interrupted, as the R wave detected is no longer valid, and therefore the software used to eliminate motion artifacts will have to be terminated. An interrupt to the display/audio driver will start a routine to display the lead fall off information and generate some alarms. After this problem has been fixed, another interrupt would trigger the operation to resume. During interrupt routine execution the MBS stalls for a while until the process generating the interrupt has been serviced.

Also, if the physician wants to refer to the pulse rate of the patient recorded a few minutes back, the interrupt raised will cause the current routine to branch, retrieve the data from the memory and continue with the recording. Usually while user-triggered interrupts are generated, the main routine continues with the measurements and has this raised interrupt serviced in parallel.

8.8 POWER SUPPLY

The power supplies present on most boards are switched mode power supplies (SMPS). A SMPS-based power supply is either in the flyback or the flyforward converter mode. Figure 8.13 shows the power supply present on the Nellcor N-200®, which contains switching power supplies in flyback converter configuration. These power supplies are capable of generating low voltages at high currents. The supply is capable of providing 2 A at +5 V and 100 mA at ±18 V.

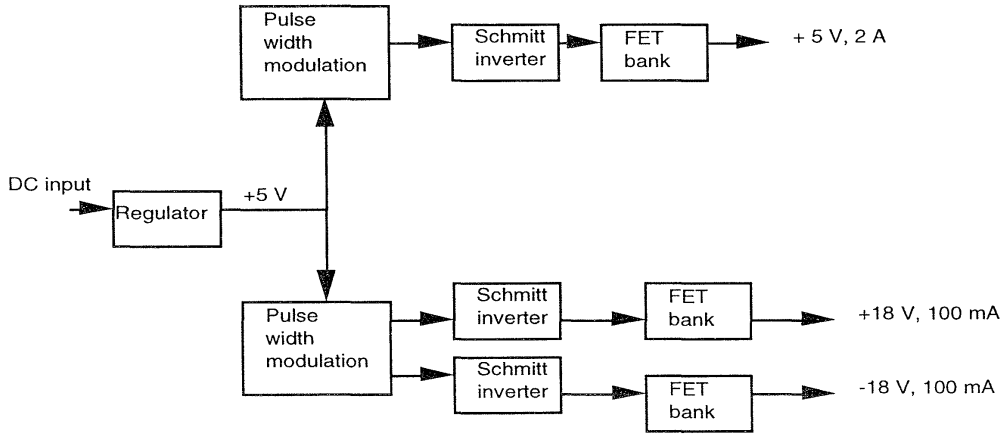

Figure 8.13 Basic power supply block diagram (adapted from Nellcor N-200® (Nellcor 1989)).

The essence of a SMPS supply is the pulse width modulator (PWM). In figure 8.13 the two PWMs control the 5 V and the ±18 V supply. The PWM senses the dc voltages at their inputs and controls the pulse width at the gates of switching FETs. A voltage regulator provides reference voltages for the two PWMs.

Field effect transistors are characterized by the rise and fall times of their drain currents. As the gates of the FETs are slightly capacitive, there is a need to minimize the rise and fall times of the drain current. Schmitt inverters are present to provide low impedance active current drive to these capacitive gates.

8.8.1 Recharging

Battery charger circuits are necessary to charge up a battery in case of a power line failure. In such an application when the main system is on line a battery charging circuit charges up a battery making use of the ac line voltage. In case of emergencies, because of a line failure, this system is set into the battery operated mode. However there is only a limited usage time available. Moreover the system becomes more bulky.

Figure 8.14 shows that ac power is taken from one of the secondaries of the transformers. It is rectified using a diode bridge arrangement (full wave rectifier) and filtered using a capacitor, to provide a positive voltage to the voltage regulator. Current limiting action is present via the use of a current-sensing resistor and a set of current-limiting transistors. Potentiometers are provided to trim the battery charging voltage. In order to avoid back discharge from the battery when the ac power is removed, a diode is present. Keeping in mind the efficiency of a power system, the expected voltage is 85% of the voltage provided by the battery charging circuit.

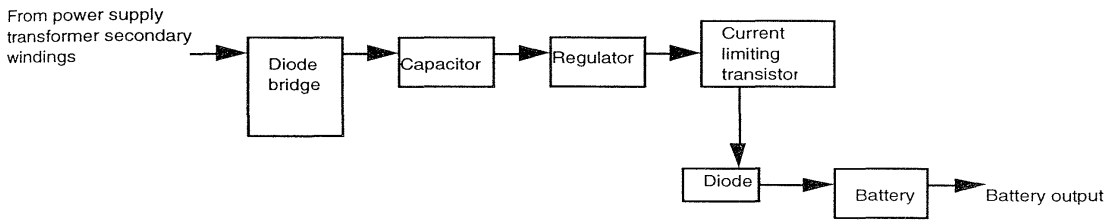

Figure 8.14 Battery charger block diagram (adapted from Nellcor N-200® (Nellcor 1989)).

8.9 ALARMS

When using pulse oximeters in critical applications, alarms are essential to give an indication to the physician that something is wrong. These alarms have to be in both audio and visual form. Comparators, power amplifiers, drivers and speakers constitute the audio alarm section. LCD bar graphs and blinkers are used for the visual section. Certain guidelines have been formulated by standardizing agencies such as the American Society for Testing and Materials (ASTM) regarding the color of the indicator, frequency of the indicator and the tone, audio level etc. Also the signals that need to be treated as emergency signal are classified (pulse rate, detached lead, etc).

8.10 STORAGE

Data concerning oxygen saturation and pulse rate can be collected and stored in memory. This may be used in the future to train the pulse oximeter system, using neural networks and artificial intelligence to generate control signals.

Memories are selected using address lines and data lines are used to load and unload data from them. In order to make the most efficient use of this storage

mechanism, some care has to be taken while designing the memory system. When no power is applied to the memory system there is danger of losing data.

8.11 FRONT END DISPLAY

This section includes the display terminal on the front end of the pulse oximeter. Liquid crystal displays (LCD) or LED displays are used depending on the clarity, resolution, power consumption, and even aesthetics. Push buttons in the form of feather touch buttons or conventional switches are provided. Interface points, alarm indicators, and other important features are also displayed.

8.11.1 Front end driver circuit

Figure 8.15 shows that the driver circuit consists of two major driving techniques, one for the digit and bargraph and the other for lightbar and other front panel indicators.

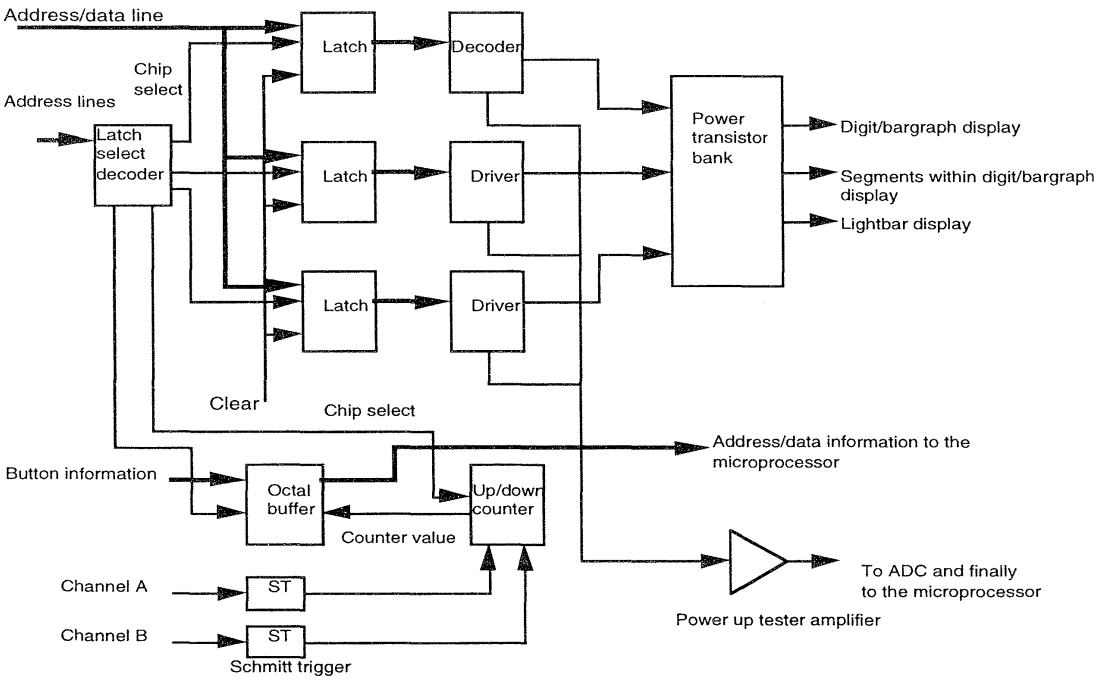

Figure 8.15 Generic display driver circuit.

In order to clear the front panel display, a reset circuit consisting of capacitors and resistors is used. During reset, these components generate a small duration reset pulse that is sent to all the latches on the driver board. This reset pulse clears all the front panel display elements.

Latches and decoders are used to generate the signals required to display information on the display elements. A set of power transistors are used to

generate the drive current required to turn on the display elements. A chip select decoder is used to select the latch–decoder combination depending on the type of display needed. In the circuit layout, signals are required for the digit/bargraph display, to select particular segments within the digit/bargraph display and signals for light bar display. The latches generate the information to be displayed via address information that comes from the microprocessor. After the microprocessor-based system has decided what is to be displayed, address information is sent to Character Generator ROMs (CG-ROMs) or Dynamic Display RAMs (DD-RAMs) which generate the digit/display information. In these devices, bit information pertaining to a particular character is stored at a specific address location. Depending on the address at the input, the required character is generated.

8.11.2 Front panel control

The chip select decoder is used to select the octal buffer, which reads in inputs from the buttons on the front panel and the up/down counter which reads in the control knob rotation information which is relayed through it.

The control knob consists of a two-channel optical chopper, with the two channels mechanically 90 degrees out of phase with each other, and a dual channel optical slot detector. There are two Schmitt triggers, one per channel, to eliminate any transients present and to clean up the signal. The two channels are used to send control signals to the up/down counter. Depending on the direction in which the knob is turned, either the up or the down mode is selected. Channel A provides the clocking pulses for the counter and channel B provides the direction control, whether it is up or down. The processor reads the counter output to determine a change in the up/down mode of the counter. It then adds the count to the accumulated count. The processor then resets the counter.

8.11.3 Power up display tests

When we power up the system for the first time the system runs a few initialization tests. The software tests run are discussed in detail in chapter 9. The primary concern is to ensure that all the display elements are operational. We therefore have a power up tester amplifier which senses the power return line from the driver ICs by monitoring a voltage developed across a resistor. The driver ICs are used to boost the drive current into the segments of the digital displays. This is amplified and given to the ADC. The processor uses this signal during start up to check whether the display is faulty.

8.12 SPEAKERS

The speaker is an inductive load needing a positive and a negative signal. Figure 8.16 shows that currents to these two inputs are controlled by two different paths. Depending on the address/data information the demultiplexer generates many signals like the VRED, VIR and the volume control signal. A sample-and-hold circuit is used to hold this signal. This signal is then passed via a series of power transistors to boost the current flowing into the speaker.

A timer and counter chip generates a count using certain address/data information and temporarily saves it into a buffer. This tone signal is used to

control a FET switch which alternately connects or disconnects the speakers negative input to ground. The frequency of the tone signal (determined by the timer/counter chip) determines the pitch of the sound produced. A capacitor is present to smoothen the sound. A diode is also present to suppress any transients from the inductive load.

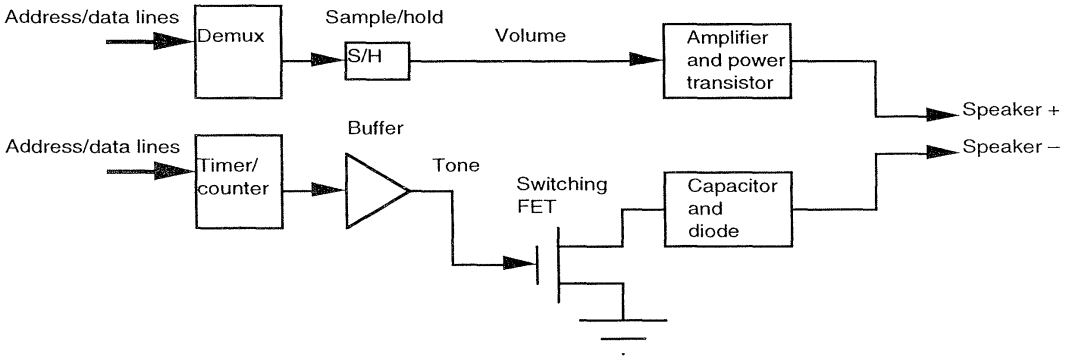

Figure 8.16 Speaker driver block diagram (adapted from Nellcor N-200® (Nellcor 1989)).

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INSTRUCTIONAL OBJECTIVES

8.1 Sketch the block diagram of the microprocessor subsystem, and highlight at least three main features that you think are vital for optimum operation of this system.
8.2 Explain the signal flow in the pulse oximeter from the photodiode to the front-end display.
8.3 Explain the kind of circuit protection associated with a patient module.
8.4 Explain how communication is established between the various chips on the microprocessor based system.
8.5 Describe the timing control involved in the microprocessor-based system.

8.6 Explain the operation of the synchronous detector and the demultiplexer in the pulse oximeter system.
8.7 Mention the need for active amplifiers and low-pass filters.
8.8 Explain the analog-to-digital conversion action involved in the pulse oximeter.
8.9 Explain the function of the pattern generator.
8.10 It is decided to improve the resolution of the ADC. List the steps you will take to improve the existing system. Explain how this will affect the system operation.
8.11 Explain the motivation for subtraction of the DC-level in the photodiode signal before the ADC.
8.12 Describe the components of an input module of a pulse oximeter.

CHAPTER 9

SIGNAL PROCESSING ALGORITHMS

Surekha Palreddy

Pulse oximeters measure and display the oxygen saturation of hemoglobin in arterial blood, volume of individual blood pulsations supplying the tissue, and the heart rate. These devices shine light through the tissue that is perfused with blood such as a finger, an ear, the nose or the scalp, and photoelectrically sense the transmittance of the light in the tissue. The amount of light that is transmitted is recorded as an electric signal. The signal is then processed using several signal processing algorithms to estimate the arterial oxygen saturation reliably in the presence of motion and other artifacts. Signal-processing algorithms implemented both in hardware and software play a major role in transforming the signals that are collected by the sensors and extracting useful information. In this chapter, the signal-processing to calculate S_aO_2 is discussed and ECG synchronization algorithms that enhance the reliability of S_aO_2 estimation and improve the signal-to-noise ratio are discussed. Commercial pulse oximeters use various algorithms for ECG synchronization. Some of these algorithms are discussed with reference to commercially available pulse oximeters such as from Nellcor® and Criticare®.

9.1 SOURCES OF ERRORS

The three general sources of errors dealt with by signal-processing algorithms are the *motion artifact*, *reduced saturation levels* (<80%) and *low perfusion levels* (Goodman and Corenman 1990). The motion artifact is a major problem that is usually due to the patient's muscle movement proximate to the oximeter probe inducing spurious pulses that are similar to arterial pulses. The spurious pulses when processed can produce erroneous results. This problem is particularly significant in active infants, and patients that do not remain still during monitoring. The quantity of motion required to disturb the signal is very small. Shivering and slight flexing of the fingers can make the signal erroneous.

Another significant problem occurs in circumstances where the patient's blood circulation is poor and the pulse strength is very weak. For example, poor circulation occurs in cases of insufficient blood pressure or reduced body temperature. In such conditions, it is difficult to separate the true pulsatile component from artifact pulses because of the low signal-to-noise ratio. Several time-domain and frequency-domain signal-processing algorithms are proposed to

enhance the performance of pulse oximeters with improved rejection of noise, spurious pulses, motion artifact, and other undesirable aperiodic waveforms.

This chapter describes the algorithms required to estimate the arterial oxygen saturation based on the Beer–Lambert law.

9.2 BEER–LAMBERT LAW

Pulse oximetry measures the effect of arterial blood in tissue on the intensity of the transmitted light (Cheung *et al* 1989). The volume of blood in the tissue is a function of the arterial pulse, with a greater volume present at systole and a smaller volume present at diastole. Because blood absorbs most of the light passing through the tissue, the intensity of the light emerging from the tissue is inversely proportional to the volume of the blood present in the tissue. The emergent light intensity varies with the arterial pulse and can be used to indicate a patient's pulse rate. In addition, the absorbance coefficient of oxyhemoglobin is different from that of deoxygenated hemoglobin for most wavelengths of light. Differences in the amount of light absorbed by the blood at two different wavelengths can be used to indicate the hemoglobin oxygen saturation, which equals

$$\%S_aO_2 = [HbO_2]/([Hb] + [HbO_2]) \times 100\%. \tag{9.1}$$

The Beer–Lambert law governs the absorbance of light by homogeneous absorbing media. The incident light with an intensity I_0 impinges upon the absorptive medium of characteristic absorbance factor A that indicates the attenuating effect and a transmittance factor T that is the reciprocal of the absorbance factor $(1/A)$. The intensity of the emerging light I_1 is less than the incident light I_0 and is expressed as the product TI_0. The emergent light intensity I_n transmitted through a medium divided into n identical components, each of unit thickness and the same transmittance factor T is equal to T^nI_0. I_n can be written in a more convenient base by equating T^n to $e^{-\alpha n}$, where α is the absorbance of medium per unit length and is frequently referred to as the relative extinction coefficient. The relative extinction coefficient α is related to the extinction coefficient ε (discussed in chapter 4) as $\alpha = \varepsilon C$, where C is the concentration of the absorptive material. The expression for the intensity of the light I_n emerging from a medium can be given by the following general equation called the Beer–Lambert law.

$$I_n = I_0 e^{-\alpha d} \tag{9.2}$$

where I_n is the emergent light intensity, I_0 is the incident light intensity, α is the absorbance coefficient of the medium per unit length, d is the thickness of the medium in unit lengths, and the exponential nature of the relationship has arbitrarily been expressed in terms of base e. Equation (9.2) is commonly referred to as the Beer–Lambert law of exponential light decay through a homogeneous absorbing medium (figure 9.1).

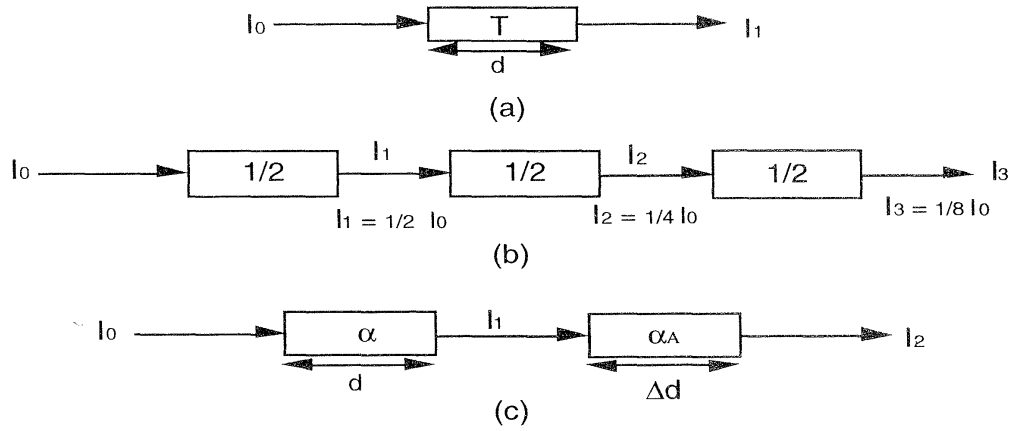

Figure 9.1. A block diagram illustrating the transmittance of light through a block model of the components of a finger. (a) Incident light having an intensity of I_0 impinges upon an absorptive medium with a characteristic transmittance factor T. (b) The effect of a medium divided into n identical components of unit thickness and same transmittance factor T on incident light intensity I_0. (c) For a finger model, the baseline component of the unchanging absorptive elements and the pulsating component of the changing absorptive portion are represented (Cheung *et al* 1989).

9.2.1 Estimation of oxygen saturation using the Beer–Lambert law

The absorbance coefficients of oxygenated and deoxygenated hemoglobin are different at most wavelengths, except at the *isosbestic* wavelength. If a finger is exposed to incident light and the emergent light intensity is measured, the difference between the two is the amount of light absorbed, which contains information relating to the oxygenated hemoglobin content of the blood in the finger. The volume of blood contained in the finger varies with the arterial pulse. The thickness of the finger also varies slightly with each pulse, changing the path length for the light that is transmitted through the finger. Also, the precise intensity of the incident light applied to the finger is not easily determined. Hence, it is desirable to eliminate the effects of intensity of the incident light and the thickness of the path length in estimating oxygen saturation. The Beer–Lambert law needs to be modified to eliminate the input light intensity and length of the path as variables.

9.2.1.1 Eliminating the input light intensity as a variable. The intensity of light transmitted through a finger is a function of the absorbance coefficient of both fixed components, such as bone, tissue, skin, and hair, as well as variable components, such as the volume of blood in the tissue. The intensity of light transmitted through the tissue, when expressed as a function of time is often said to include a baseline component, which varies slowly with time and represents the effect of the fixed components on the light, as well as a periodic pulsatile component, which varies more rapidly with time and represents the effect that changing tissue blood volume has on the light (Cheung *et al* 1989). The baseline component modeling the unchanging absorptive elements has a thickness d and an absorbance α. The pulsatile component representing the changing absorptive portion of the finger has a thickness of Δd and the relative absorbance of α_A representing the arterial blood absorbance (figure 9.1(c)).

The light emerging from the baseline component can be written as a function of the incident light intensity I_0 as follows

$$I_1 = I_0 \, e^{-\alpha d}. \tag{9.3}$$

Likewise, the intensity of light I_2 emerging from the pulsatile component is a function of its incident light intensity I_1 and can be written as follows

$$I_2 = I_1 e^{-\alpha_A \Delta d}. \tag{9.4}$$

Substituting the expression of I_1 in the expression for I_2, the light emerging from the finger as a function of the incident light intensity I_0 is as follows

$$I_2 = I_0 e^{-[\alpha d + \alpha_A \Delta d]}. \tag{9.5}$$

The effect of light produced by the arterial blood volume is given by the relationship between I_2 and I_1. Defining the change in transmittance produced by the arterial component as $T_{\Delta A}$, we have

$$T_{\Delta A} = I_2 / I_1. \tag{9.6}$$

Substituting the expressions for I_1 and I_2 in the above equation yields the following:

$$T_{\Delta A} = (I_0 e^{-[\alpha d + \alpha_A \Delta d]}) / (I_0 e^{-\alpha d}). \tag{9.7}$$

The term I_0 in the numerator and the denominator can be canceled by eliminating the input light intensity as a variable in the equation. Therefore, the change in arterial transmittance can be expressed as

$$T_{\Delta A} = e^{-\alpha_A \Delta d}. \tag{9.8}$$

A device employing this principle in operation is effectively self-calibrating, and is independent of the incident light intensity I_0.

9.2.1.2 Eliminating the thickness of the path as a variable. The changing thickness of the finger, Δd, produced by the changing arterial blood volume remains a variable in equation (9.8). To further simplify the equation, the logarithmic transformation is performed on the terms in equation (9.8) yielding the following

$$\ln T_{\Delta A} = \ln (e^{-\alpha_A \Delta d}) = -\alpha_A \Delta d. \tag{9.9}$$

The variable Δd can be eliminated by measuring arterial transmittance at two different wavelengths. The two measurements at two wavelengths provide two equations with two unknowns. The particular wavelengths selected are determined in part by consideration of a more complete expression of the arterial absorbance α_A

$$\alpha_A = (\alpha_{OA})(S_aO_2) - (\alpha_{DA})(1 - S_aO_2) \tag{9.10}$$

where α_{OA} is the oxygenated arterial absorbance, α_{DA} is the deoxygenated arterial absorbance, and S_aO_2 is the oxygen saturation of arterial Hb. α_{OA} and α_{DA} are substantially unequal at all light wavelengths in the red and near infrared wavelength regions except for the isosbestic wavelength of 805 nm. With an S_aO_2 of approximately 90%, the arterial absorbance α_A is 90% attributable to the oxygenated arterial absorbance α_{OA}, and 10% attributable to the deoxygenated arterial absorbance α_{DA}. At the isosbestic wavelength, the relative contribution of these two coefficients to the arterial absorbance α_A is of minimal significance in that both α_{OA} and α_{DA} are equal (figure 4.2).

Wavelengths selected are in a range away from the approximate isosbestic wavelength that is sufficient to allow the two signals to be easily distinguished. It is generally preferred that the two wavelengths selected fall within the red and infrared regions of the electromagnetic spectrum. The ratio of the transmittance produced by the arterial blood component at red and infrared wavelengths follows from equation (9.9).

$$\frac{\ln T_{\Delta AR}}{\ln T_{\Delta AIR}} = \frac{-\alpha_A(\lambda_R)\Delta d}{-\alpha_A(\lambda_{IR})\Delta d} \tag{9.11}$$

where $T_{\Delta AR}$ equals the change in arterial transmittance of light at the red wavelength λ_R and $T_{\Delta AIR}$ is the change in arterial transmittance at the infrared wavelength λ_{IR}. If the two sources are positioned at approximately the same location on the finger, the length of the light path through the finger is approximately the same for light emitted by each LED. Thus, the change in the light path resulting from arterial blood flow Δd is approximately the same for both the red and infrared wavelength sources. For this reason, the Δd term in the numerator and the denominator of the right side of equation (9.11) cancel, producing

$$\frac{\ln T_{\Delta AR}}{\ln T_{\Delta AIR}} = \frac{\alpha_A(\lambda_R)}{\alpha_A(\lambda_{IR})}. \tag{9.12}$$

Equation (9.12) is independent of the incident light intensity I_0 and the change in finger thickness Δd, attributable to arterial blood flow. Because of the complexity of the physiological process, the ratio indicated in equation (9.12) does not directly provide an accurate measurement of oxygen saturation. The correlation between the ratio of equation (9.12) and actual arterial blood gas measurement is therefore relied upon to produce an indication of the oxygen saturation. Thus, if the ratio of the arterial absorbance at the red and infrared wavelengths can be determined, the oxygen saturation of the arterial blood flow can be extracted from independently derived, empirical calibration curves in a manner dependent on I_0 and Δd. For simplicity, a measured ratio R_{OS} is defined from equation (9.12) as

$$\text{Ratio} = R_{OS} = \frac{\alpha_A(\lambda_R)}{\alpha_A(\lambda_{IR})}. \tag{9.13}$$

9.3 RATIO OF RATIOS

The Ratio of Ratios (R_{OS}) is a variable used in calculating the oxygen saturation level. It is typically calculated by taking the natural logarithm of the ratio of the peak value of the red signal divided by the valley measurement of the red signal. The ratio is then divided by the natural logarithm of the ratio of the peak value of the infrared signal divided by the valley measurement of the infrared signal (Cheung *et al* 1989).

9.3.1 Peak and valley method

A photodiode placed on the side of a finger opposite the red and infrared LEDs receives light at both wavelengths transmitted through the finger. The received red wavelength light intensity varies with each pulse and has high and low values R_H and R_L, respectively. R_L occurs during systole when arterial blood volume is at its greatest, while R_H occurs during diastole when the arterial blood volume is lowest (figure 9.2). Considering the exponential light decay through homogeneous media, it is observed that

$$R_L = I_0 e^{-[\alpha(\lambda_R)d + \alpha_A(\lambda_R)\Delta d]}. \tag{9.14}$$

Similarly,

$$R_H = I_0 e^{-\alpha(\lambda_R)d}. \tag{9.15}$$

Taking the ratio of equations (9.14) and (9.15) and simplifying, we have

$$\frac{R_L}{R_H} = e^{-\alpha_A(\lambda_R)\Delta d}. \tag{9.16}$$

Taking the logarithm of both sides of equation (9.16) yields

$$\ln\left(\frac{R_L}{R_H}\right) = -\alpha_A(\lambda_R)\Delta d. \tag{9.17}$$

Similar expressions can be produced for the infrared signal.

$$\ln\left(\frac{IR_L}{IR_H}\right) = -\alpha_A(\lambda_{IR})\Delta d. \tag{9.18}$$

The ratiometric combination of equations (9.17) and (9.18) yields

$$\frac{\ln\left(\frac{R_L}{R_H}\right)}{\ln\left(\frac{IR_L}{IR_H}\right)} = \frac{-\alpha_A(\lambda_R)\Delta d}{-\alpha_A(\lambda_{IR})\Delta d}. \tag{9.19}$$

Because the Δd terms in the numerator and denominator of the right side of the equation (9.19) cancel, as do the negative signs before each term, equation (9.19) when combined with equation (9.13) yields

$$\text{Ratio} = R_{OS} = \frac{\alpha_A(\lambda_R)}{\alpha_A(\lambda_{IR})} = \frac{\ln\left(\frac{R_L}{R_H}\right)}{\ln\left(\frac{IR_L}{IR_H}\right)}. \tag{9.20}$$

Thus, by measuring the minimum and the maximum emergent light intensities of both the red and infrared wavelengths (R_L, R_H, IR_L, IR_H), a value for the term R_{OS} can be computed. Empirically derived calibration curves are then used to determine the oxygen saturation based on R_{OS}.

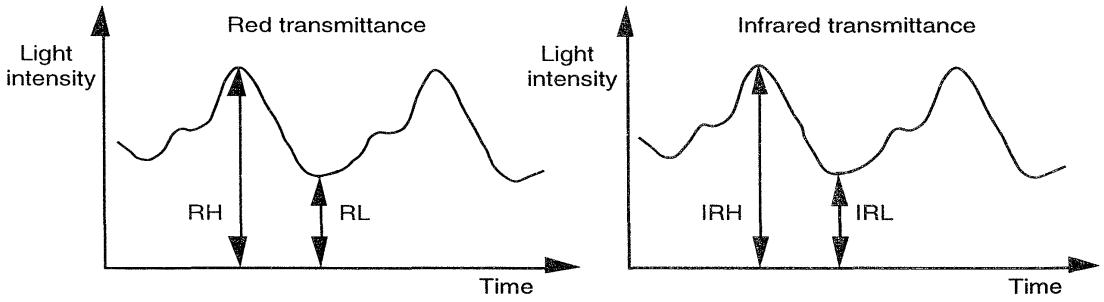

Figure 9.2. A graphical plot of transmitted light intensity converted into voltage. High (H) and low (L) signals are shown as a function of time of the transmittance of red (R) and infrared (IR) light through the finger.

9.3.2 Derivative method: noise reduction software

Yorkey (1996) derives the Ratio of Ratios by calculating using the separated AC and DC components of the measured signal. This mathematical derivation of the ratio of ratios is performed using the Beer–Lambert equation.

$$I_1 = I_0 e^{-\alpha L} \tag{9.21}$$

where I_1 is the emerging light intensity, I_0 is the incident light intensity, α is the relative extinction coefficient of the material and L is the path length. In this method, the Ratio of Ratios is determined using the derivatives. Assuming the change in path length is the same for both wavelengths during the same time interval between samples, the instantaneous change in path length (dL/dt) must also be the same for both wavelengths.

We can extend the general case of taking the derivative of e^u to our case

$$\frac{de^u}{dt} = e^u \frac{du}{dt} \tag{9.22}$$

$$\frac{dI_1}{dt} = I_0 \, e^{-\alpha L}\left(-\alpha \frac{dL}{dt}\right) \tag{9.23}$$

Therefore,

$$\frac{(dI_1/dt)}{I_1} = -\alpha \frac{dL}{dt}. \tag{9.24}$$

Here, I_1 is equal to the combined AC and DC component of the waveform and dI_1/dt is equal to the derivative of the AC component of the waveform. Using two wavelengths we have

$$\text{R of R} = \frac{(dI_R/dt)/I_R}{(dI_{IR}/dt)/I_{IR}} = \frac{-\alpha(\lambda_R)}{-\alpha(\lambda_{IR})}. \tag{9.25}$$

Instead of using the previous method of calculating the Ratio of Ratios based on the natural logarithm of the peak and valley values of the red and infrared signals, the value of the R of R can be calculated based on the derivative value of the AC component of the waveform.

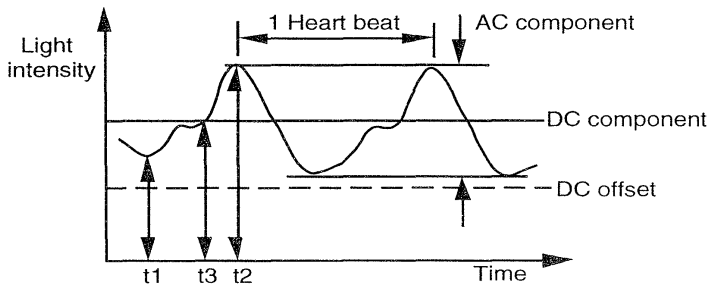

Figure 9.3. A waveform of the transmitted light intensity through a finger showing the AC component, the DC component and the DC offset.

Note in discrete time

$$\frac{dI_R(t)}{dt} \approx I_R(t_2) - I_R(t_1). \tag{9.26}$$

If we choose t_2 and t_1 to be the maximum and minimum of the waveform, we can refer to this difference as the AC value, and the denominator above evaluated at some point in time t_3 in between t_2 and t_1 as the DC value. So,

$$\frac{\dfrac{dI_R(t)/dt}{I_R}}{\dfrac{dI_{IR}(t)/dt}{I_{IR}}} \approx \frac{\dfrac{I_R(t_2) - I_R(t_1)}{I_R(t_3)}}{\dfrac{I_{IR}(t_2) - I_{IR}(t_1)}{I_{IR}(t_3)}} = \frac{\dfrac{AC_R}{DC_R}}{\dfrac{AC_{IR}}{DC_{IR}}} = R. \tag{9.27}$$

Potratz (1994) implemented another improved method for noise reduction called the derivative method of calculating the Ratio of Ratios. To calculate the Ratio of Ratios based on the derivative formula, a large number of sampled points along the waveform are used instead of merely the peak and valley measurements. A series of sample points from the digitized AC and AC + DC values for the infrared and red signals are used to form each data point. A digital FIR filtering step essentially averages these samples to give a data point. A large number of data points are determined in each period. The period is determined after the fact by noting where the peak and valley occur (figure 9.3).

From the AC signal, a derivative is then calculated for each pair of data points and used to determine the ratio of the derivatives for R and IR. A plot of these ratios over a period will ideally result in a straight line. Noise from the motion artifact and other sources will vary some values. But by doing the linear regression, a best line through a period can be determined, and used to calculate the Ratio of Ratios.

A problem with other systems was DC drift. Therefore, a linear extrapolation was performed between two consecutive negative peaks of the waveform. This adjusts the negative peak of the waveform as if the shift due to the system noise did not occur. A similar correction can be calculated using the derivative form of the waveform. In performing the correction of the DC component of the waveform, it is assumed that the drift caused by noise in the system is much slower than the waveform pulses and the drift is linear. The linear change on top of the waveform can be described by the function

$$g(t) = f(t) + mt + b \tag{9.28}$$

where m is equal to the slope of the waveform and b is equal to a constant.

The linear change added to the waveform does not affect the instantaneous DC component of the waveform. However, the derivative of the linear change will have an offset due to the slope of the interfering signal:

$$\mathrm{d}(f(t) + mt + b) / \mathrm{d}t = \mathrm{d}f(t) / \mathrm{d}t + m. \tag{9.29}$$

if we assume that the offset is constant over the period of time interval, then the Ratio of Ratios may be calculated by subtracting the offsets and dividing:

$$\text{R of R} = \frac{Y}{X} = \frac{(y - m_y)}{(x - m_x)} \tag{9.30}$$

where y and x are the original values and m_x and m_y are the offsets.

Since the Ratio of Ratios is constant over this short time interval the above formula can be written as

$$\frac{(y - m_y)}{(x - m_x)} = R. \tag{9.31}$$

Therefore,

$$y = Rx - Rm_x + m_y. \tag{9.32}$$

Since it was assumed that m_1, m_2, and R are constant over the time interval, we have an equation in the form of $y = mx + b$ where m is the Ratio of Ratios. Thus,

we do a large number of calculations of the Ratio of Ratios for each period, and then do the best fit calculation to the line $y = Rx + b$ to fit the optimum value of R for that period, taking into account the constant b which is caused by DC drift.

To determine the Ratio of Ratios exclusive of the DC offset we do a linear regression. It is preferred to take points along the curve having a large differential component, for example, from peak to valley. This will cause the mx term to dominate the constant b:

$$R = \frac{n\sum x_j y_j - \sum x_j \sum y_j}{n\sum x_j^2 - (\sum x_j)^2} \tag{9.33}$$

where n = # of samples, j = sample #, $x = I_R \, dI_{IR} / dt$, $y = I_{IR} \, dI_R / dt$.

Prior sampling methods typically calculate the Ratio of Ratios by sampling the combined AC and DC components of the waveform at the peak and valley measurements of the waveform. Sampling a large number of points on the waveform, using the derivative and performing a linear regression increases the accuracy of the Ratio of Ratios, since noise is averaged out. The derivative form eliminates the need to calculate the logarithm. Furthermore doing a linear regression over the sample points not only eliminates the noise caused by patient movement of the oximeter, it also decreases waveform noise caused by other sources.

9.4 GENERAL PROCESSING STEPS OF OXIMETRY SIGNALS

The determination of the Ratio of Ratios (R_{OS}) requires an accurate measure of both the baseline and pulsatile signal components (Frick *et al* 1989). The baseline component approximates the intensity of light received at the detector when only the fixed nonpulsatile absorptive component is present in the finger. This component of the signal is relatively constant over short intervals and does not vary with nonpulsatile physiological changes, such as movement of the probe. Over a relatively long time, this baseline component may vary significantly. The magnitude of the baseline component at a given point in time is approximately equal to the level identified as R_H (figure 9.2). However, for convenience, the baseline component may be thought of as the level indicated by R_L, with the pulsatile component varying between the values of R_H and R_L over a given pulse. Typically, the pulsatile component may be relatively small in comparison to the baseline component and is shown out of proportion in figure 9.3. Because the pulsatile components are smaller, greater care must be exercised with respect to the measurement of these components. If the entire signal, including the baseline and the pulsatile components, were amplified and converted to a digital format for use by microcomputer, a great deal of the accuracy of the conversion would be wasted because a substantial portion of the resolution would be used to measure the baseline component (Cheung *et al* 1989).

In this process, a substantial portion of the baseline component termed offset voltage V_{OS} is subtracted off the input signal V_1. The remaining pulsatile component is amplified and digitized using an ADC. A digital reconstruction is then produced by reversing the process, wherein the digitally provided information allows the gain to be removed and the offset voltage added back.

This step is necessary because the entire signal, including the baseline and pulsatile components is used in the oxygen saturation measurement process.

Feedback from the microcomputer is required to maintain the values for driver currents I_0, V_{os} and gain A at levels appropriate to produce optimal ADC resolution (figure 9.4). Threshold levels L1 and L2 slightly below and above the maximum positive and negative excursions L3 and L4 allowable for the ADC input are established and monitored by the microcomputer (figure 9.5). When the magnitude of the input to and output from the ADC exceeds either of the thresholds L1 or L2, the drive currents I_D are adjusted to increase or decrease the intensity of light impinging on the detector. This way, the ADC is not overdriven and the margin between L1 and L3 and between L2 and L4 helps assure this even for rapidly varying signals. An operable voltage margin for the ADC exists outside of the thresholds, allowing the ADC to continue operating while the appropriate feedback adjustments to A and V_{os} are made. When the output from the ADC exceeds the positive and negative thresholds L5 or L6, the microcomputer responds by signaling the programmable subtractor to increase or decrease the voltage V_{os} being subtracted. This is accomplished based on the level of the signal received from the ADC. Gain control is also established by the microcomputer in response to the output of the ADC (Cheung *et al* 1989).

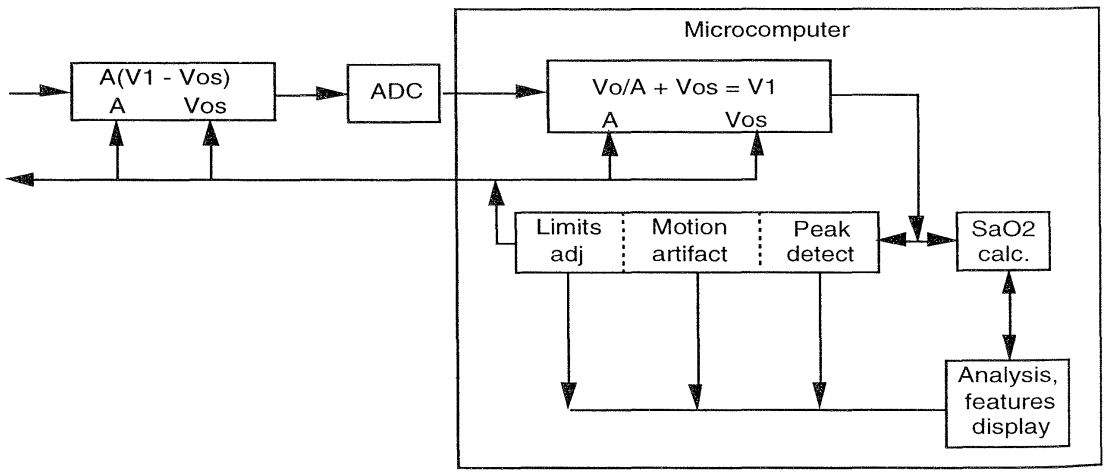

Figure 9.4. A functional block diagram of the microcomputer feedback illustrating the basic operation of the feedback control system. The DC value of the signal is subtracted before digitizing the waveform to increase the dynamic range of conversion. The removed DC value is later added to the digitized values for further signal processing (Cheung *et al* 1989).

A program of instructions executed by the Central Processing Unit of the microcomputer defines the manner in which the microcomputer provides servosensor control as well as produces measurements for display. The first segment of the software is the interrupt level routine.

9.4.1 Start up software.

The interrupt level routine employs a number of subroutines controlling various portions of the oximeter. At the start up, calibration of the oximeter is

performed. After calibration, period zero subroutine is executed which includes five states, zero through four (figure 9.6).

Period zero subroutine is responsible for normal sampling

State 0: Initialize parameters
State 1: Set drive current
State 2: Set offsets
State 3: Set gains
State 4: Normal data acquisition state.

Probe set-up operations are performed during the states zero to three of this subroutine. During these states probe parameters including the amplifier gain A and offset voltage V_{OS} are initialized, provided that a finger is present in the probe. State 4 of the interrupt period zero subroutine is the normal data acquisition state. The signals produced in response to light at each wavelength are then compared with the desired operating ranges to determine whether modifications of the driver currents and voltage offsets are required. Finally state 4 of the period zero subroutine updates the displays of the oximeter. Sequential processing returns to state 0 whenever the conditions required for a particular state are violated (Cheung *et al* 1989).

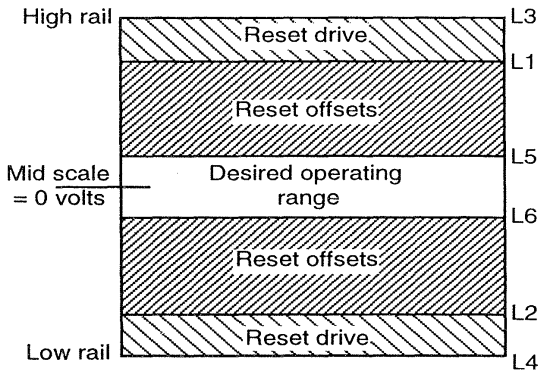

Figure 9.5 A graphical representation of the possible ranges of digitized signal, showing the desired response of the I/O circuit and microcomputer at each of the various possible ranges (Cheung *et al* 1989).

9.5 TRANSIENT CONDITIONS

The relative oxygen content of a patient's arterial pulses and the average background absorbance remain about the same from pulse to pulse. Therefore, the red and infrared light that is transmitted through the pulsatile flow produces a regularly modulated waveform with periodic pulses of comparable shape and amplitude and a steady state background transmittance. This regularity in shape helps in accurate determination of the oxygen saturation of the blood based on the maximum and minimum transmittance of the red and infrared light.

Changes in a patient's local blood volume at the probe site due to motion artifact or ventilatory artifact affect the absorbance of light. These localized

changes often introduce artificial pulses into the blood flow causing the periodic pulses ride on a background intensity component of transmittance that varies as blood volume changes. This background intensity component variation, which is not necessarily related to changes in saturation, affects the pulse to pulse uniformity of shape, amplitude and expected ratio of the maximum to minimum transmittance, and can affect the reliability and accuracy of oxygen saturation determination (Stone and Briggs 1992).

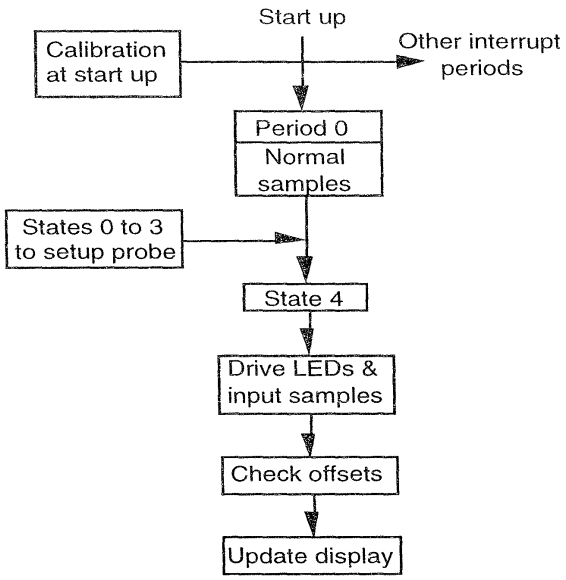

Figure 9.6. Flow chart of a portion of an interrupt level software routine included in the microcomputer (Cheung *et al* 1989).

In addition, there are times when the patient's background level of oxygen saturation undergoes transient changes, for example, when the patient loses or requires oxygen exchange in the lungs while under gaseous anesthesia. The transient waveform distorts the pulse shape, amplitude, and the expected ratio of the pulses, which in turn affects the reliability and accuracy of the oxygen saturation determination.

With changes in the background intensity absorbance component due to artifacts from changes in blood volume or transient saturation changes, the determined saturation value is not accurate and it would not become accurate again until the average absorbance level stabilizes.

The saturation calculations based upon transient signals provide an overestimation or underestimation of the actual saturation value, depending upon the trend. The transmittance of red light increases as oxygen saturation increases resulting in a signal value having a smaller pulse, and the transmittance of the infrared light decreases as saturation increases resulting in the infrared pulsatile amplitude increasing. For these wavelengths, the transmittance changes with saturation are linear in the range of clinical interest, i.e., oxygen saturation between 50% and 100%. The accuracy of the estimation is of particular concern during rapid desaturation. In such a case, the determined saturation based on the

detected signals indicates a greater drop than the actual value. This underestimation of oxygen saturation may actuate low limit saturation alarms that can result in inappropriate clinical decisions.

The pulsatile amplitude is usually quite small, typically less than 5% of the overall intensity change and any small change in overall or background transmittance, such as slight changes in average blood saturation, can have a relatively large effect on the difference in maximum and minimum intensity of the light levels. Because the change in transmittance with changing oxygen saturation is opposite in direction for the red and infrared, this can result in overestimation of the pulsatile ratio during periods when saturation is decreasing, and underestimation during periods when saturation is increasing. It is therefore essential to compensate for the effects of transient conditions and localized blood volume changes on the actual signal, thereby providing a more accurate estimation of the actual oxygen saturation value.

This can be achieved by using a determined rate of change from pulse to pulse, using interpolation techniques and by using the low frequency characteristics of the detected signal values.

The transient error is corrected by linear interpolation where the determined maxima and minima for a first and second optical pulses are obtained, the second pulse following the first. The respective rates of change in the transmittance due to the transient are determined from the maximum transmittance point of the first detected pulse to the second detected pulse (Stone and Briggs 1992). The determined rates of change are then used to compensate any distortion in the detected transmittance of the first detected pulse introduced by the transient in accordance with the following algorithm

$$V_{\max}(n)^{*} = V_{\max}(n) + [V_{\max}(n) - V_{\max}(n+1)] \times \frac{[t_{\max}(n) - t_{\min}(n)]}{[t_{\max}(n+1) - t_{\max}(n)]} \quad (9.34)$$

where $t_{\max}(n)$ is the time of occurrence of the detected maximum transmittance at the n maximum, $t_{\min}(n)$ is the time of occurrence of the detected minimum transmittance of the wavelength at the n minimum, $V_{\max}(n)$ is the detected optical signal maximum value at the maximum transmittance of the wavelength at the n maximum $V_{\max}(n)^{*}$ is the corrected value, for n being the first optical pulse, and $n + 1$ being the second optical pulse of that wavelength.

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

Similarly, the respective rates of change in the transmittance are determined from the minimum transmittance point of the first detected pulse to the minimum of the second detected pulse. The determined rates of change are then used to compensate for any distortion in the detected minimum transmittance of the

second detected pulse introduced by the transient in accordance with the following algorithm

$$V_{\min}(n)^{*} = V_{\min}(n-1) + [V_{\min}(n) - V_{\min}(n-1)] \times \frac{[t_{\max}(n) - t_{\min}(n-1)]}{[t_{\min}(n) - t_{\min}(n-1)]} \quad (9.35)$$

where $t_{\max}(n)$ is the time of occurrence of the detected maximum transmittance at the n maximum; $t_{\min}(n)$ is the time of occurrence of the detected minimum transmittance of the wavelength at the n minimum; $V_{\min}(n)$ is the detected optical signal minimum value at the minimum transmittance of the wavelength at the n minimum; $V_{\min}(n)^{*}$ is the corrected value, for n being the second optical pulse, and $n-1$ being the first optical pulse of that wavelength.

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

As is apparent from the algorithms, during steady state conditions the compensated value is equal to the detected value. Therefore, the linear interpolation routine may be applied to the detected signal at all times, rather than only when transient conditions are detected. Also, the algorithm may be applied to compensate the detected minimum or maximum transmittance values by appropriate adjustment of the algorithm terms. The amount of oxygen saturation can then be determined from this adjusted optical pulse signal by determining the relative maxima and minima as compensated for the respective wavelengths and using that information in determining the modulation ratios of the known Lambert–Beer equation.

The Nellcor® N-200 oximeter is designed to determine the oxygen saturation in one of the two modes. In the unintegrated mode the oxygen saturation determination is made on the basis of optical pulses in accordance with conventional pulse detection techniques. In the ECG synchronization mode the determination is based on enhanced periodic data obtained by processing the detected optical signal and the ECG waveform of the patient.

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

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

The detected optical signal waveform is sampled at a rate of 57 samples per second. When the digitized red and infrared signals for a given portion of

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

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

Example 1

Figure 9.7(*a*) shows the representative plethysmographic waveforms in a steady state condition for the red and infrared detected signals. $V_{\max}\mathrm{R}(1)$ equals 1.01 V, and $V_{\min}\mathrm{R}(1)$ equals 1.00 V, for $n = 1$, 2 and 3 pulses. $V_{\min}\mathrm{R}(n)$ is the detected optical signal minimum value at the minimum transmittance at the n pulse minimum. The modulation ratio for the maxima and minima red signal is:

$$\frac{V_{\max}\mathrm{R}(n)}{V_{\min}\mathrm{R}(n)} = \frac{1.01v}{1.00v} = 1.01.$$

For the infrared wavelength, $V_{\max}\mathrm{IR}(n)$ equals 1.01 V and $V_{\min}\mathrm{IR}(n)$ equals 1.00 V and the determined modulation ratio is 1.01.

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

$$R = \frac{\ln[V_{\max}\mathrm{R}(n) / V_{\min}\mathrm{R}(n)]}{\ln[V_{\max}\mathrm{IR}(n) / V_{\min}\mathrm{IR}(n)]} = \frac{0.01}{0.01} = 1.00.$$

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

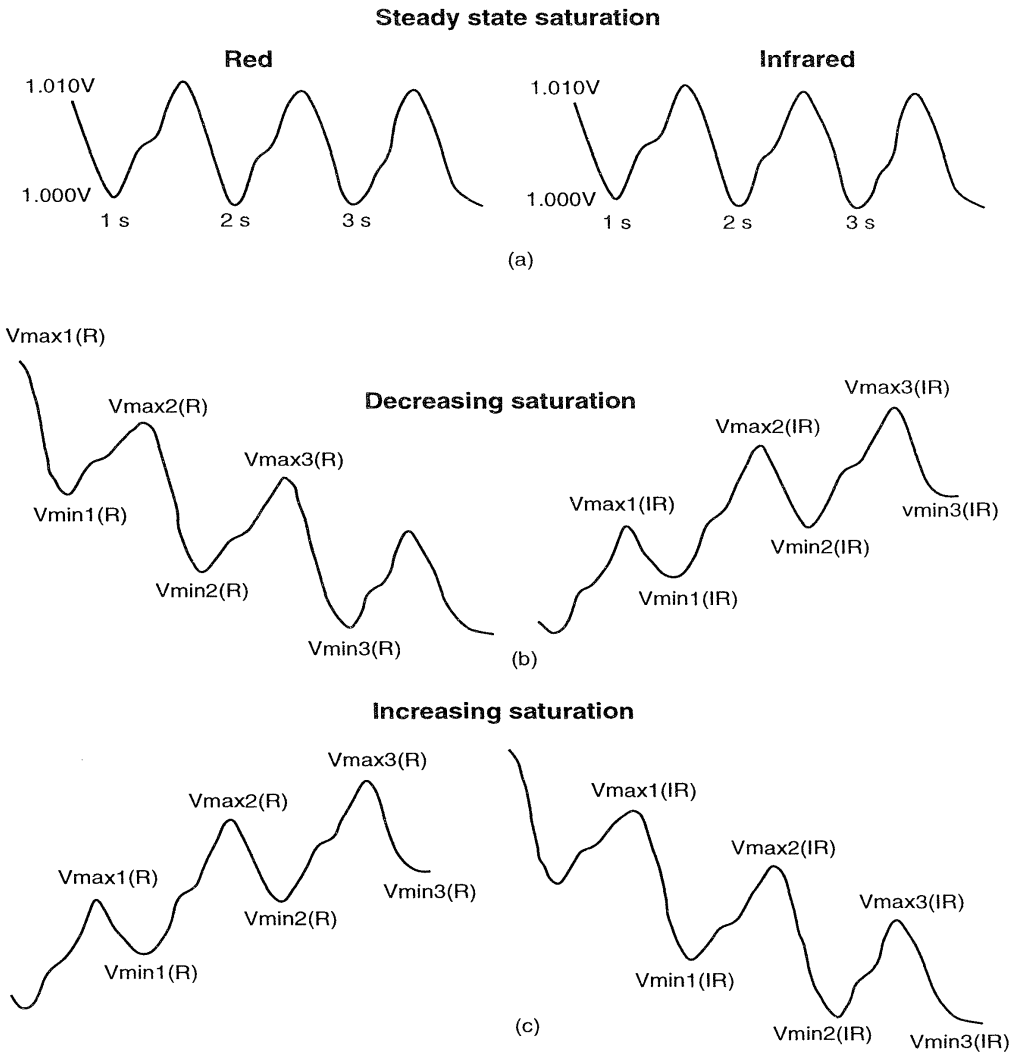

Figure 9.7. Graphical representation of detected optical signals during the steady state and transient conditions (Stone and Briggs 1992).

Example 2

Figure 9.7(*b*) shows the representative plethysmographic waveforms for a patient during desaturation or decreasing saturation transient conditions for the red and infrared detected signals having optical pulses $n = 1$, 2, and 3. However, in this transient example, it is known at $n = 1$, that the actual saturation of the patient is very close to that during the steady state conditions in example 1. In this transient example, the detected values are as follows for both the red and infrared signals:

$t_{max}(1) = 1.0$ s	$V_{max}R(1) = 1.012$ V	$V_{max}IR(1) = 1.008$ V
$t_{min}(1) = 1.2$ s	$V_{min}R(1) = 1.000$ V	$V_{min}IR(1) = 1.000$ V
$t_{max}(2) = 2.0$ s	$V_{max}R(2) = 1.002$ V	$V_{max}IR(2) = 1.018$ V
$t_{min}(2) = 2.2$ s	$V_{min}R(2) = 0.990$ V	$V_{min}IR(2) = 1.010$ V
$t_{max}(3) = 3.0$ s	$V_{max}R(3) = 0.992$ V	$V_{max}IR(3) = 1.028$ V
$t_{min}(3) = 3.2$ s	$V_{min}R(3) = 0.980$ V	$V_{min}IR(3) = 1.020$ V

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

$$\begin{aligned} R &= \frac{\ln[V_{max}R(1)/V_{min}R(1)]}{\ln[V_{max}IR(1)/V_{min}IR(1)]} \\ &= \ln[1.012/1.000]/\ln[1.008/1.000] \\ &= \ln[1.012]/\ln[1.008] \\ &= 0.012/0.008 \quad = 1.5. \end{aligned}$$

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

Applying the correction algorithm to correct the distorted maximum transmittance point of the detected red signal during the transient condition:

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

and correspondingly for the maximum transmittance of the detected infrared signal

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

Thus, by replacing $V_{max}R(n)$ with $V_{max}R(n)^*$ and replacing $V_{max}IR(n)$ with $V_{max}IR(n)^*$ in the calculations for determining the oxygen saturation ratio R, we have

$$\begin{aligned} R &= \frac{\ln[V_{max}R(1)^*/V_{min}R(1)]}{\ln[V_{max}IR(1)^*/V_{min}IR(1)]} \\ &= \ln[1.010/1.00]/\ln[1.010/1.00] \\ &= 0.01/0.01 \\ &= 1.0. \end{aligned}$$

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

Example 3

Figure 9.7(c) shows the representative plethysmographic waveforms for a patient during desaturation or decreasing saturation transient conditions for the red and infrared detected signals having optical pulses n = 1, 2 and 3. However, in this transient example, it is known that at n = 2, the actual saturation of the patient is very close to that during the steady state conditions in example 1. In this transient example, the detected values are as follows for both the red and infrared signals:

t_{max} (1) = 1.0 s	V_{max}R(1) = 1.022 V	V_{max}IR(1) = 1.002 V
t_{min} (1) = 1.2 s	V_{min}R(1) = 1.008 V	V_{min}IR(1) = 0.992 V
t_{max} (2) = 2.0 s	V_{max}R(2) = 1.012 V	V_{max}IR(2) = 1.012 V
t_{min} (2) = 2.2 s	V_{min}R(2) = 0.998 V	V_{min}IR(2) = 1.002 V
t_{max} (3) = 3.0 s	V_{max}R(3) = 1.002 V	V_{max}IR(3) = 1.022 V
t_{min}(3) = 3.2 s	V_{min}R(3) = 0.988 V	V_{min}IR(3) = 1.012 V

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

$$R = \frac{\ln[V_{max}\mathrm{R}(2) / V_{min}\mathrm{R}(2)]}{\ln[V_{max}\mathrm{IR}(2) / V_{min}\mathrm{IR}(2)]}$$
$$= \ln[1.012 / 0.998] / \ln[1.012 / 1.002]$$
$$= 0.01393 / 0.0099 \quad = 1.4.$$

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

Applying the correction algorithm to correct the distorted minimum transmittance point of the detected red signal during the transient condition, we find the following:

$$V_{min}\mathrm{R}(2)^{*} = V_{min}\mathrm{R}(2) - [V_{min}\mathrm{R}(2) - V_{min}\mathrm{R}(1)] \times \frac{[t_{max}(2) - t_{min}(1)]}{[t_{min}(2) - t_{max}(1)]}$$
$$= 1.008 - [0.998 - 1.008] \times [2.0 - 1.2] / [2.2 - 1.2]$$
$$= 1.0$$

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

$$V_{\min}\mathrm{IR}(2)^{*} = 0.992 - [1.002 - 0.992] \times 0.8$$
$$= 1.0.$$

Thus, by replacing $V_{\min}\mathrm{R}(n)$ with $V_{\min}\mathrm{R}(n)^{*}$ and replacing $V_{\min}\mathrm{IR}(n)$ with $V_{\min}\mathrm{IR}(n)^{*}$ in the calculations for determining oxygen saturation ratio R we have:

$$R = \frac{\ln[V_{\max}\mathrm{R}(2) / V_{\min}\mathrm{R}(2)^{*}]}{\ln[V_{\max}\mathrm{IR}(2) / V_{\min}\mathrm{IR}(2)^{*}]}$$
$$= \ln[1.012 / 1.0] / \ln[1.012 / 1.0]$$
$$= 1.0.$$

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

9.6 ECG SYNCHRONIZATION ALGORITHMS

Electrical heart activity occurs simultaneously with the heartbeat and can be monitored externally and characterized by the electrocardiogram waveform. The ECG waveform comprises a complex waveform having several components that correspond to electrical heart activity of which the QRS component relates to ventricular heart contraction. The R wave portion of the QRS component is typically the steepest wave therein having the largest amplitude and slope, and may be used for indicating the onset of cardiac activity. The arterial blood pulse flows mechanically and its appearance in any part of the body typically follows the R wave of the electrical heart activity by a determinable period of time. This fact is utilized in commercially available pulse oximeters to enhance their performance. Another advantage of recording ECG is that it provides a redundancy in calculating the heart rate from both the ECG signal and the optical signal to continuously monitor the patient even if one of the signals is lost (figure 9.8).

With ECG synchronization, the pulse oximeter uses the electrocardiographic (ECG) QRS complex as a timing indicator that the optical pulse will soon appear at the probe site. The R portion of the ECG signal is detected and the time delay by which an arterial pulse follows the R wave is determined to establish a time window an arterial pulse is to be expected. By using the QRS complex to time the oximeter's analysis of the optical pulse signal, ECG processing synchronizes the analysis of oxygen saturation and pulse rate data. The established time window provides the oximeter with a parameter enabling the oximeter to analyze the blood flow only when it is likely to have a pulse present for analysis. This method of signal processing passes those components of the signal that are coupled to the ECG (i.e., the peripheral pulse), while attenuating those components that are random with respect to the ECG (e.g., motion artifact or other noise in the signal).

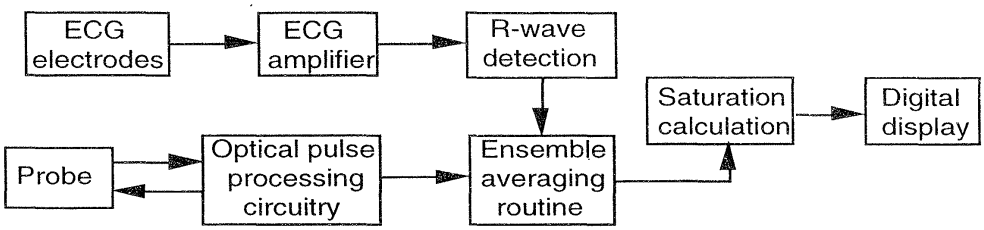

Figure 9.8. Block diagram illustrating the ECG processing components, its subcomponents and their relationship in an oximeter.

9.6.1 Nellcor® system

C-LOCK ECG synchronization enhances the signal-processing capabilities of Nellcor® systems such as the N-200 pulse oximeter and the N-1000 multifunction monitor. This improves the quality of the optical signal in certain clinical settings in which the performance of a conventional pulse oximeter may deteriorate, e.g. when a patient is moving or has poor peripheral pulses. Consequently, C-LOCK signal processing extends the range of clinical situations in which pulse oximetry may be used. Patient movement and poor peripheral pulses present similar problems for a conventional pulse oximeter: performance may deteriorate because the oximeter is unable to distinguish between the true optical pulse signal and background noise. C-LOCK ECG synchronization improves signal quality in these difficult signal-detection settings (Goodman and Corenman 1990).

The digital optical signal is processed by the microprocessor of the Nellcor N-1000 Pulse Oximeter in order to identify individual optical pulses and to compute the oxygen saturation from the ratio of maximum and minimum pulse levels as seen by the red wavelength compared to the pulse seen by the infrared wavelength.

Noninvasive pulse oximeters process optical signals which are prone to motion artifacts caused by the muscle movement proximate to the probe site. The spurious pulses induced in the optical signals may cause the pulse oximeter to process the artifact waveform and provide erroneous data. This problem is particularly significant with infants, fetuses, or patients that do not remain still during monitoring. Another problem exists in circumstances where the patient is in poor condition and the pulse strength is very weak. In continuously processing the optical data, it can be difficult to separate the true pulsatile component from the artifact pulses and noise because of low signal to noise ratio. Inability to reliably detect the pulsatile component in the pulsatile signal may result in a lack of the information needed to calculate oxygen blood saturation.

By incorporating the patient's heart activity into the pulse oximeter, problems due to motion artifact and low signal-to-noise ratio can be solved. Processing of the signals that occur during a period of time when the optical pulses are expected to be found, increases the likelihood that the oximeter will process only optical waveforms that contain the pulsatile component of arterial blood, and will not process spurious signals.

The software incorporated into the microprocessor for processing the ECG signals and displaying the calculated ECG pulse rate receives the digitized version of diagnostic ECG signal (DECG) and filtered ECG signals (FECG). The microprocessor calculates the amplitude of the ECG waveform and controls the AGC (automatic gain control) amplifier, so that DECG and FECG will fall within the voltage range limits of the electronic circuitry used to process these signals.

The microprocessor regularly searches a status input latch at a rate of 57 cycles per second. The output of detected R wave (DRW) sets the latch to a logical 1 when the R wave is detected. Depending on the status, the microprocessor selects the next operation and resets the DRW latch to 0. At this first level, the microprocessor counts the time interval beginning from the detection of an R wave pulse until the occurrence of the next logical 1 at the status input latch. Based on this time interval, the pulse oximeter displays the pulse rate. After averaging several time intervals and establishing a regular ECG pulse rate, the microprocessor will change to the second level of processing.

After the detection of an R wave pulse, the microprocessor separately analyzes the digital optical signal and correlates the period of time by which an optical pulse follows the detected R wave pulse to establish the time window during which the optical pulse is likely to occur. During this second level, the pulse oximeter just calculates and displays the time period or pulse rate between DRW pulses.

The third level of processing starts after a time window has been established. On detecting an R wave pulse, the microprocessor activates the time window so that only optical signals detected within the time window following the occurrence of an R wave pulse will be evaluated for acceptance or rejection and for use in calculating and displaying vital measurements such as oxygen saturation, pulse flow, and pulse rate. The evaluation of a detected pulse is made in conjunction with a preselected confidence factor that is associated with the quality of the optical signals. The higher the optical signal quality, the better the correlation between the recorded pulse history and the detected pulse, and the higher the confidence level. The confidence level may be set automatically by the microprocessor, or it may be adjusted by the operator. The microprocessor will reject any detected pulses occurring outside the time window. A typical time window for an adult male using a fingertip oximeter probe may be about 50 ms $\pm$10 ms after the occurrence of an R wave. The oximeter will also reject any additional pulses detected after an optical pulse is detected within the same time window, even though the time window has not expired.

However, if the optical pulse is not found within an opened time window, the microprocessor will continue to search for optical pulses using the degraded criteria during the time window period for about three successive detected R wave (DRW) pulses, after which it continues to search with degraded criteria. After a specific interval, e.g. 10 s, without detecting an optical pulse, the microprocessor will revert to independent or nonintegrated processing of the optical and ECG signals, returning the pulse oximeter to startup conditions. Therefore, if the oximeter cannot establish or maintain a reliable correlation between the R wave and the optical pulse, the waveforms will be processed independently. The display will indicate whether the pulse oximeter is operating in integrated or nonintegrated mode. After attaining the third level of processing, losing either the ECG or optical pulse signals will activate an alarm and return the program to the startup condition.

9.6.1.1 R-wave determination routine. The R-wave determination routine begins with electric signals received from the ECG leads and calculating the R–R period RRPER between the last detected R wave and the present R wave (figure 9.9). The average period HISTORY from the previous R waves and the present R wave is calculated and the determined RRPER is compared to the average period HISTORY (Goodman and Corenman 1990). If RRPER does not correspond to HISTORY, the R wave ECG flag is reset and the routine is exited to await another R wave. If RRPER does correspond to HISTORY, a timer is activated to measure the interval from the occurrence of the R wave to the occurrence of the optical pulse. Output HR (ECG heart rate) is calculated based on successive R waves. The system determines whether a series of R–R periods have been synchronized (ECG synchronization). If not synchronized, then the system checks for alarms by comparing output HR to a preselected heart rate and generates an alarm if the output HR is too low. If the ECG is synchronized but the optical pulse to optical pulse is not synchronized, the output HR is sent to the display and then checked for alarms. If the optical signal is synchronized, then the system just checks for alarms. Only if the ECG is synchronized, the optical pulse is not synchronized, and the R wave looks like a valid R wave by comparison with HISTORY, then HISTORY is updated using the new R wave. After updating HISTORY, the system itself is updated (TIME OUT) to maintain synchronization. If TIME OUT is not updated for a period of five seconds, then ECG synchronization is lost and the routine must begin building a new history.

9.6.1.2 The systems routine. The system routine for processing digital optical pulse information for optical pulses to send to LEVEL 3 is flow charted (figure 9.10). The system begins by continuously evaluating the data from the detected digital optical signal (Goodman and Corenman 1990). The data are first evaluated for compatibility with signal processing. If the data are over or undervalued electronically, i.e., beyond the voltage range of the circuitry, then the system exits the routine, and the LED intensities are adjusted to correct the electrical values accordingly. When the data are compatible, they are next evaluated for a maximum signal. A relative maximum is determined and saved. The next value is compared to the saved value, and if it is a new maximum, it is saved instead. When the value found is not a new maximum, then a MAX FLAG is set. Thereafter, the system evaluates the following data received, by passing the maximum value section, to find the maximum slope, again by successive comparisons. When the largest slope value is found, it is saved and the SLOPE FLAG is set. Thereafter, the following data are evaluated, by passing the maximum and slope calculations, to find the minimum value corresponding to the end of the pulse. When the smallest minimum is found, it is saved and the slope value that was saved is compared with a pre-established minimum threshold to determine whether it is large enough to be a possible optical pulse. If it is not large enough, then the pulse is rejected, the flags are reset, and the routine begins processing the next possible pulse. If the slope is large enough, then the pulse parameters, maximum, minimum, and slope, are saved in memory for use by LEVEL 3 processing in evaluating the possible pulse. Then, the time delay from the R wave to the possible pulse is calculated. Thereafter, the DATA FLAG is set indicating to LEVEL 3 that there is a possible pulse to be evaluated, the MAX and SLOPE FLAGs are reset, and the routine begins again to process the following data, looking for new maximum values corresponding to possible pulses.

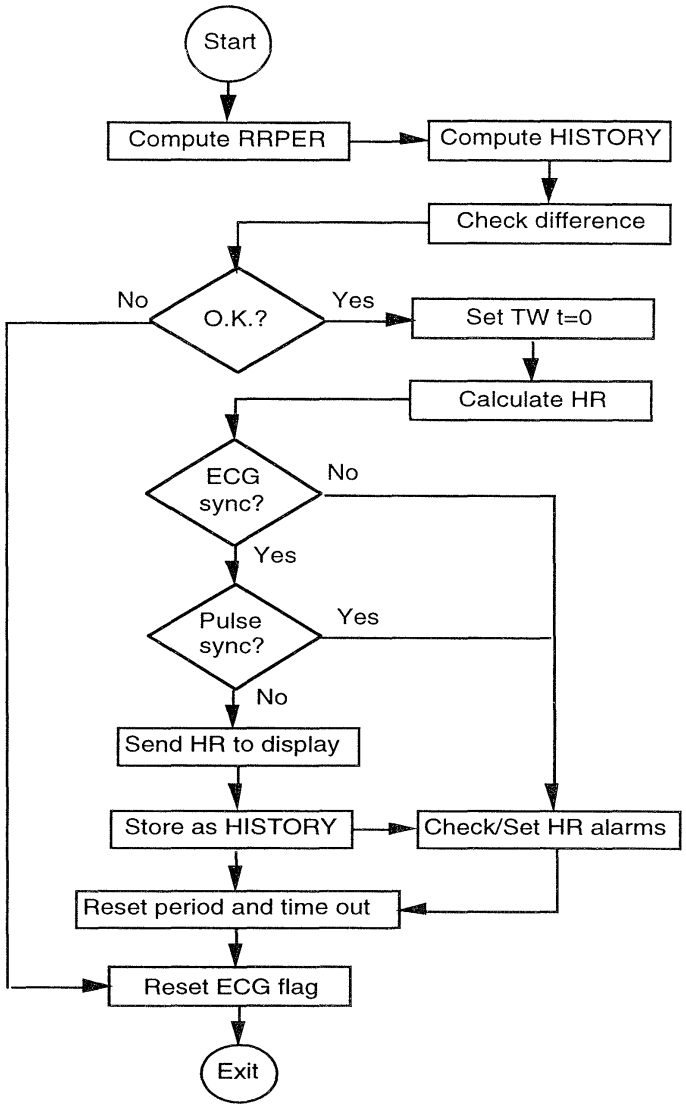

Figure 9.9. The R wave determination routine calculates RRPER, compares it with the average period HISTORY. If RRPER corresponds to HISTORY, the interval between the occurrence of R wave and occurrence of pulse is measured. The algorithm checks for ECG synchronization, alarms and displays heart rate (HR) (Goodman and Corenman 1990).

9.6.1.3 LEVEL 3 software. Figure 9.11 shows LEVEL 3 of software for computing the saturation measurements (Goodman and Corenman 1990). The system starts by acquiring a potential optical pulse after a DATA FLAG has been set and inquiring whether there is ECG synchronization i.e., a regular ECG period has been established. If a DATA FLAG has not been set, then the system exits the routine. If there has not been ECG synchronization, then the microprocessor processes the optical pulse signals independent of the ECG.

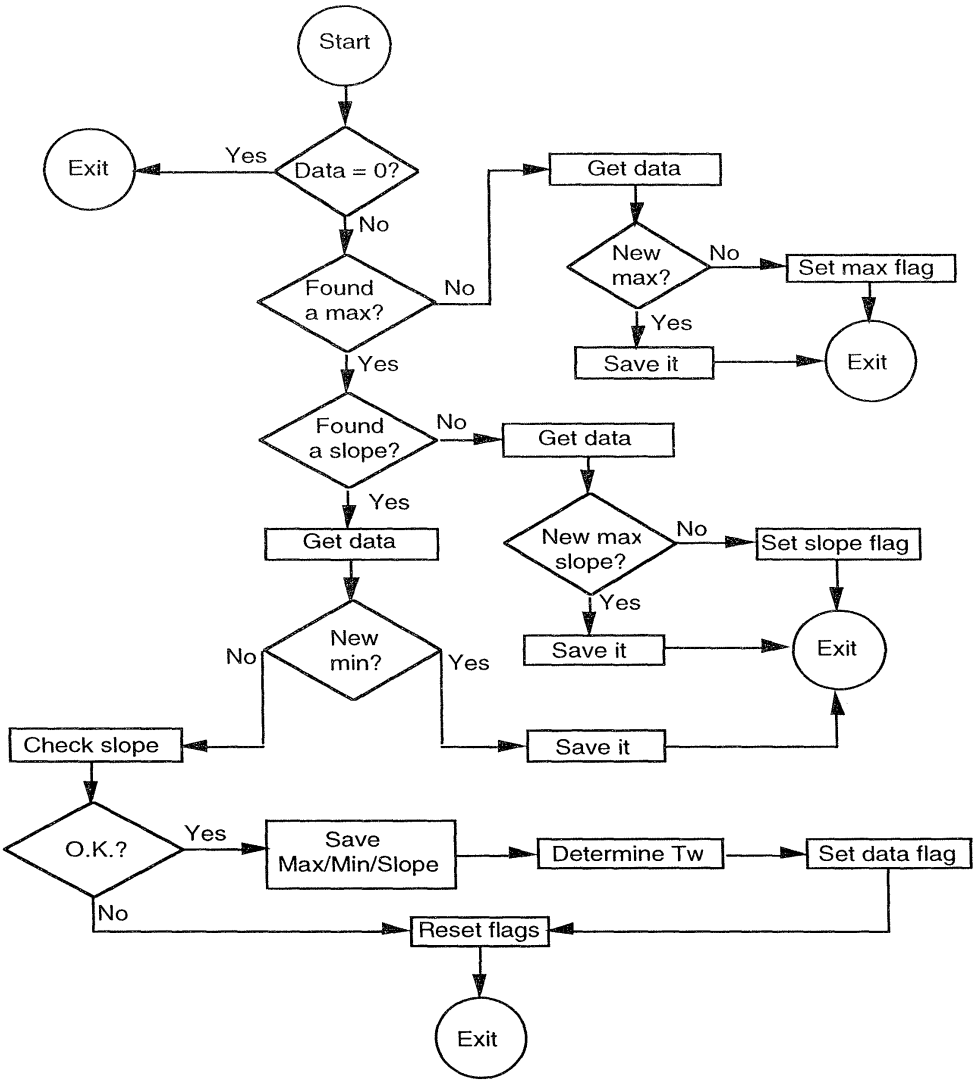

Figure 9.10. The system routine measures the maximum and minimum values in the data presented and calculates the largest slope. The slope value is compared with the normal expected values to determine whether it is a possible optical pulse (Goodman and Corenman 1990).

If there is ECG synchronization, but no R wave has occurred, then the system exits and the pulse is not processed. If there is ECG synchronization and a R wave has occurred, then the microprocessor processes the pulse. The LED intensity is evaluated to see if adjustment is necessary. The reset system gain, based on minimum LED intensity required for adequate signal strength, is checked to see if adjustment is required to the optical pulse historic period, amplitude and ratio. The system then inquires whether the ECG apparatus is operating between an R wave and the following optical pulses for the previous four pulses is computed to give the TIME WINDOW (TW). Then the pulse waveform is analyzed to see if it is a dicrotic notch rather than a real optical pulse. The downward slope of a dicrotic notch or other artifact can be

misinterpreted as an optical pulse, but typically the pulse amplitude is less than half the amplitude of an actual pulse. If the pulse is determined to be a notch or artifact, then the system exits and the next pulse presented will be processed. If not determined to be a notch, then it is analyzed to determine if it is a pulse.

Assuming the ECG is synchronized, then the system determines if two criteria are met. The first is whether the time delay falls within the above-computed TIME WINDOW. If it does not, then the microprocessor rejects the pulse. The second criterion tested is whether or not the ratio is within acceptable limits. Only if the pulse satisfies both criteria is the pulse accepted and a saturation calculation made.

If the ECG is not synchronized then the pulse must pass any two of three criteria regarding (1) pulse period, (2) amplitude, and (3) ratio, to be accepted, e.g., pulse and period, period and amplitude, pulse and amplitude, or all three. If the pulse is accepted, then the oxygenation saturation is calculated.

After the system is turned on (POWER UP) after a TIME OUT alarm (a 10 s period with no valid optical pulse found) a series of consistent pulses must be found to generate an optical pulse history before the oxygenation saturation will be sent to the display. Thus, if there is no optical pulse synchronization, there will be no saturation display. All optical pulses, those accepted and those not accepted, excluding pulses rejected as artifacts, enter the calculation routine section. If the ECG is not synchronized then a pulse-to-pulse period and either an amplitude or a ratio must exist for the optical heart rate (OHR) calculation to be made. If either the ECG or the optical pulse is synchronized, then the HR calculation made will be displayed. If there is no synchronization, then the OHR is not displayed. The system is evaluating the status for pulse evaluation, i.e., whether signals should continue to be processed after a TIME WINDOW period has expired then TIME WINDOW is closed until opened by the detection of the next R wave. The blood oxygen saturation is calculated using the Ratio of Ratios.

9.6.2 Criticare® systems

The patient wears three standard ECG electrodes which provide the pulse oximeter with an ECG signal which if present is used to enhance the quality of the optical waveforms. The oximeter computes oxygen saturation from the enhanced waveform and displays it on a screen (Conlon *et al* 1990).

An ECG amplifier and an R-wave detection algorithm routine process the ECG signal provided by the electrodes and determine the timing for an ensemble averaging algorithm routine. An oxygen saturation value is calculated by a microcomputer in a calculation algorithm routine using the ensemble averaged waveform as input, and is then displayed digitally on a screen.

If an ECG signal is not present, the absence is detected by the R wave detection algorithm routine which causes the ensemble averaging routine to be bypassed and the unenhanced optical pulse to be input into the calculation algorithm routine. The microcomputer executes the software comprising the R wave detection, ensemble averaging, calculation, and display algorithm routines.

The three lead ECG signal is amplified by a differential amplifier. This amplifier amplifies the differential component of the signal, which is the desired ECG waveform, while rejecting a large portion of the common-mode voltage. The output of this amplifier is AC-coupled by a capacitor to an amplifier which provides further gain. The gain provided by the amplifier is adjustable and can be set to 1/2 or 2 by the microprocessor. The amplifier can also accept an additional

high level input which is intended to be connected to the output of an external ECG monitoring device, thus obviating the need for an additional set of ECG electrodes on the patient. The output of the amplifier is processed by a low-pass filter to remove the unwanted artifact such as 60 Hz and electrosurgery induced noise, and is converted to a serial, digital signal by an ADC. The digitized signal then passes through an optoisolator to a serial port which resides on the bus of the microcomputer. The optoisolator serves to isolate the patient ECG leads from the external power supply and is incorporated for reasons of patient safety.

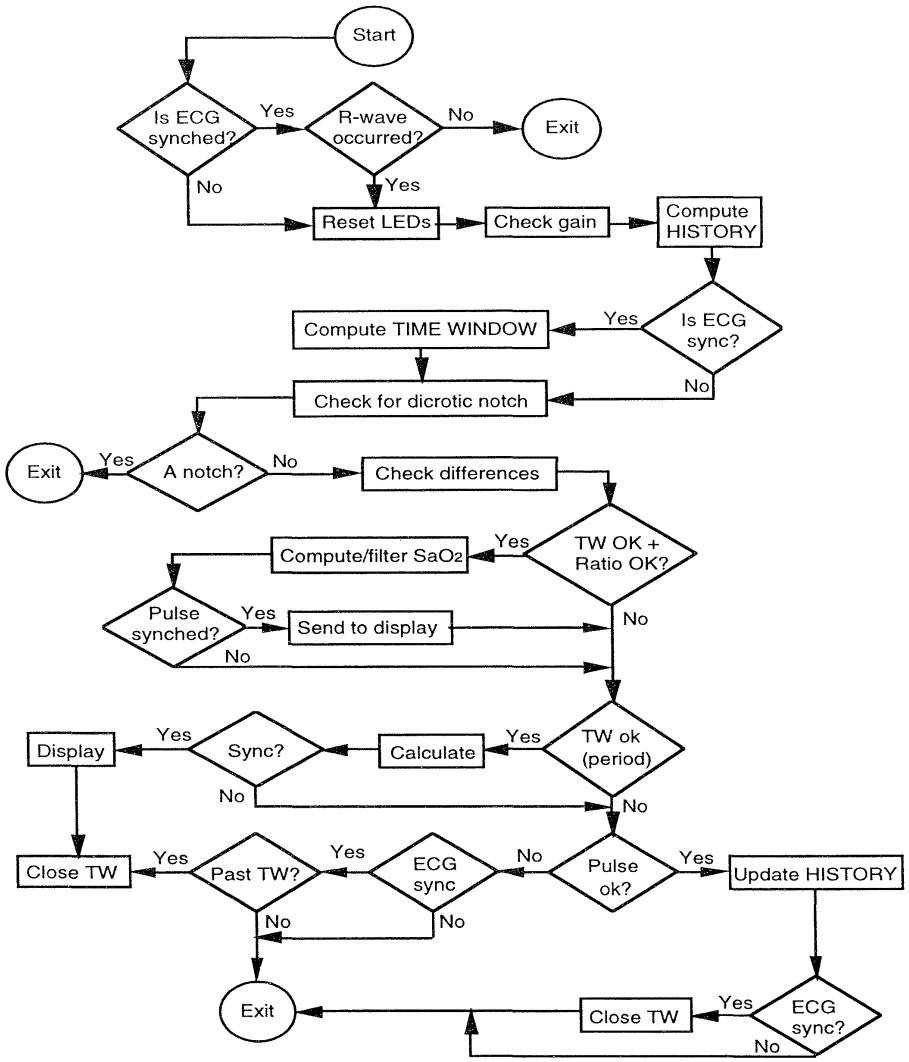

Figure 9.11. The LEVEL 3 software checks for ECG synchronization and processes the data appropriately to calculate the oxygen saturation (Goodman and Corenman 1990).

The oximeter is software driven and the operation of the software involves the process of removing motion artifact and enhancing waveform quality in low perfusion situations.

ECG synchronization is used to provide a reliable time frame upon which to base ensemble averaging, and a robust and accurate R wave detection algorithm is an integral part of the system. The R wave detection process involves three stages of processing: a low-pass digital filter, a peak excursion finding algorithm and a peak discrimination algorithm. The ECG input signal from the ADC is sampled at a rate of 240 Hz. The resulting digital waveform is low-pass filtered, with a corner frequency of 12 Hz, to remove artifact such as 60 Hz and muscle noise.

9.6.2.1 Peak excursion finding algorithm. The filtered ECG waveform then undergoes transformation by the *peak excursion finding algorithm*. The purpose of this transformation is to amplify those characteristics of the ECG waveform which are inherent in QRS complexes while inhibiting those which are not (Conlon *et al* 1990). This algorithm continually matches the ECG waveform to one of the two templates as shown in figure 9.12. The algorithm maintains a queue buffer of length N, which is searched in order to determine the parameters P1, P2, P3, and P4. The algorithm routine is called for $N = 8$, 12, 16, 20, and 24, and the individual excursion values are summed so as to give a total transformation value. More weight is placed on lower values of N in order to emphasize narrower spikes over wider ones. The newest sample is added to the buffer at each instant and the oldest sample is removed from the buffer. The maximum and the minimum values and their positions are searched in the buffer and depending on their relative positions, the matched template is chosen. The parameters P2 and P3 are assigned the appropriate maximum and minimum values accordingly. The parameters P1 and P4 are then found based on the template. For example, if the buffer matches template (a), the maximum value after P2 is assigned to P1, and the minimum before P3 is assigned to P4. Finally, the peak closed excursion on the interval N is computed as (P3 – P2 – (P4 – P1)) if the buffer matches template (a) or (P2 – P3 – (P1 – P4)) if the buffer matches template (b).

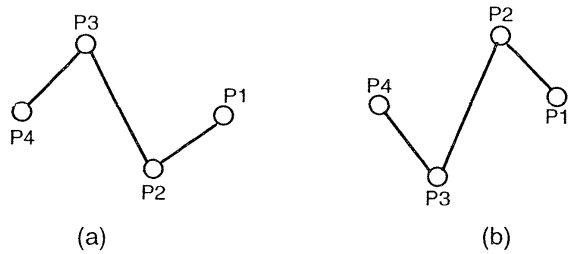

Figure 9.12. Two ECG waveform templates utilized in R-wave detection.

9.6.2.2 Peak discrimination algorithm. After transformation of the ECG waveform, the peak discrimination algorithm classifies the spikes found in the transformed waveform as either QRS complexes or artifact. The peak discrimination algorithm is a state machine with three states: peak, valley, and noise peak. The thresholds are set based upon the past history of the ECG waveform.

The algorithm enters the peak state if the algorithm is in the valley or noise state and exceeds a set threshold (threshold 2). The algorithm exits the peak state and enters the valley state when the waveform drops below one fourth of the maximum value attained in the peak state. The algorithm in valley state enters the

noise state whenever the waveform climbs above four times the minimum value attained during the valley state. The algorithm in noise state enters the valley state when the waveform drops half the distance between the maximum value attained during the noise state and the minimum during the previous valley state. The detection of QRS spike is signaled upon the transition into the peak state. The conditions for state changes are summarized in the table 9.1. The algorithm maintains an average of the last eight QRS peaks in order to set the threshold for detecting the next peak in the waveform. An average of the noise peak levels found between the last four QRS peaks, is also maintained to aid the rejection of artifact while accepting valid QRS spikes. The averages are updated whenever there is a transition between the peak and valley states.

Table 9.1 A summary of conditions for state changes.

Present state	Condition	Next state
Valley or Noise states	Exceeds a set threshold	Peak state
Peak state	< 1/4 max in peak state	Valley state
Valley state	> 4* min in valley state	Noise state
Noise state	< 1/2 (max in noise – min in previous valley)	Valley state

Additional rejection of artifact is gained by examining the length of time which has elapsed between a new peak and the last accepted peak (interval figure 9.15). If it is less than 5/8 of the previous R–R interval, the spike is assumed to be noise and is not counted as a QRS spike. If it is greater than 7/8 of the previous R–R interval, it is accepted unconditionally. If it is greater than 5/8, but less than 7/8 of the previous R–R interval, the spike is accepted on probation as long as it exceeds a second threshold (threshold 1) which is set based on the noise peaks encountered during the last four beats. It is counted as a valid QRS spike but the previous state information is also saved in order to undo acceptance of the spike if a better candidate is found. The probation interval is equal to 9/8 of the previous R–R interval minus the length of time which has elapsed since the last accepted peak. During this interval any spike which meets the threshold requirements overrides the acceptance of the spike in question.

When the algorithm is found to be in the peak state, the maximum value encountered in this state is noted. If the waveform is not a local maximum, the routine checks to see if the waveform has fallen to one fourth of the last local maximum. If it has, the routine determines whether the current peak is a noise peak or a QRS peak. If it was a noise peak, the average of the noise levels over the last four beats is calculated. If it was a QRS peak, the average of the last eight QRS peaks is updated using the local maximum. The threshold values needed to detect the next QRS peak are then determined. Threshold 1 is halfway between the current eight-beat peak average and the current four-beat noise average. Threshold 2 is one-half of the current eight beat peak average (figure 9.13).

Before exiting the peak discrimination algorithm, parameters reflecting the quality of the ECG waveform are tested. If the time elapsed since the spike was accepted exceeds four times the R–R interval and/or the baseline of the transformed signal exceeds one-half the peak value, the ECG waveform is assumed to be lost and the routine disengages the synchronization.

9.6.2.3 Ensemble averaging algorithm. The ensemble averaging algorithm makes use of the output of the R–wave peak discrimination algorithm to enhance that

part of the red and infrared plethysmographic waveforms which are correlated with the ECG, while diminishing all which is unrelated, to yield a signal with an improved signal to noise ratio (Conlon *et al* 1990).

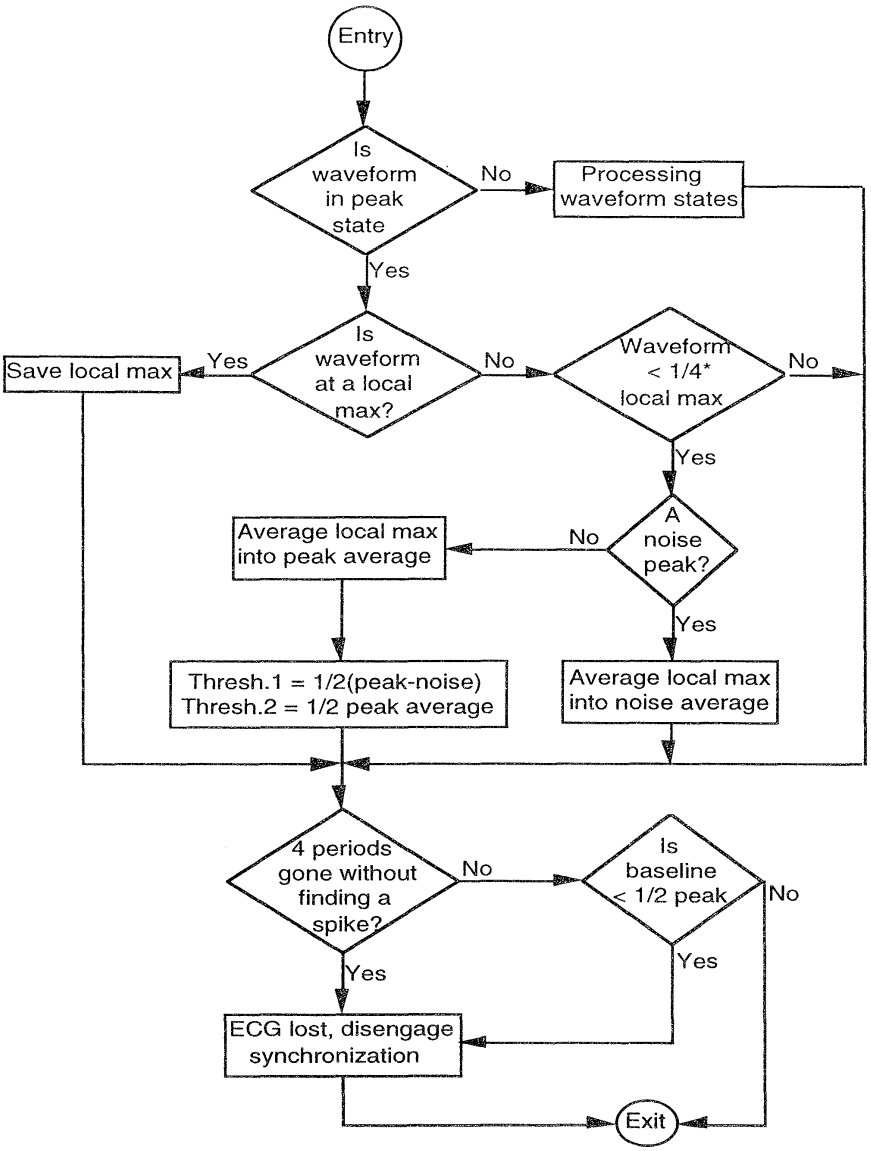

Figure 9.13. The R wave peak discrimination algorithm (Conlon *et al* 1990).

The algorithm relies on the assumption that instances of moderate to severe motion, and of low perfusion, can be detected as the plethysmographic waveforms are being sampled (figure 9.14). To do this, it was found to be advantageous to buffer these waveforms while they are being sampled, and to delay the actual averaging until the R peak is detected. The averaging weight of the current waveform cycle can then be adjusted, depending on whether the plethysmographic waveform just acquired is weak or exhibits the influence of

excessive motion artifact. An additional benefit of this buffering stage is that the oximeter is able to discard waveform pulses during which optical pulse processing circuitry has saturated and distorted the waveform. Yet another benefit of this buffering stage is that it allows a level of error tolerance in the R wave detection process whereby the peak_discrimination routine can accept certain marginal QRS spikes on probation while maintaining the flexibility to correct the error if a better candidate is subsequently detected (figure 9.15).

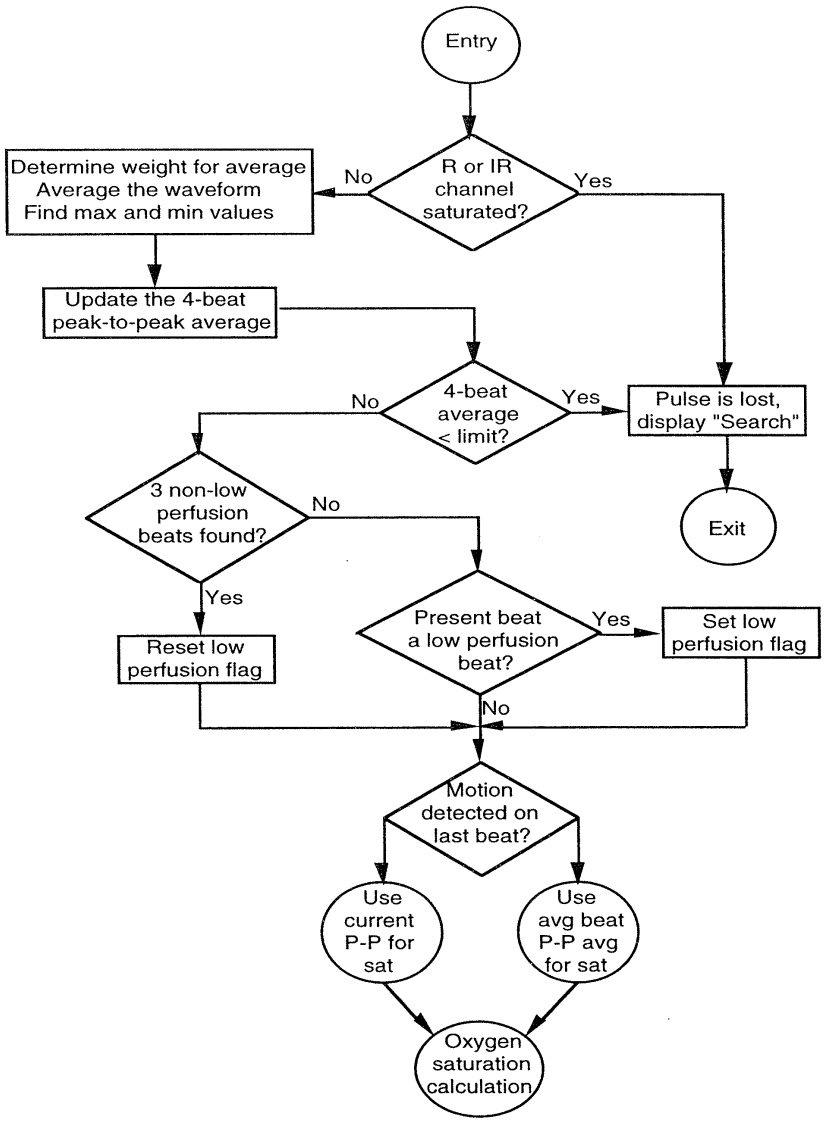

Figure 9.14. The ensemble averaging algorithm (Conlon *et al* 1990).

9.6.2.4 Motion determination algorithm. In order to give less weight to waveform pulses which are distorted by motion artifact, a criterion by which motion can be measured is established. This routine assumes that a plethysmograph unaffected by motion varies only slightly between one pulse and

the next. In addition, a change in the amplitude, not shape, of the pulse comprises the majority of the observed difference between one pulse and the next. A plethysmograph containing artifact, however, differs greatly from the previous signal. A point-by-point subtraction of the latest pulse from the one preceding it yields a signal with an average amplitude less than that of the signal. The value of the difference signal is more or less constant while the signal itself changes rapidly. The integration of the difference signal yields a good indication of the amount of motion present in the pulse. A noisy signal yields a large value on integration compared to a clean signal. This routine checks for the occurrence of an R-wave spike which would be detected by the R-wave detection algorithm. If a spike was detected, the routine saves the integrated value as an indication of the level of motion present in the pulse, and initializes the variables to prepare for the next pulse (Conlon *et al* 1990).

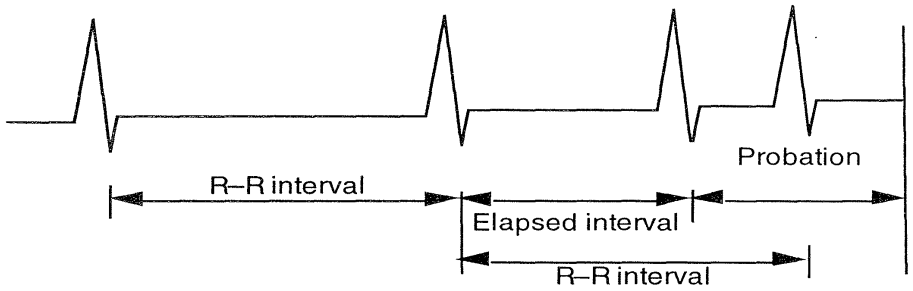

Figure 9.15. R wave artifact rejection timing subroutine (Conlon *et al* 1990).

9.6.2.5 Pulsatile waveform weight determination algorithm. It is generally known that ensemble averaging with a set of N waveforms increases signal-to-noise ratio by a factor of the $\sqrt{N}$ for uncorrelated, random noise. Thus, ensemble averaging will decrease the influence of the uncorrelated motion artifact and will enhance a low perfusion signal (which may be buried in noise) at the expense of response time. At the same time, a maximum limit on response time is set in order to ensure that the displayed saturation value is reasonably current (Conlon et al 1990).

The variable weight average is used in order to provide flexibility over a broad spectrum of pulsatile waveforms. It attempts to give a large weight to waves which are largely motion-free, while diminishing the weight given to those which have motion. Additionally, if a low perfusion situation is detected, less weight is given to all pulses until several strong pulses are found. Furthermore, the algorithm takes into account the pulse rate when determining the averaging weight. Since the averaging occurs each time a beat is detected, more averaging can be used on a patient with a fast pulse rate than one with a slow pulse rate while maintaining a constant response time. More averaging is needed in cases of motion artifact and low perfusion because the signal-to-noise ratio of these pulses is less than normal pulses (figure 9.16).

The weight determination algorithm uses two empirically determined thresholds to determine whether the motion is significant. One of these thresholds applies during the normal perfusion, while the other is used in cases of low perfusion. The algorithm decides which of the two thresholds to use by checking for the low perfusion state. If the low perfusion has not been detected, the

algorithm checks the motion against the high motion threshold. If significant motion is not found, the algorithm checks whether the heart rate is above 120 bpm. If it is, the beat is assigned an average weight of 1/8, otherwise an average weight of 1/4. If significant motion is found, the algorithm checks for the heart rate and if it is above 120 bpm, assigns an average weight of 1/16. Further, if the heart rate is below 60 bpm, the algorithm assigns an average weight of 1/8.

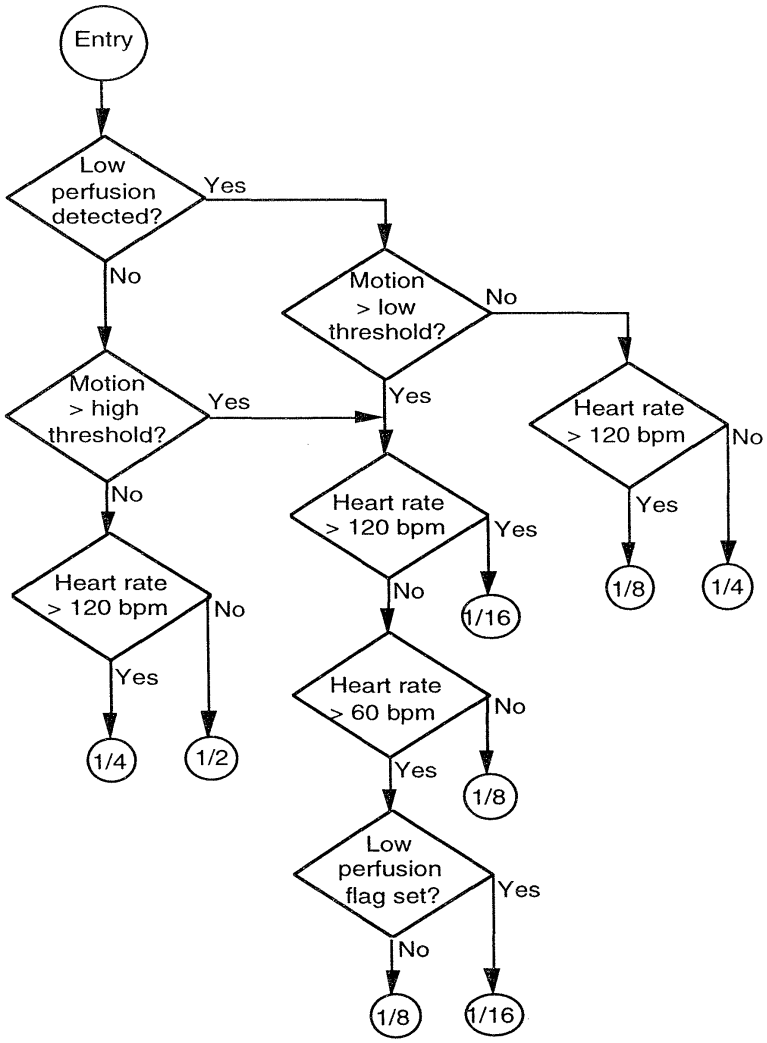

Figure 9.16. The weight determination algorithm (Conlon *et al* 1990).

If the heart rate is above 60 bpm and less than 120 bpm, the software has to differentiate between low perfusion with motion and motion alone. The algorithm checks the low perfusion flag and if set, assigns an average weight of 1/16, otherwise it assigns a weight of 1/8. The ensemble_averaging routine employs the

weight determination algorithm to find the average weight of the waveform and averages the buffered waveform with the composite averaged waveform stored in the microcomputer memory using a tail-weight average of the form (W × NEW) + (1 − W) × COMPOSITE, with W being the averaging weight. Because the averaged pulses are of varying duration, some pulses will overlay more points of the averaged waveform than others. Thus, the tail of the averaged waveform may not accurately reflect the most recent plethysmographic information. Hence the minimum and maximum of the averaged waveform were found only up to the minimum length of the last eight pulses. After determining the minimum and maximum values, the four beat average of peak-to-peak values are updated.

The algorithm then checks to ensure that the average has not fallen below the minimum low perfusion threshold. If it has, the pulse is considered lost. Then the algorithm checks if three non-low perfusion beats have been found. If so, it resets the low perfusion flag. If not, it checks if the current beat is a low perfusion beat, setting the perfusion flag appropriately. The algorithm then checks for motion in the last beat. If there is motion, it sends the four-beat, peak-to-peak average to the saturation_calculation algorithm routine. Otherwise, the last peak-to-peak value of the routine is sent to the saturation_calculation algorithm which calculates the oxygen saturation and displays it.

9.7 SPECTRAL METHODS OF ESTIMATING S_pO_2

Arterial oxyhemoglobin saturation (S_pO_2) values are currently computed using weighted moving average (WMA) techniques (Rusch *et al* 1994). These methods process the time domain signals and give a precision of no better than ± 2% (± one standard deviation). Researchers have explored other digital signal processing algorithms for improved estimation of S_pO_2. The fast Fourier transform (FFT) and discrete cosine transform (DCT) were identified as potentially superior algorithms (Rusch *et al* 1994) and useful to optimize the portability of pulse oximetry systems. Preliminary studies indicate that a 64-point FFT, with a 15 Hz sample rate, over a data collection period of 4.3 s was found to be the optimal combination for pulse oximetry applications, minimizing hardware expense, footprint, and power consumption. S_pO_2 values were calculated from a transform size of 64 points using

$$S_pO_2 = 110 - 25 \times R \tag{9.36}$$

where R is the ratio of the red and infrared normalized transmitted light intensity. The R value is

$$R = \frac{AC_R/DC_R}{AC_{IR}/DC_{IR}}. \tag{9.37}$$

The AC component is the signal variation at the cardiac frequency and the DC component is the average overall transmitted light intensity. The AC component is selected as the highest spectral line in the cardiac frequency band.

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INSTRUCTIONAL OBJECTIVES

9.1. Name the general sources of error that could be corrected with signal processing algorithms.
9.2. Explain the process of eliminating incident light intensity and thickness of the path as variables from Beer–Lambert law.
9.3. How is R_{OS} (Ratio of Ratios) estimated from the red and infrared optical signals?
9.4. Discuss the advantages of estimating R_{OS} using the derivative method over the peak and valley method. Explain how noise reduction is achieved using the derivative method.
9.5. Discuss the role of the construction–reconstruction process in improving the accuracy of S_aO_2 estimation.
9.6. Explain the function of the start-up interrupts.
9.7. Discuss the function of the five different states in the period zero subroutine.
9.8. Discuss the C-Lock ECG synchronization algorithm used in Nellcor®.
9.9. Explain the motion detection algorithm used in Criticare.
9.10. Name the advantages of using spectral methods in estimating oxygen saturation.
9.11. Explain the advantages of using ECG synchronization.

CHAPTER 10

CALIBRATION

Jeffrey S Schowalter

The calibration curves of *R* (Ratio of Ratios) values used to calculate oxygen saturation levels are critical to the accuracy of the entire pulse oximeter system. Without an accurate table of appropriate *R* values, the pulse oximeter has no way of determining oxygen saturation levels. As such, it is important to understand how the pulse oximeter calibration curve data are acquired. In addition, it is important to understand some of the past and present simulation techniques used to test the accuracy and functionality of pulse oximeters.

10.1 CALIBRATION METHODS

Chapter 4 states that Beer's law does not apply for a pulse oximetry system due to the scattering effects of blood. Therefore, pulse oximeter manufacturers are currently forced to use an empirical method of determining the percentage of arterial oxygen saturation for a given *R* ratio.

10.1.1 Traditional in vivo calibration

The traditional method of pulse oximeter calibration involves comparison of oximeter *R* value to the oxygen saturation ratio obtained from *in vivo* samples using human test subjects. In fact, this was the only method used to calibrate these devices up until 1993 (Moyle 1994). Although this method requires a variety of laboratory instrumentation and is typically done in a hospital setting, this data collection process is only required during the design and development of the device.

10.1.1.1 Procedure. In general, the calibration procedure is fairly straightforward. Test subjects are fitted with an indwelling arterial cannula, which is placed in the radial artery. A sample of blood is taken and analyzed with a CO-oximeter (see chapter 3) to determine the subject's levels of COHb and MetHb. In most cases, samples are taken over a broad population. Typically, data come from nonsmokers with background carboxyhemoglobin levels between 1% and 2%. Wukitsch *et al* (1988) mentions that subjects used for the Ohmeda Biox 3700 calibration had an average COHb level of 1.6% and a MetHb level of 0.4%.

Once a low level of COHb and MetHb are verified, the subject is also fitted with one or more pulse oximeter probes. The test begins by first ensuring that the subject is at the 100% oxygen saturation level. The subject breathes an oxygen/air mix so as to bring the arterial oxygen saturation level to 100% (as determined from arterial blood analyzed with the CO-oximeter). Oxygen saturation level is incrementally decreased by breathing gas mixtures of progressively less oxygen and more nitrogen. At each level where the pulse oximeter indicates a stable reading, an arterial blood sample is immediately taken and analyzed with the CO-oximeter. Corresponding readings are recorded and the data are then plotted with oxygen saturation percentage (as determined by the CO-oximeter) on the y-axis and R ratio (as determined by the pulse oximeter under test) on the x-axis yielding a traditional R curve as shown in figure 4.7. Typical values for the R ratio vary from 0.4 to 3.4 (Pologe 1989). A best fit calibration equation is then calculated from the data. If the pulse oximeter manufacturer has selected LEDs for their probes that have relatively narrow bands of center wavelength (as discussed in chapter 5), then only one curve is required. If they have a number of probes with differing red and infrared center wavelengths, then each probe with unique LED combination must be tested to obtain its unique curve characteristics. Some manufacturers have as many as 30 different probes.

10.1.1.2 Problems. One of the problems with this traditional method is the limited range of oxygen saturation that can be acquired. Ethical issues prevent intentional desaturation of healthy subjects below a certain point due to risk of hypoxic brain damage. As a result, saturation levels can only be reduced to around 60%. This leaves a large range of values on the curve that need to be calculated by extrapolation. This has the potential to induce errors and in fact, Severinghaus *et al* (1989) tested 14 pulse oximeter models and showed that most pulse oximeters performed poorly under relatively low levels of saturation (see chapter 11). Another problem of this calibration method is that it does not address the spacing and number of data points needed to build a curve. Moyle (1994) states that well spaced data points over the entire range from 100% down to 80% is more accurate than having many data points clustered between 95% and 100%.

There has been a great deal of debate over the years as to what the pulse oximeter is actually measuring and as such, a unique term has been created to specify an oxygen saturation reading as determined by a pulse oximeter. The problem is that the pulse oximeter uses two wavelengths to measure oxygen saturation. However, there are four common species of hemoglobin (Hb, HbO_2, COHb, and MetHb). Since there are routinely four light absorbing substances in a sample in a system which is assuming it is measuring only two substances, much discussion and misconception arise as to what the pulse oximeter is actually measuring (Pologe 1989). Equation (4.5) shows that functional S_aO_2 is the ratio of oxygenated hemoglobin to the sum of oxygenated and reduced hemoglobin. If a person were found that had no COHb or MetHb, this is what the pulse oximeter would measure. However, since some COHb and MetHb are typically present in everyone's blood, and these terms show up in the fractional S_aO_2 formula, it is easy to assume that the pulse oximeter is measuring fractional S_aO_2. However, this is not the case either. Moyle (1994) state that the conventional two-wavelength oximeter measures what should be defined as 'oxygen saturation as measured by a pulse oximeter', or S_pO_2.

Payne and Severinghaus (1986, p 47) state that the pulse oximeter reports

$$\frac{HbO_2 + COHb + MetHb}{HbO_2 + COHb + MetHb + Hb} \times 100\% \qquad (10.1)$$

and subtracting this quantity from 100% gives the percentage of reduced hemoglobin or Hb%. He suggests that to eliminate confusion pulse oximeters should display this value instead. If this were done, however, conventional thinking would have to change because readings would increase from zero as opposed to S_pO_2 readings which decrease currently from 100. The bottom line is that COHb and MetHb do have an effect on the accuracy of pulse oximeter readings (Reynolds *et al* 1993a,b) so they cannot be ignored as part of the calibration process.

10.1.1.3 Effects of COHb and MetHb. The effects of COHb and MetHb are typically handled in one of two ways. Some manufacturers subtract 2% for these factors so they are displaying fractional saturation (assuming a patient with nominal levels of COHb and MetHb) and others do not subtract this factor so they are displaying functional saturation (Ackerman and Weith 1995).

In a sense, the pulse oximeter will measure what it has been calibrated to measure based on the test subject profile. Tremper (Payne and Severinghaus 1986) states that Nellcor calibration data were originally based on five Olympic athletes in virtually perfect physical condition. These individuals probably had as low levels of COHb and MetHb as are found in humans. As such, anyone being tested with higher (normal) levels of COHb and MetHb yielded inaccurate readings. Today, by using a more representative subject to build the calibration curve, pulse oximeter manufacturers account for some of this during the calibration process. However, individuals with relatively high levels of COHb and MetHb will have inaccurate S_pO_2 readings.

10.1.1.4 Field calibration. Another issue of concern is field calibration. Using this technique, once the R curves are established, the transmitting wavelengths of the LEDs and corresponding R curve are provided via a coding resistor (see chapter 5) and as such only a two-point check to verify the correctly selected calibration curve is required. Typically this check will identify a problem due to a malfunctioning LED or photodiode or an incorrect coding resistor. However, other than this cursory check there is no type of field calibration done on the pulse oximeter. Cheung *et al* (1993) have proposed a system for compensating for the effects of temperature variations on the LEDs. Since the pulse oximeter photodiode cannot detect a shift in LED wavelength, the proposed system provides the capability for the temperature of the probe LEDs to be measured and thus an alternative calibration curve, as shown in figure 10.1, can be used for the new set of LED wavelengths. This system seems to be of limited usefulness however, since Reynolds *et al* (1991) have shown that the peak wavelength of a red LED will only shift by 5.5 nm and an infrared LED will shift by 7.8 nm with a temperature shift from 0 °C to 50 °C. Applying this information to a theoretical computer model based on Beer's law, causes negligible changes in accuracy of the pulse oximeter.

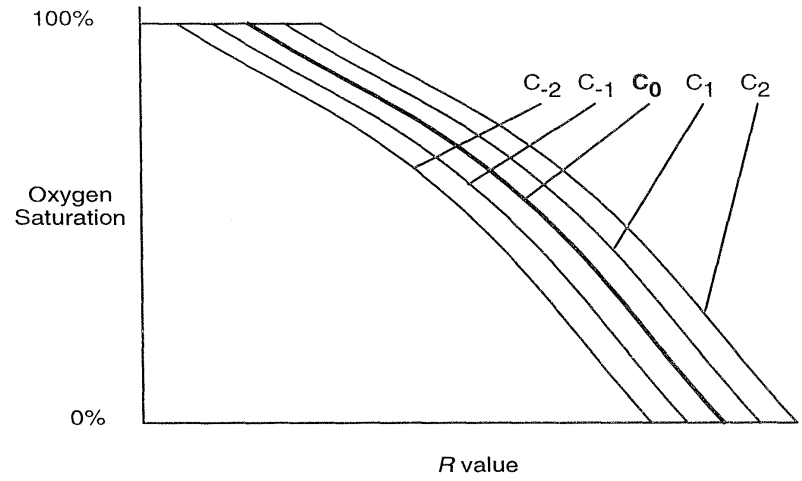

Figure 10.1 Temperature compensation curves as proposed by Cheung *et al* (1993). C values indicate different curves for use with different sensed temperatures.

10.1.2 In vitro calibration using blood

Figure 10.2 shows an *in vitro* test system that requires whole blood (Reynolds *et al* 1992). Blood is pumped through a cuvette acting as a model finger. The pulse oximeter probe is then attached to the model finger. Blood is pulsed within the system using a computer controlled peristaltic pump head capable of generating almost any shape of pulsatile waveform. Blood is oxygenated by passing through a membrane oxygenator using a gas mixture of O_2, N_2, and CO_2. The composition of the gas mixture passing through the membrane oxygenator is controlled with a gas mixing pump. A variety of model fingers were tried with the final model finger consisting of a cuvette made of two thin (0.5 mm) silicone rubber membranes and a rigid Plexiglas central section. When using whole blood, the model finger is covered with a diffuser made from translucent paper. Blood enters one end of the cuvette and flows in a thin (1 mm) layer through the cuvette over the fingertip end and back along the bottom side. Both inlet and outlet are tapered to prevent flow separation. The silicone rubber membrane is flexible enough such that pulsating blood produced volume changes in the tubes giving an AC/DC ratio in the physiological range. Readings from the pulse oximeter are recorded and a simultaneous sample taken from the sample port and analyzed by the CO-oximeter in a similar fashion to the procedure described in section 10.1.1. This system yields calibration values that are accurate to 50% and lower. Most pulse oximeters have no specified accuracy below 50%. One problem is that the system is sensitive to blood flow rate, due to changes in blood cell orientation with flow. This was verified using a hemoglobin solution instead of whole blood in the test system.

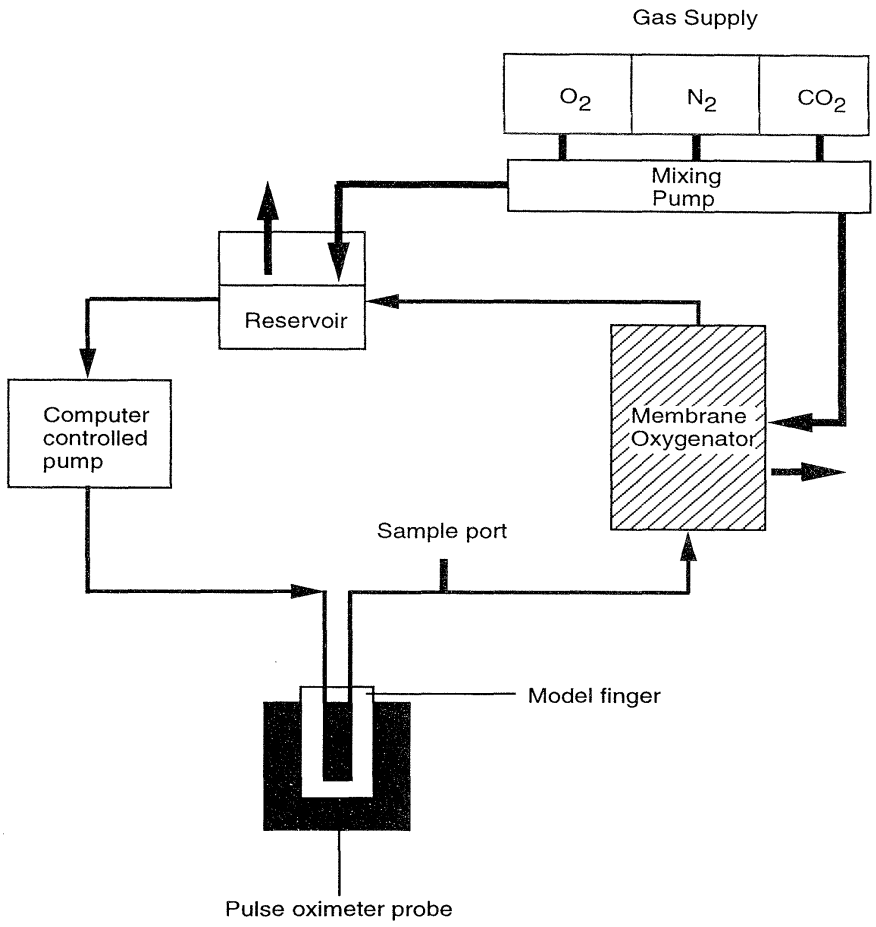

Figure 10.2 Block diagram of *in vitro* test system developed by Reynolds *et al* (1992).

10.2 TESTING SIMULATORS

Devices which check the functionality of pulse oximeters are becoming increasingly popular. Many of these devices use some type of artificial finger to verify that the pulse oximeter is functioning correctly. When pulse oximeters first came out, the only way technicians had to verify the functionality of the pulse oximeter was to use their own fingers. This, however, only indicates basic functionality at best with no way to control any parameters and with nothing with which to compare. Several devices have been developed that simulate the optical properties of the human finger and its pulsatile blood flow. In addition, optoelectronic systems, which simulate the human finger electronically, have also been developed. Finally, pulse oximeter manufacturers themselves have developed simple simulators that essentially simulate a probe's electron signals.

10.2.1 Simulators using blood

Several simulators have been proposed that need whole blood to test the functionality of the pulse oximeter. These simulators are all based on the concept of being able to simulate the absorbance of human tissue (normally the finger) between the LEDs and the photodiode of the pulse oximeter under test. Since few substances have been found that simulate the optical properties of blood, these types of systems typically provide the most accurate simulation.

10.2.1.1 Reynolds system. The system described in section 10.1.2 functions equally well as a simulator to test the functionality of pulse oximeters. In fact this system has been used to compare ten commercially available oximeters (Reynolds *et al* 1992), and has been used to evaluate the effects of dyshemoglobins on pulse oximeter accuracy (Reynolds *et al* 1993a,b). However, this *in vitro* test system is not practical in a hospital setting where most pulse oximeters are used. The system requires a laboratory setting, is not portable, uses oxygenated whole blood and needs a CO-oximeter for comparison. However, this instrument is generally considered the *gold standard* for calibrating and testing a pulse oximeter over its complete range.

10.2.1.2 Vegfors system. The Vegfors system is similar to the Reynolds system but with a focus on the artificial finger or 'finger phantom' used. Vegfors *et al* (1993) describe a system where their artificial fingers consist of silicone rubber tubes inserted in plastic Delrin cubes. The tubing system chosen was based on its characteristics of tubing diameter, wall elasticity, and blood flow velocity to simulate normal physiological characteristics of blood in motion. Delrin was used because it has similar optical scattering properties to human tissue. Figure 10.3 shows three models. Two different finger models, one with one tube and another with five tubes were tested along with a third artificial finger consisting of 15 silicone rubber tubes mounted in silicone rubber in the form of glue. The object was to develop an optical model which simulated the arterial bed of the human finger containing blood vessels and surrounding tissue. The results of these different finger configurations determined that physical dimensions of the artificial bed are of minor significance for pulse oximeter readings.

10.2.1.3 Single wedge system. Several other less complicated simulators using whole blood have been proposed. In one system, proposed by Yount (1989), a light-absorbing wedge shaped vessel containing blood of known oxygen saturation level is placed in the pulse oximeter's optical path. If the wedge (figure 10.4) is moved repetitively back and forth perpendicular to this optical path, either manually or with the aid of a mechanical device, both the pulse rate and shape of the pulse can be altered. Pulse rate can be simulated by changing the frequency at which the wedge is moved across the optical path. The shape of the pulse can be changed by altering the speed at which the wedge is moving.

10.2.1.4 Dual wedge system. In another arrangement of the system, two wedges are used. One is filled with 100% oxygen saturated blood and the other with completely unsaturated blood. The wedges are placed as shown in figure 10.5 and by varying the position along the optical path of this arrangement, virtually any saturation level can be obtained. Note however that with this second arrangement,

an additional external device is needed to obtain a pulsatile variation in the simulator. figure 10.6 shows the polarization filter system proposed by Yount (1989) to achieve this pulsatile variation needed. A pair of polarizing disks simulate the changes in transmittance expected by the pulse oximeter. A stepper motor controls the motion of one disk. This changes the angle of polarization between the two disks, and therefore the amount of light transmitted. By varying the rate of angle change, this system can simulate both the shape and pulse rate seen by the pulse oximeter. This particular system also has several glass windows. This allows for multiple samples to be loaded on the same disk so different oxygen saturation levels can be simulated by rotating the appropriate sample into the probe.

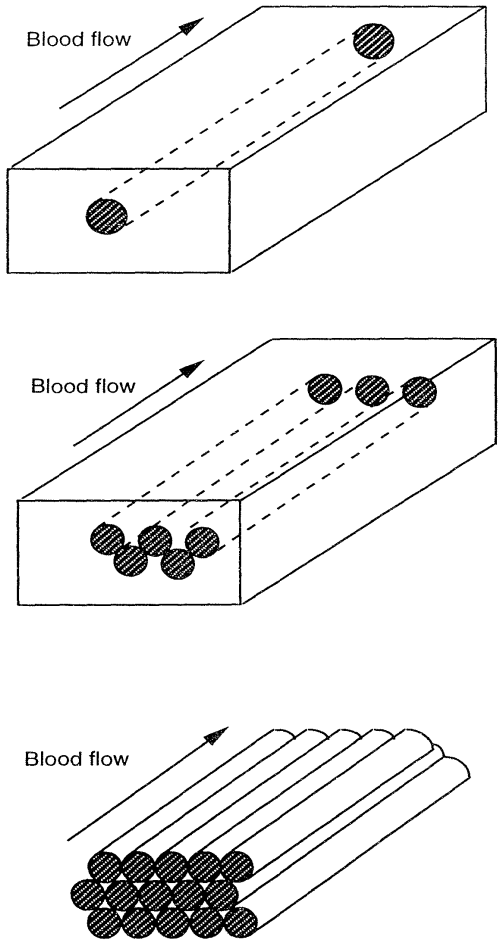

Figure 10.3 Block diagram of various artificial fingers as proposed by Vegfors *et al* (1993).

One limitation of these wedge systems is that if blood is used as the medium in the wedge, the samples either need to be prepared shortly before use or steps need to be taken to stabilize the blood.

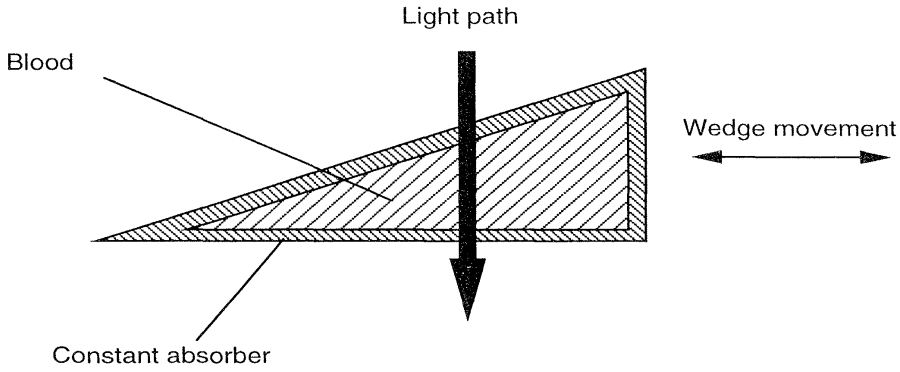

Figure 10.4 Block diagram of a wedge system as proposed by Yount (1989).

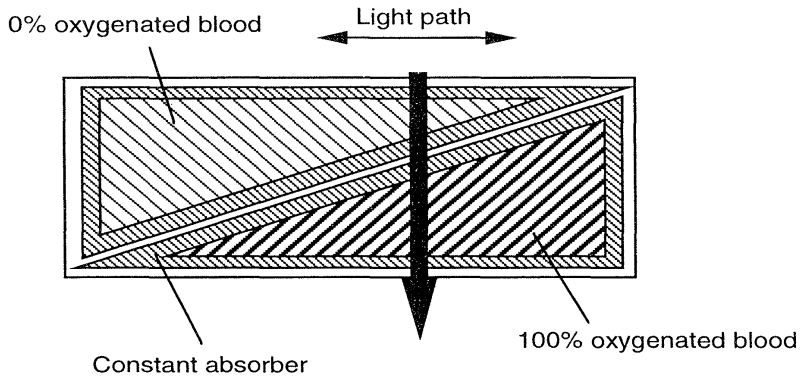

Figure 10.5 Block diagram of the dual wedge system as proposed by Yount (1989).

10.2.1.5 Bulb device. Volgyesi (1989) proposed a simple mechanical design to simulate a pulsing finger. Figure 10.7 shows the tube and bulb type device. It requires a 0.5 to 1 mL blood sample for each saturation level to be tested. A piece of silicone rubber tubing is placed inside a disposable plastic test tube which contains a blood specimen. The operator then manually squeezes the bulb at regular intervals which causes the silicone rubber tubing and the blood in the annular space between the silicone rubber tubing and the test tube to deform or *pulse*. Samples of heparinized blood are externally altered to different saturation levels so different levels of oxygen saturation can be tested. With a variety of oxygen saturation level samples prepared in individual test tubes, the pulse oximeter can be applied to the device. After the operator is able to rhythmically squeeze the bulb for a consistent plethysmograph (rate and amplitude), a reading is recorded from the pulse oximeter and the sample is sent to a CO-oximeter for a comparison reading. The main advantage of this system is its simple implementation. The disadvantage is that the pulsatile nature of the system is operator dependent and samples of known oxygen saturation levels of blood need to be prepared.

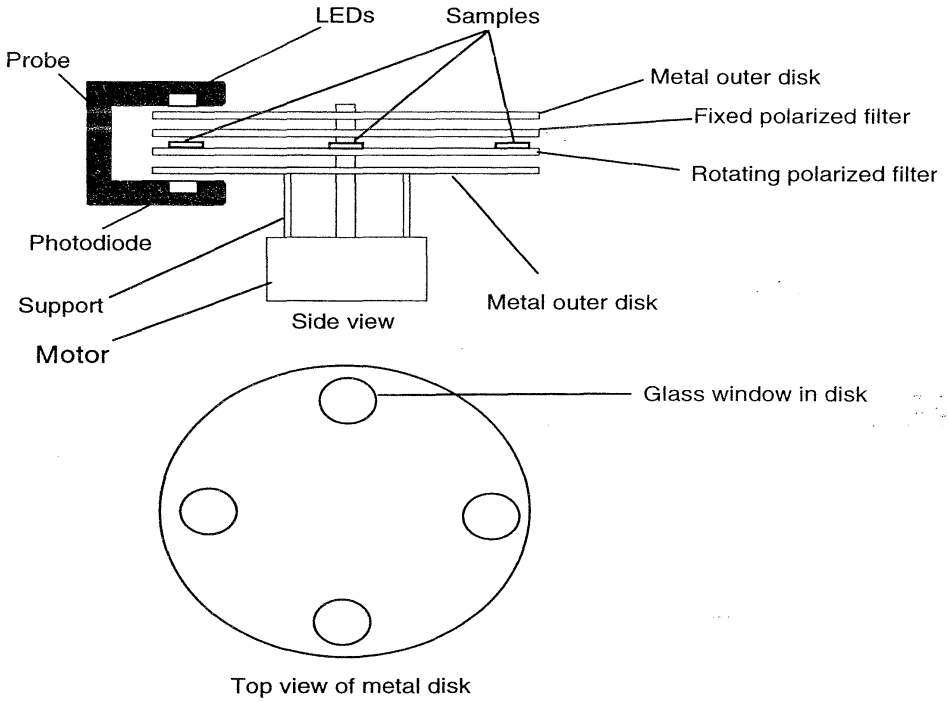

Figure 10.6 Schematic diagram of polarization system (adapted from Yount 1989).

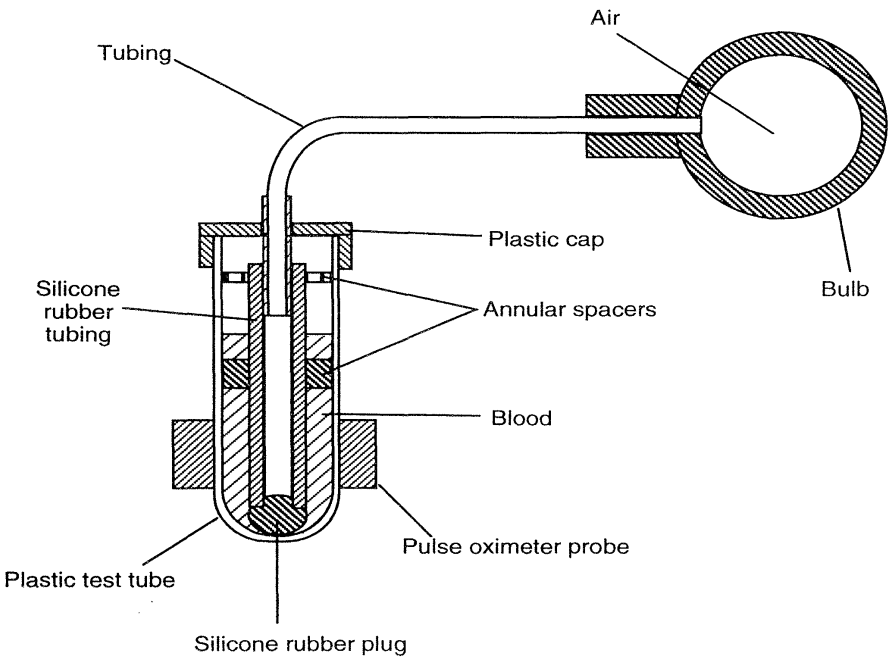

Figure 10.7 Block diagram of tube and bulb device.

10.2.2 Nonblood simulators

Nonblood simulators, like simulators that use blood, are also based on the concept of being able to simulate the absorbance of human tissue (normally the finger) between the LEDs and the photodiode of the pulse oximeter under test. These devices use colored materials to simulate blood. These simulators use a variety of mechanical and electrical devices to achieve the desired variations in absorbance. The more difficult aspect is simulating the scattering properties of whole blood. One of the most successful studies in this area (Marble *et al* 1994) used a combination of nondairy creamer mixed with solutions of red and green dye.

10.2.2.1 Bulb device. The bulb device described in section 10.2.1 above can also be used with liquids having differing optical absorbance properties corresponding to oxyhemoglobin. A commercial version of this device is currently being marketed by Nonin under the trade name *finger phantom*. This product (Nonin 1995) provides three translucent white *artificial fingers* that simulate arterial blood at nominally 80%, 90%, and 97% saturation levels. The operator gently presses the finger phantom about once every second to generate a pulse. The typical infrared percent modulation when squeezed is 0 to 5%.

10.2.2.2 Wedge device. The wedge device described in section 10.2.1 above can also be used with liquids other than blood having optical absorbance properties corresponding to those of the human finger.

10.2.2.3 Polyester resin device. Figure 10.8 shows a simple test object proposed by Munley *et al* (1989). This device consists of a piece of polyester resin that is formed in the shape of a finger. The resin is adapted to allow a core to be placed inside the artificial finger. At the end of the core, in the area exposed to the pulse oximeter LED's light path, a slotted piece of suitably colored Plexiglas is placed. As the device handle is rotated, the slot allows varying levels of LED light to reach the pulse oximeter photodiode. Speed of rotation of the crank will determine the *pulse rate* that the oximeter reads. Changing the color characteristics of Plexiglas will change the oxygen saturation reading that the pulse oximeter registers. This device was also shown to produce similar oxygen saturation readings among multiple devices of the same make and model of pulse oximeter.

10.2.2.4 Colored colloid simulator. Leuthner (1994) proposed the pulse oximeter development system shown in figure 10.9. A transparent bag is filled with a colored colloid solution. The color determines the extinction coefficients at the two wavelengths of interest. This system uses a water–gelatin mix which is heated and colored with red and black ink. To simulate different oxygen saturation levels, multiple bags with varying ratios of red and black dye need to be prepared. The bag is positioned between two acrylic disks. The disks and bag are then rotated by a stepper motor under microcontroller control. With this configuration, both the DC and AC absorbance ratio can be adjusted. Increasing the angle between the two plates increases change of absorbance over each rotation for an increase in relative AC signal. The simulated pulse shape is determined by speed of the disk rotation and the pulse rate is determined by the rotation frequency. A constant absorber material is placed on top of the disk to simulate the constant light absorbance of fingers of different people. In practice,

it can vary by a factor of four. Generally a piece of white paper of varying thickness is used as the constant absorber. Two optic fibers are integrated into an artificial finger which then plugs into the finger probe of the pulse oximeter. The other ends of fibers are connected opposite each other near the rotating plates. If testing is done using different waveforms, the angular velocity of the rotation has to change and as such is controlled through the stepper motor via microcontroller control. The whole system is enclosed in a box to prevent disturbances from ambient light.

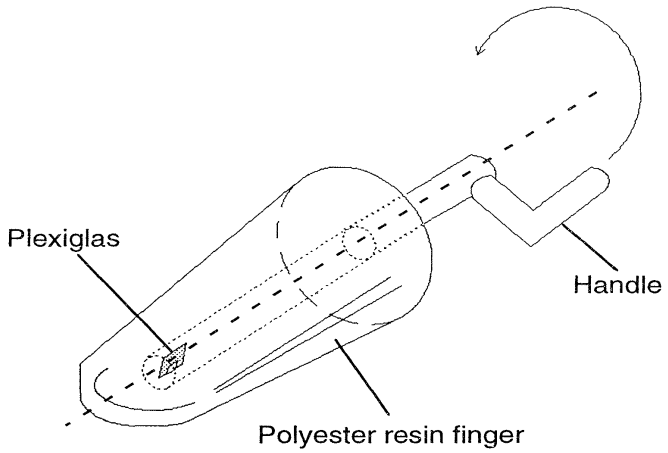

Figure 10.8 Polyester resin system proposed by Munley et al (1989).

The physical behavior of this system can be almost totally described using Beer's law, but the system cannot be used for finding the calibration table of a pulse oximeter. The main reason is that the scattering effect in whole blood is not present in this system. However this system can be used for a rough calibration table of a new instrument and to test an existing pulse oximeter for the response it gives when different colored bags are used.

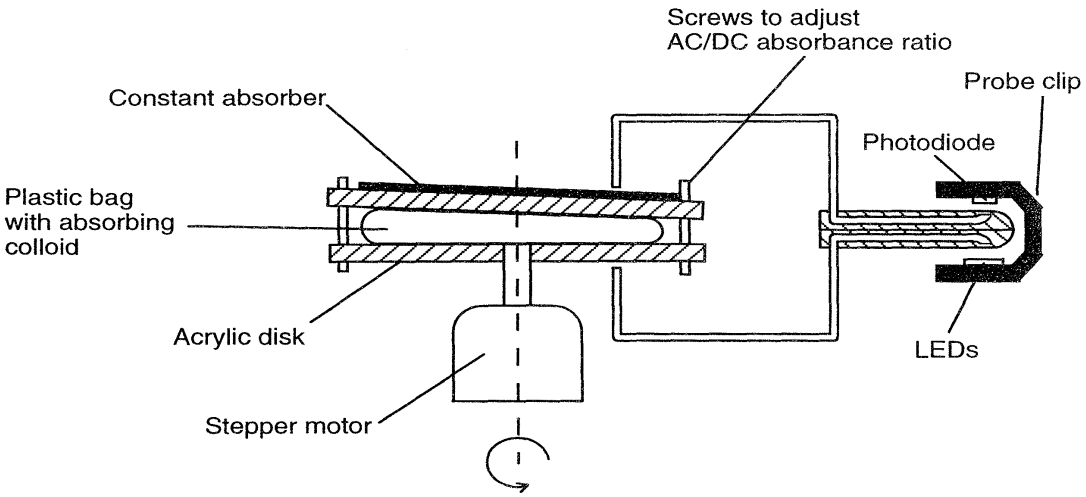

Figure 10.9 Leuthner's (1994) colored colloid disk system.

10.2.2.5 Liquid crystal retarder simulator. Zhou *et al* (1992) developed a device for generating test signals for pulse oximeters based on a voltage-controlled liquid-crystal light valve. In the first system, the pulse oximeter's LEDs are separated by an optical filter, modulated by a light valve, and recombined before detection by the probe's photodiode. The newer system does not require wavelength separation and its associated hardware as shown in figure 10.10. The transmittance characteristics are varied by taking advantage of the intrinsic wavelength dependence of a twisted-nematic liquid-crystal retarder (LCR). Polarizers are used to generate optical density variations that can be made to resemble blood perfused tissue. The intensity transmitted through the optical system can be adjusted by varying the voltage on the LCR. To simulate a pulsatile change in transmittance, the attenuation is initially made a constant DC value. A small AC voltage is then superimposed on top of the DC voltage to provide a pulsatile component. The transmittance at both the red and IR wavelengths varies depending on the voltage amplitude applied to the LCR. This allows the AC/DC ratios to be controlled by adjusting the amplitude of the voltage applied to the LCR. The polarizers are required because the angle of polarization strongly affects the range of variation of the red/IR ratio and its sensitivity to the applied voltage. Zhou *et al* are continuing work on this concept to provide the capability of simulating the shape of the plethysmographic waveform applied to the LCR.

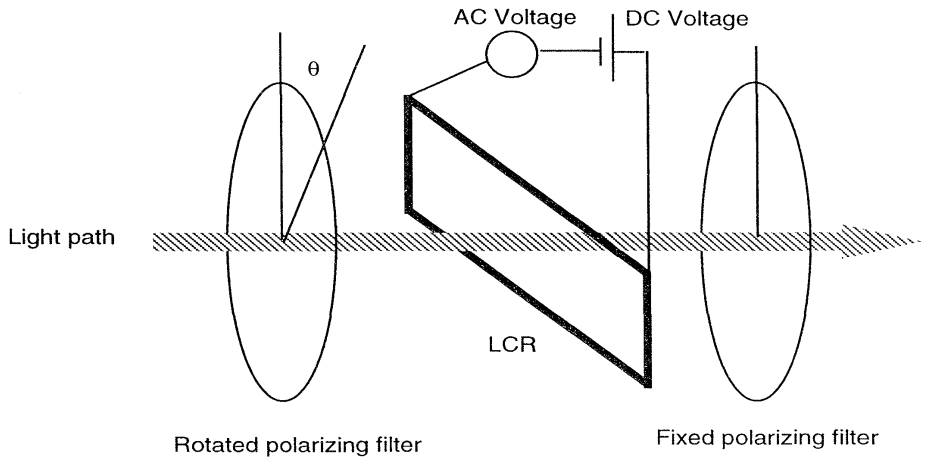

Figure 10.10 Diagram of the liquid crystal retarder (LCR) system proposed by Zhou *et al* (1992).

10.2.2.6 Aoyagi tissue model. A device based on the same general principles as the wedge system been proposed by Aoyagi *et al* (1994). Figure 10.11 shows that a static tissue model having absorption characteristics similar to a human finger is inserted into a pulse oximeter probe. A blood model having blood absorption characteristics similar to a specified oxygen saturation level is moved within the tissue model to simulate pulsatile motion and pulse rate. By altering the geometry of the blood model and/or the rate of motion of the blood model in and out of the tissue model, both the pulsatile waveform and pulse rate can be simulated.

10.2.2.7 Optoelectronic device. A number of relatively simple easy-to-use simulators have begun to appear on the market based on optoelectronic

principles. Figure 10.12 shows a block diagram for one of these types of simulators. First, the user selects the parameter(s) to be simulated. The pulse oximeter probe is then attached to the device and a signal is received from the pulse oximeter probe's LEDs by the simulator. Pulse separator and timer circuitry convert the red and infrared light pulses from the pulse oximeter probe into electric signals. These signals are modulated with the appropriate level of AC/DC ratio (under computer control) and then converted back to light pulses, via the LED bar, to the probe's photodiode. Finally, the pulse oximeter responds to the converted light pulses as it would to light pulses modulated by living tissue.

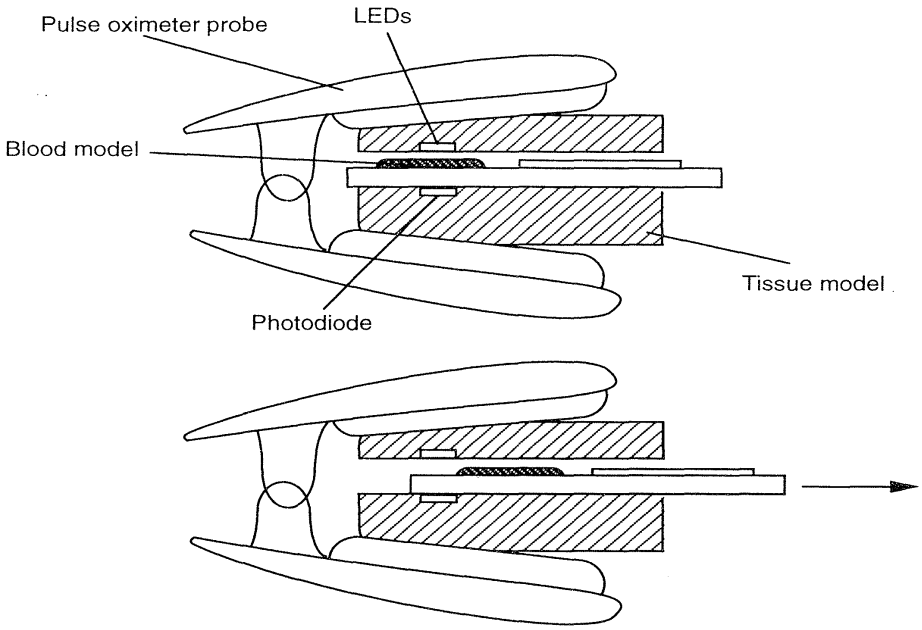

Figure 10.11 Block diagram of system as proposed by Aoyagi *et al* (1994).

These systems can test the probe and oximeter over the complete specified range of the oximeter. Also, simulation of a wide range of conditions is possible. The modulated signal can vary plethysmographic amplitude and wave shape to simulate a variety of ambient light conditions, motion artifacts, and arrhythmias. At least one system (Clinical Dynamics 1995) also includes a probe analyzer capability which independently tests LED and photodiode continuity and sensitivity. These types of simulators are primarily used by pulse oximeter manufacturers during final assembly and checkout of their products. In addition, their capability to generate automatic test sequences help document JCAHO (Joint Commission on Accreditation of Healthcare Organizations) testing requirements.

10.2.3 Electronic simulators

Electronic simulators have limited usefulness since they only simulate electronic signals to and from the probe. Usually these relatively simple devices are provided by the pulse oximeter manufacturer and only check a small number of values. These devices typically plug into the probe port on the pulse oximeter and

use the drive current of the probe LEDs to generate a simulated photodiode signal back to the pulse oximeter using the device. Figure 10.13 shows an example of such a device. In remote mode, the LEDs just drive an amplifier and the output shows up on the sensor output. This is useful for simple continuity testing. In local mode, these devices are able to electronically simulate a discrete number of simulated oxygen saturation levels, pulse rates and plethysmographic waveform strengths. In addition the calibration resistor value reading capability of the pulse oximeter can be checked. These simulators are good for functional checks of the pulse oximeter's internal circuitry, but because they bypass the pulse oximeter's probe, are of limited usefulness.

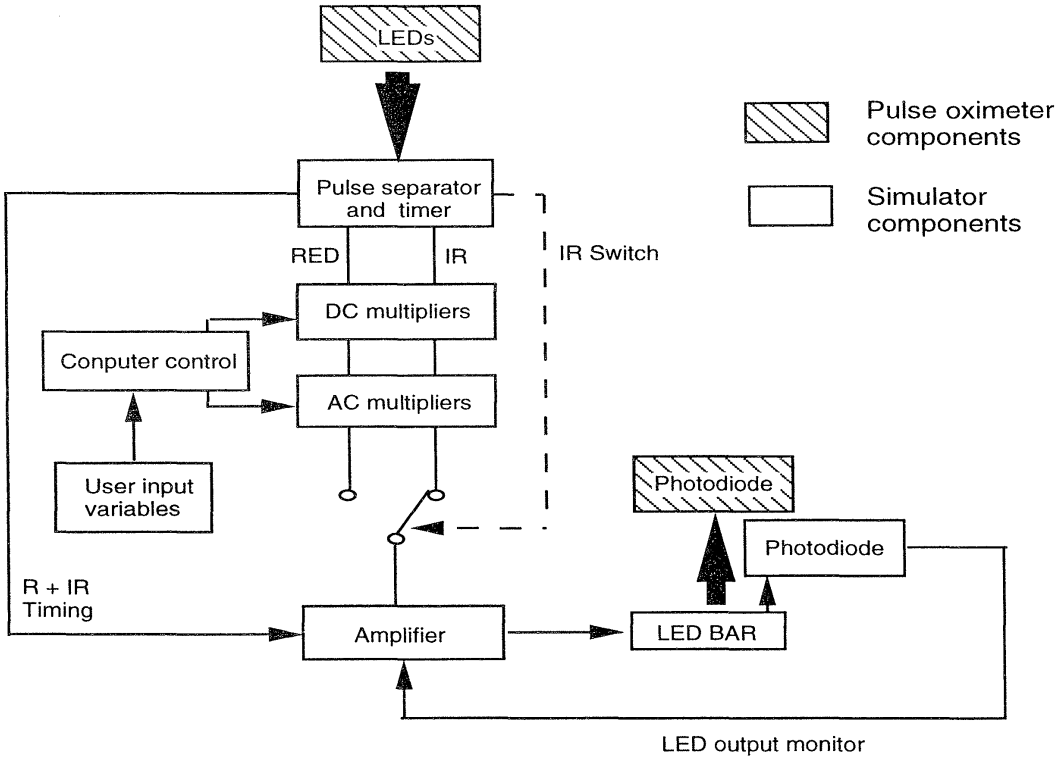

Figure 10.12 Block diagram electro-optic simulator system developed by Merrick and Haas (1994).

10.3 STANDARDS

Although the pulse oximeter has been on the market since 1977 (Santamaria and Williams 1994), surprisingly little standardization has been documented to this point. Statements like 'machines and probes are interchangeable with less than 0.5% difference', 'warm-up time factor of 0.5% to 1.0%' and 'the low perfusion light on the Ohmeda oximeter indicates the oximeter's microprocessor has low confidence level in the data' can be found in the literature. Several standards do exist, but their value from the designer's point of view is limited at best.

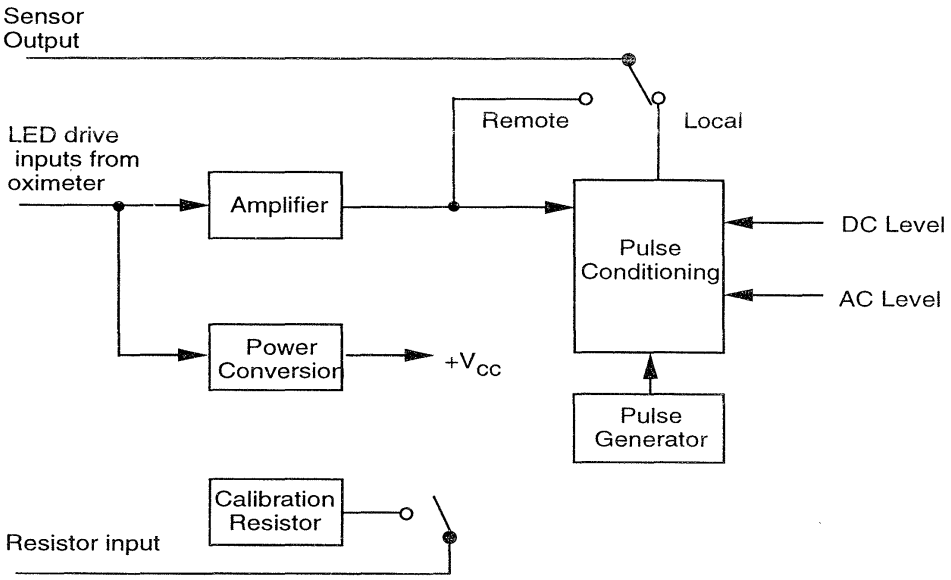

Figure 10.13 Block diagram of an electronic simulator that replaces the pulse oximeter probe (used with permission (Nellcor 1994) Pulse oximeter tester Model SRC-2).

10.3.1 ASTM F1415

The ASTM F1415 standard (ASTM 1992) contains requirements for the pulse oximeter designer in regard to marking and documenting the system, electrical safety concerns, electromagnetic interference and alarms. No specific information is provided regarding specific design requirements of the parts of the system discussed in the preceding chapters. In addition, no specific information is provided in regard to calibration or testing of these devices.

10.3.2 ISO 9919

This standard mentions a few requirements regarding calibration. These include requiring manufacturers to provide:

1. The calibration range of the pulse oximeter.
2. Whether the pulse oximeter is calibrated to display functional or fractional saturation.
3. The accuracy and range of HbO_2 saturation level displayed.
4. Whether the calibration was functional or fractional saturation.
5. Test methods for calibration need to be available from manufacturer upon request.

The ISO 9919 (International Organization for Standardization 1992) also offers this disclaimer in Annex L:

> Values derived from the pulse oximeter are not a measurement of blood or tissue oxygen tension and therefore pulse oximetry provides no direct indication of oxygen delivery to or consumption by, tissues. At present there is no widely accepted direct *in vitro* calibration

method for pulse oximeters. The only accepted *in vitro* test method for correlation of the reading from a pulse oximeter (S_pO_2) is bench-type oximetry employing more than two wavelengths of light or other methods using blood samples drawn from human subjects. Although work is progressing on the development of direct *in vitro* calibration methods, present techniques still require the use of human subjects. To include test methods in standards that require the use of human subjects, has, through past experience, been found to be unacceptable, and therefore *in vivo* test methods are not included in this International Standard.

10.3.3 Other standards

American Society of Anesthesiologists. Standards for Basic Intra-Operative Monitoring, 1986 (0696-ASA).
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INSTRUCTIONAL OBJECTIVES

10.1 Describe how R curves are determined through *in vivo* testing.
10.2 Explain the role that LED temperature plays in oxygen saturation level determination.
10.3 Explain why the term S_pO_2 is necessary when referring to oxygen saturation levels.
10.4 Explain the reason why different R curves may be needed for a manufacturer's pulse oximeter system.
10.5 Describe how oxygen saturation level is altered through an *in vitro* test system.
10.6 Explain why pulse oximeters are less accurate for S_pO_2 saturation levels below 60%.
10.7 Describe the operation of an optoelectronic simulator system.
10.8 Describe the operation of an colored colloid simulator system.
10.9 Describe the operation of polyester resin device simulator system.
10.10 Describe the operation of a wedge simulator system.
10.11 Describe the operation of the tube and bulb simulator system.
10.12 Explain the limitations of the electronic simulators used for testing pulse oximeters.

CHAPTER 11

ACCURACY AND ERRORS

Supan Tungjitkusolmun

Continuous assessment of arterial oxygen saturation (S_aO_2) is important in clinical management of critically ill patients. Pulse oximeters have been widely used as blood oxygen monitoring devices since the early 1980s. Currently, pulse oximeters can be found in virtually every operating room, recovery room, and intensive care unit. The advantages of pulse oximetry include noninvasiveness, ease of use, portability, and patient comfort. A light source generated by two LEDs, with wavelengths at approximately 660 nm and 940 nm, and a photodiode are mounted in a probe of a pulse oximeter. Circuit control, saturation calculation, and display are managed by a microprocessor instrument as described in chapter 8. Unlike earlier techniques such as the *in vivo* eight-wavelength oximeter (chapter 3), no heating or arterialization techniques are required in pulse oximetry.

All pulse oximeters work using absorption spectrophotometry, however, considerable differences exist in the way different manufacturers obtain and process the data. These differences occur in the light-emitting diodes, sampling frequency, microprocessor algorithms, and the constants used in the calculations, or the look-up tables. Since the technique has come into wide clinical use over the past decade, it is important to examine circumstances where its reliability may be questioned. The objective of this chapter is to describe several sources of error in pulse oximetry which may cause hazardous consequences to the patients. Recognizing the limitations described in this chapter and applying appropriate corrective interventions are essential to optimize the clinical use of pulse oximeters.

11.1 EVALUATION OF PULSE OXIMETERS

The *gold standard* measurement of arterial oxygen saturation is the CO-oximeter, described in chapter 3. A comparison of the pulse oximeters' readings and CO-oximeters' readings is thus required to verify the reliability of the pulse oximetry technique. Comparisons between pulse oximeters' arterial oxygen saturation values and the CO-oximeters' readings, as well as the HP eight-wavelength ear oximeter will be discussed in this section.

11.1.1 Accuracy, bias, precision, and confidence limit

Accuracy is a measure of systemic error or bias; the greater the error, the less accurate the variable. The accuracy of a measurement is the degree to which it actually represents what it is intended to represent. The location of the mean errors reflects the accuracy of the measurement. The accuracy of pulse oximeter oxygen saturations can usually be tested by comparing with the reference techique, CO-oximetry. Parameters frequently used to represent the degree of accuracy are bias, and absolute mean errors. *Bias,* in this case, is defined as the mean of the differences between the pulse oximeter readings and the CO-oximeter readings, which can be expressed as

$$\text{bias} = \frac{\sum_{i=1}^{N} x_i}{N} = \bar{x} \tag{11.1}$$

where x_i is calculated by subtracting the ith CO-oximeter measurement from the corresponding oximeter saturation displayed by a pulse oximeter. N is the total number of measurements. Units are percent saturation.

Precision is a measure of variation of random error, or degree of reproducibility. The dispersion of points around the mean reflects the precision of the measurement. Precision is often described statistically using the standard deviation (SD) of the differences between the pulse oximeter readings and the CO-oximeter readings of repeated measurements (Nickerson *et al* 1988) as in equation (11.2). Units are percent saturation.

$$\text{precision} = \text{SD} = \sqrt{\frac{\sum_{i=1}^{N} (x_i - \bar{x})^2}{N-1}}. \tag{11.2}$$

Some researchers frequently use a *95% confidence limit,* which for a normal distribution is equal to 1.96 times SD:

$$95\%\ \text{confidence limit} = 1.96 \times \text{SD} \approx 2 \times \text{SD}. \tag{11.3}$$

Example 1

The results from an experiment to compare pulse oximeter and CO-oximeter readings are shown in table 11.1. Ten measurements were made.

From table 11.1,

$$\text{bias} = \bar{x} = \frac{\sum_{i=1}^{10} x_i}{10} = \frac{15}{10} = 1.5\%$$

$$\text{precision} = \sqrt{\frac{\sum_{i=1}^{10}(x_i - \bar{x})^2}{10-1}} = \sqrt{\frac{20.5}{9}} = 1.51\%,$$

Table 11.1 Comparison of pulse oximeter and CO-oximeter readings.

Measurement (i)	CO-oximeter readings (%)	Pulse oximeter readings (%)	x_i (%)	$x_i - \bar{x}$
1	97	100	3	1.5
2	98	99	1	−0.5
3	92	91	−1	−2.5
4	96	98	2	0.5
5	97	99	2	0.5
6	90	93	3	1.5
7	89	90	1	−0.5
8	95	98	3	1.5
9	88	90	2	0.5
10	93	92	−1	−2.5

and

$$95\%\ \text{confidence limit} \approx 2 \times 1.51\% = 3.02\%.$$

The bias of 1.5% means that the test pulse oximeter tends to *overestimate* the oxygen saturation level (postive bias). A 95% confidence limit of 3.02% means that the pulse oximeter will give an outcome in the range between 1.5 − 3.02% and 1.5% + 3.02%, or between −1.52% and 4.52% from the true value (the CO-oximeter reading) with a probability of 0.95.

The use of bias and precision is helpful in getting a clear picture of a pulse oximeter's performance and how this compares to other units or other studies. A unit may be very precise, so that the results are highly reproducible with a low scatter, but have a high bias so that the results are not centered on the true values. In contrast, a unit may have a very low bias, but have poor precision, with values swinging widely from side to side of the true value. In clinical practice, a 95% confidence limit of less than ±3% is considered acceptable for most cases.

Other statistical terms from the regression analysis (correlation coefficient, positive error, intercept, and slope) are also used in several studies (Yelderman and New 1983, Taylor and Whitwam 1988).

11.1.2 What do pulse oximeters really measure?

Pulse oximeters only measure a ratio of transmitted red and infrared light intensities, and relate this to a look-up table of empirical oxygen saturation values (see chapter 9). The values in the table depend on the manufacturer's purpose of estimating functional or fractional oxygen saturation, but will in reality be neither of these unless the dyshemoglobin (dysfunctional hemoglobin) levels, and the pH levels in a subject's arterial blood are exactly the same as the average values of those used in the empirical calibration to create the look-up table. Choe *et al* (1989) found that the measured oxygen saturations in two instruments (Ohmeda Biox 3700 and Radiometer Pulse Oximeter) were close to the fractional oxygen saturation (fractional SO_2). On the other hand, the other four units used in the study (Minolta/Marquest Pulsox 7, Novametrix 500, Physio-Control Lifestat, and Datex Satlite) gave results in the proximity of functional oxygen

saturation (functional SO_2). The data used for calibration processes are usually obtained from healthy adults breathing hypoxic gas mixtures (see section 10.1.1).

Pulse oximeters can measure neither fractional SO_2 nor functional SO_2. However, the use of fractional SO_2 as the reference in the calibration process provides the clinician with a realistic assessment of the magnitude of the errors of physiological illness which is likely to be found for the group of patients under consideration.

11.1.3 Pulse oximeter versus CO-oximeter

Pulse oximeters are empirically calibrated by the manufacturer against a CO-oximeter. The IL (Instrumentation Laboratories, Inc.) 482 and 282 model CO-oximeters use four wavelengths of light (535.0, 585.2, 594.5, 626.6 nm) to detect the concentrations of HbO_2, Hb, COHb, and MetHb, and give the oxygen saturation as a percentage of the sum of the four species. This saturation is known as *fractional saturation* (section 4.2.2).

According to its operator's manual, the IL 482 has a precision of 0.5% (95% confidence limit of 1%) for HbO_2 measurements for samples with 0 to 10% MetHb and a pH of 7.0 to 7.4. The pH sensitivity of MetHb can cause significant changes in absorption at all four wavelengths outside these MetHb and pH ranges. Accuracy is also compromised by the presence of high lipid levels which can cause light scattering. It is not feasible to validate the value of 0.5% precision claim, since there is no quality control sample of accurately known or measured saturation that can be used to verify this. It is reasonable to accept this precision, given the high degree of reproducibility of the results.

Yelderman and New (1983) conducted a study to evaluate the accuracy of pulse oximeters over a broad range of arterial blood oxygen saturation in 1983 when the first Nellcor pulse oximeter became commercially available. A comparison of a pulse oximeter and the CO-oximeter readings was performed on five healthy, nonsmoking students ranging in age from 18 to 25. The precision of the measurements was found to be 1.83%. They concluded that pulse oximetry is a reliable technique for a measurement of arterial blood oxygen saturation in the range of 100 to 70%.

11.1.4 Pulse oximeter versus in vivo eight-wavelength ear oximeter

Hewlett-Packard ear oximetry, using eight wavelengths, was considered as a standard technique of measurement of arterial oxygen saturation before pulse oximeters were invented (see chapter 3). A comparison of the two techniques is thus necessary to see whether their results agree sufficiently for the pulse oximeter to replace the previous technique. Cahan *et al* (1990) determined that the difference between the HP ear oximeter (Hewlett-Packard 47201A ear oximeter) and the CO-oximeter (IL 282) readings was 0.9 ±4.3% (expressed as bias ± 95% confidence limit).

In a study by Cahan *et al* (1990), the difference between the individual pulse oximeters and the HP ear oximeters was found to be 2.6 ± 10.3% in the range of 99 to 70%. All five pulse oximeters studied gave higher values than the HP oximeter, and the differences between pulse oximeters and the HP readings increased as oxygen saturation fell below 85%. The greater discrepancies might be due to the longer *delay* of pulse oximeters during the progressive hypoxia.

The agreement of discrete measurements of the two methods was found to be acceptable at high oxygen saturation but unacceptable for arterial oxygen saturation levels lower than 85%. We must be careful when making an assessment of the oxygen saturation levels from two experiments in which different arterial oxygen monitoring devices were used. The continuous measurements from pulse oximeters and from the HP ear oximeters cannot be assumed to be in the same range.

11.2 ACCURACY VERSUS SATURATION

Accuracy at different levels of oxygen saturation is not the same. To make the discussion more effective, oxygen saturation is divided into three ranges: normal saturation, high saturation, and hypoxic condition (low saturation level).

11.2.1 High saturation (greater than 97.5%)

Pulse oximeters are designed to give a saturation reading of less than or equal to 100%; this limits the potential for positive errors and makes precision calculations difficult to interpret in this high range. Table 11.2 offers some outcomes of the evaluations of 20 brands of pulse oximeters. Even though precision calculations cannot be determined unbiasedly due to positive errors, the correct corresponding oxygen saturation is not critical in this range. As long as the oxygen saturation is over 97%, the patients are in favorable conditions and they require no urgent medical attention.

Table 11.2 Number of S_pO_2 readings of 100% when CO-oximeter reading was 97 to 98%. The results are expressed as the ratio of S_pO_2 readings of 100% and the number of measurements (percentage). Adapted from Webb *et al* (1991). Study 1 is from ECRI (1989). Study 2 is from Clayton *et al* (1991a).

Oximeter	Study 1	Study 2
Criticare CSI 503	–	0/17 (0%)
Engstrom EOS	–	0/15 (0%)
Spectramed Pulsat	0/17 (0%)	0/15 (0%)
Criticare CSI 504	–	0/14 (0%)
Biochem Microspan 3040	–	0/10 (0%)
Radiometer Oximeter	1/11 (9%)	1/17 (6%)
Simed S-100	1/17 (6%)	1/15 (0%)
Invivo 4500	2/9 (22%)	2/15 (13%)
Datex Satlite	1/9 (11%)	3/22 (14%)
Datascope Accusat	4/9 (44%)	3/14 (21%)
Physio-Control 1600	2/17 (12%)	4/16 (25%)
Nonin 8604D	3/9 (33%)	4/16 (25%)
Sensormedics Oxyshutle	2/7 (29%)	6/16 (38%)
Novametrix 505	3/17 (18%)	11/22 (50%)
Pulsemate Colin BX-5	–	10/16 (63%)
Minolta Pulsox 7	–	11/17 (65%)
Ohmeda Biox 3700	4/9 (44%)	11/15 (73%)
Ohmeda Biox 3740	5/16 (31%)	13/16 (81%)
Nellcor N-200	3/17 (18%)	13/18 (83%)
Kontron 7840	–	13/15 (87%)

11.2.2 Normal saturation (90 to 97.5%)

After more than a decade of development since first becoming commercially available, most models of pulse oximeters have a reliable performance in this range. In an experiment by Webb *et al* (1991), 10 of the 13 units had absolute mean errors of less than 1.0%; the standard deviation was less than 2% in eight units, and between 2 and 3% in the remaining five. Choe *et al* (1989), Taylor and Whitwam (1988), and Yelderman and New (1983) also found similar results. Pulse oximeters are well calibrated in this range since it is the most commonly found condition.

11.2.3 Low saturation (less than 80%)

Pulse oximeters have a high potential for errors at low saturations, mainly because ethically manufacturers cannot induce severe hypoxia repeatedly in volunteers for calibration purposes. Also, figure 11.1 illustrates that the absorption characteristics of 0% oxygen saturation blood are much steeper than that of 100% oxygen saturation blood at a 660 nm wavelength. At this range, when the percentage of hemoglobin saturation decreases, the slope of the absorption spectrum increases. Any slight error in the LED peak wavelength will change the readings of the pulse oximeter drastically.

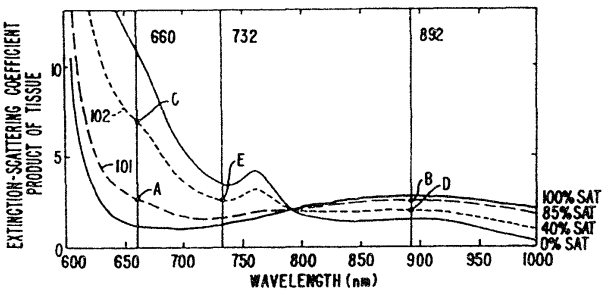

Figure 11.1 Variation in extinction coefficients over a range of wavelengths of 600 to 1000 nm at different saturation values. At 660 nm (red) wavelength, the slope of an absorption spectrum increases as oxygen saturation level decreases. From Casciani *et al* (1995).

The error associated with low saturations can also be explained by a reduction in the signal-to-noise ratio in pulse oximetry. As saturation decreases, less red light is able to penetrate through the tissues due to a high absorbance of Hb, thus the AC signal becomes weaker. To compensate for this drawback, the LED-driving current and the photodiode amplifier gain are increased to maintain the AC signal in a usable range. As the gain increases, incidental electrical and physiological noise also increase, thus resulting in a decline in the pulse oximeter's accuracy.

The accuracy of 13 pulse oximeters at low saturations was determined by ECRI (1989) in intensive care patients. Figure 11.3 shows the experimental results. All units examined were less accurate and nine out of 13 were less precise than when saturations were greater than 80%; eight out of 13 units tended to underestimate S_aO_2 by substantial amounts at low saturations.

In summary, pulse oximeters are poorly calibrated for saturations below 80%. In general, accuracy and precision are worse than for saturations above

80%, but this depends on the model and the brand. For example, Sensormedics Oxyshuttle pulse oximeter's bias only increases slightly (–0.1%), and the precisions are the same in both ranges.

Table 11.3 Accuracy of 13 pulse oximeters using finger probes on patients in the Intensive Care Unit. Adapted from Webb *et al* (1991).

Oximeter	Saturation > 80% Bias% (precision%)	Saturation < 80% Bias% (precision%)
Datascope Accusat	–0.3 (1.9)	–7.1 (3.2)
Datex Satlite	+0.0 (2.0)	+1.4 (1.5)
Invivo 4500	–0.3 (1.8)	–0.6 (4.9)
Nellcor N-200	+0.8 (1.7)	–5.5 (3.5)
Nonin 8604	+1.4 (1.8)	+8.8 (4.8)
Novametrix 505	+0.7 (1.9)	–8.1 (4.3)
Ohmeda 3700	–1.0 (2.5)	–5.3 (6.2)
Ohmeda 3740	–0.1 (2.8)	–5.5 (1.9)
Physio-Control 1600	+0.0 (1.9)	–6.0 (6.9)
Radiometer Oximeter	–1.5 (1.8)	–6.7 (3.2)
Sensormedics Oxyshuttle	–0.3 (1.8)	–0.4 (1.8)
Simed S-100	+0.1 (2.2)	+1.8 (1.6)
Spectramed Pulsat	+0.7 (1.6)	–3.4 (3.2)

11.3 ACCURACY VERSUS PERFUSION

Pulse oximeters require adequate plethysmographic (photoplethysmographic) pulsations to differentiate arterial blood absorbance from the absorbances of other substances (venous blood, tissue, and bone). A significant decrease in peripheral vascular pulsation, such as in hypothermia, vasoconstriction, hypotension, during cardiopulmonary bypass, or cardiac arrest, may result in a plethysmographic signal insufficient to be processed reliably by the oximeter. Most pulse oximeters have the ability to recognize a weak waveform which could cause an erroneous reading. They usually display a '*Low Perfusion*' or similar message to alert the user of possible problems in peripheral blood perfusion.

In a study to compare the performance of 20 pulse oximeters under the conditions of poor perfusion by Clayton *et al* (1991a), only two out of 20 oximeters had 95% confidence limits that were less than 4%. Generally the clinically acceptable range for the readings is about ±3%. Table 11.4 shows the results from the experiment.

Locally applied vasodilating drugs could be useful to enhance the plethysmographic pulsation in certain situations. The use of a pediatric warming blanket wrapped around the forearm is a simple method to increase perfusion due to a cold finger if the pulse oximeter signal is weak. Finger probes are preferable for patients with poor perfusion (see section 11.9).

11.3.1 Venous congestion

Another potential problem with pulse oximeter measurements is venous congestion, which leads to artifacts due to venous pulsation. Venous congestion is an accumulation of blood within an organ, which is the result of back pressure within its veins. Because the pulse volume amplitude of the plethysmograph is a measure of the pulsatility of the compliant vessels, some of the pulse may be

attributed to venous blood of lower oxygen content mixed with the signal due to higher oxygen content in the arterial blood. Also, the decrease in venous wall compliance by congestion should decrease the pulse volume amplitude in the organs (such as the finger). The pulse oximeter is unable to distinguish between the absorption due to pulsatile veins and that caused by arteries and arterioles. Pulsatile venous flow is generated by a transmitted arterial pulse through *arteriovenous anastomoses* in the finger. Therefore, if the S_pO_2 measured by the pulse oximeter is shunted arterial blood in the vein, the S_pO_2 reading will be affected by venous blood. Pulsatile veins may lead to the pulse oximeter indicating a lower value of S_pO_2 than is the actual saturation.

Table 11.4 Accuracy of pulse oximeters, ranked according to number of readings within 3% and showing ranking for number of readings within 3% of total number of readings expressed as percentage. Each pulse oximeter was tested on 40 patients. Total = total number of measurements obtained. Adapted from Clayton *et al* (1991a).

Pulse oximeter	Total	# within ±3%	Percent ±3%/Total	Rank
Criticare CSI 503	40	40	100	1
Datex Satlite	40	38	95	2
Biochem Microspan 3040	28	26	93	3
Novametrix 505	38	35	92	4
Criticare CSI 504	39	35	90	5
Invivo 4500	38	34	89	6
Sensormedics Oxyshuttle	36	32	89	6
Physio-Control 1600	36	31	89	6
Ohmeda Biox 3740	30	26	87	9
Minolta Pulsox 7	40	34	85	10
Nellcor N-200	39	33	85	10
Simed S-100	36	30	83	12
Datascope Accusat	33	27	82	13
Radiometer Oximeter	40	32	80	14
Nonin 8604D	35	28	80	14
Spectramed Pulsat	32	25	78	16
Pulsemate Colin BX-5	39	30	77	17
Ohmeda Biox 3700	36	25	69	18
Kontron 7840	40	27	68	19
Engstrom Eos	35	20	57	20

Much of the ac display of the plethysmographic signal may be due to pulsatile cutaneous venules which have an oxygen saturation similar to the arterial saturation due to patient arteriovenous communications in the skin. However, if the large venules and veins, which carry hemoglobin with a lower oxygen saturation, are pulsating, then the technique cannot distinguish between the two. Therefore, the S_pO_2 values may be lower than the arterial oxygen saturation if venous congestion is present. Other causes of increased pulsatility in veins are arteriovenous disassociation, right atrial myxoma, and right heart block.

11.4 ACCURACY VERSUS MOTION ARTIFACTS

As with most medical devices, motion artifacts contribute a significant error to pulse oximetry. Pulse oximeters detect a pulsatile signal that normally is only a small percentage of the total plethysmographic signal. Therefore, any transient motion of the sensor relative to the skin can cause a significant artifact in the

optical measurement. Furthermore, if these transient artifacts mimic a heartbeat, the instrument may be unable to differentiate between the pulsations that are due to motion artifacts and normal arterial pulsations, thereby causing erroneous readings. Practically, these artifacts can be reduced by digital signal processing and averaging the S_pO_2 values over several seconds before they are displayed. Motion artifacts, such as during shivering, seizure activity, or exercise, are usually recognized by false or erratic heart-rate displays or by distorted plethysmographic waveforms (figure 11.2).

Some manufacturers use the R wave of the patient's electrocardiogram to synchronize the optical measurements; they thereby improve the detection of noisy pulsatile signals by enhancing the signal-to-noise ratio of the measurements through the use of multiple time-averaged signals (see chapter 9).

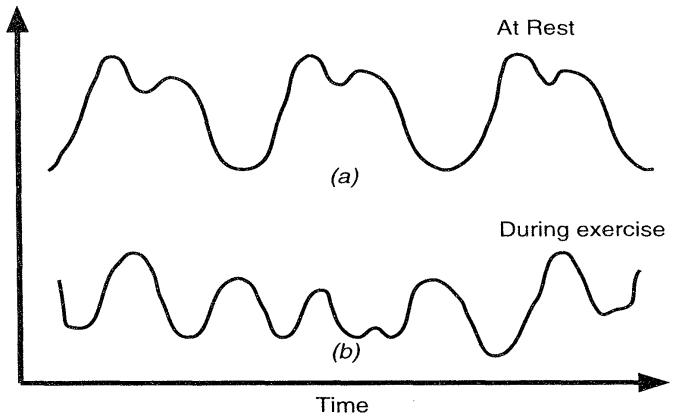

Figure 11.2 The plethysmographic waveform of a subject at rest is periodic (*a*) and during exercise is not periodic (*b*).

11.5 ACCURACY VERSUS OPTICAL INTERFERENCE

Bright external light sources are known to affect pulse oximeters and all pulse oximeters share this sensitivity. This occurs because these instruments use optical means to make their measurements. Consequently, to obtain accurate measurements, potential sources of optical interference must be controlled. Because pulse oximeters' optical components are located in the probe, proper probe application and use are key factors in reducing optical interference. Optical interference occurs when bright light from an external source (ambient light) reaches the photodiode, or when light reaches the photodiode without passing through a pulsatile arteriolar bed.

Pulse oximeters are designed to reject ambient light since the photodiodes can measure weak signals. When the intensity of ambient light is high (as from heat lamps or sunlight), the photodiode cannot sense light transmitted through tissue for S_pO_2 calculations. Protecting the photodiode from bright light obviates the problem. One solution is to cover the probe site with some opaque material, such as a surgical towel. Although this approach is generally useful, with active neonates or restless patients, the towel frequently becomes displaced and exposes the oximeter probe. One of the effective remedies to this problem is covering the

probe, while it is attached to a digit, with a packaging from an alcohol swab as suggested by Siegel and Gravenstein (1987). This packaging is manufactured in a shape that makes a convenient, dark receptacle for a digit, even one on which a flexible pulse oximeter probe has been placed.

Another type of optical interference may occur when some of the light from the LEDs reaches the photodiode without passing through an arteriolar bed. Such an optical shunt results in either erratic or stable but inaccurate measurements. Figure 11.3 shows some optical interferences to pulse oximetry. Oximeter probes should be manufactured of black opaque material that does not transmit light, or enclosed in an opaque plastic housing. Although there is no substitute for continual vigilance, shielding the probes from excessive ambient light, as strongly recommended by the manufacturer, will reduce the possibility of false readings.

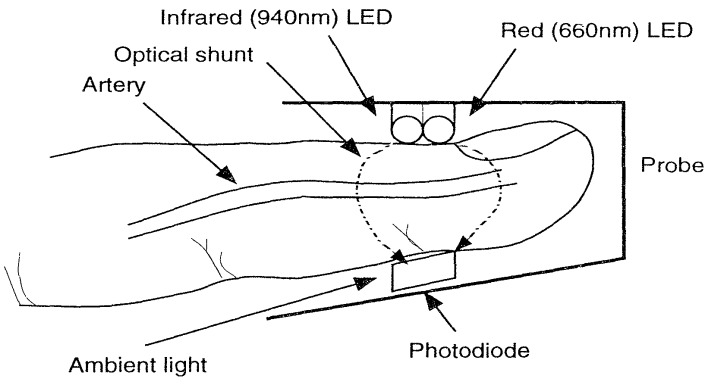

Figure 11.3 Ambient light interference and optical shunt in pulse oximetry. Optical shunt occurs when the light from the LEDs reaches the photodiode without passing through arterial blood.

11.6 ACCURACY VERSUS INTRAVENOUS DYES

During medical procedures, the use of substances such as dyes may be necessary. This section investigates the effects of dyes on pulse oximeter readings.

Several intravenous-administered dyes appeared to be associated with abrupt decreases in pulse oximetry S_pO_2 readings (Scheller *et al* 1986). Fifteen white subjects were studied, five with each of the three dyes, indigo carmine (InCa), indocyanine green (InGr), and methylene blue (MeBl). In all subjects, baseline readings were 97% or greater in both the toe and finger locations. Table 11.5 summarizes subject characteristics, the time from injection to the first noticeable decrease in S_pO_2 readings (latency), the lowest S_pO_2 reading (nadir), and the time required to return to baseline (duration), for each of the three dyes. Of the three dyes, InCa produced the fewest and smallest changes in S_pO_2 readings. Decreases from baseline were observed in three of the five subjects given indigo carmine, but only in the toe location. The magnitude of the measured oxygen saturation decreases were small following InCa, and the lowest S_pO_2 reading observed in any subject was 92%. By contrast, oxygen saturation reading decreases were observed in all subjects in both sensing locations following the administration of MeBl, with a median lowest S_pO_2 reading of 65%. The lowest S_pO_2 reading observed in any subject following MeBl was 1%. In subjects given

MeBl, measured oxygen saturations remained below baseline for between approximately 1 and 2 min in both the finger and toe. S_pO_2 reading decreases following the administration of InGr were intermediate between those observed with MeBl and InCa. Figure 11.4 shows the absorbance spectra for the three dyes as determined by spectrophotometry.

Table 11.5 Subject characteristics and S_pO_2 reading responses to IV Dyes. Adapted from Scheller *et al* (1986). Latency = the time from injection to the first noticeable decrease in S_pO_2 readings. Nadir = the lowest S_pO_2 reading. Duration = the time required to return to baseline reading. NC = no observed change.

Dye	Weight (kg)	Height (cm)	Latency (s) Finger/Toe	Duration (s) Finger/Toe	Nadir (O_2 saturation, %) Finger/Toe
MeBl	75	178	80/65	70/90	91/98
	68	175	35/30	105/80	58/65
	79	183	40/40	65/50	76/59
	93	180	40/35	50/50	80/69
	46	163	35/30	115/80	1/32
InGr	83	188	35/45	10/40	96/96
	67	175	45/40	35/25	95/93
	70	178	45/35	45/70	93/84
	86	191	50/45	70/30	93/92
	70	175	NC/65	NC/60	99/88
InCa	83	188	NC/NC	NC/NC	NC/NC
	67	178	NC/40	NC/40	NC/93
	46	163	NC/25	NC/30	NC/92
	86	175	NC/NC	NC/NC	NC/NC
	65	173	NC/20	NC/20	NC/94

All the three dyes absorb light in the region of the 660 nm wavelength at which the red LED of a pulse oximeter emitted light. Methylene blue has an extremely high absorbance in this region. This explains why methylene blue interferes to a greater degree with S_pO_2 readings than the other dyes (from Beer's law). Likewise, the absorbance of indocyanine green is slightly greater than indigo carmine at this wavelength, which is consistent with the observation that S_pO_2 readings were affected to a greater degree in those subjects given indocyanine green than in those given indigo carmine.

Absorbances of all three dyes are negligible in the region of 940 nm and thus have insignificant effects on the IR light intensities detected by photodiodes. The variable responses of the individual subject's S_pO_2 readings following dye injection may have been related to differences in cardiac output or blood volume. For example, following methylene blue, the largest S_pO_2 reading decrease and longest duration of decrease was seen in the smallest subject (body surface area = 1.34 m^2). The measurement of cardiac output by the transcutaneous detection of various intravenous dyes has been studied in both adults and children and found to correlate well with dye dilution methods that use continuous arterial blood sampling (Scheller *et al* 1986).

Saito *et al* (1995) observed that after intra-arterial injection of the blue dye *patent blue* in an anemic patient, the reduction in the pulse oximeter readings sustained for more than 20 min.

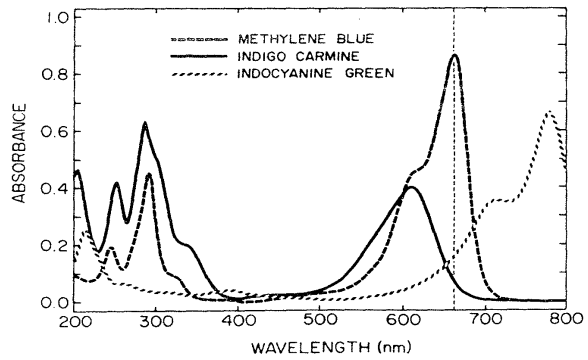

Figure 11.4 Absorbances of dyes. MeBl has the highest absorbance in the region of the 660 nm wavelength. From Scheller (1986).

Clinicians should be aware of the potential influences of intravenously administered dyes on S_pO_2 monitor readings so that operating room time is not wasted and more invasive analysis not undertaken, e.g., arterial blood gases, should falsely low S_pO_2 readings be temporarily induced by administration of these dyes (Scheller *et al* 1986).

11.7 EFFECT OF DYSHEMOGLOBINS AND FETAL HEMOGLOBIN

Dyshemoglobins are abnormal hemoglobins which cannot transport oxygen to the tissues. The presence of dyshemoglobins may cause inaccuracy in pulse oximetry. This section will discuss the two most commonly found in adults, carboxyhemoglobin and methemoglobin, as well as fetal hemoglobin.

11.7.1 Carboxyhemoglobin (COHb)

Seidler *et al* (1993) observed limitations of S_pO_2 readings in patients treated after inhalation of CO. Serial measurements of COHb concentration (IL 482 CO-oximeter) were done hourly in 6 patients until the results became normal, and arterial blood pressure, heart rate, and S_pO_2 were also monitored (by M1020 module, Hewlett-Packard). Figure 11.5 shows mean COHb values with corresponding S_pO_2 levels.

For all 18 measurements, the mean S_pO_2 reading was above 91%, which would be readily accepted as sufficient oxygenation. Decrease in COHb concentrations led to a slight increase of S_pO_2, as would be expected by the formula (Tremper and Baker 1989)

$$S_pO_2 = \frac{(c_{HbO_2} + 0.9c_{COHb})}{c_{\text{total hemoglobins}}} \times 100\%. \qquad (11.4)$$

As the level of COHb concentration in the blood reduces, the concentration of HbO_2 will rise while the concentration of total hemoglobins remain the same. Therefore, the magnitude of the numerator (c_{HbO_2} + $0.9c_{COHb}$) of equation (11.4) will increase which results in a larger $S_pO_2$value.

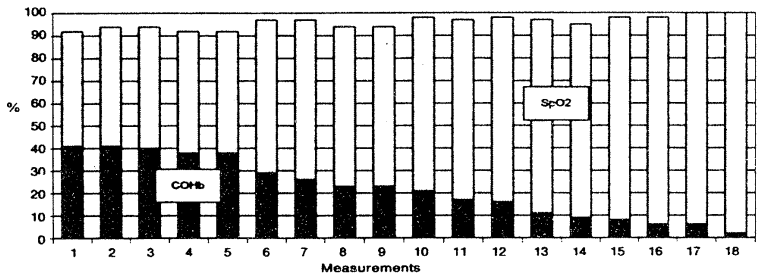

Figure 11.5 Mean measured arterial blood oxygen saturation (S_pO_2) with corresponding COHb values for 18 measurements in 6 patients. From Seidler (1993).

The increasing availability of pulse oximetry in intensive care units may lead to a false interpretation of oxygen transport capacity in cases of CO poisoning, especially if S_pO_2 is between 91% and 98%. Physicians should be aware that the diagnosis of CO poisoning still depends on a high degree of clinical suspicion and direct measurement of CO (Seidler *et al* 1993). The normal level of COHb in the arterial blood is less than 2%. Smokers or smoke-inhalation victims may have COHb levels greater than 10%. A high level of COHb overestimates the S_aO_2 values.

11.7.2 Methemoglobin (MetHb)

Methemoglobin is hemoglobin with iron oxidized from the normal (or reduced) ferrous (Fe^{2+}) state to the ferric (Fe^{3+}) state as described earlier in chapter 4. Methemoglobin is incapable of transporting oxygen.

Methemoglobinemia (high level of MetHb present in the blood) may be induced by a large number of drugs including local anesthetics (prilocaine, benzocaine), nitrates (nitroglycerin), nitrites, phenacetin, pyridium, primiquine, and sulfonamides. There are several case reports of potentially serious methemoglobin levels (greater than 30%) induced by topical anesthetics used in the airway. There are also case reports describing pulse oximeter readings during methemoglobinemia. However, the MetHb levels in these were too low (6% or less) to accurately characterize pulse oximeter behaviour.

At 660 nm the extinction coefficient of MetHb is similar to that of Hb and much greater than that of HbO_2 (figure 4.2). At 940 nm MetHb has a greater extinction coefficient than either Hb or HbO_2. MetHb thus adds to the pulse additional absorbance at both wavelengths. In contrast, COHb adds significant absorbance only at the shorter wavelength, where COHb has an extinction coefficient comparable to that of HbO_2. S_pO_2 is computed from the ratio R of the pulse-added absorbances at the two wavelengths. The presence of MetHb increases both the numerator and denominator of this ratio, which tends to drive R toward unity.

The arterial oxygen saturation can be expressed as

$$S_pO_2 = HbO_2\% = \frac{c_{HbO_2}}{c_{\text{total hemoglobins}}} \times 100\% \qquad (11.5)$$

while the functional hemoglobin saturation (measured arterial saturation)

$$S_pO_2 = \frac{c_{HbO_2}}{c_{Hb} + c_{HbO_2}} \times 100\% \tag{11.6}$$

$$= \frac{c_{HbO_2}}{c_{\text{total hemoglobins}} - c_{MetHb} - c_{COHb}} \times 100\%. \tag{11.7}$$

Theoretically, from equations (11.5) and (11.7), we can see that in the presence of MetHb, pulse oximeters overestimate the value of oxygen saturation in arterial blood, i.e., S_pO_2 is greater than S_aO_2.

11.7.3 Fetal hemoglobin

One of the concerns clinicians often have related to the interpretation of pulse oximeter readings in newborn infants is the fetal hemoglobin (HbF) present in the blood because pulse oximeters are calibrated empirically by inducing hypoxia in healthy adults. At birth, newborns have approximately 60 to 95% of the total hemoglobin in the form of fetal hemoglobin while the remainder is adult hemoglobin (HbA). In infants older than nine months, HbF levels higher than 2% often indicate an anemia such as sickle-cell anemia.

Mendelson and Kent (1989), and Zijlstra *et al* (1991) demonstrated that there is no significance difference in absorption spectra of adult and fetal hemolyzed blood in the 650 to 1000 nm wavelength region, which is used in pulse oximetry. On the other hand, adult and fetal hemoglobin absorption characteristics differ in the range of wavelengths below 650 nm.

The theoretical S_pO_2 readings for the adult and fetal hemoglobin can be determined by substituting the extinction coefficients given in table 11.6 into equation (4.19), which is

$$S_aO_2 = \frac{\varepsilon_{Hb}(\lambda_R) - \varepsilon_{Hb}(\lambda_{IR})R}{\varepsilon_{Hb}(\lambda_R) - \varepsilon_{HbO_2}(\lambda_R) + [\varepsilon_{HbO_2}(\lambda_{IR}) - \varepsilon_{Hb}(\lambda_{IR})]R} \times 100\%. \tag{11.8}$$

Table 11.6 Extinction coefficients of adult and fetal blood expressed in ($L \cdot mmol^{-1} \cdot cm^{-1}$) (from Mendelson and Kent 1991).

	Hb		HbO_2	
λ	Adult	Fetal	Adult	Fetal
660 nm	0.86	0.90	0.12	0.16
940 nm	0.20	0.20	0.29	0.30

Figure 11.6 shows the results of the theoretical simulation. Mendelson and Kent (1989) suggested that a maximum error of approximately 3% in pulse oximeter oxygen saturation readings could be expected when measurements from adult and fetal blood are compared.

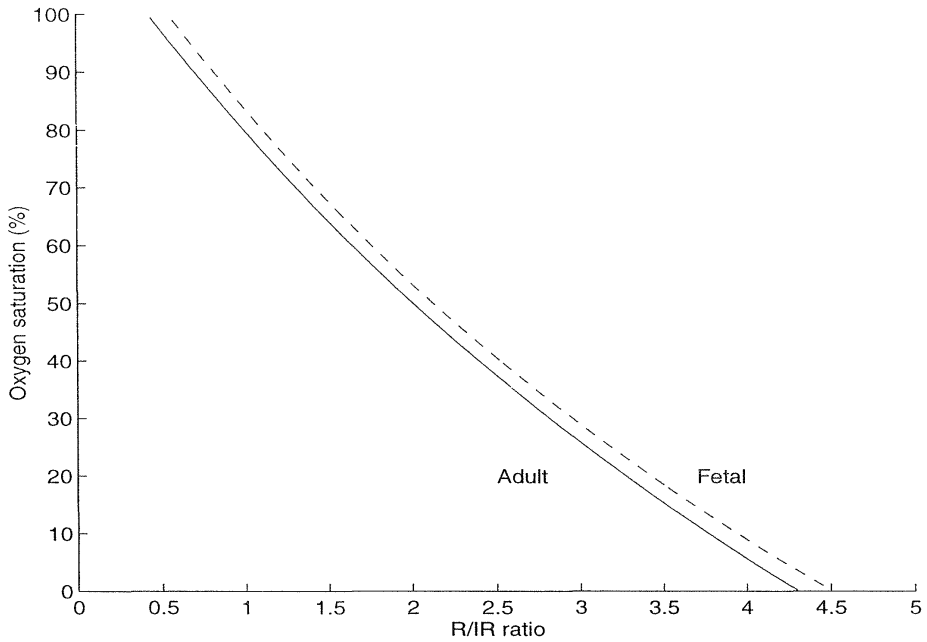

Figure 11.6 The calibration curves derived from a theoretical simulation show that pulse oximeters will read about 3% high for fetal hemoglobin. The R/IR ratio is R in equation (11.6).

11.7.4 Bilirubin

Bilirubin is an orange or yellow colored compound which is a breakdown product of heme. High levels of bilirubin can affect absorbance at lower wavelengths used by the CO-oximeters. A bilirubin concentration of 20 mg/dl will cause up to 1% error in the measurement of four main hemoglobin species. The absorption spectrum of bilirubin has a peak at 460 nm and much smaller peaks at 560 and 600 nm. Veyckemans *et al* (1989) showed that there was no significant error detected from the influence of high bilirubin plasma levels. The presence of bilirubin in the arterial blood will not induce any significant errors in pulse oximetry measurements.

11.8 EFFECT OF TEMPERATURE

11.8.1 Ambient temperature

An exposure of the body to cold temperatures can cause changes in peripheral perfusion which may cause inaccuracy. The temperature dependence of LEDs in pulse oximeter probes is unlikely to affect the pulse oximetric values. Reynolds *et al* (1991) showed that there was a 5.5 nm increase in the peak wavelength for a 660 nm LED, and a 7.8 nm increase in the peak wavelength for a 950 nm LED as temperature increased from 0 to 50 °C (see chapter 10).

Table 11.7 Extinction coefficients at 0 °C and 50 °C expressed in (L $mmol^{-1}$ cm^{-1}). Adapted from Reynolds *et al* (1991).

	Hb		HbO_2	
λ	0 °C	50 °C	0 °C	50 °C
660 nm	0.856	0.811	0.123	0.117
950 nm	0.153	0.139	0.274	0.265

Table 11.7 lists the extinction coefficients of Hb and HbO_2 at different wavelengths and temperatures. Substituting these values into the relationship between S_pO_2 and R given in equation (11.6) which is derived from Beer's law, theoretical calibration curves can be obtained as in figure 11.7. Thus the effect of shifts in wavelength of the LEDs on pulse oximeter accuracy is neglibible as the temperature increases from 0 °C to 50 °C.

The reduced amplitude of the ac signals occurring during cold exposure causes the pulse oximeter to be more sensitive to motion artifacts, for example those caused by shivering or coughing. These artifacts may cause the pulse oximeter to give an erroneous value of S_pO_2. Reynold *et al* (1991) concluded that inaccuracies in pulse oximeter readings at extreme temperatures are far more likely to be caused by reductions in peripheral perfusion, rather than a result of the temperature dependence of the LEDs in the pulse oximeter probe.

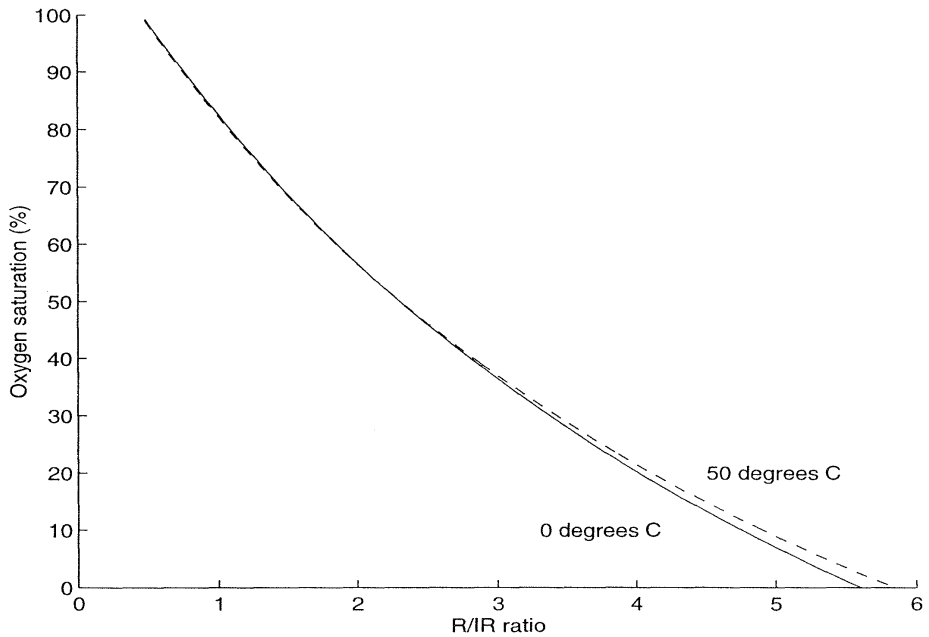

Figure 11.7 The calibration curves from a theoretical model show a shift from 0 °C to 50 °C.

11.8.2 Patient temperature

Errors in pulse oximetry readings do not increase significantly with a decrease in patient temperature. Palve and Vuori (1989) found that, in a recovery room

study of the Nellcor N-100 and Ohmeda Biox 3700 pulse oximeters, they were reliable on patients with low cardiac output and hypothermia after open heart surgery, with standard deviations ranging from 1.8% to 3.9% for finger probes and from 0.9% to 2.1% for ear probes which are comparable to the outcomes of normal cases.

11.9 ACCURACY VERSUS MEDICAL CONDITIONS

Although pulse oximeters are designed to help detect pathophysiological oxygenation conditions of patients that might lead to a life threatening situation, some medical conditions cause pulse oximeters to be unreliable. Fortunately, pulse oximetry works well in the majority of the cases. The following are some frequent encounters where the accuracy of pulse oximeters is often questioned.

11.9.1 Cardiac arrhythmia

The heart rate derived from a pulse oximeter should match that from an ECG signal for the patient with a healthy heart. If the two differ, either of the monitors may be in error because of poor signal quality, or the electrical activity of the heart may appear to be normal while it produces beats with inadequate stroke volume output due to inadequate filling or contraction (Webb *et al* 1991).

Wong *et al* (1989) conducted an experiment to test the accuracy of pulse oximeters for 163 patients with cardiac arrhythmias. They found that for the group of 24 patients with a pulse oximeter to ECG pulse rate discrepancy of greater than 3 beats/min, S_pO_2 measurements were as accurate as those for the group of 139 patients with pulse rate agreement, as long as the S_pO_2 reading was stable on the pulse oximeter and there was reasonable signal strength.

11.9.2 Myxoma

Fearley and Manners (1993) described a case of inaccurate oximetry in a patient with a right ventricular myxoma. The ventilation/perfusion scan of the patient was normal but cardiac angiography revealed a rounded mass in the right ventricular outflow tract. Before cardiopulmonary bypass, pulse oximetry using an ear probe gave a consistent hemoglobin saturation of 75%, but repeated arterial blood gas analysis showed an arterial oxygen saturation exceeding 95%. The ear probe gave readings of 96 to 98% on volunteers in the operating room. Postoperative oximetry was consistently more than 96%. It was concluded that a ventricular contribution to the central venous pressure due to the dilated tricuspid ring might lead to the inaccuracy in pulse oximetry. The pulsatile venous pressure presumably induced an alternating current in the oximeter giving rise to a saturation not related to the arterial oxygen saturation. Thus pulse oximeter readings must be interpreted carefully in the clinical context of the patient being monitored.

11.10 ACCURACY VERSUS PROBE POSITION

Severinghaus *et al* (1989) found that ear and forehead probes generally had a much faster response to changing S_pO_2 values than finger probes. It was

suggested that finger probes require a greater transit time for blood to reach the finger compared to ear. Kagle *et al* (1987) found the Ohmeda 3700 finger probe to be on average 24 s behind the Ohmeda 3700 ear probe in its response to rapid desaturation. West *et al* (1987) found that measurement accuracy was related to response delay times, with longer delays associated with lower accuracy. The ear probe with the shortest delay had some accuracy problems at low saturations, and the slowest responding finger probe was claimed to be totally inadequate as a monitor of rapid changes in saturation due to its delayed and highly damped response.

Forehead probes have been tested at stable low saturations on volunteers by Cheung and Stommel (1989) using a commercially available unit and Mendelson *et al* (1988) using a custom-built reflectance probe. Both groups found good correlation between the forehead measured values and CO-oximetry measurements for saturations down to 65%. Severinghaus *et al* (1989) found the accuracy of seven forehead probes to be comparable to that of finger probes during rapidly induced desaturation in volunteers.

Table 11.8 Accuracy of pulse oximeters ranked according to percentage of readings within 3% of the CO-oximeter readings out of the total number of readings. From Clayton *et al* (1991b).

Pulse oximeter	Total	# within ±3%	Percent ±3%/Total	Rank
Criticare CSI 503 finger	40	40	100	1
Datex Satlite finger	40	38	95	2
Criticare CSI 503 ear	17	16	94	3
Novametrix 505 finger	38	35	92	4
Criticare CSI 504 finger	39	35	90	5
Datex Satlite ear	35	31	89	6
Physio-Control 1600 ear	36	32	89	6
Invivo 4500 finger	38	34	89	6
Radiometer Oximeter ear	36	32	89	6
Sensormedics Oxyshuttle finger	36	32	89	6
Ohmeda Biox 3740 finger	28	26	87	11
Criticare CSI 504 ear	14	12	86	12
Physio-Control 1600 finger	36	31	86	12
Sensormedics Oxyshuttle ear	35	30	86	12
Radiometer Oximeter finger	40	32	80	15
Ohmeda Biox 3700 ear	40	30	75	16
Ohmeda Biox 3740 ear	34	25	74	17
Ohmeda Biox 3700 finger	36	25	69	18
Datex Satlite forehead	37	22	59	19
Novamatrix 505 nose	34	19	56	20
Invivo 4500 nose	26	8	31	21

Under poor perfusion conditions, pulse oximeters might either fail to provide a reading or give a '*Low signal quality*' warning. Clayton *et al* (1991b) studied the performance of probes under conditions of poor peripheral perfusion in patients who have undergone cardiopulmonary bypass in the immediate postoperative period. The results are shown in table 11.8. Finger probes were to found to have better performances than the ear, nose, and forehead probes and the authors recommended using them during poor perfusion situations. It was also noted that ear probes generally had the faster response as reported by other studies (Severinghaus *et al* 1989, West *et al* 1987, Kagle *et al* 1987). The delay of finger probes should be taken into account when planning critical management algorithms.

11.11 ELECTROMAGNETIC INTERFERENCE

Electromagnetic interference (EMI) includes several different sources of interference from the electromagnetic spectrum. It may be generated by many sources, mostly man made but also results from atmospheric events and cosmic noise. Even nuclear explosions produce an enormous electromagnetic pulse interference. All electronic devices are affected by EMI, but the consequences are more serious when affecting medical devices such as pacemakers and pulse oximeters. Frequent sources of interference are electrostatically charged operators, communications transmissions, other medical devices, and other electrical and electronic equipment.

Pulse oximeters contain a microprocessor and many other electronic circuits that are very sensitive to EMI. The requirement in their design for a high degree of electromagnetic compatibility (EMC) is now required by statute, such as the Food and Drug Administration (FDA) in the United States. The Center for Devices and Radiological Health (CDRH) is developing a comprehensive strategy of EMC requirements for medical devices.

A performance degradation in pulse oximetry due to radiated interference was reported by Silberberg (1996). A pulse oximeter displayed a hemoglobin saturation level of 100% and a pulse rate of 60 for a patient who had deceased earlier that day. This anomalous performance was because a telemetry transceiver had been placed too close to the pulse oximeter. Thus, EMI can contribute a large error to pulse oximetry. Care should be taken to make sure that there is no significance presence of EMI in the environment.

11.11.1 Interference from magnetic resonance imaging (MRI)

The radio frequency transmissions from the magnet and rapidly switching magnetic field gradients are two majors sources of artifact generated in medical devices during magnetic resonance imaging (MRI).

The magnetic resonance scanner places unusual demands on the equipment and practices of patients' safety. As sedation or anesthesia is necessary for successful MRI of some patients (particularly infants and young children), reliable patient monitoring is essential. The strong magnetic field, radio frequency (RF) radiation, and reduced patient access complicate traditional methods of patient monitoring. Conventional ECG monitoring, for instance, is subject to artifactual changes during MRI. Moreover, infants have smaller oxygen reserves which, coupled with their higher metabolic rate, can lead to rapid decreases in blood oxygenation S_pO_2. Pulse oximetry is ideal to use during MRI. It is flexible as to the choice of monitoring site, and suffers few problems from induced electromagnetic noise.

The difficulties in using pulse oximetry in MRI stem largely from the design of the monitor unit. Pulse oximeters adapted to the MRI environment have a compact nonmetallic housing and are battery operated. Extended fiber optic leads are also used to keep the electronics outside the bore of the MRI magnet as described in chapter 7. Because there are no electric cables extending through the magnetic resonance imager bore, there is no possibility of RF burns to the patient or RF-induced noise in the signal conveyed to the processor and display unit. However, the fiber optic leads tend to be relatively delicate and easily broken. Once damaged, the cost of repair is very high. Furthermore, fiber optic systems

normally require different probes for patients of different size, particularly separate adult and pediatric probes. Individual probes are very expensive.

Blakeley *et al* (1994) proposed a design system for a MRI-compatible pulse oximeter which is shown in figure 11.8. The radio frequency signals can be eliminated by using notch filters and a low-pass filter. This system can prevent radio frequency burns in patients. The proposed system also worked with existing pulse oximeters. No modifications of pulse oximeters are needed.

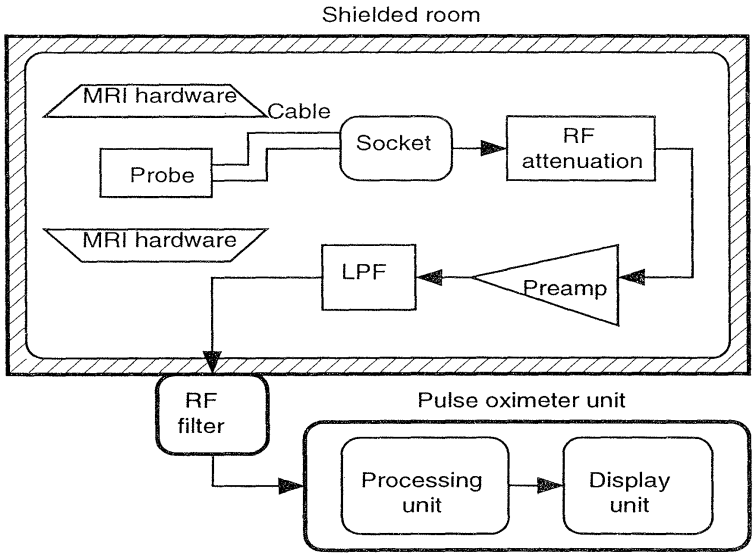

Figure 11.8 MRI compatible pulse oximetry (adapted from Blakeley *et al* 1994).

11.12 OTHER EFFECTS ON ACCURACY

Besides the major sources of errors described in previous sections, users frequently encounter other circumstances where the accuracy of a pulse oximeter is questioned. The followings are some factors which have some effects on the performance of a pulse oximeter, although no large error is expected.

11.12.1 Exercise

The presence of cardiorespiratory abnormalities during physical stress may not be noticeable under resting conditions. These abnormalities can be investigated by exercise stress testing which requires the pulse oximetry technique (see section 13.6.2). Powers *et al* (1989) and Williams *et al* (1986) found that pulse oximeters using ear probes underestimated arterial saturation by 10 to 15% during heavy exercise. It was suggested that this is caused by reduced ear perfusion in exercise. Smyth *et al* (1986) in contrast found up to 15% overestimation by a pulse oximeter using an ear probe during exercise under hypoxic conditions.

In a more recent study by Norton *et al* (1992), 10 subjects were used to perform strenuous exercise on a bicycle ergometer. Blood oxygen saturations

were measured using the Ohmeda Biox pulse oximeter 3700R with the ear probe, and the blood gas analyzer (Ciba-Corning, model 278). The results of oxygen saturation levels obtained indicated that relatively large underestimations of S_aO_2 can occur when a pulse oximeter is used, and these errors increase as the severity of exercise increases. Powers *et al* (1989) found similar results. Further studies are still needed to investigate the performance of pulse oximeters during exercise. Estimations of arterial blood oxygen saturation during severe exercise using the pulse oximetry technique should be viewed with caution, as potentially large errors may occur.

11.12.2 Dried blood

Trauma patients may have significant quantities of dried blood remaining on their hands upon arrival in the emergency department. There is often insufficient time to clean the patient's hand thoroughly before the application of the pulse oximeter probe (Rosewarne and Reynolds 1991). In a study by Rosewarne and Reynolds (1991), the finger probes of six commercially available pulse oximeters were applied to the fingers of a healthy male Caucasian volunteer. Two of the fingers had previously been coated in whole blood which was allowed to dry. Rosewarne and Reynolds (1991) found that there was no significant difference in saturation range among those fingers with or without dried blood. The variation in readings between brands of pulse oximeter was of the same order as between fingers.

In emergency situations, the presence of dried blood is unlikely to cause a decline in pulse oximeter accuracy and performance as long as adequate perfusion is maintained.

11.12.3 Pigments

In theory, skin pigmentation and other surface light absorbers such as nail polish, should not cause errors in S_pO_2 readings since the pigments absorb a constant fraction of the incident light, and the pulse oximeters use only pulsatile absorption data. The absorbances of light by the pigments are nonpulsatile and, just as for tissue absorption, are cancelled out of the saturation calculation.

However, Cote *et al* (1988) found that black, blue, and green nail polishes caused a significant lowering of S_pO_2 readings of the Nellcor N-100, while red and purple nail polish did not. Cecil *et al* (1988) also showed apparently greater inaccuracy in pulse oximeter readings for black patients. This is probably caused by the fact that N-100 increases its light output in response to low detected light levels, and the higher LED current caused a shift in the output spectrum (see chapter 5). The shifting of the peak wavelength of LEDs affects the measured transmitted red and infrared light intensities, and thus alters the oxygen saturation reading. For the nail polish problem, the solution is to mount the probe side-to-side on the finger (White and Boyle 1989). This technique may also help to avoid the saturation underestimation problem caused by only partial placement of the LEDs over the finger because of very long fingernails.

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INSTRUCTIONAL OBJECTIVES

11.1 Explain the differences between between bias, precision, and the 95% confidence limit.
11.2 Describe the accuracy of pulse oximeters in the three ranges of oxygen saturation levels.
11.3 Using the absorption spectra shown in figure 11.1, explain why the accuracy is worse at low oxygen saturation level.
11.4 Describe the accuracy of pulse oximeters at low perfusion and how to prevent the errors.
11.5 Explain how venous congestion occurs and its results on pulse oximeter accuracy.
11.6 Describe two sources of optical intereferences and their effects on pulse oximeter accuracy.
11.7 Describe how to prevent errors from high intensity ambient light.
11.8 Describe how the absorbance of dyes affects the accuracy of pulse oximeters.
11.9 Explain the effects of MeBl on pulse oximeter readings.
11.10 Given c_{HbO_2} and c_{COHb}, calculate the estimated S_pO_2
11.11 Describe how MetHb and bilirubin affect the readings of pulse oximeters.
11.12 Describe how fetal hemoglobin affects the readings of pulse oximeters.
11.13 Explain how temperature affects pulse oximeter accuracy and describe how the theoretical calibration curve shifts from 0 °C to 50 °C.
11.14 Describe the accuracy and response time of finger probes and ear probes during rapid desaturation and low perfusion.
11.15 Explain the effect of EMI on pulse oximeter accuracy.
11.16 Describe the effect of MRI on pulse oximetry and explain the system of MRI-compatible pulse oximetry.
11.17 Describe the effect of pigments on the accuracy of pulse oximeters.

CHAPTER 12

USER INTERFACE FOR A PULSE OXIMETER

Albert Lozano-Nieto

12.1 INTRODUCTION

This chapter deals with some important aspects that need to be considered when designing any kind of product whose final goal is to be marketed rather than be used as a laboratory prototype. The product has to be built so that it will solve a need for the customer. A product that is technologically perfect can result in an economic failure if it is not sold because it does not meet the user's expectations or needs, it is not sold because it is too complicated to operate, or is removed from the market by the regulatory agencies because it does not meet the applicable regulations.

This chapter will highlight those aspects of the overall design for a pulse oximeter that may not receive enough attention when designing the hardware and software that make up the core of the system. These aspects are the design of an optimal user interface system, so that the final product will comply with all the regulations that apply to that specific product.

The chapter is organized by discussing the options available to the designers for the different stages that form a pulse oximeter, by reviewing how choices have been made in commercially available equipment, and by discussing which standards are applicable to the different parts of the pulse oximeter and their consequences for the design. The standards are a collection of rules, most of them based on common sense, used to ensure the best results in the use of pulse oximeters. In particular, we must comply with the *Standard Specifications for Pulse Oximeters, F1415-1992* from the American Society for Testing and Materials (ASTM) that compiles the current regulations for the design of pulse oximeters (ASTM 1992). This Standard references the *Safety of Medical Electrical Equipment—Part 1, General Safety Requirements, IEC 601-1* standard from the International Electrical Commission (IEC) for many general requirements concerning safety, and discusses the specific variations from the IEC 601-1 in the case of pulse oximeters (IEC 1988). A more detailed discussion about some aspects of the IEC 601-1 Standard for pulse oximeters is in the ISO 9919 Standard, *Pulse Oximeters for medical use—Requirements* (IOS 1992). Nevertheless, all the standards are subjected to revision, and undergo changes with the development of technology and other standards that affect related

equipment. For example, in 1996, development began on a standard that will apply to all medical devices used during anesthesia. So, it is the responsibility of the designer to know and comply with the current applicable standards.

12.2 FRONT PANEL

The front panel of a pulse oximeter communicates between the patient and the healthcare professionals. This communication is expected to be accurate and clear. The accuracy problems are related to the core design, discussed in the previous chapters. This chapter will focus on how to make this communication as effective as possible, designing the pulse oximeter to display the necessary information in the way that is most useful to healthcare professionals.

Figure 12.1 shows how to model a pulse oximeter as a transducing system that transforms a variable from the chemical domain (arterial oxygen saturation), to a variable in the electrical domain that can be further processed, stored or displayed. While previous chapters have treated the first conversion stages, we will discuss the last conversion stages, that is, how the information is presented to the operator.

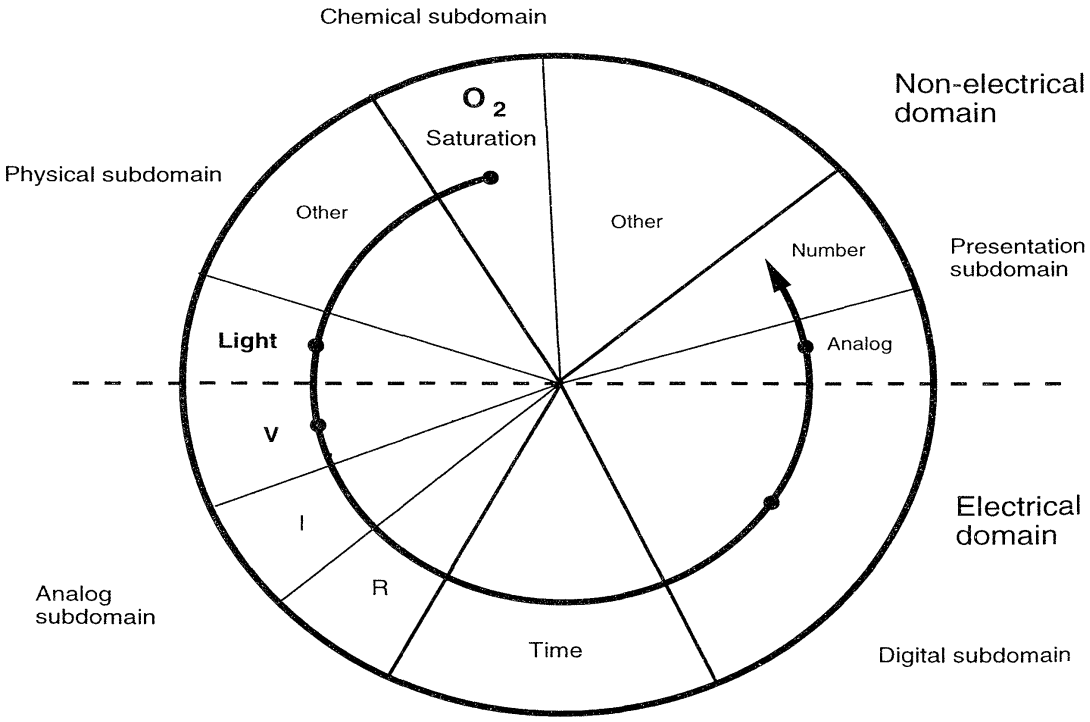

Figure 12.1 Change of domains of information in a pulse oximeter. Adapted from Malmstad *et al* (1973).

We will consider two main ways of presenting information to a human operator. These are visually and acoustically. The acoustic way is mainly used to alert the operator of a possible malfunction of the monitoring equipment or a medical

problem. Other applications are to provide feedback to an input from the operator, and in some units to codify the patient pulse strength by changing the sound pitch accordingly to the strength as defined in the Standards (ASTM 1992).

Despite these acoustical outputs, the primary output of a pulse oximeter is visual. Pulse oximeters can be primarily classified based on the technique used to present visual information into two categories:

1. Graphical displays that present analog and digital information.
2. Numerical displays that only present digital information.

12.2.1 Graphical displays

It is common knowledge that 'a picture is worth thousand words', and pulse oximeters are not an exception. Graphs produce a spatial presentation to communicate quantitative information to the exterior world, making them very flexible (Gillan and Lewis 1994). The displays used in pulse oximeters are normally liquid crystal displays (LCDs), although some models from Protocol Systems Inc. (Propaq 102/104/106) also have versions with an electroluminescent display (ELD). ELD displays perform better when it is necessary to view them from long distances. They are aimed toward bedside monitoring, where the units can be plugged to a power line source, because of the higher power that these displays require. On the other hand, LCD displays are better in direct sunlight and require much less power, which increases both the display life and the battery discharge cycle (Bosman 1989). Most of the commercially available LCD units have a backlight that increases display readability but also dramatically decreases the battery operating time. For example, Criticare specifies for its 503 model, a battery use time of 20 h when the backlight is turned off, while it decreases to 10 h when the backlight is turned on.

Graphical displays present one or more real-time waveforms. Normally, the units that incorporate graphical displays are also the ones that acquire more physiological signals, so there are more choices for display. All the units with graphical displays can simultaneously present different waveforms, although for readability it is not convenient to present more than two. The most common waveforms are the plethysmographic waveform and the ECG. The model POET TE Plus from Criticare also monitors CO_2 and can display the capnographic waveform. The Propaq models from Protocol Systems, Inc., have different modular systems that can measure oxygen saturation, ECG, CO_2 consumption, and invasive and noninvasive blood pressure. The units from Medical Research Laboratories, Inc. can be used as stand-alone systems or as a part of an integrated monitoring system as previously described. The model 9500 from Magnetic Resonance Equipment Co. is a multigas monitoring system that measures oxygen saturation, CO_2, NO_2, O_2 and invasive and noninvasive blood pressure. The model BIOX 3700 from Ohmeda, shown in figure 12.2 has two separated LCD displays with different functions for each one. One displays different waveforms, while the other displays the values of oxygen saturation and pulse rate.

In addition to real-time waveforms, displays can also present the trend from a past period of time. This feature does not involve a major increase in the complexity of the electronic design because it only requires storage of the already digitized values and further processing. The length of time that is available for display depends on the amount of the memory used in the design, but also on the sampling frequency, which is normally user selectable. There is a large variation

among the length of time that different models store trend display. In the Biox 3700 from Ohmeda, the length of the trend can be selected between 20 and 60 min, by pressing a key in the front panel, as shown in figure 12.2. The model N-3000 from Nellcor has three different ways of recording data for trend analysis. In the first two modes, the unit stores the average of oxygen saturation and heart rate measured over a period of 5 or 10 s, with a total duration of 12 or 24 h respectively. In the third mode, the unit stores the maximum and minimum values obtained over a period of 20 s, with a total duration of 32 h. The length of the recording also changes with presentation. The Propaq models from Protocol Systems, Inc. can display a total of 5 h on the screen and 8 h on a printer with a resolution of 2 min. The data can be presented in graphical or tabular form.

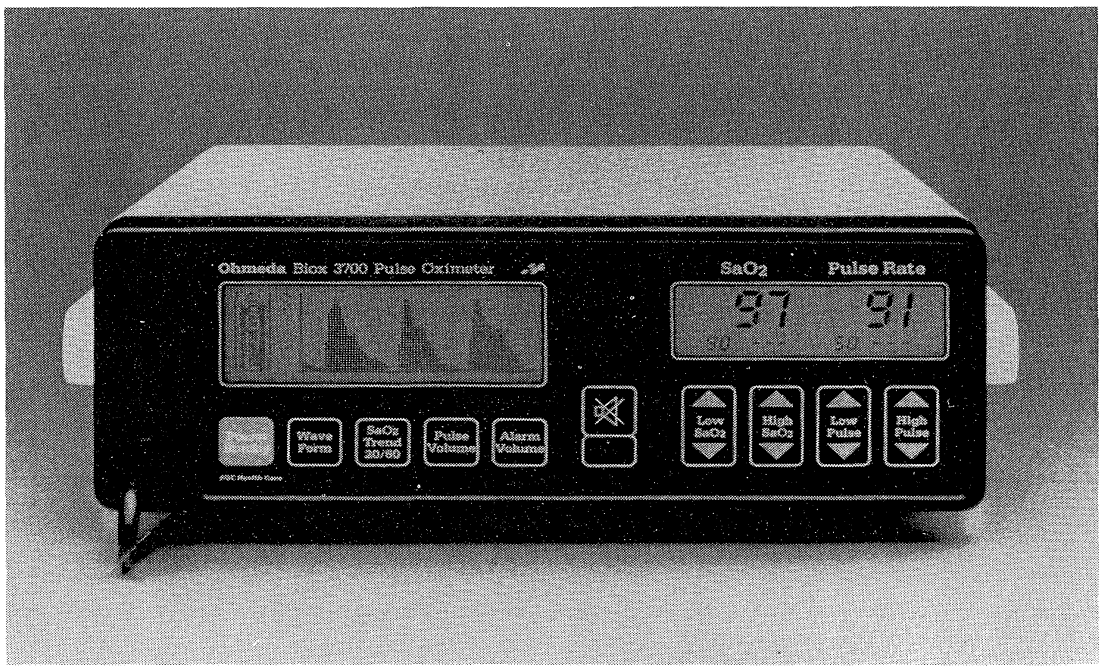

Figure 12.2 Front panel of Ohmeda Biox 3700 pulse oximeter (Courtesy of Ohmeda). The display at the left side shows real-time waveforms and pulse strength, while the display at the right side is used for alarm settings.

In some units, for example the model 504 from Criticare, the memory in which the trend data are being stored is not erasable on power-off. When trend data that contain periods of time in which the unit was turned off are displayed, the time during which the unit was turned off is shown as special characters so that the operator can be aware of this situation. This feature allows us to follow a patient during a long duration in which constant monitoring is not required. The drawback of this feature is that it can acquire the trend from the wrong patient if the previous data are not erased before starting to monitor a new patient. The trend display also marks times during which alarm set points have been exceeded or the pulse has been lost.

Trend graphs incorporate cursors that can be scrolled through the display with numeric readouts that normally show the values of the waveform and the time. This feature is particularly useful when the screen displays different waveforms because they do not incorporate a numerical vertical axis and it is not possible to distinguish magnitude by only reading the screen. It is also very important to properly label the different waveforms, as the most commonly displayed waveforms (pulse rate versus time, and oxygen saturation versus time) can present numerical values very similar to each other and confuse the system operator. It is also important that the trend display have the capability to use the dynamic range available in the screen to more clearly show small changes. For example, the model 504 from Criticare displays the trend in oxygen saturation between 75% and 100%. Although large changes in oxygen saturation can be easily recognized, it is difficult to notice small changes at a glance because most of the monitored patients will not have such a large oxygen saturation change.

A series of menus that appear on the screen normally permit the operator to select between the displayed waveforms, cursor displacement, and other function controls. The selection keys are placed under the display screen or at its sides, and the function of a particular key is automatically changed depending on the displayed screen mode.

The display of pulse strength is mandatory for those pulse oximeters that display a normalized pulse waveform (ASTM 1992). The reason for this feature is because the amplitude of the plethysmographic signal can be changed by the operator in order to achieve a good dynamic range on the screen, and it is desirable to have an indication of pulse strength regardless of the operator settings. In units with graphical displays, it is commonly done by a graphic bar whose amplitude is proportional to the pulse strength, situated on one side of the screen, as for example the unit shown in figure 12.2. The display of the pulse strength must be accompanied by acoustical signals.

Other information commonly found in graphical display units is the values at which alarms have been set, their status, low battery indication, system malfunctions, and other messages of interest to operators.

12.2.2 Numerical displays

The majority of the marketed pulse oximeters use only a numerical display made of red LED segments. In all the units examined, information on oxygen saturation and heart rate is presented. In addition to these variables, the models 507 and 5070 from Criticare Systems, Inc., that are complex monitoring units, also display the values of systolic, diastolic, and mean blood pressure. POET TE Plus from Protocol Systems, Inc. displays the values of oxygen saturation and CO_2. Because in some patients, oxygen saturation and heart rate can reach the same numerical values, it is highly desirable that the displays incorporate a fast and reliable way for the operator to associate the number on the panel with the physiological variable of interest. However, only a few units have this feature. For example, the model POET TE Plus from Criticare Systems, Inc. uses different colors for LED segments to display oxygen saturation and CO_2. The model 3500 from Magnetic Resonance Equipment Co. and the models 504 and 504S from Criticare Systems, use different size LED segments to display oxygen saturation and pulse rate, and Medical Research Laboratories, Inc. uses larger

green LEDs for oxygen saturation display and smaller red LEDs for heart rate display. The pulse strength in all the units with numerical output is displayed using a LED bargraph.

12.3 FUNCTION CONTROLS

Function controls carry out communication from the healthcare professionals to the pulse oximeter to achieve the proper monitoring and care for the patient. Function controls are basically used to operate alarms (set alarm values, activate, deactivate and silence alarms) and displace the cursors along the graphical screen in those units with this feature.

It is possible to distinguish three different function controls: switches, turning knobs and keys. They do not all need to exist in the same unit.

The main function of switches is to turn the device on or off. In some units switches are replaced by keys. Since this is the most basic function in a pulse oximeter, it is important that it cannot be turned off accidentally. For this reason, some units have the main power switch or key in a lateral panel where it is unlikely to turn the power off by accident.

There are few units that incorporate turning knobs. The model N-200 shown in figure 12.3 and model N-3000 from Nellcor use turning knobs as an intuitive and quick way to increase or decrease the alarm settings. The turning knobs are placed on the front panel or on the top of the unit, where they are large and thus are easier to manipulate without affecting other controls. A function that uses turning knobs for control has to be designed so that a movement upwards, to the right or in a clockwise direction increases the control function (ASTM 1992).

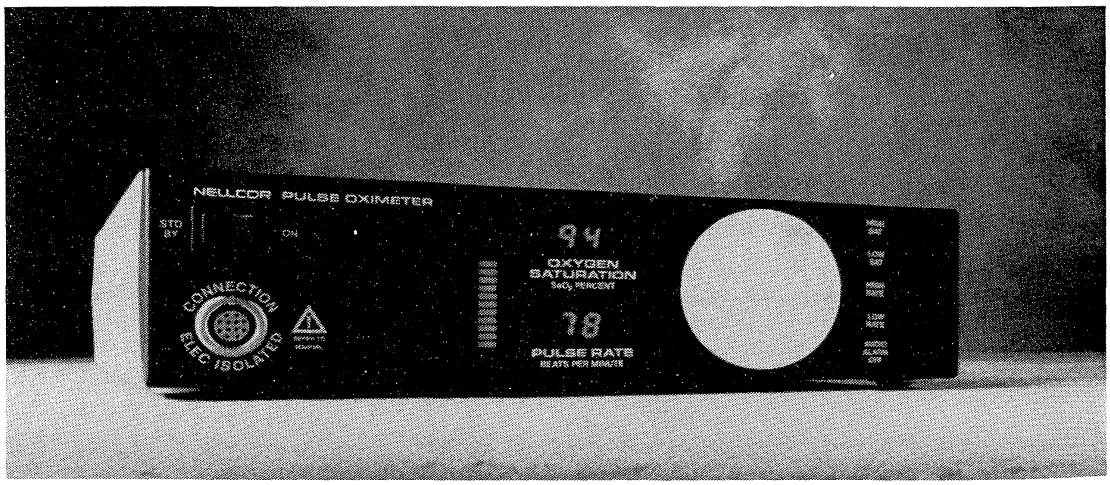

Figure 12.3 Nellcor Puritan Bennett N-200 pulse oximeter (Reprinted by permission of Nellcor Puritan Bennett, Pleasanton, California).

The majority of pulse oximeters use keys as input devices to control the instrument. We can distinguish between units that use touch panel keys and units

that use push buttons. Touch panel keys have the advantage that they are cheaper to manufacture and insert during the manufacturing process and can accommodate LEDs to indicate that the function is active. They also contribute to a better seal of the unit's front panel, thus making it more suitable for use in hostile environments. Figure 12.2 shows a unit that uses these kind of keys for front panel functions. On the other hand, push buttons have a better feel and require lower pressure to activate. However, they have open spaces around them, can permit dust, humidity and other chemical agents to shorten the life of their electrical contacts.

For any kind of keys used, it is desirable that the operator has a feedback that the key has been pressed successfully, either by a visual stimulus such as turning on a LED in a touch panel key, an audio stimulus by emitting a characteristic sound, or tactile feedback from the release of the pressed key pressing on the operator's finger (Cakir *et al* 1980).

It is important to consider the number of different keys that are available in a pulse oximeter. In general, it is best to have as few keys as possible to simplify the access to the most common and critical functions, such as setting the alarm values. For example, the model N-200 from Nellcor has a very intuitive way of setting the alarm values (low oxygen saturation, high oxygen saturation, low pulse rate, and high pulse rate) that consists of pressing a single key to select the alarm, and modify the actual value by rotating the turning knob as can be seen in figure 12.3. However, this device has only five different keys, so the operator needs to press two different keys simultaneously to activate other functions. Because the key labeling only refers to the basic function, it can become difficult to remember which keys need to be pressed in order to activate the desired function, and it is therefore harder to perform. In this particular unit, the manufacturer supplies a quick reference card to be placed on the bottom of the unit. It provides a helpful reminder to the operator if the operator knows where to look.

On the other hand, the model 504US from Criticare uses the dynamic key function and labeling that has been described in previous sections. With only three touch panel keys for menu purposes, the operator enters a series of menus and submenus, changing the function of the keys according to the menu that is active. Although this way of controlling the functions has the advantage that the operator always knows the function of the set of keys, it is very easy to forget the depth of the menu entered, in which submenu a particular function of interest is located. It can also be time consuming to move between functions located in different submenus.

In the same way that the operator needs feedback to indicate that a particular key has been pressed successfully, the operator also needs some feedback that indicates that the key, or combination of pressed keys, is valid, and a control function has been executed. The most common way to produce this feedback is by turning on a visual indicator that is related to the function executed, or by emitting a characteristic sound in the case of invalid keys.

It is also important to pay attention to the layout of displays and indicators and their control keys, selecting the position of the controls in a place that is consistent with the display. Figure 12.4 shows different examples of good and poor relative positions between displays or indicators and controls, based on the idea that they have to be laid out in such a way that the relationship between controls and their indicators is obvious.

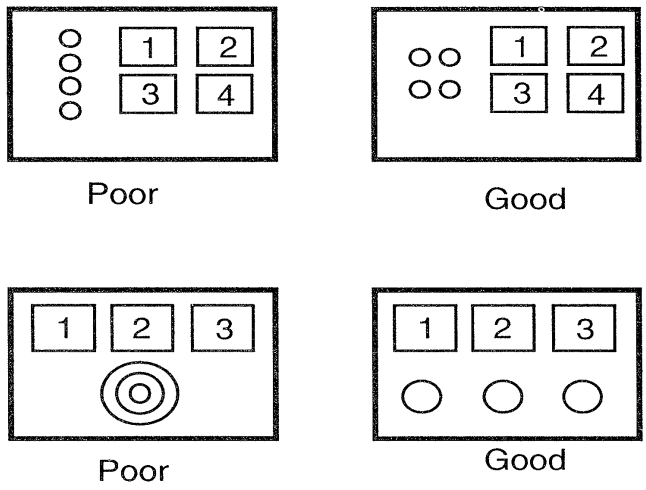

Figure 12.4 Layout of controls and indicators to ensure good operator interaction. From Salvendy (1987).

12.4 ALARM CONTROLS

The alarms communicate the patient to the healthcare professionals, alerting of a potentially dangerous situation. Because the alarms are the most critical functions in a pulse oximeter, it is absolutely necessary to be sure of their proper working condition, as well as to take extra effort to design them in such a way that they cannot be disconnected accidentally.

The design of alarms and their controls section is by far the most regulated by the standards. The most common type of pulse oximeters, the units that display the oxygen saturation and heart rate, provide alarms for the following situations:

1. High oxygen saturation.
2. Low oxygen saturation.
3. High pulse rate.
4. Low pulse rate.

Other sections in the ASTM Standard regarding the operation of alarms require that the alarm set points be operator adjustable, that the default limits on low oxygen saturation be 80% saturation or greater, and the difference between the alarm set point and the actual value of arterial oxygen saturation when the alarm is activated not exceed 2% of oxygen saturation (ASTM 1992).

In most of the units, it is possible to deactivate at least the alarm for high oxygen saturation, except in the case when the pulse oximeter is configured for neonatal monitoring. The pulse oximeter shown in figure 12.2 has deactivated the alarms for high oxygen saturation and high puse rate.

From these alarms, only the low oxygen saturation alarm is required for the pulse oximeter to be qualified as a monitoring device. Those devices without low oxygen saturation the alarm shall be marked as 'NOT FOR MONITORING' (ASTM 1992). All the marketed units examined provide these four alarm

situations, except the models 8500 and 9500 from Nonin Medical, Inc. These units have been designed not for a bedside monitoring situation in a hospital where the alarms are used to attract the operator's attention, but in a one-on-one working situation where a healthcare professional is always present with the patient, using the pulse oximeter to measure the oxygen saturation, for example, during ambulance transport.

The 9500 unit, shown in figure 12.5, is the smallest available in the market. With a weight of only 36 g without batteries and an extremely small size, just slightly larger than most of the reusable finger probes, it displays heart rate and oxygen saturation. The unit 8500 is a hand-held pulse oximeter that has been designed to provide 100 h of continuous operation with batteries. Both units have been designed for evacuation situations. They both comply with the USAF vibration standards for helicopter flight use, can operate at temperatures below freezing, and the manufacturer stresses their use in helicopter evacuation.

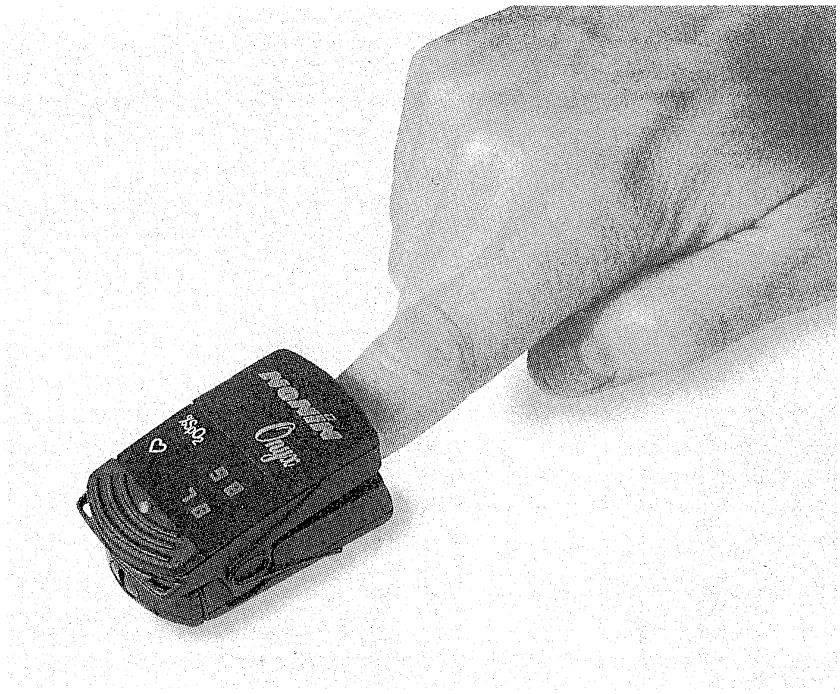

Figure 12.5 A small Nonin model 9500 pulse oximeter designed for emergency evacuation purposes (courtesy of Nonin Medical Inc.).

The visual and acoustic characteristics of the alarms are also regulated by the ASTM Standards, as shown in table 12.1. The ASTM differentiates three kinds of alarms based on their priority, assigning different colors and flashing frequency to each one.

Table 12.1 Alarm characteristics for pulse oximeters (ASTM 1992).

Alarm category	Operator response	Audible indicators	Indicator color	Flashing frequency (Hz)
High priority	Immediate	Not medium or low priority	Red	1.4 to 2.8
Medium priority	Prompt	Not high or low priority	Yellow	0.4 to 0.8
Low priority	Awareness	Not high or medium priority	Yellow	Constant

The current ASTM Standard specifies neither the frequency nor the volume of the acoustic alarm sounds. Good practice suggests that the frequency of warning sounds should be between 150 Hz and 1000 Hz. It should have at least four frequency components in order to avoid masking from environmental noise. The acoustic level recommended is 15 dB to 16 dB above the masked threshold for signals that are triggered by situations that require a rapid response, and levels between 6 dB and 10 dB above the masked threshold for all other kinds of signals, to achieve 100% detectability in controlled situations. In all cases, the level should be less than 30 dB above the masked threshold to minimize operator annoyance and disruption of communications (Salvendy 1987).

The alarms in a pulse oximeter can be disconnected or silenced. Temporary silencing should be used when the operator has been alerted of the potentially dangerous situation and has taken steps in order to solve the problem. The Standard specifies that if this feature is provided in the pulse oximeter, it should not exceed 120 s, and a visual condition of the alarm has to remain on until the condition that triggered the alarm is corrected (ASTM 1992). The reason pulse oximeters incorporate a permanent silencing alarm is to avoid nuisance noise when the device and probe are being connected to the patient. The permanent alarm silencing activation must be designed in such a way that it requires a deliberate action for deactivation by the operator to be sure that it is not done in error. It also requires a visual indication of this condition.

As most of the pulse oximeters monitor heart rate from the plethysmographic waveform, they also incorporate alarms in case the pulse is lost. This increases security for the patient by monitoring more vital signs, but it also triggers false alarms, in particular due to motion artifacts. To avoid this problem, Nellcor has developed what they call Oxismart, which, for loss of pulse, aims to distinguish between a real clinical condition and a motion artifact. This feature is incorporated in the latest models, such as the N-3000.

Motion artifacts are detected by processing the plethysmographic waveform and before validating a pulse, requiring three different steps. Only the signals that pass all the steps are used to calculate S_pO_2 (Nellcor 1995). To differentiate between a loss of pulse due to motion artifact from a loss of pulse due to a clinical condition, the system assumes that if the pulse is lost, but the patient is moving, the patient has pulse and the loss is due to a motion artifact. Figure 12.6 illustrates this fact. If the pulse oximeter fails to detect at least one pulse in 10 s, it enters into pulse search mode. The operator is aware of this situation because the PULSE SEARCH indicator lights, and the display alternates between data and dashes. In this condition, the pulse oximeter enters an evaluation period of 50 s. If the patient is moving, each time that the pulse oximeter detects a valid pulse, readings for heart rate and oxygen saturation are validated. The device returns to

its normal operation after detecting an adequate sequence of validated pulses. If during the 50 s evaluation period, an adequate pulse sequence is not detected, a low-priority alarm sounds, and there is a visual indication of this condition as shown in table 12.1. On the other hand, if the pulse oximeter does not detect motion after 60 s in pulse search mode, a high-priority alarm sounds, and there is also a visual indication of this condition. With this feature, it is possible to track the oxygen saturation even in patients that produce signals of poor quality, and at the same time warning can be given of a potentially dangerous condition.

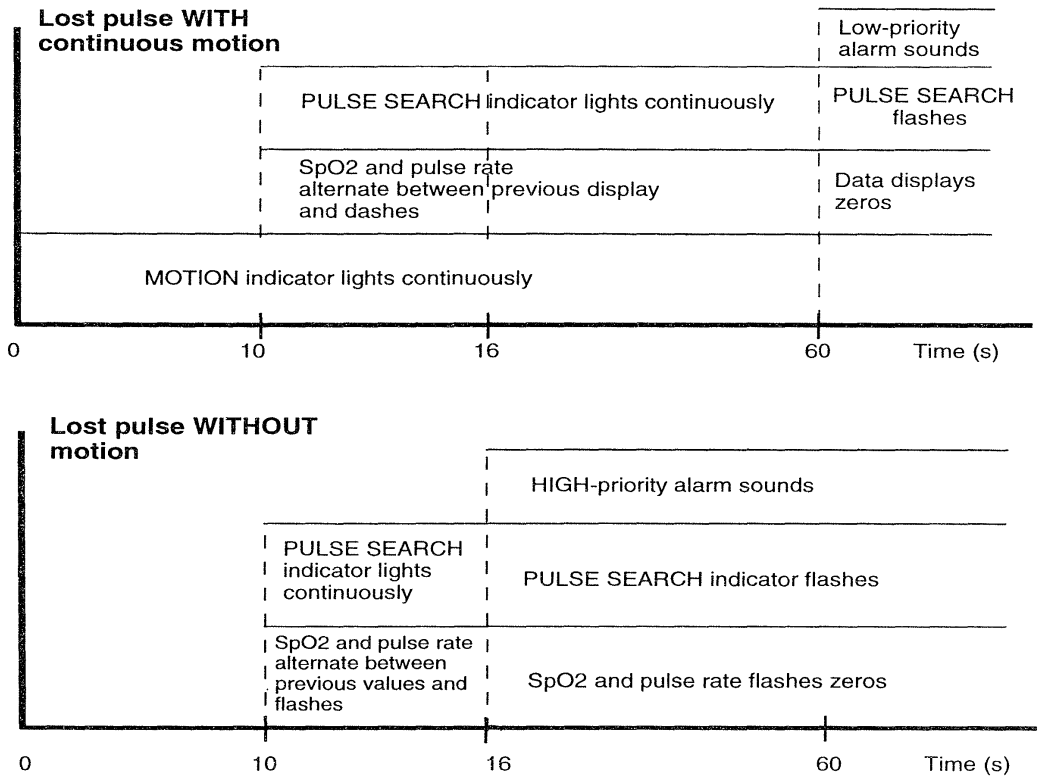

Figure 12.6 Oxismart© alarm detectors used in some Nellcor units to reduce false alarms due to motion artifacts (Nellcor 1995).

12.5 COMMUNICATION FUNCTIONS

Communication functions are not a primary function, but an added value feature for a pulse oximeter. Communication functions can be found in all types of devices, but they provide a great improvement to the units with only numerical display, because it gives them the graphical features that otherwise are missing. They are used to send data to a printer or plotter. The most common use is to print the trend for both oxygen saturation and heart rate for a patient. This feature converts the most simple units into units that act like solid state Holter

monitors, with the clinical advantage associated with the knowledge of trend over time. There are few units that incorporate an internal printer, normally a thermal one, thus eliminating the need for extra connectors and cables.

The most common method of communication is using the RS-232 protocol. It is also possible to obtain analog signals proportional to the plethysmographic and pulse rate waveforms. The voltage output is normally selectable between a range of 0 to 1 V dc and 1 to 10 V dc.

12.6 CABLES AND CONNECTORS

The cables and connectors are used to transmit power and signals between the device and the surrounding accessories and power supplies. We can roughly distinguish three levels of communication:

1. Interface with the power source.
2. Interface with the lead and probe.
3. Interface with auxiliary equipment.

The power connector is used to transfer the energy required from the power source to the unit for its operation. The Standard requires that it should be designed so that it protects the patient from human errors (ASTM 1992). This means that it has to be clearly different from the connectors that will be attached to the patient. Power connectors are used to operate the units when it is turned on, and to recharge the battery when the unit is turned off.

The connector for the lead and probe is usually placed on the front panel, and it is usually mechanically incompatible between different manufacturers, unless they specify that the probe is compatible. For example, Protocol Systems advertises that their Propaq models can use probes from Nellcor. The most common types of probe connectors are DB9 and DIN. In all cases, the connectors are mechanically designed with physical alignment aids and visual indicators to be sure that the lead is inserted the correct way into the connector. It is important that the connectors be constructed robustly, because the unit can be subjected to severe mechanical stress and vibration. Because most of the units can be synchronized with the ECG signal, obtained through a separate module, it is common to have an ECG connector.

The auxiliary connectors are normally located on the side or the back panels, and they are normally used for communication functions. The most common ones are the transfer of digital data to a printer or analog data for further recording or to a graphical plotter. For these auxiliary functions almost every manufacturer uses their own set of connectors, voltage levels, and communication protocols that make them work only with their own peripheral units.

12.7 OTHER FEATURES

Other indications that need to be displayed in a pulse oximeter are those regarding the correct labeling of all inputs, outputs, control knobs, and keys. Some models of pulse oximeters are manufactured in different levels of electrical isolation. For example, Criticare manufactures the unit 504/504US in BF (body floating) and CF (cardiac floating) versions. Because they look externally very

similar, if not the same, it is very important to carefully mark its application on the front panel to avoid connecting a patient that needs a CF unit to a BF unit.

For those units that can be operated using an internal rechargeable battery, or disposable batteries, it is important to have an external indication of the approximate level of charge of the batteries and the remaining operating time, to control their replacement. The units from Medical Research Laboratories, Inc. display the charge level on an indicator. Most other units display a low-battery warning signal.

12.8 COMPLIANCE REQUIREMENTS

The Electromagnetic Compliance (EMC) requirements for electrical equipment in general, and biomedical equipment in particular, are changing at a fast pace. Because most of the new regulations have long transition periods during which they are not mandatory, it is wise to design products for future compliance with those regulations. We do not describe the current applicable regulations and standards, but describe their existence and probably future evolution.

The basic idea behind the set of EMC regulations is to ensure the safety of operation of electrical equipment during normal circumstances. This means that a particular device should not cause harmful interference to other devices and this device should not be affected by interference from other devices. Figure 12.7 illustrates these effects. They can be summarized as conducted emissions, radiated emissions, and immunity from interference generated by other equipment that can be either radiated or conducted to the device in question (Gerke and Kimmel 1994a). For the interference generated in the unit, most of the problems are caused by the radiated emissions, because the use of microprocessors running at high clock frequencies is becoming more common in medical devices and these generate radiated interference.

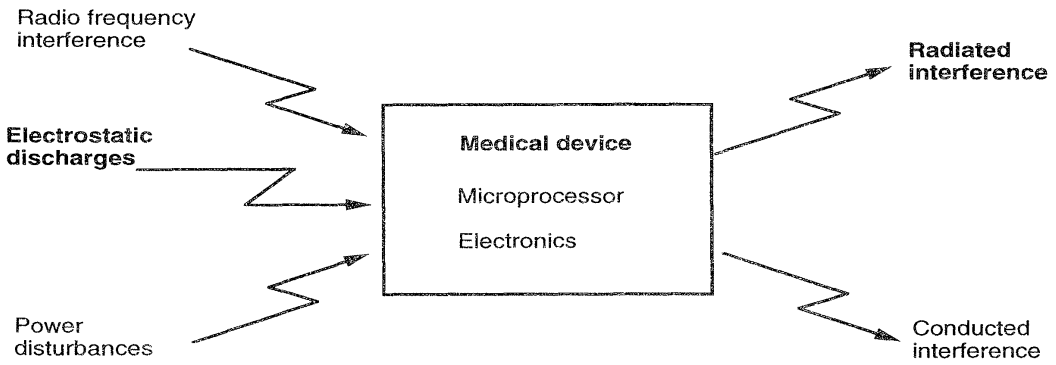

Figure 12.7 Different sources of disturbances and interferences for EMC purposes.

The ASTM Standard refers to the IEC 601-1 and IEC 801-2 Standards for electromagnetic compatibility requirements in pulse oximeters (IEC 1988, 1990). The IEC 601-1 Standard describes a general set of requirements for the safety of electrical equipment for medical use. The unit only needs to be tested against electrostatic discharges (ESD) for its accessible parts, rather than in the interior

of the device. The Standard justifies this procedure based on the fact that pulse oximeters are not life-support devices, but vigilance adjuncts. Therefore, the cost to provide immunity against ESD in the interior of the system is not justified (ISO 9919, annex L). The same Standard, however, serves as a reminder to exercise common sense and provides acceptable work procedures for maintenance personnel that require them to open the device.

However, many times the manufacturers try to expand their market by exporting their products to other countries. Therefore the designers must be aware of the existence of other EMC regulations, which are generally less strict in the US and more strict in European, Asian and most other countries. As a rule of thumb, the European Economic Community (EEC) countries have more regulations and fewer exceptions to those regulations than the US, where most of the regulations are voluntary for most of the medical equipment. However, medical regulations are undergoing significant changes, and we may expect mandatory EMI regulations in the future, regarding ESD, RF fields and power disturbances, driven by the Food and Drug Administration (FDA) and the regulations in the EEC. At the present time, there are no mandatory regulations in the US, as medical devices are exempted from Federal Communications Commission (FCC) emission regulations, and they are covered only by voluntary susceptibility requirements. On the other hand, in the EEC countries, the equipment is required to be tested for emissions but not for immunity (Gerke and Kimmel 1994b). This situation is expected to change soon, and in the future we may expect mandatory regulations for RFI, ESD, and power disturbances in the US. Because of the need to be competitive in international markets, designers should consider that the best way to avoid unnecessary delays, and to lower the economic impact of changing a design, is to design for compliance from the first stages, without overdesign that implies an increment of cost with no additional value.

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INSTRUCTIONAL OBJECTIVES

12.1 Describe the role of the user interface in a pulse oximeter.
12.2 Discuss the advantages and drawbacks of graphical representation of information.
12.3 Describe the most important features when designing a pulse oximeter user interface.
12.4 For pulse oximeters that only have a numerical output, describe how they can present oxygen saturation over a long period of time.
12.5 Describe and compare different types of alarms in a pulse oximeter.
12.6 Discuss how the number of keys in a pulse oximeter affect its use.
12.7 Name and describe the mandatory alarms in a pulse oximeter.
12.8 Describe the need to comply with EMC regulations.

CHAPTER 13

APPLICATIONS OF PULSE OXIMETRY

Joanna B Ruchala

Pulse oximetry is noninvasive, easy to use, readily available, and accurate. It provides information about blood oxygen saturation, heart rate, and pulse amplitude. Due to these characteristics, it has an abundance of clinical uses. Some of the main areas in which it is used are anesthesia, patient transport, childbirth, neonatal and pediatric care, sleep studies, and veterinary medicine. This chapter will discuss the causes of patient desaturation in these and other areas and how pulse oximetry is used to detect it and prevent severe hypoxemia from occurring. Some of the applications require special apparatus for pulse oximetry. Some require special calibration or specific methods of measurement.

13.1 ANESTHESIA

Air contains 20.9% oxygen which is often not sufficient during anesthesia due to problems such as airway closure, ventilation/perfusion imbalance, and CO_2 retention (Tyler *et al* 1985). Also, most anesthetics cause respiratory depression. This is when the pons and *medulla oblongata*, which control respiration, are not functioning properly. Respiratory depression reduces ventilation and can cause desaturation. Due to these problems, patients are generally preoxygenated and given a 30% oxygen mixture while under anesthesia. This, however, does not ensure prevention of desaturation. Episodes of desaturation are most often caused by human error. J B Cooper of the Department of Anesthesia at Harvard University found that human error caused 82% of incidents of desaturation during anesthesia, while equipment failure caused only 4.3% (Cooper *et al* 1984). Human error includes such things as misreading the flow meter and inadvertently allowing a lower inspired oxygen pressure than required by the patient, positioning the patient incorrectly such that the airway is obstructed, performing tracheal intubation incorrectly, administering sedatives which hinder alveolar ventilation, and encountering complications during surgical retraction. Equipment failure includes blocks in the flow meter and leaks in the anesthesia machine or breathing apparatus.

Cyanosis, a bluish tint to the skin caused by lack of oxygen, cannot be detected by a physician until the S_aO_2 is around 80% (Payne and Severinghaus 1986). Once the arterial oxygen saturation is that low, any decrease in partial

pressure will cause a dramatic decrease in S_aO_2 due to the steepness of the oxygen dissociation curve (see figure 1.7). Other physiological signs of desaturation such as a drop in blood pressure or reduced heart rate also do not occur until the patient's arterial oxygen saturation is dangerously low. Blood gas analysis is very accurate, but it is invasive and slow (it takes approximately 5 min to obtain a measurement). Pulse oximetry can detect desaturation quickly and accurately and has significantly reduced the number of anesthesia-related deaths. The Datex Satlite is a pulse oximeter specially designed for anesthesia monitoring. The plethysmograph reveals circulatory depression and arrhythmia. Signal processing algorithms detect trends in pulse amplitude, S_aO_2, and pulse rate. Amplitude trends describe the course of the anesthetic (trends during a 1 h, 45 min period) and recovery (trends during a 7 h period). It can also display the CO_2, O_2, or agent waveforms.

Patients who have been under general anesthesia for surgery are often given supplemental oxygen during the procedure and in recovery. However, it is important to monitor their arterial oxygen saturation during transfer as well. Their ventilation is often poor due to residual anesthetics and muscle relaxants (Tyler *et al* 1985). Also, their alveolar–arterial oxygen tension gradient may be abnormal due to a ventilation/perfusion imbalance.

13.1.1 Problems encountered during induction to anesthesia

Desaturation is often a problem during induction to anesthesia. Moller *et al* (1991) found that during this phase, arterial oxygen saturations of 90% or less occur with a frequency of 25% of patients. Pulse oximetry can detect desaturation in real time and indicate the need for an increased oxygen mixture or adjustment of an endotracheal tube. Tracheal intubation can be a problem during anesthesia due to improper tube placement or subsequent tube movement.

Buchanan (1991) combined an endotracheal tube and a pulse oximeter probe to allow monitoring of both tube placement and arterial oxygen saturation as shown in figure 13.1. Light emitting diodes (LEDs) are attached to the leading end of the tube. Lead wires are embedded in the body of the tube, extending out of the patient's mouth. A photodiode is located outside the patient's body and placed on the anterior surface of the neck, opposite the LEDs. The photodiode's position is adjusted to detect the maximum amount of light from the LEDs and then secured with surgical tape. The LEDs and photodiode are connected to a pulse oximeter to measure arterial oxygen saturation. Measurement in this location as opposed to at extremities such as the finger or ear is more accurate and more sensitive to rapid changes in oxygen saturation. This is because blood flow in the arteries of the neck leading to the brain is preserved at the expense of blood flow to peripheral regions. If the physician prefers to keep the LEDs outside the patient's body, fearing burns to sensitive tracheal tissue, optical fiber can be used to transport the light into the trachea. If the signal to the pulse oximeter is lost during the surgical procedure, this indicates that the tracheal tube has been displaced.

Application of a laryngeal mask can also be troublesome. Haynes *et al* (1992) determined a 3% failure rate in the insertion of a laryngeal mask, and application difficulty in 18% of patients. Difficulty applying the mask sometimes occurred because the depth of the anesthesia was not great enough.

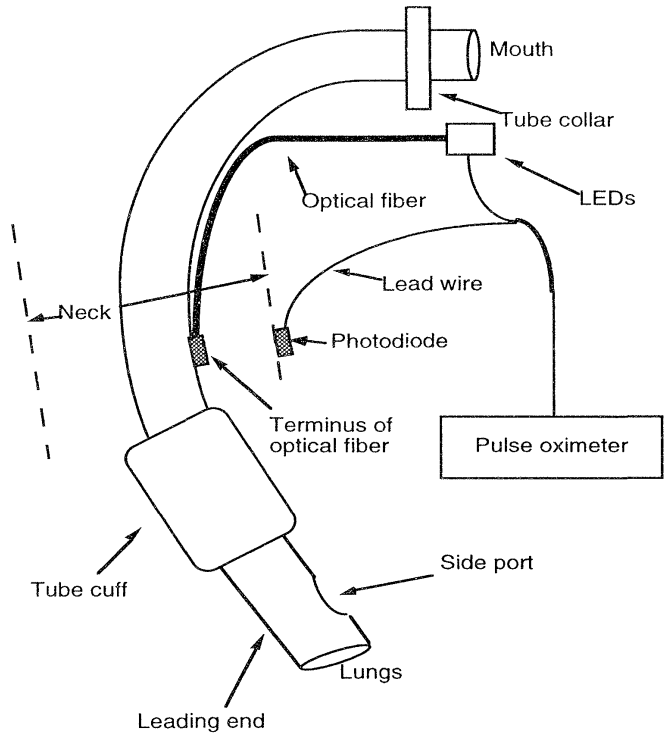

Figure 13.1 Endotracheal tube with pulse oximetry attachment. In this version, the light source is located outside the mouth, and light is transported into the trachea via optical fiber (adapted from Buchanan 1991).

13.1.2 Surgery under anesthesia

13.1.2.1 Abdominal surgery. Use of anesthesia during abdominal surgery can cause patient desaturation. During this type of surgery gas exchange in the lungs can become impaired due to a reduction in functional residual capacity (FRC). This condition can persist for several days after the operation (Knudsen 1970). Reduced FRC is thought to be caused by a reduction in the resting tone of the inspiratory muscles of the rib cage and diaphragm, which oppose the elastic recoil of the lungs (Roberts *et al* 1993). Reduced FRC can in turn cause alveolar collapse. The chance of collapse is increased by the presence of gases such as nitrous oxide which have a high solubility in blood (Roberts *et al* 1993). Alveolar collapse causes *atelectatic areas* (airless pockets) to develop in the lungs which cause desaturation (Strandberg *et al* 1986). Pulse oximetry can also be used to test the viability of internal organs in the abdomen by applying a reflectance probe covered with a sterile plastic bag directly to the organ (Moyle 1994). After the operation, postoperative pain and analgesia (sedatives) have also been found to increase desaturation (Catley *et al* 1985).

13.1.2.2 Thoracic surgery. During thoracic surgery, the anesthetic agent is often introduced to one lung. This causes a reduction in the volume of that lung, and the ventilation/perfusion of the lungs becomes unequal. The lung with the anesthetic agent has poor ventilation and good perfusion, while the other lung has

good ventilation and poor perfusion (Payne and Severinghaus 1986). Therefore, while the patient has no trouble expelling CO_2, the one active lung cannot accommodate enough oxygen to sustain the patient. This results in desaturation. Pulse oximetry monitoring is necessary to determine the need for increased oxygen mixtures.

13.1.2.3 Dental surgery. In dental surgery, desaturation often occurs during particular stages such as induction to anesthesia, laryngeal mask application, prop insertion (to keep the mouth open), and dental extraction. Sometimes respiration can be detected simply by observing the reservoir bag (Bone *et al* 1987). After anesthesia, lateral positioning, oral packs, and a loose fitting face mask make it harder to detect. In a study by Lanigan (1992), 32 out of 120 patients experienced significant desaturation after dental surgery. Nitrous oxide is often used for anesthesia in dental surgery. It is 40 times more soluble in blood than nitrogen. Therefore when a patient is removed from nitrous oxide, the nitrous oxide diffuses out of the lungs faster than nitrogen diffuses into the lungs. This can cause diffusion hypoxia if the oxygen–nitrogen mixture is not high enough. At least 40% oxygen should be inspired for 10 min after nitrous oxide is stopped (Moyle 1994). Also, combining sedatives such as diazepam and midazolem with anesthesia can increase desaturation (Payne and Severinghaus 1986).

13.2 MONITORING TISSUE BLOOD SUPPLY AND ORGAN VIABILITY

A specific organ or tissue bed may not be receiving an adequate blood supply even though the patient's S_pO_2 as measured from an extremity is normal. Direct application of pulse oximetry to an organ or tissue bed can be used to determine its blood flow and viability.

13.2.1 Intestinal blood flow and bowel viability following surgery

Macdonald *et al* (1993) conducted a study to determine if pulse oximetry could be used to monitor intestinal blood flow. Oxygen saturation was measured using a Nellcor D-20 transmission probe folded around the intestine of dogs at three different sites. Blood flow was measured by an ultrasonic flow probe at the root of the superior mesenteric artery. Just prior to the flow probe, a clamp was placed for reducing the blood flow by 50% and 75%. A 15 min equilibration period was given after each reduction before measurements were taken. Blood gas analysis was used to compare with pulse oximeter measurements. The S_pO_2 reduced from 93 ±1% to 83 ±1% and then to 76 ±1%, respectively, for the reductions in blood flow. Macdonald *et al* (1993) concluded that in tissue beds that are not very metabolically active such as the ear lobe or finger tip, blood flow will not have much effect on arterial oxygen saturation. In tissue beds which are very metabolically active such as the intestine, blood flow can have a significant effect on arterial oxygen saturation. Therefore, pulse oximetry is useful for determining intestinal viability after surgery.

13.2.2 Tissue transfer and setting of limb fractures

When transferring tissue such as skin, muscle flaps, and digits, it is important to detect whether the tissue is getting an adequate blood supply. The muscle should be monitored via pulse oximetry for 24 to 48 h to determine for certain whether it will survive (Lindsey *et al* 1991). If a transmission probe is used, it is important to avoid pressure *necrosis* of the delicate muscle. In patients with limb fracture, the pulse oximeter can detect inadequate blood flow distal to the fracture. Two pulse oximeters should be used for this test, one on the injured limb and another on the healthy limb (Moyle 1994). Both pulse oximeters should obtain the same oxygen saturation measurement. Inadequate blood flow could be the sign of an entrapped artery or other complications due to incorrect setting of the fracture (David 1991). One drawback of measuring limb perfusion with a pulse oximeter is that although a signal may be obtained at the extremity of the limb, it does not ensure that muscle beds are well perfused (Clay and Dent 1991).

13.2.3 Dental pulp blood supply and viability

Pulse oximetry can also be used to diagnose dental pulp viability (Schmitt *et al* 1991). A tooth may be degenerating even though it appears normal to the naked eye or via x-ray images. Also, pulp inflammation can occasionally subside without intervention. Blood flow determines the viability of dental pulp and S_aO_2 determines the state of degeneration of a still viable tooth. Past techniques to determine dental pulp viability involved nerve stimulation. This was painful, often inaccurate, and gave no information about the state of degeneration. Nerves can sometimes function although blood flow is impaired.

To understand how monitoring oxygen saturation of dental pulp with pulse oximetry is accomplished, it is important to be familiar with the morphology of the tooth. The outer layers of the tooth consist of bone-like enamel and *dentin*. Collagen fibers connect the jaw bone to a layer of cementum at the base of the tooth, fixing the tooth in its socket. *Apical foramen*, small holes in the roots of the tooth, allow nerves and blood vessels to access the dental pulp. The blood provides oxygen, mineral salts, and nutrients to sustain the *odontoblasts* and neural tissues. Figure 13.2 shows that to measure the blood oxygen saturation, an adapted transmission probe in the shape of a U is applied over the tooth (Schmitt *et al* 1991). A black-foam insert conforms to the tooth and provides shielding from ambient light. It can be replaced and the probe reused on successive patients. The U-shaped probe is flat on top, providing a surface for the patient to bite down on to increase probe stability. The bone-like layers which surround the pulp create an optical shunt of sorts, allowing some light from the LEDs to be transmitted to the photodiode without passing through blood. Due to this extra variable, three wavelengths are needed to isolate the extinction coefficients of the blood. A wavelength in the range of 540 to 570 nm (green) is used because the extinction coefficients of enamel and dentin at this wavelength are similar to their extinction coefficients at 660 and 940 nm. Also, the extinction coefficients of oxygenated and deoxygenated blood at this wavelength greatly exceed their values at the red and IR wavelengths. The hardware of the pulse oximeter is similar to that of a two-wavelength pulse oximeter and the ratio of ratios computation of oxygen saturation is used. However, the denominator of each ratio is adjusted by subtracting off the detected DC value of the green wavelength (see equation (9.30)).

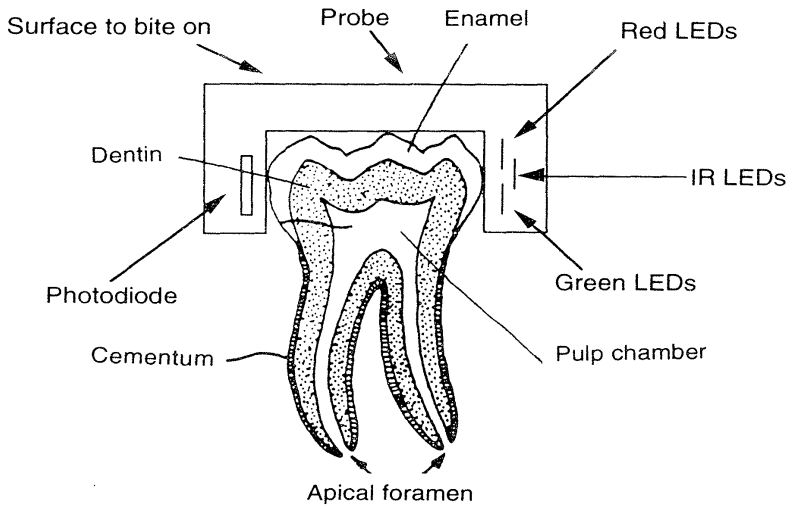

Figure 13.2 Morphology of the tooth and adapted pulse oximeter probe for determining the viability of dental pulp (adapted from Schmitt *et al* 1991).

13.3 MONITORING ON THE ROAD AND IN THE AIR

Pulse oximeters provide accurate, continuous, real-time oxygen saturation monitoring. Since they are also noninvasive, easy to use, and portable they are beneficial for monitoring in ambulances and aircraft. Both ambulances and helicopters are used for patient transport, during which vital signs need to be monitored. Altitude can cause desaturation, especially in critically ill patients. Pilots in the military are also subject to strong forces due to high acceleration, which can move blood out of the brain. These factors can cause loss of consciousness. Pulse oximeters intended for use in these types of environments are subject to special design considerations due to noise and vibration.

13.3.1 Ambulances

Pulse oximeters to be used in ambulances should be light weight and portable so the ambulatory team can apply the monitor as soon as they reach the patient. This provides immediate feedback as to the patient's condition and continuous monitoring while moving the patient into the ambulance. Once inside the ambulance the team is often very busy applying supplemental oxygen, tracheal intubation, CPR, etc. Therefore it is important that the pulse oximeter display is easy to read and the alarms are loud and distinct. During transport, the bouncing of the vehicle can cause the probe to be displaced and temporarily lose the signal. It is important for finger and ear probes to fit properly and snugly on the patient. Poorly fitting probes are often a problem when monitoring children. Vehicle motion can also create artifacts, increasing the need for signal-processing algorithms such as ECG synchronization and signal averaging.

13.3.2 Flight

13.3.2.1 Patient transport. In rural areas and in the military, helicopters rather than ambulances are used for patient transport. Patients are transported from the field to trauma centers as well as from smaller medical facilities to metropolitan hospitals (Short *et al* 1989). During flight, it is again important for the pulse oximeter to be lightweight and portable. However, since flights may take longer than ambulance rides, battery life is also an important consideration. The American Academy of Pediatrics in their 1986 air and ground transportation guideline stated that equipment battery life should be twice the expected travel time (Committee on Hospital Care). In helicopters, noise interferes a great deal with the ability to hear alarms. Therefore it is crucial that displays be readable. Visual indications of problems such as a lighted display which flashes when a patient's oxygen saturation falls below a particular level would be useful. Once again the stability of the signal is important. Rotary wing aircrafts create more vibration than either planes or ambulances (Campbell *et al* 1984).

13.3.2.2 Commercial flight regulations. Pulse oximetry monitoring during flight can also help to set commercial plane regulations. Modern planes can fly at very high altitudes and it is necessary to determine at what altitude cabin conditions become dangerous for both passengers and crew. Currently federal regulations require aircraft to maintain an equivalent cabin altitude of 2438 m or less. As altitude increases, barometric pressure decreases, and partial pressure of oxygen decreases as well. Recall that partial pressure of oxygen is related to oxygen saturation by the dissociation curve. Increasing altitude can cause hypoxia. Exposure to mild hypoxia during air travel is not generally a problem for a healthy person, though altitudes over 2438 m can cause impaired night vision (Ernest and Krill 1971) and color discrimination (Kobrick 1970). Even slight hypoxia which could affect the cognitive and decision-making skills of the crew could be dangerous. Also, passengers on board form a mixed population, some of whom could suffer from heart or lung disease. Even slight desaturation could put them at risk (Cottrell *et al* 1995).

13.3.2.3 High performance aircraft. Pilots flying high performance military aircraft, such as fighter pilots are often affected by both low partial pressure of oxygen and G-loading. *G-forces* are the forces of acceleration acting on the pilot. The pilot can lose consciousness if the partial pressure of oxygen is low and G-forces become too great. Monitoring the oxygen saturation in the head and pulse rate of the pilot during flight can determine if the pilot is in danger of losing consciousness. Once this determination has been made, control of the aircraft can be directed to an automatic pilot system and the aircraft unloaded (slowed down or taken out of a sharp turn or dive). One of the problems with monitoring a pilot during flight is that many of the methods are invasive or require equipment which can hinder the pilot's movement or ability to fly. For example, a finger probe in this situation would not be possible.

Tripp (1993) patented a design, modifying a Nellcor R-15 pulse oximeter probe such that the LEDs and photodiode are mounted on an ear plug as shown in figure 13.3. The LEDs and photodiode face outward such that light is reflected around the ear canal through the vascular tissue and detected by the photodiode. There are several advantages to his design. First, ear plugs are already worn by the pilots to protect them from the loud operating noise of the crafts. Second,

placement in the ear canal reduces interference from ambient light. Third, the oxygen saturation monitored in the ear canal is closer to the oxygen saturation in the brain than the level measured at an extremity. Head movement was found not to affect the ability of the oximeter to obtain accurate measurements (Tripp 1993). The ear canal probes were constructed by drilling a 3 mm hole through the length of the plug and a second hole perpendicular to the first. The LEDs and photodiode could then be threaded into the channels and mounted on each side of the plug. Alternatively, a clay mold could be used with the LEDs and photodiode pressed into the clay on opposite sides. Silicone rubber is then poured into the mold and allowed to harden. The leads of the sensor are connected to a portable pulse oximeter. Further, the oximetry data can be input into a data bus and eventually into the aircraft computer system. In this way the aircraft can automatically unload if the S_pO_2 of the pilot falls below a specified level.

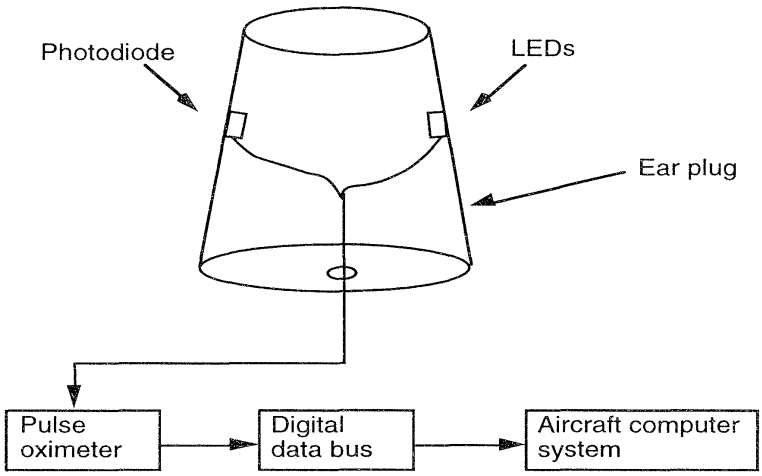

Figure 13.3 Modified pulse oximeter probe for use in the ear canal. In this version, a clay mold has been used to produce the ear plug with the LEDs and photodiode pressed into the sides (adapted from Tripp 1993).

13.4 CHILDBIRTH

Pulse oximetry is used to monitor arterial oxygen saturation of both the mother and the fetus during childbirth. Due to the inaccessibility of the fetus, special apparatus is needed for monitoring.

13.4.1 Causes of desaturation in mother and fetus

Many factors can cause desaturation and hypoxemia in a woman during labor and delivery: *hypovolemia* (diminished blood volume), hypertension (high blood pressure), anemia, maternal position, and anesthesia (Minnich *et al* 1988, Cunningham *et al* 1989). Pope and Hankins (1991) also found that desaturation frequently occurs during the administration of Demerol (a pain killing drug) and during vaginal examinations. Amniotic fluid *embolism* (AFE) can occur when amniotic fluid escapes into the mother's circulatory system. The embolism can

cause the mother to develop a pulmonary shunt and thus experience arterial desaturation. If the embolism is not treated early the patient can suffer cardiorespiratory collapse, neurologic compromise, and *coagulopathy*, resulting in death (Quance 1988). A small amount of amniotic fluid can be found in the pulmonary circulation of pregnant and even nonpregnant women, which complicates the diagnosis of AFE (Clark *et al* 1986). Pulse oximetry monitoring during labor can help detect problems early (Quance 1988).

Fetal monitoring can indicate fetal distress and hypoxia. Chapter 1 noted that fetal hemoglobin has a higher affinity for oxygen than normal hemoglobin so the fetus's oxygen needs are met before those of the mother. This seems to indicate that if the mother's oxygen saturation is adequate, so is that of the fetus. However, maternal monitoring will not detect if oxygen being delivered by the mother is properly reaching the fetal blood stream. Pulse oximetry monitoring is crucial during difficult births such as breech presentation and cesarean section. These types of births put added stress on the fetus. Gardosi *et al* (1991) found that fetal oxygen saturation levels are generally lower in the breech presentation than in the vertex presentation. Fetal monitoring can also detect acidemia which results when a fetus experiences an increase in hydrogen ion concentration. Pulse oximeters can detect this problem because increasing pH causes the oxygen dissociation curve to shift to the right, resulting in low saturation levels. Fetal acidemia can result in acidotic and hyperoxemic infants. It is important to note that infants often experience mild hypoxemia due to the normal stress of labor (Kubli 1968). Johnson *et al* (1991) found that average S_pO_2 values of 68% ±13% occurred at cervical dilation of less than 5 cm and 58% ±17% at cervical dilation greater than or equal to 9 cm. Dildy *et al* (1994) determined even lower values of 62% ±9% and 53% ±10% respectively.

13.4.2 Special apparatus for fetal monitoring

Physicians have encountered many difficulties when attempting to monitor fetal S_aO_2 via pulse oximetry. The first problem is that the fetus is not very accessible. A device is needed to advance the probe into the uterus and position it properly on the fetus. Correct initial placement, however, does not necessarily lead to successful monitoring. During cervical dilation of early labor, the probe position can become unstable. Also, the fetal head is often covered with hair, vernix (a waxy, cheese-like substance), amniotic fluid, and maternal blood, all of which hinder the ability to obtain a stable and accurate signal. Hair not only attenuates the light from the LEDs, but also can create a shunt from the LEDs to the photodiode. During cesarean section, bleeding from the uterine incision can prevent signal detection (Johnson *et al* 1990). Other considerations when performing fetal pulse oximetry include the risk of burns to sensitive fetal skin and the risk of trauma to the fetus.

Several designs for fetal apparatus have been developed to overcome these monitoring difficulties. Two such patented designs follow.

Figure 13.4 shows a reflectance pulse oximeter probe (Chung and McNamara 1993). An abdominal examination is performed to define the position of the fetus and the state of the cervix. A cable, which is stiffer near the probe, is used to guide the probe into the correct position. The probe must be placed beyond the presenting part and the transcervical region (just beyond the cervix).

This is because cervical pressure on the presenting part creates local *edema* which lowers the pulse amplitude and makes signal detection more difficult. Also, the amplitude will vary due to cervical dilation. Figure 13.5 shows that the cable bends around the head of the fetus and conforms to the curve of the mother's pelvis. The cable contains calibration grooves and markings to aid physician placement. The probe is positioned on the temple of the fetus and therefore has less interference from hair. As labor progresses, the probe moves along with the fetus and calibration markings indicate the station of head. The Nellcor N-400 Fetal Oxygen Saturation Monitor uses this type of design. The system electronics have increased sensitivity to small signals to accommodate low amplitude fetal pulses. The probe can also detect if it becomes displaced. Within the probe body there are two small surface electrodes which measure skin impedance. If the impedance is too low, implying contact with amniotic fluid as opposed to fetal tissue, the system does not accept the data (Dildy *et al* 1993).

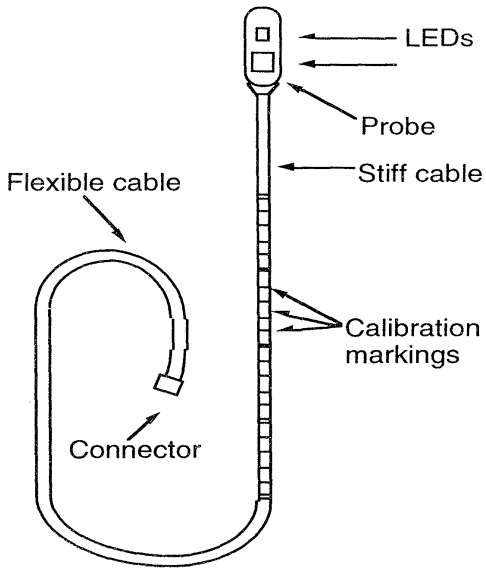

Figure 13.4 Apparatus for fetal pulse oximetry (adapted from Chung and McNamara 1993).

Figure 13.6 shows a design containing a light source located external to the mother. Light is transmitted to the fetus via an optical fiber (Joseph and Guzman 1995). This is advantageous for preventing burns due to high intensity LEDs. Wires from an external monitor and the optical fiber from the light source are threaded through a handle and a plastic tube. Figure 13.7 shows that at the end of the tube is a cylindrical base in which one monitor wire connects to a photodiode and the other connects to a reference electrode. A spiral probe containing the optical fiber extends from the base. By twisting the handle, the probe is inserted 1 to 2 mm into the scalp. The photodiode rests on top. Inserting the probe into the fetal scalp lessens interference from hair and increases the stability of the probe during labor.

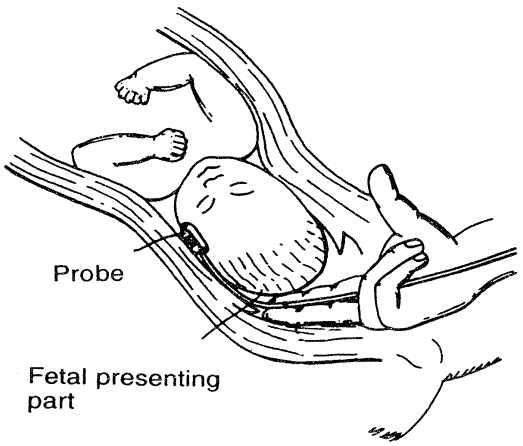

Figure 13.5 Placement of fetal probe within the uterus (Chung and McNamara 1993). The sensor rests on the infant's temple when the physician's fingers reach the saggital suture of the fetus's head.

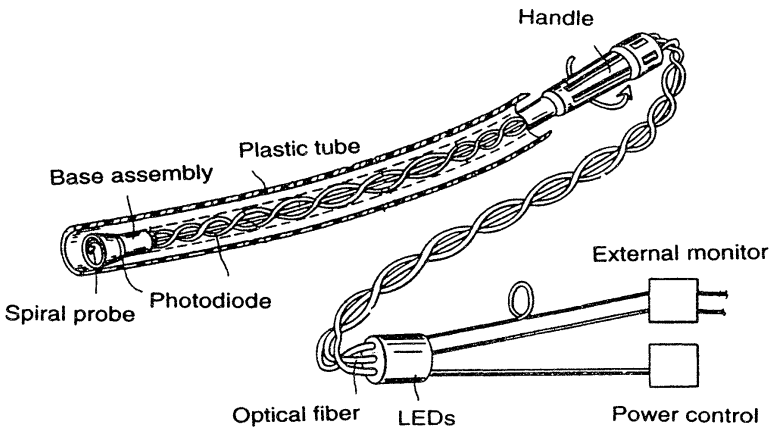

Figure 13.6 Fetal pulse oximetry apparatus with the LEDs located outside of the uterus and transmitted via optical fiber (Joseph and Guzman 1995).

13.5 NEONATAL AND PEDIATRIC CARE

A fetus generally has an S_aO_2 of about 50%. Within the first 15 min after birth, it normally rises to 90% (Oliver *et al* 1961). It is important to monitor the progress of this process and provide ventilatory aid if needed. Infants who experience problematic births are especially vulnerable. For example, infants delivered by cesarean section may be desaturated due to complications which made this type of delivery necessary. Premature infants sometimes develop *retinopathy* due to hyperoxia. High levels of retinal oxygen cause spasm of the

developing vasculature, leading to *ischemia* and blindness (Moyle 1994). Pulse oximeters are often used by new parents in the home as a precaution to prevent sudden infant death syndrome.

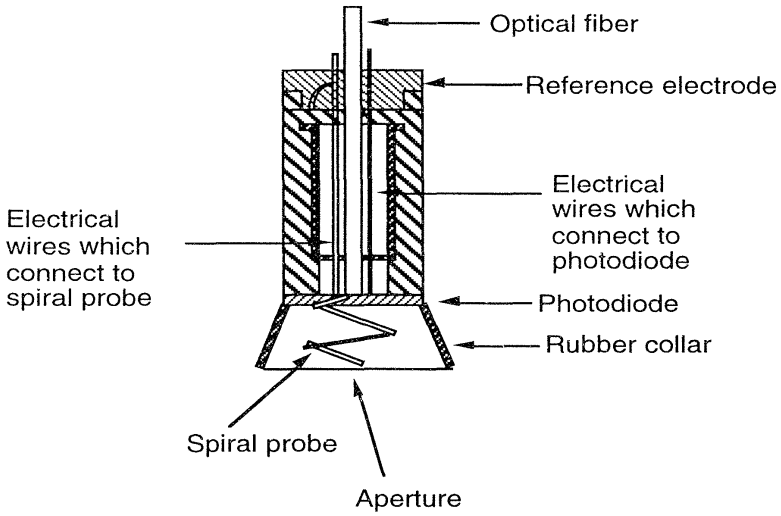

Figure 13.7 Close up cross sectional view of the sensor, showing the helical termination of the optical fiber which is inserted in the fetus's scalp (adapted from Joseph and Guzman 1995).

Determining alarm limits for pulse oximetry in neonatal care can be difficult. Figure 13.8 shows that during the weeks following birth, fetal hemoglobin is replaced by adult hemoglobin. Since the oxyhemoglobin dissociation curve of a fetus is to the left of that of the mother, the curve moves towards the right as the transition to adult hemoglobin takes place. This means that oxygen saturation levels considered safe may correspond to unsafe P_aO_2 levels and cause hypoxia. Paky and Koeck (1995) determined limits for detecting hypoxemia and hyperoxemia in neonates and found that limits to maintain an oxygen tension of 40 to 90 mmHg could only be established with less than 90% reliability. Attempting to obtain better reliability resulted in a S_pO_2 alarm limit for hypoxemia which was greater than that for hyperoxemia. This is obviously clinically unacceptable. However, with 85% reliability the range was only 92.5% to 95%. Deckardt and Steward (1984) determined that infant S_aO_2 levels between 80% and 95% are acceptable. Fanconi (1988) found detecting hypoxia in infants problematic due to inaccuracies in pulse oximeters at arterial oxygen saturations less than 65%.

Morozoff *et al* (1993) developed a system which uses a pulse oximeter as a controller to automatically adjust the air-oxygen mixture received by a neonate. The analog signal (plethysmographic waveform) measured by the pulse oximeter is input into a controller for a motorized gas blender. The blender adjusts the infant's inspired air-oxygen mixture, replacing the need for constant manual adjustment by an attending nurse. The benefits of this system are that it increases the amount of time the infant spends at normal S_aO_2 levels, reduces the need for human intervention, and reduces hospital costs by promoting early removal of oxygen therapy.

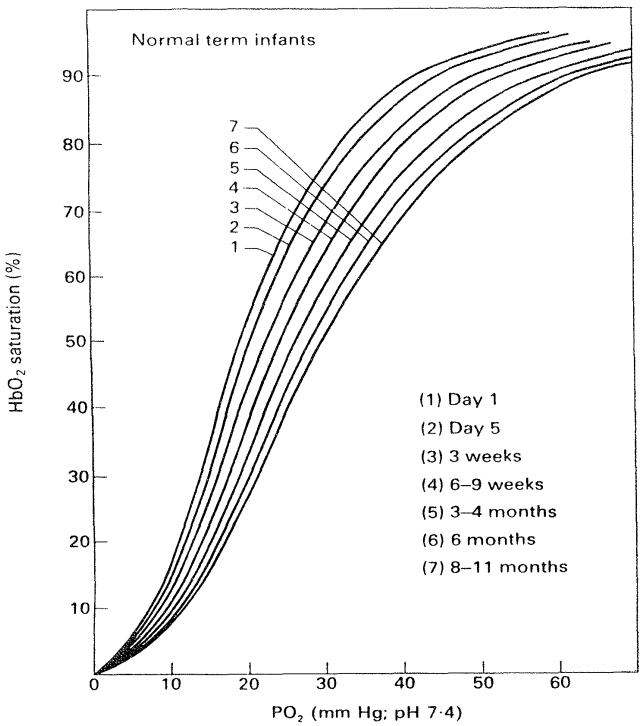

Figure 13.8 Mean oxyhemoglobin dissociation curves of infants ranging from 1 day old to 11 months. From Delivoria-Papadopoulous *et al* (1971).

The S_aO_2 controller operates according to the following algorithm. A patient's oxygen saturation is measured with a pulse oximeter. The signal is converted to a digital representation and low-pass filtered. The corner frequency of the filter is determined by the user and sets the sensitivity of the controller. The observed S_pO_2 minus the desired S_aO_2 is denoted as the error. The signs of the error's magnitude, velocity, and acceleration are input into a state machine. The state machine determines the trend of the S_aO_2 error. It analyzes the signs of the three inputs and determines if the neonate's S_aO_2 is on target, above the target, or below the target. If it is off target, the state machine goes on to determine if it is accelerating, decelerating, moving at a constant velocity, or not changing. If it is moving, it determines if the movement is toward or away from the target. Once the trend is identified by the state machine, it adjusts the F_iO_2 mixture relative to the current mixture. There is also a delay so that the system can react to the adjustment made. Alarms were added for mechanical or electrical failure as well as for S_aO_2 and F_iO_2 limits. Manual intervention can override the controller at all times.

Smaller probes are needed for both neonatal and pediatric care. Infants and children are much less willing to accept the application of a probe and remain still. Probe displacement and motion artifacts due to ill fitting probes can be a big problem. Ear probes made for adults can squeeze the softer newborn tissue too tightly. After a short time they can occlude the artery and have to be moved to

regain a signal. Howell *et al* (1993) developed a modified probe design for children which uses a 5 ml syringe barrel cut in half to house the sensor. The probe is secured to the syringe and can be slipped onto the child's finger. Disposable probes with adhesive bandages are often the best for neonatal and pediatric application. The LEDs and photodiode are attached to the bandage with the proper spacing so that they are positioned correctly when the adhesive is wrapped around the infant or child's finger or toe. Meier-Stauss *et al* (1990) studied the use of pulse oximetry during the first 17 min of life and determined that signal detection occurs faster when a probe is applied to an infant's hand as opposed to its foot. They also found that saturation values from the hand were always higher than those from the foot. This observation suggests that pulse oximetry can be used to document right-to-left shunting in newborns during the first few minutes of life (Meier-Stauss *et al* 1990). This is the passage of blood from the right to the left side of the heart or from pulmonary circulation to systemic circulation.

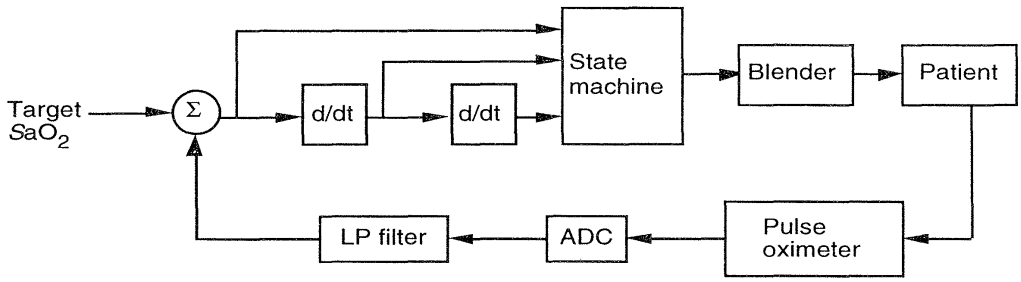

Figure 13.9 Block diagram of S_aO_2 controller. Adapted from Morozoff *et al* (1993).

13.6 SLEEP STUDIES AND PHYSICAL STRESS TESTING

Many people are able to maintain normal oxygen saturation levels while pursuing normal daily activities, but become desaturated during sleep or heavy exercise. The most common cause of desaturation during sleep is due to a disorder known as sleep apnea. Desaturation can occur during heavy exercise due to such things as poor ventilation or chronic obstructive pulmonary disease (COPD). The use of pulse oximetry during sleep and exercise aids in the diagnosis of these respiratory problems.

13.6.1 Sleep

Pulse oximetry monitoring is used during sleep to diagnose sleep disorders which cause desaturation. Sleep is composed of several stages with different characteristics. The first stage is when the person is still awake, but is drowsy and less in tune to stimuli. Two other stages which alternate throughout the night are REM (rapid eye movement) sleep and non-REM or quiet sleep. During REM sleep, rapid changes in metabolic rate do not seem to affect respiration. *Sleep apnea* is the most common sleep disorder which causes desaturation. It is defined as the cessation in breathing due to the relaxation of upper airway musculature. There are three types of sleep apnea: obstructive, central, and mixed. Obstructive

sleep apnea is the most common type and is often caused by anatomical abnormalities such as a nasal obstruction, enlarged tonsils or adenoids, or an abnormal bone structure (Hauri 1992). Patients with obstructive sleep apnea often snore and are obese. They often experience bradycardia and cardiac arrhythmias and are at risk of sudden death during sleep. Central apneas are characterized by the absence of respiratory effort due to a neurological or cardiac problem. As described in chapter 1, respiratory muscles are controlled by neurons in the brainstem as well as chemoreceptors and mechanoreceptors. In patients with central sleep apnea, these neurons cease to provide control during sleep. As the muscles relax, the airway shrinks. The pressures associated with inhalation cause the airway to collapse and become completely closed off. Once breathing has stopped, the patient's oxygen saturation begins to fall. The lack of oxygen is soon detected by chemoreceptors which cause the patient to wake up, renewing control by neurons in the brainstem. The airway muscles become firm again and allow breathing to resume. However, once the patient falls asleep, the airway muscles will relax again. This cycle affects *hemodynamics*, autonomic tone, and arterial blood gas tensions (Davies and Stradling 1993).

Polysomnography is the standard for diagnosing sleep apnea. It measures and records the EEG, EMG, ECG, chest wall plethysmogram, airway flow, and arterial oxygen saturation. However, it is both expensive and of limited availability. Pulse oximetry is easy to use and widely available. Not all desaturation during sleep is indicative of sleep apnea. It could be due to hypopnea (abnormal, shallow breathing), artifact, hypoventilation, or ventilation/perfusion imbalance.

Siem *et al* (1995) used a pulse oximeter in conjunction with a polysomnograph and determined particular patterns of desaturation to be associated with sleep apnea. They divided desaturation patterns into three categories: periodic, cluster, and isolated. Periodic consisted of a minimum of four events with a fall in S_pO_2 of 2% or more with less than 2 min between events. A cluster consisted of 3 or more events with a fall in S_pO_2 of 3% or more and 2 to 10 min between events. Isolated events were separated from any other event by more than 10 min. They found that all periodic patterns were associated with sleep apnea, 65% of clusters were associated with sleep apnea, and none of the isolated events were associated with sleep apnea. Therefore, identifying patterns of desaturation with a pulse oximeter can help to identify sleep apnea.

Lynn (1995) patented a method and apparatus for specifically diagnosing moderate to severe sleep apnea using only a pulse oximeter (no polysomnograph). His method involved analyzing the slopes of the desaturation and resaturation events throughout the night, where an event was defined if the oxygen saturation fell below a specified level for a specified period of time. During an apneic event, the initial fall in arterial oxygen saturation is a function of the oxygen saturation of mixed venous blood and oxygen uptake from residual in the lungs. Then it continues to fall as a function of oxygen consumption and global oxygen stores. Oxygen stores exist first in the lungs, then arteries, tissue, and veins in that order. During apnea, oxygen depletion occurs first in the tissue, then the veins, lungs, and arteries. Therefore, desaturation of arterial blood occurs only after desaturation in other areas. The slope of the desaturation of an event must be within a certain range to be characteristic of sleep apnea. If the slope is too big (rapid desaturation) it is considered an artifact, and if the slope is to small (slow desaturation) it is considered to be due to either hypoventilation,

ventilation/perfusion imbalance, or an artifact. Lynn (1995) performed a study and found that specifically the descending slope as shown in figure 13.10 is a fall in S_pO_2 within the range of 1.1% per second and 0.3% per second. The mean was 0.8% per second. Once the desaturation is detected by the chemoreceptors, resulting in arousal, oxygen rushes into the lungs. The resaturation slope is much larger than the desaturation slope. Specifically, Lynn (1995) found that it is a rise in S_pO_2 in the range of 2.5% per second and 8.3% per second, the mean being 7.6%. The duration of an apneic event is 3 to 3.5 min.

Other parameters are considered in Lynn's diagnosis of sleep apnea. Consecutive events have similar desaturation slopes. Also, an event can increase the initial desaturation slope of a following event. This occurs because oxygen stores do not have enough time to replenish between events. The depletion of oxygen stores is not always detected by the pulse oximeter because arteries replenish their oxygen supply before tissue and veins. Desaturation slope increases occur when cyclic apneic events occur with less than 10 s between and when the depth of desaturation of the first event is larger than 15%. Thus the initial desaturation slope depends on the mixed venous saturation at the onset of sleep apnea and the amount of oxygen left in the lungs after the onset of sleep apnea. The continuing desaturation slope is a function of oxygen consumption versus stores.

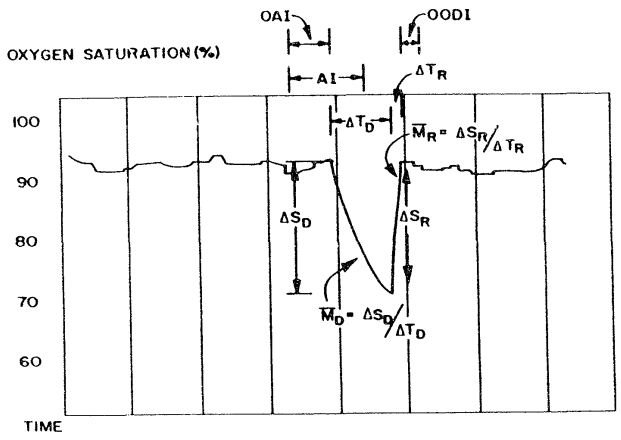

Figure 13.10 A typical apneic event. The vertical lines are 30 s apart. ΔS_D is the fall in saturation, ΔS_R is the rise in saturation, ΔT_D is the duration of the fall in saturation, ΔT_R is the duration of the rise in saturation, MD is the slope of the desaturation, MR is the slope of resaturation, AI is the apneic interval, OAI is the occult apneic interval (apnea has begun, but the arterial oxygen saturation is maintained via oxygen stores), and OODI is the occult apnea interval. This is the period following the return to baseline after a desaturation. If another apneic event occurs within this interval it will have an increased desaturation slope (Lynn 1995).

The operation of Lynn's method begins with measuring the patient's oxygen saturation with a pulse oximeter for a period of 10 min. A mean baseline measurement of arterial oxygen saturation is made during this interval. During subsequent recording, a desaturation event is defined and the duration and slope of the event is determined. The resaturation slope is then determined. Events in which the duration of the desaturation and resaturation is less than a particular

value and the desaturation slope falls within a finite range are defined as phasic desaturations. The ratio of desaturation slope to resaturation slope of the phasic desaturation events is measured. From the above data, the number of apneic events which have occurred can be determined and marked. The apnea can then be treated and the diagnosis process can be repeated to confirm the success of the treatment. Figure 13.11 shows that the measurement of the slopes, computation of the ratios, and comparison of the parameters with known characteristics of sleep apnea is all done within a microprocessor. The microprocessor can be connected to a printer to obtain a hard copy of apneic event data for further analysis by a physician. A variation on the above method is to use the area under the desaturation slope and the area under the resaturation slope. A ratio of these areas can be used instead of the ratio of the slopes. When the microprocessor identifies a phasic desaturation event, it can trigger the collection and/or storage of another parameter such as sound or video. For example a microphone, either separate or as part of the probe can be used to record such things as snoring, which is characteristic of obstructive sleep apnea. Sound could be recorded throughout the night, but only stored during a suspected apneic event. In Lynn's design, sound would be stored for the duration of the event and 1 min prior to and following the event. Short, low-frequency sounds often occur prior to apnea, and high-frequency sounds due to hyperventilation often precede the recovery period.

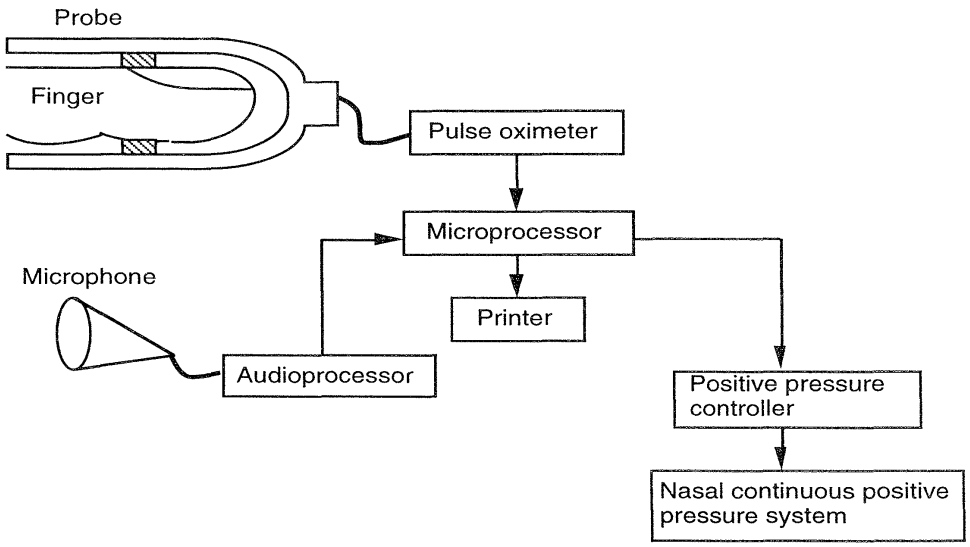

Figure 13.11 A block diagram of the apparatus used along with a pulse oximeter for sleep apnea diagnosis (adapted from Lynn 1995).

Many pulse oximeters such as the portable Protocol Propaq 106EL contain apnea delay alarms. The alarms go off when they detect more than one event of desaturation below a specified level within a specified amount of time. When patients experience recurring apnea events of 15 to 20 per hour, they are in danger and must undergo some kind of treatment. There are several methods of treating sleep apnea. A simple solution can sometimes be sleeping in a more upright position. Another way is by applying *continuous positive airway pressure*

(CPAP) via the nasal passages to support the airway and prevent the collapse of pharyngeal tissue when the muscles relax. This type of treatment requires wearing a mask while sleeping and the air flow can be uncomfortable for patients. Finally, in extreme cases uvulopalatopharyngoplasty (UPPP) or tracheostomy may be necessary. UPPP is a surgical procedure in which excess tissue or a bony abnormality is removed. A tracheostomy involves removing part of the trachea to make a new airway opening.

Other conditions which can cause desaturation during sleep although the patient maintains normal saturation levels while awake are bronchopulmonary dysplasia (BPD), chronic obstructive lung disease (COLD), cystic fibrosis, central alveolar hypoventilation syndrome (CAHS), hypopnea, airway resistance syndrome, and neuromuscular disease.

13.6.2 Exercise

Pulse oximetry can be used to evaluate pulmonary or circulatory dysfunction and performance limitations during exercise. During heavy exercise, a reduction in the partial pressure of oxygen can cause hypoxemia (Dempsey 1986). Miyachi and Tabata (1992) found that ventilation is also a major factor. Athletes tend not to desaturate as quickly as those who do not exercise as often. This is because trained athletes breathe less per unit of metabolic rate than the untrained. Monitoring the oxygen saturation of an athlete can thus determine his physical condition. Also, patients with COPD experience limited ventilation during exercise (Vas Fragoso *et al* 1993). If the condition is severe, ventilation is limited and thus the patient desaturates more quickly during exercise. Pulse oximeters tend to underestimate S_aO_2 readings during extreme exercise, possibly due to high levels of *catecholamines* and neural activity which restrict cutaneous blood flow (Norton *et al* 1992). Catecholamines are chemical compounds derived from catechol ($C_6H_6O_2$) which can affect nervous transmission and muscle tone.

13.7 MANAGEMENT OF CARDIOPULMONARY RESUSCITATION

Pulse oximeters were added as part of the emergency equipment carried by a British anesthetic resuscitation registrar to determine the effectiveness of pulse oximetry to aid in the management of CPR (Spittal 1993). The oximeters used were standard Nonin 8500 with Flex Sensor ear probes. The team found the pulse oximeter to be helpful in primary respiratory arrest, but not too useful in cardiac arrest. Its use during the cases with primary respiratory arrest helped determine if a tracheal tube was needed or if a tracheal tube already in use was not positioned properly. For example, in one patient the tube had been inadvertently placed in the esophagus. External cardiac massage often produces a distorted ECG and it is difficult to obtain reliable oxygen saturation readings. Seventeen patients the team worked on suffered from cardiac arrest and required chest compressions. During compressions, saturation readings were detected for only seven of the patients, and of the seven only three readings were thought to be reliable. The team felt that better fitting ear probes would have been useful because chest compressions cause the body to move and create motion artifacts. Also audible tones to indicate a satisfactory pulse signal and S_pO_2 level would have been useful because it is difficult to watch a display while administering CPR.

13.8 COMPUTER-CONTROLLED OXYGEN WEANING

Pulse oximetry can be used to monitor the weaning process of ventilated patients. During this process, the air/oxygen mixture is gradually adjusted, reducing the amount of oxygen until it matches that of room air. Often the amount of oxygen in the mixture has to be raised and lowered several times if the patient is not able to adjust. Strickland and Hasson (1993) developed a computer-controlled weaning system for patients with complex medical problems. The system was tested on elderly patients recovering from respiratory failure requiring ventilation. An external computer monitored the patient's oxygen saturation as measured with a pulse oximeter as well as the ventilator data. If the respiration rate, tidal volume, and oxygen saturation of the patient were normal, the computer decreased the rate of oxygen inhalation by 2 mL/kg every 2 h until a rate of 2 mL/kg was reached. If the measured values were not normal, it raised the ventilator support to the previous setting. Five minutes were allowed between measurements for the patients to stabilize. They found that the computer-controlled weaning reduced the need for blood gas sampling, shortened the weaning time, and reduced the time the patient spent with an unacceptable respiration rate and tidal volume, as compared with physician-controlled weaning.

13.9 SYSTOLIC BLOOD PRESSURE MEASUREMENT

A pulse oximeter will only obtain an oxygen saturation measurement and a plethysmographic waveform if pulsatile blood flow is detected. This characteristic was exploited by Chawla *et al* (1992) to develop a method to measure blood pressure using a pulse oximeter. An occlusive cuff and a sphygmomanometer are used along with a pulse oximeter. The cuff is occluded until the plethysmographic waveform disappears and the pressure is recorded. The disappearance of the waveform indicates that the artery has been occluded such that blood flow is too weak to be detected by the pulse oximeter. The cuff is then inflated rapidly to 200 mmHg and gradually deflated until the waveform reappears. This indicates that blood flow has increased to a detectable level in the artery. The pressure is again recorded. Specifically, the two pressure values correspond to 8.6% and 4% of the original blood flow respectively. Taking the average of the two pressure values results in a systolic blood pressure measurement which is at most 14 mmHg in error. This is within the clinically acceptable error range. This measurement technique is useful for patients with Takayasu's syndrome (pulseless disease) and critically ill patients with a weak pulse.

13.10 CEREBRAL OXYGEN SATURATION

Pulse oximetry on the *retinal fundus* allows measurement of cerebral oxygen saturation because blood supply to the retinal arteries comes from the *ophthalmic artery* which supplies cerebral tissue. Cerebral tissue is more vulnerable to permanent damage during hypoxemia. Also retinal circulation, unlike peripheral circulation is not affected during shock, hypothermia, and hemorrhage. Retinal oximetry is extremely useful in the critically ill who have weak peripheral circulation. Problems with retinal circulation and oxygen saturation are

associated with diseases such as diabetic retinopathy, hypertension, sickle cell disease, and vascular occlusive diseases and can result in severe damage to retinal tissue (Delori 1988). De Kock *et al* (1993) designed special apparatus for retinal pulse oximetry monitoring. Figure 13.12 shows that a black Plexiglas cone was glued to a haptic contact lens. Holes were drilled to allow a vacuum environment and create suction. The suction kept the lens in place. Slight displacement from the center of the pupil would result in loss of a signal as the light would no longer hit the retinal arteries. An aluminum tube (8 mm in diameter and 1 mm thick) fitted inside the cone and was divided into two sections by a metallic screen. One section contained the LEDs and the other the photodiode. The LEDs and photodiode had been removed from a Nellcor finger probe. When the apparatus was tested on patients, the eye was put under local anesthesia and the pupil dilated to 6 mm. A pulsatile signal was obtained, but blinking and eye movement hindered the pulse oximeter readings.

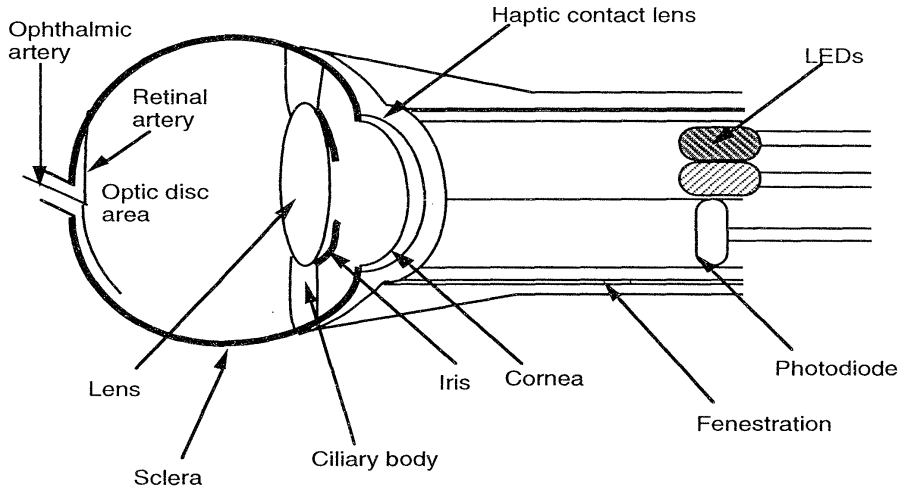

Figure 13.12. Cross section of an adapted haptic contact lens and pulse oximeter probe for use in cerebral oxygen saturation measurement. Adapted from de Kock *et al* (1993).

13.11 VETERINARY CARE

Pulse oximetry is often used in veterinary care. Pulse oximeters need to be able to monitor a wide range of heart rates to accommodate the metabolisms of different animals. Also, specialized probes are used. Common sites for probe placement include the tongue and ear for large animals, Achilles tendon, across the paw pads of dogs and cats, esophagus, nasal septum, rectum, and caudal tail. Limitations associated with the application of pulse oximetry to animals are low perfusion, motion artifacts, darkly pigmented skin, thick skin, and excessive hair (Allen 1990). Whitehair *et al* (1990) noted that oxygen saturation measurements were not obtained when a human ear probe was used on horses' nostrils, lips, and vulva. This could have been because the LEDs were not strong enough to allow sufficient light to be transmitted through the thick skin to the photodiode. Pulse oximeters are often used during anesthesia because the position of ruminant

animals can cause bloating, which in turn can lead to compromised respiration, regurgitation, and death (Allen 1992). Detection of hypoxemia early can prevent the unnecessary demise of the animal. Sensor Devices Inc. and Palco both make pulse oximeters specially designed for veterinary use. The SDI Vet/Ox Plus and 4402 Pulse Oximeter can both measure pulse rates between 20 and 350 bpm with an accuracy of 2%. They also have widely variable gains to accommodate small or large pulse amplitudes.

13.12 FUTURE IMPROVEMENTS FOR PULSE OXIMETRY

Although pulse oximetry seems to be at the peak of its development, there are still improvements to be made. Many of these improvements relate to specific applications. Improvements which will increase the performance of pulse oximetry during transport are to lengthen the battery life in portable units, create even better algorithms for motion artifact reduction, and further miniaturize units. Reducing the occurrence of false alarms would be beneficial in all applications, but especially during long term monitoring when staff cannot always be in the room. In hospital environments for monitoring during surgery, recovery, and intensive care, all-in-one monitors seem to be the goal. HORNET (Hospital Operating Room Network) is a prototype for this type of monitoring (Lecky *et al* 1988). It is designed to monitor respiratory and circulatory variables such as ECG, blood pressure, oxygen saturation, and inspiratory and expiratory gas. It is also designed to handle physiological, demographic, and administrative data. It is to be used for scheduling, intraoperative monitoring, preparation of reports, permanent storage of perioperative information, and research. In addition to all-in-one monitors, the aim is to eventually equip hospitals to transmit information via radio waves to central stations.

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INSTRUCTIONAL OBJECTIVES

13.1 Describe possible causes of desaturation during induction to anesthesia.
13.2 Describe applications of pulse oximetry to determine organ/tissue viability.
13.3 Discuss the special problems encountered when using pulse oximetry in moving environments such as ambulances and helicopters.
13.4 Describe the affects of altitude and G-forces on oxygen saturation levels.
13.5 Explain why it is important to monitor oxygen saturation levels of both the mother and the fetus during labor and delivery.
13.6 Explain difficulties of fetal pulse oximetry monitoring and describe apparatus which overcome these difficulties.
13.7 Explain the need for pulse oximetry monitoring in neonatal care and discuss problems with obtaining alarm limits.
13.8 Explain why monitoring oxygen saturation during heavy exercise is useful for diagnosing pulmonary and circulatory dysfunction and discuss the problems with obtaining accurate measurements.
13.9 Describe a method for diagnosing sleep apnea using pulse oximetry monitoring.
13.10 Explain why pulse oximetry on the retinal fundus is useful and describe how it is administered.
13.11 Describe how systolic blood pressure can be measured using pulse oximetry.
13.12 Discuss the special difficulties of pulse oximetry monitoring in the field of veterinary care.
13.13 Describe future goals for improvement of pulse oximetry monitoring.

GLOSSARY

95% confidence limit: 1.96 times the standard deviation; a 4% confidence limit means that 95% of the S_pO_2 readings should be within 4% when compared to the readings from the CO-oximeter

absorbance: negative logarithm of the transmittance in a light absorbing medium; a measured value equal to the product of the extinction coefficient, optical path length and concentration of the light absorbers

absorption spectrum: extinction coefficients of a certain absorber versus wavelength

absorptivity: see extinction coefficient

accuracy: a statistical term used to represent the correctness of data

acid-base imbalance: abnormal pH of the blood

ADC: analog to digital converter

address/data bus: the bus is the link or path between one unit and the other on the processor board; address information required for data retrieval or storage is passed via the address bus; buses can be unidirectional or bidirectional; data information is passed on data buses

airway resistance: resistance to air flowing through passageways of the lungs; work used to overcome airway resistance during inhalation and expiration is lost as heat

alveolar ducts: respiratory tract between the alveoli and the bronchioles

alveolar sacs: a group of alveoli clustered together

alveolus: small sacs at the end of the respiratory tract where gas exchange occurs

anoxia: total lack of oxygen, e.g., cardiac arrest

apical foramen: small holes in the roots of the tooth; they provide an opening for blood vessels to reach dental pulp

ARDS: adult respiratory distress syndrome

arterial oxygen saturation: oxygen saturation of arterial blood, which delivers oxygen to the tissue; can be either functional or fractional oxygen saturation of the arterial; usually measured in percent

arterial pulsation: pressure and volume change in the arteries and arterioles due to pump function of the heart

arterialization: when venous blood near the skin is brought to nearly arterial oxygen levels by some external influence such as heating

arteriovenous anastomoses: a thick-walled blood vessel that connects an arteriole directly with a venule, thus bypassing the capillaries

artificial finger: a man-made device that simulates the absorbance properties of a human finger.

asthma: sudden dyspnea with wheezing caused by spasms of the bronchial or swelling of its mucous membrane

atelectic areas: shrunken, airless portions of the lung

ATP (adenosine triphosphate): a compound in cells composed of adenine, ribose, and three phosphate groups found in cells; the phosphate bonds store energy needed by the cell

atrium: either of two upper muscular chambers of the heart

baseline component: the signal which doesn't vary with time

beam angle: the angular measure of radiated power measured on an axis from half-power point to half-power point

Beer's law: describes the exponential light attenuation in an absorbing medium

BF equipment: body floating; equipment with parts in direct contact with the patient are isolated

bias: the fixed DC voltage applied between the base and emitter of a transistor, to keep the device on; the average of the differences between the pulse oximeter readings and the CO-oximeter readings

bilirubin: the orange or yellow compounds which are the breakdown products of hemoglobin

blue dye 'patent blue': a commonly used dye to distinguish the area of arterial perfusion
body surface area: the surface area of a body which can be estimated from charts related to height and weight
bronchioles: respiratory tract between the alveolar duct and the bronchus
bronchitis: inflammation of bronchial tube mucus membrane
bronchus: one of two respiratory tracts between the trachea and the bronchioles, which provide a pathway into the lungs
calibrating resistor: the resistance associated with the probe; this is useful in disposable probes, as this is helpful in determining the wavelengths associated with that probe, so the suitable calibration curves may be used
calibration: the process of fine tuning the device to measure accurately; due to constant use or change in one of the measuring parameters it is necessary to retune the device
cardiac index: the cardiac output normalized by the body surface area of an individual
cardiac output: the rate of blood flow through the heart
cardiopulmonary bypass: a method to maintain the circulation of the body while the heart is deliberately stopped during heart surgery
cardiopulmonary resuscitation: providing assistance in order to restore respiration and cardiac contraction
catecholamines: amino compounds derived from catechol ($C_6H_6O_2$); they have sympathomimetic activity and affect nervous transmission and muscular tone
Central Processing Unit (CPU): the heart of any digital control system; this unit is used to generate control signals for the various operating systems on the processor board
CF equipment: cardiac floating; equipment suitable to be used in direct cardiac applications
chemoreceptors: function in sensing the chemical concentrations of CO_2, O_2, and H^+ of the blood
circulatory system: sends blood around the body to deliver oxygen and transport waste products
coagulopathy: a disease which affects blood clotting
comparator: a device used to determine whether two numbers or bits of information are equal
compliance: set of rules and standards that apply to a specific product; see lung compliance
control bus: information relating to control of various units on the processor board are passed on the control bus; these buses originate at the CPU and are bidirectional
CPAP: continuous positive airway pressure; applying air pressure through the nasal cavities to create a pneumatic splint, keeping the airway from collapsing
current noise (I_n): the random variation of input bias current in an op amp; it produces noise when it reacts with the feedback resistance of the transimpedance amplifier
cuvette: in spectrophotometers, the container that holds the blood sample; it is designed so that it affects the transmission of light as little as possible
cyanosis: bluish discoloration of skin and lips due to severe hypoxemia and excessive reduced hemoglobin
DCT: discrete Fourier transform
decoder: a digital device used to decode the input signal into a set of output signals
defibrillation: application of high energy pulses to the heart when the heart loses synchronization of the heart muscle fibers; the fibers contract irregularly, usually at a rapid rate
delay: response time of a pulse oximeter
demodulate: used to demultiplex the R and IR signals from the output of the photodiode
dentin: hard tissue surrounding dental pulp; it forms most of the tooth and is covered by enamel
desaturation: a process which lowers the oxygen level in the blood
diastole: a rhythmically recurrent expansion especially the dilation of the cavities of the heart during which they fill with blood
diffusion: transport of particles across membranes
dissociation: the process of a molecule being separated into ions, atoms, molecules or free radicals
drift: baseline wandering due to the changing characteristics of the components
driven right leg circuit: during ECG measurements the electrical signals are given a separate ground path thus maintaining patient safety
duty cycle: the ratio of the on time to the total operation time; it is the fraction of the time the device remains on; for a Nellcor system, this is usually 25%; it is 33% for an Ohmeda system
dysfunctional hemoglobins: do not support oxygen transport to the tissue
dyshemoglobins: see dysfunctional hemoglobins
ECG: electrocardiogram
edema: swelling of tissue
eigenvalue spread: ratio of largest eigenvalue to smallest eigenvalue

eigenvalue: a scalar λ which satisfies $\mathbf{A}v = \lambda v$ where $\mathbf{A}$ is a square matrix and v are associated eigenvectors
electrocautery: destroying tissue by electrical heating of a wire
electroluminescence: the emission of light by electrons falling from the higher-energy conduction band to the lower-energy valence band; the electrons emit light energy in the form of photons of light
embolism: obstruction of a blood vessel by a clot or foreign object
EMC: electromagnetic compatibility
EMI: electromagnetic interference
emission spectrum: the frequency response of an LED, displayed on a wavelength scale
emphysema: accumulation of air in tissue; usually refers to destruction of the walls of the respiratory bronchioles
Erasable Programmable Read Only Memory (EPROM): ROMs that can be written into only through specialized means; as ROMs are read only devices, we cannot reprogram them through conventional ways; ultraviolet rays are used to erase the locations, and new data can be burned into them
error: the difference between the pulse oximeter reading and the CO-oximeter reading
ESD: electrostatic discharge
extinction coefficient: numeric measure of opaqueness; the greater the value, the greater the opaqueness
feedback: the technique of returning to a machine or system part of its output so that the machine or system exercises self-correction or control of the process
FFT: fast Fourier transform
fibrosis: formation of scar tissue in the connective tissue of the lungs; results from pneumonia or similar type of infection
filter: a filter is basically a voltage dividing network arranged to possess frequency-discriminating properties
finger phantom: see artificial finger
F_iO_2: fraction of inspired oxygen (normal atmospheric fraction is 0.21)
flip flop: a storage device which can be used to retain one bit of information
fractional oxygen saturation: ratio of oxygenated hemoglobin over total hemoglobin; usually measured in percent
fractional S_aO_2: see fractional oxygen saturation and arterial oxygen saturation
functional hemoglobins: capable of carrying oxygen molecules (Hb and HbO_2)
functional oxygen saturation: ratio of oxygenated hemoglobin over functional hemoglobin; usually measured in percent
functional S_aO_2: see functional oxygen saturation and arterial oxygen saturation
G forces: forces created by large accelerations
Hb: see reduced hemoglobin
HbO_2: see oxygenated hemoglobin
hemodynamics: relating to blood circulation
hemoglobin: a molecule in red blood cells for transport of oxygen molecules
hemolyzed: describes blood in which the red blood cells have been destroyed and the hemoglobins released into the plasma; this process is commonly done on blood for *in vitro* oximetry measurements to reduce the effects of scattering
heparinized blood: blood that has been treated to prevent clotting
hypercapnia: excess carbon dioxide in the blood
hyperoxia: excess oxygen in the system due to high P_iO_2
hypotension: condition in which the arterial blood pressure is abnormally low
hypothermia: reduction of body temperature below the normal range in the absence of protective reflex actions, such as shivering; sometimes body temperature is lowered for therapeutic purposes such as during surgery to reduce the patient's requirement for O_2
hypovolemia: diminished blood volume
hypoxemia: deficient oxygenation of blood
hypoxia: deficient oxygenation of tissue
hypoxic hypoxemia: hypoxemia caused by a drop in oxygen tension as a consequence of decreased lung function
illumination: the respective luminous or radiant flux density incident on a photodetector
***in vitro*:** outside the body
***in vivo*:** within the body
instrumentation amplifier: a very high precision differential amplifier
interrupt: an event which invokes higher priority algorithms to attend to emergencies
interstitial fluid: fluid in between the cells, other than blood cells

intubation: placing a ventilation tube into trachea of the patient to assist mechanical ventilation
ischemia: lack of blood in an area of the body due to blood vessel constriction or mechanical obstruction
isosbestic point: wavelength at which the extinction coefficients of oxyhemoglobin and reduced hemoglobin are equal (805 nm)
Kreb's cycle: a series of chemical reactions during which molecules are oxidized and energy is released
larynx: structure located between the pharynx and trachea which contains the vocal cords
latch: a digital unit used to latch data/address
linear extrapolation: predict values beyond measured values
linear regression: a straight line fit through the data points
linearly independent: a set of vectors $\{\boldsymbol{x}_i\}_{i=1}^{n}$ is linearly independent if $\sum_{i=1}^{n} a_i \boldsymbol{x}_i = \boldsymbol{0}$ is true only if scalar $a_i = 0$ for all i
lookup table: used by hardware instead of an equation to determine the oxygen saturation by the ratio of absorbances based on empirical data
lung compliance: a measure of the elasticity of the lungs; work used to overcome compliance during inhalation is restored during expiration
mechanoreceptors: sensory receptors that are stimulated by mechanical changes such as pressure
medulla oblongata: portion of the brain stem which connects the pons and the spinal cord
memory: the storage element in a digital system; it can be in the form of read only memory or random access memory
monochromatic light: light consisting of only one wavelength
motion artifact: errors introduced into the signal due to motion
MRI: magnetic resonance imaging
multiple scattering: the effect when scattering occurs more than once
myoglobin: a respiratory pigment found in the muscles which store oxygen
myxoma: benign gelatinous tumor of connective tissue
necrosis: death of tissue
odontoblasts: special cells within the dental pulp which form the dentin in the tooth
oxidation: a chemical reaction by which the molecule or atom loses an electron
oximeter: an instrument that uses optical measurements to determine the oxygen saturation of the blood
oxyhemoglobin: hemoglobin combined with an oxygen molecule which will be released freely to tissue
***p–i–n* photodiode:** a p–n junction photodiode that has a large intrinsic layer providing lower capacitance and faster response than the conventional photodiode
P_aO_2: partial pressure of oxygen dissolved in arterial blood
partial pressure: the pressure of one gas in a mixture of gases
patient isolation: to avoid the lack of ohmic continuity or physical separation; this can be provided by a transformer
pattern generator: a unit used to generate timing patterns used for synchronous detection gating, LED control, synchronizing the power supply, calibration patterns, and diagnostic timing
peak wavelength: the wavelength at which the radiated power (or light output) of an LED is a maximum
perfusion: the passage of a fluid through the vessels of an organ
pH: negative log of the concentration of hydrogen ion (H^+) concentration relative to a standard solution; a pH of 7 is neutral, below 7 is acidic and above 7 is alkaline
pharynx: respiratory tract that connects the nasal cavity to the larynx
photocell: a device whose resistance changes as a function of light intensity
photoconductors: see photocell
photodetector: a generic term for any device which is able to convert an optical signal input to an electrical signal output
photodiode: a *p–n* junction diode which converts incident light to an electrical signal; in pulse oximeters, this optical sensor is located in the probe and is configured to produce a current linearly proportional to incident light
photoplethysmograph: a plethysmograph that uses a photodetector
photoplethysmographic signal: time varying signal of transmitted light intensity in living tissue due to arterial pulsation
photoresistors: see photocell
P_iO_2: partial pressure of inspired oxygen

plethysmograph: an instrument that detects variations in size of a part due to blood contained in the part
plethysmographic signal: time varying signal in living tissue due to arterial pulsation
pneumonia: inflammation of the lungs that can occur from a variety of sources
polarization filter: an optical filter that only transmits light that is in that state of polarization; used in pairs to vary optical transmission
polypeptide: compound composed of amino acids molecules
polysomnography: monitors EEG, EMG, ECG, chest wall plethysmogram, airway flow, and oxygen saturation; it is a gold standard for sleep apnea diagnosis
precision: a measure of variation of random error or degree of reproducibility; it is usually represented by the standard deviation of the differences between the pulse oximeter and CO-oximeter readings
programmable gain amplifier: amplifiers whose gains can be adjusted and varied depending on the circuit requirement (for example, due to change in ambient light level, the dc offset can vary, thereby increasing the risk of sending the amplifier into saturation)
pulmonary: related to the lungs
pulsatile component: the signal which varies with time
pulse capability: the maximum allowable pulse current of an LED as a function of duty cycle and frequency
pulse oximeter: an oximeter that takes advantage of the pulsatile nature of the blood in the arteries
QRS: peak of the ECG waveform which corresponds to ventricular depolarization
R wave: the peak in the QRS complex of the heart beat
Random Access Memory (RAM): a memory location capable of being read from and written into. This unit is used to store and retrieve data in a digital system
Read Only Memory (ROM): a memory location capable of only being written into; this used to store calibration related information
rectifier: a device that offers a much higher resistance to current in one direction than the other; rectifiers are used to obtain a unidirectional current (DC) from an alternating current
reduced hemoglobin: functional hemoglobin unbound to oxygen
reduction: a chemical reaction by which the molecule or atom gains an electron
respiration: the process of gas exchange
respiratory quotient: ratio of volume of CO_2 produced per volume of O_2 consumed
retinal fundus: posterior portion of the interior of the eye
retinopathy of prematurity: disorder in the retina of neonates due to supplemental oxygen among many other factors
RFI: radio frequency interference
sample-and-hold: a circuit used to hold a value for a given period of time; this is very useful during analog-to-digital conversion; it consists of a high gain FET and a large capacitor
S_aO_2: see arterial oxygen saturation
scattering: light is refracted by a small object causing a deviation of the light beam from its initial direction of propagation
sensitivity: the ratio of the electrical output signal to the intensity of incident light
signal-to-noise ratio: indicates the quality of the signal
simulator: a device that behaves in a like manner to the original device
sleep apnea: cessation of breathing during sleep for episodes of 15 s or greater; there are three types: obstructive, central, and mixed
spectral bandwidth: the half-power bandwidth of the light emitted from an LED, measured in nanometers
spectral response: the relationship of output signal of a photodetector to the incident light at a particular wavelength
spectrophotometry: the process of measuring the absorbance of light at different wavelengths to determine the concentration of the substance in a solution
S_pO_2: arterial oxygen saturation as measured by the pulse oximeter; usually measured in percent
spurious pulses: erroneous pulses introduced from disturbing sources
stemmed trigger: an emitter coupled multivibrator which is used as a voltage discriminator; this is also useful as a squaring circuit as it can be used to convert the sine waves into square waves
switching time: the time required for an LED to switch from its ON state to its OFF state, or vice versa
synchronization: correlation of specific events to improve accuracy
synchronous detector: the circuit component used to synchronously demultiplex the signal from the photodiode into its R and IR components
systemic: related to the body in its entirety

systole: the period of contraction of the heart, especially that of the ventricles
thermal resistance: causes the increase in junction temperature above ambient per unit of power dissipation for the given LED's package and mounting configuration
thoracic cavity: the body cavity between the neck and the diaphragm
thresholds: signal levels established to make appropriate decisions in algorithms
transcutaneous: (transdermal) through the skin, e.g., administration of medicine via a patch
transimpedance amplifier: an amplifier used in pulse oximetry to convert the current produced by the photodiode to a voltage for further processing in the system
transmittance: ratio of transmitted light to incident light intensity in an absorbing medium; the greater the value, the less light is passing through the medium
trauma: wound or injury
UART: (universal asynchronous receiver–transmitter) a device which can be programmed to do asynchronous communication
UPPP: uvulopatatopharyngoplasty; surgical procedure to remove excess tissue in the upper airway
vasoconstriction: a decrease in the diameter of blood vessels
vasodilation: an increase in the diameter of blood vessels which results in an increase in blood flow
ventilation: passage of air into and out of the respiratory tract
ventricle: either of two lower muscular chambers of the heart
wait state generator: a combination of one clock storage devices, used to store data for one clock cycle; it is useful to slow down the microprocessor when the I/O devices are communicating at a very slow rate
watchdog timer: a fail safe timer used to turn off the pulse oximeter, if the microprocessor system fails

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INDEX

The Medical Science Series books describe the applications of physical science, engineering and mathematics in medicine and biology. The books are written for graduate students and researchers in many disciplines including medical physics, biomedical engineering, radiology, radiotherapy and clinical research.

The Medical Science Series is the official book series of the International Organization for Medical Physics and the International Federation for Medical and Biological Engineering.

Pulse oximetry provides early information on problems in the delivery of oxygen to tissue. Recognized worldwide as the standard of care in anesthesiology, it is used in diverse applications from hospital intensive care units to veterinary surgeries.

Design Of Pulse Oximeters is a unique handbook which describes the hardware and software needed to make a pulse oximeter, and includes the equations, methods, and software required for them to function effectively. It is written for biomedical engineers, medical physicists, and health care providers and organized so that a nonbiomedical engineer can learn enough about oximetry to understand the design information.

The book begins with a brief discussion on how oxygen is delivered to the tissue and discusses the problems and diseases that can occur. It relates the background to the pulse oximeter, including historical oxygenation measurement, and the CO-oximeter 'gold standard'.

Subsequent chapters provide:

- full technical descriptions for hemoglobin oxygen saturation display and light-emitting diode operation;
- a survey of the different types of light sensor, with particular emphasis on the single photodiode;
- a review of the design of reusable and disposable probes and cables;
- hardware descriptions, including signal amplification and calculation of oxygen saturation;
- worked examples of flow charts and algorithms for oxygen saturation calculations;
- an assessment of different techniques used to evaluate pulse oximeter performance;
- a brief overview of pulse oximetry applications.

Additional features include a glossary of terms, instructional objective summaries by chapter, and a useful reference list to direct the reader to sources for further reading.

John G Webster leads a world-ranking research team at the University of Wisconsin-Madison. Its re
catheter radio-fr
sensor-based co
electrocardiogra
The contributors