Wheelchair Positioning and Pulmonary Function in Children with Cerebral Palsy

Lee Barks

University of South Florida

Follow this and additional works at: https://digitalcommons.usf.edu/etd

Part of the American Studies Commons

Scholar Commons Citation
https://digitalcommons.usf.edu/etd/616
Wheelchair Positioning and Pulmonary Function
in Children with Cerebral Palsy

by

Lee Barks

A dissertation submitted in partial fulfillment of the requirements for the degree of
Doctor of Philosophy
College of Nursing
University of South Florida

Major Professor: Audrey Nelson, Ph.D.
Jason Beckstead, Ph.D.
Mary Evans, Ph.D.
William Lee, Ph.D.

Date of Approval:
July 5, 2007

Keywords: posture, respiration, breathing, seating, postural management

© Copyright 2007, Lee Barks
Dedication

For my family and those who I am proud to call my friends,

You are all my heroes; you are very strong and very kind, and the value of your love and support is beyond measure.
Acknowledgments

With deepest gratitude, I acknowledge the members of my dissertation committee Dr. Audrey Nelson, Committee Chair and my mentor these past five years, your leadership and vision are extraordinary. Thank you for steady, reasoned, calm guidance, and unbelievable email responsiveness, as well as enthusiasm, encouragement, and countless unexpected favors. Dr. Jason Beckstead, for always having higher expectations of me than I did, and for so many patient explanations of statistical concepts. Dr. Bill Lee, for encouragement, teaching, and scholarliness in biomedical engineering, and especially for telling me I really could have been an engineer. Dr. Mary Evans, for your candid confession that you are still a curious scientist, for guidance in the intricacies of our academic program, for unflagging cheerfulness, and for encouraging me to remain true to my original goals. I also thank Tricia Holtje for her encouragement and wisdom over these past five years, as well as her unique skills and practical knowledge of research documentation, and Dean Patricia Burns, who saw potential in me. I have been richly blessed to learn from each of you.

Grateful acknowledgement is extended to Elaine Miller, editor of Rehabilitation Nursing for permission to reprint Chapters One and Two; to Shriners Hospitals for Children, Tampa, for participation as a study site; and to the Rehabilitation Nurses Foundation, who funded this study.
Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>List of Tables</td>
<td>iii</td>
</tr>
<tr>
<td>List of Figures</td>
<td>iv</td>
</tr>
<tr>
<td>ABSTRACT</td>
<td>v</td>
</tr>
<tr>
<td>Chapter One: Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Problem Statement</td>
<td>5</td>
</tr>
<tr>
<td>Purpose</td>
<td>5</td>
</tr>
<tr>
<td>Research Questions</td>
<td>6</td>
</tr>
<tr>
<td>Definition of Terms</td>
<td>6</td>
</tr>
<tr>
<td>Significance to Nursing</td>
<td>8</td>
</tr>
<tr>
<td>Research Progress</td>
<td>12</td>
</tr>
<tr>
<td>Construct One: Genesis of Deformity/Scoliosis</td>
<td>14</td>
</tr>
<tr>
<td>Construct Two: Scoliosis/Respiratory Dysfunction</td>
<td>15</td>
</tr>
<tr>
<td>Construct Three: Seated Position/Pulmonary Function</td>
<td>17</td>
</tr>
<tr>
<td>Seven Gaps in the Research</td>
<td>20</td>
</tr>
<tr>
<td>Conceptual Framework</td>
<td>22</td>
</tr>
<tr>
<td>Research Design</td>
<td>25</td>
</tr>
<tr>
<td>Objectives</td>
<td>26</td>
</tr>
<tr>
<td>Purpose</td>
<td>26</td>
</tr>
<tr>
<td>Research Questions</td>
<td>26</td>
</tr>
<tr>
<td>Variables</td>
<td>27</td>
</tr>
<tr>
<td>Power</td>
<td>42</td>
</tr>
<tr>
<td>Inclusion/Exclusion Criteria</td>
<td>43</td>
</tr>
<tr>
<td>Setting</td>
<td>44</td>
</tr>
<tr>
<td>Procedures</td>
<td>44</td>
</tr>
<tr>
<td>Approvals</td>
<td>44</td>
</tr>
<tr>
<td>Human Subjects Protections</td>
<td>45</td>
</tr>
<tr>
<td>Participant Recruitment</td>
<td>45</td>
</tr>
<tr>
<td>Data Collection</td>
<td>46</td>
</tr>
<tr>
<td>Data Analysis</td>
<td>50</td>
</tr>
<tr>
<td>Chapter Four: Results</td>
<td>52</td>
</tr>
<tr>
<td>Sample Characteristics</td>
<td>52</td>
</tr>
<tr>
<td>Verbal Ability and Motor Control</td>
<td>55</td>
</tr>
<tr>
<td>Findings</td>
<td>56</td>
</tr>
</tbody>
</table>
List of Tables

Table 1  Definitions of Terms 7
Table 2  Variables and Measurement Plan 27
Table 3  Data Collection Protocol 47
Table 4  Sample Composition 53
Table 5  Study Completion, Age, and Verbal Ability 56
Table 6  Effect of Seating Condition on RAW Means (SDs) 62
Table 7  Process Log Themes and Data 63
### List of Figures

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>Wheelchair Seating/Pulmonary Mechanics Logic Model</td>
<td>23</td>
</tr>
<tr>
<td>Figure 2</td>
<td>Prairie Reflections Seating Simulator</td>
<td>32</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Respironics Non-Invasive Cardiac Output Monitor</td>
<td>35</td>
</tr>
<tr>
<td>Figure 4</td>
<td>Viasys Jaeger Impulse Oscillometry System</td>
<td>38</td>
</tr>
<tr>
<td>Figure 5</td>
<td>Child with Viasys Jaeger Impulse Oscillometry System Attached to Facemask</td>
<td>39</td>
</tr>
<tr>
<td>Figure 6</td>
<td>Four HRI Facemasks</td>
<td>41</td>
</tr>
<tr>
<td>Figure 7</td>
<td>Total Airway Respiratory Means by Seating Parameter (+ or - SD), (n = 8)</td>
<td>59</td>
</tr>
<tr>
<td>Figure 8</td>
<td>Mean Minute Ventilation by Seating Parameter (+ or - SD), (n = 8)</td>
<td>60</td>
</tr>
<tr>
<td>Figure 9</td>
<td>Scatterplot of $R_{AW}$ by Seating Parameter (n = 8)</td>
<td>61</td>
</tr>
</tbody>
</table>
Wheelchair Positioning and Pulmonary Function in Children with Cerebral Palsy

Lee Barks

ABSTRACT

Background: In children with cerebral palsy (CP), poor trunk control fosters spinal deformity, pulmonary compromise (Canet, et al., 1998), increased health risks, and costs of long-term care (Braddock, 2001). Evidence links posture and pulmonary function, but influence of wheelchair parameters on pulmonary mechanics is unknown.

Objectives: 1) Determine relative contribution of five wheelchair configuration parameters to improvement in pulmonary mechanics--total airway resistance ($R_{aw}$), tidal volume, minute ventilation (MV), and deadspace to tidal volume ratio; 2) Describe recruitment and retention of school-aged children with CP; and 3) Discuss response of the participants to the protocol.

Method: This within-subjects, descriptive study employed a sample of 8 school-aged children with CP and flexible spines who could not sit alone. In a single session, participants experienced five seating parameters manipulated in a Prairie wheelchair simulator: 1) left and right upper extremity supports; 2) left and right lateral trunk
supports; 3) secured, level, derotated pelvis; 4) tilt in space; and 5) all four parameters.

The Viasys Jaeger Impulse Oscillometry System and Respironics Non Invasive Cardiac Output monitor (NICO) measured the dependent variable, pulmonary mechanics, via Hans Rudolph facemasks. Spasticity (by Modified Ashworth Scale), patient characteristics, and medications were recorded. A process log captured participant recruitment and retention challenges and response to protocol.

Results: Recruitment was challenging; retention was 50%. For this sample, despite lack of power, both $R_{AW}$ and MV improved with upper extremity and lateral trunk supports. Highest $R_{AW}$ was seen with total absence and total presence of the parameters, and secured, level pelvis. The data collection protocol was feasible for 50% of participants, none of whom could execute conventional measurement. Facemask and seating simulator acceptability were 75%, improving with participant verbal communication ability. The facemask seal was vulnerable to tilted positioning; 75% of participants became fatigued. $R_{AW}$ measures differed from manufacturer’s directions but were reliable.

Conclusions: The Prairie seating simulator, Jaeger IOS, Respironics NICO, and Hans Rudolph facemasks effectively measured pulmonary mechanics as a function of wheelchair seating parameters in this sample. Upper extremity and lateral trunk supports most greatly reduced $R_{AW}$, maintaining MV. Verbal children tolerated the procedure best.
Chapter One: Introduction

When children with severe cerebral palsy (CP) do not develop trunk control, including the ability to sit independently, a series of events unfolds. They experience functional difficulties with eating, speaking, moving about, and executing other activities of daily living. Their immobility is associated with increased health risks known as the “hazards of immobility” (Olson, 1967).

Over time, spinal deformity, or scoliosis, develops in individuals who lack ability to co-contract their paraspinal and abdominal muscles in a balanced fashion on right and left sides when in upright position. When trunk control is absent, the upper trunk collapses downward, with associated spinal deformity. In the beginning this spinal deformity is somewhat flexible, but over time it becomes “fixed” or immovable (Hale, et al., 1987; Shannon, et al., 1971). Without intervention, lateral and rotational spinal deformity develops in nonambulatory individuals who lack trunk control, generally becoming fixed during and after the adolescent growth spurt. Persons who never ambulate must be positioned extensively in wheelchairs for mobility, stability, and activities of daily living (Fraser, 1990; Cox, 1987). Morbidity and mortality develop chiefly in the respiratory system (Eyman, et al., 1990). As they age and increase in size, nonambulatory persons often move into long term care facilities with associated increases in cost (Braddock, 2001) and loss of daily family interaction.

---

1 Portions of Chapters One and Two have been published by this author (Barks, 2004). They are updated and reprinted with permission for this dissertation.
Recent prevalence data (United States (U.S.), 2003) show 258,000 have a diagnosis of infantile CP, and 2 per 1000 are under 18 years of age. Thirty-nine percent of these persons have had a related hospitalization annually, and 74% experienced limitation of activity (U.S. National Center on Health Statistics, 2003). All had experienced one or more related physician visits. For all racial groups, age of death with CP as an underlying cause is significantly younger than in the general population (United CP, 1995). Death from respiratory causes is listed as the leading cause of death in this group (42.1%); in the non-disabled population, respiratory causes are not among the top four (United CP). *Healthy People 2010* states this goal: “Promote the health of people with disabilities, prevent secondary conditions, and eliminate disparities between people with and without disabilities in the US population” (U.S. Department of Health and Human Services, 2000, p. 7). For such persons, medical treatment alone is insufficient in improving function and respiratory outcomes. Finding a way to augment medical treatment of pulmonary issues through better positioning could be worthwhile and could also reduce health disparities.

Wheelchair seating for people with CP and scoliosis is the most prevalent form of upright positioning. Proper wheelchair positioning appears simple but can be deceptively complex. It may either be “adaptive,” conforming to the prevailing posture of the disability and gravity’s pull, or it may be strategic and “therapeutic,” when the main goal is to prevent or reverse development of deformity (Fraser, et al., 1990; Cox, 1987). Each supporting surface of a wheelchair contributes to the resulting seated posture of a person placed in it. In practice, when wheelchairs are contoured to accommodate the scoliotic curve, the pelvis may be level and secure but upper extremity support is absent; or there
may be upper extremity support, but the pelvis is positioned obliquely with contoured surfaces. In either case, there may be mal-alignment of the trunk, such that there is reduced respiratory volume exchange and a resistive, rather than obstructive, pattern of breathing (Canet, et al., 1998). It is well known that reduced respiratory volume exchange can lead to hypoxemia, pneumonia, and atelectasis, which may all be seen in the population of those with CP. The mechanism producing increased resistance of the chest, with resulting reduced volume exchange in persons with scoliosis, has been summarized by Canet, et al. (p. 796). Possibly total airway resistance ($R_{AW}$) is increased, related to the spinal deformity, and is also responsible. At the present time, this is unknown, as is the effect on other pulmonary mechanics—tidal volume (VT), minute ventilation (MV), and deadspace to tidal volume ratio ($V_D/V_T$)—of wheelchair parameters supporting posture of the trunk. Tidal volume, minute ventilation, and deadspace to tidal volume ratio can be used to clinically interpret changes in total airway resistance.

In fact, many custom wheelchairs are made using contoured surfaces that hold the rib cage statically in its deformity. Such wheelchair seating parameters as securing and leveling the pelvis, lateral trunk supports, and upper extremity supports are not always used in wheelchair seating and may be critical factors in pulmonary mechanics. Leveling the pelvis and securing it to remain level provides a biomechanical base of support for the rest of the spine; lateral trunk supports may straighten the trunk, and upper extremity supports can lift weight of the upper trunk off the abdomen and dependent lung segments, improving volume exchange and decreasing restriction by allowing greater movement. Airway resistance may improve with trunk straightening.
In addition to genesis of scoliosis, extent of the problem, and possible role of parameters of wheelchair seating, there are considerable issues in studying the population with CP. Traditionally, spirometric testing, including plethysmography using a “body box,” has been used to conduct pulmonary function tests; however, this form of testing is not appropriate for children with CP for three reasons: (1) children with disabilities have difficulty complying with required spirometric protocols; (2) procedures for manipulating postural supports would be logistically impossible in a body box, and (3) primitive reflexive movement can prohibit reliable measurement. The Respironics Non Invasive Cardiac Output monitor (NICO) can be used passively by all ages for VT, MV, and \( V_D/V_T \) measurement, but another instrument is needed for the primary outcome variable, \( R_{AW} \). Although one instrument, the Jaeger Impulse Oscillometry System (IOS), has been marketed for testing \( R_{AW} \) in children, its factory-approved usage employs a mouthpiece which, although intended for use in children, cannot be used in children with CP, due to its oral intrusiveness. Made of hard silicone rubber and extending far into the mouth over the tongue, this mouthpiece can trigger primitive reflexes common in children with CP, such as tonic biting, gagging, and uncoordinated movements of lips and tongue, making consistent measurement potentially noxious and unreliable.

A silicone facemask may be used to obtain measures with the IOS and NICO, if an adequate seal is obtained, although obtained \( R_{AW} \) measures may not correspond to usual clinical values. \( R_{AW} \) measures could be expected to increase because the surface of the face, lips, tongue, and inner surface of the facemask could provide some increased resistance to airflow. This resistance could be greater than the resistance of the recommended method, in which the mouthpiece is placed into the mouth at about mid-
tongue. Finally, the Waugh protocol (2004) contains at least nineteen possible wheelchair
determinants of posture: pelvis support; two upper extremity supports; three lateral trunk
supports; tilt in space support; left and right seat depths; seat width; back rest height; left
and right leg rest lengths; left and right seat to leg rest angles; right and left hip
abduction/adduction; tilt in space; and headrest/neck flexion or extension.

*Problem Statement*

The cumulative effect of poor trunk control and the inability to sit independently can lead
to spinal deformity and pulmonary compromise in children with disabilities including
severe CP (Canet, et al., 1998). This postural instability limits mobility, with resultant
health risks and costs of long-term care (Braddock, 2001). For persons lacking trunk
control, supporting surfaces, including wheelchair parameters, dictate posture. Although
some evidence links posture and pulmonary function, the extent to which wheelchair
parameters influence pulmonary mechanics in seating of children with disabilities is
largely unknown.

*Purpose*

The purpose of this study was to estimate the relative importance of five wheelchair
configuration parameters as predictors of pulmonary mechanics improvement, reflected
in total airway resistance of school-aged children with CP who cannot sit alone but have
flexible spines. These configuration parameters were: (1) left and right upper extremity
supports; (2) left and right lateral trunk supports; (3) secured, level, and derotated pelvis;
(4) tilt in space; and (5) presence of all four parameters (“totally supported”).
Research Questions

The questions to be answered in this study are:

1. What is the relative contribution of each of five wheelchair parameters to improvement in pulmonary mechanics?

2. What are the challenges associated with subject recruitment and retention in a sample of school-aged children with CP?

3. What is the response of children with CP to the data collection protocol?

Definition of Terms

For purposes of this study, terms are defined and listed in Table 1 on the following page.
Table 1  

**Definition of Terms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deadspace to tidal volume ratio (V_D/V_T)</td>
<td>A pulmonary convention denoting the ratio of the volume of gas contained in the trachea, bronchi, and bronchioles (which do not participate in gas exchange), divided by the tidal volume. Pulmonary convention is V_D/V_T.</td>
</tr>
<tr>
<td>Planar system</td>
<td>A positioning system in which cushioned, planar surfaces passively apply some force to a body part or parts. Generally, force applied is equal to the force of gravity such as in an upper extremity support or armrest.</td>
</tr>
<tr>
<td>Pulmonary function</td>
<td>Capability of the pulmonary system to function, measured by clinical laboratory tests such as forced expiratory volume in 1 second (FEV1), the volume of gas measured in one second of forced exhalation. Generally, pulmonary function measures require the participant’s ability to actively engage in volitional physical responses. Children with CP may or may not be capable of such responses. (Often, the term <em>pulmonary function</em> also includes measures of pulmonary mechanics, but pulmonary function includes at least some volitional response. It does not refer to any variables in this study; it is defined here only to distinguish traditional, clinical, pulmonary function measures from <em>pulmonary mechanics measures</em>.)</td>
</tr>
<tr>
<td>Pulmonary mechanics</td>
<td>Pulmonary measures of mechanical forces and volumes and their quotients in ventilation. In this study, these are total airway resistance (R_{AW}), tidal volume (V_T), minute ventilation (MV), and deadspace to tidal volume ratio (V_D/V_T). Participation may be passive; that is, some instruments that measure pulmonary mechanics do not require active, volitional responses.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Minute ventilation (MV)</td>
<td>A pulmonary convention denoting the amount of gas in liters exhaled from the airway in one minute, equal to the tidal volume multiplied by the respiratory rate. Pulmonary convention is MV.</td>
</tr>
<tr>
<td>Tidal volume (VT or VT&lt;sub&gt;E&lt;/sub&gt;)</td>
<td>A pulmonary convention denoting the amount of gas in milliliters exhaled from the airway in one exhalation. Pulmonary convention is VT or VT&lt;sub&gt;E&lt;/sub&gt;.</td>
</tr>
<tr>
<td>Total airway resistance (RAW, or R at 5Hz)</td>
<td>A pulmonary convention denoting the total resistance of the airway to gas flow, at 5 Hz frequency of oscillation. Measured in kPascals/L/sec.</td>
</tr>
<tr>
<td>Wheelchair parameters</td>
<td>Nineteen characteristics of a wheelchair that combine to shape the posture of a seated human body according to the Waugh protocol (2004). Six “wheelchair seating conditions” varied in this study include: one condition of each of the four wheelchair parameters, one condition of total absence of the four parameters (“unsupported”), and one condition of presence of all of the four parameters (“totally supported”).</td>
</tr>
</tbody>
</table>

**Significance to Nursing**

There is no unifying nursing mid-range theory of positioning despite widespread, strategic use of positioning to relieve pressure and protect skin integrity in immobile persons. Based on clinical intervention studies, nurses now position strategically for pneumonia and mechanical ventilation and Acute Respiratory Distress Syndrome (ARDS) (Yeaw, 1996; Bridges, 2001). In addition to nursing use of positioning in other conditions, positioning could be strategic for persons with disabilities due to the fact that various medical treatments, such as spinal surgery, often have limited success when used
alone. The primary goal of surgical treatments is to arrest progression of spinal
deformity, thereby reducing morbidity and mortality and improving quality of life.
Surgical interventions are associated with serious risks, are not always employed, and do
not appreciably reverse existing pulmonary compromise (Cassidy, et al., 1994).
Practitioners in the field know that surgically-placed rods can dissect out of the spine.
Therefore, there is still a need for upright, supported, seated positioning of individuals
who do not have trunk control. It is reasonable for a descriptive nursing study to inquire
into factors that may produce healthy pulmonary function, in support of future
interventions. Nurses have responsibility for positioning their patients and may do so
strategically to oppose the pull of gravity, prevent deformity, and assist pulmonary
mechanics. The effects of various wheelchair parameters on pulmonary mechanics have
not been definitively studied, and currently, the wheelchair industry does not show
evidence that positioning for adequate breathing is understood. In fact, many custom
wheelchairs are made using contoured surfaces that hold the rib cage statically in its
deformity. Such wheelchair seating parameters as securing and leveling the pelvis, lateral
trunk supports, and upper extremity supports are not always used in wheelchair seating
yet may be critical factors in pulmonary mechanics. Leveling the pelvis and securing it to
remain level provides a biomechanical base of support for the rest of the spine. Lateral
trunk supports may straighten the trunk; upper extremity supports can lift the upper
trunk’s weight from the abdomen and dependent lung segments, thus improving volume
exchange and decreasing restriction by allowing greater movement. Trunk straightening
may decrease airway resistance. These circumstances point to the need for development
of evidence-based nursing recommendations on seating parameters to support healthy pulmonary function.

Chapter One describes the genesis of scoliosis in children with CP who cannot sit alone and discusses morbidity and mortality for this group. Other than medical interventions, such as spinal stabilization surgery, there are few interventions for this problem, and surgical interventions are not always effective or restorative. Although this is a small population, disability is severe and expensive. It directly confers health disparity from the general population, along with separation of the individual from the family, as care demands rise with immobility. There are many parameters of wheelchair seating, and children with CP are a complex group to study. A within-subjects, descriptive study was proposed to test a new method for determining the extent to which wheelchair parameters may influence pulmonary mechanics.
Chapter Two: Review of Literature

This chapter presents a synthesis of the research literature in the domain of posture, particularly wheelchair seating, and pulmonary function in persons with CP who lack trunk control. An electronic search was conducted of PubMed, Ovid Medline, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases from 1966 through February 2007. Search terms included posture, body position, wheelchair, CP, pulmonary function, respira* and seat.* Ancestral searching and the ISI Web of Knowledge were then used to find studies citing Nwaobi and Smith (1986), who conducted a study of the effects of wheelchair seating on pulmonary function of children with severe CP.

The number of articles and websites reviewed was 107; an additional 16 articles or websites were reviewed about the instruments, with a total of 65 articles eventually used. In the synthesis, people with spinal cord injuries were excluded because their spasticity may be symmetrical, so that scoliosis may not develop. Those with spina bifida, including myelomeningocele, were also excluded. In spina bifida, there is some trunk control down to the level of the spinal defect, and the level of the defect can vary over most of the length of the spine. Resulting posture may differ from posture of persons with CP who lack control throughout the trunk, possibly affecting breathing. Other excluded research reports addressed body positioning, posture, and breathing in a host of

---

2 Portions of Chapters One and Two have been published by this author (Barks, 2004) and are updated and reprinted with permission for this dissertation.
other conditions and positions such as bariatrics, surgery, non-seated positions, and pulmonary function testing not useful for a population who cannot follow directions. Of the articles, 21 were primarily literature reviews, and 25 were research reports, which were evaluated using an abbreviated form of the Research Analysis Tool (RAT) (Moody, 2001). The RAT instrument systematically orders 35 characteristics of reported research and can be used to quantify studies. Only one of the articles concerned nursing theory, process, or interventions (Raven, 1989). The research reports fell into three main areas, or constructs: *genesis of deformity/scoliosis*, *scoliosis/respiratory dysfunction*, and *seated posture/pulmonary function*. In addition, a treatment approach identified as *postural management*, for which a review of the evidence base has been conducted (Farley, et al., 2003), was also reviewed and a robust link found between physiological function and posture.

*Research Progress*

Research into the three constructs—*genesis of deformity/scoliosis*, *scoliosis/respiratory dysfunction*, and *seated posture/pulmonary function*—has shown progress over the review time period from 1966 through early 2007. For each construct, for purposes of this study, the predominating conceptual model was physiologic. In some studies, physical therapists used, implied, and sometimes stated a model of “function” (Nwaobi, 1986; Myhr & vonWendt, 1991) In a function model, the treatment goal (and treatment effect) is function in activities of daily living; these studies were excluded because health or physiologic outcomes generally were not used as outcome measures. A physiologic model contrasts with a function model in that physiologic, or health,
outcomes may be precursors of function such as self-feeding, typing, sitting, and dressing. Each model has been the focus of research on wheelchair seating, but only a physiologic model is presented here.

In addition to differences between function and physiologic models, Fraser, Hensinger, and Phelps (1990) differentiated the concept of “adaptive” positioning or equipment, from “therapeutic.” The goals of adaptive equipment use and interventions are to accommodate a person’s disability and modify the environment; the goal of therapeutic interventions is to change the course of the disability. In this study’s model, then, the goal of every nursing intervention can be said to be therapeutic. The concepts of Fraser, et al. are important for nurses in helping to improve respiratory function through postural support by changing the course of trunk alignment, rather than accommodating abnormal posture.

The three constructs support this study in a logical progression: genesis of deformity/scoliosis; scoliosis/respiratory dysfunction, and seated positioning/respiratory function. These constructs are related in the following way: Lack of trunk control, which is present in spastic quadriparetic CP and other neuromuscular disorders, eventually fosters fixed spinal deformity, or scoliosis (Berven & Bradford, 2002; Letts, et al., 1992). In severe CP, scoliosis is associated with a restrictive pattern of respiratory movement and deficient pulmonary mechanics and pulmonary function (Ting & Lyons, 1963; Bjure & Berg, 1970). In the absence of normal pulmonary mechanics, the respiratory system is a known locus of morbidity and mortality (Nilsonne & Lundgren, 1968; Nachemsson, 1968); this is particularly true among persons with severe CP and scoliosis (Eyman, et al., 1990). If scoliosis and fixed deformity could be prevented, or if at least the individual
could be consistently positioned in alignment, much of the respiratory morbidity and mortality might be preventable. Customarily, this patient group is seated in wheelchairs for long periods daily. Therefore, wheelchair seating is of interest to nurses engaged in engineering respiratory health in this group, especially if such seating does not provide adequate alignment.

Construct One: Genesis of Deformity/Scoliosis

For the first construct, *genesis of deformity/scoliosis*, many authors have documented the genesis of spinal deformity in persons with neuromuscular disorders, including severe CP (Berven & Bradford, 2002; Letts, et al., 1992; Makley, et al., 1968). These authors note the collapsing nature of the spinal curves and development of associated deformity over time, all confirmed by clinical observation. Conversely, Frankeny, et al. (1982) showed that at least 30 minutes of daily stretching is required to result in muscle growth of normal and dystrophic muscle. It is well known that when stretching and movement are absent, the soft tissue of the spine becomes rigid. One requisite in prevention of deformity is balanced stretch of soft tissue on all sides of moveable joints; in order to maintain healthy muscle tissue, continued stretch is needed, on a daily basis. Cherry (1980) concluded that prolonged maintenance in a desired position to prevent or reverse deformity may be more effective than passive manual stretching (Passive Range of Motion), due to very brief periods of execution of the intervention. This conclusion applies to joints and muscles of the spine, as well as to other joints, and may suggest that nursing intervention to consistently position individuals lacking trunk control in spinal alignment is needed. While medical interventions have
focused on surgical spinal stabilization and orthotic bracing to halt deformity progression, these interventions have not prevented deformity on a large scale. More importantly, it is well known that scoliosis is associated with respiratory dysfunction, the second construct for consideration here. Taken together, these studies demonstrate a need for strategic positioning in sustained positions for immobile persons with CP to prevent deformity. This is therapeutic positioning; it is a foundation for the second construct.

**Construct Two: Scoliosis/Respiratory Dysfunction**

Many studies are concerned with *scoliosis/respiratory dysfunction*. Long ago, Itovici & Lyons (1956) and Bergofsky, et al. (1959) found scoliosis to be associated with decreased vital capacity and maximal breathing capacity, with restrictive patterns of movement and pulmonary function measures. Ting & Lyons (1964) found the same restrictive pattern with kyphoscoliosis as for lateral spinal curvature. In a study to measure static and dynamic lung volumes in subjects with CP, Bjure & Berg (1970) found respiratory dysfunction from respiratory muscle weakness, again with a restrictive pattern and a total lung capacity 85% of normal volume, with low maximal oxygen uptake. They studied seven- to twenty-three year olds with CP (n = 22). Their sample included patients with less severe disabilities, because they could voluntarily cooperate with spirometric tests. It also probably included, by stated age, a mixed group of postpubertal participants who had completed their pubertal growth spurts and already had fixed deformity, along with some who were still children. These studies are important, however, because they show the relationship between the architecture of the deformity and pulmonary mechanics, primarily restriction of movement and volume phenomena.
Nilsonne and Lundgren (1968) and Nachemsson (1968) noted remarkable cardiopulmonary morbidity and mortality among patients with scoliosis. Their studies are important in showing the seriousness of this problem. An inference may also be drawn that studies on scoliosis/respiratory dysfunction show that deficits culminate in increased need for nursing care, generally in costly long term care settings (Braddock, 2002).

After the 1960s, interventions to straighten the spinal curve(s) and influence respiratory function in the form of pulmonary mechanics have been the subject of research (Sevastikoglou, et al., 1976; Nwaobi & Smith, 1986; Noble-Jamieson, et al., 1986; Letts, et al., 1992; Cassidy, et al., 1994; Leopando, et al., 1999; Tangsrud, et al., 2001;). Among these interventions are spinal stabilization surgery, such as Harrington rod insertion, Luque and other procedures, as well as use of positioning with rigid and soft orthoses and seating. Cassidy, et al. studied 37 persons with severe CP and scoliosis, evenly divided into patients with spinal fusions and patients without, in a mixed group of children and adults, ages 11-27 years, most of whom were post-pubertal. Surgery in the fused group did not improve pulmonary function after problems had developed, so prevention is of primary importance, particularly in children whose spines are generally still flexible until the pubertal growth spurt (Samilson, 1972). Even when medical interventions such as surgery or bracing are used, there is still a need to consistently support the trunk in alignment to reduce lateral and gravitational force on the spine when seated and ensure normal pulmonary mechanics. Rigid orthoses have been found to decrease tidal volume or vital capacity (Sevastikoglou, et al.; Noble-Jamieson, et al.; Tangsrud, et al.), and although soft orthoses have not reduced lung volumes, they have also produced no improvement (Letts, et al.; Leopando, et al.). This fact increases the
importance of noninvasive nursing solutions, underscoring nursing responsibility for strategic positioning to prevent reduced volume exchange, and raising the question of how straightening the spine by positioning might improve pulmonary mechanics if soft orthoses do not.

Construct Three: Seated Position/Pulmonary Function

Nwaobi and Smith (1986) compared the effects of nonadaptive and adaptive seating on pulmonary function in children with CP, using a within-subjects, quasi-experimental design, spirometry, and both a sling-seat wheelchair and an optimally-supported seating system. A convenience sample was used (n = 8), with sequence of testing randomized. Mean Vital Capacity (VC), mean Fractional Expired Volume at 1 second (FEV₁) as a percent of Vital Capacity, and Mean Expiratory Time all increased significantly in “adaptive” seating, with differences in pulmonary measures in the two types of seating measured by t tests, with p<.05. Post hoc power analysis showed that this study was sufficiently powered due to very large effect sizes (Cohen’s d of 2.07 for VC and 1.53 for 1-second FEV₁) although there was a small effect for expiratory time (Cohen’s d = 0.37). The sample included children aged 5-12 years with spastic CP. Selection of children uniformly lacking trunk control and possessing only CP is important. Postures in other neuromuscular disorders may be dissimilar, according to the level of spinal defect in spina bifida and variations in muscle tone among muscular dystrophy subjects or spinal muscle atrophy subjects. These variations in posture could affect the mechanics of breathing. Although this study was well-powered despite small sample size, its limitations are that only participants who could actively assist with
voluntary tests of pulmonary function were used, thus excluding the most disabled children with the most pathology who could most benefit from therapeutic positioning. This study also did not measure airway resistance, which may be increased when the weight of the unsupported upper trunk presses on the dependent portions of the lung or whenever the trunk is not straight. The study showed improvement with the aggregate of the pulmonary function variables, but it did not distinguish which of the multiple properties of adaptive wheelchair seating produced improvement.

Redstone’s study (2004) is notable because it inquired into the effects of seating position on respiratory patterns of preschoolers with CP. However Redstone’s interest was in respiration and positioning the individual for speech production, a function model, rather than physiologic/health outcomes. The Nwaobi and Smith study (1986) and the Redstone study are important because they are the first and only studies to link scoliosis, pulmonary function, and CP.

In addition to these studies, Druz and Sharp (1981) suggested that gravity as a stimulus for stretch of human respiratory muscles and increased muscle activity may explain the influence of body position on ventilation and volume exchange. They asked why chest movement is greater in upright postures and abdominal movement is greater in supine positions; they found a “combination of increased activation of rib cage inspiratory muscles plus greater activation of the diaphragm” (p. 1552) in upright positions. Human studies about respiratory function and posture from 1960 to the present also included Crosbie and Myles (1985), Dean (1985), Geubelle and Goffin (1962), Hough (1984), Landers, et al. (2003), and Moreno and Lyons (1961). Although Hough and Dean published review articles, all authors used physiologic measures to explain or
quantify effects of posture on respiratory function. In prospective studies, Moreno and Lyons (1961), Geubelle and Goffin, Crosbie and Myles, and Landers, et al. measured and compared the effects of seated, prone, and supine postures, among some others, on respiratory volumes. Moreno and Lyons (1961) found ventilation in prone and seated almost identical but found a statistically significant reduction in ventilation from seated to supine. Geubelle and Goffin also found prone and seated values virtually equal in children and a significant reduction in functional reserve capacity from seated to supine, in both children and adults. Crosbie and Myles found significant differences in ventilation in seated, supine, prone with hips elevated, and slumped-at-45-degrees-seated postures. They noted the sameness of this slumped posture and sitting upright in bed and that slumping appears to cause decreases of 12% and 15 % respectively in both vital capacity and forced expiratory volume in 1 sec (FEV₁). Landers, et al. found statistically significant increases in tidal volume and minute ventilation in seated upright as opposed to slumped postures. The posture of the insufficiently-supported trunk of a person with scoliosis may be equivalent to kyphotic slumping. This slumping from lack of support may have the same effects on ventilation as any other slumped posture. Conversely, the properties of an effective seated posture produce better ventilation in seated than slumped postures. A review by Pynt, et al. (2001) evaluated properties of “optimal seated posture” for the lumbar spine of healthy adults, defined as posture associated with intervertebral disc health and absence of pain. This posture was slightly lordotic, with a slightly forward-tilted pelvis and periodic movement about. For immobile persons who do not move themselves about, the hips must be placed against the seat back in order to provide
a base of support for the spine and to avoid slumping, and a seatbelt may be needed to maintain seated posture.

Presumably, in both the lateral spinal curvature of scoliosis and kyphotic slumping, additional weight of the head, neck, and upper chest is unsupported by the spine. This constitutes a hypothetical load arm that places additional weight and force on the distal lungs (alveoli), restricting both abdominal and chest wall expansion and probably also increasing both alveolar and total airway resistance. In order to measure the effect of various supports in straightening the posture, then, it is germane to measure total airway resistance ($R_{AW}$) and the volume of gas exchanged over a unit of time (MV). In clinical research, these measures could be included in a standard protocol of pulmonary function studies that requires the participant to inhale and forcefully exhale. Many people in the population of persons who lack trunk control, those with great pulmonary pathology, are unable to execute this maneuver, excluding them heretofore from research into these issues. For this reason, a measurement method that simply yields physical measures of pulmonary mechanics should be used, rather than one that also includes the functional ability to volitionally produce these measures, pulmonary function tests.

**Seven Gaps in the Research**

Based on this systematic literature review, seven gaps in the research were identified:

1) Although Nwaobi and Smith’s study (1986) was innovative and sufficiently powered with very large effects in vital capacity change and FEV$_1$ improvement, it aggregated the specific wheelchair seating properties that produced change. Future
studies need to characterize changes in pulmonary function according to specified wheelchair seating parameters.

2) Many studies (Makley, et al., 1968; Noble-Jamieson, et al., 1986; Letts, et al., 1992; Sevastikoglou, et al., 1976) used a sample of various ages with mixed etiologies for absent trunk control. A homogeneous sample of children with CP who have not experienced their pubertal growth spurt and who lack trunk control is needed, however, so that postures are similar before and after correction, and influence on pulmonary mechanics is attributable to the treatment, not to postural differences. These postures are also similar to those of the immobile elderly and may inform later studies.

3) Studies using spirometry (Leopando, et al., 1999; Nwaobi & Smith, 1986) were limited to participants who could cooperate with traditional pulmonary function measures and excluded the most compromised individuals most likely to benefit from intervention. Future studies need to test other measurement approaches for pulmonary function to capture subjects with more severe disabilities.

4) Except for the Leopando, et al. study (1999), airway resistance has not been widely used to reflect pulmonary mechanics in these studies. Total airway resistance ($R_{AW}$) is potentially important in reflecting trunk straightness and in allowing sufficient volume exchange.

5) A simple, short procedure is needed, both for positioning and for some measuring of pulmonary mechanics. The Leopando, et al. study used a precise but lengthy method to measure pulmonary mechanics, sometimes requiring up to five hours (G. Rempel, personal communication, February 12, 2004), thus possibly resulting in fatigue and change in outcome measures. A simpler but precise procedure is needed.
6) Except for that of Nwaobi and Smith (1986), studies did not determine the role of multiple wheelchair seating parameters in multiple planes in producing pulmonary outcomes. The difficulty is to meaningfully evaluate one parameter at a time because multiple parameters probably produce respiratory movement in multiple planes.

7) In the literature, medical research has attempted various interventions to find adequate treatment. To inform intervention studies with this population, a preliminary study is needed to test a new method of measuring pulmonary mechanics in persons who cannot comply with the testing and to determine the specific positioning variables that may predict improvement in pulmonary mechanics.

**Conceptual Framework**

For each of the three constructs, the predominating conceptual model is a physiologic model. Intentionally positioning the individual to maintain passive stretch and gain range in joints that have no active motion (Samilson, et al., 1972; Frankeney, et al., 1983; Cherry, 1980) may decrease internal physiologic deficits in respiratory and other systems by allowing movement and internal space. This approach is congruent with Orem (2001) in supplying trunk support to address the Self-Care Deficit of lack of trunk control and meet the Universal Self-Care Requisite of Air. There is a need for sufficiently-powered research with children with CP that can fill gaps in understanding of respiratory function for this group. This study is intended to provide the next level of evidence in the research, with particular attention to the seating properties that may be associated with any changes in pulmonary mechanics. In the future, greater understanding of the physiologic outcomes of specific properties of wheelchair
Positioning may allow research of more effective interventions that reduce associated morbidity and mortality, improve health and quality of life, and decrease costs. A logic model is presented in Figure 1.

### Figure 1. Wheelchair Seating/Pulmonary Mechanics Logic Model.

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Environment/Wheelchair Seating Parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Age</td>
<td>• L Arm Rest Height</td>
</tr>
<tr>
<td>• Gender</td>
<td>• L Lower Lateral Trunk Support Ht.</td>
</tr>
<tr>
<td>• Medications</td>
<td>• R Lateral Trunk Support Ht.</td>
</tr>
<tr>
<td>• Spasticity</td>
<td>• L Upper Lateral Trunk Support Ht.</td>
</tr>
<tr>
<td>• Ethnicity</td>
<td>• Leg Rest Length</td>
</tr>
<tr>
<td>• Neurological Deficits</td>
<td>• Seat to Leg Rest Angle</td>
</tr>
<tr>
<td></td>
<td>• R Hip ab-, adduction</td>
</tr>
<tr>
<td></td>
<td>• L Hip ab-, adduction</td>
</tr>
<tr>
<td></td>
<td>• Tilt in Space Angle</td>
</tr>
</tbody>
</table>

### Pulmonary Mechanics

- Total Airway Resistance ($R_{AW}$)
  - (Improved: decreased from usual)
- Tidal Volume (VT)
  - (Improved: increased from usual)
- Minute Ventilation (MV)
  - (Improved: increased from usual)
- Deadspace to Tidal Volume Ratio (VD/VT)
  - (Improved: Decreased from usual)

### Health Outcomes:

- Physiologic Function
- Functional Status
- Morbidity
- Mortality

Note: **Shading** denotes variables used in this study. All other variables were held constant.
Patient characteristics such as age, gender, ethnicity, medications influencing muscle tone, degree of spasticity, and neurological deficits may also be predictors of pulmonary mechanics. Although effects of wheelchair seating properties are unknown, Figure 1 depicts their hypothesized relationship as predictors of pulmonary mechanics measured in $R_{AW}$, $VT$, $MV$, and $V_{D}/V_{T}$. Under these circumstances, pulmonary mechanics may be observed as usual for the individual in an unsupported position or improved from the unsupported position as the trunk is straightened. Pulmonary mechanics may be predictors of the health outcomes of physiologic function, functional status, morbidity, and mortality, but these outcomes will not be studied in the proposed study. This is a physiologic model. Currently lacking in the scientific literature, an intervention study is anticipated, building on this description of relationship of wheelchair seating properties to pulmonary mechanics. The independent variables were the unsupported condition (baseline) and wheelchair seating parameters; the patient characteristics may be treated as covariates in analysis. The dependent variable was pulmonary mechanics, reflected in $R_{AW}$, and minute ventilation (MV) will clinically explain some changes in $R_{AW}$. In the future study, tidal volume ($VT$) and deadspace to tidal volume ratio ($V_{D}/V_{T}$) will also be used to explain changes in $R_{AW}$.
Chapter Three: Method

Research Design

The purpose of this descriptive, within-subjects study was to estimate the relative importance of five wheelchair configuration parameters as predictors of pulmonary mechanics, reflected in total airway resistance of school-aged children with CP who cannot sit alone but have flexible spines. During a single data collection session, participants were placed in a wheelchair simulator in which five seating parameters were manipulated; pulmonary mechanics served as the dependent variable, using the Viasys Jaeger Impulse Oscillometry System, Respironics NICO, and Hans Rudolph facemasks (Appendix D). Spasticity was measured using the Modified Ashworth Scale. Patient characteristics and medications were recorded. A process log was used to capture challenges associated with subject recruitment and retention as well as the subjects’ responses to the data collection protocol.

A wheelchair seating simulator provided six conditions of support (four experimental wheelchair parameters and one condition with all four parameters present, plus one control condition with none), employed independently during configuration of the simulator for each participant. The order of introduction of the four experimental wheelchair parameters—two upper extremity supports; two lateral trunk supports; level, de-rotated pelvis secured with seatbelt; and tilt in space—was randomized. These parameters were intended to serve as predictors of change in the dependent variable,
pulmonary mechanics, measured in four components, $R_{AW}$, VT, MV, and $V_D/V_T$.

However, VT, MV, and $V_D/V_T$ were included only to provide further clinical explanation of potential differences in $R_{AW}$.

**Objectives**

The study had three objectives: 1. determine the relative contribution of each of five wheelchair configuration parameters to improvement in pulmonary mechanics (total airway resistance ($R_{AW}$), tidal volume (VT), minute ventilation (MV), and deadspace to tidal volume ratio ($V_D/V_T$)); 2. describe the challenges associated with subject recruitment and retention; 3. discuss the response of children with CP to the data collection protocol.

**Purpose**

The purpose of this within-subjects, descriptive study was to estimate relative importance of five wheelchair configuration parameters as predictors of pulmonary mechanics, reflected in total airway resistance of school-aged children with CP who cannot sit alone but have flexible spines.

**Research Questions**

The questions to be answered in this study are:

1. What is the relative contribution of each wheelchair parameter to improvement in pulmonary mechanics?

2. What are the challenges associated with subject recruitment and retention?
3. What is the response of children with CP to the data collection protocol?

*Variables.* Table 2, below, presents a list of study variables including the domain, operational definitions, data source, and type of variable.

**Table 2**

*Variables and Measurement Plan*

<table>
<thead>
<tr>
<th>Domain</th>
<th>Variable</th>
<th>Operational Definition</th>
<th>Data Source/Recording</th>
<th>Type, Treatment of Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient</td>
<td>Age</td>
<td>Age in years</td>
<td>Interview with parent</td>
<td>Continuous</td>
</tr>
<tr>
<td>Characteristics</td>
<td>Gender</td>
<td>Male/female</td>
<td></td>
<td>Dichotomous</td>
</tr>
<tr>
<td></td>
<td>Ethnicity</td>
<td>White, non-Hispanic; African American; Hispanic; Other</td>
<td></td>
<td>Nominal</td>
</tr>
<tr>
<td>Medications</td>
<td></td>
<td>Names of currently used medications that can reduce muscle tone</td>
<td></td>
<td>Nominal</td>
</tr>
<tr>
<td>Spasticity</td>
<td>Greatest amount of spasticity present in body, as measured by Ashworth scale.</td>
<td>Direct observation</td>
<td>Ordinal</td>
<td></td>
</tr>
<tr>
<td>Environment/</td>
<td>Unsupported</td>
<td>Seated in wheelchair seating simulator with only seat surface for support and hands of investigator to hold onto surface; without back.</td>
<td>Direct observation; Prairie Reflections; Seating Simulator</td>
<td>Dichotomous (support present or absent); Predictor variable</td>
</tr>
<tr>
<td>Domain/Environment/Wheelchair Seating Parameters 1 – 4)\textsuperscript{a}</td>
<td>Partially Supported</td>
<td>Operational Definition</td>
<td>Data Source/Recording</td>
<td>Type, Treatment of Variable</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Pelvis Support</td>
<td>No conditions of support present except head, seat, back, leg and foot support; one condition of partial support\textsuperscript{b} introduced at a time, then removed for introduction of next condition.</td>
<td>Direct Observation</td>
<td>Dichotomous, (support present or absent); predictor variable</td>
<td></td>
</tr>
<tr>
<td>Upper Extremity Supports (2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral Trunk Supports (2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tilt in Space Support</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other wheelchair seating parameters held constant in this study.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Operational Definition</th>
<th>Data Source/Recording</th>
<th>Type, Treatment of Variable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seat depth</td>
<td>Depth of seat; equal to length of longest of both femurs at hip flexion of 100 degrees</td>
<td>Direct observation &amp; recording of presence of these conditions within subjects, as set into seating simulator, using Waugh Protocol (2004). (These conditions will vary between subjects, but will be constant within subjects.)</td>
<td>Dichotomous; presence or absence of equal measures; Constant within subjects, across all conditions of support</td>
</tr>
<tr>
<td>Seat width</td>
<td>Width of seat, equal to width of buttocks in hip flexion, no wider</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back rest height</td>
<td>Height of back rest at the participant’s shoulder level</td>
<td>Waugh Protocol</td>
<td></td>
</tr>
<tr>
<td>Leg rest length (Left and Right leg rests)</td>
<td>Length of foot support from the seat surface, equal to length of the lower leg from lower surface of thigh to bottom of foot, for each leg, ankle dorsiflexed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Domain</td>
<td>Variable</td>
<td>Operational Definition</td>
<td>Data Source/Recording</td>
</tr>
<tr>
<td>-------------------</td>
<td>-----------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Environ-</td>
<td>Seat to leg rest angle</td>
<td>Angle of leg rest to seat, equal to angle of tibias to femurs of both legs, seated. (90 degrees for all).</td>
<td>Same as above</td>
</tr>
<tr>
<td>-ment/</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheelchair</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seating</td>
<td>Right and left hip abduction/adduction</td>
<td>Positioning of thighs parallel to seat sides, maintaining seat width as stated above.</td>
<td>Same as above</td>
</tr>
<tr>
<td>Parameters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Continued</td>
<td>Tilt in space</td>
<td>Seat and back will be tilted as a unit, 30 degrees from vertical for each participant.</td>
<td>Same as above</td>
</tr>
<tr>
<td></td>
<td>Headrest position</td>
<td>Headrest will be present throughout all conditions, placed at a height equal to the child’s neck length, occiput to top of shoulders, in same plane as seat back.</td>
<td>Same as above</td>
</tr>
<tr>
<td></td>
<td>Totally supported</td>
<td>All conditions of support present</td>
<td>Direct observation of presence of all conditions of support</td>
</tr>
<tr>
<td></td>
<td>(Wheelchair Seating Parameter 5,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>manipulated in this study)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Domain</td>
<td>Variable</td>
<td>Operational Definition</td>
<td>Data Source/Recording</td>
</tr>
<tr>
<td>-----------------</td>
<td>---------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>Total airway resistance ($R_{aw}$)</td>
<td>As measured with Jaeger IOS, Respironics NICO, and reusable Hans Rudolph facemask</td>
<td>Observation &amp; recording of IOS &amp; NICO measures, in each positioning</td>
</tr>
<tr>
<td>Mechanics</td>
<td>Tidal volume (VT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Minute ventilation (MV)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dead space to tidal volume ratio (VD/VT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subject</td>
<td>Subject recruitment and retention</td>
<td>Challenges associated with study recruitment and retention of children and parents to the study.</td>
<td>Direct observations recorded in Process Log</td>
</tr>
<tr>
<td>Responses</td>
<td>Data collection protocol</td>
<td>Children’s response to equipment (facemask, simulator, IOS) and data collection procedures.</td>
<td></td>
</tr>
</tbody>
</table>

Notes.  

a One seating condition (unsupported) and five wheelchair parameters were manipulated in this study.  
b With: pelvis secured with seat belt at 60 degrees to horizontal, snug (admits 2 fingers only under belt); anterior superior iliac spines (ASIS’S) level, with a line through both ASIS’S congruent with frontal plane & parallel to level seat surface; armrests placed directly under elbows/under shoulders, at a distance from the seat equal to the height of the elbow from seat when the pelvis is at neutral or in anterior tilt; 2 trunk supports in place directly at alternating sides of the trunk, with first one at apex of scoliotic curve if present; the seat and back tilted as a unit, backward in space, 30 degrees from vertical; and the headrest present, with support height adjusted to the length of the participant’s neck to shoulder, at the occiput, and no recline from vertical.
Instruments and Reliability

*Prairie Reflections Seating Simulator.* The fully adjustable Prairie Reflections Seating Simulator (Prairie Seating Corporation, 2007), a clinical tool, provides multiple surfaces as described by the list of seating parameters and variables; all measurements were made manually with a goniometer or metal tape measure. The simulator also has a gauge at the seat to backrest angle vertex giving a measure in degrees of tilt in space used to measure 30 degrees backward tilt from vertical. It was zeroed daily. The investigator was trained and certified to measure and apply the seating parameters uniformly by two experts in the Waugh protocol (Waugh, 2004; Shaw, 2006) to + or – 10% of the expert’s measurements. The simulator was decorated with a large spangled hat and ladybug, flower, and bird hand puppets to appear softened and more child-friendly.
Figure 2. Prairie Reflections Seating Simulator.

The decorated simulator used in this study is shown on the left, and a proprietary photograph (Prairie Seating Corporation, 2007) on the right.

Respironics Non-Invasive Cardiac Output (NICO) Monitor. The NICO measures flow rate and pressure of respired gas flowing through a fixed orifice differential pressure pneumotachometer. A capnostat sensor passes an infrared beam through a tubing sample of respired air, with carbon dioxide (CO₂) sensitively absorbing the infrared light energy, in direct proportion to CO₂ concentration. A photodetector measures and subtracts the remaining light energy with resultant difference equaling the amount of carbon dioxide in the tubing sample. NICO software compensations in the monitor allow accurate computation of volume and flow of respired gas (Respironics, 2007). This technology is distinguished by its infrared beam and effective isolation of the proprietary sensors from
respiratory secretions, along with its accuracy and point of measurement at the immediate external airway. Accuracy is ensured by several mechanisms. First, the electronic capnostat signal of CO₂ concentration is compared to a signal of a known CO₂ concentration stored at the factory in the monitor’s memory, requiring no calibration by the user. Second, single-use flow and pressure sensors are also correlated to factory-installed flow measurements stored inside the monitor, and user calibration is not required, due to ability of the plastic injection mold to produce precision sensors. The pressure transducer automatically “zeroes” to correct for changes in ambient temperature and electronics, with software compensations. This was done every morning at startup. Third, carbon dioxide elimination is calculated based on a mathematical integration of flow and CO₂; both measures are obtained from sensors at the same point on the external airway itself, rather than some other point in the tubing (Respironics, 2007c; Respironics Novametrix 2003). The sensor and short tubing are disposable. Pediatric size for persons between 15 and 45 pounds (Reference number 9766) and adult size for persons over 45 pounds (Reference number 9767) were used in this study, after each participant was measured for weight and height. Published proprietary data state CO₂ sensor accuracy is + or – 2 mm Hg for 0-40 mmHg, + or – 5% of reading for 41-70 mmHg, and + or – 8% of reading for 71-150 mm Hg. Accuracy of the flow [volume] sensor is + or – 3% of the reading or .5 L/min (Respironics, 2003a).

Other NICO measures (MV, VT, and V₅/VT) are calculated by the instrument, based on end tidal CO₂ (ETCO₂) and volume measurement. Minute ventilation (MV) is measured in liters per minute, tidal volume (VT) in milliliters or liters per one breath, and deadspace to tidal volume ratio (V₅/VT), or physiologic deadspace, as a numerical ratio,
calculated by the NICO to two decimal places. In order to obtain $V_D/V_T$, an adjustment value of 5 mmHg for less healthy individuals is input to each ETCO$_2$ measure, and this was done for each position, for each participant, according to the manufacturer’s instructions (Respironics, 2007b; G. Williams, personal communication, October 27, 2004). (Only values for MV were used in addition to $R_{AW}$ values in the analysis for this study as values for VT and VD/VT were designed to assist with further clinical interpretation of the $R_{AW}$ measures.) Independent evaluation of NICO’s precursor, VenTrak1550, found accuracy within clinically acceptable limits (Bak, et al., 2002). The manufacturer’s representative, a biomedical engineer, conducted training and certified the investigator in use of the NICO System (Williams, 2006). Both NICO and IOS displayed measurements electronically until recorded and purged.
Figure 3. Respironics Non-Invasive Cardiac Output Monitor.
The NICO monitor, shown in Figure 3 with cartoon sticker, includes a transcutaneous capillary oxygen concentration sensor (“pulseox”), which was used to monitor participants’ heart rate and peripheral oxygen saturation during the study procedure. Oxygen capillary saturation of 92% or less was used to identify desaturation and excuse the participant. This criterion was provided by a pediatric pulmonary researcher (P. Kuster, personal communication, February 17, 2005). No child’s oxygen saturation dropped below 95% at any time.

**Pulmonary Measurement—NICO.** The recommended locus for sampling in NICO measurement of VT, MV, and \( V_D/V_T \), is immediately proximal to the airway, and a facemask is acceptable. No difficulty was experienced with the NICO in collecting data at 30 degrees tilt in space, because the tubing and sensor do not need to be presented solely in the frontal plane and were quite mobile. Only the flow sensor was used; it was not necessary to use the Fick rebreathing method (with a rebreathing loop) to obtain reliable data for VT, MV, and \( V_D/V_T \); the rebreathing loop is used primarily to obtain a CO2 baseline for cardiac output measures (Respironics, 2007b). The only requirement was to allow approximately 30 seconds, or 8 breaths, for end tidal CO2 (ETCO2) determination, in order for the \( V_D/V_T \) measurement to be made and display on the screen. If insufficient breaths were exchanged for a determination, there simply was no display until a reliable ETCO2 value had been obtained and input. The NICO manufacturer (Respironics, Wallingford, CN) states that NICO ETCO2 is 3-5 torr, or mmHg below arterial ETCO2, so to obtain the \( V_D/V_T \) value, ETCO2 must be obtained and 3 to 5 mmHg added to it, with 5 added for individuals who are chronically challenged, and 3 for well individuals. A value of 5 was systematically added to ETCO2 for all \( V_D/V_T \) measures, for
all participants. VT, MV, and $V_D/V_T$ values were recorded as soon as displayed after 30 seconds or 8 breaths to get a representative measure of the parameter efficiently and limit participant burden due to duration of the study. For this reason, no additional time for “settling” was allowed, and the measurement was taken immediately as positioned by the investigator.

The Viasys Jaeger Impulse Oscillometry System (IOS). The Viasys Jaeger IOS uses a pseudorandom noise signal in a normal tidal breathing column (“forced oscillation technique”) with advanced digital signal analysis. An attached computer uses Fast Fourier Transforms to fit the forced oscillation technique data to algorithms and deliver measurements of airway status during tidal breathing previously available only with more invasive procedures. The IOS allows determination of total airway resistance ($R_{AW}$) in kiloPascals/Liter/second, with virtually no active patient participation, only relaxed breathing. $R_5$, or resistance at 5 Hz, was used in this study as the measure of total airway resistance. Accuracy of the IOS pneumotach is 0.2-12 Liters/second, + or –2%, with accuracy of the mouth pressure transducer [error rate] of + or –2%. Disposable Viasys Microgard microbial filters, reference number 769344G, were used with the IOS. The IOS has been found to offer reliable measures in subjects who cannot comply (Horan, et al., 2001). An expert skilled in use of the IOS trained and certified the investigator in use of the Viasys Jaeger system at the Shands/University of Florida pulmonary neurophysiology laboratory (P. Davenport, personal communication, January 26, 2006).

An IOS volume calibration check was completed monthly, as recommended by the manufacturer in proprietary information (Viasys, 2000b).
Figure 4. Viasys Jaeger Impulse Oscillometry System.

The system is shown here with a filter/mouthpiece, arm, and computer. A facemask/airway is recommended by the manufacturer for IOS use with children; however, it proved unacceptable to the participants in this study by stimulating gagging in some. This study’s participants, who have CP and oral incoordination, were also unable to close their lips around it, to provide a seal, so a noninvasive replacement facemask by Hans Rudolph, Inc., providing an adequate seal, was found. This facemask design produced $R$ at 5Hz ($R_{AW}$) measures that were different from the software predicted values, but it was consistently applied to all participants, who served as their own controls, and it was not used for clinical testing, so the values obtained were deemed
reliable. In addition, the predicted software values were means for normally-abled individuals, for height, weight, age, and gender. No such means were offered as predicted values for individuals with disabilities. In order to reduce the shunt impedance of the cheeks, measurement protocol from the manufacturer (Viasys, 2000b) requires the patient to hold his hands against his cheeks; however, the study participants were unable to do so, and the HRI facemasks passively applied this pressure in the study.

Figure 5. Child with Viasys Jaeger Impulse Oscillometry System Attached to Facemask.

Pulmonary Measurement—IOS. The manufacturer states (Viasys, 2000a, p. 10) that it is possible for small leakages to occur at the corners of the mouth around the mouthpiece and lower the mouth pressure and recorded respiratory resistance measurement; however, the Hans Rudolph oro-nasal facemasks were used instead of the
Jaeger mouthpiece and a seal was scrupulously secured and monitored before measurement took place. With loss of the seal, the flow and pressure trend in the lower half of the screen display is lost, so that a clear display of red pressure tracing and green overlay of tidal breathing is not visualized, only an irregular, red, indistinct pattern. When this occurred, the seal was restored and a clear tracing visualized; if 30 seconds of data were obtained, the value was displayed onscreen and data were kept. This occurred for 3 participants retained in the completing sample. The same was true of obstruction of the airway with the tongue, which was observed on several occasions as an irregular red tracing without its green overlay and with markedly elevated $R_{AW}$ values on the screen display; this occurred for 2 participants who were excused. In either case, the participant was excused if 30 seconds of valid tracing could not be obtained with an observable seal for each parameter.

The IOS pneumotach and elbow piece are designed to be presented in the frontal plane, with the participant sitting upright. In the 30 degrees tilt in space condition, the facemask of some of the participants lost a seal at the nasal bridge. In these situations, the guardian was recruited to lightly hold the mask down with one finger over the bony prominence of the nasal bridge. The difference in the IOS tracing was immediately restored, and additional pressure was not placed on the cheeks or the airway, so no increase in $R_{AW}$ is expected to have been reflected. The IOS also will not display a $R_{AW}$ value if there are insufficient tidal breathing cycles before attempting to capture data. Then there must be at least 30 seconds for a reliable measurement, which was secured for each participant with the tilt in space parameter.
Hans Rudolph Oro-Nasal NIV Facemasks, Headgear, and Custom Connectors.

Soft silicone rubber facemasks in various sizes (Hans Rudolph, Inc., 2006) were used to secure tubing to each child’s head, by means of an attaching, quick-release, porous mesh headset. Two custom connectors were fabricated by the manufacturer and affixed to the NICO tubing and IOS plastic pneumotach and filter, respectively; to alternately attach the NICO and IOS to the facemask with a competent seal (Figure 6, below).

Figure 6. Four HRI Facemasks.

This figure shows one facemask attached to a mesh headset with clips, and two connectors for attaching a facemask to IOS and NICO.

*Modified Ashworth Scale.* Spasticity is defined here as excessive muscle tone. Presence of spasticity was measured with the Modified Ashworth Scale (MAS) (Haley &
Inacio, 1990), a single scale with six possible choices (0, 1, 1+, 2, 3, 4; Appendix A) for grading the extent of muscle tone in joints of the extremities. Since trunk control was judged to be a very important contributor to posture and breathing, scores on muscle tone at the hip and shoulder joints (proximal to the trunk, in flexion/extension) were averaged to obtain an overall score for each participant. This was done by the investigator during measurement of height, weight, and body dimensions for seating in the simulator. Gregson, et al. (1999) found reliability very good (kappa = .84 for interrater and .83 for intrarater comparisons). The investigator's Modified Ashworth Scale scoring was certified by an occupational therapist skilled in its use (Shaw, 2006).

**Power**

*A priori* power analysis was conducted, assuming an expected small effect size (Cohen’s *d* of .20 for small effect size = 0.1 to 0.3). Therefore, assuming small effect size and controlling for expected power of 0.8 (the condition in which 80% of variance in the dependent variable is explained by the phenomenon(a) of interest), the *a priori* estimation of sample size was 42. Over a 2-month period, 5 participants were recruited for a pilot test of the protocol. This sample size was far less than the *a priori* sample size expectation of 42. Given that alpha remains constant, but with smaller sample size than originally estimated, power may still be sufficient if effect size is large. Therefore it is important to reassess power and sample size after the pilot study has been completed to determine an effect size which may ultimately be used to estimate the number of participants actually needed in a future study. In order to know how many more participants would be needed to achieve sufficient power, and with alpha set at 0.05, a
*post hoc* analysis to estimate effect size and power was conducted for the pilot. Cohen’s d was used as the measure of effect size, subtracting the means of totally supported and unsupported conditions, divided by the pooled standard deviation. This revealed Cohen’s d of 0.69, indicating a medium effect size for n = 5; the pilot study was expanded with efforts to recruit participants continuing, based on Cohen’s table (1992, p. 158). The table indicates 35 participants are needed for a medium effect size with ANOVA of 6 wheelchair parameters (groups) and alpha set at 0.05.

There are different measure of effect size, according to the type of test. Cohen’s d for a simple (two group) t-test and Cohen’s f for an ANOVA (comparing more than two means) are two examples of effect size measure that can be used to estimate the power of completed studies. *A priori* estimates of power are used to plan the number of subjects needed for adequate power in a study and effect size is estimated; *post hoc* power estimates are used to estimate the power of a completed study in which actual effect size has been discerned for a given sample. For one-way analysis of variance using Cohen’s f, Cohen established small, medium, and large effect sizes as 0.10, 0.25, and 0.40, respectively (Cohen, 1992, p. 157).

*Inclusion/Exclusion Criteria*

Inclusion criteria were the following: English-speaking, pre-pubertal children aged 5 to 10 years with CP who do not sit alone, in equal numbers of males and females, who have not had a full meal in the previous 2 hours. Exclusion criteria were: children with spinal cord injury, spina bifida/myelomeningocele, or degenerative neurologic diseases, due to potential variety in postures; children with existing cardiovascular,
hematologic, or respiratory pathology; or history of either respiratory illness in the past 3
weeks or of apnea, based on a nursing history and respiratory assessment performed by
the investigator onsite; children with a history of pain upon body movement; and those
with stated, fixed spinal deformity or history of spinal surgery, on physical therapy
assessment at the clinic visit.

Setting

The sample for this study was recruited from two sites, the outpatient pediatric
neurology clinic for the Shands Children’s Hospital in Gainesville, Florida, and the
outpatient pediatric orthopedic clinics at the Shiners’ Hospitals for Children, Tampa,
Florida. The outpatient pediatric neurology clinic at Shands in Gainesville is in the
pediatric outpatient department of a freestanding outpatient building on the University of
Florida campus, adjacent to a tertiary care teaching hospital in north central Florida.
Patients receive either Medicaid or private insurance benefits. The Shriners Hospital for
Children, Tampa, is on the University of South Florida campus and serves all patients at
no cost to the family. Patients come from all of Florida, south Georgia, and
internationally, especially for spinal, hand, and foot surgery. At least 50% of the
participants reside within 30 minutes’ drive of the clinics.

Procedures

Approvals. Approval was obtained from Institutional Review Boards at both the
University of South Florida and the University of Florida (Appendix B), as well as from
the Medical Research Department at the Shiners’ Hospitals for Children, Tampa, and the supervising clinic staff.

*Human Subjects Protections.* The study participants came from a vulnerable population, defined as nonambulatory minor children with relatively high respiratory morbidity and mortality. Some of the children also had cognitive delays and communication disabilities. Prepubertal children were needed, because it is possible to use a within-subjects design if subjects have flexible spines and can assume both control and treatment positions in the wheelchairs, thereby requiring a smaller number of subjects overall. Legal guardians who received a flyer in clinic and indicated interest were visited by the investigator in the clinic patient room, and questions about the study were answered. Guardians supplied informed consent, and assent was also sought from the children at this time, if able to communicate. A copy of the signed, combined informed consent/assent form was given to guardians (Appendix C).

*Participant Recruitment.* Enrollment took place over a four-month period. The sampling goal was to reflect the ethnic and gender composition of Florida, 51.2% female; 48.8% male; 65.4% white, non-Hispanic; 16.8% Hispanic; 14.6% Black or African American; 3.2% other groups (U.S. Census Bureau, 2000). Parents and children were approached through the clinic staff. First, a flyer was offered to the guardian of all nonambulatory, school-aged children by a nurse in the private patient rooms of the outpatient clinic. If the guardian indicated interest, the investigator went into the room to answer questions. Guardians were consented and assent sought from children. Then the children were screened for study criteria. The study took place by appointment, in the pulmonary neurophysiology research laboratory in the University of Florida Department
of Physiological Sciences and in a wheelchair fitting room in the seating department at Shriners. All guardians but two chose to have the study procedure immediately following the medical visit on the clinic day.

**Data Collection.** For each participant, data were collected in one session after recruitment, over approximately 1 to 1.5 hours, with the trunk in each of the six seating conditions. Children were tested no less than 2 hours after eating a full meal. Some had had a small snack in order to get them through the procedure without pronounced hunger, but parents stated that in all cases they “were not full,” which otherwise could alter pulmonary mechanics values. The order in which the six seating conditions were introduced independently was determined by drawing number sequences from a hat. The pulmonary measures of tidal volume (VT), minute ventilation (MV), and deadspace to tidal volume ratio ($V_D/V_T$) were collected solely for clinical interpretation of changes in total airway resistance ($R_{AW}$). Qualitative data such as verbal and cognitive ability were recorded in a study log following the measurement session and later analyzed.

Use of only one data collector, the investigator, reduced inter-rater variability of all measurements. Data collection steps are listed in Table 3 below. After admission to the study, the investigator screened each participant, measured vital signs, height, weight, and body dimensions for seating; collected demographic information; inspected and auscultated the child’s chest; and made a Modified Ashworth Scale determination.
Table 3

Data Collection Protocol

<table>
<thead>
<tr>
<th>Step</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Informed consent obtained, with assent solicited.</td>
</tr>
<tr>
<td>2.</td>
<td>Respiratory history for recent past also taken, as well as presence of inclusion and exclusion criteria.</td>
</tr>
<tr>
<td>3.</td>
<td>Overall spasticity estimated and recorded Using Modified Ashworth Scale.</td>
</tr>
<tr>
<td>4.</td>
<td>Patient characteristics, recent health history, and vital signs recorded.</td>
</tr>
<tr>
<td>5.</td>
<td>Mat examination to measure: elbow height above seat; hip, knee and ankle flexion angles; trunk length; thigh length; and lower leg length According to Waugh (2004) protocol purpose: to formulate seating simulator dimensions for seating conditions; angles measured with a manual goniometer; height and lengths measured from joint to joint with a metal tape measure, according to published protocol.</td>
</tr>
<tr>
<td>6.</td>
<td>Facemask explained to the child; child allowed to handle it, and mask placed 30 seconds allowed to become accustomed to mask.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>7. Partially-supported conditions applied in random order, independently. Using the NICO and the Jaeger IOS, pulmonary mechanics measured in each partially-supported condition.</td>
<td>Position condition noted for each. Each instrument digitally displays measurements. Investigator records measurements onto data flow sheet, along with PaO2. For NICO, 8 breaths must elapse, approximately 30 seconds, before ETCO₂ analysis allows VD/VT display. For IOS, 3 full breaths precede data collection of R₄₆ (R @ 5 Hz), which takes at least 30 seconds of clear flow cycle tracing, according to manufacturer’s instructions. If tracing shows obstructed pattern or lack of seal, data cannot be collected until at least 30 seconds of clear tracing are obtained.</td>
</tr>
<tr>
<td>8. Fully-supported and unsupported seating conditions are applied in simulator, with pulmonary mechanics measures recorded</td>
<td>Measurements taken immediately, upon positioning</td>
</tr>
</tbody>
</table>

The following should be noted: The facemask was positioned snugly with intrinsic Velcro straps and plastic clips. Recording of each pulmonary mechanics measure with the NICO and IOS occurred immediately following positioning in each of the six conditions of support for each child. As soon as the position condition (wheelchair parameter) was introduced, the 30-second period began for the NICO or 3 breaths for the IOS. The same instrument as for the last measure of the last position began the next
condition, to minimize skin breakdown due to friction from excessive switching of the tubing on each silicone rubber mask. That is, the starting instrument of the two (NICO or IOS) was alternated, in each condition.

In the “unsupported” condition, the child received no extrinsic trunk support except from the seat surface of the simulator and leg support, plus the guardian’s hands holding the thighs on the seat surface to prevent falling. Partially- and totally-supported conditions included optimal positioning in the Prairie Reflections Seating Simulator according to the Waugh protocol (2004). For all conditions of “partially-secured”, one condition of support at a time was imposed. Observational monitoring for discomfort and capillary/pulse oximetry detection of any desaturation occurred throughout the procedure. The investigator was assisted in positioning by the guardian, who held the child on the seat in the unsecured position and in some cases, held the top of the facemask lightly on the nose in the tilt in space position, to maintain a seal. The seal was validated by the flow tracing display observed by the investigator. (Lack of seal is displayed as jagged, red, irregular tracing.) Angles of seating parameters (seat to back angle, tilt in space) were measured by manual goniometer, in degrees, as trained by Waugh: participant ankle, knee, and hip flexion/extension range of motion were ascertained with body measurements at the start of the session, and joint angles were held constant for these settings, for all participants. These were 90 degrees ankle and knee flexion and 100 degrees hip flexion. Linear measurement was by tape measure in inches (back rest height, headrest height, seat depth and width), matched to body dimensions, also as trained by Waugh. The hips were positioned against the backrest, with slight anterior pelvic tilt for secured, level pelvis. Participants not allowing measurement due to invasiveness of the
facemask were noted. Any two episodes of desaturation comprised stopping criteria for the study, but none occurred.

A “safe” environment was provided in the seating department at Shriners, a signal to these children that they were in a place friendly to children. Stuffed animals were placed on the mat table in the room, cartoons were visible on a television overhead, 4 hand puppets were placed on the simulator, and a large floppy, sequined hat was available to wear. Choice of a new toy was offered to each child engaging in the procedure, provided by the hospital child life specialist.

Data Analysis. Data are presented descriptively for categorical variables as percentages and as means and standard deviations for continuous variables. A content analysis of the study log was conducted to answer study questions 2 and 3 using observation for themes and coding. For study question 1, the Statistical Package for the Social Sciences (SPSS version 14.0) was used for data management and analysis. The data were examined for missing values, outliers, and inconsistent data as recommended by Tabachnick & Fidell (2001, pp. 56-9), with a scatterplot executed to identify subjects. To determine the relationship between all six wheelchair seating parameters and total airway resistance, a within-subjects, one-way repeated measures analysis of variance was conducted, with six conditions of wheelchair parameter configuration and total airway resistance serving as independent and dependent variables, respectively. Type 1 error, or alpha, was set at 0.05.

Type 1 error is the probability of rejecting a true null hypothesis (H₀), in effect saying a difference between groups (or treatments) exists when, in fact, one does not. In statistical analysis, the investigator sets alpha, and it is the chance of making a Type 1
error, expressed customarily as a percentage such as 0.01 (1%). Another way to say this is that Type 1 error is called alpha and can be decreased by altering the significance level. For example, if alpha is set at 0.01, there is a 1% chance that the result termed significant would occur by chance alone; the greater the percentage, the greater the possibility that finding a difference is due to chance, rather than to the treatment. Type 2 error, or beta, is the opposite or the probability of accepting the null hypothesis, saying no difference exists between groups when, in fact, one does. Since only one of these errors can occur in a study (Stevens, p. 122), there is an inverse relationship between the two. As we control Type 1 error (reduce it), chance of making a Type 2 error increases, and the reverse: when the chance of a Type 1 error increases, the chance of a Type 2 error decreases.

The percentage of participants who had difficulty with the facemask was noted. Optimal time intervals for introduction of seating parameters and measurement of pulmonary mechanics were determined by noting total time elapsed in the procedure, due to the need for measurement immediately upon application of the parameter. Participant recruitment and retention rates were calculated by computing: the ratio of number approached to number recruited, ratio of number recruited to number completing study procedure, and ratio of number completing study procedure to total study time elapsed (4 months). Necessary sample size for power of 0.8 was 42.
Chapter Four: Results

The study results are presented in Chapter Four. These include a profile of the sample, results of the data analysis, and findings, by study question. In order to evaluate the method, it is useful to also consider the characteristics and observed experience of the excused participants, so this chapter also includes a summary of the profile of the excused participants; all participants were consented before data collection.

Sample Characteristics

A sample of 8 children was recruited; these were prepubertal male and female children (ages 5-10 years) who lack trunk control and have a medical diagnosis of CP, as stated in a current physical therapy assessment and confirmed by the guardian. There were equal numbers of males and females. Five of the eight participants were 10 years old (the mode); the median age was 8 years; the mean was 8.9 years. There were 6 Hispanic participants, 1 Caucasian, and 1 African American. Only two participants of eight were receiving any medication, oral Valium, Baclofen, and Trileptal; this was far fewer than expected for special-needs children. Extent of spasticity was evenly-distributed, with 2 participants with considerable tone (score of 3), 3 with moderately increased tone (score of 2), and 3 with only a slight increase in tone (score of 1). (A score of zero on the Modified Ashworth Scale denotes no increased muscle tone, so each
participant had some abnormally increased tone.) No data were missing. A summary of the sample composition is located in Table 4.

Table 4

<table>
<thead>
<tr>
<th>Sample Composition</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Completing</td>
</tr>
<tr>
<td>Total n</td>
<td>8</td>
</tr>
<tr>
<td>Age in years</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
</tr>
<tr>
<td>Male</td>
<td>4</td>
</tr>
<tr>
<td>Characteristics</td>
<td>Frequency</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td></td>
<td>Completing</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>6</td>
</tr>
<tr>
<td>Caucasian</td>
<td>1</td>
</tr>
<tr>
<td>African American</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
</tr>
<tr>
<td>Medication Use</td>
<td>2</td>
</tr>
<tr>
<td>Modified Ashworth Scale score (spasticity)</td>
<td></td>
</tr>
<tr>
<td>Slightly increased tone</td>
<td>(score 1)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Moderately increased</td>
<td>(score 2)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Considerably increased</td>
<td>(scores 3 and 4)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The excused participants were similar in gender, age, and ethnicity although there were fewer Hispanic participants. These participants were notably different, however, on medications, spasticity, and verbal ability, with 6 of 8 excused participants receiving medication on a regular basis; 5 of the 8 with high levels of spasticity; and 7 nonverbal
with only 1 verbal. Data has been included only for consented participants, and all excused participants were consented.

*Verbal Ability and Motor Control*

The cognitive ability of these children was notable. Although cognitive testing data were unavailable, 75%, or 6 of 8 participants who completed the study were verbal communicators. Two participants appeared to have low cognitive function and were nonverbal but completed the procedure; one nonverbal child’s guardian showed remarkable rapport and ability to communicate with her. Nearly the opposite was true for excused participants. Of these, 6 appeared to have very low cognitive function and 88%, or 7 of the 8, were nonverbal. Only two excused participants, or 12.5% of the 16 enrolled, appeared to have moderate cognitive function, with some receptive language and ability to cooperate with the procedure but very little motor control to allow stable positioning or pulmonary measurement. Verbal ability did not necessarily correspond to greater age; 2 of the younger participants were quite verbal and enthusiastic, and two 10-year-olds were noted to have very limited communication skills. Table 5 shows study completion, age, and verbal ability.
Table 5

Study Completion, Age, and Verbal Ability

<table>
<thead>
<tr>
<th>Age in Years</th>
<th>Verbal Ability*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completing</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>V</td>
</tr>
<tr>
<td>10</td>
<td>V</td>
</tr>
<tr>
<td>10</td>
<td>V</td>
</tr>
<tr>
<td>10</td>
<td>V</td>
</tr>
<tr>
<td>6</td>
<td>V</td>
</tr>
<tr>
<td>7</td>
<td>V</td>
</tr>
<tr>
<td>10</td>
<td>NV</td>
</tr>
<tr>
<td>10</td>
<td>NV</td>
</tr>
<tr>
<td>Excused</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>NV</td>
</tr>
<tr>
<td>7</td>
<td>NV</td>
</tr>
<tr>
<td>8</td>
<td>NV</td>
</tr>
<tr>
<td>8</td>
<td>NV</td>
</tr>
<tr>
<td>9</td>
<td>NV</td>
</tr>
<tr>
<td>5</td>
<td>NV</td>
</tr>
<tr>
<td>8</td>
<td>NV</td>
</tr>
<tr>
<td>8</td>
<td>V</td>
</tr>
</tbody>
</table>

Note. *V = verbal; NV = nonverbal

Findings

Due to limited time and resources and the challenges associated with recruiting the sample of 42 needed to sufficiently power the study, the analysis was limited to
descriptive statistics and qualitative data from the process log. The research questions were:

1. What is the relative contribution of each wheelchair parameter to pulmonary mechanics?

2. What are challenges associated with subject recruitment and retention?

3. What is the response of children with CP to the data collection protocol?

**Research Question One: Contribution of Wheelchair Parameters to Total Airway Resistance and Minute Ventilation.** The within-subjects, one-way analysis of variance revealed that for this sample, total airway resistance varied by seating parameter. Although these data are dependent, research has shown that using Cohen’s $d$ and $f$ is appropriate to reflect effect size in this situation (Becker, 1999). Cohen’s $f$ for effect of all six conditions of wheelchair parameters on $R_{AW}$, considered simultaneously and using eta squared was found to be 0.27, a medium effect. Power was low, 0.46. Using Cohen’s table (1992, p. 158), this post hoc analysis of the pilot sample size confirms the need for 35 participants to ensure power of 0.8.

Power is the probability of detecting a difference if such exists; anything that decreases the probability of a Type 2 error increases power and vice versa. More power means that one is more likely to reject the null when it is false. If beta is subtracted from perfect probability, 1.0, the resulting number is the probability of rejecting the null hypothesis when it is false, that is, of making a correct decision. This is 1 minus beta, or power, also called the probability of correctly detecting a relationship between the two variables if a relationship is present. Effect is the strength of this relationship. Power is dependent on the significance (alpha level) set, sample size, and effect size. (The
statistical test and research design can also influence power.) When the sample is small, it is easier to decide erroneously that a difference exists between two groups (reject $H_0$), that is, to have insufficient power. As the size of the effect increases, it becomes easier to detect accurately in a smaller sample; thus, power is increased. Effect size is the degree to which the null is false, the magnitude of the effect of an independent variable on the dependent variable, or strength of relationship between two variables.

Total airway resistance varied by seating parameter. Mean $R_{AW}$ and MV for each seating parameter are depicted in Figures 7 and 8 below. The MV means show that participants maintained minute ventilation essentially uniformly, for all seating conditions, to within 1 standard deviation, although $R_{AW}$ varied by seating condition. (VT and VD/VT are not reported here, as they were only relevant to explain differences clinically, if sufficient power had been achieved.) The seating parameters responsible for the lowest (best) total airway resistance were upper extremity supports and lateral trunk supports.
Figure 7. Total Airway Resistance Means by Seating Parameter (+ or - SD), (n = 8).

Seating parameters are: 1 = unsupported; 2 = totally supported; 3 = upper extremity supports; 4 = lateral trunk supports; 5 = secured, level pelvis; 6 = tilt in space.

When airway resistance was highest (seating parameters 1, 2, 5, and 6), minute ventilation was maintained.
Figure 8. Mean Minute Ventilation by Seating Parameter (+ or -SD), (n=8).

Seating parameters are: 1 = unsupported; 2 = totally supported; 3 = upper extremity supports; 4 = lateral trunk supports; 5 = secured, level pelvis; 6 = tilt in space.

A scatterplot of all measures of $R_{AW}$ was constructed to identify subjects and inspect distribution of data points, depicted in Figure 9, below. The parameters responsible for the highest $R_{AW}$ measures were “unsupported,” “totally supported,” and “secured, level pelvis.”
Figure 9. Scatterplot of $R_{AW}$ by Seating Parameter (n = 8).

Seating parameters are: 1 = unsupported; 2 = totally supported; 3 = upper extremity supports; 4 = lateral trunk supports; 5 = secured, level pelvis; 6 = tilt in space.

Using the means and standard deviations in Table 6 below, the strength of the relationship between total airway resistance and seating conditions, represented by computed effect size as Cohen’s $f$, for this sample was found to be 0.27, a medium effect with low power (0.46) when Type I error rate was set at 0.05 and a within-subjects ANOVA was used.
Table 6

*Effect of Seating Condition on $R_{AW}$ Means (SDs)*

<table>
<thead>
<tr>
<th>Position/Condition</th>
<th>$R_{AW}$ Mean</th>
<th>(SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unsupported</td>
<td>9.84</td>
<td>(7.06)</td>
</tr>
<tr>
<td>2. Totally secured</td>
<td>8.61</td>
<td>(5.18)</td>
</tr>
<tr>
<td>3. UE supports</td>
<td>6.20</td>
<td>(2.25)</td>
</tr>
<tr>
<td>4. Lateral trunk</td>
<td>6.94</td>
<td>(3.15)</td>
</tr>
<tr>
<td>5. Secured, level pelvis</td>
<td>10.27</td>
<td>(5.83)</td>
</tr>
<tr>
<td>6. Tilt in space</td>
<td>10.79</td>
<td>(3.20)</td>
</tr>
</tbody>
</table>

F 1.51

df<sub>num</sub> 5

df<sub>denom</sub> 42

p-value 0.25

Qualitative Data from the Process Log. The remainder of this chapter addresses qualitative data and findings from the study process log that answer Research Questions Two and Three. The process log data were coded and summarized according to emerging themes which are summarized in Table 7 on the following pages.
Table 7.

*Process Log Themes and Data*

<table>
<thead>
<tr>
<th>Theme</th>
<th>Data Summary, (n = 8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Challenges of Participant Recruitment and Retention</td>
<td></td>
</tr>
<tr>
<td>Postural instability</td>
<td>The first two participants had severely alternating muscle tone, were placed in the unsupported position first, and may have had a decreased ability to tolerate the procedure, in a strange place, if unable to feel secure in the upright position without any postural support except the seat. It is known that many children with CP have difficulty orienting in space and holding themselves upright. In order to minimize participant burden, the totally supported and unsupported positions were moved to next-to-last and last, respectively, for each participant. This change eliminated identified postural instability, although it also eliminated randomization of these two parameters.</td>
</tr>
<tr>
<td>Verbal ability</td>
<td>As described in the sample profile, participants with greater verbal ability tolerated the protocol more often than others.</td>
</tr>
<tr>
<td>Reflexive activity</td>
<td>Four participants demonstrated primitive reflex activity that is common in many persons with CP. One exhibited a startle each time the IOS was introduced, but was able to complete the protocol after acclimating a few seconds. One participant experienced persistent gagging and one participant had repeated sneezing, both likely due to facial stimulation of the facemask. One of these two was excused; the other was able to complete the protocol. One participant experienced persistent tongue thrusting; this interfered with a clear $R_{AW}$ tracing at the end of the protocol, so he was withdrawn by the investigator.</td>
</tr>
<tr>
<td>Theme</td>
<td>Data Summary, (n = 8)</td>
</tr>
<tr>
<td>--------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Clinic recruitment</td>
<td>Due to the fact that these participants had come to clinic intending a medical visit, the investigator was obliged to wait until the morning or afternoon clinic was completed by the family; this could take up to 4 hours. At one point, a clinic staff member stated that she had not alerted the investigator to one potential participant out of courtesy, because the family had traveled a distance. It is unknown whether this affected recruitment for others. In addition, one spine surgeon left the medical team; although clinic staff stated there was no decline in clinic appointments, it is unknown whether this affected recruitment.</td>
</tr>
<tr>
<td>Airway obstruction</td>
<td>Only one participant was excused for identifiable airway obstruction that interfered with IOS (R_{AW}) reading. Obstruction can be identified by the fairly straight red line of the IOS oscillations in the respiratory cycle, with no green line. This participant experienced repeated gagging and may have also retracted his tongue, resulting in distinguishable upper airway obstruction on the tracing.</td>
</tr>
<tr>
<td>Intolerance of facemask, simulator, or IOS</td>
<td>Four participants of 16 would not accept the facemask; two were unable to tolerate the simulator sufficiently to sit on the surface of the seat, and two were unable to accept the IOS. All of these were excused.</td>
</tr>
</tbody>
</table>
Data Collection Protocol (Response of Participants to)

<p>| Situational characteristics | Three participants had some difficulty maintaining the facemask seal at the nasal bridge in the tilt in space position, or 30 degrees from vertical, for which the IOS was designed. This was handled by having the guardian place slight finger pressure at the nasal bridge, a bony prominence, to contact the nose and seal the facemask to the nose and face. Because the finger pressure was slight and was applied over a bony prominence, it was not believed to increase airway resistance. One participant also had extreme lack of trunk control, so that his unsupported position had him facing the floor; in this position, IOS measurement was impossible, so the guardian held his shoulders up for this condition, without any other support. The resulting position was equivalent to the slumped position of each of the other participants. There was also a need for participants to have as pleasant an experience as possible, while not interfering with measurement, so scented lip balm (chocolate cherry, mint, or berry) was used on the facemask, as well as decoration of the simulator for children who could see. The Disney channel also played on a television above the instruments. Over the 1- to 1.5-hour period, 4 participants developed redness over the nasal bridge from the facemask; some of the lip balm was applied, and no one developed any skin breakdown. When upright at 100 degrees hip flexion, for 2 participants without head control, the Whitmyer small headrest did not fully support the head. Guardians held these participants’ occiputs in the headrest, making this position equivalent to the other participants without placing stress on the anterior neck and airway. Three participants also were unable to balance their arms on the upper extremity supports alone; guardians held their arms on the armrests to duplicate the posture of others. |</p>
<table>
<thead>
<tr>
<th>Fatigue</th>
<th>Six of eight participants either stated, or a guardian stated they were tired at the end of data collection.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased</td>
<td>One participant experienced increased secretions; this girl had a history of gastroesophageal reflux. Her peripheral oxygen saturation level dropped briefly to 95% when her neck was in extension, but then rose to an acceptable level for protocol completion.</td>
</tr>
</tbody>
</table>

**Research Question Two: Challenges Associated with Participant Recruitment and Retention.** Twenty guardians received study information; 2 of these declined to participate; 2 were excluded due to not meeting study criteria; 16 enrolled; 8 were retained. Participant recruitment and retention themes from the Process Log follow.

Postural instability was a factor in retention: when the first 2 participants became agitated when their posture was destabilized by removing support at the outset of the protocol, they were excused. This change eliminated the opportunity to randomize order of presentation of totally supported and unsupported parameters. The second theme was verbal ability; participants with greater verbal ability tolerated the protocol more often than others. Third, 4 participants demonstrated primitive reflex activity: startle, persistent gagging, repeated sneezing, and persistent tongue thrusting. This reflex activity stopped the protocol for half of these participants, who had to be excused. Fourth, clinic recruitment was a factor; participants were not available until the end of the clinic duration, which averaged 3.5 hours. It is unknown whether length of time in clinic also influenced staff not to approach potential participants, or whether loss of one surgeon decreased the number of potential participants in clinic. The fifth challenge to participant
recruitment and retention found in the Process Log was airway obstruction, which occurred for only 1 participant who experienced repeated gagging that interfered with IOS measurement. He may have retracted his tongue and involuntarily, briefly obstructed his upper airway, resulting in his being excused. Finally, intolerance of the instruments was a factor. Of 16 participants, 4 did not tolerate the facemask; 2 did not tolerate the seating simulator, and 2 did not accept the IOS; all were excused.

**Research Question Three: Response of Children with CP to the Data Collection Protocol.** The challenge posed to recruitment and retention by intolerance of the facemask, simulator, or IOS, also was a response of participants to the data collection protocol. Other themes were situational characteristics such as difficulty maintaining the facemask seal for IOS measurement at 30 degrees tilt in space, extreme lack of trunk control of one participant, skin redness at the nasal bridge from the facemask, and poor support of the headrest for participants with extreme lack of head control. In addition, three participants were unable to balance their arms on the armrest without having them held. Of 8 participants, 6 stated, or a guardian stated, that they were tired at the end of the protocol. Finally, 1 participant experienced increased respiratory secretions, and her peripheral oxygen concentration dropped briefly to 95%. She was, however, able to complete the protocol.

**Seating Simulator and Facemask Acceptability.** Of the 16 participants enrolled, 2 (12.5%) were unable to tolerate the simulator and assumed a total extension posture, with high spasticity and inability to maintain the position for measurement, so they were excused. Of the total 16 enrolled, 4 participants (25%) either cried or responded to the mask with reflexive activity such as gagging, tongue thrusting, or spastic movement.
preventing measurement; they were also excused. Conversely, 12 (75%) of those enrolled found the facemask acceptable.

*Other Process Log Themes and Data.* In addition to data about optimal measurement intervals; recruitment and retention; simulator, IOS, and facemask acceptability; and postural instability, other themes were also found: situational characteristics of the method; fatigue; verbal ability; reflexive activity related to CP; airway obstruction; and increased airway secretions. There were varying amounts of head and trunk control. The facemask seal was difficult to maintain in 30 degrees tilt in space. Uniform application of seating parameters was difficult when participants had extremely low muscle tone, complete lack of head and trunk control, and movement of arms off upper extremity supports; these were situational characteristics of the protocol when used with persons with CP. Of the participants, 75% experienced fatigue at the end of the procedure. Participants with greater verbal ability tolerated the protocol better than others. Reflexive activity such as startle and sneezing, occurred but did not interfere with data collection. Gagging and tongue thrusting, however, prevented data collection. Airway obstruction occurred briefly with gagging, with which tongue retraction may also have been associated; this made IOS measurement impossible for 1 participant. Increased respiratory secretions occurred with only 1 participant and did not interfere with oxygen saturation level.

*Discussion of Findings*

These findings will be discussed in the next chapter, which includes contribution of each wheelchair parameter to pulmonary mechanics; effects of data collection protocol
on subject recruitment and retention; seating simulator and facemask acceptability; reliability of pulmonary measurement; optimal measurement intervals; participant recruitment and retention rates; differences in total airway resistance ($R_{AW}$) by wheelchair parameter; study limitations; recommendations for future research; and conclusions.
Chapter Five: Discussion

The purpose of this within-subjects, descriptive study was to estimate the relative importance of four wheelchair configuration parameters as predictors of pulmonary mechanics, reflected in total airway resistance of school-aged children with CP who cannot sit alone but have flexible spines. This chapter will discuss the contribution of each wheelchair parameter to pulmonary mechanics, effects of data collection protocol on subject recruitment and retention, seating simulator and facemask acceptability, reliability of pulmonary measurement, optimal measurement intervals, participant recruitment and retention rates, differences in total airway resistance ($R_{AW}$) by wheelchair parameter, study limitations, recommendations for future research, and conclusions.

Contribution of Each Parameter to Pulmonary Mechanics

For this sample, the lowest $R_{AW}$ means were seen with independent application of the upper extremity supports and lateral trunk supports. It is possible that upper extremity and lateral trunk supports contributed most to trunk straightening and support of the upper trunk, lifting weight off dependent lobes and reducing resistance to flow throughout the entire tracheobronchial tree. Straightening the spine could also remove the load arm on the spine placing force on the lower lung fields. Highest $R_{AW}$ means were seen with secured, level pelvis and tilt in space. It is possible that derotating the pelvis and simply securing with a seatbelt, while forming a base of support for the spine, does
not remove the load arm of the upper trunk sufficiently to straighten the upper spine and reduce force on the dependent portions of the lung, alveolar resistance, and total airway resistance. It is also possible that in tilt in space, the tongues of these participants fell to the back of the throat, increasing upper and total airway resistance. It was impossible to ascertain tongue position from outside, but the one person who showed full obstruction was in the tilt in space position. The two next lowest RAW measures were in the totally supported position and the unsupported position. Minute ventilation was maintained even in the presence of the higher airway resistance measures, possibly indicating relative relaxation and low fear. In the presence of high RAW, minute ventilation will fall, even with increased rate of breathing. These findings show trends only for this small sample. With sufficient power, other findings are possible.

*Effects on Subject Recruitment, Retention, & Responses to Data Collection Protocol*

*Seating Simulator and Facemask Acceptability.* Characteristics of participants who accepted the seating simulator and facemask--those completing the protocol in this sample--were higher verbal ability, lower levels of spasticity, and freedom from medication use. Participants with less disability handled the challenge of the procedure more easily, but the intent was to study a very disabled population who could benefit most from future intervention. For the excused group, with greater disability, the seating simulator and facemask were poorly accepted. It may be possible, however, to conduct a similar study with participants lacking full trunk control, but having greater verbal ability, such as frail elderly persons with spinal cord injury, muscular dystrophy, or multiple sclerosis, to estimate effects of wheelchair parameters on pulmonary mechanics.
Postural Instability and Unsupported Position. The earliest 2 participants had extremely athetoid movement, were in constant motion, and were initially placed into the unsupported position (baseline) first, which essentially destabilized the participant. These participants responded with increased movement in the simulator and some agitation that prevented pulmonary measurement of tidal breathing, so they were excused. The remaining 14 participants who were recruited received random presentation of the four partially-supported conditions, with the fully supported and unsupported conditions applied last, and this problem was resolved. Of these 14 participants, 6 were excused for other reasons as reported previously.

Usefulness of Pulmonary Measurement. Measurement of $R_{AW}$ with the IOS was difficult, but obtainable. First, the 30-degree tilt in space seating condition did not accommodate the IOS connection well; it was necessary to hold the connection together manually and for some, to hold the facemask to the nasal bridge to maintain the seal. The nasal bridge is bony, so it would not be possible to exert additional pressure on the airway and result in erroneously higher $R_{AW}$ measurement. This problem could be addressed by tilting only 15 degrees, rather than 30; this would still provide substantial tilt from vertical in seating to help the individual stay in the seat and isolate this condition for measurement. Second, difficulties with obstruction were overcome by astutely watching the tracing and only including 30 seconds of good data. If 30 seconds of good data could not be obtained, the participant was excused, but excusing participants contributed to low power. Third, several participants experienced difficulty directly related to their disabilities, such as athetoid or reflexive movement; they were excused, and this also contributed to low power. This issue could be addressed in a subsequent
study by employing a sample of persons lacking trunk control but without CP, so that the
deeply reflexive activity associated with CP would not be seen. Finally, the most serious
challenge was to get a reasonable $R_{AW}$ measurement using the facemask instead of a
mouthpiece: Measurements were not exactly the same as those predicted by the software,
but they were generally within 1 to 2 kPa/L/sec. Since this study was a within-subjects
design, participants were compared to themselves rather than to a clinical standard. The
NICO had no similar issues and was used easily; however, it cannot measure $R_{AW}$.
Although research exists on use of the Jaeger recommended facemask with oral tube, this
equipment is not useable in persons with CP. In addition, there is no research to date in
normally-abled children on use of the Hans Rudolph facemasks and headsets, which
compressed the cheeks and provided an excellent seal with the IOS. Using the facemask
in another population with less disability could allow hypothesis testing of effects of
wheelchair parameters on $R_{AW}$, as well as establish confidence intervals. This study’s
procedure was sufficiently straightforward to allow MV to continue virtually unchanged,
even when airway resistance increased, indicating anxiety was not a factor for
participants who were able to complete the protocol.

The Prairie wheelchair seating simulator was sufficiently operable to consistently
apply the seating conditions for pulmonary measurement. The participant who had to
have his arms held on the upper extremity supports still received support for his upper
trunk from the armrests equivalent to other participants. The condition was consistently
applied although his arms were kept from slipping off. The participant who had such low
trunk control that he had to have his shoulders held up was actually placed in a posture
that other participants in the sample intrinsically possessed, so his seating condition was
consistently applied, as for other participants. All participants tolerated the unsupported seating condition when it was applied last.

*Optimal Measurement Intervals.* Preserving skin integrity was a potential issue with the facemasks at the nasal bridge, with redness noted at the end of the procedure for 4 participants. This resolved in a few minutes, but Chap-Stick was applied to lubricate and reduce friction; no participant developed a skin break. In the interests of skin integrity, the procedure time was kept as short as could be accomplished.

However, some participants still showed signs of fatigue, such as verbalizing being tired and dark circles under the eyes. Due to priorities of the patient, the clinic schedule was honored before the participant could enter the study procedure, so 5 of the sample did not begin the study procedure until the end of clinic; the average length of time the child had been in clinic was 3.5 hours. The other 3 had made appointments to return specifically for the study procedure at a preferred time. It would be difficult to compare $R_{AW}$ data for these participants to participants without disabilities due to lack of reference values for school-aged children using facemasks.

One-half of the sample experienced fatigue, but it was impossible to shorten the duration of the protocol, which was not unduly burdensome, considering the usual duration of an outpatient clinic visit, the average duration of conventional pulmonary function testing (up to one hour), and the study protocol’s lack of invasiveness (wearing a face mask, sitting in a chair, and breathing). The measurement intervals for this sample were no longer than immediately following presentation of the parameter, due to the length of the study protocol (one presentation after another), fatigue, the possibility of movement out of the position, and the fact that pulmonary mechanics measures are
available immediately. The protocol took no less than one hour; the longest duration was
1.5 hours. The investigator was familiar with all the instruments and prompt in
manipulating them. A better arrangement may be to conduct the study at the beginning of
clinic, rather than at the end, or to work with a less disabled population who could still
offer lack of trunk control, to measure effects of wheelchair seating parameters on
pulmonary mechanics. Optimal measurement intervals would be less than those allowed
by the 1-1.5 hours session duration. That is, if protocol duration could be shortened,
optimal measurement intervals would be smaller; however, shortening these was not
possible in this protocol.

**Participant Recruitment and Retention Rates**

In twelve, 8-hour clinic days at Shands over 2 months, only 2 participants were
recruited; both were excused. In 35 days of pediatric orthopedic CP and “spinal” clinics
at Shiners, over 4 months, 1594 outpatient visits were registered for the CP and “spinal”
clinics, but the overwhelming number of these were ambulatory. Before and during the
study, no breakdown of patients by ambulatory status was available, but the consensus of
clinical staff was that the spinal pediatric orthopedic clinic would be a rich resource for
study participants. During the study, nursing staff approached 23 families and reported
that only 3 guardians of nonambulatory children with CP aged 5 to 10 years refused to
hear more about the study from the investigator. Each family was told that refusal to
participate would not result in loss or reduction of any health care benefits. Of the 20 who
received study information and were consented, 16 enrolled, 2 were excluded due to not
meETING study criteria; the schedule of 1 enrollee conflicted with that of another enrollee,
who had arrived at the only time the former enrollee could participate. One remaining family declined to participate, stating their child had experienced many surgeries and would not cooperate with the mask. Sixteen children with a medical diagnosis of CP, who cannot sit alone, were enrolled to participate in this study. The ratio of those enrolled to those approached is 16 to 23, or 70%. Eight children were excused, leaving a sample of 8 children who completed the study: the ratio of the number retained to number recruited is 8 to 16, a 50 % retention rate. Eight participants completed the study over a 4-month period, or 8 participants/4 months. There was a preponderance of ambulatory children who did not meet study criteria at both sites, with a correspondingly small number of children meeting study criteria.

The small sample was associated with stringent study criteria, which were intended to control confounding variables in measurement of pulmonary mechanics and posture as well as excusal of participants unable to tolerate or comply with the protocol. A better solution may be to study a less disabled group such as older adults, who still present lack of trunk control, or to identify a larger outpatient clinic base of nonambulatory children with CP.

*Differences in Total Airway Resistance (R_{AW}) By Wheelchair Parameter*

Due to low power associated with small sample size, it was not possible to conduct hypothesis testing regarding R_{AW} and wheelchair parameters. This should be done when power is achievable.
**Study Limitations**

*Sample.* In order to achieve power of 0.8 to detect a small effect, sample size would need to equal 42. Low enrollment and a 50% attrition rate contributed to low power. There is no known reason for low enrollment except for the stringent inclusion criteria. The investigator was present in the clinic area and observed no patients who met inclusion criteria who were not approached by clinic nurses and offered a flyer. Explaining the preponderance of Hispanic persons is difficult, especially since no available breakdown of the Shriners outpatient population by ethnic group is available, but ethnicity is not a known factor in CP that would bias pulmonary mechanics findings. Finally, the sample was limited by the participants’ low verbal ability. Eligible nonverbal participants tended not to complete the protocol, thus reducing the study’s retention and power.

*Method.* Because selection was not randomized, there may have been some bias in recruitment of participants. Some desirable subjects were selected out by their level of ability to comply with the study protocol or possibly how long they had been in clinic and how far they had traveled. Randomizing the full complement of wheelchair seating parameters was not possible, only the order of presentation of the four partial supports, due to destabilizing some children when they first began the protocol with the unsupported parameter, which was burdensome. This may have introduced some bias. Characteristics of persons with CP were the very attributes that complicated this method: reflexive activity, severely absent head and trunk control, and lack of verbal ability. In addition, despite every effort to observe objectively, the complexity of the procedure made detailed observation challenging. A second observer/recorder would have been
useful. Further, the method was unwieldy and may be difficult to replicate. With only one data collector, there was no estimate of measurer-to-measurer variability, so information about interrater reliability is not available, and collection of descriptive data was limited. Finally, effect of residing locally is unknown. Having traveled a distance to clinic, staying in unfamiliar surroundings, and undergoing unfamiliar routines may have contributed to fatigue or to higher stress on participants, thereby perhaps resulting in intolerance of the protocol. Possible relation between residing locally and completion of study protocol were not analyzed, and sample size was limited.

Recommendations for Future Research

Nurses should continue to investigate wheelchair parameters, posture, and pulmonary mechanics. A different group within the population of persons lacking full trunk control should be studied, to remove the conditions of the disability that complicate study of persons with CP. Another possibility would be to recruit a larger, verbal sample of children in a clinic with known numbers of nonambulatory patients and to conduct the study at the beginning of clinics rather than at the end. Although the IOS is marketed as a device that can be used for individuals who cannot comply with traditional pulmonary testing, the recommended mouthpiece did not prove useable with this sample. Other methods need to be explored. Finally, reference values for Hans Rudolph facemask and headset use should be developed for normally-abled children, to compare the facemask and mouthpiece protocols.
Conclusions

By study question, the following conclusions were drawn for this sample:

1. **What is the relative contribution of each wheelchair parameter to improvement in pulmonary mechanics?**
   a. For this sample, $R_{AW}$ was lowest in the presence of upper extremity supports and lateral trunk supports; MV was maintained, even when $R_{AW}$ was highest.

2. **Using the IOS, NICO, Prairie seating simulator, and Hans Rudolph facemasks, what is the effect on subject recruitment, retention, and response to the data collection protocol for $R_{AW}$, VT, MV, and $V_D/V_T$, in this population?**

   The challenges associated with subject recruitment and retention were:
   a. The level of disability of the participants.
   b. The data collection protocol, particularly the seating simulator, IOS, and facemasks used, for nonverbal children and those with primitive reflex activity, and presentation of the unsupported position first.
   c. The small number of eligible participants.
   d. The logistics of travel and time in clinic.

3. **What is the response of children with CP to the data collection protocol?**
   a. School-aged children with CP, lacking trunk control, participated successfully in measurement of total airway resistance with Hans
Rudolph facemasks and headsets, in conjunction with the Viasys Jaeger IOS and Respironics NICO.

b. Although the IOS is marketed as a device that can be used for individuals who cannot comply with conventional pulmonary testing, the recommended mouthpiece did not prove usable with this sample.

c. For this sample, optimal measurement intervals began immediately upon presentation of each seating parameter and ended when the pulmonary mechanics measure was obtained.

d. Seating simulator and facemask acceptability were increased, in the presence of greater verbal ability.

e. Wearing an HRI facemask for one hour in this protocol posed a small risk of skin breakdown at the nasal bridge.

f. This method may contribute to fatigue; fatigue may also be related to scheduling of data collection at the end of the clinic schedule.

g. Other methods of measuring wheelchair configuration parameters and pulmonary mechanics need to be explored, including establishment of \( R_{AW} \) reference values using the Jaeger IOS in normally-abled children for HRI facemasks.

h. No conclusions for nursing practice can be drawn as wheelchair influences on breathing still need to be estimated in a larger study.
References


Appendix A: Modified Ashworth Scale
MODIFIED ASHWORTH SCALE (Haley & Inacio, 1990)

<table>
<thead>
<tr>
<th>SCORE</th>
<th>CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No increase in tone.</td>
</tr>
<tr>
<td>1</td>
<td>Slight increase in muscle tone, manifested by a catch and release, or by minimal resistance at the end of Range Of Motion (ROM) when the affected part(s) is/are moved into flexion or extension.</td>
</tr>
<tr>
<td>1+</td>
<td>Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM.</td>
</tr>
<tr>
<td>2</td>
<td>More marked increase in muscle tone through most of the ROM, but affected part(s) is/are easily moved.</td>
</tr>
<tr>
<td>3</td>
<td>Considerable increase in muscle tone, passive movement is difficult.</td>
</tr>
<tr>
<td>4</td>
<td>Affected part(s) is/are rigid in flexion or extension.</td>
</tr>
</tbody>
</table>
Appendix B: Consent to Participate
Informed Consent to Participate in Research and Authorization for Collection, Use, and Disclosure of Protected Health Information

University of Florida Health Center Institutional Review Board APPROVED FOR USE
From 10/1/05* Through 9/30/06* 

You are being asked to allow your child to take part in a research study. This form provides you with information about the study and seeks your authorization for the collection, use, and disclosure of your protected health information necessary for the study. The Principal Investigator (the person in charge of this research) or a representative of the Principal Investigator will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. Before you decide whether or not to take part, read the information below and ask questions about anything you do not understand. If you choose not to participate in this study you will not be penalized or lose any benefits to which you would otherwise be entitled.

1. Name of Participant ("Study Subject")

2. Title of Research Study

Wheelchair Seating and Pulmonary Function in Children: Pilot Study

3. Principal Investigator and Telephone Number(s)

Paul Davenport, PhD (352) 392-4700, extension 13824

Contact information for emergencies after hours or on weekends or holidays:

Unaffiliated Investigator: Lee Barks, MN, ARNP (407) 741-4023 (cell); University of South Florida College of Nursing

484-2005 / 09-12-05 / Page 1 of 10
4. Source of Funding or Other Material Support

University of Florida

5. What is the purpose of this research study?

We all have some difficulty breathing if our chest movement is inhibited, sometimes just by our body position in the environment. Children who already have difficulty positioning themselves due to cerebral palsy may have some difficulty with the positions their wheelchairs hold them in. To understand how wheelchair design and positioning affect children’s breathing, we want to study the kinds of positioning supports that a wheelchair can provide. We want to see which ones (or all) help to improve children’s normal breathing in seated position. In this pilot study, we will test the method we use to do this, for a later, larger study.

6. What will be done if your child takes part in this research study? (These procedures will be done only because you are participating in this research study.)

The researcher will ask a few questions about your child’s recent health, look at and listen to your child’s breathing, and take his or her temperature, pulse, and respirations.

Then the researcher will place a comfortable facemask on your child to measure breathing. Your child will be placed in 6 positions: One will be in the sitting position they are in without support. (We will measure breathing.) The other five positions will be in a special wheelchair. This looks like a machine but is really just a big adjustable seat. We will adjust different parts of the wheelchair to fit your child in 5 more positions. Then we will measure breathing in each position through a facemask. Throughout the entire procedure, your child will have a small oxygen sensor attached to one finger to sense how much oxygen is in his or her system at all times.

6.a. What procedures would be done as part of normal clinical care (even if you did not participate in this research)?

No procedures in this study would be done as part of normal clinical care.

If you have any questions now or at any time during the study, you may contact the Principal Investigator listed in #3 of this form.

6.b. What procedures will be done only because your child is participating in this research study?

All of the procedures will be done only because your child is participating in the research.
7. If you choose to participate in this study, how long will you be expected to participate in
the research?

Your child will be expected to participate in this study for about one hour.

8. How many people are expected to participate in this research?

Up to 40 children will participate, one at a time, at the Shands/UF pulmonary physiology lab.

9. What are the possible discomforts and risks?

Positioning of children by parents and teachers happens throughout every day and is not
expected to be risky. Unsupported position is the upright sitting position the child goes into
without support and is not expected to pose any risk, unless it goes on too long. The
positioning and measuring will be brief. If your child has any difficulty breathing, your child
will be immediately re-positioned and assisted to breathe. The other 5 positions are various
positions of the wheelchair arm rests, seat belts, seat angle in space and side supports. If there
are any sitting positions that you know your child cannot tolerate (that make your child
ill), tell the investigator and you may leave without positioning for the study.

Your child’s mouth may feel a little dry from breathing through the facemask; if this is the
case, the test can be stopped briefly and the child may drink a small amount of water or have
the mouth moistened to relieve this feeling.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you.
Please inform the Principal Investigator (listed in #3 of this consent form) or the person
reviewing this consent with you before enrolling in this or any other research study or
project.

Throughout the study, the researchers will notify you of new information that may become
available and might affect your decision to remain in the study.

If you wish to discuss the information above or any discomforts your child may experience, or
if you have any questions about the research, you may ask questions now or call the Principal
Investigator listed on the front page of this form, or call Lee Barks, (407) 741-4023.

10a. What are the possible benefits to you?

You or your child may personally benefit from participating in this study, if we learn whether
breathing is compromised in certain positions and which positions are better. You will be
providing valuable information to help us learn about how children breathe in wheelchairs. We
don’t know if how we position children will help breathing. That is why we are doing this
study. What we learn may help wheelchair design in the future. Your child may not benefit
directly from this study unless we learn if breathing is compromised in certain positions, or if your child’s future wheelchairs can be designed even better than we are now able to design.

10b. What are the possible benefits to others?

This is a pilot study that will give us information about how to conduct a larger study. That study may help us learn more about how children breathe in wheelchairs so that wheelchairs can be designed better for all children who use them.

11. If you choose to allow your child to take part in this research study, will it cost you anything?

No.

12. Will you receive compensation for taking part in this research study?

No. Neither you nor your child will be paid any cash or other benefits for taking part in this research study.

13. What if your child is injured because of the study?

If your child experiences an injury that is directly related to this study, you should contact Paul Davenport, PhD (352) 392-4700, extension 13824.

Only professional consultative care that you receive at the University of Florida Health Science Center will be provided without charge. Hospital expenses will have to be paid by you or your insurance provider. No other compensation is offered. Please contact the Principal Investigator listed in Item 3 of this form if you experience an injury or have any questions about any discomforts that you experience while participating in this study.

14. What other options or treatments are available if you do not want to be in this study?

This is not a treatment study; no other treatment options are being offered. The other option to taking part in this study is doing nothing. If you do not want to take part in this study, tell the Principal Investigator or his/her assistant and do not sign this Informed Consent Form.
15a. Can you withdraw your child from this research study?

You are free to withdraw your consent and to stop participation in this research study at any time. If you do withdraw your consent, there will be no penalty, and you will not lose any benefits you are entitled to.

If you decide to withdraw your consent to participate in this research study for any reason, you should contact Lee Banks at (407) 741-4025 cell.

If you have any questions regarding your rights as a research subject, you may phone the Institutional Review Board (IRB) office at (352) 846-1454.

15b. If you withdraw, can information about your child still be used and/or collected?

If you withdraw, information already collected can be used. No further information about your child can be collected.

15c. Can the Principal Investigator withdraw your child from this research study?

Your child may be withdrawn from the study without your consent if the investigator decides that continuing in the study would be harmful to your child or if your child does not meet the study requirements for admission to the study. Ask the Principal Investigator if you would like more information about this.

16. If you agree to participate in this research study, the Principal Investigator will create, collect, and use private information about your child and your child's health. Once this information is collected, how will it be kept secret (confidential)? In order to protect your privacy?

Information collected about your child's health (called protected health information), will be stored in a locked filing cabinet or in a computer with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Otherwise your research records will not be released without your permission unless required by law or a court order.

If you participate in this research study, the researchers will collect, use, and share your protected health information with others. Items 17 to 26 below describe how this information will be collected, used, and shared.
17. If you agree to allow your child to participate in this research study, what protected health information about your child may be collected, used, and shared with others?

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you, your child, your child’s physical therapist, and from physical examinations and interviews. This information will be created by participating in study procedures, or from your study visit. More specifically, the following information may be collected, used, and shared with others:

Your child’s name,
Telephone number,
Age,
Gender,
Ethnicity,
Medications, and
Body dimensions for seating;
Recent and past health history, including history of heart-lung, nervous, and bone-spine systems;
Findings from the chest examination,
Temperature, pulse, and respirations, and
Measurements of breathing (lung) function (total airway resistance, tidal volume, minute ventilation, and empty space to tidal volume ratio (ratio of air left in the airway to amount of air moved in and out in respiration)
Personally reported history of respiratory disease
Personally reported history of nervous system disease
Date participated in the study

If you agree to be in this research study, it is possible that some of the information collected might be copied into a "limited data set" to be used for other research purposes. If so, the limited data set may only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, or any other photographs, numbers, codes, or so forth that link you to the information in the limited data set. If used, limited data sets have legal agreements to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your child’s protected health information be collected, used, and shared with others?

Protected health information may be collected, used, and shared with others to make sure your child can participate in the research, and to evaluate the results of the research study. More specifically, your protected health information may be collected, used, and shared with others for the following study-related purposes:

• to see how possible it is to measure breathing and wheelchair positioning, in children who cannot sit alone;
• to develop the study method, finding the best times for measurement, without tiring the children.
• to see how long it will take to recruit enough participants, on a small scale; and
• to find out the effect of wheelchair positioning on breathing, in a very small sample of children

19. Who will be allowed to collect, use, and share your child’s protected health information?

Your protected health information may be collected, used, and shared with others by:
• the study Principal Investigator Dr. Paul Davenport;
• the Unaffiliated Investigator, Lee Barks, MN, ARNP;
• other professionals or assistants at the University of Florida or Shands Hospital that provide study-related procedures; and
• the University of Florida Institutional Review Board.

20. Once collected or used, who may your child’s protected health information be shared with?

Your protected health information may be shared with:
• Ms. Barks’ faculty advisors: Audrey Nelson, RN, PhD, University of South Florida; Jason Beckstead, PhD, University of South Florida; and Mary Evans, RN, PhD, University of South Florida;
• United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections; and
• government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and Federal, State, and local health departments

21. If you agree to participate in this research, how long will your child’s protected health information be used and shared with others?

Your protected health information will be collected, used, and shared until the end of the study.

22. Why are you being asked to allow the collection, use and sharing of protected health information?

Under a new Federal Law, researchers cannot collect, use, or share with others any of your protected health information for research unless you allow them to by signing this consent and authorization.
23. Are you required to sign this consent and authorization and allow the researchers to collect, use and share with others your child's protected health information?

No, and your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent/authorization.

24. Can you review or copy your protected health information that has been collected, used or shared with others under this authorization?

You have the right to review and copy your protected health information. However, you will not be allowed to do so until after the study is finished.

25. Is there a risk that your protected health information could be given to others beyond your authorization?

Yes. There is a risk that information received by authorized persons could be given to others beyond your authorization and not covered by the law.

26. Can you revoke (cancel) your authorization for collection, use and sharing with others of your protected health information?

Yes. You can revoke your authorization at any time before, during, or after your participation in the research. If you revoke, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete and protect the validity of the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

27. How will the researcher(s) benefit from your child being in this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator may benefit if the results of this study are presented at scientific meetings or in scientific journals. The Unaffiliated Investigator will also benefit by completing requirements for her doctoral degree.
28. Signatures

As a representative of this study, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how the participant’s protected health information will be collected used and shared.

__________________________  _______________________
Signature of Person Obtaining Consent & Authorization  Date

Consenting Adults. You have been informed about this study’s purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared. You will get a copy of this Form. You have been given the opportunity to ask questions before signing this form, and you have been told that you can ask other questions at any time.

Adult Consenting for Self. By signing this form, you voluntarily agree to participate in this study and hereby authorize the collection, use and sharing of your protected health information as described in sections 17-26 above. By signing this form, you are not waiving any of your legal rights.

__________________________  _______________________
Signature of Adult Consenting & Authorizing for Self  Date

Parent/Adult Legally Representing the Subject. By signing this form, you voluntarily give your permission for the person named below to participate in this study and hereby authorize the collection, use and sharing of protected health information for the person named below as described in sections 17-26 above. You are not waiving any legal rights for yourself or the person you are legally representing. After your signature, please print your name and your relationship to the subject.

__________________________  _______________________
Consent & Authorization Signature  Date
of Parent/Legal Representative

Print: Name of Legal Representative of and Relationship to Participant:

__________________________  _______________________
Assent Signature of Participant  Date

484-2005 / 09-12-05 / Page 9 of 10
Telephone Contact Script:

My name is Lee Barks. I'm a nurse getting my PhD, studying how wheelchair design affects breathing in children. Dr. Paul Davenport is on the University of Florida faculty, and he is the Principal Investigator for this study.

We all have some difficulty breathing if our chest movement is inhibited, sometimes just by our body position in the environment. Children who already have difficulty positioning themselves due to cerebral palsy sometimes have difficulty breathing. To understand how wheelchair design and positioning affect children’s breathing, we want to study the kinds of positioning supports that a wheelchair can provide. We want to see which ones (or all) help to improve children’s normal breathing in seated position. In this pilot study, we will test the method we use to do this, for a later, larger study.

Are you interested in your child participating?

In this study, I will ask a few questions about your child’s recent health, look at and listen to your child’s breathing, and take his or her temperature, pulse, and respirations.

Then I will place a comfortable facemask on your child to measure breathing. Your child will be placed in 6 positions: One will be in the sitting position they are in without support. (We will measure breathing.) The other five positions will be in a special wheelchair. This looks like a machine but is really just a big adjustable seat. We will adjust different parts of the wheelchair to fit your child in 5 more positions. Then we will measure breathing in each position through a facemask. Throughout the entire procedure, your child will have a small oxygen sensor attached to one finger to sense how much oxygen is in his or her system at all times.

The positioning and measuring will be brief and the entire study should take no more than an hour.

If there are any sitting positions that you know your child cannot tolerate (that make your child ill), please tell me. (If any are reported, the parent will be told that this may pose risk to the child, and that the child will not be admitted to the study.)

If you would like your child to participate, let’s set a time for you to come to the pulmonary physiology lab. At that time, I will go over your consent for your child to participate and screen your child, then the study will take place if your child meets study criteria. May I have your name and contact information? How can I get directions to you?
Appendix C: Invitation to Participate
OPPORTUNITY

For Children With Cerebral Palsy
To Participate in Research
On Wheelchair Positioning and Breathing

**Through this pilot study, we hope to find ways to help children breathe better while in their wheelchairs.**

The study takes about one hour and involves having breathing measured while being positioned in a fully adjustable seat.

If your child has all of these:
- Cerebral palsy
- Cannot sit up without support
- Is between 5 and 10 years old
- Does not have a fixed spinal curve
- Has no breathing, heart, or blood illness, your child is eligible for this study.

If you are interested or have questions,
Call **Lee Barks, RN** at **1-888-373-2133**
(free call)
Appendix D: Instrument Specifications
Specifications

General

Specifications for the NICO₂ Monitor, Model 7600, are listed for informational purposes only and are subject to change without notice.

CO₂

- Principle of Operation: Non-Dispersive Infrared (NDIR) absorption, dual wavelength ratiometric-single beam optics, mainstream sensor.
- Response Time: Less than 60 ms
- Gas composition effects: O₂, N₂O (operator selectable)
- CAPNOSTAT® CO₂ Sensor:
  - Weight: Less than 18 g without cable
  - Sensor Size: 1.3 x 1.67 x .85 inches (3.3 x 4.2 x 2.2 cm), 8 foot cable (2.44 m)
  - Construction: Durable high performance plastic, ultra-flexible cable. Shock Resistant:
    Sensor will withstand a 6 foot drop to a tile floor.
- End Tidal CO₂:
  - Range: 0-150 mmHg, 0-20 kPa or % at Pb 760 mmHg
  - Accuracy: ± 2 mmHg for 0-40 mmHg, ± 5% of reading for 41-70 mmHg, ± 8% of reading for 71-150 mmHg
- Respiratory Rate:
  - Range: 2-150 breaths/min
  - Accuracy: ± 1 breath/min

Flow

- Flow Range (L/min) at Pb 760 mmHg, room air, 35°C
  - Adult: 2 to 180
  - Pediatric: .5 to 100
  - Neonatal: .25 to 25
- Flow Accuracy: Greater of ± 3% reading or:
  - Adult: ±5 L/min
  - Pediatric: ±25 L/min
  - Neonatal: ±125 L/min
- Tidal Volume Range (ml)
  - Adult: 200 to 3000
  - Pediatric: 30-400
  - Neonatal: 1-100
- Airway Pressure Range (cmH₂O): ± 120
  - Accuracy: greater of 0.5 cmH₂O or ± 2% reading
- Gas composition effects: O₂, anaesthetic agent, CO₂, N₂O, N₂, He (operator selectable)

SpO₂

- Oxygen Saturation
  - Range: 0-100%
  - Accuracy: ± 2% for 70 - 100%, ± 3% during motion conditions, for 1 standard deviation, unspecified for 0-69%. Applies to Finger Sensor, Y-Sensor®, and Single Patient Use (SPU) sensors. Use of the earclip can add an additional 1%.
  - Averaging Time: 2 seconds, or selectable, none, 2, 4, or 8 seconds.
  - Display Resolution: 1%
  - Settling Time: Display settles to within 1% of the final reading less than 15 seconds after the sensor is properly applied.
- Pulse Rate:
  - Range: 30-250 beats per minute
  - Accuracy: ± 1% of full scale (for 1 standard deviation or approximately 68% of readings)
  - Averaging Time: 8 seconds, or selectable 0, 2, 4, or 8 seconds, based on SpO₂ setting.
  - Display Resolution: 1 bpm
• Settling Time: Display settles to within 1% of the final reading less than 15 seconds after the sensor is properly applied.

**Cardiac Output (Optional)**

- Measurement Frequency: Rebreathing cardiac output measurement made every three minutes, rebreathing period is 35 seconds.
- Cardiac Output Range: 0.5-19.9 liters/minute
- Cardiac Output Resolution: 0.1 liters/minute
- Pulmonary Capillary Blood Flow (PCBF) Range: 0.5-19.9 L/min, Resolution: 0.1 L/min
- Cardiac Index Range: 0-9.9 L/min/meter², Resolution: 0.1 L/min/meter²
- Stroke Volume Range: 0-250 ml, Resolution: 1 ml
- Rebreathing Valve/sensor:
  - Valve type: dual diaphragm, pneumatically controlled
  - Return spring: automatically returns valve to normal position
  - Resistance: 3 cmH₂O/L/min maximum
- Rebreathed volume: normal position 35 ml; rebreathing position 150-450 ml (std.)
- CO₂/flow sensor: integrated into valve assembly
- Parameter limits for NICO measurements:
  - VO₂: >20 ml/min
  - RR: >3, <60
  - Vt: >200 (small and standard), >400 (large)
  - ETCO₂: >15, <85 mmHg (<100 mmHg during rebreathing) >2.0, <11.5 kPa or % (<13.5 kPa or % during rebreathing)

**Monitor Specifications**

- Classification (IEC60601-1): Class I/external power source, type BF, continuous operating mode, enclosure protection rating IPX0.
- Operating Environment: 50-104°F (10-40°C), 10-90% relative humidity (non-condensing)
- Size: Height 6.5 in., Width 10.75 in., Depth 9.5 in.
- Weight: 9 lbs, 10 oz.
- Power: 100-120/200-240 V~ 50/60 Hz 70VA
- Fuse Rating: F 2X: 1A 250V~T
- Battery: Internal, Sealed lead-acid gel-cell, 45 minute life on full charge (on-screen life indicator), 12 hours recharge time.
- Display: 4.625 x 3.5 inch EL, 320 x 240 pixels

**RS232 Communications**

- RS232 Communications Ports:

<table>
<thead>
<tr>
<th>Pin #</th>
<th>RS232-1</th>
<th>RS232-2</th>
<th>RS232-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Rx</td>
<td>Rx</td>
<td>Rx</td>
</tr>
<tr>
<td>3</td>
<td>Tx</td>
<td>Tx</td>
<td>Tx</td>
</tr>
<tr>
<td>5</td>
<td>Ground</td>
<td>Ground</td>
<td>Ground</td>
</tr>
<tr>
<td>7</td>
<td>n/a</td>
<td>RTSB</td>
<td>n/a</td>
</tr>
<tr>
<td>8</td>
<td>n/a</td>
<td>CTSB</td>
<td>n/a</td>
</tr>
<tr>
<td>9</td>
<td>n/a</td>
<td>Power</td>
<td>n/a</td>
</tr>
</tbody>
</table>

**Analog Specifications**

- Analog Input/Output Port (selectable, 0 to 1 volt range):
  - ETCO₂: 0-150 mmHg, 0-20 kPa or %, 6.67mV/mmHg
  - SpO₂: 0-100%, 10mV/%
  - Resp Rate: 0-150 br/min, 6.67mV/br/min
  - Pulse Rate: 0-250 bpm, 4mV/bpm
  - CO₂ Waveform: 0-150 mmHg, 0-20 kPa or %, 6.67mV/mmHg
  - Pleth Waveform: auto scaled

---

114 NICO₂® Monitor User's Manual Rev. C

104
- Flow Waveform - -125 to +125 L/m, 4mV/L/m
- Airway Pressure Waveform - -20 to +105 cmH₂O, 8mV/cmH₂O
- C.O. - Cardiac Output, 0-20 L/m, 50mV/L/m (optional)
- CI - Cardiac Index, 0-20 L/min./m², 50mV/L/min./m² (optional)
- SV - Stroke Volume, 0-200 ml, 5mV/ml (optional)
- PCBF - 0-20 L/m, 50 mV/L/m (optional)

<table>
<thead>
<tr>
<th>Pin #</th>
<th>Description</th>
<th>Pin #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ground</td>
<td>9</td>
<td>Ground</td>
</tr>
<tr>
<td>2</td>
<td>Channel 1 - input (not enabled)</td>
<td>10</td>
<td>Ground</td>
</tr>
<tr>
<td>3</td>
<td>Channel 2 - input (not enabled)</td>
<td>11</td>
<td>Channel 1 - output</td>
</tr>
<tr>
<td>4</td>
<td>Channel 3 - input (not enabled)</td>
<td>12</td>
<td>Channel 2 - output</td>
</tr>
<tr>
<td>5</td>
<td>Channel 4 - input (not enabled)</td>
<td>13</td>
<td>Channel 3 - output</td>
</tr>
<tr>
<td>6</td>
<td>Ground</td>
<td>14</td>
<td>Channel 4 - output</td>
</tr>
<tr>
<td>7</td>
<td>Ground</td>
<td>15</td>
<td>Input/Output Sense</td>
</tr>
<tr>
<td>8</td>
<td>Ground</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Technical Specifications

System for the oscillometric determination of respiratory impedance by Impulse Oscillometry (IOS)

- Global mean values of the respiratory impedance separated into resistance- and reactance spectrum
- Easy-to-understand graphic model-based interpretation including respiratory parameters for central and peripheral airways
- Breath by breath analysis including volume and flow dependency of respiratory impedance
- Slow and forced spirometry (inspiratory and expiratory flow-volume curve and Tiffeneau Test)

Components:
- Computer and TFT monitor or as portable notebook version, multi-color ink-jet printer
- Heated JAEGGER pneumotach
- ICS head including loudspeaker generator
- Reference impedance for calibration
- Complete recording and analysis software including powerful data management features
- Complete range of accessories including 3-liter-calibration pump
- Option: easy-to-move trolley

Technical data

- Flow measurement
  - Range: ± 20 L/s
  - Accuracy: 0.2 - 12 L/s ±2%
  - Resistance: < 0.05 kPa/(L/s) at 10L/s
  - Resolution: 10 mL/s
- Common mode rejection ratio (CMRR): 70 dB at 35 Hz
  - 60 dB at 50 Hz
- Volume determination
  - Range: ± 20 L
  - Resolution: 1 mL
- Mouth pressure
  - Range: ± 2 kPa
  - Accuracy: < ± 2 %
- Test signal
  - Impulse
  - Pulse interval: 0.1 - 6 s
  - Impulse length: 45 ms
  - Frequency range: 0 - 100 Hz
  - Power spectrum: - 20 dB at 40 Hz
- Calibration
  - CAL-Pock, automatically
- Reference impedance
  - Range: 0.2 kPa/(L/s)
  - Accuracy: < ± 2 %

Oscillometric parameters

- Z5: Magnitude of respiratory impedance
- R5: Total respiratory resistance
- R20: Proximal respiratory resistance
- X5: Distal capacitive reactance
- Pres: Resonant frequency

Spirometric parameters

- Static lung volumes:
  - VT, ERV, IRV, IC, IVC, EVC, VCmax, ...
- Dynamic lung volumes:
  - FEV1, FEV1/FVC, FEV1/VC, FEV1/VCmax, PEFR1, PEFR2, PEFR3, PEF1, PEF2, PEF3, MEF25, MEF50, ...

MasterScreen IOS

Available with spring or tube support arm
(not illustrated)

Dimensions

MasterScreen IOS Trolley (option)

- Trolley with adjustable, swivel-mounted desktop:
  - 60 x 66 cm (23.6 x 26 inches)
- Required space:
  - 90 x 120 cm (35.4 x 47.2 inches)

Viasys Healthcare Germany

Labsinnstr. 7
D-79224 Freiburg

+49 (0) 31 4972 423

www.viasyshealthcare.com
MasterScreen IOS
An Overview:

Measurement Programs:
- Impulse Oscillometry ●
- Spirometry/Flow-Volume ●
- Animation (Spirometry) ●
- Bronchial Test incl. APS Pro ○
- Anterior Rhinomanometry ○
- Tidal Breathing Analysis in Children ○

Administrative Programs:
- Data Base ●
- Data Base Tools ○
- Export/Statistics via SQL Data Base ○
- Screen and Printer Report ●
- Trend Report Module ●
- Interpretation Oscillometry ●
- Interpretation Spirometry ○
- Off-line Input ○
- Report Designer ●
- Predicted Value Generation ●
- User Predicted Values ○
- Language Maker ●
- User Parameters ○
- Patient Manager ○
- AMOS ●
- Network Data Base ○
- Interface for Hospital/Practice System ○

Hardware Options
- Trolley ○
- Provocation System APS ○
- Anterior Rhinomanometry ○
- Bedside ○

Upgrade Options
- Body Plethysmography ○
- Diffusion ○
- Ergospirometry ○
- Pediatric applications (baby lung function) ○

Examples:
- MasterScreen IOS PC including the options Bronchial Challenge (APS) and Trolley
- MasterScreen IOS as notebook version

Performance Features:
- Desktop version, portable as notebook version or mounted on trolley
- Heated pneumotach for highest accuracy
- New, user-friendly graphical user interface
- Comprehensive standard equipment
- Meets international guidelines and standards
- Especially suited for:
  - Pulmonology and allergy
  - Pediatrics and geriatrics
  - Occupational medicine
  - Screening, epidemiology and experimental respiratory physiology

The NEW Rudolph Nasal & Mouth Breathing Two-Way Non-Rebreathing Face Mask is primarily designed for Stress/Exercise Testing, Pulmonary Function Studies, & Metabolic Measurements. It is similar in function to our previous blue 7310 Series Face Mask. The primary improvements include a lower rebreathing volume dead space, one inhalation valve port instead of two (as with the 7310 series), a new translucent silicone rubber material, and improved facial sealing. All design changes result in enhanced subject comfort and improved quality of test results.

Two-Way Non-Rebreathing Masks are especially useful with subjects who have difficulty in using a mouthpiece and noseclip with a Two Way Non-Rebreathing Valve. Subject comfort and the secure fit afforded with this Nasal & Mouth Breathing Face Mask will result in more accurate test results. As opposed to a mouthpiece / noseclip technique, this mask design has the advantage of eliminating jaw fatigue, salivary build-up, dry mouth, throat irritation and leakage of air around the lips that would otherwise hinder a mouthpiece.

This Pediatric Size Series has Large and Small Mask Face Pieces available adapted with Hans Rudolph Y-Shaped™ and T-Shaped™ Two Way Non-Rebreathing Valves. The user can select from those valve sizes to meet the optimum test parameters such as dead space and flow characteristics. Other mask sizes, Infant, Neonatal & Premature, for adapting with Hans Rudolph Low Volume Dead Space Two-Way Non-Rebreathing Valves will be available.

**SPECIAL FEATURES**

- The face mask allows vocal communication between the subject and the technician.
- Our new head cap is designed of polyester net material which is light in weight and allows for greater heat loss during exercise testing.
- There are two Pediatric Head Cap sizes, Small & Large.
- Sampling Ports, Couplers & Tubing - (Gas & Pressure)

Two plastic nylon Female Luer Lock Type Sampling Ports are located 180° apart on one side of the mouth of the catheter that the examiner may use to observe the subject's naso and mouth breathing mask.

Each Female Luer Lock Sampling Port is sealed with a Male Luer Plug PN 171190.

A set of three couplers is supplied with each mask. One end connects to the sampling port Female Luer Lock, the other end is a hose barb which fits to the hose of flexible plastic tubing. These three hose barb sizes provide the user flexibility in tubing size usage.

Tygon® Tubing for Sampling Ports (Gas & Pressure) is available in the following bore sizes to fit over the Coupler hose Barb: 0.062” (1.6mm) PN 866060, 0.080” (2.4mm) PN 866061 and 0.125” (3.3mm) PN 866062. The maximum working pressure of this Tygon® Tubing is 40 psi (275kPa).

**GENERAL INFORMATION**

- **Face Mask sizes** 800, 90, 81, 82, 83, 84, 85, 86 represent a commonly designated size configuration with anasthesia face masks. To help the end user relate to those different sizes, this series of numbers will be shown on all of the Rudolph Human Face Mask product line.
- **Valving -** Utilizes one inhalation port and one exhalation port, using Hans Rudolph, inc. time proven, low resistance to flow Spiral-Type™ Diaphragms. Diaphragm sizes used in the inhalation/exhalation ports are shown in the tabulation.

**NEW RUDOLPH NASAL & MOUTH BREATHING FACE MASK TWO-WAY NON-REBREATHEING**

Stress/Exercise/Pulmonary Function Testing & Metabolic Measurements

Pediatric Small 8960 Size #2, Large 8950 Size #3

Nasal & Mouth Breathing Pediatric Face Mask with T-Shape™ and Y-Shape™ Configuration of Two-Way Non-Rebreathing Valves attached.

- **T-Shape™ Valve**
- **Y-Shape™ Valve**

Side view of Nasal & Mouth Breathing Face Mask fitted to a Two-Way Non-Rebreathing Valve on a subject's face. This illustrates the common air flow passageway between the nose and mouth as compared to our mouth breathing face mask, which has a partition separating & sealing the nose chamber from the mouth chamber.

**GENERAL INFORMATION (continued)**

- **Breathing Tube** - All Inhale / exhalation port tube adapters on the Two-Way Non-Rebreathing Valves have outside diameters for fitting into Large Bore 1.275” (32mm) and Infant 0.75” (22mm) Bore Tubings as follows:
- **Tubing Bore (Diameter) - Two-Way Non-Rebreathing Valve Series 1.275” (32mm) - Series 2650, 2650 0.75” (22mm) - Series 1420, 1410**

- **Rebreathing Volume Dead Space:** Includes the volume of mask face piece chamber, which has some variance because of users facial differences, plus the Two-Way Non-Rebreathing valve and adapter, which is the passageway volume between the inhalation and exhalation One-Way Valve Spiral-Type™ Diaphragms. Refer to Physical Characteristics.
- **Beards are a factor which can possibly cause leakage.**
- **Designed and Manufactured for Multiple Patient Use.**
- **Packaged: This product is individually polyethylene bagged and sterilized clean, non-sterile.**
- **Caution:** Federal law restricts this device to be sold by or on the order of a physician.
- **User熟悉 & OEM applications invited.**

PRINTED IN U.S.A.
681140 1/1985

- Prices & Specifications subject to change without notice •

© 1985 Hans Rudolph, inc.
RESISTANCE TO FLOW DATA

Pediatric Small Series 8690

<table>
<thead>
<tr>
<th>Flow Line</th>
<th>Differential Pressure Loss in Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>L6</td>
</tr>
<tr>
<td>1.0</td>
<td>L6</td>
</tr>
<tr>
<td>2.0</td>
<td>L6</td>
</tr>
<tr>
<td>3.0</td>
<td>L6</td>
</tr>
<tr>
<td>5.0</td>
<td>L6</td>
</tr>
</tbody>
</table>

Pediatric Large Series 8950

<table>
<thead>
<tr>
<th>Flow Line</th>
<th>Differential Pressure Loss in Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5</td>
<td>L6</td>
</tr>
<tr>
<td>1.0</td>
<td>L6</td>
</tr>
<tr>
<td>2.0</td>
<td>L6</td>
</tr>
<tr>
<td>3.0</td>
<td>L6</td>
</tr>
<tr>
<td>5.0</td>
<td>L6</td>
</tr>
</tbody>
</table>

**GUIDELINES FOR MASK FIT SELECTION**

Series Model No. (Nasal & Mouth Breathing- Type)

- **Mask Size**: 00 Premature
- **Age**: Less than 50 weeks
- **Model**: 8680

**COUPLERS** For Sampling Ports to Tubing

- **Coupless adjust the Female Luer Lock Sampling Port to different Bore sizes of flexible Plastic Tubing.**

**RUDOLPH NASAL & MOUTH BREATHING PEDIATRIC MASK FACE PIECE DIMENSIONS**

For ordering information and part number of replacement components, refer to Exploded Drawings & Table of parts numbers (PIN).

**REFERENCES**

For a validation study of the large Adult Rudolph Mouth Breathing Face Mask compared with the Historic Multipiece/Nonrebreathing technique refer to abstract titled "Comparison of the Rudolph Face Mask with the standard Multipiece/Nonrebreathing Apparatus in Measuring Respiratory Variables." (J.W. A.D. Reinhart, T.E. Dehmeler, W.L. Lake Human Performance Lab, Western Illinois University, Macomb, IL & Condell Medical Center, Medical Center Health Institute, Libertyville, IL. Medicine and Science in Sports and Exercise, Volume 24, Number 9, Supplement.


For additional information on the advantages of using the Rudolph Mouth Breathing Face Mask to collect expired air in spontaneously breathing patients refer to "Nutritional Assessment in Critical Care: A Training Handbook" by Donald C. Zawada, M.D., First Edition, Chapter 3, pages 21-55.

For information on the effects of breathing patterns comparing the face mask with mouthpiece technique, refer to "Human breathing patterns on mouthpiece of face mask during air, CO2, or O2" by Joseph Arm Hirsch and Beverly Bishop, Journal of Applied Physiology, Nov. 1962 - Vol. 53, No. 5, pages 1291-1295. This mask discussed in the article is not the Rudolph Nasal & Mouth Breathing Face Mask Series 9900 or the Rudolph Mouth Breathing Face Mask Series 7900.

PRINTED IN U.S.A.

*Prices & Specifications subject to change without notice.*

© 1996 Hans Rudolph, Inc.
Creating Possibilities ® "plane and simple" ®

Reflection PSS 98 PLANAR SIMULATOR

* Specifications

Standard equipment
- Mounted on a reinforced Luv-Base ®
- 3 pair lateral pads and mounting brackets
- 1 pair abductors and mounting brackets
- 1 pair arm supports and mounting brackets
- 1 head support mounting bracket to fit Whitmyer ® and Otto Bock ® type head supports
- 1 pair leg supports
- 1 pair medium Ankle Huggers ™ from BODYPOINT DESIGNS
- 1 pelvic strap
- Seat depth 6" to 20"
- Back height 10" to 24"
- Seat & back width to 20"
- Seat to back angle 65 degrees through 180 degrees
- Tilt 10 degrees anterior to 45 degrees posterior
- Arm supports fully adjustable, mounted to back rails to recline with back
- Leg supports fully adjustable
- Client weight limit 200 lbs
- Biangular Back 12" x 20" overall dim. hinged pad

Weight of Planar Simulator
- Including all asseccories 120 lbs

* Specifications subject to change without notice

Prairie Seating Corp. 7515 Linder Avenue - Skokie, IL 60077 847-568-0001 Fax 847-568-0002 prairieusa@aol.com www.prairieseating.com

http://www.prairieseating.com/PSsimulators.htm
Appendix E: Institutional Review Board Approvals
March 3, 2006

Lelia Barks
VA Patient Safety Center
11605 N. Nebraska Avenue
Tampa, FL 33612

Attn: Tricia Holtje

RE: Approved Application for Initial Review
IRB#: 104363

Title: Wheelchair Positioning and Pulmonary Function in Children: Pilot Study
Study Approval Period: 02/24/06 to 02/13/07

Dear Ms. Barks:

On 02/14/06, Institutional Review Board (IRB) reviewed and APPROVED your Application for Initial Review for the above noted protocol. Approval is granted for the period indicated above for the following:

Study Protocol, Version 3, dated 03/09/04.

Please note, if applicable, the enclosed informed consent/assent documents are valid during the period indicated by the official, IRB-Approval stamp located on page one of the form. Valid consent must be documented on a copy of the most recently IRB-approved consent form. Make copies from the enclosed original.

Please reference the above IRB protocol number in all correspondence regarding this protocol with the IRB or the Division of Research Compliance. In addition, we have enclosed an Institutional Review Board (IRB) Quick Reference Guide providing guidelines and resources to assist you in meeting your responsibilities in the conduct of human subjects research. Please read this guide carefully. It is your responsibility to conduct this study in accordance with IRB policies and procedures and as approved by the IRB.
We appreciate your dedication to the ethical conduct of human subject research at the University of South Florida and your continued commitment to the Human Research Protections Program. If you have any questions regarding this matter, please call 813-974-9343.

Sincerely,

Barry B. Berku, M.D., Chairperson
USF Institutional Review Board

Enclosures: (If applicable) IRB-Approved, Stamped Informed Consent/Assent Documents(s)
IRB Quick Reference Guide

Cc: Sandra Partap, USF IRB Professional Staff
FAO
JAH-VA

IA-AX-05-01
MEMORANDUM

DATE: October 20, 2005

TO: Paul W. Davenport, Ph.D.
Box 100144

FROM: Richard E. Neiberger, M.D., Ph.D.
Vice Chairman, IRB - 01

SUBJECT: EXPEDITED IRB #484-2005

EXPIRES: Sunday, October 01, 2006

TITLE: EXPEDITED: WHEELCHAIR POSITIONING AND PULMONARY FUNCTION IN
CHILDREN: PILOT STUDY

You have received IRB approval to conduct the above-listed research study. Approval of this study was granted on October 1, 2005. Enclosed is the dated, IRB-approved Informed Consent Form that must be used for enrolling subjects into this project from October 1, 2005 through September 30, 2006. This study is approved as expedited as it poses minimal risk and is approved under the following expedited category/categories: Expedited #4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate to the age, weight, and health of the individual.

You are responsible for applying for renewal of this study prior to the expiration date. Re-approval of this study must be granted before the expiration date, or the study will automatically be suspended. If suspended, new subject accrual must stop. Research interventions must also stop unless there is a concern for the safety or well-being of the subjects. You MUST respond to the Continuing Review questions within 90 days or your study will be referred to the Board for termination.

The IRB has approved exactly what was submitted. Any change in the research, no matter how minor, may not be initiated without IRB review and approval, except where necessary to eliminate hazards to human subjects. If a change is required due to a potential hazard, that change must be promptly reported to the IRB.

If applicable, only a qualified clinician may be responsible for study-related healthcare decisions.

Any severe and unanticipated side effects or problems and all deviations from federal, state, university, or IRB regulations must be reported, in writing, within 5 working days.

Upon completion of the study, you are REQUIRED to submit a summary of the study and a Study Closure report to the IRB office.

An Equal Opportunity Institution
Research records must be retained for 3 years after completion of the research; if the study involves medical treatment, it is recommended that the records be retained for 8 years.

If VAMC patients will be included in this study, or if the study is to be conducted in part on VA premises or performed by a VA employee during VA-compensated time, review by the VA Subcommittee for Clinical Investigations is required.

You are responsible for notifying all parties about the approval of this study, including your co-Investigators and Department Chair. If you have any questions, please telephone the IRB-01 office at (352) 846-1494.

cc: IRB file / Pharmacy / VA Research Center / Clinical Research Center
About the Author

Lee Barks received a Bachelor of Science in Nursing degree from the University of Virginia and a Master of Nursing degree from the University of Florida. She has held positions as staff nurse, clinical nurse specialist, and nurse practitioner, primarily in pediatrics. For the past 23 years, she has consulted on federal litigation regarding long term care of persons with disabilities of all ages in fifteen states, and has been admitted as an expert by the US Department of Justice. She has extensive experience with interdisciplinary teams and has most recently held the position of health services specialist at the Patient Safety Center of Inquiry, Tampa Veterans Administration. Ms. Barks is a 2007 inaugural Interdisciplinary Fellow in Patient Safety for the Veterans Administration and has authored publications in Rehabilitation Nursing, numerous training programs, and chapters in several textbooks.