1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT, INC. and NELLCOR PURITAN BENNETT INC.,

Plaintiffs,

v.

MASIMO CORPORATION and IVY BIOMEDICAL SYSTEMS, INC.,

Defendants.

Civil Action No. 99-796

00-06506-GAF (AJWx)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mallinckrodt, Inc. ("Mallinckrodt") and Nellcor Puritan Bennett Inc. ("Nellcor"), for their complaint against defendants, Masimo Corporation ("Masimo") and Ivy Biomedical Systems, Inc. ("Ivy") (collectively "Defendants"), aver as follows:

THE PARTIES

1. Plaintiff Mallinckrodt is a corporation organized and existing under the laws of the State of Delaware, and has a place of business in St. Louis, Missouri.

2. Plaintiff Nellcor is a corporation organized and existing under the laws of the State of Delaware, and has a place of business in Pleasanton, California.

3. Upon information and belief, defendant Masimo is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2852 Kelvin Avenue, Irvine, California 92614. Masimo is engaged in the business of making, using, offering to sell, selling and/or importing OEM circuit boards for pulse oximeters and pulse oximeter sensors.

4. Upon information and belief, defendant Ivy is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 11 Business Park Drive, Branford, Connecticut 06405. Ivy is engaged in the business of making, using, offering to sell, selling and/or importing pulse oximeter sensors and pulse oximeters, including pulse oximeters incorporating Masimo OEM circuit boards and pulse oximeter sensors made by Masimo.

JURISDICTION

5. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

VENUE

6. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

PLAINTIFFS' PATENTS

7. United States Patent No. 4,653,498, entitled "Pulse Oximeter Monitor" was duly and legally issued by the United States Patent and Trademark Office on March 31, 1987 and Reexamination Certificate B1 4,653,498 therefore was duly and legally issued by the United States Patent and Trademark Office on April 18, 1989 (collectively, "the '498 patent"). The '498 patent is assigned to Nellcor.

8. United States Patent No. 5,078,136 ("the '136 patent"), entitled "Method and Apparatus For Calculating Arterial Oxygen Saturation Based Plethysmographs Including Transients," was duly and legally issued by the United States Patent and Trademark Office on January 7, 1992. The '136 patent is assigned to Nellcor.

9. United States Patent No. Re. 36,000 ("the '000 patent"), entitled "Adhesive Pulse Oximeter Sensor With Reusable Portion," was duly and legally reissued by the United States Patent and Trademark Office on December 22, 1998. The '000 patent is assigned to Nellcor.

10. Mallinckrodt is the exclusive sales agent in the United States for Nellcor brand oximeters and oximeter sensors, including oximeters and oximeter sensors covered by the '498 patent, the '136 patent and the '000 patent.

11. Copies of the '498 patent, the '136 patent and the '000 patent are attached to this Complaint as Exhibits A through C, respectively.

CLAIM FOR PATENT INFRINGEMENT

12. In violation of 35 U.S.C. §§ 271(a), (b) and (c), Masimo has infringed, induced infringement of, and contributed to infringement of, and is continuing to infringe, induce infringement of and contributorily infringe, one or more claims of the '136 patent and the '000 patent by making, using, offering for sale and/or selling in the United States products that embody or use the inventions claimed in the '136 patent and the '000 patent, including without limitation Masimo's MS Boards and the LNOP ® family of sensors.

13. In violation of 35 U.S.C. §§ 271(b) and (c), Masimo also has induced infringement of, and contributed to infringement of, and is continuing to induce infringement of and contributorily infringe, one or more claims of the '498 patent, by inducing others, including Ivy, to make, use, offer for sale and/or sell in the United States products that embody or use the inventions claimed in the '498 patent.

14. Upon information and belief, Masimo's infringement, inducement of infringement and contributory infringement of the '136 patent and the '000 patent, and Masimo's

inducement of infringement and contributory infringement of the '498 patent, has been and continues to be willful, intentional and deliberate.

15. Mallinckrodt and Nellcor have been damaged, in an amount not yet fully determined, by Masimo's infringement, inducement of infringement and/or contributory infringement and will be irreparably injured unless those activities are enjoined.

16. In violation of 35 U.S.C. §§ 271(a), (b) and (c), Ivy has infringed, induced infringement of, and contributed to infringement of, and is continuing to infringe, induce infringement of and contributorily infringe, one or more claims of the '498 patent, the '136 patent and the '000 patent by making, using, offering for sale and/or selling in the United States products that embody or use the inventions claimed in the '498 patent, the '136 patent and the '000 patent, including without limitation the SAT-GUARD 2000, Vital-GUARD 405CM and Vital-GUARD 405TM, which incorporate Masimo's OEM circuit boards.

17. Upon information and belief, Ivy's infringement, inducement of infringement and contributory infringement of the '498 patent, the '136 patent and the '000 patent has been and continues to be willful, intentional and deliberate.

18. Mallinckrodt and Nellcor have been damaged, in an amount not yet fully determined, by Ivy's infringement, inducement of infringement and/or contributory infringement and will be irreparably injured unless those activities are enjoined.

WHEREFORE, Plaintiff Mallinckrodt and Nellcor pray for judgment and relief against Defendants, including:

A. Adjudging that Defendants have infringed, induced infringement of and contributorily infringed, and continue to infringe, induce infringement of and contributorily infringe the '498 patent, the '136 patent and the '000 patent.

B. Preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them who receive notice of the injunction, from continuing acts of infringement, inducement of infringement and/or contributory infringement of the '498 patent, the '136 patent and the '000 patent;

C. Awarding to Mallinckrodt and Nellcor their damages caused by infringement, inducement of infringement and contributory infringement by each Defendant, together with pre-judgment and post-judgment interest;

D. Adjudging that each of the Defendants has willfully infringed, and that damages awarded to Mallinckrodt and Nellcor be trebled pursuant to 35 U.S.C. § 284;

E. Adjudging this to be an exceptional case and awarding Mallinckrodt and Nellcor their costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

F. Granting such other and further relief as this Court may deem just and proper.

Respectfully submitted,

MORRIS, NICHOLS, ARSHT & TUNNELL

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Palo Alto, California 94301
650-617-4000

November 17, 1999

144927

REEXAMINATION CERTIFICATE (1042nd)

United States Patent [19] [11] **B1 4,653,498**

New, Jr. et al. [45] **Certificate Issued Apr. 18, 1989**

[54] **PULSE OXIMETER MONITOR**

[75] Inventors: **William New, Jr., Woodside; James E. Coreman, Alameda, both of Calif.**

[73] Assignee: **Nellcor Incorporated, Haywood, Calif.**

Reexamination Request:
No. 90/001,452, Mar. 1, 1988

Reexamination Certificate for:

Patent No.:	4,653,498
Issued:	Mar. 31, 1987
Appl. No.:	867,005
Filed:	May 20, 1986

Certificate of Correction issued Mar. 31, 1987.

Related U.S. Application Data

[63] Continuation of Ser. No. 417,312, Sep. 13, 1982, abandoned, which is a continuation-in-part of Ser. No. 414,175, Sep. 2, 1982, abandoned.

[51] Int. Cl.[4] A61B 5/02
[52] U.S. Cl. 128/633; 128/666; 128/689
[58] Field of Search 128/633, 634, 666, 689, 128/690

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,706,927	4/1955	Wood	88/14
3,565,058	2/1971	Mansfield	128/701
3,638,640	2/1972	Shaw	128/2 R
3,658,060	4/1972	Eklof	128/673
3,704,706	12/1972	Herczfeld et al.	128/2 R
3,895,316	7/1975	Fein	128/696 X
3,998,550	12/1976	Konishi et al.	356/39
4,013,067	3/1977	Kresse et al.	128/2.05 R
4,038,976	8/1977	Hardy	128/690
4,052,977	10/1977	Kay	128/661
4,109,643	8/1978	Bond et al.	128/666
4,167,331	9/1979	Nielsen	128/633
4,266,554	5/1981	Hamaguri	128/633
4,424,814	1/1984	Secunda	128/663

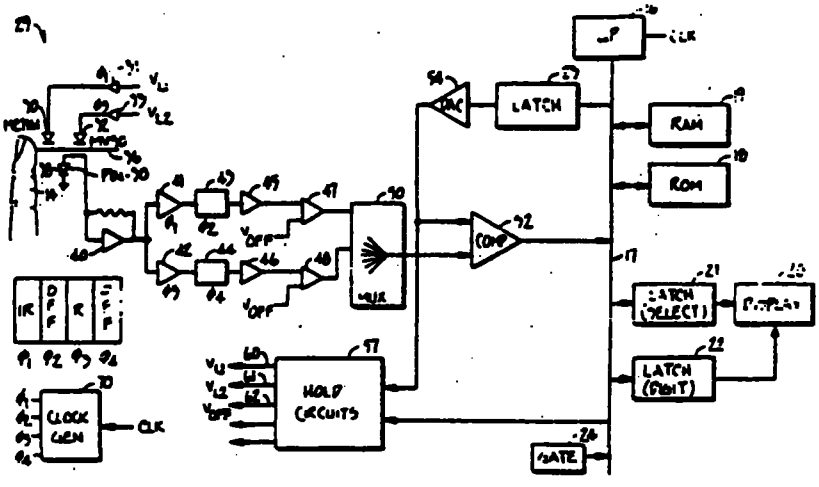
FOREIGN PATENT DOCUMENTS

1589461	3/1970	France .
53-53184	5/1978	Japan .
8201948	6/1982	PCT Int'l Appl. .
2039364	8/1980	United Kingdom .

Primary Examiner—Lee S. Cohen

[57] **ABSTRACT**

A display monitor is disclosed for a pulse oximeter of the type wherein light of two different wavelengths is passed through body tissue, such as a finger, an ear or the scalp, so as to be modulated by the pulsatile component of arterial blood therein and thereby indicate oxygen saturation. A tonal signal is emitted having a pitch proportional to the ratio of oxygen saturation and a sequential repetition proportional to pulse. A visual cue consisting of an array of strobed light emitting diodes is flashed having a total light output proportional to the magnitude of the pulse and a sequential flashing rate proportional to pulse rate. A systematic rejection of extraneous or irregular detected data prevents undue sounding of alarms.



REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claim 1 is determined to be patentable as amended.

Claims 2 and 3, dependent on an amended claim, are determined to be patentable.

1. An oximeter apparatus for use in measuring pulse rate and oxygen saturation of blood by means of absorption of optical radiation through living tissue comprising:

first and second light sources for emitting light at a first and second wavelength, respectively;

a light sensor;

said light sources and light sensor being adapted to be addressed to said tissue to define a light path through said tissue between said light sources and said light sensor;

means for detecting signals corresponding to light received by said light sensor at each of said first and second wavelengths and for deriving from said signals a pulsatile signal corresponding to a pulsatile characteristic of arterial blood flow and generating a signal corresponding to oxygen saturation of the blood; and

means for generating an audible intermittent tone signal, said tone signal generating means further comprising:

means responsive to said pulsatile signal for controlling the occurrence of said audible tone signal, and

means responsive to said oxygen saturation signal for *continuously* varying the tonal frequency of said audible tone signal with oxygen saturation.

* * * * *

United States Patent [19]

New, Jr. et al.

[11] **Patent Number: 4,653,498**

[45] **Date of Patent: Mar. 31, 1987**

[54] **PULSE OXIMETER MONITOR**

[75] Inventors: **William New, Jr., Woodside; James E. Corenman, Alameda, both of Calif.**

[73] Assignee: **Nellcor Incorporated, Haywood, Calif.**

[21] Appl. No.: **867,005**

[22] Filed: **May 20, 1986**

Related U.S. Application Data

[63] Continuation of Ser. No. 417,312, Sep. 13, 1982, abandoned, which is a continuation-in-part of Ser. No. 414,175, Sep. 2, 1982, abandoned.

[51] Int. Cl.[4] **A61B 5/02**

[52] U.S. Cl. **128/633**; 128/666; 128/689

[58] Field of Search 128/633, 634, 666, 689, 128/690

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,706,927	4/1955	Wood	88/14
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3,638,640	2/1972	Shaw	128/2 R
3,658,060	4/1972	Eklof	128/673
3,895,316	7/1975	Fein	128/696 X
3,998,550	12/1976	Konishi et al.	356/39
4,013,067	3/1977	Kresse et al.	128/2.05 R
4,038,976	8/1977	Hardy	128/690
4,052,977	10/1977	Karn	128/661
4,109,643	8/1978	Bond et al.	128/666
4,167,331	9/1979	Nielsen	128/633
4,266,554	5/1981	Hamaguri	128/633
4,424,814	1/1984	Secunda	128/633

FOREIGN PATENT DOCUMENTS

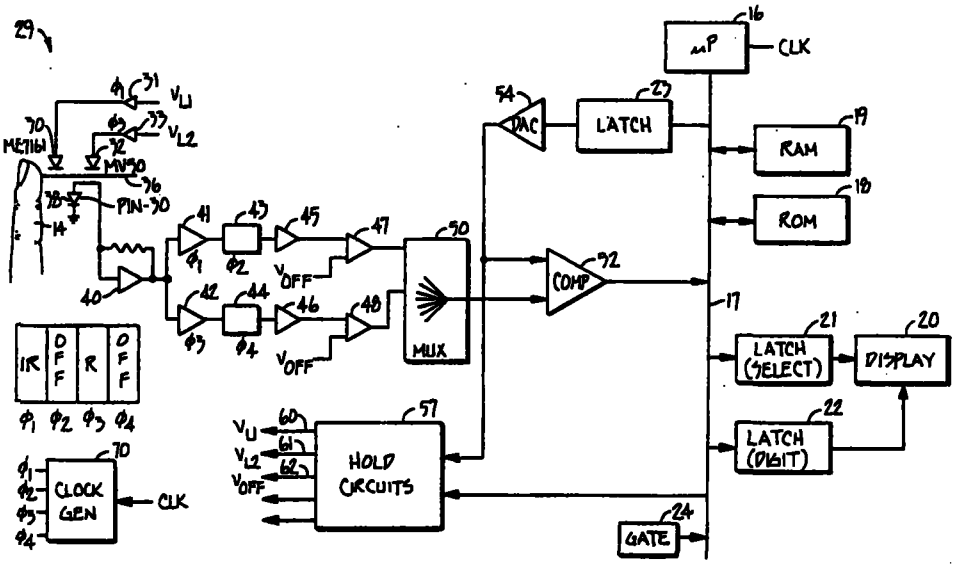
1589461	5/1970	France .
8201948	6/1982	PCT Int'l Appl. .
2039364	8/1980	United Kingdom .

Primary Examiner—Kyle L. Howell
Assistant Examiner—John C. Hanley

[57] **ABSTRACT**

A display monitor is disclosed for a pulse oximeter of the type wherein light of two different wavelengths is passed through body tissue, such as a finger, an ear or the scalp, so as to be modulated by the pulsatile component of arterial blood therein and thereby indicate oxygen saturation. A tonal signal is emitted having a pitch proportional to the ratio of oxygen saturation and a sequential repetition proportional to pulse. A visual cue consisting of an array of strobed light emitting diodes is flashed having a total light output proportional to the magnitude of the pulse and a sequential flashing rate proportional to pulse rate. A systematic rejection of extraneous or irregular detected data prevents undue sounding of alarms.

3 Claims, 19 Drawing Figures



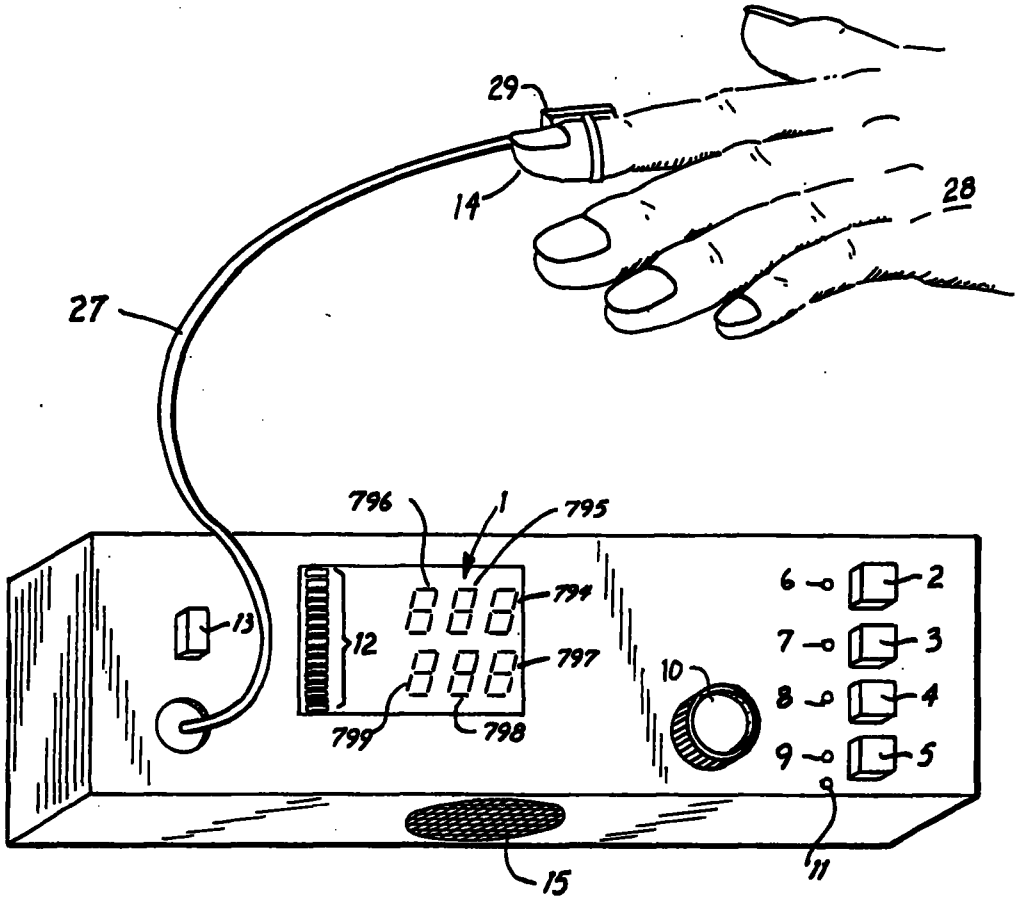

29
14
28
27
796
1
795
794
797
798
799
12
13
10
6
7
8
9
2
3
4
5
11
15

FIG. 1.

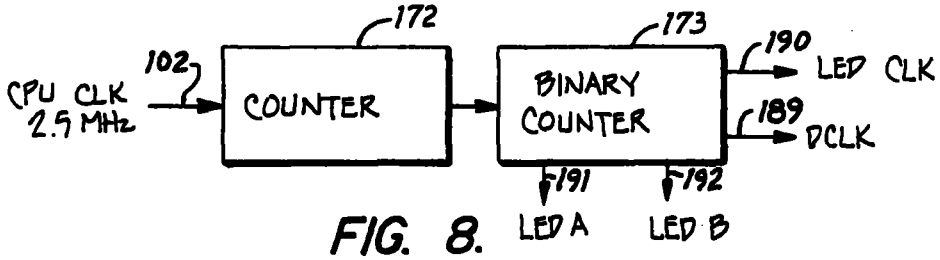

172
173
102
CPU CLK
2.5 MHz
COUNTER
BINARY
COUNTER
190
LED CLK
189
DCLK
191
192
LED A
LED B

FIG. 8.

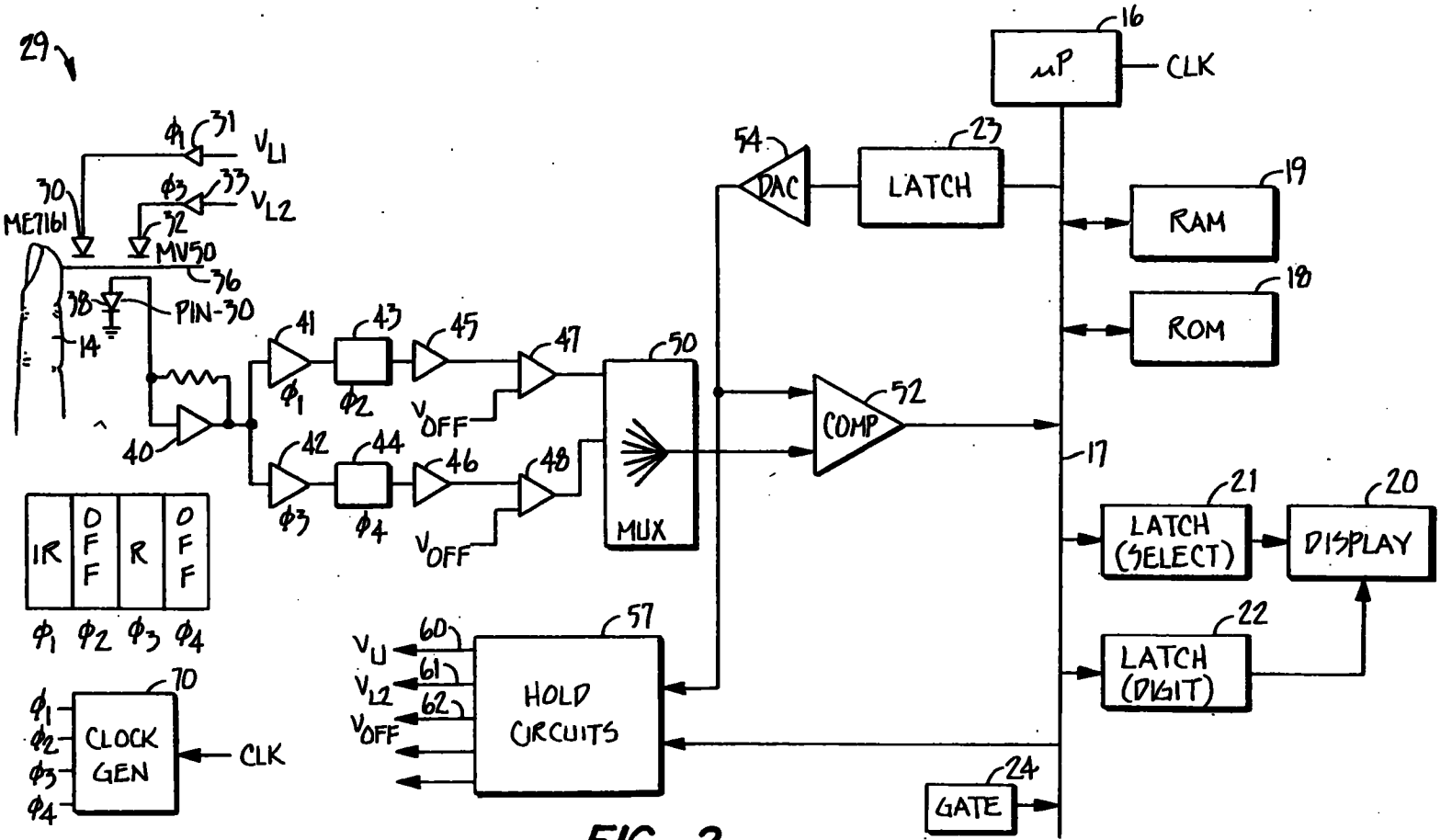

29
16
μP
CLK
54
DAC
23
LATCH
19
RAM
18
ROM
φ1
31
VL1
φ3
33
VL2
30
ME7161
32
MV50
36
38
PIN-30
14
40
41
43
45
47
50
φ1
φ2
VOFF
42
44
46
48
φ3
φ4
VOFF
MUX
52
COMP
17
IR
OFF
R
OFF
φ1 φ2 φ3 φ4
21
LATCH (SELECT)
20
DISPLAY
22
LATCH (DIGIT)
70
φ1
φ2
φ3
φ4
CLOCK GEN
CLK
60
VU
61
VL2
62
VOFF
57
HOLD CIRCUITS
24
GATE

FIG. 2.

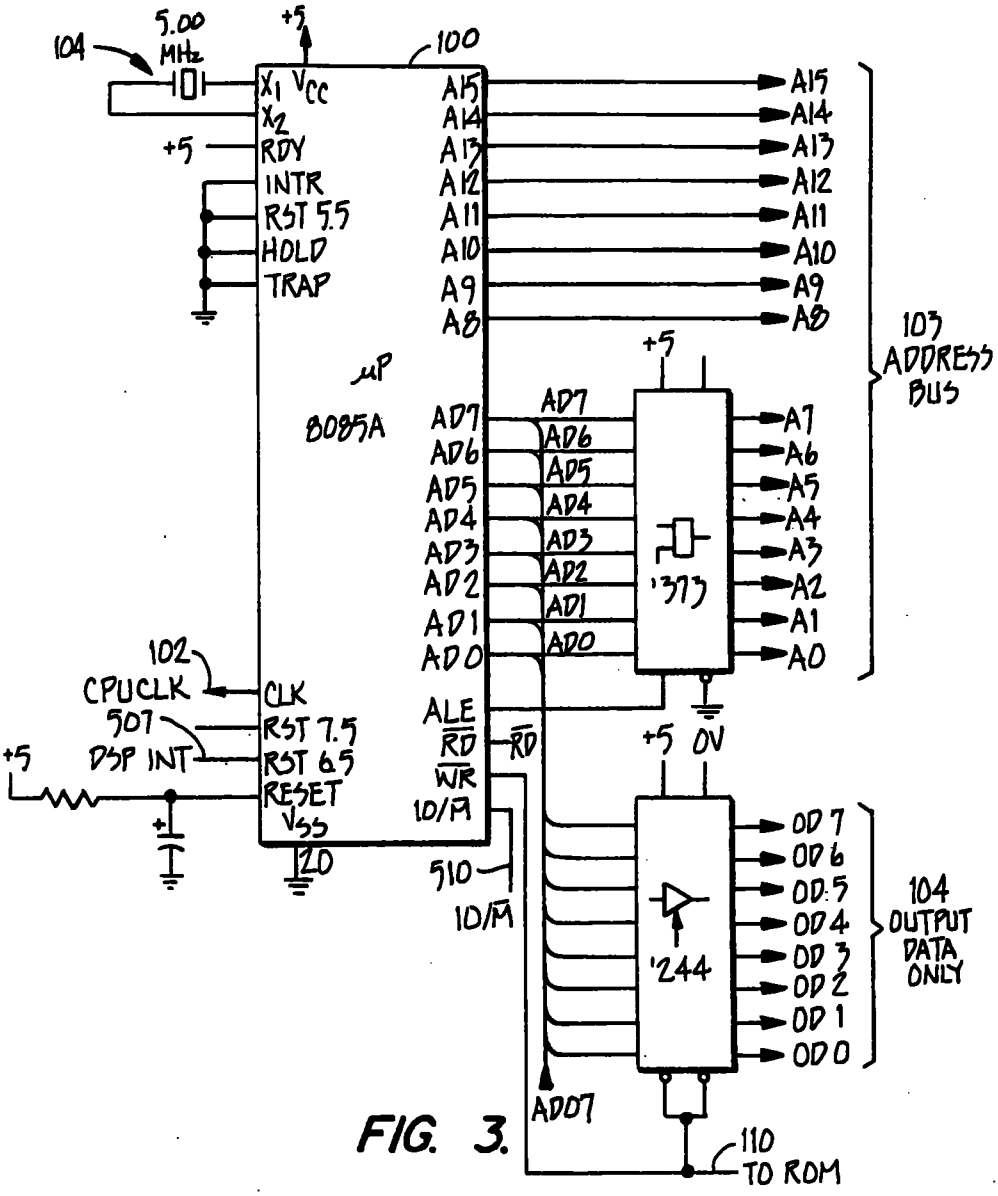

104
5.00 MHz
+5
100
X1 VCC
X2
RDY
INTR
RST 5.5
HOLD
TRAP
A15
A14
A13
A12
A11
A10
A9
A8
μP
8085A
AD7
AD6
AD5
AD4
AD3
AD2
AD1
AD0
ALE
RD
WR
IO/M
SOD
SID
RST 7.5
RST 6.5
RESET
VSS
CLK
102
CPUCLK
507
DSP INT
510
IO/M
'373
'244
107 ADDRESS BUS
104 OUTPUT DATA ONLY
OD7
OD6
OD5
OD4
OD3
OD2
OD1
OD0
OV
110 TO ROM

FIG. 3.

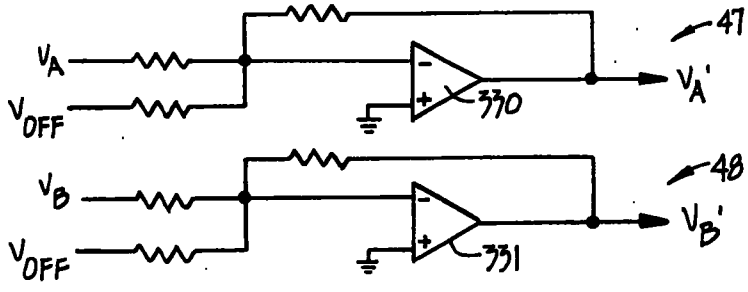

VA
VOFF
330
47
VA'
VB
VOFF
331
48
VB'

FIG. 11.

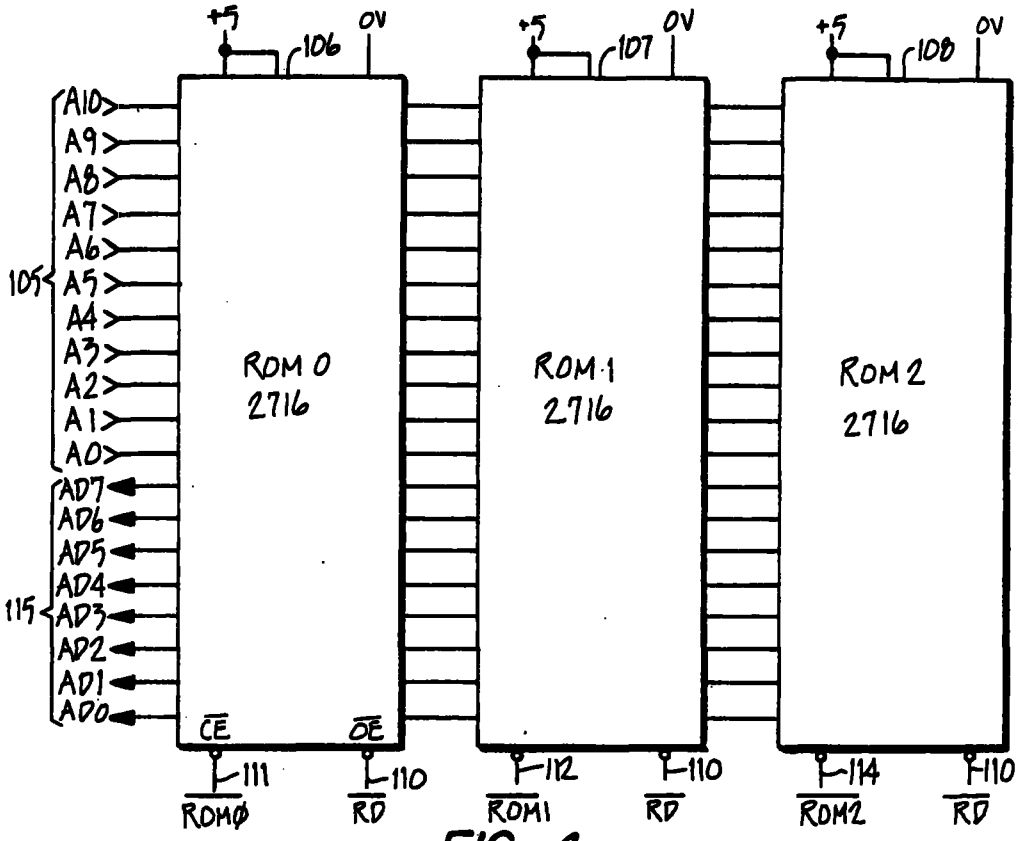

+5
106
0V
+5
107
0V
+5
108
0V
A10
A9
A8
A7
A6
A5
A4
A3
A2
A1
A0
105
AD7
AD6
AD5
AD4
AD3
AD2
AD1
AD0
115
ROM 0
2716
ROM 1
2716
ROM 2
2716
CE
OE
111
110
112
110
114
110
ROMØ
RD
ROM1
RD
ROM2
RD

FIG. 4.

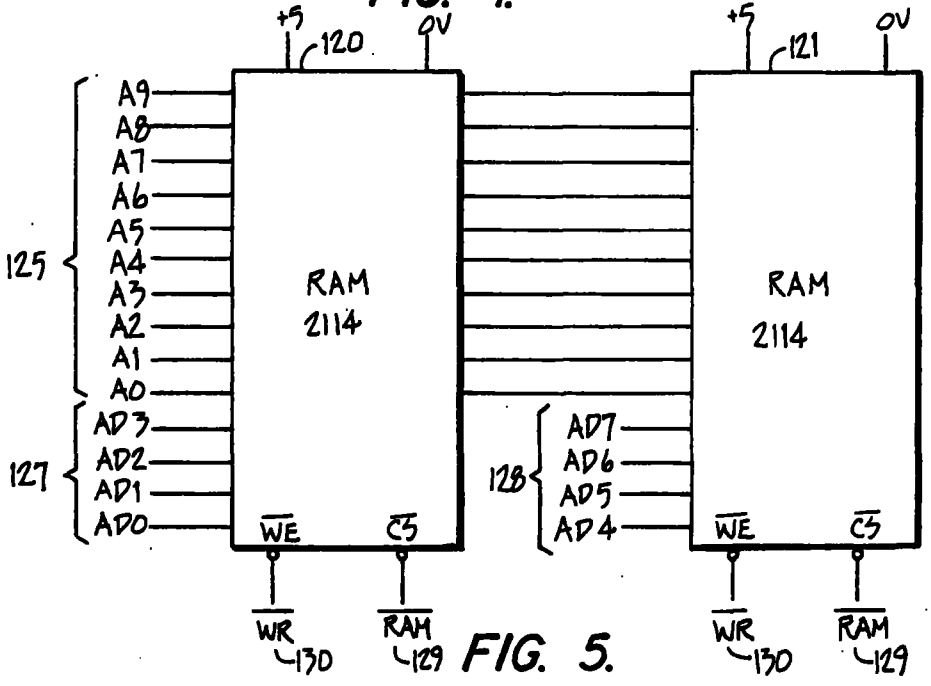

+5
120
0V
+5
121
0V
A9
A8
A7
A6
A5
A4
A3
A2
A1
A0
125
AD3
AD2
AD1
AD0
127
RAM
2114
RAM
2114
AD7
AD6
AD5
AD4
128
WE
CS
WE
CS
WR
130
RAM
129
WR
130
RAM
129

FIG. 5.

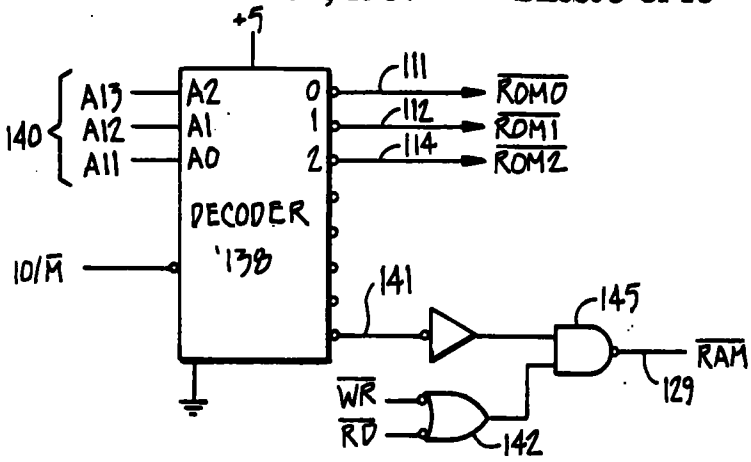


FIG. 6.

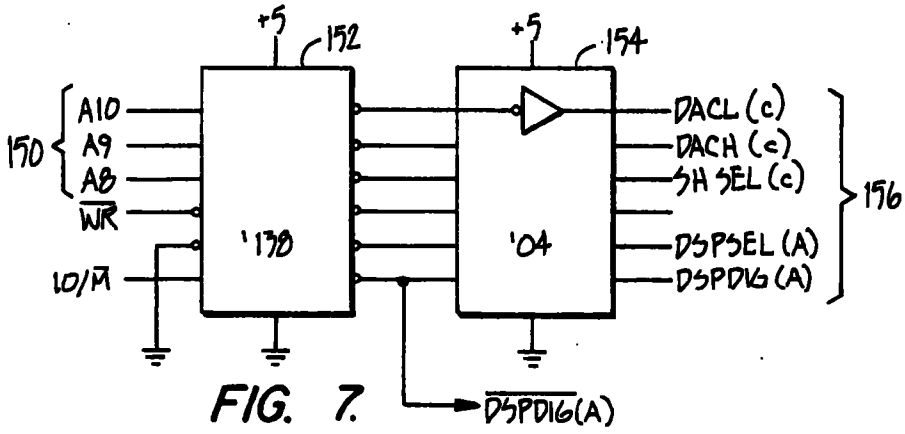


FIG. 7.

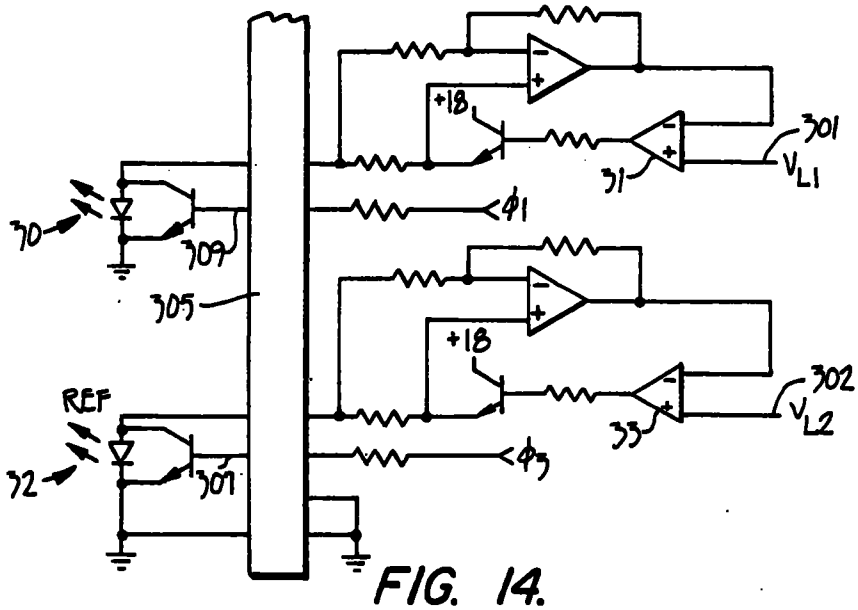


FIG. 14.

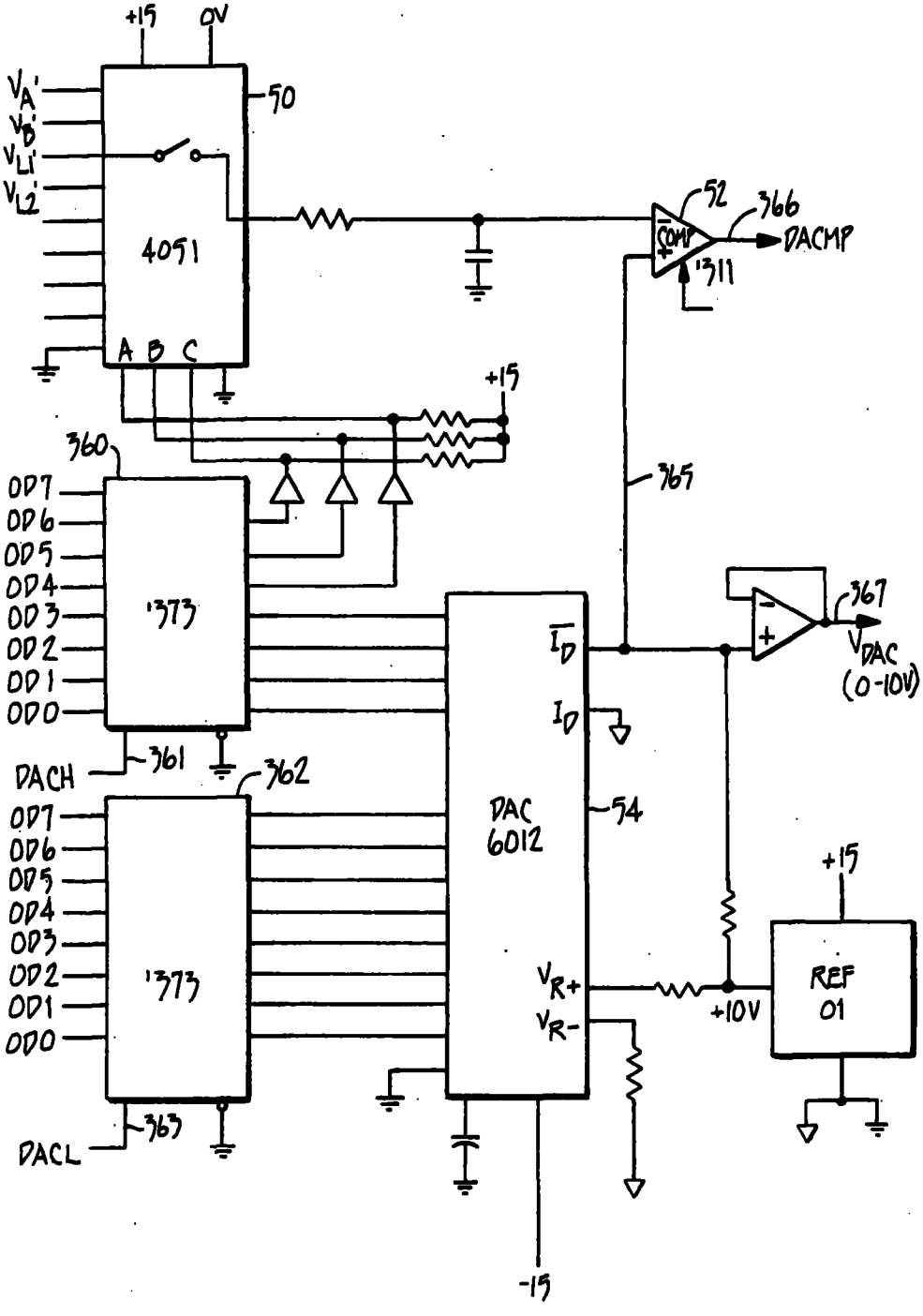

+15
0V
V_A'
V_B'
V_{L1}'
V_{L2}'
50
4051
A B C
52
366
COMP
DACMP
'311
+15
360
365
OD7
OD6
OD5
OD4
OD3
OD2
OD1
OD0
'373
367
V_{DAC}
(0-10V)
$\overline{I_D}$
I_D
DACH
361
362
DAC
6012
54
OD7
OD6
OD5
OD4
OD3
OD2
OD1
OD0
'373
+15
V_{R+}
V_{R-}
+10V
REF
01
DACL
363
-15

FIG. 9.

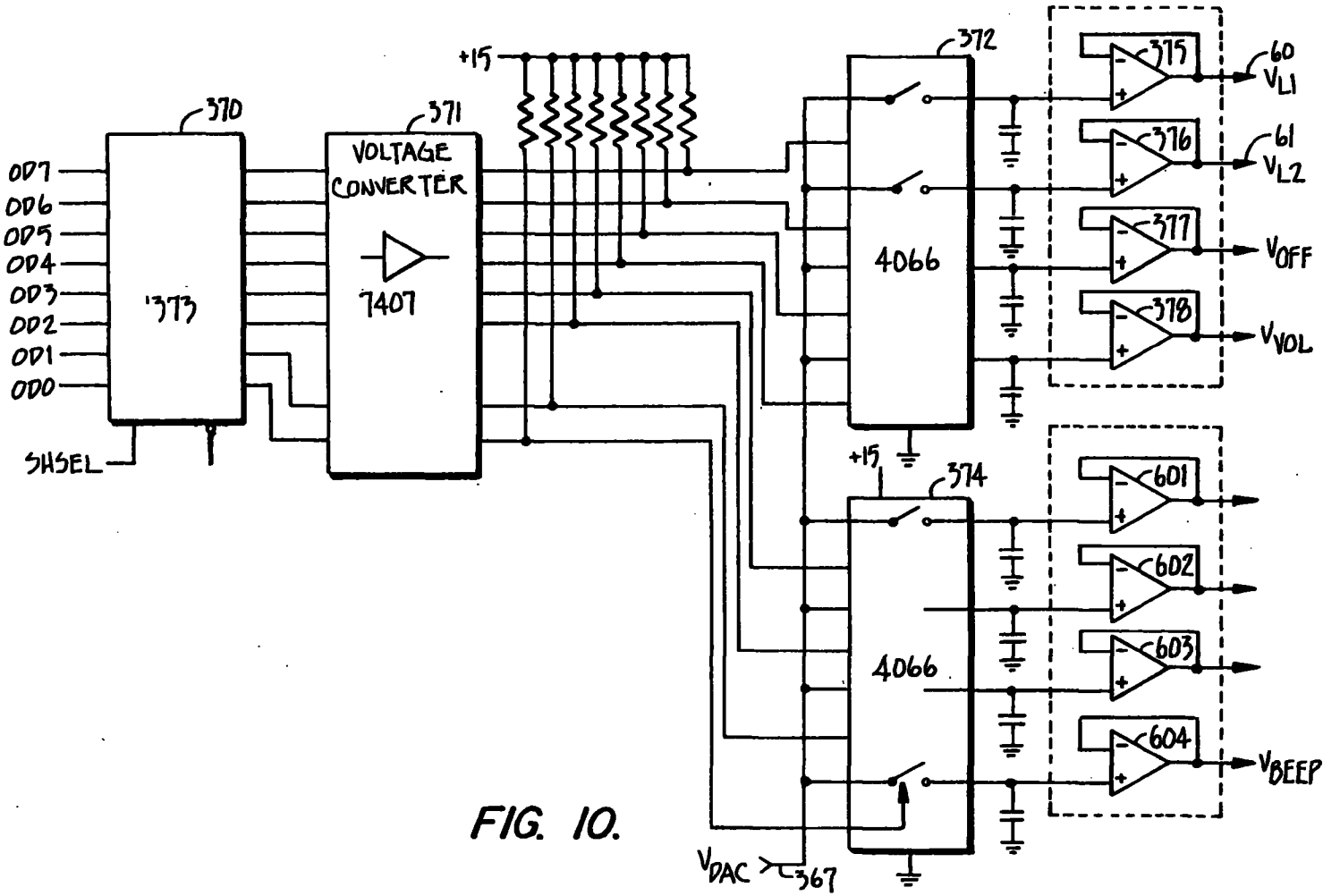

370
'373
OD7
OD6
OD5
OD4
OD3
OD2
OD1
OD0
SHSEL
371
VOLTAGE CONVERTER
7407
+15
372
4066
375
376
377
378
60
V_{L1}
61
V_{L2}
V_{OFF}
V_{VOL}
+15
374
4066
601
602
603
604
V_{BEEP}
V_{DAC}
367

FIG. 10.

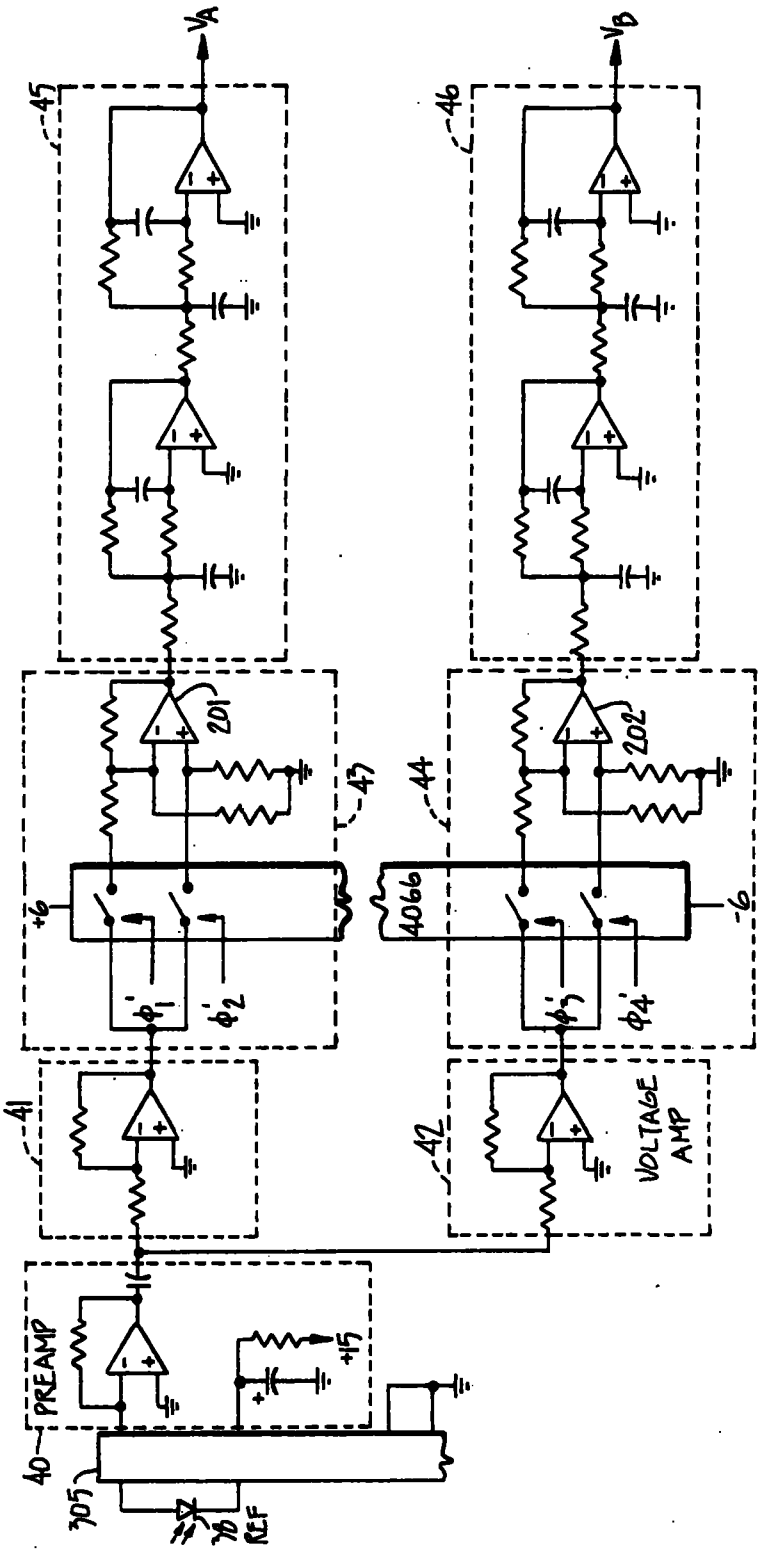

V_A
V_B
45
46
201
202
47
44
+6
4066
-6
ϕ_1
ϕ_2
ϕ_3
ϕ_4
41
42
VOLTAGE AMP
PREAMP
+15
40
705
REF

FIG. 12.

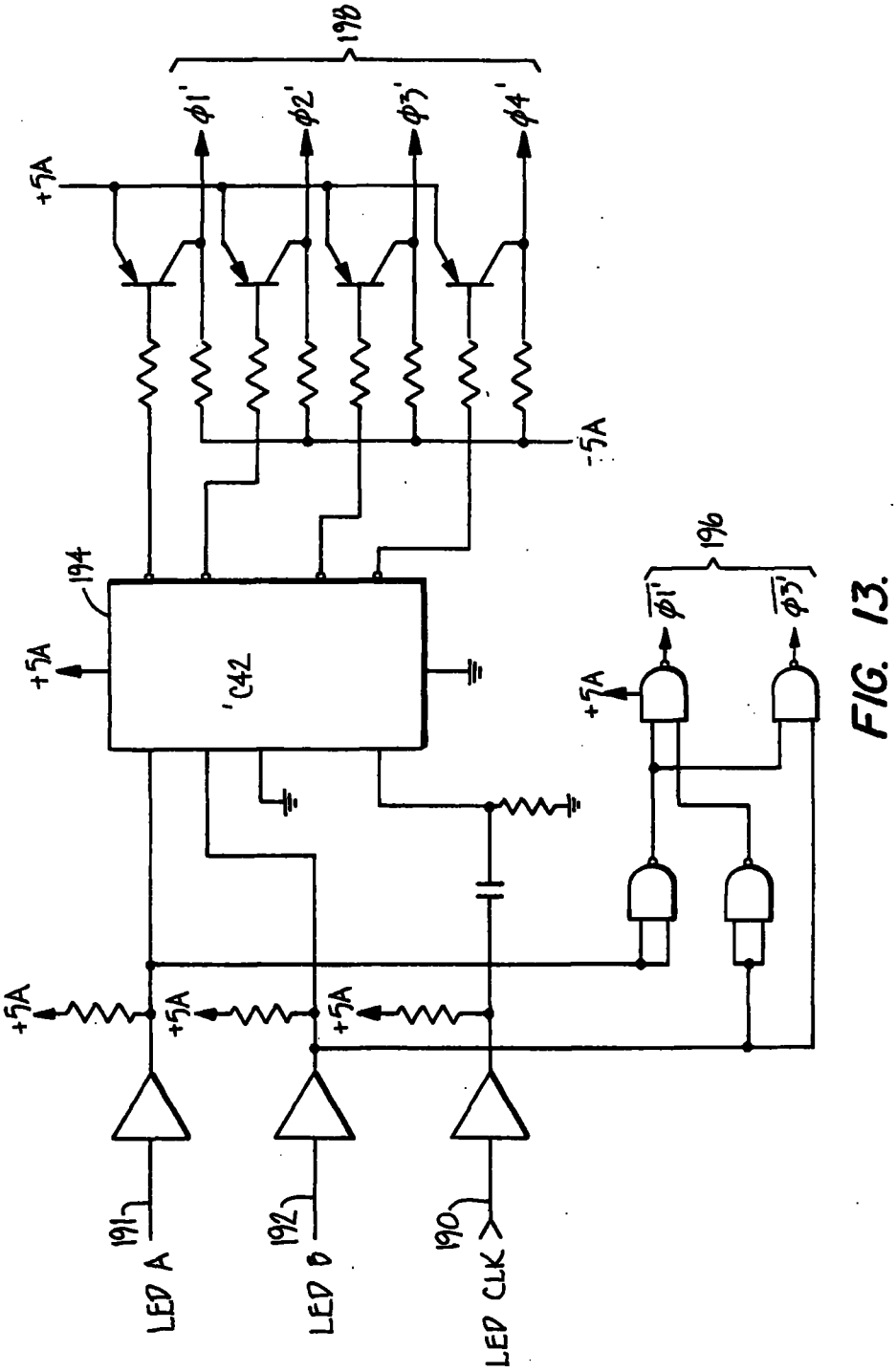

198
φ1'
φ2'
φ3'
φ4'
+5A
-5A
194
'C42
196
φ1'
φ3'
191
LED A
192
LED D
190
LED CLK

FIG. 13.

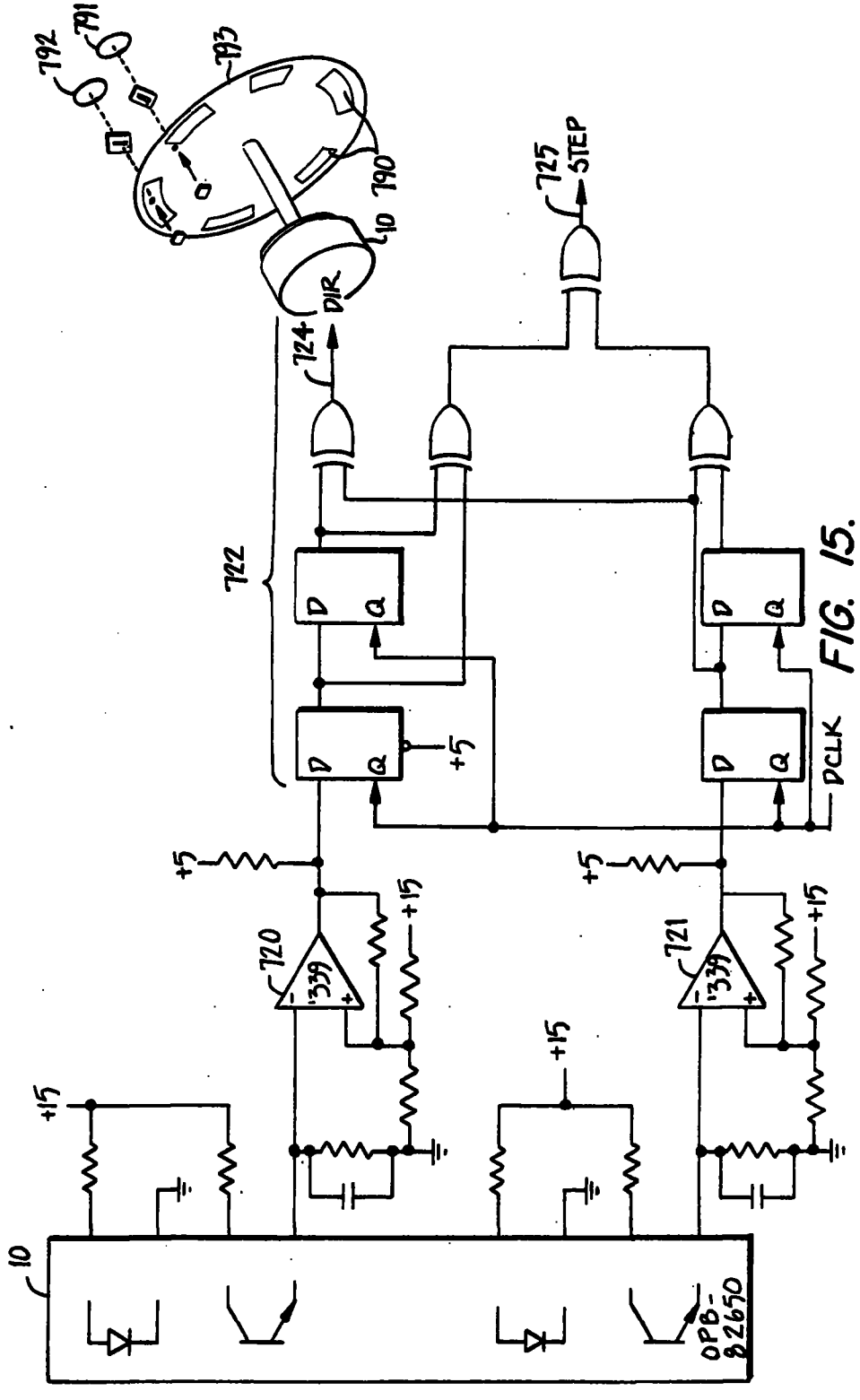

791
792
793
790
10
DIR
724
725
STEP
712
D
Q
+5
DCLK
720
721
339
+15
OPB-
82650

FIG. 15.

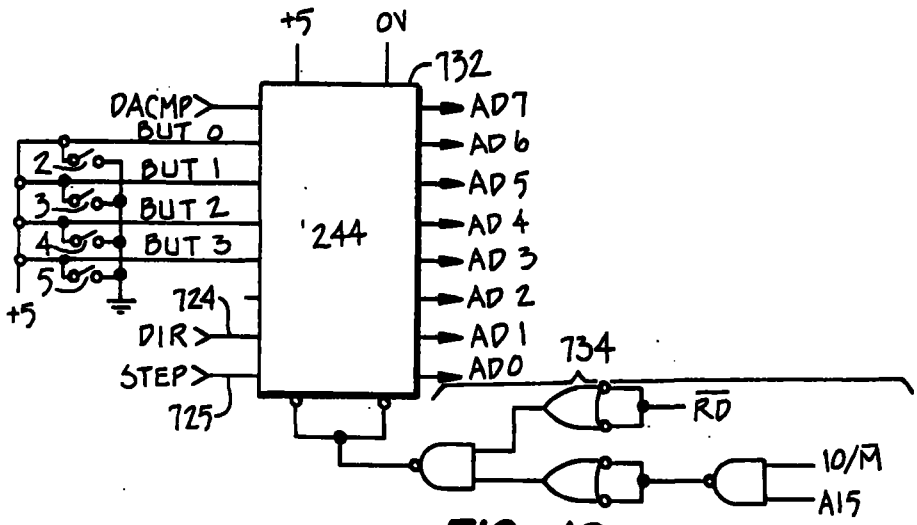

+5
0V
732
DACMP
BUT 0
BUT 1
BUT 2
BUT 3
2
3
4
5
+5
'244
724
DIR
STEP
725
AD7
AD 6
AD 5
AD 4
AD 3
AD 2
AD 1
AD0
734
RD
10/M
A15

FIG. 16.

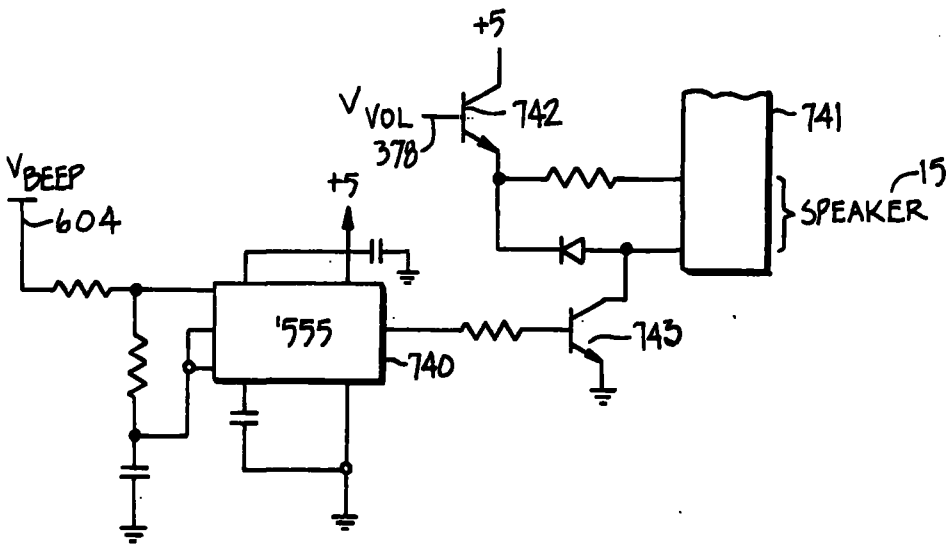

+5
V VOL
378
742
741
15
SPEAKER
V BEEP
604
+5
'555
740
743

FIG. 18.

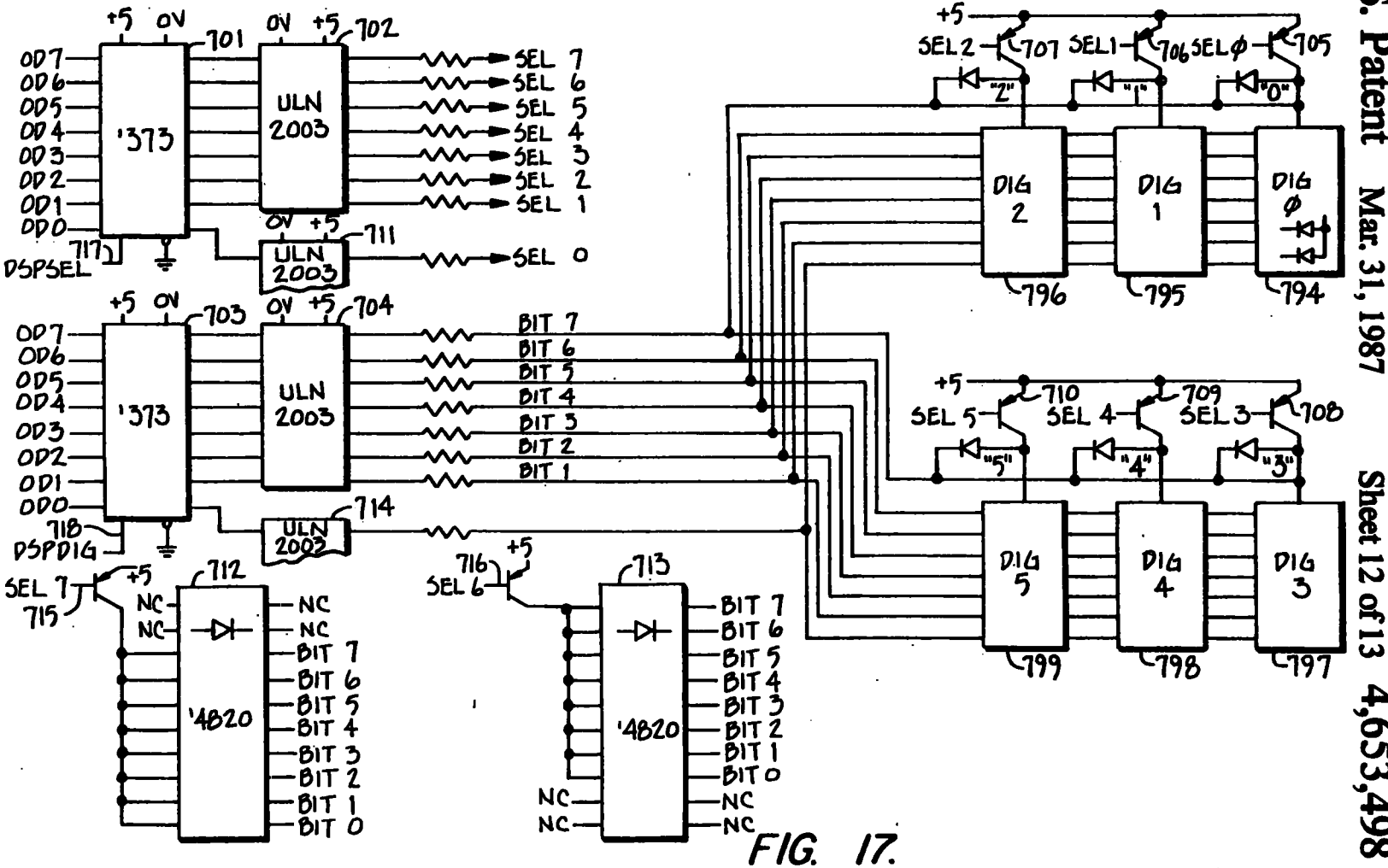

+5
0V
701
702
OD7
OD6
OD5
OD4
OD3
OD2
OD1
OD0
'373
ULN 2003
SEL 7
SEL 6
SEL 5
SEL 4
SEL 3
SEL 2
SEL 1
SEL 0
711
717
DSPSEL
703
704
BIT 7
BIT 6
BIT 5
BIT 4
BIT 3
BIT 2
BIT 1
714
718
DSPDIG
712
713
716
715
'4820
NC
BIT 0
SEL 2
SEL 1
SEL 0
707
706
705
"2"
"1"
"0"
DIG 2
DIG 1
DIG 0
796
795
794
SEL 5
SEL 4
SEL 3
710
709
708
"5"
"4"
"3"
DIG 5
DIG 4
DIG 3
799
798
797

FIG. 17.

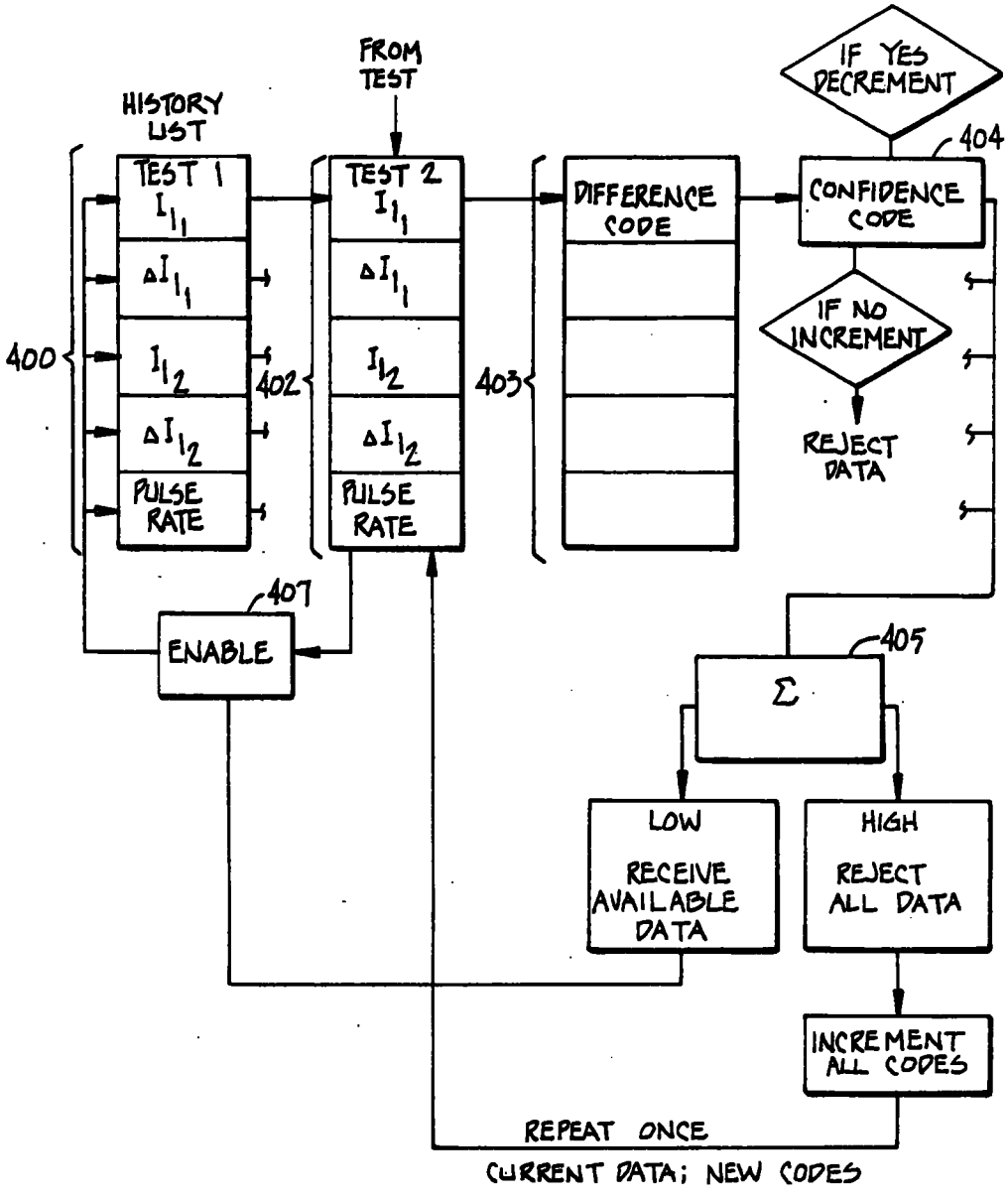

HISTORY LIST
FROM TEST
IF YES DECREMENT
404
TEST 1
I_{1_1}
ΔI_{1_1}
I_{1_2}
ΔI_{1_2}
PULSE RATE
400
TEST 2
I_{1_1}
ΔI_{1_1}
I_{1_2}
ΔI_{1_2}
PULSE RATE
402
DIFFERENCE CODE
403
CONFIDENCE CODE
IF NO INCREMENT
REJECT DATA
407
ENABLE
405
Σ
LOW
RECEIVE AVAILABLE DATA
HIGH
REJECT ALL DATA
INCREMENT ALL CODES
REPEAT ONCE
CURRENT DATA; NEW CODES

FIG. 19.

PULSE OXIMETER MONITOR

This is a continuation of copending application Ser. No. 417,312, filed Sept. 13, 1982, now abandoned, entitled "PULSE OXIMETER MONITOR", which is a continuation-in-part of application Ser. No. 414,175, filed Sept. 2, 1982, now abandoned.

A two fiche microfiche appendix is included herein, consisting of a total of 67 frames.

This invention relates to pulse oximeters and specifically to the photoelectric determination of arterial oxygen saturation in humans with techniques for initializing data, receiving data for processing, setting and triggering alarms all being set forth.

BACKGROUND OF THE INVENTION

Electronic, non-invasive techniques for determination of oxygen content are known. U.S. Pat. No. 2,706,927 to Wood disclosed the computation of oxygen saturation from measurement of light absorption of body tissue at two wavelengths. A "bloodless" measurement was first taken in which as much blood as possible was squeezed from the area where measurement was taken. Thereafter, arterial blood was allowed to flow into the tissue as the condition of normal blood flow was restored. A comparison of the light absorption in the two states provided information on the arterial oxygen saturation of the subject. A series of devices and procedures have been founded using this technology.

In procedures based on this technology, difficulty has been experienced in reliably determining the "bloodless" parameters; due in part to geometrical distortion due to the compression of the tissue; imperfect measurement of this parameter gave imperfect results.

The transmission of light of each wavelength is a function of the thickness, color, and structure of skin, flesh, bone, blood and other material through which the light passes. This attenuation in transmission has been asserted to have a logarithmic characteristic, in accordance with the Lambert-Beers Law.

In a pulse oximeter, the primary material of interest is pulsatile arterial blood. Arterial blood is the only material whose quantity in the tissue varies with time in synchrony with the beating of the heart. Variations in light transmission therefore indicate variations in blood flow permitting direct optical recording of the pulsatile component of arterial blood flow. This ability to separate out the light absorption of arterial blood is especially convenient; since the oxyhemoglobin component of blood is a substance for which the absorption coefficients can be determined, the fraction of any oxyhemoglobin in arterial blood can be determined.

Optical plethysmographs are well known. Such instruments measure pulse rate and provide information on the quantity of blood forced into the tissues on each heart beat. These instruments generally utilize a light frequency near or at the isobestic point where measurement of pulsatile flow is made independent of oxygen saturation. Consequently, they intentionally eliminate information on oxygen saturation.

Following the Wood U.S. Pat. No. 2,706,927 patent, numerous attempts have been directed at eliminating the difficulties connected with arterial saturation measurements using light absorption where the analysis requires the comparing the "bloodless" measurement either artificially induced or naturally occuring during the rest state of the heart cycle with the measurement of

fresh arterial blood when fresh arterial blood enters the tissue. For example, the signal received has been divided into its "AC" and "DC" components and passed through a log amplifier before digital analysis of the signal occurs. See Koneshi et al., U.S. Pat. No. 3,998,550. Likewise, a generation at both wavelengths of subtraction outputs has been utilized before digital analysis. Subtraction outputs have been used to eliminate the DC component and to approximate the logarithmic response of the prior art. See Hamaguri, U.S. Pat. No. 4,266,554. Simply stated, because the pulsatile component constitutes a small portion of the total signal of transmitted light, numerous manipulations based on logarithms have been attempted to screen out the unchanging component of the resultant signal before analysis.

U.S. Pat. No. 3,704,706 to Herczfeld et al disclosed use of a single coherent red light source, preferably a laser. Use of a single light source is unable to separate information dealing with the arterial flow component from that dealing with the arterial oxygen component. The output of such a single red light source instrument can only be an indication of the product of blood flow and the saturation level present. Neither blood flow alone or saturation alone can be known.

In all of the above schemes for the measurement of pulse rate, pulse flow and oxygen saturation, the variant or AC component is a small portion of the total absorption occurring. In such circumstances, discrimination of the signal from other possible sources must occur. When it is remembered that measurements of unconscious, partially anesthetized and otherwise non-responsive patients must occur, and such patients have random and irregular movements (and heart beats), the establishment of thresholds for the reception and analysis of data is critical.

SUMMARY OF INVENTION

A display monitor is disclosed for a pulse oximeter of the type wherein light of two different wavelengths is passed through body tissue, such as a finger, an ear or the scalp, so as to be modulated by the pulsatile component of arterial blood therein and thereby indicate oxygen saturation. The disclosed instrument first receives and compares signal to parameters to check for a pulse like signal. Assuming that a pulse like signal is detected a tonal signal is emitted having a pitch proportional the ratio of oxygen saturation and a sequential repetition proportional to pulse. A visual cue consiting of an array of strobed light emitting diodes is flashed having the number of lights strobed increase with increasing magnitude of the pulses and having a sequential flashing rate proportional to pulse rate. A systematic rejection of extraneous or irregular detected data prevents undue sounding of alarms.

OTHER OBJECTS, FEATURES, AND ADVANTAGES OF INVENTION

An object of this invention is to disclose an instrument which can simultaneously trace and indicate the pulse as well as the degree of oxygen saturation of the individual. According to this aspect of the invention, at least one of the wavelengths of light, preferably infrared, is monitored for slope change. A signal is emitted proportional to and typically synchronous with the slope change rate to indicate heart rate. A second signal is emitted containing pulse rate and oxygen saturation information.

An advantage of this aspect of the invention is that each pulsatile component is individually analyzed. The heart beat and arterial oxygen level of the patient is continually monitored.

Yet another object of this invention is to disclose a series of audible signals which convey pulse rate and oxygen saturation. Pulse rate is indicated by emitting sequential tones at time intervals corresponding to the rate of negative slope reversals (indicating pulse wave maximum). Oxygen saturation is indicated by having pitch decrease proportional to decreasing oxygen saturation.

An advantage of this aspect of the invention is that the human ear is particularly sensitive to both changes in frequency of sequential sound signals and tonal variations in sequential sound signals. A simple beating signal can make all in the immediate vicinity well aware of both the pulse rate and oxygen saturation of the patient.

Yet another aspect of this invention is to emit a visual signal conveying similar information. According to this aspect of the invention, a column of light emitting diodes flashes in height proportional to pulse magnitude and flashes in frequency proportional to pulse rate. As the eye is particularly sensitive to changes in both flashing rate and angular dimension or height of the flashing LED array, an indication of pulse quality is given.

Yet another object of this invention is to disclose a plurality of alarms, which alarms can all be individually set in accordance with the current condition of the patient. According to this aspect of the invention, high pulse rate, low pulse rate and oxygen saturation levels can all be utilized as an alarm limit.

An advantage of this aspect of the invention is that the parameter of the patient's warning limits can be tailored by the anesthesiologist or other attending physicians. Individual adjustment can be made to the particular physiology present.

Yet another object of this invention is to disclose a regimen in combination with the instrument for rejecting extraneous data. Remembering that patients are often in an unconscious or semi-conscious state when this instrument is used, it can be realized that the instrument does not operate in a perfect environment. Shaking or moving the sensor head or even local variations in the patients pulsatile profile could unnecessarily trigger alarms. According to this aspect, incoming processed data is compared to confidence factors. If the data falls within expected levels, confidence factors remain unchanged or are upgraded to the highest level. Where data falls without the anticipated confidence levels, the data itself may be rejected. The confidence levels are eroded or opened in the range of data that can be processed. This process occurs until data consistent with the confidence limits is received. When data consistent with the confidence factor is received, it is compared to the alarm limit.

An advantage of this aspect of the invention is that small local variations in the received signal do not trigger the alarms.

Yet another aspect of this invention is to disclose a totality of data utilized for tracking the pulse. According to this aspect of the invention, the points of maximum light transmission (commencement of inflowing pulse) and maximum light absorption (end of arterial pulse) are tracked for at least one wavelength. A maximum negative slope intermediate the maxima and minima is plotted for avoidance of the dicrotic notch. Finally, the percent of oxygen saturation is determined by comparison of light transmission at both frequencies.

All of these data are analyzed against the confidence limits for reception. Where three out of the six data values are outside the limits, the entirety of the data is rejected. Where four or more of the data values are within, the data is received and the confidence limits under the acceptable catagories upgraded or maintained at the narrowest limit. Confidence limits of unacceptable data are eroded or opened.

An advantage of this aspect of the invention is that interruption of data often occurs at more than one parameter. With such interruption, the entire data block may be averaged to prevent the premature sounding of alarms.

A further object of this invention is to disclose a simplified control for adjusting alarm limits. According to this aspect, adjustment occurs to a shaft encoder directly coupled to an alarm limit adjustment knob. The alarm limit to be set is selected by pressing at least one selector button. Thereafter, turning of the alarm limit adjuster knob updates the limit by sign—depending upon direction of turn—and in limit—depending upon amount of turns. The current alarm limit being changed is shown in the visual display. If the alarm limit does not change for a preset period, that is, the knob is no longer being turned, the knob to the alarm limit is disconnected and the knob is again connected to its original connection and the display returns to its original status.

An advantage of this aspect of the invention is that alarm limit control is easily and simply adjusted. The complex environment of the operating room and intensive care unit is provided with a useful instrument having simplified adjustinent. In particular, the alarms can be controlled by one hand, important in some aspects of patient care. It is not necessary to manually reset the instrument to its original status of displaying saturation or pulse rate.

Other objects, features and advantages of this invention will become more apparent after referring to the following specifications and attached drawings in which:

DESCRIPTION OF THE DRAWING

FIG. 1 is a perspective view of the instrument of this invention illustrating the instrument housing and attachment of a sensor to the digit of a patient;

FIG. 2 is an overall circuit schematic of this invention;

FIG. 3 is a circuit schematic in the vicinity of the microprocessor;

FIG. 4. is a circuit schematic in the vicinity of the read only memory or ROM of this invention;

FIG. 5 is a circuit schematic in the vicinity of the random access memory or RAM of this invention;

FIG. 6 is a circuit schematic of the memory select;

FIG. 7 is a circuit schematic of the input/output select;

FIG. 8 is a circuit schematic of the counter of this invention;

FIG. 9 is a circuit schematic of the comparator circuit wherein 12 bit digital to analog conversion occurs;

FIG. 10 is a circuit schematic of the sample-hold circuitry of this invention;

FIG. 11 is a circuit schematic of the offset amplifier circuit of this invention;

FIG. 12 is a circuit schematic of the detector of this invention;

FIG. 13 is a detail of a clock circuit having an output for powering the light emitting diodes;

FIG. 14 is a detail of circuitry for powering the light emitting diodes, the diodes being switched at a point proximate to the detector;

FIG. 15 is a circuit schematic illustrating the operation of the optically coupled adjustment knob;

FIG. 16 is a view of the control button circuitry of this invention;

FIG. 17 is a view of L.E.D. circuitry outputs;

FIG. 18 is a view of the audio output circuitry; and

FIG. 19 is a block logic diagram of the numerical process steps which result in the instrument output.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, the instrument housing 26 of this invention is illustrated. Outwardly, the housing includes a digit display 1, circuitry select button array 2 through 5, alarm status lights 6 through 9, an optically coupled adjustment knob 10, sync status light 11, LED digital viewmeter 12, and power switch 13. A speaker 15 is placed under and in the instrument housing.

From a connector (not shown) in housing 26 there extend leader wires 27. Wires 27 extend to a detector probe 29. Detector 29 is placed upon the finger 14 of a patient 28. Utilizing the placement of the detector 29 at the finger 14, all of the readings in this invention are made possible.

Oximeter Operation

A broader view of the operation of this invention can be made by considering carefully the circuit schematic of FIG. 2.

Referring to FIG. 2, conventional microprocessor 16 has a bus 17 extending therefrom. Bus 17 has connected thereto conventional ROM 18 and RAM 19. An LED display 20 is schematically illustrated having a select latch 21 and a digit designation latch 22. The circuit select button array 2–5 and optically coupled control knob 10 previously illustrated are gated through controls generally denominated 24.

Having set forth the more or less conventional portions of the microprocessor, attention will now be directed to the analog portions of the circuitry.

Finger 14 of patient 28 is illustrated with detector 29 having schematic detection circuitry. First light emitting diode 32 in the red range and a second light emitting diode 30 in the infrared range are sequentially pulsed to emit light in their respective frequencies by amplifiers 31,33. Typically, LED 32 is in the 660 nanometer range with LED 30 being in the 940 nanometer range.

It is necessary that all the light from the active light emitting diode go through the flesh in finger 14. Therefore, a light impervious barrier 36 is placed between photosensor 38 and finger 14. Barrier 36, terminating in contact with the flesh of finger 14, makes the path between the respective light emitting diodes 30, 32 and the light receiving diode 38 occur only through the flesh of finger 14.

In the instrument herein we utilize two discrete wavelengths. These wavelengths are 660 nanometers (red) and 940 nanometers (infrared). A small amount of discussion related to these parameters is in order.

First, the wavelengths are chosen so that they are far enough apart so that the transmission of light appreciably varies with changes in oxygen saturation.

Secondly, the wavelength are chosen so that the same tissue is sampled. For example, a wavelength in the ultraviolet would not sample the same tissue due to scattering.

While wavelengths extremely close could be used, we have chosen not to do so. We find that drifting of light source wavelengths can occur with accompanying problems.

Signal received from the respective light emitting diodes first passes through a pre-amplifier 40. This signal is thereafter amplified in parallel at amplifiers 41, 42. As amplified, the signal is passed in parallel from each amplifier through respective phase detectors 43, 44. Passage through respective low pass filters 45, 46 thereafter occurs. Amplification at offset amplifiers 47, 48 then takes place. The pulsatile component is passed to multiplexer 50.

Multiplexer 50 has output to a comparator 52. Comparator 52 is ramped in half steps by a 12 bit digital to analog converter (hereinafter DAC) 54. DAC 54 places a comparison signal divided in one part from 4096 parts with the comparator outputting to bus 17.

The reader will recognize that not all human fingers and appendages are the same. Specifically, the difference between the races, skin pigment, weight, age, maturity and other factors all can lead to different signals being sensed at photosensor 38, even though the wavelength and intensity of the light signal output at each of the diodes 30, 32 is the same.

Accordingly, microprocessor 16 is programmed to receive a signal from photosensor 38 within an optimum range. Utilizing a second operating phase of DAC 54, and communicating signal to a sample hold 57, the individual LED's 30, 32 are given voltage outputs 60, 61. These voltage outputs 60, 61 are adjusted so that in each case photosensor 38 looks at a signal well withing the range of the DAC.

Clock 70 controls the sequential output of light from the light emitting diodes 30, 32 to a duty cycle of at least 1 in 4. This is schematically illustrated by signals $\phi 1$ through $\phi 4$. Reception of signal at detector 43 occurs during time periods $\phi 1$ and $\phi 2$ and reception of signal occurs at detector 44 during time periods $\phi 3$ and $\phi 4$.

It can be immediately realized that during respective time periods $\phi 1$, $\phi 3$ active signal from the light emitting diodes 30, 32 is being received. During the time periods $\phi 2$ and $\phi 4$ no signal and only noise is being received. As will hereinafter become apparent, by amplifying the negative signal before passage through the low pass filter, noise can be subtracted out utilizing the illustrated 1 in 4 duty cycle.

Having given the reader an overview of the circuitry utilized with this invention, the invention will now be discussed in detail.

Referring to FIG. 3, the microprocessor 100 is illustrated having an attached crystal 104. This crystal, in combination with clock circuitry incorporated within the microprocessor 100, generates the clock signals required by the microprocessor chip itself as well as providing clock pulses to the rest of the oximeter circuitry through output 102.

Microprocessor 100 is an 8085A CPU integrated circuit chip available from Intel Corporation of Santa Clara, Calif. The family identification suffixes of the remaining IC components are listed on the drawing and the components are readily available from various manufacturers.

An address bus 103 includes address lines A0 through A15. To accommodate the eight bit processor, lines A0 through A7 on the address bus are latched from microprocessor pins AD0 through AD7 so that during the address time state these lines may be read. During an alternate time state, lines AD0 through AD7 become output data lines 104, OD0 through OD7, which lines as here configured are only capable of outputting data.

Referring to FIG. 4, the ROM configuration is seen to be standard. The ROM is addressed with a conventional address bus including lines A0 to A10 addressing in parallel ROMs 106, 107 and 108. These respective ROMs are enabled by three decoded address bits from lines A11–A13 (see FIG. 6). As will hereinafter be set forth with respect to FIG. 6, enabling outputs for reading of the ROMs include read enable 110 (see FIGS. 3, 4) and specific ROM addresses including ROM 0 address 111, ROM 1 address 112, and ROM 2 address 114. The particular ROMs here utilized are of the optically erasable programmable read only memory variety and include an output data bus 115.

Referring to FIG. 5, two conventional RAMs 120, 121 are shown addressed in parallel at address bits A0 through A9 at bussing 125. These RAMs write and read over eight bits with four bus lines AD0 to AD3 at bus 127 addressing RAM 120 and AD4–AD7 addressing RAM 121 at bussing 128. RAMs 120, 121 are read when enabled through enable ports 129 in the absence of a write signal on port 130. These RAMs are written when enabled by port 129 in the presence of a write signal through write ports 130. As each of the RAMs connect to four separate data bits, individual enabling of each of the RAMs is not required.

Referring to FIG. 6, the memory select circuit of this invention is illustrated. The memory seiect has a three bit input 140 at lines A11–A13. Output occurs when memory is selected at ROM 0 enable 111, ROM 1 enable 112, ROM 2 enable 114. A RAM enable 141 passes through an inverter and NAND gate to enable reading of RAMs 120, 121 for either reading or writing.

Referring to FIG. 8, a counter used as a divider is illustrated. Referring briefly back to FIG. 3, it will be seen that the microprocessor 100 is provided with a clock running at 2.5 MHz generally denominated 102. The CPU clock outputs at 102 to a counter 172 (see FIG. 8.) Counter 172 divides signal 102 by the number 171 and outputs to binary counter 173 in order to generate an LED clock frequency of 1.827 kHz, which is unrelated to room light frequencies. Counter 173 outputs signals LED A 191, LED B 192, LED CLK 190 and DCLK 189. This circuit in cooperation with the circuit of FIG. 13, effects light and detector switching to enable signal phasing.

Having set forth in generality the microprocessor, it will be realized that much of that disclosed is already known in the art. Specifically, complete descriptions of the wiring of this microprocessor can be found in the MCS-8085 Family Users Manual, published October 1979 by Intel Corporation. Those having skill in the art are referred to this publication should question arise about the circuitry thus far described.

Referring briefly back to FIG. 8, LED clock outputs 190, 191, 192 are inputed to the clock divider 194 of FIG. 13. Divider 194 outputs four sequential duty cycle states denominated $\phi 1'$ through $\phi 4'$. Complements of signals $\phi 1'$ and $\phi 3'$ are outputed directly at clock driver outputs 196. It will be noted that all four signals $\phi 1'$–$\phi 4'$ are outputed at 198 for timing purposes hereinafter discussed.

Having set forth the timer, the remainder of this disclosure will be broken down into five discrete parts. First, timing for the light emission of the LED's will be discussed. Emphasis will be placed on the fact that the diodes are switched locally.

Second, light reception will be set forth. With respect to the reception, emphasis will be made to the fact that the signal is digitally extracted without any analog treatment whatsoever. The pure digital signal is thereafter processed and utilized to create the light curves herein. Effort is made to eliminate all variables present, including those in the flesh analyzed as well as ambient light noise.

Thirdly, and in view of variant light transmission qualities of human flesh, the light level adjustment circuit of this invention will be traced. It will be pointed out that the adjustment of the emitted light occurs so that the sensor receives an amount appropriate for the amplification circuitry.

Fourth, setting of the alarm limits will be analyzed. Illustration will be made.

Fifth, and finally, the program alarm will be discussed. Specifically, the utilization of "confidence limits" and a totality of data received in the monitoring program will be disclosed as screening extraneous data yet permitting a timely alarm to ward off catastrophe.

Referring to FIG. 14, and assuming that sufficient voltage is present across leads 301, 302, current of an appropriate level will be emitted to each of the light emitting diodes 30, 32. The diodes here are illustrated schematically across a connector 305 and are shown being switched by respective transistors 307, 309. Specifically, when a negation pulse is received at each of the transistors, the transistors open, voltage appears across the respective diodes 30, 32, and light is emitted.

Assuming light is transmitted, it is passed to the flesh of the digit 14 and is thereafter received at the receiving photosensor 38.

Referring to FIG. 12, photosensor 38 is illustrated. It is coupled across a connector 305. Connector 305 in turn passes its signal through amplifier 40. The signal is then split and passed to voltage amplifiers 41, 42, the amplification here occurring in parallel, allowing differences in gain between red and infrared signal processing. Respective phase detectors 43, 44 are clocked at inputs $\phi 1'$–$\phi 4'$ from the clock circuit of FIG. 13. Remembering that a 1 in 4 duty cycle is here utilized with each of the signals $\phi 1'$, $\phi 2'$, $\phi 3'$, $\phi 4'$ being clock periods, it is seen that the signal is gated. Specifically, and during the $\phi 1'$ time period, negative amplification of the total light signal, including pulsatile component and noise, occurs at amplifier 201 with passage of the resultant signal through the low pass filter 45.

Referring to FIG. 14, in the next sequential time period, and due to the signal $\phi 1'$ no longer appearing to close transistor 309, transistor 309 will be shunted to ground. At the same time, during time period 02' gate 43 will open to amplify the positive component received. This component received, however, will have no light emission whatsoever; it instead will represent pure electronic or optical noise. The timing of this circuit will therefore yield on equal bases first light containing the pulsatile component and noise and thereafter just noise. Amplifier 201 amplifies one signal positively and the other signal negatively in equal amounts. It will be seen that integrated over the full four periods of the

clock, through amplifier 201 the instrument sees equal components of noise which cancel and unequal components of signal which do not cancel. By the expedient of taking the respective intermittent pulses and passing them through the low pass filter 45, there results a signal out containing valid signal only; noise cancels.

The remaining channel is analogous. Specifically, during time period $\phi 3'$, noise and light signal are amplified negatively and passed through low pass filter 46. During time period $\phi 4'$, noise only is positively amplified and cancelled in passage through the low pass filter 46.

The emitted signal V_A and V_B can be described as having two components. The first component is constant. It is that element of light which remains essentially invariant. This signal includes an absorption component because of skin pigment, bone, flesh and venous blood. The second component represents the pulsatile inflow of arterial blood.

The ratio of that second component to the first component is what is sought by the instrument. What is sought is the ratio of the arterial and pulsatile component of the blood to that of the total absorbing tissue. The color of the arterial component of the blood produces the differential light absorption that is dependant upon the oxygen saturation of the hemoglobin. The instrument must isolate this component.

Referring to FIG. 11, amplification of the signal to an idealized state is illustrated. Specifically, in taking respective signals VA', VB', an offset voltage VOFF introduced. This signal is a constant voltage which subtracts out part of the constant portion of the received light signal which relates to passage through the nonvariant portions of the flesh. Since it is known that the pulsatile component is always very small with respect to the total signal, an improvement on the accuracy of digital conversion can be obtained by this subtraction. It is necessary, however, for the microprocessor program to mathematically reinsert this subtracted voltage prior to processing the signal. This subtraction and amplification occurs at the respective amplifiers 330, 331 with passage of the signals VA' and VB' from the network.

With digital to analog conversion of these signals, a combination of the pulsatile component and the remainder of the constant component is then required. This can best be seen through the circuitry of FIG. 9.

Referring to FIG. 9, a multiplexor 50 is illustrated. During the analytical operation here shown, this multiplexor samples signals VA' and VB'. Signal is passed to the negative side of comparator 52. Signal for driving the multiplexor passes through lines OD4–OD6 in the DAC high latch 360. The DAC low latch 362 is thereafter actuated in sequence responsive to enabling signals on enabling line 363. Output occurs to a digital to analog converter 54 on a twelve bit basis. Division to one part in 4096 occurs.

Typically, the signal is compared in halves. Output of DAC 54 occurs over lead 365 to comparator 52. The comparator output 366 is passed to the microprocessor. Depending upon whether a high or low signal is received, stepping of the twelve bit DAC 54 occurs in halves, enabling the twelve bit division to occur rapidly. Consequently, the output level of the voltage of the receiving photosensor is rapidly determined with the result that the pulsatile component can be rapidly followed. This process is repeated for both signals VA' and VB' at a rate that allows the microprocessor to faithfully track both signals.

Having set forth the light reception circuitry of this invention, attention will now be directed to the level of light adjustment.

It will be remembered that each of the patients, due to flesh, skin pigment, skin thickness, bone, venous blood present and other invariants, will present his own factor of constant light absorption at both wavelengths. This being the case, it is necessary to adjust the level of current applied. This is done through the DAC circuit of FIG. 9 and the sample hold circuit of FIG. 10.

The sampling of the light signals by the microprocessor was described above. In the case where the signals are not within the useful range of the conversion circuitry, the light level must be adjusted up or down as required to restore the signal level to the voltage range acceptable to the analog to digital conversion. Referring to FIG. 9, the program will output a code corresponding to the desired voltage level through its data bus into latches 362 and 360, setting the DAC 54 output to a voltage corresponding to desired LED current. Note that this is only done during a time period when the DAC is not used for input conversion. The program will then output using the same bus a bit corresponding to the selected LED into latch 370 of FIG. 10. This bit, or selection signal, is converted to a compatible voltage by voltage converter 371 and applied to one of eight analog switches 372 and 374. These have the effect of applying the voltage from the DAC, corresponding to the desired LED current level, to a storage capacitor which will latch this voltage after the input has been removed. This voltage is buffered by amplifiers 375 and 376 and applied to the LED circuitry. Thus, dependant upon the intensity of the signal received by the photosensor, the respective light emitting diodes can be driven with greater or lesser voltage to produce the optimum voltage output.

It is noted that only two of the available eight channels of this sample hold circuitry are required to adjust the LED intensities. The remaining channels provide a general purpose analog output from the microprocessor for a variety of unrelated functions. The output of amplifier 377 provides the fixed offset for the offset amplifiers described above; VVOL, the output of amplifier 378, provides a volume control for the alarm; outputs of amplifiers 601, 602, and 603 provide external outputs for an optional chart recorder; and the output of amplifier 604 provides a control for the pitch of the alarm.

Monitor Operation

The manner in which the signal information derived by the oximeter apparatus is presented to the attendant physician through the oximeter monitor of this invention will now be discussed.

Referring to FIG. 1, when the instrument power is turned on via power switch 13, digit display 1 and LED digital viewmeter 12 both flash momentarily until microprocessor 16 begins its operation. Speaker 15 also emits a beep. As soon as the microprocessor 16 takes control of the instrument, which is on the order of a millisecond, the digit display 1 is cleared, with zeros flashing on digits 794–796. On power up, the oximeter default is for the audio alarm to be inhibited so that LED alarm inhibit light 9 begins flashing. Synchronization of the pulse rate of patient 28 through detector probe 29 is not yet established. Therefore, the sync status light 11 flashes, indicating no sync. Microproces-

sor 16 begins to sample the signals from photosensor 38 until it determines that valid pulses are being received, at which point digits 794–796 of digit display 1 indicate in decimal numbers the percentage of oxygen saturation in the patient's 28 blood. Digits 797–799 numerically indicate the pulse rate. The LED digital viewmeter 12 begins to flash synchronously with the pulse rate with the vertical height of each flash being proportional to the strength of the received pulse. After about 4 or 5 valid pulses have been received no-sync LED light 11 is disabled and switches off. The alarm, which operates when triggered through speaker 15, may be manually enabled by the user at this point, through alarm button 5. When button 5 is pressed, alarm inhibit light 9 ceases to flash. The alarm will sound when the alarm limits are exceeded as discussed in detail below.

When pulse synchronization is achieved, speaker 15 begins emitting beep tones at a frequency synchronous with that of the perceived pulse rate and at a pitch proportional to oxygen saturation. Defaults provide an initial volume and pitch to these signals.

The information is updated from the microprocessor 16 on a continual and regular basis, modified ouly by a digital filter which serves the purpose of averaging recent pulse history with present information. This simply serves to smooth out transient small deviations in pulse rate and oxygen saturation due to physiologic and artifactual noise variations.

The microprocessor 16 continues to sample data and compare it to the current alarm limits in the instrument. Upon power up, in the presently preferred embodiment the alarm limits are defaulted to an 85% lower oxygen saturation limit, a lower pulse rate limit of 55 and an upper pulse rate limit of 140.

The alarm limit defaults and the audio signal from speaker 15 may be changed in the following manner. The volume of the beep tone from speaker 15 can be set by the user by turning optically coupled control knob 10 (FIG. 1). Turning control knob 10 clockwise will enable volume to be maximized; turning knob 10 counter-clockwise can enable the audio output of speaker 15 to be totally inhibited.

To alter an alarm limit parameter, one of buttons 2–4 is pressed. For example, when saturation limit button 2 is pushed, the current saturation level alarm limit is displayed on digit 794–796. Initially, that will be the defaulted limit of 85. Optical knob 10 is then enabled for adjustment of oxygen saturation limit. By turning knob 10 in either direction, that limit may be changed anywhere from 0 to 100%, depending on what the clinician decides is an appropriate saturation alarm for the patient's situation. After about two seconds of inactivity on knob 10, knob 10 will automatically be disabled for saturation limit adjustment and will return to the volume adjustment mode. Concurrently, the display 1 is switched back to show the current oxygen saturation level and the current pulse rate. High pulse rate limit button 3 and low pulse rate limit button 4 work in an analogous fashion. Alarm status indicator lights 6, 7 and 8 flash when their respective alarm limits are exceeded. Lights 6–8 flash irrespective of whether the audio alarm is enabled or disabled by alarm inhibit button 5.

Recall that in the absence of parameters exceeding alarm limits, speaker 15 is emitting a pulsed tone whose frequency of repetition equals the patient's pulse rate and whose pitch is proportional to oxygen saturation. When the alarm is enabled by button 5, should any parameter exceed its respective alarm limit, speaker 15 emits a continuous tone of constant pitch until either the alarm is disabled or the parameter comes back within the set boundary. Again, when the alarm is inhibited LED 9 flashes to indicate to the user that audio alarms will not sound.

A more detailed understanding of the oximeter monitor operation discussed so far can be had by reference to the circuitry of FIGS. 15–18. Further understanding may be had by reference to the program listing contained in the microfiche appendix.

FIG. 15 is a circuit schematic illustrating operation of the optically coupled control knob 10. Shaft of knob 10 is connected to a shaft encoder 793. Shaft encoder 793 is pierced at regular intervals by windows 790. LED-photosensor pairs are placed in proximity to each other on opposite sides of encoder 793. Pair 792 is shown optically coupled through a window 790 while pair 791 is blocked by encoder 793. The width of each slot is half of the interval between them. Each pair is also equipped with a narrow slit to improve resolutions. The reiationship between LED-photosensor pair 791 and 792 is such that they are separated by an angle representing 25% of the slot-to-slot angle, a reiationship known as quadrature.

Were encoder 793 to be rotated in a clockwise direction, pair 791 would remain occluded at the point in time when 792 became occluded, whereas if rotated counter clockwise the opposite would be true, that is 791 would be non-occluded when 792 became occluded. A similar unambiguous relationship exists between the two pairs of LED-photosensors for each edge of each window. In such manner, signals may be sent to microprocessor 16 which indicate the direction of rotation and step of knob 10.

Signals from optically coupled pairs, such as pair 791, are presented to comparators 720 and 721. Through control logic 722, both the direction of turn and the step of knob 10 is presented to the microprocessor. Signal on output DIR 724 enables the microprocessor 16 to calculate direction of turn and signal on output STEP 725 enables determination of step. The advantage of this particular arrangement is that the absolute position of the knob 10 becomes immaterial. Only when the microprocessor 16 is receiving signals from a changing knob position does the position of the knob 10 have any import.

Referring to FIG. 16, direction signal 724 and step signal 725 are passed to input gate 732. Chip 732 is enabled through control logic 734. Inputs from buttons 2–5, in combination with direction signal 724 and step signal 725, output through bus AD0–AD7 to give, in turn, direction and amount of alarm limit correction in RAM memory.

Referring to FIG. 17, the LED display circuitry is therein illustrated. Digit selection data presented on data lines OD0–OD7 enters latch 701 enabled by display select DSPSEL 717. The data is outputed to driver 702 and driver 711 to derive numerical digit select signals SEL 0 through SEL 7, 705–710. SEL 0 through SEL 5 enable 7 segment LED decimal numerical displays 794–799.

Data representing the numerical values to be displayed on digits 794–799 enters latch 703, enabled by a display digit DSPDIG 718. The outputs of latch 703 are inputed to drivers 704 and 714. The output of drivers 704 and 714, bit 0 through bit 7, switch on segments of the individually selected standard 7 segment LED display, presenting 1 decimal digit of the current oxygen

saturation level or limit, or the current pulse rate level or limit. The other digits are displayed, in turn, in similar fashion.

SEL 7 715 and SEL 6 716 each operate 8 LEDs per chip of LED chips 712, 713. The number of LEDs per chip lit is determined by bit 0 through bit 7. The number of LEDs lit will be proportional to the pulse strength and the rate of flashing of displays 712, 713 is synchronous to heart rate, as discussed above.

Finally, FIG. 18 illustrates control of the audio output of speaker 15. Voltage levels VVOL 378 and VBEEP 604 (see FIG. 10) correspond to desired volume and desired pitch, respectively. Passing VBEEP 604 to timer 740 and transistor 743 to speaker 15 via connector 741, results in a modulated pitch and tone repetition rate. Passing VVOL 378 to transistor 742 and connector 741 to speaker 15 modulates the volume of the tone.

THEORY OF OPERATION

The method of operations involves taking measurements of light transmission in tissue at two distinct wavelengths (red and infrared) at two arbitrary points in time, these points in time being but a small fraction of the time for a complete pulse. The wave form of a pulse of blood in the human flesh is digitally plotted. By considering the change in the transmission of light due to inflowing arterial blood, a measurement is made.

Regarding this transmission, as blood flows in, light is absorbed. Consequently the resident detector of light, photosensor 38, sees less light. Thus, it is the drop in light received at the photosensor that indicates the pulsatile component.

Assuming that the ambient transmission (approximately 99% of the signal) is represented by the letter I and the change in transmission during the pulse is defined by the letter ΔI then the equation for representing the change in transmission relative to the unchanging matter in the flesh to be integrated is represented by the equation:

$$\frac{\Delta I}{I} \alpha \Delta M \tag{1}$$

where ΔM is the change in material in the flesh during the pulse.

Interposing a constant to produce an equation yields the form:

$$\frac{\Delta I}{I} = K\Delta M \tag{2}$$

where K is a constant of proportionality in the resultant equation.

Realizing that the change in mass is composed of blood whose optical absorption is larger than the tissue and that this blood includes two forms of hemoglobin: oxy-hemoglobin (hemoglobin with appended oxygen) and reduced hemoglobin (hemoglobin without oxygen), this equation can be expanded for two variants of matter thus:

$$\frac{\Delta I}{I} = K_A\Delta M_A + K_B\Delta M_B \tag{3}$$

where K_A is a constant for oxy-hemoglobin ΔM_A is the amount of matter due to the influx of oxy-hemoglobin; K_B is a constant for reduced hemoglobin and ΔM_B is the change in reduced hemoglobin.

It will be remembered, that we are conducting our examination at two discrete wavelengths. This being the case, the above relation can be expanded to include the applicable constants at each wavelength thus:

$$\left.\frac{\Delta I}{I}\right|_{\lambda 1} = K_{A1}\Delta M_A + K_{B1}\Delta M_B \tag{4a}$$

$$\left.\frac{\Delta I}{I}\right|_{\lambda 2} = K_{A2}\Delta M_A + K_{B2}\Delta M_B \tag{4b}$$

where K_{A1} and K_{B1} are the respective oxy-hemoglobin and reduced hemoglobin constants at a first wavelength λ1 (say the red wavelength) and K_{A2} and K_{B2} and are the constants at a second wavelength λ2.

It will be appreciated that each of the constants having the form K_{xy} is a constant that relates the relation of the change of absorption to the total light absorption for a particular color and change of matter due to pulsatile flow.

Realizing that we are after the fraction S (saturation) of oxy-hemoglobin to total hemoglobin then we know that:

$$\Delta M_A = S\,\Delta M \tag{5a}$$

$$\Delta M_B = (1-S)\Delta M \tag{5b}$$

where

$$\Delta M = \Delta M_A + \Delta M_B \tag{6}$$

where S equals the saturation and (1−S) equals the fractional presence of the reduced hemoglobin. Placing this into the previous equation yields the results:

$$\left.\frac{\Delta I}{I}\right|_{\lambda 1} = K_{A1}S\Delta M + K_{B1}(1-S)\Delta M \tag{6a}$$

$$\left.\frac{\Delta I}{I}\right|_{\lambda 2} = K_{A2}S\Delta M + K_{B2}(1-S)\Delta M \tag{6b}$$

It can be seen from the above equations that once saturation is determined, solution for blood perfusion (ΔM) is trivial.

At this juncture, we surprisingly define a ratio related to the light transmission at two different wavelengths. In defining this ratio, the reader will realize that we avoid manipulation in accordance with logarithmic proportionality. Specifically, we define the ratio between light transmitted and received at the wavelength λ1 and at the wavelength λ2 as follows:

$$R = \frac{\left.\frac{\Delta I}{I}\right|_{\lambda 1}}{\left.\frac{\Delta I}{I}\right|_{\lambda 2}} \tag{7}$$

Substituting the values of change of light absorption over total light transmission yields:

$$R = \frac{K_{A1} S + K_{B1} - S K_{B1}}{K_{A2} S + K_{B2} - S K_{B2}} \quad (8)$$

Likewise, substituting for S yields:

$$S = \frac{K_{B1} - R K_{B2}}{R(K_{A2} - K_{B2}) - (K_{A1} - K_{B1})} \quad (9)$$

Thus, it can be seen that a relationship exists for both the ratio R and the saturation S.

Those in the medical arts will realize that the numbers sought to be determined electronically by the absorption of light, are also capable of laboratory tests. Specifically, there are a number of laboratory protocols and tests whose accepted results yields saturation. This being the case, a procedure for the calibration of all instruments becomes immediately apparent.

Specifically, by taking laboratory arterial oxygen saturations from individuals at differing saturations S_1, S_2, S_3, and S_4, we can measure specific transmission ratios R_1, R_2, R_3, and R_4. To reliably obtain these ratios R_i, the present instrument itself is used, in particular the portion of the device related to obtaining reliable measurements at hand herein. We thereafter can make an initial guess as to coefficients for both oxy-hemoglobin and reduced hemoglobin.

Taking one of the aforementioned constants K_{A1}, this constant can be broken down into two discrete components. First, one component can come from a previously determined value and be denominated C_{A1}. Secondly, and for each instrument, this constant will of necessity change. This change will be due to the conditions of observation, individual instrument electronics and the like. This value can be express ΔC_{A1}. Each of the four constants in the above equation can likewise be expanded in the same way.

$$(C_{A2}+\Delta C_{A2})(S_i R_i)+(C_{B2}+\Delta C_{B2})(R_i - S_i R_i) = (C_{A1}+\Delta C_{A1})((S_i)+(C_{B1}+\Delta C_{B1})(1-S_i) \quad (10)$$

where i is an index related to at least four measured saturations and transmission ratios.

Those skilled in math and instrument calculation can now see that the ΔC quantities in all states and wavelengths can be simultaneously solved provided that four independent saturations are utilized. Therefore, a set of constants is attained, which constants can be utilized for programming individually produced instruments at all values of S.

The aforegoing relations can be alternatively stated. We have found that the relation of R (the ratio of transmission) to S (saturation of the hemoglobin with oxygen) is capable of simple curve fitting. Specifically, for at least human beings a constant and predictable curve of S with respect to R results. By utilizing this relationship in a look-up table, one may quickly compute the saturation of a patient.

Note that in our device, unlike in the prior art, a light source of isobestic wavelength is not used, nor is apparatus for taking logarithms necessary (see equation 7).

The reader will realize that the disclosed pulse oximeter or plethysmograph is targeted for use typically on a human digit. It should be realized that the disclosed pulse oximeter works equally well on any number of cutaneous locations. Idealized and a preferred use of the extremely small and local sensor of this invention is on the scalp of children being born. Avoidance of oxygen poor conditions during birth resulting in cerebral palsy is contemplated. Likewise, any other cutaneous location will suffice, e.g. the nasal septum.

THEORY OF MONITOR CONFIDENCE LIMITS

In order to provide an "intelligent" separation of the patient's pulses from noise and motion artifacts, a method of storing expected pulse characteristics and comparison to potential pulse wave forms is employed. This method requires five "vectors" or lists of parameters. These parameters are $\Delta I_{\lambda 1}$, $I_{\lambda 1}$, $\Delta I_{\lambda 2}$, $I_{\lambda 2}$, and the pulse rate and are shown schematically in memory 400 of FIG. 19. It should be noted that these parameters are the same as the transmission parameters described above with scaling appropriate to 16-bit binary arithmetic.

A set of historical values for each parameter is stored in RAM, the history list. Each of these lists is five elements long in the present application, but could be shortened or expanded as required. The history lists are used as references for the current parameters being tested, also stored in RAM. This comparison yields a set of differences, which are similarly stored in coded form as difference codes. Associated with each parameter is also a "confidence" code which is, in essence, a tolerance level for each current parameter, as will be described below.

The first step in the confidence checking is to store the current parameters and then to compare the value of these parameters with the values stored in the history list. Note that the contents of the history list presumably contain the previous good pulse parameters. In the start up condition these pulse parameters are loaded with arbitrary initial values, and associated with a low confidence code admitting wide variations of data. Here, the parameter of total light transmission $I_{\lambda 1}$ is illustrated stored in memory 402.

Once the difference codes have been computed and placed in memory 403, they are compared with the corresponding stored confidence codes in memory 404. These confidence codes, which have the same range as the difference codes, are a description of how close the current parameter must be to the historical value to be considered acceptable. Both the difference codes and the confidence codes are coded in such a way that a code of 0 represents a difference or tolerance of 0–12%, 1 represents 13–25%, 2 represents 26–37%, and so forth, to the code of 8 which represents a 100% mismatch.

The meaning of this code with respect to this difference is that simply the ratio of the current parameter to the historical parameter, and with respect to the confidence codes, represents the tolerance for the parameter.

Once the confidence codes have been computed for each parameter, they are then summed at register 405 to generate a confidence score for the set of parameters. This total score is then compared to a threshold or a maximum acceptable score. It should be noted that a low score represents a close match to the expected value, and activates an enable 407 which allows data reception.

If the total confidence score is below the threshold, then the program assumes that the pulse is indeed a good pulse and takes a branch to update the confidence codes and exits to process the pulse. If the confidence code is above the threshold all data is rejected.

The confidence codes are individually adjusted by comparing the confidence code with the difference

code for each parameter. If the difference code is smaller, then the confidence code is decremented by one count, expressing a higher level of confidence for the next text. If the difference code is larger, reflecting a parameter that was not within tolerance, although the total was satisfactory as a set, then that individual confidence code is incremented, representing an eroded confidence level. This process of incrementing or decrementing is repeated twice if the pulse was successful so that the confidence codes quickly converge on good pulses.

In the event that the score was not acceptable, the program retests all of the parameters except for the pulse period, this being the parameter most likely to go out of bounds from motion induced artifact. Assuming that it still fails, the confidence codes are re-adjusted once as described above in order to erode the confidence levels somewhat in preparation for the next trial.

The program then makes one last check with these updated confidence codes before exiting and rejecting the pulse. The reason for this last check is that the confidence codes which will be applied to the next pulse might as well be applied to the current pulse as well, in the event that the pulse is only slightly outside the acceptable window. This technique provides a good response to changing pulse conditions.

The above description outlines in a general way the confidence code processing used in the oximeter to provide an intelligent processor for physiologically based signals. A more detailed description is contained within the comments of the program listing contained in the microfiche appendix.

The reader will appreciate that the disclosed process is an intermediate step in the indication of the measurement.

In addition, the reader will appreciate that for the purposes of determining the calibration of the instrument in human subjects, the technique of determining measurements of R_i with high levels of confidence use the instrument itself to determine the calibration parameters as outlined herein.

In summary, it can be seen that the pulse oximeter monitor of the present invention provides a wide variety of essential information to attending physicians and in a variety of visual and audio forms. While the above provides a full and complete disclosure of the preferred embodiments of the invention, various modifications, alternate constructions, and equivalents may be employed without departing from the true spirit and scope of the invention. For example, high oxygen saturation limits are needed on applications involving newborn infants to prevent bronchopulmonary dysplasia and retrolental fibroplasia. Provision of an additional alarm limit for high oxygen saturation is well within the scope of this invention. Therefore, the above description and illustrations should not be construed as limiting the scope of the invention which is defined by the appended claims.

What is claimed:

1. An oximeter apparatus for use in measuring pulse rate and oxygen saturation of blood by means of absorption of optical radiation through living tissue comprising:

first and second light sources for emitting light at a first and second wavelength, respectively;

a light sensor;

said light sources and light sensor being adapted to be addressed to said tissue to define a light path through said tissue between said light sources and said light sensor;

means for detecting signals corresponding to light received by said light sensor at each of said first and second wavelengths and for deriving from said signals a pulsatile signal corresponding to a pulsatile characteristic of arterial blood flow and generating a signal corresponding to oxygen saturation of the blood; and

means for generating an audible intermittent tone signal, said tone signal generating means further comprising

means responsive to said pulsatile signal for controlling the occurrence of said audible tone signal, and

means responsive to said oxygen saturation signal for varying the tonal frequency of said audible tone signal with oxygen saturation.

2. The apparatus of claim 1 wherein said means for varying the tonal frequency of said audible signal comprises means for decreasing said tonal frequency with decreasing oxygen saturation.

3. The apparatus of claim 1 further comprising:

an array of lights;

circuit means coupled to receive said pulsatile signal from said detecting means for flashing said lights; and

circuit means for varying the number of said lights which are flashed in relation to the intensity of said pulsatile signal.

* * * * *

US005078136A

United States Patent [19]

Stone et al.

[11] Patent Number: 5,078,136

[45] Date of Patent: Jan. 7, 1992

[54] **METHOD AND APPARATUS FOR CALCULATING ARTERIAL OXYGEN SATURATION BASED PLETHYSMOGRAPHS INCLUDING TRANSIENTS**

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[73] Assignee: **Nellcor Incorporated, Hayward, Calif.**

[21] Appl. No.: **389,633**

[22] Filed: **Aug. 4, 1989**

Related U.S. Application Data

[62] Division of Ser. No. 175,115, Mar. 30, 1988, Pat. No. 4,869,254.

[51] Int. Cl.[5] **A61B 5/02**

[52] U.S. Cl. **128/633; 128/666**

[58] Field of Search 128/633, 634, 665, 666

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,694,833	9/1987	Hamaguri	128/633
4,759,369	7/1988	Tanlar	128/633
4,800,885	1/1989	Johnson	128/633
4,819,646	4/1989	Cheung et al.	128/633
4,819,752	10/1987	Zelin	128/633
4,859,056	8/1986	Prosser et al.	356/41

FOREIGN PATENT DOCUMENTS

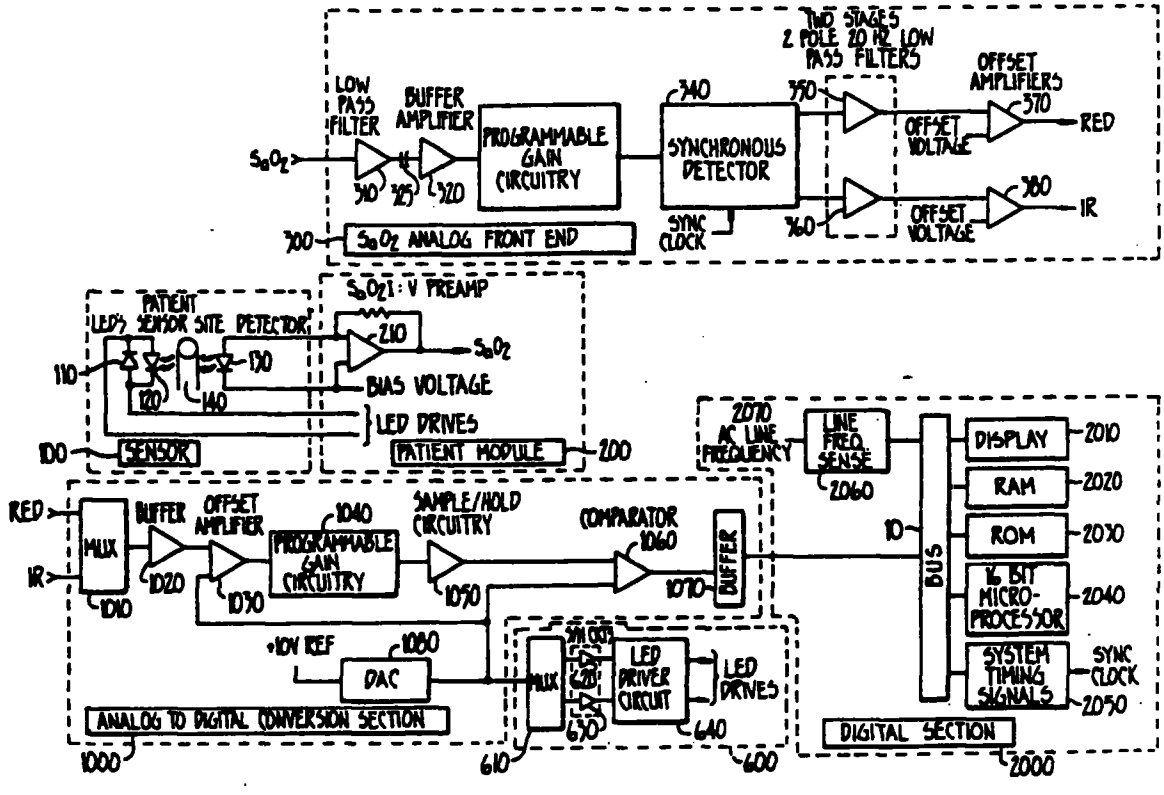
102816	3/1984	European Pat. Off. .
WO82/03322	10/1982	PCT Int'l Appl. .
WO88/01149	2/1988	PCT Int'l Appl. .

Primary Examiner—Kyle L. Howell
Assistant Examiner—J. Hanley
Attorney, Agent, or Firm—Townsend & Townsend

[57] **ABSTRACT**

A method and apparatus for improving the calculation of oxygen saturation by non-invasive pulse oximeters during transient conditions. Transient conditions introduce artifactual errors into the detected optical signal because of changes in transmittance of the light with localized blood volume changes and as the average background oxygen saturation level of the patient's blood changes. The invention relates to correcting the detected optical pulses by linear interpolation and rate of change techniques or by selective frequency filtering and compensating the detected optical signal using the filtered signal to provide accurate estimates of oxygen saturation during transient conditions.

14 Claims, 10 Drawing Sheets



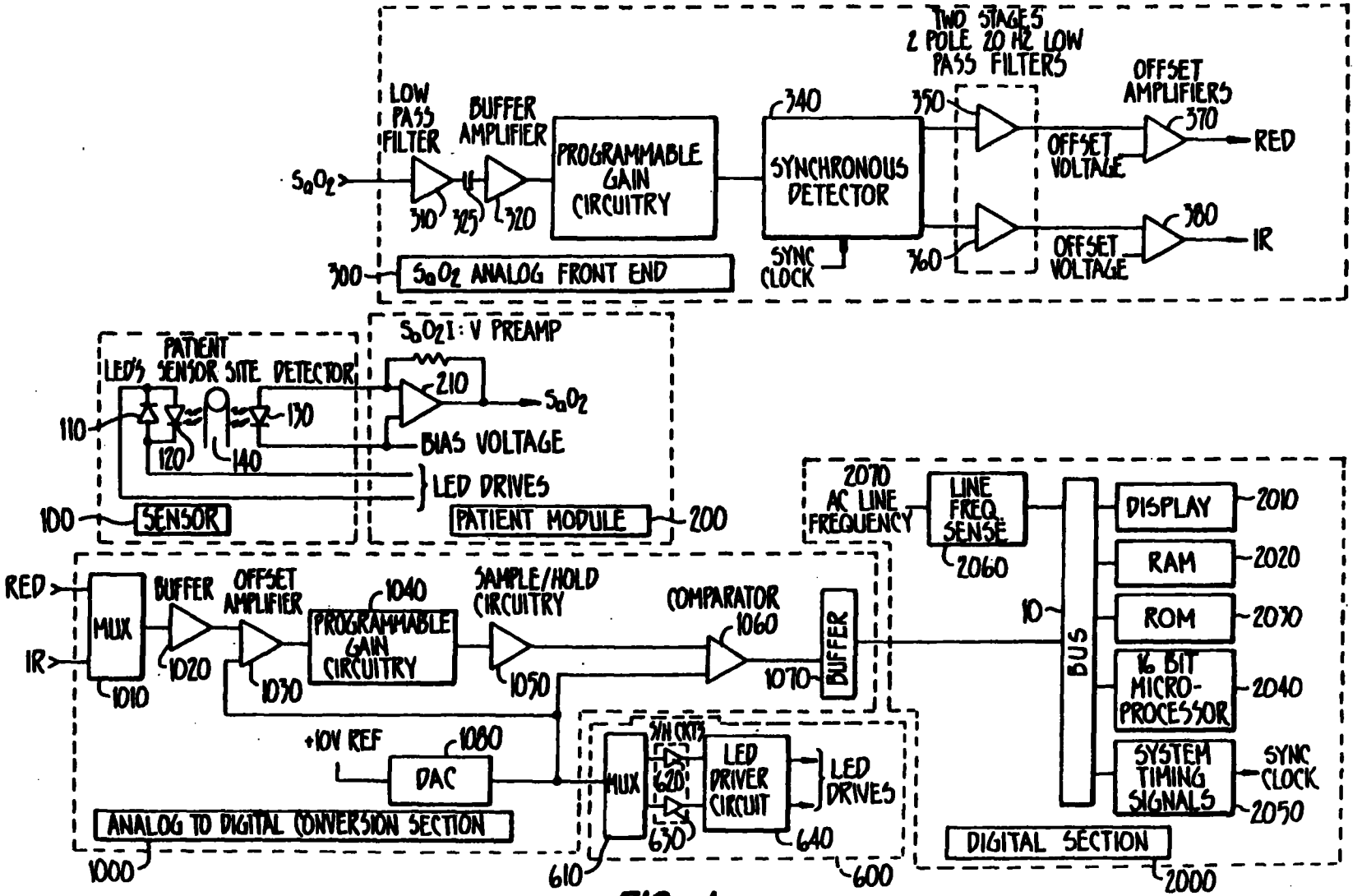

TWO STAGE 5 2 POLE 20 HZ LOW PASS FILTERS
OFFSET AMPLIFIERS
LOW PASS FILTER
BUFFER AMPLIFIER
PROGRAMMABLE GAIN CIRCUITRY
SYNCHRONOUS DETECTOR
OFFSET VOLTAGE
RED
IR
SYNC CLOCK
SaO2 ANALOG FRONT END
SaO2I: V PREAMP
PATIENT LED's SENSOR SITE DETECTOR
BIAS VOLTAGE
LED DRIVES
SENSOR
PATIENT MODULE
AC LINE FREQUENCY
LINE FREQ SENSE
DISPLAY
RAM
ROM
16 BIT MICRO-PROCESSOR
SYSTEM TIMING SIGNALS
SYNC CLOCK
BUS
MUX
BUFFER
OFFSET AMPLIFIER
PROGRAMMABLE GAIN CIRCUITRY
SAMPLE/HOLD CIRCUITRY
COMPARATOR
+10V REF
DAC
LED DRIVER CIRCUIT
ANALOG TO DIGITAL CONVERSION SECTION
DIGITAL SECTION

FIG. 1.

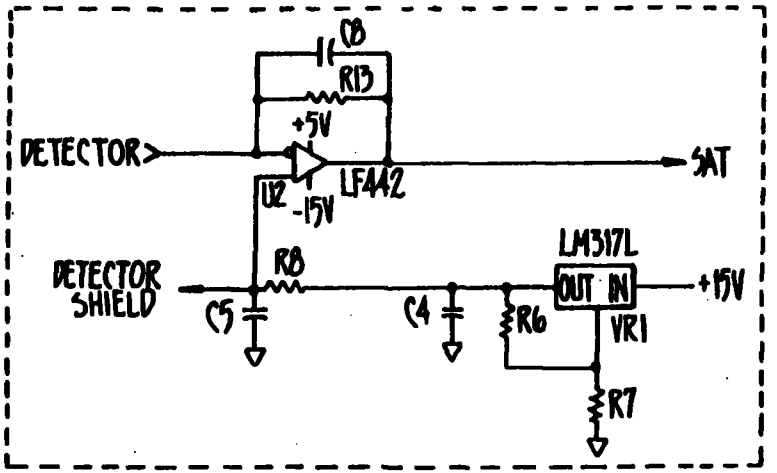

C8
R13
+5V
DETECTOR
U12
LF442
-15V
SAT
LM317L
OUT IN
+15V
DETECTOR SHIELD
R8
C5
C4
R6
VR1
R7

FIG. 2.

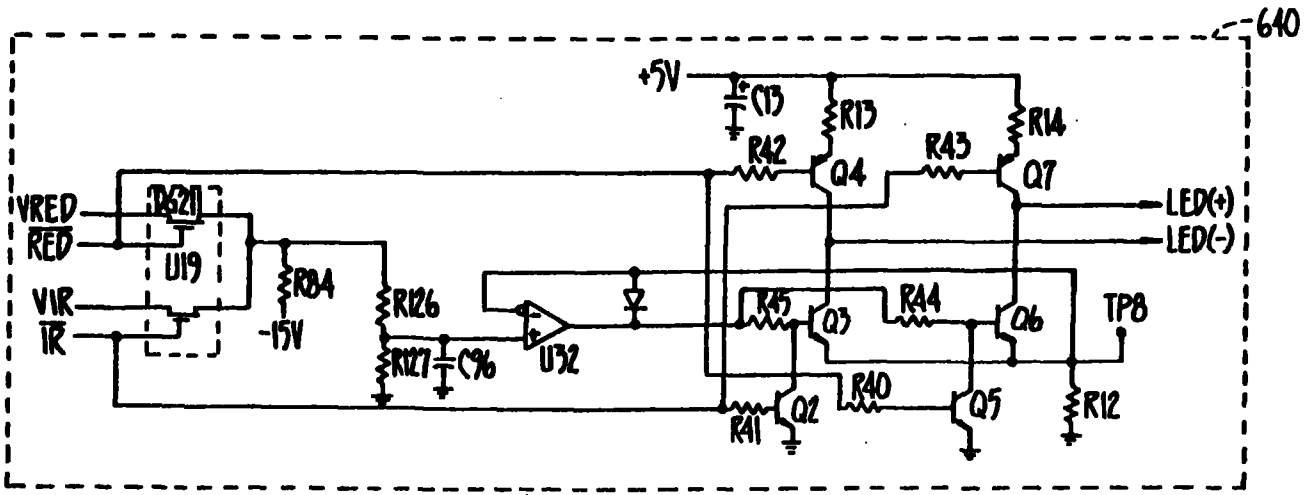

640
+5V
C13
R13
R14
R42
R43
Q4
Q7
LED(+)
LED(-)
VRED
RED
U19
VIR
IR
R84
-15V
R126
R127
C96
U32
R45
Q3
R44
Q6
TP8
R40
Q5
R12
R41
Q2

FIG. 4.

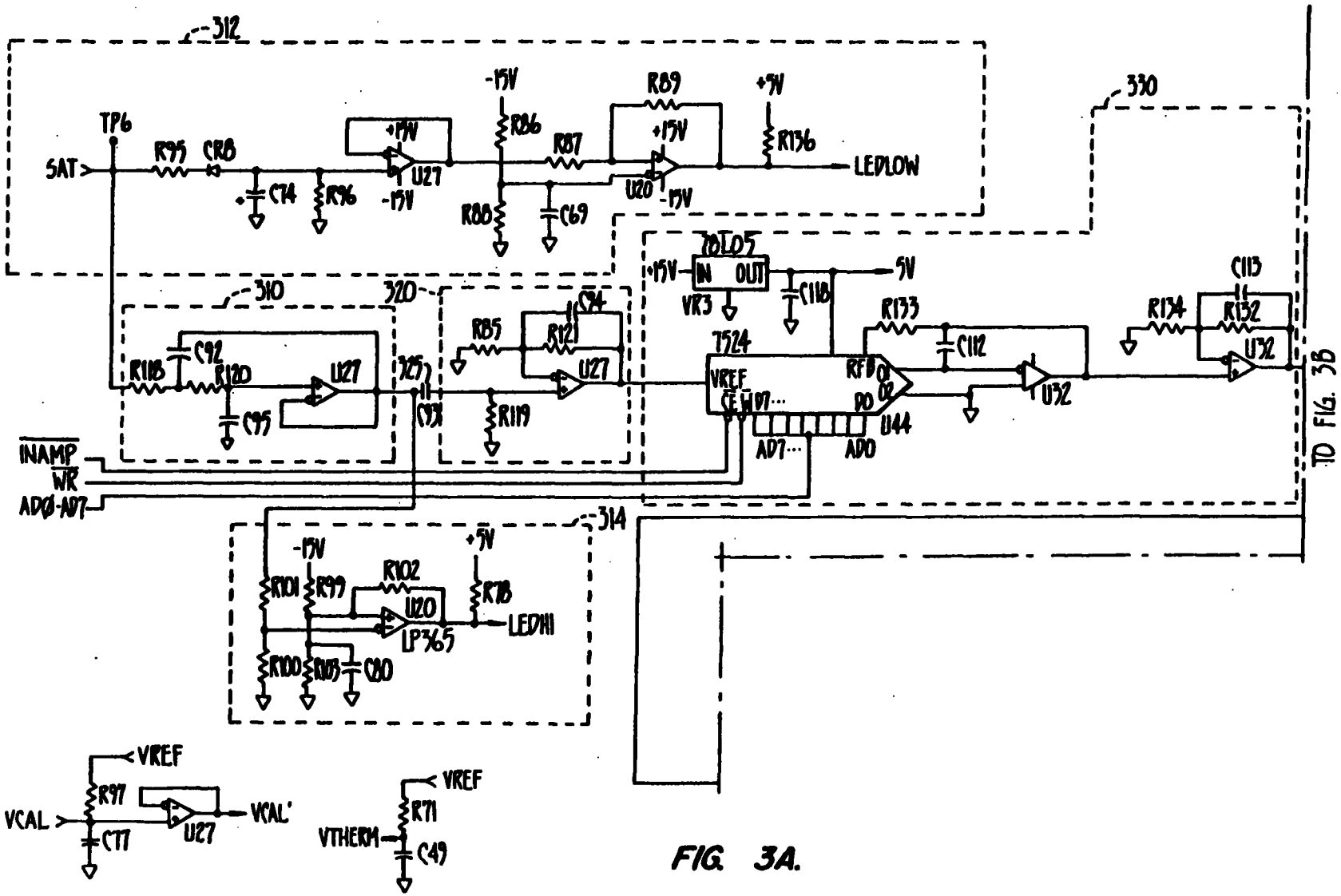

312
330
310
320
314
TP6
SAT
R95
CR8
C74
R96
U27
-15V
+15V
R86
R87
R89
R136
LEDLOW
U20
R88
C69
78L05
IN
OUT
5V
VR3
C118
C113
R134
R132
U32
R133
C112
7524
VREF
RFB
D1
D2
D7...
D0
U44
AD7...
AD0
R85
R121
C94
R119
C93
C92
R118
R120
C95
INAMP
WR
AD0-AD7
TO FIG 3B
R101
R99
R102
R98
LP365
LEDHI
R100
R103
C80
VREF
R97
C77
VCAL
VCAL'
R71
C49
VTHERM

FIG. 3A.

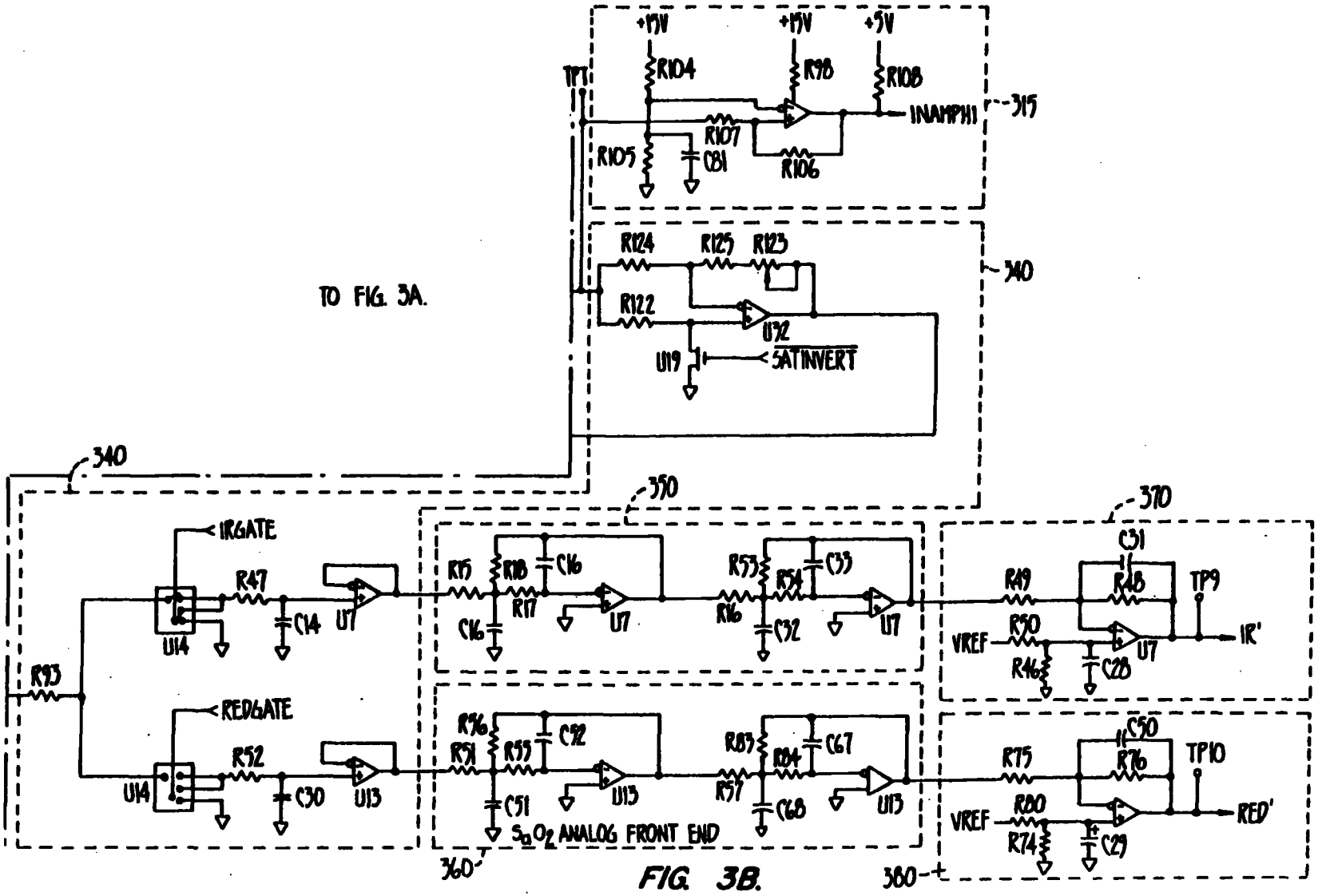
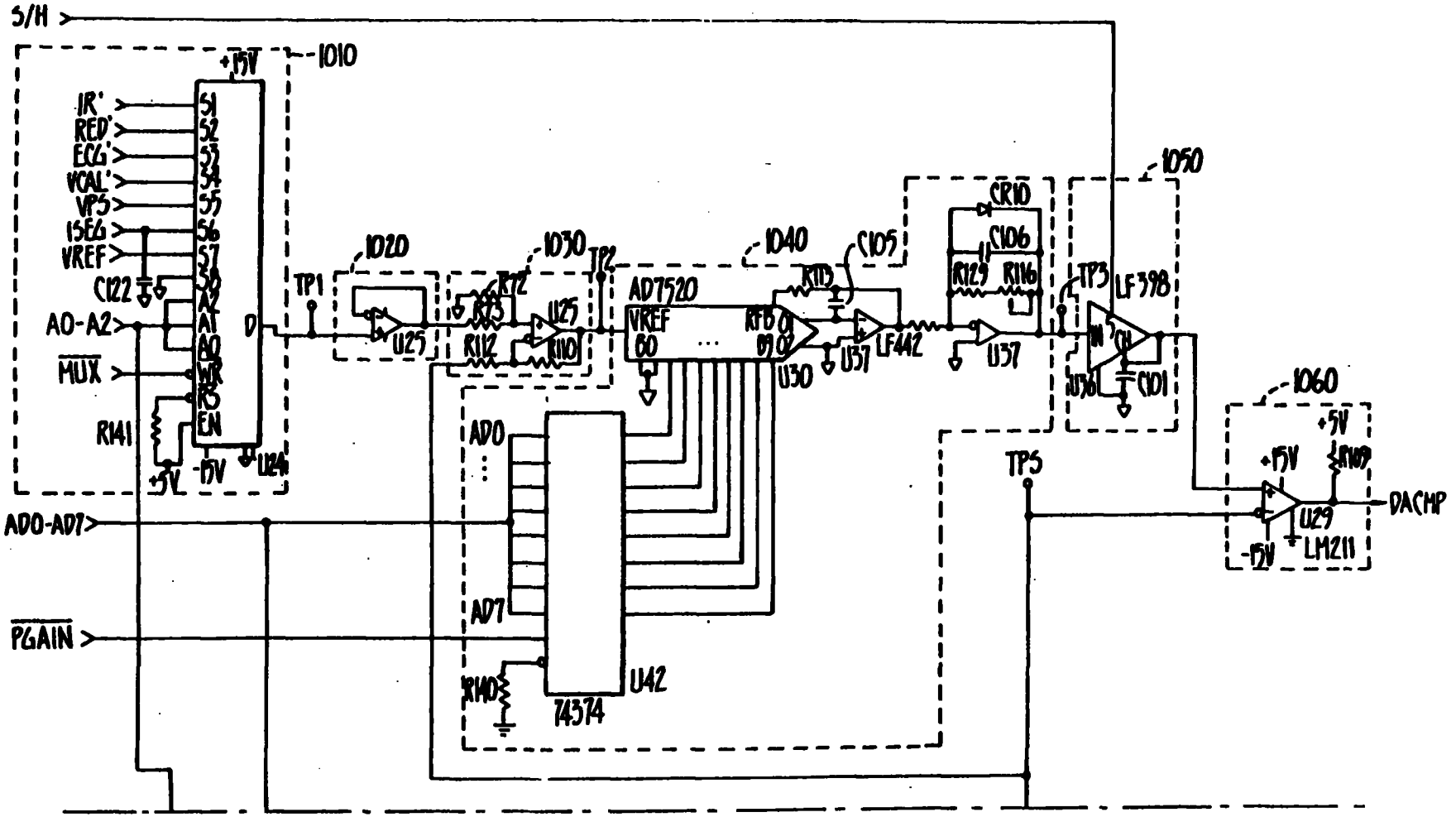

TO FIG. 3A.
+15V
+15V
+5V
TP1
R104
R98
R108
R107
R105
C81
R106
INAMPH1
315
R124
R125
R123
R122
U32
U19
SATINVERT
340
340
350
370
IRGATE
R47
U14
C14
U7
R93
REDGATE
R52
U14
C30
U13
R15
R18
C16
C16
R17
U7
R53
R54
C33
R16
C32
U7
R49
C31
R48
TP9
VREF
R50
R46
C28
U7
IR'
R96
R91
R97
C32
C51
U13
R83
R84
C67
R97
C68
U13
R75
C50
R76
TP10
VREF
R80
R74
C29
RED'
S$_a$O$_2$ ANALOG FRONT END
360
380

FIG. 3B.



TO FIG. 5B.

FIG. 5A.

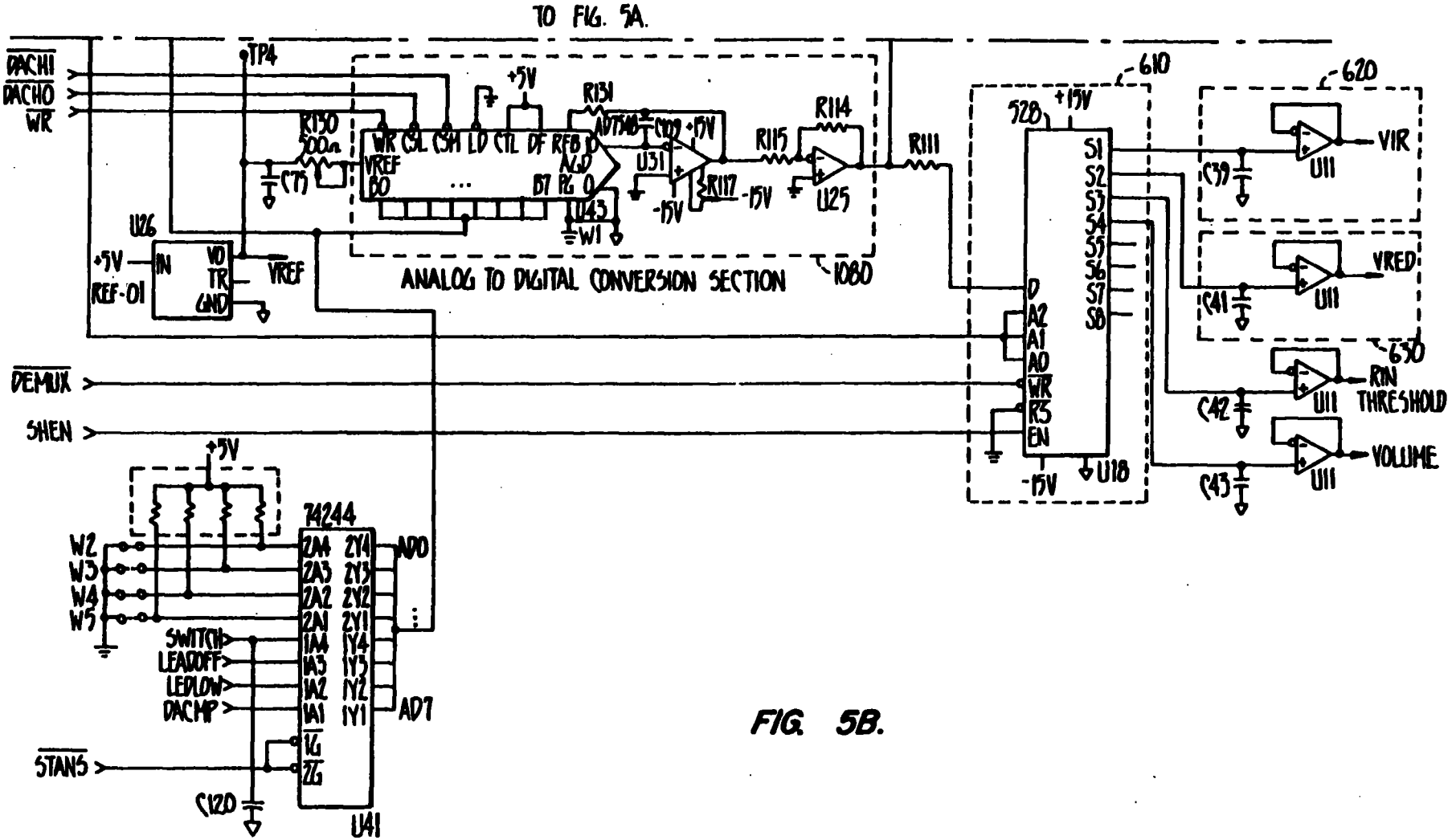
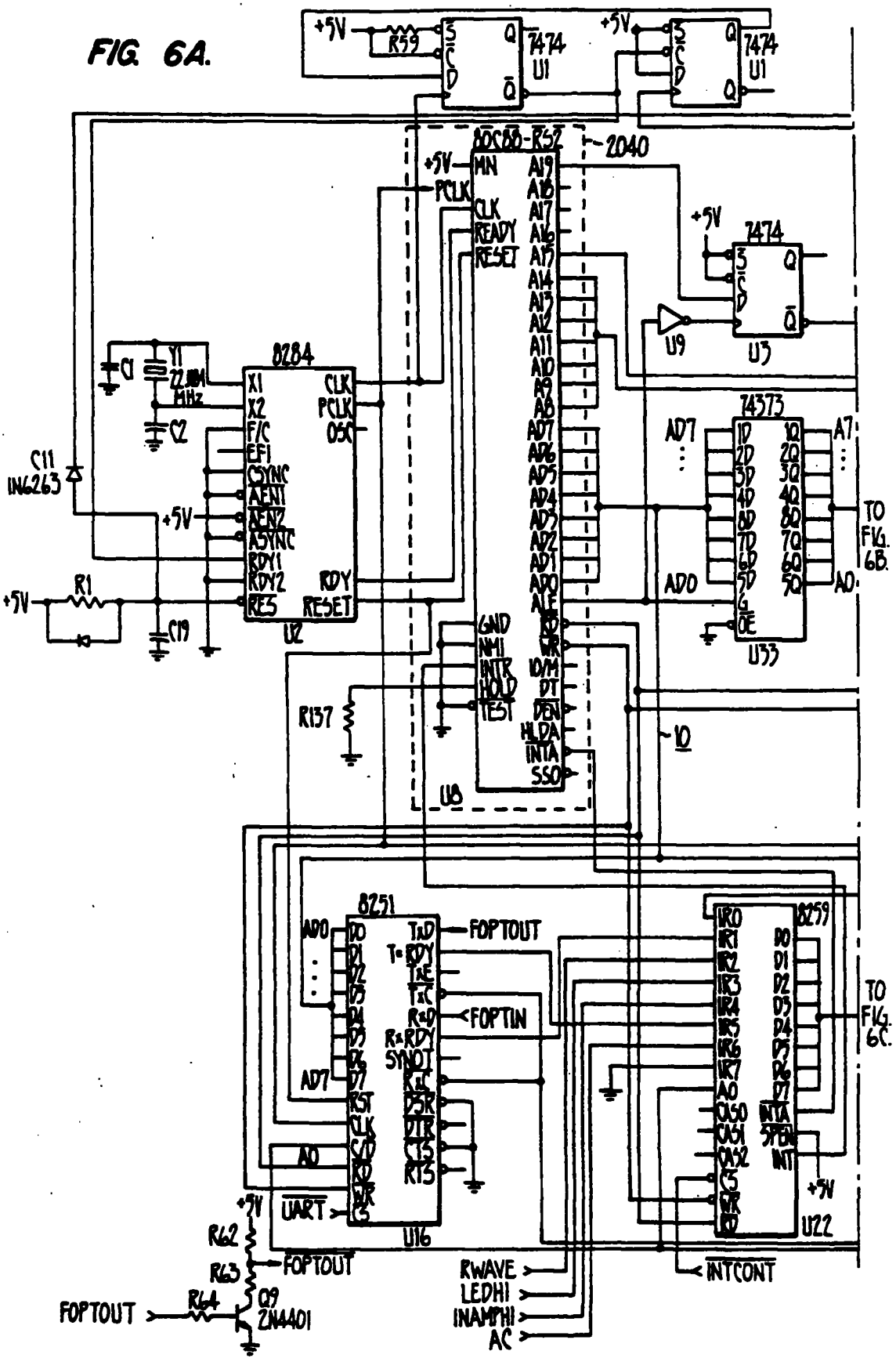

TO FIG. 5A.
DACHI
DACHO
WR
TP4
R130
500Ω
C7
+5V
R131
R114
R115
R111
R117
-15V
U31
U43
W1
U125
U26
+5V
REF-01
IN
VO
TR
GND
VREF
ANALOG TO DIGITAL CONVERSION SECTION
1080
610
620
630
528
+15V
-15V
U18
U11
VIR
VRED
RIN
THRESHOLD
VOLUME
C39
C41
C42
C43
DEMUX
SHEN
74244
W2
W3
W4
W5
SWITCH
LEADOFF
LEDLOW
DACMP
AD0
AD7
STANS
C120
U41

FIG. 5B.

FIG. 6A.


+5V
R59
7474
U1
8284
X1
X2
F/C
EFI
CSYNC
AEN1
AEN2
ASYNC
RDY1
RDY2
RES
CLK
PCLK
OSC
RDY
RESET
U12
C1
Y1
22.1184 MHz
C2
C11
IN6263
R1
C19
8088-BSZ
2040
MN
PCLK
CLK
READY
RESET
A19
A18
A17
A16
A15
A14
A13
A12
A11
A10
A9
A8
AD7
AD6
AD5
AD4
AD3
AD2
AD1
AD0
ALE
RD
WR
IO/M
DT
DEN
HLDA
INTA
SSO
GND
NMI
INTR
HOLD
TEST
U6
R137
U9
U3
74373
AD7
AD0
A7
A0
TO FIG. 6B.
U33
IO
8251
TxD
TxRDY
TxE
RxD
RxRDY
SYNDT
DSR
DTR
CTS
RTS
RST
CLK
C/D
RD
WR
CS
AD0
AD7
A0
UART
U16
FOPTOUT
FOPTIN
8259
IR0
IR1
IR2
IR3
IR4
IR5
IR6
IR7
A0
CAS0
CAS1
CAS2
SP/EN
INT
INTA
U22
TO FIG. 6C.
INTCONT
R62
R63
R64
Q9
2N4401
RWAVE
LEDHI
INAMPHI
AC

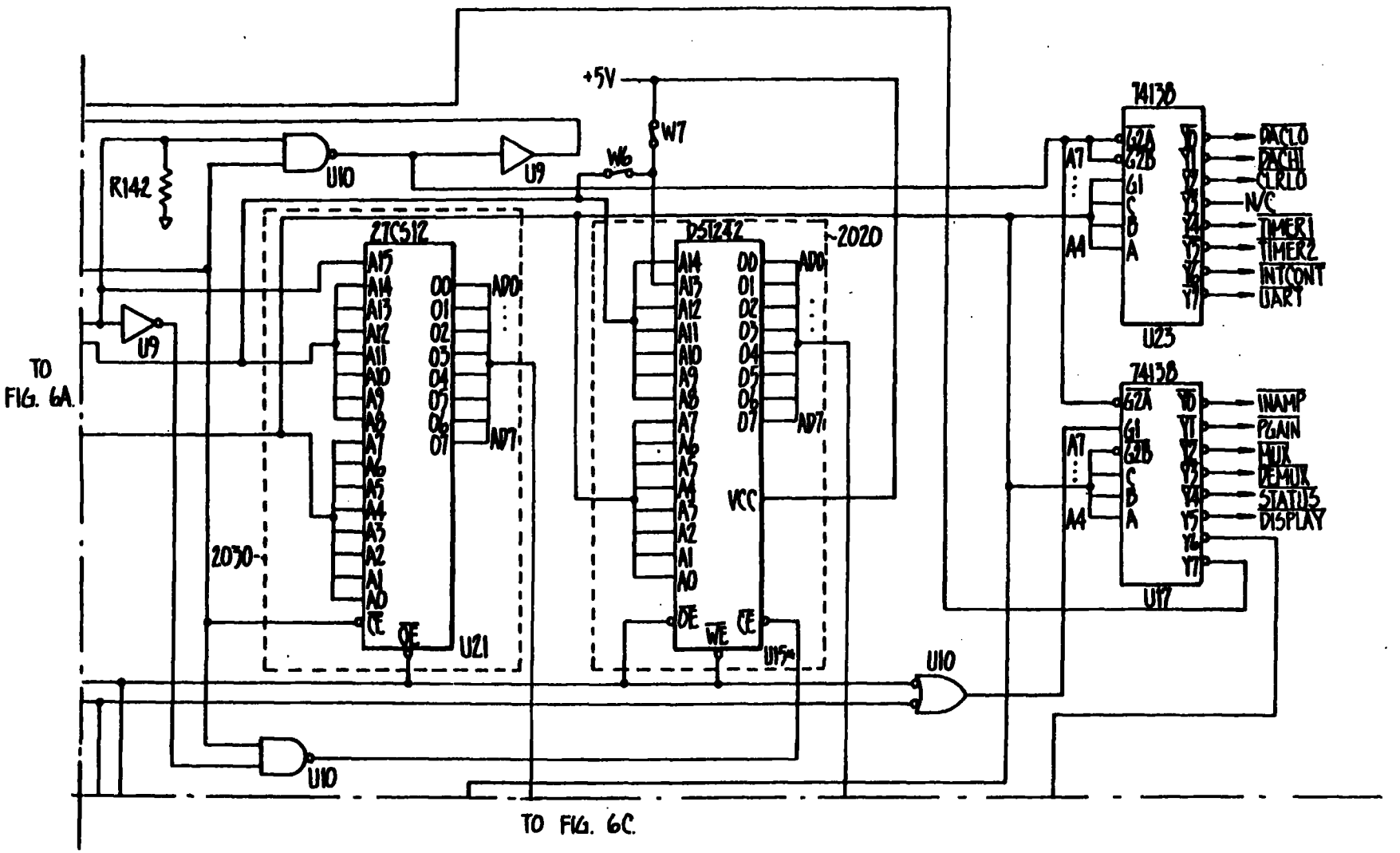

+5V
W7
W6
R142
U10
U9
74138
ZTC512
D512A2
2020
2030
U21
U17
U23
A7
A4
VCC
WE
OE
CE
DACLO
DACHI
CLRLO
NVC
TIMER1
TIMER2
INTCONT
UART
INAMP
PGAIN
MUX
DEMUX
STATUS
DISPLAY
TO FIG. 6A
TO FIG. 6C

FIG. 6B.

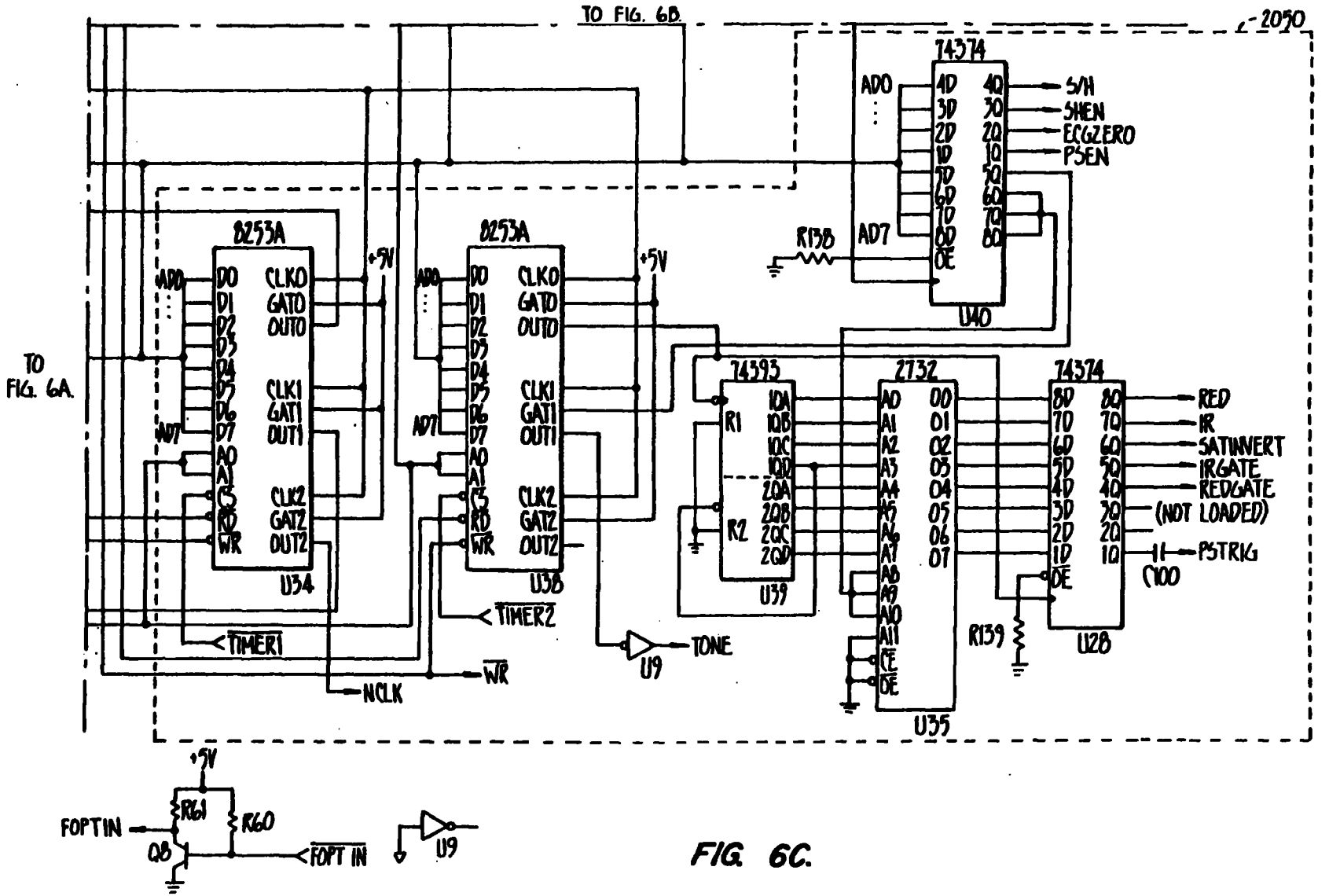

TO FIG. 6B
2050
TO FIG. 6A
8253A
U34
8253A
U36
74374
U40
74393
U39
2732
U35
74374
U28
R138
R139
AD0
AD7
+5V
TIMER1
TIMER2
NCLK
WR
TONE
U9
S/H
SHEN
ECGZERO
PSEN
RED
IR
SATINVERT
IRGATE
REDGATE
(NOT LOADED)
PSTRIG
C100
FOPTIN
R61
R60
Q8
FOPT IN
U9

FIG. 6C.

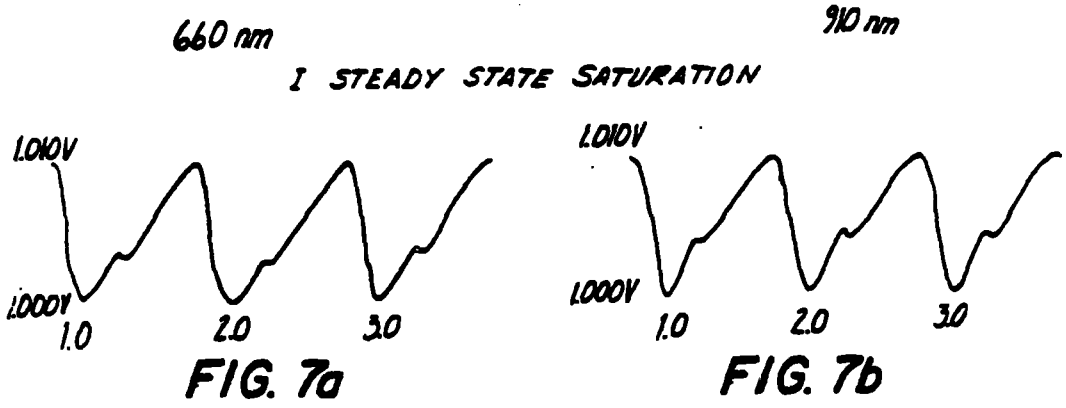


FIG. 7a

FIG. 7b

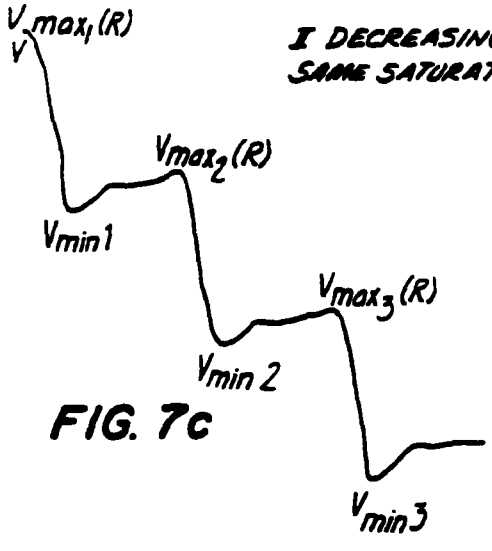


FIG. 7c

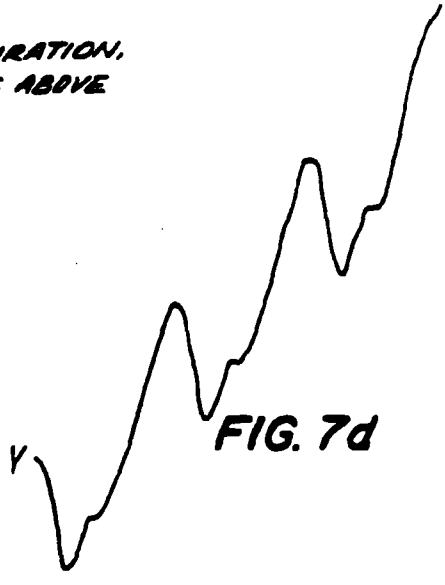


FIG. 7d

FIG. 7e

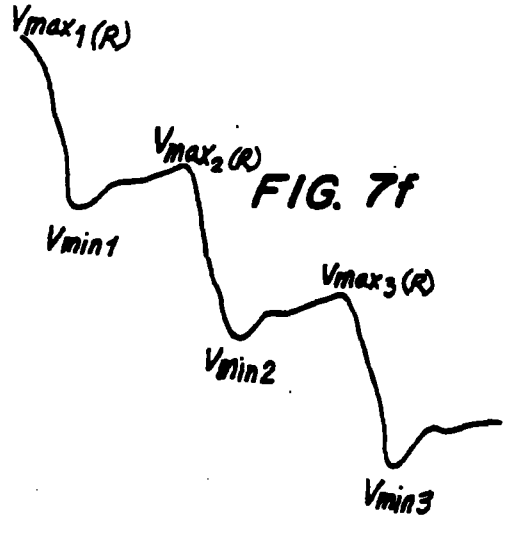


FIG. 7f

METHOD AND APPARATUS FOR CALCULATING ARTERIAL OXYGEN SATURATION BASED PLETHYSMOGRAPHS INCLUDING TRANSIENTS

This is a division of application Ser. No. 07/175,115, filed Mar. 30, 1988, now U.S. Pat. No. 4,869,254.

This invention relates to non-invasive pulse oximetry and specifically to an improved method and apparatus for calculating arterial saturation during transient conditions based upon photoelectric determination of a patient's plethysmograph. This specification is accompanied by a software appendix.

BACKGROUND OF THE INVENTION

Non-invasive photoelectric pulse oximetry has been previously described in U.S. Pat. No. 4,407,290, U.S. Pat. No. 4,266,554, U.S. Pat. No. 4,086,915, U.S. Pat. No. 3,998,550, U.S. Pat. No. 3,704,706, European Patent Application No. 102,816 published Mar. 13, 1984, European Patent Application No. 104,772 published Apr. 4, 1984, European Patent Application No. 104,771 published Apr. 4, 1984, and PCT International Publication WO 86/05674 published Oct. 8, 1986. Pulse oximeters are commercially available from Nellcor Incorporated, Hayward, Calif., U.S.A., and are known as, for example, Pulse Oximeter Model N-100 (herein "N-100 oximeter") and Model N-200 (herein "N-200 oximeter").

Pulse oximeters typically measure and display various blood flow characteristics including but not limited to blood oxygen saturation of hemoglobin in arterial blood, volume of individual blood pulsations supplying the flesh, and the rate of blood pulsations corresponding to each heartbeat of the patient. The oximeters pass light through human or animal body tissue where blood perfuses the tissue such as a finger, an ear, the nasal septum or the scalp, and photoelectrically sense the absorption of light in the tissue. The amount of light absorbed is then used to calculate the amount of blood constituent being measured.

The light passed through the tissue is selected to be of one or more wavelengths that is absorbed by the blood in an amount representative of the amount of the blood constituent present in the blood. The amount of transmitted light passed through the tissue will vary in accordance with the changing amount of blood constituent in the tissue and the related light absorption.

For example, the N-100 oximeter is a microprocessor controlled device that measures oxygen saturation of hemoglobin using light from two light emitting diodes ("LED's"), one having a discrete frequency of about 660 nanometers in the red light range and the other having a discrete frequency of about 925 nanometers in the infrared range. The N-100 oximeter microprocessor uses a four-state clock to provide a bipolar drive current for the two LED's so that a positive current pulse drives the infrared LED and a negative current pulse drives the red LED to illuminate alternately the two LED's so that the incident light will pass through, e.g., a fingertip, and the detected or transmitted light will be detected by a single photodetector. The clock uses a high strobing rate, e.g., one thousand five hundred cycles per second, to be easily distinguished from other light sources. The photodetector current changes in response to the red and infrared light transmitted in sequence and is converted to a voltage signal, amplified, and separated by a two-channel synchronous detector—one channel for processing the red light waveform and the other channel for processing the infrared light waveform. The separated signals are filtered to remove the strobing frequency, electrical noise, and ambient noise and then digitized by an analog to digital converter ("ADC"). As used herein, incident light and transmitted light refers to light generated by the LED or other light source, as distinguished from ambient or environmental light.

The light source intensity may be adjusted to accomodate variations among patients' skin color, flesh thickness, hair, blood, and other variants. The light transmitted is thus modulated by the absorption of light in the variants, particularly the arterial blood pulse or pulsatile component, and is referred to as the plethysmograph waveform, or the optical signal. The digital representation of the optical signal is referred to as the digital optical signal. The portion of the digital optical signal that refers to the pulsatile component is labeled the optical pulse.

The detected digital optical signal is processed by the microprocessor of the N-100 oximeter to analyze and identify optical pulses corresponding to arterial pulses and to develop a history as to pulse periodicity, pulse shape, and determined oxygen saturation. The N-100 oximeter microprocessor decides whether or not to accept a detected pulse as corresponding to an arterial pulse by comparing the detected pulse against the pulse history. To be accepted, a detected pulse must meet certain predetermined criteria, for example, the expected size of the pulse, when the pulse is expected to occur, and the expected ratio of the red light to infrared light of the detected optical pulse in accordance with a desired degree of confidence. Identified individual optical pulses accepted for processing are used to compute the oxygen saturation from the ratio of maximum and minimum pulse levels as seen by the red wavelength compared to the maximum and minimum pulse levels as seen by the infrared wavelength, in accordance with the following equation:

$$\text{Saturation} = 100\% \times \frac{BR2 - R(BR1)}{R(BO1 - BR1) + BR2 - BO2}$$

wherein

BO1 is the extinction coefficient for oxygenated hemoglobin at light wavelength 1 (Infrared)

BO2 is the extinction coefficient for oxygenated hemoglobin at light wavelength 2 (red)

BR1 is the extinction coefficient for reduced hemoglobin at light wavelength 1

BR2 is the extinction coefficient for reduced hemoglobin at light wavelength 2 light wavelength 1 is infrared light light wavelength 2 is red light and

R is the ratio of the optical density of wavelength 2 to wavelength 1 and is calculated as:

$$R = \frac{\ln[I_{max2}/I_{min2}]}{\ln[I_{max1}/I_{min1}]}$$

wherein

I_{max2} is the maximum light transmitted at light wavelength 2

I_{min2} is the minimum light transmitted at light wavelength 2

I_{max1} is the maximum light transmitted at light wavelength 1

I_{min1} is the minimum light transmitted at light wavelength 1

The various extinction coefficients are determinable by empirical study as are well known to those of skill in the art. For convenience of calculation, the natural log of the ratios may be calculated by use of the Taylor expansion series for the natural log.

Several alternate methods of processing and interpreting optical signal data have been disclosed in the patents and references cited above.

Normally, the relative oxygen content of the patient's arterial pulses remains about the same from pulse to pulse and the average background absorption between pulses remains about the same. Consequently, the red and infrared light that is transmitted through the pulsatile flow produces a regularly modulated pletheysmograph waveform having periodic optical pulses of comparable shape and amplitude and a steady state background transmittance. This regular pulse provides for an accurate determination of the oxygen saturation of the blood based on the detected relative maximum and minimum transmittance of the red and infrared light.

Changes in the patient's local blood volume at the optical detection site affect the absorption of light. These localized changes often result from motion artifact or respiratory artifact which introduce artificial pulses into the blood flow. For example, on each inhalation, the venus return is occluded slightly, which results in the background intensity component of transmittance being decreased due to the relatively larger volume of blood at the optical detection site. Exhalation allows the venus return to expand, thereby decreasing the volume of blood and increasing the background intensity component of transmittance. Consequently, the periodic optical pulses ride on a background intensity component of transmittance that rises and falls with blood volume change. This background intensity component variation, which is not necessarily related to changes in saturation, affects the pulse to pulse uniformity of shape, amplitude and expected ratio of the maximum to minimum transmittance, and can affect the reliability and accuracy of the saturation determination.

In addition, there are times when the patient's background level of oxygen saturation undergoes transient changes, for example, when the patient loses or reacquires oxygen exchange in the lungs while under gaseous anethesia. Consequently, the detected red and infrared light transmittance changes and the detected plethysmograph waveform rises or falls over time with changes in the average oxygen saturation level in the patient's blood. The transient waveform distorts the pulse shape, amplitude, and the expected ratio of the pulses, which in turn affects the reliability and accuracy of the saturation determination.

Heretofore, with the foregoing known techniques for calculating arterial oxygen saturation, it was known that, during changes in the background intensity absorption component due to artifacts from changes in the patient's blood volume or transient saturation changes, the determined saturation value was not accurate and that it would not become accurate again until the average absorption (or transmittance) level stabilized at the end of the artifact or the saturation transient.

It also was known that saturation calculations based upon transient optical signals provided an over-estimation or under-estimation of the actual saturation value, depending upon the trend. The transmittance of red light near the 660 nanometer wavelength increases as oxygen saturation increases. This results in the detected optical signal value having a smaller pulsatile amplitude, i.e., a smaller relative difference between the maximum and mimimum of the pulse. In contrast, the transmittance of the infrared light near the 910 nanometer wavelength decreases as saturation increases, which causes the infrared pulsatile amplitude—relative maximum to minimum—to increase. For both wavelengths, the transmittance changes with changing saturation are substantially linear and continuous in the range of clinical interest, i.e., oxygen saturations between 50% and 100%.

The accuracy of the estimation is of particular concern during rapid desaturation, where average oxygen saturation drops rapidly, but the saturation determination based on the detected optical signals indicates a greater drop than has actually occurred. The determined saturation thus may actuate low limit saturation alarms on an oximeter device that can result in unnecessary and wasteful efforts to rescusitate a patient not in danger.

Applicants believe that the change in transmittance that occurs between the maximum transmittance time and minimum transmittance time is due to the difference in arterial pulsatile length of pulse that has the same oxygen saturation. Because the pulsatile amplitude is quite small, typically less than 5% of the overall intensity change, any small change in overall or background transmittance, such as slight changes in average blood saturation, can have a relatively large effect in the difference in maximum and minimum intensity of the light levels. Because the transmittance effect of changing oxygen saturation is opposite in direction for the red light at 660 nanometers than for infrared light at 910 nanometers, this can result in over-estimation of the pulsatile ratio during periods when saturation is decreasing, and under-estimation during periods when saturation is increasing.

It is therefore an object of this invention to provide a method and apparatus for compensating for the effects of transient conditions in the actual optically detected signal, thereby providing a more accurate estimation of the actual oxygen saturation value.

It is another object of this invention to compensate for the effects of distortion in the detected oxygen saturation signal caused by artifacts due to localized blood volume changes.

It is another object of this invention to compensate for the effects of distortion in the detected oxygen saturation signal caused by transient saturation or blood volume artifact by using a determined rate of change from pulse to pulse, including using interpolation techniques.

It is another object of this invention to compensate for the effects of distortion in the detected oxygen saturation signal caused by transient saturation or blood volume artifact by using the low frequency characteristics of the detected signal values.

SUMMARY OF THE INVENTION

This invention provides a method and apparatus for compensating for the artifactual errors in light transmittance during blood volume changes or transient saturation changes (hereinafter collectively referred to as "transient conditions"), thereby providing for improved accuracy of oxygen saturation calculations during transient conditions. The invention provides apparatus for processing the detected optical signals during

transient conditions so that the distortion in transmittance caused by the transient can be compensated. In one embodiment, the compensation is made by converting a transient plethysmograph waveform into a steady state waveform whereby the ratio of the maximum and minimum transmittance can be determined based on the converted waveform and used in making the saturation determination. In an alternate embodiment, the compensation is made by dividing the detected optical signal by its low frequency components, i.e., the background and transient frequencies below the heart beat frequency, from which quotient signal the compensated maximum and minimum transmittance values can be detected and used in making the saturation determination. Throughout this application, the words compensate, correct and adjust are intended to have the same meaning in that the actual detected value is converted to an artificial value that results in a more accurate estimation of the actual oxygen saturation of the patient.

In the preferred embodiment, the detected optical signals are obtained conventionally by passing red and infrared light through a patient's blood perfused tissue, detecting the transmitted light which is modulated by the blood flow, and providing red and infrared detected optical signals that are preferably separately processed and optionally converted from analog to digital signals. The corresponding red and infrared digital optical signals are then processed in accordance with the present invention and the light modulation ratios are determined based on the resulting corrected transmittance pulse and used to calculate oxygen saturation.

In one embodiment, the transient error is corrected by linear interpolation whereby the determined maxima and minima for a first and second optical pulses are obtained, the second pulse following the first and preferably immediately following the first pulse, and the respective rates of change in the transmittance of that wavelength is determined from the maximum transmittance point of the first detected pulse to the second detected pulse. The determined rates of change are then used to compensate any distortion in the detected transmittance of the first detected pulse introduced by the transient in accordance with the following algorithm:

$$V\max(n)^* = V\max(n) - [V\max(n) - V\max(n+1)]\frac{[t\max(n) - t\min(n))]}{[t\max(n+1) - t\max(n))]}$$

where tmax(n) is the time of occurence of the detected maximum transmittance at the n maximum; tmin(n) is the time of occurrence of the detected mimimum transmittance of the wavelength at the n minimum; Vmax(n) is the detected optical signal maximum value at the maximum transmittance of the wavelength at the n maximum; Vmax(n)* is the corrected value, for n being the first optical pulse, and n+1 being the second optical pulse of that wavelength.

By application of the foregoing linear interpolation routine, the detected maximum transmittance value at t=n can be corrected, using the detected values detected at the next coming pulse t=n+1, to correspond to the transmittance value that would be detected as if the pulse were detected at steady state conditions. The corrected maximum value and the detected (uncorrected) minimum value thus provide an adjusted optical pulse maximum and minimum that correspond more closely to the actual oxygen saturation in the patient's blood at that time, notwithstanding the transient condition. Thus, using the adjusted pulse values in place of the detected pulse values in the modulation ratio for calculating oxygen saturation provides a more accurate measure of oxygen saturation than would otherwise be obtained during transient operation.

In the preferred embodiment, the transient error is corrected by linear interpolation whereby the determined maxima and minima for a first and second optical pulses are obtained, the second pulse following the first and preferably immediately following the first pulse, and the respective rates of change in the transmittance of that wavelength is determined from the minimum transmittance point of the first detected pulse to the minimum of the second detected pulse. The determined rates of change are then used to compensate for any distortion in the detected minimum transmittance of the second detected pulse introduced by the transient in accordance with the following algorithm:

$$V\min(n)^* = V\min(n-1) + [V\min(n) - V\min(n-1)] \times \frac{[t\max(n) - t\min(n-1))]}{[t\min(n) - t\min(n-1)]}$$

where tmax(n) is the time of occurrence of the detected maximum transmittance at the n maximum; tmin(n) is the time of occurrence of the detected mimimum transmittance of the wavelength at the n minimum; Vmin(n) is the detected optical signal minimum value at the mimimum transmittance of the wavelength at the n minimum; Vmin(n)* is the corrected value, for n being the second optical pulse, and n-1 being the first optical pulse of that wavelength.

By application of the foregoing linear interpolation routine, the detected minimum transmittance value at t=n can be compensated, using the detected values detected at the preceding pulse t=n-1, to correspond to the transmittance value that would be detected as if the pulse were detected at steady state conditions. The compensated minimum value and the detected (uncompensated) maximum value thus provide an adjusted optical pulse maximum and minimum that correspond more closely to the actual oxygen saturation in the patient's blood at that time, notwithstanding the transient condition. Thus, using the adjusted pulse values in place of the detected pulse values in the modulation ratio for calculating oxygen saturation provides a more accurate measure of oxygen saturation than would otherwise be obtained during transient operation.

As is apparent from the algorithms, during steady state conditions the compensated value is equal to the detected value. Therefore, the linear interpolation routine may be applied to the detected signal at all times, rather than only when transient conditions are detected. Also, the algorithm may be applied to compensate the detected other minimum or maximum transmittance values by appropriate adjustment of the algorithm terms.

The amount of oxygen saturation can be then determined from this adjusted optical pulse signal by determining the relative maxima and minima as compensated for the respective wavelengths and using that information in determining the modulation ratios of the known Lambert-Beers equations. Indeed, the present invention may be applied to any pulsatile flow detected by light absorption or transmittance corresponding to the flow having transient changes or conditions, whether based

on the occurrence of individual pulses or averaged pulses.

Applicants also have discovered that the detected optical signals can be processed and corrected in accordance with the present invention by using the frequency characteristics of the detected optical signal. The optical signals for a given wavelength corresponding to the pulsatile arterial blood flow have spectral components including a zero frequency at the background transmittance intensity level, a fundamental frequency at the frequency of the beating heart, and additional harmonic frequencies at multiples of the fundamental frequency. Noise, spurious signals, and motion artifact that appear in the detected optical signal have frequencies that spread across the spectrum. Transient changes to the background transmittance intensity appear as low frequency signals that are below the heart rate frequency.

In accordance with an alternate embodiment of the invention, for each of the wavelengths of the light transmitted, the detected optical signal is split into two portions. For one of the portions, the frequency domain corresponding to the frequency components below the range of the measured heart rate, including the background and any transient frequency components, is separated from the higher frequency components. Applicants have discovered that if the first domain is separated so that no phase shifting occurs relative to the other portion of the unfiltered detected signal, the first domain signal can be divided into the unfiltered signal, thereby to correct for changes in the pulsatile amplitude in the unfiltered signal portion on a continuous basis, for the background transmittance during steady state conditions, during artifactual blood volume changes and transient saturation transmittance changes. It may be appropriate to amplify the separated or filtered signal, the unfiltered signal, or the resulting quotient signal to obtain an adjusted signal having an appropriate amplitude and resolution for making the saturation determination.

Separation of the low frequency components may be realized in either the time domain or the frequency domain. In the time domain, the separation may occur by passing one portion of the analog detected optical signal through conventional electronic circuits such as low pass filters configured to avoid any phase shifting to obtain a filtered signal having only the background and low frequency components, and then passing the filtered signal and a portion of the unfiltered analog detected signal into dividing amplifiers to divide the low passed signal into the unfiltered signal in phase. This process results in a compensated opticai signal that can be processed as if it were the actual detected optical signal to determine the relative maxima and minima of the detected pulses for the satuation calculations. Alternately, the detected optical signal may be digitized and processed using digital signal processing techniques to filter the detected signal and divide the filtered signal into the unfiltered detected signal.

Digital processing techniques also may be applied to process the detected optical signal in the frequency domain by the application of well-known Fourier Transforms. In this embodiment, a time-measure of the detected optical signal for a predetermined number of heartbeats is collected and transformed into its spectral components. The frequency components are then separated into two domains, the first domain including spectrai components below the measured heart rate so that it includes the zero frequency spectral components of the background intensity and any gradual changes in the background intensity corresponding to the transient condition, and the second domain being above the first so that it includes the spectral components of the fundamental and higher order harmonics of the fundamental for the number of heartbeats in the sample. The separation must occur so that no phase shifting occurs in the first domain. Then, the filtered first domain spectral components can be transformed back into the time domain, into the background and changing background intensity, and divided into the unfiltered detected pulsatile waveform in phase thereby compensating for transient conditions in the unfiltered waveform. As the time-measure is updated to include the patient's current condition, the divison of the unfiltered waveform by its low frequency components thus corrects the pulsatile amplitude for changes in the background transmittance on a continuous basis. Thereafter, the oxygen saturation calculation can be based upon the compensated quotient waveform.

Similar to the preferred embodiment, this frequency compensation embodiment may be used all the time.

The apparatus of the preferred embodiment present invention can be used for either time domain or frequency domain transient correction, and includes inputs for the detected opticai signals, an analog to digital converter for converting the analog plethysmograph signal to the digital optical signals (unless the plethysmograph signals are provided in digital form), and a digitial signal processing section for receiving the digital signals and processing the digital detected optical signal in accordance with one of the foregoing analysis techniques of the present invention, including a microprocessor, memory devices, buffers, software for controlling the microprocessor, and display devices.

In its context, the apparatus of the present invention is a part of an oximeter device which has the capability to detect the red and infrared light absorption. In the preferred embodiment, the apparatus of this invention is a part of the Nellcor N-200 oximeter which includes a 16 bit microprocessor manufactured by Intel Corporation, Model No. 8088, software for controlling the microprocessor to perform the operations of the preferred embodiment of the time domaln analysis techniques of present invention (in addition to the conventional oximeter functions), and has structure and processing methods that are unrelated to the present invention, and therefore are not discussed herein. The software could be modified to perform the frequency domain analysis techniques of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of the apparatus of this invention and the apparatus associated with the present invention.

FIG. 2 is a detailed circuit schematic of the saturation preamplifier in the patient module of FIG. 1.

FIGS. 3*a–b* are a detailed circuit schematic of the saturation analog front end circuit of FIG. 1.

FIG. 4 is a detailed circuit schematic of the LED drive circuit of FIG. 1.

FIGS. 5*a–b* are a detailed circuit schematic of the analog to digital converter section of FIG. 1.

FIGS. 6*a–b* are a detailed circuit schematic of the digital signal processing section of FIG. 1.

FIGS. 7*a*, 7*b*, 7*c*, 7*d*, 7*e*, and 7*f* are graphical representations of detected optical signals during steady state and transient conditions.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to FIG. 1, the preferred embodiment of the present invention relates to the apparatus for processing the detected analog optical plethysmograph signal and comprises portions of analog to digital conversion section ("ADC converter") 1000 and digital signal processing section ("DSP") 2000, including the software for driving microprocessor 2040, which processes the digitized optical signals in accordance with the present invention to determine the oxygen saturation of hemoglobin in arterial blood. Associated with the invention, but not forming a part of the invention, is the apparatus for obtaining the detected analog optical signals from the patient that is part of or is associated with the commercially available Nellcor N-200 Pulse Oximeter. Such apparatus include plethysmograph sensor 100 for detecting optical signals including periodic optical pulses, patient module 200 for interfacing plethysmograph sensor 100 with saturation analog front end circuit 300, and saturation analog circuit 300 for processing the detected optical signals into separate red and infrared channels that can be digitized. The N-200 oximeter also includes LED drive circuit 600 for strobing the red and infrared LEDs in plethysmograph sensor 100 at the proper intensity to obtain a detected optical signal that is acceptable for processing, and various regulated power supplies (not shown) for driving or biasing the associated circuits, as well as ADC 1000 and DSP 2000, from line current or storage batteries.

The associated elements are straightforward circuits providing specified functions which are within the skill of the ordinary engineer to design and build. The associated elements are briefly described here, and reference is made to the corresponding detalled schematics in the Figures and circuit element tables set forth below, to place the apparatus of the present invention in its operating context in the preferred embodiment.

In the preferred embodiment, the invention requires two input signals, the two plethysmograph or detected optical signals at the first and second wavelengths (e.g., red and infrared). More than two wavelengths may be used. If analog signals are provided, they must be within or be adjusted by, for example, offset amplifiers to be within the voltage input range for the ADC. In circumstances where the signals have been digitized already, they must be bit compatible with the digital signal processing devices, DSP.

The plethysmograph signal is obtained in a conventional manner for a non-invasive oximeter, typically by illuminating the patient's tissue with red and infrared light in an alternating fashion, for example, in the manner described above for the N-100 oximeter. Referring to FIG. 1, sensor circuit 100 has red LED 110 and infrared LED 120 connected in parallel, anode to cathode, so that the LED drive current alternately illuminates one LED and then the other LED. Circuit 100 also includes photodetector 130, preferably a photodiode, which detects the level of light transmitted through the patient's tissue, e.g., finger 140, as a single, analog optical signal containing both the red and infrared light plethysmographic, detected optical signal waveforms.

Referring to FIGS. 1, and 2, patient module 200 includes preamplifier 210 for preamplifying the analog detected optical signal of photodetector 130. Preamplifier 210 may be an operational amplifier configured as a current to voltage converter, biased by a positive voltage to extend the dynamic range of the system, thereby converting the photocurrent of photodiode 130 into a usable voltage signal. Patient module 200 also includes leads for passing the LED drive voltages to LEDs 110 and 120.

Referring to FIGS. 1 and 3, saturation analog front end circuit 300 receives the analog optical signal from patient module 200 and filters and processes the detected signal to provide separate red and infrared analog voltage signals corresponding to the detected red and infrared optical pulses. The voltage signal is passed through low pass filter 310 to remove unwanted high frequency components above, for example, 100 khz, AC coupled through capacitor 325 to remove the DC component, passed through high pass filter 320 to remove any unwanted low frequencies below, for example, 20 hertz, and passed through buffer 320 and passed through programmable gain stage 330 to amplify and optimize the signal level presented to synchronous detector 340.

Synchronous detector 340 removes any common mode signals present and splits the time multiplexed optical signal into two channels, one representing the red voltage signals and the other representing the infrared voltage signals. Each signal is then passed through respective filter chains having two 2-pole 20 hertz low pass filters 350 and 360, and offset amplifier 370 and 380. The filtered voltage signals now contain the signal information corresponding to the red and infrared detected optical signals. Additionally, circuits for use in preventing overdriving the amplifiers in saturation circuit 300 may be applied, for example, level-sensing circuits 312 and 314 (located before and after low pass filter 310 respectively) for indicating unacceptable LED drive current, and level sensing circuit 315 (located after programmable gain amplifier 330) for indicating unacceptable input amplifier gain setting.

Referring to FIGS. 1 and 5, ADC 1000 provides the analog to digital conversions required by the N-200 oximeter. The aforementioned two voltage signals, the red detected optical signal and the infrared detected optical signal from patient module 200, are input to ADC 1000. These signals are conventionally multiplexed and digitized by an expanded range 12-bit analog-to-digital conversion technique, yielding 16-bit resolution. The input signals are passed through multiplexor 1010 and buffer amplifier 1020. The converter stage includes offset amplifier 1030 and programmable gain circuitry 1040 which allows a portion of the signal to be removed and the remainder to be further amplified for greater resolution, sample and hold circuit 1050, comparator 1060, and 12-bit digital to analog converter 1080. The buffered signal is passed through offset amplifier 1030 to add a DC bias to the signal wherein a portion of the signal is removed and the balance is amplified by being passed through programmable gain circuitry 1040 to improve the resolution. The amplified signal is then passed through sample and hold circuit 1050, the output of which is fed to one input of comparator 1060. The other input of comparator 1060 is the output of digital to analog ("DAC") converter 1080 so that when the inputs to comparator 1060 are the same, the analog voltage at the sample and hold circuit is given the corresponding digital word in DAC converter 1080 which is then stored in an appropriate memory device as the digitized data for the sample and the next sample is sent to sample and hold circuit 1050 to be digitized.

Referring to FIGS. 1, 4, 5, and 6, DAC 1080 also generates the sensor LED drive voltages, under the control of microprocessor 2040, using analog multiplexor 610, which separates the incoming analog signal into one of two channels for respectively driving the red and infrared LEDs, having respective sample and hold circuits 620 and 630, and LED driver circuit 640 for converting the respective analog voltage signals into the respective positive and negative bipolar current signals for driving LEDs 110 and 120.

Alternate techniques of converting the analog signals to digital signals could be used, for example, a 16-bit analog to digital converter.

Referring to FIGS. 1 and 6, DSP 2000 controls all aspects of the signal processing operation including the signal input and output and intermediate processing. The apparatus includes 16-bit microprocessor 2040 and its associated support circuitry including data bus 10, random access memory (RAM) 2020, read only memory (ROM) 2030, a conventional LED display device 2010 (not described in detail), system timing circuit 2050 for providing the necessary clock synchronizing signals. In the preferred embodiment, microprocessor 2040 is a model 8088 microprocessor, manufactured by Intel Corporation, Santa Clara, Calif. Alternate microprocessors processors may be used, such as any of model nos. 8086, 80186, and 80286, also made by Intel Corporation.

The N-200 oximeter incorporating the present invention is designed to determine the oxygen saturation in one of two modes, an unintegrated mode wherein the oxygen saturation determination is made on the basis of pulses detected in the optical pulse signal that are determined to be optical pulses in accordance with conventional pulse detection techniques, and in an ECG synchronization mode wherein the determination is based on enhanced periodic data obtained by processing the detected optical signal and the ECG waveform of the patient in accordance with an invention that is not a part of the present invention.

The present invention applies to the calculation of saturation based on detecting maximum and minimum transmittance of two or more wavelengths, whether the determination is made pulse by pulse (the umintegrated mode) or based on an averaged or composite pulse that is updated with the occurrence of additional pulses to reflect the patient's actual condition (the ECG synchronized mode).

Interrupt programs control the collection and digitization of incoming optical signal data. As particular events occur, various software flags are raised which transfer operation to various routines that are called from a main loop processing routine.

The detected optical signal waveform is sampled at a rate of 57 samples per second. When the digitized red and infrared signals for a given portion of detected optical signals are obtained, they are stored in a buffer called DATBUF and a software flag indicating the presence of data is set. This set flag calls a routine referred to as MUNCH, which processes each new digitized optical signal waveform sample to identify pairs of maximum and minimum amplitudes corresponding to a pulse. The MUNCH routine first queries whether or not there is ECG synchronization. If there is ECG synchronization, then the MUNCH routine obtains the enhanced composite pulse data in the ECG synchronization mode. Otherwise, MUNCH obtains the red and infrared optical signal sample stored in DATBUF, in the unintegrated mode. The determined maximum and minimum pairs are then sent to a processing routine for processing the pairs. Preferably, conventional techniques are used for evaluating whether a detected pulse pair is acceptable for processing as an arterial pulse and performing the saturation calculation, whether the pulse pair is obtained from DATBUF or from the enchanced composite pulse data.

The MUNCH routine takes the first coming pulse data and determines the maximum and minimum transmittance for each of the red and infrared detected optical signals, takes the second coming pulse data, and determines the relative maximum and minimum transmittance. The routine for processing the pairs applies the aforementioned algorithm to the first and second pulse data of each wavelength and determines the corrected minimum transmittance for the second pulse each wavelength. Then the oxygen saturation can be determined using the corrected minimum and detected maximum transmittance for the second pulses of the red and infrared optical signals.

The application of the present invention and the pair processing routine correction is demonstrated by the following comparative examples, with reference to FIGS. *7a*, *7b*, *7c*, *7d*, *7e* and *7f* and the software appendix.

EXAMPLE I

FIGS. *7a* and *7b* show representative plethysmograph waveforms for a patient's steady state condition for the red and infrared detected optical signals. Vmaxr(n) equals 1.01 volts, and Vminr(n) equals 1.00 volts, for n=1,2, and 3 pulses. Vmin(n) is the detected optical signal minimum value at the minimum transmittance at the n pulse minimum. The modulation ratio for the maxima and minima red signal is

$$\frac{Vmaxr(n)}{Vminr(n)} = \frac{1.01v}{1.00v} = 1.01$$

For the infrared wavelength, Vmaxi(n)=1.01 v and Vmini(n)=1.00 v and the determined modulation ratio also is 1.01.

Using these determined modulation ratios in the formula for calculating the ratio R provides:

$$R = \frac{\ln[Vmaxr(n)/Vminr(n)]}{\ln[Vmaxi(n)/Vmini(n)]} = \frac{.01}{.01} = 1.00$$

A determined R=1 corresponds to an actual saturation value of about 81% when incorporated into the aforementioned saturation equation. A saturation of 81% corresponds to a healthy patient experiencing a degree of hypoxia for which some corrective action would be taken.

EXAMPLE II

FIGS. *7c* and *7d* correspond to representative plethysmographic waveforms for a patient during desaturation or decreasing saturation transient conditions for the red and infrared detected optical signals having optical pulses n=1, 2, and 3. However, in this transient example it is known that at n=1, the actual saturation of the patient is very close to that during the steady state conditions in the Example I. In this transient example, the detected values are as follows:

For both the red and infrared signals:

tmax(1)=1.0 secs.

tmin(1)=1.2 secs.
tmax(2)=2.0 secs.
tmin(2)=2.2 secs.
tmax(3)=3.0 secs.
tmin(3)=3.2 secs.

For the red optical signals:

Vmaxr(1)=1.012 v
Vminr(1)=1.000 v
Vmaxr(2)=1.002 v
Vminr(2)=0.990 v
Vmaxr(3)=0.992 v
Vminr(3)=0.980 v

For the infrared optical signals:

Vmaxi(1)=1.008 v
Vmini(1)=1.000 v
Vmaxi(2)=1.018 v
Vmini(2)=1.010 v
Vmaxi(3)=1.028 v
Vmini(3)=1.020 v.

Calculating the oxygen saturation ratio R at n=1, using the detected optical signals provides the following:

$$\begin{aligned} R &= \ln[V_{maxr}(1)/V_{minr}(1)]/\ln[V_{maxi}(1)/V_{mini}(1)] \\ &= \ln[1.012/1.000]/\ln[1.008/1.000] \\ &= \ln[1.012]/\ln[1.008] \\ &= .012/.008 \\ &= 1.5 \end{aligned}$$

Thus, the determined saturation ratio R of 1.5 based on the detected transmittance corresponds to a calculated oxygen saturation of about 65% for the patient, which corresponds to severe hypoxia in an otherwise healthy patient. This contrasts with the known saturation of about 81% and demonstrates the magnitude of the under-estimation of the oxygen saturation (over-estimation of desaturation) due to the distortion in transmittance of the red and infrared light caused by transient conditions.

Applying the present invention to correct the distorted maximum transmittance point of the detected red optical signal during the transient condition, we find the following:

$$\begin{aligned} V_{maxr}(1)^* &= V_{max}(1) - [V_{max}(1) - V_{max}(2)] \times \frac{[t_{max}(1) - t_{min}(1)]}{[t_{max}(2) - t_{max}(1)]} \\ &= 1.012 - [1.012 - 1.002] \times [1.0 - 1.2]/[1.0 - 2.0] \\ &= 1.010 \end{aligned}$$

and correspondingly for the maximum transmittance of the detected infrared optical signal we find:

$$\begin{aligned} V_{maxi}(1)^* &= 1.008 - [1.008 - 1.018] \times [1.0 - 1.2]/[1.0 - 2.0] \\ &= 1.010 \end{aligned}$$

Thus, by replacing Vmaxr(n) with Vmaxr(n)* and replacing Vmaxi(n) with Vmaxi(n)* in the calculations for determining oxygen saturation ratio R we find:

$$\begin{aligned} R &= \ln[V_{maxr}(1)^*/V_{minr}(1)]/\ln[V_{maxi}(1)^*/V_{mini}(1)] \\ &= \ln[1.010/1.00]/\ln[1.010/1.00] \\ &= .01/.01 \\ &= 1.0. \end{aligned}$$

Thus, basing the saturation calculations on the corrected maximum transmittance values and the detected minimum transmittance values, the corrected R value corresponds to the same R for the steady state conditions and the actual oxygen saturation of the patient.

EXAMPLE III

FIGS. 7*e* and 7*f* correspond to representative plethysmographic waveforms for a patient during increasing saturation transient conditions for the red and infrared detected optical signals having optical pulses n=1, 2, and 3. However, in this transient example it is known that at n=1, the actual saturation of the patient is very close to that during the conditions in the steady state Example I. In this transient example, the detected values are as follows:

For both the red and infrared signals:

tmax(1)=1.0 secs.
tmin(1)=1.2 secs.
tmax(2)=2.0 secs.
tmin(2)=2.2 secs.
tmax(3)=3.0 secs.
tmin(3)=3.2 secs.

For the red optical signals:

Vmaxr(1)=1.008 v
Vminr(1)=1.000 v
Vmaxr(2)=1.018 v
Vminr(2)=1.010 v
Vmaxr(3)=1.028 v
Vminr(3)=1.020 v

For the infrared optical signals:

Vmaxi(1)=1.012 v
Vmini(1)=1.000 v
Vmaxi(2)=1.002 v
Vmini(2)=0.990 v
Vmaxi(3)=0.992 v
Vmini(3)=0.980 v.

Calculating the oxygen saturation ratio R at n=1, using the detected optical signals provides the following:

$$\begin{aligned} R &= \ln[V_{maxr}(1)/V_{minr}(1)]/\ln[V_{maxi}(1)/V_{mini}(1)] \\ &= \ln[1.008/1.000]/\ln[1.012/1.000] \\ &= \ln[1.008]/\ln[1.012] \\ &= .008/.012 \\ &= .667 \end{aligned}$$

Thus, the determined saturation R of 0.667 corresponds to a calculated oxygen saturation of about 95% for the patient which corresponds to a satisfactorily oxygenated patient breathing room air. This contrasts with the known saturation of about 81% and demonstrates the magnitude of the over-estimation of saturation due to the distortion in transmittance of the red and infrared light caused by transient conditions.

Applying the present invention to correct the distorted maximum transmittance point of the detected red optical signal during the transient condition we find:

$$V\text{max}r(1)^* = V\text{max}(1) - [V\text{max}(1) - V\text{max}(2)] \times \frac{[t\text{max}(1) - t\text{min}(1)]}{[t\text{max}(2) - t\text{max}(1)]}$$

$$= 1.008 - [1.008 - 1.018] \times [1.0 - 1.2]/[1.0 - 2.0]$$

$$= 1.010$$

and correspondingly for the detected infrared optical signal:

$$V\text{max}i(1)^* = 1.012 - [1.012 - 1.002] \times [1.0 - 1.2]/[1.0 - 2.0]$$

$$= 1.010$$

Thus, by replacing Vmaxr(n) with Vmaxr(n)* and replacing Vmaxi(n) with Vmaxi(n)* in the calculations for determining oxygen saturation ratio R we find:

$$R = \ln[V\text{max}r(1)^*/V\text{min}r(1)]/\ln[V\text{max}i(1)^*/V\text{min}i(1)]$$

$$= \ln[1.010/1.00]/\ln[1.010/1.00]$$

$$= .01/.01$$

$$= 1.0.$$

Thus, basing the saturation calculations on the corrected maximum transmittance values and the detected minimum transmittance values, the corrected R value corresponds to the same R for the steady state conditions and the actual oxygen saturation of the patient.

EXAMPLE IV

FIGS. 7*c* and 7*d* also correspond to representative plethysmographic waveforms for a patient during desaturation or decreasing saturation transient conditions for the red and infrared detected optical signals having optical pulses n=1, 2, and 3. However, in this transient example it is known that at n=2, the actual saturation of the patient is very close to that during the steady state conditions in the Example I. In this transient example, the detected values are as follows:

For both the red and infrared signals:

tmax(1)=1.0 secs.
tmin(1)=1.2 secs.
tmax(2)=2.0 secs.
tmin(2)=2.2 secs.
tmax(3)=3.0 secs.
tmin(3)=3.2 secs.

For the red optical signals:

Vmaxr(1)=1.022 v
Vminr(1)=1.008 v
Vmaxr(2)=1.012 v
Vminr(2)=0.998 v
Vmaxr(3)=1.002 v
Vminr(3)=0.988 v

For the infrared optical signals:

Vmaxi(1)=1.002 v
Vmini(1)=0.992 v
Vmaxi(2)=1.012 v
Vmini(2)=1.002 v
Vmaxi(3)=1.022 v
Vmini(3)=1.012 v

Calculating the oxygen saturation ratio R at n=2, using the detected optical signals provides the following:

$$R = \ln[V\text{max}r(2)/V\text{min}r(2)]/\ln[V\text{max}i(2)/V\text{min}i(2)]$$

$$= \ln[1.012/.998]/\ln[1.012/1.002]$$

$$= .01393/.0099$$

$$= 1.4$$

Thus, the determined saturation ratio R of 1.4 based on the detected transmittance corresponds to a calculated oxygen saturation of about 51% for the patient, which corresponds to severe hypoxia in an otherwise healthy patient. This contrasts with the known saturation of about 81% and demonstrates the magnitude of the under-estimation of the oxygen saturation (over-estimation of desaturation) due to the distortion in transmittance of the red and infrared light caused by transient conditions.

Applying the preferred embodiment of the present invention to correct the distorted minimum transmittance point of the detected red optical signal during the transient condition, we find the following:

$$V\text{min}r(2)^* = V\text{min}(2) + [V\text{min}(2) - V\text{min}(1)] \times \frac{[t\text{max}(2) - t\text{min}(1)]}{[t\text{min}(2) - t\text{min}(1)]}$$

$$= 1.008 + [.998 - 1.008] \times [2.0 - 1.2]/[2.2 - 1.2]$$

$$= 1.0$$

and correspondingly for the minimum transmittance of the detected infrared optical signal we find:

$$V\text{min}i(2)^* = .992 + [1.002 - .992] \times .8$$

$$= 1.0$$

Thus, by replacing Vminr(n) with Vminr(n)* and replacing Vmini(n) with Vmini(n)* in the calculations for determining oxygen saturation ratio R we find:

$$R = \ln[V\text{max}r(2)/V\text{min}r(2)^*]/\ln[V\text{max}i(2)/V\text{min}i(2)^*]$$

$$= \ln[1.012/1.0]/\ln[1.012/1.0]$$

$$= 1.0.$$

Thus, basing the saturation calculations on the corrected minimum transmittance values and the detected maximum transmittance values, the corrected R value corresponds to the same R for the steady state conditions and the actual oxygen saturation of the patient.

EXAMPLE V

FIGS. 7*e* and 7*f* also correspond to representative plethysmographic waveforms for a patient during increasing saturation transient conditions for the red and infrared detected optical signals having optical pulses n=1, 2, and 3. However, in this transient example it is known that at n=2, the actual saturation of the patient is identical to that during the conditions in the steady state example. In this transient example, the detected values are as follows:

For both the red and infrared signals:

tmax(1)=1.0 secs.
tmin(1)=1.2 secs.
tmax(2)=2.0 secs.
tmin(2)=2.2 secs.
tmax(3)=3.0 secs.

tmin(3)=3.2 secs.

For the red optical signals:

Vmaxr(1)=1.002 v
Vminr(1)=0.992 v
Vmaxr(2)=1.012 v
Vminr(2)=1.002 v
Vmaxr(3)=1.022 v
Vminr(3)=1.012 v

For the infrared optical signals:

Vmaxi(1)=1.022 v
Vmin(1)=1.008 v
Vmaxi(2)=1.012 v
Vmini(2)=0.998 v
Vmaxi(3)=1.002 v
Vmini(3)=0.988 v

Calculating the oxygen saturation ratio R at n=2, using the detected optical signals provides the following:

$$R = \ln[V_{maxr}(2)/V_{minr}(2)]/\ln[V_{maxi}(2)/V_{mini}(2)]$$
$$= \ln[1.012/1.002]/\ln[1.012/.988]$$
$$= .713$$

Thus, the determined saturation R of 0.713 corresponds to a calculated oxygen saturation of about 92% for the patient which corresponds to a mildly hypoxic patient breathing room air. This contrasts with the known saturation of about 81% and demonstrates the magnitude of the over-estimation of saturation due to the distortion in transmittance of the red and infrared light caused by transient conditions.

Applying the preferred embodiment of the present invention to correct the distorted minimum transmittance point of the detected red optical signal during the transient condition we find:

$$V_{minr}(2)^* = V_{min}(1) + [V_{min}(2) - V_{min}(1)] \times \frac{[t_{max}(2) - t_{min}(1)]}{[t_{min}(2) - t_{min}(1)]}$$
$$= .992 + [1.002 - .992] \times [2.0 - 1.2]/[2.2 - 1.2]]$$
$$= 1.0$$

and correspondingly for the detected infrared optical signal:

$$V_{mini}(2)^* = 1.008 + [.998 - 1.008] \times [.8]$$
$$= 1.010$$

Thus, by replacing Vminr(n) with Vminr(n)* and replacing Vmini(n) with Vmini(n)* in the calculations for determining oxygen saturation ratio R we find:

$$R = \ln[V_{maxr}(2)/V_{minr}(2)^*]/\ln[V_{maxi}(2)/V_{mini}(2)^*]$$
$$= \ln[1.012/1.00]/\ln[1.012/1.00]$$
$$= 1.0.$$

Thus, basing the saturation calculations on the corrected minimum transmittance values and the detected maximum transmittance values, the corrected R value corresponds to the same R for the steady state conditions and the actual oxygen saturation of the patient.

Circuit Tables

REF #	CHIP	MFR PART #	Manufacturer	DESCRIPTION OF CHIP
FIG. 2				
210	U2	LF442	NATIONAL SEMICONDUCTOR	DUAL LOW POWER OP AMP
FIG. 3				
312	U27	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
312	U28	LP365N	NATIONAL SEMICONDUCTOR	QUAD VOLTAGE COMPARATOR
310	U27	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
320	U27	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
330	U44	MP7524LN	MICROPOWER	8-BIT DAC
330	U32	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
330	U32	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
315	U20	LP365N	NATIONAL SEMICONDUCTOR	QUAD VOLTAGE COMPARATOR
340	U32	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
340	U14	DG243CJ	SILICONIX INCORPORATED	ANALOG SWITCH
340	U7	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
340	U13	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
350	U7	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
360	U13	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
370	U7	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
380	U13	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
340	U19	DG211CJ	SILICONIX INCORPORATED	CMOS ANALOG SWITCH

-continued

Circuit Tables

REF #	CHIP	MFR PART #	Manufacturer	DESCRIPTION OF CHIP
FIG. 4				
640	U19	DG211CJ	SILICONIX INCORPORATED	CMOS ANALOG SWITCH
640	U32	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
FIG. 5				
1010	U24	DG528CK	SILICONIX INCORPORATED	OCTAL ANALOG SWITCH
1020	U25	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
1030	U25	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
1040	U38	AD7524LN	ANALOG DEVICES	DAC
1040	U42	74HC374	TEXAS INSTRUMENTS	HIGH SPEED CMOS
1040	U37	LF442N	NATIONAL SEMICONDUCTOR	LOW POWER OP AMP
1050	U36	LF398N	NATIONAL SEMICONDUCTOR	SAMPLE & HOLD OP AMP
1060	U29	LM211P	TEXAS INSTRUMENTS	LOW OFFSET VOLTAGE COMPARATOR
1080	U43	AD7548KN	ANALOG DEVICES	CMOS 12-BIT DAC
1080	U31	LF411ACN	NATIONAL SEMICONDUCTOR	LOW OFFSET OP AMP
1080	U25	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
610	U18	DG528CK	SILICONIX INCORPORATED	OCTAL ANALOG SWITCH
620	U11	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
630	U11	LF444	NATIONAL SEMICONDUCTOR	QUAD JFET OP AMP
FIG. 6				
	U2	82C84A-2	NEC	CMOS 8 MHZ CLOCK GENERATOR
	U1	74HC74	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U1	74HC74	TEXAS INSTRUMENTS	HIGH SPEED CMOS
2040	U8	MSM80C88RS-2	OKI ELECTRIC	CPU 8 MHZ, 125 ns
	U3	74HC74	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U33	74HC374	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U9	74HC04	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U3	74HC74	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U9	74HC04	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U19	74HC00	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U9	74HC04	TEXAS INSTRUMENTS	HIGH SPEED CMOS
2030	U21	MBM27C512-25	FUJITSU LIMITED	CMOS 64K × 8 ROM
2020	U15	DS1242	DALLAS SEMICONDUCTOR	CMOS 32K × 8 RAM
	U23	74HC138	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U17	74HC138	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U19	74HC00	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U19	74HC00	TEXAS INSTRUMENTS	HIGH SPEED CMOS
	U16	82C51A	OKI ELECTRIC	CMOS UART
	U22	MSM82C59A-2RS	OKI ELECTRIC	CMOS INTERRUPT CONTROLLER
2050	U34	MSM82C53-2	OKI ELECTRIC	CMOS TRIPLE TIMER
2050	U38	MSM82C53-2	OKI ELECTRIC	CMOS TRIPLE TIMER
2050	U9	74HC04	TEXAS INSTRUMENTS	HIGH SPEED CMOS
2050	U39	74HC393	TEXAS INSTRUMENTS	HIGH SPEED CMOS
2050	U35	D2732A	INTEL CORPORATION	4096 × 8 ROM
2050	U40	74HC374	TEXAS INSTRUMENTS	HIGH SPEED CMOS
2050	U28	74HC374	TEXAS	HIGH SPEED CMOS

-continued

Circuit Tables

REF #	CHIP	MFR PART #	Manufacturer	DESCRIPTION OF CHIP
			INSTRUMENTS	

```
CRMIN – CORRECT MINIMUM – ASSUMES BX CONTAINS Ymin(n)
;
CR1MIN:
        PUSH    AX
        PUSH    DX
        MOV     AX,PVMIN1       ;GET Ymin(n-1)
        JMP     SHORT CRMIN4
CR2MIN:
        PUSH    AX
        PUSH    DX
        MOV     AX,PVMIN2       ;GET Ymin(n-1)
CRMIN4:
        CMP     AX,BX           ;IF Ymin(n-1) = Ymin(n) RETURN
        JE      SHORT CRMIN2
        CMP     CORRSW,0
        JE      SHORT CRMIN2
        CMP     BPCTR,3         ;IF BAD PULSE COUNTER <3, THEN A BAD PULSE
        JC      SHORT CRMIN2    ;DON'T CORRECT
        CMP     PERIOD,0
        JE      SHORT CRMIN2
        OR      AX,AX
        JZ      SHORT CRMIN2
        CALL    CORR
CRMIN2:
        POP     DX
        POP     AX
        RET
CORR:
;CORRECT MINIMUM – ASSUMES BX = Ymin(n) AND AX = Ymin(n-1)
;       CORRECTED  Ymin(n) = Ymin(n-1) + (t/T)*(Ymin(n) - Ymin(n-1))
;                  WHERE t = PERIOD OF MIN TO MAX, AND T = PERIOD
        CMP     AX,BX           ;Ymin(n-1) <= Ymin(n)?
        PUSH    BX              ;SAVE Ymin(n)
        PUSHF
        MOV     CL,1            ;SET DIRECTION FLAG ACCORDINGLY
        JC      SHORT CORR4
        DEC     CL
CORR4:
        CMP     DIRMIN,CL       ;DIRECTION THE SAME?
        MOV     DIRMIN,CL       ;SAVE ANYWAY
        JE      SHORT CORR5     ;SAME, CONTINUE
        POPF
        POP     BX
        JMP     SHORT CORR2     ;NOT SAME. ABANDON SHIP
CORR5:
        SUB     BX,AX           ;Ymin(n) - Ymin(n-1)
        PUSH    AX              ;SAVE Ymin(n-1)
        JNF     SHORT CORR6
        NEG     BX
CORR6:
        PUSH    BX              ;SAVE :DELTA:
        MOV     AX,MAXMINPCTR
        MOV     CX,PERIOD
        MOV     BX,CX
        SUB     CX,AX           ;PERIOD - MAXMINPCTR
        JNS     SHORT CORR9
        POP     BX              ;RESULT SHOULD BE POSITIVE
        POP     AX
        POPF
        POP     BX              ;RESTORE ORIGINAL Ymin(n)
        JMP     SHORT CORR2
CORR9:
        CMP     CX,PERIOD       ;MUST BE LESS THAN PERIOD
        JC      SHORT CORR10
        POP     BX
        POP     AX
        POPF
        POP     BX              ;RESTORE ORIGINAL Ymin(n)
        JMP     SHORT CORR2
CORR10:
        XCHG    DX,CX           ;CX = PERIOD - MAXMINPCTR
        or      bx,bx           ;no zero divisor
        jz      cr10a
        cmp     bx,dx           ;dx must be ( bx
        jbe     cr10a
```

-continued

```
        xor     ax,ax
        div     bx              ;CX = (PERIOD - MAXMINPCTR)/PERIOD
        mov     cx,ax           ;save result in cx
        jmp     short cr10b
cr10a:
        mov     cx,0f fffh
cr10b:
        POP     AX              ;GET :DELTA:
        XOR     DX,DX
        MUL     CX
        OR      AH,AH
        JNS     SHORT CORR8
        INC     DL
CORR8:
        ;DX = (t/T)*: DELTA:
        POP     AX              ;GET ORIGINAL Ymin(n-1)
        POPF
        JC      SHORT CORR7
        NEG     DX
CORR7:
        ADD     AX,DX           ;Ymin(n-1) + [(t/T)*(Ymin(n) - Ymin(N-1))]
        POP     BX              ;DISGARD ORIGINAL Ymin(n)
        MOV     BX,AX
CORR2:
        RET
```

We claim:

1. Apparatus for compensating distortion in transmittance caused by transient conditions in a patient's plethysmograph waveform having periodic changes related to the patient's beating heart, aperiodic changes unrelated to the beating heart, background transmittance, and transient background transmittance changes at frequencies below the heart rate for use in an oximeter device, comprising:

means for receiving a detected optical signal corresponding to the transmittance of a first and second light frequency passing through the patient's tissue;

filter means for eliminating frequency components of the detected optical signal other than those that have a frequency below the frequency of the fundamental heart rate, thereby providing a filtered signal; and

dividing means for dividing the detected optical signal by the filtered signal in phase, thereby providing a compensated optical signal.

2. The apparatus of claim 1 further comprising means for calculating oxygen saturation using the compensated optical signal.

3. The apparatus of claim 1 wherein the filter means passes all frequencies below the fundamental heart rate in phase with the detected optical signal.

4. The apparatus of claim 1 wherein the filter means includes:

means for transforming the optical signal into the frequency domain;

spectral filter means for separating the spectral components below the fundamental heart rate into a filtered spectrum; and

means for transforming the filtered spectrum back into the time domain, thereby forming the filtered signal.

5. The apparatus of claim 1 wherein the filter means and dividing means include a digital microprocessor device and said apparatus further comprises means for digitizing the detected optical signal into data acceptable for processing by the microprocessor device.

6. Apparatus for compensating distortion in transmittance caused by transient conditions in a patient's plethysmograph waveform having periodic changes related to the patient's beating heart, aperiodic changes unrelated to the beating heart, background transmittance, and transient background transmittance changes at frequencies below the heart rate for use in an oximeter device, comprising:

means for receiving first and second optical signals corresponding to the transmittance of first and second light frequencies passing through the patient's tissue;

first filter means for eliminating the frequency components of the first optical signal other than those that are below the fundamental heart rate, thereby providing a first filtered signal;

second filter means for eliminating the frequency components of the second optical signal other than those that are below the fundamental heart rate, thereby providing a second filtered signal;

a first dividing means for dividing the first optical signal by the first filtered signal in phase, thereby providing a compensated first optical signal; and

a second dividing means for dividing the second optical signal by the second filtered signal in phase, thereby providing a compensated second optical signal.

7. The apparatus of claim 6 further comprising means for calculating oxygen saturation using the first compensated optical signal and the second compensated optical signal.

8. The apparatus of claim 6 wherein the first and second filter means pass all frequencies below the fundamental heart rate in phase with the unfiltered signal.

9. The apparatus of claim 6 wherein the first and second filter means include:

first means for transforming the first optical signal into the frequency domain;

first spectral filter means for eliminating the spectral components other than those below the fundamental heart rate into a first filtered spectrum;

means for transforming the filtered spectrum back into the time domain, thereby forming the first filtered signal;

second means for transforming the second optical signal into the frequency domain;

second spectral filter means for eliminating the spectral components other than those below the funda-

mental heart rate into a second filtered spectrum; and

means for transforming the second filtered spectrum back into the time domain, thereby forming the second filtered signal.

10. The apparatus of claim 6 wherein the first and second filter means and dividing means further comprise a digital microprocessor device and said apparatus further comprises means for digitizing the first and second optical signals into data acceptable for processing by the microprocessor device.

11. A method for detecting and processing arterial pulses of a patient during transient conditions comprising:

passing a first light frequency through the patient's tissue and detecting a first optical signal corresponding to changes in the transmittance of the first frequency including periodic transmittance changes related to the patient's beating heart, aperiodic transmittance changes unrelated to the beating heart, background transmittance, and transient background transmittance changes at frequencies below the heart rate;

passing a second light frequency through the patient's tissue and detecting a second optical signal corresponding to changes in the transmittance of a second frequency including periodic transmittance changes related to the patient's beating heart, aperiodic transmittance changes unrelated to the beating heart, background transmittance, and transient background transmittance changes at frequencies below the heart rate; and, for each of the first and second detected optical signals;

processing the first and second detected optical signals to obtain first and second filtered signals substantially comprising the background transmittance and transient background transmittance components of the first and second detected optical signals below the heart rate frequency; and

adjusting the first and second detected optical signals by dividing the first and second detected optical signals by the first and second filtered signals, respectively, in phase, thereby providing compensated first and second optical signals.

12. The method of claim 11 further comprising calculating oxygen saturation of the patient's arterial blood flow by processing the compensated first optical signal and the compensated second optical signal to detect the maximum or minimum transmittances in the compensated signals for use in calculating saturation.

13. The method of claim 12 wherein said processing step further comprises passing the first and second optical signals through a low pass filter to remove substantially all of the frequency components above the background transmittance and transient background transmittance frequency components so that the first and second filtered optical signals remain in phase with the first and second detected optical signals.

14. The method of claim 12 wherein said processing step further comprises transforming the first and second detected optical signals into the frequency domain, eliminating frequency spectral components other than low frequencies spectral components below the heart rate of the first and second light frequencies corresponding to the background transmittance and the transient background transmittance changes to provide a filtered low frequency spectrum, and transforming the filtered low frequency spectrum back into the time domain as the filtered signal.

* * * * *

USRE36000E

United States Patent [19]

Swedlow et al.

[11] E Patent Number: Re. 36,000

[45] Reissued Date of Patent: Dec. 22, 1998

[54] **ADHESIVE PULSE OXIMETER SENSOR WITH REUSABLE PORTION**

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[73] Assignee: **Nellcor Puritan Bennett Incorporated**, Hayward, Calif.

[21] Appl. No.: **437,964**

[22] Filed: **May 10, 1995**

Related U.S. Patent Documents

Reissue of:

[64] Patent No.: **5,209,230**
Issued: **May 11, 1993**
Appl. No.: **741,290**
Filed: **Aug. 6, 1991**

U.S. Applications:

[63] Continuation-in-part of Ser. No. 600,541, Oct. 19, 1990, abandoned.

[51] **Int. Cl.**[6] **A61B 5/02**

[52] **U.S. Cl.** **128/633**; 128/637; 128/664; 128/665; 356/41

[58] **Field of Search** 128/633, 637, 128/664, 665; 606/13; 356/39–41

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,167,658	1/1965	Richter	250/239
3,599,629	8/1971	Gordy	128/2.06 E
3,602,213	8/1971	Howell et al.	128/2.05 F
3,617,374	11/1971	Hodson et al.	117/212
3,769,974	11/1973	Smart et al.	128/2.05 P
3,807,388	4/1974	Orr et al.	128/205 R
4,013,067	3/1977	Kresse et al.	128/2.05 R
4,091,803	5/1978	Pinder	128/2.05 P
4,305,401	12/1981	Reissmueller et al.	128/690
4,350,165	9/1982	Striese	128/640
4,370,984	2/1983	Cartmell	128/640
4,380,240	4/1983	Jöbsis et al.	128/633
4,406,289	9/1983	Wesseling et al.	128/670
4,611,601	9/1986	Bowman	128/673
4,644,092	2/1987	Gentry	174/36
4,653,498	3/1987	New, Jr. et al.	128/633
4,653,501	3/1987	Cartmell et al.	128/640
4,700,708	10/1987	New, Jr. et al.	128/633
4,824,242	4/1989	Frick et al.	356/41
4,825,879	5/1989	Tan et al.	128/633
4,830,014	5/1989	Goodman et al.	128/665
4,834,532	5/1989	Yount	356/41
4,848,335	7/1989	Manes	128/303
4,863,757	9/1989	Durand	427/47
4,865,038	9/1989	Rich et al.	128/633
4,867,165	9/1989	Noller et al.	128/633
4,928,691	5/1990	Nicolson et al.	128/633
4,960,614	10/1990	Durand	427/54.1
4,964,408	10/1990	Hink et al.	128/633
5,006,397	4/1991	Durand	428/209
5,036,128	7/1991	Durand	524/440
5,047,260	9/1991	Durand	427/54.1
5,061,551	10/1991	Durand	428/209
5,069,213	12/1991	Polczynski	128/665
5,080,098	1/1992	Willett et al.	128/633
5,090,410	2/1992	Saper et al.	128/664
5,094,240	3/1992	Muz	128/633
5,193,547	3/1993	Evans, II et al.	128/668
5,209,230	5/1993	Swedlow et al.	128/633
5,261,415	11/1993	Dussault	128/719

FOREIGN PATENT DOCUMENTS

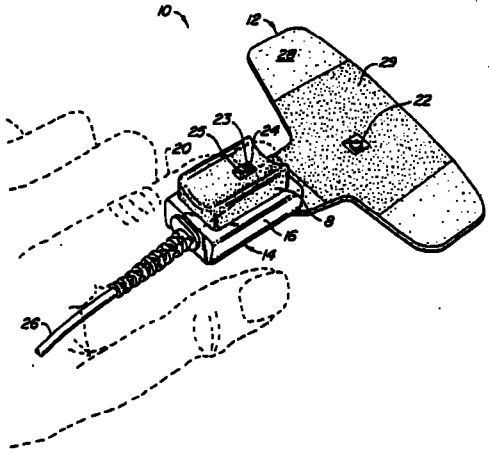
671279	10/1963	Canada	128/2
0019478	11/1980	European Pat. Off. .	
0284943	10/1988	European Pat. Off. .	
2348992	4/1974	Germany .	
WO8909566	10/1989	WIPO .	

Primary Examiner—Brian L. Casler
Attorney, Agent, or Firm—Rothwell, Figg, Ernst & Kurz

[57] **ABSTRACT**

A pulse oximeter sensor that is designed to surround an appendage of the patient, such as a finger, toe or foot is disclosed. The sensor has a reusable member which preferably includes a photodetector. A disposable, flexible member preferably contains the photoemitter and can be wrapped around the patient's appendage to secure it to the appendage and the reusable member. When secured, the photoemitter and photodetector end up on opposite sides of the appendage. The disposable member connects to the reusable member to establish electrical contact. The reusable member is connected to a cable which can be plugged into a sensor monitoring system.

27 Claims, 2 Drawing Sheets



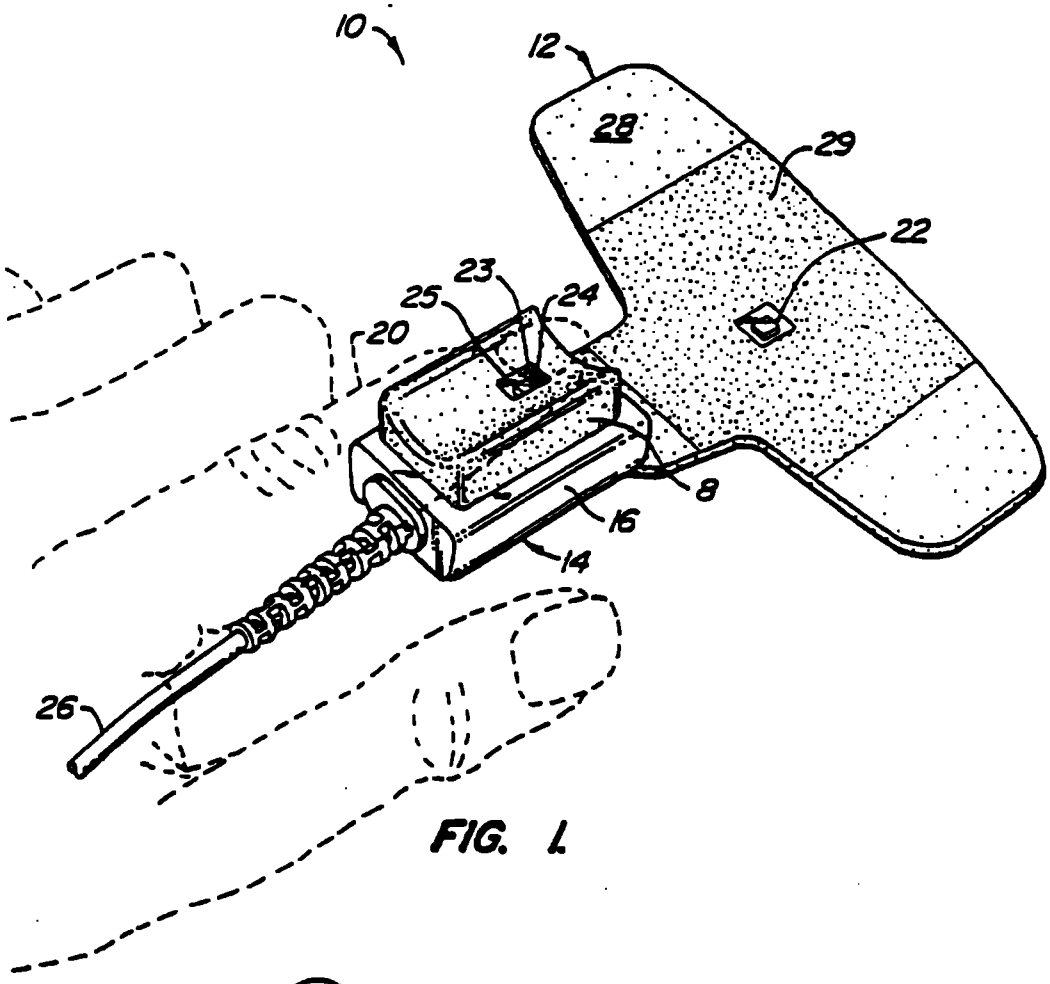


FIG. 1.

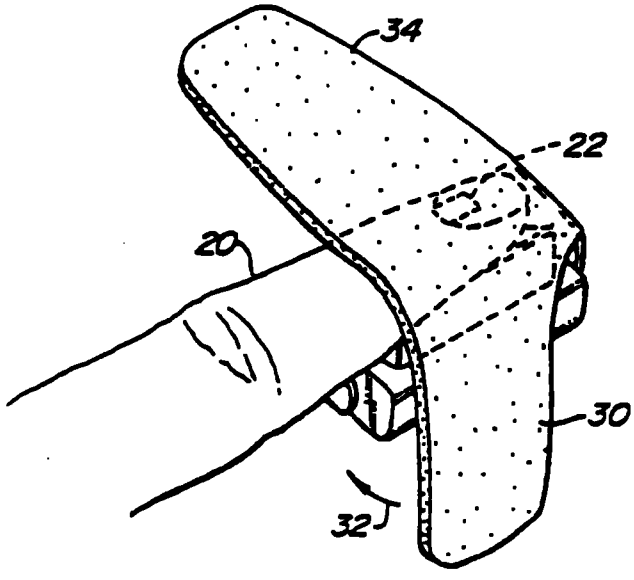


FIG. 2.

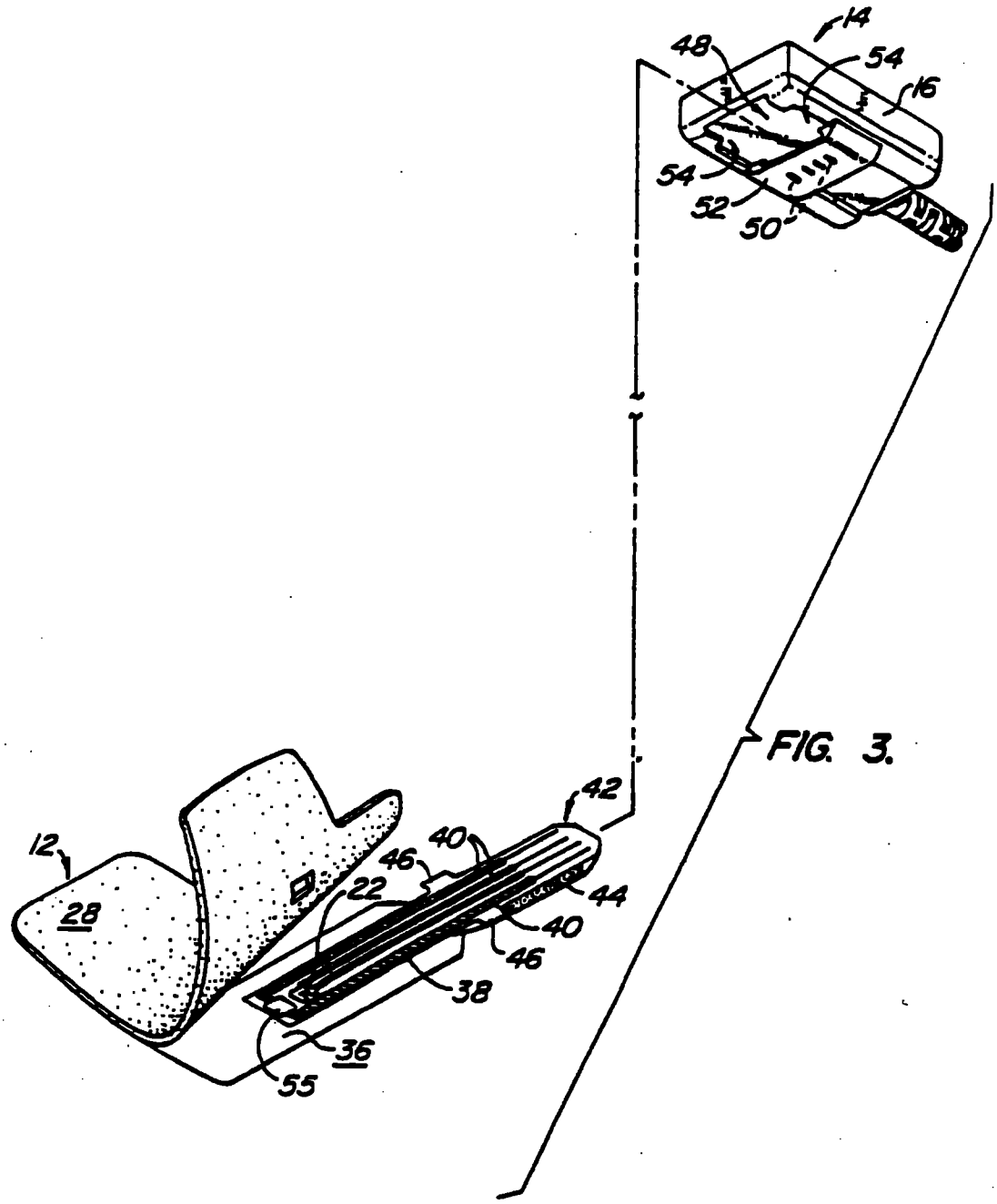


FIG. 3.

ADHESIVE PULSE OXIMETER SENSOR WITH REUSABLE PORTION

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

BACKGROUND OF THE INVENTION

This is a continuation-in-part of patent application Ser. No. 07/600,541, filed Oct. 19, 1990, now abandoned.

This invention relates to sensors for use with noninvasive pulse monitors such as plethysmographs or pulse oximeters.

A plethysmograph is a pulse monitor The plethysmograph sensor shines light into the patient's tissue, and the light transmitted through the tissue is received by a photodetector. The photodetector generates electrical signals corresponding to the transmitted light levels and transmits the signals to a monitor for processing. Arterial blood will absorb some of the light, with more light being absorbed when there is more blood. Thus, changes in the amount of transmitted light are related to pulses of arterial blood in the illuminated tissue.

A pulse oximeter is a device for noninvasively determining the oxygen saturation of arterial blood. The pulse oximeter sensor shines light at two different wavelengths (one in the red range, the other in the infrared range) through a portion of the patient's blood-perfused tissue. The red and infrared light transmitted through the tissue is detected by a photodetector. The amount of light absorbed varies with the amount of oxygen in the blood, and varies differently for red and infrared light. The pulse oximeter monitor computes blood oxygen saturation based on the changes in the two detected light levels between two points in time.

There are several types of sensors for plethysmographs and pulse oximeters. One is a surface sensor in which the light emitter and the photodetector are mounted on the same sensor face. The sensor is attached to the patient with both the light emitter and the detector on the same side of the patient's appendage (e.g., on the patient's forehead). This type of sensor detects light reflected back from the tissue, rather than light transmitted through an appendage. The signal detected will thus be weaker in most cases. The sensor is typically attached with a strap, headband or tape over the sensor, or an adhesive pad between the sensor and the skin.

Another type of sensor is a clamp design, such as that described in U.S. Pat. No. 4,685,464. The durable sensor described in that patent has deformable pads creating conforming tissue contacting surfaces to which the emitters and photodetector are secured. The deformable pads are disposed in a hinged rigid housing that clips on the patient like a clothes pin. This relies on a clamping force to secure the sensor to the patient. The force of the sensor against the patient's tissue could reduce the flow of blood to that region. This exsanguination of the tissue beneath the sensor adversely affects pulse detection and analysis by suppressing the pulse in that portion of the tissue. As a result, the sensor site must typically be checked or moved every four hours to insure adequate perfusion. Because of its relatively large mass, however, the clamp design is more susceptible to signal-distorting motion artifact, i.e., differential motion between the sensor and the patient.

A third sensor design is described in U.S. Pat. No. 4,830,014. The conformable sensor described in that patent has emitters and a photodetector mounted in the same side of a flexible web. The web wraps around a portion of the patient's tissue (such as a finger) so that the light from the emitters must travel through the tissue before reaching the detector. The web attaches to the skin with an adhesive surface on the emitter and detector side of the web. Because of its relatively low mass and the adhesive, this sensor adheres closely to the patient's skin and minimizes the effects of motion artifact. In addition, its flexibility and use of adhesive to secure it minimizes the exsanguination caused by rigid sensors. Thus the sensor site typically only needs to be checked every eight hours. Conformable sensors, however, are typically restricted to one application due in part to a decrease in adhesive effectiveness with each application and in part to difficulties in cleaning and sterilization for reuse. Replacement of the sensor after only one use can make pulse oximetry expensive.

SUMMARY OF THE INVENTION

The present invention provides a pulse oximeter sensor that is designed to surround an appendage of the patient, such as a finger, toe or foot. The sensor has a reusable member which preferably includes a photodetector. A disposable, flexible member preferably contains the photoemitter and can be wrapped around the patient's appendage to secure it to the appendage and the reusable member. When secured, the photoemitter and photodetector end up on opposite sides of the appendage. The disposable member connects to the reusable member to establish electrical contact. The reusable member is connected to a cable which can be plugged into a sensor monitoring system.

In the preferred embodiment, the flexible member is a flexible adhesive web with arms extending laterally from a central portion. The reusable member is preferably a rigid housing with a deformable pad for contacting the appendage.

To attach the sensor to the patient, the flexible web is adhesively attached to one side of the patient's appendage, and the rigid housing is placed on the other side directly opposite the flexible web. The arms extend around the appendage to adhesively hold the conformable pad of the rigid housing against the appendage. By reducing the mass of the sensor and by adhesively attaching the emitters to the skin, this configuration minimizes motion artifact by reducing the relative movement between the sensor and the patient's skin experienced by previous clamp-type sensors. In addition, the flexible web and conformable surface of the rigid housing minimize exsanguination of the tissue beneath the sensor. Since the sensor relies on adhesion to secure it to the patient, the sensor site should not need to be checked as often as for a clamping-type sensor.

After use, the flexible web may be separated from the rigid housing, the rigid housing cleaned, and a new flexible web attached to the rigid housing. The fresh adhesive on the new flexible web provides a more reliable bond between the sensor and the patient than the adhesive on the previously-used web. In addition, since the flexible web covers four out of the five surfaces of the patient's appendage (including, when worn on the finger, the cuticle and subungual region), one time use of the flexible portion of the sensor minimizes cross-contamination between patients when the sensor is reused. Furthermore, because a portion of the sensor may be cleaned and reused, this new sensor design reduces the cost of using flexible sensors.

The electrical connection between the flexible web and the rigid housing is preferably made with a tab extending from the flexible web having conductive traces printed on it which connect to the photoemitter. The conductive traces are inserted into a channel in the back of the housing which is

covered by a bridge. Underneath the bridge are a series of electrical contacts for making connection with the conductive traces. The tab contains an internal resilient foam which is compressed as it is inserted between the housing and the bridge, and exerts an outward force to maintain the tab in place and create an electrical connection between the conductive traces and the contacts.

For a fuller understanding of the nature and advantages of the invention, reference should be made to the ensuing detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a sensor according to the present invention;

FIG. **2** is a perspective view of the sensor of FIG. **1** showing the flexible web being wrapped around a finger; and

FIG. **3** is a perspective view of the separated disposable and reusable members of FIG. **1** illustrating how the connection is made.

DETAIL OF THE PREFERRED EMBODIMENT

FIG. **1** shows a sensor **10** according to the present invention. Sensor **10** consists of a flexible, disposable webbing **12** and a reusable housing **14**. Housing **14** includes a rigid portion **16** and a deformable pad **18**. A patient's finger **20**, shown in phantom, is shown placed on top of deformable pad **18**.

Flexible web **12** includes a photoemitter **22**, which preferably includes two photoemitters, one for red light and one for infrared light. A photodetector **24** is included in deformable pad **18**. A copper grid **23** is disposed over photodetector **24**. A transparent window **25** covers photodetector **24**. All or substantially all of the portion of window **25** extending beyond photodetector **24** is colored black. In addition, a black area **29** is printed on the underside of foam layer **28**. Grid **23**, photodetector **24** and photoemitter **22** are electrically connected to a sensor monitoring system through conductors in a cable **26** connected to housing **14**.

Grid **23** is a Faraday shield (electrostatic screen) connected to ground for reducing interference. The thin window **25** extends over the copper grid so that the grid will not bulge out pad **18**. Before the black coating was added, shift errors in the data values were noticed. The black coating eliminated these errors. The reason is not certain, but the coating over the window may prevent reflections from most of the copper, while the black coating on the foam layer **28** may prevent light from being shunted through the foam layer to the detector, bypassing the finger.

Webbing **12** has a top foam layer **28** with an adhesive surface. Before use, this adhesive layer is covered with protective plastic (not shown), which is peeled off for use.

FIG. **2** illustrates how the flexible webbing **12** is bent over and attached to finger **20**. A first arm **30** of the flexible web is wrapped around the side of housing **14** and will continue to be wrapped around its bottom in the direction of arrow **32**. Similarly, the other arm **34** will be wrapped around finger **20** and housing **14**. As can be seen, photoemitters **22**, shown in phantom, are now on top of the finger, directly opposite photodetector **24**, which is not visible in this view. As can be seen, only the bottom of finger **20** contacts deformable pad **18**. At least the top of the finger will be adhered to by web **12**. The sides and front may also be adhered to, depending on the shape of the finger and how the sensor is attached.

The top is the portion which is most important to be adhering, since it contains the photoemitter which should not move relative to the finger. This provides a secure connection which reduces motion artifacts and puts the disposable, flexible portion in contact with most of the surfaces of the finger so that it is exposed to more contamination than the reusable portion.

FIG. **3** illustrates the electrical connection between flexible web **12** and rigid housing **14**. FIG. **3** shows adhesive layer **28** partially peeled back from a web base **36**. In between web base **36** and adhesive layer **28**, an elongate plastic substrate **38** is placed, with a series of conductive traces **40** on its top surface. Two conductive traces connect to photoemitters **22**, and two connect to a calibration resistor **55**, described below. Elongate plastic substrate **38** forms a tail **42**. Web base **36** can be just large enough to hold tail **42** to adhesive layer **28**, as shown, or could conform to the shape of adhesive layer **28**. Web base **36** has an adhesive surface for holding tail **42** to layer **28**.

A compressible foam member **44** is placed between the halves of tail **42**. In the preferred embodiment, the foam is made of Poron foam from Roger's Corp. A pair of tabs **46** extend from the top half of the tail having the conductive traces. The tabs and the foam member provide part of the attachment mechanism as explained below.

A channel **48** is formed on the bottom side of the rigid housing **16**, opposite deformable pad **18**. A series of electrical contacts **50** (shown in phantom) are located in the channel. The contacts are covered by a bridge **52** extending across the housing. A pair of grooves **54** are formed in the channel. The grooves are slightly larger than the tabs **46** on the flexible web.

To connect the flexible web to the rigid housing, the tail **42** of the flexible circuit is inserted into the space beneath bridge **52**. As the tail moves forward, the plastic foam **44** compresses. As the tail's tabs **46** move over the channel's grooves **54**, the spring action of the foam pushes the tabs into the grooves. The tabs and grooves ensure that the flexible circuit is not inserted too far and prevent inadvertent removal of the flexible circuit. The spring action of the foam also pushes one set of contacts against the other to enhance the electrical connection. In addition, the scraping action of one set of contacts against the other during insertion and withdrawal of the flexible circuit will help remove any oxidation or debris on the contacts. To remove, the tabs are lifted out of the grooves by pulling the flexible web away from the housing and the tail is withdrawn from the space beneath the bridge.

Cable **26** contains 6 wires. Two are connected to calibration resistor **55** through two of contacts **50** and conductive traces **40**. Two are connected to photoemitters **22** through the other two of contacts **50** and conductive traces **40**. The remaining two wires are connected to photodetector **24**.

In the preferred embodiment, the plastic substrate is formed from white, substantially opaque polyester. White nylon may also be used, or a clear plastic. The adhesive may be white, with a clear window for the photoemitters.

The preferred embodiment of the sensor according to this invention includes an encoding/decoding system such as that described in U.S. Pat. No. 4,621,643. The flexible web supports an encoding resistor **55** in electrical communication with the monitor. As explained in that patent, the value of the resistor is selected to match the wavelengths of the red and infrared LED's. That patent also describes the necessary sensor monitoring electronics.

In an alternative embodiment, the sensor's photodetector may be mounted in the flexible web with the emitters and the encoding resistor mounted in the rigid housing.

In the preferred embodiment, the rigid housing is made from injection molded polycarbonate. Alternatively, injection molded ABS plastic may be used. U.S. Pat. No. 4,685,464 contains additional details on construction of a rigid housing and deformable pad including the placement of the photodetector.

As will be understood by those familiar with the art, the present invention may be embodied in other specific forms without departing from the spirit or essential characteristics thereof. For example, the compression effect of foam **44** could be obtained instead by making bridge **52** a spring-action clip, which is opened by holding one end down during insertion and then released, with a spring on the clip holding the tab in place. Other variations in the way electrical contact is made are also possible. Instead of the adhesive layer, the flexible portion could be attached to the finger and rigid housing using velcro or other securing mechanisms. The flexible web could be made of foil or other color materials than white or clear. The sensor could be a surface sensor, with adhesive for reducing motion artifact on the disposable portion. Accordingly, the disclosure of a preferred embodiment of the invention is intended to be illustrative, but not limiting, of the scope of the invention which is set forth in the following claims.

What is claimed is:

1. A sensor for attaching to a patient for electrooptical measurement of blood characteristics, comprising:

a reusable member including a first electronic means for emitting or detecting electromagnetic radiation;

conducting means, connected to said reusable member, for electrically connecting said first electronic means to an external sensor monitoring system;

a disposable, flexible member including a second electronic means for detecting electromagnetic radiation emitted by said first electronic means or emitting electromagnetic radiation to be detected by said first electronic means;

means for removably coupling said flexible member to said reusable member to provide a connection between said second electronic means and said conducting means; and

means for securing said disposable, flexible member and reusable member to said patient.

2. The sensor of claim **1** wherein said means for securing comprises an adhesive on said disposable, flexible member.

3. The sensor of claim **1** wherein said second electronic means is at least one photoemitter.

4. The sensor of claim **1** wherein said means for removably coupling comprises a tail extending from said disposable, flexible member having at least one exposed first electrical conductor, at least one exposed second electrical conductor extending from said reusable member, and a bridge means connected to said reusable member and extending across said second electrical conductor for allowing said tail to be inserted between said bridge means and said second conductor.

5. The sensor of claim **4** wherein said tail includes resilient means for applying force between said second conductor and said bridge means to hold said tail in place.

6. The sensor of claim **1** wherein said reusable member comprises a rigid housing and a deformable means, attached to said housing, for securely gripping and complying to an appendage of said patient.

7. The sensor of claim **1** wherein said second electronic means comprises a red light photoemitter and an infrared photoemitter.

8. The sensor of claim **7** wherein said first electronic means comprises a photodetector.

9. The sensor of claim **1** wherein said means for securing attaches said sensor to an appendage of said patient so that said first electronic means is on an opposite side of said appendage from said second electronic means.

10. The senor of claim **1** further comprising a black coating on said flexible member around said second electronic means.

11. The sensor of claim **1** further comprising:

an electrostatic screen adjacent said first electronic means; and

a thin film covering said first electronic means and at least a portion of said electrostatic screen, said film being transparent over said first electronic means and opaque over said portion of said electrostatic screen.

12. A sensor for attaching to an appendage of a patient for electrooptical measurement of blood characteristics, comprising:

a reusable member including a first electronic device for emitting or detecting light;

conducting means for electrically connecting said first electronic device to an external sensor monitoring system;

a disposable, flexible member including a second electronic device for detecting light emitted by said first electronic device or emitting light to be detected by said first electronic device;

a tail extending from said disposable, flexible member having at least one exposed first electrical conductor, at least one exposed second electrical conductor extending from said reusable member, and a bridge connected to said reusable member and extending across said second electrical conductor to allow said tail to be inserted between said bridge and said second conductor;

means for securing said disposable, flexible member to said appendage and said reusable member so that said first electronic device is on an opposite side of said appendage from said second electronic device.

13. The sensor of claim **12** wherein said means for securing comprises an adhesive on said disposable, flexible member.

14. The sensor of claim **12** wherein said second electronic device is a photoemitter.

15. The sensor of claim **12** wherein said tail includes resilient means for applying force between said second conductor and said bridge to hold said tail in place.

16. A sensor for attaching to an appendage of a patient for electrooptical measurement of blood characteristics, comprising:

a reusable member including a photodetector;

conducting means, connected to said reusable member, for electrically connecting said photodetector to an external sensor monitoring system;

a disposable, flexible member including at least one photoemitter for emitting light to be detected by said photodetector;

means for removably coupling said flexible member to said reusable member to provide a connection between said photoemitter and said conducting means; and

an adhesive coating on said disposable, flexible member for securing said disposable, flexible member to said appendage and said reusable member so that said photodetector is on an opposite side of said appendage from said photoemitter.

17. A sensor for attaching to an appendage of a patient for electrooptical measurement of blood characteristics, comprising:

a reusable member including at least one photodetector, said reusable member including a rigid housing and a deformable means, attached to said housing, for securely gripping and complying to said patient's appendage;

conducting means, connected to said reusable member, for electrically connecting said photodetector to an external sensor monitoring system;

a disposable, flexible member including a red light photoemitter and an infrared photoemitter for emitting light to be detected by said photodetector;

a tail extending from said disposable, flexible member having at least one exposed first electrical conductor;

at least one exposed second electrical conductor extending from said rigid housing;

a bridge connected to said rigid housing and extending across said second electrical conductor to allow said tail to be inserted between said bridge and said second conductor;

resilient means, coupled to said tail, for applying force between said second conductor and said bridge to hold said tail in place; and

an adhesive coating on said disposable, flexible member for securing said disposable, flexible member to said appendage and said reusable member so that said photoemitters are on an opposite side of said appendage from said photodetector.

18. A sensor for attaching to a patient for electrooptical measurement of blood characteristics, comprising:

a disposable, flexible member having a plurality of conductors disposed on a substrate and including at least one electronic means for emitting or detecting electromagnetic radiation, said at least one electronic means being connected to at least one of said conductors disposed on said substrate;

conducting cable means for electrically connecting said electronic means to an external sensor monitoring system;

means for releasably connecting said flexible member conductors to said conducting cable means to provide a connection between said electronic means and said conducting cable means; and

means for securing said flexible member to said patient.

19. The sensor of claim 18, wherein said means for securing comprises an adhesive connected to said substrate.

20. The sensor of claim 18, wherein said at least one electronic means is a photoemitter.

21. The sensor of claim 18, wherein said at least one electronic means is a photodetector.

22. The sensor of claim 18, wherein an end of said conducting cable means opposite said releasably connecting means is adapted to be connected to an oximeter monitor.

23. The sensor of claim 18, wherein said blood characteristics include arterial oxygen saturation.

24. The sensor of claim 18, wherein said substrate is elongated and flexible.

25. The sensor of claim 18, wherein said plurality of conductors, include a plurality of contacts on a surface of said substrate which can be connected to said releasably connecting means for electrically connecting said conducting cable means to said at least one electronic means.

26. The sensor of claim 18, wherein said plurality of conductors comprise a plurality of conductive traces disposed on said substrate.

27. The sensor of claim 26, wherein said traces comprise printed traces.

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