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. (Propag 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<sub>2</sub> and can display the capnographic waveform. The Propaq models from Protocol Systems, Inc., have different modular systems that can measure oxygen saturation, ECG, CO<sub>2</sub> 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, CO2, NO2, O2 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

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015835 IPR2022-01300 RX-0035.0218

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.

219

# User interface for a pulse oximeter 203

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<sub>2</sub>. 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<sub>2</sub>. 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).

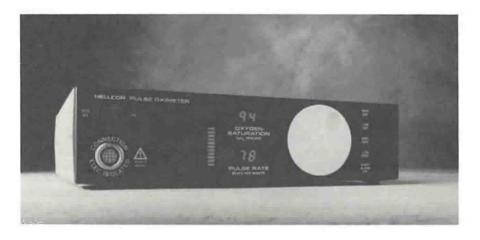


Figure 12.3 Nellcor Puritan Bennett N-200 pulse oximeter (Reprinted by permission of Nellcor Puritan Bennett, Pleasanton, California).

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.

222

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015839 IPR2022-01300 RX-0035.0222

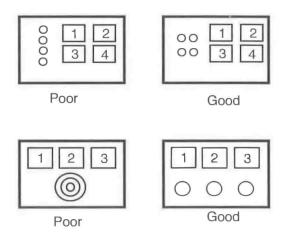


Figure 12.4 Layout of controls and indicators to ensure good operator interaction. From Salvendy (1987).

# **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

223

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.

224

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015841 IPR2022-01300 RX-0035.0224

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).

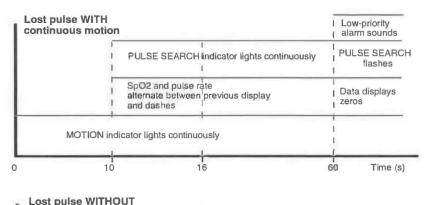
The alarms in a pulse oximeter can be disconnected or silenced. Temporary silencing should be used when the operator has been alerted of the potentially dangerous situation and has taken steps in order to solve the problem. The Standard specifies that if this feature is provided in the pulse oximeter, 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

#### User interface for a pulse oximeter 209

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.



motion		-			
		HIGH-priority a	larm sounds		
	PULSE SEARCH indicator lights continuously	1	PULSE SEARCH indicator flashes		
	SpO2 and pulse rat alternate between previous values and flashes	SpO2 and pulse rate flashes zeros			
0	10	16	T 60	Time (s)	

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

226

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015843 IPR2022-01300 RX-0035.0226

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

227

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.

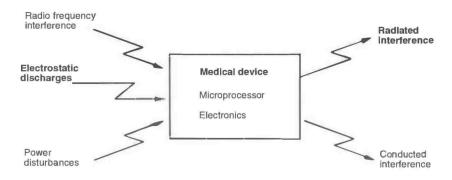


Figure 12.7 Different sources of disturbances and interferences for EMC purposes.

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.

#### REFERENCES

ASTM 1992 Standard Specification for Pulse Oximeters, F1415-1992 (Philadelphia, PA: American Society for Testing and Materials)

IOS 1992 Pulse oximeters for medical use—Requirements, ISO 9919:1992 (E) (Geneva: International Organization for Standardization)

IEC 1988 Safety of Medical Electrical Equipment—Part I, General Safety Requirements IEC 601-1: 1988 (Geneva: International Electrical Commission)

IEC 1990. Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment. Part 2: Electrostatic Discharge Requirements IEC 801-2 (Geneva: International Electrical Commission)

Bosman D (ed) 1989 Display Engineering. Conditioning, Technology, Applications (New York: Elsevier)

Cakir A, Hart D J and Stewart T F M 1980 Visual Display Terminals (New York: Wiley)

Gerke D and Kimmel B 1994a Noise and interference: a different game *Electron*. Design News **39** (2) 5-14

Gerke D and Kimmel B 1994b EMI regulations. Why, where and what do they mean *Electron*. Design News 39 (2) 15-22

Gillan DJ and Lewis R 1994 A compartmental model of human interaction with graphs: 1. Linear regression modeling Human Factors 36 419-40

Malmstad H V, Enke C G and Crouch S R 1973 Electronic Analog Measurements and Transducers (Menlo Park CA: Benjamin)

Nellcor 1995 Technology Overview: Nellcor Symphony N-3000—The next generation on Nellcor Pulse Oximetry. Reference Note: Pulse Oximetry Note Number 8 (Pleasanton, CA: Nellcor) Salvendy G (ed) 1987 Handbook of Human Factors (New York: Wiley)

#### User interface for a pulse oximeter 213

# 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.

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015847 IPR2022-01300 RX-0035.0230

# **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 CO2 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

214

231

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015848 IPR2022-01300 RX-0035.0231

### Applications of pulse oximetry 215

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<sub>2</sub>, O<sub>2</sub>, 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.

232

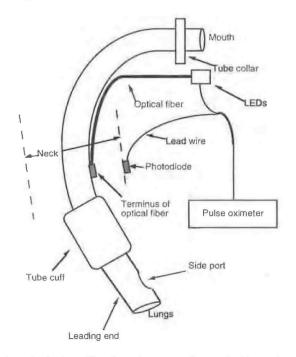


Figure 13.1 Endotracheal tube with pulse oximetry attachment. In this version, the light source is located outside the mouth, and light is transported into the trachea via optical fiber (adapted from Buchanan 1991).

#### 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

ć

5

τ

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 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.

 MASIMO 2053

 Apple v. Masimo
 APL\_MAS\_ITC\_00015851

 IPR2022-01300
 RX-0035.0234

#### 13.2.2 Tissue transfer and setting of limb fractures

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

#### 13.2.3 Dental pulp blood supply and viability

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

To understand how monitoring oxygen saturation of dental pulp with pulse oximetry is accomplished, it is important to be familiar with the morphology of the tooth. The outer layers of the tooth consist of bone-like enamel and dentin. Collagen fibers connect the jaw bone to a layer of cementum at the base of the tooth, fixing the tooth in its socket. Apical foramen, small holes in the roots of the tooth, allow nerves and blood vessels to access the dental pulp. The blood provides oxygen, mineral salts, and nutrients to sustain the odontoblasts and neural tissues. Figure 13.2 shows that to measure the blood oxygen saturation, an adapted transmission probe in the shape of a U is applied over the tooth (Schmitt et al 1991). A black-foam insert conforms to the tooth and provides shielding from ambient light. It can be replaced and the probe reused on successive patients. The U-shaped probe is flat on top, providing a surface for the patient to hite 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 eximeter 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)).

Applications of pulse oximetry 219

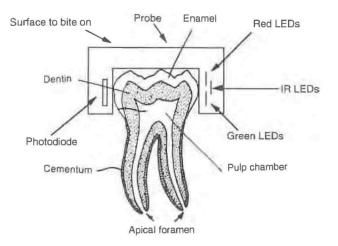


Figure 13.2 Morphology of the tooth and adapted pulse oximeter probe for determining the viability of dental pulp (adapted from Schmitt *et al* 1991).

# 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.

236

#### 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,

#### Applications of pulse oximetry 221

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.

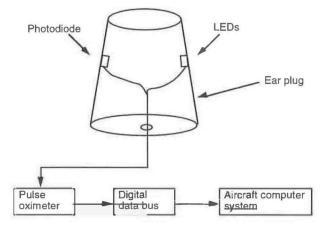


Figure 13.3 Modified pulse oximeter probe for use in the ear canal. In this version, a clay mold has been used to produce the ear plug with the LEDs and photodiode pressed into the sides (adapted from Tripp 1993).

# 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

238

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015855 IPR2022-01300 RX-0035.0238

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 SpO2 values of 68% ±13% occurred at cervical dilation of less than 5 cm and 58% ±17% at cervical dilation greater than or equal to 9 cm. Dildy et al (1994) determined even lower values of 62% ±9% and 53% ±10% respectively.

#### 13.4.2 Special apparatus for fetal monitoring

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

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

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

# Applications of pulse oximetry 223

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).

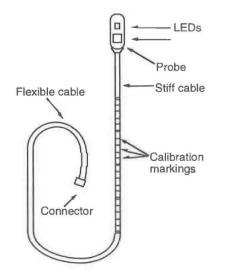




Figure 13.6 shows a design containing a light source located external to the mother. Light is transmitted to the fetus via an optical fiber (Joseph and Guzman 1995). This is advantageous for preventing burns due to high intensity LEDs. Wires from an external monitor and the optical fiber from the light 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.

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015857 IPR2022-01300 RX-0035.0240

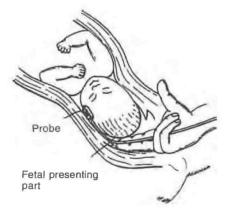


Figure 13.5 Placement of fetal probe within the uterus (Chung and McNamara 1993). The sensor rests on the infant's temple when the physician's fingers reach the saggital suture of the fetus's head.

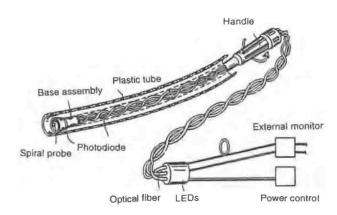


Figure 13.6 Fetal pulse eximctry apparatus with the LEDs located outside of the uterus and transmitted via optical fiber (Joseph and Guzman 1995).

# 13.5 NEONATAL AND PEDIATRIC CARE

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

#### Applications of pulse oximetry 225

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

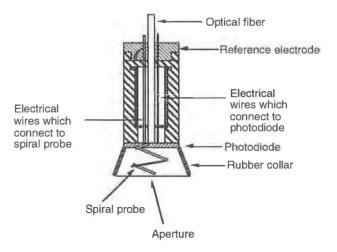
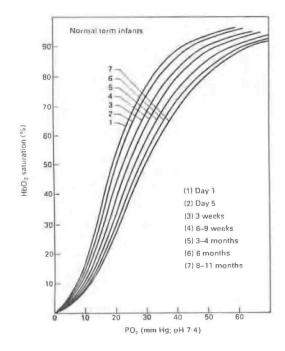


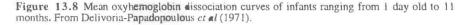
Figure 13.7 Close up cross sectional view of the sensor, showing the helical termination of the optical fiber which is inserted in the fetus's scalp (adapted from Joseph and Guzman 1995).

Determining alarm limits for pulse oximetry in neonatal care can be difficult. Figure 13.8 shows that during the weeks following birth, fetal hemoglobin is replaced by adult hemoglobin. Since the oxyhemoglobin dissociation curve of a fetus is to the left of that of the mother, the curve moves towards the right as the transition to adult hemoglobin takes place. This means that oxygen saturation levels considered safe may correspond to unsafe PaO2 levels and cause hypoxia. Paky and Koeck (1995) determined limits for detecting hypoxemia and hyperoxemia in neonates and found that limits to maintain an oxygen tension of 40 to 90 mmHg could only be established with less than 90% reliability. Attempting to obtain better reliability resulted in a SpO2 alarm limit for hypoxemia which was greater than that for hyperoxemia. This is obviously clinically unacceptable. However, with 85% reliability the range was only 92.5% to 95%. Deckardt and Steward (1984) determined that infant  $S_aO_2$  levels between 80% and 95% are acceptable. Fanconi (1988) found detecting hypoxia in infants problematic due to inaccuracies in pulse oximeters at arterial oxygen saturations less than 65%.

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

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015859 IPR2022-01300 RX-0035.0242





The S<sub>a</sub>O<sub>2</sub> controller operates according to the following algorithm. A patient's oxygen saturation is measured with a pulse oximeter. The signal is converted to a digital representation and low-pass filtered. The corner frequency of the filter is determined by the user and sets the sensitivity of the controller. The observed  $S_pO_2$  minus the desired  $S_aO_2$  is denoted as the error. The signs of the error's magnitude, velocity, and acceleration are input into a state machine. The state machine determines the trend of the SaO2 error. It analyzes the signs of the three inputs and determines if the neonate's SaO2 is on target, above the target, or below the target. If it is off target, the state machine goes on to determine if it is accelerating, decelerating, moving at a constant velocity, or not changing. If it is moving, it determines if the movement is toward or away from the target. Once the trend is identified by the state machine, it adjusts the  $F_iO_2$ mixture relative to the current mixture. There is also a delay so that the system can react to the adjustment made. Alarms were added for mechanical or electrical failure as well as for  $S_aO_2$  and  $F_jO_2$  limits. Manual intervention can override the controller at all times.

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

> MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015860 IPR2022-01300 RX-0035.0243

### Applications of pulse oximetry 227

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

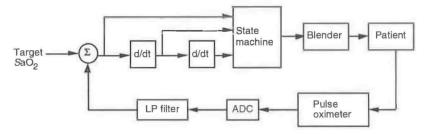


Figure 13.9 Block diagram of S<sub>a</sub>O<sub>2</sub> controller. Adapted from Morozoff et al (1993).

#### 13.6 SLEEP STUDIES AND PHYSICAL STRESS TESTING

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

# 13.6.1 Sleep

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

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015861 IPR2022-01300 RX-0035.0244

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

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

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

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

245

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015862 IPR2022-01300 RX-0035.0245 ventilation/perfusion imbalance, or an artifact. Lynn (1995) performed a study and found that specifically the descending slope as shown in figure 13.10 is a fall in  $S_pO_2$  within the range of 1.1% per second and 0.3% per second. The mean was 0.8% per second. Once the desaturation is detected by the chemoreceptors, resulting in arousal, oxygen rushes into the lungs. The resaturation slope is much larger than the desaturation slope. Specifically, Lynn (1995) found that it is a rise in  $S_pO_2$  in the range of 2.5% per second and 8.3% per second, the mean being 7.6%. The duration of an apneic event is 3 to 3.5 min.

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

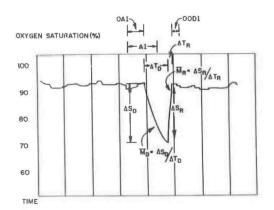


Figure 13.10 A typical apnetic event. The vertical lines are 30 s apart.  $\Delta S_D$  is the fall in saturation,  $\Delta S_R$  is the rise in saturation,  $\Delta T_D$  is the duration of the fall in saturation,  $\Delta T_R$  is the duration of the rise in saturation, MD is the slope of the desaturation,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

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

> MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015863 IPR2022-01300 RX-0035.0246

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

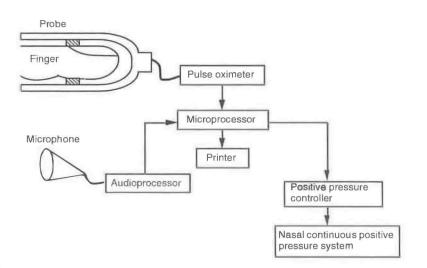


Figure 13.11 A block diagram of the apparatus used along with a pulse oximeter for sleep apnea diagnosis (adapted from Lynn 1995).

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

247

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015864 IPR2022-01300 RX-0035.0247 (CPAP) via the nasal passages to support the airway and prevent the collapse of pharyngeal tissue when the muscles relax. This type of treatment requires wearing a mask while sleeping and the air flow can be uncomfortable for patients. Finally, in extreme cases uvulopalatopharyngoplasty (UPPP) or tracheostomy may be necessary. UPPP is a surgical procedure in which excess tissue or a bony abnormality is removed. A tracheostomy involves removing part of the trachea to make a new airway opening.

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

#### 13.6.2 Exercise

Pulse oximetry can be used to evaluate pulmonary or circulatory dysfunction and performance limitations during exercise. During heavy exercise, a reduction in the partial pressure of oxygen can cause hypoxemia (Dempsey 1986). Miyachi and Tabata (1992) found that ventilation is also a major factor. Athletes tend not to desaturate as quickly as those who do not exercise as often. This is because trained athletes breathe less per unit of metabolic rate than the untrained. Monitoring the oxygen saturation of an athlete can thus determine his physical condition. Also, patients with COPD experience limited ventilation is limited and thus the patient desaturates more quickly during exercise. Pulse oximeters tend to underestimate  $S_aO_2$  readings during extreme exercise, possibly due to high levels of *catecholamines* and neural activity which restrict cutaneous blood flow (Norton *et al* 1992). Catecholamines are chemical compounds derived from catechol (C<sub>6</sub>H<sub>6</sub>O<sub>2</sub>) which can affect nervous transmission and muscle tone.

# 13.7 MANAGEMENT OF CARDIOPULMONARY RESUSCITATION

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

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015865 IPR2022-01300 RX-0035.0248

## 13.8 COMPUTER-CONTROLLED OXYGEN WEANING

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

# 13.9 SYSTOLIC BLOOD PRESSURE MEASUREMENT

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

#### 13.10 CEREBRAL OXYGEN SATURATION

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

249

MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015866 IPR2022-01300 RX-0035.0249

# Applications of pulse oximetry 233

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

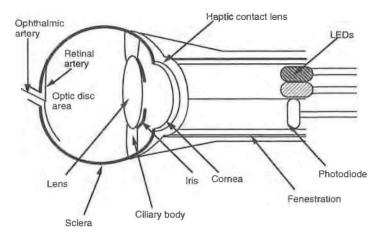


Figure 13.12. Cross section of an adapted haptic contact lens and pulse oximeter probe for use in cerebral oxygen saturation measurement. Adapted from de Kock *et al* (1993).

# 13.11 VETERINARY CARE

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

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

# 13.12 FUTURE IMPROVEMENTS FOR PULSE OXIMETRY

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

#### REFERENCES

Allen J L 1990 Proc. 1990 Am. Assoc. Zoo Veterinarians 163

Allen J L 1992 Pulse oximetry: everyday uses in a zoological practice Vet. Record 130 354-5

Bone M E, Galler D and Flynn P J 1987 Arterial oxygen desaturation during general anaesthesia for paediatric dental extractions *Anaesthesia* 42 879–82

Buchanan D C 1991 Endotracheal tube with oximetry means US patent 5,005,573

Campbell M B, Lightstone A D, Smith J M, Kirpalani H and Perlman M 1984 Mechanical vibration sound levels experienced in neonatal transport Am. J. Dis. Child. 138 967–70 Catley D M, Thorton C, Jordon C, Tech B, Lehane J R, Royston D and Jones J G 1985

Pronounced episodic oxygen desaturation in the post-operative period: its association with ventilatory pattern and analgesic regimen Anesthesiology 63 20–8

ventilatory pattern and analgesic regimen Anesthesiology 63 20-8
Chawla R, Kumarvel V, Girdhar K K, Sethi A K, Indrayan A and Bhattacharya A 1992 Can pulse oximetry be used to measure systolic blood pressure? Anesth. Analg. 74 196–200

Chung C and McNamara H M 1993 Fetal pulse oximetry apparatus and method of use US patent 5,228,440

Clark S L, Pavlov Z, Greenspoon J, Horenstein J and Phelan J P 1986 Squamous cells in the maternal pulmonary circulation Am. J. Obstet. Gynecol. 154 104-6

 Clay N R and Dent C M 1991 Limitations of pulse oximetry to assess limb vascularity Br. J. Bone Joint Surg. 71-B 141
 Committee on Hospital Care—American Academy of Pediatrics 1986 Guidelines for air and

ground transportation of pediatric patients *Pediatrics* 78: 943–50

Cooper J B et al 1984 An analysis of anesthetic mishaps from medical liability claims Int. Anesthesia Clinics 60: 39

Cottrell J J, Lebovitz B L, Fennel R G and Kohn G M 1995 Inflight arterial saturation: continuous monitoring by pulse oximetry Aviation, Space, Environ. Med. 66 126-30

Cunningham F G, MacDonald P C and Gant N F 1989 Williams Obstetrics 18th edn (Norwalk, CT: Appleton-Century-Crofts) pp 95, 96, 805 David H G 1991 Pulse oximetry in closed limb fractures Ann. R. Coll. Surg. England 73 283–4

Davies R J O and Stradling J R 1993 Acute effects of obstructive sleep apnoea Br. J. Anaesth. 71 725-9

de Kock J P, Tarassenko L, Glynn C J and Hill A R 1993 Reflectance pulse oximetry measurements from the retinal fundus *IEEE Trans. Biomed. Eng.* 40 817–22 Deckardt R and Steward D J 1984 Non-invasive arterial hemoglobin oxygen saturation versus

transcutaneous oxygen tension monitoring in the preterm infant Crit. Care Med. 12 935-9

Delivoria-Papadopoulous M, Roncevic N and Oski F A 1971 Postnatal changes in oxygen transport of term, preterm, and sick infants: the role of red cell 2,3-diphosphoglycerate and adult haemoglobin Pediatric Res. 5 235-45

Delori F C 1988 Noninvasive technique for oximetry of blood in retinal vessels Appl. Opt. 27 1113-25

Dempsey J A 1986 Is the lung built for exercise? Med. Sci. Sports Exercise 18 143-55

Dildy G A, Clark S L and Louks C A 1993 Preliminary experience with intrapartum fetal pulse

Dildy G A, Clark S L and Louks C A 1995 rieminiary experience with intrapartum retar purse oximetry in humans Obstet. Gynecol. 81 630-4
Dildy G A, Clark S L and Louks C A 1994 Intrapartum fetal pulse oximetry: the effects of maternal hyperoxia on fetal arterial saturation Am. J. Obstet. Gynecol. 171 1120-4
Ernest J T and Krill A E 1971 The effect of hypoxia on visual function Invest. Ophthalmol. 10

323-8

Fanconi S 1988 Reliability of pulse oximetry in hypoxic infants J. Pediatr. 112 424-7

Gardosi J O, Schram C M and Symonds E M 1991 Adaptation of pulse oximetry for fetal monitoring during labour Lancet 337 (8752) 1265-7

Hauri P J 1992 The Sleep Disorders (Kalamazoo, MI: Upjohn Company)

Haynes S R, Allsop J R and Gillies G W A 1992 Arterial oxygen saturation during induction of anaesthesia and laryngeal mask insertion: prospective evaluation of four techniques Br. J. Anaesthesia 68 519-22

Howell S J, Blogg C E and Ashby M W 1993 A modified sensor for pulse oximetry in children Anaesthesia 48 1083-5

Johnson N, Johnson V A, Bannister J, Lyons G, Lilford R J, Griffiths-Jones M, Tuffnell D and Onwude J L 1990 Monitoring the fetus with a pulse oximeter during caesarean section Br. J.Obstet. Gynaecol. 97 653–8

Johnson N, Johnson V A, Fisher J, Jobbings B, Bannister J and Lilford R J 1991 Fetal monitoring with pulse oximetry *Br. J. Obstet. Gynaecol.* **98** 36–41 Joseph B M and Guzman F A 1995 Internal apparatus for continuous electrical and oximetric intrapartum monitoring of the fetus *US patent* 5,419,322

Knudsen J 1970 Duration of hypoxemia after uncomplicated upper abdominal and thoracoabdominal operations Anaesthesia 25 372-7

Kobrick J L 1970 Effects of hypoxia and acetazolamide on color sensitivity zones in the visual field J. Appl. Physiol. 28 741–7
 Kubli F W 1968 Influence of labor on fetal acid-base balance Clin. Obstet. Gynecol. 11 168–91

Lanigan C J 1992 Oxygen desaturation after dental anaesthesia Br. J. Anaesthesia 68 142-5 Lecky J H, Matsiras P V, Garfinkel D, Aukburg S J and Carson E R 1988 PONI: A prototype

respiratory and circulatory monitoring system for operating rooms Proc. Ann. Int. Conf. IEEE Eng. Med. Biol. Soc. 10 1406

Lindsey L A, Watson J D D and Quaba A A 1991 Pulse oximetry in postoperative monitoring of free muscle flaps Br. J. Plastic Surg. 44 27–9

Lynn L A 1995 Method and apparatus for the diagnosis of sleep apnea utilizing a single interface with a human body part US patent 5,398,682
 Macdonald P H, Dinda P K, Beck I T and Mercer C D 1993. The use of pulse oximetry in

determining intestinal blood flow *Surgery* **176** 451–8 Meier-Stauss P, Bucher H U, Hurlimann R, Konig V and Huch R 1990 Pulse oximetry used for

documenting oxygen saturation and right-to-left shunting immediately after birth *Eur. J. Pediatr.* 149 851–5 Minnich M E, Clark R B, Miller F C, et al 1988 Pulse oximetry during labor and delivery

Perinatol. Neonatol. 12 24

Miyachi M and Tabata I 1992 Relationship between arterial oxygen desaturation and ventilation

Mysch W and Tabata 1752 Relationship between alterna oxygen desautation and ventilation during maximal exercise J. Appl. Physiol. 73 2588–91
 Moller J T, Johannessen N W, Berg H, Esperson K and Larsen L E 1991 Hypoxemia during anaesthesia: an observer study Br. J. Anaesth. 66 437–44

Morozoff P E, Evans R W and Smyth J A 1993 Automatic control of blood oxygen saturation in premature infants. Proc. 2nd IEEE Conf. on Control Applications Vancouver, BC pp 415-9

- Moyle J T B 1994 Pulse Oximetry (London: BMJ) Norton L H, Squires B, Craig N P, McLeay G, McGrath P and Norton K I 1992 Accuracy of
- Participation of the second sec
- Paky F and C M Kocck 1995 Pulse oximetry in ventilated preterm newborns: reliability of detection of hyperoxaemia and hypoxaemia, and feasibility of alarm settings ACTA Paediatr. 84 613-6

Payne J P and Severinghaus J W (eds) 1986 Pulse Oximetry (New York: Springer)

Pope C L L and Hankins D V 1991 Pulse oximetry: application in the labor-and-delivery unit of a tertiary care center J. Reproductive Med. 36 853-6

Quance D 1988 Amniotic fluid embolism: detection by pulse oximetry Anesthesiology 68 951-2

Roberts C J, Parke T J and Sykes M K 1993 Effect of intraoperative inspired gas mixtures on

postoperative nocturnal oxygen saturation Br. J. Anaesth. 71 476-80 Schmitt J M, Webber R L and Walker E C 1991 Pulse oximeter for diagnosis of dental pulp pathology US patent 5.040.539

Short L. Hecker R B, Middaugh R E and Menk E J 1989 A comparison of pulse oximeters during helicopter flights J. Emer. Med. 7 639-43
 Siem K, Pennock B E, Koliner C M and Kaplan P D 1995 Can pulse oximetry identify episodes of sleep apnea? Sleep Res. 24 497

Spittal M J 1993 Evaluation of pulse oximetry during cardiopulmonary resuscitation Anaesthesia 48 701-3

Strandberg A, Tokics L, Brismar B, Lundqvist H and Hedenstierna G 1986 Atelectasis during anaesthesia and in the postoperative period ACTA Anaesthesial. Scand. 30 154-8

Strickland J H and J H Hasson 1993 A computer controlled ventilator wearing system Chest 103 1220-6

Tripp L D 1993 Ear canal pulse/oxygen saturation measurement device US patent 5,213,099

Tyler I L, Tantisira B, Winter P M and Motoyama E K 1985 Continuous monitoring of arterial saturation with pulse oximetry during transfer to the recovery room Anesth. Analg. 64 1108–

Vas Fragoso C A, Clark T and Kotch A 1993 The tidal volume response to incremental exercise in COPD Chest 103 1438–41 Whitehair K J, Watney G C, Leith D E and Debowes R M 1990 Pulse oximetry in horses Vet.

Surg. 19 243-8

# INSTRUCTIONAL OBJECTIVES

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

# **GLOSSARY**

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

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

absorption spectrum: extinction coefficients of a certain absorber versus wavelength

absorptivity: see extinction coefficient

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

acid-base imbalance: abnormal pH of the blood

ADC: analog to digital converter

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

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

alveolar ducts: respiratory tract between the alveoli and the bronchioles

alveolar sacs: a group of alveoli clustered together

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

anoxia: total lack of oxygen, e.g., cardiac arrest apical foramen: small holes in the roots of the tooth; they provide an opening for blood vessels to reach dental pulp

ARDS: adult respiratory distress syndrome

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

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

arterialization: when venous blood near the skin is brought to nearly arterial oxygen levels by some external influence such as heating arteriovenous anastomoses: a thick-walled blood vessel that connects an arteriole directly with

a venule, thus bypassing the capillaries

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

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

atelectic areas: shrunken, airless portions of the lung

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

atrium: either of two upper muscular chambers of the heart

**baseline component:** the signal which doesn't vary with time **beam angle:** the angular measure of radiated power measured on an axis from half-power point to half-power point

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

BF equipment: body floating; equipment with parts in direct contact with the patient are isolated bias: the fixed DC voltage applied between the base and emitter of a transistor, to keep the device on; the average of the differences between the pulse oximeter readings and the CO-oximeter

readings

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



blue dye 'patent blue': a commonly used dye to distinguish the area of arterial perfusion body surface area: the surface area of a body which can be estimated from charts related to

height and weight

bronchioles: respiratory tract between the alveolar duct and the bronchus

bronchitis: inflammation of bronchial tube mucus membrane

bronchus: one of two respiratory tracts between the trachea and the bronchioles, which provide a pathway into the lungs calibrating resistor: the resistance associated with the probe; this is useful in disposable

probes, as this is helpful in determining the wavelengths associated with that probe, so the suitable calibration curves may be used

calibration: the process of fine tuning the device to measure accurately; due to constant use or change in one of the measuring parameters it is necessary to retune the device

cardiac index: the cardiac output normalized by the hody surface area of an individual

cardiac output: the rate of blood flow through the heart

cardiopulmonary bypass: a method to maintain the circulation of the body while the heart is deliberately stopped during heart surgery cardiopulmonary resuscitation: providing assistance in order to restore respiration and

cardiac contraction

catecholamines: amino compounds derived from catechol (C6H6O2); they have sympathomimetic activity and affect nervous transmission and muscular tone Central Processing Unit (CPU): the heart of any digital control system; this unit is used to

generate control signals for the various operating systems on the processor board

CF equipment: cardiac floating; equipment suitable to be used in direct cardiac applications

chemoreceptors: function in sensing the chemical concentrations of CO2, O2, and H' of the blood

circulatory system: sends blood around the body to deliver oxygen and transport waste products

coagulopathy: a disease which affects blood clotting

comparator: a device used to determine whether two numbers or bits of information are equal

compliance: set of rules and standards that apply to a specific product; see lung compliance

control bus: information relating to control of various units on the processor board are passed on the control bus; these buses originate at the CPU and are bidirectional

CPAP: continuous positive airway pressure; applying air pressure through the nasal cavities to create a pneumatic splint, keeping the airway from collapsing current noise  $(I_n)$ : the random variation of input bias current in an op amp; it produces noise

when it reacts with the feedback resistance of the transimpedance amplifier

cuvette: in spectrophotometers, the container that holds the blood sample; it is designed so that it affects the transmission of light as little as possible

cyanosis: bluish discoloration of skin and lips due to severe hypoxemia and excessive reduced hemoglobin

DCT: discrete Fourier transform

decoder: a digital device used to decode the input signal into a set of output signals

defibrillation: application of high energy pulses to the heart when the heart loses synchronization of the heart muscle fibers; the fibers contract irregularly, usually at a rapid rate delay: response time of a pulse oximeter demodulate: used to demultiplex the R and IR signals from the output of the photodiode

dentin: hard tissue surrounding dental pulp; it forms most of the tooth and is covered by enamel desaturation: a process which lowers the oxygen level in the blood

diastole: a rhythmically recurrent expansion especially the dilation of the cavities of the heart during which they fill with blood

diffusion: transport of particles across membranes

dissociation: the process of a molecule being separated into ions, atoms, molecules or free radicals

drift: baseline wandering due to the changing characteristics of the components

driven right leg circuit: during ECG measurements the electrical signals are given a separate ground path thus maintaining patient safety

duty cycle: the ratio of the on time to the total operation time; it is the fraction of the time the device remains on; for a Nellcor system, this is usually 25%; it is 33% for an Ohmeda system dysfunctional hemoglobins: do not support oxygen transport to the tissue

dyshemoglobins: see dysfunctional hemoglobins ECG: electrocardiogram

edema: swelling of tissue

eigenvalue spread: ratio of largest eigenvalue to smallest eigenvalue

eigenvalue: a scalar  $\lambda$  which satisfies  $A\nu = \lambda\nu$  where A is a square matrix and  $\nu$  are associated eigenvectors

electrocautery: destroying tissue by electrical heating of a wire electroluminescence: the emission of light by electrons falling from the higher-energy conduction band to the lower-energy valence band; the electrons emit light energy in the form of photons of light

embolism: obstruction of a blood vessel by a clot or foreign object

EMC: electromagnetic compatibility

EMI: electromagnetic interference

emission spectrum: the frequency response of an LED, displayed on a wavelength scale

emphysema: accumulation of air in tissue; usually refers to destruction of the walls of the respiratory bronchioles

Erasable Programmable Read Only Memory (EPROM): ROMs that can be written into only through specialized means; as ROMs are read only devices, we cannot reprogram them through conventional ways; ultraviolet rays are used to erase the locations, and new data can be burned into them

error: the difference between the pulse oximeter reading and the CO-oximeter reading ESD: electrostatic discharge

extinction coefficient: numeric measure of opaqueness; the greater the value, the greater the opaqueness

feedback: the technique of returning to a machine or system part of its output so that the machine or system exercises self-correction or control of the process

FFT: fast Fourier transform

fibrosis: formation of scar tissue in the connective tissue of the lungs; results from pneumonia or similar type of infection

filter: a filter is basically a voltage dividing network arranged to possess frequency-discriminating properties

Finger phantom: see artificial finger  $F_iO_2$ : fraction of inspired oxygen (normal atmospheric fraction is 0.21) flip flop: a storage device which can be used to retain one bit of information

fractional oxygen saturation: ratio of oxygenated hemoglohin over total hemoglobin; usually measured in percent fractional  $S_aO_2$ : see fractional oxygen saturation and arterial oxygen saturation

functional hemoglobins: capable of carrying oxygen molecules (Hb and HbO<sub>2</sub>) functional oxygen saturation: ratio of oxygenated hemoglobin over functional hemoglobin; usually measured in percent

functional SaO2: see functional oxygen saturation and arterial oxygen saturation

G forces: forces created by large accelerations

Hb: see reduced hemoglobin

HbO2: see oxygenated hemoglobin

hemodynamics: relating to blood circulation

hemoglobin: a molecule in red blood cells for transport of oxygen molecules hemoglobins released into the plasma; this process is commonly done on blood for *in vitro* oximetry measurements to reduce the effects of scattering heparinized blood: blood that has been treated to prevent clotting

hypercapnia: excess carbon dioxide in the blood

**hyperoxia:** excess oxygen in the system due to high  $P_iO_2$ **hypotension:** condition in which the arterial blood pressure is abnormally low

hypothermia: reduction of body temperature below the normal range in the absence of protective reflex actions, such as shivering; sometimes body temperature is lowered for therapeutic

purposes such as during surgery to reduce the patient's requirement for O2

hypovolemia: diminished blood volume

hypoxemia: deficient oxygenation of blood

hypoxia: deficient oxygenation of tissue

hypoxic hypoxemia: hypoxemia caused by a drop in oxygen tension as a consequence of decreased lung function

illumination: the respective luminous or radiant flux density incident on a photodetector in vitro: outside the body

in vivo: within the body

instrumentation amplifier: a very high precision differential amplifier

interrupt: an event which invokes higher priority algorithms to attend to emergencies

interstitial fluid: fluid in between the cells, other than blood cells

intubation: placing a ventilation tube into trachea of the patient to assist mechanical ventilation ischemia: lack of blood in an area of the body due to blood vessel constriction or mechanical obstruction

isosbestic point: wavelength at which the extinction coefficients of oxyhemoglobin and reduced hemoglobin are equal (805 nm)

Kreb's cycle: a series of chemical reactions during which molecules are oxidized and energy is released

larynx: structure located between the pharynx and trachea which contains the vocal cords

latch: a digital unit used to latch data/address

linear extrapolation: predict values beyond measured values

linear regression: a straight line fit through the data points

linearly independent: a set of vectors  $\{x_i\}_{i=1}^n$  is linearly independent if  $\sum_{i=1}^n a_i x_i = 0$  is true only if scalar  $a_i = 0$  for all i

lookup table: used by hardware instead of an equation to determine the oxygen saturation by the ratio of absorbances based on empirical data

lung compliance: a measure of the elasticity of the lungs; work used to overcome compliance during inhalation is restored during expiration

mechanoreceptors: sensory receptors that are stimulated by mechanical changes such as pressure

medulla oblongata: portion of the brain stem which connects the pons and the spinal cord memory: the storage element in a digital system; it can be in the form of read only memory or random access memory

monochromatic light: light consisting of only one wavelength

motion artifact: errors introduced into the signal due to motion

MRI: magnetic resonance imaging

multiple scattering: the effect when scattering occurs more than once

myoglobin: a respiratory pigment found in the muscles which store oxygen

myxoma: benign gelatinous tumor of connective tissue

necrosis: death of tissue

odontoblasts: special cells within the dental pulp which form the dentin in the tooth

oxidation: a chemical reaction by which the molecule or atom loses an electron

oximeter: an instrument that uses optical measurements to determine the oxygen saturation of the blood

oxyhemoglobin: hemoglobin combined with an oxygen molecule which will be released freely to tissue

p-i-n photodiode: a p-n junction photodiode that has a large intrinsic layer providing lower capacitance and faster response than the conventional photodiode

 $P_{\mu}O_2$ : partial pressure of oxygen dissolved in arterial blood

partial pressure: the pressure of one gas in a mixture of gases patient isolation: to avoid the lack of ohmic continuity or physical separation; this can be provided by a transformer

pattern generator: a unit used to generate timing patterns used for synchronous detection gating, LED control, synchronizing the power supply, calibration patterns, and diagnostic timing

peak wavelength: the wavelength at which the radiated power (or light output) of an LED is a maximum

perfusion: the passage of a fluid through the vessels of an organ pH: negative log of the concentration of hydrogen ion (H<sup>+</sup>) concentration relative to a standard solution; a pH of 7 is neutral, below 7 is acidic and above 7 is alkaline

pharynx: respiratory tract that connects the nasal cavity to the larynx

photocell: a device whose resistance changes as a function of light intensity

photoconductors: see photocell

photodetector: a generic term for any device which is able to convert an optical signal input to an electrical signal output

photodiode: a p-n junction diode which converts incident light to an electrical signal; in pulse oximeters, this optical sensor is located in the probe and is configured to produce a current linearly proportional to incident light

photoplethysmograph: a plethysmograph that uses a photodetector photoplethysmographic signal: time varying signal of transmitted light intensity in living tissue due to arterial pulsation

photoresistors: see photocell

PiO2: partial pressure of inspired oxygen

plethysmograph: an instrument that detects variations in size of a part due to blood contained in the part

plethysmographic signal: time varying signal in living tissue due to arterial pulsation

**pneumonia:** inflammation of the lungs that can occur from a variety of sources **polarization filter:** an optical filter that only transmits light that is in that state of polarization;

polyaeptide: compound composed of amino acids molecules
 polyaeptide: compound composed of amino acids molecules
 polysomnography: monitors EEG, EMG, ECG, chest wall plethysmogram, airway flow, and oxygen saturation; it is a gold standard for sleep apnea diagnosis

precision: a measure of variation of random error or degree of reproducibility; it is usually represented by the standard deviation of the differences between the pulse oximeter and COoximeter readings

programmable gain amplifier: amplifiers whose gains can be adjusted and varied depending on the circuit requirement (for example, due to change in ambient light level, the dc offset can vary, thereby increasing the risk of sending the amplifier into saturation)

pulmonary: related to the lungs

pulsatile component: the signal which varies with time

pulse capability: the maximum allowable pulse current of an LED as a function of duty cycle and frequency

pulse oximeter: an oximeter that takes advantage of the pulsatile nature of the blood in the arteries

QRS: peak of the ECG waveform which corresponds to ventricular depolarization

**R** wave: the peak in the QRS complex of the heart beat **Random Access Memory (RAM):** a memory location capable of being read from and written into. This unit is used to store and retrieve data in a digital system

Read Only Memory (ROM): a memory location capable of only being written into; this used to store calibration related information

rectifier: a device that offers a much higher resistance to current in one direction than the other; rectifiers are used to obtain a unidirectional current (DC) from an alternating current

reduced hemoglobin: functional hemoglobin unbound to oxygen

reduction: a chemical reaction by which the molecule or atom gains an electron

respiration: the process of gas exchange

respiratory quotient: ratio of volume of CO2 produced per volume of O2 consumed

retinal fundus: posterior portion of the interior of the eye retinopathy of prematurity: disorder in the retina of neonates due to supplemental oxygen among many other factors

RFI: radio frequency interference

sample-and-hold: a circuit used to hold a value for a given period of time; this is very useful during analog-to-digital conversion; it consists of a high gain FET and a large capacitor SaO2: see arterial oxygen saturation

scattering: light is refracted by a small object causing a deviation of the light beam from its initial direction of propagation

sensitivity: the ratio of the electrical output signal to the intensity of incident light

signal-to-noise ratio: indicates the quality of the signal simulator: a device that behaves in a like manner to the original device

sleep apnea: cessation of breathing during sleep for episodes of 15 s or greater; there are three types: obstructive, central, and mixed

spectral bandwidth: the half-power bandwidth of the light emitted from an LED, measured in nanometers

spectral response: the relationship of output signal of a photodetector to the incident light at a particular wavelength

spectrophotometry: the process of measuring the absorbance of light at different wavelengths to determine the concentration of the substance in a solution

 $S_{n}O_{2}$ : arternal oxygen saturation as measured by the pulse oximeter; usually measured in percent spurious pulses: erroneous pulses introduced from disturbing sources

stemmed trigger: an emitter coupled multivibrator which is used as a voltage discriminator; this is also useful as a squaring circuit as it can be used to convert the sine waves into square waves switching time: the time required for an LED to switch from its ON state to its OFF state, or vice versa

synchronization: correlation of specific events to improve accuracy synchronous detector: the circuit component used to synchronously demultiplex the signal from the photodiode into its R and IR components

systemic: related to the body in its entirety

**MASIMO 2053** Apple v. Masimo APL\_MAS\_ITC\_00015875 IPR2022-01300 RX-0035.0258

systole: the period of contraction of the heart, especially that of the ventricles thermal resistance: causes the increase in junction temperature above ambient per unit of power dissipation for the given LED's package and mounting configuration thoracic cavity: the body cavity between the neck and the diaphragm

thresholds: signal levels established to make appropriate decisions in algorithms

transcutaneous: (transdermal) through the skin, e.g., administration of medicine via a patch

transimpedance amplifier: an amplifier used in pulse oximetry to convert the current produced by the photodiode to a voltage for further processing in the system transmittance: ratio of transmitted light to incident light intensity in an absorbing medium; the

greater the value, the less light is passing through the medium

trauma: wound or injury UART: (universal asynchronous receiver-transmitter) a device which can be programmed to do asynchronous communication UPPP: uvulopatatopharyngoplasty; surgical procedure to remove excess tissue in the upper

airway

vasoconstriction: a decrease in the diameter of blood vessels

vasodilation: an increase in the diameter of blood vessels which results in an increase in blood flow

ventilation: passage of air into and out of the respiratory tract

ventricle: either of two lower muscular chambers of the heart

wait state generator: a combination of one clock storage devices, used to store data for one clock cycle; it is useful to slow down the microprocessor when the I/O devices are communicating at a very slow rate

watchdog timer: a fail safe timer used to turn off the pulse oximeter, if the microprocessor system fails

> **MASIMO 2053** Apple v. Masimo APL\_MAS\_ITC\_00015876 IPR2022-01300 RX-0035.0259

# INDEX

Absorbance 27, 41, 46 Accuracy 177 arrhythmia 192 bilirubin 190 carboxyhemoglobin 187 dried blood 196 exercise 195 fetal hemoglobin 189 intravenous dye 185 methemoglobin 188 myxoma 192 optical interference 184 pigments probe position 193 temperature 190 versus motion artifact 183 versus perfusion 182 versus saturation 180 ADC 107, 116 Aircraft 220 Alarms 119 controls 206 Alveoli 4 Ambulances 219 Amplifier, transimpedance 80 Anesthesiology 16, 214 Anoxia 14 Bcer's law 27, 40, 125 Block diagram 99 Blood pressure measurement 232 Bowel viability 217 Burns 69 Cables 210 Calibration 159 in vitro 162 Calibration curve 51, 54 Carboxyhemoglobin 43, 161 Cardiac index 10 Cardiac output 9 Cardiopulmonary resuscitation 231 Cardioputitionary resuscia Catheter oximeter 31 Ccrebral oxygenation 232 Chemoreceptors 2 Circulation 8 Clark electrode 23 CO-oximeter 28, 176, 179

Coding resistor 105 Communications 209 Critical care 18 Cyclops 30 DC offset 107 Demodulator 106 Dental surgery 217 Derivative method 130 Diaphragm 3 Diffusion 10 Display 120, 201 graphical 201 numerical 203 Dysfunctional hemoglobin 42 ECG synchronization 143, 150 Edema 95 Eight-wavelength oximeter 32, 179 Electrocardiogram 9, 113

Electroluminescence 57 Endotrachial oximeter 216 Energy gap 58 Ensemble averaging 152 Exercise 231 Extinction coefficient 44, 46

Fetal monitoring 222 Fluorescent dye oximeter 32 Fractional hemoglobin 43 Functional hemoglobin 42

Gas exchange 5

Hemoglobin 6 Hypoxemia 15 Hypoxia 15, 19

In vivo oximeter 30 Input module 100 Interference compliance 211 electromagnetic 194 MRI 194 optical 79, 94, 112 Isosbestic point 27, 44

Kreb's cycle 12

243

 MASIMO 2053

 Apple v. Masimo
 APL\_MAS\_ITC\_00015877

 IPR2022-01300
 RX-0035.0260

244 Index

Lactic acidosis 16 Light-emitting diodes 35, 56 driver 64, 108, 110 temperature 59 wavelength variation 63, 66 Light intensity 126 Light scattering 52 Limitations of pulse oximetry 19 Linear interpolation 137

Methemoglobin 42, 161 Microprocessor 101 Mixing syringe method 23 Monitoring 17 Motion determination 154 Myoglobin 11

Nail polish 95 Neonatal monitoring 224 Normalized ratio 49

Optical filters 79 Optical shunt 95 Oxygen weaning 232 Oxyhemoglobin 42 Oxyhemoglobin dissociation curve 7

Peak and valley method 129 Peak discrimination 151 Peak excursion 151 Photocells 71 Photodiodes 36, 72 area 81 avalanche 72 integrated circuit 73 **MSM 72** p-i-n 75 packaging 78 phototransistor 73 Shottky 75 Photoplethysmography 18 Polysotnography 228 Power supply 118 Preamplifier 105 Probes 36 connectors 92 disposable 94 MRI 91 reflectance 87 reusable 93 skin temperature 90 spacing 89 transmittance 86 Pulsation of blood 46

R-wave determination 146 Ratio of ratios 129

Respiratory quotient 6 Sample and hold 112, 117 Shielding, electric 82 Signal processing 37 Simulators Aoyagi tissue model 170 bulb device 166, 168 colored colloid 168 dual wedge system 164 electronic 171 liquid crystal retarder nonblood 168 optoelectronic 170 polyester resin device Reynolds system 164 single wedge system 164 using blood 164 Vegfors system Sleep studies 227 Speakers 121 Spectral methods 157 Spectrophotometer 26 Standards 172 Start up software 134 Sulfhemoglobin 43 Survival time 14 Tallqvist method 21 Temperature sensor 105 Thickness of path 127

Reduced hemoglobin 42

Reflectance oximcter 30

Three-wavelength oximeter 37 Time window 145 Timing diagram 109, 113 Timing patterns 104 Tissue transfer 218 Transcutaneous oxygen sensor 25 Transient changes 136, 140 Transmittanee 41 Twersky's multiple scattering 53

**UART 102** 

Van Slyke method 22 Ventilation 1 Veterinary care 233

Wait state generator 103 Watchdog timer 104 Wavelength choice 45 Weight determination 155

Zeroing circuit 83

## Series Editors

R F Mould, Scientific Consultant, Croydon, UK C G Orton, Karamanos Cancer Institute, Detroit, USA J A E Spaan, University of Amsterdam, The Netherlands J G Webster, University of Wisconsin-Madison, USA

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

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

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

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

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

Subsequent chapters provide:

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

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

John G Webster lea Wisconsin-Madiso catheter radio-free sensor-based cont electrocardiograpi The contributors h



Used, Very Good - Design of Pulse O ximeters (Serles in Medical Physics and Biomedical Engineering)

Institute of Phys Bristol and Phile

> MASIMO 2053 Apple v. Masimo APL\_MAS\_ITC\_00015879 IPR2022-01300 RX-0035.0262