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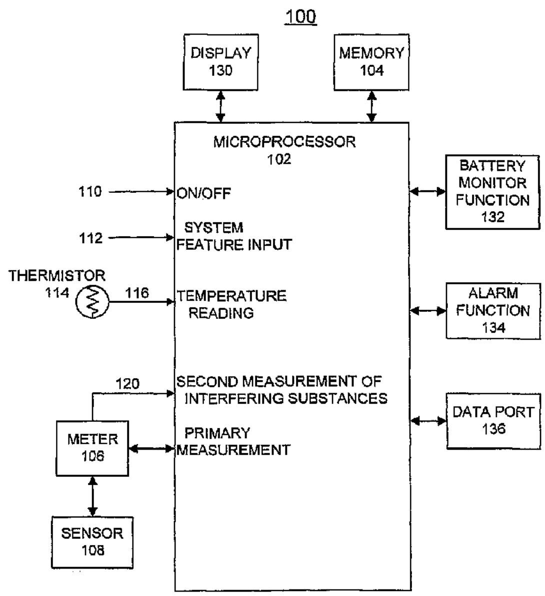
(54) Titre : PROCEDE ET APPAREIL DE MISE EN OEUVRE DE FONCTIONS DE CORRECTION BASEES SUR UN SEUIL POUR BIOCAPTEURS

(54) Title: METHOD AND APPARATUS FOR IMPLEMENTING THRESHOLD BASED CORRECTION FUNCTIONS FOR BIOSENSORS




(57) Abrégé/Abstract:
A biosensor system, method and apparatus are provided for implementing threshold based correction functions for biosensors. A primary measurement of an analyte value is obtained. A secondary measurement of a secondary effect is obtained and is compared with a threshold value. A correction function is identified responsive to the compared values. The correction function is applied to the primary measurement of the analyte value to provide a corrected analyte value. The correction method uses correction curves that are provided to correct for an interference effect. The correction curves can be linear or non-linear. The corrction method provides different correction functions above and below the threshold value. The correction functions may be dependent or independent of the primary measurement that is being corrected. The correction functions may be either linear or nonlinear.

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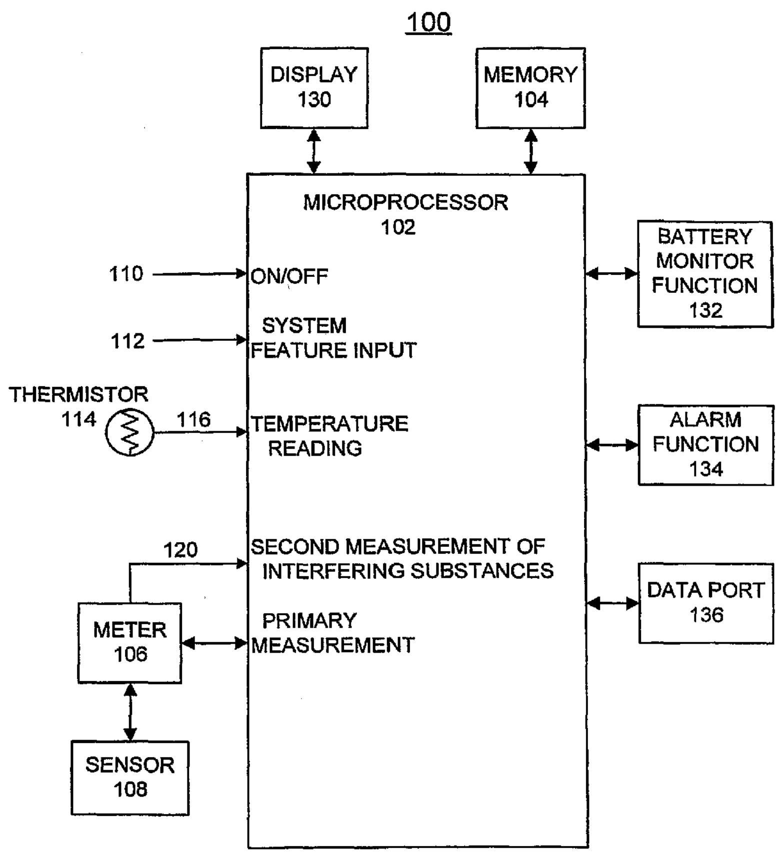
# (54) Title: METHOD AND APPARATUS FOR IMPLEMENTING THRESHOLD BASED CORRECTION FUNCTIONS FOR BIOSENSORS

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# METHOD AND APPARATUS FOR IMPLEMENTING THRESHOLD BASED CORRECTION FUNCTIONS FOR BIOSENSORS

## Field of the Invention

The present invention relates generally to biosensors, and more particularly, relates to a method and apparatus for implementing threshold based correction functions for biosensors.

## Description of the Related Art

The quantitative determination of analytes in body fluids is of great importance in the diagnoses and maintenance of certain physiological abnormalities. For example lactate, cholesterol and bilirubin should be monitored in certain individuals. In particular, the determination of glucose in body fluids is of great importance to diabetic individuals who must frequently check the level of glucose in their body fluids as a means of regulating the glucose intake in their diets. While the remainder of the disclosure herein will be directed towards the determination of glucose, it is to be understood that the procedure and apparatus of this invention can be used for the determination of other analytes upon selection of the appropriate enzyme. The ideal diagnostic device for the detection of glucose in fluids must be simple, so as not to require a high degree of technical skill on the part of the technician administering the test. In many cases, these tests are administered by the patient which lends further emphasis to the need for a test which is easy to carry out. Additionally, such a device should be based upon elements which are sufficiently stable to meet situations of prolonged storage.

Methods for determining analyte concentration in fluids can be based on the electrochemical reaction between an enzyme and the analyte specific to the enzyme and a mediator which maintains the enzyme in its initial oxidation state. Suitable redox enzymes include oxidases, dehydrogenases, catalase and peroxidase. For example, in the case where glucose is the analyte, the reaction with glucose oxidase and oxygen is represented by equation (A).

$$\text{glucose} + O_2 \xrightarrow{\text{glucose oxidase (GO)}} \text{gluconolactone} + H_2O_2 \quad \text{(A)}$$

In a colorimetric assay, the released hydrogen peroxide, in the presence of a peroxidase, causes a color change in a redox indicator which color change is proportional to the level of glucose in the test fluid. While colorimetric tests can be made semi-quantitative by the use of color charts for comparison of the color change of the redox indicator with the color change obtained using test fluids of known glucose concentration, and can be rendered more highly quantitative by reading the result with a spectrophotometric instrument, the results are generally not as accurate nor are they obtained as quickly as those obtained using an electrochemical biosensor. As used herein, the term biosensor system refer to an analytical device that responds selectively to analytes in an appropriate sample and converts their concentration into an electrical signal via a combination of a biological recognition signal and a physico-chemical transducer.

$$H_2O_2 \longrightarrow O_2 + 2H^+ + 2e^- \quad \text{(B)}$$

The electron flow is then converted to the electrical signal which directly correlates to the glucose concentration.

In the initial step of the reaction represented by equation (A), glucose present in the test sample converts the oxidized flavin adenine dinucleotide (FAD) center of the enzyme into its reduced form, ($FADH_2$). Because these redox centers are essentially electrically insulated within the enzyme molecule, direct electron transfer to the surface of a conventional electrode does not occur to any measurable degree in the absence of an unacceptably high overvoltage. An improvement to this system involves the use of a nonphysiological redox coupling between the electrode and the enzyme to shuttle electrons between the ($FADH_2$) and the electrode. This is represented by the following scheme in which the redox coupler, typically referred to as a mediator, is represented by M:

Glucose + GO(FAD) ——> gluconolactone + $GO(FADH_2)$

$GO(FADH_2)$ + $2M_{OX}$ ——> GO(FAD) + $2M_{red}$ + $2H^+$

$2M_{red}$ ——> $2M_{OX}$ + $2e^-$ (at the electrode)

In this scheme, GO(FAD) represents the oxidized form of glucose oxidase and $GO(FADH_2)$ indicates its reduced form. The mediating species $M_{red}$ shuttles electrons from the reduced enzyme to the electrode thereby oxidizing the enzyme causing its regeneration in situ which, of course, is desirable for reasons of economy. The main purpose for using a mediator is to reduce the working potential of the sensor. An ideal mediator would be re-oxidized at the electrode at a low potential under which impurity in the chemical layer and interfering substances in the sample would not be oxidized thereby minimizing interference.

Many compounds are useful as mediators due to their ability to accept electrons from the reduced enzyme and transfer them to the electrode. Among the mediators known to be useful as electron transfer agents in analytical determinations are the substituted benzo- and naphthoquinones disclosed in U.S. Patent 4,746,607; the N-oxides, nitroso compounds, hydroxylamines and oxines specifically disclosed in EP 0 354 441; the flavins, phenazines, phenothiazines, indophenols, substituted 1,4-benzoquinones and indamins disclosed in EP 0 330 517 and the phenazinium/phenoxazinium salts described in U.S. Patent 3,791,988. A comprehensive review of electrochemical mediators of biological redox systems can be found in Analytica Clinica Acta. 140 (1982), Pp 1-18.

Among the more venerable mediators is hexacyanoferrate, also known as ferricyanide, which is discussed by Schläpfer et al in Clinica Chimica Acta., 57 (1974), Pp. 283-289. In U.S. Patent 4,929,545 there is disclosed the use of a soluble ferricyanide compound in combination with a soluble ferric compound in a composition for enzymatically determining an analyte in a sample. Substituting the iron salt of ferricyanide for oxygen in equation (A) provides:

$$\text{Glucose} + Fe^{+++}(CN)_6 \xrightarrow{GO} \text{gluconolactone} + Fe^{++}(CN)_6$$

since the ferricyanide is reduced to ferrocyanide by its acceptance of electrons from the glucose oxidase enzyme.

Another way of expressing this reaction is by use of the following equation (C):

$$\text{Glucose} + GO_{X(OX)} \longrightarrow \text{Gluconalactone} + GO_{X(red)}$$

$$GO_{X(red)} + 2\ Fe(CN_3)^{3-}{}_6 \longrightarrow GO_{X(OX)} + 2\ Fe(CN)^{4-} + 2e^-$$

(C)

The electrons released are directly equivalent to the amount of glucose in the test fluid and can be related thereto by measurement of the current which is produced through the fluid upon the application of a potential thereto. Oxidation of the ferrocyanide at the anode renews the cycle.

U.S. patent 6,391,645 to Huang et al., issued May 21, 2002 and assigned to the present assignee, discloses a method and apparatus for correcting ambient temperature effect in biosensors. An ambient temperature value is measured. A sample is applied to the biosensors, then a current generated in the test sample is measured. An observed analyte concentration value is calculated from the current through a standard response curve. The observed analyte concentration is then modified utilizing the measured ambient temperature value to thereby increase the accuracy of the analyte determination. The analyte concentration value can be calculated by solving the following equation:

$$G2=(G1-(T_2^2-24^2)*I2-(T_2-24)*I1)/((T_2^2-24^2)*S2+(T_2-24)*S1+1)$$

where G1 is said observed analyte concentration value, $T_2$ is said measured ambient temperature value and I1, I2, S1, and S2 are predetermined parameters.

While the method and apparatus disclosed by U.S. patent 6,391,645 provided improvements in the accuracy of the analyte determination, a need exists for an improved correction mechanism and that can be applied to any system that measures an analyte concentration.

As used in the following specification and claims, the term biosensor means an electrochemical sensor strip or sensor element of an analytical device or biosensor system that responds selectively to an analyte in an appropriate sample and converts their concentration into an electrical signal. The biosensor generates an electrical signal directly, facilitating a simple instrument design. Also, a biosensor offers the advantage of low material cost since a thin layer of chemicals is deposited on the electrodes and little material is wasted.

The term sample is defined as a composition containing an unknown amount of the analyte of interest. Typically, a sample for electrochemical analysis is in liquid form, and preferably the sample is an aqueous mixture. A sample may be a biological sample, such as blood, urine or saliva. A sample may be a derivative of a biological sample, such as an extract, a dilution, a filtrate, or a reconstituted precipitate.

The term analyte is defined as a substance in a sample, the presence or amount of which is to be determined. An analyte interacts with the oxidoreductase enzyme present during the analysis, and can be a substrate for the oxidoreductase, a coenzyme, or another substance that affects the interaction between the oxidoreductase and its substrate.

**Summary of the Invention**

Important aspects of the present invention are to provide a new and improved biosensor system for determining the presence or amount of a substance in a sample including a method and apparatus for implementing threshold based correction functions for biosensors.

In brief, a method and apparatus are provided for implementing threshold based correction functions for biosensors. A sample is applied to the biosensor and a primary measurement of an analyte value is obtained. A secondary measurement of a secondary effect is obtained and is compared with a threshold value. A correction function is identified responsive to the compared values. The correction function is applied to the primary measurement of the analyte value to provide a corrected analyte value.

In accordance with features of the invention, the correction method uses correction curves that are provided to correct for an interference effect. The correction curves can be linear or non-linear. The correction method provides different correction functions above and below the threshold value. The correction functions may be dependent or independent of the primary measurement that is being corrected. The correction functions may be either linear or nonlinear.

In accordance with features of the invention, the secondary measurement of a secondary effect includes a plurality of effects that are use separately or together in combination to identify the correction function. For example, the secondary effects include temperature, Hemoglobin, and the concentration of hematocrit of a blood sample that are identified and used to minimize the interference of the secondary effects on the accuracy of the reported results.

**Brief Description of the Drawing**

The present invention together with the above and other objects and advantages may best be understood from the following detailed description of the preferred embodiments of the invention illustrated in the drawings, wherein:

FIG. 1 is a block diagram representation of biosensor system in accordance with the present invention;

FIG. 2 is a flow chart illustrating exemplary logical steps performed in accordance with the present invention of the method for implementing threshold based correction of secondary effects, such as correcting ambient temperature effect, in the biosensor system of FIG. 1; and

FIGS. 3 and 4 are graphs of exemplary stored correction curves illustrating corrections characteristics in accordance with the present invention.

**Detailed Description of the Preferred Embodiments**

Having reference now to the drawings, in FIG. 1 there is shown a block diagram representation of biosensor system designated as a whole by the reference character 100 and arranged in accordance with principles of the present invention. Biosensor system 100 includes a microprocessor 102 together with an associated memory 104 for storing program and user data and correction curves for implementing threshold based correction of secondary effects in accordance with the present invention. A meter function 106 coupled to a biosensor 108 is operatively controlled by the microprocessor 102 for recording test values, such as blood glucose test values. An ON/OFF input at a line 110 responsive to the user ON/OFF input operation is coupled to the microprocessor 102 for performing the blood test sequence mode of biosensor system 100. A system features input at a line 112 responsive to a user input operation is coupled to the microprocessor 102 for selectively performing the system features mode of biosensor 100. A thermistor 114 provides a temperature signal input indicated at a line 116 is coupled to the microprocessor 102 for detecting interfering effects, for example, the temperature information for the sensor 108 in accordance with the invention. A signal input indicated at a line 120 is coupled to the microprocessor 102 for a second measure of interfering substances, for example, Hemoglobin, optionally provided by the meter function 106.

A display 130 is coupled to the microprocessor 102 for displaying information to the user including test results. A battery monitor function 132 is coupled to the microprocessor 102 for detecting a low or dead battery condition. An alarm function 134 is coupled to the microprocessor 102 for detecting predefined system conditions and for generating alarm indications for the user of biosensor system 100. A data port or communications interface 136 is provided for coupling data to and from a connected computer (not shown). Microprocessor 102 contains suitable programming to perform the methods of the invention as illustrated in FIG. 2.

Biosensor system 100 is shown in simplified form sufficient for understanding the present invention. The illustrated biosensor system 100 is not intended to imply architectural or functional limitations. The present invention can be used with various hardware implementations and systems.

In accordance with the invention, biosensor system 100 performs a correction method of the preferred embodiment, for example, to reduce the temperature bias having a general form as shown in the following TABLE 1 and as illustrated and described with respect to FIG. 2. This invention provides an algorithmic correction method that advantageously improves the accuracy of diagnostic chemistry tests by correcting for secondary effects, such as interfering substances or temperature effects.

It should be understood that the present invention can be applied to any system, electrochemical or optical, that measures an analyte concentration as a primary measurement and then uses a second measure of interfering substances, for example, Hemoglobin, or interfering effects for example, temperature, to compensate for the secondary effect and improve the accuracy of the reported result.

It is also desirable to minimize the interference from hematocrit or volume fraction of erythrocytes on the accuracy of the reported results. The conductivity or impedance of whole blood is dependent on the concentration of hematocrit. Meter function 120 can be used to measure the resistance of the sample fluid at signal input line 120 and the measured value advantageously used to correct for the effect of hematocrit on the reported result. For example, the measured resistance advantageously is used to estimate the concentration of hematocrit of a blood sample and then to correct the measurement for hematocrit effect for determining the concentration of a substance of interest in blood. This invention provides an algorithmic correction method that advantageously improves the accuracy of diagnostic chemistry tests by correcting for secondary effects including interference from hematocrit and temperature effects.

In accordance with the invention, the algorithmic correction method uses correction curves, for example, as illustrated and described with respect to FIGS. 3 and 4, that can be tailored to correct for any well-defined interference effect. The correction curves can be linear or non-linear. The algorithmic correction method has characteristics that can be modified by changing only the equation coefficients as follows. First, different correction functions can be provided above and below a threshold. Second, the correction functions may be dependent or independent of the primary measurement that is being corrected. Third, functions used for correction may be either linear or nonlinear.

TABLE 1: General Correction Algorithm Form

Step 1. Obtain primary measurement ($G_n$).
Step 2. Obtain secondary measurement used to correct $G_n(T)$
Step3A If $T \leq T_c$ then:
1. $A = f(G_n)$
2. $C_n = F * T + A * (T_c - T) + H$

Step 3B If $T > T_c$ then:
3. $I = f_2(G_N)$
4. $C_n = F*T + I*(T-T_c) + H$

5. $G_c = (G_N / C_n)$

Where:
$G_n$ = Uncorrected measurement of analyte concentration;
T = Secondary measurement used to correct primary measurement;
$T_c$ = Decision point or threshold, secondary measurements greater of less than threshold advantageously can use different correction functions;
$G_c$ = Final corrected result; and
A, I, F, H, are coefficients that control magnitude of correction lines or define correction curves.

Referring now to FIG. 2, there are shown exemplary logical steps performed in accordance with the present invention of the method for implementing threshold based correction of secondary effects, such as correcting ambient temperature effect, in the biosensor system 100. A strip is inserted as indicated in a block 200 and then waiting for a sample to be applied is performed as indicated in a block 202. A primary measurement Gn is obtained as indicated in a block 204. Then a secondary measurement T to be used for correction Gn(T) is obtained as indicated in a block 206. The secondary measurement T is compared with the threshold value Tc as indicated in a decision block 208. If the secondary measurement T is less than or equal to the threshold value Tc, then a coefficient A to control magnitude of the correction is identified as indicated in a block 210, where A = f(Gn). Then a correction Cn is calculated as indicated in a block 210, where $C_n = F * T + A * (T_c - T) + H$. Otherwise If the secondary measurement T is greater than the threshold value Tc, then a coefficient I to control magnitude of the correction is identified as indicated in a block 214, where I = f2(Gn). Then a correction Cn is calculated as indicated in a block 216, where $C_n = F*T + I*(T-T_c) + H$. A final corrected result Gc is calculated as indicated in a block 218, where Gc = Gn/Cn to complete the correction algorithm as indicated in a block 220.

Referring now to FIGS. 3 and 4, there are shown respective first and second examples generally designated by reference characters 300 and 400 illustrating exemplary theoretical lines of correction. In FIGS. 3 and 4, a percentage (%) correction is illustrated relative to a vertical axis and a secondary measurement T is illustrated relative to a horizontal axis. A threshold value Tc is indicated by a line labeled Tc.

FIG. 3 illustrates isometric correction lines at different primary measurement concentrations Gn where the correction is dependent on the primary measurement concentrations Gn. As shown in the example 300 in FIG. 3, the magnitude of the correction Cn changes with analyte concentration Gn when the secondary measurement T is above or below the threshold Tc. FIG. 4 illustrates isometric correction lines at different primary measurement concentrations Gn where the correction is dependent on the primary measurement concentrations Gn above the threshold value Tc and is constant and independent of the primary measurement concentrations Gn below and equal to the threshold value Tc.

The scope of the claims should not be limited by the preferred embodiments, but should be given the broadest interpretation consistent with the Description as a whole.

The embodiments of the present invention for which an exclusive property or privilege is claimed are defined as follows:

1. A method for implementing threshold based correction functions for a biosensor comprising the steps of:

applying a sample to the biosensor and obtaining a primary measurement of an analyte value;

obtaining a secondary measurement of a secondary effect;

comparing, using a processor, said secondary measurement of the secondary effect with a threshold value;

responsive to said compared values, identifying, using the processor, a correction function from a plurality of potential correction functions based on said compared values; and

applying said identified correction function to said primary measurement to provide a corrected analyte value.

2. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the step responsive to said compared values, of identifying a correction function includes the steps of identifying said secondary measurement of the secondary effect less than or equal to said threshold value, identifying a first coefficient A, said first coefficient A to control magnitude of said correction function.

3. The method for implementing threshold based correction functions for a biosensor as recited in claim 2 further includes the steps of calculating said correction function represented by

$$C_n = F * T + A * (T_C - T) + H,$$

where T represents said secondary measurement of the secondary effect, $T_C$ represents said threshold value; and F, H are predefined coefficients.

4. The method for implementing threshold based correction functions for a biosensor as recited in claim 3 wherein the step of applying said identified correction function to said primary measurement to provide a corrected analyte value

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further includes the steps of calculating said corrected analyte value represented by

$$Gc = Gn/Cn,$$

where Gn represent said primary measurement of said analyte value.

5. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the step responsive to said compared values, of identifying a correction function includes the steps of identifying said secondary measurement of the secondary effect greater than said threshold value, identifying a coefficient I, said coefficient I being used to control magnitude of said correction function.

6. The method for implementing threshold based correction functions for a biosensor as recited in claim 5 further includes the steps of calculating said correction function represented by

$$C_n = F * T + I * (T - T_c) + H,$$

where T represents said secondary measurement of the secondary effect, $T_c$ represents said threshold value; and F, H are predefined coefficients.

7. The method for implementing threshold based correction functions for a biosensor as recited in claim 6 wherein the step of applying said identified correction function to said primary measurement to provide a corrected analyte value further includes the steps of calculating said corrected analyte value represented by

$$Gc = Gn/Cn,$$

where Gn represent said primary measurement of said analyte value.

8. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the step of responsive to said compared values, identifying a correction function includes the steps of storing predefined correction curves; said predefined correction curves being provided to correct for an interference effect.

9. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the step of responsive to said compared

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values, identifying a correction function includes the steps responsive to said secondary measurement of the secondary effect being less than or equal to said threshold value of identifying a first coefficient A and identifying said correction function responsive to said identified first coefficient A.

10. The method for implementing threshold based correction functions for a biosensor as recited in claim 9 wherein the step of responsive to said compared values, identifying a correction function includes the steps responsive to said secondary measurement of the secondary effect being greater than said threshold value of identifying a second coefficient I and identifying said correction function responsive to said identified second coefficient I.

11. The method for implementing threshold based correction functions for a biosensor as recited in claim 10 wherein the steps of identifying said first coefficient A and identifying a second coefficient I include the steps of providing stored correction curves; said correction curves representing characteristics of said secondary measurement of the secondary effect.

12. The method for implementing threshold based correction functions for a biosensor as recited in claim 10 wherein the steps of identifying said correction function responsive to said identified second coefficient A and identifying said correction function responsive to said identified second coefficient I includes the steps of identifying a linear function for said correction function.

13. The method for implementing threshold based correction functions for a biosensor as recited in claim 10 wherein the steps of identifying said correction function responsive to said identified first coefficient A and identifying said correction function responsive to said identified second coefficient I includes the steps of identifying a nonlinear function for said correction function.

14. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the steps of identifying said correction function includes the steps of identifying said correction function using at least one

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coefficient value; said at least one coefficient value being dependent upon said primary measurement of said analyte value.

15. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the steps of identifying said correction function includes the steps of identifying said correction function using at least one coefficient value; said at least one coefficient value being a predefined value independent of said primary measurement of said analyte value.

16. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the step of obtaining a secondary measurement of a secondary effect include the step of obtaining a temperature measurement.

17. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the analyte is glucose and wherein the step of obtaining a secondary measurement of a secondary effect includes the step of obtaining a hemoglobin measurement.

18. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the analyte is glucose and wherein the step of obtaining a secondary measurement of a secondary effect includes the step of obtaining a measurement indicating a concentration of hematocrit.

19. The method for implementing threshold based correction functions for a biosensor as recited in claim 1 wherein the analyte is glucose and wherein the step of obtaining a secondary measurement of a secondary effect includes the steps of obtaining a measurement indicating a concentration of hematocrit and obtaining a temperature measurement.

20. An apparatus for implementing threshold based correction functions comprising:

a biosensor for receiving a sample;

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a processor coupled to said biosensor;

said processor responsive to said biosensor for receiving the sample for obtaining a primary measurement of an analyte value;

said processor for obtaining a secondary measurement of a secondary effect;

said processor for comparing said secondary measurement of the secondary effect with a threshold value;

said processor responsive to said compared values, for identifying a correction function from a plurality of potential correction functions based on said compared values; and

said processor for applying said identified correction function to said primary measurement to provide a corrected analyte value.

21. The apparatus for implementing threshold based correction functions as recited in claim 20 includes stored correction curves used by said processor for identifying said correction function; said correction curves representing characteristics of said secondary measurement of the secondary effect.

22. The apparatus for implementing threshold based correction functions as recited in claim 20 wherein said processor is responsive to identifying said secondary measurement of the secondary effect less than or equal to said threshold value, for identifying a first coefficient A, said first coefficient A being used to control magnitude of said correction function.

23. The apparatus for implementing threshold based correction functions as recited in claim 22 wherein said processor is responsive to identifying said secondary measurement of the secondary effect greater than said threshold value, for identifying a second coefficient I, said second coefficient I being used to control magnitude of said correction function.

24. An apparatus for implementing threshold based correction functions comprising:

a biosensor for receiving a sample;

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a processor coupled to said biosensor, said processor responsive to said biosensor for receiving the sample for obtaining a primary measurement of an analyte value;

said processor for obtaining a secondary measurement of a secondary effect;

said processor for comparing said secondary measurement of the secondary effect with a threshold value;

said processor responsive to said compared values, for selecting a correction function from a plurality of potential correction functions based on said compared values, said selected correction function using at least one coefficient value, said at least one coefficient value being dependent upon said primary measurement of said analyte value; and

said processor for applying said identified correction function to said primary measurement to provide a corrected analyte value.

25. The method of claim 1, wherein a first correction function is identified in response to the secondary measurement being above the threshold value and a second correction function is identified in response to the secondary measurement being below the threshold value, the first correction function being different from the second correction function.

26. The method of claim 25, wherein the first correction and the second correction function include predetermined coefficients, the first function having different predetermined coefficients than the second correction function.

27. The method of claim 1, wherein the primary measurement of the analyte value is obtained via a plurality of electrodes of the biosensor.

28. The method of claim 1, wherein the primary measurement of the analyte value is obtained via one or more optical components of the biosensor.

29. The method of claim 1, further comprising displaying, via a display device, a test result based on the corrected analyte value.

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30. The method of claim 1, wherein the step of obtaining a secondary measurement of a secondary effect includes obtaining a temperature measurement via a temperature sensor.

31. The method of claim 30, wherein the temperature sensor is a thermistor.

32. The method of claim 1, wherein the step of obtaining a secondary measurement of a secondary effect includes obtaining a resistance measurement of a sample fluid via a meter.

33. The apparatus of claim 20, wherein the biosensor includes a plurality of electrodes for determining the primary measurement of the analyte value.

34. The apparatus of claim 20, wherein the biosensor includes one or more optical components for determining the primary measurement of the analyte value.

35. The apparatus of claim 20, further comprising a display device for displaying a test result based on the corrected analyte value.

36. The apparatus of claim 20, further comprising a temperature sensor configured to measure a temperature, the temperature being the secondary effect, the temperature sensor being coupled to the processor such that the processor obtains the secondary measurement of the secondary effect from the temperature sensor.

37. The apparatus of claim 36, wherein the temperature sensor is a thermistor.

38. The apparatus of claim 24, wherein the biosensor includes a plurality of electrodes for determining the primary measurement of the analyte value.

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39. The apparatus of claim 24, wherein the biosensor includes one or more optical components for determining the primary measurement of the analyte value.

40. The apparatus of claim 24, further comprising a display device for displaying a test result based on the corrected analyte value.

41. The apparatus of claim 24, further comprising a temperature sensor configured to measure a temperature, the temperature being the secondary effect, the temperature sensor being communicatively coupled to the processor such that the processor obtains the secondary measurement of the secondary effect from the temperature sensor.

42. The apparatus of claim 41, wherein the temperature sensor is a thermistor.

43. An apparatus for determining an analyte concentration, comprising:

a biosensor configured to receive a fluid sample, the biosensor including a plurality of electrodes for measuring a primary measurement of an analyte value in the fluid sample;

a sensor for measuring a secondary measurement of a secondary effect;

a processor coupled to said biosensor,

a memory storing program data, which when executed by the processor, cause the processor to:

obtain the primary measurement of the analyte value in the fluid sample;

obtain the secondary measurement of the secondary effect;

compare said secondary measurement of the secondary effect with a threshold value;

select a correction function from a plurality of potential correction functions based on said compared values; and

apply said identified correction function to said primary measurement to determine a corrected analyte value.

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44. The apparatus of claim 43, further comprising a display device, wherein the processor, executing the program data, further causes the display device to display a test result based on the determined corrected analyte value.

45. The apparatus of claim 43, wherein the sensor is configured to measure a temperature effect.

46. The apparatus of claim 43, wherein the sensor is configured to measure a hematocrit effect.

47. The apparatus of claim 43, wherein the sensor is configured to measure a Hemoglobin effect.

48. The apparatus of claim 43, wherein said selected correction function includes at least one coefficient value dependent upon said primary measurement of said analyte value.

49. The apparatus of claim 43, wherein the processor selects the correction function by identifying said secondary measurement of the secondary effect less than or equal to said threshold value, identifying a first coefficient A, said first coefficient A to control magnitude of said correction function.

50. The apparatus of claim 49 further wherein the program data, when executed by the processor, further causes the processor to calculate said correction function represented by

$$C_n = F * T + A * (T_C - T) + H,$$

where T represents said secondary measurement of the secondary effect, $T_C$ represents said threshold value; and F, H are predefined coefficients.

51. The apparatus of claim 50, wherein the processor applies said identified correction function to said primary measurement to provide a corrected analyte value by calculating said corrected analyte value represented by

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$$Gc = Gn/Cn,$$

where Gn represent said primary measurement of said analyte value.

52. The apparatus of claim 43, wherein the processor selects the correction function by identifying said secondary measurement of the secondary effect greater than said threshold value, identifying a coefficient I, said coefficient I being used to control magnitude of said correction function.

53. The apparatus of claim 52, wherein the program data, when executed by the processor, further causes the processor to calculate said correction function represented by

$$C_n = F * T + I * (T - T_c) + H,$$

where T represents said secondary measurement of the secondary effect, $T_c$ represents said threshold value; and F, H are predefined coefficients.

54. The apparatus of claim 53, wherein the processor applies said identified correction function to said primary measurement to provide a corrected analyte value further by calculating said corrected analyte value represented by

$$Gc = Gn/Cn,$$

where Gn represent said primary measurement of said analyte value.

55. The apparatus of claim 43, wherein the step of responsive to said memory stores a plurality of predefined correction curves for correcting for an interference effect, the processor being programmed to select the correction function by selecting one of the plurality of predefined correction curves.

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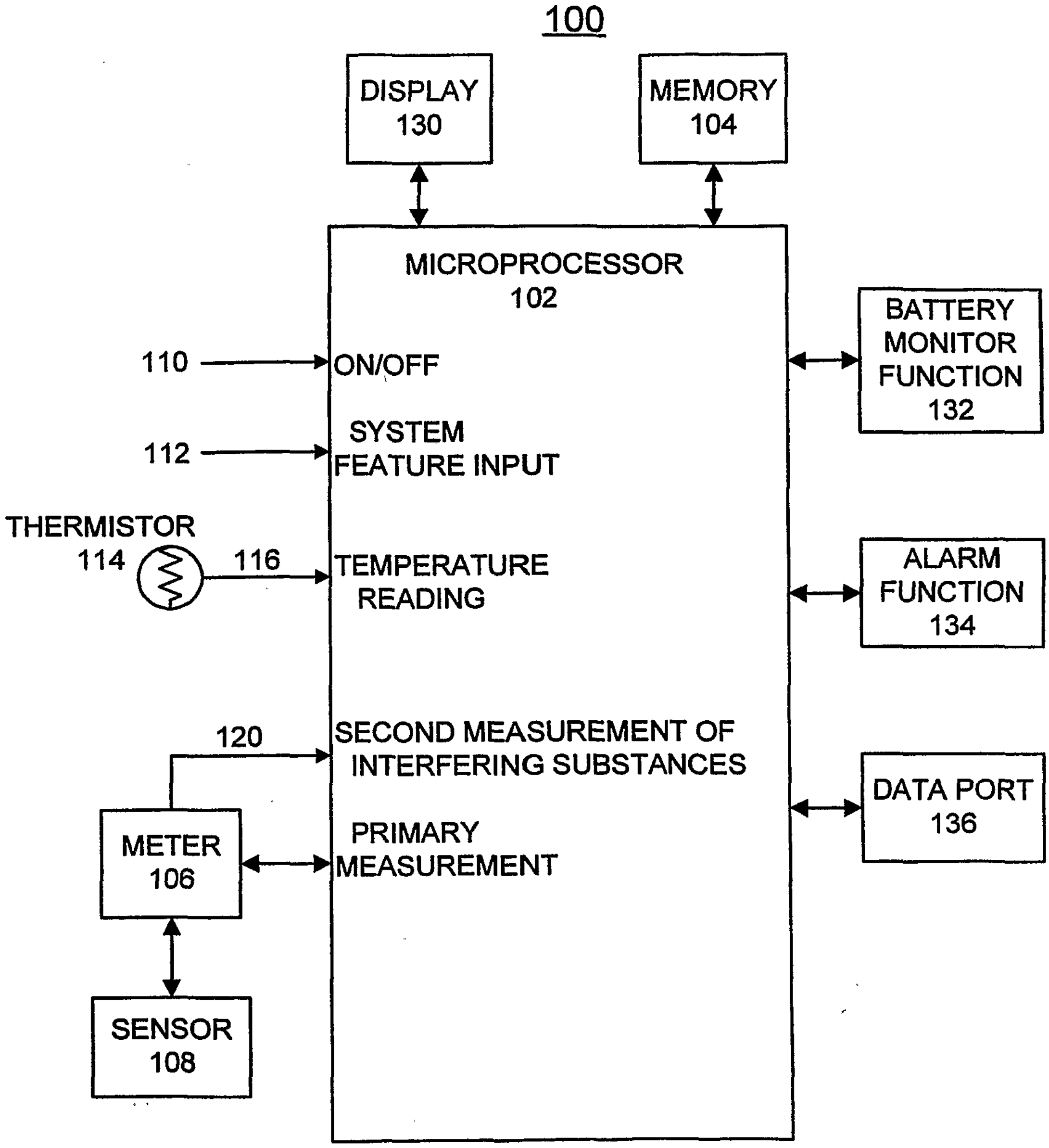
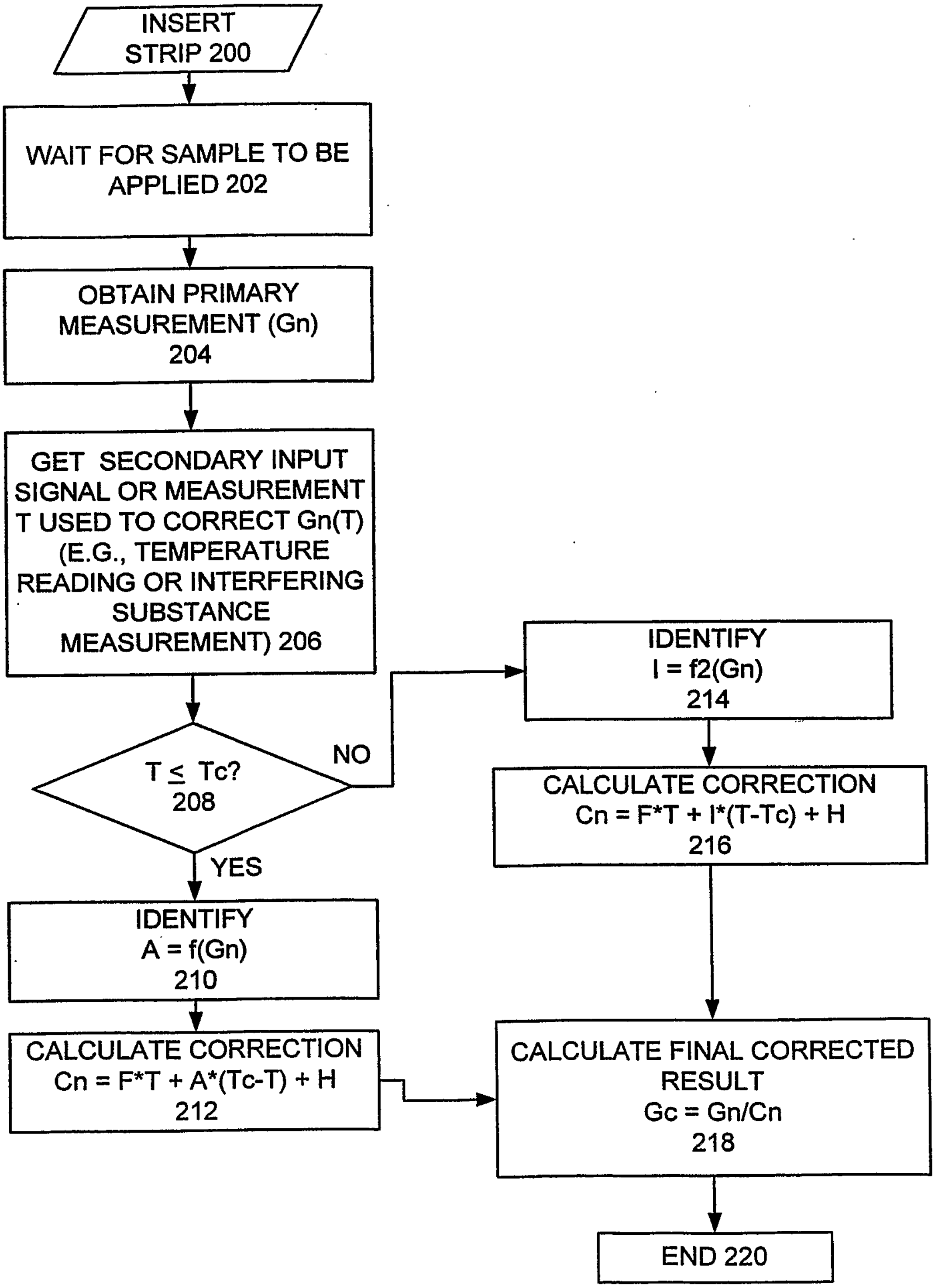

100
DISPLAY 130
MEMORY 104
MICROPROCESSOR 102
110
ON/OFF
112
SYSTEM FEATURE INPUT
THERMISTOR 114
116
TEMPERATURE READING
120
SECOND MEASUREMENT OF INTERFERING SUBSTANCES
PRIMARY MEASUREMENT
METER 106
SENSOR 108
BATTERY MONITOR FUNCTION 132
ALARM FUNCTION 134
DATA PORT 136

FIG. 1

FIG. 2


INSERT STRIP 200
WAIT FOR SAMPLE TO BE APPLIED 202
OBTAIN PRIMARY MEASUREMENT (Gn) 204
GET SECONDARY INPUT SIGNAL OR MEASUREMENT T USED TO CORRECT Gn(T) (E.G., TEMPERATURE READING OR INTERFERING SUBSTANCE MEASUREMENT) 206
T ≤ Tc? 208
NO
YES
IDENTIFY I = f2(Gn) 214
CALCULATE CORRECTION Cn = F*T + I*(T-Tc) + H 216
IDENTIFY A = f(Gn) 210
CALCULATE CORRECTION Cn = F*T + A*(Tc-T) + H 212
CALCULATE FINAL CORRECTED RESULT Gc = Gn/Cn 218
END 220

# FIG. 3

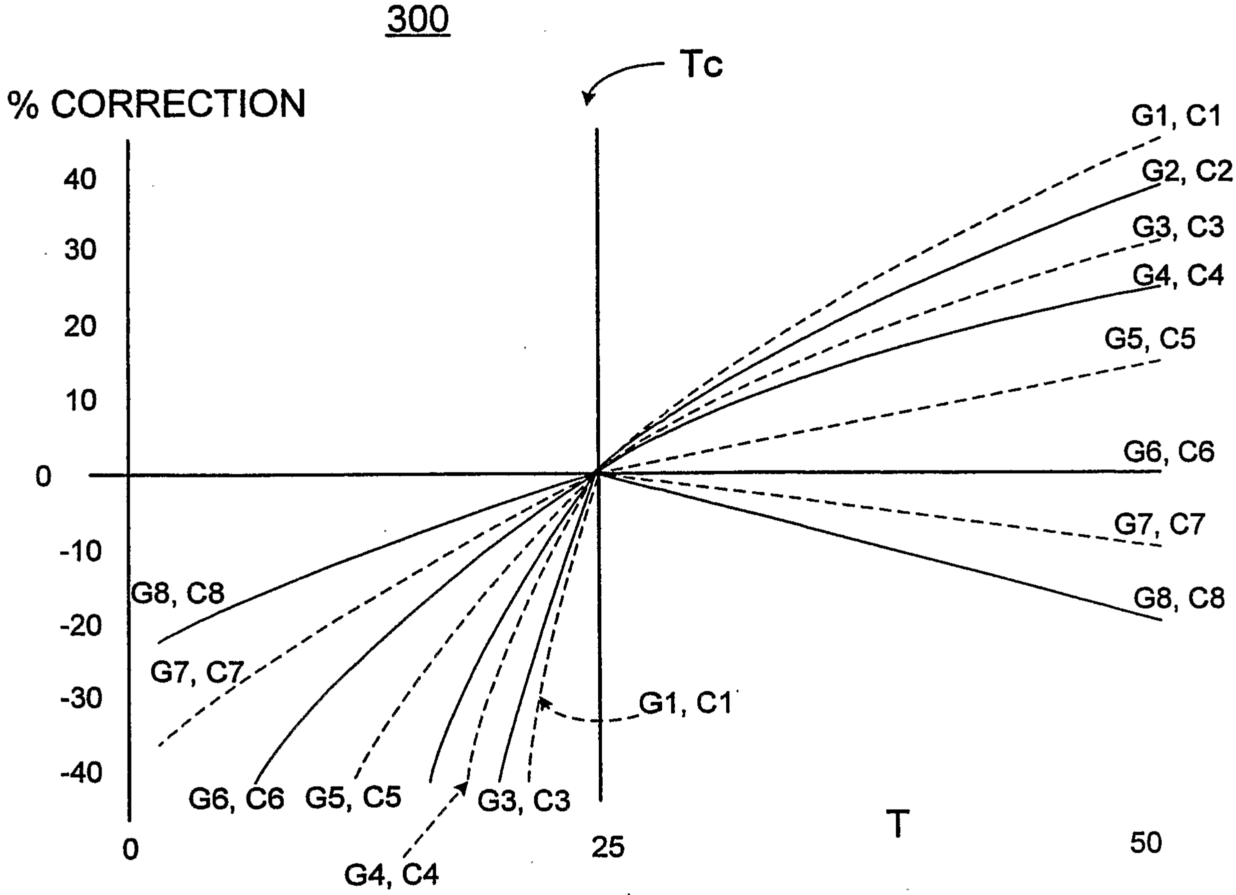
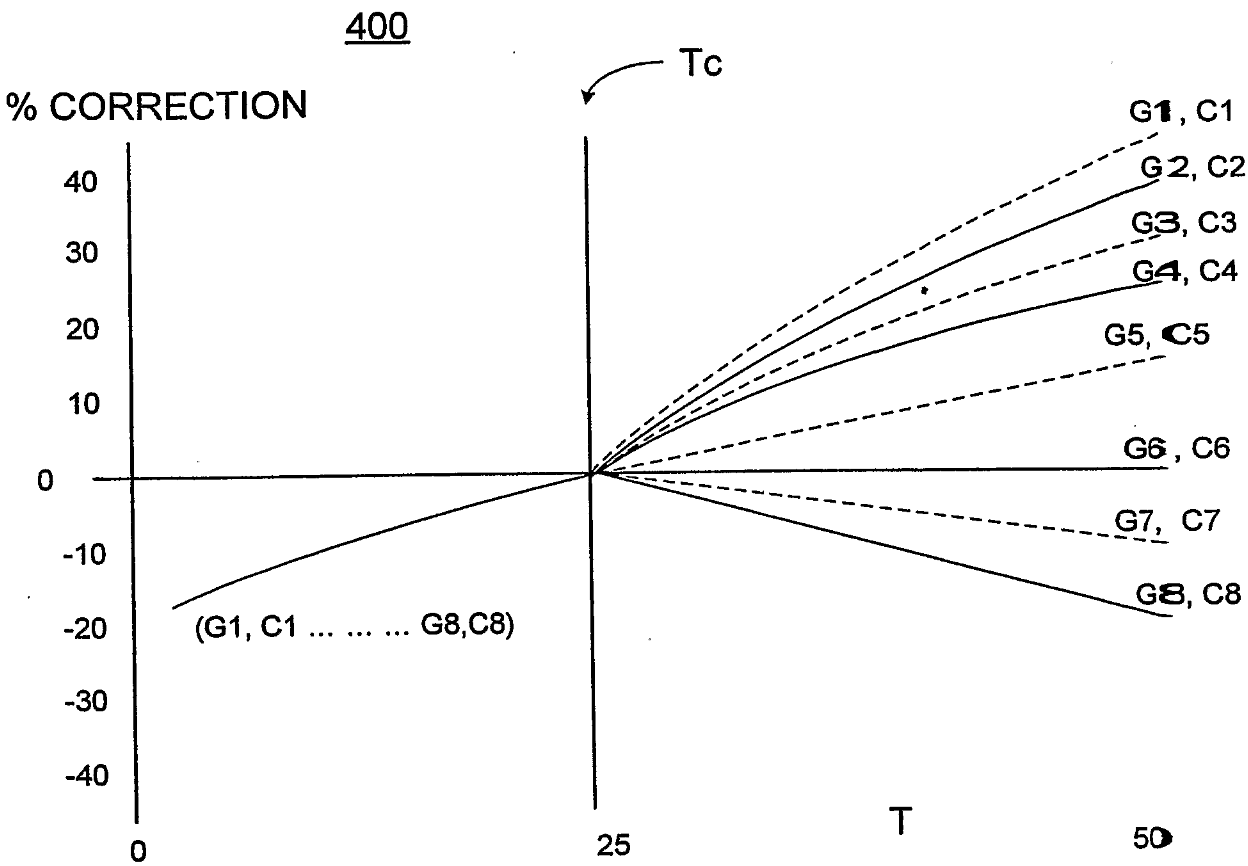
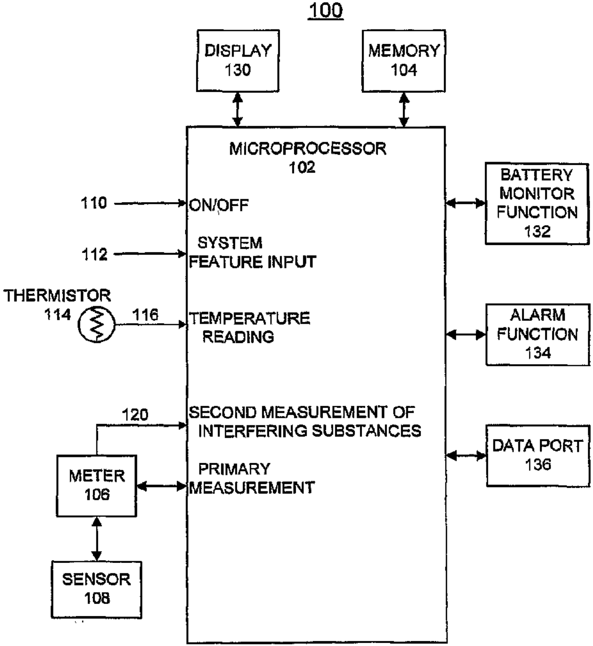

300
Tc
% CORRECTION
40
30
20
10
0
-10
-20
-30
-40
0
25
T
50
G1, C1
G2, C2
G3, C3
G4, C4
G5, C5
G6, C6
G7, C7
G8, C8
G8, C8
G7, C7
G6, C6
G5, C5
G4, C4
G3, C3
G1, C1

FIG. 4


400
Tc
% CORRECTION
G1, C1
G2, C2
G3, C3
G4, C4
G5, C5
G6, C6
G7, C7
G8, C8
40
30
20
10
0
-10
-20
-30
-40
(G1, C1 ... ... ... G8,C8)
0
25
T
50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DISPLAY 130
MEMORY 104
MICROPROCESSOR 102
110
ON/OFF
112
SYSTEM FEATURE INPUT
THERMISTOR 114
116
TEMPERATURE READING
120
SECOND MEASUREMENT OF INTERFERING SUBSTANCES
PRIMARY MEASUREMENT
METER 106
SENSOR 108
BATTERY MONITOR FUNCTION 132
ALARM FUNCTION 134
DATA PORT 136