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.

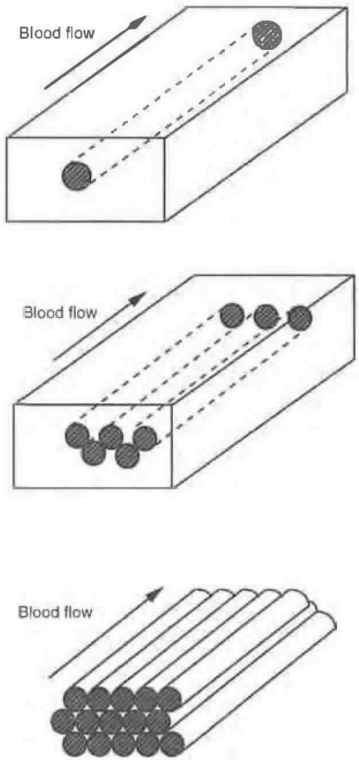

Figure 10.3 Block diagram of various artificial fingers as proposed by Vegfors *et al* (1993).

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.

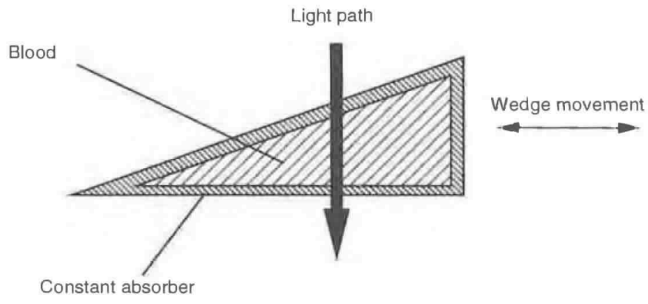

Figure 10.4 Block diagram of a wedge system as proposed by Yount (1989).

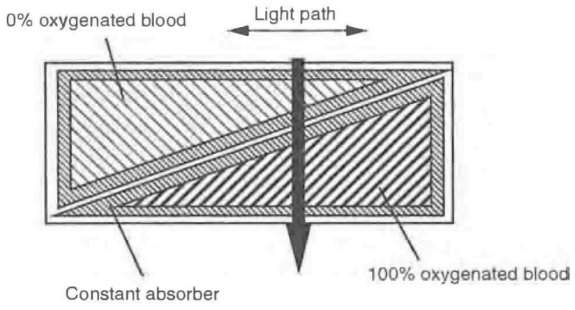

Figure 10.5 Block diagram of the dual wedge system as proposed by Yount (1989).

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.

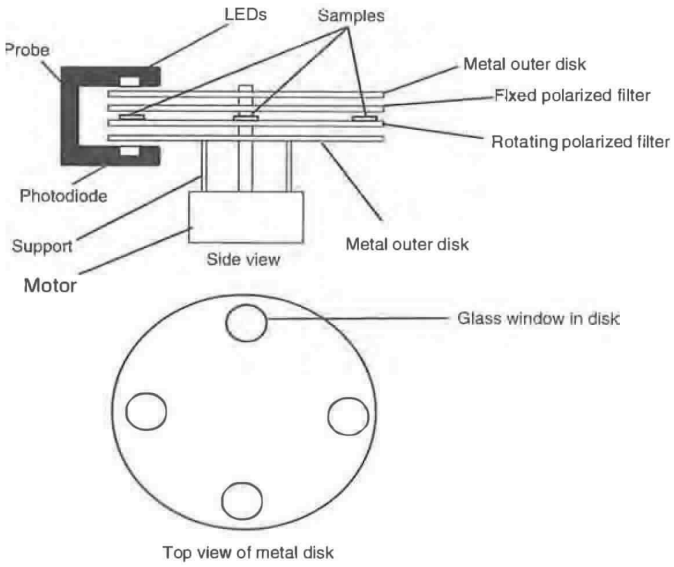

Figure 10.6 Schematic diagram of polarization system (adapted from Yount 1989).

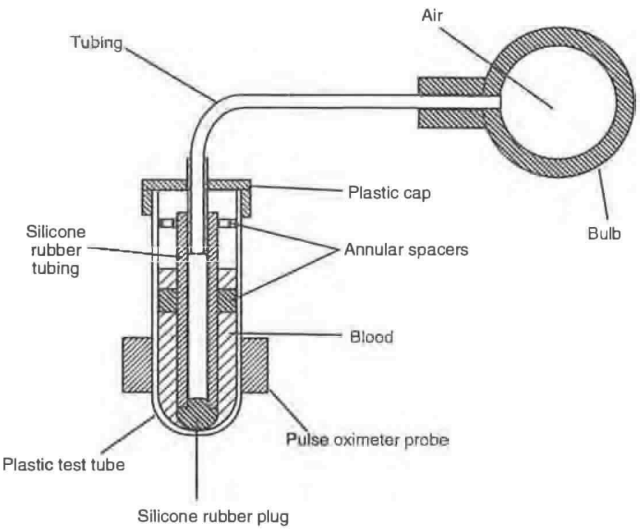

Figure 10.7 Block diagram of tube and bulb device.

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.

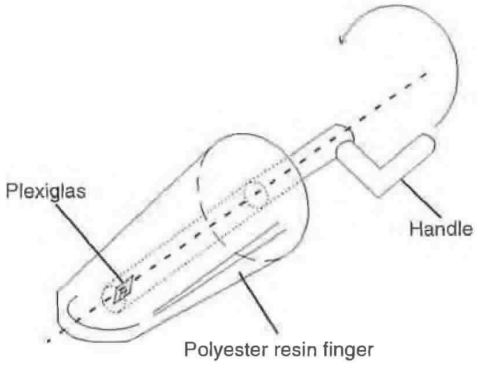

Figure 10.8 Polyester resin system proposed by Munley et al (1989).

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.

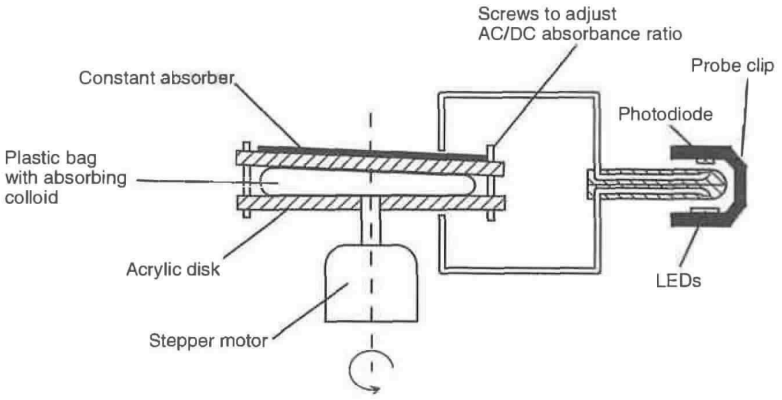

Figure 10.9 Leuthner's (1994) colored colloid disk system.

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.

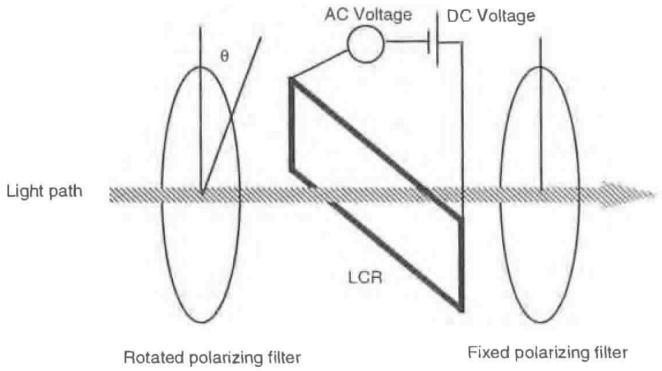

Figure 10.10 Diagram of the liquid crystal retarder (LCR) system proposed by Zhou *et al* (1992).

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.

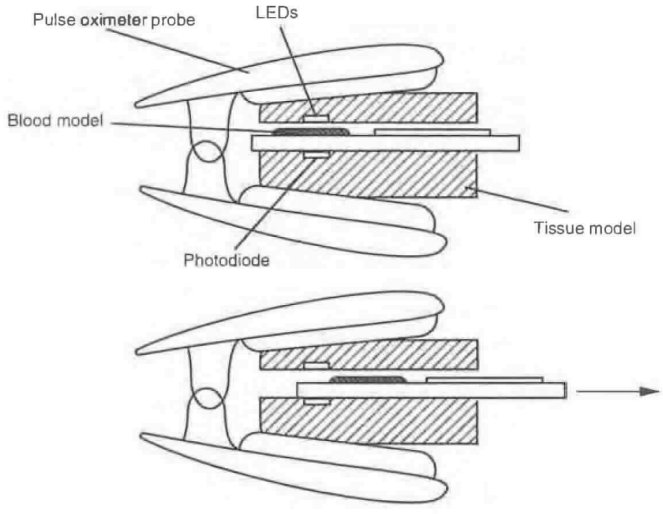

Figure 10.11 Block diagram of system as proposed by Aoyagi *et al* (1994).

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.

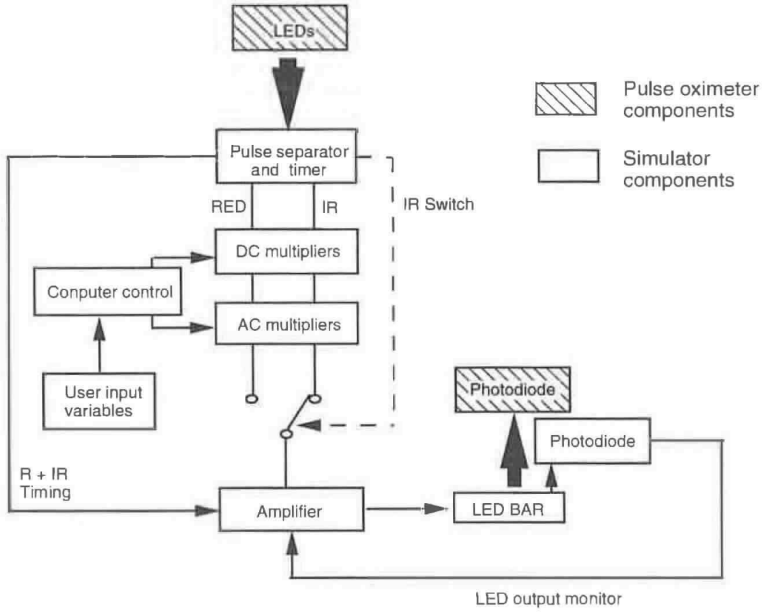

Figure 10.12 Block diagram electro-optic simulator system developed by Merrick and Haas (1994).

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.

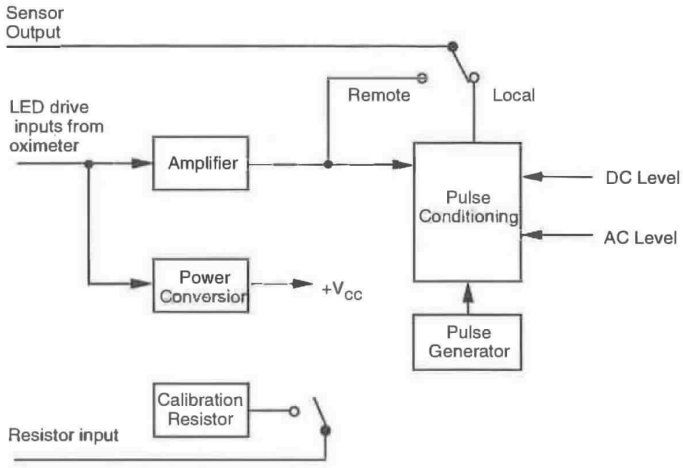

Figure 10.13 Block diagram of an electronic simulator that replaces the pulse oximeter probe (used with permission (Nellcor 1994) Pulse oximeter tester Model SRC-2).

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).
American Society of Anesthesiologists. Standards for Post-Anesthesia Care, 1989 (0697-ASA).
European Committee for Standardization. Drafting European norm for pulse oximeters.

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Reynolds K J, Moyle J T B, Sykes M K and Hahn C E W 1993a Responses of 10 pulse oximeters to an in vitro test system *Brit. J. Anaesthesiol.* **68** 265–9
Reynolds K J, Palayiwa E, Moyle J T B, Sykes M K and Hahn C E W 1993b The effects of dyshaemoglobins on pulse oximetry *J. Clin. Monit.* **9** 81–90
Santamaria T and Williams J S 1994 Device focus: pulse oximetry *Med. Device Res. Rep.* **1** (2) 8–10
Severinghaus J W, Naifeh K H and Koh S O 1989 Errors in 14 pulse oximeters during profound hypoxia *J. Clin. Monit.* **5** 72–81
Vegfors M, Lindberg L G, Oberg P A and Lennmarken C 1993 Accuracy of pulse oximetry at various haematocrits and during haemolysis in and in vitro model *Med. Biol Eng. Comput.* **31** 135–41

Volgyesi G A 1992 Method of testing the accuracy of pulse oximeters and device therefor *US patent 5,166,517*
Wukitsch M W, Petterson M T, Tobler D R and Pologe J A 1988 Pulse oximetry: analysis of theory, technology, and practice *J Clin. Monit.* **4** 290–301
Yount J E 1989 Device and procedures for in vitro calibration of pulse oximetry monitors *US patent 4,834,532*
Zhou G X, Schmitt J M and Walker E C 1992 Electro-optical simulator for pulse oximeters *Med. Biol. Eng. Comput.* **31** 534–9

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 ($S_a\bullet_2$) 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.

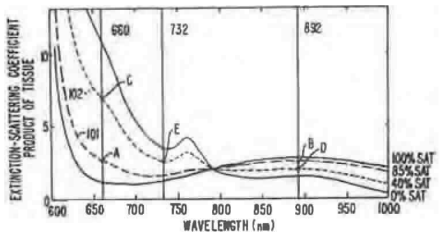

Figure 11.1 Variation in extinction coefficients over a range of wavelengths of 600 to 1000 nm at different saturation values. At 660 nm (red) wavelength, the slope of an absorption spectrum increases as oxygen saturation level decreases. From Casciani *et al* (1995).

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).

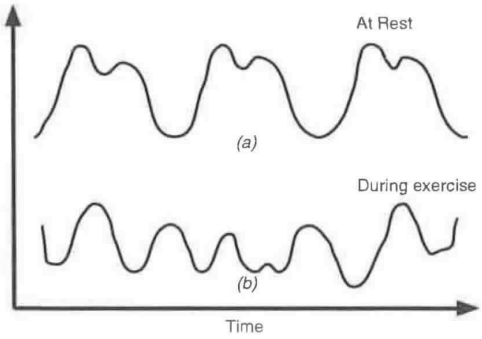

Figure 11.2 The plethysmographic waveform of a subject at rest is periodic (*a*) and during exercise is not periodic (*b*).

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.

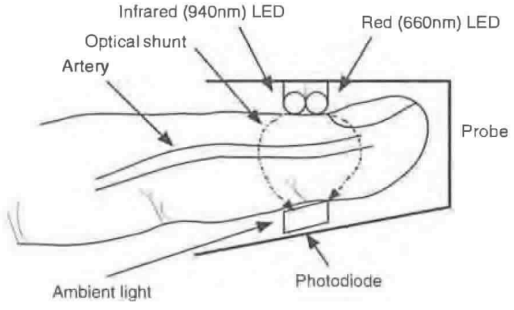

Figure 11.3 Ambient light interference and optical shunt in pulse oximetry. Optical shunt occurs when the light from the LEDs reaches the photodiode without passing through arterial blood.

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.

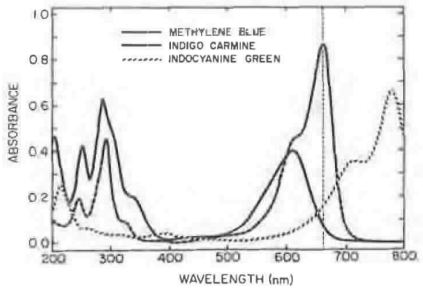

Figure 11.4 Absorbances of dyes. MeBl has the highest absorbance in the region of the 660 nm wavelength. From Scheller (1986).

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.

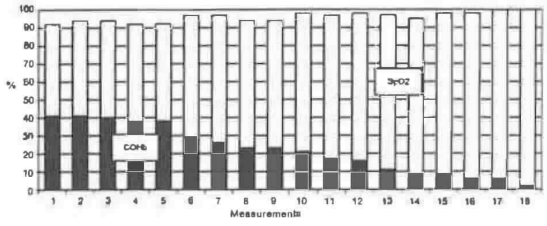

Figure 11.5 Mean measured arterial blood oxygen saturation (S_pO_2) with corresponding COHb values for 18 measurements in 6 patients. From Seidler (1993).

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.

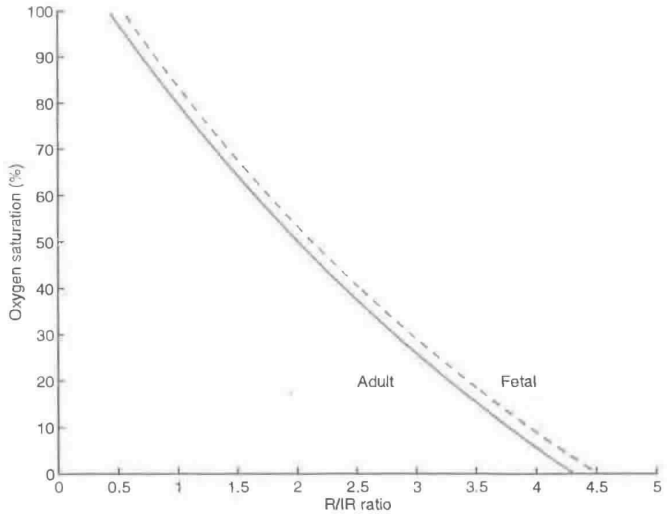

Figure 11.6 The calibration curves derived from a theoretical simulation show that pulse oximeters will read about 3% high for fetal hemoglobin. The R/IR ratio is R in equation (11.6).

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.

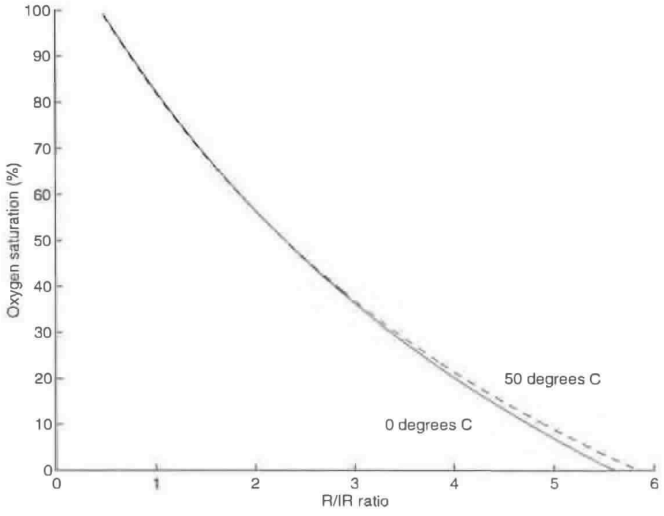

Figure 11.7 The calibration curves from a theoretical model show a shift from 0 °C to 50 °C.

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.

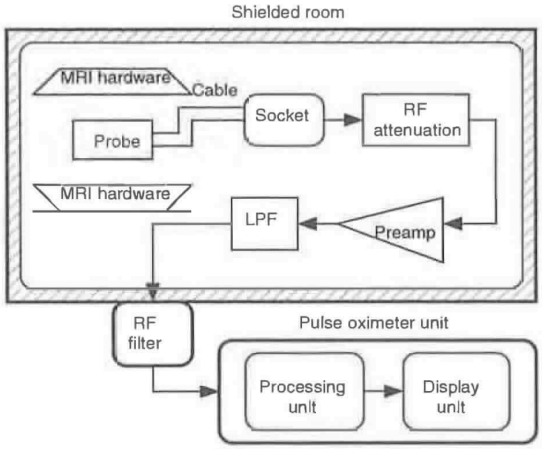

Figure 11.8 MRI compatible pulse oximetry (adapted from Blakeley *et al* 1994).

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.

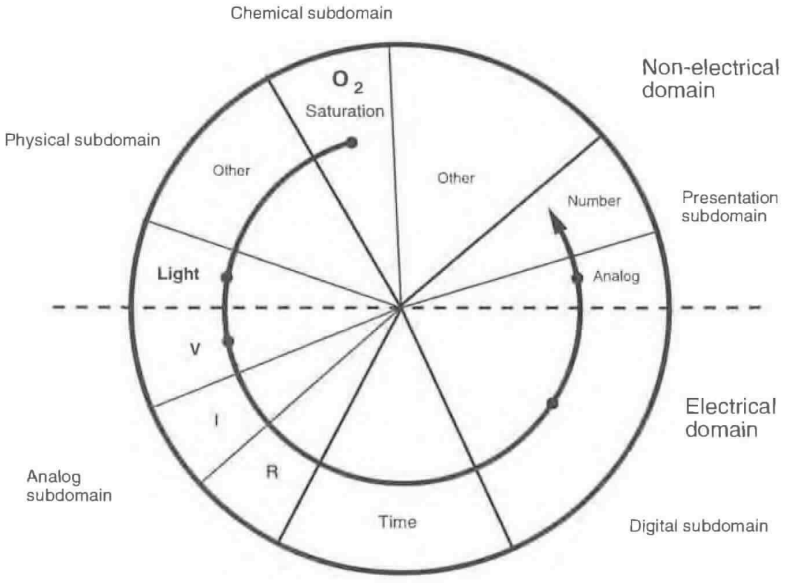

Figure 12.1 Change of domains of information in a pulse oximeter. Adapted from Malmstad *et al* (1973).

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.

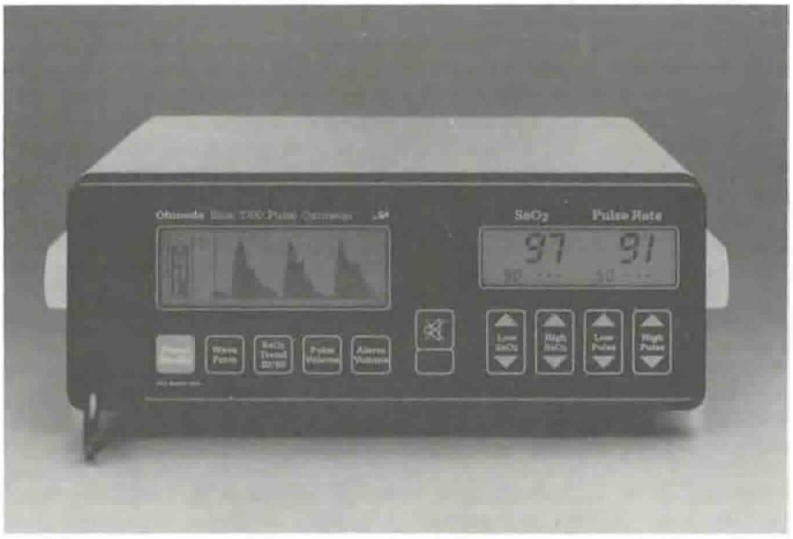

Figure 12.2 Front panel of Ohmeda Biox 3700 pulse oximeter (Courtesy of Ohmeda). The display at the left side shows real-time waveforms and pulse strength, while the display at the right side is used for alarm settings.

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).

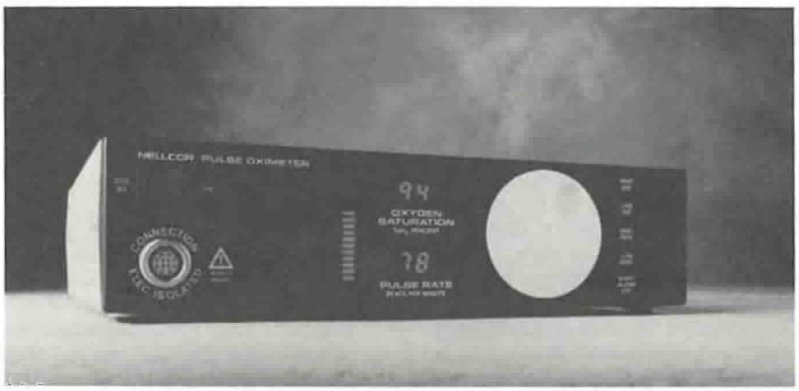

Figure 12.3 Nellcor Puritan Bennett N-200 pulse oximeter (Reprinted by permission of Nellcor Puritan Bennett, Pleasanton, California).

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.

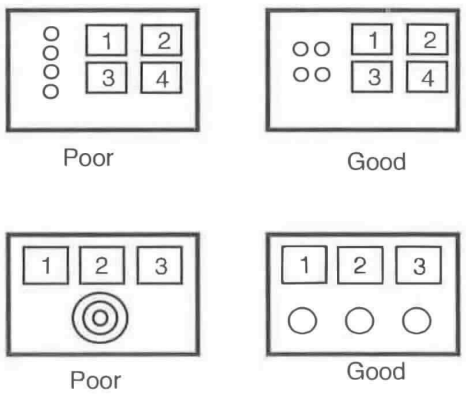

Figure 12.4 Layout of controls and indicators to ensure good operator interaction. From Salvendy (1987).

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.

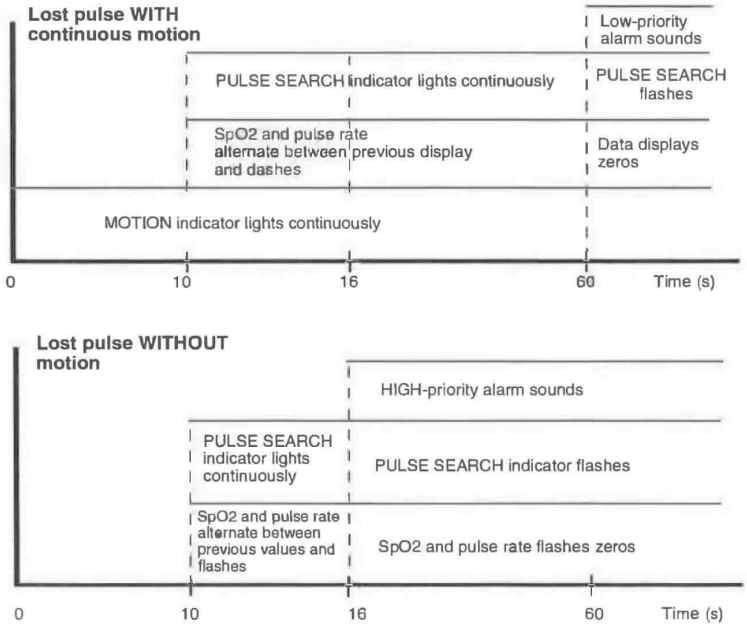

Figure 12.6 Oxismart© alarm detectors used in some Nellcor units to reduce false alarms due to motion artifacts (Nellcor 1995).

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.

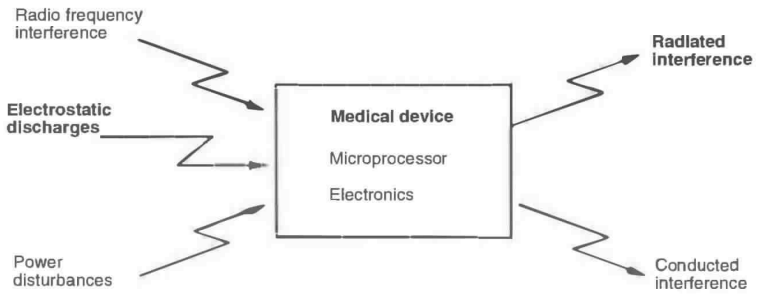

Figure 12.7 Different sources of disturbances and interferences for EMC purposes.

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.

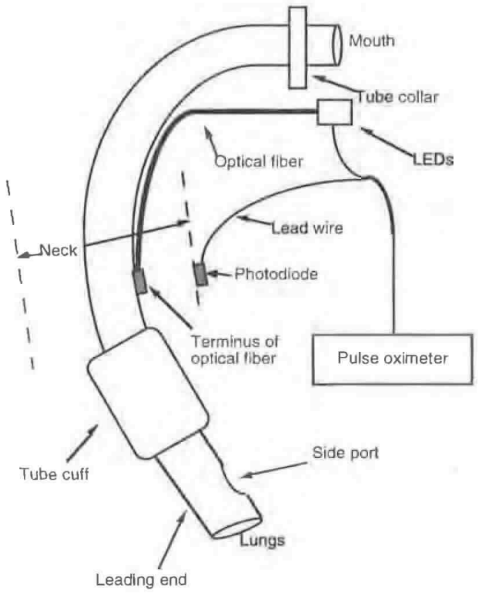

Figure 13.1 Endotracheal tube with pulse oximetry attachment. In this version, the light source is located outside the mouth, and light is transported into the trachea via optical fiber (adapted from Buchanan 1991).

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_tO_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)).

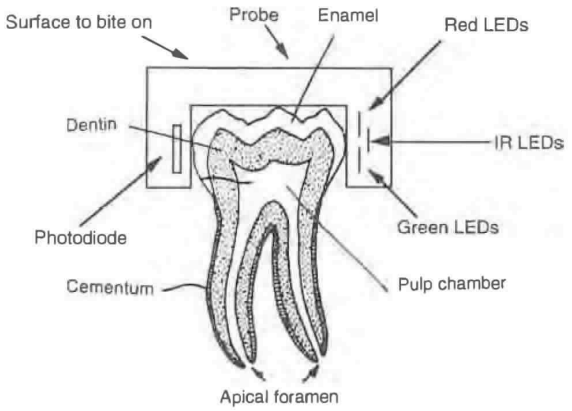

Figure 13.2 Morphology of the tooth and adapted pulse oximeter probe for determining the viability of dental pulp (adapted from Schmitt *et al* 1991).

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.

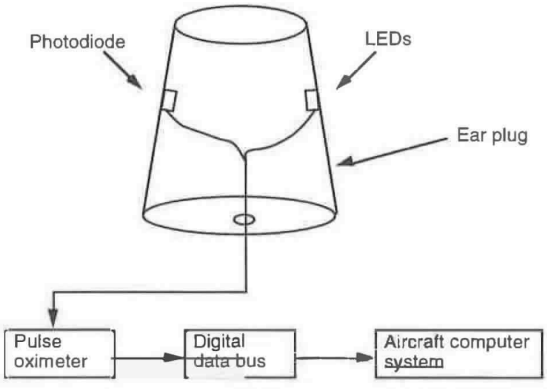

Figure 13.3 Modified pulse oximeter probe for use in the ear canal. In this version, a clay mold has been used to produce the ear plug with the LEDs and photodiode pressed into the sides (adapted from Tripp 1993).

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_uO_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).

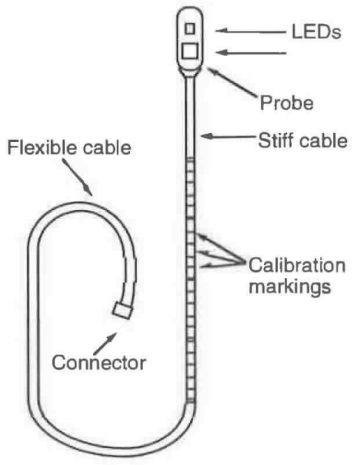

Figure 13.4 Apparatus for fetal pulse oximetry (adapted from Chung and McNamara 1993).

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.