VALIDITY OF PULSE OXIMETRY DURING VENTILATOR WEANING
OF ADULT OPEN HEART SURGERY PATIENTS

by

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SUPERVISORY COMMITTEE APPROVAL

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I have read the dissertation of Rebecca S. Appleton in its final form and have found that (1) its format, citations and bibliographic style are consistent and acceptable; (2) its illustrative materials including figures, tables, and charts are in place; and (3) the final manuscript is satisfactory to the supervisory committee and is ready for submission to The Graduate School.

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ABSTRACT

The aims of this research were (a) to evaluate the validity of pulse oximetry as a criterion of tissue oxygenation for nurses to use during ventilator weaning in adult open heart surgery patients, (b) determine which measure of tissue oxygenation (via pulse oximeter or arterial blood gas analyzer) is most valid to use during three phases of ventilator weaning. Little research has been done on ventilator weaning, even though it is an established nursing procedure in critical care units. Measurements of oxygen saturation via pulse oximetry are an established standard of care when weaning ventilator supported patients, yet no research-based data are available to support its widespread use.

A descriptive, repeated-measures design was used to assess the agreement of blood oxygen saturation measured by three instruments during three phases of ventilator weaning. Study participants were 16 fair-skinned adults who had open heart surgery. Graphical analyses were computed to assess the agreement between the three blood oxygen saturations.

Analyses of data suggest that mean pulse oximeter and mean arterial blood gas oxygen saturations differed by less than 1.7% during ventilator weaning. When mean oxygen saturations from the pulse oximeter and arterial blood gas analyzer were compared with the mean hemoximeter oxygen saturation both exceeded the "standard"
(hemoximeter) by more than 5%, making the measured agreement between them unacceptable. The findings of this study suggest that oxygen saturation measured via pulse oximetry is accurate when compared with data obtained via an arterial blood gas analyzer. However, it is not recommended that nurses abandon the practice of performing arterial blood gases to verify whether or not low SpO₂ values measured by pulse oximeter are accurate. Wide fluctuations in Po₂ can occur without corresponding changes in SpO₂.

One statistically significant relationship was found between SpO₂ and Po₂, \( r(16) = .63 \). No significant association was found among pH, Pco₂, and core body temperature with SpO₂ during ventilator weaning.
This work is dedicated to three people: one whom I lost, one whom I gained, and one who has been unwavering. Anton William Staker (1905-1991), my grandfather, I lost during the process of this research. He started me down the path of education by enrolling me in preschool some 30 years ago. He was a man who only completed six grades of formal education because he had to work in the family butcher shop to help support the family. At the time of his death, he was highly educated and the greatest teacher I have known. My only regret is that he will not share with me the joy of the completion of this project. However, his memory lives on in all that I accomplish.

Martin Lee Appleton, my partner in life, I do not have words to describe adequately the support and sacrifice made by you during my education. I love you.

Samuel Martin Appleton, born April 8, 1994, my son and hope for the future, you came into my life during this research and changed my perspective on living. I hope I can guide you and give you opportunities that will make your life meaningful and happy, much like my grandfather did for me.
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CHAPTER 1

INTRODUCTION AND STATEMENT OF THE PROBLEM

Introduction

The purpose of this chapter is to describe the problem which initiated the research conducted for this dissertation. The problem has its roots deep in clinical nursing. Without exception, all patients undergoing open heart surgery are placed on life supporting ventilators, and postoperatively must always go through the process of ventilator weaning. The process of weaning requires expert nurses to monitor patients closely for oxygen desaturation and shifts in arterial blood gases (ABGs). Nearly all intensive care patients require ventilator support or oxygen therapy, which places a high demand on nurses to continually monitor patients' levels of oxygenation. As expected, measurement of arterial blood gases, including oxygen saturation, are the most frequently ordered diagnostic test for intensive care patients (Mauakkassa, Rutledge, & Fakhry, 1991).

Pulse oximetry is a new technology designed to measure blood oxygen saturation continuously; it has quickly replaced the more traditional technology, arterial blood gases, which not only measures blood oxygen saturation but blood pH, Po₂, Pco₂, hemoglobin, and several other variables as well. The incentive to
substitute pulse oximetry data for arterial blood gas data is understandable because it provides real-time continuous data, is inexpensive, and is noninvasive. On the one hand, there are serious negative aspects about drawing arterial blood such as the potential for bleeding, infection, and pain. On the other hand, arterial blood gas data provide crucial information about the ventilatory status of the patient that cannot be obtained from a pulse oximeter. Little research exists to support that data obtained via pulse oximetry can safely be substituted for arterial blood gas data during weaning of ventilator assisted patients. At present, nurses have no research-based data on blood oxygen saturation to guide their practice during ventilator weaning. This issue is of extreme importance for critical care nurses caring for critically ill adults whose lives are being supported by mechanical ventilation.

The specific aims of this research are (a) to evaluate the validity of pulse oximetry as a measure of tissue oxygenation for nurses to use during ventilator weaning of open heart surgery patients and (b) to evaluate which method of measuring tissue oxygenation, pulse oximetry, or arterial blood gases is most appropriate to use during three phases of ventilator weaning. To meet these aims, the research was designed to measure the agreement between two commonly used indirect clinical measures of oxygen saturation, via the pulse oximeter and arterial blood gas analyzer, in comparison to a direct measure of oxygen saturation obtained via a hemoximeter.
There are two compelling reasons for doing this study. First, little research has been done on the process of ventilator weaning itself, a common critical care nursing procedure. Second, even less research has been done to support the validity of using pulse oximetry to measure oxygen saturation in patients during ventilator weaning, yet it has quickly become a standard of care for weaning ventilator assisted patients in intensive care units.

The American Association of Critical Care Nurses (AACN) has identified ventilator weaning as their second most important clinical research priority. AACN has also identified a need for research on invasive and noninvasive monitoring devices (AACN, 1991). The purpose of the AACN directives is to encourage and support research in the clinical arena where care delivery lacks support of research data. At present, research does not suggest if pulse oximetry can safely be used in place of arterial blood gases during ventilator weaning.

During the process of ventilator weaning both invasive and noninvasive methods of monitoring oxygen saturation are utilized. The ability of a patient to progress through ventilator weaning is based in part on the nurse's evaluation of a patient's pulse oximeter measurement of oxygen saturation (SpO₂), arterial blood gas calculated oxygen saturation (SaO₂-abg), as well as arterial blood pH, Po₂, Pco₂, and bicarbonate levels when reductions in ventilator support have been made.
The Problem

Current monitoring techniques used to measure oxygenation during ventilator weaning are highly variable and controversy exists over which method is most valid (Recker, 1991). Some nurses believe that SaO2-abg, the calculated oxygen saturation from the arterial blood gas analyzer is the most valid, whereas others believe SpO2 is more valid. The amount of variation between SpO2 and SaO2-abg data during ventilator weaning is unknown and difficult to evaluate because the primary type of analyses used in reported research have been correlational. The clinical controversy surrounding these instruments, however, is not related to the strength of their linear associations. Other research studies have reported a high degree of correlation between the three variables (SpO2, SaO2-abg, and hemoximeter oxygen saturation [SaO2-co]). Controversy exists about the acceptable amount of variation that occurs between these variables during ventilator weaning. The accepted clinical accuracy of the pulse oximeter is within 5% (+2 SD) of an in vitro oximeter in the SaO2-co range of 70 to 100% saturation (Kelleher, 1989).

Problematic also is how blood samples are obtained for analyses. Measurement of ABGs requires performance of one of two possible invasive procedures (a) a nurse, physician, or phlebotomist does repeated arterial punctures of the radial, brachial, or femoral arteries, to withdraw approximately 4 ml of arterial blood with each puncture or (b) a physician inserts an indwelling intra-arterial catheter in one of the above mentioned arteries so that multiple withdraws of arterial blood can be obtained. On the one hand,
arterial punctures are extremely painful and risk-related when blood is drawn directly from an artery. On the other hand, pain is decreased after the initial puncture when an indwelling intra-arterial catheter is used. However, with either procedure blood exposure remains a risk. Also problematic is the fact that blood draws to measure ABGs are intermittent rather than continuous. As such, rapid changes in oxygen saturation will not be detected quickly by ABG, because 30 min to 1 hr may elapse from the time ABGs are ordered and when results are obtained. A patient's level of oxygenation has been shown to change rapidly during ventilator weaning (Tobin, 1988). Frequently the information obtained from ABG analyses does not provide an accurate picture of the patient's oxygen status when ventilator changes are made. It is understandable why, when given a choice, critical care nurses prefer to use pulse oximetry data over arterial blood gas data. Pulse oximetry is a real-time, continuous noninvasive way of monitoring oxygen saturation. The bottom line is that it is safer and simpler to use.

Nurses need to know which measure is the most valid measure of oxygen saturation during different phases of ventilator weaning in order to make decisions that promote recovery rather than those that adversely affect patients, such as premature extubation requiring reintubation or prolonging the amount of time on the ventilator. The lack of standards in this area is a significant patient care problem. For example, patients are placed at risk for: undetected hypoxia, shifts in pH, \( P_O_2 \), and \( P_C_O_2 \), increased pain and cost, as
well as premature extubation or a prolonged period of ventilator support. Nurses also are at risk because they have increased blood exposure, not withstanding the fact that decisions are being made that are not protective of the physiologic state of the patient.

Much of the literature published following the 1983 (Lewandowski & Kositsky, 1983) call for research on ventilator weaning centered on preweaning assessment of patients and identification of problems that complicate the weaning process such as hyperventilation, hypoventilation, and pain management (Handerhan & Allegrezza, 1989; Henneman, 1989; Norton & Newreuter, 1989; Winters, 1988). To date, no research was found that evaluated or suggested when nurses could safely rely on SpO₂ during short-term ventilator weaning, and/or when it would be necessary to verify low SpO₂ readings with ABGs. Critical care nurses have identified differences of 5% and larger between SpO₂ readings and SaO₂-abg readings during ventilator weaning, causing them to question the validity of the pulse oximeter (Hafey, 1991; Recker, 1991). In my own practice I have found that tracking the oxygen saturation via pulse oximeter is generally valid when titrating the ventilator fraction of inspired oxygen (FiO₂), but the readings becomes questionable when changing ventilator respiratory rate (VRR) or ventilator tidal volume (VT).

The research proposed in this study will determine whether or not SpO₂ measurements are valid, or if they overestimate the SaO₂-abg and SaO₂-co when decreases in ventilator fraction of inspired oxygen, tidal volume (TV), and respiratory rate (RR) are
made during weaning. Regardless of study outcome, patient safety will be enhanced. On the one hand, if SpO₂ measurements are found to be valid, then, increased use of pulse oximetry during ventilator weaning will reduce the occurrence of hypoxia, eliminate the need for arterial punctures or blood withdraw from intra-arterial catheters to assess oxygenation, and reduce pain and costs. On the other hand, should study findings identify that SpO₂ data are not valid when changes in VTV and VRR are made, patient safety will also be enhanced, because nurses will have data on which to base decision making, e.g., whether they will rely on SpO₂ or SaO₂-abg data during these times. In either case, an important first step will have been taken to develop a standardized nursing protocol for nurses when weaning open heart surgery patients.

Research Questions

The specific questions to be answered in this study are based on the assumption that as certain ventilator changes are made (VTV and VRR) during the weaning process, these changes shift arterial blood pH, which in turn shifts the oxyhemoglobin dissociation curve, altering the validity of pulse oximeter readings. The research questions of this study are: During ventilator weaning of adult patients recovering from open heart surgery:

1. What is the degree of agreement between SpO₂, SaO₂-abg, and SaO₂-co, when changes are made in (a) ventilator Fio₂, (b) VTV, while monitoring the patient's total TV, (c) VRR, while monitoring the patient's total RR?
2. What is the strength of the relationship between SpO₂ data and arterial blood pH, the partial pressure of oxygen dissolved in blood (P₀₂), and the partial pressure of carbon dioxide dissolved in blood (P₉₀₂) measured by an arterial blood gas analyzer?
CHAPTER 2

CONCEPTUAL FRAMEWORK AND LITERATURE REVIEW

The material in this chapter describes the conceptual framework for this study. The clinical problem stated in Chapter 1 can best be understood and studied within a framework that includes (a) Levine's conservation of energy theory, (b) the physiologic basis of respiration and perfusion, (c) the process of tissue oxygenation, (d) and assisted-ventilator respiration. This chapter concludes with a review of the relevant literature.

Conceptual Framework

Levine's Conservation Theory

Levine's (1967) conservation theory of nursing has been selected as the nursing model that best describes the interaction between the intensive care nurse and the ventilator supported patient during weaning. Levine's theory provides a holistic approach to nursing practice for adults requiring acute care (Leonard, 1990). It is based on four conservation principles: (a) conservation of energy, (b) conservation of structural integrity, (c) conservation of personal integrity, and (d) conservation of social integrity. According to the theory, the nurse receives and interprets adaptive messages of the patient during acute illness and intervenes with supportive and therapeutic care guided by the
principles of conservation. Within this theory, illness is conceptualized as a stressor that places patients in a dependent position, restricting their ability to participate in care. The nurse then is responsible for care administered to patients during dependent states. Extrapolating Levine's theory to patients on respirators during weaning, by definition, is a physiologic and psychologic stress. During the process of weaning, patients who have become dependent on ventilators require intervention based on in-depth knowledge of respiratory physiology and ventilator assisted respiration, as well as psychological support from critical care nurses in order to facilitate the patient's return to self-supported breathing.

Monitoring the physiologic state of dependent patients is a priority of critical care nurses who are responsible for the care of ventilator dependent patients. Most acutely ill patients that require mechanical ventilation eventually reach a point in their recovery when artificial ventilation is no longer necessary for survival. Weaning ventilator assisted patients, based upon accurate methods of assessing oxygen saturation, will enable nurses to intervene appropriately to promote adaptation of these patients toward self-supported breathing.

Levine's model has been incorporated into the conceptual framework of this study, and a discussion of the model follows (see Figure 1). The conceptual model pictured in Figure 1 represents an overall schema for continued research on the validity of pulse oximetry during short-term ventilator weaning; however the focus of
Current Clinical Practice

1. ILLNESS/STRESSOR
   - The physiologic need for oxygen places the patient in a dependent state

2. Hospital Admission requiring Ventilator Support
   - Initiation of Supportive Nursing Care

3. Recovery Phase Stressor
   - Need to be Weaned

4. Unstandardized Monitoring of Weaning
   - Indiscriminate use of Arterial Blood Gas and Pulse Oximetry

5. Can lead to: Hypoxia and Unsuccessful Weaning

6. Mixed Successful and Unsuccessful Weaning

7. Expected Outcome:
   - ↑ Stress of the patient
   - ↓ Adaptation
   - ↑ Hospital Stay
   - ↑ Risk of Infection
   - ↑ Cost

8. Standardized Monitoring of Weaning Progress by Acute Care Nurses

9. Pulse Oximetry will be used during Ventilator FIO2 Weaning

10. Arterial Blood Gases will be used during TV and RR Weaning

11. More Consistent Successful Weaning and Standardized Nursing Care

12. Expected Outcome:
   - ↓ Stress of the patient
   - ↑ Adaptation
   - ↓ Hospital Stay
   - ↓ Risk of Infection
   - ↓ Cost
   - Improved Nursing Care Delivery

Application of Research Findings

Figure 1. Conceptual Framework, Evaluation of Pulse Oximetry
the present study is on the boxes labeled 1 through 4 in the model. Box 1, the illness or stressor: patients enter the hospital for treatment of illness; in this study the illness is a problem with the heart that requires surgery. Box 2: the need for surgery places the patient in a dependent position in which most biological functions are cared for and supported by nurses; this includes ventilator support. Box 3: once the surgery has been completed, the work of recovery begins; many stressors can intervene to slow a patient's recovery. Weaning can be a major stressor. Research has reported that the work of weaning may be equivalent to that experienced during vigorous exercise (Prakash, 1986). Box 4: the immediate aim of this research is to intervene here by assessing pulse oximeter accuracy during ventilator weaning, with the long-term goal being that of establishing safe monitoring protocols for weaning ventilator patients. The nurse plays a pivotal role in the process of ventilator weaning; he/she receives and interprets the adaptive messages of the patient during acute illness and intervenes with supportive, research-based care guided by the principles of conservation.

**Physiologic Basis of Pulmonary Respiration**

Physiologic respiration is a process whereby oxygen is transferred from the air to the lungs, to the capillary bed, and on to the tissues. Oxygen is utilized in the tissues. The by-product of respiration is carbon dioxide which diffuses into the expired air. The process of respiration is divided into three main stages (a) pulmonary ventilation, which by definition, is the inflow and
outflow of a mixture of gases between the atmosphere and the lung alveoli; (b) diffusion of oxygen and carbon dioxide between the alveoli and the blood; and (c) cellular respiration, the transport of oxygen and carbon dioxide in the blood and body fluids to and from the cells (Guyton, 1991; Pace, 1970).

The basic anatomical element of the respiratory system is the respiratory lobule. The functional unit is the alveolus, a small gas-containing sac, which is constantly washed out with fresh gas from the atmosphere, brought to it through a system of airway tubes, and separated from the blood in the pulmonary capillaries by a gas permeable membrane (Pace, 1972). The alveolar-capillary membrane is the barrier between gas (air) and liquid (blood) across which actual exchange of $O_2$ and $CO_2$ takes place by the process of diffusion.

Adequate ventilation must occur to maintain proper alveolar gas concentration. A normal distribution of ventilation/perfusion ratios and adequate alveolar-capillary membrane permeability are required for normal arterialization of venous blood. It follows then that if ventilation of an alveolus is occurring and perfusion of its capillaries is simultaneously occurring, diffusion across that particular (normally permeable) alveolar-capillary membrane will occur (Pace, 1970). However, the direction and quantity of movement of a particular gas depend on the relative tension, or partial pressure of that gas on each side of the membrane, and its solubility.

Air moves in and out of the lungs because pressure gradients are created between the atmosphere and the alveoli by muscular
mechanical means. During inspiration the thoracic volume increases because of the descent of the diaphragm and elevation of the ribs causing the intra-alveolar pressure to become slightly negative with respect to atmospheric pressure. The difference in the pressure gradients causes air to flow inward through the respiratory passageways. Expiration is a passive movement produced by the elastic recoil of the chest wall and lungs; intra-alveolar pressure rises to slightly more than +1 mm Hg, which causes air to flow out of the respiratory passages. Compliance of the lung (a measure of its distensibility) is reduced by anything that obstructs the normal flow of air in and out of the lung, i.e., mechanical ventilation. Compliance is determined by alveolar surface tension and the elastic recoil of the lung and chest wall.

As in other comparable systems, when pressures (or concentrations) differ on two sides of a permeable membrane the effective direction of movement is from the high pressure (more concentrated) side toward the low pressure (more dilute) side until equilibrium is reached (Guyton, 1991). The partial pressure of O2 is normally higher in the alveolus than in the venous blood coming to the capillary, a condition that promotes rapid diffusion down the concentration gradient from the alveolus into the capillary. The reverse is true of CO2.

The Process of Tissue Oxygenation

The physiologic process of oxygenation is an integral part of the broader concept of pulmonary ventilation and perfusion. The interplay of oxygen diffusion from the lungs to cellular tissues and
the reciprocal diffusion of carbon dioxide from cellular tissues to the lungs is cyclical. Once oxygen has diffused from the alveoli into the pulmonary blood, 97% of it is transported in combination with hemoglobin known as oxyhemoglobin (HbO₂) to the tissue capillaries where it is released for cellular metabolism. A small percentage of oxygen is dissolved in the plasma, which is inadequate for normal human metabolic needs (Pace, 1970). In the tissue cells oxygen reacts with various organic metabolites (i.e., glucose and fatty acids) to form large quantities of carbon dioxide. Carbon dioxide, which is 20 times more soluble than oxygen, rapidly diffuses from the cells into the interstitial fluids and thence into the capillary blood, where it is transported back to the lungs for expiration.

The oxyhemoglobin dissociation curve. Oxygen forms an easily reversible combination with hemoglobin to give oxyhemoglobin: O₂ + Hb ↔ HbO₂. The ability of oxygen to combine with hemoglobin is largely dependent on the partial pressure of oxygen, the affinity or attraction of hemoglobin for oxygen, and the amount of hemoglobin present in the blood. When the affinity of hemoglobin for oxygen is increased, oxygen rapidly binds with hemoglobin at the alveolar-capillary level but is not easily released at the capillary tissue level; thus tissue oxygenation may be decreased (Comer, 1991). Conversely, when the affinity is decreased, less oxygen is bound to hemoglobin at the alveolar-capillary level, but the oxygen transported on hemoglobin is readily released at the capillary-tissue level (Comer, 1991).
Figure 2 illustrates the oxyhemoglobin dissociation curve, which shows the progressive increase in the percentage of hemoglobin that is bound with oxygen as the Po$_2$ increases. This is called the percent saturation of the hemoglobin. Oxygen saturation is defined as

\[
\frac{O_2 \text{ combined with Hb}}{O_2 \text{ capacity}} \times 100
\]

(West, 1995)

Blood that has been shunted through the bronchial tree usually has a Po$_2$ of about 100 mm Hg. One can see from the dissociation curve that the usual oxygen saturation of arterial blood is about 97% (Guyton, 1991). In normal venous blood returning from the tissues the Po$_2$ is about 40 mm Hg and the saturation of the hemoglobin is about 70% (Guyton, 1991).

The curved shape of the oxygen dissociation curve has several distinct features: an S shape, a flat top, and a steep midpart. The flat upper portion represents the binding of oxygen. This portion is so flat that the Po$_2$ in alveolar gas can fall somewhat, and the loading of oxygen will not be significantly affected (Guyton, 1991; West, 1974), whereas the steep lower part represents the release of oxygen to tissue capillaries. The advantage of this steep section is that peripheral tissues can withdraw large amounts of oxygen for only a small drop in capillary Po$_2$ (Guyton, 1991).
Figure 2. The Oxyhemoglobin Dissociation Curve and Factors That Affect Hemoglobin Oxygen Affinity. The Solid Line is the Normal Dissociation Curve, and the Dotted Line is the Shift Either to the Left or the Right of Normal.
Several factors can affect the shape of the curve, including the hydrogen ion concentration (pH), partial pressure of carbon dioxide ($P_{CO_2}$), body temperature, and the concentration of 2,3 diphosphoglycerate (2,3-DPG) in the blood. With an increase in any of these factors, the curve shifts to the right, representing decreased oxygen affinity for hemoglobin and improved tissue oxygenation (Comer, 1991; Guyton, 1991). A decrease in any of the factors shifts the curve to the left, representing increased oxygen affinity for hemoglobin and impeded release of oxygen to the tissues (Comer, 1991; Guyton, 1991).

**Ventilator Assisted Respiration**

Mechanical ventilatory support is one of the major supportive modalities used in critical care (Tobin, 1988). Mechanical ventilation minimizes the work of breathing while optimizing pulmonary gas exchange (Reichman, 1988). The need for mechanical ventilation becomes necessary when patients are unable to ventilate their lungs effectively. A variety of physical disorders may result in respiratory insufficiency or failure requiring ventilator support.

Mechanical devices designed to assist ventilation were first described in the literature of the 16th century, but not until the early 1950s did mechanical ventilation gain widespread use during the polio epidemic in the United States (Rattenborg, 1981). The majority of available ventilators are volume or pressure-cycled. Ventilators perform four functions for patients: (a) inflation of the lungs, (b) passive expiration, (c) regulation of inflation,
(d) regulation of the expiratory phase and the start of the next inspiratory phase (Dupuis, 1992).

**Ventilator types.** There are basically two types of ventilators: pressure-cycled and volume-cycled. Pressure-cycled ventilators will inflate the lungs and automatically terminate inspiration when a preset pressure has been reached. The pressure-cycled ventilator allows the clinician to set the flow, pressure, and frequency. The volume of air delivered to the patient and the inspiratory to expiratory ratio are a result of those settings. Advantages of this type of ventilator are that patients accept the ventilator better because exhalation can occur at any time while keeping intrathoracic pressure at a minimum, and flow rate tapers downward making passage of gas easier in obstructed airways (Rattenborg, 1981).

Volume-cycled ventilators have the ability to deliver a preset volume of gas during each mechanical ventilation. This type of ventilator develops a pressure that can maintain the tidal volume when changes in resistance and compliance occur. The clinician can control the flow, frequency, and volume of air delivered (Richless, 1991).

**Ventilator settings.** TV is the amount of gas inspired and expired during normal breathing, usually about 6-8 cc/kg (Guyton, 1991). This volume is produced and regulated inside the ventilator and usually is controlled by a calibrated control knob located outside the ventilator. The volume is selected by adjusting the knob from 100 to 2,000 ml. The resistance and compliance of the
patient, ventilator, and tube system create changes in the patient's TV that must be taken into account.

All ventilators have some way of setting the minimal VRR. An elective timing mechanism divides a minute into equal parts for the rate of the machine (Rattenborg, 1981).

Many different ventilator techniques are used to control Fio2. Some common ways are with blenders, reservoir chambers, and venturi mechanisms. Oxygen concentration can be set to deliver 21% to 100% oxygen (Rattenborg, 1981).

Many changes occur when converting a patient from spontaneous respiration to mechanical ventilation. The use of an endotracheal tube can increase the resistance to air up to three times that of the upper airway (Richless, 1991). Intrathoracic pressure changes occur in the chest because of the forcing of air into the lungs. As thoracic pressure increases, it becomes progressively more difficult for the venous blood to return to the heart, in turn causing decreased cardiac output.

Within the classification of pressure and volume-cycled ventilators are numerous modes of ventilation. Three common ventilator modes are as follows:

- Control mode: This mode gives the clinician total control of the patient's ventilatory rate and volume.
- Assist-control: This mode gives the patient the ability to initiate his/her own spontaneous ventilations with each breath assisted by the ventilator to a preset volume.
- Intermittent mandatory ventilation (IMV): This mode allows the patient to breathe spontaneously without assistance, but he/she also receives breaths delivered by the ventilator at a preset rate and volume (Richless, 1991).

**Review of the Literature**

The focus of the literature review is on (a) ventilator weaning and (b) monitoring oxygenation during ventilator weaning.

**Ventilator Weaning**

Ventilator weaning is the process of slowing removing mechanical ventilatory support until patients are able to support their own breathing. Although little research on ventilators or weaning exists, the need for research-based data in this area is essential. Little standardization of the process of ventilator weaning has occurred over the last 30 years (Recker, 1991).

The literature describes four ways in which a patient can be weaned from a ventilator; they are described as follows:

1. T-piece weaning: This method involves disconnecting the patient from the ventilator while delivering a higher concentration of oxygen to the patient to compensate for a lower tidal volume while off the ventilator. The length of time the patient remains off the ventilator and on the T-piece is increased with every trial (Adams, 1979; Handerhan & Allegrezza, 1989).

2. Synchronized intermittent mandatory ventilation (SIMV): With the SIMV mode of weaning patients breathe their own TV at their own rate. At timed intervals, the ventilator supplements the
patient's effort by delivering a preset TV, and the rate of machine
breaths is decreased over time (Adams, 1979; Rattenborg, 1981).

3. Continuous positive airway pressure (CPAP): When CPAP is
initiated patients breathe independently while connected to the
ventilator, which serves as a source of humidified oxygen and
maintains positive pressure in the lungs to prevent alveolar
collapse. Like the T-piece method the amount of time a patient
stays on CPAP increases every hour (Handerhan & Allegrezza, 1989),

4. Pressure support (PS): This is the newest technique made
possible by improvements in ventilators. The ventilator delivers a
preset amount of positive pressure as the patient inhales; flow and
tidal volume increases, which decreases the work of breathing
(Handerhan & Allegrezza, 1989). Although these four weaning methods
are used clinically, wide variations in weaning procedures exist
within the types described above as well as among health care
providers.

Research on Weaning

In 1983, a call for research on weaning was issued by AACN
(Lewandowski & Kositsky, 1983). In response to the call much of the
research that followed centered on preweaning assessment of patients
and identification of problems that complicate the weaning process
(Handerhan & Allegrezza, 1989; Henneman, 1989; Norton & Newreuter,
1989; Winters, 1988) To date, no research has been done to evaluate
the validity of implementing a weaning protocol based on pulse
oximetry measurements or the need to verify oxygen saturations with
ABGs. Jubran and Tobin (1990) suggested that a target SpO₂ value of
92% is reliable in predicting a satisfactory level of oxygenation in Whites and 95% in Blacks during ventilator adjustments in Fio₂. This guideline is offered for titrations of the ventilator Fio₂, not ventilator weaning.

Current research on ventilators is plagued by a lack of clinical data from which to compare the use of various modes of mechanical ventilation, as well as reliable assessment parameters (Richless, 1991). The application and refinement of monitoring parameters to evaluate the impact of nursing interventions on mechanically ventilated patients should be a key focus (Richless, 1991). The challenge for future research in the area of ventilator technology is to generate controlled studies to support its application (Richless, 1991). No research studies were found that evaluated the validity and reliability of pulse oximeter derived oxygen saturation readings when ventilator changes were made in tidal volume, respiratory rate, or ventilator mode during weaning.

In clinical practice nurses have identified as a priority the need to refine their ability to monitor and assess patients during the process of ventilator weaning (Lewandowski & Kositsky, 1983; Richless, 1991; Szaflarski, 1989). Nurses have identified discrepancies in pulse oximeter readings during weaning, large enough differences between the pulse oximeter and the arterial blood gases that caused them to question the reliability of the pulse oximeter. In my own clinical practice I have found that tracking the oxygen saturation from a pulse oximeter is generally reliable for weaning the ventilator Fio₂; however I believe that it can
become unreliable and overestimated the true oxygen saturation when adjustments are made in the ventilator tidal volume and respiratory rate. If the pulse oximeter does overestimate the true oxygen saturation during the above mentioned ventilator changes, it would be necessary for a nurse to do arterial blood gases to verify the patient's oxygenation and ventilatory status in order to protect the patient. Verifying the patient's oxygenation every time there is a question about the reliability of the pulse oximeter is potentially painful, risky, and expensive for the patient. Clinical monitoring guidelines are needed to reduce the cost and risk of unnecessary arterial blood gases, as well as provide for the safe use of pulse oximetry during ventilator weaning.

**Monitoring Oxygenation During Weaning**

Continuous monitoring of important respiratory indices has the potential for predicting catastrophes and providing an opportunity for instituting lifesaving measures. The major goals of monitoring are to measure continuously key indices that improve our understanding of underlying pathology, aid in diagnosis, guide management, and provide alarms that alert nurses and physicians of significant changes in a patient's condition (Tobin, 1988).

**Arterial blood gases.** ABGs are universally employed in the assessment of respiratory function (Tobin, 1988). They can be influenced by changes in ventilation as well as factors such as mixed venous tensions of oxygen and carbon dioxide. Measurement of ABGs requires an invasive procedure (arterial puncture or intra-
arterial catheter), and information is provided only on an intermittent basis. Several problems exist with the sole use of ABGs for monitoring. Intermittent sampling may miss sudden changes, and frequently there is a considerable lag between ordering the test and obtaining results (Tobin, 1988). The information obtained does not provide a complete picture, deterioration in ABGs occurs relatively late in the evolution of respiratory failure. A discussion of other sources of error in ABG measurements are contained in the literature as well as a discussion of how much accuracy is required of ABGs (Clausen & Murray, 1985; Eichhorn, 1985; Lott & Bibbey, 1980).

Today, blood gas instruments are fully automated and can measure directly the pH and partial pressures of oxygen and carbon dioxide in whole blood. All three of these measures are made using electrodes, which operate under the same basic principles and differ only in size, shape, and location in the instrument.

**Arterial pH** is a direct measure of the free hydrogen ion concentration in arterial blood. This measurement has a twofold clinical application: (a) The pH is a reflection of the total acid-base balance of the body and, (b) a sudden significant change in the arterial carbon dioxide tension will chemically alter blood pH.

**Arterial Po₂** is a direct measure of the dissolved oxygen gas tension in the arterial blood. This measurement is closely related to the saturation of the hemoglobin with oxygen and oxygen content of the blood; however Po₂ does not reflect tissue oxygen state.
Arterial $Pco_2$ is a direct reflection of the adequacy of alveolar ventilation. The only nonmetabolic factor that affects the level of arterial $Pco_2$ is the efficiency with which the lung exchanges air with blood (Lott & Bibbey, 1980).

Arterial oxygen saturation ($SaO_2$) is an indirect measure of the amount of hemoglobin saturated with oxygen. Blood gas analyzers measure $Po_2$ directly and then use pH and temperature data to calculate the $SaO_2$. This measure is subject to potentially significant inaccuracies because of shifts in the oxyhemoglobin dissociation curve (Kelleher, 1989).

Pulse oximetry. In the early 1980s, pulse oximetry (PO) was introduced as an indirect method of measuring oxygen saturation (Kelleher, 1989). Because pulse oximeters are calibrated empirically, it is widely accepted that they are accurate to within 5% of in vitro oximetry in the $SaO_2$ range of 70-100% (Kelleher, 1989). Although pulse oximetry is considered accurate for some clinical purposes, such as assessment of intraoperative oxygenation, there are limitations on the applicability of data obtained from pulse oximeters under various clinical conditions (Kelleher, 1989). Nonetheless, the use of pulse oximetry to monitor the oxygenation of patients is widespread; nearly all hospitalized patients on mechanical ventilation have their oxygen saturation monitored by a pulse oximeter.

Seven research-based studies were found that assessed PO during titration of supplemental oxygen. False normal oxygen saturation readings from pulse oximeters have been reported in the literature,
but none have documented ventilator changes as a possible source of error. A few studies have assessed the use of PO while making ventilator changes in the Fio₂. These studies are summarized below.

Prakash (1986) first reported that pulse oximetry was accurate in predicting arterial oxygen saturation during weaning. Many of the specifics related to how the data were collected during this study are omitted. Flaws identified in this study were that data were collected randomly during three ventilator phases: preweaning, weaning, and postextubation; the amount and type of ventilator changes made were not discussed; SpO₂ was not systematically compared with SaO₂-abg or with SaO₂-co; the statistical analysis are not clear; and the degree of agreement between pulse oximetry and arterial blood gases was not calculated.

Sendak, Harris, and Donham (1988) evaluated the accuracy of pulse oximetry in ventilated dogs over a wide range of oxyhemoglobin desaturation. They found that PO readings closely reflected CO-oximeter findings and that there was more variance between pulse oximeter readings and ABGs. The findings of this study while informative do not allow comparison of results with human subjects: sample size was small, and the manipulation of the Fio₂ of the Harvard ventilator cannot be compared with ventilators presently in use on humans.

King and Simon (1992) evaluated tapering of supplemental oxygen in nonventilated patients with pulmonary disease. Investigators found that using PO decreased the number of days on oxygen and ABG punctures.
Nickerson, Sarkisian, and Tremper (1988) looked at the accuracy of four pulse oximeters when compared with oxygen saturations measured via ABGs and a CO-oximeter. They studied five healthy nonventilated subjects without pathology, manipulating their Fio₂. They found oxygen saturation measured by pulse oximetry compared well with CO-oximeters but that oxygen saturation calculated from the arterial blood gas analyzer was imprecise.

Niehoff et al. (1988) reported that pulse oximeter oxygen saturation correlated well with the partial pressure of oxygen in the blood (PaO₂). The specificity of oximetry in predicting hypoxia in 12 postoperative coronary artery bypass graft (CABG) patients during ventilator weaning was only 82%. The authors suggested that ABG measurements should be used to confirm low pulse oximeter oxygen saturations. This study had several flaws, such as a small sample size, weaning protocol and data collection methods were not described, and correlation coefficients were computed to assess agreement.

Jubran and Tobin (1990) manipulated the Fio₂ of 54 ventilator patients. They found pulse oximetry (when compared with ABGs), accurately predicted a satisfactory level of oxygenation in White patients but was inaccurate in predicting oxygen saturation in Black patients. This study suggested that a target SpO₂ of 92% be used for White patients, and 95% oxygen saturation be used for Black patients. The guideline was offered for titrations of ventilator Fio₂ and may not be reliable with other types of ventilator changes. This study used four different contrived algorithms to manipulate
the ventilator Fio\textsubscript{2}; these algorithms in no way simulated the process of weaning. This study did not compare the previous measurements with a standard of oxygen saturation.

Cheng, Renschler, Mihm, Sladen, and Rosenthal (1986) studied pulse oximetry in comparison to ABGs and CO-oximetry in 12 CABG patients undergoing ventilator weaning. They found measures of pulse oximeter oxygen saturation were significantly different from arterial oxygen saturation. They also reported that an unacceptably high incidence of false positive and false negative information necessitated the need for intermittent ABG analysis during ventilator weaning (VW). Investigators gave no indication as to what may have caused the false readings, such as a patient's physiologic state, instrument malfunction, the phase of VW, ventilator mode or change, nor did they suggest guidelines for how often ABGs should be done.

In summary, four of the seven previous studies evaluated pulse oximetry during manipulation of ventilatory Fio\textsubscript{2}; none looked at the affect on pulse oximeter oxygen saturation during changes in ventilator respiratory rate or tidal volume. Half of the studies reported inaccuracies in pulse oximeter oxygen saturation in comparison to an ABG analyzer or CO-oximeter, but none indicated under what weaning conditions or ventilator conditions the inaccuracies were occurring. According to Bland and Altman (1986) to determine the amount of agreement between two instruments measuring the same variable, regression and correlation analyses are inappropriate statistics. All of the above listed studies used
correlation coefficients as their primary analysis; none used the method outlined by Bland and Altman (1986). All of the studies concluded that noninvasive PO monitoring was beneficial but that ABGs needed to be used to verify low oxygen saturations. However, guidelines for specific ventilator conditions that would require ABGs were not given. Tobin (1988) stated that oximetry was not a sensitive guide to gas exchange in patients with high baseline Po2 values because of the shape of the oxyhemoglobin dissociation curve. Large changes in Po2 may occur with little change in SpO2; this finding may account for some of the discrepancies in the previous studies. Szaflarski's (1989) review of the use of pulse oximetry in critically ill adults concluded that pulse oximetry was useful for weaning patients from mechanical ventilation. However, no literature was cited to support this claim.

**Inherent machine limitations of the pulse oximeter.**

Inaccuracies in pulse oximetry have been reported and are related either to inherent machine limitations or to the shape of the oxyhemoglobin dissociation curve (Kelleher, 1989). Pulse oximetry has been documented as inaccurate in the following clinical situations: (a) at low SpO2 values below 70% (Fanconi, 1988; Pologe, 1987) patients do not typically drop their SpO2 below 70% as it is incompatible with life; (b) in low-amplitude states, one study found no significant loss of accuracy in postoperative hypothermia (Gabrielczyk & Buist, 1988), and Lawson et al. (1987) found that peripheral flows of 4.0 to 8.6% of baseline could trigger a PO signal; (c) for venous congestion, one study found that dependent
extremities have a falsely lower SpO₂ value (Kim, Arakawa, Benson, & Fox, 1986); (d) for anemia and dyshemoglobins, Lee, Tremper, and Barker (1988) found that patients with anemic hematocrits (less than 10%) SpO₂ was underestimated. Several studies found that when higher than normal methemoglobin and carboxyhemoglobin are present, SpO₂ was falsely normal (Eisenkraft, 1988; Payne & Severinghaus, 1986); (e) Dyes: methylene blue, indocyanine green, and indigo carmine have been documented to cause false desaturation (Scheller, Unger, & Kelner, 1986; Sidi, et al. 1987); (f) with ambient light, such as sunlight, fluorescent lights, a xenon arc surgical lamp, and another PO probe, have been found to elevate SpO₂ falsely; a foil shield over the PO probe is recommended to prevent ambient light distortion (Abbott, 1986; Nellcor, 1987; Siegel & Gravenstein, 1987); (g) with skin pigment, Black adults and infants have been found to have falsely high SpO₂ readings (Emery, 1987; Payne & Severinghaus, 1986); (h) with motion artifact, shivering and persistent motion will cause SpO₂ to give a reading of a specific value depending on the PO's calibration algorithm (Pologe, 1987); (i) finger nail polish and synthetic nails have been shown to cause interference in SpO₂ readings (Cote, Goldstene, Fuchsman, & Hoaglin, 1988; New, 1985).
CHAPTER 3

RESEARCH DESIGN AND METHODS OF PROCEDURE

The purpose of this chapter is to describe the design chosen to answer the research questions, the sample, the instruments, and the methods of procedures that were utilized. The aim of this study is to evaluate the validity of pulse oximetry to accurately measure SpO₂ on patients being weaned from ventilators. The research questions of this study are: During ventilator weaning of adult patients recovering from open heart surgery:

1. What is the degree of agreement between SpO₂, SaO₂-abg, and SaO₂-co, when changes are made in (a) ventilator FiO₂, (b) VTV, while monitoring the patient's total TV, (c) VRR, while monitoring the patient's total RR?

2. What is the strength of the relationship between SpO₂ data and arterial blood pH, the partial pressure of oxygen dissolved in blood (Po₂), and the partial pressure of carbon dioxide dissolved in blood (Pco₂) measured by an arterial blood gas analyzer?

Research Design

To answer the research questions posed in this study a descriptive repeated-measures design was chosen to examine the degree of agreement between SpO₂, SaO₂-abg, and SaO₂-co, as well as
the relationships between SpO$_2$ and arterial pH, Po$_2$, and Pco$_2$ during short-term ventilator weaning.

**Methodology**

**The Sample**

A convenience sample of 19 postoperative open heart surgery patients consented to participate during the 19-month period of data collection. Only fair-skinned or White patients were recruited into the study. Previous research findings support that dark skin pigment increased measurement error of pulse oximeter readings (Emery, 1987; Jubran & Tobin, 1990; Payne & Severinghaus, 1986). Ethnicity and race were not factors in the current study; few people of color reside in Utah, approximately 6.2%; the remaining 93.8% are Caucasian (Minorities of Utah, 1991). None of the patients who were eligible for the study were excluded because of race or skin color. However, there was racial and ethnic diversity within study participants; one participant was Asian American, and another was Mexican American.

All subjects were patients at the University of Utah Hospital, in Salt Lake City, Utah, a 300+ bed, tertiary health care facility, in the Intermountain West. Data collection was carried out in the surgical intensive care unit (SICU) at the University of Utah Hospital, a 12-bed unit in which all open heart surgery patients are admitted after the completion of their surgery.

Open heart surgery (OHS) patients were selected as the subject population because they are all ventilator-supported for the first 12-24 hr postoperatively and are weaned as quickly as possible once
their condition has stabilized. This population was also chosen out of necessity. Originally, only CABG patients were targeted to participate in the study. When it was discovered that the population of CABG patients at the study hospital was very small (11.5% of the total thoracic surgery population were CABG patients, 11 patients in the first 4 months of data collection), a decision was made to invite all OHS patients to participate in the study to increase the available pool of subjects.

**Method of subject recruitment.** In order to obtain up-to-date information on subjects, the operating room nurse in charge of scheduling surgeries was contacted by me the day prior to possible surgeries. Thoracic surgeries were performed 3 days of the week: Monday, Wednesday, and Thursday. When an open heart surgery was scheduled, the patient's name and phone number were obtained from the nurse, as well as information about admission status (inpatient or outpatient). Inpatients, those admitted to the hospital at least 1 day prior to their surgery, were visited by me in their hospital room. The study was explained in terms of information contained in the informed consent, and any questions participants had were answered at that time. A signed consent to participate in the study was then obtained. Patients who were admitted through outpatient admitting the morning of surgery, when possible, were contacted by phone by me the day before surgery. The study was explained over the telephone, and, if the patient showed interest in participating, I met them prior to surgery in the outpatient area. The study was explained again, and the consent to
participate was signed if he/she chose to participate. At the time
the consent form was signed, each participant was given a copy of
the consent form, a participant number was assigned, and the consent
was then placed in a locked file cabinet in Lab 501 in the College
of Nursing.

**Participant screening criteria.** Open heart surgery patients
who agreed to participate in the study had to meet the following
preoperative criteria: (a) be at least 35 years of age, (b) not have
hypertrophic fingernails or wear synthetic fingernails, and (c) be
fair skinned. Patients who met the above three criteria also had to
meet additional postoperative criteria: (a) be on the coronary
bypass pump intraoperatively no longer than three hr, (b) have an
indwelling intra-arterial catheter, (c) be on a ventilator, (d) have
a postoperative hemoglobin level of at least 9 gm/100 ml of blood,
and (e) have no more than 7% combined abnormal hemoglobin.
The preoperative criteria were imposed to eliminate problems described
in the literature with fingernail polish and synthetic nails and
skin color, which cause increased measurement error in the pulse
oximeter. The age restriction was applied to ensure a more
homogeneous group of participants, e.g., to eliminate those who were
having OHS who would not be representative of the majority of
subjects having OHS for coronary artery disease. The same reasoning
was applied in setting up the postoperative criteria. Its purpose
was to eliminate from the study patients who might make the
participant group less homogenous and, as such, create a source of
measurement error in the pulse oximeter. Examples of these patients
would be patients who are critically ill with multiple system failures that require longer surgeries and have lower hemoglobins, more dyshemoglobins, and decreased peripheral circulation.

The Instruments

The pulse oximeter. The SICU unit on which data were collected used the Hewlett-Packard Component Monitoring System with a modular SpO₂/Pleth Setup and a disposable Nellcor PO probe to measure oxygen saturation for all patients. The pulse oximeter estimates SpO₂ by sensing differences in the absorption spectra of reduced hemoglobin and oxyhemoglobin during arterial pulsations. The color change in the blood represents the changing optical properties of the hemoglobin molecules when it is saturated and desaturated with oxygen (Pologe, 1987). The Nellcor PO Probe emits light at 660 nm and 940 nm.

The functional components of the Hewlett-Packard pulse oximeter consist of the probe or transducer, analog and digital processors, and microprocessors (Hewlett Packard, 1992). The disposable probe consists of a light source and a photodetector; it was placed on the end of the third finger on the hand opposite the arterial line. It was positioned so that the hand would be parallel to the body or slightly elevated, to prevent measurements being taken on a dependent extremity. If it was not possible to use the third finger the index finger of the hand opposite the arterial line was used. The disposable probe was chosen for this study because it is the predominant probe used at the study site, it is sanitary and less
expensive, and it was adjustable to different finger diameters. Nondisposable probes have been documented to cause blisters of the skin and ischemia of the finger (Berge, Lanier, & Scanlon, 1988). An aluminum foil shield was wrapped around the PO probe to prevent ambient light interference. All fingernail polish was removed from the nails. The microprocessor box of the PO was contained with other modular monitoring equipment housed at the head of the bed.

Performance characteristics. POs are internally calibrated by the manufacturer; calibration is based upon empirically derived calibration curves from healthy adult male volunteers. It is not possible for the pulse oximeter operator to calibrate this instrument in any way.

The landmark research of Yelderman and New (1983) found that pulse oximeters were accurate to within 5% of an in vitro oximeter in the \( \text{Sa}_2 \) range of 70-100%, as long as limitations of the pulse oximeter are not violated. Although this degree of accuracy is acceptable for many clinical situations, such as assessing intraoperative oxygenation trends or adequacy of oxygen therapy, it is not adequate for other applications. The acceptability of \( \text{Sp}_2 \) results in a given clinical setting is a matter of clinical judgment. In a review of the accuracy of pulse oximetry data on various populations, and at varying \( \text{Sa}_2 \) levels, correlation coefficients are reported to range from .71-.98 (Kelleher, 1989). When pulse oximeters are compared with in vitro oximeters the percent of bias reported in the literature can range from 9.0% to -13.1% and the reported precision can range from 1.8% to 16.0% (Kim,
The arterial blood gas analyzer. This instrument calculates $\text{SaO}_2$ indirectly via direct measurement of $\text{Po}_2$, $\text{pH}$, and body temperature (Kelleher, 1989). A fully automated Radiometer Blood Gas Analyzer the ABL3 was used in this study. The analyzer was placed on a cart directly inside the SICU. Arterial blood samples were analyzed immediately after withdrawal from the patient. The position of the instrument and immediate analysis of blood eliminated any time lag, or the need to store blood samples in a slurry of ice. All ABGs were temperature corrected to the patient's core body temperature. Core body temperature was determined by the Hewlett-Packard modular monitoring system via continuous electronic display from the thermister of the Swan-Ganz catheter. The hemoglobin value from the ABL3 is intended for use with calculations, and was not used as an index for clinical treatment because the calculations were performed on nonhemolyzed blood.

One-point and 2-point calibrations were done automatically by internal microprocessors within the ABL3 every 2 and 8 hr respectively. Green and red calibration solutions are two different bicarbonate/phosphate solutions which are equilibrated with two different known gas mixtures that come from the built-in gas mixer in the ABL3. One-point calibrations were performed with the red calibrating solution, which flushes the measuring chamber three times before being used to determine the reference points of the $\text{pH}$ and $\text{Pco}_2$ electrodes, and the sensitivity of the $\text{Po}_2$ electrode. Two-
point calibrations begin with a 1-point calibration as described above; afterwards the measuring chamber is flushed five times with green calibrating solution before it is used to determine the sensitivity of the pH and the Pco₂ electrodes. The Po₂ is not measured using the green calibrating solution; instead, the Po₂ channel is zeroed electrically. When errors occur during calibration, they were indicated on the screen, and a question mark appeared. Warnings are given by the ABL3 when there are deviations from ideal conditions by the pH and Pco₂ channels. Sensitivity errors are displayed when the accuracy of the three electrodes are different when compared with the calculated, theoretical values. A built-in stability criterion is used to monitor the pH electrode, and stability and response criteria are used to monitor the Pco₂ and Po₂ electrodes. If a criterion is not satisfied, the ABL3 will respond with an error warning. When warnings were displayed, the manufacturers instructions were followed, usually requiring that cleaning solution or protein remover first be run through the measuring chamber and the instrument again calibrated. If warnings appeared the second time, usually the electrodes required cleaning and remembraning. Calibration procedures as outlined by Radiometer are contained in Appendix C.

Performance characteristics. Reference methods within the field of blood gas determination are not well defined (Radiometer America Inc., 1981). Radiometer has established reference methods for the determination of pH, Pco₂, and Po₂ in blood. These reference methods are presented in the Radiometer ABL3 User's
Handbook (1981). In order to evaluate the performance characteristics of the ABL3, Radiometer collected repeated measures data on a group of ABL3 instruments. The results obtained on these test instruments are compared with the values obtained from the reference methods. Two types of performance characteristics are reported by Radiometer, inaccuracy and repeatability. Inaccuracy is defined as "the mean difference between the measured value on a group of test instruments and the estimated true value, as assayed by the reference method" (Radiometer America Inc., 1981, p. 145). Repeatability is defined as "the standard deviation obtained from repeated measurements using the same sample and the same instrument" (Radiometer America Inc., 1981, p. 146). The reported inaccuracy and repeatability established by Radiometer for the ABL3 is contained in Appendix A. According to the manufacturer, there is a very small amount of inaccuracy in the three measures and a high degree of repeatability.

The hemoximeter. The Radiometer OSM2b Hemoximeter was used in this study to measure SaO₂ directly. The instrument was located on the same cart with the blood gas analyzer, in the SICU. It operates much in the same way as a blood gas analyzer. It is a completely automated instrument for the photometric determination of total hemoglobin and oxygen saturation in blood. This instrument is an accepted "standard" for the assessment of pulse oximeter data (Kelleher, 1989). The OSM2 is composed of two sections, an electronic section and a wet section. When a sample is introduced into the inlet it is ultrasonically hemolyzed in the cuvette. The
photo cell measures absorbances at 506.5 and 600.0 nm. The signals are passed from the photo cell to the arithmetic unit and the calculations are performed and sent to the display (Radiometer America Inc., 1979).

The analytical wavelengths of hemoglobin are fixed and known, therefore calibration coefficients for each species of hemoglobin have been accurately determined and stored in memory. Blood and water calibrations are required with the OSM2. Water calibration is performed as the first step in the calibration procedure, as water is introduced the hemoglobin and saturation channels are set to zero. Blood calibrations are carried out with blood samples that are fully saturated with 100% oxygen, and fully deoxygenated blood with 0% oxygen. These calibration procedures are outlined in the OSM2 Hemoximeter Users' Handbook, (1979) and are included in Appendix D. These procedures were followed as recommended by the manufacturer. A Radiometer Technical Expert performed the blood calibrations prior to data collection. Water calibrations were performed by me prior to beginning data collection on each study participant and every 8 hr of operation thereafter.

Performance characteristics. The reference method for hemoglobin requires mixing Drabkin's solution with blood concentrate and plasma; this procedure is well described by Radiometer and is contained in Appendix D. "There is no universally adopted reference for oxygen saturation measurements," and Radiometer has chosen not to establish its own reference method (Radiometer America, 1979). Therefore, the performance characteristics for oxygen saturation do
not include information on inaccuracy (Radiometer America Inc., 1979, p. 90). In order to evaluate the performance characteristics of the OSM2, Radiometer collected repeated measures data on a group of five OSM2 instruments. The results obtained on these test instruments are compared with the values obtained from the reference methods. The definitions of inaccuracy and repeatability that were given in the above section on the performance characteristics of the ABL3 are the same for the OSM2 and will not be repeated here. The reported inaccuracy and repeatability established by Radiometer for total hemoglobin are contained in Appendix B. The Radiometer reported inaccuracy of hemoglobin is plus or minus 1.1% of the reference measurement of hemoglobin, and the precision is within 0.3%. The precision for oxygen saturation is 0.3% for the OSM2 according to the manufacturer.

The ventilators. A ventilator is a device which is used to move gas into the lungs. The designs of the ventilators used in this study inflate the lungs by applying positive pressure to the airway. Positive-pressure ventilation must provide four basic functions: inflating the lungs, stopping lung inflation, allowing the lungs to empty, and initiating lung inflation. Although the functional characteristics among ventilators are varied, all ventilators provide these basic functions. Three specific types of positive-pressure ventilators were used in this research: (a) the Bear 2 ventilator, (b) the Puritan-Bennett 7200 Series microprocessor ventilator, and (c) the Servo 900C ventilator. The individual ventilators are described in the next section.
The Bear 2 ventilator. Only 1 participant was ventilated via the Bear 2, an electrically operated, electronically controlled, single-circuit ventilator. This ventilator operates on a pneumatic source of wall air and oxygen under pressure (Dupois, 1992). This ventilator operates in four modes: (a) control, (b) assist/control (AC), (c) synchronized intermittent mandatory ventilation (SIMV), and (d) continuous positive airway pressure (CPAP). A discussion of the modes of ventilation will follow the discussion of the ventilators.

The Servo 900C ventilator. Six participants were ventilated using a Servo 900C, a single circuit, electrically powered, electronically operated, microprocessor-controlled ventilator. The Servo like the Bear operates on a pneumatic source of wall air and oxygen. The ventilator operates in the following modes: (a) volume control, (b) pressure controlled, (c) pressure support (PS), (d) SIMV, (e) SIMV and PS, (f) and CPAP (Dupois, 1992).

The Puritan-Bennett 7200 Series microprocessor ventilator. This ventilator was used 56% of the time in this study, 9 participants. The Puritan-Bennett 7200 is electrically powered, electronically operated, and microprocessor controlled. It has a single pneumatic circuit, which requires wall air and oxygen pressure. Its modes of operation are: (a) continuous mandatory ventilation (CMV), (b) SIMV, (c) CPAP, (d) PS (Dupois, 1992).

Modes of ventilation. The modes of ventilation presented below can be classified into three categories: total ventilator control,
assisted ventilator control, or spontaneous breathing with minimal ventilator support.

The controlled ventilation mode has a regular pattern, the respiratory rate is constant, and peak inflation pressures are nearly identical. With the volume control mode the patient receives a specific volume of gas triggered by the ventilator or patient, as determined by the settings on the ventilator. The pressure control mode is pressure-limiting; a constant level of pressure is maintained throughout the set inspiratory time. Breaths can be triggered by the ventilator or patient. With continuous mandatory ventilation the inspiratory phase continues until a preset volume of gas has been delivered; the breath can be triggered by the ventilator, patient, or operator.

With assist-controlled ventilation and SIMV, patients receive a combination of mandatory and spontaneous breaths. In these modes the ventilator will give a breath when the patient does not initiate a breath within a specified time frame. SIMV, CPAP, and PS are modes of ventilation used just prior to extubation. In the CPAP mode the patient breathes spontaneously and receives a constant elevated baseline pressure; no assisted or controlled breaths are given by the ventilator. PS mode adds positive airway pressure, which is maintained throughout a spontaneous inspiration while the ventilator is in the SIMV or CPAP mode. PS can range from 0 to 30 cm H₂O above positive end-expiratory pressure (PEEP) or CPAP (Dupois, 1992).
All of the ventilators used in this study were able to deliver PEEP. While on PEEP a constant positive airway pressure is delivered to the patient. During inspiration, patients do not have to inspire below the level of PEEP to trigger the ventilator. PEEP keeps the lungs slightly inflated throughout inspiratory and expiratory phases; this makes the work of taking a breath easier.

**Data Collection Procedures**

Prior to data collection I assessed the data collection instruments, made any needed adjustments, performed instrument calibrations, and ensured that participants met the postoperative selection criteria. Data collection was carried out in three phases.

- **Phase 1**: steady-state measurement of ventilator supported OHS patients.
- **Phase 2**: measurement during VW when changes were made in ventilator Fio₂, TV, and RR.
- **Phase 3**: measurement after endotracheal tube was removed.

During the three phases of data collection serial simultaneous measurements of the following variables were made: SpO₂, SaO₂-abg, SaO₂-co, as well as measurements of arterial blood pH, Po₂, and Pco₂. Data were also collected at the same time on total hemoglobin, vital signs, the angle of the head of the bed in degrees, spontaneous respirations, spontaneous tidal volume, ventilator Fio₂, VTV, VRR, mode, and the type of ventilator change.

**Instrument set-up and calibration.** Prior to data collection it was necessary to assess all instruments to ensure that they were functioning according to the manufacturer's specifications.
Typically, participants were in the SICU at least 1 hr before data collection began. During that hr, the pulse oximeter was observed for warnings and error messages, such as "low pulsatile flow" or "searching for pulse." If error messages were given the probe was changed first; if errors continued then the Hewlett-Packard modular unit was replaced.

Prior to data collection a 2-point calibration was done on the ABL3 to detect error warnings. If an error warning appeared the manufacturer's handbook was followed, usually requiring cleaning of the measuring chamber or remembraning the electrodes. Then another 2-point calibration was done to determine that the instrument was properly calibrated. One-point calibrations were done every 2 hr and 2-point calibrations were done every 8 hr automatically during data collection by the ABL3. Similar procedures were followed with the OSM2. Water calibration/zeroing of the hemoglobin and saturation chambers was carried out prior to data collection, and then every 6-8 hr of operation thereafter.

A second level of quality control was used with the ABL3 and OSM2. Datacheck/Qualicheck a data management system produced by Radiometer. Datacheck coupled with Qualicheck provides a comprehensive quality control system for pH and blood gas, as well as hemoximetry (Radiometer America Inc., 1988). In this study three levels of the Radiometer Qualicheck system of high-precision aqueous dye solutions were used for every participant, before data collection began and every 8 hr thereafter. This system allowed me to double check the function of the instruments. It
guaranteed that the ABL3 was working within a specified range of pH, 
Pco₂, and Po₂ and that the OSM2 is working within a specified range 
of hemoglobin, and oxygen saturation. The limits of the aqueous 
Qualicheck solutions are predetermined by Radiometer and vary with 
each batch. During this study the limits of the Qualicheck were 
never exceeded. Datacheck results indicated that the ABL3 and OSM2 
were working within acceptable limits, when compared with composite 
data from peer laboratories.

Phase 1: steady-state ventilation. Steady-state ventilation 
was defined as the first 2 to 6 hr following surgery. During this 
time period ventilator stabilization occurred and few ventilator 
changes were made. The purpose of this phase was to determine the 
validity of SpO₂ data while ventilator settings were not being 
manipulated. The first sample was taken early in the recovery phase 
approximately 1-2 hr after admission to the SICU. Three more 
measurements were taken at 1/2 hr intervals after the first when 
possible if suctioning, or a ventilator change occurred, a 40-60 min 
period of blood equilibration was allowed to elapse before another 
measurement was made.

Steps in data collection in Phase 1 are as follows:

1. Prior to data collection I ensured instrument calibration, 
rang Qualicheck and verified the results. I made sure that the 
ventilator mode and settings had not been changed for 60 min, and 
that the patient's breathing was stable. The PO foil shield was in 
place; with the patient's hand in a parallel or slightly elevated 
position.
2. Four minutes prior to blood sampling, data were collected from bedside monitors and the clinical environment on the following variables: time, vital signs, the angle of the head of the bed in degrees, spontaneous respirations, spontaneous tidal volume if available, Fio₂, VTV, VRR, and ventilator mode. The data were recorded on a flow sheet.

3. Two minutes prior to blood sampling, four readings were taken at 30 s intervals from the bedside pulse oximeter. These data were recorded on a flow sheet.

4. Once the pulse oximeter readings had been recorded the arterial blood sample was drawn. Three milliliters of blood were withdrawn from the arterial line and discarded, then 1 ml of blood was withdrawn into a heparinized syringe, all of the air was expelled from the syringe and a cap placed on the end, and the syringe was gently agitated. The A-line was then flushed with heparinized saline.

5. The 1 ml of blood was hand carried immediately to the ABL3 and OSM2 (approximately 20 ft from the patient) inside the SICU for immediate analysis. The analysis was run simultaneously on the ABL3 and the OSM2. Blood gases were not placed on ice because the analysis was done within 1 min of withdraw. Temperature correction for P0₂ was entered into the ABL3. Blood gas measurements as well as total hemoglobin and oxygen saturation from the OSM2 were recorded on the flow sheet.

6. Blood was discarded into an appropriately designated disposal container. Blood samples in the ABL3 and OSM2 were
automatically washed out in preparation for the next sample.

Steps 1-6 completed the first set of measurements in Phase 1. After a 30-min period, in which no ventilator changes were made, steps 2-6 were repeated, for a total of four sets of measurements in Phase 1. No data were shared with staff during data collection.

**Phase 2: ventilator weaning.** As patients progressed in their recoveries, the attending nurse and respiratory therapist made decisions about ventilator changes based on the patient's condition; trend of pulse oximeter readings, and arterial blood gas data that nursing staff had collected. Respiratory parameters were not always assessed prior to weaning: therefore these data were not collected. Each participant was cared for by an SICU staff RN, who carried out the ventilator weaning. Therefore, every participant had a personalized weaning experience. I did not manipulate the weaning process in anyway. All participants received the same nursing care they would have received had they not participated in the research. According to hospital policy the ventilator Fio2 was reduced to 50% before changes in the TV and RR were made to prevent oxygen toxicity. When ventilator changes were made it was recorded on the flow sheet.

**Steps in data collection in Phase 2 are as follows:**

1. I again ensured: instrument calibration, ran the Qualicheck and verified the results; the PO foil shield was in place with the hand in a parallel or slightly elevated position.

2. When a change in the ventilator was made, 20-30 min was allowed to elapse prior to blood sampling to allow for blood
equilibration after the ventilator change.

3. Four minutes prior to blood sampling, data were collected from bedside monitors and the clinical environment on: time, vital signs, the angle of the head of the bed in degrees, spontaneous RR, spontaneous TV if available, ventilator Fio₂, VTV, VRR, and ventilator mode. The data were recorded on a flow sheet.

4. Two minutes prior to blood sampling, four readings were taken at 30 s intervals from the bedside pulse oximeter. These data were recorded on a flow sheet.

5. Once the pulse oximeter readings had been recorded the arterial blood sample was drawn. Three milliliters of blood were withdrawn from the arterial line and discarded, then 1 ml of blood was withdrawn into a preheparinized syringe, all of the air was expelled from the syringe and a cap placed on the end, and the syringe was gently agitated. The A-line was then flushed with heparinized saline.

6. The 1 ml of blood was hand carried immediately to the ABL3 and OSM2 (approximately 20 ft from the patient) inside the SICU for immediate analysis. The analysis was run simultaneously on the ABL3 and the OSM2. Blood gases were not placed on ice because the analysis was done within 1 min of withdraw. Temperature correction for Po₂ was entered into the ABL3. Blood gas measurements as well as hemoglobin and oxygen saturation from the OSM2 were recorded on the flow sheet.

7. Blood was discarded into an appropriately designated disposal container. Blood samples in the ABL3 and OSM2 were
automatically washed out in preparation for the next sample.

Steps 1-7 completed the first set of measurements in Phase 2. An average of four ventilator changes were made prior to extubation and with each of these changes a set of measurements were made. Four measurements were made in this phase for each participant.

The weaning procedure. As was mentioned above the weaning procedure was not manipulated in any way by me. SICU nurses assigned to the participant conducted the weaning. The following general protocol was followed by SICU nurses when weaning patients off of ventilators; it was adapted from Hafey (1991).

If the patient is on full ventilator support:

1. and their pH is greater than 7.45, their ventilator RR greater than 10/min, and VTV is greater than 10cc/kg of body weight (BW), then the ventilator RR will be decreased by two breaths/minute or the ventilator TV will be reduced by 100cc. Reevaluate the patient's status in 15 min.

2. and their pH is less than 7.35, their ventilator RR is greater than 10/minute, and VTV is less than 10cc/kg, then increase the VTV to 10cc/Kg. However, if the VTV is greater than 10cc/Kg and the VRR is less than 10/min increase the VRR by two breaths/min. Reevaluate the patient's status in 15 min.

If the patient is on assisted ventilator support and in either the CMV or SIMV mode, and their RR is greater than the VRR:

1. and their pH is greater than 7.45 or normal and the total RR is greater than 10/min, then switch to SIMV of eight breaths/min. Reevaluate the patient's status in 15 min.
2. and their pH is less than 7.35, assess level of consciousness and evaluate pain; if splinting, then medicate for pain and reevaluate the patient in 15 min.

If the patient is on partial ventilator support in an SIMV mode, and their RR is greater than the VRR:

1. if their SIMV rate is eight and the total RR is greater than 12 breaths/min, and the total TV is consistently greater than 300cc and can be aroused easily, then decrease the SIMV rate to six breaths/min or decrease the VTV by 100cc. Reevaluate the patient's status in 15 min.

2. if their SIMV rate is eight, pH is less than 7.45, the patient's RR is less than 12 breaths/min, and their TV is less than 300cc, assess for pain, medicate as needed, and reevaluate the patient in 15 min. If the patient's RR is greater than 12 breaths/min their TV is greater than 300cc, and their pH is normal or greater than 7.45, decrease the SIMV rate to six breaths/min or decrease the VTV by 100cc. Reevaluate the patient's status in 15 min.

3. if their SIMV rate is six, the total RR is greater than six or less than 15 breaths/min, with a normal pH, decrease the SIMV to four breaths/min and reevaluate the patient in 15 min.

4. if their SIMV rate is six, pH is normal, and the TV is less than 300cc, do not change the ventilator settings. If their pH is normal and the TV is greater than 300cc, decrease the SIMV to four breaths/min or decrease the VTV by 100cc and re-evaluate the patient in 15 min.
5. if their SIMV rate is four, pH is normal, and the TV is greater than 300cc, advance them to CPAP and reevaluate them in 15 min.

6. if on CPAP and the patient's RR is 10-25 breaths/min and the pH is normal, extubate to 40% face mask and reevaluate the patient in 15 min. However, if the pH is normal and the TV is less than 300cc, return to an SIMV of six breaths/min; if the pH is less than 7.35, increase the SIMV to six breaths/min and reevaluate the patient in 15 min. Continue this process until the patient can be extubated and placed on a face mask at 40% oxygen.

Phase 3: postextubation. This phase was defined as the first 4 to 6 hr after extubation. Following removal of the endotracheal tube, 69% of the participants were placed on 40-55% oxygen via face mask, 25% were on 4 L of oxygen per nasal cannula, and one participant was extubated to room air. The purpose of this phase was to determine the validity of SpO₂ data in the first few hours following extubation. Monitoring oxygenation is crucial during this time because of the probability of recurring respiratory failure. Four separate sets of measurements were made on each subject after extubation. One hour after extubation, the first set of measurements was made, and three more measurements were made at 1/2 hr intervals after the first, for a total of four measurements.

Steps in data collection in Phase 3 are as follows:

1. I ensured: instrument calibration, and QualiCHECK was run if needed and results verified; the PO foil shield was in place with the hand in a parallel or slightly elevated position. Once the
participants had been extubated, the amount of oxygen that they were receiving did not change again during Phase 3.

2. Four minutes prior to blood sampling, data were collected from bedside monitors and the clinical environment on: time, vital signs, the angle of the head of the bed in degrees, spontaneous respirations, spontaneous tidal volume if available, ventilator Fio$_2$, VTV, VRR, and ventilator mode. The data were recorded on a flow sheet.

3. Two minutes prior to blood sampling four readings were taken at 30 s intervals from the bedside pulse oximeter. These data were recorded on a flow sheet.

4. Once the pulse oximeter readings had been recorded, the arterial blood sample was drawn. Three ml of blood were withdrawn from the arterial line and discarded, then 1 ml of blood was withdrawn into a preheparinized syringe, all of the air was expelled from the syringe and a cap placed on the end, and the syringe was gently agitated. The A-line was then flushed with heparinized saline.

5. The 1 ml of blood was hand carried immediately to the ABL3 and OSM2 (approximately 20 ft from the patient) inside the SICU for immediate analysis. The analysis was run simultaneously on the ABL3 and the OSM2. Blood gases were not placed on ice because the analysis was done within one minute of withdraw. Temperature correction for P0$_2$ was entered into the ABL3. Blood gas measurements as well as hemoglobin and oxygen saturation from the OSM2 were recorded on the flow sheet.
6. Blood was discarded into an appropriately designated disposal container. Blood samples in the ABL3 and OSM2 were automatically washed out in preparation for the next sample.

Steps 1-6 completed the first set of measurements in Phase 3. After a 30-min period in which there were no changes in oxygen administration, steps 2-6 were repeated for a total of four sets of measurements in Phase 3. No data were shared with staff during the time of the data collection.

Data Analysis

Descriptive statistics were computed for sex, age, type of surgery, smoking status, the length of time they were on the bypass pump, the percentage of methemoglobin and carboxyhemoglobin, and medical history in order to describe the demographics of the sample.

The data set consists of serial simultaneous SpO2, SaO2-abg, and SaO2-co data, as well as ABG pH, Po2, Pco2 measurements. Within each of the three phases, there were four repeated measurements taken at four different times.

A limitation related to how instrument comparison has been done in previous research is the inappropriate use of correlation coefficients to describe the degree of agreement between the three derivations of blood oxygen saturation. Correlation coefficients computed in previous research similar to this project have reported high correlations; generally \( r \) has been above .80 (Kelleher, 1989). Although the use of correlation coefficients involves limitations, the majority of researchers in this area has calculated correlational analyses. Therefore, correlation coefficients were
calculated to allow for a comparison between this study and previous research.

In clinical measurement, comparison of a new technique with an established method is needed to validate that the methods agree sufficiently for the new method to replace the old (Bland & Altman, 1986). According to Bland and Altman (1986) use of Pearson correlation coefficients will not detect certain kinds of systematic lack of agreement between two measurement methods. Bland and Altman (1986) suggest that in order to measure the strength of the agreement between instruments a researcher should (a) plot the data and visually inspect the data points, (b) calculate the precision of estimated limits of agreement, (c) determine the relationship between the difference in the two instruments and the mean, and (d) assess repeatability. This graphical method was used to assess the degree of congruence among the three instruments and to answer the first research question: What is the degree of agreement between SpO₂, SaO₂-abg, and SaO₂-co, when changes are made in (a) ventilator Fio₂, (b) VTV, while monitoring the patient's total TV, (c) VRR, while monitoring the patient's total RR?

The pearson correlational statistic was calculated to answer the second research question: What is the strength of the relationship between SpO₂ data and arterial blood pH, the partial pressure of oxygen dissolved in blood (Po₂), and the partial pressure of carbon dioxide dissolved in blood (Pco₂) measured by an arterial blood gas analyzer? This analysis will provide information about how arterial pH, Po₂, and Pco₂ influence SpO₂ during weaning.
The statistical computer package, SPSS/PC+ studentware plus was used to analyze data. It is based on SPSS/PC+ version 4.0.
CHAPTER 4

RESULTS

The purpose of this chapter is to describe characteristics of the sample and present the results of data analysis. The findings of the study are presented in two sections. The first section answers the first research question using Bland and Altman's (1986) graphical method of analyzing agreement among oxygen saturation measurements made via pulse oximeter, blood gas analyzer, and hemoximeter. Also included in the first section are the statistical correlations among the three instruments. The second section includes the correlational data analyses calculated to evaluate the strength of the relationship between SpO\textsubscript{2} and arterial blood gas pH, Pco\textsubscript{2}, Po\textsubscript{2} and core body temperature.

The Sample

Sixteen of 19 subjects completed the three phases of data collection. Three subjects were dropped from the study: 1 became critically ill during data collection, 1 did not meet preoperative admission criteria, and 1 was precipitously weaned before all data could be collected.

Eight-eight patients had open heart surgery during the 19 months of data collection. Fifty-five percent of the patients were placed on the surgery schedule after 5 p.m., the day prior to
surgery and were considered emergency or add-on cases. Because of this, I was unable to access these patients or obtain informed consent prior to their surgery. The remaining 40 patients were invited to participate in the study; 21 (53%) decided not to participate. Of those who declined to participate, 90% were men and 10% women. Reasons given for refusal were fear, either of possible complications because of study participation or of the surgery itself and its possible outcomes. Of the 19 individuals who agreed to participate, 32% were inpatients and 68% were outpatients. Data were collected from each participant's chart regarding past medical history and present medical problems. Eleven of the 16 participants had a history of coronary artery disease and had been receiving pharmaceutical treatment prior to their surgery. It is of interest that only 2 participants had diagnoses of multiple organ disease. None had pulmonary disease, even though 50% were smokers. No participant had postoperative complications. These data and specific demographic and other relevant characteristics of the sample are presented in Table 1.

During recovery from OHS, all study participants progressed through several modes of ventilator support from full ventilator support, to ventilator-assisted breathing, and then to spontaneous respiration. On average, study participants spent 3 hr on a ventilator in full ventilator support, 1.2 hr in an assisted mode, and 1.8 hr in a spontaneous mode prior to being extubated. These data are displayed in Table 2.
Table 1.

Demographic Characteristics of the Sample (N = 16)

<table>
<thead>
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<th>Characteristic Variables</th>
<th>M</th>
<th>SD</th>
<th>Min</th>
<th>Max</th>
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<td>9.9</td>
<td>39</td>
<td>75</td>
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<tr>
<td>Length of Time on Bypass Pump</td>
<td>100.5</td>
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<td>Methemoglobin (%)</td>
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<td>Carboxyhemoglobin (%)</td>
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<table>
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<tr>
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<tr>
<td>*MVR</td>
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<td>*AVR</td>
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<table>
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<td>Diabetes</td>
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</tbody>
</table>

* Abbreviations: CABG, Coronary Artery Bypass Graft Surgery, the number refers to the number of grafts, MVR, mitral valve replacement, AVR, aortic valve replacement.
Table 2.

*Average Time in Ventilator Modes (N = 16)*

<table>
<thead>
<tr>
<th>Ventilator Mode</th>
<th>M Time</th>
<th>Minimum Time</th>
<th>Maximum Time</th>
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<tbody>
<tr>
<td>Full Support (hour)</td>
<td>3</td>
<td>1.5</td>
<td>8</td>
</tr>
<tr>
<td>Assisted mode (hour)</td>
<td>1.2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Spontaneous mode (hour)</td>
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Findings: Research Question 1

Bland and Altman's Analysis Technique

The findings here apply to research question 1: During ventilator weaning of adult patients recovering from OHS, what is the degree of agreement between SpO$_2$, SaO$_2$-abg, SaO$_2$-co, during ventilator weaning? Data were collected in three phases: Phase 1, stable ventilation; Phase 2, ventilator weaning; Phase 3, postextubation. Bland and Altman's (1986) graphical method of analysis was utilized to evaluate the degree of agreement between blood oxygen saturation measured by the three instruments. The discussion of the analysis is presented in a stepwise manner across the phases of data collection to allow for a comparison of the instruments across time. Bland and Altman's analytical approach to assess agreement between different measurement methods has four steps:

1. plotting the results of one method against the results of the other method;
2. plotting the difference between the methods against their mean;
3. determining the estimated limits of agreement for the differences between the two methods (also known as the 95% confidence interval);
4. assessing repeatability of the different methods.

Findings applicable to Step 1: Plotting the data from one instrument with the data of another instrument. The data obtained via the pulse oximeter are plotted with the data from the arterial blood gas analyzer across the three phases of data collection. Each participant had four measurements of SpO$_2$ made with each instrument in each of three phases. A mean score was computed for each
participant, for each instrument, in each phase. These data are shown in Figure 3. Participant 4, during Phase 2, was weaned slightly faster than the other participants and therefore had only three measurements made. Because of the missing data, this participant's data were not included in the analyses in Phase 2. However, his data are included in the analyses in Phases 1 and 3.

The plots shown in Figure 3 represent each participant's average SpO\textsubscript{2} measurement with his/her average SaO\textsubscript{2}-abg. Although these plots are crude, one can judge visually how closely the measurements made using the two instruments agree by observing how close the mean data points lie to the line of equality. The line of equality by definition is the line on which all measurements would fall if the two instruments measured the exact same blood oxygen saturation each time (Bland & Altman, 1986). The data plotted in Figure 3 displays how SpO\textsubscript{2} is consistently higher than SaO\textsubscript{2}-abg during stable ventilation (Phase 1) and after extubation (Phase 3), whereas during weaning (Phase 2) the data points lie closer to the line of equality, suggesting less variability in measurements obtained during this phase.

In Figure 4, data from the pulse oximeter are plotted along with data from the hemoximeter across the three phases of data collection. The plots in Figure 4 represent each participants' average SpO\textsubscript{2} measurement with their average SaO\textsubscript{2}-co measurement. The plots indicate that SpO\textsubscript{2} consistently overestimated the SaO\textsubscript{2}-co in all phases. All data points lie above the line of equality in all phases. During Phases 2 and 3, the data points
Figure 3. Plot of Mean SpO₂ and Mean SaO₂-abg. The Diagonal Line is the Line of Equality.
Figure 4. Plot of Mean SpO₂ and Mean SaO₂-co. The Diagonal Line is the Line of Equality.
lie closer to the line of equality than in Phase 1, however, the data in Phase 2 have less variability than that in Phase 3.

The data obtained via the arterial blood gas analyzer and hemoximeter are plotted across the three phases of data collection and are shown in Figure 5. The plots in Figure 5 represent each participants' average $SaO_2$-abg measurement with their average $SaO_2$-co measurement. The $SaO_2$-abg and $SaO_2$-co data lie closer to the line of equality than had the $SpO_2$ data shown in Figure 4. In Phase 1 the data points are the farthest away from the line of equality, in Phases 2 and 3, the data points are closer to the line of equality.

Findings applicable to step 2: Plotting the difference between the methods against their mean. The next step in Bland and Altman's method (1986) is executed to assess between-instrument differences with the eye, as well as investigation of possible relationships between measurement error and the "true value." Theoretically the true value is an unknown; thus, the mean difference between the scores of the two instruments is the best estimate available. An artifact of repeated measures is that the standard deviations (obtained from available statistical programs) of the differences will be artificially reduced. This occurs because some of the effect of repeated measurement error has been removed. The formula derived by Bland and Altman was used to determine the corrected standard deviation of the differences (cSD) calculated in this study. Then, the corrected standard deviations of the differences were used to determine the limits of agreement.
Figure 5. Plot of Mean \( \text{SaO}_2 \)-abg and Mean \( \text{SaO}_2 \)-co. The Diagonal Line is the Line of Equality.
Figure 6 displays three plots. Each plot represents the difference between $\text{SaO}_2$-abg and $\text{SpO}_2$ measurements, plotted against their mean, for each participant for all three phases. The mean differences between $\text{SaO}_2$-abg data and $\text{SpO}_2$ data range from -1.5% to -1.8%, with the overall differences ranging from 1.14% to -5.44%. The mean differences and limits of agreement are smaller between the arterial blood gas analyzer and the hemoximeter. The average size of the limits of agreement are 6.69%. These data suggest that measurements made via the pulse oximeter can be 5.4% above or 2% below data obtained via the arterial blood gas analyzer. The corrected standard deviations across the phases are small, e.g., 1.47, 1.87, 1.68, and one might conclude that the instruments would be considered clinically acceptable because the mean differences are small.

Table 3 displays the mean difference scores, cSD, and the 95% limits of agreement (95% confidence intervals) for the instruments. The plots contained in Figure 6 show the overall pattern of each participant's difference score with their mean difference score. Histograms of the mean data reveal a normal distribution and are shown in Figure 7.

Figure 8 shows three plots, which display the difference between $\text{SaO}_2$-co and $\text{SpO}_2$ data plotted against their mean for all participants across the three phases. The mean differences between $\text{SaO}_2$-co and $\text{SpO}_2$ data range from -6.9% to -7.2%. While this range is narrow, the overall difference is very large. The limits of agreement range from -1.12% to -12.68% difference between the two
Figure 6. Plot of the Difference Between SaO₂-abg and SpO₂ With Each Participants's Mean Oxygen Saturation. The Vertical Line at the Top of the Graphs is the Upper Limit of Agreement, the Middle Vertical Line is the Mean, and the Lower Vertical Line is the Lower Limit of Agreement.
Table 3

Means, Corrected Standard Deviations, and Limits of Agreement for the Three Instruments, by Phase

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**Figure 7.** Histograms of Mean SaO$_2$-abg and SpO$_2$ Data Across the Phases of Data Collection.
Figure 8. Plot of the Difference Between SaO₂-co and SpO₂ With Each Participants's Mean Oxygen Saturation. The Vertical Line at the Top of the Graphs is the Upper Limit of Agreement, the Middle Vertical Line is the Mean, and the Lower Vertical Line is the Lower Limit of Agreement.
instruments, which is quite large. The average size of the limits of agreement for these instruments is 9.37%. This means that the pulse oximeter can give measurements of oxygen saturation ranging from 12.7% above or 3.2% below the oxygen saturation measured via the hemoximeter. The corrected standard deviations across the phases are moderately large, e.g., 2.16, 1.98, 2.89. The calculated mean differences between these instruments exceed the accepted published level of accuracy between a pulse oximeter and an in-vitro oximeter by approximately 2% (Kelleher, 1989). The agreement between pulse oximeter and the hemoximeter is not clinically acceptable. The plots, contained in Figure 8, displays the overall pattern of each participants difference score with their average oxygen saturation; the upper and lower 95% confidence intervals are also plotted. The lack of systematic measurement error can be visualized. Histograms of the mean data revealed that it is normally distributed and are shown in Figure 9.

In Figure 10 the difference between $\text{SaO}_2$-co and $\text{SaO}_2$-abg data is plotted against their mean for all participants across the three phases. The mean differences between measurements of $\text{SaO}_2$-abg and $\text{SaO}_2$-co range from -5.3% to -5.4%; again the range is very narrow, yet the overall difference is large. The limits of agreement range from -0.4% to -10.2% difference between the two instruments, which is quite large. This large difference indicates that measurements from the arterial blood gas analyzer can range from 10.2% above or 0.4% below values measured via the hemoximeter. The average size of the limit of agreement is 9.05%. The corrected standard deviations
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**Figure 9.** Histograms of Mean SaO\textsubscript{2}-co and SpO\textsubscript{2} Data Across the Phases of Data Collection.
Figure 10. Plot of the Difference Between SaO$_2$-co and SaO$_2$-abg With Each Participant's Mean Oxygen Saturation. The Vertical Line at the Top of the Graphs is the Upper Limit of Agreement, the Middle Vertical Line is the Mean, and the Lower Vertical Line is the Lower Limit of Agreement.
across the phases are moderately large, e.g., 2.45, 2.02, 2.32. The arterial blood gas analyzer exceeds the hemoximeter consistently by 5.3%. The agreement between arterial blood gas analyzer and the hemoximeter is clinically not acceptable. The plots contained in Figure 10 displays the overall pattern of each participant's difference score with his/her average oxygen saturation. The upper and lower 95% confidence intervals are also displayed, and the lack of systematic measurement error can be visualized. Histograms of the mean data reveal that it is normally distributed and are shown in Figure 11.

Findings related to Step 3: Determination of the estimated limits of agreement. The estimated limits of agreement were calculated to determine the oxygen saturation values that apply to the whole population. In other words, determining the estimated limits of agreement gives the 95% confidence interval for the bias between the instruments. An artifact of repeated measures is that the standard deviations (obtained from available statistical programs) of the differences will be artificially reduced. This occurs because some of the effect of repeated measurement error has been removed. The formula derived by Bland and Altman (1986) was used to determine the corrected standard deviation of the differences (cSD) calculated in this study. Then, the corrected standard deviations of the differences were used to calculate the limits of agreement. These data are presented in Table 3. The limits of agreement are small for differences in $\text{SaO}_2$-abg and $\text{SpO}_2$ data (suggesting that these instruments are clinically acceptable),
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**Figure 11.** Histograms of Mean SaO\textsubscript{2}-co and SaO\textsubscript{2}-abg Data Across the Phases of Data Collection.
whereas the limits of agreement for the differences between $\text{SaO}_2$-co and $\text{SpO}_2$ and $\text{SaO}_2$-co with $\text{SaO}_2$-abg are large (one value exceeds 10%), which makes $\text{SpO}_2$ and $\text{SaO}_2$-abg data unacceptable when compared with the standard.

**Findings related to Step 4: Assessing repeatability.** In this step, the repeatability of the three instruments was assessed using the bias and precision determined for the instruments. The bias is the mean value of $\text{SaO}_2$-abg minus $\text{SpO}_2$, the mean value of $\text{SaO}_2$-co minus $\text{SpO}_2$, and the mean value of $\text{SaO}_2$-co minus $\text{SaO}_2$-abg. The precision, by definition, is the standard deviation of the bias. Table 4 shows the bias and precision for calculated differences between the three instruments by measurement. One would expect the theoretical mean difference between the instruments to be zero if both instruments gave the same reading for each sample. However, this is not the case. A systematic amount of bias was observed between the instruments. Bias is approximately 7.1% difference between the hemoximeter "standard" and the pulse oximeter, 5.4% difference between the arterial blood gas analyzer and the hemoximeter, and 1.7% difference between the pulse oximeter and the arterial blood gas analyzer. The calculated precision, or repeatability of the data, is consistent among the three instruments and is reflective of the small sample size and a moderate amount of variation within each measurement.
Table 4.

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</tr>
<tr>
<td>10</td>
<td>-7.2</td>
<td>3.7</td>
<td>-5.8</td>
<td>3.3</td>
<td>-1.5</td>
<td>1.8</td>
</tr>
<tr>
<td>11</td>
<td>-6.6</td>
<td>2.7</td>
<td>-5.1</td>
<td>2.3</td>
<td>-1.5</td>
<td>1.3</td>
</tr>
<tr>
<td>12</td>
<td>-6.6</td>
<td>2.9</td>
<td>-5.1</td>
<td>2.0</td>
<td>-1.5</td>
<td>1.9</td>
</tr>
<tr>
<td>TOTAL</td>
<td>-7.1</td>
<td>2.5</td>
<td>-5.4</td>
<td>2.2</td>
<td>-1.7</td>
<td>1.9</td>
</tr>
</tbody>
</table>
Correlational Analysis

A correlational analysis was done to measure the strength of the relationship between oxygen saturation measured via pulse oximeter and oxygen saturation measurements obtained via an arterial blood gas analyzer and hemoximeter during the three phases of ventilator support and weaning. This analysis was computed to compare the findings obtained in this study with research reported in the literature.

Bland and Altman (1986) caution against using correlation coefficients to assess agreement between two measurement techniques because the data obtained can be misleading. The Pearson $r$ measures the strength of the relationship between two variables, not the agreement between them. Therefore, it is possible that two instruments could have a very high degree of correlation, yet the degree of agreement between them could be poor. For example, both the pulse oximeter and arterial blood gas analyzer have given consistently higher readings than the hemoximeter during ventilator weaning; their correlations are strong $r(15) = .76, .75, p < .001$. However, the degree of agreement is poor between these instruments because the average mean difference between the instruments is very large. This situation would be unacceptable when evaluating the accuracy of one instrument in order to replace it with another instrument in the clinical setting.

The correlational data are presented in Table 5. Correlations on mean data indicate that there is a strong positive relationship between all of the oxygen saturations measurements derived from the
Table 5

Correlations Between $\text{SpO}_2$, $\text{SaO}_2$-abg, and $\text{SaO}_2$-co

<table>
<thead>
<tr>
<th>Mean data correlations (complete data set)</th>
<th>r</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\text{SpO}_2$ with $\text{SaO}_2$-abg</td>
<td>0.84**</td>
<td>16</td>
</tr>
<tr>
<td>$\text{SaO}_2$-abg with $\text{SaO}_2$-co</td>
<td>0.76**</td>
<td>16</td>
</tr>
<tr>
<td>$\text{SpO}_2$ with $\text{SaO}_2$-co</td>
<td>0.75**</td>
<td>16</td>
</tr>
</tbody>
</table>

Phase 1 - Stable Ventilator

| $\text{SpO}_2$ with $\text{SaO}_2$-abg     | 0.69* | 16 |
| $\text{SaO}_2$-abg with $\text{SaO}_2$-co | 0.58* | 16 |
| $\text{SpO}_2$ with $\text{SaO}_2$-co      | 0.69* | 16 |

Phase 2 - Ventilator Weaning

| $\text{SpO}_2$ with $\text{SaO}_2$-abg     | 0.71* | 15 |
| $\text{SaO}_2$-abg with $\text{SaO}_2$-co | 0.87**| 15 |
| $\text{SpO}_2$ with $\text{SaO}_2$-co      | 0.78**| 15 |

Phase 3 - Postextubation

| $\text{SpO}_2$ with $\text{SaO}_2$-abg     | 0.71* | 16 |
| $\text{SaO}_2$-abg with $\text{SaO}_2$-co | 0.71* | 16 |
| $\text{SpO}_2$ with $\text{SaO}_2$-co      | 0.48  | 16 |

*P < .01.  **P < .001.
three instruments. All three correlations are statistically significant, e.g., $r(15) = .84, .76, .75, p < .001$. An alpha level of .05 was used for all correlational statistical tests.

Oxygen saturation data were separated by phase and correlations calculated to examine the strength of the relationships between the oxygen saturations during ventilator weaning. In the stable ventilator phase (Phase 1) the relationships between measures remain strong and are statistically significant, $r(16) = .69, .58, .69, p < .01$, but are not as strong as the mean data correlations for the complete set of data. In Phase 2, ventilator weaning, the relationships are strongly positive and are statistically significant, $r(15) = .71, p < .01, r(15) = .87, .78, p < .001$. Of the relationships examined across the three ventilator phases, those in Phase 2 are the strongest. In Phase 3, (postextubation) the correlations between SpO$_2$ and SaO$_2$-abg and SaO$_2$-abg and SaO$_2$-co remain very strong and statistically significant, $r(16) = .71, .71, p < .01$. The correlation between SpO$_2$ and SaO$_2$-co is moderate and statistically not significant, e.g., $r(16) = .48$.

In Phase 1, when participants were transferred from the operating room to the SICU and data collection began, the participants were not receiving the same level of ventilation. Some had one ventilator change made prior to drawing the first blood sample, whereas others did not have a ventilator change prior to the first blood sample. Because of this difference, there is more variation in the data measured on the first blood sample than in the other three samples in Phase 1. Correlation coefficients were rerun
on Phase 1 data, omitting the first sample (to observe whether they would change), and significant changes were noted. For example, the correlation between SpO2 and SaO2-abg changed from $r(16) = .69$ to an $r(16) = .87$, $p < .001$, between SaO2-abg and SaO2-co $r(16)$ changed from $.67$ to $r(16) = .80$, $p < .001$, and between SpO2 with SaO2-co $r(16)$ increased from $.69$ to $r(16) = .71$, $p < .01$. These correlations are more reflective of the strong relationships between these variables during stable ventilation.

In summary, the findings for research question 1 indicate that the pulse oximeter and arterial blood gas analyzer oxygen saturations agree sufficiently during ventilator weaning; however both of these instruments overestimate the "true" oxygen saturation when compared with the hemoximeter. The relationships between the three oxygen saturations are moderate to strongly positive throughout ventilator weaning.

Findings: Research Question 2

Correlational Analysis

This section addresses research question 2: During ventilator weaning of adult patients recovering from OHS, what is the strength of the relationship among SpO2 data, arterial blood pH, the partial pressure of oxygen dissolved in blood (Po2), and the partial pressure of carbon dioxide dissolved in blood (Pco2) measured by an arterial blood gas analyzer?

Descriptive statistics for SpO2, pH, Po2, Pco2, and core body temperature are presented in Table 6. The range of values for SpO2 and body temperature data are within the normal biologically
Table 6

Means, and Standard Deviations for SpO₂, pH, Po₂, Pco₂, and Core Body Temperature (N = 16)

<table>
<thead>
<tr>
<th>Variable</th>
<th>M</th>
<th>SD</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO₂ (%)</td>
<td>97.90</td>
<td>1.98</td>
<td>92.00</td>
<td>100.00</td>
</tr>
<tr>
<td>pH</td>
<td>7.40</td>
<td>0.06</td>
<td>7.23</td>
<td>7.61</td>
</tr>
<tr>
<td>Po₂ (mm Hg)</td>
<td>101.70</td>
<td>33.60</td>
<td>58.00</td>
<td>241.00</td>
</tr>
<tr>
<td>Pco₂ (mm Hg)</td>
<td>38.90</td>
<td>6.20</td>
<td>24.10</td>
<td>62.70</td>
</tr>
<tr>
<td>Core Temp (C)</td>
<td>37.40</td>
<td>0.60</td>
<td>36.00</td>
<td>38.80</td>
</tr>
</tbody>
</table>
expected range. The range of pH, P0₂, and Pco₂ exceed what is considered to be normal. Table 7 presents the means and standard deviations of the variables of interest across the three phases of data collection. There is little variation in SpO₂, pH, and core body temperature across the phases. It should be noted that participants on average became more acidotic across the phases and retained carbon dioxide, whereas P0₂ dropped 22% across the phases.

Scatter plots display the relationship of SpO₂, with pH, P0₂, Pco₂, and core body temperature. In each plot, the data displayed are the average SpO₂, pH, P0₂, Pco₂, and body temperature for each subject for all three phases of data collection. Figure 12 displays two plots: the first is the plot of mean SpO₂ with mean pH, and the second is the bivariate regression plot which displays the line of least squares for SpO₂ with pH. The mean data points are randomly scattered, indicating that the relationship between SpO₂ and pH is weak. The correlation is slightly negative and can be visualized in the negative slope of the regression line.

In Figure 13 two plots are displayed: the first is the mean SpO₂ plotted with mean P0₂, and the second is the bivariate regression plot of SpO₂ with P0₂ which shows the line of least squares. The mean data points appear to lie along a straight line, indicative of a positive relationship. The correlation is positive. The slope of the regression line is also strongly positive, indicating that a small change in P0₂ can result in a large change in SpO₂.
Table 7

**SpO₂, pH, P<sub>O₂</sub>, P<sub>co₂</sub> and Core Body Temperature Across the Phases of Data Collection (N = 16)**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Phase 1 (stable vent.)</th>
<th>Phase 2 (weaning)</th>
<th>Phase 3 (postextubation)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>SD</td>
<td>M</td>
</tr>
<tr>
<td>SpO₂ (%)</td>
<td>98.8</td>
<td>1.4</td>
<td>98.1</td>
</tr>
<tr>
<td>(range)</td>
<td>(94.5-100)</td>
<td>(93-100)</td>
<td>(92-100)</td>
</tr>
<tr>
<td>pH</td>
<td>7.4</td>
<td>0.07</td>
<td>7.38</td>
</tr>
<tr>
<td>(range)</td>
<td>(7.2-7.6)</td>
<td>(7.2-7.5)</td>
<td>(7.2-7.4)</td>
</tr>
<tr>
<td>P&lt;sub&gt;O₂&lt;/sub&gt; (%)</td>
<td>113.7</td>
<td>41.9</td>
<td>99.7</td>
</tr>
<tr>
<td>(range)</td>
<td>(58-241)</td>
<td>(58-179)</td>
<td>(62-149)</td>
</tr>
<tr>
<td>P&lt;sub&gt;co₂&lt;/sub&gt; (%)</td>
<td>36.3</td>
<td>5.6</td>
<td>38.2</td>
</tr>
<tr>
<td>(range)</td>
<td>(24-52)</td>
<td>(29-61)</td>
<td>(33-63)</td>
</tr>
<tr>
<td>Core Temperature (C)</td>
<td>37.2</td>
<td>0.6</td>
<td>37.6</td>
</tr>
<tr>
<td>(range)</td>
<td>(36-38.4)</td>
<td>(36.4-38.6)</td>
<td>(36.9-38.8)</td>
</tr>
</tbody>
</table>
Figure 12. Plot of Mean $\text{SpO}_2$ With Mean pH, and Bivariate Regression Plot. The Diagonal Line is the Regression Line, the Line of Least Squares.
Figure 13. Plot of Mean SpO₂ with Mean Po₂, and Bivariate Regression Plot. The Diagonal Line is the Regression Line, the Line of Least Squares.
Figure 14 contains two graphs, the first is the plot of mean SpO\textsubscript{2} and mean Pco\textsubscript{2}, and the second is the bivariate regression plot which displays the line of least squares for SpO\textsubscript{2} with Pco\textsubscript{2}. The mean data points are randomly scattered, indicating that the relationship is weak, at best. The correlation and slope of the regression line are zero, indicating that there is no relationship between SpO\textsubscript{2} and Pco\textsubscript{2}.

Figure 15 contains two graphs, the first is the plot of mean SpO\textsubscript{2} and mean body temperature, and the second is the bivariate regression plot which displays the line of least squares for SpO\textsubscript{2} with core body temperature. The mean data points are randomly scattered, indicating that the relationship is weak. The correlation and slope of the regression line are zero, indicating that there is no relationship between SpO\textsubscript{2} and core body temperature.

Correlational analyses were done to determine the strength of the relationship between SpO\textsubscript{2} with pH, Po\textsubscript{2}, Pco\textsubscript{2}, and body temperature. The statistics were calculated first for the raw data and, second, for all data by phase. These analyses were done to allow comparison of the calculated relationships across the phases of ventilator weaning. The correlational data measured are presented in Table 8. The raw data correlations for the complete data set show a strong positive relationship between SpO\textsubscript{2} and Po\textsubscript{2} ($r(15) = .63$, $p < .001$) which was statistically significant. The correlation between SpO\textsubscript{2} and pH is weak, $r(15) = -.08$, and negative.
Figure 14. Plot of Mean SpO2 With Mean Pco2, and Bivariate Regression Plot. The Diagonal Line is the Regression Line, the Line of Least Squares.
Figure 15. Plot of Mean SpO₂ with Mean Core Body Temperature, and Bivariate Regression Plot. The Diagonal Line is the Regression Line, the Line of Least Squares.
Table 8

**Correlations Between SpO$_2$, pH, Po$_2$, Pco$_2$, and Core Body Temperature (N = 16)**

<table>
<thead>
<tr>
<th></th>
<th>r</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw Data Correlations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(complete data set)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SpO$_2$ with pH</td>
<td>-.08</td>
<td>15</td>
</tr>
<tr>
<td>SpO$_2$ with Po$_2$</td>
<td>0.63**</td>
<td>15</td>
</tr>
<tr>
<td>SpO$_2$ with Pco$_2$</td>
<td>-.03</td>
<td>15</td>
</tr>
<tr>
<td>SpO$_2$ with Temp</td>
<td>0.03</td>
<td>15</td>
</tr>
</tbody>
</table>

**Phase 1 - Stable Ventilator**

<table>
<thead>
<tr>
<th></th>
<th>r</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO$_2$ with pH</td>
<td>-.14</td>
<td>16</td>
</tr>
<tr>
<td>SpO$_2$ with Po$_2$</td>
<td>0.63**</td>
<td>16</td>
</tr>
<tr>
<td>SpO$_2$ with Pco$_2$</td>
<td>0.04</td>
<td>16</td>
</tr>
<tr>
<td>SpO$_2$ with Temp</td>
<td>0.11</td>
<td>16</td>
</tr>
</tbody>
</table>

**Phase 2 - Ventilator Weaning**

<table>
<thead>
<tr>
<th></th>
<th>r</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO$_2$ with pH</td>
<td>0.04</td>
<td>15</td>
</tr>
<tr>
<td>SpO$_2$ with Po$_2$</td>
<td>0.61**</td>
<td>15</td>
</tr>
<tr>
<td>SpO$_2$ with Pco$_2$</td>
<td>-.04</td>
<td>15</td>
</tr>
<tr>
<td>SpO$_2$ with Temp</td>
<td>0.19</td>
<td>15</td>
</tr>
</tbody>
</table>

**Phase 3 - Postextubation**

<table>
<thead>
<tr>
<th></th>
<th>r</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO$_2$ with pH</td>
<td>-.60**</td>
<td>16</td>
</tr>
<tr>
<td>SpO$_2$ with Po$_2$</td>
<td>0.72**</td>
<td>16</td>
</tr>
<tr>
<td>SpO$_2$ with Pco$_2$</td>
<td>0.37</td>
<td>16</td>
</tr>
<tr>
<td>SpO$_2$ with Temp</td>
<td>0.22</td>
<td>16</td>
</tr>
</tbody>
</table>

*P < .01. **P < .001.
The relationships between SpO2 with Pco2 and body temperature are positive but are also weak, \( r(15) = -0.03 \), and 0.03.

When the data were separated by phase, the correlation between SpO2 and Po2 remained strong and positive, \( r(16) = 0.63 \) and 0.72, \( r(15) = 0.61 \), \( p < 0.001 \), as well as statistically significant across all phases of data collection. The correlation of SpO2 with pH varied the most across across the three phases, from \( r(16) = -0.60 \) to 0.04. This relationship is weak, suggesting that these variables are independent of each other and that the variation in the correlation is due to other intervening variables or the small sample size. The correlations across all three phases for SpO2 with Pco2 and body temperature remained weak.

In summary, the research findings for research question 2 indicate that during ventilator weaning there is a strong statistically significant relationship between SpO2 and Po2. No relationship or only weak relationships were found between SpO2 and pH, Pco2, and core body temperature.
CHAPTER 5

DISCUSSION AND INTERPRETATION

Discussion of the results of data analyses and interpretation of the results will be outlined in this chapter. A brief overview of the significant findings of the study are presented first, followed by a discussion that addresses each of the research questions in light of the existing research. Also included in this chapter are the limitations of the study, implications for nursing practice, and recommendations for further research.

Overview of the Significant Findings

The overall conclusions reached for research question 1 are that measurements of oxygen saturations, obtained via a pulse oximeter and arterial blood gas analyzer, agree sufficiently to be used interchangeably in postoperative OHS patients during the process of ventilator weaning. Even though the limits of agreement are moderately small, the mean difference in measurements between the instruments is very small, giving them good agreement. It may also be concluded from this research that both the pulse oximeter and ABG analyzer overestimate the "true" oxygen saturation by more than 5% when each is compared with the oxygen saturation obtained via in vitro hemoximeter, during ventilator weaning of adult OHS patients. The limits of agreement between the pulse oximeter and
arterial blood gas analyzer, when compared with the hemoximeter, are moderately large. However, it is the large mean difference between the instruments that makes their agreement with the standard unacceptable. With the exception of one correlation coefficient, all coefficients were very strong or moderately strong and above 0.50 across all of the ventilator phases. All correlations were statistically significant ($p < .001$), indicating that the relationships among the oxygen saturations derived from the three instruments were strongly positive across all phases of ventilator weaning.

Related to research question 2, only one statistically significant relationship was found between $P_{O_2}$ and $S_{PO_2}$, and this relationship remained constant and strong throughout all phases of ventilator weaning. The other variables of interest $pH$, $P_{CO_2}$, and core body temperature had either very weak or no measurable relationship at all with $S_{PO_2}$ throughout the process of ventilator weaning.

**Findings: Research Question 1**

Before pulse oximetry can be accepted into clinical practice as a valid criterion to use for weaning ventilator supported patients, nurses need information about accuracy (bias) and precision, as well as the limitations of the instrument. The findings of this study confirm that data obtained via noninvasive pulse oximeter are reliable and valid for clinical decision making over the $S_{PO_2}$ range of 92% - 100%. However, both pulse oximeter and arterial blood gas oxygen saturations were found to overestimate the oxygen saturation
by more that 5% throughout all phases of ventilator weaning when compared with measurements derived from a hemoximeter.

Figure 16 displays the plot of mean the SpO₂, the mean SaO₂-abg, and the mean SaO₂-co for each of the 12 data collection points. Samples 1-4 were collected during Phase 1, stable ventilation; samples 5-8 were collected during Phase 2, ventilator weaning; and samples 9-12 were collected during Phase 3, postextubation. From this plot it is apparent that the pulse oximeter and arterial blood gas analyzer measured oxygen saturations are overestimating those measured by the hemoximeter across the three phases of data collection. It is also clear that pulse oximeter and arterial blood gas saturation data are more closely related to each other than the hemoximeter. The large variation between the pulse oximeter and arterial blood gas saturation measurements in comparison to the hemoximeter, may be due to inherent limitations in the methods in which each instrument calculates its oxygen saturation. In other words, each instrument calculates oxygen saturation differently. The pulse oximeter has empirical algorithms derived from the oxyhemoglobin dissociation curve, which are formulated from a specific population. All manufacturers of pulse oximeters derive their own algorithms, resulting in different instruments having slightly different algorithms. The arterial blood gas analyzers input data on pH, P0₂, and body temperature to calculate oxygen saturation, whereas the hemoximeter computes oxygen saturation using standardized arithmetic calculations, based on the known fixed
Mean Saturations from the 3 Instruments

![Plot of Mean SpO2, SaO2-abg, and SaO2-co Across the Phases of Data Collection.](image)

Figure 16. Plot of Mean SpO2, SaO2-abg, and SaO2-co Across the Phases of Data Collection.
spectrum of hemoglobin. Much of the variability among the three measurements of oxygen saturation is caused by inherent machine differences and the way each instrument computes oxygen saturation.

Nickerson et al. (1988) reported that pulse oximeter data agreed adequately with conventional co-oximeter data when oxygen saturations were above 90%. However, below 80% the degree of bias increased. In a laboratory setting, these investigators manipulated the concentration of inspired oxygen among 5 healthy, nonsmoking adult males, free from heart, lung, and blood diseases. The findings of agreement reported by Nickerson et al. (1988) cannot be compared with those of this study, primarily because of differences between how data were collected and the type of participants studied, e.g., healthy versus ill, nonventilated versus ventilated, not withstanding the small sample size. With the exception of the above study which evaluated pulse oximeter bias and precision in healthy males, no research was found related to bias/precision on a clinical sample during ventilator weaning of critically ill adults. The findings of this study represent a first-step toward validating the use of pulse oximeter oxygen saturation data for weaning adult SICU ventilator supported patients.

The majority of previous research has assessed agreement between the instruments based on the strength of the correlation between the pulse oximeter and the hemoximeter. The literature is replete with strong correlation coefficients ($r > .85$), suggesting that oxygen saturation measurements made by the pulse oximeter and hemoximeter agree sufficiently (Cecil, Thorpe, Fibuch, & Tuohy,
(1988); Kim et al. (1984); Sendak et al. (1988); Taylor & Whitwam, (1988). A conclusion of this study however is that the use of correlation coefficients is inappropriate for analyzing agreement between these instruments or, in fact, any instrument. The findings of this study demonstrate unequivocally that it is possible to have strong correlations and weak agreement between instruments. The strong positive correlations among the three instruments: pulse oximeter, arterial blood gas analyzer, and hemoximeter, support the correlational findings reported in the literature. This does not mean that the correlational findings are valid.

Findings: Research Question 2

Based on previous research findings, it was assumed that pH, Pco₂, Po₂, and core body temperature would influence the levels of on SpO₂, if for no other reason than these variables can have a significant impact on the oxyhemoglobin dissociation curve upon which pulse oximeter algorithms for the determination of oxygen saturation are based. One study was reported in the literature that addressed the relationship between SpO₂ and pH, Pco₂, Po₂, and core body temperature during ventilator weaning. Prakash (1986) tracked the pH, Pco₂, and Po₂ of patients on ventilators and found that pH and Po₂ dropped significantly, whereas Pco₂ increased during weaning. The trends reported by Prakash (1986) are supported by the findings of the present study. Table 7 in chapter 4 displays the trends of SpO₂, pH, Po₂, Pco₂, and core body temperature across the three phases of data collection.
The trends in these variables (SpO₂, ph, Po₂, Pco₂) across the phases are indicators of the strenuous metabolic demands and stress placed on patients as they are being weaned. A slight drop in mean oxygen saturation occurred across the phases, whereas Po₂ dropped more than 22% from Phase 1 to Phase 3. During weaning, participants became more acidotic, and retained carbon dioxide. It is interesting to note that this large drop in Po₂ across the phases had little or no effect on the SpO₂. Generally, SpO₂ is well protected from shifts in Po₂ because of the shape of the oxyhemoglobin dissociation curve. The drop in Po₂ coupled with the decrease in pH and retention of carbon dioxide during weaning is attributable to several factors. First, there is an increase in the work of the respiratory muscles during weaning, which, in turn, creates a higher oxygen demand by the tissues. Second, the artificial airway needed for ventilator support can also increase the resistance and, thus, the work of breathing. Third, postoperative surgical pain can cause patients to splint their breathing. Fourth, narcotic analgesics used to treat pain can also decrease a patient's respiratory rate, which may result in acidosis and retention of Pco₂.

Limitations of the Study

The bicarbonate levels of patients were not measured. Therefore, it was not possible to determine the extent of acidosis (was it only compensated respiratory acidosis, or was there a metabolic component?) in the patients across the three phases.
The results of this study may be generalizable to fair-skinned patients who have undergone OHS, and who were weaned from a ventilator 24-48 hr postoperatively. The findings may be generalizable to fair-skinned patients who were on short-term ventilator support. The small sample size and the fact that the sample was all fair-skinned, reduces the ability to generalize to a larger population of patients on ventilator support.

Correlation coefficients reported in this research could have been artificially reduced, because of the restriction in the range of oxygen saturation. The restriction in the range of oxygen saturation was from 92% to 100% in the present study, whereas the theoretical range of oxygen saturation is from 0% to 100%. Cohen and Cohen (1983) state that when the relationship between variables is homoscedastic, little change will be observed in the correlation coefficient. Because the correlations in this study, generally, were strong, range reduction was not believed to be a serious problem.

Implications for Nursing Practice

The purpose of this discussion is to elaborate the findings of the research in terms of clinical nursing practice. It is imperative for nurses to have accurate and precise, up-to-the-minute data about the oxygen state of a patient during ventilator weaning. Without these data patients are continually at risk for respiratory decompensation and compromise during a time in which additional stress on their body systems is intolerable.
The use of pulse oximetry has become a standard of care for patients receiving ventilator support after surgery. The need for accurate monitoring of critically ill patients (i.e., SpO₂ data) during ventilator weaning was first identified by critical care nurses as a priority patient care problem. Current monitoring practices of nurses during ventilator weaning are not standardized, e.g., they lack empirically based research data upon which to standardized monitoring practices. The purpose of this study was to begin the process of evaluating the accuracy of pulse oximetry with the ultimate long-term goal being that of establishing safe monitoring protocols for weaning ventilator supported patients.

Although the findings of this study suggest that pulse oximeter data are accurate when compared with data from an arterial blood gas analyzer, it is not recommended that nurses abandon the practice of performing arterial blood gases to verify SpO₂ measurements obtained from a pulse oximeter. Data obtained from pulse oximetry are limited in that they only provide information about oxygenation, whereas arterial blood gas data give insight into oxygenation and ventilation status. Data on both oxygenation and ventilation are vital for nurses to safely treat critically ill patients. At the present time, the nurse is the person best able to judge the patient's status and, therefore, the best person to determine when ABGs are needed. Continuous real-time pulse oximetry is beneficial for predicting trends in arterial oxygenation during ventilator weaning. However, its value in predicting cardio-respiratory instability and response to ventilator therapy is doubtful. Because
of the shape of the oxyhemoglobin dissociation curve, wide fluctuations in levels of P0₂ are not reflected by corresponding changes in Sp0₂.

**Recommendations for Further Research**

Several future studies have been identified that will give added information about the accuracy and use of pulse oximetry during ventilator weaning. They are as follows:

1. develop guidelines for nurses to use that suggest under the precise patient conditions that warrant ABGs during ventilator weaning. These guidelines would include how Sp0₂ should be used in conjunction with arterial blood gas data;

2. evaluate the magnitude of measurement error of the pulse oximeter related to skin pigment. A quantified measure of skin pigment is needed first, then the present study should be repeated using different groups of participants with different degrees of skin pigments. This would lead to improved accuracy in pulse oximetry for people of color; it may be necessary to alter calibration curves and algorithms used to determine oxygen saturation for those individuals with skin pigments other than White;

3. repeat the present study collecting a larger sample size possibly using multiple hospital sites, to evaluate if the degree of agreement and correlation coefficients remain unaltered. Several different data collectors and several different instrument set-ups would increase the reliability of the results because bias
(associated with one investigator) would be eliminated in a repeat study.

4. repeat this study using different types of patients on ventilator support (not just OHS patients) in order to make the findings more generalizable. Examples of patients might be SICU patients on a ventilator with: traumatic injury, pulmonary and renal disease, multiple body system failures, and those on long-term ventilator support.

5. measure pain in order to evaluate its impact on SpO2, SaO2-abg, SaO2-co, pH, Po2, Pco2 during ventilator weaning.

Summary

In conclusion, the results of this study indicate that it is acceptable to use pulse oximetry measures of oxygen saturation in lieu of arterial blood gas measures during ventilator weaning. However, it is not recommended that pulse oximetry data be used without intermittent arterial blood gas analyses, as wide fluctuations in Po2 can occur without corresponding changes in SpO2.
APPENDIX A

ACCURACY AND PRECISION OF THE ABL3
SECTION 12
SPECIFIC PERFORMANCE CHARACTERISTICS

12.1 BACKGROUND

Since there exist no well-defined reference methods within the field of blood gas determination, Radio-
meter A/S has taken measures to define reference methods for the
determination of pH and the partial
pressure of CO₂ (PCO₂) and O₂ (PO₂) in blood. These reference
methods are defined below.

Evaluation of the performance character-
istics requires that a number
of measurements be performed on a
group of instruments. Results ob-
tained on these test instruments
are compared with the values fur-
nished by the specified reference
method.

In describing the performance char-
acteristics, two types of specifica-
tions are distinguished: Inac-
curacy and imprecision.

The inaccuracy specifications are
based on the following conditions:
- ambient temperature 25°C
- humidity 50%
- barometric pressure 760 mmHg

12.2 REFERENCE METHODS

Verification of claims stated for
Radiometer pH/Blood Gas Instruments
on pH, PCO₂, PO₂ and hemoglobin
concentration is established ac-
cording to the reference methods
defined below:

PH

The reference method is based on a
PH measuring system comprising:
- a thermostatted (37°C, S.D. = 0.02°C) capillary-type pH glass
electrode
- a thermostatted saturated calo-
mel electrode
- a thermostatted liquid junction
containing saturated KCl solution
- a thermostatted water bath main-
tained at 37°C (SD = 0.02°C)
- a three-decimal pH meter

Calibration is carried out using
RADIOMETER S1500 and S1510 PRECI-
SION BUFFER SOLUTIONS which have
been checked by comparison with two
other buffer solutions prepared
according to the same formulas. The
pH of each solution was determined
using a hydrogen electrode system
as described by Durst (22).

PCO₂ and PO₂

Reference material was obtained by
equilibrating blood samples in a
bubble tonometer at 37.0°C (S.D. = 0.02°C) with analyzed gas mixtures
containing CO₂, O₂ and nitrogen.
The Pco₂ and P0₂ of the gas mixtures used are calculated from the equation:

\[
\frac{B - P_{H_2O}}{P_i} = \frac{100 \times i}{100}
\]

where B is the barometric pressure, \( P_{H_2O} \) is the vapour pressure of water at 37°C, and i is the vol. % of CO₂ and O₂ respectively in the gas mixture.

The percentage by volume of CO₂ in the gas mixture used is determined by means of a Pco₂ electrode system calibrated with gravimetrically produced gas mixtures.

Subsequently, the percentage by volume of CO₂ in the gravimetrically produced gas mixtures is checked with the same Pco₂ electrode system now calibrated with gas mixtures obtained from the National Bureau of Standards, Washington D.C. (NBS).

The percentage by volume of O₂ in the gas mixtures used is determined by means of a P0₂ electrode system calibrated with pure oxygen, atmospheric air, and pure argon.

Hemoglobin

Hb is determined with an OSM2 HEMOXIMETER® (Radiometer A/S) calibrated by means of blood samples whose Hb has been analyzed according to the cyanmethemoglobin method.

In the cyanmethemoglobin method, Hb is calculated from the absorbance, A, measured at 540 nm using a 1 cm light path cuvette:

\[
Hb = A \times 36.8 \text{ g/100 ml}
\]

Barometric pressure

The barometric pressure is read on a mercury barometer. The reading is corrected to the standard conditions: 0°C and gravity = 980.665 cm/sec².

Temperature

The temperature is measured with a mercury thermometer and an electronic thermistor which have been calibrated using Radiometer's reference methods which are traceable to the NBS.

Blood Samples

Heparinized blood samples for the tonometry and succeeding measurements were obtained from healthy voluntary donors at the University Hospital of Copenhagen.

Blood samples were introduced into the ABL3 from 125 ul capillaries or from iced glass syringes.

Gas Samples

Gas samples were directly introduced into ABL3 from a 2.5 l gas bottle at a flow rate of 30 ml/min.

12.3 DEFINITIONS

Inaccuracy

The inaccuracy of a quantity determined on the ABL3 is defined as the mean difference between the measured value on a group of test instruments and the estimated true value (as assayed by the reference method):

\[
\text{Inaccuracy} = X_{ABL3} - X_{REF}
\]
Specific Performance Characteristics

As the inaccuracy may depend on the level of the measured quantity, the interval investigated is specified.

Imprecision

Repeated measurements on presumably identical samples, using a number of instruments, will not yield identical results. The variability of the results may be influenced by the following factors:

- instrument
- time
- environment (temperature, humidity, air, pollution, etc.)

The variability will be greater when the measurements have been performed over several days and/or with different instruments than when they have been carried out within a short interval of time using the same instrument.

The following measures of variability (standard deviations) are useful in characterizing the distribution of results.

Repeatability, \( S_0 \):

The repeatability is the standard deviation obtained from repeated measurements within a short interval of time using the same sample and the same instrument.

\( S_0 \), for each level, is pooled for all test instruments and test days.

Day-to-day variation, \( S_D \):

The day-to-day variation (standard deviation) is obtained from successive determinations over all test days. The day-to-day variation then includes contributions from differences in state of calibration of the instruments and the sample variations throughout the test days.

Uncertainty of inaccuracy on a random ABL3, \( S_{ABL3} \):

\( S_{ABL3} \) includes the inter-instrument variations and uncertainties from standard solutions and reference methods.

Uncertainty of inaccuracy on a random ABL3 for a single measurement, \( S_X \):

\( S_X \) (standard deviation) includes the \( S_{ABL3} \), \( S_D \) and \( S_0 \).

12.4 Specifications

The specifications are based on data obtained from ten ABL3s.

Experimental Conditions:

- ambient temperature 24.2°C (S.D. = 1.6°C)
- humidity 34% (S.D. = 7.4%)
- barometric pressure 757.2 mmHg (S.D. = 9.8 mmHg)
Inaccuracy and imprecision

Specifications: pH/blood

<table>
<thead>
<tr>
<th>pH level</th>
<th>Inaccuracy pH (ABL3) minus pH (ref)</th>
<th>Repeatability</th>
<th>Day-to-day variation</th>
<th>Uncertainty of inaccuracy on a random ABL3</th>
<th>Uncertainty of inaccuracy on a single measurement</th>
<th>Verified by number of measurements</th>
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### Inaccuracy and imprecision

#### Specifications: ch/blood

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<th>Day-to-day variation</th>
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### Inaccuracy and imprecision

#### Specifications: \( P_{CO_2}/blood \)

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<th>Day-to-day variation</th>
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<th>Uncertainty of inaccuracy on a random ABL3 for a single measurement</th>
<th>Verified by number of measurements</th>
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### Specifications: $\text{PCO}_2$/blood

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<th>Inaccuracy $\text{PCO}_2$ (ABL3) minus $\text{PCO}_2$ (ref)</th>
<th>Repeatability</th>
<th>Day-to-day variation</th>
<th>Uncertainty of inaccuracy on a random ABL3</th>
<th>Uncertainty of inaccuracy on a random ABL3 for a single measurement</th>
<th>Verified by number of measurements</th>
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<td>$S_D$ kPa</td>
<td>$S_{ABL3}$ kPa</td>
<td>$S_X$ kPa</td>
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## Inaccuracy and Imprecision

### Specifications: $P_{co2}/gas$

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<th>Uncertainty of inaccuracy on a random ABL3 $S_{ABL3}$ mmHg</th>
<th>Uncertainty of inaccuracy on a random ABL3 for a single measurement $S_x$ mmHg</th>
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### Specifications: $P_{CO_2}/gas$

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<th>Repeatability ($S_0$)</th>
<th>Day-to-day variation ($S_D$)</th>
<th>Uncertainty of inaccuracy on a random ABL3 ($S_{ABL3}$)</th>
<th>Uncertainty of inaccuracy on a random ABL3 for a single measurement ($S_x$)</th>
<th>Verified by number of measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
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<td>0.03</td>
<td>0.03</td>
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</tr>
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<td>0.04</td>
<td>0.04</td>
<td>0.07</td>
<td>100</td>
</tr>
<tr>
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<td>0.05</td>
<td>0.05</td>
<td>0.07</td>
<td>0.11</td>
<td>90</td>
</tr>
<tr>
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<td>0.05</td>
<td>0.07</td>
<td>0.07</td>
<td>0.11</td>
<td>95</td>
</tr>
<tr>
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<td>0.07</td>
<td>0.07</td>
<td>0.08</td>
<td>0.13</td>
<td>95</td>
</tr>
<tr>
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<td>-0.03</td>
<td>0.08</td>
<td>0.08</td>
<td>0.12</td>
<td>0.17</td>
<td>100</td>
</tr>
<tr>
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<td>-0.05</td>
<td>0.09</td>
<td>0.11</td>
<td>0.15</td>
<td>0.20</td>
<td>95</td>
</tr>
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<td>0.13</td>
<td>0.21</td>
<td>0.27</td>
<td>0.37</td>
<td>90</td>
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</table>
Inaccuracy and imprecision

<table>
<thead>
<tr>
<th>Po₂ level</th>
<th>Inaccuracy</th>
<th>Repeatability</th>
<th>Day-to-day variation</th>
<th>Uncertainty of inaccuracy on a random ABL3</th>
<th>Uncertainty of inaccuracy on a random ABL3 for a single measurement</th>
<th>Verified by number of measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>mmHg</td>
<td>Po₂ (ABL3) minus Po₂ (ref)</td>
<td>Ase.</td>
<td>Inject.</td>
<td>S₀</td>
<td>Sₚ</td>
<td>SABL3</td>
</tr>
<tr>
<td>15</td>
<td>0.1</td>
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<td>0.8</td>
<td>1.5</td>
<td>1.0</td>
<td>2.0</td>
</tr>
<tr>
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<td>0.1</td>
<td>0.1</td>
<td>0.7</td>
<td>1.4</td>
<td>1.2</td>
<td>2.0</td>
</tr>
<tr>
<td>75</td>
<td>0.6</td>
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<td>0.7</td>
<td>1.4</td>
<td>1.2</td>
<td>2.0</td>
</tr>
<tr>
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</tr>
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<td>0.5</td>
<td>2.6</td>
</tr>
<tr>
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<td>0.9</td>
<td>0.7</td>
<td>2.3</td>
<td>0.7</td>
<td>2.6</td>
</tr>
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<td>1.9</td>
<td>0.7</td>
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<td>3</td>
<td>2</td>
<td>4</td>
</tr>
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<td>8</td>
</tr>
<tr>
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<td>0.7</td>
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<td>10</td>
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<tr>
<td>550</td>
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### Inaccuracy and imprecision

**Specifications: \(\text{PO}_2/\text{blood}\)**

<table>
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<tr>
<th>PO(_2) level</th>
<th>Inaccuracy (\text{PO}_2) (ABL3) minus (\text{PO}_2) (ref)</th>
<th>Repeatability</th>
<th>Day-to-day variation</th>
<th>Uncertainty of inaccuracy on a random ABL3</th>
<th>Uncertainty of inaccuracy on a single measurement</th>
<th>Verified by number of measurements</th>
</tr>
</thead>
<tbody>
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<td>kPa</td>
<td>Asp. kPa</td>
<td>Inject. kPa</td>
<td>(S_o) kPa</td>
<td>(S_d) kPa</td>
<td>(S_{ABL3}) kPa</td>
<td>(S_x) kPa</td>
</tr>
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<td>2.0</td>
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<td>0.11</td>
<td>0.20</td>
<td>0.13</td>
<td>0.27</td>
</tr>
<tr>
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<td>0.01</td>
<td>0.01</td>
<td>0.09</td>
<td>0.19</td>
<td>0.16</td>
<td>0.27</td>
</tr>
<tr>
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<td>0.19</td>
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<td>0.27</td>
</tr>
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</tr>
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<td>0.07</td>
<td>0.35</td>
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<td>0.31</td>
<td>0.09</td>
<td>0.35</td>
</tr>
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<td>0.25</td>
<td>0.09</td>
<td>0.36</td>
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<tr>
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</tr>
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<td>0.53</td>
<td>0.80</td>
<td>1.07</td>
</tr>
<tr>
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<td>0.09</td>
<td>0.53</td>
<td>0.67</td>
<td>1.07</td>
<td>1.33</td>
</tr>
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<td>0.12</td>
<td>0.80</td>
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<td>2.00</td>
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</table>
### Inaccuracy and Imprecision

#### Specifications: PO₂/gas

<table>
<thead>
<tr>
<th>PO₂ level</th>
<th>Inaccuracy PO₂ (ABL3) minus PO₂ (ref)</th>
<th>Repeatability</th>
<th>Day-to-day variation</th>
<th>Uncertainty of inaccuracy on a random ABL3 for a single measurement</th>
<th>Verified by number of measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td>mmHg</td>
<td>mmHg</td>
<td>mmHg</td>
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</tr>
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</tr>
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</tr>
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<td>5</td>
<td>7</td>
</tr>
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<td>8</td>
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</tr>
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<td>10</td>
<td>10</td>
<td>15</td>
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### Inaccuracy and imprecision

#### Specifications: $P_{O_2}$/gas

<table>
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<tr>
<th>$P_{O_2}$ level (kPa)</th>
<th>Inaccuracy $P_{O_2}$ (ABL3) minus $P_{O_2}$ (ref) (kPa)</th>
<th>Repeatability $S_o$ (kPa)</th>
<th>Day-to-day variation $S_d$ (kPa)</th>
<th>Uncertainty of inaccuracy on a random ABL3 $S_{ABL3}$ (kPa)</th>
<th>Uncertainty of inaccuracy on a single measurement $S_x$ (kPa)</th>
<th>Verified by number of measurements</th>
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<td>100</td>
</tr>
<tr>
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<td>0.07</td>
<td>0.20</td>
<td>0.16</td>
<td>0.27</td>
<td>100</td>
</tr>
<tr>
<td>10.0</td>
<td>0.01</td>
<td>0.07</td>
<td>0.20</td>
<td>0.16</td>
<td>0.27</td>
<td>100</td>
</tr>
<tr>
<td>18.7</td>
<td>0.01</td>
<td>0.07</td>
<td>0.20</td>
<td>0.16</td>
<td>0.27</td>
<td>95</td>
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<td>0.20</td>
<td>0.20</td>
<td>0.27</td>
<td>100</td>
</tr>
<tr>
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<td>0.53</td>
<td>0.67</td>
<td>0.93</td>
<td>95</td>
</tr>
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<td>0.80</td>
<td>1.07</td>
<td>1.33</td>
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<td>1.33</td>
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</table>
### Inaccuracy and Imprecision

#### Hemoglobin Inaccuracy Repeatability

<table>
<thead>
<tr>
<th>Hemoglobin Range</th>
<th>Hb (ABL3) minus Hb (ref)</th>
<th>Repeatability</th>
<th>Day-to-day variation</th>
<th>Uncertainty of inaccuracy on a random ABL3</th>
<th>Uncertainty of inaccuracy on a single measurement</th>
<th>Verified by number of measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>$S_o$</td>
<td>$S_d$</td>
<td>$S_{ABL3}$</td>
<td>$S_x$</td>
<td></td>
</tr>
<tr>
<td>4-5</td>
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<td>0.4</td>
<td>0.2</td>
<td>0.5</td>
<td>60</td>
</tr>
<tr>
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<td>0.2</td>
<td>0.5</td>
<td>0.3</td>
<td>0.6</td>
<td>60</td>
</tr>
<tr>
<td>10-17</td>
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<td>0.5</td>
<td>0.3</td>
<td>0.6</td>
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</tr>
<tr>
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<td>0.2</td>
<td>0.6</td>
<td>0.3</td>
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<td>120</td>
</tr>
<tr>
<td>24-26</td>
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<td>0.2</td>
<td>0.7</td>
<td>0.4</td>
<td>0.8</td>
<td>105</td>
</tr>
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</table>

**Specifications: Hemoglobin**
### Inaccuracy and Imprecision

#### Specifications: Hemoglobin

<table>
<thead>
<tr>
<th>Hemoglobin Range mmol/l</th>
<th>Inaccuracy Hb (ABL3) minus Hb (ref)</th>
<th>Repeatability</th>
<th>Day-to-day variation</th>
<th>Uncertainty of inaccuracy on a random ABL3 for a single measurement</th>
<th>Verified by number of measurements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Asp. mmol/l</td>
<td>Inject. mmol/l</td>
<td>S_o mmol/l</td>
<td>S_d mol/l</td>
<td>S_ABL3 mmol/l</td>
</tr>
<tr>
<td>2-3</td>
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<td>-0.2</td>
<td>0.1</td>
<td>0.2</td>
<td>0.1</td>
</tr>
<tr>
<td>5-6</td>
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<td>-0.1</td>
<td>0.1</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>6-11</td>
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<td>-0.1</td>
<td>0.1</td>
<td>0.3</td>
<td>0.2</td>
</tr>
<tr>
<td>11-14</td>
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<td>0.0</td>
<td>0.1</td>
<td>0.4</td>
<td>0.2</td>
</tr>
<tr>
<td>15-16</td>
<td>0.0</td>
<td>-0.1</td>
<td>0.1</td>
<td>0.4</td>
<td>0.2</td>
</tr>
</tbody>
</table>
APPENDIX B

ACCURACY AND PRECISION OF THE OSM2
12. SPECIFIC PERFORMANCE CHARACTERISTICS

12.1 INTRODUCTION

Background

Evaluation of the performance characteristics requires that a number of measurements be performed on a group of instruments randomly selected from the production line. Results obtained on these test instruments are compared with the values furnished by the specified reference method. In describing the performance characteristics, two types of specifications are distinguished: Inaccuracy and imprecision.

Definitions

INACCURACY: The inaccuracy of a quantity determined on the OSM2 is defined as the mean difference between the measured value on a group of test instruments and the estimated true value (as measured by the reference method), e.g.:

\[ \text{Inaccuracy} = \text{COSAT(OSM2)} - \text{COSAT(REF)} \]

As the inaccuracy may depend on the level of the measured quantity, the level investigated must be specified (see Tables 12.1 and 12.2).

IMPRECISION: Repeated measurements on identical samples, using the same instrument, will not yield identical results. To characterize the distribution of results, the repeatability, \( S_0 \), is stated (standard deviation). To characterize the uncertainty of the inaccuracy, two types of standard deviations are stated:

\( S_y \): Uncertainty of inaccuracy on a random OSM2 when repeated measurements on one sample are performed (includes inter-instrument variation and uncertainties from the reference method).

\( S_x \): Uncertainty of inaccuracy on a random OSM2 for a single measurement (includes all known uncertainties).

All specifications are based on one standard deviation.
12.2 HEMOGLOBIN

Reference Method

Blood samples containing different levels of hemoglobin are obtained by mixing blood concentrate and plasma.

The samples are mixed with Drabkin's Solution (20 ul sample + 5 ml Drabkin's Solution). The samples are then analyzed for cyanmethemoglobin, HiCN, using a spectrophotometric method.

Spectrophotometer: Hitachi
Perkin-Elmer, model 139
Glass cuvette: 10 mm
Wavelength: 540 nm

Expressed in mmol/l and g%, respectively, ctHb is calculated from:

\[ \text{ctHb} = 22.8 \times A_{\text{HiCN}}^{540} \text{ mmol/l or} \]

\[ \text{ctHb} = 36.8 \times A_{\text{HiCN}}^{540} \text{ g%} \] (12.1) (12.2)

Repurified blood samples were obtained from healthy, voluntary, non-smoker donors at the University Hospital in Copenhagen.

Specifications

The following performance characteristics are based upon data obtained from five OSM2s from a production series.

These specifications have been established with both fully oxygenated and fully deoxygenated blood samples.

In addition, experiments with oxygen saturation values between 0 and 100 % have been carried out. The results are presented in table 12.5.

All OSM2s were completely calibrated as described in Section 5.6.
### SPECIFIC PERFORMANCE CHARACTERISTICS

<table>
<thead>
<tr>
<th>Hb level g%</th>
<th>Inaccuracy</th>
<th>$S_0$</th>
<th>$S_y$</th>
<th>$S_x$</th>
</tr>
</thead>
<tbody>
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<td>Aspiration</td>
<td></td>
<td></td>
</tr>
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<td>-0.4</td>
<td>0.3</td>
<td>0.1</td>
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<td>0.1</td>
</tr>
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<td>0.2</td>
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<td>0.2</td>
<td>0.4</td>
</tr>
</tbody>
</table>

**Table 12.1** Hemoglobin Performance Characteristics, conventional units.  
($O_2$SAT = 100% or 1.000 mol/mol)

<table>
<thead>
<tr>
<th>Hb level mmol/l</th>
<th>Inaccuracy</th>
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<th>$S_y$</th>
<th>$S_x$</th>
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</thead>
<tbody>
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<td>Aspiration</td>
<td></td>
<td></td>
</tr>
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<td>-0.3</td>
<td>0.2</td>
<td>0.1</td>
</tr>
<tr>
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<td>-0.1</td>
<td>0.1</td>
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</tr>
<tr>
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<td>0.2</td>
<td>0.0</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
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<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
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<td>-0.1</td>
<td>0.1</td>
<td>0.3</td>
</tr>
</tbody>
</table>

**Table 12.2** Hemoglobin Performance Characteristics, SI units.  
($O_2$SAT = 100% or 1.000 mol/mol)
### SPECIFIC PERFORMANCE CHARACTERISTICS

<table>
<thead>
<tr>
<th>Hb level (g%)</th>
<th>Inaccuracy</th>
<th>$S_0$</th>
<th>$S_y$</th>
<th>$S_x$</th>
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<td>Aspiration</td>
<td></td>
<td></td>
</tr>
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<tr>
<td>10.1</td>
<td>0.3</td>
<td>0.4</td>
<td>0.4</td>
<td>0.5</td>
</tr>
<tr>
<td>14.5</td>
<td>1.0</td>
<td>0.5</td>
<td>0.2</td>
<td>0.3</td>
</tr>
<tr>
<td>22.8</td>
<td>1.1</td>
<td>0.8</td>
<td>0.4</td>
<td>0.5</td>
</tr>
</tbody>
</table>

Table 12.3 Hemoglobin Performance Characteristics, conventional units.

\( O_2 \text{SAT} = 0\% \text{ or } 0.000 \text{ mol/mol} \)

<table>
<thead>
<tr>
<th>Hb level (mmol/l)</th>
<th>Inaccuracy</th>
<th>$S_0$</th>
<th>$S_y$</th>
<th>$S_x$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Injection</td>
<td>Aspiration</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3</td>
<td>-0.1</td>
<td>-0.6</td>
<td>0.7</td>
<td>0.2</td>
</tr>
<tr>
<td>6.3</td>
<td>0.2</td>
<td>0.3</td>
<td>0.3</td>
<td>0.3</td>
</tr>
<tr>
<td>9.0</td>
<td>0.6</td>
<td>0.3</td>
<td>0.1</td>
<td>0.2</td>
</tr>
<tr>
<td>14.1</td>
<td>0.7</td>
<td>0.5</td>
<td>0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Table 12.4 Hemoglobin Performance Characteristics, SI units.

\( O_2 \text{SAT} = 0\% \text{ or } 0.000 \text{ mol/mol} \)
SPECIFIC PERFORMANCE CHARACTERISTICS

<table>
<thead>
<tr>
<th>$O_2$ SAT level</th>
<th>Hb reading</th>
</tr>
</thead>
<tbody>
<tr>
<td>% mol/mol</td>
<td>g%</td>
</tr>
<tr>
<td>100</td>
<td>1.0</td>
</tr>
<tr>
<td>60</td>
<td>0.6</td>
</tr>
<tr>
<td>20</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Table 12.5 Hb-reading at different $O_2$ SAT levels.
(ctHb = 12.7 g% or 7.9 mmol/l)

12.3 CARBON MONOXIDE SATURATION

Reference Method

Blood samples containing different levels of carboxyhemoglobin are obtained by mixing blood containing no HbCO and blood containing 100% HbCO. The mixture is analyzed for HbCO using a spectrophotometric method.

Spectrophotometer
Hitachi
Perkin-Elmer, model 139
Glass cuvette: 0.1 mm
Wavelengths: 470 nm, 600 nm

Expressed in mol/mol, $x$HbCO is calculated from:

\[
x_{\text{HbCO}} = \frac{A_{470} \times 0.02272 - A_{600} \times 0.02172}{A_{470} \times 0.01588 + A_{600} \times 0.01692}
\]  \hspace{1cm} (12.3)

where $A_{470}$ and $A_{600}$ are the absorbances measured at 470 and 600 nm, respectively.

The constants used in the equation are calculated from measurements of blood samples with $x$HbCO = 0 and $x$HbCO = 1, respectively.

The method is a modified version of the method described by Bent Nørgaard-Pedersen, Ole Siggaard-Andersen and Jørgen Rem (ref. 2.)
Heparinized venous blood samples were obtained from healthy, voluntary non-smoker donors at the University Hospital in Copenhagen.

Specifications

The following performance characteristics are based upon data obtained from five aSM2s taken from a production series.

All aSM2s were completely calibrated as described in Section 6.6.

The blood samples for the HbCO measurements are deoxygenated using the D684-10-80 Blood Deoxygenation Kit.

The specifications are given in conventional units. To convert the "%" to "mol/mol", divide by 100.

<table>
<thead>
<tr>
<th>HbCO level</th>
<th>Inaccuracy</th>
<th>Repeatability</th>
<th>Uncertainty of OSM2 inaccuracy</th>
<th>Uncertainty of OSM2 inaccuracy for a single measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>$S_0$</td>
<td>$S_y$</td>
<td>$S_x$</td>
</tr>
<tr>
<td>3.5</td>
<td>-1.2</td>
<td>0.3</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>6.0</td>
<td>-1.1</td>
<td>0.3</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>8.5</td>
<td>-1.2</td>
<td>0.3</td>
<td>0.7</td>
<td>0.8</td>
</tr>
<tr>
<td>11.2</td>
<td>-2.0</td>
<td>0.5</td>
<td>0.8</td>
<td>1.0</td>
</tr>
<tr>
<td>13.5</td>
<td>+0.5</td>
<td>0.5</td>
<td>0.8</td>
<td>1.0</td>
</tr>
<tr>
<td>21.7</td>
<td>-1.0</td>
<td>0.7</td>
<td>0.9</td>
<td>1.1</td>
</tr>
<tr>
<td>45.3</td>
<td>-2.5</td>
<td>1.2</td>
<td>1.4</td>
<td>1.8</td>
</tr>
<tr>
<td>71.4</td>
<td>-2.5</td>
<td>1.6</td>
<td>2.3</td>
<td>2.8</td>
</tr>
<tr>
<td>85.0</td>
<td>-1.4</td>
<td>1.4</td>
<td>1.8</td>
<td>2.3</td>
</tr>
<tr>
<td>100.0</td>
<td>-1.4</td>
<td>1.0</td>
<td>1.6</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Table 12.6 HbCO Performance Characteristics.
12.4 OXYGEN SATURATION

Reference Method

Today, there is no universally adopted reference method for oxygen saturation measurements, and Radiometer has chosen not to establish its own reference method.

Therefore, the performance characteristics for oxygen saturation measurements do not include information on inaccuracy.

The repeatability, $S_0$, quoted in table 12.7 is defined as stated earlier (page 84).

In addition, another series of experiments has shown that for oxygen saturation values greatly differing from 100 % or zero, injection and aspiration of replicate samples yield different results, see table 12.8.

Specifications

Five instruments from a production series were used for the experiments together with blood samples of known saturation values (fully saturated and fully deoxygenated samples) and known hemoglobin values.

<table>
<thead>
<tr>
<th>Hb</th>
<th>$O_2$SAT = 100 %</th>
<th>$O_2$SAT = 0 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>g%</td>
<td>mmol/l</td>
<td>Average reading</td>
</tr>
<tr>
<td>----</td>
<td>--------</td>
<td>-----------------</td>
</tr>
<tr>
<td>5.4</td>
<td>3.3</td>
<td>99.5</td>
</tr>
<tr>
<td>10.1</td>
<td>6.3</td>
<td>98.4</td>
</tr>
<tr>
<td>14.1</td>
<td>9.0</td>
<td>100.2</td>
</tr>
<tr>
<td>22.8</td>
<td>14.1</td>
<td>98.9</td>
</tr>
<tr>
<td>31.0</td>
<td>19.2</td>
<td>99.6</td>
</tr>
</tbody>
</table>

Table 12.7 Oxygen Saturation Performance Characteristics.
The calibration point was 15 g% (or 9.3 mmol/l) hemoglobin. Average reading and repeatability are specified in %. To convert the "%" to "mol/mol", divide by 100.

<table>
<thead>
<tr>
<th>$O_2$SAT level</th>
<th>Injection-Aspiration</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>100</td>
<td>0.0</td>
</tr>
<tr>
<td>80</td>
<td>0.4</td>
</tr>
<tr>
<td>60</td>
<td>0.7</td>
</tr>
<tr>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Table 12.8 $O_2$SAT difference between injected and aspirated sample.
APPENDIX C

CALIBRATION OF THE ABL3
6.4 CALIBRATION PROCEDURE

6.4.1 Calibration

The calibration solutions are two different bicarbonate/phosphate solutions which are equilibrated with two different, known gas mixtures coming from the built-in gas mixer. The pH of each solution is dependent on the barometric pressure. The higher the barometric pressure, the more CO₂ is forced into the solution. The more CO₂ in the solution, the lower is the pH of the solution.

The exact values of the calibrating solutions are calculated by the computer using the barometric pressure, the gas percentages and the formulas described in the following section (6.4.2).

1-point calibrations are performed with the Red Calibrating Solution which initially flushes the measuring chamber three times before being used to determine the reference points of the pH and Pco₂ electrodes, the zero point of the Hb photometer and the sensitivity of the P0₂ electrode.

2-point calibrations begin with a 1-point calibration as described above. Subsequently, the measuring chamber is flushed five times with the Green Calibrating Solution before this is used to determine the sensitivity of the pH and the Pco₂ electrodes.

The P0₂ is not measured on the Green Calibrating Solution; instead, the P0₂ channel is zeroed electrically.

The time intervals between 1-point calibrations should be shorter than, or equal to, those selected for 2-point calibrations, because the reference points of the pH and Pco₂ electrodes are less stable than their sensitivity.

When a calibration is initiated, the test sequence number, time and date are shown on the CRT screen and printout. During the calibration, the values measured relative to the last calibration are displayed on the CRT to give the user a direct impression of the stability of the electrodes. When a calibration is terminated, the ABL3 automatically rinses itself and at the same time displays and prints out the values to which the electrodes have been corrected. Their drift since the last 1- and/or 2-point calibration is also shown and printed out.

Via the DIAGNOSTIC key on the keyboard, it is possible to obtain information about the status and the sensitivity of the electrodes. Status gives information about deviations from ideal conditions of the Hb, pH and Pco₂ channels. The values are based on the last calibration.

Sensitivity (or linearity) expresses how accurately the three electrodes measure compared with the calculated, theoretical values. Via the programme keys, it is possible to obtain a TEST PRINTOUT (see Programme Book). This printout allows the user to follow the electrode response and to check the calculations of the measured values.
It is recommended to let the ABL3 perform an automatic 2-point calibration every 4 hours and a 1-point calibration every 2 hours. Other intervals can be chosen for automatic 1- and 2-point calibrations by entering the programme "CAL FREQ" in the Programme Book. A 2-point calibration can be scheduled every 2, 4, 6 or 8 hours and a 1-point calibration every 1 or 2 hours. In addition, the exact time for a calibration can be chosen by the operator. The time for the next calibration is permanently displayed in the bottom right corner of the basic CRT screen. 1- and 2-point calibrations can also be called by activating the appropriate button (1 POINT CAL. or 2 POINT CAL.) on the keyboard.

When the power is switched on, the ABL3 enters into a start-up procedure during which a 2-point calibration is carried out. This first calibration differs from the subsequent 2-point calibrations in that it here is the status*) (i.e., reference points) and the sensitivity of the electrodes that are assessed, displayed and printed out, whereas normal 2-point calibrations show the calculated drift (if any) since the previous calibration. (See the illustrated example below.) To provide comparative data during the START UP CAL, a "previous calibration" is assumed to have been made with a standard electrode chain in a buffer with pH = 7.383, PC02 = 40 mmHg and electrode sensitivities of pH = 100%, PC02 = 100% and PO2 = 20 pA/mmHg.

*) See formulas 6.32 and 6.35
Once a start-up calibration has been approved (i.e., no question marks appear on the printout), measurements can be performed. The calibration values are those calculated by means of the formulas listed in Section 6.4.2. If question marks appear, a 2-point calibration must be called (see also Section 6.6 Troubleshooting).

Any automatic calibration can be interrupted by depressing the RINSE key. If no measurement is initiated within the next 2 minutes, a new calibration will be performed automatically. This feature makes a STAT analysis possible even when the ABL3 is calibrating.

Should errors occur during a calibration, they will be indicated on the screen, and question marks will appear on the printout. Further, the message "CALL DIAGNOSTIC" will be displayed. Additional information on the cause of error is then obtainable via the DIAGNOSTIC key on the keyboard (see Programme Book). If error warnings other than question marks should occur, please refer to Troubleshooting Section 6.6.

Since all electrodes are subject to drift if used for extended periods, it is necessary to calibrate them from time to time. If the electrodes are calibrated frequently with solutions of known pH, Pco2, and Po2 values, their tendency to drift will be effectively compensated, and this will result in higher reliability of the measurements.

In addition, the ABL3 has a new electrode monitoring feature. To assure optimal accuracy of the ABL3 during measurement and calibration, the pH, Pco2, and Po2 electrodes are monitored for their response. A stability criterion is used to monitor the pH electrode and stability and response criteria are used to monitor the Pco2 and Po2 electrodes. If a criterion is not satisfied, the ABL3 will respond with an error warning (i.e., UNSTABLE) in the DIAGNOSTIC programme.

The stability of the Po2 electrode is monitored by a periodic flush with low calibrating gas. This flush is performed every 6th minute and lasts 24 seconds. When a
calibration is completed and the rinse cycle starts, the first flush also starts. The P$_{O_2}$ value of the monitoring gas from this initial flush is assigned the arbitrary value 1.000 in the computer. To be accepted, the drift of the P$_{O_2}$ electrode during the subsequent flushes must not exceed this value by more than ±3% (0.970 to 1.030).

A flush programme following a sample measurement is initiated when the ABL3 is in the READY mode. The monitoring begins 3 minutes later to avoid any influence from the measured sample. If the drift exceeds 1.000 by more than ±3%, the warning "CALL DIAGNOSTIC" will appear on the screen and "1POINT CAL NEEDED" in DIAGNOSTIC, page 2.

6.4.2 Calibrating Formulas

The calibration procedure is entirely automatic, based on the following formulas in the computer memory:

**CALCULATED (CORRECTED) VALUES**

P$_{co_2}$ and P$_{O_2}$

\[
P_{co_2} = \frac{B - P_{H_2O}}{100} \times CO_2^2 \quad (6.1)
\]

\[
P_{O_2} = \frac{B - P_{H_2O}}{100} \times O_2^2 \quad (6.2)
\]

P$_{co_2}$ and P$_{O_2}$ are expressed in mmHg (conventional) or in kPa (SI) units, 1 mmHg = 0.1333 kPa.

See also section 6.2.1 and programme CAL GASES in the Programme Book.
**Instruments**

**pH - conventional units**

\[
pHR^* = 8.499 - 0.6965 \log \text{Pco}_2 \text{ (low)} \quad (6.3)
\]

\[
pHG^* = 7.814 - 0.5114 \log \text{Pco}_2 \text{ (high)} \quad (6.4)
\]

**pH - nmol/l (SI units)**

\[
\text{cHR} = 10^{-(pHR^* - 9)} \quad (6.5)
\]

\[
\text{cHG} = 10^{-(pHG^* - 9)} \quad (6.6)
\]

**Example:**

Let \( B = 760 \text{ mmHg} \), the calibrating solution's low \text{Pco}_2 = 40.0 \text{ mmHg} , its high \text{Pco}_2 = 80.0 \text{ mmHg} , its \text{Po}_2 = 140.9 \text{ mmHg} \) (if gas mixer percentages are 5.61% \text{CO}_2 and 11.22% \text{CO}_2).

The values for the \text{Red Calibrating Solution} (used for both 1- and 2-point calibrations) are then:

**\text{Pco}_2 (low) = 40.0 \text{ mmHg} \text{ (or 5.33 kPa)}**

**\text{Po}_2 = 140.9 \text{ mmHg} \text{ (or 18.78 kPa)}**

**\text{Hb} = 0.0 \text{ g/}l \text{ (or 0.0 nmol/l)} \text{ (the computer is preadjusted).}**

\[
pHR^* = 8.499 - 0.6965 \log 40
\]

\[
= 8.499 - 1.116
\]

\[
= 7.383
\]

or

\[
\text{cHR} = 10^{-(7.383 -9)}
\]

\[
= 10^{1.617}
\]

\[
= 41.4 \text{ nmol/l}
\]
The values for the Green Calibrating Solution (used only for 2-point calibrations) are then:

\[ P_{CO_2} \text{(high)} = 80.0 \text{ mmHg (or 10.66 kPa)} \]

\[ p_{HG}^* = 7.814 - 0.5114 \log 80 \]
\[ = 7.814 - 0.973 \]
\[ = 6.841 \]

or

\[ c_{RG} = 10^{-(6.841 - 9)} \]
\[ = 10^{2.159} \]
\[ = 144.2 \text{ nmol/l} \]

**SENSITIVITY**

**pH electrode**

The sensitivity, \( S \), of the pH electrode is calculated from the previous 2-point calibration as:

\[ S (%) = \frac{E_{pHR} - E_{pHG}}{61.5 (p_{HR} - p_{HG}^*)} \times 100 \]  \hspace{1cm} (6.7)

where

\( E_{pHR} \) = electrode chain potential (mV) in the red buffer with \( pH = p_{HR}^* \)

\( p_{HR}^* \) = calculated pH value in the red buffer

\( E_{pHG} \) = electrode chain potential (mV) in the green buffer with \( pH = p_{HG}^* \)

\( p_{HG}^* \) = calculated pH value in the green buffer

61.5 = theoretical electrode sensitivity at \( t = 37^\circ C \) divided by 100

\( S \) is expressed in % for both conventional and SI units.
**Pco₂ electrode**

The sensitivity, $S$, of the Pco₂ electrode is calculated from the previous 2-point calibration as:

$$S (\%) = \frac{\text{EPCO₂R} - \text{EPCO₂G}}{61.5 \times (\log \text{PCO₂G} - \log \text{PCO₂R}^*)} \times 100$$  \hspace{1cm} (6.8)

where

- EPCO₂R = electrode chain potential (mV) in the red buffer with Pco₂ = PCO₂R*
- PCO₂R* = calculated Pco₂ value (mmHg or kPa) in the red buffer
- EPCO₂G = electrode chain potential (mV) in the green buffer with Pco₂ = PCO₂G*
- PCO₂G* = calculated Pco₂ value (mmHg or kPa) in the green buffer

$S$ is expressed in % for both conventional and SI units.

**Po₂ electrode**

The sensitivity, $S$, of the Po₂ electrode is calculated from the previous 1- or 2-point calculation as:

$$S = \frac{\text{IPO₂R}}{\text{PO₂R}}$$  \hspace{1cm} (6.9)

where

- IPO₂R = electrode current (nA) in the red buffer with Po₂ = PO₂R*
- PO₂R* = calculated Po₂ value (mmHg or kPa) in the red buffer

$S$ is expressed in pA/mmHg (conventional) or in pA/kPa (SI) units, 1 mmHg = 0.1333 kPa.
**ELECTRODE DRIFT**

**pH electrode**

The electrode drift is defined as the difference between the pH value measured in the present calibrating solution and the calculated pH value.

Drift on **red** buffer:

\[ \Delta R = pH_R - pH_R^* \]  
(6.10)

Drift on **green** buffer:

\[ \Delta G = pH_G - pH_G^* \]  
(6.11)

where \( pH_R \) is calculated from formula (6.12) and \( pH_G \) from formula (6.13):

\[ pH_R = \frac{E_{pH_R} - E'_{pH_R}}{S'' \cdot 0.615} + pH'R^* \]  
(6.12)

\[ pH_G = \frac{E_{pH_G} - E'_{pH_R}}{S'' \cdot 0.615} + pH'R^* \]  
(6.13)

where

- \( pH_R \) = measured red pH value in the present 1- or 2-point calibration
- \( S'' \) = pH electrode sensitivity (%) from the previous 2-point calibration (see also formula 6.7)
- \( E'_pH_R \) = electrode chain potential from the previous 1- or 2-point calibration (mV), where \( pH = pH'R^* \) in the red calibrating solution
- \( pH'R^* \) = calculated red pH value from the previous 1- or 2-point calibration.

For definitions of \( pH'R^* \), \( pH_G^* \), \( E_{pH_R} \) and \( E_{pH_G} \), see under SENSITIVITY.
In SI units:

\[ \Delta R = 10^{-(\text{pHR} - 9)} - 10^{-(\text{pHR}^* - 9)} \text{ nmol/l} \]  
(6.14)

\[ \Delta G = 10^{-(\text{pHG} - 9)} - 10^{-(\text{pHG}^* - 9)} \text{ nmol/l} \]  
(6.15)

\[ c_{HR} = 10^{-(\text{pHR} - 9)} \text{ nmol/l} \]  
(6.16)

\[ c_{HG} = 10^{-(\text{pHG} - 9)} \text{ nmol/l} \]  
(6.17)

**PCO₂ electrode**

The electrode drift is defined as the difference between the PCO₂ value measured in the present calibrating solution and the calculated PCO₂ value.

Drift on red buffer:

\[ \Delta R = \text{PCO₂R} - \text{PCO₂R}^* \]  
(6.18)

Drift on green buffer:

\[ \Delta G = \text{PCO₂G} - \text{PCO₂G}^* \]  
(6.19)

where PCO₂R is calculated from formula (6.20) and PCO₂G from formula (6.22):

\[ \log \text{PCO₂R} = \frac{E'\text{PCO₂R} - E\text{PCO₂R}}{S} + 0.615 + \log \text{PCO₂'R}^* \]  
(6.20)

or

\[ \text{PCO₂R} = 10^{\log \text{PCO₂R}} \]  
(6.21)
Instruments

\[
\log PCO2G = \frac{E^'PCO2R - EPCO2G}{S'' \cdot 0.615} + \log PCO2'R^* \quad (6.22)
\]

or

\[
PCO2G = 10^{\log PCO2G} \quad (6.23)
\]

where

\[PCO2R\] = measured red \(PCO2\) value in the present 1- or 2-point calibration (mmHg or kPa)

\[S''\] = \(PCO2\) electrode sensitivity (%) from the previous 2-point calibration (see also formula 6.8)

\[E^'PCO2R\] = electrode chain potential from the previous 1- or 2-point calibration (mV), where \(PCO2 = PCO2'R^*\) in the red calibrating solution

\[PCO2'R^*\] = calculated red \(PCO2\) value from the previous 1- or 2-point calibration (mmHg or kPa)

For definitions of \(PCO2'R^*\), \(PCO2G\), \(EPCO2R\) and \(EPCO2G\), see under SENSITIVITY.

\(PCO2\) is expressed in mmHg (conventional) or in kPa (SI) units,

1 mmHg = 0.1333 kPa.

\(PCO2\) electrode

The electrode drift is defined as the difference between the \(PCO2\) value measured in the present calibrating solution and the calculated \(PCO2\) value.

Drift on red buffer:

\[
\Delta R = PO2R - PO2R^* \quad (6.24)
\]

where \(PO2R\) is calculated from the following formula:

\[
PO2R = \frac{IPO2R}{S''} \quad (6.25)
\]
where

\[
\text{PO2R} = \text{measured red } P_{O2} \text{ value in the present 1- or 2-point calibration (mmHg or kPa)}
\]

\[
\text{IPO2R} = \text{the electrode current (pA) in the present red calibrating solution}
\]

\[
S'' = P_{O2} \text{ electrode sensitivity (pA/mmHg or pA/kPa) from the previous 1- or 2-point calibration (see also formula 6.9).}
\]

\[P_{O2}\] is expressed in mmHg (conventional) or in kPa (SI) units,
\[1 \text{ mmHg} = 0.1333 \text{ kPa}.
\]

**STATUS** (i.e., reference values for Hb photometer and pH and \(P_{CO2}\) electrode)

**Hb-channel**

The Hb value is measured in every 1- and 2-point calibration.

\[
\text{Hb} = \frac{(S_w - 200)}{100} \quad (6.26)
\]

where \(S\) stands for signal from the Hb lamp and \(S_w = 200\) is factory preset.

Hb in every calibration is calculated as:

\[
(S_w - 200)/100 \text{ in g\%} \quad (6.27)
\]

\[
(S_w - 200)/100 \times 0.6206 \text{ in mmol/l} \quad (6.28)
\]

Hb is expressed in g\% (conventional) or in mmol/l (SI) units,
\[1 \text{ g\%} = 0.6206 \text{ mmol/l}.
\]
pH electrode

The status value of the pH electrode is calculated in the red buffer:

\[ \text{Ep}_{\text{HRo}} = \text{Ep}_{\text{HR}} + 61.5 \left( 7.383 - \text{pHR}' \right) \quad (6.31) \]

and

\[ \text{pH}_{\text{status}} = \frac{\text{Ep}_{\text{HRo}} - \text{E}^*_{\circ}}{100 \cdot 0.615} + 7.383 \quad (6.32) \]

where the electrode's sensitivity is assumed to be 100% and where

\[ \text{Ep}_{\text{HRo}} = \text{the electrode chain potential (mV) in a buffer with pH = 7.383} \]
\[ \text{Ep}_{\text{HR}} = \text{the electrode chain potential (mV) in red buffer during START UP CAL} \]
\[ \text{E}^*_{\circ} = \text{potential of a standard electrode chain (= 79.0 mV) in a buffer with pH = 7.383} \]

In SI units:

\[ \text{cH}_{\text{status}} = 10^{-(\text{pHR} - 9)} \text{nmol/l} \quad (6.33) \]

\text{pH}_{\text{status}} and \text{cH}_{\text{status}} are substantially independent of the barometric pressure.

Pco₂ electrode

The status value of the Pco₂ electrode is calculated in the buffer:

\[ \text{EPCO2R}_{o} = \text{EPCO2R} - 61.5 \left( \log 40 - \log \text{Pco2R}' \right) \quad (6.34) \]

\[ \log \text{Pco2}_{\text{status}} = \frac{\text{E}^*_{\circ} - \text{EPCO2R}_{o}}{100 \cdot 0.615} + \log 40 \quad (6.35) \]
\[ \text{PCO}_2\,\text{status} = 10^{\log \text{PCO}_2\,\text{status}} \] (6.36)

where the electrode's sensitivity is assumed to be 100% and where

\[
\begin{align*}
E^* & = \text{potential of a standard electrode (}= 53 \text{ mV}) \text{ in balance with} \\
& \quad \text{gas/liquid having a partial pressure of } 40 \text{ mmHg (or } 5.33 \text{ kPa)} \\
E_{\text{PCO}_2R_0} & = \text{the electrode chain potential (mV) in a buffer with } \text{PCO}_2 = 40 \text{ mmHg (or } 5.33 \text{ kPa)} \\
E_{\text{PCO}_2R} & = \text{the electrode chain potential (mV) in a buffer during START UP CAL} \\
\text{PCO}_2\,\text{status} & \text{ is substantially independent of the barometric pressure.}
\end{align*}
\]

\text{PCO}_2\,\text{status} \text{ is expressed in mmHg (conventional) or in kPa (SI units),} \\
1 \text{ mmHg} = 0.1333 \text{ kPa.}
APPENDIX D

CALIBRATION OF THE OSM2
6.6 CALIBRATION

6.6.1 Introduction

The OSM2 is calibrated against blood samples with known values of hemoglobin concentration and oxygen saturation. However, a water calibration - i.e., a zero-point adjustment - must be performed as the first step in the calibration procedure. Water is introduced as the sample and the OSM2 is switched to the WATER CALIBRATION mode. The display readings are then adjusted to zero, that is, the absorbances at 506.5 and 600.0 nm are set to zero. When the OSM2 is switched back to MEASURE, these absorbance signals are fed to the analogue computing circuit, which calculates the "unknowns" according to (4.8) and (4.9):

\[
\text{ctHb} = k_1 \times A_{506.5} = k_1 \times 0 = 0 \quad (4.8)
\]

\[
\text{O}_2\text{SAT} = k_2 - k_3 \times A_{600.0} = k_2 - k_3 \times 0 = ? \quad (4.9)
\]

Consequently, the hemoglobin display reads zero, while the oxygen saturation display may read anything.

The actual value of \( k_1 \) is fed to the analogue computing circuit when calibrating the hemoglobin channel. The hemoglobin concentration of the blood sample used for this calibration is determined by means of a separate spectrophotometer. This determination is based on the absorption of cyanmethemoglobin, HiCN, formed when mixing Drabkin's Solution and blood.

The actual values of \( k_2 \) and \( k_3 \) are fed to the analogue computing circuit, when calibrating the oxygen saturation channel. This calibration is a two-point adjustment:
A blood sample with $O_2\text{SAT} = 0.000 \text{ mol/mol}$ or 0.0 % is obtained by deoxygenation in accordance with eq. (4.11), page 15.

A blood sample with $O_2\text{SAT} = 1.000 \text{ mol/mol}$ or 100 % is obtained by swirling the blood sample in atmospheric air.

The blood calibrations are carried out with the OSM2 in the mode BLOOD CALIBRATION, using the adjustment knobs Hb STD., SAT=100 and SAT=0. During the SAT=0 and SAT=100 Blood Calibrations, it is recommended to use blood having a hemoglobin concentration which is within the range of normally expected values at the particular location. For details, see Section 12.1, page 84.

A calibration should be followed by a check of the hemoglobin channel by means of S2100 OSM2 Hemoglobin Check Solution. For details, please refer to page 71 f.

IMPORTANT: When performing a complete calibration of the OSM2
- always start with the zero-point adjustment
- always let the SAT=0 Blood Calibration precede the SAT=100 Blood Calibration.

6.6.2 Calibration Procedures

Fig. 6.3 Control Panel.
CAUTION: Do not leave the function selector knob (15) in a calibration position longer than necessary. The automatic rinsing procedure takes place only when the function selector knob is in position MEASURE.

Zero-point Adjustment

a) Make sure that the OSM2 has been properly conditioned (heating-up time: 10 minutes)

b) Check that the READY lamp is lit.

c) Turn the function selector knob (15) to position WATER CALIBRATION.

d) Draw distilled water into a syringe, open the inlet flap and inject until the READY lamp goes off. Remove the syringe and close the inlet flap.

e) After 15 seconds, check that the two display readings are zero. Any required zero-adjustment should be performed within the next 15 seconds. Use the Hb=0 and SAT=0 WATER CALIBRATION knobs for the adjustment.

f) Turn the function selector knob to position MEASURE, thereby starting the rinse programme.

g) Wait for the READY lamp to light and then repeat steps (c) to (f). At step (e), check that the display readings are within the limits:

- Hemoglobin $0 \pm 0.1$ mmol/l or g%
- $O_2$ SATURATION and HbCO: $0.000 \pm 0.001$ mol/mol or $0.0 \pm 0.1$ %

If agreement is not obtained, repeat steps (c) to (f) until agreement is obtained.
Fig. 6.8 CALIBRATION SCHEME

### Once a Day:

**Zero-point Adjustment:**
- **Materials**
  - Deionized water
  - Glass syringe

### Every Three Months¹:

**Hemoglobin Blood Calibration:**
- **Materials**
  - Spectrophotometer + 4 glass cuvettes
  - Constriction pipette, 20 ul
  - Pipette, 5 ml
  - 3 test tubes, 10-25 ml
  - Drabkin's Solution
  - 5 ml whole blood + anticoagulant
- **Remarks**
  - Wavelength: 540 nm
  - Lightpath: 10 mm
  - Preparation, see Section 5, page 20.
  - Blood from a healthy adult non-smoker. Anticoagulant, see Section 7, page 61.
  - Capillary, Type D551-7.5-60.

---

¹ If it has been decided to change from whole blood to blood concentrate (or vice versa) as the sample medium, SAT-0 and SAT-100 Blood (Re-) Calibrations are required. However, it is not required to (re-)calibrate the hemoglobin channel, due to its high linearity. The linearity can be verified using the S2100 OSM2 Hemoglobin Check Solutions.
### SAT-0 Blood Calibration, Methods I and II:

<table>
<thead>
<tr>
<th>Materials</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood deoxygenation kit</td>
<td>Type D684-10-80</td>
</tr>
<tr>
<td>5 ml whole blood + anticoagulant</td>
<td>Blood from a healthy adult non-smoker. Anticoagulant, see page 61.</td>
</tr>
<tr>
<td>Haematocrit centrifuge</td>
<td>For calibration on blood concentrate only.</td>
</tr>
</tbody>
</table>

### SAT-0 Blood Calibration, Methods III and IV:

<table>
<thead>
<tr>
<th>Materials</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium dithionite, TRIS-buffer, water, beaker</td>
<td>The reduction liquid must be freshly prepared.</td>
</tr>
<tr>
<td>Glass syringe, 2 ml</td>
<td>Blood from a healthy adult non-smoker. Anticoagulant, see page 61.</td>
</tr>
<tr>
<td>5 ml whole blood + anticoagulant</td>
<td></td>
</tr>
<tr>
<td>Laboratory balance</td>
<td>For calibration on blood concentrate only.</td>
</tr>
<tr>
<td>End-cap or rubber stopper for syringe</td>
<td></td>
</tr>
<tr>
<td>Tubing fitted for syringe needle</td>
<td></td>
</tr>
<tr>
<td>Glass pellet fitting the syringe</td>
<td></td>
</tr>
<tr>
<td>D551-7.5-60 Capillary tubes</td>
<td></td>
</tr>
<tr>
<td>Haematocrit centrifuge</td>
<td></td>
</tr>
</tbody>
</table>

### SAT-100 Blood Calibration:

<table>
<thead>
<tr>
<th>Materials</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test tube, 10-25 ml</td>
<td>Blood from a healthy adult non-smoker. Anticoagulant, see page 61.</td>
</tr>
<tr>
<td>500-600 ul whole blood + anticoagulant</td>
<td>For calibration on blood concentrate only.</td>
</tr>
<tr>
<td>D551-7.5-60 Capillary tubes</td>
<td></td>
</tr>
<tr>
<td>Haematocrit centrifuge</td>
<td></td>
</tr>
</tbody>
</table>
Hemoglobin Blood Calibration

a) Collect the items needed (see Fig. 6.8, page 42). In particular, make sure that a suitable anticoagulant has been added to the blood sample.

b) Perform a zero-point adjustment, if not already done.

c) Pipette 5 ml Drabkin's Solution into each of the 3 test tubes.

d) Pipette 20 ul whole blood (well mixed with anticoagulant) into each of the 3 test tubes and mix well. Store the remaining blood for later use.

e) Wait 4 minutes in order to obtain a complete conversion of the hemoglobin pigments into cyanmethemoglobin, HICN. While waiting, carry out step (f).

f) Use one of the glass cuvettes for a blank solution: Pipette Drabkin's Solution (no blood) into the cuvette and zero the photometer against this sample, temperature 20°C.

g) When ready, transfer Drabkin's Solution-blood mixtures to the 3 glass cuvettes.

h) Measure the absorbances, $A_{540}^{\text{HICN}}$ (approx. 0.4). Check that the results are in good accordance with each other - max. deviation: approx. 0.008.

i) Calculate the mean absorbance, $A_{540}^{\text{HICN}}$, and the hemoglobin concentration:

$$c\text{Tb} = 22.8 \times A_{540}^{\text{HICN}} \text{ mmol/l or}$$

$$c\text{Tb} = 36.8 \times A_{540}^{\text{HICN}} \text{ g/l}$$

j) From the same blood sample as was used in step (d), draw a sample into a glass syringe or a capillary tube.

k) Check that the OSM2's READY lamp is lit.

l) Turn the function selector knob (15) to position BLOOD CALIBRATION.

m) Open the inlet flap and introduce blood (by injection or aspiration) until the READY lamp goes off. Close the inlet flap.

n) Wait 15 seconds and then, within the next 15 seconds, adjust the HEMOGLOBIN display to the value calculated in step (i), using the Hb STD. adjustment knob (12).
o) Set the function selector knob to position MEASURE, and wait for the READY lamp to go on.

p) Repeat steps (j) to (o) once. At step (n), check that the HEMOGLOBIN reading is within \( \pm 0.2 \text{ mmol/l} \) or g\% of the adjustment value. If agreement is not obtained, repeat steps (j) to (o) once more. (If agreement is still not obtained, please consult Section 6.8 Troubleshooting, page 54.)

SAT-O Blood Calibration

A fully reduced blood sample, i.e., containing no oxyhemoglobin, can be prepared by one of four methods. The methods are characterized as outlined in Fig. 6.9.

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Whole blood + D683-10-80 Deoxygenation Tubes</td>
</tr>
<tr>
<td>II</td>
<td>Blood concentrate + D683-10-80 Deoxygenation Tubes</td>
</tr>
<tr>
<td>III</td>
<td>Whole blood + reduction liquid</td>
</tr>
<tr>
<td>IV</td>
<td>Blood concentrate + reduction liquid</td>
</tr>
</tbody>
</table>

Fig. 6.9 Fully Reduced Blood for SAT-O Blood Calibration.

The methods of preparation are outlined below. Radiometer recommends Method I or II since these methods are fairly simple and much less time-consuming than Methods III and IV. Whole blood calibrations are the basis for whole blood measurements, and likewise, blood concentrate calibrations are the basis for blood concentrate measurements.

The instructions in the following will include a number of directions for preparing the capillary tubes (e.g., cutting off one or both seals, removing the plasma phase or stirrer, etc.) which may cause the operator to forget at which end of the tube the bubble-free, uncontaminated sample is ultimately located. Since it is imperative that the OSM2 be fed a "pure" sample, it is urged that he should attempt to retain a mental image of its location in the capillary throughout all stages of the procedure.
SAT-O Blood Calibration
(including sample preparation I and II)

a) Collect the items needed (see Fig. 6.8, page 42). In particular, make sure that a suitable anticoagulant has been added to the blood sample, and that blood and anticoagulant are well mixed.

b) Perform a zero-point adjustment, if not already done.

c) Cut off both ends of a D683-10-80 Deoxygenation Capillary Tube (942-818) by means of a D572 Glass Cutter (922-255). Use the 920-616 Cutting Device as a support.

d) Fill the tube completely with blood. Filling by capillary action is accomplished when the tube is held in a nearly horizontal position.

e) Keep the tube in a horizontal position and seal one end with D553 Sealing Wax (943-800).

f) Insert a short steel wire (960-217) into the tube.

g) Seal the other end of the tube with sealing wax. Then turn the tube to a vertical position.

**IMPORTANT:** The blood sample may contain air bubbles which can give rise to erroneous measurements. However, holding the tube vertically, as instructed above, causes the bubbles to collect at the top end of the tube, and a bubble-free sample can then be transferred to OSM2 from the opposite end.

h) Still holding the tube in a vertical position, move the wire up and down for 30 seconds with the D571 Magnet (912-031). In order to obtain adequate mixing and quantitative deoxygenation, it is necessary to move the wire the full length of the tube.

i) Prepare some more (e.g., 3) fully reduced blood samples as outlined above.

Whole blood calibration: proceed from step (k).

Blood concentrate calibration: proceed from step (j).

j) Cut off the top end of the capillary tubes, remove the wire by means of the magnet and place the tubes in a haematocrit centrifuge (13,000 r.p.m.) with the bubble-free end downwards. Let the centrifuge work for 3 minutes.
INSTRUMENT

k) Check that OSM2's READY lamp is lit.

l) Turn the function selector knob (15) to position BLOOD CALIBRATION.

m) Whole blood calibration: Score and break off the sealed ends of one of the tubes, using a glass cutter and the cutting device. Then remove the wire by means of the magnet.

Blood concentrate calibration: Cut off both ends of one of the tubes to remove the seal and the plasma phase respectively.

n) Transfer the deoxygenated blood sample to the OSM2 from the bubble-free end of the capillary tube by placing this end over the inlet stub of the OSM2 and pressing the ASPIRATE button until the READY lamp goes off. Close the inlet flap.

o) After approx. 15 seconds and within 30 seconds, adjust the oxygen saturation display to 0.000 mol/mol or 0.0% by means of the Blood Calibration SAT-O adjustment knob.

p) Turn the function selector knob to MEASURE and wait until the READY lamp goes on.

q) Repeat steps (l) to (p) three times, using the reduced blood samples already prepared. Check that the readings of the oxygen saturation display are within the limits 0.000 ± 0.002 mol/mol or 0.0 ± 0.2%. If these tolerances are not obtained, please refer to Section 6.8 Troubleshooting, page 54.

SAT-O Blood Calibration
(including sample preparation III and IV)

a) Collect the items needed (see Fig. 6.8, page 43). In particular, make sure that a suitable anticoagulant has been added to the blood sample, and that blood and anticoagulant are well mixed.

b) By gravitation, let the blood cells concentrate at the bottom of the test tube containing the blood sample.

c) Perform a zero-point adjustment of the OSM2, if not already done.

d) Withdraw the plunger from the syringe, insert the glass pellet in the syringe barrel and remount the plunger.

e) Mount a length of tubing on the syringe needle.

f) Immerse the tubing into the blood concentrate and aspirate 1 ml into the syringe. Remove the tubing.
g) Prepare the reduction liquid:

62 mg sodium dithionite (Na₂S₂O₄) +
44 mg trishydroxymethylaminomethane (TRIS-buffer, C₄H₁₁NO₃) +
5 ml distilled water.

Transfer the sodium dithionite and the TRIS-buffer to a beaker, add the water and mix by swirling. As soon as the crystals are dissolved, proceed from step (h).

h) Aspirate 1 ml of the reduction liquid into the syringe.

i) Expel any air bubbles and seal the syringe. For sealing, use either a rubber stopper on the needle or an end cap on the syringe needle hub.

j) Hold the syringe in a horizontal position, and roll it between your hands for 8 minutes.

k) Prepare the syringe for injection. Discard the first few drops of reduced blood.

Whole blood calibration: proceed from step (n).

Blood concentrate calibration: proceed from step (l).

l) Fill some capillary tubes (e.g., 4) completely with reduced blood from the syringe and seal them anaerobically at one end with D553 Sealing Wax (943-800).

m) Place the capillaries in a haematocrit centrifuge (13,000 r.p.m.) for 3 minutes with the sealed end downwards.

n) Check that OSM2's READY lamp is lit.

o) Turn the function selector knob (15) to position BLOOD CALIBRATION.

p) Transfer reduced blood to OSM2:

Whole blood calibration: Open the inlet flap, inject blood until the READY lamp goes off, and then close the flap.

Blood concentrate calibration: Cut off both ends of one of the capillary tubes to remove the seal and the plasma phase respectively. Open the inlet flap, let the OSM2 aspirate from the formerly sealed end until the READY lamp goes off, and then close the flap.

q) After approx. 15 seconds and within 30 seconds, adjust the oxygen saturation display to 0.000 mol/mol or 0.0% by means of the adjustment knob SAT=0 BLOOD CALIBRATION.
r) Turn the function selector knob to position MEASURE and wait until the READY lamp goes on.

s) Repeat steps (o) to (r) three times. (See step (t).)
   For whole blood calibration: Discard a little of the reduced blood prior to injection in OSM2.

t) Check that the readings of the oxygen saturation and HbCC display are within the limits 0.000 ± 0.002 mol/mol or 0.0 ± 0.2%. (If these tolerances cannot be obtained, please refer to Section 6.8 Troubleshooting, page 54.)

SAT=100 Blood Calibration

a) Collect the items needed (see Fig. 6.8., page 43). In particular, make sure that a suitable anticoagulant has been added to the blood and that blood and anticoagulant are well mixed.

b) Perform a SAT=0 Blood Calibration, if not already done.

c) Place the blood sample (500–600 ul) in the test tube. Tilt the tube, thereby giving the blood the largest possible surface area.

d) Roll the test tube between your horizontally held hands for 90 seconds, thereby oxygenating the blood.

e) Holding the test tube in an almost horizontal position, fill some capillary tubes with fully oxygenated blood:

   Whole blood calibration: Without sealing, fill one capillary tube and proceed to step (f).

   Blood concentrate calibration: Fill some capillary tubes (e.g., 4) and seal them at one end with D553 Sealing Wax (943-800). Place the capillary tubes in a haematocrit centrifuge (13,000 r.p.m.) for 3 minutes with the sealed end downwards.

f) Check that OSM2's READY lamp is lit.

g) Turn the function selector knob (15) to position BLOOD CALIBRATION.
h) Transfer a fully oxygenated sample to the OSM2:

Whole blood calibration: Open the inlet flap, let OSM2 aspirate sample until the READY lamp goes off, remove the capillary tube, and then close the flap.

Blood concentrate calibration: Cut off both ends of one of the capillary tubes to remove the seal and the plasma phase respectively. Open the inlet flap, let the OSM2 aspirate from the formerly sealed end until the READY lamp goes off, remove the capillary, and then close the inlet flap.

i) After 15 seconds and within 30 seconds, adjust the oxygen saturation display to 1.000 mol/mol or 100.0% by means of the adjustment knob SAT=100 BLOOD CALIBRATION.

j) Turn the function selector knob to position MEASURE and wait until the READY lamp goes on.

k) Repeat steps (g) to (j) two or three times:

Whole blood calibration: Fill a capillary tube and use this sample for the analysis.

Blood concentrate calibration: Use one of the already prepared samples (step (e)).

l) Check that the readings of the oxygen saturation display are within the limits 1.000 ± 0.002 mol/mol or 100.0 ± 0.2%.
11. EXPECTED VALUES

The following data on normal ranges are from the literature. The normal values are suggested guidelines only. The clinical laboratory is recommended to establish its own normal ranges.

**Total Hemoglobin Concentration (ref.7.)**

<table>
<thead>
<tr>
<th>(whole blood)</th>
<th>Range of variation (mmol/l)</th>
<th>Range of variation (g %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborn</td>
<td>8.7 – 14.9</td>
<td>14 – 24</td>
</tr>
<tr>
<td>Adults</td>
<td>7.4 – 11.2</td>
<td>12 – 18</td>
</tr>
</tbody>
</table>

**Oxygen Saturation (ref.1.)**

<table>
<thead>
<tr>
<th></th>
<th>Range (mol/mol)</th>
<th>Range (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults (arterial blood, 100 subjects, age 20 to 70 yrs)</td>
<td>0.919 – 0.985</td>
<td>91.9 – 98.5</td>
</tr>
<tr>
<td>Adults (capillary blood, 15 subjects, age 20 to 45 yrs)</td>
<td>0.940 – 0.992</td>
<td>94.0 – 99.2</td>
</tr>
<tr>
<td>Adults (capillary blood, 24 subjects, age 21 to 40 yrs)</td>
<td>0.938 – 0.974</td>
<td>93.8 – 97.4</td>
</tr>
<tr>
<td>Adults (capillary blood, 16 subjects, age 23 to 40 yrs)</td>
<td>0.934 – 0.978</td>
<td>93.4 – 97.8</td>
</tr>
</tbody>
</table>

**Carboxyhemoglobin Fraction, xHbCO (ref.2.)**

<table>
<thead>
<tr>
<th></th>
<th>Range (mol/mol)</th>
<th>Range (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premature infants (capillary blood, 12 subjects, age 24 to 72 hours)</td>
<td>0.013 – 0.045</td>
<td>1.3 – 4.5</td>
</tr>
<tr>
<td>Adults (capillary blood, non-smokers, 12 subjects)</td>
<td>0 – 0.009</td>
<td>0 – 0.9</td>
</tr>
<tr>
<td>Adults (capillary blood, smokers, 12 subjects)</td>
<td>0.013 – 0.078</td>
<td>1.3 – 7.8</td>
</tr>
</tbody>
</table>
APPENDIX E

PARTICIPANT CONSENT FORM
VALIDITY OF PULSE OXIMETRY DURING VENTILATOR WEANING OF ADULT SURGICAL PATIENTS

Principal Investigator: Rebecca S. Appleton, R.N., M.S.

DESCRIPTION OF THE STUDY

My name is Rebecca S. Appleton. I am a critical care nurse, and a doctoral student in the College of Nursing at the University of Utah. Because you are going to have open heart surgery at the University of Utah Hospital today, and you are 35 years of age or older, you are invited to participate in a study to determine if pulse oximetry data is valid during ventilator/respirator weaning.

The purpose of this research is to determine if non-invasive pulse oximetry data is a valid indicator of the amount of oxygen in a patient's blood during ventilator weaning. At present, nurses use two different instruments to determine if a patient's blood oxygen is adequate. The newer method mentioned above is pulse oximetry, and the more traditional method is arterial blood gas analysis. Previous research with these instruments have shown that pulse oximetry data can be significantly different from arterial blood gas data during ventilator weaning.

A pulse oximeter is a non-invasive instrument that nurses use on all patients in the hospital that are on ventilators/respirators. Pulse oximetry is painless, and has a probe with a small light in it that is placed on one of your fingers. It continuously tells nurses how much oxygen is being carried in your blood stream to the rest of your body. It is very important that nurses know how much oxygen is in your blood because your ventilator/respirator settings are changed depending on how much oxygen is in your blood.

Arterial blood gases are an invasive method of determining the amount of oxygen in your blood. While you are asleep, during your surgery, a small plastic catheter will be placed in an artery in your wrist by a doctor. This catheter will be used to draw small samples of your blood, to determine the amount of oxygen in your blood.

Every patient having open heart surgery is placed on a ventilator/respirator. The ventilator/respirator is the machine that helps you breath after your surgery. You will probably need it for the first 12-24 hours after surgery. Approximately 12 hours after your surgery, the amount of breathing help you need from your ventilator will be gradually reduced until you are able to breath on your own. Nurses call this process weaning. It is during the weaning process that the research measurements will be made. It is important for nurses to know which instrument (pulse oximeter or arterial blood gas analyzer) is more valid during weaning, this will provide nurses with better information to judge how well patients are adjusting to ventilator changes.

STUDY PROCEDURES

SHOULD YOU AGREE TO PARTICIPATE IN THIS STUDY, THIS IS WHAT YOU CAN EXPECT:

1. The study will begin after your surgery has been completed and you are moved to a room in the Surgical Intensive Care Unit (SICU) at the hospital. During this research you will NOT be required to do anything. I will make all the measurements in the study, and a qualified critical care nurse that works in the SICU will be doing the ventilator weaning and managing your care. Throughout the first portion of the study you will be asleep, or recovering from the anesthesia you received during surgery.
Validity of Pulse Oximetry During Ventilator Weaning of Adult Surgical Patients
Principal Investigator: Rebecca S. Appleton, R.N., M.S.

2. Consenting to be a part of the study does not guarantee that you will be a participant, you must also meet the following criteria after surgery:
   1. must not have been on the coronary bypass pump longer than three hours;
   2. must have an indwelling arterial catheter;
   3. must be on a ventilator;
   4. hemoglobin must be at least 9 gm./100 ml of blood;
   5. must not have more than 7% abnormal hemoglobins;

3. You will be assigned a code number, to separate your identity from your data. Only the investigator will have access to the codes and participants' identities. This information will be kept in a locked file until the completion of the study, at which time the record will be destroyed. Only code numbers will be used for data collection and analysis.

4. The pulse oximeter probe will be connected to the middle finger of the hand opposite the hand with the arterial catheter. A foil shield will be placed over the probe to prevent interference from other light sources, and the hand with the probe will be secured to an arm board to reduce movement of the probe.

5. The arterial blood gas analyzer that will be used by the researcher will be located outside your room, so that it will not disturb you.

6. As changes are made in the ventilator, I will record measurements from the visual display of the pulse oximeter, then I will withdraw and discard 3cc of blood from your arterial catheter. This small amount of blood must be discarded because it contains Heparin, a drug that helps keep your artery open. Then I will withdraw 1cc of blood into a syringe for arterial blood gas and CO-oximeter measurements. Each measurement taken requires that 4cc of blood (4cc of blood is approximately one teaspoon) be withdrawn from the arterial catheter in your wrist. You could have a total of eighteen blood samples drawn during the entire study. This represents a small amount of blood taken over approximately 24-48 hours. The distribution of measurements are as follows: (1) five measurements will be taken before you begin weaning; (2) up to eight measurements may be taken when ventilator changes are made during weaning, if you progress rapidly less measurements will be taken; (3) and five more measurements will be made after you are off the ventilator and breathing on your own. The total amount of blood that could be withdrawn from you in this study is 72 mls of blood, which is the same as 2.4 ounces, or 14.5 teaspoons of blood.

7. The study will continue until you have been off your ventilator for approximately three to four hours.

8. This study will cause you no additional pain, risks, or costs. You will experience the same pain and risks that every patient has associated with this type of surgery. Pulse oximetry and arterial blood gases are a standard requirement for all open heart surgery patients at University Hospital.

9. If at anytime during the study your condition should change and become critical, your participation in the study will be ended.
Validity of Pulse Oximetry During Ventilator Weaning of Adult Surgical Patients
Principal Investigator: Rebecca S. Appleton, R.N., M.S.

BENEFITS OF PARTICIPATION IN THIS STUDY

You will incur no costs by participating in this study. You will also receive free consultation with the investigator at anytime throughout the study.

Your participation in this study will help health care providers to better understand how these two instruments should be used during ventilator weaning, this knowledge will directly benefit future open heart surgery patients by improving how patients are monitored during ventilator weaning, and reducing costs associated with arterial blood gases. At the completion of the study the investigator will provide you with information about the findings of the study at your request. After you have signed your name on the consent, please check the appropriate box if you would like this information.

Your participation in this study is voluntary. Should you at any time wish to withdrawal you may do so and you may request that I destroy any data collected.

Should you have any questions about any aspect of the study at anytime you may call me at home (801) 531-6210. If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the investigator, please contact the Institutional Review Board Office at (801) 581-3655.

I have received a copy of the consent form. I have read and understood the explanation of the study. Questions about my participation in the study have been answered to my satisfaction. I agree to participate in the study - VALIDITY OF PULSE OXIMETRY DURING VENTILATOR WEANING OF ADULT SURGICAL PATIENTS.

-----------------------------------------------
Participant Name (printed)            Witness Name (printed)
-----------------------------------------------
Participant Signature            Witness Signature

Date

_____ Yes, I would like information about the findings of this study

_____ No, I do not want information about the findings of this study
APPENDIX F

CALCULATIONS FOR THE CORRECTED STANDARD DEVIATION
Calculations for the Corrected Standard Deviation

The following calculations were adapted from Bland and Altman's (1986) formula for the corrected standard deviation of differences (cSD) between instruments when using repeated measurements.

\[ cSD = \sqrt{(S_D^2 + 1/4 \, S_1^2 + 1/4 \, S_2^2)} \]

In this study there were four repeated measurements on each of the three instruments, for each participant during the three phases of data collection. Therefore, a comparison was made between pairs of instruments, for each phase of data collection, for a total of nine corrected standard deviations. The comparisons were as follows:

- pulse oximeter with arterial blood gas analyzer (SpO₂ with SaO₂-abg)
- pulse oximeter with hemoximeter (SpO₂ with SaO₂-co)
- arterial blood gas analyzer and hemoximeter (SaO₂-abg with SaO₂-co)

To calculate the standard deviation of the differences between instruments (S_D²) for this study, first, a mean score was computed for each participant for each of the three instruments. Using the mean scores, a difference score was computed for the combinations of instruments (shown above). Then an overall standard deviation was computed for the differences, then that number was squared.

Overall standard deviations of the differences, by instrument were as follows:

<table>
<thead>
<tr>
<th></th>
<th>S_D² Phase 1</th>
<th>S_D² Phase 2</th>
<th>S_D² Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO₂ - SaO₂-abg</td>
<td>(1.327)² = 1.76</td>
<td>(1.233)² = 1.52</td>
<td>(1.616)² = 2.611</td>
</tr>
<tr>
<td>SpO₂ - SaO₂-co</td>
<td>(1.803)² = 3.251</td>
<td>(1.691)² = 2.859</td>
<td>(2.799)² = 7.834</td>
</tr>
<tr>
<td>SaO₂-abg - SaO₂-co</td>
<td>(1.990)² = 3.960</td>
<td>(1.356)² = 1.839</td>
<td>(2.204)² = 4.858</td>
</tr>
</tbody>
</table>

The next step was to compute the standard deviations for the group of participants, by instrument, by phase (S₁² + S₂²).
An individual standard deviation (SD) was computed for the four measurements obtained from each participant, by instrument, by phase.

SD for each Subject for their four SpO2 readings in Phase 1

<table>
<thead>
<tr>
<th>Subject</th>
<th>SD</th>
<th>SD^2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.395</td>
<td>0.156</td>
</tr>
<tr>
<td>2</td>
<td>1.005</td>
<td>1.010</td>
</tr>
<tr>
<td>3</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>4</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>5</td>
<td>0.739</td>
<td>0.546</td>
</tr>
<tr>
<td>6</td>
<td>2.142</td>
<td>4.58</td>
</tr>
<tr>
<td>7</td>
<td>0.678</td>
<td>0.459</td>
</tr>
<tr>
<td>8</td>
<td>0.236</td>
<td>0.055</td>
</tr>
<tr>
<td>9</td>
<td>0.299</td>
<td>0.089</td>
</tr>
<tr>
<td>10</td>
<td>0.000</td>
<td>0.000</td>
</tr>
<tr>
<td>11</td>
<td>1.500</td>
<td>2.25</td>
</tr>
<tr>
<td>12</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>13</td>
<td>0.289</td>
<td>0.083</td>
</tr>
<tr>
<td>14</td>
<td>2.616</td>
<td>6.84</td>
</tr>
<tr>
<td>15</td>
<td>0.624</td>
<td>0.389</td>
</tr>
<tr>
<td>16</td>
<td>0.629</td>
<td>0.395</td>
</tr>
</tbody>
</table>

total 17.852

After the SDs were totalled and squared, then the total was divided by the number of participants, 16.

So the S_1^2 for the pulse oximeter in Phase 1 is...

\[
\frac{17.852}{16} = 1.115
\]

These calculations were also done for the SaO2-abg and SaO2-co in Phase 1, as well as SpO2, SaO2-abg, and SaO2-co for Phase 2 and 3. And are shown in the table below.

<table>
<thead>
<tr>
<th>S_1^2 + S_2^2</th>
<th>SpO2</th>
<th>SaO2-ABG</th>
<th>SaO2-co</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1</td>
<td>1.115</td>
<td>3.65</td>
<td>4.636</td>
</tr>
<tr>
<td>Phase 2</td>
<td>1.63</td>
<td>6.35</td>
<td>2.74</td>
</tr>
<tr>
<td>Phase 3</td>
<td>0.420</td>
<td>0.435</td>
<td>1.62</td>
</tr>
</tbody>
</table>
The final step is to insert these numbers into the Bland and Altman's formula:

\[ cSD = \sqrt{(S_D^2 + \frac{1}{4} S_1^2 + \frac{1}{4} S_2^2)} \]

For the corrected SD for the comparison between SpO₂ and SaO₂-abg in Phase 1.

\[ \sqrt{1.760 + \frac{1}{4} (1.115) + \frac{1}{4} (3.65)} \]
\[ = \sqrt{1.760 + 0.278 + 0.135} \]
\[ = \sqrt{2.173} \]
\[ cSD = 1.474 \]

For the corrected SD for the comparison between SpO₂ and SaO₂-abg in Phase 2.

\[ \sqrt{1.520 + \frac{1}{4} (1.63) + \frac{1}{4} (6.35)} \]
\[ = \sqrt{1.520 + 0.40 + 1.58} \]
\[ = \sqrt{3.5} \]
\[ cSD = 1.87 \]

The cSD for the comparison between instruments by phase were as follows:

<table>
<thead>
<tr>
<th>cSD</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpO₂ - SaO₂-abg</td>
<td>1.47</td>
<td>1.87</td>
<td>1.68</td>
</tr>
<tr>
<td>SpO₂ - SaO₂-co</td>
<td>2.16</td>
<td>1.98</td>
<td>2.89</td>
</tr>
<tr>
<td>SaO₂-abg - SaO₂-co</td>
<td>2.45</td>
<td>2.02</td>
<td>2.32</td>
</tr>
</tbody>
</table>
REFERENCE


