THE DEVELOPMENT OF A CONTINUOUS BLOOD OXYGEN SATURATION MEASURING AND CONTROL SYSTEM

by

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1. INTRODUCTION

An increasing number of surgical and research preparations require the temporary replacement of heart and lung function by electro-mechanical devices (1). The need for extracorporeal oxygenation arises in some instances of severe adult and newborn respiratory distress, congenital heart defects, and open-heart surgery. The lung function of oxygen transfer and carbon dioxide removal from the blood is performed by a device called an oxygenator. This thesis describes the development of an instrument that continuously monitors and controls the blood oxygen saturation at the outlet of such a device. Dr. Leon J. Arp, of the Mechanical Engineering Department of Virginia Polytechnic Institute and State University, is currently developing a membrane-type oxygenator capable of delivering blood to a patient at varying degrees of oxygen saturation. The Arp membrane-type oxygenator achieves its excellent gas transfer characteristics, approximately 200 $cc/min/m^2$ (2), by directing the blood flow over silicon rubber tubes pressurized with oxygen. The partial pressure gradient between the CO_2 and O_2 in the blood and that within the tubes results in O_2 being transferred to and CO_2 from the blood. The gas transfer achieved by other membrane-type oxygenators is approximately 40 $cc/min/m^2$ (3). A manual adjustment is required to alter the amount of O_2 and CO_2 transferred by the Arp oxygenator.

Blood gas data, partial pressure of carbon dioxide (P_{co_2}) and partial pressure of oxygen (P_{o_2}), are the parameters usually used to

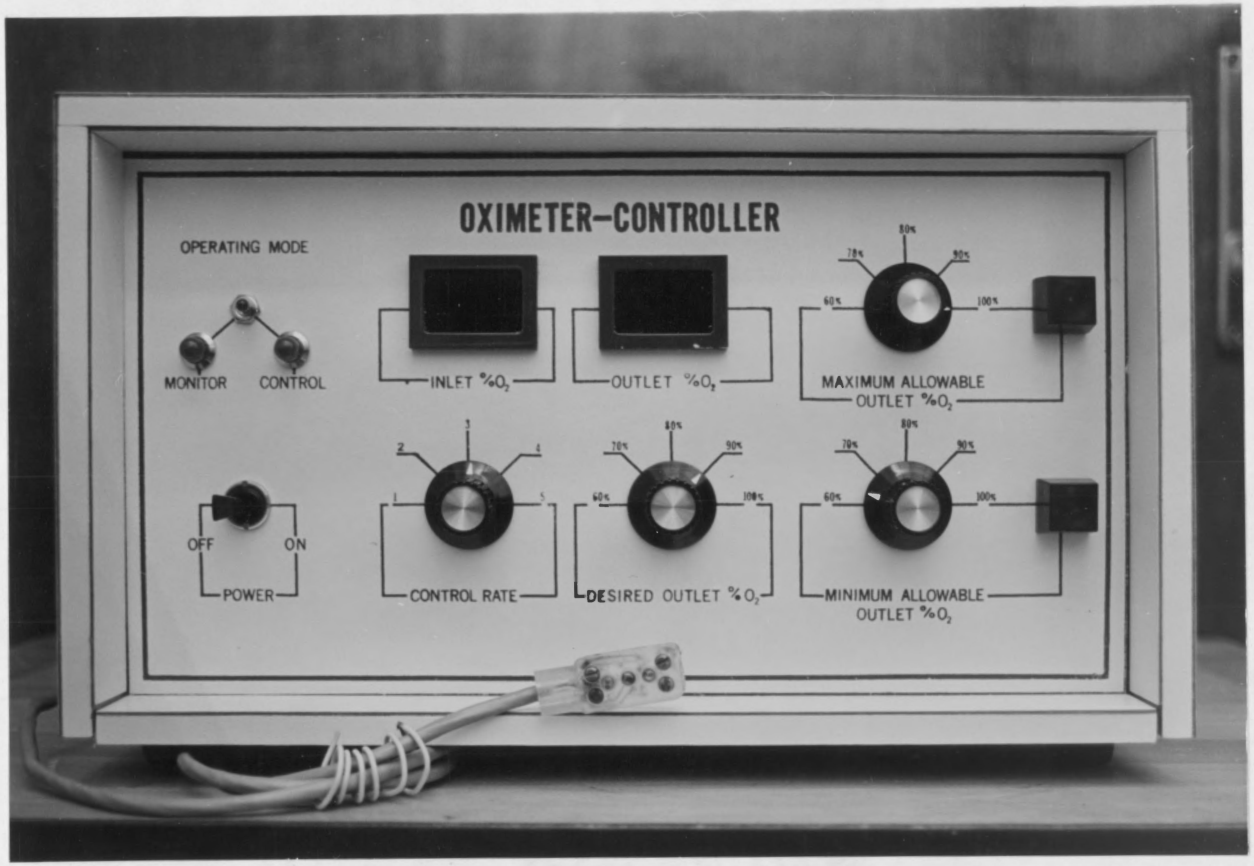


Figure 1. Oximeter-Controller

determine the effectiveness of gas transfer by the oxygenator. The per cent blood oxygen saturation is often used to give a measure of the blood oxygen tension (P_{o_2}). Oxygen saturation, the per cent of hemoglobin that is bound with oxygen, can be related to P_{o_2} by the use of Hill's equation (4), which describes the oxyhemoglobin disassociation curve. Several blood samples an hour may be required in order to follow the changing conditions of a patient so that the patient's P_{o_2} and P_{co_2} are kept at desired levels by the oxygenator. Even with frequent blood sampling, the patient's blood gases may be far from the desired levels for prolonged periods of time. A system that continuously monitors the blood oxygen saturation level and automatically controls the output from an oxygenator to a preselected oxygen saturation would be an improvement over the current method of periodic blood gas determination and manual oxygenator adjustment. Such an instrument, shown in Fig. 1, has been designed and will be described in the following pages of this thesis.

The determination of the continuous oxygen saturation measurement is achieved by the method of oximetry. Most oxygen in the bloodstream does not exist in simple solution but in loose combination with hemoglobin forming oxyhemoglobin (5). All photoelectric methods for the determination of the oxygen saturation of the blood depend on the different reflection or transmission characteristics of hemoglobin and oxyhemoglobin at two different wavelengths. The reflection or transmission of light at one wavelength gives a measure of the amount of hemoglobin in the optical path. The other wavelength results in a measure of both the hemoglobin and oxygemoglobin. The oxygen saturation is related to the ratio of the reflected or transmitted light intensities at these two wavelengths. The carbon dioxide partial pressure cannot be measured by photoelectric methods because of the absence of blood color change with different levels of P_{co_2}. The measurement of P_{co_2} by use of a P_{co_2} electrode is not practical because of the danger of membrane breakage and the release of the electrolyte solution into the bloodstream. There are no other continuous P_{co_2} measurement techniques known; therefore, the oxygen saturation will be the only continuous blood gas parameter measured.

The spectrophotometric determination of oxygen saturation, by either the transmission or reflection method, has been used for a number of years. Early investigators (6-10) made oxygen saturation measurements by observing the transmission of light through a hemolyzed sample of blood. Hemolyzed blood has its hemoglobin released into the blood plasma rather than being contained within the corpuscular structure of the red blood cells. Reflection oximetry was introduced by Brinkman and Zijlstra (11) in 1949, and further developed by Rodrigo (12). The transmission method for determination of oxygen saturation has several distinct disadvantages compared to the reflectance technique for this particular application. One major disadvantage associated with the transmission method is that a hemolyzed blood sample is required for a linear relationship to exist between the ratio of the transmitted light intensities and the per cent oxygen saturation. This linear relationship is desired to facilitate the design of the oxygenator controller. The transmission method may be used without hemolyzing the blood, but the relationship between the oxygen saturation and the ratio of the light transmitted at the two wavelengths is non-linear. Reflection oximetry does not require the destruction of the red blood cells as does the transmission technique. The relationship between the ratio of the reflected light at two wavelengths and the oxygen saturation has been derived and shown to be linear by a number of investigators (11-15), provided the blood is illuminated to a critical depth of 3.0 mm. The transmission method requires a thin blood layer, typically less than 1.0 mm, in order that a detectable amount of light may pass through the solution. The minimum tube diameter used in the oxygenation system would have too great a diameter for the transmission method to be applicable.

The reflection method of oximetry was used in this instrument's design to obtain the continuous inlet and outlet oxygen saturation measurement of blood flowing through the Arp oxygenator. The control of the membrane-type oxygenator was accomplished by using the difference between the actual oxygenator outlet saturation and a preselected value to initiate a change in the oxygen partial pressure gradient.

The rest of this thesis concerns;

1) the theoretical design considerations,
2) circuit logic,
3) detailed circuit descriptions,
4) test results,
5) conclusions and recommendations.

2. INSTRUMENT DESIGN

2.1 THE OXIMETER

2.1.1 THEORETICAL CONSIDERATIONS

The operation of a reflection oximeter is based on the principles of bichromatic photometry. The reflectance oximeter determines oxygen saturation by comparing the light diffusely reflected by unhemolyzed blood in two separate spectral regions. One waveband is chosen in the near infrared region where the light reflectance is ideally independent of oxygenation, giving only a measure of the total hemoglobin in the optical path. The other waveband is chosen in the red region where the difference between the light reflected by hemoglobin and the oxygenated hemoglobin is at a maximum. The reflected light at this wavelength is thus, an indication of the amount of both reduced and oxygenated hemoglobin.

The choice of wavelengths is of paramount importance in the design of an oximeter. In most clinical laboratory situations when one is working with an extracted sample of blood, the dilution of the solution and the depth of the containment chamber can be controlled exactly so that measurements can be made at any wavelength. In oximetry, the situation is reversed; the hemoglobin concentrations are fixed and it is necessary to find suitable wavelengths to meet the criteria mentioned previously (16). One of the parameters used to describe the optical characteristics of blood is the extinction coefficient (e). The working form of the extinction coefficient is given by the Bunsen-Roscoe equation (17):

$$e = \frac{-\log_{10} \frac{I_\lambda'}{I_\lambda}}{d}$$

where I' -- transmitted light intensity at wavelength λ.

I -- incident light intensity at wavelength λ.

d -- depth of the blood containment chamber.

The extinction coefficient, thus, gives a measure of the light transmitted through a solution at a certain wavelength. The extinction spectra of reduced and oxygenated hemoglobin has been demonstrated by a number of investigators (17-19). Nilson (20) observes that in the region of wavelengths from 300 to 1200 millimicrons, the specific extinction coefficients generally do not deviate from one another to any large degree and that they both show a general fall with increasing wavelengths. In the region about 600 millimicrons there is a rather large difference between the extinction spectra of reduced hemoglobin and oxyhemoglobin. This is a suitable area to choose one of the wavelengths needed. In this region, the extinction coefficient of oxyhemoglobin is only about one-ninth that of reduced hemoglobin (15). Light in this waveband is reflected to a greater extent, resulting in the red appearance of hemoglobin solutions.

The second wavelength, for reasons stated previously, should be in the near infrared region. It has been shown that there is a region about 805 millimicrons where the extinction coefficients of oxyhemoglobin and reduced hemoglobin do not differ from one another to any great extent. This wavelength is referred to as the isobestic point. Thus, the isobestic point is the second wavelength which is desired ideally in the measurement of oxygen saturation by oximetry.

The reflection of light by blood is a complex phenomenon involving absorbtion, reflection, and refraction of light within a particulate suspension: that is, red blood cells, white blood cells and platelets in plasma. To further confuse the issue, the oxygen saturation measurements are to be made with blood flowing within a closed system, resulting in periodic alteration of orientation and concentration of the particles (13). There are complex studies available on the reflection of light by a particulate suspension, but the use of empirical data simplifies the derivation of the governing equations. A derivation of these relationships follows.

Let I_o be the incident light intensity illuminating the blood layer and I_R the intensity of the diffusely back-scattered and reflected light. It has been shown (12) that if blood is illuminated to a critical depth of greater than 3.0 millimeters, the following relationship exists (13):

$$I_R = I_o \frac{d_\lambda}{2e_\lambda} \tag{2-1}$$

where λ is the wavelength of the incident light and e_λ the specific extinction coefficient at that wavelength. The diffusion coefficient, d_λ, is a parameter that gives a measure of the amount of light diffusely back-reflected at a particular wavelength λ.

Considering blood as a two-pigment system, the specific extinction coefficient becomes:

$$e_\lambda = (C_r\ e_{r\lambda} + C_o\ e_{o\lambda}) \tag{2-2}$$

where C_r is the relative concentration of hemoglobin and C_o is the relative concentration of oxyhemoglobin in the solution. The specific extinction coefficients of the reduced and oxygenated hemoglobin are represented by er_λ and $e_{o\lambda}$, respectively. Equation (2-1) then becomes

$$I_R = I_o \frac{d_\lambda}{2(C_r\ e_{r\lambda} + C_o\ e_{o\lambda})} \tag{2-3}$$

Assume the two wavelengths of incident light used are 660 mμ and 805 mμ. Then,

$$I_{R_{660}} = I_{o_{660}} \frac{d_{660}}{2(C_r\ e_{r_{660}} + C_o\ e_{o_{660}})} \tag{2-4}$$

$$I_{R_{805}} = I_{o_{805}} \frac{d_{805}}{2(C_r\ e_{r_{805}} + C_o\ e_{o_{805}})} \tag{2-5}$$

The ratio of reflected light intensity is found by dividing equation (2-4) by equation (2-5), resulting in:

$$\frac{I_{R_{660}}}{I_{R_{805}}} = \frac{I_{o_{660}}}{I_{o_{805}}} \frac{(d_{660}/d_{805})}{(C_r\ e_{r_{660}} + C_o\ e_{o_{660}})/(C_r\ e_{r_{805}} + C_o\ e_{o_{805}})} \tag{2-6}$$

At the isobestic point of 805 mμ, the specific extinction coefficients are equal. Also, the relative concentrations of the reduced and oxygenated hemoglobin must equal one. Further, if $I_{o_{660}} = I_{o_{805}}$, rearranging equation (2-6) and solving for C_o, the oxygen concentration, one obtains:

$$C_o = \frac{I_{R_{805}}}{I_{R_{660}}} \frac{d_{660}}{d_{805}} \left[\frac{e_{805}}{e_{o_{660}} - e_{r_{660}}}\right] - \left[\frac{e_{r_{660}}}{e_{o_{660}} - e_{r_{660}}}\right] \tag{2-7}$$

or

$$C_o = A \frac{I_{R_{805}}}{I_{R_{660}}} - B \tag{2-8}$$

Therefore, the oxygen saturation is linearly related to the ratio of the reflected light intensity at the two wavelengths chosen.

The constants A and B represent terms containing combinations of the extinction and diffusion coefficients for the two pigments at the two wavelengths. The derivation was presented by Enson, Briscoe, Polanyi, and Cournand (13) and the resulting equation has been experimentally verified. They state that the minimum depth of 3.0 mm is required perhaps because of the need for a certain minimal number of red blood cells in the optical path in order to obtain the linear relationship predicted.

The design of this oximeter follows the linear principle given by equation (2-8), but utilizes it in a slightly altered fashion. If the reflected light intensity at the two chosen wavelengths, $I_{R_{660}}$ and $I_{R_{805}}$, is equal instead of the incident light intensities, $I_{o_{805}}$ and $I_{o_{660}}$, keeping in mind that $C_o + C_r = 1$, and $e_{r_{805}} = e_{o_{805}}$, the following relationship is obtained:

$$C_o = \frac{I_{o_{660}}}{I_{o_{805}}} \frac{d_{660}}{d_{805}} \left[\frac{e_{805}}{e_{o_{660}} - e_{r_{660}}}\right] - \left[\frac{e_{r_{660}}}{e_{o_{660}} - e_{r_{660}}}\right] \qquad (2\text{-}9)$$

or

$$C_o = C \frac{I_{o_{660}}}{I_{o_{805}}} + D \qquad (2\text{-}10)$$

Again, the constants C and D are merely combinations of the extinction and diffusion coefficients for the two blood components at the two wavelengths. The oximeter design is, therefore, based on the theory that the ratio of the red to infrared incident light intensity varies linearly to the oxygen content in the blood if the reflected light intensities are held constant.

2.1.2 CIRCUIT LOGIC

The following discussion describes the logic of the oximeter circuit designed to measure the oxygen saturation. It has been shown that the oxygen saturation varies linearly with the ratio of the visible red incident light intensity to the infrared incident light intensity, provided the reflected light intensities at these two wavelengths are equal.

Solid state light emitting diodes, LED's, are used as the light sources in the oximeter. One LED, used as the red source, has a peak emitting frequency of about 660 mμ, and the infrared diode has a peak emitting frequency of around 900 mμ. Light emitting diodes are used because they are inherently stable, and do not require filtering or optical chopping as do some other light sources. One other essential characteristic of the LED's is the linearity between input current and light output. This linearity between current and light output is essential for the linear operation of the circuitry. The light receiving element of the design is a phototransistor. As is the case with the light emitting diodes, the phototransistor also has the required linearity between output current and input light intensity.

Figure 2 shows a block diagram of the oximeter logic. The block diagram will be discussed for one complete cycle of operation. During operation of the oximeter circuitry, the LED's are pulsed on alternately. The multiplexer supplies a half-wave rectified sine wave of approximately eight milliseconds duration as the LED current source. Suppose LED-1 has been pulsed on and LED-2 is off. LED-1 is kept on until the inte-

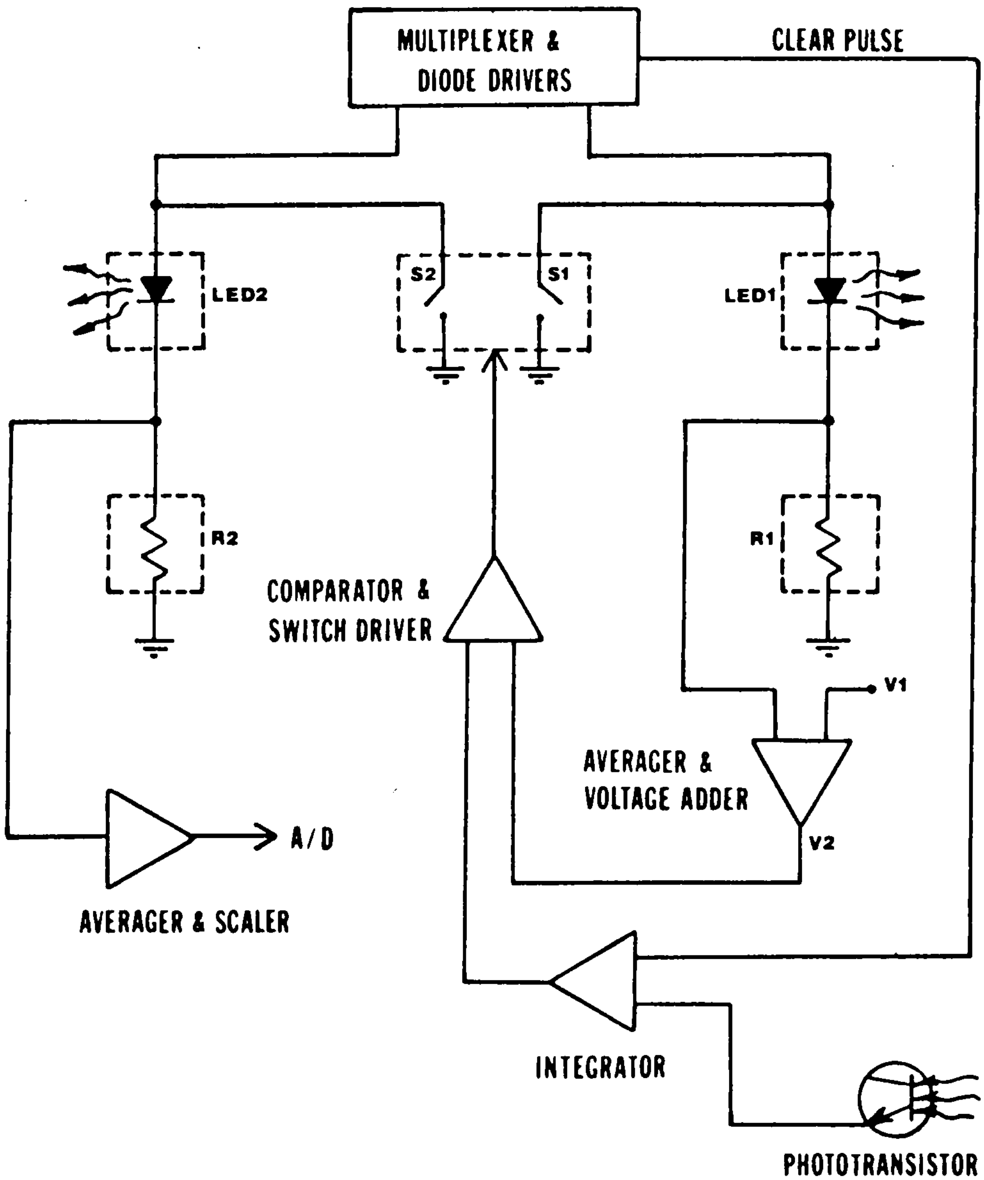


FIGURE 2. OXIMETER LOGIC

grated output of the phototransistor, representing the total reflected light received during this pulse, reaches the reference voltage V2. When this occurs, the comparator and switch driver amplifier closes switch S1, a silicon controlled rectifier (SCR), turning LED-1 off by shorting the current to ground. Both LED's are off at this time. At a later time determined by the multiplexer timing, a pulse is delivered to the integrator which returns the integrator output to zero. LED-2 is then pulsed on. The signal processing for LED-2 is identical to that for LED-1. LED-2 is kept on until the integrator output reaches the reference voltage level V2, causing the switch driver circuitry to close S2, also an SCR, and turn LED-2 off. The total light received by the phototransistor is the same for both LED's, provided the phototransistor is operating linearly. If the LED's light output is proportional to the input current, the ratio of the two averaged LED currents will give an indication of the incident light ratio and correspondingly the percentage of the hemoglobin saturated with oxygen. Summarizing, the reflected light received by the phototransistor is held constant and the ratio of the incident light intensities at the two wavelengths is measured in order to obtain the measure of oxygen saturation.

The ratio of the current through the two LED's must be computed. The computation of this ratio would be facilitated by maintaining the current through LED-1 constant at one unit and then the current through LED-2 could be measured and scaled to give a direct indication of the ratio. The averager and voltage adder are used to accomplish this function. The current through LED-1 is proportional to the voltage across R1, and similarly the current through LED-2 is proportional to the voltage across R2. The average voltage across R1 does not change quickly because of the long time constant associated with the averager, approximately one-half second. This voltage then does not change appreciably over many cycles of circuit operation. In turn, the voltage V2, the output from the voltage adder circuitry, also remains essentially constant during many cycles of circuit operation. It is this voltage, V2, which determines how long LED-1 and LED-2 stay on. Because of the high gain associated with the voltage adder, a small change in the averaged LED-1 current results in a much larger change in the output voltage V2. LED-1 will be kept on until the integrated output from the phototransistor, representing the total received light during this pulse, reaches the reference voltage V2. The reference voltage V2 is then whatever level is needed to maintain the current through LED-1 constant. If the oxygen content in the blood changes, resulting in a change of reflectance properties, the voltage level V2 then will change in order to maintain LED-1 current constant at one unit. Suppose, for example, that the amount of oxygen held by the red blood cells changed in such a way that more light was reflected per unit of current. This would result in the output of the integrator reaching the reference voltage quicker, and in turn LED-1 would not be kept on as long. The average voltage level would then begin to decrease. Because of the high gain applied to the average voltage level, as soon as the average level began to decrease, the voltage adder output would increase, thereby increasing the amount of light received and correspondingly, increasing the time LED-1 was kept on. It is in this manner that the current through LED-1 is maintained constant. The constancy of the LED-1 current is even more apparent because of its operating wavelength. LED-1 is the infrared light source. The infrared source is ideally dependent only upon the amount of hemoglobin in the optical path, and therefore, the reflected light at this wavelength should stay nearly constant unless the hemoglobin level shifts. The current through LED-1 is maintained constant at one unit; therefore, the scaled LED-2 current gives an analog signal representing the oxygen saturation of the blood.

2.1.3 CIRCUIT DESCRIPTION

The oximeter circuit schematic and parts list are shown in Fig. 3 and Table 1, respectively. The oximeter circuitry will be explained by relating it to the functional blocks of the logic diagram, Fig. 2.

The timing and multiplexing for the oximeter circuit are obtained by using the 60 cycle line frequency. One channel of the circuit is activated for one-half-cycle, approximately 8 ms, and the other channel is on during the next half-cycle. The LED-1 driving current is the transformer output half-wave rectified by D1, and presented to the infrared light emitting diode after the signal passes through the potentiometer, labeled P1, and the resistor, R1a to limit the current. Similarly, but one half-cycle later, the current path for LED-2, the red light source, is through D2 and R14 to the anode of LED-2. R2 and R15, corresponding to R1 and R2 in Fig. 2, respectively, are the resistors used to monitor the LED currents. The upper trace of Fig. 4 shows the half-wave rectified signal used as the LED current source. The bottom scope trace shows the voltage across one of the monitoring resistors. Figure 5 shows the multiplexing of the two LED's and also displays the different operating times of the two LED's. The current through LED-1 and LED-2, proportional to the voltage drop across R2 and R15, is averaged by R1b and C1 for LED-1 and R16 and C4 for LED-2. Provided that the time constant is very long, the capacitor voltage in a series RC circuit is proportional to the integral of the input voltage.

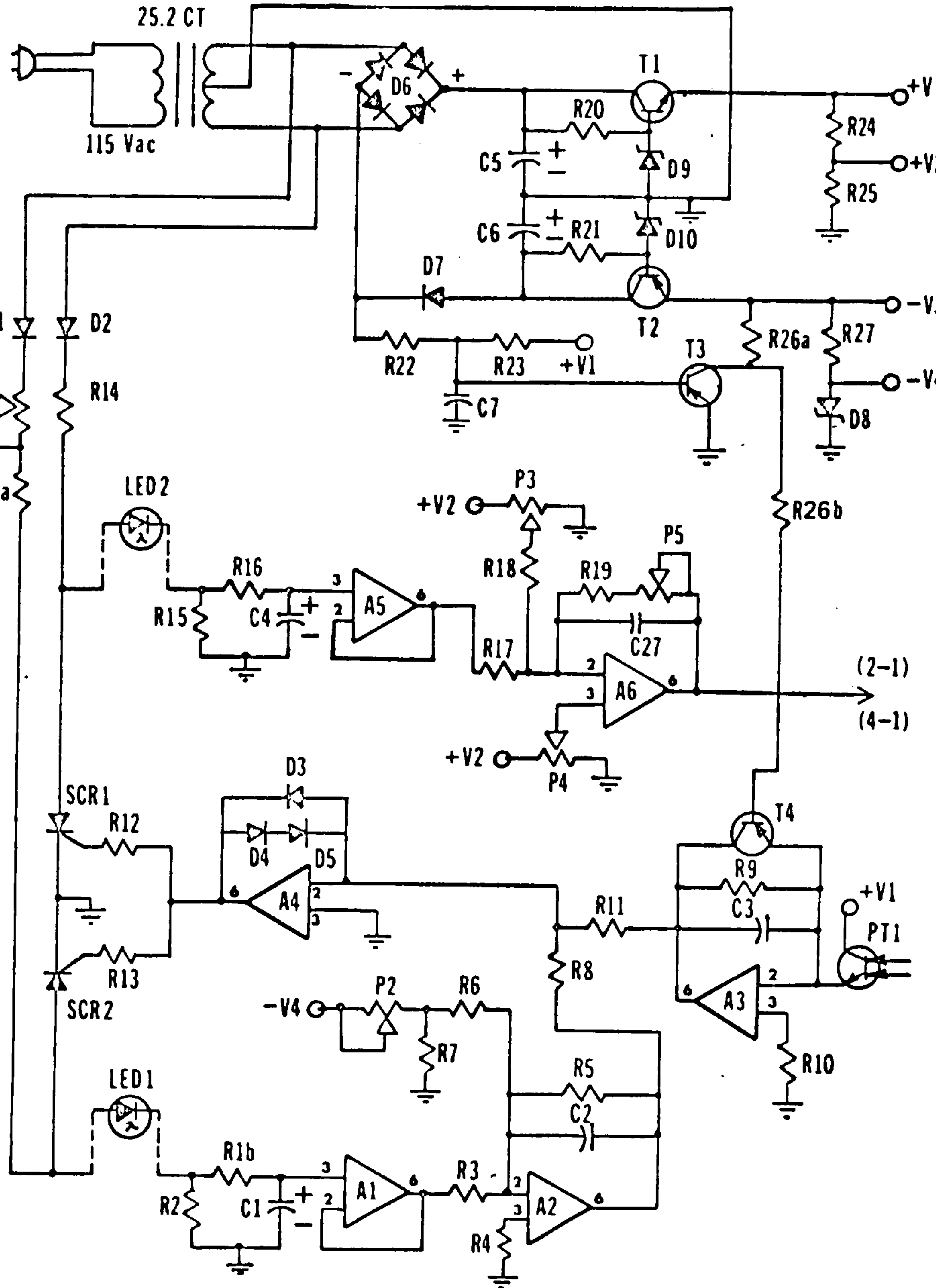


FIGURE 3. OXIMETER CIRCUIT SCHEMATIC

TABLE 1 OXIMETER CIRCUITRY PARTS LIST

<u>Resistors</u>

R1a - 220, ½ watt
R1b - 10K, ¼ watt
R2 - 10K, ¼ watt
R3 - 2.2K, ¼ watt
R4 - 2.2K, ¼ watt
R5 - 1M, ¼ watt
R6 - 12K, ¼ watt
R7 - 1.5K, ¼ watt
R8 - 33K, ¼ watt
R9 - 1M, ¼ watt
R10 - 1M, ¼ watt
R11 - 12K, ¼ watt
R13 - 100, ¼ watt
R14 - 220, ½ watt
R15 - 33, ¼ watt
R16 - 10K, ¼ watt
R17 - 22K, ¼ watt
R18 - 22K, ¼ watt
R19 - 10K, ¼ watt
R20 - 1K, ¼ watt
R21 - 1K, ¼ watt
R22 - 10K, ¼ watt
R23 - 100K, ¼ watt
R24 - 4.7K, ¼ watt
R25 - 2.7K, ¼ watt
R26a - 10K, ¼ watt
R26b - 10K, ¼ watt
R27 - 220, ½ watt

<u>Transistors</u>

T1 - HEP S5000(NPN)
T2 - HEP 700 (PNP)
T3 - HEP 715(PNP)
T4 - HEP 715(PNP)

SCR1 - HEP R1002
SCR2 - HEP R1002
LED1 - ME-6
LED2 - MV-3
PT1 - MT-2

<u>Capacitors</u>

C1 - 47 μf
C2 - 0.3 μf
C3 - 0.01 μf
C4 - 47 μf
C5 - 300 μf
C6 - 300 μf
C7 - 0.1 μf
C27 - 47 μf

<u>Diodes</u>

D1 - HEP 154, 1 Amp, 50 Volts
D2 - HEP 154, 1 Amp, 50 Volts
D3 through D5 - Germanium Signal Diodes
D6 - HEP 175, Diode Bridge, 1 Amp, 50 Volts
D7 - HEP 154, 1 Amp, 50 Volts
D8 - 6.2 Zener
D9 - 13 Volt Zener
D10 - 13 Volt Zener

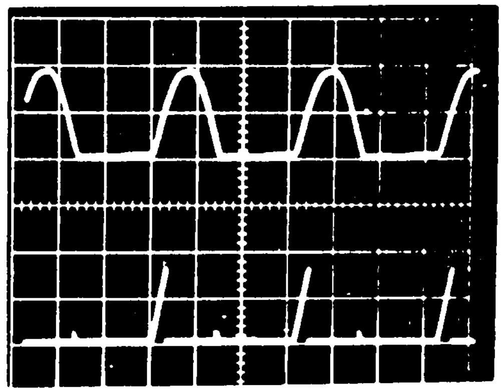
<u>Potentiometers</u>

P1 - 200
P2 - 20K
P3 - 20K
P4 - 10K
P5 - 100K

<u>Operational Amplifiers</u>

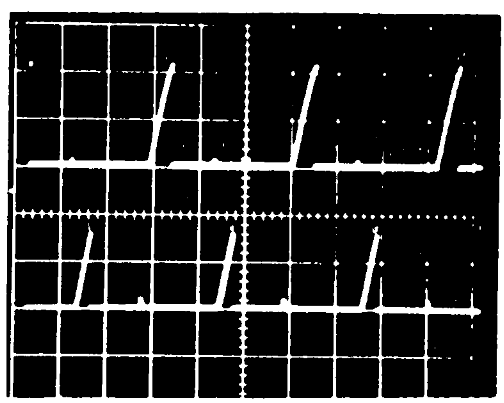
A1 through A7 - Type 741 OP. AMP.

Note: All resistance are in ohms.



Top - 1 Volt/Div. 5 ms/Div
Bottom - 1 Volt/Div.

Figure 4. Half-wave Rectified LED1 Current Drive and LED1 Voltage Traces



Top - 1 Volt/Div. 5 ms/Div.
Bottom - 1 Volt/Div

Figure 5. LED1 and LED2 Voltage Traces

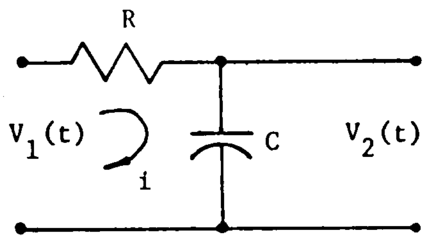


Figure 6. Series RC Circuit

$$V_2(t) = \frac{1}{C}\int i\,dt = V_1(t) - Ri \qquad (2\text{-}11)$$

When the output voltage, V_2, is small compared to the input, the approximate relationship $V_1(t) = Ri$ results, and therefore,

$$V_2(t) \simeq \frac{1}{RC}\int V_1(t)dt \qquad (2\text{-}12)$$

The capacitor eventually charges to the dc level of the input, provided the circuit time constant is long. The time constants for R1b and C1, and R16 and C4 are approximately 0.5 second, which is considerably longer than the operating time of 8ms for the LED's. The currents through the LED's, proportional to the voltage drops across the two monitoring resistors, are then effectively averaged.

All operational amplifiers in the oximeter circuitry are powered by +12 volts and -12 volts, denoted by V1 and -V3 respectively. For the sake of simplicity these power connections are not shown on the circuit schematic. The average voltage drop across R_2, proportional to the average current through LED-1, is connected to pin 3 of the op. amp A1. Similarly, the average voltage drop across R_{15}, proportional to the average current through LED-2, is connected to pin 3 of amplifier A5. Amplifiers A1 and A5 are in a voltage follower configuration. These unity gain circuits are used as electrical buffers to isolate circuits from one another and prevent undesired interactions. The output from amplifier A1 is presented to the voltage adder circuitry built about amplifier A2, shown below. The average voltage level across R2 in Fig. 3 is effectively 'clamped' to a preset reference level, set by P2, to maintain the current through LED-1 constant at one unit. The voltage adder circuitry is shown below.

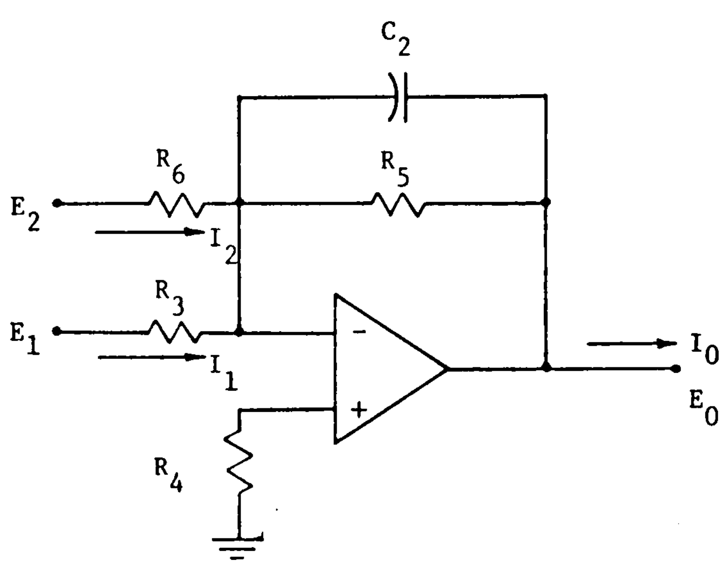


Figure 7. Voltage Adder Circuitry

The various amplifier configurations were analyzed using the method and summing point restraints given by Burr-Brown (21). The summing point restraints are:

(1) No current flows into either input terminal of the ideal operational amplifier.

(2) When negative feedback is applied around the ideal operational amplifier, the differential input voltage approaches zero.

With these summing point restraints in mind, the voltage adder circuitry will be analyzed. Let the average voltage across resistor R2 be E1. The reference voltage, denoted by V1 in the logic diagram, is shown as E2. The current in the feedback loop is the algebraic sum of the current due to each input. Each source, E1 and E2, contributes to the total current and no interaction occurs between them. Assuming that pin 2 is at ground potential,

$$I_o = I_1 + I_2 \tag{2-13}$$

The current, I_o, is given by:

$$I_o = \frac{-E_o}{Z_o} = \frac{E_1}{Z_1} + \frac{E_2}{Z_2} \tag{2-14}$$

The complex feedback impedence is the parallel combination of the impedences of R5 and C2,

$$Z_o = \frac{R_5}{1 + s\, R_5\, C_4} \tag{2-15}$$

where the symbol s is the complex frequency $j2\pi f$ for ac sinusoidal analysis. Equation (2-14) becomes,

$$\frac{-E_o}{\dfrac{R_5}{1 + s\,R_5\,C_4}} = \frac{E_1}{R_3} + \frac{E_2}{R_6} \qquad (2\text{-}16)$$

Rearranging,

$$E_o = \frac{-R_5}{R_3}\left[\frac{E_1}{1 + s\,R_5\,C_4}\right] - \frac{R_5}{R_6}\left[\frac{E_2}{1 + s\,R_5\,C_4}\right] \qquad (2\text{-}17)$$

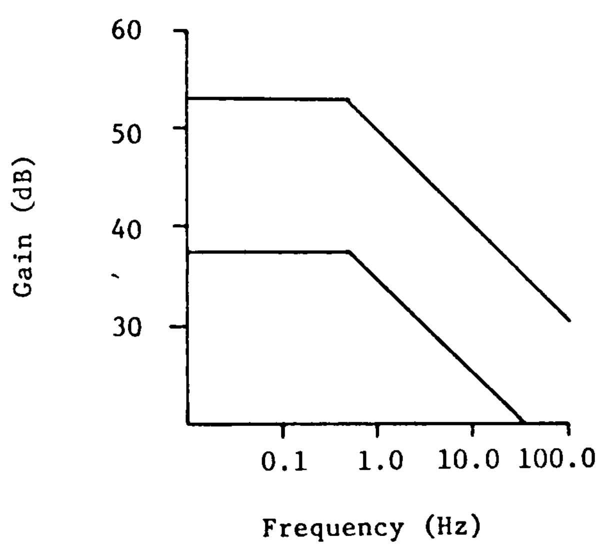


Figure 8. Voltage Adder Gain-Frequency Response

The gain-frequency response of the circuit is shown in Fig. 8. The gain computation for the average LED-1 voltage is given by:

$$\begin{aligned} \text{Gain (dB)} &= 20 \log_{10} R_5/R_6 \\ &= 20 \log_{10} 10^6/2.2 \times 10^3 \\ &\simeq 53 \end{aligned} \qquad (2\text{-}18)$$

Similarly, for the reference voltage input,

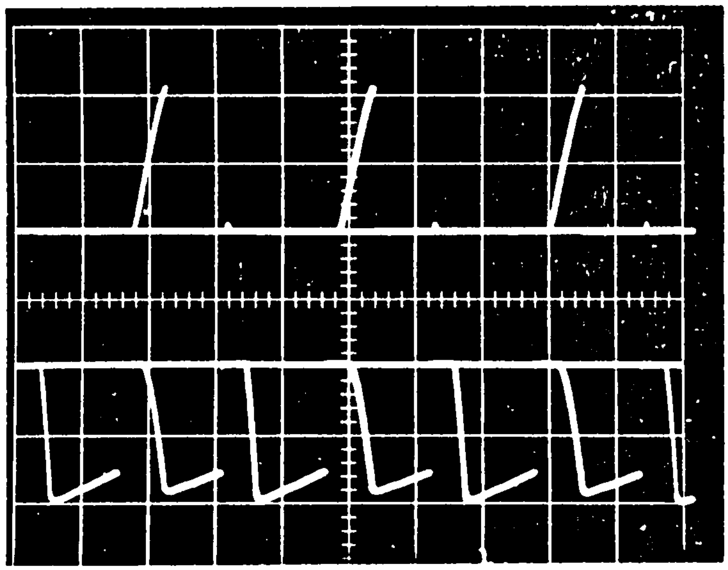
$$\begin{aligned} \text{Gain (dB)} &= 20 \log_{10} R_5/R_6 \\ &= 20 \log_{10} 10^6/12 \times 10^3 \\ &\cong 38 \end{aligned} \qquad (2\text{-}19)$$

The breakpoint for the circuit is given by:

$$\begin{aligned} f_c &= \frac{1}{2\pi R_5 C_4} \\ &= 0.53 \text{ Hz} \end{aligned} \qquad (2\text{-}20)$$

From the diagram, one observes that the gain associated with the LED voltage input is much greater than that applied to the reference voltage input. It is also noted that the circuit exhibits a 6dB per octave roll-off at frequencies above the corner frequency of 0.5 Hz. The circuit, therefore, acts as an integrator at frequencies above 0.5 Hz. The 60 cycle noise in the circuitry is thus, reduced by the attenuation of the higher frequencies, resulting in a stable dc output.

It is this dc output from amplifier A2 that determines the voltage level that the output of amplifier A3, the integrating circuit, must attain before the LED in operation may be turned off. The current from the phototransistor is fed directly into the inverting input of op. amp A3. The circuit built around amplifier A3 transforms the phototransistor current into a voltage which is then integrated to produce the output at pin 6. The upper trace of Fig. 9 shows the LED voltage in relation to the output of the integrating circuitry, bottom trace. Note the difference in the slope of the alternating integrated signal. The difference



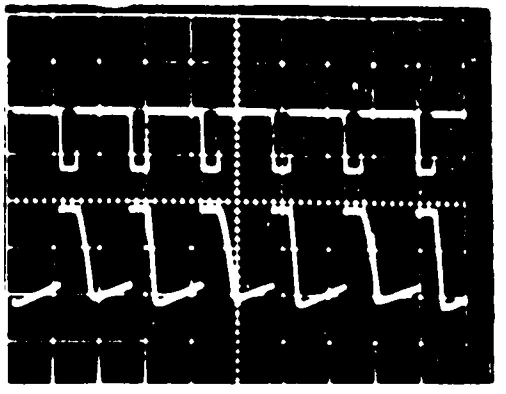
Top - 1 Volt/Div.
Bottom - 0.2 Volt/Div.
5 ms/Div.

Figure 9. LED Voltage and Integrator Output Traces

in the slopes is a result of the different amount of light reflected at the two wavelengths. Also note that the LED is turned off at the time when the integrated signal reaches the reference voltage level. The integrated signals do not attain the same negative voltage level. This is because of the small change in the reference voltage level caused by the cycle to cycle variation in the LED operation time. The voltage gain and source impedence of the phototransistor are indeterminate. Resistor R10 was chosen to minimize the bias current error. The analysis of this circuit could be made in a fashion similar to that for the voltage adder circuitry if the source impedence were known. The circuit acts as a low pass filter with the corner frequency well below the operating range of the LED-phototransistor combination. The circuit will then perform the mathematical operation of integration of the phototransistor current. Transistor T4 provides the circuit with a means of establishing initial conditions. T4 serves as a switch in the feedback path of amplifier A3. When the transistor is turned on, the feedback signal can go from pin 6, through the transistor, back to the inverting input, pin 2. When T4 is on, the amplifier is connected in the unity gain configuration and the capacitor, C3, is discharged forcing the output at pin 6 to zero. When the transistor is off and does not conduct, the circuit acts as an integrator. Its output will change proportionally to the integral of the phototransistor output current. The pulse used to clear the integrator is obtained from transistor T3 which turns T4 on. When the output from the negative side of the diode bridge, D6, is not zero, transistor T3 is on and consequently, the base of T4 is at ground and the transistor is off. If the bridge signal is nearly zero, T3 is off, resulting in the base of T4 being at a negative potential, turning T4 on and clearing the integrator. The voltage level at which T3 switches is determined by the bias voltage applied through resistor R23. The greater the resistance of R23, the closer the transistor comes to actually switching when the bridge output becomes zero. The duration of the clear pulse is then also determined by the value of R23. The oscilliscope traces in Fig. 10 detail the action of the clear pulse on the integrator output. The upper trace represents the voltage level applied to the base of T4. Observe that when the base of T4 is negative, the output of A3, the lower trace, is cleared to zero and the integration does not begin again until the transistor base voltage is zero.

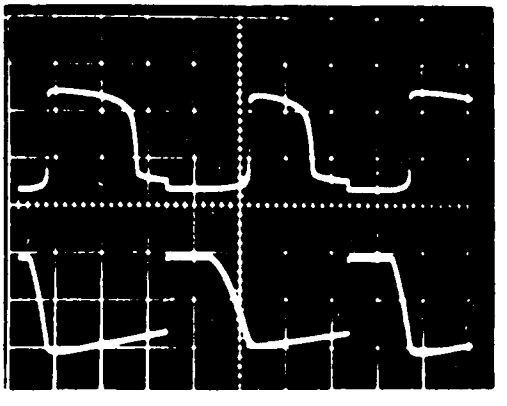
The output of A3 is a negatively increasing voltage which continues to increase until its absolute value reaches a voltage level determined by the ratio of R8 and R11 times the output of amplifier A2. When this occurs, amplifier A4 turns the SCR's on, which conducts the current away from the LED in operation and, thus, turns it off. Figure 11 depicts the simultaneous action of the switch driver circuitry A4 (upper trace) and the integrated phototransistor output. The shift in A4 output from a negative value to a positive one which turns the LED off, is shown by Fig. 12.

The operation of the circuitry associated with op. amp A4 will be examined more closely. The operation of A4 can be viewed as a comparator



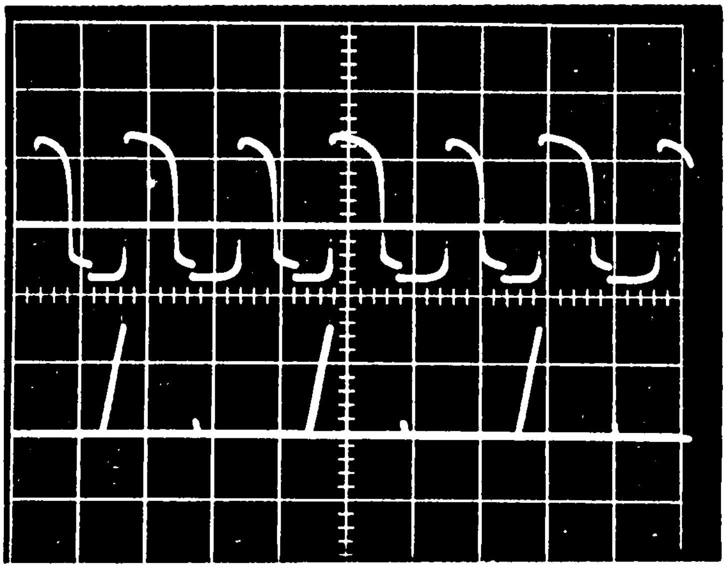
Top - 1 Volt/Div.
Bottom - 0.2 Volt/Div.
5 ms/Div.

Figure 10. Clear Pulse and Integrator Output Traces



Top - 1 Volt/Div.
Bottom - 0.2 Volt/Div.
2 ms/Div.

Figure 11. Switch Driver and Integrator Output Traces



Top - 1 Volt/Div.
Bottom - 1 Volt/Div.
5 ms/Div.

Figure 12. Switch Driver Output and LED1 Voltage Signal Traces

with the output clamped at a definite positive or negative value, depending on the sign of the signal present at the inverting input. The output of A2 is delivered through resistor R8 to the inverting input of A4, as is the output of amplifier A3 after it passes through resistor R11. The voltage at pin 2 of A4 will be positive as long as the output from the integrator circuit is less than the ratio of R11/R8 times the output of A2. During this time period, a positive voltage is present at the inverting input of A4. The amplifier output will attempt to approach negative saturation, but D3 clamps the output of A4 at approximately -0.6 volts, the voltage drop across the diode. If the voltage present at the amplifier summing point becomes slightly negative, because the integrator output has exceeded the reference level, the amplifier will attempt to swing to a positive saturation. Again, the output is clamped, this time by diodes D4 and D5, to a value of about 1.2 volts; the summation of the voltage drops across the two diodes. It is this positive voltage which turns the SCR's on and results in the LED in operation being turned off.

The scaling of the average voltage across R15, proportional to the current through LED-2, is achieved by the circuitry associated with amplifier A6, Fig. 13. The capacitor, C27, in the feedback path is not shown in the following diagram. Its function is identical to that of feedback capacitor, C2, in the voltage adder circuitry. The capacitor merely makes the circuit behave as a low-pass filter to eliminate any 60 cycle noise which might be present. The breakpoint frequency is defined by:

$$f_c = \frac{1}{2\pi(R_{19} + P_5)C_{27}} \qquad (2\text{-}21)$$

Since the resistance of P5 can vary from nearly zero to 100kΩ, the break frequency will be dependent on the resistance set at P5. Even with the minimum values of resistance used in the computation, the corner frequency is below 1 Hz.

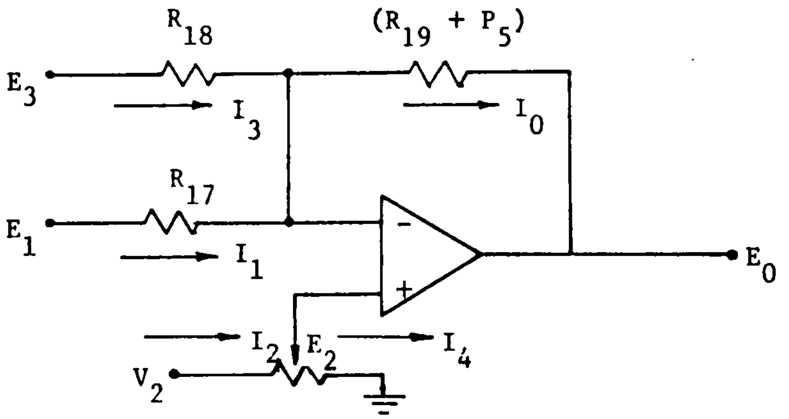


Figure 13. Scaling Amplifier Circuitry

Using the previously mentioned input summing point restraints, the relationships governing the scaling amplifier will be formulated. Let E3 be the voltage determined by pot P3, E1 the average LED-2 voltage, and E2 some positive voltage set by P4. Since no current flows into either operational amplifier input, the following relationships may be written;

$$I_o = I_1 + I_3 \tag{2-22}$$

$$I_2 = I_4 \tag{2-23}$$

Because pins 2 and 3 are at the same common mode voltage, E_f,

$$I_o = \frac{E_f - E_o}{(R_{19}+P_5)}, \quad I_3 = \frac{E_3 - E_f}{R_{18}}, \quad I_1 = \frac{E_1 - E_f}{R_{17}} \tag{2-24}$$

Substituting,

$$\frac{E_f - E_o}{(R_{19}+P_5)} = \frac{E_1 - E_f}{R_{17}} + \frac{E_3 - E_f}{R_{18}} \tag{2-25}$$

Solving for E_o,

$$E_o = -(R_{19}+P_5)\left[\frac{E_1 - E_f}{R_{17}}\right] - (R_{19}+P_5)\left[\frac{E_3 - E_f}{R_{18}}\right] + E_f \tag{2-26}$$

Due to the current in the bottom leg:

$$E_f = E_2 \tag{2-27}$$

Substituting,

$$E_o = -\frac{(R_{19}+P_5)}{R_{17}}(E_1 - E_2) - \frac{(R_{19}+P_5)}{R_{18}}[E_3 - E_2] + E_2 \tag{2-28}$$

Since $R_{17} = R_{18} = R$

$$E_o = -\frac{(R_{19}+P_5)}{R}[E_1 + E_3 - 2E_2] + E_2 \tag{2-29}$$

Calibration of the scaling amplifier is as follows:

(1) The first calibration point is 100% saturation. The corresponding output, pin 6 of amplifier A6, E_o, should be 1.0 volts. This is achieved by setting the voltage at pin 3, E2, by P4 at 1.0 volts and adjusting P3 until E_o is the desired value of 1.0.

(2) The second calibration point is some low value of saturation,

for example, 40%. Potentiometer P5 is adjusted until the output of A6, pin 6, is 0.40 volts.

This completes the calibration procedure. The output of A6 will be an analog signal corresponding to the per cent oxygen saturation.

2.2 THE ANALOG TO DIGITAL CONVERTER

2.2.1 CIRCUIT LOGIC

The analog-to-digital conversion is made by using an eight bit counter-comparator circuit. The analog-to-digital logic is shown in Fig. 14. The analog input, representing the oxygen saturation, is compared with the output of an eight bit digital-to-analog converter; the digital input being the counters' output. The digital-to-analog conversion is accomplished by use of a resistance ladder and an inverting operational amplifier. At the start of the conversion, the counters begin counting and continue to count until the D/A output crosses the input voltage. When this occurs, the clock input to the counters is blocked, resulting in the counters' output being held at the count at which the comparator switched. The counters' output values are transferred to the storage resisters, and then to the BCD to decimal decoder-drivers for display. The counters are then cleared and readied for the next conversion.

Although the design is simple in concept, this type of converter has the disadvantage of limited speed, since the conversion time for a full scale change is equal to the clock frequency divided by the maximum number of counts. This presents no problem in this application, though, because of the low frequencies employed in the instrument's design.

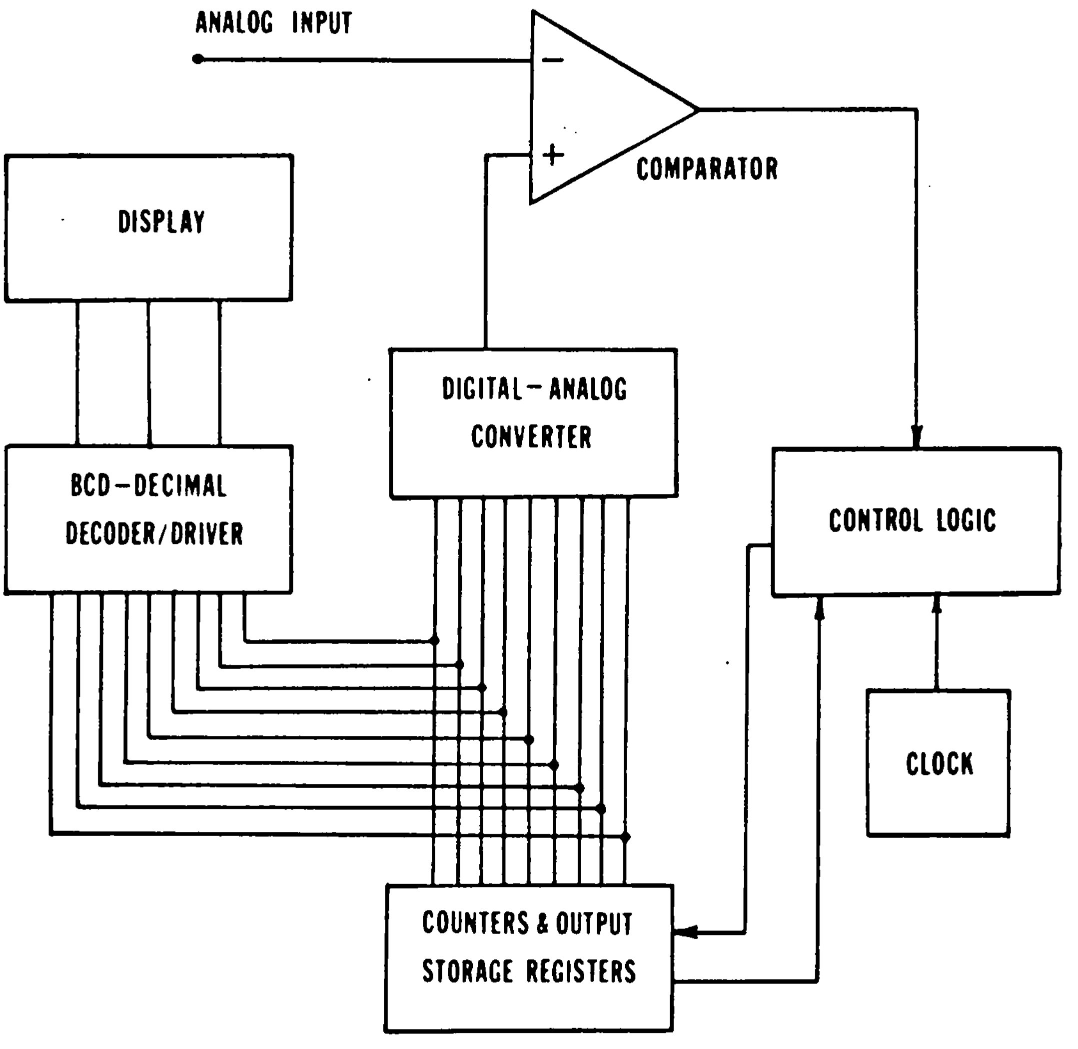


FIGURE 14. ANALOG-TO-DIGITAL LOGIC

2.2.2 CIRCUIT DESCRIPTION

The analog-to-digital circuit schematic and parts list are shown in Fig. 15 and Table 2, respectively. As stated previously, the analog-to-digital conversion is made by an eight-bit counter-comparator circuit, with an over-range detector.

The output from the oximeter circuitry, representing the oxygen saturation, is directed through resistor R40 into the inverting input of operational amplifier A8. Amplifier A8 is in an inverting configuration, with the gain determined by the ratio of P9 to R40. Resistance R41 was chosen such that it was very nearly equal to the parallel combination of R40 and P9. The function of the amplifier is to invert the input and increase its value such that it is in the proper voltage range for comparison with the generated ramp.

The negatively increasing ramp is produced by use of a clock, counters, and a resistance ladder network in conjunction with an inverting amplifier. In the explanation of the digital circuitry, a logical "0" or synonymously a low state will imply a voltage level of less than one volt. A logical "1" or high state will imply a five volt level, unless otherwise stated. The power supply voltage to each integrated circuit, Vcc, is five volts. A SN7413, a dual Schmitt-trigger, is connected in such a way that is performs as a free running multivibrator, with the output frequency determined by the combination of the capacitance, C14, and the resistance, P11. The clock frequency in this application was set to be approximately 2000 Hz. The output from 7413A passes to pin 12 of a 7400A, a quad 2-input Nand gate. If pin 13 of

DRAWING NO. 2

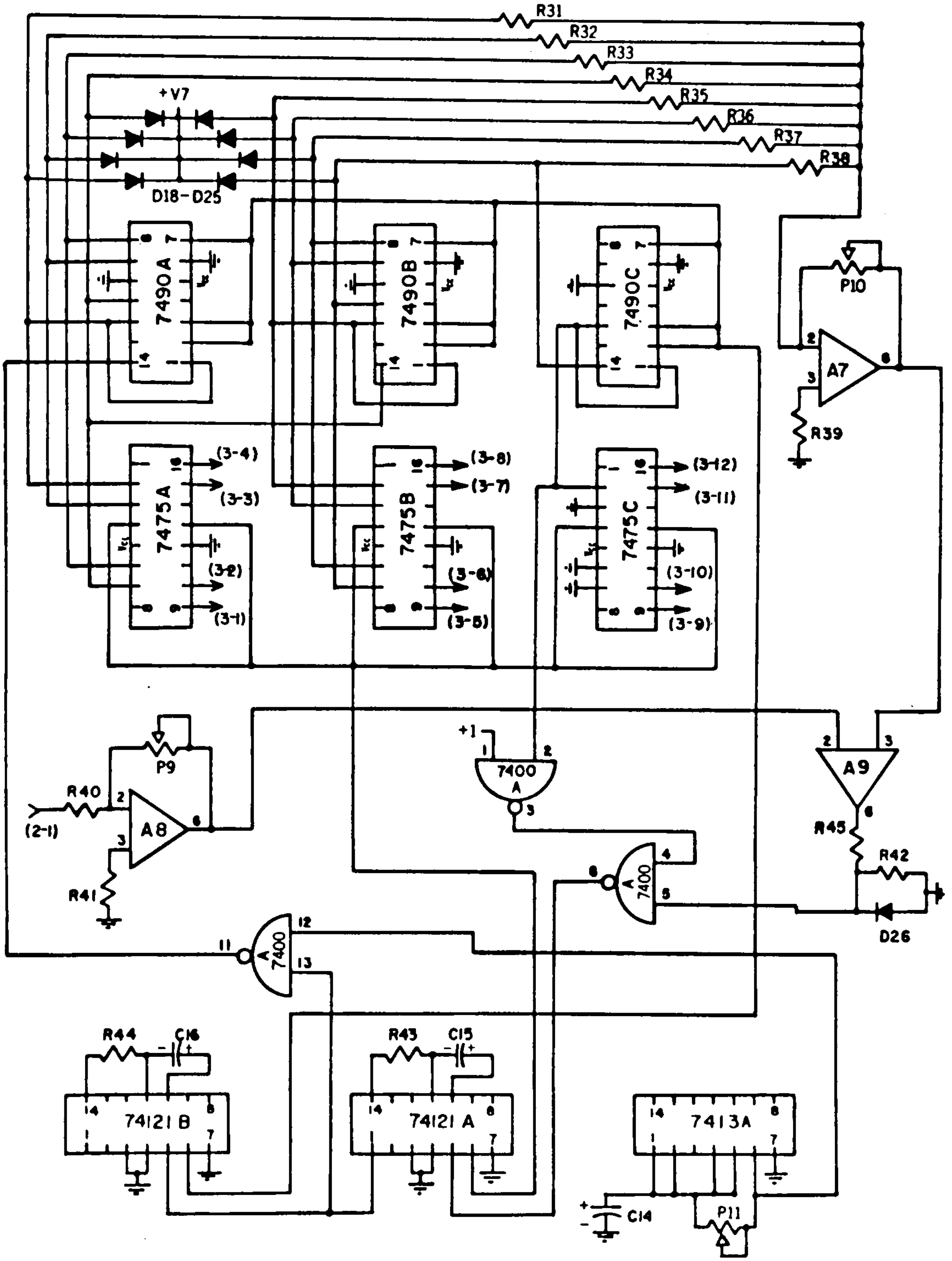


FIGURE 15. ANALOG-TO-DIGITAL CONVERSION CIRCUIT SCHEMATIC

TABLE 2 ANALOG TO DIGITAL CIRCUITRY PARTS LIST

Resistors

R31 - 80K, 0.1% Tolerance
R32 - 40K, 0.1% Tolerance
R33 - 20K, 0.1% Tolerance
R34 - 10K, 1.0% Tolerance
R35 - 8K, 1.0% Tolerance
R36 - 4K, 1.0% Tolerance
R37 - 2K, 1.0% Tolerance
R38 - 1K, 1.0% Tolerance
R39 - 300, ¼ watt
R40 - 510, ¼ watt
R41 - 510, ¼ watt
R42 - 5.6K, ¼ watt
R43 - 33K, ¼ watt
R44 - 22K, ¼ watt
R45 - 10K, ¼ watt

Integrated Circuits

7400A - Quad 2-Input Nand Gate
74121A,B - Monostable Multivibrators
7413A - Dual Schmitt Trigger
7475A,B,C - Quad Latches
7490A,B,C - Decade Counters

Operational Amplifiers

A7 through A9 - Type 741 Op. Amps

Diodes

D18 through D26 - Germanium Signal Diodes

Capacitors

C14 - 0.1 μf
C15 - 1.0 μf
C16 - 1.0 μf

Pots

P9 - 5K
P10 - 5K
P11 - 1K

Note: All resistances are in ohms.

that same gate is at a logical "1" level, the clock pulses will be allowed to pass to the input, pin 14, of 7490A, a decade counter. The outputs of 7490A and 7490B are a group of 4-binary coded digits used to represent a decimal digit. Counters 7490A and 7490B are cascaded so that a maximum count of 99 is attainable. The D output, pin 11 of 7490B, is connected to pin 14 of 7490C, which allows the three counters together to count to maximum of 100. If the maximum allowable count of 100 is attained, the conversion is stopped. This will be elaborated on later in the discussion.

The BCD count given by the counters' outputs is transformed to a corresponding analog signal by a weighted resistance ladder network and an inverting operational amplifier. Tables 3 and 4 shows the count at 7490A and 7490B, the counter output at the different counts, and the resistance value associated with each output. The 7490A and 7490B logical "1" output states are limited to a maximum value of 3.0 volts, V7, by diodes D18-D25. If the voltage level of each output of 7490A are denoted by A1, B1, C1, and D1, respectively; and, likewise, the outputs of 7490B by A2, B2, C2, and D2, the relationship describing the operation of amplifier A7 can be written,

$$E_o = -P_{10}\left[\frac{A_1}{R_{31}} + \frac{B_1}{R_{32}} + \frac{C_1}{R_{33}} + \frac{D_1}{R_{34}} + \frac{A_2}{R_{35}} + \frac{B_2}{R_{36}} + \frac{C_2}{R_{37}} + \frac{D_2}{R_{38}}\right] \qquad (2\text{-}30)$$

The operation of A7 is that of a scaling adder; that is, each input is multiplied by a constant before summing and inverting. From Eq. (2-30) it is noted that the most significant counter output, D2, will be

TABLE 3 BCD COUNT SEQUENCE FOR 7490A

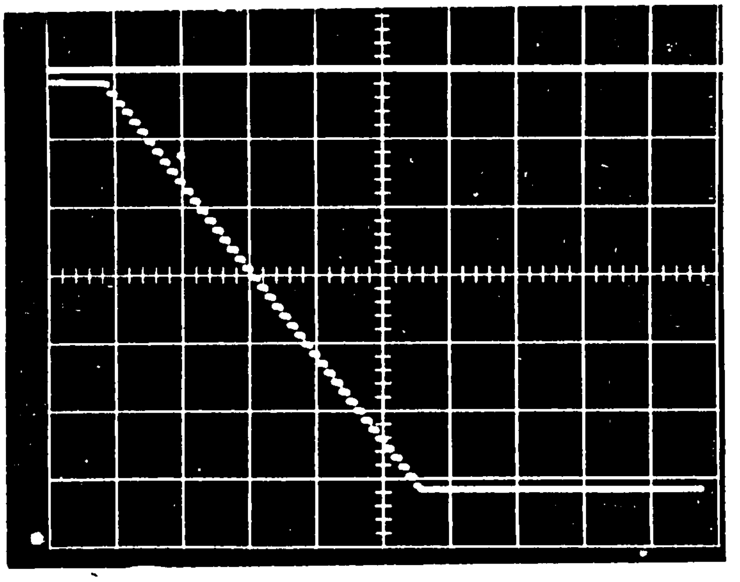
COUNT	7490A			
	OUTPUT (RESISTANCE)			
	A1(80K)	B1(40K)	C1(20K)	D1(10K)
0	0	0	0	0
1	0	0	0	1
2	0	0	1	0
3	0	0	1	1
4	0	1	0	0
5	0	1	0	1
6	0	1	1	0
7	0	1	1	1
8	1	0	0	0
9	1	0	0	1

TABLE 4 BCD COUNT SEQUENCE FOR 7490B

COUNT	7490B			
	OUTPUT (RESISTANCE)			
	A2(8K)	B2(4K)	C2(2K)	D2(1K)
0	0	0	0	0
1	0	0	0	1
2	0	0	1	0
3	0	0	1	1
4	0	1	0	0
5	0	1	0	1
6	0	1	1	0
7	0	1	1	1
8	1	0	0	0
9	1	0	0	1

multiplied by the largest constant, with less significant bits being multiplied by a proportionately smaller constant. If the count represented by the outputs of 7490A and 7490B is zero, A1 through D1, and A2 through D2 will all have a logical "0" voltage level, ideally zero volts. Therefore, the output of amplifier A7 ideally would be zero. In reality, the counters have some small non-zero output voltage, 0.4 volts maximum, when the outputs are in the "0" state. E_o will then be at some level slightly above zero, dependent on the resistance setting of P10. If the count increases, the output states of the counters switch successively from a low to high value of 3.0 volts. Each time the count increases by one count, the output of A7 increases negatively by a factor of P10/R31 times the logical "1" output voltage level of the counters. The result is the generation of a negatively increasing ramp with the step size determined by the resistance of P10. Figure 16 shows a partial sweep of the generated ramp.

The output of A7 is connected to pin 3 of op. amp A9. The scaled analog oxygen saturation signal from A8 is presented to pin 2 of the same amplifier. The amplifier is used open-loop as a comparator. As long as the ramp voltage is positive with respect to the saturation signal, the comparator output voltage will be at a positive saturation value. This output signal is scaled by R45 and R42 to make the voltage from A9 TTL (Transistor-Transistor Logic) compatible. This logical "1" level is connected to pin 5 of Nand gate A. If the maximum count of 100 has not been reached, pin 4 of the same package will also be at a "1". Therefore, the output at pin 6 of Nand gate A will be at a logical "0".



1 Volt/Div.   0.2 ms/Div.

Figure 16. Analog-Digital Ramp Trace

As long as the output from pin 6 of 7490A is "0", the clock will continue to supply pulses to the counters. In turn, the BCD output of the counters will increase, resulting in the continued generation of the negatively increasing ramp. When the ramp voltage becomes negative with respect to the saturation signal, comparator A9 output state switches from a positive saturation to a negative saturation value. This output is taken to ground by diode D26, producing a logical "0" state at pin 5 of 7400A. The output of this Nand gate then becomes high with the input transistion from a "1" to a "0" at either input. The output change of pin 6 of 7400A is also the input to pin 5 of SN74121A, a monostable multivibrator. The 74121A is in a connected so that an input transistion from a "0" to a "1" at pin 5 results in a pulse of approximately 1.2 seconds duration at the Q output, pin 6, and at the $\bar{Q}$ output, pin 1. The Q output changes from "0" to "1", and conversely, the $\bar{Q}$ output swings from "1" to "0" during this time. Once the 74121 has fired, the outputs are independent of further transistions at the input, and are a function of the timing components only (9). The $\bar{Q}$ output from 74121A is connected to pin 5 of 74121B and pin 13 of 7400A. The application of a logical "0" to pin 13 of 7400A prohibits any further clock pulses being input to the 7490A counter. This gate will be closed as long as the $\bar{Q}$ output from 74121A is low. The counters' output states are, therefore, held at the count at which the ramp voltage became more negative than the analog saturation signal. The transistion of the input to 74121B from high to low does not result in any change of its output states. The Q output of 74121A is used to strobe the quad latches, 7475A, 7475B, and 7475C. When a "1" is delivered to the latch clock inputs, pins 4 and 13, the counter output states, present at the quad latch D inputs, are transferred to the Q outputs of each latch. The Q outputs of 7475A, 7475B, and 7475C are transferred to the decoder-drivers 7447A, 7447B, and 7447C, respectively. Figure 17 shows the circuit schematic for the display signal processing. The BCD to seven-segment decoder drivers transforms the binary coded decimal at its input to a series of signals used to drive the seven segment MAN-1 display circuits. The 7447A, 7447B, and 7447C outputs are input the MAN-1 A, MAN-1 B, and MAN-1 C displays after the current has been limited by resistors R111-R131.

After approximately 1.2 seconds, the Q output of 74121A returns to the "0" state and the $\bar{Q}$ output returns to the "1" state. This transition causes a number of circuit actions. The transition at pin 5 of 74121B from "0" to "1" causes the Q output to switch from a "0" to a "1" state for approximately 0.8 seconds. This logical "1" level is applied to pins 2, 3, and 7 of 7490A, 7490B, and 7490C, which results in the output of each counter being cleared to zero. This in turn results in the output of A9 and the input 5 of 7400A swinging high. Pin 6 of 7400A then changes from a high to a low state which is also seen at the 74121A input. The transition from "1" to "0" at the 74121A input does not effect its output state. The return of the Q output of 74121A to its low value causes the data latches to hold their Q outputs at their present state. The low Q output also allows clock pulses to be input to 7490A once more. The counter output will not change though, as long as

DRAWING NO. 3

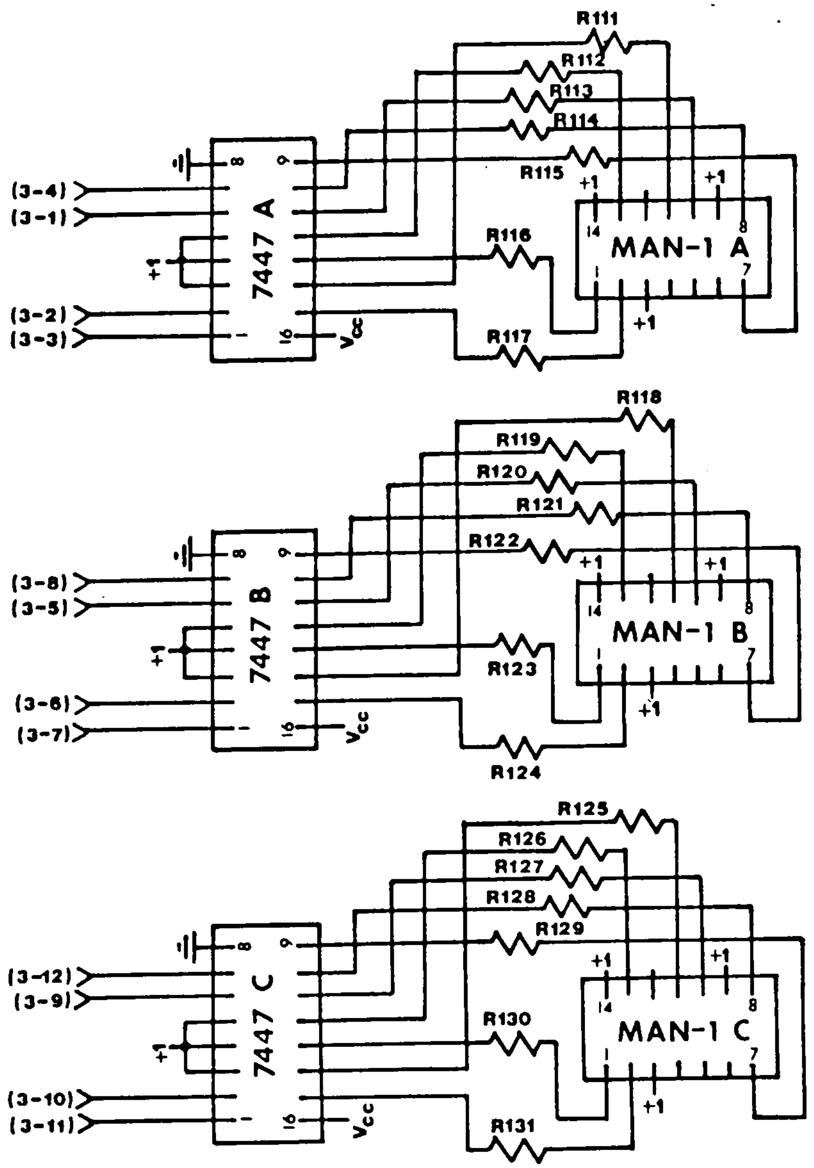


FIGURE 17. DISPLAY CIRCUIT SCHEMATIC

TABLE 5 DISPLAY CIRCUITRY PARTS LIST

Resistors

R111 through R131 - 47Ω, ¼ watt

Integrated Circuits

7447A,B,C - BCD to 7-Segment Decoder Drivers

MAN-1 A,B,C - LED Displays

the clear pulse applied by the Q output of 74121B is high. When the Q output of 74121B returns to the logical "0" state, the decade counters are free to count again and the circuit is ready to perform another conversion.

2.3 THE OXYGENATOR CONTROLLER

2.3.1 THEORETICAL CONSIDERATIONS

The function of the controller is to maintain the outlet oxygen saturation from a membrane-type oxygenator at a desired level. The inlet and outlet values of oxygen saturation of blood flowing through the oxygenator are available from the oximeter circuitry as analog signals. Normally, the first step in any control problem would be to derive the mathematical equations describing the processes occurring. The determination of the mathematical relationships for a membrane-type oxygenator with irregular blood flow over pressurized tubes has not been obtained. The possibility of using a "compartment-type" solution as described by Milhorn (22) was also deemed to be impractical because of the insufficient operating data required to define the emperical constants needed. Because of the void of experimental data and mathematical relationships, a simple control scheme to regulate the outlet oxygen saturation had to be formulated.

The oxygen saturation level at the outlet of the oxygenator is dependent upon a number of physical parameters associated with the oxygenating system and the blood itself. The hemoglobin concentration, the amount of hemoglobin already bound with oxygen, the temperature, pH, and viscosity of the blood entering the oxygenator are all significant factors. Other parameters associated with the degree of oxygenation attained are the inlet flow velocity, flow patterns in the oxygenator, tube surface area, thickness and permeability, and the oxygen partial pressure gradient. Of these, the partial pressure gradient existing between the oxygen contained in free solution and within the red blood cells and the Silastic® tubes lends itself most conveniently to be varied and used for control purposes. Further confirmation of the variability of oxygen saturation by change in the tube pressure is the ability of the Arp oxygenator to transfer such a large amount of oxygen by the use of elevated pressures, that free oxygen can be transferred to the blood. The outlet oxygen saturations possible by the utilization of elevated tube pressures range from the unaltered inlet condition, up to 100% saturation.

The control philosophy is then to measure the outlet saturation, compare it to the desired saturation level, and then to initiate a change of tube oxygen pressure dependent upon the magnitude and sign of the difference between the actual and desired outlet saturation.

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2.3.2 CIRCUIT LOGIC

The logic for the controller is shown in Fig. 18. The analog signal representing the actual oxygen saturation is subtracted from the desired oxygen saturation signal to produce an error signal, e_o. The difference signal is then input into eight voltage comparators. Four comparators are used for processing of negative values of e_o, and the remaining branch of comparators are used for the positive values of e_o. Since the signal processing is identical for either positive or negative values of e_o, this discussion will describe only one branch of the logic. The error signal is compared to the reference voltage levels, V_1 through V_4, at successive voltage comparators which increase from a minimum value at comparator A to a maximum value at comparator D. An equivalent binary number ranging from zero to fifteen is produced by the voltage comparators' output states dependent upon the magnitude of the error signal. If the desired saturation is very nearly equal to the actual saturation level, the resulting binary number will be zero, that is, the reference voltage at each comparator is greater than the error signal. If the difference signal is quite large, the voltage comparators' outputs will all be "high"; positive saturation, and the binary equivalent of fifteen will be formed. This binary number is then presented to the input of a four bit comparator. The binary number from the voltage comparators is compared to the output of a binary counter. If the comparators' output has produced a number other than zero, the two inputs will not be equal because the counter output is always zero at the beginning of the comparison. Since the two inputs

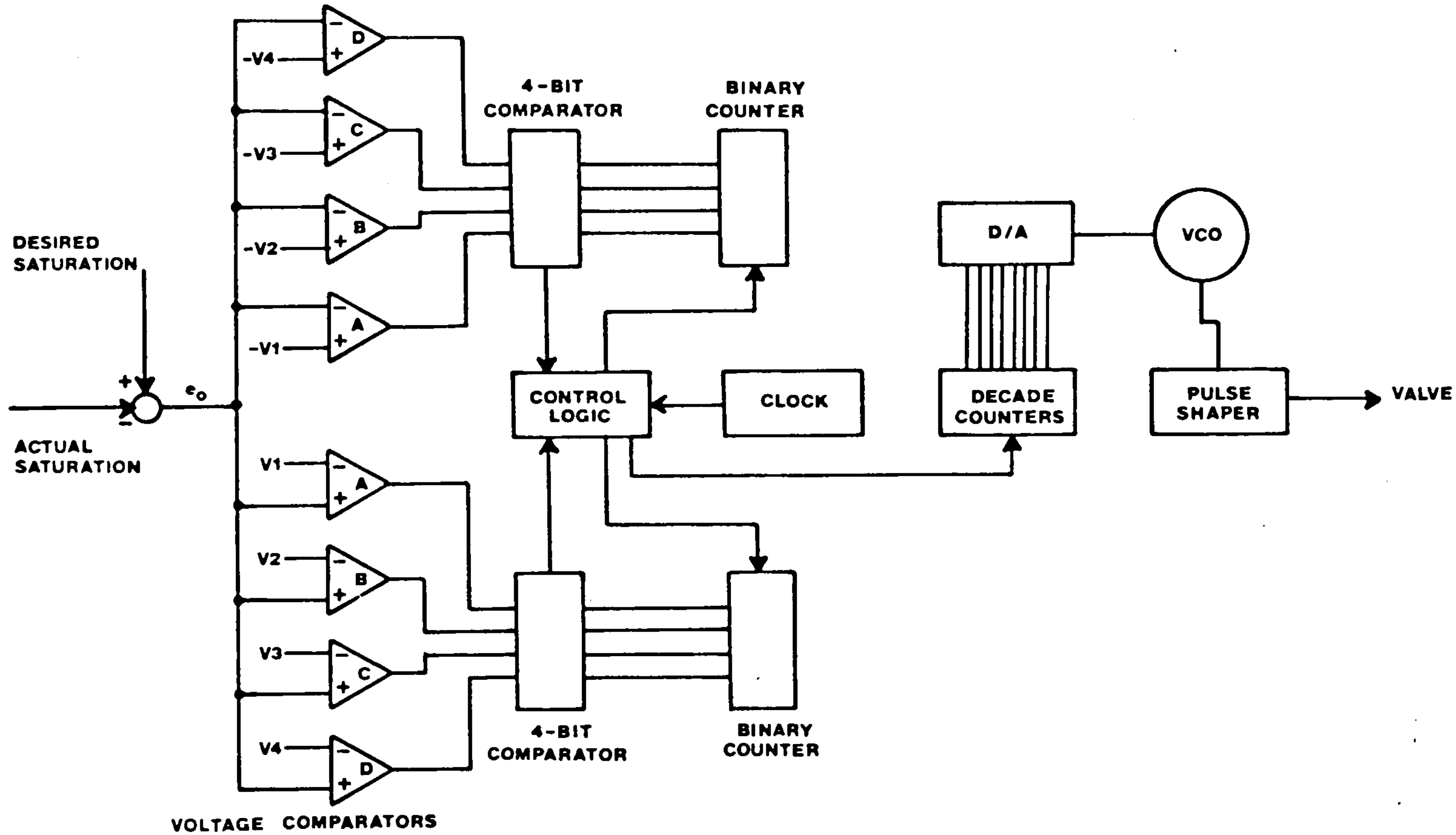

FIGURE 18. OXYGENATOR CONTROL LOGIC

are not equal, the logic is such that a gate is opened, allowing clock pulses to enter the binary counter and simultaneously to the decade counters. If the signal processing is taking place on the "negative" side of the circuitry, the clock pulses are presented to the input of the decade counter which causes the counter to count down. Similarly, if the error signal is positive, the clock pulses are directed to the input which causes the counter to count up. The binary counter's output will increase with the number of clock pulses and will continue to increase until the binary counter has counted to the number represented by the voltage comparators' output. When equality is attained, the clock gate is shut and no more pulses are applied to either counter. If the voltage comparators' outputs were zero, no clock pulses would be applied to either counter because of the parity between the two inputs of the four bit comparator. After the two inputs have been made equal, if necessary, the binary counters are cleared. The decade counters' output will have been increased or decreased, depending on the sign of the error signal, by the number of counts determined by the voltage comparators' output states. The decade counters' outputs are converted from a binary number to an analog signal by a resistor type D/A converter. Therefore, the greater the count, the greater the analog signal produced. This analog signal is then applied to a voltage controlled oscillator (VCO). The higher the voltage input, the lower the VCO output frequency will be. The VCO output is a series of square waves with a frequency determined by the input voltage. These signals are then shaped so that the on versus off time may be varied. It is this pulse train that is used to trigger a solenoid actuated valve located in the oxygen exhaust line from the oxygenator tubes.

In summary, the difference signal between the desired and actual oxygen saturations is used to regulate the operating frequency of a valve that exhausts oxygen from the oxygenator. It is this change of valve operating frequency which either increases or decreases the mean oxygenator tube pressure and correspondingly controls the outlet oxygen saturation.

2.3.3 CIRCUIT DESCRIPTION

The oxygenator control circuit schematic is shown in Fig. 19 and the indicated components are given in Table 6. The analog oxygen saturation signal is connected to the inverting input of the differential input amplifier A10 after passing through R46. The input to pin 3, of A10 is the voltage representing the desired saturation value. This desired level is set by adjustment of P13. This value reaches pin 3 after passing through the voltage divider created by R47 and R48. The configuration of A10 is such that the output voltage, E_o, will be the difference between the desired oxygen saturation signal and the actual saturation signal multiplied by the ratio of P12/R46 (23). This will be true only if the resistance of R46 and R47 are equal, and if the resistance of P12 is adjusted to equal R48. The output of A10 is then the error signal, e_o, between the desired and actual oxygen saturation.

This error signal is then processed by amplifiers A11 through A14 if the difference signal has a negative value, or by A15 through A18 if e_o is positive. Diodes D27 and D28 channel the error siganl to the proper amplifiers. Amplifiers A11 through A18 are operated open-loop to act as voltage comparators. For the positive error processing comparators, the reference voltages are applied at pin 2 and e_o at pin 3. The reference has a minimum value at A15 and a maximum value at A18. These positive voltage levels are obtained from a ladder network formed by resistors R49 through R55 to give reference values of 0.22 volts, 0.43 volts, 0.85 volts, and 1.7 volts at comparators A15, A16, A17, and A18, respectively. For negative error signal processing, the reference

DRAWING NO. 4

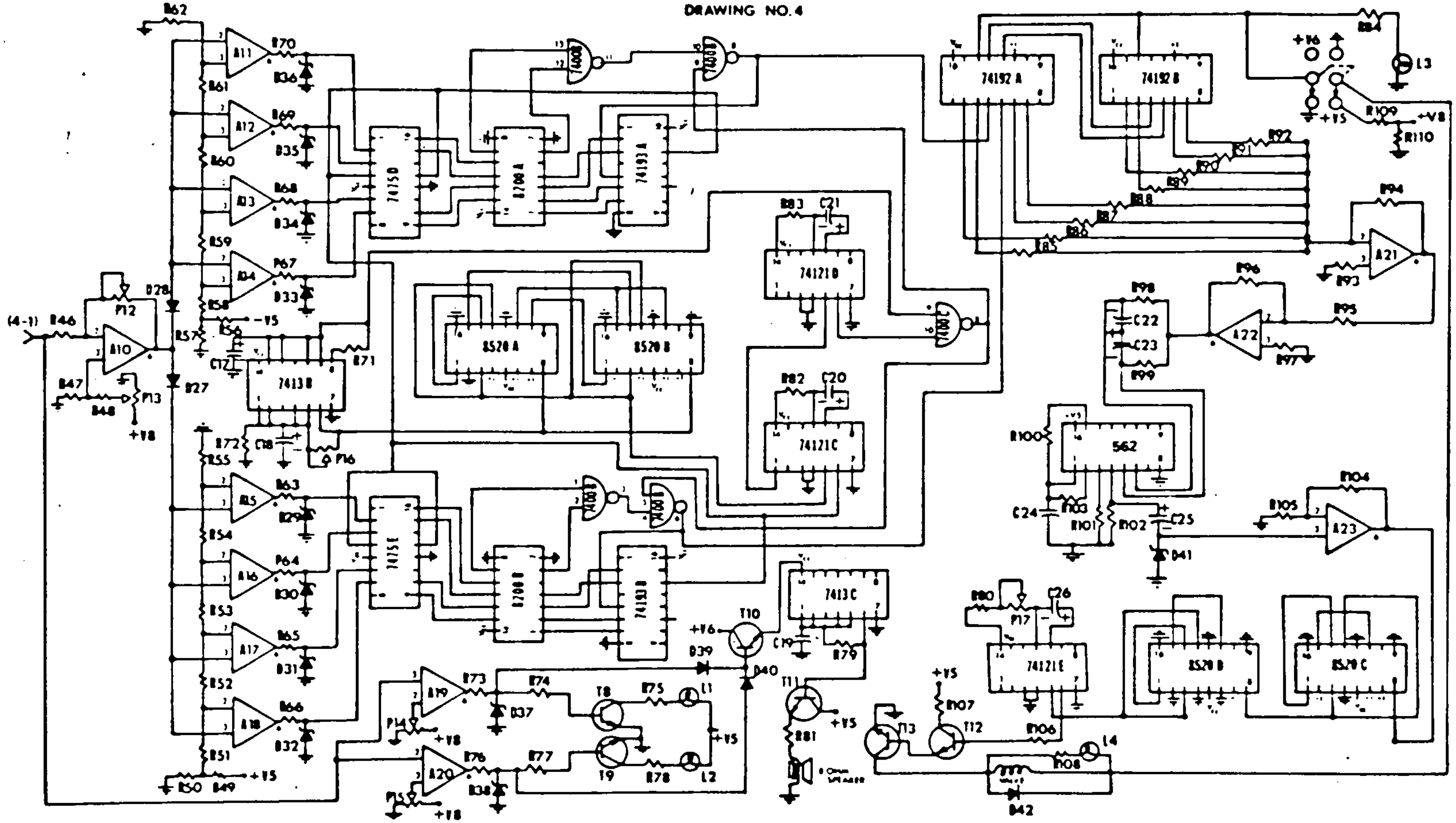

FIGURE 19. CONTROL CIRUIT SCHEMATIC

TABLE 6 CONTROL CIRCUITRY PARTS LIST

Resistors

R46 - 1K, ¼ watt
R47 - 8.3 K, ¼ watt
R48 - 1K, ¼ watt
R49 - 15K, ¼ watt
R50 - 22K, ¼ watt
R51 - 5.6K, ¼ watt
R52 - 2.2K, ¼ watt
R53 - 1K, ¼ watt
R54 - 470, ¼ watt
R55 - 470, ¼ watt
R56 - 15K, ¼ watt
R57 - 22K, ¼ watt
R58 - 5.6K, ¼ watt
R59 - 2.2K, ¼ watt
R60 - 1K, ¼ watt
R61 - 470, ¼ watt
R62 - 470, ¼ watt
R63 - 330, ¼ watt
R64 - 330, ¼ watt
R65 - 330, ¼ watt
R66 - 330, ¼ watt
R67 - 330, ¼ watt
R68 - 330, ¼ watt
R69 - 330, ¼ watt
R70 - 330, ¼ watt
R71 - 1.2K, ¼ watt
R72 - 2.7K, ¼ watt
R73 - 470, ¼ watt
R74 - 1K, ¼ watt
R75 - 56, ½ watt
R76 - 470, ¼ watt
R77 - 1.3K, ¼ watt
R78 - 56, ½ watt
R79 - 180, ¼ watt
R80 - 4.7K, ¼ watt
R81 - 15, ½ watt
R82 - 1.2K, ¼ watt
R83 - 33K, ¼ watt
R84 - 56, ½ watt
R85 - 80K, 1.0% Tolerance
R86 - 40K, 1.0% Tolerance
R87 - 20K, 1.0% Tolerance
R88 - 10K, 1.0% Tolerance
R89 - 8K, 1.0% Tolerance
R90 - 4K, 1.0% Tolerance
R91 - 2K, 1.0% Tolerance
R93 - 470, ¼ watt
R94 - 3.3K, ¼ watt
R95 - 3.3K, ¼ watt
R96 - 3.3K, ¼ watt
R97 - 3.3K, ¼ watt
R98 - 18K, ¼ watt
R99 - 18K, ¼ watt
R100 - 1K, ¼ watt
R101 - 12K, ¼ watt
R102 - 12K, ¼ watt
R103 - 1K, ¼ watt
R104 - 100, ¼ watt
R105 - 1K, ¼ watt
R106 - 220, ½ watt
R107 - 220, ½ watt
R108 - 56, ½ watt
R109 - 220, ½ watt
R110 - 56, ½ watt

Diodes

D27 - Germanium Signal Diode
D28 - Germanium Signal Diode
D29 through D38 - 4.7 Volt Zener
D39 through D40 - Germanium Signal Diodes
D41 - 3.9 Volt Zener
D42 - Calectro K4-557,1 Amp, 130 Volts

Capacitors

C17 - 0.1 μf
C18 - 100 μf
C19 - 1.0 μf
C20 - 33 μf
C21 - 33 μf
C22 - 110 μf
C23 - 10 μf
C24 - 0.1 μf
C25 - 10 μf
C26 - 100 μf

Operational Amplifiers

A10 through A23 - Type 741 Op. Amps

Note: All resistances are in ohms.

TABLE 6 CONTINUED

Integrated Circuits

7413B,C - Dual Schmitt Triggers
7475D,E - Quad Latches
8200A,B - 4-Bit Comparators
8520A,B,C,D - Modulo-n Dividers
74193A,B - Up/Down Binary Counters
74121C,D,E - Monostable Multivibrators
74192A,B - Up/Down Decade Counters
7400B,C - Quad 2-Input Nand Gate

Transistors

T8 through T12 - K4-510 (NPN)
T13 - K4-525 (NPN)

Pots

P12 - 10K
P13 - 5K
P14 - 5K
P15 - 5K
P16 - 10K
P17 - 20K

Lamps

L1 through L4 - 12.2 volt bulbs

Speaker

8 Ohm Speaker

Valve

12 Volt Skinner Solenoid Valve

voltages are applied to the non-inverting input of the amplifiers and e_o is input to the inverting input. The reference voltage has its minimum value at A11 and its maximum value at A14. The negative reference voltages are also obtained by a ladder network comprised of resistors R56 through R62. The reference voltages at pin 3 of A11, A12, A13, and A14 are -0.23 volts, -0.45 volts, -0.85 volts, and -1.7 volts, respectively. These reference voltage levels will be at the specified levels only if +V5 and -V5 are at +14 and -14 volts, respectively.

Suppose the error signal, e_o, is some positive value. The output of voltage comparators A15 through A18 will depend on the voltage of e_o compared to the reference voltage level at each comparator. The output at any comparator will be positive saturation if the error signal is greater than the reference, or at negative saturation if the error signal is less than the reference. Therefore, the number of comparators at positive saturation is dependent upon the magnitude of e_o. The output of each comparator is made TTL compatible by the use of 4.7 zener diodes. The comparator output currents are limited by resistors R63 through R70. A positive saturation output will be regulated by the zener diodes to give a logical "1" level, and the negative saturations will result in a "0" logic level. The outputs from each comparator group are used to form a binary coded digit, ranging from zero to 15, depending on the number of comparators at the "1" output level. The TTL logic levels from the positive signal processing comparators are then connected to a quad latch, 7475E. The comparator outputs for the negative signal processing circuitry will all be at "0" logic levels because the value of e_o presented to these comparators is zero. These outputs are directed to the D inputs of 7475D. The D inputs of 7475D and 7475E will not be transferred to the latch outputs until the latch clock inputs, pin 4 and 13, are taken to a logical "1". The strobing of the latches is performed by the combination of 7413B, 8520A, 8520B, and 74121C. One-half of a dual Schmitt trigger is arranged to provide pulses at its output that vary in frequency from 0.9 Hz to 34 Hz. The output frequency, pin 6 of 7413B, is determined by the timing components C18, R72, and P16. The frequency is varied by changing the resistance setting of P16, since C18 and R72 are constant values. The output from pin 6 is delivered to pin 8 of 8520A and 8520B. These modulo-n dividers are cascaded such that the input frequency is divided by 255, giving a range of output pulses that vary from a period of approximately eight seconds to a maximum period of over four minutes. The output from the modulo-n dividers then passes to pin 5 of 74121C. Each time the input changes from a "0" to a "1", the one-shot fires, except when the Q output is already high. This results in the Q output, pin 6, going from "0" to "1", and the $\bar{Q}$ output changing from "1" to "0". The duration of these transitions is determined by the timing components R82 and C20. The transition at the $\bar{Q}$ output of 74121C is seen at the input of 74121D. This high to low transition at the 74121D input causes no change in the Q and $\bar{Q}$ outputs. They remain at "1" and "0". A "1" at the Q output of 74121C is used to clear the up/down binary counters 74193A and 74193B by application of the signal to pin 14 of these packages. The outputs of 74193A become the inputs of the 4-bit comparator 8200A; likewise, the outputs of 74193B become the inputs of 8200B. The A, B, C, and D outputs of the 74193's are input to the B inputs of the 8200's, pins 4, 3, 2, and 1. Since the counters have just been cleared, the equivalent binary number present at the 8200's B inputs is zero. The high Q pulse of 74121C is also input to pins 4 and 13 of 7475D and 7475E. The presentation of a "1" to these pins causes the information stored in the D inputs to be transferred to the Q outputs. The outputs of 7475D and 7475E are also the A inputs of 8200A and 8200B, respectively. The binary number formed by the voltage comparators output states is to be compared to the binary number from the up/down binary counters by the 4-bit comparators. If the binary number formed by the voltage comparators outputs is some non-zero number, the output of the 8200's at pin 6, the X output, will be "1", and pin 9, the Y output, will be "0". Parity between the A and B inputs will result in a "1" at the X and Y outputs.

Continuing the discussion of the circuit operation with a positive value of e_o, if the value of e_o is such that one or more of the comparators output is at a logical "1" level, the A and B inputs of 8200B will not be equal. This results in a "1" at the X output and a "0" at the Y output. The X and Y outputs are input to pins 1 and 2 of 7400B. The output, pin 3, of the gate then will be high because of the "0" at the input. This output becomes the input to pin 4 of Nand gate B. The other input, pin 5, is the output of 7400C, pin 8. The output from pin 8 of 7400C will be high as long as the $\bar{Q}$ output of 74121D is low, and consequently, output 6 of 7400B will be low for this period also. When the outputs of 74121C return to their original states, "0" for the Q output, and "1" for the $\bar{Q}$ output, a number of circuit actions take place. The return of Q to a logical "0" causes the data latches to store the information at their outputs until another strobe pulse is applied to their clock inputs. The low Q output of 74121C also enables the binary counters, 74193A and 74193B, to count any pulses which are presented to their clock inputs. Simultaneously, the $\bar{Q}$ transition from "0" to "1", the input to pin 5 of 74121D, causes the 74121D package to switch. Its Q output then changes from a logical "0" to a "1" for a duration determined by the timing components, R83 and C21. The output Q of 74121D is also the input to pin 10 of 7400C. The other input of that Nand gate, pin 9, is a series of clock pulses from pin 8 of 7413B. The gate then allows the clock pulses to be directed to pin 9 of 7400B and pin 5 of 7400B, as long at the Q output of 74121D is high. The output at pin 8 of 7400B is also the clock down input of 74192A and the clock input of 74193A. This output will remain high because of the equality of the X and Y outputs of 8200A, resulting in a "0" at pin 10 of 7400B. Because of the inequality of the A and B inputs of the 4-bit comparator 8200B, the clock pulses at pin 5 of Nand gate B will be allowed to pass to the clock input of 74193B and the clock up input of 74192A. The clock pulses will be counted by 74193B, resulting in the increase of the binary number presented to the B inputs of 8200B. The 74193B output will continue to increase until equality is attained between the A and B inputs of the 4-bit comparator. When this parity is attained, the output at pin 6 of 7400B will go to a logical "0" level. This logical "0", presented at pin 4 of 7400B, causes the output of

7400B at pin 6 to a logical "1", resulting in the termination of the counting at 74193B and 74192A. The up/down decade counters, 74192A and 74192B, are cascaded so that they are able to count from zero to 99. The decade counters' output will have been increased or decreased, depending on the sign of the error signal (in this case the output increased). The change in count is equal to the equivalent binary number determined by the voltage comparators output states. The decade counters' outputs are converted to an analog signal by a weighted resistor network and an inverting amplifier. The D/A conversion used here is similar to that used in the analog-to-digital converter circuitry. Therefore, the higher the count, the more negative the output of A21 will be. The output from A21, pin 6, is increased by the inverting amplifier A22. The output voltage from amplifier A21 is presented to a circuit built around a Signetics phase locked loop integrated circuit, an SN562. The 562 is used as a voltage controlled oscillator in this application. The timing capacitors, C22 and C23, were chosen such that the center frequency of the VCO, the output frequency with zero input voltage, would be approximately 70 Hz with a supply voltage of 14 volts. Table 7 gives the VCO output frequency as a function of the input voltage.

The VCO output frequency will decrease proportionally to an increasing input voltage. The output from the 562 is a variable frequency with an amplitude alternating between 10 and 14 volts. The alternating signal of 4.0 volts peak-to-peak amplitude rides on a 12 volt dc level. The signal is made TTL compatible by capacitor C25, zener diode, D41,

TABLE 7 VCO OUTPUT FREQUENCIES

Input Voltage	Output Frequency (Hz)
0.0	66
1.0	61
2.0	57
3.0	53
4.0	49
5.0	45
6.0	41
7.0	37
8.0	33
9.0	29
10.0	25
11.0	21

and the non-inverting amplifier A23. The 562 output signal is ac coupled by capacitor C25, eliminating the dc component of the signal. The resulting signal is a square wave with an amplitude swing of -2.0 to +2.0 volts. Zener diode D41 eliminates the negative portion of the signal. A zener diode had to be used at this point because the dc level from the 562 is not blocked until the capacitor has had time to charge when the circuit is first activated. This pulse train is input to the non-inverting pin of amplifier A23. Operational amplifier A23 is in a non-inverting configuration so that its output will be the square waves increased in magnitude by the ratio of (R105 + R104)/R105 (24). The signal amplitude is now approximately five volts. The output from A23 is passed to pin 8 of modulo-n divider 8520C. Dividers 8520C and 8520D are arranged such that the input frequency is divided by 70, resulting in an output period range of 1.06 seconds to 3.33 seconds. The frequencies are scaled down so that they are in the operating frequency range of the solenoid actuated valve. The output frequencies from the modulo-n dividers are input to pin 5 of the monostable multivibrator, 74121E. The function of this integrated circuit is to regulate the pulse widths of the input signals. Figure 20 shows the pulse shaping function of 74121E. Recall that once the one-shot has fired, the outputs are independent of further transitions that occur at the input. The upper waveform shown is the resulting output frequency of the system when the VCO is operating at its center frequency. P17 is adjusted so that the pulse length of the Q output of 74121E is approximately 0.9 seconds. The lower waveform is the output frequency of the circuit when

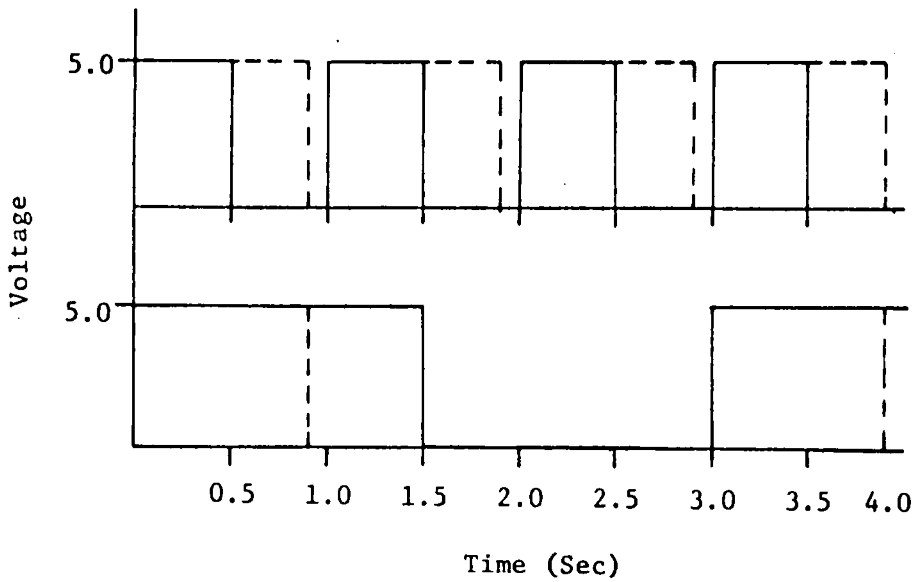

Figure 20. Valve Pulse Width Adjustments

the VCO is operating at its minimum frequency. Figure 20 demonstrates that with the pulse duration of Q adjusted to 0.9 seconds at the VCO maximum output frequency, the "on" versus "off" time of the 74121E ranges from 30% to 90%, depending on the input frequency to the one-shot.

The Q output is connected to the base of transistor T12. A positive voltage at its base turns it on and results in the emitter output going to a positive five volt level. The T12 emitter is applied to the base of T13, a K4-525 transistor. The positive voltage at the base of T13 results in the collector of that transistor being brought to a ground potential. The collector of T13 is connected to one input of the solenoid actuated valve; the other input is wired to an unregulated 14 volt supply. Therefore, when the collector of T13 is at ground, the solenoid valve is actuated.

Upper and lower oxygen saturation limits are determined by the use of A19 and A20, respectively. The analog oxygen saturation signal is presented to pin 3 of A19 and to pin 2 of A20. The maximum allowable saturation signal, pin 2 of A19, is set by adjustment of P14. Similarly, the minimum value, input 3 of A20, is set by P15. If the saturation voltage at pin 3 of A19 is more positive than the desired saturation level at pin 2, the comparator output will be at a positive saturation. The output is held at 4.7 volts by D37. This voltage is used to turn transistor T8 on, resulting in the display light, L1, being turned on. Also, this same transistor turns T10 on, resulting in a five volt signal from the emitter of T10 being connected to pin 14 of 7413C. This five volt signal supplies power to the 7413C. The 7413C then produces a 2000 Hz frequency output signal at pin 6. This signal is amplified by T11 and then used to drive an eight ohm speaker used as the warning signal. The signal processing for the lower alarm is identical to that for the upper alarm circuitry.

The final discussion concerning this control circuit centers on the operation of the mode selector switch. The switch is a double-throw, double-pole type. One of the center terminals is connected to the clear input, pin 14, of decade counters 74192A and 74192B, and also to a display light. The remaining center terminal is connected to one input of the solenoid valve and also to another display light. With the switch in the upper position, as shown in the circuit schematic, the clear inputs are at a logical "1" and the solenoid input is at ground. This is the monitor mode position. In this switch position, the counters remain clear and the valve does not operate. With the switch in the lower position, the control mode position, the clear inputs are at ground and the valve has an unregulated 14 volts supplied to it. Therefore, the decade counters are free to count. Also, the valve will now operate in such a manner that the mean oxygenator tube pressure is regulated in order to bring the actual outlet oxygen saturation value closer to the desired saturation level.

3. OXIMETER-CONTROLLER TESTING AND RESULTS

3.1 CALIBRATION AND TEST PROCEDURE

The procedure used to calibrate and test the oximeter instrumentation in the "monitor" operating mode will be discussed first, followed by a discussion of the "control" operating mode procedure. The blood pump and oxygenation system, Fig. 21, was primed with bovine blood having an oxygen saturation level of 50% or less. If the saturation was greater than 50%, the saturation level was reduced by bubbling nitrogen through the blood. The oxygen supply and exhaust lines of the oxygenator were clamped shut to prevent the introduction of any further oxygen to the system. The blood was pumped around the circuit for a short time to dislodge any bubbles that may have collected in the pump and oxygenation system. Because the oxygen lines to the oxygenator were closed, the blood could be pumped around the circuit for a short time without changing the percent saturation significantly.

There are a number of instrument checks to be made in preparation for a saturation measurement test. These checks are listed below.

1) Check the voltage at pins A, F, K, and L on the power supply printed circuit board, Figs. 22 and 23. The voltage at these pins should be +3.0 volts, +5.0 volts, +14.0 volts, and -14.0 volts, respectively. Adjust P8 to change the +5.0 volt supply, P7 to change the -14.0 volt supply, and P6 to change the +14.0 volt supply. The +3.0 volt supply is obtained by use of zener diode D17 (refer to Fig. 24). If the voltage

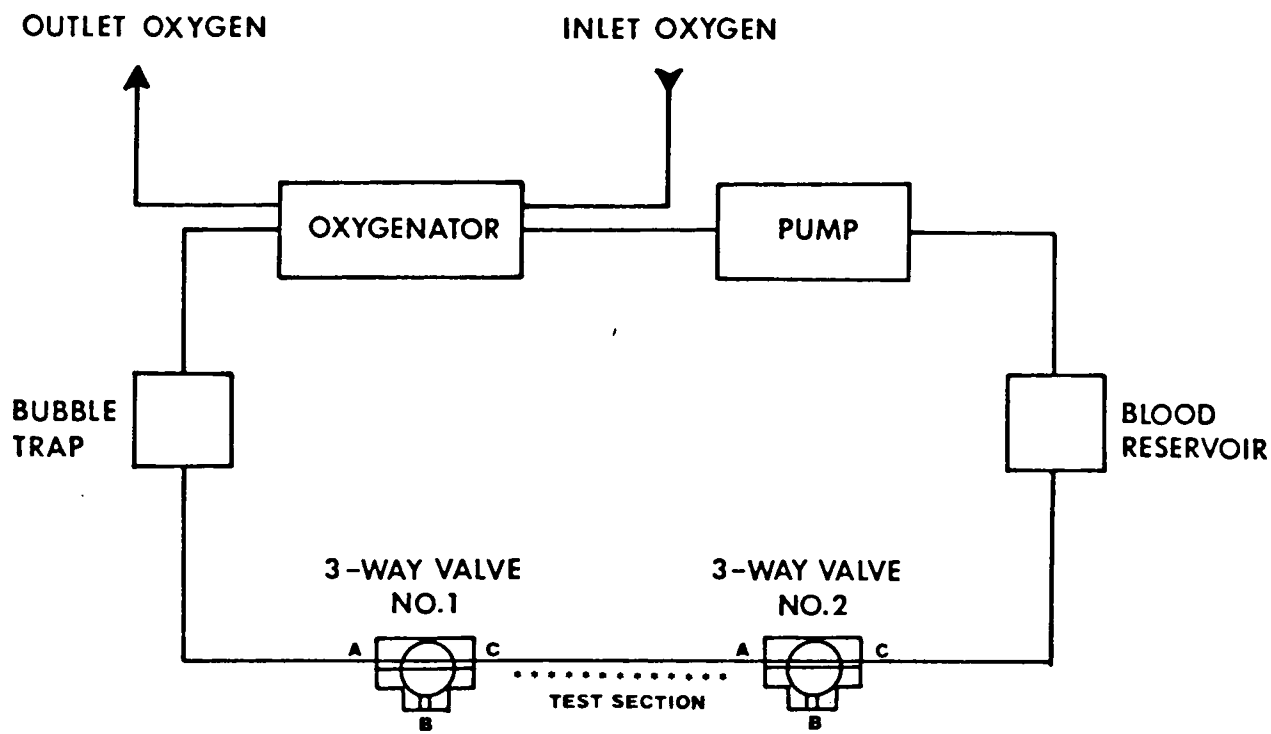

FIGURE 21. BLOOD PUMP AND OXYGENATOR SYSTEM MONITOR MODE TEST CONFIGURATION

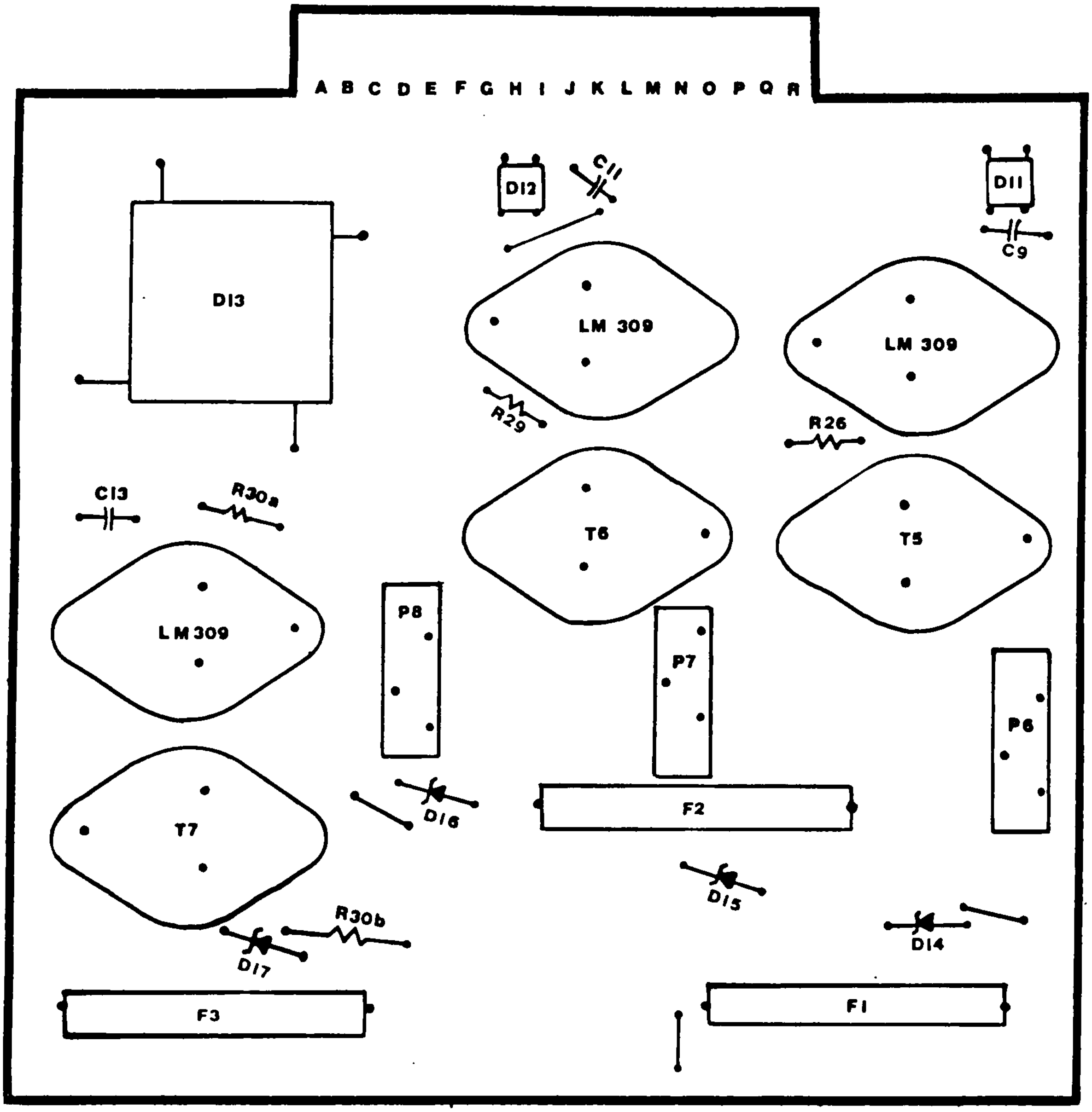

FIGURE 22. COMPONENT SIDE OF POWER SUPPLY BOARD

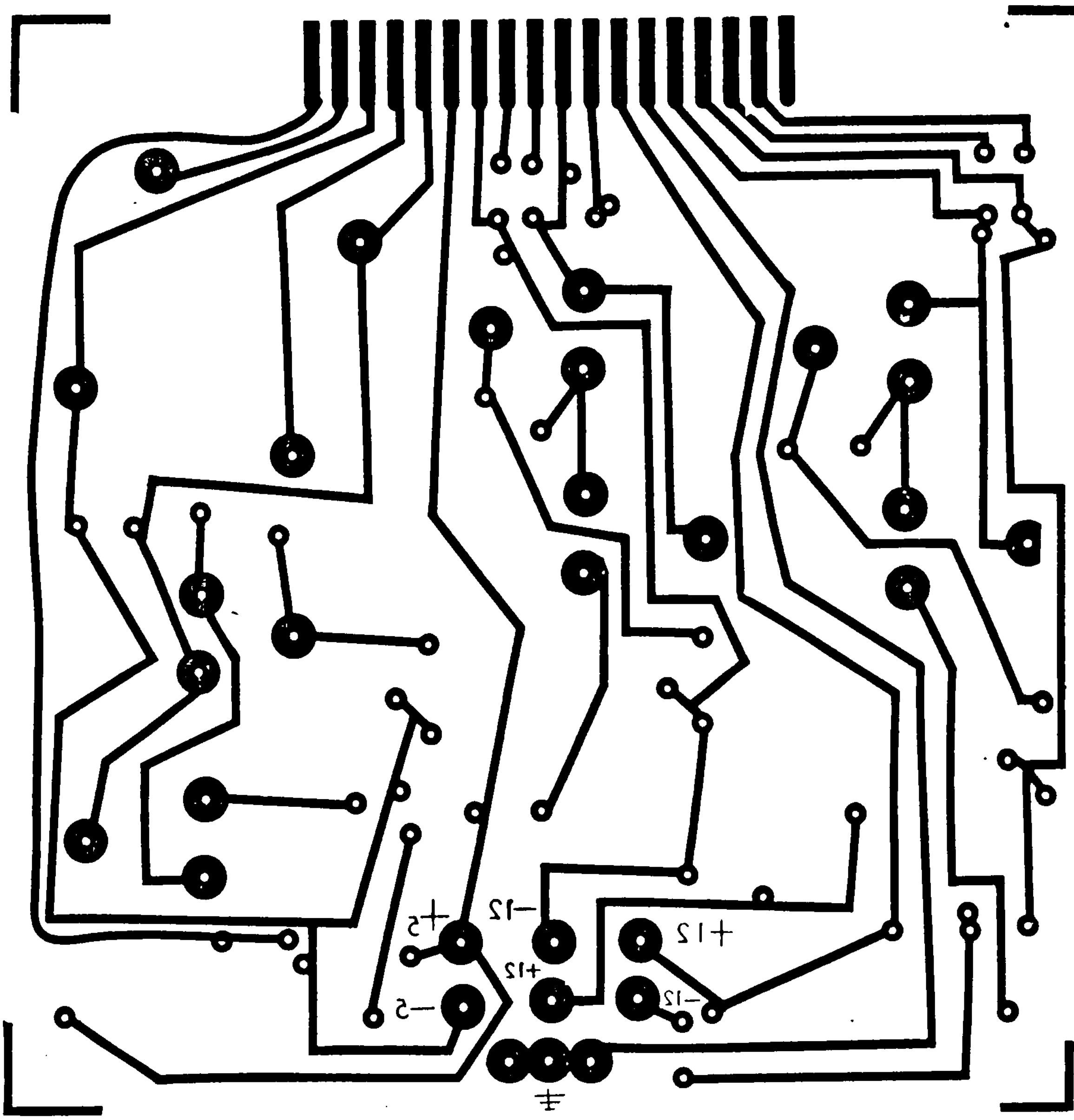

Figure 23. Power Supply Printed Circuit Board Layout

TABLE 8 POWER CIRCUIT BOARD PIN CONNECTIONS

PIN A	-	+3 volts dc
B	-	Secondary of 25.2 volt Transformer
C	-	To Negative Terminal of 50,000 μf Capacitor
D	-	Center Tap of 25.2 volt Transformer
E	-	To Positive Terminal of 50,000 μf Capacitor
F	-	+5 volts dc
G	-	To Negative Terminal of 3000 μf Capacitor
H	-	Secondary of 12.6 volt Transformer
I	-	Secondary of 12.6 volt Transformer
J	-	To Positive Terminal of 3000 μf Capacitor
K	-	-14 volts dc
L	-	+14 volts dc
M	-	Ground
N	-	To Positive Terminal of 3000 μf Capacitor
O	-	To Negative Terminal of 3000 μf Capacitor
P	-	Secondary of 12.6 volt Transformer
Q	-	Secondary of 12.6 volt Transformer
R	-	No Connection

DRAWING NO. 5

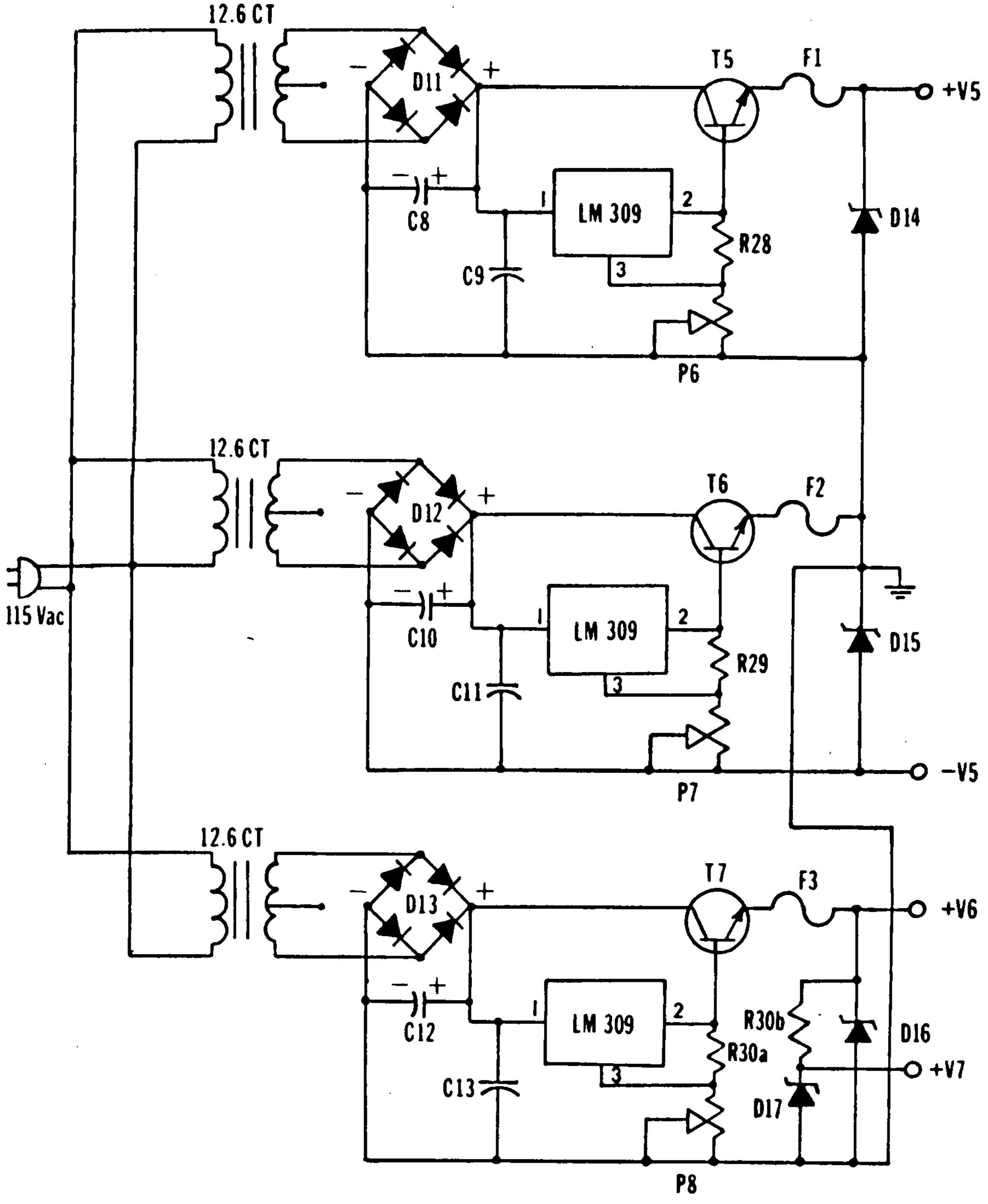

FIGURE 24. POWER SUPPLY CIRCUIT SCHEMATIC

TABLE 9 POWER SUPPLY CIRCUITRY PARTS LIST

Resistors

R28 - 300, ½ watt
R29 - 300, ½ watt
R30a - 300, ½ watt
R30b - 150, ½ watt

Pots

P6 through P8 - 1K

Diodes

D11 - HEP R0841; Diode Bridge, 1.8 Amp, 600 Volts
D12 - HEP 175, Diode Bridge, 1 Amp, 50 Volts
D13 - HEP MDA 980-1, Diode Bridge, 12 Amps, 50 Volts

Capacitors

C8 - 3000 μf
C9 - 0.1 μf
C10 - 3000 μf
C11 - 0.1 μf
C12 - 50,000 μf
C13 - 0.1 μf

Transistors

T5 - Calectro K4-525 (NPN)
T6 - Calectro K4-525 (NPN)
T7 - HEP 704 (NPN)

Regulators

LM309 - 5 Volt Regulator

Note: All resistances are in ohms.

at pin A is not approximately +3.0 volts, check the zener to insure that it is functioning properly.

2) On the oximeter circuit board, Figs. 25 and 26, measure the voltage at pin M. The voltage should be approximately +13.0 volts.

3) Measure the voltage at pins G and M on the analog-to-digital circuit board, Figs. 27 and 28, they should be at voltage levels of +5.0 volts, and +3.0 volts, respectively.

4) On the oxygenator control circuit board, Figs. 29 and 30, the voltage at pin D should be -14.0 volts, +14.0 volts at pin E, and +5.0 volts at pin J. Steps 1 through 4 insure that the voltage levels at each board are correct.

5) Attach the channel one oscilloscope lead to pin B and channel two oscilloscope lead to pin J of the oximeter circuit board. With the transducer exposed to room light, adjust the pot P1 until the amplitude of the two waveforms displayed by the oscilloscope are equal. This assures that the two LED currents will be equal when the amount of light incident to the phototransistor is the same during both LED's operation.

After the above checks have been made, the transducer, Fig. 31, can be attached to the test section of the circuit. With the transducer clamped to the test section, the following checks are made.

6) With the oscilloscope leads in the same position as step 5, the waveforms displayed should be similar to those of Fig. 5. If the waveforms appear more similar to the top trace of Fig.

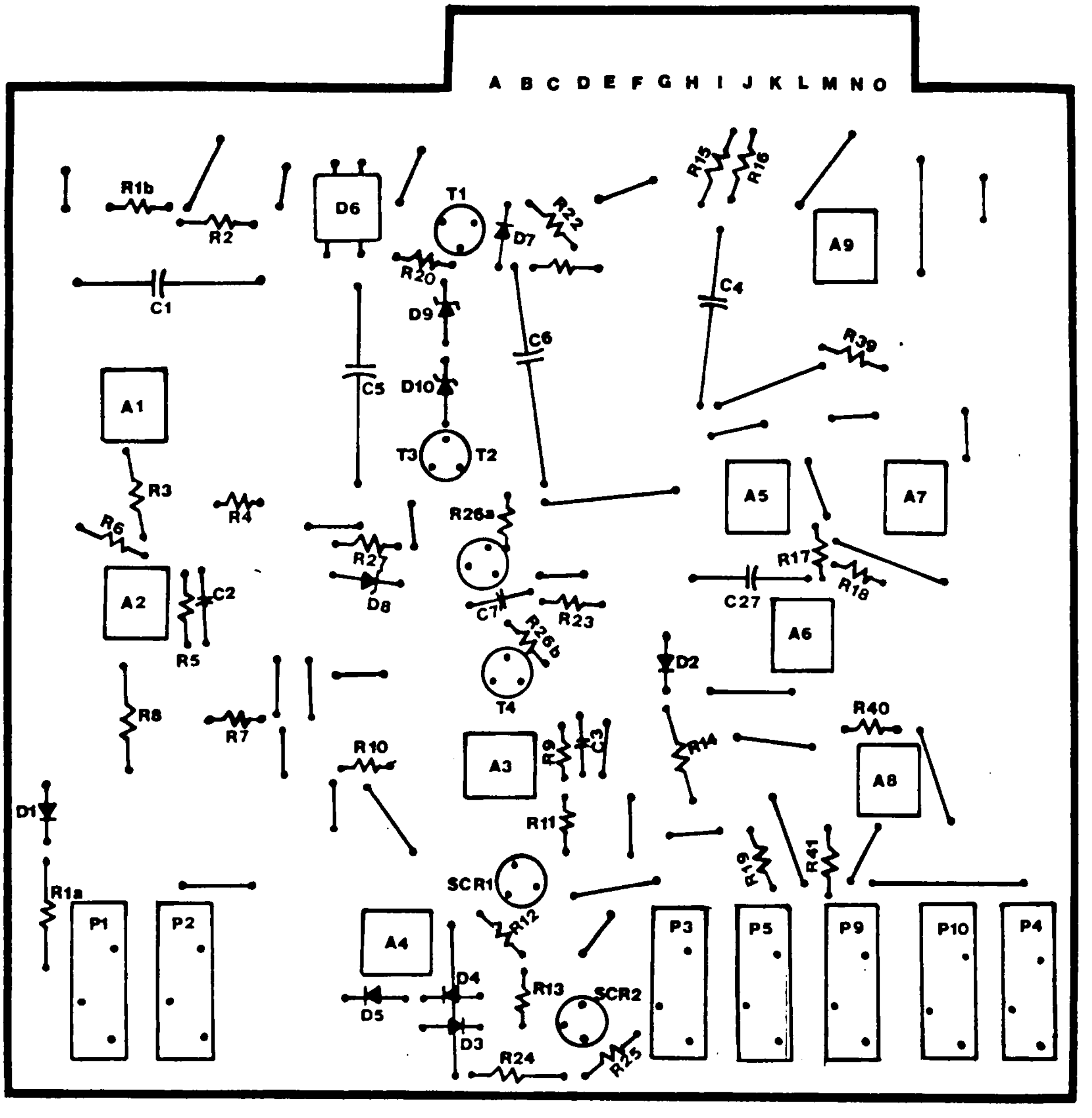

FIGURE 25. COMPONENT SIDE OF OXIMETER BOARD

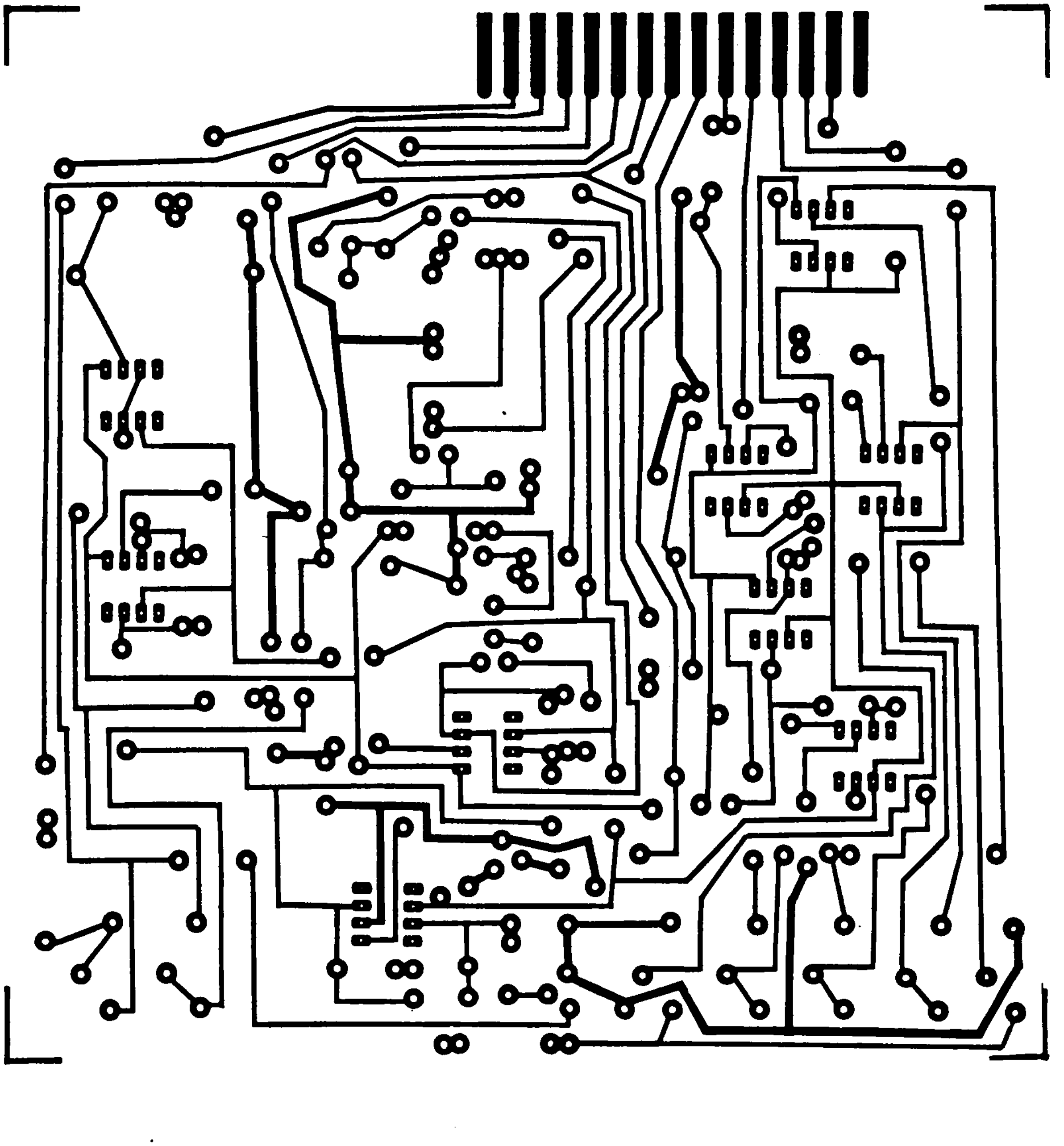

Figure 26. Oximeter Printed Circuit Board Layout

TABLE 10 OXIMETER CIRCUIT BOARD PIN CONNECTIONS

PIN A	-	No Connection
B	-	Cathode ME-6
C	-	Anode ME-6
D	-	-6.2 volts
E	-	Center Tap of 25.2 volt Transformer
F	-	Secondary of 25.2 volt Transformer
G	-	Secondary of 25.2 volt Transformer
H	-	MT-2
I	-	Anode MV-3
J	-	Cathode MV-3
K	-	Analog Oxygen Saturation Output
L	-	From Pin B of A/D Circuit Board
M	-	+12 volts dc
N	-	To Pin A of A/D Circuit Board
O	-	No Connection

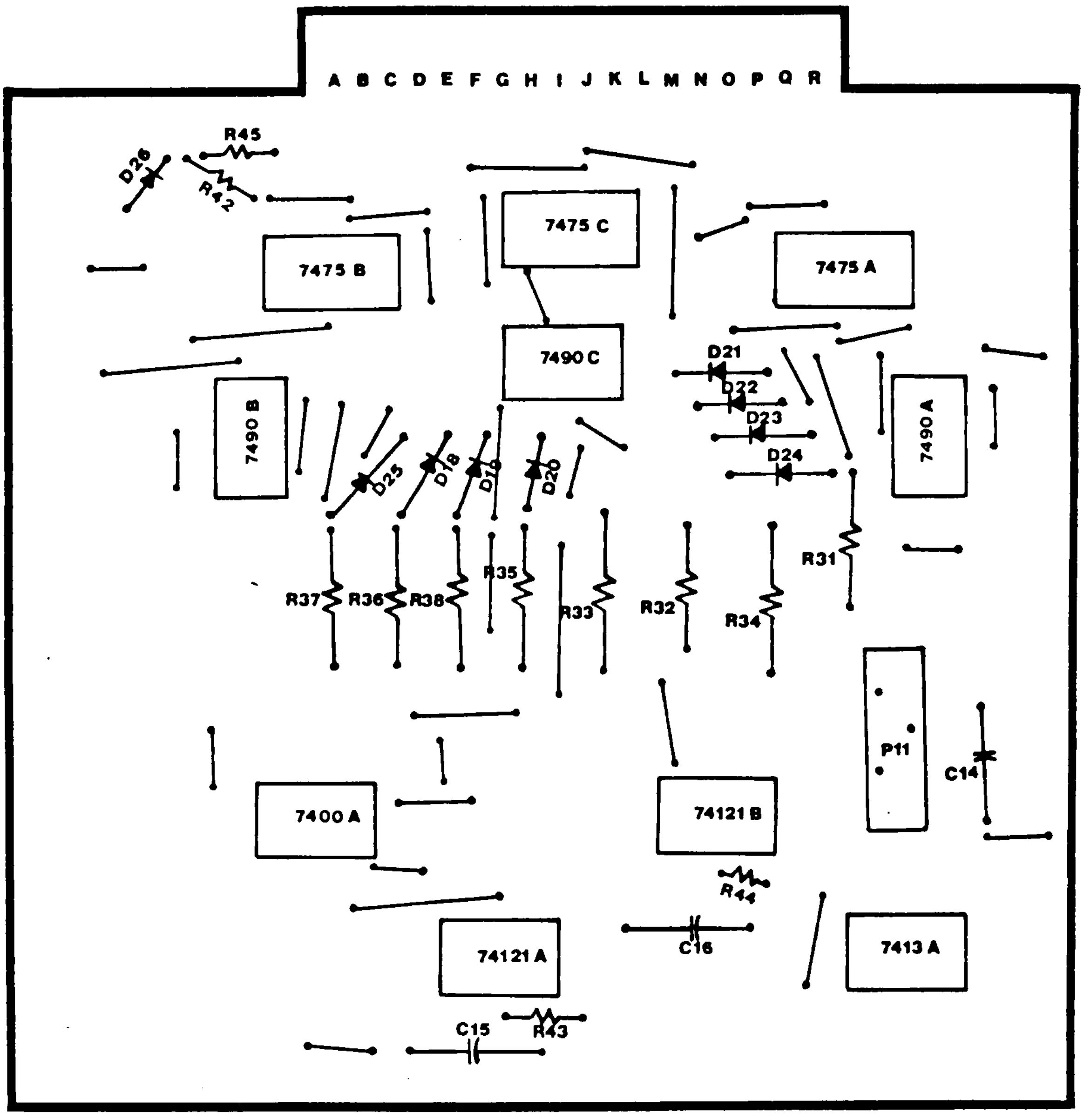

FIGURE 27. COMPONENT SIDE OF A/D BOARD

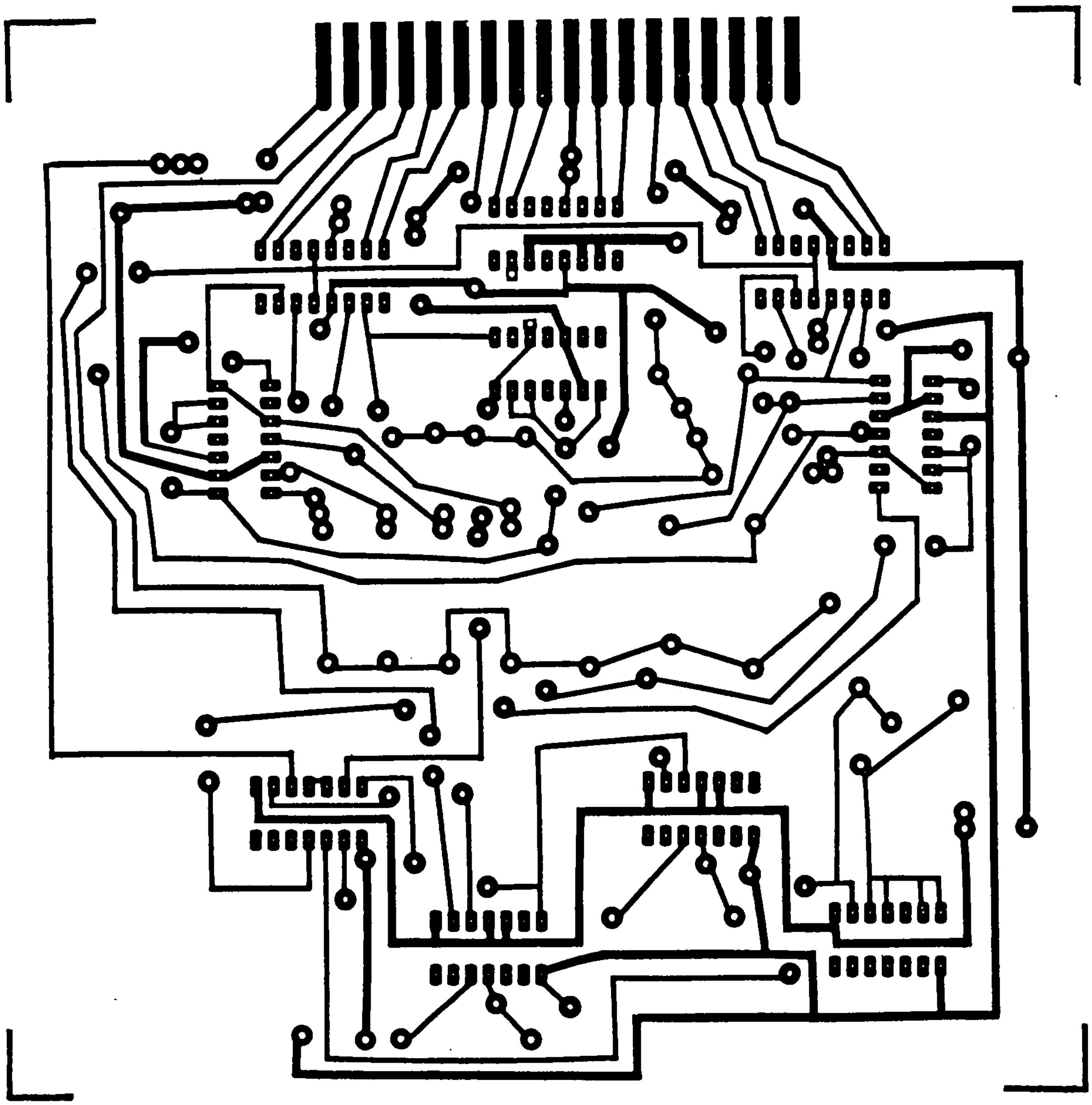

Figure 28. Analog-to-Digital Printed Circuit Layout

TABLE 11 ANALOG-TO-DIGITAL CIRCUIT BOARD PIN CONNECTIONS

PIN	A	-	From Pin N of Oximeter Circuit Board
	B	-	To Pin L of Oximeter Circuit Board
	C	-	To Pin 7 of 7447B
	D	-	To Pin 1 of 7447B
	E	-	To Pin 2 of 7447B
	F	-	To Pin 6 of 7447B
	G	-	+5 volts dc
	H	-	To Pin 7 of 7447C
	I	-	To Pin 1 of 7447C
	J	-	Ground
	K	-	To Pin 2 of 7447C
	L	-	To Pin 6 of 7447C
	M	-	+3 volts dc
	N	-	To Pin 7 of 7447A
	O	-	To Pin 2 of 7447A
	P	-	To Pin 2 of 7447A
	Q	-	To Pin 6 of 7447A
	R	-	No Connection

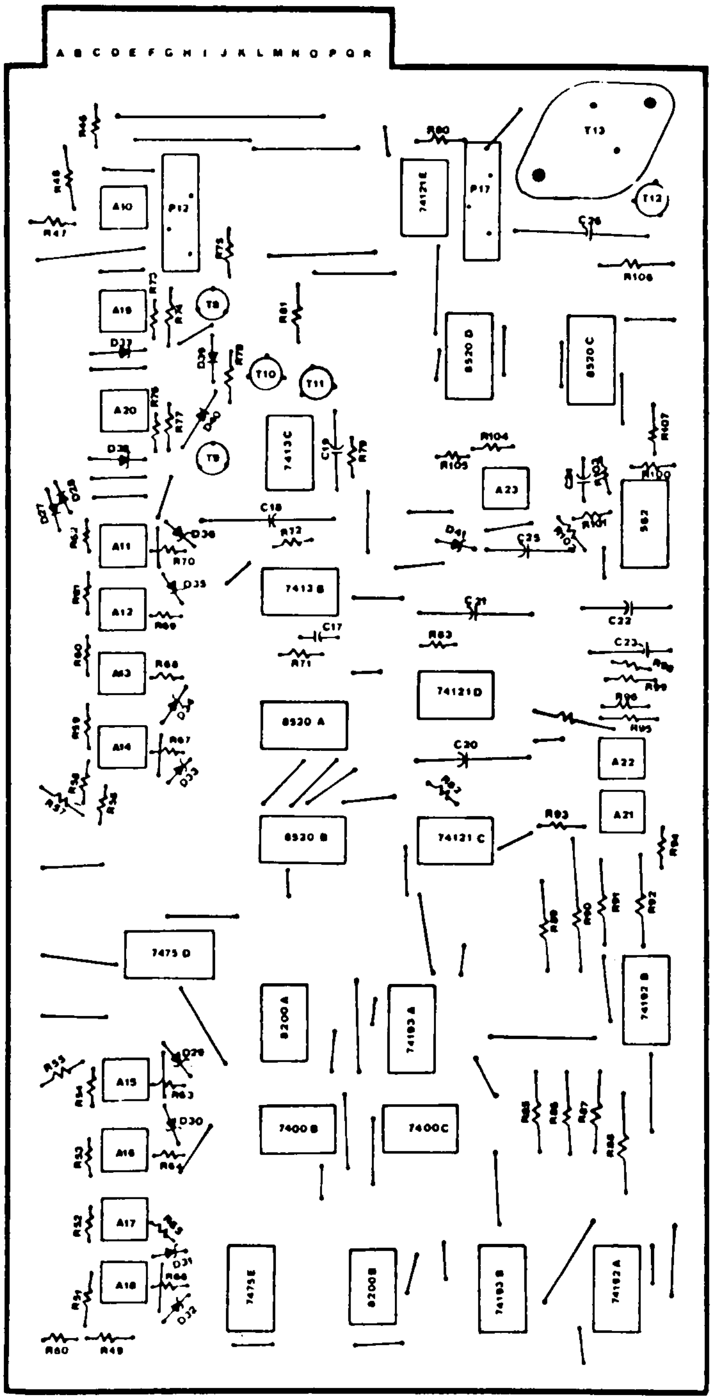

FIGURE 29 COMPONENT SIDE OF CONTROL BOARD

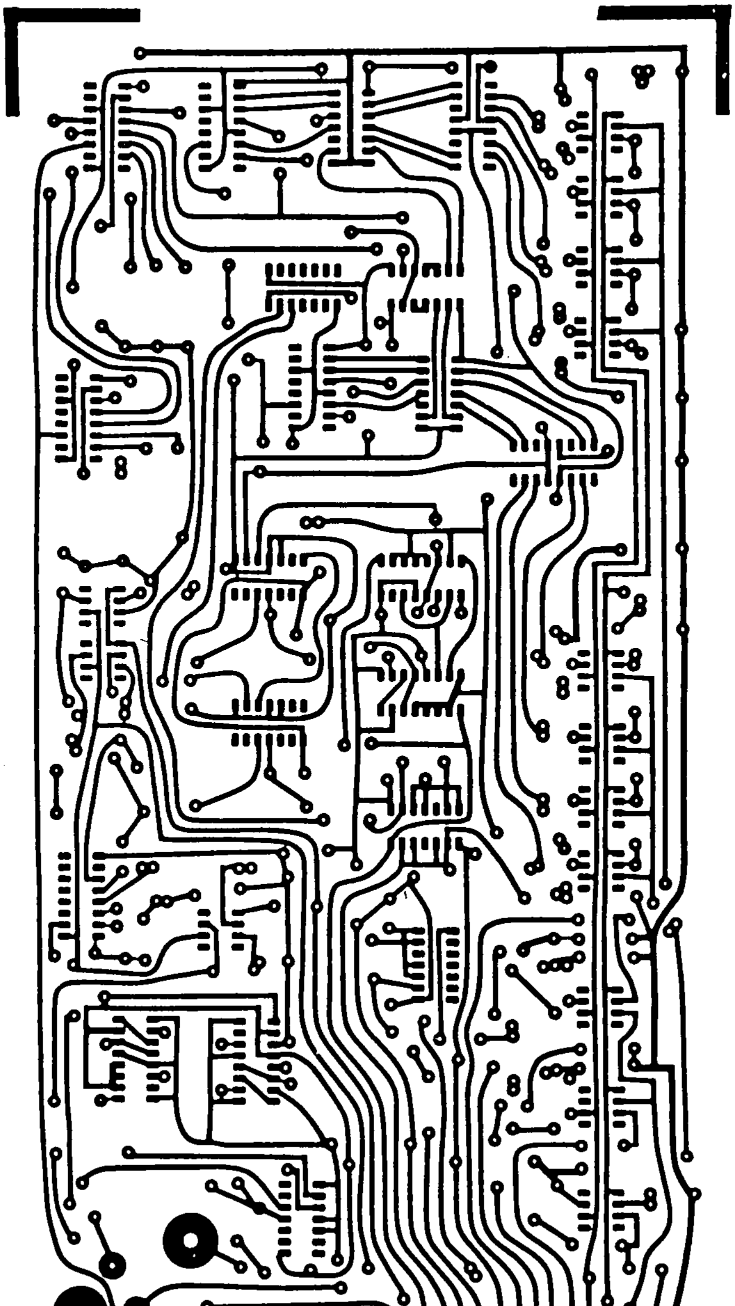

Figure 30. Oxygenator Control Printer Circuit Layout

TABLE 12 CONTROL CIRCUIT BOARD PIN CONNECTIONS

PIN A	-	Ground
B	-	Wiper of Desired Saturation Pot
C	-	From Pin K of Oximeter Circuit Board
D	-	-14 volts dc
E	-	+14 volts dc
F	-	Wiper of Upper Limit Pot
G	-	To Upper Limit Lamp
H	-	To Lower Limit Lamp
I	-	Wiper of Lower Limit Pot
J	-	+5 volts dc
K	-	To Warning Speaker
L	-	Ground
M	-	To Control Timing Pot
N	-	To Control Timing Pot
O	-	To Solenoid Actuated Valve
P	-	To Operating Mode Selector Switch
Q	-	No Connection
R	-	No Connection

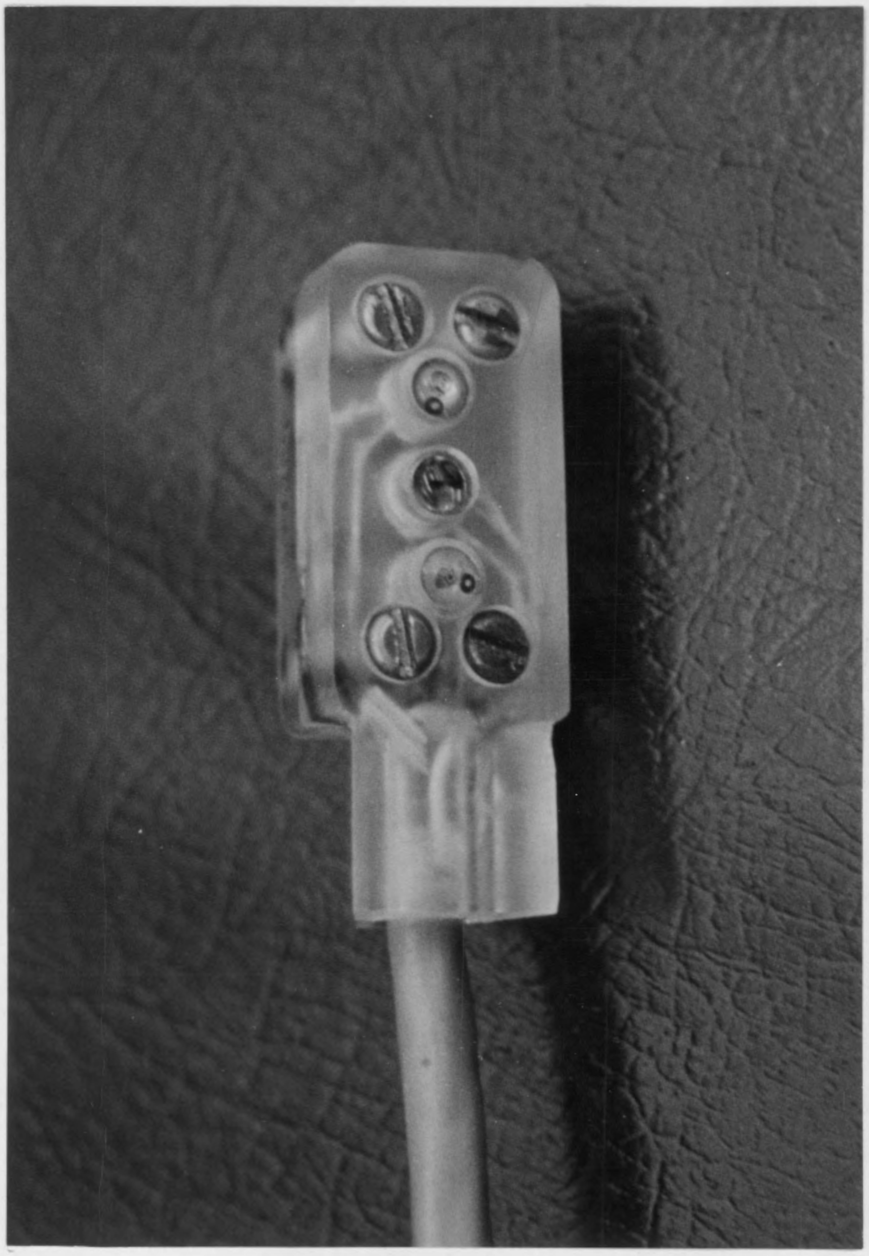

Figure 31. Oximeter Transducer

4, adjust P2 until the proper waveforms are obtained. The adjustment will decrease the reference voltage level that the phototransistor's integrated current has to attain, resulting in the LED's being kept on for a shorter period of time.

When the above steps have been completed, the test section between the two three-way valves is to be filled with 100% oxygen saturated blood. This complete saturation can be accomplished by filling a 50cc syringe with about 20cc of blood. The remaining volume of the syringe is filled with oxygen. The syringe is then rotated and gently agitated to promote the oxygen transfer to the blood. After the procedure has been repeated three or four times, the blood should have a bright red color. The oxygen saturation is checked by the Instrumentation Laboratory (IL) Co-oximeter, model 182. If the Co-oximeter reading is 100%, ± 1%, the sample has been saturated sufficiently. This reading should be recorded as the "upper calibration point saturation value". The blood sample is now ready to be input to the test section of the circuit. With the syringe attached to port B of three-way valve number 1, the valve is switched to a position where the flow path is from B to C. The pump must be off during this part of the procedure. The 100% oxygen saturated blood is used to fill the test section. The position of valve 2 should be switched so that the flow path from A to C is closed. The test section is now full of oxygenated blood and the upper calibration point procedure can be started.

7) Adjust P4 until the voltage at pin 3 of A6 on the oximeter

board is the value of oxygen saturation recorded for the upper calibration point. For example, if the saturation level recorded was 99%, P4 would be adjusted until the voltage at pin 3 was +0.99 volts.

8) P3 is then adjusted so that the output at pin K of the oximeter circuitry is equal to the voltage at pin 3 of A6. Using the previous example, P3 would be adjusted until the voltage at pin K was +0.99 volts.

At this point the valves are positioned such that flow is from ports A to C for each valve. The pump is turned on and the blood is circulated through the system a few times to insure mixing of the 100% oxygen saturated blood with the less saturated blood. The pump is turned off and the calibration procedure for the lower saturation point is begun.

9) A small sample of blood is extracted from the system and analyzed for oxygen saturation by the Co-oximeter. This reading is recorded as the "lower calibration point oxygen saturation value".

10) P5 is adjusted until the output at pin K is the value of the lower calibration point. If the Co-oximeter reading was 40%, P5 would be adjusted to obtain at +0.40 volt output at pin K.

11) P9 is now adjusted until the output of A8, pin 6, or pin 2 of A9 is somewhere between +3.0 and +4.0 volts. This insures that the voltage presented to the A/D converter will be within the ramp voltage range and that a 100 percent readout will be attainable.

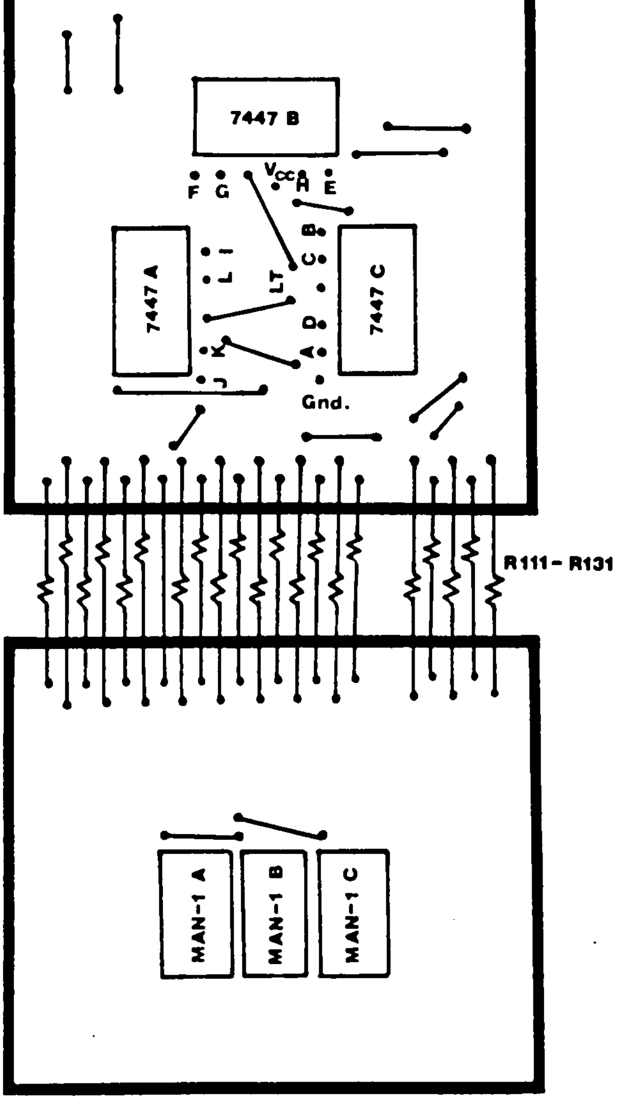

FIGURE 32. COMPONENT SIDE OF DISPLAY BOARD

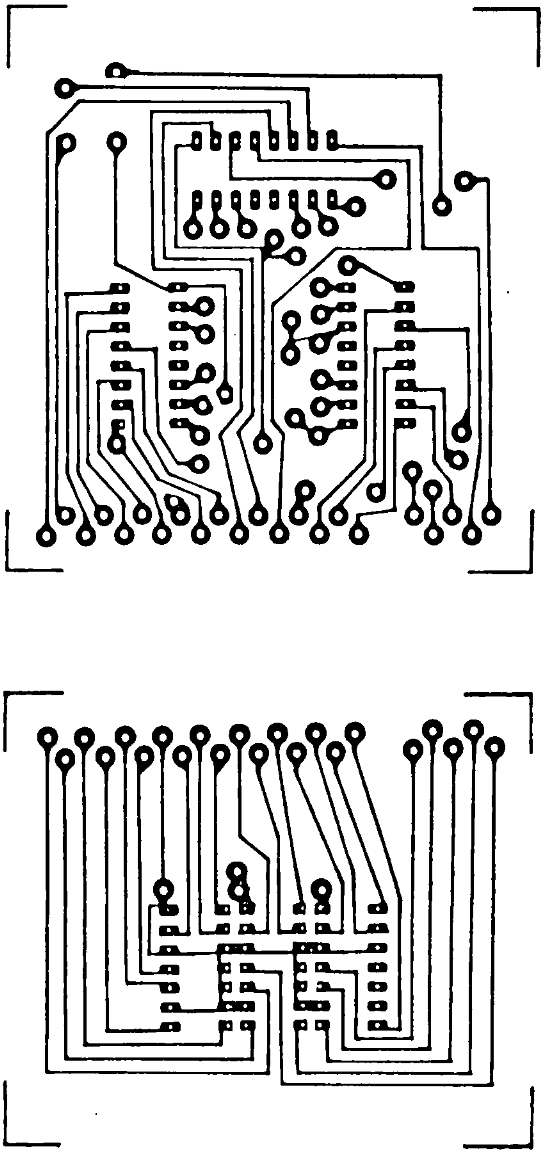

Figure 33. Display Printed Circuit Board Layout

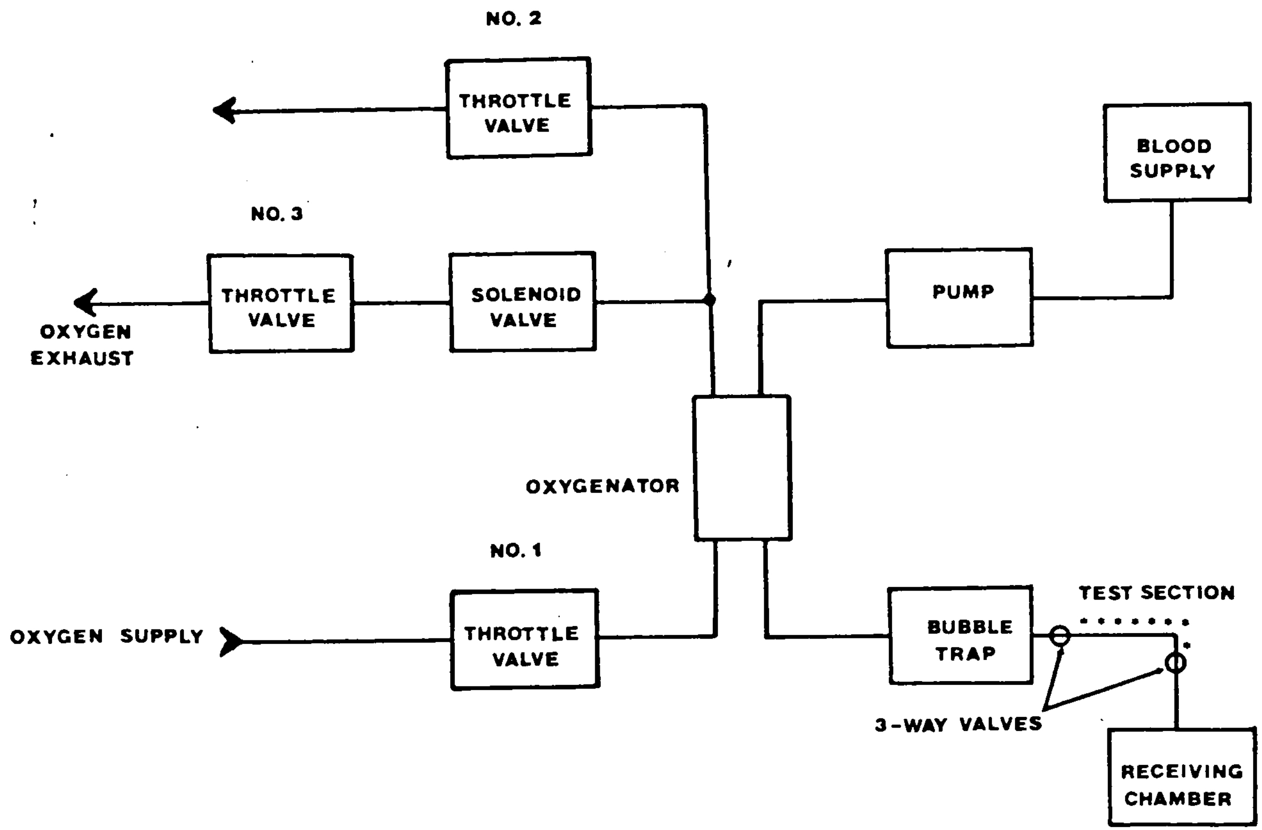

FIGURE 34. PUMP AND OXYGENATOR SYSTEM-CONTROL MODE TEST CONFIGURATION

12) P10 is then changed until the digital display, Figs. 32 and 33, of the oximeter reads the correct saturation value.

With steps 1 through 12 completed, the oximeter is calibrated and ready to test. The clamps are removed from the oxygen lines allowing air to enter the oxygenator. The pump is turned on and the testing is begun. The output saturation level from the oxygenator will change slowly with no elevated oxygen pressure supplied to the oxygenator. If the saturation is desired to increase at a faster rate, oxygen can be supplied at pressures greater than atmospheric to enhance the oxygen transfer. Oximeter saturation readings should be taken with every 5% change in the indicated saturation level. A sample of blood shall be drawn immediately after the oximeter reading is taken, and analyzed by the Co-oximeter. This reading should be recorded beside the oximeter reading. When the outlet saturation has reached 100%, the test is concluded.

The control operating mode test procedure follows steps 1 through 12 of the monitoring procedure. Note in Fig. 34, that the blood is not recirculated as it was for the monitor mode test, but rather it passes through the oxygenator one time only. Because the control test procedure requires an open system, the amount of blood required is somewhat greater than that required for the monitor mode test. The pump should be adjusted so that the minimum flow rate is obtained. Future tests will use flow rates other than the minimum to observe the system response. The maximum oxygen flow to the oxygenator with values 2 and 3 open is determined by throttle value 1. Value number 2 controls the minimum flow through the oxygenator required for CO_2 removal with throttle value 3 closed. Throttle value 3 is used to vary the pressure discharge time from the oxygenator. The additional calibration steps required follow.

13) With the mode selector switch in the control position, adjust P17 on the control circuit board until the pulse duration of the Q output of 74121E, pin 6, is approximately 0.9 seconds.

14) Set the control rate pot, located on the front panel, somewhere between 1 and 5. A setting of 1 will result in a control action every 10 seconds, and a setting of 5 will produce a control time of over four minutes.

15) The maximum allowable saturation and the minimum allowable saturation levels are set by the indicated adjustments on the front panel. If these levels are exceeded, a display light on the panel will be turned on and a warning buzzer will sound.

16) The final adjustment made is to set the desired outlet saturation value with the indicated dial on the instrument front panel.

3.2 RESULTS

Test results for the instrument in its present configuration were limited by the improper operation of the Instrumentation Laboratory Co-oximeter. Without the use of the IL Co-oximeter, no accurate method of oximeter calibration was available. However, two tests made with the basic oximeter circuit, corresponding to the monitor operating mode, are presented. The test data for each trial is given in Table 13 and Table 14, with the results plotted as Fig. 35 and Fig. 36, respectively. The tests were conducted at a stage in the oximeter development when the scaling of the output analog signal did not give the direct per cent oxygen saturation value. Figures 35 and 36 show the per cent oxygen saturation, measured by the Co-oximeter, obtained at the corresponding oximeter output voltage. Both figures demonstrate the predicted linearity between the oxygen saturation and the ratio of the incident light intensities at the two wavelengths. The differences in the output voltage scales (X-axis) and the slopes for the graphs is a result of the different calibration pot settings for the two tests.

The control operating mode was tested by simulating the actual outlet oxygen saturation and adjusting the desired oxygen saturation setting to obtain varying values of error signals. With the simulated oxygen saturation remaining constant, the solenoid valve stepped through its full range of operating frequencies (0.3 Hz-1.1 Hz). This sweep through the valve operating range could be accomplished only because of the constancy of the error signal. In actual operation, a change in valve operating frequency would cause the actual outlet saturation to

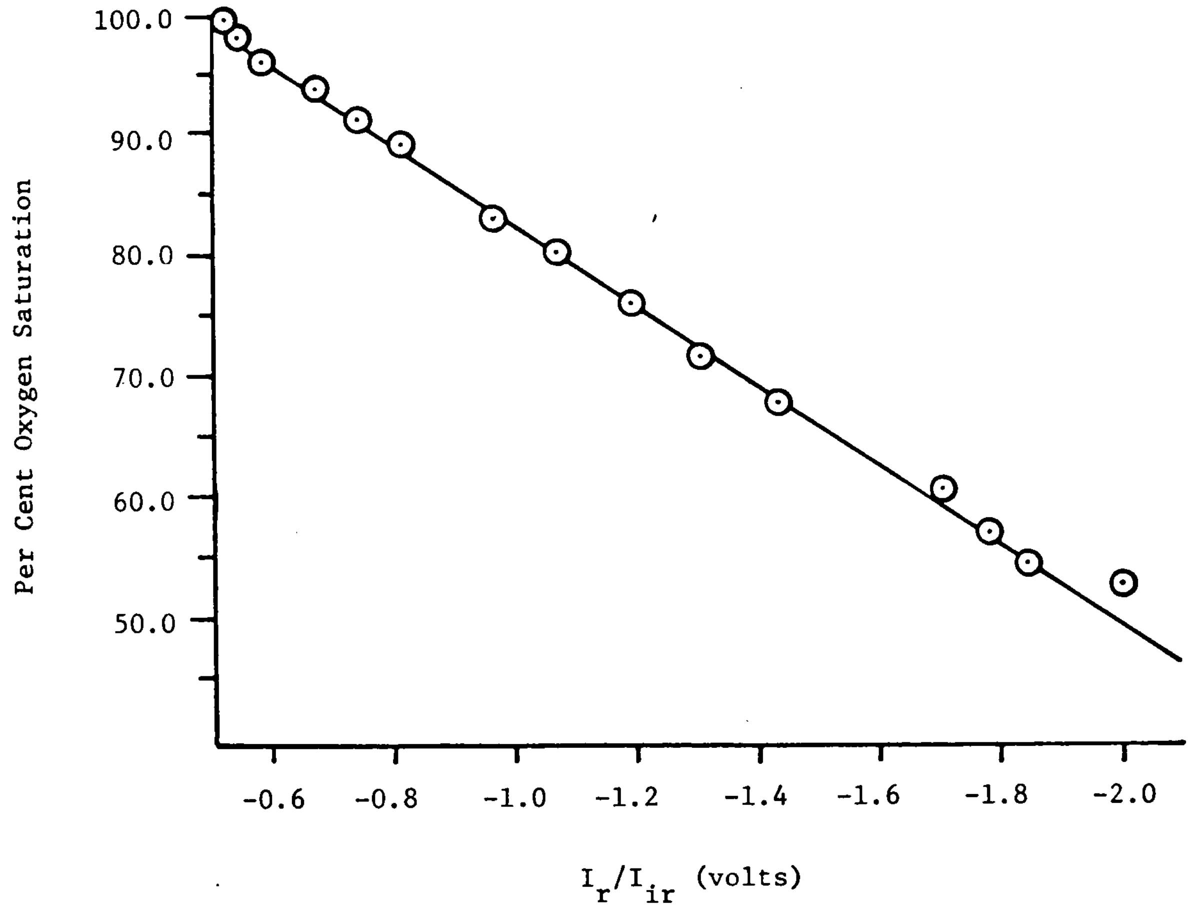

Figure 35. Test No. 1 Oximeter Output Values at Test Saturations

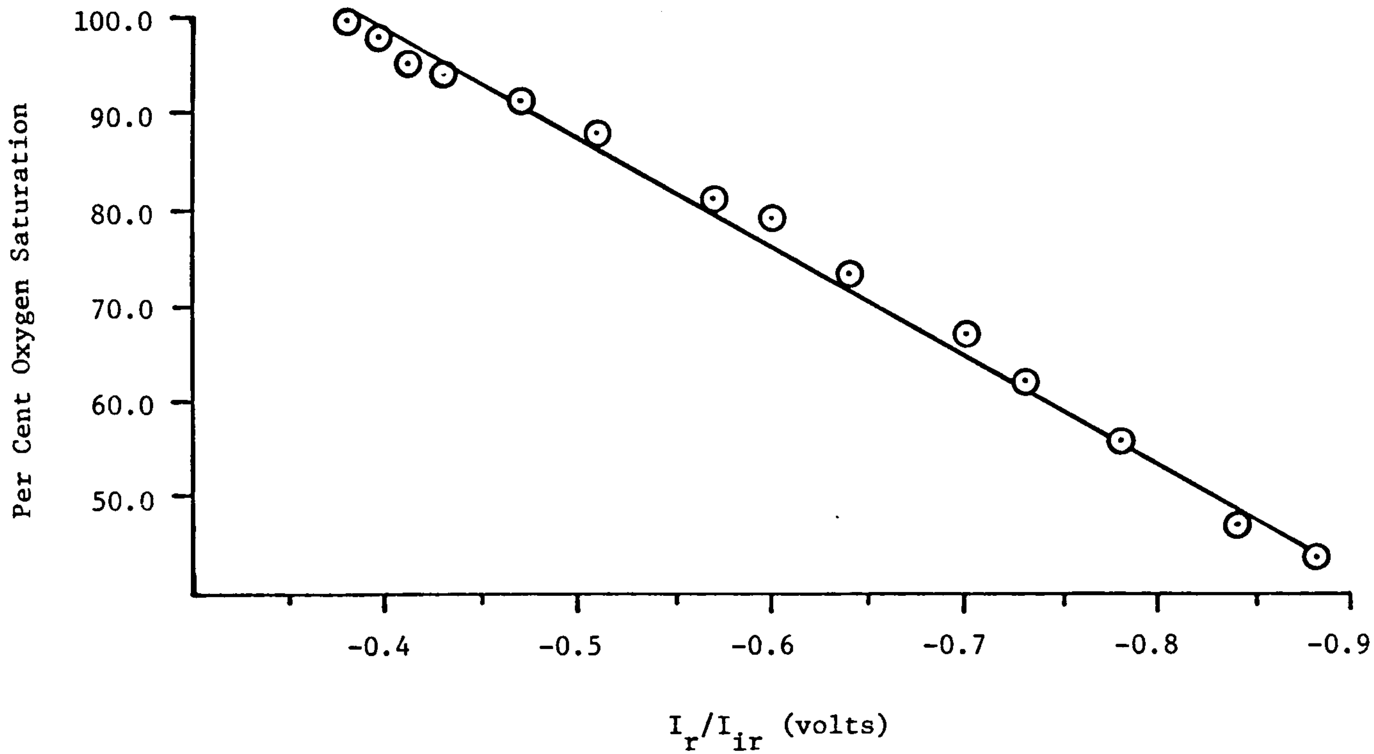

Figure 36. Test No. 2 Oximeter Output Values at Test Saturations

approach the desired level more closely, producing a smaller error signal, resulting in a smaller change in the valve operating frequency. Finally, when the difference between the desired and actual oxygen saturations became small enough, the valve frequency would not change.

The upper and lower limit alarms were tested using the simulated oxygen saturation signal. The warning light and buzzer for each alarm operated correctly at the indicated dial settings. Also, the control rate adjustment was checked and found to give the design range of control timing.

The control circuit has been tested and shown to work as designed. However, future tests should be conducted to determine the effectiveness of the instrument for regulation of the actual oxygenator outlet blood oxygen saturation.

TABLE 13 OXIMETER TEST NO. 1 DATA

Point No.	Oximeter (volts)	Co-oximeter (per cent oxygen saturation)
1	-2.00	53.0
2	-1.86	54.6
3	-1.80	57.1
4	-1.70	60.8
5	-1.43	68.0
6	-1.30	71.6
7	-1.19	75.0
8	-1.07	80.4
9	-0.96	83.0
10	-0.81	89.0
11	-0.74	91.3
12	-0.67	94.2
13	-0.58	96.0
14	-0.54	98.0
15	-0.52	99.5

TABLE 14 OXIMETER TEST NO. 2 DATA

Point No.	Oximeter (volts)	Co-oximeter (per cent oxygen saturation)
1	-0.878	44.4
2	-0.841	46.8
3	-0.783	56.0
4	-0.730	61.6
5	-0.700	67.0
6	-0.641	73.4
7	-0.599	79.0
8	-0.572	81.0
9	-0.510	88.2
10	-0.468	91.0
11	-0.429	94.0
12	-0.412	95.2
13	-0.395	98.0
14	-0.382	99.5

4. CONCLUSIONS AND RECOMMENDATIONS

From the limited test data, few conclusions may be drawn about the operation of the total instrument. The operation of the basic oximeter appears to behave in a linear manner as predicted by the theory. The instrument should be able to give a continuous measurement of the inlet and outlet percent oxygen saturations of the blood flowing through the Arp oxygenator. The control ability of the instrument is yet to be determined; therefore, a change in the range of the solenoid valve operating frequency may be required to adequately regulate the oxygenator's outlet per cent oxygen saturation. One possible method that could be used to change the operating frequency range would be to alter the division of the VCO output performed by the 8520C and 8520D. The modulo-n dividers in their present configuration divide the VCO output by a constant value of 70. A voltage comparator section could be formed so that the magnitude of the VCO input voltage would determine the number by which the 8200's divide. In this way, the valve operating frequency range could be increased.

The instrument sensitivity to the difference between the actual and the desired per cent oxygen saturation signals may need to be adjusted for proper oxygenator control. The instrument's action on the valve operating frequency is determined by the number of voltage comparators (A11-A18) whose outputs are in the positive saturation state. The output is dependent on the magnitude of the error signal in relation to the reference voltage at that comparator. If the reference voltage level at each comparator was increased, the system response to a given error signal would be decreased and the chance of the actual outlet per cent oxygen saturation overshooting the desired value would be diminished. The system sensitivity then will be controlled by the reference voltage levels at the comparators. The system time response is determined by the "control rate" setting. Further tests should be conducted to determine the proper reference voltage levels and control rate settings for the most effective regulation of the oxygenator by the control circuit.

The following recommendations are directed to improvements for the instrument circuits. The +13 and -13 volt power supply on the oximeter circuit board could be eliminated. The power supply circuit board could supply the oximeter board with the required ±13 volts. The LED driving currents could be obtained from the secondary of one of the power supply transformers. Of course, the resistance of R1a, P1, and R14 would have to be changed to maintain the LED currents in the proper range, unless the transformer used had a 25.2 volt secondary. The output from the negative side of the +14 volt bridge on the power circuit board would also have to be supplied to the oximeter circuit. This is required to obtain the pulse needed to clear the integrating amplifier A3. Further reduction in circuit components could be achieved by replacing the analog-to-digital circuit board with an integrated circuit that performs the same function. As mentioned previously, the sensitivity of the system is determined in part by the reference voltage levels presented to voltage comparators A11 through A18. Resistor pairs R49 and R50, and R56 and R57, could be replaced by trim pots that would facilitate the alteration of these positive and negative reference voltage levels.

The oximeter transducer could possibly be redesigned for more efficient operation. In its present configuration the LED's and phototransistor are arranged in line along the flow axis of the tube with the phototransistor located between the two LED's. The outer diameter of the phototransistor is approximately 2mm from the outside diameters of the LED's. It is felt that the reflected light signal could be improved by positioning the two LED's closer to the phototransistor. Other improvements to the transducer would be to machine the transducer from an opaque material instead of the translucent plexiglass used in the current design. An opaque transducer and mount is required to prevent extraneous room light from affecting the oximeter operation. Also, the transducer length should be extended two inches beyond the LED's on each side to further reduce the possibility of extraneous light interference.

There are several possibilities for utilization of the oximeter in other applications where the oxygen saturation measurement is desired. The LED's and phototransistor could be coupled with a fiberoptics catheter for the purpose of making continuous in vivo oxygen saturation measurements (6-7). Another possible area of application to be investigated is the modification of the present oximeter design to enable it to make continuous, non-invasive oxygen saturation measurements. The oxygen saturation measurements would be obtained by positioning the oximeter transducer on a part of the human body where the blood reflection characteristics could be determined.

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THE DEVELOPMENT OF A CONTINUOUS BLOOD OXYGEN SATURATION MEASUREMENT AND CONTROL SYSTEM

by

Ralston Ray Cavender, Jr.

(ABSTRACT)

An instrument is described which continuously monitors and controls the blood oxygen saturation at the outlet of a membrane-type oxygenator. A reflection oximeter was developed which employs the ratio of the incident light intensity at two wavelengths to obtain the continuous blood oxygen saturation measurement. The ratio of the intensities of incident light at the two wavelengths is linearly related to the oxygen saturation, provided the reflected light intensities at these two wavelengths are held constant. The continuous oxygen saturation measurement from the oximeter is compared to a preselected oxygen saturation value by the instrument. The difference between the actual and the desired oxygen saturation is used to change the oxygen partial pressure gradient in the oxygenator in such a way that the oxygenator outlet saturation approaches the preselected value. A detailed description of the instrument's design is presented along with data obtained from the instrument's operation.