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Direct versus indirect blood pressure measurement in the hemodynamically unstable infant and child

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Direct Versus Indirect Blood Pressure Measurement in the Hemodynamically Unstable Infant and Child

by

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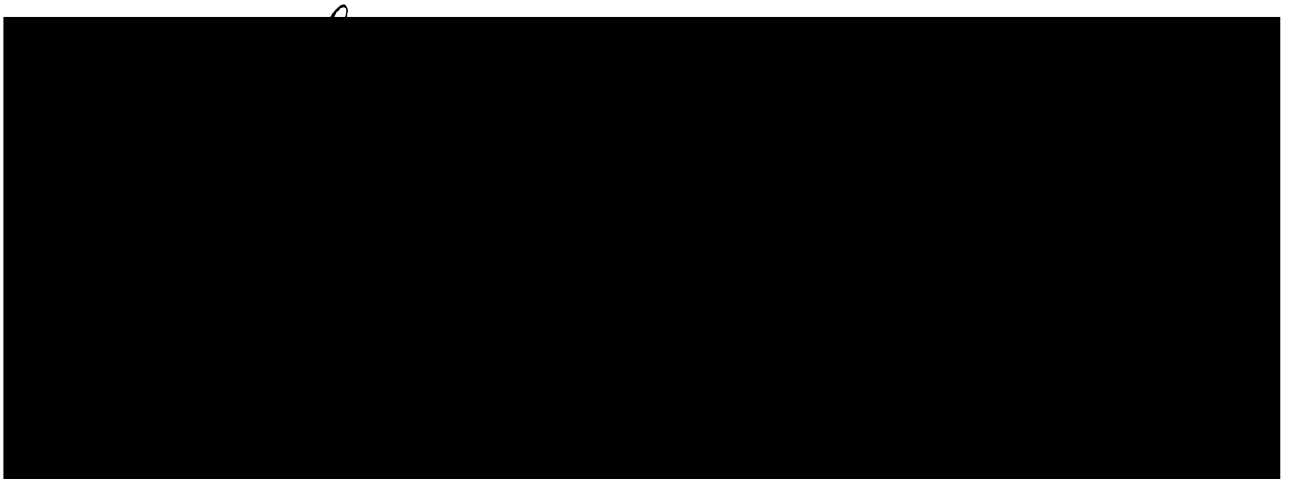

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Abstract

The purpose of this study was to determine to what extent blood pressure measurements obtained from an automatic, indirect blood pressure measuring device, the Dinamap[tm] monitor, correlate with the direct radial intraarterial measurements in hemodynamically unstable children (birth up to, but not including, seven years of age) who have undergone intracardiac surgery with cardiopulmonary by-pass support. A descriptive, correlational design was used with a convenience, non-probability sample of ten infants and children, mean age of 18.5 months ± SD of 23.7. Subjects were required to have a radial intraarterial line for continuous blood pressure monitoring prior to the surgical intervention, and were excluded from participation if there was a history of coarctation of the aorta, or limb contractures. Simultaneous blood pressure measurements were obtained by the Dinamap[tm] and the intraarterial system at fifteen minute intervals during two time phases. Phase I, the late intraoperative period, began at the completion of cardiopulmonary by-pass and continued until the child left the operating suite. Phase II, the early postoperative period, began within the first hour of the child's transfer into the pediatric intensive care unit and extended for a period of time equal to that of Phase I. The Dinamap[tm] and intraarterial estimations of mean arterial blood pressure were in closest approximation. (mean error and SD Phase I= 1.02 ± 6.86, Phase II=-1.02 ± 3.48) Systolic blood pressure estimation was not as close as the mean comparison, but remained within

the American Academy of Medical Instrumentation (AAMI) accepted standard, a mean <5mmHg with a SD of ≤7mmHg, difference between two measurements. The greatest difference between the Dinamap^{tm} and intraarterial blood pressure occured in the Phase II, diastolic measurements. The Dinamap^{tm} significantly ($p < 0.05$) overestimated the intraarterial diastolic blood pressure in all three measurements. The size and limited degree of instability for the sample limits the generalizability of this study beyond this critically ill, but relatively hemodynamically stable subgroup of children having intracardiac surgery with cadiopulmonary by-pass support. However, the degree of difference between Dinamap^{tm} and intraarterial diastolic blood pressure estimation necessitates that the health care provider consider the accuracy of diastolic estimations by the Dinamap^{tm}. Dinamap^{tm} measurements should only augment other physiologic parameters and assessment tools to evaluate diastolic blood pressure in the young, critically ill child.

With great respect and deep love,

this text is dedicated to my father on his upcoming retirement

Acknowledgments

The idea for this study originated from an interesting question regarding clinical practice. The support and encouragement of numerous individuals enabled me to translate this question into an empirical study. First, I would like to express my sincere gratitude to my family, classmates, and other special friends for their unconditional support during this graduate school experience. I would also like to acknowledge the support, as well as time, offered by my thesis committee members DeLois Weekes, RN, DNS; Mary Lynch, RN, MS; Elizabeth Tong, RN, MS; and Ida Martinson, RN, PhD.

Appreciation is extended to the University of California, San Francisco Hospital cardiology and cardiac surgery teams, and the staff of the operating room, pediatric and neonatal units. In particular, I would like to thank Dr. Cahalan, as well as the operating room and pediatric intensive care unit nursing staffs, for supporting this study and facilitating data collection. I would like to thank Steve Paul for his assistance with statistical analyses. I am extremely grateful for the funding provided by the Northern California Chapter of the Association for the Care of Children in Hospitals and the University of California School of Nursing Century Club, and the loan of a Dinamap^{tm} monitor by the Bay Area Critikon, Inc. representative.

Special thanks go to two nurses whom I consider to be friends as well as mentors. Mary Fran Hazinski, RN, MS, and Mary Lynch, RN, MS, have fostered a sense of pride in the profession of nursing, and have encouraged me to pursue goals toward an advanced practice role.

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Chapter One : Introduction

This chapter will include the background of the problem, as well as the steps to translating this problem into a researchable question. Terms utilized in this research are theoretically and operationally defined, and a list of the author's assumptions in designing this project are presented.

Background and Purpose of the Study.

Blood pressure monitoring is a critical factor in the evaluation of the hemodynamically unstable infant and child. Blood pressure is a reflection of the pressure within an artery which is generated by the volume of blood flow and the resisting force against the blood as it is ejected from the artery into the systemic vascular network. The primary factors that regulate this pressure are intravascular volume and circulation. (Daily & Schroeder, 1989)

There are several mechanisms for direct and indirect monitoring of arterial blood pressure. Intraarterial blood pressure monitoring is one example of a direct monitoring system. The Dinamap^{tm} is an oscillometric, device that indirectly estimates blood pressure based on the changes in frequency of oscillations as a cuff is deflated. Although both instruments are used in clinical practice, direct intraarterial measurement is considered as supporting an accurate reflection of arterial blood pressure and is the preferred method of measurement in the

critically ill child. (Bruner, Krenis, Kunsman, Sherman, 1981; Cohn, 1967; Hazinski, 1989)

The Research Question.

This study addressed the following question: To what extent do blood pressure measurements obtained by the Dinamap[tm], an indirect, automatic blood pressure monitoring device, correlate with direct, radial intraarterial blood pressure measurements in children (ages birth up to, but not including, seven years of age) undergoing open-heart surgery.

The primary current research regarding the accuracy of the Dinamap[tm] in the critically ill patient has been reported in the adult population. In the critically ill adult population, contradictory findings of the Dinamap[tm]'s accuracy in reflecting systolic and diastolic blood pressure have been reported. (Kimble, Darnall, Yelderman, Ariagno, & Ream, 1981; Venus, Mathru, Smith, & Pham, 1985) The research investigating the Dinamap[tm]'s performance and reliability in children experiencing hypotension or sudden decreases in blood pressure is both scarce and controversial. (Hazinski, 1989; Rebenson-Piano & Holm, 1988). One author (Hazinski, 1989) indicated, based on the limited pediatric and neonatal research, that the oscillometric device cannot be used with confidence in monitoring the hemodynamically unstable child.

Despite this lack of empirical data, several authors recognize the Dinamap[tm] as a standard piece of equipment in pediatric critical care areas utilized to monitor blood pressure (BP) during periods of hemodynamic stability as well as instability. (Colan, Fujii, Borow, MacPherson, & Sanders, 1983; Critikon, 1986; National Heart, Lung, and Blood Institute Task Force on Blood Pressure Control, 1987) For example, when an intraarterial line becomes occluded or the waveform damped, the Dinamap[tm] is used to obtain a second estimation of blood pressure and to evaluate the accuracy of the intraarterial estimation. Based on physical examination and the information from the Dinamap[tm], the nurse or physician makes a judgement as to the most accurate reflection of blood pressure, and which method of measurement will be used to estimate blood pressure in this patient in the future. Further empirical data would assist in evaluating the ability of the Dinamap[tm] to substitute for a dysfunctional intraarterial system, or the need to insert a second intraarterial line.

Arterial cannulation is not always accessible or appropriate for the critically ill child, particularly when complicated by immunosuppression. In this situation, the Dinamap[tm] may be the chosen method for blood pressure determination. The bedside nurse needs an understanding of the limitations of the Dinamap[tm], in order to know when the pressure estimation may be inaccurate and when the use of other physiologic parameters or physical assessment may be necessary. A statement in recent literature suggests that a non-invasive, indirect

method of measurement, such as the Dinamap[tm], will soon become the preferred method of blood pressure estimation. (Colan et al., 1983) However, without a greater foundation of research that evaluates the accuracy and dependability of the Dinamap[tm] in children, this step would be premature.

Significance.

Reliable blood pressure measurement is critical for the documentation of fluctuations in blood pressure, as well as the management of critically ill, hemodynamically unstable children. Blood pressure directly reflects systemic vascular resistance and circulatory status. Thus, it is an indirect reflection of cardiac output. (Daily & Schroeder, 1989) Blood pressure and other indicators, such as heart rate and peripheral perfusion, must be continually assessed to rapidly recognize changes in cardiac output and prevent potential complications (ie, physiologic shock).

The processes of hemodilution, hypothermia, and anticoagulation required during cardiopulmonary bypass can have transient effects on the hemodynamic status and organ system function. During the first 24 hours following intracardiac surgery, variations in blood pressure may reflect intravascular fluid volume deficits, interstitial edema, and alterations in urine output. Mean arterial blood pressure may fluctuate rapidly in response to large volume shifts from the intravascular space into the interstitial area, and subsequent alterations in cardiac

output. Weiland and Walker (1986) recommend observation of the mean arterial blood pressure as a parameter to guide postoperative volume repletion.

Blood pressure is also relied upon as an indicator of the effectiveness of therapeutic interventions. For example, a reliable blood pressure is essential in determining the titration of medications supportive of cardiac function, such as Nipride, Dopamine, and Dobutamine. The choice of which blood pressure monitoring device to use is often based on convenience and accessibility. In the pediatric critical care setting, direct and indirect measures are frequently used interchangeably to monitor fluctuations in blood pressure.

This study contributes to the available information regarding comparisons of direct and indirect blood pressure measuring devices in infants and children. The results of this study may be important to consider in the development and implementation of care for infants and children in the critical care setting. For example, in the case of the unstable child who has a dysfunctional or occluded arterial line, empirical research data becomes a vital part of the decision to either continue monitoring blood pressure with a non-invasive device such as the Dinamap^{tm}, or to re-insert an arterial line for direct blood pressure monitoring.

Assumptions.

In this study, the operating room and the pediatric critical care unit, were used for data collection. Both clinical environments used the Hewlett-Packard

Merlin cardiopulmonary monitor. It was assumed that each bedside monitor would reflect similar interpretations of blood pressure when identical calibration and operating procedures were followed. It was also assumed that changes in blood pressure measurements would occur in the post-operative hemodynamically unstable child.

Definition of Terms.

The terms used in this research reflect physiological concepts and phenomena. For this reason, terms will be both theoretically and operationally defined. The primary terms of interest include hemodynamic instability, arterial blood pressure, direct intraarterial blood pressure indirect arterial blood pressure, the intraoperative phase, and the immediate post-operative phase.

HEMODYNAMIC INSTABILITY. Theoretically, hemodynamic instability is an alteration in the determinants of oxygen delivery or transport to the tissues. These determinants include cardiac output, hemoglobin, and arterial oxygen saturation. The sample was expected to be at risk for hemodynamic instability as a result of cardiopulmonary by-pass, the operative procedure, and subsequent changes in intravascular volume and circulation. (Weiland & Walker, 1986) A child was operationally defined as hemodynamically unstable if he/she required the administration of a) colloid substances, b) crystalloid substances and/or c) pharmacologic therapy to support blood pressure.

ARTERIAL BLOOD PRESSURE. Theoretically, arterial blood pressure refers to the amount of pressure within an artery. It is generated by the volume of blood flow and the resisting force against the blood as it is ejected from the artery into the systemic vascular network. (Daily & Schroeder, 1989) The three parameters of arterial blood pressure are 1) systolic blood pressure, which reflects the pressure of blood as it is ejected from the left ventricle into the aorta, 2) diastolic blood pressure, which reflects the pressure from the proximal aorta to the peripheral arteries (1991), and 3) mean arterial pressure, the average pressure tending to push blood through the systemic circulatory system (Guyton,1981). For this study, arterial blood pressure was operationally defined as those readings obtained by 1) a direct/intraarterial monitoring system and 2) an indirect, oscillometric blood pressure monitoring system.

DIRECT/INTRAARTERIAL BLOOD PRESSURE. Theoretically, direct blood pressure is equal to the total pressure, both static and dynamic, measured by an end-hole catheter placed within a moving column of blood. (Perkin, 1989) The direct monitoring system used to monitor pressure in this study was the Abbott "Sorenson 'Transpac'™ disposable transducer with monitoring kit ". The stiff, non-compliant tubing and transducer system in this kit were connected to a catheter that was inserted into the radial artery by a physician at the start of the operative procedure. The physiologic data reflecting the pressure and volume within the radial artery were interpreted by the system transducer and ultimately

displayed and recorded by the Hewlett Packard Merlin[tm] bedside monitor. These data were used as a reflection of direct/intraarterial blood pressure.

INDIRECT ARTERIAL BLOOD PRESSURE. Indirect blood pressure is the amount of static pressure within an artery as measured by an inflatable cuff as it compresses a limb and its vasculature. (Perkin, 1989; Ramsey, 1991) For purposes of this study, indirect blood pressure measurements were obtained by the Dinamap[tm] 1846 SX-P monitor (Critikon, Incorporated, Tampa, Florida). The Dinamap[tm] monitor is an automatic oscillometric device utilized as a standard piece of equipment in pediatric critical care areas to monitor blood pressure (BP) during periods of hemodynamic stability as well as instability. (Colan, Fujii, Borow, MacPherson, & Sanders, 1983; Critikon, 1986; National Heart, Lung, and Blood Institute Task Force on Blood Pressure Control, 1987) Similar to other indirect cuff measurement methods, the oscillometric method requires compression of a limb and its vasculature by an inflatable cuff. The oscillometric method is unique in that the cuff, and the amount of air volume within the cuff, is used to automatically sense blood pressure values. (Ramsey, 1991)

PHASE I, THE LATE INTRAOPERATIVE PHASE. Simultaneous blood pressure measurements were recorded from the direct and indirect devices over two periods of time, in two critical care settings. Phase I, the late intraoperative phase reflects the first time period and clinical setting used for blood pressure measurement. Phase I included only the measurements recorded while the child

was in the operating room, and was operationalized as the time from the termination of cardiopulmonary by-pass until the patient was transported from the operating room.

PHASE II, THE IMMEDIATE POST-OPERATIVE PHASE. The second period of time and clinical setting were operationalized as Phase II, the immediate post-operative phase. Phase II began within one hour of the patient's return to the intensive care unit. The time period for data collection was comparable to that of Phase I. That is, if data were collected for 45 minutes in Phase I, data were collected for 45 minutes in Phase II.

Limitations.

The direct, intraarterial method is the standard against which indirect blood pressure measurements are compared. (Bruner et al., 1981; Cohn, 1967). An attempt was made to control all variables that might effect the intraarterial system's accuracy, however, the system was not infallible. (Ramsey, 1980) Using two different extremities for Dinamap^{tm} and intraarterial blood pressure measurements was a source of potential error. However, excluding subjects with known variations in bilateral extremity blood flow helped to control for this error.

The sample inclusion criteria of infants and children having open-heart surgery at University of California further limits the generalizability to this population and setting. Children having open-heart surgery were chosen for

participation in this study because of the frequent fluctuations in blood pressure occurring within this population. However, these subjects are also more likely to experience arrhythmias which could also influence blood pressure determination.

Chapter Two: Review of Relevant Literature

During the past decade, a number of studies have been conducted and findings supported the use of the oscillometric method as an accurate or superior means of indirect blood pressure monitoring (compared to the doppler and auscultatory methods) in normotensive newborns (Friesen & Lichtor, 1981); normotensive infants and children (Colan, Fujii, Borow, MacPherson, & Sanders, 1983; Park & Menard, 1987); and normotensive adults (Borow & Newburger, 1982; David, 1980; Ramsey, 1979; Silas, Barker, & Ramsay, 1980). Results of research in critically ill or hemodynamically unstable adults and newborn infants, have not consistently supported the accuracy or superiority of the indirect, oscillometric method of measurement of systolic and diastolic pressure. (Baker, 1986; Colin et al., 1983; Venus et al., 1985) In the following text, recent literature evaluating the accuracy of the Dinamap^{tm} in critically ill or hemodynamically unstable adults and newborn infants will be discussed according to the characteristics of the sample.

Accuracy of the Dinamap^{tm} Monitor in Adults.

Venus et al. (1985) investigated the accuracy of the Dinamap^{tm}'s indirect measurement of arterial pressure in a convenience sample of 43 adults admitted to a multidisciplinary critical care center. The selection of the time for blood pressure measurement, and the exact method for interpretation of intraarterial

pressure values were not provided in the research report. Data analysis indicated a significant difference between the Dinamap[tm] and the radial intraarterial systems in measuring systolic and diastolic blood pressure. The Dinamap[tm] underestimated systolic blood pressure by a mean error of 9.2mmHg ± 16.4mmHg, and overestimated diastolic blood pressure by 8.7mmHg ± 10.6mmHg.

Venus et al. (1985) acknowledged previous research by Carl, VanHerwaarden, & Smulders that identified pulse amplification as a possible explanation for observed variances between blood pressures measured at the radial and brachial arteries. However, regardless of the error attributable to anatomic location, the variance between measurements, exceeded the standard set by the Association for the Advancement of Medical Instrumentation (AAMI) of 5mmHg mean error ± a standard deviation of no greater than 8mmHg. Any slight variability relative to anatomic location has been considered in setting this standard for indirect blood pressure measuring devices (Ramsey, 1980). The authors expressed a concern about the use of the Dinamap[tm] for measuring systolic and diastolic blood pressure in clinical situations such as drug titration. Replication of the study would require more information about data collection and analysis procedures.

The method of interpreting the multiple intraarterial readings recorded during the Dinamap[tm] cycle into a single value was not discussed by Venus et al. (1985). Because the Dinamap[tm] takes longer to display each measurement than

the intraarterial system, multiple intraarterial readings are displayed while the Dinamap[tm] is completing one cycle. For purposes of comparison of the data from the two instruments, the intraarterial readings must be interpreted as a single value. Venus et al. did not provide this information.

Accuracy of the Dinamap[tm] in Newborns.

Kimble et al. (1981) compared mean blood pressure measurements between the Dinamap[tm] and an intraarterial umbilical catheter in a sample of 17 critically ill newborns. Findings from this study supported the Dinamap[tm]'s reflection of mean arterial pressure, but did not evaluate the systolic and diastolic blood pressure measurements. There are several concerns about the procedure and method of data analysis. For example, the investigators did not discuss the exact procedure for data collection and intraarterial value interpretation. Not only does this limit the ability to replicate this study, but also does not allow the reader to interpret the clinical relevance of the method used for intraarterial data value interpretation.

Accuracy of the Dinamap[tm] in Infants and Children.

Colan et al. (1983) compared Dinamap[tm] and central aortic catheter blood pressure measurements in 32 neonates, infants, and children with a median age of six months. Blood pressure measurements were taken during aortic catheter

placement with the child in a sedated, quiet resting state. The authors averaged all the intraarterial blood pressures in order to obtain a single value. Seventy-five percent of the Dinamap[tm]'s systolic blood pressure readings, 84% of the diastolic , and 97% of the mean arterial pressures were within 5mmHg of the corresponding aortic pressure values. Ninety-four percent of the Dinamap[tm] systolic pressures, 97% of the diastolic, and 100% of the mean arterial pressures were within 10mmHg. The investigators concluded that variables such as age, weight, heart rate, cardiac index, systemic vascular resistance had little effect on the percentage of error for the blood pressure readings.

One concern about the methodology of this study (Colan et al., 1983) is the use of two different Dinamap[tm]s. The rationale for using of two machines was not disclosed, and the analysis did not reflect a differentiation between the data collected by each machine. The researchers identified the sample as being limited to a moderately stable physiologic state and activity level, yet supported the future elimination of direct intraarterial blood pressure measurements in some patients requiring monitoring during titration of pharmacologic effect or diagnostic interventions.

Park and Menard (1987) studied a sample of children, hospitalized in an intensive care unit, primarily for cardiac post-operative management. Simultaneous blood pressure measurements were obtained from a radial intraarterial system and the Dinamap[tm] monitor at an unspecified time. Fourteen

of the 29 subjects received three repeated Dinamap[tm] measurements. The findings of this study supported the Dinamap[tm]'s approximate estimation of direct radial intraarterial blood pressure in normotensive infants and children.

By limiting the intraarterial placement site to the radial artery and using children who had been sedated, the researchers were able to controll for variables such as pulse amplification and extremity movement. However, there was no indication of consideration for the potential effect of pain, medications, temperature, and prior placement of an extracardiac shunt that may alter bilateral upper extremity blood flow.

A fast-flush test was performed on the intraarterial system in order to evaluate dynamic response, the ability of the system to respond to pressure changes. According to Gardner and Hollingsworth's (1986) description of adequate dynamic response, the intraarterial system used for the Park and Menard study (1987) would have tended to overestimate systolic blood pressure. The intraarterial system would adequately reproduce typical waveforms, but not necessarily waveforms of a faster heart rate or rapid pressure upstrokes.

The procedure for data collection did not include a specific time for blood pressure measurement, and it was not stated if the same Dinamap[tm] instrument was used throughout the study. The intraarterial pressure values were reported as a range of the highest and lowest pressures recorded. This method of intraarterial value interpretation is very complex and has limited clinical practicality. The

statistical analyses were appropriate for this descriptive, correlational study. However, with a sample of 29, the stability of the Pearson r coefficient is questionable. Repeated measurements established adequate internal consistency of the Dinamap^{tm} monitor, however data analysis did not differentiate which blood pressure values were an average of three readings and which were based on one reading.

Baker (1986) measured blood pressure in a sample of 40 children, ages birth to six years of age with a variety of medical-surgical conditions in the recovery room and critical care units of a large mid-western children's hospital. Thirty-six of the children were sleeping or sedated during the blood pressure recordings. Simultaneous blood pressure measurements were taken at an undisclosed time.

The investigator presented two different methods of data analysis. When the data from the 40 subjects were pooled, the analysis indicated that the Dinamap^{tm} had an acceptable mean error and standard deviation when compared with simultaneously recorded intraarterial pressures. When the subjects were analyzed individually, however, over 50% of the Dinamap^{tm} systolic and diastolic measurements exceeded the acceptable mean error and standard deviation set by the AAMI.

As stated previously, the Dinamap^{tm} takes longer to display each measurement than the intraarterial system. Multiple intraarterial readings are

displayed while the Dinamap[tm] is completing one cycle. Therefore, for purposes of comparison of data from the Dinamap[tm] and the intraarterial system, intraarterial readings must be interpreted as a single value. Baker's (1986) method of combining two measurements to obtain this singular value has more clinical practicality than the complex method used by Park and Menard (1987).

Summary of literature review.

The research reports discussed in this text support the accuracy of the Dinamap[tm] monitor, in comparison with other non-invasive methods of blood pressure measurement, in monitoring normotensive, or hemodynamically stable patients. The disagreement in reports of the accuracy of the Dinamap[tm] monitor center around its use with subjects who are not normotensive or are hemodynamically unstable.

There is limited empirical research addressing the accuracy of the Dinamap[tm] in the pediatric population. Colan et al. (1983) and Park and Menard (1987) evaluated the Dinamap[tm] in a sample of normotensive infants and children admitted to critical care units for various medical and surgical problems. Both reported adequate correlation between the Dinamap[tm] measurements and those obtained by an intraarterial system.

Neither the Colan et al. (1983) nor the Park and Menard (1987) research findings are generalizable to a sample of hemodynamically unstable infants and

children. Park and Menard (1987) indicate, "It is not known how accurate this technique [Dinamap^{tm}] is in patients with severe hypertension or hypotension...this aspect needs to be studied further in children with the oscillometric device" (p. 912). Baker (1986) addressed this gap in the literature in her study of the relationship between the blood pressure estimations of the Dinamap^{tm} monitor and an intraarterial system in critically ill children. However, this one study does not provide the necessary empirical data needed to support the decision of the pediatric health care professional at the bedside regarding appropriate method for blood pressure monitoring.

Conceptual Framework for the Study.

Blood pressure is the amount of pressure within a vessel generated by the volume of blood and the resisting force against blood flow as it is ejected from the vessel into the systemic vascular network. Blood pressure can be evaluated by an invasive, direct method of measurement, such as the radial intraarterial catheter, or by a non-invasive, indirect method, such as the Dinamap^{tm} automatic oscillometric device. The optimum method is one that responds to changes in hemodynamic stability and accurately reflects intravascular pressure.

Variables of interest to this study were primarily physiological in nature and included factors that may precipitate blood pressure changes or account for errors in measurement between a direct and indirect method of blood pressure

measurement. If a child is hemodynamically unstable, he/she may experience periods of hypotension or hypertension. Fluctuations in blood pressure are reflective of changes in intravascular volume and circulation within the vessel. These changes may be the result of blood volume changes, vasoconstriction, vasodilation, and changes in activity level. In order to determine the effect of these key variables, the following factors were monitored and recorded: the administration of colloid and/or crystalloid solutions, medication administration, activity, temperature, the use of ventilatory support, oxygen saturation, and electrocardiogram changes.

Chapter Three: Methodology

This chapter explicates the design and implementation of this study. The author discusses the selection of the sample and setting, as well as the development and operationalization of the tools and instruments used for data collection. The step-by-step procedure for data collection is detailed adequately for future replication of this study.

Research Design.

The design for this instrumentation study was descriptive, correlational. This study was a modified replication of the Baker study (1986) discussed in the previous chapter. The primary changes included restricting the sample population to infants and children having intra-cardiac surgery, and the use of repeated measurements on each subject. The use of repeated measures enabled the child to serve as his/her own control. The decision to restrict the sample population limited the extraneous variables introduced by having a sample with varying pathophysiology. However, this restriction proved to be a disadvantage as it decreased the availability of candidates for the sample.

Setting.

This study was conducted at the University of California, San Francisco, a large, university-affiliated, teaching hospital. At the initiation of this study, the

pediatric cardiovascular surgery team performed approximately five open-heart surgical procedures each week. From the operating room, all patients having open-heart procedures were taken directly to the 12-bed pediatric intensive care unit for recovery and further management. An unexpected change in cardiac surgical personnel occurred during data collection, and the number of surgical procedures dropped dramatically. This created further limitations in obtaining potential subjects.

Sample.

NATURE AND SIZE. This study included a non-probability, convenience sample of 11 infants and children (ages birth up to, but not including, seven years of age) undergoing open-heart surgery at the University of California, San Francisco Hospital over a four month period in 1991.

CRITERIA FOR SAMPLE SELECTION. Inclusion criteria were: 1) scheduled for cardiovascular surgery requiring cardiopulmonary by-pass, 2) the insertion of a radial artery catheter prior to or during the operative procedure, for continuous blood pressure monitoring, and 3) in order to be classified as hemodynamically unstable, the subject must have required the administration of a) colloid substances, b) crystalloid substances and/or c) pharmacologic therapy, such as dopamine, dobutamine, and nipride, to support blood pressure.

Exclusion criteria selected were 1) a history of coarctation of the aorta or known variation between right and left arm pulses and, 2) the presence of contractures preventing placement of the blood pressure cuff. If a subject had to undergo a second by-pass run, all previous readings were discarded and the child was re-entered into the study. Subjects were dropped from the study if deterioration in their condition necessitated emergency interventions, if unsatisfactory correction of the damping of the arterial wave form occurred during data collection, or if the operation was cancelled or if the child died before completion of both phases of measurement. No subjects were excluded on the basis of these three criteria. The primary reasons for exclusion were the history of a coarctation, which could create a difference in blood pressure between upper extremities, and the absence of a radial arterial line.

Human Subjects Assurance.

Approval was obtained from the University of California, San Francisco Committee on Human Research (See Appendix A), the appropriate medical and nursing administrators (See Appendix B) from the sites designated for this study, and the physicians responsible for the care of these subjects. Subject selection began each week with review of the published surgical schedule for infants and children having intra-cardiac surgery. The appropriateness of each potential subject in relation to the inclusion criteria was discussed at a pre-surgical

conference and with the pediatric cardiology clinical nurse specialist. Based on this information, the investigator approached the parents of potential subjects with a letter of introduction and a verbal explanation of the study. The investigator offered parents the opportunity and the time to review the consent form and further discuss the decision to participate among family, friends, or a health care provider.

Information regarding the costs, risks, and benefits; strategies for maintaining confidentiality and data storage were also shared with prospective subjects and/or his/her parents. (See Appendix C). Risks associated with participation in this study were minimal. There were no known risks associated with the two machines being used simultaneously to measure blood pressure. The inflation of the cuff may have caused some slight, temporary discomfort, but the investigator was able to stop inflation at any time if the child became restless or too uncomfortable with the procedure. There were no direct benefits or reimbursement for participants. The results of this study may assist health professionals in evaluating the accuracy of indirect, automatic blood pressure measurements, as compared to direct intraarterial measurements, in hemodynamically unstable infants and children.

Subject confidentiality was protected by assigning all participants a code number. Data were kept in a locked file cabinet in a locked office and only accessible to the investigator. Information from this study has been reported with

no references to individual participants. Parents were given the opportunity to refuse to allow their son/daughter to participate and to withdraw from the study at any time. Refusal or withdrawal in no way influenced the medical or nursing care given to the child. All subjects were given a copy of the Subjects Bill of Rights and a signed and dated copy of the consent form. The child was enrolled in the study once parental consent was obtained and sample criteria were met.

Instruments for Data Collection.

Three tools were used for data recording; 1) the demographic data sheet, 2) the preoperative data collection sheet, and 3) the Phase I and Phase II data collection sheet. All three tools were developed by the investigator and evaluated by a panel of clinical nurse specialists and physicians who were experts in the area of hemodynamic monitoring of the hemodynamically unstable infant and/or child. The data sheets were revised as suggested to insure content validity and ease in data recording.

DEMOGRAPHIC DATA SHEET. This instrument was used to record demographic data. This information would be analyzed at the completion of this study to identify the characteristics of the sample, and the potential influence of each variable on blood pressure. (See Appendix D) Data included age, date of birth, gender, disease and/ or physiologic state, and operative procedure.

PREOPERATIVE DATA COLLECTION SHEET. This instrument was used to record pertinent information regarding the subject's preoperative state of health and physical measurements. (See Appendix E) It included an assessment of vital signs, the position of the patient during blood pressure measurement, arm circumference, arm length, Dinamap^{tm} cuff size, weight, and current medications. Preoperative vital signs were measured to record baseline Dinamap^{tm} blood pressure, temperature, respirations, and apical heart rate.

PHASE I & PHASE II DATA COLLECTION SHEET. This instrument was used to record subject status and activities during Phase I, the intraoperative phase and Phase II, the post-operative phase. This data collection sheet enabled the recording of blood pressure and key variables which may effect blood pressure during Phases I and II.(See Appendix F) Data were recorded every fiftenn minutes. Other variables of interest were: current vital signs (pulse, respiration, temperature), position of the patient, Dinamap^{tm} cuff size, a description of medication, including anesthesia, administered before or during the measurement, ventilator mode and settings, a description of any arrhythmias, the cumulative blood loss. Any movement, intervention, or environmental stimulation to the patient that occurred within the five minutes before or during the measurement procedure was also recorded. Based on clinical experience, stimulation or activity occurring within this time period may directly influence blood pressure measurement.

DIRECT AND INDIRECT BLOOD PRESSURE MEASUREMENT. Two instruments were used to measure blood pressure. The radial intraarterial system reflected a direct measurement of blood pressure whereas the Dinamap^{tm} reflected an indirect, non-invasive interpretation.

Intraarterial Catheter-Transducer System. Direct arterial systolic, diastolic, and mean arterial pressures were obtained from the radial intraarterial catheter-tubing-transducer apparatus. Data were displayed by the bedside monitor, and permanently recorded by the attached printer.

Operation. The three basic components of the arterial catheter-tubing-transducer system were the transducer, amplifier, and recorder. The transducer senses the pressure within the vessel and converts this physiologic signal into an electrical signal. This signal is then transmitted via a cable to an amplifier. The amplifier modifies and filters the signal for visual display on a monitor screen or oscilloscope. The waveform and blood pressure values were permanently recorded by the bedside monitor's graphic printout.

Validity and Reliability. There are many variables which could affect the accuracy of the intraarterial catheter-tubing-transducer system. These variables include: atmospheric pressure, air bubbles and/or blood clots in the tubing or stopcocks, the catheter diameter, the tubing length and stiffness, kinks in the tubing, loose or leaking tubing or stopcock connections, the level of the transducer

at time of measurement, respirations/ventilation, and the position of the arterial catheter inside the vessel.

All unnecessary stopcocks and extension tubing were removed. In accordance with standards set by Ramsey (1980), the tubing was stiff and non-compliant in order to prevent absorption of the pressure amplitude as it passes through the tubing. The catheter size was the largest diameter that is appropriate for the child's vessel size, that did not unnecessarily increase the risk for thrombosis.

In a patient who is hypovolemic or has labored breathing, spontaneous or assisted ventilation may cause beat-to-beat variations in blood pressure.(Ramsey, 1991) Ramsey (1991) credits the Dinamap^{tm} with having the ability to minimize the effect of beat-to-beat variations, because it takes an average of two matching, consecutive amplitudes to obtain a representative oscillation amplitude. To monitor for any potential error related to mode of ventilation in this study, the amount and mode of oxygen delivery were recorded prior to each measurement.

The overall accuracy of an intraarterial system, as well as its ability to respond to changes in pressure and reproduce waveforms without distortion, is measured by its dynamic response. The dynamic response was evaluated using the fast-flush method. Adequate dynamic response was established prior to each phase of blood pressure measurement.

Dinamap[tm]. Indirect arterial blood pressure was obtained by the Dinamap[tm]. The same Dinamap[tm] 1846 SX-P monitor with attached printer was used throughout the study. The Dinamap[tm] automatically switches between an adult/pediatric mode and a neonatal mode by detecting the cuff and hose size at the beginning of each determination. This Dinamap[tm] 1846 SX-P monitor was issued on loan for use throughout the entire study. Calibration by the manufacturer (Critikon) and inspection by the hospital biomedical engineering department was completed prior to use in this study.

Operation. The Dinamap[tm] is based on the principle that blood flow through a vessel produces oscillation of the arterial wall which is transmitted to a blood pressure cuff encircling the extremity. As cuff pressure decreases, there are changes in the magnitude of oscillation. These changes are interpreted as the levels of systolic, diastolic, and mean arterial pressure (See Appendix G). The systolic blood pressure is measured at the point of rapid increase in oscillation amplitude. At this point, arterial pressure just exceeds pressure created by the cuff. As cuff pressure decreases, the oscillation amplitude increases. When the amplitude reaches the maximum point, this is taken as the mean pressure (Park & Menard, 1987; Ramsey, 1980).

Average blood pressure determination time for the Dinamap[tm] is 15-35 seconds (Critikon, 1986). The measurement is aborted if the reading takes over 120 seconds. The Dinamap[tm] does not determine blood pressure readings until

after all of the oscillation and cuff pressure data have been taken. Data are stored as averaged pairs of oscillation amplitudes and the corresponding cuff pressures, and then analyzed to determine the systolic, diastolic, and mean arterial pressure. Therefore, it is impossible to determine the single beat at which each pressure is determined (Ramsey, 1991).

Reliability and Validity. The Dinamap[tm] measurements were taken from the upper arm which did not have the radial intraarterial catheter. Previous literature has consistently found a negligible difference between the radial and brachial blood pressures of both arms and does not support the need for randomizing the arm used for blood pressure determination (Yelderman & Ream, 1979; Gould, Hornug, & Kieso, 1985; Sardove, Schmidt, Wu, & Katz, 1973). The size and application of the cuff can effect blood pressure measurements. For example, applying the cuff loosely can result in a falsely elevated blood pressure. Also, if the patient is peripherally vasoconstricted, the additional volume necessary to inflate the cuff may so attenuate the oscillations, that the device fails to function (Gardner, 1981). The placement and size of the Dinamap[tm] blood pressure cuff was based on limb circumference and length measurements in accordance with the recommendations of the Dinamap[tm] manufacturer and the NHLBI (Critikon, 1986; NHLBI, 1987) (See Appendix H). According to previously cited studies (Kimble et al., 1981; Park & Menard, 1987), the best correlation between direct and indirect blood pressure measurement is with a cuff

width to arm circumference ratio between 0.45 and 0.70. The cuff was positioned at the level of the heart along the mid-axillary line, using a carpenter's leveling device to assure correct placement.

Procedure.

Preoperatively, the investigator completed the demographic and preoperative data collection sheets. Baseline blood pressure was measured by the Dinamap[tm] within one hour of the beginning of the surgical procedure. Temperature, pulse, respiration, and weight were also recorded. Data, including the effect or presence of key variables were collected every fifteen minutes with each blood pressure measurement during the two time periods, referred to as Phase I and Phase II. The late intraoperative/ immediate postoperative data collection sheet was used to record these data.

During Phase I, the late intraoperative period, the first set of direct and indirect blood pressure measurements were taken after the completion of cardiopulmonary by-pass and the return to total circulatory independence for the patient. Readings were taken every 15 minutes throughout the remainder of the operative procedure until the child left the operating room. At least three readings were obtained during this phase that lasted approximately 45 minutes to one hour.

Measurements for Phase II, the immediate postoperative period, began within the first hour of the child's transfer to the pediatric intensive care unit. Upon arrival in the unit, the intraarterial system was re-connected to the unit's bedside monitor and the system was re-calibrated. Readings were taken every 15 minutes during this postoperative phase for a period of time equal to that of Phase I.

The intraarterial blood pressure value was defined as two measurements. One intraarterial blood pressure reading was recorded just prior to initiating the Dinamap^{tm} measurement sequence. The second reading was recorded simultaneously with the Dinamap^{tm}'s display of its blood pressure estimation. The two measurements were averaged in order to compare the mean value with the single corresponding Dinamap^{tm} reading. The pressures being displayed during the Dinamap^{tm}'s cycles were not to be used for analysis since they might be a reflection of sudden, inadvertent stimulation caused by the inflation and deflation of the Dinamap^{tm} cuff.

The weight of air and atmospheric pressure, can create a measurable pressure within the system. In order to negate the effect of atmospheric pressure, the transducer was calibrated by a technique called zeroing. The guidelines presented by Gardner and Hollingsworth (1986) were used for zeroing. Zeroing was completed prior to each phase of blood pressure measurements to support system accuracy, and adjust for significant weather and subsequent barometric

changes. Once in the intensive care unit, the arterial line was zeroed after the child was re-connected to a bedside monitor, and the arterial monitoring system was changed from a pressure bag set-up to a controlled infusion set-up, as per unit protocol. Manual calibration of a disposable transducer against a mercury manometer was not necessary and is unadvisable, since it places the patient at risk for mercury intoxication (Gardner & Hollingsworth, 1986; Hollingsworth, 1990). During data collection, the transducer was secured to a device which was attached to the bed. Re-zeroing was completed with any change in the patient's position or the position of the bed.

A clot at the tip of the catheter or a lodging of the catheter tip against the vessel wall may dampen the waveform. A damped waveform was identified by a pressure tracing with a slow upstroke, rounded appearance, poorly defined dicrotic notch, and narrow pulse pressure (Daily & Schroeder, 1989). All visible air bubbles and/or blood clots were flushed out or removed from the system, in order to reduce distortion of the physiologic signal during transmission, waveform damping, and subsequent underestimation of intraarterial pressure. As per hospital protocol, a solution of isotonic saline with one unit heparin per cc added was infused in all intraarterial catheters used in this study in an effort to reduce the formation of blood clots. Any other obstructions to flow within the system, such as kinks in the tubing, were eliminated.

A fast-flush test was performed prior to Phase I readings, according to Gardner's (1986) recommendations, in order to evaluate and adjust the adequacy of the intraarterial system's dynamic response. Fast-flush testing is not a standard of practice in the pediatric intensive care unit, and therefore this test was not preformed prior to the initiation of Phase II. In accordance with clinical practice within this unit, the intraarterial system was electronically zeroed prior to the initiation of Phase II measurements. In an effort to maintain adequate dynamic response and the internal consistency of the intraarterial system throughout each phase, the variables discussed in the preceeding text, such as removing any bubbles or obstruction in the intraarterial tubing, were addressed by the investigator prior to each blood pressure measurement.

Specific steps completed prior to each phase of blood pressure measurement were: 1) determination of printer function, 2) supine positioning, 3) deflation of the Dinamap^{tm} cuff, 4) placement of the Dinamap^{tm} cuff on arm opposite arm with radial arterial line, 5) flush and calibration of the arterial catheter, 6) evaluation of arterial waveform for damping, 7) record and obtain printout of arterial line pressure measurement, 8) press start on the Dinamap^{tm} (using the auto mode), and 9) at the end of the Dinamap^{tm} cycle, and digital display with printout of the blood pressure, obtain a simultaneous printout of the arterial line blood pressure reading. The printers attached to each device produced a documented account of each blood pressure data.

Each set of measurements included one Dinamap[tm] reading and two arterial line readings. If the Dinamap[tm] reading was aborted by the machine, a second reading was obtained. The Dinamap[tm] cuff was removed at the end of Phase I, and the deflated cuff was replaced on the subject upon the child's arrival into the intensive care unit. The same cuff and extremity were used in both phases. The above detailed procedural steps were repeated prior to the initiation of data collection in Phase II.

The investigator performed and recorded all blood pressure readings for both the Dinamap[tm] and the radial intraarterial system. The specific operating instructions and precautions for each device were reviewed and considered in design development.

Chapter Four : Results

This chapter will report the results obtained from the analysis of the data collected. The significance of the data, relative to the purpose of this study will be highlighted. This study addressed the following question: "To what extent do blood pressure measurements obtained by the Dinamap[tm], an indirect, automatic blood pressure monitoring device, correlate with direct, radial intraarterial blood pressure measurements in children (ages birth up to, but not including, seven years of age) undergoing open-heart surgery?".

Sample Demographic

Eighteen families were approached and consent was obtained for participation in this study. Seven children were dropped from participation in this study. Three had temperature elevations or abnormal lab values that cancelled surgery and four had the intraarterial line placed in an artery other than the radial artery. Data collection was performed on eleven children. One subject was excluded because of incomplete data. In comparison with the ten remaining subjects, the eight dropped were similar in disease and type of surgery, and slighty older, with a mean of two years of age in comparison with the ten subjects included in the final data analysis.

Data were compiled for the ten remaining children, ages birth up to but not including seven years of age, who underwent intracardiac surgery with cardiopulmonary by-pass support at the University of California, San Francisco Hospital from February through May of 1991. As identified in Table 1, the children presented with congenital heart defects, and underwent various intracardiac surgical procedures that required cardiopulmonary bypass. Five percent of this group had a diagnosis of ventricular septal defect and underwent an intracardiac surgical procedure for closure. Three had undergone a previous palliative surgical procedure such as a pulmonary banding, atrial septectomy, or central (aorto-pulmonary) shunt placement.

The mean age of the sample was 18.5 ± a standard deviation of 23.7 months. The median age was 11 months, with a range of 1 to 79 months. Eight of the 10 subjects were less than 12 months of age, which is representative of the age of the population having surgical treatment of congenital heart defects. An equal number of males and females were members of this convenience sample. The ethnicity of this sample was represented by five Caucasian, three Mexican-American, one African-American, and one Middle Eastern. Except for the exclusion of a small percentage of Asian-Americans, this ethnic distribution is reflective of the this San Francisco Bay area hospital's population. All families were English-speaking. The investigator offered an oral interpretation of this

Table 1.
Demographic Data

Subject #	Age (months)	Gender	Disease	Surgical procedure
1	11	male	VSD, Sub-aortic stenosis	vsd repair, resection of sub-aortic membrane
2	1	male	Type II truncus,right aortic arch truncal valve stenosis	truncus repair
3	79	male	VSD, aortic insufficiency	VSD repair
4	10	female	VSD, moderate pulmonary HTN	VSD repair
5	7	male	Ventricular aneurysm, pulmonary stenosis	resection of aneurysm, right ventricular outflow patch
6	2	female	VSD	VSD repair
7	11	female	VSD, sub-aortic stenosis	VSD repair, resection of sub-aortic stenosis
8	11	female	AV Canal	AV canal repair
9	48	female	ASD	ASD repair
10	6	male	TGA, ASD, VSD	resection of pulmonary artery aneurysm, Bi-directional Glenn

Note. Final data analysis included ten infants and children, who presented with various congenital heart defects and underwent intracardiac surgery with cardiopulmonary bypass support. ASD= Atrial Septal Defect; AV= Atrio-ventricular; TGA= Transposition of the Great Arteries; VSD= Ventricular Septal Defect.

study's purpose and consent form in Spanish, and/or the use of the hospital multilingual translation service to the appropriate families.

Subjects were enrolled in this study and data were collected according to the procedure discussed in the Methodology segment of Chapter Three. Four principle factors impacted this study and resulted in the accrual of a smaller sample who were less likely to develop hemodynamic instability. First, one of the principle members of the cardiac surgery team left early into data collection, resulting in a decrease in the number of children having intracardiac surgery and meeting the inclusion criteria. The number dropped from approximately three potential subjects a week, to one potential subject per week.

Second, another study was simultaneously being conducted in the pediatric intensive care unit, which limited the number of potential subjects, particularly those diagnosed with pulmonary hypertension. Therefore, this sample is representative of a subgroup, primarily hemodynamically stable, of the population admitted for intracardiac surgery at this institution. The exclusion of children with pulmonary hypertension limited the sampling of children who would have had a greater potential for developing hemodynamic instability.

Third, the infants and children sample used was relatively healthy preoperatively and less likely to experience instability postoperatively. All ten subjects were being managed successfully at home prior to admission for surgery. Seventy percent had been managed on medication alone and none required

oxygen prior to surgery. The decision for surgery was related to the changes in cardiac function as reflected by echocardiography or cardiac catherization. The relative healthy state of study participants further defined the sample as a relatively hemodynamically stable subgroup of the population of infants and children having intracardiac surgery, and limits the conclusions drawn from study findings.

Fourth, the majority of the infants and children in the sample underwent a relatively common intracardiac surgical procedure, a ventricular septal defect repair, which has a lower associated complication rate and decreased potential for hemodynamic instability in comparison to more complex porcedures. For example, the average time of by-pass for this sample was limited to 45-60 minutes, wheras the potential for complications is increased in children requiring cardiopulmonary bypass lasting longer than two hours. (Weiland & Walker, 1986)

Data Analysis

Statistical analysis of data was completed using the assistance of the CRUNCH 4.0 statistical software package. Data were grouped two ways. First, single, individual systolic, diastolic, and mean pressures were combined to determine the overall sample mean for each time blood pressure was recorded. Data were grouped according to the time when data were recorded in order to

assess for trends that indicated the relationship of time on blood pressure determination.

Secondly, data for each individual were combined and averaged to determine the overall sample mean values. Using the mean of repeated blood pressures on each subject to obtain the comparisons between each individual not only reflected the work of previous research (Baker, 1986), but also allowed the Dinamap[tm] and intraarterial mean error to be based on repeated measures from one subject. These grouping procedures were completed for Phase I and II Dinamap[tm] and intraarterial systolic, diastolic, and mean pressures, and two methods of matched pairs analyses were completed. These methods were 1) mean error and standard deviation, and 2) Wilcoxin signed-ranks test.

Comparison of Intraarterial and Dinamap Pressures Recorded at Fifteen Minute Time Intervals

Mean Error and Standard Deviation. Mean Dinamap[tm] and intraarterial systolic, diastolic, and mean pressure values were determined for each time blood pressure was recorded, and were compared between each individual. The mean error and standard deviation between the Dinamap and intraarterial estimations of each blood pressure parameter were defined by subtracting the Dinamap[tm] value from the corresponding intraarterial value. The differences were defined as the mean errors, and were evaluated according to AAMI standards which

recommend a mean error of less than ± 5mmHg, with a standard deviation no greater than ± 8mmHg. The number of times that the mean error met this standard is illustrated in Table 2.

The mean error between the three Dinamap^{tm} and intraarterial diastolic pressure estimations in Phase II did not meet the AAMI standards at two determinations, and approached the limit of the AAMI requirement in the third. This may be suggestive of a decrease in vascular resistance, and a resultant decrease in oscillation amplitude, occuring during this time in the postoperative period.

The Dinamap diastolic pressure estimation was higher than the intraarterial value in each of the six mean, comparisons between each individual. Overall, in comparing the 66 pairs of Dinamap^{tm} and intraarterial diastolic determinations taken over the course of this study, 39 (60%) were higher by the Dinamap^{tm}. Assuming that the calibration and testing of the intraarterial system supported the accuracy of the system, the higher Dinamap^{tm} diastolic readings are an indication of a consistant overestimation of diastolic blood pressure by the Dinamap^{tm}.

Table 2.
Mean Error and Standard Deviation Between Intaarterial(x) and Dinamap(y) Pressure Estimations[n] Recorded at Time Intervals

	Phase I		Phase II	
	Mean error (x-y)	**SD**	**Mean error (x-y)**	**SD**
SYS:0"	-10.1#	10.6	-4.5#	8.4
SYS:15"	-1.4	14.5	1.4	11.4
SYS:30"	0.4	4.4	0.9	0.7
DIA:0"	-0.8	8.1	-6.0#	7.0
DIA:15"	-0.9	8.1	-4.7#	3.6
DIA:30"	-1.5	5.3	-5.5#	6.7
MAP:0"	-0.1	10.0	-0.9	5.5
MAP:15"	-1.4	10.9	-0.4	5.5
MAP:30"	1.8	7.6	-1.8	3.3
HR:0"	1.2	9.9	2.1	2.3
HR:15"	-1.6	5.6	2.1	2.8
HR:30"	1.1	2.2	0.3	4.6

Note. In each of the three diastolic pressure determinations in Phase II, the difference between Intraarterial and Dinamap[c] pressure estimations (mean error) surpassed the AAMI range of acceptable mean error for instrument comparison. In both phases, the systolic mean error tended to decrease over time. The mean error between Intraarterial and Dinamap[c] heart rate estimation did not reflect the degree of correlation of sytolic, diastolic, or mean pressure values. DIA= diastolic pressure; HR= heart rate; MAP= mean pressure; SYS= systolc pressure; 0",15",30"= indicates,in minutes, which time interval measurement was taken; #mean error, when rounded to the nearest whole number did not meet AAMI acceptable range of less than 5mmHg.[n]n=10.

Of particular interest in this analysis is the decrease in the Dinamap[tm] and intraarterial systolic mean error during Phase I and Phase II. Systolic mean error decreased 10mmHg between the measurements taken at 0 minutes and 30 minutes in Phase I, and 3.6mmHg over the same time period in Phase II. This decrease may have been reflective of a progressive hemodynamic stabilization following the vasodilation and/or changes in intravascular volume occuring during the rewarming phase post-cardiopulmonary bypass.

The mean error between Dinamap[tm] and intraarterial mean blood pressure estimation was less than that of the systolic and diastolic comparisons. Whereas the largest mean error for the mean blood pressure comparison was 1.75mmHg, the mean errors for the systolic and diastolic comparisons were as high as 10.1mmHg and 6.0mmHg, respectively. The mean blood pressure comparison at the first measurement in Phase I had the smallest mean error, and thus the strongest relationship between Dinamap[tm] and intraarterial pressure estimation. The largest mean error, and weakest relationship between the Dinamap[tm] and intraarterial measurements, occured at the first blood pressure determination in Phase I.

In order to monitor for potential indicators of the accuracy of Dinamap[tm] pressure estimation, the heart rate was recorded simultaneously from both devices at each blood pressure measurement. Changes in the mean comparison of heart

rate did not consistently correspond with changes in the mean comparisons of systolic, diastolic, or mean blood pressure.

Wilcoxin Signed-Ranks Test. There was a statistically significant difference in Dinamap[tm] and intraarterial blood pressure estimation at the following time determinations: the first systolic measurement comparison in Phase I (SYS:O") (Wilcoxin matched-pairs signed ranks tests $T=-2.2$ $p<.05$, $n=10$), all three diastolic measurement comparisons in Phase II (DIA:0", DIA:15", DIA:30") (respective Wilcoxin matched-pairs signed ranks test $T=-2.2, -2.6, -2.2$, all $p<.05$, $n=10$); and the first and second heart rate comparisons in Phase II (HR:0", HR:15") (respective Wilcoxin matched-pairs signed ranks test $T= 2.1, 2.1$, all $p<.05$, $n=10$).

Comparison of Intraarterial and Dinamap Pressures Using Mean Intraindividual Data/ "Combined " Analysis

Mean Error and Standard Deviation. Analysis of the mean error and standard deviations for the Dinamap[tm] and direct intraarterial system were performed at each individual blood pressure determination, and then data for each subject were then combined and averaged. The mean error between the Dinamap[tm] and intraarterial pressures were computed based on these mean values for each subject. In the future, this method of grouping will be referred to as the "COMBINED" analysis.

Baker (1986) used the mean of three consecutive measurements obtained from each subject as the basis for comparison. In this study, the mean was computed from three repeated measurements taken on each subject at fifteen minute intervals. For example, in order to obtain the overall sample mean error and standard deviation between the Dinamap^{tm} and intraarterial comparisons in Phase I, the mean intraindividual systolic, diastolic, and mean blood pressure values were determined based on the three blood pressure measurements taken on each subject. From this information, the mean error and standard deviation between each individual were determined for the Dinamap^{tm} and intrarterial estimations of systolic, diastolic, and mean blood pressure. The same procedure was repeated for Phase II comparisons.

As detailed in Table 3, The mean error between the Dinamap^{tm} and intraarterial estimation of diastolic blood pressure in Phase II exceeded the AAMI standard. In contrast, the diastolic, along with the mean, Phase I comparison had the lowest mean error. In both phases, the Dinamap^{tm} estimation of diastolic blood pressure was higher than the intraarterial estimation.

Wilcoxin Signed-Ranks Test. There was a statistically significant difference in Dinamap^{tm} and intraarterial diastolic blood pressure estimations in Phase II. (Wilcoxin matched pairs signed-ranks tests, $T=-2.7$, $p<.05$, $n=10$)

Table 3.
Mean Error and Standard Deviation Between Intraarterial(x) and Dinamap^{tm} (y) Pressure Estimations^{n} for Overall Phase

	Phase I		Phase II	
	Mean error (x-y)	**SD**	**Mean error (x-y)**	**SD**
Systolic	-3.7	6.8	2.3	7.8
Diastolic	-1.0	6.1	-5.4#	4.7
Mean	1.0	6.9	-1.0	3.5
Heart rate	-2.3	3.3	1.5	2.2

Note. #mean error, when rounded to the nearest whole number did not meet AAMI acceptable range of less than 5mmHg.^{n}n = 10.

Impact of Key Variables on Blood Pressure Determination

In order to identify factors that may have had an impact on the measurement of blood pressure, key variables were recorded such as: diagnosis and surgical procedure, age, Dinamap^{tm} cuff size, intraarterial catheter size and system components, the location of peripheral intravenous site used for vasoactive medication administration, ventilatory status, medication administration, colloid and crystalloid administration, blood and urine output, temperature, activity, and arrythmias. An outline of the occurrence and variations of each variable within the sample (n = 10) is presented in Table 4, and is briefly discussed in the following text.

Table 4.
Occurance and Variation in Key Variables

	Subject Number (n=10)									
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Key variables										
cuff size	child	infant #4	child	infant #5	infant #5	child	child	infant	small adult	child
catheter size	22g	22g	22g	22g	22g	22g	22g	22g	22g	22g
venous access site	IA	/	D	D	/	D	IA	D	IA	D
Mode of Ventilation										
Phase I*	V	V	V	V	V	V	V	V	V	V
Phase II*	V	V	FT	V	FT	V	FT	V	FT	V
Vasoactive Drips	/	yes	/	/	/	yes	/	/	/	yes
Colloid intake(per kg)										
Phase I**	40	8	10	10	16	4	14	14	2	37
Phase II*	0	25	2	6	0	18	0	4	0	26

Table 8 continued on next page

Table 8- continued

	1	2	3	4	5	6	7	8	9	10
Key Variables										
Crystalloid intake (per kg)										
Phase I**	30	64	28	50	48	29	29	30	12	64
Phase II*	8	4	2	3	4	10	6	4	2	4
Blood loss and Chest tube output (per kg)										
Phase I**	14	13	3	2	4	3	8	1	0	2
Phase II*	3	13	2	5	2	12	4	4	2	6
Urine output (per kg)										
Phase I**	3	0	0	17	7	1	4	0	0	11
Phase II*	0	14	0	19	0	0	4	12	0	10
temperature										
Phase I*	↑	↑	↑	↑	↑	-	↑	↓	-	↓
Phase II*	↓	-	-	-	-	↑	-	-	↓	-
Activity (all in Phase II)	yes					yes	yes			

Note. Assume variable constant throughout both phases unless noted seperately. D= same extremity as Dinamap[tm] cuff. IA= same extremity as arterial catheter. FT= face tent. V= ventilator. /= not applicable. ↑= temperature increased from first (0") measurement to last (30"). ↓= temperature decreased from 0" to 30". -= no change in temperature. * recorded during 45" of data collection only. ** = recorded from beginning of surgery until left operating room.

Diagnosis & Surgical Procedure. The ten children included in this study presented with various congenital heart defects, although five had a diagnosis of ventricular septal defect and had surgical closure of this defect. Three children had undergone previous palliative surgeries, such as a pulmonary artery banding, an atrial septectomy, and a central (aorto-pulmonary), during a previous admission. During the surgical procedure, cardiopulmonary by-pass was utilized and lasted, approximately, 45-60 minutes. The ventricular septal defect repair procedure required the shortest by-pass time, approximately 35 minutes. None of the subjects experienced difficulty in removal from cardiopulmonary bypass supports, or required a second surgical procedure for postoperative complications.

Age. The mean and median age of the group was 18.6 and 11 months respectively, with a range of one month to 79 months. Eight of the subjects were less than 12 months of age. Because of the known developmental and physiological differences for children under one year of age, which may impact on cardiac functioning as reflected in the hemodynamic monitoring systems (Hazinski, 1989), the sample was divided into a subgroup of children less than 12 months of age and the statistical analyses were repeated. The exclusion of the two children ages 48 and 79 months, and limitation of the sample to children less than one year of age created a subgroup that was more representative of the children having these types of surgical repairs.

A comparison of the mean errors and standard deviations for the subgroup, children less than 12 months of age, and the combined sample, all children, is detailed in Table 5.

Table 5.
Mean Error and Standard Deviation Between Intraarterial(x) and Dinamap(y) Pressure Estimations for Overall Sample and Children Less Than 12 Months of Age

	All Sample (n=10)		**Children <12 months (n=8)**	
	Mean error (x-y)	**SD**	**Mean error (x-y)**	**SD**
PHASE I				
Systolic	-3.7	6.8	-2.8	7.4
Diastolic	-1.0	6.1	-0.7	6.7
Mean	1.0	6.9	1.3	7.5
Heart rate	-2.3	3.3	1.3	2.4
PHASE II				
Systolic	2.3	7.8	0.6	7.7
Diastolic	-5.4#	4.7	-6.1#	5.1
Mean	-1.0	3.5	-0.9	3.9
Heart rate	1.5	2.2	1.5	2.5

Note. #mean error, when rounded to the nearest whole number did not meet AAMI acceptable range of less than 5mmHg.

This analysis revealed a decrease in the mean error between the Dinamap^{tm} and intraarterial pressure estimations in ten of the 18 measurement comparisons for Phase I and Phase II when the sample was limited to children under 12 months of age. In contrast, a consistent increase in the mean error was evident in the comparisons of diastolic pressure estimations during Phase II. The difference between Dinamap^{tm} and intraarterial blood pressure estimation in each of the Phase II diastolic comparisons (DIA:0", DIA:15", DIA:30") were statistically significant (Wilcoxin matched-pairs signed-ranks tests, $T=-2.4$, $T=-2.4$, $T=-2.0$, respectively, $p<.05$ & $n=8$ for all values).

Dinamap^{tm} cuff size. The range of cuff width to arm circumference was between .40 - .70 in all subjects. This range was in close approximation to the optimal range of .45-.70 described by Kimble et al. (1981). Cuff selection was determined in accordance with the manufacturer's recommendations. The size and number of Dinamap^{tm} cuffs used in this sample were the child (5), infant #5 (2), infant #4 (1), infant (1), and small adult (1).

Intraarterial system components. A 22 gauge catheter was used in all ten subjects. The site of catheter insertion was selected by the physician, based on accessibility of the artery. The right and left upper extremities were selected for catheter placement an equal number of times (5). Throughout Phase I and Phase II, a crystalloid solution of 0.9 normal saline with one unit heparin per cubic centimeter of fluid infused through the intraarterial system into the radial artery.

In the operating room, a pressure bag inflated to 300mmHg was used to infuse this solution. In the intensive care unit, the solution infused via an electronic pump at a rate of three cubic centimeter per hour. The identical intraarterial transducer and pressure tubing was used in both settings/phases. The length of pressure tubing from the transducer to the catheter insertion site was 188 cm and all unnecessary extension tubing and stopcocks were removed.

Peripheral infusion site. In five of the subjects, a peripheral intravenous line was inserted in the same extremity that was used for Dinamap^{tm} measurement. The peripheral access system was far from the antecubital area, and probably did not hinder the inflation or deflation of the Dinamap^{tm} cuff. During Phase I, three of these five subject's required the infusion of a vasoactive pharmacologic agent, Dopamine or Nipride, through a peripheral vein. These infusions were continued in Phase II through central intravenous lines that were commenced in the operating room.

Ventilatory status. All ten subjects were mechanically ventilated during Phase I. Four of the 10 subjects were extubated prior to the initiation of Phase II blood pressure measurements and given oxygen support via a face tent.

Medication administration. Two subjects received Dopamine and one received Nipride as a continuous infusion at a rate of 5mcg/kg/minute and 0.2 mg/kg/minute respectively. The three infusions were initiated by the second measurement in Phase I, and continued at the same rate throughout Phase II.

These three subjects experienced blood pressure fluctuations as large as 30mmHg between the repeated blood pressure measurements. The greatest fluctuation in blood pressure in the children not receiving vasoactive medications was 20mmHg. Without a larger sample, it is not feasible to perform a seperate analysis using the children on continuous vasoactive medications to determine the effect of these medications on Dinamap^{tm} and intraarterial blood pressure determination.

All subjects received Nitrous Oxygen, Halothane, Heparin, Protamine, Vecuronium, Fentanyl, and Calcium Gluconate during Phase I. During Phase II, each child received intermittent infusions of Calcium Gluconate, one child received a continuous infusion of Fentanyl and Nipride, and a single dose of Morphine Sulfate was administered in three of the children. The time of Morphine Sulfate administration was different for each child.

Colloid and crystalloid administration. All subjects received intermittent colloid and continuous crystalloid infusions during each phase. Intermittent colloid infusions were completed over the period of two or more blood pressure determinations and did not occur more often at any one particular time. The volume of colloid and crystalloid administered during Phase I ranged from 2-20cc/kg and 2-10cc/kg, respectively. During Phase II, colloid and crystalloid intake ranged from 2-25cc/kg and 2-10 cc/kg, respectively.

Volume losses. Chest tube and urine output were recorded. No subject experienced measurable bleeding from the incision area postoperatively. Urine

output was measured by the weight of diapers or the amount of urine collected in a specimen bag attached to the skin over the urethra area. In Phase I, blood and chest tube output ranged from 2-14 cc/kg, and urine output 0-17 cc/kg. The ranges for Phase II were 2-13 cc/kg blood and 0-19 cc/kg urine.

Temperature. Over the course of Phase I, rectal temperatures ranged from 36.4-38.5 degrees celsius. The temperature increased an average of 0.6 degrees celsius in eight of the subjects, remained unchanged in one, and decreased by 0.4 degrees celsius in one. During Phase II, temperature remained unchanged in nine, and decreased in one by 0.7. Six of the subjects had a greater average temperature during Phase I than Phase II. The range of rectal temperatures during Phase II was 36.0-37.7 degrees celsius. The greatest fall in temperature between the end of Phase I and the beginning of Phase II was 1.0 degree celsius.

Activity. During Phase I, all subjects were anesthetized and no extremity movement was observed. The final reading obtained in Phase I consistently occurred during the skin closing procedure. Eight subjects were reported to have no observed spontaneous activity at the time of, or during the five minutes prior to, a blood pressure measurement. Two subjects had spontaneous activity such as periodic eye, hand, and finger movements or having an occasional cough. This observed movement did not alter or impede the inflation and deflation cycle of the Dinamap cuff.

Arrythmias. None of the children displayed electrocardiogram changes during data collection.

The potential influence of these key variables and a further description of the analyses completed on the results of this study are discussed in the following chapter.

Chapter Five: Discussion

This chapter will examine the results of this study, and describe any trends and/or significant comparisons that may assist in the clinical decision-making process required in answering the above questions. The results of this study provide direction guidelines for further research.

Dinamap[tm] and Intraarterial System Mean Error.

The mean error, or difference, between the Dinamap[tm] and intraarterial estimations of diastolic blood pressure did not meet the AAMI standards at any of the three times of measurement in Phase II. The difference in the Dinamap[tm] and intraarterial estimations of diastolic blood pressure in the immediate post-operative period exceeded the acceptable range set by the AAMI in both the overall sample (n=10), as well as the subgroup of children less than 12 months of age (n=8). This finding is difficult to interpret in such a small sample. The fact that the diastolic mean error between the Dinamap[tm] and the intraarterial system was greatest in the subjects less than 12 months of age, indicated an apparent tendency for the Dinamap[tm] to overestimate diastolic pressure in the younger children during the immediate postoperative period following open-heart surgery. This interpretation, however, is based on the assumption that the accuracy of this system was adequately tested by electronic zeroing and fast-flush testing, and that

callibration remained stable throughout each phase. This assumption is based on current clinical practice interventions concerning system callibration.

It is somewhat puzzling as to why the greatest diastolic mean error occurred during Phase II. A decrease in systemic vascular resistance may effect the ability of the Dinamap^{tm} to detect the sudden decrease in oscillations necessary to interpret the diastolic pressure. Given the fact that systemic vascular resistance should have been lowest during the post-bypass, re-warming period of Phase I, if systemic vascular resistance played a role in the diastolic pressure determination, the diastolic mean error should have been greatest during Phase I when body temperature was highest.

In examining possible explanations for the large mean error between Dinamap^{tm} and intraarterial diastolic pressure determination in Phase II, it is important to consider that intraarterial system zeroing and fast-flush testing may not have adequately established intraarterial system accuracy. If the intraarterial system was accurate, a lower intraarterial diastolic pressure reading would indicate an overestimation of diastolic blood pressure by the Dinamap^{tm}. If accuracy testing of the intraarterial transducer was not adequate; however, it would be difficult to interpret if the intraarterial system was underestimating diastolic blood pressure or the Dinamap^{tm} was overestimating diastolic blood pressure.

Since a fast-flush test and fluid-column calibration test on the intraarterial transducer were not a standard of practice in the pediatric intensive care unit of this hospital, the investigator did not perform these tests to evaluate transducer accuracy. In accordance with clinical practice in this unit, intraarterial accuracy testing was completed by electronic zeroing by the bedside monitor. For the nurse in this particular setting, it is important to recognize the discrepancy in the determination of diastolic blood pressure between the Dinamap^{tm} and the intraarterial system, and the subsequent need for the use of other physiologic parameters and physical assessment tools to evaluate diastolic blood pressure. It would not be possible to determine which measurement was a closer approximation of diastolic arterial pressure without further accuracy testing of the intraarterial transducer and system componenets.

Dinamap^{tm} and Intraarterial System Measurement Correlation.

It is not surprising that the Dinamap^{tm} and intraarterial mean blood pressure determination had the strongest correlation. Mean arterial pressure is defined as the amount of force that carries the blood from the intravascular system into the systemic network and tissues. (Guyton, 1981) It is determined by the amount of bloodflow through the vessel (cardiac output) and the resistance or elasticity of the vessels (systemic vascular resistance). (Daily & Schroeder, 1989) Mean arterial pressure is recorded by the Dinamap^{tm} as the point of maximum

oscillation amplitude. (Critikon, 1986) Even with changes in hemodynamic stability, as characterized by a decrease in systemic vascular resistance or a decrease in effective circulation, the point of maximum oscillation amplitude would be more easily interpreted than a sudden increase or decrease in amplitude.

Impact of key variables on blood pressure determination.

The sample size and characteristics limited any definitive analysis of variables, particularly diagnosis and procedure. Overall, the children appeared to tolerate the intracardiac procedures very well, and manifested limited signs of hemodynamic instability and minimal variation in the key variables monitored during this study. For example, since only three children received vasoactive pharmacologic agents, and volume intake and volume losses did not greatly vary among this sample, the effect of these variables on blood pressure determination is unknown. A description of any noted trends or potential influence of key variables on blood pressure determination will be presented in the following text.

Age. When analysis was limited to children less than 12 months of age, the Dinamap^{tm} and intraarterial mean errors decreased in the majority of comparisons (10), and increased in each of the Phase II diastolic comparisons. (See Table 5) The decrease in the mean error suggests a closer correlation in Dinamap^{tm} and intraarterial blood pressure estimation in the child under one year of age, as

compared to the child 1-6 years of age. The increase in the diastolic mean error in Phase II indicates a possible discrepancy between the Dinamap^{tm} and intraarterial system estimation of diastolic blood pressure. A larger sample and further intraarterial accuracy testing would be necessary to interpret which system offers a closer approximation of arterial blood pressure at this point in postoperative management.

Cuff size. Cuff size may be a concern in the accuracy of indirect blood pressure measurement, however, cuff size was taken into consideration and appropriate manufacturer guidelines were followed for each subject. In a state of shock or vasoconstriction, if the cuff is not completely evacuated before snug application to the extremity, the residual air volume can so attenuate the oscillations that the Dinamap^{tm} may abort the measurement (Ramsey, 1980). The cuff was removed between each phase; however, it was not possible to remove the cuff between each pressure determination to check for complete deflation.

Intraarterial components. The diameter of arterial catheter and type of solution did not vary within the sample. The site for radial artery cannulation was equally distributed within the sample between the right and left upper extremity. The method of solution infusion was different for the operating room and the pediatric intensive care unit. Since the data from these two sites were analyzed and compared separately, any resultant discrepancies in blood pressure determination should not have been reflected in data analysis.

The direct, intraarterial method is considered to be the standard to which indirect blood pressure measurements are compared. (Bruner et al., 1981; Cohn, 1967). An attempt was made to address all variables that might effect the intraarterial system's accuracy, however, any system is fallible. (Ramsey, 1980) Using two different extremities for Dinamap[tm] and intraarterial blood pressure measurements also created a potential for error. However, excluding subjects with known variations in bilateral extremity blood flow limited this risk for error.

In the operating room, prior to the beginning of Phase I measurements, electronic zeroing of the system by the bedside monitor and a fast flush test determined the system to be within an adequate dynamic response range. Prior to Phase II, electronic zeroing of the system was completed by the bedside monitor in an identical fashion as in Phase I. However, fast-flush testing was not standard practice in the intensive care unit. Also, it would have been difficult to control the amount of fluid infused in a fast flush using the particular intraarterial infusion set-up used in this unit. Therefore, a fast-flush test was not completed in Phase II, and it is possible that the accuracy of the intraarterial system transducer could have varied and potentially effected the results in this phase.

Peripheral infusion site. The number of subjects with a peripheral intravenous line inserted in the same extremity as the Dinamap[tm] were evenly distributed in this sample. Indirect blood pressure determinations may be effected by the simultaneous infusion of a vasoactive substance into the same extremity

used for measurement. With only three subjects, receiving such an infusion, it is difficult to discern the effects of this variable within this sample.

Ventilatory status. The fact that four of the children were extubated by the initiation of Phase II appeared to demonstrate the rapidly improving ventilatory status of this sample. Once again the effect of this variable on blood pressure determination was difficult to interpret with this small sample.

Temperature. The higher average temperature during Phase I is reflective of the rewarming phase that occurs post-cardiopulmonary by-pass. A decrease in temperature during the process of transport to the intensive care unit, offers a possible explanation for the lower Phase II average temperature. Since this is one variable that was different between Phase I and II, it could possibly been directly or indirectly accountable for the increased mean diastolic blood pressure during Phase II.

Activity. In the two subjects who did demonstrate extremity movement during blood pressure determination, the movement was very controlled and did not appear to effect the operation of the Dinamap^{tm} or intraarterial system. The influence of activity in this study was minimal.

Limitations.

The inclusion of infants and children having open-heart surgery at one instituition limited the generalizability to this population and setting. The

complications in obtaining subjects further limited generalizability to a small subgroup of children having intracardiac surgery. Children having open-heart surgery were chosen for participation because of the occurance of frequent fluctuations in blood pressure. However, the children sampled appeared to tolerate the intracardiac procedure very well, and showed minimal signs of hemodynamic instability. It is difficult to support the idea that this sample was representative of a hemodynamically unstable group of children. Instead the sample represents a subgroup of children having intracardiac surgery who are critically ill, but not necessarily hemodynamically unstable.

Limitations in the methods used for data collection include the inability to interface the Dinamap^{tm} and intraarterial system and obtain a singular printout of blood pressure determinations. The investigator simultaneously activated the printers from the Dinamap^{tm} and the bedside monitor. A simultaneous permanent recording of measurements would have removed observer bias, and reduced the potential for error in data recording.

This descriptive, correlational design does not allow for generalizability of findings beyond this sample of infants and children (ages newborn up to seven years) who have undergone cardiopulmonary by-pass. However, the results may be used to guide development of other studies to further evaluate the Dinamap^{tm}'s estimation of blood pressure in the hemodynamically unstable infant and child.

Implications for further research.

This study was developed to address the use of the Dinamap[tm] monitor for blood pressure evaluation and comparison in the hemodynamically unstable infant and child. Due to the small sample size, the results did not adequately answer the stated research question or define the correlation of Dinamap[tm] and intraarterial blood pressure measurements in the hemodynamically unstable infant and child. Nevertheless, the findings, particularly in relation to mean arterial pressure support, those of other investigators (Baker, 1986; Colan, et.al., Park & Menard, 1987), and further substantiates the Dinamap[tm]'s use in monitoring the normotensive, hemodynamically stable child. However, the instrument's use in monitoring the hemodynamically unstable infant or child has not been adequately evaluated, and must only be used in conjunction with a physical assessment of cardiac output and perfusion. The intermittent use of the Dinamap[tm] in the hemodynamically unstable child must be done with an appreciation of the fact that the Dinamap[tm] may not always adequately reflect arterial blood pressure.

This author encourages the replication of this study with the inclusion of recommendations discussed previously such as the use of a fluid column calibration for determining intraarterial transducer accuracy. Because so many children are able to tolerate an intracardiac procedure, future research would need a much larger sample in order to capture a wider variability in sample characteristics and level of hemodynamic instability. Limiting the sample to a

particular age group, less than one year of age, would offer a better representation of the population of children having intracardiac surgery. Defining the sample inclusion criteria to include only certain, more complicated surgical procedures may increase the degree of variability in hemodynamic status that was not captured in this study sample. It is recommended that repeated measures be used to maintain each subject as his own control. The specific timing of the measurement would not necessarily need to be at 15 minute intervals, but far enough apart to allow the effects of having taken a cuff blood pressure to dissipate. Consecutive measurements were not taken immediately one after the other, and then averaged, in order to correlate the methods used in this study with those used in the clinical practice area.

Among the questions for future research are:

1) "Can a non-invasive oscillometric device be considered to be a reliable method of blood pressure measurement and a standard for comparison in the critically ill infant or child?"

2) If an intraarterial line is occluded and/or does not provide an accurate reflection of blood pressure, " Can an indirect, oscillometric device be substituted for the method of measurement, or is it necessary to insert a second intraarterial line and continue direct blood pressure measurement?"

3) arterial cannulation is not always accessible or appropriate for the critically child, particularly when complicated by immunosuppression. In this situation, is an indirect, oscillometric blood pressure device adequate?

4) an invasive monitoring system may increase the potential for pediatric infections, and increase the exposure to blood for the

health care personnel. Is it reasonable to think that a non-invasive, indirect method of measurement, such as the Dinamap[tm], will soon become the preferred method of blood pressure estimation?

This study adds to the information needed by the health care team in the critical care setting using the Dinamap[tm] for clinical assessment and evaluation of care for the critically ill child. However, empirical data is still limited regarding the use of the Dinamap[tm] in the hemodynamically unstable infant and child. For the critical care nurse at the bedside, the results of this study indicate that the Dinamap[tm]'s estimation of mean arterial blood pressure is in close approximation with direct, intraarterial blood pressure estimation. Estimations of systolic blood pressure are not as close as the mean comparisons, but remain within the AAMI acceptable range. This degree of difference between Dinamap[tm] and intraarterial diastolic blood pressure estimations necessitates that the health care provider consider that diastolic estimations by the Dinamap[tm] may not accurately reflect diastolic arterial blood pressure. The Dinamap[tm] must be used only in cooperation with other physiologic parameters and assessment tools to evalate diastolic blood pressure.

Appendix A

Committee on Human Research Approval

COMMITTEE ON HUMAN RESEARCH
OFFICE OF RESEARCH AFFAIRS, Box 0962
UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

TO: DeLois Weekes, R.N., M.S.
Box 0606

Catherine L. Headrick, RN
Box 0606

RE: Direct versus Indirect Blood Pressure Measurement in the Hemodynamically Unstable Infant and Child

The Committee on Human Research, the UCSF Institutional Review Board holding Department of Health and Human Services Multiple Assurance #M-1169, has reviewed and approved this application to involve humans as research subjects, with the following

COMMENT: The members asked that the Confidentiality section of the consent form be revised to include the following standard wording in addition to the specific details about how confidentiality will be protected: "Participation in research may involve a loss of privacy. However, your child's records will be kept as confidential as is possible under the law. No individual identities will be used in any reports or publications resulting from this study."

APPROVAL NUMBER: H2502-06155-01. This number is a UCSF CHR number and should be used on all consent forms, correspondence and patient charts.

APPROVAL DATE: November 1, 1990. **Expedited Review**

EXPIRATION DATE: October 15, 1991. If the project is to continue, it must be renewed *by the expiration date.* See reverse side for details.

ADVERSE REACTIONS/COMPLICATIONS: All problems having to do with subject safety must be reported to the CHR within ten working days.

MODIFICATIONS: All protocol changes involving subjects must have prior CHR approval.

QUESTIONS: Please contact the office of the Committee on Human Research at (415) 476-1814 or campus mail stop, Box 0962.

Sincerely,

Rebecca Coleman

Rebecca L. Coleman, Pharm.D.
Chair
Committee on Human Research

HEPC Project # 90006155

1/23/91

DeLois Weekes, RN, DNS, Principal Investigator
Catherine L. Headrick, RN, BSN, Co-Principal Investigator
Department of Family Health Care Nursing
UCSF School of Nursing, Box 0606

TO: UCSF Committee on Human Research
Office of Research Affairs, Box 0962

RE: Minor modification application
STUDY: Direct Versus Indirect Blood Pressure Measurement in the Hemodynamically Unstable Infant and Child
CHR APPROVAL #: H2502-06155-01

We are requesting a minor modification for the investigation "Direct versus Indirect Blood Pressure Measurement in the Hemodynamically Unstable Infant and Child". The purpose of this study is to determine to what extent blood pressure (BP) measurements obtained from an indirect, external device (Dinamap monitor) correlate with the direct intraarterial BP measurements in the hemodynamically unstable infant and child.

The following minor modifications are requested:
1. The frequency of BP measurement
2. The addition of recording intraaortic pressure from the monitor during the intra-operative phase.
3. A clarification of the age criteria for inclusion in this study.

1.) Change in frequency of blood pressure measurement. The current approved CHR short-form application reads as follows:

> "During the first phase, the late intraoperative phase, BP will be recorded every half hour from the time of completion of cardiopulmonary by-pass until the patient leaves the operating suite. During the second phase, the early post-operative phase, BP will be recorded every hour for the first eight hours after the child's transfer into the intensive care unit." Every half-hour/hour time increment, BP will be simultaneously be recorded by the two devices, then the investigator will "wait two minutes, then repeat this measurement sequence three times". A mean of these three recordings would be used for the purpose of data analysis."

The proposed modification would read as follows:

> During the first phase, the late intraoperative phase, BP will be recorded every fifteen minutes from the time of completion of cardiopulmonary by-pass until the patient leaves the operating suite. During the second phase, the early post-

operative phase, BP will be recorded every fifteen minutes. The first measurement will be taken within the first hour of the child's transfer into the PICU. BP will be recorded every fifteen minutes until a number of measurements equal to that recorded in the first phase have been collected. Only one BP measurement from each machine will be taken at each time interval.

This modification was suggested by a member of the medical staff and agreed upon by the thesis committee. The proposed modification is based on the following:

A) wide variance in BP occurs in a very short period of time following cardiopulmonary by-pass as reperfusion occurs and large amounts of crystalloid and colloid solutions are given intravenously. Therefore, one measurement taken at shorter intervals may be more clinically relevant and reflective of Bp changes than the mean of three repeated BP measurements taken at longer intervals.

B) Decreasing the time for BP evaluation during the post-operative phase would concentrate data collection during the time period when the child is most likely to be hemodynamically unstable.

C) The timing of the post-operative data collection would be revised so that there would be a similar data collection method used in each phase.

2.) I am requesting the following addition to the proposal.

In those children with an intraaortic blood pressure monitoring device intact, intraaortic BP will be recorded from the display screen. There will be no manipulation of the monitoring device by the investigator. The determination of which children have this measuring device is the decision of the medical and/or surgical team. The data obtained from this monitoring device will be additional information used to evaluate the hemodynamic status of the child.

This addition is proposed as, with the utilization of cardiopulmonary by-pass, there may be a discrepancy between the intraarterial and Dinamap BP measurements secondary to the physiological phenomenon of reperfusion. Recording the intra-aortic pressure would assist in determining the hemodynamic status of the child, as well as the etiology of any discrepancies in BP during this time period.

3.) Clarification of the age criteria for inclusion in this study. The modified proposal would change the phrase birth to six years of age to birth up to, but not including, seven years of age.

As instructed in the modification application form, I have enclosed a copy of the approved consent form. The proposed modifications would not change the wording of this form.

Please contact DeLois Weekes (476-4697) or Catherine Headrick (461-6524) if there are any questions or concerns. Thank you for your time and prompt attention to this matter.

Sincerely,

DeLois Weekes, RN, DNS
Principal Investigator

Catherine L. Headrick, RN, BSN
Co-Principal Investigator

cc: Mary Lynch, member, thesis committee
Patricia Sparacino, chair, UCSF Nursing Research Committee
Elizabeth Tong, member, thesis committee
DeLois Weekes, chair, thesis committee

Appendix B

Letters of Support

5/29/90

To:

From: Catherine L. Headrick, graduate student UCSF School of Nursing.

Re: Approval of research study- "Direct versus indirect blood pressure measurement in the hemodynamically unstable child"

My name is Cathy Headrick and I am a graduate student in the Pediatric Critical Care Program at the UCSF School of Nursing. I am conducting a study to compare the direct and indirect methods of blood pressure measurement in the critically ill, hemodynamically unstable infant and child. I am the principal investigator. Thesis committee members are DeLois Weekes, DNS, RN, (chair); Mary Lynch, MSN, RN; and Liz Tong, MSN, RN.

Projected time for the initiation of this study is early Fall 1990. The sample is comprised of all infants and children (newborn-6 years of age) scheduled for open-heart surgery at UCSF. Simultaneous Dinamap and radial intraarterial blood pressure measurements will be recorded at periodic intervals from the time the child completes cardiopulmonary by-pass, and returns to circulatory independence, through the first eight hours of post-operative care in the PICU.

The Dinamap is often used to monitor the critically ill, hemodynamically unstable child, however the accuracy of this device has not been evaluated under these circumstances.

All data will be collected by the principal investigator. Parental consent and human subjects approval will be obtained prior to any data collection. The subjects and all data collected will remain anonymous.

I presently work in several PICUs in the Bay Area. I also have experience with a team of cardiovascular-thoracic surgeons. I appreciate the high level of clinical expertise, as well as common sense, expected of me while in the operating room and the pediatric intensive care unit.

I would be happy to go over the research proposal with you at greater length at your convenience, if there are any further questions.

I would greatly appreciate your permission to use the above named facilities and sample. Attached is a return memo. If appropriate, you may indicate your support and approval of this investigation on this form. Feel free to attach a letter expressing any additional comments or opinions. If there are any questions, please feel free to call me at 461-6524 (home/answering machine).

Thank you for your time and your prompt attention to this matter.

Sincerely,

Catherine L. Headrick

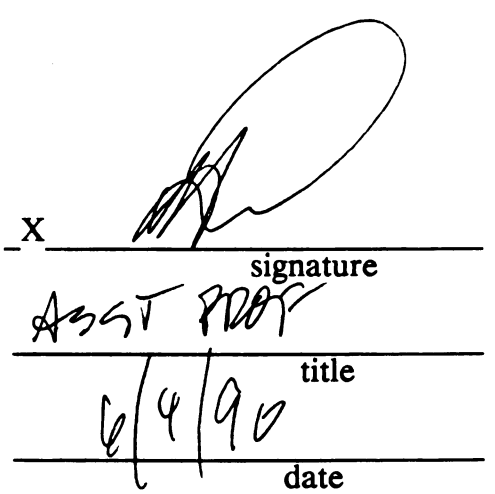
Graduate student
UCSF School of Nursing

TO: Catherine L. Headrick
Graduate Student, UCSF School of Nursing, Department of Family Health Care

RE: Request for support of research study and approval of use of site and sample designated for the study.

TITLE OF THE STUDY: Indirect versus direct blood pressure measurement in the hemodynamically unstable infant and child

I have received information regarding the proposal for the above named study. Any questions or concerns have been appropriately addressed by the investigator. I support the importance of this research and its implementation in the UCSF Pediatric Intensive Care Unit.



TO: Catherine L. Headrick
Graduate Student, UCSF School of Nursing, Department of Family Health Care

RE: Request for support of research study and approval of use of site and sample designated for the study.

TITLE OF THE STUDY: Indirect versus direct blood pressure measurement in the hemodynamically unstable infant and child

I have received information regarding the proposal for the above named study. Any questions or concerns have been appropriately addressed by the investigator. I support the importance of this research and its implementation in the UCSF Pediatric Intensive Care Unit.

_x Vicky Dwyer RN
signature

Admin. Nurse III
title

6/4/90
date

TO: Catherine L. Headrick
Graduate Student, UCSF School of Nursing, Department of Family Health Care

RE: Request for support of research study and approval of use of site and sample designated for the study.

TITLE OF THE STUDY: Indirect versus direct blood pressure measurement in the hemodynamically unstable infant and child

I have received information regarding the proposal for the above named study. Any questions or concerns have been appropriately addressed by the investigator. I support the importance of this research and its implementation in the UCSF Pediatric Intensive Care Unit.

x [signature]
signature

Director, PICU
title

6/4/90
date

TO: Catherine L. Headrick, RN, BS
Graduate Student, UCSF School of Nursing, Department of Family Health Care

FROM: Trisha Montague, RN, MS, Head Nurse Pediatric Intensive Care Unit

RE: Request for support of research study and approval of use of site and sample designated for the study.

TITLE OF THE STUDY: Indirect versus direct blood pressure measurement in the hemodynamically unstable infant and child

I have received information regarding the proposal for the above named study. Any questions or concerns have been appropriately addressed by the investigator. I support the importance of this research and its implementation in the UCSF Operating Room and Pediatric Intensive Care Unit.

_X Pat Montague RN
signature

Head Nurse PICU/SMTU
title

1/11/91
date

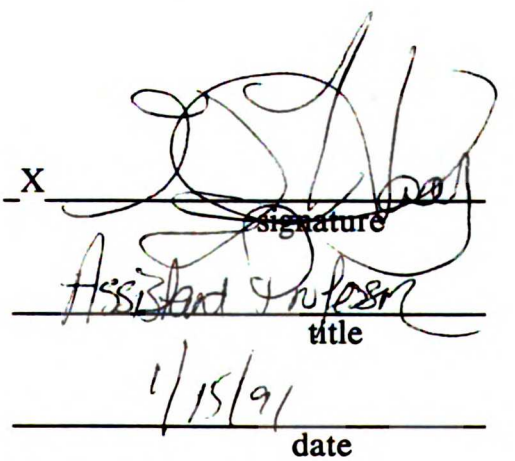
TO: Catherine L. Headrick, RN, BS
Graduate Student, UCSF School of Nursing, Department of Family Health Care

FROM: Dr. Gary S. Haas,
Cardiovascular Surgeon

RE: Request for support of research study and approval of use of site and sample designated for the study.

TITLE OF THE STUDY: Indirect versus direct blood pressure measurement in the hemodynamically unstable infant and child

I have received information regarding the proposal for the above named study. Any questions or concerns have been appropriately addressed by the investigator. I support the importance of this research and its implementation in the UCSF Operating Room and Pediatric Intensive Care Unit.



TO: Catherine L. Headrick
Graduate Student, UCSF School of Nursing, Department of Family Health Care

FROM: S. Scott Rankin, MD, Chief of Cardivascular and Thoracic Surgery

RE: Request for support of research study and approval of use of site and sample designated for the study.

TITLE OF THE STUDY: Indirect versus direct blood pressure measurement in the hemodynamically unstable infant and child

I have received information regarding the proposal for the above named study. Any questions or concerns have been appropriately addressed by the investigator. I support the importance of this research and its implementation in the UCSF Operating Room and Pediatric Intensive Care Unit.

_x_____
signature

Professor of Surgery
title

_____
date

Appendix C

Parental Consent Form

Consent to Have Your Child Participate in a Research Study

University of California, San Francisco

PURPOSE

My name is Cathy Headrick. I am a pediatric nurse and a graduate student at the University of California, San Francisco School of Nursing. DeLois Weekes, RN, DNS and Mary Lynch, RN, MS from the Department of Family Health Care Nursing; and Elizabeth Tong, RN, MS, pediatric cardiology clinical nurse specialist; and I are conducting a study to compare two instruments that are routinely used to measure blood pressure in children in the operating room and in the pediatric intensive care unit. I am trying to see if one instrument measures blood pressure changes as well as the other in children having open-heart surgery. Because your child is scheduled for open-heart surgery, he/she is invited to participate in this study.

PROCEDURE

The operating room and pediatric intensive care unit staff will be monitoring blood pressure as often, and as carefully, as they have done with all open-heart surgery patients. The difference will be that I will have both machines taking blood pressure at the same time.

If you decide to permit your child to participate in this study, I will be recording his/her blood pressures, using both machines, during the last part of the surgery and during the first part of recovery in the pediatric intensive care unit.

RISKS

There are no known risks associated with the use of two machines to measure blood pressure at the same time. The inflation of the blood pressure cuff may cause some slight, temporary discomfort. I will be able to stop inflation at any time if the child becomes restless or too uncomfortable with the procedure.

BENEFITS

There are no direct benefits or reimbursements for the participants in this study. The study may help health professionals caring for other children, like your son/daughter, to know if blood pressure can be measured adequately with a non-invasive method.

CONFIDENTIALITY

Your child's identity will be protected. No name will be used on the record of blood pressure measurements. All participants will be given a code number and all information will be kept in a locked file cabinet in the investigator's locked office. Information from this study will be reported with no references to individual participants.

Participation in research may involve a loss of privacy. However, your child's records will be kept as confidential as is possible under the law. No individual identities will be used in any reports or publications resulting from this study.

RIGHT TO REFUSE OR WITHDRAW

You may refuse to allow your son/daughter to participate or withdraw from the study at any time. Refusal or withdrawal from the study will in no way influence the medical care your child receives.

QUESTIONS

If you have any questions, please feel free to ask me. I can also be reached at (415) 461-6524. You will be given a signed and dated copy of this form to keep.

CONSENT

If you choose to have your child participate in this study, please read the following statement and sign below.

"I wish to have my child be a participant in this study and know of no reason why he/she would refuse. I have received copies of this consent form and the Experimental Subject's Bill of Rights to keep."

_____ _____

DATE SIGNATURE OF PARENT OR GUARDIAN

_____

RELATIONSHIP

_____ _____

DATE SIGNATURE OF PERSON OBTAINING CONSENT

UNIVERSITY OF CALIFORNIA. SAN FRANCISCO

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out.

2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice.

3) To be told about the frequent and/or important risks, side effects or discomforts of the things that will happen to me for research purposes.

4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be.

5) To be told the other choices I have and how they may be better or worse than being in the study.

6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study.

7) To be told what sort of medical treatment is available if any complications arise.

8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study.

9) To receive a copy of the signed and dated consent form.

10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the Committee on Human Research, University of California, San Francisco, CA 94143.

Call X1814 for information on translations.

Appendix D

Demographic Data Sheet

NAME_____ CODE #_____

DATE OF BIRTH_____

GENDER: MALE____ FEMALE_____

1. DIAGNOSIS_____

2. DISEASE OR PHYSIOLOGIC STATE_____

3. SURGICAL PROCEDURE_____

Appendix E

Preoperative Data Collection Sheet

1. ARM CIRCUMFERENCE:_____cm.

2. ARM LENGTH:_____cm.

3. VITAL SIGNS:
BLOOD PRESSURE: _____(per Dinamap; including systolic, diastolic, and mean) taken with the Dinamap; attach printout)
A. Dinamap cuff size used_____
B. position during blood pressure:
prone___supine___right side up___left side up___
HOB:
<30°____ 30-60°_____ 60-90°_____

C. any movement, environmental stimulation, or interventions within 5 minutes before or during measurement:

APICAL HEART RATE:_____
RESPIRATIONS: _____/minute
TEMPERATURE:_____(axillary___or rectal___)

4. OXYGEN: method of delivery:_____
FiO_2:_____

5. WEIGHT:_____KG.
scale used: infant scale_____ swing_____
stand-up_____ other___(indicate)

6. CURRENT MEDICATIONS:
(include name, dose, frequency, and any scheduled times)

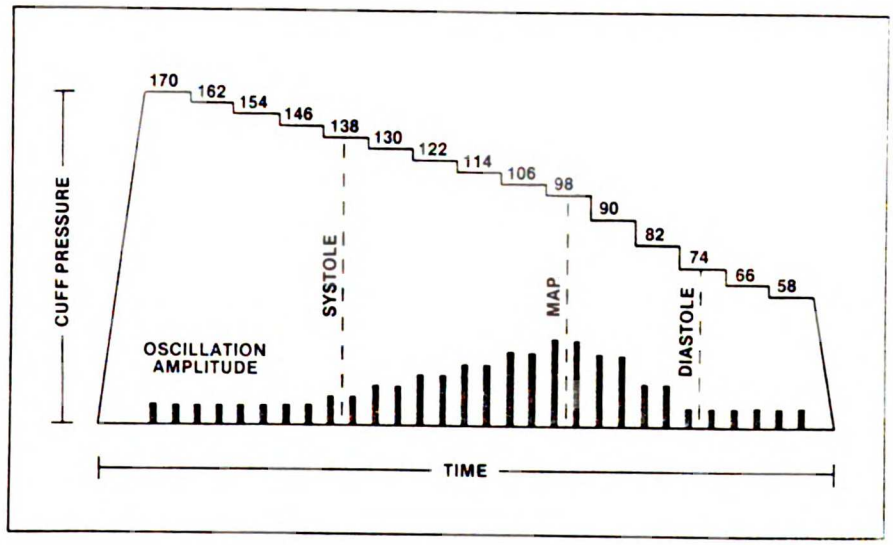
Appendix F

Phase I & II Data Collection Sheet

CODE #_____ D Cuff___Arm___ IA Cath___Arm___ IV Access_____	INTRA-OP / POST-OP NN'91 In: Colloid_____ Crystalloid_____ Out: Urine_____ Blood_____								
IA BP #1A #1B Mean									
Intra Aortic BP									
Dinamap BP									
Dinamap HR									
Monitor HR									
Temp									
Respirations									
FiO_2 Method Settings O_2 Sat									
Meds Given									
Crystal/Colloids									
Arrythmias									
Position									
HOB									
Activity									
Dynamic Response Frequency Damping Coefficient									
Waveform									

Appendix G

Diagram of Dinamap© Estimation of Systolic, Diastolic, And Mean Arterial Pressure



CRITIKON, INC.

DINAMAP™ ADULT/PEDIATRIC and NEONATAL VITAL SIGNS MONITOR OPERATION MANUAL

(reprinted from Dinamap operator's manual with permission of Critikon, Inc. Tampa, FL.)

Appendix H

Manufacturer Cuff Size Recommendations

CUFF TYPE	CUFF SIZE/ LIMB CIRCUMFERENCE
Neonate #1	3.1 cm—5.7 cm
Neonate #2	4.3 cm—8.0 cm
Neonate #3	5.8 cm—10.9 cm
Neonate #4	7.1 cm—13.1 cm
Neonate #5	8.3 cm—15.0 cm
Infant	8.3 cm—15.0 cm
Child	12.0 cm—19.0 cm
Small adult	17.0 cm—25.0 cm
Adult	23.0 cm—33.0 cm
Large Adult	31.0 cm—40.0 cm
Thigh	38.0 cm—50.0 cm

DINAMAP™ ADULT/PEDIATRIC and NEONATAL VITAL SIGNS MONITOR OPERATION MANUAL

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