Intertek

Technical Report

Carbon Dioxide Dispersion Assessment and Consultation for Vertical Crib Liners

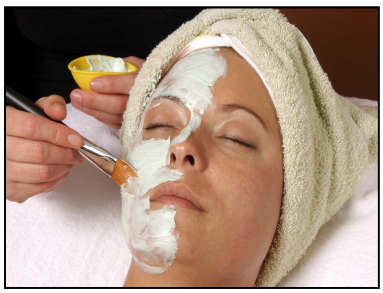
Intertek Report Number WOUS07474

Prepared for:

Ms. Georgia Fiebrich
Go Mama Go Designs







August 23, 2011

Essential Safety Evaluation for the Vertical Crib Linerss

Prepared for:

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1 INTRODUCTION

1.1 Human Factors Analysis

Human factors analysis is the study of the physical interaction of a consumer and a product. When this interaction is understood, the hazard types and severity levels associated with a product can be determined. The etiology of injuries from consumer products includes three components[1]. These components are exposure to the hazardous characteristics, consequences of contact with the hazard, and mitigation of the effects of the hazard.

1.1.1 Exposure to Hazard

If a consumer can gain access or become exposed to hazardous product characteristics, the probability of this event must be determined. For example, if a small part releases from product. Probable exposure to the hazard may be determined using anthropometrics data, pediatric biomechanics, and foreseeable use analysis. Anthropometrics data and pediatric biomechanics are used to evaluate the impact of size, strength, and kinetic behaviors/capabilities of consumers on their ability to access hazardous product characteristics.

1.1.2 Consequences of Hazard

If a consumer is exposed to hazardous product characteristics, the severity level or potential consequence of this exposure must be evaluated. For example, a small part is aspirated. Human factors analysis is conducted to determine the consequences, or potential product related injuries, based on the foreseeable behaviors consumers will use when interacting with products. Virtual and physical models of the human anatomy are used to effectively diagnose and demonstrate hazardous product characteristics.

Human factors analysis utilizes accurate virtual and physical simulations of the human anatomy to identify the potential hazards posed by consumer products. The conclusions of these analyses are developed with the assistance of, and confirmed by, leading physicians. In order to determine the level of product related hazard, both product characteristics and anatomical characteristics of likely consumers are examined. Virtual and physical human factors tools are used to conduct this research.

1.1.3 Mitigation of Hazard

The severity level of a hazard may be reduced by design characteristics that lead to reduced consequence or decreased time to effective treatment. For example, air passages in a small part may prevent fatal injury.

[1] Haddon, W. J. (1999). The changing approach to the epidemiology, prevention and amelioration of trauma: The transition to approaches etiologically rather than descriptively based. *Injury prevention; 5*; 231-236.

1.2 Product Evaluation

In fulfillment of the requirements laid out in the project proposal for the analysis of Vertical Crib Liners, Intertek has provided Go Mama Go Designs with an analysis of the potential carbon dioxide dispersion that the design of the Vertical Crib Liners allows for. To this end, Intertek has carried out a Carbon Dioxide Dispersion Assessment as well as engaged external medical experts to review Vertical Crib Liners.

Go Mama Go Designs has requested for Intertek to evaluate the Vertical Crib Liners to understand the effect that the product design has on carbon dioxide accumulation on the sleep environment. Intertek reviewed the Vertical Crib Liners in conjunction with external medical experts and also considered other potential hazards. These evaluations were conducted based on the samples provided by Go Mama Go Designs, as shown in Figure 1 through Figure 3. Intertek also conducted carbon dioxide dispersion measurements using a crib with no crib bumpers and no crib at all. Carbon dioxide dispersion was the primary focus; however Intertek also reviewed other potential hazards and provided comment throughout this evaluation. Physical measurements were not taken on the other hazards.

Dr. William W. Fox, Division of Neonatology, Children's Hospital of Philadelphia, and Dr. Thomas H. Shaffer, Director of Respiratory Physiology, Professor of Physiology and Pediatrics, Temple University School of Medicine provided consultation in regards to respiration. Intertek regularly consults with Dr. Fox and Dr. Shaffer on matters related to respiration and they provided valuable contributions to the discussion of carbon dioxide dispersion and suffocation specifically in this evaluation.

Figure 1 Vertical Crib Liner Sample

Figure 2 Mesh Bumper

Figure 3 Off the Shelf Bumper

2 CARBON DIOXIDE DISPERSION ASSESSMENT

2.1 Carbon Dioxide and the Respiratory System

Carbon dioxide rebreathing increases respiratory effort. Rebreathing of exhaled air is one proposed mechanism for the increased risk for Sudden Infant Death Syndrome (SIDS) among prone sleeping infants.[2] An increased risk for SIDS has been noted for infants at the age of 13 to 24 weeks.[3]

Carbon dioxide (CO_2) is an end product in organisms that obtain energy from breaking down sugars or fats with oxygen as part of their metabolism, in a process known as cellular respiration. This includes all animals, many fungi and some bacteria. In higher animals, the carbon dioxide travels in the blood from the body's tissues to the lungs where it is exhaled. In plants using photosynthesis, carbon dioxide is absorbed from the atmosphere.

The primary function of the respiratory system is to obtain oxygen for use by body's cells and eliminate carbon dioxide that cells produce. The structure includes respiratory airways leading into and out of the lungs as well as the lungs themselves.

2.2 Experiment Design

The capability of the Vertical Crib Liner samples provided by Go Mama Go Designs to allow for air flow was compared with the air flow capability of other crib bumpers currently on the market as well as no crib bumper, which is the optimal set-up for the reduction of carbon dioxide in the sleep environment.

To understand the effect that airflow has on the dispersion of carbon dioxide Intertek wanted to create a device that would produce carbon dioxide as if a baby was present in the sleep environment. In order for the carbon dioxide cloud to disperse air flow is introduced and Intertek measured how much the amount of carbon dioxide changed and how long it took to disperse. The shorter the amount of dispersion time, the less the amount of exposure to a hazard condition, which ultimately leads to less risk.

The experimental design allows for the categorization of the effects that varying crib bumper designs have on the dispersion of carbon dioxide in the infant sleeping environment. A fixture was developed to evaluate the effect that moving air will have on the dispersion of carbon dioxide. The fixture consisted of a main body fabricated from a plastic tube with an inner diameter of two inches and 4.25 inches in length. The main body was placed horizontally along the crib mattress surface aligned with the direction of airflow introduced into the system.

At a distance of 1.5 inches from one end of the main body tube, a small reservoir was fashioned at the bottom of the main body orthogonally from the centerline axis. Two small holes were placed in the bottom of the reservoir to allow the sampling of the air contained within.

Complementary to the reservoir a small hole was placed through the wall of the main body tube allowing for the insertion of an injector to control the point at which the detection gas could be introduced into the system. The detection gas introduced into the system was a mixture of carbon dioxide and other gasses to closely resemble the gasses exhaled by a child at rest. The detection gas was pre-mixed to contain approximately five percent carbon dioxide as indicated in Table 1.

To sample the gas within the reservoir a closed loop system was employed therefore any changes in percentage of carbon dioxide that was detected could be attributed to the air flowing through the main

[2] Kemp JS, Kowalski RM, Burch PM, Graham MA, Thach BT Unintentional suffocation by rebreathing: a death scene and physiological investigation of a possible cause of sudden infant death. J Pediatrics 1993; 122:874-880

[3] Oyen, N. et al. Combined Effects of Sleeping Position and Prenatal Risk Factors in Sudden Infant Death Syndrome: The Nordic Epidemiological SIDS Study. J Pediatrics 1997; 100(4): 613-621.

body of the fixture. To keep the detection loop closed the gas drawn from the reservoir was pulled through the sensor and exhausted directly back into the reservoir.

The sensor used to monitor the percentage of carbon dioxide used in this experiment was a TreyMed OEM Compact CO2 Waveform Analyzer. "The OEM Compact CO2 Waveform Analyzer (CO2WFA) is a complete data collection and analysis system for monitoring respiratory carbon dioxide concentration. The CO2WFA module includes a miniature carbon dioxide sensor, barometric pressure transducer, sampling flow control and a miniature low-power vacuum pump. A microprocessor collects the sensor data and calculates various real-time parameters: instantaneous carbon dioxide concentration, respiration rate, end-tidal carbon dioxide, inspired carbon dioxide, inspiration and expiration times." – *From the TreyMed website.*

The pump provided with the CO2WFA module is capable of sampling patient gas at a regulated 50-250 cc/min, and can provide some protection from occlusions in the sample line. The module automatically performs calibrations to correct for changes in temperature, altitude and electronic component drift by switching a solenoid valve from the sample line to ambient air for a few seconds in order to collect a reference point used in the carbon dioxide calculation. All communications between the host computer and the module i.e. sent commands; received waveforms, breath parameters and command responses are via 3.3V asynchronous serial data lines. *–From the TreyMed website www.treymed.com.*

Table 1 Gas Mixture for Carbon Dioxide Dispersion Assessment

Component	Expired Air (%)
Nitrogen	76%
Oxygen	17%
Argon	2%
Carbon Dioxide	5%
Total	**100%**

A crib agreed to represent a standard crib was erected according to the manufacturer's instructions and provide the testing environment for the dispersion of carbon dioxide assessments. Each of the samples was evaluated along with the crib with no crib bumper as well as no crib at all. The sampling chamber was placed inside the crib at a distance of three inches from the surface to be evaluated. A small fan (Sunpentown Model #SF-0703) was placed outside the crib three inches from the surface to be evaluated directly in line with the center of the main body of the sample chamber.

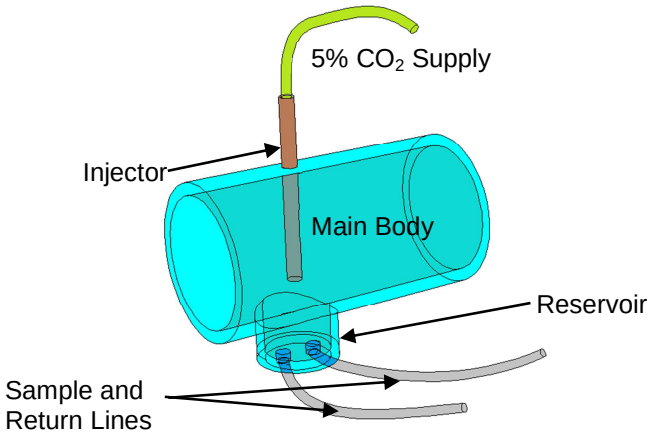

Figure 4 Test Fixture

2.3 Product Samples

This carbon dioxide dispersion evaluation was conducted on the Vertical Crib Liners and compared to a Mesh Bumper, an off the shelf bumper, a crib with no bumper, and no crib. These products were decided in conjunction with Go Mama Go Designs. The crib with no bumper represents an ideal sleep environment from an airflow standpoint. No crib present at all represents an ideal environment overall in regards to airflow. The crib used contains rails all around and was manufactured in 2011.

2.4 Test Setup

For all experiments, the test setup remained consistent, as shown in Figure 5 through Figure 9.

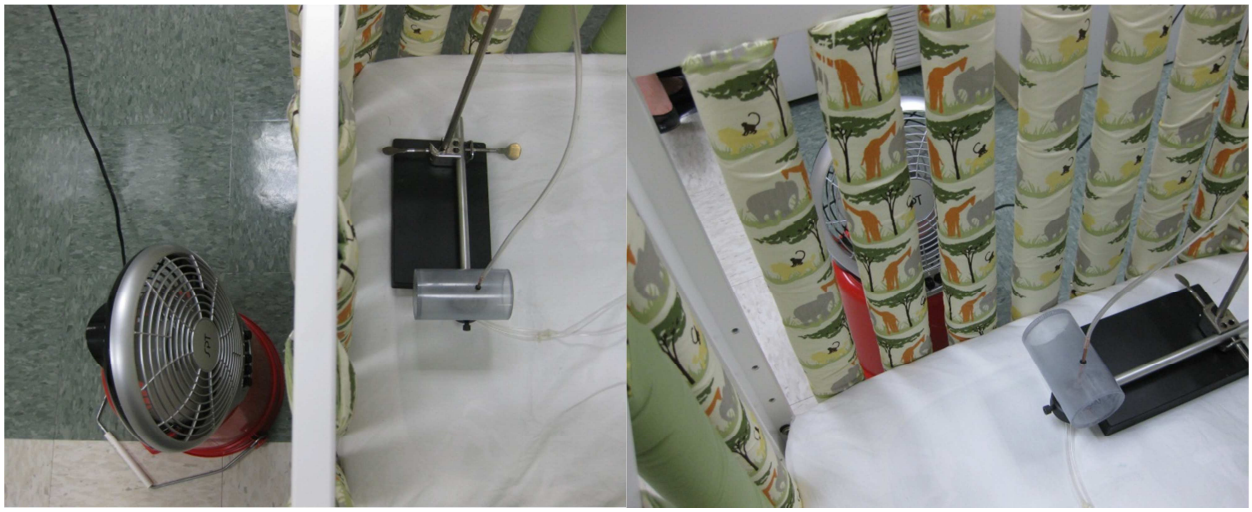

Figure 5 Vertical Crib Liners

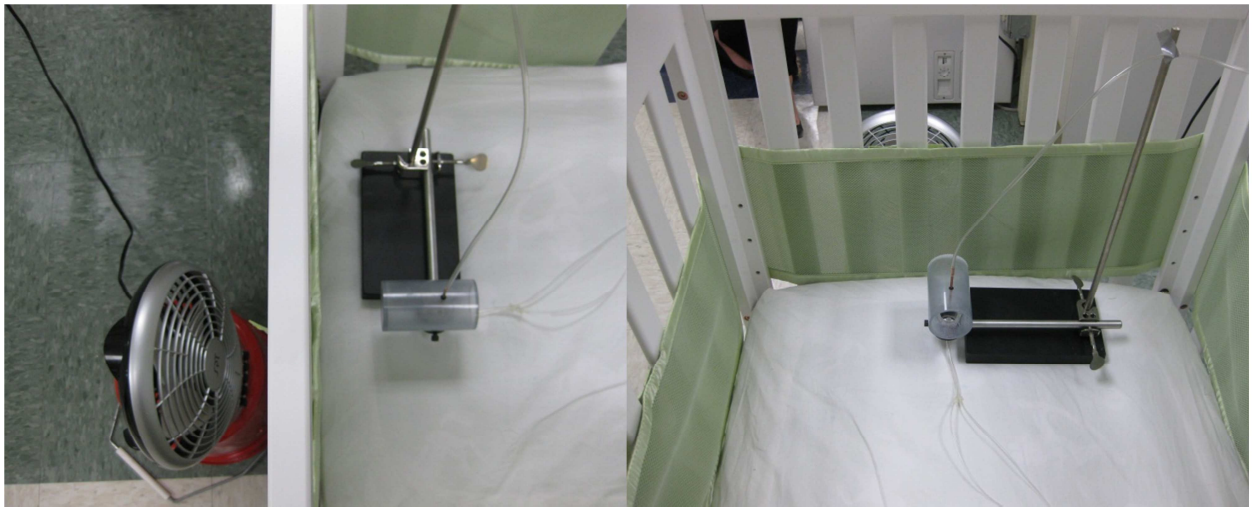

Figure 6 Mesh Bumper

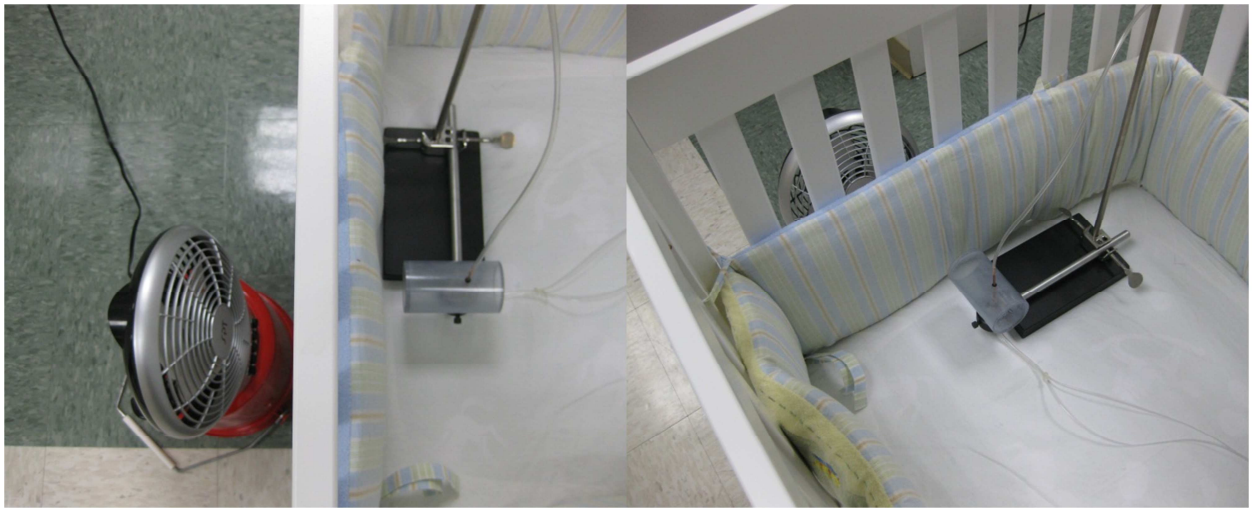

Figure 7 Off the Shelf Crib Bumper

Figure 8 No Crib Bumper

Figure 9 No Crib

2.5 Results

The capability of the Vertical Crib Liner samples provided by Go Mama Go Designs to allow for air flow was compared with the air flow capability of other crib bumpers currently on the market as well as no crib bumper, which is the optimal set-up for the reduction of carbon dioxide in the sleep environment. The results of the carbon dioxide dispersion evaluation indicate that the Vertical Crib Liners allow for significant airflow, which reduces the amount of carbon dioxide present in the sleep environment thus significantly lessening the possibility that carbon dioxide rebreathing would occur.

Dr. Fox and Dr. Shaffer experienced the on-site carbon dioxide dispersion evaluation during the proof of concept phase. Dr. Shaffer commented that the design of the Vertical Crib Liners allowed for increased ventilation, which resulted in a reduction of carbon dioxide. This is captured in the data documented below. Furthermore, the increased air flow is ideal, but the Vertical Crib Liners allows for something even more significant. The doctors commented that the Vertical Crib Liners change the environment that the infant is breathing in, and this is an improved environment with significantly reduced carbon dioxide.

As detailed below in Table 2 and depicted in Figure 10, the Vertical Crib Liners allow for nearly a 32% reduction in carbon dioxide in the sleep environment. This is a dramatically improved environment than the off the shelf crib bumper that was assessed in this evaluation. At nearly 32%, the Wonder Bumper does not perform as favorably as no crib bumper; however the result is only about 5% less. Furthermore, the rate of change in the percentage of carbon dioxide present in the environment was extremely rapid in all cases, indicating that favorable overall percentages of carbon dioxide reduction in the environment occur quickly. The rapid nature of dispersion is important to note as the reduction results are favorable because they occur very rapidly. Results would not be as favorable if the dispersion occurred more gradually over multiple hours. The reduction of carbon dioxide was measureable immediately for all scenarios, however the off the shelf crib bumper allowed for less than 2% of a reduction. The 2% reduction did happen immediately, however the reduction is quite small.

The reduction of carbon dioxide is caused by airflow, which is also an important variable to consider. Intertek captured the airflow during the dispersion evaluation and as expected, the samples that allowed for the most dispersion of carbon dioxide had the highest amount of air flow registered. The off the shelf crib bumper produced a result of essentially 0.00 cubic inches per second. In comparison, the crib with no bumper allowed for 185.30 cubic inches per second. The Vertical Crib Liners also enjoyed a significant

amount of airflow with a result of 92.65 cubic inches per second. For another comparison, the Mesh Bumper allowed for an airflow amount of only 12.87 cubic inches per second. Lastly, for reference, the amount of airflow registered with no crib present was 252.22 cubic inches per second.

Research indicates that the usual infant response to an increase in inspired carbon dioxide is hyperventilation and/or arousal. According to Dr. Fox and Dr. Shaffer in infancy this may manifest itself in the form of a headache and lethargy. Caregivers will not likely realize that carbon dioxide may be to blame for their irritable, tired child. The design of the Vertical Crib Liners allows airflow in the sleep environment, which as noted above, reduces the amount of carbon dioxide by almost 32%. This reduction significantly lessens the likelihood of an infant rebreathing carbon dioxide, therefore the potential for infants to experience negative side effects are much lower than with crib bumpers that do not allow for carbon dioxide dispersion. The unique design of the Vertical Crib Liners decrease the surface area that young children are exposed to by approximately 50%, which allows for dramatically improved air exchange when compared to a traditional crib bumper. It is important to note that the doctor's comments regarding surface area were specifically related to the crib that was used for the evaluation.

Further discussion on the importance of carbon dioxide dispersion in the sleep environment and the impact that carbon dioxide can have on very young children is provided by the doctors. Dr. Fox and Dr. Shaffer have extensive experience in clinical settings and as physiology consultants. Dr. Fox broke down the possible outcomes of carbon dioxide retention in very young children by providing short term and chronic effects of carbon dioxide retention. The short term affects may have an impact on the overall quality of life for the baby and include gasping spells, headache, fatigue (baby that tires easily), irritability, and abnormal respiration. The chronic affects are actual physiologic changes and are less likely, but include increased blood pressure, increased heart rate, increased work to breathe, and increased respiratory rate. These chronic issues are particularly noteworthy because they are actual physiologic changes that can affect several systems of the young body. In extremely severe cases of excessive carbon dioxide retention the doctors have observed decreased growth, an increase in pulmonary pressure, and extreme fatigue throughout the day.

Table 2 Carbon Dioxide Reduction in Environment

Sample	Initial % CO2 Steady State	Final % CO2 Steady State	Overall % CO2 Reduction in Environment
No Crib	2.313	1.048	54.7
No Bumper	2.058	1.317	36.0
Vertical Crib Liners	2.189	1.5	31.5
Mesh Bumper	2.02	1.454	28.0
Off the Shelf Bumper	1.99	1.956	1.8

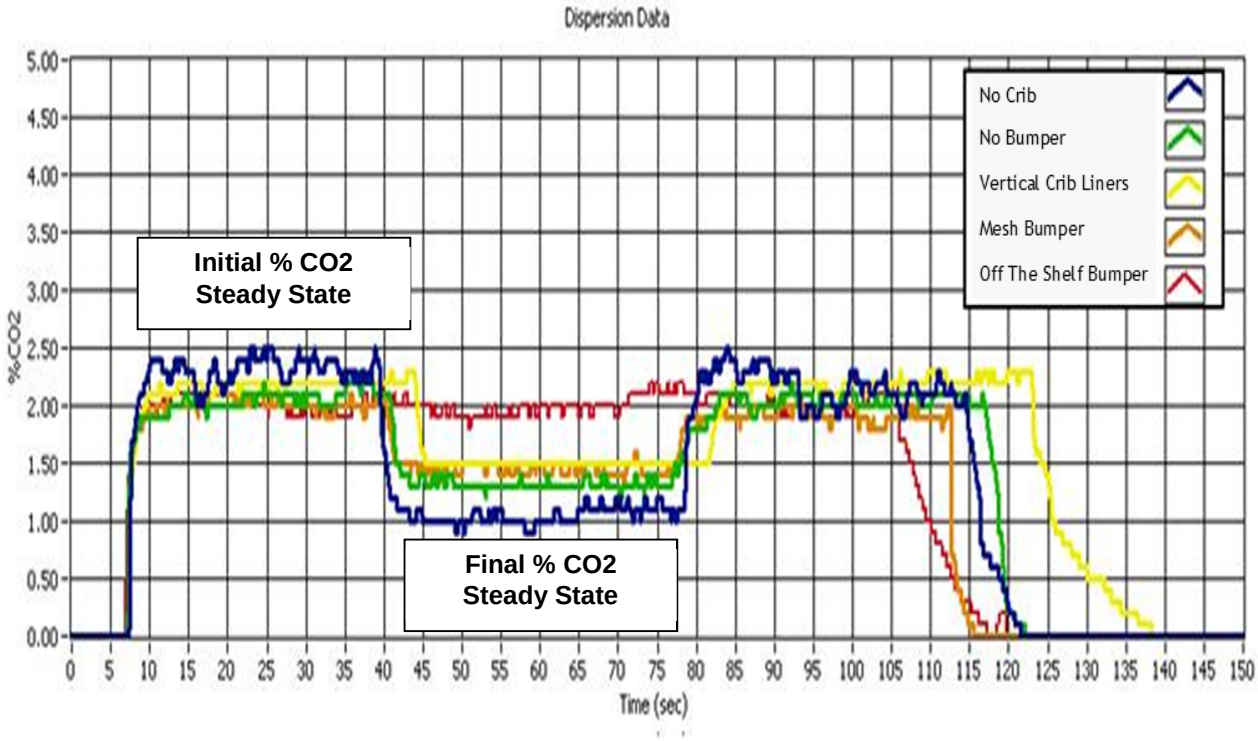

Figure 10 Carbon Dioxide Dispersion Data*

* The data used for analysis is depicted under the text boxes placed in the figure. The variable “time” depicted on the X-axis was not part of the analysis.

3 OTHER HAZARD CONSIDERATIONS

During an on-site workshop with Go Mama Go representatives and external medical experts, Intertek reviewed the Vertical Crib Liners products for specific potential hazards identified by Go Mama Go. These include suffocation, entrapment, and fall hazards. No physical measurements were taken to assess these hazards, however comments provided by the medical experts and Intertek are documented below.

Suffocation

Suffocation due to asphyxia – the condition caused by a lack of oxygen being supplied to the body – is caused by the mechanical resistance of an object in direct contact with the body. Asphyxia is the consequence of suffocation and is caused by low oxygen levels in the blood.

If the openings to the oral and nasal cavities are completely or substantially blocked, air is prevented from reaching the lungs. Blood will continue to circulate but the oxygen level within the blood will rapidly drop, potentially resulting in serious injury to the brain, and if the blockage is not removed, death.

The compliant tissue of the infants face in combination with the likely presence of saliva and mucous, makes it easier to form an airtight seal

The lungs are the primary organs used for breathing as part of the respiratory system. Oxygen is brought into the body through the lungs (inspiration) and CO_2 is expelled (expiration) during normal respiration (ventilation). The respiratory cycle, shown in Figure 11, brings air into the body when one inhales and pushes air out of the body when one exhales. Pressure is required to overcome normal airway flow resistance. The respiratory system can sustain pressures over certain periods of time to overcome resistance in the airway, e.g., a one-year-old can sustain approximately 18.6 cm H_2O (182.4 Pa) for six hours and 23.6 cm H_2O (231.4 Pa) for one hour.

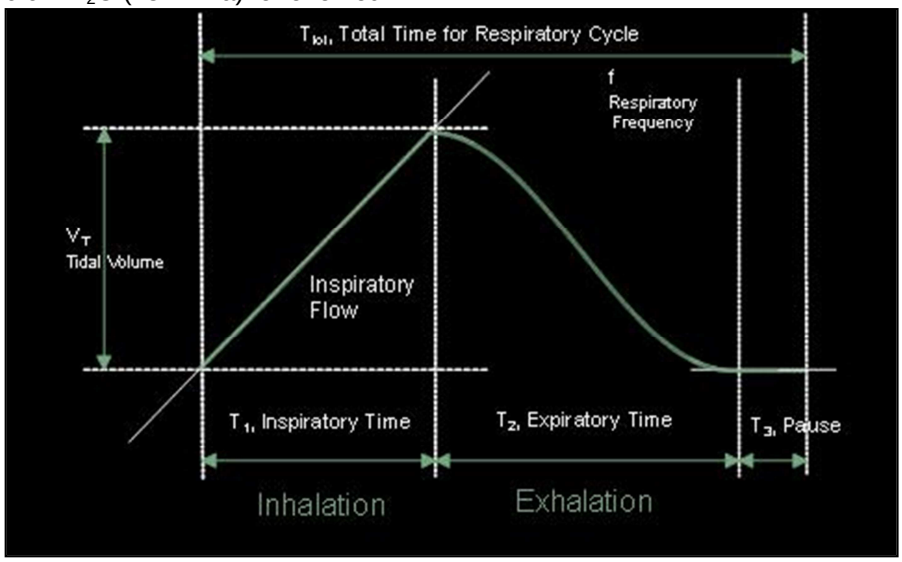

Figure 11 Respiration Cycle

Air first enters the mouth and/or nose during inspiration as it is drawn further into the respiratory system. Any object which creates a mechanical barrier for air to enter the body must effectively seal off both the nose and the mouth. Children from birth to 3 years old are typically most at-risk of injury or fatality from suffocation, according to consumer product injury and fatality data. The breadth of the mouth ranges

from approximately 2.5 cm for newborns to 4 cm for three-year-olds. The distance from the bridge of the nose to the chin ranges from approximately 7 cm for newborns to 9 cm for three-year olds.

The cartilage that forms the ridge of the adult nose is absent in infants, whose noses are formed of fatty tissue. Infants nostrils point forward and are more easily pressed closed or covered. Materials that are flexible enough to conform or deform to fit the surface geometry of the infant face may pose a suffocation hazard. Such materials may still possess a low level of hazard if they have the ability to absorb liquids and are permeable to air.

In regards to Vertical Crib Liners, Intertek in conjunction with Dr. Fox and Dr. Shaffer evaluated the natural shape the materials used in Vertical Crib Liners make when securely fastened to each crib rail. The convex nature of the Vertical Crib Liner was appreciated by the doctors and Intertek due to the fact that a complete seal would not likely be possible. When used as intended, Vertical Liners pose an extremely low level of hazard for a suffocation incident to occur. The Vertical Liners enjoy a significant level of mitigation due to the fact that the individual rail guards decrease the total accessible surface area by creating a ventilation system between the crib rails that mimic the inherent design of the crib. In comparison, traditional crib bumpers cover 100% continuous accessible surface area that the child is exposed to. Furthermore, due to the convexity of the Vertical Liners, material characteristics such as permeability do not require consideration as they cannot create a hazard for suffocation. Material characteristics are critically important with traditional crib bumpers.

Dr. Fox commented that if the nose was blocked by the Vertical Liner, it is highly unlikely that the mouth would also be comprised, and vice versa. The curvature and radius produced by the design of the Vertical Liner makes it virtually impossible that a suffocation incident could occur, according the Dr. Fox and Dr. Shaffer. Additionally, Dr. Fox commented that there is an ideal amount of firmness to the Vertical Liner that prevents an infant from burying their face. This coupled with the designed convexity prevents the face from being occluded, which Dr. Fox stated is a strong advantage of the Vertical Crib Liners. In comparison to a traditional crib bumper, such as the off the shelf crib bumper evaluated in the carbon dioxide dispersion evaluation, the Vertical Liners' curvature and radius significantly reduce the possibility that an infant's nose and mouth could be compromised. A traditional crib bumper has total surface area surrounding the sleep environment and allow for an infant's mouth and nose to be simultaneously occluded if the infant burrows against the bumper.

Entrapment

Entrapment is a potentially hazardous condition in which a limb, digit, or entire body enters a gap or opening from which it is difficult to be removed. Entrapment hazards can also lead to positional asphyxia in young children when their entire body is inserted and trapped in an object in a position in which it difficult to breathe and could possibly result in death. This specific hazard, also commonly referred to as entanglement, is eliminated by the design of Vertical Crib Liners. The snug fit and vertical design of the Vertical Liners do not allow for an infant's body to become inserted or trapped. With traditional crib bumpers, such as the off the shelf and Mesh Bumper examined in this study, it may be possible for an infant to wedge themselves underneath the crib bumper ending up in a potentially hazardous position in regards to the crib mattress, crib rails, and crib bumper. This may be possible due to the inability of the product to stay in place. The vertical design of the Vertical Crib Liner extends well below the crib mattress to the base of the rails, preventing the above described scenario.

In regards to the Vertical Crib Liners, the primary entrapment issue is not severe enough to result in the loss of life, limb, or function. The design of the Vertical Liners allows for space between the crib rails. It is foreseeable that children attempting to explore or climb out of the crib tent will place a hand, arm, foot, or leg into any openings between the crib rails. Therefore, it is possible that a young child's body part could become entrapped. However, these openings are not circular and would be classified as "nuisance" hazards rather than an entrapment hazard since they would not completely restrict blood flow. Further, the convexity of the Vertical Crib Liners described above also serves to mitigate this nuisance hazard by creating an almost opposite effect that undesirable circular openings would. The openings created by the Vertical Crib Liners should assist with a very young child removing a hand, arm, foot, or leg.

A crib with no bumper does not enjoy this mitigating effect as there is nothing assisting the young child with removal.

Fall

Foreseeable use indicates that individuals may attempt to climb out of their crib when the Vertical Liners are in place, which may lead to individuals falling out of the crib or back into the crib. While falls from cribs commonly occur, the Vertical Liners may actually serve to decrease the likelihood that an infant could climb out of the crib. Mobile infants can often climb onto standard crib bumpers and there is a risk that they can then fall out of the crib, therefore users of standard crib bumpers often remove the crib bumpers once children are able to climb. The design of the Vertical Liners does not provide a step that infants can use to step on and climb out. Children are more likely to slide back down onto the mattress regardless of their age or physical dexterity, which allows the Vertical Liners to be used for children of all ages sleeping in a crib. Furthermore, the Vertical Crib Liners will provide some cushioning if an infant falls against the crib rails as they attempt to climb and maneuver. The cushioning is likely to protect the head, face, and teeth from injury if the child does fall in the crib. Dr. Fox and Dr. Shaffer commented that the Vertical Crib Liners are padded, but not pillow-like, which is an optimal level of padding to prevent fall injuries without introducing a suffocation hazard. The doctors preferred this greatly over the design of the off the shelf and Mesh Bumper, which provide no more than approximately 11 inches of material to protect the head and body from injury.

This vertical design that does not compress to create a step along with cushioning that is provided by the Vertical Liners are very important features that mitigate potential fall hazards. The Consumer Product Safety Commission (CPSC) prepared an analysis of injuries and deaths associated with nursery products among children under age five and identified that falls were the leading cause of injury. Cribs were listed as being associated with the most injuries in the document from November 2009, which amplifies the mitigating factors that the Vertical Crib Liners uniquely possess.

3.1 Conclusion

Intertek examined two potential hazards of Vertical Crib Liners that have the largest potential severity when considering all possible hazards presented by the product: carbon dioxide rebreathing and suffocation. These hazards have increased significance because it is foreseeable that caregivers will leave children unattended in a crib for long periods of time. The results of the carbon dioxide dispersion evaluation indicate that the Vertical Crib Liners allow for significant airflow, which reduces the amount of carbon dioxide present in the sleep environment by almost 32%, thus significantly lessening the possibility that carbon dioxide rebreathing would occur. In regards to a possible suffocation hazard, the shape of the Vertical Crib Liners due to its material properties is convex and sized in a manner that does not allow a seal to be formed, dramatically reducing the potential for a suffocation incident to occur. The significant reduction of surface area is a significant advantage of the Vertical Crib Liners in comparison to many standard crib bumpers. This allows for dramatically improved air exchange.

Additionally, Intertek examined the Vertical Crib LIners to consider other potential hazards: entrapment and falls. These hazards vary in severity. Falls from a crib have the potential to result in loss of life, limb and/or function while possible entrapment injuries are not likely to have a severe outcome. Intertek commented on various mitigating factors present in Vertical Liners that positively affect the potential for falls and entrapment. The doctors consulting on this evaluation agree with the concept of Vertical Crib Liners for protection against fall hazards, suffocation, and entrapment as well as reduction of carbon dioxide in the sleep environment.

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Curriculum Vitae

Date: May, 2009

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The Children's Hospital of Philadelphia
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Philadelphia, PA 19104

Education:

1958-62	B.S.	Duke University, Durham, NC
1962-66	M.D.	Duke University Medical School, Durham, NC

Postgraduate Training and Fellowship Appointments:

1966-67	Internal Medicine Internship, Presbyterian University Hospital, University of Pittsburgh, Pittsburgh, PA
1969-70	Internal Medicine Residency, Hospital of the University of Pennsylvania, Philadelphia, PA
1970-72	Pediatric Residency, The Children's Hospital of Philadelphia, Philadelphia, PA
1972-73	Pulmonary Neonatology Fellowship, Department of Pediatrics McGill University School of Medicine and Montreal's Children's Hospital, Montreal, Canada

Military Service:

1967-69	Teaching in Bolivia Medical School, Co-Director of Tuberculosis Control Program, Peace Corps — U.S. Public Health Service, Bolivia, South America

Faculty Appointments:

1973-74	Associate in Pediatrics, Department of Pediatrics University of Pennsylvania School of Medicine
1974-79	Assistant Professor of Pediatrics, Department of Pediatrics The Children's Hospital of Philadelphia University of Pennsylvania School of Medicine
1979-85	Associate Professor of Pediatrics, Department of Pediatrics The Children's Hospital of Philadelphia University of Pennsylvania School of Medicine

1985-	Professor of Pediatrics, Department of Pediatrics The Children's Hospital of Philadelphia University of Pennsylvania School of Medicine

Hospital and Administrative Appointments:

1973-	Staff Neonatologist The Children's Hospital of Philadelphia, Philadelphia, PA
1973-	Staff Neonatologist The Hospital of the University of Pennsylvania, Philadelphia, PA
1974-82	Director, Pulmonary Function Laboratory The Children's Hospital of Philadelphia, Philadelphia, PA
1977-	Senior Physician The Children's Hospital of Philadelphia, Philadelphia, PA
1978-94	Medical Director, Infant Intensive Care Unit The Children's Hospital of Philadelphia, Philadelphia, PA
1982-pres/	Director, Infant Breathing Disorder Center The Children's Hospital of Philadelphia, Philadelphia, PA
1982-85	Attending Neonatologist, Lankenau Hospital, Philadelphia, PA
1986-90	Attending Neonatologist, Frankford Hospital, Philadelphia, PA
1989-91	Attending Neonatologist, Jeanes Hospital, Philadelphia, PA
1982-2007	Director, CHOP GCRC Scatterbed Research Nurse Program
2007-pres.	Medical Coordinaotr, CHOP GCRC Scatterbed Research Nurse Program

Specialty Certification:

1974	Diplomate of the American Board of Pediatrics
1975	Diplomate of the American Subspecialty Board of Neonatal/Perinatal Medicine

Licensure:

1966	North Carolina
1973	Pennsylvania

Awards Honors, and Membership in Honorary Societies:

1964	Davison Fellowship Duke University Medical School, Durham, NC
1976	Elected to "The Best Doctors in America"
1994	Elected to "The Best Doctors in America"
1997	Elected to "The Best Doctors in the Northeast"
1998	Elected to "The Best Doctors in America"
1998	CHOP Teaching Honor Roll
1999	CHOP Teaching Honor Roll
2000	CHOP Teaching Honor Roll

2002	Elected to "The Best Doctors in America"
2003	CHOP Teaching Honor Roll
2002	Quality and Safety Award for the Clinical Practices of the University of Pennsylvania
2004	Elected to "The Best Doctors in America"
2004	Top Doctors, Philadelphia Magazine, Philadelphia, PA
2004	CHOP Teaching Honor Roll
2005	CHOP Teaching Honor Roll
2006	CHOP Teaching Honor Roll
2007	CHOP Teaching Honor Roll
2007	Top Doctors, Philadelphia Magazine, Philadelphia, PA
2007	Graduation Speaker, CHOP Resident's Graduation
2008	Top Pediatrician in the U.S.
2009	Americas Best Pediatrician

Membership in Professional and Scientific Societies:

National Societies:

Society for Pediatric Research
American Pediatric Society
Southern Society for Pediatric Research

Local Societies:

Philadelphia Perinatal Society

Editorial Positions:

1982 Editor, Monograph Series on Sudden Infant Death Syndrome

Scientific Reviewer for Journals:

Pediatrics
Journal of Pediatrics
Critical Care Medicine
Pediatric Research
Pediatric Pulmonology

Scientific Reviewer for Grants:

March of Dimes
Thrasher Foundation
National Institutes of Health

Academic Committees at the University of Pennsylvania and Affiliated Hospitals:

1989- Member, Fellowship Committee
The Children's Hospital of Philadelphia

1991-	Founder and Co-director, Research Poster Day The Children's Hospital of Philadelphia Member, Advisory Board, Clinical Research Center The Children's Hospital of Philadelphia
2002-2007	Founder and Co-director Resident's International Fellowship Program The Children's Hospital of Philadelphia

Major Teaching and Clinical Responsibilities at the University of Pennsylvania:

1.	Attending Physician, Infant Intensive Care Unit, 5 months/year The Children's Hospital of Philadelphia
2.	Attending Physician, Infant Intensive Care Unit, 4 months/year Hospital of the University of Pennsylvania
3.	Neonatal Fellowship Program Participant, throughout the year
4.	Lecturer, Wilderness Medicine Course University of Pennsylvania School of Medicine
5.	Nurse Practitioners CHOP & HUP Neonatal Pulmonary Function - Annual

Lectures by Invitation:

February 1997	"Liquid Ventilation" — University of Pennsylvania School of Veterinary Medicine, Philadelphia, Pennsylvania
March 1997	"Liquid Ventilation" — Grand Rounds, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
June 1997	"Mechanical Ventilation of the Neonate" "Advances in Neonatal Care/Liquid Ventilation" "Pulmonary Function Evaluation" Neonatology Symposium, Cochabamba Bolivia
June 1997	"Mechanical Ventilation of the Neonate" National Medical School of Bolivia, La Paz, Bolivia
October 1997	"Liquid Ventilation in the Surgical Neonate" Surgical Grand Rounds, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
November 1997	"Mechanical Ventilation of the Neonate" 1) "PPHN in the Neonate" 2) "Liquid Ventilation of the Neonate" 3) "Nitric Oxide in the Neonate" International Symposium, Concepción, Chile

Lectures by Invitation: ***(continued)***

November 1997	"Advances in Mechanical Ventilation of the Neonate" Neonatal Grand Rounds, St. Christopher's Hospital for Children, Philadelphia, Pennsylvania
April 1998	"International Medicine" — Grand Rounds The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania.
October 1998	"Liquid Ventilation" "Persistent Pulmonary Hypertension of the Newborn" "Mechanical Ventilation of the Neonate" "Respiratory Failure in the Neonate" "High Frequency Ventilation and Cases" Philadelphia-Salzburg Seminars Sponsored by The American Austrian Foundation Salzburg, Austria
March 10, 1999	"An Update of Liquid Ventilation" Philadelphia Perinatal Society, Phila., Pennsylvania
June, 1999	"New Advances in Mechanical Ventilation of the Neonate" "Liquid Ventilation and Respiratory Failure" Cochabamba Medical School, Cochabamba Bolivia
June 1999	"Neonatal Respiratory Distress Syndrome" "Mechanical Ventilation of the Neonate" La Paz Medical School, La Paz Bolivia
March 16, 2000	"Liquid Ventilation for the Next Milennium" Surgical Grand Rounds, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
November, 2000	"Travel Electives in South America" — International Group, University of Pennsylvania School of Medicine
April, 2001	"High Altitude Pulmonary Edema" Wilderness Medicine Course, International Group University of Pennsylvania School of Medicine
April, 2002	"High Altitude Pulmonary Edema" Wilderness Medicine Course, International Group University of Pennsylvania School of Medicine
January 24, 2003	"Ventilating the Very Low Birthweight Infant: When, How, Why?" A Day with the Newborn Seminar St. Christopher's Hospital, Philadelphia, PA

Lectures by Invitation: ***(continued)***

April, 2003	"High Altitude Pulmonary Edema" Wilderness Medicine Course, International Group University of Pennsylvania School of Medicine
July 2003	"Early Continuous Positive Airway Pressure" La Paz Medical School, La Paz Bolivia
July 2003	"Neonatal Mechanical Ventilation" Cochabamba Medical School, Cochabamba Bolivia
July 2006	Keynote Speaker National Youth Leadership Forum in Medicine Villanova University, Villanova, PA
July 2006	"Advances in Neonatal Care" La Paz Medical School, La Paz Bolivia
July 2006	"Unusual Neonatal Conditions and Treatment" Cochabamba Medical School, Cochabamba Bolivia
July 2007	"Modern Neonatal Care", La Paz Medical School, La Paz Bolivia
July 2007	"Complex Neonatal Cases and Therapy", Cochabamba Medical School, Cochabamba Bolivia
June 2007	Coordinator National Youth Leadership in Medicine for CHOP
July 2007	"Update in Neonatal Care" La Paz Medical School, La Paz Bolivia
July 2007	"Review of new Technologies in Neonatology" La Paz Medical School, La Paz Bolivia
October 18, 2007	"Apnea Monitoring" – Grand Rounds Chester County Hospital, West Chester, PA
October 19, 2007	Pulmonary Function Testing on The Advanced Neonatal Nursing Respiratory Symposium The Children's Hospital of Philadelphia
January 30, 2008	"Lung Physiology in Neonate" Advanced Critical Care Nursing Course The Children's Hospital of Philadelphia
July 2008	"Special Cases in Neonatology" La Paz Medical School, La Paz Bolivia
	"Modern Neonatal Intensive Care"

Lectures by Invitation: ***(continued)***

	Cochabama Medical School, Cochabamba Bolivia
February 2009	"Lung Physiology in Neonate" Advanced Critical Care Nursing Course The Children's Hospital of Philadelphia

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2-3 cm H_2O continuous positive airway pressure (CPAP). Pediatrics, 59:257, 1977.

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Principal Investigator of Grants:

Neonatal Pulmonary Research, sponsored by Ohmeda Medical
December 2002 to July 2004 — $3,600.

NIH-CRC Neonatal Scatterbed Nurse Program
July 2000 to June 2005 — $175,000/year x 5 years.

A Collaborative Clinical Trial on High Frequency Jet Ventilation
in Premature Infants,
National Institutes of Health, $820,000, 1984-1990.

Burroughs-Wellcome Co., Beta-Casomorphin Study. $30,000/2 years, 1989-1991

Glaxo Inc., Effects of Albuterol on Pulmonary Mechanics in Infants with Bronchopulmonary Dysplasia, $15,000, 1987-1989

Parker B. Francis Foundation, Fellowship Training Grant, $50,000/year, 1978-1983

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Training

Drexel University, Philadelphia, PA	B.S.	1968	Mechanical Engineering
Penn State University		1968	Mathematics
Drexel University, Philadelphia, PA	MS.E.	1970	Applied Mathematics
Drexel University, Philadelphia, PA	PhD	1972	Applied Mathematics
University of Pennsylvania, Philadelphia, PA	Post-Doc	1972	Respiratory Physiology

Research Interests

Thomas H. Shaffer, MS.E., Ph.D., is Professor Emeritus of Physiology and Pediatrics. He also holds the position of Professor of Pediatrics at Thomas Jefferson Medical College. Dr. Shaffer received his doctorate from Drexel University in Philadelphia, Pennsylvania. He did postdoctoral work at the University of Pennsylvania School of Medicine where he was promoted to Assistant Professor of Physiology and Medicine. He was recruited as an Associate Professor at Temple University School of Medicine in 1977. Dr. Shaffer has 38 years of experience as an active scientist in pulmonary research with special attention to the needs of the neonatal and pediatric populations. Dr. Shaffer's revolutionary work with treatments for respiratory distress syndrome is known world-wide, and he is considered an international expert in this field. In addition, he is renown for his work in developmental airway physiology and clinical pulmonary function evaluation in neonates.

In this regard, Dr. Shaffer's pulmonary expertise was essential in the development of the "Virtual Infant Model" at Intertek Testing. This infant model has been instrumental in identifying toys, household objects and consumer products that are a potential suffocation treat to infants should they find their way into an infants mouth or cover their face. It has been rewarding to use basic knowledge of infant respiratory function to develop this model with Intertek for the safety of infants and children. Over the last 10 years, we have used this model to detect numerous suffocation treats that consumer products could have inflicted on kids safety.

Since 1974, Professor Shaffer has been continuously supported by NIH grants (22) and academic, corporate and private institutional awards (48 total). His early NIH grants were awarded during a period when corporate sponsors were not readily supporting work in his area of interest, and the resultant science acted as a catalyst for procuring many other grants from the private and corporate sectors. The excellence of his corporate-sponsored research has resulted in 12 licensed patents. In September, 2004, Dr. Shaffer was awarded a $10.2 million Center for Biomedical Research Excellent (COBRE) grant

from the National Institutes of Health for the development of a Center for Pediatric Research (CPR) at the Alfred I. duPont Hospital for Children in Wilmington, Delaware. In addition, as part of the ARRA program, he was awarded a $1.6 million in supplements to this program for 2009-2010. On September 17, 2010, the Center for Pediatric Research (CPR) at the Nemours/Alfred I. duPont Hospital for Children was awarded an additional 5-year, $9.5-million Center for Biomedical Research Excellence (COBRE) grant from the National Institutes of Health (NIH), National Center for Research Resources (NCRR). This competitive award will allow Nemours to continue to expand the CPR and support the recruitment of additional faculty to this diverse pediatric clinical and research facility. He serves as the Director of the new Center and administers its staff, revenues and research. Dr. Shaffer clearly understands translational research, having moved multiple intellectual properties from the bench top to the clinic and on to industry.

Dr. Shaffer's contribution to the literature has been significant. He has published 75 book chapters, 232 peer-reviewed manuscripts (with another 20 in review or in press), and 489 abstracts. His clinical manuscripts have been published in *Lancet*, *The New England Journal of Medicine*, the *Journal of Pediatrics*, *Pediatrics*, *Critical Care Medicine* and many more highly respected and well-read periodicals. In addition, he has published basic science manuscripts in the *Journal of Applied Physiology*, the *American Journal of Physiology*, and the *American Journal of Circulatory Research*. He serves on the Editorial Boards of three scientific journals and is a journal reviewer for another 22 publications.

In his faculty role at the Temple University School of Medicine and the University of Pennsylvania School of Medicine, Dr. Shaffer has mentored 43 graduate students and 55 post-doctoral Fellows during the past 38 years. Many of these former students now hold faculty positions in prestigious medical schools at the University of Pennsylvania, Stanford University, Columbia University, the University of California at Davis, SUNY in Buffalo, New York, the Temple University School of Medicine, Bowman Gray, and the University of Washington.

POSITIONS

1968	Instructor of Mechanical Engineering, Pennsylvania State University, State College PA
1972-74	Postdoctoral Fellow in Physiology, University of Pennsylvania, Philadelphia PA
1974-75	Research Associate in Physiology, University of Pennsylvania, Philadelphia PA
1975-76	Associate in Physiology and Medicine, University of Pennsylvania, Philadelphia PA
1976-77	Assistant Professor of Physiology, University of Pennsylvania, Philadelphia, PA
	Associate Professor of Physiology, Temple University School of Medicine, Philadelphia PA
1987-present	Professor of Physiology and Pediatrics, Temple University School of Medicine, Philadelphia, PA
1999-present	Professor of Pediatrics, Thomas Jefferson University, Philadelphia PA
2001-present	Associate Director of Biomedical Research; Director, Nemours Center for Pediatric Research; Director Nemours Research Lung Center; Director, Nemours Office of Technology Transfer, Nemours Children's Clinic/Alfred I duPont Hospital for Children, Wilmington, DE

HONORS AND AWARDS

1964-1968	Dean's List, Drexel University; Pi Tau Sigma; Olin Matheson Fellowship; Awarded Ford Foundation Fellowship; Tau Beta Pi
1969	Inventors Fulcrum of Progress Award
1974	Scholar of the Pennsylvania Plan; Sigma Xi
2005	Temple University Million Dollar Research Award Club
2010	Who's Who in America

ORIGINAL ARTICLES (selected 30 out of 308)

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