October 2022

CPSC Staff Statement[1] on Boise State University's, "Pillows Product Characterization and Testing"

The report titled, "Pillows Product Characterization and Testing," presents the findings of research conducted by Boise State University ("the contractor"), under Task Order No. 61320621F1015, Pillows Intended for Infant Care and Use, for the indefinite-delivery, indefinite-quantity (IDIQ) Contract No. 61320620D0002 for infant biomechanics and suffocation research and consultancy services.

This research included an analysis of the risk of injury or death to infants associated with the use of infant pillows, including nursing pillows and other types of pillows marketed as aiding infants during activities such as feeding, nursing, sleeping, propping, and lounging. The report recommends that hospitals' discharge information for parents of newborns include specific information on infant positioning and infant pillow products to educate parents and caregivers. The report also includes recommendations and conclusions related to the performance and design of infant pillows, including the following:

- *Firmness Testing*. The contractor recommends that all infant pillows be required to undergo firmness testing, using a contractor-developed test device and test method. Passing the firmness test would mean that the product has firmness comparable to current infant mattresses.

- *Airflow Testing*. The contractor recommends that infant pillows that do not pass the firmness test be required to pass an airflow test, using a contractor-developed test device and test method. Passing the airflow test would mean that the product has airflow characteristics comparable to current mesh crib liners.

- *Sagittal-Plane Testing*. The contractor developed new sagittal-plane testing devices to allow for a better assessment of infant positioning in and on infant pillows than similar testing devices. The contractor recommends further research to determine appropriate worst-case positions for testing and to set threshold values for acceptable body positions that would not negatively impact infant breathing.

- *Nursing Pillow Shape*. The contractor concludes that nursing pillows that are firm and feature sharper corners, rather than cylindrical sides, are likely the safest option for

[1] This statement was prepared by the CPSC staff, and the attached report was prepared by Boise State University, for CPSC staff. The statement and report have not been reviewed or approved by, and do not necessarily represent the views of, the Commission.

infants, because there would be no reasonable way for consumers to use such a product as a lounger.

Pillows Product Characterization and Testing

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Research conducted from September 2021 to June 2022.

June 30, 2022

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Abbreviations

AS/NZS	Australian Standard / New Zealand Standard
ASTM	ASTM International
BS	British Standard
BS/EN/ISO	British Standard / European Standard / International Organization for Standardization
CO_2	Carbon Dioxide
CPSC	Consumer Product Safety Commission
H_2O	Water
IDI	In-Depth Investigation
O_2	Oxygen

1. Introduction and Report Overview

Each year, almost a thousand infants tragically suffocate in their sleep. The United States Consumer Product Safety Commission (CPSC) has long been concerned with infant deaths related to consumer products such as cribs, inclined sleepers, and pillows. The CPSC has recently warned parents and caregivers that pillow-like infant products, including nursing pillows and "lounging pads," are not designed for sleep and are not safe for sleep.

The CPSC has identified deaths associated with pillow-like products and continues to analyze incident data with the goal of determining the risks with these products and providing more clarity to the public on any risks associated with these products. The initial assessment of incidents shows deaths when children are left on or near pillows, and the child rolls over, rolls off, or falls asleep.

Our research team consists of the Principal Investigator, Dr. Erin Mannen, who has a PhD in mechanical engineering with research expertise in infant biomechanics; Dr. John Carroll, who is a research-active pediatric pulmonologist; Dr. Brandi Whitaker, who is a pediatric psychologist with expertise in infant development; and research scientists and graduate assistants Dr. Safeer Siddicky, Wyatt Davis, and Sarah Goldrod.

Our team conducted research to analyze the death or injury risk to infants associated with the use of infant pillows, including nursing pillows and other types of pillows that are marketed as aiding or supporting infants (hereafter referred to as “pillows”), in various ways, including but not limited to, feeding, nursing, sleeping, propping, and lounging in foreseeable product positions and foreseeable infant body and face positions outside of the marketed use.

Our review of the in-depth investigation (IDI) documents (Section 2) elucidates that suffocation related hazards occur in infant pillow products in two main ways: (1) occlusion or rebreathing, meaning the nose or mouth is occluded by contact with the product or the infant’s face is in contact or near contact with a product that promotes CO_2 rebreathing; and (2) positional asphyxia, meaning that the infant’s body position (trunk flexion, chin-to-chest position, and/or neck hyperextension) inhibits normal breathing. In this research, we have explored both suffocation hazard types by designing and conducting tests to measure product characteristics that would be dangerous for both suffocation scenarios: occlusion and positional asphyxia.

We developed a biofidelic probe (Section 4) that is subsequently used for both firmness (Section 5) and airflow (Section 6) testing to understand how a product may promote or inhibit occlusion or CO_2 rebreathing scenarios. We designed positional measurement tools to elucidate how a product may impact a baby's face or body position when using the product (Section 7). We summarize our findings and provide recommendations and future work (Section 8). A schematic of our experimental process is detailed in Figure 1.

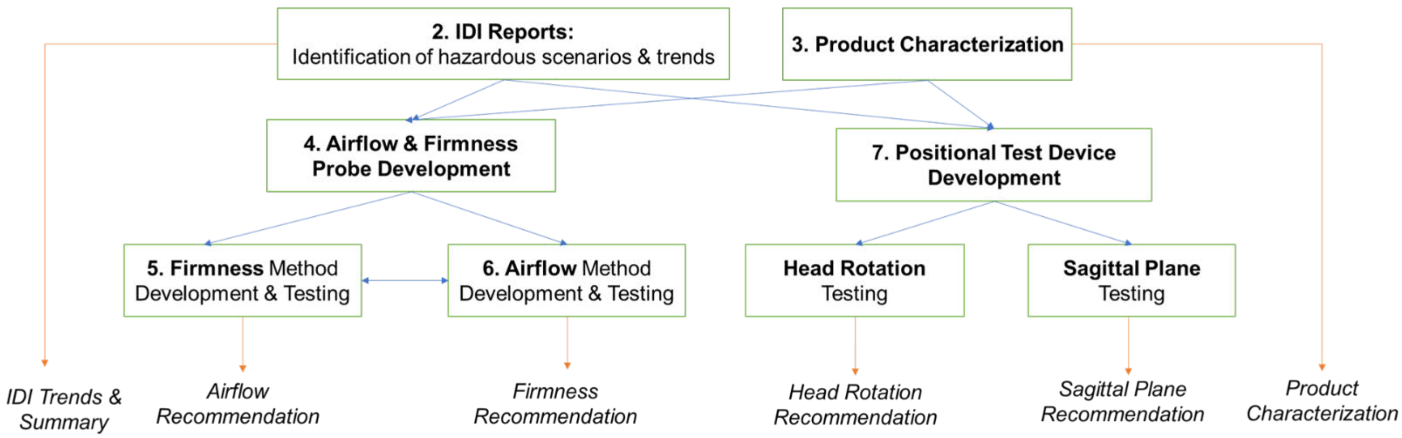


Figure 1. Schematic of overall report, experimental design, and outcomes. The numbers represent the section numbers in this report.

2. In-Depth Investigations

The CPSC staff provided our team with 50 In-Depth Investigation (IDI) packets which involved hazards, injuries, or deaths of infants when a lounging pillow or nursing pillow was present. Each IDI packet contained portions of the following information: police reports, medical records and health information, EMT reports, coroner reports, medical examiner reports, toxicology or laboratory reports, autopsy reports, forensic investigations, parental or caregiver statements, photos of the scene, photos of the infant or child, photos of the products involved, detailed information of the products involved, any related product recall information, product purchase information, correspondence from the CPSC to others seeking information regarding the incident, source documentation, and a CPSC staff summary of the investigation. The incidents spanned from January 2019 to March 2021.

The goal of our IDI review was to summarize the data into an easily accessible table so we could better analyze the group of incidents. We noted victim details, incident details, and pillow details. Drs. Carroll, Mannen, and Whitaker individually reviewed each IDI and provided a short interpretation of the incident. The CPSC staff summaries of the incidents were not considered in our reviews. We assessed the contribution of the infant pillow to each incident by asking the question "What is the likelihood that this incident would have occurred had the pillow not been involved?" Although each investigator reviewed every IDI packet independently, we each have complementary expertise that allowed us to assess the role of the pillow in the incidents with specific considerations in mind: Dr. Carroll focused on respiratory compromise related to the pillow and medical condition or clinical status of the infants which would increase physiological vulnerability; Dr. Mannen focused on body position and movement-related characteristics of the incidents; and Dr. Whitaker focused on developmental considerations of the infants. We chose not to average our scores but rather provide all three individual scores to show how our decisions were made based on our own expertise.

Based on our individual interpretations of the IDIs, we each scored every incident on a Likert scale from 1 to 5, with "1" meaning the pillow was *very unlikely* to have contributed to the incident, "2" meaning *unlikely*, "3" meaning *neutral*, "4" meaning *likely*, and "5" meaning the pillow was *very likely* to have contributed to the incident. A score of "0" indicated there was *not enough information* in the IDI packet to make a judgment on the contribution of the pillow to the reported incident. We did not indicate whether the pillow was the primary cause of the incident, only if the pillow likely contributed to the incident. After the preliminary independent reviews, if any of the three investigators scored the incident a 4 or 5, the incident was considered for further analysis regarding its probable role in the incident. Figure 2 shows a flow chart of the IDI review and analysis process. Of the 50 IDIs provided to the team, 47 were classified as deaths, while 3 were injuries or potential hazards. Of the 47 IDIs involving deaths, 10 IDIs either did not contain enough information to make an assessment or we assessed that the pillow did not contribute to the death. Thus, 37 fatal incidents remained that we explored in more detail and categorized into four scenarios: rolling, sagittal plane position, occlusion/CO_2 rebreathing, and other. Rolling scenarios accounted for 14 of the IDIs, with 9 of the incidents occurring when babies rolled off the pillow into dangerous environments and 5 of the incidents occurring when babies rolled from supine to prone but remained on the pillow. Even if suffocation was the apparent cause of death for these events, we grouped these events as rolling events because the death would not have occurred if the baby did not first roll off or onto the pillow. Sagittal Plane Position scenarios accounted for 10 of the IDIs, with 9 of the incidents occurring when babies slouched down into the center of the product resulting in a flexed trunk, a chin-to-chest position, or both, and 1 of the incidents occurring when a baby pushed back on the product, arching backwards and resulting in neck hyperextension. Occlusion/CO_2 Rebreathing scenarios accounted for 10 IDIs, with 7 incidents occurring when the baby's face was found in contact with the side (usually the center) of the pillow and 3 incidents occurring when babies were placed prone and found prone with their face in contact with the pillow. None of these occlusion/ CO_2 rebreathing incidents involved rolling. Three IDIs occurred under other circumstances.

The 37 deaths occurred in nursing or nursing / lounger pillows (28 incidents), infant lounger pillows (8 incidents), and an unknown infant pillow (1 incident). Products identified in the IDIs came from four companies. For nursing pillows, we considered any mention of u-shape, c-shape, or horseshoe-shape to be a nursing pillow. Of the 28 incidents involving nursing pillows, 14 were products from Company A, 4 from Company B, 1 from Company C, 1 from Company D, and 8 were unknown. Of the 8 incidents involving lounger pillows, 7 were from Company A and 1 was unknown. The incident involving the unknown pillow type did not include a manufacturer. Company information is found in Appendix A.

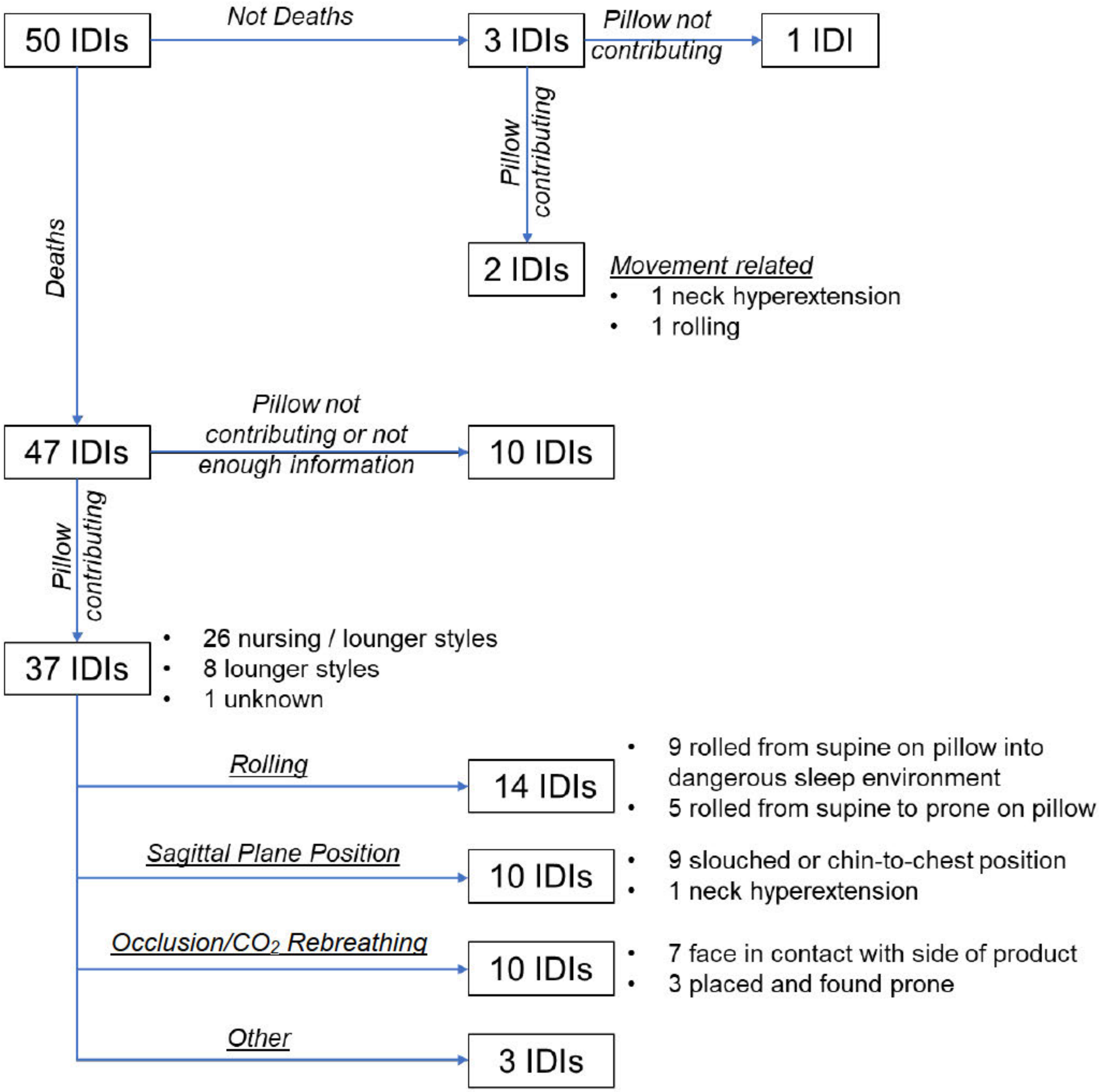


Figure 2. Flowchart showing the IDI review and analysis process.

Demographics

Demographics of the babies involved in the 37 deaths are: *Age*: 3.4 ± 2.2 months [range: 0.7 to 11.2 months]; *Sex*: 16 female / 21 male; and *Race/ethnicity*: 20 white, 9 black / African American, 3 Hispanic, 2 other, 3 unknown. Figure 3 shows the geographic distribution of the 50 incidents. Incidents were reported from 25 states in a mix of rural and metropolitan areas.

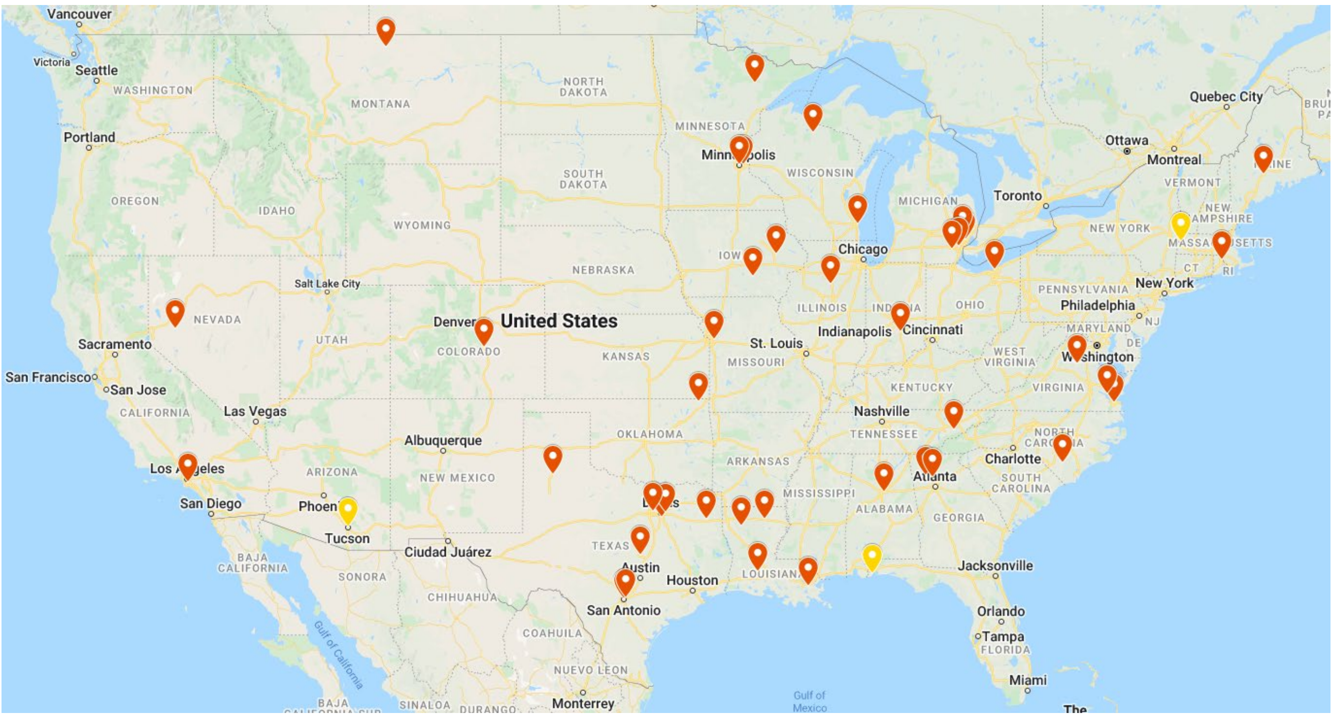


Figure 3. Map of the continental United States showing locations of all 50 incidents. Red points indicate deaths, while yellow points indicate injuries or hazards.

Health Considerations

Prematurity and underlying health issues may have contributed to these incidents, though our team did not determine them to be a *primary* cause of the incidents. Six babies were reportedly pre-term (gestational age < 37 weeks), two had chronic health conditions which were not considered to be the cause of death, and eight babies had a current illness (low-grade fever, congestion, fussiness, etc.). A few IDIs contained statements either directly from a caregiver or investigator indicating caregivers were influenced by healthcare professionals, friends and family, or advertisements to prop the baby up for sleep to alleviate acid reflux, congestion and to aid with opening the airways for more comfortable breathing. Other caregivers noted products similar to the various pillows involved in the incidents were used in the hospital with their baby, and they wanted something similar for their home. We observed a theme that many caregivers apparently believed that use of pillow products made situations which otherwise would not be safe for the baby into a safe environment.

Sleep Considerations

Nearly all incidents occurred when a baby was put to sleep on the pillow. However, two incidents involved breastfeeding (categorized as “other” incidents), where the deaths occurred when the mother unintentionally fell asleep while or immediately after using the product as intended for nursing. For the incidents where the pillow was used for sleeping, the pillow was a part of an overall dangerous sleep environment. The team quantified the dangers in each sleep environment by giving one point for each of the following situations: (1) co-sleeping, (2) not placed on their back, (3) not in a crib or bassinet, (4) pillow present, (5) other plush items present, and (6) blankets present. Sleep environment scores could range from 0 to 6. Our first three points were modeled after the American Academy of Pediatrics’ ABCs of Safe Sleep: A – alone, B – on their back, and C – in a crib. Even though some pillow products contained warnings to not use the product in a crib, we chose to include incidents that occurred in a crib as complying with that safe sleep guideline since babies were put in the crib for sleep.

In all cases, the pillow was present in the sleep environment indicating that all cases posed an additional risk in a sleep scenario, despite manufacturer warnings on most products to not use the pillow when sleeping. Two instances included an infant sleeping in a crib with the pillow. Infants were reportedly placed with the pillow on/in a playpen or play yard (4 instances), bassinet (9 instances), adult mattress (17 instances), on the floor (2 instances), or on a couch or reclining chair (3 instances). Of these incidents, there were 18 instances of co-sleeping with an adult, sibling, or both.

The average sleep environment rating was 4.3, meaning that most incidents occurred in sleep environments involving 4 or more identified hazards. Babies were commonly placed on the pillow alone on an adult bed with blankets and other plush items; on the pillow within a crib, bassinet, or in a play yard; or on the pillow in a co-sleeping environment with their parent or sibling on an adult bed. Many caregivers noted that the pillow was the usual location for sleeping for the baby, and in some cases, the family did not own a crib.

The incident analysis elucidated the **dangerous sleep environments** with every single case having two or more potential dangers identified. The majority of incidents occurred outside of a traditional crib. Statements from caregivers in several of the reports indicate that caregivers believed that using the pillow increased safety either for infants who were sick or who did not have a crib available in which to sleep. Some reports indicated that caregivers used blankets or other items (e.g., towels, additional pillows) to "prop-up" the infant to help avoid rolling or to keep bottles near the infants' mouth to allow for self-feeding. In the two cases where the incident occurred after the pillow was used during breastfeeding, neither mother intended to sleep with the infant in that position but instead accidentally fell asleep. Both incidents noted the infant had unlatched and there was nothing in the infant's mouth, but the proximity to the mother was unclear in the IDIs.

Incident Categories

Rolling scenarios accounted for 14 of the IDIs, with 9 of the incidents occurring when babies rolled off the pillow into dangerous environments and 5 of the incidents occurring when babies rolled from supine to prone but remained on the pillow. The characteristics of the pillows facilitated the movement of very young infants, and enabled supine-to-prone rolling of infants as young as 24 days old. There were nine cases of rolling involving infants between 4 and 9 weeks of age, which is developmentally unlikely without the added benefit of the body positioning on the pillow. For some cases involving infants over 3 months, statements from caregivers indicated their infant could not yet roll over or move to another location on his or her own. In many of these incidents, the pillow was not the direct cause of suffocation, but instead allowed the infant to move into a dangerous situation or position that otherwise would have been unlikely or impossible based on their developmental stage. Similar to our previous research on infant inclined sleep products (Wang et al., 2020; Wang et al., 2021), it is likely that the body position of infants on some pillow products induced an incline angle, which made it easier for younger infants to roll over or maneuver out of the product compared to a flat and firm surface.

Sagittal Plane Position scenarios accounted for 10 of the IDIs, with 9 of the incidents occurring when babies slouched down into the center of the product resulting in a flexed trunk, chin-to-chest position, or both, and 1 of the incidents occurring when a baby pushed back on the product, arching backwards and resulting in neck hyperextension. Some babies who initially were propped in a semi-reclined position within a nursing-style pillow experienced trunk flexion or neck flexion as they slid down into the center of these products. In the flexed trunk or chin-to-chest position within the center of the product, babies found themselves entrapped in a dangerous body position, often with their faces also in contact with the plush pillow product.

Occlusion/CO_2 Rebreathing scenarios accounted for 10 IDIs, with 7 incidents occurring when the baby's face was found in contact with the side (usually the center) of the pillow and 3 incidents occurring when babies were placed prone and found prone with their face in contact with the pillow. Some caregivers placed the baby's head in the center of the nursing pillows in an attempt to restrict the baby's movement during sleep. In most of these incidents, the infants were found with their faces in contact or nearly in contact with the plush side of the pillow, having suffered from suffocation likely due to nasal occlusion and / or CO_2 rebreathing.

Summary

To summarize, we identified five common themes for the pillow product IDIs: (1) nearly all incidents resulted from infants sleeping on or with the pillow; (2) the pillow aided in infant movement leading to dangerous scenarios; (3) the pillow contributed to apparent suffocation, with the infant's face found in contact with the plush surface; (4) parents used the pillow because they believed it was safer or medically beneficial for the baby; and (5) use of the pillow was associated with other dangerous sleeping environment features such as co-sleeping, sleeping outside of a crib, and in the presence of other blankets or plush items. The incidents generally involved (1) occlusion or rebreathing, or (2) positional concerns where the baby's body position on or within the pillow either facilitated unsafe movement to a dangerous sleep environment or contributed to positional asphyxia. Based on our review of the IDIs, we recommend that discharge information from hospitals and infant well-child visits include guidance on unsafe use of infant pillow products.

3. Product Selection, Characterization, and Measurement

3.1 Product Selection

Products were selected by the team to represent the breadth of the product class. Two products were marketed as “anti-flat head” products, ten products were considered “lounger” type of pillows, and seven products were marketed as “nursing” pillows. Products were from several different manufacturers. Most products were new and were ordered directly from the manufacturers’ websites or online retailers. A few products were recalled prior to our selection, so we requested some from the U.S. CPSC staff and found secondhand products on online marketplaces.

3.2 Product Characterization and Measurement Methods

We took measurements and made observations related to the size, shape, materials, instructions and use, and construction of each product (Table 1).

Table 1. Measurements and characteristics with procedures.

Measurement	Procedure
Shape of Product	Descriptive text explaining overall shape of product.
Mass (kg)	Placed on a mass scale and recorded the value.
Overall Diameter or Height/Length (cm)	Used a tape measure and recorded value.
Tube Circumference or Width (cm)	Used a tape measure and recorded value.
Thickness (cm)	Used a tape measure and recorded value.
Number of Pieces	The number of individual pieces was recorded.
Assembly Method	The setup method is explained if it is required.
Material (cover and filler)	Recorded cover and filler materials on label.
User Instructions (Y/N)	If user instructions were included on the box, on a label, or on any packaging.
Marketed Use	The use that the product was marketed for was recorded.

3.3 Product Characterization and Measurement Results

We ordered 23 total pillows, and each pillow was given a unique identifier (P01 through P23). We then selected in consultation with CPSC staff 20 of the products to be included in the study, and we organized the pillows into three categories based on marketed use: anti-flat head, nursing, and lounger pillows (Figure 4, Appendix A). Some nursing pillows were also marketed for use as loungers, but we included these in the “nursing” category. For nursing products that were also marketed as loungers, we conducted additional positional assessments to account for both of the intended uses (section 7).

We selected these products to represent the range of infant pillow products available in the U.S. marketplace and corresponded with CPSC staff to ensure the products met the criteria of the project. Product P04 was the model of the product involved in 7 of the lounger IDIs, while various versions of Product P14 were involved in 14 of the nursing pillow IDIs. We took several measurements to further describe the size, material composition, design, and labeling of this broad product class. Tables 2 and 3 show the measurements and characteristics of all 20 products. Tables 4 and 5 describe the number of pieces each product has, the assembly methods, and the material composition of each product as reported on labels, packaging, and listing. Table 6 includes any relevant notes taken by our team regarding the products during the characterization process.

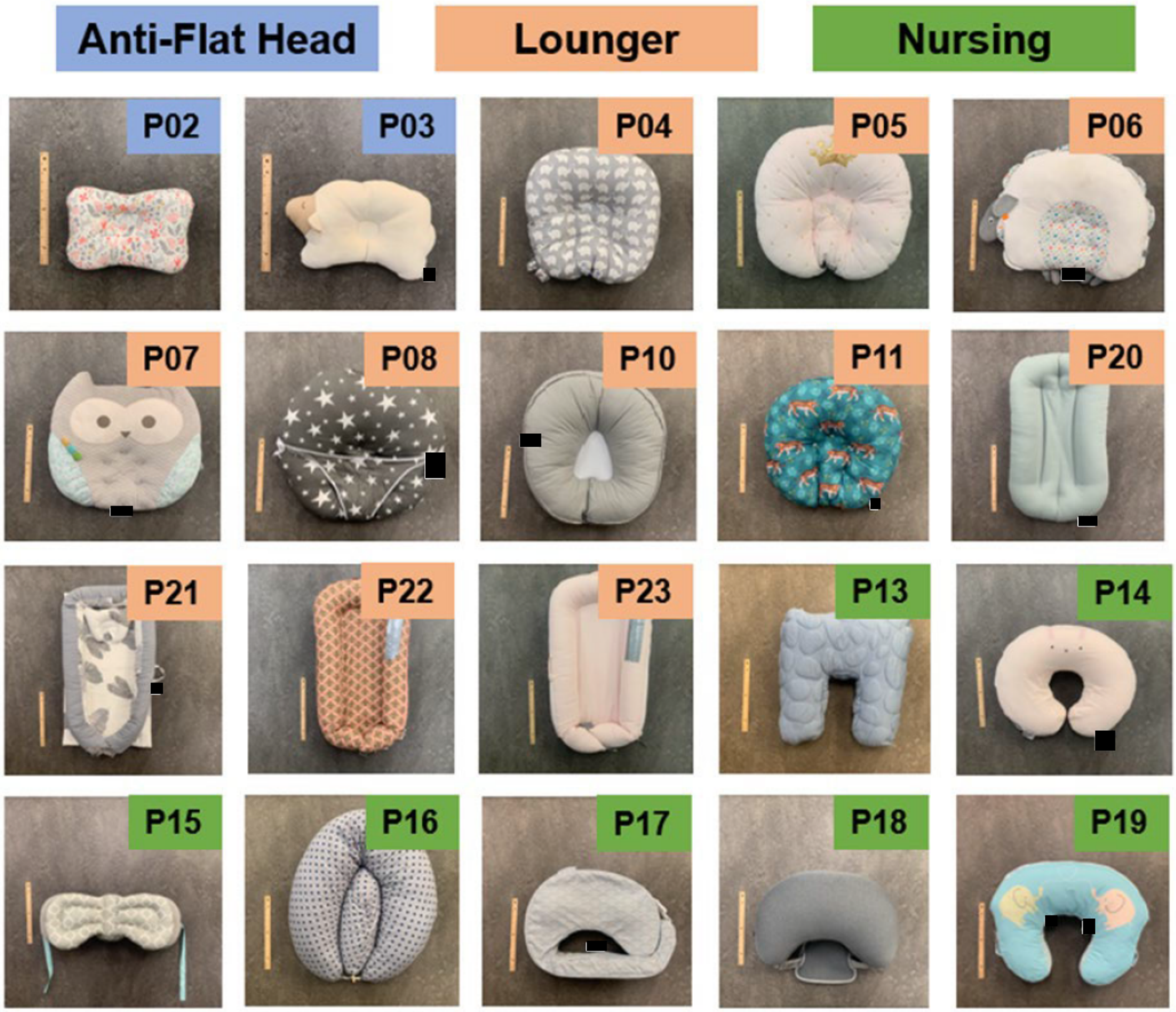


Figure 4. Photographs of each sample with its respective identification number.

Table 2. Measurements and characteristics of anti-flat head and lounger pillows.

Samples	Category	Shape of Product	Mass (kg)	Overall Diameter or Height/length (cm)		Tube Circumference or Width (cm)		Thickness (cm)	
				Min	*Max*	*Min*	*Max*	*Min*	*Max*
P02	Anti-flat Head Pillow	Small head pillow, rectangular with quilted center portion	0.14	30	32	17	22	4* center portion <1 cm	6
P03		Oval, Sheep-shaped head pillow, center with quilting	0.20	20	38	N/A	n/a	center portion <1cm	7
P04	Lounger Pillow	Circular with quilting in the front-center, forming a seat-like surface	N/A	57	57	N/A	N/A	11* center quilted portion <2 cm	19
P05		Circular with quilting in the front-center, forming a seat-like surface	1.26	57	57	N/A	N/A	16* center quilted portion <2 cm	18
P06		Oval; sheep-shaped	0.94	50	71	N/A	N/A	10	12
P07		Oval; owl-shaped	0.83	46	55	N/A	N/A	8	11
P08		Circular with 3-point fabric harness with buckles; concave; quilting in the low center	1.21	dia 62	dia 65	N/A	N/A	10* <4 cm near quilting	15
P10		Oval, with center thin support fabric sling	1.57	53	60	N/A	N/A	12* fabric sling <0.5 cm	19
P11		Oval, with center quilting in the front-center forming a seat-link surface	1.23	56	56	N/A	N/A	9* ; center section <3 cm	21
P20		Lounger, rectangular with quilted center portion	1.16	n/a	74	N/A	42	center portion <1cm	12
P21		Rectangular foam base with polyfill tube, circular attached; separate small pillow	1.15	n/a	86 (base)	circum of tube 30	47 (base)	N/A	2 (base)
P22		Rectangular foam base with polyfill tube, circular attached	1.45	70 (base)	79	circum of tube 34	38 (base)	N/A	3 (base)
P23		Rectangular foam base with polyfill tube, circular attached	1.51	70 (base)	79	circum of tube 34	38 (base)	N/A	3 (base)

Table 3. Measurements and characteristics of nursing pillow products.

Samples	Category	Shape of Product	Mass (kg)	Overall Diameter or Height/length (cm)		Tube Circumference or Width (cm)		Thickness (cm)	
				Min	*Max*	*Min*	*Max*	*Min*	*Max*
P13	Nursing Pillow	square arch; rectangular u-shaped pillow	1.33	29 (tube portion)	51	19 (tube portion)	55	13	16
P14		U-shaped pillow	1.00	45	55	53	58	16	19
P15		Unique design similar to butterfly with 3 overlapping wings per side.	1.18	N/A	23 from center	N/A	63	N/A	16
P16		Long tubular pillow with clasp to make into a round donut-shape (Part A); separate small bean-shaped pillow to fill center (Part B) which does not connect	1.84	54 (assembled)	66 (assembled)	Bean: 42 cm length x 18 cm width x 13 cm thickness	N/A	11	20
P17		Shallow u-shaped pillow with connected back support; foam	0.49	N/A	52	N/A	23	N/A	10 (w/o bump)
P18		Shallow u-shaped pillow with back support; foam based with filling on top	1.78	N/A	56	N/A	27	N/A	20
P19		U-shaped pillow with toy bar accessories for overhead or tummy time	0.88	44	62	47 circum	58 circum	N/A	N/A

Table 4. Number of pieces, assembly method, and composition of products as listed on product tags or packaging for anti-flat head and lounger pillows.

Sample	Category	No. of pieces	Assembly Method	Material	
				Cover	*Filler*
P02	Anti-flat Head Pillow	1	N/A	Non-removable; canvas-like top, mesh-like bottom; fiber contents, Front: Organic Cotton 100%, Back: 3D Air Mesh 100%	N/A
P03		1	N/A	Non-removable; somewhat minky-like; organic cotton; 100% Organically Grown Cotton	100% polyester fiber
P04	Lounger Pillow	1	N/A	100% polyester	N/A
P05		1	N/A	Minky-like top; cotton bottom (observationally); 100% polyester fiber	100% Polyester
P06		1	N/A	Minky-like	100% resin treated polyester fiber batting
P07		1	N/A	Minky-like	100% resin treated polyester fiber batting
P08		1	N/A	none listed	N/A
P10		1	Hook and loop to make product slightly smaller.	100% polyester fiber	N/A
P11		1	N/A	N/A	100% polyester fiber
P20		1	N/A	GOTS certified organic cotton fabrics	Polyester fiber fill
P21		2 (small head pillow: 23 x 19 x 5, though one part is only 2 layers of fabric with no filling)	Ties for tubing piece	Removable cover; handle; base and tube fillings are different and separate pieces when removed; concerning tube/base interface where baby's head could easily become covered; Cotton	Polyester
P22		1	Buckle for tubing ends	Cover Fabric: 100% Cotton; Inner sleeve: 100% Cotton	Tube Filling: Polyester Fibers; Pad: Polyester Padding: 71% Polyester Fiber, 29% Polyester Fiber Batting (% listed separately)
P23		1	Buckle for tubing ends	Cover Fabric: 100% Cotton; Inner sleeve: 100% Cotton	Tube Filling: Polyester Fibers; Pad: Polyester Padding: 71% Polyester Fiber, 29% Polyester Fiber Batting (% listed separately)

Table 5. Number of pieces, assembly method, and composition of products as listed on product tags or packaging for nursing pillows.

Sample	Category	No. of pieces	Assembly Method	Material	Sample
P13	Nursing Pillow	1	N/A	35% Dyed Eucalyptus Lyocell, 55% Dyes Cotton Polyester Yarns, 15% Dyed Organic Cotton	100 Organic Kapok
P14		1	N/A	75% organic cotton fibers; 25% tencel (lyocell)	100% Polyester
P15		1 piece with multiple configurations	ties can configure product differently	N/A	100% Polyester Fibers
P16		2	N/A	Outer cover: 100% Cotton, velvet fiber (check boxes on tag next to each?); Inner cover: 100% Cotton Fiber	PP Cotton
P17		1	Buckle back support piece	100% Polyester	100% Polyurethane Foam Pad
P18		2	Buckle for back support piece	Outer cover: 90% Polyester, 10% Spandex; Inner Cover: 100% Cotton; Back Rest Cover: 90% Polyester, 10% Spandex; Back Rest Cover Mesh: 100% Polyester	68% Polyurethane Foam Pad, 32% Polyester Fiber-Fill
P19		1 (plus toybar)	N/A	N/A	100% Resin-Treated Polyester Fiber Batting

Table 6. Sample notes describing product set and other pertinent details.

Samples	Category	Notes/Descriptive Text	Marketed Use
P02	Anti-Flat Head Pillow	N/A	N/A
P03		Notes that show how to move filler around for different elevations/thicknesses	Anti-flat head pillow
P04	Lounger Pillow	Gray cover with elephant pattern; handle; non-removable cover	0-4 month; 16 lbs; or when baby can roll over
P05		Gray cover; handle; non-removable cover	"Uniquely recessed to cradle baby"; 0-4 month; 16 lbs; or when baby can roll over
P06		Used condition; non-uniform filling; decorative components (ears, legs, tabs not included in measurements); no removable cover; additional mirror accessory	Infant positioner and tummy-time toy
P07		Ears not included for diameter measurements; taggies throughout product; stitching on front of product	Infant positioner and tummy-time toy
P08		Handle, non-removable cover; harness has buckles but attached at base; observationally not firm	N/A
P10		Removable cover with zipper; Unique design with slung center	N/A
P11		Non-removable cover; handle for carrying	Lounging 3+;
P20		N/A	N/A
P21		N/A	N/A
P22		N/A	N/A
P23		N/A	N/A
P13	Nursing Pillow	Removable cover with zipper; quilted design	N/A
P14		Removable cover	Nursing (0-12), propping (3+), tummy-time (6+), sitting (9+), feeding (0-12)
P15		N/A	Nursing pillow, 3 elevations (neutral, moderate, max), 0+ months
P16		Removable covers; non-uniform / consistent filling	N/A
P17		Removable cover	N/A
P18		Removable cover; ability to remove layers internally to adjust size/firmness. We are taking measurements as-is.	N/A
P19		Removable cover	Feeding, lounging, tummy-time, sitting upright

3.4 Product Characterization and Measurement Discussion

The infant pillows featured a variety of shapes, sizes, materials, and designs. The marketed use of pillows also varied, from nursing to lounging or napping. Based on the marketed use of the product, the designs tended to vary. Anti-flat head pillows were much smaller and featured a small concave feature to cradle the baby's head. Nursing pillows often featured a c-, u-, or horseshoe-shaped design that allows for a mother to place the pillow around her torso to accommodate nursing. However, a few nursing pillows also were marketed for lounging or propping up the baby. These dual-purpose nursing pillows were typically plush and were made of polyester filling with a more tubular design, while the nursing-only pillows had sharper edges and were made of firmer foam. The dual-purpose pillows observationally appeared to be "comfortable", while the nursing-only pillows were more unusual and boxy designs that do not appear to be designed for comfortable lounging. Lounger pillows featured two main designs: one with a flat lying surface surrounded by a plush outer cylindrical wall, and one that was more like a c-shaped nursing pillow except with a slung or solid centerpiece designed to support the baby's bottom.

The labeling of materials, inclusion of warnings, separate usage instructions, and laundering instructions varied widely. Even within the same product class, products contained different warnings. One product marketed as dual-purpose for nursing and lounging depicted the baby lying on the pillow within a crib in the online marketplace. In general, we did not find consistent labeling in either wording or locations on the products. Products with greater brand-recognition were typically better marked with warning labels and instructions compared to "knock-off" versions found in online marketplaces.

4. Probe Design

4.1 Probe Design Overview

The airflow of a material is crucial to understand suffocation hazards for infant products. For example, a pillow that features free airflow through the product would be unlikely to cause a suffocation hazard in the context of CO_2 rebreathing or nasal occlusion since air could be easily exchanged, even if the infant's face was completely covered by the material, as long as the nares were not mechanically closed off.

Airflow testing methodology for infant crib bumper-like products has been previously explored (unpublished work with CPSC, 2021), but limitations regarding threshold development and probe design remain. In this section, we describe the development and testing of various airflow probe designs ranging from simple to complex, and we compare the testing results with experimentally measured values from previous studies. We justify the use of a single probe that we then use for firmness and airflow testing described in Sections 5 and 6.

4.2 Probe Development

Our previous work on crib bumpers and mesh liners used modified methods from the British Standard BS 4578:1970*, Test for Hardness of, and for Air Flow Through Infant Pillows* (BS 4578:1970), to determine a threshold to detect differences between mesh liners and traditional bumpers. The BS 4578:1970 test was originally designed in response to occasional reports of accidental suffocation by children in bedding, specifically involving infant pillows. The testing can be conducted using a probe apparatus: a metal tube that is 150 mm in length, has an internal diameter of 36 mm, and an attached metal flange with a diameter of 100 mm on the bottom (Figure 5). This apparatus also has a connection on the side for connection to an inclined manometer. The original test called for a volumetric flow rate of 12 L/min; however, at a more physiologically accurate volumetric flow rate of 2 L/min (U.S. EPA, 2009; Carleton, 1998; Maltese, 2019; Office of the Office of the Federal Register, 2020), the threshold value we found for our previous crib bumper project was extremely low and challenging to implement into a standard. Furthermore, the probe itself was dissimilar to an infant's face and nare sizes, resulting in mechanical situations and pressure differentials that were not physiologically meaningful (unpublished research, CSSC contract, 2021). The current apparatus has a large diameter of 36 mm, nearly 10 times the size of an infant's nare size, which can range from 3 to 7 mm in diameter (Mazmanyan 2020; Haase, 2021; Sivieri, 2013). Additionally, the device is flat and not representative of the three-dimensional shape of an infant's face, and a single hole is used for the flow rather than two nares.

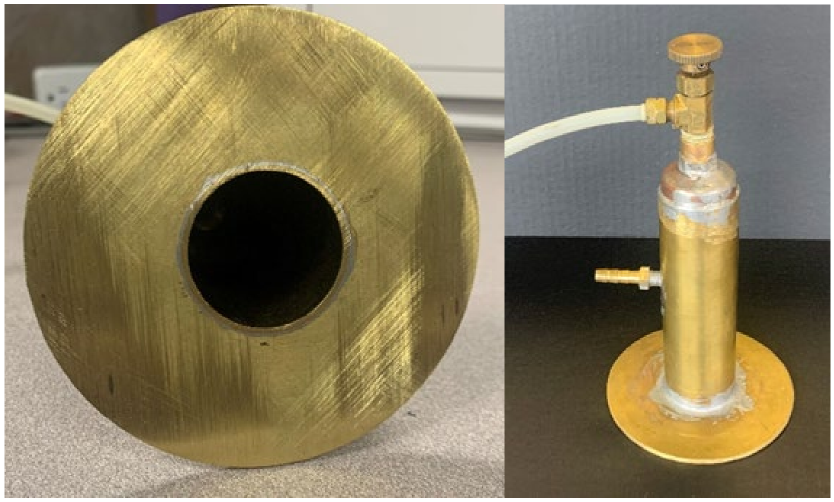


Figure 5. Different views of metal apparatus described in BS 4578:1970.

The overall testing setup was constructed following the guidelines in the standard (Figure 6). This included a flowmeter (E500; Matheson Tri-Gas, Inc., Irving, TX) with an included diaphragm-type valve for adjustment of the flow rate. The outlet of this flowmeter was connected to the vacuum side of an AC linear piston vacuum pump (VP0125; Nitto Kohki USA, Inc., Roselle, IL). This connection was also attached to a needle valve that allowed for gross control of the flow rate. The inlet of the flowmeter was connected to the metal apparatus described above. A digital differential manometer (EM201B; UEi Test Instruments, Portland, OR) was connected to the side of the metal apparatus. The metal apparatus itself was attached to a vertical lifter mechanism (Leshner & Associates, Inc., Elkton, MD) that allowed the assembly to be lowered such that the product experienced a thrust of 10 N. This 10 N of force comes from the original BS 4578:1970 standard, but also serves as an approximation of a newborn's head weight at 23% of the total body weight (Coats, 2008; CDC, 2001). A weight scale (ZK14-S; Ozeri) was used to verify the magnitude of this force.

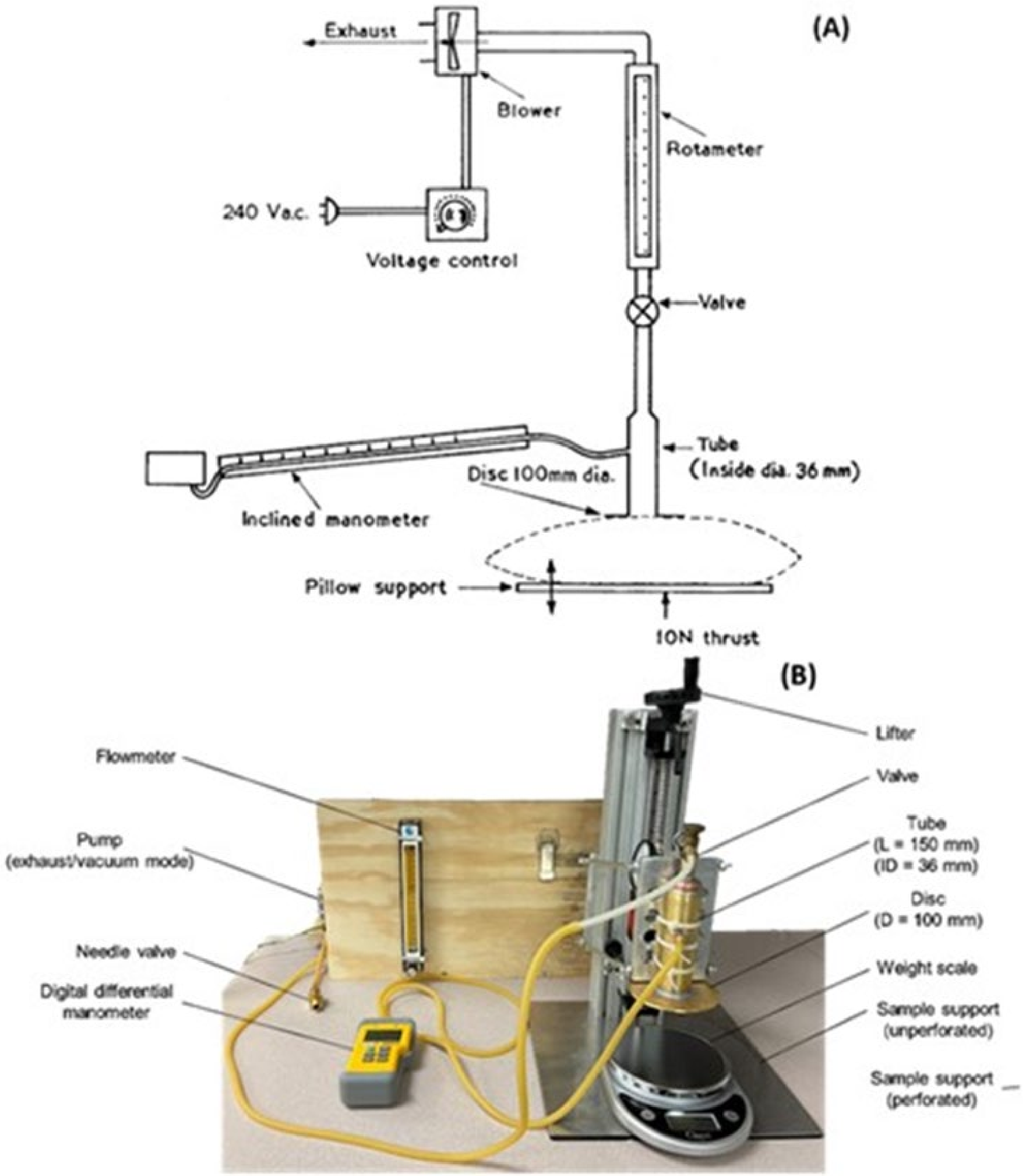


Figure 6. BS 4578:1970 (A) Schematic and (B) Experimental Setup for Airflow Testing.

To further expand on the CPSC staff's modification to BS 4578:1970 to make it more physiologically representative, we designed several different probes with increasing complexity featuring differing probe shapes, nare sizes, and 3D geometry (Table 7).

As we increased the complexity of our probes, we sought a design that remained simple to manufacture while providing physiologically representative results. With our first step of improving the original probe (Table 7 – Probe 1), we altered the diameter of the channel that air is drawn through from 36 mm to 4.5 mm. This nare diameter is more representative of the average nare size for infants (Mazmanyan 2020; Haase, 2021; Sivieri, 2013). While this probe altered the air channel size, it still maintained the overall dimensions of the original probe's flange at 100 mm diameter (Table 7 – Probe 2).

In the next step of increased biofidelity, we changed the overall geometry of the probe to be hemispheric instead of maintaining the large flat surface. However, we maintained a single 4.5-mm diameter air channel from the previous alteration (Table 7 – Probe 3). The size of the hemisphere was a diameter of 5-inches, as this is representative of the average infant head size. This size was calculated from the average measurement of head circumference for 0- to 6-month-old infants (CDC, 2001). In our next step, we increased the number of air channels to two to better represent a nose with two nares (Table 7 – Probe 4). These channels were spaced approximately 8-mm apart by centerline.

We then examined two parallel development paths: one for increasing the complexity of the probe, and one for decreasing the dimensions of the probe to better match the smallest values in each range. For the first path, we added a flexible ridge 3.125 mm thick, located between the nares to represent the soft tissue of the nose (Table 7 – Probe 5). For the second path, we minimized all dimensions of the probe. The air channels were decreased to be 3.125 mm in diameter to represent the smallest infant nare sizes reported in the literature and remaining simple to manufacture (Mazmanyan 2020; Haase, 2021; Sivieri, 2013). The distance between the centers of each channel was approximately 8-mm. Beyond that, the diameter of the hemisphere was decreased to 3 inches to represent the bizygomatic breadth of an infant's face (Brandt, 1990).

While the probe designs listed above represent steps for increasing the biofidelity from the original probe while remaining easy to manufacture, we also wanted to compare them to a more complex idealized model for both a newborn (~1-month-old) and a 9-month-old. These models were obtained by our team from the University of Alberta (Tavernini, 2018) as 3D SolidWorks files. They were originally created using computerized tomography scans of 10 infants (Storey-Bishoff, 2008). These scans were used to find 24 cross sections, which were then connected using splines. This led to an airway model that begins at the nostril entrance and ends distal to the larynx (Tavernini, 2018; Javaheri, 2013). This model geometry represents different portions of the nasal airway, such as a constriction leading to an offset axis to represent the laryngopharynx (Tavernini, 2018). The authors shared with us the same geometry at different isotropic scaling which can be seen in Figure 7. Both model sizes have previously been used as physiological geometry to filter "the correct proportion of specifically sized inertial particles at realistic inhalation flow rates" (Tavernini, 2018). In the research done by the team at the University of Alberta, both models were shown to serve as a simplified and representative geometry for the actual airway system. As the 3D models we received represented the negative space of the airway system, an outer casing was formed around the model to create a usable probe (Table 7 – Probes 7 and 8). The nare sizes on these probes also matched the literature and other designs with openings of approximately 3.1 mm and 4.5 mm diameters for the idealized newborn and idealized 9-month-old, respectively. We also examined the inclusion of a similar flexible ridge to that used in Probe 5 between the two nares of each model (Table 7 – Probes 9 and 10).

Beyond the probes that show an increasing complexity and the idealized models, one additional probe design was explored as requested by CPSC staff (Table 7 – Probe 11), based on a prototype anthropometry-based probe developed by CPSC staff in support of Crib Bumpers rulemaking (Boniface & Smith, 2019). This probe features a porous, conical frustum with a base opening diameter of 30.6 mm, representing the smallest mouth width reported for 0- to 5-month-old infants (Farkas, 1994). The frustum protrudes 8.4 mm in length to represent the smallest nasal tip protrusion for 0- to 5-month-old infants and ends with a final opening diameter of 24.5 mm to represent the smallest nose width for infants in this age group. For this probe to withstand the force of being applied to products, it has a thickness of 4 mm. This frustum also features 20 openings that are all 3 mm in diameter. There are 10 openings that are 3 mm from the base and 10 openings that are 3 mm from the top which alternate in order. Lastly, the base of the probe features a 100 mm diameter flange and was attached to the original probe in a method similar to Probes 2 through 5.

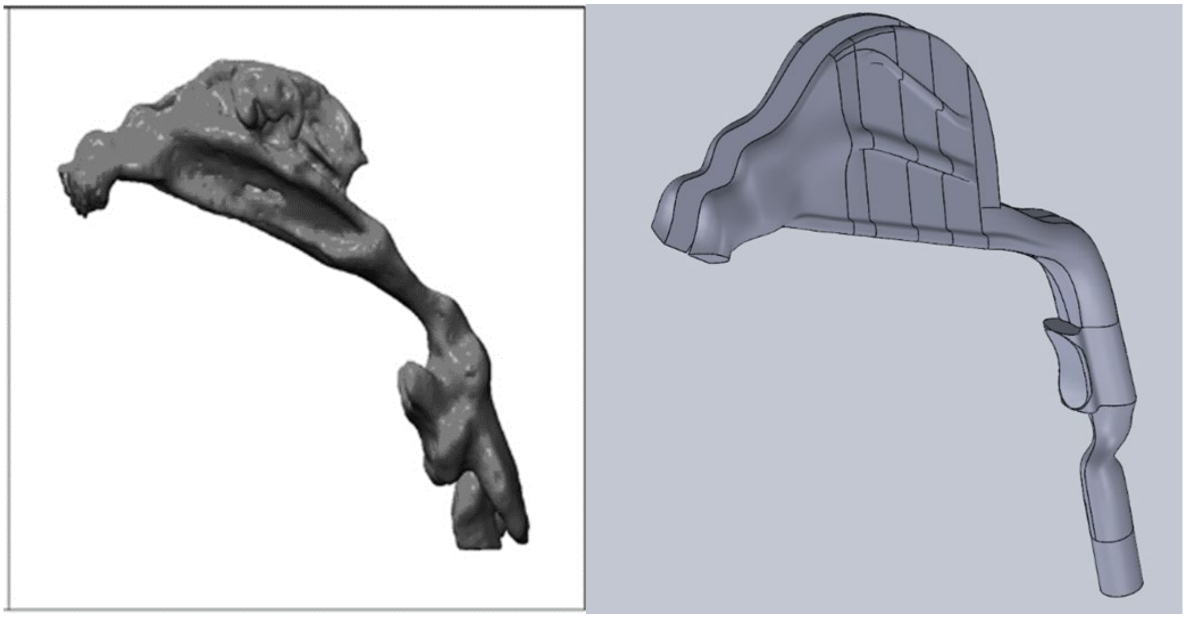
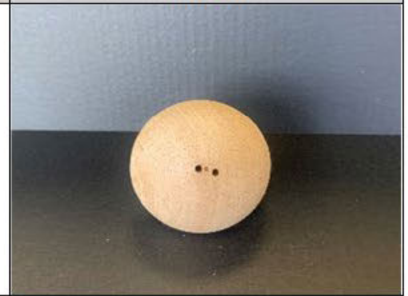


Figure 7. Real infant airway (Javaheri, 2013) (Left) and idealized model negative space geometry (Right).

We used a variety of materials to manufacture these new probes. To prevent leakage as air is drawn through the different hemispheric probes, air channels for most probes were created using an LCD UV-Curing Resin (Elegoo, Inc., Shenzhen, China) in combination with an Elegoo Mars 2 Pro Mono LCD MSLA Resin 3D Printer (Elegoo, Inc., Shenzhen, China). We created interchangeable pieces to allow for various nare configurations to fit within an outer 5 inch diameter hemisphere. The outer hemispheric shapes of most probes were made of a 1.75 mm polylactic acid (PLA) filament (Hatchbox, Pomona, CA) and were created by Prusa i3 MK3S+ printers (Prusa Research a.s.,Prague, Czech Republic). Probe 6 was created with a 3 inch diameter wood hemisphere with two 3.125 mm diameter channels placed approximately 8 mm apart by centerline. These channels were formed with brass tubing to allow for attachment to the airflow testing setup. Lastly, Probe 11 was created using the same PLA filament used for the overall outer shapes. All of these new probes and their descriptions can be viewed in detail in Table 7.

Table 7. Novel probe design descriptions and photos.

Probe	Description	Photo
Probe 1	**Geometry:** 100-mm diameter flat disc **Channel diameter:** 36-mm **Number of Channels:** 1 **Presence of Ridge:** No	
Probe 2	**Geometry:** 100-mm diameter flat disc **Channel diameter:** 4.5-mm **Number of Channels:** 1 **Presence of Ridge:** No	
Probe 3	**Geometry:** 5-inch diameter hemisphere **Channel diameter:** 4.5-mm **Number of Channels:** 1 **Presence of Ridge:** No	
Probe 4	**Geometry:** 5-inch diameter hemisphere **Channel diameter:** 4.5-mm **Number of Channels:** 2 **Presence of Ridge:** No	
Probe 5	**Geometry:** 5-inch diameter hemisphere **Channel diameter:** 4.5-mm **Number of Channels:** 2 **Presence of Ridge:** Yes	

Probe	Description	Photo
Probe 6	**Geometry:** 3-inch diameter hemisphere **Channel diameter:** 3.125-mm **Number of Channels:** 2 **Presence of Ridge:** No	
Probe 7	**Geometry:** Idealized Newborn **Channel diameter:** 3.125-mm **Number of Channels:** 2 **Presence of Ridge:** No	
Probe 8	**Geometry:** Idealized 9-month-old **Channel diameter:** 4.5-mm **Number of Channels:** 2 **Presence of Ridge:** No	
Probe 9	**Geometry:** Idealized Newborn **Channel diameter:** 3.125-mm **Number of Channels:** 2 **Presence of Ridge:** Yes	
Probe 10	**Geometry:** Idealized 9-month-old **Channel diameter:** 4.5-mm **Number of Channels:** 2 **Presence of Ridge:** Yes	
Probe 11	**Previously developed probe** (Boniface & Smith, 2019) featuring porous, conical frustum.	

4.3 Probe Testing

With the new probes of increasing complexity designed and developed, we conducted airflow testing following the previously described method in the initial modification of BS 4578:1970 using crib bumper and mesh liner products. We chose these products for two main reasons: (1) bumper designs are typically flat, so testing can be repeatably and reliably conducted, and (2) some traditional bumper designs with thick plush padding are known to cause dangerous rebreathing and/or suffocation scenarios, while mesh liners are not known to exhibit these associated risks, based on available IDI data from our previous project (unpublished research, CPSC project, 2021). We chose six crib bumper products from different manufacturers: four traditional bumpers and two mesh liners. We hid all manufacturer information and assigned the products unique identifiers (T1 to T4, M1 and M2) to represent each product category.

We used each probe (Table 7 – Probes 1 through 11) in our airflow testing setup with a thrust of 10 ± 0.2 N applied into each product while air was drawn through the product at a flow rate of 2 L/min; we then recorded the pressure differential. We applied weights on either side of the testing setup to limit movement of the product for all testing. To achieve the required thrust, we lowered the probes into each product by the lifter mechanism until the measured force settled at the desired value. We completed three trials for each probe and product combination, where the product was reset between each trial. We randomized the testing order of the products for each probe. Because the probes varied in design, each probe connected to the lifter mechanism using one of two methods. The first method was used for Probes 2 to 5 and Probe 11, where each probe was attached to the original metal apparatus by a PLA disk (Figure 8). A 100-mm inner diameter O-ring (McMaster-Carr, Santa Fe Springs, CA) was used to prevent leakage from this setup. For these probes, the digital manometer remained connected to the original apparatus.

Figure 8. (Left) Attachment of 5 inch diameter hemisphere to original testing device with additional weight to achieve 10 N of thrust; (Right) Example of connection of airflow setup directly to Probe 6. The branch of the T-fitting connects to the digital barometer, and the run section of the T-fitting connects to the flowmeter.

The other method of attachment applied to Probes 6 through 10 which includes the 3 inch hemisphere and the idealized models. For these, direct attachment to the lifter was feasible. In these cases, the digital manometer was connected to tubing near the probe by a T-branch.

4.4 Probe Testing Results, Selection, and Threshold Development

The mean pressure drops found for each probe varied significantly and are summarized by product category in Table 8. Box plots for each probe can be found in Figures 9 and 10.

Table 8. Mean and Standard Deviation Pressure Values for Traditional and Mesh Categories when Tested with Different Probe Designs. Probe 6 is Highlighted as it was chosen to be the Preferred Model.

Probe	Category	Mean Pressure Values (in. H_2O)	Standard deviation
Probe 1	Traditional	0.053	0.011
	Mesh	0.000	0.000
Probe 2	Traditional	0.672	0.094
	Mesh	0.028	0.004
Probe 3	Traditional	0.379	0.051
	Mesh	0.178	0.068
Probe 4	Traditional	0.348	0.042
	Mesh	0.082	0.018
Probe 5	Traditional	0.138	0.019
	Mesh	0.017	0.001
Probe 6	Traditional	2.038	0.417
	Mesh	0.254	0.019
Probe 7	Traditional	2.191	0.201
	Mesh	0.435	0.019
Probe 8	Traditional	0.976	0.094
	Mesh	0.087	0.008
Probe 9	Traditional	0.294	0.066
	Mesh	0.047	0.008
Probe 10	Traditional	0.127	0.009
	Mesh	0.014	0.001
Probe 11	Traditional	0.005	0.005
	Mesh	0.000	0.000

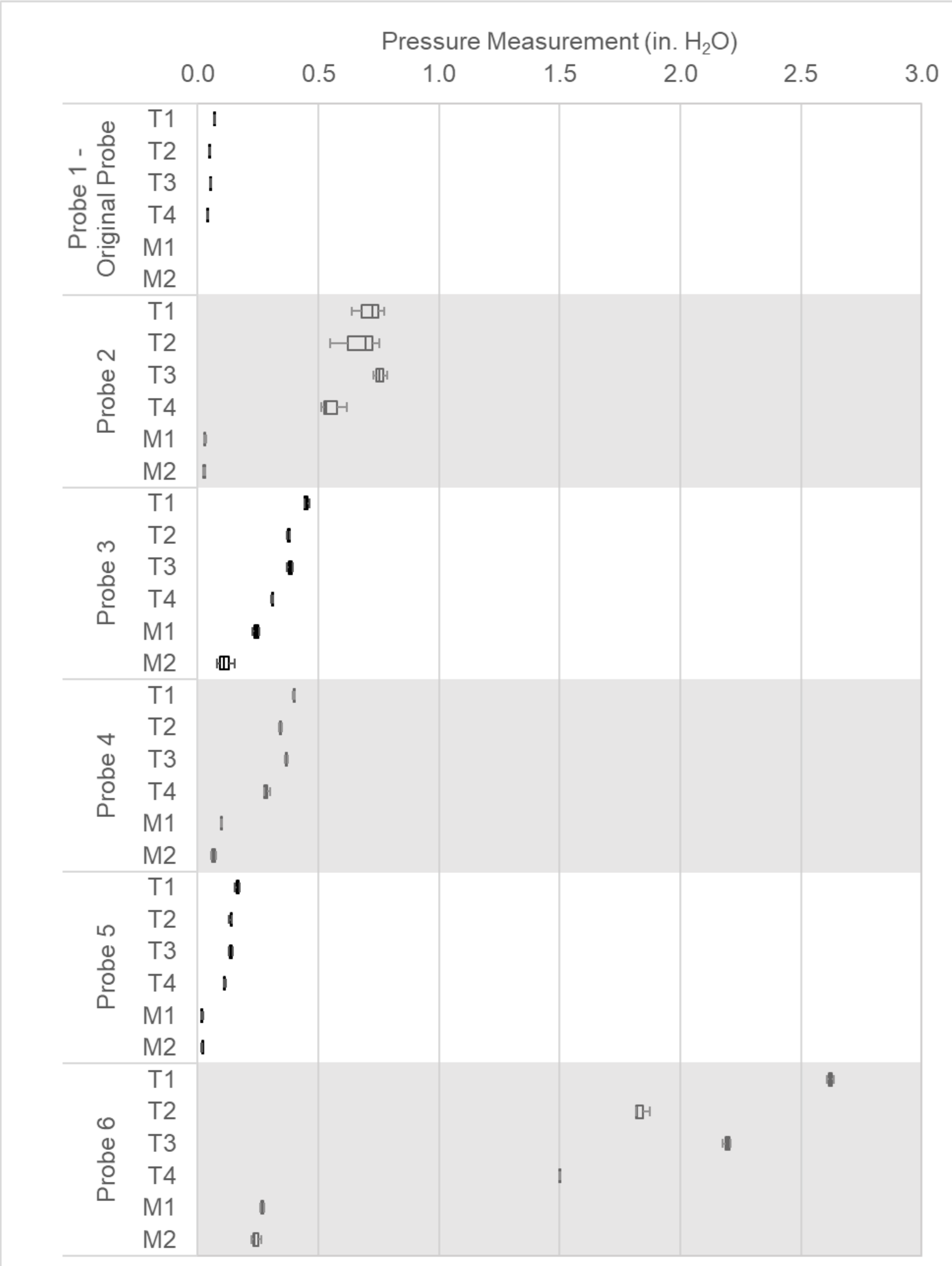


Figure 9. Box plots of pressure measurements for Probes 1 to 6 for each bumper product (traditional bumpers T1-4; mesh bumpers M1-2). Higher pressure values represent less airflow through a product.

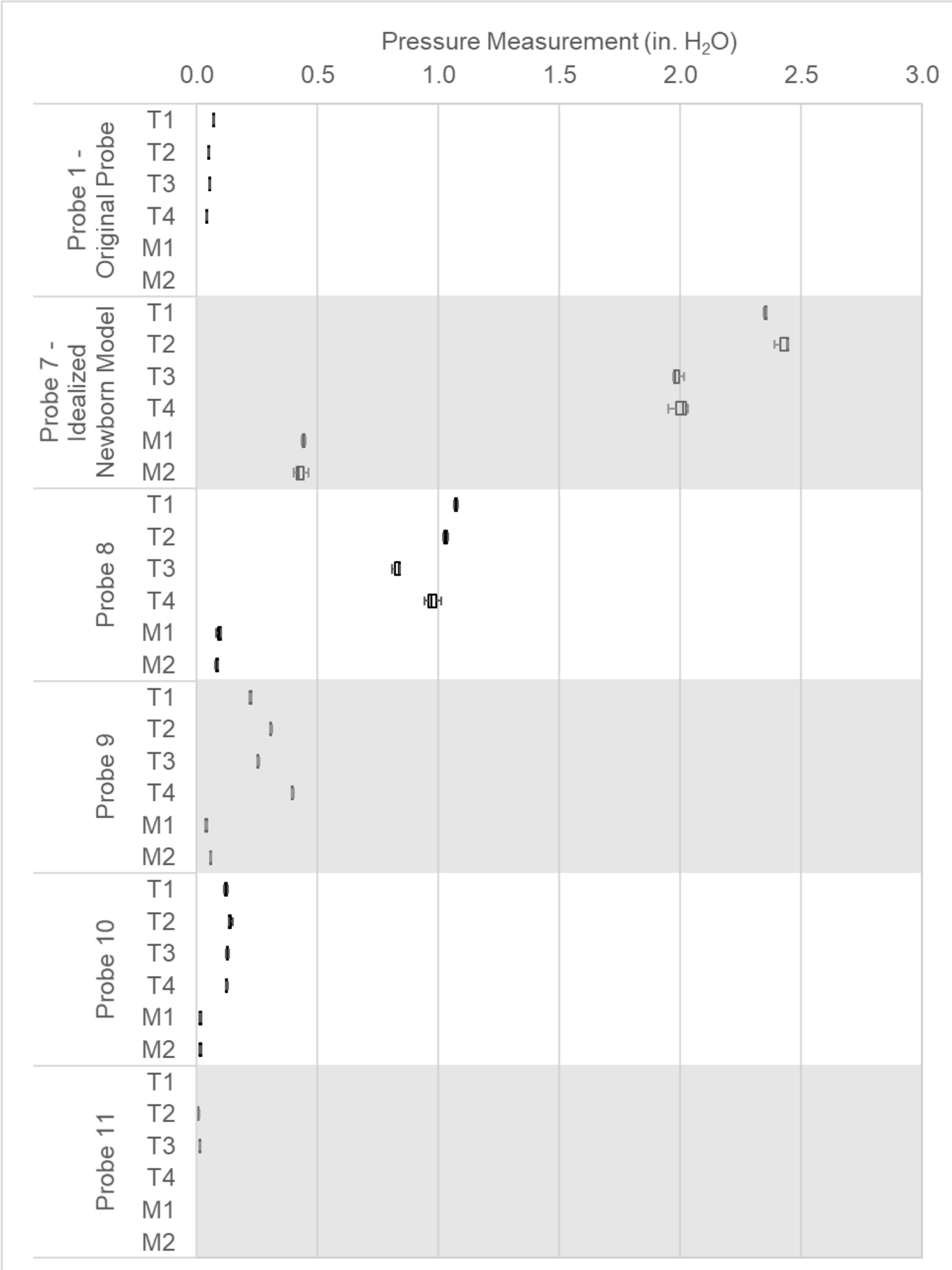


Figure 10. Box plots of pressure measurements for Probes 1 and 7 to 11 for each product (traditional bumpers T1-4; mesh liners M1-2).

Two tailed t-tests with equal variance were used to compare the pressure measurements between the two product categories (traditional vs. mesh) for different probes. All probes were able to significantly differentiate between the two product categories, with various levels of significance (all $p<0.05$). This was also true for the original probe (Probe 1). However, no pressure readings were able to be measured for the mesh products (<0.001 in. H_2O), limiting the functionality of this probe design. A threshold based on the original probe was 0.003 in. H_2O. This low value approaches the limits of the manometer and does not represent infant pressure drops due to occlusion in infants, as recorded in the medical literature (Cohen, 1986). Furthermore, the airway diameters of Probe 1 are not anatomically similar to an infant.

With the goal of achieving a more physiologically representative model, we concluded that the idealized newborn airway model would serve as our "idealized" model (Probe 7), and the values recorded for each probe were compared to its values. In this comparison, the desired outcome was to identify an easily manufacturable probe whose values were not significantly different from our idealized model. The mean pressure reading for Probe 6 for all crib bumper and mesh liner products was 2.04 in. H_2O, which is not significantly different ($p = 0.59$) from the mean pressure reading from the idealized newborn probe (Probe 7) of 2.19 in. H_2O (Figure 11).

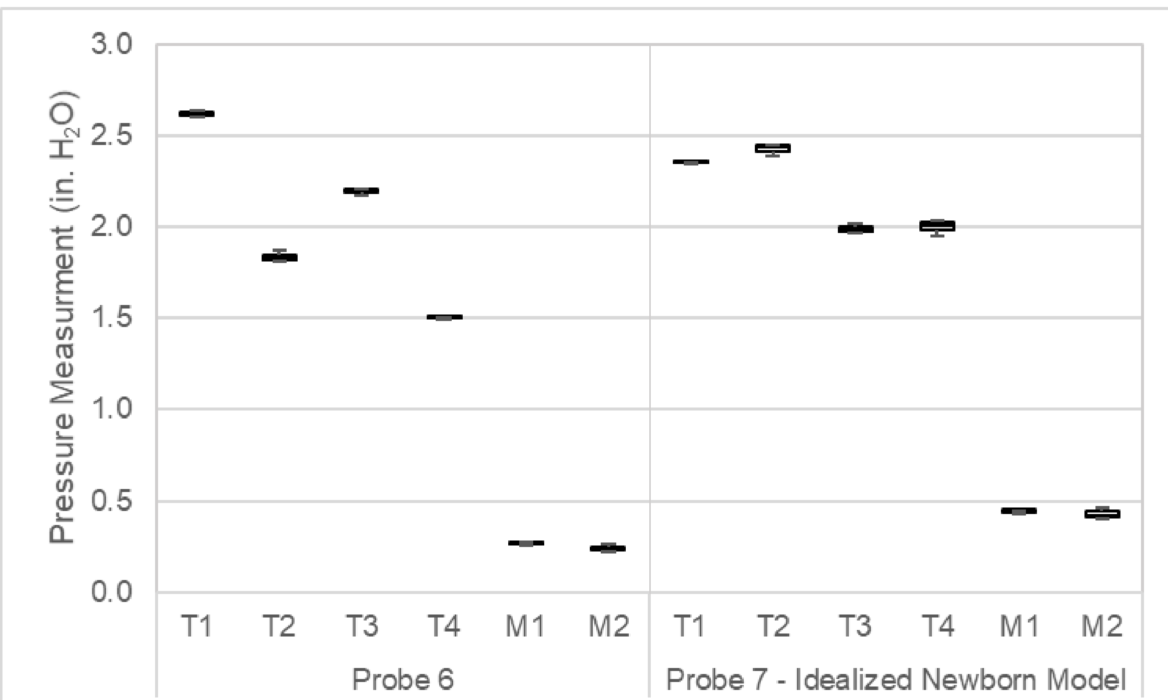


Figure 11. Box Plots of the pressure readings for the selected 3" hemisphere probe (Probe 6) and the idealized newborn model probe (Probe 7).

The mean pressure readings of all other probes (Probes 1 to 5 and Probes 8 to 11) were less than half of the readings from the idealized newborn model (Probe 7), resulting in significant differences in all other probes compared to the idealized newborn model ($p < 0.001$). While Probe 6 was the only probe capable of matching magnitudes from the idealized newborn model (Probe 7), a few probes resulted in pressure measurements that were comparable to the idealized 9-month-old model (Probe 8), including Probe 2, Probe 3, and Probe 6.

For a testing method implemented into a standard to be useful, it needs to clearly define a threshold value for determining the failure or passage of a product. In this case, the threshold has been identified from the results of airflow testing on representative crib bumper and mesh liner products to distinguish products with mesh-like airflow (mesh), which are not known to have resulted in fatalities, from products without mesh-like airflow (traditional), which are known to be involved in fatal incidents, potentially involving nasal occlusion and rebreathing. It is our recommendation that a threshold to distinguish products which would have mesh-like airflow be set at a pressure reading of 0.31 in. H_2O while using the recommended Probe 6 and a flow rate of 2 L/min, with failure of a product occurring above this value. This threshold lies three standard deviations above the mean reading for the mesh liners tested meaning that 99.7% of mesh liners should fall within the safe region.

To further validate the mesh-like airflow threshold, 18 crib bumper and mesh liner products (16 Traditional crib bumpers, 2 Mesh liners) not used for developing the threshold were tested a single time under the same airflow conditions. The results of this testing are shown in Figure 12.

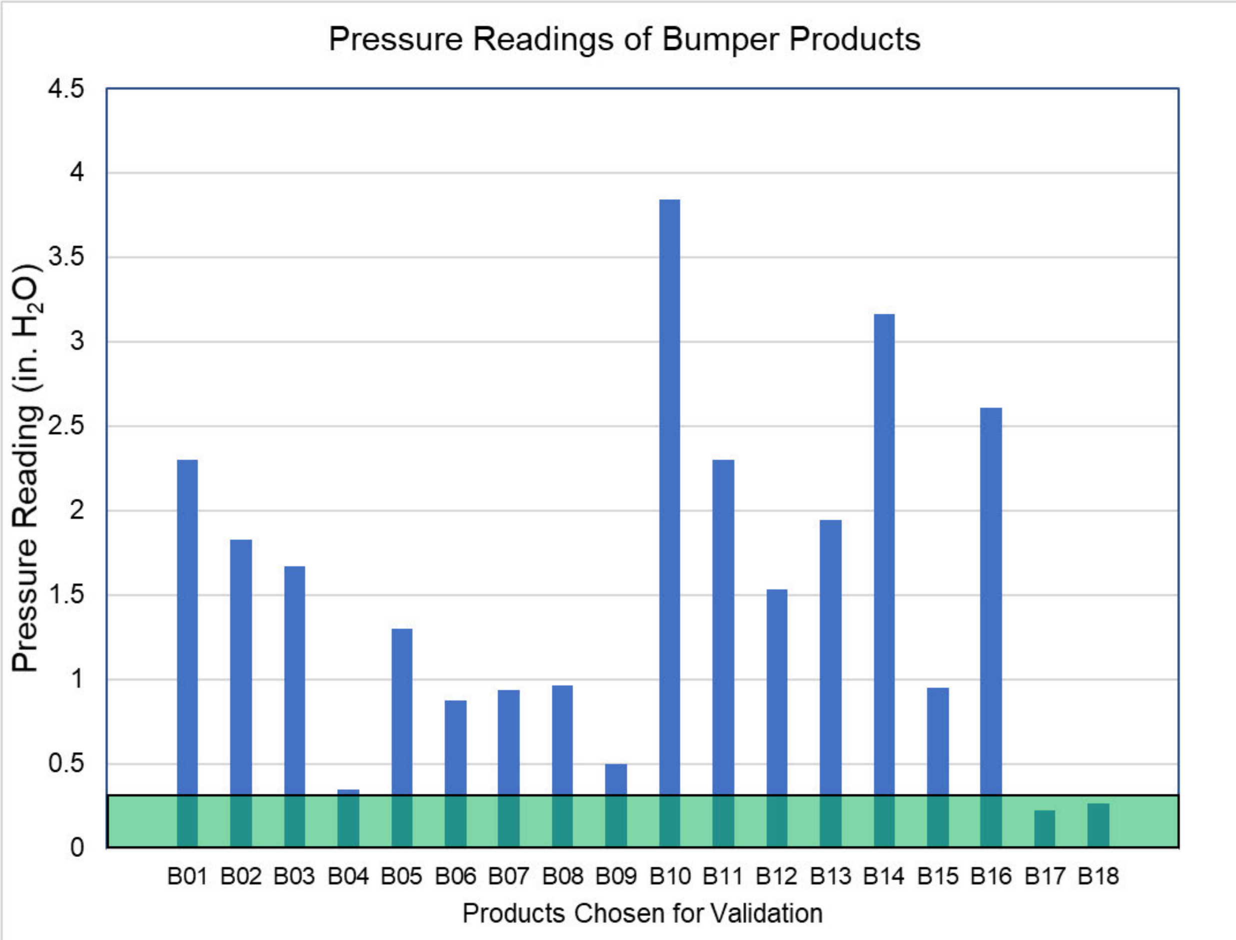


Figure 12. Results of Airflow Testing on 18 different products. B01 to B16 are traditional bumpers. B17 and B18 are mesh liners. Green shading indicates measurements under the mesh-like airflow threshold of 0.31 in. H_2O.

In this testing, only the mesh liner products (B17 and B18) were able to meet the mesh-like airflow threshold, validating our expectation that the threshold would distinguish between traditional bumpers and mesh-like airflow. For the other products, B04 was very close to meeting this threshold with a pressure reading of 0.35 in. H_2O. This product is categorized as a traditional bumper but is marketed as "breathable" and has a unique design among the products used, as it has two different surface materials. The outward facing side of this product is a 100% polyester solid cover and the inward facing side has a mesh pattern. Testing was conducted on the mesh pattern, as that is the intended surface that an infant would be in contact with.

4.4 Probe Design Discussion

We designed and tested eleven probes representing a range of complexity, and we selected a probe with a simple design that resulted in similar pressure readings compared to a complex idealized model, and within the range of the first breath occlusion pressure measurements from previously published research on babies, as discussed below. The probe we selected (probe 6) represents physiologically accurate nare sizes and hemispheric face diameter of infants, while remaining simple to manufacture. The probe does not feature a soft ridge to model the nose, resulting in a worst-case scenario during some tests where the nares are completely occluded. However, the repeatability of the testing of the selected probe without the ridge was much better compared to the probe with the ridge, and the probe without the ridge resulted in larger and more easily measurable pressure drops. We are unaware of previous research describing the deformation characteristics of the infant nose, so this could be a future area of study to further improve the biofidelic accuracy of this probe.

Furthermore, the recorded pressure drops of our selected probe and our idealized model are similar to real-life values. When an infant initially suffers from occlusions in the nares, the esophageal pressure has been measured to be 9.5 ± 5.0 cm H_2O (3.74 ± 1.96 in. H_2O) (Cohen, 1986). Our measurements of 2.038 ± 0.417 in. H_2O for the selected probe and 2.191 ± 0.435 in. H_2O for the idealized model fall into that realistic range. While these probes currently match the initial esophageal pressure under occlusion, they are not able to match the drastic increase in pressure that occurs as an infant alters their breathing pattern by increasing the rate of breathing and tidal volume of each breath to counteract the decreasing oxygen levels. With this response, a maximum drop of 23.5 ± 9.0 cm H_2O (9.25 ± 3.54 in. H_2O) has been recorded (Cohen, 1986).

The probe we developed is geometrically similar to an infant's face and nare sizes while still being easy to manufacture, features a volumetric flow rate within physiological values, and results in pressure drops that are reasonable compared to those measured in previous infant research.

4.5 Probe Design Recommendations

We recommend using the design of Probe 6 described in Table 7 above for both firmness testing (Section 5) and airflow testing (Section 6). For airflow testing, a threshold of 0.31 in. H_2O provides a conservative target value to ensure mesh-like airflow, which is unlikely to pose a hazard from a suffocation or rebreathing perspective. In Section 5, we discuss firmness methods using this probe. In Section 6, we discuss airflow methods using this probe and also offer more insight into threshold values for safety specific to pillow products.

5. Firmness Testing

5.1 Firmness Testing Overview

The firmness of an infant product is important to understand for suffocation safety. A perfectly firm product such as a crib slat is considered safe, even though the firm slat is impermeable and allows for no airflow through the slat material itself. The reason a firm yet impermeable material is still safe from a suffocation perspective can be attributed to the 3D geometry of the human nose, which results in a nearly impossible situation for nasal occlusion on a perfectly firm surface. In a rare case when the nose and mouth are occluded against a firm and flat surface, even slight movements by the infant will break the seal and allow for free airflow. The arousal response of an infant would likely result in this slight movement, freeing them from the occlusion situation. However, if a material lacks firmness, that soft material is more likely to conform around a baby's nose and mouth. If a seal forms around the baby's face when it is in contact with the soft product, and the infant is unable to break this seal, then airflow from breathing must take place through the material itself. Thus, firmness is a critical factor in understanding product safety from a suffocation perspective, as a sufficiently firm product may prevent a seal from forming or being maintained, facilitating airflow and reducing suffocation hazards.

This section first describes the development of a firmness testing method that can be administered to non-flat products consistently, and then describes the use of that technique to test six commercially available crib mattresses (as a representation of a safe level of firmness) and the range of pillow products.

5.2 Firmness Testing Methods

5.2.1 Firmometer Firmness Testing

We first conducted firmness testing on all 20 pillow products (Figure 3, above) and six crib mattress products (Figure 13) using the firmometer device described in the AS/NZS 8811.1:2013 with each pillow product or mattress lying on a flat and firm surface. In this standard, a firmometer device (shown in Figure 14) with a mass of 5220 g allows for a pass/fail firmness test if the feeler arm contacts the product.

Figure 13. Six crib mattress products to serve as a control for the pillow products testing.

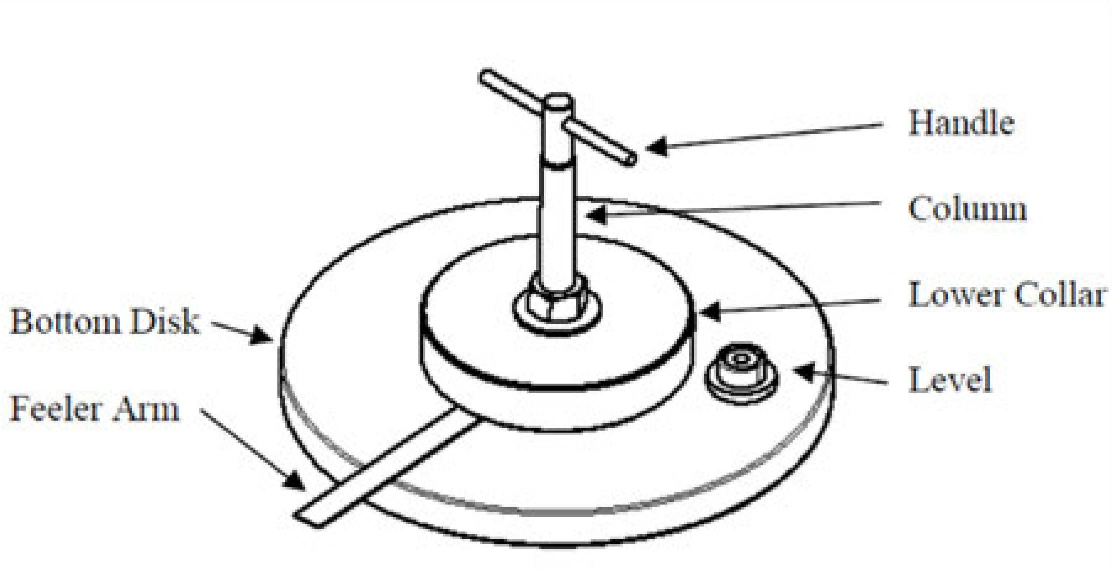


Figure 14. Firmometer device described in the AS/NZS 8811.1:2013.

Three locations of interest were tested on each pillow product (Figure 15); locations 1 and 2 were located at the maximum and minimum thicknesses of the product, respectively, and location 3 was a subjective location of interest. This subjective location was found by following the guidelines of the original AS/NZS 8811.1:2013 standard and included particularly soft spots or areas of folding, depending on the product. If the product lacked both of these features, the location was chosen to represent a portion of the product not previously examined at the maximum or minimum thicknesses. Crib mattresses were tested in a single location. The firmometer device was placed on the product at each desired location (Figure 16). The test would result in a “pass” if the feeler arm was not in contact with the product, a “fail” if the feeler arm was in contact with the product, and “n/a” if the test could not be performed as written.

Figure 15. A sample of testing locations on a flat surface. Location 1 is at the maximum product thickness, Location 2 is at the minimum product thickness, and Location 3 is a subjective location of interest, which varies between products.

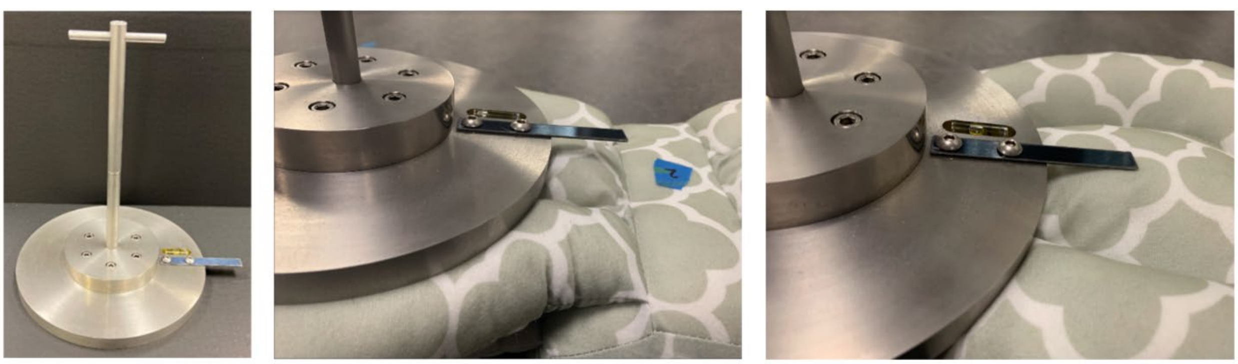


Figure 16. (Left) Firmometer device machined according to Australian/New Zealand Standard 8811.1:2013; (Center) Example of passed test with feeler arm not in contact with product; (Right) Example of failed test with feeler arm in contact with product.

5.2.2 Vertically Guided Firmness Testing

The Australian/New Zealand Standard 8811.1:2013 was designed for horizontal sleep surfaces, and as such, may not represent the firmness of nonuniform and non-flat pillow products. Using the firmometer test methodology on the 3D geometry of pillow products also proved challenging, as the device would not balance reliably on non-flat surfaces. Based on our previous research (unpublished research, CPSC project, 2021), we developed a vertically guided lifter device to assess product firmness because, at that time, we found that lounger products which featured non-flat geometry were not easily tested using the firmometer device detailed as a part of Australian/New Zealand Standard 8811.1:2013. We developed a new method with a vertically guided test fixture to assess a pillow product's firmness more accurately.

The vertically guided firmness fixture features the wooden, 3 inch diameter anthropometry-based hemispheric probe discussed earlier (Probe 6, see Section 4). The probe is fixed to a force gauge which is attached to a lifter that allows the force gauge to travel a prescribed vertical distance. The vertically guided firmness fixture was anchored to a base for support. The probe was positioned to apply a preload of 0.1 N and the digital calipers on the lifter were zeroed. The probe was lowered into each product to a displacement of 2.0 inches in increments of 0.25 inches. At each 0.25 inch increment, we measured the force for that displacement (Figure 17).

For the crib mattress testing, a single location was tested since the products are uniform. For the pillow products, the probe was positioned on the products in the three locations of interest, as discussed previously (Figure 15). Force and displacement were recorded, and we plotted force versus displacement curves to provide a more robust measure of firmness compared to the currently used pass/fail firmometer device method detailed in AS/NZS 8811.1:2013 and described above. The vertically guided firmness test was performed three times for each product at each of the three locations. Time was allowed between each trial for the product to resettle.

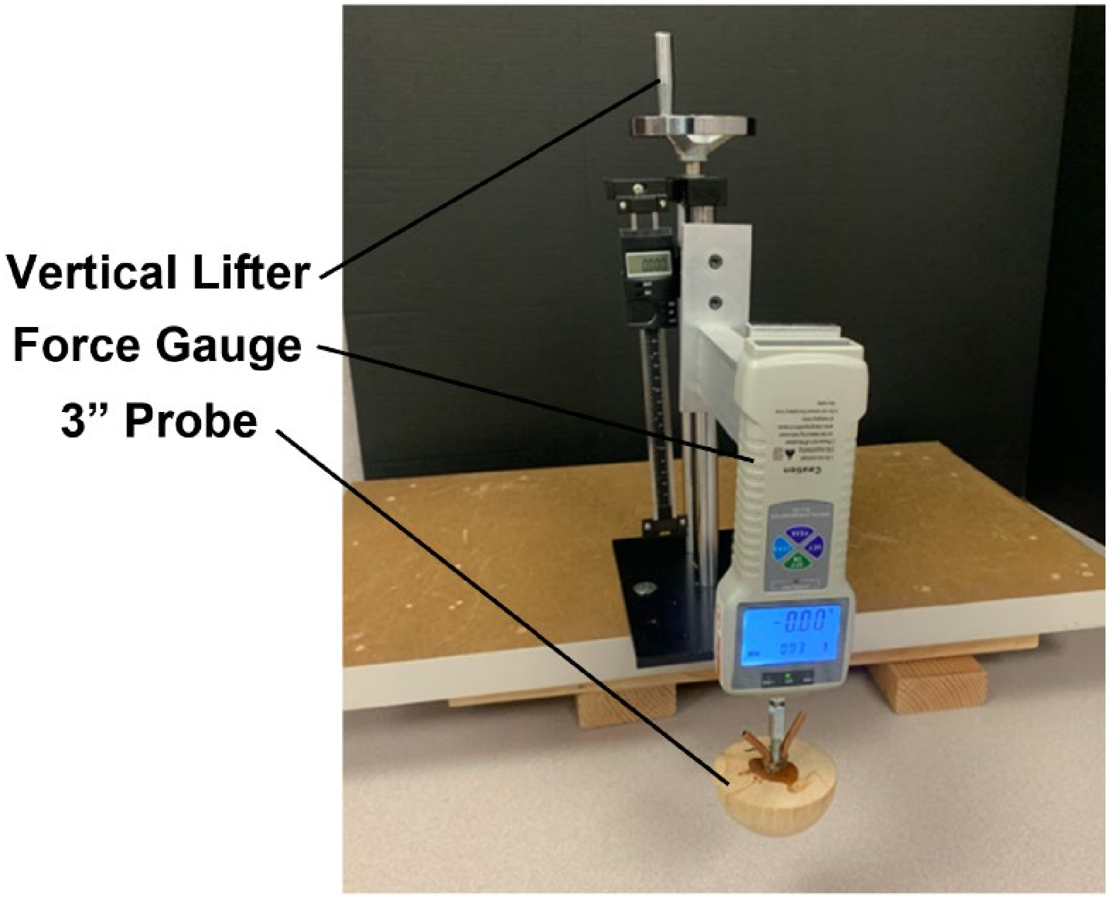


Figure 17. Vertically guided firmness fixture featuring a 6 inch vertical travel distance and force gauge.

5.3 Firmness Testing Results

5.3.1 Firmometer Device Testing Results

The results of the Australian/New Zealand standard firmness testing indicate that many pillow products were **unable to be tested** using this method due to instability from the curvature of the products (Table 9). All crib mattress samples passed the tests.

Table 9. Australian /New Zealand standard firmness testing results. The products that failed are highlighted in red and the products that passed are highlighted in green. N/A indicates the test could not be performed adequately.

Sample	Maximum	Minimum	Other
P02	N/A	Fail	N/A
P03	N/A	Fail	N/A
P04	Fail	N/A	N/A
P05	Fail	N/A	N/A
P06	Fail	N/A	Fail
P07	Fail	N/A	Fail
P08	Fail	Fail	N/A
P10	Fail	N/A	N/A
P11	Fail	N/A	N/A
P20	N/A	Pass	N/A
P21	N/A	Pass	N/A
P22	N/A	Pass	Pass
P23	N/A	Pass	Pass
P13	Fail	N/A	Fail
P14	Fail	N/A	Fail
P15	Pass	N/A	N/A
P16	Fail	Fail	N/A
P17	Pass	Pass	Pass
P18	Fail	Pass	Fail
P19	Pass	Fail	Fail

5.3.2 Vertically Guided Firmness Results

The force versus displacement results from our vertically guided firmness testing of mattresses indicate that mattresses require large forces (>10 N) to displace the probe by at least 1 inch (Figure 18). Observationally, the mattresses also exhibited non-linear behavior.

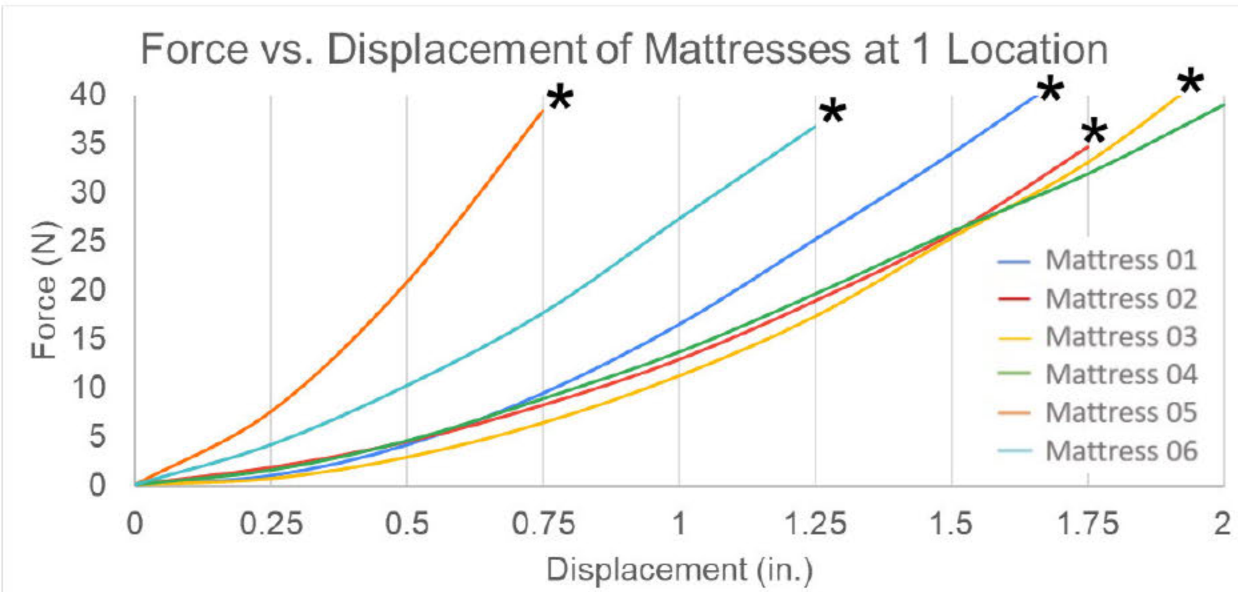
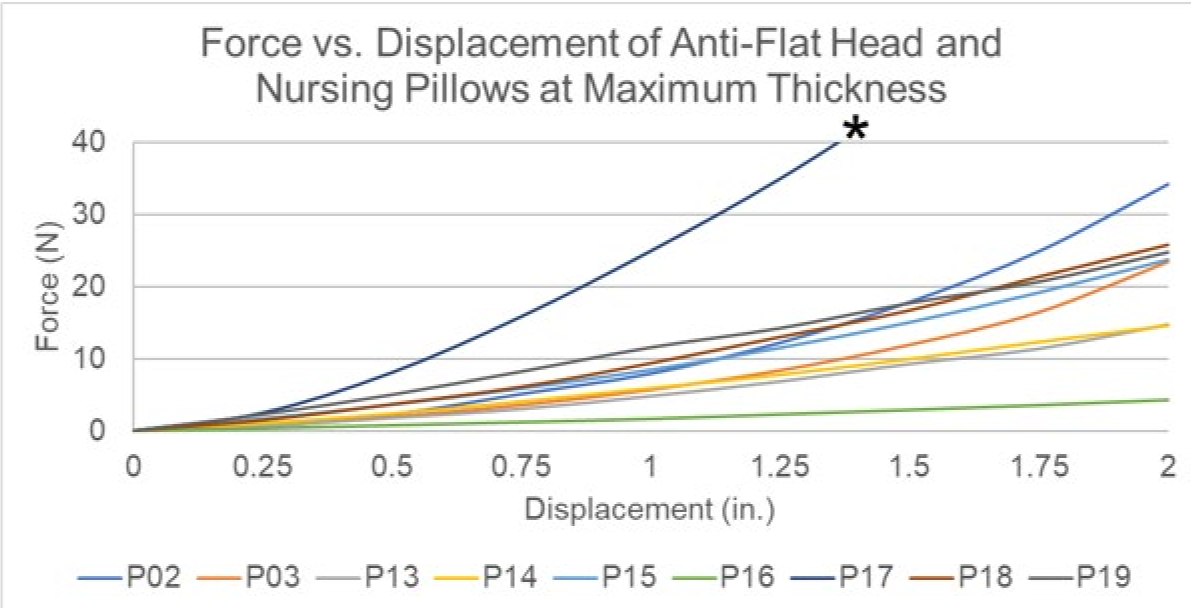


Figure 18. Firmness results for force versus displacement testing of the mattresses. (*represents results greater than 40 N)

The force versus displacement plots for the pillow products are displayed in Figure 19.



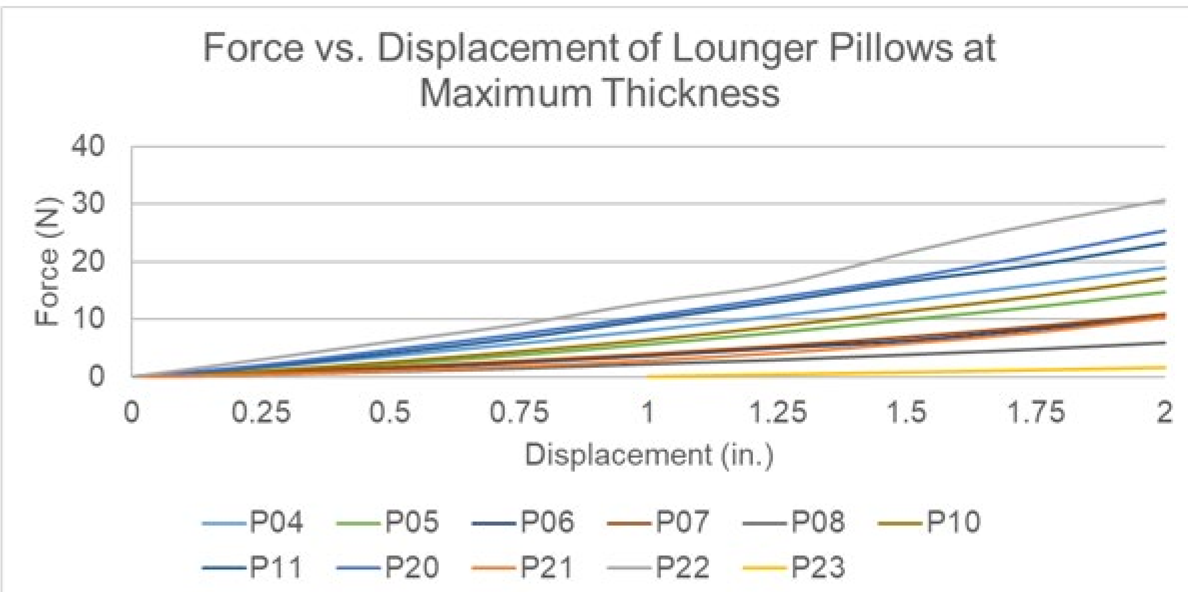


Figure 19. Firmness results for force versus displacement testing at the maximum thickness of (Top) anti-flat head and nursing pillows, and (Bottom) lounger pillows at the maximum thickness of the products. (*represents results greater than 40 N)

Based on the force versus displacement results of the mattress testing, we identified that at a 1 inch displacement, all crib mattresses exhibited forces *above* 10 N (Figure 20).

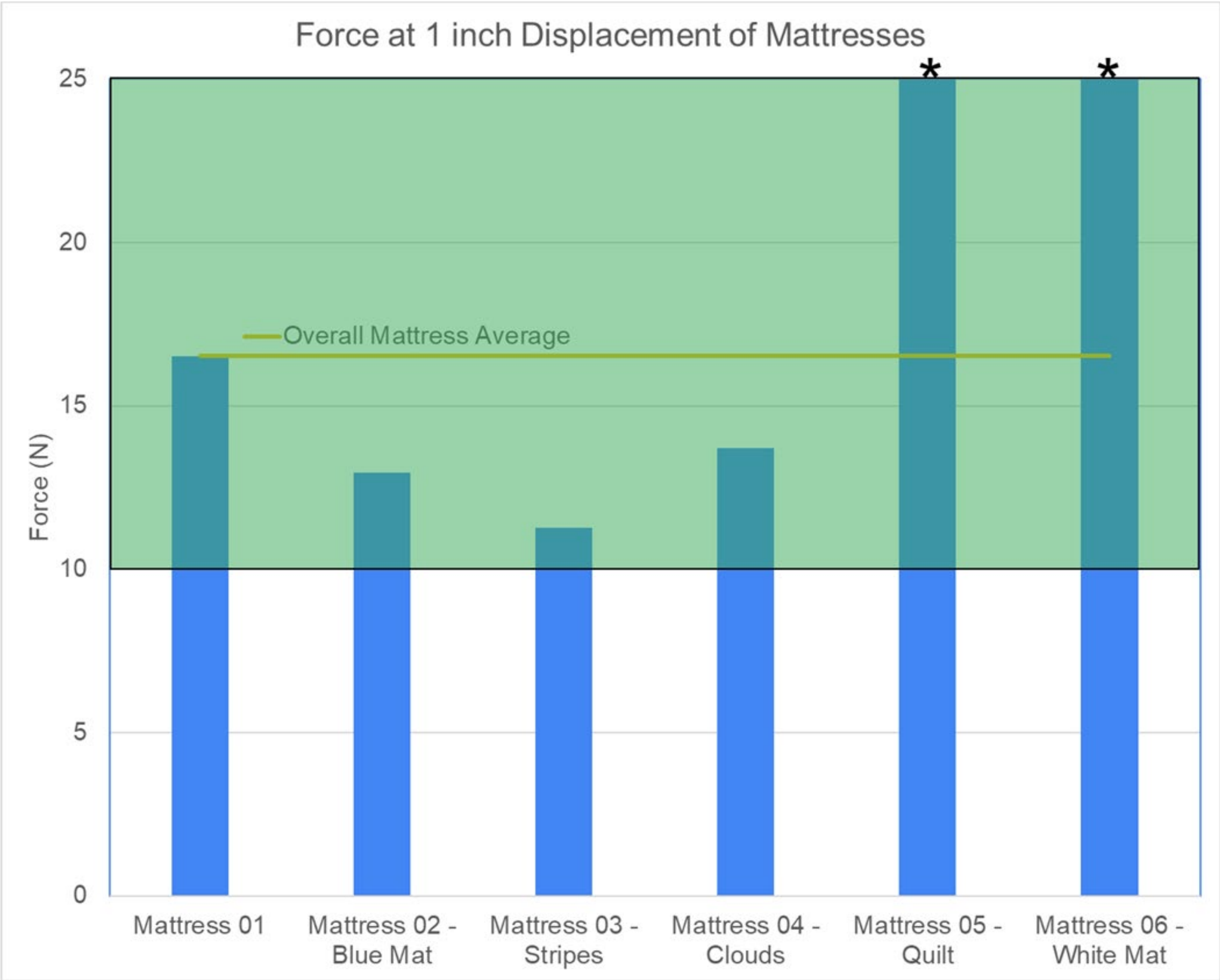


Figure 20. Firmness results of the force versus displacement testing of the mattresses at a displacement of 1 inch at one location. Green shading indicates measurements over the recommended threshold of 10 N, which would be considered safe from a firmness perspective (*represents result greater than 25 N).

Because crib mattresses are considered the safest place for a baby to sleep, we applied this 10 N threshold to all pillow products for comparison, where a force greater than 10 N at a 1 inch displacement would be considered adequately firm (Figures 21 and 22).

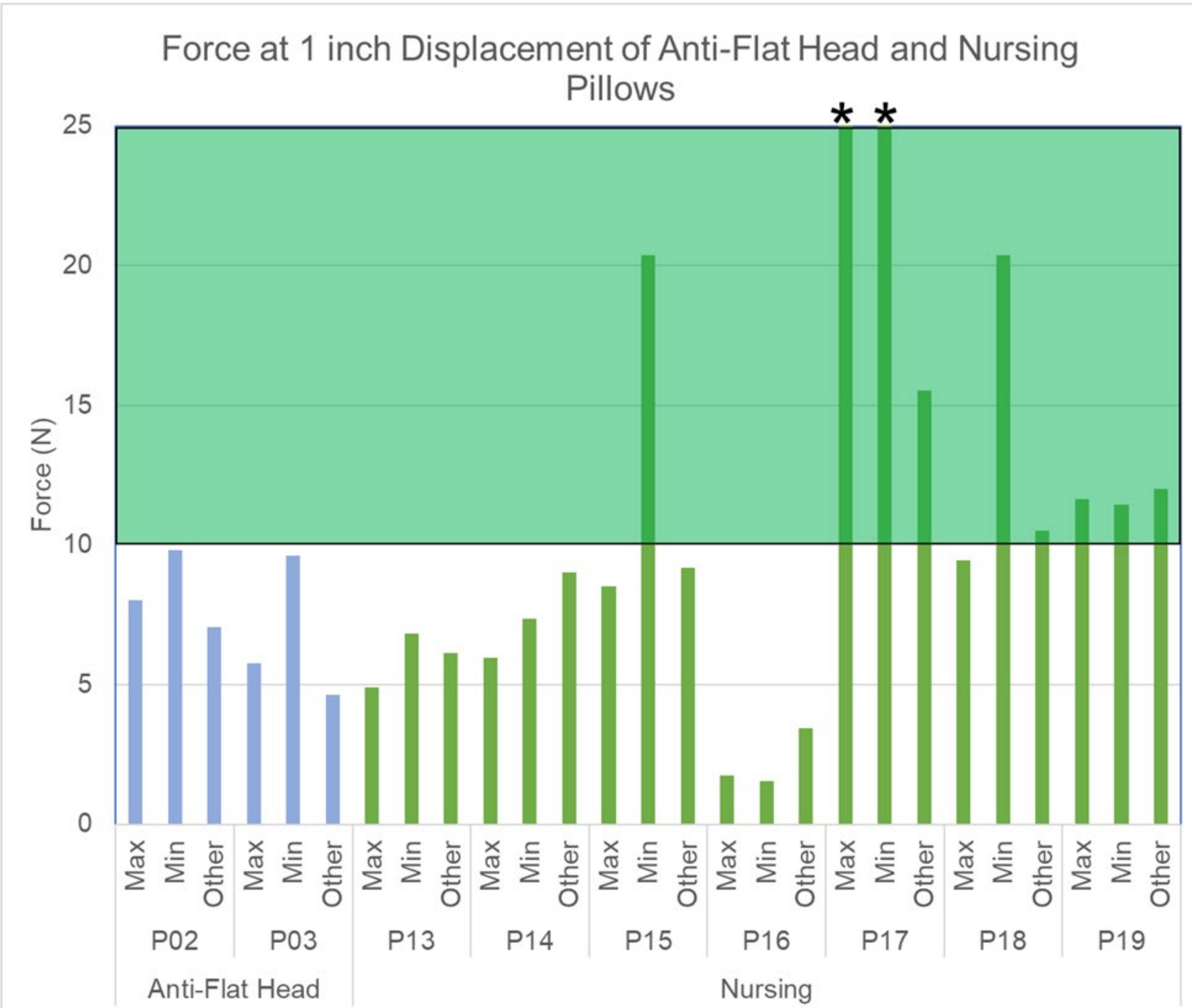


Figure 21. Firmness results of the force versus displacement testing of the Anti-Flat Head and Nursing pillows at a displacement of 1 inch for three locations (maximum thickness, minimum thickness, and other location of interest) of each product. Green shading indicates measurements over the recommended threshold of 10 N which are considered safe from a firmness perspective (*represents results >25 N).

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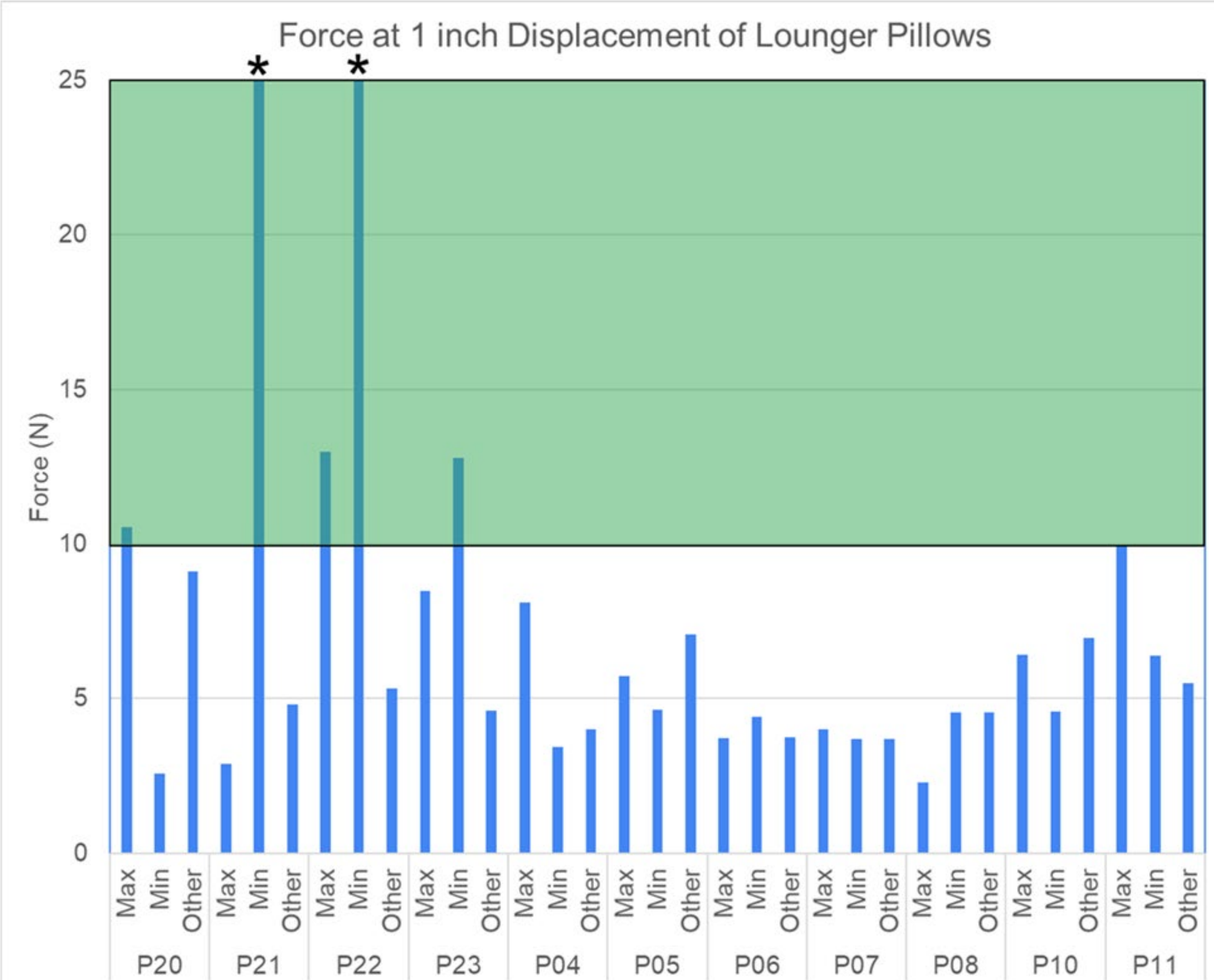


Figure 22. Firmness results of the force versus displacement testing of the Lounger pillows at a displacement of 1 inch for each of three product locations (maximum thickness, minimum thickness, and other location of interest). Green shading indicates measurements over the recommended threshold of 10 N which are are considered safe from a firmness perspective (*represents result >25 N).

In an effort to understand how the cover material may impact firmness, we compared two pairs of products which featured the same design but with different cover materials: P04 and P05, and P22 and P23 (Figure 23). Though we did not statistically compare these results, we noted some differences in firmness due to the outer cover material only for products P22 and P23.

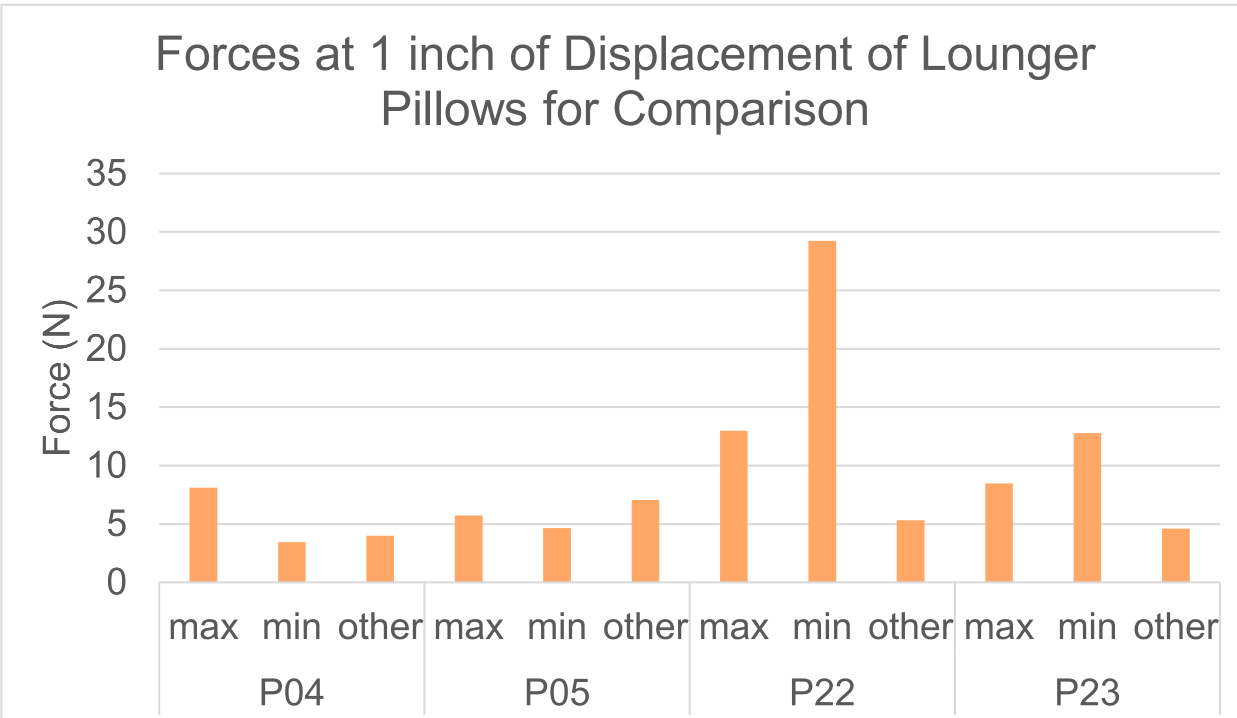


Figure 23. Comparison showing products of a similar design (P04 and P05, and P22 and P23).

5.4 Firmness Testing Discussion

The disk firmometer device currently used is optimal for flat products but cannot be reliably used for uniquely shaped pillow products. Another limitation of the disk firmometer is that it is a pass/fail test. This means that there is little feedback for manufacturers to understand “how close” a product might be to passing the test. The test method we designed allows for quantification of how close a product might be to passing the firmness test, which is valuable information for product designers as they consider design changes to meet a safety standard. We developed a displacement controlled, vertically guided firmness tester that can be used on products which feature curvature and are not conducive to the disk firmometer testing. We used crib mattresses as a basis for establishing an acceptable amount of firmness. We measured the force at many displacements, and found that at a 1 inch displacement, a force of greater than 10 N indicated firmness equivalent to crib mattresses. Neither of the pillow products which were reportedly involved in the IDIs (P04 and P14) had an acceptable amount of firmness according to our newly developed test.

5.5 Firmness Testing Recommendations

A product that is as firm as a crib mattress likely does not pose a suffocation hazard in terms of CO_2 rebreathing or nose and mouth occlusion, as a seal is difficult to form around the nose and mouth of a baby on firm products, and slight movements from the baby's arousal response should break any seal that may form. However, there is a difference between a flat crib mattress and a 3D-shaped pillow product that must be considered. It is possible that the shapes of some products may be perfectly contoured to form a seal around the face more easily than a flat crib mattress.

We recommend that a firmness test should be performed on all pillow products, using a vertical lifter device and a 3 inch wooden hemisphere to displace a product by 1 inch at three locations: the location of maximum thickness, the location of minimum thickness, and a location of interest. The force required for this 1-inch displacement should be >10 N to pass the firmness test.

If a product passes a firmness test, then airflow testing should not be required. If a product does not pass the firmness test, it is possible that the product may still not be hazardous if airflow is sufficient (see Section 6).

If this recommended firmness test was applied to the current pillow products, four nursing pillow products would pass or come very close to passing (P15, P17, P18, and P19), while three lounger products would pass in some locations, meaning a redesign of other parts of the products may result in a sufficiently firm product (P20, P21, and P22).

6. Airflow Testing

6.1 Airflow Testing Overview

The airflow of a material relates to suffocation hazards for infant products. For example, a product that features free airflow would be unlikely to cause a suffocation hazard in the context of CO_2 rebreathing or nasal occlusion, since air could be easily exchanged even if the infant's face was completely covered by the material.

We previously described methodology for testing crib bumper and mesh liner products using our new biofidelic probe (see Section 4). In this section, we use that test methodology to evaluate the airflow through six crib mattresses and the twenty pillow products (Figure 3).

6.2 Airflow Testing Methods

We conducted airflow testing on 20 pillow products in three locations: locations 1 and 2 which were located at the maximum and minimum thicknesses of the product, respectively, and location 3 being a subjective location of interest, as was described in Section 5.2 above (Figure 15). The subjective location of interest was determined to be a worst-case scenario position from an occlusion or airflow perspective not including the maximum or minimum thickness locations. This subjective location of interest was not necessarily the same as the location of interest chosen for the firmness testing. The goal of this testing was to quantify how the products impact airflow. We also tested the six crib mattresses described in Section 5 to which to compare our results.

The relevant airflow test we used was a modified version of BS 4578:1970 standard. The experimental apparatus included a vertically guided firmness fixture featuring a wooden, 3 inch diameter hemispheric probe which was anthropometrically based and featured 3.175 mm airways that are more indicative of an infant's nares (see Section 4). The probe was fixed to a ZP 50 N digital force gauge (Boshi Electronic Instrument, Yueqing City, Zhejiang Province, China) which was attached to the vertical lifter (APH Test Stand, Boshi Electronic Instrument, Yueqing City, Zhejiang Province, China) which allows the force gauge to travel a known vertical distance. The apparatus was anchored to a base for balance. A tubing system connected the probe to a manometer and an air pump as seen in Figure 24.

The pressure differential was recorded during an airflow rate of 2 L/min and a thrust of 10 ± 0.2 N into the product. To achieve the required thrust, the probe was lowered via the lifter apparatus into the product until it settled at 10 ± 0.2 N (Figure 25). This test was performed three times for each product at each location, with a resetting of the product occurring between tests.

Figure 24. Airflow set up connected to the vertically guided lifter device.

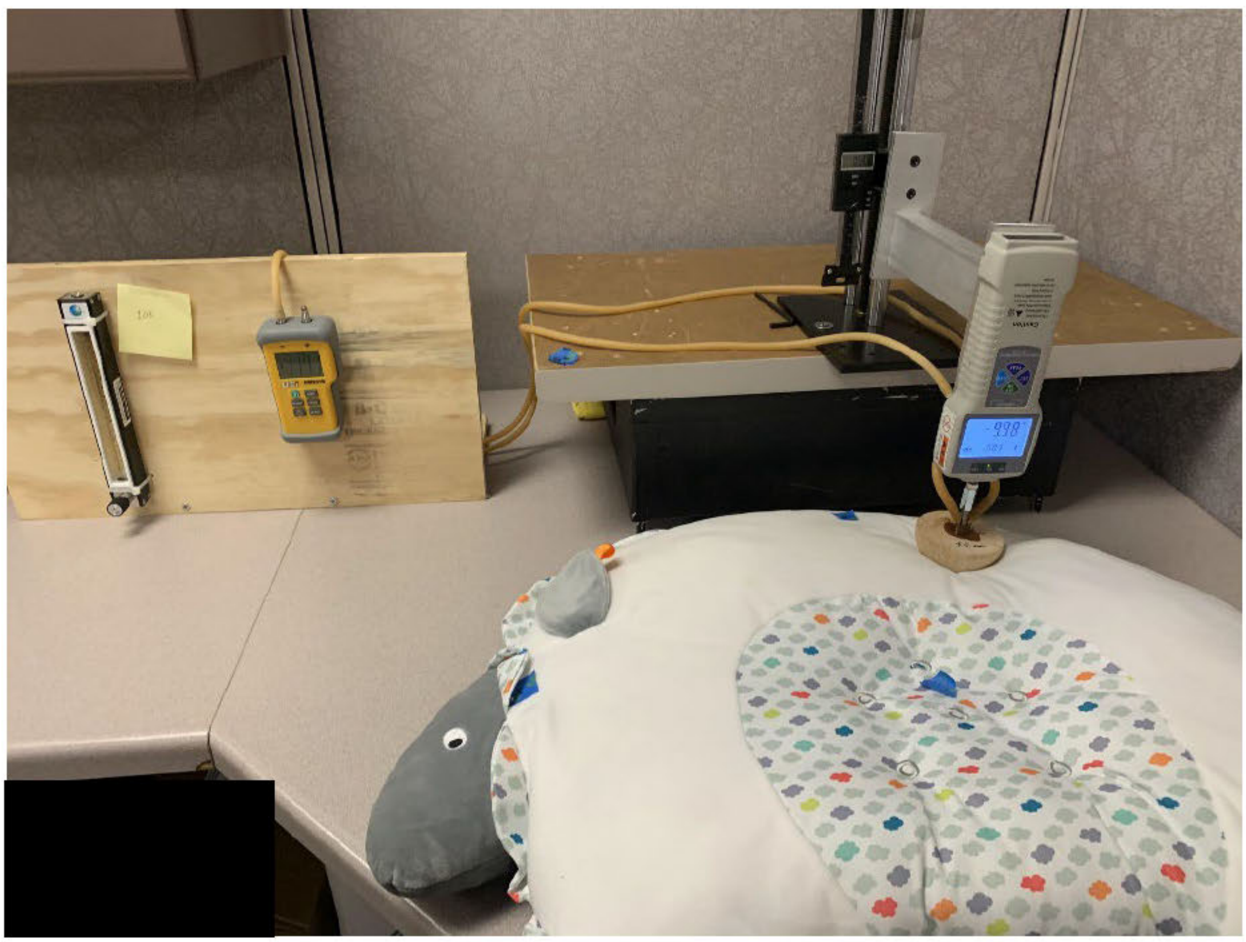


Figure 25. Airflow testing of P06 at Location 1, the maximum product thickness.

6.3 Airflow Results

The airflow testing results of the six crib mattresses are as expected – all mattresses exhibited high pressure drops during testing indicating full or nearly full occlusion and the creation of a seal under the 10 N load (Figure 26).

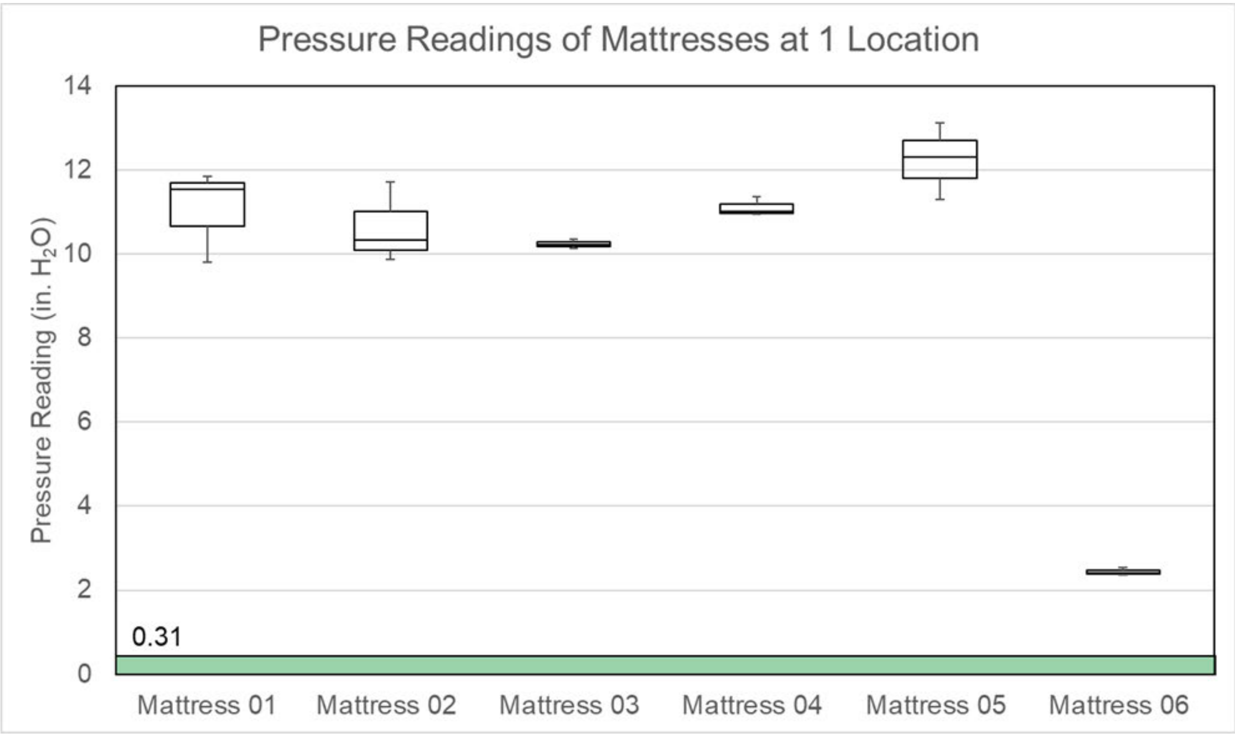
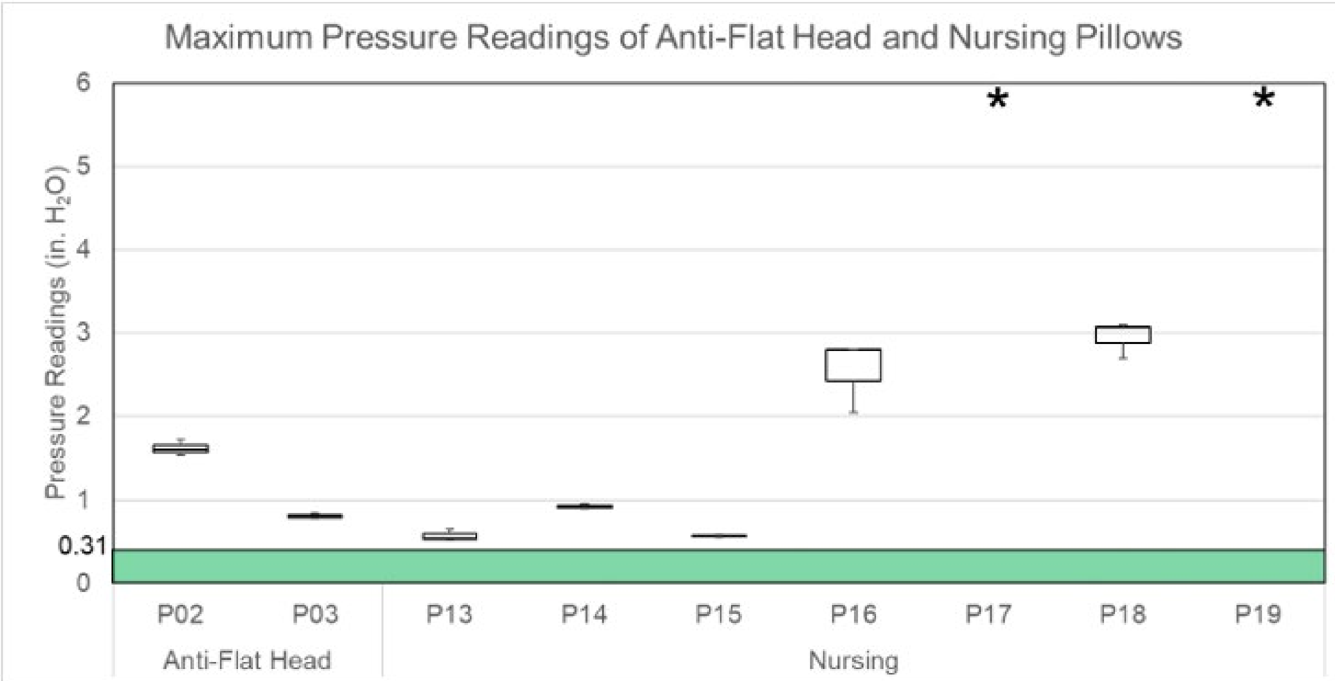


Figure 26. Airflow results of crib mattresses. Green shading indicates measurements under the recommended threshold 0.31 in. H_2O which would be considered safe from an airflow perspective.

The airflow results for the pillow products at the maximum thickness location only are summarized in Figure 27. Many nursing pillow products exhibited pressure drops below 1 in. H_2O, while lounger products tended to exhibit pressure drops greater than 1.5 in. H_2O. Two nursing pillows (P17 and P19) exhibited high pressure drops in the range of the crib mattresses (~10 in. H_2O). Both of these products (P17 and P19) were two of the firmest products we tested in Section 5; both passed our recommended firmness testing.



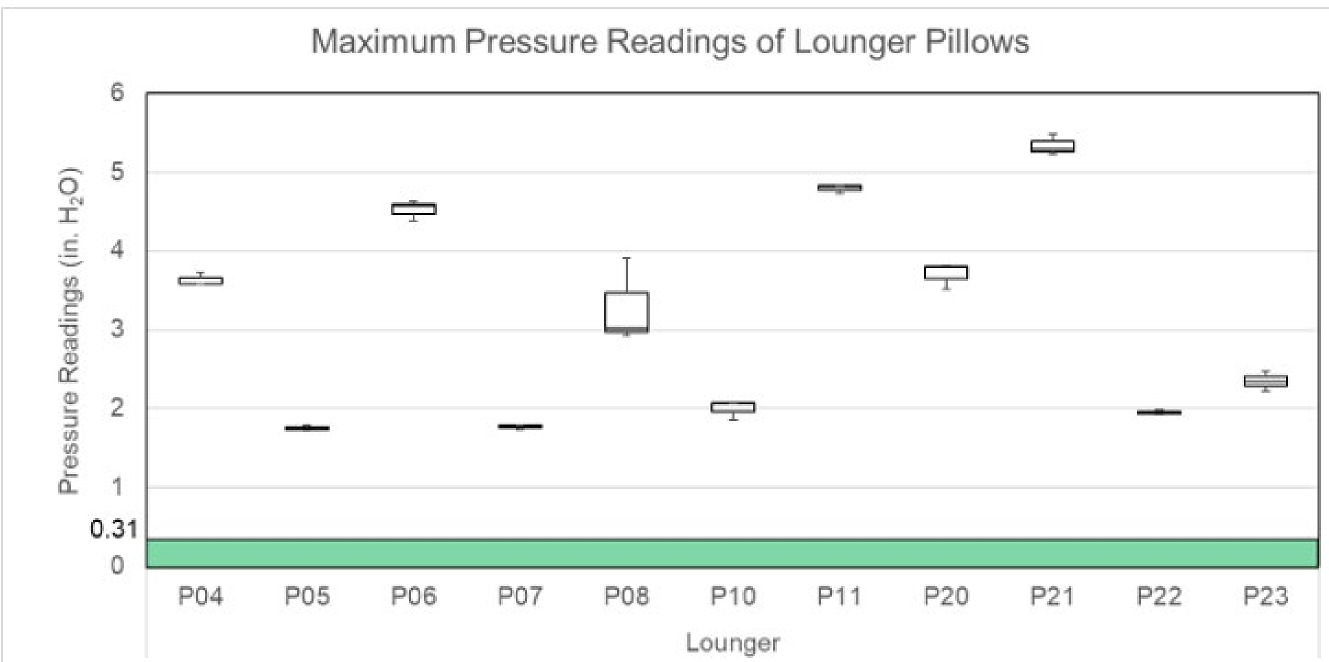


Figure 27. Airflow results of (Top) Anti-Flat Head and Nursing pillows, and (Bottom) Lounger pillows. Green shading indicates measurements under the mesh-like airflow threshold 0.31 in. H_2O . *P17 and P19 created seals at the nares and resulted in high pressure readings, >10 in. H_2O.

We compared two pairs of products which featured the same designs but different cover materials, Products P04 and P05 are lounger pillow designs from Company A, while P22 and P23 are lounger designs from a different company (Figure 28). These results suggest that differences in cover materials on the same product design impact airflow.

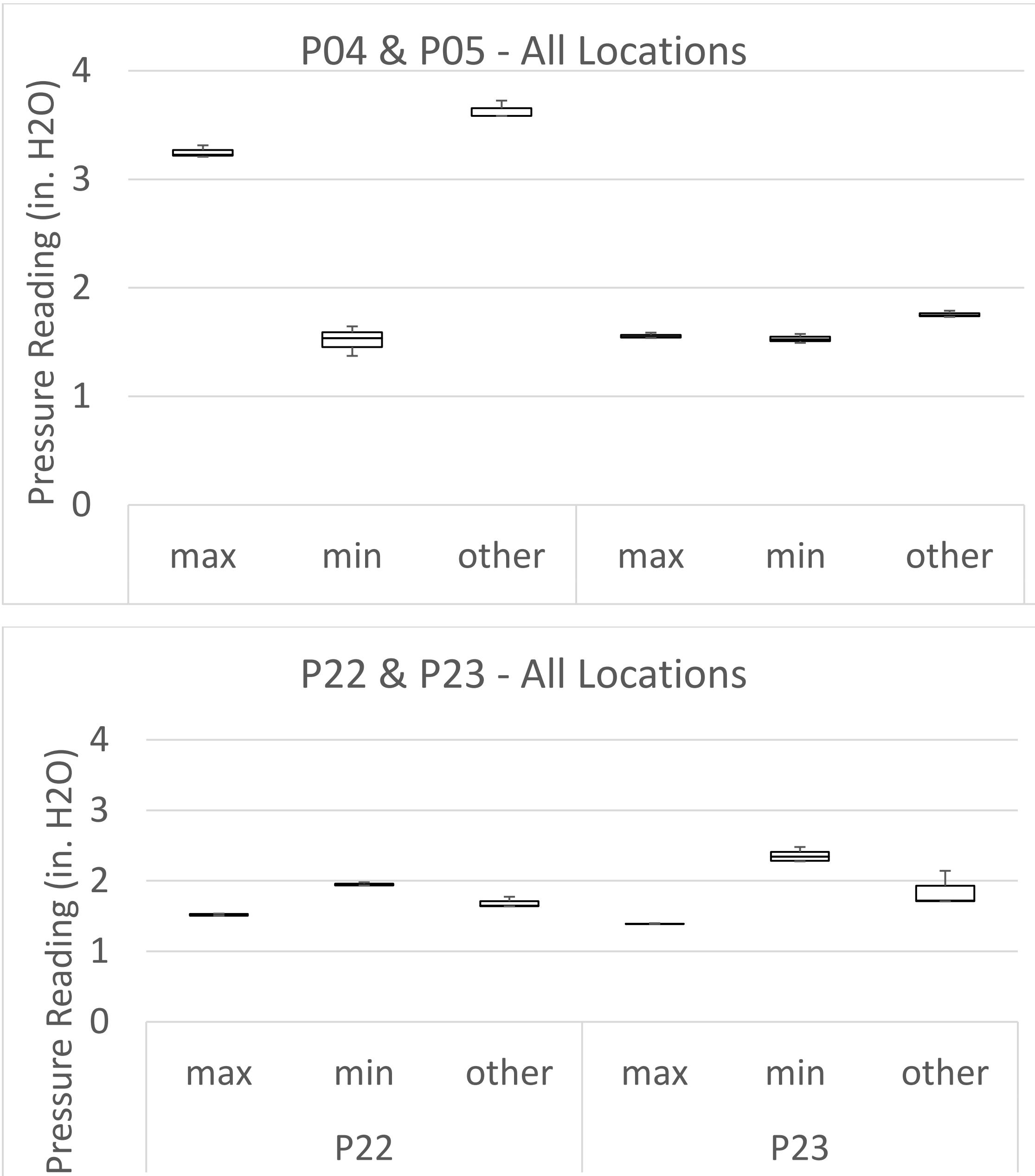


Figure 28. Airflow results of lounger pillows, P04 and P05 (top), and P22 and P23 (bottom) at all locations (maximum thickness, minimum thickness, and other location of interest). The two pairs of products have same designs but different outer covers.

6.4 Airflow Discussion

When we tested the representative crib mattress products with the selected probe, all mattresses resulted in high pressure drops due to full occlusion of the probe. Since our probe does not feature a 3D ridge, full occlusion is more likely than in a real-life scenario. However, in a firm and flat product like a crib mattress, any slight movement by an infant, including those from a typical arousal response, would break the seal and allow for essentially free airflow. Thus, the firmness of the mattresses makes them safe enough that lack of airflow is not typically a hazard.

Most crib mattresses feature a waterproof design, meaning the outer covering is an impermeable plastic. This plastic does not allow for airflow, which is consistent with, and accounts for, our results. Mattress 06 was not considered waterproof, with a cover made of 100% polyester. The airflow results of this particular mattress are lower than the other five, likely due to the material difference. Because crib mattresses are considered the safest sleep surface for a baby, we must consider these seemingly concerning airflow results in conjunction with firmness (Section 5). Crib mattresses are firm and flat, meaning that if a baby found their nose and mouth occluded in a face-down position, that their arousal response would result in a slight movement that would break the seal and allow for free airflow. Thus, we must consider the airflow results in the context of firmness rather than as a separate and unrelated measurement.

Nursing pillows P17 and P19 exhibited high pressure readings (lack of airflow) in the same range of crib mattresses, likely due to their firmness which was also similar to the crib mattresses. Both P17 and P19 passed our recommended firmness test (section 5). These two products featured 100% Polyurethane Foam Pad (P17) and 100% Resin-Treated Polyester Fiber Batting (P19). Nursing pillows P13, P51, and P18 and anti-flat head pillow P03 exhibited airflows close to the 0.31 in. H_2O mesh-like threshold, A slight product redesign may result in a pass, meaning the products would feature mesh-like airflow.

Even if a product does not pass the firmness test, it is possible that it could feature high enough airflow to not pose a significant suffocation or rebreathing risk. We recognize that the 0.31 in. H_2O mesh-like airflow threshold may be conservative as it is based on mesh liner results, and that there is likely a small range of airflow values higher than this threshold which may not pose a suffocation or rebreathing danger for the baby. The 0.31 in. H_2O is three standard deviations above (i.e., less conservative than) the mesh liner airflow results (Section 4). We note that many prone-lying suffocation incidents we reviewed occurred in lounger product P04 included in our study, which we found to have low airflow, with pressure values of 3.6 in. H_2O. Suffocation incidents also occurred in various models of nursing product P14, which featured a much higher airflow, with pressure values approximately 0.93 in. H_2O. Thus, we do believe that the safe range of airflow as measured by pressure drop must be below this 0.93 H_2O threshold, where many suffocation incidents have occurred. However, our testing and the available literature do not adequately define what upper limit is safe.

In order to better elucidate the relationship between firmness and airflow, we performed a linear regression analysis to consider airflow and firmness results together by plotting each pillow product and mattress product results (Figure 29). A very low association was found (R^2 = 0.2702), meaning that these there is a very low positive correlation between firm products (high forces on the x-axis), and products with low airflow (high pressure readings on the y-axis). The mattress products and two firm nursing pillows (P17 and P19) all featured high firmness and low airflow (high pressure) and influenced this regression significantly. There is no meaningful relationship between the less firm pillows products in regard to firmness and airflow.

It is likely that normal use of pillow products will change the airflow properties as the filling compresses and the cover becomes dirty or worn. Additionally, shelf life and normal storage conditions were not considered in this analysis. We also did not consider the relationship between airflow and rebreathing in this analysis. There may be products which allow air to flow but pool CO_2 in a dangerous way. More research could explore rebreathing potential within pillow products.

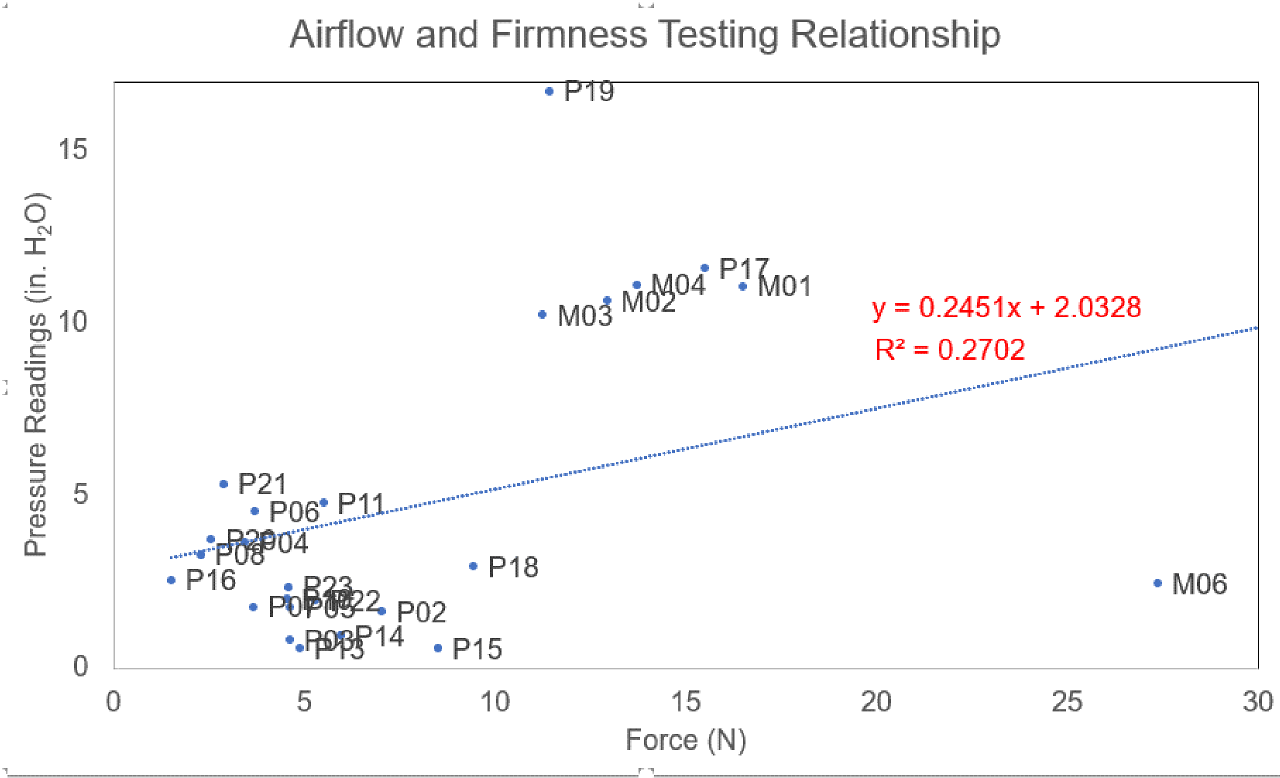


Figure 29. Relationship between pressure drop (airflow) and force (firmness) for pillow and mattress products.

6.5 Airflow Recommendations

We recognize that the safest sleeping surface for a baby (a crib mattress) features a firm surface that is interestingly not conducive to free airflow. A product that is as firm as a crib mattress likely does not pose a suffocation hazard in terms of CO_2 rebreathing or nose and mouth occlusion, as a seal is difficult to form around the nose and mouth of a baby on firm products, and slight movements related to the infant's arousal response would break any seal that may form.

Thus, we recommend a multi-step approach for testing firmness and airflow. The firmness test should be performed first, using a vertical lifter device and a 3-inch wooden hemisphere to displace a product by 1 inch. The force required for this displacement should be greater than 10 N to pass a firmness test (see Section 5). If a product passes the firmness test in all tested locations, airflow testing need not be performed. If a product does not pass the firmness test, then airflow testing should be performed using the methods and threshold recommended below.

We took both firmness and airflow recommendations and plotted them together to show where each pillow product falls in passing our firmness and airflow testing recommendation or not (Figure 23). Each of these points represent the worst-case scenario of the three locations tested (highest pressure value representing less airflow and lowest force value representing less firmness).

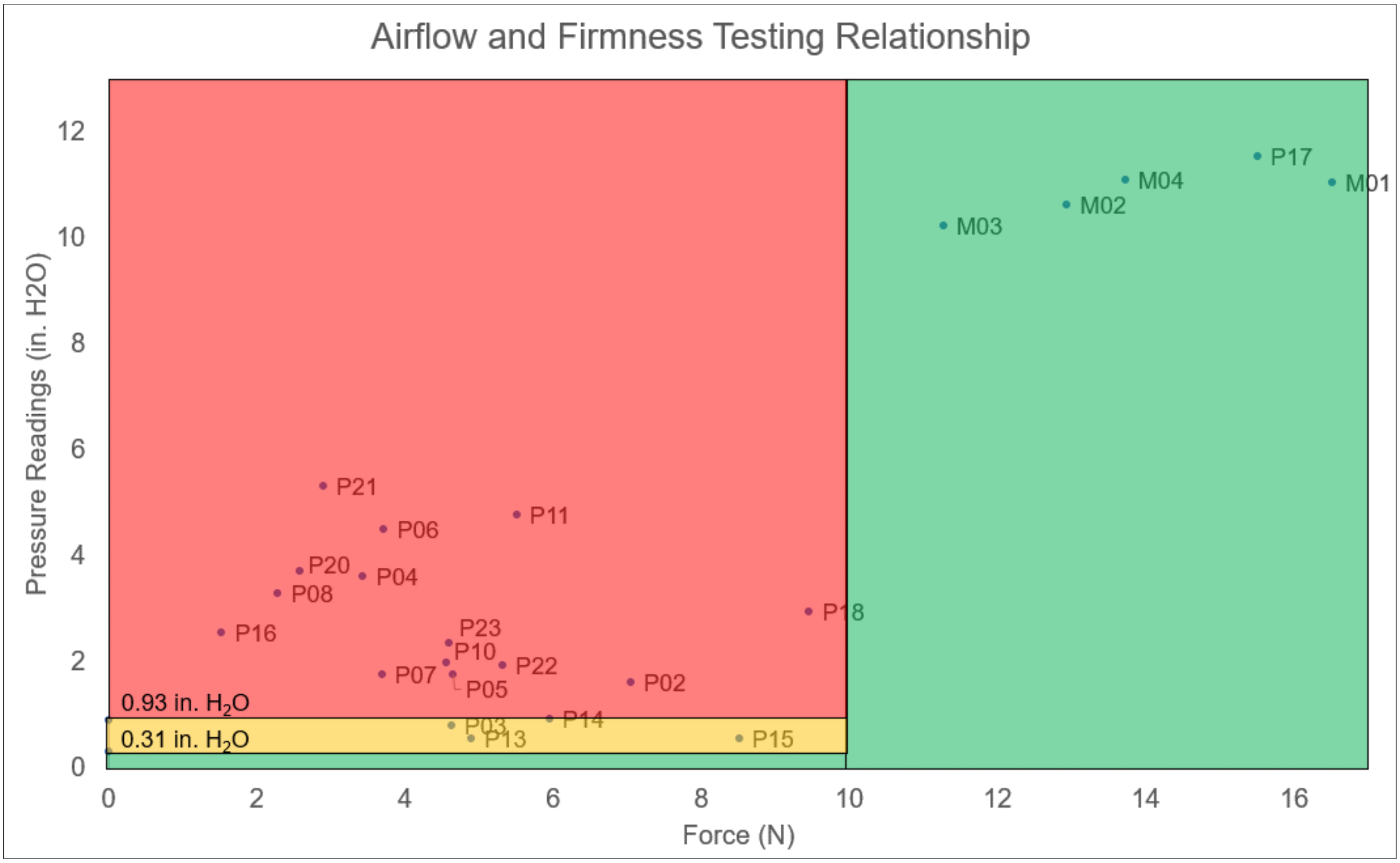


Figure 30. To determine the safety of a product at its worst-case scenario the relationship between the minimum average force and maximum average pressure reading of all three locations are found here. Products and mattresses P19, M05, and M06 greatly exceeded the recommended force threshold of 10 N or exhibited very low airflow (high pressure drop) at >12 in. H_2O, and are therefore not shown on this graph due to space considerations. A pressure drop of <0.31 in. H_2O is within the range of mesh liners, meaning exhibits mesh-like airflow. The 0.93 in. H_2O is an upper limit based on products involved in the IDIs to illustrate the idea that a middle ground may exist in airflow safety. However, we note that several models of product P14 (0.93 in. H_2O) were involved in many nursing pillow incidents where babies died of apparent suffocation.

If this methodology was applied to the pillow products tested as part of this project, nursing pillows P17 and P19 would both pass the firmness testing, while P18 would likely pass with slight redesign. For products that did not pass the firmness test, airflow testing should be conducted. For products that undergo airflow testing, we recommend a conservative threshold value of 0.31 in. H_2O to maintain safety comparable to a mesh liner. Several nursing pillow products exhibited pressure drops near the 0.31 in. H_2O threshold, so we believe it is possible to develop a pillow which would pass this airflow test and provide airflow similar to a mesh liner bumper which has no known fatalities associated with suffocation or rebreathing. There is likely a higher pressure drop threshold that does not pose rebreathing or suffocation risk, but the known IDIs we reviewed revealed that the product involved in seven incidents exhibited a pressure drop of 0.93 in. H_2O in our airflow testing.

7. Infant Positional Assessment

7.1 Infant Positional Assessment Overview

In addition to suffocation scenarios where a baby's face is in contact with a pillow product, the IDIs also elucidate hazard scenarios where the body position of a baby resulted in compromised breathing (chin-to-chest neck flexion, neck hyperextension, and/or trunk flexion). Some scenarios indicated that a baby's face may have been in contact with a pillow product upon normal head rotation (not a rolling scenario). Thus, the purpose of this section is to develop methods to test for infant positioning within a product in ideal and worst-case scenario situations. We focus on head rotation and sagittal plane body position.

7.2 Infant Positional Assessment Methods

7.2.1 Head Rotation

We used an anthropometry-based infant (Prestan Professional Infant Manikin Mayfield Village, OH) with a head which rotates in the axial plane. We machined custom rotation plates which allow for 240° of rotation, based on previously published range-of-motion studies in infants 2 to 10 months of age that indicate approximately 220° of rotation is possible (Ohman and Beckung, 2008). We placed the infant manikin at the selected locations of interest on each product and rotated the device's head from 0° to 120° in 30° increments as shown in Figure 31. We measured the horizontal distance between the nose/mouth region and the side of the product using digital calipers (Figure 32). If we could not measure a distance horizontally from the mouth to the product, it was considered not applicable (N/A). For example, on a flat crib mattress with little deformation, the mouth was not a measurable horizontal distance from the mattress from 90° to -90°. For symmetric products, measurements were assumed to reflect similar results for the 0° to +120° and the 0° to -120° head rotation positions.

Understanding the CO_2 Rebreathing hazard that might be introduced due to contact or proximity of the infant's face with the side of a product is important to interpret these data. Previous research has shown that with increased load, that CO_2 rebreathing increases on traditional crib bumpers (Maltese and Leshner, 2019). We conducted additional CO_2 rebreathing testing using the 3 inch diameter probe described in Section 4 and a CO_2 rebreathing machine described previously (Maltese and Leshner, 2019; and unpublished research, CPSC project, 2021). Using the vertical lifter device described (Sections 5 and 6), we tested CO_2 rebreathing between the probe and three surfaces (plywood to represent a solid firm surface, a thick traditional crib bumper, and a lounger product). At each 0.2 inch increment, we measured the CO_2 rebreathing, and found that the CO_2 rebreathing values begin to increase at 0.8 inches, which is approximately 2 cm (Figure 33). We also applied a 10 N force (approximate weight of a newborn's head) and measured rebreathing, finding that the firm plywood surface resulted in 4.5% CO_2 rebreathing, the traditional crib bumper resulted in 22.9% CO_2 rebreathing, and the lounger resulted in 19.4% CO_2 rebreathing. Thus, we will interpret our data for the head rotation testing using the 2 cm distance as a cautionary threshold and contact or 0 cm as a dangerous scenario since imperfect placement within the pillow product or prone placement would induce a load and increase the CO_2 rebreathing potential to potentially fatal amounts.

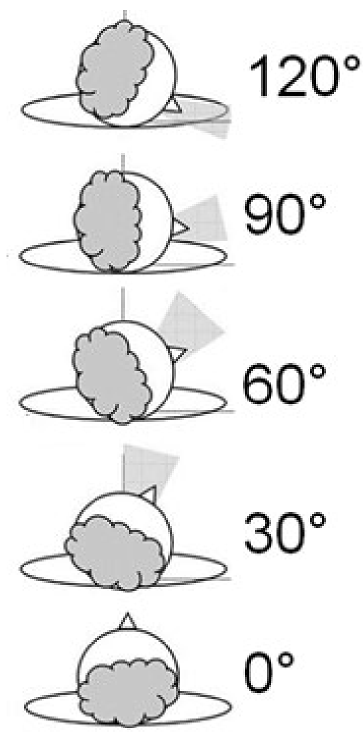


Figure 31. Example of head rotation device in various 30° increments. The distance from the nose and the side of the product horizontally was measured using digital calipers.

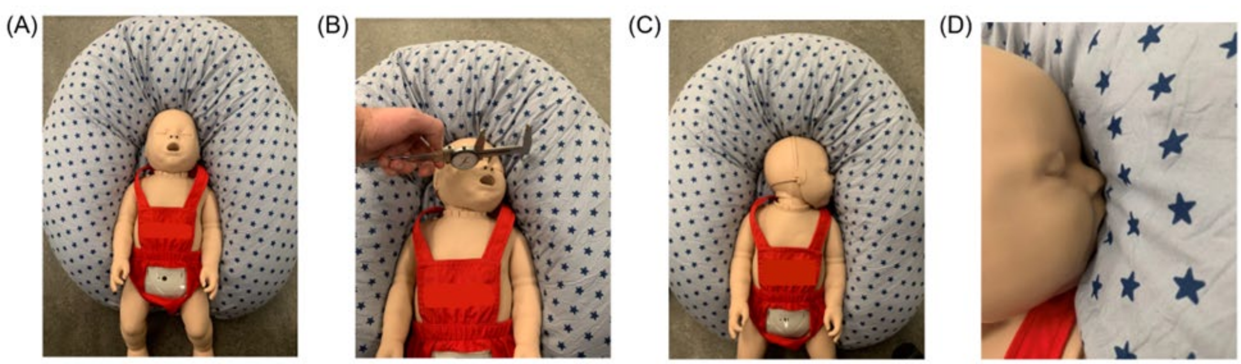


Figure 32. Head rotation testing photos of P16. Representative photos of (A) distance that cannot be measured, (B) a measurement, (C) a 0 cm distance, and (D) a close-up of 0 cm distance.

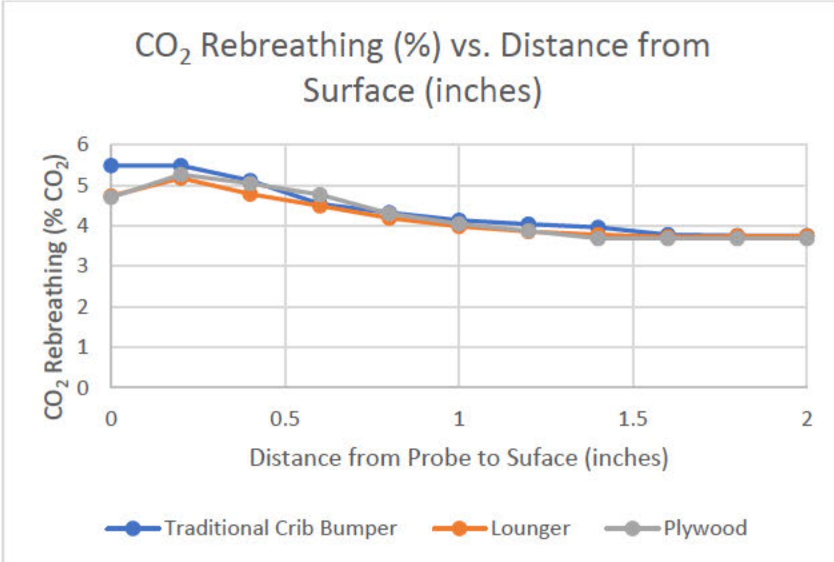


Figure 33. CO_2 Rebreathing (%) vs. Distance from Surface (inches) for three surfaces. Values begin to increase < 0.8 inch or < 2 cm distance.

7.2.2 Head/Neck and Trunk Flexion

Currently, there exists a standard testing device referred to as a hinged weight gage that is capable of estimating the back inclined angle and hip flexion angle of infants as they sit in different products (ASTM F3118-17a Standard Consumer Safety Specification for Infant Inclined Sleep Products). While this device may be relevant for hip position and back incline angle of sufficiently firm products, it can be improved to further examine the suffocation risk posed by these same products in the context of neck flexion or extension angle, and trunk flexion.

To accomplish this, we developed two anthropometry-based devices similar to the hinged weight gage model that allowed us to measure head/neck flexion angle, trunk flexion angle, and hip flexion angle. This anthropometric data is summarized in Table 10. The overall lengths and masses of each sagittal plane testing device are based on data from the CDC Growth Charts, 2001. With the newborn device, the head's length, width, and mass, and the leg's mass all come from Coats et al. (2008). Other values, including the chest width, the hip width, and the leg's length are representative of values recorded in Snyder et al. (1977). To estimate the torso segment length and mass, the known values in the leg and the head were subtracted from the average overall values. This was then divided by two to allow for two equally sized segments. The 3-month-old version followed a similar methodology to the newborn, except for the head length was based on Huelke et al. (1998).

Table 10. Targeted Anthropometric Measurements for Sagittal Plane Devices.

Desired Newborn Device Parameters			**Desired 3-Month-Old Device Parameters**		
Head	Length (cm)	13.60	**Head**	Length (cm)	15.01
	Width (cm)	10.40		Width (cm)	11.40
	Mass (kg)	0.90		Mass (kg)	1.33
Torso x2	Length (cm)	7.74	**Torso x2**	Length (cm)	10.02
	Chest Width (cm)	12.20		Chest Width (cm)	13.00
	Mass (kg)	0.92		Mass (kg)	1.36
Legs	Length (cm)	23.10	**Legs**	Length (cm)	25.00
	Hip Width (cm)	13.20		Hip Width (cm)	13.75
	Mass (kg)	1.17		Mass (kg)	1.74

While the segment parameters of the newborn and 3-month-old models listed above were the targeted values, some changes were made to simplify the creation of the physical prototype. These changes are shown in Table 11 with the finished models shown in Figure 34.

Table 11. Actual Measurements for Sagittal Plane Device prototypes.

Actual Newborn Device Parameters			Actual 3-Month-Old Device Parameters		
Head	Length (cm)	11.43	**Head**	Length (cm)	13.34
	Width (cm)	9.50		Width (cm)	10.16
	Mass (kg)	0.80		Mass (kg)	1.26
Upper Torso	Length (cm)	12.07	**Upper Torso**	Length (cm)	13.34
	Chest Width (cm)	9.50		Chest Width (cm)	10.16
	Mass (kg)	0.95		Mass (kg)	1.64
Lower Torso	Length (cm)	12.07	**Lower Torso**	Length (cm)	13.34
	Chest Width (cm)	9.50		Chest Width (cm)	10.16
	Mass (kg)	0.95		Mass (kg)	1.58
Legs	Length (cm)	18.42	**Legs**	Length (cm)	19.05
	Hip Width (cm)	14.85		Hip Width (cm)	16.51
	Mass (kg)	1.19		Mass (kg)	1.81

Both the newborn and the 3-month-old models were created with 303 stainless steel and different segments were connected using pins with a mass of 0.03 kg. The models also had material removed to achieve the approximate desired mass. In the newborn model, the head piece had a square hole that was sized 4.6 cm x 5.2 cm. Similarly, the 3-month-old model had a hole that was 5.6 cm x 6.2 cm. Both models featured a series of drilled holes in the torso pieces, all of which had a diameter of 1 cm, to achieve the desired mass.

Figure 34. Newborn and 3-month-old anthropometry-based devices used to measure head/neck angle, trunk flexion angle, and hip flexion angle.

For testing, each sagittal plane device (newborn and 3-month-old) was placed in each pillow product in three positions: intended supine position, a slouched position (neck and trunk flexion), and a prone/hyperextended neck position, which is a position that captures both a prone position with the face into the pillow and a supine position with the neck hyperextended (Figure 35). As several of the c-shaped nursing pillows also have a marketed use as loungers, testing was also completed examining this additional placement for those four products. The angle of each segment compared to a flat surface was then recorded using a Wixey Digital Angle Gauge (WR300 Type 2), which has a precision of 0.1 degrees. The difference between segment angles was taken to find the flexion/extension angles for each joint.

Figure 35. Example photos of the newborn device in a product of each position. Intended (Top), Slouched (Middle), Prone (hyperextended) (Bottom).

All nursing pillows were tested in the intended use position – with the model lying on the nursing pillow as if the pillow was being used for nursing. The slouched and prone positions were based on if the infant moved from that intended nursing position into a slouched or prone position. Four nursing pillows were also described as lounging products in the packaging or marketing. For these four products, we completed three additional sets of testing to evaluate intended supine, slouched, and prone / neck hyperextension for lounging intended placement (Figure 36).

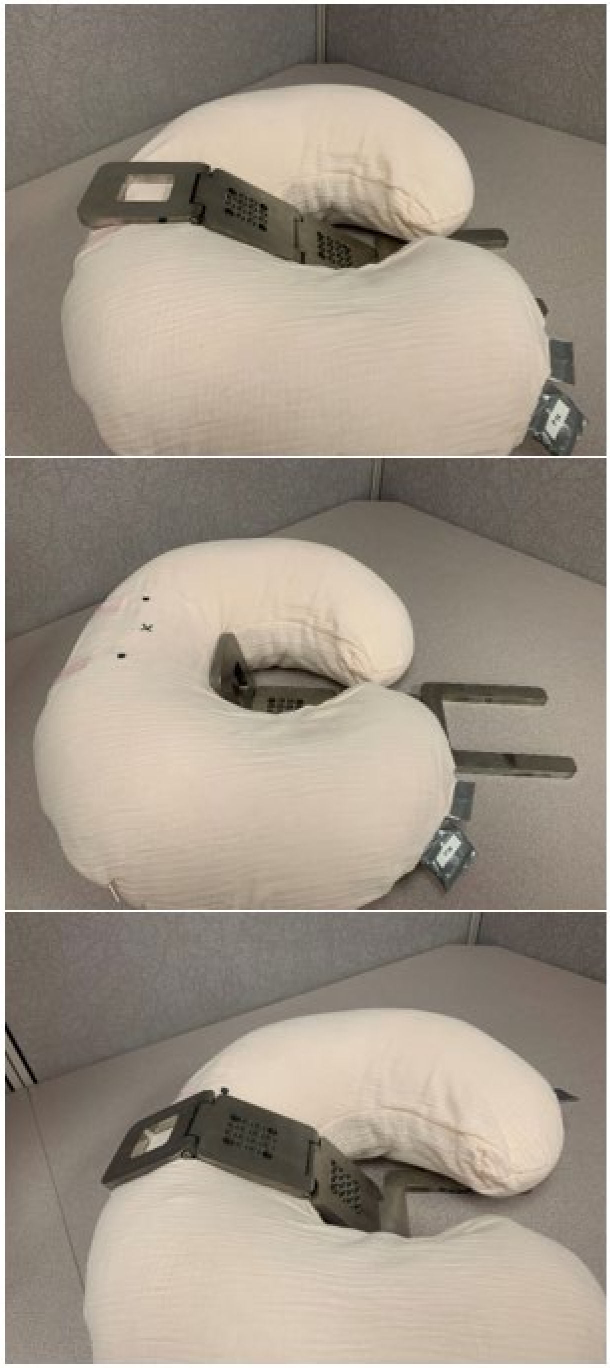


Figure 36. Example photos of the newborn device in a C-shaped nursing pillow in each position during lounging-intended use. Intended supine (Top), slouched (Middle), and prone / neck hyperextended (Bottom) positions.

7.3 Infant Positional Assessment Results

7.3.1 Head Rotation Results

Results for the head rotation testing in the ideal and worst-case scenarios are presented in Tables 12 and 13.

Table 12. Head rotation distances in centimeters from center of nose/mouth to the side of the product of an infant lying supine in the intended supine position of the product. The distances that could not be measured, likely indicating free airflow, are highlighted in grey; the results that were 0 cm indicating direct contact are highlighted in red; and the results that were between 0 and 2 cm are highlighted in orange.

Samples	Nose/mouth to side of product distance (cm) when infant is lying supine in the intended position of the product				
	0°	30°	60°	90°	120°
P02	N/A	N/A	N/A	N/A	0
P03	N/A	N/A	N/A	N/A	0
P04	N/A	N/A	N/A	N/A	1.67
P05	N/A	N/A	N/A	3.27	0
P06	N/A	N/A	N/A	N/A	0.93
P07	N/A	N/A	N/A	N/A	0.23
P08	N/A	N/A	N/A	5.00	0
P10	N/A	N/A	N/A	4.56	0
P11	N/A	N/A	N/A	N/A	1.34
P20	N/A	N/A	N/A	1.71	1.74
P21	N/A	N/A	9.95	6.49	0
P22	N/A	N/A	5.85	2.60	0
P23	N/A	N/A	4.99	2.09	0
P13	N/A	N/A	N/A	N/A	1.13
P14	N/A	N/A	N/A	8.03	0.98
P15	N/A	N/A	N/A	N/A	0
P16	N/A	N/A	N/A	2.22	0
P17	N/A	N/A	N/A	N/A	N/A
P18	N/A	N/A	N/A	N/A	N/A
P19	N/A	N/A	N/A	N/A	2.81
Mattress	N/A	N/A	N/A	N/A	3.4
Mattress 02 – Blue Mat	N/A	N/A	N/A	N/A	4.97
Mattress 03 - Stripes	N/A	N/A	N/A	N/A	3.58
Mattress 04 - Clouds	N/A	N/A	N/A	N/A	3.95
Mattress 05 - Quilt	N/A	N/A	N/A	N/A	8.42
Mattress 06 – White Mat	N/A	N/A	N/A	N/A	9.1

Table 13. Head rotation distances in centimeters from the center of the nose/mouth to the side of the product of an infant lying supine in the worst-case alignment of the product. The distances that could not be measured, likely indicating free airflow, are highlighted in grey, the results that were 0 cm indicating direct contact are highlighted in red, and the results that were between 0 and 2 cm are highlighted in orange.

Samples	Nose/mouth to side of product distance (cm) when infant is lying supine in worst case alignment				
	0°	30°	60°	90°	120°
P02	N/A	N/A	N/A	2.30	0
P03	N/A	N/A	N/A	1.04	0
P04	14.00	8.74	3.81	0.71	0
P05	11.71	7.3	2.65	0	0
P06	N/A	N/A	N/A	N/A	0
P07	N/A	N/A	N/A	5.01	0.61
P08	N/A	13.57	5.99	3.15	0
P10	15.09	7.37	4.28	0	0
P20	N/A	4.28	0	0	0
P21	N/A	N/A	2.96	0	0
P22	N/A	N/A	1.03	0	0
P23	N/A	N/A	1.10	0	0
P11	12.12	8.07	3.09	0	0
P13	9.11	4.72	0.64	0	0
P14	11.99	6.86	2.47	0	0
P15	0	0	0	0	0
P16	9.54	5.35	0.17	0	0
P17	N/A	N/A	N/A	N/A	0
P18	6.01	2.25	0	0	0
P19	9.69	5.67	1.71	0	0

7.3.2 Sagittal Plane Testing Results

The mean resulting angles for the neck, torso, and hip flexion over three trials are shown in the tables below (Tables 14 to 25). For these, a negative value represents extension while a positive value represents flexion of the joint. Aside from the tables, Figures 37 to 42 represent the sagittal plane segmental angles with the lower torso / pelvic segment coincident.

Table 14. Joint Flexion Angles for Newborn Model Placed in Intended Supine Position

Newborn Model Intended Placement						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P02	-9.07	1.00	15.43	0.68	0.60	0.00
P03	-7.43	2.15	16.80	0.89	0.57	0.06
P04	-33.83	8.36	49.90	3.50	30.37	7.58
P05	-31.30	3.97	52.37	2.45	6.00	1.92
P06	-25.30	0.70	16.53	4.80	-8.93	7.45
P07	-23.63	1.29	1.83	5.69	-1.83	4.82
P08	-9.90	9.05	37.93	10.60	-10.03	22.47
P10	-16.93	3.07	39.87	3.14	41.27	3.98
P11	-24.63	7.51	50.37	1.62	14.80	5.41
P20	32.90	1.97	3.20	1.55	25.83	1.69
P21	6.63	2.50	4.60	2.21	-0.20	0.26
P22	13.50	1.11	0.73	0.15	1.50	0.26
P23	15.73	0.31	-1.83	0.42	2.13	0.12
P13	-14.10	3.21	8.03	3.10	-25.83	3.28
P14	-20.80	2.01	14.27	2.84	-12.87	0.84
P15	-10.67	1.33	21.60	2.31	-9.40	2.72
P16	53.10	10.77	-10.37	6.21	16.10	1.66
P17	8.97	4.39	10.73	1.89	-18.53	1.10
P18	-10.07	1.82	-1.03	0.49	-26.17	6.72
P19	-2.37	1.86	-5.13	1.69	-5.93	1.27

Table 15. Joint Flexion Angles for Newborn Model Placed in Lounging-Intended Supine Position on Nursing Pillows.

Newborn Model Lounging-Intended Placement in Nursing Pillows						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P13	-20.73	1.99	-13.57	9.88	39.00	5.50
P14	-34.67	2.27	0.77	2.94	35.33	0.84
P16	-25.63	3.24	4.97	14.57	32.80	8.90
P19	-33.33	1.80	-6.77	5.52	42.03	3.15

Table 16. Joint Flexion Angles for Newborn Model Placed in Slouched Position. P15 and P17 were unable to be tested in the slouched position for nursing intended use.

Newborn Model Slouched Placement						
Sample	Mean Neck	St. Dev.	Mean Torso	St. Dev.	Mean Hip	St. Dev.
P02	55.50	3.47	0.03	0.12	0.70	0.00
P03	61.33	3.95	0.10	0.20	0.73	0.06
P04	46.90	3.73	42.23	5.01	-56.60	1.82
P05	55.80	1.21	14.47	1.97	-50.80	1.49
P06	-1.80	1.70	18.67	1.48	-31.23	1.20
P07	-4.97	4.60	9.07	3.04	-6.77	3.25
P08	46.63	3.35	-6.10	12.01	-28.33	8.79
P10	33.70	1.78	46.20	4.06	-55.87	1.18
P11	39.93	2.64	32.00	3.40	-50.93	3.27
P20	37.53	3.26	12.47	1.88	13.13	0.85
P21	7.97	2.50	2.90	3.02	8.03	1.21
P22	47.90	0.75	17.43	0.15	0.90	0.26
P23	42.97	1.43	20.77	0.50	-1.17	0.12
P13	73.60	3.15	73.53	6.06	-70.93	6.17
P14	75.87	1.70	84.77	2.46	-69.03	3.55
P15	N/A	N/A	N/A	N/A	N/A	N/A
P16	-2.57	2.03	17.37	2.57	-22.43	1.68
P17	65.50	1.71	51.73	0.76	-51.53	1.01
P18	N/A	N/A	N/A	N/A	N/A	N/A
P19	73.30	3.90	61.63	3.48	-49.67	7.52

Table 17. Joint Flexion Angles for Newborn Model Placed in Lounging-Slouched Position on Nursing Pillows.

Newborn Model Lounging-Slouched Placement in Nursing Pillows						
Sample	Mean Neck	St. Dev.	Mean Torso	St. Dev.	Mean Hip	St. Dev.
P13	80.57	1.02	0.10	0.10	0.80	0.10
P14	81.70	5.45	0.13	0.35	0.67	0.40
P16	83.03	2.50	0.07	0.06	0.90	0.17
P19	84.10	1.37	-0.17	0.15	0.90	0.17

Table 18. Joint Flexion Angles for Newborn Model Placed in Prone or Hyperextended Neck Position.

Newborn Model Prone Placement						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P02	-30.67	1.51	-10.33	2.25	17.17	0.85
P03	-36.53	1.19	-10.77	1.85	19.20	0.96
P04	-52.07	2.93	-7.67	5.33	58.73	4.06
P05	-50.87	1.25	-6.90	1.30	48.73	2.59
P06	-25.90	1.05	-17.73	1.85	20.27	0.45
P07	-34.93	4.43	-12.50	0.78	8.10	0.62
P08	-25.97	4.46	-18.70	2.35	27.07	4.83
P10	-42.07	2.45	-13.60	2.25	52.30	3.91
P11	-50.50	3.03	-6.60	5.60	54.07	4.36
P20	-54.30	1.95	41.37	2.47	9.10	0.98
P21	-31.57	2.54	7.33	0.83	9.50	0.30
P22	-63.10	4.05	41.40	1.91	6.20	1.66
P23	-59.03	2.21	40.20	1.21	4.20	5.02
P13	-8.10	9.37	90.87	0.25	-28.17	7.72
P14	0.33	1.29	90.73	0.06	-17.40	3.65
P15	-45.57	0.40	0.70	1.65	16.37	0.95
P16	-53.83	4.34	16.73	9.63	7.77	3.93
P17	-20.63	9.25	64.43	0.86	10.33	3.14
P18	-33.30	2.54	-8.00	0.89	-5.60	1.15
P19	-20.00	3.56	89.47	0.95	-19.27	5.35

Table 19. Joint Flexion Angles for 3-Month-Old Model Placed in Lounging-Prone Position on Nursing Pillows.

Newborn Model Lounging-Prone Placement in Nursing Pillows						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P13	-26.93	1.17	-34.30	2.27	51.70	1.44
P14	-56.40	1.66	-34.20	8.49	57.57	5.40
P16	-25.87	1.66	-50.73	6.89	69.20	6.01
P19	-48.03	2.87	-43.37	8.63	67.23	5.83

Table 20. Joint Flexion Angles for 3-Month-Old Model Placed in Intended Supine Position.

3-Month-Old Model Intended Placement						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P02	-3.03	2.40	11.03	0.80	0.93	0.21
P03	0.80	1.20	11.00	0.44	1.13	0.06
P04	-56.27	1.56	24.43	6.20	48.20	5.35
P05	-37.97	2.43	40.53	5.01	-21.87	2.97
P06	-30.50	2.00	3.00	1.95	-1.10	3.12
P07	-28.67	2.12	-10.37	2.12	1.37	3.09
P08	-19.73	1.45	-2.20	1.73	31.13	0.71
P10	-47.03	0.78	17.27	3.74	63.43	1.24
P11	-48.30	3.99	22.83	3.55	22.30	2.43
P20	43.00	4.26	1.73	0.21	33.47	2.35
P21	13.53	0.91	1.90	1.56	0.83	0.21
P22	39.33	1.01	3.80	0.79	2.10	0.44
P23	37.07	1.90	0.00	0.56	1.87	0.15
P13	-2.83	5.31	-4.23	6.91	-27.70	8.06
P14	-2.17	2.72	4.93	2.07	-39.27	1.94
P15	9.13	1.72	15.33	0.59	-7.07	1.54
P16	17.70	9.72	15.73	5.10	12.27	0.12
P17	13.87	1.50	-2.50	2.61	-19.70	1.35
P18	-15.70	0.75	0.17	1.11	-31.40	1.71
P19	0.73	1.46	-2.90	2.10	-20.93	2.66

Table 21. Joint Flexion Angles for 3-Month-Old Model Placed in Lounging-Intended Supine Position on Nursing Pillows.

3-Month-Old Model Lounging-Intended Placement in Nursing Pillows						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P13	-40.90	1.92	49.23	0.75	0.57	0.06
P14	-53.67	6.67	59.17	3.83	0.43	0.06
P16	-30.57	3.80	39.47	10.06	4.73	5.69
P19	-52.23	1.48	61.83	0.91	0.33	0.06

Table 22. Joint Flexion Angles for 3-Month-Old Model Placed in Slouched Position. P15 and P17 were unable to be tested in the slouched position for nursing intended use.

3-Month-Old Model Slouched Placement						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P02	48.27	8.83	1.00	0.26	0.77	0.15
P03	52.37	2.77	0.77	0.15	0.77	0.15
P04	29.37	3.11	46.27	2.42	-52.30	0.78
P05	28.90	7.52	29.13	8.17	-46.67	6.07
P06	-9.77	2.47	13.33	0.67	-21.47	0.72
P07	-5.70	0.79	3.00	1.31	-2.43	2.47
P08	45.00	3.80	-13.23	7.24	-14.53	5.99
P10	40.63	4.38	34.40	7.46	-64.27	5.85
P11	25.40	8.52	22.80	4.86	-27.80	2.52
P20	-29.40	4.84	27.37	0.85	11.63	0.86
P21	3.63	2.32	8.67	2.18	3.23	1.61
P22	-20.13	1.42	31.50	0.36	2.33	0.21
P23	-20.67	6.25	33.93	1.40	0.07	0.55
P13	64.97	2.35	60.30	1.82	-78.77	0.58
P14	74.10	2.09	74.37	2.41	-79.60	2.01
P15	N/A	N/A	N/A	N/A	N/A	N/A
P16	32.40	1.04	8.03	6.67	-18.60	3.05
P17	73.40	1.71	48.90	2.57	-61.00	2.95
P18	N/A	N/A	N/A	N/A	N/A	N/A
P19	75.87	1.10	58.77	2.08	-70.37	3.13

Table 23. Joint Flexion Angles for 3-Month-Old Model Placed in Lounging-Slouched Position on Nursing Pillows.

3-Month-Old Model Lounging-Slouched Placement in Nursing Pillows						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P13	80.33	2.66	0.60	0.00	-0.27	0.06
P14	78.33	3.93	0.63	0.06	-0.13	0.06
P16	78.43	1.15	0.53	0.12	-0.17	0.06
P19	81.53	2.65	0.40	0.35	-0.10	0.35

Table 24. Joint Flexion Angles for 3-Month-Old Model Placed in Prone or Hyperextended Neck Position.

3-Month-Old Model Prone Placement						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P02	-20.60	0.96	-8.70	1.18	12.73	0.50
P03	-24.20	3.20	-5.57	2.58	11.83	0.65
P04	-51.57	6.72	-53.50	1.22	44.63	2.90
P05	4.37	11.04	-51.13	1.99	26.83	6.71
P06	22.47	2.54	-31.57	1.10	6.97	0.83
P07	5.90	25.38	-23.53	1.37	5.57	1.04
P08	-19.37	1.95	-23.67	0.76	17.77	2.76
P10	-58.03	3.46	-39.67	1.38	30.43	8.49
P11	-63.03	2.73	-47.93	3.01	38.27	3.84
P20	-65.93	5.71	28.97	4.28	11.47	2.50
P21	-30.43	8.60	4.70	0.44	8.27	0.29
P22	-75.27	1.65	4.43	10.11	19.27	3.80
P23	-64.40	4.78	33.43	0.92	6.60	1.04
P13	-25.07	3.12	87.13	2.66	-53.23	4.91
P14	-9.93	3.51	91.20	1.56	-42.07	2.27
P15	-55.53	4.47	-2.30	6.07	17.07	3.33
P16	-45.40	5.43	-1.63	1.53	19.17	0.29
P17	-25.50	6.51	69.53	1.81	-34.37	2.27
P18	-41.10	2.33	-13.93	1.27	-4.27	1.14
P19	-10.43	3.76	76.63	0.51	-30.90	5.20

Table 25. Joint Flexion Angles for 3-Month-Old Model Placed in Lounging-Prone Position on Nursing Pillows.

3-Month-Old Model Lounging-Prone Placement in Nursing Pillows						
Sample	**Mean Neck**	**St. Dev.**	**Mean Torso**	**St. Dev.**	**Mean Hip**	**St. Dev.**
P13	-32.73	3.40	-43.13	11.30	47.87	5.80
P14	-64.47	2.18	-38.60	7.81	46.33	2.84
P16	-41.47	4.25	-60.83	8.33	58.70	5.39
P19	-51.77	2.47	-58.93	6.29	62.53	3.95

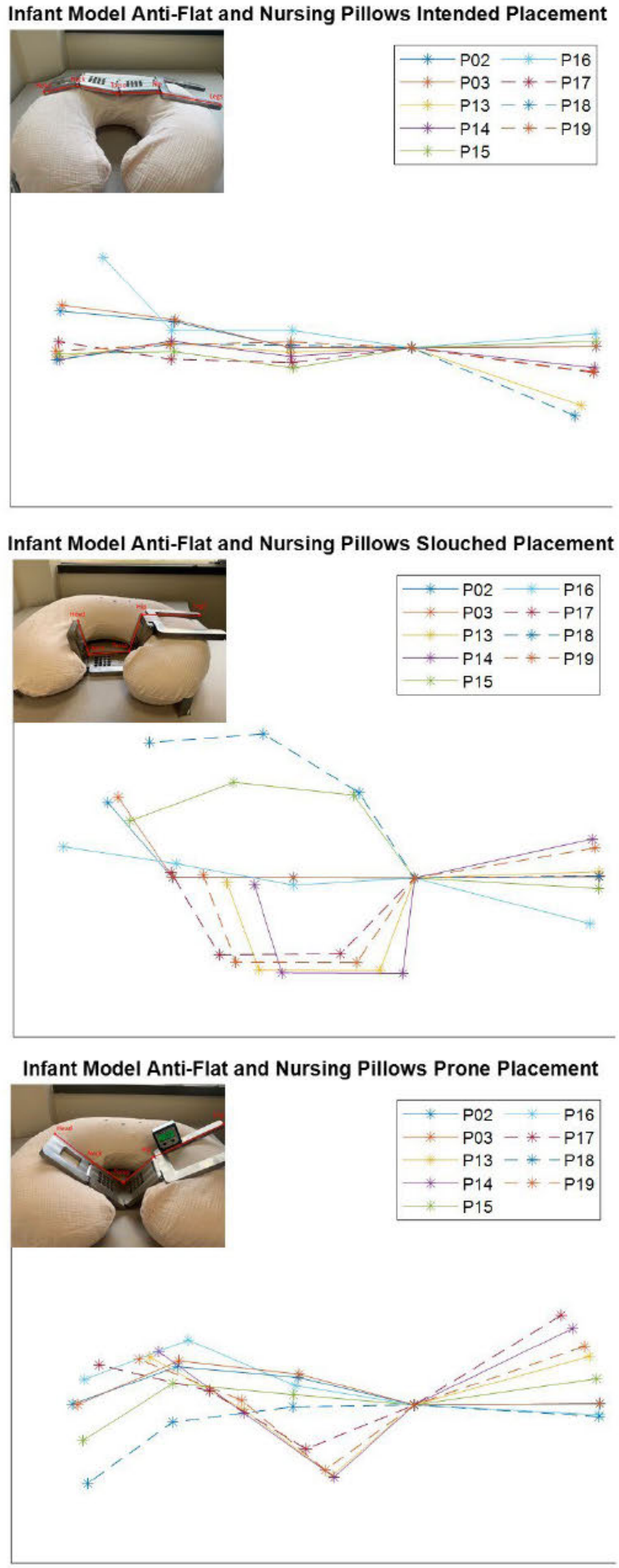
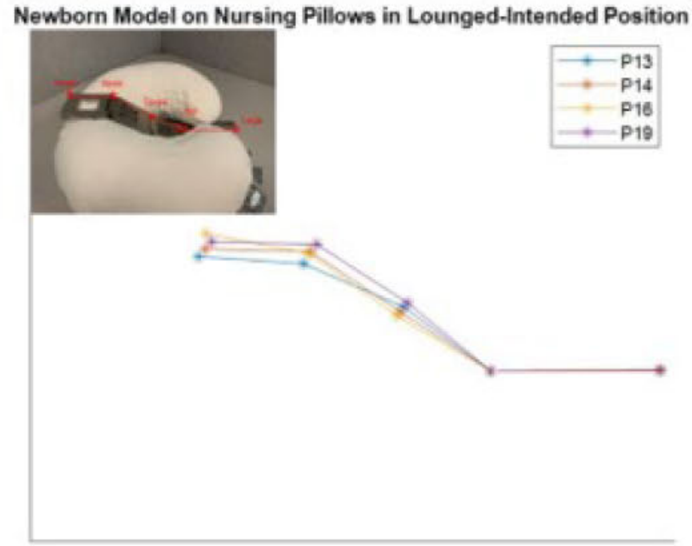
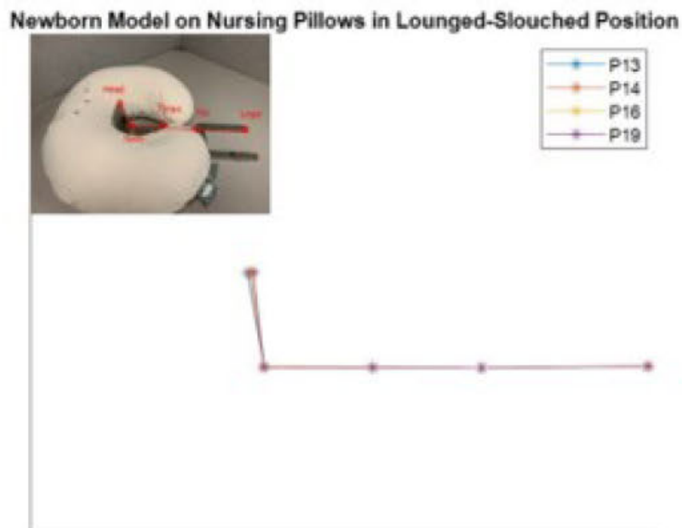


Figure 37. Three Testing Positions for the Newborn Sized Model in Anti-Flat and Nursing Pillow Categories: (Top) ideal supine placement, (Middle) slouched placement, and (Bottom) prone or hyperextended neck position.





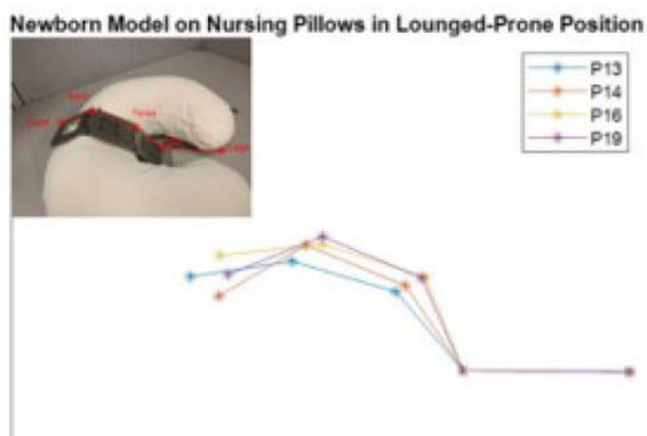
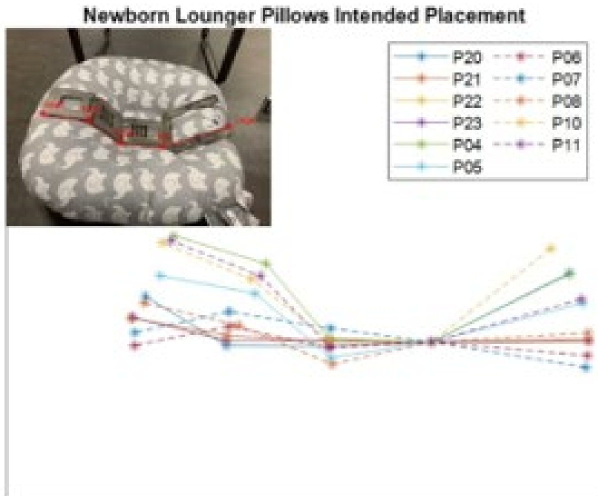
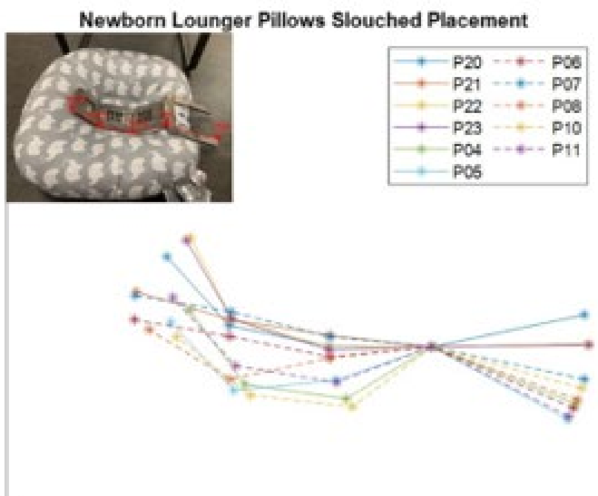


Figure 38. Three testing positions for the newborn sized model in nursing pillow categories marketed for lounging use: (Top) ideal supine placement, (Middle) slouched placement, and (Bottom) prone or hyperextended neck position.





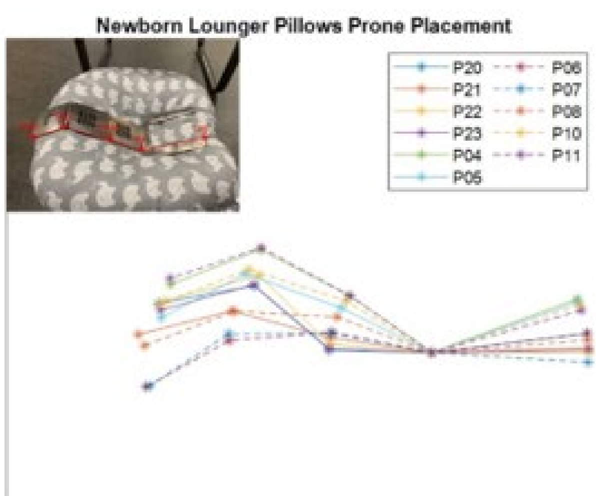


Figure 39. Three testing positions for the newborn sized model in lounger pillow categories: (Top) ideal supine placement, (Middle) slouched placement, and (Bottom) prone or hyperextended neck position.

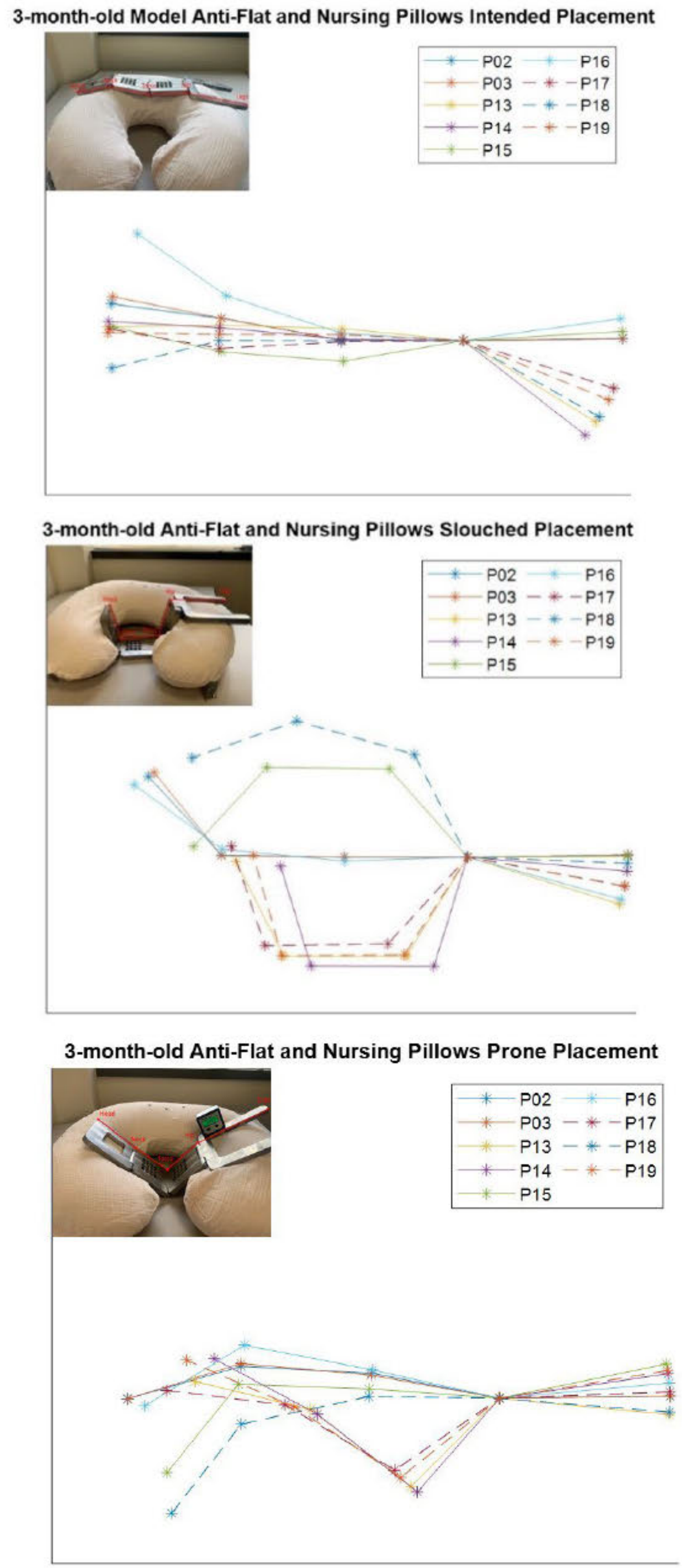


Figure 40. Three testing positions for the 3-month-old sized model in anti-flat head and nursing pillow categories. (Top) ideal supine placement, (Middle) slouched placement, and (Bottom) prone or hyperextended neck position.

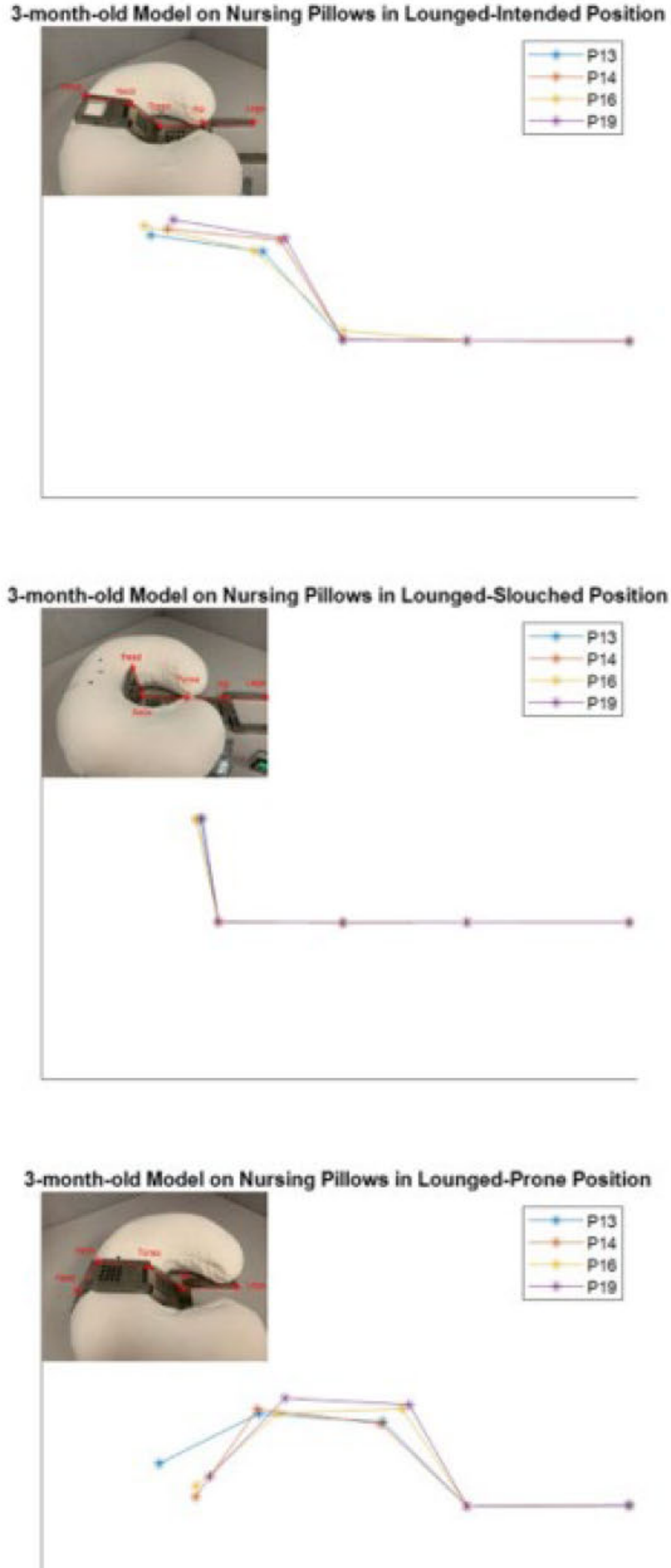


Figure 41. Three testing positions for the 3-month-old sized model in nursing pillow categories marketed for lounging use: (Top) ideal supine placement, (Middle) slouched placement, and (Bottom) prone or hyperextended neck position.

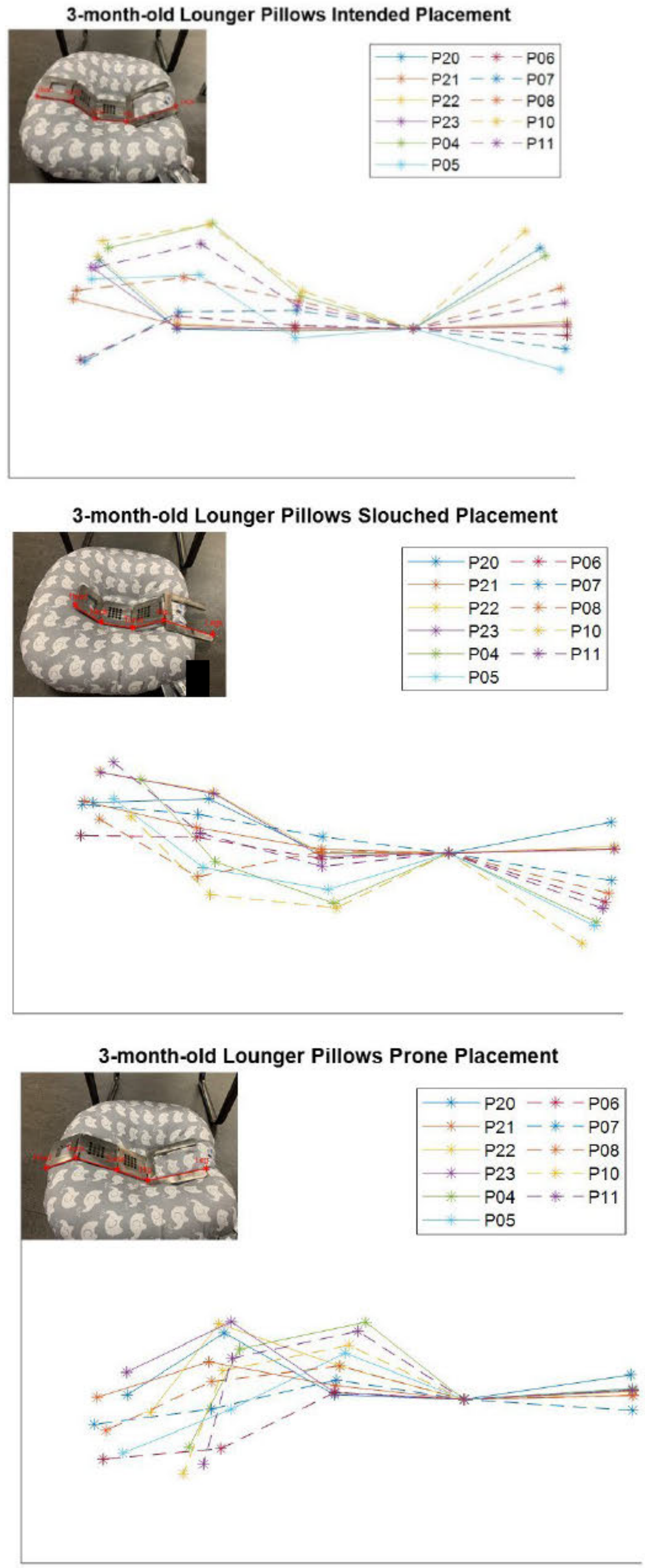
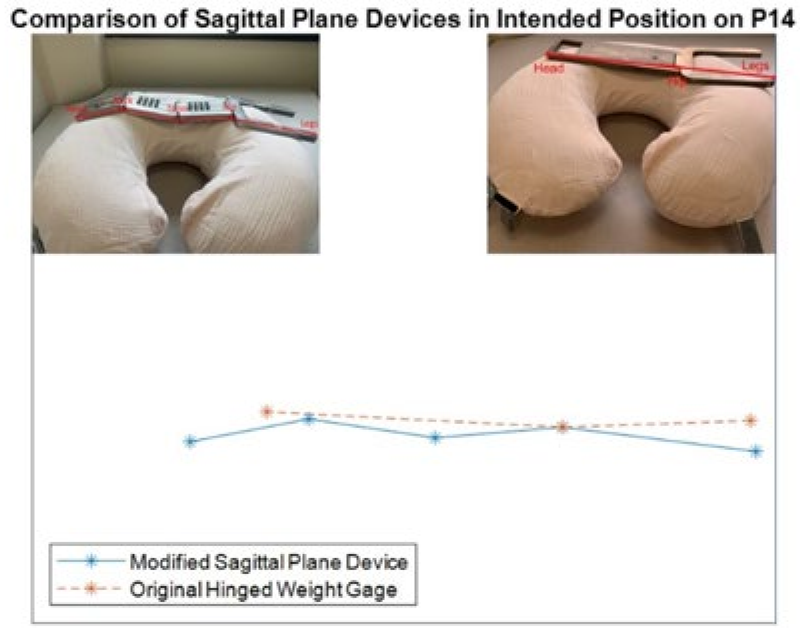


Figure 42. Three testing positions for the 3-month-old sized model in lounger pillow categories. (Top) ideal supine placement, (Middle) slouched placement, and (Bottom) prone or hyperextended neck position.

We also compared the results of the new newborn sagittal plane testing device to those from the hinged weight gage – newborn device on five representative products to illustrate the differences between these two evaluation tools (Table 26, Figure 43).



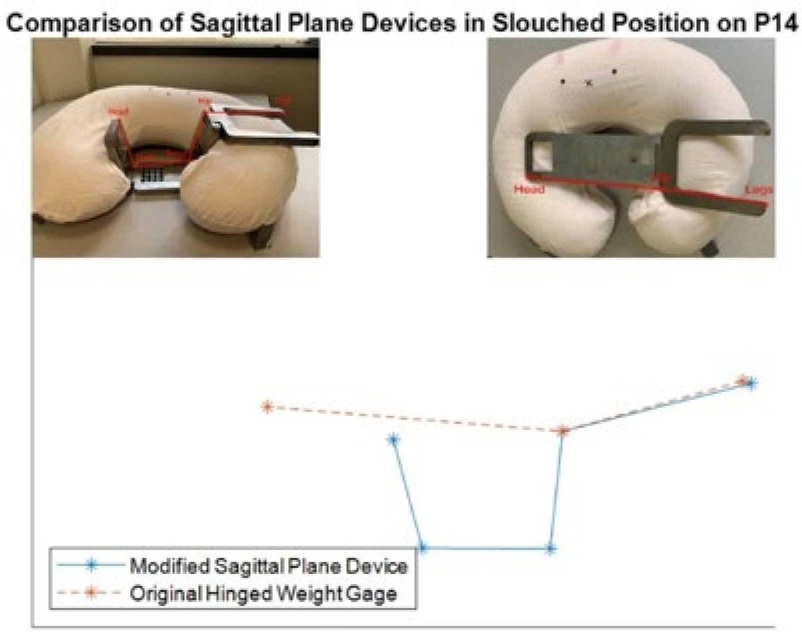


Figure 43. Comparison of results from hinged weight gage device and new sagittal plane testing device.

Table 26. Comparison of hinged weight gage and new sagittal plane testing device for five representative products.

Intended Position								
Samples	Mean Neck	St. Dev.	Mean Torso	St. Dev.	Mean Hip	St. Dev	Mean Hinged Gage	St. Dev
P03	-7.43	2.15	16.80	0.89	0.57	0.06	10.77	0.68
P10	-16.93	3.07	39.87	3.14	41.27	3.98	78.07	1.51
P22	13.50	1.11	0.73	0.15	1.50	0.26	9.93	1.07
P14	-20.80	2.01	14.27	2.84	-12.87	0.84	5.40	3.90
P17	8.97	4.39	10.73	1.89	-18.53	1.10	-2.93	0.15
Slouched Position								
Samples	Mean Neck	St. Dev.	Mean Torso	St. Dev.	Mean Hip	St. Dev	Mean Hinged Gage	St. Dev
P03	61.33	3.95	0.10	0.20	0.73	0.06	8.13	0.32
P10	33.70	1.78	46.20	4.06	-55.87	1.18	6.93	1.78
P22	47.90	0.75	17.43	0.15	0.90	0.26	27.27	1.03
P14	75.87	1.70	84.77	2.46	-69.03	3.55	21.87	8.35
P17	65.50	1.71	51.73	0.76	-51.53	1.01	9.43	4.30
Prone Position								
Samples	Mean Neck	St. Dev.	Mean Torso	St. Dev.	Mean Hip	St. Dev	Mean Hinged Gage	St. Dev
P03	-36.53	1.19	-10.77	1.85	19.20	0.96	9.43	2.97
P10	-42.07	2.45	-13.60	2.25	52.30	3.91	26.47	1.33
P22	-63.10	4.05	41.40	1.91	6.20	1.66	26.37	4.47
P14	0.33	1.29	90.73	0.06	-17.40	3.65	94.27	0.35
P17	-20.63	9.25	64.43	0.86	10.33	3.14	85.10	5.41

Table 26 compares the results from the two devices, with the mean neck, torso, and hip angles reported from the new sagittal plane device and the hinged gage device showing the included angle from the two segments. These data illustrate the added information related to body position that our four-segment sagittal plane model provides compared to the two-segment hinged weight gage.

7.4 Infant Positional Assessment Discussion

Body position impacts a person's ability to breathe. Chin-to-chest or head/neck flexion, head/neck hyperextension, and trunk flexion all influence normal breathing mechanics in adult populations. Lin et al. (2006) reported that a flexed trunk posture during sitting, not unlike the slouched flexed trunk postures in some of the pillows in our study, resulted in reduced lung capacity and lower expiratory flow compared to a normal standing posture. Another study demonstrated that slumped sitting posture altered ribcage configuration and chest wall movements compared normal sitting posture during breathing (Lee et al., 2010). Thus, it is important to understand how a baby's body is positioned in ideal placement and in worst-case scenarios within infant pillow products. We developed (1) a model to enable measurements to understand proximity of an infant's face to the side of a product at normal head rotations, and (2) a model that can be used to measure sagittal plane body position of critical body segments.

The head rotation testing results show that in most ideal infant placement positions, a baby's face is not in contact or near contact (<2 cm) for 0 to 90 degree head rotation, consistent with a crib mattress. However, in worst-case scenario placement, most products were in direct contact with the baby's face during normal head rotation (0 to 90 degrees). This is concerning from a suffocation perspective if the product is not firm and features low airflow. Some of the IDIs we reviewed indicate that a baby's face was in direct contact with the side of a product, so assuring that the sides of products are either firm or feature nearly free airflow should reduce the injury or death rate associated with this hazard type. The results of this head rotation testing may not be worth exploring further, as the firmness testing and guidelines related to the side height of the products may offer better guidance.

Our sagittal plane testing results elucidate that in most ideal infant placement positions on nursing pillows for nursing use, sagittal body position is fairly neutral. Some lounger pillows resulted in some degree of head/neck flexion and trunk flexion, even in neutral or intended use positions. Nursing pillows used as loungers resulted in concerning neck flexion angles which could result in a chin-to-chest position, especially if babies are sleeping. Worst-case scenario placement shows concerning sagittal plane body position with extreme head/neck flexion angle and trunk flexion angle, especially for nursing pillows with a recessed center or a c-shape pillow. This is consistent with some of the IDIs we reviewed which indicate babies have been found in "slouched" positions in these types of pillows. The prone position testing mimics data found in the IDIs where babies had apparently been placed prone or had rolled from supine to prone with their faces found in contact with the pillow. The nursing pillows P15, P17, and P18 which passed or nearly passed the firmness and airflow combination test described in section 6.5 were not marketed as dual-use pillows, and we observed no obvious way that a baby could be placed for lounging or sleep on these three pillows. They featured firm designs with sharper corners (P17 and P18) and unusually shaped modular design (P15), and we believe this type of design which does not easily facilitate lounging would result in a safe product for use in nursing. Contrarily, product P19 was a c-shaped nursing pillow also marketed for lounging use. While P19 passed the airflow and firmness tests, it also resulted in concerning sagittal plane angles in our positional assessment in the lounger-intended use testing.

The results of our sagittal plane testing also allow us to understand what might happen if a baby rolls from supine to prone in a pillow product. Because the body position in a prone position features trunk and neck flexion, in order to prevent suffocation into a pillow product, a baby would need to lift his or her head via neck extension and/or head rotation. Due to the soft nature of many of the pillows, the distance required of a baby to move their head to break the seal between their mouth/nose and the pillow to avoid suffocation is greater than it would be on a firm flat surface which would only require a slight movement even if full nasal occlusion had occurred. Furthermore, the lack of firmness in pillow products means that if a baby is working to move into a safer position, that the forces they are applying the pillow are dissipating in a way that is less conducive to facilitating movement compared to a firm flat surface like a crib mattress.

Our sagittal plane testing devices provide new information related to head and neck angles of infants with various placements on infant products. Compared to the two-segment hinged weight gage device, the sagittal plane testing devices can elucidate dangerous body positions that manufactures can work to prevent with product design.

There are limitations with our testing methods. For the head rotation measurements, the horizontal displacement was taken using calipers, and repeatability of those measurements is likely not high. We do not have a clear understanding of how close is “too close” in these measurements. Our preliminary CO_2 rebreathing testing suggests that dangerous scenarios may begin to occur at less than 2 cm from a plush surface, so we have set that measure as a preliminary cautionary threshold for this testing. Future work in CO_2 rebreathing can better define the best value for the threshold, which may differ based on materials used. For the sagittal plane devices, the current designs do not have mechanical stops to mimic physiological ranges of motion. More design work should be done to make the manufacturing process easier. For example, we used several holes to best match the targeted segmental weights. In the future, we could design a single cutout of known dimensions to reach the targeted weights. Finally, consistent placement into the pillow devices was difficult, but likely represents a real-life scenario where caregivers are not consistently placing babies in exactly the same position each time.

7.5 Infant Positional Assessment Recommendations

We conducted head rotation and sagittal plane body position testing in intended use and worst-case scenario positions for the infant pillow products. The head rotation testing may not offer additional information. For these pillow products, nearly every product resulted in an infant's face in contact with the product in either intended use or a worst case scenario position simply due to the nature of pillow designs. Thus, by focusing on firmness and airflow, potential suffocation or rebreathing scenarios can be mitigated. We do not recommend moving forward with head rotation testing for pillow products. However, we do believe that head rotation testing may be beneficial for other infant products where the worst-case scenario of the product is not as straightforward as it is with the pillow products.

The sagittal plane testing devices we developed offer a more robust quantification and visualization of infant position within pillow products compared to the hinged weight gage device. Further research is required to determine appropriate worst-case positions for testing and to set a threshold value for acceptable body positions. We recommend that this device be considered for use in other infant product classes. More work should be done to simplify the design for easier manufacturability. We could also consider adding mechanical stops to prevent the device from achieving impossible body positions.

8. Summary and Key Points

We conducted research to analyze the death or injury risk to infants associated with the use of infant pillows, including nursing pillows and any other types of pillows that are marketed as aiding or supporting infants, including but not limited to, for feeding, nursing, sleeping, propping, and lounging, in foreseeable product positions and foreseeable infant body and face positions.

Our review of the IDI documents (Section 2) elucidated that suffocation related hazards occur in infant pillow products in two main ways: (1) occlusion or rebreathing, meaning the nose or mouth is occluded due to contact with the product or the infant's face is in contact or near contact with a product that promotes CO_2 rebreathing; and (2) positional asphyxia, meaning that the infant's body position inhibits normal breathing. In this research, we have explored both suffocation hazard types by designing and conducting tests to measure product characteristics that would be dangerous for both suffocation scenarios: occlusion and positional asphyxia.

We developed a biofidelic probe (Section 4) that was subsequently used for both firmness (Section 5) and airflow (Section 6) testing to understand how a product may promote or inhibit occlusion or CO_2 rebreathing scenarios. We designed positional measurement tools to elucidate how a product may impact a baby's face or body position when using the product (Section 7). We summarize our findings and provide recommendations and future work (Section 8).

Recommendations

Based on our knowledge of the field, review of IDI documents, and testing of the pillow products, we recommend the following:

1. Hospitals' discharge information for parents of newborns should include information specific to infant positioning on and misuse of infant pillow products to educate parents and caregivers of potential hazards.
2. A firmness test should be performed on all pillow products, using a vertical lifter device and a 3 inch wooden hemisphere (Probe 6 described in Section 4) to displace a product by 1 inch at three locations: maximum thickness, minimum thickness, and a location of interest. The force required for this 1 inch displacement should exceed 10 N at all locations to pass the firmness test.

3. If a product does not pass a firmness test, it must undergo airflow testing based on the modified version of BS 4578:1970 standard using Probe 6 described in Section 4 with a volumetric flow rate of 2 L/min and a threshold value of 0.31 in. H_2O to maintain safety comparable to a mesh liner. Future work could consider a higher threshold, which may also be safe, but based on products involved in fatal incidents in the IDIs, this threshold should not exceed 0.93 in. H_2O.
4. The head rotation testing may not offer additional information or benefits, but guidance related to side height of the product could be considered instead.
5. The sagittal plane testing devices offer a more robust quantification and visualization of infant position within pillow products compared to the hinged weight gage device. Further research is required to determine appropriate worst-case positions for testing and to set a threshold value for acceptable body positions. This device should also be considered for use in other infant product classes. More work should be done to simplify the design for easier manufacturability.
6. Nursing pillows which are firm and feature sharper corners rather than a cylindrical sides are likely the safest option for babies, as there is no reasonable way to use this product as a lounger, limiting the dangers associated with sagittal plane positioning in nursing pillows.

Future Work

Future work could consider CO_2 rebreathing, impact of body position on infant breathing and movement, and material evaluations. In particular, we recommend two studies that would inform product design for a range of infant products:

(1) ***In vivo*** **biomechanics study on living infants to elucidate impact of body position on breathing mechanics**. In this study, we would control the infant's body position to understand how supine, prone, semi-reclined, and seated postures impact respiration, chest and abdominal expansion, abdominal muscle activity, and oxygen saturation during awake time. It may be possible to also conduct a simplified version of this study in an at-home setting to understand the relationship between body position and breathing mechanics during sleep. This robust study would inform product designers and manufacturers on the impact of various positions on infant breathing.

(2) **Material characterization analysis**. Infant products, including the pillow products, feature a range of materials and compositions of materials. While the current study and our past studies have measured fully assembled products for metrics like airflow, firmness, and rebreathing, a more basic and foundational study to elucidate the impact of common materials and combinations of materials have on these meaningful suffocation-related outcome measures would further inform product design across many infant product categories. Our current study showed differences in airflow between two pairs of products of the same designs but different outer covers, providing support that material selection in conjunction with product shape impacts important suffocation metrics.

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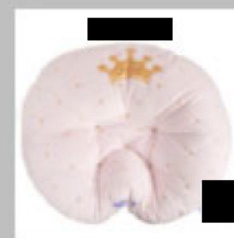
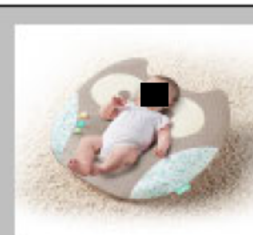
Appendix A: Pillow Product Information

Category	Name	Manufacturer	Price	Notes	Photo
Anti flat head pillows / Other pillows (2)					
P02	[redacted]		$20	Unique composition - mesh on back	
P03			$14	Plush	
Category	**Name**	**Manufacturer**	**Price**	**Notes**	**Photo**
Lounger pillows (11)					
P20	[redacted]		$69	Typical lounger style product	
P21			$52	"Ultra soft"	
P22			$195	Popular lounger design	
P23			$140	Product is quite deep, plush sides, and has a firm bottom surface with removable solid insert	

P04	[redacted]	N/A	Recalled - [redacted]	
P05	[redacted]	N/A	Recalled - [redacted]	
P06	[redacted]	OOS	Advertised to have a "recessed well" for "deep cradling". Unique pillow-like design, appears plush	
P07	[redacted]	OOS	Advertised to have a "recessed well" for "deep cradling". Unique pillow-like design, appears plush	
P08	[redacted]	$44	Unique safety restraint design	
P10	[redacted]	$50	"Deeply contoured sides, upper body elevation" claims	

P11	[redacted]	[redacted]	$40	Traditional looking pillow	

Category	Name	Manufacturer	Price	Notes	Photo
Nursing pillows (7)					
P13	[redacted]	[redacted]	$129	Cover features unique design (quilted bumps)	
P14	[redacted]	[redacted]	$39	Traditional nursing pillow	
P15	[redacted]	[redacted]	$44	Unique layered design	
P16	[redacted]	[redacted]	$27	Multiple configurations	[redacted] 

P17	[redacted]	$42	One of the original nursing pillows	
P18	[redacted]	$50	Different design vs. others	
P19	[redacted]	$53	Unique duel design - nursing pillow + play	

[redacted]