the invention;

Figure 15 is a block diagram of a low frequency cognition spectrophotometer;

Figure 16 illustrates the response of the Fourier transform oscilloscope of the cognition spectrophotometer, shown in Figure 15, to 300 μV peak-to-peak square wave (top trace) and 225 μV sine wave (lower trace);

Figure 17 illustrates the response of the DC amplifier to a square wave;

Figure 18 shows frequency analyses of optical signals of subject U obtained by the cognition spectrophotometer of Figure 15;

Figure 19 shows frequency analyses of optical signals of subject B obtained by the cognition spectrophotometer of Figure 15;

Figure 20 shows frequency analyses of optical signals of subject U at rest obtained by the cognition spectrophotometer of Figure 15;

Figure 21 shows a histogram display of the distribution of frequencies obtained by the cognition spectrophotometer of Figure 15;

Figure 21a shows a histogram display of the distribution of energy (area) in the peaks obtained by the cognition spectrophotometer of Figure 15;

Figure 22 is a block diagram of a fast lateralization detector of the cognition spectrophotometer of Figure 15;

Figure 23 is a block diagram of a low frequency lateralization detector of the cognition spectrophotometer of Figure 15.

Detailed Description

A preferred embodiment of the apparatus of the present invention is illustrated in Figure 2. In this embodiment an electro-optical pickoff detector unit 10 is worn on the leg of the exercising subject 50. It is preferred that the weight of the detector be kept to a minimum so that hindrance to a competing athlete is negligible. In a preferred embodiment, the detector will be housed in a flexible array constructed from a suitable non-irritating, lightweight material.

Power is provided to the detector unit 10 from a replaceable battery pack 30. The replaceable power pack 30 is preferably designed to be of minimal dimensions and weight. Most preferably, the battery pack 30 would be designed to last only for the duration of the activity, e.g., several minutes of sprinting, several hours for a marathon runner, etc. In competitive sports applications, the life of the battery pack is preferably based upon the interval between substitutions or other interruptions between periods of competition.

The embodiment illustrated in Figure 1 further comprises an arm indicator 40, which is preferably worn on the arm in the manner of a wristwatch. The arm indicator 40 displays the percentage of deoxyhemoglobin (%Hb) as a measure of the subject's metabolic state. As seen in Figure 1A, such a display may comprise a simple readout of this information, such as a bar graph. Alternatively, the information displayed may be placed on

a time scale, to graphically illustrate the change in %Hb concentration over the course of the activity, as illustrated by Figure 1B. In a most preferred embodiment, the graphic displays illustrated by Figures 1A and 1B are comprised of liquid crystal displays (LCD's), although other electrical or electronic display means may also be used. The amplitude interval of this embodiment is preferably divided into 6-10 levels, each covering a portion of the designated %Hb scale.

It will be appreciated that the range of the %Hb scale may be adjusted depending upon the range expected to occur during the activity. Since the precision of the present invention is limited by that of the indicator, the range which is displayed is an important variable parameter. In the most accurate embodiment of the present invention, with the endpoints of the %Hb scale set at 20% and 40%, the apparatus would have an accuracy of about 6%, which is about the limit of precision which can be obtained from a moving limb. One of ordinary skill will realize that the gain of the apparatus is preset, depending upon the intensity of the activity expected. In a most preferred embodiment, a button placed on the arm indicator 40 allows the gain to be set.

Referring now to Figure 2, there is illustrated a partially schematic, partially diagrammatic representation of a preferred embodiment of a circuit which comprises the optical pickoff component of a DC tissue spectrophotometer detector 10 contemplated for use in the system of the present invention. The detector 10 is shown for illustrative purposes mounted against a skin surface 25 of a subject. In a typical configuration, the detector is mounted against either large, homogeneous muscles, such as the gastrocnemius or the quadriceps or against the forehead of an adult. Two lamps 12,14 and two detectors 16,18 are contained in a flexible

waterproof array. Also contained in the array is an opaque specular barrier, which is a concentric ring of material 11 between the lamps 12,14 and the detectors 16,18 which acts as a barrier zone to light of a specified wavelength. Most preferably, the material which comprises the barrier zone will not only be opaque to light within a specified region, but will further act as an absorber as well. The configuration of dual wavelength light sources combined with a barrier zone is disclosed in "Optical Coupling System for Use in Monitoring Oxygenation State Within Living Tissue," Application No.266,116; filed November 2, 1988, which is incorporated herein by reference, as noted above.

Thus, superficial light rays from the skin are, in effect, blocked by the opaque barrier 11 from entering the detectors 16,18. This blocking action by the barrier 11 of these superficial rays enables the system to determine the oxygenation state of hemoglobin within the muscle rather than at the skin surface. The rays that migrate deep within the tissue are received by the detectors 16,18. The light rays that migrate superficially "escape" through the skin surface and will be absorbed by the opaque barrier 11. When, for example, a 760 nm impulse is applied, the deoxygenated hemoglobin (Hb) within the muscle is detected and when an 800 nm signal is applied, the oxygenated and deoxygenated hemoglobin (HbO_2 and Hb) within the tissue region are detected. The system is able to ignore the oxygenation state at the skin surface and determine that within the tissue.

The lamps 12,14 may be, for example, 1/2 W flashlight bulbs that are periodically illuminated in the NR region. The lamps are provided with cutoff filters 13,15 so that only energy of a specified wavelength illuminates the tissue. The silicon diode detectors

16,18 are sensitive to 760 ± 20 nm and 800 ± 20 nm (or 850 ± 20 nm) wavelengths, respectively.

In a preferred embodiment, the lamps 12,14 are light emitting diode (LED) sources, which emit light having a wavelength of about 760 ± 150 nanometers and about 800 ± 150 nanometers (or 850 ± 150 nanometers), respectively. In either embodiment, the lamps are flashed or pulsed at a predetermined repetition rate. The repetition rate of sampling, i.e., the rate at which the lamps are flashed determines the rate at which data may be collected. Thus, for a long distance runner, the lamps are flashed slowly; the output is commensurately changed for a sprinter, the lamps flashed rapidly to produce sufficient data to evaluate an exercise having a duration on the order of seconds. The selection of LEDs as sources of electromagnetic radiation provides a further advantage, since these sources produce a signal-to-noise ratio (S/N) approximately one order of magnitude greater than previously disclosed optical coupling systems using optical light fiber sources.

Referring now to Figure 4, an alternate embodiment of a circuit for use with the present invention is illustrated. In this case a single detector 17 responding to separate light flashes collects and transmits signals to an amplifier 24, which has bipolar outputs that are connected intermittently to an integrator 27 by a switch 25. Another switch 26 adjusts the relative duration of the two light pulses to equalize the two signals. One of ordinary skill will understand that those portions of Figure 2 and Figure 4 having the same reference numerals perform substantially similar functions. Many details of the particular circuits comprising the present invention need not be set forth with particularity as they are well known or will be obvious to those of ordinary skill.

Referring to Figure 2, it can be seen that the detectors 16,18 are also protected by a transmitting filter 19 pressed against the skin to minimize the effect of background light. The filter 19 may be comprised of a separate member, a coating or integrated into the housing of the circuit. The DC output of each of the detectors 16,18 is timeshared into its respective differential amplifier 20,22. The amplifiers are connected in opposite polarity, one non-inverting, the other inverting. The dwell time of the switch 23 connecting the amplifiers 20,22 is adjusted to equalize the response of the two signals by appropriate circuitry 28. The signal from the integrator is coupled to a recorder (not illustrated). As shown in Figure 4, the signal from the 800 nm lamp 12 may be simultaneously employed to vary the gain of the amplifier 24 so as to correct the signals for changes of blood volume and to produce the ratio of the two signals, and thus maintaining constant sensitivity for difference detection. One of ordinary skill will appreciate that a similar gain compensation circuit can be incorporated into the circuitry of the 800 nm detector amplifier 22, shown in Figure 2. Whether incorporated into the circuits of Figure 2 or Figure 4, the 800 nm signal is also coupled to a second recorder channel to collect data reflecting total absorption or blood volume.

Another configuration of the present invention is illustrated in Figure 3. In this embodiment, a radio-linked telemetry system comprised of a transmitter 60 attached to the subject and a receiver 62, allows the remote monitoring of the subject. A supervisor, coach, or clinician is thereby enabled to monitor the performance of the subject. The data display is remote, one of ordinary skill will appreciate that the displays utilized may be similar to those illustrated in Figures 1A and 1B, or may be more complex, displaying data using

various scales, time overlays, colors, etc. In a most preferred embodiment the telemetry signal would be carried on the 220-400 MHz band, using a transmitter in the 100 MW range.

The configuration illustrated by Figure 3 allows the present invention to monitor athletes in competition or workers and military/space personnel located in remote locations. For example, the apparatus of the present invention may be used in training to determine the duration of peak performance and the appropriate times for the substitution of fresh players or other adjustments. This configuration would also be preferred for monitoring the metabolic condition of an animal such as a racehorse, racing dog, or any animal whose metabolic condition is being studied for clinical or other purposes. A "postage stamp" oximeter may be provided for, e.g., emergency use, where the oximeter is held to the subject by an adhesive pad positioned peripherally around the device.

In any of the embodiments of the present invention, it is preferred that the data be integrated over at least about ten seconds to smooth out irregularities which normally occur in the concentration of deoxyhemoglobin during exercise. However, it will be understood that the period integration can be varied, depending upon the duration of the activity being monitored.

Although manual balancing of the apparatus of the present invention is required, in a preferred embodiment, the balancing is accomplished by depressing a button, which will normalize the output of the two wavelengths. Automatic balancing performed by an intelligent gain control CPU is also envisioned.

Another preferred embodiment of the oximeter is shown in Figures 5 and 6a-6c. A rubber-backing member

101, provides support for two lamps 100 spaced equidistant from two detectors 102 also mounted on backing member 106. The backing member is formed of an opaque, e.g., black, silicone rubber of suitable durometer to enable it to conform to the curvature of the subject part of the human body to which it is applied. For this embodiment, which may be as long (L_1) as e.g., 12, especially 8 centimeters, flexure configurations 106 are provided. Light barrier members 103, 104 serve to depress the subcutaneous fat layer and thereby reduce light interference directly between the light sources 100, located at input ports, and the detectors 102, located at detection ports, see description below regarding Figure 7. Behind the detectors 102 of Figure 6a, as shown in Figure 6c, housing 107, defined by the rubber wall, contains the supporting circuitry for these lamps and detectors. As shown in Figure 6c, narrow band optical filter 110, located at the detection port, lies over photodetector 111, which lies over circuitry 108. Depth D is typically 2 cm. Wiring harness 115 carries power to the lamp.

On the rubber supporting member 101 there are a number of integral raised members 103, 104, 105 and 106. Raised rib 105, which extends about the perimeter, both prevents external light from interfering with the reading and serves to support comfortably the backing member 101 on the subject. Rib 104 extending laterally, adjacent the lamp, and disposed across the line projected between the lamp 100 and the detectors 102, serves as a second light barrier to prevent interfering light transmission between light source 101 and detectors 102. Rib 103 closely surrounds the detectors, and serves as a primary eliminator of environmental light interference, and also serves to absorb light migrating along subcutaneous fat and other subsurface interposed layers, etc. All of

these ribs are on the order of 1/2 centimeter high and 1/2 centimeter thick. Their outside flesh-engaging edges are rounded for comfort to the wearer. The supporting member 101 and its associated ribs are manufactured in one piece of molded rubber. A suitable mold is provided and black silicone rubber is poured into the mold, cured and dried, leaving the subsequent rubber backing 101 with integral ribs and structures. Suitable mounting sites are provided in the backing into which the detectors 102 and the lamp 100 are mounted during final manufacturing. The backing member for the oximeter sensor of Figures 6a-6c has width, W, length, L1, and depth, D, which may be varied depending upon the application. L2 represents the spacing between light source 100 and the center of detectors 102. Sensors with dimension (L_2) from one centimeter to four or five centimeters with corresponding changes in L1 and W are appropriate. One centimeter separation L2 is useful for muscles of very shallow depth while L2 of four or five centimeters is useful for deeper tissue penetration, for example for the brain or other organs.

Small L2 spacings of as low as one centimeter are also appropriate for monitoring tissue flaps, though the best configuration of the sensor for flaps is that shown in Figure 8c, described below, because flaps are of varying thickness and the adjustability of the device of Figure 8c enables L_2 adjustment proportional to the thickness of the flap. It will also be realized that monitoring may be achieved through wound dressings, bandages, etc.

In the currently preferred embodiment, the light sources 100 are lamps having tungsten filaments, are broad band light sources which eliminating the problem of matching the light sources to the detector filters.

Each detector is comprised of interference filter 110 which blocks out all light except for that which is desired, each of two detectors having a separate wavelength of interest. At this time 760 nm and 850 nm are preferred, although one can envision that changing, depending upon the application. Beneath the filter is a photosensitive detector which picks up the light and transduces it to an electrical signal which is amplified in the circuit 108 and later transmitted to the control circuitry represented in either Figure 10 or 11.

In the presently preferred embodiment, the interference filter is manufactured by Omega, Inc., and the photodiode beneath it is Part No. F1227-66BR, available from Hamamatsu, having a large sensitive area for favorable signal to noise ratio and an NIR wavelength sensitivity. The sensitive area is approximately 6 millimeters squared.

In the present embodiment the filter and detector are epoxied together around and an electronic shield 115 surrounds the diode/filter pair 110 and 111. This surrounding electronic shield eliminates or reduces extraneous electronic interference. It is presently preferred to form this shield of copper in the form of a windowed box which surrounds the detector filter pair.

Once the two separate filter diode pairs are constructed, they are soldered together and then mounted directly to the circuit board 108. Connected also to circuit board 108 is an ultra low noise operational amplifier with high gain, which converts the current signal from the diodes to a voltage applicable to the control circuitry of Figures 10 or 11. The circuit board 108 can be connected via either telemetry or cabling to the oximetry system 99 of Figure 5, which contains the circuitry shown in Figures 10 or 11. Power supply for the amplifier of 108 is supplied by the oximetry system

99 where a cable connection is employed. In other embodiments, a battery is provided for operating the oximeter sensor along with the telemetry system, to be described below in connection with an implantable embodiment.

Referring now to Figure 7, the preferred embodiment of Figures 6a-6c is shown diagrammatically as it is placed upon the skin of a subject. The edges of the upstanding rib-form barrier members serve to concentrate pressure upon the skin, depressing the skin layer and the underlying fat layer. The barriers 103 and 104 serve to prevent light from migrating directly between the source 100 and the detectors 102 and because the barriers are placed with pressure upon the surface of the skin, they serve to reduce the area of the fat through which light can pass directly. If one were to imagine the situation without a barrier, one would see light passing almost directly between the source and the photodiodes, the fat layer serving, effectively as a light guide. The absorbing ribs reduce this noise effect. Light which is emitted by the sources 100 enters the skin directly beneath the source, passes through the fat to the underlying tissue, migrates through the tissue, is absorbed, scattered. and eventually is received by the photodiode. The migration path has been described in prior art as a banana-shaped path which is due to the photon migration between the source and the detector. "Banana-shaped" is a mean representation of the photon path, whereas the actual migration path constitutes many scattering changes of direction of the photons as they course between the light source, located at the input port, and the photodiode, located at the detection port.

Figure 8a-8c show alternate preferred embodiments of the oximetry sensor.

The embodiment of Figure 8a is useful for muscle. It is shown here as a comparison to Figures 6a-6c, wherein the overall length L1 and the overall width W depends upon the application and L2 as in Figures 6a-6c can vary dependent upon the application from one centimeter or less to five centimeters or more.

The overall length L1 is determined chiefly as a result of the source 100 to detector 102 spacings L2. The spacing determines the depth of penetration of the light which is scattered and migrated through the tissue. The farther the source is from the detector, the deeper the mean penetration. So for shallow penetrations, one would envision a short L2 and thereby L1. The penetration desired depends upon the muscle of interest. For a large muscle, for example, in the thighs or the calf, which tend to be fairly large, one needs a substantial separation to both (a) penetrate the thicker fat layer and (b) to sense deeper into the larger muscle.

For such muscles, a common dimension for L2 would be 3 to 5 centimeters and L1 would thereby be 7 to 11 centimeters.

The width of the sensor is chiefly dependent upon the size of the detectors 102. In the configuration of the presently preferred embodiment wherein each detector has a photosensitive area of approximately 6 millimeters squared, the width is dependent almost entirely upon those two dimensions. As the photodetectors reduce in dimension width W decreases.

The larger photodetector units provide better signal to noise ratio and thereby enable more accurate representation of the oxygenation state of the tissue. As improvements in technology occur and better photodetectors and initial amplification circuitry are developed, the detector size will decrease, with consequent decrease in W.

As with Figure 6a-6c, the supporting member 101 of Figure 8a carries numerous rib-form barriers. In this case barriers 103, 104 and 105 serve both support and light reduction functions. Perimeter barrier 105 in this case completely surrounds the light source and detector grouping. Between the light source and barrier 103, is barrier 104 on opposite sides of the detectors. Barrier 104, as previously mentioned, serves to reduce light as it travels between source and detector in the subcutaneous layer.

The embodiment of Figure 8b represents an alternate to that of Figure 8a wherein the dimensions of Figure 6a are significantly reduced to achieve a smaller probe. In addition to the backing member 101 being reduced in size, in Figure 8b, barrier 104 has been eliminated and barrier 103 serves as the primary and only eliminator of both external light and interference between source 100 and detector 102. The typical dimensions for L2 of Figure 8b would be 3 centimeters or less, L1 being 6 centimeters maximum or less. In comparison, the minimum size for the embodiment of figures 8a and 6a-6c of L2 would be 3 centimeters or greater.

The embodiment pictured in Figure 8b is suitable to be used for example in neonate applications where the desired tissue volume is extremely small and one needs a small probe. It would also be used for very shallow depth muscle and for example, skin flap measurements where skin flaps are created either by surgery or by wound. The sensor is placed over the skin flap to determine the health of that flap as it heals.

The smaller sensor sizes improve the flexibility of the device to correspond to perhaps smaller target muscles and smaller regions of interest.

Referring to Figure 8c, a similar embodiment to that of Figure 6a-6C is shown, but having a light source track 109 to enable variable spacing between the light source 100 and detector. Barrier 103 has been omitted in favor of allowing for user settable variations of L2. L2 may be varied between for example 2 centimeters to say 5 centimeters depending upon the application. This may be used for skin flap work in determining the health of a skin flap as described above, with the distance L2 set in accordance with measurement of the thickness of the skin flap.

For this adjustability, a slide mechanism is employed in manner to keep L2 equal on both sides, in dependent motion such that as the spacing of one varies, the spacing of the other will also change.

The embodiments of Figures 5-8 share the desirable features of a parallel pair of detectors 102, side-by-side extending across the line between the light source. By simultaneous flashing of both lamps each detector receives photons at its wavelength from both lamps, simultaneously.

Figure 9 shows another preferred embodiment of the tissue oximeter sensor, in the form of an implantable probe. To further reduce size, one of the light sources 100 is omitted. As in Figure 8b, light barrier 104 is omitted. The lone barrier in this case 117 serves to reduce direct light interference.

As previously mentioned, backing member 101 holds in fixed relation the light source 100 and the detectors 102. The length L1 is solely dependent upon a single L2 between the single source and the dual detectors. The spacing depends chiefly upon the muscle location internally of the organ which is being studied. As previously mentioned, from 1/2 centimeter or 1 centimeter to 5 centimeters may be appropriate, depending upon the

application. Applications envisioned are horse muscle studies.

For application, the physician makes an incision in the skin and slips the oximeter sensor underneath the skin and cutaneous fat layer. There are suture points 113, e.g., biocompatible webbing, surrounding the backing member 101. A coating over the entire sensor is comprised of a biocompatible base material 112, which protects the circuitry from the human system, and protects the human from the invasive nature of the circuitry.

The thickness of the device is of the order of 1 to 2 centimeters maximum. That depth dimension will diminish as technology changes. In Figure 9c the supporting circuitry is shown. As previously described, the filter/photodiode pair 110, 111 is disposed above the circuit 108. In addition to receiving and amplifying the signal, the circuit shown here is responsible for telemetric communication of the signal to a receiver outside of the body. A battery 114 powers that circuitry.

By employing a radio signal to transmit the information from within the body to a receiver outside the body there is no need for wires and the like puncturing the skin.

Referring to Figure 10, one embodiment of the circuitry for driving the device is shown. (Schematic diagram of the embodiment of Figure 10 is shown in Figure 10a.) This is an analog circuit wherein the signal from photodetectors 118 and 119 is amplified by amplifiers 120 and sent to three manipulative circuits that take the difference, the sum and the derivative of the signal. The difference 123, as described above, simply subtracts 760 nm minus 850 nm to obtain a signal representing deoxygenation.

The sum circuit 124 takes a weighted sum of the 760 nm and 850 nm signals, weighting being chosen appropriate to the fact that the signal variation due to oxygenation or deoxygenation is greater for 760 nm than it is for 850 nm. Because these contrabestic wavelengths tend to cancel the signal due to the difference in oxygenation, the sum shows independent of the difference and is taken as representative of the blood volume changes in the tissue.

The derivative circuit 125 takes the simple derivative to show the rate of change of both of the signals. This is useful, as described above, to trigger alarm circuitry based upon established standards, wherein the higher the rate of the change, and the more sustained that rate of change, the more potentially dangerous the rate of change. This is useful, as mentioned, for example in monitoring aviators for possible black-out conditions and for apnea.

The outputs of these units 123, 124 and 125 are applied to the control circuit which controls where the signals are directed and how they are displayed and/or sent to a computer. The control circuit may be simply embodied as a switch to switch the output to an LCD display, for example. The analog signal from control circuit can be digitized in the display unit 127 and displayed as a digital number. Additionally it can be digitized and sent to a computer or sent in analog form to a computer for digitization.

The oscillator 121 is an independent source for determining the frequency of lamp flashing. Lamps flash at frequency of 1/2 Hz or 2 flashes per second or greater. This frequency may be independent of heart rate or any other external factor and is set externally by the user, and may be dependent upon application as mentioned earlier. For example, during exercise, the frequency

chosen for the lamp will depend upon the frequency of the exercise, such as the revolutions per minute on a bicycle. If one is expected to encounter a slow change in oxygenation due to the nature of the exercise or the muscle of interest, one can employ a fairly low flashing rate. There is no need for high resolution measure of the rate of change as is required in pulse oximetry.

The lamp rate is tied to the control circuit. The oscillator establishes the timing for the sum and difference circuits because the sum, difference and derivative circuits need to be synchronous. In operation, the lamp flashes, the signal is picked up by the photodetectors and while the lamps are on, the difference, sum and derivative are calculated and are thereby stored in the appropriate memories, and via the control circuit can be directed to the display and to the computer.

The derivative system is the basis of the alarm system. Output from the derivative is compared to a standard within the alarm circuitry, which then determines if there is, for example, a normal rate of change, represented say by a green light, a cautionary rate of change, which may be represented by a yellow light, and a fairly rapid and/or sustained rate of change, which would be for example shown by a red light, an alarm or a buzzer or the like, which would alarm both the wearer or act remotely for example to warn the parents of a neonate in the case of SIDS (Sudden Infant Death Syndrome).

The embodiment shown in Figure 10a enables correction for the dark current/noise that comprises background light, DC offset of the operational amplifiers, photodiode dark current, temperature effects on the outputs of individual components and variations due to changing environment. The dark current/noise

correction is explained on the circuit of Figure 10b which is a section on the analog circuit, shown in Figure 10a. The oximeter (Figure 10) performs data acquisition in four steps which are synchronized by an internal oscillator. In the first step, the lamps are off. The output is directed to an integrator 154 and integration capacitor 156 is charged to the dark level voltage. In the second step, the lamps are turned on. The preamplifier output that corresponds to the intensity of the detected light is directed to integrator 154 in a way to charge capacitor 156 with current of polarity opposite to the polarity of the charging current in the first step. This is achieved using appropriate ON/OFF combination of switches S1 and S2. The voltage of capacitor 156 is charging to a value which, at the end of this step, represents the total signal minus the dark level noise signal. In the third step, both switches S1 and S2 are turned OFF to disconnect both the positive unity gain and the negative unity gain operational amplifiers (150 and 152). Then, the output of integrator A is moved via switch S3 to a hold circuit 158 which also functions as a low pass filter. This output is the detected signal at one wavelength corrected for the background noise. In the fourth step, the switches S1, S2 and S3 are open and switch S4 is closed in order to discharge capacitor 156 through a 47K resistor. At this point, the circuit of integrator 154 is reset to zero and ready for the first step.

In another preferred embodiment, digital version of the circuitry depicted in Figure 11, the identical photodetectors 118 and 119 and similar amplifiers output signal to an analog to digital conversion system 128 and to a derivative circuit 124. The derivative circuit outputs signal to the analog digital converter, in this case for evaluation by the central processing unit, CPU,

or microprocessor 129. Software, shown in Figure 12, controls the system of data collection and lamp frequency 122 as well as the storing of data, interfacing with external computers and displaying or telemetrically communicating this information. The heart of this circuit is the central processing unit driven by software which collects data, stores it, displays it and sounds alarm if necessary.

Figure 12 shows the software. Initialization of the system 140 takes place whereby the analog and digital system is set up and configured properly. The digital memory, communication and telemetry are configured as in Figure 11. Secondly the device calibration takes place such that the gain of the amplifiers is set electronically by software. The gain of the amplifiers is set to an acceptable range so that digitization can take place accurately, as well as other small internal routines to determine whether the derivative is working properly or not. In the case that the calibration cannot take place, the program will stop and alarm the user. The alarm 134 represents "not working properly, please reset", etc. After calibration is completed successfully, data collection is begun. Data collection is taken in a loop format starting with 142. It starts with turning the lamp on, and sampling the signal, 143. Approximately 500 points of data are taken in rapid succession over approximately 1/2 second sampling interval or less. That data is accumulated, then the lamp is turned off after a delay period, which is set by the user and by the software. The samples are collected and then averaged at 144. This average is then used at 145 to calculate the sum, difference and derivative. In this case the calculated derivative serves as a redundant comparison with the analog derivative calculated in 125 of Figure 11. In addition to the averaging of 760 and

850 nm, the derivative signal is also averaged and sampled in the same way, for example with 500 points. By this means a calculated derivative as well as a sample derivative are obtained which are compared to provide a much more repeatable and reliable result for an alarm.

The data after it has been manipulated in 145 will be stored, appropriately transmitted and/or displayed. In addition the alarm is set off if necessary at this point. Then finally an independent timer or delay would be introduced. The processor is delayed for a set period to obtain desired lampflash/data collections frequency.

The sequence is thus: lamp on, collect sample data, lamp off, collect noise data, average sample, calculate sum, difference and derivative, then transmit, display etc., wait if necessary, and then turn on the lamp again and repeat the whole procedure.

Referring to Figure 11, dark current/noise correction in this analog system is accomplished by sequencing the data collection using the microcontroller. The data is collected in two sequencing steps. One step has light on and the other step has light off. The data collected with the light off represents the dark current. The data collected in the first and in the second cycle are digitally subtracted in order to obtain intensity data corrected for the dark current noise.

Referring now to Fig. 13, a helmet 170 is shown having a tissue oximeter 172 molded at a position to snugly engage the head of the wearer when the helmet is put on, typically at a position free of body hair, e.g., at the forehead above the eyebrow. The oximeter is of the type, e.g., as described in Fig. 8b, having a source for transmitting NIR light, a detector to receive the light scattered from tissue such as brain tissue and a barrier to engage the head between the light source and the detector to prevent light traveling laterally between

source and detector through subcutaneous layers. Preferably, the oximeter in the helmet includes a control circuitry on a miniature chip and preferably circuitry and/or software are provided for determining the rate of change of oximetry readings and for comparing the rate of change to a standard.

Referring now to Figs. 14a-14b, an oximeter 180 is disposed on a catheter 150 (e.g., an endoscopic catheter), having an inflatable balloon 160 and endoscope optics 190. The oximeter 180 is preferably of the design illustrated in Fig. 7, and is molded or otherwise attached to the outer surface of the balloon. Controlling and detected signals may be passed to and received from the oximeter by wires passing through the balloon and a lumen within the catheter or by transmission from the oximeter to a receiver outside the body by telemetry as discussed, e.g., with respect to Fig. 9. In operation, the catheter, with the balloon deflated, is passed through a body lumen to the position of interest, guided for example, by fluorimetry or by endoscopic viewing. The balloon is then inflated to press the oximeter against the tissue of interest and measurements taken as described above. The technique and apparatus may be applied, for example, to body lumens such as the GI tract (e.g., for measurements of GI track wall ischemia or hypoxia as determined to be a preliminary indicator of multiple organ failure) or to blood vessels, employing an angiographic catheter for analysis and treatment of occlusions, etc. Still other embodiments are possible. For example, a "postage stamp" oximeter may be provided, e.g., for emergency use (self-contained system with alarm as discussed), where the oximeter is held to the subject by an adhesive pad, positioned peripherally around the device. Another embodiment includes providing a water impermeable coating

about the device for applications in the presence of water, e.g., for scuba divers, etc. In yet another embodiment a phase modulation spectrophotometer may be employed for calibration of the oximeters described above, especially for in-home or long-term portable monitoring applications, e.g., greater than 3 hours. Such calibration allows more quantitive measure of blood oxygen levels, etc. One example of such a spectrophotometer can be found in U.S. 4,972,331, the entire contents of which is hereby incorporated by reference. It will also be understood that implantable probes may be configured using direct wiring, with corresponding punctures in the skin as an alternative to telemetry.

Another preferred embodiment of the present invention is a cognition spectrophotometer system, shown diagrammatically in Figure 15. The cognition spectrophotometer examines the relationship between brain activity, oxygen delivery, oxidative metabolism, and blood flow by employing photon migration from a source placed on the surface of the head through the skin, skull and underlying brain tissues to a detector also located on the surface of the head. As already discussed, light is absorbed and scattered along the migration path.

Referring to Figure 15, the system comprises the following five modules: a stimulation module 250, a sensor module 252, a control circuit module 254, an analyzer/display module 256, and a computer/printer module 258. Stimulation module 250 is used to stimulate a specific brain function through a visual, acoustic, sensorimotor, or other stimulation. Sensor module 252 is connected to control circuit module 254; preferred embodiments are shown in Figures 5 through 13, 22, and 23. Figures 10 and 11 diagrammatically show the sensor, control circuit, display and computer/printer modules.

The display module of Figure 15 is a fast Fourier transform oscilloscope. The operation of sensor module 252 is governed by control circuit module 254 which controls the radiation emission and detection, collects the data, and sends the data to analyzer/display module 256 and to computer/printer module 258. The operation of the whole cognition system is controlled by a computer of computer/printer module 258.

The cognition spectrophotometer system, in one embodiment, measures the low frequency and power spectra of fluctuations of absorbances attributed to the blood concentration changes in the frontal region of the brain. The low frequency recurrences of brain activity are linked to blood concentration increases and are detected in human subjects with an optical device. The spectrophotometer employs wavelengths of light sensitive to oxygenation/deoxygenation of hemoglobin in the red region of the spectrum, i.e., absorbency changes at 760 nm are balanced against those at 850 nm in equal proportions. The difference in the absorbency changes is highly sensitive to the oxygenation/deoxygenation of hemoglobin (HbO_2/Hb) and is insensitive to the changes of blood concentration. The sum of the absorbency changes of these two wavelengths is sensitive to the blood concentration changes and insensitive the hemoglobin to oxygenation/deoxygenation of hemoglobin changes (approximately one-half of the 760 nm signal is added to the 850 nm signal). The data reported in Figures 16-21 have been obtained in the sum mode and the time dependence of changes of blood concentration has been measured. An alternative method to the sum of two wavelengths is to use a single wavelength apparatus, shown in Figures 22 and 23, for example, 800 nm which is an isosbestic point in the Hb/HbO_2 spectrum. Other wavelengths can be also used, for example, 950 nm which

is sensitive to water absorption, or wavelengths sensitive to endogenous or exogenous pigments.

The cognition spectrophotometer of Figure 15 was tested on several human subjects who were juniors or seniors from Central and Girls High Schools in West Philadelphia. The subjects were exposed to visual stimulation by a series of abstractions composed of analogies taken from SAT examinations. (All studies were conducted under IRB-approved protocol #M1025 for acquiring optical signals from the forehead of human subjects at rest and under test. Parental approval was obtained for those subjects under 18 years of age.) Sixty of these abstractions were displayed for an intended time of 11 minutes corresponding to 16 iterations of the Fourier transform oscilloscope 256 of the display module (Figure 15). The advance of one analogy to the next was dictated by the subject's conclusion that the analogy has been understood. The analogies presented to the subjects in this study were intended to simulate associative responses. The analogies continued within the 11-minute interval as long as the subject felt that he/she was adequately able to concentrate on them. If the subject's attention was diminished due to fatigue, etc., the test was terminated. Usually more than 11 out of the 16 iterations of the Fourier transformations were obtained and often the full 16 were obtained. At this point the subject was told to "rest".

No analogies were presented during the "rest" intervals. The Fourier transformations of the optical data for two successive 11-minute intervals were recorded and subtracted and were entitled "rest"-"rest" (Figure 20).

The sensor module used in this study consisted of two tungsten flashlight bulbs placed 4 cm each from the

two silicon diodes (4 mm X 10 mm), each equipped with an interference filter transmitting a 10 nm wide band centered at 760 nm and 850 nm. Thus, this system provided two photon migration paths with input-output separation of 4 cm. A preamplifier coupled the optical signals to an amplifier unit that took the sum and difference of the signals suitably corrected as described above. The tungsten lamps were pulsed at 3 Hz so that absorbance measurements were time shared with background measurements and the one was subtracted from the other to provide background light correction via sample and hold techniques for the difference circuit.

In a response speed test, the output of the filtered sum response reached 70% in 1 sec, as shown in Figure 17. The output signal was directly connected to the Fast Fourier transformer Tupe 440 (Nicolet) which was used in the DC-coupled mode on the 200 millivolts scale. The conditions were set for 16 iterations in the 0-5 Hz scale for a total interval of data acquisition of 10 min. The recording sensitivity was 220 μv/cm at X512 gain (Figure 16) and 440 μv/cm at x256 gain. The noise level of Figures 16-20 was about 20 mV. The total signal was 115 mv and the noise level was 0.2%. The full scale sensitivity was 1.0% of absorbance change at x512 and 2.0% at x256. Figure 16 illustrates the response of the Fourier transform oscilloscope to 300 μV peak-to-peak square wave (top trace) and 225 μV sine wave (lower trace), wherein 16 iterations at x512 gain were used.

Referring to Figure 17, the response of the DC amplifier to a square wave reaches 70% in 1 sec. Thus, the system is responsive only to frequency components in the 0-3 Hz region and records the recurrence of these components. Static experiments carried out simultaneously indicate that the sum of the peaks of the

test trace corresponds to an increase of blood concentration of approximately 5% of the total signal.

The ideal study control would repeat every feature of the study except the specific changes due to recognition of the analogies given to the subjects. Thus, the study was repeated with two intervals of "rest" of duration equal to that of the "rest"-"test" study. The "test"-"test" was not considered appropriate because the double duration of the "test" might have led to accommodation in the responses, and because the response to different "tests" could be different. This study had the sensor module placed in one location during the test interval; however, mapping of the "test" response by locating the sensor module in different locations on the exterior of the head is feasible.

Each recurrent signal is indicated by a peak at a particular frequency (Hz) in the illustrations. Peaks present in the "rest" recording are usually related to arterial pulse and related frequencies. Additional frequencies are usually observed in the "test" interval, and the Fournier transforms are readily subtracted by the instrument ("test"-"rest"). Some recurrent frequencies may also contribute to the increasing intensity of the spectra in the low frequency region. Peak size, as well as the 1/f noise is increasing as the frequency decreases.

Both the "test" and "rest" signals contain a signal of the arterial pulse of the brain tissue. At "rest" and "test", signals at 1-2 Hz and related harmonics are often observed. At "rest", a low frequency component is detected at various locations on the forehead and tracks closely the frequency of arterial pulse as detected on the wrist. However, these signals nearly completely cancel in the "rest"-"rest" difference Fourier and are thus attributed to the arterial pulse in

the brain tissue. Occasionally, the "test"-"rest" shows a difference signal due to altered arterial pulse rate during the "test".

Referring to Figures 18 and 19, the Fourier transform spectrum of the "test" interval and the "rest" interval of a female subject (U) are displayed as traces b and a, respectively. 16 out of the 16 scans were obtained (study 24, Table I). The frequency scale is 0-5 Hz, the amplitude scale represents a gain of x256. The subject's heart rate was 81 BPM (1.3 Hz). However, in the "rest" spectrum, the predominant peak is at 0.8 Hz, approximately 2% of the total signal. Small, sharp peaks appear at 1.7, 2.7, 3.5 and 4.7 Hz. Similar peaks of similar amplitude appear in the "test" study and are thus not "activity related". However, new large peaks appear at 1.6 and 1.8 Hz in the test spectrum.

The difference of the two Fourier transforms designated "test"-"rest" shows a recurrence of signals at particular frequencies associated with presentation of analogies. There is a preponderance of the 0.8, 1.6 and 1.8 Hz peaks and a small contribution of a 2.8 Hz peak. The largest peak corresponds to 1% of the total signal. Of interest from the theoretical standpoint is a large component of 1/f noise in the "test"-"rest" diagram suggesting that recurrence at the very low frequencies is less probable than at the higher frequencies. In a repetition of this study (#25), a 2.3 Hz peak was observed (see Table I) and the doublet peaks at 1.7 and 1.9 Hz were again observed in "test"-"rest".

Another frequency spectrum of a female subject (B) is shown in Figure 19 where the rest spectrum shows a strong peak at 0.8 Hz, presumably due to the heart rate, and a second peak at 2.7 Hz. After 7 iterations, the subject spontaneously ceased the study. The Fourier transform of the "test"-"rest" spectrum contains broad

peaks at 0.8, 1.5, 2.0, 2.7 and a peak at 4.3 Hz. The largest peaks exceed 1% of the total signal. The 1/F noise observed in the spectra appears to contain an unresolved peak at 0.2 Hz.

Referring to Figure 20, frequency analysis of two "rest" spectra of a subject U shows somewhat stronger peaks than in the "rest" study of Figure 18 at 1.2 and 2.3 Hz with a small peak at 4.6 Hz. In the "rest"-"rest" traces, only small broad peaks are observed. There are small differences that are attributed to variations in the arterial pulse and its higher frequency components of amplitude and frequency that differ in the first "test" as compared to the second. This is confirmed in Tests 27 and 28. In no case was a new distinctive peak observed as in "test"-"rest" studies. Table I summarizes 31 tests of 9 individuals (6 females, 3 males) over a six-week period. Column F lists the frequencies observed at "rest", Column G, the frequencies during the "test" interval (except Cases 8, 27, 28). Column H gives the recurrence of frequencies appearing in the substraction of "test" and "rest" in the Fourier transform. A high consistency is indicated by our observation of recurring frequencies in 24 out of 28 tests (85%) (all but four tests 2,3,9, and 24). In No. 24, increased 1/f noise was observed (Column H). Tests 8, 27, 28 were controls in which "rest"-"rest" intervals were subtracted.

Referring to Figure 21, the histogram displays the recurrence of frequencies in the range 0-4 Hz taken from Column H of Table I. Each individual's frequencies are cross hatched. There appears to be a preponderance of 1-2 Hz signals taking into account that the frequency range is limited by commingling with 1/f noise at the low end, and the frequency response of the instrument diminishes signals above 2.5 Hz.

The intensity value at the particular frequency gives the power spectrum of Figure 21a for 1 Hz intervals. The largest peak is at 1.5-2.5 Hz. In both cases, the stippling of the chart identifies the nine subjects.

A more detailed plot of the data of Table I, including those that exhibited three or more frequencies, indicated that this ensemble exhibited equal maxima at the harmonic frequencies 0.8 and 1.6 Hz and approximately equal peaks at 1.2, 2.6 and 4.2 Hz respectively, a rough approximation to harmonics of frequencies of 0.08 and 1.2 Hz. However, there was no peak at 3.0, 2.1 Hz at the exact harmonic frequencies.

The cognition spectrophotometer system, used in this trial, utilizes only the sum of the 760 nm and 850 nm signals. The isosbestic point in the Hb/HbO_2 spectrum is approximately at 800 nm, and thus the balanced sum of Hb/HbO_2 absorbances at 760 and 850 nm measures the blood concentration. Hb/HbO_2 is the principal absorber at these wavelengths since the signal is over 20 times that of cytochrome aa_3. The fact that no significant results were obtained in the difference recording suggests that the oxygenation/deoxygenation of the frontal lobe tissue was not a predominant effect in these studies. Changes of light scattering are not separated from absorbance changes when using continuous light, and would be expected to uniformly affect both 760 and 850 nm.

Furthermore, results of the present trial are compatible with other studies using PET, SPEC, and MRI which also suggest existence of blood flow changes during brain stimulation and the fact that the arterial pulse is the strongest signal in both "rest" and "test"; this supports the interpretation attributing the measured signal to blood concentration changes.

It is expected that the metabolic activities induced by brain stimulation contain low frequency component signals. The cognition spectrophotometer system of Figure 15 records repetitive fluctuations in the optical signal in a 10 min stimulus interval. Thus, the employed method requires not only a blood concentration increase during stimulation, but also periodic repetition of the increase within the tissue volume optically sampled. Such increases need not be repeated at identical locations but may have a spatio-temporal distribution. A 4 cm separation of input/output gives a mean penetration of 2 cm and a tissue volume of roughly 5 ml within which the repetitive response is observed.

Our narrow band width and relatively short iteration time (<11 min.) in this trial was set by the characteristics of an available instrument, and the detected spectrum may be only a portion of the total frequency spectrum. As shown in Figure 22, a much faster instrument can be also used. The limits to the bandwidth of optical studies are set both by signal-to-noise and by the intrinsic relaxation time of photon migration in the brain.

In the above described trial only a crude localization of the response was employed by placement of the input and output ports. The optical system was designed to respond optimally to blood concentration changes (in a volume of about 3-5 ml) in the frontal/temporal cortex, and the analogies were designed to stimulate activity in the frontal region. When left and right sides of the forehead were compared, the success rate of new peaks in the Fourier transform was two times greater in the left side.

An important aspect of future development of the optical methods is the rate at which data may be

accumulated. The travel time of photon migration over a path length of one meter is 23 ns with a 4 cm input/output separation. The signal to noise ratio will determine the number of iterations of the test, which in these preliminary studies, was approximately 50 over a period of 11 minutes.

The photon migration kinetics are responsive to both light scattering and light absorption. Whilst absorption has been stressed in these studies, light scattering is much closer to the primary events of neuronal/axonal response than to the blood flow/blood concentration change, both in anatomy and in time.

In this trial, the low frequency recurrence of changes of blood concentration was measured in portions of the brain that are approximately 2 cm deep from the surface of the skull of the subjects. Application to other stimuli (for example, visual, acoustic, sensorimotor) that affect function in other regions of the brain may be possible. (Visual stimulation registered in the visual cortex was not used in the present trial because dense hair covered the surface of the back of the head in the population studied.) It is expected that the recurrence frequencies which are observed in the cognitive tests would be significantly diminished in cases of neuronal deterioration. Thus, the cognition spectrophotometer system enables simple non-invasive and rapid testing of cognitive function of different regions of the brain.

The cognition spectrophotometer system is designed to provide objective evaluation of functional activity of the brain with a simple and inexpensive device. The system enables a wide range of studies of the brain activity in responding to appropriate tasks and presents an alternative to several expensive techniques (for example, MEG and EEG) or ones that involve radioactive

techniques. Thus, screening for neuronal deterioration and/or deterioration of brain function can be done conveniently and continuously.

In another embodiment, shown in Figures 22 and 23, the cognition spectrophotometer simultaneously records lateralized potential difference of two brain hemispheres. It has been suggested that lateralized readiness potential can measure electrical brain activity that is related to preparation of movement. This measure has been used to illuminate pre-setting processes that prepare the motor system of the brain for action. The lateralized potential also demonstrates the presence of transmission of partial information in the cognitive system and identifies processes responsible for the inhibition of responses.

The cognition spectrophotometer, shown in Figures 22 and 23, measures the lateralized difference potential optically by measuring increased blood concentration in localized regions of the brain that are activated by the lateralized readiness potential. The spectrophotometer simultaneously records and compares optical signals from both hemispheres. The detected data are subtracted in real time, the difference signal is recorded as an analog signal via an A/D converter and a computer manipulates the data and takes the Fourier transform of the data. The lateralized difference potential is measured as blood concentration changes using 800 nm light; however, light of other wavelengths sensitive to other constituents of the brain tissue can be used.

For high frequency measurements, the cognition spectrophotometer can use a fast lateralization detector, shown in Figure 22. The detector has two tungsten light sources 200 placed on the left and right parietal bones and two light-to-frequency converters 202 placed also on the parietal bones at a distance of 4 centimeters from

the sources. The intensity of each lamp 200 is regulated differentially by a lamp balance 206 in order to achieve the same light intensity output from the two light sources. An 800 nm interference filter 208 is placed on each silicon detector 202. The silicon light-to-frequency converters are adjusted by the frequency light intensity control to output the same frequency in the range of 10^6 to 10^7 Hz.

The fast lateralization detector measures a frequency difference between the two silicon detector converters 204. The signal of each detector is routed to a differential counter 212 using a 50 Hz clock 210. If the differential count is zero, both detectors are outputting the same frequency signal. If there is a difference in the signals detected at the two detectors, the differential count is not zero. The differential signal is processed by a frequency-to-voltage converter 214. Converter 214 operates in a low frequency range and detects frequency differences. The voltage output is Fourier transformed, stored and analyzed in view of a visual stimulus 218 or other brain activity stimulus.

Referring to Figure 23, in another preferred embodiment the cognition spectrophotometer utilizes a narrow band lateralization detector which is sensitive to the low frequency changes. Tungsten lamps 228 placed on the parietal bone are flashed at frequencies on the order of 2 to 3 Hz in order to provide for correction of the dark current. Each detector 230 has an 800 nm interference filter 232. A differential amplifier 234 is used to measure difference in the light intensity arriving at the two detectors. The output of the differential amplifier is coupled to the "RunMan" control unit, a modified version of the control unit shown in Figures 10 and 11. Balance 240 is set so that the two signals are balanced at zero millivolts. The output

signal is connected to the fast Fourier transformer 242, recorded on the strip chart recorder 244 or send to a computer. The lateralization detector of Figure 23 measures differential low frequency fluctuations of absorbances attributed to the brain blood concentration changes in different respective regions of the two brain hemispheres. The localization of the radiation to the appropriate region of the brain hemisphere is achieved by selecting proper location and separation of the input and output ports of the source-detector pair (Figures 15, 22, 23 and 24). For example, as described above, 4 cm separation of the source and detector on the exterior of the head gives a penetration of about 2 cm of the banana-shaped migration path of the radiation.

Referring to Figure 24, another preferred embodiment of the present invention is a differential spectrophotometer system for in vivo examination of a tissue of a human by measuring changes in electromagnetic radiation migrated in a path of two localized tissues of interest. The first tissue of interest, used to collect reference data, is expected to have normal physiological properties. The second tissue of interest is a tissue expected to have regions of pathological or pathophysiological changes, for example, a tumor or bleeding. An approximate localization of the tissue of interest having pathological or pathophysiological changes can be determined by diagnostic assessment of the subject, for example, by a neurologic examination, evaluation of the symptoms, etc.. In absence of any pathophysiological changes both the first and second localized tissues of interest (for example, regions of the left and right hemisphere of the brain, left and right breast, or left and right arm) are expected to produce nearly identical signals of photon migration. On the other hand, if a region of an organ, for example, the

right hemisphere of the brain, has a tissue of abnormal pathophysiological state, the tissue is expected to produce a signal which differs from the signal of the normal tissue of the left hemisphere; thus, the differential signal will be non zero.

Referring to Figure 24, the differential spectrophotometer system comprises the following five modules: two sensor modules 271 and 272, a control circuit module 274, an analyzer/display module 276, and a computer/printer module 278. Each of the two sensor modules 271 and 272, placed on the subject's head 273, comprises at least one source and detector as shown in Figures 5 to 8c, 22, 23. The operation of each sensor module is governed by control circuit module 274 which controls the radiation emission and detection, collects the data and sends the data to analyzer/display module 276 and to computer/printer 278. The operation of the whole cognition system is controlled by a computer of computer/printer module 278.

The differential spectrophotometer introduces electromagnetic radiation of at least one selected wavelength (for example, 800 nm) into the brain simultaneously at a first and second input port of the 271 and 272 sensor modules. Both the first input port and the second input port are placed at a first selected location and a second selected location on the exterior of the head, respectively. Two detectors, placed at a first and second location on the exterior of the head, are simultaneously detecting radiation that migrated along the banana-shaped paths in the two brain hemispheres from the first and second input ports to the first and second output ports, respectively. Control module 274 collects the detector signals, corrects for the noise signals and sends the corrected signals to analyzer/display module 276 and to computer/printer

module 278. Control module 274 can also create a differential signal, as described in Figures 22 and 23.

The system processes the signals of the two detectors and evaluates the processed data to determine whether the radiation migrated in a tissue of abnormal physiological or pathophysiological properties.

In another application, the differential spectrophotometer system can be used to determine physiological or pathophysiological properties of a breast tissue. Here, one sensor is placed on one breast and the other sensor on the other breast. Similarly as for the brain, breast tissue is examined by comparing the two signals of the radiation that migrated in the two paths in the respective breast.

The lateralized detection technique that simultaneously measures photon migration in two migration paths (Figures 22, 23, and 24) achieves better signal-to-noise ratio than the technique which detects signals from only one migration path (Figure 15). Some lateralized events involve only blood volume changes or only blood concentration changes; thus, the system can probe the tissue using radiation of only one selected wavelength. Other lateralized events may result in oxygenation/deoxygenation changes; thus, the system uses radiation of at least two wavelength (for example, 760 nm and 850 nm) coupled into an organ alternatively. In this case, each sensor comprises either one source-detector pair adapted to operate at at least two selected wavelengths, or two wavelength specific source-detector pairs. Signals of each wavelength obtained from the two sensors are again differentially manipulated to determine desired tissue properties. As described above, the localization of the radiation is controlled by placement and position of each source and detector.

One of ordinary skill in the art will appreciate that the present invention is not limited to the particular embodiments described in detail. Modifications to the circuitry disclosed, and other aspects of the spectrophotometer configurations disclosed, as well as other modifications to the physical arrangement of the present apparatus will be obvious to those of ordinary skill. Further, the present invention is not limited to any of the uses described herein. In order to fully appreciate the scope of the present invention, reference should be made to the following claims.

What is claimed is:

Claims

1. An oximeter for determining the oxygenation state of localized body tissue per se, constructed to be worn over a period of activity by a user and comprising a flexible, body-conformable support member which supports, adjacent the skin of a user, over the localized tissue of interest, at least a pair of spaced apart light sources, and intermediate thereof, at least a pair of wavelength-specific photo detectors, each light source exposed to transmit wavelengths of both of said specific wavelengths toward the localized tissue of interest lying below the skin and below the associated subcutaneous fat layer of the user, and each detector exposed to receive photons of the respective specific wavelength that have originated from each light source, and scattered from the localized tissue and passed back to the detectors through the subcutaneous fat layer and skin of the user, the support member including conformable barrier means disposed between each light source and the detectors, said barrier means being of substance capable of conforming to the contour of the wearer and preventing light energy proceeding laterally in the region of the barrier means from reaching the detectors.

2. An oximeter for determining the oxygenation state of localized body tissue per se, constructed to be worn over a period of activity by a user and comprising a flexible support member which supports, over the localized tissue of interest, at least a pair of spaced apart light sources, and intermediate thereof, at least a pair of wave length-specific light detectors, each light source exposed to transmit wavelengths of both of said specific wavelengths toward the localized tissue of interest, and each detector exposed to receive photons of

the respective specific wavelength that have originated from each light source, and scattered from the localized tissue and passed back to the detectors.

3. The oximeter of claim 1 or 2 in which the light sources comprise broad spectrum CW light sources.

4. The oximeter of claim 3 in which the light sources comprise tungsten filament lamps.

5. The oximeter of claim 1 or 2 including control means for simultaneously flashing the light sources to enable each detector to pick up light energy at its specific wavelength simultaneously from each light source.

6. The oximeter of claim 1 or 2 including means constructed to flash said light sources at selected intervals unrelated to the interval of heart beats of the user.

7. An oximeter comprising a flexible support member comprised of a molded-elastomeric backing member, said backing member mounting at least one light source means capable of producing two selected wavelengths and oriented to direct said light to tissue of a user and said backing member mounting detector means capable of separately detecting energy at each of said wavelengths scattered by tissue of the user, integral elastomeric portions of said backing member defining a barrier exposed for conformable contact with an exposed surface of the user, in position to prevent lateral movement of light in subcutaneous layers from the source means to the detector means.

8. An oximeter comprising a flexible support member, said support member mounting at least one light source means capable of producing two selected wavelengths and oriented to direct said light to tissue of a user and said support member mounting detector means capable of separately detecting energy at each of said wavelengths scattered by tissue of the user, said support member supporting a barrier member exposed for conformable contact with an exposed surface of the user in position to prevent lateral movement of light from the source means to the detector means, said barrier comprising a member having an edge sized and positioned to indent skin and the flesh of the user thereby to intercept light migrating laterally in the subcutaneous fat layer and prevent such light from reaching said detector means.

9. The oximeter of claim 8 wherein said barrier member is elastomeric, adapted to conform to the contour of the skin of the wearer.

10. The oximeter of claim 9 wherein said flexible support member comprises a molded-elastomeric backing member and said barrier member is integral with said backing member.

11. The oximeter of claim 8, 9 or 10 wherein the member defining said flesh-indenting edge is about 0.5 cm thick in the region that engages the skin.

12. The oximeter of claim 7 or 8 wherein said barrier member comprises a rib-form member.

13. The oximeter of claim 7 or 8 including in series at least two barrier members, one closely adjacent

to said light source means and one closely adjacent to said detector means.

14. The oximeter of claim 7 or 8 in which said support member mounts two spaced-apart light sources and a pair of detectors are disposed parallel to each other, disposed laterally relative to the line between said light sources and equal distance from each of said light sources.

15. The device of claim 14 wherein said light sources comprise broad spectrum CW light sources.

16. The oximeter of claim 1, 2, 7 or 8 including electronic control circuitry for said light source and said detector means, the circuitry disposed upon a miniature semiconductor chip carried by said support member.

17. The oximeter of claim 1, 2, 7 or 8 in combination with a real-time readout device constructed to be worn by the user and having a display responsive to said oximeter disposed for viewing by the user.

18. The oximeter of claim 17 wherein said oximeter is associated with means securing it to an appendage of the user and said readout device is constructed to be worn by a user.

19. The oximeter of claim 1, 2, 7 or 8 in combination with radio frequency telemetry means for transmitting oximeter data on a real time basis to a station remote from the user or to a receiver in a readout device constructed to be worn by a user.

20. The oximeter of claim 1, 2, 7 or 8 including electronic control circuitry for said light source and said detector means, the circuitry disposed upon a miniature semiconductor chip carried by said support member in combination with radio frequency telemetry means controlled by said circuitry for transmitting oximeter data on a real time basis to a station remote from the user.

21. The oximeter of claim 1, 2, 7 or 8 including means for battery-operation of said oximeter and means to record oximetry data in internal digital memory for subsequent display or data analysis on a computer.

22. The oximeter of claim 1, 2, 7 or 8 including electronic control circuitry for said light source and said detector means, the circuitry disposed upon a miniature semiconductor chip carried by said support member, and means for battery-operation of said oximeter and means to record oximetry data in internal digital memory for subsequent display or data analysis on a computer.

23. The oximeter of claim 7 or 8 encapsulated in biocompatible material, the oximeter constructed and arranged for implantation under the skin of a user for monitoring internal tissue oxygen trends.

24. An oximeter comprising a support mounting a light source and detector means at fixed spacing, and electronic control circuitry for said light source and said detector means, the circuitry disposed upon a miniature semiconductor chip carried by said support member, said oximeter encapsulated in biocompatible water impermeable material, the oximeter constructed and

arranged for implantation under the skin of a user for monitoring internal tissue oxygen trends.

25. The method of monitoring the derivative or rate of change of the time based curve representing detected change of tissue oxygen levels and blood volume and employing these rates as a quantitative standard of measurement of tissue oximetry.

26. The method of assisting an aviator or other person engaged in activity that can subject the person to high G-forces including providing to the person a comfortable oximeter sensor suitable to be worn about the head and capable of responding to tissue oxygen level, blood volume of brain tissue on a real time basis, employing said oximeter sensor to monitor oxygen level of brain tissue of the wearer as the wearer engages in said activity, comparing the monitored value to a standard and generating a signal, such as a warning or control signal, in the event the monitored level violates a pre-established standard.

27. The method of claim 26 wherein said oximeter is constructed to monitor the trend of oxygen level in the brain, and means to evaluate the rate of change being detected and using said rate of change as the control value and alarm reference.

28. The method of monitoring a person suspect of sleep apnea or sudden infant death syndrome including providing to the person a comfortable oximeter sensor capable of automatically responding to oxygen level of the person while permitting the person to sleep, automatically monitoring the output of the oximeter by comparing it to a standard and generating a signal, such

as a warning or control signal, in the event the monitored level violates a pre-established standard.

29. The method of claim 28 wherein the oximeter sensor is taped comfortably to the head for monitoring.

30. The method of claim 28 used in conjunction with impedance pneumography (breathing rate measurement using chest-wall impedance) and/or EKG to provide an effective in-home apnea monitor to alarm the patient or other individuals in the area so as to wake the patient and prevent hypoxic tissue damage during sleep.

31. The method of monitoring the cerebral tissue oxygen rate of change as a means of triggering alarm to awaken a subject in danger of infarct due to hypoxia.

32. The method of monitoring both tissue oxygen level and blood volume in skin flaps such as are produced either by wound or surgery, as said flaps heal, the separation between the source and the detector being established in relation to the thickness of the skin flap to ensure tissue of the flap per se is being monitored.

33. The method of emergency monitoring of cerebral tissue oxygen level and blood volume in an emergency care situation with the device of claim 21.

34. The method of employing the device of any of the claims 1, 2, 7, or 8 wherein the oxygen levels, blood volume, and/or rate of charge are measured in cancerous tissue to indicate the activity and viability of the tissue.

35. The method of employing the device of claim 24 wherein the oxygen levels and blood volume are measured in cancerous tissue to indicate the activity and viability of the tissue.

36. The method of claim 34 including monitoring of the viability of a tumor following treatment intended to wipe out said cancerous tissue.

37. A helmet into which is molded a tissue oximeter in position to engage the head of the wearer when the helmet is put on, the oximeter being of the NIR type, comprising light source means for transmitting near infrared light into the head, detector means held in spaced position relative to the light source means for receiving light scattered by brain tissue and a barrier disposed to engage the head between the light source means and the detector means to prevent light traveling laterally from the light source means from reaching the detector means.

38. The helmet of claim 37 wherein the oximeter includes control circuitry on a miniature chip.

39. The helmet of claim 37 or 38 including means for determining the rate of change of oximetry readings and for comparing the rate of change to a standard.

40. A tissue oximeter comprising a support, a detector fixed to the support and a light source mounted in an adjustable manner to the support to enable selection of the spacing between light source and detector for adjusting the mean depth of tissue to which the oximeter responds.

41. A tissue oximeter in combination with means connected to receive tissue oxygen readings from the oximeter, determine the rate of change of said readings, said rate of change serving as a quantifiable indication of the state of the metabolic process of the tissue.

42. The oximeter of claim 1, 2, 7 or 8 including electronic control circuitry comprised of entirely non-magnetic components enabling use of the device in conjunction with nuclear magnetic resonance imaging.

43. An oximeter disposed on an endoscope, catheter, guidewire or the like for insertion via a body passage to internal tissue, and including means such as an inflatable balloon to press the oximeter sensor against the localized tissue of interest.

44. The oximeter of claim 1, 2, 7, or 8 including a water impermeable coating about said device for applications in the presence of water.

45. The oximeter of claim 1, 2, 7, or 8 wherein said light source comprises a light emitting diode.

46. The oximeter of claim 1, 2, 7, or 8 wherein said detector comprises a silicon diode.

47. The oximeter of claim 1 or 2 wherein said wavelength specific detector comprises a silicon diode and an interference filter.

48. The oximeter of claim 1, 2, 7, or 8 including electronic control circuitry for said light source and said detector, said circuitry being adapted to correct

for a noise signal not attributable to detected light that migrated through said localized tissue of interest.

49. The oximeter of claim 48 wherein said correction of said noise signal being achieved by charging a capacitor of an integrator for said detector with current of one polarity during a light off cycle and subsequently charging said capacitor with current of opposite polarity during a light on cycle, whereby subtracting said noise signal occurring during said light off cycle from the total signal occurring during said light on cycle.

50. A method of transcranial examination of brain activity by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in the brain comprising

(a) introducing electromagnetic radiation of a selected wavelength into the brain at an input port placed at a selected location on the exterior of the head,

(b) detecting, at a detection port placed at a selected location on the exterior of the head, radiation of said selected wavelength that has migrated in the brain,

(c) causing stimulation of a brain activity while introducing said radiation at said input port and while detecting radiation of said detection port,

(d) processing signals of said detected radiation that has migrated in the brain to create processed data, and

(e) determining a characteristic of said brain activity by correlating said processed data with said caused stimulation of said brain activity.

51. The method of claim 50 wherein said steps of introducing said radiation into the brain and detecting said radiation that has migrated in the brain, while causing stimulation of said brain activity, are repeated at different locations on the exterior of the head, and said step of processing said detected radiation to create processed data is correspondingly repeated.

52. The method of claim 50 or 51 wherein said input port and said output port are located on one of the following: the frontal bone, parietal bone, temporal bone or occipital bone; said input port and said output port being separated by a predetermined distance in order to localize said migration of said radiation to a selected region of the brain.

53. The method of claim 52 wherein said predetermined distance is 4 centimeters.

54. The method of claim 50 further comprising

(a) introducing electromagnetic radiation of said selected wavelength into the brain at a second input port placed at a second selected location on the exterior of the head,

(b) detecting, at a second detection port placed at a selected location on the exterior of the head, radiation of said selected wavelength that has migrated in the brain from said second input port to said second detection port,

(c) processing signals of said detected radiation that has migrated in the brain from said second input port to said second detection port to create second processed data, and

(d) determining a characteristic of said brain activity by correlating both first mentioned and said

second processed data with said caused stimulation of said brain activity.

55. The method of claim 54 wherein said radiation is simultaneously introduced at said first and second input ports and detected at said first and second detection ports.

56. The method of claim 54 wherein said radiation is first introduced at said first input port and detected at said first detection port, and subsequently said radiation is introduced at said second input port and detected at said second detection port.

57. A method of transcranial examination of brain activity by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in the brain comprising

(a) introducing electromagnetic radiation of a selected wavelength into the brain simultaneously at a first input port and at a second input port, said first input port and said second input port being placed at a first selected location and a second selected location on the exterior of the head, respectively,

(b) detecting simultaneously, at a first detection port placed at a selected location on the exterior of the head, radiation that has migrated in the brain from said first input port to said first detection port and, at a second detection port placed at second selected location on the exterior of the head, radiation that has migrated in the brain from said second input port to said second detection port,

(c) causing stimulation of a brain activity while introducing said radiation at said first and second input

ports and while detecting radiation at said first and second detection ports,

(d) processing signals of said detected radiation that has migrated in the brain to create processed data, and

(e) determining a characteristic of said brain activity by correlating said processed data to said caused stimulation of said brain activity.

58. The method of claim 54 or 57 wherein said first input port and said first output port are located on one parietal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the respective hemisphere of the brain, and said second input port and said second output port are located on the other parietal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the other hemisphere of the brain.

59. The method of claim 58 wherein said processing comprises comparing electromagnetic radiation detected at said first and second detection ports to create processed data representing a differential signal.

60. The method of claim 54 or 57 wherein said first input port and said first output port are located on one temporal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the respective hemisphere of the brain, and said second input port and said second output port are located on the other temporal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the other hemisphere of the brain.

61. The method of claim 60 wherein said processing comprises comparing electromagnetic radiation detected at said first and second detection ports to create processed data representing a differential signal.

62. The method of claim 50, 54 or 57 wherein said processing of said detected radiation comprises Fourier transformation.

63. The method of claim 50, 54 or 57 wherein said stimulation is visual stimulation.

64. The method of claim 50, 54 or 57 wherein said stimulation is acoustic stimulation.

65. The method of claim 50, 54 or 57 wherein said stimulation is sensorimotor stimulation.

66. The method of claim 50, 54 or 57 further comprising examining cognitive function of a selected region of the brain based on correlation between said processed data and said caused stimulation of said brain activity.

67. The method of claim 50, 54 or 57 further comprising examining pathological/pathophysiological state of a tissue of a selected region of the brain based on correlation between said processed data and said caused stimulation of said brain activity.

68. A cognition spectrophotometer system for transcranial examination of brain activity by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in the brain comprising

(a) a light source adapted to introduce electromagnetic radiation of a selected wavelength into the brain at an input port placed at a selected location on the exterior of the head,

(b) a detector adapted to detect, at a detection port placed at a selected location on the exterior of the head, radiation of said selected wavelength that has migrated in the brain,

(c) stimulation means adapted to cause stimulation of a brain activity while introducing said selected wavelength and while detecting radiation at said detection port,

(d) processing means adapted to process signals of said detected radiation that has migrated in the brain to create processed data, and

(e) evaluation means adapted to determine a characteristic of said brain activity by correlating said processed data with said caused stimulation of said brain activity.

69. The system of claim 68 wherein said processing means adapted to process detected radiation that has migrated in the brain in said migration path between said input port and said output port being separated by a predetermined distance and being located at different locations on the exterior of the head.

70. The system of claim 68 or 69 wherein said input port and said output port are located on one of the following: the frontal bone, parietal bone, temporal bone or occipital bone; said input port and said output port being separated by a predetermined distance in order to localize said migration of said radiation to a selected region of the brain.

71. The system of claim 70 wherein said predetermined distance is 4 centimeters.

72. The system of claim 68 further comprising

(a) a second light source adapted to introduce electromagnetic radiation of said selected wavelength into the brain at a second input port placed at a second selected location on the exterior of the head,

(b) a second detector adapted to detect, at a second detection port placed at a selected location on the exterior of the head, radiation of said selected wavelength that has migrated along said migration path in the brain from said second input port to said second detection port, and

(c) processing means adapted to process signals of said detected radiation that has migrated in the brain from said second input port to said second detection port to create second processed data,

wherein said evaluation means determine said characteristic of said brain activity by correlating both first mentioned and said second processed data with said caused stimulation of the brain.

73. The system of claim 72 adapted to introduce simultaneously said radiation at said first and second input ports and detect at said first and second detection ports.

74. The system of claim 72 adapted to introduce said radiation first at said first input port and detected at said first detection port, and subsequently introduce said radiation at said second input port and detected at said second detection port.

75. A cognition spectrophotometer system for transcranial examination of brain activity by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in the brain comprising

(a) a first light source and a second light source adapted to introduce electromagnetic radiation of a selected wavelength into the brain simultaneously at a first input port and at a second input port, said first input port and said second input port being placed at a first selected location and a second selected location on the exterior of the head, respectively,

(b) a first detector and a second detector adapted to detect simultaneously, at a first detection port placed at a selected location on the exterior of the head, radiation that has migrated in the brain from said first input port to said first detection port and, at a second detection port placed at second selected location on the exterior of the head, radiation that has migrated in the brain from said second input port to said second detection port,

(c) stimulation means adapted to cause stimulation of a brain activity while introducing said radiation at said first and second input ports and while detecting radiation at said first and second detection ports,

(d) processing means adapted to process signals of said detected radiation that has migrated in the brain to create processed data, and

(e) evaluation means adapted to determine a characteristic of said brain activity by correlating said processed data to said caused stimulation of said brain activity.

76. The system of claim 72 or 75 wherein said first input port and said first output port being located

on one parietal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the respective hemisphere of the brain, and said second input port and said second output port being located on the other parietal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the other hemisphere of the brain.

77. The system of claim 76 wherein said processing means further adapted to compare electromagnetic radiation detected at said first and second detection ports to create processed data representing a differential signal.

78. The system of claim 72 or 75 wherein said first input port and said first output port are located on one temporal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the respective hemisphere of the brain, and said second input port and said second output port are located on the other temporal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the other hemisphere of the brain.

79. The system of claim 78 wherein said processing means further adapted to compare electromagnetic radiation detected at said first and second detection ports to create processed data representing a differential signal.

80. The system of claim 68, 72 or 75 wherein said processing of said detected radiation comprises Fourier transformation.

81. The system of claim 68, 72 or 75 wherein said stimulation means adapted to cause visual stimulation.

82. The system of claim 68, 72 or 75 wherein said stimulation means adapted to cause acoustic stimulation.

83. The system of claim 68, 72 or 75 wherein said stimulation means adapted to cause sensorimotor stimulation.

84. The system of claim 68, 72 or 75 wherein said evaluation means further adapted to examine cognitive function of a selected region of the brain based on correlation between said processed data and said caused stimulation of said brain activity.

85. The system of claim 68, 72 or 75 wherein said evaluation means further adapted to examine tissue of a selected region of the brain based on correlation between said processed data and said caused stimulation of said brain activity.

86. The system of claim 75 wherein said first light source and said second light source are tungsten lamps or light emitting diodes.

87. The system of claim 75 wherein said first detector and said second detector are silicon diodes each having an interference filter adapted to detect said radiation of said selected wavelength.

88. The system of claim 75 wherein said first detector and said second detector are light-to-frequency

convertors each having an interference filter adapted to detect said radiation of said selected wavelength.

89. The system of claim 88 wherein said processing means comprise

(a) differential counter adapted to register differential signals received from said light-to-frequency convertors,

(b) clocking means adapted to route signals of said detected radiation from said light-to-frequency convertors to said differential counter, and

(c) a frequency-to-voltage converter adapted to convert signals from said differential counter.

90. The system of claim 89 wherein said processing means further comprise a fast Fourier transformer adapted to process differential signal from said frequency-to-voltage converter.

91. The system of claim 90 wherein said evaluation means comprise a storage oscilloscope adapted to analyze the Fourier transformed differential signal of said fast Fourier transformer.

92. The system of claim 89 or 91 wherein said evaluation means further comprises computational means adapted to analyze said differential signal.

93. A cognition spectrophotometer system for transcranial examination of brain activity by measuring changes in light scattered and absorbed in a migration path in the brain comprising

(a) the oximeter of claim 2 or 7,

(b) stimulation means adapted to cause stimulation of a brain activity while introducing said

light using said light source and while detecting said light that migrated in the localized tissue of interest of the brain,

(d) processing means adapted to process signals of said detected light that has migrated in the brain to create processed data, and

(e) evaluation means adapted to determine a characteristic of said brain activity by correlating said processed data to said caused stimulation of said brain activity.

94. A method of transcranial examination of a brain tissue by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in the brain comprising

(a) introducing electromagnetic radiation of a selected wavelength into the brain simultaneously at a first input port and at a second input port, said first input port and said second input port being placed at a first selected location and a second selected location on the exterior of the head, respectively,

(b) detecting simultaneously, at a first detection port placed at a selected location on the exterior of the head, radiation that has migrated in the brain from said first input port to said first detection port and, at a second detection port placed at second selected location on the exterior of the head, radiation that has migrated in the brain from said second input port to said second detection port,

(c) processing signals of said radiation detected at said first and second detection port that have migrated in the brain to create first and second processed data, respectively, and

(d) determining a selected property of said brain tissue by correlating said processed first and second data.

95. The method of claim 94 wherein said first input port and said first output port are located on one parietal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the respective hemisphere of the brain, and said second input port and said second output port are located on the other parietal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the other hemisphere of the brain.

96. The method of claim 94 wherein said first input port and said first output port are located on one temporal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the respective hemisphere of the brain, and said second input port and said second output port are located on the other temporal bone, separated by a predetermined distance, in order to localize migration of said radiation in a selected region of the other hemisphere of the brain.

97. The method of claim 94, 95 or 96 wherein said processing comprises comparing electromagnetic radiation detected at said first and second detection ports to create processed data representing a differential signal.

98. The method of claim 97 wherein said selected property of said brain tissue is a pathophysiological state of said tissue.

99. A method of in vivo examination of a tissue of a human by measuring changes in electromagnetic radiation scattered and absorbed in a migration path in said tissue comprising

(a) introducing electromagnetic radiation of a selected wavelength into the tissue at a first input port placed at a selected location on said human,

(b) detecting, at a first detection port placed at a selected location on said human, radiation of said selected wavelength that has migrated in the first localized tissue of interest from said first input port to said first detection port,

(c) introducing electromagnetic radiation of said selected wavelength into the tissue at a second input port placed at a second selected location on said human,

(d) detecting, at a second detection port placed at a selected location on said human, radiation of said selected wavelength that has migrated in the second localized tissue of interest from said second input port to said second detection port, said first localized tissue of interest having normal physiological properties, said second localized tissue of interest being examined for pathophysiological changes,

(e) processing signals of said detected radiation that has migrated in said first and second localized tissues of interest to create first and second processed data, and

(f) determining pathophysiological changes in said second localized tissue of interest by correlating both said first and said second processed data.

100. The method of claim 99 wherein said radiation is simultaneously introduced at said first and second input ports and detected at said first and second detection ports.

101. The method of claim 99 wherein said radiation is first introduced at said first input port and detected at said first detection port, and subsequently said radiation is introduced at said second input port and detected at said second detection port.

FIG. 1A FIG. 1B

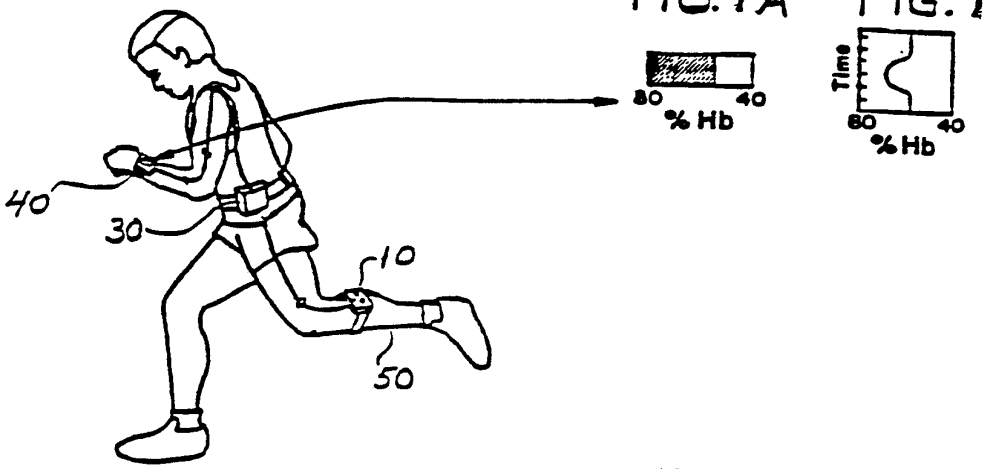


FIG. 1

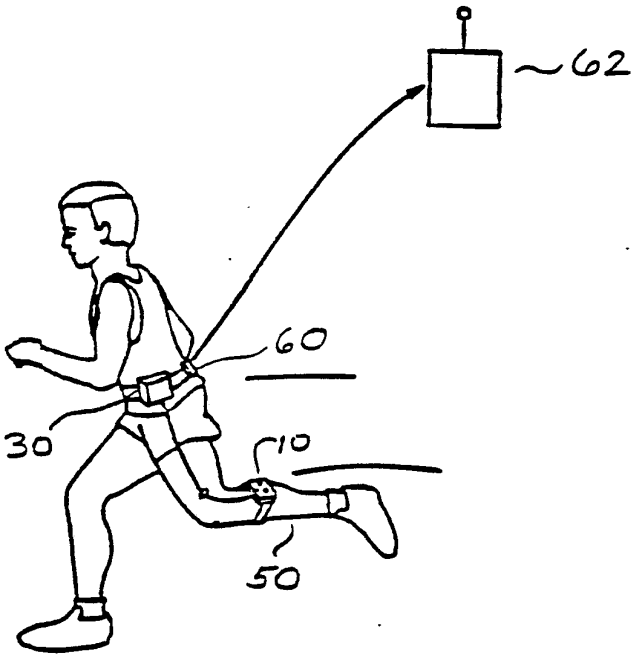


FIG. 3

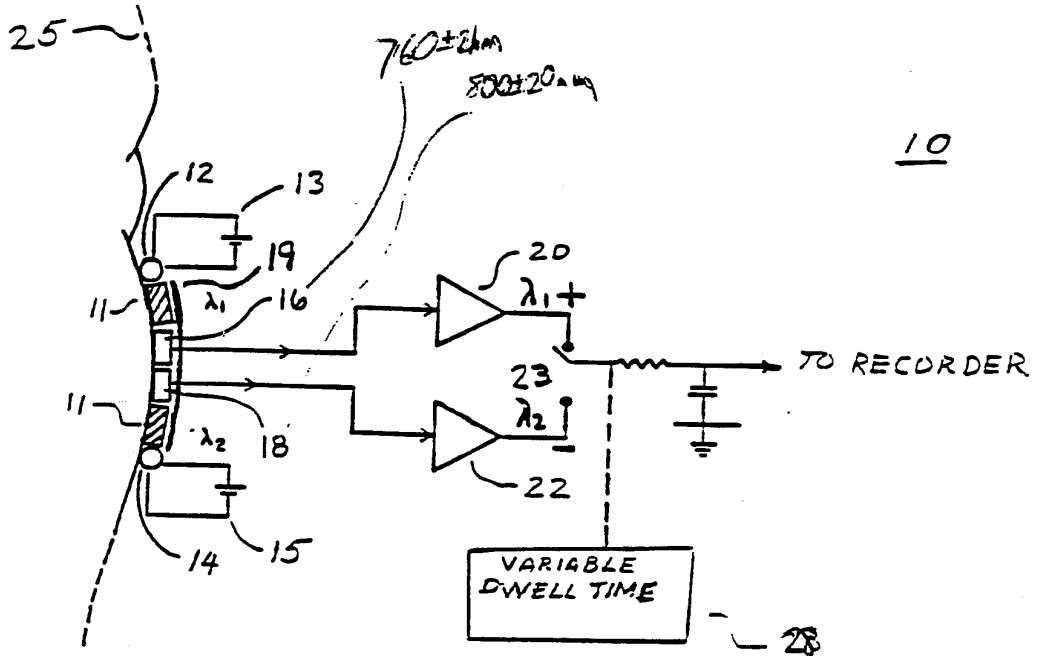

25
760±2nm
800±20nm
10
12
13
19
20
λ1+
λ1
16
11
TO RECORDER
23
λ2
11
λ2
18
22
14
15
VARIABLE
DWELL TIME
28

FIG. 2

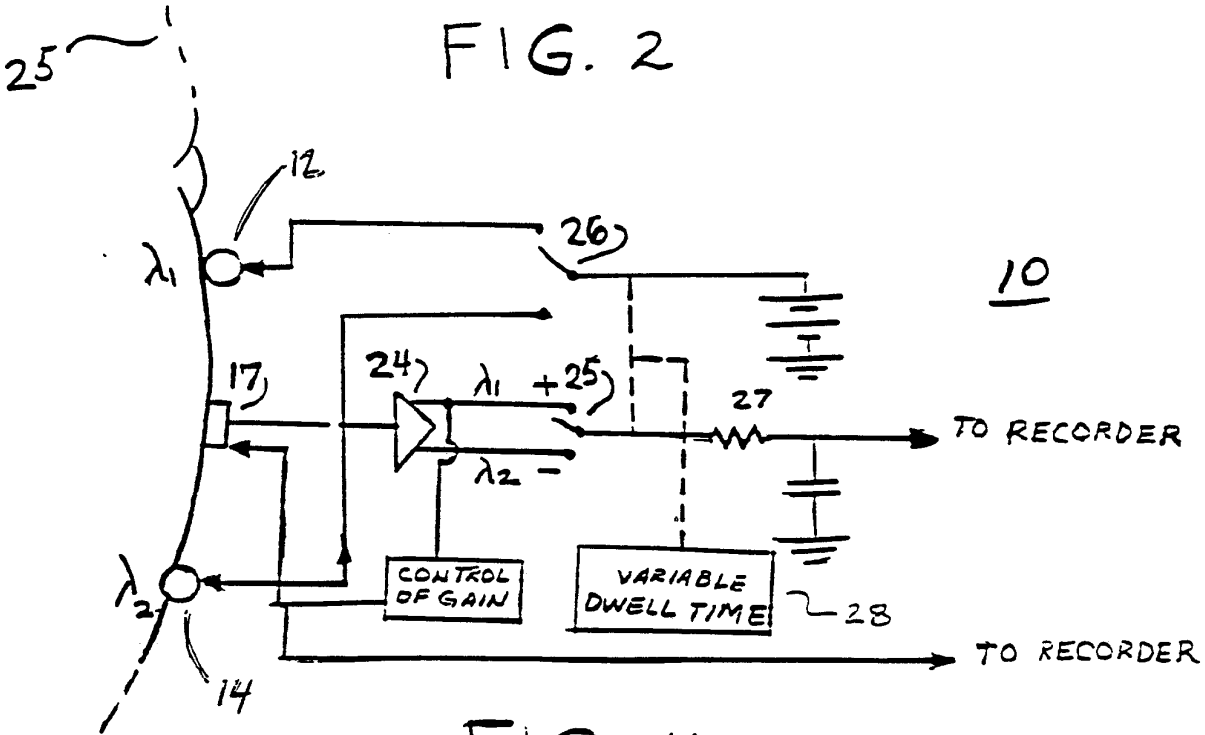

25
12
26
λ1
10
17
24
λ1
+25
27
TO RECORDER
λ2 −
CONTROL
OF GAIN
VARIABLE
DWELL TIME
28
λ2
TO RECORDER
14

FIG. 4

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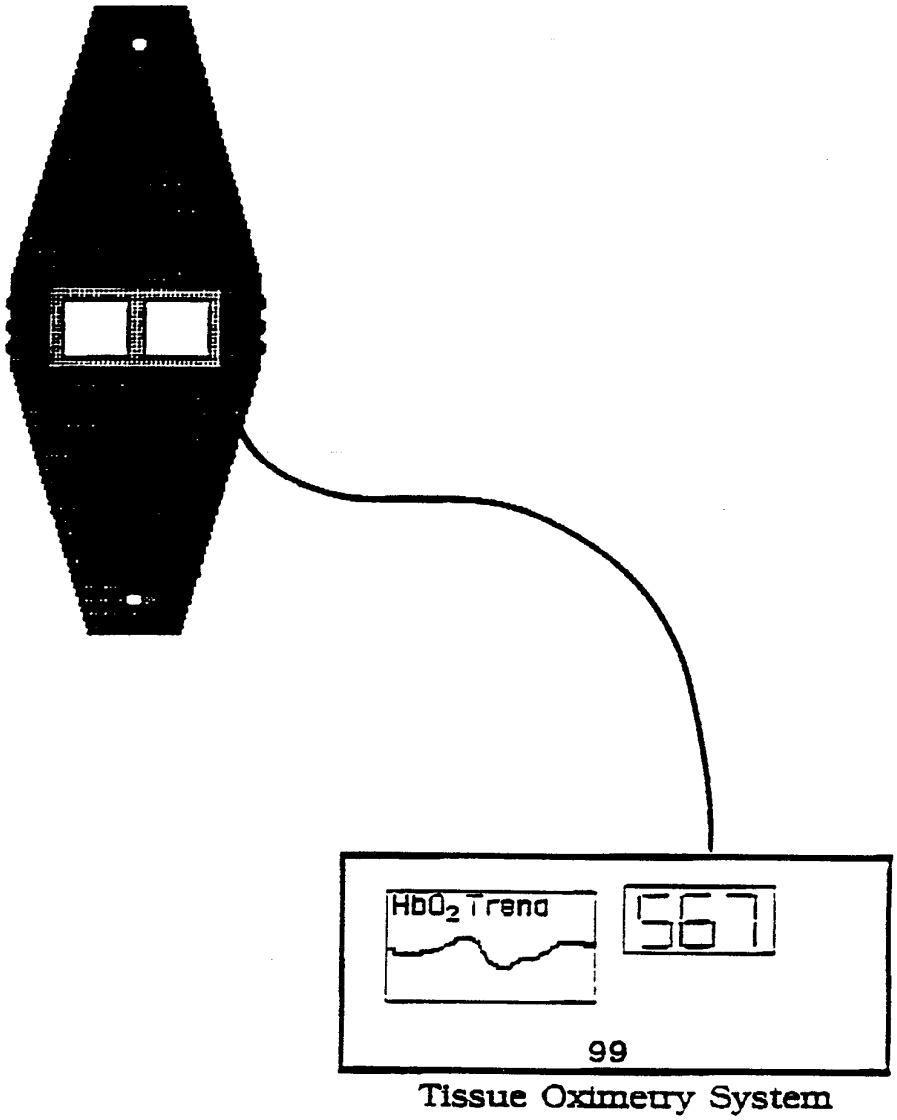


Figure 5

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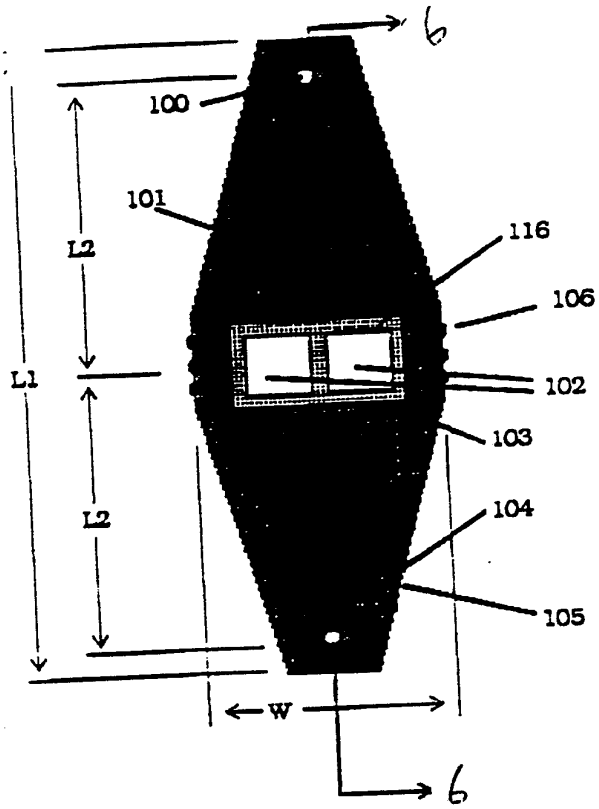


Figure 6A

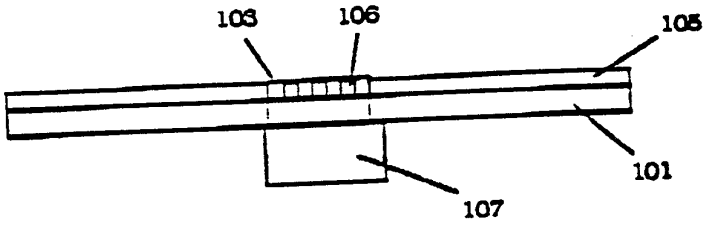


Figure 6B

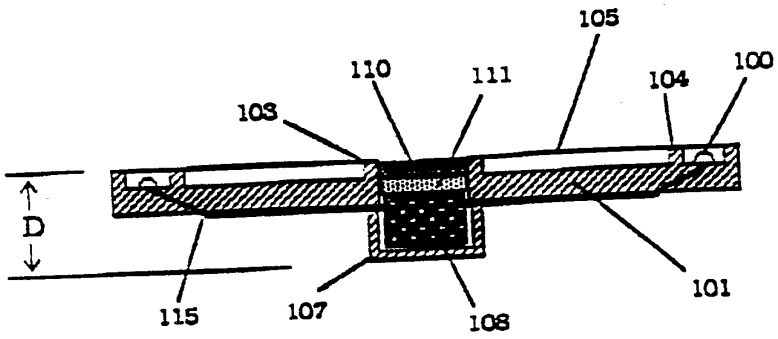


Figure 6C

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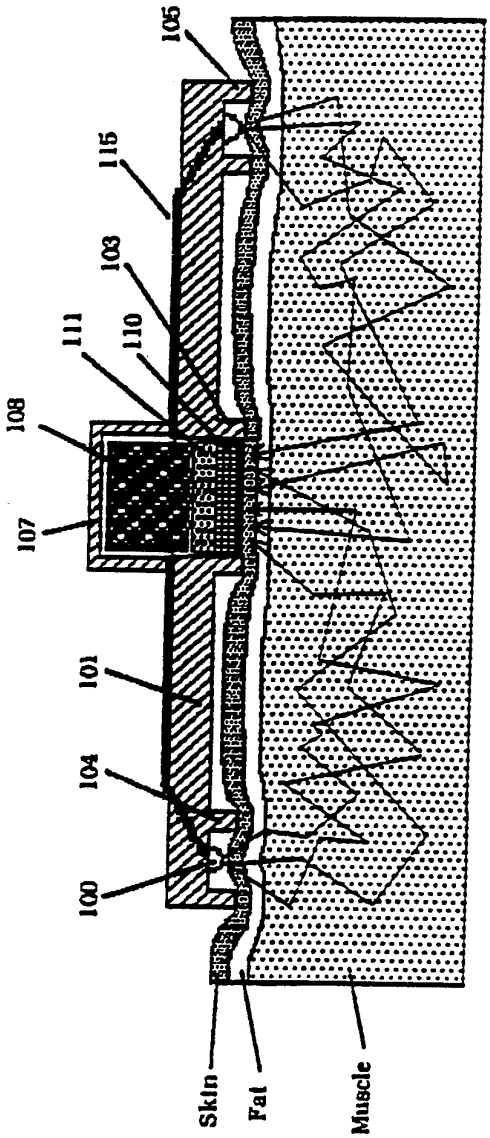


Figure 7

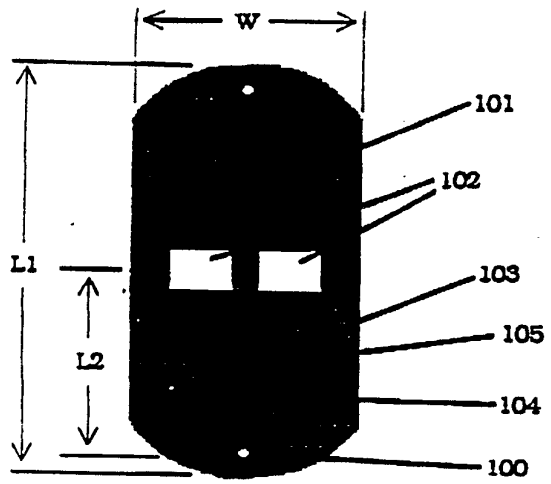


Figure 8A

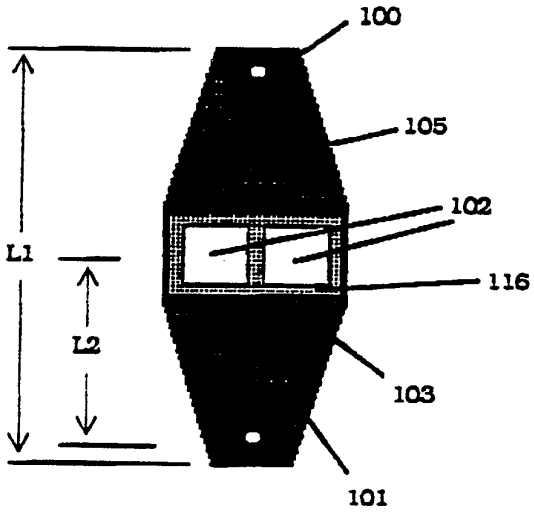


Figure 8B

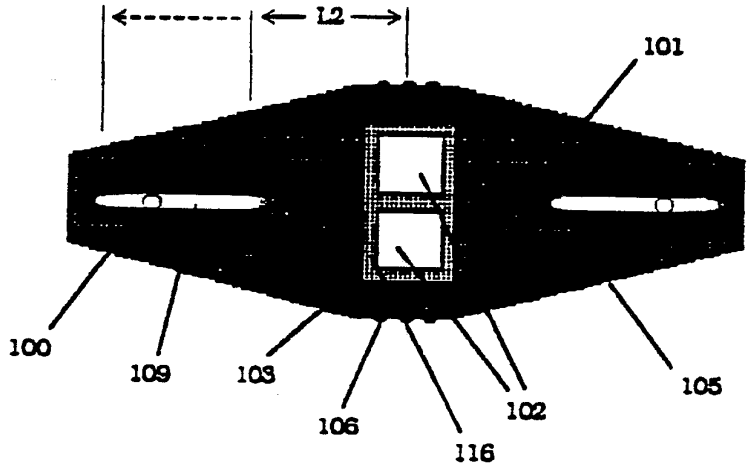


Figure 8C

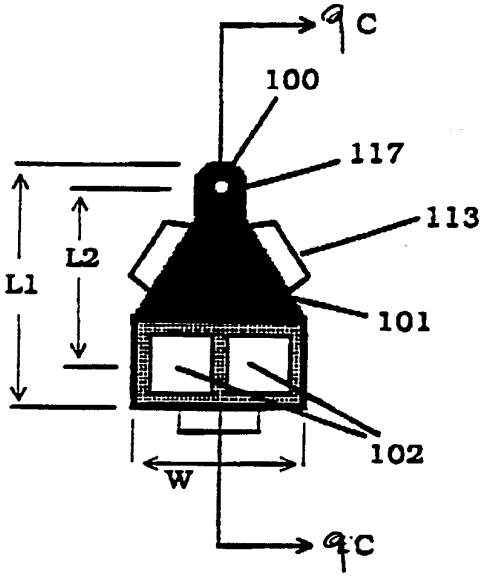


Figure 9A

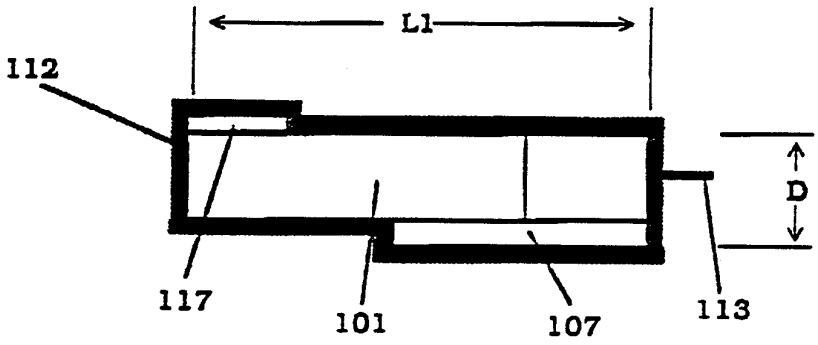


Figure 9B

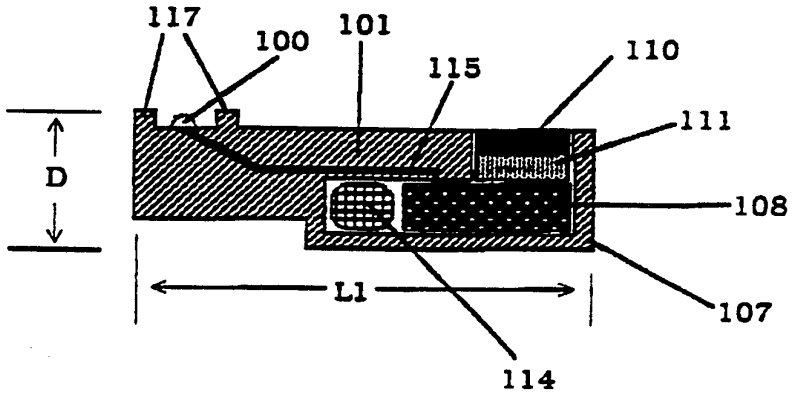


Figure 9C

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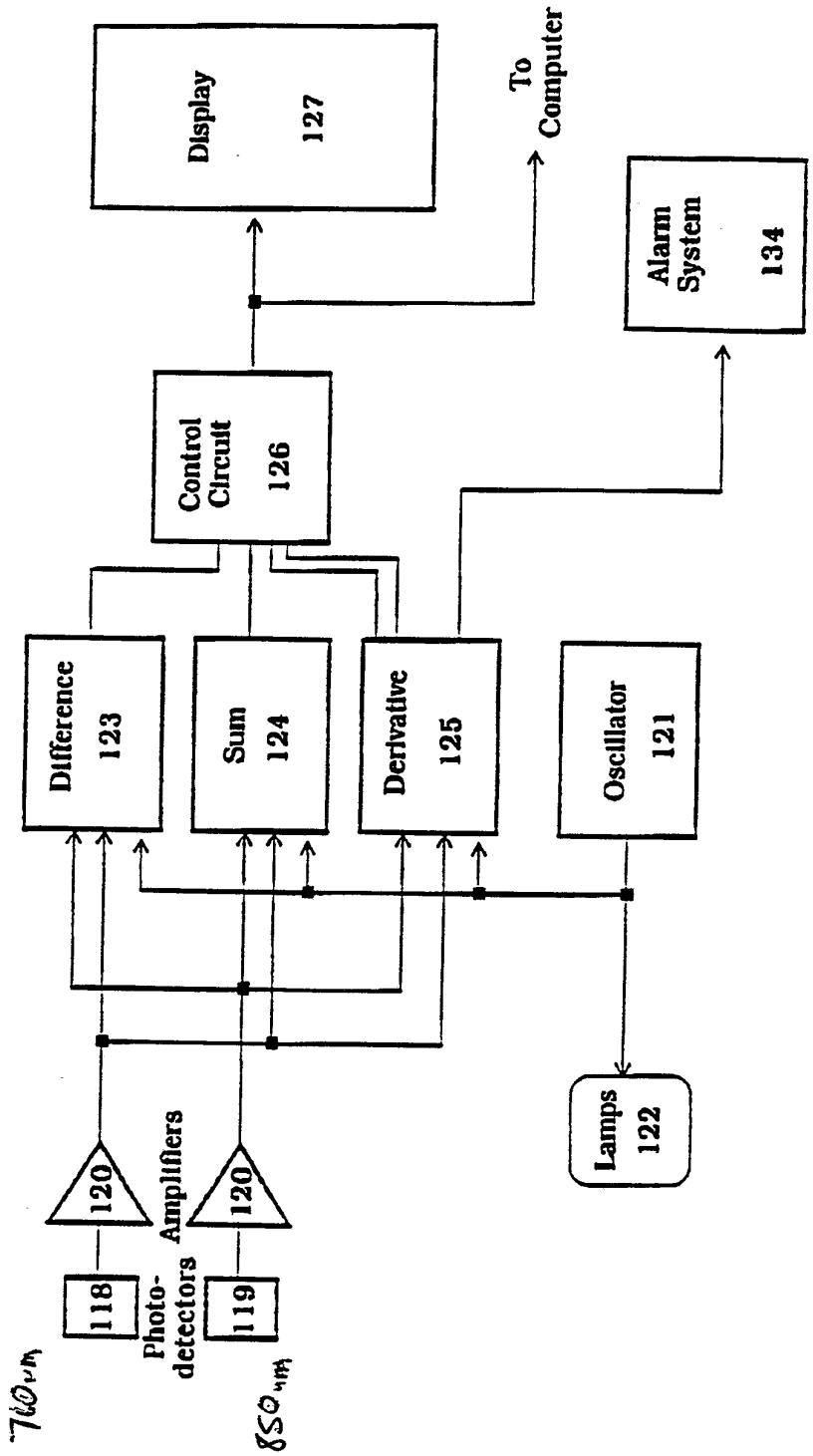


Figure 10

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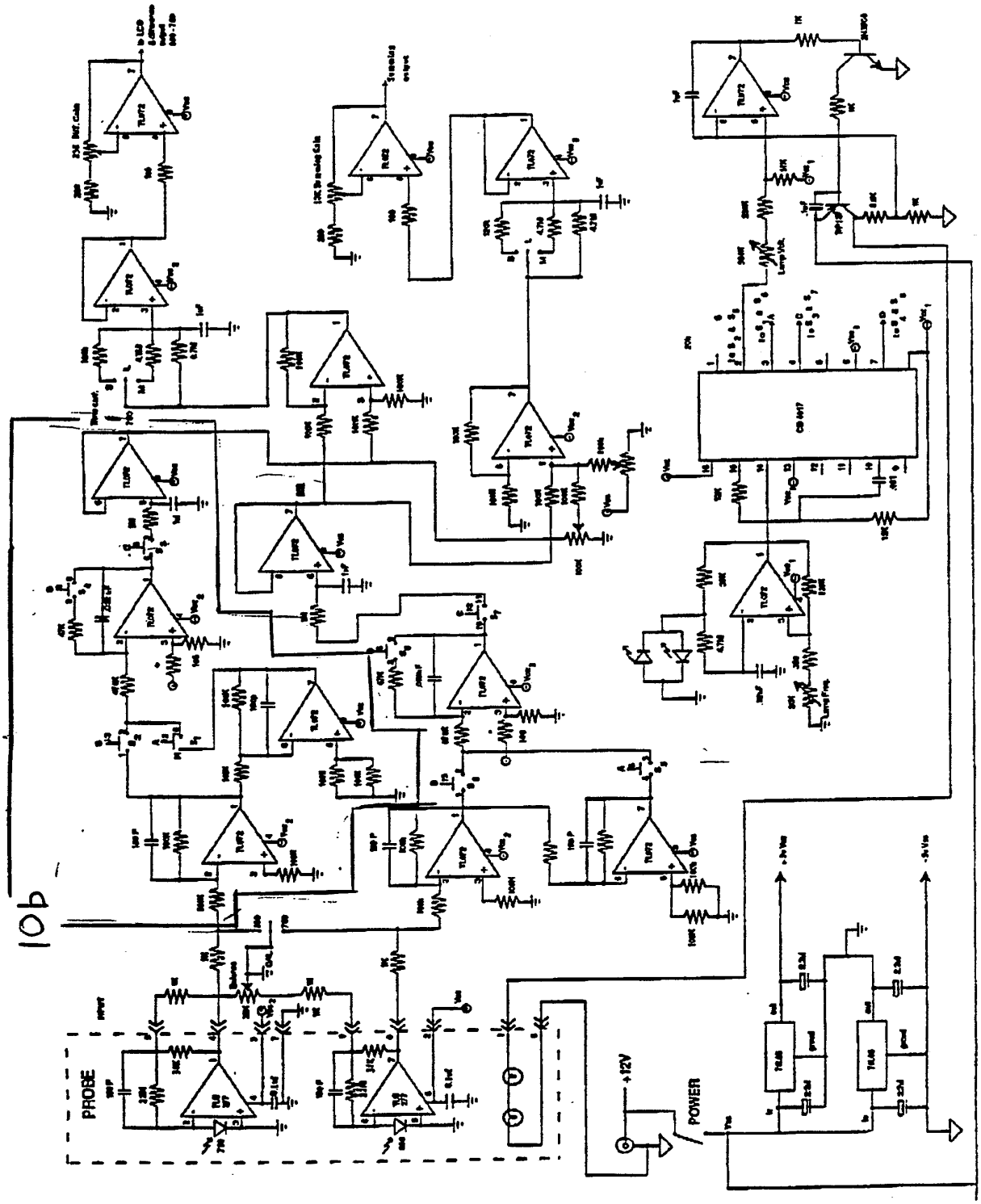

PROBE
+12V
POWER
© NIM Inc., 1990
Run Man™ Circuit Diagram Nov 7, 1990

FIG 10a

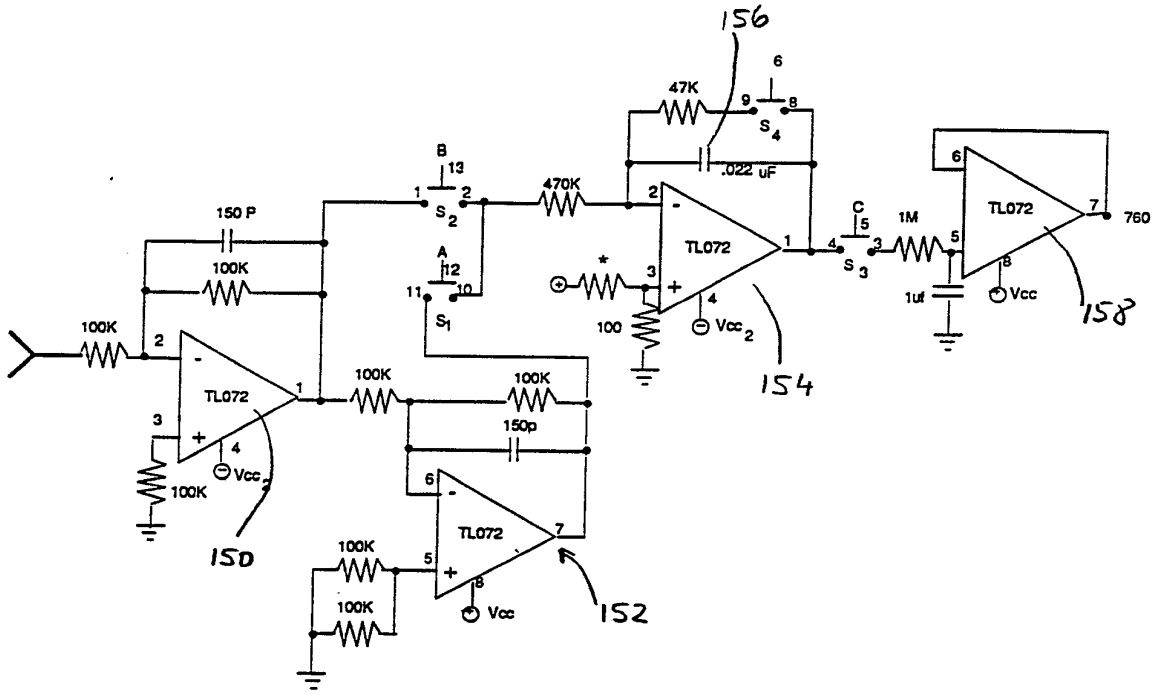

156
47K
6
9
8
S4
.022 uF
B
13
1
2
S2
470K
150 P
100K
A
12
11
10
S1
100K
2
TL072
1
3
4
Vcc2
150
100K
100K
150p
100K
6
TL072
7
5
8
Vcc
100K
152
2
TL072
1
3
4
Vcc2
100
154
C
5
4
3
S3
1M
6
TL072
7
760
5
8
Vcc
1uf
158

Fig. 10b

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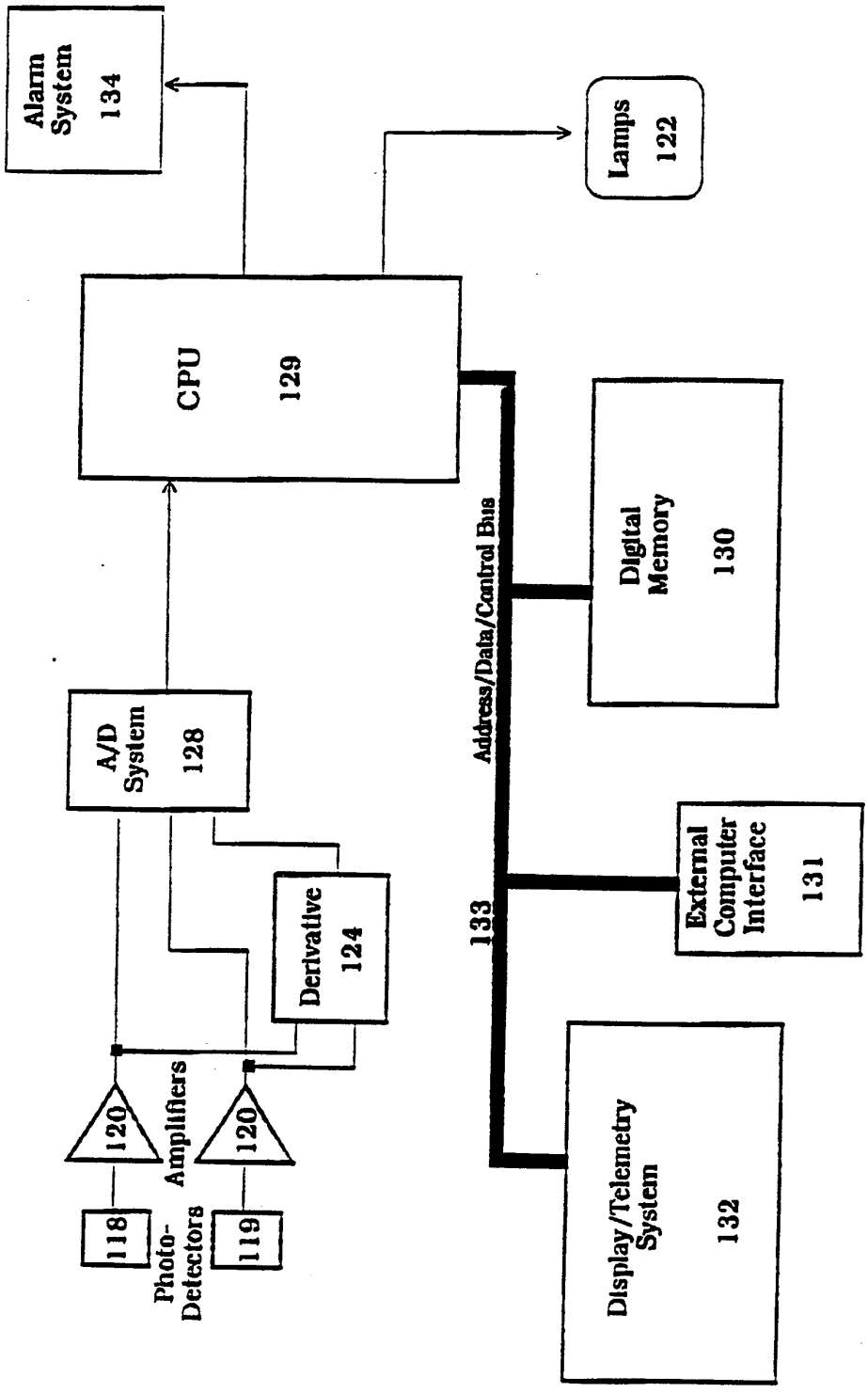
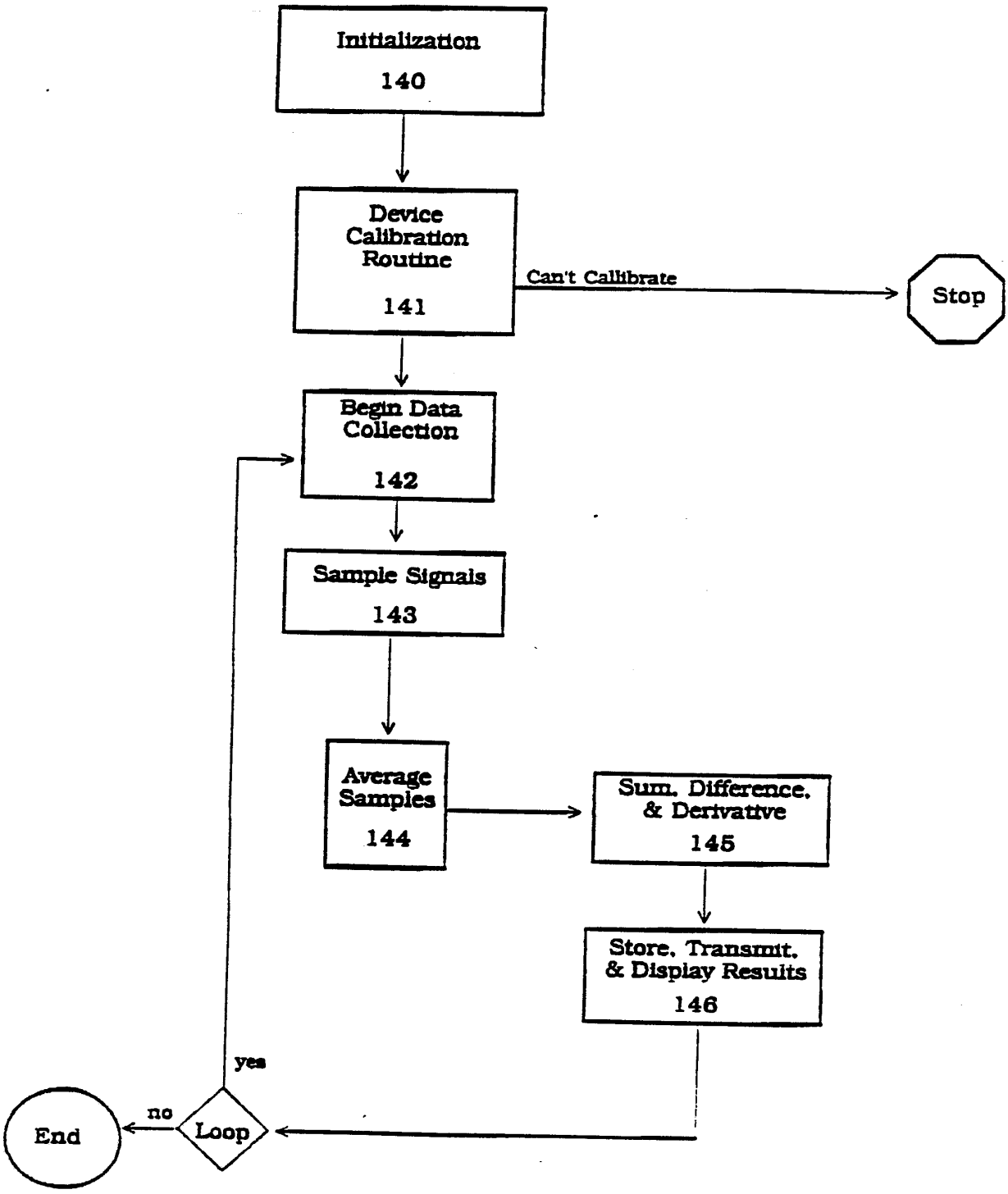


Figure 11

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Figure 12
Software Flow Diagram



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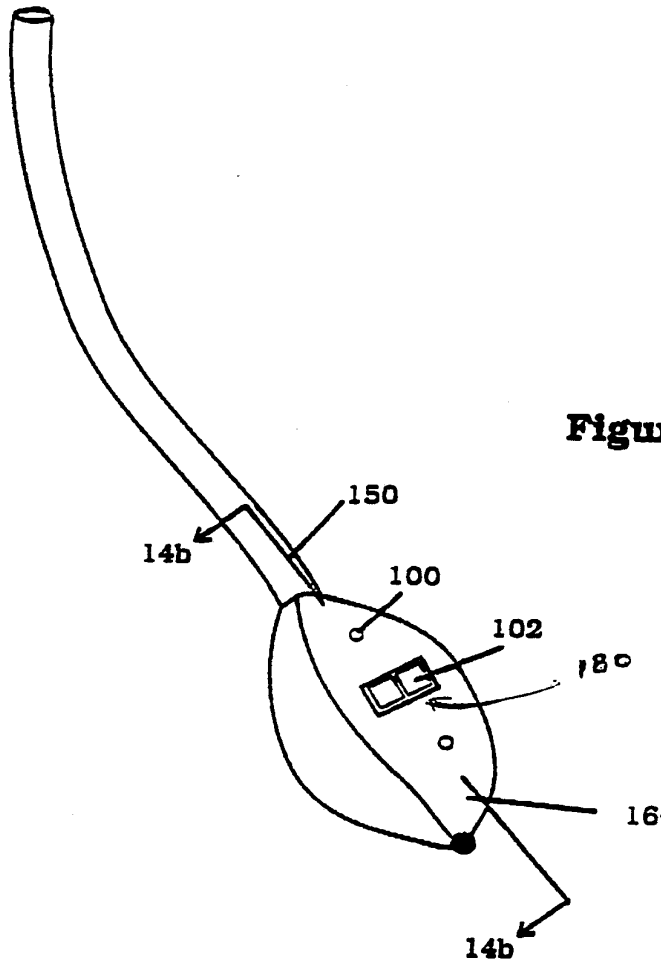


Figure 14a

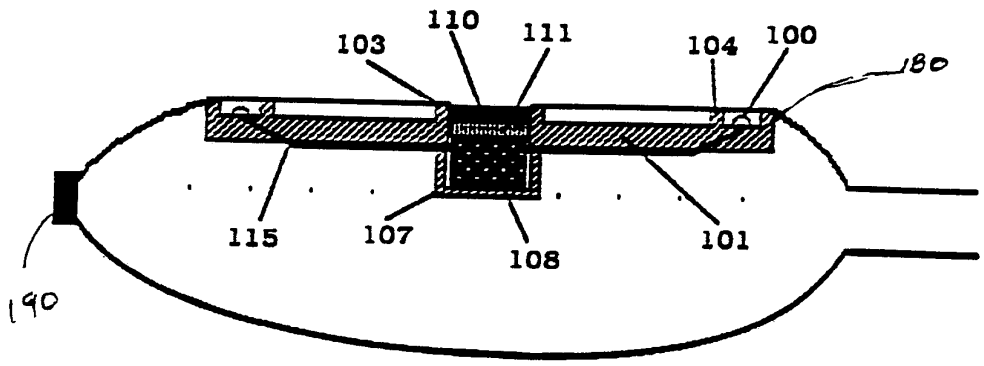


Figure 14b

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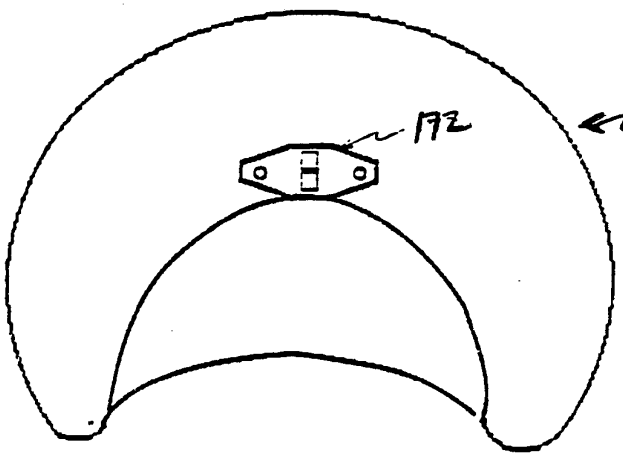


Figure 13

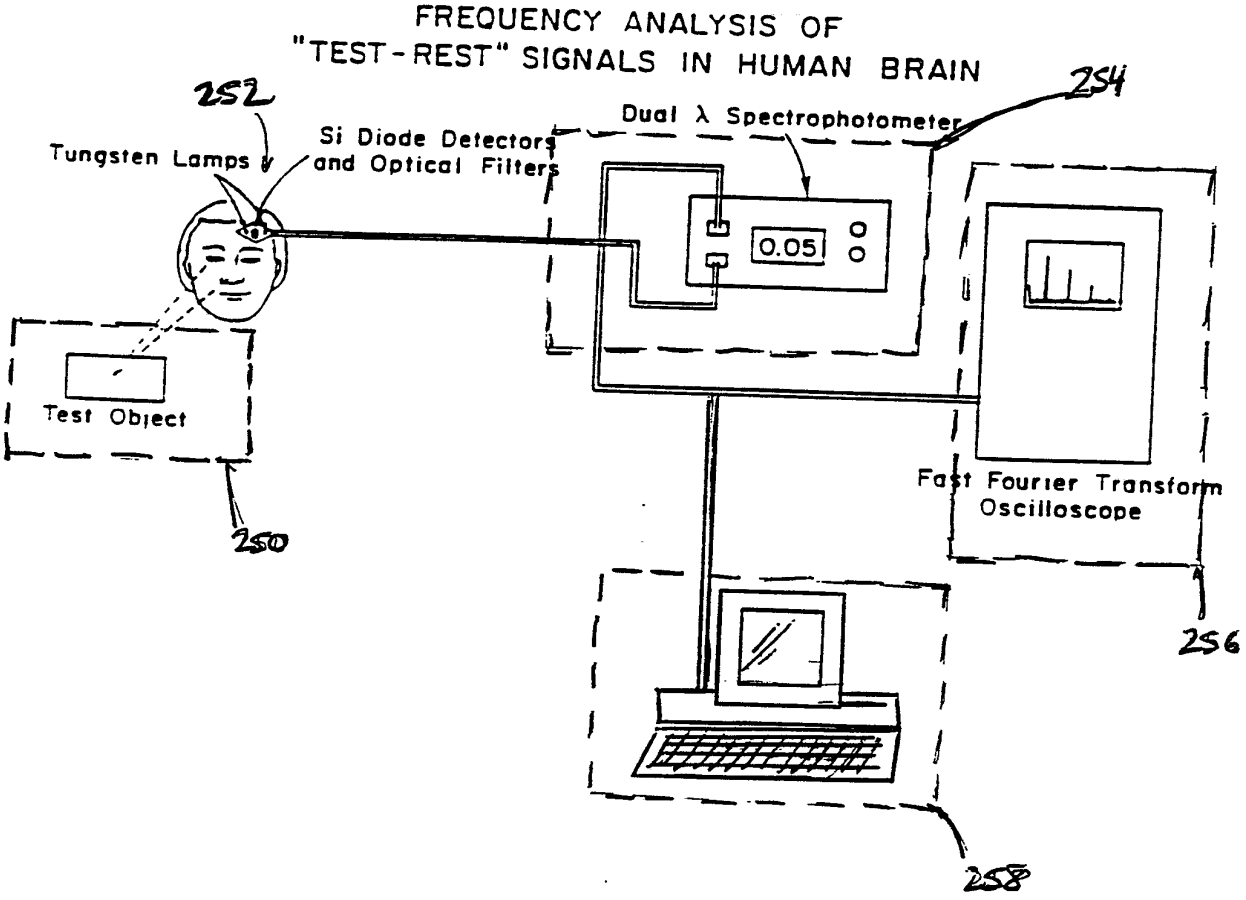


FIG 15

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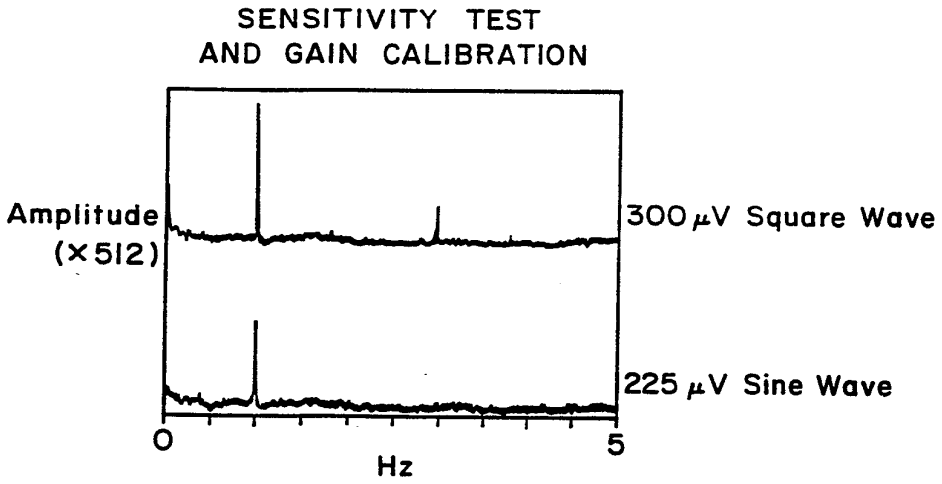


FIG 16 BC 120

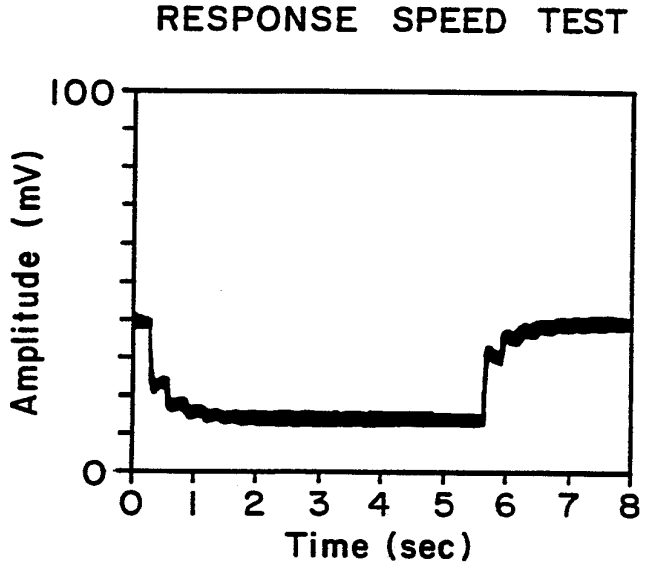


FIG. 17

BC 128

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SUBJECT U.
07/31/91 81 BPM n = 16

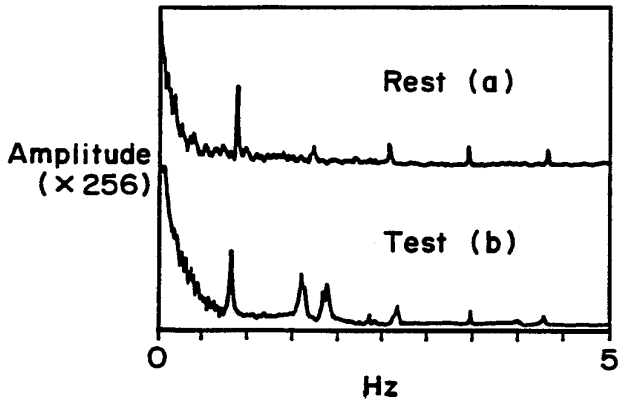


FIG 18a

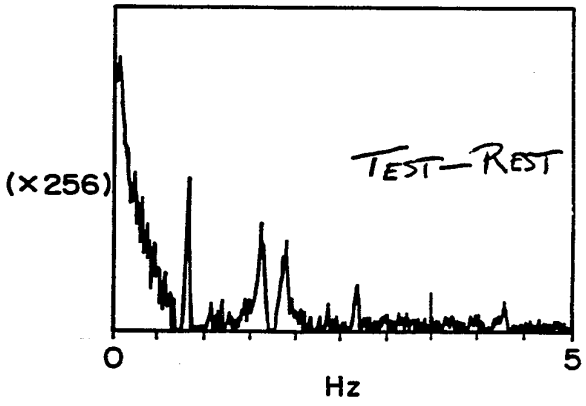


FIG 18b BC 115

SUBJECT B.
07/30 n=7

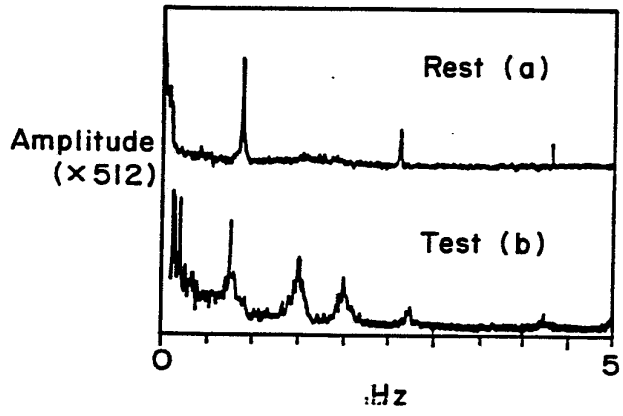


FIG 19a

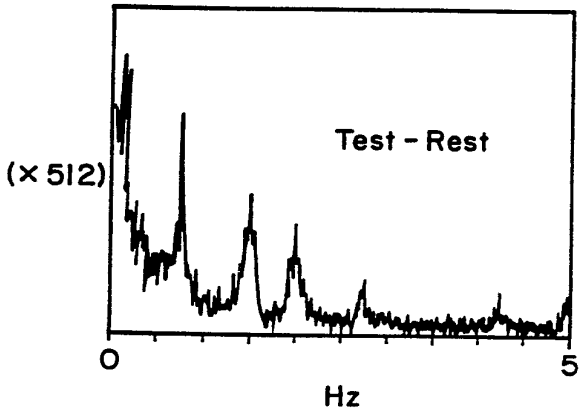


FIG 19b BC 116

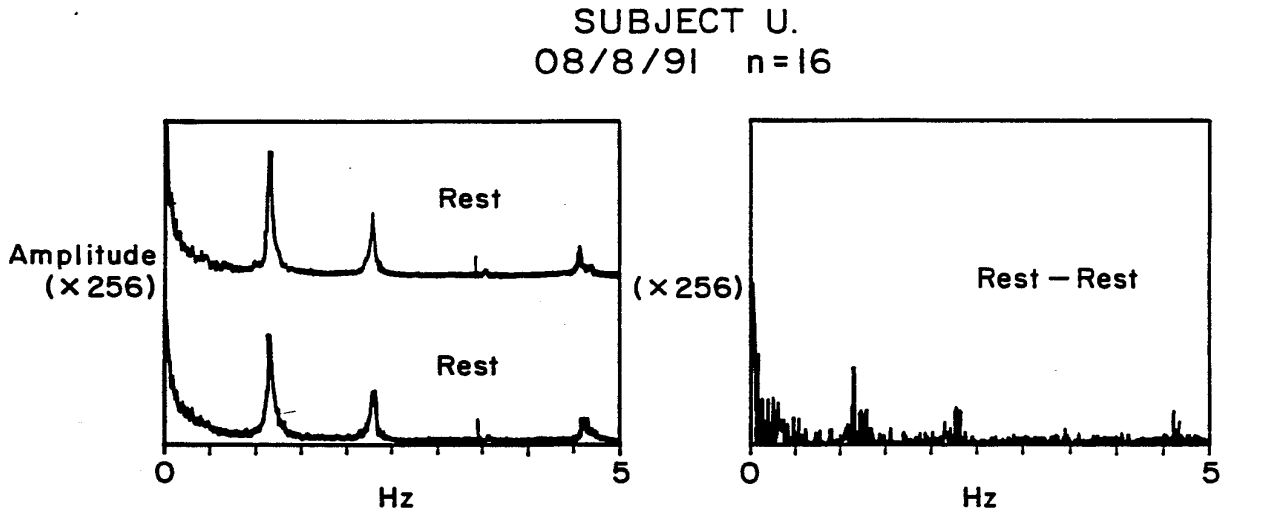


FIG 20a

FIG 20b

BC 121

18|21

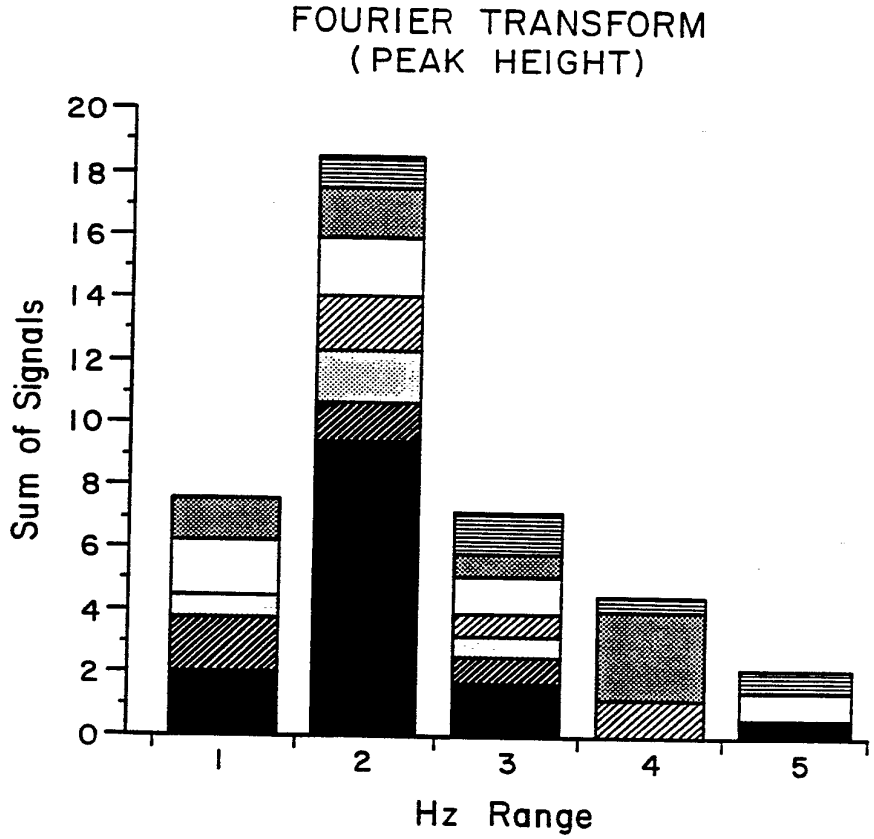
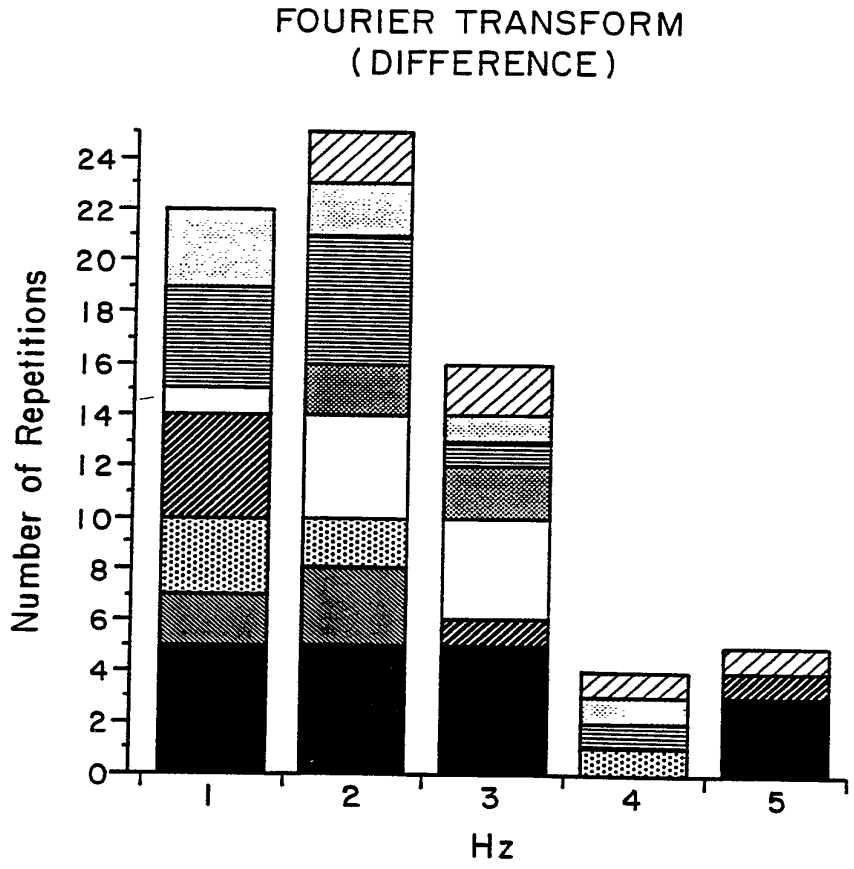

FOURIER TRANSFORM
(PEAK HEIGHT)
Sum of Signals
0
2
4
6
8
10
12
14
16
18
20
1
2
3
4
5
Hz Range
BC 132

Fig 21



BC 131

Fig 21a

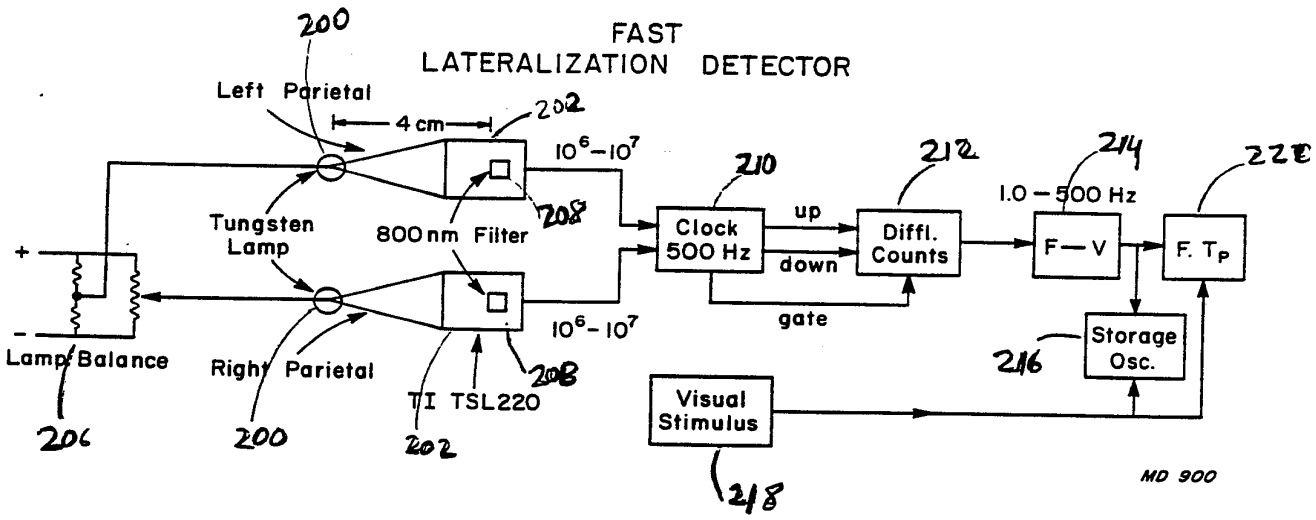

FAST
LATERALIZATION DETECTOR
200
Left Parietal
4 cm
202
10^6–10^7
208
210
212
214
220
1.0 – 500 Hz
Tungsten Lamp
800 nm Filter
Clock 500 Hz
up
down
Diffl. Counts
F — V
F. T_P
+
–
Lamp Balance
206
Right Parietal
200
TI TSL220
202
gate
Storage Osc.
216
Visual Stimulus
218
MD 900

Fig 22

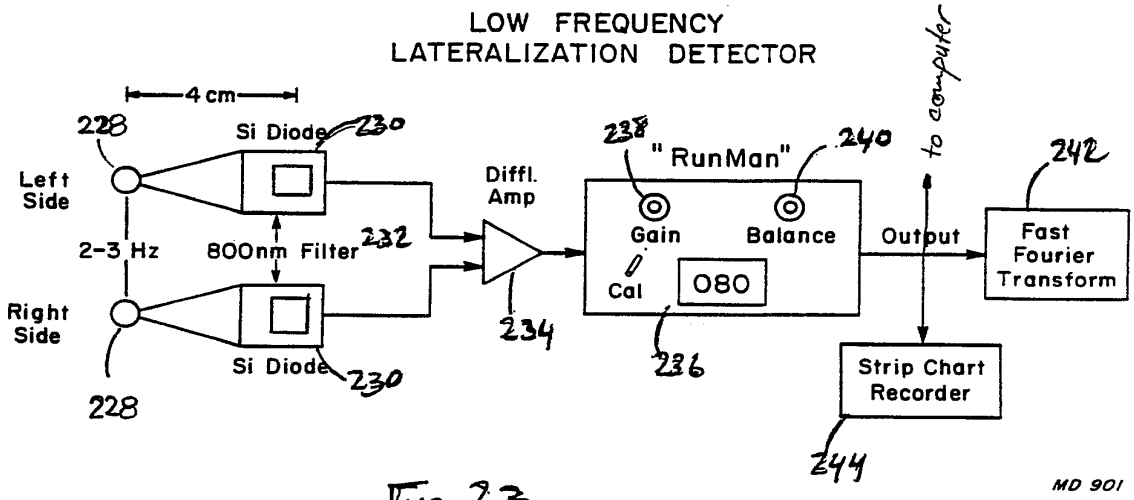

LOW FREQUENCY
LATERALIZATION DETECTOR
to computer
4 cm
228
Si Diode
230
238
"RunMan"
240
242
Left Side
Diffl. Amp
Gain
Balance
Output
Fast Fourier Transform
2-3 Hz
800nm Filter
232
Cal
080
Right Side
234
236
Strip Chart Recorder
244
MD 901

Fig. 23

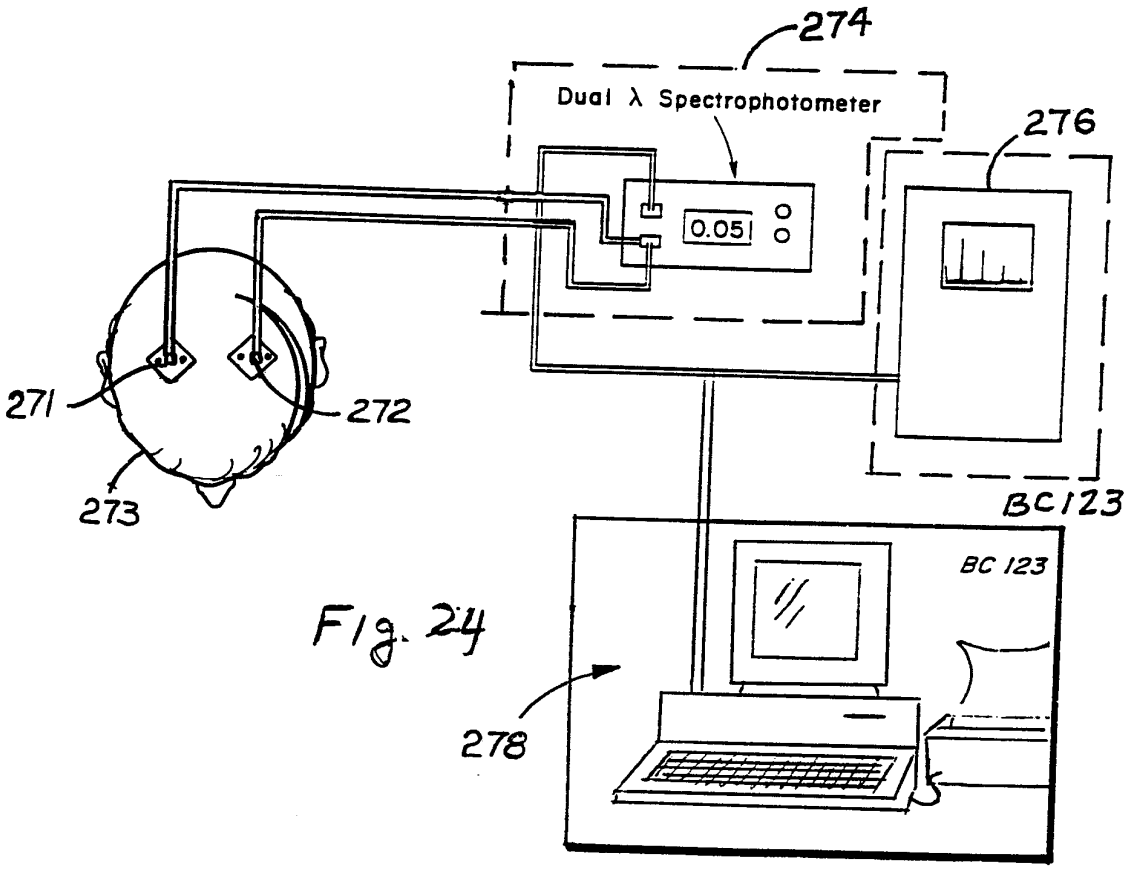

274
Dual λ Spectrophotometer
276
0.05
271
272
273
BC123
BC 123
278

Fig. 24

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

(54) Title: METHOD AND APPARATUS FOR ARBITRATING TO OBTAIN BEST ESTIMATES FOR BLOOD CONSTITUENT VALUES AND REJECTING HARMONICS

(57) Abstract

A method of measuring a blood constituent value using data comprising a single data set comprises: (a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and (b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

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METHOD AND APPARATUS FOR ARBITRATING TO OBTAIN BEST ESTIMATES FOR BLOOD CONSTITUENT VALUES & REJECTING HARMONICS

This invention relates to a method and apparatus for measuring physiological parameters, in particular for processing data so that its reliability can be assessed. It relates in particular to a method and apparatus for arbitrating to obtain best estimates for blood constituent values and rejecting harmonics.

Pulse oximeters typically measure and display various blood flow characteristics including the oxygen saturation of haemoglobin in arterial blood and pulse rate. Oximeters pass light through blood perfused tissue such as a finger or an ear, and photoelectrically sense the absorption of light in the tissue. The amount of light absorbed is then used to calculate the amount of the blood constituent (for example oxyhaemoglobin) being measured.

Techniques for calculating blood oxygen saturation levels in haemoglobin are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR ADAPTIVELY AVERAGING DATA SIGNALS, which bears the reference P21977A. Information concerning these features of the present invention that is disclosed in those documents is incorporated in the specification of the present application by this reference. The disclosed technique involves assigning varying weights to different measurements, the weighted measurements being averaged to obtain a filtered measurement. It employs Kalman filtering techniques to calculate blood oxygen saturation. Kalman filtering allows one to fit parameters in a least squares sense when the parameters are varying in time.

Other techniques for calculating blood oxygen saturation levels in haemoglobin, in which a harmonic filter is used to reduce noise effects, are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR HARMONICALLY FILTERING DATA,

entitled METHOD AND APPARATUS FOR HARMONICALLY FILTERING DATA, which bears the reference P21977D. Information concerning these features of the present invention that is disclosed in that document is incorporated in the specification of the present application by this reference.

Techniques for determining pulse rates are disclosed in International patent application no. IB96/ filed with the present application entitled METHOD AND APPARATUS FOR MEASURING PULSE RATE AND SATURATION, which bears the reference P21977B. Information concerning these features of the present invention that is disclosed in this document is incorporated in the specification of the present application by this reference. A technique disclosed in the document involves use of a comb filter to isolate signal energy which corresponds to fundamental and related frequencies.

The present invention provides a technique for assessing signals relating to physiological parameters, in particular blood oxygen saturation and pulse rate, to determine whether and how they are to be displayed. The signals can be derived using techniques of the type that are disclosed in the specifications of the three applications referred to above. The technique of the invention involves arbitrating between possible values of the parameter in question according to a confidence level associated with each value based in a quality metric.

Accordingly, in one aspect, the invention provides a method of measuring a blood constituent value (for example, oxygenated haemoglobin in blood) using data comprising a single data set, which comprises:

(a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the

possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

In another aspect, the invention provides apparatus for measuring a blood constituent using a single data set, by applying the method referred to above.

In a further aspect, the invention provides a method of determining a patient's pulse rate using data comprising a single data set corresponding to electromagnetic energy transmitted through the tissue of a patient, the method comprising the steps of:

(a) determining a plurality of possible pulse rates using a plurality of pulse rate estimators, each of the pulse rate estimators using the single data set, each of the possible pulse rates having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible pulse rates with regard to the confidence levels to determine the patient's pulse rate.

In yet another aspect, the invention provides apparatus for determining a patient's pulse rate using a single data set, by applying the method referred to above.

Preferably, the arbitrating step comprises:

(a) comparing the confidence levels for each of the values with the confidence levels for other values; and

(b) selecting as the measure of the blood constituent or of the pulse rate (as the case may be) one of the plurality of possible values having a confidence level greater than all other confidence levels by at least a first amount.

Preferably, the arbitrating step comprises linearly interpolating between the plurality of possible values to generate the measure of the blood constituent or the patient's pulse rate (as the case may be) where none of the confidence levels is greater than all other confidence levels by more than a first amount.

When the method is measuring a blood constituent value, it is preferred that the quality metric is selected from the group comprising age of the possible blood constituent value and variance of the possible blood constituent value.

Preferably, in the second method aspect of the invention, the pulse rate estimator determines its corresponding possible pulse rate by:

(a) defining a comb filter to remove signal energy from the data corresponding to a fundamental frequency and harmonics thereof;
(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency; and
(c) generating the possible pulse rate corresponding to the particular harmonic frequency.

Preferably, the step of determining the harmonic frequency comprises:

(a) calculating squared noise for the data;

(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and

(c) performing a Newton-Raphson search to determine the particular harmonic frequency.

The determination of the pulse rate by the pulse rate estimator can include the steps of:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and

(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

When the method is determining a patient's pulse rate, it is preferred that the quality metric is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, arrhythmia probability, and, when there are two wavelengths of electromagnetic energy, a correlation between the data corresponding to the two wavelengths.

The pulse rate estimator in the second method aspect of the invention can determine its corresponding possible pulse rate by:

(a) comparing the data to a predetermined waveform template;

(b) identifying a sequence of waveform characteristics indicative of a waveform period;

(c) averaging a number of successive waveform periods to determine an average waveform period; and

(d) determining the corresponding possible pulse rate from the average waveform period.

The method can include a step of identifying pulse data that is corrupted by motion, and rejecting that data.

The quality metric can then be selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

In a yet further aspect, the invention provides a method of determining a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, which comprises:

(a) tracking a fundamental frequency using an adaptive comb filter to filter the data and to thereby generate a first pulse rate, the first pulse rate having a first confidence level associated therewith based on at least one quality metric;

(b) comparing the data to a predetermined waveform template to generate a second pulse rate, the second pulse rate having a second confidence level associated therewith based on the at least one quality metric; and

(c) arbitrating between the first and second pulse rates with regard to the first and second confidence levels to determine the patient's pulse rate.

Preferably, the tracking step comprises:

(a) defining a comb filter to remove signal energy from the data corresponding to the fundamental frequency and harmonics thereof; and

(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency.

Preferably, the step of determining the harmonic frequency then comprises:

(a) calculating squared noise for the data;
(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and
(c) performing a Newton-Raphson search to determine the fundamental frequency.

The tracking step can comprise:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and
(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

It might also include a step of filtering the first pulse rate to determine a filtered first pulse rate, for example by a filtering technique such as Kalman filtering.

Preferably, the comparing step of the method comprises:

(a) identifying a sequence of waveform characteristics indicative of a waveform period;
(b) averaging a number of successive waveform periods to determine an average waveform period; and
(c) determining the second pulse rate from the average waveform period.

Preferably, the arbitrating step of the method comprises:

(a) comparing the first and second confidence levels; and

(b) selecting as the patient's pulse rate one of the first and second confidence levels which is greater than the other of the first and second confidence levels by at least a first amount.

The arbitrating step can comprise linearly interpolating between the first and second pulse rates to generate the patient's pulse rate where neither of the first and second confidence levels is greater than the other of the first and second confidence levels by more than a first amount.

Preferably, the at least one quality metric corresponding to the first confidence level is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

Preferably, there are two wavelengths of electromagnetic energy, and the at least one quality metric corresponding to the first confidence level comprises a correlation between the data corresponding to the two wavelengths.

Preferably, the at least one quality metric corresponding to the second confidence level is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

Preferably, prior to the processing step, the method includes the steps of:

(a) taking the logarithm of a signal representative of the at least one wavelength of electromagnetic energy, thereby generating a first signal;
(b) band pass filtering the first signal, thereby generating a second signal; and
(c) normalizing the second signal, thereby generating the data;

the tracking step comprising taking the derivative of the data.

The invention can involve reduction of noise effects when measuring a physiological parameter. It can include apparatus for reducing the noise effects which comprises:

means for generating a plurality of measurements derived from at least one wavelength of electromagnetic energy transmitted through living tissue;

means for providing a signal indicative of the at least one wavelength of electromagnetic energy;

means for comparing selected measurements with at least one expected measurement characteristic;

means for assigning one of a plurality of variable weights to each selected measurement based on the comparing step thereby generating a plurality of differently weighted measurements for each wavelength, the variable weights being assigned, in part, in response to a similarity between each selected measurement and a corresponding previous measurement, the variable weights comprising a plurality of different non-zero numbers;

means for averaging a plurality of the differently weighted measurements to obtain a filtered measurement for use in estimating the physiological parameter; and

means for calibrating the system to measure the physiological parameter in response to the signal indicative of the at least one wavelength of electromagnetic energy.

The invention also includes a monitor for measuring a physiological parameter, the monitor being for use with a sensor having emitting means for emitting at least one wavelength of electromagnetic energy, sensing means for sensing the electromagnetic energy and for generating a first signal representative thereof, means for detachably coupling the sensor to the oximeter and for providing communication of signals between the sensor and the oximeter, and means for providing a second signal indicative of the at least one wavelength of electromagnetic energy, the monitor comprising:

means for generating a plurality of measurements derived from the first signal;

means for comparing selected measurements with at least one expected measurement characteristic;

means for assigning one of a plurality of variable weights to each selected measurement based on the comparing step thereby generating a plurality of differently weighted measurements, the variable weights being assigned, in part, in response to a similarity between each selected measurement and a corresponding previous measurement, the variable weights comprising a plurality of different non-zero numbers;

means for averaging a plurality of the differently weighted measurements to obtain a filtered measurement for use in estimating the physiological parameter; and

means for calibrating the monitor to measure the physiological parameter in response to the second signal.

There now follows a discussion of preferred methods of processing and displaying the blood oxygen saturation and pulse rate for use on a hospital floor. With metrics that are available from algorithms for measuring oxygen saturation levels and pulse rates, confidence levels for the saturation and the pulse rate values that are calculated can be estimated, thus determining which saturation and which pulse rate of the multiple pulse rates and multiple saturations can be considered reliable, and how long the saturation or pulse rate previously selected should be held when a current estimate is not considered sufficiently reliable.

The present invention can be applied to blood oxygen saturation values calculated using Kalman filtering techniques (with or without cardiac gated averaging) as disclosed in the International patent application no. IB96/ (P21977A) referred to above. Metrics that can be calculated from these algorithms include:

Age: effective averaging period is double this; and

Deviation: standard deviation of saturation estimate in saturation points.

The present invention can be applied to pulse rate values calculated using a comb filter as disclosed in the International patent application no. [] referred to above. Metrics that can be calculated from these algorithms include:

Validity:	a heuristic metric based on the strength of harmonics in the pulse, i.e., the shape of the pulse;
S/N:	signal-to-noise ratio;
Arrhythmia probability:	a function of S/N vs. Uncorrelation averaged over time; and
Uncorrelation (IR & red)	$\sqrt{1-crosscorrelation\ (IR, red)^2}$ where crosscorrelation is over an appropriate number of sample points.
Motion flag:	set when motion is detected; and
Motion Percent:	percentage of motion corrupted patterns detected in the last ten seconds.

The confidence interval for a pulse rate measured using an adaptive comb filter is a function of the validity metric and the arrhythmia probability metric. This space divides into several regions in which one or both metrics are the determining factor in how likely the adaptive comb filter is to be tracking the correct rate.

The Age and Deviation metrics can be used to determine saturation. A general algorithm for calculating the age of the output of an IIR filter having the form

$$Filtered(n+1) = (1 + W) * Filtered(n) - W * Raw,$$

where the age of Filtered and Raw are known, and Filtered(n) is the value at sample number n, is described by the following steps:

1) Increment the age of Filtered by the amount of time elapsed since it was last calculated; and
2) Age of Filtered(n + 1) = (1 + W) * Age of Filtered(n) + W * Age of Raw

Preferably, the technique of the invention involves evaluation of several properties of the incoming oximetry signal, independent of the confidence metrics for the parameter in question (for example oxygen saturation and pulse rate) to determine whether the signal is actually due to a human pulse and what should appear on the display that is provided. Possible states include:

Disconnect:	when the sensor is unplugged;
No Contact:	when the sensor does not make sufficient contact with the patient;
Pulse lost:	when the pulse disappears and the sensor is still on the patient;
Non-pulse:	when the oximetry signal comes from a signal other than a human pulse because the sensor has fallen off or is seeing an enormous amount of interference;
Pulse Present:	when the oximetry signal comes from a human pulse; and
Not Sure:	a waiting period before declaring a Disconnect or Non-pulse state.

The possible actions in response to the occurrence of these various states are to update the display, hold the current values, or clear the display, for example blanks, dashes, zeroes, etc.

The criteria for the various states are evaluated in the following order:

Pulse lost:	The % IR modulation is below a threshold for period of seconds, or the criteria for Non-pulse are met and the previous state had been Pulse lost.
Non-pulse:	The uncorrelation is high and the percentage of energy above 5 Hz is high, OR the percent IR modulation is low. This criterion has been true for ten seconds continuously. If this criterion has been true for less than ten seconds, the Not Sure state is declared.
Pulse present:	The state is not one of the above states.

The criteria for the various display actions are UPDATE when the state is Pulse present, HOLD when the state is Not Sure or No contact, and CLEAR when the state is Disconnect, Pulse lost, or Non-pulse.

The best saturation is displayed when 1) the signal state action is UPDATE, and 2) the best saturation is sufficiently recent. Saturation is held when 1) the conditions for displaying the best saturation are not met, 2) the displayed saturation is less than sufficiently recent, and 3) the signal state action is not CLEAR. Saturation is blanked when 1) the conditions for displaying the best saturation are not met, and 2) the conditions for holding the saturation are not met.

The best heart rate is displayed when 1) the best calculated heart rate has a high confidence, and 2) the signal state action is UPDATE. The heart rate is held when 1) the conditions for displaying the current heart rate are not met, 2) the displayed heart rate is sufficiently recent, and 3) the signal state action is not CLEAR. The heart rate is blanked when 1) the conditions for displaying the current heart rate are not met, and 2) the conditions for holding the heart rate are not met.

CLAIMS:

1. A method of measuring a blood constituent value using data comprising a single data set, which comprises:

(a) determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

2. A method as claimed in claim 1, in which the arbitrating step comprises:

(a) comparing the confidence levels for each of the possible blood constituent values with the confidence levels for other blood constituent values; and

(b) selecting as the measure of the blood constituent one of the plurality of possible blood constituent values having a confidence level greater than all other confidence levels by at least a first amount.

3. A method as claimed in claim 1, in which the arbitrating step comprises linearly interpolating between the plurality of possible blood constituent values to generate the measure of the blood constituent where none of the confidence levels is greater than all other confidence levels by more than a first amount.

4. A method as claimed in claim 1, in which the at least one quality metric is selected from the group comprising age of the possible blood constituent value and variance of the possible blood constituent value.

5. A method as claimed in claim 1, in which the blood constituent comprises oxygenated haemoglobin in arterial blood.

6. Apparatus for measuring a blood constituent using a single data set, comprising:

(a) means for determining a plurality of possible blood constituent values using a plurality of blood constituent value calculators, each of the blood constituent value calculators using the single data set, each of the possible blood constituent values having a confidence level associated therewith based on at least one quality metric; and

(b) means for arbitrating between the plurality of possible blood constituent values with regard to the confidence levels to determine a measure of the blood constituent.

7. A method of determining a patient's pulse rate using data comprising a single data set corresponding to energy transmitted through the tissue of a patient, the method comprising the steps of:

(a) determining a plurality of possible pulse rates using a plurality of pulse rate estimators, each of the pulse rate estimators using the single data set, each of the possible pulse rates having a confidence level associated therewith based on at least one quality metric; and

(b) arbitrating between the plurality of possible pulse rates with regard to the confidence levels to determine the patient's pulse rate.

8. A method as claimed in claim 7, in which the arbitrating step comprises:

(a) comparing the confidence levels for each of the possible pulse rates with the confidence levels for other possible pulse rates; and

(b) selecting as the patient's pulse rate one of the plurality of possible pulse rates having a confidence level greater than all other confidence levels by at least a first amount.

9. A method as claimed in claim 7, in which the arbitrating step comprises linearly interpolating between the plurality of possible pulse rates to generate the patient's pulse rate where none of the confidence levels is greater than all other confidence levels by more than a first amount.

10. A method as claimed in claim 7, in which one pulse rate estimator determines its corresponding possible pulse rate by:

(a) defining a comb filter to remove signal energy from the data corresponding to a fundamental frequency and harmonics thereof;

(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency; and

(c) generating the possible pulse rate corresponding to the particular harmonic frequency.

11. A method as claimed in claim 10, in which the determining step comprises:

(a) calculating squared noise for the data;

(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and

(c) performing a Newton-Raphson search to determine the particular harmonic frequency.

12. A method as claimed in claim 10 further comprising the steps of:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and

(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

13. A method as claimed in claim 10, in which the at least one quality metric is selected from the group comprising pulse signal shape, signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

14. A method as claimed in claim 10, in which there are two wavelengths of electromagnetic energy, and the at least one quality metric comprises a correlation between the data corresponding to the two wavelengths.

15. A method as claimed in claim 7, in which one pulse rate estimator determines its corresponding possible pulse rate by:

(a) comparing the data to a predetermined waveform template;

(b) identifying a sequence of waveform characteristics indicative of a waveform period;

(c) averaging a number of successive waveform periods to determine an average waveform period; and

(d) determining the corresponding possible pulse rate from the average waveform period.

16. A method as claimed in claim 15, in which the at least one quality metric is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

17. A method of determining a pulse rate of a patient using data corresponding to at least one wavelength of electromagnetic energy transmitted through tissue of the patient, which comprises:

(a) tracking a fundamental frequency using an adaptive comb filter to filter the data and to thereby generate a first pulse rate, the first pulse rate having a first confidence level associated therewith based on at least one quality metric;

(b) comparing the data to a predetermined waveform template to generate a second pulse rate, the second pulse rate having a second confidence level associated therewith based on the at least one quality metric; and

(c) arbitrating between the first and second pulse rates with regard to the first and second confidence levels to determine the patient's pulse rate.

18. A method as claimed in claim 17, in which the tracking step comprises:

(a) defining a comb filter to remove signal energy from the data corresponding to the fundamental frequency and harmonics thereof; and

(b) determining a particular harmonic frequency which minimizes noise energy at an output of the comb filter, the particular harmonic frequency corresponding to the fundamental frequency.

19. A method as claimed in claim 18, in which the determining step comprises:

(a) calculating squared noise for the data;

(b) calculating a second derivative of the squared noise with respect to the fundamental frequency; and

(c) performing a Newton-Raphson search to determine the fundamental frequency.

20. A method as claimed in claim 18, in which the tracking step comprises:

(a) evaluating a power spectrum corresponding to the data to determine which of a plurality of peaks in the power spectrum corresponds to the fundamental frequency; and

(b) verifying that the particular harmonic frequency corresponds to the fundamental frequency based on the evaluating step.

21. A method as claimed in claim 17, in which the tracking step comprises Kalman filtering the first pulse rate to determine a filtered first pulse rate.

22. A method as claimed in claim 17, in which the comparing step comprises:

(a) identifying a sequence of waveform characteristics indicative of a waveform period;

(b) averaging a number of successive waveform periods to determine an average waveform period; and

(c) determining the second pulse rate from the average waveform period.

23. A method as claimed in claim 17, in which the arbitrating step comprises:

(a) comparing the first and second confidence levels; and

(b) selecting as the patient's pulse rate one of the first and second confidence levels which is greater than the other of the first and second confidence levels by at least a first amount.

24. A method as claimed in claim 17, in which the arbitrating step comprises linearly interpolating between the first and second pulse rates to generate the patient's pulse rate where neither of the first and second confidence levels is greater than the other of the first and second confidence levels by more than a first amount.

25. A method as claimed in claim 17, in which the at least one quality metric corresponding to the first confidence level is selected from the group comprising pulse signal shape,

signal-to-noise ratio, correlation of the at least one wavelength of electromagnetic energy, and arrhythmia probability.

26. A method as claimed in claim 17, in which there are two wavelengths of electromagnetic energy, and the at least one quality metric corresponding to the first confidence level comprises a correlation between the data corresponding to the two wavelengths.

27. A method as claimed in claim 17, in which the at least one quality metric corresponding to the second confidence level is selected from the group comprising a motion indication, and a proportion of motion corrupted pulse periods detected over a time interval.

28. A method as claimed in claim 17, which includes, before the processing step, the steps of:

(a) taking the logarithm of a signal representative of the at least one wavelength of electromagnetic energy, thereby generating a first signal;

(b) band pass filtering the first signal, thereby generating a second signal; and

(c) normalizing the second signal, thereby generating the data;

and in which the tracking step comprises taking the derivative of the data.

INTERNATIONAL SEARCH REPORT

Inte...ational Application No
PCT/IB 97/00292

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01N21/27 G01N21/31

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G01N A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 355 880 A (THOMAS ET AL.) 18 October 1994	1,7
A	see the whole document	17

A	EP 0 522 674 A (UNIVERSITY OF NEW MEXICO & SANDIA NATIONAL LABORATORIES) 13 January 1993	1-28
	see the whole document	

A	WO 96 30742 A (CIBA CORNING DIAGNOSTICS CORP.) 3 October 1996	1-28
	see the whole document	

A	US 5 435 309 A (THOMAS ET AL.) 25 July 1995	1-28
	see the whole document	

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
25 November 1997	08/12/1997

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040. Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Bosma, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte...ational Application No
PCT/IB 97/00292

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 34806 A (LIESENHOFF, TIM ET AL.) 21 December 1995 see the whole document	1-6
A	DE 43 39 067 A (JENOPTIK GMBH) 18 May 1995 see the whole document	1-6

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IB 97/00292

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5355880 A	18-10-94	CA 2099400 A	07-01-94
		EP 0586025 A	09-03-94
		JP 6178767 A	28-06-94
		US 5630413 A	20-05-97
EP 522674 A	13-01-93	JP 5261088 A	12-10-93
		US 5494032 A	27-02-96
WO 9630742 A	03-10-96	AU 4889096 A	16-10-96
US 5435309 A	25-07-95	NONE	
WO 9534806 A	21-12-95	DE 4420401 A	21-12-95
		AU 2881195 A	05-01-96
DE 4339067 A	18-05-95	WO 9513739 A	26-05-95
		EP 0679064 A	02-11-95

Form PCT/ISA/210 (patent family annex) (July 1992)

INFORMATION DISCLOSURE STATEMENT

Inventor	:	Diab, et al.
App. No.	:	90/012559
Filed	:	September 13, 2012
For	:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
Examiner	:	Nasser, Robert L
Art Unit	:	3992
Conf. No.	:	6710

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The Applicants enclose for filing in the above-identified reexamination application a PTO/SB/08 Equivalent listing 103 references, of which 16 are uploaded to the EFS Web server concurrently with the present filing.

Timing

In accordance with 37 C.F.R. § 555 and M.P.E.P. § 2280, the Applicants file the present submission within (2) two months of the date of the order to reexamine the parent U.S. patent corresponding to the present reexamination application.

Explanation of Relevance

The references listed on the PTO/SB/08 herein represent a compilation of references cited across (23) twenty-three third party reexamination requests simultaneously filed against patents owned by Masimo Corporation, or it's related company, Cercacor Laboratories, Inc. (formerly, Masimo Laboratories, Inc.). Certain references relied on in the reexamination requests along with the construction of claim elements of the corresponding patents were unsuccessfully asserted as invalidating during litigation in the U.S. District Court, *see Mallinckrodt, Inc. v. Masimo Corp.*, No. 00-6506, slip op. at 21 (C.D. Cal. July 14, 2004). The decision in favor of Masimo was affirmed by the U.S. Court of Appeals for the Federal Circuit. *Mallinckrodt, Inc. v. Masimo*

Corp., 2005 WL 2139867 (Fed. Cir. *Mallinckrodt, Inc. v. Masimo Corp.*, 2005 WL 2139867 (Fed. Cir. Sept. 7, 2005). Other references are part of allegations in currently pending litigation. *Masimo Corp. v. Philips Elecs. North America Corp.*, No. 1:09-cv-00080-LPS-MPT (D. Del. Filed Feb. 3, 2009); *Masimo Corp. v. Philips Elecs. North America Corp.*, No. 1:11-cv-00742-LPS-MPT (D. Del. Filed Aug. 19, 2011).

The following actions have already been taken by the Reexamination Group:

- U.S. Reexamination Pat. App. Ser. No. 90/012,546, was found to make inappropriate allegations characterized by the office as "LUMPING; NO DETAILED EXPLANATION."
- U.S. Reexamination Pat. App. Ser. No. 90/012,543, was found on October 23, 2012, to fail to raise any new substantial questions of patentability.
- U.S. Reexamination Pat. App. Ser. No. 90/012,541, received a Notice of Intent to Issue a Reexamination Certificate (NIRC) on November 15, 2012, without comment from the patent owner.
- U.S. Reexamination Pat. App. Ser. No. 90/012,561, was found to have missing elements. In particular, the request failed to "clearly point out and explain how each asserted SNQ is substantially different from those raised in the previous examination of the patent before the Office."

Copending Reexamination Applications

The following table lists the (23) twenty-three copending reexaminations filed against Masimo or Cercacor patents.

	Reexam App. No.	Patent No.	Reexam File Date	Attorneys for Reexam
1	90/012403	6263222	7/23/2012	Mayer Brown
2	90/012409	6699194	8/17/2012	Mayer Brown
3	90/012463	7215984	9/5/2012	Mayer Brown
4	90/012532	7499835	9/13/2012	Oblon, Spivak et al.
5	90/012534	7962188	9/13/2012	Kilpatrick Townsend et al.
6	90/012538	7377899	9/13/2012	Kilpatrick Townsend et al.
7	90/012541	7899507	9/13/2012	Kilpatrick Townsend et al.
8	90/012542	8180420	9/13/2012	Kilpatrick Townsend et al.
9	90/012546	7438683	9/13/2012	Kilpatrick Townsend et al.
10	90/012551	6970792	9/13/2012	Oblon, Spivak et al.
11	90/012553	7024233	9/13/2012	Oblon, Spivak et al.
12	90/012555	7440787	9/13/2012	Oblon, Spivak et al.
13	90/012557	8150487	9/13/2012	Oblon, Spivak et al.
14	90/012559	8190223	9/13/2012	Oblon, Spivak et al.
15	90/012561	8019400	9/14/2012	Kilpatrick Townsend et al.
16	90/012562	6463311	9/14/2012	Kilpatrick Townsend et al.
17	90/012566	7530955	9/14/2012	Kilpatrick Townsend et al.
18	90/012567	6684090	9/14/2012	Kilpatrick Townsend et al.
19	90/012568	8128572	9/14/2012	Kilpatrick Townsend et al.
20	90/012699	6002952	10/4/2012	Mayer Brown
21	95/002183	7530955	9/12/2012	Mayer Brown
22	90/012543	6850787	9/13/2012	Kilpatrick Townsend et al.
23	90/012548	7880606	9/13/2012	Kilpatrick Townsend et al.

The Applicants understand that the Examiner has access to sophisticated Patent Office computing systems that provide ready access to, for example, reexamination requests and their often voluminous appendices including the cited references, associated claims charts and allegations. In fact, such systems provide access to the reexamination application's complete file history as well as that of the underlying original patent. Thus, the Applicants have not enclosed copies of the reexamination requests and their appendices.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: November 16, 2012

By: /John M. Grover/
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Certificate of Service
I hereby certify on November 16, 2012, that a true and correct copy of this submission was mailed by first class mail, postage paid, to:

Tia Fenton
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Maier & Neustadt, LLP
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Alexandria, VA 22314

/John M. Grover/
John M. Grover

14366701

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/012,559	09/13/2012	8190223	403381US104RX	6710

20995 7590 10/23/2012
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
NASSER, ROBERT L	
ART UNIT	**PAPER NUMBER**
3992	

MAIL DATE	DELIVERY MODE
10/23/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

OBLON, SPIVAK, MCCLELLAND MAIER &
NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA. 22314

Date:

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90012559
PATENT NO. : 8190223
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Order Granting / Denying Request For Ex Parte Reexamination	Control No.	Patent Under Reexamination
	90/012,559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

The request for *ex parte* reexamination filed *13 September 2012* has been considered and a determination has been made. An identification of the claims, the references relied upon, and the rationale supporting the determination are attached.

Attachments: a)☐ PTO-892, b)☒ PTO/SB/08, c)☐ Other: _____

1. ☒ The request for *ex parte* reexamination is GRANTED.

RESPONSE TIMES ARE SET AS FOLLOWS:

For Patent Owner's Statement (Optional): TWO MONTHS from the mailing date of this communication (37 CFR 1.530 (b)). **EXTENSIONS OF TIME ARE GOVERNED BY 37 CFR 1.550(c).**

For Requester's Reply (optional): TWO MONTHS from the **date of service** of any timely filed Patent Owner's Statement (37 CFR 1.535). **NO EXTENSION OF THIS TIME PERIOD IS PERMITTED.** If Patent Owner does not file a timely statement under 37 CFR 1.530(b), then no reply by requester is permitted.

2. ☐ The request for *ex parte* reexamination is DENIED.

This decision is not appealable (35 U.S.C. 303(c)). Requester may seek review by petition to the Commissioner under 37 CFR 1.181 within ONE MONTH from the mailing date of this communication (37 CFR 1.515(c)). **EXTENSION OF TIME TO FILE SUCH A PETITION UNDER 37 CFR 1.181 ARE AVAILABLE ONLY BY PETITION TO SUSPEND OR WAIVE THE REGULATIONS UNDER 37 CFR 1.183.**

In due course, a refund under 37 CFR 1.26 (c) will be made to requester:

a) ☐ by Treasury check or,

b) ☐ by credit to Deposit Account No. _____, or

c) ☐ by credit to a credit card account, unless otherwise notified (35 U.S.C. 303(c)).

cc:Requester (if third party requester)

Decision on Request

A substantial new question of patentability affecting claims 1-47 of US Patent 8,190,223 to Al-Ali et al (the '223 patent) is deemed to have been raised by the request for Ex Parte Reexamination, filed 9/13/2012.

Prior Art Cited in the Request

U.S. Patent Application Publication 2002/0082488, filed December 21, 2001 and published June 27, 2002 to Al-Ali et al. ("A1-Ali").

U.S. Patent No. 6,658,276, filed February 12, 2002 and issued December 2, 2003 to Kianl et al.("Kianl").

U.S. Patent No. 5,842,979, filed February 14, 1997 and issued December 1, 1998 to Jarman ("Jarman").

U.S. Patent No. 4,051,522, filed May 5, 1975 and issued September 27, 1977 to Healy et al. ("Healy").

U.S. Patent Application Publication 2003/0120164, filed December 20, 2001 and published June 26, 2003 to Nielsen ("Nielsen").

U.S. Patent No. 5,743,262, filed June 7, 1995 and issued April 28, 1998 to Lepper et al. ("Lepper").

Issues Raised By the Request

Issue 1: The request alleges that the technological teachings of Al-Ali et al alone or in combination with other references raise a substantial new question (SNQ) of patentability regarding claims 1-47 of the '223 patent as follows:

A. The request alleges that the technological teachings of Al-Ali raise a substantial new question of patentability with respect to claims 1-4, 6, 15, 18-22, 27, 28, 36, 42, and 43.

B. The request alleges that the technological teachings of Al-Ali and Kianl raise a substantial new question of patentability with respect to claims 29, 31-35, 37, 38, and 44-47

C. The request alleges that the technological teachings of Al-Ali and Jarman raise a substantial new question of patentability with respect to claims 8-10, 24-26, and 39-41.

D. The request alleges that the technological teachings of Al-Ali and Healy raise a substantial new question of patentability with respect to claims 11-14, 16, 17, and 30

E. The request alleges that the technological teachings of Al-Ali and Nielsen raise a substantial new question of patentability with respect to claims 5 and 23.

F. The request alleges that the technological teachings of Al-Ali and Lepper raise a substantial new question of patentability with respect to claim 7.

Al-Ali published June 27, 2002, which predates the '223 patent by more than one year. Kianl issued December 2, 2003, which predates the '223 patent by more than one year. Jarman issued December 1, 1998, which predates the '223 patent by more than one year. Healy issued September 27, 1997 which predates the '223 patent by more than one year. Nielsen published December 20, 2001, which predates the '223

patent by more than one year. Lepper issued April 28, 1998, which predates the '223 patent by more than one year. As such, Al-Ali, Kianl, Jarman, Healy, Nielsen, and Lepper all qualify as prior art under 35 USC 102(b).

Background

Claims 1-47 are the current claims in US patent 8,190,223 to Al-Ali et al, which issued May 29, 2012 from application 11/367,033, filed March 1, 2006. The '223 application claims priority to US provisional applications 60/657596, 60/657281, 60/657268, and 60/657759, all filed March 1, 2005.

The '188 patent is generally drawn to pulse oximeter with a backup alarm that is activated when a first alarm is determined to be unavailable.

Prosecution of the '033 application resulted in issuance of claims 1-3, 7, 9-13, 15-29, and 41-63 (patent claims 1-47). The examiner did not issue a reasons for allowance. However, after the first action in which all of the pending claims were rejected, the applicant submitted an amendment on September 15, 2012, in which claim 1 was amended to recite that the common area of the displaying changes from displaying one of the parameters to the other when one of the parameters approaches one or more threshold values indicating a worsening of a patient's condition. Claim 7 (patent claim 15) was amended to recite that the common area of the displaying changes from displaying one of the parameters to the other when one of the parameters alarms. Claim 10 (patent claim 18) was amended to recite that the common area of the

displaying changes from displaying one of the parameters to the other based on which is a more critical value of the measured values of the parameters. Claim 24 (patent claim 21) was amended to recite that the display replaces the displayed first parameter with a second parameter when the value of the second parameter indicates a worsening of a patient's condition. Claim 43 (patent claim 27) was amended to recite that the display changes from displaying a first blood parameter to displaying a second blood parameter when the second parameter exceeds an alarm limit. In an interview summary of an August 17, 2011 interview, the examiner Nielsen did not change the output based on an alarm threshold or an evaluation of the relative criticality of the parameters. No further comment distinguishing the claims from the references was made.

As such, it appears from the record that the key feature missing at the time of allowance of claims 1-3, 7, 9-13, 15-29, and 41-63 of the '223 patent was a the display changing from displaying one of a first and second parameters to displaying the other of the first and second parameters, when a measured value of one of the parameters indicates that the patient's condition is worsening (claims 1 and 21), when one of the parameters is in an alarm state (claims 15 and 27), or based on the relative criticality of the two parameters (claim 18).

Scope of Reexamination

On November 2, 2002, Public Law 107-273 was enacted. Title III, Subtitle A, Section 13105, part (a) of the Act revised the reexamination statute by adding the following new last sentence to 35 U.S.C. 303(a) and 312(a):

The existence of a substantial new question of patentability is not precluded by the fact that a patent or printed publication was previously cited by or to the Office or considered by the Office.

For any reexamination ordered on or after November 2, 2002, the effective date of the statutory revision, reliance on previously cited/considered art, i.e., "old art," does not necessarily preclude the existence of a substantial new question of patentability (SNQ) that is based exclusively on that old art. Rather, determinations on whether a SNQ exists in such an instance shall be based upon a fact-specific inquiry done on a case-by-case basis. In the present instance, an SNQ appears to exist based on the existence of newly uncovered prior art that was not before the examiner at the time of examination.

Analysis

Issue 1: Healy is new art. Al-Ali was of record during prosecution of the '233 patent, but was never applied or commented on. Kianl, Jarman, Nielsen, and Lepper were applied during prosecution of the '233 patent, but were not used in combination with Al-Ali. As such, the references are being viewed in a new light.

It is agreed that the technological teachings of Al-Ali raise substantial new question of patentability with respect to claims 1-47 of the '233 patent. Al-Ali teaches a multi-parameter, multi-site display of two blood parameters, SPaO2 and SPvO2, at two tissue sites. Each display parameter has its own display area as well as a common display area 1660 where the waveforms are displayed (see figures 16a and 16b). Upon occurrence of a triggering event, such as an alarm condition, the display switches from a single site display mode shown in figure 16a where one parameter, for example SPaO2 for site one is displayed to a multi-site display mode shown in figure 16b, where SPaO2 for both sites are displayed. The alarm condition can be considered to indicate a worsening of a patient's condition. As such, it appears that Al-Ali provides a new teaching of some of the features found to be lacking at the time of allowance of claims 1-47 of the '223 patent, e.g. changing the parameters that are displayed based on a change in the patient's condition based on measured values of parameters. Therefore, Al-Ali provides a teaching of new technological features that were not present at the time of allowance of claims 1-47 of the '223 patent.

Since the teachings of Al-Ali are directly related to the subject matter considered as the basis for allowability of patent claims 1-47, a reasonable examiner would consider the evaluation of the Al-Ali to be important in determining the patentability of claims 1-47 of the '223 patent.

As such, it is agreed that the technological teachings of Al-Ali raise a substantial new question of patentability with respect to claims 1-47 that was not decided in a previous examination of the '223 patent.

Kianl, Jarman, Nielsen, Healy, and Lepper are all utilized by the requester for reading on dependent claims. The dependent claims all depend on independent claims which have raised an SNQ as noted above. Therefore, Kianl, Jarman, Nielsen, Healy, and Lepper raises an SNQ through dependency.

Service of Papers

After the filing of a request for reexamination by a third party requester, any document filed by either the patent owner or the third party requester must be served on the other party (or parties where two or more third party requester proceedings are merged) in the reexamination proceeding in the manner provided in 37 CFR 1.248. See 37 CFR 1.550(f).

Waiver of Right to File Patent Owner Statement

In a reexamination proceeding, Patent Owner may waive the right under 37 C.F.R. 1.530 to file a Patent Owner Statement. The document needs to contain a statement that Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement and proof of service in the manner provided by 37 C.F.R. 1.248, if the request for reexamination was made by a third party requester, see 37 C.F.R 1.550(f). The Patent Owner may consider using the following statement in a document waiving the right to file a Patent Owner Statement:

WAIVER OF RIGHT TO FILE PATENT OWNER STATEMENT

Patent Owner waives the right under 37 C.F.R. 1.530 to file a Patent Owner Statement.

Extensions of Time

Extensions of time under 37 CFR 1.136(a) will not be permitted in these proceedings because the provisions of 37 CFR 1.136 apply only to "an applicant" and

not to parties in a reexamination proceeding. Additionally, 35 U.S.C. 305 requires that *ex parte* reexamination proceedings "will be conducted with special dispatch" (37 CFR 1.550(a)). Extensions of time in *ex parte* reexamination proceedings are provided for in 37 CFR 1.550(c).

Amendment in Reexamination Proceedings

Patent owner is notified that any proposed amendment to the specification and/or claims in this reexamination proceeding must comply with 37 CFR 1.530(d)-(j), must be formally presented pursuant to 37 CFR 1.52(a) and (b), and must contain any fees required by 37 CFR 1.20(c). See MPEP § 2250(IV) for examples to assist in the preparation of proper proposed amendments in reexamination proceedings.

Submissions

In order to insure full consideration of any amendments, affidavits or declarations or other documents as evidence of patentability, such documents must be submitted in response to the first Office action on the merits (which does not result in a close of prosecution). Submissions after the second Office action on the merits, which is intended to be a final action, will be governed by the requirements of 37 CFR 1.116, after final rejection and by 37 CFR 41.33 after appeal, which will be strictly enforced.

Notification of Concurrent Proceedings

The patent owner is reminded of the continuing responsibility under 37 CFR 1.565(a), to apprise the Office of any litigation activity, or other prior or concurrent proceeding, involving Patent No. 8,190,223 throughout the course of this reexamination proceeding. Likewise, if present, the third party requester is also reminded of the ability to similarly apprise the Office of any such activity or proceeding throughout the course of this reexamination proceeding. See MPEP §§ 2207, 2282 and 2286.

All correspondence relating to this *ex parte* reexamination proceeding should be directed as follows:

By **U.S. Postal Service Mail** to:

Mail Stop *Ex Parte* Reexam
ATTN: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22312-1450

By EFS: Registered users may submit via the electronic filing system EFS-Web, at https://efs.uspto.gov/efile/myportal/efs-registered

By FAX to: (571) 273-9900
Central Reexamination Unit

By hand to: Customer Service Window
Randolph Building
401 Dulany St.
Alexandria, VA 22314

For EFS-Web transmissions, 37 CFR 1.8(a)(1)(i) (C) and (ii) states that correspondence (except for a request for reexamination and a corrected or replacement request for reexamination) will be considered timely filed if (a) it is transmitted via the Office's electronic filing system in accordance with 37 CFR 1.6(a)(4), and (b) includes a certificate of transmission for each piece of correspondence stating the date of transmission, which is prior to the expiration of the set period of time in the Office action.

Any inquiry concerning this communication or earlier communications from the Reexamination Legal Advisor or Examiner, or as to the status of this proceeding, should be directed to the Central Reexamination Unit at telephone number (571) 272-7705.

/Robert L. Nasser Jr./
Robert L. Nasser Jr.
CRU Primary Examiner
AU 3992
(571) 272-4731

Conferee: /FOF/

/Alexander J Kosowski/
Supervisory Patent Examiner, Art Unit 3992

Form PTO 1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO.	CONTROL NO.
		403381US104RX	New Request for Ex Parte Reexamination
LIST OF REFERENCES CITED BY APPLICANT		APPLICANT	
		Ammar AL-ALI, et al.	
		FILING DATE	GROUP
		Herewith	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	8,190,223	05-29-2012	Al-Ali et al.			
	AB	20020082488	06-27-2002	Al-Ali, et al.			
	AC	6,658,276	12-02-2003	Kianl, et al			
	AD	5,842,979	12-01-1998	Jarman			
	AE	4,051,522	09-27-1977	Healy, et al			
	AF	20030120164A1	06-26-2003	Nielsen, et al.			
	AG	5,743,262	04-28-1998	Lepper, Jr., et al.			
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	TRANSLATION NO
	AO					
	AP					
	AQ					
	AR					
	AS					
	AT					
	AU					
	AV					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	Selected Documents from the Prosecution History of USP 8,190,223
	AX	Int'l Preliminary Report on Patentability, PCT/US2006/007389, September 11, 2007
	AY	
	AZ	☐ Additional References sheet(s) attached

Examiner	/Robert Nasser/	Date Considered	10/16/2012

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /B.N./

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	90012559	8190223
	Examiner	Art Unit
	ROBERT NASSER	3992

SEARCHED			
Class	Subclass	Date	Examiner

SEARCH NOTES		
Search Notes	Date	Examiner
reviewed prosecution history of US Patent 8190223	10/11/2012	nasser
reviewed references of record	10/11/2012	nasser

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

Reexamination	**Application/Control No.** 90012559	**Applicant(s)/Patent Under Reexamination** 8190223
	Certificate Date	**Certificate Number**

Requester Correspondence Address: ☐ **Patent Owner** ☒ **Third Party**
KNOBBE MARTENS OLSON & BEAR, LLP 2040 MAIN STREET, FOURTEENTH FLOOR IRVINE, CALIFORNIA 92614

LITIGATION REVIEW ☒	nasser (examiner initials)	10/11/2012 (date)
Case Name		Director Initials
none		/AJK/ for IY

COPENDING OFFICE PROCEEDINGS	
TYPE OF PROCEEDING	**NUMBER**

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
90/012,559	09/13/2012	8190223	403381US104RX	6710

20995 7590 10/16/2012
KNOBBE MARTENS OLSON & BEAR LLP
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EXAMINER	
NASSER, ROBERT L	
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THIRD PARTY REQUESTER'S CORRESPONDENCE ADDRESS

OBLON, SPIVAK, MCCLELLAND MAIER &
NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA. 22314

Date:

EX PARTE REEXAMINATION COMMUNICATION TRANSMITTAL FORM

REEXAMINATION CONTROL NO. : 90012559
PATENT NO. : 8190223
ART UNIT : 3993

Enclosed is a copy of the latest communication from the United States Patent and Trademark Office in the above identified ex parte reexamination proceeding (37 CFR 1.550(f)).

Where this copy is supplied after the reply by requester, 37 CFR 1.535, or the time for filing a reply has passed, no submission on behalf of the ex parte reexamination requester will be acknowledged or considered (37 CFR 1.550(g)).

Ex Parte Reexamination Interview Summary – Pilot Program for Waiver of Patent Owner's Statement	Control No. 90/012,559	Patent For Which Reexamination is Requested 8,190,223
	Examiner Robert Nasser	Art Unit 3992

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address. --

All participants (USPTO official and patent owner):

(1) Alicia Kelley-Collier CRU Paralegal (3)

(2) Jarom Kesler 57,046 (4)

Date of Telephonic Interview: October 9, 2012.

The USPTO official requested waiver of the patent owner's statement pursuant to the pilot program for waiver of patent owner's statement in *ex parte* reexamination proceedings.*

☐ The patent owner **agreed** to waive its right to file a patent owner's statement under 35 U.S.C. 304 in the event reexamination is ordered for the above-identified patent.

☒ The patent owner **did not agree** to waive its right to file a patent owner's statement under 35 U.S.C. 304 at this time.

The patent owner is not required to file a written statement of this telephone communication under 37 CFR 1.560(b) or otherwise. However, any disagreement as to this interview summary must be brought to the immediate attention of the USPTO, and no later than one month from the mailing date of this interview summary. Extensions of time are governed by 37 CFR 1.550(c).

*For more information regarding this pilot program, see *Pilot Program for Waiver of Patent Owner's Statement in Ex Parte Reexamination Proceedings*, 75 *Fed. Reg.* 47269 (August 5, 2010), available on the USPTO Web site at http://www.uspto.gov/patents/law/notices/2010.jsp.

☐ USPTO personnel were unable to reach the patent owner.

The patent owner may contact the USPTO personnel at the telephone number provided below if the patent owner decides to waive the right to file a patent owner's statement under 35 U.S.C. 304.

/A. Kelley-Collier/ (571) 272-6059
Signature and telephone number of the USPTO official who contacted or attempted to contact the patent owner.

cc: Requester (if third party requester)

Litigation Search Report CRU 3999

Reexam Control No. 90/012,559

To: Robert Nasser Location: CRU Art Unit: 3992 Date: 10/9/12 Case Serial Number: 90/012,559	From: Alicia Kelley-Collier Location: CRU 3999 MDE 5A74 Phone: (571) 272-6059 alicia.kelley@uspto.gov

Search Notes

U.S. Patent No. **8,190,223**

1) I performed a KeyCite Search in Westlaw, which retrieves all history on the patent including any litigation.

2) I performed a search on the patent in Lexis CourtLink for any open dockets or closed cases.

3) I performed a search in Lexis in the Federal Courts and Administrative Materials databases for any cases found.

4) I performed a search in Lexis in the IP Journal and Periodicals database for any articles on the patent.

5) I performed a search in Lexis in the news databases for any articles about the patent or any articles about litigation on this patent.

No litigation involving this patent was found.

Date of Printing: Oct 09, 2012

KEYCITE

C US PAT 8190223 NONINVASIVE MULTI-PARAMETER PATIENT MONITOR, Assignee: Masimo Laboratories, Inc. (May 29, 2012)

History

Direct History

=> 1 **NONINVASIVE MULTI-PARAMETER PATIENT MONITOR,** US PAT 8190223 (U.S. PTO Utility May 29, 2012)

Patent Family

2 PATIENT MONITOR FOR USE IN ACCESSING PATIENT'S CONDITION, DISPLAYS MEASURED VALUE OF PHYSIOLOGICAL PARAMETER DETERMINED USING OUTPUT SIGNAL OF NON-INVASIVE LIGHT SENSITIVE DETECTOR, Derwent World Patents Legal 2006-788376

Assignments

3 Action: CORRECTIVE ASSIGNMENT TO CORRECT THE CONVEYING PARTY TO MASIMO LABORATORIES, INC. INSTEAD OF THE INVENTORS PREVIOUSLY RECORDED ON REEL 028177 FRAME 0534. ASSIGNOR(S) HEREBY CONFIRMS THE CHANGE OF NAME. Number of Pages: 004, (DATE RECORDED: May 11, 2012)

4 Action: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS). Number of Pages: 004, (DATE RECORDED: May 08, 2012)

Prior Art (Coverage Begins 1976)

C 5 ACCOMMODATING SUBJECT AND INSTRUMENT VARIATIONS IN SPECTROSCOPIC DETERMINATIONS, US PAT APP 20040033618 (U.S. PTO Application 2004)

C 6 ACTIVE OPTICAL OXIMETER PROBE ADAPTER, US PAT 6023541Assignee: Nellcor Puritan Bennett Incorporated, (U.S. PTO Utility 2000)

C 7 ACTIVE PULSE BLOOD CONSTITUENT MONITORING, US PAT 7239905Assignee: Masimo Laboratories, Inc., (U.S. PTO Utility 2007)

C 8 ACTIVE PULSE BLOOD CONSTITUENT MONITORING, US PAT 6931268Assignee: Masimo Laboratories, Inc., (U.S. PTO Utility 2005)

C 9 ACTIVE PULSE BLOOD CONSTITUENT MONITORING, US PAT 6151516Assignee: Masimo Laboratories, (U.S. PTO Utility 2000)

C 10 ACTIVE PULSE BLOOD CONSTITUENT MONITORING, US PAT 5638816Assignee: Masimo Corporation, (U.S. PTO Utility 1997)

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C 11 ACTIVE PULSE BLOOD CONSTITUENT MONITORING METHOD, US PAT 5860919Assignee: Masimo Corporation, (U.S. PTO Utility 1999)

C 12 ADAPTIVE CALIBRATION FOR PULSE OXIMETRY, US PAT 6839580Assignee: RIC Investments, Inc., (U.S. PTO Utility 2005)

C 13 ADAPTIVE CALIBRATION PULSED OXIMETRY METHOD AND DEVICE, US PAT 6760609Assignee: Providence Health System - Oregon, (U.S. PTO Utility 2004)

C 14 ADAPTIVE COMPENSATION FOR MEASUREMENT DISTORTIONS IN SPECTROSCOPY, US PAT APP 20050143943 (U.S. PTO Application 2005)

H 15 ADHESIVE PULSE OXIMETER SENSOR WITH REUSABLE PORTION, US PAT RE36000Assignee: Nellcor Puritan Bennett Incorporated, (U.S. PTO Reissue 1998)

C 16 ADHESIVE PULSE OXIMETER SENSOR WITH REUSABLE PORTION, US PAT 5209230Assignee: Nellcor Incorporated, (U.S. PTO Utility 1993)

C 17 AMBULATORY MONITORING SYSTEM WITH REAL TIME ANALYSIS AND TELEPHONE TRANSMISSION, US PAT 4531527Assignee: Survival Technology, Inc., (U.S. PTO Utility 1985)

C 18 AMOUNT OF USE TRACKING DEVICE AND METHOD FOR MEDICAL PRODUCT, US PAT 7186966Assignee: Masimo Corporation, (U.S. PTO Utility 2007)

C 19 APPARATUS AND METHOD FOR IMPROVED PHOTOPLETHYSMOGRAPHIC MONITORING OF MULTIPLE HEMOGLOBIN SPECIES USING EMITTERS HAVING OPTIMIZED CENTER WAVELENGTHS, US PAT 5983122Assignee: Ohmeda Inc., (U.S. PTO Utility 1999)

C 20 APPARATUS AND METHOD FOR MEASURING BLOOD CONSTITUENTS, US PAT 4863265Assignee: Mine Safety Appliances Company, (U.S. PTO Utility 1989)

C 21 APPARATUS AND METHOD FOR MEASURING AN INDUCED PERTURBATION TO DETERMINE BLOOD PRESSURE, US PAT 5590649Assignee: Vital Insite, Inc., (U.S. PTO Utility 1997)

C 22 APPARATUS AND METHOD FOR MEASURING AN INDUCED PERTURBATION TO DETERMINE A PHYSICAL CONDITION OF THE HUMAN ARTERIAL SYSTEM, US PAT 5830131Assignee: Vital Insite, Inc., (U.S. PTO Utility 1998)

C 23 APPARATUS AND METHOD FOR MEASURING AN INDUCED PERTURBATION TO DETERMINE A PHYSIOLOGICAL PARAMETER, US PAT 6045509Assignee: Vital Insite, Inc., (U.S. PTO Utility 2000)

C 24 APPARATUS AND METHOD FOR MEASURING AN INDUCED PERTURBATION TO DETERMINE A PHYSIOLOGICAL PARAMETER, US PAT 5833618Assignee: Vital Insite, Inc., (U.S. PTO Utility 1998)

C 25 APPARATUS AND METHOD FOR MEASURING AN INDUCED PERTURBATION TO DETERMINE A PHYSIOLOGICAL PARAMETER, US PAT 5810734Assignee: Vital Insite, Inc., (U.S. PTO Utility 1998)

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May 29, 2012

Noninvasive multi-parameter patient monitor

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CORE TERMS: display, parameter, monitor, sensor, measured, advantageously, patient, alarm, indicator, displayed, button, disclosure, multi-mode, wavelength, activation, measurement, pulse rate, displaying, caregiver, physiological, perfusion, artisan, audio, saturation, blood, flash, visual, exemplary, color, threshold

ENGLISH-ABST:

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("$SpO_{(2)}$"), fractional arterial oxygen saturation ("$SpaO_{(2)}$"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.

NO-OF-CLAIMS: 47

EXMPL-CLAIM: 18

NO-OF-FIGURES: 18

NO-DRWNG-PP: 18

PARENT-PAT-INFO:

PRIORITY CLAIM TO RELATED PROVISIONAL APPLICATIONS

[0001]The present application claims priority benefit under 35 U.S.C. 119(e) to U.S. Provisional Patent Application Ser. No. 60/657,596, filed Mar. 1, 2005, entitled Multiple Wavelength Sensor, No. 60/657,281, filed Mar. 1, 2005, entitled Physiological Parameter Confidence Measure, No. 60/657,268, filed Mar. 1, 2005, entitled Configurable Physiological Measurement System, and No. 60/657,759, filed Mar. 1, 2005, entitled Noninvasive Multi-Parameter Patient Monitor. The present application incorporates the foregoing disclosures herein by reference.

INCORPORATION BY REFERENCE OF RELATED UTILITY APPLICATIONS

[0002]The present application is related to the following copending U.S. utility applications:

[0003]

Search terms may have been found within the contents of this table. Please see the table in the original document.

[0004]The present application incorporates the foregoing disclosures herein by reference.

SUMMARY:

FIELD OF THE DISCLOSURE

[0005]The present disclosure relates to the field of noninvasive patient monitors. More specifically, the disclosure relates to monitors displaying measurements derived using signals from optical sensors.

BACKGROUND

[0006]Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration $c_{(i)}$ of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the pathlength $d_{(\lambda)}$, the intensity of the incident light $I_{(0,\lambda)}$, and the extinction coefficient ϵ$_{(i,\lambda)}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

[0007]Iλ=I0,λ⁢ⅇ-dλ·μ0,λ(1)μ0,λ=∑i=1n⁢i,λ·ci(2)

[0008]where $\mu_{(0,\lambda)}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve Equations 1-2 are the number of significant absorbers that are present in the solution.

[0009]A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation ($SpO_{(2)}$) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for $SpO_{(2)}$, pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

[0010]Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785. Read which are owned by Masimo, and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY OF THE DISCLOSURE

[0011]Despite the success of read through motion oximeter systems, there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to $SpO_{(2)}$, plethysmograph waveforms, or pulse rates. For example, in accessing a patient's condition, caregivers often desire knowledge of other blood constituents, including for example, a percent value for arterial carbon monoxide saturation ("HbCO") or a percent value for methemogobin saturation ("HbMet") or the like. For example, in an embodiment, the display advantageously displays one or more of the following: pulse rate, plethysmograph waveform data, perfusion index, values of blood constituents in body tissue, including for example, HbCO, HbMet, total hemoglobin ("Hbt"), arterial oxygen saturation ("$SpO_{(2)}$"), fractional arterial oxygen saturation ("$SpaO_{(2)}$"), or the like. In other embodiments, the monitor may advantageously and accurately determine values for one or more of $HbO_{(2)}$, Hb, blood glucose, water, the presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide ("$CO_{(2)}$") or oxygen ("O"), ph levels, bilirubin, perfusion quality, signal quality or the like. Accordingly, the present disclosure includes a multi-parameter patient monitor capable of determining one or more of the foregoing parameters, other than or in addition to, $SpO_{(2)}$, plethysmograph waveforms, or perfusion quality index.

[0012]In an embodiment, the display of a noninvasive multi-parameter patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display area or real estate. In an embodiment, a user may cycle different parameter values through an area of the display common to both parameters even when one parameter is shifted, through, for example, actuation of a user input key. The patient monitor may also display different parameters as color-coded. For example, when the following measured parameters are within "normal" ranges, $SpO_{(2)}$ may be displayed red, pulse rate (BPM) may be displayed green, HbCO may be displayed orange, HbMet may be displayed blue, or the like. In an embodiment, measured values of $SpO_{(2)}$ may be displayed in white, BPM may be displayed in yellow green or aquamarine, PI™ may be displayed in violet, Hbt may be displayed in grass green, HbMet may be displayed in blue or light blue, HbCO may be displayed in orange, and $SpaO_{(2)}$ may be displayed in electric blue.

[0013]Moreover, parameter trend data may also be displayed using the same or similar color coding, especially when multiple trends are displayed on one or more display graphs. In addition, more coarse or gross parameter indications may be displayed for quick reference to indicate to a caregiver whether any of a variety of monitored parameters, such as, for example, $SpO_{(2)}$, HbCO or HbMet is within acceptable ranges. The monitor may advantageously include additional display information, such as, for example, parametric displays where one parameter is displayed as a function of another, three dimensional displays (for example, extending a parametric display along time or an additional parameter), directional indicators predicting where a parameter is likely heading or reporting a general direction a parameters has been trending, or the like.

[0014]In addition to the foregoing, caregivers often desire to more closely monitor parameters that are close to, approaching, or beyond normal safe thresholds. In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical monitored parameters. In alternative embodiments, the patient monitor automatically changes display modes to show parameters moving closer to or beyond normal thresholds.

[0015]In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the monitor may determine how many wavelengths a particular attached sensor will emit through communication with memory devices associated with the attached sensor or cable.

[0016]Additional embodiments include audio or visual alarms for each of multiple monitored parameters, combinations of parameters, an indication of perfusion in the tissue of the measurement

site, an indication of the confidence the signal processing has in its output measurements, or the like.

[0017]For purposes of summarization, certain aspects, advantages and novel features are described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features need to be present in any particular embodiment.

DRWDESC:

BRIEF DESCRIPTION OF THE DRAWINGS

[0018]The drawings and the associated descriptions are provided to illustrate embodiments of the disclosure and not to limit the scope of the claims.

[0019]FIG. 1 illustrates a block diagram of an exemplary embodiment of a patient monitoring system including a sensor and a multi-parameter patient monitor.

[0020]FIG. 2 illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO, such as, for example, the patient monitor of FIG. 1.

[0021]FIG. 3 illustrates an exemplary display of the patient monitor of FIG. 2.

[0022]FIG. 4 illustrates the display of FIG. 3 showing measured values of $SpO_{(2)}$, BPM, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1.

[0023]FIG. 5 illustrates the display of FIG. 3 showing measured values of HbCO, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1.

[0024]FIG. 6 illustrates the display of FIG. 3 showing measured values of $SpO_{(2)}$, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. 1.

[0025]FIG. 7 illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. 1.

[0026]FIG. 8 illustrates an exemplary display of the patient monitor of FIG. 7.

[0027]FIG. 9 illustrates the display of FIG. 8 showing measured values of $SpO_{(2)}$, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1.

[0028]FIG. 10 illustrates the display of FIG. 8 showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1.

[0029]FIG. 11A illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor such as, for example, the patient monitor of FIG. 1.

[0030]FIGS. 11B-11H illustrate display screens of the patient monitor of FIG. 11A.

DETDESC:

DETAILED DESCRIPTION OF PREFERRED AND ALTERNATIVE EMBODIMENTS

[0031]Embodiments of the present disclosure include a portable or other multi-parameter patient monitor capable of determining multiple physiological parameters from one or more signals output from one or more light sensitive detectors capable of detecting light attenuated by body tissue carrying

pulsing blood. For example, in an embodiment, the monitor advantageously and accurately determines a wide variety of physiological parameters or other calculations as discussed above.

[0032]In an embodiment, the display of patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate. For example, the patient monitor may include one or more user input keys capable of toggling through measurement data. In an embodiment, the displays include mode indicators providing caregivers easily identifiable visual queues, such as LED's, text, icons, or other indicia providing readily identifiable queues as to which parameter is being displayed. In an embodiment, the display may shift, may be parameter color-coded, or the like to further ensure quick comprehension of which measured parameter is the displayed parameter. For example, in an embodiment, the monitor displays $SpO_{(2)}$ in white, pulse rate (BPM) in green, HbCO in orange, and HbMet in blue when the respective measured parameter is within a "normal" range.

[0033]In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical or time sensitive measured parameters, specific caregiver selected parameters, or the like. For example, the patient monitor may advantageously sound audio or visual alarms that alert the caregiver to particular one or more of worsening parameters, parameters changing in a predetermined pattern or rate, parameters stabilizing below user defined or safe thresholds, caregiver selected parameters, or the like. The monitor may also use alerts that provide audio or visual indications of the severity of the condition, severity of the change, or the like. In alternative embodiments, the patient monitor may automatically change display modes when a particular parameter crosses one or more thresholds. For example, a patient monitor may be displaying a first parameter, such as a plethysmograph, and upon determining measurements indicating that HBMet is trending toward an alarm condition, the monitor may automatically switch from displaying the first parameter to the alarming parameter, or in this case, a trend of the alarming parameter.

[0034]In an embodiment, a switch is provided to allow a user to switch displays to view an alarming measurement. In an embodiment, during an alarm condition, a parameter display may switch to a trend graph in the same or different color, line weight, flash, flash rate, intensity, size, or the like.

[0035]The patient monitor may also include one or more displays capable of displaying trend data for any one or more of the monitored or derived patient parameters. For example, the trend data may be displayed in graph form, may include multiple trend lines, each representing a different monitored or derived patient parameter. Moreover, each trend line may be color-coded to facilitate quick comprehension of which trend line represents which measured parameter. However, an artisan will recognize from the disclosure herein a large number of identification techniques including color-coding, identifying text, or the like. Additionally, user input may toggle displayed trend data, may select which parameters to display simultaneously, or the like.

[0036]In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the patient monitor may provide a particular audio or visual indication, such as a beep, LED activation, graphic activation, text messages, voice messages, or the like, to indicate communication with or connection to an approved sensor, patient cable, combination, or the like. In an embodiment, the indication may change based on the manufacturer, type of sensor recognized or not recognized, type of patient, type of physiological parameters measurable with the attached sensor, or the like. Additional embodiments include an indication of perfusion in the tissue of the measurement site and an indication of the confidence the signal processing has in its output measurements or input signal quality.

[0037]To facilitate an understanding of the disclosure, the remainder of the description references exemplary embodiments illustrated in the drawings. Moreover, in this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported herein in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this

application does not restrict the term to any particular manner in which the designated constituent is reported.

[0038]FIG. 1 illustrates a block diagram of an exemplary embodiment of a patient monitoring system **100**. As shown in FIG. 1, the system **100** includes a patient monitor **102** comprising a processing board **104** and a host instrument **108**. The processing board **104** communicates with a sensor **106** to receive one or more intensity signal(s) indicative of one or more parameters of tissue of a patient. The processing board **104** also communicates with a host instrument **108** to display determined values calculated using the one or more intensity signals. According to an embodiment, the board **104** comprises processing circuitry arranged on one or more printed circuit boards capable of installation into the monitor **102**, or capable of being distributed as some or all of one or more OEM components for a wide variety of host instruments monitoring a wide variety of patient information. In an embodiment, the processing board **102** comprises a sensor interface **110**, a digital signal processor and signal extractor ("DSP" or "processor") **112**, and an instrument manager **114**. In general, the sensor interface **110** converts digital control signals into analog drive signals capable of driving sensor emitters, and converts composite analog intensity signal(s) from light sensitive detectors into digital data.

[0039]In an embodiment, the sensor interface **110** manages communication with external computing devices. For example, in an embodiment, a multipurpose sensor port (or input/output port) is capable of connecting to the sensor **106** or alternatively connecting to a computing device, such as a personal computer, a PDA, additional monitoring equipment or networks, or the like. When connected to the computing device, the processing board **104** may upload various stored data for, for example, off-line analysis and diagnosis. The stored data may comprise trend data for any one or more of the measured parameter data, plethysmograph waveform data acoustic sound waveform, or the like. Moreover, the processing board **104** may advantageously download from the computing device various upgrades or executable programs, may perform diagnosis on the hardware or software of the monitor **102**. In addition, the processing board **104** may advantageously be used to view and examine patient data, including raw data, at or away from a monitoring site, through data uploads/downloads, or network connections, combinations, or the like, such as for customer support purposes including software maintenance, customer technical support, and the like. Upgradable sensor ports are disclosed in copending U.S. application Ser. No. 10/898,680, filed on Jul. 23, 2004, titled "Multipurpose Sensor Port," incorporated by reference herein.

[0040]As shown in FIG. 1, the digital data is output to the DSP **112**. According to an embodiment, the DSP **112** comprises a processing device based on the Super Harvard ARChitecture ("SHARC"), such as those commercially available from Analog Devices. However, a skilled artisan will recognize from the disclosure herein that the DSP **112** can comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In particular, the DSP **112** includes program instructions capable of receiving multiple channels of data related to one or more intensity signals representative of the absorption (from transmissive or reflective sensor systems) of a plurality of wavelengths of emitted light by body tissue. In an embodiment, the DSP **112** accepts data related to the absorption of eight (8) wavelengths of light, although an artisan will recognize from the disclosure herein that the data can be related to the absorption of two (2) to sixteen (16) or more wavelengths.

[0041]FIG. 1 also shows the processing board **104** including the instrument manager **114**. According to an embodiment, the instrument manager **114** may comprise one or more microcontrollers controlling system management, including, for example, communications of calculated parameter data and the like to the host instrument **108**. The instrument manager **114** may also act as a watchdog circuit by, for example, monitoring the activity of the DSP **112** and resetting it when appropriate.

[0042]The sensor **106** may comprise a reusable clip-type sensor, a disposable adhesive-type sensor, a combination sensor having reusable and disposable components, or the like. Moreover, an artisan will recognize from the disclosure herein that the sensor **106** can also comprise mechanical structures, adhesive or other tape structures, Velcro wraps or combination structures specialized for the type of patient, type of monitoring, type of monitor, or the like. In an embodiment, the sensor **106** provides data to the board **104** and vice versa through, for example, a patient cable. An artisan will also recognize from the disclosure herein that such communication can be wireless, over public or private networks or computing systems or devices, or the like.

[0043]As shown in FIG. 1, the sensor **106** includes a plurality of emitters **116** irradiating the body tissue **118** with differing wavelengths of light, and one or more detectors **120** capable of detecting the light after attenuation by the tissue **118**. In an embodiment, the emitters **116** comprise a matrix of eight (8) emission devices mounted on a flexible substrate, the emission devices being capable of emitting eight (8) differing wavelengths of light. In other embodiments, the emitters **116** may comprise twelve (12) or sixteen (16) emitters, although other numbers of emitters are contemplated, including two (2) or more emitters. As shown in FIG. 1, the sensor **106** may include other electrical components such as, for example, a memory device **122** comprising an EPROM, EEPROM, ROM, RAM, microcontroller, combinations of the same, or the like. In an embodiment, other sensor components may include a temperature determination device **123** or other mechanisms for, for example, determining real-time emission wavelengths of the emitters **116**.

[0044]The memory **122** may advantageous store some or all of a wide variety data and information, including, for example, information on the type or operation of the sensor **106**; type or identification of sensor buyer or distributor or groups of buyer or distributors, sensor manufacturer information, sensor characteristics including the number of emitting devices, the number of emission wavelengths, data relating to emission centroids, data relating to a change in emission characteristics based on varying temperature, history of the sensor temperature, current, or voltage, emitter specifications, emitter drive requirements, demodulation data, calculation mode data, the parameters for which the sensor is capable of supplying sufficient measurement data (e.g., HpCO, HpMet, HbT, or the like), calibration or parameter coefficient data, software such as scripts, executable code, or the like, sensor electronic elements, whether the sensor is a disposable, reusable, multi-site, partially reusable, partially disposable sensor, whether it is an adhesive or non-adhesive sensor, whether the sensor is a reflectance, transmittance, or transreflectance sensor, whether the sensor is a finger, hand, foot, forehead, or ear sensor, whether the sensor is a stereo sensor or a two-headed sensor, sensor life data indicating whether some or all sensor components have expired and should be replaced, encryption information, keys, indexes to keys or hash functions, or the like, monitor or algorithm upgrade instructions or data, some or all of parameter equations, information about the patient, age, sex, medications, and other information that may be useful for the accuracy or alarm settings and sensitivities, trend history, alarm history, or the like. In an embodiment, the monitor may advantageously store data on the memory device, including, for example, measured trending data for any number of parameters for any number of patients, or the like, sensor use or expiration calculations, sensor history, or the like.

[0045]FIG. 1 also shows the patient monitor **102** including the host instrument **108**. In an embodiment, the host instrument **108** communicates with the board **104** to receive signals indicative of the physiological parameter information calculated by the DSP **112**. The host instrument **108** preferably includes one or more display devices **124** capable of displaying indicia representative of the calculated physiological parameters of the tissue **118** at the measurement site. In an embodiment, the host instrument **108** may advantageously comprise a handheld housing capable of displaying one or more of a pulse rate, plethysmograph data, perfusion quality such as a perfusion quality index ("PI™"), signal or measurement quality ("SQ"), values of blood constituents in body tissue, including for example, $SpO_{(2)}$, HbCO, HbMet, Hbt, or the like. In other embodiments, the host instrument **108** is capable of displaying values for one or more of Hbt, Hb, blood glucose, bilirubin, or the like. The host instrument **108** may be capable of storing or displaying historical or trending data related to one or more of the measured values, combinations of the measured values, plethysmograph data, or the like. The host instrument **108** also includes an audio indicator **126** and user input device **128**, such as, for example, a keypad, touch screen, pointing device, voice recognition device, or the like.

[0046]In still additional embodiments, the host instrument **108** includes audio or visual alarms that alert caregivers that one or more physiological parameters are falling below predetermined safe thresholds. The host instrument **108** may include indications of the confidence a caregiver should have in the displayed data. In a further embodiment, the host instrument **108** may advantageously include circuitry capable of determining the expiration or overuse of components of the sensor **106**, including, for example, reusable elements, disposable elements, or combinations of the same.

[0047]Although described in terms of certain embodiments, other embodiments or combination of embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **102** may comprise one or more monitoring systems monitoring parameters,

such as, for example, vital signs, blood pressure, ECG or EKG, respiration, glucose, bilirubin, or the like. Such systems may combine other information with intensity-derived information to influence diagnosis or device operation. Moreover, the monitor **102** may advantageously include an audio system, preferably comprising a high quality audio processor and high quality speakers to provide for voiced alarms, messaging, or the like. In an embodiment, the monitor **102** may advantageously include an audio out jack, conventional audio jacks, headphone jacks, or the like, such that any of the display information disclosed herein may be audiblized for a listener. For example, the monitor **102** may include an audible transducer input (such as a microphone, piezoelectric sensor, or the like) for collecting one or more of heart sounds, lung sounds, trachea sounds, or other body sounds and such sounds may be reproduced through the audio system and output from the monitor **102**. Also, wired or wireless communications (such as Bluetooth or WiFi, including IEEE 801.11a, b, or g), mobile communications, combinations of the same, or the like, may be used to transmit the audio output to other audio transducers separate from the monitor **102**.

[0048]For example, patterns or changes in the continuous noninvasive monitoring of intensity-derived information may cause the activation of other vital sign measurement devices, such as, for example, blood pressure cuffs.

[0049]FIG. 2 illustrates a perspective view of an exemplary handheld noninvasive multi-parameter patient monitor **200**, such as, for example, the patient monitor **102** of FIG. 2. Patient monitors **200** exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57c." As shown in FIG. 1, the monitor **200** includes a patient cable connector **202** capable of mechanical mating with a patient cable to establish communication between the board **104** and the sensor **106**. In an embodiment, the connector **202** comprises a multipurpose cable connector such as that disclosed in the incorporated U.S. application Ser. No. 10/898,680, titled "Multipurpose Sensor Port," disclosing communication between the board **104** and an external computing device.

[0050]The monitor **200** also comprises a HbCO indicator **204** advantageously providing a visual queue that a HbCO capable sensor is properly connected through the connector **202**. For example, the HbCO indicator **204** may advantageously activate when a sensor is connected that communicates sufficient information to determine HbCO, such as, for example, a sensor capable of emitting sufficient different wavelengths of light, a sensor storing sufficient data on the memory **122**, a sensor having appropriate encryption data or key, combinations of the same, or the like. For example, in an embodiment, the processor **112** may receive information from a memory **122** indicating a number of available LED wavelengths for the attached sensor. Based on the number of wavelengths, or other information stored on the memory **122**, the processor **112** may determine whether an HbCO-ready sensor has been attached to the monitor **200**. An artisan will also recognize from the disclosure herein that the HbCO indicator **204** may advantageously comprise a HbMet indicator, Hbt indicator, or the like, which activates to a predetermined color associated with a parameter, or any color, or deactivates the same, to convey a type of attached sensor. Moreover, the artisan will recognize from the disclosure herein other parameters that may use other sensor components and the monitor **200** may include indicators capable of indicating communication with those types of sensors.

[0051]In an embodiment, the monitor **200** may also audibly indicate the type of sensor connected. For example, the monitor **200** may emit predetermined number or frequency of beeps associated with recognition of a particular sensor, a particular manufacturer, failure to recognize the sensor, or the like. Moreover, the sensor type may be indicative of the componentry, such as, for example, whether the sensor produces sufficient data for the determination of HbCO, HbMet, Hbt and $SpO_{(2)}$, $SpO_{(2)}$ only, $SpO_{(2)}$ and HbMet, any combination of the foregoing or other parameters, or the like. Additionally, the sensor type may be indicative of specific sensors designed for a type of patient, type of patient tissue, or the like. In other embodiments, the monitor **200** may announce the type of connector through speaker **236**.

[0052]An artisan will also recognize from the disclosure herein that other mechanical (such as keys), electrical, or combination devices may inform the monitor **200** of the type of attached sensor. In an embodiment, the processor **112** also may select to drive less emitters that are currently available, such as, for example, in the presence of low noise and when power consumption is an issue.

[0053]The monitor **200** also comprises a multi-mode display **206** capable of displaying, for example,

measurements of $SpO_{(2)}$ and HbCO (or alternatively, HbMet). In an embodiment, the display **206** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **200**. Thus, the multi-mode display **206** may advantageously cycle through two or more measured parameters in an area common to both parameters even when shifted. In such embodiments, the monitor **200** may also advantageously include parameter indicators **208**, **210**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **206** displays measured values of $SpO_{(2)}$ that are normal, the numbers may advantageously appear in green, while normal measured values of HbCO may advantageously appear in orange, and normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **206** flashes at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

[0054]The monitor **200** also comprises a HbCO bar **212** where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. For example, the bar **212** is lowest when the dangers from carbon monoxide poisoning are the least, and highest when the dangers are the greatest. The bar **212** includes indicia **214** that provide an indication of the severity of carbon monoxide saturation in a patient's blood. As shown in FIG. 2, the bar **212** and the indicia **214** continuously indicate the concentration of HbCO in about 5% increments. The indicia **214** indicate a measurement of HbCO saturation percentage between about 0 and about 50% with a granularity of about 5%. However, an artisan will also recognize from the disclosure herein a wide variety of ranges and granularities could be used, the indicia **214** could be electronically displayed in order to straightforwardly increase or decrease resolution, or the like. For example, HbCO may advantageously be displayed with greater resolution than ± about %5 in a lower portion of the scale. For example, an HbCO bar may advantageously include a scale of about <3%, about 6%, about 9%, about 12%, about 15%, about 20%, about 25%, about 30%, about 35%, and about >40%.

[0055]As is known in the art, carbon monoxide in the blood can lead to serious medical issues. For example and depending upon the particular physiology of a patient, about 10% carbon monoxide saturation can lead to headaches, about 20% can lead to throbbing headaches, or dyspnea on exertion, about 30% can lead to impaired judgment, nausea, dizziness and/or vomiting, visual disturbance, or fatigue, about 40% can lead to confusion and syncope, and about 50% and above can lead to comas, seizures, respiratory failure and even death.

[0056]In an embodiment, the bar **212** is the same or similar color as the multi-mode display **206** when displaying HbCO. In other embodiments, the bar **212** is lowest and green when the dangers from carbon monoxide poisoning are the least, and highest and red when the dangers are the greatest. In an embodiment, as HbCO increases, the entire bar **212** may advantageously change color, such as, for example, from green to red, to provide a clear indication of deepening severity of the condition. In other embodiments, the bar **212** may advantageously blink or flash, an audio alarm may beep or provide a continuation or rise in pitch or volume, or the like to alert a caregiver of deepening severity. Moreover, straightforward to complex alarm rules may be implemented to reduce false alarms based on, for example, knowledge of the physiological limitations on the rate of change in HbCO or the like.

[0057]Additionally, the monitor **200** may be capable of storing and outputting historical parameter data, display trend traces or data, or the like. Although the foregoing bar **212** has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

[0058]FIG. 2 also shows the monitor **200** including a pulse display **216** displaying measured pulse rate in beats per minute ("BPM"). In an embodiment, the display **212** flashes when searching for a pulse. The pulse display **216** advantageously displays measured pulse rates from about zero (0) to about two hundred and forty (240) BPM. Moreover, when the measured pulse rates are considered normal, the pulse display **216** is advantageously green. Similar to other displays associated with the monitor **200**, the pulse display **216** may employ a variety of color changes, audio alarms, or combinations of the same to indicate measured BPM below predetermined safe thresholds. In an embodiment, the pulse rate display **216** displays the measured pulse rate during the display of $SpO_{(2)}$ and displays message data during the display of other parameters. For example, during the display of HbCO, the display **216**

may advantageously display the term "CO." In an embodiment, the display of the message data may be in the same or similar color as the other displays. For example, in an embodiment, the multi-mode display **206**, the bar **212**, and the pulse display **216** may all display data or messages in orange when the multi-mode display **206** displays measured HbCO values.

[0059]FIG. 2 also illustrates the monitor **200** comprising user input keys **218**, including a HbCO button **220**, mode/enter button **222**, next button **224**, power on/off button **226**, up/down button **228**, and alarm silence button **230**. In an embodiment, activation of the HbCO button **220** toggles the measured value displayed in the multi-mode display **206**. For example, activation of the HbCO button **220** toggles the multi-mode display **206** from displaying measured values of $SpO_{(2)}$ to HbCO for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **206** back to $SpO_{(2)}$. A skilled artisan will also recognize that activation of the HbCO button **220** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to $SpO_{(2)}$, may remain displayed until further activation of the button **220**, or the like.

[0060]Activation of the mode/enter button **222** cycles through various setup menus allowing a caregiver to select or activate certain entries within the menu setup system, including alarm threshold customizations, or the like. Activation of the next button **224** can move through setup options within the menu setup system and in an embodiment is not active during normal patient monitoring. For example, a caregiver may activate the mode/enter button **222** and the next button **224** to specify high and low alarm thresholds for one or more of the measured parameters, to specify device sensitivity, trend settings, display customizations, color code parameters, or the like. In an embodiment, the high alarm setting for $SpO_{(2)}$ can range from about two percent (2%) to about one hundred percent (100%) with a granularity of about one percent (1%). The low alarm setting for $SpO_{(2)}$ can range from about one percent (1%) to about one hundred percent (100%) with a granularity of about one percent (1%). Moreover, the high alarm setting for pulse rate can range from about thirty (30) BPM to about two hundred and forty (240) BPM with a granularity of about five (5) BPM. The low alarm setting for pulse rate can range from about twenty five (25) BPM to about two hundred and thirty five (235) BPM with a granularity of about five (5) BPM. Other high and low ranges for other measured parameters will be apparent to one of ordinary skill in the art from the disclosure herein.

[0061]In a further embodiment, a caregiver may activate the mode/enter button **222** and the next button **224** to specify device sensitivity, such as, for example, device averaging times, probe off detection, whether to enable fast saturation calculations, or the like. Various embodiments of fast saturation calculations are disclosed in U.S. patent application Ser. No. 10/213,270, filed Aug. 5, 2002, titled "Variable Indication Estimator" and incorporated by reference herein. Using the menus, a caregiver may also advantageously enter appropriate information governing trend collection on one or more of the measured parameters, input signals, or the like.

[0062]FIG. 2 also shows the power on/off button **226**. Activation of the power on/off button **226** activates and deactivates the monitor **200**. In an embodiment, press-and-hold activation for about two (2) seconds shuts the monitor **200** off. In an additional embodiment, activation of the on/off button **226** advantageously initiates detection of a type of attached sensor. For example, activation of the on/off button **226** may advantageously cause the monitor **200** to read information from a memory on an attached sensor and determine whether sufficient wavelengths exist on the sensor to determine one or more the physiological parameters discussed in the foregoing.

[0063]An artisan will recognize from the disclosure herein that the on/off button **226** may advantageously cause an electronic determination of whether to operate in at powers consisted with the U.S. (60 Hz) or another nationality (50 Hz). In an embodiment, such automatic determination and switching is removed from the monitor **200** in order to reduce a likelihood of problematic interfering crosstalk caused by such power switching devices.

[0064]Activation of the up/down button **228** may advantageously adjust the volume of the pulse beep tone. Additionally, activation of the up/down button **228** within the menu setup system, causes the selection of values with various menu options.

[0065]Moreover, activation of the alarm silence button **230** temporarily silences audio alarms for a

predetermined period, such as, for example, about one hundred and twenty (120) seconds. A second activation of the alarm silence button **230** mutes (suspends) the alarm indefinitely, while a third activation returns the monitor **200** to standard alarm monitoring. FIG. 2 also shows the alarm silence button **230** includes an alarm silenced indicator **232**. The alarm silenced indicator **232** may advantageously flash to indicate one or more alarms are temporarily silenced, may illuminate solid to indicate the alarms have been muted, or the like. Moreover, an artisan will recognize from the disclosure herein a wide variety of alarm silencing methodologies.

[0066]The monitor **200** also includes a battery level indicator **234** indicating remaining battery life. In the illustrated embodiment, four LED's indicate the status of the battery by incrementally deactivating to indicate proportionally decreasing battery life. In an embodiment, the four LED's may also change color as the battery charge decreases, and the final LED may begin to flash to indicate that the caregiver should replace the batteries.

[0067]FIG. 2 also shows the monitor **200** including an audio transducer or speaker **236**. The speaker **236** advantageously provides audible indications of alarm conditions, pulse tone and feedback for key-presses, or the like. Moreover, the monitor **200** includes a low signal quality indicator ("SQ" or "SIQ™") **238**. The signal IQ indicator **238** activates to inform a caregiver that a measured value of the quality of the incoming signal is below predetermined threshold values. For example, in an embodiment, the measured value for signal IQ is at least partially based on an evaluation of the plethysmograph data's correspondence to predetermined models or characteristics of physiological signals. In an embodiment, the signal IQ indicator **238** output may be associated with the displayed parameter. For example, the output may be associated with one threshold for the display of $SpO_{(2)}$ and another for the display of other parameter data.

[0068]The monitor **200** also comprises a perfusion quality index ("PI™") bar **240** (which quantifies the measure of perfusion of the patient) where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. In one embodiment, the PI™ bar **240** shows a static value of perfusion for a given time period, such as, for example, one or more pulses. In another embodiment, or functional setting, the PI™ bar **240** may advantageously pulse with a pulse rate, may hold the last reading and optionally fade until the next reading, may indicate historical readings through colors or fades, or the like. Additionally, the PI™ bar **240** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

[0069]The PI™ bar **240** can be used to simply indicate inappropriate occlusion due, for example, to improper attachment of the sensor **106**. The PI™ bar **240** can also be used as a diagnostic tool during low perfusion for the accurate prediction of illness severity, especially in neonates. Moreover, the rate of change in the PI™ bar **240** can be indicative of blood loss, sleep arousal, sever hypertension, pain management, the presence or absence of drugs, or the like. According to one embodiment, the PI™ bar **240** values may comprise a measurement of the signal strength of the arterial pulse as a percentage of the total signal received. For example, in one preferred embodiment, the alternating portion of at least one intensity signal from the sensor **106** may advantageously be divided by the static portion of the signal. For example, an infrared intensity signal may advantageously be used as it is less subjective to noise.

[0070]In an embodiment, a measurement below about 1.25% may indicate medical situations in need of caregiver attention, specifically in monitored neonates. Because of the relevance of about 1.25%, the PI™ bar **240** may advantageously include level indicia **242** where the indicia **242** swap sides of the PI™ bar **240**, thus highlighting any readings below about that threshold. Moreover, behavior of the PI™ bar **240**, as discussed above, may advantageously draw attention to monitored values below such a threshold.

[0071]As discussed above, the monitor **200** may include output functionality that outputs, for example, trend perfusion data, such that a caregiver can monitor measured values of perfusion over time. Alternatively or additionally, the monitor **200** may display historical trace data on an appropriate display indicating the measured values of perfusion over time. In an embodiment, the trend data is uploaded to an external computing device through, for example, the multipurpose sensor connector **202** or other input output systems such as USB, serial or parallel ports or the like.

[0072]The monitor **200** also includes an alarm indicator **244** capable of providing visual queues of the status of one or more of the measured parameters. For example, the alarm indicator **244** may advantageously be green when all of the measured parameters are within normal conditions, may gradually fade to red, may flash, increasing flash, or the like, as one or more of the measured values approaches or passes predetermined thresholds. In an embodiment, the alarm indicator **244** activates when any parameter falls below an associated threshold, thereby advantageously informing a caregiver that perhaps a nondisplayed parameters is at an alarm condition. In another embodiment, the alarm indicator **244** may indicate the status of the parameter displayed on the multi-mode display **206**. In an embodiment, the speaker **236** may sound in conjunction with and/or in addition to the indicator **244**. Moreover, in an embodiment, an alarming parameter may automatically be displayed, may be emphasized, flashed, colored, combinations of the same or the like to draw a user's attention to the alarming parameter.

[0073]Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

[0074]FIG. 3 illustrates an exemplary display of the patient monitor **200**. As shown in FIG. 3, the display includes the multi-mode display **206**, the pulse rate display **216**, parameter indicators **208**, **210**, the HbCO bar **212** and indicator **204**, the PI™ bar **240**, and the alarm indicator **244**. In an embodiment, the multi-mode display **206** and the pulse rate display **216** each comprise a plurality of seven segment displays **302** capable of displaying alpha-numeric information. As disclosed in the foregoing, the exemplary display may advantageously include color-coded parameter displays. Moreover, the exemplary display may include color progressions, flashing, flashing progressions, audible alarms, audible progressions, or the like, indicating worsening measured values of physiological data. In addition, in an embodiment, some or all of the displays may flash at a first rate to indicate attempts to acquire data when actual measured values are unavailable. Moreover, some or all of the display may flash at a second rate to indicate low signal quality where confidence is decreasing that the measured values reflect actual physiological conditions.

[0075]FIG. 4 illustrates the display of FIG. 3 showing measured values of $SpO_{(2)}$, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. 1. As shown in FIG. 4, the multi-mode display **206** is displaying a percentage value of $SpO_{(2)}$, and the pulse rate display **216** is displaying a pulse rate in beats per minute. Accordingly, the parameter indicator **210** is activated to confirm the display of measured values of $SpO_{(2)}$. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** is red, indicating blood oxygen measurements while the pulse rate display **216** is green, indicating normal values of a patient's pulse.

[0076]FIG. 4 also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the HbCO indicator **204** is showing communication with a sensor producing insufficient data to determine measured values of additional parameters, such as, HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about two (2) different wavelengths, may comprise sensors with insufficient data stored on a memory associated therewith, or the like.

[0077]FIG. 5 illustrates the display of FIG. 3 showing measured values of HbCO, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. 1. As shown in FIG. 5, the multi-mode display **206** is displaying a percentage value of HbCO, and the pulse rate display **216** is displaying an appropriate message indicating the HbCO measurement, such as, for example, "CO". Also, the multi-mode display **206** has shifted the data to the left to quickly and efficiently indicate that the displayed parameter is other than $SpO_{(2)}$. Accordingly, the parameter indicator **208** is also activated to confirm the display of measured values of HbCO. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** and pulse rate display message **216** are orange.

[0078]FIG. 5 also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about eight (8) or more different wavelengths; however, such sensors may comprise about two (2) or more different wavelengths. Moreover, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. 5 also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode

display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

[0079]FIG. 6 illustrates the display of FIG. 3 showing measured values of $SpO_{(2)}$, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. 1. In contrast to FIG. 4, FIG. 6 shows that the monitor **200** is communicating with a sensor capable of producing sufficient data to determine measured values of HbCO, even though the displayed values are that of $SpO_{(2)}$ and BPM. Thus, FIG. 6 shows the activation of the HbCO indicator **204**, and the continuous monitoring of HbCO by the HbCO bar **212**. FIG. 6 also shows a high value of HbCO, and therefore, the indication of an alarm condition by activation of the alarm indicator **244**. In an embodiment, upon determination of an alarm condition on a nondisplayed parameter, the monitor **200** may advantageously provide an alarm indication through speaker and alarm indicator activation, automatic toggle to the nondisplayed parameter on the multi-mode display **206** for a defined or undefined time, or the like.

[0080]FIG. 7 illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor **700** capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. 1. Patient monitors exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57 cm." As shown in FIG. 7, the monitor **700** comprises a monitor similar to monitor **200** disclosed with reference to FIG. 2. Moreover, monitor **700** further includes a multi-mode display **706** capable of displaying, for example, measurements of HbMet and BPM. In an embodiment, the display **706** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **700**. Thus, the multi-mode display **706** may advantageously cycle through two or more measured parameters. In such embodiments, the monitor **700** may also advantageously include parameter indicators **708**, **710**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display **706** may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **706** displays measured values of BPM that are normal, the numbers may advantageously appear in green, while normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **706** may flash at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

[0081]FIG. 7 also illustrates the monitor **700** comprising user input keys **718**, including an HbCO/HbMet button **220**. In an embodiment, activation of the HbCO/HbMet button **720** toggles the measured value displayed in the multi-mode display **706**. For example, activation of the HbCO/HbMet button **720** toggles the multi-mode display **206** from displaying measured values of $SpO_{(2)}$ and BPM, to HbCO and HbMet for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **706** back to $SpO_{(2)}$ and BPM. A skilled artisan will also recognize that activation of the HbCO/HbMet button **720** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to $SpO_{(2)}$ and BPM, may remain displayed until further activation of the button **720**, or the like.

[0082]The monitor **700** also comprises a coarser indication of HbMet through an HbMet bar **740**. In an embodiment, a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value, with increments at about 0.5%, about 1%, about 2%, about 3%, about 4%, about 5%, about 7.5%, about 10%, about 15% and greater than about 20%, although an artisan will recognize from the disclosure herein other useful delineations. Additionally, the HbMet bar **740** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

[0083]Although disclosed with reference to the HbMet bar **740**, and artisan will recognize from the disclosure herein other coarse or even gross indications of HbMet, or any measured parameter. For example, a single LED may advantageously show green, yellow, and red, to indicate worsening coarse values of HbMet. Alternatively, a single LED may simply light to indicate an alarm or approaching alarm condition.

[0084]FIG. 8 illustrates an exemplary display of the patient monitor **700** of FIG. 7. As shown in FIG. 8, the display includes the multi-mode displays **206**, **706**, parameter indicators **208**, **210**, **708**, **710**, the HbCO bar **212** and indicator **204**, the HbMet bar **740**, and the alarm indicator **244**. In an embodiment, the multi-mode display **706** is similar to multi-mode display **206**, comprising a plurality of seven segment displays **302** capable of displaying alpha-numeric information, and capable of altering its display characteristics or aspects in a wide variety of configurations discussed with reference to the display **206**.

[0085]FIG. 9 illustrates the display of FIG. 8 showing measured values of $SpO_{(2)}$, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1. FIG. 9 also shows the HbMet bar **740** near the bottom and corresponding to about 1%, representing acceptable HbMet, while the HbCO bar **212** hovers at a dangerous near 20%. In addition, the HbCO indicator **204** is showing communication with a sensor producing sufficient data to determine measured values of additional parameters, such as, HbMet, HbCO or the like. In an embodiment, such sensors may comprise sensors capable of emitting light of more than two (2) different wavelengths, preferably more than four (4) different wavelengths, and more preferably eight (8) or more different wavelengths.

[0086]FIG. 10 illustrates the display of FIG. 8 showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. 1. As shown in FIG. 10, the multi-mode display **706** is displaying a percentage value of HbMet that is shifted using the parameter indicator **708**. The data has been advantageously shifted to the left to quickly and efficiently indicate that the displayed parameter is other than BPM. Accordingly, the parameter indicator **708** is also activated to confirm the display of measured values of HbMet. As disclosed in the foregoing, in an embodiment, the multi-mode display **706** is blue.

[0087]FIG. 10 also shows the HbMet bar **740** nearly empty, representing acceptable HbMet. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. 10 also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

[0088]FIG. 11A illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor **1100**, such as, for example, the patient monitor of FIG. 1. Moreover, FIGS. 11B-11E illustrate exemplary display screens of the patient monitor of FIG. 11A. As shown in FIGS. 11A-11B, an embodiment of the monitor **1100** includes a display **1101** showing a plurality of parameter data. For example, the display may advantageously comprise a CRT or an LCD display including circuitry similar to that available on oximeters commercially available from Masimo Corporation of Irvine, Calif. sold under the name Radical™, and disclosed in the U.S. patents referenced above and incorporated above. However, an artisan will recognize from the disclosure herein many commercially available display components capable of displaying multiple parameter data along with the ability to display graphical data such as plethysmographs, trend traces, and the like.

[0089]In an embodiment, the display includes a measured value of $SpO_{(2)}$ **1102**, a measured value of pulse rate **1104** in BPM, a plethysmograph **1106**, a measured value of HbCO **1108**, a measured value of HbMet **1110**, a measured value of a perfusion quality **1112**, a measured value of Hbt **1114**, and a derived value of fractional saturation "$SpaO_{(2)}$" **116**. In an embodiment, $SpaO_{(2)}$ comprises $HbO_{(2)}$ expressed as a percentage of the four main hemoglobin species, i.e., $HbO_{(2)}$, Hb, HbCO, and HbMet.

[0090]In an embodiment, one or more of the foregoing parameter includes trending or prediction indicators **1118** showing the current trend or prediction for that corresponding parameter. In an embodiment, the indicators **1118** may advantageously comprise an up arrow, a down arrow, and a hyphen bar to indicate up trending/prediction, down trending/prediction, or neutral trending/prediction.

[0091]FIG. 11C illustrates an exemplary display screen showing trend graph **1140** including trend line **1142** for HbMet. In an embodiment, the trend line **1142** may be advantageously colored for quick straightforward recognition of the trending parameter, may be associated with any one or more of the

foregoing alarm attributes, may include trending lines for other parameters, or the like. The display screen also shows trending directional indicators **1142**, **1144** for many of the displayed physiological parameters. In an embodiment, the directional indicators **1142**, **1144** may advantageously comprises arrows showing the recent trend, predicted trend, user-customizable trend, combinations thereof, or the like for the associated parameters. In an embodiment, the directional indicators **1142**, **1144** comprises an up arrow indicating a rising trend/predicted trend, a middle bar indicating a somewhat stable trend/predicted trend, and a down arrow indicating a lowering trend/predicted trend. An artisan will recognize a wide variety of other directional indicators **1142**, **1144** from the disclosure herein.

[0092]FIG. 11D shows an exemplary display screen in vertical format. Such vertical format could be user actuated or based on a gravity switch. FIGS. 11E-11F illustrate additional displays of various physiological parameters similar to those discussed in the foregoing. being As shown in FIG. 11G, the display includes a measured value of $SpO_{(2)}$**1162**, a measured value of pulse rate **1164** in BPM, a plethysmograph **1166**, a HbCO bar **1168**, and a HbMet bar **1170**. In an embodiment, the HbCO bar **1168** and HbMet bar **1170** may advantageously behave the same or similarly to the HbCO bar **212** and HbMet bar **712**. Moreover, similar bars may advantageously display any of the physiological parameters discussed herein using display indicia appropriate to that parameter. For example, a $SpO_{(2)}$ or $SpaO_{(2)}$ bar may advantageously range from about 0% to about 100%, and more preferably range from about 50% to about 100%, while a Hbt bar may advantageously range from about 0 to about 30.

[0093]Moreover, similar to the disclosure above, the measured value of $SpO_{(2)}$**1162** may advantageously toggle to measured values of HbCO, HbMet, Hbt, or the like based on, for example, actuation of user input keys, or the like.

[0094]In addition to the foregoing, the display may also include graphical data showing one or more color-coded or other identifying indicia for traces of trend data. Moreover, other graphical presentations may advantageously provide readily identifiable indications of monitored parameters or combinations of monitored parameters of the patient. For example, in an embodiment, the display includes a $SpaO_{(2)}$ graph **1172**. The $SpaO_{(2)}$ graph **1172** plots $SpO_{(2)}$ as a function of other blood analytes (1-$SpaO_{(2)}$), where $SpaO_{(2)}$ comprises $HbO_{(2)}$ expressed as a percentage of the four main hemoglobin species, i.e., $HbO_{(2)}$, Hb, HbCO, and HbMet. Thus, as shown in FIG. 11C, as the slope of the displayed line or arrow increases, the caregiver can readily note that the majority of hemoglobin carriers are being used to carry oxygen, and not, for example, harmful carbon monoxide. On the other hand, as the slope decreases, the caregiver can readily and advantageously note that the number of hemoglobin species available to carry oxygen is decreasing, regardless of the current value of $SpO_{(2)}$. Moreover, the length of the arrow or line also provides an indication of wellness, e.g., the higher the line the more oxygen saturation, the lower the line, the more likely there may be desaturation event, or the like.

[0095]Thus, the $SpaO_{(2)}$ graph **1172** provides the caregiver with the ability to recognize that even though the measured value of $SpO_{(2)}$ may be within acceptable ranges, there are potentially an unacceptable number of hemoglobin carriers unavailable for carrying oxygen, and that other potential problems may exist, such as, for example, harmful carbon monoxide levels, or the like. In an embodiment, various alarm conditions may cause the graph **1172** to change color, flash, or any combination of alarm indications discussed in the foregoing. Moreover, FIG. 11 illustrates yet an additional display of the foregoing parameters.

[0096]An embodiment may also include the monitor **1000** advantageously defining regions of wellness/severity of the monitored patient. For example, because the graph **1172** comprises two dimensions, the monitor **1000** may advantageously define regions where the patient's measured physiological parameters are considered acceptable, regions where the patient is considered at risk, regions where the patient is critical, and the like. For example, one region of acceptability may include a high $SpO_{(2)}$ and a low 1-$SpaO_{(2)}$, another region of risk may include a high $SpO_{(2)}$ and a high 1-$SpaO_{(2)}$, and another critical region may include a low $SpO_{(2)}$ and a high 1-$SpaO_{(2)}$. Moreover, an artisan will recognize from the disclosure herein that different parameters may also be combined to provide readily identifiable indications of patient wellness.

[0097]In addition to or as an alternative to the two dimensional $SpaO_{(2)}$graph **1172**, the monitor **1000** may also include a three dimensional graph, such as, for example, extending the graph **1172** along the variable of time. In this embodiment, the forgoing regions advantageously become three dimensional surfaces of wellness. Moreover, trend data may also be advantageously added to the surface to provide a history of when particular monitored parameters dipped in and out of various surfaces of wellness, risk, criticality, or the like. Such trend data could be color-coded, text identified, or the like. An artisan will also recognize that such surfaces may be dynamic. For example, measurements of HbCO> about 5 may dictate that trend data showing $SpO_{(2)}$< about 90% should be considered critical; however, measurements of HbCO< about 5 may dictate only $SpO_{(2)}$< about 85% would be critical. Again, an artisan will recognize from the disclosure herein other parameter combinations to create a wide variety of wellness/critical regions or surfaces that provide readily available visual or audio indications of patient well being, trigger specific alarms, or the like.

[0098]Moreover, the monitor **1000** may advantageously employ enlargement or reorganization of parameter data based on, for example, the severity of the measurement. For example, the monitor **1000** may display values for HbCO in a small portion of the screen or in the background, and when HbCO begins to approach abnormal levels, the small portion may advantageously grown as severity increases, even in some embodiments to dominate the display. Such visual alarming can be combined with audio alarms such as announcements, alarms, rising frequencies, or the like, and other visual alarms such as flashing, coloration, or the like to assist a caregiver in noticing the increasing severity of a monitored parameter. In an embodiment, a location of the display of an alarming value is changed to be displayed in a larger display area, such as **1102**, so as to be readily noticeable and its display values readily ascertainable.

[0099]Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **100** may advantageously be adapted to monitor or be included in a monitor capable of measuring physiological parameters other than those determined through absorption spectroscopy, such as, for example, blood pressure, ECG, EKG, respiratory rates, volumes, inputs for blood pressure sensors, acoustical sensors, and the like. Moreover, the monitor **100** may be adapted for wireless communication to and from the sensor **106**, and/or to and from other monitoring devices, such as, for example, multi-parameter or legacy monitoring devices.

[0100]Also, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

[0101]Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

ENGLISH-CLAIMS:
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What is claimed is:

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

2. The patient monitor of claim 1, wherein the first display area and the second display area comprise the common display area.

3. The patient monitor of claim 1, wherein activation of a user input causes the common display area to change from displaying one of the measured value of the first or second physiological parameter to displaying the other of the measured value of the first or second physiological parameter.

4. The patient monitor of claim 1, wherein the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.

5. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an invasively measured value.

6. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises a non-invasively measured value.

7. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises glucose.

8. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

9. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

10. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

11. The patient monitor of claim 1, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters.

12. The patient monitor of claim 11, wherein the aspect that changes comprises a display color.

13. The patient monitor of claim 11, wherein the aspect that changes comprises a display size.

14. The patient monitor of claim 11, wherein the aspect that changes comprises a display intensity.

15. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

16. The patient monitor of claim 15, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters.

17. The patient monitor of claim 16, wherein the aspect that changes comprises a display color.

18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the

second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

19. The patient monitor of claim 18, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.

20. The patient monitor of claim 18, wherein at least one of measured physiological parameters is determined noninvasively.

21. A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

- -

  displaying a measured value of a first physiological parameter in a display location of an electronic display; and
- -

  replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.

22. The method of claim 21, wherein the indication of the worsening state comprises an alarm condition.

23. The method of claim 21, wherein the measured value of the first physiological parameter comprises an invasively measured value.

24. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

25. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

26. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

- -

  a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and
- -

  a user input button, the activation of which causes the display to change from displaying the

measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

- -

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

28. The patient monitor of claim 27, wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

29. The patient monitor of claim 27, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.

30. The patient monitor of claim 27, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.

31. The patient monitor of claim 27, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.

32. The patient monitor of claim 27, wherein the attached sensor can provide data through the output signal and through a memory device.

33. The patient monitor of claim 27, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.

34. The patient monitor of claim 27, further comprising a memory for storing trend data on one or more of the first and second blood parameters.

35. The patient monitor of claim 27, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.

36. The patient monitor of claim 27, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.

37. The patient monitor of claim 36, wherein the alarm comprises at least one of an audio or visual alarm.

38. The patient monitor of claim 27, further comprising an additional display indicating perfusion through the body tissue.

39. The patient monitor of claim 27, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.

40. The patient monitor of claim 39, comprising an additional display capable of indicating the percent carbon monoxide saturation.

41. The patient monitor of claim 39, comprising an additional display capable of indicating the percent methemoglobin saturation.

42. The patient monitor of claim 27, wherein the display comprises a first display and the patient

monitor further comprises a second display capable of displaying a pulse rate.

43. The patient monitor of claim 42, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.

44. The patient monitor of claim 42, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

45. The patient monitor of claim 27, wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

46. The patient monitor of claim 45, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.

47. The patient monitor of claim 45, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button.

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REEXAM CONTROL NUMBER	FILING OR 371 (c) DATE	PATENT NUMBER
90/012,559	09/13/2012	8190223

CONFIRMATION NO. 6710

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P
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REEXAMINATION REQUEST NOTICE

OC000000056902441

Date Mailed: 10/04/2012

NOTICE OF REEXAMINATION REQUEST FILING DATE

(Third Party Requester)

Requester is hereby notified that the filing date of the request for reexamination is 09/13/2012, the date that the filing requirements of 37 CFR § 1.510 were received.

A decision on the request for reexamination will be mailed within three months from the filing date of the request for reexamination. (See 37 CFR 1.515(a)).

A copy of the Notice is being sent to the person identified by the requester as the patent owner. Further patent owner correspondence will be the latest attorney or agent of record in the patent file. (See 37 CFR 1.33). Any paper filed should include a reference to the present request for reexamination (by Reexamination Control Number).

cc: Patent Owner
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Legal Instruments Examiner
Central Reexamination Unit 571-272-7705; FAX No. 571-273-9900

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NOTICE OF ASSIGNMENT OF REEXAMINATION REQUEST

The above-identified request for reexamination has been assigned to Art Unit 3993. All future correspondence to the proceeding should be identified by the control number listed above and directed to the assigned Art Unit.

A copy of this Notice is being sent to the latest attorney or agent of record in the patent file or to all owners of record. (See 37 CFR 1.33(c)). If the addressee is not, or does not represent, the current owner, he or she is required to forward all communications regarding this proceeding to the current owner(s). An attorney or agent receiving this communication who does not represent the current owner(s) may wish to seek to withdraw pursuant to 37 CFR 1.36 in order to avoid receiving future communications. If the address of the current owner(s) is unknown, this communication should be returned within the request to withdraw pursuant to Section 1.36.

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Patent Assignment Abstract of Title

Total Assignments: 3

Application #: 11267033 **Filing Dt:** 03/01/2006 **Patent #:** 8190223 **Issue Dt:** 05/29/2012
PCT #: NONE **Publication #:** US20060226992 **Pub Dt:** 10/12/2006
Inventors: Ammar Al-Ali, Joe E. Kiani, Mohamed Diab, Greg Olsen, Roger Wu, Rick Fishel
Title: NONINVASIVE MULTI-PARAMETER PATIENT MONITOR

Assignment: 1

Reel/Frame: 017995 / 0131 **Received:** 06/19/2006 **Recorded:** 06/15/2006 **Mailed:** 07/25/2006 **Pages:** 5
Conveyance: ASSIGNMENT OF ASSIGNORS INTEREST (SEE DOCUMENT FOR DETAILS).
Assignors: AL-ALI, AMMAR **Exec Dt:** 05/22/2006
KIANI, JOE E. **Exec Dt:** 05/22/2006
DIAB, MOHAMED **Exec Dt:** 05/22/2006
OLSEN, GREG **Exec Dt:** 05/22/2006
WU, ROGER **Exec Dt:** 05/22/2006
FISHEL, RICK **Exec Dt:** 05/22/2006
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Assignment: 2

Reel/Frame: 028177 / 0534 **Received:** 05/08/2012 **Recorded:** 05/08/2012 **Mailed:** 05/10/2012 **Pages:** 4
Conveyance: CHANGE OF NAME (SEE DOCUMENT FOR DETAILS).
Assignors: AL-ALI, AMMAR **Exec Dt:** 05/22/2006
KIANI, JOE E **Exec Dt:** 05/22/2006
DIAB, MOHAMED **Exec Dt:** 05/22/2006
OLSEN, GREG **Exec Dt:** 05/22/2006
WU, ROGER **Exec Dt:** 05/22/2006
FISHEL, RICK **Exec Dt:** 05/22/2006
Assignee: CERCACOR LABORATORIES, INC.
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Assignment: 3

Reel/Frame: 029194 / 0450 **Received:** 05/11/2012 **Recorded:** 05/11/2012 **Mailed:** 05/14/2012 **Pages:** 4
Conveyance: CORRECTIVE ASSIGNMENT TO CORRECT THE CONVEYING PARTY TO MASIMO LABORATORIES, INC. INSTEAD OF THE INVENTORS PREVIOUSLY RECORDED ON REEL 028177 FRAME 0534. ASSIGNOR(S) HEREBY CONFIRMS THE CHANGE OF NAME.
Assignor: MASIMO LABORATORIES, INC. **Exec Dt:** 08/02/2010
Assignee: CERCACOR LABORATORIES, INC.
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Web interface last modified: Jan 26, 2012

REQUEST FOR *EX PARTE* REEXAMINATION TRANSMITTAL FORM

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Commissioner for Patents
Alexandria, VA 22313-1450

Attorney Docket No.: 403381US104RX

Date: September 13, 2012

1. ■ This is a request for *ex parte* reexamination pursuant to 37 CFR 1.510 of patent number 8,190,223 issued May 29, 2012. The request is made by:

   ☐ patent owner. ■ third party requester.

2. ■ The name and address of the person requesting reexamination is:

   Tia D. Fenton

   OBLON, SPIVAK, ET AL.

   1940 Duke Street, Alexandria, Virginia 22314

3. ■ Payment is being made online (if electronically filed), or is attached hereto (if paper filed), in the amount of $2,520.00 to cover the reexamination fee, 37 CFR 1.20(c)(1);

4. ■ Any refund should be made by ■ Credit to Deposit Account No. 15-0030 37 CFR 1.26(c). If payment is made by credit card, refund must be to credit card account.

5. ■ A copy of the patent to be reexamined having a double column format on one side of a separate paper is enclosed. 37 CFR 1.510(b)(4)

6. ☐ CD-ROM or CD-R in duplicate, Computer Program (Appendix) or large table
   ☐ Landscape Table on CD

7. ☐ Nucleotide and/or Amino Acid Sequence Submission
   If applicable, items a. – c. are required.
   a. ☐ Computer readable Form (CRF)
   b. Specification Sequence Listing on:
      i. ☐ CD-ROM (2 copies) or CD-R (2 copies); **or**
      ii. ☐ paper
   c. ☐ Statements verifying identity of above copies

8. ■ A copy of any disclaimer, certificate of correction or reexamination certificate issued in the patent is included.

9. ■ Reexamination of claim(s) 1-47 is requested.

10. ■ A copy of every patent or printed publication relied upon is submitted herewith including a listing thereof on Form PTO/SB/08, PTO-1449, or equivalent.

11. ☐ An English language translation of all necessary and pertinent non-English language patents and/or printed publications is included.

12. ■ The attached detailed request includes at least the following items:

a. A statement identifying each substantial new question of patentability based on prior patents and printed publications. 37 CFR 1.510(b)(1)

b. An identification of every claim for which reexamination is requested, and a detailed explanation of the pertinency and manner of applying the cited art to every claim for which reexamination is requested. 37 CFR 1.510(b)(2)

13. ☐ A proposed amendment is included (only where the patent owner is the requester). 37 CFR 1.510(e)

14. ■ a. It is certified that a copy of this request (if filed by other than the patent owner) has been served in its entirely on the patent owner as provided in 37 CFR 1.33(c).
The name and address of the party served and the date of service are:

KNOBBE MARTENS OLSON & BEAR, LLP
2040 MAIN STREET, FOURTEENTH FLOOR
IRVINE, CALIFORNIA 92614

Date of Service: September 13, 2012 ; or

☐ b. A duplicate copy is enclosed since service on patent owner was not possible.

15. Correspondence Address: Direct all communication about the reexamination to:

■ The address associated with Customer Number: 22850

16. ☐ The patent is currently the subject of the following concurrent proceeding(s):

☐ a. Copending reissue Application No. _____.

☐ b. Copending reexamination Control No. _____.

☐ c. Copending Interference No. _____.

☐ d. Copending litigation styled:

_____

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Tia Fenton
Authorized Signature

Sept. 13, 2012
Date

Tia D. Fenton
Typed/Printed Name

55,170
Registration No.

☐ For Patent Owner Requester
☒ For Third Party Requester

10/08

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent No. 8,190,223	§	Attorney Docket No.: 403381US104RX
	§	
Inventor: Al-Ali et al.	§	Issued: May 29, 2012
	§	
Filed: March 1, 2006	§	
	§	
For: Noninvasive Multi-Parameter Patient Monitor	§	
	§	

REQUEST FOR *EX PARTE* REEXAMINATION OF U.S. PATENT NO. 8,190,223

Mail Stop "*Ex Parte* Reexam"
Attn: Central Reexamination Unit
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Pursuant to the provisions of 35 U.S.C. § 302-307, the undersigned, on behalf of Third-Party Requester ("Requester"), requests *ex parte* reexamination of all claims (claims 1-47) of U.S. Patent No. 8,190,223 ("the '223 patent," Ex. A) that issued on May 29, 2012 to Ammar Al-Ali et al., resulting from U.S. Patent Application No. 11/367,033 ("the '033 Application") filed on March 1, 2006. The patent is assigned on its face to Masimo Laboratories, Inc. (the "Patent Owner").

Pursuant to 37 C.F.R. § 1.510(a), this Request is accompanied by the fee set forth in 37 C.F.R. § 1.20(c)(1).

Pursuant to 37 C.F.R. § 1.510(b)(1), statements pointing out each substantial new question of patentability based on prior patents and printed publications are provided in Section IV of this Request.

Pursuant to 37 C.F.R. § 1.510(b)(2), reexamination is requested for all claims (1-47) of

the '223 patent, and a detailed explanation of the pertinence and manner of applying the cited prior art to every claim for which reexamination is requested is provided in Section VI of this Request.

Pursuant to 37 C.F.R. § 1.510(b)(3), a copy of every patent or printed publication relied upon or referred to in the statement pointing out each substantial new question of patentability or in the detailed explanation of the pertinence and manner of applying the cited prior art are provided as Exhibits C-H of this Request.

Pursuant to 37 CFR § 1.510(b)(4), a copy of the entire '223 patent, including a copy of any disclaimer, certificate of correction, or re-examination certificate, is attached as Exhibit A.

Pursuant to 37 C.F.R. § 1.510(b)(5), the attached Certificate of Service indicates that a copy of this Request, in its entirety, has been served on Patent Owner at the following address of the attorney of record for Patent Owner, in accordance with 37 C.F.R. § 1.33(c):

KNOBBE MARTENS OLSON & BEAR LLP
2040 Main Street
Fourteenth Floor
Irvine, CA 92614

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C. Al-Ali in View of Kianl Renders Claims 29, 31-35, 37, 38, and 44-47 of the '223 Patent Unpatentable Under 35 U.S.C. § 103(a) 33

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I. CONCURRENT PROCEEDINGS

To our knowledge, the '223 patent is not the subject of any concurrent proceedings.

II. CITATION OF PRIOR ART PATENTS

Reexamination of all claims (1-47) of the '223 patent is requested in view of the following prior art patents and publications:

Exhibit C	U.S. Patent Application Publication 2002/0082488, filed December 21, 2001 and published June 27, 2002 to Al-Ali et al. ("Al-Ali"). Al-Ali is available as prior art under 35 U.S.C. § 102(b).
Exhibit D	U.S. Patent No. 6,658,276, issued December 2, 2003 to Kianl et al. ("Kianl"). Kianl is available as prior art under 35 U.S.C. § 102(b).
Exhibit E	U.S. Patent No. 5,842,979, issued December 1, 1998 to Jarman ("Jarman"). Jarman is available as prior art under 35 U.S.C. § 102(b).
Exhibit F	U.S. Patent No. 4,051,522, issued September 27, 1997 to Healy et al. ("Healy"). Healy is available as prior art under 35 U.S.C. § 102(b).
Exhibit G	U.S. Patent Application Publication 2003/0120164, filed December 20, 2001 and published June 26, 2003 to Nielsen ("Nielsen"). Nielsen is available as prior under 35 U.S.C. § 102(b).
Exhibit H	U.S. Patent No. 5,743,262, issued April 28, 1998 to Lepper et al. ("Lepper"). Lepper is available as prior art under 35 U.S.C. § 102(b).

III. THE '223 PATENT

There are substantial new questions of patentability not previously considered by the United States Patent and Trademark Office ("the Office") for all claims (1-47) of the '223 patent.

A. Overview of the '223 Patent

The '223 patent discloses and claims a pulse oximeter capable of displaying at least two measured physiological parameters. A pulse oximeter is a type of noninvasive patient monitor used to measure various parameters of circulating blood, most typically blood oxygen saturation (SpO_2) and pulse rate. Ex. A, col. 2, lines 16-26. While pulse oximeters are generally known in the art, the summary of the '223 patent states that "there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to SpO_2, plethysmograph waveforms, or pulse rates." *Id.* at col. 2, lines 51-54. Accordingly, the '223 patent describes a patient monitor which can display at least two physiological parameters and selectively display the measured parameter(s) that are of most importance to a caregiver.

For instance, the patient monitor of the '223 patent may provide:

> an indication that the caregiver should change display modes to view more critical or time sensitive measured parameters, specific caregiver selected parameters, or the like. ... [T]he patient monitor may advantageously sound audio or visual alarms that alert the caregiver to particular one or more of worsening parameters, parameters changing in a predetermined pattern or rate, parameters stabilizing below user defined or safe thresholds, caregiver selected parameters, or the like. The monitor may also use alerts that provide audio or visual indications of the severity of the condition, severity of the change, or the like. In alternative embodiments, the patient monitor may automatically change display modes when a particular parameter crosses one or more thresholds.

Id. at col. 5, lines 6-19.

Figure 11A, reproduced below, shows an exemplary patient monitor 1000 as described in the '223 patent. The embodiment includes a display 1101, which indicates a measured value of SpO_2 1102, a measured value of pulse rate 1104 in BPM, a plethysmograph 1106, and other

measured physiological parameters shown as elements 1108-1116. *Id.* at col. 17, lines 33-41. The monitor 1000 may also "employ enlargement or reorganization of parameter data based on, for example, the severity of the [measured parameters]." *Id.* at col. 19, lines 24-26. For instance, parameters that may be displayed in a small portion of the screen or in the background will be displayed in a larger display area once an alarm threshold is reached. *Id.* at col. 29, lines 26-39. Additional visual alarming, such as by flashing or changing coloration, may also be combined with the described audio alarms of the '223 patent. *Id.*

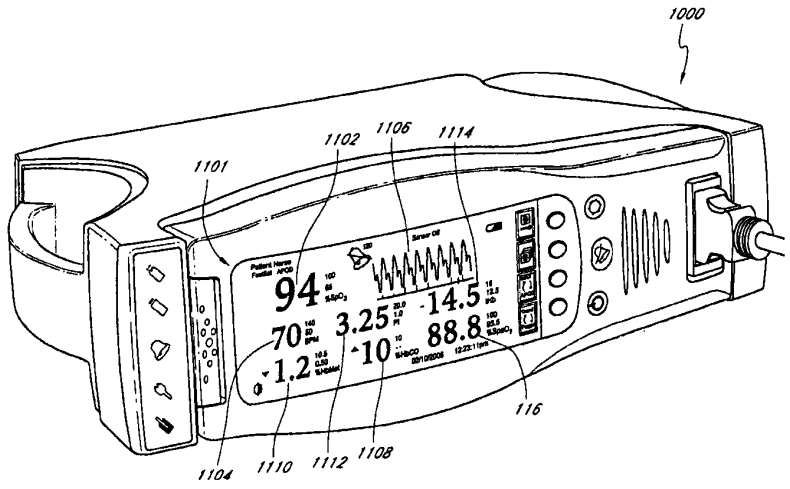


Figure 11A of the '223 patent

Figures 2 and 7 of the '223 patent illustrate a smaller, handheld patient monitor, as described and claimed.

The '223 patent includes claims 1-47, of which claims 1, 15, 18, 21, and 27 are the only independent claims. Claims 1, 15, 18, 21, and 27 are set forth below:

> **Claim 1**: A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information,

wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

Claim 15: A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

Claim 18: A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

Claim 21: A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

displaying a measured value of a first physiological parameter in a display location of an electronic display; and

replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.

Claim 27: A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

B. Prosecution History of the '223 Patent

The '223 patent was filed on March 1, 2006, as Application No. 11/367,033, claiming the benefit of Provisional Application Nos. 60/657,596, 60/657,281, 60/657,268, and 60/657,759, all filed on March 1, 2005.

The '223 patent was originally filed with claims 1-63. Ex. B, File History of the '223 Patent, March 1, 2006 application at 33-39.

On April 15, 2011, the Examiner issued a non-final Office Action rejecting claims 2, 7, 9-23, and 26-29 under 35 U.S.C. § 112, second paragraph as indefinite; rejecting claims 1-7, 9-12, 14, 24-26, 30-32, 36-43, 50, 57, 59, and 63 under 35 U.S.C. § 102(b) as anticipated by U.S. Pub. 2003/0120164 ("Nielsen"); rejecting claims 1-5 and 8 under 35 U.S.C. § 102(e) as anticipated by U.S. Pub. 2004/0262046 ("Simond"); rejecting claim 13 under 35 U.S.C. § 103(a) as obvious over Nielsen in view of U.S. Patent No. 4,014,321 ("March"); rejecting claims 15-17, 27-29, and 44-49 under 35 U.S.C. § 103(a) as obvious over Nielsen in view of U.S. Patent No. 5,842,979 ("Jarman"); rejecting claims 18-23 and 55 under 35 U.S.C. § 103(a) as obvious over Nielsen in view of U.S. Patent No. 5,575,284 ("Athan"); rejecting claims 33-34, 51-54, 56, 58, and 60-62 under 35 U.S.C. § 103(a) as obvious over Nielsen in view of U.S. Pub. 2002/0161291 ("Kianl"); and rejecting claim 35 under 35 U.S.C. § 103(a) as obvious over Nielsen in view of U.S. Patent No. 6,542,763 ("Yamashita"). *Id.* at April 15, 2011 Office Action.

On September 9, 2011, the Examiner issued an interview summary noting that Nielsen, the primary reference relied upon in the April 15, 2011 Office Action, **did not teach a "changing output based on alarm threshold or an evaluation of the relative criticality of measured parameters."** *Id.* at Examiner Interview Summary of September 9, 2011 (emphasis added).

In the Applicant's September 15, 2011 response to the non-final Office Action, claims 4-6, 8, 14, and 30-40 were canceled and claims 1-3, 7, 9-13, 15-29, and 41-43 were amended. *Id.* at Amend. of September 15, 2011. In particular, independent claims 1, 7, 10, 24, and 43 were **amended to include specific limitations directed to the missing teachings of Nielsen (*i.e.*, "changing output based on alarm threshold or an evaluation of the relative criticality of measured parameters") as identified in the Examiner interview summary** of September 9, 2011. *Id.* at Amend of September 15, 2011, at 7-11 (emphasis added). For example, claim 1 was amended to include the following:

***

> wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

***

On December 2, 2011, the Office mailed a Notice of Allowance for the '223 patent. *Id.* at Notice of Allowance of December 2, 2011. In response, the Applicant submitted a Request for Continued Examination for the limited purpose of submitting documents as part of an Information Disclosure Statement. *Id.* at Request for Continued Examination of January 24, 2012.

On February 3, 2012, the Office mailed a second Notice of Allowance. No reasons for

allowance were provided in the notice beyond those identified in the Examiner's interview summary of September 9, 2011. *Id.* at Notice of Allowance of February 3, 2012, page 2.

IV. STATEMENT POINTING OUT SUBSTANTIAL NEW QUESTIONS OF PATENTABILITY

The standard for a "substantial new question of patentability" is set forth in the *Manual of Patent Examining Procedure* (MPEP) § 2242 (8th ed., Rev. 8, July 2010) (emphasis in original):

> For "a substantial new question of patentability" to be present, it is only necessary that: (A) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim, i.e., the teaching of the (prior art) patents and printed publications is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and (B) the same question of patentability as to the claim has not been decided by the Office in a previous examination or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim.

For a substantial "new" question of patentability, "[i]t must first be demonstrated that a patent or printed publication that is relied upon in a proposed rejection presents a new, non-cumulative technological teaching that was not previously considered and discussed on the record during the prosecution of the application that resulted in the patent for which reexamination is requested, and during the prosecution of any other prior proceeding involving the patent for which reexamination is requested." MPEP § 2216.

Further, during reexamination, the claims must be interpreted as broadly as their terms reasonably allow. MPEP § 2111.01. The words of a claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *Id.* Thus, in the analysis and discussion below, the identified claims are given their broadest reasonable interpretation.

A. Office Determination of Allowable Subject Matter Indicates what Technical Features Raise a Substantial New Question of Patentability

During prosecution of the '223 patent, the Examiner indicated that the prior art of record and relied upon by the Office, specifically Nielsen (the primary reference relied upon in the April

15, 2011 Office Action), did not teach "**changing output based on alarm threshold or an evaluation of the relative criticality of measured parameters**." Ex. B, Examiner Interview Summary of Sept. 9, 2011 (emphasis added). Accordingly, prior art patents and printed publications teaching this feature present important, new, and non-cumulative technological teachings that were not considered and discussed on the record during the original prosecution of the '223 patent and raise a substantial new question of patentability. *See, e.g.*, MPEP § 2242 (stating that a "prior art patent or printed publication raises a substantial new question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether or not the claim is patentable").

B. Substantial New Questions of Patentability

1. Al-Ali Raises a Substantial New Question of Patentability for All Claims (1-47) of the '223 Patent

Al-Ali (Ex. C) was not relied upon during the original prosecution of the '223 patent, nor is it cumulative of any prior art considered by the Examiner.[1] Al-Ali discloses the very feature that the Examiner identified as missing from the prior art relied upon during prosecution of the '223 patent, namely, a pulse oximeter display monitor that adjusts the displayed output data based upon an alarm threshold or an evaluation of the relative criticality of measured input

[1] Al-Ali was disclosed to the Office in an Information Disclosure Statement ("IDS") filed September 20, 2011. Ex. B, IDS of Sept. 20, 2011, sheet 2 of 8. A continuation of Al-Ali, published as US 2004/0059209 ("the '209 publication"), was also disclosed to the Office in the same IDS. *See id.* The '209 publication was cited in a Preliminary Report on Patentability (dated September 11, 2007) against International Application No. PCT/US2006/007389, directed to a patient monitor capable of displaying a first or second measured physiological parameter, and which claims priority to the same provisional applications as the '223 patent. (Ex. I, Int'l Preliminary Report on Patentability of September 11, 2007). Although this Preliminary Report on Patentability was not disclosed to the Office, the patent holder later disclosed an International Search Report regarding PCT/US2006/007389, which also cited the '209 publication. Ex. B, International Search Report for PCT/US2006/007389.

parameters. Al-Ali was filed December 21, 2001 and published June 27, 2002, and thus, is available as prior art to all claims of the '223 patent under 35 U.S.C. § 102(b).

Al-Ali discloses a "multiple-site, multiple-parameter pulse oximeter ... [which] simultaneously measures both arterial and venous oxygen saturation at any specific site and generates a corresponding plethysmograph waveform." Ex. C at Abstract. Figure 16B, reproduced below, illustrates the details of a multi-site display as described by Al-Ali. More specifically, the screen 180 displays "a value for Sp_aO_2 1622 and Sp_vO_2 1632 for a first tissue site ... [and] a value for Sp_aO_2 1624 and Sp_vO_2 1634 for a second tissue site. In addition, a value for pulse rate 1642 derived from either the first or second tissue site, or both, is displayed." *Id.* at ¶ 0095. Further, a first and second plethysmograph, 1664 and 1666, respectively, corresponding to the first and second tissue sites is also displayed. *Id.*

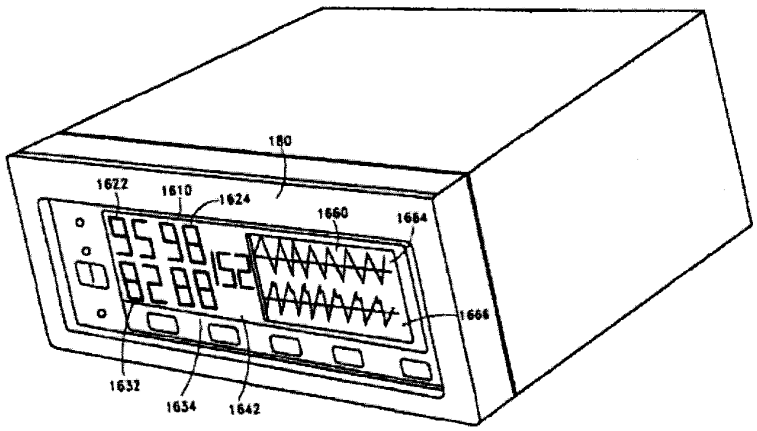


Figure 16B of Al-Ali

Although figure 16B depicts a multi-site display, displaying measured parameters from both a first and second tissue site, the screen 180 may also be arranged as a single-site display, only showing measured parameters from a particular, individual tissue site. *Id.* at ¶ 0094. In this

single-site configuration, Al-Ali states that "**a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display, enabling the user a better view of the conditions that caused the triggering event.**" *Id.* at ¶ 0095 (emphasis added). Further, Al-Ali describes that parameter measurements may be obtained from at least three different tissue sites (*see id.* at ¶ 0038), and thus, the single site display of Al-Ali may display any one of the measured parameters from a first, second, or third tissue site, for example. Accordingly, when switching from single site to multi-site mode, the display of Al-Ali is not limited to displaying only the measured parameters from the first particular tissue site shown in the single site display and the identified second tissue site, but any combination of tissue sites in accordance with a user input, or alternatively, in response to a triggering event. *Id.* at ¶ 0038, 0095.

During the original prosecution of the '223 patent, the Examiner indicated that all claims of the '223 patent were patentable because the prior art of record and relied upon by the office did not teach "changing output based on alarm threshold or an evaluation of the relative criticality of measured parameters." Ex. B, Examiner Interview Summary of Sept. 9, 2011. Al-Ali expressly discloses this feature, and thus, provides new, non-cumulative technological teachings that were not considered during the prosecution of the '223 patent.

In addition, "[t]he existence of a substantial new question of patentability is not precluded by the fact that a reference was previously cited by or to the Office or considered by the Office." 35 U.S.C. § 303(a). So-called "old art" can be the basis of a substantial new question of patentability "where the old art is being presented/viewed in a new light, or in a different way, as compared with its use in the earlier concluded examination(s), in view of a material new argument or interpretation presented in the request." MPEP § 2258.01. Although Al-Ali was

disclosed to the Office by way of an Information Disclosure Statement dated September 20, 2011, the reference was never cited by the Examiner against any claim of the '223 patent. Because Al-Ali was not substantively considered by the Office during prosecution of the '223 patent and teaches the very feature deemed missing from the prior art of record, this Request presents Al-Ali in a new light not previously considered by the Office. Thus, a reasonable examiner would consider Al-Ali important in determining the patentability of all claims (1-47) of the '223 patent, and therefore, presents a substantial new question of patentability. Moreover, Al-Ali anticipates claims 1-4, 6, 15, 18-20, 27, 36, 42, and 43 of the '223 patent, and on this basis alone, presents a separate substantial new question of patentability.

V. ADDITIONAL REFERENCES RELIED UPON IN PROPOSED REJECTIONS

The following additional references are relied upon for particular claims, as set forth in more detail below. Specifically, the combined teachings of Al-Ali, Kianl, Jarman, Healy, Nielsen, and Lepper raise at least one substantial new question of patentability as to the claims of the '223 patent.

Kianl (Ex. D) describes a pulse oximeter user interface, which has a "display and a plurality of views each configured to occupy at least a portion of the display. [Further], each of the views are adapted to present data responsive to a physiological signal." Ex. D at col. 2, lines 18-21. As shown in Figure 4, reproduced below, the user interface of Kianl displays "an oxygen saturation 412 [measured in units of percentage SpO_2], a pulse rate 414 [measured in beats per minute], a perfusion index 418 [displaying the percentage of pulsatile signal to non-pulsatile signal], and a pulse waveform 422." *Id.* at col. 5 line 66 - col. 6, line 15.

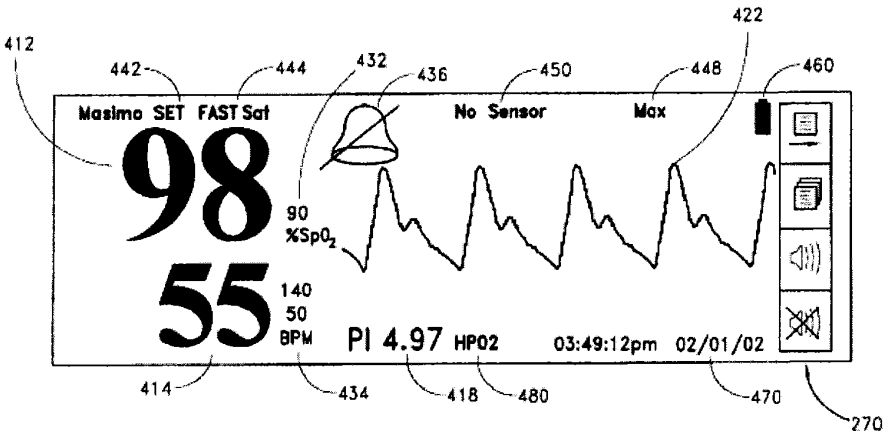


Figure 4 of Kianl

Further, the user interface of Kianl is configured to display saturation and pulse rate limits. In this manner, when a "measured value reaches or exceeds an alarm limit 432, 434 the associated number display 412, 414 and the corresponding violated limit 432, 434 **flash**." *Id.* at col. 6, lines 15-25 (emphasis added). The teachings of Kianl disclose the limitations recited in dependent claims 29, 31-35, 37, 38, and 44-47 of the '223 patent. A prior publication of Kianl (U.S. Pub. No. 2002/0161291) was cited and relied upon by the Examiner during the original prosecution of the '223 patent. Ex. B, non-final Office Action of April 15, 2011.

Jarman (Ex. E) describes a photoplethysmographic monitor for measuring blood analyte parameters, in particular, methemoglobin saturation and carboxyhemoglobin (or carbon monoxide saturation), as recited in dependent claims 8-10, 24-26, and 39-41 of the '223 patent. Ex. E at Abstract. Jarman was cited and relied upon by the Examiner during the original prosecution of the '223 patent. Ex. B, non-final Office Action of April 15, 2011.

Healy (Ex. F) describes a "hospital patient monitoring and display system ... including various patient sensors such as ECG, pulse rate, patient temperature and blood pressure." Ex. F at Abstract. The system of Healy includes controls for setting parameter threshold values, and whenever a measured parameter varies from the entered threshold value, the display of Healy

shifts "from one color display to a different one …, e.g., normal trace, green and abnormality, red." *Id.* The teachings of Healy disclose the limitations recited in dependent claims 11-14, 16, 17, and 30 of the '223 patent. Healy was not considered by the Office during prosecution of the '223 patent.

Nielsen (Ex. G) describes a patient monitoring system for measuring and displaying various physiological parameters, including "an NBP (non-invasive blood pressure)…, an ART (blood pressure from an invasive arterial blood pressure reading)…, SpO_2 …, [and] CO_2," as recited in dependent claims 5 and 23 of the '223 patent. Ex. G at ¶ 0047. Nielsen was cited and relied upon by the Examiner during the original prosecution of the '223 patent. Ex. B, non-final Office Action of April 15, 2011.

Lepper (Ex. H) describes a blood glucose monitoring system for non-invasively determining blood glucose concentration using a broadband light source and optical detector attached to a fleshy medium of a patient, as recited in dependent claim 7 of the '223 patent. Ex. H. at col. 3, lines 28-47. Lepper was cited, but not relied upon during the prosecution of the '223 patent.

Accordingly, the combined teachings of Al-Ali, Kianl, Jarman, Healy, Nielsen, and Lepper raise at least one substantial new question of patentability as to the claims of the '223 patent.

VI. DETAILED EXPLANATION OF THE PERTINENCE AND MANNER OF APPLYING THE CITED PRIOR ART TO THE TARGETED CLAIMS

Each of the permutations of rejections that the Requester desires the Office to consider are set forth directly below. Specifically:

A. Al-Ali anticipates claims 1-4, 6, 15, 18-20, 27, 36, 42, and 43 of the '223 patent under 35 U.S.C. § 102(b).

B. Al-Ali alone renders claims 21, 22, and 28 of the '223 patent unpatentable under 35 U.S.C. § 103(a).

C. Al-Ali in view of Kianl renders claims 29, 31-35, 37, 38, and 44-47 of the '223 patent unpatentable under 35 U.S.C. § 103(a).

D. Al-Ali in view of Jarman renders claims 8-10, 24-26, and 39-41 of the '223 patent unpatentable under 35 U.S.C. § 103(a).

E. Al-Ali in view of Healy renders claims 11-14, 16, 17, and 30 of the '223 patent unpatentable under 35 U.S.C. § 103(a).

F. Al-Ali in view of Nielsen renders claims 5 and 23 of the '223 patent unpatentable under 35 U.S.C. § 103(a).

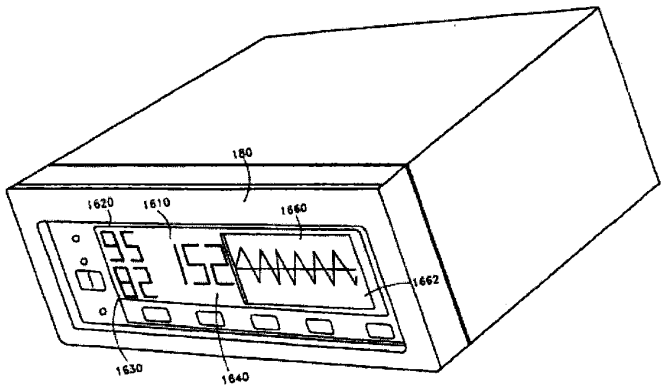
G. Al-Ali in view of Lepper renders claim 7 of the '223 patent unpatentable under 35 U.S.C. § 103(a).

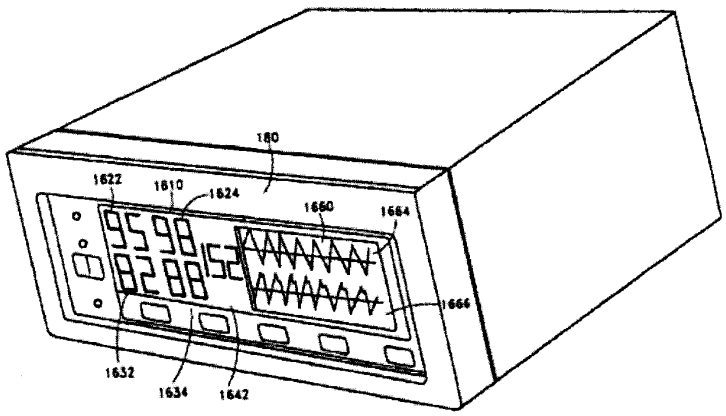
The claim charts below also demonstrate that the claims of the '223 patent are obvious combinations of old elements performing known functions. When a patent claims a combination of old elements performing their known functions, one "must ask whether the improvement is more than the predictable use of prior art elements according to their established functions." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007). "[C]ommon sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions ...." *Id.* at 1741.

Pursuant to M.P.E.P. § 2111.01, the analysis and discussion below gives the identified claims of the '223 patent their broadest reasonable interpretation.

A. Al-Ali Anticipates Claims 1-4, 6, 15, 18-20, 27, 36, 42, and 43 of the '223 Patent Under 35 U.S.C. § 102(b)

Requester respectfully submits that claims 1-4, 6, 15, 18-20, 27, 36, 42, and 43 of the '223 patent are anticipated by Al-Ali under 35 U.S.C. § 102(b). Al-Ali (Ex. C) was filed December 21, 2001 and published June 27, 2002. The earliest priority date that the claims of the '223 patent may be entitled to is March 1, 2005. Therefore, Al-Ali is available as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). The following claim chart demonstrates, on a limitation-by-limitation basis, how claims 1-4, 6, 15, 18-20, 27, 36, 42, and 43 of the '223 patent are anticipated by Al-Ali under 35 U.S.C. § 102(b).

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising	Al-Ali discloses a stereo pulse oximeter that measures and displays "multiple pulse oximetry outputs, such as, arterial oxygen saturation, Sp_a0_2, the associated plethysmograph waveform and the derived pulse rate." Ex. C at ¶ 0040. Thus, Al-Ali discloses a patient monitor capable of measuring at least two physiological parameters.
a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area	As shown in Fig. 16A, Al-Ali discloses a single tissue site display, which displays a value for Sp_a0_2 1620 (arterial oxygen saturation), Sp_v0_2 1630 (venous oxygen saturation), and pulse rate 1640 for a particular tissue site. *Id.* at ¶ 0094. When arranged in the **single tissue site display mode**, the patient monitor of Al-Ali displays a measured value of **Sp_a0_2 and Sp_v0_2 for a particular tissue site in a first display area**.  **Fig. 16A of Al-Ali**

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
	As shown in Fig. 16B, the multi-site display of Al-Ali displays a value for Sp_aO_2 1622 and Sp_vO_2 1632 for a first tissue site, and a value for Sp_aO_2 1624 and Sp_vO_2 1634 for a second tissue site. *Id.* at ¶ 0095. A pulse rate 1642, derived from either the first tissue site or the second tissue site, is also shown on the multi-site display 1610. *Id.*  **Fig. 16B of Al-Ali** In this manner, the **multi-tissue site display mode** of Al-Ali displays **Sp_aO_2 and Sp_vO_2 for a first tissue site, displays Sp_aO_2 and Sp_vO_2 for a second tissue site, and displays a pulse rate**. Moreover, in both the single site and multi-site display modes, the patient monitor of Al-Ali displays a plethysmograph waveform. Thus, Al-Ali discloses a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area.
where the first display area and the second display area comprise at least some common display area capable of displaying information,	As shown in Figs. 16A and 16B, above, the first display area (showing, *e.g.*, numerical display 1622, 1632) and the second display area (showing, *e.g.*, numerical display 1624, 1634) share a portion of the overall numerical display area 1610. Thus, the first display and second display areas of Al-Ali are part of the common display area 1610 that displays both numerical and graphical information for at least a first and second tissue site.

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event,	Fig. 16A of Al-Ali discloses a single site display, which displays measured values of Sp_aO_2 1620, Sp_vO_2 1630, and pulse rate 1640 for a particular tissue site. *Id.* at ¶ 0094. Fig. 16B of Al-Ali discloses a multi-site display, which displays a value for Sp_aO_2 1622 and Sp_vO_2 1632 for a first tissue site, and a value for Sp_aO_2 1624 and Sp_vO_2 1634 for a second tissue site. *Id.* at ¶ 0095. A pulse rate 1642, derived from either the first or second tissue site, is also shown on the multi-site display 1610. *Id.* When arranged in a multi-site display format, the patient monitor of Al-Ali displays Sp_aO_2 and Sp_vO_2 for a first tissue site, and Sp_aO_2 and Sp_vO_2 for a second tissue site. Further, **Al-Ali states that the common display area 1610 may change from the single site display to the multi-site display in response to a push button execution by the user, or another triggering event, such as an alarm**. *Id.* at ¶ 0094-95 (emphasis added). Upon switching from a single site display to a multi-site display, the common display area of Al-Ali changes from showing a first set of physiological parameters measured from a particular tissue site, to displaying a first and a second set of physiological parameters measured from first and second tissue sites. *Id.* Because Al-Ali describes that parameter measurements may be obtained from at least three different tissue sites (*see id.* at ¶ 38), the single site display of Al-Ali may display any one of the measured parameters from a first, second, or third tissue site, for example. However, in multi-site mode, the display of Al-Ali will display the measured parameters from any two tissue sites in accordance with the user input or, alternatively, in response to a triggering event. Thus, Al-Ali discloses a common display area that changes from displaying one of the measured values of the first or second physiological parameter (*i.e.*, **only displaying Sp_aO_2 and Sp_vO_2 from a particular tissue site**) to displaying the other of the measured values based on an occurrence of an event (*i.e.*, **displaying Sp_aO_2 and Sp_vO_2 from a first tissue site and a second tissue site**).

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.	As discussed *supra*, the common display area of Al-Ali switches from showing a first set of physiological parameters measured from a particular tissue site, to displaying a first and a second set of physiological parameters in response to a triggering event. Specifically, Al-Ali states that "**a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display**, enabling the user better view the conditions that caused the triggering event." *Id.* at ¶ 0095 (emphasis added). By way of example, Al-Ali teaches that stereo pulse oximetry can be used to monitor for Persistent Pulmonary Hypertension in Neonates, Patent Ductus Arteriosus, and Aortic Coarctation by monitoring and comparing blood saturation levels, associated plethysmograph waveforms and pulse rates from multiple tissue sites on a patient's body. *Id.* at ¶¶ 0111-0124. An alarming event based on multiple-site oxygen status parameters is indicative of the occurrence/exacerbation of the aforementioned conditions and, therefore, indicates a worsening state of the patent (*i.e.*, "enabling the user [to] better view the conditions that caused the triggering event"). *Id.* at ¶ 0095. Thus, Al-Ali discloses that the triggering event may occur when one of the first or second physiological parameters approaches one or more threshold values indicative of a worsening state of a patient. **Accordingly, claim 1 of the '223 patent is anticipated by Al-Ali under § 102(b).**
2. The patient monitor of claim 1, wherein the first display area and the second display area comprise the common display area.	See claim 1. As discussed with respect to claim 1, *supra*, and as shown in Fig. 16B, the first display area of the multi-site display (showing, *e.g.*, numerical display 1622, 1632) and the second display area of the multi-site display (showing, *e.g.*, numerical display 1624, 1634) comprise a common numerical display area (1610) of the patient monitor disclosed in Al-Ali. Thus, the first display area and the second display area of Al-Ali comprise the common display area as claimed. **Accordingly, claim 2 of the '223 patent is anticipated by Al-Ali**

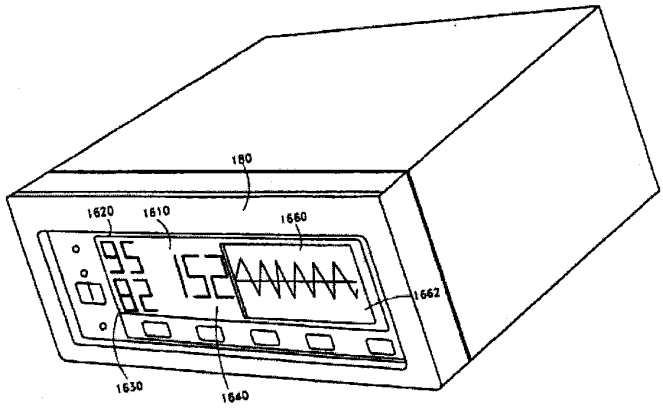
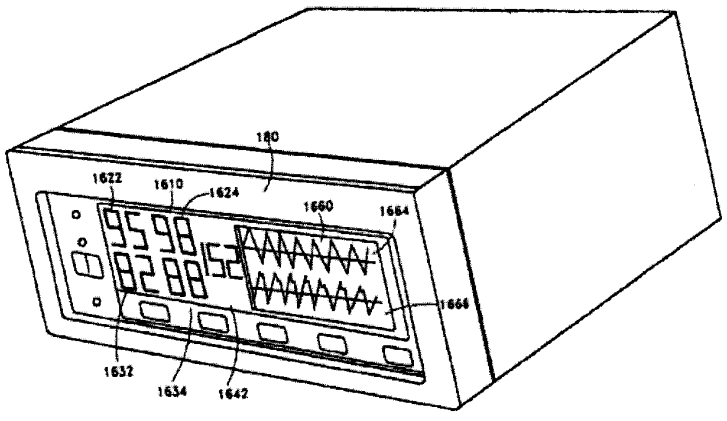
'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
	under § 102(b).
3. The patient monitor of claim 1, wherein activation of a user input causes the common display area to change from displaying one of the measured value of the first or second physiological parameter to displaying the other of the measured value of the first or second physiological parameter.	See claim 1. As discussed with respect to claim 1, *supra,* and as shown in Fig. 16B, the common numerical display area of Al-Ali 1610 may change from the single site display to the multi-site display in response to a push button execution by the user, or another triggering event, such as an alarm. Ex. C at ¶ 0094-95 ("A push button, menu selection allows the user to manually switch between the single site display (FIG. 16A) and the multi-site display (FIG. 16B)."). Thus, Al-Ali discloses a patient monitor wherein activation of a user input (push button execution) causes the common display area to change from displaying one of the measured value of the first or second physiological parameter (*i.e.*, only displaying Sp_aO_2 and Sp_vO_2 from a particular tissue site) to displaying the other of the measured value of the first or second physiological parameter (*i.e.*, displaying Sp_aO_2 and Sp_vO_2 from, for example, the particular tissue site and a second tissue site). **Accordingly, claim 3 of the '223 patent is anticipated by Al-Ali under § 102(b).**
4. The patient monitor of claim 1, wherein the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.	See claim 1. Al-Ali teaches that in normal operation, the user of the disclosed patient monitor may manually switch between a single site display (Fig. 16A) and a multi-site display (Fig. 16B). Ex. C at ¶ 0094. Thus, by default, the patient monitor of Al-Ali is configured in single site mode and displays one of the measured values of the first or second physiological parameters (*i.e.*, displaying Sp_aO_2 and Sp_vO_2 from a particular tissue site). **Accordingly, claim 4 of the '223 patent is anticipated by Al-Ali under § 102(b).**

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
6. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises a non-invasively measured value.	See claim 1. Al-Ali discloses a stereo pulse oximeter patient monitor including "**sensor 110**, [which] is used to **measure the intensity of red and infrared light after transmission through a portion of the body** where blood flows close to the surface, such as a fingertip 202," in order to obtain oxygen saturation values, photoplethysmograph measurements, and pulse rate. Ex. C at ¶ 0038; 0042 (emphasis added). Thus, Al-Ali teaches that the measured value of the first physiological parameter may comprise a non-invasively measured value. **Accordingly, claim 6 of the '223 patent is anticipated by Al-Ali under § 102(b).**
15. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising	See claim 1, preamble, *supra*, stating that Al-Ali discloses a stereo pulse oximeter that measures and displays "multiple pulse oximetry outputs, such as, arterial oxygen saturation, $Spa0_2$, the associated plethysmograph waveform and the derived pulse rate." Ex. C at ¶ 0040.
a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area	See claim 1, first clause, *supra*. In particular, and as shown in Fig. 16A, when arranged in the single tissue site display mode, the patient monitor of Al-Ali displays a measured value of $Spa0_2$ and $Spv0_2$ for a particular tissue site in a first display area. *Id.* at ¶ 0094. As shown in Fig. 16B, the multi-site display of Al-Ali displays a value for $Spa0_2$ and $Spv0_2$ for the particular tissue site and a value for $Spa0_2$ and $Spv0_2$ for a second tissue site. *Id.* at ¶ 0095. A pulse rate, derived from either the particular tissue site or the second tissue site, is also shown on the multi-site display 1610. *Id.*
where the first display area and the second display area comprise at least some common display area capable of displaying information,	See claim 1, second clause, *supra*. In particular, and as shown in Fig. 16B, the first display area (showing, *e.g.*, numerical display 1622, 1632) and the second display area (showing, *e.g.*, numerical display 1624, 1634) share a portion of the overall numerical display area 1610.
wherein the common display area changes from displaying one of the measured values of the first or second physiological	See claim 1, third clause, *supra*. In particular, Al-Ali states that the common display area 1610 may change from the single site display to the multi-site display in response to a push button execution by the user, or another

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
parameters to displaying the other of the measured values of the first or second physiological parameters based on an occurrence of an event,	triggering event, such as an alarm. *Id.* at ¶ 0094-95. Upon switching from a single site display to a multi-site display, the common display area of Al-Ali changes from showing a first set of physiological parameters measured from a particular tissue site, to displaying a first and a second set of physiological parameters measured, for example, from the particular tissue site of the single site display and a second tissue site. *Id.*
the event being one of the measured values of the first or second physiological parameters alarming.	As discussed with respect to claim 1, *supra*, the common display area of Al-Ali switches from showing only a first set of physiological parameters (Sp_aO_2 and Sp_vO_2) measured from a particular tissue site, to displaying a first and a second set of physiological parameters (Sp_aO_2 and Sp_vO_2) measured, for example, from the particular tissue site and a second tissue site in response to a triggering event. Specifically, Al-Ali states that "**a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display**, enabling the user better view the conditions that caused the triggering event." *Id.* at ¶ 0095 (emphasis added). Thus, Al-Ali discloses a patient monitor display that changes from displaying a first or second measured parameter to the other measured parameter when the measured value of one of the first or second physiological parameters alarms. **Accordingly, claim 15 of the '223 patent is anticipated by Al-Ali under § 102(b).**
18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising	See claim 1, preamble, *supra*, stating that Al-Ali discloses a stereo pulse oximeter that measures and displays "multiple pulse oximetry outputs, such as, arterial oxygen saturation, Sp_aO_2, the associated plethysmograph waveform and the derived pulse rate." Ex. C at ¶ 0040.
a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area	See claim 1, first clause *supra*. In particular, and as shown in Fig. 16, when arranged in the single tissue site display mode, the patient monitor of Al-Ali displays a measured value of Sp_aO_2 and Sp_vO_2 for a particular tissue site in a first display area. *Id.* at ¶ 0094. As shown in Fig. 16B, the multi-site display of Al-Ali displays a value for Sp_aO_2 and Sp_vO_2 for the particular tissue site and a value for Sp_aO_2 and Sp_vO_2 for a second tissue site. *Id.* at ¶ 0095. A pulse rate, derived from either the particular tissue site or the second tissue site is also shown on the multi-site display 1610. *Id.*

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
where the first display area and the second display area comprise at least some common display area capable of displaying information,	See claim 1, second clause, *supra*. In particular, and as shown in Fig. 16B, the first display area (showing, *e.g.*, numerical display 1622, 1632) and the second display area (showing, *e.g.*, numerical display 1624, 1634) share a portion of the overall numerical display area 1610.
wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.	As discussed with respect to claim 1, *supra*, the common display area of Al-Ali switches from showing only a first set of physiological parameters (Sp_aO_2 and Sp_vO_2) measured from a particular tissue site, to also displaying a first and a second set of physiological parameters (Sp_aO_2 and Sp_vO_2) measured, for example, from the particular tissue site and a second tissue site in response to a triggering event. Specifically, Al-Ali states that "a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display, enabling the user better view the conditions that caused the triggering event." *Id.* at ¶ 0095. By way of example, Al-Ali teaches that stereo pulse oximetry can be used to monitor for Persistent Pulmonary Hypertension in Neonates, Patent Ductus Arteriosus, and Aortic Coarctation by monitoring and comparing blood saturation levels, associated plethysmograph waveforms and pulse rates from multiple tissue sites on a patient's body. *Id.* at ¶¶ 0111-0124. An alarming event triggered by a measured value at one of the monitored tissue sites causes the single site display of Al-Ali to change to the multi-site display, and thereby indicates to the user which of the particular tissue site or the second tissue site measured values is more critical (*i.e.*, "enabling the user [to] better view the conditions that caused the triggering event"). *Id.* at ¶ 0095. Thus, Al-Ali discloses a patient monitor display that changes from displaying a first or second measured parameter to the other measured parameter based on which is a more critical one of the measured values of the first or second physiological parameters. **Accordingly, claim 18 of the '223 patent is anticipated by Al-Ali under § 102(b).**

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
19. The patient monitor of claim 18, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.	See claim 18. Al-Ali discloses a stereo pulse oximeter patient monitor including "**sensor 110**, [which] is used to **measure the intensity of red and infrared light after transmission through a portion of the body** where blood flows close to the surface, such as a fingertip 202," in order to obtain oxygen saturation values, photoplethysmograph measurements, and pulse rate." Ex. C at ¶ 0038; 0042 (emphasis added). Thus, Al-Ali teaches that the measured value of the first and second physiological parameter are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue. **Accordingly, claim 19 of the '223 patent is anticipated by Al-Ali under § 102(b).**
20. The patient monitor of claim 18, wherein at least one of measured physiological parameters is determined noninvasively.	See claim 18. See also claims 6 and 19, *supra*, indicating that the stereo pulse oximeter of Al-Ali non-invasively measures oxygen saturation values, photoplethysmograph measurements, and pulse rate using optical absorption and attenuation principles. **Accordingly, claim 20 of the '223 patent is anticipated by Al-Ali under § 102(b).**
27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:	Al-Ali discloses a stereo pulse oximeter patient monitor including "**sensor 110**, [which] is used to **measure the intensity of red and infrared light after transmission through a portion of the body** where blood flows close to the surface, such as a fingertip 202," in order to obtain oxygen saturation values, photoplethysmograph measurements, and pulse rate. Ex. C at ¶ 0038; 0042 (emphasis added). Thus, Al-Ali discloses a patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue.
a display capable of displaying a measured value of a first blood parameter of body tissue of	As shown in Fig. 16A, Al-Ali discloses a single tissue site display, which displays a value for Sp_aO_2 1620 (arterial oxygen saturation), Sp_vO_2 1630 (venous oxygen saturation), and pulse rate 1640 for a particular tissue site. *Id.* at ¶ 0094. When arranged in the **single-**

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and	**tissue site display mode**, the patient monitor of Al-Ali displays a measured value of **Sp_aO_2 and Sp_vO_2 for a particular tissue site in a first display area**.  **Fig. 16A of Al-Ali** As shown in Fig. 16B, the multi-site display of Al-Ali displays a value for Sp_aO_2 1622 and Sp_vO_2 1632 for a first tissue site, and a value for Sp_aO_2 1624 and Sp_vO_2 1634 for a second tissue site. *Id.* at ¶ 0095. A pulse rate 1642, derived from either the first tissue site or the second tissue site, is also shown on the multi-site display 1610. *Id.*  **Fig. 16B of Al-Ali** In this manner, when arranged in the **multi-tissue site display mode**, the patient monitor of Al-Ali displays **Sp_aO_2 and Sp_vO_2 for**

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
	a first tissue site, displays Sp_aO_2 and Sp_vO_2 for a second tissue site, and displays a pulse rate. Moreover, in both the single site and multi-site display modes, the patient monitor of Al-Ali displays a plethysmograph waveform. Thus, Al-Ali discloses a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue.
a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter,	As discussed, *supra,* and as shown in Fig. 16B, the common numerical display area of Al-Ali 1610 may change from the single site display to the multi-site display in response to a push button execution by the user, or another triggering event, such as an alarm. *Id.* at ¶ 0094-95. Upon switching from a single site display to a multi-site display, the common display area of Al-Ali changes from showing a first set of physiological parameters measured at a particular tissue site, to displaying a first and a second set of physiological parameters measured from first and second tissue sites. *Id.* Because Al-Ali describes that parameter measurements may be obtained from at least three different tissue sites (*See id.* at ¶ 38), the single site display of Al-Ali may display any one of the measured parameters from a first, second, or third tissue site, for example. However, in multi-site mode, the display of Al-Ali will display the measured parameters from any two tissue sites in accordance with the user input or, alternatively, in response to a triggering event. Thus, Al-Ali discloses a patient monitor wherein activation of a **user input (push button execution)** causes the common display area to change from displaying the measured value of the **first blood parameter (Sp_aO_2 and Sp_vO_2 from a particular tissue site)** to displaying the measured value of the **second blood parameter (Sp_aO_2 and Sp_vO_2 from a second tissue site)**.
wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,	As discussed, *supra*, the common display area of Al-Ali switches from showing a first set of physiological parameters (Sp_aO_2 and Sp_vO_2) measured from a particular tissue site, to displaying a first and a second set of physiological parameters (Sp_aO_2 and Sp_vO_2) measured, for example, from the particular tissue site and a second tissue site in response to a triggering event. Specifically, Al-Ali states that "**a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display**, enabling the user better view the conditions that caused the triggering event." *Id.* at ¶ 0095 (emphasis added).

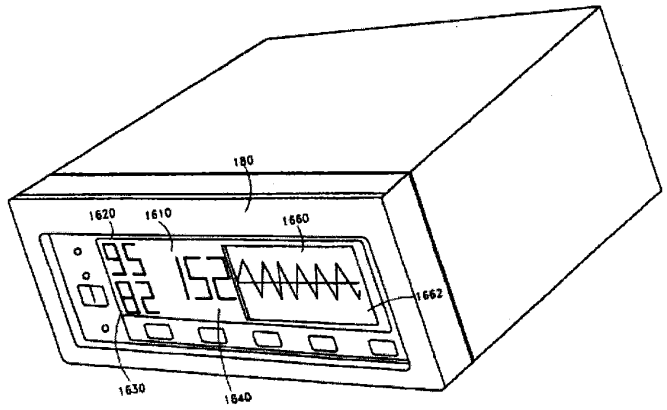
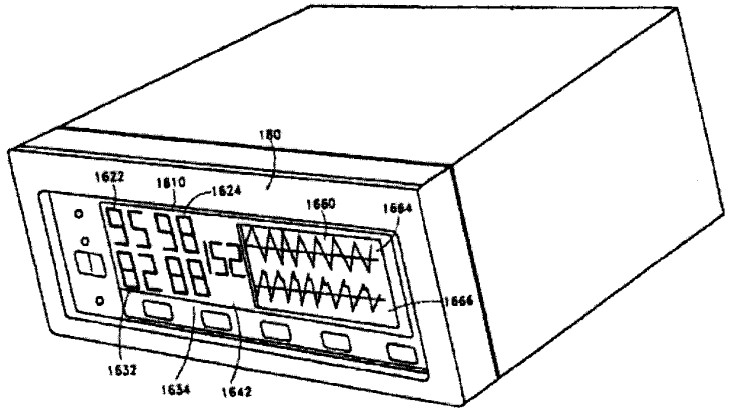
'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
	Thus, Al-Ali discloses a patient monitor wherein the change from displaying the measured value of the first blood parameter (*i.e.*, displaying Sp_aO_2 and Sp_vO_2 from a particular tissue site) to displaying the measured value of the second blood parameter (*i.e.*, displaying Sp_aO_2 and Sp_vO_2 from a second tissue site) is controlled by an alarm threshold.
wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.	See preamble, *supra*. **Accordingly, claim 27 of the '223 patent is anticipated by Al-Ali under § 102(b).**
36. The patient monitor of claim 27, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.	See claim 27. As discussed with respect to claim 27, *supra*, in response to a triggering event, the common display area of Al-Ali switches from showing a first set of physiological parameters measured from a particular tissue site, to displaying a first and a second set of physiological parameters measured, for example, from the particular tissue site and a second tissue site. Specifically, Al-Ali states that "a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display, enabling the user better view the conditions that caused the triggering event." Ex. C at ¶ 0095. By way of example, Al-Ali teaches that stereo pulse oximetry can be used to monitor for Persistent Pulmonary Hypertension in Neonates, Patent Ductus Arteriosus, and Aortic Coarctation by monitoring and comparing blood saturation levels, associated plethysmograph waveforms and pulse rates from multiple tissue sites on a patient's body. *Id.* at ¶¶ 0111-0124. An alarming event based on multiple-site oxygen status parameters is indicative of the occurrence/exacerbation of the aforementioned conditions and, therefore, indicates that one of the measured blood parameters has fallen below a predetermined threshold (*i.e.*, "enabling the user [to] better view the conditions that caused the triggering event." *Id.* at ¶ 0095).

'223 Patent Claims	Al-Ali (Ex. C) under 35 U.S.C. § 102(b)
	Thus, Al-Ali discloses a patent monitor comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values. **Accordingly, claim 36 of the '223 patent is anticipated by Al-Ali under § 102(b).**
42. The patient monitor of claim 27, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate.	See claim 27. As shown in Fig. 16A, Al-Ali discloses a single tissue site display, which displays a value for Sp_aO_2 1620 (arterial oxygen saturation), Sp_vO_2 1630 (venous oxygen saturation), and pulse rate 1640 for a particular tissue site. Ex. C at ¶ 0094. When arranged in the single-tissue site display mode, the patient monitor of Al-Ali displays a measured value of Sp_aO_2 and Sp_vO_2 for a particular tissue site in a first display area, and a pulse rate in a second display area. Thus, Al-Ali disclose a patient monitor wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate. **Accordingly, claim 42 of the '223 patent is anticipated by Al-Ali under § 102(b).**
43. The patient monitor of claim 42, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.	See claim 42. As described with respect to claim 42, and as shown in Fig. 16A, the pulse oximeter of Al-Ali displays a measured value of Sp_aO_2 1620 and Sp_vO_2 1630 in a first numerical display area, and a measured value of pulse rate 1640 in a second numerical display area. Thus, Al-Ali teaches the claimed patient monitor, wherein the second display area displays a pulse rate when the first display area displays the measured value of the first blood parameter, such as oxygen saturation (SpO_2). **Accordingly, claim 43 of the '223 patent is anticipated by Al-Ali under § 102(b).**

B. Al-Ali Renders Claims 21, 22, and 28 of the '223 Patent Unpatentable Under 35 U.S.C. § 103(a)

Requester respectfully submits that claims 21, 22, and 28 of the '223 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Al-Ali. Al-Ali (Ex. C) was filed December 21, 2001 and published June 27, 2002; the earliest priority date that the claims of the '223 patent may be entitled to is March 1, 2005. Therefore, Al-Ali is available as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). The following claim chart demonstrates, on a limitation-by-limitation basis, how claims 21, 22, and 23 of the '223 patent are rendered obvious by Al-Ali under 35 U.S.C. § 103(a).

'223 Patent Claims	Al-Ali Alone Under § 103(a)
21. A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:	Al-Ali discloses a stereo pulse oximeter that measures and displays "multiple pulse oximetry outputs, such as arterial oxygen saturation, Sp_aO_2, the associated plethysmograph waveform, and the derived pulse rate." Ex. C at ¶ 0040. Further, and as shown in Fig. 16A, which illustrates the details of a single tissue site display, "[t]he numerical display portion 1610 displays a value for Sp_aO_2 1620, Sp_vO_2 1630 and pulse rate 1640 for a particular tissue site." *Id.* at ¶ 0094. Thus, Al-Ali discloses a method of displaying two physiological parameter measurements (Sp_aO_2, Sp_vO_2, and/or pulse rate) using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement.
displaying a measured value of a first physiological parameter in a display location of an electronic display; and	As shown in Fig. 16A, Al-Ali discloses a single tissue site display, which displays a value for Sp_aO_2 1620 (arterial oxygen saturation), Sp_vO_2 1630 (venous oxygen saturation), and pulse rate 1640 for a particular tissue site. *Id.* at ¶ 0094. When arranged in the **single tissue site display mode**, the patient monitor of Al-Ali displays a measured value of **Sp_aO_2 and Sp_vO_2 for the particular tissue site in a first display area**.

'223 Patent Claims	Al-Ali Alone Under § 103(a)
	 **Fig. 16A of Al-Ali** Thus, Al-Ali discloses displaying a measured value of a first physiological parameter ($Spa0_2$ and $Spv0_2$ for the particular tissue site) in a display location of an electronic display.
replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.	As shown in Fig. 16B, the multi-site display of Al-Ali displays a value for $Spa0_2$ 1622 and $Spv0_2$ 1632 for a particular tissue site, and a value for $Spa0_2$ 1624 and $Spv0_2$ 1634 for a second tissue site. *Id.* at ¶ 0095. A pulse rate 1642, derived from either the particular tissue site or the second tissue site, is also shown on the multi-site display 1610. *Id.*  **Fig. 16B of Al-Ali** In this manner, when arranged in **multi-tissue site display mode**, the patient monitor of Al-Ali displays **$Spa0_2$ and $Spv0_2$ for a first tissue site, displays $Spa0_2$ and $Spv0_2$ for a second tissue site, and displays a**

'223 Patent Claims	Al-Ali Alone Under § 103(a)
	pulse rate. Further, Al-Ali states that the common display area 1610 may change from the single site display to the multi-site display in response to a push button execution by the user, or another triggering event, such as an alarm. *Id.* at ¶ 0094-95. Upon switching from the single site display to the multi-site display, the common display area of Al-Ali changes from showing a first set of physiological parameters (Sp_a0_2 and Sp_v0_2) measured from a particular tissue site, to displaying a first and a second set of physiological parameters (Sp_a0_2 and Sp_v0_2) measured from first and second tissue sites. *Id.* Because Al-Ali describes that parameter measurements may be obtained from at least three different tissue sites (*see id.* at ¶ 38), the single site display of Al-Ali may display any one of the measured parameters from a first, second, or third tissue site, for example. However, in multi-site mode, the display of Al-Ali will display the measured parameters from any two tissue sites in accordance with the user input or, alternatively, in response to a triggering event. More specifically, Al-Ali states that "**a triggering event, such as an alarm based on multiple-site oxygen status parameters, causes the display to automatically switch from the single-site display to the multi-site display,** enabling the user better view the conditions that caused the triggering event." *Id.* at ¶ 0095 (emphasis added). By way of example, Al-Ali teaches that stereo pulse oximetry can be used to monitor for Persistent Pulmonary Hypertension in Neonates, Patent Ductus Arteriosus, and Aortic Coarctation by monitoring and comparing blood saturation levels, associated plethysmograph waveforms and pulse rates from multiple tissue sites on a patient's body. *Id.* at ¶¶ 0111-0124. An alarming event based on multiple-site oxygen status parameters is indicative of the occurrence/exacerbation of the aforementioned conditions and, therefore, indicates a worsening state of the patent (*i.e.*, "enabling the user [to] better view the conditions that caused the triggering event"). *Id.* at ¶ 0095. Thus, when a change in the measurement of one of the monitored physiological parameters indicates a worsening state of the patient, Al-Ali teaches that the common numerical display area may change from the single tissue site display to the multi-tissue site display, enabling the user to better view the condition that caused the triggering event. Although Al-Ali does not disclose replacing the measured value shown in the single site display with the measured value of the second physiological parameter shown in the multi-site display, this is nothing

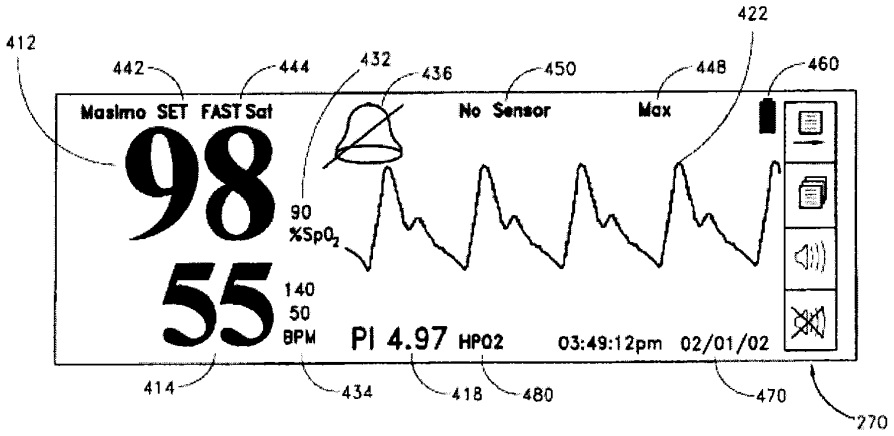
'223 Patent Claims	Al-Ali Alone Under § 103(a)
	more than a trivial and obvious substitution of design elements (**replacing the display of one measured parameter for another, rather than updating the display to include both the first and second measured parameter**) to achieve the same, predictable, result (enabling the user to better view the conditions that caused the triggering event). *See In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). *See also In re Dailey*, 357 F.2d 669, 672-73 (CCPA 1966) (holding that a particular shape of a container was merely a design choice absent persuasive evidence that the particular configuration of the claimed container was significant). **Accordingly, claim 21 of the '223 patent is unpatentable under § 103(a) in view of Al-Ali.**
22. The method of claim 21, wherein the indication of the worsening state comprises an alarm condition.	See claim 21. As discussed with respect to claim 21, *supra*, in response to a triggering event, the common display area of Al-Ali switches from showing a first set of physiological parameters measured from a particular tissue site, to displaying a first and a second set of physiological parameters measured from, for example, the particular tissue site and a second tissue. Specifically, Al-Ali states that "**a triggering event, such as an alarm based on multiple-site oxygen status parameters**, causes the display to automatically switch from the single-site display to the multi-site display, enabling the user better view the conditions that caused the triggering event." Ex. C at ¶ 0095 (emphasis added). Thus, Al-Ali discloses a patient monitor display that changes from displaying a first or second measured parameter to the other measured parameter, wherein the indication of the worsening state comprises an alarm condition. **Accordingly, claim 22 of the '223 patent is unpatentable under § 103(a) in view of Al-Ali.**
28. The patient monitor of claim 27, wherein the display	See claim 27, *supra*. As discussed with respect to claim 27, and as shown in Fig. 16B, the

'223 Patent Claims	Al-Ali Alone Under § 103(a)
shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.	common numerical display area of Al-Ali 1610 may change from the single site display to the multi-site display in response to a push button execution by the user, or another triggering event, such as an alarm. *Id.* at ¶ 0094-95. Upon switching from a single site display to a multi-site display, the common display area of Al-Ali changes from showing a first set of physiological parameters measured at a particular tissue site, to displaying a first and a second set of physiological parameters measured, for example, from the particular tissue site and a second tissue site. *Id.* Moreover, the plethysmograph waveform 1662 and pulse rate 1640 shown in Fig. 16A shift up and to the right, respectively, when the device of Al-Ali switches from single site display mode to multi-site display mode. *Compare* Fig. 16A, features 1662 and 1640 *with* Fig. 16B, features 1664 and 1642. Although Al-Ali does not explicitly disclose shifting the measured values of Sp_aO_2 and Sp_vO_2 from a first tissue site with respect to the measured values from a second tissue site, Al-Ali's disclosure regarding pulse rate and plethysmograph shift, as discussed above, shows that this feature is nothing more than a trivial and obvious substitution of design elements (shifting the display of one measured parameter relative to another, rather than changing the display to include both the first and second measured parameter) to achieve the same, predictable, result (enabling the user to better view the conditions that caused the triggering event). *See In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). *See also In re Dailey*, 357 F.2d 669, 672-73 (CCPA 1966) (holding that a particular shape of a container was merely a design choice absent persuasive evidence that the particular configuration of the claimed container was significant). **Accordingly, claim 28 of the '223 patent is unpatentable under § 103(a) in view of Al-Ali.**

C. Al-Ali in View of Kianl Renders Claims 29, 31-35, 37, 38, and 44-47 of the '223 Patent Unpatentable Under 35 U.S.C. § 103(a).

Requester respectfully submits that claims 29, 31-35, 37, 38, and 44-47 of the '223 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Al-Ali in view of Kianl. Al-Ali (Ex.

C) was filed December 21, 2001 and published June 27, 2002; and Kianl (Ex. D) issued December 2, 2003. The earliest priority date that the claims of the '223 patent may be entitled to is March 1, 2005. Therefore, Al-Ali is available as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b), and Kianl qualifies as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). The following claim chart demonstrates, on a limitation-by-limitation basis, how claims 29, 31-35, 37, 38, and 44-47 of the '223 patent are rendered obvious by Al-Ali in view of Kianl under 35 U.S.C. § 103(a).

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
29. The patient monitor of claim 27, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.	As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Kianl (Ex. D) describes a pulse oximeter user interface, which has a "display and a plurality of views each configured to occupy at least a portion of the display. [Further], each of the views are adapted to present data responsive to a physiological signal." Ex. D at col. 2, lines 18-21. As shown in Figure 4, reproduced below, the user interface of Kianl displays "an oxygen saturation 412 [measured in units of percentage SpO_2], a pulse rate 414 [measured in beats per minute], a perfusion index 418 [displaying the percentage of pulsatile signal to non-pulsatile signal], and a pulse waveform 422." *Id.* at col. 5 line 66 - col. 6, line 15.  **Fig. 4 of Kianl** Kianl also discloses that "[i]f the user scrolls through the data set to display previously recorded trend data or if the trend scale is greater than 2 hours, **the**

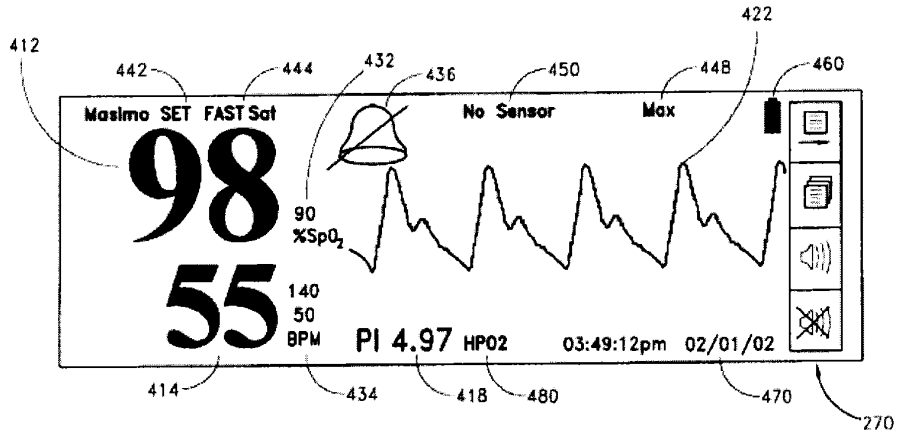
'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
	trend view will time out after 1 minute of inactivity (*i.e.* the user does not press any of the soft key buttons) **and the previous display view will be shown.**" *Id.* at col. 11, lines 54-58 (emphasis added). It would have been obvious to one of skill in the art at the time of the '223 patent filing combine the teachings of Al-Ali and Kianl to arrive at the claim so as to have the display of Al-Ali change back to showing the previously displayed parameter after a predetermined duration, which will allow the user to monitor the initially displayed parameter shown on the display without having to manually press the user input button. Thus, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed change in the display for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter. **Accordingly, claim 29 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**
31. The patient monitor of claim 27, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.	See claim 27, *supra.* As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, senses, measures, and displays blood oxygen saturation and blood oxygen saturation limits. Additionally, Kianl discloses with respect to Fig. 4, that "the pleth view 400 has system messages generated by the instrument that are displayed in a system message area 450. Each message and its meaning are described immediately below. An 'AMBIENT LIGHT' message indicates that too much light is on the patient (sensor). A 'DEFECTIVE SENSOR' message indicates that the oximeter cannot identify the connected sensor or the sensor has failed, which, for example, may be caused by a broken sensor cable wire, inoperative LEDs, an unauthorized sensor, or a faulty detector." *Id.* at col. 7 lines 1-10. Further, Kianl discloses that "A 'NO SENSOR' message indicates that a sensor is not fully inserted into the connector, which may be due to an incorrect sensor, or a defective sensor or cable, or that the sensor is inserted upside down." *Id.* at col. 7 lines 22-26. Thus, Kianl discloses an indicator that indicates whether the sensor is providing sufficient data. It would have been obvious to combine the teachings of Al-Ali and Kianl to arrive at the claim limitation to provide a

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
	visual indication on the display for the user to alert the user to a potential problem with a sensor and thus, a potential problem with the patient data being provided. As such, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter. **Accordingly, claim 31 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**
32. The patient monitor of claim 27, wherein the attached sensor can provide data through the output signal and through a memory device.	See claim 27, *supra*. As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures, and displays blood oxygen saturation and blood oxygen saturation limits. It is well known that a sensor will provide its sensed data through an output signal. Further, Kianl discloses that "once the trend display icon 864 (FIG. 8B) is selected, the trend data is shown on the trend view 1000. The instrument stores one data set of oxygen saturation, pulse rate and system messages in a dedicated memory area. Depending on 35 the trend period, a setting for how often the data is stored in the **trend memory**, the instrument can store between 72 hours and 30 days worth of trend data." *Id.* at col. 11 lines 32-38 (emphasis added). It would have been obvious to a skilled artisan at the '223 patent filing date to combine the teachings of Al-Ali and Kianl to arrive at the claim to provide a memory device to store the data provided by the sensor in order to allow the user to access previously detected data for future use. As such, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed memory device for the sensed data. **Accordingly, claim 32 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
33. The patient monitor of claim 27, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.	See claim 27, *supra*. As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation and blood oxygen saturation limits. Kianl discloses the display of the status of the sensor along with other blood parameters. *Id.* at col. 7 line 1 to col. 8, line 16. For example, as best shown in Fig. 4, **a "No Sensor" display 450 will be displayed** when there is a potential problem with the sensor**, along with a display of, for example, the oxygen saturation 412, pulse rate 414, perfusion index 418, and pulse waveform 422.** It would have been obvious to combine the teachings of Al-Ali and Kianl to arrive at the claim to continue to provide a display of the first blood parameter even with a sensor problem so the user can continue to monitor the first blood parameter. As such, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed displaying the first blood parameter when the attached sensor cannot provide the sufficient data. **Accordingly, claim 33 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**
34. The patient monitor of claim 27, further comprising a memory for storing trend data on one or more of the first and second blood parameters.	See claim 27, *supra*. As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation and blood oxygen saturation limits. Further, Kianl discloses that "once the trend display icon 864 (FIG. 8B) is selected, the **trend data** is shown on the **trend view** 1000. The instrument stores one data set of oxygen saturation, pulse rate and system messages in a dedicated **memory area**. Depending on 35 the trend period, a setting for how often the data is stored in the **trend memory**, the instrument can store between 72 hours and 30 days worth of trend data." *Id.* at col. 11 lines 32-38 (emphasis added).

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
	It would have been obvious to combine the teachings of Al-Ali and Kianl to arrive at the claim to provide a memory device to store the trend data provided by the sensor in order to allow the user to access previously detected data for future use. As such, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed memory for storing the trend data. **Accordingly, claim 34 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**
35. The patient monitor of claim 27, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.	See claim 27, *supra.* As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation and blood oxygen saturation limits. Kianl further discloses with respect to Figs. 5A-B, "a pleth and **signal quality view** 500, in horizontal and vertical format, respectively, having the features of the pleth only view 400 (FIG. 4) in addition to **a signal quality waveform 510**. The signal quality waveform 510 provides a visual indicator of the plethysmogram signal quality. In particular, the signal quality waveform 510 displays the acquired signal quality and the timing of a patient's pulse by a series of vertical lines 512." *Id.* at col. 7 lines 40-63 (emphasis added). It would have been obvious to one of skill in the art t combine the teachings of Al-Ali and Kianl to arrive at the claim to provide an indication to the user of the signal quality so the user can diagnose a potential problem with the sensor or the attachment of the sensor to the patient as well as the reliability of the sensed and displayed data. As such, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters. **Accordingly, claim 35 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
37. The patient monitor of claim 36, wherein the alarm comprises at least one of an audio or visual alarm.	See claim 36, *supra.* As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation and blood oxygen saturation limits. Kianl discloses with respect to Figs. 11A-B, an alarms menu 1100 in horizontal and vertical formats, respectively, having a high Sp02 alarm limit 1110, a low Sp02 alarm limit 1120, a high pulse rate alarm limit 1130, and a low pulse rate alarm limit 1140. Alarm limit settings are typically checked each time the pulse oximeter is used to ensure that they are appropriate for the patient being monitored. An **audible alarm** and a **flashing alarm status indicator** 432 (FIG. 4) will occur when an alarm limit is met or exceeded." *Id.* at col. 12 lines 27-35 (emphasis added). It would have been obvious to one of skill in the art at the time of the '223 patent filing combine the teachings of Al-Ali and Kianl to arrive at the claim to provide at least one of an audio or visual alarm in order to provide an additional alert to the user to indicate a potential issue with the measured data. As such, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed audio or visual alarm. **Accordingly, claim 37 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**
38. The patient monitor of claim 27, further comprising an additional display indicating perfusion through the body tissue.	See claim 27, *supra.* As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation and blood oxygen saturation limits. Kianl discloses with respect to Fig. 4, "a pleth only view 400 having an oxygen saturation 412, a pulse rate 414, a **perfusion index** 418 and a pulse waveform 422." *Id.* at col. 5 line 66 – Col. 7 line1 (emphasis added). It would have been obvious to combine the teachings of Al-Ali and Kianl to arrive at the claim to provide an additional parameter to measure in Al-Ali,

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
	which would help further diagnose and treat medical conditions of the patient. As such, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed perfusion display. **Accordingly, claim 38 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**
44. The patient monitor of claim 42, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.	See claim 42, *supra*. Kianl discloses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation 412 and blood oxygen saturation limits 432. As shown in Fig. 4, reproduced below, measured blood oxygen saturation 412 is shown in a first display area, whereas **blood oxygen saturation limits 432**, which provides an indicia that measured value 412 is that of a blood oxygen saturation, is displayed in a second display area. In this manner, the second display area of Kianl displays an indicia identifying the blood parameter displayed in the first display area of Kianl.  **Fig. 4 of Kianl** The display characteristics of Kianl's multi-parameter/multi-display patient monitor may be predictably combined with the multi-parameter/multi-display patient monitor of Al-Ali (as described with respect to claim 42) to arrive at the claim, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter. Further, it would have been obvious to a skilled artisan to combine the teachings of Al-Ali and Kianl to provide a parameter indicia display, which would help further enable the user to better view the conditions that caused a triggering event.

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
	Accordingly, claim 44 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.
45. The patient monitor of claim 27, wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.	See claim 27, *supra*. As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation and blood oxygen saturation limits. Kianl also discloses **pressing user input buttons to change the display**. *Id.* at col. 11 line 32 to col. 12 line 35. It would have been a matter of design choice to alter the duration of display depending on the type of activation of the button in order to vary the length of a display of a particular parameter being shown. *See In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). *See also In re Dailey*, 357 F.2d 669, 672-73 (CCPA 1966) (holding that a particular shape of a container was merely a design choice absent persuasive evidence that the particular configuration of the claimed container was significant). Thus, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration. **Accordingly, claim 45 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
46. The patient monitor of claim 45, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.	See claim 45, *supra*. As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation and blood oxygen saturation limits. Kianl also discloses **pressing user input buttons to change the display**. *Id.* at col. 11 line 32 to col. 12 line 35. It would have been a matter of design choice to have a first type of activation and a second type of activation that includes an additional depression, which would allow the user to change the duration of the display. *See In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). *See also In re Dailey*, 357 F.2d 669, 672-73 (CCPA 1966) (holding that a particular shape of a container was merely a design choice absent persuasive evidence that the particular configuration of the claimed container was significant). Thus, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button. **Accordingly, claim 46 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**
47. The patient monitor of claim 45, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type	See claim 45, *supra*. As indicated with respect to claim 27, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation at any specific site..." Ex. C at Abstract. Similarly, as discussed with respect to claim 29, Kianl discusses a multi-parameter/multi-display pulse oximetry device which, among other physiological parameters, measures and displays blood oxygen saturation and blood oxygen saturation limits. Kianl also discloses **pressing user input buttons to change the display**. *Id.* at col. 11 line 32 to col. 12 line 35. It would have been a matter of design choice to have a shorter first type of activation and a second longer type of

'223 Patent Claims	Al-Ali in view of Kianl under § 103(a)
comprises a long duration first depression of the user input button.	activation to allow the user to change the duration of the display as desired. *See In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). *See also In re Dailey*, 357 F.2d 669, 672-73 (CCPA 1966) (holding that a particular shape of a container was merely a design choice absent persuasive evidence that the particular configuration of the claimed container was significant). Thus, the combined teachings of Al-Ali (as described with respect to claim 27) and Kianl disclose the claimed first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button. **Accordingly, claim 47 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Kianl.**

D. Al-Ali in View of Jarman Renders Claims 8-10, 24-26, and 39-41 of the '223 Patent Unpatentable Under 35 U.S.C. § 103(a)

Requester respectfully submits that claims 8-10, 24-26, and 39-41 of the '223 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Al-Ali in view of Jarman. Al-Ali (Ex. C) was filed December 21, 2001 and published June 27, 2002; the earliest priority date that the claims of the '223 patent may be entitled to is March 1, 2005. Therefore, Al-Ali is available as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). Jarman (Ex. E) issued December 1, 1998, and thus, qualifies as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). The following claim chart demonstrates, on a limitation-by-limitation basis, how claims 8-10, 24-26, and 39-41 of the '223 patent are rendered obvious by Al-Ali in view of Jarman under 35 U.S.C. § 103(a).

'223 Patent Claims	Al-Ali in view of Jarman under § 103(a)
8. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.	See claim 1, *supra*. As indicated with respect to claim 1, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation..." Ex. C at Abstract. Jarman discloses an improved photoplethysmographic monitoring device (*i.e.*, pulse oximeter) for **noninvasively measuring** a "plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, **carboxyhemoglobin** and methemoglobin levels in the blood." Ex. E at col. 2, lines. 56-62 (emphasis added). Jarman also teaches that **carboxyhemoglobin represents an indication of carbon monoxide saturation in the blood** as "carboxyhemoglobin is generated when carbon monoxide molecules bind to hemoglobin." *Id.* at col. 1, lines 28-30. It would have been obvious to a person having ordinary skill in the art to combine the teachings of Al-Ali and Jarman to arrive at the claim because Al-Ali provides a specific motivation to combine references teaching additional blood analyte parameters that may be measured using pulse oximetry techniques. *See, e.g.*, Ex. C at ¶ 0008 (stating that the signal processor of Al-Ali "advantageously provide[s] continuous and simultaneous multiple-parameter oxygen status and plethysmograph measurements from a particular tissue site. This is in contrast to a conventional pulse oximeter that provides only arterial oxygen saturation data from a tissue site"). Further, it would have been obvious to combine the teachings of Al-Ali and Jarman to arrive at the claim to provide an additional parameter to measure in Al-Ali, which would help further diagnose and treat medical conditions of the patient. Thus, the combined teachings of Al-Ali (as described with respect to claim 1) and Jarman disclose the claimed patient monitor, wherein the measured first and second physiological parameters comprise an indication of oxygen saturation and carbon monoxide saturation, respectively. **Accordingly, claim 8 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**

'223 Patent Claims	Al-Ali in view of Jarman under § 103(a)
9. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.	See claim 1, *supra*. As indicated with respect to claim 1, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation..." Ex. C at Abstract. Jarman discloses an improved photoplethysmographic monitoring device (*i.e.*, pulse oximeter) for **noninvasively measuring** a "plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and **methemoglobin** levels in the blood." Ex. E at col. 2, lines. 56-62 (emphasis added). It would have been obvious to a person having ordinary skill in the art to combine the teachings of Al-Ali and Jarman to arrive at the claim for at least the reasons stated with respect to claim 8 and, further, to provide for a pulse oximetry device capable of measuring and displaying oxygen saturation and methemoglobin saturation, which would help further diagnose and treat medical conditions of the patient. Thus, the combined teachings of Al-Ali (as described with respect to claim 1) and Jarman disclose the claimed patient monitor, wherein the measured first and second physiological parameters comprise an indication of oxygen saturation and methemoglobin saturation, respectively. **Accordingly, claim 9 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**
10. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.	See claim 1, *supra*. As discussed with respect to claims 8 and 9, Jarman discloses a pulse oximeter for measuring, among other physiological parameters, carboxyhemoglobin, or carbon monoxide saturation, and methemoglobin saturation. Ex. E at col. 1, lines 28-30; col. 2, lines. 56-62; and col. 3, lines 63-67. It would have been obvious to a person having ordinary skill in the art to combine the teachings of Al-Ali and Jarman to arrive at the claim for at least the reasons stated with respect to claim 8 and, further, to provide for a pulse oximetry device capable of measuring and displaying carbon

'223 Patent Claims	Al-Ali in view of Jarman under § 103(a)
	monoxide saturation and methemoglobin saturation, which would help further diagnose and treat medical conditions of the patient. Thus, the combined teachings of Al-Ali (as described with respect to claim 1) and Jarman disclose the claimed patient monitor, wherein the measured first and second physiological parameters comprise an indication of carbon monoxide saturation and methemoglobin saturation, respectively. **Accordingly, claim 10 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**
24. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.	See claim 21, *supra.* See claim 8, *supra.* In particular, Jarman discloses an improved photoplethysmographic monitoring device (*i.e.*, pulse oximeter) for noninvasively measuring a "plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, **carboxyhemoglobin** [or carbon monoxide saturation] and methemoglobin levels in the blood." Ex. E at col. 2, lines. 56-62 (emphasis added). Thus, the combined teachings of Al-Ali (as described with respect to claim 21) and Jarman disclose the claimed patient monitor, wherein the measured first and second physiological parameters comprise an indication of oxygen saturation and carbon monoxide saturation, respectively. **Accordingly, claim 24 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**

'223 Patent Claims	Al-Ali in view of Jarman under § 103(a)
25. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.	See claim 21, *supra*. See claim 9, *supra*. In particular, Jarman discloses an improved photoplethysmographic monitoring device (*i.e.*, pulse oximeter) for noninvasively measuring a "plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and **methemoglobin** levels in the blood." Ex. E at col. 2, lines. 56-62 (emphasis added). Thus, the combined teachings of Al-Ali (as described with respect to claim 21) and Jarman disclose the claimed patient monitor, wherein the measured first and second physiological parameters comprise an indication of oxygen saturation and methemoglobin saturation, respectively. **Accordingly, claim 25 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**
26. The method of claim 21, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.	See claim 21, *supra*. See claim 10, *supra*. In particular, Jarman discloses a pulse oximeter for measuring, among other physiological parameters, carboxyhemoglobin, or carbon monoxide saturation, and methemoglobin saturation. Ex. E at col. 1, lines 28-30; col. 2, lines. 56-62; and col. 3, lines 63-67. Thus, the combined teachings of Al-Ali (as described with respect to claim 21) and Jarman disclose the claimed patient monitor, wherein the measured first and second physiological parameters comprise an indication of carbon monoxide saturation and methemoglobin saturation, respectively. **Accordingly, claim 26 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**

'223 Patent Claims	Al-Ali in view of Jarman under § 103(a)
39. The patient monitor of claim 27, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.	See claim 27, *supra*. See claim 8, *supra*. In particular, Jarman discloses an improved photoplethysmographic monitoring device (*i.e.*, pulse oximeter) for noninvasively measuring a "plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, **carboxyhemoglobin** [or carbon monoxide saturation] and methemoglobin levels in the blood." Ex. E at col. 2, lines. 56-62 (emphasis added). Thus, the combined teachings of Al-Ali (as described with respect to claim 27) and Jarman disclose the claimed patient monitor, wherein the measured first and second physiological parameters comprise an indication of oxygen saturation and carbon monoxide saturation, respectively. **Accordingly, claim 39 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**
40. The patient monitor of claim 39, comprising an additional display capable of indicating the percent carbon monoxide saturation.	See claim 39, *supra*. As discussed with respect to claim 39, Jarman discloses a pulse oximeter which, among other physiologically parameters, measures carboxyhemoglobin, or carbon monoxide saturation, as a percent of total hemoglobin. Ex. E at col. 1, lines 28-30; col. 2, lines. 56-62. Measured analyte concentrations, such as carboxyhemoglobin, are displayed on the graphic 114 and/or numeric display 115 of Jarman. *Id.* at col. 4, lines 44-46; Fig. 1. Thus, Jarman teaches that percent carbon monoxide saturation is one of the many physiological parameters of interest to measure and display on a pulse oximetry device. In addition to the reasons for combining Al-Ali and Jarman described with respect to claim 8, this teaching may be predictably combined with the display of Al-Ali (which includes multiple display areas for multiple measured physiological parameters) to arrive at the claimed patient monitor. Further, it would have been obvious to one of skill

'223 Patent Claims	Al-Ali in view of Jarman under § 103(a)
	in the art at the time of the '223 filing to combine the teachings of Al-Ali and Jarman to display the percent carbon monoxide saturation, which would help further enable the user to better view the conditions that caused a triggering event. **Accordingly, claim 40 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**
41. The patient monitor of claim 39, comprising an additional display capable of indicating the percent methemoglobin saturation.	See claim 39, *supra.* As discussed with respect to claims 9 and 25, Jarman discloses an improved photoplethysmographic monitoring device (*i.e.*, pulse oximeter) for noninvasively measuring a "plurality of blood analyte concentrations, particularly the concentrations (as a percent of total hemoglobin) of the oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin and **methemoglobin** levels in the blood." Ex. E at col. 2, lines. 56-62 (emphasis added). Further, measured analyte concentrations, such as methemoglobin saturation, are displayed on the graphic 114 and/or numeric display 115 of Jarman. *Id.* at col. 4, lines 44-46; FIG. 1. Thus, Jarman teaches that percent methemoglobin saturation is one of the many physiological parameters of interest to measure and display on a pulse oximetry device. In addition to the reasons for combining Al-Ali and Jarman described with respect to claim 8, this teaching may be predictably combined with the display of Al-Ali (which includes multiple display areas for multiple measured physiological parameters) to arrive at the claimed patient monitor. Further, it would have been obvious to combine the teachings of Al-Ali and Jarman to display the percent methemoglobin saturation, which would help further enable the user to better view the conditions that caused a triggering event. **Accordingly, claim 41 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Jarman.**

E. Al-Ali in View of Healy Renders Claims 11-14, 16, 17, and 30 of the '223 Patent Unpatentable Under 35 U.S.C. § 103(a)

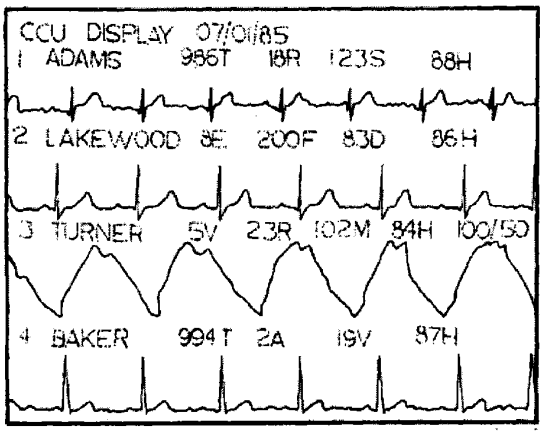
Requester respectfully submits that claims 11-14, 16, 17, and 30 of the '223 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Al-Ali in view of Healy. Al-Ali (Ex. C) was filed December 21, 2001 and published June 27, 2002; the earliest priority date that the claims of the '223 patent may be entitled to is March 1, 2005. Therefore, Al-Ali is available as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). Healy (Ex. F) issued September 27, 1977. Thus, Healy qualifies as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). The following claim chart demonstrates, on a limitation-by-limitation basis, how claims 11-14, 16, 17, and 30 of the '223 patent are rendered obvious by Al-Ali in view of Healy under 35 U.S.C. § 103(a).

'223 Patent Claims	Al-Ali in view of Healy under § 103(a)
11. The patient monitor of claim 1, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters.	See claim 1, *supra.* As indicated with respect to claim 1, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation [and pulse rate] at any specific site…" Ex. C at Abstract. Healy (Ex. F) describes a "hospital patient monitoring and display system … including various patient sensors such as ECG, pulse rate, patient temperature and blood pressure." Ex. F at Abstract. The system of Healy includes controls for setting parameter threshold values and, "whenever the patient parameters vary from [an] allowable value," the display of Healy shifts "**from one color display to a different one …, e.g., normal trace, green and abnormality, red.**" *Id* (emphasis added). Further, Healy states that **flashing or higher intensity traces** may be used to indicate a sensed alarm condition. *Id.* at col. 6, lines 56-67. Thus, Healy teaches that it was well known in the art to change an aspect of a patient monitor display (*e.g.*, color, or intensity modulation) to illustrate a change in the severity of one of the measured values of the first or second physiological parameter (*i.e.*, to illustrate a change "whenever the patient parameters vary

'223 Patent Claims	Al-Ali in view of Healy under § 103(a)
	from [an] allowable value," as described by Healy). It would have been obvious to a skilled artisan at the time of the '223 patent filing to combine the teachings of Al-Ali and Healy to arrive at the claim varying the display of Al-Ali, as described by Healy, to change an aspect of the display to illustrate a change in the severity of one of the measured parameters. Al-Ali provides an explicit motivation that would have led a person of ordinary skill in the art to combine the teachings of these two references as Al-Ali teaches that the display of a patient monitor should automatically update, based upon a triggering event, to "enable[] the user better view [of] the conditions that caused the triggering event." Ex. C at ¶ 0095. **Accordingly, claim 11 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Healy.**
12. The patient monitor of claim 11, wherein the aspect that changes comprises a display color.	See claim 11, *supra*. In addition, Healy states that "[w]hen color displays are employed, the signal from the auto update controller 121 is applied to **change the trace color in the mixer 114, e.g. from white to red**." Ex. F at col. 6, lines 56-59 (emphasis added). Thus, the combined teachings of Al-Ali (as described with respect to claim 1) and Healy disclose the claimed patient monitor, wherein the aspect that changes comprises a display color. **Accordingly, claim 12 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Healy.**

'223 Patent Claims	Al-Ali in view of Healy under § 103(a)
13. The patient monitor of claim 11, wherein the aspect that changes comprises a display size.	See claim 11, *supra*. Although Healy does not specifically teach changing a display size, Healy teaches that it is well known in the art to change an aspect of a patient monitor display (*e.g.*, color, intensity modulation or flashing) to indicate that an alarm threshold has been reached. **It would be a simple matter of design choice to change the size of the displayed parameter to indicate that an alarm threshold has been reached - rather than, for example, changing the parameters color** - to achieve the claimed effect (*i.e.*, to illustrate a change "whenever the patient parameters varies from [an] allowable value," as described by Healy). *See In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (claims to a hydraulic power press which read on the prior art except with regard to the position of the starting switch were held unpatentable because shifting the position of the starting switch would not have modified the operation of the device.); *In re Kuhle*, 526 F.2d 553, 188 USPQ 7 (CCPA 1975) (the particular placement of a contact in a conductivity measuring device was held to be an obvious matter of design choice). *See also In re Dailey*, 357 F.2d 669, 672-73 (CCPA 1966) (holding that a particular shape of a container was merely a design choice absent persuasive evidence that the particular configuration of the claimed container was significant). Thus, the combined teachings of Al-Ali (as described with respect to claim 1) and Healy disclose the claimed patient monitor, wherein the aspect that changes comprises a display size. **Accordingly, claim 13 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Healy.**
14. The patient monitor of claim 11, wherein the aspect that changes comprises a display intensity.	See claim 11, *supra*. In addition, Healy states that "[i]n the case of black and white displays, an alarm condition may be represented as **intensity modulation or flashing of the display**." Ex. F at Abstract (emphasis added). Thus, the combined teachings of Al-Ali (as described with respect to claim 1) and Healy disclose the claimed patient monitor, wherein the aspect that changes comprises a display intensity.

'223 Patent Claims	Al-Ali in view of Healy under § 103(a)
	Accordingly, claim 14 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Healy.
16. The patient monitor of claim 15, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters.	See claim 15, *supra*. As described with respect to claim 11, Healy teaches that it was well known in the art to change an aspect of a patient monitor display (*e.g.*, color, or intensity modulation) in response to a measured value alarming (*i.e.*, to illustrate a change "whenever the patient parameters varies from [an] allowable value," as described by Healy). It would have been obvious to combine the teachings of Al-Ali and Healy to arrive at the claim by varying the display of Al-Ali - which changes from a single site display mode to a multi-site display mode in response to an alarming event - to further incorporate an aspect change - such as color or intensity - as described by Healy. Al-Ali provides an explicit motivation that would have led a person of ordinary skill in the art to combine the teachings of these two references as Al-Ali teaches that the display of a patient monitor should automatically update, based upon a triggering event, to "enable[] the user better view [of] the conditions that caused the triggering event." Ex. C at ¶ 0095. In this manner, further changing an aspect of an alarm (such as by color or intensity modulation, as described by Healy) would more easily enable the user of the device of Al-Ali to view the condition that caused a triggering event, thus further serving Al-Ali's stated objective. Thus, the combined teachings of Al-Ali (as described with respect to claim 15) and Healy disclose the claimed patient monitor, wherein an aspect of an alarm changes (*i.e.*, color or intensity modulation, as described by Healy) when the common display area changes from displaying one of the measured values of the first or second physiological parameters. **Accordingly, claim 16 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Healy.**

'223 Patent Claims	Al-Ali in view of Healy under § 103(a)
17. The patient monitor of claim 16, wherein the aspect that changes comprises a display color.	See claim 16, *supra.* In addition, Healy states that "[w]hen color displays are employed, the signal from the auto update controller 121 is applied to **change the trace color** in the mixer 114, e.g. from white to red." Ex. F at col. 6, lines 56-59 (emphasis added). Thus, the combined teachings of Al-Ali (as described with respect to claim 15) and Healy disclose the claimed patient monitor, wherein the aspect that changes comprises a display color. **Accordingly, claim 17 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Healy.**
30. The patient monitor of claim 27, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.	See claims 11 and 27, *supra.* In addition, and as shown in Fig. 6 of Healy, reproduced below, the patient monitor **displays vital parameters** such as ECG, temperature, pulse rate, blood pressure, **and one trace** (graphical representation **of a selected parameter**) for a number of patients. *Id.* at col. 8, lines 25-33.  **Fig. 6 of Healy** When the described display is a color monitor, Healy teaches that "**the normal trace [for example, ECG measurements] may be in white and the trace converted to a distinguishable color, e.g., red, when present limits are exceeded.**" *Id.* at col. 8, lines 46-50 (emphasis added). Further, "[a]ctual pulse rate, in addition to being conveyed to the central station on lead 340 is amplified in amplifier 341 which drives an LED 342, for example green in

'223 Patent Claims	Al-Ali in view of Healy under § 103(a)
	color, to provide a visual indication of pulse rate." In this manner, the patient monitor of Healy may **display a first measured parameter (such as an ECG trace) in white under normal conditions, and a second measured parameter (such as pulse rate) in green under normal conditions**. Thus, the combined teachings of Al-Ali (as described with respect to claim 27) and Healy disclose the claimed patient monitor, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions. **Accordingly, claim 30 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Healy.**

F. Al-Ali in View of Nielsen Renders Claims 5 and 23 of the '223 Patent Unpatentable Under 35 U.S.C. § 103(a)

Requester respectfully submits that claims 5 and 23 of the '223 patent are unpatentable under 35 U.S.C. § 103(a) as obvious over Al-Ali in view of Nielsen. Al-Ali (Ex. C) was filed December 21, 2001 and published June 27, 2002; the earliest priority date that the claims of the '223 patent may be entitled to is March 1, 2005. Therefore, Al-Ali is available as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). Nielsen (Ex. G) was filed on December 20, 2001 and published June 26, 2003, and thus, qualifies as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). The following claim chart demonstrates, on a limitation-by-limitation basis, how claims 5 and 23 of the '223 patent are rendered obvious by Al-Ali in view of Nielsen under 35 U.S.C. § 103(a).

'223 Patent Claims	Al-Ali in view of Nielsen under § 103(a)
5. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises an invasively measured value.	See claim 1, *supra*. As indicated with respect to claim 1, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation [and pulse rate] at any specific site..." Ex. C at Abstract. Nielsen discloses a patient monitoring system for measuring and displaying various physiological parameters, including "an NBP (non-invasive blood pressure)..., an ART (blood pressure from an **invasive arterial blood pressure reading**)..., SpO_2 ..., [and] CO_2." Ex. G at ¶ 0047 (emphasis added). Thus, Nielsen teaches that invasively measured values, such as blood pressure, are one of the many physiological parameters of interest to measure and display on a pulse oximetry device. This teaching may be predictably combined with the device of Al-Ali (which includes multiple display areas for multiple measured physiological parameters) to arrive at the claimed patient monitor, wherein the measured value of the first physiological parameter comprises an invasively measured value. Moreover, Al-Ali states that the disclosed signal processor advantageously provide[s] continuous and simultaneous multiple-parameter oxygen status and plethysmograph measurements from a particular tissue site. This is in contrast to a conventional pulse oximeter that provides only arterial oxygen saturation data from a tissue site". Ex. C at ¶ 0008. Thus, Al-Ali provides a specific motivation to combine reference teaching additional blood analyte parameters that may be measured and displayed using pulse oximetry techniques. Similarly, it would have been obvious to combine the teachings of Al-Ali and Nielsen to provide an additional parameter to measure in Al-Ali, which would help further diagnose and treat medical conditions of the patient. **Accordingly, claim 5 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Nielsen.**
23. The method of claim 21, wherein the measured value of the	See claims 5 and 21, *supra*.

'223 Patent Claims	Al-Ali in view of Nielsen under § 103(a)
first physiological parameter comprises an invasively measured value.	**Accordingly, claim 23 of the '223 patent is unpatentable under § 103(a) as obvious over Al-Ali in view of Nielsen.**

G. Al-Ali in view of Lepper renders claim 7 of the '223 patent unpatentable under 35 U.S.C. § 103(a)

Requester respectfully submits that claim 7 of the '223 patent is unpatentable under 35 U.S.C. § 103(a) as obvious over Al-Ali in view of Lepper. Al-Ali (Ex. C) was filed December 21, 2001 and published June 27, 2002; the earliest priority date that the claims of the '223 patent may be entitled to is March 1, 2005. Therefore, Al-Ali is available as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). Lepper (Ex. H) issued on April 28, 1998, and thus, qualifies as prior art against all claims of the '223 patent under 35 U.S.C. § 102(b). The following claim chart demonstrates, on a limitation-by-limitation basis, how claim 7 of the '223 patent is rendered obvious by Al-Ali in view of Lepper under 35 U.S.C. § 103(a).

'223 Patent Claims	Al-Ali in view of Lepper under § 103(a)
7. The patient monitor of claim 1, wherein the measured value of the first physiological parameter comprises glucose.	See claim 1, *supra*. As indicated with respect to claim 1, Al-Ali discloses a pulse oximeter which "simultaneously measures both arterial and venous oxygen saturation [and pulse rate] at any specific site..." Ex. C at Abstract. **Lepper describes a blood glucose monitoring system** for non-invasively determining blood glucose concentration using a broadband light source and optical detector, which is attached to a fleshy medium of a patient, such as a fingertip. Ex. H. at col. 3, lines 28-47. Light emitted from the broadband light source passes through the finger, is attenuated by the tissue of the finger and, based upon the intensity of the emitted light after it passes through the finger, **a blood glucose concentration can be determined**. *Id.* at col. 7, lines 18-42. In particular, absorption of optical radiation through the finger is defined by Beer-Lambert's law. Similarly, the patient monitor of Al-Ali derives oxygen

	saturation values using the same underlying theory and absorption principles (Beer-Lambert's law) as discussed in Lepper. Ex. C at ¶¶ 0042, 0049. Thus, when the teachings of Lepper are applied to Al-Ali (as described above with respect to claim 1), the measured value of the first physiological parameter of the claimed patient monitor would comprise a blood glucose concentration. It would have been obvious to a person having ordinary skill in the art at the time of the '223 patent filing to combine the teachings of Al-Ali and Lepper to arrive at the claim because doing so represents a simple combination of one known prior art element (the non-invasive glucose finger sensor of Lepper) with another known prior art element (the multi-site non-invasive patient monitor of Al-Ali) to achieve predictable results (the measurement and display of glucose, as claimed). Further, it would have been obvious to combine the teachings of Al-Ali and Lepper to arrive at the claim by providing an additional parameter to measure in Al-Ali, which would help further diagnose and treat medical conditions of the patient. **Accordingly, claim 7 of the '223 patent is unpatentable under § 103(a) over Al-Ali in combination with Lepper.**

VII. LIST OF EXHIBITS

Exhibit A	U.S. Patent No. 8,190,223 to Al-Ali (the "'223 patent).
Exhibit B	Selected documents from the prosecution file history of the '223 patent.
Exhibit C	U.S. Patent Application Publication 2002/0082488 to Al-Ali et al. ("Al-Ali").
Exhibit D	U.S. Patent No. 6,658,276 to Kianl et al. ("Kianl").
Exhibit E	U.S. Patent No. 5,842,979 to Jarman ("Jarman").
Exhibit F	U.S. Patent No. 4,051,522 to Healy et al. ("Healy").
Exhibit G	U.S. Patent Application Publication 2003/0120164 to Nielsen ("Nielsen").
Exhibit H	U.S. Patent No. 5,743,262 to Lepper et al. ("Lepper").
Exhibit I	Int'l Preliminary Report on Patentability of September 11, 2007.

VIII. CONCLUSION

Based on the above discussion and analysis, the specifically identified and applied references show that there exist substantial new questions of patentability as to all claims (1-47) of the '223 patent. For the reasons set forth in this Request, it is respectfully requested that the *ex parte* reexamination of the '223 patent be granted and that claims 1-47 of the '223 patent be rejected.

Respectfully submitted,

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Form PTO 1449 (Modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO. 403381US104RX	CONTROL NO. New Request for Ex Parte Reexamination
LIST OF REFERENCES CITED BY APPLICANT	APPLICANT Ammar AL-ALI, et al.	
	FILING DATE Herewith	GROUP

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	8,190,223	05-29-2012	Al-Ali et al.			
	AB	20020082488	06-27-2002	Al-Ali, et al.			
	AC	6,658,276	12-02-2003	Kianl, et al			
	AD	5,842,979	12-01-1998	Jarman			
	AE	4,051,522	09-27-1977	Healy, et al			
	AF	20030120164A1	06-26-2003	Nielsen, et al.			
	AG	5,743,262	04-28-1998	Lepper, Jr., et al.			
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES	TRANSLATION NO
	AO					
	AP					
	AQ					
	AR					
	AS					
	AT					
	AU					
	AV					

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

	AW	Selected Documents from the Prosecution History of USP 8,190,223
	AX	Int'l Preliminary Report on Patentability, PCT/US2006/007389, September 11, 2007
	AY	
	AZ	☐ Additional References sheet(s) attached

Examiner	Date Considered

*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DOCKET NO.: 403381US104RX

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: GROUP: Unassigned

Ammar AL-ALI, et al.

CONTROL NO: NEW REQUEST FOR EX PARTE REEXAMINATION EXAMINER: Unassigned

FILED: Herewith

FOR: NONINVASIVE MULTI-PARAMETER PATIENT MONITOR

CERTIFICATE OF SERVICE

COMMISSIONER FOR PATENTS
Alexandria, VA 22313-1450

Commissioner:

I hereby certify that on September 13, 2012, a copy of the foregoing Request for *Ex Parte* Reexamination Transmittal Form and *Ex Parte* Reexamination Request for U.S. Patent No. 8,190,223 with Exhibits A-I, and a PTO Form-1449 is being sent by first-class U.S. mail to the following:

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EXHIBIT A

US008190223B2

(12) **United States Patent**
Al-Ali et al.

(10) **Patent No.: US 8,190,223 B2**
(45) **Date of Patent: May 29, 2012**

(54) **NONINVASIVE MULTI-PARAMETER PATIENT MONITOR**

(75) Inventors: **Ammar Al-Ali**, Tustin, CA (US); **Joe Kiani**, Laguna Niguel, CA (US); **Mohamed Diab**, Mission Viejo, CA (US); **Greg Olsen**, Irvine, CA (US); **Roger Wu**, Irvine, CA (US); **Rick Fishel**, Orange, CA (US)

(73) Assignee: **Masimo Laboratories, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1661 days.

(21) Appl. No.: **11/367,033**

(22) Filed: **Mar. 1, 2006**

(65) **Prior Publication Data**

US 2006/0226992 A1 Oct. 12, 2006

Related U.S. Application Data

(60) Provisional application No. 60/657,596, filed on Mar. 1, 2005, provisional application No. 60/657,281, filed on Mar. 1, 2005, provisional application No. 60/657,268, filed on Mar. 1, 2005, provisional application No. 60/657,759, filed on Mar. 1, 2005.

(51) **Int. Cl.**
A61B 5/1455 (2006.01)

(52) **U.S. Cl.** **600/310**; 600/323; 600/324; 600/326

(58) **Field of Classification Search** 600/309–344
See application file for complete search history.

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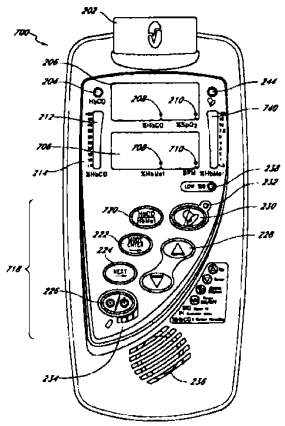
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(57) **ABSTRACT**

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.

47 Claims, 18 Drawing Sheets



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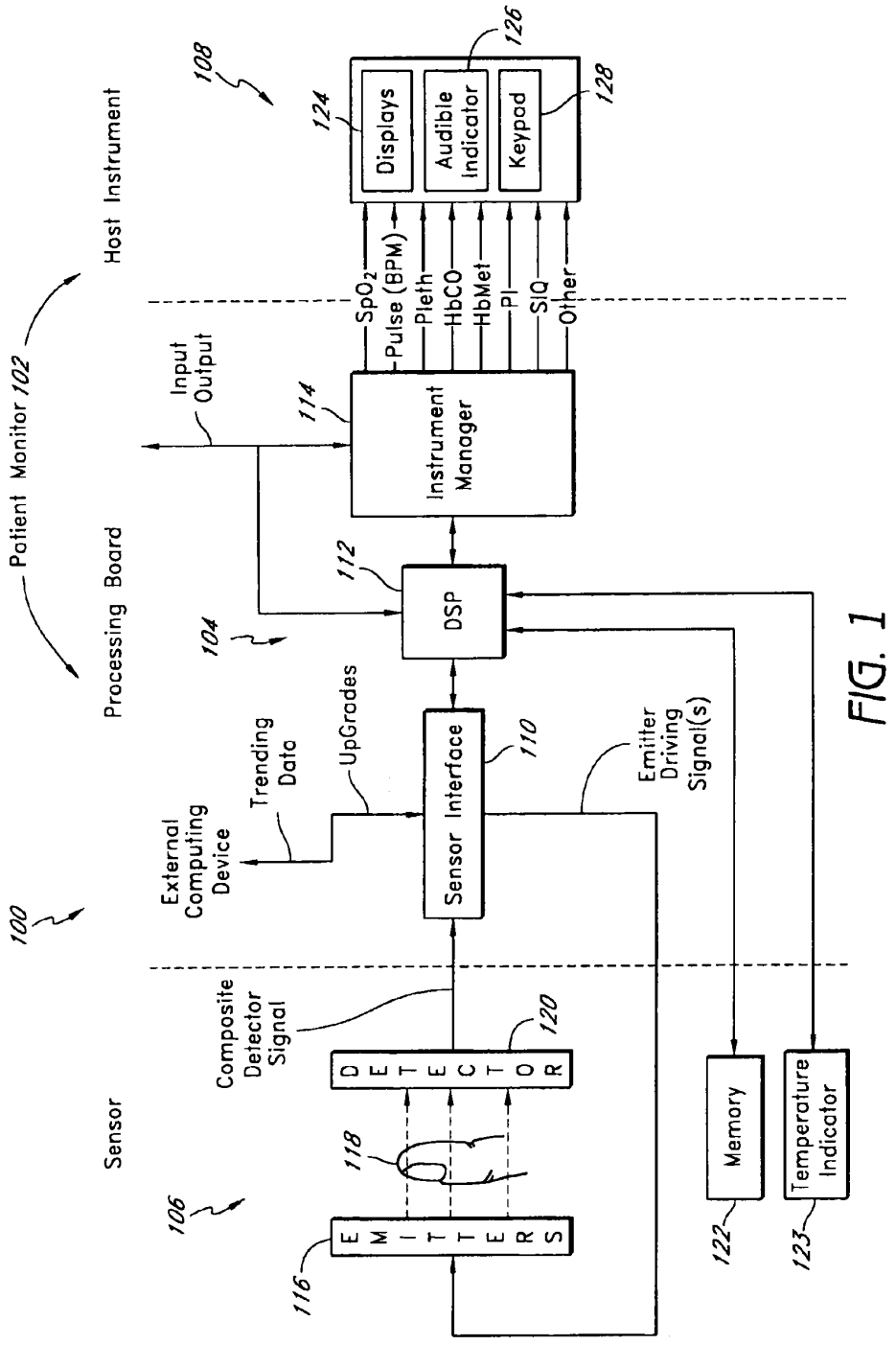

Patient Monitor 102
Host Instrument
Processing Board
Sensor
100
104
106
108
110
112
114
116
118
120
122
123
124
126
128
Displays
Audible Indicator
Keypad
SpO2
Pulse (BPM)
Pleth
HbCO
HbMet
PI
SIQ
Other
Input
Output
Instrument Manager
DSP
Sensor Interface
UpGrades
Trending Data
External Computing Device
Emitter Driving Signal(s)
Composite Detector Signal
DETECTOR
EMITTERS
Memory
Temperature Indicator

FIG. 1

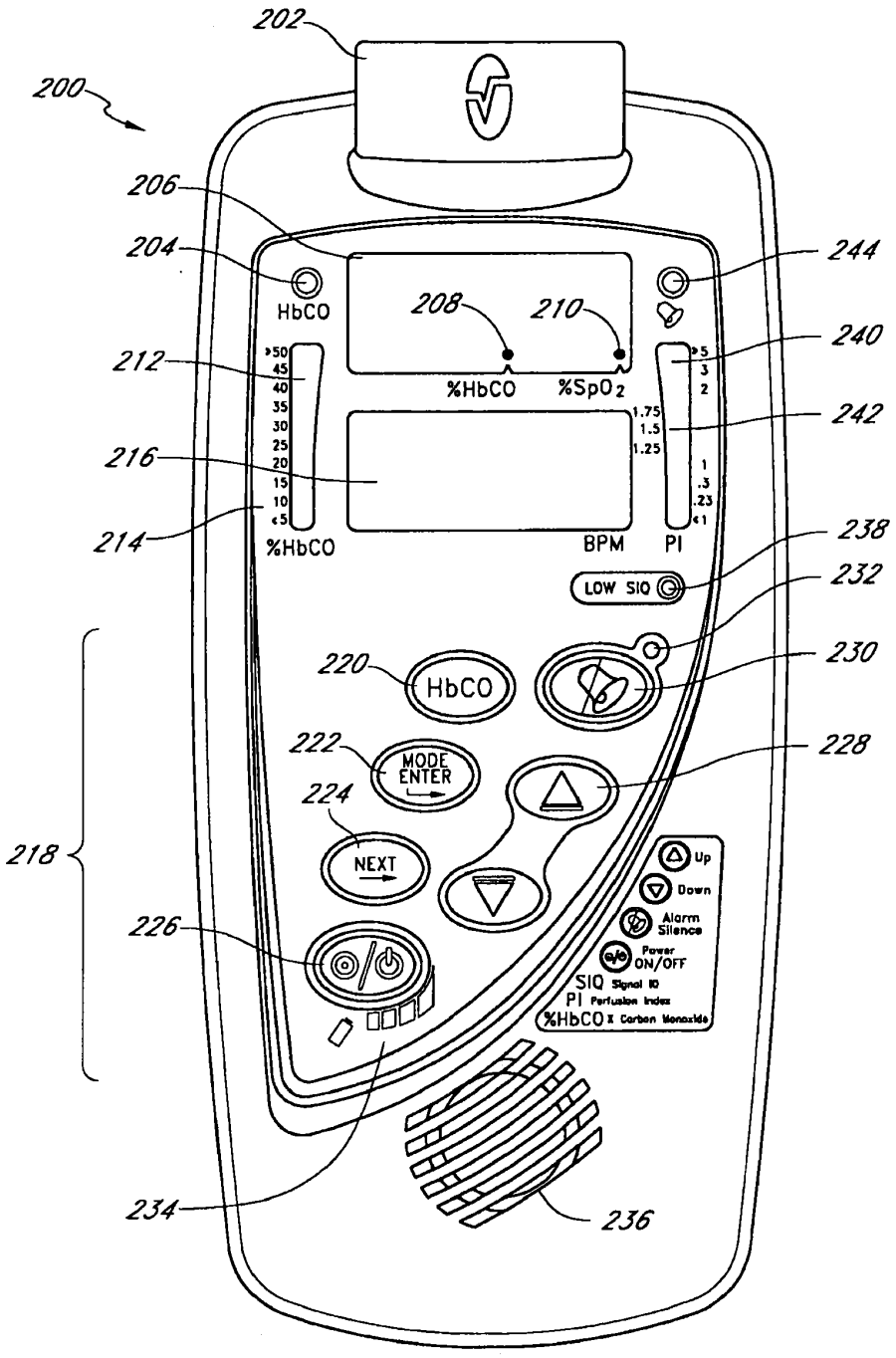

202
200
206
204
HbCO
208
210
244
240
212
%HbCO
%SpO2
242
216
214
%HbCO
BPM
PI
238
LOW SIQ
232
220
HbCO
230
222
MODE ENTER
228
224
NEXT
218
226
Up
Down
Alarm Silence
Power ON/OFF
SIQ Signal IQ
PI Perfusion Index
%HbCO Carbon Monoxide
234
236

FIG. 2

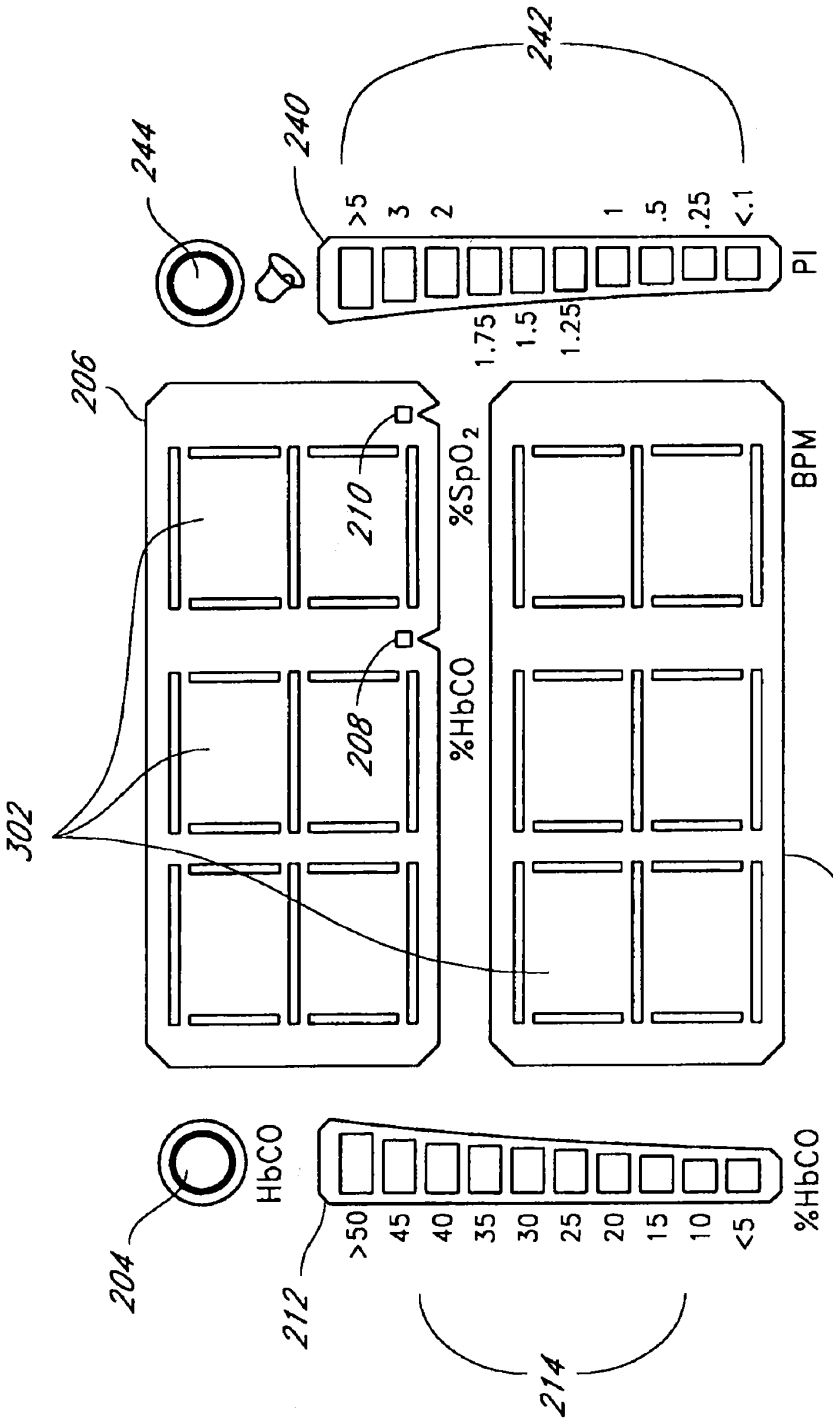

242
240
244
>5
3
2
1
.5
.25
<.1
PI
1.75
1.5
1.25
206
210
%SpO2
BPM
208
%HbCO
302
216
HbCO
%HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
214

FIG. 3

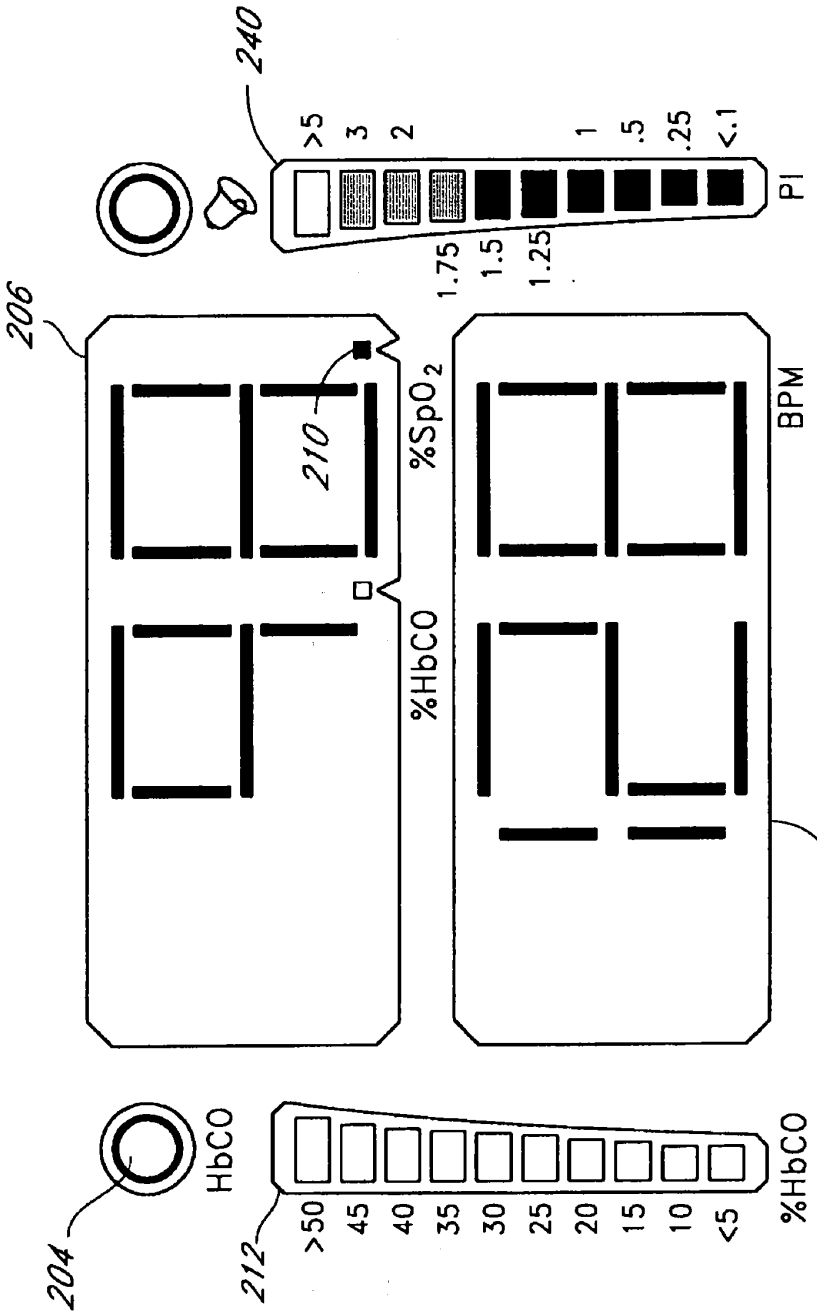

240
>5
3
2
1
.5
.25
<.1
PI
1.75
1.5
1.25
206
210
%SpO2
BPM
%HbCO
216
HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 4

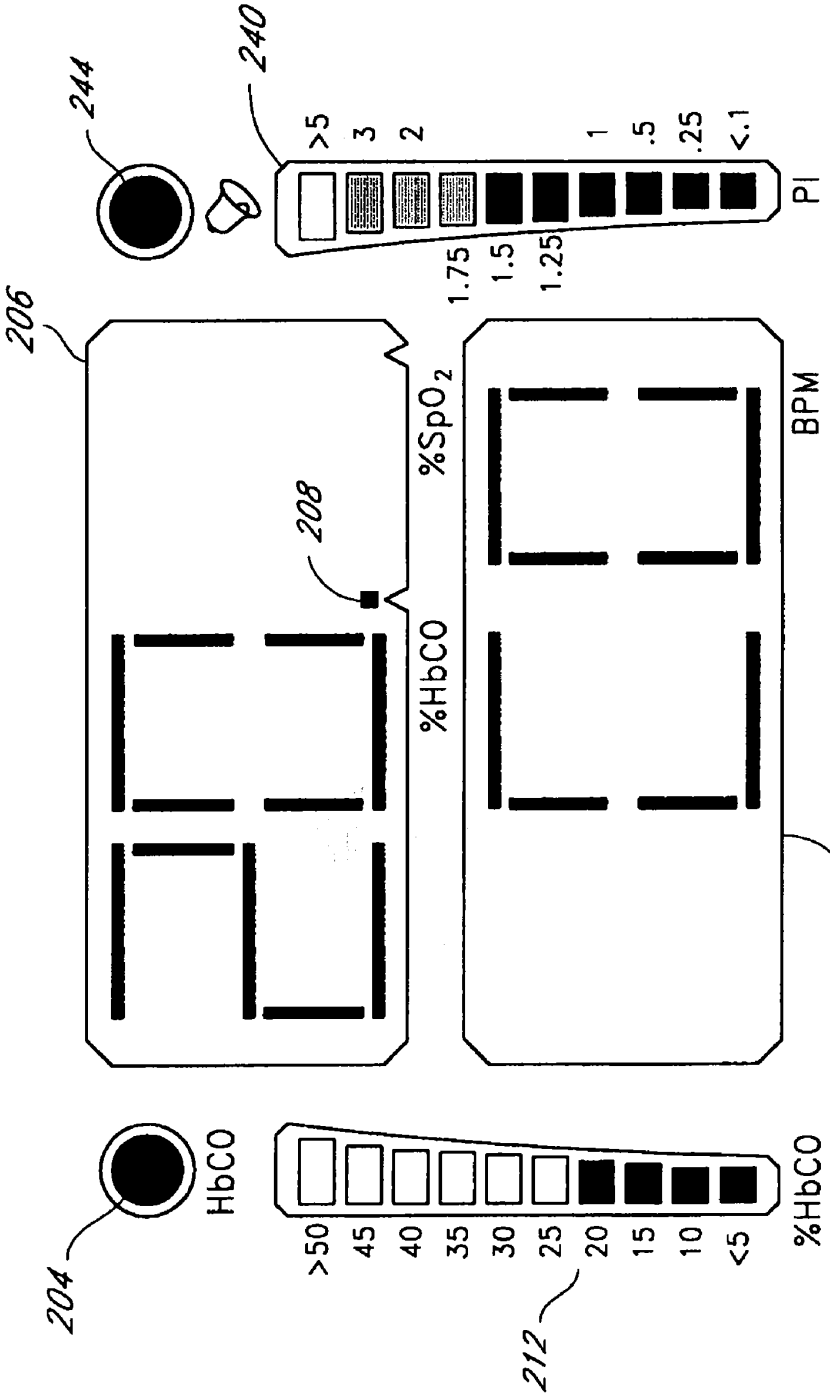

244
240
>5
3
2
1
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.25
<.1
PI
1.75
1.5
1.25
206
%SpO2
208
%HbCO
BPM
216
204
HbCO
>50
45
40
35
30
25
20
15
10
<5
%HbCO
212

FIG. 5

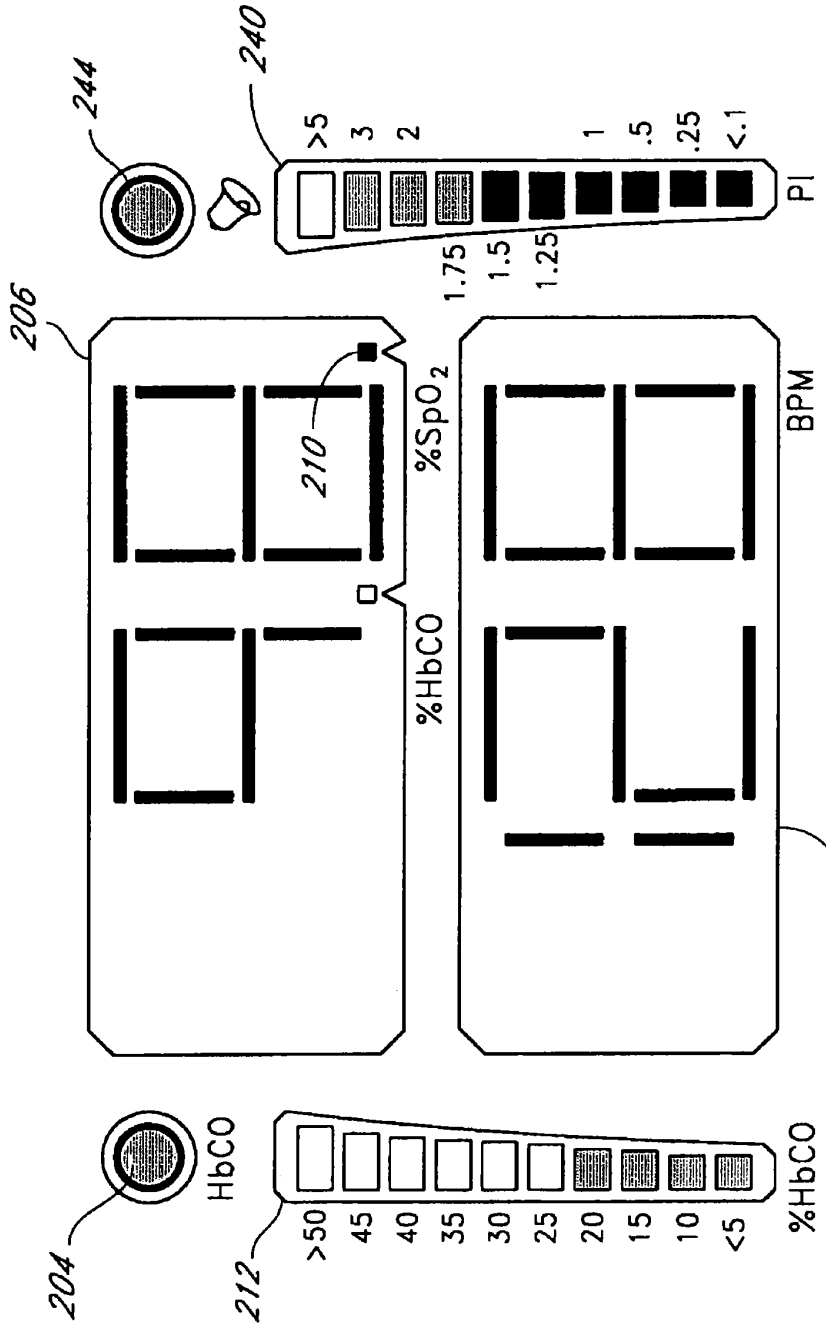

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%HbCO
BPM
216
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 6

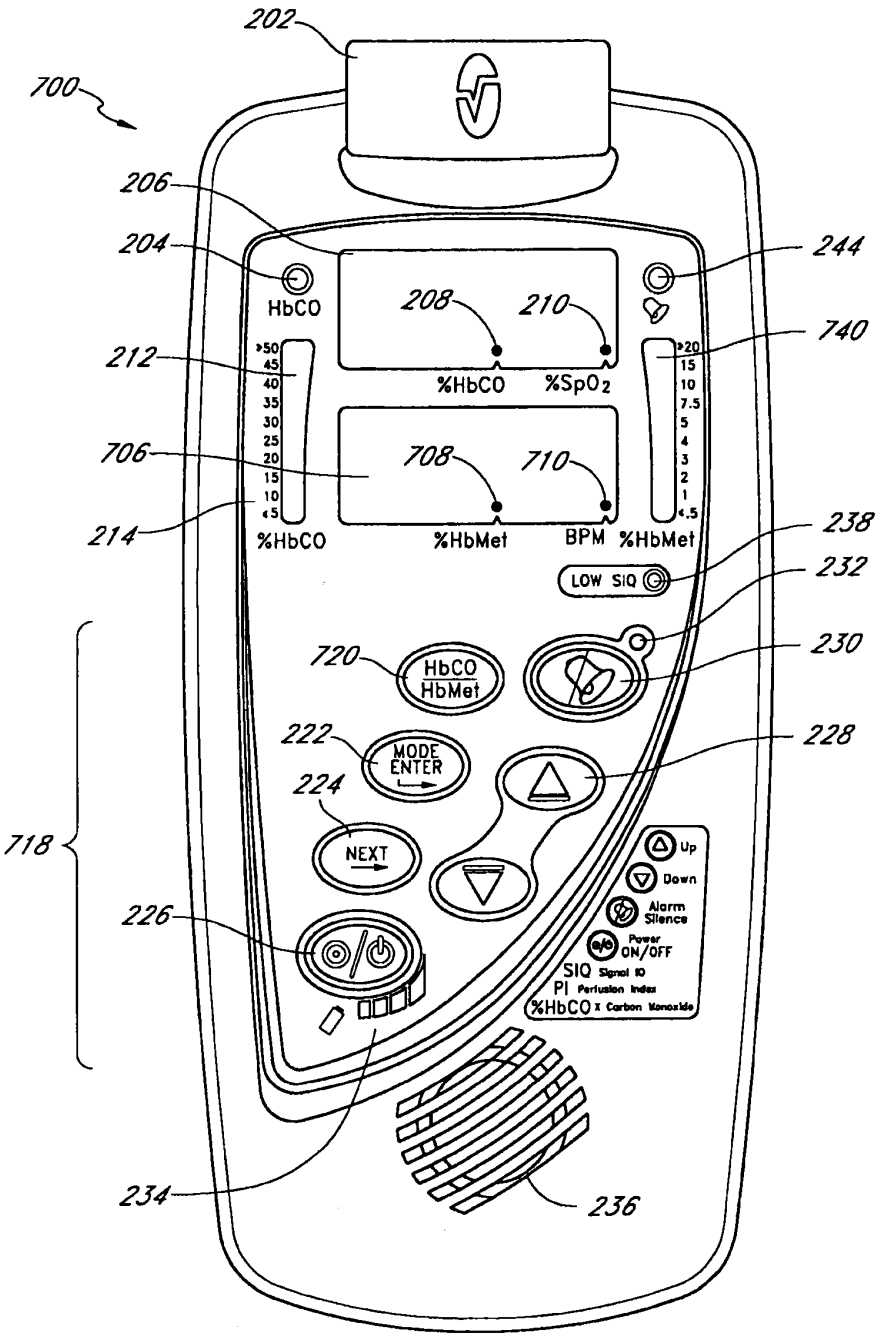

202
700
206
204
244
HbCO
208
210
740
212
%HbCO
%SpO2
706
708
710
214
%HbCO
%HbMet
BPM
%HbMet
238
LOW SIQ
232
720
HbCO
HbMet
230
222
MODE
ENTER
228
224
718
NEXT
Up
Down
Alarm
Silence
Power
ON/OFF
SIQ Signal IQ
PI Perfusion Index
%HbCO Carbon Monoxide
226
234
236

FIG. 7

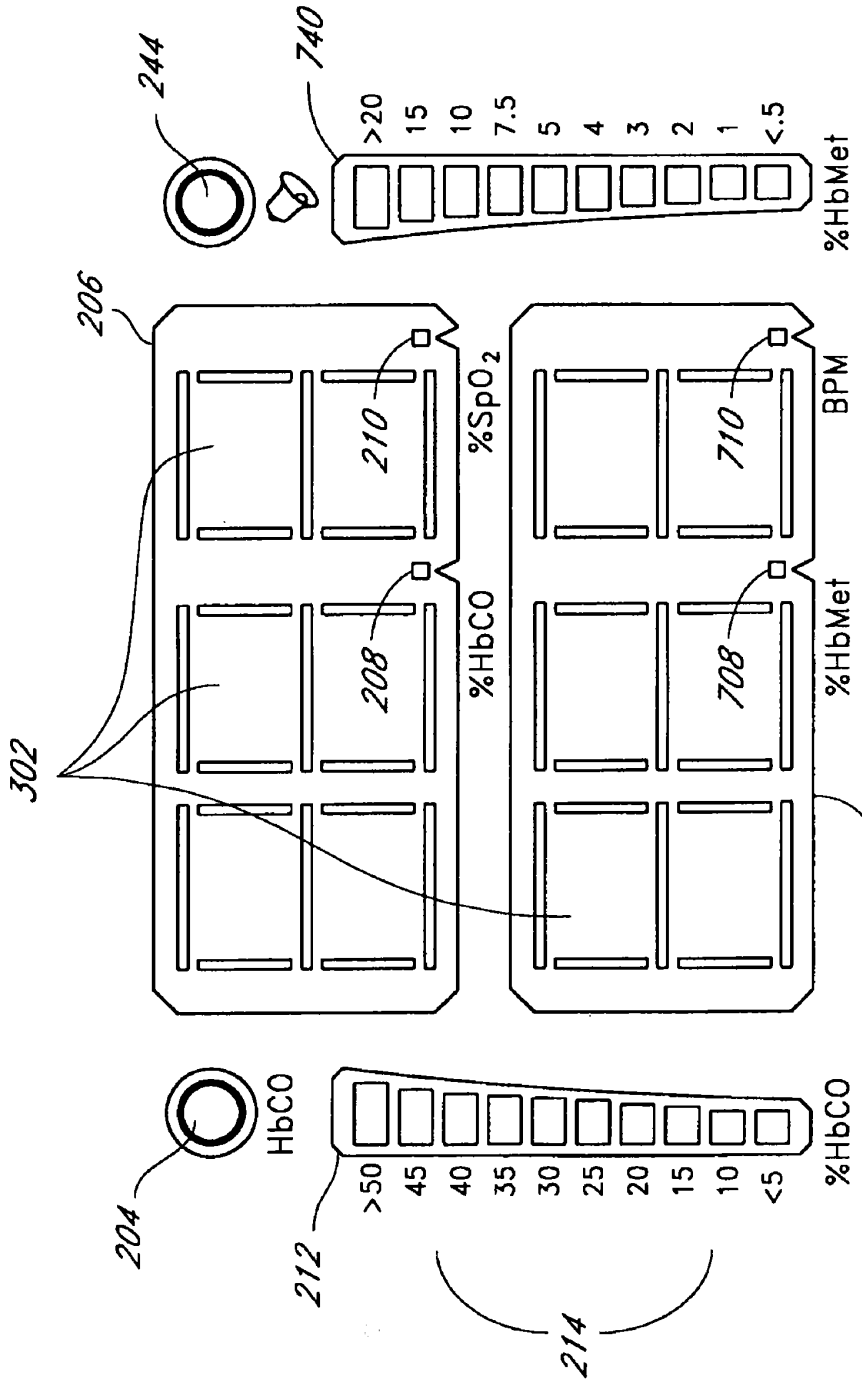

244
740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
710
BPM
208
%HbCO
708
%HbMet
302
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO
214

FIG. 8

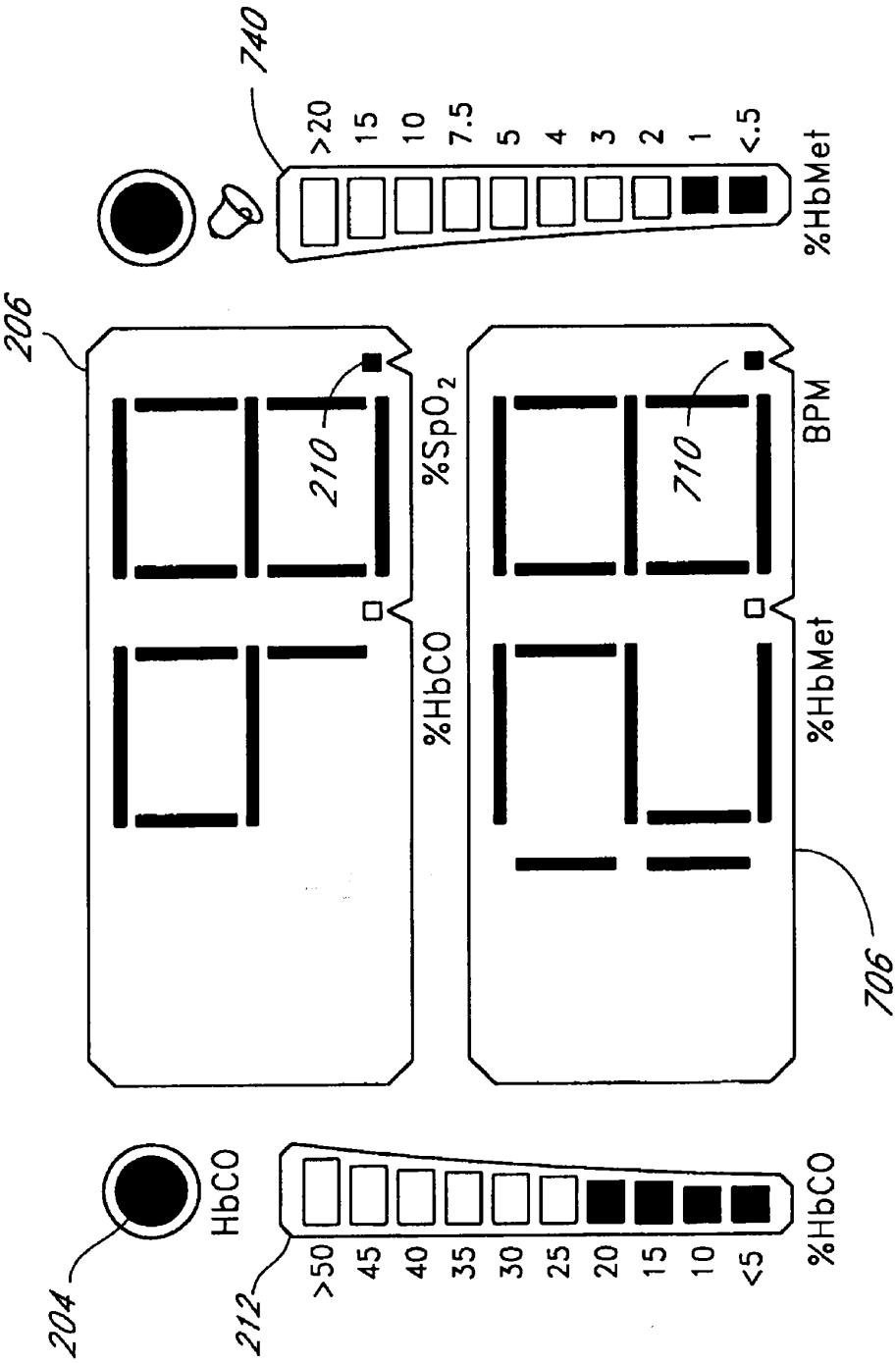

740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
%HbCO
710
BPM
%HbMet
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 9

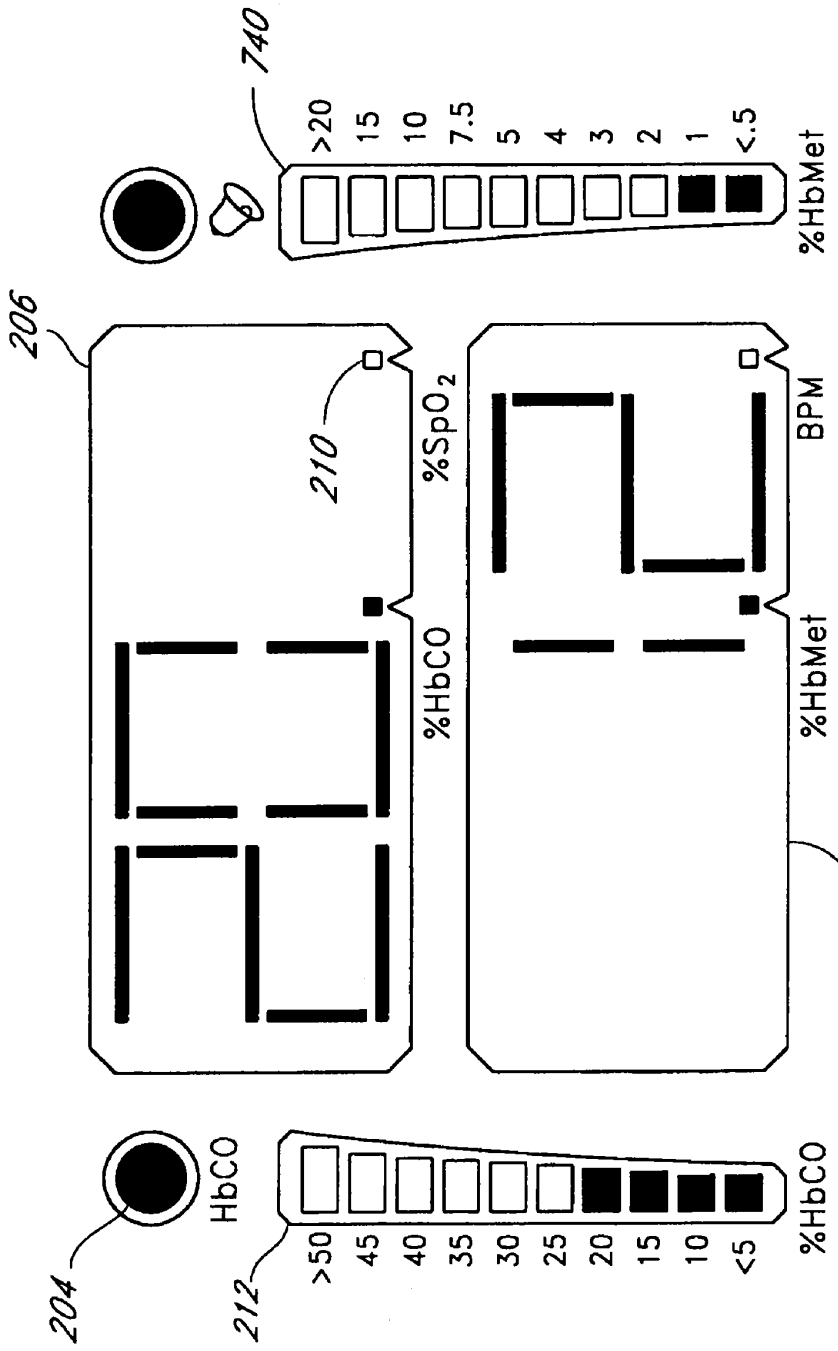

740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
%HbCO
BPM
%HbMet
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 10

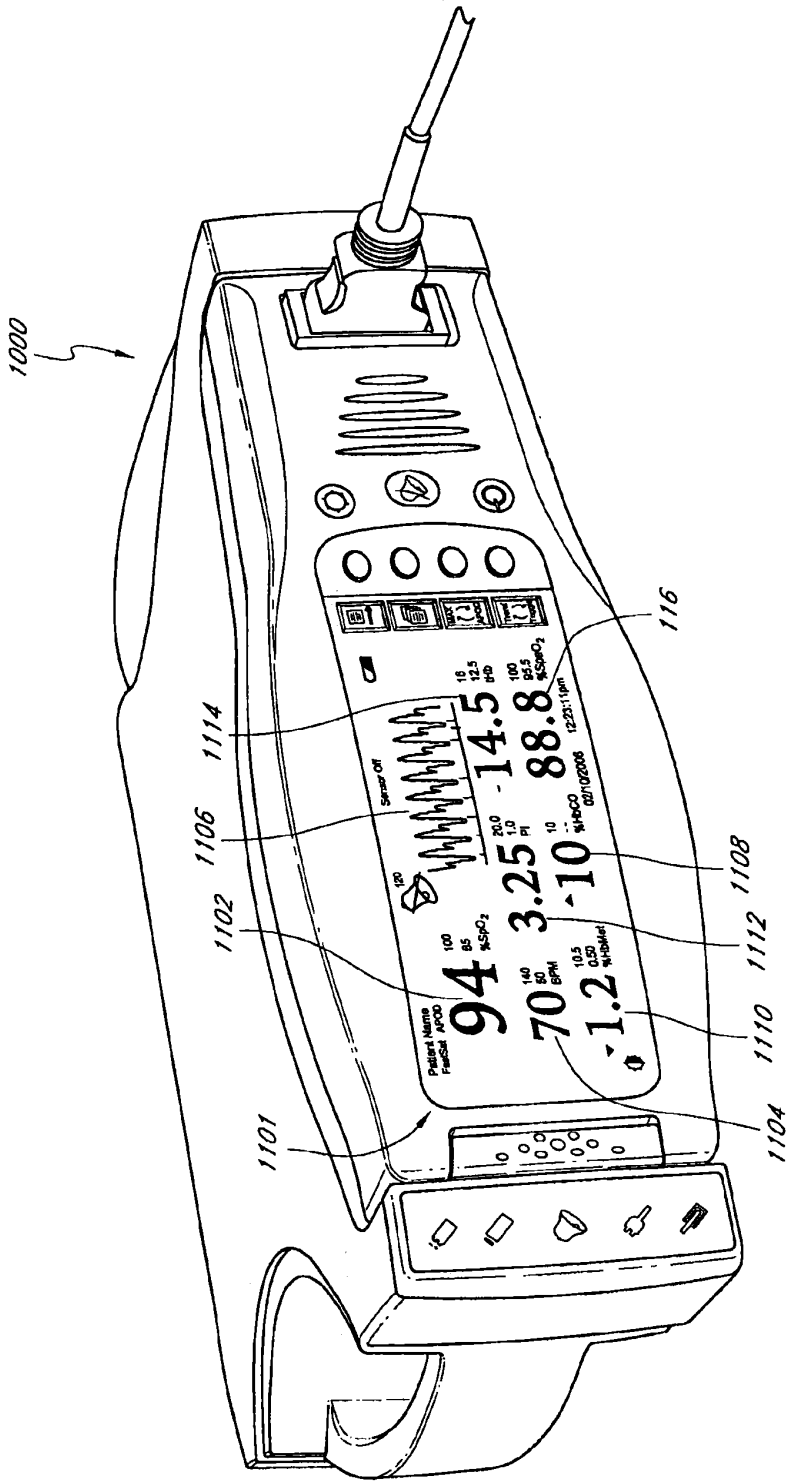

1000
1114
116
1106
1102
1108
1112
1110
1104
1101
Sensor Off
94
70
3.25
-14.5
88.8
-10
-1.2

FIG. 11A

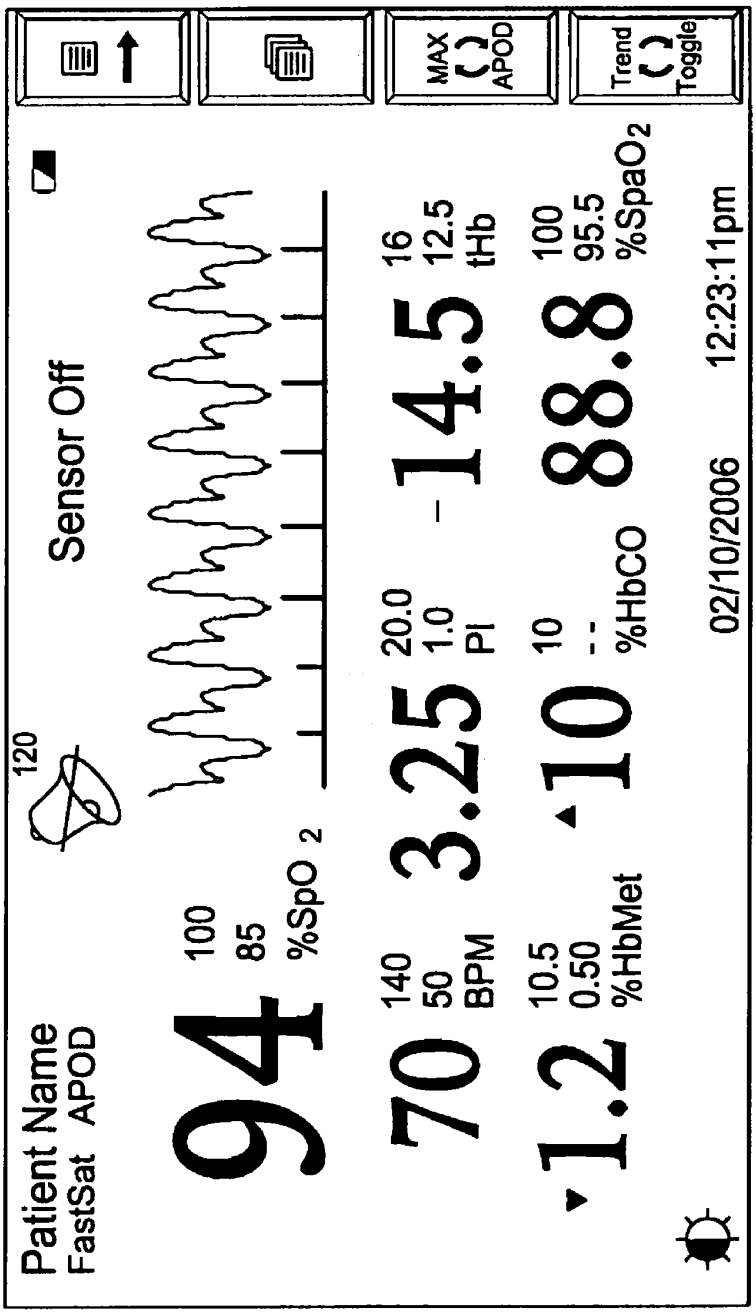

Patient Name
FastSat APOD
Sensor Off
120
MAX APOD
Trend Toggle
94
100
85
%SpO 2
70
140
50
BPM
3.25
20.0
1.0
PI
-14.5
16
12.5
tHb
1.2
10.5
0.50
%HbMet
10
10
--
%HbCO
88.8
100
95.5
%SpaO2
02/10/2006
12:23:11pm

FIG. 11B

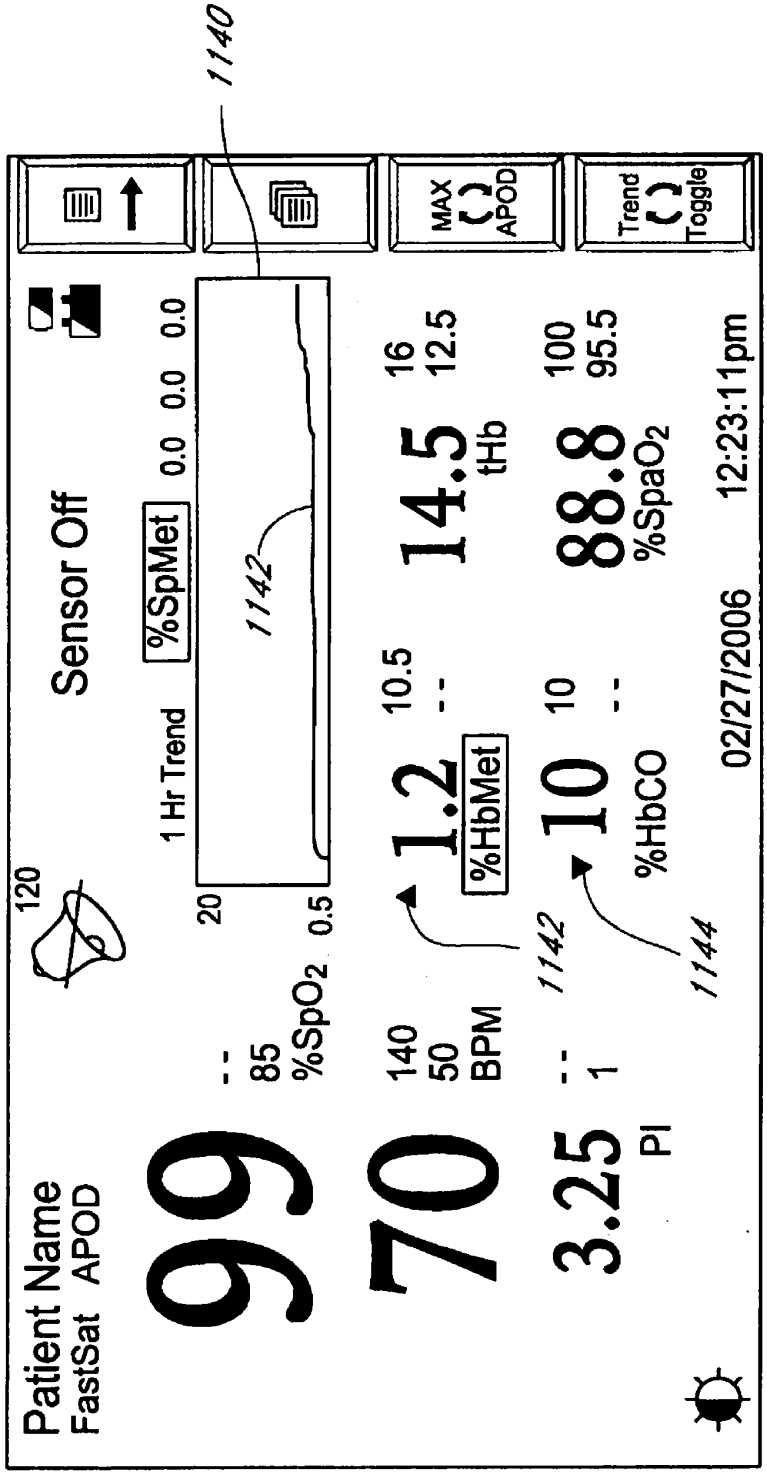

1140
MAX APOD
Trend Toggle
Patient Name
FastSat APOD
Sensor Off
120
1 Hr Trend
%SpMet
0.0 0.0 0.0
1142
20
0.5
%SpO2
99
85
--
140
50
BPM
70
1.2
%HbMet
10.5
--
1142
10
%HbCO
10
--
1144
3.25
PI
1
--
14.5
tHb
16
12.5
88.8
%SpaO2
100
95.5
02/27/2006
12:23:11pm

FIG. 11C

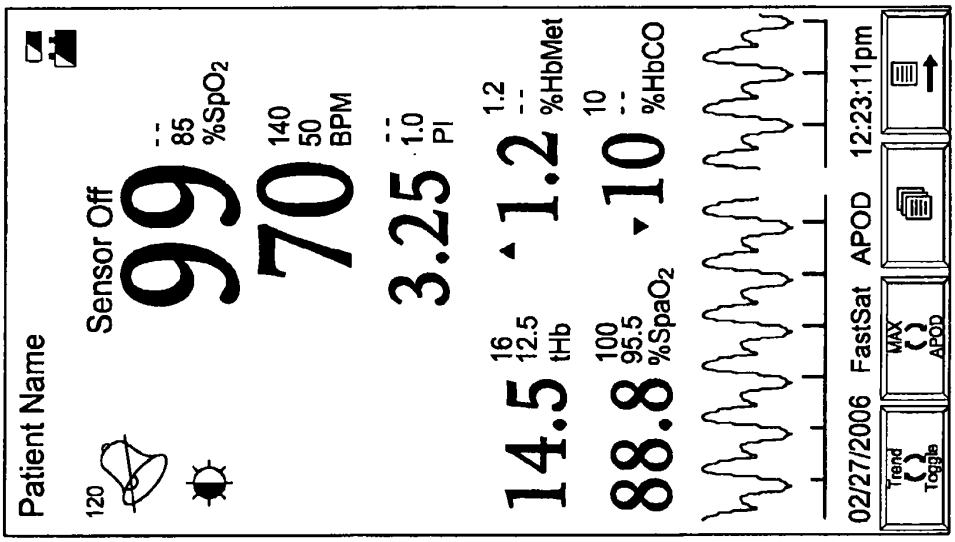

Patient Name
120
Sensor Off
99
85
%SpO2
70
140
50
BPM
3.25
1.0
PI
14.5
16
12.5
tHb
1.2
1.2
%HbMet
88.8
100
95.5
%SpaO2
10
10
%HbCO
02/27/2006
FastSat
APOD
12:23:11pm
Trend
Toggle
MAX
APOD

FIG. 11D

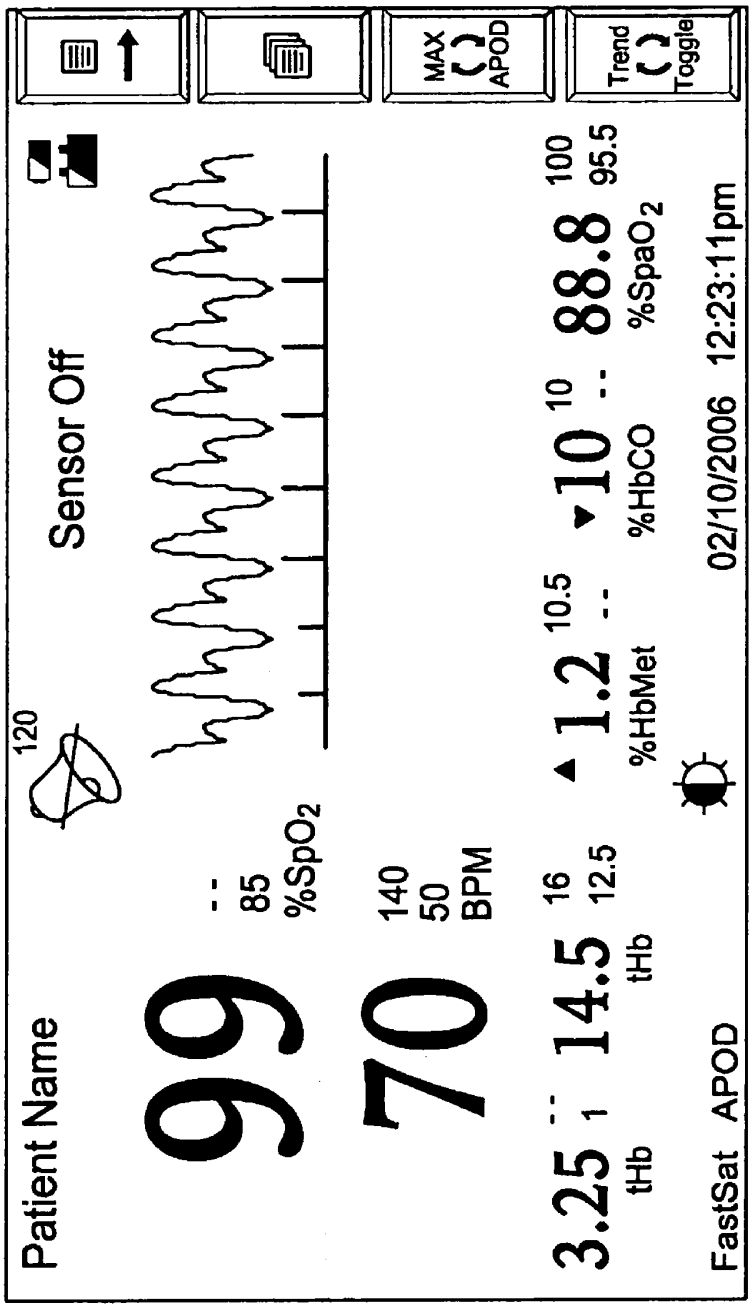

Patient Name
120
Sensor Off
MAX APOD
Trend Toggle
99
85
%SpO2
70
140
50
BPM
3.25
14.5
16
12.5
tHb
1.2
10.5
%HbMet
10
88.8
100
95.5
%SpaO2
%HbCO
02/10/2006 12:23:11pm
FastSat APOD

FIG. 11E

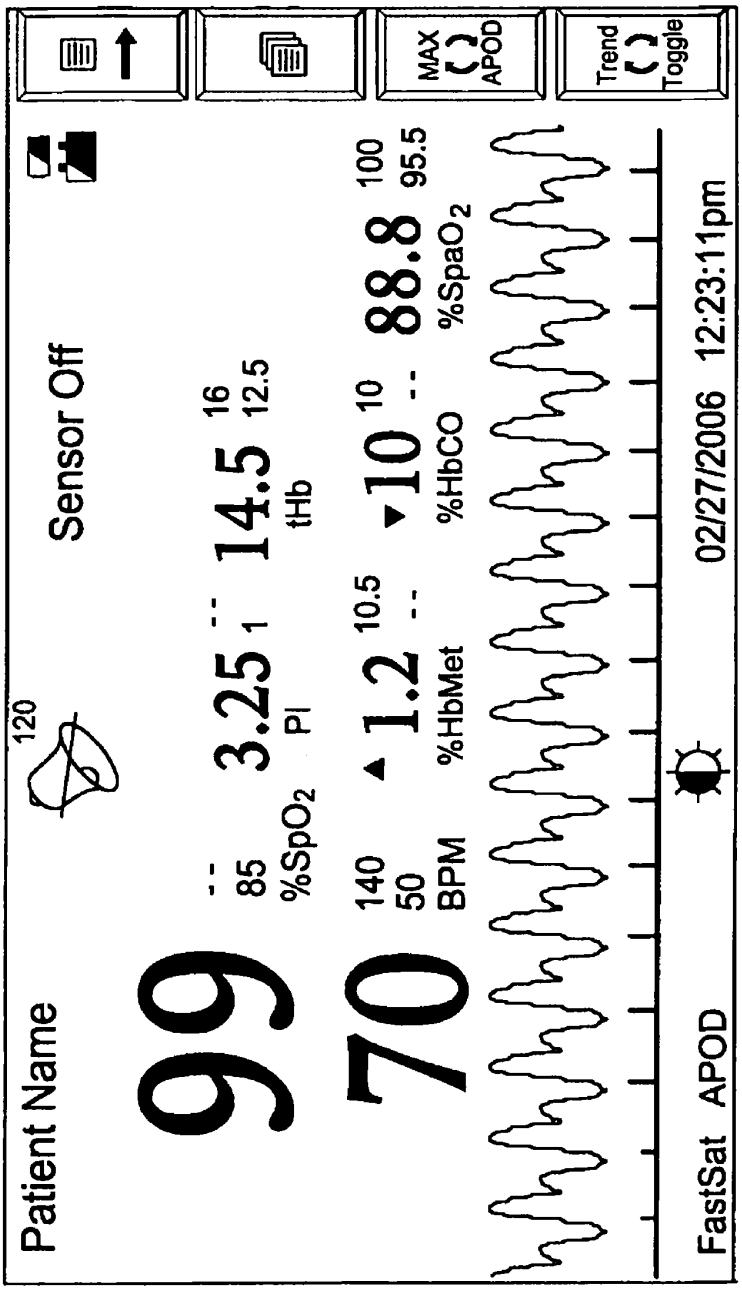

Patient Name
120
Sensor Off
MAX APOD
Trend Toggle
99
%SpO2
85
--
3.25
PI
1
--
14.5
tHb
16
12.5
70
BPM
140
50
1.2
%HbMet
10.5
--
10
%HbCO
10
--
88.8
%SpaO2
100
95.5
FastSat APOD
02/27/2006 12:23:11pm

FIG. 11F

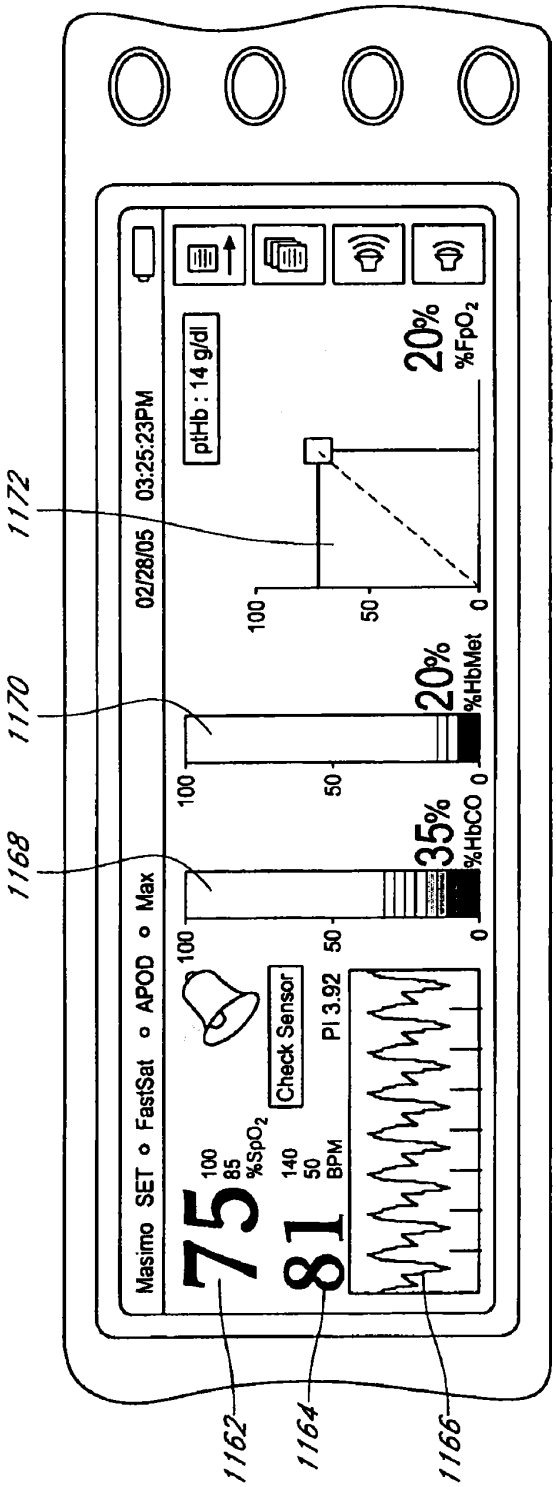

1172
1170
1168
1162
1164
1166
Masimo SET ○ FastSat ○ APOD ○ Max
02/28/05
03:25:23PM
ptHb : 14 g/dl
20%
%FpO2
100
50
0
20%
%HbMet
35%
%HbCO
Check Sensor
PI 3.92
75
81
100
85
%SpO2
140
50
BPM

FIG. 11G

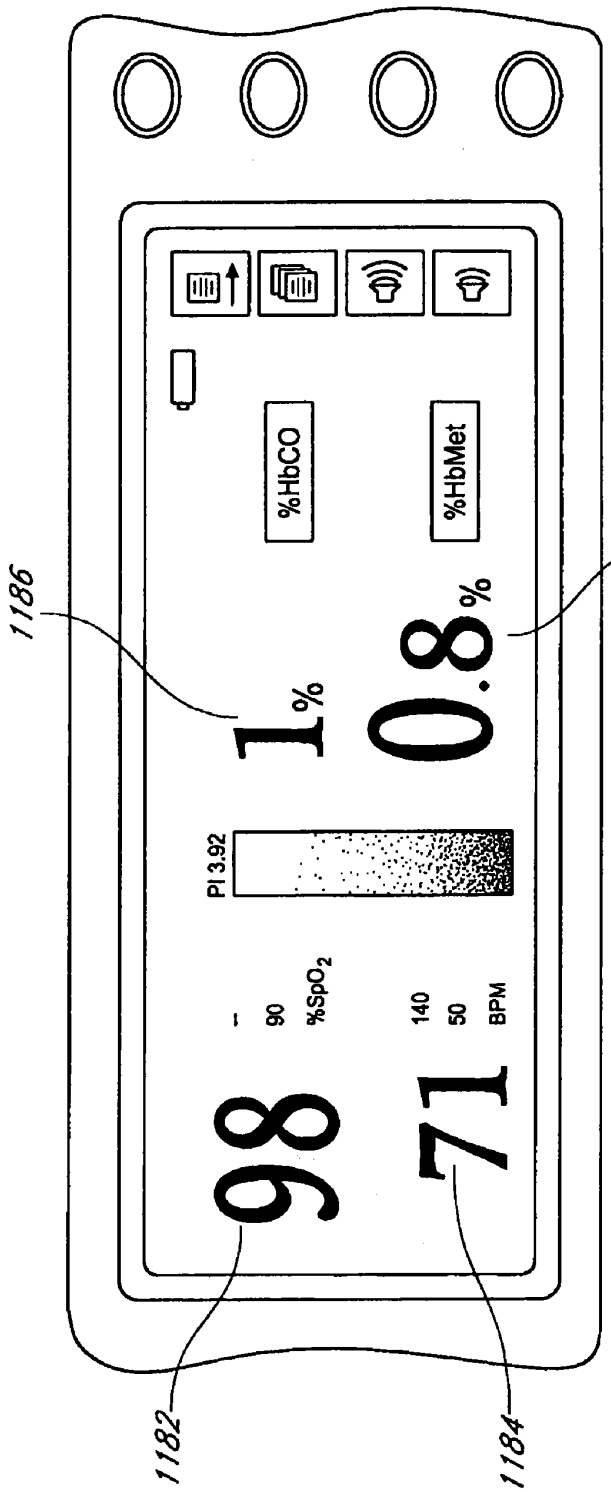

%HbCO
%HbMet
1%
0.8%
PI 3.92
90
%SpO2
140
50
BPM
98
71
1186
1188
1182
1184

FIG. 11H

NONINVASIVE MULTI-PARAMETER PATIENT MONITOR

PRIORITY CLAIM TO RELATED PROVISIONAL APPLICATIONS

The present application claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 60/657,596, filed Mar. 1, 2005, entitled "Multiple Wavelength Sensor," No. 60/657,281, filed Mar. 1, 2005, entitled "Physiological Parameter Confidence Measure," No. 60/657,268, filed Mar. 1, 2005, entitled "Configurable Physiological Measurement System," and No. 60/657,759, filed Mar. 1, 2005, entitled "Noninvasive Multi-Parameter Patient Monitor." The present application incorporates the foregoing disclosures herein by reference.

INCORPORATION BY REFERENCE OF RELATED UTILITY APPLICATIONS

The present application is related to the following copending U.S. utility applications:

	App. Sr. No.	Filing Date	Title	Atty Dock.
1	11/367,013	Mar. 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
2	11/366,995	Mar. 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/366,209	Mar. 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/366,210	Mar. 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/366,833	Mar. 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/366,997	Mar. 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/367,034	Mar. 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/367,036	Mar. 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/367,014	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
10	11/366,208	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

The present application incorporates the foregoing disclosures herein by reference.

FIELD OF THE DISCLOSURE

The present disclosure relates to the field of noninvasive patient monitors. More specifically, the disclosure relates to monitors displaying measurements derived using signals from optical sensors.

BACKGROUND

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ, the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{0,\lambda}} \tag{1}$$

$$\mu_{0,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \tag{2}$$

where $\mu_{0,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve Equations 1-2 are the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2, pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785. Read which are owned by Masimo, and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY OF THE DISCLOSURE

Despite the success of read through motion oximeter systems, there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to SpO_2, plethysmograph waveforms, or pulse rates. For example, in accessing a patient's condition, caregivers often desire knowledge of other blood constituents, including for example, a percent value for arterial carbon monoxide saturation ("HbCO") or a percent value for methemogobin saturation ("HbMet") or the like. For example, in an embodiment, the display advantageously displays one or more of the following: pulse rate, plethysmograph waveform data, perfusion index, values of blood constituents in body tissue, including for example, HbCO, HbMet, total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In other embodiments, the monitor may advantageously and accurately determine values for one or more of HbO_2, Hb, blood glucose,

water, the presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide ("CO_2") or oxygen ("O"), ph levels, bilirubin, perfusion quality, signal quality or the like. Accordingly, the present disclosure includes a multi-parameter patient monitor capable of determining one or more of the foregoing parameters, other than or in addition to, SpO_2, plethysmograph waveforms, or perfusion quality index.

In an embodiment, the display of a noninvasive multi-parameter patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display area or real estate. In an embodiment, a user may cycle different parameter values through an area of the display common to both parameters even when one parameter is shifted, through, for example, actuation of a user input key. The patient monitor may also display different parameters as color-coded. For example, when the following measured parameters are within "normal" ranges, SpO_2 may be displayed red, pulse rate (BPM) may be displayed green, HbCO may be displayed orange, HbMet may be displayed blue, or the like. In an embodiment, measured values of SpO_2 may be displayed in white, BPM may be displayed in yellow green or aquamarine, PI™ may be displayed in violet, Hbt may be displayed in grass green, HbMet may be displayed in blue or light blue, HbCO may be displayed in orange, and $SpaO_2$ may be displayed in electric blue.

Moreover, parameter trend data may also be displayed using the same or similar color coding, especially when multiple trends are displayed on one or more display graphs. In addition, more coarse or gross parameter indications may be displayed for quick reference to indicate to a caregiver whether any of a variety of monitored parameters, such as, for example, SpO_2, HbCO or HbMet is within acceptable ranges. The monitor may advantageously include additional display information, such as, for example, parametric displays where one parameter is displayed as a function of another, three dimensional displays (for example, extending a parametric display along time or an additional parameter), directional indicators predicting where a parameter is likely heading or reporting a general direction a parameters has been trending, or the like.

In addition to the foregoing, caregivers often desire to more closely monitor parameters that are close to, approaching, or beyond normal safe thresholds. In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical monitored parameters. In alternative embodiments, the patient monitor automatically changes display modes to show parameters moving closer to or beyond normal thresholds.

In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the monitor may determine how many wavelengths a particular attached sensor will emit through communication with memory devices associated with the attached sensor or cable.

Additional embodiments include audio or visual alarms for each of multiple monitored parameters, combinations of parameters, an indication of perfusion in the tissue of the measurement site, an indication of the confidence the signal processing has in its output measurements, or the like.

For purposes of summarization, certain aspects, advantages and novel features are described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features need to be present in any particular embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings and the associated descriptions are provided to illustrate embodiments of the disclosure and not to limit the scope of the claims.

FIG. **1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system including a sensor and a multi-parameter patient monitor.

FIG. **2** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO, such as, for example, the patient monitor of FIG. **1**.

FIG. **3** illustrates an exemplary display of the patient monitor of FIG. **2**.

FIG. ***4*** illustrates the display of FIG. **3** showing measured values of SpO_2, BPM, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **5** illustrates the display of FIG. **3** showing measured values of HbCO, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **6** illustrates the display of FIG. **3** showing measured values of SpO_2, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. **1**.

FIG. **8** illustrates an exemplary display of the patient monitor of FIG. **7**.

FIG. **9** illustrates the display of FIG. **8** showing measured values of SpO_2, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **10** illustrates the display of FIG. **8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **11**A illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor such as, for example, the patient monitor of FIG. **1**.

FIGS. **11**B-**11**H illustrate display screens of the patient monitor of FIG. **11**A.

DETAILED DESCRIPTION OF PREFERRED AND ALTERNATIVE EMBODIMENTS

Embodiments of the present disclosure include a portable or other multi-parameter patient monitor capable of determining multiple physiological parameters from one or more signals output from one or more light sensitive detectors capable of detecting light attenuated by body tissue carrying pulsing blood. For example, in an embodiment, the monitor advantageously and accurately determines a wide variety of physiological parameters or other calculations as discussed above.

In an embodiment, the display of patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate. For example, the patient monitor may include one or more user input keys capable of toggling through measurement data. In an embodiment, the displays include mode indicators providing caregivers easily identifiable visual queues, such as LED's, text, icons, or other indicia providing readily identifiable queues as to which parameter is being displayed. In an embodiment, the display may shift, may be parameter color-coded, or the like to further ensure

quick comprehension of which measured parameter is the displayed parameter. For example, in an embodiment, the monitor displays SpO_2 in white, pulse rate (BPM) in green, HbCO in orange, and HbMet in blue when the respective measured parameter is within a "normal" range.

In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical or time sensitive measured parameters, specific caregiver selected parameters, or the like. For example, the patient monitor may advantageously sound audio or visual alarms that alert the caregiver to particular one or more of worsening parameters, parameters changing in a predetermined pattern or rate, parameters stabilizing below user defined or safe thresholds, caregiver selected parameters, or the like. The monitor may also use alerts that provide audio or visual indications of the severity of the condition, severity of the change, or the like. In alternative embodiments, the patient monitor may automatically change display modes when a particular parameter crosses one or more thresholds. For example, a patient monitor may be displaying a first parameter, such as a plethysmograph, and upon determining measurements indicating that HBMet is trending toward an alarm condition, the monitor may automatically switch from displaying the first parameter to the alarming parameter, or in this case, a trend of the alarming parameter.

In an embodiment, a switch is provided to allow a user to switch displays to view an alarming measurement. In an embodiment, during an alarm condition, a parameter display may switch to a trend graph in the same or different color, line weight, flash, flash rate, intensity, size, or the like.

The patient monitor may also include one or more displays capable of displaying trend data for any one or more of the monitored or derived patient parameters. For example, the trend data may be displayed in graph form, may include multiple trend lines, each representing a different monitored or derived patient parameter. Moreover, each trend line may be color-coded to facilitate quick comprehension of which trend line represents which measured parameter. However, an artisan will recognize from the disclosure herein a large number of identification techniques including color-coding, identifying text, or the like. Additionally, user input may toggle displayed trend data, may select which parameters to display simultaneously, or the like.

In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the patient monitor may provide a particular audio or visual indication, such as a beep, LED activation, graphic activation, text messages, voice messages, or the like, to indicate communication with or connection to an approved sensor, patient cable, combination, or the like. In an embodiment, the indication may change based on the manufacturer, type of sensor recognized or not recognized, type of patient, type of physiological parameters measurable with the attached sensor, or the like. Additional embodiments include an indication of perfusion in the tissue of the measurement site and an indication of the confidence the signal processing has in its output measurements or input signal quality.

To facilitate an understanding of the disclosure, the remainder of the description references exemplary embodiments illustrated in the drawings. Moreover, in this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported herein in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

FIG. **1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system **100**. As shown in FIG. **1**, the system **100** includes a patient monitor **102** comprising a processing board **104** and a host instrument **108**. The processing board **104** communicates with a sensor **106** to receive one or more intensity signal(s) indicative of one or more parameters of tissue of a patient. The processing board **104** also communicates with a host instrument **108** to display determined values calculated using the one or more intensity signals. According to an embodiment, the board **104** comprises processing circuitry arranged on one or more printed circuit boards capable of installation into the monitor **102**, or capable of being distributed as some or all of one or more OEM components for a wide variety of host instruments monitoring a wide variety of patient information. In an embodiment, the processing board **102** comprises a sensor interface **110**, a digital signal processor and signal extractor ("DSP" or "processor") **112**, and an instrument manager **114**. In general, the sensor interface **110** converts digital control signals into analog drive signals capable of driving sensor emitters, and converts composite analog intensity signal(s) from light sensitive detectors into digital data.

In an embodiment, the sensor interface **110** manages communication with external computing devices. For example, in an embodiment, a multipurpose sensor port (or input/output port) is capable of connecting to the sensor **106** or alternatively connecting to a computing device, such as a personal computer, a PDA, additional monitoring equipment or networks, or the like. When connected to the computing device, the processing board **104** may upload various stored data for, for example, off-line analysis and diagnosis. The stored data may comprise trend data for any one or more of the measured parameter data, plethysmograph waveform data acoustic sound waveform, or the like. Moreover, the processing board **104** may advantageously download from the computing device various upgrades or executable programs, may perform diagnosis on the hardware or software of the monitor **102**. In addition, the processing board **104** may advantageously be used to view and examine patient data, including raw data, at or away from a monitoring site, through data uploads/downloads, or network connections, combinations, or the like, such as for customer support purposes including software maintenance, customer technical support, and the like. Upgradable sensor ports are disclosed in copending U.S. application Ser. No. 10/898,680, filed on Jul. 23, 2004, titled "Multipurpose Sensor Port," incorporated by reference herein.

As shown in FIG. **1**, the digital data is output to the DSP **112**. According to an embodiment, the DSP **112** comprises a processing device based on the Super Harvard ARChitecture ("SHARC"), such as those commercially available from Analog Devices. However, a skilled artisan will recognize from the disclosure herein that the DSP **112** can comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In particular, the DSP **112** includes program instructions capable of receiving multiple channels of data related to one or more intensity signals representative of the absorption (from transmissive or reflective sensor systems) of

a plurality of wavelengths of emitted light by body tissue. In an embodiment, the DSP **112** accepts data related to the absorption of eight (8) wavelengths of light, although an artisan will recognize from the disclosure herein that the data can be related to the absorption of two (2) to sixteen (16) or more wavelengths.

FIG. **1** also shows the processing board **104** including the instrument manager **114**. According to an embodiment, the instrument manager **114** may comprise one or more microcontrollers controlling system management, including, for example, communications of calculated parameter data and the like to the host instrument **108**. The instrument manager **114** may also act as a watchdog circuit by, for example, monitoring the activity of the DSP **112** and resetting it when appropriate.

The sensor **106** may comprise a reusable clip-type sensor, a disposable adhesive-type sensor, a combination sensor having reusable and disposable components, or the like. Moreover, an artisan will recognize from the disclosure herein that the sensor **106** can also comprise mechanical structures, adhesive or other tape structures, Velcro wraps or combination structures specialized for the type of patient, type of monitoring, type of monitor, or the like. In an embodiment, the sensor **106** provides data to the board **104** and vice versa through, for example, a patient cable. An artisan will also recognize from the disclosure herein that such communication can be wireless, over public or private networks or computing systems or devices, or the like.

As shown in FIG. **1**, the sensor **106** includes a plurality of emitters **116** irradiating the body tissue **118** with differing wavelengths of light, and one or more detectors **120** capable of detecting the light after attenuation by the tissue **118**. In an embodiment, the emitters **116** comprise a matrix of eight (8) emission devices mounted on a flexible substrate, the emission devices being capable of emitting eight (8) differing wavelengths of light. In other embodiments, the emitters **116** may comprise twelve (12) or sixteen (16) emitters, although other numbers of emitters are contemplated, including two (2) or more emitters. As shown in FIG. **1**, the sensor **106** may include other electrical components such as, for example, a memory device **122** comprising an EPROM, EEPROM, ROM, RAM, microcontroller, combinations of the same, or the like. In an embodiment, other sensor components may include a temperature determination device **123** or other mechanisms for, for example, determining real-time emission wavelengths of the emitters **116**.

The memory **122** may advantageous store some or all of a wide variety data and information, including, for example, information on the type or operation of the sensor **106**; type or identification of sensor buyer or distributor or groups of buyer or distributors, sensor manufacturer information, sensor characteristics including the number of emitting devices, the number of emission wavelengths, data relating to emission centroids, data relating to a change in emission characteristics based on varying temperature, history of the sensor temperature, current, or voltage, emitter specifications, emitter drive requirements, demodulation data, calculation mode data, the parameters for which the sensor is capable of supplying sufficient measurement data (e.g., HpCO, HpMet, HbT, or the like), calibration or parameter coefficient data, software such as scripts, executable code, or the like, sensor electronic elements, whether the sensor is a disposable, reusable, multisite, partially reusable, partially disposable sensor, whether it is an adhesive or non-adhesive sensor, whether the sensor is a reflectance, transmittance, or transreflectance sensor, whether the sensor is a finger, hand, foot, forehead, or ear sensor, whether the sensor is a stereo sensor or a two-headed sensor, sensor life data indicating whether some or all sensor components have expired and should be replaced, encryption information, keys, indexes to keys or hash functions, or the like, monitor or algorithm upgrade instructions or data, some or all of parameter equations, information about the patient, age, sex, medications, and other information that may be useful for the accuracy or alarm settings and sensitivities, trend history, alarm history, or the like. In an embodiment, the monitor may advantageously store data on the memory device, including, for example, measured trending data for any number of parameters for any number of patients, or the like, sensor use or expiration calculations, sensor history, or the like.

FIG. **1** also shows the patient monitor **102** including the host instrument **108**. In an embodiment, the host instrument **108** communicates with the board **104** to receive signals indicative of the physiological parameter information calculated by the DSP **112**. The host instrument **108** preferably includes one or more display devices **124** capable of displaying indicia representative of the calculated physiological parameters of the tissue **118** at the measurement site. In an embodiment, the host instrument **108** may advantageously comprise a handheld housing capable of displaying one or more of a pulse rate, plethysmograph data, perfusion quality such as a perfusion quality index ("PI™"), signal or measurement quality ("SQ"), values of blood constituents in body tissue, including for example, SpO_2, HbCO, HbMet, Hbt, or the like. In other embodiments, the host instrument **108** is capable of displaying values for one or more of Hbt, Hb, blood glucose, bilirubin, or the like. The host instrument **108** may be capable of storing or displaying historical or trending data related to one or more of the measured values, combinations of the measured values, plethysmograph data, or the like. The host instrument **108** also includes an audio indicator **126** and user input device **128**, such as, for example, a keypad, touch screen, pointing device, voice recognition device, or the like.

In still additional embodiments, the host instrument **108** includes audio or visual alarms that alert caregivers that one or more physiological parameters are falling below predetermined safe thresholds. The host instrument **108** may include indications of the confidence a caregiver should have in the displayed data. In a further embodiment, the host instrument **108** may advantageously include circuitry capable of determining the expiration or overuse of components of the sensor **106**, including, for example, reusable elements, disposable elements, or combinations of the same.

Although described in terms of certain embodiments, other embodiments or combination of embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **102** may comprise one or more monitoring systems monitoring parameters, such as, for example, vital signs, blood pressure, ECG or EKG, respiration, glucose, bilirubin, or the like. Such systems may combine other information with intensity-derived information to influence diagnosis or device operation. Moreover, the monitor **102** may advantageously include an audio system, preferably comprising a high quality audio processor and high quality speakers to provide for voiced alarms, messaging, or the like. In an embodiment, the monitor **102** may advantageously include an audio out jack, conventional audio jacks, headphone jacks, or the like, such that any of the display information disclosed herein may be audiblized for a listener. For example, the monitor **102** may include an audible transducer input (such as a microphone, piezoelectric sensor, or the like) for collecting one or more of heart sounds, lung sounds, trachea sounds, or other body sounds and such

sounds may be reproduced through the audio system and output from the monitor **102**. Also, wired or wireless communications (such as Bluetooth or WiFi, including IEEE 801.11a, b, or g), mobile communications, combinations of the same, or the like, may be used to transmit the audio output to other audio transducers separate from the monitor **102**.

For example, patterns or changes in the continuous noninvasive monitoring of intensity-derived information may cause the activation of other vital sign measurement devices, such as, for example, blood pressure cuffs.

FIG. **2** illustrates a perspective view of an exemplary handheld noninvasive multi-parameter patient monitor **200**, such as, for example, the patient monitor **102** of FIG. **2**. Patient monitors **200** exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57e." As shown in FIG. **1**, the monitor **200** includes a patient cable connector **202** capable of mechanical mating with a patient cable to establish communication between the board **104** and the sensor **106**. In an embodiment, the connector **202** comprises a multipurpose cable connector such as that disclosed in the incorporated U.S. application Ser. No. 10/898,680, titled "Multipurpose Sensor Port," disclosing communication between the board **104** and an external computing device.

The monitor **200** also comprises a HbCO indicator **204** advantageously providing a visual queue that a HbCO capable sensor is properly connected through the connector **202**. For example, the HbCO indicator **204** may advantageously activate when a sensor is connected that communicates sufficient information to determine HbCO, such as, for example, a sensor capable of emitting sufficient different wavelengths of light, a sensor storing sufficient data on the memory **122**, a sensor having appropriate encryption data or key, combinations of the same, or the like. For example, in an embodiment, the processor **112** may receive information from a memory **122** indicating a number of available LED wavelengths for the attached sensor. Based on the number of wavelengths, or other information stored on the memory **122**, the processor **112** may determine whether an HbCO-ready sensor has been attached to the monitor **200**. An artisan will also recognize from the disclosure herein that the HbCO indicator **204** may advantageously comprise a HbMet indicator, Hbt indicator, or the like, which activates to a predetermined color associated with a parameter, or any color, or deactivates the same, to convey a type of attached sensor. Moreover, the artisan will recognize from the disclosure herein other parameters that may use other sensor components and the monitor **200** may include indicators capable of indicating communication with those types of sensors.

In an embodiment, the monitor **200** may also audibly indicate the type of sensor connected. For example, the monitor **200** may emit predetermined number or frequency of beeps associated with recognition of a particular sensor, a particular manufacturer, failure to recognize the sensor, or the like. Moreover, the sensor type may be indicative of the componentry, such as, for example, whether the sensor produces sufficient data for the determination of HbCO, HbMet, Hbt and SpO_2, SpO_2 only, SpO_2 and HbMet, any combination of the foregoing or other parameters, or the like. Additionally, the sensor type may be indicative of specific sensors designed for a type of patient, type of patient tissue, or the like. In other embodiments, the monitor **200** may announce the type of connector through speaker **236**.

An artisan will also recognize from the disclosure herein that other mechanical (such as keys), electrical, or combination devices may inform the monitor **200** of the type of attached sensor. In an embodiment, the processor **112** also may select to drive less emitters that are currently available, such as, for example, in the presence of low noise and when power consumption is an issue.

The monitor **200** also comprises a multi-mode display **206** capable of displaying, for example, measurements of SpO_2 and HbCO (or alternatively, HbMet). In an embodiment, the display **206** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **200**. Thus, the multi-mode display **206** may advantageously cycle through two or more measured parameters in an area common to both parameters even when shifted. In such embodiments, the monitor **200** may also advantageously include parameter indicators **208**, **210**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **206** displays measured values of SpO_2 that are normal, the numbers may advantageously appear in green, while normal measured values of HbCO may advantageously appear in orange, and normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **206** flashes at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

The monitor **200** also comprises a HbCO bar **212** where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. For example, the bar **212** is lowest when the dangers from carbon monoxide poisoning are the least, and highest when the dangers are the greatest. The bar **212** includes indicia **214** that provide an indication of the severity of carbon monoxide saturation in a patient's blood. As shown in FIG. **2**, the bar **212** and the indicia **214** continuously indicate the concentration of HbCO in about 5% increments. The indicia **214** indicate a measurement of HbCO saturation percentage between about 0 and about 50% with a granularity of about 5%. However, an artisan will also recognize from the disclosure herein a wide variety of ranges and granularities could be used, the indicia **214** could be electronically displayed in order to straightforwardly increase or decrease resolution, or the like. For example, HbCO may advantageously be displayed with greater resolution than ± about %5 in a lower portion of the scale. For example, an HbCO bar may advantageously include a scale of about <3%, about 6%, about 9%, about 12%, about 15%, about 20%, about 25%, about 30%, about 35%, and about >40%.

As is known in the art, carbon monoxide in the blood can lead to serious medical issues. For example and depending upon the particular physiology of a patient, about 10% carbon monoxide saturation can lead to headaches, about 20% can lead to throbbing headaches, or dyspnea on exertion, about 30% can lead to impaired judgment, nausea, dizziness and/or vomiting, visual disturbance, or fatigue, about 40% can lead to confusion and syncope, and about 50% and above can lead to comas, seizures, respiratory failure and even death.

In an embodiment, the bar **212** is the same or similar color as the multi-mode display **206** when displaying HbCO. In other embodiments, the bar **212** is lowest and green when the dangers from carbon monoxide poisoning are the least, and highest and red when the dangers are the greatest. In an embodiment, as HbCO increases, the entire bar **212** may advantageously change color, such as, for example, from green to red, to provide a clear indication of deepening severity of the condition. In other embodiments, the bar **212** may advantageously blink or flash, an audio alarm may beep or

provide a continuation or rise in pitch or volume, or the like to alert a caregiver of deepening severity. Moreover, straightforward to complex alarm rules may be implemented to reduce false alarms based on, for example, knowledge of the physiological limitations on the rate of change in HbCO or the like.

Additionally, the monitor **200** may be capable of storing and outputting historical parameter data, display trend traces or data, or the like. Although the foregoing bar **212** has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

FIG. **2** also shows the monitor **200** including a pulse display **216** displaying measured pulse rate in beats per minute ("BPM"). In an embodiment, the display **212** flashes when searching for a pulse. The pulse display **216** advantageously displays measured pulse rates from about zero (0) to about two hundred and forty (240) BPM. Moreover, when the measured pulse rates are considered normal, the pulse display **216** is advantageously green. Similar to other displays associated with the monitor **200**, the pulse display **216** may employ a variety of color changes, audio alarms, or combinations of the same to indicate measured BPM below predetermined safe thresholds. In an embodiment, the pulse rate display **216** displays the measured pulse rate during the display of SpO_2 and displays message data during the display of other parameters. For example, during the display of HbCO, the display **216** may advantageously display the term "CO." In an embodiment, the display of the message data may be in the same or similar color as the other displays. For example, in an embodiment, the multi-mode display **206**, the bar **212**, and the pulse display **216** may all display data or messages in orange when the multi-mode display **206** displays measured HbCO values.

FIG. **2** also illustrates the monitor **200** comprising user input keys **218**, including a HbCO button **220**, mode/enter button **222**, next button **224**, power on/off button **226**, up/down button **228**, and alarm silence button **230**. In an embodiment, activation of the HbCO button **220** toggles the measured value displayed in the multi-mode display **206**. For example, activation of the HbCO button **220** toggles the multi-mode display **206** from displaying measured values of SpO_2 to HbCO for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **206** back to SpO_2. A skilled artisan will also recognize that activation of the HbCO button **220** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO_2, may remain displayed until further activation of the button **220**, or the like.

Activation of the mode/enter button **222** cycles through various setup menus allowing a caregiver to select or activate certain entries within the menu setup system, including alarm threshold customizations, or the like. Activation of the next button **224** can move through setup options within the menu setup system and in an embodiment is not active during normal patient monitoring. For example, a caregiver may activate the mode/enter button **222** and the next button **224** to specify high and low alarm thresholds for one or more of the measured parameters, to specify device sensitivity, trend settings, display customizations, color code parameters, or the like. In an embodiment, the high alarm setting for SpO_2 can range from about two percent (2%) to about one hundred percent (100%) with a granularity of about one percent (1%). The low alarm setting for SpO_2 can range from about one percent (1%) to about one hundred percent (100%) with a granularity of about one percent (1%). Moreover, the high alarm setting for pulse rate can range from about thirty (30) BPM to about two hundred and forty (240) BPM with a granularity of about five (5) BPM. The low alarm setting for pulse rate can range from about twenty five (25) BPM to about two hundred and thirty five (235) BPM with a granularity of about five (5) BPM. Other high and low ranges for other measured parameters will be apparent to one of ordinary skill in the art from the disclosure herein.

In a further embodiment, a caregiver may activate the mode/enter button **222** and the next button **224** to specify device sensitivity, such as, for example, device averaging times, probe off detection, whether to enable fast saturation calculations, or the like. Various embodiments of fast saturation calculations are disclosed in U.S. patent application Ser. No. 10/213,270, filed Aug. 5, 2002, titled "Variable Indication Estimator" and incorporated by reference herein. Using the menus, a caregiver may also advantageously enter appropriate information governing trend collection on one or more of the measured parameters, input signals, or the like.

FIG. **2** also shows the power on/off button **226**. Activation of the power on/off button **226** activates and deactivates the monitor **200**. In an embodiment, press-and-hold activation for about two (2) seconds shuts the monitor **200** off. In an additional embodiment, activation of the on/off button **226** advantageously initiates detection of a type of attached sensor. For example, activation of the on/off button **226** may advantageously cause the monitor **200** to read information from a memory on an attached sensor and determine whether sufficient wavelengths exist on the sensor to determine one or more the physiological parameters discussed in the foregoing.

An artisan will recognize from the disclosure herein that the on/off button **226** may advantageously cause an electronic determination of whether to operate in at powers consisted with the U.S. (60 Hz) or another nationality (50 Hz). In an embodiment, such automatic determination and switching is removed from the monitor **200** in order to reduce a likelihood of problematic interfering crosstalk caused by such power switching devices.

Activation of the up/down button **228** may advantageously adjust the volume of the pulse beep tone. Additionally, activation of the up/down button **228** within the menu setup system, causes the selection of values with various menu options.

Moreover, activation of the alarm silence button **230** temporarily silences audio alarms for a predetermined period, such as, for example, about one hundred and twenty (120) seconds. A second activation of the alarm silence button **230** mutes (suspends) the alarm indefinitely, while a third activation returns the monitor **200** to standard alarm monitoring. FIG. **2** also shows the alarm silence button **230** includes an alarm silenced indicator **232**. The alarm silenced indicator **232** may advantageously flash to indicate one or more alarms are temporarily silenced, may illuminate solid to indicate the alarms have been muted, or the like. Moreover, an artisan will recognize from the disclosure herein a wide variety of alarm silencing methodologies.

The monitor **200** also includes a battery level indicator **234** indicating remaining battery life. In the illustrated embodiment, four LED's indicate the status of the battery by incrementally deactivating to indicate proportionally decreasing battery life. In an embodiment, the four LED's may also change color as the battery charge decreases, and the final LED may begin to flash to indicate that the caregiver should replace the batteries.

FIG. **2** also shows the monitor **200** including an audio transducer or speaker **236**. The speaker **236** advantageously

provides audible indications of alarm conditions, pulse tone and feedback for key-presses, or the like. Moreover, the monitor **200** includes a low signal quality indicator ("SQ" or "SIQ™") **238**. The signal IQ indicator **238** activates to inform a caregiver that a measured value of the quality of the incoming signal is below predetermined threshold values. For example, in an embodiment, the measured value for signal IQ is at least partially based on an evaluation of the plethysmograph data's correspondence to predetermined models or characteristics of physiological signals. In an embodiment, the signal IQ indicator **238** output may be associated with the displayed parameter. For example, the output may be associated with one threshold for the display of SpO_2 and another for the display of other parameter data.

The monitor **200** also comprises a perfusion quality index ("PI™") bar **240** (which quantifies the measure of perfusion of the patient) where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. In one embodiment, the PI™ bar **240** shows a static value of perfusion for a given time period, such as, for example, one or more pulses. In another embodiment, or functional setting, the PI™ bar **240** may advantageously pulse with a pulse rate, may hold the last reading and optionally fade until the next reading, may indicate historical readings through colors or fades, or the like. Additionally, the PI™ bar **240** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

The PI™ bar **240** can be used to simply indicate inappropriate occlusion due, for example, to improper attachment of the sensor **106**. The PI™ bar **240** can also be used as a diagnostic tool during low perfusion for the accurate prediction of illness severity, especially in neonates. Moreover, the rate of change in the PI™ bar **240** can be indicative of blood loss, sleep arousal, sever hypertension, pain management, the presence or absence of drugs, or the like. According to one embodiment, the PI™ bar **240** values may comprise a measurement of the signal strength of the arterial pulse as a percentage of the total signal received. For example, in one preferred embodiment, the alternating portion of at least one intensity signal from the sensor **106** may advantageously be divided by the static portion of the signal. For example, an infrared intensity signal may advantageously be used as it is less subjective to noise.

In an embodiment, a measurement below about 1.25% may indicate medical situations in need of caregiver attention, specifically in monitored neonates. Because of the relevance of about 1.25%, the PI™ bar **240** may advantageously include level indicia **242** where the indicia **242** swap sides of the PI™ bar **240**, thus highlighting any readings below about that threshold. Moreover, behavior of the PI™ bar **240**, as discussed above, may advantageously draw attention to monitored values below such a threshold.

As discussed above, the monitor **200** may include output functionality that outputs, for example, trend perfusion data, such that a caregiver can monitor measured values of perfusion over time. Alternatively or additionally, the monitor **200** may display historical trace data on an appropriate display indicating the measured values of perfusion over time. In an embodiment, the trend data is uploaded to an external computing device through, for example, the multipurpose sensor connector **202** or other input output systems such as USB, serial or parallel ports or the like.

The monitor **200** also includes an alarm indicator **244** capable of providing visual queues of the status of one or more of the measured parameters. For example, the alarm indicator **244** may advantageously be green when all of the measured parameters are within normal conditions, may gradually fade to red, may flash, increasing flash, or the like, as one or more of the measured values approaches or passes predetermined thresholds. In an embodiment, the alarm indicator **244** activates when any parameter falls below an associated threshold, thereby advantageously informing a caregiver that perhaps a nondisplayed parameters is at an alarm condition. In another embodiment, the alarm indicator **244** may indicate the status of the parameter displayed on the multi-mode display **206**. In an embodiment, the speaker **236** may sound in conjunction with and/or in addition to the indicator **244**. Moreover, in an embodiment, an alarming parameter may automatically be displayed, may be emphasized, flashed, colored, combinations of the same or the like to draw a user's attention to the alarming parameter.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

FIG. **3** illustrates an exemplary display of the patient monitor **200**. As shown in FIG. **3**, the display includes the multi-mode display **206**, the pulse rate display **216**, parameter indicators **208**, **210**, the HbCO bar **212** and indicator **204**, the PI™ bar **240**, and the alarm indicator **244**. In an embodiment, the multi-mode display **206** and the pulse rate display **216** each comprise a plurality of seven segment displays **302** capable of displaying alpha-numeric information. As disclosed in the foregoing, the exemplary display may advantageously include color-coded parameter displays. Moreover, the exemplary display may include color progressions, flashing, flashing progressions, audible alarms, audible progressions, or the like, indicating worsening measured values of physiological data. In addition, in an embodiment, some or all of the displays may flash at a first rate to indicate attempts to acquire data when actual measured values are unavailable. Moreover, some or all of the display may flash at a second rate to indicate low signal quality where confidence is decreasing that the measured values reflect actual physiological conditions.

FIG. **4** illustrates the display of FIG. **3** showing measured values of SpO_2, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **4**, the multi-mode display **206** is displaying a percentage value of SpO_2, and the pulse rate display **216** is displaying a pulse rate in beats per minute. Accordingly, the parameter indicator **210** is activated to confirm the display of measured values of SpO_2. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** is red, indicating blood oxygen measurements while the pulse rate display **216** is green, indicating normal values of a patient's pulse.

FIG. **4** also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the HbCO indicator **204** is showing communication with a sensor producing insufficient data to determine measured values of additional parameters, such as, HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about two (2) different wavelengths, may comprise sensors with insufficient data stored on a memory associated therewith, or the like.

FIG. **5** illustrates the display of FIG. **3** showing measured values of HbCO, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **5**, the multi-mode display **206** is displaying a percentage value of HbCO, and the pulse rate display **216** is displaying an appropriate message indicating the HbCO measurement, such as, for example, "CO". Also, the multi-mode display **206** has shifted the data to the left to quickly and

efficiently indicate that the displayed parameter is other than SpO_2. Accordingly, the parameter indicator **208** is also activated to confirm the display of measured values of HbCO. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** and pulse rate display message **216** are orange.

FIG. **5** also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about eight (8) or more different wavelengths; however, such sensors may comprise about two (2) or more different wavelengths. Moreover, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. **5** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

FIG. **6** illustrates the display of FIG. **3** showing measured values of SpO_2, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. In contrast to FIG. **4**, FIG. **6** shows that the monitor **200** is communicating with a sensor capable of producing sufficient data to determine measured values of HbCO, even though the displayed values are that of SpO_2 and BPM. Thus, FIG. **6** shows the activation of the HbCO indicator **204**, and the continuous monitoring of HbCO by the HbCO bar **212**. FIG. **6** also shows a high value of HbCO, and therefore, the indication of an alarm condition by activation of the alarm indicator **244**. In an embodiment, upon determination of an alarm condition on a nondisplayed parameter, the monitor **200** may advantageously provide an alarm indication through speaker and alarm indicator activation, automatic toggle to the nondisplayed parameter on the multi-mode display **206** for a defined or undefined time, or the like.

FIG. **7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor **700** capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. **1**. Patient monitors exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57 cm." As shown in FIG. **7**, the monitor **700** comprises a monitor similar to monitor **200** disclosed with reference to FIG. **2**. Moreover, monitor **700** further includes a multi-mode display **706** capable of displaying, for example, measurements of HbMet and BPM. In an embodiment, the display **706** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **700**. Thus, the multi-mode display **706** may advantageously cycle through two or more measured parameters. In such embodiments, the monitor **700** may also advantageously include parameter indicators **708**, **710**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display **706** may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **706** displays measured values of BPM that are normal, the numbers may advantageously appear in green, while normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **706** may flash at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

FIG. **7** also illustrates the monitor **700** comprising user input keys **718**, including an HbCO/HbMet button **220**. In an embodiment, activation of the HbCO/HbMet button **720** toggles the measured value displayed in the multi-mode display **706**. For example, activation of the HbCO/HbMet button **720** toggles the multi-mode display **206** from displaying measured values of SpO_2 and BPM, to HbCO and HbMet for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **706** back to SpO_2 and BPM. A skilled artisan will also recognize that activation of the HbCO/HbMet button **720** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO_2 and BPM, may remain displayed until further activation of the button **720**, or the like.

The monitor **700** also comprises a coarser indication of HbMet through an HbMet bar **740**. In an embodiment, a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value, with increments at about 0.5%, about 1%, about 2%, about 3%, about 4%, about 5%, about 7.5%, about 10%, about 15% and greater than about 20%, although an artisan will recognize from the disclosure herein other useful delineations. Additionally, the HbMet bar **740** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

Although disclosed with reference to the HbMet bar **740**, and artisan will recognize from the disclosure herein other coarse or even gross indications of HbMet, or any measured parameter. For example, a single LED may advantageously show green, yellow, and red, to indicate worsening coarse values of HbMet. Alternatively, a single LED may simply light to indicate an alarm or approaching alarm condition.

FIG. **8** illustrates an exemplary display of the patient monitor **700** of FIG. **7**. As shown in FIG. **8**, the display includes the multi-mode displays **206**, **706**, parameter indicators **208**, **210**, **708**, **710**, the HbCO bar **212** and indicator **204**, the HbMet bar **740**, and the alarm indicator **244**. In an embodiment, the multi-mode display **706** is similar to multi-mode display **206**, comprising a plurality of seven segment displays **302** capable of displaying alpha-numeric information, and capable of altering its display characteristics or aspects in a wide variety of configurations discussed with reference to the display **206**.

FIG. **9** illustrates the display of FIG. **8** showing measured values of SpO_2, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**. FIG. **9** also shows the HbMet bar **740** near the bottom and corresponding to about 1%, representing acceptable HbMet, while the HbCO bar **212** hovers at a dangerous near 20%. In addition, the HbCO indicator **204** is showing communication with a sensor producing sufficient data to determine measured values of additional parameters, such as, HbMet, HbCO or the like. In an embodiment, such sensors may comprise sensors capable of emitting light of more than two (2) different wavelengths, preferably more than four (4) different wavelengths, and more preferably eight (8) or more different wavelengths.

FIG. **10** illustrates the display of FIG. **8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **10**, the multi-mode display **706** is displaying a percentage value of HbMet that is shifted using the parameter indicator **708**. The data has been advantageously shifted to the left to quickly and efficiently indicate that the displayed parameter is other than BPM. Accordingly, the parameter indicator **708** is also activated to confirm the display of mea-

sured values of HbMet. As disclosed in the foregoing, in an embodiment, the multi-mode display **706** is blue.

FIG. **10** also shows the HbMet bar **740** nearly empty, representing acceptable HbMet. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. **10** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

FIG. **11**A illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor **1100**, such as, for example, the patient monitor of FIG. **1**. Moreover, FIGS. **11**B-**11**E illustrate exemplary display screens of the patient monitor of FIG. **11**A. As shown in FIGS. **11**A-**11**B, an embodiment of the monitor **1100** includes a display **1101** showing a plurality of parameter data. For example, the display may advantageously comprise a CRT or an LCD display including circuitry similar to that available on oximeters commercially available from Masimo Corporation of Irvine, Calif. sold under the name Radical™, and disclosed in the U.S. patents referenced above and incorporated above. However, an artisan will recognize from the disclosure herein many commercially available display components capable of displaying multiple parameter data along with the ability to display graphical data such as plethysmographs, trend traces, and the like.

In an embodiment, the display includes a measured value of SpO_2 **1102**, a measured value of pulse rate **1104** in BPM, a plethysmograph **1106**, a measured value of HbCO **1108**, a measured value of HbMet **1110**, a measured value of a perfusion quality **1112**, a measured value of Hbt **1114**, and a derived value of fractional saturation "$SpaO_2$" **116**. In an embodiment, $SpaO_2$ comprises HbO_2 expressed as a percentage of the four main hemoglobin species, i.e., HbO_2, Hb, HbCO, and HbMet.

In an embodiment, one or more of the foregoing parameter includes trending or prediction indicators **1118** showing the current trend or prediction for that corresponding parameter. In an embodiment, the indicators **1118** may advantageously comprise an up arrow, a down arrow, and a hyphen bar to indicate up trending/prediction, down trending/prediction, or neutral trending/prediction.

FIG. **11**C illustrates an exemplary display screen showing trend graph **1140** including trend line **1142** for HbMet. In an embodiment, the trend line **1142** may be advantageously colored for quick straightforward recognition of the trending parameter, may be associated with any one or more of the foregoing alarm attributes, may include trending lines for other parameters, or the like. The display screen also shows trending directional indicators **1142**, **1144** for many of the displayed physiological parameters. In an embodiment, the directional indicators **1142**, **1144** may advantageously comprises arrows showing the recent trend, predicted trend, user-customizable trend, combinations thereof, or the like for the associated parameters. In an embodiment, the directional indicators **1142**, **1144** comprises an up arrow indicating a rising trend/predicted trend, a middle bar indicating a somewhat stable trend/predicted trend, and a down arrow indicating a lowering trend/predicted trend. An artisan will recognize a wide variety of other directional indicators **1142**, **1144** from the disclosure herein.

FIG. **11**D shows an exemplary display screen in vertical format. Such vertical format could be user actuated or based on a gravity switch. FIGS. **11**E-**11**F illustrate additional displays of various physiological parameters similar to those discussed in the foregoing. being As shown in FIG. **11**G, the display includes a measured value of SpO_2 **1162**, a measured value of pulse rate **1164** in BPM, a plethysmograph **1166**, a HbCO bar **1168**, and a HbMet bar **1170**. In an embodiment, the HbCO bar **1168** and HbMet bar **1170** may advantageously behave the same or similarly to the HbCO bar **212** and HbMet bar **712**. Moreover, similar bars may advantageously display any of the physiological parameters discussed herein using display indicia appropriate to that parameter. For example, a SpO_2 or $SpaO_2$ bar may advantageously range from about 0% to about 100%, and more preferably range from about 50% to about 100%, while a Hbt bar may advantageously range from about 0 to about 30.

Moreover, similar to the disclosure above, the measured value of SpO_2 **1162** may advantageously toggle to measured values of HbCO, HbMet, Hbt, or the like based on, for example, actuation of user input keys, or the like.

In addition to the foregoing, the display may also include graphical data showing one or more color-coded or other identifying indicia for traces of trend data. Moreover, other graphical presentations may advantageously provide readily identifiable indications of monitored parameters or combinations of monitored parameters of the patient. For example, in an embodiment, the display includes a $SpaO_2$ graph **1172**. The $SpaO_2$ graph **1172** plots SpO_2 as a function of other blood analytes (1-$SpaO_2$), where $SpaO_2$ comprises HbO_2 expressed as a percentage of the four main hemoglobin species, i.e., HbO_2, Hb, HbCO, and HbMet. Thus, as shown in FIG. **11**C, as the slope of the displayed line or arrow increases, the caregiver can readily note that the majority of hemoglobin carriers are being used to carry oxygen, and not, for example, harmful carbon monoxide. On the other hand, as the slope decreases, the caregiver can readily and advantageously note that the number of hemoglobin species available to carry oxygen is decreasing, regardless of the current value of SpO_2. Moreover, the length of the arrow or line also provides an indication of wellness, e.g., the higher the line the more oxygen saturation, the lower the line, the more likely there may be desaturation event, or the like.

Thus, the $SpaO_2$ graph **1172** provides the caregiver with the ability to recognize that even though the measured value of SpO_2 may be within acceptable ranges, there are potentially an unacceptable number of hemoglobin carriers unavailable for carrying oxygen, and that other potential problems may exist, such as, for example, harmful carbon monoxide levels, or the like. In an embodiment, various alarm conditions may cause the graph **1172** to change color, flash, or any combination of alarm indications discussed in the foregoing. Moreover, FIG. **11** illustrates yet an additional display of the foregoing parameters.

An embodiment may also include the monitor **1000** advantageously defining regions of wellness/severity of the monitored patient. For example, because the graph **1172** comprises two dimensions, the monitor **1000** may advantageously define regions where the patient's measured physiological parameters are considered acceptable, regions where the patient is considered at risk, regions where the patient is critical, and the like. For example, one region of acceptability may include a high SpO_2 and a low 1-$SpaO_2$, another region of risk may include a high SpO_2 and a high 1-$SpaO_2$, and another critical region may include a low SpO_2 and a high 1-$SpaO_2$. Moreover, an artisan will recognize from the dis-

closure herein that different parameters may also be combined to provide readily identifiable indications of patient wellness.

In addition to or as an alternative to the two dimensional $SpaO_2$ graph **1172**, the monitor **1000** may also include a three dimensional graph, such as, for example, extending the graph **1172** along the variable of time. In this embodiment, the forgoing regions advantageously become three dimensional surfaces of wellness. Moreover, trend data may also be advantageously added to the surface to provide a history of when particular monitored parameters dipped in and out of various surfaces of wellness, risk, criticality, or the like. Such trend data could be color-coded, text identified, or the like. An artisan will also recognize that such surfaces may be dynamic. For example, measurements of HbCO> about 5 may dictate that trend data showing SpO_2< about 90% should be considered critical; however, measurements of HbCO< about 5 may dictate only SpO_2< about 85% would be critical. Again, an artisan will recognize from the disclosure herein other parameter combinations to create a wide variety of wellness/critical regions or surfaces that provide readily available visual or audio indications of patient well being, trigger specific alarms, or the like.

Moreover, the monitor **1000** may advantageously employ enlargement or reorganization of parameter data based on, for example, the severity of the measurement. For example, the monitor **1000** may display values for HbCO in a small portion of the screen or in the background, and when HbCO begins to approach abnormal levels, the small portion may advantageously grown as severity increases, even in some embodiments to dominate the display. Such visual alarming can be combined with audio alarms such as announcements, alarms, rising frequencies, or the like, and other visual alarms such as flashing, coloration, or the like to assist a caregiver in noticing the increasing severity of a monitored parameter. In an embodiment, a location of the display of an alarming value is changed to be displayed in a larger display area, such as **1102**, so as to be readily noticeable and its display values readily ascertainable.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **100** may advantageously be adapted to monitor or be included in a monitor capable of measuring physiological parameters other than those determined through absorption spectroscopy, such as, for example, blood pressure, ECG, EKG, respiratory rates, volumes, inputs for blood pressure sensors, acoustical sensors, and the like. Moreover, the monitor **100** may be adapted for wireless communication to and from the sensor **106**, and/or to and from other monitoring devices, such as, for example, multi-parameter or legacy monitoring devices.

Also, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

What is claimed is:

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

2. The patient monitor of claim **1**, wherein the first display area and the second display area comprise the common display area.

3. The patient monitor of claim **1**, wherein activation of a user input causes the common display area to change from displaying one of the measured value of the first or second physiological parameter to displaying the other of the measured value of the first or second physiological parameter.

4. The patient monitor of claim **1**, wherein the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.

5. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an invasively measured value.

6. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises a non-invasively measured value.

7. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises glucose.

8. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

9. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

10. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

11. The patient monitor of claim **1**, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters.

12. The patient monitor of claim **11**, wherein the aspect that changes comprises a display color.

13. The patient monitor of claim **11**, wherein the aspect that changes comprises a display size.

14. The patient monitor of claim **11**, wherein the aspect that changes comprises a display intensity.

15. A patient monitor capable of measuring at least two physiological parameters. the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values

of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

16. The patient monitor of claim **15**, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters.

17. The patient monitor of claim **16**, wherein the aspect that changes comprises a display color.

18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

19. The patient monitor of claim **18**, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.

20. The patient monitor of claim **18**, wherein at least one of measured physiological parameters is determined noninvasively.

21. A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

displaying a measured value of a first physiological parameter in a display location of an electronic display; and

replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.

22. The method of claim **21**, wherein the indication of the worsening state comprises an alarm condition.

23. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an invasively measured value.

24. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

25. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

26. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

28. The patient monitor of claim **27**, wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

29. The patient monitor of claim **27**, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.

30. The patient monitor of claim **27**, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.

31. The patient monitor of claim **27**, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.

32. The patient monitor of claim **27**, wherein the attached sensor can provide data through the output signal and through a memory device.

33. The patient monitor of claim **27**, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.

34. The patient monitor of claim **27**, further comprising a memory for storing trend data on one or more of the first and second blood parameters.

35. The patient monitor of claim **27**, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.

36. The patient monitor of claim **27**, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.

37. The patient monitor of claim **36**, wherein the alarm comprises at least one of an audio or visual alarm.

38. The patient monitor of claim **27**, further comprising an additional display indicating perfusion through the body tissue.

39. The patient monitor of claim **27**, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.

40. The patient monitor of claim **39**, comprising an additional display capable of indicating the percent carbon monoxide saturation.

41. The patient monitor of claim 39, comprising an additional display capable of indicating the percent methemoglobin saturation.

42. The patient monitor of claim 27, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate.

43. The patient monitor of claim 42, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.

44. The patient monitor of claim 42, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

45. The patient monitor of claim 27, wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

46. The patient monitor of claim 45, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.

47. The patient monitor of claim 45, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button.

* * * * *

EXHIBIT I

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference MLR.012VPC	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2006/007389	International filing date *(day/month/year)* 01 March 2006 (01.03.2006)	Priority date *(day/month/year)* 01 March 2005 (01.03.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant MASIMO LABORATORIES, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 11 September 2007 (11.09.2007)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Athina Nickitas-Etienne
Facsimile No. +41 22 338 82 70	e-mail: pt04.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2006/007389	01.03.2006	01.03.2005

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/00

Applicant
MASIMO LABORATORIES, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	see form PCT/ISA/210	Abraham, V Telephone No. +49 30 25901-563

Form (PCT/ISA/237) (Cover Sheet) (April 2005)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6,7,13,15-23,27-29,33,35-37,41,43-63
	No:	Claims	1-5,8-12,14,24-26,30-32,34,38-40,42
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-63
Industrial applicability (IA)	Yes:	Claims	1-63
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item V.

1 Reference is made to the following documents:
D1 : US 2004/262046 A1 (SIMOND BENEDICTE [FR] ET AL) 30 December 2004 (2004-12-30)
D2 : US 6 397 093 B1 (ALDRICH THOMAS K) 28 May 2002 (2002-05-28)
D3 : US 2002/111748 A1 (KOBAYASHI NAOKI ET AL) 15 August 2002 (2002-08-15)
D4: US 2004/059209 A1 (AL-ALI AMMAR ET AL) 25 March 2004 (2004-03-25)
D5: US 2002/161291 A1 (KIANL MASSI E ET AL) 31 October 2002 (2002-10-31)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parentheses applying to this document):
A patient monitor capable of measuring at least two physiological parameters (paragraph [0023]), the patient monitor comprising a display (10) capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area (figure 4) or displaying a measured value of a second physiological parameter of the body tissue in a second display area (paragraph 0025]) where the first display area and the second display area comprise at least some common display area capable of displaying information (figure 4).

2.2 The subject-matter of claim 1 also lacks novelty over document D2 (see figure 7).

3. Since the subject-matter of independent claims 24 and 30 corresponds to the subject-matter of claim 1, the same reasoning as given for claim 1 will apply mutatis mutandis.

4 INDEPENDENT CLAIM 43

4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 43 does not involve an inventive step in the sense of Article

33(3) PCT. Document D1 discloses a display and a user input button to change from displaying the measured value of a first to a second parameter (paragraph [0025]). It is further disclosed that such a display may be useful in any body parameters measuring system (paragraph [0074]). The provision of a display according to document D1 in a blood parameter determining system measuring light attenuation by body tissue is thus an obvious design measure for the skilled person in order to simplify the display of multiple parameters.

5 DEPENDENT CLAIMS 2-23, 25-29, 31-42, 44-63
Dependent claims 2-23, 25-29, 31-42, 44-63 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty or inventive step (Article 33(2) and (3) PCT). The additional features of the dependent claims are either known from the prior art documents D1-D5 or are obvious design measures and would be readily incorporated by one skilled in the art according to circumstances and in view of their known technical effect.

6 The set of claims is not concise as required by Article 6 PCT since it is not drafted in terms of a single independent claim per category. The plurality of independent claims makes it difficult to determine the matter for which protection is sought.

7 The independent claims are not drafted in the two part form as required by Rule 6.3(b) PCT, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).

8 The features of the claims are not provided with reference signs placed in parentheses as required by Rule 6.2(b) PCT.

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
First Named Inventor/Applicant Name:	Ammar AL-ALI
Filer:	Marvin Jay Spivak/Diana Bowen
Attorney Docket Number:	403381US

Filed as Large Entity

ex parte reexam Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Request for ex parte reexamination	1812	1	2520	2520
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**2520**

Electronic Acknowledgement Receipt	
EFS ID:	13742804
Application Number:	90012559
International Application Number:	
Confirmation Number:	6710
Title of Invention:	NONINVASIVE MULTI-PARAMETER PATIENT MONITOR
First Named Inventor/Applicant Name:	Ammar AL-ALI
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Filer:	Marvin Jay Spivak/Diana Bowen
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Attorney Docket Number:	403381US
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The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees) Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		403381USRX223.pdf	6843885 c02f644f2e444a1c86f4777d2fbdf3b9f65e4964	yes	68
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Reexam Miscellaneous Incoming Letter		1	2	
	Receipt of Orig. Ex Parte Request by Third Party		3	66	
	Reexam - Info Disclosure Statement Filed by 3rd Party		67	67	
	Reexam Certificate of Service		68	68	
Warnings:					
Information:					
2	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	Ex-A-US8190223.pdf	1937199 76f2113c67176e7719e92dd320903565048c5707	no	38
Warnings:					
Information:					
3	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	EX-B-SelectedDocOf223FH.pdf	2881078 df7f3c08ed9c3ede709aa1383e4504e6ba8cc68e	no	71
Warnings:					
Information:					
4	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	Ex-C-US2002-0082488.pdf	1865085 66e5813e4afb5badfe09caacbd8f8c34a5b7f2c2	no	41
Warnings:					
Information:					
5	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	EX-D-US6658276Kianl.pdf	1246866 11db507cf9478278670be70cce33f91c0971c733	no	43
Warnings:					
Information:					
6	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	EX-E-US5842979Jarman.pdf	606807 5a16ebae3d1e4579784d874edc374dad900f5064	no	13
Warnings:					
Information:					

7	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	EX-F-US4051522Healy.pdf	794039 010a3f095cf4237f658b867ccbc2bb2c957f5640	no	14
Warnings:					
Information:					
8	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	Ex-G-US2003-0120164.pdf	1404299 3e4b6ee3e4eb58dc84f973bb6f8c1a0b822f2279	no	35
Warnings:					
Information:					
9	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	EX-H-US5743262.pdf	2026705 2f0e3753cb16acf18f27db75350467b52962cea8	no	34
Warnings:					
Information:					
10	Reexam - Affidavit/Decl/Exhibit Filed by 3rd Party	EX-I-PCTUS2006007389.pdf	218116 beb4882092ffd3e0ca4fc1a3e5891057743c7503	no	7
Warnings:					
Information:					
11	Fee Worksheet (SB06)	fee-info.pdf	29810 4da337b7fcc40c0ca7657ba9d6d1a7c743ac1dff	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	19853889		

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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Bib Data Sheet

CONFIRMATION NO. 6710

SERIAL NUMBER	FILING OR 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
90/012,559	09/13/2012 RULE	600	3993	403381US104RX

APPLICANTS

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**** CONTINUING DATA ***************************

This application is a REX of 11/367,033 03/01/2006 PAT 8190223
which claims benefit of 60/657,596 03/01/2005
and claims benefit of 60/657,281 03/01/2005
and claims benefit of 60/657,268 03/01/2005
and claims benefit of 60/657,759 03/01/2005

**** FOREIGN APPLICATIONS *********************

Foreign Priority claimed	STATE OR COUNTRY	SHEETS DRAWING	TOTAL CLAIMS	INDEPENDENT CLAIMS
☐ yes ☐ no			47	5
35 USC 119 (a-d) conditions met ☐ yes ☐ no ☐ Met after Allowance				
Verified and Acknowledged Examiner's Signature Initials				

ADDRESS
20995

TITLE

NONINVASIVE MULTI-PARAMETER PATIENT MONITOR

FILING FEE RECEIVED	FEES: Authority has been given in Paper	
2520	No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit